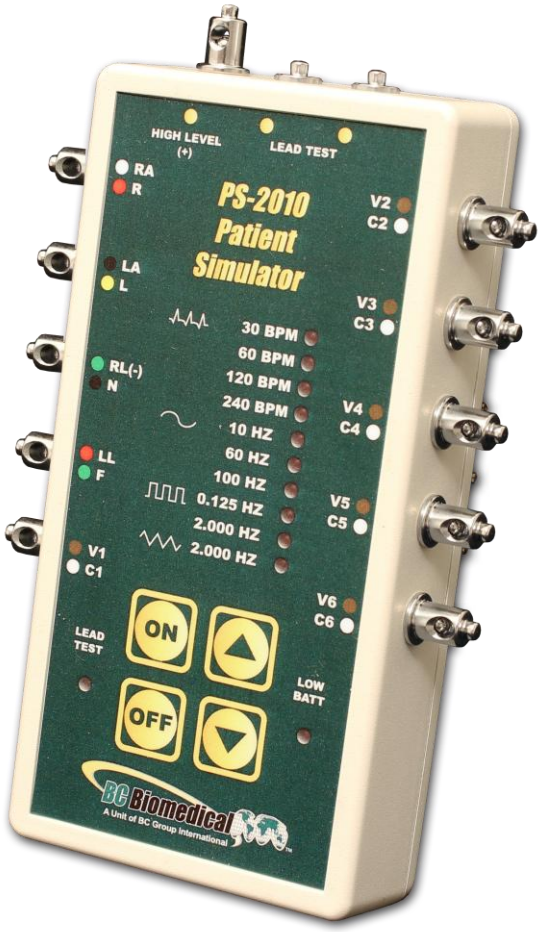
BC Biomedical
A UNIT OF BC GROUP INTERNATIONAL, INC.

ECG PATIENT SIMULATOR
TEN LEAD



PS-2010

USER MANUAL

BC BIOMEDICAL
PS-2010
TABLE OF CONTENTS

WARNING - USERS

The PS-2010 Series are for use by skilled technical personnel only.

WARNING - USE

The PS-2010 is intended for testing only and should never be used in diagnostics, treatment or any other capacity where it would come in contact with a patient.

WARNING - CONNECTIONS

All connections to patients must be removed before connecting the DUT to the PS-2010. A serious hazard may occur if the patient is connected when testing with the PS-2010. Do not connect any leads from the patient directly to the PS-2010 or DUT.

CAUTION - MODIFICATIONS

The PS-2010 is intended for use within the published specifications. Any application beyond these specifications or any unauthorized user modifications may result in hazards or improper operation.

CAUTION - SERVICE

The PS-2010 is intended to be serviced only by authorized service personnel. Troubleshooting and service procedures should only be performed by qualified technical personnel.

CAUTION - INSPECTION

The PS-2010 should be inspected before each use for obvious signs of abuse or wear. The PS-2010 should not be used and should be serviced if any parts are in question.

CAUTION - CLEANING

Do not immerse. The PS-2010 should be cleaned by wiping gently with a damp, lint-free cloth. A mild detergent can be used if desired.

CAUTION - LIQUIDS

Do not submerge or spill liquids on the PS-2010 Series. Do not operate the PS-2010 Series if exposed to fluid.

CAUTION - ENVIRONMENT

Exposure to environmental conditions outside the specifications can adversely affect the performance of the PS-2010. Allow the PS-2010 to acclimate to specified conditions for at least 30 minutes before attempting to operate it.

CAUTION - INSPECTION

The PS-2010 should be inspected before each use for obvious signs of abuse or wear. The PS-2010 should not be used and should be serviced if any parts are in question.

NOTICE – CE

The PS-2010 Series Simulators bear the CE mark
Based on the following testing standards:

ELECTROMAGNETIC COMPATIBILITY DIRECTIVE
EMC – Directive 89/336/EEC as amended by 92/31/EEC and 93/68/EEC & Directive 91/263/EEC[TTE/SES]

EN 61326-1:2006

"Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements"

This equipment has been type tested and compliance was demonstrated to the above standard to the extent applicable.

EMISSIONS
Radiated Emissions

EN 61326-1	Radiated Emissions

IMMUNITY:

EN 61000-4-2	Electrostatic Discharge
EN 61000-4-3	Radiated Electric Field Immunity

LOW VOLTAGE DIRECTIVE
EC – Directive 73/23/EC

EN 61010-1:2001
"Safety requirements for electrical equipment for measurement, control, and laboratory use – General requirements"

This equipment has been type tested and compliance was demonstrated to the above standard to the extent applicable.

NOTICE – SYMBOLS

Symbol	Description
	**Caution** (Consult Manual for Further Information)
	**Center Negative**
	Per European Council Directive 2002/95/EC, do not dispose of this product as unsorted municipal waste.
CAT I	IEC Measurement Category I – CAT I equipment designed to protect against transients in equipment on circuits not directly connected to MAINS. Under no circumstances should the terminals of the Analyzer be connected to any MAINS voltage

NOTICE – ABBREVIATIONS

AHA	**American Heart Association**
ANSI	**American National Standards Institute**
BPM	**Beats Per Minute**
C	**Celsius**
°	**degree(s)**
ECG	**Electrocardiogram**
F	**Fahrenheit**
Hz	**hertz**
IEC	**International Electrotechnical Commission**
Lbs	**pounds**
LED	**Light Emitting Diode**
mm	**millimeter(s)**
mV	**millivolt(s)**
NEDA	**National Electronic Distributors Association**
Ω	**ohm(s)**
USA	**United States of America**
V	**Volts**

NOTICE – DISCLAIMER

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NOTICE – DISCLAIMER

BC GROUP INTERNATIONAL, INC. RESERVES THE RIGHT TO MAKE CHANGES TO ITS PRODUCTS OR SPECIFICATIONS AT ANY TIME, WITHOUT NOTICE, IN ORDER TO IMPROVE THE DESIGN OR PERFORMANCE AND TO SUPPLY THE BEST POSSIBLE PRODUCT. THE INFORMATION IN THIS MANUAL HAS BEEN CAREFULLY CHECKED AND IS BELIEVED TO BE ACCURATE. HOWEVER, NO RESPONSIBILITY IS ASSUMED FOR INACCURACIES.

NOTICE – CONTACT INFORMATION

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BC BIOMEDICAL
PS-2010
PATIENT SIMULATOR

The Model PS-2010 is a Microprocessor based Patient Simulator. It provides ECG Simulation with four waveforms with constant QRS duration and six machine performance testing waveforms. The following are highlights of some of the main features:

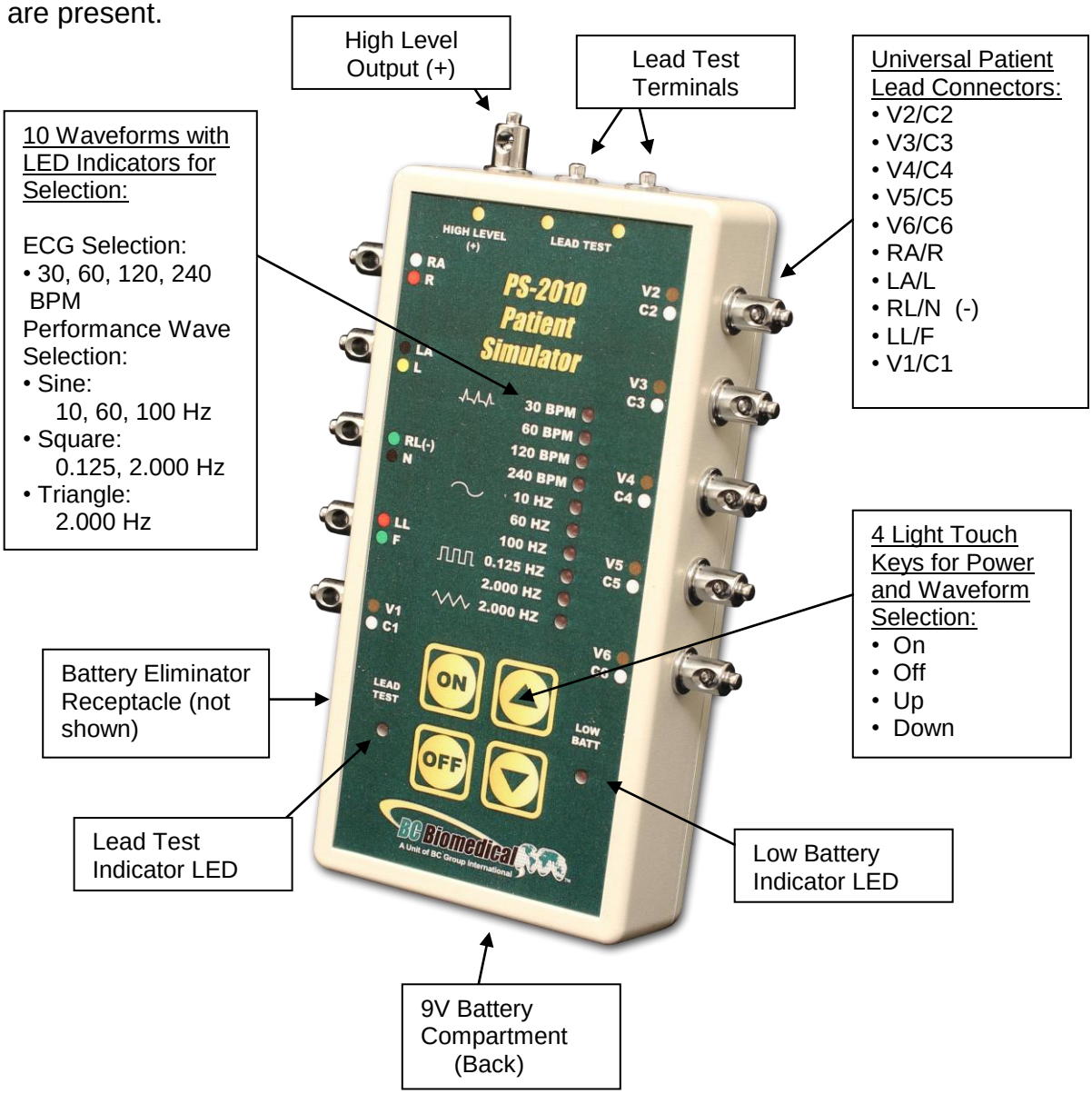
- 10 UNIVERSAL PATIENT LEAD CONNECTORS
- ECG: 30, 60, 120 AND 240 BPM
- SINE: 10, 60 AND 100 Hz
- SQUARE: 0.125 AND 2.000 Hz
- TRIANGLE: 2.000 Hz
- HIGH LEVEL OUTPUT (1 V p-p)
- AMPLITUDE ACCURACY: ± 2%
- FREQUENCY ACCURACY: ± 0.5% OF SETTING
- 9 VOLT BATTERY POWER
- LOW BATTERY INDICATOR
- % BATTERY LIFE INDICATOR
- OPTIONAL BATTERY ELIMINATOR
- LEAD TEST FUNCTION
- HIGH IMPACT PLASTIC CASE
- LIGHT TOUCH KEYS

OPTIONAL ACCESSORIES:

- BC20-30103 SOFT-SIDED CARRYING CASE
- BC20-21100 BATTERY ELIMINATOR (USA Version)
- BC20-21101 BATTERY ELIMINATOR (Euro Version)
- BC20-21110 BATTERY ELIMINATOR (Universal Version)

LAYOUT

This section looks at the layout of a PS-2010 and gives descriptions of the elements that are present.



The unit is controlled by 4 light touch keys. They allow the user to select waveforms and control the power for the unit. There is an audio click when a key is depressed.

There are 10 LEDs to provide the user with information about waveforms that are generated; 1 LED for Lead Test confirmation and 1 LED for Low Battery Indication.

Universal Patient Lead Connectors

The 10 Universal Patient Lead Connectors allow for 12 lead ECG simulation with independent outputs. AHA and IEC color-coded labels are located on the face of the unit to aid in connecting the corresponding AHA and IEC Patient Leads.

AHA Label	IEC Label	Description
RA	R	Right Arm
LA	L	Left Arm
RL	N	Right Leg (reference or ground)
LL	F	Left Leg
V1 V2 V3 V4 V5 V6	C1 C2 C3 C4 C5 C6	V Leads (V1-V6) (U.S. and Canada) also referred to as pericardial, precordial or unipolar chest leads Chest Leads (C1-C6) (International)

High Level Output (+)

An additional Universal Patient Lead Connector is located on the top of the unit for connecting the high level ECG output signal (1 Volt p-p). The connection is between the High Level (+) and RL/N (-) Patient Lead Connectors.

Waveform Selection

There are two keys and 10 LEDs in the Waveform Selection Control Section. The LEDs indicate which waveform is generated. The  keys sequentially select each waveform. The microprocessor sends the stored waveform information of the selected waveform to a Digital to Analog converter that generates an accurate analog

representation. This waveform is then sent through a resistor network, developing the appropriate signals on the output terminals.

Lead Test Terminals

There are two test terminals on the top of the unit that allow for a quick test of the continuity of the lead cables. Connecting one end of the cable to one terminal and the other end to the other terminal will test the cable. If the cable is OK (less than 1000 ohms), the LEAD TEST LED in the lower left of the face will light.

Power Keys

The 

keys control the power for the unit.

Auto Power Off

The unit will automatically turn off after 10 minutes of no key activity to conserve the battery.

To override this feature and keep the unit on continuously, depress the 

key twice after the unit is on. This will keep the unit on until it is manually turned off. The “Low Batt” LED will illuminate for 3 sec to indicate that the Auto Power Off feature has been turned off.

Percent of Battery Life Indicator

The unit provides an indication of the Percent of battery life left on the 9 Volt Alkaline Battery. An analog to digital converter monitors the battery voltage. Continuously holding

down the ON key will change the 10 waveform LEDs into a Percent of Battery Life display, with each LED representing 10% intervals. The indicator will strobe up to the present level and flash. This sequence will continue while the ON key is depressed.

Battery

The unit utilizes a 9 Volt Alkaline Battery in the rear battery compartment. When the unit detects a LOW BATTERY, the LED in the lower right of the face will light, indicating the need to change the battery.

Battery Eliminator Input – A 2.1 mm receptacle is provided for the optional 9 VDC Battery Eliminator power supply that may be used for continuous run applications. It bypasses the internal battery when plugged in.

NOTE: The unit is shipped with a Red Battery Lock-Out plug installed into the line power connector as shown below. Its purpose is to prevent the unit from accidentally being turned on during handling and transport, subsequently depleting the battery. This plug must be removed before any use.

MANUAL REVISIONS

Revision #	Program #	Revisions Made
Rev 01	DT7345CA	Origination
Rev 02	DT7345CA	Format and Pictures Updated
Rev 03	DT7345CA	Misc. Edits, Format Updated, and Pictures Updated
Rev 04	DT7345CA	Misc. Edits
Rev 05	DT7345CA	Misc. Edits

LIMITED WARRANTY

WARRANTY: BC GROUP INTERNATIONAL, INC. WARRANTS ITS NEW PRODUCTS TO BE FREE FROM DEFECTS IN MATERIALS AND WORKMANSHIP UNDER THE SERVICE FOR WHICH THEY ARE INTENDED. THIS WARRANTY IS EFFECTIVE FOR TWELVE MONTHS FROM THE DATE OF SHIPMENT.

EXCLUSIONS: THIS WARRANTY IS **IN LIEU OF** ANY OTHER WARRANTY EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO ANY IMPLIED WARRANTY OF **MERCHANTABILITY** OR FITNESS FOR A PARTICULAR PURPOSE.

BC GROUP INTERNATIONAL, INC. IS NOT LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

NO PERSON OTHER THAN AN OFFICER IS AUTHORIZED TO GIVE ANY OTHER WARRANTY OR ASSUME ANY LIABILITY.

REMEDIES: THE PURCHASER'S SOLE AND EXCLUSIVE REMEDY SHALL BE: (1) THE REPAIR OR REPLACEMENT OF DEFECTIVE PARTS OR PRODUCTS, WITHOUT CHARGE. (2) AT THE OPTION OF **BC GROUP INTERNATIONAL, INC.**, THE REFUND OF THE PURCHASE PRICE.

SPECIFICATIONS

PATIENT SIMULATION			
RATE	NORMAL SINUS RHYTHM	30, 60, 120, 240 BPM	
	PERFORMANCE WAVEFORMS	SINE	10, 60, 100 Hz
		SQUARE	0.125, 2.0 Hz
		TRIANGLE	2.0 Hz
	ACCURACY	± 0.5 %	
AMPLITUDE	LEAD 1	1.75 mV	
	LEAD 2	2.75 mV	
	LEAD 3	1.00 mV	
	ACCURACY	± 2 % Lead II	
IMPEDANCE	LEAD TO LEAD	1000 Ω	
	LEAD TEST	< 1000 Ω	

PHYSICAL & ENVIRONMENTAL		
CONSTRUCTION	ENCLOSURE	ABS Plastic
	FACEPLATE	Lexan, Back printed
SIZE	7.26 x 4.46 x 1.51 Inches (184.4 x 113.3 x 38.4 mm)	
WEIGHT	≤ 1 Lbs (0.45 kg)	
OPERATING RANGE	15 to 40 °C (59 to 104 °F)	
STORAGE RANGE	-20 to 65 °C (-4 to 149 °F)	

ELECTRICAL	
BATTERY	9 V Alkaline Battery (ANSI/NEDA 1604A or equivalent)
BATTERY ELIMINATOR (Optional)	9VDC, 50 mA  BC20-21100 (USA Version) BC20-21101 (Euro Version) BC20-21110 (Universal Version)

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