

Background Information “Breast Care“

Breast Care Solutions by Siemens offer a comprehensive product spectrum for the diagnosis and therapy of breast cancer

Among women, breast cancer is with numbers reaching close to 30 percent the most common cause of cancer death in Germany and Europe. On a yearly basis 57,000 women¹ are diagnosed with it and more than 17,000 die from it in Germany.² This adds special importance to high-quality early detection and individual therapy. To this end, Siemens Healthcare developed comprehensive solutions for the early detection and treatment of breast cancer under the collective name of “Breast Care Solutions”. These comprise a combination of different imaging methods such as Ultrasound, Mammography and Magnetic Resonance Imaging (MRI) augmented by IT as well as solutions from lab diagnostics and radiation therapy.

The multi-modality approach to breast diseases (senology) is becoming more popular among physicians. Imaging techniques such as MRI and ultrasound as well as 3D breast tomosynthesis play an increasingly larger role. These imaging modalities offer comprehensive solutions from early detection and diagnostics to after-care for breast cancer patients. The new technologies provide improved image quality and optimized workflows which support the physician during the examination. This enables the examination of more patients within a shorter timeframe. Immune diagnostics tests provide revealing information about the therapy. The most current developments in “Breast Care“ are detailed below.

¹ Federal ministry of Health “Mammographie-Screening in Deutschland – Erfahrungen und Perspektiven” (“Mammography-Screening in Germany–Experiences and Perspectives”), ddb-forum Berlin, April 2008, www.mammographie-kongress.de

² Statistisches Bundesamt (Census Bureau), March 2007.

The digital mammography system Mammomat Inspiration

The digital full-field system Mammomat Inspiration with its basic function for screening has been on the market since the end of 2007. Presently, it has been implemented worldwide in close to 300 hospitals and private practices. Many new components provide the physician with improved exposures of the patient's breasts facilitating diagnostic activities. At the same time, the novel MoodLight function makes the system more comfortable for the patient than conventional mammography devices. MoodLight is a LED glass disk that glows in freely-selectable colors. A host of functions and technical details allow for very low radiation expositions during the examination by using, e.g., a special X-ray tube with a Tungsten anode or new AEC algorithms³ which calculate individual doses depending on the size of the breast and type of tissue present.

For several months now, the physician is able to – whenever necessary - perform biopsies in a simple and automated way at the Mammomat Inspiration. This is made possible by an additional biopsy unit that slides onto the mammography platform by hand. The mammography system recognizes the biopsy unit and automatically converts all functions of the hardware and software for the biopsy mode.

Tomosynthesis expands conventional 2D mammography into an imaging technique similar to computed tomography and generates 3D exposures of the breast. During this process, the X-ray tube takes exposures from several angles. The software uses the projection images to calculate a set of slice images together with the algorithms. The resulting 3D data provide the radiologist with better information as compared to previous methods because overlapping tissue is prevented. The first mammography systems equipped with tomosynthesis will be implemented in hospitals in the summer of 2009.

Ultrasound for early breast cancer detection

In case of dense breast tissue or ambiguous mammography findings, an additional imaging mode supports the physician in reaching a correct diagnosis: the ultrasound device. According to the *New England Journal of Medicine*⁴, dense breast tissue increases the risk of breast cancer by a factor of five. While conventional mammography is the method of choice for early breast cancer

³ AEC = Adaptive Exposure Correction (AEC); A new AEC algorithm further optimized dose calculation. All exposure parameters are adjusted automatically to the size and structure of the breast. Adaptive AEC offers significant flexibility in positioning the breast.

⁴ N Engl J Med 356;3. Boyd N.F. et Al., Mammographic Density and the Risk and Detection of Breast Cancer

detection, a study published by the RSNA (Radiological Society of North America) in 2002⁵ showed that the rate of detection for non-palpable invasive breast cancer increases by 42 percent when combining mammography with an ultrasound examination.

The Acuson S2000 Automated Breast Volume Scanner (ABVS) from Siemens is the first multi-functional ultrasound breast scanner which automatically acquires volumes of the female breast. Sonographic volumes provide an even better overview of the anatomy and architecture of breast tissue than previous techniques. In addition, these 3D images also display the coronal view of the breast (from the nipple to the breast wall) which to date has not been available with conventional ultrasound imaging. This coronal view facilitates and accelerates the diagnostic process and is also a valuable instrument in OR planning. The system is especially suitable for the early detection of breast cancer in women with dense breast tissue. Automatic image exposure via the ABVS can be generated in minutes and is faster than hand-held exposures. The scanner is besides early detection also highly suitable for the aftercare of breast cancer patients.

Another ultrasound examination method is the so-called elastography. It is especially suitable for examinations of nodes or changes in tissue (lesions) that are indicative of malignant changes. The technology known as “eSie Touch Elasticity Imaging“ is based on the elastic property of biological tissue and displays the different tissue strain, that is, the change in tissue elements at various locations in the region of interest. According to the American Cancer Society, 80 percent of all biopsied breast lesions are benign. The medical community hopes to reduce the number of unnecessary invasive breast biopsies with this method. The new application provides the physician with a higher level of accuracy when characterizing breast lesions. Tissue that shows a low compression profile can be indicative for malignant changes. Ultrasound in combination with mammography is the method of choice for women with dense breast tissue. In Europe and North America this holds true for two out of five women.

Innovations in magnetic resonance imaging (MRI) for breast cancer screening

Siemens developed the MRI system Magnetom Espree Pink especially for breast imaging. The large magnet aperture of 70 cm makes examinations more comfortable or even possible for obese or claustrophobic patients than previous systems. Depending on requirements, patients are positioned head or feet first. For patients who felt cramped in previous systems, the design of the Magnetom Espree Pink is highly advantageous. A so-called coil can be adjusted to different breast

⁵ Radiology 2002;225:165-175. Kolb T.M. et Al., Comparison of the Performance of Screening Mammography, Physical Examination, and Breast US and Evaluation of Factors that Influence Them: An Analysis of 27,825 Patient Evaluations

sizes. In addition, biopsies can be performed with this MR breast scanner. Other software applications also enable 3D images of the breast and provide for pristine image quality despite slight patient movement.

Another technology is the proton MRI spectroscopy of the breast, which can replace biopsies for determining the malignancy or benignity of lesions. This method provides the physician with essential metabolic information about the bio-chemical characteristics of breast lesions, which supports him in differentiating between malignant or benign lesions. According to a study ⁶ in Radiology, 68 percent of biopsies for breast lesions could be avoided with proton MRI spectroscopy without underdiagnosing malignant cases in this patient cohort. With the syngo Grace software, Siemens offers an excellent solution for proton MRI spectroscopy of the breast that prevents unnecessary biopsies for many patients. Syngo Grace uses choline as the biomarker ⁷ which not only improves differential diagnosis, but also provides simultaneous analysis of the biochemical characteristics of breast lesions.

Therapy monitoring - advances in immune diagnostics

More recent developments in immune diagnostics resulted in a biomarker that can support the physician in selecting from a wide range of medication - especially when he is dealing with the presence of metastases. The amount of this biomarker known as HER-2/neu is expressed in the blood of the patient. HER-2/neu is a protein that plays a key role in a certain aggressive form of breast cancer. The serum HER-2/neu assay by Siemens Diagnostics is the first and only blood test so far that has been approved by the Food and Drug Administration (FDA) for determining HER-2/neu proteins in the blood of patients with metastasizing breast cancer. The HER-2/neu values measured during the course of this disease reflect the patient's response to therapy and disease progression. This allows the treating physician to adjust the therapy, if necessary. Additionally, the serum test provides information for the prognosis of the disease.

⁶ Bartella L, et al "Enhancing Nonmass Lesions in the Breast: Evaluation with Proton (1H) MR Spectroscopy" Radiology 2007; 245: 80-87.

⁷ Biomarkers are molecules that make certain processes or substances in the human body visible, that is, they "mark" them. Detectable in blood, other bodily fluids or tissue, they can be indicators for diseases. Biomarkers can be produced by the body itself (e.g., special proteins after a heart attack) or in the lab: specifically developed biomarkers mark suspicious substances that indicate cancer or special proteins that are considered the cause of Alzheimer's. Biomarkers also indicate whether a certain therapy is likely to be successful, i.e. HER-2/neu: Reduced concentrations indicate successful treatment.

The **Siemens Healthcare Sector** is one of the world's largest suppliers to the healthcare industry. The company is a renowned medical solutions provider with core competence and innovative strength in diagnostic and therapeutic technologies as well as in knowledge engineering, including information technology and system integration. With its laboratory diagnostics acquisitions, Siemens Healthcare is the first integrated healthcare company, bringing together imaging and lab diagnostics, therapy, and healthcare information technology solutions, supplemented by consulting and support services. Siemens Healthcare delivers solutions across the entire continuum of care – from prevention and early detection, to diagnosis, therapy and care. Additionally, Siemens Healthcare is the global market leader in innovative hearing instruments. The company employs more than 49,000 people worldwide and operates in 130 countries. In the fiscal year 2008 (Sept. 30), Siemens Healthcare reported sales of €11.17 billion, orders of €11.78 billion, and group profit of €1.23 billion. Further information can be found by visiting www.siemens.com/healthcare.