Heart Recovery
Now Possible with the Impella Heart Pump

The only percutaneous heart pump FDA indicated as safe and effective for High-Risk PCI and the treatment of Cardiogenic Shock to enable heart recovery.

50K Patients Treated in the United States.

Review protocols and best practices on ProtectedPCI.com

To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit: www.protectedpci.com/hcp/information/si and www.cardiogenichock.com/information/si

ABIOMED
The Role of Dose Tracking in Radiation Safety Programs

New software enables recording and tracking of patient X-ray dose

By Jeff Zagoudis

For all the benefits of medical imaging, most forms come with the inherent danger of radiation exposure. Public radiation exposure has increased significantly overall in the last 30 years, and according to a 2006 report from the National Council on Radiation Protection and Measurements (NCRP), medical imaging accounted for nearly half (48 percent) of all public exposure that year. Several high-profile cases of excessive radiation exposure due to medical imaging have brought the discussion into the public eye, which in turn has spurred greater focus on radiation safety among healthcare facilities and various regulatory bodies.

As hospitals begin to expand or create radiation safety programs, the emergence of dose tracking software has provided a new, critical tool for collecting, measuring, analyzing and reporting patient dose — activities that have been difficult until recently.

One-stop Dose Monitoring

The advent of dose tracking software in the last decade now allows hospitals to aggregate all of their dose data in one place, protected behind firewalls. Rather than simply tracking patient dose and scanner output, however, these next-generation systems allow users to take a deep dive into the data to help with quality improvement, training and a host of other functions.

Dose tracking software collects exam dose data either directly from the scanner or from the radiology PACS or the cardiovascular information system (CVIS). “From a safety point of view, it’s better to take information from the machines because we know

An example of dose monitoring software from Sectra, which can record dose levels by exam type, modality and set alert levels.

Participants

Bayer Healthcare  
www.bayerhealthcare.com

GE Healthcare  
www.gehealthcare.com

Imalogix  
www.imalogix.com

Infinitt North America  
www.infinittna.com

Novarad  
www.novarad.net

PACSHealth  
www.dosemonitor.com

Philips Healthcare  
www.usa.philips.com/healthcare/clinical-solutions/dosewise

Sclimage  
www.scimage.com

Sectra  
www.sectra.com

Siemens Healthineers  
usa.healthcare.siemens.com

Toshiba Medical  
medical.toshiba.com

Unfors RaySafe  
raysafe.com

Scranton Gillette Communications obtained the model specifications from the manufacturers.
that technologists don’t always send every image to the PACS,” said Dominic Siewko, clinical marketing manager for DoseWise solutions at Philips. Nearly all modalities are compatible with dose tracking software (with the exception of nuclear imaging, since dose is dependent on the type of radiotracer and amount injected into the patient).

**Data Sharing**

While automated data collection is a critical first step in dose monitoring, the data is only effective when seen by the right people. Most dose tracking software includes a mechanism to disseminate information from its central source to anyone who needs access. Systems use either a physical server or are cloud-based. Cloud dose tracking software also makes it easier to expand a collaborative network, according to Anders Österholm, vice president, sales operations for Sectra North America. “If two facilities were to merge and they were both using the same system, you could connect them with a single click,” he said.

**Radiation Safety Committees**

Once the dose tracking capabilities are in place, the next question is who should have access to the data, and what should they do with it. According to Siewko, many hospitals already have radiation safety committees, but their responsibilities may vary from one hospital to the next. New Joint Commission standards that went into effect in September 2016 now require a specific committee to review computed tomography (CT) protocol; however, the standards do not specify how often a review must take place.

Once the committee is established, the metrics for monitoring dose must be determined. A variety of parameters can be used to measure dose, each looking at it in a different way:

- Diagnostic reference levels (DRL) are determined using a phantom, and are not intended for commercial or regulatory purposes. Rather, they are an internal benchmark that, if exceeded, indicate an investigation should be conducted. Computed tomography dose index volume (CTDVol) is one of the most frequently used DRLs for CT.
- Reference levels (RL), not to be confused with DRLs, are derived from real patient exam results. RLs are most appropriate for use with fluoroscopically guided interventional procedures due to the variability and sources of error.
- For facilities consistently unable to meet DRLs, achievable dose (AD) offers a step toward dose optimization.

**Regulatory Compliance**

As with many current changes in healthcare, new regulatory guidelines are pushing many hospitals to adopt or at least consider dose tracking software. If asked to identify a particular source of persuasion, most healthcare facilities would likely point to the Joint Commission, which released new regulations for hospital imaging departments that went into effect Sept. 1, 2016.

CT machines are also subject to the XR-29 “Smart Dose” standard, which was released by the Medical Imaging and

---

**Additional Dose Management Resources**

Read the article “Regulatory Requirements The Impact on Cardiac Imaging and Dose Management.”


Read the article “Discussion on CT Dose Reduction” with Richard Morin, Ph.D., Mayo Clinic, Jacksonville, Fla., and co-chair of the Image Wisely committee.

http://bit.ly/2sgFESi

Watch the VIDEO “Eye-tracking For Dose Reduction in the Cath Lab,” an interview with Guillaume Baillaird, CEO of ControlRad Systems.

http://bit.ly/2rTC3zP

Watch the VIDEO “Radiation Dose Monitoring in Medical Imaging,” an interview with Mahadevappa Mahesh, MS, Ph.D., at RSNA 2016.


Technology Alliance (MITA) and went into effect Jan. 1, 2016. It specifies dose-lowering attributes for CT scanners:

- DICOM-compliant radiation dose structured reporting;
- Dose check features;
- Automatic exposure control; and
- Reference adult and pediatric protocols.

Individual states have begun contemplating dose reporting laws, though California and Texas are the only states to have passed legislation. California’s SB 1237 went into effect in 2012, requiring hospitals and clinics that use CT systems to record the dose on every CT study; the dose must be verified annually by a medical physicist unless the facility is accredited. A second provision, enacted in 2013, required accreditation by a Centers for Medicare and Medicaid Services (CMS)-recognized organization.

Texas followed suit with a radiation reporting law in 2013 as an amendment to Title 25 of the Texas Administrative Code. Under the terms, facilities that perform fluoroscopically guided interventional procedures and CT exams are required to form radiation protocol committees that must include: a licensed physician (or a radiologist or radiation oncologist for CT); a licensed medical physicist; and a radiation safety officer.

Dose must be recorded for all fluoroscopy and CT exams, with CTDI, dose-length product (DLP) and air kerma values as the specified metrics. It is up to each facility to determine its own acceptable dose threshold and to notify patients if that threshold is exceeded.

---

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

Scranton Gillette Communications assumes no responsibility or liability for any errors or omissions in this chart.
Azurion is the new-generation Image Guided Therapy platform that provides a foundation for today and the innovations of tomorrow. It is backed by innovative services and support, such as our multi-year Clinical Excellence Agreement that provides a full breadth of clinical support options, helping you to meet the challenges of controlling costs, streamlining workflow and improving patient care.

For more information on Azurion or our Clinical Excellence Agreement, visit www.philips.com/azurion
Take control of dose management across your organization

The Philips DoseWisePortal solution is the only turnkey dose management solution that gives you control over patient dose and staff occupational dose. It increases transparency across the entire enterprise and enables you to make data-driven decisions concerning quality initiatives and radiation management.

innovation + you

www.Philips.com/DoseWise
## Radiation Dose Monitoring

<table>
<thead>
<tr>
<th>Company name</th>
<th>Bayer Healthcare LLC</th>
<th>GE Healthcare</th>
<th>Imalogix</th>
<th>Infinit Health Care</th>
<th>Novarad</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product name</td>
<td>Radmetrics Enterprise Platform</td>
<td>DoseWatch</td>
<td>DoseWatch Explore</td>
<td>Imalogix</td>
<td>DoseM</td>
</tr>
<tr>
<td>FDA cleared year</td>
<td>Registered as a Class 1 device under FDA 2013</td>
<td>Compliant w/ FDA regulations</td>
<td>Compliant w/ FDA regulation</td>
<td>Class 1 device under FDA 2014</td>
<td>FDA Class 1 device (2015)</td>
</tr>
<tr>
<td>CE mark approval year</td>
<td>Yes, 2013</td>
<td>Yes, 2012</td>
<td>N/A</td>
<td>Yes, 2014</td>
<td>CE Class 1</td>
</tr>
</tbody>
</table>

### Briefly explain what the software monitors, reports

| | Radmetrics Enterprise Platform | DoseWatch | DoseWatch Explore | Imalogix | Innovative cloud-based performance management and dose monitoring solution. Takes the complexity out of the process to achieve compliance. There is virtually no IT involvement – automates the process to map protocols and provide advanced analytics that go beyond dose monitoring. Can compare dose trends in a concise dashboard to identify outliers and trend performance across enterprise. Imalogix is simple, powerful, smart, sophisticated | DoseM, abbreviated from Dose Monitoring, extracts radiation dose info from the image data and stores them in a Web-based system. User can view and manage radiation dose info in a user-friendly environment. Compliant with international standards, such as HL7 and DICOM, integrates with hospital info systems (HIS, EMR, PACS) to auto collect rad dose information. Furthermore, the user can manage dose radiation amounts by comparing with the recommended dose level (DRL: diagnostic reference level) |

### At what level is dose monitored and analyzed (e.g. patient, study, department, site)

| | Patient cumulative, study, acquisition, injection, and organ dose levels; by modality, enterprise, site, equipment, staff, protocol, specialty | Patient, series, study and cumulative dose metrics with support for multi-site/department configurations | Series-level dose and protocol details for connected GE CTs, excludes directly identifiable patient information | Acquisition, study, location(s), manufacturer, size, age, sex, protocol, time, tech, physician | Filtered to patient, study/series, depart, gender, age, examination room | Patient, study, modality and facility |

### What modalities can be monitored

| | CT, CT/PET, PET, CR/OR, MG, angiography for IR or cardiology, fluoroscopy, MRI | CT, XA, RF, MG, PET, SPECT, isodinated contrast | CT | CT, fluor (cardiovascular, IR, XA and RF), molecular imaging, mammo, CR/DX | CT, CR, DR, DX, XA, MG, RF |

### Does the system support diagnostic reference levels (DRLs) set locally, by registries or by regulatory bodies

| | Yes, customizable patient cumulative, exam and acquisition DRLs, based on a percentile of local performance, or standards from registries and regulatory bodies | Yes, ACR, national and custom DRLs are supported; segment by age, weight, height, study and series type | Manual upper threshold entry only | DRLs are set by age, sex and size and evaluated at acquisition, exam and patient cumulative dose | Yes, provision of DRL range setup and separate display | Yes |

### Does software offer pediatric DRLs

| | Offers DRLs filtered to patient age, gender, weight, height, BMI, diameter and/or WED | ACR DRLs are provided as well as DRLs for many EU nations. Custom DRLs as a function of patient age and / or size can also be set | Alert thresholds can be set for individual protocols | DRLs are set by age, sex and size and evaluated at acquisition, exam and patient cumulative dose | Yes, set up DRL values by age | Yes |

### How does the software help providers comply with Joint Commission requirements

<p>| | Web-based protocol management system including RadLex Master Protocol names, assists with DRLs, dose analysis, benchmarks and automated reporting to speech recognition, RIS and PACS | Yes, documents radiation dose index on every examination produced during CT exam; captures exam specific dose index and summarizes by series or anatomic region; documents dose in a retrievable format, displays performed and scheduled studies; documents incidents where dose indices exceed defined ranges. Supports alert on patient cumulative dose for IR procedures | Tracks and records exam, dosimetric information, overexposures and protocol parameters for each exam for each CT connected | Imalogix provides protocol review, threshold, DRLs, alerts and documented follow up | Collect and record dose and notify when exceed DRL. Provide the examination and patient reports | Yes |</p>
<table>
<thead>
<tr>
<th>PACSHealth</th>
<th>Philips Healthcare</th>
<th>Siemens</th>
<th>Toshiba</th>
<th>Unfors RaySafe</th>
</tr>
</thead>
<tbody>
<tr>
<td>DoseMonitor</td>
<td>DoseWise Portal</td>
<td>PICOM385</td>
<td>Dose Tracking System</td>
<td>iz real-time dose monitoring</td>
</tr>
<tr>
<td>PICOM385</td>
<td>2013</td>
<td>Yes, 2014</td>
<td>Yes, 2014</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>2016</td>
<td>2017</td>
<td>2012</td>
<td></td>
</tr>
</tbody>
</table>

Automated ionizing dose data collection, reporting and analysis solution

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DoseWise Portal</td>
<td>A vendor-agnostic and multi-modality Web-based solution that collects, measures, analyzes and reports patient and staff radiation exposure, assisting healthcare providers to take control of quality of care, efficiency, patient and staff safety. The DoseWise Portal has a powerful analytics engine that allows for easy analysis of important dose metrics such as CTDIvol, SSDR, DTPA, DAP, air kerma and occupational dose in the OR.</td>
</tr>
<tr>
<td>PICOM385</td>
<td>Provides support for dose monitoring by collecting exposure data from the diagnostic modality contained in the metadata (DICOM) Tags of each series or image. The dose information is captured and database within PICOMAnalytics providing comprehensive dose monitoring reports. The dose information can be automatically included in the reading physician diagnostic report and/or transmitted via HL7 to the EHR, registry or any app capable of receiving HL7 messaging.</td>
</tr>
</tbody>
</table>

Patient, study, modality and facility

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient dose is monitored directly from imaging systems to capture all exposure events, not just those sent to PACS. All dose-related DICOM info is captured, even MPPS and static dose pages can be read via optical character recog. Dose info is collected, sorted by location, machine, exam/study and patient.</td>
<td></td>
</tr>
<tr>
<td>Dose is captured from DICOM tags of each image within a series and cumulative dose is calculated.</td>
<td></td>
</tr>
<tr>
<td>Series, study, patient, room department, site, hospital, region, operator, equipment make, model, type</td>
<td></td>
</tr>
<tr>
<td>Patient, study</td>
<td></td>
</tr>
<tr>
<td>Patient, study</td>
<td></td>
</tr>
</tbody>
</table>

Dose info is collected, sorted by location, machine, exam/study and patient.

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>All X-ray modalities can be monitored including CT, fluoroscopy, DR and mammography.</td>
<td></td>
</tr>
<tr>
<td>All modalities that embed dose within DICOM tags of each image within a series or study level.</td>
<td></td>
</tr>
<tr>
<td>Any modality, CX, DX, RF, YA, CT, NM, MG</td>
<td></td>
</tr>
</tbody>
</table>

CT, XA, IR, CR, MG, NM, PET, MR

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT, XA, DR, CR, MG, NM, PET, MR</td>
<td></td>
</tr>
</tbody>
</table>

CT, CR, DR, MG, NM, PET, MR

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, the DoseWise Portal has the capability to set custom DRLs at the exam level. The software will show exams that have exceeded the DRL in real-time making the data review process easy for healthcare providers. The software can also send automatic reports at desired frequencies for DRL exceedances.</td>
<td></td>
</tr>
<tr>
<td>SlimeDose Imaging Diagnostic Reporting supports DRL by color highlighting levels out of range.</td>
<td></td>
</tr>
<tr>
<td>Set locally, by exam type, adult/peds, and body habitus. The system also allows national and dynamic DRL calculations to occur.</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

Yes

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, the DoseWise Portal has the capability of setting a custom pediatric ages and DRLs.</td>
<td></td>
</tr>
<tr>
<td>Supports DRL by highlighting levels out of pediatric-specific, customer modifiable, preset ranges.</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

Yes

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>The DoseWise Portal has a robust capability to easily create custom graphs and charts related to Joint Commission requirements, and then save them to a dashboard. These dashboards will continue to collect data for reporting and analysis automatically.</td>
<td></td>
</tr>
<tr>
<td>Dose monitoring reports generated by Picom Analytics support compliance with Joint Commission.</td>
<td></td>
</tr>
<tr>
<td>Integration to external registries, such as the ACR. Integration to voice reporting systems. Solution is able to publish the patient dose, as well as patient imaging historic doses, to third-party systems via API and URL integrations. To dictation systems such as Powerscribe 360 via Nuance API, to printed media in the form of a dose report, to PACS, RIS and ENR solutions via HL7 messaging. Can set DRLs and allows users to track, report, follow-up on scans outside of these ranges.</td>
<td></td>
</tr>
<tr>
<td>The software enables the healthcare agency utilizing this technology to minimize dose to patients by tracking and mapping estimated dose received to the patient's body on a real time visual display.</td>
<td></td>
</tr>
<tr>
<td>The software enables the healthcare agency utilizing this technology to minimize dose to patients by using next generation ABC ROI logic to control radiation output.</td>
<td></td>
</tr>
</tbody>
</table>

Yes
## COMPUTATION TOGRAPHY (CT)

<table>
<thead>
<tr>
<th>Dosimetric information</th>
<th>Protocol parameters</th>
<th>Size specific dose estimate</th>
<th>Quality review</th>
<th>Data collection method</th>
<th>How is dose data transferred into software</th>
<th>INTERVENTIONAL ANGIOGRAPHY</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTDvol, DLP, SSDE, ICRP, organ dose, kVp, mAs; cumulative (for some metrics), exam and acquisition</td>
<td>Customizable</td>
<td>Yes, based on effective diameter or water-equivalent (WED) diameter</td>
<td>Yes, analytics evaluating dose by customizable variables, DRLs, automated alerts, interactive dosimetry tool</td>
<td>PACS and/or device integration: data from available DICOM headers, RDSR, MPPS, dose sheet OCR, Cimetra Workstation; supports historical data migration via PACS</td>
<td>Query retrieve or auto-route DICOM data from PACS and/or device; MPPS from device</td>
<td>DAP, reference point dose, fluoro time, acquisition count, beam on time, fluoro DAP, kVp, (max) mAs</td>
</tr>
<tr>
<td>CTDvol, DLP, SSDE, Water-Equivalent SSDE (see note), effective and cumulative dose, target region</td>
<td>Name, technique, iterative recon, RPD, RIS, kVp, mAs, max mA, pitch, noise reduction, scan length, range, phantom type, exp time and rotation/single collimation width and total.</td>
<td>No</td>
<td>Positioning, mA modulation, patient centering and reviewer comments</td>
<td>Many data collection options: DICOM header, MPPS, RDSR, PACS (OCR/DICOM), HL7, proprietary</td>
<td>Original data is collected either directly from medical device or from PACS, stored and parsed into database tables; can be reloaded if necessary</td>
<td>DAP, reference point dose, fluoro time, acquisition count, beam on time, fluoro DAP, kVp, (max) mAs</td>
</tr>
<tr>
<td>Series number, CTDvol, DLP, series type, scan length</td>
<td>Series #, series description, kV, auto mA, mA, max mA, mAs, exp time, rotation time, pitch, single coll. width, total coll., noise index, percent iterative recon</td>
<td>No</td>
<td>Comprehensive tools for review and education</td>
<td>Through proprietary GEHC CT scanner Insite connection and GE CT log files</td>
<td>Data collected directly from GE CT using the Insite connection, stored in cloud and available through Web app; does not provide any patient info</td>
<td>Air kerma, DAP, cine/fluoro time, number of exposures</td>
</tr>
<tr>
<td>DLP, CTDvol, SSDE, effective, organ, cumulative</td>
<td>All</td>
<td>Yes</td>
<td>Automatic SSDE per AAPM Task Group 204</td>
<td>PACS/Scanner direct; DICOM, RDSR, proprietary</td>
<td>Maligix appears as a DICOM device on network and receives data collected directly from the scanner or PACS</td>
<td>DAP, fluoro time, air kerma, peak skin dose</td>
</tr>
<tr>
<td>CTDvol, DLP, SSDE, effective dose</td>
<td>All</td>
<td>Yes</td>
<td>1. Statistical and Comprehensive analytics. 2. In environment of Infinifit PACS installation, DB Synchronizing (reduce cost)</td>
<td>1. Automatic SSDE per AAPM Task Group 204</td>
<td>Feature set, ease of use, straightforward implementation</td>
<td>DAP, fluoro time, air kerma, peak skin dose</td>
</tr>
</tbody>
</table>

### Quality review
- Yes, ability to acquire all necessary dose information, calculate additional dose values (ICRP 103/98, SSDE), and automate export to patient record and / or registry
- Yes, CT and interventional/cardiac dose tracking, patient and protocol analytics, identification of outliers, EMR/RIS/dic平tion integration
- Displays protocol and dose data for GE CTs; data is aggregated, analyzed and summarized within the application to provide insights about practice-level dose performance
- Yes, Provides a comprehensive library of alerts to meet state requirements and workflows as well as the ability to analyze, annotate and export results to the appropriate reporting systems
- Yes, 1. Acquisition of various information including dose. 2. SSDE calculation

### If you are an OEM, what vendors offer your solution
- McKesson, Siemens, Philips, Toshiba, Carestream, CMS, 1st American
- GE Healthcare is the sole owner of DoseWatch; GEHC sells the product directly via internal sales channels
- GE Healthcare is the sole owner of DoseWatch Explore; GEHC sells the product directly via internal sales channels
- N/A
- N/A

### What differentiates your software from competitors
- Vendor neutral, multi-modality software for integrated radiation and contrast dose management; supporting historical data migration; dynamic, interactive analytics including advancing trending analysis for process control; protocol management tool. Monte Carlo-based dosimeter and phantom library for patient/organ specific dose values
- Multiple connectivity/data acquisition options; e.g. DICOM header, MPPS, RDSR, PACS (OCR/DICOM) and proprietary; CT, IR, mammography, and fluoroscopy support; designed and supported by medical physicists; advanced tools: incidence map in CV-IR, SSDE, water-equivalent SSDE, CT patient centering tool, mA modulation quality tool; plus, ALARA/Image Gently/Wisely education. Supports contrast injection data acquisition from multiple injector vendors
- Cloud-deployed Web application, without any IT integration required and no required hardware; automatically retrieves, tracks and reports radiation dose for GE CT devices
- Cloud solution. Installation times are best in class. Automatically map protocols, TruSize patients, optional physics support. Elegant and intuitive interface
- 1. Statistical and Comprehensive analytics. 2. In environment of Infinifit PACS installation, DB Synchronizing (reduce cost)

### COMPUTATION TOGRAPHY (CT)

#### Dosimetric information
- CTDvol, DLP, SSDE, ICRP, organ dose, kVp, mAs; cumulative (for some metrics), exam and acquisition

#### Protocol parameters
- Name, technique, iterative recon, RPD, RIS, kVp, mAs, max mA, pitch, noise reduction, scan length, range, phantom type, exp time and rotation/single collimation width and total. Acq parameters tracked vary by modality

#### Size specific dose estimate
- Yes, based on effective diameter or water-equivalent (WED) diameter

#### Quality review
- Yes, analytics evaluating dose by customizable variables, DRLs, automated alerts, interactive dosimetry tool

#### Data collection method
- PACS and/or device integration: data from available DICOM headers, RDSR, MPPS, dose sheet OCR, Cimetra Workstation; supports historical data migration via PACS

#### How is dose data transferred into software
- Query retrieve or auto-route DICOM data from PACS and/or device; MPPS from device

#### INTERVENTIONAL ANGIOGRAPHY

#### Dosimetric info: refer point air kerma; DAP, fluoro time
- DAP, reference point dose, fluoro time, acquisition count, beam on time, fluoro DAP, kVp, (max) mAs

### Scranton Gillette Communications obtained the model specifications from the manufacturers.
<table>
<thead>
<tr>
<th>Feature set, ease of use, straightforward implementation integration with NCICT Organ Dose</th>
<th>Philips Healthcare manufactures and sells the DoseWise Portal</th>
<th>Carestream Vue Cardio PACS</th>
<th>N/A</th>
<th>Only Toshiba sells this product</th>
<th>Only Toshiba offers this product</th>
<th>We are vendor neutral</th>
</tr>
</thead>
<tbody>
<tr>
<td>DoseWise Portal is the only dose management solution that combines real-time staff radiation exposure and patient data by integrating with DoseAware personal dosimeters. DoseWise Portal is now integrated into the Philips IntelliSpace PACS and also the Philips IntelliBridge Enterprise offering HL7 functionality</td>
<td>For reading physicians, the solution is automated and simple. Dose is displayed in the worklist, so it is easily dictated into the DX report without clicking, switching apps or running a report</td>
<td>Reporting flexibility, the UI offers an effective method to interrogate the data at a high and low level with ease. The solution is Saas based model and allows customers to come and go and scale up and down in a real-time reflection of their business needs. The collaborative effect of joining different &quot;like&quot; institutions together to create a dose network is very powerful and sophisticated. The ability to manually enter dose using the web based GUI allows non RDSR and MPPS modalities to be utilized and incorporated within the patient dose history</td>
<td>DTS utilizes actual estimated skin dose to the patients body based on body type and detector angle in both field of view maximums and procedure maximums. All competitors utilize air kerma which estimates dose to an imaginary point outside of the body</td>
<td>Conventional collimation prevents the seeing outside of collimated area and the patient input dose may be increased as system compensates for the reduced amount of scatter radiation. The collimator may enter the ABC region of interest, which further increases radiation output. With Spot Fluoro, the last image acquired in normal fluoro is continuously displayed while only the spot field is active, so it it easier to see the guidewire tip and landmarks. The size of the spot field can be selected tabletop</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, the DoseWise Portal will export patient dose data to the EMR via integration with leading dictation software</td>
<td>Slimage developed dose monitoring to comply with state mandates first introduced in CA and TX. Automated and/or easy incorporation of dose data into the diagnostic report was the first priority</td>
<td>All inline systems inherently record cumulative dose to patients for display on the DICOM header and for output as a structured report. Software augments system's ability, but is not required to meet specific state regulations</td>
<td>All infrxus systems inherently record cumulative dose to patients for display on the DICOM header and for output as a structured report. This software augments that inherent system ability but is not required to meet specific state regulations</td>
<td>No, used for internal usage</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>All including CTDIvol, DLP, SSDE, effective dose, organ specific dose</th>
<th>All CT machine DICOM outputs such as kV, effective mAs, pitch, width, etc.</th>
<th>N/A</th>
<th>Yes</th>
<th>Not supported on CT</th>
<th>Not supported on CT</th>
<th>N/S</th>
</tr>
</thead>
<tbody>
<tr>
<td>The DoseWise Portal can capture CTDIvol, DLP, calculate SSDE and calculate effective dose (mSv)</td>
<td>Calculates SSDE using water-equivalent diameter method recommended by AAPM TG220 using patient surview and associated correction factors</td>
<td>N/A</td>
<td>Yes</td>
<td>Not supported on CT</td>
<td>Not supported on CT</td>
<td>N/S</td>
</tr>
<tr>
<td>The DoseWise Portal can capture CTDIvol, DLP, calculate SSDE and calculate effective dose (mSv)</td>
<td>Data quality review on proper patient positioning, outlier analysis and a intuitive reporting tool</td>
<td>N/A</td>
<td>Yes</td>
<td>Not supported on CT</td>
<td>Not supported on CT</td>
<td>N/S</td>
</tr>
<tr>
<td>All CT machine DICOM outputs such as kV, effective mAs, pitch, width, etc.</td>
<td>Data is collected directly from the machine via RDSR, MPPS, OCR image capture and may be collected remotely via the EMR/PACS</td>
<td>Dose data is collected from DICOM tags as study is processed before archived to Slimage PACS</td>
<td>Dose data is stored in SQL database, can be automatically mapped to reports and exported via HL7</td>
<td>The dose is received using any of the methods in line 31. This is received by the locally deployed proxy/gateway service, which encrypts the data and transmits it to the data center</td>
<td>Not supported on CT</td>
<td>Not supported on CT</td>
</tr>
<tr>
<td>Dose data is transferred via a DICOM node LAN connection between the CT machine and DoseWise Portal and uploaded into a SQL database</td>
<td>Dose data is stored in SQL database, can be automatically mapped to reports and exported via HL7</td>
<td>DICOM dose SR, MPPS, OCR of CT secondary capture image, HL7 PACS U/R integration (DICOM headers), manual entry</td>
<td>DICOM dose SR, MPPS, OCR of CT secondary capture image, HL7 PACS U/R integration (DICOM headers), manual entry</td>
<td>DICOM dose SR, MPPS, OCR of CT secondary capture image, HL7 PACS U/R integration (DICOM headers), manual entry</td>
<td>Not supported on CT</td>
<td>Not supported on CT</td>
</tr>
<tr>
<td>Yes</td>
<td>Air kerma, DAP fluoro time, peak skin dose (if provided)</td>
<td>Yes</td>
<td>Yes, this information is captured by the DoseWise Portal via DICOM</td>
<td>Fluoro time</td>
<td>Provide by the standard system</td>
<td>Provide by the standard system</td>
</tr>
</tbody>
</table>
### COMPARISON CHART

#### Radiation Dose Monitoring

<table>
<thead>
<tr>
<th>Protocol parameters</th>
<th>Customizable</th>
<th>Technique, filter, table position, positioner primary and secondary angulation, radiation mode, focal spot, filter, FOV, frame rate, etc.</th>
<th>N/A</th>
<th>All</th>
<th>Rotation, angulation, no. of images, single/biplane, Procedure</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence mapping</td>
<td>Yes, if provided by the modality</td>
<td>2-D cumulative air kerma by angulation</td>
<td>N/A</td>
<td>Yes</td>
<td>Yes (depending on modality)</td>
<td>If provided</td>
</tr>
<tr>
<td>Fluoroscopy time</td>
<td>Yes, if provided by the modality</td>
<td></td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Gantry angulation</td>
<td>Yes, if provided by the modality</td>
<td></td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Air kerma</td>
<td>Yes, if provided by the modality</td>
<td></td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Exposure time</td>
<td>Yes, if provided by the modality</td>
<td></td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Table position</td>
<td>Yes, if provided by the modality</td>
<td>PACS and/or device; RDSR, MPPS, dose sheet OCR, manual entry for non-RDSR devices</td>
<td>DICOM MPPS, RDSR</td>
<td>N/A</td>
<td>PACS/scanner direct. DICOM, RDSR, smart OCR. All images processed in study for complete picture</td>
<td>Dose report OCR, RDSR, MPPS, DICOM header</td>
</tr>
<tr>
<td>Data collection method</td>
<td>PACS and/or device; RDSR, MPPS, dose sheet OCR, manual entry for non-RDSR devices</td>
<td>DICOM MPPS, RDSR</td>
<td>N/A</td>
<td>PACS/scanner direct. DICOM, RDSR, smart OCR. All images processed in study for complete picture</td>
<td>Acquire dose data from DICOM data in the PACS image storage. (No query / retrieve)</td>
<td>DICOM</td>
</tr>
<tr>
<td>How is dose data transferred into software</td>
<td>Query retrieve or auto-route DICOM data from PACS and/or device; MPPS from device</td>
<td>Collected from modality or PACS, data can be reloaded or re-analyzed</td>
<td>N/A</td>
<td>PACS/scanner direct. DICOM, RDSR, smart OCR. All images processed in study for complete picture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DOSE SOFTWARE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient name</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Summary of order</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Exam type</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Modality type</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Cumulative dose</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Alert tracking</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Exposure time</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>What parameters are used to record dose and set alerts</td>
<td>Customized per client’s preference; variety of parameters available for thresholds and alerts</td>
<td>Standard metrics supported; alerts based on CTDIvol, DLP, cumulative dose, scheduled repeats; age, height, weight specific</td>
<td>DLP, CTDIvol, mA, kV, scan length, pitch, noise index, percent iterative recon, etc; DLP, CTDIvol, number irrad events for alerts</td>
<td>Dose metrics, scanner, location, physician, technologist, scan length, size, age, sex, etc.</td>
<td>Standard metrics supported; alerts based on CTDIvol, DLP, DAP, AGD.</td>
<td>Any system collected parameter can be alerted on</td>
</tr>
<tr>
<td>Effective dose measurements</td>
<td>Yes, calculated in mSv for ICRP 103, 60 standards using Monte Carlo simulation</td>
<td>Yes, DLP conversion factors, mSv</td>
<td>No</td>
<td>Yes, effective dose (AAPM 96); organ dose (ICRP 103)</td>
<td>Yes, using RDSR, DICOM MPPS, OCR capture image, DICOM header, DAP meter</td>
<td>ICRP 103, mSv</td>
</tr>
<tr>
<td>Send data to ACR Dose Index, registries</td>
<td>Yes, can automate transfer data to ACR/DIR registry</td>
<td>Updated RDSR (with SSDE) can be sent to ACR DIR; RDF specified in DoseWatch or DIR</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
All | Yes, all machine operating parameters are collected via DICOM such as collimation, mA, frame rate, operating mode, etc. at the event level | N/A | Yes | Provide by the standard system | Provide by the standard system | N/S
---|---|---|---|---|---|---
Yes | Peak skin dose, incidence mapping in development | No | Yes, (requires RDSR messaging) | Provide by the standard system | Provide by the standard system | N/S
---|---|---|---|---|---|---
Yes | Yes, fluoroscopy time is captured from the machine | Yes | Yes | Provide by the standard system | Provide by the standard system | N/S
---|---|---|---|---|---|---
Yes | Yes, gantry angulation is captured from the machine | Yes | Yes | Provide by the standard system | Provide by the standard system | N/S
---|---|---|---|---|---|---
Yes | Yes, Air kerma is captured from the machine | No | Yes | Provide by the standard system | Provide by the standard system | N/S
---|---|---|---|---|---|---
Yes | Yes, exposure time is captured and displayed at the event level | Yes | Yes, (requires RDSR messaging) | Provide by the standard system | Provide by the standard system | N/S
---|---|---|---|---|---|---
Yes | Yes, table position is captured from the machine | Yes | Yes, (requires RDSR messaging) | Provide by the standard system | Provide by the standard system | N/S
---|---|---|---|---|---|---
RDSR, MPPS | Data is collected directly from the machine via RDSR, MPPS, OCR image capture and may be collected remotely via the EMR/PACS | DICOM | DICOM | Dose SR, MPPS, OCR, HL-7, PACS Q/R integration, manual entry | Rad exp monitoring profile used, can export DICOM RDSR to compatible PACS. Offers C-arm gantry, table angle | Standard dose data is recorded by the system. This feature reduces dose, thus data collection is not inherent to the technology | N/S
---|---|---|---|---|---|---|---
DICOM from either the PACS or direct from the modality | Dose data is transferred via a DICOM node LAN connection between the machine and DoseWise Portal and uploaded into a SQL database | DICOM | DICOM | This is received by the locally deployed proxy/gateway service which encrypts the data and transmits it to the data center | Dose date is transferred digitally within internal hardware network | N/A | N/S
---|---|---|---|---|---|---|---
Yes | Yes, name can be anonymized | Yes | Yes | Provide by the standard system | Provide by the standard system | Dosimeters named to staffers
---|---|---|---|---|---|---|---
PACS or modality | Yes, summary of order is possible if supported by workflow | Yes | Yes | N/A | N/A | N/A
---|---|---|---|---|---|---|---
Yes | Yes, exam type is captured | Yes | Yes | Provide by the standard system | Provide by the standard system | N/A
---|---|---|---|---|---|---|---
Yes | Yes, modality type is captured and segregated | Yes | Yes | Provide by the standard system | Provide by the standard system | N/A
---|---|---|---|---|---|---|---
Yes | Yes, patient cumulative dose and EDE calculated | Yes | Yes | Provide by the standard system | Provide by the standard system | Yes
---|---|---|---|---|---|---|---
Yes | Yes, new portal release has improved alert tracking, e-mail alerts | No | Yes | Provide by the standard system | Provide by the standard system | Cumulative data on each staffer
---|---|---|---|---|---|---|---
Yes | Yes, exposure time is captured and displayed at the event level | Yes | Yes | Provide by the standard system | Provide by the standard system | N/A
---|---|---|---|---|---|---|---
All parameters supplied by a modality can be recorded and an alert created | Yes, common dose attributes may be used to record dose and set alerts such as DLP, SSDE [WED], CTDiVol, DAP, Cak, EDE, etc. | No | | ScImage records all dose data in DICOM metadata. Alerts are configured in Picom Structured Reports | Any other field in the database is able to be used by the system to create an alert. Therefore it is possible to use visit frequency as an example to alert as well as the dose | N/A | REM, SV
---|---|---|---|---|---|---|---
CT effective dose uses ICRP 103, displays in mSv | Yes, avail in patient summary using current industry standard dose conversion factors. Dose conversion factors are configurable | Yes, supports custom calculations using on dose data in DICOM | Yes, supports custom calculations using on dose data in DICOM | CT effective dose is calculated using ICRP103 or ICRP66 methodology using deformable phantoms | N/A | N/A | Yes, mSv, mGy, etc.
---|---|---|---|---|---|---|---
Yes | Yes, the Support of ACR DI-R. Software is included | Yes, HL7, DICOM, XML or xls. Flexible auto process to export data required | Yes, DICOM message to ACR triad appliance | No | No | N/A
---|---|---|---|---|---|---|---

**N/A = Not applicable**

**N/S = Not specified**
Take control of dose management across your organization

DoseWise Portal is the core component in your radiation dose management program. DoseWise Portal is a vendor-agnostic, web-based solution that collects, measures, analyzes, and reports patient and staff radiation exposure, assisting you to make data-informed decisions, improve efficiency, and demonstrate a commitment to quality, satisfaction, patient and staff safety.

www.philips.com/dosewise
## Contents

### July/August 2017

<table>
<thead>
<tr>
<th>Pages</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Editor’s Note</strong></td>
</tr>
<tr>
<td>17</td>
<td>A Glimpse Into the Future of Cardiac Ultrasound</td>
</tr>
<tr>
<td></td>
<td><strong>Comparison Charts</strong></td>
</tr>
<tr>
<td>8</td>
<td>Radiation Dose Monitoring</td>
</tr>
<tr>
<td>24</td>
<td>Contrast Media</td>
</tr>
<tr>
<td></td>
<td><strong>Features</strong></td>
</tr>
<tr>
<td>3</td>
<td>The Role of Dose Tracking in Radiation Safety Programs</td>
</tr>
<tr>
<td>18</td>
<td>FDA Clears Sapien 3 TAVR Valve for Aortic, Mitral Valve-In-Valve Procedures</td>
</tr>
<tr>
<td>19</td>
<td>First Nasal Spray Successfully Treats Supraventricular Tachycardia</td>
</tr>
<tr>
<td>24</td>
<td>Recent Developments and Issues in Contrast Media</td>
</tr>
<tr>
<td>30</td>
<td>Latest Advances in Electrophysiology Technology</td>
</tr>
<tr>
<td>35</td>
<td>The Offbeat: Gray Hair Linked With Increased Heart Disease Risk</td>
</tr>
<tr>
<td></td>
<td><strong>Products</strong></td>
</tr>
<tr>
<td>34</td>
<td>New Cardiac Technology</td>
</tr>
</tbody>
</table>
About the Cover

Philips DoseWise Portal radiation dose monitoring system is a vendor-agnostic, multi-modality, Web-based system that collects, measures, analyzes and reports patient and staff medical imaging radiation exposure. This type of software offers alerts and analytics to assist with better management of quality of care, efficiency and patient and staff safety. See the article and comparison chart starting on Page 3.

VIDEO: MACRA’s Impact on Cardiology

Kim A. Williams, Sr., M.D., chief of cardiology at Rush University Medical Center, Chicago, and former president of both the American College of Cardiology (ACC) and the American Society of Nuclear Cardiology (ASNC), explains the impact of healthcare reform on cardiology and specifically on nuclear perfusion imaging.

Watch the video at: http://bit.ly/2rwI8i7

---

Advertiser Index

<table>
<thead>
<tr>
<th>Advertiser</th>
<th>Website</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abiomed</td>
<td><a href="http://www.abiomed.com">www.abiomed.com</a></td>
<td>2</td>
</tr>
<tr>
<td>Bayer</td>
<td><a href="http://www.radiologysolutions.bayer.com">www.radiologysolutions.bayer.com</a></td>
<td>20-23</td>
</tr>
<tr>
<td>GE Healthcare</td>
<td><a href="http://www.gehealthcare.com">www.gehealthcare.com</a></td>
<td>Back cover</td>
</tr>
<tr>
<td>Philips Healthcare</td>
<td><a href="http://www.usa.philips.com/healthcare">www.usa.philips.com/healthcare</a></td>
<td>5-7, 14, 29</td>
</tr>
</tbody>
</table>
From Your Editor
Dave Fornell

A Glimpse Into the Future of Cardiac Ultrasound

I saw several elements of what will likely make up the next generation of echocardiography imaging systems at the American Society of Echocardiography (ASE) 2017 scientific sessions in June.

• **Real 3-D Image Navigation in the Cath Lab:** One of the newest technologies I have seen in recent years is true 3-D imaging offered by EchoPixel. The technology allows 3-D image datasets to be displayed in actual 3-D from computed tomography (CT), magnetic resonance imaging (MRI), and 3-D ultrasound. GE Healthcare and EchoPixel announced at ASE they created a formal co-development agreement to make true 3-D imaging available in the near future. The technology currently is only available as post processing, so it cannot be used for live procedures, but that may change as the two companies work together. If live, true 3-D transeosophageal echo (TEE) were developed, it could eliminate the need for X-ray angiography to guide transcatheter structural heart procedures.


• **Vector Blood Flow:** Vector flow imaging offers detailed tracking of the flow of blood inside the heart and arteries, allowing visualization of the speed of the blood in various anatomy, how it is influenced by atherosclerosis, stenotic valves, structural changes in the heart, or the implantation of devices. It is believed disruption of blood flow causing turbulence or the formation of swirling vortices play a role in disease development and may one day offer risk assessments of heart or vascular conditions long before the onset of symptoms. Until now, this has only been a research tool and has not been available on any of the premium echo systems, but Hitachi just released its first premium echo system at ASE, the Liscendo B80. It comes standard with vector flow imaging. GE Healthcare also unveiled its prototype vector flow imaging technology at a lunch symposia at ASE 2017.


We welcome your comments on the topics found in *Diagnostic and Interventional Cardiology*. Please send your thoughts to dcfornell@sgmail.com
The U.S. Food and Drug Administration (FDA) has granted market clearance for aortic and mitral valve-in-valve procedures using the Edwards Lifesciences Sapien 3 transcatheter heart valve (THV). The Sapien 3 valve is the first transcatheter heart valve approved in the U.S. for the treatment of both aortic and mitral patients who are at high risk for a subsequent open-heart surgery to replace their bioprosthetic valve.

“This approval brings a safe and effective transcatheter therapy to patients who would do very poorly with repeat open-heart surgery,” said John Carroll, M.D., professor of cardiology at the University of Colorado School of Medicine and director of interventional cardiology at the University of Colorado Hospital, Denver, and member of the TVT Registry Steering Committee. “I am pleased to see that the FDA recognizes the value of the high-quality evidence generated by the STS-ACC TVT Registry and its ability to play an important role in assessing ‘real-world’ clinical results in specialty indications, such as valve-in-valve, and for particular patient groups, such as those needing replacement of a bioprosthetic mitral valve.”

This anticipated FDA approval of the indication expansion was supported by real-world data collected from the Society of Thoracic Surgeons and American College of Cardiology (STS/ACC) Transcatheter Valve Therapy (TVT) Registry. The TVT Registry includes information and outcomes on patients undergoing transcatheter valve replacement procedures in the United States.

The FDA evaluated data from the outcome registry to support the marketing application. It consisted of 314 patients who had undergone aortic valve-in-valve procedures and 311 patients who had undergone mitral valve-in-valve procedures. The registry data showed that more than 85 percent of patients who underwent aortic or mitral valve-in-valve procedures experienced clinically meaningful improvement in their heart failure symptoms 30 days after the procedure, as shown by their New York Heart Association (NYHA) classifications. The NYHA classification is a common classification system by which heart failure symptoms are rated. In both aortic and mitral valve-in-valve patients, the observed mortality rates were substantially lower than the expected mortality rate for repeat surgery. The STS/ACC TVT Registry will be used to ensure FDA surveillance of the device for the next five years.

The new self-expanding Edwards Lifesciences’ Centera aortic valve demonstrated a very high survival rate of 99 percent, a low 2.5 percent disabling stroke rate and a 4.9 percent permanent pacemaker rate – the lowest rate ever reported in a multi-center trial for a self-expanding valve. The 30-day results are the first data and were presented as a late-breaking presentation at EuroPCR 2017 in May.

A large-scale analysis of percutaneous coronary intervention (PCI)-related hospitalizations showed people admitted to the hospital on a weekend were twice more likely to die than those hospitalized on a weekday. Ten years of data were presented at the Society for Cardiovascular Angiography and Interventions (SCAI) 2017 Scientific Sessions in May, derived from the Nationwide Inpatient Sample database (2004-2013), the largest publicly available all-payer inpatient healthcare database. The cohort included 1.3 million patients. Data revealed that weekend admissions are on the rise, increasing from 12.4 percent in 2004 to 21.5 percent in 2013 and were associated with higher in-hospital mortality (2.1 vs. 1.2 percent), with a relative increase of 20.5 percent on the weekend versus 98.2 percent on the weekdays. Weekend admissions were associated with longer hospital stays (4.2 vs. 2.9 days) and higher cost of care ($23,630 vs. $20,080) compared to weekdays.

The Heart Rhythm Society (HRS) released a first-of-its-kind consensus statement on indications of patients who undergo magnetic resonance imaging (MRI) and radiation exposure with cardiovascular implantable electronic devices (CIEDs). Read to the recommendations at: http://bit.ly/2syxCLt
First Nasal Spray Successfully Treats Supraventricular Tachycardia

Results of a ground-breaking clinical trial demonstrate the effectiveness of a novel, fast-acting nasal spray therapy called Etripamil to stop a common rapid heart rate condition known as paroxysmal supraventricular tachycardia (PSVT). The multicenter, randomized trial enrolled 104 patients from more than 35 centers across the U.S. and Canada, and the results were presented at Heart Rhythm 2017, the Heart Rhythm Society’s 38th Annual Scientific Sessions.

PSVT results in more than 50,000 U.S. hospital visits every year. In order to restore normal heart rhythm, patients are often treated with adenosine, calcium channel blockers or beta-blockers, which must be administered through an IV in a hospital or monitored setting. There are no existing therapy options that can be administered by a patient at their home or without the presence of a trained medical professional. Etripamil, made by Milestone Pharmaceuticals, is a novel, potent, short-acting calcium channel blocker and is being developed as a fast-acting nasal spray that can be administered by the patient to acutely terminate PSVT episodes wherever and whenever they occur.

The NODE-1 Trial is a phase two, multicenter, randomized, parallel-group, double-blind placebo-controlled study designed to evaluate the efficacy of different doses of Etripamil in terminating PSVT. The study included 104 patients that were randomized and received the drug in an electrophysiology (EP) lab setting. Following a five-minute induced atrioventricular re-entrant tachycardia (AVRT) or atrioventricular nodal re-entrant tachycardia (AVNRT), types of PSVT, patients received a placebo or one of four doses of Etripamil at 35 mg, 70 mg, 105 mg or 140 mg. The primary endpoint was the termination rate of PSVT within 15 minutes of drug administration.

Etripamil at doses of 70 mg, 105 mg and 140 mg yielded conversion rates of 87%, 75% and 95%, respectively, that were all significantly better than the 35% conversion rate in the placebo group. The mean conversion time ranged from 2.6 minutes to 3.37 minutes in the Etripamil groups. Times were faster with patients given higher doses. The most common adverse event that occurred to patients who used the Etripamil therapy was transient nasal congestion or irritation.

The U.S. Food and Drug Administration (FDA) said gadolinium-based contrast agents for magnetic resonance imaging (MRI) show no identified adverse health effects from gadolinium retained in the brain. The FDA released a drug safety communication regarding all gadolinium-based contrast agents (GBCAs) earlier in May. The FDA said GBCAs may be associated with gadolinium retention in the brain and other body tissues. However, there is no evidence to date that it is harmful.

Abbott recently recalled 449,661 coronary balloon catheters after 19 reports of injury and one death. The issue with the NC Trek RX and NC Traveler coronary dilatation catheters and the NC Tenku RX PTCA balloon was due to difficulty removing the protective balloon sheath, which may result in issues with inflating or deflating the balloon. Abbott recalled products from several identified lots because physicians may experience difficulty in removing the protective balloon sheath, which may result in issues with inflating or deflating the balloon during procedures, with adverse consequences including air embolism, thrombosis and myocardial infarction.

Enrollment started in the STEMI Door-to-Unloading (DTU) study with the Abiomed Impella CP percutaneous ventricular assist (pVAD) system in acute myocardial infarction. This FDA-approved prospective feasibility study will focus on safety of unloading the left ventricle using the Impella CP heart pump prior to primary PCI in patients presenting with STEMI without cardiogenic shock with the hypothesis that this will potentially reduce infarct size.
**Indications and Usage**

Gadavist® (gadobutrol) injection is a gadolinium-based contrast agent indicated for use with magnetic resonance imaging (MRI):

- To detect and visualize areas with disrupted blood brain barrier (BBB) and/or abnormal vascularity of the central nervous system in adult and pediatric patients (including term neonates)
- To assess the presence and extent of malignant breast disease

Gadavist® is indicated for use in magnetic resonance angiography (MRA):

- To evaluate known or suspected supra-aortic or renal artery disease in adult and pediatric patients (including term neonates)

**Important Safety Information**

**WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)**

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.

- The risk of NSF appears highest among patients with:
  - Chronic, severe kidney disease (GFR <30 mL/min/1.73m²), or
  - Acute kidney injury
- Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (for example, age >60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.
- For patients at highest risk for NSF, do not exceed the recommended GADAVIST dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

**Contraindication and Important Information about Hypersensitivity Reactions:**

Gadavist® is contraindicated in patients with history of severe hypersensitivity reactions to Gadavist®. Anaphylactic and other hypersensitivity reactions with cardiovascular, respiratory, or cutaneous manifestations, ranging from mild to severe, including death, have uncommonly occurred following Gadavist® administration. Before Gadavist® administration, assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders. These patients may have an increased risk for a hypersensitivity reaction to Gadavist®.

**Acute Kidney Injury:** In patients with chronic renal impairment, acute kidney injury sometimes requiring dialysis has been observed with the use of some GBCAs. Do not exceed the recommended dose; the risk of acute kidney injury may increase with higher than recommended doses.

**Extravasation and Injection Site Reactions:** Ensure catheter and venous patency before the injection of Gadavist®. Extravasation into tissues during Gadavist® administration may result in moderate irritation.

**Overestimation of Extent of Malignant Disease in MRI of the Breast:**

Gadavist® MRI of the breast overestimated the histologically confirmed extent of malignancy in the diseased breast in up to 50% of the patients.

**Low Sensitivity for Significant Arterial Stenosis:**

The performance of Gadavist® MRA for detecting arterial segments with significant stenosis (>50% renal, >70% supra-aortic) has not been shown to exceed 55%. Therefore, a negative MRA study alone should not be used to rule out significant stenosis.

Please see brief summary on following pages.
Approved for Magnetic Resonance Angiography (MRA).

Gadavist is the First and Only Macrocyclic Gadolinium-based Contrast Agent Approved for MRA of the Supra-aortic and Renal Vasculature

Compared to Time-of-Flight MRA, Gadavist demonstrated:

- **Increased Identification** of accessory renal arteries for surgical planning and renal donor evaluation
  - Of 1,752 main arteries visualized by the central computed tomography angiography (CTA) readers, 266 (15%) were also associated with positive visualization of at least one accessory (duplicate) artery. With the central MRA readers, the comparable rates were 232 of 1,752 (13%) for Gadavist MRA compared to 53 of 1,752 (3%) for ToF MRA.

- **Improved Visualization** in patients with known or suspected supra-aortic arterial disease, including prior stroke or transient ischemic attack (TIA). Percent visualization ranged from 88–97% with Gadavist vs. 24–82% with unenhanced MRA among three readers. The lower bound of the 95% confidence interval (CI) for the difference ranged from 13–61% and the upper bound ranged from 17–67%

**Patient History:** 66-year-old male with a history of hypertension and dyslipidemia

**Patient History:** 69-year-old Caucasian male with history of hypertension, smoking, and recent stroke

**Important Safety Information (continued)**

**Adverse Reactions:** The most frequent (>20.5%) adverse reactions associated with Gadavist in clinical studies were headache (1.5%), nausea (1.1%) and dizziness (0.5%).


*Relaxivity of Gadavist is 5.21 mmol⁻¹ s⁻¹ at 1.5 Tesla (r₁ in plasma at 37°C)

Bayer, the Bayer Cross, and Gadavist® are trademarks of the Bayer group of companies.
© 2016 Bayer, 100 Bayer Boulevard, P.O. Box 915, Whippany, NJ 07981. PP-325-US-0400 September 2016
WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle, and internal organs.

- The risk for NSF appears highest among patients with:
  - Chronic, severe kidney disease (GFR < 30 mL/min/1.73m²), or
  - Acute kidney injury.
- Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (for example, age > 60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.
- For patients at highest risk for NSF, do not exceed the recommended Gadavist dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration [see Warnings and Precautions (5.1)].

5.3 Acute Kidney Injury

In patients with chronic renal impairment, acute kidney injury sometimes requiring dialysis has been observed with the use of some GBCAs. Do not exceed the recommended dose; the risk of acute kidney injury may increase with higher than recommended doses.

5.4 Extravasation and Injection Site Reactions

Ensure catheter and venous patency before the injection of Gadavist. Extravasation into tissues during Gadavist administration may result in moderate irritation [see Clinical Toxicology (13.2)].

5.5 Overestimation of Extent of Malignant Disease in MRI of the Breast

Gadavist MRI of the breast overestimated the histologically confirmed extent of malignancy in the diseased breast in up to 50% of the patients [see Clinical Studies (14.2)].

6. ADVERSE REACTIONS

The following serious adverse reactions are discussed elsewhere in labeling:

- Nephrogenic Systemic Fibrosis (NSF) [see Boxed Warning and Warnings and Precautions (5.1)].
- Hypersensitivity reactions [see Contraindications (4) and Warnings and Precautions (5.2)].

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The adverse reactions described in this section reflect Gadavist exposure in 6,809 subjects (including 184 pediatric patients, ages 0 to 17 years) with the majority receiving the recommended dose. Approximately 51% of the subjects were male and the ethnic distribution was 61% Caucasian, 29% Asian, 5% Hispanic, 2% Black, and 3% patients of other ethnic groups. The average age was 56 years (range from 1 week to 93 years).

Overall, approximately 4% of subjects reported one or more adverse reactions during a follow-up period that ranged from 24 hours to 7 days after Gadavist administration. Adverse reactions associated with the use of Gadavist were usually mild to moderate in severity and transient in nature.

Table 2 lists adverse reactions that occurred in ≥ 0.1% subjects who received Gadavist.

### Table 2: Adverse Reactions

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Rate (%)</th>
<th>n=6809</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>1.1</td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>Dysgeusia</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Feeling Hot</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Injection site reactions</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Rash (includes generalized, macular, papular, pruritic)</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Pruritus (includes generalized)</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Erythema</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Hypersensitivity/Anaphylactoid</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Dyspnea</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Paresthesia</td>
<td>0.1</td>
<td></td>
</tr>
</tbody>
</table>

*Hypersensitivity/anaphylactoid reaction may occur with one or more of the following adverse reactions: for example, hypotension, urticaria, face edema, eyelid edema, flushing.

Adverse reactions that occurred with a frequency of < 0.1% in subjects who received Gadavist include: loss of consciousness, convulsion, parosmia, tachycardia, palpitation, dry mouth, malaise and feeling cold.

6.2 Postmarketing Experience

The following additional adverse reactions have been reported during postmarketing use of Gadavist. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Cardiac arrest
- Nephrogenic Systemic Fibrosis (NSF)
- Hypersensitivity reactions (anaphylactic shock, circulatory collapse, respiratory arrest, pulmonary edema, bronchospasm, cyanosis, oropharyngeal swelling, laryngeal edema, blood pressure increased, chest pain, angioedema, conjunctivitis, hyperhidrosis, cough, sneezing, burning sensation, and pallor) [see Warnings and Precautions (5.2)].
There are no available data of Gadavist in pregnant women to inform the drug-associated risk. Gadolinium-based contrast agents (GBCAs) are reported to cross the placenta. Limited human data on exposure to GBCAs during pregnancy does not show adverse effects in exposed neonates. Animal reproductive studies were conducted. Although teratogenicity was not observed, embroyotoxity was observed in monkeys, rabbits and rats receiving intravenous gadobutrol during organogenesis at doses 8 times and above the recommended human dose. Retardation of embryonal development was observed in rabbits and rats receiving intravenous gadobutrol during organogenesis at doses 8 and 12 times, respectively, the recommended human dose [see Data]. Advise pregnant women of the potential risk to a fetus. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and is 15 to 20%, respectively.

**Data**

**Animal Data**

Embryotoxicity was observed when gadobutrol was administered intravenously to monkeys during organogenesis at doses 8 times the recommended single human dose (based on body surface area); gadobutrol was not maternally toxic or teratogenic at this dose. Embryotoxicity and retardation of embryonal development also occurred in pregnant rats receiving maternally toxic doses of gadobutrol (> 7.5 mmol/kg body weight; equivalent to 12 times the human dose) at this dose. Embryotoxicity and retardation of embryonal development also occurred in pregnant rabbits (> 2.5 mmol/kg body weight; equivalent to 8 times the recommended human dose based on body surface area). In rabbits, this finding occurred without evidence of pronounced maternal toxicity and with minimal placental transfer (0.01% of the administered dose detected in the fetuses).

Because pregnant animals received repeated daily doses of Gadavist, their overall exposure was significantly higher than that achieved with the single standard dose administered to humans.

**8.2 Lactation**

**Risk Summary**

There are no data on the presence of gadobutrol in human milk, the effects on the breastfed infant, or the effects on milk production. However, published lactation data on other GBCAs indicates that 0.01 to 0.04% of the maternally gadolinium dose is present in breast milk and there is limited GBCA gastrointestinal absorption in the breast-fed infant. Gadobutrol had no effect on fertility and general reproductive performance of male and female rats when given in doses less than 0.1% of the dose intravenously administered and the gastrointestinal absorption is poor (approximately 5% of the dose orally administered was excreted in the urine). The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Gadavist and any potential adverse effects on the breastfed infant from Gadavist or from the underlying maternal condition.

**Clinical Considerations**

A lactating woman may consider interrupting breastfeeding and pumping and discarding breast milk up to 18 hours after Gadavist administration in order to minimize exposure to a breastfed infant.

**Data**

In lactating rats receiving 0.5 mmol/kg of intravenous [153Gd]-gadobutrol, 0.01% of the total administered radioactivity was transferred to the pup via maternal milk within 3 hours after administration.

**8.4 Pediatric Use**

The safety and effectiveness of Gadavist have been established in pediatric patients born at 37 weeks gestation or later based on imaging and pharmacokinetic data in 138 patients ages 2 to 17 years and 44 patients ages 0 to less than 2 years and extrapolation from adult data. The frequency, type, and severity of adverse reactions in pediatric patients were similar to adverse reactions in adults [see Adverse Reactions (6.1)]. No dose adjustment according to age is necessary in pediatric patients [see Dosage and Administration (2.1), Clinical Pharmacology (12.3), and Clinical Studies (14.1)]. The safety and effectiveness of Gadavist have not been established in premature infants.

**NSF Risk**

No case of NSF associated with Gadavist or any other GBCA has been identified in pediatric patients ages 6 years and younger. Gadobutrol had no effect on fertility and general reproductive performance of male and female rats when given in doses less than 0.1% of the dose intravenously administered and the gastrointestinal absorption is poor (approximately 5% of the dose orally administered was excreted in the urine). The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Gadavist and any potential adverse effects on the breastfed infant from Gadavist or from the underlying maternal condition.

**Clinical Considerations**

A lactating woman may consider interrupting breastfeeding and pumping and discarding breast milk up to 18 hours after Gadavist administration in order to minimize exposure to a breastfed infant.

**Data**

In lactating rats receiving 0.5 mmol/kg of intravenous [153Gd]-gadobutrol, 0.01% of the total administered radioactivity was transferred to the pup via maternal milk within 3 hours after administration.

**8.5 Geriatric Use**

In clinical studies of Gadavist, 1,377 patients were 65 years of age and over, while 104 patients were 80 years of age and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, the use of Gadavist in elderly patients should be cautious, reflecting the greater frequency of impaired renal function and concomitant disease or other drug therapy. No dose adjustment according to age is necessary in this population.

**8.6 Renal Impairment**

Prior to administration of Gadavist, screen all patients for renal dysfunction by obtaining a history and/or laboratory tests (see Warnings and Precautions (5.1)). No dosage adjustment is recommended for patients with renal impairment. Gadavist can be removed from the body by hemodialysis [see Warnings and Precautions (5.1) and Clinical Pharmacology (12.3)].

**10 OVERDOSAGE**

The maximum dose of Gadavist tested in healthy volunteers, 1.5 mL/kg body weight (1.5 mmol/kg; 15 times the recommended dose), was tolerated in a manner similar to lower doses. Gadavist can be removed by hemodialysis [see Warnings and Precautions (5.1) and Clinical Pharmacology (12.3)].

**13 NONCLINICAL TOXICOLOGY**

**13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

Gadobutrol had no effect on fertility and general reproductive performance of male and female rats when given in doses 12 times the human equivalent dose (based on body surface area).

**13.2 Animal Toxicology and/or Pharmacology**

Local intolerance reactions, including moderate irritation associated with infiltration of inflammatory cells was observed after paravenous administration to rabbits, suggesting the possibility of occurrence of local irritation if the contrast medium leaks around veins in a clinical setting [see Warnings and Precautions (5.4)].

**17 PATIENT COUNSELING INFORMATION**

**Nephrogenic Systemic Fibrosis**

Instruct patients to contact their physician if they:

- Have a history of kidney disease and/or liver disease, or
- Have recently received a GBCA

GBCAs increase the risk of NSF among patients with impaired elimination of drugs. To counsel patients at risk of NSF:

- Describe the clinical manifestation of NSF
- Describe procedures to screen for the detection of renal impairment

Instruct the patients to contact their physician if they develop signs or symptoms of NSF following Gadavist administration, such as burning, itching, swelling, scaling, hardening and tightening of the skin; red or dark patches on the skin; stiffness in joints with trouble moving, bending or straightening the arms, hands, legs or feet; pain in the hip bones or ribs; or muscle weakness.

**Common Adverse Reactions**

Instruct patients that they may experience:

- Reactions along the venous injection site, such as mild and transient burning or pain or feeling of warmth or coldness at the injection site
- Side effects of headache, nausea, abnormal taste and feeling hot

**General Precautions**

Instruct patients receiving Gadavist to inform their physician if they:

- Are pregnant or breastfeeding
- Have a history of allergic reaction to contrast media, bronchial asthma or allergic respiratory disorder

© 2011, Bayer HealthCare Pharmaceuticals Inc. All rights reserved.

Bayer HealthCare
Bayer HealthCare Pharmaceuticals Inc.
Whippany, NJ 07981
Manufactured in Germany
6905902BS
Recent Updates in Medical Imaging Contrast Media Agents

Here are recent updates in medical imaging contrast media agents. Two of the biggest news items were related to safety concerns over magnetic resonance imaging (MRI) gadolinium agents and echocardiography contrast agents. However, in both cases the U.S. Food and Drug Administration (FDA) has weighed in that the agents are safe in the majority of patients.

Concern Over MRI Gadolinium Agents Retained in Brain

Over the past decade, several clinical studies have shown gadolinium-based MRI contrast agents accumulate in tissues inside patients. This has raised concern because prolonged, elevated levels of gadolinium in the body may cause a nephrogenic systemic fibrosis in patients with severe kidney disease. Adding to this concern were three studies in 2015, which raised new gadolinium safety concerns after it was found the agent also accumulates in the brain.

On its own, gadolinium can be toxic. Therefore, when used in contrast agents, gadolinium is bonded with a molecule called a chelating agent, which controls the distribution of gadolinium within the body. It was thought, prior to 2006, that gadolinium was completely excreted from the body. In patients found to retain traces of the agent, it was believed it was due to severe renal dysfunction. However, the 2015 brain studies found gadolinium retention in the brain also occurred in patients with normal renal function. Another 2015 study from the University of Heidelberg Medical Center in Heidelberg, Germany, suggests that the molecular structure of the contrast agent may play a role in gadolinium retention. There are two structurally distinct categories of gadolinium-based contrast agents: linear and macrocyclic. In the macrocyclic structure, the gadolinium is bound more tightly to the chelating agent and, therefore, less likely to release free gadolinium into the body.

However, no studies have yet shown that retained gadolinium in the brain causes negative long-term health effects. This was the determination of the FDA review of the safety ramifications of gadolinium-based contrast agents, released in a drug safety communication in May 2017. The FDA said it has not identified adverse health effects from gadolinium retained in the brain. The FDA said there is no evidence to date that gadolinium retention in the brain from any of the gadolinium agents is harmful, so restricting use of these agents is not warranted at this time. FDA said it will continue to assess the safety of these agents. The FDA reported that studies show linear agents retain more gadolinium in the brain than macrocyclic agents. However, the review did not identify adverse health effects related to this brain retention.

Echo Contrast Updates

Echocardiography experts say up to 20 percent of all resting echocardiography studies, and up to 30 percent of those conducted in critical care patients, can result in suboptimal echocardiograms. A suboptimal image is one in which two or more contiguous left ventricular segments in any of the three apical views cannot be visualized. The use of contrast in suboptimal echocardiograms can improve the diagnostic quality of these otherwise suboptimal exams.[4,5,6]

Echo contrast consists of perflutren lipid or protein microspheres. They contain gas, such as a high-molecular weight perfluorocarbon, which aids in reflecting ultrasound waves and in the sphere stability. These micro-bubbles are between 1-8 microns in size, so they can pass through the microcirculation.

In the past there was concern about the microspheres embolizing, which was why the FDA issued a “black-box” warning for Lantheus Medical Imaging’s Definity and GE Healthcare’s Optison agents in October 2007. This followed 11 deaths that appeared to be related to the agents. The warning contraindicated use in patients with worsening or unstable heart failure, acute myocardial infarction or serious ventricular arrhythmias or conditions that cause pulmonary hypertension. However, these events...
occurred over a period of six years and it was not clear if the contrast was the cause. Thirty minutes of close monitoring with vital signs and ECG after contrast administration were required, and the use of echo contrast plummeted.

The FDA revised these guidelines in May 2008 and replaced the extended contraindications with warnings after recognizing the favorable risk/benefit ratio for these contrast agents and the potential risks of alternative procedures. The FDA also considered evidence from several clinical studies initiated after the black box warning, showing the agents had a very good safety profile. Since then, use of echo contrast has rebounded.

A lingering contraindication due to the fear of embolization has been a ban on using echo contrast agents if there is a right-to-left or bidirectional cardiac shunt. The restrictions on patients with shunts was lifted for Optison in October 2016, and for Definity in February 2017. Previously, in suspected cardiac shunt populations, an agitated saline procedure was needed to determine if a shunt existed and whether the patient was contraindicated to receive an ultrasound contrast agent.

At the same time, the FDA also expanded Optison’s indication, allowing for administration by intra-arterial injection.

“Up to one-third of our patients have known or suspected cardiac shunts and, thanks to this important FDA decision, they too will now have access to ultrasound contrast agents, which offer an inexpensive and radiation-free option for diagnostic imaging,” said Steven Feinstein, M.D., co-president of the International Contrast Ultrasound Society.

In October 2014, the FDA cleared a third echo contrast agent, Bracco’s Lumason (sulfur hexafluoride lipid microsphere). The first U.S. imaging procedures took place in May 2015. The agent is supplied as a three-part kit. Also in 2015, Lumason was approved by the Centers for Medicare and Medicaid Services (CMS) for pass-through payment status under the Hospital Outpatient Prospective Payment System (HOPPS). The agent comes in a kit containing a Lumason vial with 25 mg of lipid-type A lyophilized powder and 60.7 mg sulfur hexafluoride headspace, a prefilled syringe containing 5 mL of sodium chloride 0.9 percent injection, USP (Diluent) and a mini-spike.

New Agents, Indications

In May 2017, the FDA expanded the indication for GE Healthcare’s Visipaque (iopamidol) 320 mg iodine/mL injection for use in coronary computed tomography angiography (CCTA) for diagnostic evaluation of adult and pediatric patients 12 years of age or older with suspected coronary artery disease. The new CCTA indication allows physicians to non-invasively image the coronary arteries, rather than use of traditional invasive coronary angiography to diagnose coronary artery disease.

FDA cleared Bayer’s Gadavist (gadobutrol) injection for use with magnetic resonance angiography (MRA), to evaluate known or suspected supra-aortic or renal artery disease, in April 2016.

New Types of Contrast Packaging

In 2014, Bracco released its Isovue (iopamidol) imaging bulk package (IBP), a specific combination multi-patient, multi-dose compliant contrast medium approved by the FDA for point-of-care use in the CT suite. It was designed to increase safety and improve workflow, while minimizing risk and maintaining compliance regarding the use of multi-dose CT contrast media-based on FDA and Joint Commission guidelines.

GE Healthcare offers its +PlusPak plastic packaging, which the vendor said offers advantages over traditional glass vials. This includes reduced storage, improved workplace safety and decreased cost of waste disposal due to the lighter-weight packaging, reducing red bag waste weight by 75 percent.

Comparison Chart Compiled by Diagnostic and Interventional Cardiology

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

<table>
<thead>
<tr>
<th>Company name</th>
<th>Lantheus</th>
<th>Bracco</th>
<th>GE Healthcare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand name</strong></td>
<td>Definity Injectable Suspension</td>
<td>Lumason</td>
<td>Optison</td>
</tr>
<tr>
<td><strong>Drug name</strong></td>
<td>Perfluor lipid microsphere</td>
<td>Sulfur hexafluoride lipid-type A microspheres</td>
<td>Perfluor protein-Type A Microspheres Injectable Suspension, USP</td>
</tr>
<tr>
<td><strong>FDA cleared</strong></td>
<td>FDA 2001</td>
<td>FDA 2814</td>
<td>N/S</td>
</tr>
<tr>
<td><strong>Indications</strong></td>
<td>Ultrasound contrast agent indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border</td>
<td>Indications in echocardiography, ultrasonography of the liver, and ultrasonography of the urinary tract. In echocardiography, to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult patients with suboptimal echocardiograms. In ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients. In ultrasonography of the urinary tract for the evaluation of suspected or known vesicoureteral reflux in pediatric patients</td>
<td>Optison is an ultrasound contrast agent indicated for use in patients with suboptimal echocardiograms to opacify the left ventricle and to improve the delineation of the left ventricular endocardial borders</td>
</tr>
<tr>
<td><strong>What differentiates your contrast from other vendors’ products</strong></td>
<td>Offers mechanical activation, which contributes to consistent image quality. It has a clinical study which displays a diagnostic advantage in echo that optimizes outcomes, patient management and cost-effectiveness. (Kurt, et al) Has extensive safety experience and a consistent safety profile across broad patient populations (gender and race in adults, and those 65 and older) and in multiple care settings. (Main ML et al) Published in over 1,800 peer-reviewed clinical studies. No.1 prescribed ultrasound agent in the U.S.</td>
<td>Lumason is the only ultrasound contrast agent with approved indications in echocardiography, ultrasonography of the liver and ultrasonography of the urinary tract</td>
<td>N/S</td>
</tr>
<tr>
<td><strong>Product dose units available</strong></td>
<td>Supplied as a single use 2 mL clear glass vial containing clear liquid in packages of four and 16 single-use vials</td>
<td>25 mg vial</td>
<td>3 mL</td>
</tr>
<tr>
<td><strong>Administration route</strong></td>
<td>Flexible dosing options: 1) diluted bolus; 2) continuous infusion; 3) IV bolus</td>
<td>IV</td>
<td>IV</td>
</tr>
<tr>
<td><strong>Contraindications</strong></td>
<td>Do not administer Definity to patients with known or suspected hypersensitivity to perfluor</td>
<td>Contraindicated in patients with history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in Lumason</td>
<td>Do not administer to patients with known or suspected hypersensitivity to perfluor, blood, blood products or albumin. High ultrasound mechanical index values may cause microsphere rupture and lead to ventricular arrhythmias</td>
</tr>
<tr>
<td><strong>Black Box Warnings</strong></td>
<td>Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perfluor-containing microsphere administration. Most serious reactions occur within 30 minutes of administration. Assess all patients for the presence of any condition that precludes contrast administration. Always have resuscitation equipment and trained personnel readily available</td>
<td>Adverse events most frequently reported in NDA clinical trials were mild. These included headache, nausea and/or vomiting, warm sensation or flushing, and dizziness in 5.4 percent or less of patients</td>
<td>N/S</td>
</tr>
<tr>
<td><strong>Reported side effects of the agent</strong></td>
<td>The most common adverse reactions (&gt;0.5%) are headache, back or renal pain, flushing, nausea, chest pain, injection site reactions and dizziness.</td>
<td>The most common adverse reactions were headache (1%), nausea, dysgeusia, injection site pain, feeling hot, chest discomfort, chest pain, dizziness and injection site warmth were reported in less than 1% of patients</td>
<td>Adverse events most frequently reported in NDA clinical trials were mild. These included headache, nausea and/or vomiting, warm sensation or flushing, and dizziness in 5.4 percent or less of patients</td>
</tr>
<tr>
<td><strong>Does the product need refrigeration</strong></td>
<td>Stored between 2-8°C (36-46°F). Activated Definity can be stored at room temperature for up to 12 hours, otherwise refrigerate</td>
<td>Store the kit at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)</td>
<td>Yes, refrigerate at 36-46 F. Vials can go directly from storage to cart without prepping or premixing. Stable at room temperature for up to 24 hours</td>
</tr>
<tr>
<td><strong>Recommended mean doses</strong></td>
<td>Diluted Bolus: Combine 1.3 mL activated Definity with 8.7 mL of preservation-free saline in a 10-cc syringe, gently hand-agitate to evenly distribute microbubbles and administer –1 to 2 mL slowly with subsequent injections as needed. Continuous Infusion: Combine 1.3 mL activated agent with 50 mL of preservation-free saline, gently squeeze IV bag to evenly distribute microbubbles, infuse at 4 mL/minute; max 10 mL/minute, adjust flow rate for optimal image enhancement. IV Bolus: Withdraw 10 μL/kg, administer slowly over 30 to 60 seconds, follow with a 10 mL preservative-free saline flush, as needed, using 0.2 mL to 0.3 mL, max allowable dose dose is 20 μL/kg.</td>
<td>Recommended dose of Lumason after reconstitution is 2 mL administered as an intravenous bolus injection during echocardiography. During a single examination, a second injection of 2 mL may be administered to prolong contrast enhancement. Follow each Lumason injection with an intravenous flush using 5 mL of 0.9% sodium chloride injection</td>
<td>Requires rotating/rolling the vial gently between the hands to ensure suspension of the microspheres</td>
</tr>
<tr>
<td><strong>Does the product require activation, preparation prior to administration? If so, please briefly explain the process and the life span of the agent after activation</strong></td>
<td>Activate by shaking the vial for 45 seconds using a Vialmix to produce a consistent activation. This delivers small, consistently-sized microbubbles, and contributes to predictable image quality. May be used for up to 12 hours after activation with Vialmix. If not used within 12 hours, vial may be returned to refrigeration and reactivated once with Vialmix within 24 hours. Reactivated Definity may be used for up to 12 hours</td>
<td>Needs to be reconstituted by injecting the prefilled syringe with 5 mL sodium chloride 0.9% injection into the Lumason vial. Use immediately after reconstitution. If the suspension is not used immediately, resuspend the microspheres for a few seconds by hand agitation before it is drawn into the syringe. Reconstituted suspension within a vial may be used for up to 3 hours from the time of reconstitution. Maintain vial at room temperature</td>
<td>N/S</td>
</tr>
</tbody>
</table>

* Data in this column was taken from from the vendor's website

Vendor supplied

Additional submitted information appears on our website at www.DIcardiology.com.
<table>
<thead>
<tr>
<th>Company name</th>
<th>Bayer</th>
<th>Bracco</th>
<th>GE Healthcare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand name</strong></td>
<td>Ultravist</td>
<td>Isovue</td>
<td>Omnipaque</td>
</tr>
<tr>
<td><strong>Drug name</strong></td>
<td>Iopamid injection</td>
<td>iopamid injection</td>
<td>Iohexol</td>
</tr>
<tr>
<td><strong>FDA cleared</strong></td>
<td>1995</td>
<td>N/S</td>
<td>1986</td>
</tr>
<tr>
<td><strong>Type</strong></td>
<td>CT, interventional angiography</td>
<td>CT, interventional angiography</td>
<td>CT, interventional angiography</td>
</tr>
<tr>
<td><strong>Indications</strong></td>
<td>Indicated for intra-arterial procedures: 300 mgI/mL for cerebral arteriography and peripheral arteriography, 370 mgI/mL for coronary arteriography and left ventriculography, visceral angiography and aortography. Intravenous procedures: 240 mgI/mL for peripheral venography, 300 mgI/mL for excretory urography, 300 mgI/mL and 370 mgI/mL for contrast CT of the head and body (intrathecal, intra-abdominal and retroperitoneal) for the evaluation of neoplastic and non-neoplastic lesions.</td>
<td>Indicated for angiography throughout the cardiovascular system, including cerebral and peripheral arteriography, coronary arteriography and ventriculography, pediatric angiocardiology, selective visceral arteriography and aortography, peripheral venography (phlebography), and adult and pediatric intravenous excretory urography and intravenous adult and pediatric contrast enhancement of computed tomographic (CECT) head and body imaging.</td>
<td>Total of 39 FDA indications. Intravascular: coronary, cerebral, peripheral and renal arteriography; aortography, ventriculography; CT-body, CT-neck, CT-head; excretory urography (IV-DSA, IA-DSA), Intrathecal: lumbar, thoracic, cervical, total columbar and CT myelography, CT cystography, CT venoclysis. Oral/body cavity: Arthrography; GI tract; hysterosalpingography; endoscopic retrograde pancreatography; cholangiopenchrectography; herniography; and CT-abdominal.</td>
</tr>
<tr>
<td><strong>Product dose units available</strong></td>
<td>Ready-to-use in vials or bottles in concentrations of 240, 300 and 370 mgI/mL per mL. Avail. in a number of vial sizes, including 500 mL pharmacy bulk package</td>
<td>Isovue-200 (Iopamidol injection 41%); Isovue-250 (Iopamidol injection 51%); Isovue-300 (Iopamidol injection 61%); Isovue-370 (Iopamidol injection 76%)</td>
<td>Concentrations of 140, 180, 240, 300, 350 mgI/mL available in glass vials, +PlusPak polymer bottles, pharmacy bulk package</td>
</tr>
<tr>
<td><strong>Boxed Warning</strong></td>
<td>Not for intrathecal use. See full prescribing information for complete boxed warning.</td>
<td>Not for intrathecal use. Iopamidol injection is available as Isovue-M (Iopamidol Injection) for intrathecal administration</td>
<td>Not for intrathecal use. Inadvertent intrathecal administration may cause death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia and brain edema</td>
</tr>
<tr>
<td><strong>Drug interactions</strong></td>
<td>In patients with renal impairment, biguanides can cause lactic acidosis. Ultravist appears to increase the risk of biguanide induced lactic acidosis, possibly as a result of worsening renal function. Refer to Section 7 of the Ultravist Package Insert for more information</td>
<td>Renal toxicity has been reported in a few patients with liver dysfunction who were given oral cholecystographic agents followed by intravascular contrast agents. Administration of intravascular agents should therefore be postponed in any patient with a known or suspected hepatic or biliary disorder who has recently received a cholecystographic contrast agent. Other drugs should not be admixed with iopamidol</td>
<td>Drugs which lower seizure threshold, especially psychoactive drugs described as analeptics, major tranquilizers or antipsychotic drugs. Such medications should be discontinued at least 48 hours before myelography, should not be used for the control of nausea or vomiting during or after myelography, and should not be resumed for at least 24 hours postprocedure. In nonselective procedures in patients on these drugs, consider prophylactic use of anticonvulsants.</td>
</tr>
<tr>
<td><strong>Concentration, mg/mL</strong></td>
<td>Ultrastin injection is available in three strengths: 240 mgI per mL, 300 mgI per mL, 370 mgI per mL</td>
<td>Isovue-200 (Iopamidol injection 41%); Isovue-250 (Iopamidol injection 51%); Isovue-300 (Iopamidol injection 61%); Isovue-370 (Iopamidol injection 76%)</td>
<td>Concentrations of 140, 180, 240, 300 and 350 mgI/mL</td>
</tr>
<tr>
<td><strong>Concentration, mg/mL</strong></td>
<td>In concentrations of 270 and 320 mgI/mL single-dose vials, single-dose glass bottles, +PlusPak polymer bottles</td>
<td>Concentrations of 140, 180, 240, 300, 350 mgI/mL available in glass vials, +PlusPak polymer bottles, pharmacy bulk package</td>
<td>Not for intrathecal use. Inadvertent intrathecal administration may cause death, convulsions, seizures, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, rhabdomyolysis, hyperthermia and brain edema</td>
</tr>
<tr>
<td><strong>Concentration, mg/mL</strong></td>
<td>In concentrations of 270 and 320 mgI/mL single-dose vials, single-dose glass bottles, +PlusPak polymer bottles</td>
<td>Not for intrathecal use. Inadvertent intrathecal administration may cause death, convulsions, seizures, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, rhabdomyolysis, hyperthermia and brain edema</td>
<td>Not for intrathecal use. Inadvertent intrathecal administration may cause death, convulsions, seizures, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, rhabdomyolysis, hyperthermia and brain edema</td>
</tr>
<tr>
<td><strong>Osmolarity</strong></td>
<td>240 mgI per mL: 483 mOsm/kgH2O; 368 mOsm/L. 300 mgI per mL: 607 mOsm/kgH2O; 429 mOsm/L. 370 mgI per mL: 774 mOsm/kgH2O; 496 mOsm/L</td>
<td>Concentration 200 mgI/mL = 413 mOsm/kg water; 250 mgI/mL = 524; 300 mgI/mL = 616; 370 mgI/mL = 798</td>
<td>Concentration 140 mgI/mL = 322 mOsm/kg water; 180 = 400; 240 = 520; 300 = 672; 350 = 844</td>
</tr>
<tr>
<td><strong>Method of filtering from body (excretion)</strong></td>
<td>The amounts of Ultrastin excreted unchanged in urine represent 97% of the dose in young healthy subjects. Only 2% of the dose is recovered in the feces. Similar recoveries in urine and feces are observed in middle-aged and elderly patients.</td>
<td>Renal</td>
<td>N/S</td>
</tr>
</tbody>
</table>

*Data in this column was taken from the vendor’s website

N/A = Not applicable
N/S = Not specified
<table>
<thead>
<tr>
<th>Company name</th>
<th>Gadavist</th>
<th>Evist</th>
<th>Magnevist</th>
<th>MultiHance</th>
<th>ProfHance</th>
<th>Dotarem</th>
<th>Gadoxetate meglumine</th>
<th>Gadodiamide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug name</td>
<td>Gadobutrol injection</td>
<td>Gadodextrate disodium injection</td>
<td>Gadopentetate dimeglumine injection</td>
<td>Gadobenate dimeglumine</td>
<td>Gadobenate dimeglumine</td>
<td>Gadobenate dimeglumine</td>
<td>Gadoxetate meglumine</td>
<td>Gadodiamide</td>
</tr>
<tr>
<td>FDA cleared</td>
<td>2011</td>
<td>2008</td>
<td>1988</td>
<td>N/S</td>
<td>N/S</td>
<td>N/S</td>
<td>N/S</td>
<td>N/S</td>
</tr>
</tbody>
</table>

**Indications**

- **Gadavist**: Indicated for use with MRI. To detect and visualize areas with disrupted blood brain barrier (BBB) and/or abnormal vascularity of the central nervous system in adult and pediatric patients (including term neonates), to access the presence and extent of malignant breast disease. Also indicated for use in MRA. To evaluate known or suspected supra-aortic or renal artery disease in adult and pediatric patients (including term neonates).

- **Evist**: Evist is indicated for intravenous use in MRI of the liver to detect and characterize lesions in patients with known or suspected focal liver disease.

- **Magnevist**: Indicated for use with MRI in adults, and pediatric patients (age 2 and older) to visualize lesions with abnormal vascularity in the brain (intracranial lesions), spine, and associated tissues. Magnevist injection has been shown to facilitate visualization of intracranial lesions including, but not limited to, tumors. Extracranial/Extraspinal Tissues: (indicated for use with MRI in adults and pediatric patients (age 2 and older) to facilitate the visualization of lesions with abnormal vascularity in the head and neck. Body: indicated for use in MRI in adults and pediatric patients (2 years of age and older) to facilitate the visualization of lesions with abnormal vascularity in the body.

- **MultiHance**: Indicated for intravenous use in MRI of the central nervous system (CNS) in adults and children over 2 years of age to visualize lesions with abnormal blood-brain barrier or abnormal vascularity in the brain, spine, and associated tissues. Extracranial/Extraspinal: Tissues (MRA) to evaluate adults with known or suspected renal or aorto-iliac occlusive vascular disease.

- **ProfHance**: Indicated for use in MRI for central nervous system (CNS) in adults and children over 2 years of age to visualize lesions with abnormal blood-brain barrier or abnormal vascularity in the brain, spine, and associated tissues. Extracranial/Extraspinal: Tissues in adults to visualize lesions in the head and neck.

- **Dotarem**: Indicated for intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adult and pediatric patients (2 years of age and older) to visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity.

- **Gadoxetate meglumine**: Indicated for intravenous use in MRI to visualize lesions with abnormal vascularity in the brain, spine and associated tissues; and within the thoracic (noncardiac), abdominal, pelvic cavities and the retroperitoneal space.

---

**What differentiates your contrast from other vendors’ products**

- **Gadavist**: A high relaxivity (0.21 • 1 mmol-1 • s–1 at 1.5 Tesla) macrocyclic GBCA. It is the first and only contrast agent indicated for breast MRI (BMR). First and only GBCA indicated for MRI of the CNS in patients less than 2 years of age (including term neonates) and for MRI of the supra-aortic vasculature.

- **Evist**: Approximately 50% of the Evist dose is selectively taken up by functioning hepatocytes allowing for an additional phase of imaging. In clinical trials, it demonstrated improved lesion detection and characterization of focal liver lesions, as compared to pre-contrast MRI (1). Blumenk DA, Sahani D, Amendola M, et al. Efficacy and safety of MRI imaging with liver-specific contrast agents: U.S. multicenter phase III study. Radiology. 2005;237(1):89–98. Significant improvement in detection of additional metastases and hepatocellular carcinomas.

- **Magnevist**: Magnevist was the first FDA-approved MRI contrast agent.

- **MultiHance**: First macroyclic and ionic gadolinium-based contrast agent in the U.S.

- **ProfHance**: A nonionic, low-osmolar contrast agent. Approved for a wide range of contrast enhanced MRI indications in both adult and pediatric (2-16 years). A low rate of reported allergic reactions. It has been used in a clinical setting for more than 15 years in more than 40 million scans.

**Product dose units available**

- **Gadavist**: Gadavist injection is supplied in single dose vials: 2, 7.5, 10, 15 mL, and single dose pre-filled syringes: 7.5 L, 10 L, 15 mL, and pharmacy bulk packages 30 and 65 mL.

- **Evist**: Supplied in 10 and 15 mL single-dose, rubber-stoppered vials containing 181.43 mg/mL of gadodextrate disodium, equivalent to 0.25 mmol/mL.

- **Magnevist**: Magnevist injection is an MRI-contrast agent with a 24-hour time of use for both 50 and 100 mL multi-dose pharmacy bulk packages. It is also available as single-dose vials (5, 15, 15 and 20 mL) and single-dose, pre-filled syringes (10, 15, 20 mL).

**Administration route**

- **Gadavist**: Intravenous bolus injection. Follow injection with a normal saline flush.

- **Evist**: Administer undiluted as an intravenous bolus at a flow rate of 2 mL/second. Flush the intravenous cannula with normal saline after injection.

- **Magnevist**: Intravenous injection, rate not to exceed 10 mL per 15 seconds. Follow with 5 mL saline flush after the injection.

**Method of filtering from body (excretion)**

- **Gadavist**: Excreted in an unchanged form via the kidneys.

- **Evist**: Equally eliminated via the renal and hepatobiliary routes.

- **Magnevist**: Exclusively eliminated in the urine.

**Contraindications**

- **Gadavist**: Contraindicated in patients with history of severe hypersensitivity reactions to Gadavist.

- **Evist**: Contraindicated in patients with history of severe hypersensitivity reactions to Evist.

- **Magnevist**: Contraindicated in patients with known or suspected hypersensitivity reactions to gadopentetate dimeglumine.

**Boxed warning, warnings and precautions**

**WARNING: NEPHROGENIC SYSTEMIC FIBRODYSPLASIA (NSF)**: See full prescribing information for complete boxed warning. GBCAs increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. The risk for NSF appears highest among patients with: chronic, severe kidney disease (GFR < 30 mL/min/1.73m2), acute kidney injury. Screen patients for acute kidney injury and other conditions that may reduce renal function.

**Hypersensitivity reactions**

Hypersensitivity reactions: Anaphylactic and other hypersensitivity reactions with cardiovascular, respiratory or cutaneous manifestations, ranging from mild to severe, including death, have uncommonly occurred. Assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders. These patients may have an increased risk for a hypersensitivity reaction.

**Website for instructions for use and other drug information**


**Recommended mean doses**

- **Gadavist**: The recommended dose of Gadavist for adult patients is 0.1 mL/kg body weight (0.8052 mmol/kg body weight).

- **Evist**: The recommended dose of Evist is 0.1 mL/kg body weight (0.8052 mmol/kg body weight).

- **Magnevist**: Magnevist is administered intravenously, 0.2 mL/kg (0.1 mmol/kg), at a rate not to exceed 10 mL per 15 seconds. Dosing for patients in excess of 286 lbs has not been studied systematically. Refer to Section 2. Dosing and Administration of the Magnevist Prescribing Information to determine the volume to be administered.

- **Gadoxetate meglumine**: For MRA exam: 0.1 mmol/kg (0.2 mL/kg) rapid bolus intravenous injection followed by at least 20 mL saline flush. The recommended dose for CNS is 0.1 mmol/kg (0.2 mL/kg) rapid bolus. Follow with saline flush of 5 mL. See prescribing information.

**Vendor supplied**

- **Gadavist**
- **Evist**
- **Magnevist**

- **Data in this column was taken from the vendor’s website**
We at Philips thank you

Your insights have helped us introduce Azurion, the next generation in image guided therapy. We’re certain this state-of-the-art interventional platform is like nothing you’ve seen before. Develop cutting-edge treatment protocols and conduct more procedures efficiently with a unique user experience that helps to optimize your lab performance.

With Azurion, performance and superior care become one.

Discover all the benefits Azurion can bring to your interventional suite.

innovation + you

Visit: www.philips.com/azurion
The Latest Advances in Electrophysiology Tech
Innovations making EP less invasive and improving therapy efficacy

By Dave Fornell

Electrophysiology (EP) technology has been advancing rapidly the past few years, with new ablation tools to improve arrival fibrillation (AF) treatments, more accurate mapping systems and new implantable rhythm management devices that are making procedures much less invasive. Here are some of the recent advances highlighted at the Heart Rhythm Society (HRS) 2017 annual meeting in May.

Leadless Pacemakers
One of the biggest issues with implantable EP devices is the leads that connect the device to the heart. Leads are frequently cited as the weakest component of pacing, implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy (CRT) due to wearing out or complications due to infection. Traditional implantable devices also require surgery to install the leads and the can, increasing the complexity of the procedure, adding cost and exposing the patient to infection risks. Wireless technologies and the miniaturization of both electronic components and the batteries have enabled the development of transcatheter implantable pacing and now CRT systems, eliminating the need for surgery or venous leads.

In early 2016, the U.S. Food and Drug Administration (FDA) approved the Medtronic Micra device, the first headless, catheter-implanted pacemaker approved in the United States. It is the world’s smallest pacemaker at 0.8 cc in size, being a little smaller than its competitor, the Abbott/St. Jude Medical Nanostim. The device has a 20 French diameter and uses a 27 French introducer in the femoral vein, allowing catheter access to the right ventricle. Micra has four self-expanding nitinol hooks that extend as it is unsheathed from its delivery catheter. These act as an anchor, hooking into the trabeculation at the apex of the right ventricle. The operator performs a tug on it to ensure it will not embolize prior to final release. Out of more than 1,600 patients in the post-FDA approval study of the device, there has only been one embolization of a Micra. The battery, while small, is expected to have a 12-year life.

The Abbott/St. Jude Medical Nanostim pacemaker is currently pending final FDA review. The single chamber pacemaker device is designed to be fully retrievable. It has a docking button on the top of the device which can be grasped by a snare catheter and twisted to turn the device and unscrew the corkscrew-like anchor in the myocardium.

There were recent battery issues with the Nanostim device, causing its distribution in Europe, where it is currently approved, to be paused in 2016. St. Jude said it has now updated the battery technology. The battery life is expected to be nine to 10 years, depending on the pacing requirements.

It is an 18 French device that is delivered via catheter directly into the apex of the right ventricle under angiography. Vascular access is gained through the femoral vein.
NewPace Ltd. has developed the ISSD string ICD, which eliminates the can and transvenous leads. Implanting the flexible, cable-like device only requires two very small incisions, with no need to create a pulse generator pocket.

One issue with these two leadless pacing systems is that they are single-chamber devices, which only account for about 10-15 percent of the U.S. pacemaker market. Medtronic is working on a system to implant a Micra in each ventricle and enabling wireless communications between the two devices.

“The problem with regular pacemakers is the wire that goes to the heart, because as the heart is beating and the wire has all this motion, over the course of time you can hear breaks in the wires. The idea with a leadless pacemaker is that you take the whole wire out of the equation,” said Vivek Reddy, M.D., director of cardiac arrhythmia services and professor of medicine, cardiology, Mount Sinai Hospital, N.Y.

Reddy said as a single-chamber pacing system, both the Micra and the Nanostim perform very well according to clinical trial data, and Medicare is now reimbursing use of these devices. He said the main limitation to wider adoption is the single-chamber pacing. “Today, the main limitation with these devices is that we do not have the possibility of doing atrial pacing, and most importantly dual-chamber pacing. These devices are just the first step and the companies are working on ways to do atrial/ventricular pacing,” he explained. “Ultimately, the goal is to avoid the use of a lead, which has always been the weak link in pacemaker systems.”

**Wireless CRT**

CRT systems typically use an epicardial coronary sinus pacing lead for the left ventricle (LV), but placement of the lead on the outside of the heart is not ideal because of issues with the coronary sinus anatomy or scar tissue. Placing the lead inside the LV is ideal, but not practical with current technology.

EBR Systems is developing the WISE CRT system, the first endocardial, leadless CRT pacing system. It uses an electrode about the size of a large grain of rice that is implanted inside the wall of the LV using transcatheter delivery. A wireless ultrasound transducer is surgically implanted between the ribs to send ultrasound energy to the electrode, which converts the waves into electrical energy for pacing, eliminating the need for a battery or lead wire, allowing the device to be very small. This works as an adjunct device to work in combination with an existing connected pacemaker, ICD or CRT device. The conventional system senses the RV pacing and can work with the WISE system to synchronize the LV.

EBR Systems has European CE mark, where there are about 100 patients implanted with the WISE system. It is working to initiate a FDA investigational device exemption (IDE) trial.

**Improved Ablation Technologies**

Intracardiac ablation systems can cure or improve cardiac function due to arrhythmias by killing tracts of heart tissue to block the pathways of faulty electrical signals. This is most often done using pulmonary vein isolation (PVI). However, this technology requires EPs to literally connect the dots with point-by-point ablation catheters. This can be difficult in the moving heart with the surrogate mapping visualization, even for the experienced operators. This has led to about 40 percent of atrial fibrillation (AF) ablations being unsuccessful.

“Ablation therapy is growing at an extremely rapid rate, but it is still not a perfect procedure,” said Hugh Calkins, M.D., FACC, FAHA, FHRS, director of cardiac arrhythmia services and professor of medicine at Johns Hopkins Hospital. “Part of that is because we don’t have a perfect understanding of the mechanisms of atrial fibrillation, and part of that is because we don’t have perfect tools to accomplish what we want to accomplish.”

Calkins said about 70-80 percent of AF patients who go back for a repeat ablation procedure have at least one PVI that failed and reconnected to continue the arrhythmia.

He said Medtronic’s cryoballoon ablation system has seen rapid, widespread adoption in the past year since the positive data from the FIRE AND ICE trial. The study showed better outcomes with the cryoballoon compared to radiofrequency (RF) ablation. An economic analysis from that trial also showed savings from fewer rehospitalizations and repeat ablations.

HeartLight was granted FDA clearance in 2016 for its laser ablation balloon technology indicated for PVI to treat AF. The system consists of a compliant balloon that seats in the oristia of the PV, and a laser inside the catheter can be rotated around to ablate the tissue. It also has a camera inside the catheter to offer direct visualization of the ablation and location of the laser, eliminating the need for electro-mapping and cutting procedural time. The lesions are created with 20-30 second ablations. About 25 ablations are needed to isolate a PV with lesion overlap. The energy of the laser can be dialed down when ablating near the esophagus or other neighboring critical structures.

A late-breaking HRS trial highlighted a first-in-human study for the Biosense Webster RF balloon catheter in treating
patients with AF. The 39-patient RADIANCE study showed it could uniformly achieve pulmonary vein isolation in all patients without the need for “touch-up” with a focal ablation catheter. The system uses a balloon that is lined with several electrodes. The energy level can be changed for each electrode.

**Increasing Safety in Lead Extractions**

One of the biggest safety concerns in removing old device leads is the possibility of tearing the superior vena cava (SVC). This requires immediate emergency surgical repair to stop the bleeding and the complication currently has a 50 percent mortality rate. However, Spectranetics’ Bridge Occlusion Balloon, introduced in 2016, offers a new safety net during procedures, allowing rapid inflation of an intravascular balloon to seal the tear and allow the surgical team time to prep and perform a repair without fear of the patient bleeding out. The device is credited with saving several lives in the past year.

**Subcutaneous ICDs**

Boston Scientific introduced the first subcutaneous implantable cardioverter defibrillator (S-ICD) system in 2009. Since then, there have been many studies published showing it delivers very effective therapy and reduces the invasiveness of traditional ICD implants by eliminating the leads to the heart.

Medtronic is developing substernal ICD leads that are placed under the ribs to be closer to the heart, but not inside vessels. Unlike the S-ICD, it will include a pacing electrode.

A new technology in development is the “string ICD,” which replaces the can and cardiac leads with a long, thin cable-like device implanted subcutaneously in the chest. The first-of-its-kind NewPace Ltd. ISSD string ICD only requires two very small incisions with no need to create a pulse generator pocket.

**New Electro-mapping Systems**

For years the EP mapping system market was dominated by Biosense Webster and St. Jude Medical, but there were complaints that there was little advancement in the technology. This changed in 2014, when Boston Scientific launched the Rhythmia mapping system. At HRS 2017, the updated Rhythmia HDx was launched. It shows lower voltages than on previous systems. It uses a 64-electrode basket catheter to create very detailed, high-density maps with as many as 50,000 to 60,000 points.

“All the mapping systems are getting better, and the introduction of the Rhythmia super-high density mapping system has really put pressure on the other companies to come up with their own really-high-density mapping systems,” Calkins said. “Clearly, the whole field is moving toward more accurate mapping, more points, clearer electrograms, and hopefully this will translate into better efficacy with outpatients.”

Biosense Webster is now developing a new mapping system. In December 2016, Abbott/St. Jude Medical received FDA clearance for the Ensite Precision system. It was designed to improve the reliability and accuracy of AF ablation procedures. It includes the launch of the Advisor mapping catheter, which incorporates magnetic sensing technology. This works with a magnetic sensor placed under the patient to more accurately locate mapping points and the tip of the catheter inside the anatomy. It also helps increase the accuracy of the anatomical model of the heart the system creates to guide procedures. St. Jude said this has eliminated distortion of the model that was a drawback of the previous-generation system.

A new technology being developed that may offer a big reduction in mapping/procedural times is the Acutus Medical AcQMap system. It uses a basket catheter with 48 electrodes combined with 48 tiny ultrasound transducers. The basket can be manually rotated around inside the atrium to rapidly “paint” a very accurate combined electro- and anatomical map simultaneously in about five minutes. Conventional EP mapping systems can take 20 minutes or longer. The electrodes do not need to contact the walls because the vendor said they can detect the electrical field created by cardiac contractions. It gained CE mark in 2016, and will soon be submitted for FDA 510(k).
**Zoll Hospital Wearable Defibrillator Receives FDA Premarket Approval**

Zoll Medical’s Hospital Wearable Defibrillator (HWD) has been granted FDA pre-market approval (PMA). It is specifically designed to continuously protect patients at risk of ventricular tachycardia or ventricular fibrillation (VT/VF) during their stay in the hospital. It uses automatic detection and immediate treatment to manage patients at risk of VT/VF.

*Zoll | www.zoll.com*

**First Dedicated Coronary Bifurcation Stent Approved in U.S.**

The FDA granted PMA for the Tryton Side Branch Stent for the treatment of coronary bifurcation lesions involving large side branches. It is the first dedicated bifurcation device to receive regulatory approval in the United States and addresses an unmet need in coronary interventions. Tryton signed a distribution agreement with Cardinal Health enabling Cordis, its interventional vascular business, to be the exclusive distributor of the Tryton Side Branch Stent in the U.S.

*Tryton | www.trytonmedical.com*

**Philips Launches Azurion Platform Angiography System**

Philips began its launch of the Azurion next-generation image-guided therapy cath lab imaging system. The angiography system was developed in close collaboration with leading clinicians in the field. It features a state-of-the-art ergonomic design with an intuitive user interface. Azurion is designed to address budget challenges and is equipped with new workflow options and performance dashboards. It features more than 1,000 new components, including an enhanced flat-panel detector and an operating system for better integration. It uses ultra-low X-ray dose and real-time image processing. Parallel working enables the team to complete different tasks simultaneously in the lab.

*Philips | www.usa.philips.com/healthcare*

**Medtronic Receives FDA for Reveal Linq Insertable Cardiac Monitor With TruRhythm Detection**

The U.S. Food and Drug Administration (FDA) cleared Medtronic’s Reveal Linq Insertable Cardiac Monitor (ICM) with TruRhythm Detection. The monitor offers improved accuracy to better identify abnormal heartbeats. It offers exclusive algorithms that result in a 95 percent reduction in false bradycardia episodes and a 47 percent reduction in false pause episodes when compared with its predecessor. It also features a self-learning atrial fibrillation algorithm.

*Medtronic | www.medtronic.com*

**FDA Clears Nano-coated Coronary Stent to Reduce DAPT**

The FDA cleared CeloNova BioSciences’ first-in-class Cobra PzF NanoCoated Coronary Stent System. Coated with a proprietary nano-thin polymer that is designed to be highly biocompatible, it requires a minimum 30-day dual antiplatelet therapy (DAPT) regimen following intervention. The pivotal PzF SHIELD clinical trial successfully met its primary safety and effectiveness endpoints, with no stent thrombosis and low target lesion revascularization of 4.6 percent.

*CeloNova | www.celonova.com*
FDA Clears New Peripheral Artery Disease Treatment

The FDA granted market clearance to Ra Medical Systems’ DABRA (Destruction of Atherosclerotic Blockages by laser Radiation Ablation) System to treat peripheral artery disease (PAD). The catheter is unique in its ability to cross chronic total occlusions (CTOs) without having to cross the lesion with a wire, and it debulks and modifies arterial blockages using laser energy. Users say it is safe because it stays in the patient’s true lumen and does not go subintimal or perforate, common complications of other devices. It also is effective on all types of lesions.

Ra Medical Systems | www.ramed.com

New Teleflex Intra-aortic Balloon Pump (IABP) introduced

The U.S. Food and Drug Administration (FDA) granted 510(k) clearance for the Teleflex Inc. AC3 Optimus Intra-Aortic Balloon Pump (IABP). Clinicians may use the pump on patients with the most severe arrhythmias or with heart rates as high as 200 beats per minute. It has a third-generation AutoPilot Mode, which uses algorithms to address key clinical challenges and to simplify the delivery of IABP therapy. It automatically adjusts timing and triggering parameters, freeing clinicians to focus on the patient rather than the pump. It includes several exclusive algorithms, such as WAVE Inflation timing, deflation timing management and best signal analysis.

Teleflex | www.teleflex.com

FDA Approves Medtronic Resolute Onyx Drug-eluting Stent

The FDA approved Medtronic’s Resolute Onyx Drug-eluting Stent (DES). The device is the first DES to feature core wire technology, an evolution of Medtronic’s continuous sinusoid technology (CST). CST is a unique method of stent manufacturing, which involves forming a single strand of cobalt alloy wire into a sinusoidal wave to construct a stent. The vendor said this enables greater deliverability and conformability to the vessel wall. With core wire technology, a radiopaque inner core is incorporated within the cobalt alloy wire to enhance visibility for accurate stent placement. The technology also enables thinner struts while maintaining structural strength.

Medtronic | www.medtronic.com

First TAVR Embolic Protection System Cleared in U.S.

The FDA granted market clearance for the Claret Medical Sentinel Cerebral Protection System (CPS), the first device available in the U.S. that offers protection against the risk of stroke by capturing and removing debris dislodged during transcatheter aortic valve replacement (TAVR). In the pivotal SENTINEL randomized controlled trial, use of Sentinel reduced strokes by 63 percent in the first 72 hours after TAVR and maintained a substantial difference at 90 days. Claret Medical launched the device in selected high-volume TAVR centers. The company is also collaborating with the Centers for Medicare and Medicaid Services (CMS) to develop a pathway to achieve a new technology add-on payment and has already established an ICD code for reimbursement of the Sentinel.

Claret Medical | www.claretmedical.com
Gray Hair Linked With Increased Heart Disease Risk

Observational study finds high hair whitening score associated with increased CAD risk independent of chronological age and established cardiovascular risk factors

Gray hair has been linked with an increased risk of heart disease in men, according to research presented recently at EuroPrevent 2017, April 6-8 in Malaga, Spain. EuroPrevent is an annual congress of the European Society of Cardiology (ESC).

"Ageing is an unavoidable coronary risk factor and is associated with dermatological signs that could signal increased risk," said Dr. Irini Samuel, a cardiologist at Cairo University, Egypt. 

"More research is needed on cutaneous signs of risk that would enable us to intervene earlier in the disease process."

Atherosclerosis and hair graying share similar mechanisms such as impaired DNA repair, oxidative stress, inflammation, hormonal changes and senescence of functional cells. This study assessed the prevalence of gray hair in patients with coronary artery disease and whether it was an independent risk marker. This was a prospective, observational study that included 545 adult men who underwent multi-slice computed tomography (CT) coronary angiography for suspected coronary artery disease. Patients were divided into subgroups according to the presence or absence of coronary artery disease, and the amount of gray hair.

The amount of gray hair was graded using the hair whitening score: 1 = pure black hair, 2 = black more than white, 3 = black equals white, 4 = white more than black, and 5 = pure white. Each patient's grade was determined by two independent observers.

Data was collected on traditional cardiovascular risk factors including hypertension, diabetes, smoking, dyslipidaemia and family history of coronary artery disease.

The researchers found that a high hair whitening score (grade 3 or more) was associated with increased risk of coronary artery disease independent of chronological age and established cardiovascular risk factors. Patients with coronary artery disease had a statistically significant higher hair whitening score and higher coronary artery calcification than those without coronary artery disease.

In multivariate regression analysis, age, hair whitening score, hypertension and dyslipidaemia were independent predictors of the presence of atherosclerotic coronary artery disease. Only age was an independent predictor of hair whitening.

"Atherosclerosis and hair graying occur through similar biological pathways and the incidence of both increases with age," said Samuel. "Our findings suggest that, irrespective of chronological age, hair graying indicates biological age and could be a warning sign of increased cardiovascular risk."

Samuel said asymptomatic patients at high risk of coronary artery disease should have regular check-ups to avoid early cardiac events by initiating preventive therapy.

"Further research is needed, in coordination with dermatologists, to learn more about the causative genetic and possible avoidable environmental factors that determine hair whitening," she added. "A larger study including men and women is required to confirm the association between hair graying and cardiovascular disease in patients without other known cardiovascular risk factors."

She concluded, "If our findings are confirmed, standardization of the scoring system for evaluation of hair graying could be used as a predictor for coronary artery disease."
Vivid™ iq
The power to take you places.

GE Healthcare’s new compact directly addresses your changing needs with a combination of portability and power that makes it a great companion – wherever your journey takes you.

Cath Lab ... Interventional ... ER ... Pediatrics ... Even a tented exam room in a remote locale

Learn more at gehealthcare.com/vividiq

* The device has been verified for limited use outside of professional healthcare facilities and has not been evaluated for use during transport.
Use is restricted to environmental properties described in the user manual; please contact your GE Healthcare sales representative for detailed information.