Boston Scientific

REF **3140**
reference number

ZOOM® Wireless Transmitter	reference guide
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This literature is intended for use by professionals trained or experienced in device implant and/or follow-up procedures.

CAUTION: US Federal law restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.

ZOOM is a registered trademark of Boston Scientific or its affiliates. LATITUDE is a trademark of Boston Scientific or its affiliates.

DESCRIPTION AND USE

The ZOOM® LATITUDE™ Programming System, which includes Model 3120 Programmer/Recorder/Monitor (PRM), Model 3140 ZOOM® Wireless Transmitter (ZWT), and accessories, is a portable cardiac rhythm management system designed to be used with Boston Scientific implantable pulse generators.

INTENDED USE

The ZWT is intended to be used as part of the ZOOM LATITUDE Programming System to communicate with Boston Scientific implantable pulse generators. The PRM software controls all pulse generator communication functions. Refer to model-specific pulse generator product literature for detailed information about software application instructions.

CONTRAINDICATIONS

The ZWT is contraindicated for use with any pulse generator other than Boston Scientific pulse generators. Refer to model-specific pulse generator product literature for other contraindications for use.

WARNINGS

Use of unspecified cables and accessories

The use of any cables or accessories with the ZWT other than those specified by Boston Scientific in this manual may result in increased emissions or decreased immunity of the ZWT. Anyone connecting such cables or accessories to the ZWT may be configuring a medical system and is responsible for ensuring that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for the medical electrical systems.

Radio interference by other equipment

Other equipment may interfere with the ZWT, even if that equipment complies with the International Special Committee on Radio Interference (CISPR) emission requirements.

Proximity to other equipment
Do not use the ZWT adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, check the ZWT for normal operation in that configuration.

ZWT and PRM must remain outside sterile field
The ZWT and the PRM are non-sterile and cannot be sterilized. They must both remain outside the sterile field. Maintain a minimum operating distance of 7.6 cm (3 in) between the ZWT and the PRM.

ZWT is MR Unsafe
The ZWT is MR Unsafe and must be kept outside MRI sites classified Zone III and above, as defined by the American College of Radiology Guidance Document for Safe MR Practices . Under no circumstances should the ZWT be brought into the MRI scanner room, the control room, or MRI site Zone III or IV areas.

Modifications
No modification of this equipment is allowed unless approved by Boston Scientific.

PRECAUTIONS

Connect only to Boston Scientific Model 3120 PRM
Connect the ZWT only to a Model 3120 Boston Scientific PRM equipped with current level software.

Electrical and magnetic interference
Avoid establishing telemetry communication between the ZWT and the pulse generator when the ZWT is in close proximity to monitors, high-frequency electrosurgical equipment, or strong magnetic fields. The telemetry link may be impaired.

MAINTENANCE AND HANDLING

Cleaning the ZWT

When necessary, clean the ZWT housing with a soft cloth lightly dampened with water, isopropyl alcohol, a 5% bleach solution, or window cleaner. Do not allow any amount of cleaning solution or moisture to come in contact with the USB port. Do not use an abrasive cloth or volatile solvents to clean any portion of the ZWT.

Magnet handling

Do not place a magnet on the ZWT.

ZWT use

The ZWT is not waterproof or explosion-proof and cannot be sterilized. Do not use it in the presence of flammable gas mixtures including anesthetics, oxygen, or nitrous oxide.

Disconnecting the ZWT

Disconnect the USB cable from the ZWT unit to completely isolate it from the power source.

ZWT accessibility

Make certain that the USB connection point is accessible at all times so that power may be disconnected.

ADVERSE EFFECTS

None known.

SYSTEM FEATURES

The ZWT enables cordless, hands-free, 2-way radio frequency (RF) communication between the Model 3120 Programmer/Recorder/Monitor (PRM) and Boston Scientific pulse generators specifically designed to use the Medical Implant Communications Service (MICS).

NOTE: *The MICS telemetry feature is not available for all pulse generators. For more information, refer to the associated product literature for the pulse generator being interrogated.*

SYSTEM COMPONENTS AND ACCESSORIES

The ZOOM Wireless Transmitter system consists of Model 3140 ZOOM Wireless Transmitter and Model 3141 USB Cable.

CAUTION: The ZWT must be directly connected to either of the two 3120 PRM USB ports using only the Model 3141 USB cable. Do not use USB cables other than the Model 3141. Intermittent or unreliable telemetry may result if the ZWT is connected to the PRM using an unapproved USB cable.

CAUTION: Do not connect the ZWT to any equipment other than Boston Scientific Model 3120 PRM.

WARNING: The use of any cables or accessories with the ZWT other than those specified by Boston Scientific in this manual may result in increased emissions or decreased immunity of the ZWT. Anyone connecting such cables or accessories to the ZWT may be configuring a medical system and is responsible for ensuring that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for medical electrical systems.

SYSTEM SERVICING AND REPAIR

Unless otherwise agreed, the ZWT remains the property of Boston Scientific and Boston Scientific must perform all necessary servicing and repair work. For additional information, contact Boston Scientific using the information on the back cover.

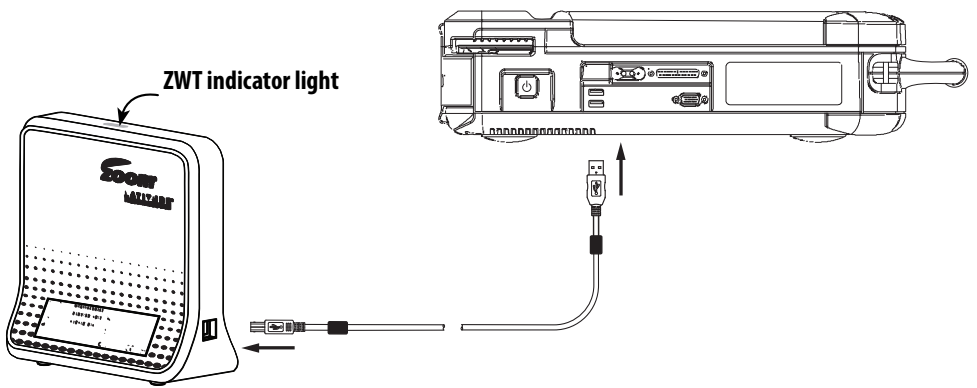
PREPARING THE ZWT FOR USE

Connect 3140 ZWT and 3120 PRM as shown below. Note location of indicator light on top surface of ZWT.

The 3120 PRM may be powered on or off during 3140 ZWT installation.

Model 3120 PRM

View of left side



BEGIN ZIP TELEMETRY

NOTE: The MICS telemetry feature is not available for all pulse generators. For more information, refer to the associated product literature for the pulse generator being interrogated.

1. Raise the PRM screen to a comfortable viewing angle.
2. Press the PRM On/Off button.
3. Wait until both the PRM startup screen and the ZWT green indicator light appear, usually less than 60 seconds.
4. Place the telemetry wand over the pulse generator. Use either the ***Quick Start*** button on the PRM screen or the ***Select PG*** button located on the toolbar below the startup screen to begin interrogation. Remove the wand once the telemetry indicator  on the PRM is illuminated.

For optimum MICS telemetry communication, position the ZWT at least 7.6 cm (3 in) away from the PRM. Remove any obstructions between the two instruments. Repositioning the ZWT may improve MICS telemetry performance. If MICS telemetry performance is not satisfactory, use the telemetry wand instead.

USING THE ZWT

Operation

The ZWT requires special handling. To protect the ZWT from damage, refer to the following information:

- Do not subject the ZWT to abusive shocks or vibrations.
- When transporting the ZWT from an outside environment to an inside environment, allow the ZWT to come to ambient temperature before use.
- Do not place a magnet on the ZWT.
- Do not pour or splash liquid into or onto the ZWT.

- Do not disassemble the ZWT.
- Disconnect the USB cable prior to transporting the ZWT.

Operate the ZWT and accessories within the following conditions:

- Temperature range of 10°C to 35°C (50°F to 95°F)
- Humidity between 25% and 90%

Transport and store the ZWT within the following conditions:

- Temperatures between -40°C and 70°C (-40°F and 158°F)
- Relative humidity between 25% and 95%
- Atmospheric pressure between 50 kPa to 106 kPa (7.252 psi to 15.374 psi)

The ZWT is capable of continuous operation and will not shut off automatically if it is unused for an extended time.

CAUTION:

The ZWT is not waterproof or explosion-proof and cannot be sterilized. Do not use it in the presence of flammable gas mixtures including anesthetic mixture with air, oxygen, or nitrous oxide.

Storage

1. Unplug the USB cable.
2. Protect the ZWT and the USB cable from damage.
3. Store the system at -40°C to 70°C (-40°F to 158°F) temperature and 25% to 95% relative humidity.

MAINTENANCE CHECK AND SAFETY MEASURES

Maintenance Check

Prior to each use, perform a visual inspection and verify the following:

- Mechanical integrity of the ZWT and its USB cable.
- Legibility and adhesion of the ZWT labels.

The ZWT contains no user-accessible components and must be returned to Boston Scientific for repair or replacement of any internal components.

Safety Measurements

National regulations may require that the user, manufacturer, or manufacturer representative periodically perform and document safety tests of the device. If such testing is required in your country, follow the testing interval and extent of testing as regulated in your country. If you do not know the national regulations in your country, please contact your local Boston Scientific representative.

Service

For questions regarding operation or repair of the ZWT, contact Boston Scientific using the information on the back cover.

The ZWT must be serviced by Boston Scientific personnel only.

If the ZWT malfunctions and requires repair, help to ensure efficient service by following these guidelines:

1. Leave the configuration of the instrument exactly as it was at the time of malfunction. Contact Boston Scientific using the information on the back cover of this manual.
1. Write a detailed description of the malfunction(s).
2. If the ZWT must be returned to Boston Scientific for service, pack it in the shipping container in which it was received or in a shipping container provided by Boston Scientific.
3. Contact Boston Scientific using the information on the back cover of this manual to obtain the proper ship-to address.

TROUBLESHOOTING

If the ZWT does not operate properly, check that the USB cable is securely connected to both the ZWT and the PRM. Also check that the PRM cords and cables are free of visible defects and are properly connected. Possible causes and corrective actions for ZWT problems are shown below.

Symptom	***Possible Cause***	***Corrective Action***
Green indicator light on ZWT does not light within 60 seconds of powering on PRM	USB cable not securely connected to ZWT and PRM	Remove and reconnect both ends of USB cable. Reposition wand over the pulse generator and repeat interrogation.
	USB cable damaged	Replace with Model 3141 USB Cable only.
	ZWT fault	Contact Boston Scientific representative.
Intermittent or no RF telemetry communication	Telemetry RF signal obstructed	Assure that a clear line-of-sight path exists between ZWT and pulse generator. Repeat interrogation.
	Telemetry RF signal interference	Reposition or reorient ZWT at least 7.6 cm (3 in) away from PRM. Repeat interrogation.
	USB cable not securely connected to ZWT and PRM	Remove and reconnect both ends of USB cable. Reposition wand over the pulse generator and repeat interrogation.
	RF Telemetry fails	Reposition wand over pulse generator; repeat interrogation.
	PRM software version not current	Contact Boston Scientific representative.

SYMBOLS ON PACKAGING

The following symbols may be used on packaging and labeling:

Symbol	Description	Symbol	Description
REF	Reference number	SN	Serial number
LOT	Lot number		Date of manufacture
	Non-ionizing electromagnetic radiation		Consult instructions for use
	Temperature limitation	CE 0086	CE mark of conformity with the identification of the notified body authorizing use of the mark
EC REP	Authorized Representative in the European Community	N 20593 Z 1088	C-tick with supplier codes Meets Australia and New Zealand EMC requirements
AUS	Australian Sponsor Address		Universal Serial Bus (USB)

Symbol	Description	Symbol	Description
	RESTRICTED DEVICE. Federal law (USA) restricts the sale, distribution, or use of this device to, by, or on the lawful order of a physician		Waste, Electrical, and Electronic Equipment (WEEE). Discard with electronic waste.
	Assembly number		This side up
	Fragile, handle with care		Keep dry
	Do not use hooks		Humidity limitations
	Atmospheric pressure limitations		Magnetic Resonance Unsafe

ENVIRONMENTAL PROTECTION AND DISPOSAL

Return the ZWT and accessories to Boston Scientific at the end of their useful lives for appropriate disposal.

COMPLIANCE STANDARDS

The following standards apply to the ZWT:

Safety Standards

This equipment has been tested and found to comply with applicable safety portions of the following standards:

- IEC 60601-1:2005 + C1:2006 + C2:2007 + INT1:2008 + INT2:2009
- ANSI/AAMI ES60601-1:2005 + C1:2009 + A2:2010
- BS EN 60601-1:2006 + C1:2006 + C2:2007 + C3:2010
- CAN/CSA-C22 No. 60601-1-08

Electromagnetic Compatibility Standards

This equipment has been tested and found to comply with the applicable portions of the following electromagnetic compatibility (EMC) standards:

- EN 301 489-1 v1.9.2:2011
- EN 301 489-27 v1.1.1:2004
- EN 301 839-2 v1.3.1:2009
- IC RSS-243:2010

NOTE: *Use special precautions regarding EMC during the installation and the use of the ZWT, according to the EMC instructions given throughout this manual. Refer to the details about the ZWT electromagnetic emissions and immunity.*

NOTE: *Use caution when using RF portable and mobile equipment in close proximity to the ZWT. Refer to the details about the ZWT electromagnetic immunity.*

FCC: 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. FCC ID#: ESCCRM314013

Industry 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 harmful interference, and 2) 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. IC# 4794A-CRM31403

CAUTION: Changes or modifications not expressly approved by Boston Scientific could void the user's authority to operate the equipment.

R&TTE: Boston Scientific hereby declares that this transmitter is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. To obtain a full text Declaration of Conformity, contact Boston Scientific using the information on the back cover.

NOTE: *As with other telecommunications equipment, verify national data privacy laws.*

IEC 60601-1-2:2007 Information

This equipment has been tested and found to comply with the applicable limits for medical devices in ANSI/AAMI/IEC 60601-1-2:2007. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, try to correct the interference by one or more of the following measures:

- Reorient or relocate the devices
- Increase the separation between the devices
- Connect the equipment to an outlet on a different circuit
- Consult the manufacturer or field service technician for help

Electromagnetic Emissions and Immunity

The ZWT was determined to have no essential performance. Nevertheless, functions related to communication with the implanted pulse generator were included in testing.

Table 1: Guidance and manufacturer's declaration — electromagnetic emissions and environment

Guidance and manufacturer's declaration – electromagnetic emissions		
The ZWT is intended for use in the electromagnetic environment specified below. The customer or the user of the ZWT should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions (CISPR 11)	Group 1	The ZWT 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.

Guidance and manufacturer's declaration – electromagnetic emissions		
RF emissions (CISPR 11)	Class A	The ZWT 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	
Voltage fluctuations / flicker emissions (IEC 61000-3-3)	Complies	

Table 2: Guidance and manufacturer's declaration — electromagnetic immunity and environment

Guidance and manufacturer's declaration – electromagnetic immunity			
The ZWT is intended for use in the electromagnetic environment specified below. The customer or the user of the ZWT 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)	±6 kV contact ±8 kV air	±6 kV contact ±8 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 ±1 kV for input/output lines	±2 kV for power-supply lines ±1 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) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance 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[b]. 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle[b]. 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ZWT requires continued operation during power mains interruptions, it is recommended that the PRM to which the ZWT is connected be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Table 3: Guidance and manufacturer's declaration — electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity		
The ZWT is intended for use in the electromagnetic environment specified below. The customer or the user of the ZWT should ensure that it is used in such an environment.		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF (IEC 61000-4-6)	3 Vrms 150 kHz to 80 MHz	3 Vrms
Radiated RF (IEC 61000–4-3)	3 V/m 80 MHz to 2.5 GHz	3 V/m
Electromagnetic environment – guidance		
Portable and mobile RF communications equipment should be used no closer to any part of the ZWT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**		
$d = 1.2 * \sqrt{P}$ 150 KHz to 80 MHz	$d = 1.2 * \sqrt{P}$ 80 MHz to 800 MHz	$d = 2.3 * \sqrt{P}$ 800 MHz to 2.5 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,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 		

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. 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 in the location in which the ZWT is used exceeds the applicable RF compliance level above, the ZWT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ZWT.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the ZWT

The ZWT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ZWT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ZWT as recommended in this table, 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

For transmitters rated at a maximum output power not listed in the table, the recommended separation distance d in meters (m) 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.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

SPECIFICATIONS

Characteristic	Nominal
Ingress protection rating	IPX0
Dimensions (overall)	17.6 cm (6.9 in) wide, 17.3cm (6.8 in) high, 7.6 cm (3 in) deep
Weight (approximate)	.6 kg (1.3 lb)
Power rating	5 V DC
Power cord	Power supplied via USB data cable
Duty cycle	Continuous
Frequency band	402 – 405 MHz (MICS/MedRadio)
Bandwidth	< 300 KHz
Modulation	FSK
Effective radiated power	25 µW (-16 dBm)

ENVIRONMENTAL REQUIREMENTS

Characteristic	Nominal
Operating temperature	10°C to 35°C (50°F to 95°F)
Transport and storage temperature	-40°C to 70°C (-40°F to 158°F)
Operating humidity	25% to 90%
Transport and storage humidity	25% to 95%
Operating altitude	<= 2000 m
Transport and storage atmospheric pressure	50 kPa to 106 kPa (7.252 psi to 15.374 psi)

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