FMVantage Point™
HealthCare Appraisers' Industry Insight

2023 OUTLOOK FOR MEDICAL DIAGNOSTIC IMAGING EQUIPMENT:

APPRAISAL CONSIDERATIONS WHEN DETERMINING FAIR MARKET VALUE OF MAMMOGRAPHY SYSTEMS

KIRSTEN HODGES, ASA AND JEFFREY DOYLE, ASA

WHAT IS A MAMMOGRAM?

A mammogram is a low-dose x-ray image used to screen for and diagnose breast cancer and other diseases and disorders of the breast. Mammography produces images of breast tissue to enable radiologists to search for abnormalities such as fibroids, cysts, tumors or microcalcifications. Mammograms are the primary screening method for detecting breast disease, as the images can often reveal irregularities in the breast tissue before any symptoms are noticeable. There are two types of mammograms: (i) screening, a preventative scan using a small number of images; and (ii) diagnostic, used to investigate known changes, symptomatic conditions or abnormal findings yielded via a screening mammogram.

HISTORY OF MAMMOGRAPHY

In 1913, a German surgeon named Dr. Albert Salomon, who had used radiological technology to assess mastectomy specimens, was the first to publish his thoughts on the concept of using radiographic technology to differentiate benign and malignant findings through correlative radiological, macro and microscopic anatomical studies. In the 1960s, researchers in New York launched a large-scale randomized trial of mammography screening as a tool to reduce breast cancer mortality rates. In the course of the study, which lasted for nearly two decades, diagnostic x-ray breast screenings were conducted on more than 60,000 women. The long-term results of the trial, published in 1982 in the *Journal of the National Cancer Institute*, were shocking; participants saw a *30 percent* reduction in deaths from breast cancer when compared to the control group.

In the 1990s, the National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA) began establishing regulations and guidelines pertaining to digital mammography, with Congress passing the Mammography Quality Standards Act (MQSA) in 1992. The MQSA sought to establish minimum quality and safety standards to ensure universal access to quality mammography, as breast cancer posed the most commonly diagnosed and second most lethal oncological threat to women's health in America. In 2000, the FDA approved the first digital mammography unit, the *GE Senographe 2000D*. Eleven years later, Hologic introduced the *Selenia Dimensions*, the world's first three-dimensional (3D) digital breast tomosynthesis (DBT) machine. DBT is an advanced form of 3D imaging which uses two-dimensional (2D) images from multiple angles to build a stacked 3D image. With a 40 percent higher detection rate, 3D tomography units quickly became the preferred option in women's health clinics around the world.

SPECIALIZED TECHNOLOGY

Approximately 50 percent of women over 40 years of age have dense breast tissue, which reduces accurate detection rates of breast cancer on mammograms. Dense breast tissue has also been shown to increase the risk of developing breast cancer. Given these challenges, unique variations of the traditional mammography system have been developed in hopes of more timely diagnosis and greater accuracy in cancer detection rates among women with dense breast tissue.

Molecular breast imaging (MBI) takes an alternative approach to imaging breasts in comparison to traditional 3D mammography. MBI uses a specialized gamma camera to examine high-risk patients with dense breast tissue in cases where a mammogram may leave a tumor undetected. One disadvantage of MBI is the higher dose of radiation exposure for patients, so MBIs are generally only performed when a mammogram may prove ineffective.

Breast specific gamma imaging (BSGI) is a similar procedure to MBI, but with the added requirement of intravenous radioactive injections to develop the nuclear image. This technology involves even higher radiation exposure risks than MBI; therefore, BSGI is typically only used when mammography or magnetic resonance imaging (MRI) systems cannot confirm a diagnosis. Due to the heightened exposure risk, BSGI is not used for routine screenings and, when supplemental screenings are needed for dense breast tissue scans, MBI is preferred over BSGI.

APPRAISAL CONSIDERATIONS

- *Normal Useful Life (NUL)* – The NUL for a mammography system in a cost approach appraisal is estimated to be 7 to 10 years, with x-ray tube replacement expected by year 7. These estimates are largely based on usage volume and, more importantly, presuppose routine maintenance of the system.
- *Replacement Cost New (RCN)* – The RCN for mammography systems can vary depending on the capabilities of the system. A 2D system, such as the *GE Senographe Essential* or *Hologic Selenia*, costs around $60,000 to $80,000. An intermediate 3D system, like the *GE Pristina* or *Hologic Dimensions*, doubles the cost at $140,000 to $180,000. The latest models, such as the *Fuji Aspire Crystalle* or *Hologic 3Dimensions HD*, start at around $250,000. If a clinic wishes to expand their breast screening services, they may acquire a stereotactic breast biopsy system, such as the *Siemens Mammotest*, which can start around $50,000. These prices typically include installation costs and a one-year service agreement.
- *Functional Obsolescence* – Advancements in mammography and the overall diagnostic imaging industry have led to new milestones in patient care. Accordingly, older mammography systems gradually become less comparatively effective since they lack certain features found on their newer counterparts. One example of this is digital breast tomosynthesis (DBT), which is a superior system compared to its 2D alternative, given its advantage of higher detection rates and fewer false positives than in most 2D systems. To achieve optimal patient care, facilities must regularly assess the capabilities of their existing mammography equipment to determine if a system upgrade or replacement is warranted. Technological capabilities and comparative use case advantages are important to consider when valuating mammography systems.
- *Economic Obsolescence* – Since 1992, the MQSA has been leveraged to ensure that facilities provide high-quality mammograms and communicate clear and accurate results to their patients. Under the MQSA, all mammography facilities are required to be accredited by an FDA-approved certifying agency and undergo annual MQSA inspections. If a facility fails accreditation, it must stop providing mammography services until the deficiency has been corrected and accreditation is awarded. If violations are found during an inspection, the facility

is given notice and a specified amount of time to remedy the violation and pass a follow-up inspection. The value of a mammography system can be dependent on both current compliance considerations as well as the evolution of current and future regulatory guidelines.

CONCLUSION

In recent decades, mammography systems have significantly reduced breast cancer related deaths in women around the world. Proficiency surrounding the technology, various features and capabilities of mammography equipment is necessary when appraising these diagnostic imaging machines. As the value of a mammography system can be significantly affected by the unique characteristics and conditions discussed above, it is of the utmost importance to hire a qualified healthcare valuation firm, such as HealthCare Appraisers, to competently and reliably appraise mammography systems.