

# IMG-96-001 - ULTRASOUND - 3D Ultrasound Imaging System and Process for Percutaneous Breast Tissue Biopsy

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## Technology description

This invention describes a three-dimensional (3-D) ultrasound system and process of performing percutaneous tissue biopsy for the diagnosis of breast cancer.

## Description

A breast biopsy procedure involves obtaining a sample of tissue from a section of the breast that has been identified as being abnormal through mammography to determine whether it is cancerous or benign. In the past, the majority of breast biopsies were performed using open surgical techniques in order to obtain sufficient samples of tissue to permit an accurate diagnosis. More recently, less invasive, image-guided, percutaneous methods of obtaining tissue samples have received increased acceptance in the diagnosis of breast cancer. These new procedures for breast biopsy can be performed on an outpatient basis in about half the time. This invention describes a three-dimensional (3-D) ultrasound system and process of performing percutaneous tissue biopsy for the diagnosis of breast cancer. The system allows a practitioner to accurately plan the entry of biopsy instruments, to guide their movement to a specific location within the breast, and to continuously monitor their position throughout the procedure.

Access to breast tissue for biopsy is best achieved when a patient is lying face down or in the prone position. Accordingly, the invention describes a three-portion table that serves to independently position the head and lower torso of the patient parallel to the floor with the breasts protruding from rounded apertures within an angled chest portion. The ultrasound transducer and a means for positioning the biopsy instrument (e.g., fine needle, core needle, vacuum-assisted) are attached to the underside of the table in a known relationship relative to each other. The breasts are immobilized by two soft curved pads that restrict movement of the lesions, push out the surrounding normal tissue, reduce the possibility of haematoma formation, and improve ultrasound visibility. Once immobilized, the entire breast or specific portions can be scanned by placement of the ultrasound transducer against the breast. The 3-D ultrasound images generated can then be used to determine the precise location of the lesion and establish the most suitable entry points for performing the tissue biopsies. Following insertion, the movement of the biopsy instrumentation to the precise location of the lesion is

performed under the guidance of continuous ultrasound imaging. As a result, percutaneous breast tissue biopsies performed using this system can be performed in less time and with less patient discomfort than more invasive procedures or those involving the use of other imaging modalities (e.g., X-ray, MRI).

According to the World Health Organization, more than 1.2 million people worldwide are diagnosed with breast cancer each year. The American Cancer Society estimates that approximately 211,300 women in the United States will be diagnosed as having invasive breast cancer this year, resulting in about 40,000 deaths. More than 1.5 million biopsies are performed each year for breast cancer diagnosis. Half of these procedures continue to be open surgical biopsies. The costs for breast tissue biopsy procedures range between \$1000 and \$5000. Aside from increased patient comfort, it is estimated that between \$500 and \$1000 per biopsy can be saved by substituting image-guided for existing open surgical biopsy procedures. As a result, systems and processes of image-guided percutaneous breast tissue biopsy are expected to continue to gain increased acceptance.

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