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Merlin™

Patient Care System



1	PURPOSE & SCOPE	2
2	INTRODUCTION / INTENDED USE	2
3	GENERAL INSTALLATION INSTRUCTION	2
4	MERLIN ANTENNA TECHNICAL DATA	3
5	ELECTROMAGNETIC COMPATIBILITY	4
6	RF OPERATING FREQUENCIES	5
7	MERLIN ANTENNA SPECIFIC SYMBOLS.....	6

1 Purpose & Scope

This document includes the User's Manual input for the Merlin™ Antenna Model 3638 related to show compliance of this device.

The final user manual for Merlin™ Antenna Model 3638 will be included in the manual for Merlin™ Patient Care System Model 3650.

2 Introduction / Intended use

The Merlin™ Antenna Model 3638 is a dedicated radio antenna accessory designed to enable radio frequency (RF) communication between the Merlin™ Patient Care System (Merlin PCS) Model 3650 and St. Jude Medical® implantable devices with RF communication capability.

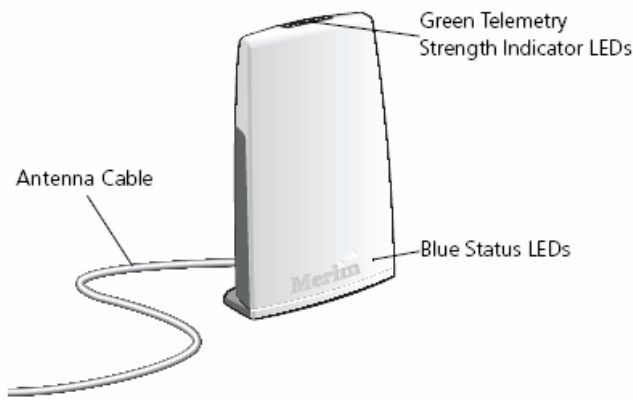


Figure 1. Merlin™ Antenna Model 3638

3 General installation instruction

1. Turn off the Merlin PCS.
2. Open the storage compartment door of the Merlin PCS and locate the RF Telemetry port. Connect the cable from the Merlin Antenna to the RF Telemetry port labeled:
3. Place the Merlin Antenna on a flat surface approximately 1-2m (2-6 ft) from the implantable device. The front panel should face the device.
4. When the Merlin PCS is turned on, the status LEDs on the Merlin Antenna will light, indicating the unit is powered and operational, see Figure 1.
5. When the Merlin PCS startup screen appears, the "Ready to connect to device" icon appears under the Tools menu button, see Table 1.

Disconnected Antenna/ Not Working	Ready to connect to device	Active RF telemetry connection	Inactive RF telemetry connection
Startup Screen Icons		Application Icons	

Table 1. RF Telemetry icons

6. Place the inductive telemetry wand over the patient's device.
7. On Merlin PCS, select the Interrogate button. On the FastPath™ Summary Screen, the "Active RF telemetry connection" icon appears under the Tools menu button, see Table 1.
8. The Telemetry Strength Indicators on the Merlin Antenna and the Merlin PCS indicate RF telemetry communication between the Antenna and the device. A single lighted LED indicates telemetry is established. A greater number of lighted LEDs indicates greater signal strength. If necessary, relocate the Antenna for better communication.
9. Once RF telemetry is established, you may remove the inductive telemetry wand from the patient. Begin the programming session.

CAUTION

The Model 3638 Antenna is only allowed to be connected to the Merlin PCS.

Position the Merlin Antenna at least 20 cm from the patient and from any device connected to the Merlin PCS wireless port.

Do not use the Merlin Antenna if its enclosure is damaged.

A section related to trouble shooting RF will also be included in the User's Manual for the Merlin Antenna:

Suboptimal RF communication: The Merlin PCS indicates the quality of the RF communication by the telemetry strength indicator LEDs on both the programmer and the Merlin Antenna. Below is a list of potential causes to suboptimal radio communication:

Possible Causes	Solutions
The Merlin Antenna orientation/location is suboptimal.	Move or reorient the Antenna slightly. Make sure that the front of the Antennafaces the implantable device.
People or objects interfere with the communication between the Antenna and the device.	Make sure that the space between the Antenna and the device is free from interfering objects/people.
The Antenna is too far away from the device.	Move the Antenna closer to the device.
Somone is holding the Antenna.	Place the Antenna on a flat surface. Do not hold the Antenna.
Other products in the vicinity are causing electromagnetic interference (EMI).	Power off or remove equipment that could cause EMI.
The Antenna cable is wound around the Antenna.	Make sure the Antenna cable is not wound around the Antenna.

4 Merlin Antenna Technical data

Mechanical

Length	5.0 cm
Width	10.3 cm
Height	15.3 cm
Case material	High-impact plastic

Cord to Merlin™ PSC 2.9 m

Electrical

Dokumentnamn / Title RF Compliance input to Merlin™ Antenna Model 3638 User's Manual
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Input power (mains)	Powered by Merlin™ PSC
Input voltage	5.0 V
Maximum current consumption	0.5 A
Expected Service Life	10 years

5 Electromagnetic Compatibility

The Merlin Antenna requires special precautions with regard to electromagnetic compatibility (EMC) and should be used in accordance with the information provided in this manual.

The Merlin Antenna complies with the requirements of the international EMC standard IEC 60601-1-2:2001.

The Merlin Antenna is intended for use in the electromagnetic environment specified in Table 2 and Table 3.

WARNING

The Merlin Antenna is intended for use only by healthcare professionals. It complies with the limits for medical devices contained in IEC/EN 60601-1-2:2001.

However, the Merlin Antenna may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to mitigate this effect by reorienting or relocating the receiving device or shielding the location.

Test	Compliance	Electromagnetic Environment – Guidance
RF Emission CISPR 11	Group 1	The Merlin Antenna must emit electromagnetic energy in order to perform its intended function. This is identified by the RF Transmitter symbol (Section 6). Nearby electronic equipment may be affected.
	Class A	The Merlin Antenna can be used in those establishments that are directly connected to the public low-voltage power supply network that supplies commercial buildings and in domestic environments under the supervision of healthcare professionals.

Table 2. Guidance and manufacturer's declaration – electromagnetic emissions

Test	IEC 60601 Test Level (Actual Level)*	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact (±6 kV contact) ±8 kV air (±8 kV air)	None
Power Frequency (50/ 60 Hz) Magnetic Field IEC 61000-4-8	3 A/m (3 A/m)	None
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms (3 Vrms) 150 kHz to 80 MHz 3 V/m (3 V/m) 80 MHz to 2.5 GHz	Interference may occur in the vicinity of equipment marked with the RF Transmitter symbol (Section 6).

Table 3. Guidance and manufacturer's declaration – electromagnetic immunity

* Figures in parentheses are the immunity compliance levels for each test.

6 RF Operating Frequencies

Nearby equipment emitting strong fields can interfere with the RF telemetry, even if the other equipment complies with CISPR emission requirements. The operating characteristics are as follows:

Merlin Antenna:

- MICS band: 402-405 MHz. The effective radiated power is below the limits as specified in:
 - Europe: EN ETSI 301 839-2
 - USA: FCC 47 CFR Part 95; 95.601-95.673 Subpart E, 95.1201-95.1219
- 2.45 GHz. The effective radiated power is below the limits as specified in:
 - Europe: EN ETSI 300 328
 - USA: FCC part 15.249

WARNING

This transmitter is authorized by rule under the Medical Implant Communications Service (part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (i.e. transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.”






Note

Maintain a reasonable distance between other electronic equipment and the Merlin Antenna.

Dokumentnamn / Title

RF Compliance input to Merlin™ Antenna Model 3638 User's Manual

7 Merlin Antenna specific symbols

<p>RF Telemetry</p> 	<p>Connection to the RF Telemetry port of Merlin PCS</p>
	<p>Follow instructions for use</p>
	<p>Intertek Listed US and Canada. Conforms to UL STD 60601-1. Certified to CAN/CSA C22.2 STD No.601.1</p>
	<p>Interference may occur in the vicinity of this equipment.</p>
	<p>Affixed to this device in accordance with European Council Directive 90/385/EEC and 1999/5/EC.</p> <p>Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of these Directives.</p>
<p>SN</p>	<p>Serial number</p>
<p>FCC ID: RIASJMRFANT</p>	<p>FCC US</p>