SMART SPOT™

KC861

USER'S MANUAL

USA with mobile communication

MicroPort™ CRM | SORIN

English

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ABOUT THIS MANUAL

Your doctor should be your first source of information regarding your health.

This manual addresses many of the questions you or your family may have about your Smart Spot and its use. In this manual the patient can be considered as an intended operator.

If you have technical or usage questions that are not covered in this manual or you want more in-depth information, please contact MicroPort technical assistance.

1. INTRODUCTION

The Smart Spot you received is part of the SMARTVIEW Remote Monitoring System. This system has been specially designed to transmit information stored in your MicroPort implanted cardiac device to your doctor on demand. Your MicroPort cardiac device is equipped with a transmitter which sends clinical information and device parameters to your doctor through the Smart Spot using a telemetry head. The data retrieved by your Smart Spot is routed through the mobile phone network, converted to a format that can be reported to your doctor.

The SMARTVIEW Remote Monitoring System designed by MicroPort can be used only on a doctor's instruction.

The Smart Spot sends data to a back office managed and controlled by MicroPort.

2. INDICATION

The Smart Spot is indicated for the remote follow up of patients who are implanted with a MicroPort implanted cardiac device only according to the applicable Medical Guidelines (2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay, Journal of the American College of Cardiology (2018)).

3. USER PROFILE

Any person who was prescribed for remote monitoring by and under supervision of a physician.

4. WARNINGS AND PRECAUTIONS

4.1. WARNINGS

The SMARTVIEW Remote Monitoring System is not intended as an emergency response system.

If at any time you feel that you need a fast response, CALL YOUR LOCAL EMERGENCY SERVICE IMMEDIATELY.

4.2. SAFETY PRECAUTIONS

Alteration – Your Smart Spot and supplied parts shall not be modified, altered, or changed in any way without signed written permission from MicroPort. Unauthorized modification may void the equipment authorization from the FCC and will void the MicroPort warranty. Use only MicroPort supplied parts.

Keep out of the reach of children – Do not let children touch the Smart Spot.

Environmental factors – To reduce the risk of fire, electric shock and personal injury, do not expose this appliance to rain, moisture or extreme temperatures and avoid any installation or Patient Initiated Transfer operation during an electrical storm. If the Smart Spot is damaged due to a shock or liquid exposure, do not plug it in again and call our MicroPort technical assistance.

Keep the device dry – Keep it away from moisture and do not spill or drip liquids on it.

Keep the cables free – Do not use the cables for any purpose other than for performing a transmission.

Mobile communication – Keep the Smart Spot more than 20 cm (8 inches) away from your body while it is transferring the data to your doctor (Step 7 of §6.1 Normal functioning).

For continued IP21 protection (from solid and liquid body intrusions) - Do not remove the silicon sleeve from the USB connector.

4.3. PRECAUTIONS FOR SAFE OPERATION

Location – The Smart Spot should be placed in a stable position during its normal utilisation. It is recommended that the Smart Spot not be used adjacent to or stacked with other equipment but if adjacent or stacked use is unavoidable, verify that the equipment operates normally in the configuration in which it is intended.

Power supply – The Smart Spot should be connected exclusively to a MicroPort power adaptor.

Power supply protection – Power adaptors should be routed so they are not likely to be walked on or pinched by items placed on or against them.

Power supply disconnection – The power socket must be near the Smart Spot and easily accessible. The power socket isolates the Smart Spot circuits from the supply mains. You can only remove power from the Smart Spot by disconnecting the power adaptor from the outlet. Always carefully disconnect all plugs by pulling on the plug and not on the cord.

English

Wireless communication – The Smart Spot is designed for use with a mobile phone network. It is intended to transmit your personal data using a mobile phone operator. The operator and number to call are pre-configured, there is nothing to set up.

Check button – Do not press the Check button on the bottom of the Smart Spot unless requested to do so by our MicroPort technical assistance.

Interference – Using Smart Spot may potentially disturb your TV. You are advised to switch off the TV while using Smart Spot.

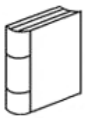
5. FAMILIARIZE YOURSELF WITH YOUR SMART SPOT

5.1. PACKAGE CONTENTS

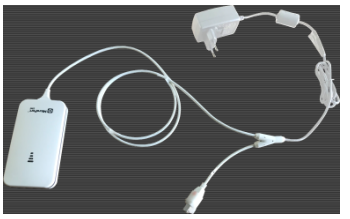
Inside the box you will find:

1 Smart Spot

Silicon sleeve (do not remove from the USB connector)



User manual



1 Power supply (European plug) with telemetry head

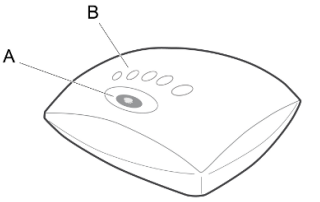
— 1 Power adaptor for United Kingdom

— 1 Power adaptor for Australia

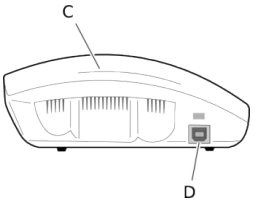
— 1 Power adaptor for Japan / United States

Do not use any other parts than those supplied with the Smart Spot, as this may result in increased emissions or decreased immunity of the equipment.

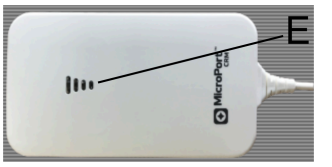
5.2. DESCRIPTION OF CONTENTS



***A:** Patient Initiated Transfer button (PIT button).*
***B:**Progression lights.*



***C:** Status light.* ***D:**Power supply inlet (cable with the orange mark).*



***E:** The array of blue LEDs is a locator.*

***F:** The whole underside is a Type BF applied part.*

6. USING YOUR SMART SPOT

The Smart Spot can only be used upon your doctor's request.

6.1. NORMAL FUNCTIONING

In order to use your Smart Spot quickly, easily and safely, follow the instructions in the table below. If you need any help please call our technical assistance (see phone numbers in the separate leaflet). Our technicians will assist you. It takes little time.

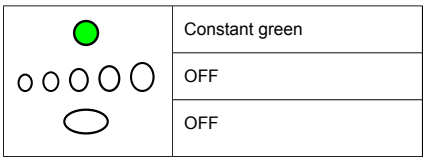
1. Take all the items out of the box.
2. Place the Smart Spot in a stable position.
3. Plug the end of the cable with the orange mark into the appropriate inlet in the Smart Spot identified with the same orange mark.

For continued IP21 protection (solid and liquid body intrusions protection), do not remove the silicon sleeve from the USB connector.

4. Plug the power supply block into the mains.

   You should observe the following:

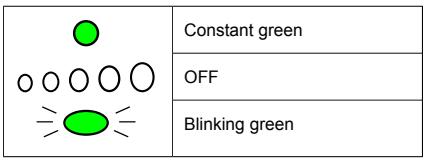
   The status light turns steady amber for around 45 seconds and then turns green as shown below.



   Your Smart Spot is now ready to operate.

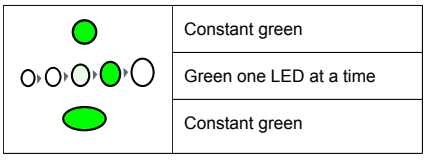
5. Place the telemetry head on your chest over your implanted device. (You can place the telemetry head over your clothes).

   When the telemetry head detects your device, the PIT button blinks green (status LED is already ON, constant green and progression lights OFF) as shown below:



   Keep the telemetry head in this position.

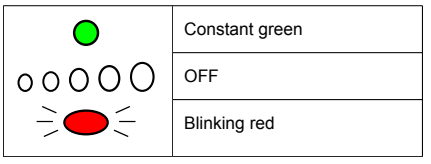
6. Press the PIT button until you feel a click. You will see the PIT button turn constant green, and the progression lights light up one after the other from left to right, as shown below:



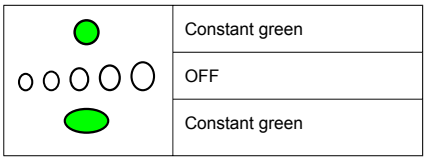
   Keep the telemetry head in this position until the progression bar turns OFF.

   Should the PIT button blink red, and the progression bar turn OFF, your telemetry head is not properly placed over your cardiac device.

   Reposition the telemetry head over your implanted device as indicated in step 5.

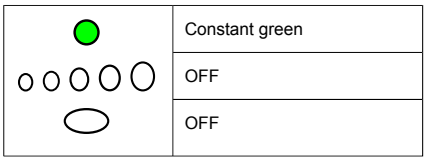


7. When the progression bar is OFF (status led and PIT button are ON), remove the telemetry head from your chest.



   Your Smart Spot is currently transferring your data to your doctor. DO NOT TOUCH THE Smart Spot.

8. The transmission is successful once the PIT button turns OFF.



   You can now unplug your Smart Spot.

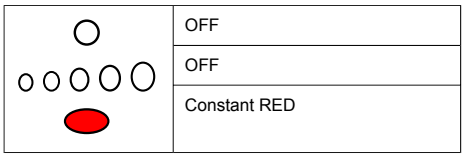
If the PIT button turns a constant RED, please refer to chapter 6.2.

To operate properly, your Smart Spot should be connected to the mains power outlet during the whole process.

6.2. POSSIBLE ISSUES DURING TRANSMISSION

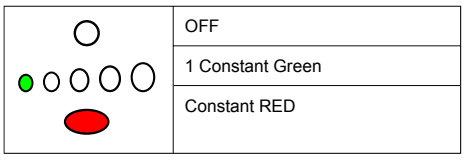
If the PIT button is a constant red, this means that the transmission could not occur. The reasons are shown on your Smart Spot with the PIT button and the progression bar.

Please refer to the diagrammes below and follow the recommended actions. Should the behaviour continue, please call our technical assistance.



Meaning: Smart Spot detected an internal issue *(self test)*.

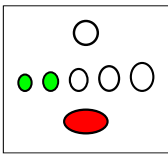
Action: Unplug the Smart Spot and plug it back in again, then proceed to transmission.



Meaning: The Smart Spot cannot interrogate the device.

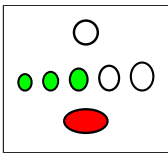
Action: Unplug the Smart Spot and plug it back in

again, then proceed to transmission.

	OFF
	2 Constant Green
	Constant RED

Meaning: The implanted device is not compatible with the Smart Spot. It cannot be interrogated.

Action: Contact MicroPort technical assistance for guidance.

	OFF
	3 Constant Green
	Constant RED

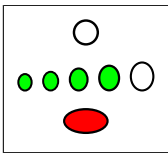
Meaning: The Smart Spot cannot connect to the network.

Action:

— Unplug the Smart Spot.

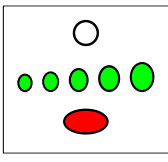
— Move it to another location to recover cell signal.

— Plug the power supply block into the mains, then proceed to transmission.

	OFF
	4 Constant Green
	Constant RED

Meaning: The Smart Spot can connect to the network, but data cannot be transferred.

Action: Contact technical assistance for guidance.

	OFF
	5 Constant Green
	Constant RED

Meaning: Patient is not enrolled in the SMARTVIEW remote monitoring system.

Action: Contact the clinic who has to enroll patient details in the SMARTVIEW website before any new transmission.

7. TRAVELING

To know whether your Smart Spot will operate in the country where you travel, please call our technical assistance who will give you relevant instructions.

8. SMART SPOT BASIC CARE

Your Smart Spot has been designed to successfully pass the safety and regulatory standards. To maintain your Smart Spot in proper working order, prevent it from being splashed with any kind of liquid. If you need to clean it, please use only a soft dry cloth. Any other cleaning method could damage your Smart Spot. Do not use any kind of detergents even dry ones.

9. MAINTENANCE AND RECYCLING

The Smart Spot requires no maintenance.

As with all electronic devices, recycling your Smart Spot is mandatory, therefore please return it to MicroPort if it no longer functions, or you no longer use or need it.

Please contact our MicroPort technical assistance for more information on the collection procedure. MicroPort will be in charge of its collection and recycling.

10. FAQ

Why do I need to be monitored?

You have been advised to use MicroPort's Smart Spot so that your doctor can closely follow your heart disease and identify potential needs for adjustments to your treatment. Should you have any questions or need further information, please contact your doctor.

What should I do if I don't feel well?

When experiencing symptoms, you should call your doctor or your local emergency service. Our technology does not replace them under any circumstances.

Does the communication cost me anything?

The communication will be free of charge.

Our Smart Spot does not use your personal phone lines to transfer information to your doctor. It uses an embedded communication system, and costs are covered by MicroPort.

11. TECHNICAL SPECIFICATIONS

If you suspect any kind of fault, please call our MicroPort technical assistance. Our technicians will help you and investigate if needed.

Part number	KC861
Dimensions of the Smart Spot	Height: 59 mm Width: 156 mm Depth: 122 mm
Weight of the Smart Spot	250 g

Power supply	AC input: 100-240V ~ 50-60Hz 600 mA (to wall socket) Class II
Telemetry head	Type BF applied part on the lower side of telemetry head (applied part temperature can reach a maximum of 45°C/113°F)
Operating conditions	from 0°C to +35°C (32 °F to 95 °F) from 5% to 93% RH non condensing
Transport and storage conditions	from -15°C to +70°C (5 °F to 158 °F) from 5% to 90% RH non condensing
Transport and storage Atmospheric air-pressure limits	Min: 700 hPa Max: 1060 hPa
Telemetry head transmitter	frequency ~25 kHz modulation pulsed -10 dBµA/m at 10m
Telemetry head receiver	Preferred frequencies: 8 KHz, 16 KHz
Modem	Class 4 (33dBm ± 2dB) for GSM 850 Class 1 (33dBm ± 2dB) for GSM 1900 Class 3 (24dBm +1/-3dB) for WCDMA (B2/B4/B5) Class 3 (23dBm ± 2dB) for LTE FDD (B2/B4/B5/B7/B12/B13/B25/B26) Class 3 (23dBm ± 2dB) for LTE TDD (B38/B41) FCC approvals

11.1. RADIO EQUIPMENT EMISSION

Radio Equipment	Transmitter Frequency Bands/ Maximal Power	Receiver Frequency Bands
Inductive Telemetry CPR4BR	frequency ~25 kHz modulation pulsed -10 dBµA/m at 10m	8kHz, 16kHz

Radio Equipment	Transmitter Frequency Bands/ Maximal Power	Receiver Frequency Bands
Modem 2G/3G/4G Quectel EG25-G	Class 4 (33dBm ± 2dB) for GSM 850 Class 1 (33dBm ± 2dB) for GSM 1900 Class 3 (24dBm +1/-3dB) for WCDMA (B2/B4/B5) Class 3 (23dBm ± 2dB) for LTE FDD (B2/B4/B5/B7/ B12/B13/B25/B26) Class 3 (23dBm ± 2dB) for LTE TDD (B38/B41) FCC approvals	B2: 1900 MHz B4: 1700 MHz B5: 850 MHz B7: 2600 MHz B12: 700 MHz B13: 700 MHz B25: 1900 MHz B26: 850 MHz B38: 2600 MHz B41: 2500 MHz

The Smart Spot may be subject to interference by other equipment, even if the equipment complies with CISPR emission requirements.

11.2. RAW MATERIALS

The following materials (CPR4BR) may remain in contact with body tissues.

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 polyesther B423	POLYESTER
Main cable	Polyurethane (UL 94 V-2)	POLYURETHANE

12. DATA PROTECTION

MicroPort CRM undertakes to take all necessary security measures to protect the clinical data and in particular to strictly restrict access to it. For any information regarding processing of your personal data, please refer to the information and patient consent that you have signed with your physician who is the data controller.

13. DECLARATION OF CONFORMITY

The FCC Product ID is YSGKC861, which contains FCC ID: XMR201903EG25G.

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 interference by one or more 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 circuit different from that to which the receiver is connected.
— Consult the dealer or an experienced radio/TV technician for help.

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.

This device complies with FCC RF radiation exposure limits set forth for general population. This device must be installed to provide a separation distance of at least 20cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

14. ELECTROMAGNETIC COMPATIBILITY

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 of the medical device must be kept separate 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. 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.

14.1. 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 and flickers	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 by radio-frequency fields	IEC61000-4-6
		Radiated immunity - Magnetic fields	IEC61000-4-8
		Voltage dips, short interruptions and voltage variation immunity	IEC 61000-4-11

14.2. ELECTROMAGNETIC EMISSIONS

The Smart Spot is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart Spot 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 Smart Spot uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
Disturbing voltage at supply terminals conducted emissions CISPR 11	Class B	The Smart Spot is suitable for use in home health care environment and a professional health care establishment.
Harmonic current emissions IEC 61000-3-2	Class A	
Voltage variations, voltage fluctuations and flicker IEC 61000-3-3	Complies	

14.3. ELECTROMAGNETIC IMMUNITY

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Home health care environment and Professional health care establishment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Home health care environment and Professional health care establishment.
	± 1 kV for input/output lines	± 1 kV for input/output lines	
Surge IEC 61000-4-5	± 1 kV between phases	± 1 kV between phases	Home health care environment and Professional health care establishment.
	± 2 kV between line(s) to earth	± 2 kV between line(s) to earth	
Magnetic field at industrial rated frequency (IEC61000-4-8)	30 A/m	30 A/m	Home health care environment and Professional health care establishment.
Voltage dips (IEC 61000-4-11)	0% U_T For 0.5 cycle A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle and 70% U_T for 25 cycles, 50Hz 30 cycles, 60 Hz, Monophase: 0°	0% U_T For 0.5 cycle A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle and 70% U_T for 25 cycles, 50Hz 30 cycles, 60 Hz, Monophase: 0°	Mains power quality should be that of a Home health care environment or Professional health care establishment. If operation of the system requires continued use during power cuts, it is recommended that the medical device be powered by a separate power source (UPS, etc.).

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage Interruptions (IEC 61000-4-11)	0 % U_T; For 250 cycles, 50 Hz For 300 cycles, 60 Hz	0 % U_T; For 250 cycles, 50 Hz For 300 cycles, 60 Hz	Mains power quality should be that of a Home health care environment or Professional health care establishment If operation of the system requires continued use during power cuts, it is recommended that the medical device be powered by a separate power source (UPS, etc.).

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

14.4. ELECTROMAGNETIC IMMUNITY, PORTABLE RADIO FREQUENCY EQUIPMENT

WARNING: Portable RF communication devices (including peripherals such as antenna cables and external antennae) should not be used closer than 30 cm (12 inches) on any part of the Smart Spot, including the cables specified by the manufacturer. Otherwise, the performance of these devices may be impaired.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electromagnetic fields Radiated RF (IEC 61000-4-3)	10 V/m 80 MHz – 2,7 GHz 80 % MA at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % MA at 1 kHz	Home health care environment and Professional health care establishment.
Proximity fields emitted by RF wireless communication devices IEC 61000-4-3 (provisional method)	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	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	Home health care environment and Professional health care establishment.
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 Amateur band includes 80% MA at 1 KHz	3 V 150 kHz to 80 MHz 6V in ISM Band between 0.15 MHz - 80 MHz 80% MA to 1 KHz Amateur band includes 80% MA at 1 KHz	Home health care environment and Professional health care establishment.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

14.5. RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE SMART SPOT

The Smart Spot is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Smart Spot can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Smart Spot as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

15. INTENDED USE AND ESSENTIAL PERFORMANCE

The Smart Spot's intended use is to:

1. Collect Patient data from a MicroPort implanted brady cardiac device using a telemetry head.
2. Transfer collected Patient data to a data management system through a mobile telephone line.

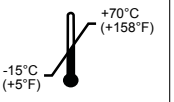
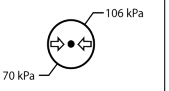
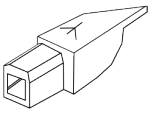
The essential performance of the Smart Spot is to ensure data integrity when it transfers data from a MicroPort implanted cardiac device to the central data management system. Should the Smart Spot's essential performance deteriorate, a new transmission or an in-clinic follow up could be necessary.

16. TECHNICAL ASSISTANCE

For any assistance or question you may have about your Smart Spot, please call our MicroPort technical assistance. Our technical assistance is open from Monday to Friday local time, except on public holidays. See the leaflet “Technical assistance numbers” to know which number corresponds to your country.

17. EXPLANATION OF SYMBOLS

Symbols	Explanation of symbols
IP21	Protected against solid foreign objects of 12.5 mm diameter and greater Protected against vertically falling water drops
	Follow instructions for use.
	Follow instructions for use.
FC	This symbol confers the approval of the US Federal Communications Commission.
CE	This symbol indicates that the device is in full conformity with European Directive 90/385/EEC and R&TTE Directive 1999/5/EC.
	The Giteki Mark indicates that the device complies with Japanese Radio Law.
	Name and address of the manufacturer
	Date of manufacture
	This symbol concerns the telemetry head. It indicates that this is a BF Type part, according to standard IEC 60601-1 for electrical medical equipment.
SN	Serial number
	Keep the device dry – Keep it away from liquid and do not spill or drip water on it.
	The Smart Spot shall be powered only with direct current. The power block packaged with your Smart Spot fulfils this requirement.

Symbols	Explanation of symbols
	Humidity limits for storage and transportation.
	Temperature limits for storage and transportation.
	Atmospheric pressure limits for storage and transportation.
	This symbol indicates that the device is in full conformity with ACMA regulatory arrangements.
REF	Device reference
	USB Type B Power supply connector for Smart Spot.
	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.
	Medical equipment with respect to electric shock, fire, and mechanical hazards, only in: — AAMI/ES 60601-1(2006) / A2 (2010) — CSA 22.2 NO 60601-1 CAN/CSA:2008
	This icon is used to call your attention to a particularly important point.
	This icon alerts you to a hazard that may result in equipment damage or personal injury. Carefully read the instructions provided with this icon.

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CAUTION:

FEDERAL LAW RESTRICTS THIS DEVICE

TO SALE BY OR ON THE ORDER OF A PHYSICIAN

2020-03

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