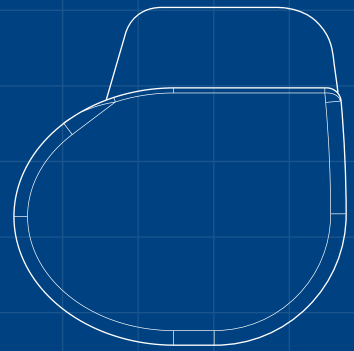


Eno™ DR



DUAL-CHAMBER PACEMAKER

World's smallest transvenous pacemaker¹
1.5 T and 3 T Full body MR conditional

[Technical specifications](#)



MECHANICAL CHARACTERISTICS

ORDER NUMBER — **TPM014C**

SIZE — **41.2 X 41.5 X 6.1 mm**

WEIGHT — **20 g**

VOLUME — **8 cm³**

CONNECTOR — **IS-1**

ELECTRICAL CHARACTERISTICS

LONGEVITY IN SAFER-R MODE (50% A & 5% V PACING)* — **12 YEARS**

LONGEVITY IN DDDR MODE (100% A & V PACING)* — **9.6 YEARS**

BATTERY TYPE — **GB8711 LITHIUM IODINE (2.8 V, 0.81 Ah)**

MAGNET RATE — **BOS: 96 min⁻¹ / RRT: 80 min⁻¹**

*60 min⁻¹ AT 2.5 V, 0.35 ms, 750 Ω, SENSORS ON, EGMS ON & DIAGNOSTICS ON

1. REFER TO MANUFACTURERS MANUALS.

2. MARTIN STOCKBURGER ET AL. LONG-TERM CLINICAL EFFECTS OF VENTRICULAR PACING REDUCTION WITH A CHANGEOVER MODE TO MINIMIZE VENTRICULAR PACING IN A GENERAL PACEMAKER POPULATION. EUROPEAN HEART JOURNAL 2014

3. BOVEDA S ET AL. RESULTS FROM THE ANSWER STUDY, EUROPACE ABSTRACTS SUPPLEMENT. (2 0 1 5) 1 7 (SUPPLEMENT 3), III24

Highlights

- ✓ Mimics the natural activity of the heart
With **INTELLIGENCE™**
- ✓ Reduces ventricular pacing
in SND and AVB patients
With **[SAFER]™²**
- ✓ Crosschecks sensors to support
all types of exercise
With **[DUAL SENSOR]**
- ✓ Unique rest rate adaptation
based on respiration
With **Rest Rate**
- ✓ 12 years longevity in 8 cc
With **RATIO DESIGN™**
- ✓ Manages patients at risk of AF
With **AF RISK MANAGEMENT™**
- ✓ Reduces the risk of 1st onset of AF³
With **[SAFER]™**
- ✓ Screens sleep apnea
With **[SAM]™**

8 cc only

AUTOMRI™

Visit. Scan. Go.

APPROVED FOR 1.5 T AND 3 T FULL BODY MR CONDITIONAL

Ease the Workflow.

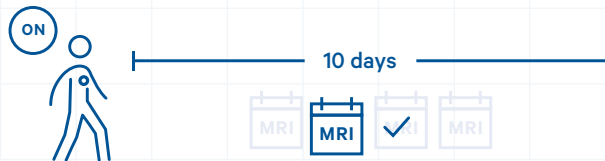
1. Patient visits the cardiologist.

Cardiologist turns AutoMRI ON.



2. There is a 10 day window where the patient can have an MRI scan.

No limitation on the numbers of scans during these 10 days.
No need to return to the cardiologist or any additional check ups etc. This allows for flexibility with scheduling MRI scans.



3. Patient enters MRI Scan.

Approaching and detecting the scan, the device switches into asynchronous MRI mode. Moving away from the scan, 5 minutes after the patient leaves, the device switches back to initial settings.



4. Patient can go home.

Without any assistance or intervention.
No visit to cardiologist, patient is free to go home autonomously.



SafeR™ Parameters

AVB I SWITCH	Rest+Exercise - Exercise
LONG PR (max.)	250 - 300 - 350 - 400 - 450 ms
LONG PR (min.)	200 - 250 - 300 - 350 - 400 - 450 ms
PAUSE (max.)	2 - 3 - 4 s

Rate-Response Parameters

SENSOR CHOICE	MV+G (Twin Trace) - MV - G
RATE RESPONSE MODE	Learn ¹ - RRAuto - RRFixed - <u>OFF</u>
PHYSICAL EXERCISE	Very low - Low - Medium - High - Very high

Special Features

FALLBACK MODE SWITCHING (FMS)	ON - OFF
PMT PROTECTION	Termin - Reprog
RATE SMOOTHING	<u>OFF</u> - Very slow - Slow - Medium - Fast
ACCELERATION	0 - 5 - 15 - 25 - 35 - 45 %
AV DELAY SHORTENING	0 - 15 - 30 - 45 - 65 - 80 - 95 - 110 ms

Basic Parameters

MODE	SafeR ² - SafeRR - SafeR/DDIR - Dplus DplusR - Dplus/DDIR - DDDR - DDD DDD/DDIR - AAIR - AAI - VVIR - <u>VVI</u> - VDDR VDD - DDIR - DDI - DDTAV - DDTA - DDTV AAT - VVT- DOO - AOO - VOO - OOO
BASIC RATE	30 - 40 - 45 - 50 - 55 - 60 - 65 - <u>70</u> 75 - 80 - 85 - 90 - 95 min ⁻¹
REST RATE	50 - 55 - 60 - 65 - 70 - 75 - 80 - 85 90 - 95 min ⁻¹
MAXIMUM TRACKING RATE	100 - 110 - 120 - 130 - 140 - 155 - 165 - 175 - 185 min ⁻¹
RATE HYSTERESIS	<u>0</u> - 5 - 10 - 20 - 35 %
REST AV DELAY	30 - 45 - 65 - 80 - 95 - 110 - 125 - 140 - 155 170 - 190 - 205 - 220 - 235 - 250 ms
EXERCISE AV DELAY	30 - 45 - 65 - 80 - 95 - 110 - 125 - 140 155 - 170 - 190 - 205 - 220 - 235 - 250 ms
AVD PACED / SENSED OFFSET	0 - 15 - 30 - 45 - 65 - 80 - 95 - 110 - 125 ms

Sensing Parameters

ATRIAL SENSITIVITY	0.1 - 0.2 - 0.3 - 0.4 - 0.6 - 0.8 - 1.0 - 1.2 - 1.5 - 1.8 2.0 - 2.2 - 2.5 - 2.7 - 3.0 - 3.5 - 4.0 - 4.5 - 5.0 - 6.0 mV
VENTRICULAR SENSITIVITY	0.4 - 0.6 - 0.8 - 1.0 - 1.2 - 1.5 - 1.8 - 2.0 - <u>2.2</u> - 2.5 2.7 - 3.0 - 3.5 - 4.0 - 4.5 - 5.0 - 6.0 - 8.0 - 10.0 15.0 mV
POST VENTRICULAR ATRIAL BLANKING (PVAB)	150 - 165 - 180 - 195 - 210 - 225 - 240 - 255 ms
ATRIAL AND VENTRICULAR SENSING POLARITY	<u>Unipolar</u> - Bipolar ³
ATRIAL AND VENTRICULAR AUTOSENSING	Auto - <u>Monitor</u>

Pacing Parameters

ATRIAL AND VENTRICULAR AMPLITUDE	1.5 - 2.0 - 2.5 - 3.0 - 3.5 - 4.0 - <u>5.0</u> - 7.5 V
ATRIAL AND VENTRICULAR PULSE WIDTH	0.10 - 0.25 - 0.35 - <u>0.50</u> - 0.60 - 0.75 - 0.85 1.00 ms
ATRIAL AND VENTRICULAR PACING POLARITY	<u>Unipolar</u> - Bipolar ³
ATRIAL AND VENTRICULAR AUTOTHRESHOLD	Auto - Monitor - <u>OFF</u>
MIN. VENTRICULAR AMPLITUDE	1.5 - 2.0 - 2.5 - 3.0 - 3.5 V
MIN. ATRIAL AMPLITUDE	1.0 - 1.5 - 2.0 - 2.5 V
SAFETY ATRIAL AMPLITUDE	2.5 - 3.5 - 4.0 - 5.0 V
ATRIAL AUTOTHRESHOLD MAX RATE	75 - 80 - 85 - 90 - 95 - 100 - 110 min ⁻¹

Atrial and Ventricular lead polarity switch

ATRIAL AND VENTRICULAR LEAD POLARITY SWITCH	ON - <u>OFF</u>
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SAM™ — Sleep Apnea Monitoring

MONITORING	<u>ON</u> ⁴ - OFF
MONITORING PERIOD	22:00-03:00 - 23:00-04:00 - 00:00-05:00 01:00-06:00

MRI Mode Parameters⁵

MRI MODE	Auto - Manual - OFF
MRI PACING MODE	DOO - VOO - OOO
MRI PACING RATE ⁶	50 - 55 - 60 - 65 - 70 - 75 - 80 - 85 - 90 - 95 100 - 105 - 110 - 115 - 120 min ⁻¹
MRI MONITORING PERIOD	2h - 4h - 6h - 12h - 24h - 48h - 3 days 7 days - 10 days

1. Twenty minutes after the automatic detection of implantation by the device, the as-shipped rate response mode (OFF) is automatically programmed to Learn, and Diagnostics will be ON.
2. 20 minutes after implant, the as-shipped pacing mode "DDD" is automatically programmed to SafeR.
3. As soon as the detection of implantation has been confirmed, the lead configuration is automatically programmed to unipolar pacing and bipolar sensing (if a bipolar lead is used) or to bipolar pacing bipolar sensing (if the values are re-programmed to bipolar in the box and a bipolar lead is used).
4. Automatic activation at first interrogation after automatic implantation detection.
5. The pacemaker system (ENO pacemaker and MRI tested leads) is MR conditional under specific conditions. Refer to the MRI Solutions manual (UA10006) for the complete MRI checklist to be fulfilled at the time of MRI examination.
6. Default pacing rate is 20 min⁻¹ over programmed basic rate.



Atrial Arrhythmia Prevention Parameters

OVERDRIVE	ON - OFF
MAX. OVERDRIVE RATE	100 - 110 - 130 - 155 - 185 min ⁻¹
PAUSE SUPPRESSION	A - V - A+V - OFF
PAC ACCELERATION	ON - OFF

Non Programmable Parameters

COMMITTED PERIOD	95 ms
RATE LIMIT	195 min ⁻¹
LEAD IMPEDANCE MEASUREMENT	Automatic (every 6 hours)
REFRACTORY PERIODS	Dynamic

Automatic Detection of Implantation

SAFER AUTO LAUNCH	Yes - No
ATRIAL PACING POLARITY	Unipolar - Bipolar
VENTRICULAR PACING POLARITY	Unipolar - Bipolar

Diagnostics Aida

(Automatic Interpretation for Diagnosis Assistance)

ALL DIAGNOSTICS

Always ON (24 hours - 6 months)

INTRACARDIAC EGM

22.2 min., A and V, 512 Hz sampling, 22 stored episodes, Annotated markers, synchronized with intracardiac EGM

AV CONDUCTION

Number of AVB episodes and switches day & night: AVB I, II, III and pauses; SafeR switch criteria

EGM TRIGGERS

Mode switching; Atrial bursts; Ventricular bursts; Switches in SafeR mode

HISTOGRAMS AND COUNTERS

A and V rate; Pacing %; Atrial arrhythmias (number and time in mode switch, bursts, Premature Atrial Contractions (PACs)); Ventricular bursts and Premature Ventricular Contractions (PVCs); Pacing threshold follow-up; Amplitudes of normal and abnormal P and R waves; over 7 days 24-hour heart rate curve

SLEEP APNEA MONITORING (SAM)

Respiratory Disturbance Index over 6 months; Number and duration of events, SAM Observations

Follow-Up Functions

TEST ASSISTANT SMARTCHECK

Chained test sequence with automatic saving/printing of results

PATIENT DATA

Detailed patient information

BATTERY STATUS

Magnet rate; Battery impedance; Battery curve

A AND V LEAD IMPEDANCE

Automatic every 6 hours

ATRIAL AND VENTRICULAR PACING THRESHOLD TESTS

Simultaneous visualization of intracardiac EGM and markers

TEMPORARY PROGRAMMING

Automatic measurement of P and R amplitudes: Simultaneous visualization of intracardiac EGM and markers

NIPS (ELECTROPHYSIOLOGIC STUDIES)

A burst, V burst, extra-stimuli sequences

IMPLANT AND FOLLOW-UP REPORT

Available paper print and electronic format (Adobe® PDF)

REFER TO USER'S MANUAL FURNISHED WITH THE DEVICE FOR COMPLETE INSTRUCTIONS FOR USE.

NOT AVAILABLE FOR DISTRIBUTION OR SALE IN THE USA.

Manufactured in Europe by MicroPort CRM.

MICROPORT CRM S.R.L.
VIA CRESCENTINO S.N. 13040 SALUGGIA (VC)
ITALY