

Pressure Monitoring using the Wireless Physiologic Monitoring System And TruWave Disposable Pressure Transducer

- DRAFT -

Operator's Manual

For Wireless Models:
WTP1000, WTMXXX



Edwards Lifesciences

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Introduction

General Safety

This section provides information on the safe use of the Wireless Physiologic Monitoring System with the TruWave Disposable Pressure Transducer. Read and understand the information contained in this section before operating the Wireless Physiologic Monitoring System with the TruWave Disposable Pressure Transducer. Always follow the warnings, cautions and notes throughout this document.

Warnings, Cautions and Notes

WARNINGS

When using the Wireless Physiologic Monitoring System with the TruWave Disposable Pressure Transducer, appropriately qualified medical staff must routinely monitor all patient vital signs and comply with the following;

- Patient monitor vital signs alarm limits must be set and active while using the Wireless Physiologic Monitoring System with the TruWave Disposable Pressure Transducer. Failure to activate alarms may cause delay or absence of notification pressure signal loss.
- Performance of installation, operation or maintenance procedures other than those described in this manual may create hazards and may cause the manufacturer's warranty to become void.
- Sterile components are designed for a single use only. If unauthorized disposable components are used, proper operation cannot be guaranteed.
- Adherence to sterile technique must be observed when making all sterile connections to the TruWave Wireless pressure transducer.
- Never operate damaged or wet equipment.
- Do not use this device in the presence of flammable anesthetic gases.
- The Wireless Physiologic Monitoring System should only be used on patient monitors that have been validated for compatibility. Refer to Table 1 Qualified Monitors list in this manual or contact the manufacturer for the most current list.

- The Wireless Physiologic Monitoring System should be inspected and tested routinely prior to and during use.
- The Wireless Physiologic Monitoring System should not be used to provide pressure triggered synchronization for intra aortic balloon pumps.
- The Wireless Physiologic Monitoring System is not Magnetic Resonance Imaging compatible. Damage and/or injury to the patient or operator may result if exposed to the MRI magnetic fields.

CAUTIONS

- Batteries should not be left in the devices for extended periods of time.
- Do not immerse or soak devices in any liquids.
- Do not steam, radiation or EO sterilize the electronic devices. Damage or failure to operate may result.
- 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.
- The Wireless Physiologic Monitoring System has been tested for compliance of US FCC CFR47 Part 95 H. Any modifications or tampering of the device may cause failure of compliance.
- Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

NOTES

- 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:
 - Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

- Other devices operating in the Wireless Medical Telemetry Service bands can adversely affect the operation of the Wireless Physiologic Monitoring System.

- For best performance, allow device to equilibrate to room temperature.

Intended Use

INDICATIONS FOR USE

The Wireless Physiologic Monitoring System is indicated for use on patients requiring physiologic monitoring. The Wireless Physiologic Monitoring System is intended to perform wireless transmission of physiological patient information to remote patient monitors using standard digital communication technologies and protocols.

CONTRAINDICATIONS

The Wireless Physiologic Monitoring System is contraindicated for the following clinical applications;

Invasive pressure wave trigger synchronization for intra aortic balloon pump devices. This is contraindicated due to timing sensitivities.

Device Description

SYSTEM FUNCTIONAL DESCRIPTION

The Wireless Physiologic Monitoring System is a wireless device designed to be used in place of a standard cable. The system communication operates using frequency bands designated for use by the Wireless Medical Telemetry Service.

The system RFID link process operates using the 134.2 KHz frequency band and is compliant per US FCC CFR47 Part 15.

The Wireless Physiologic Monitoring System is comprised of two components.

Transducer Module (X Unit, Model WTP1000) – This component provides the excitation voltage to the transducer and transmits the transducer signal via radiofrequency to the M unit.

Monitor Module (M Unit, Model WTM XXX – See Table 1) – This component connects to the patient monitor (via the Invasive Blood Pressure (IBP) connection in the case of pressure monitoring) and receives the radiofrequency data transmission from the X unit Transducer module. The data is then displayed on the patient's bedside monitor. Each M Unit comes with a connector specific to the monitor it has been designed for. See Table 1 for applications and model numbers.

The Transducer modules (X Units) are battery powered and also provide the excitation voltage to the pressure transducer. The Monitor modules (M Units)

obtain their operating power from the bedside monitor. Some exceptions exist that require a supplemental power source for the Monitor modules.

To use the Wireless Physiologic Monitoring System for pressure monitoring, a Transducer module is connected to a TruWave disposable pressure transducer and a Monitor module is connected to a patient monitor pressure signal input. The system uses radiofrequency transmission to communicate pressure data from the transducer to the monitor in place of the cable.

The Transducer modules are typically mounted to an IV pole or on the patient. The Monitor modules are plugged into the monitor input connectors and hang from the monitor.

TABLE 1 – QUALIFIED PATIENT MONITORS

Monitor Manufacturer	Monitor Model	M Unit Model
GE	Dash 4000	WTM 507
MDE	Escort 2	WTM 021
Philips/HP	Omnicare/M1006B Module	WTM 083
Spacelabs	Ultraview 90367	WTM019

ACCESSORIES

The Wireless Physiologic Monitoring System for pressure monitoring is used in conjunction with the following accessories.

IV Pole Holder (Model WDTH1)– A holder assembly is provided for mounting the Transducer Modules conveniently to an IV pole.

AC Adapter (Model WAC1)- An AC power supply is provided for those Monitor modules that cannot obtain adequate power from the monitor.

Battery Pack (Model W9VBP1)– A 9 volt battery pack is provided for those Monitor modules that are used with Transport monitors that do not supply adequate operating power.

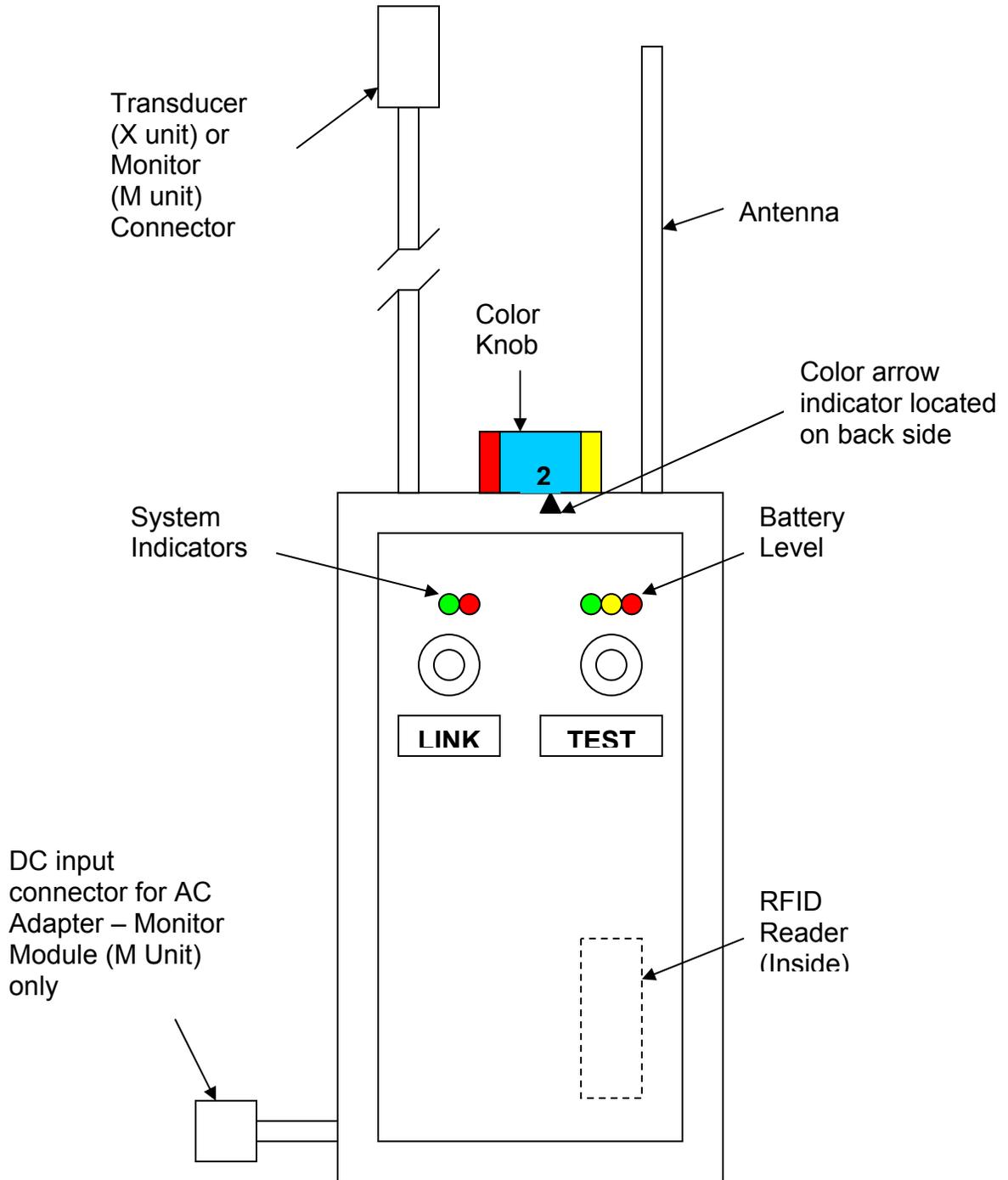
FastLink (Model WLINK1) – A passive RFID transponder card with unique serial number is used as a unique identifier for the operator to link pairs of modules.

Frequency Programming Card (Model WDATA1) – A passive RFID transponder card with programmed frequency data is used to program the operating frequencies of the Transducer and Monitor Modules.

Wireless Patient Mount (Model WDTPM1)- A holder assembly is provided for mounting the Transducer Module to the patient, adjacent to the pressure transducer.

SYSTEM CONTROLS AND INDICATORS

The controls and indicators for the Transducer module and the Monitor module are similar. Differences are noted in the figure.



SYSTEM CONTROLS AND INDICATORS

FUNCTIONAL DESCRIPTIONS

CONTROLS

A simple method of linking the appropriate X unit (example; Arterial blood pressure transducer) to the appropriate M unit (example: Monitors' Arterial blood pressure channel) must occur before the TruWave transducer can be zeroed and physiologic data is displayed on the bedside monitor.

LINK (On/Off) Button – Pressing the LINK button for ½ second, initiates the pairing process between the Transducer Module (X Unit) and the Monitor Module (M Unit) by activating the RFID reader system. The linking process can be initiated from either the X Unit or the M Unit.

The LINK button also serves to terminate an existing communication link. Pressing and holding the LINK button for two seconds, while already linked, will terminate the link. Pressing the Link button again will initiate a new link process. If no RFID user card is presented, the Module will time out (approximately 10 seconds) and turn off.

TEST Button – Pressing the TEST button sends a **test signal** (approximately 100 mmHg) from the Module to the monitor display for purposes of testing and verifying proper module and link performance. The test signal is sent as long as the TEST button is held. If the M Unit TEST button is used, the test pulse is generated from the M Unit and the function and connection of the M unit is verified. If the X Unit TEST button is used, the test pulse is generated from the X Unit and the link performance is verified.

Pressing the TEST button on the X Unit will also indicate the **battery level**.

Pressing the TEST button on the M Unit will only indicate battery level if the M Unit is battery powered. It does not indicate the battery level of the X Unit that it is linked to.

Note: The battery in the X Unit should always be replaced with a new one when setting up a new pressure transducer line. A new AA Alkaline battery will typically provide 40 hours of continuous operation.

Color Channel Knob – A rotating selector knob provides 5 color channels. The channel colors (also with #'s) are Red (1), Blue (2), Yellow (3), Green (4) and White (5). The color channel selection is indicated by the arrow on the rear panel.

The color channel selector is used to aide the operator in organizing pressure signals on how they appear on the patient monitor. These color settings also provide channel information between X and M units. The color RED is typically

selected for an arterial pressure. The M Unit plugged into the monitor where arterial pressure is displayed would be set to RED on the color knob. The X Unit connected to the patient's arterial line would then also be set to RED. (**Blue**: CVP/RAP, **Yellow**: Pulmonary Artery Pressures, **Green/White**: Misc. physiologic pressures)

Another benefit of the color channel is ease of patient set up. Using different colors for different pressure signals on the same patient allows the operator to simultaneously LINK all X Units to their respective M units. See LINK instructions.

RFID Reader (Inside housing) – The Wireless Physiologic Monitoring System for pressure monitoring has a RFID (Radio Frequency Identification) reader incorporated into each X and M unit. The FastLink Cards provided with the system are each encoded with a unique identification number so that none are the same. The FastLink card provides the unique ID code that will be read by each X unit and M unit and will be used by the modules to identify each other.

INDICATORS

System Indicator LED's – Green LED indicates linking status. Red LED indicates system fault conditions.

Battery Level LED's – Green indicates full battery level. Yellow indicates medium power level. Red LED indicates low power and replacement required. The Red LED will automatically begin blinking when there is approximately 4 hours or less of battery power remaining.

Audible beeper (not shown) – The X Unit will automatically begin emitting an audible signal (approximately once every 5 seconds) when there is approximately 4 hours or less of battery power remaining.

The beeper signals the corresponding color channel number selected during linking.

System Operation

System Receiving, Inspection and Assembly

The components of the Wireless Physiologic Monitoring System are shipped separately. Each package should be carefully inspected for shipping damage. If damage is detected, file a damage claim with the carrier.

Each transmitter module should be carefully unpacked and inspected. These modules are electronic devices and should be handled accordingly.

The Wireless Physiologic Monitoring System Modules (X and M units) are fully assembled and are ready for use. The IV holder assembly is comprised of a Module holder and a Backplate holder.

System Programming and Set Up

The Wireless Physiologic Monitoring System operates in the frequency bands designated for use by the Wireless Medical Telemetry Service. The devices require registration and deployment by an authorized frequency coordinator. ASHE (American Society for Healthcare Engineering) has been designated by the FCC (Federal Communications Commission) to manage the WMTS frequencies.

The factory default settings for the operating frequency bands are as follows;
1395 – 1400 MHz
1427 – 1429.5 MHz

Devices can be reprogrammed to operate in portions of these bands if required by the frequency coordinator. Programming RFID cards may be obtained from Edwards Lifesciences if reprogramming of the frequencies is required.

PROGRAMMING FREQUENCIES

The Wireless Physiologic Monitoring System is reprogrammed as follows.

1. Verify that a battery is installed in the X Unit or that the M Unit is connected to a monitor that has been powered.
2. Verify that the proper Frequency Programming Card (FPC) has been selected by checking the Frequency information printed on the card.
3. Momentarily press the LINK button on the Module to be reprogrammed. The system indicator LED will begin blinking green once per second. This indicates that the reader is active and ready.
4. Hold the FPC against the lower portion of the module housing.
5. When the Module system indicator LED blinks green quickly (3 times per second), the module has been programmed.

6. If the system indicator LED blinks red (2 times per second), the programming has failed and needs to be retried.
7. Test each module for linking to verify proper frequency programming.

SYSTEM SET UP

The Wireless Physiologic Monitoring System for pressure monitoring is set up as follows;

1. Clamp the Transducer Module Holder bracket to the desired IV Pole.
2. Clamp the Transducer Backplate bracket to the IV Pole, a few inches below Module bracket. This will later be adjusted to the patient height per TruWave instructions.
3. Remove the battery compartment cover from the Transducer Module.
4. Install an Alkaline AA size battery into the battery compartment noting the polarity for positive and negative terminals.

NOTE: The unit will not operate if the battery has been installed incorrectly.

5. Replace battery compartment cover.
6. Mount Transducer module onto Holder by firmly pressing the hook and loop fastening system together.
7. Plug the Monitor Module into the patient monitor pressure input connector. Note that position of input connector will determine position of trace on the monitor display.

CAUTION: The link performance range is designed to operate up to 15 feet in unobstructed space. Obstacles in between modules may cause some signal interference and should be avoided.

8. Using standard disposable transducer set up procedures, set up and prime a TruWave pressure transducer and install in Holder Backplate.
9. Plug the transducer connector into the Transducer Module connector.
10. Repeat steps 3 through 9 for additional pressure lines.

Set up is complete.

SYSTEM SET UP USING PATIENT MOUNT (WDTPM1)

The Wireless Physiologic Monitoring System for pressure monitoring is set up as follows using the patient arm band accessory;

1. Remove the battery compartment cover from the Transducer Module.
2. Install an Alkaline AA size battery into the battery compartment noting the polarity for positive and negative terminals.

NOTE: The unit will not operate if the battery has been installed incorrectly.

3. Replace battery compartment cover.
4. Open the internal fabric flap on the Patient Mount arm band.
5. Place the Transducer Module into the pocket by feeding the antenna, cable and color knob through the access hole. The control panel should face the clear window.

6. Place the Patient Mount arm band on the patients upper arm on the same arm that the transducer has been mounted.
7. Use the adjustable fastening belt to secure the Patient Mount.
WARNING: Do not overtighten the patient mount to prevent discomfort, injury or compromise blood circulation.
8. Plug the transducer cable into the transducer module connector.
WARNING: Remove bedding, gown, pillow from the immediate area of the Patient Mount and the transducer module. Covering of the module may impair the ability to visualize and hear the system indicators and low battery alert.

CAUTION: The link performance range is designed to operate up to 15 feet in unobstructed space. Obstacles in between modules may cause some signal interference and should be avoided.

Set up is complete.

SYSTEM SET UP USING BATTERY PACK (W9VBP1)

The Wireless Physiologic Monitoring System for pressure monitoring is set up as follows using the battery pack accessory;

1. For instances where a Monitor Module is being used with a bedside or transport monitor that requires supplemental power, the Battery Pack accessory can be used. This can be determined when the Monitor Module fails to power on when the patient monitor is turned on.
2. Remove the battery cover on the Battery Pack housing.
3. Install a new 9 Volt Alkaline battery.
4. Plug the Battery Pack connector into the Monitor Module power adaptor connector.

Set up is complete.

Note: The Battery Pack accessory should be unplugged from the Monitor Module when not in use to prevent battery drainage.

Operation

CHECKING THE BATTERY LEVEL

1. Press and hold the TEST button on the X unit (or M Unit if battery powered) to activate the Battery level LED indicators.
2. The Battery level LED's will illuminate as follows;
Green – indicates good charge
Yellow – indicates medium charge
Red – indicates low charge and battery change required.

WARNING: Do not begin use if a low battery condition is detected. Replace with a new battery even if the alert has not begun flashing or beeping.

CAUTION: Replace the module if a battery check is performed and no LED lights up. One of three conditions should be lighted or a LED has failed.

Note: The Battery level LED indicators on the M unit are not active if it is not battery powered. Pressing the M unit TEST button will then activate the pressure test signal function only.

SETTING THE COLOR CHANNEL

1. Verify that the X and M unit to be paired have been set to the same color channel. Rotate the Color knob to the desired color indicated by the arrow on the rear panel.

Caution: If paired X and M units are not set to the same color, they cannot be LINKED.

2. If more than one pressure line is being used on the same patient, X and M pairs should be set to different colors to minimize confusion.

WARNING: Do not attempt to link multiple units with the same color wheel setting, with the same FastLink card, at the same time. It is possible that the signals may be crossed.

Note: Once the link has been established, turning the color wheel will **not** disrupt the link.

CAUTION: Do not turn the color wheel once the pressure link to avoid confusion of paired modules that may indicate different colors.

ESTABLISHING THE LINK

Verify that the system set up has been completed and that a FastLink Card is available.

Note: The link may be initiated from either the X or M unit. For instructional purposes, this example will be started from the X unit.

1. Press and hold the LINK button of the X unit for at least ½ second. The system green LED will begin blinking indicating that the RFID reader is ready.
2. Position the FastLink card against the **lower portion** of the X Unit housing. The system green LED will change to a quick blink and an audible beep will sound indicating that the FastLink card is being read.

CAUTION: The Fastlink card being held against the module in a position other than the recommended lower portion may result in the FastLink card not being properly read even if an audible beep is heard.

3. Press the LINK button of the desired M unit. The system green LED will begin blinking indicating that the RFID reader is ready.
4. Position the FastLink card against the lower portion of the M Unit housing. The system green LED will change to a quick blink and an audible beep will be heard indicating that the FastLink card is being read.

CAUTION: The Fastlink card being held against the module in a position other than the recommended lower portion may result in the FastLink card not being properly read even if an audible beep is heard.

Once the X and M units have successfully identified each other, a confirming audible beep corresponding to the color channel number will be heard from each unit and the green LED will light constant for a few seconds. The pressure trace will be displayed. The system green LED will then slowly blink, continuously.

Note: Monitors will require that the zero procedure be completed prior to any pressure trace being displayed.

ESTABLISHING MULTIPLE LINKS ON THE SAME PATIENT

Verify that the system set up steps have been completed and that a FastLink Card is available.

Note: The link may be initiated from either the X or M unit. For instructional purposes, this example will be started from the X unit.

1. Select different color channels for each pair of X and M units for the patient. The center of the color band should be aligned with the color indicator arrow located on the rear panel.
2. Press the LINK button of each X unit. The system green LEDs will begin blinking indicating that the RFID readers are ready.
3. Position the FastLink card against the lower portion of the first X Unit housing. When the system green LED changes to a quick blink indicating that the FastLink card has been read, move to the next X unit. Repeat until all X units have read the FastLink. The X module allows approximately 10 seconds from pressing the LINK button to reading the FastLink card.
4. Press the LINK button of each M unit. The system green LEDs will begin blinking indicating that the RFID readers are ready.
5. Position the FastLink card against the lower portion of the first M Unit housing. When the system green LED changes to a quick blink indicating that the FastLink card has been read, move to the next M unit. Repeat until all M units have read the FastLink. The M module allows approximately 10 seconds from pressing the LINK button to reading the FastLink card.

Once the X and M units have successfully identified each other, a confirming audible beep corresponding to the color channel number will be heard from each unit. The pressure trace will be displayed. The system green LED will slowly blink, continuously.

Note: Once a X or M module has read the FastLink card, the user has approximately 30 seconds to execute the link steps or the unit will time out and entire linking sequence must be repeated.

Note: Some monitors may require that the zero procedure be completed prior to the pressure trace being displayed.

CONFIRMING THE LINK

Note: There are three locations that the Wireless System can be tested or diagnosed from, the M unit, the X unit and the pressure transducer.

1. Press the TEST button on the M unit to send a test signal (approximately 100 mmHg) to the monitor. This verifies proper connection to the monitor and M unit function.
2. Press the TEST button on the X unit to send a test signal (approximately 100 mmHg) to the monitor. This verifies proper X unit function and link performance.
3. If clinically indicated, pull the Snap-Tap flush device on the TruWave transducer to send a pressure pulse to the monitor. This verifies proper transducer connection and function.

TERMINATING THE LINK

1. Press the LINK button for at least 2 seconds, release and wait approximately 10 seconds. The unit will terminate the existing link communication and turn itself off.

CHANGING THE LINK

1. Press the LINK button for two seconds to terminate the existing link. Press the LINK button for at least ½ second and the RFID reader will be turned on
2. Follow instructions above for “Establishing the Link”.

TRANSPORT LINKS

To prevent interference between a transported patient who is entering an area of other patients who are already linked, it is recommended that the transport patient links be terminated prior to entering the area. Once the patient is in the area, the link may be relinked without interfering with other links.

Maintenance

Transmitter Modules

The Wireless Physiologic Monitoring System modules should always be cleaned and inspected after each use.

Batteries

The Wireless Physiologic Monitoring System uses size AA Alkaline batteries. A new battery should always be used when starting a procedure. There are no federal regulations governing the handling and disposal of these batteries.

Batteries should not be left in the Transducer Module for extended periods of time. Disposal of batteries should coincide with the disposal of the pressure transducer.

See hospital, state or local regulations for disposal or recycling instructions.

AC Adapter

The Wireless Physiologic Monitoring System Monitor Module requires power obtained from the patient monitor pressure module to operate. Some monitor models do not provide adequate levels of power. For these cases, an AC Adapter can be used.

These power supply adapters can be installed and secured to the hospital monitor mounting bracket system. They do not require maintenance. Use only the hospital grade power cord supplied with the adaptor.

IV Pole Holder Assemblies

The Wireless Physiologic Monitoring System Holders should always be cleaned and inspected after each use.

Cleaning

The Wireless Physiologic Monitoring System is comprised of several components. Cleaning instructions for those components are listed here.

WARNING: Unplug the AC Adapter from its wall power source prior to any cleaning. Disconnect all modules from patient monitors and remove all batteries prior to any cleaning.

Caution: Use only approved cleaning agents and solutions.

Component	Approved cleaning agents
Transducer Module Monitor Module IV Pole Holders	Isopropyl Alcohol
FastLink card	Warm soapy water
AC Adapter	Warm soapy water
TruWave transducer	Not Applicable – disposable single use unit

Transducer Module/Monitor Module/AC Adapter/ Holders

Apply cleaning solution to moistened towel to clean unit. Do not immerse. Wipe off any excess solution immediately.

Troubleshooting

System Fault Indicators

The following conditions will be reflected by the system indicators.

CONDITION	INDICATOR	RESPONSE
Incorrect FastLink read Simultaneous pairs with same color channel	System Red LED	2 blinks per second
System malfunction requiring service	System Red LED	Continuous on
Network full Excess interference	System Red LED	1 blink per second
Battery Low	Test Red LED Beeper	1 blink per second Beep once per 5 seconds
Lost link System failure	Monitor trace	Negative 100 mmHg signal

Symptoms and Remedies

Should the listed Corrective Action fail to remedy the condition, the unit should not be used.

SYMPTOM	PROBABLE CAUSE	CORRECTIVE ACTION
X Unit does not respond	No power	Replace battery
	Battery installed backwards	Replace battery
	Battery voltage below start up threshold	Replace battery
M Unit does not respond	No power	Verify Monitor power is turned on
	Insufficient power	Verify if AC adapter is plugged in
X and M Units will not link	Conflicting color channels; color wheel not in switch detent position	Verify that the paired X and M units are set to the same color channel
	More than one pair of X and M units are set to same channel	Verify that different paired X and M units are set to different color channels
	Local Network is full, excessive interference present	Move X unit location around patient Convert to cable usage

	FastLink card has not been properly read	Redo Link procedure placing the FastLink card adjacent to the lower portion of the module
Monitor trace is gone	X Unit battery is dead	Verify battery level
	M Unit is unplugged	Verify M connection is good to monitor input
	System malfunction	Confirm M and X function with TEST button to isolate

Technical

Reorder Information

ITEM DESCRIPTION	MODEL #
Transducer Module (X Unit)	WTP1000
Monitor Module (M Unit)	
GE/Marquette	WTM 507
Philips	WTM 083
Spacelabs	WTM 019
MDE	WTM 021
IV Holder – Modules	WDTH1
IV Holder – Backplate	
FastLink Card	WLINK1
Frequency Programming Card	WDATA1
AC Adapter	WAC1
Monitor Module 9V Battery Pack	W9VBP1
Wireless Patient Mount	WDTPM1

Specifications

PARAMETER	SPECIFICATION
Environmental Operating	15 deg C to 35 deg C
Physical Dimensions (X&M units)	1.5" W x 6.0"H x 1.5"D 3.8 cm W x 15.2 H x 3.8 D
Weight	6 oz. (170 gm)
Fluid protection	IEC 60529 level IPX1

<p>Electrical Power Input Transducer module: Monitor module: AC Adapter: Safety Electromagnetic Immunity Electromagnetic Emissions</p>	<p>1.5 VDC – single AA Alkaline battery, 2500 mAh, (Duracell MX1500) 3.0 VDC, 25 mA 100-240 VAC 47-63 Hz Input 9.0 VDC, 1.1 A Output EN60601-1 EN60601-1-2, IEC 61000-4 EN60601-1-2, CISPR 11, IEC 61000-3</p>												
<p>Radiofrequency RFID Reader System Operating Frequency Data Link Operating Frequencies Frequency channels (6 ea) Channel bandwidth Power output level Range</p>	<p>US FCC CFR47 Part 15.209 Compliant 134.2 kHz WMTS Bands 1395 MHz- 1400 MHz, 1427 MHz- 1429.5 MHz US FCC CFR 47 Part 95 Subpart H Compliant FCC has designated ASHE (American Society for Healthcare Engineering) to manage the WMTS (Wireless Medical Telemetry Service) frequencies</p> <table border="0" data-bbox="776 1066 1179 1283"> <tr><td>1</td><td>1395.625 MHz</td></tr> <tr><td>2</td><td>1396.875</td></tr> <tr><td>3</td><td>1398.125</td></tr> <tr><td>4</td><td>1399.375</td></tr> <tr><td>5</td><td>1427.625</td></tr> <tr><td>6</td><td>1428.875</td></tr> </table> <p>600 kHz -5 dBm 15 feet, 4.6 m in free space</p>	1	1395.625 MHz	2	1396.875	3	1398.125	4	1399.375	5	1427.625	6	1428.875
1	1395.625 MHz												
2	1396.875												
3	1398.125												
4	1399.375												
5	1427.625												
6	1428.875												
<p>FCC ID Transducer/Monitor Module</p>	<p>FCC ID: S8HWPMS</p>												

System Performance	
Network link capacity	9 links
X Unit battery life	40 hrs typ.
Pressure Range	-75 to 325 mmHg
Accuracy	+/- 4 mmHg or 4% of reading whichever is greater
Frequency Response	No less than 3 dB up to 10 Hz
Data Latency	≤ 60 msec
Input impedance (M unit)	200-400 ohms
Output impedance (M unit)	300 ohms +/- 5%
Low battery warning	≤ 4 hours

Returned Goods Authorization

When returning a Wireless Physiologic Monitoring System module or accessory, please pack the unit carefully in its original shipping container or another similarly protective container. In the United States, call Edwards toll-free Technical Support telephone number 800.822.9837 and obtain a Returned Goods Authorization number and further instructions.

Technical Assistance

For technical assistance, please call Edwards Technical Support at the following telephone numbers:

Inside the U.S. and Canada
 (24 hours) 800.822.9837
 Outside the U.S. and Canada
 (24 hours) 949.250.2222

Warranty

Edwards warrants that the Wireless Physiologic Monitoring System is fit for the purposes and indications described in the labeling for a period of one year after the date of purchase when used in accordance with the directions for use. Unless the equipment is used in accordance with such instructions, this warranty is void and of no effect. No other express or implied warranty exists, including any warranty of merchantability or fitness for a particular purpose. This warranty does not include cables, tubing sets, or batteries used with this Wireless Physiologic Monitoring System. Edwards' sole obligation and purchaser's exclusive remedy for breach of any warranty shall be limited to repair or replacement of the Wireless Physiologic Monitoring System at Edwards' option. Edwards shall not be liable for proximate, incidental, or consequential damages.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Because of continuing product improvements, prices, specifications, and model availability are subject to change without notice.

U.S. Patents Pending

Trademarks

Edwards Lifesciences, stylized E logo, Edwards and TruWave are trademarks of Edwards Lifesciences and TruWave are registered in the U.S. Patent and Trademark Office.

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