

THE PACEMAKER FOLLOW-UP SYSTEM
PDT CarryAll® Transmitter

Clinician's Guide

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NOTE: Operation of this instrument near sources of electromagnetic interference; such as, radio transmitters, may adversely affect the quality of the transmitted ECG signal.

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

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INTRODUCTION

The PDT CarryAll® Transmitter is a portable, battery powered instrument which enables remote monitoring of a patient's single lead electrocardiogram (ECG) and pacemaker function. The PDT CarryAll® Transmitter converts the ECG to audible tones which are transmitted over the telephone line to a LifeSigns™, Receiving Center (LRC™). It also measures and transmits both atrial and ventricular pacemaker pulse widths. The LRC™ converts these audible tones into an ECG chart strip which can be immediately reviewed and interpreted. If the LRC™ is equipped with an A+V Pacemaker Data Module, it can print out both pulse widths, as well as the calculated rate, interval, and A-V interval.

The PDT CarryAll® Transmitter can be used to monitor patients implanted with all common types of generators, including those which emit sub-threshold bio-impedance pulses.

The PDT CarryAll® Transmitter includes a magnet, a low battery indicator, electrodes and permanently attached ECG leads. To aid in prompt identification by the patient, the leads are color coded black and white, and the POWER and ECG buttons on the touch panel are different in both color and shape.

Three Operating Modes

Pulse Width Data Mode

Each pacemaker data pulse is marked with a distinctive spike. Its leading edge coincides with the actual pacer spike. When the ECG is received with a LifeSigns™ Receiving Center equipped with an A+V Pacemaker Data Module, the pulse width information, the pacemaker rate, the pacing pulse interval and the A-V interval are available for edge-print.

ECG Mode

In ECG Mode, the instrument suppresses transmission of the pacemaker pulse width artifact, allowing the clinician to view only the patient's intrinsic ECG.

Enhance Mode

Enhance Mode is available only during remote operation of the unit, described on the following page. Like Pulse Width Data Mode, this mode marks each pacemaker data pulse with a distinctive spike. Its leading edge coincides with the actual pacer spike. Enhance Mode does not, however, include edge-print information.

INTRODUCTION

Remote Capabilities

If the clinician is using a Touch-Tone telephone, there are additional commands available which allow remote control of the PDT CarryAll® Transmitter's full range of capabilities.

Patient Alert

The Patient Alert feature is used during a transmission to signal the patient to pick up the telephone and receive instructions from the clinician.

By pressing the * key on the telephone keypad, the Clinician can activate the PDT CarryAll® Transmitter Patient Alert - the red ALERT light on the PDT CarryAll® Transmitter flashes and a tone sounds for ten seconds.

NOTE: *The Patient Alert button on the LRC™ will not activate the PDT CarryAll® Transmitter Patient Alert feature.*

Remote Mode Control

Using the 1, 4, and 7 keys on the telephone keypad, the clinician can change the transmission mode between Pulse Width Data Mode, ECG Mode, and Enhance Mode without disturbing the patient.

Indications for Use

The PDT CarryAll® Transmitter is intended for use in transtelephonic transmission of an ECG and is typically used in the follow-up of patients who have implanted pulse generators.

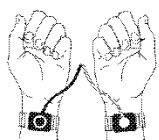
Contraindications for Use

There are no known contraindications for use.

PREPARING FOR TRANSMISSION

- Instruct the patient to prepare the electrodes packed inside the PDT CarryAll® Transmitter:

WRIST ELECTRODES



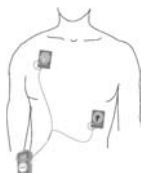
- ✓ Moisten the inside of each wrist with water.
- ✓ Put on the wristbands with the flat plate on the inside of the wrist.
- ✓ Snap the lead wires onto the wristbands; white on the right and black on the left.

FINGERTIP ELECTRODES



- ✓ Moisten the fingertips to be used for the electrodes.
- ✓ Slide the electrode bands onto the damp fingertips. They must fit snugly.
- ✓ Snap the lead wires onto the electrodes; white on the right and black on the left.

PASTE ON CHEST ELECTRODES



- ✓ Select lead configuration. Typically, good results are obtained with Lead II, as shown here.
- ✓ Prepare the skin surface at the placement site; clean, wipe with alcohol and abrade lightly.
- ✓ Attach the electrodes to the prepared locations.
- ✓ Snap the lead wires onto the electrodes; white on the right and black on the left.

CHEST PROBE ELECTRODE



- ✓ Press the two metal feet of the electrode firmly against the bare chest, with the lead wires at the bottom.
- If the transmission is to be performed with the pacemaker in magnet mode, explain the use of the magnet included in the PDT CarryAll® Transmitter case.
 - Tell the patient how long to transmit, both with and without the magnet, and when to pick up the telephone for further instructions.

TRANSMISSION — STANDARD OPERATION

- Instruct the patient to turn on the PDT CarryAll® Transmitter by pressing the square green POWER button.

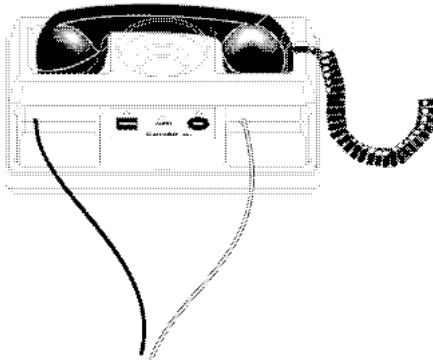
(If the green POWER light shines steadily, the battery is good. If it flashes, the battery should be replaced immediately following this transmission; see page 9.)

The PDT CarryAll® Transmitter automatically powers up in Pulse Width Data Mode.

- Select the appropriate transmission mode: Pulse Width Data Mode or ECG Mode (see page 5 for examples of output).
 - √ To enter ECG Mode, instruct the patient to press the round, purple ECG button. The amber light directly above the button will illuminate, indicating that ECG Mode is active.
 - √ To return to Pulse Width Data Mode, instruct the patient to press the ECG button again (the amber light will turn off).

When you are ready to receive a transmission:

- Instruct the patient to place the telephone handset into the cradle of the PDT CarryAll® Transmitter with the cord end on the right, as shown below:

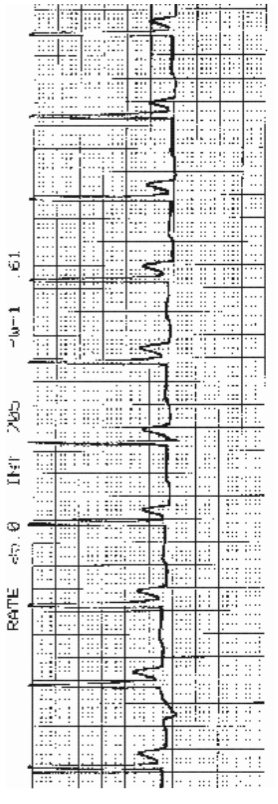

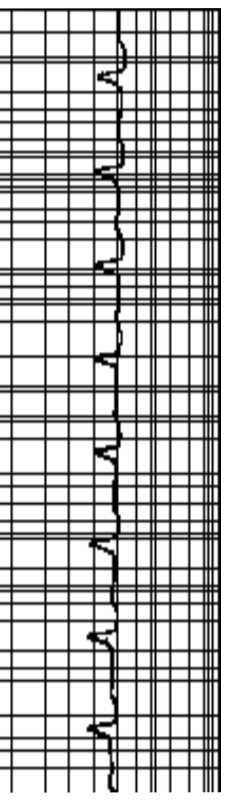


- Receive the transmission and take data.

When the transmission is complete:

- Instruct the patient to turn off the unit by pressing the square, green POWER button. All lights on the unit will turn off.
- Instruct the patient to remove the electrode(s) and store the PDT CarryAll® Transmitter in a safe place.

TRANSMISSION - STANDARD OPERATION

Activated By	Mode	Clinician Will See
Power-Up	Pulse Width Data Mode	 <p>The image shows a standard ECG waveform on a grid. The waveform is labeled with 'RATE' and 'INFT' at the top. The grid has a vertical scale of 1.51 and a horizontal scale of 1.51. The waveform shows a regular rhythm with distinct P waves, QRS complexes, and T waves.</p>
	ECG Mode	 <p>The image shows a standard ECG waveform on a grid. The waveform is labeled with 'RATE' and 'INFT' at the top. The grid has a vertical scale of 1.51 and a horizontal scale of 1.51. The waveform shows a regular rhythm with distinct P waves, QRS complexes, and T waves.</p>

REMOTE OPERATION

During transmission, optional remote commands are available to the clinician using a Touch Tone telephone.

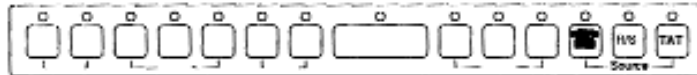
Requirements for Remote Operation

1. The clinician is using a Touch Tone telephone.
2. The patient's telephone is correctly placed in the cradle of the CarryAll® Transmitter.

If the telephone is linked to the receiver by an acoustic coupler:

- Press the desired key on the telephone keypad.

If the telephone is directly connected to an LRC™:



- Press the **TAT** button on the front of the LRC™.
- Press the desired key on the telephone keypad.
- Press the **Source** button on the LRC™.

NOTE: This must be done quickly, or the confirmation pulses shown on page 7 will be missed.

Remote Options

Patient Alert

To activate the Patient Alert feature of the PDT CarryAll® Transmitter:



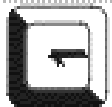
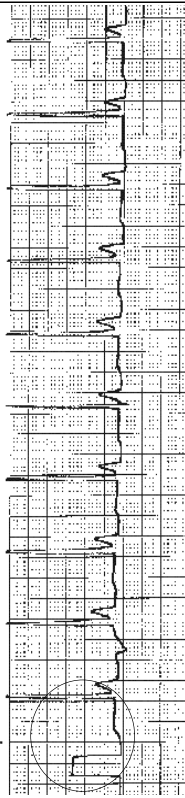

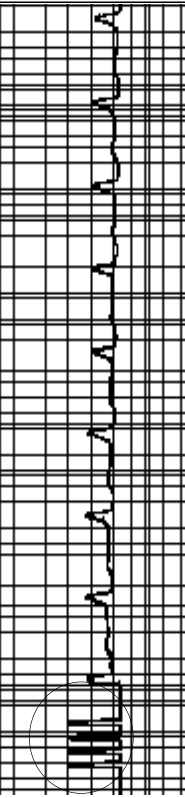

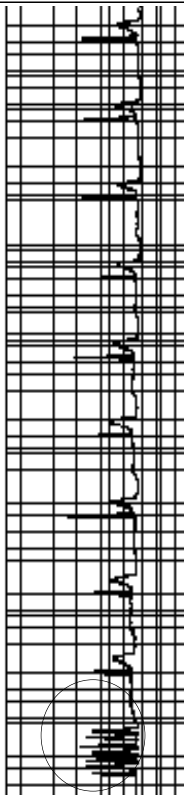
- Press and release the * on the telephone keypad.

Remote Mode Control

Without disturbing the patient the clinician can press the 1, 4, or 7 key on the telephone keypad to change the transmission mode between Pulse Width Data Mode, ECG Mode, and Enhance Mode.

When the PDT CarryAll® Transmitter detects the 1, 4, or 7 tone, in addition to changing its operating mode, it also transmits back to the clinician a series of 1, 4, or 7 confirmation pulse(s). See the examples on the following page.

REMOTE OPERATION

Activated By	Mode	Clinician Will See
	Pulse Width Data Mode	 <p style="text-align: center;">1 confirmation pulse</p>
	ECG Mode	 <p style="text-align: center;">4 confirmation pulses</p>
	Enhance Mode	 <p style="text-align: center;">7 confirmation pulses</p>

TROUBLESHOOTING

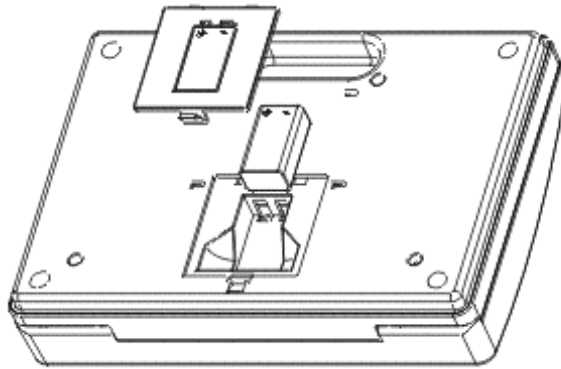
IF YOU HAVE THIS PROBLEM	TRY THIS
No audible output from the PDT CarryAll® Transmitter	(1) Verify that the patient telephone is placed correctly in the cradle. (2) Replace the battery.
False Artifacts	(1) Check electrode connections and remoisten the skin. (2) Make sure that the PDT CarryAll® Transmitter and the receiving center are not operating near a source of electrical magnetic interference (e.g., defective fluorescent lighting or household appliances).
Upside-down ECG	Instruct the patient to switch each lead wire to the other electrode.
Poor quality ECG	<p>Wristbands:</p> <p>(1) Instruct the patient to rotate the flat plate on the wristband to the inside of the wrist and moisten the skin surface beneath the plates.</p> <p>(2) If the wristbands are loose, instruct the patient to slide them up the arm until snug.</p> <p>Paste on chest electrodes:</p> <p>(1) Instruct the patient to repress the electrodes onto the skin and to verify that the snap attachments are secure.</p> <p>(2) Electrodes which do not adhere securely must be replaced or the ECG signal will be affected. Instruct the patient to prep the skin area slightly to the left or right of the original site and to affix a fresh electrode.</p>
Wandering Baseline	Instruct the patient to rest arms comfortably relax and remain calm and still.

MAINTENANCE

There are no user serviceable parts in the PDT CarryAll® Transmitter. The battery, however, needs to be replaced whenever the green POWER light flashes.

To Replace the Battery

1. Make sure that the unit is off.
2. Remove the battery compartment door on the bottom of the unit.
3. Remove the old battery.
4. Replace with a 9-volt alkaline battery, aligning it to match the diagram on the battery compartment door.
5. Replace the battery compartment door.



SPECIFICATIONS

Characteristics	Testing Conditions	Minimum	Typical	Maximum	Units
Mechanical					
Length			7.5		inches
Width			10.5		inches
Height			2.4		inches
Weight			2.3		lbs
Environmental					
Operating Temperature		10		40	°C
Storage Temperature		-20		60	°C
Relative Humidity		10		90	%
Electrical					
Battery Type	9-volt alkaline				
Current			44		mA
Battery Life			10		hours
Low Battery Indicator Light			5.6		V
ECG Bandwidth	-3dB	0.5		100	Hz
Recovery Time	At turn-on or after large voltage			3	seconds
Common Mode Rejection Rate	@ 50 and 60 HZ	60			dB
Range	AC + DC	±1.0			V
Input Impedance			2.4		MOhm
Center Frequency		1915	1965	2015	Hz
Frequency Deviation		90	100	110	Hz/mV
Pacemaker Pulse Sensitivity	square pulse, 0.2 to 2.5 ms long				
Refractory Period			40	1.0	mV ms

SPECIFICATIONS

Characteristics	Testing Conditions	Minimum	Typical	Maximum	Units
Electrical (Continued)					
Pulse Width Range Accuracy		0.20		2.50 ±0.02	ms ms
Patient Alert (*key) Tone Duration	pulse or steady; DTMF tone	40			ms
Pulse Width Data Mode (1 key) Tone Duration		40			ms
ECG Mode (4 key) Tone Duration		40			ms
Enhance Mode (7 key) Tone Duration		40			ms
Modes					
Pulse Width Data Mode	Each pacemaker data pulse is marked with a distinctive spike. Its leading edge coincides with the actual pacer spike. If received with a LifeSigns™ Receiving Center equipped with an A+V Pacemaker Data Module, the pulse width information, along with the pacemaker rate, pulse interval and the A–V interval, are available for edge-print.				
ECG Mode	This mode turns off the display of pacemaker data and the marker spikes; only the intrinsic ECG is shown.				
Enhance Mode	Selectable only by the clinician, this mode includes enhanced pacer markers, but it does not include edge-print information.				
Specification change privileges reserved.					

LIMITED WARRANTY

This Instromedix® (“Instromedix”) product is warranted against defective material and workmanship (excluding batteries and cables) for five years following delivery of the product to the original purchaser.

If any product or any part thereof in the judgment of Instromedix is proven to be defective in material or workmanship within five years from date of original purchase, such defects will be repaired or replaced (at Instromedix’ option) free-of-charge for parts or labor.

This warranty does not apply to any product which has been damaged by accident or which has been misused, abused, altered or repaired by anyone other than Instromedix or its representatives.

Instromedix shall not be liable to any person for any direct or consequential damages resulting from or caused by any defect, failure or malfunction of this product.

This warranty is in lieu of all other warranties expressed or implied including any implied warranty of merchantability or fitness for a particular purpose, and no person is authorized to assume for Instromedix any other liability in connection with the sale of this product.

To obtain repairs, the product should be shipped prepaid to Instromedix at the address shown below. In-warranty units will be returned postage prepaid.

In the USA contact:
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