



MEDICAL IMAGING 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

The purpose of this report is to describe the specific market segment of the diagnostics market sector called medical imaging. This sector includes all of the generally accepted imaging activities used today, such as X-ray film and digital radiography, mammography, computed tomography (CT), magnetic resonance imaging (MRI), ultrasound, and nuclear imaging, as well as gamma camera (GC), single photon emission computed tomography (SPECT), and positron emission tomography (PET). This report examines these clinical measurement devices, their reagents, and supplies as used in hospitals, clinics and doctor's offices. It also includes information on associated segments such as picture archiving and communications system (PACS) markets, cardiology imaging markets, three-dimensional (3D) imaging markets and other emerging technologies.

1.2 Scope of this Report

The main objectives of this report are to:

- Identify viable technology drivers through a comprehensive look at various platform technologies for medical imaging markets.
- Obtain a complete understanding of the chief medical imaging markets tests: predictive, screening, prognostic, diagnostic and monitoring, from their basic principles to their applications.
- Discover feasible market opportunities via an identification of high-growth applications in different imaging areas, with a focus on the biggest and expanding markets for medical imaging markets.
- Focus on global industry development through an in-depth analysis of the major world markets for medical imaging, including forecasts for growth.
- Establish the essentials of the medical imaging market including definitions, processes and trends.

Market figures regarding the current value of the medical imaging market are taken from the most recently available data of the global medical products industry. This study will cover the following categories of medical imaging:

- General radiography and digital X-ray products.
- Mammography.
- Computed tomography (CT).
- Magnetic resonance (MR or MRI).
- Ultrasound (US).
- Gamma camera (GC).
- Positron emission tomography (PET).

Analysis includes the use of tables and graphs measuring product growth and trends within the marketplace. In addition, a discussion of research into the medical imaging arena provides the reader with a deeper understanding of the possibilities for future treatment and avenues for possible research and development (R&D) budgets. Company-specific information, including sales figures, product pipeline status and R&D trends is provided throughout the report. This report will:

- Assess the medical imaging market drivers and bottlenecks from the perspective of the medical and scientific communities.
- Discuss the potential benefits of the medical imaging market for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the medical imaging market and analyze the current size and growth of various segments.
- Provide current and forecasted market shares by company.
- Discuss profit/business opportunities by imaging segment.
- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of the medical imaging market.

Medical imaging products are hardware, software and supplies used to create, view and manage visual images of nonvisible organs of the human body for research, diagnosis and guidance of minimally invasive surgery. This report will focus on end-user markets including hospitals, research facilities, freestanding clinics, doctor's offices and equipment-leasing companies.

The following well-established technologies will be included in the study:

- X-ray, including analog and digital X-ray.
- Fluoroscopy, including standard and video fluoroscopy.
- Magnetic resonance imaging, including standard MRI and functional MRI (*fMRI*) or MR fluoroscopy.
- Computed tomography, including standard, multi-slice, or ultrafast electron beam tomography (EBT).
- Single photon emission computed tomography (SPECT).
- Positron emission tomography (PET).
- Ultrasound, including two-dimensional (2D) and 3D ultrasound.
- Endoscopy.
- Magnetic source imaging.

In the past few years, several multimodal products have been developed in an attempt to combine the advantages of structural and functional imaging. Multimodal combinations currently on the market include CT/SPECT units, PET/CT, MRI/magnetic source imaging and endoscopic ultrasound, which combines fiberoptic endoscopy and ultrasound. Emerging technologies referenced in the study are:

- Global picture archiving and communications systems.
- Image processing techniques.
- Magnetic resonance imaging and spectroscopy (MRS).
- Computed tomography for calcium scoring.
- Myocardial perfusion imaging.
- Real-time 3D scanning.
- Optical imaging including:
 - Optical spectroscopic imaging.
 - Optical coherence-based imaging.
 - Laser Doppler blood flow imaging.

Technologies excluded from the study are electroencephalogram (EEG) and electrocardiogram (ECG), except when combined with one of the included technologies, and thermal imaging. Products used for radiotherapy, non-medical imaging (*e.g.*, in physics, chemistry, geology and industry) and veterinary medicine are excluded from the study to the extent possible.

Medical imaging products usually are sold bundled as systems for creating or managing images. Systems include some or all of the following:

- Radiation source.
- Radiation detector.
- Patient table and gantry.
- Computers and displays.
- Robotic software.
- Image acquisition software.
- Image management software.
- Virtual reality software.
- Computer-aided detection (CAD) software.

Supplies, replacements or accessories will be discussed only if a significant after-market exists for them. The emphasis in this report is on those companies actively developing and marketing medical imaging technologies. The

reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for a detailed discussion of the important individual market segments related to the medical imaging markets such as picture archiving and communication systems.

This study concentrates on the medical imaging market segment in important worldwide markets such as the United States, Europe and Japan. It focuses primarily on the hospital market segment, and, separately, on a description of the instruments, reagents and supplies marketed by major companies in the hospital market segment. The analysis discusses the market size, growth rates and market components for instruments and reagents, controls and consumables used in medical imaging, with emphasis on contrast media and biopharmaceuticals used to enhance imaging resolution. This study reviews the market for medical imaging in the clinical hospital market. It defines both the national and worldwide dollar volume of sales of the market and analyzes the factors that influence the size and the growth of the market segments. The review details market sizes and growth rates, with projections usually through 2012 and beyond, when applicable, for the U.S. and world markets.

Activity and trends in the hospital markets are discussed in this report, particularly the trends that have stimulated this market. This analysis also comments in detail on the patterns of information processing in the medical imaging markets. It surveys all of the companies known to be marketing, manufacturing or developing medical imaging in the U.S. and worldwide. Leading companies are discussed in depth with a section on the history of the company, the product line, a business and marketing analysis, and a subjective commentary of the position of the company in its market.

The scope of this examination covers the global market for digital radiography (DR) imaging products, with emphasis on the U.S. The market for DR technologies can be divided into sectors according to application, such as mammography and angiography, and as a result, companies have developed different DR systems per application or have focused their entire business on one modality. This report examines these divisions and the markets for general radiography, mammography and cardiovascular radiography. Specific objectives of the report include:

- Types of DR imaging systems on the market.
- Competitive DR technologies.
- Digital X-ray technologies in research and development.
- Companies competing in the DR market.
- Company strategies.

This report deals with the analysis of the sector of medical imaging of the patient. The two most important areas where such tests are measured are the hospital and the clinic. The third most important place where these tests are measured is in physician's offices. Newer areas of testing interest for these analytes are satellite clinics and corporate locations.

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 senior editor is a Ph.D. in physiology from the University of Toronto and is a post-doctoral research fellow in the Department of Cell and Systems Biology at the University of Toronto. The editor of this report holds a Ph.D. in biomedical engineering and medical physics from Worcester Polytechnic Institute and the University of Massachusetts Medical School.

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). 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

The expanding and aging population, in which more diagnostic procedures are required, combined with the growing ability to do more procedures due to technological advances, are increasing the need for medical diagnostics and medical imaging. The worldwide medical imaging market is characterized by both large global players, with a solution available in each of the imaging modalities, and hundreds of small regional companies with a few products or a key technology aiming at niche markets. Regional differences in the quality of current equipment, regulatory requirements, and clinician preferences continue to be confounding factors in acceptance and penetration of each imaging modality.

Medical spending cuts worldwide will continue to pressure this market, particularly in regard to service and maintenance contracts. Yet, downtime risk portends revenue loss to hospitals and service providers will be forced to adopt new survival strategies. Price competition has had a severe effect on medical imaging equipment service providers, particularly independent service organizations, which are still acquisition targets for large original equipment manufacturers (OEMs) and vendors. It seems like everyone is just waiting to see what will happen, with mixed reports about the sales outlooks for [REDACTED]. Depending on the individual company's global breadth of product line and market penetration, most expect only a short-term blip.

Many medical imaging products and mammography services are specifically targeted at markets outside the traditional hospital. Competition in the development and marketing of medical imaging products is intense, and diagnostic technologies have been subject to rapid change. The major competitive factors in the medical imaging market include convenience, privacy, price and product performance as well as the distribution, advertising, promotion and brand-name recognition of the vendor or manufacturer.

There is a still considerable amount of old equipment in use, even in U.S. hospitals and facilities—some more than a decade old—particularly in modalities that are the most popular and commonly used, such as X-rays, CT and MRI. TriMark Publications expects pretty much across-the-board growth by equipment type (*e.g.*, filmless X-ray/radiography, ultrasound, MRI, CT scanning, nuclear medicine and PET) and by market (*e.g.*, hospitals, outpatient facilities, physician's offices, home health care, dental offices, veterinarian's offices and educational).

The U.S. market for the overall medical imaging equipment is expected grow up to [REDACTED]% annually through [REDACTED], driven by more procedures involving diagnostic imaging. However, legislation against self-referral for stand-alone imaging centers along with increased scrutiny of third party insurers in their pre-authorization processes may result in the market for high-end medical imaging purchases, such as PET and MRI, experiencing a slowdown in procedure growth.

According to a recent report from Centers for Medicare and Medicaid Services (CMS), imaging services use was on the rise among Medicare beneficiaries in [REDACTED]; the most common class of procedures performed, by far, was general radiography, the next most common modality was ultrasound, followed by CT, nuclear medicine, interventional radiology and magnetic resonance according to the CMS report. However, recent studies show that as many as [REDACTED]% to [REDACTED]% of the procedures should never have been done because their results did not help diagnose ailments or treat patients. These observations may lead to tighter regulations, hospitals scrambling to meet minimum standards, and a drive for outpatient facilities to become accredited.

The transition from film to digital imaging within the medical community is still in its early stages; however, the market potential is enormous. The continual replacement of conventional analog X-ray machines with computed and digital radiography (DR) equipment will provide modest growth for radiographic and fluoroscopic systems, despite the maturity of these markets. The U.S. medical X-ray film market is expected to continue its steady and slow decline between [REDACTED]% to [REDACTED]% per year. The digital radiography and mammography equipment markets combined should experience significant growth from approximately \$[REDACTED] in [REDACTED] to nearly \$[REDACTED] in [REDACTED], with a corresponding compound annual growth rate (CAGR) of [REDACTED]%. One of the biggest potential impacts will be the continued growth of wireless digital radiography. Wireless portable DR units already have been on the market for several years.

Breast cancer is the most common type of cancer in women worldwide, with [REDACTED] new cases reported each year. The U.S. is the leader in the annual volume of mammography screening procedures. Of these mammograms, [REDACTED]% to [REDACTED]% show some abnormality, with most cases undergoing a second test and about [REDACTED]% undergoing biopsies. In [REDACTED], [REDACTED]% of the mammography breast cancer screening systems sold in the U.S. were digital. Furthermore, the FDA Scorecard for [REDACTED] reported that [REDACTED] Mammography Quality Standards Act (MQSA) sites have adopted digital mammography—[REDACTED]% of all MQSA-approved sites. The reason for the continued interest in digital mammography systems stems from studies that have shown that up to [REDACTED]% of breast tissue cancers may be missed by conventional film-based mammography reading methods.

Digital mammography is still currently a young market, but growing well despite higher costs because of the increased resolution and ease of manipulation of the images produced digitally. The total digital mammography market size reached about \$ [REDACTED] in [REDACTED]. Film-based systems comprised less than half of the total mammography system sales worldwide also at the end of [REDACTED]. TriMark expects film-based systems sales to continue to decline in the coming years.

X-ray computed tomography, or CT scanning, has had a great impact on the medical diagnostics market. CT scanning allows cross-sectional imaging of the body with exquisite depiction of anatomic detail, and is finding growing use in coronary angiography and interventional procedures. The development of multi-slice CT machines, which are capable of performing sub-second imaging of millimeter-thin slices of body tissues, has opened up a host of new applications. The CT market structure has become increasingly complex as a result of the rapid technology platform changes. The rapid growth of the multi-slice CT market has been accompanied by the steep descent of single-slice CT, which is rapidly going out of clinical use. Overall sales in the CT equipment market are currently leading the growth of all medical imaging sectors. Comprising over one-third of the market, it reached an estimated \$ [REDACTED] in [REDACTED]. It is expected to grow to \$ [REDACTED] by [REDACTED], a CAGR of [REDACTED] %.

Magnetic resonance imaging (MRI) produces images using a magnetic field and radio frequency (RF) gradients under computer control to produce proton density images. Faster image scanning, new coil technology, more channels and more bandwidth performance are some of the advantages of buying MRI now. The MRI scanner market holds the second largest share of the overall global medical imaging market, and is the fastest growing segment with a projected CAGR of [REDACTED] % through [REDACTED], or \$ [REDACTED]. The U.S. MRI market reached an estimated \$ [REDACTED] in [REDACTED]. However, the refurbished MRI market might cannibalize some new sales if the economy and health reform pressures continue over the next few years. While the mid-range MRI systems are gaining ground in the market, the advent of high-field MRI technology in the 3T range is making in-roads in clinical applications.

Ultrasound vendors are working to push the envelope by creating faster, smaller, smarter systems. Typically, it is estimated that a mid-range ultrasound workstation, including the cost of an ergonomically designed state-of-the-art system, a table or cart, chair and accessories, can be purchased for about \$ [REDACTED]. New 4-dimensional (4D) imaging systems for existing markets and laptop or handheld devices for point-of-care testing will drive overall growth for diagnostic ultrasound. As the third largest segment, the global compact ultrasound equipment market is expected to grow at a CAGR of [REDACTED] % to reach over \$ [REDACTED] by [REDACTED] from its current value at around \$ [REDACTED]. Hand-carried units (HCUs) are the biggest sellers; global revenues for HCUs alone grew by [REDACTED] % in [REDACTED] and could represent more than [REDACTED] % of the global ultrasound market by [REDACTED]. General ultrasound (both cart-based and more portable systems) revenues should be fairly robust, with worldwide revenues continuing to experience solid growth and exceed \$ [REDACTED] by [REDACTED]. The general ultrasound market in the U.S. is estimated to reach about \$ [REDACTED] in [REDACTED].

Despite past reimbursement cuts for PET procedures as well as the overall imaging market observed decline over the past couple of years purportedly triggered by the [REDACTED] Deficit Reduction Act, the U.S. medical imaging market is expected to recover fully by [REDACTED] and PET will experience strong growth. Procedures will shift towards hospital-based PET procedures. The impact of these cuts, however, will be limited due to procedure volume growth and the ever increasing number of PET applications. The sector is expected to grow at a CAGR of [REDACTED] % from \$ [REDACTED] in [REDACTED] to \$ [REDACTED] in [REDACTED]. Also in the nuclear medicine realm is single photon emission computed tomography (SPECT), a medical and scientific tool that has finally come into its own to be fully appreciated. Virtually every hospital in the U.S. has SPECT as do several thousand outpatient diagnostic centers, so there is no issue of access. By comparison, about [REDACTED] PET systems exist and most of them are in fairly large hospitals. SPECT has the advantage of experience and technological advances that now are making it an important player in nuclear imaging. The most common SPECT system sold now, the dual-headed gamma camera, comprises [REDACTED] % to [REDACTED] % of the total U.S. market. Nevertheless, the market will be overwhelmingly dominated by PET/CT and hybrid SPECT/CT machines as PET-only and SPECT-only technology become outdated or just not enough for today's clinical multiple demands.

Demand for consumables (*e.g.*, contrast media, supplies, radiopharmaceuticals) will continue to expand at [REDACTED] % annually, to \$ [REDACTED] in [REDACTED]. Radiographic contrast agents make up more than [REDACTED] % of the market.

Radiopharmaceuticals will provide the best growth opportunities, based on the rising numbers of nuclear medicine, PET and PET/CT procedures. Clinician preference for value-added, biotechnology-derived agents that enhance not only image resolution and detail but also allow further understanding of disease states and potentially tailoring treatment to the individual, will increase the drive for more radiopharmaceutical research.

A picture archiving and communication system (PACS) integrates with a medical imaging modality, such as CT or MRI, and provides the ability to accept key patient and study information, associate this information with sets of images, and then transmit both the images and related information to an on-site storage device with archival and retrieval capabilities. Although a PACS reduces the costs of film-based imaging, the biggest challenge is economical storage and archiving, which requires intensive internal management and can strain hospital IT resources. An annual growth rate of █% is expected for PACSs in Europe and North America combined to reach an estimated \$█ by █.

The increasing three-dimensional (3D) and dynamic four-dimensional (4D) imaging capture and software rendering demands will make storage and retrieval requirements and capabilities stretched to the maximum. MRI, CT, and ultrasound images are most amenable to creating 3D images fairly easily. New modalities and software or hardware technologies that offer solutions to a burgeoning bandwidth problem stand to gain in getting the technologist or clinician to screen or diagnose in 3D more often than not. The world 3D medical imaging market is forecast to reach \$█ by █. Technological advancement associated with 3D medical imaging systems, visualization techniques, and procedures constitutes a principal factor driving growth in the global market.

The advent of new computer software and technology usually means improved care from institutions utilizing medical imaging equipment. In addition, the merger and acquisition trends of the past few years probably won't be slowing down anytime soon, as cost containment is a serious topic amongst almost all medical imaging equipment vendors and executives. New medical device regulations that have or will come into force soon in U.S. and in Europe will mean manufacturers will have to be in the business of proving efficacy and meeting more stringent controls. Looking ahead, it's important to consider those four drivers of the market: improved patient care, increased productivity, greater diagnostic accuracy and new applications. Each new advance in the technology brings surprises in its usefulness. It's wholly possible that new applications for the equipment in the pipeline will not be fully realized until it is available.

The continuous improvements in technology are producing a growing number of new or significantly improved imaging modalities that combine high levels of accuracy with a rapid, easy-to-use product format. It is clear that will be a steady increase in demand for quality medical imaging services in the next decade. Combined with pressures to improve the quality of healthcare delivered in the home and to lower its cost, those companies who able to meet these demands should perform the best in the face of increasing regulatory and health reforms and challenging economic times.