Merlin@home™

Transmitter
Model EX1150, EX1150W

User's Manual

Abbott

Contents

Introduction

Your doctor has given you the Merlin@home™ transmitter that is part of the Abbott Medical Merlin@home Remote Monitoring System. This manual describes this system and explains how to set up and use the transmitter.

What Does the Merlin@home™ Transmitter Do?

The Merlin@home™ transmitter conducts your Merlin@home session. During your Merlin@home session, the transmitter reads the information from your implanted device and sends it to a server where your clinic can view it. This information includes:

- The type and serial number of your device
- The settings for your device
- What has happened since your last follow-up session
- Battery status of your device

Your transmitter can perform a status check on your device.

Your device continues to work normally while the transmitter reads the information. Your doctor can use this information to help check the status of your device.

Depending on the transmitter provided by your doctor (either EX1150 or EX1150W), your Merlin@home transmitter works with the following:

Model EX1150

- landline telephone (landline)
- cellular adapter
- wireless broadband kit

Model EX1150W

- cellular adapter
- wireless broadband kit

  NOTE:

  - Only your clinic, and Technical Support (page 6) if requested by your doctor, can view the confidential information you send during your Merlin@home session.
  - The Merlin@home transmitter model EX1150W is not available in all geographies.

The Merlin@home Transmitter is contraindicated for use with any implanted medical device other than supported Abbott medical implanted devices.

The intended users of the Merlin@home transmitter include the following:

- Clinician, which includes implanting physician, managing cardiologist or electrophysiologist, and allied health professionals
- Patient and caregiver
- Abbott Medical field staff such as technical service specialists, field clinical engineers, and sales representatives

Using your Merlin@home™ Transmitter with a Cellular Adapter

The Merlin@home™ transmitter models EX1150 and EX1150W can be used with the cellular adapter provided with your transmitter. For more information, see the Merlin@home Start Up Guide.

Using your Merlin@home™ Transmitter with a Wireless Broadband Kit

The Merlin@home™ transmitter models EX1150 and EX1150W can be used with a wireless broadband kit. For more information, see the Merlin@home Start Up Guide.

Using your Merlin@home™ Transmitter with your Landline

The following information is applicable if you are using a landline to connect the transmitter. If you are using the cellular or wireless broadband adapters to connect the transmitter, a landline is not needed.

The Merlin@home™ transmitter plugs into your landline, see Setting Up the Transmitter (page 4), and uses the telephone network to send information to the server, where your clinic can view the information. As far as your landline is concerned, this is like any other call to a toll-free number within the United States and Canada.

Before your Merlin@home session starts, you must hang up all phones. If someone calls during your session, you receive a Can't Send Information message. For more information, see the Merlin@home Start Up Guide.

When the transmitter is not reading or sending information, it is idle. Leaving the transmitter connected to your landline does not affect your landline's normal operation. You can still make and receive calls.

NOTE: At any time during your Merlin@home session, you can interrupt your session to use the landline. If you do not hear a dial tone when you pick up your landline handset, hang up and pick up your handset again. If your Merlin@home session is interrupted, the transmitter may display a Can't Send Information message. If so, press the Start button and the transmitter will attempt to send your information at a later time.

To use the Merlin@home™ transmitter, your landline service provider must support touch-tone dialing. You must use a push-button telephone with a standard landline plug (RJ-11). Your wall phone jack must also accept a standard plug. If you have an older plug or jack, you can purchase an RJ-11 adapter that allows you to use the transmitter.

NOTES:

- If your landline is wired into the wall, you cannot use the transmitter unless you install standard wall phone jacks. To do this, contact the telephone company for help.
- If DSL shares your telephone line, contact your DSL service provider for a filter to prevent any possible interference. Plug the filter into the wall phone jack and plug the phone connector into the filter. For more information on how to use the filter, contact your DSL service provider.

  CAUTION: The transmitter is designed for use with direct analog landlines. It may be damaged by any other type of phone line. See Technical Support (page 6).

Can You Use the Transmitter While Traveling?

The Merlin@home™ transmitter works within your country, but it might not work outside your country. The typical recommendation is to take your transmitter only if you are going to be away from home for a long periods of time. Check with your doctor before traveling with the transmitter.

If your doctor recommends not traveling with the transmitter, leave your transmitter plugged in at home and it will read your device information when you return home.

If your doctor agrees that it is all right, carefully repackage the transmitter in its original packaging.

- If you are using a landline with your Merlin@home transmitter, you may want to purchase a standard plug adapter in case you need to plug the transmitter into an older wall phone jack.
- If you are using a connectivity accessory such as a cellular adapter, ensure that you bring your cellular adapter with you.

Important Safeguards

Always follow basic safety precautions when using electrical products, especially when children are present. These include:

- Read all instructions before using.
- Keep these instructions.

  WARNING: For emergencies, call 911

- **Do not spill any liquid on the transmitter. If you spill any liquid, unplug the transmitter and wipe the liquid off right away. Do not plug the transmitter in until it is completely dry.**

To reduce the risk of shock:

- Do not use the transmitter while bathing.
- Do not place or store the transmitter where it can fall or be pulled into a tub or sink.
- Do not place or drop the transmitter into water or other liquid
- Do not reach for a transmitter that has fallen into water. Unplug it immediately.

To reduce the risk of burns, shock, fire, or injury to persons:

- Supervision is necessary when the transmitter is used by, on, or near children.
- Use the transmitter only for its intended use as described in this manual. Only use attachments recommended by Abbott Medical.
- Never operate the transmitter if it is not working properly, if it has been dropped or damaged, or if it has been dropped into water. Contact Technical Support (page 6) for service or replacement instructions.
- Keep the cord away from heated surfaces.
- Do not operate the transmitter on heated surfaces.
- Do not use outdoors or operate where aerosol (spray) products are being used. Do not operate in an oxygen-rich environment (for example, in an oxygen tent or oxygen chamber).
- Do not use the transmitter near flammable substances.

Security Considerations

Merlin@home™ is a monitoring device and does not affect the critical functionality of an implantable medical device (IMD) even in the case of a cybersecurity compromise. In the unlikely event of a cybersecurity breach, please contact your clinician

Merlin@home is configured to have appropriate cybersecurity controls by default. There are no manual configurations required for secure network setup.

There are no infrastructure requirements, except for the presence of an internet connection for Wi-Fi‡ access point or RJ-11 port for dial up connections.

Merlin@home uses a hardened Linux-based operating system with a firewall and intrusion detection system (AIDE).

Merlin@home does not allow any incoming connections, unless initiated by itself. Only the DHCP client is expected to receive the DHCP responses for establishing a network connection. All other network ports are closed.

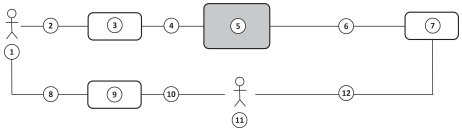
Merlin@home automatically downloads the software updates, whenever a newer version is available. The software updates are encrypted and cryptographically verified before installation.

Merlin@home collects session logs, interface event logs, software update logs, and AIDE logs. These logs are sent to Merlin.net™ Patient Care Network regularly.

A Cybersecurity Bill of Materials (CBOM) is available upon request).

Merlin@home automatically downloads available software updates.

Figure 1. System diagram



1. Patient
2. Sensing therapeutic signals
3. Implantable medical device (IMD)
4. Diagnostic information sent over secure channel
5. Merlin@home
6. Encrypted Patient Diagnostic data sent over secure channel (using dial-up or cellular network or Wi-Fi‡ network)
7. Merlin.net
8. Configuration/diagnostic information sent over secure channel
9. Programmer
10. Configurations/ diagnostic data
11. Clinician

Setting Up the Transmitter

For instructions on how to set up the transmitter, see the Merlin@home Start Up Guide.

- Place the transmitter on a sturdy, flat, hard surface. The transmitter must be flat on the surface at all times.
- If you do not place your transmitter on your night stand, contact your clinic for a recommendation.
- The Merlin@home transmitter is not magnetic and has no moving parts. However, you should avoid devices which generate a strong electric or magnetic interference (EMI). EMI could interfere with the performance of the transmitter. Moving the source of EMI away from the transmitter or turning the source of EMI off will usually allow the transmitter to return to its normal mode of operation. Sources of EMI may include communication equipment, wireless communication devices, household appliances, and industrial equipment.
- Do not press the Reset button on the back of the transmitter unless requested to do so by Technical Support (page 6).
- Use only Abbott Medical supplied accessories in the USB port. Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see clause 16 of the 3.1Ed. of IEC 60601-1). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.
- Sometimes issues with your phone, cellular adapter, or internet service provider may prevent your transmitter from sending your information. Contact Technical Support (page 6) or your clinic. Keep the original shipping box in case you need to return the transmitter for service.
- Leave your transmitter plugged into the wall electrical outlet, unless otherwise indicated by your clinic.

Merlin@home Sessions and Device Checks

There are two types of Merlin@home™ sessions and device checks:

- Scheduled
- Unscheduled

  NOTE: Do not press the Start button while the Merlin@home transmitter is reading or sending your information.

Scheduled Session

Scheduled sessions and device checks occur automatically if requested by your clinic. Your schedule is defined by your clinician. Most often the information transfer occurs sometime during the night while you sleep. After setting up your Merlin@home™ transmitter, leave it connected at all times and placed on your nightstand or table close to your bed.

Unscheduled Session

An unscheduled session sends your data manually. Conduct an unscheduled session or device check only if your clinician instructs you to do so. For instructions on how to send your data manually, see the Merlin@home™ Start Up Guide.

Device Check

To conduct an unscheduled device check:

Do one of the following:

- If only the green light is lit, go to Step 1.

- If the "Stars" icon is lit, go to Step 2.

1. Press the Start button. The "Stars" icon lights up.
2. Press the Start button for 3 to 4 seconds until you hear two beeps.
3. Move close to your transmitter.
4. The "Read" icon flashes when the transmitter searches for your device. It will stop flashing but remains lit while the transmitter reads the device and the progress lights will move left to right.
5. The "Tower" icon lights up when the transmitter has read your device.
6. The "Stars" icon lights up when your device check is complete. The "Stars" icon will turn off after a short time.

Shut Down

To power down the Merlin@home™ transmitter, unplug the power supply from the wall electrical outlet. If using a landline, you may leave the phone cord from the transmitter plugged into the wall or disconnect it. It should not affect your landline.

Transmitter Reset

Reset your transmitter only if Technical Support (page 6) instructs you to do so.

Transmitter Messages

Errors may result from variations in landline equipment, information transmission time, or the quality of the landline connection. For more information on transmitter errors and messages and how to respond to them, see the Merlin@home™ Start Up Guide.

Software Updates and Your Transmitter

It is important to keep your transmitter powered on and the connectivity accessory plugged in so that the transmitter can receive occasional automatic software updates. If transmitter connectivity is not maintained, your transmitter's software may not be updated to the current version and your transmitter may no longer be able to transmit or receive information. The software updates are cryptographically verified before installing.

Caring for the Transmitter

If necessary, you can clean the outside of the Merlin@home™ transmitter with a cloth dampened with water. Do not clean the transmitter while a session is in progress. The transmitter is classified as IPX0 because it is not waterproof. Do not immerse the transmitter in any liquid.

If there is a problem with the transmitter, contact Technical Support (page 6) for a replacement.

WARNING: The transmitter does not contain any user-serviceable parts. This product complies with medical product regulatory standards. In order to maintain that compliance, do not open the case.

Glossary

Clinic — The place that views your information after the Merlin@home™ transmitter sends your information to the server.

Information — The information stored in your device. The information includes your device type and serial number, settings, and battery status.

Device — Your implanted device, also known as an ICD (implantable cardioverter-defibrillator), CRT-D (cardiac resynchronization therapy defibrillator), pacemaker, or CRT-P (cardiac resynchronization therapy pacemaker).

Merlin@home session — A remote monitoring session in which your information is sent to the server, where the clinic can view your information.

Server — The place where your information from the Merlin@home session is sent.

Transmitter — The part of the Merlin@home Remote Monitoring System that reads the information in your device and sends it to the server.

Technical Support

For Merlin@home™ transmitter issues:

Monday through Friday (8AM to 8PM Eastern Standard Time)

- 1 877 696 3754 (1 877 MY MERLIN) (toll-free within North America)
- 1 818 493 4258

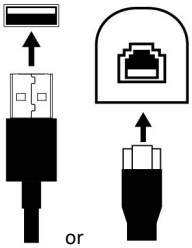
Monday through Friday (8AM to 5PM Central European Time)

- 46 8 474 4756 (Sweden) (Support in English and Swedish. For additional assistance, contact your clinic.)

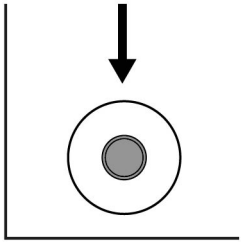
Rebooting Your Transmitter

If your transmitter cannot send information, it may have an unsecured connection and you may need to reboot your transmitter.

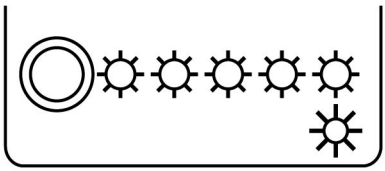
1. Secure the connection.
   Secure either the USB port to the adapter or the phone cord from your landline phone to the phone jack.



2. Press and release the black reset button on the back of your transmitter.



3. The progress lights on the transmitter will blink 1 to 2 minutes, but no icons will be lit.

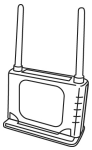
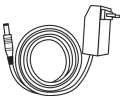


Rebooting can take a while. After the reboot is complete, the transmitter attempts to send the information again.

Symbols

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at https://medical.abbott/manuals.

Symbol	Description
Transmitter	Transmitter

Symbol	Description
	Model EX1150, EX1150W Merlin@home™ transmitters
	Phone cord and splitter (phone connector)
	Merlin@home inductive wand
	Product literature
	Follow instructions for use on this website
	USB wireless adapter
	USB wireless adapter's clip and USB cable
	Wireless access point
	Wireless access point's ethernet cable
	Wireless access point's power supply
	To identify the terminals to which a standard plug adapter is to be connected
	Transmitter works with a landline telephone
	Transmitter works with a wireless broadband kit

Symbol	Description
	Transmitter works with a cellular adapter
	Transmitter does not work with a landline telephone
	To identify a combined input/output connector or mode
	Accessories
PN	Part number
℞ ONLY	For prescription use only
	TÜV Listed, US and Canada. Conforms to UL60601-1. Certified to CAN/CSA C22.2 No.601.1-M90
CE 0123	European conformity, affixed according to the relevant provisions of AIMD directive 90/385/EEC and RE directive 2014/53/EU Annex II. Hereby, Abbott Medical declares that this device complies with the essential requirements and other relevant provisions of these directives. The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.cardiovascular.abbott/int/en/hcp/products/declarations-of-conformity.html. This product operates in the 2.4-2.4835 GHz band with an RF output power of less than 9.2 mW EIRP. This product operates in the 402-405 MHz band with an effective radiated power of less than 25 µW ERP.
	Affixed to this device in accordance with European Council Directives 2002/96/EC. These directives call for separate collection and disposal of electrical and electronic equipment. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. Return the device to Abbott Medical at the end of its operating life.
IP21	Ingress Protection Rating. "2" indicates the Merlin@home enclosure is protected against a solid object > 12.5 mm. "1" indicates the enclosure is protected against vertically falling drops of water.
Product of Malaysia	Product of Malaysia

Technical Information

The Merlin@home™ transmitter is Class II medical equipment and complies with IEC60601-1:2012 and UL60601-1:2012 and CAN/CSA-C22.2 No. 601.1-M90. The Merlin@home transmitter is a Canadian ICES-003 Class B digital apparatus. Operation is subject to the following two conditions: 1) This device may not cause interference, and 2) This device must accept any interference that may cause undesired operation of the device.

NOTES:

- There are no user-serviceable parts in the Merlin@home transmitter. No calibration is required. Do not modify the Merlin@home transmitter.
- When used under normal operating circumstances, this equipment generates no pollution.

Table 1. Electrical ratings

Input/Output	Rating
Transmitter input	100-240 VAC, 50-60 Hz
Power consumption (maximum)	350 - 150 mA
Power consumption (standby)	4 VA

Table 2. Storage conditions

Parameter	Condition
Minimum Temperature	-13°F (-25°C)
Maximum Temperature	158°F (70°C)
Maximum Humidity	90%
Minimum Atmospheric Pressure (hPa)	500
Maximum Atmospheric Pressure (hPa)	1060

Table 3. Operating conditions

Parameter	Condition
Minimum Temperature	50°F (10°C)
Maximum Temperature	104°F (40°C)
Maximum Humidity	75%
Minimum Atmospheric Pressure (hPa)	700
Maximum Atmospheric Pressure (hPa)	1060

The device may take up to two hours to reach an operating temperature of 20°C (68°F) from the minimum storage temperature of -20°C (-4°F). The device may take up to two hours to reach an operating temperature of 20°C (68°F) from the maximum storage temperature of 70°C (158°F).

Transmitter Accessories

Landline accessories included with the transmitter (Model EX1150 only) are:

- Landline cable
- Landline connector

Optional transmitter accessories are:

- Model EX1151 Wireless USB Adapter series

- Model EX1170 Wireless Broadband Kit series [1]

  NOTE: As with all wireless communications, there is a very small chance that transmitted information might be intercepted. For added security, your transmissions to the secure server are encrypted.

Electromagnetic Compatibility

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

The Merlin@home transmitter complies with the requirements of the international EMC standard IEC 60601-1-2:2014 when used with the cables listed in Transmitter Accessories (page 9).

The Merlin@home transmitter is intended for use in the electromagnetic environment specified in Tables 5 through 8. The user should ensure that it is used in such an environment.

WARNING: The Merlin@home transmitter complies with the limits for medical devices contained in IEC/EN 60601-1-2:2014. However, the Merlin@home transmitter 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.

Table 4. Guidance and manufacturer's declaration - electromagnetic emissions

Test	Compliance	Electromagnetic Environment - Guidance
RF Emission CISPR 11	Group 1	The Merlin@home™ transmitter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR 11	Class B	The Merlin@home transmitter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 5. Guidance and manufacturer's declaration - electromagnetic immunity

Test	IEC 60601 Test Level (Actual Level) [2]	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact (±8 kV contact) ±15 kV air (±15 kV air)	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines (±2 kV for power supply lines) ±2 kV for input/output lines (±2 kV for input/output lines)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line[s] to line[s] (±1 kV line[s] to line[s]) ±2 kV line[s] to earth (±2 kV line[s] to earth)	Mains power quality should be that of a typical commercial or hospital environment.

[1] You can use an equivalent access point instead of the wireless access point provided in the Model EX1170 Wireless Broadband Kit series. For more information, see Technical Support.

[2] Figures in parentheses are the immunity compliance levels for each test.

Table 5. Guidance and manufacturer's declaration - electromagnetic immunity

Test	IEC 60601 Test Level (Actual Level)	Electromagnetic Environment - Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_T*; >95% dip in U_T for 0.5 cycle (<5% U_T; >95% dip in U_T for 0.5 cycle) 40% U_T; 60% dip in U_T for 5 cycles (40% U_T; 60% dip in U_T for 5 cycles) 70% U_T; 30% dip in U_T for 25 cycles (70% U_T; 30% dip in U_T for 25 cycles) <5% U_T; >95% dip in U_T for 5 s (<5% U_T; >95% dip in U_T for 5 s)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Merlin@home transmitter requires continued operation during power mains interruptions, it is recommended that the Merlin@home transmitter be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m (30 A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

* U_T is the AC mains voltage prior to application of the test level.

Table 6. Guidance and manufacturer's declaration - electromagnetic immunity (conducted RF and radiated RF)

Test	IEC 60601 Test Level [3]	Immunity Compliance Level	Electromagnetic Environment - Guidance [4]
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms [V_1=3]	Portable and mobile RF communications equipment should be used no closer to any part of the Merlin@home transmitter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ **(80 MHz to 800 MHz)** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 Vrms [E_1=3]	

[3] At 80 MHz and 800 MHz, the higher frequency range applies.

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

Table 6. Guidance and manufacturer's declaration - electromagnetic immunity (conducted RF and radiated RF)

Test	IEC 60601 Test Level	Immunity Compliance Level	Electromagnetic Environment - Guidance
			(800 MHz to 2.7 GHz) where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range**. Interference may occur in the vicinity of equipment marked with the following symbol: 

*Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength of the location in which the Merlin@home transmitter is used exceeds the applicable RF compliance level above, the Merlin@home transmitter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Merlin@home transmitter.

**Over the frequency range of 150 kHZ to 80 MHz, field strengths should be less than $[V_1]$V/m.

NOTE: The Merlin@home transmitter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Merlin@home transmitter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Merlin@home transmitter as recommended below in Table 8, according to the maximum output power of the communications equipment. For transmitters rated at a maximum output power not listed in Table 8, the recommended separation distance (**d**) in meters can be estimated using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watts (**W**) according to the transmitter manufacturer.

Table 7. Recommended separation distances between portable and mobile RF communications equipment and the Merlin@home transmitter

Rated maximum output power of transmitter (W)	**Recommended separation distance according to frequency of transmitter (m)** [5]		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** [6] $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.7 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10.0	3.8	3.8	7.3
100.0	12	12	23

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

The Merlin@home transmitter complies with the requirements of the EMC international standard IEC 60601-1-2 when used with the cables listed in Transmitter Accessories (page 9).

The Merlin@home transmitter is intended for use in the electromagnetic environment specified in the following tables. The user should ensure that they are used in such an environment.

CAUTION: The Merlin@home transmitter 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.

Table 8. Guidance and manufacturer's declaration — electromagnetic emissions

Test	**Compliance**	**Electromagnetic Environment — Guidance**
RF Emission CISPR 11	Group 1	The Merlin@home™ transmitter uses RF energy only for its internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	The Merlin@home transmitter is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	The Merlin@home is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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

[6] At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Table 9. Guidance and manufacturer's declaration — electromagnetic immunity

Test	IEC 60601 Test Level (Actual Level) [7]	Electromagnetic Environment — Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact (±8 kV contact) ±15 kV air (±15 kV air)	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4 [8]	±1 kV for input/output lines (±1 kV for input/output lines) ±2 kV for power supply lines (±2 kV for power supply lines)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line[s] to line[s] (±1 kV line[s] to line[s]) ±2 kV line[s] to earth (±2 kV line[s] to earth)	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field, IEC 61000-4-8	30 A/m (30 A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, shorts, interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T [9][>95% dip in U_T] for 0.5 cycle (<5% U_T [>95% dip in U_T] for 0.5 cycle) 40% U_T [60% dip in U_T] for 5 cycles (40% U_T [60% dip in U_T] for 5 cycles) 70% U_T [30% dip in U_T] for 25 cycles (70% U_T [30% dip in U_T] for 25 cycles) <5% U_T [>95% dip in U_T] for 5 s (<5% U_T [>95% dip in U_T] for 5 s)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Merlin@home™ transmitter requires continued operation during power mains interruptions, it is recommended that the Merlin@home transmitter be powered from an uninterruptible power supply or a battery.

Table 10. Guidance and manufacturer's declaration - electromagnetic immunity (conducted RF and radiated RF)

Test	IEC 60601 Test Level [10]	Immunity Compliance Level	Electromagnetic Environment - Guidance [11]
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(3 Vrms) [V1=3]	Portable and mobile RF communications equipment should be used no closer to any

[7] Figures in parentheses are the immunity compliance levels for each test.

[8] Applies only to the Merlin 2 PCS.

[9] U_T is the a.c. mains voltage level prior to application of the test level.

[10] At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Table 10. Guidance and manufacturer's declaration - electromagnetic immunity (conducted RF and radiated RF)

Test	IEC 60601 Test Level	Immunity Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m [E1=3]	part of the Merlin@home ™ transmitter including cables, than the recommended separation distance [12] calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ **80 MHz to 800 MHz** [13] $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ **800 MHz to 2.7 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol: 

*Electromagnetic site survey- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV

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

[13] At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Table 10. Guidance and manufacturer's declaration - electromagnetic immunity (conducted RF and radiated RF)

Test	IEC 60601 Test Level	Immunity Compliance Level	Electromagnetic Environment - Guidance

broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength of the location in which the Merlin@home transmitter is used exceeds the applicable RF compliance level above, the Merlin@home transmitter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Merlin@home transmitter.

**Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than [V_1]V/m.

NOTE: The Merlin@home transmitter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Merlin@home transmitter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Merlin@home transmitter as recommended in the table below, according to the maximum output power of the communications equipment. For transmitters rated at a maximum output power not listed in the table below, the recommended separation distance (**d**) in meters can be estimated using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watts (**W**) according to the transmitter manufacturer.

Table 11. Recommended separation distances between portable and mobile communications equipment and the Merlin@home™ transmitter

Rated maximum output power of transmitter (W)	Recommended separation distance according to frequency of transmitter (m) [14]		
	150 kHz to 80 MHz $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz [15] $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10.0	3.8	3.8	7.3
100.0	12	12	23

Radio Frequency Information

EX1150 and EX1150W Merlin@home™ transmitters use a 2.45 GHz wake-up sequence then switch to Medical Implant Communications Service (MICS) -based RF telemetry to communicate with Abbott Medical implantable devices.

MICS band: 402-405 MHz. The effective radiated power is below the limits as specified in:

- Europe: EN ETSI 301 839
- USA: FCC 47 CFR Part 95.601-95.673 Subpart E, 95.1201-95.1219

MICS operates at 200kb/s or lower.

2.45 GHz. The effective radiated power is below the limits as specified in:

- Europe: EN ETSI 300 328
- USA: FCC 47 CFR Part 15.249

NOTE:

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

[15] At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

- Maintain a reasonable distance between other electronic equipment and the Merlin@home™ transmitter.
- Nearby or hidden equipment emitting strong magnetic fields, such as Radio-Frequency IDentification emitters, other medical and radio devices, etc., can interfere with the Merlin@home™ transmitter's RF communication, even if the other equipment complies with applicable emission requirements. If interference occurs, you can minimize its effect by reorienting or relocating the Merlin@home transmitter or by shielding its location.

  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 (that is, 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.

Wireless Security

EX1150 and EX1150W Merlin@home™ transmitters communicate with Abbott Medical implantable devices over a short range (less than 10 feet in normal use). Implantable devices introduced in 2010 and later use an MICS-based proprietary communications protocol. This protocol prevents unauthorized device communication and recording and protects sensitive patient information using:

- An authentication algorithm
- Data encryption

Quality of Service for Wireless Technology

During use, EX1150 and EX1150W Merlin@home™ transmitters display a signal strength indicator that is visible to the patient. The transmitter automatically monitors and recovers from most communication errors. If wireless Quality of Service (QoS) is inadequate, the transmitter displays an error indication and retries communication. The patient can also retry communication.

NOTE: Use of the Merlin@home transmitter does not affect device therapy.

Wireless Communication Troubleshooting

If the Merlin@home™ transmitter is unable to communicate with an Abbott Medical implanted device:

- Re-orient the Merlin@home transmitter
- Minimize the amount of objects or people between the transmitter and the patient
- Avoid holding the transmitter
- Move away from or turn the power off of equipment that could generate electromagnetic interference or strong magnetic fields

FCC Information

This equipment complies with Part 68 of the FCC rules and the requirements adopted by the ACTA. On the exterior of this equipment is a label that contains, among other information, a product identifier in the format:

Transmitter: FCC: RIASJMRFMERLIN

Modem: US: SJMMM01BMERLIN

If requested, this number must be provided to the telephone company (model EX1150 only).

Table 12. FCC identification information

Identifier	Description
FCC Registration Number (transmitter)	**FCC: RIASJMRFMERLIN**
FCC Registration Number (modem)	**US: SJMMM01BMERLIN**
Ringer Equivalence Number (REN)	**0.8B**
USOC Jack Type	**RJ11 (US)**

A FCC compliant telephone cord and modular plug is provided with this equipment. This equipment is designed to be connected to the telephone network or premises wiring using a compatible modular jack that is Part 68 compliant. See installation instructions for details.

The REN is used to determine the quantity of devices that may be connected to the telephone line. Excessive RENs on the telephone line may result in the devices not ringing in response to an incoming call. Typically, the sum of RENs should not exceed five (5.0). To be certain of the number of devices that may be connected to a line (as determined by the total RENs) contact the local telephone company.

If the Merlin@home™ transmitter causes harm to the telephone network, the telephone company will notify you in advance that temporary discontinuance of service may be required. But if advance notice isn't practical, the telephone company will notify the customer as soon as possible. Also, you will be advised of your right to file a complaint with the FCC if you believe it is necessary.

The telephone company may make changes to its facilities, equipment, operations or procedures that could affect the operation of the equipment. If this happens the telephone company will provide advance notice so you can make the necessary modifications to maintain uninterrupted service.

If you have trouble with the Merlin@home transmitter, for repair or warranty information, contact Technical Service.

If the equipment is causing harm to the telephone network, the telephone company may request that you disconnect the equipment until the problem is resolved.

Connection to party line service is subject to state tariffs. (Contact the state public utility commission, public service commission or corporation commission for information.)

CAUTION: Per FCC Rules, changes or modifications of the Merlin@home transmitter not approved by Abbott Medical could void your right to operate the Merlin@home transmitter.

NOTE:

- 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 or more of the following measures: (1) Reorient or relocate the receiving antenna. (2) Increase the separation between the equipment and transmitter. (3) Connect the equipment into an outlet on a circuit different from that to which the transmitter is connected. (4) 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 may not interfere with stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

- **Disclosure**
  This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in 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 stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication 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.

Warranty

Abbott Medical warrants that for a period of one year following delivery to the original purchaser, the Merlin@home™ Transmitter will be free from defects in materials and workmanship.

This warranty does not cover damage due to external causes, including but not limited to accident, electrical power problems, servicing not authorized by Abbott Medical, usage not in accordance with product instructions, failure to perform required preventive maintenance, abuse, and misuse.

During the one year warranty period, Abbott Medical will repair or replace a malfunctioning transmitter if it is returned to Abbott Medical. To qualify for such repair or replacement, Abbott Medical must be notified within 30 days of the malfunction and, if so directed by Abbott Medical, the purchaser must return the transmitter for repair or replacement to:

Abbott Medical

Attention: Returned Goods

15900 Valley View Court

Sylmar, CA 91342

If warranty service is required, contact Abbott Medical.

If Abbott Medical repairs or replaces your transmitter, the warranty term will be for the remainder of the original term or 60 days, whichever is longer.

THIS WARRANTY REPRESENTS THE ENTIRE OBLIGATION OF ABBOTT MEDICAL AND IS MADE IN LIEU OF ANY OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ABBOTT MEDICAL WILL NOT BE LIABLE FOR ANY DAMAGES, WHETHER DIRECT, CONSEQUENTIAL, OR INCIDENTAL, CAUSED BY DEFECTS, FAILURES, OR MALFUNCTIONS OF ITS PRODUCTS, WHETHER SUCH A CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.

Some states do not allow the exclusion of incidental or consequential damages, so the preceding limitation or exclusion may not apply. Some states do not allow limitations on how long an implied warranty lasts, so the preceding limitation may not apply.

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