



ÚVN

ÚSTŘEDNÍ VOJENSKÁ NEMOCNICE
Vojenská fakultní nemocnice Praha

12. Nedílnou součástí smlouvy jsou tyto přílohy:

Příloha č. 1: Specifikace zboží

Příloha č. 2: Ceník zboží

Příloha č. 3: Ověřená kopie pojistné smlouvy nebo pojistného certifikátu (bude přiloženo pouze ke smlouvě s vybraným účastníkem)

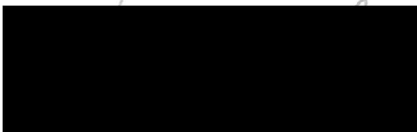
29 -03- 2018

V Praze dne.....2018

V Praze dne 6.3.2018

za kupujícího

za prodávajícího



prof. MUDr. Miroslav Zavoral, Ph.D.

ředitel

Ústřední vojenské nemocnice –

Vojenská fakultní nemocnice Praha



Dr. Petr Větrovský, Ph.D.

jednatel

Biotronik Praha spol. s r.o.



BIOTRONIK

BIOTRONIK Praha spol. s r.o.

POLYGON HOUSE

Doudlebská 1699/5

140 00 Praha 4

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Příloha č. 1

Specifikace zboží



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 **BIOTRONIK**
BIOTRONIK Praha spol. s r.o.
POLYGON HOUSE
Doudlebská 1699/5
140 00 Praha 4

Inlexa 3 VR-T

Jednodutinové ICD



Informace o produktu

■ BIOTRONIK Home Monitoring®

Efektivní vzdálené sledování srdečního selhání. Systém je založen na automatických bezdrátových denních přenosech. Umožňuje dřívější zásah a vzdálené kontroly jsou schváleny U.S. FDA a CE notifikovaným orgánem.

■ MorphMatch

Zlepšuje diskriminaci SVT, aby se zabránilo neadekvátním terapiím. Nabízí možnost nastavení citlivosti diskriminačních kritérií.

■ Automatické monitorace prahů

Umožňuje vzdálené vyhodnocování stimulační hodnoty komorových prahů.

■ DF-4 konektor

Zjednodušuje a zkracuje implantační proceduru a snižuje materiál v kapse pro přístroj.

Informace k objednání

Model	Konektory	Objem/váha	Rozměry	Objednací číslo
Inlexa 3 VR-T	DF-1 (2x), IS-1 (1x)	33 cm ³ /82 g	65 mm × 55 mm × 11 mm	404703
Inlexa 3 VR-T	DF4 (LLHH) (1x)	31 cm ³ /81 g	65 mm × 54 mm × 11 mm	404704

Inlexa 3 VR-T

Technical Data

Therapy and monitoring zones	
Bradycardia	30 ... 15 ... 100 ... 110 ... 160 bpm
VT1	OFF, 270 ... 110 ... 600 ms
VT2	OFF, 270 ... 110 ... 500 ms
VF	OFF, 240 ... 110 ... 400 ms
Ventricular arrhythmia detection and redetection	
VT detection criteria	Interval: Onset: Stability: MorphMatch: Sustained V [†]
Detection counter VT1 and VT2	For VT1: 10 ... 2 ... 100; For VT2: 10 ... 2 ... 80
Redetection counter VT1 and VT2	For VT1: 10 ... 2 ... 50; For VT2: 10 ... 2 ... 40
Detection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30; 30 out of 40
Redetection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30
Onset	OFF, 4 ... 14 ... 32 %
Stability	OFF, ± 8 ... 14 ... ± 48 ms and ± 8 ... 14 ... ± 48 %
MorphMatch	OFF; Monitoring: ON
MorphMatch threshold	Std., Low: High
Sustained VT	OFF, 1 ... 11 ... 3, 5, 10 ... 10; ... 20 min
Tachycardia therapy (VT1/VT2 zone)	
Attempts	OFF, 1 ... 11 ... 10
ATP type	Burst: Ramp
Number S1	1 ... 11 ... 15
R-S1 interval	70 ... 151 ... 85; 88; 90; 95 %
ATP optimization	OFF, ON
Minimum ATP interval	200 ms (fixed)
Tachycardia therapy (VF zone)	
ATP type (ATP One Shot)	OFF; Burst: Ramp
Stability criterion	12 % (fixed)
Number S1	1 ... 11 ... 15
R-S1 interval	70 ... 151 ... 85; 88; 90; 95 %
Cardioversion/defibrillation therapy	
Number of shocks	For VT zones: OFF, 1; 2; 6 or 8 For the VF zone: 6 or 8
Confirmation (in VT1, VT2, VF)	OFF; ON
Polarity (in VT1, VT2, VF)	Normal; Reversed; Normal $\rightarrow$ alternating
Waveform (in V1, V2, VF)	Biphasic; Bichasic 2
Shock path (in VT1, VT2, VF)	RV $\rightarrow$ SVC+Can; RV $\rightarrow$ Can; RV $\rightarrow$ SVC
Energy of 1st shock	OFF; 2 ... 12 ... 20 ... 151 ... 40 J
Energy of 2nd shock	OFF, 4 ... 12 ... 20 ... 151 ... 40 J
Post-shock mode	VVI if permanent; VVI(S); OFF
Post-shock pulse amplitude	7.5 V (RV)
Post-shock duration	OFF, 10 s; 30 s; 1 min; 2 min; 5 min; 10 min
Pacing parameters	
Mode	VVIR; VVI; OFF; VGO
Pulse amplitude (RV)	0.5 ... 10.25 ... 4.0 ... 10.51 ... 6.0; 7.5 V
Pulse width (RV)	0.4; 0.5 ... 10.25 ... 1.5 ms
Capture contr. (RV)	OFF; ATM
Basic rate	30 ... 151 ... 100 ... 110 ... 160 bpm
■ Rate hysteresis	OFF; -5 ... -151 ... -25 ... -20 ... -65 bpm
■ Scan/Repetitive	OFF; ON
■ Night rate	OFF; 30 ... 151 ... 100 bpm
Sensing (RV)	Std. - Standard; TWE - Enhanced T-wave suppression; V-S - Enhanced VF sensitivity; Individually programmable sensing parameters
Sensor	Accelerometer
Diagnostic functions	
Recording episodes for SVI	OFF; ON
Recording episodes for mVI	OFF; ON
Periodic recording	OFF; 30 ... 301 ... 120; 180 days (if Home Monitoring: OFF)
ICGM Holter	2 x 14 min (far-field, RV)
Length of prehistory	Fixed: 30 s; 5 s (when onset was fulfilled or at induced episodes)
Physical parameters	
Telemetry	RF (Saarland), programming head
Material	Titanium
Battery	3.2 V; 1520 mAh
Longevity	10.1 years ^{††}

^{††} RV: 2.5 V/0.4 ms; 60 bpm; 500 Ω ; RV pacing: 15 %; 4 max. energy shocks/year
Home Monitoring: ON (daily transmission); diagnostics: ON

Tests	
Different tests for	Impedance, Sensing, Pacing threshold, DFT (LPR/ATP) Rapid ventricular pacing
Program sets	
Programs	Standard program; ProgramConsult; Individual program (1-3, individually programmable); first interrogation program; Safe program

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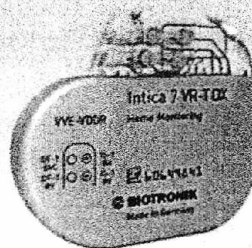
Transmitted data	Detection and therapy counters; Statistics; Lead measurement values; Battery and system status; ICD program parameters
Message types	
Trend message	Triggered automatically once every 24 hours
Event message	Triggered automatically after certain cardiac events
Test message	Triggered manually via programmer
Programmer settings	
Home Monitoring	OFF, ON
IEGM for therapy episodes	OFF, ON
IEGM for monitoring episodes	OFF, ON
Home Monitoring-supported follow-up	
Remote Scheduling	Enable; Disable
RM follow-up intervals/alignment	Individually programmable first date and repetition intervals varying from 28-366 days; Alignment with a specific day of the week; Only working days or no day alignment
Intermediate RM follow-up	Can be requested at any time via the Home Monitoring Service Center
Transmitted data	Periodic; ICDM; Rate histogram (V); Device settings and statistics

Please refer to the technical manual of the device for further technical information.

Intica 7 VR-T DX

MR kompatibilní jednodutinové ICD
s kompletní diagnostikou síní

ProMRI®



Informace o produktu

■ Complete atrial diagnostics

Umožňuje kompletní nahrávání všech sínových událostí díky DX elektrodě.

■ Closed Loop Stimulation (CLS)

Unikátní fyziologická modulace srdeční frekvence během fyzického a emocionálního napětí.

■ BIOTRONIK Home Monitoring®

Efektivní vzdálené sledování srdečního selhání. Systém je založen na automatických bezdrátových denních přenosech. Umožňuje dřívější zásah a vzdálené kontroly jsou schváleny U.S. FDA a CE notifikovaným orgánem.

■ ProMRI®1)

Umožňuje pacientům podstoupit vyšetření v magnetické rezonanci za specifických podmínek.

■ MRI AutoDetect

Zlepšuje diskriminaci SVT, aby se zabránilo neadekvátním terapiím. Nabízí možnost nastavení citlivosti diskriminačních kritérií.

■ MorphMatch

Improves SVT discrimination to prevent unnecessary therapies and provides insight into discrimination decision.

■ Capture Control

Zvyšuje bezpečnost pacientů a prodlužuje životnost přístroje automatickou úpravou stimulační amplitudy.

1) Pro jednotlivé kombinace MR zařízení si prosím přečtěte manuál "ProMRI® MR kompatibilní zařízení"

Informace k objednání

Model	Konektory	Objem/váha	Rozměry	Objednací číslo
Intica 7 VR-T DX	DF-1 (2x), IS-1 (2x)	33 cm ³ /82 g	65 mm × 55 mm × 11 mm	404633



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excellence for life

Intica 7 VR-T DX

Technical Data

Therapy and monitoring zones	
Bradycardia	30 ... 15 ... 100 ... 110 ... 160 bpm
AT/AF	100 ... 110 ... 250 bpm
VT1	OFF, 270 ... 110 ... 600 ms
VT2	OFF, 270 ... 110 ... 600 ms
VF	OFF, 240 ... 110 ... 400 ms
Ventricular arrhythmia detection and redetection	
VT detection criteria	Interval: SMART detection, Onset, Stability, MorphMatch (if SMART: OFF); Sustained VT
Detection counter VT1 and VT2	For VT1: 10 ... 12 ... 100; For VT2: 10 ... 12 ... 80
Redetection counter VT1 and VT2	For VT1: 10 ... 12 ... 50; For VT2: 10 ... 12 ... 40
Detection counter VF	4 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30; 30 out of 40
Redetection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30
Onset	If SMART = OFF: OFF; 4 ... 14 ... 32 % If SMART = ON: 4 ... 14 ... 32 %
Stability	If SMART = OFF: OFF; 4 ... 14 ... 48 ms and ± 8 ... 14 ... ± 48 % If SMART = ON: 4 ... 14 ... 48 %
MorphMatch	OFF, Monitoring: ON
MorphMatch threshold	Std., Low, High
Sustained VT	OFF; 1 ... 11 ... 5, 10 ... 10 ... 20 min
SMART detection	OFF; ON
Tachycardia therapy (VT1/VT2 zone)	
Attempts	OFF, 1 ... 11 ... 10
ATP type	Burst, Ramp
Number S ¹	1 ... 11 ... 15
R-S1 interval	70 ... 10 ... 85, 88, 90, 95 %
ATP optimization	OFF; ON
Minimum ATP interval	200 ms [fixed]
Tachycardia therapy (VF zone)	
ATP type (ATP One Sheet)	OFF, Burst, Ramp
Early ATP delivery	OFF; ON
Stability criterion	12 % [fixed]
Number S ¹	1 ... 11 ... 15
R-S1 interval	70 ... 10 ... 85, 88, 90, 95 %
Cardioversion/defibrillation therapy	
Number of shocks	For VT zones: OFF, 1, 2, 4 or 8 For the VF zone: 6 or 8
Confirmation (in VT1, VT2, VF)	OFF; ON
Polarity (in VT1, VT2, VF)	Normal, Reversed, Normal → alternating, Reversed → alternating
Waveform (in VT1, VT2, VF)	Biphasic, Biphase 2, Biphase c → alternating, Biphase 2 → alternating
Shock path (in VT1, VT2, VF)	RV → SVC+Can, RV → Can, RV → SVC
Energy of 1st shock	OFF, 2 ... 12 ... 20 ... 15 ... 40 J
Energy of 2nd shock	OFF, 4 ... 12 ... 20 ... 15 ... 40 J
Post-shock mode	VVI if permanent: VVI(R), VVI-CLS, OFF VDD if permanent: VDD(R), VDD(R)
Post-shock pulse amplitude	7.5 V RV
Post-shock duration	OFF, 10 s, 30 s, 1 min, 2 min, 5 min, 10 min
Closed Loop Stimulation	
CLS mode	VVI-CLS
Max. CLS rate	80 ... 110 ... 160 bpm
Extended CLS settings	
■ CLS response	Very low, Low, Medium, High, Very high
■ CLS resting rate control	OFF, +10 ... 110 ... +50 bpm
■ Vp required	Yes, No
Pacing parameters	
Mode	VVI-CLS, VVR, VVI, VDDR, VDIR, VDD, VDI, OFF, VDD
Pulse amplitude (RV)	0.5 ... 10.25 ... 4.0 ... 10.5 ... 5.0, 7.5 V
Pulse width (RV)	0.4, 0.5 ... 10.25 ... 1.5 ms
Capture control (RV)	OFF; ATM: ON
Basic rate	30 ... 15 ... 100 ... 110 ... 160 bpm
■ Rate hysteresis	OFF, -5 ... (-5) ... -25 ... (-20) ... +35 bpm
■ Scan/Repetitive	OFF; ON
■ Night rate	OFF, 30 ... 15 ... 100 bpm
AV dynamics	Low, Medium, High, Fixed, Individual
AV delay after sensing	13, 40 ... 15 ... 350 ms
AV hysteresis mode	OFF, Positive, Negative, RSplus
■ AV hysteresis mode (RSplus)	400 ms [fixed]
■ AV hysteresis mode (Positive)	OFF; ON
Rate fading	OFF; ON
Upper rate (UTR)	90 ... 110 ... 160 bpm
Mode switching (Mode)	VDD, VDIR if permanent: VDDR
■ Intervention rate	OFF, 120 ... 110 ... 200 bpm
■ Change of basic rate during MS	OFF, +5 ... 15 ... +50 bpm
■ Post mode switching rate	OFF, +5 ... 15 ... +50 bpm
■ Post mode switching duration	1 ... 11 ... 30 min
■ Onset criterion/Resolution criterion	3 ... 11 ... 8 out of 8
■ Rate stabilization during mode switching	OFF; ON
PVARP	AUTO, 175 ... 120 ... 600 ms
PVAT detection/termination	OFF; ON

Pacing parameters	
Sensing (SV)	Std., Standard, TWS, Enhanced T-wave suppression, VFS, Enhanced VF sensitivity, Individually programmable sensing parameters
Sensing (A)	Std., OFF
Sensor	Accelerometer
MRI program	OFF, ON, AUTO
Expiration date (for AUTO)	Adjustable to today's date + 14 days
Diagnostic functions	
Recording episodes For AT/AF	OFF, ON, Advanced ON
Recording episodes For SV	OFF; ON
Recording episodes For nsVT	OFF; ON
Periodic recording	OFF, 30 ... 130 ... 120, 180 days (if Home Monitoring: OFF)
IEGM Holter	3 x 56 min (Far-field, A and RV)
Length of prehistory	Fixed, 30 s, 5 s (when onset was fulfilled or at induced episodes), 1 min for AT/AF episode if Advanced ON was programmed
Thoracic impedance (TI)	OFF; ON
Physical parameters	
Telemetry	NF (SafeSync), programming head
Material	Titanium
Battery	3.2 V, 1520 mAh
Longevity	9.7 years
1) RV: 7.5 V/14 ms, 60 bpm, 500 J; RV pacing: 15 % max. energy shock/year, Home Monitoring, ON (fully transvenous), diagnostics, ON	
Tests	
Different tests for	Impedance, Sensing, Pacing threshold, DFT (EPE/ATP), Retrograde conduction, Rapid ventricular pacing
Program sets	
Programs	Standard program, ProgramConsult, Individual program (1-3, individually programmable), First interrogated program, Safe program

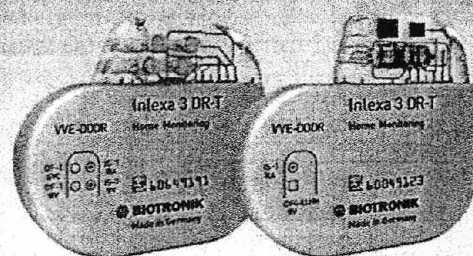
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Transmitted data	All diagnostics, Heart Failure Monitor diagnostics, Detection and therapy counters, Statistics, Lead measurement values, Battery and system status, ICD program parameters
Message types	
Trend message	Triggered automatically once every 24 hours
Event message	Triggered automatically after certain cardiac events
Test message	Triggered manually via programmer
Programmer settings	
Home Monitoring	OFF; ON
IEGM for therapy episodes	OFF; ON
IEGM for monitoring episodes	OFF; ON
Ongoing atrial episode	OFF, 6 h, 12 h, 18 h
Home Monitoring-supported follow-up	
Remote Scheduling	Enable, Disable
HM follow-up intervals/alignment	Individually programmable first date and repetition intervals varying from 20-366 days; Alignment with a specific day of the week, Only working days or no day alignment
Intermediate HM follow-up	Can be requested at any time via the Home Monitoring Service Center
Transmitted data	Periodic IEGM, Rate histogram (A, V), Device settings and statistics

Please refer to the technical manual of the device for further technical information.

Inlexa 3 DR-T

Dvoudutinové ICD



Informace o produktu

■ BIOTRONIK Home Monitoring®

Efektivní vzdálené sledování srdečního selhání. Systém je založen na automatických bezdrátových denních přenosech. Umožňuje dřívejší zásah a vzdálené kontroly jsou schváleny U.S. FDA a CE notifikovaným orgánem.

■ Automatická monitorace prahů

Umožňuje vzdálené vyhodnocování stimulační hodnoty komorových prahů.

■ DF-4 konektor

Zjednodušuje a zkracuje implantační proceduru a snižuje materiál v kapse pro přístroj.

Informace k objednání

Model	Konektory	Objem/váha	Rozměry	Objednací číslo
Inlexa 3 DR-T	DF-1 (2x), IS-1 (2x)	33 cm ³ /82 g	65 mm × 55 mm × 11 mm	404701
Inlexa 3 DR-T	DF4 (LLHH) (1x), IS-1 (1x)	32 cm ³ /82 g	65 mm × 56 mm × 11 mm	404702

Inlexa 3 DR-T

Technical Data

Therapy and monitoring zones	
Bradycardia	30 ... [5] ... 100 ... [10] ... 160 bpm
AT/AF	100 ... [10] ... 250 bpm
VT1	OFF, 270 ... [10] ... 600 ms
VT2	OFF, 270 ... [10] ... 600 ms
VF	OFF, 240 ... [10] ... 400 ms
Ventricular arrhythmia detection and redetection	
VT detection criteria	Interval: SMART detection: Onset, Stability, MorphMatch (SMART: OFF); Sustained VT
Detection counter VT1 and VT2	For VT1: 10 ... [2] ... 100; For VT2: 10 ... [2] ... 80
Redetection counter VT1 and VT2	For VT1: 10 ... [2] ... 80; For VT2: 10 ... [2] ... 40
Detection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30; 30 out of 40
Redetection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30
Onset	If SMART = OFF: OFF; 4 ... [4] ... 32 % If SMART = ON: 4 ... [4] ... 32 %
Stability	If SMART = OFF: OFF; 8 ... [8] ... 48 ms and $\pm 8 ... [4] ... 48 %$ If SMART = ON: 8 ... [8] ... 48 %
MorphMatch	OFF; Monitoring: ON
MorphMatch threshold	Std., Low, High
Sustained VT	OFF, 1 ... [1] ... 3, 5, 10 ... [10] ... 30 min
SMART detection	OFF; ON
Tachycardia therapy (VT1/VT2 zone)	
Attempt	OFF, 1 ... [1] ... 10
ATP type	Burst; Ramp
Number S1	1 ... [1] ... 15
R-S1 interval	70 ... [5] ... 85; 85; 90; 95 %
ATP optimization	OFF; ON
Minimum ATP interval	200 ms (fixed)
Tachycardia therapy (VF zone)	
ATP type (ATP One Shot)	OFF; Burst; Ramp
Stability criterion	12 % (fixed)
Number S1	1 ... [1] ... 15
R-S1 interval	70 ... [5] ... 85; 85; 90; 95 %
Cardioversion/defibrillation therapy	
Number of shocks	For VT zones: OFF, 1; 2, 6 or 8 For the VF zone: 6 or 8
Confirmation (in VT1, VT2, VF)	OFF; ON
Polarity (in VT1, VT2, VF)	Normal, Reversed, Normal $\rightarrow$ alternating
Waveform (in VT1, VT2, VF)	Biphasic, Bichasic 2
Shock path (in VT1, VT2, VF)	RV $\rightarrow$ SVC+Can; RV $\rightarrow$ Can; RV $\rightarrow$ SVC
Energy of 1st shock	OFF, 2 ... [2] ... 20 ... [5] ... 40 J
Energy of 2nd shock	OFF, 4 ... [2] ... 20 ... [5] ... 40 J
Post-shock mode	VI, DOI, VOI
Post-shock pulse amplitude	7.5 V (RV, RA)
Post-shock duration	OFF, 10 s; 30 s; 1 min; 2 min; 5 min; 10 min
Pacing parameters	
Mode	DDDR, DDD, DDIR, DOI, VVR, VVI, VDDR, VOIR, VDD, VOI, AAR, AA, OFF, VOO, DOO
Pulse amplitude (A, RV)	0.5 ... [0.25] ... 4.0 ... [0.5] ... 6.0; 7.5 V
Pulse width (A, RV)	0.4; 0.5 ... [0.25] ... 1.5 ms
Capture control (A, RV)	OFF, ATM
Basic rate	30 ... [5] ... 100 ... [10] ... 160 bpm
■ Rate hysteresis	OFF; -5 ... [5] ... +20 ... [20] ... +60 bpm
■ Sense/repetitive	OFF; ON
■ Night rate	OFF, 30 ... [5] ... 100 bpm
AV dynamics	Low, Medium, High, Fixed, Individual
AV delay after pacing and sensing	15, 40 ... [5] ... 350 ms
Sense compensation	OFF, -5 ... [5] ... +120 ms
AV hysteresis mode	OFF, Positive, Negative, TNSplus
■ AV hysteresis mode (TNSplus)	400 ms (fixed)
■ AV hysteresis mode (Positive)	OFF; ON
Upper rate (UIR)	90 ... [10] ... 160 bpm
Atrial upper rate	OFF, 175, 200, 240 bpm
Mode switching (Model)	VDD, VOIR, DOI, DDIR
■ Intervention rate	OFF, 120 ... [10] ... 200 bpm
■ Change of basic rate during MS	OFF, -5 ... [5] ... +30 bpm
■ Post mode switching rate	OFF, -5 ... [5] ... +50 bpm
■ Post mode switching duration	1 ... [1] ... 30 min
■ Onset criterion/Resolution criterion	3 ... [1] ... 8 out of 8
PVARP	AUTO, 175 ... [25] ... 600 ms
PMT detection/termination	OFF; ON
Sensing (SVI)	Std., Standard, TWS - Enhanced T-wave suppression; VFS - Enhanced VF sensitivity; Individually programmable sensing parameters
Sensing (A)	Std., OFF
Sensor	Accelerometer

Diagnostic functions	
Recording episodes For AT/AF	OFF; ON
Recording episodes For SVT	OFF; ON
Recording episodes For nsVT	OFF; ON
Periodic recording	OFF, 30 ... [30] ... 120; 180 days (If Home Monitoring: OFF)
IEGM Holder	3 x 55 min (Far-field, A and RV)
Length of prehistory	Fixed, 30 s; 6 s (when onset was fulfilled or at induced episodes), 1 min for AT/AF episode if Advanced ON was programmed

Physical parameters	
Telemetry	RF (SafeSync) programming head
Material	Titanium
Battery	3.2 V, 1520 mAh
Longevity	8.5 years*

II RA, RV, 2.5 V/0.4 ms, 80 bpm, 500 Hz, RV pacing: 15 %, RA pacing: 50 %, 4 max. energy shocks/year, Home Monitoring: ON (daily transmission) diagnostics: ON

Tests	
Different tests for	Impedance, Sensing, Pacing threshold, DFT (EPE/ATP), Retrograde conduction, Rapid ventricular pacing

Program sets	
Programs	Standard program: ProgramConsult, Individual program (1-3, individually programmable); First interrogated program, Safe program

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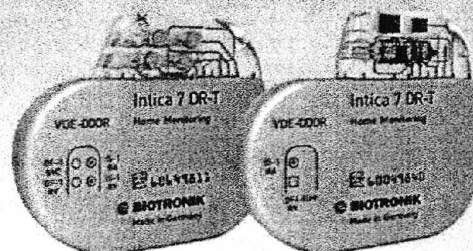
Transmitted data	AF diagnostics, Heart Failure Monitor diagnostics, Detection and therapy counters, Statistics, Lead measurement values, Battery and system status, ICD program parameters
Message types	
Trend message	Triggered automatically once every 24 hours
Event message	Triggered automatically after certain cardiac events
Test message	Triggered manually via programmer
Programmer settings	
Home Monitoring	OFF, ON
ILGM for therapy episodes	OFF, ON
ILGM for monitoring episodes	OFF, ON
Ongoing atrial episode	OFF, 6 h, 12 h, 18 h
Home Monitoring-supported follow-up	
Remote Scheduling	Enable, Disable
HM follow-up intervals/alignment	Individually programmable first date and repetition intervals varying from 20-366 days, Alignment with a specific day of the week. Only working days or no day alignment
Intermediate HM follow-up	Can be requested at any time via the Home Monitoring Service Center
Transmitted data	Periodic IEGM, Rate histogram (A, V), Device settings and statistics

Please refer to the technical manual of the device for further technical information.

Intica 7 DR-T

MR kompatibilní dvoudutinové ICD

ProMRI®



Informace o produktu

■ Closed Loop Stimulation (CLS)

Unikátní fyziologická modulace srdeční frekvence během fyzického a emocionálního napětí.

■ BIOTRONIK Home Monitoring®

Efektivní vzdálené sledování srdečního selhání. Systém je založen na automatických bezdrátových denních přenosech. Umožňuje dřívější zásah a vzdálené kontroly jsou schváleny U.S. FDA a CE notifikovaným orgánem.

■ ProMRI®¹⁾

Umožňuje pacientům podstoupit vyšetření v magnetické rezonanci za specifických podmínek.

■ MRI AutoDetect

Pomocí automatické detekce MRI prostředí se zjednodušují pracovní postupy a zkracuje se čas, po který je ICD v režimu MRI.

■ Capture Control

Zvyšuje bezpečnost pacientů a prodlužuje životnost přístroje automatickou úpravou stimulační amplitudy.

■ Automatické síňové terapie

Automatické dodání síňových terapií při řešení AT/AF epizod.

¹⁾ Pro jednotlivé kombinace MR zařízení si prosím přečtěte manuál "ProMRI® MR kompatibilní zařízení"

Informace k objednávce

Model	Konektory	Objem/váha	Rozměry	Objednací číslo
Intica 7 DR-T	DF-1 (2x), IS-1 (2x)	33 cm ³ /82 g	65 mm × 55 mm × 11 mm	404631
Intica 7 DR-T	DF4 (LLHH) (1x), IS-1 (1x)	32 cm ³ /82 g	65 mm × 56 mm × 11 mm	404632

Intica 7 DR-T

Technical Data

Therapy and monitoring zones

Bradycardia	30 ... [5] ... 100 ... [10] ... 160 bpm
AT/AF	100 ... [10] ... 250 bpm
V11	OFF, 270 ... [10] ... 600 ms
V12	OFF, 270 ... [10] ... 500 ms
VF	OFF, 240 ... [10] ... 400 ms
Arrhythmia detection and redetection	
AT/AF detection criteria	Interval; Stability
VF detection criteria	Interval; Onset; Stability; MorphMatch (if SMART+ OFF); Sustained VT
Detection counter V11 and V12	For V11: 10 ... [2] ... 100; For V12: 10 ... [2] ... 80
Redetection counter V11 and V12	For V11: 10 ... [2] ... 50; For V12: 10 ... [2] ... 40
Detection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30; 30 out of 40
Redetection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30
Onset	If SMART+ OFF: OFF; $\leq 4 \dots [4] \dots 32 \%$ If SMART+ ON: $4 \dots [4] \dots 32 \%$
Stability	If SMART+ OFF: OFF; $\geq 8 \dots [4] \dots 48 \text{ ms and } \geq 8 \dots [4] \dots 48 \%$ If SMART+ ON: $8 \dots [4] \dots 48 \%$
MorphMatch	OFF; Monitoring; ON
MorphMatch threshold	Std.; Low; High
Sustained VT	OFF; 1 ... [1] ... 3; 5; 10 ... [10] ... 30 min
SMART detection	OFF; ON
Tachycardia therapy (AT/AF zone)	
AT therapy	OFF; Burst; Ramp
■ Backup mode	OFF; VM
AF therapy	OFF; HF burst
■ Rate	10 ... [5] ... 40 Hz
■ Duration	2 ... [1] ... 10 s
■ Backup mode	OFF; V20
Backup stimulation	OFF; 70; 90 bpm
Atrial therapy (NIPS)	Programmed stimulation; Burst pacing
Tachycardia therapy (V11/V12 zone)	
Attempts	OFF; 1 ... [1] ... 10
ATP type	Burst; Ramp
Number S ¹	1 ... [1] ... 15
R-S1 interval	70 ... [5] ... 85; 85; 90; 95 %
ATP optimization	OFF; ON
Minimum ATP interval	200 ms (fixed)
Tachycardia therapy (VF zone)	
ATP type (ATP One Shot)	OFF; Burst; Ramp
Early ATP delivery	OFF; ON
Stability criterion	(2 % fixed)
Number S ¹	1 ... [1] ... 15
R-S1 interval	70 ... [5] ... 85; 85; 90; 95 %
Cardioversion/defibrillation therapy	
Number of shocks	For VT zones: OFF; 1; 2; 6 or 8 For the VF zone: 6 or 8
Confirmation (in V11, V12, VF)	OFF; ON
Polarity (in V11, V12, VF)	Normal; Reversed; Normal → alternating; Reversed → alternating
Waveform (in V11, V12, VF)	Biphasic; Biphasic 2; Biphasic 3 → alternating; Biphasic 2 → alternating
Shock path (in V11, V12, VF)	RV → SVC; Can; RV → Can; RV → SVC
Energy of 1st shock	OFF; 2 ... [2] ... 20 ... [5] ... 40 J
Energy of 2nd shock	OFF; 4 ... [2] ... 20 ... [5] ... 40 J
Post-shock mode	V11, DDI, VDI
Post-shock pulse amplitude	7.5 V (RV, RA)
Post-shock duration	OFF; 10 s; 30 s; 1 min; 2 min; 5 min; 10 min
Closed Loop Stimulation	
CLS mode	DDD-CLS; VVI-CLS
Max. CLS rate	80 ... [10] ... 160 bpm
Extended CLS settings	
■ CLS response	Very low; Low; Medium; High; Very high
■ CLS resting rate control	OFF; +10 ... [10] ... +50 bpm
■ Vp required	Yes; No
Pacing parameters	
Mode	DDDR-ADIR, DDD-ADI, DDD-ADIR, DDD-ADIR, DDI, VVI-CLS, VWS, VVI, VDDR, VDIR, VDD, VDI, AAIR, AA1, OFF, VDD, DDD
Pulse amplitude (A, RV)	0.5 ... [0.25] ... 4.0 ... [0.5] ... 6.0; 7.5 V
Pulse width (A, RV)	0.4; 0.5 ... [0.25] ... 1.5 ms
Capture control (A, RV)	OFF; ATM; ON
Basic rate	30 ... [5] ... 100 ... [10] ... 160 bpm
■ Rate hysteresis	OFF; -5 ... [-5] ... -25 ... [-20] ... -65 bpm
■ Scan/Repetitive	OFF; ON
■ Night rate	OFF; 30 ... [5] ... 100 bpm
AV dynamics	Low; Medium; High; Fixed; Individual
AV delay after pacing and sensing	15; 40 ... [5] ... 350 ms
Sense compensation	OFF; -5 ... [-5] ... -120 ms
AV hysteresis mode	OFF; Positive; Negative; IR Split
■ AV hysteresis mode (IR Split)	400 ms (fixed)
■ AV hysteresis mode (Positive)	OFF; ON

Pacing parameters

Vp suppression	OFF or ON (only in the modes DDDR-ADIR and DDD-ADI)
■ Pacing suppression	1 ... [1] ... 8 consecutive Vs
■ Pacing support	1 ... [1] ... 4 out of 8 cycles
Rate fading	OFF; ON
Upper rate (UTR)	90 ... [10] ... 160 bpm
Atrial upper rate	OFF; 175; 200; 240 bpm
Mode switching (Mode)	VDD, VDIR, DDI, DDIR
■ Intervention rate	OFF; 120 ... [10] ... 200 bpm
■ Change of basic rate during MS	OFF; +5 ... [5] ... +30 bpm
■ Post mode switching rate	OFF; +5 ... [5] ... +50 bpm
■ Post mode switching duration	1 ... [1] ... 30 min
■ Onset criterion/Resolution criterion	3 ... [1] ... 8 out of 8
■ Rate stabilization during mode switching	OFF; ON
RVARP	AUTO; 175 ... [25] ... 600 ms
PMT detection/termination	OFF; ON
Sensing (RV)	Std.; Standard; TW5 - Enhanced T-wave suppression; VFS - Enhanced VF sensitivity; Individually program-mable sensing parameters
Sensing (IA)	Std.; Off
Sensor	Accelerometer
MRI program	OFF; ON; AUTO
Expiration date (for AUTO)	Adjustable to today's date + 14 days
Diagnostic functions	
Recording episodes For AT/AF	OFF; ON; Advanced ON
Recording episodes For SV ¹	OFF; ON
Recording episodes For VF	OFF; ON
Periodic recording	OFF; 30 ... [30] ... 120; 160 days (if Home Monitoring: OFF)
IEGM Holter	3 x 60 min (Far-field, A and RV)
Length of prehistory	Fixed; 30 s; 5 s (when onset was fulfilled or at induced episodes); 1 min for AT/AF episode if Advanced ON was programmed
Thoracic impedance (TI)	OFF; ON

Physical parameters

Telemetry	RF (SafeSync) programming head
Material	Titanium
Battery	3.2 V; 1620 mAh
Longevity	8.5 years

1) RA, RV; 2.5 V/0.4 ms; 80 bpm; 500 D; RV pacing; 15 %; RA pacing; 50 %; 4 max. energy shocks/year; Home Monitoring; ON (daily transmission; diagnostics; ON)

Tests

Different tests for	Impedance; Sensing; Pacing threshold; DFT (EPE/ATP); Retrograde conduction; Atrial NIPS; Rapid ventricular pacing
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Program sets

Programs	Standard program; ProgramConsult; Individual program (1-3, individually programmable); First interrogated program; Safe program
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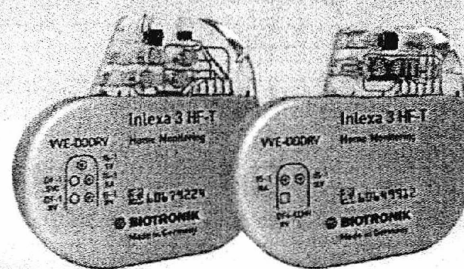
BIOTRONIK Home Monitoring®

Transmitted data	AF diagnostics; Heart Failure Monitor diagnostics; Detection and therapy counters; Statistics; Lead measurement values; Battery and system status; ICD program parameters
Message types	
Trend message	Triggered automatically once every 24 hours
Event message	Triggered automatically after certain cardiac events
Test message	Triggered manually via programmer
Programmer settings	
Home Monitoring	OFF; ON
IEGM for therapy episodes	OFF; ON
IEGM for monitoring episodes	OFF; ON
Ongoing atrial episode	OFF; 6 h; 12 h; 18 h
Home Monitoring-supported follow-up	
Remote Scheduling	Enable; Disable
HM follow-up intervals/alignment	Individually programmable first date and repetition intervals; varying from 20-day days; Alignment with a specific day of the week; Only working days or no day alignment
Intermediate HM follow-up	Can be requested at any time via the Home Monitoring Service Center
Transmitted data	Periodic IECM; Rate histogram (A, V); Device settings and statistics

Please refer to the technical manual of the device for further technical information.

Inlexa 3 HF-T

CRT-D



Informace o produktu

■ LV VectorOpt

Uživatelsky přívětivé rozhraní pro testování LV elektrody. Zjednodušuje výběr optimálního stimulačního vektoru.

■ BIOTRONIK Home Monitoring®

Efektivní vzdálené sledování srdečního selhání. Systém je založen na automatických bezdrátových denních přenosech. Umožňuje dřívější zásah a vzdálené kontroly jsou schváleny U.S. FDA a CE notifikovaným orgánem.

■ Automatická monitorace prahů

Umožňuje vzdálené vyhodnocování stimulační hodnoty komorových prahů.

■ DF-4 konektor

Zjednodušuje a zkracuje implantační proceduru a snižuje materiál v kapse pro přístroj.

Informace k objednání

Model	Konektory	Objem/váha	Rozměry	Objednací číslo
Inlexa 3 HF-T	DF-1 (2x), IS-1 (3x)	34 cm ³ /83 g	65 mm × 58.5 mm × 11 mm	404699
Inlexa 3 HF-T	DF4 (LLHH) (1x), IS-1 (2x)	33 cm ³ /82 g	65 mm × 56 mm × 11 mm	404700

Inlexa 3 HF-T

Technical Data

Therapy and monitoring zones	
Bradycardia	30 [5] 100 ... [10] ... 160 bpm
AT/AF	100 ... [10] ... 250 bpm
VT1	OFF, 270 ... [10] ... 400 ms
VT2	OFF, 270 ... [10] ... 500 ms
VF	OFF, 240 ... [10] ... 400 ms
Ventricular arrhythmia detection and redetection	
VT detection criteria	Interval: SMART detection; Onset: Stability, MorphMatch (if B.V. OFF, if SMART: OFF); Sustained VT
Detection counter VT1 and VT2	For VT1: 10 ... [2] ... 100; For VT2: 10 ... [2] ... 60
Redetection counter VT1 and VT2	For VT1: 10 ... [2] ... 50; For VT2: 10 ... [2] ... 40
Detection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30; 30 out of 40
Redetection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30
Onset	If SMART = OFF: OFF; 4 ... [4] ... 32 % If SMART = ON: 4 ... [4] ... 52 %
Stability	If SMART = OFF: OFF; 1 ... 8 ... [4] ... 148 ms and ± 8 ... [4] ... ± 48 % If SMART = ON: 4 ... [4] ... 148 %
MorphMatch	OFF; Monitoring: ON
MorphMatch threshold	Std., Low, High
Sustained VT	OFF, 1 ... [1] ... 3; 5; 10 ... [10] ... 30 min
SMART detection	OFF; ON
Tachycardia therapy (VT1/VT2 zone)	
Attempts	OFF, 1 ... [1] ... 10
ATP type	Burst, Ramp
Number ST	1 ... [1] ... 15
R-S1 interval	70 ... [5] ... 85; 88; 90; 95 %
Ventricular pacing	RV, LV, RV
ATP optimization	OFF; ON
Minimum ATP interval	200 ms (fixed)
Tachycardia therapy (VF zone)	
ATP type (ATP One Shot)	OFF; Burst; Ramp
Stability criterion	12 % (fixed)
Number ST	1 ... [1] ... 15
R-S1 interval	70 ... [5] ... 85; 88; 90; 95 %
Cardioversion/defibrillation therapy	
Number of shocks	For VT zones: OFF, 1; 2; 6 or 8 For the VF zone: 6 or 8
Confirmation (in VT1, VT2, VF)	OFF; ON
Polarity (in VT1, VT2, VF)	Normal, Reversed, Normal → alternating
Waveform (in VT1, VT2, VF)	Biphasic, Biphasic ?
Shock path (in VT1, VT2, VF)	RV → SVC+Can; RV → Can; RV → SVC
Energy of 1st shock	OFF, 2 ... [2] ... 20 ... [5] ... 40 J
Energy of 2nd shock	OFF, 4 ... [2] ... 20 ... [5] ... 40 J
Post-shock mode	VI, DOI, VDI
Post-shock pulse amplitude	7.5 V (RV, RA), permanent (LV)
Post-shock duration	OFF, 10 s; 30 s; 1 min; 2 min; 5 min; 10 min
Post-shock ven. pacing	RV, B.V.
Pacing parameters	
Mode	DDDR, DDD, DDDR, DDI, VVIR, VVI, VDDR, VDIR, VDD, VDI, AAI, AA, OFF, VOO, DOO
Pulse amplitude (A, RV, LV)	0.5 ... [0.25] ... 4.0 ... [0.5] ... 6.0; 7.5 V
Pulse width (A, RV, LV)	0.4; 0.5 ... [0.25] ... 1.5 ms
Capture control (A, RV, LV)	OFF; A/M
Basic rate	30 ... [5] ... 100 ... [10] ... 160 bpm
■ Rate hysteresis	OFF; -5 ... [-4] ... -25 ... [-20] ... -45 bpm
■ Scan/Repetitive	OFF; ON
■ Night rate	OFF; 30 ... [5] ... 160 bpm
AV dynamics	Low, Medium, High, Fixed, Individual
AV delay after pacing and sensing	15; 40 ... [5] ... 350 ms
Sense compensation	OFF; -5 ... [-5] ... -120 ms
AV hysteresis mode	OFF; Positive, Negative
Upper rate (UTR)	90 ... [10] ... 160 bpm
Atrial upper rate	OFF, 175; 210; 240 bpm
Mode switching (Mode)	VDD, VDIR, DDI, DDDR
■ Intervention rate	OFF, 120 ... [10] ... 200 bpm
■ Ventricular pacing	RV; B.V.
■ Change of basic rate during MS	OFF; +5 ... [5] ... +30 bpm
■ Post mode switching rate	OFF; +5 ... [5] ... +50 bpm
■ Post mode switching duration	1 ... [1] ... 30 min
■ Onset criterion/Resolution criterion	3 ... [1] ... 8 out of 8
PVARP	AUTO; 175 ... [25] ... 600 ms
PMT detection/termination	OFF; ON
Ventricular pacing	RV, B.V, LV
LV T-wave protection	OFF; ON
Triggering	OFF; RVs, RVs-PVC
W delay after Vp	0 ... [5] ... 100 ms
Initially paced chamber	RV; LV
Pacing polarity (L.V)	5 vectors
Sensing polarity (L.V)	2 vectors
Sensing (RV)	Std., Standard; TWS - Enhanced T-wave suppression, VFS - Enhanced VF sensitivity. Individually programmable sensing parameters
Sensing (LV)	Std., OFF, Individual
Sensing (A)	Std., OFF
Sensor	Accelerometer

Diagnostic functions	
Recording episodes For AT/AF	OFF, ON
Recording episodes For SV	OFF, ON
Recording episodes For nsVT	OFF, ON
Periodic recording	OFF; 30 ... [30] ... 120; 180 days (if Home Monitoring: OFF)
IEGM Hister	3 x 56 min (5 channels according to IEGM configuration)
Length of prehistory	Fixed: 30 s; 5 s (when onset was fulfilled or at induced episodes); 1 min for AT/AF episode if Advanced ON was programmed

Physical parameters	
Telemetry	RF (SafeSync), programming hood
Material	Titanium
Battery	3.2 V, 1520 mAh
Longevity	6.6 years

1) RA, RV, LV: 2.5 V/0.4 ms, 10 bpm, 300 Hz; IV pacing: 1 V pacing, 100 %; IAA pacing: 15 %, 4 max. energy shocks/year, Home Monitoring: ON (daily transmission, diagnostics: ON)

Tests	
Different tests for	Impedance, Sensing, Pacing threshold, DFT (EPE/ATP), Retrograde conduction, Rapid ventricular pacing

Program sets	
Programs	Standard program, ProgramConsult, Individual program 1-3, individually programmable; First interrogated program, Safe program

BIOTRONIK Home Monitoring®

Transmitted data	AF diagnostics, Heart Failure Monitor diagnostics, Detection and therapy counters, Statistics, Lead measurement values, Battery and system status, ICD program parameters
Message types	
Trend message	Triggered automatically once every 24 hours
Event message	Triggered automatically after certain cardiac events
Test message	Triggered manually via programmer
Programmer settings	
Home Monitoring	OFF; ON
IEGM for therapy episodes	OFF; ON
IEGM for monitoring episodes	OFF; ON
Ongoing atrial episode	OFF; 6 h, 12 h, 18 h
Home Monitoring-supported follow-up	
Remote Scheduling	Enable, Disable
HM follow-up intervals/alignment	Individually programmable first date and repetition intervals, varying from 20-366 days; Alignment with a specific day of the week; Only working days or no day alignment
Intermediate HM follow-up	Can be requested at any time via the Home Monitoring Service Center
Transmitted data	Periodic IEGM, Rate histogram (A, V), Device settings and statistics

Please refer to the technical manual of the device for further technical information.

