

TriMark Publications

January 2005  
Volume: TMRMAM05-0101

# MAMMOGRAPHY WORLD MARKETS

*(SAMPLE COPY, NOT FOR RESALE)*

Trends, Industry Participants, Product Overviews and Market Drivers

**TABLE OF CONTENTS**

1.	Overview	5
1.1	Statement of Report	5
1.2	Scope of this Report	5
1.3	Methodology	6
1.4	Executive Summary	6
2.	Imaging Market	8
2.1	Global Medical Imaging Market	8
2.1.1	Total Healthcare Expenditures and Demographics	8
2.1.2	Number of Hospitals	10
2.1.3	Number of Radiologists	11
2.1.4	Medical Imaging Companies	14
2.2	Market Drivers	15
2.3	Market Restraints	17
2.4	Market Segments for Medical Imaging	17
2.5	Key Players in the Medical Imaging Segment	19
2.6	Medical Imaging Sector Analysis	20
3.	Mammography Market: Market Segment Analysis: Size, Growth and Share	22
3.1	Global Mammography Markets	22
3.1.1	Market Drivers in the Women's Mammography Testing Sector	22
3.1.2	Market Segments for Mammography	22
3.1.3	Key Players in the Women's Health Diagnostics Testing Segment	22
3.1.4	Mammography Sector Analysis	23
4.	World Mammography Market	24
4.1	Mammography Overview	24
4.2	Market Overview	31
4.2.1	Introduction to Market Overview	31
4.2.2	World Mammography Markets Revenue	31
4.2.3	Mammography Markets by Region	32
4.2.4	Total Market Share	33
4.2.5	Competitive Structure	33
4.3	Market Opportunities	34
4.3.1	Resource Management for Mammography Markets	34
4.3.2	Movement to Higher Reimbursement Rates	34
4.3.3	Market Benchmarks for Increased Mammography Utilization	34
4.4	Market Analysis	34
4.4.1	Product Leadership	34
4.4.2	Product Line Strategy	35
4.4.3	Technology Innovation	35
4.4.4	Pricing Strategy	35
4.4.5	Strategic Partnerships	35
4.4.6	Long Term Trends	36
4.5	Strategic Outlook	36
4.5.1	Competitive Elements of Mammography Markets	36
4.5.2	Higher Reimbursement Rates	36
4.5.3	Volume Requirements	37
4.5.4	Product Innovation	37
4.5.5	Product Leadership	37
4.5.6	Product Line Strategy	37
4.5.7	Pricing Strategy and Reimbursement	37
4.5.8	Strategic Partnerships	38
4.6	Film-based Mammography Market	41

4.6.1	Market Overview	41	
4.6.1.1	Unit and Revenue Forecasts	41	
4.6.1.2	Product Analysis	41	
4.6.2	Market Drivers	43	
4.6.3	Market Restraints	43	
4.6.4	Film-based Mammography Market and Technology Trends	44	
4.6.5	U.S. Market for Film-based Screening Systems	44	
4.6.5.1	Unit Shipment and Revenue Forecasts	45	
4.6.5.2	Competitive Analysis	45	
4.6.5.3	U.S. Installed Base Analysis	45	
4.6.6	European Market for Film-based Mammography Systems	46	
4.6.6.1	Unit Shipment and Revenue Forecasts	46	
4.6.6.2	Competitive Analysis	46	
4.6.6.3	Installed Base Analysis	47	
4.6.7	Japanese Market for Analog Screening Systems	47	
4.6.7.1	Unit Shipment and Revenue Forecasts	47	
4.6.7.2	Competitive Analysis	47	
4.6.7.3	Installed Base Analysis	48	
4.6.8	Rest of the World Market for Analog Screening Systems	49	
4.6.8.2	Installed Base Analysis	49	
4.7	Digital X-ray Mammography Market	50	
4.7.1	Market Overview	50	
4.7.2	Product Background	51	
4.7.3	Product Description	52	
4.7.4	Market Drivers	56	
4.7.5	Market Restraints	57	
4.7.6	Unit Shipment and Revenue Forecasts	60	
4.7.7	Percentage Breakdown of Revenues by Region	61	
4.7.8	Market Share	62	
4.7.9	U.S. Market for Digital Mammography Systems	63	
4.7.9.1	Unit Shipment and Revenue Forecasts	63	
4.7.9.2	Competitive Analysis	63	
4.7.9.3	U.S. Installed Base Analysis	64	
4.7.10	European Market for Digital Mammography Systems	64	
4.7.10.1	Unit Shipment and Revenue Forecasts	64	
4.7.10.2	Competitive Analysis	65	
4.7.10.3	Installed Base Analysis	65	
4.7.11	Japanese (Pacific Rim) Market for Digital Mammography Systems	66	
4.7.11.1	Unit Shipment and Revenue Forecasts	66	
4.7.11.2	Competitive Analysis	66	
4.7.11.3	Installed Base Analysis	66	
5.	Mammography: Moderators of Growth for Mammography	67	
5.1	Moderators of Growth	67	
5.2	Personnel Acceptance	68	
5.3	Key People for Mammography	68	
5.4	Key Elements for Mammography	68	
5.5	Mammography and Reimbursement	68	
5.7	Satellite Facilities	70	
5.8	Regionalization of Laboratory Care	71	
5.9	Requirements for Mammography	72	
5.10	Reimbursement for Mammography	72	
6.	Business Trends in the Industry	75	
6.1	Sector Consolidation	75	
6.2	Mammographic Testing Growth Trends	75	

6.3	Acquisition, License Agreements, Internal Development, Partnerships	75
6.4	Product Testing Depth in Mammography	76
6.5	Government Regulation	77
6.5.1	U.S. Regulation	77
6.5.1.1	Importing Medical Devices into the U.S.	78
6.5.1.2	Exporting Medical Devices from the U.S.	79
6.5.2	U.K. Regulation	79
6.5.3	E.U. Regulation	81
6.5.4	Japanese Regulation	82
6.6	Increased Market Penetration	83
7.	Important Technology Trends	84
7.1	Stereoscopic Digital Mammography (SDM)	84
7.2	MRI	84
7.3	Mammography Trends	84
7.4	Computer-Aided Detection (CAD)	86
7.5	Laser Image Development	88
8.	Appendices	89
A.	DDSM: Digital Database for Screening Mammography	89
B.	Sources of National Cancer Institute Information	89
C.	Screening Mammograms: Questions and Answers	90
D.	FDA Rule: State Certification of Mammography Facilities	94

## LIST OF FIGURES

Figure 1:	Cancer Survival Rates	12
Figure 2:	Worldwide Market for Mammography Systems by Region 2002	32
Figure 3:	Worldwide Market for Film Based Mammography Systems by Region 2002	44
Figure 4:	Worldwide Market for Digital Mammography Systems by Region 2001	62

## LIST OF TABLES

Table 1:	U.S. Medical Imaging Market Size 2001-2008	8
Table 2:	Global Medical Imaging Market Size 2001-2008	8
Table 3:	U.S. Healthcare Expenditures	9
Table 4:	U.S. Health Expenditures as a Percentage of GDP, 1999-2008	9
Table 5:	U.S. User Expenditures for Medical Imaging Equipment and Related Products to 2007	9
Table 6:	Comparison of Spending on Health by Country, 2001	9
Table 7:	Spending on Health by Country	10
Table 8:	Millions of Americans Over 65 Years of Age 2000-2050	10
Table 9:	Public and Private Healthcare Expenditures 1960-2000	10
Table 10:	Total Number of U.S. Hospitals	11
Table 11:	Percent Change in Volume of Examinations per Imaging Modality between 1993 and 1996	13
Table 12:	Worldwide Market Share Medical Imaging Companies	15
Table 13:	Worldwide X-ray Testing 2001-2007	15
Table 14:	Worldwide MRI Testing 2001-2007	15
Table 15:	U.S. Use of Mammography in Women Over 40	25
Table 16:	Annual Mammography Procedures in the U.S.	25
Table 17:	Annual Mammography Procedures in Europe	26
Table 18:	Annual Mammography Procedures in Japan	26
Table 19:	Annual Mammography Procedures in the ROW	26
Table 20:	Mammography Facts (U.S.)	27
Table 21:	Breast Cancer Survival Rates by Country	28

Table 22: Surgical Biopsies Performed in the U.S.	28
Table 23: Benefits of Digital Mammography	31
Table 24: The Worldwide Mammography Instrument Market	32
Table 25: Worldwide Mammography Instrumentation Placements	33
Table 26: Worldwide Film-based Mammography Instrumentation Placements	41
Table 27: Worldwide Mammography Film-based Instrument Market	41
Table 28: Worldwide Mammography Film-based Instrument Market by Region	44
Table 29: U.S. Mammography Film-based Instrument Market	45
Table 30: U.S. Mammography Film-based Instrument Market Manufacturer Share	45
Table 31: U.S. Film-based Mammography Instrumentation Placements	45
Table 32: European Mammography Film-based Instrument Market	46
Table 33: European Film-based Mammography Instrumentation Placements	47
Table 34: European Mammography Film-based Instrument Market Manufacturer Share	47
Table 35: Japanese Mammography Film-based Instrument Market	47
Table 36: Japanese Film-based Mammography Instrumentation Placements	48
Table 37: Japanese Mammography Film-based Instrument Market Manufacturer Share	49
Table 38: ROW Mammography Film-based Instrument Market	49
Table 39: ROW Film-based Mammography Instrumentation Placements	49
Table 40: Advantages of Digital Mammography	51
Table 41: Worldwide Digital General Radiography Market	60
Table 42: Worldwide Market for Digital Mammography Systems Annual Unit Sales 2000 to 2007	61
Table 43: Worldwide Market for Digital Mammography Systems Dollar Volume 2000 to 2007	61
Table 44: Worldwide Mammography Digital Instrumentation Placements	61
Table 45: Worldwide Mammography Digital Instrument Market by Region	62
Table 46: Share of Worldwide Market for Digital Mammography Systems by Competitor 2002	62
Table 47: U.S. Mammography Digital Instrument Market	63
Table 48: U.S. Digital Mammography Instrumentation Placements	64
Table 49: European Mammography Digital Instrument Market	64
Table 50: European Digital Mammography Instrumentation Placements	65
Table 51: Japanese Mammography Digital Instrument Market	66
Table 52: Japanese Digital Mammography Instrumentation Placements	66
Table 53: 2005 Medicare Reimbursement for Mammography Services	74
Table 54: CAD Mammography Systems	88

## 1. Overview

### 1.1 Statement of Report

The purpose of this report is to describe the specific market segment of the *in vitro* diagnostics market called mammography. It covers the worldwide mammography market, discussing the market size, growth rates, market components and five-year projections for each of the important mammography tests. Moreover, it addresses business trends, technology trends and developing areas of clinical mammography, especially in the hospital and commercial market areas.

### 1.2 Scope of this Report

The emphasis in this report is on those companies and products that are actively developing and marketing clinical laboratory instrumentation and reagents and supplies for performing diagnostic tests on conditions specifically related to women's health. 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 mammography market such as imaging methods, computer tomography, MRI and digital X-ray.

This report concentrates on the mammography market segment in large worldwide markets such as the U.S., Japan and Europe. It focuses 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. Certain areas that are not covered include what is generally characterized as digital imaging techniques instruments and reagents, PACS or other data storage methods, or other medical imaging technologies, although many of the instruments, reagents and techniques in the mammography market segment are intimately associated with these broader areas.

Specialty areas in medical imaging are touched upon, 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 and their 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. Emphasis here is 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 women's health testing sector.

Also emphasized in this analysis are the hospital and commercial segments of the mammography market. Additionally, the physician's office and clinic mammography devices are described. Included are reviews of the clinical mammography reagents and equipment market in the U.S. and worldwide. This market can be divided into three broad areas: the hospital market, the doctor's office market and the freestanding clinic sector.

This report reviews the market for clinical mammography equipment and supplies in the clinical hospital market using screening methods. It defines the dollar volume of sales, both worldwide and in the U.S., and analyzes the factors that influence the size and the growth of the market segments. It details market sizes and growth rates, with projections usually through 2010 or beyond, for the U.S. and world market.

Activity and trends in the hospital markets are discussed here, including the numbers of institutions using mammography and the factors influencing purchasing activity. The report goes on to discuss in detail the trends that have developed which have stimulated this market. The patterns of information processing in mammography instruments are also discussed here.

Included in this analysis are surveys of most of the companies known to be marketing, manufacturing or developing instruments and reagents for the clinical mammography market in the U.S. and worldwide. Special effort was made to include mention of smaller companies and companies located around the world. Each company is discussed in depth with a section on the history of the company, the product line, business and marketing analysis and a

subjective commentary on the position of the company in its market. Finally the relative merits and market sizes of digital and film-based mammography is explored in detail.

### 1.3 Methodology

The information in this TriMark report is based upon interviews with sales and marketing professionals of companies in the mammography market. People from virtually every company mentioned in this analysis were queried, some several times, about their companies' products and marketing strategies as well as their overall thoughts about their industry segment. Information was also obtained from interviews with founders, CEOs and vice presidents of some of the companies discussed here. The structure of the hospital laboratories and near patient facilities was derived from interviews with laboratory directors and medical technologists working in these areas. Some of the information obtained was taken from Biotechnology Associates' proprietary databases and from the private data stores of TriMark Publications.

Other sources of information for the report were trade association publications and meetings, product brochures and catalogs, and company literature. Where the companies under discussion were publicly held, an examination of the annual reports, 10k filings and financial reports were analyzed as the basis of the data reported. The main data sources include the "Health for All Database" of the World Health Organization (WHO), data published by the statistical office of the European Communities (Eurostat), as well as various health data from the United Nations (UN) and the Organization for Economic Co-operation and Development (OECD). Where possible and practicable, the most recent data available have been used. The information set forth in this study was obtained from sources that we believe to be reliable, but we do not guarantee its accuracy, adequacy or completeness of any information, omission, or for the results obtained by the use of such information.

### 1.4 Executive Summary

There will be a steady increase in demand for medical imaging services, along with pressures to improve the quality of healthcare delivered and lower its cost. The women's mammography segment is poised for a major new phase of growth fueled by the availability of new technology coming out of the computer and digital areas and the higher interest of individual patients and general healthcare consumers to take charge of their own health status. Continuous improvements in technology are resulting in a growing number of new imaging diagnostic tests that combine high levels of accuracy with rapid, easy-to-use product formats. Digital mammography is driving more screening programs.

Many women's health imaging diagnostic products and mammography services are increasingly targeted at markets outside of the traditional hospital. Competition in the development and marketing of women's health diagnostic products is intense, and diagnostic imaging technologies have been subject to rapid change. We estimate that the competitive factors in the women's diagnostic mammography market include convenience, privacy, price and product performance as well as the distribution, advertising, promotion and brand name recognition of the marketer. There are approximately eight large dominant global players in mammography imaging. These are matched by hundreds of small companies with a few or one product aiming at niche markets. Large companies characterize the mammography market, and the segment is dominated by two or three very large players (e.g., General Electric).

During TriMark's analysis, we identified significant growth opportunities in the women's health diagnostic mammography business outside the United States. During [REDACTED], the total European women's health-oriented diagnostic testing business increased [REDACTED]% over the prior year. Europe spends a larger share of its healthcare expenditures on diagnostic testing ([REDACTED]%) than the U.S. ([REDACTED]%) but less than Japan ([REDACTED]%). The European market as a whole is slowly recovering from the weak performance of the [REDACTED], particularly the period from [REDACTED] to [REDACTED]. Slow growth was seen in [REDACTED], and it began to strengthen in [REDACTED]. The rate of growth in the European *in vitro* diagnostics market was about [REDACTED]% through [REDACTED]. TriMark projects that the European women's care diagnostics market is growing at a projected rate of [REDACTED]% through [REDACTED], somewhat higher than the general laboratory reagent market. The total value of the women's care market was \$[REDACTED] million in [REDACTED], with mammography testing strong throughout Europe.

According to the U.S. Centers for Disease Control and Prevention (CDC), [REDACTED]% of women over age [REDACTED] received a mammogram in [REDACTED]. As such, TriMark estimates that in [REDACTED] there were more than [REDACTED] million screening

mammograms in the U.S. According to the U.S. Census Bureau, the number of women over age 40 in the U.S. in 2000 was 100 million, and the projected U.S. population in 2010 for women aged 40 and above is 105 million. The American Cancer Society has adopted a goal that 75% of women over age 40 comply with screening guidelines by 2010.

TriMark estimates that the volume of mammography procedures in the U.S. in 2010 will total around 100 million, and that in 2000 there were more than 80 million screening mammograms performed in Europe. It is estimated that the annual growth is about 5%. Assuming this growth rate, a continued push to cover more eligible women and the introduction of digital techniques, the volume of mammography procedures in Europe in 2010 will total around 100 million. In 2000, there were about ten million screening mammograms performed in Japan. It is estimated that the annual growth is about 5%. Assuming this growth rate, and a continued push to cover more eligible women, the volume of mammography procedures in Japan in 2010 will total about 100 million, while the continued downward reimbursement structure in Japan will act as a brake on market expansion of mammography.

The U.S. is the leader in annual volume of mammography screening procedures. Over 100 million women age 40 or above annually undergo breast examinations, resulting in as many as 100 million mammograms annually that need to be interpreted. 10 percent of these mammograms show some abnormality, with most cases undergoing a second test and about 5% undergoing biopsies. The \$1 billion film-based mammography market of 2000 is expected to double to close to almost \$2 billion within 10 years, driven primarily by the growth of screening mammography markets. The film-based mammography imaging equipment market was approximately \$1 billion in 2000 and is projected to grow to \$2 billion by 2010. Digital mammography is currently a young and small market but growing well despite higher costs due to the increased resolution and ease of manipulation of the digitally-produced images. The total digital market size is projected to reach \$1 billion by 2010.

The total worldwide market for mammography, both film-based and digital, will grow from current levels of \$1 billion to over \$2 billion in 2010. By 2010 it is projected that the digital mammography segment will be nearly half of the total sales for the mammography sector. The digital segment had less than 10% of total worldwide placements of mammography instruments in 2000, and it is projected to grow to more than 50% by 2010. Sales of film-based mammography systems will grow at rates of 5% to 10% through 2010, reaching \$1 billion from the current market size of \$1 billion. By 2010, film-based systems will comprise about half of the total mammography system sales worldwide. Sales for the European market are estimated to grow from a base of \$1 billion in 2000 to an estimated \$1 billion by 2010. We anticipate a good solid growth rate based upon continued brisk sales of new, first time mammography units as well as replacements. Sales for the Japanese market will grow from a rather small base of \$1 billion in 2000 to an estimated \$1 billion by 2010. We anticipate slow growth rate based upon downward price pressures and the waning Japanese economy.