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GlobalData
MediPoint

CARDIAC RHYTHM MANAGEMENT – US ANALYSIS AND MARKET FORECASTS

Executive Summary

Cardiac Rhythm Management Devices: Key Metrics in US	
Sick Sinus Syndrome Prevalence, 2012	0.3 million
Atrioventricular Block Prevalence, 2012	0.7 million
Ventricular Tachycardia Prevalence, 2012	1.8 million
Ventricular Fibrillation Prevalence, 2012	0.6 million
Cardiac Rhythm Management Market Revenue, 2012	
US	$6.1bn
US Market Revenue by Device Type, 2012	
Pacemakers	$2.1bn
Implantable Cardioverter-Defibrillators	$2.6bn
Cardiac Resynchronization Therapy Pacemakers	$73m
Cardiac Resynchronization Therapy Defibrillators	$1.4bn
Events Affecting the CRM Market	**Level of Impact**
Approval of S-ICD (Boston Scientific) by US FDA	↑↑
Launch of Advisa MRI (Medtronic) in US	↑
Forecast US Revenue by Device Type, 2020	
Pacemakers	$2.1bn
Implantable Cardioverter-Defibrillators	$2.9bn
Cardiac Resynchronization Therapy Pacemakers	$88m
Cardiac Resynchronization Therapy Defibrillators	$1.9bn

Source: GlobalData.

Cardiac Rhythm Management Market to Experience Significant Expansion Through 2020

Revenue from the US cardiac rhythm management market, consisting of pacemaker (PM), implantable Cardioverter-defibrillator (ICD), cardiac resynchronization pacemaker (CRT-P) and cardiac resynchronization therapy defibrillator (CRT-D) devices, is forecast to increase at a compound annual growth rate of 2.7% from $6.1 billion in 2012 to over $7.5 billion by 2020. This growth will come as a result of increasing incidences of arrhythmia and heart failure, combined with rising market penetration of pacing and pulse generator technology. Programs supporting this type of therapy are increasingly desirable as the occurrence of cardiac dyssynchrony continues to rise; it is estimated roughly 1% of the population suffers from an irregular heartbeat, although pervasiveness rises to over 20% in elderly people. While tachycardia and bradycardia are the most common indications for treatment, heart failure, diabetes, and obesity can contribute to ongoing rhythm management concerns.

The extremely competitive CRM market is dominated by several key players, who must continue to innovate in the face of mounting pricing pressure and strict regulation as they battle to gain market share.

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New technologies being developed, including leadless pacemakers and energy harvesting generators, promise to heighten products sales and new account openings, while industry standards continue to develop in regards to remote home monitoring and rate-adaptive therapy. Ongoing studies investigating applicability and appropriateness of varying rhythm management modalities are expected to further clarify suitable device indications and therapy best-practices, while advances in diagnostics as well as adjunctive therapy will assure better patient outcomes and shorter hospital stays in future years.

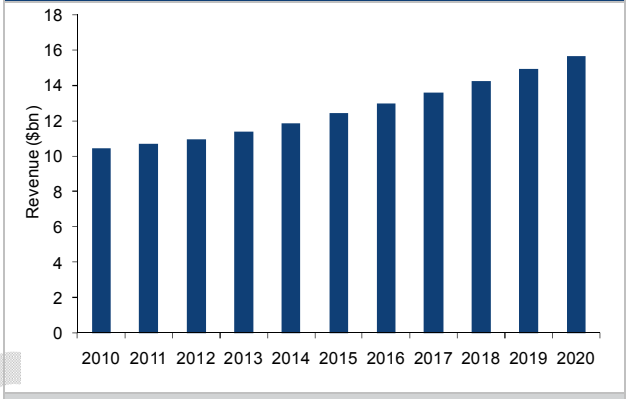
Key Drivers during the Forecast Period

- Growing incidences of arrhythmia and heart failure
- Heightened adoption rates
- New advancements in leadless devices and energy harvesting technology
- Increased emphasis on early intervention and primary prevention
- Strong CRM program adoption in hospitals, resulting in new account openings

Key Barriers during the Forecast Period

- High-costing devices to hinder CRM adoption
- Lacking reimbursement expected to limit market expansion and hospital product offerings
- Intense CRM market competition with limited innovation on the horizon

Pacemaker, ICD, CRT-D, CRT-P Market, Global, Revenue, ($bn), 2010–2020



Source: GlobalData.

Biventricular Therapy on the Rise as Devices Approved

Newly developed biventricular CRT-P and CRT-D devices are expected to undergo significant market adoption in the coming years as physician adoption increases, additional patient outcomes are published, and average selling price declines. Furthermore, as more centers develop their CRT offerings, hospitals will be looking to implement new programs for advanced CRM, to enable their physicians to begin implanting the devices.

Despite higher prices when compared with single-chamber pacemakers, dual-chamber and biventricular CRT-P products have experienced notable rises in procedure volumes, driving growth in total sale revenue from these market segments.

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Currently, dual-chamber devices account for the largest segment of the CRM market, although CRT is experiencing adoption rates similar to what dual-chamber devices did several years ago.

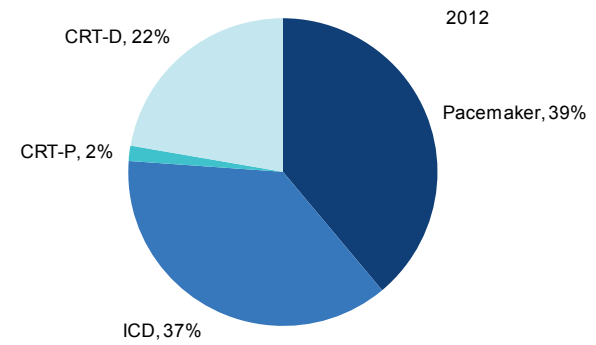
Given improved efficacy, better outcomes and physician partiality, these next-generation devices have seen significant adoption in the US market.

Significant Growth in Target Population

The population requiring CRM therapy continues to grow, due to increasing prevalence of serious risk factors, including obesity, diabetes, hypertension, and congestive heart failure. According to a 2013 briefing published by the World Health Organization, over 1 billion people suffer from hypertension worldwide, which is a major cause of congestive heart failure, a condition common in over 25 million people (WHO, 2013). Similarly, the International Diabetes Federation states an estimated 285 million people had diabetes in 2010, which is predicted to increase to 438 million by 2030 (International Diabetes Federation, 2013). Additionally, the global obesity population is increasing at a rapid, uncontrolled rate. Lifestyle factors, including tobacco, alcohol and caffeine intake, can also greatly increase the risk of arrhythmias.

With limited pharmacotherapy to treat dyssynchrony, CRM devices are expected to remain the go-to option for patients with rhythm management concerns.

Pacemaker, ICD, CRT-D, CRT-P Market Breakdown (%), Global, 2012



Source: GlobalData.

Primary Prevention on the Rise

Traditionally, the majority of implantable Cardioverter-defibrillators implanted have been implanted for secondary prevention indications; however, this is slowly changing. As mature markets undergo a paradigm shift in treatment, the percentage of primary prevention cases continues to rise; nearly 70% of ICDs implanted in the US in 2012 were for primary prevention indications. As treatment schedules evolve, CRM companies will have an ever-growing opportunity to sell their products for primary prevention indications.

Device Innovation Expected to Drive Sales

While advancements in device algorithms and rate-adaptive programming, as well as reductions in size and weight, have all distinguished various brands on the market to date, these technological advancements offer limited patient outcome improvements from brand to brand.

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However, the introduction of remote home monitoring promises to dramatically change treatment. Home monitoring telemetry will decrease the number of patient hospital visits, a particularly attractive feature for customers living in remote regions far from access to healthcare. Furthermore, advances in leadless and energy harvesting technology are expected to be revolutionary to the CRM industry, especially in the US. Through eliminating the need for lead replacement and, especially, generator battery replacement, manufacturers hope to boost device sales in younger and more remote populations, who are reluctant to receive a new device that requires substitution every seven to 12 years.

What do Physicians Think?

While CRM therapy has been around for many years, a majority of patients don't fully understand the treatment, or are unaware of their own dyssynchrony. Increases in patient awareness as well as physician diagnosis are expected to drive CRM sales.

"[Patients] are not aware that there is a device that can prevent sudden cardiac death, and they don't know to ask for [therapy]."

Key Opinion Leader

While advancements in treatment guidelines and industry best-practices have provided greater clarity in regards to appropriateness of treatment, gaps remain in the understanding of arrhythmia, and there is significant room for procedural improvement as well as international guideline development.

"The guidelines as envisioned are tremendously important and have a great use and a great purpose. However, the implementation [of] these guidelines is confused by competing other documents."

Key Opinion Leader

While advancements in CRM therapy have provided improved patient outcomes, this evolution has been in parallel with developments in adjunctive therapy, which continues to progress as well and greatly affects patient outcomes.

"Although there are a lot of achievements within the CRM field, the advantages in the adjunctive therapy go hand-in-hand."

Key Opinion Leader

While improvements in programming and rate-adaptive algorithms have driven device sales and established physician preferences to an extent, the introduction of leadless technology and energy harvesting devices is expected to be far more impactful, and will mark the next revolution for CRM products.

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"Energy harvesting is very interesting. If physicians don't have to replace the generator, that is perfect."

Key Opinion Leader

While many companies are striving to completely eliminate device leads, other advances in lead technology have done the opposite. In particularly, multi-electrode ventricular leads are increasingly common in company pipelines, and many believe that these next-generation products will provide significant improvements in patient treatment.

"In the future, we are looking at multi-electrode LV leads, and I'm pretty enthusiastic about those multi-polar leads, as I think this is probably one of the future trends."

Key Opinion Leader

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2 Introduction

Cardiac rhythm management (CRM) comprises any method of treatment aimed at regulating the heart's rhythm, including medication, medical devices, and occasionally surgery. There can be a number of reasons why CRM is needed, all of which generally involve malfunctions of the heart's electrical system, and are related to cardiac dyssynchrony. While medication can be effective in mild to moderate cases, patients with more severe conditions must turn to device use or surgical intervention in order to receive the therapy they require. Over the years, CRM device treatment has become less invasive, and significant advances in pacing and pulse generator technology have enabled effective long-term device therapy with limited complications.

There are a number of devices that are utilized for CRM, and depending on the patient's arrhythmia, they may receive a pacemaker (PM), implantable cardioverter-defibrillator (ICD), cardiac resynchronization therapy pacemaker (CRT-P) or cardiac resynchronization therapy defibrillator (CRT-D). CRM device implementation depends on the patient's current status and how the physician expects their dysrhythmia to progress, although other concerns in regards to pricing, reimbursement, and complication rates all have an effect on the decision to implant as well, especially in emerging markets where patient awareness is lacking and healthcare budgets are limited.

2.1 Catalyst

The CRM industry continues to experience meaningful growth through improved device therapy, adoption in remote regions, increased patient awareness, and updates in national and international guidelines. Companies are increasingly looking to provide tiered product offerings to target larger patient populations with differing reimbursement options. While 15 years ago CRM products were not programmable, most current devices have 200 parameters, which can be reprogrammed non-invasively using telemetry, and result in substantial performance differences between the various brands of CRM products. Despite innovation and new product launches, many customers are genuinely happy with the performance and features of current devices, and as a result, the CRM market continues to be troubled by a challenging pricing environment that does not reward innovation. Companies now must figure out how to add value in different ways, principally related to device cost effectiveness.

Introduction

The CRT-P and CRT-D markets in the US have experienced significant growth in recent years despite relatively static pacemaker and ICD sales. With competition tight between just a few major players, added emphasis will be put on affordability, technology innovation, and distribution networks in the coming years.

- Next-generation CRT products have experienced significant adoption in recent years
- Pipeline technologies including leadless generators and energy harvesting devices will drive future device sales
- Remote home monitoring telemetry is expected to increase CRM device adoption, especially in remote areas
- The industry shift from single-chamber to dual-chamber ICDs will drive additional revenue
- Pricing headwinds, especially in developing countries, will steadily reduce the average selling price of CRM products
- New distribution channels globally will strengthen market access for US-based companies

2.2 Related Reports

- MediPoint: Cardiac Assist Devices Global Analysis and Market Forecasts GDME0175MAR / Published March 2013
- MediPoint: Transcatheter Aortic Valve Replacement Global Analysis and Market Forecasts GDME0165MAR / Published November 2012

2.3 Upcoming Related Reports

- MediPoint: EP Ablation Global Analysis and Market Forecasts / To be published February 2014

Appendix

10.6 About MediPoint

MediPoint is the flagship product for GlobalData's Medical team. Each MediPoint report is built from the ground-up by our team of healthcare analysts in the US and UK. Each report includes input from experienced physicians and leading Key Opinion Leaders (KOLs). Running throughout each report in the series, "What Do Physicians Think" quotes provide a unique insight into how healthcare professionals are reacting to events within the industry, and what their responses could mean for industry strategists.

10.7 About GlobalData

GlobalData is a leading global provider of business intelligence in the Healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in medical device research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports and forecasts. Our analysis is supported by a 24/7 client support and analyst team. GlobalData has offices in New York, Boston, London, India and Singapore.

10.8 Disclaimer