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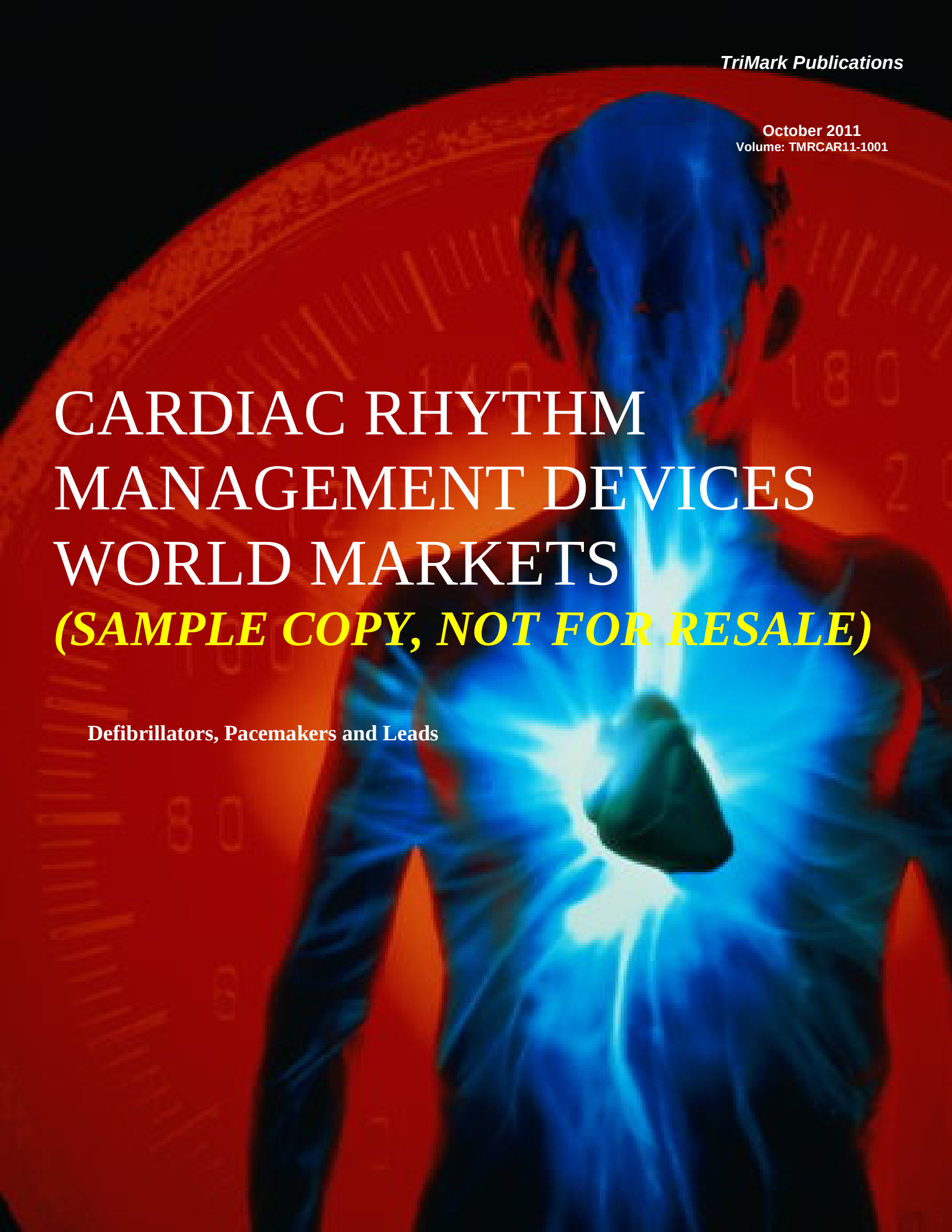

CARDIAC RHYTHM MANAGEMENT DEVICES WORLD MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Defibrillators, Pacemakers and Leads

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1. Overview

In the last five decades, electronic cardiac medicine has witnessed dramatic technological developments. The cardiac rhythm management products mainly marketed by a handful of global players are used to treat arrhythmias, specifically supraventricular arrhythmias (SVA) and ventricular arrhythmias (VA). The different types of SVA are premature atrial contractions (PAC), supraventricular tachycardia (SVT), sick sinus syndrome (SSS), atrial fibrillation (A-fib) and atrial flutter (AFL). Varying forms of VA are premature ventricular complex (PVC), ventricular tachycardia (VT) and ventricular fibrillation (VF). These cardiac disorders are treated with the aid of different types of electronic cardiac devices. This report focuses on the global and regional markets for all cardiac rhythm management (CRM) devices, and includes data on implant volumes, procedure costs and reimbursement coverage.

Since the introduction of the cardiac pacemaker in the early [redacted]s, and then the launching of the implantable cardioverter-defibrillator (ICD), the range of implantable electronic devices has grown staggeringly, covering multiple applications in cardiology, neurology, endocrinology, urology and gastroenterology. Now, cardiovascular implantable electronic devices (CIEDs) comprise implantable pacemakers, ICDs, cardiac resynchronization therapy (CRT), implantable loop recorders (ILRs) and implantable hemodynamic monitoring (IHM). Accompanying the innovative designs of implantable electronic devices, progress in communication technology has considerably expanded the possibility to share key physiological and device information between implanted devices, external home monitors and healthcare providers.

Pacemaker implants are gradually increasing each year in industrialized nations mainly because of the general aging of the population. Nearly [redacted]% of all new pacemaker implants are for treating atrioventricular (AV) block, and about [redacted]% are for sick sinus syndrome. Currently, there are three active research areas in pacemaker technology: 1) minimization of frequency of pacing, 2) MRI compatibility and 3) device miniaturization. ICDs have evolved from a niche application (implanted abdominally) to primary prevention therapy for sudden cardiac death (SCD) in the last two decades. Innovations have greatly enhanced battery longevity, memory capability and telemetry function. Moreover, there is considerable reduction in the size of the ICDs from the volume of over [redacted] ml to the current ICD which has a volume of less than [redacted] cc.

1.1 Scope of This Report

The main objectives of this analysis are:

- Estimate the current and future U.S. and global markets for cardiac rhythm management (CRM) devices.
- Assess market opportunities and the potential market pertaining to pacemakers, ICDs and CRT products.
- Discuss the shift in trends towards ICDs from pacemakers.
- Analyze the need for CRM devices for various cardiac indications.
- Examine the segment market in cardiac rhythm management.
- Review the impact of changes in reimbursement rates in the U.S. for the different heart rhythm management procedures.
- Identify the key players in cardiac device industry and their contribution to the continuing innovations in the development of new devices.

Key questions answered in this study are:

- Which are the major cardiac rhythm disorders affecting the global, the U.S. and European population?
- What market drivers are responsible for the growth of CRM products?
- Which cardiac disorders contribute more to the growth of electronic heart devices?
- What regulatory and technical challenges are being confronted by the CRM device industry?
- How far the industry has progressed in developing miniature devices?
- What is the average life of a CRM device?
- What is the quality of patients' life with an implanted CRM device?
- What is the average cost of a CRM implant?
- What is the estimated future market size of cardiac devices at the U.S. and international level?

- Who are the leading vendors in CRM sector and what are their shares in the global market?
- What are the markets for pacemakers, ICDs and CRT devices?
- How many electronic cardiac devices were implanted in the U.S.?
- What, according to the U.S. ICD registry, are the rates of single chamber, dual chamber and CRT device implants in the U.S.?
- Which type of implant is gaining uninhibited growth in the U.S. market?
- What are the costs of CRT-D, ICDs and pacemakers in the U.S.?
- What are the rates of CRT, ICDs and pacemaker implants in European countries?
- How do the implant rates compare between the U.S., European and Latin American regions?

This report contains:

- An introduction to the various cardiac rhythm disorders and the different treatment options.
- A brief discussion on pacemakers; their components such as the battery, circuitry, connector blocks, electrodes, leads, conductor coils, connector type and the various concepts in pacemaker techniques.
- An overview on implantable cardioverter-defibrillators (ICDs) and components of ICDs such as battery, capacitors and the various concepts in ICD techniques.
- A synopsis on cardiac resynchronization therapy (CRT) and its clinical benefits.
- Application of CRT-P and CRT-D implants.
- A summary of implantable cardiac loop recorders (ILR), external cardioverter-defibrillators and wearable cardioverter-defibrillators.
- Leading global CRM device vendors.
- Data from U.S. ICD Registry that provide data on number of device implants, number of adverse cases reported and indications for ICD implantation.
- Pacemaker cost as a percentage of total reimbursement in the U.S.
- Costs for pacemaker, ICDs and CRT implants and reimbursement guide for ICD implants in the U.S.
- Pacemaker, ICDs, CRT-P and CRT-D implant rates in European countries.

The emphasis in this report is on those companies and products that are actively developing and marketing cardiology instrumentation. The reader should consult other TriMark reports at http://www.trimarkpublications.com for a detailed discussion of the important individual market segments related to the cardiac health, such as nuclear cardiology markets and cardiac marker diagnostic testing markets.

1.2 Methodology

The author of this report is a Ph.D. in biochemistry from the University of Minnesota with 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 is a retired college professor with three decades of experience in teaching biochemistry, biotechnology and pharmacology. 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, Heart Rhythm Society, *Journal of American College of Cardiology (JACC)*, National Heart, Lung and Blood Institute, Berkeley Center for Health Technology, *Diagnostic & Interventional Cardiology*, MD Buyline, European Heart Rhythm Association (EHRA), World Society of Arrhythmia, Israel Heart Society, U.K. National Survey on Heart Diseases, *European Journal of Heart Failure*, Heart Rhythm Congress (HRC), The Israeli Working Group on Pacing and Electrophysiology, etc.

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 TriMark believes to be reliable, but 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 and Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark's research in the past three years as part of this data collection. We also extract qualified data feeds from e-questionnaire responses and primary research responses for this compilation.

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. The report conclusions are verified through intensive interviewing of the top-ranking companies in the industry.

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.

1.3 Executive Summary

In many ways, medical implantable electronics corresponds with the electronics being used in a cell phone. Both are striving to get maximum functionality in a minimal space. The driving forces of the two industries are a number of market and technological pressures. Both the industries continue to develop and introduce new features and applications. The marked differences between the consumer electronics and implantable electronics are the need for absolute reliability along with better performance, compact size and reasonable cost for the implantable devices. In the previous decade, double-digit revenue growth had been the norm in the cardiac medical implants industry. The market for cardiac rhythm management (CRM) products enlarged in both application and geographic market. However, in the past four to five years, the growth rate has declined below [redacted]% and the cardiac implant industry has become severely competitive and undergone consolidation. Additionally, the environment of cost containment, managed care, large buying groups, government contracting and hospital consolidation have imposed pressure to bring down costs. This is a field which requires huge investments in research and development (R&D) for developing new products and we are yet to see efforts taken by the prominent vendors to drive the implant market back to double-digit growth.

Electronics gained entry into implantable cardiac devices since the invention of transistors in the late [redacted]s, and the initially developed pacemakers augmented their functionality and acceptance throughout the [redacted]s and [redacted]s. The implantable cardioverter-defibrillator (ICD) made its appearance for implantations in humans in [redacted]. Together, these two devices constitute the life-critical cardiac rhythm management (CRM) market segment. Throughout the long history of CRM electronics, circuits and components have not undergone changes very much, with good reason. With lives on the line, patients and caregivers did not want to take the risk of unnecessary changes of electronics inside the body. But the industry has always been witnessing a consistent pressure for smaller size, increased functionality and extended battery life in the newly developed devices. Miniaturization is the primary growth driver for implantable cardiac devices. For the patient, a small implantable device is less inconvenient than a large one. With a smaller device, the incision will be smaller, the procedure will be less obtrusive, the wound will heal more rapidly and the implant will be minimally noticeable. Enhanced features in modern pacemakers and ICDs comprise RF transceivers for wireless communication, improvements made in sensors to optimally time pacing and defibrillation shocks and backup systems in case the main system fails. Processing power and memory have also been augmented and integrated circuits (ICs) are being loaded on top of each other. Yet, in most modern devices, the discrete components have not undergone any changes. With such a type of innovation, discrete packaging has become a nagging concern.

The aging of the world's population will play an important role in driving the market for implantable electronics. By [redacted], over two billion people will be above the age of [redacted] and over two million will be more than [redacted] years old according to the World Health Report. The average age of a CRM device recipient is [redacted] and thus the global aging population will continue to drive the implant market. Global spending for healthcare is on the rise. The U.S. spends about $[redacted] per person per year on healthcare. The Office of the Actuary estimates that U.S. healthcare expenditure is nearly [redacted]% of the gross domestic product (GDP) and it is anticipated to continue its upward trend to reach [redacted]% of the GDP by [redacted]. Developing markets are becoming increasingly prosperous and these countries will provide one of the largest opportunities for sustained growth for the devices. Chinese healthcare sector spends $[redacted] per person and as part of its stimulus package; it will spend $[redacted] in healthcare upgrades in the next three years. Taiwan's national healthcare expenditure increased to [redacted]% of the GDP in [redacted]. Indian government took steps in [redacted] to increase public spending on healthcare from [redacted]% to [redacted]% of the GDP, but India's huge private healthcare sector offers much scope. These developing nations do not produce their own CRM devices and respect U.S. firms' brand recognition, reliability and technological superiority. Researchers in medical electronics are striving to create new customers for CRM devices. Presently, most patients who get a defibrillator implant have late-stage heart disease. By conducting clinical trials on patients with early-stage heart disease, the researchers hope to find out whether implanting defibrillators will yield health benefits.

If the implants of CRM devices in early-stage heart disease patients can offer better health and longer lives, insurance companies are more likely to approve the procedure. Researchers are continually working on shrinking discretes, transformers, capacitors and batteries. It is yet to be seen whether power discrete manufacturers are working on the right solution.

The global demand for cardiac rhythm management (CRM) equipment continues to gain strength with rising incidences of cardiac rhythm abnormalities, expanded clinical indications of CRM devices, and technological innovations such as, product miniaturization, development of durable batteries and biocompatible materials. Internal cardiac defibrillators (ICDs), pacemakers and external defibrillators are experiencing diverse application possibilities in addition to its present use in cardiac rhythm management. Besides CRM, pacemakers also find applications in treating heart blocks and bradycardia, atrial arrhythmias to brain and spinal cord injuries, cerebral palsy, Parkinson's disease, severe pain management and certain forms of cardiomyopathy. Biotechnology Associates, a leading market research company, estimates that the global market for CRM devices was worth about $[redacted] and predicts this to grow with a CAGR of [redacted]% and reach $[redacted] in [redacted].

Acute and persistent arrhythmias affect over eight million people in the U.S., accounting for over [redacted]% of all medical conditions treated by cardiology specialists. Moreover, each year cardiac rhythm disorders cause the death of about [redacted] U.S. citizens and lead to about [redacted] hospitalizations, resulting in an estimated $[redacted] in direct and indirect annual healthcare costs. In the U.S., CRM, electrophysiology and ablation equipment market will be driven by the aging population, increase in cardiac ablation procedures and adoption of advanced CRM devices. As tachyarrhythmia's incidence increases in the U.S. population, implantable cardioverter defibrillators (ICDs) are likely to continue to drive revenues in the implantable cardiac rhythm management device markets. According to

Biotechnology Associates, the U.S. market for CRM devices in [redacted] was worth about $[redacted] and this is predicted to grow with a CAGR of [redacted]% and reach $[redacted] in [redacted].

The incidence of cardiac rhythm disorders in Europe is on the rise year after year. The aging population in Europe is prone to cardiac disorders necessitating more number of implantations of cardiac devices and this has augmented the growing demand for CRM devices throughout the European region. Hospital admission statistics for cardiac rhythm disorders indicate that nearly about [redacted] Europeans are affected. This number is most likely to double by [redacted]. The guidelines issued by the European Society of Cardiology (ESC) designate ICD and CRT devices as class I for cardiac rhythm disorders and therefore hospitals in Europe have recognized these devices as a standard of care for patients of heart failure. Results of clinical trials also have produced a promotional effect for these devices. The adoption of the devices has also been encouraged by the offer of reimbursements by various healthcare agencies. According to Biotechnology Associates, the market for CRM devices in Europe in [redacted] was worth about $[redacted] and this figure is likely to grow and reach $[redacted] in [redacted].

According to the WHO, over [redacted] people die from cardiovascular disease each year throughout the world. Over [redacted]% of these deaths occur in Asia. As the economy is growing in many parts of the Asia-Pacific region, the Asian lifestyle is getting increasingly unhealthy giving rise to increased cardiovascular disease. The Chinese government has invested more than $[redacted] in healthcare with the goal of offering coverage to [redacted]% of the population by the end of [redacted]. This liberal healthcare spending offer increased funding for procedures, though actual reimbursement varies regionally. China is a huge market for CRM products in the Asia-Pacific region and the market for cardiac resynchronization therapy defibrillator (CRT-D) is to have a significant growth in the next seven years. In India, the rate of ICD implantation has increased due to the increasing awareness and significant improvement in the technology of these devices. Patients with ICDs are regularly being monitored at an interval of three to six months in order to keep a check on the functioning of these devices. According to the estimates of Biotechnology Associates, the CRM devices market in Asia-Pacific region in [redacted] was worth about $[redacted] and the research company predicts that it will reach $[redacted] in [redacted].

