

CHAPTER ONE: INTRODUCTION.....	1
STUDY OBJECTIVES.....	1
REASONS FOR DOING THIS STUDY.....	1
INTENDED AUDIENCE.....	2
SCOPE OF THE STUDY.....	2
METHODOLOGY.....	2
INFORMATION SOURCES.....	2
ABOUT THE AUTHOR.....	3
RELATED BCC RESEARCH REPORTS.....	3
BCC ONLINE SERVICES.....	4
DISCLAIMER.....	4
 CHAPTER TWO: EXECUTIVE SUMMARY.....	 5
EXECUTIVE SUMMARY.....	5
<i>SUMMARY TABLE GLOBAL REVENUE OF FETAL MONITORING AND DIAGNOSIS, THROUGH 2016 (\$ MILLIONS)</i>	6
<i>SUMMARY FIGURE GLOBAL REVENUE OF FETAL MONITORING AND DIAGNOSIS, 2009-2016 (\$ MILLIONS)</i>	6
EXECUTIVE SUMMARY (CONTINUED).....	7
 CHAPTER THREE: OVERVIEW.....	 8
DEFINITIONS.....	8
TYPES OF FETAL MONITORING.....	9
EXTERNAL FETAL MONITORING.....	10
Need of External Fetal Monitoring.....	11
Advantages and Disadvantages of External Fetal Monitoring.....	12
<i>TABLE 1 ADVANTAGES AND DISADVANTAGES OF EXTERNAL FETAL MONITORING</i>	12
INTERNAL FETAL MONITORING.....	12
Advantages and Disadvantages of Internal Fetal Monitoring.....	13
<i>TABLE 2 ADVANTAGES AND DISADVANTAGES OF INTERNAL FETAL MONITORING</i>	13
<i>TABLE 3 EXTERNAL FETAL MONITORING VERSUS INTERNAL FETAL MONITORING</i>	13
TYPES OF FETAL MONITORS.....	14
FETOSCOPE.....	14
DOPPLER.....	14
ELECTRONIC FETAL MONITOR.....	14
Denigration of the Routine Use of Electronic Fetal Monitoring.....	14
TELEMETRY.....	15
INTERNAL FETAL MONITOR.....	15

PRENATAL DIAGNOSIS.....	15
NEED OF PRENATAL DIAGNOSIS	16
PREREQUISITES OF PRENATAL DIAGNOSIS	16
ADVANTAGES OF PRENATAL DIAGNOSIS.....	16
TECHNIQUES FOR PRENATAL DIAGNOSIS	17
Noninvasive Prenatal Diagnosis Techniques	17
Fetal Cells in Maternal Blood	17
Preimplantation Genetic Diagnosis	17
Ultrasonography	17
Magnetic Resonance Imaging Test	18
Ultrasound Versus MRI in Fetal Diagnosis	18
<i>TABLE 4 ULTRASOUND VERSUS MRI.....</i>	<i>19</i>
Non-Stress Test.....	19
Florescence <i>In Situ</i> Hybridization	20
New Noninvasive Nucleic Acid Technologies	20
Cell-Free DNA Technologies	20
Transrenal DNA Technology	21
Less-Invasive Prenatal Diagnosis Techniques.....	21
Maternal Serum Screening	21
Transcervical Retrieval of Trophoblast Cells	22
Detection of Fetal Blood Cells in Maternal Blood	23
More-Invasive Prenatal Diagnosis Techniques.....	24
Amniocentesis	24
Chorionic Villus Sampling.....	24
Percutaneous Umbilical Blood Sampling.....	25
Skin and Organ Biopsy.....	25
CHAPTER FOUR: REGULATORY ASPECTS	26
REGULATORY ASPECTS	26
PREMARKET CLEARANCE AND 510(K) CLEARANCES	27
<i>TABLE 5 PRE-MARKET APPROVALS, 2006 TO DECEMBER 2010</i>	<i>27</i>
<i>TABLE 5 (CONTINUED).....</i>	<i>28</i>
<i>TABLE 5 (CONTINUED).....</i>	<i>29</i>
<i>TABLE 5 (CONTINUED).....</i>	<i>30</i>
<i>TABLE 5 (CONTINUED).....</i>	<i>31</i>
<i>TABLE 5 (CONTINUED).....</i>	<i>32</i>
<i>TABLE 5 (CONTINUED).....</i>	<i>33</i>
<i>TABLE 5 (CONTINUED).....</i>	<i>34</i>
<i>TABLE 5 (CONTINUED).....</i>	<i>35</i>
CHAPTER FIVE: CLASSIFICATION	36
FETAL MONITORING.....	36
FETAL DOPPLERS	36
ELECTRONIC FETAL MONITORS	37
OTHER FETAL EQUIPMENT AND INSTRUMENTS.....	37

PRENATAL DIAGNOSIS.....	38
ULTRASOUND AND ULTRASONOGRAPHY.....	38
Ultrasound and Ultrasonography (Continued)	39
FETAL MAGNETIC RESONANCE IMAGING.....	40
AMNIOCENTESIS AND CHORIONIC VILLUS SAMPLING	40
OTHER TESTS.....	41
NEONATAL MONITORING	41
NEONATAL MONITORING (CONTINUED)	42
CHAPTER SIX: TESTS FOR GENETIC DISORDERS	43
DOMINANT GENE DISORDERS	43
HUNTINGTON'S DISEASE.....	43
ACHONDROPLASIA	44
RECESSIVE GENE DISORDERS	44
CYSTIC FIBROSIS	45
SICKLE CELL DISEASE	45
TAY-SACHS DISEASE.....	45
BETA THALASSEMIA	46
X-LINKED DISORDERS.....	46
HEMOPHILIA.....	47
CHROMOSOMAL DISORDERS.....	47
DOWN SYNDROME	47
TURNER'S SYNDROME.....	48
CHAPTER SEVEN: INDUSTRY STRUCTURE	49
MANUFACTURERS AND SUPPLIERS OF FETAL MONITORS AND DIAGNOSTIC INSTRUMENTS	49
FETAL DOPPLER	49
<i>TABLE 6 LEADING MANUFACTURERS AND SUPPLIERS OF FETAL DOPPLERS.....</i>	<i>49</i>
<i>TABLE 6 (CONTINUED).....</i>	<i>50</i>
<i>TABLE 6 (CONTINUED).....</i>	<i>51</i>
FETAL MONITORS.....	51
<i>TABLE 7 LEADING MANUFACTURERS AND SUPPLIERS OF FETAL MONITORS.....</i>	<i>51</i>
<i>TABLE 7 (CONTINUED).....</i>	<i>52</i>
FETAL SCALP ELECTRODES, FETOSCOPES, AND CATHETERS	52
<i>TABLE 8 LEADING MANUFACTURERS AND SUPPLIERS OF FETAL SCALP ELECTRODES, FETOSCOPES, AND CATHETERS.....</i>	<i>52</i>
<i>TABLE 8 (CONTINUED).....</i>	<i>53</i>
ULTRASOUND SYSTEMS.....	53
<i>TABLE 9 LEADING MANUFACTURERS AND SUPPLIERS OF ULTRASOUND SYSTEMS.....</i>	<i>53</i>
<i>TABLE 9 (CONTINUED).....</i>	<i>54</i>

<i>TABLE 9 (CONTINUED)</i>	55
MRI SYSTEMS.....	55
<i>TABLE 10 LEADING MANUFACTURERS AND SUPPLIERS OF MRI SYSTEMS</i>	55
<i>TABLE 10 (CONTINUED)</i>	56
NEONATAL SYSTEMS.....	56
<i>TABLE 11 LEADING MANUFACTURERS AND SUPPLIERS OF NEONATAL SYSTEMS</i>	56
MARKET SHARES OF INDUSTRY LEADERS OF FETAL MONITORING SYSTEMS AND DIAGNOSTICS.....	57
FETAL DOPPLERS	57
<i>TABLE 12 GLOBAL MARKET SHARES OF MANUFACTURERS AND SUPPLIERS OF FETAL DOPPLERS, 2010 (%)</i>	57
<i>FIGURE 1 GLOBAL MARKET SHARES OF MANUFACTURERS AND SUPPLIERS OF FETAL DOPPLERS, 2010 (%)</i>	58
FETAL MONITORS.....	58
<i>TABLE 13 GLOBAL MARKET SHARES OF MANUFACTURERS AND SUPPLIERS OF FETAL MONITORS, 2010 (%)</i>	59
<i>FIGURE 2 GLOBAL MARKET SHARES OF MANUFACTURERS AND SUPPLIERS OF FETAL MONITORS, 2010 (%)</i>	59
OTHER FETAL MONITORING DEVICES.....	60
<i>TABLE 14 GLOBAL MARKET SHARES OF MANUFACTURERS AND SUPPLIERS OF OTHER FETAL MONITORING DEVICES, 2010 (%)</i>	60
<i>FIGURE 3 GLOBAL MARKET SHARES OF MANUFACTURERS AND SUPPLIERS OF OTHER FETAL MONITORING DEVICES, 2010 (%)</i>	60
<i>TABLE 15 GLOBAL MARKET SHARES OF MANUFACTURERS AND SUPPLIERS OF ULTRASOUND SYSTEMS IN FETAL MONITORING AND DIAGNOSIS, 2010 (%)</i>	61
<i>FIGURE 4 GLOBAL MARKET SHARES OF MANUFACTURERS AND SUPPLIERS OF ULTRASOUND SYSTEMS IN FETAL MONITORING AND DIAGNOSIS, 2010 (%)</i>	61
MAGNETIC RESONANCE IMAGING IN FETAL MONITORING AND DIAGNOSIS	62
<i>TABLE 16 GLOBAL MARKET SHARES OF MANUFACTURERS AND SUPPLIERS OF MAGNETIC RESONANCE IMAGING SYSTEMS USED IN FETAL MONITORING AND DIAGNOSIS, 2010 (%)</i>	62
<i>FIGURE 5 GLOBAL MARKET SHARES OF MANUFACTURERS AND SUPPLIERS OF MAGNETIC RESONANCE IMAGING IN FETAL MONITORING AND DIAGNOSIS, 2010 (%)</i>	63
NEONATAL MONITORING SYSTEMS.....	63
<i>TABLE 17 GLOBAL MARKET SHARES OF MANUFACTURERS AND SUPPLIERS OF NEONATAL MONITORING SYSTEMS, 2010 (%)</i>	64
<i>FIGURE 6 GLOBAL MARKET SHARES OF MANUFACTURERS AND SUPPLIERS OF NEONATAL MONITORING SYSTEMS, 2010 (%)</i>	64

CHAPTER EIGHT: NEW DEVELOPMENTS	65
NEW DEVELOPMENTS	65
<i>TABLE 18 NEW DEVELOPMENTS, 2008–FEBRUARY 2011</i>	66
<i>TABLE 18 (CONTINUED)</i>	67
OTHERS	68
CHAPTER NINE: MARKET ANALYSIS	69
MARKET ANALYSIS	69
MARKET REVENUE	70
<i>TABLE 19 GLOBAL MARKET FOR FETAL MONITORING AND</i> <i>DIAGNOSTICS BY REGION, THROUGH 2016 (\$ MILLIONS)</i>	70
<i>FIGURE 7 GLOBAL MARKET FOR FETAL MONTINORING AND</i> <i>DIAGNOSTICS BY REGION, 2009-2016 (\$ MILLIONS)</i>	70
FETAL MONITORING.....	71
FETAL DOPPLER	71
Market Overview	72
Market Revenue	72
<i>TABLE 20 GLOBAL MARKET FOR FETAL DOPPLERS BY REGION,</i> <i>THROUGH 2016 (\$ MILLIONS)</i>	72
<i>FIGURE 8 GLOBAL MARKET FOR FETAL DOPPLERS BY REGION,</i> <i>2009-2016 (\$ MILLIONS)</i>	73
FETAL MONITORS.....	73
Market Overview	74
Market Overview (Continued).....	75
Market Revenue	76
<i>TABLE 21 GLOBAL MARKET FOR FETAL MONITORS BY REGION,</i> <i>THROUGH 2016 (\$ MILLIONS)</i>	76
<i>FIGURE 9 GLOBAL MARKET FOR FETAL MONITORS BY REGION,</i> <i>2009-2016 (\$ MILLIONS)</i>	76
OTHERS	77
Market Overview	77
Market Revenue	78
<i>TABLE 22 GLOBAL MARKET FOR OTHERS CATEGORY OF FETAL</i> <i>MONITORING BY REGION, THROUGH 2016 (\$ MILLIONS)</i>	78
<i>FIGURE 10 GLOBAL MARKET FOR OTHERS CATEGORY FOR FETAL</i> <i>MONITORING BY REGION, 2009-2016 (\$ MILLIONS)</i>	78
PRENATAL DIAGNOSTICS.....	79
ULTRASONOGRAPHY	80
Market Overview	80
Market Overview (Continued).....	81
Market Revenue	82
<i>TABLE 23 GLOBAL MARKET FOR PRENATAL MONITORING BY</i> <i>ULTRASOUND AND ULTRASONOGRAPHY BY REGION,</i> <i>THROUGH 2016 (\$ MILLIONS)</i>	82

<i>FIGURE 11 GLOBAL MARKET FOR PRENATAL MONITORING BY ULTRASOUND AND ULTRASONOGRAPHY BY REGION, 2009-2016 (\$ MILLIONS)</i>	82
MAGNETIC RESONANCE IMAGING	83
Market Overview	83
Market Overview (Continued).....	84
Market Revenue	85
<i>TABLE 24 GLOBAL MARKET FOR PRENATAL MONITORING BY MAGNETIC RESONANCE IMAGING BY REGION, THROUGH 2016 (\$ MILLIONS)</i>	85
<i>FIGURE 12 GLOBAL MARKET FOR PRENATAL MONITORING BY MAGNETIC RESONANCE IMAGING BY REGION, 2009-2016 (\$ MILLIONS)</i>	85
AMNIOCENTESIS AND CHORIONIC VILLUS SAMPLING	86
Market Overview	86
Market Revenue	87
<i>TABLE 25 GLOBAL MARKET FOR PRENATAL MONITORING BY AMNIOCENTESIS AND CHORIONIC VILLUS SAMPLING BY REGION, THROUGH 2016 (\$ MILLIONS)</i>	87
<i>FIGURE 13 GLOBAL MARKET FOR PRENATAL MONITORING BY AMNIOCENTESIS AND CHORIONIC VILLUS SAMPLING BY REGION, 2009-2016 (\$ MILLIONS)</i>	88
SCREENING TESTS AND OTHER TESTS.....	89
Market Overview	89
Market Revenue	90
<i>TABLE 26 GLOBAL MARKET FOR PRENATAL MONITORING BY SCREENING AND OTHER TESTS BY REGION, THROUGH 2016 (\$ MILLIONS)</i>	90
<i>FIGURE 14 GLOBAL MARKET FOR PRENATAL MONITORING BY SCREENING AND OTHER TESTS BY REGION, 2009-2016 (\$ MILLIONS)</i>	90
NEONATAL MONITORING	91
Market Overview	91
Market Revenue	92
<i>TABLE 27 GLOBAL MARKET FOR NEONATAL MONITORING BY REGION, THROUGH 2016 (\$ MILLIONS)</i>	92
<i>FIGURE 15 GLOBAL MARKET FOR NEONATAL MONITORING BY REGION, 2009-2016 (\$ MILLIONS)</i>	93
MARKET SHARES OF FETAL MONITORING AND DIAGNOSIS BY REGION	93
<i>TABLE 28 GLOBAL FETAL MONITORING AND DIAGNOSTICS MARKET SHARES BY REGION, 2010 (%)</i>	94
<i>FIGURE 16 GLOBAL FETAL MONITORING AND DIAGNOSTICS MARKET SHARES BY REGION, 2010 (%)</i>	94

CHAPTER TEN: MARKET BY APPLICATIONS.....	95
ANTEPARTUM FETAL MONITORING	95
MARKET REVENUE.....	96
<i>TABLE 29 GLOBAL MARKET FOR ANTEPARTUM MONITORING AND DIAGNOSTICS, THROUGH 2016 (\$ MILLIONS)</i>	96
<i>FIGURE 17 GLOBAL MARKET FOR ANTEPARTUM MONITORING AND DIAGNOSTICS, 2009-2016 (\$ MILLIONS)</i>	97
INTRAPARTUM FETAL MONITORING.....	97
MARKET REVENUE.....	98
<i>TABLE 30 GLOBAL MARKET FOR INTRAPARTUM MONITORING AND DIAGNOSTICS, THROUGH 2016 (\$ MILLIONS)</i>	99
<i>FIGURE 18 GLOBAL MARKET FOR INTRAPARTUM MONITORING AND DIAGNOSTICS, 2009-2016 (\$ MILLIONS)</i>	99
NEONATAL MONITORING FOR CARDIOPULMONARY DISEASES	99
MARKET REVENUE.....	100
<i>TABLE 31 GLOBAL MARKET FOR NEONATAL MONITORING FOR CARDIOPULMONARY DISEASES, THROUGH 2016 (\$ MILLIONS)</i>	101
<i>FIGURE 19 GLOBAL MARKET FOR NEONATAL MONITORING FOR CARDIOPULMONARY DISEASES, 2009-2016 (\$ MILLIONS)</i>	101
Neonatal Monitoring for Congenital Heart Diseases.....	102
<i>TABLE 32 GLOBAL MARKET FOR NEONATAL MONITORING FOR CONGENITAL HEART DISEASES, THROUGH 2016 (\$ MILLIONS)</i>	102
<i>FIGURE 20 GLOBAL MARKET FOR NEONATAL MONITORING FOR CONGENITAL HEART DISEASE, 2009-2016 (\$ MILLIONS)</i>	102
Neonatal Monitoring for Pulmonary Diseases	103
<i>TABLE 33 GLOBAL MARKET FOR NEONATAL MONITORING FOR PULMONARY DISEASES, THROUGH 2016 (\$ MILLIONS)</i>	103
<i>FIGURE 21 GLOBAL MARKET FOR NEONATAL MONITORING FOR PULMONARY DISEASES, 2009-2016 (\$ MILLIONS)</i>	104
MARKET SHARE OF APPLICATIONS	104
<i>TABLE 34 SHARES OF VARIOUS CATEGORIES OF FETAL MONITORING AND DIAGNOSIS BY APPLICATION, 2010 (%)</i>	104
<i>FIGURE 22 SHARE OF VARIOUS CATEGORIES OF FETAL MONITORING AND DIAGNOSIS BY APPLICATION, 2010 (%)</i>	105
CHAPTER ELEVEN: PATENT ANALYSIS	106
PATENTS BY YEAR.....	106
<i>TABLE 35 SIGNIFICANT PATENTS BY YEAR, 2007-2011</i>	107
<i>FIGURE 23 PATENTS BY YEAR, 2007-2011</i>	107
<i>FIGURE 24 PATENTS BY YEAR, 2007-2011 (%)</i>	107
PATENTS BY TYPE	108
<i>TABLE 36 PATENTS BY TYPE, 2007-2011</i>	108
<i>FIGURE 25 TOTAL PATENTS BY TYPE, 2007-2011 (%)</i>	108
<i>FIGURE 25 (CONTINUED)</i>	109
PATENTS BY COMPANY.....	109

FETAL MONITORING	109
TABLE 37 U.S. PATENTS BY COMPANY FOR FETAL MONITORING, 2007–2011	109
PRENATAL DIAGNOSIS	109
TABLE 38 U.S. PATENTS FOR PRENATAL DIAGNOSIS BY COMPANY, 2007–2011	110
NEONATAL MONITORING	110
TABLE 39 U.S. PATENTS FOR NEONATAL MONITORING BY COMPANY, 2007–2011	110
PATENTS BY COUNTRY	110
FETAL MONITORING	110
TABLE 40 U.S. PATENTS FOR FETAL MONITORING BY COUNTRY, 2007–2011	111
PRENATAL DIAGNOSIS	111
TABLE 41 U.S. PATENTS FOR PRENATAL DIAGNOSIS BY COUNTRY, 2007–2011	111
FIGURE 26 U.S. PATENTS FOR PRENATAL DIAGNOSIS BY COUNTRY, 2007–2011	112
NEONATAL MONITORING	112
TABLE 42 U.S. PATENTS FOR NEONATAL MONITORING BY COUNTRY, 2007–2011	112
TABLE 43 U.S. PATENTS FOR ALL FETAL AND NEONATAL MONITORING AND DIAGNOSIS BY COUNTRY, 2007–2011 (%).....	113
FIGURE 27 PATENT SHARES FOR ALL FETAL AND NEONATAL MONITORING AND DIAGNOSIS BY COUNTRY, 2007–2011 (%).....	113
PATENTS BY ASSIGNEE	113
FETAL MONITORING	114
TABLE 44 PATENTS FOR FETAL MONITORING BY ASSIGNEE TYPE, 2007–2011	114
FIGURE 28 PATENTS FOR FETAL MONITORING BY ASSIGNEE TYPE, 2007–2011	114
PRENATAL DIAGNOSIS	115
TABLE 45 PATENTS FOR PRENATAL DIAGNOSIS BY ASSIGNEE TYPE, 2007–2011	115
FIGURE 29 PATENTS FOR PRENATAL DIAGNOSIS BY ASSIGNEE TYPE, 2007–2011	115
NEONATAL MONITORING	116
TABLE 46 PATENTS FOR NEONATAL MONITORING BY ASSIGNEE TYPE, 2007–2011	116
CHAPTER TWELVE: FETAL MONITORING AND PRENATAL DIAGNOSTICS TO HELP REDUCE STILLBIRTHS	
FETAL MONITORING AND PRENATAL	117
FETAL MONITORING AND PRENATAL ... (CONTINUED)	118

CHAPTER THIRTEEN: CURRENT SITUATION AND MARKET PROSPECTS.....	119
FACTORS AFFECTING THE MARKET.....	119
INCREASING AWARENESS.....	119
ADVANCED MATERNAL AGE.....	120
AVAILABILITY OF MONITORING AND DIAGNOSTIC DEVICES.....	120
MEDICAL REIMBURSEMENTS.....	121
MERGERS AND ACQUISITIONS.....	121
COLLABORATIONS AND AGREEMENTS.....	121
FUTURE PROSPECTS OF THE MARKETS.....	122
 CHAPTER FOURTEEN: COMPANY PROFILES.....	 123
ALIMED INC.	123
ALLEN MEDICAL INSTRUMENTS CORPORATION.....	123
ANALOGIC CORPORATION.....	123
ATOM MEDICAL CORPORATION.....	124
BIONET AMERICA INC.	125
CARDINAL HEALTH.....	125
CAREFUSION CORPORATION.....	126
CAS MEDICAL SYSTEMS, INC.....	127
CLINICAL INNOVATIONS, INC.	127
COOPER SURGICAL, INC.	127
COVIDIEN.....	128
DRE MEDICAL EQUIPMENTS.....	129
ESAOTE SA.....	129
FONAR CORPORATION.....	130
GE HEALTHCARE.....	130
GIMA PROFESSIONAL MEDICAL PRODUCTS.....	131
HITACHI MEDICAL SYSTEMS, INC.....	131
ARJOHUNTLEIGH.....	132
MASIMO CORPORATION.....	132
MED-ELECTRONICS, INC.	133
MEDISON AMERICA, INC.....	134
MEDLINE INDUSTRIES.....	134
NEOVENTA MEDICAL, INC.	135
NIHON KOHDEN CORPORATION.....	135
NONIN MEDICAL, INC.....	136
PARAMED MEDICAL SYSTEMS.....	136
PHILIPS HEALTHCARE.....	136
ROCKET MEDICAL, PLC.....	137
SHENZHEN OSEN TECHNOLOGY CO., LTD.....	138
SHIMADZU EUROPE, GMBH.....	138
SIEMENS HEALTHCARE.....	138
SONOSITE, INC.....	139

SUMMIT DOPPLER.....	140
SUNRAY MEDICAL APPARATUS COMPANY, LTD.....	140
SUPERIOR MEDICAL, LTD.....	141
TERASON ULTRASOUND.....	141
THAMES MEDICAL, LTD.....	142
TOSHIBA AMERICA MEDICAL SYSTEMS, INC.	142
UTAH MEDICAL PRODUCTS, INC.	143
WALLACH SURGICAL DEVICES, INC.	143
APPENDIX I: ABBREVIATIONS AND DEFINITIONS	144
ABBREVIATIONS AND DEFINITIONS	144
ABBREVIATIONS AND DEFINITIONS (CONTINUED)	145