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NUCLEAR CARDIOLOGY MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Medical Imaging, Technologies and Industry Leaders

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1. Overview

1.1 Objectives

The purpose of this report is to analyze and describe the nuclear cardiology market segments in the U.S. and worldwide. It examines the measurement devices that are utilized by physicians to diagnose and monitor heart diseases. This study also discusses key products in nuclear cardiology and examines the trends that are stimulating this market. It includes a survey of all major companies actively engaged in marketing, manufacturing or developing nuclear cardiological instrumentation, with each company discussed in depth. The main objectives of this analysis are to:

- Identify viable technology drivers through a comprehensive look at platform technologies for nuclear cardiology testing.
- Obtain a complete understanding of the individual nuclear cardiology testing platforms from their basic principles to their clinical applications.
- Discover feasible market opportunities by identifying high-growth applications in different clinical diagnostic areas.
- Focus on global industry developments through an in-depth analysis of the major world markets for nuclear cardiology technology, including growth forecasts.
- Present market figures related to the current value of nuclear cardiology, market projections, market share, key players, and sector growth rates.

An analysis of the nuclear cardiology market must include several key areas of related activity. The most important segments discussed in this report include:

- Hardware (*e.g.*, nuclear cardiology instrumentation).
- Software (*e.g.*, nuclear cardiology image processing, PACS).
- Radiopharmaceuticals and pharmaceuticals.
- Ancillary products.
- Service and support.

This study aims at providing the reader with the following:

- An understanding of the most exciting nuclear cardiology market segments.
- Up-to-date information on the leading products, recent developments and R&D initiatives in the market.
- Knowledge of the nuclear cardiology market as an area of growth, research and investment.
- An extensive review of the nuclear cardiology hardware, software and radiopharmaceuticals markets, as well as the leading companies in these segments.
- A review of the market for clinical nuclear cardiology testing equipment and supplies used in the clinical hospital market.
- Dollar volume of the market sales, both worldwide and in the U.S., with an analysis of the factors that influence the size and growth of the market segments.
- Detailed analyses of new applications and trends in the nuclear cardiology marketplace.
- Views on the nuclear cardiology industry from leading industry experts.

Key questions answered in this examination are:

- How can nuclear cardiology tools and technologies facilitate improved patient care?
- What are the main types of nuclear cardiology technologies currently available?
- Who are the current key players in this marketplace?
- What is the current state of the nuclear cardiology market?
- What are the major trends in nuclear cardiology solutions?
- What is the impact of regulatory changes on nuclear cardiology markets?

1.2 Scope

This examination primarily focuses on three major segments of the nuclear cardiology market: 1) devices, 2) PACS (picture archiving and communications systems) and RIS (radiology information systems) and 3) radiopharmaceuticals. It discusses products, trends, new developments and compensation issues that are currently affecting or are likely to affect the market soon. Moreover, this report contains:

- Analysis of potential new nuclear cardiology testing applications in the clinical sector.
- Market predictions and trends analysis concerning U.S. expenditures on nuclear cardiology testing solutions.
- Projections of nuclear cardiology testing market sizes for European and Asian markets.
- Projections of future applications of non-invasive tests in nuclear cardiology testing-related screening.
- Analysis of commercial nuclear cardiology testing business strategies, such as co-branding.
- A comprehensive overview and insight into nuclear cardiology testing business strategies for growth in foreign markets.

The emphasis in this report is on those companies and products that are actively developing and marketing nuclear cardiology instrumentation. 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 nuclear cardiology market, such as cardiac rhythm management devices and medical imaging markets.

1.3 Methodology

This report is based upon a collection of government data made publicly available, as well as trade association reviews and company data. Other sources of information include trade association publications and meetings, product brochures and catalogs, and company literature. Where the companies under discussion were publicly held, annual reports, 10k filings and financial reports were used as the basis of the data reported. Some of the information was taken from TriMark Publications' databases, Biotechnology Associates' files and the private data stores of the author. The information set forth in this study was obtained from sources that are believed to be reliable, but the accuracy, adequacy or completeness of any information, omission or results obtained by the use of such information are not guaranteed.

1.4 Executive Summary

In the U.S., the rapid growth of the over-50 population where more diagnostic procedures are required—combined with the growing ability to do more procedures due to technological advances in the equipment sector—is expanding the need for medical diagnostics. Pricing has been maintained at fairly stable levels. In Europe, the tough reimbursement environment continues to affect pricing. The markets are still dominated by state funding, although the private market is growing. The installed hardware base in Europe is expanding, which will allow further volume growth. The Japanese diagnostic market continues to show modest volume growth, though the overall environment remains challenging due to ongoing healthcare reform measures and government-mandated reimbursement price cuts.

Diagnostic and therapeutic medical imaging worldwide constitutes a \$ [REDACTED] market with consistent growth in double digits for many sectors. Already strong demand drivers are being further strengthened by favorable population-aging demographic trends. The imaging markets have always been exciting and growing, and there are a number of new imaging modalities being introduced on an annual basis. The medical imaging equipment market in the U.S. is estimated to achieve gains of between [REDACTED]% and [REDACTED]% per year through [REDACTED], to over \$ [REDACTED].

There are over [REDACTED] hospitals and healthcare facilities being supported by as many as [REDACTED] physician group practices in the U.S. The annual combined total of all radiological images exceeds [REDACTED]—and this number is increasing at approximately [REDACTED]% per year. There are about [REDACTED] radiologists currently practicing in the U.S. However, cost pressures and competitions from other medical specialties are forcing the consolidation of radiologist practices. In [REDACTED], [REDACTED]% of diagnostic imaging centers and chains consolidated their operations.

In contrast to the generally rosy picture of growth and innovation in the medical imaging sector in the U.S., European medical imaging companies are finding it increasingly difficult to develop technologically advanced products and to expand their reach in a stringent regulatory environment. In addition to the E.U.'s Medical Device Directive, numerous multilayered and diffused local legislatures complicate regulatory compliance, thereby increasing the time to market. Companies also face rising costs due to constant alterations required in product specifications to meet the varying technical standards in different locations. However, even in the U.S. markets, many of the major diagnostic imaging modalities are mature or approaching maturity, including conventional X-ray systems, computed tomography (CT), magnetic resonance imaging (MRI), ultrasound and nuclear medicine. This implies that much future demand in these segments will be for replacement purposes. In addition, despite a few bright spots, such as positron emission tomography (PET), the healthcare funding climate is likely to remain challenging, impacting both reimbursements for imaging procedures performed, and the capital equipment budgets of medical providers.

In [REDACTED], approximately [REDACTED] medical imaging procedures were performed worldwide. Of these, about [REDACTED] scans were enhanced or made possible with medical diagnostic products or contrast agents, generating revenues of over \$ [REDACTED] in this market niche alone. Bracco, GE, Tyco Healthcare, Schering and Bristol-Myers Squibb Medical Imaging (formerly DuPont), together with their respective licensees, are the major players in the medical diagnostics market, with over [REDACTED] share among them.

The U.S. sales of medical imaging contrast media reached \$ [REDACTED] in [REDACTED], and are expected to rise to \$ [REDACTED] by [REDACTED]. Contrast media sales grew [REDACTED]% in [REDACTED], increased by [REDACTED]% to [REDACTED]% per year between [REDACTED] and [REDACTED] and are projected to rise at the rate of [REDACTED]% to [REDACTED]% per year between [REDACTED] and [REDACTED]. Biotechnology Associates predicts that the number of imaging procedures worldwide for cancer diagnosis and patient management will increase from [REDACTED] scans in [REDACTED] to [REDACTED] procedures in [REDACTED] at an estimated [REDACTED]% per year, and to over [REDACTED] by [REDACTED]. Both areas could see significant gains in the next few years.

The National Electrical Manufacturers Association (NEMA) estimates that revenues from sales of nuclear imaging equipment, excluding maintenance revenue, declined approximately [REDACTED]% in [REDACTED] to \$ [REDACTED], and declined approximately [REDACTED]% in the first quarter of [REDACTED], as compared to the first quarter of [REDACTED]. NEMA projects double-digit declines for the next three quarters of [REDACTED], representing a modest decline on a sequential quarter basis. It further forecasts the rate of descent to slow in [REDACTED] to approximately [REDACTED]% with little or no anticipated decline in [REDACTED]. It attributes the declining sales to questions about reimbursement, such as reimbursement cuts to imaging embodied in the U.S.'s Deficit Reduction Act, cost containment pressures, lack of technology innovation and possible shifts to other imaging modalities. In the products business, industry sources predict that purchases of multi-head cameras will far outpace those of single-head cameras.

On the other hand, cardiac imaging is booming. New applications are being adopted for older technologies. Magnetic resonance imaging, for example, is being applied for both screening and diagnostic purposes in cardiology. Ultrasound and computed tomography are guiding new interventions, such as cryosurgery and RF ablation.

The MR and PET installed base growth is driving demand for servicing. The medical imaging equipment service market is undergoing significant changes due in large part to an increase in the installed base for MR and PET devices sectors. Over the forecast period of [REDACTED] years, these modalities are expected to rise [REDACTED]% and [REDACTED]%, respectively, translating into greater servicing revenues. Moreover, the installed equipment growth is projected to emerge as a powerful driver bolstering the industry's growth. Currently estimated at \$ [REDACTED], this segment is likely to reach \$ [REDACTED] by [REDACTED].

Cardiovascular magnetic resonance imaging continues to hold a front-row seat among the hottest medical imaging market segments worldwide, but the elbow space is shrinking as cardiac computed tomography makes its entrance into this same market. The new generation of 16-slice CT scanners will offer quick studies of ventricular function, improved coronary artery imaging and calcium scoring that will benefit the diagnosis of cardiovascular diseases.

The target market for products and services is comprised of approximately [REDACTED] cardiologists and the larger group practices of four or more practitioners among the [REDACTED] internists and family practitioners in the U.S. that perform

or could perform nuclear cardiac procedures. It is estimated that there are approximately [REDACTED] cardiology practices comprising one to four practitioners and [REDACTED] internist practices comprising more than four internists.

According to industry sources, [REDACTED] nuclear imaging procedures were performed in the U.S. in [REDACTED], of which [REDACTED] were cardiac-specific procedures. In [REDACTED], [REDACTED] PET scanners were sold in the U.S. and [REDACTED] scanners sold worldwide. The U.S. sales were \$[REDACTED] and worldwide sales were \$[REDACTED], an increase from the previous year of [REDACTED]% and [REDACTED]%, respectively. This reflects a slowdown in PET orders in the U.S., as users attempt to utilize the existing capacity more efficiently. International sales have increased recently with the growth rates higher than that of the U.S., reflecting a growing awareness of PET and expanded reimbursement, particularly in Japan. PET-CT has been adopted very rapidly both in the U.S. and internationally. In [REDACTED], PET-CT comprised [REDACTED]% of total billings. By [REDACTED], U.S. bookings will increase to [REDACTED] with sales of \$[REDACTED]. Worldwide bookings will reach [REDACTED] units and \$[REDACTED] in sales volume.

The U.S. sales of diagnostic radiopharmaceuticals reached \$[REDACTED] in [REDACTED] and are expected to rise to \$[REDACTED] by [REDACTED]. Radiopharmaceutical sales grew [REDACTED]% in [REDACTED] and should continue growth in a range between [REDACTED]% and [REDACTED]% through [REDACTED]. This growth will be based on the introduction of new products, strong demand for cardiology procedures and increased sales of oncology products, particularly FDG (fluorine-18 deoxyglucose) for PET imaging. Sales of nuclear cardiology products will continue to drive the radiopharmaceutical market, with high utilization of nuclear perfusion studies coupled with advanced pharmacological stress agents. Nuclear cardiology sales of \$[REDACTED] in [REDACTED] will increase to \$[REDACTED] by [REDACTED].

The FDG sales for oncology, as well as cardiology and neurology, are expected to increase from \$[REDACTED] in [REDACTED] to \$[REDACTED] by [REDACTED]. The FDG distribution will continue to improve, allowing more widespread use of PET in community hospitals. With reimbursement stabilizing and procedure volumes increasing, PET should become more profitable for providers as well as suppliers of FDG. In addition, new PET radiopharmaceuticals in the pipeline for specialized applications should add to these sales estimates. Market growth should also benefit from higher prices for many of the new products.

Most of today's cardiology studies are performed with single-photon-emission computed tomography (SPECT). Presently, cardiology dominates single-photon-emission computed tomography, representing about [REDACTED]% of SPECT procedures. A relatively cost-efficient modality, SPECT does not require its gamma cameras to have the shielding and room preparation necessary for other modalities, such as CT and MRI. The SPECT equipment is also less expensive. Additionally, it doesn't need expensive disposable parts, such as the CT X-ray tube. This cost advantage has made it an attractive imaging modality, especially for certain specialties, including cardiology.