Dear Valued Hologic Customer,

As we approach the end of a busy 2011, it is worth looking back and taking stock of the year. For many of you and our associates, I would have to say the biggest moment of the year was receiving final FDA approval for the first commercial 3D breast tomosynthesis system, which some have called the most significant advance in mammography in many years. Approval of 3D tomosynthesis opens the door for many new possibilities in breast cancer detection. We can’t thank you enough for your patience and support.

Our commitment to advancing breast care does not stop with 3D imaging. We are keenly aware that 3D tomosynthesis represents just one facet of breast cancer detection, diagnosis and therapy. Comprehensive breast care involves what we like to call a "continuum" of care. That’s why over the past year, you have seen the scope of Hologic solutions available to you expand with the addition of the Aixplorer™ breast ultrasound solution, the Sentinelle™ breast MR imaging and biopsy coils, Aegis™ software and new biopsy guidance workflow solutions, and the recent release of our Trident specimen radiography solution. You have also driven the rapid adoption of our Eviva®, ATEC®, and Celero® biopsy devices, which are used by more radiologists today than any other product in North America. These solutions have in common our commitment to a compassionate patient experience and unsurpassed clinical performance.

While we have expanded our solution offerings, we have not let up on our internal research and development efforts. We continue to invest heavily in the technologies and solutions of the future, always sensitive to the need to balance technological advance with economic reality. We do strive to focus on solutions that create clinical and economic benefit for your patients and your practice. And we expect to be on the forefront of the new frontiers that personalized medicine promises to bring. The continuum of care for breast cancer will evolve and our passionate commitment to saving more lives will never waver.

Thank you for your support!

Peter Soltani, Senior Vice President & General Manager, Breast Health

November 7-8, 2011
Breast MRI Course
Reston, VA
Go to www.acr.org for registration information.
**Spotlight on Breast Tomosynthesis Reimbursement**

*Sara Davis, Director, Managed Care*

**Q:** What is the Current Procedural Terminology (CPT) code for breast tomosynthesis?

**A:** There is not a specific CPT code for breast tomosynthesis at this time. Hologic is engaged in efforts to secure a specific code, which can take many months.

**Q:** When will Hologic have a billing code for breast tomosynthesis?

**A:** There are many moving pieces to this issue, including timing, clinical data and society support.

We are currently working with the American College of Radiology (ACR) to develop a strategy and to determine the appropriate time for the submission of a coding application.

**Q:** In lieu of a billable code specifically for breast tomosynthesis, is there a way to code for providing this service (screening and/or diagnostic)?

**A:** In the June 2011 addition of Radiology Coding Source, the ACR stated: “Breast tomosynthesis performed in conjunction with digital mammography is appropriately reported with the unlisted diagnostic procedure code 76499 to describe breast tomosynthesis and one of the HCPCS Level II "G" codes (G0202, G0204, or G0206) to describe the full-field digital mammography performed. If computer-aided detection (CAD) also is performed, it should be reported separately using one of the mammography CAD codes, 77051 (CAD performed in conjunction with diagnostic mammography) or 77052 (CAD performed in conjunction with screening mammography).”

Hologic cannot instruct accounts on how to bill, as there are various options that may exist. We are aware that some of our early adopters plan to bill for breast tomosynthesis utilizing the procedure code of digital mammography, an unlisted breast procedure code, a code modifier, or some combination of these codes and modifiers. It is the responsibility of the provider to determine and submit the appropriate codes and modifiers for the breast tomosynthesis service. It is important for the provider to be in touch with payers to seek guidance on the way to bill for breast tomosynthesis.

**Q:** Will commercial payers cover this procedure?

**A:** Commercial payers set their own medical policies and rates and are not obligated to follow Medicare.

As such, Hologic will be asking payers to cover breast tomosynthesis and to add the service to their medical policies to facilitate billing for breast tomosynthesis.

**Q:** What are my options for billing my patients if their insurance plan does not cover breast tomosynthesis?

**A:** Many payers allow patients to be charged for a service that is not covered, provided that a patient signs a document in advance acknowledging that the service may not be covered and the patient will assume financial responsibility for the service. Patients can choose to accept or decline breast tomosynthesis, understanding that they will have financial responsibility for this service if they accept. Providing such a document to patients explaining that breast tomosynthesis is a new technology and that it may not be covered can facilitate your ability to bill patients for the service.

**Q:** What resources are available to assist me with reimbursement questions and efforts?

**A:** Hologic has a dedicated Managed Care department that can:

- Discuss coverage, reimbursement and coding with you in greater detail
- Provide clinical documentation regarding breast tomosynthesis to support efforts with insurance coverage
- Work closely with accounts to support efforts at petitioning payers to cover and reimburse appropriately for tomosynthesis

For additional information, contact the Hologic Managed Care Department

Your Account Manager can provide information for the Managed Care contact in your area. For reimbursement and coding details: Contact the Reimbursement Hotline

**Monday – Friday | 8:30 am – 5:30 pm ET | (866) 369-9290 | Hologic@thepinnaclehealthgroup.com**
Introducing the Trident™ Specimen Radiography System

Pat Hall, Director, Strategic Marketing, Breast Health

In September, 2011 Hologic first released to market its Trident™ specimen radiography system. Trident is a dedicated, self-contained system that provides optimal image quality and an efficient workflow solution in biopsy suites, operating rooms (OR), or pathology departments. Eliminating the need to transport breast biopsy samples from the biopsy or OR suite to be imaged on a digital mammography system can decrease a patient’s time under anesthesia by as much as 19 minutes, as well as reduce the need for re-excision.*

The Trident detector, with a 12 cm x 14 cm active image area, uses Hologic’s 70µm, amorphous selenium, direct conversion technology to provide enhanced image quality and accommodate the majority of sample sizes. It also employs breast tissue specific specimen processing algorithms and five levels of image sharpening, providing user-selectable options based on the specimen type.

The system also offers a number of workflow enhancing features:
- An ergonomic, mobile cart for efficient transfer from one area to another
- Lighted specimen chamber with storage for magnification trays
- Contact, 1.5x and 2.0x magnification imaging positions, with auto-sensing magnification trays
- Once-monthly auto-calibration, which can be performed at system shutdown
- One-click transfer of images to PACS and/or SecurView® diagnostic workstations
- An optional uninterruptable power system, allowing Trident to move from room to room without powering down.


Applications Tip

Adding a new procedure at a manager level to the Selenia® Dimensions® system.

Patty Ayala, R.T. (R) (M), Clinical Applications Specialist

To add a new Tomo or Combo procedure as a manager level user, complete the following steps.

- Log into the Dimensions System as a manager level user.
- Select the Admin button.
- Select the Procedure Editor button.
- From the Manage Procedures page, select New, on the right hand side of the page.
- From the Add Procedure page, fill in the appropriate information. Name, Procedure Group, Type and RIS Code.

Add the views to be included in the procedure.
- Select Add View on the right hand side of the page.
- Select the Tomo or Combo tab (Be sure to be on the correct tab for the procedure).
- Select the Icons needed for the procedure (The order that the icons are chosen, will place the icons in the preferred order for your site).
- Touch Add to add the icons to the procedure.
- At the Add Procedure page, touch Save to add procedure to your Procedure list.
- Touch OK
- Touch Back twice.
SecurView® DX Version 7.3 New Software Addresses Requests from Early Tomosynthesis Adopters

Dave Mislan, Product Manager, Breast Imaging

As the use of tomosynthesis grows at breast imaging centers, radiologists and administrators face new challenges in incorporating these cases into their clinical workflow. Successful adoption of this new modality requires rapid review of three dimensional datasets at the diagnostic workstation, and also the seamless integration of tomosynthesis images with enterprise PACS. SecurView software version 7.3, released in October, 2011, contains a number of improvements and new features in response to the requests of early tomosynthesis adopters.

As with conventional mammography, a key requirement for radiologists reading tomosynthesis cases is to have instantaneous access to all the views that comprise a patient’s study. For tomosynthesis, this means tools must be available to allow for scrolling through all the slices in a three dimensional dataset, typically 40-80 images, without delays. Because of the size of tomosynthesis images, this presents a challenge for diagnostic workstation applications; images must be read from disk before being loaded into the workstation memory, and delays can result, particularly for the first pass through a tomosynthesis dataset. In response to feedback from users, SecurView software version 7.3 provides improvements in scrolling performance over earlier versions of between 50% and 100%, depending on the hardware configuration.

![Indicators on the tomo scroll bar show “tagged” slices that can be exported to PACS](image)

As with conventional mammography, a key requirement for radiologists reading tomosynthesis cases is to have instantaneous access to all the views that comprise a patient’s study.

When a new modality such as tomosynthesis is introduced, an area of concern for system administrators is compatibility with PACS and seamless integration with existing clinical workflow. Version 7.3 contains a number of new features that address some of these concerns. During review of tomosynthesis images, radiologists need to mark slices of interest that can then be exported for viewing on other workstations by technologists, surgeons, or referring physicians. SecurView software version 7.3 includes expanded ability to easily “tag” slices of interest that may then be automatically exported to PACS or other destinations when the study is marked as read. These tagged slices are stored as DICOM Secondary Capture images and can be viewed on any PACS workstation.

SecurView software version 7.3 is also compatible with the DICOM object for Breast Tomosynthesis Image Storage. This is a new addition to the DICOM standard that is being implemented by many PACS vendors, and will allow for viewing of tomosynthesis images on any PACS workstation that supports the new object. Hologic is actively working with a number of PACS vendors to help accelerate adoption of the standard. Support for the Breast Tomosynthesis Object will be available on Selenia Dimensions with the release of version 1.6 in early 2012.

It is strongly recommended that all sites using SecurView to review tomosynthesis exams be upgraded to version 7.3 to take advantage of the performance benefits and new tomosynthesis features. Contact your Hologic Service representative to arrange an upgrade.

FOR MORE INFORMATION contact your Hologic Account Manager
A Global Commitment to Women’s Health
Sarah Downs, Contributing Writer

In few places around the world does this Hologic mission statement resonate more than in the district of Aguablanca in Cali, Colombia. Here, nearly one million people live in extreme poverty. These are people who have been evicted from their rural lands or who have fled natural disasters, misery and armed gangs. While many permanent neighborhoods have sprung up – and some basic services are provided – there is a dire lack of healthcare services.

Thankfully, Dr. Amando Sardi, a cancer surgeon from Mercy Medical Center in Baltimore, Maryland hadn’t forgotten his roots when he came to the U.S. in 1981 as a young resident. “He always wanted to do a mission back in Cali,” says John Singer, M.D., F.A.C.S., a retired surgeon from St. Agnes Hospital in Baltimore who originally trained Dr. Sardi. That long-held dream became a reality six years ago, when Dr. Sardi, Dr. Singer and 20 other volunteers journeyed 2,500 miles to Cali to begin their first six-day mission.

This past April, United Hands for Health, as the group is now called, completed its sixth mission. “In six years, we have seen 33,000 patients and performed 2,300 procedures,” notes Dr. Singer, who says that today, the mission has grown to about 90 volunteers – including all kinds of physicians – who work out of three hospitals in Cali. Each volunteer is assigned a translator – a local student from one of Cali’s two bilingual high schools – to act as an intermediary.

Breast biopsies are among the procedures that Dr. Singer performs – thanks, in large part, to Hologic. As Dr. Singer explains: “While the hospitals are well-established, we often must bring in our own equipment, particularly disposables, to supplement what the facilities have.”

Each year, Hologic donates 50 Celero® ultrasound-guided breast biopsy devices to the cause. “If a patient has a palpable mass or a mass that can be seen on ultrasound, we can now do minimally invasive breast biopsies using the Celero device, rather than open surgery,” says Dr. Singer. “We just make a tiny incision, insert the device and the needle is fired into the mass. It’s much less painful and the woman recovers faster.”

Typically, of the 50 women who undergo breast biopsy each year, at least one is diagnosed with breast cancer – often at a later stage than in the U.S. As Dr. Singer notes, while 85 percent of women in the U.S. are diagnosed at Stage 1 or 2, in Colombia, most are diagnosed with Stage 3 or 4 breast cancer. Thanks to the coordinated support of United Hands for Health, women are able to receive treatment at one of the three hospitals where the volunteers work. In addition, a local surgical oncologist provides her services at no cost.

United Hands for Health is also working to establish a breast and cervical cancer program in Cali. “In the entire Aguablanca district, there isn’t even one mammography system available. So it’s not surprising that breast cancer is typically found in more advanced stages,” says Dr. Singer.

“These are very proud people,” he adds. “They may be poor and have nothing, but they are incredibly thankful for the care we provide. On their behalf, we greatly appreciate companies like Hologic. Having Hologic support our mission to take care of poor people of Cali is incredibly helpful and we are grateful for their efforts.”

For more information about United Hands for Health, visit www.colombiamission.org or www.unitedhandsforhealth.com

The district of Aguablanca in Cali is home to more than 900,000 people, the majority of whom initially settled in illegally constructed shacks, such as these.
Aegis™ Software: A New Vision for Early Detection

*Wes Hodges, Director of Software, MRI Solutions*

Aegis™ software is a multi-modality viewer that offers real-time 3D and 4D interactivity for 3D modalities. While all 2D imaging modalities are supported, such 3D modalities as MR and CT are loaded into true 3D volumes. They can then be instantly displayed as reformats, MIPs, thin MIPs, subtractions and surface renderings, without having to waste any time or disk space on lengthy reconstruction processing.

Aegis sofware is more than a viewer; it is actually an extensible, plug-in based framework. Plug-ins can offer a variety of functionality, including, but not limited to, anatomy and modality-specific image processing, interventional planning, and communication with third-party systems, such as PACS and reporting systems. Plug-ins share a common look and feel that makes it easier to learn how to use new functionality as new plug-ins are developed by Hologic for Aegis.

Two existing plug-ins for MR in Aegis are the Aegis Breast plug-in and the Aegis Prostate plug-in. These offer analysis capabilities including dynamic contrast enhancement (DCE) colorization, lesion analysis, reporting, and key image/series generation. More importantly, they allow the user to change important diagnostic parameters on the fly, including DCE colorization threshold values and the maximum size of blood vessels from which the software should remove DCE colorization in order to better circumscribe lesions. Users aren’t restricted by processing and presentation decisions made beforehand; they can control their visualization on a study-by-study basis. This flexibility is complemented by various automated report generation tools, so reading a case can also be as automated or as manual as the user likes.

The Aegis Breast plug-in also offers MR-guided interventional functionality. The breast biopsy solution built fully in 3D space to improve targeting accuracy and visual confirmation.

The breast biopsy plug-in supports a multitude of grids and needles from a variety of vendors. The Hologic grid itself offers a specialized fiducial marker, so that grid-to-image registration can be automatically performed with a single mouse click.

Aegis sofware is available as a collection of standalone workstations, or as a thin-client web-based application. Both look and behave identically, so a site can choose the solution that best fits their size and needs. Standalone workstations often work well for low-volume sites that may only need a single reading station. The web-based enterprise solution favors medium- to high-volume sites by offering the flexibility of reading cases with Aegis sofware from any existing workstation in the institution, without the need to install any Hologic software. Aegis sofware is fundamentally designed to fit what a site requires, and what the site’s users require.

For more information on Aegis sofware, contact your Hologic Account Manager.

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**Hologic Hosts the Start of National Breast Cancer Awareness Month Ceremonies at NASDAQ**

On Monday, October 3rd, Rob Cascella, Hologic’s President and Chief Executive Officer, and a team of Hologic associates presided over the NASDAQ Stock Market Opening Bell Ceremony marking the start of Breast Cancer Awareness Month. This is the 6th year in a row that Hologic has been selected to host the event.

Mr. Cascella spoke to the importance of empowering women to make their health a priority and the role of companies like Hologic in finding and fighting breast cancer. “Early and accurate diagnosis of breast cancer is crucial to improving the outcome of women afflicted with this terrible, yet treatable, disease,” Mr. Cascella said. “We take our role as the leader in breast health very seriously and are excited to now be able to offer women 3D breast tomosynthesis for breast cancer screening and diagnosis. We are confident this new technology will help clinicians in catching breast cancers earlier and in significantly reducing the number of unnecessary diagnostic work-ups.”
Hologic Adds Pelvic Coil to Its MRI Solutions Portfolio

Julia Geer, Senior Manager, Product Marketing, MRI Solutions

The U.S. Food and Drug Administration has cleared Hologic’s Sentinelle™ Endo Coil array for pelvic imaging including the prostate and the surrounding tissues in the pelvis.

The Sentinelle MRI Endo Coil array for pelvic imaging provides a new solution for imaging and analysis of the prostate. With a similar profile to a transrectal ultrasound probe and the high signal-to-noise ratio of the array, allows radiologists and urologists to be more aligned than ever in the diagnosis and treatment of prostate and other forms of cancer in the pelvic region.

With an estimated 33,720 deaths in 2011, next to skin cancer, prostate cancer is the most frequently diagnosed cancer in men. Standard PSA screening, digital rectal exams and even the gold standard – transrectal ultrasound (TRUS) and TRUS guided biopsy – often miss or misdiagnose prostate cancer. TRUS guided biopsy fails to detect cancer in more than 20 percent of patients. Yet, when the disease is discovered in the local or regional stage, the five-year survival rate approaches 100 percent.

The Hologic Prostate Endo Coil array is a rigid type coil offering a two-channel array that is designed for easy insertion and optimal patient comfort. “The coil array deforms the tissue in the same way as the ultrasound device, so you can compare the anatomy in more similar positions between the two modalities. This, combined with its high signal-to-noise ratio, helps radiologists and urologists manage prostate cancer. “Our patients who have experienced different probes prefer the array’s smooth profile, especially during insertion and removal,” adds Iris Elliott, Pelvic MR Advanced Technologies Leader with Hologic.

The Hologic’s Prostate MR Solution also includes Aegis™ Prostate software, which offers comprehensive prostate image analysis and reporting. “The software provides a streamlined platform to perform multi-parametric image comparison. Each type of image provides useful information that, when combined with analysis tools, gives radiologists an easy to use and efficient way to look at the prostate MRI images,” says Iris. Aegis Prostate software provides all of the visualization and processing power of Hologic’s Aegis software and is DICOM-compatible, making it possible to read images taken with different MR coils or from different imaging modalities at the same time.


2 American Cancer Society, Cancer Facts and Figures: 2011

Advanced Workstation Manager

Chris Fischer, Program Manager, Advanced Workflow Manager

Hologic is excited to introduce the Advanced Workflow Manager (AWM) for Selenia® Dimensions® mammography systems. The AWM provides the ability to “network” multiple Dimensions systems together to operate more efficiently, resulting in faster image availability and distribution, and optimized departmental workflow.

The AWM enables all Dimensions systems within a facility to share a common patient list and allows studies to be seamlessly opened in any room in seconds, eliminating the need to retrieve the images from PACS. Additionally, when prior studies are sent to the AWM from PACS or pre-fetched with the help of a SecurXchange™ router, they become available to all Dimensions and are automatically displayed when a patient is opened. The AWM also provides additional enhancements to Dimensions/SecurView® DX bi-directional communications with real-time notice synchronization. When a radiologist creates a notice on the SecurView DX, the AWM distributes the notice to all Dimensions systems. After a technologist views the notice and performs the requested tasks, they can mark the notice viewed. Viewed notices are communicated to all Dimensions systems, as well as any SecurView RT or TechMate™ workstation to synchronize the status of the patient across all systems, allowing efficient task management and eliminating any manual steps.

Using Selenia Dimensions with the Advanced Workflow Manager provides a more streamlined departmental workflow, saving time and enabling technologists to focus more on patients and less on technology.

FOR MORE INFORMATION contact your Hologic Account Manager
To confidently rule out breast cancer without recalling your patients

Visit us at RSNA 2011.

The Hologic Selenia® Dimensions® clinical studies presented to the FDA as part of Hologic’s PMA P080003 submission that compared Hologic’s Selenia Dimensions 2D + 3D tomosynthesis to Hologic’s 2D FFDM. Based on ROC Analysis.

Marketing Corner
Helpful hints to market your facility

Billboard Advertising

Billboards are a great way to gain attention for your imaging facility/office. Remember, less is more when creating billboards. Use just enough words to entice both existing and potential new patients to call, to check out your website or even to schedule an appointment.

When it comes to billboard advertising, drivers typically have just a few seconds to grasp who you are and what you have to say. So keep your message simple. For contact information, we suggest to you only add your logo, website address and phone number.

Upcoming Events

Please visit us at one of these upcoming events to learn more about our products and services.

November
11/27 – 12/2 Radiological Society of North America (RSNA), Chicago, Illinois

January
1/28 – 1/29 SBI Practical Breast MRI Orlando, Florida

March
3/2 – 3/5 European Congress of Radiology (ECR), Vienna, Austria

To see a complete listing, visit hologic.com

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