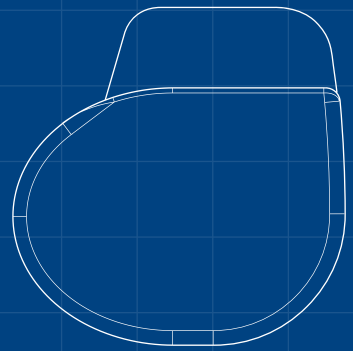


Oto™ DR



DUAL-CHAMBER PACEMAKER

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

[Technical specifications](#)



MECHANICAL CHARACTERISTICS

ORDER NUMBER — **TPM018C**

SIZE — **41.2 X 41.5 X 6.1 mm**

WEIGHT — **20 g**

VOLUME — **8 cm³**

CONNECTOR — **IS-1**

ELECTRICAL CHARACTERISTICS

LONGEVITY IN DDDR MODE (100% A & V PACING)* — **10 YEARS**

LONGEVITY IN DDDR MODE (50% A & V PACING)* — **11.7 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.

Highlights

- ✓ 10 years longevity* (100% pacing) in the world's smallest dual-chamber pacemaker.¹
With **RATIO DESIGN™**
- ✓ Automatically activates algorithms at implant
With **Auto Implant Detect**
- ✓ Fast and Easy follow-up at a click of a button
With **Smartcheck**
- ✓ Capture & sensing automaticity
With **Autosensing and Autothreshold**
- ✓ Clinical excellence standards
With **Mode Switch**
With **PMT Protection**
With **Lead Polarity Safety Switch**
With **Rate Response...**

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.

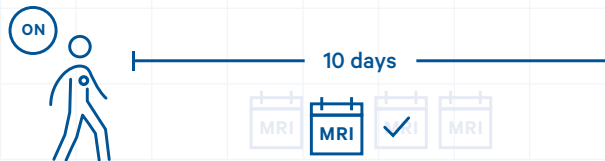
Cardiologist turns AutoMRI ON.



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.



Automatic Detection of Implantation

ATRIAL PACING POLARITY **Unipolar** - Bipolar
 VENTRICULAR PACING POLARITY **Unipolar** - Bipolar

Atrial and Ventricular lead polarity switch

ATRIAL AND VENTRICULAR LEAD POLARITY SWITCH ON - **OFF**

Basic Parameters

MODE Dplus - DplusR - Dplus/DDIR - **DDDR** - **DDD**
 DDD/DDIR - AAIR - AAI - VVIR - VVI - VDDR
 VDD - DDIR - DDI- DDTAV- DDTA - DDTV - AAT
 VVT - DOO-AOO-VOO-OOO

BASIC RATE 30 - 40 - 45 - 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 0 - 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

Special Features

FALLBACK MODE SWITCHING (FMS) **ON** - OFF

PMT PROTECTION Termin - **Reprog**

RATE SMOOTHING **OFF** - Very slow - Slow - Medium - Fast

ACCELERATION 0 - 5 - 15 - 25 - 35 - 45 %

AV DELAY SHORTENING 0 - 15 - 30 - 45 - 65 - 80 - 95 - 110 ms

Pacing Parameters

ATRIAL AND VENTRICULAR AMPLITUDE 1.5 - 2.0 - 2.5 - 3.0 - **3.5** - 4.0 - 5.0 - 7.5 V

ATRIAL AND VENTRICULAR PULSE WIDTH 0.10 - 0.25 - **0.35** - 0.50 - 0.60 - 0.75 - 0.85
 1.00 ms

ATRIAL AND VENTRICULAR PACING POLARITY **Unipolar** - Bipolar¹

ATRIAL AND VENTRICULAR AUTO THRESHOLD Auto - Monitor - **OFF**

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 AUTO THRESHOLD MAX RATE 75 - 80 - 85 - 90 - 95 - 100 - **110** min⁻¹

Rate-Response Parameters

SENSOR Accelerometer (G)

RATE RESPONSE MODE **Learn**² - RRAuto - RRFixed - **OFF**

PHYSICAL EXERCISE Very low - Low - Medium - High - Very high

MRI Mode Parameters³

MRI MODE Auto - Manual - **OFF**

MRI PACING MODE **DOO** - VOO - OOO

MRI PACING RATE⁴ 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

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 - 2.2 - **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 **Unipolar** - Bipolar¹

ATRIAL AND VENTRICULAR AUTOSENSING Auto - **Monitor**

COMMITTED PERIOD 95 ms

RATE LIMIT 195 min⁻¹

LEAD IMPEDANCE MEASUREMENT Automatic (every 6 hours)

REFRACTORY PERIODS Dynamic

1. 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).
2. 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.
3. The pacemaker system (OTO 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.
4. Default pacing rate is 20 min⁻¹ over programmed basic rate.



Diagnostics Aida

(Automatic Interpretation for Diagnosis Assistance)

ALL DIAGNOSTICS

Always ON (24 hours - 6 months)

INTRACARDIAC EGM

9.4 min., A and V, 512 Hz sampling,
9 stored episodes, annotated markers,
synchronized with intracardiac EGM

EGM TRIGGERS

Mode switching; Atrial bursts;
Ventricular bursts.

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

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 visualisation 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.

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ITALY