

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

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Statement of Compliance With License-Exempt RSS Standard (Canada)

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Table 4. Compliance label information

Identifier Type	Registration Identifier
Compliance Label Number	CAN ICES-3 (B)/NMB-3(B)

Disposal Guidelines for Battery-Powered Devices

This device contains a battery and a label is affixed to the device in accordance with European Council directives 2002/96/EC and 2006/66/EC. These directives call for separate collection and disposal of electrical and electronic equipment and batteries. 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. The device and its battery should be disposed of according to local laws and regulations.

Electromagnetic Compatibility Guidelines

The device should be used in accordance with the information provided in this manual.

NOTE: Maintain a reasonable distance between other electromagnetic equipment and the device.

The device is intended for use in the electromagnetic environment specified in the following tables. The user should ensure that it is used in such an environment.

WARNING: This device is intended for use in a hospital or medical clinic environment. It complies with the limits for medical devices contained in IEC 60601-1-2:2014+A1:2020.

Table 5. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1 Class B	The device must emit electromagnetic energy in order to perform its intended function. The device is suitable for use in all establishments including domestic establishments.

Table 6. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601-1-2 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	OET was tested to Level 4 ESD. OET may be momentarily affected by ESD. But, normal performance is unlikely to be affected.

Table 6. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Interference may occur in the vicinity of equipment marked with the following symbol:  Maintain a reasonable distance between other electronic equipment and the device. Refer to the following table for separation distance.

Table 7. Recommended separation distances between portable and mobile communications equipment and the device

Rated maximum output power of transmitter (W)	Recommended separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
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

Table 7. Recommended separation distances between portable and mobile communications equipment and the device

Rated maximum output power of transmitter (W)	Recommended separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
100.0	12	12	23

RF Operating Frequencies

The operating characteristics of the device are as follows:

- Inductive Telemetry
 - RF Transmission - Carrier frequency 65.5 kHz (inductive telemetry). The effected radiated power is below the limits as specified in FCC Part 15.209, RSS-210, EN 300 330.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format.

Table 8. Registration identification information

Identifier Type	Registration Identifier
FCC Registration Number	PX2-ORMET1
IC Registration Number	30752-ORMET1

Symbols and Definitions

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 medical.abbott/manuals.

Table 9. Symbols and definitions

Symbol	Definition
	Error or Timeout
	Out of MRI Mode
	Function Button to exit MRI Mode
	Power On button
	Power Off button

Table 9. Symbols and definitions

Symbol	Definition
	Caution
	Refer to instruction manual/booklet
	Consult instructions for use
 medical.abbot/manuals	Follow instructions for use on this website
	Type BF Applied Part
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment.

Table 9. Symbols and definitions

Symbol	Definition
	Use-by date
	Date of manufacture
	Keep dry; keep away from rain
	Temperature limit
	Humidity limitation
	Manufacturer

Table 9. Symbols and definitions

Symbol	Definition
	Packaging unit
	Includes Accessories
	Do not use if package is damaged
	Catalog number NOTE: This symbol also refers to the model number.
	Batch code
	Serial number
	Interference may occur in the vicinity of this equipment

Table 9. Symbols and definitions

Symbol	Definition
	Temperature
	Excursion temperature limit
	Atmospheric pressure limitation
	Physician telephone
	This product shall not be treated as household waste. Instead it is the user's responsibility to return this product to Abbott Medical for reprocessing. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health,

Table 9. Symbols and definitions

Symbol	Definition
	which could be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. For more information about how to return this product for recycling, please contact Abbott Medical.
	Authorized representative in the European Community

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

2024-07
ARTEN600341279 A

