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PATIENT MONITORING MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

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1. Introduction

Patient monitoring is vital to care in operating rooms, emergency rooms, intensive care units and critical care units. It has proven invaluable for respiratory therapy, recovery rooms, outpatient care, transport, radiology, catheterization laboratories and gastroenterology departments, as well as for ambulatory, home and sleep screening applications. Patient monitoring can reduce the risk of infection and other complications, and it can assist in providing for patient comfort. Moreover, patient monitoring products measure, display and document physiological information obtained at regular intervals over time from sensors attached to the patient or other input devices. The qualifier “at regular intervals over time” is used to distinguish patient monitoring devices from diagnostic kits and devices, which are typically used once or a few times to diagnose a patient’s condition and/or plan a course of therapy. Measured parameters include electrocardiogram (ECG), invasive and noninvasive blood pressure, pulse rate, pulse oximetry, body temperature, respiration rate, end-tidal CO₂ and other specialized parameters. Products vary from specialized single-parameter instruments to monitors with the ability to measure multiple parameters and interface with other instruments.

1.1 Objectives of this Report

The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for the main types of patient monitoring devices that have been commercialized to date.
- Obtaining a complete understanding of the patient monitoring device market in each of the product segments in specified applications and end-user markets.
- Discovering feasible market opportunities by identifying high-growth applications in different patient monitoring areas and by focusing on expanding markets, such as capnography or telemedicine.
- Focusing on global industry development through an in-depth analysis of the major world markets for patient monitoring devices and related equipment and analysis of the industry structure.

This review 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 patient monitoring device market segments. Also examined are the subsections of each market segment, including use in physician office labs, hospital labs and commercial laboratories. Additionally, the numbers of institutions using this type of testing and the factors that influence purchases are also discussed. This examination surveys most of the medical device companies known to be currently marketing, manufacturing or developing devices for the patient monitoring market in the world. Each company is discussed in depth with a section on its history, product line, business and marketing analysis, and a subjective commentary of the company’s market position.

We assess the patient monitoring device market drivers and bottlenecks from the perspective of medical and manufacturer communities; discuss the potential benefits of the patient monitoring device market for various sectors of the medical community; establish the current total market size and future growth of the patient monitoring device market and analyze the current size and growth of various segments; provide current and forecasted market shares by the company; provide strategic recommendations for near-term business opportunities and assess current commercial uses of the patient monitoring market.

This review answers the key questions of cutting-edge technologies developed, validated and implemented for clinical use; the impediments still existing to incorporating promising patient monitoring devices into clinical practice; new patient monitoring devices showing the most promise for approval; and the economic challenges to approval.

1.2 Scope of this Report

This report reviews the design, manufacturing and marketing of patient monitors, focusing on multiparameter patient monitors used in critical care, peri-operative (operating room, post-anesthesia care unit and ambulatory surgery centers), emergency room and transport. There are multitudes of single parameter monitors such as blood pressure monitors, pulse oximeters, end-tidal carbon dioxide (EtCO₂) monitors and so forth that are part of the focus

of this report. The primary objective of this analysis is to provide information on the leading manufacturers of patient monitors along with an overview of their product offerings and to outline trends in the patient monitoring marketplace.

This analysis includes electrocardiograph systems, but does not examine other advanced diagnostic and therapeutic cardiology devices and systems, including automated external defibrillators (AEDs), stress test systems, Holter monitoring systems, hospital defibrillators, cardiac rehabilitation telemetry systems, and cardiology data management systems (informatics) that connect with a hospital information system (HIS) and electronic medical records (EMRs).

The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for detailed discussions of important individual market segments related to the molecular diagnostics market, such as clinical chemistry testing, glucose testing monitors, blood gas and electrolyte monitors, and over-the-counter (OTC) diagnostic testing devices. Monitoring devices marketed primarily as OTC are generally not included in this report, although there is inevitably some overlap.

1.3 Methodology

The author of this report holds a Ph.D. in biochemistry from the University of Minnesota and has 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 holds a Ph.D. and is a retired college professor with vast experience in biochemistry, biotechnology, pharmacology and environmental biology.

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 we believe to be reliable, but we 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 we publish annually. We extract 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

Patient monitoring systems are an integral part of any hospital network. They provide clinicians and physicians with information from bedside and other departments instantaneously and help bolster the overall productivity of the clinical setting thereby improving patient outcomes. Though these systems have been in existence for quite sometime, what is required is a need to promote interoperability among departments within clinical settings. Medical information technology now, as a discipline, is recognized a lot more and applied by hospitals, doctors/nurses, even governments to improve operational efficiencies. Moreover, patient monitors are widely used in medical facilities for real-time monitoring of changes in patient status. With an increase in the complexities of patient diseases and diagnosis, doctors need more and more information to make a decision.

1.4.1 The U.S. Medical Device Market

U.S. firms dominate the \$ [REDACTED] medical devices industry and are thriving. For example, Abbott reported double-digit sales growth in each major global business with worldwide sales growth of [REDACTED] % in the third quarter for [REDACTED] when compared with the third quarter of [REDACTED]. Similarly Medtronic recorded [REDACTED] quarter revenue of \$ [REDACTED], a [REDACTED] % increase over the \$ [REDACTED] reported in the [REDACTED] quarter of fiscal year [REDACTED]. These companies along with Johnson & Johnson, Baxter, Cardinal Health, Braun, 3M Health Care, Roche Diagnostics and Becton, Dickinson and Company (BD) are fairly insulated from current economic concerns due to medical professionals' unwillingness to switch from a product they are comfortable with. Unlike the pharmaceuticals and biotech industries which are characterized by lengthy product development, regulatory approval processes, patent law suites and huge R&D investments, medical equipment companies are cash rich and do not have many patent issues.

1.4.2 Supply and Demand Fundamentals

Growth in the U.S. medical devices industry is being driven by the demands of an aging population. Healthcare spending in the U.S. will almost [REDACTED] over the next decade, hitting \$ [REDACTED] by [REDACTED], according to *The Wall Street Journal*. The U.S. medical devices industry will also benefit from the opening of new markets in less well-

developed countries, according to Ernst & Young. Demand from the global market will drive growth in this sector. As access to healthcare in less well-developed countries increases, that will open up more opportunities, especially for technology that is under \$ [REDACTED] such as disposables and womb care.

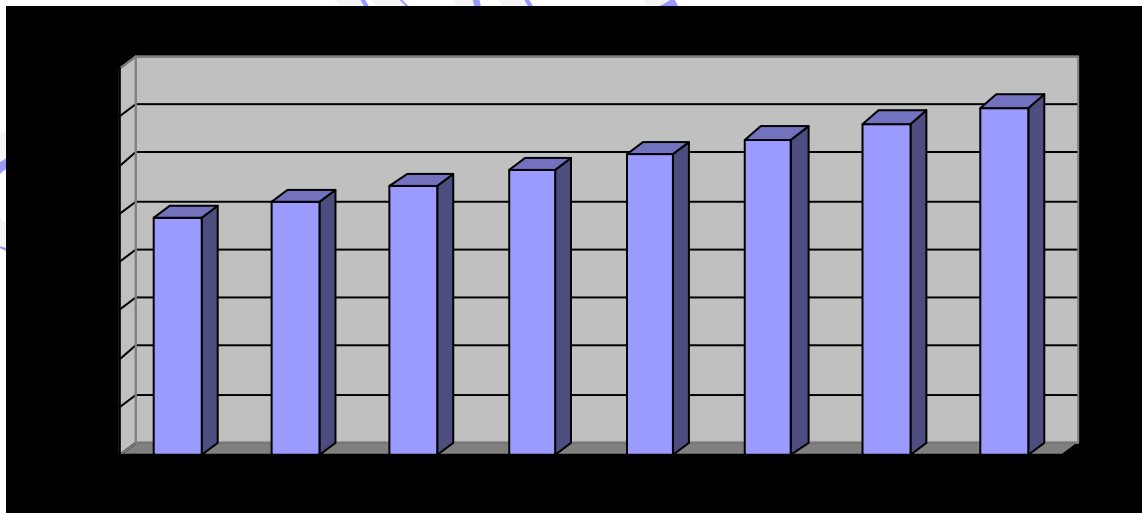
1.4.3 Sector Convergence

The U.S. medical device industry has benefited from convergence between sub-sectors like diagnostic and imaging companies. One example of this is Siemens' acquisition of Dade-Behring. There has also been greater collaboration with the pharmaceutical industry. So-called "combo products," such as drug-eluting stents that embed medical devices in pharmaceutical or biologic components, are expected to be worth \$ [REDACTED] by [REDACTED]. Drug-eluting stents have solved a major clinical need. Normal stents might cost \$ [REDACTED], but drug-eluting stents cost around \$ [REDACTED], so they have allowed manufacturers the chance to double their revenue.

1.4.4 Future Forecast

The medical devices industry already represents [REDACTED]% of the global pharmaceutical sector and, as it is growing at a faster rate than its drug counterpart, will soon be the biggest market in this field. As the dominant player in the market, the U.S. medical devices sector can expect to enjoy growth over the coming years. According to a report by GlobalData, the patient monitoring market is an expanding and profitable sector in the global healthcare industry and shows the global patient monitoring market to be valued at \$ [REDACTED] in [REDACTED]. Driven by the rise of the chronic disease population, the market is forecast to grow by [REDACTED]% annually until [REDACTED] to reach \$ [REDACTED]. Driving growth in the patient monitoring market are wireless and ambulatory monitoring and micro electromechanical systems, promoted by an increased desire for flexibility. Together, these accounted for [REDACTED]% of the overall market in [REDACTED].

Figure 1.1: Global Market for Patient Monitors, 2008-2015



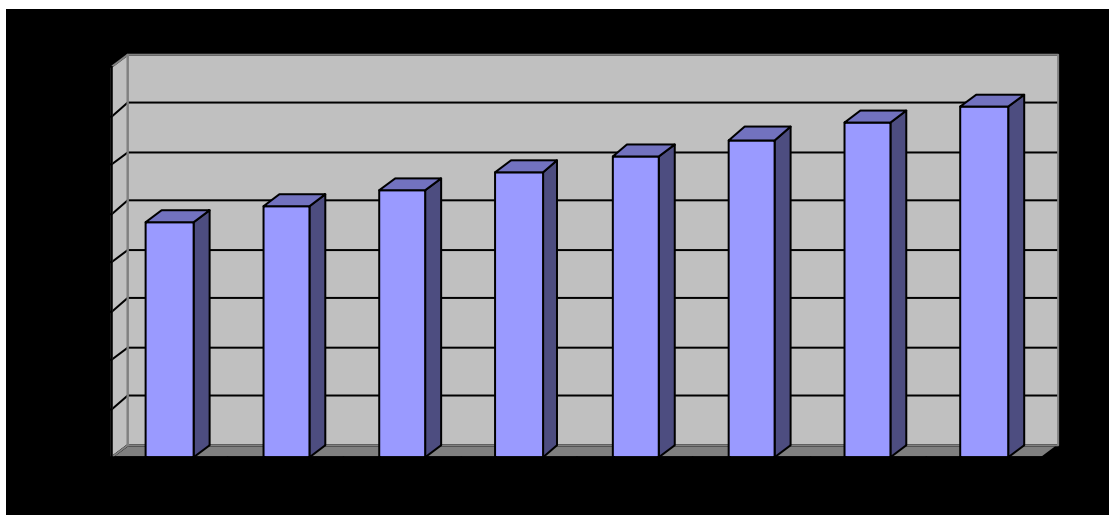
Source: GlobalData

Globally, the U.S. remains the largest patient monitoring market. In [REDACTED], it was valued at \$ [REDACTED] and is forecast to grow by [REDACTED]% annually during [REDACTED] to [REDACTED], to reach \$ [REDACTED]. However, with most of the demand originating from the emerging economies, the center of the global patient monitoring market activity is up for a huge shift. India and China are forecast to grow faster than the average, driven by rise in the number of hospitals and large chronic disease populations.

On March 1, [REDACTED], Nihon Kohden America, Inc. signed a new three year agreement with Premier Purchasing Partners, L.P., the group purchasing unit of Premier, Inc., one of the nation's largest healthcare alliances in the U.S.,

for physiological monitoring equipment and accessories. Nihon Kohden's patient monitoring solutions utilize miniaturization technology and high speed processing to provide clinicians with a feature-rich value-oriented product offering. Nihon Kohden offers the five-year warranty for patient monitoring products in the industry, complimented by a lifetime of software upgrades.

Figure 1.2: U.S. Market for Patient Monitors, 2008-2015



Source: GlobalData

Philips Healthcare, GE Healthcare and Omron Healthcare remain the leading competitors in the sector. Together, these companies accounted for █% of the global market share in █. Philips remained the market leader with a share of █%. However, with multiple new products expected to hit the market in the next few years, a shift in the prevailing competitive landscape cannot be ruled out.

Frost & Sullivan analysis states that sleep apnea, hospital wireless, and diabetes blood glucose monitoring are the fastest-growing segments in the North American patient monitoring industry. The sleep apnea segment holds significant opportunity as █ in every █ adults in the U.S. suffers from some form of obstructive sleep apnea (OSA). Industry sources estimate that less than █% of people suffering from this disease have been diagnosed or treated, thus creating a huge market opportunity for device manufacturers. Favorable regulation and increased knowledge about this breathing disorder together with the emergence of new alternatives to current diagnostics tools will aid market expansion.

According to GlobalData, the global self monitoring blood glucose (SMBG) market is forecast to grow from \$█ in █ to \$█ in █. The self-monitoring blood glucose market has a robust pipeline product portfolio, with expectations of increased uptake of the devices in the future. A recently FDA-approved glucose meter developed by Arkray, Inc. does not require calibration and coding, thus eliminating human error in the outcome of the tests. The non-invasive blood glucose monitoring systems pipeline products are gaining a lot of market and patient attention. The real push behind the non-invasive technologies is to eliminate the daily discomfort of diabetic patients.

Globally, the market leaders in patient monitoring products are Philips Healthcare, GE Healthcare, Dräger, Mindray and Nihon Kohden, and there are hundreds of other smaller players around the globe who make monitors of different types to be used for various monitoring purposes. Nearly about █% of the market demand is met by the products made by the leading █ players and █% of the products are provided by the smaller players.