

THE PACEMAKER FOLLOW-UP SYSTEM

DDD CarryAll®

Clinician's Guide

Instromedix®
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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 CarryAll® Transmitter is a portable, battery powered instrument which enables remote monitoring of a patient's single lead electrocardiogram (ECG) and pacemaker function. The 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. 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 interval and the A-V interval are available for edge-print.

The 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 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.

Patient Alert

If the clinician is using a Touch Tone telephone, the Patient Alert feature may be 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 CarryAll® Transmitter Patient Alert - the red ALERT light on the CarryAll® Transmitter flashes and a tone sounds for ten seconds.

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

Indications for Use

The 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.

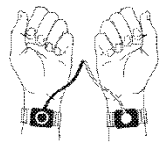
Contraindications for Use

There are no known contraindications for use.

PREPARING FOR TRANSMISSION

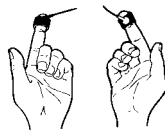
- Instruct the patient to prepare the electrodes packed inside the CarryAll® Transmitter:

WRIST ELECTRODES



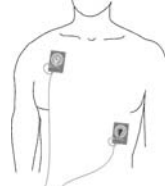
- ✓ Moisten the inside of each wrist with water.
- ✓ Put on the wristbands with the flat plate on the inside of the wrist.
- ✓ Snap the lead wires onto the wristbands; white on the right and black on the left.

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.

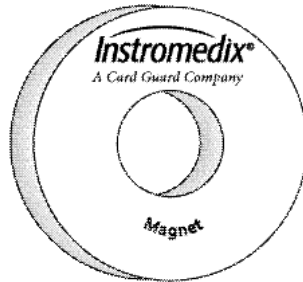
CHEST PROBE ELECTRODE



- ✓ Press the two metal feet of the electrode firmly against the bare chest, with the lead wires at the bottom.

PREPARING FOR TRANSMISSION

- If the transmission is to be performed with the pacemaker in magnet mode, explain the use of the magnet included in the 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.

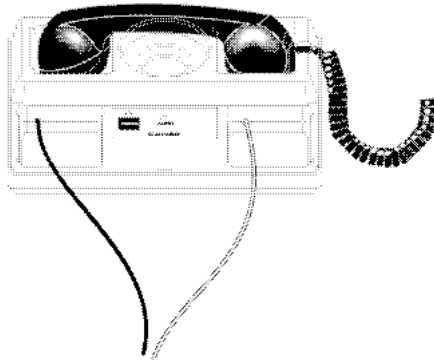
TRANSMISSION

- Instruct the patient to turn on the 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 8.)

When you are ready to receive a transmission:

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

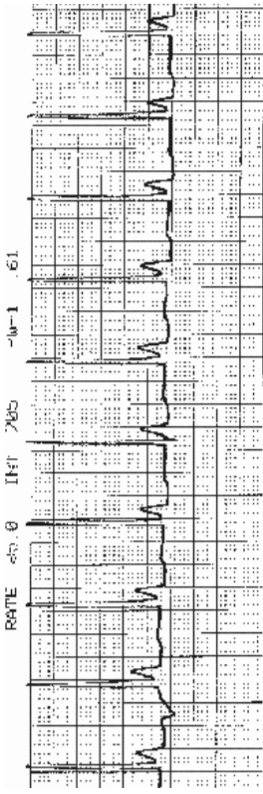


- Receive the transmission and take data.

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 CarryAll® Transmitter in a safe place.

TRANSMISSION

<p>CarryAll® Transmitter Model</p> <p>DDD CarryAll® Transmitter</p>	<p>Clinician Will See</p> 
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PATIENT ALERT

Remote activation of the Patient Alert feature of the CarryAll® Transmitter is available if:

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 and release the * on the telephone keypad.

If the telephone is directly connected to an LRC™:



- Press the **TAT** button on the front of the LRC™.
- Press and release the * on the telephone keypad.
- Press the  button on the LRC™.

TROUBLESHOOTING

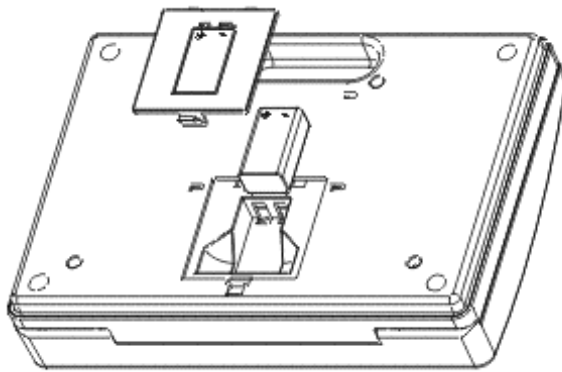
IF YOU HAVE THIS PROBLEM	TRY THIS
No audible output from the CarryAll® Transmitter	(1) Verify that the patient telephone is placed correctly in the cradle. (2) Replace the battery.
False Artifacts	(1) Check electrode connections and remoisten the skin. (2) Make sure that the CarryAll® Transmitter and 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. (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. (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 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			1.0	mV
Pulse Width Range		0.20		2.50	ms
Accuracy				±0.02	ms
Patient Alert (*key) Tone Duration	pulse or steady; DTMF tone				ms
		40			

SPECIFICATIONS

Transmitted Data

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.

NOTE: *The LRC™ must be operating in STD mode when receiving signals from the DDD CarryAll® Transmitter.*

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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