BP Pump 2

NON-INVASIVE
BLOOD PRESSURE
SIMULATOR
AND TESTER

Operator's Manual

BIO-TEK®

BP Pump 2 Manual Update

P/N 2781000, Rev. B1

As part of Bio-Tek's continuing product improvement, enhancements and changes have been made to the BP Pump 2 NIBPM Tester. This update describes these changes as well as revisions to the BP Pump 2 Operator's Manual. Please keep this update with the manual.

New features and functionality found in **firmware version 1.15** include:

- Updated Neonate NIBP Simulations
- Updated Computer Control Commands

Updated Neonate NIBP Simulations

The four pre-programmed neonate simulations shown in the *Neonate Simulations* table on page 4-4 have been changed to the following in version 1.15 firmware:

Internal Neonate Cuff	Blood Pressure (mmHg) (MAP)	Heart Rate (bpm)	Pulse Volume (cc)
#1	35/15	120	0.3
#2	60/30	120	0.3
#3	80/50	120	0.3
#4	100/70	120	0.3

Updated Computer Control Commands

The updated neonate simulations (replacing the commands shown in the table on page 7-2) can be accessed from the following computer control commands. See *Chapter* 7 for computer control details.

Description	Command	Returned String
Neonate Cuff Simulation	[SIM_NEO35_15]	NAK
	[SIM_NEO60_30]	NAK
	[SIM_NEO80_50]	NAK
	[SIM_NEO100_70]	NAK

BIO-TEK®

BP Pump 2

Operator's Manual

Bio-Tek® Instruments
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Notices

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Revision Record

Revision	Date	Change
A	8/01	First Issue
B	1/02	Various Updates
B1	1/02	Addendum - Interface adapter
C	1/03	Add Addendum per ECO 3478

Document Conventions

This manual uses the following typographic conventions:

Example	Description
SETUP	Text in TAHOMA font (UPPER CASE and Mixed Case) represents menu options as they appear on the *BP Pump 2* display.
	This icon indicates the next step following the operator's soft key press or numeric keypad selection.
Note	Bold text is used for emphasis.
neonate	Lower-case, Italicized bold text represents the Test and Simulation keys.
	This icon calls attention to important information.
	This icon calls attention to important **safety** notes.
	This icon represents the "Home" key.

Safety Considerations

Warnings and Cautions

Read the manual carefully before operating the *BP Pump 2*.

☛ The following warning and informational symbol may be found on the *BP Pump 2*.

Symbol	Description
	**Caution: Refer to accompanying documentation**

☛ **The *BP Pump 2* operates at a range of 100 to 240 volts. Disconnect from the power source before changing the supply voltage.**

Hazard Warnings

APPROPRIATE WARNINGS.

☛ **Warning! Power Rating.** The *BP Pump 2* mains power input must be connected to an external power supply that provides voltage and current within the specified rating for the system.

☛ **Warning! Electrical Grounding.** Never use a two-prong plug adapter to connect primary power to the *BP Pump 2*. Use of a two-prong adapter disconnects the utility ground, creating a severe shock hazard. Always connect the system power cord directly to a three-prong receptacle with a functional ground.

Precautions

Please observe the following to avoid damaging the system:

- **Caution: Service.** Authorized service personnel should service the *BP Pump 2*. Only qualified technical personnel should perform troubleshooting and service procedures on internal components.

- **Caution: Environmental Conditions.** Do not expose the system to temperature extremes. Ambient temperatures should remain between 18° and 40°C. System performance may be adversely affected if temperatures fluctuate above or below this range.

- **Caution: Liquids.** Do **NOT** Immerse. Clean only with a mild detergent, and gently wipe down with a clean, lint-free cloth.

- **Caution: Pressure Port.** Do not apply pressures greater than 400 mmHg (53 kPa) to the **pressure port** or you may damage internal parts. **Product warranty will be voided.**

Applicable Testing Standards

The *BP Pump 2* has been tested by an independent laboratory and meets the requirements listed here.

Safety Requirements

USA	UL 3101-1, Electrical Equipment for Laboratory Use; Part 1: General Requirements.
Canada	CAN/CSA C22.2 No. 1010.1 (1992), Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use, Part 1: General Requirements.
EC Directive 73/23/EEC	EN 61010-1, Safety requirement for electrical equipment for measurement, control and laboratory use, Part 1: General Requirements.

Electromagnetic Interference and Susceptibility

☛ USA FCC Class A

Warning: Changes or modifications to this unit not expressly approved by the manufacturer could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules.

These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. Like all similar equipment, this equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause interference, in which case the user will be required to correct the interference at his/her own expense.

☛ Canadian Department of Communications Class A

This digital apparatus does not exceed Class A limits for radio emissions from digital apparatus set out in the Radio Interference Regulations of the Canadian Department of Communications.

Le present appareil numerique n'met pas du bruits radioelectriques depassant les limites applicables aux appareils numerique de la Class A prescrites dans le Reglement sur le brouillage radioelectrique edicte par le ministere des Communications du Canada.

CE Based on the testing standards below, this device bears the CE mark.

EC Directive 89/336/EEC Electromagnetic Compatibility

☛ Emissions - Class A

The system has been type tested by an independent, accredited testing laboratory and found to meet the requirements of EN 61326-1:1998 for Radiated Emissions and Line Conducted Emissions. Verification of compliance was conducted to the limits and methods of the following:

CISPR 16-1:1993 and CISPR 16-2:1996

☛ Immunity

The system has been type tested by an independent, accredited testing laboratory and found to meet the requirements of EN 61326-1:1998 for Immunity. Verification of compliance was conducted to the limits and methods of the following:

EN 61000-4-2 (1991) Electrostatic Discharge

EN 61000-4-3 (1995) Radiated EM Fields

EN 61000-4-4 (1995) Electrical Fast Transient/Burst

EN 61000-4-5 (1995) Surge Immunity

EN 61000-4-6 (1996) Conducted Disturbances

EN 61000-4-11 (1994) Voltage Dips, Short Interruptions and Variations

EC Directive 73/23/EEC Low Voltage (User Safety)

The system has been type tested by an independent testing laboratory and found to meet the requirements of EC Directive 73/23/EEC for Low Voltage. Verification of compliance was conducted to the limits and methods of the following:

EN 61010-1 (1993)

"Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use, Part 1: General requirements" (including amendments 1 and 2).

Warranty

This Warranty is limited and applies only to new products, except for computer-based software, which is covered under a separate Warranty Policy, manufactured by Bio-Tek Instruments. ("Bio-Tek"). Bio-Tek makes no warranty whatsoever regarding the condition of used products.

Bio-Tek warrants the instrument (hereinafter collectively referred to as "Products" or "Product") for a period of one (1) year from the original purchase date against defective materials or workmanship. This Warranty is limited to the original purchaser (the "Purchaser") and cannot be assigned or transferred. All claims under this Limited Warranty must be made in writing to Bio-Tek, Attention: Service Department. Purchaser must ship the Product to Bio-Tek, postage pre-paid. Bio-Tek shall either repair or replace with new or like new, at its option and without cost to the Purchaser, any Product which in Bio-Tek's sole judgment is defective by reason of defects in the materials or workmanship.

This Warranty is VOID if the Product has been damaged by accident or misuse, or has been damaged by abuse or negligence in the operation or maintenance of the Product, including without limitation unsafe operation, operation by untrained personnel, and failure to perform routine maintenance. This Warranty is VOID if the Product has been repaired or altered by persons not authorized by Bio-Tek, or if the Product has had the serial number altered, effaced, or removed. This Warranty is VOID if any of the Products has not been connected, installed or adjusted strictly in accordance with written directions furnished by Bio-Tek. Batteries, fuses, light bulbs, and other "consumable" items used in any of the Products are not covered by this Warranty. Software utilized in conjunction with any of the Products is not covered by the terms of this Warranty but may be covered under a separate Bio-Tek software warranty.

We will continue to stock parts for a maximum period of five (5) years after the manufacture of any equipment has been discontinued. Parts shall include all materials, charts, instructions, diagrams, and accessories that were furnished with the standard models.

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THIS WARRANTY IS VOID UNLESS THE PURCHASE REGISTRATION CARD HAS BEEN COMPLETED AND MAILED TO US WITHIN TEN (10) DAYS OF PURCHASE.

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Introduction and Description

Chapter 1

1. Introduction to the BP Pump 2
2. Package Contents
3. Accessories
4. System Characteristics

1. Introduction to the BP Pump 2

The Bio-Tek *BP Pump 2* is a multi-purpose test instrument for use with Oscillometric Non-Invasive Blood Pressure Monitors (NIBPMs). The *BP Pump 2* NIBPM Tester provides dynamic blood pressure simulations, static calibration, automated leak testing, and pressure relief valve testing. The following models are available:

- *BP Pump 2L* (Basic Model)
- *BP Pump 2M* (High-Accuracy Model)

The *BP Pump 2* allows the operator to verify performance claims of different blood pressure monitors. The operator can quickly recall the fixed onboard simulations or define their own. With its internal pump, the *BP Pump 2* can generate pressures up to 400 mmHg (53.3 kPa) for leak testing, pressure sourcing, and relief valve testing.

Note: Refer to *Appendix A, Specifications*.

In addition, the operator can define auto sequences that automate the sequencing of tests and NIBP simulations and provide an optional printed report.

Figure 1-1 illustrates the *BP Pump 2* Top Panel, and *Figure 1-2* illustrates the Side Panel.

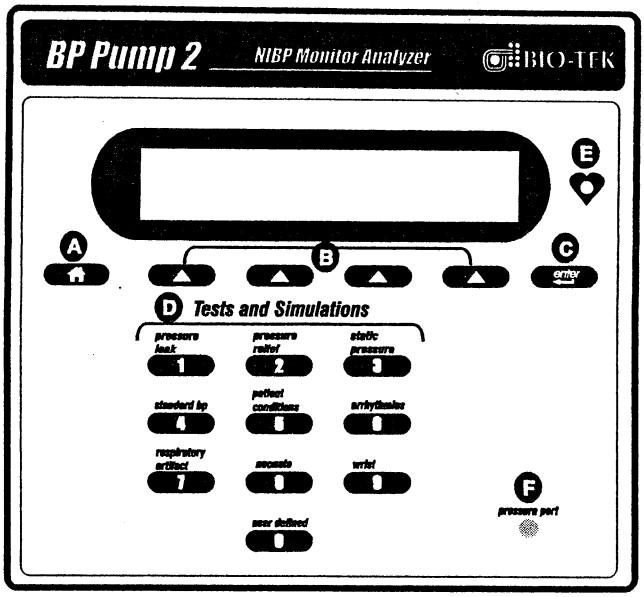


Figure 1-1. BP Pump 2 Top Panel Illustration

Top Panel: Identifying BP Pump 2 Components

Use the drawing of the BP Pump 2 top panel, displayed above, to locate the following components. The **On-Off switch** and **power outlet** are located on the rear panel of the instrument.

A	**Home Key**	Returns the operator to the **Main Menu**.
B	**Soft Keys 1-4**	Make dynamic assignments based on the current screen.
C	**Enter Key**	Advances to the next menu or saves/selects options.
D	**Tests and Simulations Keys**	Allow the operator to perform auto sequences and simulations using numeric keys.
E	**Pulse Indicator**	LED blinks/emits sound indicating that the pump is generating a simulated blood pressure pulse.
F	**Pressure Port**	Connects to the diaphragm pump, which is used as a pressure source for the relief valve, leak, and pressure source tests.

Keys Used to Select Auto Tests and Simulations

The keys described below (**1** through **0**) can be used to perform auto tests and simulations.

1	**Pressure Leak**	Pressurizes a pneumatic system to an operator-defined target pressure up to 400 mmHg (53.3 kPa), and then measures the loss of pressure over time.
2	**Pressure Relief**	Increases the pressure in the pneumatic system until the relief valve on the NIBP monitor opens, or until the **Setpoint** is reached, whichever occurs first.
3	**Static Pressure**	Accessed via the Pressure Gauge Test, which enables the *BP Pump 2* to measures static pressure generated by an external source in the range of 0 to 400 mmHg (0 to 53.3 kPa).
4	**Standard BP**	Provides seven variations of NIBP simulations for both arm and wrist cuffs.
5	**Patient Conditions**	Includes simulations for healthy, geriatric, and obese patients, a well as various levels of exercise.
6	**Arrhythmias**	Measures erratic heart rhythms, including atrial fibrillation and premature ventricular contraction.
7	**Respiratory Artifact**	Exhibits a beat-to-beat variation in the blood pressure caused by intra-thoracic pressure.
8	**Neonate**	Tests the ability of the NIBP monitors to detect blood pressure on neonatal patients.
9	**Wrist**	Tests wrist cuff NIBP monitors.
0	**User Defined**	Allows the operator to define blood pressure simulations.

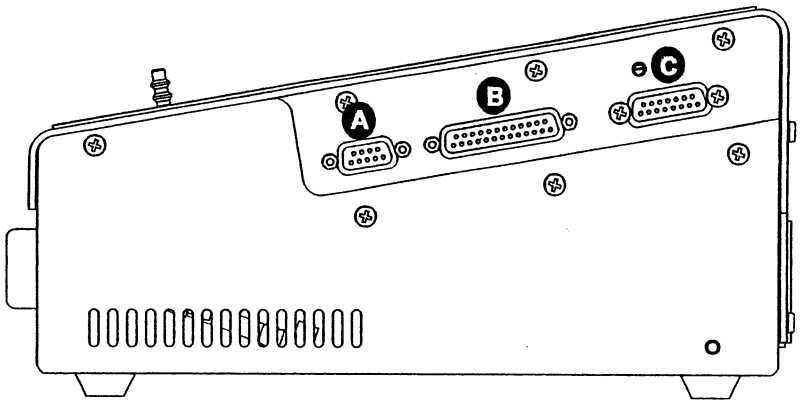


Figure 1-2. BP Pump 2 Side Panel Illustration

Side Panel Components

Use the drawing of the *BP Pump 2* side panel, displayed above, to locate the following components.

A	**RS-232 Serial Port**	Provides serial D-9 female connector for bi-directional computer control.
B	**Printer Port**	Provides D-25 female connector for external parallel printer.
C	**ECG Interface Port**	Allows connection of optional ECG accessory (refer to *Appendix B, ECG Option*).

2. Package Contents

The following accessories are shipped standard with the *BP Pump 2*. To order additional quantities, contact your Bio-Tek equipment dealer, and use the Bio-Tek Part Numbers provided.

Description	Qty. Supplied	Part No.
Operator's Manual	1	2781000
Warranty Card	1	94001
Tubing and Fittings	1	2780003
Country-Specific Power Cord:		
• USA	1	75011
• Schuko	1	75010
• UK	1	75012
• AU	1	75013

3. Accessories

The following optional accessories are available for the *BP Pump 2*. To order, contact your Bio-Tek equipment dealer, and use the Bio-Tek Part Numbers provided.

Description	Part No.
Wrist Cuff Mandrel	2783000
ECG adapter	2780512
Carrying Case	5022010
RS-232 Serial Cable (9M-9F)	75034
BP Pump 2M Upgrade	2780001

4. System Characteristics

Some of the key features and tests available on the *BP Pump 2* include:

- Pressure leak testing on cuff, tubing, and connections
- Relief valve testing on Patient Monitor
- Pressure gauge measurements
- Pressure source capability
- NIBP simulations including adult, neonate, arrhythmias, and respiratory artifacts
- Auto sequences with optional reports
- Internal Adult and Neonatal reservoirs

The *BP Pump 2* capabilities can be extended with the purchase of optional accessories that will allow:

- ECG synchronization with non-invasive output
- External wrist cuff simulations

The *BP Pump 2* pressure accuracy capability can be improved with the upgrade to a high-accuracy pressure transducer (Upgrade, Part Number 2780001). This is a service upgrade and is provided for those customers wanting to meet the DIN EN 1060 requirements for pressure measurement accuracy. For more information, refer to *Chapter 8, Maintenance and Support.*

Setting Up the BP Pump 2

Chapter 2

1. **Language**
2. **Printer Output**
3. **Units of Measure**
4. **RS-232 Settings**
5. **User-Defined Simulations**
6. **Self Test**
7. **Zero Pressure**
8. **Enable ECG Signal**

The *BP Pump 2* has several configurable options, available from the **SETUP** menu. It is recommended that these items be configured the first time the *BP Pump 2* is used. These settings will be saved and only need to be configured once.

1. Language

Besides the default of English, the *BP Pump 2* can support up to four additional languages. Italian and Spanish are currently available; additional languages will be released in the future. To change the language, use the soft keys to follow the menu path shown here.

SETUP → LANGUAGE → Display/Print Language

2. Printer Output

Printouts are available for auto sequences. By default, the **Printer Output** is set to **NONE**. To generate printouts when running auto sequences, select the desired print format by using the soft keys to follow the menu path shown here.

SETUP → PRINTER OUTPUT → Printer Output

The available options are **ASCII**, **HP PCL3**, and **NONE** (default).

3. Units of Measure

The *BP Pump 2* has separate definable measurement units for the Blood Pressure simulations and for the Pressure Tests. For the Blood Pressure simulations, units of mmHg (default) and kPa are available. For the Pressure Tests, units of mmHg (default), kPa, cmH2O, inH2O, and PSI are available.

To define the pressure units from the **Main Menu**, use the soft keys to follow the menu path shown here.

SETUP → *MORE → UNITS OF MEASURE →
Blood Pressure Units: (mmHg or kPa) → enter→
Pressure Measurement Units → *MORE → enter

Note: Changing the **UNITS OF MEASURE** also changes the units used in the auto sequences.

4. RS-232 Settings

The *BP Pump 2* serial port parameters are fixed at the following settings:

Baud Rate:	9600
Parity:	None
Data Bits:	8
Stop Bit:	1

5. User-Defined Simulations

The *BP Pump 2* supports up to 9 user-definable blood pressure simulations. They are configured through the **SETUP MENU** and are accessible by pressing the ***user defined*** key on the front panel.

The parameters available for configuration and their valid ranges are:

- Systolic: 20 – 250 mmHg
- Diastolic: 10 – 200 mmHg
- Pulse Volume: 0.1 cc – 2.4 cc in increments of 0.1 cc
- Heart Rate: 30 – 250 bpm

The systolic and diastolic settings are interdependent. The diastolic must always be below the systolic. The pulse volume and the heart rate are also interdependent. The maximum pulse volume cannot be achieved at the maximum heart rate.

6. Self Test

The *BP Pump 2* displays the software version and checksum, the serial number, and the model number. A motor check is also performed.

7. Zero Pressure

The Zero pressure option allows the operator to re-zero the pressure. The function is similar to the tare of a scale. This re-zeroing lasts until the unit is zeroed again or the power is shut off.

8. Enable ECG Signal

The ECG output is enabled or disabled by the operator. If the patient monitor under test does not make use of ECG signals, we recommend that the ECG output be disabled. (The factory default is for ECG to be disabled.) ECG signals are present for all Standard BP, Patient Condition, and Arrhythmia NIBP simulations. The ECG signals are present on the ECG Interface Port as shown in *Figure 1-2*. An optional ECG Interface adapter, as described in *Appendix B*, can also be purchased.

Pressure Tests

Chapter 3

1. **Pressure Leak Test**
2. **Pressure Relief Test**
3. **Pressure Source Test**
4. **Pressure Gauge Test**

1. Pressure Leak Test

The Pressure Leak Test will pressurize a pneumatic system to an operator-defined target pressure up to 400 mmHg (53.3 kPa) and will then measure the loss of pressure over time.

Once defined, the target pressure (labeled **Setpoint**) can be changed in increments of 1 least significant digit (LSD). Press the **VENT** soft key to release any unwanted pressure in the system before performing the test. This feature vents the system for approximately five seconds and can be repeated as needed to return pressure to zero. Press the **<START>** soft key for the *BP Pump 2* to begin delivering air to the system.

To define the target pressure, use the soft keys to follow the menu path shown here.

PRESSURE TESTS → PRESSURE LEAK TEST → SETUP → Leak Test (Setpoint) → enter → (VENT) → <START>

Once the system under test reaches the target pressure, the test begins. The pressure leak rate of the system and the current system pressure are shown during the test. The leak rate is expressed in mmHg/min by default or can appear in kPa/min, cmH2O/min, inH2O/min, or psi/min, depending on the pressure measurement unit selection.

The leak rate of the *BP Pump 2* is < 2 mmHg/minute.

Note: When testing with an NIBP monitor in the system, it will be necessary to put the monitor in "Service" mode, since most monitors leave the system open to atmosphere.

2. Pressure Relief Test

The Pressure Relief Test will increase the pressure in the pneumatic system until the relief valve on the NIBP monitor opens, or until the **Setpoint** is reached, whichever occurs first.

For the *BP Pump 2* to perform a Pressure Relief Test, the NIBP monitor must be in "Calibrate" or "Service" mode. Putting the monitor in "Service" mode closes its vent valve so that the *BP Pump 2* can inflate the pneumatic system. Refer to the NIBP monitor's service manual to find the method for entering "Service" mode.

The **Setpoint,** which defaults to 380 mmHg, can be changed using the **SETUP** soft key.

Press the **VENT** soft key to release any unwanted pressure in the system before performing the test. This feature vents the system for approximately five seconds and can be repeated as needed to return pressure to zero.

To initiate the test, use the soft keys to follow the menu path shown here.

PRESSURE TESTS → PRESSURE RELIEF → SETUP → Relief Valve Test (Setpoint) → enter → <START>

While the *BP Pump 2* is delivering air to the system, the current pressure (**Measured**) and peak pressure are being monitored.

If the **Setpoint** is reached and the monitor does not release the pressure, the message **No Pressure Relief** will appear on the display.

Note: It is recommended that three pressure relief measurements be taken to check for a sticky relief valve.

Some NIPB monitors may not allow access to a "Service" mode. Therefore, it will not be possible to close a vent valve so that the system can be pressurized by an outside pump. As a last resort, it is possible to start a blood pressure determination with the monitor (this closes the valve), then start the Pressure Relief tests. Now there are two pumps inflating the system. The results can vary, but the monitor will generally open a relief valve at some high pressure.

3. Pressure Source Test

The Pressure Source Test enables the *BP Pump 2* to simultaneously generate and measure pressure.

The Pressure Source Test can be used for static calibration of Non-Invasive Blood Pressure monitoring systems, checking sphygmomanometers, and evaluating any medical device that measures pressure in the ranges of 0 to 400 mmHg (0 to 53.3 kPa). Pressures can be generated in 1-mmHg (0.1 kPa) increments.

The **Setpoint,** which defaults to 200 mmHg, can be changed using the **SETUP** soft key.

Press the **VENT** soft key to release any unwanted pressure in the system before performing the test. This feature vents the system for approximately five seconds and can be repeated as needed to return pressure to zero.

To initiate the test, use the soft keys to follow the menu path shown here.

PRESSURE TESTS → STATIC PRESSURE → SETUP → Setpoint → enter → <START>

The *BP Pump 2* will pressurize the system within 10 mmHg of the **Setpoint** value. Once the **Setpoint** has been reached, the *BP Pump 2* will not maintain the pressure in the system. Therefore, it is recommended that the system be checked for leaks prior to performing any static pressure tests.

4. Pressure Gauge Test

The Pressure Gauge Test enables the *BP Pump 2* to measure static pressure generated by an external source in the range of 0 to 400 mmHg (0 to 53.3 kPa).

Press the **VENT** soft key to release any unwanted pressure in the system before performing the test. This feature vents the system for approximately five seconds and can be repeated as needed to return pressure to zero.

To initiate the test, use the soft keys to follow the menu path shown here.

PRESSURE TESTS → STATIC PRESSURE → Pressure Gauge →

<START> is not applicable to the pressure gauge test and is therefore not displayed. After selecting GAUGE, apply pressure to the **pressure port** and read the displayed pressure.

BP Simulations

Chapter 4

1. Standard BP Simulations
2. Patient Condition Simulations
3. Arrhythmias
4. Respiratory Artifacts
5. Neonate Simulations
6. Wrist Simulations
7. User-Defined Simulations

1. Standard BP Simulations

The *BP Pump 2* provides many variations of NIBP simulations for both arm and wrist cuffs.

To access the standard simulations that are provided, press the **4** key, which is also labeled ***standard bp***. Press the **OPTIONS** soft key to scroll through the simulation choices. Press the **CUFF** soft key to select Internal Adult or External cuff.

Standard Set of Blood Pressures	Blood Pressure (mmHg) (MAP)	Heart Rate (bpm)	Pulse Volume (cc)
#1	120/80 (93)	80	0.7
#2	150/100 (116)	80	0.7
#3	200/150 (166)	80	0.7
#4	255/195 (215)	80	0.7
#5	60/30 (40)	80	0.7
#6	80/50 (60)	80	0.7
#7	100/65 (76)	80	0.7

2. Patient Condition Simulations

The Patient Condition simulations are intended to provide some basic patient variations. To access these simulations, press the **5** key, which is also labeled ***patient conditions***. Press the **OPTIONS** soft key to scroll through the simulation choices. Press the **CUFF** soft key to select Internal Adult or External cuff.

Patient Conditions	Blood Pressure (mmHg) (MAP)	Heart Rate (bpm)	Pulse Volume (cc)
Healthy Heart	120/80 (93)	75	0.7
Weak Pulse	110/80 (90)	95	0.3
Mild Exercise #1	140/90 (106)	120	1.1
Strenuous Exercise #2	140/90 (106)	162	1.4
Obese Subject	120/80 (93)	90	0.4
Geriatric Subject	150/110 (123)	95	0.4
Tachycardia	120/105 (110)	130	0.3
Bradycardia	120/60 (80)	45	1.1

3. Arrhythmias

To access the Arrhythmias, press the **6** key, which is also labeled ***arrhythmias***. Press the **OPTIONS** soft key to scroll through the simulation choices. Press the **CUFF** soft key to select Internal Adult or External cuff.

These waveforms cause erratic readings on some NIBPMs. The blood pressure determination strongly depends on exactly what is happening with the subject's blood pressure when the cuff pressure is at a particular level. Some NIBPMs will pause until they see two or more equivalent beats. The pattern of step deflations and the measured blood pressure will depend on which beats occur during each step of the cuff pressure.

Simulation	Blood Pressure (mmHg) (MAP)	Heart Rate (bpm)	Pulse Volume (cc)
Premature Atrial Cont. #1	138/53 (81)	80	Varies
Premature Atrial Cont. #2	144/64 (90)	83	Varies
Premature Ventricular Cont.	118/61 (80)	83	Varies
Atrial Fib and PVCs	139/72 (94)	91	Varies

4. Respiratory Artifacts

The Respiratory Artifact exhibits a beat-to-beat variation in the blood pressure caused by intra-thoracic pressure. Changes in the intra-thoracic pressure affect filling of the ventricles during diastole. This in turn affects the stroke volume of the heart. A large stroke develops a higher systolic pressure than a small stroke.

To access the Respiratory Artifact, press the **7** key, which is also labeled ***respiratory artifact***. Press the **OPTIONS** soft key to scroll through the simulation choices. Press the **CUFF** soft key to select Internal Adult or External cuff.

Simulation	Blood Blood Pressure (mmHg) (MAP)	Heart Rate (bpm)	Pulse Volume (cc)
Spontaneous Breathing #1	138/65 (89)	104	Varies
Spontaneous Breathing #2	149/65 (93)	105	Varies
Spontaneous Breathing #3	112/47 (68)	86	Varies
Controlled Ventilation	132/44 (73)	98	Varies

5. Neonate Simulations

The Neonate simulations are provided to test the ability of the NIBP monitors to detect blood pressure on neonatal patients.

To access the Neonate simulations, press the **8** key, which is also labeled ***neonate***. Press the **OPTIONS** soft key to scroll through the simulation choices. Press the **CUFF** soft key to select External or Internal Neonate.

Simulation	Blood Pressure (mmHg) (MAP)	Heart Rate (bpm)	Pulse Volume (cc)
#1	60/30 (40)	120	0.3
#2	70/50 (57)	120	0.3
#3	20/10 (13)	120	0.3
#4	35/15 (22)	120	0.3

6. Wrist Simulations

The Wrist simulations are provided to test wrist cuff NIBP monitors. To access the Wrist simulations, press the **9** key, which is also labeled ***wrist***. Press the **OPTIONS** soft key to scroll through the simulation choices. The simulation is automatically set up to use the external cuff and cannot be changed.

Simulation	Blood Pressure (mmHg) (MAP)	Heart Rate (bpm)	Pulse Volume (cc)
#1	120/80 (93)	80	0.5
#2	160/100 (120)	80	0.5
#3	80/55 (63)	80	0.5

7. User-Defined Simulations

The User-Defined simulation option is described in *Section 5* of *Chapter 2, Setting Up the BP Pump* 2.

To select from any of the defined simulations, press the **0** key, which is also labeled ***user defined***. Press the **OPTIONS** soft key to scroll through the simulation choices. Press the **CUFF** soft key to select External, Internal Adult, or Internal Neonate cuff.

Note: It is important to select the correct cuff.

Auto Sequences

Chapter 5

1. Editing Auto Sequences
2. Printing Auto Sequences
3. Running Auto Sequences

1. Editing Auto Sequences

It is possible to create up to nine customized auto sequences. An auto sequence contains all four pressure tests and five simulations. The operator can disable any of these tests or simulations. A printout of the auto sequence result can also be enabled. The operator **must** make a cuff selection; this determines what NIBP simulations will be displayed for that selection.

To edit an auto sequence, press the **AUTO SEQUENCE** soft key to access the **Auto Sequence** menu. Press the **EDIT** soft key.

At the Select Auto Sequence prompt, press a numeric key (1-9), followed by the **enter** key. The operator will be prompted to select, enable, or disable each of the following:

- Print Auto Sequence Result
- Pressure Gauge Test
- Pressure Source Test
- Pressure Leak Test
- Pressure Relief Test
- Cuff Selection
- NIBP Simulations (1-5)

Press the **enter** key at each of the above prompts to advance to the next selection.

Note: By default, each auto sequence is configured to perform the Leak Test, Relief Test, and BP Simulation #1 (120/80).

Changing the cuff selection will change the available BP Simulation options.

2. Printing Auto Sequences

Note: Refer to *Section 2* of *Chapter 2, Setting Up the BP Pump 2* for Printer Output setup.

To determine which tests and simulations are defined in an auto sequence, press the **AUTO SEQUENCE** soft key to access the **Auto Sequence** menu, and use the soft keys to follow the menu path shown here.

PRINT → Select Auto Sequence (1-9) → enter

Figure 5-1 shows a typical printout that will be generated.

```
Auto Sequence #1 Definition

Gauge Enabled
Leak Setpoint:        200    mmHg
Relief Pressure:      380    mmHg
Source Pressure:      200    mmHg

Cuff: External
Simulation 1:  Preset #1   120/80
  80BPM 0.7cc
Simulation 2:  Preset #2   150/100
  80BPM 0.7cc
Simulation 3:  Preset #3   200/150
  80BPM 0.7cc
Simulation 4:  Preset #4   255/195
  80BPM 0.7cc
Simulation 5:  Preset #5    60/30
  80BPM 0.7cc
```

Figure 5-1. Sample auto sequence test printout

3. Running Auto Sequences

To run an auto sequence, press the **AUTO SEQUENCE** soft key to access the **Auto Sequence** menu, and use the soft keys to follow the menu path shown here.

RUN → Select Auto Sequence (1-9) → enter

The auto sequence will then begin to execute, based on the options that were enabled using the **EDIT** function.

Note: The tests and simulations that are not enabled in the executing auto sequence are skipped.

The auto sequences are executed in the following order.

Pressure Gauge: This test allows the operator to monitor system pressure, which must be generated external to the *BP Pump 2*. Press the **NEXT>** key to advance to the next test. The pressure that is displayed when the **NEXT>** key is pressed will appear on the printout.

Leak Test: This test will perform a system leak test at the **Setpoint** pressure, which was defined when the auto sequence was edited. Press the **START** soft key to initiate this test. The system will then pressurize. Once a stable pressure reading near the **Setpoint** is reached, a 60-second timer will begin to count down. Once the timer has elapsed, a **Leak Rate** will appear on the display. If the Leak Rate is unsatisfactory, press **START** again to repeat the test after repairing the possible cause of the leak. Press the **NEXT>** key to advance to the next test. Only the leak rate that is displayed when the **NEXT>** key is pressed will appear on the printout.

Note: The **NEXT>** key will not function until the Leak Test has been performed at least once.

Relief Valve Test: This test will increase the pressure in the pneumatic system until the relief valve on the NIBP monitor opens, or until the **Setpoint** is reached, depending on which occurs first. The test is initiated using the **START** soft key. It is recommended that this test be repeated multiple times. Press the **NEXT>** key to advance to the next test.

Note: The **NEXT>** key will not function until the Relief Valve Test has been performed at least once.

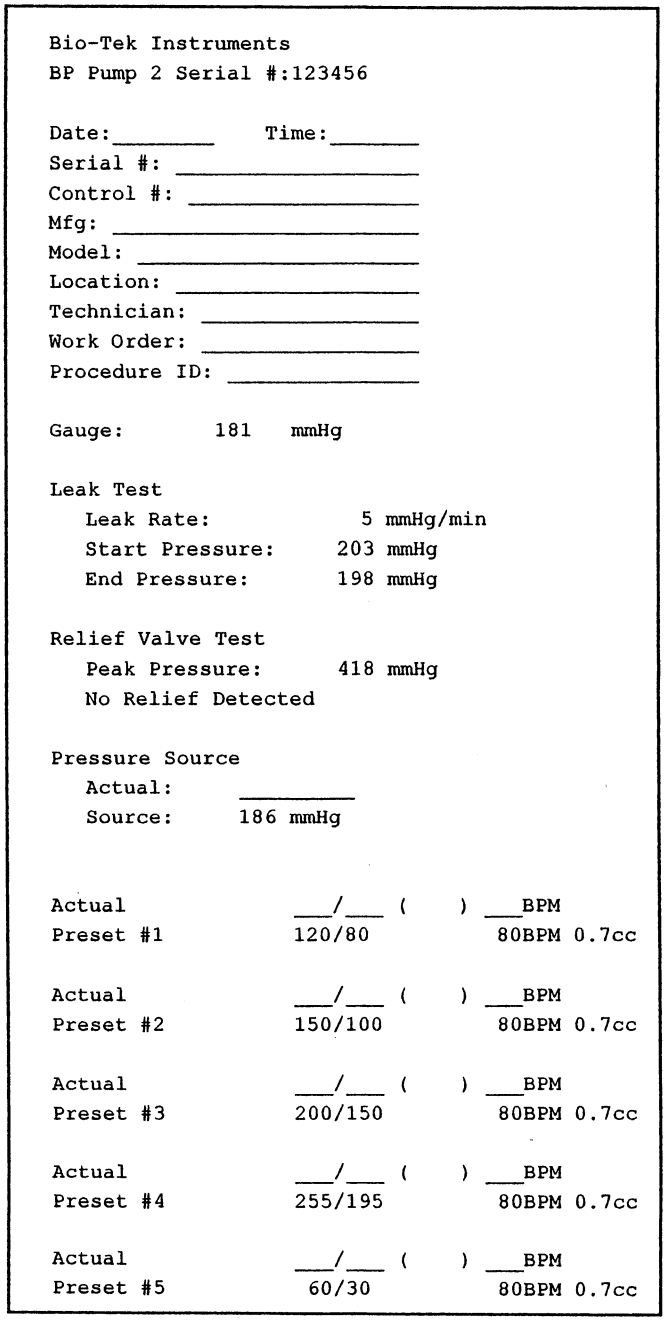
Pressure Source: This test will cause the system to rise to the **Setpoint** pressure, which was defined when the auto sequence was edited. Press the **START** soft key to initiate the test. The system will then begin to pressurize until a stable pressure reading at or near the **Setpoint** is reached. Record the monitor reading on the data sheet (if generated). Press the **NEXT>** key to advance to the next test.

Note: The **NEXT>** key will not function until the Pressure Source test has been performed.

Data Sheet Printout: When this step is reached, a printout will be generated (*Figure 5-2*), which includes a standard header, the results of the previous tests (if any), a place to record data for the Pressure Source test (if enabled), and a list of BP Simulations that will be executed.

BP Simulations: At the conclusion of the auto sequence, up to 5 different blood pressure simulations will be run in order of definition. Each simulation can be repeated as many times as desired; however, each defined simulation must be run at least once in order to advance to the next one.

Note: Some monitors cannot handle extreme changes in blood pressure. For example, it may not be possible to perform a 255/195 simulation following a 60/30 simulation on some monitors.



```
Bio-Tek Instruments
BP Pump 2 Serial #:123456

Date:_________     Time:_______
Serial #: ____________________
Control #: ___________________
Mfg: _________________________
Model: _______________________
Location: ____________________
Technician: __________________
Work Order: __________________
Procedure ID: ________________

Gauge:       181   mmHg

Leak Test
   Leak Rate:            5 mmHg/min
   Start Pressure:     203 mmHg
   End Pressure:       198 mmHg

Relief Valve Test
   Peak Pressure:      418 mmHg
   No Relief Detected

Pressure Source
   Actual:      _________
   Source:     186 mmHg


Actual              ___/___ (    ) ___BPM
Preset #1           120/80          80BPM 0.7cc

Actual              ___/___ (    ) ___BPM
Preset #2           150/100         80BPM 0.7cc

Actual              ___/___ (    ) ___BPM
Preset #3           200/150         80BPM 0.7cc

Actual              ___/___ (    ) ___BPM
Preset #4           255/195         80BPM 0.7cc

Actual              ___/___ (    ) ___BPM
Preset #5            60/30          80BPM 0.7cc
```

Figure 5-2. Sample data sheet printout

Theory of Operation

Chapter 6

1. Operation
2. Diagrams of the Device Under Test
3. Conversion Factors

1. Operation

The *BP Pump 2* contains a microprocessor that reads and controls the front panel keyboard, the display, serial port, printer port, a diaphragm pump, two solenoid valves, a step motor, a position sensor, and a pressure transducer (*Figure 6-1*).

The diaphragm pump is used as a pressure source for the relief valve, leak, and pressure source tests. The diaphragm pump pulls air through a filter and forces it through a check valve into the main manifold of the instrument. This main manifold has an internal volume of approximately 20 cc and is directly connected to the ***pressure port*** on the front panel. Pressure in the manifold is measured by a pressure transducer and can be released by a solenoid-operated valve. The volume of the main manifold can be increased by approximately 290 cc, to simulate an adult pressure cuff, by opening a second solenoid valve.

A step motor and lead screw move a piston into the manifold to decrease the manifold volume, thereby creating pressure pulses to simulate a human subject. A seal around the piston is maintained by a rolling diaphragm seal. The size and shape of the pulses are controlled by the microprocessor driving the step motor. The home position of the piston is detected by an optical interrupter. If the optional high-accuracy pressure sensor is installed, it also measures the pressure in the main manifold and is also controlled by the microprocessor.

Connect the NIBP Monitor to the ***pressure port*** on the *BP Pump 2* once it is set up.

Fig. 6-1, Pneumatic Diagram

2. Diagrams of the Device Under Test

Figures 6-2 through *6-6* show the basic configurations for NIBP monitors.

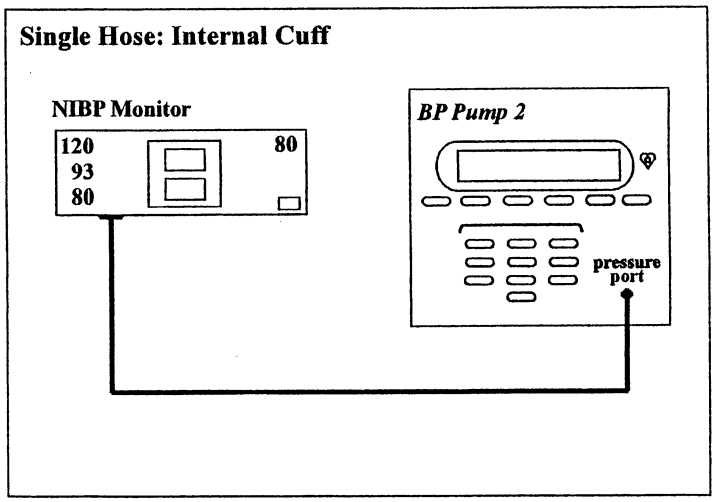


Figure 6-2. *Connecting the BP Pump 2 to a single-hose NIBP monitor (internal cuff)*

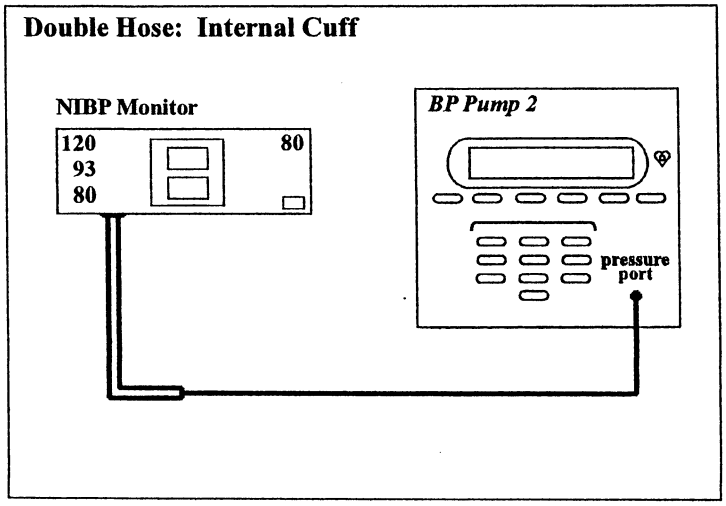


Figure 6-3. *Connecting the BP Pump 2 to a double-hose NIBP monitor (internal cuff)*

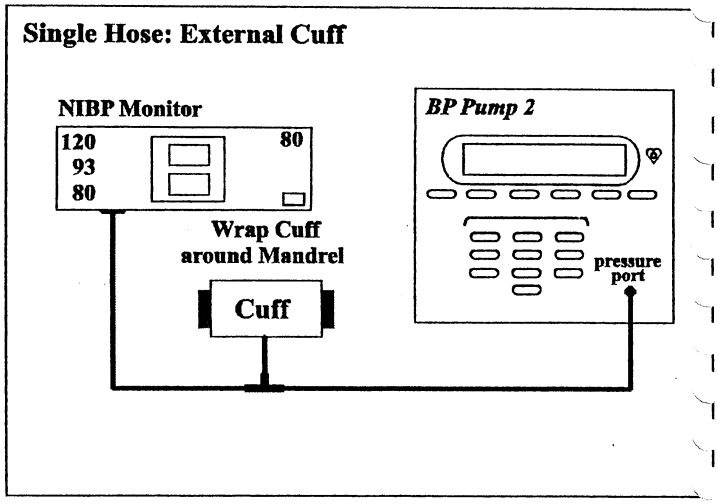


Figure 6-4. *Connecting the BP Pump 2 to a single-hose NIBP monitor (external cuff)*

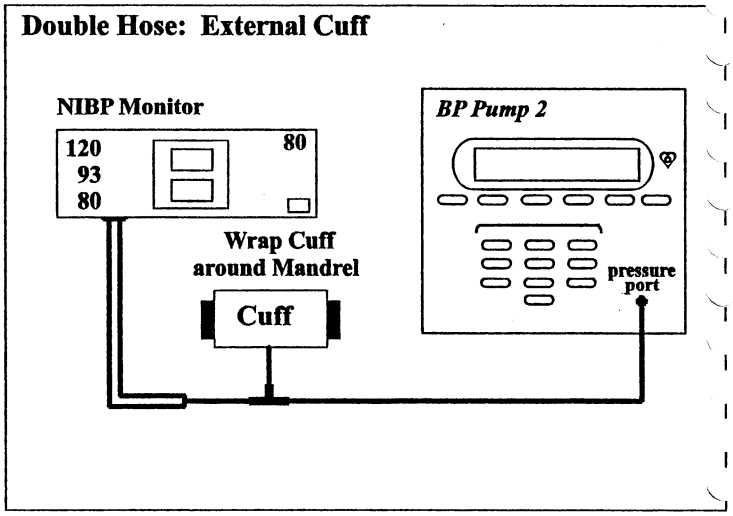


Figure 6-5. *Connecting the BP Pump 2 to a double-hose NIBP monitor (external cuff)*

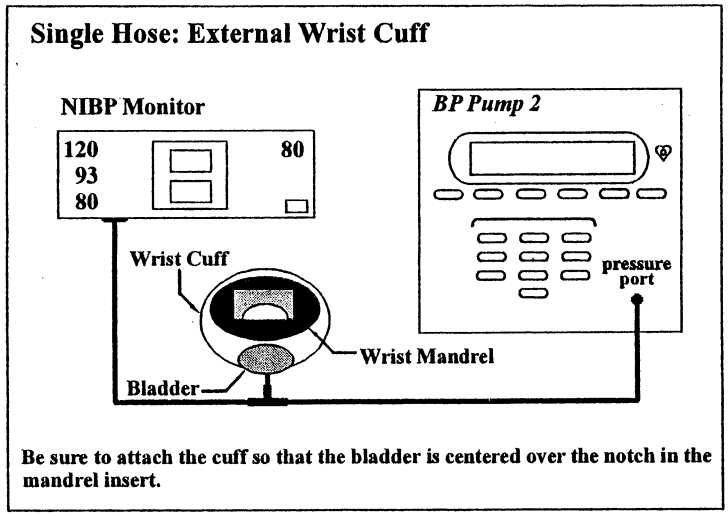


Figure 6-6. *Connecting the BP Pump 2 to a single-hose NIBP wrist monitor (external cuff)*

3. Conversion Factors

Conversion factors for the *BP Pump 2* are as follows:

Units	mmHg
PSI_PER_MMHG	0.019337
CMH2O_PER_MMHG	1.3595
INH2O_PER_MMHG	0.53525
KPA_PER_MMHG	0.13332

Computer Control Commands

Chapter 7

1. BP Pump 2 Computer Control Commands
2. RS-232 Settings

1. BP Pump 2 Computer Control Commands

The *BP Pump 2* acknowledges each valid computer control command that it receives. It responds to valid commands either with ACK (HEX 06), or ACK, followed by the data, followed by CR-LF (HEX 0D0A).

A NAK (HEX 15) is returned for invalid commands.

2. RS-232 Settings

The *BP Pump 2* serial port parameters are fixed at the following settings:

Baud Rate:	9600
Parity:	None
Data Bits:	8
Stop Bit:	1

BP Pump 2 Computer Control Commands

Description	Command	Returned String
Internal Adult Cuff	[CUFF_IA]	ACK
Internal Neonate Cuff	[CUFF_IN]	ACK
External Cuff	[CUFF_EXT]	ACK
Wrist Cuff Simulation	[SIM_WC120_80]	ACK
	[SIM_WC160_100]	ACK
	[SIM_WC80_55]	ACK
Neonate Cuff Simulation	[SIM_NEO20_10]	ACK
	[SIM_NEO35_15]	ACK
	[SIM_NEO60_30]	ACK
	[SIM_NEO70_50]	ACK
Standard BP Simulation	[SIM_STD120_80]	ACK
	[SIM_STD150_100]	ACK
	[SIM_STD200_150]	ACK
	[SIM_STD255_195]	ACK
	[SIM_STD60_30]	ACK
	[SIM_STD80_50]	ACK
	[SIM_STD100_65]	ACK
Patient Conditions	[SIM_HEALTHY]	ACK
	[SIM_WEAK_PULSE]	ACK
	[SIM_MILDEX]	ACK
	[SIM_STRENEX]	ACK
	[SIM_OBESE]	ACK
	[SIM_GERIATRIC]	ACK
	[SIM_TACHYCARDIA]	ACK
	[SIM_BRADYCARDIA]	ACK

BP Pump 2 Computer Control Commands (Cont.)

Description	Command	Returned String
Arrhythmias	[SIM_PAC1]	ACK
	[SIM_PAC2]	ACK
	[SIM_PVC]	ACK
	[SIM_AFIBPVC]	ACK
Respiratory Artifacts	[SIM_SB1]	ACK
	[SIM_SB2]	ACK
	[SIM_SB3]	ACK
	[SIM_CV]	ACK
Set Units of Blood Pressure	[BP_UNITS_KPA]	ACK
	[BP_UNITS_MMHG]	ACK
Set Units of Pressure	[PRESS_UNITS_KPA]	ACK
	[PRESS_UNITS_MMHG]	ACK
	[PRESS_UNITS_CMH2O]	ACK
	[PRESS_UNITS_INH2O]	ACK
	[PRESS_UNITS_PSI]	ACK
Perform Leak Test at XXXmmHg	[LEAK,XXX] 50<=XXX<=400	Returns ACK then Leak Rate. Returns Leak Rate after 60 seconds, followed by CR-LF, or NAK if XXX out of range
Perform Pressure Source at XXXmmHg	[PSOURCE,XXX] 50<=XXX<=400	ACK or NAK if XXX out of range

BP Pump 2 Computer Control Commands (Cont.)

[BLEED_SYSTEM]	ACK	
Performs Relief Valve Test	[RELIEF,XXX] 50<=XXX<=400	Returns ACK then Peak Pressure, followed by CR-LF, or NAK if XXX out of range
Pressure Gauge	[GAUGE]	Returns ACK then pressure port value, followed by CR-LF
	[BP_SERIAL]	Returns ACK then the serial number, followed by CR-LF
	[BP_VERSION]	ACK then 2780201 Ver X.XX, followed by CR-LF

Maintenance and Support

Chapter 8

1. Error Messages
2. Cleaning
3. Calibration
4. Service

1. Error Messages

Should you encounter any repeatable error messages, please contact your local service center.

2. Cleaning

The *BP Pump 2* requires little maintenance or special care; however, it is a calibrated measuring instrument and should be treated as such. Avoid dropping the instrument or other mechanical abuse that could cause a shift in the calibrated settings.

Clean the exterior of the analyzer occasionally with a damp cloth and a mild detergent. Take care to avoid the entrance of liquids into the pressure port.

Cables

Carefully wipe down the cables and inspect them for damage and deterioration of the insulation. Check the cable connections for integrity of the cable clamp and strain relief.

3. Calibration

Annual calibration of the *BP Pump 2* by an authorized Bio-Tek Service Center is recommended. Bio-Tek Service Centers have the appropriate tools and procedures for performing calibrations as well as factory-authorized updates.

4. Service

If your new *BP Pump 2* fails to operate successfully, please contact Bio-Tek's Technical Assistance Center immediately.

International customers should contact their Bio-Tek dealer for service/product support. To obtain the name of your local dealer or service center, call, send a fax, access Bio-Tek on the Internet, or send an e-mail message as follows:

Phone: (800)648-7952 (toll free in the U.S.) or (775)883-3400

Fax: (775)883-9541

Internet: www.flukebiomedical.com

E-mail: sales@flukebiomedical.com

If repairs are required, return the *BP Pump 2* to the factory or Service Center, packed in the original shipping container, using packing materials supplied by Bio-Tek.

Before returning the *BP Pump 2* for factory service, contact Bio-Tek's Technical Assistance Center for a required **Return Authorization Number**.

Whichever method of contact you choose, please provide the following information:

- The *BP Pump 2* serial number
- The specific steps that reproduce your problem
- A daytime phone number
- Your name/company
- A fax number (if available)

1. Pack the instrument carefully, using the original packing materials. If the original packing materials are not available, contact Bio-Tek for replacement packing. **Failure to pack the instrument properly could void your warranty.**

   Place the **Return Authorization Number** in a prominent place on the outside of the packing box, and refer to the number in any correspondence with Bio-Tek Service.

2. Enclose your return address and **Return Authorization Number**.

3. Insure the unit for full retail value and ship to:

   Bio-Tek Instruments
   Service Department
   2000 Arrowhead Dr.
   Carson City, NV. 89706

Specifications

Appendix A

1. **Environmental Conditions**
2. **Pressure Measurement**
3. **Pressure Generation**
4. **Electrical ECG**
5. **Heart Rate for NIBP Simulations**

Please contact your Bio-Tek Service representative for more information regarding the device specifications for the *BP Pump 2*.

1. Environmental Conditions

Operating Temperature:	15°C to 40°C
Storage Temperature:	-20°C to +65°C
Relative Humidity:	90% max

2. Pressure Measurement

Units:
- kPa
- mmHg
- cmH_2O
- inH_2O
- psi

Range: 0 mmHg to +400 mmHg

Resolution:
- 0.1 kPa
- 1 mmHg
- 1 cmH_2O
- 1 inH_2O
- 0.1 psi

Resolution: High-Accuracy Version:	• 0.01 kPa • 0.1 mmHg • 0.1 cmH_2O • 0.1 inH_2O • 0.01 psi
Accuracy: Standard Version:	
0 to 300 mmHg:	± 0.5% of reading ± 1 mmHg
301 to 400 mmHg:	± 2% of reading
High-Accuracy Version:	< 0.8 mmHg (0.1 kPa)

3. Pressure Generation

Pressure Generator, Static Pressure Range:	0 mmHg to +400 mmHg
Difference between target pressure and actual pressure:	± 10 mmHg from 100-400 mmHg with a minimum volume of 300 cc
Internal Leak Rate:	< 2 mmHg per minute, with a minimum volume of 300 cc

4. Electrical ECG

Signals:	RA, LA, RL, LL, V
Waveform:	Lead II
Amplitude:	1 mV peak (± 10%)
Connections:	Signals available via the optional ECG adapter

5. Heart Rate for NIBP Simulations

Heart Rate Accuracy:

With ECG disabled:	± 1 BPM
With ECG enabled:	± 1 BPM

Except for the following:

Patient Condition Weak Pulse, Tachycardia, Obese, Geriatric:	± 1% ± 1 BPM
Patient Condition Mild Exercise:	± 1.5% ± 1 BPM
Patient Condition Strenuous Exercise:	± 3% ± 1 BPM

ECG Option

Appendix B

1. Optional ECG Interface Adapter

1. Optional ECG Interface Adapter

The optional ECG Interface Adapter (Bio-Tek Part Number 2780512), shown in *Figure B-1*, is provided to aid the operator in testing those NIBP monitors that use ECG signals to assist in the detection of the pressure pulses. The ECG attachment is labeled with the five leads, RA, RL, LA, LL, and V, and is attached to the ECG Interface Port (*Figure 1-2*).

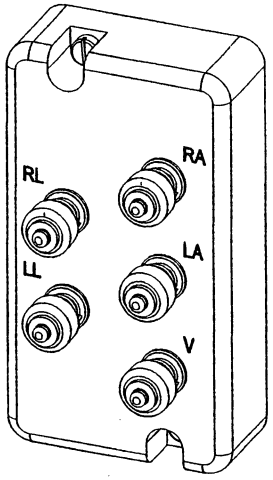


Figure B-1. *Optional ECG Interface Adapter*

Q&A

Appendix C

1. **Blood Pressure Issues**
2. **Cuff Issues**

1. Blood Pressure Issues

Q: Monitor's BP determinations vary.

"I connected the *BP Pump 2* to my Critikon DINAMAP monitor and used the preset blood pressure of 120/80 (93) with a pulse rate of 80 beats per minute. I performed three blood pressure determinations with the following results:

Trial #	Systolic	Mean	Diastolic	Pulse Rate
1	123	97	82	79
2	126	93	81	79
3	123	97	83	78

Why does the blood pressure determined by the DINAMAP vary?"

A: Some variance is normal and acceptable.

The *BP Pump 2* generates a very repeatable simulation. For this simulation, an ideal NIBP monitor would show a variation of less than 2 mmHg from one simulation to the next. Most of the variation seen here originates in the DINAMAP. This is normal and acceptable.

Section 3.4.3 of the ANSI Standard for Electronic or Automated Sphygmomanometers specifies the required efficacy of the Blood Pressure determination:

"The mean difference of the paired measurements of the test system and the comparison system shall be ± 5 mmHg or less with a standard deviation of 8 mmHg or less."

This means that variations in individual readings of 5, 6, or even 10 mmHg are quite normal and do not indicate that either the DINAMAP or the *BP Pump 2* are malfunctioning. Some monitors will be more repeatable than others, and repeatability is one measure of the overall quality of the monitor.

Q: BP results vary using the same Preset pressure.

"I checked another NIBP monitor using the same preset simulated blood pressure of 120/80 (93) with a pulse rate of 80 bpm. This time I got the following results:

Trial #	Systolic	Mean	Diastolic	Pulse Rate
1	120	89	71	80
2	120	87	73	80
3	121	91	72	80

Why does this monitor show such low Diastolic pressures?"

A: Monitors using different references – Ascultatory vs. Invasive data.

Neither the monitor or the *BP Pump 2* is broken or giving incorrect readings.

Some monitors were designed to give readings close to those obtained by the Ascultatory method of blood pressure determination. Other monitors have been designed to agree with Invasive blood pressure readings. It is well known that Invasive and Ascultatory BP readings on the same subject can be quite different. Therefore it is not surprising that automated Oscillometric NIBP monitors using Invasive readings as a reference would give different readings than a monitor based on Ascultatory readings.

2. Cuff Issues

Q: Why is an Internal Cuff used?

"Why does the *BP Pump 2* use an Internal Simulated Cuff ? Wouldn't it be better to include a real cuff in the measurement ?"

A: Internal Cuff produces accurate and repeatable simulations

The *BP Pump 2* uses an internal cuff to help ensure accurate and repeatable simulations over time. The internal "cuff" is a 310-ml fixed volume that has compliance very nearly equal to a normal adult cuff when used at typical adult mean pressures. Further, its compliance is constant over time and is independent of cuff wrapping technique.

The compliance of a standard cuff depends on the amount of air it contains. This, in turn, is dependent on what the cuff is wrapped around, and how tightly it is wrapped.

Q: Why Is compliance Important?

"Why is tightly controlled compliance so important?"

A: Air in the cuff affects Oscillations.

Blood pulsing through the arm surrounded by a cuff actually causes displacement of the air in the cuff. This must be converted into a pressure oscillation before the NIBP monitor can sense what is happening.

For a given volume displacement, the size of the pressure oscillation is inversely proportional to the volume of air in the cuff. Thus, a cuff full of of air will give a smaller pressure oscillation than one which is wrapped tightly around the arm and contains little air.

The *BP Pump 2* works just like the subject's arm. It creates a precisely controlled volume displacement. The cuff is what converts this displacement into a pressure oscillation.

By using an internal cuff of fixed volume, the *BP Pump 2* is assured of always producing the same pressure oscillation for each test.

Q. Can an External Cuff be used with the BP Pump 2?

"Can the *BP Pump 2* be used with an External Cuff?"

A. Connectors provided in Accessory Kit

The *BP Pump 2* can easily be configured to work with an External Cuff.

The available cuff options are accessible via the "cuff" soft key present during the NIBP simulations.

Note: The exceptions are neonate, which allows only the internal neonate cuff, and wrist cuff, which allows only the external cuff.

The external cuff is included in the pneumatic circuit using the "Tee" or "Y" connectors in the accessory kit.

BP Pump 2