ORDIN DE PLATA NR.: 61 TIP.DOC. 1

DATA EMITERII:2 septembrie 2021

PLATITI: 7500-00 LEI: Sapte Mii Cinci Sute lei 00 bani

PLATITOR: (R) S.C. "OXIVIT-MED" S.R.L.
CONTUL DE PLATI/CODUL IBAN
MD44ML000000002251729503
CODUL FISCAL :1007600044280 /

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

BENEFICIAR (R) MF-TR Chisinau - bugetul de stat CAPCS
CONTUL DE PLATI/CODUL IBAN
MD30TRPCCC518430D01859AA
CODUL FISCAL :1016601000212 /

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

DESTINATIA PLATII:/P102/7500,00 Pentru garantia pentru oferta la procedura de achizi?ie publica nr. ocds-b3wdp1-MD-1628002654232 din 03.09.2021

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:101:
DATA PRIMIRII:02/09/2021
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 PRESTATORUL L.S.

Digitally signed by Kojevnikov Dmitrii
Date: 2021.09.03 10:22:28 EEST
Reason: MoldSign Signature
Location: Moldova

MOTIVUL REFUZULUI L.S.

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

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. № A2114444 **din** от 24.08.2021

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 08.09.2021

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

ȘEF DIF BOTANICA — **Funcția/Должность**

Semnătura/Подпись

ANA STOICOV — **Numele și prenumele**/Фамилия и имя

L.Ș/ М.П.

Executor: Ciuga — **Numele și prenumele**/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 24.08.2021 ora 9:17:30
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)

OXIVITMED
c/f: 1007600044280; adresa: str. Independenței 28-34, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

Către Grupul de lucru pentru evaluarea
Licitației publice Nr. ocds-b3wdp1-MD-1628002654232
Din 13 aug 2021, 12:30 - 3 sept 2021, 12:30
Din cadrul CAPCS

Declarație

Prin prezenta, SRL „Oxivit-Med”, declara ca:

- Va înregistra în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale bunurile contractate pînă la momentul livrării acestora
- Termenul de valabilitate restant (la momentul livrării) va constitui 80% din termenul total de valabilitate al produsului, dar nu mai puțin de 12 luni din termenul de valabilitate total
- Va prezenta mostre pentru produsele noi sau necunoscute de specialiștii din cadrul IMSP Institutul de Cardiologie, în termen de 5 zile de la solicitarea autorității contractante

_____Kojevnikov Dmitrii

L.Ş.

Data prezentării 29.05.2020 18:40:13
SITUATIILE FINANCIARE

Anexe la SNC
"Prezentarea situatiilor financiare"
Aprobat de Ministerul Finantelor
al Republicii Moldova

2019 pentru perioada 01.01.2019 - 31.12.2019 de lichidare
BIROUL NAŢIONAL DE STATISTICĂ

Entitatea: S.C. OXIVIT-MED S.R.L.
Sediul:SEC.BOTANICA, STR.DECEBAL BD. NR.82 OF.90
Raionul(municipiul):103, DDF BOTANICA
Satul(comuna):
Strada:SEC.BOTANICA, STR.DECEBAL BD. NR.82 OF.90
Cod postal:2060
Cod CUATM:0110, SEC.BOTANICA
Activitatea principala:G4774, Comert cu amanuntul al articolelor medicale si ortopedice, in magazine specializate
Forma proprietate:15, Proprietatea privată
Forma organizatorico-juridica:530, Societăti cu răspundere limitată
Cod CUIÎO: 40424951
Codul fiscal:1007600044280
WEB:
Numele si coordonatele al contabilului-sef:KOJEVNIKOV DMITRII
Telefon:+37322808002
Numărul mediu scriptic al personalului în perioada precedentă: 3 persoane.

Unitatea de masura: leu

Notă informativă privind veniturile şi cheltuielile clasificate după natură

Anexa 8

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vinzari	010	43289243	56125772
Alte venituri din activitatea operationala	020	209007	1954484
Venituri din alte activitati	030	1171806	815541
Total venituri (rd.010 + rd.020 + rd.030)	040	44670056	58895797
Variatia stocurilor	050		
Costul vinzarilor mărfurilor vândute	060	33465025	44624941
Cheltuieli privind stocurile	070		
Cheltuieli cu personalul privind remunerarea muncii	080	71355	157075
Contributii de asigurari sociale de stat obligatorii si prime de asigurare obligatorie de asistenta medicala	090	18700	35342
Cheltuieli cu amortizarea si deprecierea activelor imobilizate	100	2139	2139
Alte cheltuieli	110	298104	682045
Cheltuieli din alte activitati	120	820441	836368
Total cheltuieli (rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	34675764	46337910
Profit (pierdere) pina la impozitare (rd.040 – rd.130)	140	9994292	12557887
Cheltuieli privind impozitul pe venit	150	1203230	1543063
Profit (pierdere) net al perioadei de gestiune (rd.140 – rd.150)	160	8791062	11014824

BILANŢUL

la 31.12.2019

Anexa 1

Nr. cpt.	A C T I V	Cod rd.	Sold la	
			Inceputul perioadei de gestiune	Sfirsitul perioadei de gestiune
1	2	3	4	5
1.	**Active imobilizate**			
	Imobilizari necorporale	010	2437	1787
	Imobilizari corporale in curs de executie	020		
	Terenuri	030		
	Mijloace fixe	040	3724	2234
	Resurse minerale	050		
	Active biologice imobilizate	060		
	Investitii financiare pe termen lung in parti neafiliate	070		
	Investitii financiare pe termen lung in parti afiliate	080		
	Investitii imobiliare	090		
	Creante pe termen lung	100		
	Avansuri acordate pe termen lung	110		
	Alte active imobilizate	120		
	Total active imobilizate(rd.010 + rd.020 + rd.030 + rd.040 + rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	6161	4021
	Active circulante			
	Materiale	140	1101	434

SITUATIA DE PROFIT SI PIERDERE

de la 01.01.2019 pina la 31.12.2019

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vinzari	010	43289243	56125772
Costul vinzarilor	020	33465025	44624941
Profit brut (pierdere bruta) (rd.010 – rd.020)	030	9824218	11500831
Alte venituri din activitatea operationala	040	209007	1954484
Cheltuieli de distribuire	050	19868	46711
Cheltuieli administrative	060	337477	668046

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Alte cheltuieli din activitatea operationala	070	32953	161844
Rezultatul din activitatea operationala: profit (pierdere) (rd.030 + rd.040 – rd.050 – rd.060 – rd.070)	080	9642927	12578714
Rezultatul din alte activitati: profit (pierdere)	090	351365	-20827
Profit (pierdere) pina la impozitare (rd.080 + rd.090)	100	9994292	12557887
Cheltuieli privind impozitul pe venit	110	1203230	1543063
Profit net (pierdere neta) al perioadei de gestiune (rd.100 – rd.110)	120	8791062	11014824

SITUATIA MODIFICARILOR CAPITALULUI PROPRIU

de la 01.01.2019 pina la 31.12.2019

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la inceputul perioadei de gestiune	Majorari	Diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6	7
1	**Capital social si suplimentar**					
	Capital social	010	5400			5400
	Capital suplimentar	020				
	Capital nevarsat	030	()	()	()	()
	Capital neinregistrat	040				
	Capital retras	050	()	()	()	()
	Total capital social si suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	5400			5400
2	**Rezerve**					
	Capital de rezerva	070				
	Rezerve statutare	080				
	Alte rezerve	090				
	Total reserve (rd.070 + rd.080 + rd.090)	100				
3	**Profit nerepartizat (pierdere neacoperita)**					
	Corectii ale rezultatelor anilor precedenti	110	X	70111	84022	-13911
	Profit nerepartizat (pierdere neacoperita) al anilor precedenti	120	14070936		3590000	10480936
	Profit net (pierdere neta) al perioadei de gestiune	130	X	11014824		11014824
	Profit utilizat al perioadei de gestiune	140	X			
	Rezultatul din tranzitia la noile reglementari contabile	150				
	Total profit nerepartizat (pierdere neacoperita) (rd.110 + rd.120 + rd.130 - rd.140 + rd.150)	160	14070936	11084935	3674022	21481849
4	**Alte elemente de capital propriu, din care**	170				
	Diferente din reevaluare	171				
	Subventii entitatilor cu proprietate publica	172				
	Total capital propriu (rd.060 + rd.100 + rd.160 + rd.170)	180	14076336	11084935	3674022	21487249

SITUATIA FLUXURILOR DE NUMERAR

de la 01.01.2019 pina la 31.12.2019

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Fluxuri de numerar din activitatea operationala			
Incasari din vinzari	010	44233939	64930280
Plati pentru stocuri si servicii procurate	020	34177570	46461976
Plati catre angajati si organe de asigurare sociala si medicala	030	89849	176515
Dobinzi platite	040		
Plata impozitului pe venit	050	2090569	1853693
Alte incasari	060		
Alte plati	070	6763644	10724653
Fluxul net de numerar din activitatea operationala (rd.010 – rd.020 – rd.030 – rd.040 – rd.050 + rd.060 – rd.070)	080	1112307	5713443
Fluxuri de numerar din activitatea de investitii			
Incasari din vinzarea activelor imobilizate	090		
Plati aferente intrarilor de active imobilizate	100		
Dobinzi incasate	110		
Dividende incasate	120		
Alte incasari (plati)	130		

Nr. cpt.	A C T I V	Cod rd.	Sold la	
			Inceputul perioadei de gestiune	Sfirsitul perioadei de gestiune
1	2	3	4	5
2.	Active biologice circulante	150		
	Obiecte de mica valoare si scurta durata	160		
	Productia in curs de executie si produse	170		
	Marfuri	180	5035582	8318982
	Creante comerciale	190	6398231	4565544
	Creante ale partilor afiliate	200		
	Avansuri acordate curente	210	2409388	1595507
	Creante ale bugetului	220	477973	491901
	Creante ale personalului	230		
	Alte creante curente	240		5989
	Numerar in casierie si la conturi curente	250	7745065	13740173
	Alte elemente de numerar	260		
	Investitii financiare curente in parti neafiliate	270		
	Investitii financiare curente in parti afiliate	280		
	Alte active circulante	290	8782	8082
	Total active circulante (rd.140 + rd.150 + rd.160 + rd.170 + rd.180 + rd.190 + rd.200 + rd.210 + rd.220 + rd.230 + rd.240 + rd.250 + rd.260 + rd.270 + rd.280 + rd.290)	300	22076122	28726612
	Total active (rd.130 + rd.300)	310	22082283	28730633
3.	**Capital propriu**			
	Capital social si suplimentar	320	5400	5400
	Rezerve	330		
	Corectii ale rezultatelor anilor precedenti	340	x	-13911
	Profit nerepartizat (pierdere neacoperita) al anilor precedenti	350	14070936	10480936
	Profit net (pierdere neta) al perioadei de gestiune	360	x	11014824
	Profit utilizat al perioadei de gestiune	370	x	
	Alte elemente de capital propriu	380		
	Total capital propriu (rd.320 + rd.330 + rd.340 + rd.350 + rd.360 - rd.370 + rd.380)	390	14076336	21487249
4.	**Datorii pe termen lung**			
	Credite bancare pe termen lung	400		
	Imprumuturi pe termen lung	410	76630	76630
	Datorii pe termen lung privind leasingul financiar	420		
	Alte datorii pe termen lung	430		
	Total datorii pe termen lung (rd.400 + rd.410 + rd.420 + rd.430)	440	76630	76630
5.	**Datorii curente**			
	Credite bancare pe termen scurt	450		
	Imprumuturi pe termen scurt	460		
	Datorii comerciale	470	7450519	6729208
	Datorii fata de partile afiliate	480		
	Avansuri primite curente	490	337734	336114
	Datorii fata de personal	500	14819	73257
	Datorii privind asigurarile sociale si medicale	510		
	Datorii fata de buget	520	62	300
	Venituri anticipate curente	530		
	Datorii fata de proprietari	540		
	Finantari si incasari cu destinatie speciala curente	550		
	Provizioane curente	560		
	Alte datorii curente	570	126183	27875
	Total datorii curente (rd.450 + rd.460 + rd.470 + rd.480 + rd.490 + rd.500 + rd.510 + rd.520 + rd.530 + rd.540 + rd.550 + rd.560 + rd.570)	580	7929317	7166754
	Total pasive (rd.390 + rd.440 + rd.580)	590	22082283	28730633

Indicatori	Cod rd	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Fluxul net de numerar din activitatea de investitii (rd.090 – rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiara			
Incasari sub forma de credite si imprumuturi	150		
Plati aferente rambursarii creditelor si imprumuturilor	160		
Dividende platite	170		
Incasari din operatiuni de capital	180		
Alte incasari (plati)	190		
Fluxul net de numerar din activitatea financiara (rd.150 – rd.160 – rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	1112307	5713443
Diferente de curs valutar favorabile (nefavorabile)	220	38680	281665
Sold de numerar la inceputul perioadei de gestiune	230	6594078	7745065
Sold de numerar la sfirsitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	7745065	13740173

Date generale

Anexa 6

1. Certificat de inregistrare a entitatii, eliberat de Camera Inregistrarii de Stat.
   Numar de inregistrare Data inregistrarii Seria Numar
2. Capital social inregistrat de Camera Inregistrarii de Stat:
   data , suma lei, inclusiv:
   1) cota statului lei,
   2) cota detinatorilor a cel putin 20% Increase lei.
   Modificari ulterioare:
   a) , suma lei, inclusiv cota statului lei,
   b) , suma lei, inclusiv cota statului lei.
3. Entitatile, activitatea carora necesita licenta, indica:
   Licenta in vigoare:

Nr. Ord.	Numar	Data eliberarii	Termen de valabilitate	Tipul de activitate	Organul care a eliberat licenta
1					

4. Numarul mediu scriptic al personalului in perioada de gestiune 3 persoane, inclusiv pe categorii:
   1) personal administrativ persoane,
   2) muncitori persoane.
5. Numarul personalului la 31 decembrie 2019 3 persoane.
6. Remunerarea personalului entitatii in perioada de gestiune 157075 lei.
7. Remunerarea membrilor organelor de administrare, de conducere si supraveghere si alte angajamente aparute sau asumate in legatura cu pensiile membrilor actuali sau ale fostilor membri ai acestor organe, pe categorii lei.
8. Avansurile si creditele acordate membrilor organelor specificate la pct.7 lei, inclusiv rambursate lei.
9. Valoarea activelor imobilizate si circulante, inregistrate in calitate de gaj
   1) valoarea de gaj lei,
   2) valoarea contabila lei.
10. Numarul actiunilor ordinare la finele perioadei de gestiune unitati.
11. Profit net (pierdere neta) a perioadei de gestiune pentru o actiune ordinara:
    1) profit lei,
    2) pierdere lei.
12. Dividende calculate pentru o actiune ordinara pentru perioada de gestiune:
    1) platite lei,
    2) planificate pentru plata lei.
13. Valuta straina disponibila, recalculata in moneda nationala a Republicii Moldova – total lei, inclusiv (lei, denumirea si codul valutei):

Nr. Ord.	lei	denumirea	codul valutei
1			

14. Numerar legat – total lei.
    In rindurile, in care se inscriu sumele de gaj, in toate coloanele prin fractie se reflecta:
    a) la numarator – valoarea de gaj;
    b) la numitor – valoarea contabila

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 1

Creante, investitii financiare si datorii pe termen lung aferente fondatorilor nerezidenti

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune	Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune
			Intrari / majorari	Iesiri / diminuari	Diferente de curs valutar	
1	2	3	4	5	6	7
Creante si investitii financiare pe termen lung - total	010					
Creante comerciale, *inclusiv pe tari:*	020					
1	2	3	4	5	6	7

1	2	3	4	5	6	7
Avansuri acordate, *inclusiv pe tari:*	030					

1	2	3	4	5	6	7
Imprumuturi acordate si creante privind leasingul financiar, *inclusiv pe tari:*	040					

1	2	3	4	5	6	7
Alte creante si investitii financiare, *inclusiv pe tari:*	050					

1	2	3	4	5	6	7
Datorii pe termen lung - total	060					
Datorii comerciale, *inclusiv pe tari:*	070					

1	2	3	4	5	6	7
Avansuri primite, *inclusiv pe tari:*	080					

1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, *inclusiv pe tari:*	090					

1	2	3	4	5	6	7
Alte datorii, *inclusiv pe tari:*	100					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050
Rd.060= rd.070 + rd.080 + rd.090 + rd.100
Col.7 = col.3+col.4-col.5±col.6

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 2

Creante, investitii financiare si datorii pe termen lung aferente nerezidentilor, cu exceptia fondatorilor

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune	Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune
			Intrari / majorari	Iesiri / diminuari	Diferente de curs valutar	
1	2	3	4	5	6	7
Creante si investitii financiare pe termen lung - total	010					
Creante comerciale, *inclusiv pe tari:*	020					

1	2	3	4	5	6	7
Avansuri acordate, *inclusiv pe tari:*	030					

1	2	3	4	5	6	7
Imprumuturi acordate si creante privind leasingul financiar, *inclusiv pe tari:*	040					

1	2	3	4	5	6	7
Depozite, *inclusiv pe tari:*	050					

1	2	3	4	5	6	7
Alte creante si investitii financiare, *inclusiv pe tari:*	060					

1	2	3	4	5	6	7
Datorii pe termen lung - total	070					
Datorii comerciale, *inclusiv pe tari:*	080					

1	2	3	4	5	6	7
Avansuri primite, *inclusiv pe tari:*	090					

1	2	3	4	5	6	7

Tabelul 4

Creante, investitii financiare si datorii curente aferente nerezidentilor, cu exceptia fondatorilor

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune		Modificari in perioada de gestiune				Sold la sfirsitul perioadei de gestiune	
		La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an	Total	Transferari din active si datorii pe termen lung in active si datorii curente	Iesiri / diminuari	Diferente de curs valutar	La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an
1	2	3	4	5	6	7	8	9	10
Creante si investitii financiare curente - total	010								
Creante comerciale, *inclusiv pe tari:*	020								

1	2	3	4	5	6	7	8	9	10
Avansuri acordate, *inclusiv pe tari:*	030								

1	2	3	4	5	6	7	8	9	10
Imprumuturi acordate si creante privind leasingul financiar, *inclusiv pe tari:*	040								

1	2	3	4	5	6	7	8	9	10
Depozite, *inclusiv pe tari:*	050								

1	2	3	4	5	6	7	8	9	10
Alte creante si investitii financiare, *inclusiv pe tari:*	060								

1	2	3	4	5	6	7	8	9	10
Datorii curente - total	070								
Datorii comerciale, *inclusiv pe tari:*	080								

1	2	3	4	5	6	7	8	9	10
Avansuri primite, *inclusiv pe tari:*	090								

1	2	3	4	5	6	7	8	9	10
Credite bancare, imprumuturi si datorii privind leasingul financiar, *inclusiv pe tari:*	100								

1	2	3	4	5	6	7	8	9	10
Alte datorii, *inclusiv pe tari:*	110								

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060
Rd.070= rd.080 + rd.090 + rd.100 + rd.110
Col.(9+10) = col.(3+4) + col.5 - col.7 ± col.8

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 5

Investitii financiare in strainatate si participarea nerezidentilor in capitalul social

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune	Intrari/ majorari	Iesiri/ diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6
Investitii financiare	010				
Cote de participatie si actiuni de pina la 10% inclusiv, in capitalul social al entitatilor nerezidente, *inclusiv pe tari:*	020				

1	2	3	4	5	6
Cote de participatie si actiuni de peste 10% in capitalul social al entitatilor nerezidente, *inclusiv pe tari:*	030				

1	2	3	4	5	6

1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, *inclusiv pe tari:*	100					

1	2	3	4	5	6	7
Alte datorii, *inclusiv pe tari:*	110					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.60
Rd.070= rd.080 + rd.090 + rd.100 + +rd.110
Col.7 = col.3+col.4-col.5±col.6

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 3

Creante, investitii financiare si datorii curente aferente fondatorilor nerezidenti

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune		Modificari in perioada de gestiune				Sold la sfirsitul perioadei de gestiune	
		La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an	Total	Transferari din active si datorii pe termen lung in active si datorii curente	Iesiri / diminuari	Diferente de curs valutar	La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an
1	2	3	4	5	6	7	8	9	10
Creante si investitii financiare curente - total	010								
Creante comerciale, *inclusiv pe tari:*	020								

1	2	3	4	5	6	7	8	9	10
Avansuri acordate, *inclusiv pe tari:*	030								

1	2	3	4	5	6	7	8	9	10
Imprumuturi acordate si creante privind leasingul financiar, *inclusiv pe tari:*	040								

1	2	3	4	5	6	7	8	9	10
Alte creante si investitii financiare, *inclusiv pe tari:*	050								

1	2	3	4	5	6	7	8	9	10
Datorii curente - total	060								
Datorii comerciale, *inclusiv pe tari:*	070								

1	2	3	4	5	6	7	8	9	10
Avansuri primite, *inclusiv pe tari:*	080								

1	2	3	4	5	6	7	8	9	10
Credite bancare, imprumuturi si datorii privind leasingul financiar, *inclusiv pe tari:*	090								

1	2	3	4	5	6	7	8	9	10
Datorii privind dividendele calculate, *inclusiv pe tari:*	100								

1	2	3	4	5	6	7	8	9	10
Alte datorii, *inclusiv pe tari:*	110								

Rd.010= rd.020 + rd.030 + rd.040 + rd.050
Rd.060= rd.070 + rd.080 + rd.090 + rd.100 + rd.110
Col.(9+10) = col.(3+4) + col.5 - col.7 ± col.8

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

1	2	3	4	5	6
Capital social	040				
Cote de participatie si actiuni de pina la 10% inclusiv, *inclusiv pe tari:*	050				

1	2	3	4	5	6
Cote de participatie si actiuni de peste 10%, *inclusiv pe tari:*	060				

Rd.010= rd.020 + rd.030
Rd.040= rd.050 + rd.060
Col.6 = col.3+col.4-col.5

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 6

Venituri si cheltuieli aferente tranzactiilor cu nerezidentii

Indicatori	Cod rd./ cod tara	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri - total	010		
Venituri aferente bunurilor procurate si vindute peste hotare fara trecerea frontierei de stat a Republicii Moldova, *inclusiv pe tari:*	020		

1	2	3	4
Venituri din dobinzi aferente activitatii operationale si altor activitati, *inclusiv pe tari:*	030		

1	2	3	4
Venituri din dividende si participatii in alte entitati,*inclusiv pe tari:*	040		

1	2	3	4
Venituri din decontarea datoriilor cu termenul de prescriptie expirat, *inclusiv pe tari:*	050		

1	2	3	4
Alte venituri, *inclusiv pe tari:*	060		

1	2	3	4
Cheltuieli - total	070		
Cheltuieli aferente bunurilor procurate si vindute peste hotare fara trecerea frontierei de stat a Republicii Moldova, *inclusiv pe tari:*	080		

1	2	3	4
Cheltuieli privind dobinzile, *inclusiv pe tari:*	090		

1	2	3	4
Cheltuieli si provizioane aferente creantelor comerciale si altor creante compromise, *inclusiv pe tari:*	100		

1	2	3	4
Alte cheltuieli, *inclusiv pe tari:*	110		

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060
Rd.070= rd.080 + rd.090 + rd.100 + rd.110

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 7

Bunuri ale nerezidentilor inregistrate in conturi extrabilantiere

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune	Intrari/ majorari	Iesiri/ diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6
Bunuri primite in baza contractelor de comision, *inclusiv pe tari:*	010				

1	2	3	4	5	6

1	2	3	4	5	6
Bunuri primite spre prelucrare,*inclusiv pe tari:*	020				

1	2	3	4	5	6
Bunuri obtinute din materialele prelucrate, *inclusiv pe tari:*	030				

Col.6 = col.3+col.4-col.5

Informațiile privind activele imobilizate

Anexa 7

Indicatori	Nr. rînd	Existența la începutul perioadei (la costul de intrare)	Amortizarea acumulată la începutul perioadei	Deprecierea acumulată la începutul perioadei	Intrarea în cursul perioadei (la costul de intrare)	Ieșirea în cursul perioadei (la costul de intrare)	Existența la sfîrșitul perioadei (la costul de intrare)	Amortizarea acumulată la sfîrșitul perioadei	Deprecierea acumulată la sfîrșitul perioadei
A	1	2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuție	100								
2. Imobilizări necorporale în utilizare, total inclusiv:	200								
2.1 brevete și mărci	210								
2.2. licențe de activitate	220								
2.3. programe informatice	230								
3. Imobilizări corporale în curs de execuție	300								
4. Terenuri	400		x					x	
5. Mijloace fixe, total din care:	500								
5.1. clădiri	510								
5.2. construcții speciale	520								
5.3. mașini, utilaje, instalații de transmisie	530								
inclusiv: tehnică de calcul	531								
5.4. mijloace de transport	540								
5.5. instrumente și inventar	550								
5.6. costuri ulterioare aferente obiectelor neînregistrate în bilanț	560								
5.7. mijloace fixe primite în leasing financiar	570								
5.8. mijloace fixe primite în gestiune economică	580								
5.9. alte mijloace fixe	590								
6. Resurse minerale	600								
7. Investiții imobiliare, total	700								

Persoanele responsabile de semnarea rapoartelor financiare ale entității*
* conform art.36 din Legea contabilității

Documente atașate - Notă explicativă (fișierul pdf)

Nota la Situatii Financiare 2019 Ox.pdf

Versiune de imprimare

Salvare

Recipisa 2

Respondent
Codul fiscal: 1007600044280, denumire: S.C. OXIVIT-MED S.R.L.
A prezentat raportul: RSF1
Pentru perioada fiscala: A/2019
Data prezentarii: 29.05.2020
Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 29.05.2020 18:40:13

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs. Urmează verificarea și validarea raportului de către specialistul BNS pe domeniu.

Versiune de imprimare

Salvare

Recipisa

Respondent
Codul fiscal: 1007600044280, denumire: S.C. OXIVIT-MED S.R.L.
A prezentat raportul: RSF1
Pentru perioada fiscala: A/2019
Data prezentarii: 29.05.2020
Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 29.05.2020 18:35:54

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

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

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 07 39709 01126

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 Pacemakers**

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.: 713106256

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

Date, 2017-10-27

Stefan Preiß

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

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

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 07 39709 01126

Model(s): **see attachment**

Parameters: ./.

Facility(ies):

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

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

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

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

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

Product Service

Attachment for Certificate no I7 17 07 39709 01126
dated 2017-10-27

Product: **Implantable Pacemakers**

Test Report No.: 70101692

Model:	**Model No:**
Adapta™	ADDR01, ADDR03, ADDR06, ADD01, ADVDD01, ADSR01, ADSR03, ADSR06
Adapta™ L	ADDRL1
Adapta™ S	ADDRS1
Sensia™	SED01, SEDR01, SESR01, SES01
Sensia™ L	SEDRL1
Versa™	VEDR01

Test Report No.: 71334026

Model:	**Model No:**
Relia™	RED01
Relia™	REDR01
Relia™	REVDD01
Relia™	RESR01
Relia™	RES01

Test Report No.: 71350693

Model:	**Model No:**
Advisa™DR	A5DR01

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Product Service

Attachment for Certificate no I7 17 07 39709 01126
dated 2017-10-27

Test Report No.: 71367018

Model:	**Model No:**
Consulta CRT-P	C3TR01
Syncra CRT-P	C2TR01

Test Report No.: 713035224

Model:	**Model No:**
Viva™ CRT-P	C5TR01

Munich, MHS-CRT, 2017-10-27

Stefan Preiß
Certification Medical Technology

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

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 07 39709 01123

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 / Defibrillators

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.: 713097118

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

Date, 2017-10-27

Stefan Preiß

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

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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 07 39709 01123

Model(s): **see attachment**

Parameters: ./.

Facility(ies):

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

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

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

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 07 39709 01123
dated 2017-10-27

Product: **Implantable Cardioverter / Defibrillators**

Test Report No.: 71331206

Model:	**Model No:**
Consulta™ CRT-D	D234TRK
Secura™ DR	D234DRG
Secura™ VR	D234VRC

Test Report No.: 71361514

Model:	**Model No:**
Protecta™ XT CRT-D	D354TRG
Protecta™ XT DR	D354DRG
Protecta™ XT VR	D354VRG
Protecta™ CRT-D	D364TRG
Protecta™ DR	D364DRG
Protecta™ VR	D364VRG

Test Report No.: 71366960

Model:	**Model No:**
Protecta™ XT CRT-D	D354TRM
Protecta™ CRT-D	D364TRM
Protecta™ XT DR	D354DRM
Protecta™ DR	D364DRM

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Product Service

Attachment for Certificate no I7 17 07 39709 01123
dated 2017-10-27

Test Report No.: 71366225

Model:	**Model No:**
Consulta® CRT-D	D214TRM
Secura® DR	D214DRM

Test Report No.: 71379214

Model:	**Model No:**
Protecta™ XT VR	D354VRM
Protecta™ VR	D364VRM
Secura® VR	D214VRM

Test Report No.: 71376978

Model:	**Model No:**
Cardia™ CRT-D	D384TRG
Cardia™ DR	D384DRG
Cardia™ VR	D384VRG
Egida™ CRT-D	D394TRG
Egida™ DR	D394DRG
Egida™ VR	D394VRG

Product Service

Attachment for Certificate no I7 17 07 39709 01123
dated 2017-10-27

Test Report No.: 713006130

Model:	Model No:
Viva™ Quad XT CRT-D	DTBA2QQ
Viva™ XT CRT-D	DTBA2D4
Viva™ XT CRT-D	DTBA2D1
Viva™ Quad S CRT-D	DTBB2QQ
Viva™ S CRT-D	DTBB2D4
Viva™ S CRT-D	DTBB2D1
Brava™ Quad CRT-D	DTBC2QQ
Brava™ CRT-D	DTBC2D4
Brava™ CRT-D	DTBC2D1

Test Report No.: 713012333

Model:	Model No:
Evera XT DR	DDBB2D1
Evera XT DR	DDBB2D4
Evera S DR	DDBC3D1
Evera S DR	DDBC3D4
Evera XT VR	DVBB2D1
Evera XT VR	DVBB2D4
Evera S VR	DVBC3D1
Evera S VR	DVBC3D4

Product Service

Attachment for Certificate no I7 17 07 39709 01123
dated 2017-10-27

Test Report No.: 713025610

Model:	**Model No:**
Viva Quad XT CRT-D	DTBA2Q1
Viva Quad S CRT-D	DTBB2Q1
Brava Quad CRT-D	DTBC2Q1

Test Report No.: 713066030

Model:	**Model No:**
Visia AF™ XT VR	DVAB2D1, DVAB2D4
Visia AF™ S VR	DVAC3D1, DVAC3D4

Munich, MHS-CRT, 2017-10-27

Stefan Preiß
Certification Medical Technology

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

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 07 39709 01122

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:
Leads for Tachy IPGs and their auxiliary components

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.: 713106253

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

Date, 2017-10-27

Stefan Preiß

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

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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 07 39709 01122

Model(s): see attachment

Parameters: ./.

Facility(ies):

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

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

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

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

Product Service

Attachment for Certificate no I7 17 07 39709 01122
dated 2017-10-27

Product: **Leads for Tachy IPGs and their auxiliary components**

Test Report No.: 70028444

Model:	**Model No:**
Transvene®-SVC Lead	6937
Stylet Kit	6093
DF-1 Y-Adaptor / Extender Kit	6726
Sprint Quattro® Lead	6944
Sprint Quattro Secure® Lead	6947

Test Report No.: 71334380

Model:	**Model No:**
Sprint Quattro Secure S™	6935

Test Report No.: 71365302

Model:	**Model No:**
Sprint Quattro Secure® Lead	6947M

Test Report No.: 71376036

Model:	**Model No:**
Lead Accessory Kit	6056M

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Product Service

Attachment for Certificate no I7 17 07 39709 01122
dated 2017-10-27

Test Report No.: 70089917

Model:	**Model No:**
Lead End Cap	6701
Lead Adaptor Kit	6707
Pin Plug Kit	6719
Sizing Sleeve Kit	6920

Test Report No.: 713022432

Model:	**Model No:**
Sprint Quattro Secure S®	6935M

Test Report No.: 713025611

Model:	**Model No:**
Sprint Quattro®	6946M

Munich, MHS-CRT, 2017-10-27

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 17 07 39709 01127

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:
Leads for Brady IPGs and their auxiliary components

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.: 713106257

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

Date, 2017-10-27

Stefan Preiß

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

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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 07 39709 01127

Model(s): **see attachment**

Parameters: ./.

Facility(ies):

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

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

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

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

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

TÜV®

Product Service

Attachment for Certificate no I7 17 07 39709 01127
dated 2017-10-27

Product: **Leads for Brady IPGs and their auxiliary components**

Test Report No.: 70089917

Model:	**Model No:**
CapSure® Z Novus Lead	5054, 5554
CapSureFix® Lead	5568
CapSure® SP Novus Lead	4092, 4592
CapSureFix® Novus Lead	5076
CapSure® SP Novus Lead	5092, 5592, 5594
CapSure® Sense Lead	4074, 4574
Lead End Cap Kit	5867-3M
Lead Anchoring Sleeve	5867-2
Rotation Tool Kit	6056
Medical Adhesive	080118
Service Kit	5873C
Wrench Kit	5873W
Stylet Kit	6048, 6052, 6054, 6057, 6082

Model:	**Model No:**
Stylet Kit	6091, 6094
Stylet Kit (Downsized knob)	6254, 6282, 6293
Pin-Plug Kit	6725
Epicardial Lead Implant Tool	10626

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Product Service

Attachment for Certificate no I7 17 07 39709 01127
dated 2017-10-27

Test Report No.: 71341359

Model:	**Model No:**
Percutaneous Lead Introducer	6207-S1, 6207-S5, 6207-D1, 6208-S1, 6208-S5, 6208-D1, 6209-S1, 6209-S5, 6209-D1, 6210-S1, 6210-S5, 6210-D1, 6211-S1, 6211-S5, 6211-D1, 6212-S1, 6212-S5, 6214-S1, 6214-S5
Solo-Trak® -KR Percutaneous Lead Introducer	6207BTK-1, 6207BTK-5, 6207BTK-D1, 6207BTKL-1, 6208BTK-1, 6208BTK-5, 6208BTK-D1, 6208BTKL-1, 6209BTK-1, 6209BTK-5, 6209BTK-D1, 6209BTKL-1, 6210BTK-1, 6210BTK-5, 6210BTK-D1, 6210BTKL-1, 6211BTK-1, 6211BTK-5, 6211BTK-D1, 6212BTK-1, 6212BTK-5, 6214BTK-1, 6214BTK-5,

Munich, MHS-CRT, 2017-10-27

Stefan Preiß
Certification Medical Technology

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01906**

Issued To: **Fiab SpA**
Via P. Costoli, 4
Vicchio
Firenze
50039
Italy

In respect of:

The design, development and manufacture of sterile leads for transoesophageal cardiac and temperature monitoring, cardiac stimulation, cardiac defibrillation and electrophysiological studies; percutaneous introducers; electronic equipments for oesophageal temperature monitoring, electrophysiological studies and emergency cardiac stimulation; sterile and non sterile electrosurgical electrodes and related accessories; electrodes for defibrillation/pacing; sterile single use neuropacers; sterile single use and reusable electrocauteries and associated accessories; sterile and non sterile, single use and reusable needle electrodes for EEG and EMG.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1998-05-11** Date: **2018-05-10** Expiry Date: **2023-05-10**

...making excellence a habit.™

bsi.

By Royal Charter

Certificate of Registration

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

This is to certify that:

Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Holds Certificate Number: **MD 613632**

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

Design, development, manufacturing, assembling and maintenance of medical devices for temporary stimulation and electrophysiology, permanent stimulation, HF-Ablation, interventional cardiology, medical components, neurology and contract sterilization services in accordance with EN ISO 11135:2014+A1:2019.
Design, Entwicklung, Produktion, Montage und Wartung von Medizinprodukten aus den Bereichen Temporäre Stimulation und Elektrophysiologie, Permanente Stimulation, HF-Ablation, Interventionelle Kardiologie, Medical Components, Neurologie und Lohnsterilisation von Medizinprodukten nach EN ISO 11135:2014+A1:2019 als Dienstleistung.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-06-30
Latest Revision Date: 2021-03-03

Effective Date: 2021-03-11
Expiry Date: 2021-09-10

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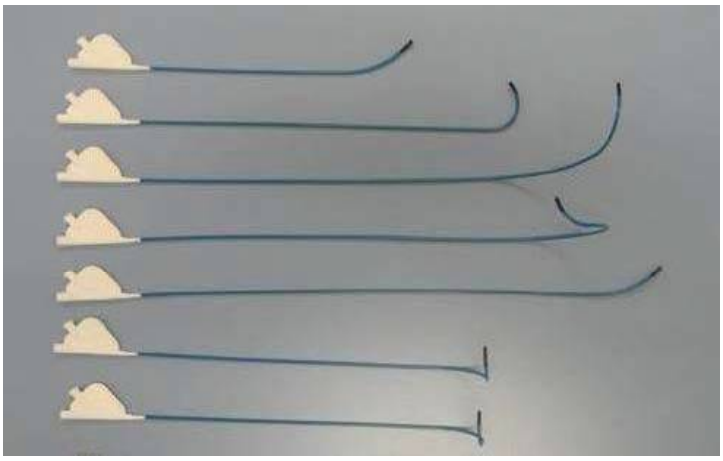
C315
CATHETERS

PACING LEADS AND 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	Fixed shape	Fixed shape	Fixed shape
Length	20 cm	30 cm	30 cm	30 cm
Compatible Lead	for 49 cm or longer 3830 leads	for 59 cm or longer 3830 leads	for 59 cm or longer 3830 leads	for 59 cm or longer 3830 leads
Inner Diameter	1.8 mm (5.4 Fr)	1.8 mm (5.4 Fr)	1.8 mm (5.4 Fr)	1.8 mm (5.4 Fr)
Outer Diameter	2.4 mm (7.0 Fr)	2.4 mm (7.0 Fr)	2.4 mm (7.0 Fr)	2.4 mm (7.0 Fr)

Model	C315S10	C315H40	C315HIS
Description	Fixed shape	Fixed shape	Fixed shape
Length	40 cm	40 cm	43 cm
Compatible Lead	for 69 cm or longer 3830 leads	for 69 cm or longer 3830 leads	for 69 cm or longer 3830 leads
Inner Diameter	1.8 mm (5.4 Fr)	1.8 mm (5.4 Fr)	1.8 mm (5.4 Fr)
Outer Diameter	2.4 mm (7.0 Fr)	2.4 mm (7.0 Fr)	2.4 mm (7.0 Fr)

Medtronic

MIRRO MRI™
DR SURESCAN™
Model DDME3D4

- MR Conditional with PhysioCurve™ Design
- DF4

Product Specifications

Physical characteristics	
Volume[a]	34 cm^3
Mass	78 g
H x W x D	68 mm x 51 mm x 13 mm
Surface area of device can	57 cm^2
Radiopaque ID[b]	PFZ
Medtronic Radiopaque Identifier[b]	
Materials in contact with human tissue[c]	Titanium, polyurethane, silicone rubber
Battery	Hybrid CFx lithium/silver vanadium oxide

[a] Volume with connector ports unplugged.
[b] The radiopaque ID, which includes a Medtronic-identifier symbol, can be viewed in a fluoroscopic image of the device.
[c] These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

Replacement indicators	
Recommended Replacement Time (RRT)	< 2.73 V on 3 consecutive daily automatic measurements
End of Service (EOS)	3 months after RRT

Maximum energy levels and typical full energy charge times	
Maximum programmed energy	35 J
Maximum delivered energy[a,b]	36 J
Maximum stored energy[c]	42 J
Typical charge time at Beginning of Service (BOS)[d]	8.3 s
Typical charge time at Recommended Replacement Time (RRT)[d]	12.3 s

[a] Energy delivered at connector block into a 50 Ω load.
[b] For 35 J programmed energy, delivered energy exceeds 35 J.
[c] Energy stored at charge end on capacitor.
[d] Charge time during a nonwireless telemetry session may be slightly higher.

Medtronic

Device parameters

Tachyarrhythmia detection parameters

Parameter	Programmable values
AT/AF Detection	Monitor ◆
VF Detection[b]	On ◆; Off
VF Interval (Rate)[a]	240; 250 ... 320 ◆ ... 400 ms
VF Initial Beats to Detect	12/16; 18/24; 24/32; 30/40 ◆; 45/60; 60/80; 75/100; 90/120; 105/140; 120/160
VF Beats to Redetect	6/8; 9/12; 12/16 ◆; 18/24; 21/28; 24/32; 27/36; 30/40
FVT Detection	Off ◆; via VF; via VT
FVT Interval (Rate)[a]	200; 210 ... 240 ◆ ... 600 ms
VT Detection	On; Off ◆
VT Interval (Rate)[a]	280; 290 ... 360 ◆ ... 650 ms
VT Initial Beats to Detect	12; 16 ◆ ... 52; 76; 100
VT Beats to Redetect	8; 12 ◆ ... 52
VT Monitor	Monitor ◆; Off
VT Monitor Interval (Rate)[a]	280; 290 ... 450 ◆ ... 650 ms
Monitored VT Beats to Detect	16; 20; 24; 28; 32 ◆ ... 56; 80; 110; 130
PR Logic™	
AF/Afl[b]	On ◆; Off
Sinus Tach[b]	On ◆; Off
Other 1:1 SVTs	On; Off ◆
SVT V. Limit[a]	240; 250; 260 ◆ ... 650 ms
Other enhancements	
Stability[a]	Off ◆; 30; 40 ... 100 ms
Onset	Off ◆; On; Monitor
Onset Percent	72; 75; 78; 81 ◆; 84; 88; 91; 94; 97%
Sensitivity	
Atrial[c,d]	0.15; 0.30 ◆; 0.45; 0.60; 0.90; 1.20; 1.50; 1.80; 2.10; 4.00 mV
RV[c,d]	0.15; 0.30 ◆; 0.45; 0.60; 0.90; 1.20 mV

[a] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.
[b] The AF/Afl, Sinus Tach, and Wavelet features are automatically set to On when VF Detection is set to On.
[c] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.
[d] Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity threshold to its minimum (most sensitive) setting of 0.15 mV. When susceptibility to modulated interference is tested under the conditions specified in CENELEC standard EN 45502-2-2, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the minimum value of 0.15 mV. The device complies with the requirements of clause 27.5.1 when the sensitivity threshold is programmed to 0.3 mV or higher.

Ventricular tachyarrhythmia therapy parameters

Parameter	Programmable values
VF Therapy parameters	
VF Therapy Status	On ◆; Off
Energy	Rx1-Rx2: 0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 ◆ J Rx3-Rx6: 10; 11 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 ◆ J
Pathway[a]	AX>B; B>AX Rx1-Rx4: B>AX ◆; Rx5-Rx6: AX>B ◆
ATP	During Charging ◆; Before Charging; Off
Deliver ATP if last 8 R-R ≥	200; 210 ... 240 ◆ ... 300 ms
Therapy Type	Burst ◆; Ramp; Ramp+
ChargeSaver	On ◆; Off
Switch when number of consecutive ATP successes equals	1 ◆; 2; 3; 4; 6; 8; 10
Smart Mode	On ◆; Off
VT/FVT Therapy parameters	
VT Therapy Status	On; Off ◆
FVT Therapy Status	On; Off ◆
Therapy Type	CV; Burst; Ramp; Ramp+ Rx1: Burst ◆; Rx2-Rx6: CV ◆
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J VT Rx1-Rx2: 20 ◆ J VT Rx3-Rx6: 35 ◆ J FVT Rx1-Rx6: 35 ◆ J
Pathway[a]	AX>B; B>AX Rx1-Rx4: B>AX ◆; Rx5-Rx6: AX>B ◆
Burst therapy parameters	
Initial # Pulses	1; 2 ... 8 ◆ ... 15
R-S1 Interval = (%RR)	50; 53; 56; 59; 63; 66 ... 84; 88 ◆; 91; 94; 97%
Interval Dec	0; 10 ◆ ... 40 ms
# Sequences	1; 2 ... 10 VT Therapies: 3 ◆; FVT Therapies: 1 ◆
Smart Mode[b]	On; Off ◆
Ramp therapy parameters	
Initial # Pulses	1; 2 ... 8 ◆ ... 15
R-S1 Interval = (%RR)	50; 53; 56; 59; 63; 66 ... 84; 88; 91 ◆; 94; 97%
Interval Dec	0; 10 ◆ ... 40 ms
# Sequences	1; 2 ... 10 VT Therapies: 3 ◆; FVT Therapies: 1 ◆
Smart Mode[b]	On; Off ◆
Ramp+ therapy parameters	
Initial # Pulses	1; 2; 3 ◆ ... 15
R-S1 Interval = (%RR)	50; 53; 56; 59; 63; 66 ... 75 ◆ ... 84; 88; 91; 94; 97%
S1S2 (Ramp+) = (%RR)	50; 53; 56; 59; 63; 66; 69 ◆ ... 84; 88; 91; 94; 97%
S2SN (Ramp+) = (%RR)	50; 53; 56; 59; 63; 66 ◆ ... 84; 88; 91; 94; 97%
# Sequences	1; 2 ... 10 VT Therapies: 3 ◆; FVT Therapies: 1 ◆
Smart Mode[b]	On; Off ◆

Shared Settings	
V-V Minimum ATP Interval	150; 160 ... 200 ◆ ... 400 ms
V. Amplitude	1; 2 ... 6; 8 ◆ V
V. Pulse Width	0.1; 0.2 ... 1.5 ◆ ms
V. Pace Blanking	150; 160 ... 240 ◆ ... 450 ms
Active Can™/SVC Coil[c]	Can+SVC On ◆; Can Off; SVC Off
Progressive Episode Therapies	On; Off ◆

[a] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.
[b] Smart Mode is available only for Rx1– Rx4.
[c] The Active Can/SVC Coil parameter applies to all automatic, manual, and emergency high-voltage therapies. It also applies to T-Shock™ inductions.

Pacing parameters

Modes, rates, and intervals

Parameter	Programmable values
Mode	DDDR; DDD; AAIR↔DDDR ◆ AAI↔DDD; DDIR; DDI; AAIR; AAI; VVIR; VVI; DOO; AOO; VOO; ODO
Mode Switch	On ◆; Off
Lower Rate[a]	30; 35 ... 60 ◆; 70; 75 ... 150 min^{-1} (± 2 min^{-1})
Upper Tracking Rate	80; 85 ... 130 ◆ ... 150 min^{-1} (± 2 min^{-1})
Paced AV	30; 40 ... 180 ◆ ... 350 ms (± 4 ms)
Sensed AV	30; 40 ... 150 ◆ ... 350 ms (+30; –4 ms)
PVARP	Auto ◆; 150; 160 ... 500 ms (+5; –30 ms)
Minimum PVARP	150; 160 ... 250 ◆ ... 500 ms (+5; –30 ms)
A. Refractory Period	150; 160 ... 310 ◆ ... 500 ms (+5; –30 ms)

[a] The corresponding Lower Rate Interval can be calculated as follows: Lower Rate Interval (ms) = 60,000/Lower Rate.

Atrial parameters

Parameter	Programmable values
Atrial Amplitude	0.5; 0.75 ... 3.5 ◆ ... 5; 5.5; 6; 8 V
Atrial Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4 ◆ ... 1.5 ms
Atrial Sensitivity[a]	0.15 mV ($\pm$ 75%); 0.3 ◆; 0.45; 0.6 mV ($\pm$ 50%); 0.9; 1.2; 1.5; 1.8; 2.1; 4.0 mV ($\pm$ 30%)

[a] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

RV parameters

Parameter	Programmable values
RV Amplitude	0.5; 0.75 ... 3.5 ◆ ... 5; 5.5; 6; 8 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4 ◆ ... 1.5 ms
RV Sensitivity[a]	0.15 mV ($\pm$ 75%); 0.3 ◆; 0.45; 0.6 mV ($\pm$ 50%); 0.9; 1.2 mV ($\pm$ 30%)
RV Pace Polarity	Bipolar; Tip to Coil
RV Sense Polarity	Bipolar; Tip to Coil

[a] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

Blanking periods

Parameter	Programmable values
PVAB Interval	10; 20 ... 150 ◆ ... 300 ms[a] 100; 110 ... 150 ◆ ... 300 ms[b]
PVAB Method	Partial ◆; Partial+; Absolute[c]
A. Blank Post AP	150; 160 ... 200 ◆ ... 250 ms
A. Blank Post AS	100 ◆; 110 ... 170 ms
V. Blank Post VP	150; 160 ... 200 ◆ ... 450 ms
V. Blank Post VS	120 ◆; 130 ... 170 ms

[a] When PVAB Method = Partial+ or Absolute.
[b] When PVAB Method = Partial.
[c] Programming the PVAB method to Absolute automatically resets the interval to 30 ms. If the PVAB method is programmed to Partial or Partial+, the interval resets to 150 ms.

Rate response pacing parameters

Parameter	Programmable values
Upper Sensor Rate	80; 85 ... 120 ◆; 150 min^{-1} (± 2 min^{-1})
ADL Rate	60; 65 ... 95 ◆ ... 145 min^{-1} (± 2 min^{-1})
Rate Profile Optimisation	On ◆; Off
ADL Response	1; 2; 3 ◆; 4; 5
Exertion Response	1; 2; 3 ◆; 4; 5
Activity Threshold	Low; Medium Low ◆; Medium High; High
Activity Acceleration	15; 30 ◆; 60 s
Activity Deceleration	Exercise ◆; 2.5; 5; 10 min
ADL Setpoint	5; 6 ... 40; 42 ... 80
UR Setpoint	15; 16 ... 40; 42 ... 80; 85 ... 180

Rate adaptive AV parameters

Parameter	Programmable values
Rate Adaptive AV	On; Off ◆
Start Rate	50; 55 ... 90 ◆ ... 145 min^{-1}
Stop Rate	55; 60 ... 130 ◆ ... 150 min^{-1}
Minimum Paced AV	30; 40 ... 140 ◆ ... 200 ms
Minimum Sensed AV	30; 40 ... 110 ◆ ... 200 ms

Ventricular rate stabilisation parameters

Parameter	Programmable values
V. Rate Stabilisation	On; Off ◆
Maximum Rate	80; 85 ... 100 ◆ ... 120 min^{-1}
Interval Increment	100; 110 ... 150 ◆ ... 400 ms

Post VT/VF shock pacing parameters

Parameter	Programmable values
Post VT/VF Shock Pacing	On; Off ◆
Overdrive Rate	70; 75; 80 ◆ ... 120 min^{-1}
Overdrive Duration	0.5 ◆; 1; 2; 3; 5; 10; 20; 30; 60; 90; 120 min

Post shock pacing parameters

Parameter	Programmable values
Post Shock A. Amplitude	1; 2; 3; 4 ◈; 5; 6; 8 V
Post Shock A. Pulse Width	0.1; 0.2 ... 1.5 ◈ ms
Post Shock V. Amplitude	1; 2 ... 6 ◈; 8 V
Post Shock V. Pulse Width	0.1; 0.2 ... 1.5 ◈ ms

Sleep parameters

Parameter	Programmable values
Sleep	On; Off ◈
Sleep Rate	30; 35 ... 50 ◈; 55; 60; 70; 75 ... 100 min^{-1}
Bed Time	00:00; 00:10 ... 22:00 ◈ ... 23:50
Wake Time	00:00; 00:10 ... 07:00 ◈ ... 23:50

Non-competitive Atrial Pacing (NCAP) parameters

Parameter	Programmable values
Non-Comp Atrial Pacing	On ◈; Off
NCAP Interval	200; 250; 300 ◈; 350; 400 ms

MRI SureScan parameters

Parameter	Programmable values
MRI SureScan	On; Off
MRI Pacing Mode	DOO (Asynchronous); AOO (Asynchronous); VOO (Asynchronous); ODO (Off)
MRI Pacing Rate	60; 70; 75... 120 min^{-1}

Additional pacing features

Parameter	Programmable values
Rate Hysteresis	Off ◈; 30; 40 ... 80 min^{-1}
PMT Intervention	On; Off ◈
PVC Response	On ◈; Off
V. Safety Pacing	On ◈; Off

Medtronic CareAlert™ parameters

Clinical management alerts

Parameter	Programmable values
Number of Shocks Delivered in an Episode[c]	
Device Tone	
Alert Enable – Urgency	Off ◈; On-Low; On-High
Patient Home Monitor	
Alert Enable[b]	Off ◈; On
Shared (Device Tone and Patient Home Monitor)	
Number of Shocks Threshold[a]	1 ◈; 2; 3; 4; 5; 6
All Therapies in a Zone Exhausted for an Episode	
Device Tone	
Alert Enable – Urgency	Off ◈; On-Low; On-High
Patient Home Monitor	
Alert Enable[b]	Off ◈; On

[a] This parameter is displayed only if an associated alert has been enabled.
[b] Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.
[c] Note that VF, VT, and FVT therapies could be delivered during a single episode (from initial detection until episode termination).

Lead/Device integrity alerts

Parameter	Programmable values
RV Lead	
Device Tone	
Alert Urgency[a]	Low; High ◈
RV Lead Integrity Enable	On ◈; Off
Patient Home Monitor	
RV Lead Integrity Enable[c]	On ◈; Off
Lead Impedance Out of Range	
Device Tone	
Alert Urgency[a]	Low; High ◈
A. Pacing Impedance Enable	On ◈; Off (Observation only)
RV Pacing Impedance Enable	On ◈; Off (Observation only)
RV Defibrillation Impedance Enable	On ◈; Off (Observation only)
SVC Defibrillation Impedance Enable[b]	On ◈; Off (Observation only)
Patient Home Monitor	
A. Pacing Impedance Enable[c]	Off; On ◈
RV Pacing Impedance Enable[c]	Off; On ◈
RV Defibrillation Impedance Enable[c]	Off; On ◈
SVC Defibrillation Impedance Enable[b,c]	Off; On ◈
Shared (Device Tone and Patient Home Monitor)	
A. Pacing Impedance Less than	200 ◈; 300; 400; 500 Ω
A. Pacing Impedance Greater than	1,000; 1,500; 2,000; 3,000 ◈ Ω
RV Pacing Impedance Less than	200 ◈; 300; 400; 500 Ω
RV Pacing Impedance Greater than	1,000; 1,500; 2,000; 3,000 ◈ Ω
RV Defibrillation Impedance Less than	20 ◈; 30; 40; 50 Ω
RV Defibrillation Impedance Greater than	100; 130; 160; 200 ◈ Ω
SVC Defibrillation Impedance Less than	20 ◈; 30; 40; 50 Ω
SVC Defibrillation Impedance Greater than	100; 130; 160; 200 ◈ Ω
Low Battery Voltage RRT	
Device Tone	
Alert Enable – Urgency	Off; On-Low; On-High ◈
Patient Home Monitor	
Alert Enable[c]	Off; On ◈
Excessive Charge Time EOS	
Device Tone	
Alert Enable – Urgency	Off; On-Low; On-High ◈
Patient Home Monitor	
Alert Enable[c]	Off; On ◈

Lead/Device integrity alerts, cont'd.

Parameter	Programmable values
VF Detection Off, 3+ VF or 3+ FVT Rx Off	
Device Tone	
Alert Enable	Off; On-High ◆
Patient Home Monitor	
Alert Enable[c]	Off; On ◆

[a] This parameter is displayed only if an associated alert has been enabled.
[b] If an SVC lead is not implanted, the alert will not sound.
[c] Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.

Shared parameters

Parameter	Programmable values
Patient Home Monitor	Yes; No ◆
Alert Time[a]	00:00; 00:10 ... 08:00 ◆ ... 23:50

[a] This parameter is displayed only if an associated alert has been enabled.

Data collection parameters

Data collection parameters

Parameter	Programmable values
LECG Source (Leadless ECG)[a]	Can to SVC ◆ [b,c] RVcoil to Aring; Can to Aring
LECG Range (Leadless ECG)	±1; ±2 ◆; ±4; ±8; ±12; ±16; ±32 mV
EGM 1 Source	RVtip to RVcoil; RVtip to RVring; Atip to RVring; Atip to Aring ◆; Aring to RVring; Aring to RVcoil
EGM 1 Range	±1; ±2; ±4; ±8 ◆; ±12; ±16; ±32 mV
EGM 2 Source	Can to RVcoil◆ ; Can to RVring; RVtip to RVcoil; RVtip to RVring; Can to SVC[b,c]; RVcoil to SVC[b]
EGM 2 Range	±1; ±2; ±4; ±8; ±12◆; ±16; ±32 mV
EGM 3 Source	RVtip to RVcoil; RVtip to RVring ◆
EGM 3 Range	±1; ±2; ±4; ±8 ◆; ±12; ±16; ±32 mV
Monitored	EGM1 and EGM2;EGM1 and EGM3 ◆; EGM1 and LECG; EGM2 and EGM3; EGM2 and LECG; EGM3 and LECG
Pre-arrhythmia EGM	Off ◆; On – 1 month; On – 3 months; On Continuous
Device Date/Time[d]	(enter time and date)
Holter Telemetry	Off ◆; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr

[a] This EGM channel displays far-field signals. To display an approximation of a surface ECG signal, choose the Can to SVC EGM source.
[b] An SVC electrode must be present for this configuration.
[c] If Can to SVC is selected, the EGM Range is automatically set to ±2 mV. The EGM Range is automatically set to ±8 mV for all other EGM Source options.
[d] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

System test parameters

System test parameters

Parameter	Selectable values
Pacing Threshold Test parameters	
Test Type	Amplitude; Pulse Width
Chamber	Atrium; RV
Decrement after	2; 3 ... 15 pulses
RV Pace Polarity	Bipolar; Tip to Coil
Mode[a] (RV test)	VVI; VOO; DDI; DDD; DOO
Mode[a] (Atrium test)	AAI; AOO; DDI; DDD; DOO
Lower Rate[b]	30; 35 ... 60; 70; 75 ... 150 min^{-1}
RV Amplitude	0.25; 0.5 ... 5; 5.5; 6; 8 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2 ... 1.5 ms
A. Amplitude	0.25; 0.5 ... 5; 5.5; 6; 8 V
A. Pulse Width	0.03; 0.06; 0.1; 0.2 ... 1.5 ms
AV Delay	30; 40 ... 350 ms
V. Pace Blanking	150; 160 ... 450 ms
A. Pace Blanking	150; 160 ... 250 ms
PVARP[c]	150; 160 ... 500 ms
Sensing Test parameters	
Mode[a]	AAI; DDD; DDI; VVI; ODO
AV Delay	30; 40 ... 350 ms
Lower Rate[b]	30; 35 ... 60; 70; 75 ... 120 min^{-1}

[a] The selectable values for this parameter depend on the programmed pacing mode.
[b] When performing the test in DDD mode, the Lower Rate must be less than the programmed Upper Tracking Rate.
[c] The selectable values for this parameter depend on the programmed PVAB values.

EP study parameters

T-Shock induction parameters

Parameter	Selectable values
Resume at Deliver	Enabled ◆; Disabled
Enable	Enabled; Disabled ◆
#S1	2; 3; 4; 5 ◆; 6; 7; 8
S1S1	300; 310 ... 400 ◆ ... 2,000 ms
Delay	20; 30 ... 300 ◆ ... 600 ms
Energy	0.4; 0.6; 0.8; 1.0 ◆ ... 1.8; 2; 3; 4 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J
Waveform	Monophasic ◆; Biphasic
Pathway[a]	AX>B; B>AX ◆

[a] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

50 Hz Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled ◆; Disabled
Chamber	Atrium; RV
Amplitude	1; 2; 3; 4 ◆; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50 ◆ ... 1.50 ms
VOO Backup (for atrial 50 Hz Burst)	On; Off ◆
Pacing Rate	60; 70 ◆ ... 120 min^{-1}
V. Amplitude[a,b]	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[a]	0.10; 0.20 ... 1.50 ms

[a] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.
[b] Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

Fixed Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled ◆; Disabled
Chamber	Atrium; RV
Interval	100; 110 ... 600 ◆ ms
Amplitude	1; 2; 3; 4 ◆; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50 ◆ ... 1.50 ms
VVI Backup (for atrial Fixed Burst)	On; Off ◆
Pacing Rate	60; 70 ◆ ... 120 min^{-1}
V. Amplitude[a,b]	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[a]	0.10; 0.20 ... 1.50 ms

[a] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.
[b] Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

PES induction parameters

Parameter	Selectable values
Resume at Deliver	Enabled ◆; Disabled
Chamber	Atrium; RV
#S1	1; 2 ... 8 ◆ ... 15
S1S1	100; 110 ... 600 ◆ ... 2,000 ms
S1S2	Off; 100; 110 ... 400 ◆ ... 600 ms
S2S3	Off ◆; 100; 110 ... 400; 410 ... 600 ms[a]
S3S4	Off ◆; 100; 110 ... 400; 410 ... 600 ms[a]
Amplitude	1; 2; 3; 4 ◆; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50 ◆ ... 1.50 ms
VVI Backup (for atrial PES)	On; Off ◆
Pacing Rate	60; 70 ◆ ... 120 min^{-1}
V. Amplitude[b,c]	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[b]	0.10; 0.20 ... 1.50 ms

[a] Default value when parameter is On is 400 ms.
[b] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.
[c] Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

Manual defibrillation parameters

Parameter	Selectable values
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 ◆ J
Pathway[a]	AX>B; B>AX ◆
Minimum R-R (atrial CV only)	400; 410 ... 500 ◆ ... 600 ms

[a] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

Shared manual ATP therapy parameters

Parameter	Selectable values
Minimum Interval (atrial ATP)	100; 110; 120; 130 ◆ ... 400 ms
Minimum Interval (ventricular ATP)	150; 160 ... 200 ◆ ... 400 ms
Amplitude	1; 2 ... 6 ◆; 8 V
Pulse Width	0.10; 0.20 ... 1.50 ◆ ms
VVI Backup (for atrial ATP therapy)	On; Off ◆
Pacing Rate	60; 70 ◆ ... 120 min^{-1}
V. Amplitude[a,b]	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[a]	0.10; 0.20 ... 1.50 ms

[a] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.
[b] Crosstalk may occur when atrial pacing amplitude is greater than 6.0V.

Manual cardioversion parameters

Parameter	Selectable values
Chamber	Atrium; RV
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 ◆ J
Pathway[a]	AX>B; B>AX ◆
Minimum R-R (atrial CV only)	400; 410; ... 500 ◆ ... 600 ms

[a] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

Manual Ramp therapy parameters

Parameter	Selectable values
Chamber	Atrium; RV
RV Ramp therapy parameters	
# Pulses	1; 2 ... 6 ◆ ... 15
%RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88; 91; 94; 97 ◆ %
Dec/Pulse	0; 10 ◆; 20; 30; 40 ms
Atrial Ramp therapy parameters	
# Pulses	1; 2 ... 6 ◆ ... 15; 20; 30 ... 100
%RR Interval	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91; 94; 97 ◆ %
Dec/Pulse	0; 10 ◆; 20; 30; 40 ms

Manual Burst therapy parameters

Parameter	Selectable values
# Pulses	1; 2 ... 8 ◆ ... 15
%RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88 ◆ ; 91; 94; 97%

Manual Ramp+ therapy parameters

Parameter	Selectable values
# Pulses	1; 2; 3 ◆ ... 15
R-S1 (%RR)	50; 53; 56; 59; 63; 66 ... 75 ◆ ... 84; 88; 91; 94; 97%
S1-S2 (%RR)	50; 53; 56; 59; 63; 66; 69 ◆ ... 84; 88; 91; 94; 97%
S2-SN (%RR)	50; 53; 56; 59; 63; 66 ◆ ... 84; 88; 91; 94; 97%

Manual Burst+ therapy parameters

Parameter	Selectable values
# S1 Pulses	1; 2 ... 6 ◆ ... 15; 20; 30 ... 100
%AA Interval	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91 ◆; 94; 97%
S1S2	Off; 28; 31; 34; 38; 41 ... 59; 63; 66 ... 84 ◆; 88; 91; 94; 97%
S2S3 Dec	Off; 0; 10; 20 ◆ ... 80 ms

Longevity

Projected service life in years

		Projected service life in years	
Pacing Mode, percent pacing	Pacing Amplitude	500 Ω pacing impedance	600 Ω pacing impedance
DDD, 0%	2.5 V 3.5 V	9.7 9.6	9.7 9.6
DDD, 15%	2.5 V 3.5 V	9.1 8.7	9.2 8.8
DDD, 50%	2.5 V 3.5 V	8.3 7.1	8.5 7.4
DDD, 100%	2.5 V 3.5 V	7.3 5.7	7.6 6.1
AAI <=>DDD MVP™ Mode 50% Atrial, 5% Ventricular	2.5 V 3.5 V	8.9 8.2	9.0 8.3

The service life projections are based on the following assumptions:

- Semi-annual maximum energy charging frequency
- Pre-arrhythmia EGM storage programmed to On for a 6-month period (two 3-month follow-up intervals), over the entire life of the device
- 3 hours of wireless telemetry during implant
- A quarterly schedule of Medtronic patient monitor remote transmissions
- 1 hour of in-office wireless telemetry annually
- Typical shelf storage time before implant

Projected service life estimates are based on accelerated battery discharge data and device modeling as specified. Do not interpret these values as precise numbers.

Indications, Safety, and Warnings
If you are located in the United States, please refer to the brief statement(s) below to review applicable indications, safety, and warning information. See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-763-514-4000 and/or consult the Medtronic website at medtronic.com.

If you are located outside the United States, see the device manual for detailed information regarding 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.com.

www.medtronic.com/manuals

Consult instructions for use at this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.

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MIRRO MRI™
VR SURESCAN™
Model DVME3D4

- MR Conditional with PhysioCurve™ Design
- DF4

Product specifications

Physical characteristics

Volume[a]	33 cm^3
Mass	77 g
H x W x D	64 mm x 51 mm x 13 mm
Surface area of device can	57 cm^2
Radiopaque ID[b]	PFZ
Medtronic Radiopaque ID[b]	
Materials in contact with human tissue[c]	Titanium, polyurethane, silicone rubber
Battery	Hybrid CFx lithium/silver vanadium oxide

[a] Volume with connector ports unplugged.
[b] The radiopaque ID, which includes a Medtronic-identifier symbol, can be viewed in a fluoroscopic image of the device.
[c] These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

Replacement indicators

Recommended Replacement Time (RRT)	< 2.73 V on 3 consecutive daily automatic measurements
End of Service (EOS)	3 months after RRT

Maximum energy levels and typical full energy charge times

Maximum programmed energy	35 J
Maximum delivered energy[a,b]	36 J
Maximum stored energy[c]	42 J
Typical charge time at Beginning of Service (BOS)[d]	8.4 s
Typical charge time at Recommended Replacement Time (RRT)[d]	12.5 s

[a] Energy delivered at connector block into a 50 Ω load.
[b] For 35 J programmed energy, delivered energy exceeds 35 J.
[c] Energy stored at charge end on capacitor.
[d] Charge time during a nonwireless telemetry session may be slightly higher.

Medtronic

Device parameters

Tachyarrhythmia detection parameters

Parameter	Programmable values
VF Detection	On ◆; Off
VF Interval (Rate)[a]	240; 250 ... 320 ◆ ... 400 ms
VF Initial Beats to Detect	12/16; 18/24; 24/32; 30/40 ◆; 45/60; 60/80; 75/100; 90/120; 105/140; 120/160
VF Beats to Redetect	6/8; 9/12; 12/16 ◆; 18/24; 21/28; 24/32; 27/36; 30/40
FVT Detection	Off ◆; via VF; via VT
FVT Interval (Rate)[a]	200; 210 ... 240 ◆ ... 600 ms
VT Detection	On; Off ◆
VT Interval (Rate)[a]	280; 290 ... 360 ◆ ... 650 ms
VT Initial Beats to Detect	12; 16 ◆ ... 52; 76; 100
VT Beats to Redetect	8; 12 ◆ ... 52
VT Monitor	Monitor ◆; Off
VT Monitor Interval (Rate)[a]	280; 290 ... 450 ◆ ... 650 ms
Monitored VT Beats to Detect	16; 20; 24; 28; 32 ◆ ... 56; 80; 110; 130
Wavelet[b]	On ◆; Off; Monitor
Template	[date]
Match Threshold	40; 43; 46 ... 70 ◆ ... 97%
Auto Collection	On ◆; Off
SVT V. Limit[a]	240; 250; 260 ◆ ... 650 ms
Other enhancements	
Stability[a]	Off ◆; 30; 40 ... 100 ms
Onset	Off ◆; On; Monitor
Onset Percent	72; 75; 78; 81 ◆; 84; 88; 91; 94; 97%
Sensitivity	
RV Sensitivity[c,d]	0.15; 0.30 ◆; 0.45; 0.60; 0.90; 1.20 mV

[a] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.
[b] The Wavelet feature is automatically set to On when VF Detection is set to On.
[c] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.
[d] Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity threshold to its minimum (most sensitive) setting of 0.15 mV. When susceptibility to modulated interference is tested under the conditions specified in CENELEC standard EN 45502-2-2:2008, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the minimum value of 0.15 mV. The device complies with the requirements of clause 27.5.1 when the sensitivity threshold is programmed to 0.3 mV or higher.

Ventricular tachyarrhythmia therapy parameters

Parameter	Programmable values
VF Therapy parameters	
VF Therapy Status	On ◆; Off
Energy	Rx1-Rx2: 0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 ◆ J Rx3-Rx6: 10; 11 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 ◆ J
Pathway[a]	AX>B; B>AX; Rx1-Rx4: B>AX ◆; Rx5-Rx6: AX>B ◆
ATP	During Charging ◆; Before Charging; Off
Deliver ATP if last 8 R-R ≥	200; 210 ... 240 ◆ ... 300 ms
Therapy Type	Burst ◆; Ramp; Ramp+
ChargeSaver	On ◆; Off
Switch when number of consecutive ATP successes equals	1 ◆; 2; 3; 4; 6; 8; 10
Smart Mode	On ◆; Off
VT/FVT Therapy parameters	
VT Therapy Status	On; Off ◆
FVT Therapy Status	On; Off ◆
Therapy Type	CV; Burst; Ramp; Ramp+ Rx1: Burst ◆; Rx2-Rx6: CV ◆
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J VT Rx1-Rx2: 20 ◆ J VT Rx3-Rx6: 35 ◆ J FVT Rx1-Rx6: 35 ◆ J
Pathway[a]	AX>B; B>AX; Rx1-Rx4: B>AX ◆; Rx5-Rx6: AX>B ◆
Burst therapy parameters	
Initial # Pulses	1; 2 ... 8 ◆ ... 15
R-S1 Interval = (%RR)	50; 53; 56; 59; 63; 66 ... 84; 88 ◆; 91; 94; 97%
Interval Dec	0; 10 ◆ ... 40 ms
# Sequences	1; 2 ... 10 VT Therapies: 3 ◆; FVT Therapies: 1 ◆
Smart Mode[b]	On; Off ◆
Ramp therapy parameters	
Initial # Pulses	1; 2 ... 8 ◆ ... 15
R-S1 Interval = (%RR)	50; 53; 56; 59; 63; 66 ... 84; 88; 91 ◆; 94; 97%
Interval Dec	0; 10 ◆ ... 40 ms
# Sequences	1; 2 ... 10 VT Therapies: 3 ◆; FVT Therapies: 1 ◆
Smart Mode[b]	On; Off ◆
Ramp+ therapy parameters	
Initial # Pulses	1; 2; 3 ◆ ... 15
R-S1 Interval = (%RR)	50; 53; 56; 59; 63; 66 ... 75 ◆ ... 84; 88; 91; 94; 97%
S1S2 (Ramp+) = (%RR)	50; 53; 56; 59; 63; 66; 69 ◆ ... 84; 88; 91; 94; 97%
S2SN (Ramp+) = (%RR)	50; 53; 56; 59; 63; 66 ◆ ... 84; 88; 91; 94; 97%
# Sequences	1; 2 ... 10 VT Therapies: 3 ◆; FVT Therapies: 1 ◆
Smart Mode[b]	On; Off ◆
Shared Settings	
V-V Minimum ATP Interval	150; 160 ... 200 ◆ ... 400 ms
V. Amplitude	1; 2 ... 6; 8 ◆ V
V. Pulse Width	0.1; 0.2 ... 1.5 ◆ ms
V. Pace Blanking	150; 160 ... 240 ◆ ... 450 ms
Active Can™/SVC Coil[c]	Can+SVC On ◆; Can Off; SVC Off
Progressive Episode Therapies	On; Off ◆

Footnotes on following page

[a] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.
[b] Smart Mode is available only for Rx1-Rx4.
[c] The Active Can/SVC Coil parameter applies to all automatic, manual, and emergency high-voltage therapies. It also applies to T-Shock™ inductions.

Pacing parameters

Modes, rates, and intervals

Parameter	Programmable values
Mode	VVI◈; VVIR; VOO; OVO
Lower Rate[a]	30; 35 ... 40 ◈; 45 ... 60; 70; 75 ... 150 min^{-1} (± 2 min^{-1})

[a] The corresponding Lower Rate Interval can be calculated as follows: Lower Rate Interval (ms) = 60,000/Lower Rate.

RV parameters

Parameter	Programmable values
RV Amplitude	0.5; 0.75 ... 3.5 ◈ ... 5.0; 5.5; 6.0; 8.0 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4 ◈ ... 1.5 ms
RV Sensitivity[a]	0.15 mV (± 75%); 0.3 ◈ ; 0.45; 0.6 mV (± 50%); 0.9; 1.2 mV (± 30%)
RV Pace Polarity	Bipolar; Tip to Coil
RV Sense Polarity	Bipolar; Tip to Coil

[a] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

Blanking periods

Parameter	Programmable values
V. Blank Post VP	150; 160 ... 200 ◈ ... 450 ms
V. Blank Post VS	120 ◈; 130 ... 170 ms

Rate response pacing parameters

Parameter	Programmable values
Upper Sensor Rate	80; 85 ... 120 ◈ ... 150 min^{-1} (± 2 min^{-1})
ADL Rate	60; 65 ... 95 ◈ ... 145 min^{-1} (± 2 min^{-1})
Rate Profile Optimisation	On ◈; Off
ADL Response	1; 2; 3 ◈; 4; 5
Exertion Response	1; 2; 3 ◈; 4; 5
Activity Threshold	Low; Medium Low ◈; Medium High; High
Activity Acceleration	15; 30 ◈; 60 s
Activity Deceleration	Exercise ◈; 2.5; 5; 10 min
ADL Setpoint	5; 6 ... 40; 42 ... 80
UR Setpoint	15; 16 ... 40; 42 ... 80; 85 ... 180

Ventricular rate stabilisation parameters

Parameter	Programmable values
V. Rate Stabilisation	On; Off ◈
Maximum Rate	80; 85 ... 100 ◈ ... 120 min^{-1}
Interval Increment	100; 110 ... 150 ◈ ... 400 ms

Post VT/VF shock pacing parameters

Parameter	Programmable values
Post VT/VF Shock Pacing	On; Off ◈
Overdrive Rate	70; 75; 80 ◈ ... 120 min^{-1}
Overdrive Duration	0.5 ◈; 1; 2; 3; 5; 10; 20; 30; 60; 90; 120 min

Post shock pacing parameters

Parameter	Programmable values
Post Shock V. Amplitude	1; 2 ... 6 ◈; 8 V
Post Shock V. Pulse Width	0.1; 0.2 ... 1.5 ◈ ms

Sleep parameters

Parameter	Programmable values
Sleep	On; Off ◈
Sleep Rate	30; 35 ... 50 ◈; 55; 60; 70; 75 ... 100 min^{-1}
Bed Time	00:00; 00:10 ... 22:00 ◈ ... 23:50
Wake Time	00:00; 00:10 ... 07:00 ◈ ... 23:50

MRI SureScan parameters

Parameter	Programmable values
MRI SureScan	On; Off
MRI Pacing Mode	VOO (Asynchronous); OVO (Off)
MRI Pacing Rate	60; 70; 75... 120 min^{-1}

Additional pacing features

Parameter	Programmable values
Rate Hysteresis	Off ◈; 30; 40 ... 80 min^{-1}

Medtronic CareAlert™ parameters

Clinical management alerts

Parameter	Programmable values
Number of Shocks Delivered in an Episode[a]	
Device Tone	
Alert Enable – Urgency	Off ◈; On-Low; On-High
Patient Home Monitor	
Alert Enable[b]	Off ◈; On
Shared (Device Tone and Patient Home Monitor)	
Number of Shocks Threshold[c]	1 ◈; 2; 3; 4; 5; 6
All Therapies in a Zone Exhausted for an Episode	
Device Tone	
Alert Enable – Urgency	Off ◈; On-Low; On-High
Patient Home Monitor	
Alert Enable[b]	Off ◈; On

[a] Note that VF, VT, and FVT therapies could be delivered during a single episode (from initial detection until episode termination).
[b] Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.
[c] This parameter is displayed only if an associated alert has been enabled.

Lead/Device integrity alerts

Parameter	Programmable values
RV Lead	
Device Tone	
Alert Urgency[a]	Low; High ◆
RV Lead Integrity Enable	On ◆; Off
Patient Home Monitor	
RV Lead Integrity Enable[c]	On ◆; Off
Lead Impedance Out of Range	
Device Tone	
Alert Urgency[a]	Low; High ◆
RV Pacing Impedance Enable	On ◆; Off (Observation only)
RV Defibrillation Impedance Enable	On ◆; Off (Observation only)
SVC Defibrillation Impedance Enable[b]	On ◆; Off (Observation only)
Patient Home Monitor	
RV Pacing Impedance Enable[c]	Off; On ◆
RV Defibrillation Impedance Enable[c]	Off; On ◆
SVC Defibrillation Impedance Enable[b,c]	Off; On ◆
Shared (Device Tone and Patient Home Monitor)	
RV Pacing Impedance Less than	200 ◆; 300; 400; 500 Ω
RV Pacing Impedance Greater than	1,000; 1,500; 2,000; 3,000 ◆ Ω
RV Defibrillation Impedance Less than	20 ◆; 30; 40; 50 Ω
RV Defibrillation Impedance Greater than	100; 130; 160; 200 ◆ Ω
SVC Defibrillation Impedance Less than	20 ◆; 30; 40; 50 Ω
SVC Defibrillation Impedance Greater than	100; 130; 160; 200 ◆ Ω
Low Battery Voltage RRT	
Device Tone	
Alert Enable – Urgency	Off; On-Low; On-High ◆
Patient Home Monitor	
Alert Enable[c]	Off; On ◆
Excessive Charge Time EOS	
Device Tone	
Alert Enable – Urgency	Off; On-Low; On-High ◆
Patient Home Monitor	
Alert Enable[c]	Off; On ◆
VF Detection Off, 3+ VF or 3+ FVT Rx Off	
Device Tone	
Alert Enable	Off; On-High ◆
Patient Home Monitor	
Alert Enable[c]	Off; On ◆

[a] This parameter is displayed only if an associated alert has been enabled.
[b] If an SVC lead is not implanted, the alert will not sound.
[c] Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.

Shared parameters

Parameter	Programmable values
Patient Home Monitor	Yes; No ◆
Alert Time[a]	00:00; 00:10 ... 08:00 ◆ ... 23:50

[a] This parameter is displayed only if an associated alert has been enabled.

Data collection parameters

Data collection parameters

Parameter	Programmable values
LECG Source (Leadless ECG)[a]	Can to SVC[b]
LECG Range (Leadless ECG)	±1; ±2 ◆; ±4; ±8; ±12; ±16; ±32 mV
EGM 1 Source	RVtip to RVcoil; RVtip to RVring ◆
EGM 1 Range	±1; ±2; ±4; ±8 ◆; ±12; ±16; ±32 mV
EGM 2 (Wavelet) Source	Can to RVcoil ◆ ; Can to RVring; RVtip to RVcoil; RVtip to RVring; Can to SVC[b,c]; RVcoil to SVC[b]
EGM 2 (Wavelet) Range	±1; ±2; ±4; ±8; ±12 ◆; ±16; ±32 mV
EGM 3 Source	RVtip to RVcoil ◆; RVtip to RVring
EGM 3 Range	±1; ±2; ±4; ±8 ◆; ±12; ±16; ±32 mV
Monitored	EGM1 and EGM2 ◆ ,EGM1 and EGM3; EGM1 and LECG; EGM2 and EGM3; EGM2 and LECG; EGM3 and LECG
Pre-arrhythmia EGM	Off ◆; On – 1 month; On – 3 months; On Continuous
Device Date/Time[c]	(Enter time and date)
Holter Telemetry	Off ◆; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr

[a] This EGM channel displays far-field signals.
[b] An SVC electrode must be present for this configuration.
[c] If Can to SVC is selected, the EGM Range is automatically set to ±2 mV. The EGM Range is automatically set to ±8 mV for all other EGM Source options.
[d] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

System test parameters

System test parameters

Parameter	Selectable values
Pacing Threshold Test parameters	
Test Type	Amplitude; Pulse Width
Decrement after	2; 3 ... 15 pulses
RV Pace Polarity	Bipolar; Tip to Coil
Mode[a]	VVI; VOO
Lower Rate	30; 35 ... 60; 70; 75 ... 150 min^{-1}
RV Amplitude	0.25; 0.5 ... 5; 5.5; 6; 8 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2 ... 1.5 ms
V. Pace Blanking	150; 160 ... 450 ms
Sensing Test parameters	
Mode[a]	VVI; OVO
Lower Rate	30; 35 ... 60; 70; 75 ... 120 min^{-1}

System test parameters, cont'd.

System test parameters

Wavelet Test parameters	Selectable values
Match Threshold	40; 43 ... 70 ◆ ... 97
Mode[a]	VVI; OVO
Lower Rate	30; 35 ... 60; 70; 75 ... 120 min^{-1}

[a] The selectable values for this parameter depend on the programmed pacing mode.

EP study parameters

T-Shock induction parameters

Parameter	Selectable values
Resume at Deliver	Enabled ◆; Disabled
Enable	Enabled; Disabled ◆
#S1	2; 3; 4; 5 ◆; 6; 7; 8
S1S1	300; 310 ... 400 ◆ ... 2,000 ms
Delay	20; 30 ... 300 ◆ ... 600 ms
Energy	0.4; 0.6; 0.8; 1.0 ◆ ... 1.8; 2; 3; 4 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J
Waveform	Monophasic ◆; Biphasic
Pathway[a]	AX>B; B>AX ◆

[a] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

50 Hz Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled ◆; Disabled
Amplitude	1; 2; 3; 4 ◆; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50 ◆ ... 1.50 ms

Fixed Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled ◆; Disabled
Interval	100; 110 ... 600 ◆ ms
Amplitude	1; 2; 3; 4 ◆; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50 ◆ ... 1.50 ms

PES induction parameters

Parameter	Selectable values
Resume at Deliver	Enabled ◆; Disabled
#S1	1; 2 ... 8 ◆ ... 15
S1S1	100; 110 ... 600 ◆ ... 2,000 ms
S1S2	Off; 100; 110 ... 400 ◆ ...600 ms
S2S3	Off ◆; 100; 110 ... 400; 410 ... 600 ms[a]
S3S4	Off ◆; 100; 110 ... 400; 410 ... 600 ms[a]
Amplitude	1; 2; 3; 4 ◆; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50 ◆ ... 1.50 ms

[a] Default value when parameter is On is 400 ms.

Manual defibrillation parameters

Parameter	Selectable values
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 ◆ J
Pathway[a]	AX>B; B>AX ◆

[a] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

Manual cardioversion parameters

Parameter	Selectable values
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 ◆ J
Pathway[a]	AX>B; B>AX ◆

[a] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

Shared manual ATP therapy parameters

Parameter	Selectable values
Minimum Interval	150; 160 ... 200 ◆ ... 400 ms
Amplitude	1; 2 ... 6 ◆; 8 v
Pulse width	0.10; 0.20 ... 1.50 ◆ ms

Manual Ramp therapy parameters

Parameter	Selectable values
# Pulses	1; 2 ... 6 ◆ ... 15
%RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88; 91; 94; 97 ◆ %
Dec/Pulse	0; 10 ◆; 20; 30; 40 ms

Manual Burst therapy parameters

Parameter	Selectable values
# Pulses	1; 2 ... 8 ◆ ... 15
%RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88 ◆ ; 91; 94; 97%

Manual Ramp+ therapy parameters

Parameter	Selectable values
# Pulses	1; 2; 3 ◆ ... 15
R-S1 (%RR)	50; 53; 56; 59; 63; 66 ... 75 ◆ ... 84; 88; 91; 94; 97%
S1-S2 (%RR)	50; 53; 56; 59; 63; 66; 69 ◆ ... 84; 88; 91; 94; 97%
S2-SN (%RR)	50; 53; 56; 59; 63; 66 ◆ ... 84; 88; 91; 94; 97%

Longevity

Projected service life in years

		Projected service life in years	
Pacing Mode, percent pacing	Pacing Amplitude	500 Ω pacing impedance	600 Ω pacing impedance
VVI, 0%	2.5 V 3.5 V	11.0 11.0	11.0 11.0
VVI, 15%	2.5 V 3.5 V	10.7 10.4	10.8 10.5
VVI, 50%	2.5 V 3.5 V	10.1 9.2	10.2 9.5
VVI, 100%	2.5 V 3.5 V	9.3 7.9	9.6 8.3

The service life projections are based on the following assumptions:

- Semi-annual maximum energy charging frequency
- Pre-arrhythmia EGM storage programmed to On for a 6-month period (two 3-month follow-up intervals), over the entire life of the device
- 3 hours of wireless telemetry during implant
- A quarterly schedule of Medtronic patient monitor remote transmissions
- 1 hour of in-office wireless telemetry annually
- Typical shelf storage time before implant

Projected service life estimates are based on accelerated battery discharge data and device modeling as specified. Do not interpret these values as precise numbers.

Indications, Safety, and Warnings
If you are located in the United States, please refer to the brief statement(s) below to review applicable indications, safety, and warning information. See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-763-514-4000 and/or consult the Medtronic website at medtronic.com.

If you are located outside the United States, see the device manual for detailed information regarding 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.com.

www.medtronic.com/manuals

Consult instructions for use at this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.

Important Reminder: This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.

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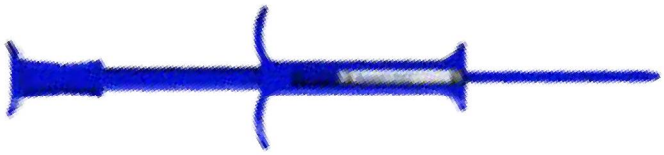
REVEAL LINQ™

DIAGNOSTICS



General

- **Insertable Cardiac Monitor** (ICM) with **3 years life**
- **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
- **70% smaller for comfortable handling and transport***
- **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**

*compared to Reveal XT model 9538

Model	LNQ11
M (g)	2.5 ± 0.5
V (cc)	1.2
Size (mm)	44.8 x 7.2 x 4.0

1. **Record Symptom Button**
   Patient presses button to record ECG when symptomatic
2. **Searching Light**
   Flashes blue indicating the patient should hold the Patient Assistant over the Reveal LINQ™ ICM
3. **Success Light**
   Illuminates green when the symptom is successfully marked
4. **Connection Slot**
   Allows patient to attach the Patient Assistant to a key chain, lanyard, or other personal item

MRI SureScan

Full Body 1.5 and 3T MRI with any MRI-labelled Medtronic 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)

Medtronic

Sistemul de stimulare cardiacă Sensia DR cu SAV+

Caracteristici fizice

Model	Dimensiuni (mm)	Masa (g)	Volum (cc)	Conector	Marcaj radioopac
SEDR01	44.7 x 47.9 x 7.5	27,1	12,1	IS-1 bipolar sau unipolar	PWL
SEDRL1	45.4 x 52.3 x 7.5	13,1	13,1	IS-1 bipolar sau unipolar	PWL

Baterie

Tip	Litiu-iod
Voltaj	2,8 V
Capacitate medie proiectată	
Model SEDR01	1.3 Ah
Model SEDRL1	1.6 Ah

Longevitate

Model SEDR01	8,9 ani*	9,4 ani**
Model SEDRL1	11,0 ani*	11,5 ani**

Stimularea anti-bradicardică

Parametri programabili

Moduri de stimulare	**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
Comutare automată a modului de stimulare (ModeSwitch)	**Pornit**, Oprit
Frecvenţa minimă de stimulare (Lower rate)	30, 35 ,40 … **60** … 170 bpm (exceptând 65 şi 85)
Frecvenţa max. a urmăririi A de către V (Upper Tracking Rate)[a]	80, 90, 95 … **130** … 180 bpm
Frecvenţa max. acceptabilă generată de senzor (Upper Sensor Rate)	80, 90, 95 … **130** … 180 bpm
Amplitudinea semnalului atrial şi ventricular drept[b]	0.5, 0.75, 1.0 … **3.5** … 4, 4.5, 5, 5.5, 6, 7.5 V
Durata semnalului atrial şi ventricular drept (ms)	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
Senzitivitatea atrială	0.18, 0.25, 0.35, **0.5**, 0.7, 1, 1.4, 2, 2.8, 4 mv
Senzitivitatea ventriculară	1, 1.4, 2, **2.8**, 4, 5.6, 8, 11.2 mv
Polaritatea de stimulare (atrial şi ventricular)	Bipolar, unipolar, **configurabilă automat**
Polaritatea de detecţie (atrial şi ventricular)	Bipolar, unipolar, **configurabilă automat**
Intervalul AV în cazul stimulării atriului (PAV)	30, 40, 50 … **150** … 350 ms
Intervalul AV în cazul activării intrinseci a atriului (SAV)	30, 40, 50 … **120** … 350 ms
Perioada de refractaritate A în urma unui eveniment V (PVARP)	**Automată,** variabilă, 150, 160, 170 … 500 ms
PVARP minim	150, 160, 170 ... **250** ... 500 ms
Perioada de *blanking* atrial în urma unui eveniment ventricular (PVAB)	130, 140, 150…**180**…350 ms
Perioada de refractaritate atrială	180, 190, 200 … **250** … 500 ms
Perioada de *blanking* atrial	130, 140, 150 … **180** … 350 ms
Perioada de refractaritate ventriculară	150, 160, 170 … **230** … 500 ms
Perioada de *blanking* ventricular după un stimul atrial (PAVB)	20, **28**, 36, 44 ms

Terapii pentru promovarea activării intrinseci

Algoritmul Search AV+™	**Pornit**, Oprit
Incrementare maximă a AV	10, 20, 30 ... **170** ... 250 ms
Algoritm Sinus Preference	Pornit, Oprit
Zona Sinus Preference	3, 5, **10**, 15, 20 bpm
Interval de cautare	5, **10**, 20, 30 min
Funcţie *Sleep*	Pornit, **Oprit**
Frecvenţa de stimulare	30, 35, 40 … **50** … 90 bpm (exceptând 65, 85)
Ora de culcare	12:00 am, 12:15 am, 12:30 am ... **10:00 pm** ... 11:45 pm
Ora de trezire	12:00 am, 12:15 am, 12:30 am ... **08:00 am** ... 11:45 pm
Hysterezis unicameral	**Oprit**, 40, 50, 60 bpm

Stimularea cu răspuns în frecvenţă

Frecvenţa ADL	60, 65, 70 ... **95** ... 175 bpm
Optimizarea Profilului de Frecvenţă	**Pornit**, Oprit
Răspunsul ADL	1, 2, **3**, 4, 5
Răspunsul la exerciţiu	1, 2, **3**, 4, 5
Pragul de activitate	Scăzut, **Mediu scăzut**, Mediu ridicat, Ridicat
Accelerare	15 s, **30 s**, 60 s
Decelerare	2.5 min, 5 min, 10 min, **Exerciţiu**
Interval AV adaptabil cu frecvenţa (RAAV)	Pornit, **Oprit**
Frecvenţa de pornire	50, 55, 60 ... **80** ... 175 bpm
Frecvenţa de oprire	55, 60, 65 ... **120** ... 180 bpm
Decalajul maxim	-10, -20, -30 ... **-40** ... -300 ms

Facilităţi suplimentare de stimulare

Intervenţie în cazul tahicardiilor mediate de către stimulator (PMT)	Pornit, **Oprit**
Răspuns la contracţiile ventriculare premature (PVC)	**Pornit**, Oprit
Stimulare ventriculară de siguranţă	**Pornit**, Oprit

Terapii şi intervenţii în cazul tahiaritmiilor atriale

Comutare automată a modului de stimulare (ModeSwitch)	**Pornit**, Oprit
Frecvenţa de detecţie	120, 125 ... **175** ... 200 bpm
Durata de detecţie	**Fără întârziere**, 10, 20 ... 60 s
Căutarea *fluttere*-lor ascunse	**Pornit**, Oprit
Stimulare atrială non-competitivă	**Pornit**, Oprit

Monitorizarea automată a stimulării, a detecţiei şi a sondei

Detecţie şi iniţializare automate ale implantului

La încetarea perioadei de 30 de minute de detectare a implantului este activată Optimizarea Profilului de Frecvenţă; sunt selectate polarităţile corespunzătoare de stimulare şi de detecţie în mod automat de către dispozitiv; sunt activate Managementul Capturii Atriale si Ventriculare (ACM si VCM) şi amplitudinea şi durata impulsurilor de stimulare devin adaptive. Este activat Sensing Assurance si senzitivitatea devine adaptiva. Este activat SAV+ la 60 de minute după ce detecţia implantului este completă

Detecţia implantului	Pornit / Restart, Oprit / Complet
Monitorizarea sondei (A şi V)	Configurare, numai monitorizare, adaptivă (comutare automată a polarităţii)
Notifică dacă <	**200 Ω**
Notifică dacă >	1000, 2000, 3000, **4000** Ω
Senzitivitatea monitorizării	2, 3, 4 ... **8** ... 16

* DDDR sau DDD, 60 bpm, 100% stimulare, 2.0 V ventricular+, 1.5 V atrial, 0.4 ms durata impulsului, 1000 Ω impedanţa de stimulare
** DDDR sau DDD, 60 bpm, SAV+ pornit, 50% stimulare, 2.0 V ventricular+, 1.5 V atrial, 0.4 ms durata impulsului, 1000 Ω impedanţa de stimulare
+ Valorile minime adaptate de către ACM si VCM la scoaterea aparatului din cutie.
Valorile nominale indicate cu litere **îngroşate**

Specificaţii pentru Sensia DR

Managementul Capturii Atriale

Managementul capturii atriale	Oprit, Doar monitorizare, Adaptiv
Marginea de amplitudine	1.5 x, **2x**, 2.5x, 3x, 4x
Amplitudinea adaptată minimă	0.5, 0.75 ... **1.5** ... 3.5 V
Frecvenţa testului de captură	15, 30 min; 1, 2, 4, 8, 12 ore; **Ziua în repaus**; Ziua la ...; la 7 zile
Ora testului de captură	12:00 am, **1:00 am** ... 11:00 pm
Zile rămase din faza acută	Oprit, 7, 14, 21 ... 84, **112**, 140, 168 ... 252

Managementul capturii ventriculare

Managementul capturii ventriculare	Oprit, Doar monitorizare, **Adaptiv**
Marginea de amplitudine	1.5 x, **2x**, 2.5x, 3x, 4x
Amplitudinea adaptată minimă	0.5, 0.75 ... **2** ... 3.5 V
Frecvenţa testului de captură	15, 30 min; 1, 2, 4, 8, 12 ore; **Ziua în repaus**; Ziua la ...; la 7 zile
Ora testului de captură	12:00 am, 1:00 am ... 11:00 pm
Zile rămase din faza acută	Oprit, 7, 14, 21 ... 84, **112**, 140, 168 ... 252
Senzitivitatea ventriculară în timpul căutării	Unipolară, Bipolară, **Adaptivă**

Sensing Assurance

Sensing assurance (A sau V)	**Pornit**, Oprit

Diagnostice

QuickLook™ II
Evidenţiază evenimentele semnificative, prezintă un sumar al stimulării, evoluţii grafice în timp ale pragurilor şi impedanţelor
Prezentări grafice ale evoluţiei în timp pentru pragurilor de stimulare atrial si ventricular
Longevitatea estimată a bateriei
Sumar al stimulării şi acces la histograme ale evoluţiei frecvenţei cardiace
Prezentări grafice ale evoluţiei în timp a impedanţelor sondelor atrială si ventriculară
Observaţii
Amplitudinile undelor P si R si acces la reprezentarea grafica a evolutiei acestora in timp

Rapoarte sub formă de histogramă
Histograme ale frecvenţei cardiace
Histograme ale conducerii AV
Histograme ale algoritmului Search AV+
Profil al frecventei indicate de senzor

Episoade atriale şi ventriculare
Episoade de frecvenţă înaltă atriale şi ventriculare
Episoade cu EGM-uri multiple

Diagnostice selectate de către medic
Evoluţia configurabilă a frecvenţei

Detalii ale Managementului Capturii Atriale
Detalii ale Managementului Capturii Ventriculare
Detalii despre frecvenţele ridicate

Gestiunea Datelor de Pacient

Ghid de pacient – Programare in functie de stare pacient
Campurile Ghidului de pacient
Statutul atrial
Conducerea AV
Insuficienta cardiaca
Varsta
Nivelul de activitate

Datele de pacient stocate în dispozitiv

Identificarea pacientului
Sondele implantate
Indicatia de implant
Dispozitivul implantat
Note memorate ale medicului

Gestionarea datelor

Tipărire automată a Raportului Iniţial de Interogare
Tipărire pe o pagină întreagă
Capacitatea de salvare pe dischetă pentru Gestionarea Electronică a Fişierelor

Verificarea şi remedierea problemelor

Facilităţi ale telemetriei

Monitorizare transtelefonică	Pornit, Oprit
Telemetrie extinsă	Pornit, Oprit
Marcaj extins	Standard, Urmărire a terapiei

Istoric al parametrilor cheie
Raport iniţial de interogare
Test al pragului putere durată
Test al pragului ventricular
Derivaţie de marcaj (Marker Channel™)
Test al limitei de prag
Test de exerciţiu
Studii electrofiziologice
Test de magnet
Test al ritmului intrinsec
Test al detecţiei
Testare temporară

Funcţionarea în modul Magnet

	BOS ***	ERI / RRT
Mod bicameral	DOO 85 bpm	65
Mod atrial unicameral	AOO 85 bpm	65
Mod ventricular unicameral	VOO 85 ppm	
ERI - RRT	Data iniţializării	

Timpul Recomandat de Înlocuire (RRT / ERI)

Mesaj de înlocuire pe ecranul programatorului	(Quick Look II)
Informaţii despre baterie / sondă	Mesaj de înlocuire şi afişarea voltajului bateriei pe ecranul programatorului
Data de iniţiere a RRT / ERI	Afişată pe ecranul programatorului

Referinţe

a Limita frecvenţei atriale şi ventriculare este 200 min^{-1}
b Toleranţa pentru amplitudini de la 0.5 V la 6.0 V este ± 10%, iar pentru 7.5 V este -20/+0%. Toleranţele sunt calculate la 37°C şi o sarcină de 500 Ω.
*** BOS = Începutul utilizării dispozitivului

Sistemul de stimulare cardiacă Sensia SR

Caracteristici fizice

Model	Dimensiuni	Masa (g)	Volum (cc)	Conector	Marcaj radioopac
SESR01	40.2x42.9x7.5	21,5	9,7	IS-1 bipolar sau unipolar	PWL

Baterie

Tip	Litiu-iod
Voltaj	2,8 V
Capacitate medie proiectată	0,91 Ah
Longevitate	8,4 ani*

Stimularea anti-bradicardică

Parametri programabili

Moduri de stimulare	**VVIR,** VVI, VVT, VOOR, VOO, AAIR, AAI, AAT, AOOR, AOO, OVO, OAO
Frecvenţa minimă de stimulare (Lower rate)	30, 35 ,40 … **60** … 175 bpm (exceptând 65 şi 85)
Frecvenţa maximă generată de senzor	80, 90, 95 … 130 … 180 bpm
Amplitudinea ** semnalului atrial şi ventricular drept	0.5, 0.75, 1.0 … **3.5** … 4, 4.5, 5, 5.5, 6, 7.5 V
Durata semnalului atrial şi ventricular drept (ms)	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
Senzitivitatea atrială	0.25, 0.35, **0.5**, 0.7, 1, 1.4, 2, 2.8, 4 mv
Senzitivitatea ventriculară	1, 1.4, 2, **2.8**, 4, 5.6, 8, 11.2 ms
Polaritatea de stimulare (atrial şi ventricular)	Bipolar, unipolar, configurabilă automat
Polaritatea de detecţie (atrial şi ventricular)	Bipolar, unipolar, configurabilă automat
Perioada de refractaritate atrială	180, 190, 200 … **250** … 500 ms
Perioada de *blanking* atrial	130, 140, 150 … **180** … 350 ms
Perioada de refractaritate ventriculară	150, 160, 170 … 3**30** … 500 ms

Terapii pentru promovarea activării intrinseci

Funcţie *Sleep*	Pornit, **Oprit**
Frecvenţa de stimulare	30, 35, 40 … **50** … 90 bpm (exceptând 65, 85)
Ora de culcare	12:00 am, 12:15 am, 12:30 am … **10:00 pm** … 11:45 pm
Ora de trezire	12:00 am, 12:15 am, 12:30 am … **08:00 am** … 11:45 pm
Hysterezis unicameral	**Oprit**, 40, 50, 60 bpm

Stimularea cu răspuns în frecvenţă

Frecvenţa ADL	60, 65, 70 … **95** … 175 bpm
Optimizarea Profilului de Frecvenţă	**Pornit**, Oprit
Răspunsul ADL	1, 2, **3**, 4, 5
Răspunsul la exerciţiu	1, 2, **3**, 4, 5
Pragul de activitate	Scăzut, **Mediu scăzut**, Mediu ridicat, Ridicat
Accelerare	15 s, **30 s**, 60 s
Decelerare	2.5 min, 5 min, 10 min, **Exerciţiu**

Monitorizarea automată a stimulării, a detecţiei şi a sondei

Detecţie şi iniţializare automate ale implantului

La încetarea perioadei de 30 de minute de detectare a implantului este activată Optimizarea Profilului de Frecvenţă, polarităţile corespunzătoare de stimulare şi de detecţie sunt selectate în mod automat de către dispozitiv; este activat Managementul Capturii Ventriculare (VCM) şi amplitudinea şi durata impulsurilor de stimulare devin adaptive. Este activat și algoritmul Sensing Assurance și detecția devine adaptivă.

Detecţia implantului	Pornit / Restart, Oprit / Complet
Monitorizarea sondei (A şi V)	Configurare, numai monitorizare, adaptivă (comutare automată a polarităţii)
Notifică dacă <	**200 Ω**
Notifică dacă >	1000, 2000, 3000, **4000** Ω
Senzitivitatea monitorizării	2, 3, 4 ... **8** ... 16

Managementul capturii ventriculare

Managementul capturii ventriculare	Oprit, Doar monitorizare, **Adaptiv**
Marginea de amplitudine	1.5 x, **2x**, 2.5x, 3x, 4x
Amplitudinea adaptată minimă	0.5, 0.75 ... **2** ... 3.5 V
Frecvenţa testului de captură	15, 30 min; 1, 2, 4, 8, 12 ore; **Ziua în repaus**; Ziua la ...; la 7 zile
Ora testului de captură	12:00 am, 1:00 am ... 11:00 pm
Zile rămase din faza acută	Oprit, 7, 14, 21 ... 84, **112**, 140, 168 ... 252
Senzitivitatea ventriculară în timpul căutării	Unipolară, Bipolară, **Adaptivă**
Sensing Assurance (asigurarea detecției)	**Pornit,** Oprit

Diagnostice

QuickLook™ II

Evidenţiază evenimentele semnificative, prezintă un sumar al stimulării, evoluţii grafice în timp ale pragurilor şi impedanţelor

- Prezentări grafice ale evoluţiei în timp pentru pragul de stimulare ventricular
- Longevitatea estimată a bateriei
- Sumar al stimulării şi acces la histograme ale evoluţiei frecvenţei cardiace
- Prezentări grafice ale evoluţiei în timp a impedanţelor sondelor atrială sau ventriculară
- Observaţii
- Valorile actuale ale undelor P şi R şi posibilitatea de a accesa prezentări grafice ale evoluţiei în timp ale acestora

Rapoarte sub formă de histogramă

- Histograme ale frecvenţei cardiace
- Profilul frecvenței indicate de senzor

Episoade atriale şi ventriculare

- Episoade de frecvenţă înaltă
- Episoade cu EGM-uri multiple

Diagnostice selectate de către medic

- Evoluţia configurabilă a frecvenţei
- Detalii ale Managementului Capturii Ventriculare
- Detalii despre frecvenţele ridicate

* SSIR sau SSI, 60 bpm, 100% stimulare, 2.0 V, 0.4 ms durata impulsului,
1000 Ω

Valorile nominale indicate cu litere îngroşate

Specificaţii pentru Sensia SR

Gestiunea Datelor de Pacient

Therapy Guide (Ghidul de Terapie) – Programare bazată pe situaţia pacientului
Câmpuri ale Ghidului de Terapie
Camera cardiacă unde este implantată sonda
Statutul atrial
Conducerea AV
Insuficienţa cardiacă
Vârsta
Nivelul de activitate
Datele de pacient stocate în dispozitiv
Identificarea pacientului
Sondele implantate
Indicaţia de implant
Dispozitivul implantat
Note memorate ale medicului

Gestionarea datelor
Tipărire automată a Raportului Iniţial de Interogare
Tipărire pe o pagină întreagă
Capacitatea de salvare pe dischetă pentru Gestionarea Electronică a Fişierelor

Verificarea şi remedierea problemelor

Facilităţi ale telemetriei

Monitorizare transtelefonică	Pornit, Oprit
Telemetrie extinsă	Pornit, Oprit
Marcaj extins	Standard, Urmărire a terapiei

Istoric al parametrilor cheie
Raport iniţial de interogare
Test al pragului putere durată
Test al pragului ventricular
Marcaje (Marker Channel™)
Test al limitei de prag
Test de exerciţiu
Studii electrofiziologice
Test de magnet
Test al ritmului intrinsec
Test al detecţiei
Testare temporară

Funcţionarea în modul Magnet

	BOS ***	ERI / RRT
Mod atrial unicameral	AOO 85 bpm	65
Mod ventricular unicameral	VOO 85 bpm	65
ERI - RRT	Data iniţializării	

Timpul Recomandat de Înlocuire (RRT / ERI)

Mesaj de înlocuire pe ecranul programatorului	(Quick Look II)
Informaţii despre baterie / sondă	Mesaj de înlocuire şi afişarea voltajului bateriei pe ecranul programatorului
Data de iniţiere a RRT / ERI	Afişată pe ecranul programatorului

Referinţe

** Toleranţa pentru amplitudini de la 0.5 V la 6.0 V este ± 10%, iar pentru 7.5 V este -20/+0%. Toleranţele sunt calculate la 37°C şi o sarcină de 500 Ω.

*** BOS = Începutul utilizării dispozitivului

SOLARA™ QUAD CRT-P MRI SURESCAN™

Model W4TR06

- MR Conditional with SureScan™ Technology
- Bluetooth® Wireless Telemetry
- VectorExpress™ 2.0 LV Automated Test
- CardioSync™ Optimisation
- OptiVol™ 2.0 Fluid Status Monitoring
- MVP™ Mode
- Complete Capture Management™ Diagnostic (ACM, RVCM, LVCM)

Heart Failure Management Report

This report provides an overview of the patient's condition over the short and long term, with a focus on heart failure management. The report includes graphs that show OptiVol™ 2.0 fluid trends and trends related to heart failure over the last 14 months.

Physical characteristics

Volume[a]	20.5 cm^3
Mass	30 g
H x W x D[b]	59 mm x 46.5 mm x 11 mm
Radiopaque ID[c]	RNP
Surface area of titanium device can	40.7 cm^2
Materials in contact with human tissue[d]	Titanium, polyurethane, silicone rubber
Battery	Lithium-hybrid CFx silver vanadium oxide

[a] Volume with connector holes unplugged.
[b] Grommets may protrude slightly beyond the can surface.
[c] The radiopaque ID, which includes a Medtronic-identifier symbol, can be viewed in a fluoroscopic image of the device.
[d] These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

Replacement indicators

Recommended Replacement Time (RRT)	180 days after 3 consecutive daily automatic measurements of ≤ 2.63 V or immediately after 3 consecutive daily automatic measurements of ≤ 2.60 V, whichever comes first
Elective Replacement Indicator (ERI)	3 months after RRT
End of Service (EOS)	3 months after ERI

Medtronic

Tachyarrhythmia detection parameters

Tachyarrhythmia detection parameters

Parameter	Programmable values
AT/AF Detection	On; Monitor ◆
Zones	1 ◆; 2
AT/AF Interval (Rate)[a]	150; 160 ... 350 ◆ ... 450 ms
Fast AT/AF Interval (Rate)[a]	150; 160 ... 200 ◆ ... 250 ms
VT Monitor	Monitor ◆; Off
VT Monitor Interval (Rate)[a]	280; 290 ... 400 ◆... 500 ms
RV Sensitivity[b]	0.45; 0.60 mV (± 50%); 0.90; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV (± 30%) Bipolar: 0.9 ◆ mV Unipolar: 2.80 ◆ mV
Atrial Sensitivity[c]	0.15 mV (± 75%); 0.30; 0.45; 0.60 mV (± 50%); 0.90; 1.20; 1.5; 1.8; 2.1; 4.0 mV (± 30%); Off Bipolar: 0.3 ◆ mV Unipolar: 0.45 ◆ mV

[a] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.

[b] The device complies with the requirements of ISO 14708-2 when the sensitivity threshold is programmed to 2.0 mV or higher.

[c] The device complies with the requirements of ISO 14708-2 when the sensitivity threshold is programmed to 1.8 mV or higher.

Atrial tachyarrhythmia therapy parameters

Parameter	Programmable values
Antitachy Pacing (ATP)	
Fast AT/AF Rx Status	On; Off ◆
Therapy Type	Ramp; Burst+ Rx1: Ramp ◆; Rx2: Burst+ ◆; Rx3: Ramp ◆
AT/AF Rx Status	On; Off ◆
Therapy Type	Ramp; Burst+ Rx1: Ramp ◆; Rx2: Burst+ ◆; Rx3: Ramp ◆
Burst+ parameters	
Initial # S1 Pulses	1; 2; 3 ... 11 ◆ ... 15; 20; 25
A-S1 Interval (%AA)	28; 31; 34; 38; 41 ... 59; 63; 66; 69 ... 84 ◆ ; 88; 91; 94; 97%
S1-S2 (%AA)	28; 31; 34; 38; 41 ... 59; 63; 66; 69 ... 81 ◆; 84; 88; 91; 94; 97%; Off
S2-S3 Decrement	0; 10; 20 ◆ ... 80 ms; Off
Interval Decrement	0; 10 ◆; 20; 30; 40 ms
# Sequences	1; 2; 3 ... 10 ◆
Ramp parameters	
Initial # S1 Pulses	1; 2; 3 ... 13 ◆; 14; 15; 20; 25
A-S1 Interval (%AA)	
Rx1	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91 ◆; 94; 97%
Rx2	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91 ◆; 94; 97%
Rx3	28; 31; 34; 38; 41 ... 59; 63; 66 ... 81 ◆ ; 84; 88; 91; 94; 97%
Interval Decrement	0; 10 ◆ ... 40 ms
# Sequences	1; 2 ... 8; 9; 10 ◆
Stop Atrial Rx after (Shared)	
Rx/Lead Suspect ...	
Disable Atrial ATP if it accelerates V. rate?	Yes ◆; No
Disable all atrial therapies if atrial lead position is suspect? (Atrial Lead Position Check)	Yes ◆; No
Duration to stop	12; 24; 48 ◆; 72 hr; None
Episode Duration before Rx Delivery	
Episode Duration before ATP	0; 1 ◆; 2 ... 5; 7; 10; 15; 20; 25; 30; 40; 50 min; 1; 2; 3; 4; 5; 6; 12; 24 hr
Reactive ATP™	
Rhythm Change	On ◆; Off
Time Interval	Off ◆; 2; 4; 7; 12; 24; 36; 48 hr
Shared A. ATP	
A-A Minimum ATP Interval[a]	100; 110... 150 ◆ ... 400 ms (± 6 ms)
A. Pacing Amplitude	1; 2 V (+0.5 V/-33%) 3; 4; 5; 6 ◆; 8 V (+20%/-33%)
A. Pacing Pulse Width	0.1; 0.2 ... 1.5 ◆ ms (± 25 µs)
VVI Backup Pacing	Off; On (Always); On (Auto-Enable) ◆
VVI Backup Pacing Rate	60; 70 ◆ ... 120 min^{-1}

[a] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.

Pacing Parameters

Modes, rates, and intervals

Parameter	Programmable values
Mode	DDDR; DDD ◆; AAIR<=>DDDR; AAI<=>DDD; DDIR; DDI; AAIR; AAI; VVIR; VVI; DOO; AOO; VOO; ODO
Mode Switch	On ◆; Off
Lower Rate[a]	30; 35 ... 50 ◆; 70; 75 ... 150 min^{-1} (±2 min^{-1})
Upper Tracking Rate	80; 85 ... 130 ◆... 175 min^{-1} (±2 min^{-1}) 180; 190 ... 210 min^{-1} (+2/-11 min^{-1})
Paced AV	30; 40 ... 130 ◆... 350 ms (± 4 ms)
Sensed AV	30; 40 ... 100 ◆... 350 ms (+30; –2 ms)
Maximum AV Interval Limit	Off ◆; 250; 260 ... 500 ms

Modes, rates, and intervals, cont'd.

Parameter	Programmable values
PVARP	Auto ◆; 150; 160 ... 500 ms (+5; –30 ms)
Minimum PVARP	150; 160 ... 250 ◆... 500 ms (+5; –30 ms)
A. Refractory Period	150; 160 ... 310 ◆... 500 ms (+5; –30 ms)

[a] The corresponding Lower Rate interval can be calculated as follows: Lower Rate interval (ms) = 60,000/Lower Rate.

Atrial parameters

Parameter	Programmable values
Atrial Amplitude	0.5; 0.75 ... 1.25 V (+0.125 V/-33%) 1.50 ... 3.5 ◆... 5; 5.5; 6; 8 V (+15%/-33%)[a]
Atrial Pulse Width	0.03; 0.06 ms (± 10 µs); 0.1; 0.2; 0.3; 0.4 ◆... 1.5 ms (± 25 µs)
Atrial Sensitivity	Off; 0.15; 0.3; 0.45; 0.6 mV (± 60%); 0.9; 1.2; 1.5; 1.8; 2.1; 4.0 mV (± 40%) Unipolar: 0.45 ◆ mV Bipolar: 0.3 ◆ mV
Atrial Pace Polarity	Bipolar; Unipolar
Atrial Sense Polarity	Bipolar; Unipolar
Atrial Lead Monitor	Monitor Only; Adaptive
Min Limit	200 ◆; 300; 400; 500 Ω
Max Limit	1,000; 1,500; 2,000; 3,000 ◆ Ω

[a] When Atrial Amplitude is 8 V, Atrial Pulse Width must be less than 1.3 ms.

RV parameters

Parameter	Programmable values
RV Amplitude	0.5; 0.75 ... 1.25 V (+0.125 V/-33%) 1.50 ... 3.5 ◆... 5; 5.5; 6; 8 V (+15%/-33%)[a]
RV Pulse Width	0.03; 0.06 ms (± 10 µs); 0.1; 0.2; 0.3; 0.4 ◆... 1.5 ms (± 25 µs)
RV Sensitivity	0.45; 0.60; 0.90; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV (±55%) Unipolar: 2.80 ◆ mV Bipolar: 0.90 ◆ mV
RV Pace Polarity	Bipolar; Unipolar
RV Sense Polarity	Bipolar; Unipolar
RV Lead Monitor	Monitor Only; Adaptive
Min Limit	200 ◆; 300; 400; 500 Ω
Max Limit	1,000; 1,500; 2,000; 3,000 ◆ Ω

[a] When RV Amplitude is 8 V, RV Pulse Width must be less than 1.3 ms.

LV parameters

Parameter	Programmable values
LV Amplitude	0.5; 0.75 ... 1.25 V (+0.125 V/-33%) 1.50 ... 3.5 ◆... 5; 5.5; 6; 8 V (+15% -33%)[a]
LV Pulse Width	0.03; 0.06 ms (± 10 µs); 0.1; 0.2; 0.3; 0.4 ◆... 1.5 ms (± 25 µs)
LV Pace Polarity	LV1 to LV2; LV1 to LV3; LV1 to LV4; LV1 to Can; LV2 to LV1; LV2 to LV3; LV2 to LV4; LV2 to Can; LV3 to LV1; LV3 to LV2; LV3 to LV4; LV3 to Can; LV4 to LV1; LV4 to LV2; LV4 to LV3; LV4 to Can
LV Lead Monitor	Monitor Only; Adaptive
Min Limit	200 ◆; 300; 400; 500 Ω
Max Limit	1,000; 1,500; 2,000; 3,000 ◆ Ω

[a] When LV Amplitude is 8 V, LV Pulse Width must be less than 1.3 ms.

CRT pacing parameters

Parameter	Programmable values
V. Pacing	RV; RV→LV; LV→RV ◆; LV
V-V Pace Delay	0 ◆; 10 ... 80 ms
V. Sense Response	On ◆; Off
Maximum Rate	95; 100 ...130 ◆... 150 min^{-1}
Atrial Tracking Recovery	On ◆; Off

Atrial Capture Management™ parameters

Parameter	Programmable values
Atrial Capture Management™	Adaptive ◆; Monitor; Off
Atrial Amplitude Safety Margin	1.5x; 2.0x ◆; 2.5x; 3.0x
Atrial Minimum Adapted Amplitude	1.0; 1.5 ◆; 2.0; 2.5; 3.0; 3.5 V
Atrial Acute Phase Remaining	Off; 30; 60; 90; 120 ◆; 150 days

RV Capture Management™ parameters

Parameter	Programmable values
RV Capture Management™	Adaptive ◆; Monitor; Off
RV Amplitude Safety Margin	1.5x; 2.0x ◆; 2.5x; 3.0x
RV Minimum Adapted Amplitude	1.0; 1.5; 2.0 ◆; 2.5; 3.0; 3.5 V
RV Acute Phase Remaining	Off; 30; 60; 90; 120 ◆; 150 days

LV Capture Management™ parameters

Parameter	Programmable values
LV Capture Management™	Adaptive ◆; Monitor; Off
LV Amplitude Safety Margin	+Auto ◆; +0.5; +1.0; +1.5; +2.0; +2.5 V
LV Maximum Adapted Amplitude	0.5; 0.75 ... 5.0; 5.5; 6 ◆ V

Blanking periods

Parameter	Programmable values
PVAB Interval	10[a]; 20 ... 100; 110; 120 ... 150 ◆ ... 300 ms
PVAB Method	Partial ◆; Partial+; Absolute
A. Blank Post AP	150; 160 ... 200 ◆ ... 250 ms (± 5 ms)
A. Blank Post AS	100 ◆; 110 ... 170 ms (± 2 ms)
V. Blank Post VP	150; 160 ... 230 ◆ ... 320 ms (± 5 ms)
V. Blank Post VS	120 ◆; 130 ... 170; 200; 220; 250; 280; 300; 320 ms (±2 ms)

[a] If the PVAB Method is set to Partial, the minimum selectable value for the PVAB Interval is 100 ms.

Rate response pacing parameters

Parameter	Programmable values
Rates	
ADL Rate	60; 65 ... 95 ◆... 170 min^{-1} (± 2 min^{-1})
Upper Sensor	80; 85 ... 120 ◆... 175 min^{-1} (± 2 min^{-1})
Rate Profile Optimisation	On ◆; Off
Adjust Rate Response	
ADL Response	1; 2; 3 ◆; 4; 5
Exertion Response	1; 2; 3 ◆; 4; 5
Additional Parameters	
Activity Threshold	Low ◆; Medium Low; Medium High; High
Activity Acceleration	15; 30 ◆; 60 s
Activity Deceleration	Exercise ◆; 2.5; 5; 10 min
ADL Set Point	5; 6 ... 40; 42 ... 80
UR Set Point	15; 16 ... 40; 42 ... 80; 85 ... 180

Rate adaptive AV parameters

Parameter	Programmable values
Rate Adaptive AV	On ◆; Off
Start Rate	50; 55 ... 90 ◆... 145 min^{-1}
Stop Rate	55; 60 ... 130 ◆... 175 min^{-1}
Minimum Paced AV	30; 40 ... 100 ◆... 200 ms
Minimum Sensed AV	30; 40 ... 70 ◆... 200 ms

Atrial rate stabilisation parameters

Parameter	Programmable values
A. Rate Stabilisation	On; Off ◆
Maximum Rate	80; 85 ... 100 ◆... 150 min^{-1}
Interval Percentage Increment	12.5; 25 ◆; 50%

Post Mode Switch Overdrive Pacing (PMOP) parameters

Parameter	Programmable values
Post Mode Switch	On; Off ◆
Overdrive Rate	70; 75; 80 ◆... 120 min^{-1}
Overdrive Duration	0.5; 1; 2; 3; 5 ◆; 10; 20; 30; 60; 90; 120 min

Conducted AF response parameters

Parameter	Programmable values
Conducted AF Response	On ◆; Off
Response Level	Low; Medium ◆; High
Maximum Rate	80; 85 ... 110 ◆ ... 130 min^{-1}

Ventricular rate stabilisation parameters

Parameter	Programmable values
V. Rate Stabilisation	On; Off ◆
Maximum Rate	80; 85; 100 ◆... 120 min^{-1}
Interval Increment	100; 110 ... 150 ◆... 400 ms

Rate drop response parameters

Parameter	Programmable values
Rate drop response[a]	On; Off ◆
Detection Type	Drop ◆; Low Rate; Both
Drop Detection	
Drop Size	10; 15 ... 25 ◆ ... 50 min^{-1}
Drop Rate	30; 40 ... 60 ◆ ... 100 min^{-1}
Detection Window	10; 15; 20; 25; 30 s 1 ◆; 1.5; 2; 2.5 min
Low Rate Detection	
Detection Beats	1; 2; 3 ◆ beats
Intervention	
Intervention Rate	70; 75 ... 100 ◆... 150 min^{-1}
Intervention Duration	1; 2 ◆... 15 min

[a] When Rate Drop Response is set to On, the lower rate is automatically set to 45 min^{-1}.

Sleep parameters

Parameter	Programmable values
Sleep	On; Off ◆
Sleep Rate	30; 35 ... 50 ◆; 55; 60; 70; 75 ... 100 min^{-1}
Bed Time	00:00; 00:10 ... 22:00 ◆ ... 23:50
Wake Time	00:00; 00:10 ... 07:00 ◆ ... 23:50

Non-competitive atrial pacing (NCAP) parameters

Parameter	Programmable values
Non-Comp Atrial Pacing	On ◆; Off
NCAP Interval	200; 250; 300 ◆; 350; 400 ms

Additional pacing features

Parameter	Programmable values
PMT Intervention	On ◆; Off
PVC Response	On ◆; Off
V. Safety Pacing[a]	On ◆; Off

[a] Delivered as LV pacing when LV pacing is permanently programmed. Delivered as RV pacing when RV only pacing is permanently programmed. Otherwise, delivered as BiV pacing.

Longevity

Projected service life in years

Percent Pacing			500 Ω pacing impedance		600 Ω pacing impedance	
Atrial %	RV%	LV%	2.5 V	3.5 V	2.5 V	3.5 V
0%	100%	100%	10.1	7.7	10.6	8.2
15%	100%	100%	9.9	7.4	10.4	8.0
50%	100%	100%	9.4	6.8	9.9	7.4
100%	100%	100%	8.7	6.1	9.3	6.8

Projected service life estimates are based on accelerated battery discharge data and device modeling as specified. Do not interpret these values as precise numbers.

IMPORTANT REMINDER
See the MRI SureScan™ technical manual before performing an MRI scan and the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative or consult the Medtronic website at medtronic.com.

INDICATIONS, SAFETY, AND WARNINGS
See the device manual at manuals.medtronic.com for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events.

www.medtronic.com/manuals

Consult instructions for use at this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.

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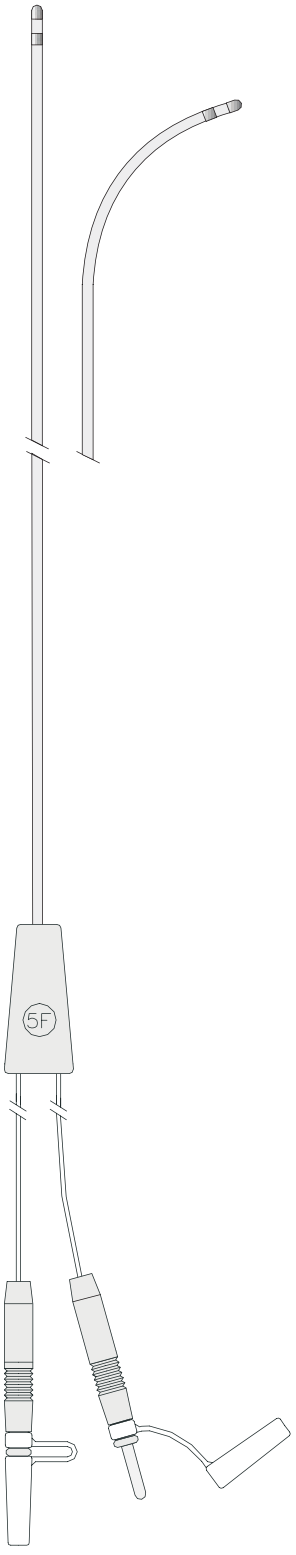
TB-FX / TB-FX J

Temporäre Elektrode (mit Schutzkappen)
Temporary Lead (with protection caps)



Artikelbeschreibung

Diese Elektrode mit 2mm Pin Konnektoren dient der temporären Stimulation mit Hilfe eines externen Herzschrittmachers.
Das berührungsgeschützte Steckersystem paßt an gängige externe Herzschrittmacher.

Typ: ***TB-FX / TB-FX J***
Durchmesser F (mm): *4 (1,33) 5(1,67) 6(2,00)*
Nutzbare Katheterlänge: 90/*125 cm*
Elektrodenkopf: *Halbkugel*
Anzahl der Elektroden: *2- polig*
Elektrodenabstand: *5 mm*
Elektrodenmaterial: *Edelstahl*
Kathetermaterial: *Pebax (shore70/40) röntgendicht*
Flexibilität: *normal, standard*
Anschlußstecker: *2 mm Pins und Berührungsschutzkappen passend für alle gängigen externen Herzschrittmacher*

Lieferumfang: 1 Elektrode mit festem Anschlußstecker

Product Description

Temporary pacing lead with 2mm pin connectors for temporary stimulation by means of an external pacemaker. The protected connector system is suitable for all common external pacemakers.

Type: ***TB-FX / TB-FX J***
Diameter F (mm): *4 (1.33) 5(1.67) 6(2.00)*
Usable lead length: 90/*125 cm*
Tip configuration: *bullet shaped*
Number of electrodes: *bipolar*
Electrode width: *5 mm*
Electrode material: *stainless steel*
Lead material: *pebax (shore 70/40) radiopaque*
Flexibilität: *normal, standard*
Connector: *2 mm pins and touch protection caps suitable for all common external pacemakers*

Delivery volume: 1 Lead with fixed connector

Artikelbezeichnung / Product name				**Artikel-Nr. / Article-no.**	**Stück / Unit**
TB-FX 2/4F	gerade,	straight	(90 cm, 4F)	27003-F	5
TB-FX 2/5F	gerade,	straight	(125 cm, 5F)	27004-F	5
TB-FX 2/6F	gerade,	straight	(125 cm, 6F)	27005-F	5
TB-FX 2/4F-J	J-Kurve,	J-Curve	(90 cm, 4F)	27006-F	5
TB-FX 2/5F-J	J-Kurve,	J-Curve	(125 cm, 5F)	27007-F	5
TB-FX 2/6F-J	J-Kurve,	J-Curve	(125 cm, 6F)	27008-F	5

Elektrodenoberfläche / Electrode surface	**4 French**	**5 French**	**6 French**		
Ring, ring	8,5 mm²	10,5 mm²	12,5 mm²		
Spitze, tip	9,2 mm²	12,3 mm²	15,5 mm²		

Zubehör / Accessory

Verlängerungskabel / extension cable	D 2-SP	81973	5
Verlängerungskabel weiß/ extension cable white	D 2P-SP	81986WS	5
Verlängerungskabel blau/ extension cable blue	D 2P-SP	81986BL	5

Die Lieferung erfolgt gas-sterilisiert.
Für Einmalgebrauch bestimmt!
Goods supplied gas-sterilized.
For single use only!

Änderungen, die dem technischen Fortschritt dienen, bleiben vorbehalten.
We reserve the right to make changes to reflect technical advancements.

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Hersteller/
Manufacturer: FIAB S.p.A., Italy

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