

TriMark Publications

December 2012
Volume: TMRMAM12-1201

MAMMOGRAPHY WORLD MARKETS *(SAMPLE COPY, NOT FOR RESALE)*

Trends, Industry Participants, Product Overviews and Market Drivers

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1. Overview

1.1 Statement of Report

Breast cancer is the most common type of cancer in women, affecting one in eight during their lives. Mammography is the most valuable method for detecting potentially cancerous anomalies in the breast. As such, the mammography segment is poised for a major new phase of growth fueled by the availability of new technologies. This TriMark Publications report examines the leading companies engaged in marketing, manufacturing or developing mammography equipment and supplies in the world. Each company is discussed in extensive depth with a section on its product line, business and marketing analysis, and a subjective commentary of the company's market position. Detailed tables and charts with sales forecasts and market share data are also included.

Mammograms are X-ray images of the breast produced from low radiation X-rays (1-3 milligrays, or mGy). The three types of mammography systems are: 1) analog systems, 2) computed tomography (CR) systems and 3) full-field digital mammography (FFDM). The analog systems are the conventional types, and they use X-ray films for capturing the breast images. The CR systems are also film-based, but are retrofitted with digital detectors. In FFDM, the X-ray film is replaced by solid-state detectors that convert X-rays into electrical signals. The electrical signals are used to generate images of the breast that can be viewed on a computer screen or printed on special film similar to conventional mammograms. Additionally, the radiation dose in FFDM is only 1.86 mGy radiation per view.

Digital tomosynthesis (DT) is a new technology with improved diagnostic capabilities of standard digital mammography. Currently, this technology is used in conjunction with FFDM, and in future it will be the standard tool for breast cancer examinations. The advantages of digital tomosynthesis include: 1) the ability to produce a number of reconstructed slices from different angles, 2) increased visibility because of improved algorithms that focus on suspicious areas of tissue and 3) a reduction in scan time. An examination of the breast with digital tomosynthesis takes only seven seconds. Additionally, digital tomosynthesis reduces patient discomfort, as it requires less compression of the breast. Mammography alone is not a reliable examination to ascertain that an anomalous area is cancerous. If the examination of mammography raises a doubt of cancer, additional breast imaging is usually recommended.

Computer-aided detection (CAD) technology is relatively a recent introduction in the field of breast imaging. The CAD technology serves as a second pair of eyes, examining a patient's mammogram film after the radiologist has already made an initial assessment. If the computer software finds any breast anomaly on the mammogram film, it marks them. Clinical studies of the CAD technology reveal that for every ██████ breast cancers detected with screening mammograms, the CAD can detect an additional ██████ breast cancers. Scintimammography (nuclear medicine breast imaging) is an additional breast exam that is used in some patients to detect a breast anomaly. Positron emission tomography (PET) imaging is also useful in detecting recurrent metastatic disease, but Medicare coverage is not presently available using PET systems.

As the mammogram facilities in the U.S. and Europe are gradually shifting to digital mammography systems, the film-based systems have been witnessing only a negative growth, and TriMark estimates that globally this sector will be worth about \$█████ in ██████ with a declining growth from \$█████ in ██████. The mammography sector has been witnessing an accelerated growth in demand for digital mammography. This has imposed more pressures on manufacturers to offer digital systems. TriMark estimates that the global digital mammography equipment market was worth about \$█████ in ██████ and anticipates this figure to reach about \$█████ in ██████.

The U.S. is the largest mammography market. However, there is decline in the number of mammography facilities and the number of units installed and yet, procedure growth in the U.S. is almost constantly at █%. The total number of procedures in the U.S. was about ██████ in ██████, and with █% growth, it is likely to reach ██████ in ██████. TriMark estimates that the mammography equipment market in the U.S. was worth about \$█████ in ██████, and it is set to reach \$█████ in ██████. The leading players of breast cancer market are consolidating their networks through international alliances, agreements, strategic acquisitions, exploring new markets and R&D initiatives that will help in more effective diagnosis and treatment of breast cancer.

1.2 Scope of This Report

This study gives priority to those companies that are actively developing and marketing clinical laboratory instrumentation, reagents and supplies for performing diagnostic tests specifically related to breast cancer surgery and screening mammograms. This focus is primarily on the hospital market and freestanding-clinic segments and, separately, on a description of the instruments, reagents and supplies marketed by major companies in this segment. Other areas covered in this study include what is generally characterized as digital imaging techniques instruments and reagents, picture archiving communications systems (PACS) or other data storage methods, or other medical imaging technologies. The reader should consult other TriMark reports for a detailed discussion of the important individual market segments related to the mammography market, such as imaging methods, computer tomography, magnetic resonance imaging (MRI) and digital X-ray. All of these subjects receive thorough treatment in other reports by TriMark and are available www.trimarkpublications.com.

Specialty areas in medical imaging are touched upon in this study, since these segments are frequently a part of the overall analytical focus of companies marketing general mammography equipment. However, no effort is made to quantify the size of this broader market. Companies that market and sell a limited number of instruments and equipment, as an OEM part of a much larger clinical laboratory product line by other companies, are only briefly mentioned. For example, Analytical Devices is discussed in terms of its relationship with Philips and Siemens Corporation. These companies are only reported in passing, since they are not a direct focus of the mammography market. Disposable supplies or imaging materials are not specifically covered here; however, business trends, technology trends and developing areas of clinical mammography are discussed in depth. This study further focuses on mergers and acquisitions in the sector, new product launches, and any important legal issues that are recent and have some bearing on the growth of the mammography testing sector.

1.3 Methodology

The author of this report is a Ph.D. in biochemistry from the University of Minnesota with many decades of experience in science writing and as a medical industry analyst. He has been a senior director of several large regional and national healthcare laboratories. The editor is a retired college professor with three decades of experience in teaching biochemistry, biotechnology and pharmacology. Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases and corporate websites, as well as annual reports for publicly-held firms. Additionally, sources of information include the non-governmental organizations (NGOs) such as the World Health Organization (WHO) and governmental entities like the U.S. Department of Health and Human Services (HHS) and U.S. federal agencies such as the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Breast cancer-related data were obtained from BreastReconstruction.org, American Society for Aesthetic Plastic Surgery (ASAP), American Cancer Society (ACS), International Agency for Research on Cancer, National Cancer Institute (NCI), National Center for Health Statistics (NCHS) and European Cancer Observatory. Where possible and practicable, the most recent data available have been used.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information in this study was obtained from sources that TriMark believes to be reliable, but do not guarantee the accuracy, adequacy or completeness of any information or omission or for the results obtained by the use of such information. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals regarding commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects, as well as Sector Snapshots that are published annually. TriMark extracts relevant data and analytics from TriMark's research as part of this data collection.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government-affiliated trade releases and other published information as part of its secondary research materials. The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations.

TriMark Publications Report, Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report in TriMark Publications includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly-available data and proprietary databases.
- Formulating a study outline with the assigned writer, including important items, as follows:
 - Market and product segment grouping, and evaluating their relative significance.
 - Key competitors' evaluations, including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
 - End-user research to evaluate analytical significance in market estimation.
 - Supply chain research and analysis to identify any factors affecting the market.
 - New technology platforms and cutting-edge applications.
- Identifying the key technology and market trends that drive or affect these markets.
- Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.
- Completing a confirmatory primary research assessment of the report's findings with the assistance of expert panel partners from the industry being analyzed.

1.4 Executive Summary

Breast cancer is the second leading cause of cancer deaths after lung cancer for women in the U.S. According to [REDACTED], nearly [REDACTED] women are afflicted with breast cancer globally and about [REDACTED] of them die. Physical breast examination and mammography are the only two options available for early detection of the disease. In [REDACTED], the U.S. Preventive Services Task Force (USPSTF) issued a dramatic change in the mammography guidelines for women between the ages of [REDACTED] and [REDACTED]. In short, the USPSTF recommended that women begin having mammograms at age [REDACTED], instead of the previous [REDACTED] starting point. This shift in government guidelines was met with swift negative reaction by several cancer and women's organizations.

The National Cancer Institute (NCI) appreciates the USPSTF's careful review and analysis of the evidence regarding breast cancer screening for women at average risk. The take-away message is that each woman needs to consider her individual benefits and risks and discuss them with her healthcare provider before making a decision on when to start screening mammography and how often to get one. The Task Force report concludes that screening mammography remains an important, effective tool for early detection of breast cancer. It also indicates, however, that the evidence of benefit might vary, according to age and individual risk factors. NCI has had screening mammography recommendations for many years, and will need to evaluate them in light of the Task Force's recommendations for all women, not only for those of average risk.

According to the [REDACTED], there are many benefits to screening mammography. Several large studies conducted around the world show that breast cancer screening with mammograms reduces the number of deaths from breast

cancer for women ages █ to █, especially for those over age █. Studies conducted to date have not shown a benefit from regular screening mammograms, or from a baseline screening mammogram (a mammogram used for comparison), in women under age █.

According to the █, the number of women over age █ is estimated to be █. The U.S. leads in its annual volume of mammography screening procedures. Over █ women age █ or above annually undergo breast examinations, resulting in as many as █ mammograms to be interpreted annually. Abnormality is evident in █% of these mammograms, with most cases undergoing a second test and about █% undergoing biopsy.

In the U.S., which is the largest market for mammography equipment, according to FDA, the number of certified mammography facilities has declined from █ in █ to █ in █. Correspondingly, the number of installed bases of mammography units also has declined from █ in █ to █ in █. Though there is decline in the number of mammography facilities and the number of units installed, procedure growth in the U.S. is almost constant at █%. The total number of procedures in the U.S. was about █ in █ and with █% growth it is likely to reach █ in █. Based on various data available from a number of sources pertaining to mammography, TriMark estimates that the digital mammography equipment market in the U.S. was worth about \$█ in █ and set to reach \$█ in █. Digital mammography equipment market is experiencing an impressive growth in the U.S. Europe has been burdened with the largest incidence of breast cancer and the market for mammography equipment in this region, according to TriMark was \$█ in █ with the potential to reach \$█ in █.