CPR4

Wired Inductive Programming Head

USER MANUAL

B10031

US

Table of Contents

1 INTRODUCTION

1.1 Intended purpose

The CPR4 is the inductive programming head intended to be used with suitable MicroPort CRM programmers for the interaction with the IMDs manufactured by MicroPort CRM, or by its predecessors Sorin Group and Ela Medical.

The CPR4 is functional to achieve the programmer's intended purpose:

- Interrogate the device to get information about the device and assist with the diagnosis and monitoring of pathological heart rhythm disturbances,
- Program the device to configure the device therapies according to patients' needs,
- Run real-time tests to check device functioning.

1.2 Indication(s), target population(s) and intended user(s)

1.2.1 Indication(s)

The CPR4 provides communication with MicroPort implantable pacemakers and defibrillators and is thus indicated in patients requiring atrial or ventricular pacing and synchronous atrio-ventricular pacing, or/and ventricular antitachycardia pacing and defibrillation for automated treatment of life-threatening ventricular arrhythmia, without or with resynchronization.

The indications are detailed below:

According to the guidelines specified below, atrial or ventricular pacing and synchronous atrio-ventricular pacing are mainly indicated for the following conditions:

- Accepted patient conditions warranting chronic cardiac pacing which include:
    - symptomatic paroxysmal or permanent second- or third-degree AV block;
    - symptomatic bilateral bundle branch block;
    - symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders;
    - bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias;
    - vasovagal syndromes or hypersensitive carotid sinus syndromes.
- Atrial or ventricular pacing and synchronous atrio-ventricular pacing is indicated for patients who may benefit from maintenance of AV synchrony and for the treatment of conduction disorders that require restoration of both rate and which include:
    - various degrees of AV block to maintain the atrial contribution to cardiac output;
    - VVI intolerance (e.g. pacemaker syndrome) in the presence of persistent sinus rhythm;
    - Low cardiac output or congestive heart failure secondary to bradycardia.
- Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in physical activity.

Guidelines on cardiac pacing are provided by the European Society of Cardiology, the American College of Cardiology and the American Heart Association ("2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy." Eur Heart J. 2021 Sep 14;42(35):3427-3520. doi:10.1093/eurheartj/ehab364. "2012 ACCF/AHA/HRS Focused Update of the 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities". J Am Coll Cardiol. 2013; 61(3):e6-75).

According to the guidelines, ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmia without resynchronization is indicated in:

- Patients who are survivors of cardiac arrest due to ventricular fibrillation or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes.

- Patients with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable.
- Patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or ventricular fibrillation induced at electrophysiological study.
- Patients with reduced LVEF due to prior myocardial infarction who are at least 40 days post-myocardial infarction and with symptomatic heart failure or LV dysfunction.
- Patients with non-ischemic dilated cardiomyopathy and reduced LVEF with symptomatic heart failure.
- Patients with non-sustained VT due to prior myocardial infarction, reduced LVEF and inducible ventricular fibrillation or sustained VT at electrophysiological study. For further details, please refer to "2008 ACCF/AHA/HRS Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities" and its 2012 Focused Update or "2017 AHA/ACC/HRS Guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death" or "2015 ESC Guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death".

According to the guidelines specified above, ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmia with resynchronization is indicated in:

- Patients who are survivors of cardiac arrest due to ventricular fibrillation or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes.
- Patients with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable.
- Patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or ventricular fibrillation induced at electrophysiological study.
- Patients with reduced LVEF due to prior myocardial infarction who are at least 40 days post-myocardial infarction and with symptomatic heart failure or LV dysfunction.
- Patients with non-ischemic dilated cardiomyopathy and reduced LVEF with symptomatic heart failure.
- Patients with non-sustained VT due to prior myocardial infarction, reduced LVEF and inducible ventricular fibrillation or sustained VT at electrophysiological study.

Biventricular pacing therapy is indicated in patients with symptomatic heart failure despite optimal pharmacological therapy, with reduced LVEF and wide QRS.

For further details, please refer to "2008 ACCF/AHA/HRS Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities" and its 2012 Focused Update or "2017 AHA/ACC/HRS Guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death" or "2015 ESC Guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death". For biventricular pacing therapy, please also refer to "2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy".

1.2.2 Target population(s)

The target populations are patient groups indicated for the implantation of either a pacemaker or a defibrillator, with or without resynchronization, and implanted with a MicroPort CRM device. For further details regarding pacemaker indications, please refer to the "2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy", or the "2012 ACCF/AHA/HRS Focused Update of the 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities". For further details regarding defibrillator indications, please refer to "ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities" or "ACC/AHA/ESC 2006 Guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death". For biventricular pacing therapy, please also refer to "2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy".

1.2.3 Intended user(s)

The CPR4 is intended to be used by electrophysiologists, cardiologists, or specialized nurses and/or technicians trained or experienced in device implant and/or follow- up procedures in order to interrogate and program implantable cardiac devices in a cardiology practice (hospital, clinic, outpatient practice…).

1.3 Contra-indications

No known contraindications to the use of the CPR4.

Any serious incident in relation to the device should be reported to MicroPort CRM and the local Competent Authority.

1.4 Intended Clinical benefits

By using the CPR4, clinicians can improve the patient's treatment in several ways, including changing the implanted device's settings, fine-tuning or adapting the therapy to suit patients' needs, and detecting issues with the implanted device or the lead(s) that may result in a required re-intervention (repositioning, replacement…).

1.5 Warnings and precautions

- Same as the programmer system, the CPR4 is Magnetic Resonance (MR) unsafe. Don't bring the CPR4 into MRI site Zone 3 or 4 as defined by the Guidance Document for Safe MR Practices published by the American College of Radiology[1].
- The equipment must be operated by qualified personnel only: physicians, nurses, technical members of hospital staff, company representatives. All of them being trained and having a comprehensive or partial knowledge of cardiac rhythm management, in keeping with their assigned task: surgery, follow-up, servicing, etc. For additional information please contact your company representative.
- To avoid damage or hazards, NEVER make any changes or modifications to the equipment. For maintenance services and support, please contact your company representative.
- Do not use the CPR4 should there be any sign of visible damage.
- Shocks or rough handling could damage the device's housing. Mishandling may affect the CPR4's operation. Even if the device appears to be operating well after the impact, damage that is not immediately detectable may arise.
- When designing and manufacturing the device, every precaution is taken to minimize the risks of infiltration. However, any liquid penetration shall alter its operation.
- Prolonged storage in a high-humidity location may alter the device's operation. For detailed information about the storage humidity constraints please refer to section 8.6.
- The CPR4 must be stored in a secure and locked room when not in use.
- The CPR4 inductive programming head must come into contact with intact skin only.

1.6 Residual risk and undesirable effects

The potential hazards related to the use of the CPR4 have been carefully evaluated by the manufacturer's risk management team. This evaluation concludes that the residual risk is at the lowest possible level.

This assessment is based on the assumption that the CPR4 is used according to its intended purpose and all of the prescriptions contained in this User Manual are carefully followed.

Based on the literature and on inductive wands' use experience, possible adverse events are:

- Prolonged follow-up programming/real life test sessions
- Non optimal patient management (related to the programming or the diagnosis)

[1] Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007

2 WARRANTY CONDITIONS

The manufacturer agrees to replace any defective material.

If a technical problem occurs, please contact your company representative or the company's service department.

WARNING: Never modify the configuration of the CPR4.

The CPR4 contains no internal parts that can be repaired by the user. In the event of a problem, please return the equipment to your company representative in the condition in which it was received.

The manufacturer waives all responsibility if a malfunction occurs following manipulation by the user as described above.

3 PACKAGE CONTENTS

Inside the box you will find the CPR4 and the related documentation

4 DESCRIPTION

The programming head provides inductive communication between the programmer and the implanted cardiac device.

For detailed information about the compatibility of programming devices and implantable patient devices, please refer to the Device-Compatibility-Matrix that is available under the reference number UA193 at www.microportmanuals.com.

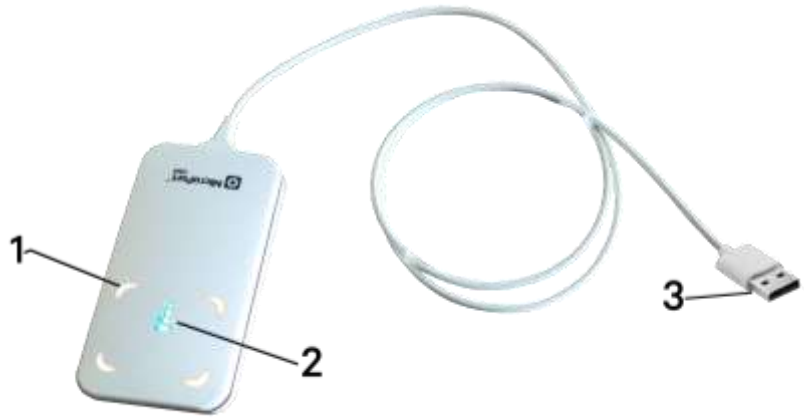
The inductive programming head is used to:

- activate the telemetry,
- identify the implanted device model,
- conduct telemetry in order to communicate with the implanted device when telemetry is performed in inductive mode.

WARNING: there is no magnet in the head. However, it may temporarily disturb the rate response function during interrogation.

4.1 COMPONENTS[2]

[2] Images and diagrams are non-contractual and are for illustrative purposes only.



1) Collimator LEDs (white)	3) USB connector
2) Locator LEDs (blue)	

4.2 CONNECTION TO THE PROGRAMMER

1. Connect the inductive programming head CPR4 to a programmer's USB port.
2. The head is automatically turned on when the programmer is switched on.
3. The programming head is functional when the related icon is displayed in the programmer's User Interface.

Do not unplug the CPR4 cable from the USB port during a follow-up or any telemetry action, as this would stop data transmission and request to restart the entire session.

Same way, if the CPR4 is connected to SmartTouch tablet through the docking station, do not disconnect the tablet from the docking station during a follow-up or a telemetry action.

5 USING THE CPR4

To perform a follow-up, CPR4 has to be placed directly on the patient's intact (unbroken) skin or over his/her clothes above the part of the body where the implanted device has been implanted (usually left and right clavicle). The side with the LEDs shall be facing up.

5.1 How to position the CPR4

The antenna, lying on the bottom side of the head, is positioned corresponding to the zone framed by the collimator LEDs. To help find the best placement, the LEDs behave as follows:

- when the head is not detecting the implant, the LEDs flashing on the opposite corners of the collimator will be alternating;
- when the head detects the implant partially, two of the LEDs will display a steady illumination and the others will be off. This indicates to the user that a full detection is possible by moving the CPR4 in the direction pointed by the LEDs;
- when the implant has fully been detected, all of the collimator LEDs will emit a steady white light, and the array of blue LEDs will enable more accurate positioning to find the optimal level of telemetry, corresponding to a position where all the blue LEDs are illuminated. If not all the blue LEDs are illuminated, the level of telemetry is not optimal and a better positioning is necessary.

The following pictures show how to use the LEDs to find the best position for the CPR4:

	
No detection (pair of white alternating LEDs)	Partial detection (two steady white LEDs). Indication to mode the head downwards.
	
Full detection (four steady white LEDs) but not optimal position (only two blue LEDs)	Full detection (four steady white LEDs) and best position (four blue LEDs)

For optimal telemetry, you are advised to keep the inductive programming head away from electromagnetic interference, which can be generated by any electronic equipment including medical equipment.

Avoid establishing telemetry communication between the programmer and the implanted device when the Programmer is close to monitors, high frequency electrocautery equipment, external defibrillator or strong magnetic fields. The telemetry link might be impaired.

5.2 Troubleshooting

As the CPR4 is powered through the USB port of the programmer, the first requirement for the CPR4 to properly work is that the programmer is fully functional, and suitable for the use with the CPR4. Please consult your MicroPort correspondent in case of any doubt about the compatibility of your programmer with the CPR4.

For the same reason, if the CPR4 does not turn on, check at first that the USB cable is properly and completely inserted into a working USB port of the programmer. Also, try changing ports.

5.3 UPGRADE OF THE PROGRAMMING HEAD'S SOFTWARE

The CPR4 contains a dedicated embedded software. When a new release of this software is available, it will be included in a comprehensive upgrade of the programmer's software (SmartView).

In this case, the first time the head is connected to the programmer after the SmartView upgrade, its software is automatically updated. During this task, the white LEDs on the CPR4 will illuminate in circle, one after the other, while a message on the screen informs the user about the progression.

6 MAINTENANCE

6.1 Cleaning

The CPR4 should never be immersed in any liquid or cleaned with sterilization products. Avoid spilling liquid on the equipment.

In order to clean the CPR4:

1. Visually inspect it for contaminants and remove loose material with a dry or water-moistened cloth.
2. Then clean it with a tissue pad or a wipe moistened with one of the following agents:
   - Ethyl alcohol
   - Isopropyl alcohol

The above-mentioned agents have been tested by the manufacturer, and validated to neither cause physical damage nor degradation to the CPR4.

6.2 Disinfection and sterilization

The CPR4 is delivered non sterile, and cannot be disinfected or sterilized. It must be covered with a sterile sleeve when using in sterile environments.

6.3 System end-of-life

At its end of life, the CPR4 shall be sent back to the manufacturer for recycling.

6.4 Regular maintenance

All of the tasks relative to regular (i.e. periodical, preventive) maintenance of CPR4 consist of cleaning the outer surfaces.

Please note that, in some jurisdictions, local regulation may require the execution of some specific safety inspections.

It is recommended to visually inspect the CPR4 before use.
In case of any visible damage, please contact your MicroPort representative.

7 GUIDANCE AND MANUFACTURER'S DECLARATION

All information below is based on the normative requirements to which the manufacturers of electro-medical devices are subject, in the sense of IEC60601-1-2.

The medical device complies with applicable electromagnetic compatibility standards, however, the user will ensure that any electromagnetic interference does not create an additional hazard, such as radio frequency transmitters or other electronic devices.

In this chapter you will find information necessary to ensure the installation and commissioning of your medical device under the best conditions in terms of electromagnetic compatibility.

The different cords/cables of the medical device must be separated from each other.

Certain types of mobile telecommunication devices such as mobile phones are likely to interfere with the medical device. The separation distances recommended in this chapter must therefore be strictly observed.

The medical device must not be used near or on another device. If this cannot be avoided, it must be checked for proper operation under the conditions of use before use.

There is no risk of reciprocal interference during normal use of the CPR4.

The use of accessories other than those specified or sold by MicroPort CRM as replacement parts, may result in an increase in the emission or a decrease in the immunity of the medical device and may cause an inappropriate operation.

7.1 Radio equipment emission

Transmitter Frequency Bands/ Maximal Power	**Receiver Frequency Bands**
Fast mode: frequency ~70 kHz modulation pulsed, 17.4 dBµA/m at 3m	16kHz
[2400 – 2483,5] MHz ; + 6dBm	[2402 – 2480] MHz

7.2 Recommended separation distances according to the maximum output power of the communications equipment

The CPR4 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

Portable RF communication devices (including peripherals such as antenna cables and external antennas) should not be closer than 30 cm (12 inches) from any part of the programmer. Otherwise, the performance of these devices may be impaired.

7.3 Cable length

Cables and accessories	**Maximum length**	**Test type**	**In compliance with**
Cables/Cords	< 3m	RF emission	CISPR 11, Class B
		Harmonic current emission	IEC61000-3-2
		Voltage fluctuation andflickers	IEC61000-3-3
		Electrostatic discharge immunity	IEC61000-4-2
		Radiated immunity – Electromagnetic fields	IEC61000-4-3
		Electrical fast transient/burst immunity	IEC61000-4-4

		Surge immunity	IEC61000-4-5
		Immunity to conducted disturbances, induced byradio-frequency fields	IEC61000-4-6
		Radiated immunity -Magnetic fields	IEC61000-4-8
		Voltage dips, short interruptions and voltagevariation immunity	IEC 61000-4-11

7.4 Electromagnetic emissions

The programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the programmer should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
Electromagnetic radiation disturbance (radiated EMISSIONS) CISPR 11	Group 1	The programmer uses RF energy only for its own function. Its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
Disturbing voltage at supply terminals con ducted emissions CISPR 11	Class B	The programmer is suitable for use in a professional health care establishment and home care environment.
Harmonic current EMISSIONS IEC61000-3-2	NA	
Voltage variations, voltage fluctuations and flicker IEC61000-3-3	NA	

7.5 Magnetic and Electromagnetic Immunity

The CPR4 is intended for use in the electromagnetic environment specified below. The customer or the user of the CPR4 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Professional health care establishment and home care environment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Professional health care establishment and home care environment.
	± 1 kV for input/output lines	± 1 kV for input/output lines	
Surge IEC 61000-4-5	± 1 kV between phases ± 2 kV between line(s) to earth	NA	Professional health care establishment and home care environment.
Magnetic field at industrial rated frequency (IEC61000-4-8)	30 A/m	30 A/m	Professional health care establishment and home care environment.
Voltage dips (IEC 61000-4-11)	0% *U*T For 0.5 cycle A 0°, 45°, 90°, 135°, 180°, 225°,	0% *U*T For 0.5 cy- cle A 0°, 45°, 90°, 135°, 180°, 225°,	Professional health care establishment and home care environment.

	270° and 315° 0% *U*T for 1 cycle and 70% *U*T for 25 cycles, 50Hz 30 cycles, 60 Hz, Monophase: 0°	270° and 315° 0% *U*T for 1 cycle and 70% *U*T for 25 cycles, 50Hz 30 cycles, 60 Hz, Monophase: 0°	
Voltage Interruptions (IEC 61000-4-11)	0 % *U*T; For 250 cycles, 50 Hz For 300 cycles, 60 Hz	NA	

NOTE: UT is the a.c. mains voltage prior to application of the test level.

7.6 Electromagnetic Immunity, Portable Radio Frequency Equipment

The CPR4 is intended for use in the electromagnetic environment specified below. The customer or the user of the CPR4 should ensure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
ATTENTION: Portable RF communication devices (including peripherals such as antenna cables and external antennae) should not be used closer to 30 cm (12 inches) to the CPR4. Otherwise, the performance of this device may be impaired.			
Radiated RF IEC 61000-4-3 Proximity fields emitted by RF wireless communication devices IEC 61000-4-3 (provisional method)	3 V/m 80 MHz to 2.7 GHz 80% MA at 1 KHz 9 V/m 710 MHz, 745 MHZ, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	3 V/m 80 MHz to 2.7 GHz 80% MA at 1 KHz 9 V/m 710 MHz, 745 MHZ, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	Professional health care establishment and home care environment.
Conducted disturbances, IEC 61000-4-6	3 V 150 kHz to 80 MHz 6V in ISM Band between 0.15 MHz - 80 MHz 80% MA to 1 KHz	3 V 150 kHz to 80 MHz 6V in ISM Band between 0.15 MHz - 80 MHz 80% MA to 1 KHz	Professional health care establishment and home care environment.

7.7 Raw materials

Item	Material	Description
Plastic parts	Cycoloy C2100 HF (ABS/PC, UL 94 V-0, White RAL9016)	POLYCARBONATE ABS (ABS-PC) White for outer parts and grey for the middle part
Label	Glossy white polyester B423	POLYESTER
Main cable	Polyurethane (UL 94 V-2)	PU
Non-slip pad	Polyurethane Bumpon SJ6032 Black	PU

8 TECHNICAL DATA

8.1 Conformity of the device

Conformity with European Regulation and Directive(s)	MDR 2017/745, 2014/53/EU 2012/19/EU (WEEE) 2011/65/EU (RoHS) Regulation (EC) 1907/2006 (REACH)
Patient safety	IEC 60601-1, Class I, BF Type
EMC	IEC 60601-1-2 EN 301 489-1 EN 301 489-31
ERM	EN 302-195 EN 62311: 2020 FCC CFR 47

8.2 FCC

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation of the device.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

CAUTION: This equipment may not be modified, altered, or changed in any way without signed written permission from MicroPort CRM. Unauthorized modification may void the equipment authorization from the FCC and will void the MicroPort CRM warranty.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines.

This equipment has very low levels of RF energy that is deemed to comply without testing of specific absorption rate(SAR).

8.3 Performances

8.3.1 PERFORMANCE CHARACTERISTICS

The table below describes the performance characteristics of the programmer (including programming software) making use of a CPR4.

Performance	Value
Interrogation time	Less than 60 seconds
AIDA reading time	No more than 180 seconds
Number of telemetry issues	No more than 5 errors per minute
Number of telemetry errors pop-ups	No more than 1 pop-up per session

8.3.2 ESSENTIAL PERFORMANCE (REFERRING TO 60601-1-2 STANDARD)

The essential performance of the CPR4 is to ensure data integrity when it reads data from the MicroPort implantable device and when it programs data in the implantable device. Should the CPR4 essential performance deteriorate, it could induce an inappropriate clinical or medical treatment (wrong interpretation of data read or misprogramming).

8.4 Dimensions

Height	136 mm
Width	73 mm
Depth	23.5 mm
Weight	0.300 kg

8.5 Use constraints

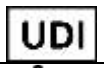
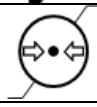
Temperature	From +0 °C to +35 °C (non-condensing)
Humidity	From 5% to 95 % HR (non-condensing)
Pressure	From 700 to 1060 hPa

8.6 Storage constraints

Temperature	From -20 °C to +70 °C (non-condensing)
Humidity	From 5% to 95% HR (non-condensing)
Atmospheric pressure	From 500 hPa to 1060 hPa

9 EXPLANATION OF SYMBOLS

General symbols	Explanation of symbols
	This symbol concerns the inductive programming head. It indicates that this is a BF Type applied part, according to standard IEC 60601-1 for electrical medical equipment.

	This electronic product is subject to disposal and recycling regulations that vary by country and region. Many countries prohibit the disposal of waste electronic equipment in standard waste receptacles. For more details, please refer to the European Directive 2012/19/EU (WEEE).
	The device is compliant with ACMA rules.
	This symbol confers the approval of the US Federal Communications Commission.
	This device holds the Bureau Veritas NTRL/SCC Mark
	Conformité Européenne (European Conformity)
	Consult the documentation and instructions for use.
	Magnetic Resonance (MR) unsafe.
	Consult instructions for use available on the company website www.microportmanuals.com.
	This icon is used to call your attention to a particularly important point.
	Manufacturer
	Medical Device
	Product reference number.
	Product serial number.
	Unique Device Identifier
	This symbol indicates the minimum and maximum storage temperature.
	This symbol indicates the minimum and maximum storage humidity.
	The product should be kept dry.
	This symbol indicates the minimum and maximum storage pressure.
	This icon alerts you to a hazard that may result in equipment damage or personal injury. Carefully read the instructions provided with this icon.

10 GLOSSARY

Term	Meaning
AC	Alternated current
ACMA	Australian Communication and Media Authority
ANSI	American National Standard Institute
AAMI	Association for the Advancement of Medical Instrumentation
BF Type	Applied part with high protection against electrical shock
CISPR	International Electrotechnical Commission (Comité International Spécial des Perturbations Radioélectriques)
CPR4	Inductive Programming Head
ECG	Electrocardiogram
EEC	European Economic Community
EMC	Electromagnetic Compatibility
ERM	EMC and Radio Spectrum Matters
FCC	Federal Communications Commission
IEC	International Electrotechnical Commission
I/O	Input/Output
LED	Light Emitting Diode
MR	Magnetic Resonance
RF	Radiofrequency
USB	Universal Serial Bus

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

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MicroPort

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