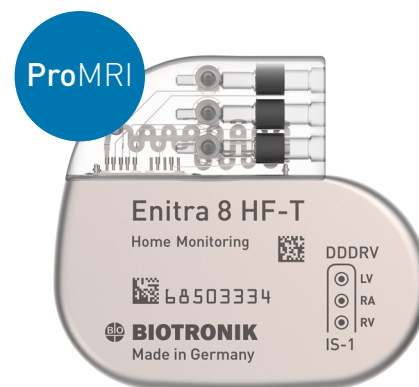


Enitra 8 HF-T

MR conditional CRT-P



1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,21 techninės charakteristikos

Ordering Information

Model	Connectors	Volume/weight	Dimensions	Order number
Enitra 8 HF-T	IS-1 (3x)	14 cm ³ /26.9 g	53 mm × 52 mm × 6.5 mm	407142

Product Highlights

LV VectorOpt

User-friendly interface for LV lead testing, simplifying the selection of the optimal pacing vector.

BIOTRONIK Home Monitoring®

Effective remote monitoring of heart failure and system integrity based on automatic and wireless daily transmissions. Enables earlier intervention and Home Monitoring-supported follow-ups that are approved by the U.S. FDA and CE Notified Body.

Event-triggered wireless IEGM transmissions within 24 hours

Enable prompt evaluations for fast and better informed therapy decisions.

ProMRI

Allows patients to undergo MR scanning under specific conditions.

MRI AutoDetect

Simplifies workflows through automatic detection of MRI environment and minimizes patients' time in MRI mode.

Closed Loop Stimulation (CLS)

Unique physiological rate response modulation during episodes of physical and emotional stress.

Capture Control (RA, RV & LV)

Automatic adjustment of pacing amplitudes for effective CRT therapy.

SafeSync RF telemetry

RF telemetry for wandless, time-saving and reliable data transmission at implantation and follow-up.

Enitra 8 HF-T

Technical Data

MR conditional	
ProMRI	For combination of MR conditional devices, please see the "ProMRI MR conditional device systems" manual
Closed Loop Stimulation	
CLS mode	DDD-CLS; VI-CLS
Max. CLS rate	80 ... [10] ... 160 bpm
Expert options	
• CLS response	Very low; Low; Medium; High; Very high
• CLS resting rate control	OFF; +10 ... [10] ... +50 bpm
• Vp required	Yes; No
Pacing parameters	
NBG code	DDDRV
Mode	DDD-CLS; VI-CLS; DDDR; VVIR; AAIR; DDIR; A00; DDD; VVI; AA1; DDI; A00R; VDD; VVT; AAT; VDI; V00; VDDR; VDIR; V00R; DDD-ADI; DVI; D00; DDDR-ADIR; DVIR; D00R; DDT; OFF
Basic rate/Night rate	
• Basic rate	30 ... [5] ... 100 ... [10] ... 200 bpm
• Night rate	OFF; 30 ... [5] ... 100 ... [10] ... 200 bpm
• Hysteresis	OFF; -5 ... [-5] ... -25 ... [-20] ... -65 bpm
• Repetitive/Scan cycles	OFF; ON (if Hysteresis was selected)
• Atrial overdrive	OFF; ON
Pulse amplitude [A/RV/LV]	0.2 ... [0.2] ... 6.0 ... [0.5] ... 7.5 V
Pulse width [A/RV/LV]	0.1 ... [0.1] ... 0.5 ... [0.25] ... 1.5 ms
Sensitivity A	AUTO; 0.1 ... [0.1] ... 1.5 ... [0.5] ... 7.5 mV
Sensitivity RV	AUTO; 0.5 ... [0.5] ... 7.5 mV
Sensitivity LV	OFF; AUTO; 0.5 ... [0.5] ... 7.5 mV
Pacing algorithm	
Atrial capture control	OFF; ON; ATM
• Min. amplitude	0.5 ... [0.1] ... 4.8 V
• Threshold test start	2.4 ... [0.6] ... 4.8 V
• Safety margin	0.5 ... [0.1] ... 1.2 V
• Search type	• Interval • Time of day
• Interval	0.1; 0.3; 1; 3; 6; 12; 24 h
• Time of day	00:00 ... [00:10] ... 23:50
Ventricular capture control [RV, LV]	OFF; ON; ATM
• Threshold test start	2.4 ... [0.6] ... 4.8 V
• Safety margin	1.0; 1.2 V
• Search type	• Interval • Time of day
• Interval	0.1; 0.3; 1; 3; 6; 12; 24 h
• Time of day	00:00 ... [00:10] ... 23:50
Vp suppression	OFF; 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
Mode switching with X/Z-out-of-8 criterion	OFF; ON
• Intervention rate	100 ... [10] ... 250 bpm
• Onset criterion	3 ... [1] ... 8 out of 8
• Resolution criterion	3 ... [1] ... 8 out of 8
• Change of basic rate	OFF; +5 ... [5] ... +30 bpm
• Rate stabilization during mode switching	OFF; ON
• 2:1 Lock-in protection	OFF; ON (if RV is selected for ven. pacing)
Atr. NIPS	Burst pacing; Programmed stimulation
Conventional rate adaptation	
Sensor	Accelerometer
• Max. activity rate	80 ... [10] ... 180 bpm
• Sensor gain	AUTO; Very low; Low; Medium; High; Very high
• Sensor threshold	Very low; Low; Medium; High; Very high
• Rate fading	OFF; ON
• Rate increase	1; 2; 4; 8 bpm/cycle
• Rate decrease	0.1; 0.2; 0.5; 1.0 bpm/cycle
Sensor optimization	Original, preview
Timing intervals	
AV delay	20; 21; 23; 25; 28; 30; 31; 33; 35; 38; 40; 43; 45; 48; 50 ... [5] ... 350 ms
AV dynamics	Low; Medium; High; Fixed
Sense compensation	OFF; -10 ... [-5] ... -120 ms
AV hysteresis mode	OFF; Negative; Positive; IRSplus
AV hysteresis (positive)	70; 110; 150; 200 ms
AV hysteresis (negative)	10 ... [10] ... 150 ms
AV repetitive/scan cycles	If AV hysteresis mode = Positive: OFF; ON

Timing intervals

Upper rate response	
• Ventricle	90 ... [10] ... 200 bpm
• Atrium	OFF; 175; 200; 240 bpm
Tachycardia behavior	2:1; WKB
Ventricular pacing	BiV; RV; LV
• Triggering	OFF; RVs; RVs+PVC
• LV T-wave protection	OFF; ON
• Maximum trigger rate	AUTO; 90 ... [10] ... 160 bpm
• Initially paced chamber	RV; LV
• VV delay after Vp	0 ... [5] ... 80 ... [10] ... 100 ms
• VV delay after Vs	0 ms
Refractory period/Blanking	
• Refract. period [A]	AUTO
• Refract. period [RV]	200 ... [25] ... 500 ms
• Refract. period [LV]	200 ms
• Auto PVARP	OFF; ON
• PVARP	175 ... [25] ... 600 ms
• PVARP after PVC	PVARP + 150 ms (max. 600 ms), automatically adjusted
• Ven. blanking after Ap	30 ... [5] ... 70 ms
• Far-field protection after Vs	100 ... [10] ... 220 ms
• Far-field protection after Vp	100 ... [10] ... 220 ms
• PMT protection	OFF; ON
• VA criterion	250 ... [25] ... 500 ms

Leads

Automatic lead check [A/RV/LV]	ON; OFF
Lead configuration [A/RV/LV]	Unipolar; bipolar
Pacing polarity [LV]	6 vectors
Auto-initialization	ON

Physical parameters

Service time	9 years, 8 months ¹⁾
Replacement indication	Programmed rate minus 11% (in DDD[R])
Electrically conductive surface	33 cm²
X-ray identification	BIOTRONIK logo

¹⁾ at A: 2.5 V/0.4 ms, 60 bpm, 500 Q; pacing: 10 %, Home Monitoring: OFF, SafeSync: OFF at RV/LV: 2.5 V/0.4 ms, 60 bpm, 500 Q; pacing: 100%, Home Monitoring: OFF, SafeSync: OFF

Additional parameters

Magnet response	AUTO (10 cycles at 90 bpm asynchronous; then basic rate synchronous); asynchronous, synchronous
IEGM recording	20 recordings, max. 10 seconds each
Recording prior to event	0; 25; 50; 75; 100%
MRI program	OFF; ON; AUTO
Expiration date (for AUTO)	Adjustable to today's date + 14 days

BIOTRONIK Home Monitoring®

Transmitted data	
Threshold [A/RV/LV], Sensing amplitude [A/RV/LV], Pacing statistics, Arrhythmia statistics [A/RV/LV], Heart Failure Monitor diagnostics, CRT statistics, Battery status, Lead measurement values, Program parameters	
Event based IEGM	
AF; HVF; Lead failure	
Message types	
Trend message	Triggered automatically once every 24 hours
Event message	Triggered automatically after certain cardiac events
Test message	Triggered manually via programmer
Findings	
Device	Battery status; Programmer-triggered message received; Backup mode active
Leads	
Pacing impedance [A/RV/LV], Lead check [A/RV/LV], Sensing amplitude [A/RV/LV], Threshold [A/RV/LV], Capture control status [A/RV/LV]	
Arrhythmias	
Number/duration of atrial arrhythmias; Number/duration of mode switching; Long ongoing atrial episode detected; Number/duration of ven. arrhythmias; Atrial burden	
Heart Failure Monitor	
Mean PVC/h; CRT and BiV pacing; Mean ven. heart rate (24 h, at rest)	
Programmer settings	
Home Monitoring	OFF; ON
Time of transmission	AUTO; 00:00 ... [01:00] ... 23:00 hh:mm
High atrial rate	OFF; ModeSw: AT
Ongoing atrial episode	OFF; 6 h; 12 h; 18 h
High ventricular rate	OFF; ON
Event based IEGM	OFF; ON