NUCLEAR CARDIOLOGY MARKETS
(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers
TABLE OF CONTENTS

1. Overview 14
1.2 Scope 15
1.3 Methodology 15
1.4 Executive Summary 17

2. Overview of Cardiovascular Diseases (CVD) 19
2.1 Heart Diseases in Men 20
2.2 Heart Diseases in Women 21
2.3 Prevalence of Cardiovascular Diseases in the U.S. 22
2.3.1 Prevalence of CVD in Ethnic Groups: U.S. 23
2.3.2 Global CVD Mortality 24
2.3.3 Economic Cost of CVD in the U.S. 26
2.3.4 CVD Mortality in Europe 26
2.4 CVD Mortality in China 28
2.5 CVD Prevalence and Mortality in India 28
2.6 Aneurysm 29
2.6.1 Detection of Aneurysm 29
2.7 Angina 31
2.7.1 Prevalence of Angina 32
2.8 Atherosclerosis 32
2.8.1 Imaging of Atherosclerosis 33
2.9 Cerebrovascular Accident (Stroke) 33
2.9.1 Embolic Stroke 34
2.9.2 Cerebral Hemorrhage 34
2.9.3 Subarachnoid Hemorrhage 34
2.9.4 Imaging Devices Used for Detecting Stroke 34
2.10 Congestive Heart Failure 35
2.10.1 Imaging Modalities Used for the Detection of Congestive Heart Failure 35
2.11 Coronary Artery Disease (CAD) 35
2.11.1 Imaging of CAD 36
2.12 Nuclear Imaging for Heart Diseases 37
2.12.1 Technological Advances in Nuclear Cardiology 37
2.12.1.1 Development of New Pharmacologic Stress Agents and Protocols 37
2.12.1.2 Development of New Tracers 38
2.12.1.3 New Computer Algorithms and Tools 39
2.12.1.3 New Gamma Camera Technology 39
2.12.1.4 Hybrid Systems and Image Fusion 39
2.13 Trends in Cardiac Imaging 40

3. Popular Modalities Used in Nuclear Cardiology 42
3.1 SPECT/CT 42
3.1.1 General Architecture of SPECT/CT 43
3.1.2 Myocardial Perfusion Imaging: CT Based Attenuation Correction 44
3.1.4 SPECT/CT for Cardiac Disease Detection: An Economic Conundrum 45
3.1.4.1 SPECT/CT from the Physician’s Point of View 45
3.1.4.2 Cost Effectiveness vs. Cost and Reimbursement 45
3.1.4.3 Factors to Drive Sales and Utilization of SPECT/CT 46
3.1.4.4 Newer SPECT Cameras 46
3.1.4.5 New Ultrafast Camera Designs 47
3.1.4.6 Basic Design of a Gamma Camera 47
3.2 Positron Emission Tomography (PET) 48
3.2.1 Basic Design of a PET System 49
3.2.2 Application of PET in Cardiology 50
3.2.3 PET and Heart Disease Diagnosis 50
3.2.4 PET and Heart Disease Staging 51
3.2.5 Reimbursement Cuts for Cardiac PET in 2011 52
3.2.6 Growth of PET in Cardiology 53
3.2.6.1 PET/CT Hybridization 54
3.2.6.2 Cost Considerations in PET Scanners 54
3.2.7 PET/CT in Cardiology 55
3.2.7.1 Positron Emitting Tracers 56
3.3.1 The Resting Electrocardiogram (ECG) 57
3.3.2 The Exercise Stress Test (Treadmill Stress Test, TMT) 57
3.3.3 Echocardiography 57
3.3.4 Magnetic Resonance Imaging (MRI) 59
3.3.5 Multi-slice Computed Tomography (MSCT) 60
3.3.6 Contrast Coronary Angiography (CA) and Intravascular Ultrasound (IVUS) 60

4. Nuclear Medicine 61
4.1 Diagnostic Radiopharmaceuticals 61
4.2 Suppliers of Radioisotopes 62
4.3 Isotopes Used in Medicine 62
4.4 Cyclotron Radioisotopes 63
4.5 Radiopharmaceuticals in PET Imaging 64
4.6 Radiopharmaceuticals for Clinical Cardiac PET Imaging 64
4.6.1 Nitrogen-13 Ammonia 64
4.6.2 Rubidium-82 65
4.6.3 Oxygen-15 Water 65
4.6.4 Fluorine-18 Fluorodeoxyglucose 65
4.7 Generator Produced PET Radiopharmaceuticals 65
4.8 Radiopharmaceuticals in SPECT 66

5. Picture Archiving and Communication Systems (PACS) in Cardiology 67
5.1 Trends in Cardiology PACS 67
5.1.1 Remote Reading of PACS 67
5.1.2 Double-Digit Growth in CardioPACS 67

6. Advances in Nuclear Cardiology 68
6.1 Myocardial Function 68
6.2 Myocardial Perfusion 68
6.3 Gated Myocardial Perfusion SPECT 68
6.4 Advances in Software for Gated SPECT 69
6.5 Gated Myocardial Perfusion SPECT in the Era of Multi-Detector CT 69
6.6 PET and Imaging of Myocardial Metabolism 69
6.7 Imaging Myocardial Innervation 70
6.8 Radionuclide Imaging of Atherosclerotic Lesions 70
6.9 Stem Cell Imaging 70
6.10 Gene Therapy 70

7. Current Status of Nuclear Cardiology 71
7.1 Current Status of Nuclear Cardiology in Asia 71
7.2 Current Status of Nuclear Cardiology in Europe 71
7.2.1 European Cardiovascular Disease Statistics 72
7.3 Current Status of Nuclear Cardiology in Latin America 73
7.4 Current Status of Nuclear Cardiology in North America 74

8. Nuclear Cardiology: Market Analysis 75
8.1 Global Utilization of Nuclear Cardiology 76
8.1.1 Future of Global Nuclear Cardiology Utilization 76
8.1.2 Utilization of Nuclear Cardiology Procedures in Developed Countries 77
8.1.3 Utilization of Nuclear Cardiology Procedures in Latin America 78
8.1.4 Utilization of Nuclear Cardiology Procedures in Asia/Oceania 79
8.1.5 Utilization of Nuclear Cardiology in Africa 80
8.2 Utilization of Nuclear Cardiology vs. Mortality Rate 81
8.3 Cost Effectiveness in Nuclear Cardiology 81
8.4 Epidemiology of Cardiovascular Diseases in Developing Countries 81
8.5 Global Opportunities for Nuclear Cardiology Products 81
8.6 Global Market for SPECT/PET 82
8.7 SPECT/PET Technology 82
8.8 Competition in Nuclear Cardiology Market 84
8.9 Global Market for SPECT 84
8.10 Product Comparisons of Gamma Cameras 85
8.10.1 Mobile Gamma Cameras 85
8.10.2 SPECT Cameras 85
8.10.3 Purchase Considerations for SPECT Cameras 86
8.10.4 Cost Containment 86
8.11 Need for Dedicated PET Devices for Cardiac Imaging 88
8.12 Market for PET Imaging Systems 88
8.12.1 Growth Rate for PET Cameras 89
8.12.2 The Decline of SPECT 90
8.12.3 PET-Only vs. PET/CT 91
8.12.4 The Different Paths of SPECT/CT and PET/CT 92
8.13 U.S. Market for PET 93
8.14 PET Market in Europe 93
8.14.1 European Market for Nuclear Imaging Equipment 95
8.14.2 Nuclear Imaging Market Leaders in Europe 95
8.14.3 European Market for PET/CT 96
8.14.4 European Market for SPECT/CT 97
8.14.5 Nuclear Imaging System Market in Germany 97
8.14.6 Nuclear Imaging System Market in France 98
8.14.7 Nuclear Imaging System Market in the U.K. 98
8.14.8 Nuclear Imaging System Market in Italy 99
8.15 PET Services in Europe 99
8.15.1 PET Services in England 99
8.16 SPECT vs. PET in Nuclear Cardiology 102
8.16.1 Future of SPECT and PET 102
8.17 Hybrid Economics 103
8.17.1 Hybrid Optimization 104
8.17.2 Image Quality 104
8.17.3 Rapid Growth of Radio Tracers 104
8.18 U.S. Market for SPECT and PET Radiopharmaceuticals 104
8.19 U.S. Reimbursement for Nuclear Cardiology Procedures 105
8.20 FDG Utilization in Europe 106
8.21 Future of Radiopharmaceutical Tracers 107
8.22 Global Market for Mo-99/Tc-99m 108
8.22.1 Global Demand for Mo-99 by Geography 109
8.23 Impact of Technetium Shortage on Cardiology Procedures 109
8.23.1 Global Impact 110
8.23.2 Popular Uses of Technetium-99M 113
8.24 FDA-Approved Radiopharmaceuticals 114
8.25 Cardiology Picture Archiving and Communication Systems (Cardiology PACS) 117
8.25.1 Growth of Cardiology PACS 117
8.25.2 Global Market for Cardiology PACS 118
8.25.3 U.S. Market for Cardiology PACS 119
8.26 General Medical Picture Archiving and Communication Systems (PACS) 121
8.26.1 PACS Adoption 121
8.26.2 Global Market for PACS 121
8.27 PACS Installations in U.S. Hospitals 123
8.27.1 PACS Modality Installations 125
8.27.2 PACS Vendor Market Share 126
8.27.3 PACS Image Distribution 127
8.28 European Market for PACS 129
8.29 PACS in India 130
8.29.1 Market Insight 130
8.30 Healthcare IT 132
8.30.1 Hospital Information System (HIS) 133
8.30.2 Electronic Medical Records (EMR) 133
8.30.3 U.S. HIS Market 134
8.30.4 U.S. Healthcare IT Industry 135

9. Company Profiles 136
9.1 3mensio Medical Imaging BV 136
9.1.1 3mensio Vascular 136
9.1.3 3mensio SDK 136
9.1.4 3mensio Valves 136
9.2 AccuSync Medical Research Corporation 136
9.2.1 AccuSync 42 136
9.2.2 SpectroAnalyser 137
9.3 Astellas Pharma US, Inc. 137
9.3.1 Adenoscan (Adenosine) 137
9.3.2 Lexiscan 138
9.4 Bracco Diagnostics, Inc. 138
9.4.1 CardioGen-82 138
9.5 Capintec, Inc. 138
9.5.1 CapIMAGE SFOV Gamma Camera 139
9.6 Cardinal Health, Inc. 139
9.6.1 Cardinal’s Cardiology Solutions 139
9.6.1.1 LABStart 139
9.6.1.2 LABComplete 140
9.6.1.3 LABManage 141
9.6.1.4 CardioWriter 142
9.6.1.5 Covidien, PLC 142
9.7 Covidien’s Nuclear Medicine Products 142
9.7.1 Duosafe 142
9.7.1.2 Indium In 111 Chloride Sterile Solution 143
9.7.1.3 Octreoscan 143
9.7.1.4 Sodium Iodide I 131 Capsules 143
9.7.1.5 Technescan HDP 144
9.7.1.6 Thallous Chloride TI 201 144
9.7.1.7 The Ultra-Technekow Dry-Top Eluting (DTE) 144
9.7.1.8 Gallium Citrate Ga 67 Injection 145
9.7.1.9 Tc 99m Sestamibi 145
9.7.1.10 Sodium iodide I-123 145
9.7.1.11 Technescan MAG3 146
9.7.1.12 Technescan PYP 146
9.7.1.13 Ultratag RBC 146
9.7.1.14 Digirad Corporation 147
9.8 FluoroPharma, Inc. 148
9.8.1 CardioPET 148
9.8.2 Digirad Corporation 147
9.8.3 Cardio x.act 148
9.9 FluoroPharma, Inc. 148
9.9.1 FluoroPharma’s Technology 148
9.9.1.1 CardioPET 148
9.9.1.2 BFPET 149
9.9.1.3 VasopET 149
9.10 Fujifilm Medical Systems USA, Inc. 149
9.10.1 Fujifilm’s Cardiology Products 149
9.10.1.1 Synapse Cardiovascular 149
9.10.1.2 Corridor4DM 150
9.11 GE Healthcare 150
9.11.1 CardIQ Function Xpress 150
9.11.2 CardIQ Fusion 150
9.11.3 ReportCard 4 151
9.11.4 CardIQ Physio 151
9.11.5 Innova EPVision 151
9.11.6 SmartScore 4.0 152
9.11.7 Dynamic VUE 152
9.11.8 Flow Analysis 4 152
9.11.9 Left Ventricle Analysis 153
9.11.10 StarMap 4 153
9.11.11 Stenosis Analysis 153
9.11.12 BrightSpeed Elite 16 slice 154
9.11.13 BrightSpeed Edge Select 8 Slices 154
9.11.14 HiSpeed CT/e (Single Slice) 154
9.11.15 LightSpeed Xtra 155
9.11.17 Ambulatory ECG-Holter 155
9.11.18 MAC Resting ECG 156
9.11.19 Discovery MR750 156
9.11.20 Discovery MR450 156
9.12 GVI Medical Devices 161
9.12.1 ClearVision 161
9.12.2 mSPECT 161
9.12.3 OnePass 162
9.13 Hermes Medical Solutions, Inc. 162
9.13.1 Hermes’ Cardiology Products 163
9.13.1.1 QBS - Blood Pool Gated SPECT Analysis 163
9.13.1.2 Hermes Hybrid Recon 163
9.13.1.3 FBP - Filtered Backprojection SPECT Reconstruction 164
9.13.1.4 FUGA - Gated Heart Analysis 164
9.13.1.5 HOSEM - Iterative Reconstruction 165
9.13.1.6 PERFIT - Cardiac Perfusion Analysis 165
9.13.1.7 QGS - Gated SPECT Ejection Fraction Analysis 166
9.13.1.8 QPS - Quantitative Perfusion SPECT 166
9.13.1.9 Quick Cardiac 166
9.13.1.10 Static Study Display 167
9.13.1.11 Volume Display 167
9.14 Lantheus Medical Imaging, Inc. 167
9.14.1 Ablavar 167
9.14.2 Definity (Perflutren Lipid Microsphere) 168
9.14.3 Cardiolite 168
9.14.4 Vialmix 168
9.15 Medisco Imaging 168
9.15.1 Spirit DH-V 168
9.15.2 Cardio-C 169
9.15.3 CardioSPECT D90 169
9.15.4 Nucline AP 169
9.15.5 X-Ring/R 170
9.15.6 X-Ring/4R 170
9.15.7 Nucline TH 171
9.16 MIM Software, Inc. 171
9.16.1 MIMfusion 171
9.16.2 MIMcardiac 172
9.16.3 MIMviewer 172
9.16.4 MIM Storage Server 173
9.17 Neusoft Medical Systems Co., Ltd. 173
9.17.1 Truesight PET 173
9.17.2 BeyondImage Workstation 174
9.17.3 CardioCARE 174
9.17.4 PETCare 175
9.18 Numa, Inc. 175
9.18.1 Numalink 175
9.18.2 Numalist 176
9.18.3 Numalist Plus 176
9.18.5 Numaread 177
9.18.6 Numaserver 177
9.18.7 Numamanage 178
9.18.8 Numa’s Core Lab System 178
9.19 Thinking Systems Corporation 179
9.19.1 MDStation 179
9.19.2 MDStation for PET and PET/CT 179
9.20 UltraSPECT, Ltd. 180
9.20.1 Xpress.Cardiac 180
9.20.1 Xpress3.Cardiac 180
9.21 Merge Healthcare, Inc. 180
9.21.1 Merge ECM 181
9.21.2 Fusion PACS Archive 181
9.21.3 Merge Cardio 181
9.21.4 Merge Hemo 181
9.21.5 AMICAS PACS 181
9.21.6 Fusion Workstation 182
9.21.2 Fusion PACS GL 182
9.22 Pharmalucence, Inc. 182
9.22.1 Sestamibi 182
9.22.2 Mbrofenin 182
9.22.3 Pyrophosphate Injection 182
9.22.4 Pentetate Injection 183
9.22.3 Hepatolite 183
9.22.4 Medronate 183
9.22.5 Sulfur Colloid 183
9.23 Philips Healthcare 184
9.24 Positron Corporation 186
9.24.1 Attrius 187
9.24.2 Cardio-Assist 187
9.24.3 Radiopharmaceuticals 187
9.24.4 Tech-Assist 188
9.25 Segami Corporation 188
9.25.1 Segami’s Workstations 188
9.25.1.1 Oasis 188
9.25.1.2 Mirage 188
9.25.1.3 Acquisition 188
9.25.2 Segami’s Viewing Stations 189
9.25.2.1 DGSCOPE 189
9.25.2.2 VebVue 189
9.26 Siemens Healthcare 189
9.26.1 Siemens’ Cardiology Products 190
9.26.1.1 Artis zeego 190
9.26.1.2 AXIOM Artis U 190
9.26.1.3 Artis zee 190
9.26.2 Siemens’ Molecular Imaging Products 191
9.26.2.1 Biograph TruePoint PET/CT 191
APPENDIX

Appendix 1: ASNC Imaging Guidelines for Nuclear Cardiology Procedures 200
Appendix 1.1: PET and PET/CT Instrumentation 200
Appendix 1.2: PET Imaging-Crystal Types 200
Appendix 1.3: PET TOF Imaging 200
Appendix 1.4: PET/CT Imaging 200
Appendix 1.5: PET Imaging-Attenuation Correction 201
Appendix 1.6: PET QC Procedures 201
Appendix 1.7: CT QC Procedures 201
Appendix 1.8: Combined PET/CT QC Procedures 202
Appendix 1.9: Attenuation Correction 202
Appendix 1.10: Rb-82 Perfusion Imaging 203
Appendix 1.11: N-13 Ammonia Perfusion Imaging 204
Appendix 1.12: F-18 FDG Metabolism Imaging 204
Appendix 2: Supply of Radioisotopes for Medical Use 207
Appendix 2.1: Nuclear Medicine 207
Appendix 2.2: In Vivo Nuclear Medicine Procedures in Numbers 207
Appendix 2.3: Current In Vivo Nuclear Medicine Diagnostic Procedures 208
Appendix 2.4: Conventional Diagnostic Nuclear Medicine (Gamma/SPECT Imaging) 208
Appendix 2.4.1: Technetium-99M (Tc-99M) 209
Appendix 2.5: Recently Developed Diagnostic Methods: Positron Emission Tomography (PET) 209
Appendix 2.6: Impact of Radioisotope Shortages in Different Countries 209
Appendix 2.7: Current Supply Situation 210
Appendix 2.8: Research Reactors Producing Molybdenum-99 210
INDEX OF FIGURES

Figure 2.1: Cardiovascular Disease: The Single Largest Cause of Mortality in Adults 19
Figure 2.2: Prevalence of CVD in Four of the Ethnic Groups in the U.S. 20
Figure 2.3: Prevalence of Cardiovascular Diseases in Adults Age 20 and Older by Age and Sex 23
Figure 2.4: CVD Deaths vs. Cancer Deaths in the U.S. 25
Figure 2.5: Percentage Breakdown of Deaths from Cardiovascular Diseases 25
Figure 2.6: Costs of Major Cardiovascular Diseases in the U.S., 2010 26
Figure 2.7: Leading Causes of Death of European Men 27
Figure 2.8: Leading Causes of Death of European Women 27
Figure 2.9: Age-Adjusted Mortality Rates for Aortic Aneurysm per 100,000 30
Figure 2.10: Prevalence of Aneurysm by Age and Smoking History 31
Figure 2.11: Age-Adjusted Prevalence of Angina in Men and Women Aged 20 and Over in the U.S. 32
Figure 3.1: Cardiac PET HOPPS Payments in the U.S., 2008-2011 52
Figure 3.2: Sensitivity of MPS and Echocardiography Using Different Types of Stress 58
Figure 3.3: Specificity of MPS and Echocardiography Using Different Types of Stress 59
Figure 7.1: Increasing Number of Heart Failures in Europe, 2010-2020 72
Figure 7.2: CVD in Middle Income Countries 73
Figure 7.3: CVD in Developed Countries 74
Figure 8.1: Nuclear Cardiology Procedures per 100,000 of Population per Year for Developing vs. Developed Countries 76
Figure 8.2: Future of Nuclear Cardiology in 2014 77
Figure 8.3: Approximate Use of Cardiac Diagnostic Testing, U.S. 77
Figure 8.4: Utilization of Nuclear Cardiology in Developed Countries 78
Figure 8.5: Utilization of Nuclear Cardiology in Latin America 79
Figure 8.6: Utilization of Nuclear Cardiology in Asia/Oceania 80
Figure 8.7: Utilization of Nuclear Cardiology in Africa 80
Figure 8.8: Global Market for PET/SPECT, 2010-2016 82
Figure 8.9: Overall Global Installed Bases of PET/SPECT Systems, 2010-2016 83
Figure 8.10: Global SPECT Market, 2010-2017 84
Figure 8.11: Global Market for PET Scanners, 2010-2017 89
Figure 8.12: Projected Market Share of PET and SPECT in 2020 90
Figure 8.13: Growth Rate for PET and SPECT, 2011-2020 91
Figure 8.14: Number of Cameras: SPECT Switching to PET, 2011-2020 91
Figure 8.15: Estimated Cameras Installed Base in Nuclear Cardiology, 2011-2020 92
Figure 8.16: U.S. Market for PET, 2009-2017 93
Figure 8.17: Location of PET Centers in Europe, 2010 94
Figure 8.18: Growth of Cyclotron Units in Europe, 2000-2010 94
Figure 8.19: European Market for Nuclear Imaging Equipment, 2010-2016 95
Figure 8.20: European Nuclear Imaging Market Share by Company, 2010 96
Figure 8.21: European Nuclear Imaging System Market for PET/CT, 2010-2017 96
Figure 8.22: European Market for SPECT/CT, 2010-2017 97
Figure 8.23: Nuclear Imaging Market in Germany, 2010-2017 97
Figure 8.24: Nuclear Imaging System Market in France, 2010-2017 98
Figure 8.25: Nuclear Imaging System Market in the U.K. 98
Figure 8.26: Nuclear Imaging System Market in Italy, 2010-20017 99
Figure 8.27: PET Studies per Million Populations in Europe 101
Figure 8.28: U.S. Market for SPECT and PET Radiopharmaceuticals, 2009-2017 105
Figure 8.29: Global Demand Trend for Mo-99/Tc-99m 108
Figure 8.30: Global Market for Mo-99 by Geography/Country, 2009 109
Figure 8.31: Composition of Nuclear Medical Procedures Where Technetium-99Mo Is Predominant 111
Figure 8.32: Approximate Global Demand for Molybdenum-99/Technetium-99 112
Figure 8.33: Cardiology PACS Market Share by Company, 2010 118
Figure 8.34: Global Cardiology PACS Market, 2010-2016 119
Figure 8.35: U.S. Cardiology PACS Market Share % by Vendors, 2010 120
Figure 8.36: Global Market for PACS, 2010-2016 123
Figure 8.37: Number of U.S. Hospitals with PACS Installed 123
Figure 8.38: Total Number of U.S. Hospitals vs. Hospitals with PACS Installed 124
Figure 8.39: PACS Replacement and New Purchases 125
Figure 8.40: PACS Modality Installations 125
Figure 8.41: PACS Vendor Market Share 126
Figure 8.42: PACS Image Distribution in Hospital Departments 127
Figure 8.43: PACS Images Accessibility by Physicians 128
Figure 8.44: RIS and PACS Interface 129
Figure 8.45: European PACS Market, 2010-2016 129
Figure 8.46: RIS/PACS Market in India 131
Figure 8.47: Total PACS Market in India 131
Figure 8.48: Leading Healthcare IT Solution: Global Vendors 132
Figure 8.49: Global Market for Hospital Information System, 2009-2016 133
Figure 8.50: Global Market for EMR, 2009-2016 134
Figure 8.51: U.S. Market for Hospital Information System (HIS), 2009-2016 134
Figure 8.52: North American Hospital IT Market ($2.7 Billion), 2010 135
Figure App. 2.1: Number of In Vivo Procedures Performed Globally 208
Figure App. 2.2: Impact of Supply Shortage in 34 European Countries, 2008 209
Figure App. 2.3: Estimation of the Relative Use of Modalities in 2008, 2015 and 2025 212
Figure App. 2.4: Estimation of the Use of Imaging Modalities in 2008, 2015 and 2025 213
Figure App. 2.5: Break-down of the Shares of SPECT Modalities 213
Figure App. 5.1: Schematic of Smart Scanner 222
Figure App. 5.2: CT Image, PET Image and Fused Image 222
Figure App. 5.3: Collision of a Positron and Electron and the Two Resultant Gamma Rays 223
Figure App. 5.4: Discharge of Two Gamma Rays at 180° 223
Figure App. 5.5: Coincidence Detection 224
Figure App. 5.6: A Sinogram with Coincidence Lines 225
Figure App. 9.1: Global Number of Nuclear Medicine Procedures Using 99mTc/99Mo, 1990-2020 250
Figure App. 9.2: Weekly Quantities of 99Mo Delivered to End-Users Worldwide, 1990-2020 250
Figure App. 9.3: Quantity of 99Mo Delivered to End-Users by Geography, 2007 251
Figure App. 9.4: Regional Shares of Reactor Production of 99Mo, 2007 251
Figure App. 9.5: Regional Shares of Reactor Production & Requirements of 99Mo, 2007 252
Figure App. 9.6: Regional shares of reactor production & requirements of 99Mo, 2008 253

INDEX OF TABLES
Table 2.1: Males and Cardiovascular Diseases in the U.S. 21
Table 2.2: Females and Cardiovascular Diseases in the U.S. 22
Table 2.3: Ethnic Groups and Cardiovascular Diseases in the U.S. 24
Table 2.4: Forecasting the Prevalence Rate (%) of Coronary Heart Disease (CHD) in India, 2000-2015 28
Table 2.5: Forecasting of Cases of Stroke in India 29
Table 3.1: Characteristics of SPECT vs. PET 55
Table 3.2: Characteristics of Positron Emitting Tracers Used in PET Perfusion Imaging 56
Table 8.1: PET scanning Facilities in England 100
Table 8.2: PET scanning Facilities in Europe 101
Table 8.3: Medicare Physician Fee Schedule for Nuclear Cardiology Procedures 105
Table 8.4: Reimbursement for Cardiac CT Procedures 106
Table 8.5: Reimbursement for Stress Tests 106
Table 8.6: Radiopharmaceuticals in Clinical Use in European Countries 107
Table 8.7: Useful Radionuclides for Molecular Imaging 107
Table 8.8: Worldwide Production Capacity of 99Mo, 2009 110
Table 8.9: Small-Scale Producers of 99Mo, 2010 110
Table 8.10: Nuclear Medicine Procedures that Use 99mTc 113
Table 8.11: FDA-Approved Radiopharmaceuticals as of August 3, 2010 114
Table 9.1: The Complete List of Medical Imaging Products from GE Healthcare 157
Table 9.2: Philips’ Computed Tomography Systems 184
Table 9.3: Philips’ Nuclear Medicine Products 185
Table 9.4: Philips' Radiography Systems 185
Table 9.5: Philips' Radiography/Fluoroscopy Products 186
Table 9.6: Philips’ Magnetic Resonance Imaging Products 186
Table App. 1.1: Suggested QC procedures for Dedicated PET Imaging Devices 201
Table App. 1.2: CT QC Procedures 201
Table App. 1.3: Schedule of CT QC for PET/CT Units 202
Table App. 1.4: Schedule of CT QC for PET/CT units 202
Table App. 1.5: General Guidelines for CT-Based Transmission Imaging 202
Table App. 1.6: Rb-82 Rest/Stress Myocardial Perfusion Imaging Guideline for BGO PET Imaging Systems 203
Table App. 1.7: Rb-82 Rest/Stress Myocardial Perfusion Imaging Guideline for GSO PET Imaging Systems 203
Table App. 1.8: N-13 Ammonia Cardiac Perfusion Studies 204
Table App. 1.9: FDG cardiac PET: Patient Preparation Guidelines: An Overview 205
Table App. 1.10: Guidelines for Blood Glucose Maintenance 205
Table App. 1.11: FDG Cardiac PET: Acquisition Guidelines for Dedicated, Multicrystal PET Scanner 205
Table App. 1.12: Semiquantitative Scoring System of Defect Severity and Extent 206
Table App. 2.1: Research Reactors Producing Radioisotopes 210
Table App. 3.1: Global Reactor Landscape 214
Table App. 3.2: Global Share of Nuclear Medicine by Reactor, 2009 215
Table App. 4.1: New CPT Codes and Global Payments for SPECT MPI Procedures, 2010 217
Table App. 4.2: CPT Code Changes and Payments for SPECT MPI Hospital-Based Procedures, 2010 218
Table App. 9.1: Radionuclides for Which Supply Is Believed to be in Jeopardy in 2010-2020 249
1. Overview

An estimated 16.7 million (29.2%) of annual global deaths are due to various forms of cardiovascular disease (CVD). Of this huge mortality incidence, ischemic heart disease and deaths are caused by ischemic heart disease and hypertension and other cardiac conditions. A minimum of people survive heart attacks and strokes every year, and a significant number of them undergo costly clinical and long-term care. As such, nuclear cardiology diagnostics has emerged as a leading non-invasive technique to evaluate myocardial blood flow, assess the pumping function of the heart, as well as visualize the size and location of a heart attack. Among the different techniques of nuclear cardiology, myocardial perfusion imaging is the most frequently used.

Despite the enhanced image quality and increasing utilization rates of competing devices such as computed tomography (CT), magnetic resonance imaging (MRI) and diagnostic procedures such as CT angiography, single-photon emission computed tomography (SPECT) procedures performed with gamma cameras will continue to be used for a significant number of cardiac specific nuclear imaging procedures. The continued use of SPECT will be due to the lower purchase and maintenance costs, smaller physical footprint and easier service logistics of gamma cameras. In recent times, SPECT technologies are being combined with other imaging modalities, such as CT to design hybrid imaging modalities such as SPECT/CT. Hybrid imaging is preferred because it brings together the anatomical image benefits of CT and the functional information offered by SPECT into a single image, although hybrid systems are relatively more expensive than gamma cameras.

The nuclear cardiology market is heavily dependent upon the U.S. The region contributes the single largest share of the worldwide market, followed by Europe and Japan. China, India and Korea are also experiencing a high growth rate in nuclear medicine. The positron emission tomography (PET) scanners segment is likely to be the largest segment in the global nuclear medicine market. But, the gamma cameras segment is predicted to drive future growth. This TriMark Publications study 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.
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

The author of this report is an M.D. with many decades of experience in science writing and as a medical industry analyst. The editor is a retired college professor with three decades of experience in teaching biochemistry, biotechnology and pharmacology. He has four years of experience in writing healthcare reports. 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, important data sources include American Hospital Association (AHA), American College of Radiology (ACR), World Health Organization (WHO), American Society of Nuclear Cardiology (ASNC), European Council of Nuclear Cardiology, European Society of Cardiology (ESC), American College of Cardiology (ACC), American Heart Association (AHA), International Society for Heart Research (ISHR) and Medical Imaging & Technology Alliance (MITA). Where possible and practicable, the most recent data available have been used. Some of the statistical information was taken from Biotechnology Associates’ databases and from TriMark’s private data stores. The information in this study was obtained from sources that 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.

**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.
1.4 Executive Summary

Nuclear imaging for cardiac diseases helps in accurately diagnosing the disease and blood flow blockages. Gamma cameras and PET scanners are the key imaging devices used for cardiac procedures. Though nuclear imaging in cardiology faces competition from other methods, the impact is relatively limited. Demand for diagnostic medical imaging equipment is mainly driven by the number of diagnostic procedures. The application of PET’s clinical use, its combined use with other imaging equipment and the current shift to PET/CT imaging and SPECT/CT imaging are the important factors driving the dramatic rise in procedural volumes. Additionally, advancements in molecular imaging, evolution of image-guided interventions, as well as aging population continue to fuel growth in the broader medical diagnostics market. New gamma cameras that are available in the market are relatively much faster and provide better quality images than earlier models.

GE Healthcare has developed a new radiotracer called Iodine-123 (AndreView) and it can be used for imaging the sympathetic nervous system to help improve heart failure (HF) screenings. This product can provide a more accurate stratification of HF. Although PET imaging provides better image quality and faster scanning times than SPECT, it is not prevalently used in cardiac imaging, because PET is more expensive and the isotopes have relatively a fast decay rate. Yet, there has been a boost in PET sales in the recent years due to the periodic SPECT isotope shortages. PET procedures employ four or five different radiotracers and the most common and standard one used in cardiac imaging is rubidium 82 (CardioGen 82). The greatest drawback of rubidium is its cost and on an average a nuclear cardiology facility will have to spend about $30,000 to $40,000 per month.

Other reasons for the SPECT witnessing some decline in the recent years was due to some decline in the number of SPECT myocardial perfusion procedures as well as reduced pricing for Cardiolite and Myoview because of generic sestamibi. Future growth in SPECT is anticipated from specialized products for imaging myocardial infarction and neuronal imbalances in patients that require pacemakers or may be subject to congestive heart failure. Most of these products are in late stage development and will be launched in the near future.

TriMark estimates that the U.S. market for SPECT and PET radiopharmaceuticals was worth about $1.61 billion and anticipates this to grow and reach $4.76 billion in 2017. Total SPECT radiopharmaceutical sales were down 11.6% in 2009 primarily due to reductions in pricing of perfusion agents with the launching of generic sestamibi. SPECT procedure volume was also down due to the technetium shortage. The pressures are only temporary and eventually the market will become stable for SPECT radiopharmaceuticals. Revenue from PET radiopharmaceuticals was slightly down because of price weakness in the FDG market. However, future sales growth will be more in line with procedure growth. Of late, there has been some relief in the reimbursement for PET procedures, specifically in cardiology. Most vendors are investing in new PET agents in all segments, which indicate increased market once the new products are introduced. Sustained enhancements in imaging technology in both SPECT and PET are permitting higher resolution and shorter imaging times. Radiopharmaceutical doses are also getting minimized due to increased imaging efficiency.

SPECT imaging is an integral part of the standard work-up for almost all cardiac diseases. SPECT is being used to measure the state and extent of disease and are used frequently in most regions around the world. Myocardial Perfusion Imaging is regarded as the standard for symptomatic detection of coronary artery disease. Over procedures are performed annually in the U.S. According to our estimates, the global market for SPECT scanner was worth about $ in and is estimated to reach $ in Vendors of nuclear medicine equipment comprise: GE Healthcare, Philips Medical Systems Siemens Medical Solutions Ltd., Toshiba Medical Systems, Lantheus and Mallinckrodt Inc. GE Healthcare is the leader among these players in the SPECT market with its radiotracer Myoview (technetium Tc-99m tetrofosmin), which is quite efficient in the diagnosis and localization of regions of reversible myocardial ischemia in the presence or absence of infarction under both rest and stress. Myoview has a half-life of six hours and therefore it can be shipped as a unit dose as required via next-day delivery.