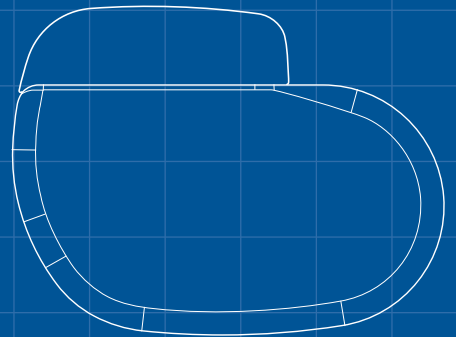


Alizea™ SR

SINGLE-CHAMBER PACEMAKER
MODEL 1300



1.5 T and 3 T Full body MR conditional

Technical specifications



MECHANICAL CHARACTERISTICS

ORDER NUMBER — **TPM021C**

SIZE — **41.4 X 54.3 X 6.1 mm**

WEIGHT — **23.3 g**

VOLUME — **10.5 cm³**

CONNECTOR — **IS-1**

ELECTRICAL CHARACTERISTICS

LONGEVITY IN VVIR MODE (50% PACING)* — **13.7 / 15.8 YEARS**

LONGEVITY IN VVIR MODE (100% PACING)* — **12.6 / 14.5 YEARS**

BATTERY TYPE — **LiS 3150 MP LiMnO₂**

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

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

Automatic Implantation Detection Parameters

AUTOMATIC IMPLANTATION DETECTION	ON - <u>OFF</u>
VENTRICULAR PACING POLARITY	Unipolar - Bipolar
VENTRICULAR AUTOTHRESHOLD	Auto - Monitor - <u>OFF</u>
LEAD POLARITY SWITCH	ON - <u>OFF</u>
REMOTE MONITORING	ON - <u>OFF</u>

Ventricular Lead Polarity Switch

VENTRICULAR LEAD POLARITY SWITCH	ON - <u>OFF</u>
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Non Programmable Parameters

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

Basic Parameters

CHAMBER	A - <u>V</u>
PACING MODE	VVI - VVIR - VVT - VOO - AAI - AAIR AAT - AOO - OOO
BASIC RATE	30 - 35 - 40 - 45 - 50 - 55 - 60 - 65 - 70 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 %

Sensing Parameters

SENSITIVITY	0.4 - 0.6 - 0.8 - 1.0 - 1.2 - 1.5 ¹ - 1.8 - 2.0 2.2 - <u>2.5</u> - 2.7 - 3.0 - 3.5 - 4.0 - 4.5 - 5.0 6.0 - 8.0 - 10.0 - 15.0 mV
SENSING POLARITY	<u>Unipolar</u> - Bipolar ²
VENTRICULAR AUTOSENSING	Auto - Monitor

Pacing Parameters

PACING AMPLITUDE	1 - 1.5 - 2.0 - 2.5 - 3.0 - 3.5 - 4.0 - <u>5.0</u> 6 - 7.5 V
PULSE WIDTH	0.12 - 0.25 - 0.35 - <u>0.50</u> - 0.60 - 0.75 0.85 - 1.00 ms
PACING POLARITY	<u>Unipolar</u> - Bipolar ²
VENTRICULAR AUTOTHRESHOLD	Auto - Monitor ³ - <u>OFF</u>
VENTRICULAR AMPLITUDE SAFETY MARGIN	x1.5 - x2 - x2.5 - x3
MIN. VENTRICULAR AMPLITUDE	1.5 - 2.0 - 2.5 - 3.0 - 3.5 V
VENTRICULAR SAFETY AMPLITUDE	2 - 2.5 - 3 - 3.5 - 4 - 4.5 - 5 - 6 V

1. As-shipped sensitivity in bipolar configuration.
2. If an unipolar lead is implanted, the pacing and sensing polarities are automatically programmed to unipolar.
3. Twenty minutes after confirmation of implantation, the as-shipped autothreshold configuration "OFF" is automatically programmed to "Monitor".

Rate Response Parameters

SENSOR CHOICE	<u>MV+G</u> – MV – G
RATE RESPONSE MODE	<u>Learn</u> ⁴ – RRAuto – RRFixed – OFF
PHYSICAL ACTIVITY	Very low – Low – <u>Medium</u> – High Very high

Special Features

RATE SMOOTHING	<u>OFF</u> – Very slow – Slow – Medium – Fast
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SAM™ — Sleep Apnea Monitoring

MONITORING	<u>ON</u> ⁵ – OFF
NIGHT PERIOD	22:00-03:00 – 23:00-04:00 <u>00:00-05:00</u> – 01:00-06:00

MRI Mode Parameters⁶

MRI MODE	Auto – Manual – <u>OFF</u>
MRI PACING MODE	<u>VOO</u> – AOO ⁷ – OOO
MRI PACING RATE ⁸	50 - 55 - 60 - 65 - 70 - 75 - 80 - 85 - <u>90</u> 95 - 100 - 105 - 110 - 115 - 120 min ⁻¹
MRI MONITORING PERIOD	2h – 4h – 6h – 12h – <u>24h</u> – 48h – 3 days 7 days – 10 days

Remote — Alerts & Warnings

BASIC PARAMETERS

RF FOR REMOTE MONITORING ⁹	<u>ON</u> – OFF
ALERTS	<u>ON</u> – OFF

SYSTEM ALERTS

BATTERY DEPLETION - RRT	<u>ON</u>
SYSTEM INTEGRITY	<u>ON</u>

LEADS ALERTS

ABNORMAL LEAD IMPEDANCE	<u>ON</u> – OFF
LOW LIMIT	200 - 250 - <u>300</u> - 350 - 400 - 450 500 Ω
HIGH LIMIT	1500 - 1750 - <u>2000</u> - 2500 - 3000 Ω
VENTRICULAR AUTOTHRESHOLD	<u>ON</u> – OFF
HIGH THRESHOLD LIMIT	OFF ; 1 - 1.25 - 1.5 - 1.75 - <u>2</u> - 2.25 - 2.5 - 3 3.5 - 4 - 4.5 V
VENTRICULAR LEAD POLARITY SWITCH	<u>ON</u> – OFF

CLINICAL ALERTS

SLEEP APNEA	<u>ON</u> – OFF
NIGHTS OVER A WEEK	<u>4</u> - 5 - 6 - 7

OTHER ALERTS

MRI NOTIFICATIONS	<u>ON</u> – OFF
ASYNCHRONOUS MODE	<u>ON</u> – OFF

4. Twenty minutes after confirmation of implantation, the as-shipped Rate response configuration "OFF" is automatically programmed to "Learn" and diagnostics will be ON.

5. Automatic activation at first interrogation after automatic implantation detection.

6. Refer to the MRI Solutions Manual (UA10377) available online at microportmanuals.com

7. Default pacing rate is 20 min⁻¹ over programmed basic rate.

8. Nominal value depending on the state of the battery (residual capacity).

Diagnostics Aida

(Automatic Interpretation for Diagnosis Assistance)

ALL DIAGNOSTICS

Always ON (24 hours - 6 months); Programmable night period

INTRACARDIAC EGM

A or V, 512 Hz sampling,
8 stored episodes, Annotated markers,
synchronized with intracardiac ECG

EGM TRIGGERS

Atrial or Ventricular bursts ; Ventricular autothreshold

HISTOGRAMS AND COUNTERS

Rate; Pacing %; Ventricular bursts and Premature
Ventricular Contractions (PVCs);
Pacing threshold follow-up;
Amplitudes of normal and abnormal waves;
over 7 days 24-hour heart rate curve

SLEEP APNEA MONITORING (SAM)

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

Follow-Up Functions

PATIENT DATA

Detailed patient information

OVERVIEW SCREEN

All useful indicators gathered in one screen

BATTERY STATUS

Magnet rate; Battery voltage

LEAD IMPEDANCE

Automatic every 6 hours

ATRIAL OR VENTRICULAR PACING THRESHOLD TESTS

Simultaneous visualization of intracardiac EGM and markers

TEMPORARY PROGRAMMING

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

TEST ASSISTANT SMARTCHECK

Chained test sequence with automatic
saving/printing of results

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