

BC BIOMEDICAL NIBP-1000 SERIES TABLE OF CONTENTS

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WARNING

All connections to patients must be removed before connecting the Device Under Test (DUT) to the Simulator. A serious hazard may occur if the patient is connected when testing with the Simulator. Do not connect any leads from the patient directly to the Simulator or DUT.

<u>NOTICE</u>

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BC GROUP NIBP-1000 SERIES NON-INVASIVE BLOOD PRESSURE SIMULATORS

The Model NIBP-1000 Series is a family of Microprocessor based, High Precision Non-Invasive Blood Pressure (NIBP) Simulators. The units are small, easy to use and have multiple features to fit many different applications. The NIBP-1020, offers ECG waveforms that are full QRS and respiration waveforms that look real.

The graphics display not only provides multiple screens that give the pressure digitally in mmHg, but also offers views of the plot of the overall pressure or a close-up of the BP waveform.

The following are highlights of some of the main features:

NIBP-1010 (BASIC FEATURES, NIBP ONLY):

- LARGE GRAPHICS DISPLAY WITH CURSOR SELECTION OF OPTIONS AND SETUP OF PARAMETERS
- FULL RANGE MANOMETER
- ADULT, NEONATAL AND HYPERTENSIVE MODES
- 0-500 mmHg PRESSURE RANGE
- +/- 1% OF READING PRESSURE ACCURACY
- OPTIONAL PEAK PRESSURE DETECT WITH SIMPLE RESET
- SpO₂ READY COMPATIBLE WITH MSP-2100 MODULE
- DIGITAL CALIBRATION NO POTS TO TURN
- SELECTABLE DISPLAY OPTIONS AND DIGIT SIZES
- SOFTWARE ADJUSTABLE CONTRAST
- FLASH PROGRAMMABLE
- BATTERY LIFE DISPLAY (0 TO 100%)
- OPTIONAL RECHARGEABLE NIMH BATTERIES
- BATTERY ELIMINATOR
- RS232 INTERFACE

NIBP-1020 (NIBP, ECG PACE & RESP)

HAS ALL THE BASIC MODEL FEATURES PLUS:

- ECG OUTPUT WITH FULL NSR WAVEFORM
- SINUSOIDAL RESPIRATION SIMULATION
- ECG TEST WAVEFORMS
- PACE WAVEFORM
- OPTIONAL PEAK PRESSURE DETECT WITH ECG ALARM TEST
- ECG SYNCRONIZED WITH BLOOD PRESSURE

AVAILABLE MODELS:

NIBP1010 BASIC UNIT + PEAK NIBP1010-P NIBP1010-BP + BATTERY & PEAK NIBP1020 **BASIC UNIT WITH EKG** NIBP1020-PA + PEAK & ALARM NIBP1020-BPA + BATTERY, PEAK & ALARM NIBP1000-KIT NIBP1020-BPA, 5 ADAPTERS & SOFT CARRYING CASE

OPTIONAL ACCESSORIES:

•	BC20-30111	SOFT CARRYING CASE
•	BC20-40714	DINAMAP/CRITIKON ADAPTER
•	BC20-40715	QUICK DISCONNECT ADAPTER
•	BC20-40716	LUER ADAPTER
•	BC20-40717	MARQUETTE ADAPTER
•	BC20-40608	BULB ADAPTER
•	BC20-40602	NIBP FITTING KIT (HP CUFF ADAPTER,
		INFLATION BULB, CPC CONNECTOR, QUICK
		COUPLER WITH 1/8" MNPT AND SILICONE
		TUBING AND TEE)
•	BC20-40605	NIRP ADAPTER KIT (11 CONNECTORS)

• BC20-40605 NIBP ADAPTER KIT (11 CONNECTORS)

OVERVIEW

This section looks at the layout of the NIBP-1010 and gives descriptions of the elements that are present.



This section looks at the layout of the NIBP-1020 and gives descriptions of the elements that are present.



KEYS

Six tactile-touch keys are provided for system operation:

- This key turns the unit off and on. The unit will return to the screen that was active when it was turned off.



 In the DISPLAY MODE, these keys toggle the display through the available main screens.

In the SELECT MODE, if a parameter has been highlighted, these keys will scroll through the available settings.

- On the Main screen, this key sequences through the available NIBP or ECG simulations. On the Setup screen, there are a number of parameters that may be selected and changed. This key sequences the cursor (Highlight) through those parameters.



This key is used to RESET the peak pressure reading

— This key toggles the unit into and out of the Setup Mode. Depressing this key will enter the Setup screen where the configuration can be viewed and adjusted. Depressing the key again will exit the Setup Mode and return to the previously viewed main screen.

SCREENS

MAIN SCREENS – There are five main screens: Pressure Only, Pressure with Output Waveform, Pressure with Pressure Graph, ECG (optional) and Battery Indicator (optional).

The available screens can be toggled using



PRESSURE ONLY – This screen has a large pressure display, as shown below. Also

displayed on this screen is the peak pressure and selected output waveform

The display will resemble the following:



OUTPUT WAVEFORM – This screen shows the output waveform as well as the pressure,

peak pressure, and output selection.

<u>NOTE</u>

This waveform is not intended to be physiologically correct.

The display will resemble the following:



PRESSURE GRAPH SCREEN - This screen provides a graph of the pressure, as well as,

the pressure, peak pressure, and output selection



ECG OUTPUT SCREEN – This screen shows the selected ECG output mode.

(NIBP-1020 units only)

NOTE: While in this mode, the NIBP simulation does not run.

NOTE: NRS ECG output is active during NIBP testing at the rate stipulated for the selected test.

The display will resemble the following:

SELECTED	ECG Wa	veform	LIST OF AV/ OUTPL	AILABLE ITS
OUTPUT	NSR NSR NSR NSR Sine Wave	BPM 60 Bpm 120 Bpm 240 Bpm 10 Hz	NSR NSR NSR Sine Wave Sine Wave Sine Wave Square Wave Square Wave Triangle Wave	30 Bpm 60 Bpm 120 Bpm 240 Bpm 10 Hz 60 Hz 100 Hz 0.125 Hz 2 Hz 2 Hz 2 Hz

BATTERY INDICATOR SCREEN – This screen shows the status of the battery voltage level with Built-In Battery Option only.

NOTE: It is only an estimate of the battery life remaining.

When the level reaches 10%, the BP simulation mode will be disabled; however, the Manometer and ECG (optional) will continue to function. Once the battery level reaches 0%, the unit will automatically turn itself off to avoid damaging the batteries.

The display will resemble the following:



Batteries charge from provided wall transformer. The charge time is about 4 hours from full

discharge. While the batteries are charging, the display will flash "charging."

CAUTION

USE ONLY THE WALL TRANSFORMER PROVIDED WITH THE NIBP-1010 AND NIBP-1020.

SETUP

The Setup Mode allows the user to adjust the configuration of the simulator. The Setup

screen can be entered using the **SETUP** key. The parameters can be changed by using



key to highlight the line and

to toggle the available options.

key.

The Setup screen can be exited using the

System Setup	
1)Systolic Shift	-2.2
2)Diastolic Shift	-3.2
3)SpO2 Output	On
4) Auto Off Timer (Min)) 30
5)Contrast Adjust	11

SETUP

The following is a breakdown of the parameters available in the configuration of the unit

and their available options:

System Setup Configuration		
Parameter	Description	Range
Systolic Shift	Adjusts the Systolic Output of the NIBP Simulation. This is not a direct mmHg adjustment.	±50.0
Diastolic Shift	Adjusts the Diastolic Output of the NIBP Simulation. This is not a direct mmHg adjustment.	±50.0
SpO ₂ Output	This parameter determines whether the SpO ₂ output pulse is active. The output drives an MSP-2100 FingerSim Module.	Off/On
Auto Off Timer (Min)	Determines the period of inactivity before the unit is turned OFF. A timer is started when the unit is turned ON and is reset each time a key is pressed. When the timer reaches the value set in this parameter, the power is automatically turned OFF. (NOTE: Setting this parameter to 0 disables the Auto Off timer. When running from line power, the unit does not automatically shut off. Auto Off timer is inactive during a test.)	0-30 Minutes
Contrast Adjust	Sets the contrast of the display screen.	0-20
Battery Life	Available only with Battery Option installed. Displays current life of the battery. At 10%, a warning screen will appear. At 0%, the unit will power down automatically.	0-100% (Read Only)
Software	Displays current software program.	(Read Only)

SYSTOLIC AND DIASTOLIC SHIFT – The NIBP-1000 Series is equipped with the option to shift test results to compensate for different methods of measuring Oscillometric NIBP by various manufacturers and models of devices under test.

<u>CAUTION</u>

These adjustments must be used with caution as they will allow the user to adjust the output results to invalid values.

These adjustments should only be used to aid in the simplification of testing and with documented controls.

There are no absolute standards for Oscillometric NIBP readings; therefore, for a number of reasons (including patents, technology, etc.), each manufacturer has established a different method for evaluating the oscillometric pulses. Due to these varying methods, precisely the same waveforms will give different results on different manufacturer's units.

The normal technique used is to run the monitor against a fixed source like the NIBP-1000, with the understanding that each manufacturer has a predictable error from this norm. While this is generally the most direct method, users have asked for a method to correct for this difference, making the monitors read the same as the test unit. The Systolic and Diastolic Shift settings allow for just such correction.

These adjustments are indicated in a line added to the main display to inform the user of any shift that has been programmed into the system. This is done so there is no misunderstanding of the meaning of the results.

OPERATIONS

CONNECTING PRESSURE

The NIBP-1010 and NIBP-1020 Blood Pressure Simulators are connected between the blood pressure cuff and the monitor (Device Under Test, DUT).

The blood pressure cuff should be disconnected from the DUT and a 'T' adapter inserted between the cuff and the DUT. The NIBP simulator is then connected to the open side.



Roll the cuff tightly on itself or around a mandrel.

CONNECTING PATIENT LEADS

For the NIBP-1020, with ECG output, test snaps are provided along the sides and are identified by the markings on the overlay.



THEORY OF OPERATIONS

A motor and piston assembly is used to generate the output waveforms. A differential pressure sensor is used to measure the pressure of the cuff. The pressure sensor is read by a 16-bit differential Digital to Analog converter. The ECG output is performed by a 12-bit Digital to Analog converter. A second 12-bit Digital to Analog converter is used to generate the respiration waveform.

RUNNING A TEST

NIBP:

To run an NIBP simulation, the cuff and monitor are connected to the pressure input. Then the measurement is initiated by the monitor and the NIBP-1010 and NIBP-1020 will output the proper waveform based on the cuff pressure.

The NIBP output mode can be changed by pressing the Select key. Once the desired operating mode is selected, the output will automatically begin once the correct pressure is detected.

ECG (NIBP-1020 Only):

The ECG output is selected by pressing the UP arrow until the ECG Waveforms menu is displayed. While in this mode, the NIBP simulation is disabled. The select key is used to choose the desired ECG output.

ECG Alarm Mode:

This mode tests the alarms of the monitor under test. The ECG output will alternate from a 47 BPM NSR with apnea respiration (0 brpm) to 160 BPM NSR with 80 brpm respiration. The time interval between alternations is 30 seconds. While in this mode, the BP simulation output is disabled.

MANUAL REVISIONS

Revision #	<u>Program #</u>	<u>Revisions Made</u>
Rev 01 Rev 02 Rev 03 Rev 04 Rev 05 Rev 06	DT7355CA DT7355CA DT7355CA DT7355CF DT7355CG DT7355CG DT7355CI	Origination Specification Information Updated Miscellaneous Edits Add Systolic/Diastolic adjustments Output Selection edited Miscellaneous 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.

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

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SPECIFICATIONS

NIBP-1010

Blood Pressure		
RANGE	0-500 mmHg @ 20°C	
ACCURACY	+/- (1% of Reading + .5 mmHg)	
RATE	80, 94 bpm	
ACCURACY	+/- 1%	

Physical		
DISPLAYS	LCD Graphical 128 X 64 Pixels	
ENCLOSURE	7 x 5 x 4 Inches (177.8 x 127.0 x 101.6 mm) ABS Plastic	
WEIGHT	< 3 Lbs (< 1.36 Kg)	
FACE PLATE	Lexan, Back printed	
OPERATING RANGE	15 to 40 C	
STORAGE RANGE	-20 to 65 C	

Electrical		
BATTERY ELIMINATOR	12VDC, 500mA ⊕-€–⊙ ===	
BATTERY (OPTIONAL)	6 AA NiMH Rechargeable (Not user serviceable)	
BATTERY RUNTIME	500 Test Cycles between charges	
BATTERY STORAGE LIFE	1 Year from full charge	

NIBP-1020

Blood Pressure		
RANGE	0-500 mmHg @ 20°C	
ACCURACY	+/- (1% of Reading + .5 mmHg)	
RATE	80, 94 bpm (synchronized to ECG)	
ACCURACY	+/- 1%	

ECG NSR		
RATE	30,60,120,240 BPM	
ACCURACY	+/- 1%	
AMPLITUDE	2.75 mV	
ACCURACY	+/- 2% @ Lead II	

ECG Performance		
SINE WAVE	10,60,100 Hz	
SQUARE WAVE	0.125, 2.000 Hz	
TRIANGLE WAVE	2.000 Hz	
RATE ACCURACY	+/- 1%	
AMPLITUDE	2.75 mV	
AMPLITUDE ACCURACY	+/- 2% @ Lead II	

Pacemaker Waveforms		
AMPLITUDE	3 mV	
ACCURACY	+/- 10%	
WIDTH	3 ms	
ACCURACY	+/- 5%	

Respiration	
RATE ACCURACY	+/- 1%
IMPEDANCE DELTA	3.0 ohms
ACCURACY	+/- 10%
BASELINE	1000 ohms
ACCURACY	+/- 5%

Physical		
DISPLAYS	LCD Graphical 128 X 64 Pixels	
ENCLOSURE	7 x 5 x 4 Inches (177.8 x 127.0 x 101.6 mm) ABS Plastic	
WEIGHT	< 3 Lbs (< 1.36 Kg)	
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OPERATING RANGE	15 to 40 C	
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NOTES