ORDIN DE PLATA NR.: 45 TIP.DOC. 1

DATA EMITERII:6 mai 2022

PLATITI: 2500-00 LEI: Doua Mii Cinci Sute lei 00 bani

PLATITOR: (R) S.C. "OXIVIT-MED" S.R.L.
CONTUL DE PLATI/CODUL IBAN MD44ML0000000022517295O3
CODUL FISCAL :1007600044280 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. suc."Invest" Chisinau
CODUL BANCII: :MOLDMD2X329:

BENEFICIAR (R) Centrul pentru Achizi?ii Publice Centralizate in Sanatate
CONTUL DE PLATI/CODUL IBAN MD23TRPCCC518430B01859AA
CODUL FISCAL :1016601000212 /

PRESTATORUL BENEFICIAR
Ministerul Finantelor - Trezoreria de Stat
CODUL BANCII: :TREZMD2X :

DESTINATIA PLATII:/P102/2500,00 Pentru garantia pentru oferta la procedura de achizi?ie publica nr. ocds-b3wdp1-MD-1651213449314 din 09.05.2022

TIPUL TRANSFERULUI NORMAL/URGENT :U:

L.S.

CODUL TRANZACTIEI:101:
DATA PRIMIRII:06/05/2022
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Kojevnikov Dmitrii

MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBIUwggSBMIIDaaADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIwMDMxNjA4NDUwM1oXDTIzMDMxNjA4NTUwM1owgbgxCzAJBgNVBAYTAk1EMRow:
YDVQQIExFSZXB1YmxpY2EgTW9sZG92YTERMA8GA1UEBxMIQ2hpc2luYXUxFzAV

(semnatura electronica)

CONTABIL-SEF:Web Kojevnikov Dmitrii

MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBIUwggSBMIIDaaADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIwMDMxNjA4NDUwM1oXDTIzMDMxNjA4NTUwM1owgbgxCzAJBgNVBAYTAk1EMRow:
YDVQQIExFSZXB1YmxpY2EgTW9sZG92YTERMA8GA1UEBxMIQ2hpc2luYXUxFzAV

L.S.

(semnatura electronica)

CONDUCATOR: _____

(semnatura manuala)

CONTABIL-SEF: _____

(semnatura manuala)

SEMNATURA PRESTATORULUI L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Kojevnikov Dmitrii
Date: 2022.05.06 17:31:01 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr.7.2 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. № A2208064 **din** от 04.05.2022

1. Destinația / Назначение

AGENȚIA ACHIZIȚII PUBLICE

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea Наименование	**Codul fiscal / Numărul de identificare** Фискальный код / Идентификационный номер
S.C. OXIVIT-MED S.R.L.	1007600044280
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localității** Код - Наименование населенного пункта
Decebal bd. nr.82 of.90	0110-SEC.BOTANICA

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat / Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет: **0,00** lei/лей.

4. Valabil pînă la / Действителен до 19.05.2022

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Șefa a DIE Botanica — Ana STOICOV

Funcția/Должность — **Semnătura**/Подпись — **Numele și prenumele**/Фамилия и имя

L.Ș. M.П.

Executor L. Grădinari

Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 04.05.2022 ora 11:30:10
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,00)

MOBIAS BANCA

Nr. 12101-304

18.03.2016

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale" S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280,** deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.

L.Ș.

Dumitru Popa
Director filială „Stejaur"

Executor : Mariana Guzun
Tel: 022 812 614

Filiala Nr. 1 „Stejaur"
Bd. Ştefan cel Mare şi Sfânt 196
MD-2004, Chişinău, Moldova
Cod MOBBMD22
Cont de corespondenţă 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale" SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova

GROUPE SOCIETE GENERALE

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1007600044280

Data înregistrării **30.07.2007**

Data eliberării **30.07.2007**

Bordeianu Tatiana, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT A REPUBLICII MOLDOVA L.Ș.

MD 0067985

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. **8871** din **05.05.2021**

Denumirea completă: **Societatea Comercială «OXIVIT-MED» S.R.L.**
Denumirea prescurtată: **S.C. «OXIVIT-MED» S.R.L.**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat şi codul fiscal: **1007600044280.**
Data înregistrării de stat: **30.07.2007.**
Sediul: **MD-2032, bd. Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
1 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;
2 Comerţul cu ridicata al parfumurilor şi produselor cosmetice;
3 Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă;
4 Intermedieri pentru vînzarea unui asortiment larg de mărfuri;
5 Alte tipuri de comerţ cu amănuntul în magazine nespecializate;
6 Alte tipuri de comerţ cu ridicata;
7 Închirierea altor maşini şi echipamente.
Capitalul social: **5400** lei.
Administrator: KOJEVNIKOV DMITRII, IDNP 0972305012362,
Asociaţi:
1. KOJEVNIKOV DMITRII , IDNP 0972305012362
cota 5400.00 lei, ce constituie 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 05.05.2021.

Specialist coordonator
tel. 022-207-840
Lazari Aliona

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

G70DR

Specifications

Model G70A2
Dual chamber MRI™ SureScan®
pacemaker system

vitatron • The Pace Makers

G70DR Specifications

Model G70A2 Dual chamber pacemaker system

Mechanical

Model	G70A2
Size (HxWxD mm)	44.7x47.9x7.5
M (g)	27.1
V (cc)	12.1
Connector	IS-1 BI or UNI
Radiopaque ID	V5

Battery

Type	Lithium-iodine
Voltage	2.8 V
Average projected capacity	1.3 Ah

Longevity	11.4 years* 10.2 years†

Bradycardia Pacing

Programmable parameters

Pacing Modes	**DDDR**, DDD, DDIR, DDI, DVIR, DVI, DOOR, DOO, VDD, VVIR, VDIR, VVI, VDI, VVT, VOOR, VOO, AAIR, ADIR, AAI, ADI, AAT, AOOR, AOO, ODO, OVO, OAO
Mode Switch	**On**, Off
Lower Rate	30, 35, 40…**60**…170 min^{-1} (exc. 65, 85)
Upper Tracking Rate[a]	80, 90, 95…**130**…180 min^{-1}
Upper Sensor Rate	80, 90, 95…**130**…180 min^{-1}
A and RV Pulse Amplitude[b]	0.5, 0.75, 1.0…**3.5**…4, 4.5, 5, 5.5, 6, 7.5 V
A and RV Pulse Width	0.12, 0.15, 0.21, 0.27, 0.34, **0.4**, 0.46, 0.52, 0.64, 0.76, 1, 1.25, 1.5 ms
Atrial Sensitivity	0.18, 0.25, 0.35, **0.5**, 0.7, 1, 1.4, 2, 2.8, 4 mV
Ventricular Sensitivity	1, 1.4, 2, **2.8**, 4, 5.6, 8, 11.2 mV
Pacing Polarity (A and V)	Bipolar, Unipolar, Configure
Sensing Polarity (A and V)	Bipolar, Unipolar, Configure
Paced AV (PAV)	30, 40, 50…**150**…350 ms
Sensed AV (SAV)	30, 40, 50…**120**…350 ms
PVARP	**Auto**, Varied, 150, 160, 170…500 ms
Minimum PVARP	150, 160, 170…**250**…500 ms
PVAB	130, 140, 150…**180**…350 ms
Atrial Refractory Period	180, 190, 200…**400**…500 ms
Atrial Blanking Period	130, 140, 150…**180**…350 ms
Ventricular Refractory Period	150, 160, 170…**230**…500 ms
Ventricular Blanking (after atrial pace) (PAVB)	20, **28**, 36, 44 ms

Therapies to promote intrinsic activation

Reduced VP™+	**On**, Off
Max Increase to AV	10, 20, 30…**170**…250 ms
Sinus Preference™	**On**, Off
Sinus Preference Zone	3, 5, **10**, 15, 20 min^{-1}
Search Interval	5, 10, 20, 30 min
Sleep	On, **Off**
Sleep Rate	30, 35, 40…**50**…90 min^{-1} (exc. 65, 85)
Bed Time	00:00, 00:15, 00:30… **22:00**…23:45
Wake Time	00:00, 00:15, 00:30… **8:00**…23:45
Single Chamber Hysteresis	Off, 40, 50, 60 min^{-1}

Rate Response Pacing

ADL Rate	60, 65, 70…**95**…175, 180 min^{-1}
Rate Profile Optimization	**On**, Off
ADL Response	1, 2, **3**, 4, 5
Exertion Response	1, 2, **3**, 4, 5
Activity Threshold	Low, **Medium Low**, Medium High, High
Acceleration	15 s, **30 s**, 60 s
Deceleration	2.5 min, 5 min, 10 min, **Exercise**
RAAV	On, **Off**
Start Rate	50, 55, 60…**80**…175 min^{-1}
Stop Rate	55, 60, 65…**120** … 180 min^{-1}
Maximum Offset	-10, -20, -30…**-40** …-300 ms

Rate Drop Response

Detection Type	Low Rate, Drop, Both, **Off**
Intervention Rate	60, 70, 75, 80…**100**…180 min^{-1} (exc. 65, 85)
Intervention Duration	1, **2**, 3…15 min
Detection Beats	1, **2**, 3 beats
Drop Rate	30, 40, **50**…100 min^{-1}
Drop Size	10, 15, 20, **25**…50 min^{-1}
Detection Window	10, 15, 20, **25**, 30 s; 1, 1.5, 2, 2.5 min

Additional pacing features

PMT Intervention	On, **Off**
PVC Response	**On**, Off
Ventricular Safety Pacing	**On**, Off

MRI Pacing Parameters

SureScan® Pacing Mode	AOO, VOO, DOO,ODO
SureScan Lower Rate Interval	60, 70, 75, 80 … 115, 120[c] min^{-1}
SureScan PAV	50, 60 … 110 ms
SureScan Atrial Amplitude	5.0, 5.5, 6.0, 7.5 V
SureScan Atrial Pulse Width	1.0, 1.25, 1.5 ms
SureScan Atrial Sensitivity	0.18, 0.25, 0.35, 0.5, 0.7, 1.0, 1.4, 2.0, 2.8, 4.0 mV
SureScan Ventricular Amplitude	5.0, 5.5, 6.0, 7.5 V
SureScan Ventricular Sensitivity	1.0, 1.4, 2.0, 2.8, 4.0, 5.6, 8.0, 11.2 mV
SureScan Ventricular Pulse Width	1.0, 1.25, 1.5 ms
SureScan Timeout Duration	24 hr
SureScan MRI Compatibility	1.5 and 3 Tesla, full body scan

Atrial Tachyarrhythmia Therapies and Interventions

Mode Switch	**On**, Off
Detected Rate	120, 125…**175**…200 min^{-1}
Detect Duration	**No Delay**, 10, 20…60 sec
Blanked Flutter Search	**On**, Off

Atrial Preference Pacing (APP) parameters

APP	On, **Off**
Maximum Rate (min^{-1})	80, 90, 95, **100**…150
Interval Decrement (ms)	**30**, 40, 50…100, 150
Search Beats	5, 10…**20**, 25, 50

Post Mode Switch Overdrive Pacing (PMOP) parameters

PMOP	On, **Off**
Overdrive Rate (min^{-1})	70, 75, **80**, 90, 95…120
Overdrive Duration (min)	0.5, 1, 2, 3, 5, **10**, 20, 30, 60, 90, 120

Nominal values indicated in **bold**

Conducted AF Response[d]

Regularize V-V during AT/AF	On, **Off**
Maximum Rate (min^{-1})	80, 85, 90…**110**…130

Non-Competitive Atrial Pacing **On**, Off

Automatic Pacing, Sensing, and Lead Monitor

Implant Detection and Initialization

At the completion of the 30-minute Implant Detection period, Rate Profile Optimization is enabled; the appropriate pacing and sensing polarities are automatically selected by the device; Atrial and Ventricular Output Management is enabled and Amplitude and Pulse Width become adaptive. Sensing Assurance™ is enabled and Sensitivity becomes adaptive. Reduced VP™+ is enabled 60 minutes after Implant Detection is complete.

Implant Detection	On/Restart, Off/Complete
Lead Monitor (A and V)	Configure, Monitor Only, Adaptive (Auto Polarity Switch), Off
Notify If <	**200** Ω
Notify If >	1000, 2000, 3000, **4000** Ω
Monitor Sensitivity	2, 3, 4 … **8** … 16

Atrial Output Management

Atrial Output Management	Off, Monitor Only, **Adaptive**
Amplitude Margin	1.5x, **2x**, 2.5x, 3x, 4x (times)
Minimum Adapted Amplitude	0.5, 0.75…**1.5**…3.5 V
Capture Test Frequency	1, 2, 4, 8, 12 hours; Day at rest; **Day at**…; 7 days at
Capture Test Time	00:00, **1:00**…23:00
Acute Phase Days Remaining	Off, 7, 14, 21…84, **112**, 140, 168…252 days

Ventricular Output Management

Ventricular Output Management	Off, Monitor Only, **Adaptive**
Amplitude Margin	1.5x, **2x**, 2.5x, 3x, 4x (times)
Minimum Adapted Amplitude	0.5, 0.75…**2.0**…3.5 V
Capture Test Frequency	15, 30 min; 1, 2, 4, 8, 12 hours; **Day at rest**; Day at…; 7 days at
Capture Test Time	00:00, 1:00…23:00
Acute Phase Days Remaining	Off, 7, 14, 21…84, **112**, 140, 168…252 days
V. Sensing During Search	Unipolar, Bipolar, **Adaptive**

Sensing Assurance

Sensing Assurance (A and V)	**On**, Off

Diagnostics

Cardiac Dashboard II

Highlights significant events, AT/AF and pacing summary, threshold and impedance trends

Atrial and ventricular pacing threshold trends
Battery longevity
Pacing summary and access to rate histogram
Atrial and ventricular lead impedance trends
Number of hours/day in atrial arrhythmia, percentage of time
Access to atrial arrhythmia diagnostics
Observations
P-wave/R-wave amplitudes and access to A and V sensitivity trends

CardioTrend™

Trend data compiles up to 6 months of daily clinical information in an easy-to-interpret graphic format

Histogram reports

Heart rate histograms
AV conduction histograms
Reduced VP™+ histogram
Sensor indicated rate profile

Atrial and ventricular episodes

Atrial and ventricular high rate episodes
Ventricular rate during atrial arrhythmias
Atrial arrhythmia durations
Multiple EGM episodes
Rate drop response episodes

Clinician selected diagnostics

Custom rate trend
Rate drop response detail
Atrial output management detail
Ventricular Output Management detail
High Rate Detail

Patient data stored in device

Patient identification
Leads implanted
Device implanted
Clinician's stored notes

Data management

Automatic printing of initial interrogation report
Full page printing
Save-to-Disk capacity for electronic file management

Follow-up and Troubleshooting

Telemetry features	
Transtelephonic monitor	On, Off
Extended telemetry	On, Off
Extended marker	Standard, Therapy Trace

Key parameter history
Initial interrogation report
Strength duration threshold test
Ventricular threshold test
Marker Channel™
Threshold margin test
Exercise test
EP studies
Magnet test
Underlying rhythm test
Sensing test
Temporary test

Magnet mode operation

	BOS	ERI
Dual chamber mode	DOO 85 min^{-1}	65
Single chamber atrial mode	AOO 85 min^{-1}	65
Single chamber ventricular mode	VOO 85 min^{-1}	65

Recommended Replacement Time (RRT) and Elective Replacement Indicator (ERI)

Replacement message on programmer (Cardiac Dashboard II)

Battery/lead information	Replacement message and battery voltage displayed on programmer
RRT and ERI initiation date	Displayed on programmer

Vitatron. The Pace Makers

Vitatron - based in Europe - is the only medical device company that specializes exclusively in pacemakers. Since 1962, Vitatron pacemakers have helped restore more than 1,000,000 people in more than 60 countries to a full life. We strive to achieve perfection in everything we do. This results in unique patient-focused therapies, as well as highly cost-effective pacemakers that are easy to use.

Head Office: Vitatron Holding BV

Endepolsdomein 5,
Maastricht
NL 6229 GW
The Netherlands
www.vitatron.com

UC201708586 EE

G70DR • Dual chamber

References

*DDDR or DDD 50%, 1.5 V and 2.0 V, 60 min^{-1}, 0.4 ms, 500 OHM. For Atrial Output Management the Minimum Adapted Amplitude is 1.5 V (nominal). For Ventricular Output Management, the Minimum Adapted Amplitude is 2.0 V (nominal).

†DDDR or DDD 100%, 1.5 V and 2.0 V, 60 min^{-1}, 0.4 ms, 500 OHM. For Atrial Output Management the Minimum Adapted Amplitude is 1.5 V (nominal). For Ventricular Output Management, the Minimum Adapted Amplitude is 2.0 V (nominal).

[a] The atrial and ventricular Rate Limit is 200 min^{-1} (± 20 min^{-1}).

[b] Tolerance for amplitudes from 0.5 V through 6.0 V is ± 10%, and for 7.5 V is -20/+0%. Tolerances are based on 37 ºC and a 500 Ω load. Amplitude is determined 200 µs after the leading edge of the pace.

[c] User selection will not include 65 min^{-1} or 85 min^{-1}.

[d] Conducted AF Response is functional during Mode Switch episodes, DDIR, VVIR and VDIR modes.

vitatron • The Pace Makers

CERTIFICATE

Number: 2090418

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

including the implementation meets the requirements of the standard:

ISO 9001:2015
EN ISO 13485:2016

Scope:
Sales, order management, warehousing and distribution of medical devices.
Including regulatory affairs, post market surveillance, technical service, customer education and spine loaner operations

Certificate expiry date: 1 July 2024
Certificate effective date: 1 July 2021
Certified since: 1 July 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

MGMT. SYS. RvA C 589

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Certified organization(s) and/or locations:

	Different scope
Medtronic Trading NL B.V. Larixplein 4 5616 VB Eindhoven The Netherlands	Sales, order management and distribution of medical devices. Including customer education
Medtronic Italia S.p.A. Via Varesina 162 20156 Milano Italy	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Danmark A/S. Arne Jacobsens Alle 17 2300 Kopenhagen Denmark	Sales, order management and distribution of medical devices. Including customer education
Medtronic Finland Oy Lentajantie 3 01530 Vantaa Finland	Sales, order management and distribution of medical devices. Including customer education.
Medtronic AB P.O. Box 1034 164 21 Kista Sweden	Sales, order management and distribution of medical devices. Including customer education
Medtronic Norge AS Martin Linges vei 25 1364 Fornebu Norway	Sales, order management and distribution of medical devices. Including customer education.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd. Waterfall Distribution Campus CNR K101 and Bridal Veil Road Waterfall Midrand 1685 Gauteng South Africa	Sales, order management, warehousing and distribution of medical devices. Including customer education and spine loaner operations.
Medtronic Medikal Teknoloji Ticaret Ltd Sti Saray Mah. Esnaf Sk. Akkom Ofis Park Laodik Plaza Sitesi B Blok Apt: 2/8 34764 Umraniye - Istanbul Turkey	Sales, order management and distribution of medical devices. Including customer education
Medtronic Ibérica S.A. Calle de Maria de Portugal, 11 28050 Madrid Spain	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Ibérica S.A. WTC Almeda Park Placa de la Pau, s/n. Edificio 7, 3 piso Cornella de Llobregat 08940 Barcelona Spain	Sales, order management and distribution of medical devices.
Medtronic Portugal LDA- Rua Tomas da Fonseca Torre E, 11 piso 1600 Lisboa Portugal	Sales, Order Management and distribution of medical devices including customer education. Warehousing and distribution of medical devices, including spine loaner operations

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Portugal, LDA- Avenida Gomes Pereira 61B Benfica 1600 Lisboa Portugal	Sales, Order Management and distribution of medical devices. Including customer education. Warehousing and distribution of medical devices, including spine loaner operations.
Medtronic GmbH Earl-Bakken-Platz 1 40670 Meerbusch Germany	Scope for EN ISO 13485:2016: Sales, order management and distribution of medical devices. Including customer education. ISO 9001:2015 excluded
Medtronic GmbH Mollsfeld 12 40670 Meerbusch Germany	Scope for EN ISO 13485:2016: Sales, order management and distribution of medical devices. Including customer education. ISO 9001:2015 excluded
Medtronic Osterreich GmbH Milennium Tower, 20th floor Handelskai 94-96 1200 Wien Austria	Sales, order management, warehousing and distribution of medical devices. Including customer education
Medtronic (Schweiz) AG Talstrasse 9 3053 Munchenbuchsee Switzerland	Sales, order management, warehousing and distribution of medical devices. Including customer education
Medtronic France SAS 9, boulevard Romain Rolland 75014 Paris France	Sales, order management and distribution of medical devices. Including customer education

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Hellas S.A. Avenue Kifisias 24 Building B 151 25 Marousi Pref. Attica Greece	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Hellas S.A. Diabetes Shop Mesogeion Avenue 2-4 115 27 Athens Greece	Sales, order management and distribution of diabetes medical devices. Including customer education.
Medtronic Romania SRL Ploiesti 42-44, Building B, B2 Wing, 2nd floor, district 1 Baneasa Business & Technology Park 013696 Bucharest Romania	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Hungária Kft. Bocskai ut 134-146 Cepulet 3. emelet 1113 Budapest Hungary	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Serbia Ltd. Bulevar Zorana Djindjica, 64a 11070 Belgrade Serbia	Sales, order management and distribution of medical devices. Including customer education.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Poland Sp.z o.o Medtronic Customer Care Center of Experience Warsaw Polna 11 00-633 Warszawa Poland	Order management of medical devices.
Medtronic Trading Ltd. 10 Hamada Street 4673344 Herzlya Israel	Import, sales, order management and distribution of medical devices. Including customer education
Medtronic Czechia s.r.o. Prosek Point, Budova B, Prosecka 852/66 852 66 Praha Czech Republic	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Bulgaria EOOD 48 Sitnyakovo blvd., R-N OBORISHTE DISTR., floor 7 1505 Sofia Bulgaria	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Limited Building 9, Croxley ParkHatters Ln WD18 8WW Watford United Kingdom	Sales, order management and distribution of medical devices. Including customer education.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Ireland Limited Block 3090-3094Lake Drive, Citywest Business Campus D24 NW2F Dublin Ireland	Sales, order management and distribution of medical devices. Including customer education.
Medtronic B.V. Medtronic Service & Repair EMEA Jan Campertstraat 21-A 6416 SG Heerlen	Order management, warehousing and technical service of medical devices including field service EMEA.
Medtronic Slovakia s.r.o. CBC III, Karadzicova 12 821 08 Bratislava Slovak Republic	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Belgium Burgemeester E. Demunterlaan 5 1090 Brussel Belgium	Sales, Order Management and distribution of medical devices. Including customer education
Medtronic Croatia Folnegoviceva 1c 10000 Zagreb Croatia	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Slovenia Ameriska Ulica 8 1000 Ljubljana Slovenia	Sales, order management and distribution of medical devices

Addendum expiry date: 1 July 2024
Addendum effective date: 1 July 2021

EC CERTIFICATE

Number: 2008481CE01

Full Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2 excluding (4)
(Other devices than custom made or intended for clinical investigation)

Manufacturer:

Vitatron Holding B.V.

Endepolsdomein 5
6229 GW Maastricht
The Netherlands

For the product category(ies)

Implantable Pacemaker Systems

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2007317CN, initially dated 15 December 2000
Addendum, initially dated 6 April 2001

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex 2 of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance. For placing on the market of Active implantable medical devices an additional EC design examination certificate according to Annex 2 (4) is mandatory.
The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 6 April 2001
Reissued: 1 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2008481CE01

CE MARKING OF CONFORMITY
ACTIVE IMPLANTABLE MEDICAL DEVICES

Implantable Pacemaker Systems

Issued to:

Vitatron Holding B.V.
Endepolsdomein 5
6229 GW Maastricht
The Netherlands

This certificate covers the following product(s):

Brady Pacemakers

These products are designed/manufactured in the facilities:

Medtronic Inc., 8200 Coral Sea Street, Mounds View, MN 5512, USA (Design)
Medtronic Europe S.A.R.L., route du Molliau 31, Case Postal., 1131 Tolochenaz, Switzerland (Manufacturing, labeling and final packaging)
Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands (Distribution)
Medtronic Singapore Operations Pte. Ltd., 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056, Singapore (Manufacturing)

Leads for Pacemakers

These products are designed/manufactured in the facilities:

Medtronic Inc., 8200 Coral Sea Street, Mounds View, MN 5512, USA (Design)
Medtronic Puerto Rico Operations Co. MPRI, Road 149, km 56.3, Villalba PR 00766 USA. (Manufacturing)
Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands (Labeling, distribution and final packaging)
Medtronic Rice Creek Pharma Operation, 7000 Central Avenue NE, Minneapolis, Minnesota 55432, USA (manufacturing MCRDs and pharmaceutical analytical testing of MCRDs and leads)

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2008481CE01

CE MARKING OF CONFORMITY
ACTIVE IMPLANTABLE MEDICAL DEVICES

Implantable Pacemaker Systems

Issued to:

Vitatron Holding B.V.
Endepolsdomein 5
6229 GW Maastricht
The Netherlands

Application software (external)

These products are designed in the facility:

Medtronic Inc., 8200 Coral Sea Street, Mounds View, MN 5512, USA (Design)
Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands (Labeling, distribution and final packaging)

Lead Introducers

These products are designed in the facility:

Medtronic Inc., 8200 Coral Sea Street, Mounds View, MN 5512, USA (Design, manufacturing)
Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands (Distribution)

Initial date: 6 April 2001

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2008481DE24

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

Manufacturer:

Vitatron Holding B.V.

Endepolsdomein 5
6229 GW Maastricht
The Netherlands

For the product

Implantable Pacemaker Vitatron G-Series

Documents, that form the basis of this certificate:

Certification Notice 2007317CN, initially dated 15 December 2000
Addendum, initially dated 16 December 2009

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 2 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 2 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 January 2024
Issued for the first time: 16 December 2009
Reissued: 1 January 2019

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

G Adams
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2008481DE24

EC DESIGN-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Implantable Pacemaker Vitatron G-Series

Issued to:

Vitatron Holding B.V.
Endepolsdomein 5
6229 GW Maastricht
The Netherlands

This certificate covers the following product(s):

- Vitatron G70 DR, model G70 A1
- Vitatron G20 SR, model G20 A1
- Vitatron MRI™ SureScan™, G70 DR, model G70A2
- Vitatron MRI™ SureScan™, G20 SR, model G20A2

Initial date: 16 December 2009

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

G Adams
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

CERTIFICATE

Number: 2250781

The management system of:

Vitatron Holding B.V.

Endepolsdomein 5
6229 GW Maastricht
The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:
Design, Manufacturing and distribution of implantable Pacemaker systems

Certificate expiry date: 1 September 2024
Certificate effective date: 1 September 2021
Certified since: 1 September 2012

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

MGMT. SYS. RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

vitatron	Document Title: *DoC0023*	Document Number: DoC0023
EC DECLARATION OF CONFORMITY	*G-Series A2 models G20A2, G70A2 and Application Software VSF21*	

Revision/History description	Revision level	Impl. Date
Initial Release	2.0	22 May 2017
Corrected EC certificate reference from 2008481DE33 to 2008481DE24 for the pulse generators	3.0	24 May 2017
Updated approver role Updated Applicable Standards Date of Issue of EN 45502-1, EN ISO 11607-1, EN 60601-1-6, EN 62304 and Standard Number and Date of Issue of EN 62366-1 ISO 15223-1 was EN 15223-1 Removed Standard ISO 11607-2, does not apply to this device Removed footnotes of EN ISO 14971, EN 60601-1-6, EN 62304 and EN 62366-1 Statement text updated	4.0	17 Aug 2017
Model number: updated Programmer Application Software VSF21 with revision 8.0	5.0	25 Sep 2017
Clarification of VSF21 revision 8.0 for both programmers.	6.0	26 Sep 2017
Updated to reflect MDT30130338 rev 1.0 standards changes from ISO 15223-1:2012 to EN ISO 15223-1:2016	7.0	16-Jul-2018
Updated EN 45502-1 title. Added “Implants for surgery”	8.0	10-Jan-2019
Updated document information to align with current template revision A Updated to match Agile MAP revision numbering convention Added Amendment 1:2019 to EN ISO 11135:2014 Changed EN 60601-1:2006+A1:2013 to EN 60601 1:2006+A12:2014. The change is due to the incorporation of technical corrigendum July 2014 (technical correction of Figure 12).	A	18-Dec-2020
Updated EN ISO 14971 revision from 2012 to 2019 Added standards ISO 14708-1 and ISO 14708-2 Updated EN ISO 10993-1 revision from 2009/AC:2010 to 2020 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019	B	Upon Approval

vitatron

EC Declaration of Conformity

Manufacturer:	Vitatron Holding BV Endepolsdomein 5 6229 GW Maastricht The Netherlands
EC Representative:	N/A
Description of device concerned:	*G-Series Implantable Pulse Generator; Programmer Application Software*
Model number:	*G20A2, G70A2, VSF21*
Variants:	*VSF21 v8.0 (Programmer 2090 and 29901)*
GMDN Code	47265 Dual-chamber pacemaker, rate-responsive 47267 Single-chamber pacemaker, rate-responsive 47206 Cardiac Pulse Generator Software
Classification, rule	AIMD
Conformity Assessment procedure:	*Annex 2.3 with Annex 2.4*
EC Certificate number:	*Implantable Pulse Generator: 2008481DE24* *Programmer application software: 2008481DE20*
EC Quality System Certificate:	*2008481CE01*
Name of Notified Body:	*DEKRA Certification B.V.* *Meander 1051* *6825 MJ Arnhem* *The Netherlands*
Identification Number Notified Body:	*0344*
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Vitatron, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC [1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***Refer to change record***

Place: Maastricht

Date: ***Refer to document approval date in the change record***

Name: Cor Mathijsen

Title: EC Management Representative

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] Including amendments issued in the years following

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements following the applicable EC Directive.

The below mentioned Standard(s) apply to all the product(s) mentioned under the scope of this DoC.

Number	Date of issue	Title
EN 556-1	2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be labeled "STERILE"- Part 1: Requirements for terminally sterilized medical devices
EN 1041	2008 + A1:2013	Information Supplied by the Manufacturer with Medical Devices
EN ISO 15223-1	2016	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 45502-1	2015	Implants for surgery - Active Implantable Medical Devices - Part 1. General requirements for safety, marking and information to be provided by the manufacturer
ISO 14708-1	2014	Implants for surgery - Active Implantable Medical Devices - Part 1. General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-1	2003	Active Implantable Medical Devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)
ISO 14708-2	2019	Implants for surgery - Active Implantable Medical Devices - Part 2: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (includes cardiac pacemakers) – Second edition
EN ISO 10993-1	2020	Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing within a Risk Management Process
ISO 10993-7	2008 + Amd1:2019	Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals
EN ISO 11135	2014 + A1:2019	Sterilization of medical devices – Validation and routine control of Ethylene Oxide sterilization
EN ISO 14971	2019	Medical devices-Application of risk management to medical devices
EN ISO 11607-1	2009 + A1:2014	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 5841-3	2013	Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers
EN 62366-1	2015	Medical devices – Application of usability engineering to medical devices
EN 60601-1-6	2010 + A1:2015	Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability
EN 60601-1[2]	2006 + A12:2014	Medical Electrical Equipment - Part 1: General Requirements for basic Safety and Essential Performance
EN 62304	2006 + A1:2015	Medical device software – Software Life-cycle processes

[2] Full Compliance (only clause 14 is applicable)

Medtronic	Document Title: DoC-4196 MRI SureScan	Document Number: BL0030512
EC DECLARATION OF CONFORMITY	Attain Ability™ MRI SureScan™ Lead, Model 4196	

Revision/History description	Revision level	Impl. Date
Initial Release for Attain Ability™ MRI SureScan™ Lead, Model 4196	2.0	18-Jun-2016
Updated to latest revision of DoC template. Updated to reflect new EC Quality System certificate number. New certificate (I2 17 11 39709 01117) replaces certificate I2 12 11 39709 844 and becomes effective November 21, 2017. As such, validity date updated to reflect November 21, 2017. Updated GMDN Code and Description from 35223 (Endocardial pacing lead) to 60190 (Coronary venous pacing lead). Updated compliance level footnotes in Attachment 1.	3.0	17-Oct-2017
Correction to GMDN Code number from 60190 to 60910.	4.0	18-Oct-2017
Updated EN 62366:2008 to EN 62366-1:2015	5.0	11-Apr-2018
Updated to reflect MDT30106734 rev 4.0 Standards Changes: 1. From EN 980:2008 to EN ISO 15223-1:2016 2. From EN 1041:2008 to EN 1041:2008/A1:2013 3. From EN 45502-1:1997 to EN 45502-1:2015	6.0	26-Jun-2018
Updated approver to Jeff Chaput Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2018	7.0	03-Dec-2019
Updated to match Agile MAP revision numbering convention Added referral to change record for signatures and approval date Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020 Added Amendment 1:2018 to EN ISO 11135:2014	A	01-Apr-2020
Updated EN ISO 11135:2014+A1:2018 to 11135:2014+A1:2019, updated title	B	12-Oct-2020
Updated EN ISO 14971 revision from 2012 to 2019 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019 Added standards ISO 14708-1 and ISO 14708-2 Updated ISO 10993-1:2018 to EN ISO 10993-1:2020	C	Upon Approval

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned:	Attain Ability MRI SureScan Lead
Model number:	4196
Variants:	4196-78, 4196-88
GMDN Code and Description	60910, Coronary venous pacing lead
Classification, rule	AIMD
Conformity Assessment Route:	Annex 3 with Annex 5
EC Certificate number:	2007841TE16
EC Quality System Certificate:	I2 17 11 39709 01117
Name & Address of Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC[1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***Refer to document approval date in the change record*** Place: Minneapolis Date: ***Refer to document approval date in the change record***

Name: Jeff Chaput
Title: Sr. Engineering Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN 45502-1	2015	Active Implantable Medical Devices - Part 1: General Requirements for Safety, Marking and Information to be provided by the Manufacturer
ISO 14708-1	2014	Implants for surgery - Active Implantable Medical Devices - Part 1: General Requirements for Safety, Marking and Information to be provided by the Manufacturer
EN 45502-2-1	2003	Active Implantable Medical Devices - Part 2-1: Particular Requirements for Active Implantable Medical Devices Intended to Treat Bradyarrhythmia (cardiac pacemakers)
ISO 14708-2	2019	Implants for surgery - Active Implantable Medical Devices - Part 2: Particular Requirements for Active Implantable Medical Devices Intended to Treat Bradyarrhythmia (cardiac pacemakers) – Second edition
EN ISO 14971	2019	Medical devices – Application of risk management to medical devices
EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041	2013	Information supplied by the manufacturer with medical devices
EN ISO 11135	2019	Sterilization of health care products – Ethylene Oxide – Requirements for development, validation and routine control of a sterilization process for medical devices
EN 556-1	2006	Sterilization of medical devices - Requirements for medical devices to be labeled “Sterile”- Part 1: Requirements for terminally sterilized medical devices
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 10993-1	2020	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process
ISO 10993-7	2008 + Amd1:2019	Biological Evaluation of Medical Devices – Part 7: Tests for Ethylene Oxide Sterilization Residuals
ISO 5841-3	2013	Cardiac Pacemakers – Pacemaker leads - Connector Assembly (IS-1) for Implantable Pacemakers – Part 1: Safety and Design Requirements
EN 62366-1	2015	Medical devices – Application of usability engineering to medical devices

Medtronic	Document Title: DoC- CapSure Fix Novus MRI SureScan Model 5076	Document Number: BL0026501
EC DECLARATION OF CONFORMITY	CapSureFix® Novus MRI SureScan Model 5076 Active Fixation Pacing Lead	

Revision/History description	Revision level	Impl. Date
Initial Release	2.0	15-Mar-2013
Update to add new EC certificate number due to CE Renewal. New certificate (I7 13 09 39709 804) replaces certificate I7 12 02 39709 768 and becomes effective September 30, 2013. As such, validity date updated to reflect September 30, 2013.	3.0	06-Sep-2013
Update EC Cert number to reflect newly released certificate I7 15 07 39709 987	4.0	30-Jul-2015
Update ISO 5841-3 reference to 2013; Update compliance statements 2, 3, & 4.	5.0	30-Jun-2016
Updated quality system certificate number Updated approver to Kiran Kuppuswamy	6.0	06-Apr-2017
Update "I, the undersigned, hereby declare…" with "We, Medtronic, hereby declare under our sole responsibility…" Updated Standards EN ISO 11135:2014 and EN ISO 11607-1:2009+A1:2014 Updated Title for Standards EN 980, EN 1041 and EN ISO 11135	7.0	14-Aug-2017
Updated to reflect full compliance with EN 62366-1:2015 and latest template	8.0	06-Apr-2018
Updated to reflect new EC certificate number. New certificate (2007841TE28) replaces certificate (I7 15 07 39709 987) and becomes effective April 30, 2018. As such, validity date updated to reflect April 30, 2018. Conformity assessment route updated from "Annex 2.3 with Annex 2.4" to "Annex 3 with Annex 5". Update to EC Quality System Certificate to applicable Annex 5 certificate I2 17 11 39709 01117.	9.0	20-Apr-2018
Updated to reflect BL0016630 Rev 19 ERM Standards Changes: 1) From EN 980:2008 To: EN ISO 15223-1:2016 2) From: EN 1041:2008 To: EN 1041:2008/A1:2013 3) From: EN 45502-1:1997 To: EN 45502-1:2015	10.0	13-Jun-2018
Updated from EN ISO 10993-1:2009/AC2010 to ISO 10993-1:2018 Updated approver from Kiran Kuppuswamy to Jeffery Chaput	11.0	26-Nov-2019
Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020	12.0	21-Feb-2020
Added Amendment 1:2019 to EN ISO 11135:2014 Updated to match Agile MAP revision numbering convention Added referral to change record for signatures and approval date	A	12-Oct-2020
Updated EN ISO 14971 revision from 2012 to 2019 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019 Added standards ISO 14708-1 and ISO 14708-2 Updated ISO 10993-1:2018 to EN ISO 10993-1:2020	B	Upon Approval

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned :	CapSureFix® Novus MRI SureScan lead
Model number:	5076
Variants:	Lead Lengths: 35cm, 45cm, 52cm, 58cm, 65cm, 85cm
GMDN Code and Description	35223, Endocardial pacing lead
Classification, rule	AIMD
Conformity Assessment Route:	Annex 3 with Annex 5
EC Certificate number:	2007841TE28
EC Quality System Certificate:	I2 17 11 39709 01117
Name & Address of Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC[1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***30-Apr-2018*** Place: Minneapolis Date: ***Refer to document approval date in the change record***

Name: Jeffery Chaput
Title: Sr. Engineering Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN 556-1	2006	Sterilization of medical devices - Requirements for medical devices to be labeled “Sterile”- Part 1: Requirements for terminally sterilized medical devices
EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041	2008 + A1:2013	Information supplied by the manufacturer of medical devices
ISO 5841-3	2013	Cardiac Pacemakers – Pacemaker leads - Connector Assembly (IS-1) for Implantable Pacemakers – Part 1: Safety and Design Requirements
EN ISO 10993-1	2020	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
ISO 10993-7	2008 + Amd1:2019	Biological Evaluation of Medical Devices – Part 7: Tests for Ethylene Oxide Sterilization Residuals
EN ISO 11135	2014 +A1:2019	Sterilization of health care products – Ethylene Oxide – Requirements for development, Validation and routine control of a sterilization process for medical devices
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971	2019	Medical devices – Application of risk management to medical devices
EN 45502-1	2015	Active Implantable Medical Devices - Part 1: General Requirements for Safety, Marking and Information to be provided by the Manufacturer
ISO 14708-1	2014	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-1	2003	Active Implantable Medical Devices - Part 2-1: Particular Requirements for Active Implantable Medical Devices Intended to Treat Bradyarrhythmia (cardiac pacemakers)
ISO 14708-2	2019	Implants for surgery – Active Implantable Medical Devices – Part 2: Particular Requirements for Active Implantable Medical Devices Intended to Treat Bradyarrhythmia (cardiac pacemakers) – Second edition
EN 62366-1	2015	Medical Devices – Part 1: Applications of Usability Engineering to Medical Devices

Medtronic	Document Title: DoC-6215	Document Number: BL0003803
EC DECLARATION OF CONFORMITY	Model 6215 Attain Venogram Balloon Catheter	

Revision/History description	Revision level	Impl. Date
Attain Venogram Balloon Catheter, Model 6215	-	29-AUG-2001
Update to implement new EC Rep Address, editorial changes, new CE mark certificate	A	25-MAR-2004
Update to align CE mark following update of CE mark from OEM, editorial changes	4.0	13-FEB-2008
Updated to support MD Directive 93/42/EEC: Amendment 2007 and New Template. Corrected Issue Date.	5.0	27-APR-2010
Updated Standards, New DoC Template Rev 7.0	6.0	19-JUN-2012
Updated to add new design certificate number due to CE Renewal; update to latest revision of DoC template 8.0	7.0	23-JAN-2013
Updated to add new quality system certificate G1 13 02 39709 857 which replaces G1 12 02 39709 781	8.0	26 June 2013
Added EN ISO 14971:2012	9.0	25 July 2013
Updated to add new Quality System Certificate number	10.0	27 Mar 2015
Updated approver to Stacey Pivovar Updated referenced Standards for EN ISO 11135, EN ISO 10555, EN ISO 11607, Added EN 62366:2008 to referenced standards Updated titles for EN ISO 11135, EN ISO 10555 Updated Compliance for EN ISO 10993-1: 2009/AC:2010 and EN ISO 14971: 2012	11.0	17 Oct 2016
Update revision of standards EN ISO 11135, EN ISO 10555 Updated approver to Kiran Kuppuswamy	12.0	06-Apr-2017
Updated to latest revision of DoC template. Updated to reflect new EC certificate number. New certificate (G7 17 08 39709 01118) replaces certificate (G7 13 01 39709 856) and becomes effective February 3, 2018. As such, validity date updated to reflect February 3, 2018.	13.0	11-Dec-2017
Corrected Directive listing to 93/42/EEC.	14.0	22-Feb-2018
Updated referenced Standards for ISO 11135:2014, and EN 62366-1:2015	15.0	08-Mar-2018
Updated footnote ([4] Full compliance only for the design changes made to released product) removed to reflect Full Compliance to standard EN 62366-1:2015.	16.0	15-Mar-2018
Updated to reflect new EC Quality System certificate number. New certificate (G1 18 02 39709 01144) replaces certificate (G1 15 02 39709 975).	17.0	26-Apr-2018
Updated to reflect BL0016436 Rev 15.0 standards changes: • From EN 980:2008 to EN ISO 15223 -1:2016 • From EN 1041:2008 to EN 1041:2008/A1:2013	18.0	15-Jan-2019
Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2018 Updated EC Quality System Certificate number	19.0	21-Oct-2019
Updated to match Agile MAP revision numbering convention Added referral to change record for signatures and approval date Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020 Added Amendment 1:2018 to EN ISO 11135:2014	AA	01-Apr-2020
Updated EN ISO 11135:2014+A1:2018 to EN ISO 11135:2014+A1:2019	AB	12-Oct-2020
Updated EN ISO 14971 revision from 2012 to 2019 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019 Added standards ISO 14708-1 and ISO 14708-2	AC	Upon Approval

Updated ISO 10993-1:2018 to EN ISO 10993-1:2020		

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned :	Attain Venogram Balloon Catheter
Model number:	6215
Variants:	Not applicable
GMDN Code and Description	10688, Angiographic catheter, single-use
Classification, rule	Class III, Rule 6
Conformity Assessment Route:	Annex 2.3 with Annex 2.4
EC Certificate number:	G7 17 08 39709 01118
EC Quality System Certificate:	G1 039709 1144
Name & Address of Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 93/42/EEC[1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***Refer to document approval date in the change record***

Place: Minneapolis

Date: ***Refer to document approval date in the change record***

Name: Jeff Chaput
Title: Sr. Engineering Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN 1041	2008 + A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 10555-1	2013 Cor 2014	Sterile, Single-Use Intravascular Catheters - Part 1: General Requirements
EN ISO 10993-1	2020	Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing within a Risk Management Process
ISO 10993-7	2008 + Amd1:2019	Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals
ISO 11135	2014 +A1:2019	Sterilization of health-care products - Ethylene Oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971	2019	Medical devices – Application of risk management to medical devices
EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 62366-1	2015	Medical devices – Part 1: Application of usability engineering to medical devices
ISO 14708-1	2014	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
ISO 14708-2	2019	Implants for surgery - Active implantable medical devices - Part 2: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers) – Second edition

EC Design Examination Certificate
Active Implantable Medical Devices Directive 90/385/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 253 of 1994)*

HAS EXAMINED THE DESIGN DOSSIER
Submitted by

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis, MN 55432
USA

For Product Family

Heart Therapy Delivery Systems

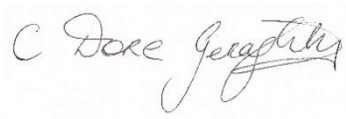
GMDN Code: 17846

CONCLUSION of EXAMINATION:

Complies with the requirements of Directive 90/385/EEC on Active Implantable Medical Devices Annex II (4)

Registration Number:	**253.100**
Original Approval:	**12 June 2002**
Last Amended on:	**03 March 2021**
Remains valid until:	**26 May 2024**

Signed:



Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

CONDITIONS OF VALIDITY:

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.

Approved model numbers are included in the associated attachment

Not valid without a valid Annex II Section 3 certificate

Note: Changes which could affect conformity with the essential requirements of Directive 90/385/EEC, or with the conditions prescribed for use of the product must receive further approval from NSAI.

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

File Ref	Model Reference	Detail
253.100.03 253.100.13 253.100.19 253.100.21 253.100.35	C304-S59	SelectSite™ C304-S59 Deflectable Catheter System
253.100.34 253.100.35	C304-HIS	SelectSite™ C304-HIS Deflectable Catheter system
253.100.03 253.100.13 253.100.19 253.100.21 253.100.35	C304-L69	SelectSite™ C304-L69 Deflectable Catheter System
253.100.13 253.100.19 253.100.21 253.100.35	C304-XL74	SelectSite™ C304-XL74 Deflectable Catheter System
253.100.13 253.100.19 253.100.35	6227DEF	Attain® 6227DEF Deflectable Catheter Delivery System
253.100.23 253.100.26 253.100.33 253.100.35	C315S4	C315S4 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315S5	C315S5 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315S10	C315S10 Delivery Catheter

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.23 253.100.26 253.100.33 253.100.35	C315J	C315J Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315HIS	C315HIS Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315H20	C315H20 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315H40	C315H40 Delivery Catheter
253.100.27 253.100.33 253.100.35	6250VIS	Attain Command™ + SureValve™ 6250VIS Left-Heart Delivery System
253.100.27 253.100.33 253.100.35	6250VIC	Attain Command™ + SureValve™ 6250VIC Left-Heart Delivery System
253.100.27 253.100.33 253.100.35	6250VI-MB2	Attain Command™ + SureValve™ 6250VI-MB2 Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-EH	Attain Command™ + SureValve™ 6250VI-EH Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-EHXL	Attain Command™ + SureValve™ 6250VI-EHXL Guide Catheter for Left-Heart Delivery

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.27 253.100.33 253.100.35	6250VI-MPR	Attain Command™ + SureValve™ 6250VI-MPR Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MP	Attain Command™ + SureValve™ 6250VI-MP Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-AM	Attain Command™ + SureValve™ 6250VI-AM Guide Catheter for Left Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MB2X	Attain Command™ + SureValve™ 6250VI-MB2X Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-45S	Attain Command™ + SureValve™ 6250VI-45S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-50S	Attain Command™ + SureValve™ 6250VI-50S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-57S	Attain Command™ + SureValve™ 6250VI-57S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MPX	Attain Command™ + SureValve™ 6250VI-MPX Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-3D	Attain Command™ + SureValve™ 6250VI-3D Guide Catheter for Left-Heart Delivery

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.27 253.100.35 253.100.36	6248VI-90	Attain Select™ II + SureValve™ 6248VI-90 Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90S	Attain Select™ II + SureValve™ 6248VI-90S Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90L	Attain Select™ II + SureValve™ 6248VI-90L Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130	Attain Select™ II + SureValve™ 6248VI-130 Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130L	Attain Select™ II + SureValve™ 6248VI-130L Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90P	Attain Select™ II + SureValve™ 6248VI-90P Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90SP	Attain Select™ II + SureValve™ 6248VI-90SP Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130P	Attain Select™ II + SureValve™ 6248VI-130P Delivery Catheter System

Quality System Approval Certificate
Active Implantable Medical Devices Directive 90/385/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 253 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis, MN 55432
USA

For the Product Family

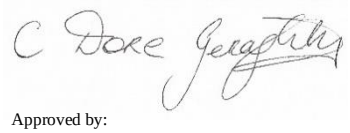
Heart Therapy Delivery Systems

GMDN Code: 17846

On the basis of examination under the requirements of Annex II, Section 3 of Directive 90/385/EEC,
The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product is hereby authorized.

Registration Number:	**253.100**
Original Approval:	**12 June 2002**
Last Amended on:	**03 March 2021**
Remains valid until:	**26 May 2024**

Signed:



Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI.
This certificate must be supported by a valid design examination certificate.

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE16

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 3
(Other devices than custom made or intended for clinical investigation)

Manufacturer:

Medtronic Inc.

710 Medtronic Parkway NE
Minneapolis MN 55432
United States Of America

For the product / product category

Left Ventricular Lead

Documents, that form the basis of this certificate:

Certification Notice 2007841CN, initially dated 1 January 2001
Addendum, initially dated 24 July 2007

DEKRA hereby declares that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 3 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 3 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 24 July 2007
Reissued: 1 August 2019

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2007841TE16

EC TYPE-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Left Ventricular Lead

Issued to:

Medtronic Inc.
710 Medtronic Parkway NE
Minneapolis MN 55432
United States Of America

This certificate covers the following product(s):

Attain Ability™ Model 4196
Attain Ability™ MRI SureScan™ 4196

The product is designed in the facility:

Medtronic, Inc., 8200 Coral Sea Street, Mounds View, MN 55112, USA

EC Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Initial date: 24 July 2007

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE28

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 3
(Other devices than custom made or intended for clinical investigation)

Manufacturer:
Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

For the product / product category

Leads for Brady IPGs and their auxiliary components

Documents, that form the basis of this certificate:

Certification Notice 2007841CN, initially dated 1 January 2001
Addendum, initially dated 30 April 2018

DEKRA hereby declares that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 3 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 3 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 29 September 2023
Issued for the first time: 30 April 2018
Reissued: 29 September 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2007841TE28

EC TYPE-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Medtronic Inc.

Issued to:

Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

This certificate covers the following product(s):

CapSure Sense MRI™ SureScan® models 4074, 4574
CapSureFix Novus MRI™ SureScan ® model 5076
CapSure Z Novus MRI SureScan TM models 5054, 5554

Initial date: 30 April 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE29

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 3
(Other devices than custom made or intended for clinical investigation)

Manufacturer:
Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

For the product / product category

Leads for Tachy IPGs/ ICDs and their auxiliary components

Documents, that form the basis of this certificate:

Certification Notice 2007841CN, initially dated 1 April 2001
Addendum, initially dated 30 April 2018

DEKRA hereby declares that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 3 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 3 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 30 March 2024
Issued for the first time: 30 April 2018
Reissued: 30 March 2019

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2007841TE29

EC TYPE-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Leads for Tachy IPGs/ ICDs and their auxiliary components

Issued to:

Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

This certificate covers the following product(s):

Sprint Quattro Secure MRI TM SureScan ™ models 6947, 6947M
Sprint Quattro Secure S MRI™ SureScan™ models 6935, 6935M
Sprint QuattroTM MRI SureScan TM 6946M

Initial date: 30 April 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1144 Rev. 02

Manufacturer: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product Category(ies): **External pacemakers, diagnostic and ablation catheter, transseptal needles**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713159141

Valid from: 2020-03-03
Valid until: 2024-05-26

Date, 2020-02-28

Christoph Dicks
Head of Certification/Notified Body

.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 17 08 39709 01118

Manufacturer:

Medtronic Inc.
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

EC-Representative:

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
THE NETHERLANDS

Product:

Catheters for single use
Cardiac Balloon Catheters

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713097898

Valid from: 2018-02-03
Valid until: 2023-02-02

Date, 2017-12-06

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 17 08 39709 01118

Model(s): **Attain Venogram Balloon Catheter 6215**

Parameters: ./.

Facility(ies): Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

Declaration of Conformity

Legal Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA
EC Authorized Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Design Facility:	Medtronic Inc. 8200 Coral Sea Street Mounds View, MN 55112 USA
Manufacturing Facility:	Medtronic Ireland Parkmore Business Park West Galway Ireland
Product Family/ies:	Heart Therapy Delivery Systems
Products:	See Attachment
Classification:	Directive 90/385/EEC (AIMD)

Notified Body	NSAI (0050)
EC Quality Certificate	253.100 issued on 12 June 2002
EC Design Certificate	253.100

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 90/385/EEC (AIMD), including amendments issued, which apply to them, as transposed into

the national laws of the EU member states, as well as the following applicable standards and guidance documents:

- Reference standards listed on the appropriate ER Checklist for each product family.

This declaration is supported by the AIMD, Annex II.3 Approval as well as the EC Design Examination Certificate listed above.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Place: Medtronic Inc. Date: 03-MAR-2021

Name: Ryan Calabrese

Title Sr. Regulatory Affairs Director Signature

Products: Heart Therapy Delivery Systems

Model Name	Model No.	Approval Date	Approval Number
SelectSite™ C304-S59 Deflectable catheter system	C304-S59	Mar. 24, 2004 October 11, 2006 October 3, 2008 April 13, 2010 March 3, 2021	253.100/03 253.100/13 253.100/19 253.100/21 253.100/35
SelectSite™ C304-L69 Deflectable catheter system	C304-L69		
SelectSite™ C304-XL74 Deflectable catheter system	C304-XL74	October 11, 2006 October 3, 2008 April 13, 2010 March 3, 2021	253.100/13 253.100/19 253.100/21 253.100/35
SelectSite™ C304-HIS Deflectable catheter system	C304-HIS	July 29, 2020 March 3, 2021	253.100/34 253.100/35
Attain® 6227DEF Deflectable Catheter Delivery System	6227DEF	October 11, 2006 October 3, 2008 March 3, 2021	253.100/13 253.100/19 253.100/35

Model Name	Model No.	Approval Date	Approval Number
C315S4 Delivery Catheter	C315S4	October 28, 2010 June 28, 2012 January 21, 2020 March 3, 2021	253.100/23 253.100/26 253.100/33 253.100/35
C315S5 Delivery Catheter	C315S5		
C315S10 Delivery Catheter	C315S10		
C315J Delivery Catheter	C315J		
C315HIS Delivery Catheter	C315HIS		
C315H20 Delivery Catheter	C315H20		
C315H40 Delivery Catheter	C315H40		

Model Name	Model No.	Approval Date	Approval Number
Attain Command™ + SureValve™ 6250VIC Left-Heart Delivery System	6250VIC	March 06, 2013 January 21, 2020 March 3, 2021	253.100/27 253.100/33 253.100/35
Attain Command™ + SureValve™ 6250VIS Left-Heart Delivery System	6250VIS		
Attain Command™ + SureValve™ 6250VI-45S Guide Catheter for Left-Heart Delivery	6250VI-45S		
Attain Command™ + SureValve™ 6250VI-50S Guide Catheter for Left-Heart Delivery	6250VI-50S		
Attain Command™ + SureValve™ 6250VI-57S Guide Catheter for Left-Heart Delivery	6250VI-57S		
Attain Command™ + SureValve™ 6250VI-AM Guide Catheter for Left-Heart Delivery	6250VI-AM		
Attain Command™ + SureValve™ 6250VI-EH Guide Catheter for Left-Heart Delivery	6250VI-EH		
Attain Command™ + SureValve™ 6250VI-EHXL Guide Catheter for Left-Heart Delivery	6250VI-EHXL		
Attain Command™ + SureValve™ 6250VI-MB2 Guide Catheter for Left-Heart Delivery	6250VI-MB2		
Attain Command™ + SureValve™ 6250VI-MB2X Guide Catheter for Left-Heart Delivery	6250VI-MB2X		
Attain Command™ + SureValve™ 6250VI-MP Guide Catheter for Left-Heart Delivery	6250VI-MP		
Attain Command™ + SureValve™ 6250VI-MPR Guide Catheter for Left-Heart Delivery	6250VI-MPR		
Attain Command™ + SureValve™ 6250VI-MPX Guide Catheter for Left-Heart Delivery	6250VI-MPX		
Attain Command™ + SureValve™ 6250VI-3D Guide Catheter for Left-Heart Delivery	6250VI-3D		

Model Name	Model No.	Approval Date	Approval Number
Attain Select™ II + SureValve™ 6248VI-90 Delivery Catheter System	6248VI-90	March 06, 2013 May 27, 2020 March 3, 2021	253.100/27 253.100/36 253.100/35
Attain Select™ II + SureValve™ 6248VI-90S Delivery Catheter System	6248VI-90S		
Attain Select™ II + SureValve™ 6248VI-90L Delivery Catheter System	6248VI-90L		
Attain Select™ II + SureValve™ 6248VI-130 Delivery Catheter System	6248VI-130		
Attain Select™ II + SureValve™ 6248VI-130L Delivery Catheter System	6248VI-130L		
Attain Select™ II + SureValve™ 6248VI-90P Delivery Catheter System	6248VI-90P		
Attain Select™ II + SureValve™ 6248VI-90SP Delivery Catheter System	6248VI-90SP		
Attain Select™ II + SureValve™ 6248VI-130P Delivery Catheter System	6248VI-130P		

Revision History

Revision	Date	Description of Change
1A	September 2010	Updated to include amendment number for the modified Attain Select II 6248DEL (Amendment # 253.100/22)
1B	November 2010	Updated to include the amendment number for the modified SelectSite™ C304 Deflectable Catheter System (Amendment # 253.100/21) and to add reference to the C315 Delivery Catheter product family (Amendment # 253.100/23)
1C	June 2011	Transpose into new template FTDOP116978-13 rev 1B. Update issue date of the EC Certificates. Remove Attain 6226DEF which is no longer manufactured. Other minor typographical updates.
1D	June 2011	Correct page numbering in the footer. Correction to a Typographical error only. No impact on the DoC content.
1E	November 2011	Updated to include amendment number for the modified Attain 6216A/6218A product family. Minor documentation updates also completed to align model names and formatting with the Design Examination Cert.
1F	July 2012	Updated to include amendment number for implementation of additional sterilisation site (Sterigenics) for the C315 Delivery Catheters and to update title of signatory
1G	March 2013	Updated to add the Attain Command + SureValve and Attain Select II + SureValve product family model names and numbers and their approval details (approval date/approval number).
1H	June 2014	Updated to remove Attain Prevail as product is no longer manufactured or in distribution. Updated also to list the specific model numbers for the Attain Select™ II delivery catheter systems and to reflect re-certification approval by NSAI
1J	November 2015	Updated to include amendment number for implementation of sterilsation cycle 7 for Attain Select™ II delivery catheter systems
1K	May 2017	Updated to reflect extension to current Design Examination certificate & Full Quality Assurance certificate
1L	July 2017	Updated to reflect re-certification approval by NSAI. Revision number corrected in footer.
AA	May 2020	Updated to reflect extension to current Design Examination certificate & Full Quality Assurance certificate for file 253.100.35 under review with NSAI. Update to current template revision FTDOP116978-13 Rev. AB.
AB	August 2020	Update to include amendment number for tip material change for C315 Delivery Catheter, Attain Command + SureValve and Attain Select II + SureValve product familes (file 253.100.33, 253.100.36). Add C304-HIS product family model name, number and approval dates as per file 253.100.34.
AC	August 2020	Updated to reflect extension to current Design Examination certificate & Full Quality Assurance certificate for file 253.100.35 under review with NSAI.
AD	November 2020	Update to reflect extension to current Design Examination certificate & Full Quality Assurance certificate for file 253.100.35

		under review with NSAI.
AE	March 2021	Updated to reflect re-certification approval by NSAI (File 253.100.35). Removed Attain Command, Attain Select II, Attain 6216A/6218A models as product is no longer manufactured or in distribution, and has been removed from the EC Design Examination Certificate as per file 253.100.35. Updated to current template.

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Product Service

EC Certificate

Full Quality Assurance System
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4)
(Other devices than custom made or intended for clinical investigation)

No. I1 039709 1185 Rev. 01

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product:

Brady IPGs
Tachy IPGs/ICDs
Implantable Monitoring and Recording Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 2. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 2 (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:I1 039709 1185 Rev. 01

Report no.: 713194270

Valid from: 2021-04-23
Valid until: 2024-05-26

Date, 2021-03-31

Christoph Dicks
Head of Certification/Notified Body

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Product Service

EC Certificate

Production Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 5
(Other devices than custom made or intended for clinical investigation)

No. I2 17 11 39709 01117

Manufacturer:
Medtronic Inc.
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

EC-Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
THE NETHERLANDS

Product:
Implantable Leads for AIMDs
Accessories for Implantable Leads for AIMDs

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 5. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 3 certificate is mandatory. See also notes overleaf.

Report No.: 713108566

Valid from: 2017-11-21
Valid until: 2022-11-20

Date, 2017-09-13

Stefan Preiß

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Product Service

EC Certificate
Production Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 5
(Other devices than custom made or intended for clinical investigation)

No. I2 17 11 39709 01117

Facility(ies):

Medtronic Puerto Rico Operations Co., Villalba
Rd. 149, Km. 56.3, Call Box 6001, Villalba, PR 00766, USA

Medtronic Singapore Operations Pte. Ltd.
49 Changi South Avenue 2, Nasaco Tech Centre, Singapore
486056, SINGAPORE

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Medtronic Bakken Research Center B.V.
Endepolsdomein 5, 6229 GW Maastricht, THE NETHERLANDS

Design Facility(ies):

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

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Product Service

EC Certificate

Production Quality Assurance System
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 5
(Other devices than custom made or intended for clinical investigation)

No. I2 039709 1117 Rev. 01

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product:

Implantable Leads for AIMDs
Accessories for Implantable Leads for AIMDs

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 5. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 3 certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:I2 039709 1117 Rev. 01

Report no.: 713194256

Valid from: 2021-04-23
Valid until: 2024-05-26

Date, 2021-03-31

Christoph Dicks
Head of Certification/Notified Body

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Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 17 10 39709 01141

Manufacturer:
Medtronic Inc.
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

EC-Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
THE NETHERLANDS

Product:
Implantable Cardioverter / Defibrillator Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713114729

Valid from: 2017-11-10
Valid until: 2022-11-09

Date, 2017-11-10

Stefan Preiß

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Product Service

EC Certificate
EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 17 10 39709 01141

Model(s): **see attachment**

Parameters: ./.

Facility(ies):

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Medtronic Puerto Rico Operations Co., Juncos
Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, PR 00777, USA

Medtronic Europe Sàrl
Route du Molliau 31, Case Postale, 1131 Tolochenaz, SWITZERLAND

Design Facility(ies):

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

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Product Service

Attachment for Certificate no I7 17 10 39709 01141
dated 2017-11-10

Product: **Implantable Cardioverter / Defibrillator Systems**

Test Report No.: 713114729

Model:	**Model No:**	**Variant:**
Primo MRI™ DR SureScan™	DDMD3D4	MR Conditional
Primo MRI™ DR SureScan™	DDMD3D1	MR Conditional
Primo MRI™ VR SureScan™	DVMD3D4	MR Conditional
Primo MRI™ VR SureScan™	DVMD3D1	MR Conditional
Mirro MRI™ DR SureScan™	DDME3D4	MR Conditional
Mirro MRI™ DR SureScan™	DDME3D1	MR Conditional
Mirro MRI™ VR SureScan™	DVME3D4	MR Conditional
Mirro MRI™ VR SureScan™	DVME3D1	MR Conditional

Munich, MHS-CRT, 2017-11-10

Stefan Preiß
Certification Medical Technology

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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 0948 Rev. 01

Manufacturer: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product: **Impl. Monitoring and Recording Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713173221

Valid from: 2020-06-08
Valid until: 2024-05-26

Date, 2020-05-19

Christoph Dicks
Head of Certification/Notified Body

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EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 0948 Rev. 01

Model(s): **see below**

Product: **Impl. Monitoring and Recording Systems**

Test Report No.: 71368814

Model:	**Model no.:**	**Variant:**
Reveal XT	9529	MR conditional
Reveal XT Patient Assistant	9539	-

Test Report No.: 713056429

Model:	**Model no.:**	**Variant:**
Patient Assistant	PA96000	-

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EC Certificate

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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Manufacturer: **Medtronic Inc.**
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

EC-Representative: Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

Product: **Implantable Pacemaker Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713127272

Valid from: 2018-09-30
Valid until: 2023-09-29

Date, 2018-09-19

Stefan Preiß

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EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Model(s): **see below**

Facility(ies):

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Medtronic Puerto Rico Operations Co., Juncos
Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, PR 00777, USA

Medtronic Europe Sàrl
Route du Molliau 31, Case Postale, 1131 Tolochenaz, SWITZERLAND

Medtronic Singapore Operations Pte. Ltd.
49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056, SINGAPORE

Design Facility(ies): Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Parameters: ./.

Implantable Pacemaker System: SureScan™

Product: **Implantable Pacemaker**

Test Report No.: 71350692

Model:	**Model No:**	**Variant:**
Advisa DR MRI™ SureScan™	A3DR01	MR Conditional

Test Report No.: 71366167

Model:	**Model No:**	**Variant:**
Ensura DR MRI™ SureScan™	EN1DR01	MR Conditional

Test Report No.: 713039269

Model:	**Model No:**	**Variant:**
Advisa SR MRI™ SureScan™	A3SR01	MR Conditional
Ensura SR MRI™ SureScan™	EN1SR01	MR Conditional

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Product Service

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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Product: Application Software (external)

Test Report No.: 71338901

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	SW005	2090	EnRhythm EMDR01

Test Report No.: 71351141

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	9995	2090	Advisa A3DR01

Test Report No.: 71368678

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	9995	2090	Ensura EN1DR01

Test Report No.: 713006624

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	SW018	2090	RevoMRI (US only)

Test Report No.: 713039234

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	9995	2090 29901	Advisa SR MRI SureScan A3SR01 Ensura SR MRI SureScan EN1SR01

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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Product: **Implantable Pacemakers**

Test Report No.: 713095776

Model:	**Model No:**	**Variant:**
Percepta™ Quad CRT-P MRI SureScan™	W4TR04	MR Conditional
Serena™ Quad CRT-P MRI SureScan™	W4TR05	MR Conditional
Solara™ Quad CRT-P MRI SureScan™	W4TR06	MR Conditional
Percepta™ CRT-P MRI SureScan™	W1TR04	MR Conditional
Serena™ CRT-P MRI SureScan™	W1TR05	MR Conditional
Solara™ CRT-P MRI SureScan™	W1TR06	MR Conditional

Product: **Application Software (external)**

Test Report No.: 713095780

Model:	**Model No:**	**for Programmer:**	**Implants to be programmed:**
Application Software (external)	SW040	2090 29901	Percepta™ Quad CRT-P MRI SureScan™ W4TR04 Serena™ Quad CRT-P MRI SureScan™ W4TR05 Solara™ Quad CRT-P MRI SureScan™ W4TR06 Percepta™ CRT-P MRI SureScan™ W1TR04 Serena™ CRT-P MRI SureScan™ W1TR05 Solara™ CRT-P MRI SureScan™ W1TR06

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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Product: Application Software

Test Report No.: 713095771

Model:	**Model No:**	**for Programmer:**	**Implants to be programmed:**
Azure / Astra Application Software	SW030	2090 29901	Azure™ XT DR MRI SureScan™ W2DR01 Azure™ S DR MRI SureScan™ W3DR01 Azure™ XT SR MRI SureScan™ W2SR01 Azure™ S SR MRI SureScan™ W3SR01 Astra™ XT DR MRI SureScan™ X2DR01 Astra™ S DR MRI SureScan™ X3DR01 Astra™ XT SR MRI SureScan™ X2SR01 Astra™ S SR MRI SureScan™ X3SR01

Product: **Implantable Pacemakers**

Test Report No.: 713095773

Model:	**Model No:**	**Variant:**
Azure™ XT DR MRI SureScan™	W2DR01	MR Conditional
Azure™ S DR MRI SureScan™	W3DR01	MR Conditional
Azure™ XT SR MRI SureScan™	W2SR01	MR Conditional
Azure™ S SR MRI SureScan™	W3SR01	MR Conditional
Astra™ XT DR MRI SureScan™	X2DR01	MR Conditional
Astra™ S DR MRI SureScan™	X3DR01	MR Conditional
Astra™ XT SR MRI SureScan™	X2SR01	MR Conditional
Astra™ S SR MRI SureScan™	X3SR01	MR Conditional

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Product: **Implantable Pacemakers**

Test Report No.: 713105247

Model:	**Model No:**	**Variant:**
Attesta™ DR MRI SureScan™	ATDR01	MR Conditional
Attesta™ L DR MRI SureScan™	ATDRL1	MR Conditional
Attesta™ S DR MRI SureScan™	ATDRS1	MR Conditional
Attesta™ SR MRI SureScan™	ATSR01	MR Conditional
Sphera™ DR MRI SureScan™	SPDR01	MR Conditional
Sphera™ L DR MRI SureScan™	SPDRL1	MR Conditional
Sphera™ SR MRI SureScan™	SPSR01	MR Conditional

Product: **Application Software (external)**

Test Report No.: 713105248

Model:	**Model No:**	**For Programmer:**	**Implants to be programmed**
Application Software	SW043	2090 29901	Attesta™ DR MRI SureScan™ ATDR01 Attesta™ L DR MRI SureScan™ ATDRL1 Attesta™ S DR MRI SureScan™ ATDRS1 Attesta™ SR MRI SureScan™ ATSR01 Sphera™ DR MRI SureScan™ SPDR01 Sphera™ L DR MRI SureScan™ SPDRL1 Sphera™ SR MRI SureScan™ SPSR01

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Product: Application Software (external)

Test Report No.: 713127914

Model:	**Model No:**	**External Device Manager System supported:**
CareLink SmartSync Azure Astra App	D00U003	CareLink SmartSync Device Manager Patient Connector 24967

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Medtronic Ireland
Parkmore Business Park West
Galway
Ireland

Holds Certificate Number: **MD 94974**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design and manufacture of vascular devices and heart valve delivery and loading systems. The manufacture of heart therapy/pacemaker delivery systems, biliary stents and delivery systems, nonactive implantable/non-implantable medical devices with drug coating/impregnation, catheter systems for renal denervation, venous occlusion systems, atherectomy systems, and implantable fixation systems. The loading & final assembly of transcatheter pacemaker systems. Provision of analytical test services for Medtronic Corporation facilities/sites.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2005-03-17
Latest Revision Date: 2021-08-04

Effective Date: 2021-08-09
Expiry Date: 2022-02-08

...making excellence a habit.™

Certificate No: **MD 94974**

Location	Registered Activities
Medtronic Ireland Parkmore Business Park West Galway Ireland	The design and manufacture of vascular devices and heart valve delivery and loading systems. The manufacture of heart therapy/pacemaker deliverysystems, biliary stents and delivery systems, nonactive implantable/non-implantable medical devices with drug coating/impregnation, catheter systems or renal denervation, venous occlusion systems, atherectomy systems, and implantable fixation systems. The loading & final assembly of transcatheter pacemaker systems. Provision of analytical test services for Medtronic Corporation facilities/sites.
Medtronic, Inc. 710 Medtronic Parkway Minneapolis Minnesota 55432 USA	Corporate Headquarters

Original Registration Date: 2005-03-17

Latest Revision Date: 2021-08-04

Effective Date: 2021-08-09

Expiry Date: 2022-02-08

Medtronic	Document Title: DoC-9529/9528	Document Number: MDT1951889
EC DECLARATION OF CONFORMITY	Insertable Cardiac Monitor (ICM) Reveal XT/DX, model 9529/9528	

Revision/History description	Revision level	Impl. Date
Declaration of Conformity was originally SQDM controlled by RA-290 version 1	-	01 Jun 2004
This Declaration of Conformity supersedes document RA290 version 1. Reveal models listed on RA290 were separated to their own individual DoCs. Updated to support AIMD Directive 90/385/EEC: Amendment 2007 and New Template	A	Upon Approval
Transfer CE marking from KEMA to TÜV SÜD Product Service as Notified Body.	B	30 Jun 2010
Update to reflect the details for the transition by serial, lot / batch number from KEMA (current notified body) to TUV (new notified body). Update compliance to EN ISO 11135-1	C	01 Octr 2010
Correct compliance statement to EN ISO 11135-1	D	12 Oct 2010
Update EC Quality System Certificate number	E	18 Nov 2010
Update for Reveal upgrade project include device firmware and software changes, functionality and labelling-added model 9528-previously included on DoC-9528-Reveal DX ICM. Note: This declaration replaces the old combined Reveal product system Declaration of Conformity. (DHF – QADoc: DSN003732)	2.0	19 Apr 2011
Conversion of Declaration of Conformity to the MRCS documentation system. Update to the latest standards and update to new template. Update to new EC Certificate and Quality System Certificate numbers. Removed notified body transfer attachment – transition was made from KEMA CE Mark to TuV CE Mark. First date of TuV marked package for European Packaged Product: July 29, 2010. First date of TuV marked package for Canadian Packaged Product: August 14, 2010.	2.0	05-Apr-2012
Updated to add new EC Quality System certificate number due to CE Renewal. New certificate (I1 13 02 39709 855) replaces certificate 9-761 and becomes effective May 2, 2013. As such, validity date updated to reflect May 2, 2013. Updated to new template.	3.0	26-Mar-2013
Update to ISO 14971:2012	4.0	26-Jul-2013
Updated to reflect new EC certificate number. New certificate (I7 15 06 39709 948) replaces certificate I7 12 02 39709 767 and becomes effective July 2, 2015. As such, validity date updated to reflect July 2, 2015.	5.0	25-Jun-2015
Updated standards: from EN ISO 11135-1:2007 to EN ISO 11135:2014; EN ISO 11607-1:2009 revision update to EN ISO 11607-1:2009+A1:2014. Added standards EN 60601-1:2006/A1:2013 and EN 60601-1-6:2010.	6.0	27-Oct-2016
Updated name of Senior Engineering Manager to Kiran Kuppuswamy. Updated standards: • from EN 60601-1-6:2010 to EN 60601-1-6:2010/Amd1:2013; Full Compliance • from EN 62366:2008 to EN 62366-1:2015	7.0	31-May-2017
Updated document template to revision AA. Updated Standards EN 60601-1-6:2010/Amd1:2013 to EN 60601-1-6:2010/A1:2015. Removed footnote on EN 62366-1:2015 to state full compliance.	8.0	16-Oct-2017
Added EN62304 to Attachment 1	9.0	25-Jan-2018
Updated to reflect new EC Quality System certificate number. New certificate (I1 18 03 39709 01185) replaces certificate I1 13 02 39709 855 and becomes effective May 2, 2018. As such, validity date updated to reflect May 2, 2018.	10.0	17-Apr-2018
Updated standards related to labelling and instructions for use: replaced EN 980 with EN ISO 15223-1, EN 1041, EN 45502-1. Updated formatting of number and date of issue and title of EN 62366-1.	11.0	24-Jan-2019
Replaced EN ISO 10993-1:2009/AC:2010 with ISO 10993-1:2018	12.0	18-Jul-2019
Update to new product certificate I7 039709 0948 (valid starting 08-Jun-2020) Added Amendment 1:2018 to EN ISO 11135:2014 Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020	13.0	02-Jun-2020
Update with cease manufacture information for 9528 Updated EN ISO 11135:2014+A1:2018 to 11135:2014+A1:2019 Changed EN 60601-1:2006+A1:2013 to EN 60601-1:2006+A12:2014. The change is due to the incorporation of technical corrigendum July 2014 (technical correction of Figure 12). Updated to match Agile MAP revision numbering convention Added referral to change record for signatures and approval date	AA	12-Oct-2020
Updated EC Quality System Certificate Number. New certificate (I1 039709 1185) replaces existing certificate and becomes effective 23 April 2021.	AB	18-May-2021
Updated standard compliance for EN ISO 14971, EN ISO 10993-1, and ISO 10993-7	AC	Upon Approval

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned : Model number: Variants:	Insertable Cardiac Monitor (ICM) – Reveal XT and Reveal DX 9529, 9528 Not Applicable
GMDN Code and Description	12103, Impedance Cardiograph
Classification, rule	AIMD
Conformity Assessment Route:	Annex 2.3 with Annex 2.4
EC Certificate number:	I7 039709 0948
EC Quality System Certificate:	I1 039709 1185
Name & Address of Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC [1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***08-Jun-2020*** Place: Minneapolis Date: ***Refer to document approval date in the change record***

Name: Jeffrey Chaput
Title: Sr. Engineering Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041	2008+A1: 2013	Information supplied by the manufacturer of medical devices
EN 45502-1	2015	Implants for surgery - Active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-1	2003	Active implantable medical devices – Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)
EN ISO 11135	2014+A1: 2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971	2019	Medical devices – Application of risk management to medical devices
EN ISO 10993-1	2020	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
EN ISO 10993-7	2008+Amd.1:2019	Biological evaluation of medical devices - Part 7: Ethylene Oxide sterilization residuals
EN 60601-1 Clause 14	2006+ A12:2014	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-6	2010/A1: 2015	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
EN 62366-1	2015	Medical Devices – Part 1: Application of usability engineering to medical devices
EN 62304	2006+A1: 2015	Medical device software. Software life-cycle processes.

Attachment 2: Cease Manufacturing Information

The following product is no longer manufactured as shown by the information provided below.

Model Name	Model Number(s)	Last Manufacture Date	Last Manufacture Lot
Reveal DX	9528	05-May-2015	**RAB778109S**

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D-ZM-11321-01-00

Product Service

Certificate

No. Q5 039709 1202 Rev. 01

Holder of Certificate: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Facility(ies): Medtronic Bakken Research Center B.V.
Endepolsdomein 5, 6229 GW Maastricht, THE NETHERLANDS

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and development and manufacturing of implantable leads and accessories and design and development of medical software. Translation of medical device software and product information**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713183409

Valid from: 2020-07-28
Valid until: 2023-05-31

Date, 2020-07-28

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 039709 1219 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Medtronic Inc.
7000 Central Avenue N.E., Minneapolis MN 55432, USA

Medtronic Inc.,
800 53rd Avenue NE, Columbia Heights MN 55421, USA

Medtronic Inc.
710 Medtronic Parkway N.E., Minneapolis, MN 55432, USA

Legal Entity with Management Oversight Responsibility for all Quality Related Matters

Medtronic Inc.
8200 Coral Sea St., Mounds View, MN 55112, USA

Design and development, production and distribution of Brady and Tachy IPGs, Pacemaker Delivery Systems, Leads and Accessories for Brady and Tachy IPGs, Ablation Systems/ Devices, Diagnostic and Ablation Catheters and their Accessories, Programmers for AIMDs, Application Software (external), External Pacemakers, Software and Hardware Systems for acquisition and management of ECG and cardiac device data, Implantable Monitoring and Recording Systems, and fully absorbable surgical implants coated with ancillary medicinal substances, and Service of Programmers for AIMDs, External Pacemakers, External Patient Monitors and RF Generators

Medtronic Inc.
7000 Central Avenue N.E., Minneapolis, MN 55432, USA

Manufacturing of Leads and Accessories for Brady and Tachy IPGs, and fully absorbable surgical implants coated with ancillary medicinal substances

Medtronic Inc. Service Center
Sullivan Lake, 800 53rd Avenue NE, Columbia Heights, MN 55421, USA

Service of Programmers for AIMDs, External Pacemakers, External Patient Monitors and RF Generators

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 039709 1219 Rev. 00

Holder of Certificate: **Medtronic Inc.**
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production and distribution of Brady and Tachy IPGs, Pacemaker Delivery Systems, Leads and Accessories for Brady and Tachy IPGs, Ablation Systems/ Devices, Diagnostic and Ablation Catheters and their Accessories, Programmers for AIMDs, Application Software (external), External Pacemakers, Software and Hardware Systems for acquisition and management of ECG and cardiac device data, Implantable Monitoring and Recording Systems, and fully absorbable surgical implants coated with ancillary medicinal substances, and Service of Programmers for AIMDs, External Pacemakers, External Patient Monitors and RF Generators**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713137849

Valid from: 2019-04-01
Valid until: 2022-03-31

Date, 2019-04-01

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 039709 1219 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Medtronic Inc.
7000 Central Avenue N.E., Minneapolis MN 55432, USA

Medtronic Inc.,
800 53rd Avenue NE, Columbia Heights MN 55421, USA

Medtronic Inc.
710 Medtronic Parkway N.E., Minneapolis, MN 55432, USA

Legal Entity with Management Oversight Responsibility for all Quality Related Matters

Medtronic Inc.
8200 Coral Sea St., Mounds View, MN 55112, USA

Design and development, production and distribution of Brady and Tachy IPGs, Pacemaker Delivery Systems, Leads and Accessories for Brady and Tachy IPGs, Ablation Systems/ Devices, Diagnostic and Ablation Catheters and their Accessories, Programmers for AIMDs, Application Software (external), External Pacemakers, Software and Hardware Systems for acquisition and management of ECG and cardiac device data, Implantable Monitoring and Recording Systems, and fully absorbable surgical implants coated with ancillary medicinal substances, and Service of Programmers for AIMDs, External Pacemakers, External Patient Monitors and RF Generators

Medtronic Inc.
7000 Central Avenue N.E., Minneapolis, MN 55432, USA

Manufacturing of Leads and Accessories for Brady and Tachy IPGs, and fully absorbable surgical implants coated with ancillary medicinal substances

Medtronic Inc. Service Center
Sullivan Lake, 800 53rd Avenue NE, Columbia Heights, MN 55421, USA

Service of Programmers for AIMDs, External Pacemakers, External Patient Monitors and RF Generators

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D-ZM-11321-01-00

Product Service

Certificate

No. Q5 039709 1219 Rev. 00

Holder of Certificate: **Medtronic Inc.**
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production and distribution of Brady and Tachy IPGs, Pacemaker Delivery Systems, Leads and Accessories for Brady and Tachy IPGs, Ablation Systems/ Devices, Diagnostic and Ablation Catheters and their Accessories, Programmers for AIMDs, Application Software (external), External Pacemakers, Software and Hardware Systems for acquisition and management of ECG and cardiac device data, Implantable Monitoring and Recording Systems, and fully absorbable surgical implants coated with ancillary medicinal substances, and Service of Programmers for AIMDs, External Pacemakers, External Patient Monitors and RF Generators**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713137849

Valid from: 2019-04-01
Valid until: 2022-03-31

Date, 2019-04-01

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Medtronic	Document Title: DoC- Sprint Quattro Secure S MRI SureScan Model 6935M	Document Number: BL0028236
EC DECLARATION OF CONFORMITY	Sprint Quattro Secure S MRI™ SureScan™ Model 6935M tripolar, active fixation lead for pacing, sensing, cardioversion, and defibrillation	

Revision/History description	Revision level	Impl. Date
Initial Release	2.0	31 March 2014
Update to add new EC certificate number. New certificate (I7 14 07 39709 938) replaces certificate I7 14 03 39709 932.	3.0	1 July 2015
Standard revision review as part of the 3T MRI labelling expansion and aligns with version 8 of ER Matrix BL0024033 and new CE certificate I7 16 01 39709 01027	4.0	25-Feb-2016
Updated quality system certificate number Updated approver to Kiran Kuppuswamy	5.0	07-Apr-2017
Correction to listing for EN 62366-1. Updated to reflect new EC certificate number. New certificate (2007841TE29) replaces certificate (I7 16 01 39709 01027) and becomes effective April 30, 2018. As such, validity date updated to reflect April 30, 2018. Conformity assessment route updated from “Annex 2.3 with Annex 2.4” to “Annex 3 with Annex 5”. Update to EC Quality System Certificate to applicable Annex 5 certificate I2 17 11 39709 01117.	6.0	18-Apr-2018
Updated to reflect BL0024732 Rev 13 ERM Standards Changes: 1) From EN 980:2008 To: EN ISO 15223-1:2016 2) From: EN 1041:2008 To: EN 1041:2008/A1:2013 3) From: EN 45502-1:1997 To: EN 45502-1:2015	7.0	14-Jun-2018
Updated Standards EN ISO 11607 and EN ISO 11135	8.0	15-Jan-2019
Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2019	9.0	04-Dec-2019
Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020	10.0	21-Feb-2020
Added Amendment 1:2019 to EN ISO 11135:2014, updated title Updated to match Agile MAP revision numbering convention Added referral to change record for signatures and approval date	A	12-Oct-2020
Updated EN ISO 14971 revision from 2012 to 2019 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019 Added standards ISO 14708-1 and ISO 14708-6 Updated ISO 10993-1:2018 to EN ISO 10993-1:2020	B	Upon Approval

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned : Model number: Variants:	Sprint Quattro Secure S MRI™ SureScan™ 6935M Lead Lengths: 55cm, 62cm
GMDN Code and Description	35853, Endocardial defibrillation lead
Classification, rule	AIMD
Conformity Assessment Route:	Annex 3 with Annex 5
EC Certificate number:	2007841TE29
EC Quality System Certificate:	I2 17 11 39709 01117
Name & Address of Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC[1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***30-Apr-2018*** Place: Minneapolis Date: ***Refer to document approval date in the change record***

Name: Jeff Chaput
Title: Sr. Engineering Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN 556-1	2001/AC: 2006	Sterilization of medical devices – Requirements for medical devices to be designated “Sterile” – Part 1: requirements for terminally sterilized medical devices
EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041	2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 10993-1	2020	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-7	2008 + Amd1:2019	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
EN ISO 11135	2014 + A1:2019	Sterilization of healthcare products —Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
ISO 27186	2010	Active implantable medical devices – Four pole connector system for implantable cardiac rhythm management devices – Dimensional and test Requirements
EN 45502-1	2015	Implants for surgery - Active implantable medical devices – Part 1: General Requirements for Safety, Marking and Information to be provided by the Manufacturer
ISO 14708-1	2014	Implants for surgery - Active implantable medical devices – Part 1: General Requirements for Safety, Marking and Information to be provided by the Manufacturer
EN 45502-2-2	2008/AC: 2009	Active implantable medical devices –Part 2- 2: Particular requirements for AIMDs Intended to Treat Tachyarrhythmia (includes implantable defibrillators)
ISO 14708-6	2019	Implants for surgery - Active implantable medical devices –Part 6: Particular requirements for AIMDs Intended to Treat Tachyarrhythmia (includes implantable defibrillators) – Second edition
EN 62366-1	2015	Medical Devices – Part 1: Applications of Usability Engineering to Medical Devices

Medtronic	Document Title: **EC DoC- Percepta/Serena/Solara Family of Devices**	Document Number: **DSN024248** DHF Project Name: **CRT-P Quad** Deliverable: **Declaration of Conformity**
EC DECLARATION OF CONFORMITY	**Percepta/Serena/Solara CRT-P MRI SureScan devices**	

Revision/History description	Revision level	Impl. Date
Initial Release for Percepta™/Percepta™ Quad, Serena™/Serena™ Quad, and Solara™/Solara™ Quad CRT-P MRI SureScan™ devices (Percepta/Serena/Solara family of devices) and Application Software (external) Model SW040	2.0	13-Feb-2017
Updated to template Rev AA Added "DHF Project Name: CRT-P Quad" to Header Updated EC Quality System certificate I1 17 11 39709 01115 (effective November 21, 2017) replaces I1 12 11 39709 842 Updated 'Validity DoC from date: Refer to cover page' to 21-November-2017 in line with new certificate effective date Updated approver name and title Updated Standard Titles to EN 1041 and EN ISO 10993-1 Updated to correct prefix and title of EN ISO 11135 Updated to correct revision of EN ISO 11607-1 Updated to correct omitted Part Number in EN 62366-1 to agree with revision year Updated Standards EN 60601-1, EN 60601-1-6, EN 62304	3.0	20-Oct-2017
Updated to reflect new EC Quality System certificate number. New certificate (I1 18 03 39709 01185) replaces certificate I1 13 02 39709 855 and becomes effective May 2, 2018. As such, validity date updated to reflect May 2, 2018.	4.0	20-Apr-2018
Updated to reflect new EC certificate number. New certificate (I7 18 04 39709 01191) replaces certificate I7 15 07 39709 987 and is effective as of April 30, 2018.	5.0	03-May-2018
Updated to reflect new EC Certificate number. New certificate (I7 039709 1199) replaces certificate I7 18 04 39709 01191 and becomes effective September 30, 2018. As such, validity date updated to reflect September 30, 2018.	6.0	09-Sep-2018
Updated to add Device App for SmartSync and updating Standards	7.0	18-Jan-2019
-Correct standard "ISO 15223-1" to "EN ISO 15223-1".Update "EN 60601-1" standard date of issue to "2006/A12:2014". -Application D00U004 is approved on June 17, 2019, updated to reflect effective date of new certificate. -Updated approver name and title on certificate	A	30-May-2019
Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2018 Changed "cover page" to "change record" to match Agile approval process	B	02-Dec-2019
Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020 Added Amendment 1 :2018 to EN ISO 11135:2014	C	01-Apr-2020
Updated to reflect compliance to EN 82304-1:2017 NOTE: EN 82304-1: 2017 is identical to IEC 82304-1:2016.	D	13-Apr-2020
Updated Quality System Certificate Number. New certificate (I1 039709 1115) replaces existing certificate (I1 17 11 39709 01115) and becomes effective 01 June 2020.	E	02-Jun-2020
Updated EN ISO 11135:2014+A1:2018 to EN ISO 11135:2014+A1:2019	F	12-Oct-2020
Updated EC Quality System Certificate Number. New certificate (I1 039709 1185) replaces existing certificate and becomes effective 23 April 2021.	G	18-May-2021
Updated EN ISO 14971 revision from 2012 to 2019 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019 Updated EN ISO 10993-1 revision from 2018 to 2020	H	Upon Approval

Added standards ISO 14708-1, ISO 14708-2 Clause 6, and ISO 14708-6		

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned :	Percepta™, Serena™, Solara™ implantable cardiac pacemakers with cardiac resynchronization therapy (CRT-P) and SureScan Technology and Programmer Application Software (External)
Model number:	See Attachment 2
Variants:	None
GMDN Code and Description	47263, Cardiac resynchronization therapy implantable pacemaker 47206, Cardiac pulse generator software
Classification, rule	AIMD
Conformity Assessment Route:	Annex 2.3 combined with 2.4
EC Certificate number:	I7 039709 1199 (for device models and SW040 & D00U004, external application software)
EC Quality System Certificate:	I1 039709 1185 (for device models) I1 039709 1115 (for application software)
Name & Address of Notified Body:	TUV SÜD PS GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC[1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date:***Refer to change record*** Place: Minneapolis Date: ***Refer to change record***

Name: Jeffrey Chaput
Title: Sr. Software Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the Percepta/Serena/Solara model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN ISO 15223-1	2016	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements Second Edition
EN 1041	2008 + Amd1: 2013	Information supplied by the manufacturer of medical devices
ISO 5841-3	2013	Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers
EN ISO 10993-1	2020	Biological Evaluation of Medical Devices - Part 1: Evaluation And Testing within a risk management process
ISO 10993-7	2008 + Amd1:2019	Biological Evaluation of Medical devices - Part 7: Ethylene Oxide sterilization residuals
EN ISO 11135	2014 + A1:2019	Sterilization of health-care products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
EN 45502-1	2015	Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
ISO 14708-1	2014	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN 45502-2-1 Clause 6	2003	Implants for surgery - Active implantable medical devices -- Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (includes cardiac pacemakers) – Second edition
ISO 14708-2 Clause 6	2019	Implants for surgery - Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (includes cardiac pacemakers) – Second edition
EN 45502-2-2	2008/AC: 2009	Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)
ISO 14708-6	2019	Implants for surgery - Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) – Second edition
EN 62304	2006 + A1:2015	Medical device software. Software life-cycle processes
EN 62366-1	2015	Medical devices – Part 1: Application of usability engineering to medical devices
EN 82304-1: 2017	2017	Health software – Part 1: General requirements for product safety NOTE: EN 82304-1: 2017 is identical to IEC 82304-1:2016.

The below mentioned Standard(s) apply to the external software (SW040 & D00U004) included under the scope of this DoC.

Number	Date of issue	Title
EN ISO 15223-1	2016	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements Second Edition
EN 1041	2008 + Amd1:2013	Information supplied by the manufacturer of medical devices
EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
EN 45502-1	2015	Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
ISO 14708-1	2014	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN 60601-1 Clause 14	2006 + A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-6	2010 + A1:2015	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
EN 62304	2006 + A1:2015	Medical device software. Software life-cycle processes
EN 62366-1	2015	Medical devices – Part 1: Application of usability engineering to medical devices
EN 82304-1: 2017	2017	Health software – Part 1: General requirements for product safety NOTE: EN 82304-1: 2017 is identical to IEC 82304-1:2016.

Attachment 2: Model Listing

The following models are included under the scope of this DoC:

Model Name	Model Number(s)	Variant(s)
Percepta™ Quad CRT-P MRI SureScan™	W4TR04	Not applicable
Percepta™ CRT-P MRI SureScan™	W1TR04	Not applicable
Serena™ Quad CRT-P MRI SureScan™	W4TR05	Not applicable
Serena™ CRT-P MRI SureScan™	W1TR05	Not applicable
Solara™ Quad CRT-P MRI SureScan™	W4TR06	Not applicable
Solara™ CRT-P MRI SureScan™	W1TR06	Not applicable
External application software (2090, Encore) for Percepta/Serena/Solara Family of Devices	SW040	Not applicable
External application software (SmartSync) for Percepta/Serena/Solara Family of Devices	D00U004	Not applicable

Medtronic	Document Title: DoC-Primo MRI and Mirro MRI ICDs and SW033 DHF Project Name: HP MRI	Document Number: DSN026518 Deliverable: Declaration of Conformity
EC DECLARATION OF CONFORMITY	**Primo MRI™ SureScan™ and Mirro MRI™ SureScan™ Implantable Cardioverter Defibrillators and Application Software SW033**	

Revision/History description	Revision level	Impl. Date
Initial Release	2.0	15-Nov-2017
Updated to reflect new EC Quality System certificate number. New certificate (I1 18 03 39709 01185) replaces certificate I1 13 02 39709 855 and becomes effective May 2, 2018. As such, validity date updated to reflect May 2, 2018.	3.0	20-Apr-2018
Updated to reflect new EC certificate number. New certificate (I7 18 04 39709 01192) replaces certificate I7 16 01 39709 01027 and is effective as of April 30, 2018.	4.0	03-May-2018
Updated to reflect DSN013032 Rev 15 ERM Standards Changes: 1) From: EN 980:2008 To: EN ISO 15223-1:2016 2) From: EN 1041:2008 To: EN 1041:2008/A1:2013	5.0	11-Jul-2018
Updated DoC DSN026518 to reflect new EC certificate number for application software which becomes valid March 31, 2019. Validity date updated to reflect March 31, 2019. Administrative updates to date and signature verbiage to refer to electronic change record. Administrative updates to document attributes in Agile MAP.	A	31-Mar-2019
Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2018 Corrected format of applicable standards in attachment 1	B	06-Dec-2019
Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020 Added Amendment 1 :2018 to EN ISO 11135:2014	C	01-April-2020
Updated Quality System Certificate Number. New certificate (I1 039709 1115) replaces existing certificate (I1 17 11 39709 01115) and becomes effective 01 June 2020.	D	02-Jun-2020
Updated EN ISO 11135:2014+A1:2018 to EN ISO 11135:2014+A1:2019 Changed EN 60601-1:2006+A1:2013 to EN 60601-1:2006+A12:2014. The change is due to the incorporation of technical corrigendum July 2014 (technical correction of Figure 12).	E	12-Oct-2020
Updated EC Quality System Certificate Number. New certificate (I1 039709 1185) replaces existing certificate and becomes effective 23 April 2021.	F	18-May-2021
Updated EN ISO 14971 revision from 2012 to 2019 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019 Updated EN ISO 10993-1 revision from 2018 to 2020 Added standards ISO 14708-1:2014, ISO 14708-2:2019 Clause 6, and ISO 14708-6:2019	G	Upon Approval

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned:	Primo MRI™ and Mirro MRI™ SureScan™ Implantable Cardioverter-Defibrillator (ICD) Devices and Application Software (External)
Model number:	See Attachment 2
Variants:	Not Applicable
GMDN Code and Description	37265, Dual-chamber implantable defibrillator and 35852, Single Chamber Implantable Defibrillator **47206, Cardiac pulse generator software**
Classification, rule	AIMD
Conformity Assessment Route:	Annex 2.3 with 2.4
EC Certificate number:	I7 17 10 39709 01141 (for devices) I7 039709 1192 (for application software)
EC Quality System Certificate:	I1 039709 1185 (for devices) I1 039709 1115 (for application software)
Name & Address of Notified Body:	TUV SUD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC[1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***Refer to document approval date in the change record***

Place: Minneapolis

Date: ***Refer to document approval date in the change record***

Name: Jeffrey Chaput
Title: Sr. Engineering Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN 556-1	2001/AC:2006	Sterilization of medical devices – Requirements for medical devices to be labeled "Sterile" – Part 1: requirements for terminally sterilized medical devices
EN ISO 15223-1	2016	Symbols for use in the labelling of medical devices
EN 1041	2008 + A1:2013	Information supplied by the manufacturer of medical devices
ISO 5841-3[2]	2013	Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers
EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-7	2008 + Amd1:2019	Biological Evaluation of Medical Devices – Part 7: Tests for Ethylene Oxide Sterilization Residuals
EN ISO 11135	2014 + A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11318	2002	Cardiac Defibrillators – Connector assembly DF-1 for implantable defibrillators - Dimensions and test requirements
ISO 11607-1	2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
ISO 27186	2010	Active implantable medical devices -- Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements
EN 45502-1	2015	Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
ISO 14708-1	2014	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-1[3] Clause 6	2003	Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)
ISO 14708-2 Clause 6	2019	Implants for surgery - Active implantable medical devices - Part 2: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (includes cardiac pacemakers) – Second edition
EN 45502-2-2	2008/AC:2009	Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)
ISO 14708-6	2019	Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) – Second edition
EN 60601-1[4] Clause 14	2006 + A12:2014	Medical Electrical Equipment - Part 1: General Requirements for basic Safety and Essential Performance

[2] *EN 50077:1993 Low-Profile connector for implantable pacemakers is equivalent to ISO 5841-3*
[3] *Full Compliance (only clause 6 applies for ICD devices)*
[4] *Full Compliance (only clause 14 is applicable)*

EN 60601-1-6	2010 + A1:2015	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62304	2015	Medical device software. Software life-cycle processes
EN 62366-1	2006 + A1:2015	Medical devices – Part 1: Application of usability engineering to medical devices

Attachment 2: Model Listing

The following models are included under the scope of this DoC:

Model Name	Model Number(s)	Variant(s)
Primo MRI™ VR SureScan™	DVMD3D1, DVMD3D4	N/A
Mirro MRI™ VR SureScan™	DVME3D1, DVME3D4	N/A
Primo MRI™ DR SureScan™	DDMD3D1, DDMD3D4	N/A
Mirro MRI™ DR SureScan™	DDME3D1, DDME3D4	N/A
Model SW033 Programmer Software Application	SW033	N/A

CARDIAC RHYTHM MANAGEMENT AND CARDIOVASCULAR DIAGNOSTICS & SERVICES

PRODUCT CATALOGUE 2021

Medtronic
Further, Together

TABLE OF CONTENT

PACEMAKERS (IPG)

Single Chamber (SR)

AZURE™ XT SR MRI
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Implant Detection
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- Lead Monitor (RV) with Auto Polarity Switch
- CareAlert Monitoring
- Carelink connectivity with CareAlerts

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- Conducted AF Response (CAFR)

HEART FAILURE (HF) MANAGEMENT
Algorithm to help manage heart failure.
- OptiVol 2.0

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Histograms Reports
- Ventricular Episodes including EGMs

Model	W2SR01
M (g)	22.5
V (cc)	12.25
Size (mm) (HxWxD)	42.6 x 50.8 x 7.4
Connector	IS-1 BI/UNI

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

AZURE™ S SR MRI
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Implant Detection
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- Lead Monitor (RV) with Auto Polarity Switch
- CareAlert Monitoring
- Carelink connectivity with CareAlerts

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Ventricular Episodes including EGMs

Model	W3SR01
M (g)	22.5
V (cc)	12.25
Size (mm) (HxWxD)	42.6 x 50.8 x 7.4
Connector	IS-1 BI/UNI

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ASTRA™ XT SR MRI
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- Lead Monitor (RV) with Auto Polarity Switch
- CareLink connectivity

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- Conducted AF Response (CAFR)

HEART FAILURE (HF) MANAGEMENT
Algorithm to help manage heart failure
- OptiVol 2.0

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Histograms Reports
- Ventricular Episodes including EGMs

Model	X2SR01
M (g)	22.5
V (cc)	12.2
Size (mm) (HxWxD)	42.6 x 50.8 x 7.4
Connector	IS-1 BI/UNI

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ATTESTA™ SR MRI
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- TherapyGuide
- Capture Management (RV)
- Sensing Assurance (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- Conducted AF Response (CAFR)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Histogram Reports
- Atrial and Ventricular Episodes including EGMs
- Additional Clinician Selected Diagnostics

Model	ATSR01
M (g)	21.5
V (cc)	9.7
Size (mm) (HxWxD)	40.2 x 42.9 x 7.5
Connector	IS-1 BI/UNI

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SPHERA™ SR MRI
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- TherapyGuide
- Capture Management (RV)
- Sensing Assurance (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Histogram Reports
- Atrial and Ventricular Episodes including EGMs
- Additional Clinician Selected Diagnostics

Model	SPSR01
M (g)	21.5
V (cc)	9.7
Size (mm) (HxWxD)	40.2 x 42.9 x 7.5
Connector	IS-1 BI/UNI

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ADVISA SR MRI™
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- Lead Monitor (RV) with Auto Polarity Switch
- CareLink connectivity

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- Conducted AF Response (CAFR)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Histograms Reports
- Ventricular Episodes including EGMs

Model	A3SR01
M (g)	21.0
V (cc)	11.9
Size (mm) (HxWxD)	51 x 42 x 8
Connector	IS-1 BI/UNI

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ENSURA SR MRI™
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- Lead Monitor (RV) with Auto Polarity Switch
- CareLink connectivity

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Histogram Reports
- Ventricular Episodes including EGMs

Model	EN1SR01
M (g)	21.0
V (cc)	11.9
Size (mm) (HxWxD)	51 x 42 x 8
Connector	IS-1 BI/UNI

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ADAPTA® SR

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE

Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.

- Implant Detection
- TherapyGuide
- Capture Management (RV)
- Sensing Assurance (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

AT/AF MANAGEMENT

Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.

- Conducted AF Response (CAFR)

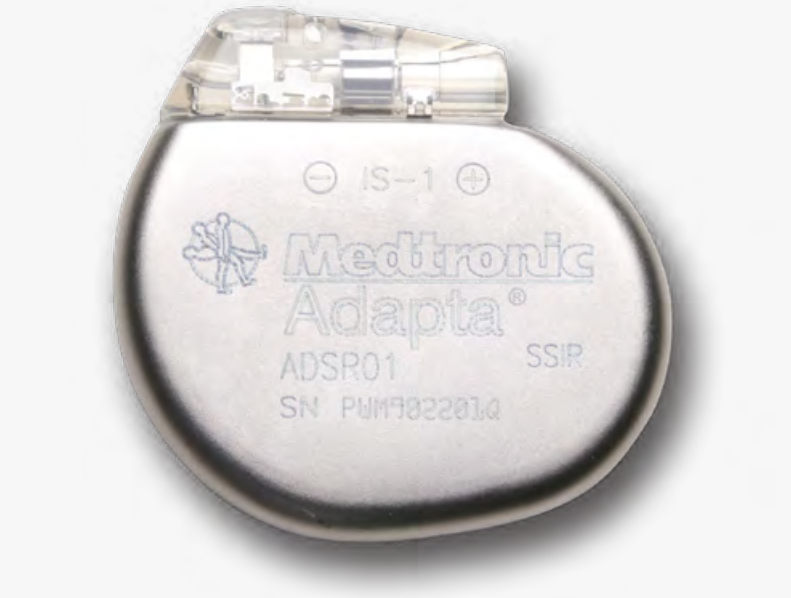
ADDITIONAL PACING FEATURES

- Rate Hysteresis
- Sleep Function
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS

- Quick Look II
- Histogram Reports
- Atrial and Ventricular Episodes including EGMs
- Additional Clinician Selected Diagnostics

Model	ADSR01	ADSR03	ADSR06
M (g)	21.5	22.5	22.5
V (cc)	9.7	10.5	11.0
Size (mm) (HxWxD)	40.2 x 42.9 x 7.5	42.9 x 42.9 x 7.5	43.3 x 42.9 x 7.5
Connector	IS-1 BI/UNI	IS-1 BI/UNI; 3.2 mm LP BI	5 or 6 mm UNI



NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SENSIA® SR

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE

Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.

- Implant Detection
- TherapyGuide
- Capture Management (RV)
- Sensing Assurance (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

ADDITIONAL PACING FEATURES

- Rate Hysteresis
- Sleep Function
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS

- Quick Look II
- Histogram Reports
- Atrial and Ventricular Episodes including EGMs
- Additional Clinician Selected Diagnostics

Model	SESR01
M (g)	21.5
V (cc)	9.7
Size (mm) (HxWxD)	40.2 x 42.9 x 7.5
Connector	IS-1 BI/UNI

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SENSIA® S

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE

Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.

- Implant Detection
- TherapyGuide
- Capture Management (RV)
- Sensing Assurance (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

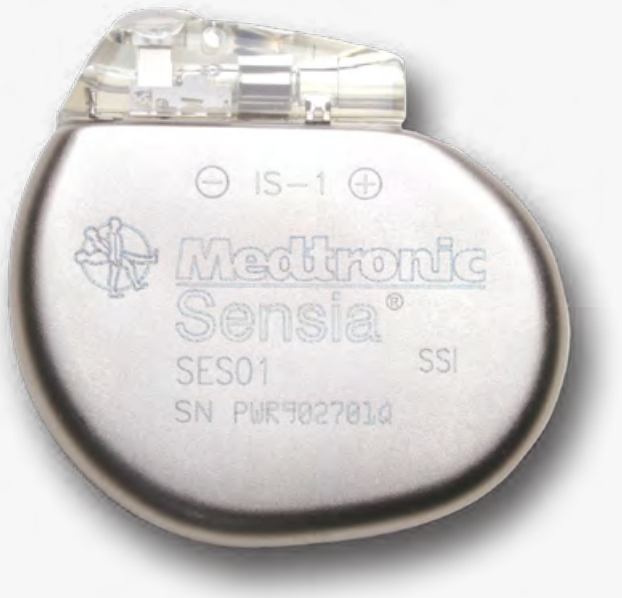
ADDITIONAL PACING FEATURES

- Rate Hysteresis
- Sleep Function

DIAGNOSTICS

- Quick Look II
- Histogram Reports
- Atrial and Ventricular Episodes including EGMs
- Additional Clinician Selected Diagnostics

Model	SES01
M (g)	21.5
V (cc)	9.7
Size (mm) (HxWxD)	40.2 x 42.9 x 7.5
Connector	IS-1 BI/UNI



NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

PACEMAKERS

(IPG)

Dual Chamber (DR)

AZURE™ XT DR MRI
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Implant Detection
- Capture Management (RA and RV)
- Auto-adjusting sensitivity (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareAlert Monitoring
- Carelink connectivity with CareAlerts

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Updated Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)

HEART FAILURE (HF) MANAGEMENT
Algorithm to help manage heart failure
- OptiVol 2.0

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- Atrial ATP with Reactive ATP
- ModeSwitch
- Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- PVC Response
- Ventricular Safety Pacinig (VSP)
- Ventricular Rate Stabilization (VRS)
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Histograms Reports
- Heart Failure Management Report
- Atrial and Ventricular Episodes including EGMs

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

Model	W2DR01
M (g)	22.5
V (cc)	12.75
Size (mm) (HxWxD)	46.6 x 50.8 x 7.4
Connector	IS-1 BI/UNI

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

AZURE™ S DR MRI
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Implant Detection
- Capture Management (RA and RV)
- Auto-adjusting sensitivity (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareAlert Monitoring
- Carelink connectivity with CareAlerts

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Updated Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- ModeSwitch
- Atrial Preference Pacing (APP)
- Non-competitive Atrial Pacing (NCAP)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- PVC Response
- Ventricular Safety Pacinig (VSP)
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Ventricular Episodes including EGMs

Model	W3DR01
M (g)	22.5
V (cc)	12.75
Size (mm) (HxWxD)	46.6 x 50.8 x 7.4
Connector	IS-1 BI/UNI

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ASTRA™ XT DR MRI
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- Capture Management (RA and RV)
- Auto-adjusting sensitivity (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Updated Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)

HEART FAILURE (HF) MANAGEMENT
Algorithm to help manage heart failure
- OptiVol 2.0

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- Atrial ATP with Reactive ATP
- ModeSwitch
- Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- PVC Response
- Ventricular Safety Pacinig (VSP)
- Ventricular Rate Stabilization (VRS)
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Histograms Reports
- Atrial and Ventricular Episodes including EGMs

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

Model	X2DR01
M (g)	22.5
V (cc)	12.75
Size (mm) (HxWxD)	46.6 x 50.8 x 7.4
Connector	IS-1 BI/UNI

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

ATTESTA™ DR MRI
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- TherapyGuide
- Capture Management (RA and RV)
- Sensing Assurance (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)
- Search AV+ up to 600ms

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- ModeSwitch with Blanked Flutter Search
- Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- PVC Response
- Ventricular Safety Pacing (VSP)
- Sinus Preference
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Histogram Reports
- Atrial and Ventricular Episodes including EGMs
- Additional Clinician Selected Diagnostics

Model	ATDR01	ATDRS1 (Small)	ATDRL1 (Longevity)
M (g)	27.1	23.6	31.3
V (cc)	12.1	11.1	13.1
Size (mm) (HxWxD)	44.7 x 47.9 x 7.5	44.7 x 42.9 x 7.5	45.4 x 52.3 x 7.5
Connector	IS-1 BI/UNI		

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SPHERA™ DR MRI
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- TherapyGuide
- Capture Management (RA and RV)
- Sensing Assurance (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Search AV+ up to 600 ms

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- ModeSwitch with Blanked Flutter Search
- Non-competitive Atrial Pacing (NCAP)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- PVC Response
- Ventricular Safety Pacing (VSP)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Histogram Reports
- Atrial and Ventricular Episodes including EGMs
- Additional Clinician Selected Diagnostics

Model	SPDR01	SPDRL1 (Longevity)
M (g)	27.1	31.3
V (cc)	12.1	13.1
Size (mm) (HxWxD)	44.7 x 47.9 x 7.5	45.4 x 52.3 x 7.5
Connector	IS-1 BI/UNI	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ADVISA DR MRI™
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- Capture Management (RA and RV)
- Auto-adjusting sensitivity (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)

HEART FAILURE (HF) MANAGEMENT
Algorithm to help manage heart failure
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- Atrial ATP with Reactive ATP
- ModeSwitch
- Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- PVC Response
- Ventricular Safety Pacinig (VSP)
- Ventricular Rate Stabilization (VRS)
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Histograms Reports
- Atrial and Ventricular Episodes including EGMs

**Subject to availability*

Model	A3DR01
M (g)	22.0
V (cc)	12.7
Size (mm) (HxWxD)	45 x 51 x 8
Connector	IS-1 BI/UNI

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ENSURA DR MRI™
SURESCAN™

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- Capture Management (RA and RV)
- Auto-adjusting sensitivity (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- ModeSwitch
- Atrial Preference Pacing (APP)
- Non-competitive Atrial Pacing (NCAP)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Histogram Reports
- Ventricular Episodes including EGMs

Model	EN1DR01
M (g)	22.0
V (cc)	12.7
Size (mm) (HxWxD)	45 x 51 x 8
Connector	IS-1 BI/UNI

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ADAPTA™ DR

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- TherapyGuide
- Capture Management (RA and RV)
- Sensing Assurance (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

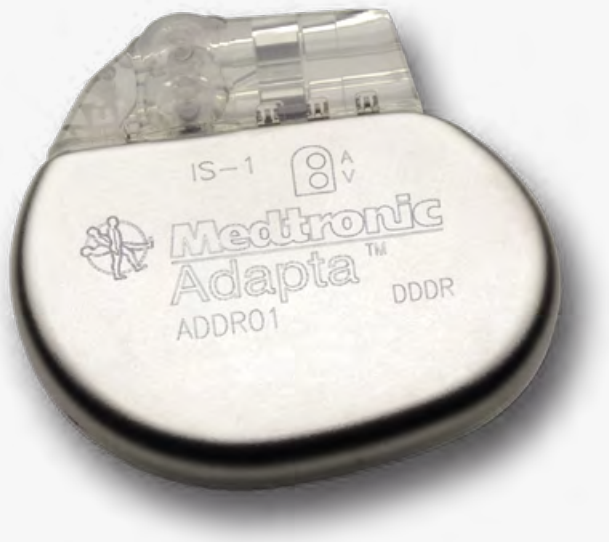
MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)
- Search AV+ up to 600ms

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- ModeSwitch with Blanked Flutter Search
- Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- PVC Response
- Ventricular Safety Pacing (VSP)
- Sinus Preference
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Histogram Reports
- Atrial and Ventricular Episodes including EGMs
- Additional Clinician Selected Diagnostics

Model	ADDR01	ADDR03	ADDR06	ADDRS1 (Small)	ADDRL1 (Longevity)
M (g)	27.1	28.1	28.5	23.6	31.3
V (cc)	12.1	13.0	14.2	11.1	13.1
Size (mm) (HxWxD)	44.7 x 47.9 x 7.5	46.7 x 47.9 x 7.5	50.3 x 47.9 x 7.5	44.7 x 42.9 x 7.5	45.4 x 52.3 x 7.5
Connector	IS-1 BI/UNI	IS-1 BI/ UNI; 3.2 mm LP BI	5 or 6 mm UNI	IS-1 BI/ UNI	IS-1 BI/ UNI



NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ADAPTA® D

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- TherapyGuide
- Capture Management (RA and RV)
- Sensing Assurance (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)
- Search AV+ up to 600 ms

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- ModeSwitch with Blanked Flutter Search
- Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- PVC Response
- Ventricular Safety Pacing (VSP)
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Histogram Reports
- Atrial and Ventricular Episodes including EGMs
- Additional Clinician Selected Diagnostics

Model	ADD01
M (g)	27.1
V (cc)	12.1
Size (mm) (HxWxD)	44.7 x 47.9 x 7.5
Connector	IS-1 BI/UNI

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ADAPTA® VDD

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- TherapyGuide
- Capture Management (RV)
- Sensing Assurance (RA and RV)
- Lead Monitor (RV) with Auto Polarity Switch
- CareLink connectivity

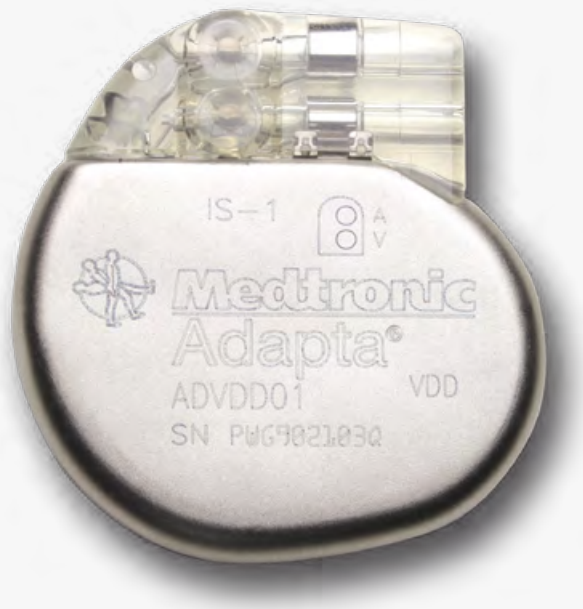
MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Search AV+ up to 600 ms

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- ModeSwitch with Blanked Flutter Search
- Conducted AF Response (CAFR)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- PVC Response
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Histogram Reports
- Atrial and Ventricular Episodes including EGMs
- Additional Clinician Selected Diagnostics

Model	ADVDD01
M (g)	23.6
V (cc)	11.1
Size (mm) (HxWxD)	44.7 x 42.9 x 7.5
Connector	IS-1 BI/UNI



NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SENSIA® DR

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- TherapyGuide
- Capture Management (RA and RV)
- Sensing Assurance (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Search AV+ up to 600 ms

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- ModeSwitch with Blanked Flutter Search
- Non-competitive Atrial Pacing (NCAP)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- PVC Response
- Ventricular Safety Pacing (VSP)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Histogram Reports
- Atrial and Ventricular Episodes including EGMs
- Additional Clinician Selected Diagnostics

Model	SEDR01	SEDRL1 (Longevity)
M (g)	27.1	31.1
V (cc)	12.1	13.1
Size (mm) (HxWxD)	44.7 x 47.9 x 7.5	45.4 x 52.3 x 7.5
Connector	IS-1 BI/UNI	

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SENSIA® D

PACEMAKERS (IPG)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Automatically monitors for implant detection and continuously adapts key device parameters to ensure the therapies are optimized.
- Implant Detection
- TherapyGuide
- Capture Management (RA and RV)
- Sensing Assurance (RA and RV)
- Lead Monitor (RA and RV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Search AV+ up to 600 ms

AT/AF MANAGEMENT
Pacing therapies to help manage atrial tachyarrhythmias and alleviate symptoms.
- ModeSwitch with Blanked Flutter Search
- Non-competitive Atrial Pacing (NCAP)

ADDITIONAL PACING FEATURES
- Rate Hysteresis
- Sleep Function
- PVC Response
- Ventricular Safety Pacing (VSP)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Histogram Reports
- Atrial and Ventricular Episodes including EGMs
- Additional Clinician Selected Diagnostics

Model	SED01
M (g)	27.1
V (cc)	12.1
Size (mm) (HxWxD)	44.7 x 47.9 x 7.5
Connector	IS-1 BI/UNI

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

PACEMAKERS (IPG)

Leadless

MICRA™ AV
TRANSCATHETER PACING SYSTEM

PACEMAKERS (IPG)

GENERAL DESCRIPTION
- Miniaturized: Completely self-contained within the heart, no leads required
- Designed to provide AV Synchrony (VDD)
- Engineered for a minimally invasive approach
- Integrated delivery system facilitates a streamlined implant procedure via femoral approach
- Atraumatic FlexFix™ nitinol tines provide secure capsule placement
- CareLink connectivity

COMPLETELY AUTOMATIC – SIMPLE TO USE
- Continuously adapts key device parameters to ensure the therapies are optimized.
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)

ENSURING AV SYNCHRONY
- Dynamic sensing that adjusts pacing based on the mechanical atrial contraction
- Accelerometer-based mechanical atrial sensing

DIAGNOSTICS
- Quick Look II
- Histogram Reports

ELECTRODES
- Surface area:
- Anode: 22 mm^2
- Cathode: 2.5 mm^2
- Steroid eluting cathode

MICRA DELIVERY CATHETER
- Catheter system with a handle that controls deflection and deployment of the Micra pacing capsule
- It can function as a retrieval catheter post tether removal
- Outer diameter: 7.8 mm (23 Fr)
- Effective length: 105 cm
- Radiopacity: Gold (99.99% purity)

MICRA INTRODUCER SHEATH
- Lubricious hydrophilic coating facilitates smooth vessel navigation
- Stopcock for aspirating and flushing
- Radiopaque marker on end of Introducer
- Inner diameter: 7.8 mm (23 Fr)
- Outer diameter: 9.0 mm (27 Fr)
- Working length: 55.7 cm
- Dilator:
  - Working length: 69.9 cm
  - Guidewire compatibility: 0.89 mm (0.035 in)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

Model	MC1AVR1
M (g)	1.75
V (cc)	0.8
Length (mm)	25.9
Outer Diameter (mm (Fr))	6.7 (20.1)

MRI SureScan
Full Body 1.5 and 3T MRI:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

MICRA™ VR
TRANSCATHETER PACING SYSTEM

PACEMAKERS (IPG)

GENERAL DESCRIPTION
- Miniaturized: Completely self-contained within the heart, no leads required
- Engineered for a minimally invasive approach
- Integrated delivery system facilitates a streamlined implant procedure via femoral approach
- Atraumatic FlexFix™ nitinol tines provide secure capsule placement
- CareLink connectivity

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- CareLink connectivity

DIAGNOSTICS
- Quick Look II
- Histogram Reports

ELECTRODES
- Surface area:
- Anode: 22 mm^2
- Cathode: 2.5 mm^2
- Steroid eluting cathode

MICRA DELIVERY CATHETER
- Catheter system with a handle that controls deflection and deployment of the Micra pacing capsule
- It can function as a retrieval catheter post tether removal
- Outer diameter: 7.8 mm (23 Fr)
- Effective length: 105 cm
- Radiopacity: Gold (99.99% purity)

MICRA INTRODUCER SHEATH
- Lubricious hydrophilic coating facilitates smooth vessel navigation
- Stopcock for aspirating and flushing
- Radiopaque marker on end of Introducer
- Inner diameter: 7.8 mm (23 Fr)
- Outer diameter: 9.0 mm (27 Fr)
- Working length: 55.7 cm
- Dilator:
- Working length: 69.9 cm
- Guidewire compatibility: 0.89 mm (0.035 in)

Model	MC1VR01
M (g)	1.75
V (cc)	0.8
Length (mm)	25.9
Outer Diameter (mm (Fr))	6.7 (20.1)

MRI SureScan
Full Body 1.5 and 3T MRI:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CRT PACEMAKERS (CRT-P)

PERCEPTA™ QUAD CRT-P MRI
SURESCAN™

CRT PACEMAKERS (CRT-P)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Implant Detection
- Therapy Guide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- Lead Monitor (RA, RV and LV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Updated Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- EffectivCRT Diagnostic and EffectivCRT During AF
- AdaptivCRT
- CardioSync Optimization Test
- Multiple Point Pacing (MPP)
- VectorExpress 2.0 LV Automated Test
- 16 LV pacing vectors with Quadripolar LV lead
- Sequential MPP
- Ventricular Sense Response (VSR)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Pacing therapies and algorithms to help manage atrial tachyarrhythmias.
- Atrial ATP with Reactive ATP
- ModeSwitch
- Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Sleep Function
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG
- Atrial and Ventricular Episodes including EGMs

**Subject to availability*

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

Model	W4TR04
M (g)	30
V (cc)	20.5
Size (mm) (HxWxD)	59 x 46.5 x 11
Connector	2x IS-1 / 1x IS-4

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

PERCEPTA™ CRT-P MRI
SURESCAN™

CRT PACEMAKERS (CRT-P)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Implant Detection
- Therapy Guide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- Lead Monitor (RA, RV and LV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Updated Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- EffectivCRT Diagnostic and EffectivCRT During AF
- AdaptivCRT
- CardioSync Optimization Test
- 5 LV pacing vectors
- Ventricular Sense Response (VSR)
- Atrial Tracking Recovery (ATR)
- Optiol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Pacing therapies and algorithms to help manage atrial tachyarrhythmias.
- Atrial ATP with Reactive ATP
- ModeSwitch
- Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Sleep Function
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG
- Atrial and Ventricular Episodes including EGMs

**Subject to availability*

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

Model	W1TR04
M (g)	30
V (cc)	20
Size (mm) (HxWxD)	59 x 46.5 x 11
Connector	3x IS-1

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

SERENA™ QUAD CRT-P MRI
SURESCAN™

CRT PACEMAKERS (CRT-P)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Implant Detection
- Therapy Guide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- Lead Monitor (RA, RV and LV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Updated Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- AdaptivCRT
- CardioSync Optimization Test
- Multiple Point Pacing (MPP)
- VectorExpress LV Automated Test
- 16 LV pacing vectors with Quadripolar LV lead
- Sequential MPP
- Ventricular Sense Response (VSR)
- Atrial Tracking Rec overy (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Pacing therapies and algorithms to help manage atrial tachyarrhythmias.
- Atrial ATP with Reactive ATP
- ModeSwitch
- Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Sleep Function
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG
- Atrial and Ventricular Episodes including EGMs

**Subject to availability*

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

Model	W4TR05
M (g)	30
V (cc)	20.5
Size (mm) (HxWxD)	59 x 46.5 x 11
Connector	2x IS-1 / 1x IS-4

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

SERENA™ CRT-P MRI
SURESCAN™

CRT PACEMAKERS (CRT-P)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Implant Detection
- Therapy Guide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- Lead Monitor (RA, RV and LV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Updated Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- AdaptivCRT
- CardioSync Optimization Test
- 5 LV pacing vectors
- Ventricular Sense Response (VSR)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Pacing therapies and algorithms to help manage atrial tachyarrhythmias.
- Atrial ATP with Reactive ATP
- ModeSwitch
- Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Sleep Function
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG
- Atrial and Ventricular Episodes including EGMs

**Subject to availability*

Model	W1TR05
M (g)	30
V (cc)	20
Size (mm) (HxWxD)	59 x 46.5 x 11
Connector	3 x IS-1

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SOLARA™ QUAD CRT-P MRI
SURESCAN™

CRT PACEMAKERS (CRT-P)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Implant Detection
- Therapy Guide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- Lead Monitor (RA, RV and LV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Updated Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- CardioSync Optimization Test
- VectorExpress LV Automated Test
- 16 LV pacing vectors
- Ventricular Sense Response (VSR)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Pacing therapies and algorithms to help manage atrial tachyarrhythmias.
- Atrial ATP with Reactive ATP
- ModeSwitch
- Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Sleep Function
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG
- Atrial and Ventricular Episodes including EGMs

**Subject to availability*

Model	W4TR06
M (g)	30
V (cc)	20.5
Size (mm) (HxWxD)	59 x 46.5 x 11
Connector	2x IS-1 /1x IS-4

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SOLARA™ CRT-P MRI
SURESCAN™

CRT PACEMAKERS (CRT-P)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Implant Detection
- Therapy Guide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- Lead Monitor (RA, RV and LV) with Auto Polarity Switch
- CareLink connectivity

MINIMIZING UNNECESSARY RV PACING
Promotes intrinsic conduction by reducing unnecessary RV pacing.
- Updated Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- CardioSync Optimization Test
- 5 LV pacing vectors
- Ventricular Sense Response (VSR)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Pacing therapies and algorithms to help manage atrial tachyarrhythmias.
- Atrial ATP with Reactive ATP
- ModeSwitch
- Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Sleep Function
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- High Upper tracking rate up to 210 min^{-1} for pediatric indications
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG
- Atrial and Ventricular Episodes including EGMs

**Subject to availability*

Model	W1TR06
M (g)	30
V (cc)	20
Size (mm) (HxWxD)	59 x 46.5 x 11
Connector	3 x IS-1

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

DEFIBRILLATORS (ICD)

Single Chamber (VR)

COBALT™ XT VR MRI
SURESCAN™

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA), Atrial Fibrillation (AF) burden and Fast V. Rate During AF
- CareLink connectivity

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- SmartShock™ 2.0+ Technology with Intrinsic ATP™ Algorithm
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging ChargeSaver with
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – Wavelet, Stability, Onset
- Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Algorithm to help manage heart failure.
- OptiVol™ 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Conducted AF Response (CAFR)
- AF Diagnostic (Trends and Histograms)

ADDITIONAL PACING FEATURES
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DVPA2D1	DVPA2D4
M (g)	79	79
V (cc)	33.2	33.8
Size (mm) (HxWxD)	66 x 51 x 13	66 x 51 x 13
Connector	IS-1 / DF-1	DF-4
Max Program. / Delivered Energy (J)	40 / 40	40 / 40

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

COBALT™ VR MRI
SURESCAN™

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA), Atrial Fibrillation (AF) burden and Fast V. Rate During AF
- CareLink connectivity

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – Wavelet, Stability, Onset
- Wavelet programmable to discriminate SVT in VF zone

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- TruAF™ Detection Algorithm
- Conducted AF Response (CAFR)
- AF Diagnostic (Trends and Histograms)

ADDITIONAL PACING FEATURES
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DVPB3D1	DVPB3D4
M (g)	79	79
V (cc)	33.2	33.8
Size (mm) (HxWxD)	66 x 51 x 13	66 x 51 x 13
Connector	IS-1 / DF-1	DF-4
Max Program. / Delivered Energy (J)	40 / 40	40 / 40

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CROME™ VR MRI
SURESCAN™

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – Wavelet, Stability, Onset
- Wavelet programmable to discriminate SVT in VF zone

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Conducted AF Response (CAFR)

ADDITIONAL PACING FEATURES
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DVPC3D1	DVPC3D4
M (g)	79	79
V (cc)	33.2	32.8
Size (mm) (HxWxD)	66 x 51 x 13	64 x 51 x 13
Connector	IS-1 / DF-1	DF-4
Max Program. / Delivered Energy (J)	40 / 40	40 / 40

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

PRIMO MRI™ VR
SURESCAN™

DEFIBRILLATORS (ICD)

AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Auto-adjusting sensitivity (RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – Wavelet, Stability, Onset
- Wavelet programmable to discriminate SVT in VF zone

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Conducted AF Response (CAFR)

ADDITIONAL PACING FEATURES
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DVMD3D1	DVMD3D4
M (g)	77	77
V (cc)	33	33
Size (mm) (HxWxD)	66 x 51 x 13	64 x 51 x 13
Connector	IS-1 / DF-1	DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

MIRRO MRI™ VR
SURESCAN™

DEFIBRILLATORS (ICD)

AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Auto-adjusting sensitivity (RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- SVT Discriminators – Wavelet, Stability, Onset
- Wavelet programmable to discriminate SVT in VF zone

ADDITIONAL PACING FEATURES
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DVME3D1	DVME3D4
M (g)	77	77
V (cc)	33	33
Size (mm) (HxWxD)	66 x 51 x 13	64 x 51 x 13
Connector	IS-1 / DF-1	DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

VISIA AF MRI™ XT VR
SURESCAN™

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA), Atrial Fibrillation (AF) burden and Fast V. Rate During AF
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – Wavelet, Stability, Onset
- Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Algorithm to help manage heart failure.
- OptiVol™ 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Conducted AF Response (CAFR)
- AF Diagnostic (Trends and Histograms)

ADDITIONAL PACING FEATURES
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DVFB2D1	DVFB2D4
M (g)	77	77
V (cc)	33	33
Size (mm) (HxWxD)	66 x 51 x 13	66 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

VISIA AF™ XT VR

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA), Atrial Fibrillation (AF) burden and Fast V. Rate During AF
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – Wavelet, Stability, Onset
- Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Algorithm to help manage heart failure.
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Conducted AF Response (CAFR)
- AF Diagnostic (Trends and Histograms)

ADDITIONAL PACING FEATURES
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DVAB2D1
M (g)	77
V (cc)	33
Size (mm) (HxWxD)	66 x 51 x 13
Connector	IS-1 / DF-1
Max Program. / Delivered Energy (J)	35 / 36

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

VISIA AF MRI™ S VR
SURESCAN™

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA), Atrial Fibrillation (AF) burden and Fast V. Rate During AF
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – Wavelet, Stability, Onset
- Wavelet programmable to discriminate SVT in VF zone

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Conducted AF Response (CAFR)
- AF Diagnostic (Trends and Histograms)

ADDITIONAL PACING FEATURES
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DVFC3D1	DVFC3D4
M (g)	77	77
V (cc)	33	33
Size(mm) (HxWxD)	66 x 51 x 13	64 x 51 x 13
Connector	IS-1 / DF-1	DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

VISIA AF™ S VR

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA), Atrial Fibrillation (AF) burden and Fast V. Rate During AF
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – Wavelet, Stability, Onset
- Wavelet programmable to discriminate SVT in VF zone

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Conducted AF Response (CAFR)
- AF Diagnostic (Trends and Histograms)

ADDITIONAL PACING FEATURES
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DVAC3D1
M (g)	77
V (cc)	33
Size (mm) (HxWxD)	66 x 51 x 13
Connector	IS-1 / DF-1
Max Program. / Delivered Energy (J)	35 / 36

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

EVERA MRI® XT VR
SURESCAN™

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – Wavelet, Stability, Onset
- Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Algorithm to help manage heart failure.
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Conducted AF Response (CAFR)

ADDITIONAL PACING FEATURES
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DVMB2D1	DVMB2D4
M (g)	77	77
V (cc)	33	33
Size (mm) (HxWxD)	66 x 51 x 13	64 x 51 x 13
Connector	IS-1 / DF-1	DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

EVERA® XT VR

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – Wavelet, Stability, Onset
- Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Algorithm to help manage heart failure.
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Conducted AF Response (CAFR)

ADDITIONAL PACING FEATURES
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DVBB2D1	DVBB2D4
M (g)	77	77
V (cc)	33	33
Size (mm) (HxWxD)	66 x 51 x 13	64 x 51 x 13
Connector	IS-1 / DF-1	DF-4
Max Program. / Delivered Energy (J)	35 / 36	

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

EVERA MRI® S VR
SURESCAN™

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – Wavelet, Stability, Onset
- Wavelet programmable to discriminate SVT in VF zone

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Conducted AF Response (CAFR)

ADDITIONAL PACING FEATURES
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DVMC3D1	DVMC3D4
M (g)	77	77
V (cc)	33	33
Size (mm) (HxWxD)	66 x 51 x 13	64 x 51 x 13
Connector	IS-1 / DF-1	DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

EVERA® S VR

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RV)
- Auto-adjusting sensitivity (RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – Wavelet, Stability, Onset
- Wavelet programmable to discriminate SVT in VF zone

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Conducted AF Response (CAFR)

ADDITIONAL PACING FEATURES
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DVBC3D1	DVBC3D4
M (g)	77	77
V (cc)	33	33
Size (mm) (HxWxD)	66 x 51 x 13	64 x 51 x 13
Connector	IS-1 / DF-1	DF-4
Max Program. / Delivered Energy (J)	35 / 36	

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

DEFIBRILLATORS (ICD)

Dual Chamber (DR)

COBALT™ XT DR MRI
SURESCAN™

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA and RV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- SmartShock™ 2.0+ Technology with Intrinsic ATP™ Algorithm
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ChargeSaver with ATP Before and During Charging
- Smart Mode
- Programmable RV sensing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Algorithm to help manage heart failure.
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Updated Managed Ventricular Pacing Mode (MVP): AAI(R)DDD(R)
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DDPA2D1	DDPA2D4
M (g)	79	80
V (cc)	33.1	33.7
Size (mm) (HxWxD)	66 x 51 x 14	66 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	40 / 40	40 / 40

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

COBALT™ DR MRI
SURESCAN™

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA and RV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Updated Managed Ventricular Pacing Mode (MVP): AAI(:R)⇄DDD(R)
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DDPB3D1	DDPB3D4
M (g)	79	80
V (cc)	33,1	33,7
Size (mm) (HxWxD)	66 x 51 x 14	64 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	40 / 40	40 / 40

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CROME™ DR MRI
SURESCAN™

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Capture Management (RA and RV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Updated Managed Ventricular Pacing Mode (MVP): AAI(R)DDD(R)
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DDPC3D1	DDPC3D4
M (g)	79	80
V (cc)	33.1	33.7
Size (mm) (HxWxD)	66 x 51 x 13	66 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	40 / 40	40 / 40

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

PRIMO MRI™ DR
SURESCAN™

DEFIBRILLATORS (ICD)

AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DDMD3D1	DDMD3D4
M (g)	77	78
V (cc)	33	34
Size (mm) (HxWxD)	66 x 51 x 15	68 x 51 x 15
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

MIRRO MRI™ DR
SURESCAN™

DEFIBRILLATORS (ICD)

AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- SVT Discriminators – PR Logic, Stability, Onset
- PR Logic programmable to discriminate SVT in VF zone

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Non-competitive Atrial Pacing (NCAP)

ADDITIONAL PACING FEATURES
- Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DDME3D1	DDME3D4
M (g)	77	78
V (cc)	33	34
Size (mm) (HxWxD)	66 x 51 x 13	66 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

EVERA MRI™ XT DR
SURESCAN™

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA and RV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Algorithm to help manage heart failure.
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DDMB2D1	DDBB2D4
M (g)	77	78
V (cc)	33	34
Size (mm) (HxWxD)	66 x 51 x 14	68 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

EVERA® XT DR

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA and RV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Algorithm to help manage heart failure.
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DDBB2D1	DDBB2D4
M (g)	77	78
V (cc)	33	34
Size (mm) (HxWxD)	66 x 51 x 13	68 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

EVERA MRI™ S DR
SURESCAN™

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA and RV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DDMC3D1	DDMC3D4
M (g)	77	78
V (cc)	33	34
Size (mm) (HxWxD)	66 x 51 x 14	68 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

EVERA® S DR

DEFIBRILLATORS (ICD)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA and RV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- Managed Ventricular Pacing Mode (MVP): AAI(R)<->DDD(R)
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DDBC3D1	DDBC3D4
M (g)	77	78
V (cc)	33	34
Size (mm) (HxWxD)	66 x 51 x 13	66 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CRT DEFIBRILLATORS (CRT-D)

COBALT™ XT HF Quad CRT-D MRI SURESCAN™

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- SmartShock™ 2.0+ Technology with Intrinsic ATP™ Algorithm
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- EffectivCRT Diagnostic and EffectivCRT During AF
- AdaptivCRT
- CardioSync Optimization Test
- Multiple Point Pacing (MPP)
- VectorExpress 2.0 LV Automated Test
- 16 LV pacing vectors with Quadripolar LV lead
- Sequential MPP
- Ventricular Sense Response (VSR)
- Managed Ventricular Pacing (MVP)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

Model	DTPA2Q1 (Quad)	DTPA2QQ (Quad)
M (g)	82	83
V (cc)	36.3	35.5
Size (mm) (HxWxD)	74 x 51 x 13	74 x 51 x 13
Connector	IS-1 / IS-4 / DF-1	IS-1 / IS-4 / DF-4
Max Program. / Delivered Energy (J)	40 / 40	40 / 40

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

COBALT™ XT HF CRT-D MRI
SURESCAN™

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- SmartShock™ 2.0+ Technology with Intrinsic ATP™ Algorithm
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- EffectivCRT Diagnostic and EffectivCRT During AF
- AdaptivCRT
- CardioSync Optimization Test
- Ventricular Sense Response (VSR)
- Managed Ventricular Pacing (MVP)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DTPA2D1	DTPA2D4
M (g)	82	82.1
V (cc)	35	35
Size (mm) (HxWxD)	71 x 51 x 13	71 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	40 / 40	40 / 40

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

COBALT™ HF Quad CRT-D MRI SURESCAN™

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- AdaptivCRT
- CardioSync Optimization Test
- Multiple Point Pacing (MPP)
- VectorExpress 2.0 LV Automated Test
- 16 LV pacing vectors with Quadripolar LV lead
- Sequential MPPVentricular Sense Response (VSR)
- Managed Ventricular Pacing (MVP)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

Model	DTPB2Q1 (Quad)	DTPB2QQ (Quad)
M (g)	83	83
V (cc)	36.3	35.5
Size (mm) (HxWxD)	74 x 51 x 13	74 x 51 x 13
Connector	IS-1 / IS-4 / DF-1	IS-1 / IS-4 / DF-4
Max Program. / Delivered Energy (J)	40 / 40	40 / 40

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

COBALT™ HF CRT-D MRI
SURESCAN™

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- AdaptivCRT
- CardioSync Optimization Test
- Ventricular Sense Response (VSR)
- Managed Ventricular Pacing (MVP)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DTPB2D1	DTPB2D4
M (g)	82	82.1
V (cc)	35	35
Size (mm) (HxWxD)	71 x 51 x 13	71 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	40 / 40	40 / 40

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CROME™ HF Quad CRT-D MRI
SURESCAN™

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- CardioSync Optimization Test
- Multiple Point Pacing (MPP)
- VectorExpress 2.0 LV Automated Test
- Ventricular Sense Response (VSR)
- Managed Ventricular Pacing (MVP)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- Mode Switch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DTPC2Q1 (Quad)	DTPC2QQ (Quad)
M (g)	83	83
V (cc)	36.3	35.5
Size (mm) (HxWxD)	74 x 51 x 13	74 x 51 x 13
Connector	IS-1 / IS-4 / DF-1	IS-1 / IS-4 / DF-4
Max Program. / Delivered Energy (J)	40 / 40	40 / 40

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CROME™ HF CRT-D MRI
SURESCAN™

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- Bluetooth® Wireless Telemetry (BlueSync™ Technology)
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- CardioSync Optimization Test
- Ventricular Sense Response (VSR)
- Managed Ventricular Pacing (MVP)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- Mode Switch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

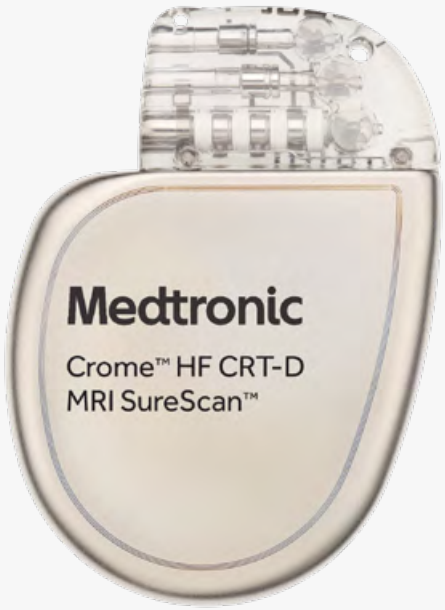
ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DTPC2D1	DTPC2D4
M (g)	82	82.1
V (cc)	35	35
Size (mm) (HxWxD)	71 x 51 x 13	71 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	40 / 40	40 / 40

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)



NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CLARIA MRI™ QUAD CRT-D
SURESCAN™

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- EffectivCRT Diagnostic and EffectivCRT During AF
- AdaptivCRT
- CardioSync Optimization Test
- Multiple Point Pacing (MPP)
- VectorExpress 2.0 LV Automated Test
- 16 LV pacing vectors and 5 vectors for MPP with Quadripolar LV lead
- Ventricular Sense Response (VSR)
- Managed Ventricular Pacing (MVP)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

Model	DTMA2Q1 (Quad)	DTMA2QQ (Quad)
M (g)	82	81
V (cc)	36	35
Size (mm) (HxWxD)	74 x 51 x 13	74 x 51 x 13
Connector	IS-1 / IS-4 / DF-1	IS-1 / IS-4 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

CLARIA MRI™ CRT-D
SURESCAN™

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- EffectivCRT Diagnostic and EffectivCRT During AF
- AdaptivCRT
- CardioSync Optimization Test
- Ventricular Sense Response (VSR)
- Managed Ventricular Pacing (MVP)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

Model	DTMA2D1	DTMA2D4
M (g)	80	80
V (cc)	35	35
Size (mm) (HxWxD)	71 x 51 x 13	73 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

AMPLIA MRI™ QUAD CRT-D
SURESCAN™

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- AdaptivCRT
- CardioSync Optimization Test
- Multiple Point Pacing (MPP)
- VectorExpress LV Automated Test
- 16 LV pacing vectors and 5 vectors for MPP with Quadripolar LV lead
- Ventricular Sense Response (VSR)
- Managed Ventricular Pacing (MVP)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

Model	DTMB2Q1 (Quad)	DTMB2QQ (Quad)
M (g)	82	81
V (cc)	36	35
Size (mm) (HxWxD)	74 x 51 x 13	74 x 51 x 13
Connector	IS-1 / IS-4 / DF-1	IS-1 / IS-4 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

AMPLIA MRI™ CRT-D
SURESCAN™

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- AdaptivCRT
- CardioSync Optimization Test
- Ventricular Sense Response (VSR)
- Managed Ventricular Pacing (MVP)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

Model	DTMB2D1	DTMB2D4
M (g)	80	80
V (cc)	35	35
Size (mm) (HxWxD)	71 x 51 x 13	73 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

COMPIA MRI™ QUAD CRT-D
SURESCAN™

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- CardioSync Optimization Test
- VectorExpress LV Automated Test
- 16 LV pacing vectors with Quadripolar LV lead
- Ventricular Sense Response (VSR)
- Managed Ventricular Pacing (MVP)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DTMC2QQ (Quad)
M (g)	81
V (cc)	35
Size (mm) (HxWxD)	74 x 51 x 13
Connector	IS-1 / IS-4 / DF-4
Max Program. / Delivered Energy (J)	35 / 36

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

COMPIA MRI™ CRT-D
SURESCAN™

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- CardioSync Optimization Test
- Ventricular Sense Response (VSR)
- Managed Ventricular Pacing (MVP)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DTMC2D1	DTMC2D4
M (g)	80	80
V (cc)	35	35
Size (mm) (HxWxD)	71 x 51 x 13	71 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan lead:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

VIVA™ QUAD XT CRT-D

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- AdaptivCRT
- CardioSync Optimization Test
- VectorExpress LV Automated Test
- 16 LV pacing vectors with Quadripolar LV lead
- Ventricular Sense Response (VSR)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

Model	DTBA2Q1 (Quad)	DTBA2QQ (Quad)
M (g)	82	81
V (cc)	36	35
Size (mm) (HxWxD)	74 x 51 x 13	74 x 51 x 13
Connector	IS-1 / IS-4 / DF-1	IS-1 / IS-4 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

VIVA™ XT CRT-D

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- AdaptivCRT
- CardioSync Optimization Test
- 4 LV pacing vectors
- Ventricular Sense Response (VSR)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DTBA2D1	DTBA2D4
M (g)	80	80
V (cc)	35	35
Size (mm) (HxWxD)	71 x 51 x 13	73 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

VIVA™ QUAD S CRT-D

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- CardioSync Optimization Test
- VectorExpress LV Automated Test
- 16 LV pacing vectors with Quadripolar LV lead
- Ventricular Sense Response (VSR)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DTBB2QQ (Quad)
M (g)	81
V (cc)	35
Size (mm) (HxWxD)	74 x 51 x 13
Connector	IS-1 / IS-4 / DF-1
Max Program. / Delivered Energy (J)	35 / 36

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

VIVA™ S CRT-D

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- CardioSync Optimization Test
- 4 LV pacing vectors
- Ventricular Sense Response (VSR)
- Atrial Tracking Recovery (ATR)
- OptiVol 2.0
- Heart Failure Risk Stratification (TriageHF)*

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Automatic and Patient-activated atrial cardioversion (CV)
- Atrial ATP with Reactive ATP
- ModeSwitch with Post Mode Switch overdrive Pacing (PMOP)
- Atrial Preference Pacing (APP)
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)
- Atrial Rate Stabilization (ARS)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Rate Drop Response with 2 detection algorithms
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Heart Failure Management Report
- Leadless ECG

**Subject to availability*

Model	DTBB2D1	DTBB2D4
M (g)	80	80
V (cc)	35	35
Size (mm) (HxWxD)	71 x 51 x 13	73 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

BRAVA™ QUAD CRT-D

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ATP Before and During Charging with ChargeSaver
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- SVT Discriminators – PR Logic, Wavelet, Stability, Onset
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- CardioSync Optimization Test
- VectorExpress LV Automated Test
- 16 LV pacing vectors with Quadripolar LV lead
- Ventricular Sense Response (VSR)
- Atrial Tracking Recovery (ATR)

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DTBC2Q1 (Quad)	DTBC2QQ (Quad)
M (g)	82	81
V (cc)	36	35
Size (mm) (HxWxD)	74 x 51 x 13	74 x 51 x 13
Connector	IS-1 / IS-4 / DF-1	IS-1 /IS-4 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

BRAVA™ CRT-D

CRT DEFIBRILLATORS (CRT-D)

COMPLETELY AUTOMATIC – SIMPLE TO USE
Continuously adapts key device parameters to ensure the therapies are optimized.
- TherapyGuide
- Capture Management (RA, RV and LV)
- Auto-adjusting sensitivity (RA and RV)
- CareAlert sounds incl. Lead Integrity Alert (LIA)
- CareLink connectivity
- Wireless telemetry

VT/VF MANAGEMENT
Therapies and algorithms to help manage ventricular tachyarrhythmias.
- Ventricular cardioversion/defibrillation
- Ventricular antitachycardia pacing (ATP)
- ChargeSaver with ATP Before and During Charging
- Smart Mode
- Programmable RV sensing and pacing polarity
- Programmable HV shocking vectors
- 3 detection zones allowing VF and FVT zone overlap
- T-Wave and RV Lead Noise Discriminators
- Confirmation+
- PR Logic and Wavelet programmable to discriminate SVT in VF zone

HEART FAILURE (HF) MANAGEMENT
Pacing therapies and algorithms to help manage heart failure.
- CardioSync Optimization Test
- 4 LV pacing vectors
- Ventricular Sense Response (VSR)
- Atrial Tracking Recovery (ATR)

AT/AF MANAGEMENT
Therapies and algorithms to help manage atrial tachyarrhythmias.
- Conducted AF Response (CAFR)
- Non-competitive Atrial Pacing (NCAP)

ADDITIONAL PACING FEATURES
- PVC Response
- Ventricular Safety Pacing (VSP)
- Ventricular Rate Stabilization (VRS)
- Dual Zone Rate Response Pacing with Rate Profile Optimization

DIAGNOSTICS
- Quick Look II
- Cardiac Compass Trends
- Leadless ECG

Model	DTBC2D1	DTBC2D4
M (g)	80	80
V (cc)	35	35
Size (mm) (HxWxD)	71 x 51 x 13	73 x 51 x 13
Connector	IS-1 / DF-1	IS-1 / DF-4
Max Program. / Delivered Energy (J)	35 / 36	

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

IPG LEADS AND SYSTEMS

CAPSURE SENSE MRI™
SURESCAN™

PACING LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting
- Lengths for 4574: 45, 53 (cm)
- Lengths for 4074: 52, 58 (cm)

CONNECTOR
- IS1 Bipolar

DIAMETER
- Body: 1.8 mm (5.3 Fr)

ELECTRODES
- Porous Ring Shape
- Electrode Surface Area
  - Tip: 2.5 mm^2
  - Ring: 24.0 mm^2
- Tip-to-Ring Spacing for 4574: 9 mm
- Tip-to-Ring Spacing for 4074: 17 mm

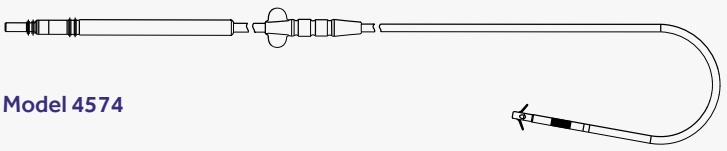
MATERIAL
- Insulator: Polyurethane (outer 55D), Silicone (inner)
- Conductor: MP35N Nickel Alloy
- Tip Electrode: Platinum/Iridium with porous Titanium Nitride coating
- Ring Electrode: Platinum Alloy with porous Titanium Nitride coating

STYLETS WITH 4574
- Inserted
  - 1 gray straight
- Packaged
  - 2 purple straight

STYLETS WITH 4074
- Inserted
  - 1 gray straight
- Packaged
  - 1 gray straight
  - 2 purple straight

Model	4574	4074
Fixation	Passive / Tines	
Shape / Chambers	J-shaped / RA	Straight / RV
Polarity	Bipolar	
Insulation	Polyurethane	
Introducer Size with/out Guidewire (Fr)	7.0 / 9.0	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)



Model 4574

Model 4074

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CAPSUREFIX NOVUS MRI®
SURESCAN™

PACING LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting
- Standard Lengths: 45, 52, 58, 65, 85 (cm)

CONNECTOR
- IS1 Bipolar

DIAMETER
Body: 1.9 mm (5.7 Fr)

ELECTRODES
- Extendable/Retractable Helix Screw
- Helix Length: 1.8 mm
- Electrode Surface Area
  - Helix: 4.2 mm^2
  - Ring: 22.0 mm^2
- Tip-to-Ring Spacing: 10.0 mm

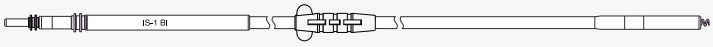
MATERIAL
- Insulator: Polyurethane (outer 55D), Silicone with Siloxane® treatment (inner)
- Conductor: MP35N Nickel Alloy
- Helix Electrode: Platinum Alloy with porous Titanium Nitride coating
- Ring Electrode: Platinum Alloy with porous Titanium Nitride coating
- Connector Ring: Stainless steel
- Connector Pin: Stainless steel

STYLETS
- Inserted
  - 1 gray straight
- Packaged
  - 1 gray straight
  - 1 blue straight
  - 1 gray J-shaped*
  - 1 blue J-shaped*
  - 1 white J-shaped*

* Not available for leads 65 or 85 cm

Model	4076
Fixation	Active/ Screw-in
Shape / Chambers	Straigh / RA and RV
Polarity	Bipolar
Insulation	Polyurethane
Introducer Size with/out Guidewire (Fr)	7.0 / 9.0

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)



Model 4076

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CAPSUREFIX NOVUS MRI®
SURESCAN™

PACING LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting
- Standard Lengths: 35, 45, 52, 58, 65, 85 (cm)

CONNECTOR
- IS1 Bipolar

DIAMETER
- Body: 2.0 mm (6.1 Fr)

ELECTRODES
- Extendable/Retractable Helix Screw
- Helix Length: 1.8 mm
- Electrode Surface Area
  - Helix: 4.2 mm^2
  - Ring: 22.0 mm^2
- Tip-to-Ring Spacing: 10.0 mm

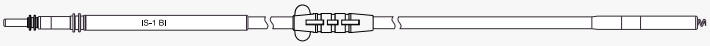
MATERIAL
- Insulator: Silicone with Siloxane® treatment (inner)
- Conductor: MP35N Nickel Alloy
- Helix Electrode: Platinized Platinum Alloy
- Ring Electrode: Platinized Platinum Alloy
- Connector Ring: Stainless steel
- Connector Pin: Stainless steel

STYLETS
- Inserted
  - 1 gray straight
- Packaged
  - 1 gray straight
  - 1 blue straight
  - 1 gray J-shaped*
  - 1 blue J-shaped*
  - 1 white J-shaped*

* Not available for leads 65 or 85 cm

Model	5076
Fixation	Active/ Screw-in
Shape / Chambers	Straigh / RA and RV
Polarity	Bipolar
Insulation	Silicone
Introducer Size with/out Guidewire (Fr)	7.0 / 9.0

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)



Model 5076

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SELECTSECURE® MRI
SURESCAN™

PACING LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting
- Standard Lengths: 59, 69, 74 (cm)

CONNECTOR
- IS1 Bipolar

DIAMETER
- Body: 1.4 mm (4.1 Fr)

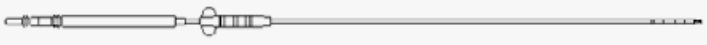
ELECTRODES
- Fixed Screw
- Helix Length: 1.8 mm
- Electrode Surface Area
  - Helix: 3.56 mm^2
  - Ring: 16.9 mm^2
- Tip-to-Ring Spacing: 9.0 mm

RECOMMENDED GUIDE CATHETER*
- C315 or C304

*Not included in the package – to be ordered separately

Model	3830
Fixation	Active/ Screw-in
Shape / Chambers	Straigh / RA and RV
Polarity	Bipolar
Insulation	Polyurethane
Introducer Size with/out Guidewire	5.5 Fr Inner Diameter

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)



Model 3830

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SELECTSITE®
DEFLECTABLE CATHETER

PACING LEADS AND DELIVERY SYSTEMS

GENERAL
- Deflectable guide catheters for SelectSecure® Model 3830 leads

DEFLECTABLE CATHETER
- Material: Polyether block amide

CATHETER DILATOR
- Material: Polyethylene
- Outer diameter: 1.85 mm (5.6 Fr)

GUIDE WIRE
- Material: Stainless steel
- Length: 120 cm
- Diameter: 0.09 cm, 0.035 in

INTRODUCER VALVE
- Material: Silicone
- Inner diameter: 9 Fr max

UNIVERSAL II SLITER
- Blade Material: Stainless steel
- Handle Material: Polycarbonate

NEEDLE (not included into C304-HIS package)
- 18 gauge, 1.2 mm

SYRINGE (not included into C304-HIS package)
- 12 cc

Model	C304 -HIS	C304S 59	C304L 69	C304XL 74
Description	Deflectable + preshaped	Deflectable		
Length	43 cm	30 cm	40 cm	45 cm
Compatible Lead	3830-59, 69,74	3830-59	3830-69	3830-74
Inner Diameter (mm (Fr))	1.9 (5.7)			
Outer Diameter (mm (Fr))	2.8 (8.4)			

Model C304S59, C304L69, C304XL74

Model C304-HIS

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

C315
CATHETER

PACING LEADS AND DELIVERY SYSTEMS

GENERAL
- Fixed shape guide catheters for SelectSecure® Model 3830 leads
- Package includes only catheter and dilator
- Package does not include introducer, guide wire, slitter, needle nor syringe
- To be ordered separately
- Use of introducer is optional – C315 catheter and dilator can be produced directly into the vein

CATHETER DILATOR
- Material: Polyether block amide
- Integrated valve
- In-line hub
- Hydrophilic coating
- Compatible with a 7 Fr Introducer
- Compatible with:
  - Universal II slitter 6230 UNI (to be ordered separately)
  - Adjustable slitter 6232 ADJ (to be ordered separately)

DILATOR
- Compatible with a 0.038" guide wire

Model	C315H20	C315J	C315S4	C315S5
Description	Fixed shape			
Length (cm)	20	30	30	30
Compatible Lead	for 49 cm or longer 3830 leads	for 59 cm or longer 3830 leads		
Inner Diameter (mm (Fr))	1.8 (5.4)			
Outer Diameter (mm (Fr))	2.4 (7.0)			

Model	C315S10	C315H40	C315HIS
Description	Fixed shape		
Length (cm)	40	40	43
Compatible Lead	for 69 cm or longer 3830 leads		
Inner Diameter (mm (Fr))	1.8 (5.4)		
Outer Diameter (mm (Fr))	2.4 (7.0)		

Model S4 Model S5 Model S10

Model J Model H20 Model H40 Model HIS

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CAPSURE® EPI

PACING LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting
- Lengths for 4965: 25, 35, 50 (cm)
- Lengths for 4968: 25, 35, 60 (cm)

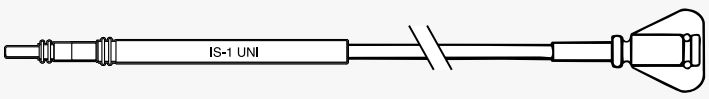
CONNECTOR
- IS1 Unipolar (4965)
- IS1 Bipolar (4968)

DIAMETER
- Body for 4965: 1.5 mm (4.5 Fr)
- Body for 4968: 2.5 mm (8.0 Fr)

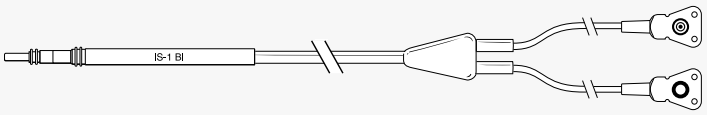
ELECTRODES
- Hemispherical, Platinized,,Porous
- Electrode Surface Area for 4965
  - Cathode: 14 mm^2
- Electrode Surface Area for 4968
  - Cathode: 6 mm^2
  - Anode: 14 mm^2

MATERIAL
- Insulator: Silicone
- Conductor: MP35N Nickel Alloy
- Electrode: Platinized Platinum

Model	4965	4968
Fixation	Sutured / Epicardial	
Shape / Chambers	RA and RV	
Polarity	Unipolar	Bipolar
Insulation	Silicone	



Model 4965



Model 4968

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SCREW-IN

PACING LEADS AND DELIVERY SYSTEMS

GENERAL
- Lengths: 25, 35, 53 (cm)

CONNECTOR
- IS1 Unipolar

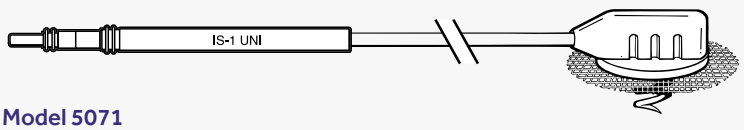
DIAMETER
- Body: 2.2 mm (6.5 Fr)

ELECTRODES
- Helical Screw
- Helix Length: 1.8 mm^2
- Electrode Surface Area
  - Cathode: 6.6 mm^2

MATERIAL
- Insulator: Silicone
- Conductor: MP35N Nickel Alloy
- Electrode: Platinized Alloy

EPICARDIAL IMPLANT TOOL 10626 – SOLD SEPARATELY
- Device Lenght
  - Overall: 350 mm
  - Shaft: 180 mm
- Shaft Angle: 65°
- Material
  - Acetal resin and stainless steel

Model	5071
Fixation	Screw-in / Epicardial
Shape / Chambers	RV
Polarity	Unipolar
Insulation	Silicone



Model 5071

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

DEFIBRILLATION LEADS AND DELIVERY SYSTEMS

SPRINT QUATTRO® MRI
SURESCAN™

DEFIBRILLATION LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting
- Standard Length: for 6946M: 55, 62 (cm)

DIAMETER
- Body: 2.8 mm (8.6 Fr)

ELECTRODES
- Electrode Surface Area
  - Tip: 2.5 mm^2
  - Ring: 25.2 mm^2
  - RV Coil: 614 mm^2
  - SVC Coil: 860 mm^2
- Electrode Lengths
  - RV Coil: 57 mm
  - SVC Coil: 80 mm
- Tip-to-Ring Spacing: 8 mm
- Tip-to-RVCoil Spacing: 12 mm

MATERIAL
- Insulator: Silicone, PTFE, ETFE
- Conductors: MP35N
- Tubing Design: Multilumen with Compression Lumens
- Tip and Ring Electrodes: Sintered (Tip) Platinum/Iridium alloy with Titanium Nitride (TiN) coating
- RV/SVC coils: Platinum-clad Tantalum

STYLETS
- Inserted
  - 1 purple straight
- Packaged
  - 2 purple straight
  - 2 gray straight

Model	6946M
Fixation	Passive / Tines
Polarity	Quadripolar
Defibrillation Coils	RV / SVC
Connectors	1x DF4
Insulation	Silicone
Introducer Size without/with Guidewire (Fr)	9.0 / 11

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

Model 6946M

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SPRINT QUATTRO®

DEFIBRILLATION LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting
- Standard Length: for 6946M: 72 (cm)

DIAMETER
- Body for 6946M: 2.8 mm (8.6 Fr)

ELECTRODES
- Electrode Surface Area
  - Tip: 2.5 mm^2
  - Ring: 25.2 mm^2
  - RV Coil: 614 mm^2
  - SVC Coil: 860 mm^2
- Electrode Lengths
  - RV Coil: 57 mm
  - SVC Coil: 80 mm
- Tip-to-Ring Spacing: 8 mm
- Tip-to-RVCoil Spacing: 12 mm

MATERIAL
- Insulator: Silicone, PTFE, ETFE
- Conductors: MP35N
- Tubing Design: Multilumen with Compression Lumens
- Tip and Ring Electrodes: Sintered (Tip) Platinum/Iridium alloy with Titanium Nitride (TiN) coating
- RV/SVC coils: Platinum-clad Tantalu

STYLETS
- Inserted
  - 1 purple straight
- Packaged
  - 2 purple straight
  - 2 gray straight

Model	6946M
Fixation	Passive / Tines
Polarity	Quadripolar
Defibrillation Coils	RV / SVC
Connectors	1x DF4
Insulation	Silicone
Introducer Size without/with Guidewire (Fr)	9.0 / 11

Model 6946M

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SPRINT QUATTRO SECURE S MRI™
SURESCAN™

DEFIBRILLATION LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting
- Lengths for 6935: 58, 65 (cm)
- Lengths for 6935M: 55, 62 (cm)

DIAMETER
- Body: 2.8 mm (8.6 Fr)

ELECTRODES
- Electrode Surface Area
  - Tip: 5.7 mm^2
  - Ring: 25.2 mm^2
  - RV Coil: 614 mm^2
- Electrode Lengths
  - RV Coil: 57 mm
- Tip-to-Ring Spacing: 8 mm
- Tip-to-RVCoil Spacing: 12 mm

MATERIAL
- Insulator: Silicone, PTFE, ETFE
- Conductors: MP35N
- Tubing Design: Multilumen with Extra Lumens
- Tip and Ring Electrodes: Platinized platinum alloy
- RV coil: Platinum-clad Tantalum

STYLETS
- Inserted
  - 1 purple straight
- Packaged
  - 2 purple straight
  - 2 gray straight

Model	6935	6935M
Fixation	Active/ Screw-in	
Polarity	Tripolar	
Defibrillation Coils	RV	
Connectors	1x IS1 1 x DF1	1x DF4
Insulation	Silicone	
Introducer Size without/with Guidewire (Fr)	9.0 / 11	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

Model 6935

Model 6935M

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SPRINT QUATTRO SECURE S®

DEFIBRILLATION LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting
- Lengths for 6935: 52, 75, 100 (cm)
- Lengths for 6935M: 49, 72, 97 (cm)

DIAMETER
- Body: 2.8 mm (8.6 Fr)

ELECTRODES
- Electrode Surface Area
  - Tip: 5.7 mm^2
  - Ring: 25.2 mm^2
  - RV Coil: 614mm^2
- Electrode Lengths
  - RV Coil: 57 mm
- Tip-to-Ring Spacing: 8 mm
- Tip-to-RVCoil Spacing: 12 mm

MATERIAL
- Insulator: Silicone, PTFE, ETFE
- Conductors: MP35N
- Tubing Design: Multilumen with Extra Lumens
- Tip and Ring Electrodes: Platinized platinum alloy
- RV coil: Platinum-clad Tantalum

STYLETS
- Inserted
  - 1 purple straight
- Packaged
  - 2 purple straight
  - 2 gray straight

Model	6935	6935M
Fixation	Active/ Screw-in	
Polarity	Tripolar	
Defibrillation Coils	RV	
Connectors	1x IS1 1 x DF1	1x DF4
Insulation	Silicone	
Introducer Size without/with Guidewire (Fr)	9.0 / 11	

Model 6935

Model 6935M

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SPRINT QUATTRO SECURE MRI™
SURESCAN™

DEFIBRILLATION LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting
- Lengths for 6947: 58, 65 (cm)
- Lengths for 6947M: 55, 62 (cm)

DIAMETER
- Body: 2.8 mm (8.6 Fr)

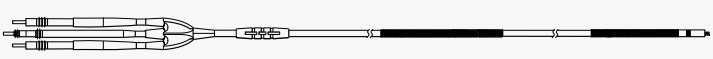
ELECTRODES
- Electrode Surface Area
  - Tip: 5.7 mm^2
  - Ring: 25.2 mm^2
  - RV Coil: 614mm^2
  - SVC Coil: 860mm^2
- Electrode Lengths
  - RV Coil: 57 mm
  - SVC Coil: 80 mm
- Tip-to-Ring Spacing: 8 mm
- Tip-to-RVCoil Spacing: 12 mm

MATERIAL
- Insulator: Silicone, PTFE, ETFE
- Conductors: MP35N
- Tubing Design: Multilumen with Extra Lumens
- Tip and Ring Electrodes: Platinized platinum alloy
- RV/SVC coil: Platinum-clad Tantalum

STYLETS
- Inserted
  - 1 purple straight
- Packaged
  - 2 purple straight
  - 2 gray straight

Model	6947	6947M
Fixation	Active/ Screw-in	
Polarity	Quadripolar	
Defibrillation Coils	RV/SVC	
Connectors	1x IS1 2x DF1	1x DF4
Insulation	Silicone	
Introducer Size without/with Guidewire (Fr)	9.0 / 11	

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)



Model 6947

Model 6947M

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SPRINT QUATTRO SECURE®

DEFIBRILLATION LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting
- Lengths for 6947: 75, 100 (cm)
- Lengths for 6947M: 72, 97 (cm)

DIAMETER
- Body: 2.8 mm (8.6 Fr)

ELECTRODES
- Electrode Surface Area
  - Tip: 5.7 mm^2
  - Ring: 25.2 mm^2
  - RV Coil: 614 mm^2
  - SVC Coil: 860 mm^2
- Electrode Lengths
  - RV Coil: 57 mm
  - SVC Coil: 80 mm
- Tip-to-Ring Spacing: 8 mm
- Tip-to-RVCoil Spacing: 12 mm

MATERIAL
- Insulator: Silicone, PTFE, ETFE
- Conductors: MP35N
- Tubing Design: Multilumen with Extra Lumens
- Tip and Ring Electrodes : Platinized platinum alloy
- RV/SVC coils: Platinum-clad Tantalum

STYLETS
- Inserted
  - 1 purple straight
- Packaged
  - 2 purple straight
  - 2 gray straight

Model	6947	6947M
Fixation	Active/ Screw-in	
Polarity	Quadripolar	
Defibrillation Coils	RV/SVC	
Connectors	1x IS1 2x DF1	1x DF4
Insulation	Silicone	
Introducer Size without/with Guidewire (Fr)	9.0 / 11	

Model 6947

Model 6947M

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

TRANSVENE LEAD

DEFIBRILLATION LEADS AND DELIVERY SYSTEMS

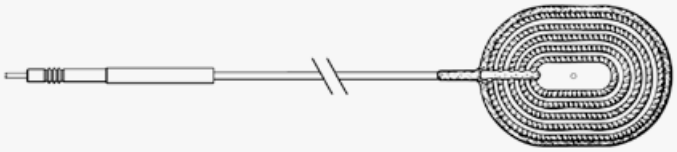
GENERAL
- Standard Length: 50 (cm)

DIAMETER
- Body: 2.5 mm (7.5 Fr)

ELECTRODES
- Electrode Surface Area
  - 6721S: 370 mm^2
  - 6721M: 660 mm^2
  - 6721ML: 840 mm^2

MATERIAL
- Insulator: Silicone
- Conductor: Multifilar MP35N Composite
- Electrode Surface: Platinum Alloy

Model	6721S	6721M	6721L
Fixation		Sutures	
Polarity		Unipolar	
Defibrillation Coils		Epi Patch	
Connectors		1x DF1	
Insulation		Silicone	
Introducer Size without/with Guidewire (cm)	3 coils: 5.0 x 8.0	4 coils: 6.1 x 9.1	5 coils: 7.2 x 10.2



Model 6721 (S/M/L)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

TRANSVENE LEAD

DEFIBRILLATION LEADS AND DELIVERY SYSTEMS

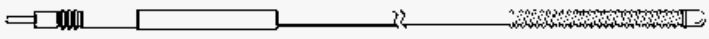
GENERAL
- Standard Lengths: 35, 52, 58, 110 (cm)

DIAMETER
- Body: 1.8 mm (7.5 Fr)

ELECTRODES
- Electrode Surface Area
  - Coil: 160 mm^2
- Electrode Lenght:
  - Coil: 80 mm

MATERIAL
- Insulator: Silicone
- Conductor: Multifilar MP35N Composite
- Electrode Surface: Platinum Alloy

Model	6937
Fixation	N/A
Polarity	Unipolar
Defibrillation Coils	SVC
Connectors	1 x DF1
Insulation	Silicone
Introducer Size without/with Guidewire (Fr)	9.0 / 10.5



Model 6937

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SUBCUTANEOUS LEAD

DEFIBRILLATION LEADS AND DELIVERY SYSTEMS

GENERAL
- Standard Lengths: 41, 58 (cm)

DIAMETER
- Body: 2.5 mm (7.5 Fr)

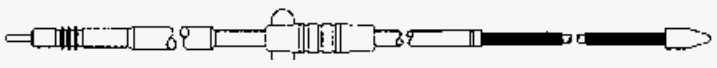
ELECTRODES
- Electrode Surface Area
  - Coil: 500 mm^2
- Electrode Lenght:
  - Coil: 250 mm

MATERIAL
- Insulator: Silicone
- Conductor: Multifilar MP35N Composite
- Electrode Surface: Platinum Alloy

CONTENTS OF STERILE PACKAGE
- 1 Model 6996 SQ Lead (with stylet + stylet guide)
- 2 introducer sheaths 10.5 Fr x 33 cm length
- 2 PTFE split tubings
- 2 slitters

TUNNELING TOOL 6996T – SOLD SEPARATELY
- Device Length
  - Overall: 421 mm
  - Tunneling: 338 mm
- Material
  - Stainless Steel
- Tunneling Diameter: 3.1 mm

Model	6996SQ
Fixation	Sutures on Achoring Sleeve
Polarity	Unipolar
Defibrillation Coils	Subcutaneus
Connectors	1 x DF1
Insulation	Silicone
Introducer Size without/with Guidewire (Fr)	10.5 x 33 cm Length



Model 6996SQ

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

LEFT-HEART LEADS AND DELIVERY SYSTEMS

ATTAIN ABILITY™ MRI
SURESCAN™

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting on all electrodes
- Standard Lengths: 78, 88 (cm)

CONNECTOR
- IS1 Bipolar

DIAMETER
- Body: 1.3 mm (4.0 Fr)

ELECTRODES
- Dual electrode, 21 mm spacing
- Electrode Surface Area
  - Tip: 5.8 mm^2
  - Ring: 5.8 mm^2

MATERIAL
- Insulator: Polyurethane-outer, SI-Polyimide-inner
- Conductor: SI-PI coated 25% Ag-core-MP35N
- Tip Electrode: Platinum/Iridium with Titanium Nitride coating
- Ring Electrode: Platinum/Iridium with Titanium Nitride coating
- Connector Pin: Stainless Steel
- Connector Ring: Stainless Steel

RECOMMENDED GUIDE WIRE
- Diameter: 0.014 to 0.018 in
- Attain Hybrid GWR419678, Purple knob, 98 cm – for 4196-78
- Attain Hybrid GWR419688, Purple knob, 108 cm – for 4196-88

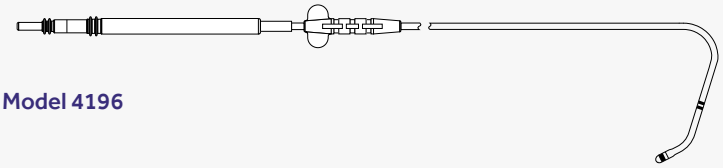
RECOMMENDED STYLET
- Diameter: 0.014 to 0.016 in

ACCESSORIES PACKAGED WITH LEAD
- Lead with Anchoring Sleeve
- Guide Wire Insertion Tool
- Guide Wire Steering Handle
- Guide Wire Clip
- Stylets

STYLETS
- Packaged
  - 2 gray straight
  - 2 purple straight

Model	4196
Fixation	Preformed Body
Shape / Chambers	Dual Canted / LV
Polarity	Bipolar
Insulation	Polyurethane
Guide Catheter Size (Inner Diameter) (Fr)	5.7

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)



Model 4196

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ATTAIN ABILITY™ PLUS MRI
SURESCAN™

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting on all electrodes
- Standard Lengths: 78, 88 (cm)

CONNECTOR
- IS1 Bipolar

DIAMETER
- Body: 1.77 mm (5.3 Fr)

ELECTRODES
- Dual electrode, 21 mm spacing
- Electrode Surface Area
  - Tip: 5.8 mm^2
  - Ring: 5.8 mm^2

MATERIAL
- Insulator: Polyurethane-outer, SI-Polyimide-inner
- Conductor: SI-PI coated 25% Ag-core-MP35N
- Tip Electrode: Platinum/Iridium with Titanium Nitride coating
- Ring Electrode: Platinum/Iridium with Titanium Nitride coating
- Connector Pin: Stainless Steel
- Connector Ring: Stainless Steel

RECOMMENDED GUIDE WIRE
- Diameter: 0.014 to 0.018 in
- Attain Hybrid GWR419678, Purple knob, 98 cm – for 4296-78
- Attain Hybrid GWR419688, Purple knob, 108 cm – for 4296-88

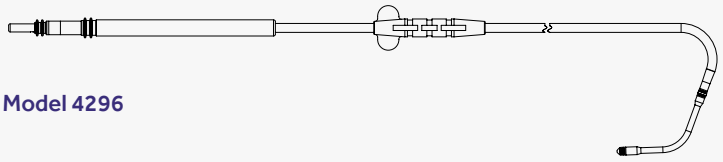
RECOMMENDED STYLET
- Diameter: 0.014 to 0.016 in

ACCESSORIES PACKAGED WITH LEAD
- Lead with Anchoring Sleeve
- Guide Wire Insertion Tool
- Guide Wire Steering Handle
- Guide Wire Clip
- Stylets

STYLETS
- Packaged
  - 2 gray straight
  - 2 purple straight

Model	4296
Fixation	Preformed Body
Shape / Chambers	Dual Canted / LV
Polarity	Bipolar
Insulation	Polyurethane
Guide Catheter Size (Inner Diameter) (Fr)	5.7

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)



Model 4296

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ATTAIN ABILITY™ STRAIGHT MRI
SURESCAN™

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting on all electrodes
- Standard Lengths: 78, 88 (cm)

CONNECTOR
- IS1 Bipolar

DIAMETER
- Body: 1.3 mm (4.0 Fr)

ELECTRODES
- Dual electrode, 21 mm spacing
- Electrode Surface Area
  - Tip: 5.8 mm^2
  - Ring: 5.8 mm^2

MATERIAL
- Insulator: Polyurethane-outer, SI-Polyimide-inner
- Conductor: SI-PI coated 25% Ag-core-MP35N
- Tip Electrode: Platinum/Iridium with Titanium Nitride coating
- Ring Electrode: Platinum/Iridium with Titanium Nitride coating
- Connector Pin: Stainless Steel
- Connector Ring: Stainless Steel

RECOMMENDED GUIDE WIRE
- Diameter: 0.014 to 0.018 in
- Attain Hybrid GWR419678, Purple knob, 98 cm – for 4396-78
- Attain Hybrid GWR419688, Purple knob, 108 cm – for 4396-88

RECOMMENDED STYLET
- Diameter: 0.014 to 0.018 in

ACCESSORIES PACKAGED WITH LEAD
- Lead with Anchoring Sleeve
- Guide Wire Insertion Tool
- Guide Wire Steering Handle
- Guide Wire Clip
- Stylets

STYLETS
- Packaged
  - 2 gray straight
  - 2 purple straight

Model	4396
Fixation	Tines
Shape / Chambers	Straight / LV
Polarity	Bipolar
Insulation	Polyurethane
Guide Catheter Size (Inner Diameter) (Fr)	5.7

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

Model 4396

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ATTAIN PERFORMA™ MRI
SURESCAN™

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting on all electrodes
- Standard Lengths: 78, 88 (cm)

CONNECTOR
- IS4-LLLL

DIAMETER
- Body: 1.7 mm (5.3 Fr)

ELECTRODES
- Electrodes Surface Area
  - All: 5.8 mm^2
- Distance between electrodes:
  - LV1-LV2: 21 mm
  - LV2-LV3: 1.3 mm
  - LV3-LV4: 21 mm

MATERIAL
- Insulator: Polyurethane-outer, SI-Polyimide-inner
- Conductor: SI-PI coated 25% Ag-core-MP35N
- Tip Electrode: Platinum/Iridium with Titanium Nitride coating
- Ring Electrode: Platinum/Iridium with Titanium Nitride coating
- Connector Pin: MP35N
- Connector Ring: MP35N

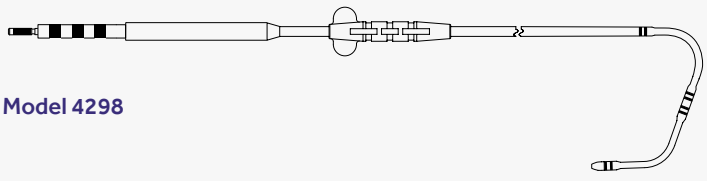
RECOMMENDED GUIDE WIRE
- Diameter: 0.014 to 0.018 in
- Attain Hybrid GWR419578, Orange knob, 98 cm – for 4298-78
- Attain Hybrid GWR419488, Orange knob, 108 cm – for 4298-88

ACCESSORIES PACKAGED WITH LEAD
- Lead with Anchoring Sleeve
- Guide Wire Insertion Tool
- Guide Wire Steering Handle
- Guide Wire Clip
- 2 AccuRead 2.0 analyzer cable interface tools
- Stylets

STYLETS
- Packaged
  - 2 gray straight
  - 2 purple straight

Model	4298
Fixation	Preformed Body
Shape / Chambers	Dual Canted/ LV
Polarity	Quadripolar
Insulation	Polyurethane
Guide Catheter Size (Inner Diameter) (Fr)	5.7

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)



Model 4298

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ATTAIN PERFORMA™ STRAIGHT MRI
SURESCAN™

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting on all electrodes
- Standard Lengths: 78, 88 (cm)

CONNECTOR
- IS4-LLLL

DIAMETER
- Body: 1.7 mm (5.3 Fr)

ELECTRODES
- Electrodes Surface Area
  - All: 5.8 mm^2
- Distance between electrodes:
  - LV1-LV2: 21 mm
  - LV2-LV3: 1.3 mm
  - LV3-LV4: 21 mm

MATERIAL
- Insulator: Polyurethane-outer, SI-Polyimide-inner
- Conductor: SI-PI coated 25% Ag-core-MP35N
- Tip Electrode: Platinum/Iridium with Titanium Nitride coating
- Ring Electrode: Platinum/Iridium with Titanium Nitride coating
- Connector Pin: MP35N
- Connector Ring: MP35N

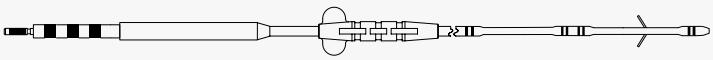
RECOMMENDED GUIDE WIRE
- Diameter: 0.014 to 0.018 in
- Attain Hybrid GWR419678, Orange knob, 98 cm – for 4398-78
- Attain Hybrid GWR419688, Orange knob, 108 cm – for 4398-88

ACCESSORIES PACKAGED WITH LEAD
- Lead with Anchoring Sleeve
- Guide Wire Insertion Tool
- Guide Wire Steering Handle
- Guide Wire Clip
- 2 AccuRead 2.0 analyzer cable interface tools
- Stylets

STYLETS
- Packaged
  - 2 gray straight
  - 2 purple straight

Model	4398
Fixation	Tines
Shape / Chambers	Straight/ LV
Polarity	Quadripolar
Insulation	Polyurethane
Guide Catheter Size (Inner Diameter) (Fr)	5.7

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)



Model 4398

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ATTAIN PERFORMA™ S MRI
SURESCAN™

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting on all electrodes
- Standard Lengths: 78, 88 (cm)

CONNECTOR
- IS4-LLLL

DIAMETER
- Body: 1.7 mm (5.3 Fr)

ELECTRODES
- Electrodes Surface Area
  - All: 5.8 mm^2
- Distance between electrodes:
  - LV1-LV2: 21 mm
  - LV2-LV3: 1.3 mm
  - LV3-LV4: 21 mm

MATERIAL
- Insulator: Polyurethane-outer, SI-Polyimide-inner
- Conductor: SI-PI coated 25% Ag-core-MP35N
- Tip Electrode: Platinum/Iridium with Titanium Nitride coating
- Ring Electrode: Platinum/Iridium with Titanium Nitride coating
- Connector Pin: MP35N
- Connector Ring: MP35N

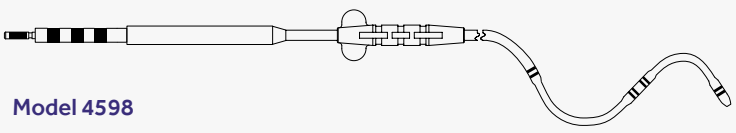
RECOMMENDED GUIDE WIRE
- Diameter: 0.014 to 0.018 in
- Attain Hybrid GWR419678, Orange knob, 98 cm – for 4598-78
- Attain Hybrid GWR419688, Orange knob, 108 cm – for 4598-88

ACCESSORIES PACKAGED WITH LEAD
- Lead with Anchoring Sleeve
- Guide Wire Insertion Tool
- Guide Wire Steering Handle
- Guide Wire Clip
- 2 AccuRead 2.0 analyzer cable interface tools
- Stylets

STYLETS
- Packaged
  - 2 gray straight
  - 2 purple straight

Model	4598
Fixation	Preformed Body
Shape / Chambers	S-Shape/ LV
Polarity	Quadripolar
Insulation	Polyurethane
Guide Catheter Size (Inner Diameter) (Fr)	5.7

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)



Model 4598

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ATTAIN STABILITY™ QUAD MRI
SURESCAN™

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Steroid eluting on all electrodes
- Standard Lengths: 78, 88 (cm)

CONNECTOR
- IS4 -LLLL

DIAMETER
- Body: 1.47 mm (4.4 Fr)
- Helix: 1.87 mm (5.6 Fr)

ELECTRODES
- Quadripolar electrode, 21 mm spacing
- Electrodes Surface Area
  - All: 5.8 mm^2
  - Ring: 5.8 mm^2
- Distance between electrodes:
  - LV1-LV2: 21 mm
  - LV2-LV3: 1.3 mm
  - LV3-LV4: 21 mm
  - LV3 – Helix tip: 10 mm

HELIX
- Fixed, side
- Not electrically active
- Length – ¾ turn exposed lenght
- Distance from Helix tip to lead body – 0.25 mm
- Helix location – 38.1 mm proximal to tip nose

MATERIAL
- Insulator: Polyurethane-outer, SI-Polyimide-inner
- Conductor: SI-PI coated 25% Ag-core-MP35N
- Tip Electrode: Platinum/Iridium with Titanium Nitride coating
- Ring Electrode: Platinum/Iridium with Titanium Nitride coating
- Helix: Platinum/Iridium alloy
- Connector Pin: MP35N
- Connector Ring: MP35N

RECOMMENDED GUIDE WIRE
- Diameter: 0.014 to 0.018 in
- Attain Hybrid GWR419578, Blue knob, 98 cm
- Attain Hybrid GWR419588, Blue knob, 108 cm

ACCESSORIES PACKAGED WITH LEAD
- Lead with Anchoring Sleeve
- Guide Wire Insertion Tool
- Guide Wire Steering Handle
- Guide Wire Clip
- Stylets

STYLETS
- Packaged
  - 2 gray straight
  - 2 purple straight
  - 2 blue J-shaped

Model	4798
Fixation	Preformed Body with Helix (active fixation)
Shape / Chambers	Canted/ LV
Polarity	Quadripolar
Insulation	Polyurethane
Guide Catheter Size (Inner Diameter) (Fr)	5.7

MRI SureScan
Full Body 1.5 and 3T MRI with any MRI SureScan cardiac device:
- No MRI scan exclusion zone and no scan duration restriction
- MRI scan possible for the entire life of the system
- No Patient size restriction and no condition restrictions (e.g. fever)

Model 4798

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ATTAIN COMMAND® SUREVALVE™

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Guide catheters for left-heart delivery
- Compatible transvenous devices:
- Leads 2.1 mm (6.2 Fr) max diameter
- Other devices 2.4 mm (7.1 Fr) max diameter
- Package **does not include** guidewire nor slitter
- To be ordered separately

CATHETER
- Material: Polyether block amide, polyamide 12
- Hydrophilic Coating distal ⅓ of the outer shaft

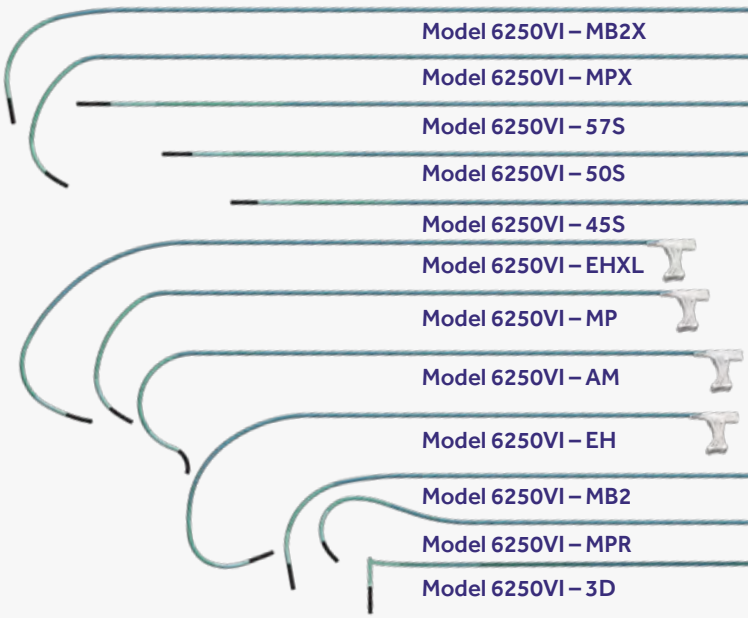
CATHETER DILATOR
- Material: Polyethylene
- Inner diameter: 0.96 mm (2.8 Fr)
- Outer diameter: 2.4 mm (7.1 Fr)

SUREVALVE INTEGRATED VALVE
- Material: Polypropylene with SBC overmold

VALVE TOOL
- Material: Polypropylene with SBC overmold

Model	6250VI-45S	6250VI-50S	6250VI-57S	6250VI-AM	6250VI-MB2	6250VI-MB2X
Description	Straight	Straight	Straight	Amplatz	Multi-purpose bend 2	Multi-purpose bend 2 extra
Usable Length (cm)	45	50	57.5	50	45	50
Min. Inner Diameter (Fr)	2.4 (7.2)					
Max. Outer Diameter Proximal / Distal (mm (Fr))	3.0 (9.0) / 2.8 (8.5)					

Model	6250VI-MP	6250VI-MPX	6250VI-MPR	6250VI-EH	6250VI-EXHL	6250VI-3D
Description	Multi-purpose	Multi-purpose extra	Multi-purpose right	Extended hook	Extended hook extra large	3-D (for right-sided implant
Usable Length (cm)	50	50	45	50	57.5	45
Min. Inner Diameter (mm (Fr))	2.4 (7.2)					
Max. Outer Diameter Proximal / Distal (mm (Fr))	3.0 (9.0) / 2.8 (8.5)					



NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ATTAIN COMMAND® SUREVALVE™ KITS

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Left-Heart Delivery System with 2 Guide
- Compatible transvenous devices:
  - Leads 2.1 mm (6.2 Fr) max diameter
  - Other devices 2.4 mm (7.1 Fr) max diameter

CATHETER
- Material: Polyether block amide, polyamide 12
- Hydrophilic Coating distal 1/3 of the outer shaft

CATHETER DILATOR
- Material: Polyethylene
- Inner diameter: 0.96 mm (2.8 Fr)
- Outer diameter: 2.4 mm (7.1 Fr)

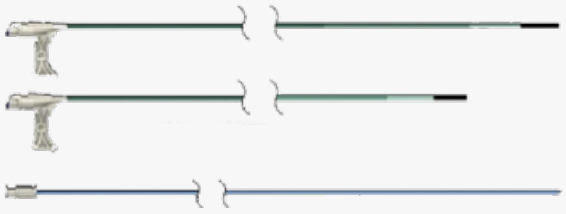
SUREVALVE INTEGRATED VALVE
- Material: Polypropylene with SBC overmold

VALVE TOOL
- Material: Polypropylene with SBC overmold

MEDTRONIC UNIVERSAL II 6230UNI SLITTER
- Material: Stainless steel, polycarbonate

GUIDEWIRE
- Material: Stainless steel
- Length: 120 cm
- Diameter: 0.9 cm (0.035 in)

Model	6250VIS	6250VIC
Description	Left-Heart Delivery System Straight Catheter Kit	Left-Heart Delivery System Curved Catheter Kit
Catheters included	6250VI-45S and 6250VI-50S	6250VI-EH 6250VI-MB2
Minimum Inner Diameter (mm (Fr))	2.4 (7.2)	
Max. Outer Diameter Proximal / Distal (mm (Fr))	3.0 (9.0) / 2.8 (8.5)	



Model 6250VIS

Model 6250VIC

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ATTAIN SELECT™ II SUREVALVE™

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Delivery Catheter System for Sub-Selection in a wide variety of patient anatomies
- 7 Fr sub-selection catheters capable of delivering 4 Fr and 5.3 Fr leads directly to vein branches
- Petite Length Attain Select II: 57 cm catheters for 78 cm lead delivery
- Compatible leads:
  - Body max outer diameter: 1.77 mm (5.3 Fr)
  - Electrode tip max outer diameter: 1.88 mm (5.6 Fr)
- Other transvenous compatible devices:
  - Delivery catheter max outer diameter: 1.85 mm (5.5 Fr)
  - Straight Blue Inner Catheter max outer diameter: 0.89 mm (2.7 Fr)
- Package does not include guidewire nor slitter
  - To be ordered separately

CATHETER
- Material: Polyether block amide, polyamide 12

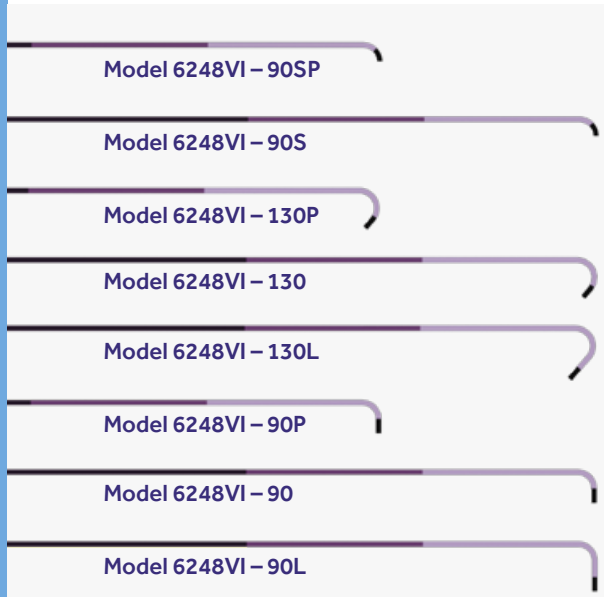
STRAIGHT BLUE INNER CATHETER
- Provides a soft distal tip and increased curve shape control
- Material: Polyether block amide
- Usable length: 80 cm
- Inner diameter: 1.0 mm (3.0 Fr)
- Outer diameter: 1.85 mm (5.5 Fr)

SUREVALVE INTEGRATED VALVE
- Material: Polypropylene with SBC overmold

VALVE TOOL
- Material: Polypropylene with SBC overmold

Model	6248VI-90S	6248VI-90	6248VI-90L	6248VI-130
Description	90° short curved tip	90° curved tip	90° long curved tip	130° curved tip
Usable Length (cm)	65			
Compatible Outer Guide Catheter Max Length (cm)	57.5			
Compatible Lead Min Length (cm)	88			
Inner Diameter (mm (Fr))	1.9 (5.7)			
Outer Diameter (mm (Fr))	2.4 (7.2)			

Model	6248VI-130L	6248VI-90SP	6248VI-90P	6248VI-130P
Description	130° long curved tip	90° short curved tip	90° curved tip	130° curved tip
Usable Length (cm)	65	57 (Petite)	57 (Petite)	57 (Petite)
Compatible Outer Guide Catheter Max Length (cm)	57.5	50		
Compatible Lead Min Length (cm)	88	78		
Inner Diameter (mm (Fr))	1.9 (5.7)			
Outer Diameter (mm (Fr))	2.4 (7.2)			



NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ATTAIN®
DEFLECTABLE

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Deflectable Catheter System for left-heart delivery
- Compatible transvenous devices:
- Leads 2 mm (6 Fr) max diameter

DEFLECTABLE CATHETER
- Material: Polyether block amide

CATHETER DILATOR
- Material: Polyethylene
- Length: 60 cm
- Outer diameter: 2.3 mm (7.0 Fr)

GUIDE WIRE
- Material: Stainless Steel
- Length: 120 cm
- Outer diameter: 0.09 cm (0.035 in)

ADJUSTABLE HEMOSTASIS VALVE
- Inner Diameter: 15 Fr max

MEDTRONIC UNIVERSAL SLITTER 6230UNI
- Material: Stainless steel, polycarbonate

NEEDLE
- Dimensions: 18 gauge, 1.2 mm

SYRINGE
- Volume: 12 cc

Model	6227DEF04
Usable Length	Deflectable
Inner Diameter (cm)	45
Outer Diameter (mm (Fr))	2.4 (7.2)
Insulation (mm (Fr))	3.3 (9.9)

Model 6227DEF04

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ATTAIN®
VENOGRAM BALLOON

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Venogram balloon catheter for coronary sinus
- Package includes:
  - Venogram balloon catheter
  - 1.25 cc syringe

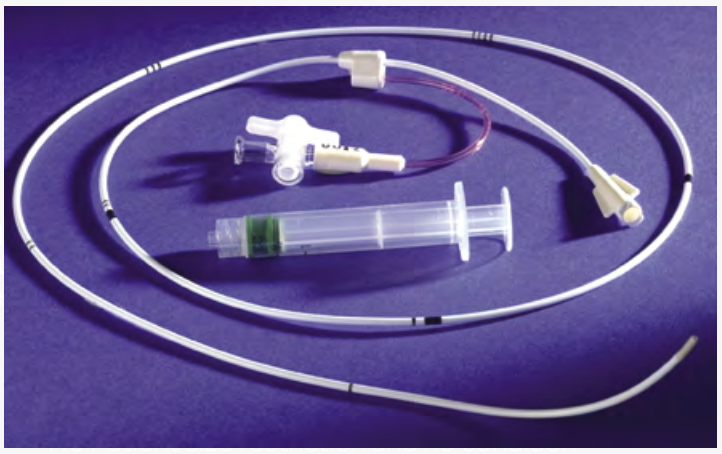
DIAMETER
- Catheter Body: 1.9 mm

BALLOON
- Max Inflation Capacity: 1.25 cc
- Inflated Balloon Diameter: 10 mm

MATERIAL
- Catheter Body: Polyurethane
- Balloon: Latex

RECOMMENDED GUIDE WIRE
- Diameter: 0.025 in (0.64 mm)

Model	6215
Description	Venogram Balloon Catheter
Usable Length (cm)	80
Guide Catheter Size (Inner Diameter) (Fr)	7.0



Model 6215

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

MEDTRONIC SLITTERS

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Slitter for LV guide catheters
- Slit two catheters in the same procedure
- Single use; Disposable

DEFLECTABLE CATHETER
- Handle: Polycarbonate
- Blade: Stainless Steel
- Trigger in 6232ADJ: ABS

Model	6232ADJ	6230UNI
Description	Medtronic Adjustable Slitter	Medtronic Universal II Slitter
Lead Stabilization	Lead mechanically secured in lead channel	Lead secured with thumb pressure

Model 6232ADJ

Model 6230UNI

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ADJUSTABLE VALVE

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL

- Adjustable Hemostasis Valve for use with LV delivery systems
- Rotating luer lock for variable positioning of side port
- Hemostatic to 103 kPa (15 PSI)

Model	6248VAL
Description	Medtronic Adjustable Valve
Max. Inner Diameter (Fr)	15

Model 6248VAL

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ATTAIN HYBRID®
GUIDE WIRE

LEFT-HEART LEADS AND DELIVERY SYSTEMS

GENERAL
- Guide wire with stylet features
- Straightens the cants of the Attain OTW leads
- Optimizes lead trackability

DIAMETER
- Body: 0.014 in

MATERIAL
- Core wire: Stainless Steel
- Sleeve: PET
- Coating: Lubricious Pro/Pel® silicone

Model	GWR419478	GWR419488	GWR419578
Knob Color	Orange	Orange	Blue
Support			
Length (cm)	98	108	98
Recommended Lead Models	4298, 4398	4298, 4398	4195, 4598
Lead Length (cm)	78	88	78

Model	GWR419588	GWR419678	GWR419688
Knob Color	Blue	Purple	Purple
Support			
Length (cm)	108	98	108
Recommended Lead Models	4195, 4598	4196, 4296, 4396	4196, 4296, 4396
Lead Length (cm)	88	78	88

GWR419478

GWR419488

GWR419578

GWR419588

GWR419678

GWR419688

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ACCESSORIES

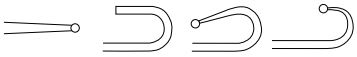
MEDTRONIC STYLETS

ACCESSORIES

GENERAL
- Stylets for use with transvenous leads
- Package includes:
  - 2 straight stylets (sterile)
  - 2 stylet guides (sterile)

MATERIAL
- Wire: Stainless Steel
- Knob: Plastic

Model	6057	6082	6054	6093
Knob Color	Blue	Gray	Rust	Purple
Shape				
Diameter (in)	0.014	0.014	0.016	0.016
Distal End	Ball-tipped	Extended taper, Ball-tipped	Tapered, Ball-tipped	Extend-ed-taper, Ball-tipped
# in kit	2	2	2	2
Lengths (cm)	45, 52, 58, 65, 75, 110	45, 52, 55, 58, 62, 65, 72, 75, 97, 110	45, 52, 53, 58, 65, 75, 85, 110	52, 58, 65, 75, 85, 100

Model	6282*	6052	6091	6094
Knob Color	Gray	White	Gray	Blue
Shape				
Diameter (in)	0.014	0.014	0.014	0.014
Distal End	Extended taper, Ball-tipped	Blunt	Extended taper, Ball-tipped	
# in kit	15	2	2	2
Lengths (cm)	75, 85	45, 53, 58	45, 53, 58, 65	45, 52, 58

* Hemostasis valve compatible (downsized knobs)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

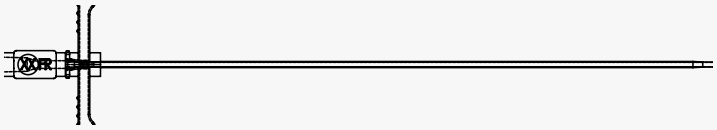
PEELABLE
INTRODUCERS

ACCESSORIES

GENERAL
- Peelable Percutaneous Lead Introducers (PLI) for use with transvenous leads

PACKAGE INCLUDES:
- 1 introducer sheath with tapered vessel dilator
- 1 thin-wall needle (18 gauge)
- 1 disposable syringe
- 1 flexible J guide wire with tip straightener:
  - Diameter: 1 mm (0.035 in)
  - Length: 60 cm (23.6 in)

Model	6207-S1	6208-S1	6209-S1	6210-S1	6211-S1	6212-S1	6214-S1
Size (Fr)	7	8	9	10.5	11	12	14
# of kits				1			



Model 62xx-S1

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

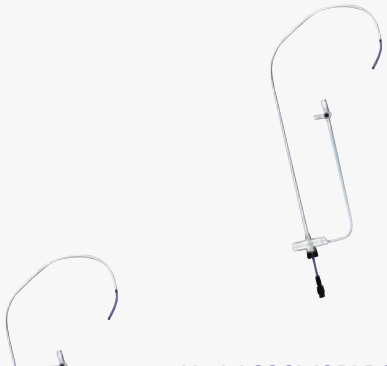
SAFESHEATH CSG®
WORLEY BRAIDED CORE INTRODUCERS

ACCESSORIES

GENERAL
- SafeSheath CSG® Worley Braided Core Introducer System for Coronary Sinus Access

PACKAGE INCLUDES:
- 1 tear-away sheath w/side port
- 1 dilator
- 1 needle (18 gauge)
- 1 syringe (12 cc)
- 1 guidewire (135 cm)
- 1 curved guiding core
- 1 transvalvular insertion tool (TVI) (7 Fr)

Model	CSGWORBC19M	CSGWORLBC19M	CSGWORBC29M
Size (Fr)		9	
# of kits		5	
Lenght (cm)	40	50	50



Model CSGWORLBC19M

Model CSGWORBC19M

Model CSGWORBC29M

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SAFESHEATH CSG®
EXTRUDED CORE INTRODUCERS

ACCESSORIES

GENERAL
- SafeSheath CSG® Worley Braided Core Introducer System for Coronary Sinus Access

PACKAGE INCLUDES:
- 1 tear-away sheath w/side port
- 1 dilator
- 1 needle (18 gauge)
- 1 guidewire (135 cm)
- 1 curved guiding core
- 1 transvalvular insertion tool (TVI) (7 Fr)

Model	CSGWORLEY109M	CSGWORL19M
Size (Fr)	9	
# of kits	5	
Length (cm)	40	50

Model CSGWORLEY109M

Model CSGWORL19M

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SAFESHEATH II®
LEAD INTRODUCERS

ACCESSORIES

GENERAL
- SafeSheath II® Hemostatic Peel-away Introducer System for Vascular Access with
- low insertion/withdrawal force lubricated valve
- ergonomically-designed, easy-splitting hub
- extruded score line sheath
- infusion side port
- snap-fit dilator

PACKAGE INCLUDES:
- 1 tear-away sheath w/side port
- 1 dilator
- 1 needle (18 gauge)
- 1 syringe (12 cc)
- 1 guidewire (Standard-50cm / Long-60cm)

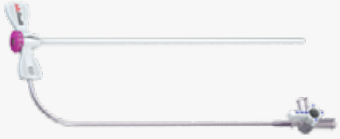
Model	SS5	SS6	SS7	SS8	SS85
Knob Color	5	6	7	8	8.5
# in kit			5		
Lengths (cm)			13		

Model	SS9	SS95	SS10	SS105	SS11
Knob Color	9	9.5	10	10.5	11
# in kit			5		
Lengths (cm)			13		

Model	SS12	SS125	SSL6	SSL7	SSL8
Knob Color	12	12.5	6	7	8
# in kit			5		
Lengths (cm)	13	13	23	23	23

Model	SSL9	SSL10	SSL105	SSL11
Knob Color	9	10	10.5	11
# in kit		5		
Lengths (cm)		23		

Model SSx



Model SSLx

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

FLOWGUARD®
VALVED PEELABLE INTRODUCERS

ACCESSORIES

GENERAL
- FlowGuard® Valved Peelable Introducers for use with transvenous leads
- Sliding valve feature for procedural flexibility
- Low-profile handle and interlock system to prevent dilator pop-out during insertion

Model	10729 -001	10729 -002	10729 -003	10729 -004
Size (Fr)	7.0	8.0	9.0	10.5
# of kits	1			
Sheath Length (cm)	13	15	15	15
Dilator Length (cm)	18	21.5	21.5	21.5

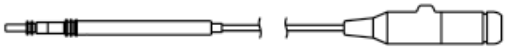
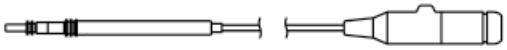
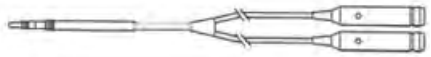
Model	10730 -001	10730 -002	10730 -003	10730 -004
Size (Fr)	7.0	8.0	9.0	10.5
# of kits	5			
Sheath Length (cm)	13	15	15	15
Dilator Length (cm)	18	21.5	21.5	21.5

Model 10729-00x
Model 10730-00x

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

PACING LEAD ADAPTORS

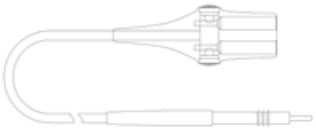
ACCESSORIES

Model	Description	
BLV-BIS-10	LV-1 Bipolar Lead to IS-1 Bipolar IPG - 10cm	
BLV-BIS-40	LV-1 Bipolar Lead to IS-1 Bipolar IPG - 40cm	
B-IS-15SS2	5mm Bifurcated Bipolar Lead or two 5mm Unipolar Leads to IS-1 Bipolar IPG	
BIS-IS-15	Two IS-1 UNI Leads to IS-1 BI IPG	
BIS-BIS-17	3.2mm Low Profile Bipolar Lead to IS-1 BI IPG - Permanent Extension	
BIS-BIS-40	IS-1 BI Lead to IS-1 BI IPG - Permanent Lead Extension	

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ICD LEAD ADAPTORS

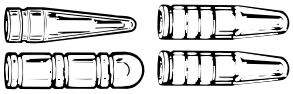
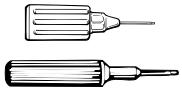
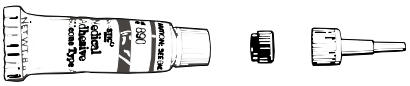
ACCESSORIES

Model	Description	
6726	DF-1 Y Adaptor/Extender – 25cm or 37cm	
6707	6,5 mm to DF-1 - Adaptor Kit – 15cm	
6920	Upsizing Sleeve for HV Leads 3,2mm LP or DF-1 to 6,5mm 3 Units per Kit	
5019	DF-4 Adapter - Removes SVC coil from shock path and allows use of additional defibrillation DF-1 lead/ patch	

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

ADDITIONAL ACCESSORIES

ACCESSORIES

Model	Description	
5867-3M	Lead End Cap Kit	
6056	Pinch-on Tool 6056 for Medtronic Screw-in Leads	
6056M	Individual package for AccuRead 2.0 tool	
5873C	Lead Service Installation Kit	
5873W	Lead wrench kit	
80118	Medical adhesive	
6717	6.5mm Unipolar Connector Port Pin Plug, 1 per kit	
6719	DF-1 unipolar connector Port Pin Plug, 1 per kit	
6725	IS-1 connector port pin plug, 1 per kit - may be used as a part of the MRI CRT-D SureScan systems in place of a right atrial lead	
6177	Sterile Programming Head Cover - 10 per kit	
9466	Patient Magnet - 4 per kit	

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

INSERTABLE CARDIAC MONITORS (ICM)

LINQ II™

INSERTABLE CARDIAC MONITORS (ICM)

GENERAL
- Insertable Cardiac Monitor (ICM) with 4.5 years longevity*
- TruRhythm™ Detection
- Pause Detection Algorithm
- PVC Detection Algorithm
- Automatically Detected Episodes: up to 27 min
- Patient-Activated Symptom: up to 30 min
- Symptom/Auto Correlated Episodes: up to 4 min
- CareLink connectivity
- Smart Memory Management
- Bluetooth® Wireless Telemetry (BlueSync™ Technology): two-way communication
- Remote programming capability

ARRHYTHMIA DETECTION
- Pause/Asystole
- Bradycardia
- Tachycardia (VT/FVT)
- Atrial Tachycardia (AT) / Atrial Fibrillation (AF) with enhanced detection

DIAGNOSTICS
- Quick Look
- Cardiac Compass:
  - Programming and interrogation events
  - Patient symptoms
  - AT/AF total time per day
  - Ventricular rate during AT/AF
  - Average ventricular rate
  - Patient activity
  - Heart rate variability
  - Ventricular rate during AT/AF histogram (time in or out od AT/AF)
  - PVC

COMPATIBLE DEVICES
- In-clinic Programmer
  - Reveal LINQ™ Mobile Manager
- Patient Monitor
  - MyCareLink Heart™ Mobile App, or MyCareLink Relay™ Home Communicator
- Symptom Marker
  - MyCareLink Heart™ Mobile App, or Patient Assistant PA97000 (for MyCareLink Relay™ Home Communicator)

PACKAGE CONTENT
- LINQ II™ Insertable Cardiac Monitor (preloaded in the included insertion tool handle)
- Incision tool
- Insertion tool plunger
- Insertion tool handle
- Product documentation

** Nominal settings*

Model	LNQ22
M (g)	3.4
V (cc)	1.4
Size (mm)	45.1 x 8.0 x 4.2

MRI Compatibility
- MR-Conditional at 3.0 and 1.5 Tesla
- No-post insertion waiting period

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

REVEAL LINQ™

INSERTABLE CARDIAC MONITORS (ICM)

GENERAL
- Insertable Cardiac Monitor (ICM) with 3 years life*
- TruRhythm™ Detection
- Auto-activated events: 29 min of ECG
- Patient-activated events: 30 min of ECG
  - Up to 14 min of ECG prior to activation
- CareLink connectivity

ARRHYTHMIA DETECTION
- Pause/Asystole
- Bradycardia
- Tachycardia (VT/FVT)
- Atrial Tachycardia (AT) / Atrial Fibrillation (AF) with enhanced detection

DIAGNOSTICS
- Quick Look
- Cardiac Compass Trends:
  - AT/AF burden
  - Ventricular rate during AT/AF
  - Day and night average ventricular rate
  - Daily activity
  - Heart rate variability
- AT/AF summary
- Rate histograms
- Episode list
- Episode counters

PATIENT ASSISTANT – MODEL PA96000
- 10cmx4cmx1cm
- Record button - captures patient-activated episodes
- Non-replaceable battery chosen for size, cost, and energy capacity
- Designed to operate at least 200 operations over 3 years plus shelf life and leakage

PACKAGE CONTENT
- Reveal LINQ™ ICM (preloaded in the included insertion tool)
- Incision tool
- Insertion tools
- Reveal PA96000

** Nominal settings*

Model	LNQ11
M (g)	2.5 ± 0.5
V (cc)	1.2
Size (mm)	44.8 x 7.2 x 4.0

MRI Compatibility
- MR-Conditional at 3.0 and 1.5 Tesla
- No-post insertion waiting period

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

REVEAL® XT

INSERTABLE CARDIAC MONITORS (ICM)

GENERAL
- Insertable Cardiac Monitor (ICM) with 3 years life*
- Auto-activated events: 27 min of ECG
- Patient-activated events: 22.5 min of ECG
  - Up to 14 min of ECG prior to activation
- Up to 30 events in total
- CareLink connectivity
- Reveal Vector Check for optimal positioning

ARRHYTHMIA DETECTION
- Asystole
- Bradycardia
- Ventricular Tachycardia (VT) / Fast Ventricular Tachycardia (FVT)
- Atrial Tachycardia (AT) / Atrial Fibrillation (AF)

DIAGNOSTICS
- Quick Look
- Cardiac Compass Trends:
  - AT/AF total time per day
  - Ventricular rate during AT/AF
  - Day and night average ventricular rate
  - Patient activity
  - Heart rate variability
- AT/AF summary
- Rate histograms
- Episode list
- Episode counters

PATIENT ASSISTANT – MODEL PA96000
- 10cmx4cmx1cm
- Record button - captures patient-activated episodes
- Non-replaceable battery chosen for size, cost, and energy capacity
- Designed to operate at least 200 operations over 3 years plus shelf life and leakage

PACKAGE CONTENT
- Reveal XT ICM
- Conductive patches for Vector Check
- Reveal PA96000

** Nominal settings*

Model	9529
M (g)	15
V (cc)	9
Size (mm)	62 x 19 x 8

MRI SureScan
- MR-Conditional at 3.0 and 1.5 Tesla
- 6-week post-insertion waiting period

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

PATIENT MANAGEMENT SOLUTIONS

CARELINK™ NETWORK

PATIENT MANAGEMENT SOLUTIONS

GENERAL

The CareLink™ Network is a remote monitoring service for patients with Medtronic implanted cardiac devices. The service allows patients to send full device data to their clinic from home or away. The monitoring solution collects patients' device data and sends it to a secure sever.

Healthcare providers can analyze the patient device diagnostic data via the CareLink™ Network Clinician Website through their internet browser. The site is also used to enroll clinic users, enroll patients, and perform other administrative duties.

- Compatible with 99.9% Medtronic implantable devices.
- Operates on the Microsoft™ Windows™ operating system with database support based on Microsoft's SQL (Structured Query Language) Server software
- Administration for hospital CareLink network service set-up
- Access to secure server space for data hosting of active patient data using CareLink
- Unlimited healthcare professional users per hospital
- Access to Vodafone worldwide data network and their roaming partners
- Patient transmissions:
  - Scheduled
  - Customizable color-coded CareAlerts
  - Patient-initiated transmissions
- Technical support
- CareLink clinician website upgrades
- CareLink monitor software upgrades
- Training of healthcare professionals and patient groups
- Online access for healthcare professionals to the Medtronic Academy for training on website
- CareLink Mobile Application for clinicians
- Updates

SECURITY MEASURES

- ISO 27001 and SOC II-certified
- Hosted in Europe at SAS70
- Certified site
- Managed by Medtronic personnel

DIEN CODE	SSA4-CLNETSERVICE (varies per country)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

MYCARELINK HEART ™ MOBILE APP

PATIENT MANAGEMENT SOLUTIONS

GENERAL

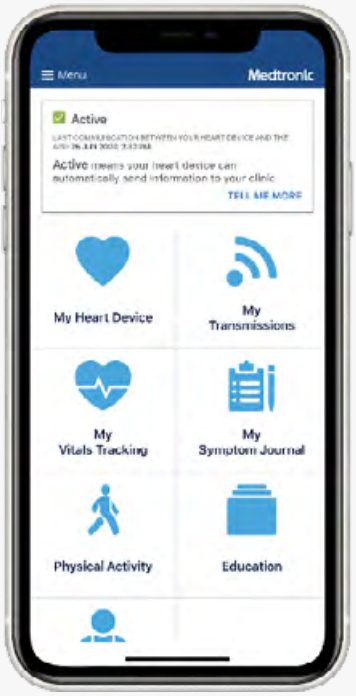
- Patient app for remote monitoring of Medtronic BlueSync™ enabled cardiac implantable devices in the Medtronic CareLink™ Network
- Replaces the traditional bedside monitor to securely transfer heart device data using patient smartphone or tablet
- Best option for patients owning compatible iOS and Android smart device[1] and comfortable with using apps or smart technology

MAIN FEATURES

- Cellular or Wi-Fi connectivity through patient's smart device
- Bluetooth® Low Energy is designed to minimize battery drain of the implantable device
- Enhanced security with data encryption from end to end
- Automatic notifications help patients stay connected
- Upgradable throughout lifetime of the device
- Allows patients to view select device data such as battery life and access in-app education content

[1] Please visit www.MCLHeart.com for a list of compatible smartphones and tablets

Model Patient app	**27000**
Model Application for IOS	MSW003
Application for Android	MSW004



NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

MYCARELINK RELAY™ HOME COMMUNICATOR

PATIENT MANAGEMENT SOLUTIONS

GENERAL
- Patient bedside communicator for remote monitoring of Medtronic BlueSync™ enabled cardiac implantable devices in the Medtronic CareLink™ Network
- Best option for patients that rarely carry a mobile device or not comfortable with using apps or smart technology

MAIN FEATURES
- Integrated cellular 4G LTE connectivity with international coverage and Wi-Fi connectivity
- Bluetooth® Low Energy is designed to minimize battery drain of the implantable device
- Enhanced security with data encryption from end to end
- Optimized Bluetooth® & cellular antenna design
- Requires little to no user interaction

POWER SUPPLY
- AC powered, 100-240 V, 50-60 Hz, 0.5 A Max

PHYSICAL CHARACTERISTICS
- Ambient light sensor automatically turns off lights in the dark
- Light Ring to show activity
- Progress bar to display transmission status
- Button to checks status or send patient-initiated transmissions

Model	24960
M (g)	N/A
Size (mm)	N/A

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

MYCARELINK SMART™ MONITOR

PATIENT MANAGEMENT SOLUTIONS

GENERAL
- Patient monitor for remote monitoring of Medtronic cardiac implantable devices in the Medtronic CareLink™ Network
- Designed to be paired with one single implantable device
- Designed to be paired with IPGs, CRT-Ps and Micra TPS devices

CONNECTIVITY AND TRANSMISSIONS
- Transmission data sent via MCL Smart App installed on patient's / caregiver's smart device
- Bluetooth connection between the reader and the smart device
- Inductive telemetry between the implanted device and the reader
- Designed for manual transmissions
- Intended to support non-wireless implantable devices

POWER SUPPLY
- Battery powered
  - 3x AA alkaline batteries

PHYSICAL CHARACTERISTICS
- Reader with 3 indicator LED lights
- App installed on a smart device

Model	25000
M (g)	164 (without batteries)
Size (mm)	155 x 80 x 30

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

MYCARELINK™ MONITOR

PATIENT MANAGEMENT SOLUTIONS

GENERAL
- Patient monitor for remote monitoring of Medtronic cardiac implantable devices in the Medtronic CareLink™ Network
- Designed to be paired with one single implantable device

CONNECTIVITY AND TRANSMISSIONS
- Cellular technology, with international coverage
- Supports wireless data transmissions (when paired to wireless implantable device)
- Can send the wireless transmission when in range of up to 3 m from the implanted device
- Designed for automatic as well as manual transmissions

POWER SUPPLY
- AC powered, 100-240V, 50-60Hz

PHYSICAL CHARACTERISTICS
- Reader with 3 indicator LED lights
- Docking station with animated LCD display

Model	24952
M (g)	N/A
Size (mm)	207 x 153 x 66

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

SMARTSYNC™ DEVICE MANAGER

PATIENT MANAGEMENT SOLUTIONS

GENERAL
- Tablet-Based programmer for interrogating and programming compatible Medtronic cardiac implantable devices*
- Includes the Pacing System Analyser (PSA)
- Intended to support implants and follow-ups
- Enables wireless, streamlined and secure digital workflow

MAIN FEATURES
- Free iOS Application, is compatible with certain models of the Apple iPad Pro and iPad Air**
- Pacing System Analyzer integrated in the Base Station
- Telemetry B (inductive), BlueSync™ Technology (wireless)
- E-strip recorder, with annotating options
- Report Exporting options: save to network folder, USB***
- Possibility to connect to external printer via WiFi

POWER SUPPLY
- Patient Connector: AC powered with 3 hours of battery back-up
- Base Unit: AC powered
- PSA: powered separately from the base, using 2 AA batteries

COMPONENTS AND ACCESSORIES
- 24970A Base unit
- 24967 Patient Connector
- 249705 Power cord
- 2090 EC/ECL ECG cable with plug and leadwires
- 2292 surgical cables
- 249704 Carry case

SYSTEM COMPONENTS
- SmartSync iOS application
- Base unit:
  - Including the Pacing System Analyzer
  - Communicating via Bluetooth® with tablet
- Patient connector:
  - Communicating via Tel B with Astra™ Pacemakers; via Bluetooth Low energy with BlueSync™ enabled devices
  - Communicating via Bluetooth® with tablet
- Tablet
  - Apple iPad Pro and iPad Air**
  - Hospital owned or Medtronic Managed Tablet (MMT)

** More information on compatible devices can be found in the CareLink SmartSync Device Manager materials*

*** More information on compatible iPad models can be found in the CareLink SmartSync Device Manager materials*

**** Depending on Country and tablet option*

Model Base unit	**24970A**
Weight (kg)	0.91
Size (cm)	4.6 x 24 x 20.8

Model Patient connector	**24967**
Weight (kg)	0.25
Size (cm)	16.7 x 7.3 x 3.0

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

REVEAL LINQ™ MOBILE MANAGER

PATIENT MANAGEMENT SOLUTIONS

GENERAL

- The Reveal LINQ™ Mobile Manager is an innovative, app-based device management system for Reveal LINQ™ and LINQ II™ insertable cardiac monitor (ICM).
  It enables procedure simplicity and programmer portability for device activation, programming, CareLink™ Network pre-enrollment and follow-up checks - all from the same tablet.
- Generate reports quickly and simply
- Simplify staff training with guided animations
- Easily access patient education modules directly from the app*
- Streamline workflows for initial device activation or follow-up
- Access a built-in Help Menu to answer device activation and follow-up device check questions
- Setting up patients up to 7 days prior to implant
- Automatically pre-enroll your patients in the Medtronic CareLink™ Network
- Access data on the CareLink™ Network within minutes after device activation or follow-up device checks, while connectivity with the CareLink™ Network is established

MAIN FEATURES

- The LMM application is a free iOS application
- www.LINQMobileManager.com - follow the links to download the app

POWER SUPPLY

- Patient connector: AC powered with 3 hours of battery back-up

SYSTEM COMPONENTS

- LMM iOS application
- Patient connector:
  - Communicating via Tel B with Reveal LINQ™
  - Communicating via Bluetooth® with LINQ II™ and tablet
- Reveal LINQ™ and LINQ II™ ICMs
- Tablet – hospital-owned or Medtronic Managed Tablet (MMT)

** May vary based on geography*

Model	
Patient connector	24967

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CARELINK EXPRESS™ MOBILE SYSTEM

PATIENT MANAGEMENT SOLUTIONS

GENERAL
- The CareLink Express™ Mobile System allows the interrogation of any compatible Medtronic cardiac Implantable device, with secure and rapid transfer of the data to the CareLink™ Network for remote interpretation.
- The CareLink Express™ System provides secure access and transfer of data, seamlessly integrating into a follow-up clinic's CareLink system.

MAIN FEATURES
- Compatible with 99% of Medtronic cardiac devices supported on the CareLink™ Network[1]
- The CareLink Express™ Mobile application is a free iOS application

POWER SUPPLY
- Patient connector: AC powered with 3 hours of battery back-up

SYSTEM COMPONENTS
- CareLink Express™ Mobile IOS application
- Patient connector (Tel A/B):
  - Communicating via Tel B with all devices
  - Communicating via Bluetooth with tablet
- Tablet – hospital-owned or Medtronic-supplied tablet
- CareLink Express™ Website
- Carrying Case for patient connector and the tablet (ordered seperately)

[1] Supported devices on CareLink™ Network - Data on File (Jan 2014)

Model Patient connector	**24967**
Model Application for IOS	**31302**
Carrying Case	249653

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CARELINK ENCORE™ PROGRAMMER

PATIENT MANAGEMENT SOLUTIONS

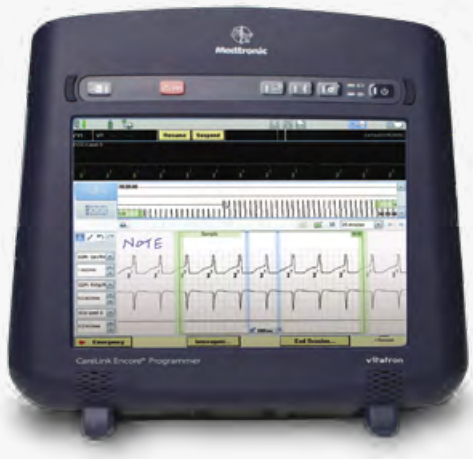
GENERAL
- System for interrogating and programming Medtronic and Vitatron cardiac implantable devices
- Intended to support follow-ups

MAIN FEATURES
- Built in WiFi and ethernet
- keyboard
- Resistive touch screen
- PDF viewer
- Electronic strip recorder
- USB printing (no integrated printer available)
- Telemetry A and B (no wireless)
- Emergency button for VVI pacing

POWER SUPPLY
- AC powered with 2hours of battery back-up

ACCESSORIES (IN THE PACKAGE)
- 26901 Programming head
- 26902 Rechargeable battery
- 26905 Stylus
- 26906 Power cord
- 26907 Power supply

Model	29901
M (g)	4.94
Size (mm)	35.5 x 35.5 x 10.2



NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CARELINK® 2090 PROGRAMMER

PATIENT MANAGEMENT SOLUTIONS

GENERAL
- System for interrogating and programming Medtronic, Vitatron and NayaMed cardiac implantable devices
- Intended to support implants and follow-ups

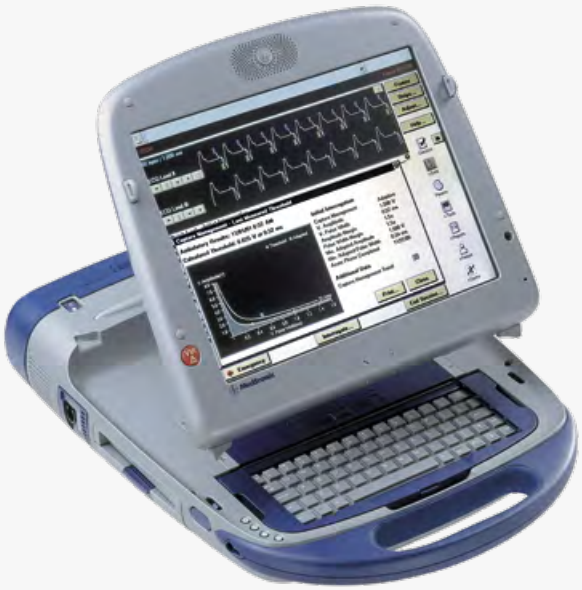
MAIN FEATURES
- Ethernet card
- Mechanical keyboard
- Display screen
- Integrated printer - possibility to connect to external printer via parallel port or USB
- Telemetry A, B (inductive) and C (wireless)
- Emergency button for VVI pacing

POWER SUPPLY
- AC powered

ACCESSORIES
- 2290 Medtronic Analyzer
- 2067/L Programmer head
- 2090TPS/XS Touch pen
- 2090EC/ECL ECG cable with plug and leadwires
- 6092 Printer paper

PACKAGE CONTENTS
- 2090 CareLink Programmer
- 2090TPS/XS Touch pen
- 2090EC/ECL ECG cable with plug and leadwires
- 6092 Printer paper

Model	2090
M (kg)	11.3
Size (mm)	12.7 x 40.6 x 55.8



NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

CARELINK® 2290 ANALYZER

PATIENT MANAGEMENT SOLUTIONS

GENERAL
- Accessory that installs into the Medtronic CareLink® 2090 Programmer
- Designed to analyze the electrical performance of a cardiac lead system
- Uses the programmer as a control and display platform

MAIN FEATURES
- Automatic measurement of P- and R-wave amplitudes and slew rates
- Automatic lead impedance measurement
- Real-time display of atrial and ventricular EGM
- Rapid atrial stimulation to 800 min^{-1} (ppm)
- Advanced analysis features, including antegrade and retrograde conduction tests, and a pulse width versus amplitude threshold analysis
- Measurement reports
- Backup battery in the event of a power loss
- Electrical isolation from the programmer
- Emergency VVI pacing

PACKAGE CONTENTS
- 2290 Analyzer
- 2292 Analyzer surgical cable
- 9 V Battery
- Screwdriver
- Product literature

Model	2290
M (kg)	N/A
Size (mm)*	N/A

* installs into the Medtronic CareLink® 2090 Programmer

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

FOCUSON™
MONITORING AND TRIAGING SERVICE

PATIENT MANAGEMENT SOLUTIONS

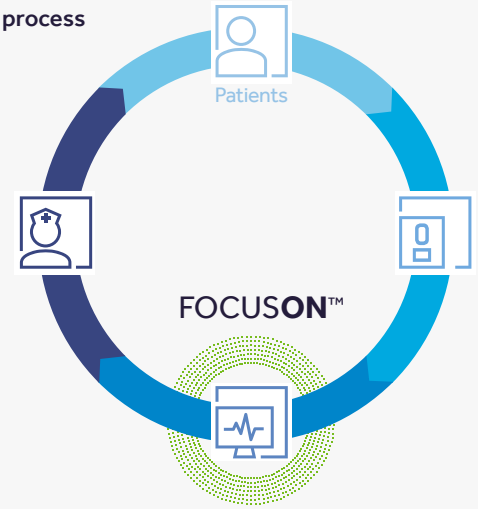
GENERAL
- FocusOn™ is a service that monitors and triages CareLink™ transmissions from all Medtronic implantable cardiac devices.
- All incoming data is reviewed and classified based on its clinical relevance (colour-code classification), according to a customized protocol instructed by the treating physicians.
- The FocusOn™ Team notifies the hospital clinical teams via email and/or phone /SMS and according to the customized colour-coding classification.
- All FocusOn™ triaged data and transmissions are accessible via the FocusOn™ platform.
- Available for:
  - IPG, CRT-P
  - ICD, CRT-D
  - ICM

QUALITY PROCESS
- All the data is reviewed by two different certified ECG/ cardiac device specialists to maximize accuracy and quality control through redundancy.
- The ECG specialists are supervised by cardiologists.

Service Time		
Days	Mon-Fri (no bank holidays)	
Hours	7am – 6pm CET	

Service Level Agreement and escalation methods		
Days	Phone/SMS and e-mail	Same working day
Days	E-mail	Next working day
Hours	Weekly e-mail	Once a week

The continuous FOCUSON™ process



Hospital Clinical Teams

Teams are promptly alerted on urgent information, so they have more time to spend with patients and with those that need immediate care.

CareLink® Network

The CareLink® Network receives data from patients with Medtronic implantable cardiac devices.

Monitoring & Triaging Service Centre

The FocusOn™ team monitors and triages all incoming CareLink™ data according to hospital customisations. The hospital clinical teams are then alerted about clinically actionable events via telephone, email and the FocusOn™ Platform.

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

BECONNECTED SERVICE

PATIENT MANAGEMENT SOLUTIONS

GENERAL

BECONNECTED is a patient support service designed to free up clinic time by directing patients to the experienced BeConnected team:

- Helping patients onboard with their optimal monitoring solution:
  - Education on remote monitoring
  - Screening for optimal monitoring solution with the ability to ship bedside monitor to patient home address
  - Set-up of patient monitoring solution.
- Helping patients with general device & remote monitoring questions.

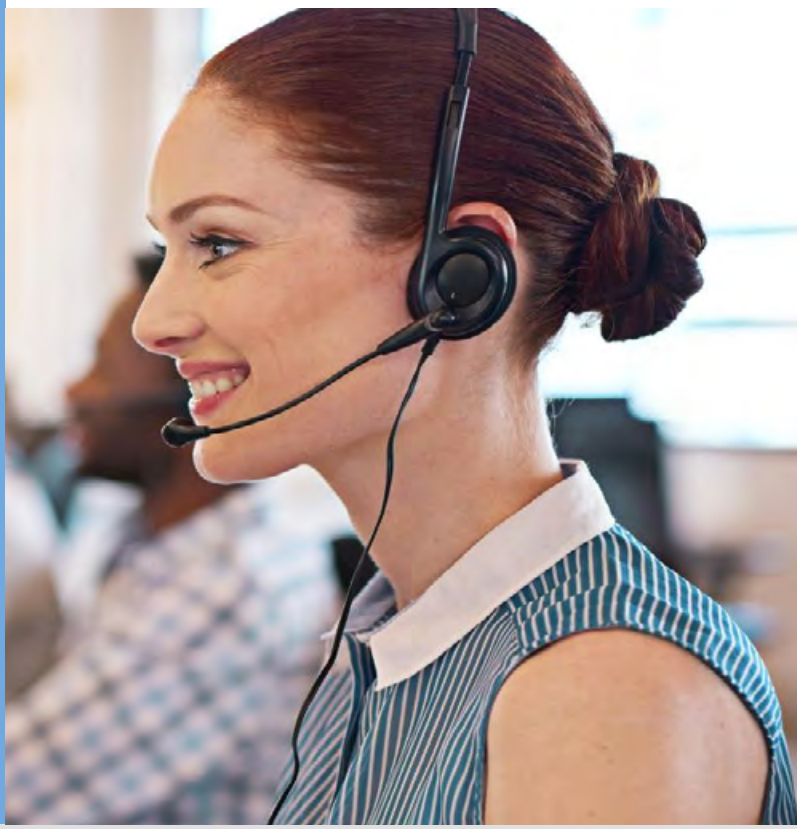
SCOPE

- Service offered in local language

CONTACT NUMBER	
Austria	00800-26663282
Belgium	00800-26663282
Finland	990800-26663282
Ireland	00800-26663282
Netherlands	00800-26663282
Portugal	00800-26663282
Spain	00800-26663282
Sweden	00800-26663282
Switzerland	00800-26663282
United Kingdom	00800-26663282

Service hours*	Monday- Friday 8am – 4pm Ability to leave voicemail outside of office hours

** Service hours may vary*



NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

PROCEDURE INNOVATIONS

TYRX™
ABSORBABLE ANTIBACTERIAL ENVELOPE

PROCEDURE INNOVATIONS

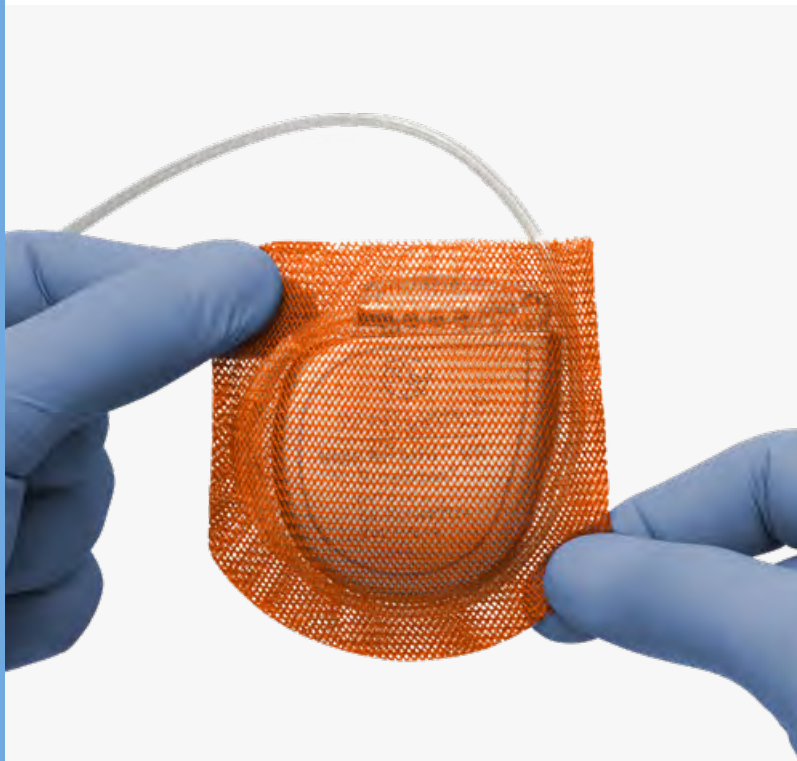
GENERAL
The TYRX Envelope is a fully absorbable sterile device designed to hold a Cardiac Implantable Electronic Device (CIED) securely in place to create a stable environment when implanted in the body. The envelope's bioabsorbable polymer coating contains antibacterial agents Minocycline and Rifampin.

- Fully absorbs into the body in ~9 weeks
- Large pore mesh:
  - Knitted from absorbable filaments (glycolide, caprolactone and trimethylene carbonate)
  - Filaments coated with a bioabsorbable polymer containing antibacterial agents
- Single Use Only
- Storage: between 2 - 25° C

ANTIBIOTICS
- Minocycline and Rifampin have been shown to reduce infection in an in vivo model of bacterial challenge following surgical implantation of the generator or defibrillator.[1]
- Locally delivered Minocycline and Rifampin sustained for 7 days
- Minocycline has been shown to be effective against:
  - Gram-positive bacteria such as *S aureus*
  - Gram-negative bacteria such as *E coli, E aerogenes, H influenzae* and *A baumannii*
- Rifampicin has been shown to be effective against:
  - Gram-positive bacteria such as *S aureus* (including MRSA) and *S epidermidis*
  - Gram-negative bacteria such as *H influenzae*

[1] *Huntingdon Life Sciences Studies TR-2011-043, TR-2011-044, TR-2011-045, TR-2011-047, TR-2011-056.*

Model	CMRM6122INT	CMRM6133INT
Description	TYRX Absorbable Antibacterial Envelope (Medium)	TYRX Absorbable Antibacterial Envelope (Large)
Size (cm)	6.3 x 6.9	7.4 x 8.5
Minocycline dose (mg)	5.1	7.6
Rifampin dose (mg)	8.0	11.9



NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

EXTERNAL PACEMAKER
SINGLE CHAMBER

PROCEDURE INNOVATIONS

GENERAL
- Battery Powered External Temporary Pacemaker
- Pacing Continuation upon Battery Removal
- Compatible with Medtronic cables 5832, 5833, 5487, 5433A/V and 5846A/V
- NO direct connection of heart wires

PACING FEATURES
- Pacing Modes: AAI, AOO, VVI, VOO
- Basic Pacing Rate: 30 – 200 ppm
- Rapid Atrial Pacing Rate: 80 – 800 ppm

ADDITIONAL PROGRAMMABLE PARAMETERS
- Output Amplitude
- Pulse Width
- Sensitivity
- Ventricular Blanking

PACKAGE CONTENT
- Single Chamber External Temporary Pacemaker Model 53401
- Two AA 1.5 V alkaline batteries
- Carrying case Model 53409

ACCESSORIES (NOT INCLUDED)
- 5409 Disposable Pouch: 5 units in package
- 53408 Replacement Covers (Main Covers and Rapid Atrial Pacing Cover)
- 53409 Carrying Case
- 53407 IV Pole Replacement Hook and Replacement Knobs

Model	53401
M (g)	499
Dimension (cm)	20.2 x 6.6 x 4.1
Battery	Two IEC type LR6-sized (AA-sized) 1.5 V alkaline batteries (Duracell MN1500, Eveready E91 or equivalent)

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

EXTERNAL PACEMAKER
DUAL CHAMBER

PROCEDURE INNOVATIONS

GENERAL
- Battery Powered External Temporary Pacemaker
- Pacing Continuation upon Battery Removal
- Compatible with Medtronic cables 5832, 5833, 5487, 5433A/V and 5846A/V
- NO direct connection of heart wires

PACING FEATURES
- Pacing Modes: DDD, DOO, DDI, AAI, AOO, VVI, VOO
- Basic Pacing Rate: 30 – 200 ppm
- Upper Rate: 80 – 230 ppm
- Rapid Atrial Pacing Rate: 80 – 800 ppm

ADDITIONAL PROGRAMMABLE PARAMETERS
- Output Amplitude
- Pulse Width
- Sensitivity
- AV Interval
- PVARP
- Ventricular Blanking

PACKAGE CONTENT
- Dual Chamber External Temporary Pacemaker Model 5392
- Two AA 1.5 V alkaline batteries

ACCESSORIES (NOT INCLUDED)
- 5409 Disposable Pouch: 5 units in package
- 53922 Disposable Cover: 3 units in package
- 53923 Carrying Case
- 53921GLBL IV Pole Replacement

Model	5392
M (g)	680
Dimension (cm)	20.3 x 8.6 x 4.45
Battery	Two IEC type LR6-sized (AA-sized) 1.5 V alkaline batteries

NOTE: This is not intended to be a full product description.
For full description, refer to the Device Specification Sheet and/or Manual.

EPG PATIENT AND SURGICAL CABLES

PROCEDURE INNOVATIONS

Model	Description	Channel	Lenght (m)	
5832S	Surgical Cable, Reusable, One channel, Small Clips	A or V	1.83	
2292	Surgical Cable, Reusable, Two channels	A and V	3.66	
5833S / 5833SL	Surgical Cable, Disposable, Small Clips	A or V	1.83 / 3.66	
5487 / 5487L	Surgical Cable, Disposable	A or V	1.83 / 3.66	
5433A / 5433AL	Patient Cable, Reusable	A	1.83 / 3.66	
5433V / 5433VL	Patient Cable, Reusable	V	1.83 / 3.66	
5846A / 5846AL	Patient Cable, Disposable	A	1.83 / 3.66	
5846V / 5846VL	Patient Cable, Disposable	V	1.83 / 3.66	

NOTE: This is not intended to be a full product description.
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GLOSSARY

GLOSSARY

2:1 block rate – a conduction ratio in which every second atrial event is refractory. This results in a ventricular pacing rate that is one half as fast as the atrial rate. Also known as second-degree Mobitz Type II AV block.

Active Can – option to select the device case as an active electrode for delivering defibrillation and cardioversion therapies.

activities of daily living rate (ADL Rate) – the approximate target rate that the patient's heart rate is expected to reach during activities of daily living.

activities of daily living response (ADL response) – a programmable parameter that alters the slope of the rate response curve to adjust the targeted rate distribution in the submaximal rate range to match the patient's activity level.

activity sensor – accelerometer in the device that detects the patient's body movement.

AdaptivCRT – algorithm that enhances cardiac resynchronization therapy (CRT) by adjusting CRT parameter values automatically while the patient is ambulatory.

AF/Afl feature – PR Logic feature designed to discriminate between rapidly conducted atrial fibrillation or atrial flutter and ventricular tachyarrhythmia.

Antitachycardia pacing (ATP) – therapies that deliver rapid sequences of pacing pulses to terminate tachyarrhythmias.

Arrhythmia episode data – system that compiles an arrhythmia episode log that the clinician can use to view summary and detailed diagnostic data quickly, including stored EGM, for the selected arrhythmia episode.

AT/AF detection – feature that analyzes the atrial rate and its effect on the ventricular rhythm to determine whether the patient is currently experiencing an atrial tachyarrhythmia. Depending on programming, the device delivers a programmed sequence of atrial therapies or continues monitoring without delivering therapy.

AT/AF Interval – programmable interval used to define the AT/AF detection zone. The median atrial interval must be shorter than this value to detect an AT/AF episode.

ATP During Charging – device delivers a ventricular antitachycardia therapy sequence while the device charges its capacitors for the first defibrillation therapy during a VF episode.

Atrial antitachycardia pacing (ATP) – therapies that respond to an AT/AF episode or a Fast AT/AF episode with rapid sequences of pacing pulses to terminate detected atrial tachyarrhythmias.

Atrial cardioversion – therapy that delivers a high-voltage shock to treat an AT/AF episode or a Fast AT/AF episode. Atrial cardioversion delivery is synchronized to a sensed ventricular event and cannot exceed a programmable daily limit within programmable times.

Atrial Preference Pacing – atrial rhythm management feature that adapts the pacing rate to slightly higher than the intrinsic sinus rate.

Atrial Preference Pacing (APP) – atrial rhythm management feature that adapts the pacing rate to slightly higher

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than the intrinsic sinus rate.

Atrial Rate Stabilization (ARS) – atrial rhythm management feature that eliminates a prolonged pause following a premature atrial contraction (PAC).

atrial refractory period – interval that follows an atrial paced or sensed event during which the device senses events but responds to them in a limited way. This interval is applied when the device is operating in a single chamber, atrial pacing mode.

Atrial therapy scheduling – feature that enables the clinician to program the delivery of automatic atrial therapies. Each time that an AT/AF therapy is needed, the device schedules one of the available therapies based on clinician programming.

atrial tracking – dual chamber pacing operation that paces the ventricle in response to atrial events.

Atrial Tracking Recovery (ATR) – feature that helps to restore atrial tracking if it is lost due to successive atrial events falling in the refractory period following ventricular senses.

Auto PVARP – Adjusts PVARP (Post-Ventricular Atrial Refractory Period) in response to changes in the patient's heart rate or pacing rate. PVARP is longer at lower tracking rates to prevent pacemaker-mediated tachycardia (PMT) and shorter at higher rates to maintain 1:1 tracking.

AV synchrony – coordinated contraction of the atria and ventricles for most effective cardiac output.

blanking period – time interval during which sensing in a chamber is disabled to avoid oversensing.

Burst+ pacing – antitachycardia pacing (ATP) therapy that delivers sequences of atrial pacing pulses with an interval that is a programmable percentage of the tachycardia cycle length, followed by up to 2 premature stimuli delivered at programmable intervals. With each sequence of Burst+ pacing delivered; the device shortens the pacing interval by a programmable interval.

Burst pacing – antitachycardia pacing (ATP) therapy that delivers sequences of ventricular pacing pulses with an interval that is a programmable percentage of the tachycardia cycle length. With each sequence of Burst pacing delivered, the device shortens the pacing interval by a programmable interval.

Capture Management – feature that monitors pacing thresholds with daily pacing threshold searches and, if programmed to do so, adjusts the pacing amplitudes toward a target amplitude.

Cardiac Compass Trends – overview of the patient's condition over the last 14 months with graphs that display long-term clinical trends in heart rhythm, such as frequency of arrhythmias, heart rates, and device therapies.

cardiac resynchronization therapy (CRT) – delivery of coordinated pacing pulses to the left and right ventricles designed to treat ventricular dysynchrony.

Combined Count detection – feature designed to prevent a delay in VF detection when ventricular tachyarrhythmia fluctuates between the VF and VT zones.

Conducted AF Response – feature that adjusts the pacing rate to help promote a regular ventricular rate during

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AT/AF episodes.

crosstalk – condition when pacing in one chamber is sensed as intrinsic activity in another chamber.

Decision Channel annotations – annotations to stored and telemetered EGM that document details about tachyarrhythmia detection operations.

device reset – automatic device operation to recover from a disruption in device memory and control circuitry. Programmed parameters may be set to default reset values. This operation triggers a device status indicator. device status indicators – warnings that describe problems with device memory or operation.

EffectivCRT Diagnostic – feature that determines the percentage of effective CRT pacing. It provides data about the effectiveness of CRT pacing on the Quick Look screen and in RATE HISTOGRAMS, Cardiac Compass TRENDS, and EffectivCRT EPISODES.

EffectivCRT During AF – algorithm that dynamically adjusts the pacing rate in response to changes in the percentage of effective CRT pacing to promote CRT delivery in non-tracking modes.

EffectivCRT episodes data – feature that compiles diagnostic information to help the clinician identify the cause of ineffective CRT pacing and reprogram the device to avoid it.

electromagnetic interference (EMI) – energy transmitted from external sources by radiation, conduction, or induction that can interfere with device operations, such as sensing, or can potentially damage device circuitry.

EOS (End of Service) – battery status indicator displayed by the implantable device app to indicate that the device should be replaced immediately and that it may not operate per specifications.

event – a sensed or paced beat.

evoked response detection – the act of detecting the electrical signal generated by the contracting myocardium immediately following a pacing pulse.

exertion rate range – rates at or near the Upper Sensor Rate that are achieved during vigorous exercise.

Flashback – diagnostic feature that records the intervals that immediately preceded tachyarrhythmia episodes or that preceded the last interrogation of the device and plots the interval data over time.

Heart Failure Management Report – report that summarizes the patient's clinical status and observations since the last follow-up appointment and provides graphs that show trends in heart rates, arrhythmias, and fluid accumulation indicators over the last 14 months.

High Rate Timeout – feature that allows the device to delivery therapy for any ventricular tachyarrhythmia that continues beyond the programmed length of time.

Holter telemetry – telemetry feature that transmits EGM and marker data continuously for a programmable number of hours, regardless of whether telemetry actually exists between the device and device manager.

Home communicator – instrument that wirelessly receives information from a patient's implanted device and then

GLOSSARY

transmits the information to the Medtronic CareLink Network via a cellular phone network or a home WiFi network. This dedicated instrument is placed within range of where the patient sleeps.

last session – refers to the last time the device was successfully interrogated before the current interrogation. A session ends 8 hours after the last interrogation.

median atrial interval – the seventh in a numerically ordered list of the 12 most recent A-A intervals.

median ventricular interval – the seventh in a numerically ordered list of the 12 most recent V-V intervals.

Medtronic CareAlert Monitoring – the continuous monitoring for, and silent, wireless transmission of, alert data between an implanted device and the Medtronic CareLink Network.

Medtronic CareAlert notifications – alert information sent via the Medtronic CareLink Network that notifies clinics and clinicians of events that impact patients or their implanted devices.

Medtronic CareLink Network – Internet-based service that allows a patient to transmit cardiac device information from home or other locations to the physician over a secure server. The CareLink Network may be unavailable in some geographic locations.

Mode Switch – feature that switches the device pacing mode from a dual-chamber atrial tracking mode to a non-tracking mode during an atrial tachyarrhythmia. This feature prevents rapid ventricular pacing that may result from tracking a high atrial rate and restores the programmed pacing mode when the atrial tachyarrhythmia ends.

MR Conditional – an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions for use.

MRI SureScan – a feature that permits a mode of operation that allows a patient with a SureScan system to be safely scanned by an MRI machine while the device continues to provide appropriate pacing.

Multiple point pacing (MPP) – feature that allows the device to deliver a second, separately programmed LV pacing pulse during CRT pacing.

MVP (Managed Ventricular Pacing) – atrial-based pacing mode that is designed to switch to a dual chamber pacing mode in the presence of AV block. The MVP feature is intended to reduce unnecessary right ventricular pacing by promoting intrinsic conduction. The MVP modes are AAIR<=>DDDR and AAI<=>DDD.

Non-Competitive Atrial Pacing (NCAP) – programmable pacing feature that prohibits atrial pacing within a programmable interval after a refractory atrial event.

non-sustained VT (VT-NS) – ventricular rhythm that is fast enough to fall within the programmed VT and VF zones for at least 5 beats but does not meet any episode detection criteria.
Onset – feature that helps prevent detection of sinus tachycardia as VT by evaluating the acceleration of the ventricular rate.

OptiVol 2.0 fluid status monitoring – feature that identifies a potential increase in thoracic fluid, which may indicate lung congestion, by monitoring changes in thoracic impedance.

GLOSSARY

OptiVol event – an occurrence of the OptiVol 2.0 Fluid Index exceeding the programmed OptiVol Threshold, which may indicate fluid accumulation in the patient's thoracic cavity.

OptiVol Threshold – a programmable value of the OptiVol 2.0 Fluid Index. Values above this threshold may indicate fluid accumulation in the patient's thoracic cavity and define the occurrence of an OptiVol event.

Other 1:1 SVTs feature – PR Logic feature designed to withhold ventricular detection for supraventricular tachycardias that exhibit nearly simultaneous atrial and ventricular activation.

oversensing – inappropriate sensing of cardiac events or noncardiac signals. Examples include far-field R-waves, T-waves, myopotentials, and electromagnetic interference.

Paced AV (PAV) interval – programmable delay between an atrial pace and its corresponding scheduled ventricular pace.

pacemaker-mediated tachycardia (PMT) – a rapid, inappropriately paced rhythm that can occur with atrial tracking modes. PMT results when a device senses and tracks retrograde P-waves in the DDD mode or the DDDR mode.

pacing threshold – minimum pacing output that consistently captures the heart.

patient alert – a tone emitted from an implanted device to notify the patient of an alert condition.

Patient app – application that automatically gathers information from a patient's implanted device and transmits it to clinicians through the Medtronic CareLink Network. This application is installed on a patient-owned tablet or smart phone and communicates with the implanted device via Bluetooth® wireless technology.

PMOP (Post Mode Switch Overdrive Pacing) – atrial intervention feature that works with the Mode Switch feature to deliver overdrive atrial pacing during the vulnerable phase following an AT/AF episode termination.

Post Shock Pacing – feature that provides temporary pacing support after a high-voltage therapy by increasing the pacing amplitude and pulse width to prevent loss of capture.

Post VT/VF Shock Pacing – feature that provides temporary overdrive pacing that may improve cardiac output after a high-voltage therapy.

Pre-arrhythmia EGM storage – programmable option to record EGM from before the onset or detection of a tachyarrhythmia. While this feature is operating, the device records EGM continuously. If a tachyarrhythmia episode occurs, the most recently collected EGM is added to the episode record to document the rhythm at onset.

PR Logic – set of features that uses pattern and rate analysis to discriminate between supraventricular tachycardias (SVTs) and true ventricular tachyarrhythmias.

Progressive Episode Therapies – feature that causes the device to skip therapies or modify high-voltage energy levels to ensure that each therapy delivered during an episode is at least as aggressive as the previous therapy.

PVAB (Post-Ventricular Atrial Blanking) – interval after ventricular events during which atrial events are ignored by bradycardia pacing features or are not sensed by the device, depending on the programmed PVAB method.

GLOSSARY

PVARP (Post Ventricular Atrial Refractory Period) – atrial refractory period following a ventricular event used to prevent inhibition or pacemaker-mediated tachycardias (PMTs) in dual chamber pacing modes.

PVC (premature ventricular contraction) – a sensed ventricular event that directly follows any other ventricular event with no atrial event between them.

PVC Response – feature that extends PVARP following a premature ventricular contraction (PVC) to avoid tracking a retrograde P-wave and to prevent retrograde conduction from inhibiting an atrial pace.

Quick Look – implantable device app screen that presents overview data about device operation and patient rhythms collected since the last patient session. It includes links to more detailed status and diagnostic information stored in the device, such as arrhythmia episodes and therapies provided.

Ramp pacing – antitachycardia pacing (ATP) therapy that delivers pacing pulses with progressively shorter pacing intervals per pulse. Each sequence of Ramp pacing that is delivered during a therapy includes an additional pacing pulse.

Rate Adaptive AV (RAAV) – dual chamber pacing feature that varies the Paced AV (PAV) and Sensed AV (SAV) intervals as the heart rate increases or decreases to maintain 1:1 tracking and AV synchrony.

Rate Drop Response – feature that monitors the heart for a significant drop in rate and responds by pacing the heart at an elevated rate for a programmed duration.

Rate Drop Response episodes data – feature that displays beat-to-beat data that is useful in analyzing Rate Drop Response episodes and the events leading up to those episodes.

Rate Histograms – diagnostic feature that shows range distributions for a patient's heart rate.

rate profile – rate histogram of the sensor rates used by Rate Profile optimization to automatically adjust Rate Response settings.

Rate Profile Optimization – feature that monitors the patient's daily and monthly sensor rate profiles and adjusts the rate response curves over time to achieve a prescribed target rate profile.

Rate Response – feature that adjusts the cardiac pacing rate in response to changes in sensed patient activity.

Reactive ATP – algorithm that allows the device to repeat programmed atrial antitachycardia pacing (ATP) therapies during long AT/AF episodes. Therapies are repeated after a programmed time interval or when the atrial rhythm changes in regularity or cycle length.

reference impedance – a baseline against which daily thoracic impedance is compared to determine if thoracic fluid is increasing.

refractory period – time interval during which the device senses events normally but classifies them as refractory and responds to them in a limited way.

Remaining longevity estimate – an estimate of remaining device longevity that is displayed on the Quick Look screen and the BATTERY AND LEAD MEASUREMENTS window. This information includes a graphical display for

GLOSSARY

easy reference and the estimatednumber of years or months of remaining longevity. In the battery and lead measurements window, the minimum and maximum number of years or months of remaining device longevity are also provided. The remaining longevity estimate is updated when parameters are reprogrammed and when the device is interrogated.

RESUME – programming command that reinstates automatic tachyarrhythmia detection.

retrograde conduction – electrical conduction from the ventricles to the atria.

RRT (Recommended Replacement Time) – battery status indicator displayed by the implantable device app to indicate when replacement of the device is recommended.

RV Lead Integrity Alert – feature that sounds an alert tone to warn the patient that a potential RV lead problem is suspected, which could indicate a lead fracture.

RV Lead Noise Alert – feature that sounds an alert tone when RV Lead Noise Discrimination withholds VT/VF detection because of the presence of noise on the RV lead. Noise could indicate lead fracture, breached lead insulation, lead dislodgment, or improper lead connection.

RV Lead Noise Discrimination – feature that compares a far-field EGM signal to the near-field sensing signal to differentiate RV lead noise from VT/VF. If lead noise is identified when these signals are compared, the device withholds VT/VF detection and therapy and triggers an RV Lead Noise Alert.

Sensed AV (SAV) interval – programmable delay following an atrial sensed event that schedules a corresponding ventricular pace.

sensed event – electrical activity across the sensing electrodes that exceeds the programmed sensitivity threshold and is identified by the device as a cardiac event.

Sensing Integrity Counter – diagnostic counter that records the number of short ventricular intervals that occur between patient sessions. A large number of short ventricular intervals may indicate double-counted R-waves, lead fracture, or a loose setscrew.

sensor rate – the pacing rate determined by the level of patient activity and the programmed rate response parameters; this rate is adjusted between the Upper Sensor Rate and the operating Lower Rate.

sequence, ATP – one programmable set of antitachycardia pacing (ATP) therapy pulses.

Sinus Tach feature – PR Logic feature designed to discriminate between high rate sinus tachycardia and ventricular tachyarrhythmia.

Sleep – feature that causes the device to pace at a slower rate during a programmed sleep period.

Smart Mode – feature that disables an ATP therapy that has been unsuccessful in 4 consecutive episodes so the device can treat subsequent episodes more quickly with therapies that have been effective.

Stability – feature that helps prevent detection of atrial fibrillation as ventricular tachyarrhythmia by evaluating the stability of the ventricular rate. If the device determines that the ventricular rate is not stable, it withholds VT detection.

GLOSSARY

SUSPEND – programming command that temporarily deactivates the tachyarrhythmia detection functions.

SVT V. Limit – feature that allows you to program a highest rate for which PR Logic and Wavelet can withhold detection and therapy.

synchronization – period during defibrillation and cardioversion therapies when the device attempts to deliver the therapy shock simultaneously with a sensed ventricular event.

thoracic impedance – impedance across the thorax as measured from 2 points within the thorax.

TWave Discrimination – feature that withholds VT/VF detection when a fast ventricular rate is detected because of oversensed T-waves.

undersensing – failure of the device to sense intrinsic cardiac activity.

ventricular antitachycardia pacing (ATP) – therapies that respond to a VT episode or an FVT episode with rapid sequences of pacing pulses to end detected ventricular tachyarrhythmias.

ventricular cardioversion – therapy that delivers a high-voltage shock to treat a VT or an FVT episode. Therapy is synchronized to a sensed ventricular event.

ventricular fibrillation (VF) therapies – therapies that deliver automatic defibrillation shocks to treat VF episodes. The first defibrillation therapy requires VF confirmation before delivery. After the first shock has been delivered, shocks are delivered asynchronously if synchronization fails.

Ventricular Rate Stabilization (VRS) – ventricular rhythm management feature that adjusts the pacing rate dynamically to eliminate the long pause that typically follows a premature ventricular contraction (PVC).

Ventricular Safety Pacing (VSP) – pacing therapy feature that prevents inappropriate inhibition of ventricular pacing caused by crosstalk or ventricular oversensing.

Ventricular Sense Response (VSR) – feature intended to promote continuous CRT pacing by providing ventricular pacing in response to ventricular sensed events.

Ventricular sensing episodes data – feature that compiles diagnostic information to help the clinician identify the cause of ventricular sensing episodes and reprogram the device to avoid these episodes.

VF confirmation – device operation that confirms the presence of VF after initial detection but before a defibrillation therapy is delivered. This feature applies only to the first programmed VF therapy.

VT/VF detection – feature that uses programmable detection zones to classify ventricular events. Depending on programming, the device delivers a scheduled therapy, re-evaluates the patient's heart rhythm, and ends or redetects the episode.

VT monitoring – programmable option that allows the device to detect fast rhythms as VT and record episode data without delivering VT therapy.

GLOSSARY

Wavelet – feature designed to prevent detection of rapidly conducted SVTs as ventricular tachyarrhythmias by comparing the shape of each QRS complex during a fast ventricular rate to a template.

Brief Statement
See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan™ device, see the MRI SureScan™ technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.
For applicable products, consult instructions for use on www.medtronic.com/manuals.
Manuals can be viewed using a current version of any major internet browser.
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