Wireless System for DPT

System Operating Manual

430-11431-001

Change History

Part Number	Reason for Revision	Pages Affected
430-11167-001	Initial Release	

How to Reach Us

For customer service within the United States, contact:

1-877-9Hospira or 1-877-946-7747

For technical assistance, product return authorization, and to order parts, accessories, or manuals within the United States, contact Hospira Technical Support Operations.

1-800-241-4002

To order parts using the online eCatalog, download technical publications, technical training courses, and additional services, visit the website at:

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Note: Outside the U.S., contact your local Hospira sales office.

Note: Decontaminate all product returns prior to shipping.

Chapter 1

Introduction

This document describes the features, functions, operation of the Wireless System for DPT® transceiver system for use with Hospira Transpac IV® and Hospira Transpac IT® disposable pressure transducers.

The base system includes a transmitter module and a minimum of 2 receiver channels to support the wireless transmission of 2 invasive blood pressure signals. Additional receiver modules can be purchased to support up to 5 transducers per system.

This manual is intended for use by trained medical clinicians familiar with multi-parameter patient monitors.

INDICATIONS FOR USE

Wireless System for DPT® is indicated for use when invasive blood pressure monitoring is needed and a cable-free connection is desired between Transpac IT® or Transpac IV® transducers and a patient monitor. Wireless System for DPT® supports only pressure transducers provided by Hospira.

CONTRAINDICATIONS

The use of Wireless System for DPT® is contraindicated:

- Do not use to synchronize external devices.
- Do not use during MRI or PET scanning.
- Do not use to trigger aortic balloon assist devices.

WIRELESS SYSTEM FOR DPT SYSTEM CONTENTS

The system and accessories are packaged as follows:

Base System Box (required)

- Transmitter
  - AC power cord
  - pre-installed battery
- Receivers
  - 1 IBP channel #1 receiver module
  - 1 IBP channel #2 receiver module
  - 1 receiver cable
  - user manual

Monitor Specific Plug Adapters Box (required)

- 20 monitor-specific plug adapters

Additional IBP Channels #3+ Receiver Modules Box (optional)

- 10 receiver modules for IBP channel #3, #4, or #5
- 10 receiver cables

Additional IBP Channels #1 & #2 Receiver Modules Box (optional)

- 2 IBP channel #1 receiver modules
- 2 IBP channel #2 receiver modules
- 2 receiver cables

Contact Hospira customer service for additional accessories.

Transmitter Front Panel

The front panel features include the following user interface:

- Calibration Buttons
- Pressure Transducer Pigtail Sockets
- Battery LED
- Alarm LED
- Power On/Off Button
- OK Button
- Next Button
- Pressure Transducer Mounting Positions

CALIBRATION BUTTONS

The calibration buttons send a 100 mmHg pressure signal to the selected channel for 10 seconds. The calibration button zeroes the channel if it is pressed while the calibration signal is displayed.

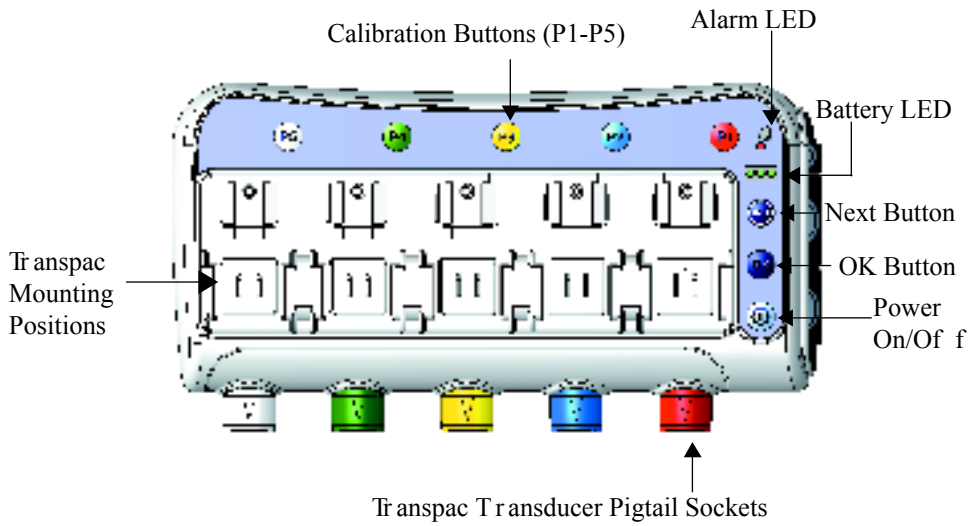


Figure 1.1

PRESSURE TRANSDUCER PIGTAIL SOCKETS

The pressure transducer pigtail sockets are color coded to aid in blood pressure channel traceability from the patient monitor to the patient.

Inserting a pressure transducer plug into a socket triggers power-on.

BATTERY LEDS

The battery indicator has 3 LEDs to indicate battery charge (full, medium, low). See **[insert cross reference to go to the Battery LED table in chapter on Troubleshooting]**

When not connected to AC, the system powers-off after 60 minutes if the battery discharges to a predefined safe low voltage.

When the transmitter is connected to AC, the LEDs flash to indicate that the battery is charging.

ALARM LED

The Alarm LED flashes to indicate and alarm state.

See [**insert cross reference to go to the Alarm LED table in chapter on Troubleshooting]**

POWER ON/OFF

The transmitter is switched ON or OFF by pressing the power button.

OK

The OK button is used during the wireless linking process.. A Wireless System for DPT equipped monitor will display a triangular “linking” waveform prior to the formation of a wireless link to a Wireless System for DPT transmitter. Press the OK button to immediately confirm the link.

The OK button is also used during ZERO ALL. When a calibration signal is displayed, press the OK button to zero all channels. See *Zeroing* on page *13* for more information.

NEXT

The NEXT button cancels a wireless linking process if pressed while the “linking” signal is displayed on a monitor. The wireless linking process is then initiated with the next available monitor.

If the NEXT button is pressed while the transmitter is already linked, the link is broken and a wireless linking process is initiated with the next available monitor.

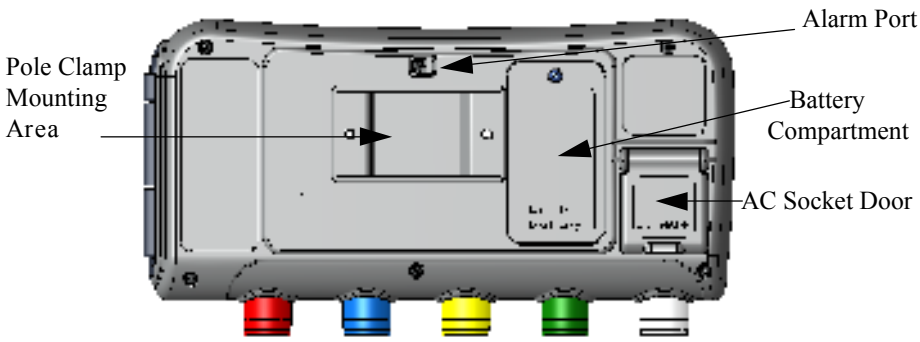
BATTERY

The Li-ion battery is accessed via the back panel. A built-in battery charger automatically charges the battery whenever the transmitter is connected to AC power.

Battery replacement should only be done by a trained technician.

Contact Hospira customer support for replacement batteries.

Back Panel



Features

Receiver Modules

Wireless System for DPT receiver modules are connected to the IBP sockets of a patient monitor and present the same electrical load and response as industry standard 5 µV/V pressure transducers. They are powered by the monitor and contain no batteries or other serviceable parts. The illustration shows the modules with GE Solar™ series adapters attached. Contact Hospira customer service to order adapters for monitors from other manufacturers.

CAUTION: ONCE THE MONITOR SPECIFIC ADAPTERS ARE CONNECTED THEY CAN NOT BE REMOVED.

RECEIVER MODULE 1(REQUIRED)

Receiver module number 1 is required. It simulates the presence of the transducer connected to transmitter socket “P1” and is color coded red.

RECEIVER MODULE 2 (REQUIRED)

Receiver module number 2 is required. It simulates the presence of the transducer connected to transmitter socket “P2” and is color coded blue.

RECEIVER MODULES 3, 4, & 5 (OPTIONAL)

Receiver modules for channels 3, 4, and 5 are optional. The channel number is selected by the switch shown below.

RECEIVER CABLES (REQUIRED)

The receiver cables distribute power and data between the modules.

MONITOR ADAPTERS (REQUIRED)

The receiver modules require plug adapters that are often unique to each monitor manufacturer. Contact Hospira customer service for a list of compatible monitors and to order adapters.

Chapter 2

System Overview

The Wireless Transducer is designed to eliminate the wires and cables that tether patients to monitoring equipment. The cable function is replaced by the Wireless Transducer.

The Wireless Transducer can be powered by a battery for portable use, but is intended to be operated using standard AC power when available. While connected to AC power, the Wireless Transducer also functions as a battery charger.

CALIBRATION BUTTONS

Five buttons provide calibration information. The Transpac Transducer sends a 100 mmhg calibration signal on the selected channel for 10 seconds. The receiver and monitor use this calibration signal for a secondary monitor and channel number confirmation. The calibration buttons zero the channel if pressed while the calibration signal is displayed.

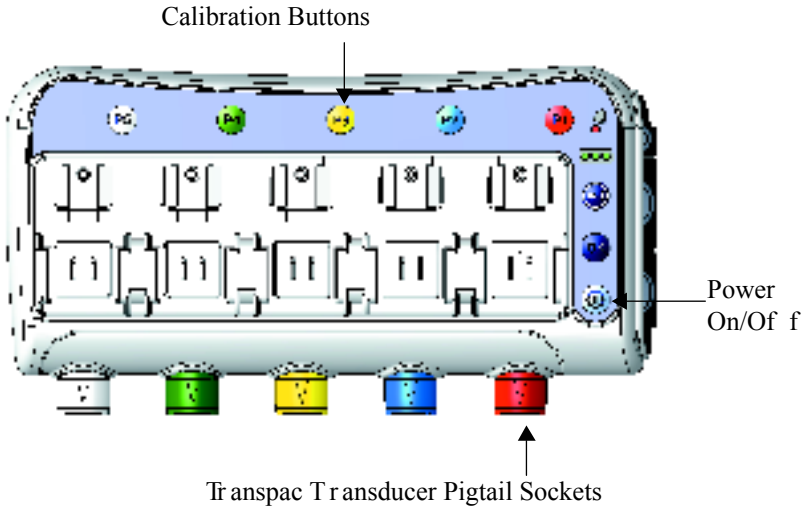


Figure 2.1

POWER ON/OFF

The Transpac Transducer is turned on by activating the power button.

TRANSPAC TRANSDUCER PIGTAIL SOCKETS

The Transpac Transducer Pigtail Sockets are color coded for jumper cable attachment. Inserting the plug into the socket triggers a power on cycle.

BATTERY LED

The Battery LED indicates that the power is on.

When not connected to AC, the LED flashes and the system powers off after 60 minutes if the battery discharges to a predefined safe low voltage.

When the Transpac Transducer is connected to AC, the LED flashes to indicate that the Transpac Transducer is charging.

ALARM LED

The Alarm LED flashes when the alarm sounds. It blinks when wireless interference is detected.

OK

Press the Ok button to immediately confirm and link. The monitor displays a corresponding “linking” waveform on the monitor.

If you press the Ok button when a calibration signal is displayed, the output of all channels are set to zero. See *Zeroing* on page *13* for more information.

NEXT

The Next Button selects the next receiver if it is pressed when the “linking” signal is displayed. The “linking” signal is redirected to the next receiver. The Next Button triggers new link.

If the Next Button is pressed when it is already linked, the link is broken, and “linking” signal is displayed on the next available monitor.

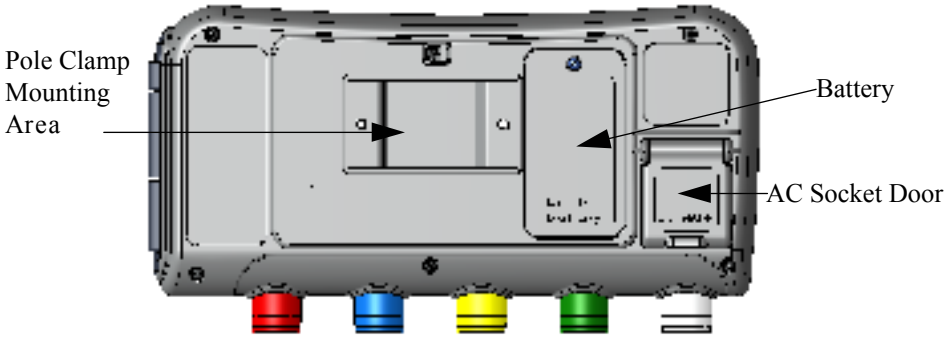
CALIBRATION

The calibration buttons are ....

Wireless Transducer Battery

The battery is located on the back panel under a compartment door. The Transpac Transducer supports the LI-ON Battery.

A built-in battery charger automatically charges the battery, whenever the Transpac Transducer is plugged into AC



power.

Figure 2.2 Transpac Battery

ACCESSORIES

- 10 cm length cable
- 25 cm length cable
- additional receiver adaptors (3) qty

Chapter 3

Basic Operations

This chapter contains instructions and information about the basic operations of the transmitter/receiver device.

Set Up

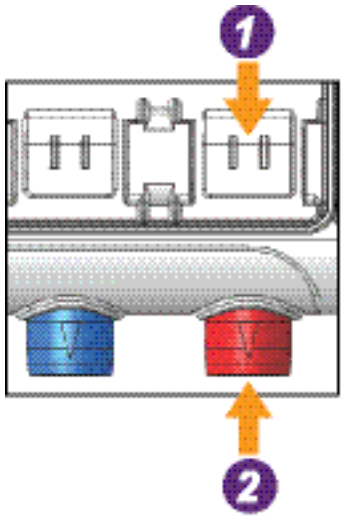
Below are instructions on how to set up the transmitter, transducers, and receiver modules.

TRANSDUCER CONNECTION

WARNING: ONLY USE TRANSDUCERS PROVIDED BY HOSPIRA. USE OF OTHER TRANSDUCERS MAY DAMAGE THE TRANSMITTER AND VOIDS THE WARRANTY.

NOTE: Transducer connection will trigger power on.

1. **SLIDE** transducer into mounting rack.
2. **PLUG** pigtail cable into socket under transducer.



POWER ON AND WIRELESS LINK

For normal operation, always keep transmitter connected to AC power.

1. **CONFIRM** AC is connected (use GFCI outlet).
2. If not already on, **PRESS** and **HOLD** power button [add graphic here] until system beeps.

CONFIRM that the power status  is OK

3. Once the transmitter autotmatically links to the strongest receiver signal:

Figure 3.1 a. CONFIRM **triangle waveform is displayed on desired monitor. See** below.

b. **PRESS "OK"** 

c. If no triangle waveform, **PRESS "NEXT"** 

d. If no triangle waverform appears, **PRESS "NEXT"**  again.

e. If there is still no triangle waveform, **POWER OFF** and **POWER ON**.

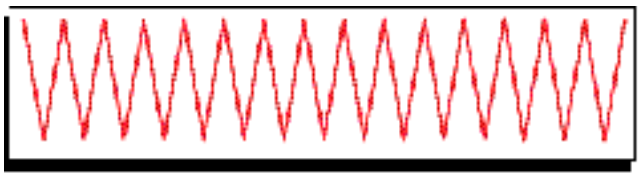


Figure 3.1 Sample of Waveform

NOTE: Waveform may appear clipped due to scaling. See Figure 4.2 below.

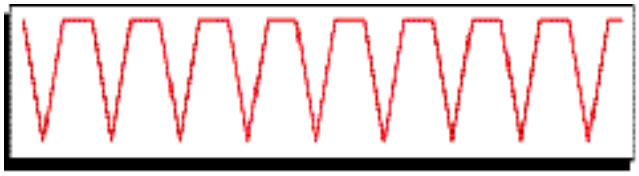


Figure 3.2 Sample of Clipped Waveform

POWER OFF

PRESS and **HOLD "POWER"**  until system beeps and shuts down.

Operation

Once the batteries have been checked and the Wireless Transducer has been set up, there are three basic steps to using the Wireless Transducer.

For normal operations, keep AC connected to a GFCI outlet.

SETTINGS

Power On the transmitter and select the appropriate settings from the receiver module channel selector. The channel selector switch offers the following selections: p3, p4 , or p5. Selection p5 is in the middle because it is difficult to select. Duplicate channels on bus will prevent system

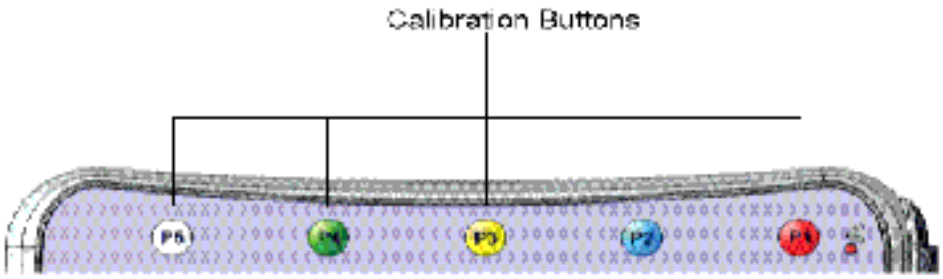
operation.

picture of receiver setting 09/18/06

CALIBRATION

begin Content from Tips Card here 09/12/06

1. **PRESS** and **RELEASE** desired calibration button.



2. **CONFIRM** monitor displays **100 mmHg** on the corresponding channel (signal appears for 10 seconds).

A. IF 100 MMHG SIGNAL DOES NOT APPEAR, reset THE WIRELESS LINK.

b. If signal appears on the wrong channel, contact Technical Services for sytem stetup.

c. If signal is not within 98 - 102 mmHg, contact Technical Services for monitor calibration.

3. **REPEAT** Steps 1 and 2 for each connected transducer.

The Transpac Transmitter sends a 100 mmhg calibration signal to the selected receiver channel and monitor for 10 seconds to provide a secondary confirmation of the monitor and channel number.

ZEROING

WARNING: BEFORE ZEROING THE TRANSDUCERS, MOUNT AND SECURE THE TRANSMITTER SO THAT THE PORTS TO THE ATMOSPHERE ARE LEVEL WITH THE PATIENT'S HEART.

Connect and prime patient tubing prior to zeroing.

ZEROING A SINGLE TRANSDUCER

1. **OPEN** the transducer to the atmosphere (see manufacturer's instructions).
2. **CONFIRM** flatline pressure trace on the monitor.
3. **PRESS** and **RELEASE** the transducer's calibration button 

(add graphic of cal. button).
4. **PRESS** and **RELEASE** the transducer's calibration button 

a second time while the calibration signal displays.
5. **CONFIRM** that the pressure trace goes to zero.
6. **CLOSE** the transducer's stopcock to the atmosphere.

ZEROING ALL TRANSDUCERS

1. **OPEN** all transducers to the atmosphere (see manufacturer's instructions).
2. **CONFIRM** flatline pressure traces for each on the monitor.

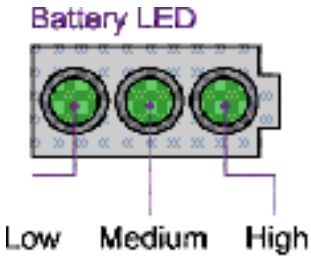
3. **PRESS** and **RELEASE** 

(add graphic of calibration button here) corresponding to first transducer

4. **PRESS** and **RELEASE** 

while the calibration signal displays.
5. **CONFIRM** that the pressure traces for all transducers go to zero.
6. **CLOSE** each transducer's stopcock to atmosphere.

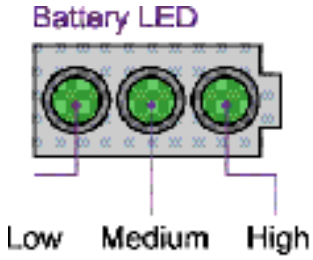
Battery Operation



CHECK BATTERY CHARGE

1. If Transducer is not already powered on, press and hold  until system beeps.

Confirm that the battery LED indicates a sufficient charge. See "Battery LED Table" on page *28*.



CHARGE BATTERY

1. Connect transmitter to AC.

   Battery LED will blink to indicate charging.
2. Charge battery for 6 hours.

NOTE: -- Keep AC connected to GFCI outlet when not in transport.
-- Battery capacity is 72 hours of operation.
-- Low battery alarm triggered when less than 1 hour of battery capacity remains.

The battery used for the Wireless Transducer is a 3.6 Volt rechargeable Lithium-ion battery. A fully charged battery will power a Wireless Transducer Patient Transceiver for a minimum of 24 hours. Batteries are shipped in the uncharged state, with a plastic film cover covering the contacts.

CAUTION: **REMOVE THE PLASTIC FILM COVER FROM THE BATTERY CONTACTS BEFORE USING. DO NOT SHORT THE BATTERY TERMINALS. DO NOT TRY TO CONNECT A BATTERY WITH ANY DEVICE OTHER THAN A WIRELESS TRANSDUCER. DO NOT EXPOSE THE BATTERY TO HIGH TEMPERATURE (ABOVE 60ÛC / 140ÛF).**

CAUTION: DO NOT INCINERATE, SUBMERGE, CRUSH, DISASSEMBLE OR AUTOCLAVE THE BATTERY. DO NOT RECHARGE OR REUSE BATTERY THAT HAS BEEN SUBMERGED; DISCARD OR RECYCLE IT IMMEDIATELY.

BATTERY LIFE/BATTERY DISPOSAL

It is recommended that batteries be discarded after one year of use, due to degradation of capacity. After extended use, the battery will deliver decreased operational life per charge. Recycle or dispose of discarded batteries according to national, state, and local regulations.

BATTERY STORAGE

Batteries should be removed from Transmitter and stored separately when not in use for more than a few days.

NOTE: **THE TRANSMITTER WILL CONTINUE TO DRAW A SMALL AMOUNT OF POWER FROM THE BATTERY EVEN WHEN NOT CONNECTED AND ALL INDICATORS ARE OFF. IF BATTERIES ARE STORED FOR MORE THAN A MONTH THEY WILL NEED CHARGING.**

NOTE: **STORING THE BATTERY FOR A LONG PERIOD OF TIME WITHOUT USE MAY DEGRADE THE BATTERY CAPACITY.**

CAUTION: STORE BATTERIES BETWEEN -40ûC AND 70ûC/ -40ûF AND 160ûF. KEEP BATTERIES IN LOW HUMIDITY LOCATION WITH LITTLE TEMPERATURE VARIATION. KEEP BATTERIES AWAY FROM DIRECT SUNLIGHT.

CHARGING BATTERIES IN THE TRANSMITTER

Whenever the Wireless Transducer Transceiver is connected to AC power, it functions as a charger for the battery.

HOW TO CHECK THE BATTERY

1. If not already on, press and hold power button until system beeps.
2. Confirm battery LED indicates sufficient charge.

HOW TO CHARGE THE BATTERY

1. Connect transmitter to AC.
2. Battery LED will blink to indicate charging.
3. Charge battery for 6 hours.

BATTERY CHARGE INDICATOR

The battery charge indicator on the front of the Wireless Transducer displays a strobe when the battery charger function is active. When the Wireless Transducer is powered by a battery (not connected to AC power), and the battery discharges to a predefined safe low voltage, the LEDS will flash and the system will power-off after 60 .

SWAPPING BATTERIES

The Wireless Transducer is intended to be used primarily with the Wireless Transducer connected to AC power. When the battery runs low, it can quickly be swapped for the fully charged battery.

CAUTION: USE ONLY A WIRELESS TRANSDUCER TRANSMITTER OR A BATTERY CHARGER TO RECHARGE THE BATTERY.

NOTE: **SWAPPING BATTERIES DOES NOT REQUIRE RE-CALIBRATION OF THE WIRELESS TRANSDUCER.**

Cleaning

The Wireless Transducer, battery, and power supply may be cleaned as needed by wiping with a nearly dry cloth, moistened with one of the following widely used hospital disinfectants: 1:10 ratio household bleach and water, Sporicidin, Manu-Klenz, warm water and soap, Fantastik®, Cidex®, 70% isopropyl alcohol or T.B.Q.® (Calgon Corp.). Thoroughly wipe off any excess cleaning solution with a dry cloth.

CAUTION: DO NOT USE THE FOLLOWING SOLVENTS FOR CLEANING THE WIRELESS TRANSDUCER, BATTERY, AND POWER SUPPLY : BUTYL ALCOHOL, ETHANOL, FREON, BLEACH, ACETONE, HYDROGEN PEROXIDE. USE OF ANY OF THESE SOLVENTS MAY LEAD TO DETERIORATION OF PLASTIC COMPONENTS. DO NOT AUTOCLAVEANY COMPONENTS.

CAUTION: TRANSCEIVERS SHOULD HAVE BATTERIES INSTALLED WHENEVER THEY ARE CLEANED. BATTERIES MAY BE CLEANED SEPARATELY BUT CARE MUST BE TAKEN TOAVOID WETTING THE METAL BATTERY CONTACTS.

WARNING: DO NOT ALLOW LIQUID INTO BATTERY SLOTS, BATTERY CONTACTS, CONNECTOR PORTS, TOKEN PORTS OR ANY OTHER OPENINGS OR CREVICES. DO NOT IMMERSE ANY COMPONENT IN LIQUID. SYSTEMS ARE INTENDED FOR SINGLE PATIENT USE ONLY. THEY MAY BE WIPED WITH A NEARLY DRY CLOTH, MOISTENED WITH WARM WATER. IF THE SYSTEMS AND/OR THE ARMBAND BECOMES BADLY SOILED, IT SHOULD BE REPLACED.

NOTE: These recommendations are provided for guidance only. The actual cleanliness of devices depends upon techniques and actual cleaning practices employed by the user.

WARNING: BEFORE ZEROING THE TRANSDUCERS, MOUNT AND SECURE THE TRANSMITTER SO THAT THE PORTS TO THE ATMOSPHERE ARE LEVEL WITH THE PATIENT'S HEART.

1. ZERO the monitor.
2. Confirm that the receiver modules have power and are not linked (un-paired) to any transmitter.
3. If the monitor displays 0.0 mmHg for each pressure channel, ZEROing is not required.

4. If the monitor does not display 0.0 mmHg for each pressure channel, ZERO each channel per the monitor manufacturer's instructions (GE example attached).
5. If the monitor does not display 0.0 mmHg for each pressure channel after ZEROing, contact your technical services department.

ZERO SINGLE TRANSDUCER

1. Open transducer to atmosphere (see manufacturer's instructions).
2. Confirm flatline

ZERO ALL TRANSDUCERS

BEFORE LINKING TO A RECEIVER, CONFIRM THAT THE MONITOR IS ZEROED AS DESCRIBED ZEROING

1. .
2. Confirm that the transmitter is linked to the desired receiver modules.
3. Prepare all transducers for ZEROing per your established procedures (GE example attached).
4. If the monitor displays 0.0 mmHg for all pressure channels, ZEROing is not required.
5. To ZERO all channels, press OK. ["LAP" WILL BE USED FOR THE CURRENT PROTOTYPE]
6. The pressure traces will go to 0.0 mmHg.

   NOTE: The ZERO request will be ignored if the any measured pressure is beyond +/- 150 mmHg or is not stable (within +/- 1 mmHg).
7. Confirm that the monitor displays 0.0 mmHg for all pressure channels.
8. If the monitor does not display 0.0 mmHg for all pressure channels, contact your technical services department.

ZERO A SINGLE TRANSDUCER

1. Before linking to a receiver, confirm that the monitor is ZEROed as described above.
2. Confirm that the transmitter is linked to the desired receiver modules.
3. Prepare the transducer for ZEROing per your established procedures (GE example attached).
4. If the monitor displays 0.0 mmHg for the pressure channel, ZEROing is not required.
5. To ZERO a single channel, press that channel's calibration button.
6. While the 100 mmHg calibration signal is displayed on the monitor, press that calibration button again. The pressure trace will go to 0.0 mmHg. NOTE: The ZERO request will be ignored if the measured pressure is beyond +/- 150 mmHg or is not stable (within +/- 1 mmHg).
7. Confirm that the monitor displays 0.0 mmHg.
8. If the monitor does not display 0.0 mmHg for the ZEROed channel, contact your technical services department.

GE Specs For Zero Balance	
Range	***+/- 150 Mmhg***
Accuracy	***+/- 1 mmHg***
Drift	***+/- 1 mmHg / 24 hrs***

8.

Transfer Between Monitors

[10/04/06 aa. title means transferring from one monitor to another? suggested title: changing monitors or switching monitors]

To redirect a wireless link from one patient monitor do the following:

1. Press and release the Next Button.
2. Follow the procedure for linking (power-on cycle)

NOTE: **THIS PROCEDURES REQUIRES A SECOND PATIENT MONITOR CONFIGURED WITH HOSPIRA ERECEIVER MODULES. SEE SETTING UP RECEIVER MODULES**

CALIBRATING MULTIPLE MONITORS

1. Calibrate one monitor at a time.

   This section goes in the setup portion.

Warnings and Precautions

WARNINGS

- Explosion Hazard – In accordance with UL 60601-1, that applies to all medical equipment, do not use this device in the presence of flammable anesthetics.
- In order for the Wireless Transducer to work properly, the P1 and P2 receiver modules must be connected to their respective transmitter sockets.
- The Wireless Transducer should only be connected as illustrated in the System Set Up section of this manual and only to those monitors validated for compatibility with the Wireless Transducer. Refer to the Cautions section of this manual for a list of validated monitors for the current list of validated monitors.
- Only use the approved Wireless Transducer Power Supply cord (for Europe - Yunhuan Group Y003/ST3, for U.S.A. - Yunhuan Group, YY-3/ST3) in order to ensure that the Wireless Transducer continues to comply with risk (leakage) current and EMI/EMC requirements.
- To ensure patient safety, only use Wireless Transducer interfaces recommended by Hospira. For a complete list of approved interfaces, see System Components and Accessories sections of this manual.
- Normal operation of the Wireless Transducer should be verified in the configuration in which it will be used before engaged in use with a patient. Inspect and test the batteries, and power supply frequently. Do not operate the Wireless Transducer if any system component appears damaged or appears not to function properly. See System Functional Check section of this manual for the procedure to verify normal operation.
- If the Battery LED flashes you have 60 minutes to connect to AC before the system will power-off.
- To ensure patient safety care should be taken to prevent physical contact between electrosurgical equipment and any Wireless Transducer component. the conductive parts of the Wireless Transducer should not contact any other conductive parts, including earth ground, at any time.
- This device should not be used in a Magnetic Resonance Imaging (MRI) suite. Strong magnetic fields may affect the device, causing injury to the patient and/or damage to the equipment.
- The Wireless Transducer can operate in the presence of pacemaker pulses. The Wireless Transducer may miss pacer pulses if high background noise is present. The Wireless Transducer captures signal spikes regardless of whether spikes are due to noise or pacer pulses. If the Wireless Transducer triggers frequently from background noise due to motion artifact, EMI, etc., then pacer pulses could be masked or missed by the Wireless Transducer.
- The Wireless Transducer should not be used for external pacing.
- Impedance pneumography detects respiratory effort via changes in chest volume. Impedance pneumography can be used to detect central apnea, but apnea episodes with continued respiratory effort, such as obstructive apnea and mixed apnea, may go undetected. Artifacts due to patient motion, apnea mattress shaking or use of electrocautery equipment may also cause apnea episodes to go undetected. Impedance pneumography is not recommended for patients with pacemakers.formation

FCC INTERFERENCE WARNING

- 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.

  (2) This device must accept any interference received, including interference that may cause undesired operation.

- This equipment has been approved for mobile applications where the equipment should be used at distances greater than 20cm from the human body (with the exception of hands, wrists, feet and ankles). Operation at distances less than 20 cm is strictly prohibited.

- Changes or modifications not expressly approved by Elcam – Medical for compliance could void the user's authority to operate the equipment

- The antenna(s) used for this transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

CAUTIONS

- The batteries should be removed when the system is not in use for extended periods of time.
- Remove the plastic film cover from the battery contacts before using.
- Do not autoclave Wireless Transducer components. Do not submerge Wireless Transducer components in any liquid.
- The Wireless Transducer transmitter and receiver have been tested and shown to comply with FCC Part 15. Any changes or modifications to the Wireless Transducer not expressly approved by Hospira could cause Wireless Transducer emissions to exceed those permitted under FCC rules, and would thus void the user's authority to operate the equipment.
- If operating under conditions according to the EMC-standard 60601-1-2 (Radiated Immunity 3V/m), field strengths above
  1.5 V/m may cause erroneous measurements of respiration at various frequencies when the Wireless Transducer is used together with the Welch Allyn Propaq Series Monitor Systems. Therefore, if it is of critical and clinical importance to monitor respiration, it is recommended to avoid the use of electrically radiating equipment (such as electrocautery surgical pencils, and high powered portable and mobile RF communications equipment) while the Wireless Transducer is being used with the Propaq Monitor. However, if respiration must be monitored in the presence of high frequency electrically radiated equipment, always monitor and set alarms for SpO2 when using the Wireless Transducer together with the Propaq Monitor to monitor respiration.
- Only use the Wireless Transducer with the following equipment that has been validated for compatibility:

  Bedside Cardiac Monitors
  Hewlett Packard Agilent Viridia Series

  Portable/Transportable Cardiac Monitors
  Welch Allyn Monitoring Propaq Encore Series

Note: Validation testing for additional equipment is ongoing. Please contact Hospira for the current list of compatible equipment

- Battery replacement is recommended after one year of use.
- The Transmitter can be operated as a Class II device per EN 60601-1 or internally powered.

- This device has been tested and certified to comply with emissions portion of EN 60601-1-2, Medical Electrical Equipment – ElectroMagnetic Compatibility – Requirements and Tests. Although this device is shielded against ElectroMagnetic Interference (EMI), it is recommended that electrically radiating devices not be used in close proximity to this device.
- Portable and mobile RF communications equipment can affect the operation of the Wireless Transducer.
- Operation of the Wireless Transducer below a minimum amplitude of patient physiological signal may cause inaccurate results.

Chapter 5

Alarms and Troubleshooting

ALARMS

TRANSDUCER ALARMS

Table 5-1: Transducer Alarm Table

LED and Tone Indicators	Cause	Action
Blinks for 1 minute ***1 beep ever 10 seconds***	-Power up failure ***-Battery empty***	***Restart on AC***
Lights up for 5 seconds 1 beep every 5 seconds	Communication errors exceed 3 in 10 seconds	-- Eliminate interference -- Move closer to monitor
3 blinks every 5 seconds	Battery charge failure	Restart on AC
Blinks once	Power On Transducer Connected	
Beeps once	-Power Off -Start up -Greeting -Active -Idle after greeting	
-Steady blinking and beeping for 2 minutes -Square wave on monitor for 30 seconds	Wireless link lost	Move closer to monitor
1 blink per second	No transducers connected ???	Confirm connection
-Beeps once 10 seconds after action	A successful transducer connection	

BATTERY LEDS

Table 5-2: Battery LED Table

LED and Tone Indicators	Cause	Action
Blinks and beeps 3 times sequentially -- consecutively??	*-Less than 60 minutes of batter life* *-No power* *-Off -- Charging only*	*Connect to AC*
6 blinks per second	*Skipping one monitor to another*	
3 blinks per second	*New connection*	
3 LED lights on	*Battery at full charge*	
2 LED lights on	*Battery at halfcharge*	*Connect to AC*
1 LED light on *3 beeps repeat*	*Battery at low charge* *Less the 60 minutes of battery life left*	*Connect to AC*
No LED lights on	*60 minutes passed* *transmitter shut down*	*Connect to AC* *Power on*
No LED lights on *2 beeps*	*Powering off*	*Connect to AC* *Power on*

RECEIVER ALARMS

Table 5-3: Receiver Alarm Table

LED and Tone Indicators	Cause	Action
Steady blinking	*Wireless linking in process*	
1 blink per second	*Active State* *Monitor passed greeting cycle* *Starts receiving sensor data*	

Steady beeping	***Improper installation***	***Contact site technical services department***
1 blink	***Sensor connected***	

TROUBLESHOOTING

Table 5-4:

Symptom	Cause	Solution
Transmitter Won't Turn On	Battery dead	• Charge battery, or replace with fully charged battery
	Shipping tape over battery contacts	• Remove tape, charge battery
	Cable connector not fully inserted in Transpac Pigtail socket	• Reposition and insert Connector correctly
Transceiver continuously restarts	Unit needs servicing	• Call Clinical Coordinator
Service Light On	Unit needs servicing	• Call Clinical Coordinator
Can't establish link	• Token not fully inserted	• Re-sync units with token, BEEP confirms sync
	• Patient Transceiver or Monitor Transceiver not turned ON	• Ensure both units are turned ON
	• Out of range	• System range exceeded –move patient back within 30 feet of Monitor Transceiver
	• 3/5 cable system not connected	• Connect 3/5 cable system as required
Periodic beeping sound heard	• Low battery	• Re-charge battery, or replace with fully charged battery
Battery does not last 24 hours	• Monitor Transceiver runs 12 hours per battery charge	• Re-charge Monitor Transceiver battery, or replace with fully charged battery

	• Battery not fully charged at start	• Ensure battery is fully charged at installation
	• Battery at end of life, or faulty battery	• Replace battery – Recycle or dispose of old batteries as directed in Wireless Transducer User's Manual
Wireless Transducer not charging battery or Wireless Transducer battery charge indicator not lit	• Power Supply not plugged in	• Plug in Power Supply
	• Faulty AC power (110V) outlet	• Call electrician
	• Power Supply failure	• Replace Power Supply – Only use Wireless Transducer Power Supply
	• Battery contacts covered	• Uncover contacts and charge battery
Intermittent or dropped link ()	• Out of range, or at edge of range	• System range exceeded –move patient back within 30 feet of Monitor Transceiver
	• Signal is blocked	• Try another unit
Excessive noise	• Receiver module too close to AC power source	• Separate receiver module and AC power source cable by 1 to 2 feet
	• Poor serial cable connection	• Reseat cable connector
	• Out of range	• System range exceeded –

Table 5-4:

Chapter 6

Specifications

Parameter	Specification
Number of Channels, single-ended, wrt RL	***?***
Channels Active	***?***
Input Dynamic Range	***?***
ECG Signal Slew Rate	***?***
Input Impedance	***?***
Leadoff Sense Current	***?***
Frequency Response ***Method A per EC11:1991***	***?***
Triangle Response ***Method D per EC13:2002***	
Line Filter (60 Hz)	
Ch-Ch Signal noise	
Multi-channel Crosstalk	
ECG Signal Gain wrt RL	
Ch-Ch Gain Difference	
CM Rejection	
Leadoff ***• Leadoff sensed by Patient Transceiver*** ***• Leadoff simulated by Monitor Transceiver***	
DC Offset – any channel	
Pacer Pulse Detection, Transmission, and	

Reconstruction	
Pacer Pulse Function Trigger Slew Rate	
Signal Latency due to radio	
Operating Battery	
Operating Battery Life	
Size	
Weight (includes battery)	
Rated Voltage/Current	
Operating Temperature	
Storage Temperature	
Atmospheric Pressure	
Housing Material	
Radio Protocol ***Class*** ***Range*** ***Operating Frequency*** ***Channels*** ***Power output level*** ***PT*** ***MT*** ***Bluetooth Revision***	
Water Ingress Rating	
Patient Applied Parts type	
Defibrillation Proof	
Recovery time after defibrillation exposure	
Safety	
EMC	

Chapter 7

Standards

This chapter contains a list of the applicable standards that the Wireless Transmitter/Receiver device meets.

APPLICABLE STANDARDS

The wireless transmitter/receiver device shall comply with the following standards or documents. The compliance shall be in accordance with the Product Performance Specification for Hospira Transpac® IV Disposable Blood Pressure Transducer as applicable.

added new from Nichol 10/02/06 300 or 301?

- ISO 13485:2003(E), Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO/IEC 14971:2000, Medical Devices - Application of Risk Management to Medical Devices
- IEC/EN/UL 60601-1 Third Edition Medical Electrical Equipment - General requirements for basic safety and essential performance
- IEC/EN60601-1-1 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
- EC/EN 60601-1-2 Edition 2.1 General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC/EN 60601-1-4 Medical electrical equipment - General requirements for safety - Collateral Standard: Programmable electrical medical systems
- EC/EN 60601-1-49 Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
- IEC/EN60601-2-34 Medical electrical equipment: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment, section 44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility
- IEC 245 or IEC 227 for flexible cables and cords
- UL 94 flammability testing
- IEC/EN 60529 Degrees of protection provided by enclosures (IP Code) consolidated edition
- EN 60950 Information technology equipment - Safety - Part 1: General requirements
- EN 55011 Measuring Radiated Emission
- IEC 61000-3-2 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current <= 16 A per phase)
- IEC 61000-3-3 Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection
- IEC 61000-4-2 Electromagnetic compatibility (EMC)- Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test Consolidated Edition
- IEC 61000-4-3 Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
- IEC 61000-4-4 Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
- IEC 61000-4-5 Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test

- IEC 61000-4-8 Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
- IEC 61000-4-11 Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
- ETSI EN 300 328-1 Title: ElectroMagnetic Compatibility and Radio Spectrum Matters (ERM);Wideband Transmission systems; data transmission equipment operating in the 2,4 GHz ISM band and using spread spectrum modulation techniques; Part 1: Technical characteristics and test conditions
- ETSI EN 300 328-2 Electromagnetic compatibility and Radio Spectrum Matters (ERM);Wideband Transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using spread spectrum modulation techniques; Part 2: Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive.
- ETSI EN 300 489-1 Terminal Equipment (TE);Conformance testing for file transfer over the Integrated Services Digital Network (ISDN);Part 1: Profile Test Specification Summary (PTS-Summary) for the FTAM profile (ETS 300 388)
- ETSI EN 300 489-17 (The PRD lists this, however I am not able to locate the title) maybe its 1 or 7.
- ETSI EN 300 489-2 Terminal Equipment (TE);Conformance testing for file transfer over the Integrated Services Digital Network (ISDN);Part 2: Profile Specific Test Specification (PSTS) for the FTAM profile (ETS 300 388)
- FCC Bulletin OET 65C Evaluating Compliance With FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields
- 802.15.1 Bluetooth class 2 Wireless Communications Standard as applicable

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- EN60601-1 for safety
- UL60601-1 for safety
- EN60601-1-1 for safety (collateral)
- IEC 245 or IEC 227 for power cords
- UL 94 for flammability
- IEC529 for enclosure protection
- EN60950 for instructions for use
- EN 60601-1-4 for software
- EN60601-1-2 for EMC
- EN60601-1-2-34 section 44 for spillage and ingress of liquids
- EN55011 for Conducted / Radiated emission.
- IEC 61000-3-2 for Harmonic emissions.
- IEC 61000-3-3 for Voltage fluctuations/flicker emissions
- IEC61000-4-2 for ESD
- IEC61000-4-3 for radiated fields
- IEC61000-4-4 for fast transient/burst
- IEC61000-4-5 for surges
- IEC61000-4-8 for power frequency magnetic fields
- IEC61000-4-11 for voltage dips
- EN55011 for emissions
- ETSI EN 300 328-1 for radio
- ETSI EN 300 328-2 for radio
- ETSI EN 301 489-1 for radio
- ETSI EN 301 489-17 for radio
- FCC Bulletin OET 65C for RF

- 802.15.1, Bluetooth class 2 Wireless Communications Standard as applicable.

System Specifications

Parameter	Specification
Number of Channels, single-ended, wrt RL	?
Channels Active	?
Input Dynamic Range	?
ECG Signal Slew Rate	?
Input Impedance	?
Leadoff Sense Current	?
Frequency Response Method A per EC11:1991	?
Triangle Response Method D per EC13:2002	
Line Filter (60 Hz)	
Ch-Ch Signal noise	
Multi-channel Crosstalk	
ECG Signal Gain wrt RL	
Ch-Ch Gain Difference	
CM Rejection	
Leadoff • Leadoff sensed by Patient Transceiver • Leadoff simulated by Monitor Transceiver	
DC Offset – any channel	
Pacer Pulse Detection, Transmission, and Reconstruction	

Pacer Pulse Function Trigger Slew Rate	
Signal Latency due to radio	
Operating Battery	
Operating Battery Life	
Size	
Weight (includes battery)	
Rated Voltage/Current	
Operating Temperature	
Storage Temperature	
Atmospheric Pressure	
Housing Material	
Radio Protocol Class Range Operating Frequency Channels Power output level PT MT Bluetooth Revision	
Water Ingress Rating	
Patient Applied Parts type	
Defibrillation Proof	
Recovery time after defibrillation exposure	
Safety	
EMC	

Chapter 8

Warranty

Subject to the terms and conditions herein, Hospira, Inc., herein referred to as Hospira, warrants that (a) the product shall conform to Hospira's standard specifications and be free from defects in material and workmanship under normal use and service for a period of one year after purchase, and (b) the replaceable battery shall be free from defects in material and workmanship under normal use and service for a period of 90 days after purchase. Hospira makes no other warranties, express or implied, as to merchantability, fitness for a particular purpose, or any other matter.

Purchaser's exclusive remedy shall be, at Hospira's option, the repair or replacement of the product. In no event shall Hospira's liability arising out of any cause whatsoever (whether such cause be based in contract, negligence, strict liability, other tort, or otherwise) exceed the price of such product, and in no event shall Hospira be liable for incidental, consequential, or special damages or losses or for lost business, revenues, or profits. Warranty product returned to Hospira must be properly packaged and sent freight prepaid.

The foregoing warranty shall be void in the event the product has been misused, damaged, altered, or used other than in accordance with product manuals so as, in Hospira's judgment, to affect its stability or reliability, or in the event the serial number or lot number has been altered, effaced, or removed.

The foregoing warranty shall also be void in the event any person, including the Purchaser, performs or attempts to perform any major repair or other service on the product without having been trained by an authorized representative of Hospira and using Hospira documentation and approved spare parts. For purposes of the preceding sentence, "major repair or other service" means any repair or service other than the replacement of accessory items such as batteries and detachable mains power cords.

In providing any parts for repair or service of the product, Hospira shall have no responsibility or liability for the actions or inactions of the person performing such repair or service, regardless of whether such person has been trained to perform such repair or service. It is understood and acknowledged that any person other than a Hospira representative performing repair or service is not an authorized agent of Hospira.