



CARDIAC RHYTHM
MANAGEMENT DEVICES
WORLD MARKETS
(SAMPLE COPY, NOT FOR RESALE)

Defibrillators, Pacemakers and Leads

TABLE OF CONTENTS

1.	Overview	13
1.1	Scope of This Report	13
1.2	Methodology	14
1.3	Executive Summary	15
2.	Cardiac Rhythm Management: An Overview	18
2.1	Cardiac Rhythm Disorders	18
2.1.1	Premature Atrial Contractions (PACs) Sinus Tachycardia	19
2.1.2	Sinus Tachycardia	19
2.1.3	Sinus Bradycardia	20
2.2	Abnormal Rhythms	20
2.2.1	Tachycardia Ventricular Fibrillation (V Fib)	20
2.2.2	Ventricular Fibrillation (V Fib)	21
2.2.3	Ventricular Flutter	21
2.2.4	Paroxysmal Supraventricular Tachycardia (PSVT)	21
2.2.5	Atrial Fibrillation (A Fib)	22
2.3	Causes of Heart Rhythm Disorders	22
2.3.1	Symptoms of Heart Rhythm Disorders, Exams and Tests	23
2.3.1.1	Treatment for Heart Rhythm Disorders	23
2.4	Sudden Cardiac Death (SCD)	24
2.4.1	Incidence of SCD in the U.S.	24
2.5	Cardiac Rhythm Management Devices: An Overview	25
2.5.1	Cardiac Pacemakers	26
2.5.1.1	NBG Codes for Permanent Pacing	26
2.5.2	Pacemaker Components	27
2.5.2.1	Batteries in Pacemakers	27
2.5.2.2	Circuitry in Pacemakers	27
2.5.2.3	Connector Blocks of Pacemakers	30
2.5.2.4	Leads in Pacemakers	30
2.5.2.5	Electrodes in Pacemakers	31
2.5.2.6	Insulation in Pacemakers	32
2.5.2.7	Conductor Coils in Pacemakers	32
2.5.2.8	Fixation Mechanisms	32
2.5.2.9	Connectors in Pacemakers	33
2.5.2.10	Unipolar and Bipolar Pacing Systems	34
2.6	Basic Concepts and Terms in Pacemaker Procedures	35
2.6.1	Pacing Threshold	35
2.6.2	Sensing of Pacemakers	35
2.6.3	Slew Rate	36
2.6.4	Impedance in Pacing	37
2.6.5	Acute Implant Values in Pacing	37
2.6.6	Post-Implant Values	38
2.6.7	Pacing Intervals	38
2.6.8	Programmability	38
2.6.9	Magnetic Response in Pacing	39
2.7	Basic Single Chamber Pacing	40
2.7.1	Automatic Interval in Basic Single Chamber Pacing	40
2.7.2	Escape Interval	41
2.7.3	Refractory Period	41
2.8	Additional Concepts in Single Chamber Pacing	44
2.8.1	Hysteresis	44
2.8.2	Fusion and Pseudofusion in Single Chamber Pacing	44
2.8.3	Latency in Single Chamber Pacing	45
2.9	Concepts and Modes in Dual Chamber Pacing	46

2.9.1	AV Interval (AVI)	46	
2.9.2	Differential AV Interval	46	
2.9.3	Adaptive AVI	47	
2.9.4	Atrial Escape Interval (AEI)	47	
2.9.5	Post-Ventricular Atrial Refractory Period (PVARP)		48
2.9.6	Total Atrial Refractory Period (TARP)	49	
2.9.7	Adaptive PVARP	49	
2.9.8	Upper Rate Limit (URL)	49	
2.9.9	Ventricular Blanking Period	50	
2.9.10	Atrial-based Timing	50	
2.9.11	DDD Mode	51	
2.9.12	Totally Inhibited (PR) Pacing	51	
2.9.13	Atrial Pace/Ventricular Inhibited (AR)	51	
2.9.14	Atrial Inhibited Ventricular Pacing (PV)	52	
2.9.15	Atrial Paced and Ventricular Paced (AV)	52	
2.9.16	DVI Pacing	52	
2.9.17	DDI Mode	53	
2.9.18	VDD Mode	54	
2.9.19	Upper Rate Behavior	54	
2.9.20	Block (Multiblock)	55	
2.9.21	Pseudo-Wenckebach	55	
2.9.22	Rate Smoothing	56	
2.9.23	Fallback Response	56	
2.9.24	Sensor-driven Rate Smoothing	57	
2.9.25	Sensor-driven Pacing in Dual Chamber Pacemakers	57	
2.9.26	Activity/Vibration	58	
2.10	Tips for Buying Cardiac Pacemakers	60	
2.10.1	Comparison of Biotronik's Cardiac Pacemakers	60	
2.10.2	Comparison of Cardiac Pacemakers from Boston Scientific		62
2.10.3	Comparison of Cardiac Pacemakers from Medtronic		63
2.11	Implantable Cardioverter-Defibrillators (ICDs)	64	
2.11.1	NBD Code for ICD	64	
2.11.2	Basic Concepts of ICDs	65	
2.11.3	Battery in ICDs	65	
2.11.4	Capacitors in ICDs	66	
2.11.5	Sensing in ICDs	66	
2.11.6	Detection in ICDs	67	
2.11.7	Defibrillation Waveform	68	
2.11.8	Defibrillation Threshold	69	
2.11.9	Anti Tachycardia Pacing (ATP)	69	
2.12	Recommended Replacement Time for ICDs		70
2.13	Cardiac Resynchronization Therapy (CRT)		70
2.13.1	Clinical Benefits of CRT in Atrial Fibrillation		71
2.13.2	Differences between Pacemaker and CRT Device		71
2.13.3	CRT-P Implantation	71	
2.13.4	CRT-D Implantation	72	
2.13.5	CRT-D Implantation Procedure	73	
2.14	Insertable Loop Recorder (ILR)	73	
2.14.1	Implantation of ILR	73	
2.15	External Cardioverter-Defibrillators	74	
2.15.1	Types of Automatic External Defibrillators (AEDs)	74	
2.15.2	External Defibrillation Procedure	74	
2.15.3	Accuracy of an AED	75	
2.15.4	Battery Core and Maintenance of an AED	75	
2.15.5	Purchase Considerations for AEDs	75	
2.16	Wearable Cardioverter-Defibrillators	81	

2.17	Devices Interfering with Cardiac Implants	81	
2.18	Future Applications for Pacemakers	82	
2.19	Device Life of CRM Implants	82	
2.20	Quality of Life with CRM Implants	83	
2.21	Cost of CRM Implants	83	
3.	Market Analysis for CRM Products	84	
3.1	Global Cardiac Devices Market	84	
3.1.1	North American Market for Cardiac Medical Devices		84
3.1.2	European Market for Cardiac Medical Devices	85	
3.1.3	Cardiac Medical Devices Market in Asia-Pacific	86	
3.1.4	Global market for Interventional Cardiac Devices	88	
3.1.5	Global Market for Peripheral Vascular Devices	88	
3.1.6	Global Peripheral Vascular Device Market by Vendor		89
3.1.7	Global market for Cardiac Electrophysiology Market		90
3.1.8	Global Market for Cardiac Prosthetic Devices (CPD)		90
3.2	Global Market for Cardiac Rhythm Management (CRM) Devices		91
3.2.1	Market for CRM Devices in BRICSS Countries	92	
3.2.2	Market for CRM Devices in China	93	
3.2.3	Leading Global CRM Device Vendors	93	
3.2.4	Global Market for Cardiac Monitoring and Diagnostic Devices		94
3.3	Global Market for Cardiac Pacemakers	95	
3.3.1	North American Market for Cardiac Pacemakers		96
3.3.2	European Cardiac Pacemaker Market	96	
3.4	Global Market for ICDs	97	
3.4.1	North American Market for ICDs		98
3.4.2	European Market for ICDs	99	
3.4.3	Asia-Pacific Market for ICDs	99	
4.	The U.S. and European Scenario of Cardiac Rhythm Management		101
4.1	U.S. Opportunities in Cardiovascular Segment		101
4.1.1	U.S. Cardiovascular Devices Market		102
4.2	Data from U.S. ICD Registry		104
4.2.1	Demographics and ICD Indications in the U.S.		105
4.2.2	Physician Training and ICD Implant Volume in the U.S.		106
4.2.3	ICD Types and Adverse Events in the U.S.		106
4.2.4	ICD Implants in the U.S.		107
4.2.5	Single Chamber, Dual Chamber and Biventricular Implants in the U.S.		108
4.2.6	Proportion of ICD Utilization for Primary and Secondary Prevention in the U.S.		108
4.2.7	Proportion of ICD/CRT-D by Type in the U.S.		109
4.2.8	Characteristics of ICD Patients in the U.S.		110
4.3	Cardiac Implants in 45 Californian Hospitals		111
4.3.1	Annual Volume of Pacemaker Procedures in California		111
4.3.2	Procedure and Average Implant Costs		111
4.3.3	Best Cardiology Hospitals in California		112
4.3.4	Pacemaker Procedure Costs in 42 Californian Hospitals		113
4.3.5	Cost as a Percentage of Total Reimbursement		113
4.3.6	Pacemaker Cost as a Percentage of Total Reimbursement		114
4.4	Future of Pacemaker Implantation in the U.S.		115
4.5	ICD Complication Rates in the U.S.		116
4.6	Cost of CRT-D Therapy in the U.S.		117
4.6.1	Cost of ICDs in the U.S.		117
4.6.2	Cost for Pacemakers in the U.S.		118
4.6.3	Options for Negotiating the Costs		119
4.7	Reimbursement Guide for ICD Implants		121
4.7.1	Coverage for ICD Therapy		122

4.7.2	Coverage with Non-Medicare Patients	122
4.7.3	Coding for ICD Therapy	122
4.7.4	Hospital Inpatients Procedure Codes	123
4.7.5	Hospital Outpatient Procedure Codes	123
4.7.6	C-Codes for ICD Implants	124
4.7.7	ICD-9-CM Diagnosis Codes	124
4.7.8	Inpatient Hospital Medicare Payment for ICD Therapy	127
4.8	ICD Implants in South America	127
4.9	Pacemaker Implant Rate in Europe	128
4.10	CRT-D Implants in Europe	129
4.11	ICD Implants in Europe	130
4.12	ICD and CRT-D Implants in Europe	131
4.13	All CRT-P Implants in Europe	132
4.14	Implanted CRM Devices in Europe by Type and Country	133
4.15	Comparison between U.S. and European Implant Rates	135
4.16	Comparison of CRT-D and CRT-P Implant Rates between the U.S. and Europe	135
4.17	Proportions of Pacing Modes Used in Europe	136
4.18	Geographic Variations in ICD Implantation in Europe	137
4.19	ICD Utilization in Europe	138
4.20	Rates of ICD Implants in Select Countries of Europe	139
4.21	ICD Implantation and Economic Factors in Europe	139
4.22	Penetration of Dual Chamber ICDs in Europe	140
4.23	Number of ICD Implanting Centers in Europe	141
4.24	Healthcare Factors and ICD Implantation in Europe	142
4.25	Potential ICD Implant Recipients in Europe	142
4.26	Status of Cardiac Electrophysiology in ESC Member Countries	142
4.27	U.K. National Survey on CRM Devices	153
4.27.1	New Pacemaker Implant Rates in U.K.	153
4.27.2	New ICD Implant Rate in U.K.	153
4.27.3	New CRT Implant Rates in U.K.	154
4.27.4	Total (New and Replacements) CRT Implant Rates in U.K.	155
4.27.5	Physiological Pacing and Age in U.K.	155
4.27.6	Projected Pacemaker Sales in U.K., 2008-2016	156
4.27.7	Projected ICD Sales in U.K.	157
4.27.8	Projected CRT Device Sales in U.K.	158
4.27.9	Top Ten CRM Device Implanting Hospitals in U.K.	158
4.28	U.K.: ICD Registry	159
4.28.1	CRT Activity in U.K.	159
4.28.2	Over-Performance of ICD and CRT-D Activity Compared to Plan	160
4.28.3	CRT Activity in U.K.	161
4.28.4	Pacemaker Activity	161
4.28.5	Increasing Role of CRT in England	162
4.28.6	High-Energy Implants for Primary Prevention in U.K.	163
4.28.7	High-Energy Implants for Secondary Prevention in U.K., 2009	164
4.28.8	Increasing Role of CRT in U.K.	164
4.28.9	CRT-P and CRT-D	165
4.28.10	Survival after CRM Device Implants in U.K.	166
4.28.11	Pacemaker Implantation Rate in U.K.'s Anglia Network Region	166
4.28.12	New ICD Implant Rate in Anglia Network	167
4.28.13	CRT Implant Rate in Anglia Network	168
4.29	CRM Device Implants in Switzerland	168
4.30	CRM Device Implants in Italy	170
4.31	ICD Implants in Spain	171
4.31.1	Total Number of Implantations in Spain	171
4.31.2	New Implants vs. Replacements in Spain	172
4.31.3	Age and Gender of Device Recipients in Spain	172

4.31.4	Underlying Heart Diseases in Spain Requiring CRM Device	172
4.31.5	LVEF Patients in Spanish Registry	173
4.31.6	Clinical Arrhythmias Requiring ICD Implants in Spain	174
4.31.7	Clinical Presentations of Arrhythmias in Spanish Patient	174
4.31.8	Cardiovascular Diseases in Serbia	175
4.31.9	CRM Devices Implants in Serbia, 2009	175
4.32	ICD Implants by Type in Israel	177
4.32.1	Initial and Replacement ICD Implants in Israel, 2010	178
4.32.2	ICD Implants in Israel by Age and Ethnicity	178
4.32.3	Doubling of ICD Implants in Israel, 2011	179
4.32.4	Off-Label ICD Implants in Israel	184
5.	Selected Company Profiles	185
5.1	Biotronik, Inc.	185
5.1.1	Selected CRM Products from Biotronik	185
5.1.1.1	Evia DR-T	185
5.1.1.2	Estella DR-T	185
5.1.1.3	Effecta DR	186
5.1.1.4	Cyclos 990 DR-T	186
5.1.1.5	Philos II DR-T	187
5.1.1.6	Talos DR	187
5.1.1.7	Axios-S	188
5.1.2	Biotronik's ICDs for Tachyarrhythmia	188
5.1.2.1	Lumax 540 VR-T DX	188
5.1.2.2	Lumax 540 VR-T	189
5.1.3	Biotronik's CRT Products	189
5.1.3.1	Lumax 540 HF-T	189
5.1.3.2	Stratos LV-T	190
5.1.3.3	Lumax 340 HF-T	190
5.2	Boston Scientific Corporation	191
5.2.1	Selected CRM Products from Boston	191
5.2.1.1	PeriVac Pericardiocentesis Kits	191
5.2.1.2	COGNIS (CRT-D)	192
5.2.1.3	Contak Renewal 3 RF	192
5.2.1.4	Contak Renewal TR	192
5.2.1.5	Livian CRT-DS	193
5.2.1.6	Confient ICD	193
5.2.1.7	Teligen ICD	193
5.2.1.8	Vitality ICD	194
5.2.1.9	The Altrua Pacemaker Family	194
5.3	Cardiac Science Corporation	194
5.3.1	Powerheart AED G3 Plus	195
5.3.2	Powerheart AED G3 Pro	195
5.3.3	Powerheart AED G3	195
5.3.4	Powerheart AED G3 Trainer	196
5.4	Esaote S.p.A	196
5.4.1	P80	196
5.4.2	P8000	196
5.5	Fukuda Denshi, Co., Ltd.	197
5.5.1	CardiMax FCP-7101	197
5.5.2	CardiMax FX-7102	197
5.5.3	CardiMax FX-7202	198
5.5.4	CardiMax FX-7402	198
5.6	Laerdal Medical AS	199
5.6.1	Defibrillation Products from Laerdal	199
5.6.1.1	HeartStart HSI First Aid Defibrillator	199

5.6.1.2	HeartStart FR2 Automated External Defibrillator	199
5.6.1.3	HeartStart FRx	200
5.6.1.4	HeartStart MRx	200
5.7	Medtronic, Inc.	201
5.7.1	Medtronic's CRM Products	201
5.7.1.1	Reveal DX and Reveal XT Insertable Cardiac Monitors	204
5.7.1.2	Protecta XT (CRT-D)	204
5.7.1.3	Protecta (CRT-D)	204
5.7.1.4	Consulta (CRT-D)	205
5.7.1.5	Maximo II (CRT-D)	205
5.7.1.6	Historical CRT Devices	205
5.7.2	Medtronic's CRT-P Devices	206
5.7.2.1	Syncra CRT-P	206
5.7.3	Medtronic's ICDs	206
5.7.3.1	Protecta XT DR and VR	206
5.7.3.2	Secura DR and VR	207
5.8	Nihon Kohden Corporation	207
5.8.1	Cardiofax ECG 9620	208
5.8.2	Cardiofax C ECG 1150	208
5.8.3	CardiofaxS ECG -1250	209
5.8.4	Cardiofax M ECG-1350	209
5.8.5	Cardiofax V ECG-1500 Series	209
5.9	Philips Healthcare	210
5.9.1	Selected CRM Products from Philips	210
5.9.1.1	HeartStart FR2+	210
5.9.1.2	HeartStart FRx Defibrillator	211
5.9.1.3	HeartStart OnSite (HIS)	212
5.9.1.4	HeartStart MRx ALS Monitor/Defibrillator	212
5.9.1.5	HeartStart XL Defibrillator/Monitor	213
5.9.1.6	Q-CPR Measurement and Feedback Tool	213
5.9.1.7	HeartStart Telemedicine System	213
5.9.1.8	HeartStart Event Review Pro—EMS	214
5.9.1.9	HeartStart Event Review Pro—Hospitals	214
5.9.1.10	HeartStart Data Messenger	215
5.9.1.11	HeartStart Event Review for AEDs	215
5.9.1.12	HeartStart Configure	216
5.9.1.13	HeartStart Event Review Pro—Hospitals	216
5.10	Schiller AG	216
5.10.1	Schiller's Public Access Defibrillators	217
5.10.1.1	FRED easy (Automatic)	217
5.10.1.2	FRED easyport	217
5.11	Sorin Group USA, Inc.	217
5.11.1	Selected CRM Products from Sorin	218
5.11.1.1	Paradym (CRT)	218
5.11.1.2	Ovatio (CRT)	218
5.11.1.3	Paradym DR	219
5.11.1.4	Paradym VR	219
5.11.1.5	Esprit DR	219
5.12	St. Jude Medical, Inc.	220
5.12.1	Accent Pacemakers	220
5.12.2	Affinity Pacemakers	220
5.12.3	Entity Pacemakers	220
5.12.4	Identity ADx Pacemakers	220
5.12.5	Integrity Pacemakers	221
5.12.6	Microny Pacemakers	221
5.12.7	Regency Pacemakers	221

5.12.8	Temporary Pacemakers	221
5.12.9	Verity ADx Pacemakers	222
5.12.10	Victory Pacemakers	222
5.12.11	Zephyr Pacemakers	223
5.12.12	Anthem CRT-P	223
5.12.13	Atlas II HF CRT-D	223
5.12.14	Epic HF CRT-D	224
5.12.15	Epic II HF CRT-D	224
5.12.16	Frontier II CRT-P	225
5.12.17	Promote Accel CRT-D	225
5.12.18	Promote Plus CRT-D	225
5.12.19	Unify CRT-D	226
5.12.20	Atlas ICD Family	226
5.12.21	Atlas II ICD Family	227
5.12.22	Current Accel ICD	227
5.12.23	Current Plus ICD	228
5.12.24	Epic ICD	228
5.12.25	Epic II ICD Family	229
5.13	Welch Allyn, Inc.	229
5.13.1	AED10 Defibrillator	230
5.14	Zoll Medical Corporation	230
5.14.1	Selected Zoll's CRM Products	231
5.14.1.1	AED Plus Automated External Defibrillator	231
5.14.1.2	AED Plus Automated External Defibrillator	231
5.14.1.3	Auto-Pulse Non-Invasive Cardiac Support Pump	232
5.14.1.4	CodeNet Resuscitation Data Management System	232
5.14.1.5	Defibrillator Dashboard Software	232
5.14.1.6	E Series Defibrillators	233
5.14.1.7	Zoll Life Vest	233
5.14.1.8	M Series CCT Defibrillators	233
5.14.1.9	M Series Defibrillators	234
5.14.1.10	Propaq MD	235
5.14.1.11	R Series Monitor Defibrillator	235
Appendix 1: The Evolution of Pacemakers: An Electronics Perspective		236
Appendix 1.1: Excitation and Conducting System in Heart		236
Appendix 1.2: Cardiac Signals		237
Appendix 1.2.1: Surface Electrocardiogram		237
Appendix 1.2.2: Intracardiac Electrogram (IECG)		238
Appendix 1.2.3: Arrhythmia		238
Appendix 1.3: History and Development of Cardiac Pacing		239
Appendix 1.3.1: Hyman's Pacemaker		240
Appendix 1.3.2: Dawn of Modern Era: Implantable Pacemakers		241
Appendix 1.3.3: Demand Pacemaker		242
Appendix 1.3.4: Dual-Chamber Pacemaker		244
Appendix 1.3.5: Rate-Responsive Pacemaker		245
Appendix 1.3.6: New Features in Modern Pacemakers		245
Appendix 2: Glossary of Terms: Cardiac Rhythm Disorders		247

INDEX OF FIGURES

Figure 2.1: Incidence of SCD in the U.S. by Age and Gender	25
Figure 2.2: Radiograph of a Nuclear Pacemaker	27
Figure 2.3: Photograph of an Older Pacemaker Showing the Discrete Components	27
Figure 2.4: Radiograph of a Current Model of Pacemaker of Microprocessor-based Design	28

Figure 2.5: Print-out of a Pacemaker Telemetry Data	29
Figure 2.6: Intracardiac Electrogram from a Pacemaker	29
Figure 2.7: Connector Block Types in Pacemakers	30
Figure 2.8: Diagram of a Typical Bipolar Pacing Lead	30
Figure 2.9: The Five Basic Types of Leads in Pacemakers	31
Figure 2.10: Diagram of a Steroid-eluting Lead Design in Pacemaker	31
Figure 2.11: Conductor Coil Types in Pacemakers	32
Figure 2.12: Fixation Types in Pacemakers	33
Figure 2.13: Connector Types in Pacemakers	33
Figure 2.14: Unipolar and Bipolar Pacing Systems	34
Figure 2.15: Strength Duration Curve	35
Figure 2.16: Comparison of Surface Cardiogram Recordings	36
Figure 2.17: Raw and Filtered Electrograms as Transmitted from a Pacemaker	37
Figure 2.18: Comparison of a Signal with a Good Slew Rate and Poor Slew Rate	37
Figure 2.19: Capture Threshold vs. Time Plot in Pacing	38
Figure 2.20: Pacing Strip Showing Magnetic Response	40
Figure 2.21: Automatic Interval in Single Chamber Pacing	40
Figure 2.22: Escape Interval in Single Chamber Pacing	41
Figure 2.23: Refractory Period in Single Chamber Pacing	41
Figure 2.24: VVI Mode in Single Chamber Pacing	42
Figure 2.25: VVT Mode in Single Chamber Pacing	42
Figure 2.26: VOO Mode in Single Chamber Pacing	42
Figure 2.27: AAT Mode in Single Chamber Pacing	43
Figure 2.28: AAI Mode in Single Chamber Pacing	43
Figure 2.29: AAT Mode in Single Chamber Pacing	43
Figure 2.30: Hysteresis in Single Chamber Pacing	44
Figure 2.31: Fusion in Single Chamber Pacing	45
Figure 2.32: Pseudofusion in Single Chamber Pacing	45
Figure 2.33: Latency in Single Chamber Pacing	46
Figure 2.34: AV Interval in Dual Chamber Pacing	46
Figure 2.35: Differential AV Interval in Dual Chamber Pacing	47
Figure 2.36: Adaptive AVI in Dual Chamber Pacing	47
Figure 2.37: Atrial Escape Interval in Dual Chamber Pacing	48
Figure 2.38: PVARP in Dual Chamber Pacing	48
Figure 2.39: URL in Dual Chamber Pacing	49
Figure 2.40: Relationship between the Major Timing Cycles in Dual Chamber Pacing	50
Figure 2.41: Ventricular-based Timing at Low and High Rates	50
Figure 2.42: Totally Inhibited Pacing in Dual Chamber Pacemaker	51
Figure 2.43: AR Pacing in Dual Chamber Pacing	52
Figure 2.44: Atrial Inhibited Ventricular Pace (PV)	52
Figure 2.45: AV Pacing in Dual Chamber Pacemaker	52
Figure 2.46: DVI-C (Committed) Mode in Dual Chamber Pacing	53
Figure 2.47: DVI-NC (Non-Committed) Mode in Dual Chamber Pacing	53
Figure 2.48: Sensing of Both Atrium and Ventricle by DDI Mode	53
Figure 2.49: Comparison of DDD, DDI and DVI in Dual Chamber Pacing	54
Figure 2.50: VDD Mode in Dual Chamber Pacing	54
Figure 2.51: Block (Multiblock) in Dual Chamber Pacing	55
Figure 2.52: Pseudo-Wenckebach Behavior in Dual Mode Pacing	56
Figure 2.53: Rate Smoothing in Dual Chamber Pacing	56
Figure 2.54: Sensor Output in Relation to Activity	58
Figure 2.55: Diagram Showing Signals from a Piezoelectric Sensor	59
Figure 2.56: The Slope Values and Determination of Target Heart Rate	59
Figure 2.57: Reaction/Acceleration Time and Recovery/Deceleration Time	60
Figure 2.58: True Bipolar and Integrated Bipolar Sensing in ICDs	66
Figure 2.59: Detection of Arrhythmia Using Rate Stability Criterion	67
Figure 2.60: Sudden Onset Criteria to Differentiate VT from Sinus Tachycardia	68

Figure 2.61: Truncated Exponential Monophasic Waveform	68
Figure 2.62: DFT Probability Curve	69
Figure 2.63: Success of ATP	70
Figure 3.1: Global Cardiac Devices Market, 2010-2017	84
Figure 3.2: North American Market for Cardiac Medical Devices, 2010-2017	85
Figure 3.3: European Market for Cardiac Medical Devices, 2010-2017	86
Figure 3.4: Asia-Pacific Market for Cardiac Devices, 2010-2017	87
Figure 3.5: Global Market for Interventional Cardiac Devices, 2010-2017	88
Figure 3.6: Global Market for Peripheral Vascular Devices, 2010-2017	89
Figure 3.7: Global Peripheral Vascular Device Market Share by Company, 2010	89
Figure 3.8: Global Market for Electrophysiology Devices (EP), 2010-2017	90
Figure 3.9: Global Market for Cardiac Prosthetic Devices, 2010-2017	91
Figure 3.10: Global Market for Cardiac Rhythm Management (CRM) Devices, 2010-2017	92
Figure 3.11: CRM Devices Market in BRICSS Countries, 2010-2017	92
Figure 3.12: Chinese Market for CRM Devices, 2010-2017	93
Figure 3.13: Global Share of CRM Products by Vendor	94
Figure 3.14: Global Market for Cardiac Monitoring and Diagnostic Devices (CM&D), 2010-2017	95
Figure 3.15: Global Market for Cardiac Pacemakers, 2010-2017	95
Figure 3.16: North American Pacemaker Market, 2010-2017	96
Figure 3.17: European Pacemaker Market, 2010-2017	97
Figure 3.18: Global Market for ICDs, 2010-2017	98
Figure 3.19: North American Market for ICDs, 2010-2017	98
Figure 3.20: European Market for ICDs, 2010-2017	99
Figure 3.21: Asia-Pacific Market for ICDs, 2010-2017	100
Figure 4.1: Percentage of Deaths from Cardiovascular Diseases in the U.S.	101
Figure 4.2: ICD Implants in the U.S., 2006-2009	107
Figure 4.3: Implanted ICD Types in the U.S., 2006-2009	108
Figure 4.4: First ICD/CRT-D Implantation by Indication in the U.S.	109
Figure 4.5: Distribution of ICD Implants by Type in the U.S.	110
Figure 4.6: Annual Volume of Pacemaker Procedures in 42 Hospitals in California	111
Figure 4.7: Average Implant Cost in 34 Californian Hospitals	112
Figure 4.8: Total Pacemaker Procedure Costs in 42 Californian Hospitals	113
Figure 4.9: Defibrillator Cost as a Percentage of Total Reimbursement for Medicare FFS Patients	114
Figure 4.10: Pacemaker Cost as a Percentage of Total Reimbursement for Commercial HMO and PPO Patients	115
Figure 4.11: Future Demand for Pacemaker Implants in the U.S. by Type of Device, 2010-2028	116
Figure 4.12: Comparison of ICD Implants between Latin America, the U.S. and Europe	127
Figure 4.13: All Pacemaker Implants in Europe, 2009	128
Figure 4.14: All CRT-D Implants in Europe, 2009	129
Figure 4.15: All ICD Implants in Europe, 2009	130
Figure 4.16: All ICD and CRT-D Implants in Europe, 2009	131
Figure 4.17: All CRT-P Implants in Europe, 2009	132
Figure 4.18: Comparison between U.S. and European Implant Rates	135
Figure 4.19: Comparison between CRT-D and CRT-P Implant Rates in the U.S. and Europe	136
Figure 4.20: Pacing Modes Used in Europe by Percentage	137
Figure 4.21: Number of ICDs Per Million Inhabitants in Select Countries of Europe, 2006-2008	139
Figure 4.22: Percentage of Single vs. Dual Chambered ICDs in Europe, 2008	140
Figure 4.23: New Implant Rates in U.K., 1999-2009	153
Figure 4.24: New ICD Implant Rates in U.K., 1999-2009	154
Figure 4.25: New CRT Implant Rates in U.K., 1999-2009	154
Figure 4.26: Total CRT Implant Rate in U.K., 1999-2009	155
Figure 4.27: Pacing as Percentage of Total New Implants in England and Wales, 2009	156
Figure 4.28: Projected Pacemaker Sales in U.K., 2008-2016	157
Figure 4.29: Projected ICD Sales in U.K., 2008-2016	157
Figure 4.30: Projected CRT Implant Sales in U.K., 2008-2016	158
Figure 4.31: Top Ten CRM Device Implanting Hospitals in U.K., 2007 and 2008	159

Figure 4.32: ICD and CRT Activity in NW London for April to July 2010	160
Figure 4.33: New, Planned and Projected Activity for CRTP in 2010-2011	161
Figure 4.34: Actual New and Changed Device in 2010 and Projected Pacemaker Activity in 2011	162
Figure 4.35: Increasing Role of CRT in England, 2000-2009	163
Figure 4.36: High-Energy Implants for Primary Prevention in U.K., 2009	163
Figure 4.37: High-Energy Implants for Secondary Prevention in U.K., 2009	164
Figure 4.38: Increasing Role of CRT Devices (New) in U.K., 2009	165
Figure 4.39: CRT Type and Symptom Indication Percentage in U.K., 2009	165
Figure 4.40: Pacemaker New Implant Rate in Anglia Network, 2003-2009	166
Figure 4.41: ICD New Implant Rate in Anglia Network, 2003-2009	167
Figure 4.42: CRT Implant Rate in Anglia Network, 2003-2009	168
Figure 4.43: Pacemaker and ICD Implants in Switzerland, 1998-2008	169
Figure 4.44: ICD Implantations Reported to the Registry and Estimated by EUCOMED, 2003-2009	171
Figure 4.45: ICD Implantation per Million People Reported to the Registry and Estimated by EUCOMED, 2003-2009	172
Figure 4.46: Types of Heart Devices Reported for Total Implantations in Spain	173
Figure 4.47: Left Ventricular Ejection Fraction (LVEF) of Patients in the Spanish Registry	173
Figure 4.48: Clinical Arrhythmias Requiring ICD Implants in Spain	174
Figure 4.49: Clinical Presentations of Arrhythmias in Spanish Patients	175
Figure 4.50: CRM Device Implants by Type in Serbia, 2008 and 2009	176
Figure 4.51: Total Number of CRM Device Implants in Serbia, 2000-2009	177
Figure 4.52: New ICD Implants by Type in Israel	177
Figure 4.53: Number of ICD Implants in Israel from July 2010 to February 2011	178
Figure 4.54: ICD Implantations in Israel by Age and Ethnicity	179
Figure 4.55: New ICD Implants in Israel, 2010-2011	180
Figure 4.56: Number of New ICD Implants in Israel by Month, 2010-2011	181
Figure 4.57: ICD Implantation by Age and Gender in Israel, 2010-2011	181
Figure 4.58: ICD Implantation Percentage by Gender in Israel vs. the U.S.	182
Figure 4.59: New ICD and CRT-D Implantation by Indication in Israel	183
Figure 4.60: Distribution of Implantations by Type of Devices in Israel	183
Figure 4.61: Off-Label ICD Implants in Israel	184
Figure A1.1: The Cardiac Conducting System	237
Figure A1.2: A Typical Electrocardiogram (ECD)	238
Figure A1.3: Basic Pacemaker Functional Block Diagram	239
Figure A1.4: The First Artificial Pacemaker	240
Figure A1.5: Block Diagram of Hyman's Pacemaker	240
Figure A1.6: Schematic of First Implanted Pacemaker	241
Figure A1.7: Block Diagram of Demand Pacemaker	242
Figure A1.8: Schematic of the Pulse Generator of the First Demand Pacemaker	242
Figure A1.9: Schematic of Dual-Chamber Demand Pacemaker	244
Figure A1.10: Block Diagram of a Rate-Responsive Pacemaker	245
Figure A1.11: Block Diagram of a Typical Modern Pulse Generator	246

INDEX OF TABLES

Table 2.1: NASPE/BPEG (NBG) Codes	26
Table 2.2: Medication Effects of Sensing in a Pacemaker	36
Table 2.3: Programmable Features of a Single Chamber Pacemaker	39
Table 2.4: Comparison of Two Models of Cardiac Pacemakers from Biotronik	61
Table 2.5: Comparison of Two Models of Pacemakers from Boston Scientific	62
Table 2.6: Comparison of Two Models of Pacemakers from Medtronic	63
Table 2.7: NBD Codes for ICDs	64
Table 2.8: Product Comparison Chart for External Defibrillators from Burdick	76
Table 2.9: Product Comparison Chart for External Defibrillators from Cardiac Science	77
Table 2.10: Product Comparison Chart for External Defibrillators from Medtronic	79

Table 4.1: Cardiovascular Medical Procedures in the U.S., 2009	102	
Table 4.2: Estimated Direct Cost of Cardiovascular Disease and Stroke in the U.S., 2009		102
Table 4.3: U.S. Cardiovascular Devices Market, 2008-2012	103	
Table 4.4: National ICD Registry (2006-2009): Medical History and Baseline Tests		105
Table 4.5: Demographics and ICD Indications in the U.S.	105	
Table 4.6: Physician Training and ICD Implant Volume in the U.S.	106	
Table 4.7: ICD Types and Adverse Events in the U.S., 2006-2009	107	
Table 4.8: Characteristics of Patients with ICD Implants in the U.S. and Canadian Registries		110
Table 4.9: Comprehensive Calculator for CRT-D	119	
Table 4.10: Comprehensive Calculator for Single Channel ICD	120	
Table 4.11: Comprehensive Calculator for Pacemaker	120	
Table 4.12: Physician Procedure Codes	122	
Table 4.13: ICD-9-CM Procedure Codes	123	
Table 4.14: ICD-9-CM Code for an Electrophysiology Study and Non-Invasive Programmed Stimulation		123
Table 4.15: Hospital Outpatient Procedure Codes	123	
Table 4.16: C-Codes for ICD Implants	124	
Table 4.17: ICD-9-CM Diagnosis Codes	125	
Table 4.18: Heart Failure Diagnosis Codes and Medicare's Classification		125
Table 4.19: Codes for Myocardial Infarction	126	
Table 4.20: Inpatient Hospital Medicare Payment for ICD Therapy	127	
Table 4.21: ICD Implants in Latin America by Country, 2006 and 2007		128
Table 4.22: Implanted CRM Devices in Europe by Type and Country	133	
Table 4.23: Demographic, Economic and Insurance Data for Europe	137	
Table 4.24: Number of ICD Implanting Centers in Europe	141	
Table 4.25: Status of Cardiac Electrophysiology in ESC Member Countries, 2008 and 2009		143
Table 2.26: Current Activity Rate Compared to National Target and National Average	160	
Table 4.27: Survival after High-Energy Implants in U.K., 2009	166	
Table 4.28: Pacemaker and ICD Implant Rate in Anglia Network, 2006-2009	167	
Table 4.29: New CRT and Total CRT Implant Rate in Anglia Network, 2006-2009	168	
Table 4.30: Number of CRM Device Implantations in Switzerland and Neighboring Countries, 2007		170
Table 5.1: Medtronic's Ablation Products for Arrhythmia	201	
Table 5.2: Medtronic's Cardiac CryoAblation System	202	
Table 5.3: Medtronic's Surgical Ablation Products	203	
Table 5.4: Medtronic's Pacemakers	207	

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 1950s, 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 70% of all new pacemaker implants are for treating atrioventricular (AV) block, and about 10% 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 100 ml to the current ICD which has a volume of less than 50 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 █% 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 1940s, and the initially developed pacemakers augmented their functionality and acceptance throughout the 1950s and 1960s. The implantable cardioverter-defibrillator (ICD) made its appearance for implantations in humans in 1980. 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 2050, over two billion people will be above the age of 65 and over two million will be more than 85 years old according to the World Health Report. The average age of a CRM device recipient is 75 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 \$1,200 per person per year on healthcare. The Office of the Actuary estimates that U.S. healthcare expenditure is nearly 17% of the gross domestic product (GDP) and it is anticipated to continue its upward trend to reach 20% of the GDP by 2050. 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 \$1,000 per person and as part of its stimulus package; it will spend \$150 billion in healthcare upgrades in the next three years. Taiwan's national healthcare expenditure increased to 6% of the GDP in 2009. Indian government took steps in 2009 to increase public spending on healthcare from 1% to 2% 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 discretely, 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 \$1.5 billion and predicts this to grow with a CAGR of 10% and reach \$2.5 billion in 2015.

Acute and persistent arrhythmias affect over eight million people in the U.S., accounting for over 10% of all medical conditions treated by cardiology specialists. Moreover, each year cardiac rhythm disorders cause the death of about 100,000 U.S. citizens and lead to about 1 million hospitalizations, resulting in an estimated \$10 billion 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].