# Mammography Equipment Market to 2019

## Growth Driven by Technical Advances in Digital Radiography that Enhance Workflow and Improve Breast Cancer Detection




GBI Research
Global Business Intelligence

## GBI Research Report Guidance

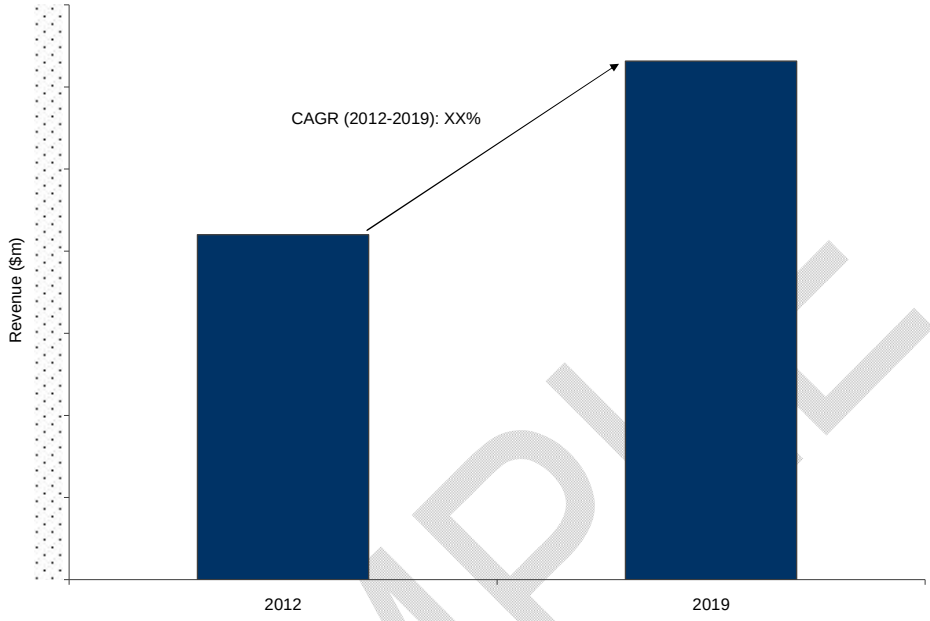
- Chapter two provides an introduction to the report and an overview of different types of mammography equipment.
- Chapter three provides information regarding market access and the regulatory process in key countries.
- Chapter four provides information on reimbursement trends in key countries.
- Chapter five provides information on the market size from 2005 to 2019. It also provides information related to market trends and dynamics, including comprehensive information on drivers and restraints. The chapter also provides a company share analysis for the global mammography equipment market.
- Chapter six provides information for the mammography market in the US, Canada, the UK, France, Germany, Italy, Spain, Japan, Australia, India, China and Brazil, including cross-country analysis, for the period from 2005 to 2019. The market information provided does not cover CR mammography equipment.
- Chapter seven provides a cost and efficacy analysis for the global mammography market.
- Chapter eight provides a comparison of DR mammography systems
- Chapter nine provides company profiles and their key marketed products. The chapter also provides a SWOT analysis for all of the companies profiled.
- Chapter 10 focuses on pipeline products in various categories. Key pipeline products are listed and discussed in detail and important clinical trials are also covered.
- Chapter 11 discusses the consolidation landscape in the global mammography market and looks at key deals for the period from 2008 to 2012.

## Executive Summary

The following figure shows the revenue generated by the global mammography equipment market from 2012 to 2019.

**Global Mammography Equipment Market to Exceed $XX by 2019**

**Mammography Equipment Market, Global, Revenue Forecast ($m), 2012–2019**




Source: GBI Research, Proprietary Database [Accessed February 28, 2013]; Interviews with marketing managers and other industry experts

The value of the global mammography equipment market amounted to an estimated $XXm in 2012 and is expected to have increased to more than $XXm by 2019 at a Compound Annual Growth Rate (CAGR) of XX%. The market is primarily driven by technical advances in Digital Radiography (DR) such as breast tomosynthesis, C-View 2D, contrast-enhanced mammography and changes in Computer-Aided Detection (CAD) algorithms. These advancements have led to improvement in breast cancer detection rates and a reduction in image acquisition and reconstruction time, which has in turn enabled medical practitioners to handle a higher volume of procedures. The high incidence of breast cancer in developed economies will continue to drive demand for mammography equipment during the forecast period. The Food and Drug Administration's (FDA) reclassification of 2D mammography equipment from a class III to class II device in 2010 helped to reduce the time and cost involved in the issuing of FDA approvals for new products. The use of other imaging modalities such as ultrasound and Magnetic Resonance Imaging ((MRI) in combination with mammography to improve breast cancer detection rates will drive rapid growth. Conventional film screen and Computed Radiography (CR) mammography equipment continues to be replaced by 2D and 3D DR mammography equipment due to the need for improved breast cancer detection and the ability to handle higher procedure volumes. Inadequate reimbursement for advanced technologies such as breast tomosynthesis and contrast-enhanced mammography will continue to negatively impact the adoption of these technologies in the short term.

# 1 Table of Contents

## 1.1 List of Tables

## 1.2 List of Figures

# 2 Introduction

Mammography is a non-invasive imaging technique, which uses a low-dose X-ray system to examine breasts. A mammography examination is referred to as a mammogram and is used for the early detection and diagnosis of breast abnormalities in women. Mammography is the most effective tool for the early detection and diagnosis of breast cancer. This report will discuss the market for DR mammography equipment, film-screen and computed radiography mammography equipment and the underlying factors influencing the market.

## *2.1 Device Overview*

A mammography unit consists of a rectangular box that houses the tubes producing X-rays. The device is used only for X-ray breast examination, and includes accessories that ensure that only the breast is exposed to X-rays. The device also consists of a unit for compression and positioning of the breast in order to obtain images at different angles. Mammography equipment is classified as DR, which comprises 2D and 3D mammography and analog mammography, which is also referred to as film-screen mammography.

Conventional film-screen mammography units use X-ray films to record images of the breast, but in DR, solid state detectors are used in place of X-ray films to record electric signals. The electric signals recorded can be viewed on a computer screen or can be printed on a film similar to conventional mammograms.

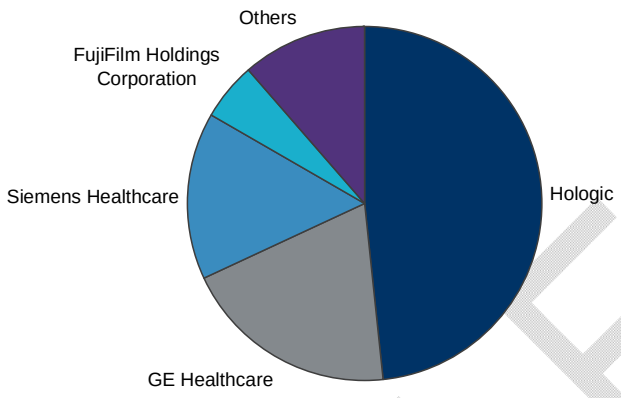
Computer-Aided Detection (CAD) systems are often used with DR mammography equipment in order to increase the breast cancer detection rate. CAD systems use digitized mammography images to highlight abnormal areas in the image in order to alert the radiologist for further investigation.

DR mammography equipment is used as a screening tool for the detection of early breast cancer in asymptomatic women. This is referred to as screening mammography. The device is also used as a diagnostic tool for the detection and diagnosis of breast cancer in women with symptoms such as lumps, nipple discharge or redness, breast or nipple pain and so on. This is referred as diagnostic mammography. According to the US Department of Health and Human Services (HHS), the American Cancer Society (ACS), the American Medical Association (AMA) and the American College of Radiology (ACR) it is recommended that women undergo screening mammography every year, beginning at age 40.

## 5.3 Mammography Equipment, Global, Company Shares (%), 2012

The following figure illustrates the market shares held by key companies in the global mammography market in 2012.

**Figure 3: Mammography Equipment Market, Global, Key Company Share(%), 2012**




Source: GBI Research, Proprietary Database [Accessed February 28, 2013]; Interviews with marketing managers and other industry experts

Note: Company share analysis considers only the leading 12 countries.

The following table provides details of the revenue generated by key companies in the global mammography market in 2012.

**Table 3: Mammography Equipment Market, Global, Key Company Share (%), 2012**

| Company | 2012 share | Revenue ($m) |
|---|---|---|
| Hologic | | |
| GE Healthcare | | |
| Siemens Healthcare | | |
| FujiFilm Holdings Corporation | | |
| Others | | |

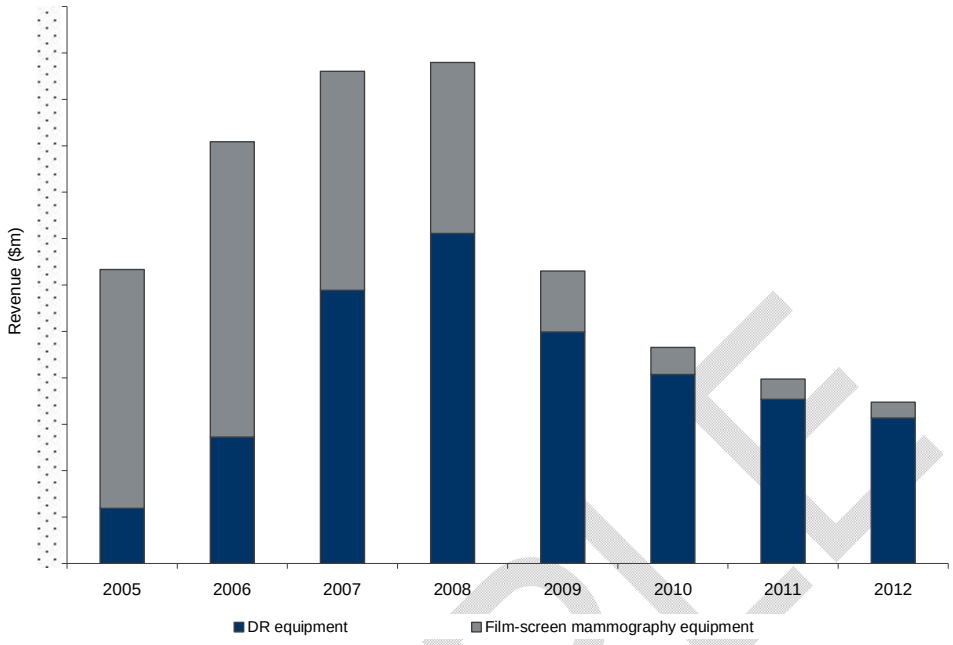
Source: GBI Research, Proprietary Database [Accessed February 28, 2013]; Interviews with marketing managers and other industry experts

Note: Company share analysis considers only the leading 12 countries.

In 2012, Hologic dominated the global mammography equipment market with a XX% share. The company strengthened its leadership position due to its first mover's advantage in the segment for breast tomosynthesis technology. The company has increased its focus on emerging economies such as China, where there is low penetration of mammography, which provides substantial scope for future growth. The company's acquisition of Beijing Healthcome in 2011 has provided the company with the opportunity to have a local and low cost manufacturing facility in China. The company is also developing its contrast-enhanced mammography in order to sustain its leadership position during the forecast period.

### 6.1.1 Mammography Equipment Market, US, Revenue ($m), 2005–2012

**Figure 8: Mammography Equipment Market, US, Revenue ($m), 2005–2012**




Source: GBI Research, Proprietary Database [Accessed February 28, 2013]; Interviews with marketing managers and other industry experts

**Table 6: Mammography Equipment Market, US, Revenue ($m), 2005–2012**

| | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | CAGR (%) |
|---|---|---|---|---|---|---|---|---|---|
| DR mammography equipment | | | | | | | | | |
| Film-screen mammography equipment | | | | | | | | | |
| Overall market | | | | | | | | | |

Source: GBI Research, Proprietary Database [Accessed February 28, 2013]; Interviews with marketing managers and other industry experts

The value of the mammography equipment market in the US amounted to an estimated $XX in 2005 and declined to $XXm in 2012 at a CAGR of XX%. The penetration of mammography in the US is close to XX% and the market is primarily a replacement market. High penetration has led to saturation and curbed demand for new mammography equipment, which led to a decline in revenue growth during the period from 2005 to 2012.

# 12 Appendix

## 12.1 Definitions

### 12.1.1 Mammography Equipment

Mammography is a type of medical imaging that uses X-rays to capture images (mammograms) of the internal structures of the breasts. Mammography plays a key role in early diagnosis of breast cancer. Film-screen mammography equipment and DR mammography equipment have been included in this market. Equipment is tracked here, but not accessories and/or additional costs associated with mammography equipment installation.

#### *12.1.1.1 Film-screen Mammography Equipment*

A film-screen mammography unit consists of an X-ray generator, X-ray source assembly, collimator, compression device, breast support, grid assemblies and automatic exposure control subsystem. Film screen mammography or analog mammography is a specific type of imaging that uses a low-dose X-ray system to examine breasts. One unit is defined as one piece of equipment.

#### *12.1.1.2 DR mammography equipment*

A DR system or DR is a mammography system in which the X-ray film is replaced by solid-state detectors that convert X-rays into electrical signals. DR mammography equipment is classified into 2D and 3D mammography equipment. One unit is defined as one piece of equipment.

## 12.2 Acronyms

AVD: Aortic Valve Disease

AVR: Aortic Valve Replacement

CAD: Computer Aided Detection

CAGR: Compound Annual Growth Rate

CE: Conformité Européenne

CMS: Centers for Medicare and Medicaid Services

CM: Centimeter

CPT: Current Procedural Terminology

CR: Computed Radiography

CT: Computed Tomography

CsI: Caesium Iodide

DBT: Digital Breast Tomosynthesis

DR: Direct Radiography

DRG: Diagnosis-Related Group

DQE: Detective Quantum Effective

FFDM: Full-Field Digital Mammography

FOV: Field of View

GB: Gigabyte

HCPCS: Healthcare Common Procedure Coding System

ISO: International organization for standardization

LP: Line Pairs

M:Meter

MB: Megabyte

mGy: Megagray

MM: Millimeter

MP: Megapixel

MRI: Magnetic Resonance Imaging

NDT: Non-Destructive Testing

NS: Sufficient Data not Available

NHS: National Health Service

PCB: Printed Circuit Board

PMA: Premarket Approval

PMDA: Pharmaceuticals and Medical Devices Agency

SFDA: The State Food and Drug Administration

SFOV: Single Field of View

TB: Terabyte

TFT: Thin Film transistor

XLV: X-ray Light Valve

SLS: Selective Laser Sintering

MJM: Multi-Jet Modeling

FTI: Film Transfer Imaging

SLM: Selective Laser Melting

PJP: Plastic Jet Printers

## 12.3 Sources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## 12.4 Research Methodology

GBI Research's dedicated research and analysis teams consist of experienced professionals in marketing and market research with consulting backgrounds in the medical devices industry and advanced statistical expertise.

GBI Research adheres to the codes of practice of the Market Research Society (www.mrs.org.uk) and the Strategic and Competitive Intelligence Professionals (www.scip.org).

All GBI Research databases are continuously updated and revised. The following research methodology is followed for all databases and reports.

### 12.4.1 Secondary Research

The research process begins with exhaustive secondary research on internal and external sources being carried out to source qualitative and quantitative information relating to each market.

The secondary research sources that are typically referred to include, but are not limited to:

- Company websites, annual reports, financial reports, broker reports, investor presentations and US Securities and Exchanges (SEC) filings
- Industry trade journals, scientific journals and other technical literature
- Internal and external proprietary databases
- Relevant patent and regulatory databases
- National government documents, statistical databases and market reports
- Procedure registries
- News articles, press releases and web-casts specific to the companies operating in the market

### 12.4.2 Primary Research

GBI Research conducts hundreds of primary interviews a year with industry participants and commentators in order to validate its data and analysis. A typical research interview fulfills the following functions:

- Provides first-hand information on the market size, market trends, growth trends, competitive landscape and future outlook
- Helps in validating and strengthening the secondary research findings
- Further develops the analysis team's expertise and market understanding
- Primary research involves email correspondence, telephone interviews and face-to-face interviews for each market, category, segment and sub-segment across geographies.

The participants who typically take part in such a process include, but are not limited to:

- Industry participants: CEOs, VPs, marketing/product managers, market intelligence managers and national sales managers
- Hospital stores, laboratories, pharmacies, distributors and paramedics
- Outside experts: investment bankers, valuation experts, research analysts specializing in specific medical equipment markets
- Key opinion leaders: physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of medical equipment

### 12.4.3 Models

Where no hard data is available, GBI Research uses modeling and estimates in order to produce comprehensive data sets. The following rigorous methodology is adopted:

Available hard data is cross-referenced with the following data types to produce estimates:

Demographic data: population, split by segment

Macro-economic indicators: GDP and inflation rate

Healthcare indicators: health expenditure, physicians base, healthcare infrastructure and facilities

Selected epidemiological and procedure statistics

Data is then cross-checked by the expert panel. All data and assumptions relating to modeling are stored and are available to clients on request.

### 12.4.4 Forecasts

GBI Research uses proprietary forecast models. The following four factors are utilized in the forecast models:

Historic growth rates

Macro indicators such as population trends and healthcare spending

Forecast epidemiological data

Qualitative trend information and assumptions

Data is then cross-checked by the expert panel.

### 12.4.5 Expert Panels

GBI Research uses a panel of experts to cross-verify its databases and forecasts.

GBI Research's expert panel includes marketing managers, product specialists, international sales managers from medical device companies; academics from research universities, KOLs from hospitals, consultants from venture capital funds and distributors/suppliers of medical equipment and supplies.

Historic data and forecasts are relayed to GBI Research's expert panel for feedback and adjusted accordingly.



## *12.6 Disclaimer*