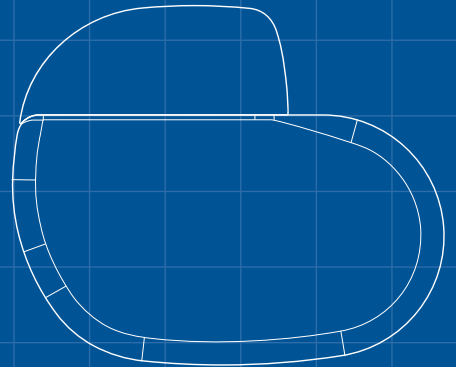


Alizea™ DR

DUAL-CHAMBER PACEMAKER
MODEL 1600



1.5 T and 3 T Full body MR conditional

Technical specifications



MECHANICAL CHARACTERISTICS

ORDER NUMBER — **TPM020C**

SIZE — **45.5 X 54.3 X 6.1 mm**

WEIGHT — **24.2 g**

VOLUME — **11 cm³**

CONNECTOR — **IS-1**

ELECTRICAL CHARACTERISTICS

LONGEVITY IN SAFER-R MODE — **13.3 / 15.3 YEARS**
(50% A & 5% V PACING)*

LONGEVITY IN DDDR MODE — **10.7 / 12.1 YEARS**
(100% A & V PACING)*

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>
SAFER AUTO LAUNCH	Yes – No
ATRIAL PACING POLARITY	Unipolar – <u>Bipolar</u>
VENTRICULAR PACING POLARITY	Unipolar – <u>Bipolar</u>
ATRIAL AUTOTHRESHOLD	Auto – <u>Monitor</u> – OFF
VENTRICULAR AUTOTHRESHOLD	Auto – <u>Monitor</u> – OFF
LEAD POLARITY SWITCH	ON – <u>OFF</u>
REMOTE MONITORING	ON – <u>OFF</u>

Basic Parameters

PACING MODE	SafeR ¹ – SafeRR – SafeR/DDIR – Dplus DplusR – Dplus/DDIR – DDDR – DDD DDD/DDIR – AAIR – AAI – VVIR – <u>VVI</u> VDDR – VDD – DDIR – DDI – DTAV DDTA – DDTV – AAT – VVT – DOO AQQ – VOO – OOO
BASIC RATE	30 - 35 - 40 - 45 - 50 - 55 - 60 - 65 - <u>70</u> 75 - 80 - 85 - 90 - 95 min ⁻¹
REST RATE	50 - 55 - 60 - 65 - <u>70</u> - 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 <u>155</u> - 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 ² - 0.8 - <u>1.0</u> - 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 ² - 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
ATRIAL AND VENTRICULAR SENSING POLARITY	<u>Unipolar</u> – <u>Bipolar</u> ³
ATRIAL AND VENTRICULAR AUTOSENSING	Auto – <u>Monitor</u>
POST R ATRIAL BLANKING	95 - 110 - 125 - 140 - 155 - 170 - 185 200 ms
POST V ATRIAL BLANKING	150 - 170 - 185 - 200 - 215 - 230 - 245 260 ms

Pacing Parameters

ATRIAL AND VENTRICULAR PACING AMPLITUDE	1 - 1.5 - 2.0 - 2.5 - 3.0 - 3.5 - 4.0 - <u>5.0</u> 6 - 7.5 V
ATRIAL AND VENTRICULAR PULSE WIDTH	0.12 - 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> – <u>Bipolar</u> ³
ATRIAL AND VENTRICULAR AUTOTHRESHOLD	Auto – <u>Monitor</u> ⁴ – OFF
VENTRICULAR AMPLITUDE SAFETY MARGIN	x1.5 - <u>x2</u> - 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
ATRIAL AMPLITUDE SAFETY MARGIN	x1.5 - <u>x2</u> - x2.5 - x3
MIN. ATRIAL AMPLITUDE	1.0 - 1.5 - 2.0 - 2.5 - 3 - 3.5 V
ATRIAL SAFETY AMPLITUDE	2 - 2.5 - 3 - 3.5 - 4.0 - 4.5 - 5.0 V
ATRIAL AUTOTHRESHOLD MAX RATE	100 - 110 - 120 min ⁻¹
ATRIAL AUTOTHRESHOLD START TIME	12pm - 01am - 02am - 12pm

Atrial and Ventricular Lead Polarity Switch

ATRIAL AND VENTRICULAR LEAD POLARITY SWITCH	ON – <u>OFF</u>
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Non Programmable Parameters

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

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

SafeR™ Parameters

AVB I SWITCH	Rest+Exercise – Exercise
LONG PR AT REST	200 - 250 - 300 - 350 - 400 - 450 - 500 ms
LONG PR AT EXERCISE	200 - 250 - 300 - 350 - 400 - 450 - 500 ms
MAX. PAUSE	2 - 3 - 4 s

Rate Response Parameters

SENSOR CHOICE	MV+G – MV – G
RATE RESPONSE MODE	Learn ⁵ – RRAuto – RRFixed – OFF
PHYSICAL ACTIVITY	Very low – Low – Medium – High – Very high

Special Features

FALLBACK MODE SWITCHING (FMS)	ON – OFF
MODE SWITCH RATE	30 - 35 - 40 - 45 - 50 - 55 - 60 - 65 - 70 - 75 80 - 85 - 90 - 95 min ⁻¹
PMT PROTECTION	Termin – Reprog – OFF
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

SAM™ — Sleep Apnea Monitoring

MONITORING	ON ⁶ – OFF
NIGHT PERIOD	22:00-03:00 – 23:00-04:00 – 00:00-05:00 01:00-06:00

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

MRI Mode Parameters⁷

MRI MODE	Auto – Manual – OFF
MRI PACING MODE	DOO – VOO – AOO – OOO
MRI PACING RATE ⁸	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

Remote — Alerts & Warnings

BASIC PARAMETERS

RF FOR REMOTE MONITORING ⁹	ON – OFF
ALERTS	ON – OFF

SYSTEM ALERTS

BATTERY DEPLETION - RRT	ON
SYSTEM INTEGRITY	ON

LEADS ALERTS

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

CLINICAL ALERTS

AF BURDEN	ON – OFF
LOW AF BURDEN	6min – 15min – 30min – 1h – 3h – 6h 12h – 24h
MID AF BURDEN	6min – 15min – 30min – 1h – 3h – 6h 12h – 24h
HIGH AF BURDEN	6min – 15min – 30min – 1h – 3h – 6h 12h – 24h
FAST V RATE DURING AT/AF	ON – OFF
FAST V RATE LIMIT	80 - 90 - 100 - 110 - 120 min ⁻¹
FAST V DURATION LIMIT	0.5 - 1 - 3 - 6 - 12 - 24 h
SLEEP APNEA	ON – OFF
NIGHTS OVER A WEEK	4 - 5 - 6 - 7

OTHER ALERTS

MRI NOTIFICATIONS	ON – OFF
ASYNCHRONOUS MODE	ON – OFF

- Twenty minutes after confirmation of implantation, the as-shipped Rate response configuration "OFF" is automatically programmed to "Learn" and diagnostics will be ON.
- Automatic activation at first interrogation after automatic implantation detection.
- Refer to the MRI Solutions Manual (UA10377) available online at microportmanuals.com
- Default pacing rate is 20 min⁻¹ over programmed basic rate.
- Nominal value depending on the state of the battery (residual capacity).



Diagnosics Aida

(Automatic Interpretation for Diagnosis Assistance)

ALL DIAGNOSTICS

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

INTRACARDIAC EGM

A and V, 512 Hz sampling,
23 stored episodes, Annotated markers,
synchronized with intracardiac ECG

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; Ventricular autothreshold;
Atrial autothreshold

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

PATIENT DATA

Detailed patient information

OVERVIEW SCREEN

All useful indicators gathered in one screen

BATTERY STATUS

Magnet rate; Battery voltage

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

TEST ASSISTANT SMARTCHECK

Chained test sequence with automatic
saving/printing of results

NIPS (ELECTROPHYSIOLOGIC STUDIES)

A 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