Glucose Monitoring Device Market to 2019
Technology Adoption and Increasing Health Awareness Serve as Distinct Regional Growth Drivers
GBI Research Report Guidance

- The report covers both type 1 and type 2 diabetes mellitus for estimation of the global glucose monitoring devices market.

- The report begins with an executive summary capturing the major factors driving the growth of the global glucose monitoring devices market.

- Chapter three provides an overview of the glucose monitoring devices that are included in the scope of the report.

- Chapter four provides information on the market size for the historic period (2005–2012) and the forecast period (2012–2019). The chapter also provides information on key company shares in the global glucose monitoring devices market. The chapter discusses the key trends and market dynamics that are expected to impact future growth. Market estimation does not cover non-invasive glucose monitoring devices, however qualitative analysis on non-invasive devices has been included since approval of these devices could lead to rapid growth of this market in the future.

- Chapter five discusses blood glucose meters, blood glucose test strips and lancets. The market sizes for the historic and forecast period are provided for each segment.

- Chapter six gives information on the market size for the historic and forecast period for the US, Japan, Germany, UK, France, Brazil, Italy, China, Canada, Australia, Spain and India, with cross-country analysis.

- Chapter seven provides information on the healthcare reimbursement system for the US, Japan, Germany, UK, France, Brazil, Italy and Spain.

- Chapter Eight comprises profiles of the leading glucose monitoring devices companies, outlining their products, features and benefits.

- Chapter nine focuses on the pipeline products for each segment. The key pipeline products are listed and discussed in detail alongside product approval and expected launch dates.

- Chapter ten discusses the deals that took place in the glucose monitoring devices industry between 2008 and 2012.
Executive Summary

The Global Glucose Monitoring Devices Market is Forecast to Grow at a Compound Annual Growth Rate of XX% During 2012–2019, to Exceed $XX Billion in 2019

The following figure shows the projected revenue growth of the global glucose monitoring market during the 2012–2019 period.

![Glucose Monitoring Devices Market, Global, Revenue ($bn), 2012–2019](image)

Source: GBI Research’s proprietary database [accessed December 4, 2013]

The global glucose monitoring devices market is expected to grow at a Compound Annual Growth Rate (CAGR) of XX% from $XX billion in 2012 to $XX billion in 2019. Major factors driving the market are the increasing incidence of diabetes across the world, gradually improving awareness about the benefits of regular glucose monitoring, and the availability of advanced solutions for monitoring based on technologies such as Continuous Glucose Monitoring (CGM), that increase the efficiency of the testing procedures. In efforts to increase physician adoption, a number of manufacturers have focused on training and education programs which are expected to drive the adoption of these devices in a big way. Emerging markets such as India and China show potential for market growth as they are home to the world’s largest patient population. However, high prices and lack of knowledge of handling advanced glucose monitoring technologies could be a restraining factor for emerging markets.
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### 2 Introduction

#### Figure 1: Glucose Monitoring Device Market, Timeline for Glucose Monitoring

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1965</td>
<td>Ames Company launch Dextrostix, a strip of paper that changes color to indicate the patient's glucose levels after a drop of blood is applied.</td>
</tr>
<tr>
<td>1971</td>
<td>The first patent for a blood glucose meter is awarded to Anton Hubert Clemens on September 14, 1971. This meter is known as the Ames reflectance meter and is able to quantify the strip's color for a more accurate glucose measurement.</td>
</tr>
<tr>
<td>1978</td>
<td>Availability of first home literature on diabetic blood glucose</td>
</tr>
<tr>
<td>1981</td>
<td>The first home glucose monitoring device Glucometer was launched by Bayer</td>
</tr>
<tr>
<td>1986</td>
<td>The FDA, CDC and ADA recognize self monitoring of glucose as key to efficient management of diabetes</td>
</tr>
<tr>
<td>1987</td>
<td>Supply side initiatives to introduce low cost home glucose meters improves access to diabetes care.</td>
</tr>
<tr>
<td>1993</td>
<td>National Institute of Diabetes and Digestive and Kidney Diseases publishes results of a study showing that patients who practice self-monitoring of glucose reduced chances of complications by by 76% for eye disease, 50% for kidney disease, and 60% for nerve disease.</td>
</tr>
<tr>
<td>2006</td>
<td>The first CGM system launches, this device is implanted under the skin.</td>
</tr>
<tr>
<td>2008</td>
<td>Integration of glucose monitoring and insulin delivery.</td>
</tr>
</tbody>
</table>

**CGM:** Continuous Glucose Monitoring  
**Source:** GBI Research

The blood glucose monitoring market is one of the fastest growing markets. With the huge growth in the incidence of diabetes there is a corresponding demand for effective treatment options. Regular monitoring of glucose levels has been shown to be both clinically and economically beneficial, preventing associated health conditions including cardiovascular diseases, diabetic retinopathy and neuropathy.

The US remains the largest market in terms of the revenue generated by the global glucose monitoring devices in 2012; given the rise in patient population, healthcare spending and the emergence of new technologies is expected to retain its position during the during the forecast period. The availability of reimbursement for traditional glucose monitoring devices is another driving factor. However, the reimbursement for Continuous Glucose Monitoring (CGM), though available, is limited to type XX diabetes patients and excludes type XX diabetics. This coupled with the high initial costs of CGM devices may limit adoption.

Emerging markets despite having the largest patient populations (in terms of absolute number of patients), suffer from low penetration of glucose monitoring devices, especially technologically advanced products. The lack of disease awareness, absence of reimbursement, and the urban-rural divide reduce the number of growth opportunities, despite a huge potential.

The glucose monitoring competitive landscape is largely dominated by established players. Most products offered by these companies cater to the traditional glucose monitoring sector that is gradually reaching maturity and commodity status. The introduction of technologically innovative and clinically beneficial CGM technology is expected encourage new players to enter the market. Though these new entrants currently occupy only a small share of the overall market, the uptake of CGM technology may cause a significant shift in market shares.
4  Global Glucose Monitoring Device Market: Market Characterization


The following figure shows the revenues generated by global glucose monitoring device market for the 2005–2012 period.

![Figure 3: Glucose Monitoring Device Market, Global, Revenue ($bn), 2005–2012](image)

Source: GBI Research’s proprietary database [accessed December 4, 2013]

The following table shows the revenues generated by global glucose monitoring device market for the 2005–2012 period.

<table>
<thead>
<tr>
<th></th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>CAGR (%)</th>
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</thead>
<tbody>
<tr>
<td>Blood glucose test strips</td>
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<td></td>
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<tr>
<td>Blood glucose meters</td>
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<td>Lancets</td>
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Source: GBI Research’s proprietary database [accessed December 4, 2013]

CAGR: Compound Annual Growth Rate

The global glucose monitoring market was valued at $XX billion in 2005 and grew at a CAGR of XX% to reach $XX billion in 2012. The increasing global prevalence of diabetes, and improving awareness of the benefits of regular glucose monitoring in diabetes treatment and management were major growth drivers. In 2012 there were a global total of XX million diabetics and XX million adults with impaired glucose tolerance (IDF, 2012). This shows that there is a significant need for routine monitoring of glucose levels. Blood glucose test strips were the most successful product, of the three types covered, over the period a value of $XX billion in 2005 that increased to $XX billion in 2012, at a CAGR of XX%.
9 Global Glucose Monitoring Device Market: Product Pipeline Analysis

The following figure shows the percentage of pipeline products in each stage of development.

**Figure 53: Global Glucose Monitoring Device Market, Pipeline Products Summary, 2013**

<table>
<thead>
<tr>
<th>Stage of Development</th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
<th>Class IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issued</td>
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<tr>
<td>Early development</td>
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</tr>
<tr>
<td>Preclinical</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In approval process</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Source: GBI Research's proprietary database [accessed November 17, 2013]

The impact of new product launches with technical advances on the future growth of this market may not take effect in the short-term future. A significant XX% of the pipeline products in this market are classified as class XX devices. These are primarily devices that have integrated glucose monitoring and insulin delivery functions which involve greater risk than standalone devices which are either used for glucose monitoring or insulin delivery. Class XX devices are subject to greater scrutiny during the approval process which results in significant additional costs and delays over class XX devices. Class XX devices may take several years to complete clinical studies to prove their equivalence or superiority over currently available marketed products. In comparison, class II devices receive regulatory approval at a much faster pace which ranges from three to XX months. Therefore, companies involved in the development of integrated glucose monitoring and insulin delivery devices can expect much longer approval processes before their products can be made available in respective geographies.

The global glucose monitoring devices market comprises XX products in the pipeline with the majority products located in the clinical stage of development (XX products, approximately XX% of the total pipeline). The forecast period is expected to witness numerous product launches since majority of the pipeline products are in the clinical stage of development. A high demand for advanced glucose monitoring products is driving the development of technologically innovative products based on emerging technology platforms such as non-invasive blood glucose monitoring technologies such as, EyeSense and NMB-200G, insulin pumps integrated with CGM; Integrated Guardian Real-Time Continuous Glucose Monitoring System and devices with connectivity to smartphones and other devices through mobile apps. Innovative technology and improved functional features will drive the demand and for the glucose monitoring devices, with both niche companies and established market players capitalizing on this trend.

Majority of pipeline products are classified as class XX devices which go through relatively less rigor in terms of time and cost involved in receiving regulatory approvals. However.
11 Appendix

11.1 Definitions

11.1.1 Blood Glucose Meter

A blood glucose meter is used to determine the approximate concentration of blood glucose levels. Currently, two types of blood glucose monitors are used: traditional glucose meters and CGM systems. Minimally invasive and non-invasive blood glucose meters are not covered in this report.

11.1.2 Blood Glucose Testing Strips

Blood glucose testing strips are a single-use component of the diabetes monitoring system and work in conjunction with a blood glucose monitor. A drop of sample blood is placed on the strip; the blood glucose is oxidized and generates an electric signal which can be read by the glucose meter. Usually a person suffering from diabetes needs to test for blood glucose levels three to four times a day.

11.1.3 Lancets

Lancets are mechanical devices which are used to prick the skin to obtain capillary blood for blood glucose monitoring. The lancet is usually held in a lancing device, which releases the lancet when triggered.

11.2 Acronyms

ALD: Affections De Longue Durée
CAGR: Compound Annual Growth Rate
CGM: Continuous Glucose Monitoring
EU: European Union
FDA: US Food and Drug Administration
HbA1c: glycated Hemoglobin
ICU: Intensive Care Unit
IDF: International Diabetes Federation
MDI: Multiple Daily Injections
mg/dl: milligrams per deciliter
mmol: millimole
NDEP: National Diabetes Education Program
NDP: National Diabetes Program
NDSS: National Diabetes Services Scheme
QALY: Quality-Adjusted Life-Years
RDC: Roche Diabetes Care
SMBG: Self-Monitoring of Blood Glucose
STS: Short-Term Sensor
USB: Universal Serial Bus
11.3 Sources


11.4.3 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: Gross Domestic Product, Inflation rate.
- Healthcare Indicators: health expenditure, physician’s 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.

11.4.4 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.

All data and assumptions relating to modeling are stored and are available to clients on request.

11.4.5 Expert Panels

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

GBI Research’s expert panel comprises 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 in accordance with this feedback.
11.6 Disclaimer

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