



Operator / Service Manual

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are trademarked names protected by law.

This product is manufactured and sold under U.S. Patent No. D468,433; 6,636,754; D471,281; and Patent Pending.

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INTRODUCTION

NOTE:	Before using the BioZ Dx, carefully and completely read the instructions in this manual. If you do not understand the instructions or need additional information contact CardioDynamics International Corporation (CDIC) at the address listed on the cover of this manual.
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1 INTRODUCTION

The BioZ Dx (cardiograph) is an innovative noninvasive impedance cardiography (ICG) device that provides hemodynamic parameters based on the measurement of thoracic electrical bioimpedance. Specifically, the BioZ Dx allows for assessment of a patient's hemodynamic status and ventricular function by determining 24 hemodynamic parameters, some of which are indexed. In addition, the BioZ Dx allows the operator to:

- Observe trends in the patient's status
- Measure Blood Pressure with the integrated Blood Pressure monitor
- View, store, and review the collected data and/or waveforms
- Print reports of hemodynamic parameters with date and time annotations
- Download files to a PCMCIA Card
- Utilize security precautions – Password protection for system configuration
- Networking capabilities

1.1 Theoretical Concepts

Note: The initial use of thoracic electrical bioimpedance was supported by impedance cardiography and plethysmography assessments. Today, many terms are used interchangeably when discussing impedance cardiography: Thoracic electrical bioimpedance (TEB), thoracic electrical impedance, and electrical bioimpedance. In this manual, the term impedance cardiography or ICG will be used.

ICG is a technology that quantifies the mechanical activity of the heart (blood flow) as opposed to its electrical activity (ECG). The fundamental theoretical basis of ICG involves direct measurement of base impedance, velocity index, acceleration index, pre-ejection period, ventricular ejection time, and heart rate. These measurements are then used to calculate additional hemodynamic parameters.

The application of ICG to determine hemodynamic parameters is based on the following principles: Biological tissues, such as muscle, bone, fat and blood, all have different electrical properties. Of these tissues, blood is the most electrically conductive. Since arterial blood flow is pulsatile and arterial vessel walls are compliant, pulsatile changes in blood volume occur in the thoracic arterial system, predominantly in the aorta, as a result of ventricular function. This change in blood volume results in a change in the electrical conductivity and thus the impedance of the thorax to electrical current. Changes in the electrical impedance of the thorax are primarily due to changes in the velocity and volume of the blood in the aorta.

The BioZ Dx measures this change in impedance by injecting a high frequency (60 kHz Minimum), low amplitude (4.0 mA rms Maximum) alternating electrical current through the thorax between a pair

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of sensors placed on the neck and another pair placed on the mid-axillary line at the xiphoid process level. Use of a high frequency current eliminates the possibility of interference with bioelectrical activity of the heart and brain. Additionally, as the skin-to-sensor impedance is very low at high frequency, there are no thermal effects to tissue, thus no sensation to the patient.

By detecting and measuring the change in thoracic impedance as a function of time, the BioZ Dx is able to *non-invasively* calculate stroke volume, cardiac output and many other hemodynamic parameters.

2 WARNINGS AND PRECAUTIONS

2.1 General Warnings and Patient Safety Information

The BioZ Dx and the ICG Patient Interface Module (PIM) isolates all connections to the patient from electrical ground and all other conductive circuits in the Cardiograph and/or ICG PIM. This reduces the possibility of hazardous currents passing from the Cardiograph and ICG PIM through the patient's heart to ground. Observe the following to ensure patient and operator safety:



Symbol for “CAUTION, CONSULT ACCOMPANYING DOCUMENTS”

Symbol for “DEFIBRILLATOR-PROOF TYPE BF APPLIED PARTS”

- **TYPE BF is generally for devices that have conductive contact with the patient, or have applied parts that are fixed in medium or long-term contact with the patient, e.g. ICG electrodes.**
- **The use of equipment that applies high frequency voltages to the patient (including electrosurgical equipment and some respiration transducers) is not supported and may produce undesired results. Disconnect the ECG Patient Interface Module (PIM) data cable from the cardiograph, or detach the ECG leads from the patient prior to performing any procedure that uses high frequency surgical equipment.**
- **Do not perform ST analysis on the Real Time ECG screen display or on ECG Rhythm reports when the 0.5 Hz Baseline Wander filter is applied.**
- **If abnormal ECG data appears on the printed ECG report, and the abnormal data does not have a physiological origin, perform the printer diagnostic test to assess printer performance.**
- **When printing an ECG Rhythm report, there may be a slight delay before the Rhythm report begins to print on the cardiograph. Rhythm printing is not completed in real-time.**
- **Pace pulse tick marks will not print on an ECG Auto report that uses simultaneous acquisition.**
- **Periodically inspect the ECG PIM data cable, lead wires, and AC power cord for any worn or cracked insulation to ensure that no inner conductive material is exposed. Discard worn accessories and replace them only with CardioDynamics authorized accessories.**

- The ECG PIM data cable (supplied with cardiograph) is an integral part of the cardiograph safety features. Use of any other patient data cable not authorized by CardioDynamics may compromise defibrillation protection, degrade cardiograph performance, and may result in distorted ECG data.
- Ensure that the ECG electrodes or lead wires do not come in contact with any other conductive materials (including earth-grounded materials) especially when connecting or disconnecting ECG electrodes to or from a patient.
- Portable medical equipment such as X-rays and MRI may produce electromagnetic interference that produces noise in the ECG signal. Move the cardiograph away from these potential sources of electromagnetic interference.
- When using additional peripheral equipment powered from an electrical source other than the cardiograph, the combination is considered to be a medical system. It is the responsibility of the operator to comply with IEC 60601-1-1 and test the medical system according to the requirements.
- Do not use non-medical peripherals within 1.83 meters or 6 feet of a patient unless the non-medical peripherals receive power from the cardiograph or from an isolation transformer that meets medical safety standards.
- Only install CardioDynamics authorized software on the cardiograph. The installation or use of software not authorized by CardioDynamics is strictly prohibited and cardiograph safety and performance are not guaranteed.
- Only use CardioDynamics authorized replacement parts and supplies with the cardiograph. The use of non-approved replacement parts and supplies with the cardiograph is strictly prohibited. Cardiograph safety and performance are not guaranteed when non-approved replacement parts and supplies are used with the cardiograph.
- Manual measurements of the 12-Lead ECG intervals and magnitudes should be performed on printed ECG reports only. Do not make manual measurements of ECG intervals and magnitudes on the R/T ECG display since these ECG representations are scaled.
- There are no cardiograph parts that can be sterilized.
- The cardiograph is not intended for direct or invasive cardiac monitoring purposes.
- The physician should not base patient clinical assessments solely on the output of the BioZ Dx device.
- Excessive, repetitive use of the cardiograph keyboard and the cardiograph Trim Knob may result in a risk of developing carpal tunnel syndrome.

WARNINGS AND PRECAUTIONS

- **Ensure that the ICG and ECG patient data cables and lead wires are tucked away from the wheels of the cardiograph cart when transporting the cardiograph. Ensure that the patient data cables do not present a hazard when pushing the cardiograph cart.**
- **When operating the BioZ Dx on AC power, ensure that the BioZ Dx and all other electrical equipment connected to or near the patient are effectively grounded.**
- **Only qualified personnel may service the cardiograph.**
- **Do not touch the patient, patient cable, ICG PIM, or BioZ Dx during defibrillation. Death or injury may occur from the electrical shock delivered by the defibrillator.**
- **Ensure that the sensor gel, sensors or lead wires do not contact any other conductive materials (including earth-grounded materials) during patient monitoring and/or when connecting and disconnecting sensors/patient cable lead wires to and from the patient. Contact with any of these materials may result in incorrect parameter values.**
- **Connecting multiple cardiographs and/or other medical devices to the same patient may pose a safety hazard due to summation of leakage currents. Any potential combination of instruments should be evaluated by local safety personnel prior to being placed into service or applied to a patient.**
- **Do not connect any equipment to the BioZ Dx RS-232, USB, media, keyboard, and/or RJ-41 port(s) that do not meet medical safety requirements and that has not been evaluated by local safety personnel.**
- **Do not connect any equipment other than authorized by CDIC to the BioZ Dx RS-232, media, keyboard, and/or RJ-41 port(s) if a patient is connected to the BioZ Dx via the ICG PIM when properly connected to the USB port.**
- **Unauthorized equipment connected to the BioZ Dx RS-232, USB, media, keyboard, and/or RJ-41 port can cause ground leakage currents exceeding the maximum specified IEC 60601-1 safety standards.**
- **Do not connect any device to the RS-232 port on the rear of the cardiograph when the patient data cable is connected to a patient.**
- **As a Class II, Type BF device under the International Electrotechnical Commission (IEC), the BioZ Dx is not specifically intended to monitor variations in cardiac performance that could result in immediate danger to the patient.**
- **Caution: In the U.S., Federal law restricts this device to sale by or on the order of a physician.**
- **Explosive Hazard: Do not use in the presence of flammable anesthetics or gases.**
- **ICG Sensors are to be placed externally on the skin only and are not for direct cardiac application.**

- **DO NOT ALLOW** patients to wear ICG Sensors when undergoing Magnetic Resonance Imaging (MRI) due to risk of second and third degree burns.
- ICG Sensors are single time use devices and should be replaced after a maximum of 24 hours of use. While the patient contact materials have been fully evaluated to the guidelines of ISO-10993-1 (Biological Evaluation of Medical Devices) for biocompatibility, skin irritation may occur at the sites of sensor placement. If local skin irritation occurs beneath or around any of the sensor sites, discontinue product use and remove the sensors. Persistent use of the device in the presence of skin irritation may be harmful.
- For safe and proper operation this device is to be connected to a grounded receptacle via a grounded power cord (three-wire power cords with grounded plugs). Never adapt a grounded plug to fit an ungrounded outlet. If an ungrounded plug adapter is required, use the Equipotential Bonding Receptacle (per DIN 42801) to connect the BioZ Dx to the institution's equipotential system.
- The patient data cables and sensors specified and included with the BioZ Dx are designed specifically for protection against the effects of cardiac defibrillators and radio-surgery equipment. Do not use any other type of patient cable or sensors with this device.
- Disposal of this product and/or any of its accessories shall be in accordance with any and all local regulations.
- Do not allow fluid of any kind to penetrate the device enclosure or come into direct contact with any cables and/or power cord connectors. Contact with fluid may result in either incorrect parameter values or damage to the device or may result in injury to operator or patient.
- Always store patient cables and/or power cords properly to avoid potential injury due to tripping.
- Do not place additional equipment on BioZ Dx cart as it may increase the risk for tipping and potential injury if BioZ Dx strikes the user or patient.
- The BioZ Dx device applies low-level AC current to the thorax of a patient during a monitoring session. Implanted devices with electrical sensors (such as Minute Ventilation-based pacemakers) may detect the BioZ's current and exhibit erratic sensor operation. It is recommended that electrical sensors of implanted devices be disabled prior to starting a BioZ monitoring session.
- Keep the patient data cables away from power cords and any other electrical equipment.
- Warranty is made on original product purchase only and is not transferable.
- CDIC products are designed, tested and warranted as complete systems consisting of integrated hardware and consumables. As a result, CDIC cannot guarantee or warrant the accuracy or results of tests done with CDIC hardware products when third party consumables (such as sensors) are used to perform tests with such products.
- Any attempt to modify any CDIC product from its original condition as delivered to Buyer, or any use or integration with or into a CDIC product of parts or components not approved by CDIC will void the warranty for that product

WARNINGS AND PRECAUTIONS

2.2 Precautions

As with electronic equipment, **Radio Frequency** (RF) interference between the BioZ Dx and any existing RF transmitting or receiving equipment at the installation site, including electrosurgical equipment, should be evaluated carefully and any limitations noted before the equipment is placed in service.

Radio frequency generation from electrosurgical equipment at close proximity to transmitters may seriously degrade performance.

Like all electronic devices, this BioZ Dx is susceptible to electrostatic discharge (ESD). Electrostatic discharge typically occurs when electrostatic energy is transferred to the patient, the sensors, or the cardiograph. ESD may result in ECG and/or ICG artifact that may appear as narrow spikes on the BioZ Dx display and/or printed report. When ESD occurs, the BioZ Dx ECG and/or ICG interpretation may be inconsistent with the physician interpretation.

CardioDynamics assumes no liability for failures resulting from RF interference between the BioZ Dx and any radio frequency generating equipment.

Use of accessories other than those recommended by CardioDynamics may compromise product performance.

Impedance Cardiography (ICG) is a theoretical model of blood flow movement and is subject to inaccuracies in cases where the model does not fit a particular patient's clinical circumstances. Conditions that may limit the accuracy of the data and/or result in the inability to obtain hemodynamic measurements are listed below:

- Septic shock
- Left bundle branch block (LBBB)
- Atrial fibrillation (Afib)
- Wolff-Parkinson-White (WPW) Syndrome
- Sustained bigeminy
- Aortic valve regurgitation
- AV valve insufficiency
- Severe hypertension (MAP > 130 mmHg)
- Patient heights below 48" (120 cm) or above 90" (230 cm)
- Patient weights less than 67 lbs. (30 kg) or greater than 341 lbs. (155 kg)
- Patient Movement
- Aortic Balloon Pump

Observe the following considerations when using the BioZ Dx:

- During open chest surgery, the BioZ Dx may produce inaccurate values because of the change in the normal pattern of blood flow and/or the electrical current flow through the chest cavity. In addition, during post-operative recovery monitoring, patient shivering and motion may produce excessive artifacts that may affect the accuracy of the BioZ Dx.
- Do not pull on the paper when printing the report. This can cause the waveform to be distorted on the report and lead to misinterpretation by the clinician.
- Signal interference caused by other equipment may occur if cables and/or power cords of the BioZ Dx and other equipment cross over each other.
- The BioZ Dx should not be used concurrently on patients with Minute Ventilation pacemakers when the MV sensor function is activated.

2.3 Indications

- The BioZ Dx is designed for use with an adult in a supine position.
- The BioZ Dx and its components are not designed, sold, or intended for use except as described in this document.
- For hygienic purposes, single use patient sensors are specified when using this device.
- The device classification for BioZ Dx is Class II (US FDA), Class IIa (European Medical Device Directive), and Class II (Canadian Medical Device Regulations)
- The blood pressure cuff provided with the BioZ Dx is non-conductive thus assuring no risk of burning the patient during radio surgical procedures such as electrocautery.
- The patient cable circuitry affords a high degree of patient isolation from potential ground faults.

2.4 Contraindications

None known.

WARNINGS AND PRECAUTIONS

2.5 Safety Symbols Marked on the Cardiograph

Attention



See *BioZ Dx Instructions for Use*.

Mouse (Not Used)



The receptacle marked by this icon is not being used at this time.

USB Connector



The USB connection on the back of the cardiograph is used to connect to the PIM.

On/Standby



Pressing the button with this symbol turns on the cardiograph or puts the cardiograph into Standby (power saving mode).

Equipotential grounding post



Equipotential grounding post used for establishing common ground between instruments.

Fuse



Cardiograph contains a 1.5 amp (250V) time-delay fuse.

Input



The connector near this symbol receives an incoming signal.

GETTING STARTED

3 GETTING STARTED

Prior to monitoring a patient, it is recommended that the User become familiar with the BioZ Dx through the use of this Manual. Please pay close attention to all of the Warnings and Cautions included in this Manual. After review of this manual, the User should feel competent to begin a “live” monitoring session on a patient.

3.1 The BioZ Dx Impedance Cardiograph

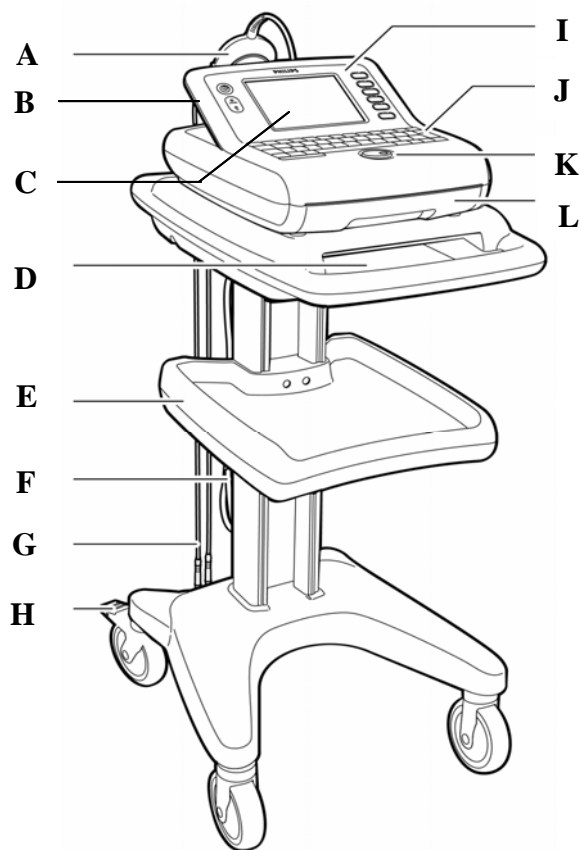


Figure 3-1 and Cart:

- | | |
|--|-------------------------------|
| A ICG Patient Cable Yoke | G ICG Lead Wires |
| B On/Standby button | H Wheel Brake |
| C Display | I Control Keys |
| D Printer Paper / Report Storage Slot | J Keyboard |
| E Storage Shelf | K Trim Knob |
| F ICG Patient Cable | L Printer Paper Drawer |

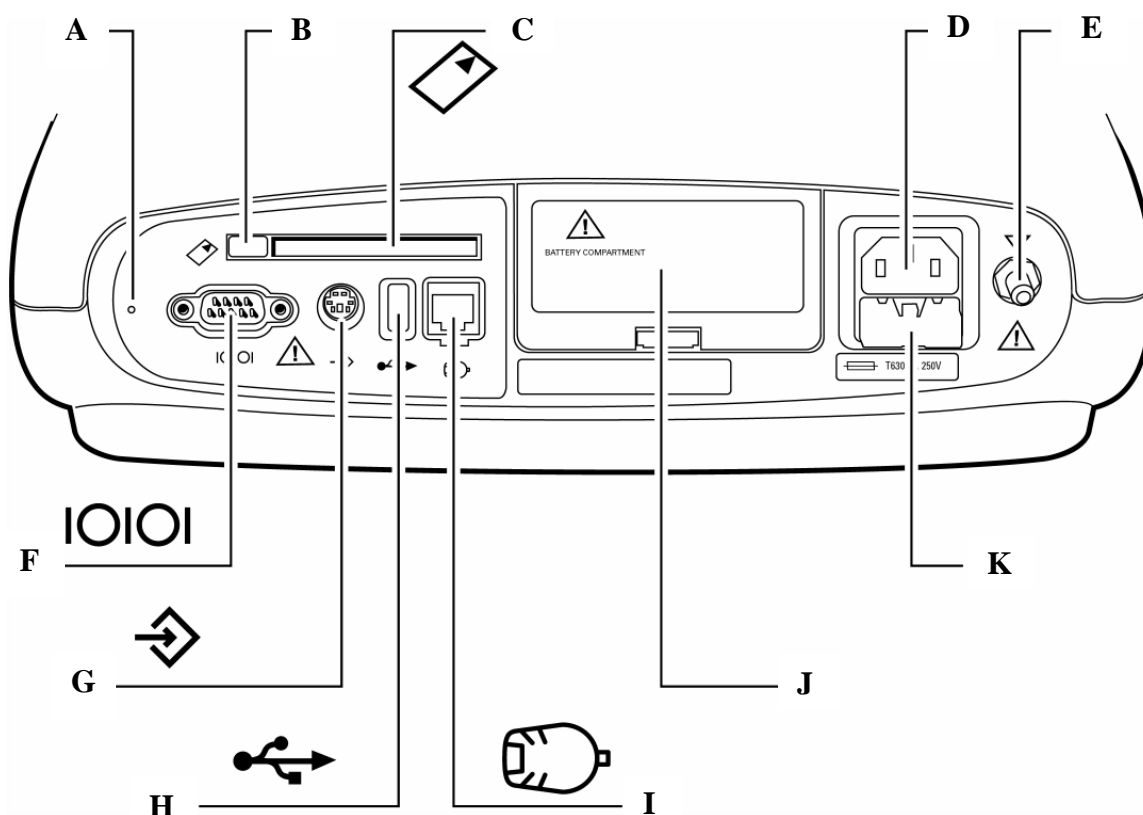


Figure 3-2 Rear Panel:

- | | |
|---|--|
| A Reset Button Pinhole | G Barcode Reader or Magnetic Card Reader Connector (ECG Application Only) |
| B PCMCIA Card Eject Button | H ICG PIM Connector (ICG Application)
SmartCard Reader (ECG Application) |
| C PCMCIA Card Slot | I ECG PIM Connector (ECG Application) |
| D AC Power Connector | J Battery Door |
| E Equipotential Ground Post | K Fuse Door |
| F Serial Connector (Not Supported) | |

GETTING STARTED

The BioZ Dx Control Keys

The Cardiograph has seven Control Keys located on the left and to the right of the display respectively.

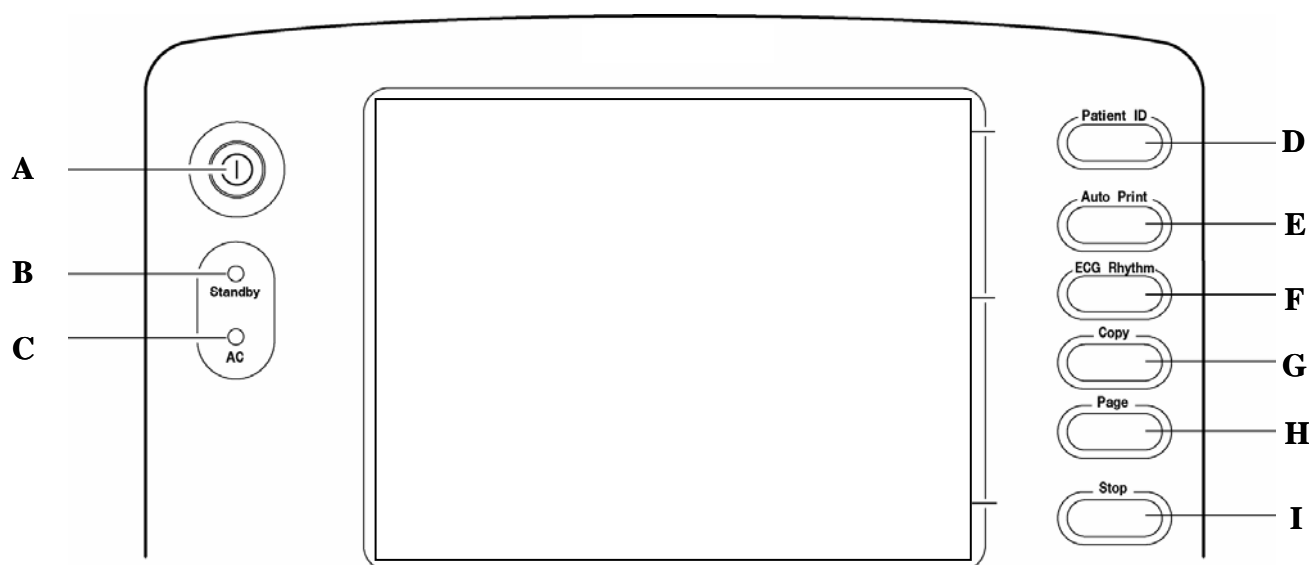


Figure 3-3 BioZ Dx Control Keys

A On / Standby: Turn ON/Off Cardiograph, or set to Standby

B Standby Indicator: When lit, the cardiograph is in Standby (power save) mode and the screen is black

C AC Power Indicator: When lit, the cardiograph is plugged into AC power

D Patient ID: Allows User to input, view, or edit patient information such as height, weight, DOB, etc. Also initiates a monitoring session.

E Auto Print: Print an ICG Report

F Rhythm: Not enabled on “ICG only” devices (See Philips Getting Started Guide, M4992-91120, for ECG application)

G Copy: Print a copy of the latest ICG report

H Page: Advance the paper to the beginning of the next page

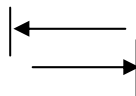
I Stop: Stop monitoring session

3.2 The BioZ Dx Keyboard

The Cardiograph keyboard is equipped with symbolically labeled keys.



SHIFT



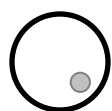
TAB: Moves cursor from field to field



ENTER: Exits a Screen and saves information



BACKSPACE / DELETE



TRIM KNOB: Rotating allows the User to navigate through various Dialog boxes, the Status and Command Bars. Pressing allows the User to accept entered information and advance to the next field and/or command as applicable.

3.3 Impedance Cardiography Patient Interface Module (ICG PIM)

- A** Noninvasive Blood Pressure (NIBP) module connector **C** System test lead wire connectors
- B** ICG Patient cable connector **D** ICG PIM data cable (connects to USB port on cardiograph)

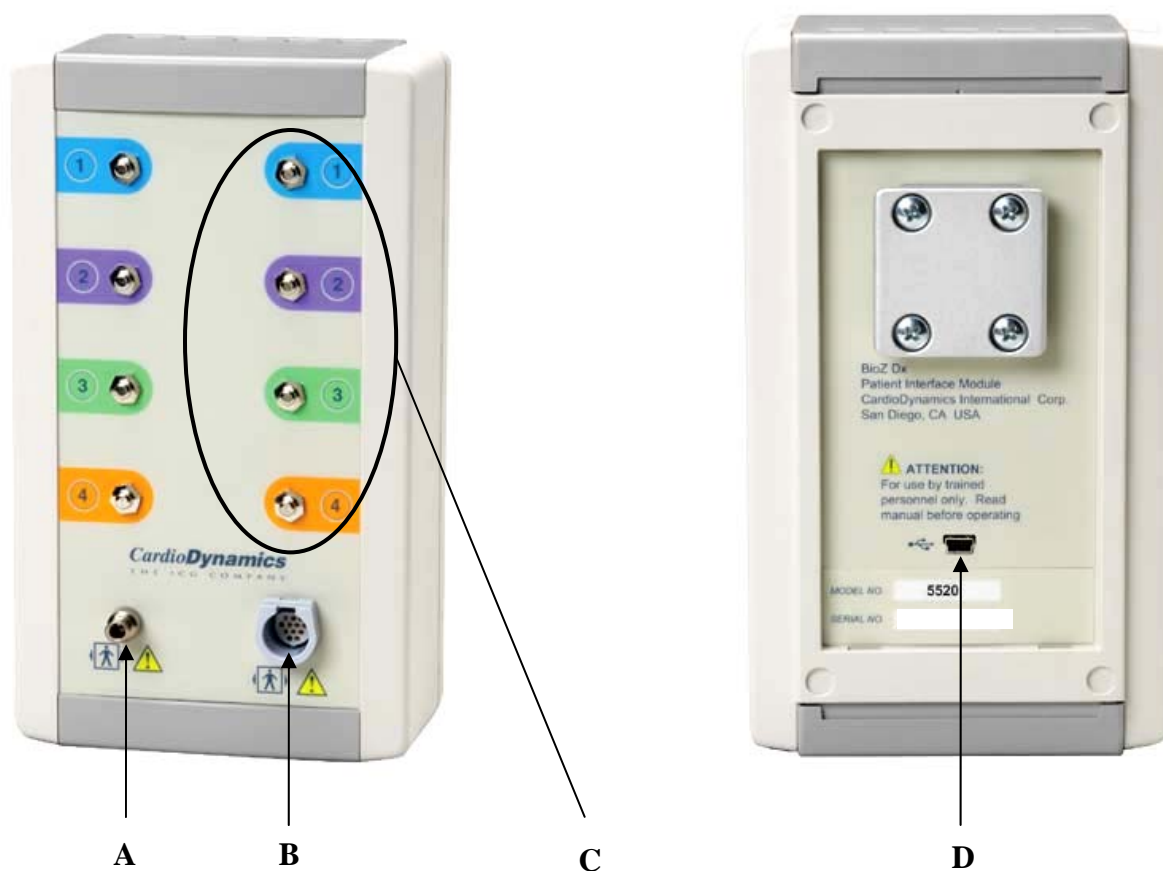


Figure 3-4 PIM Front and Rear

CAUTION:	To ensure safety and prevent damage to the system, connect the ICG PIM data cable ONLY to the USB port on the cardiograph.
-----------------	---

3.4 ICG Lead Wires



Figure 3-5 ICG Lead Wires

3.5 ICG PIM with Accessories



Figure 3-6 ICG PIM with accessories

NOTE:	The patient cable yoke and lead wires included with your unit may be different than those pictured above. Please consult the accompanying documentation or call CDIC Technical Support if you need further assistance.
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3.6 PCMCIA Card

The PCMCIA Card is an optional accessory available with the BioZ Dx. The PCMCIA Card contains a removable memory Card that can be used to transfer ICG Status Reports to and from the cardiograph.

A – PCMCIA Card Adapter

B – Removable Memory Card

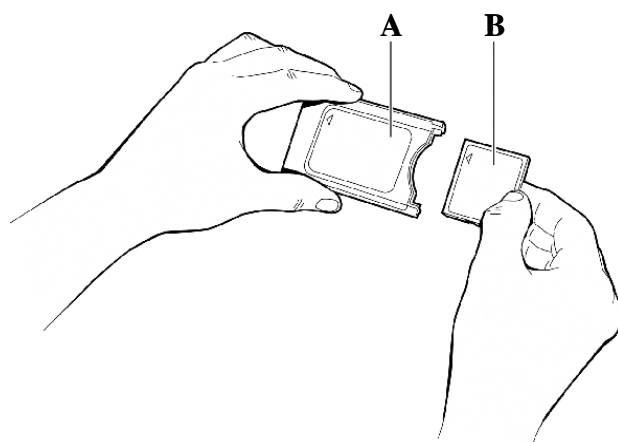


Figure 3-7 PCMCIA Card Assembly

To Insert or Remove a Card from the Cardiograph:

1. Insert the PCMCIA Card into the Card slot (rear of cardiograph) and firmly push it in.
2. Push the eject button to the left of the Card slot to eject the PCMCIA Card.
3. Pull out the Card.

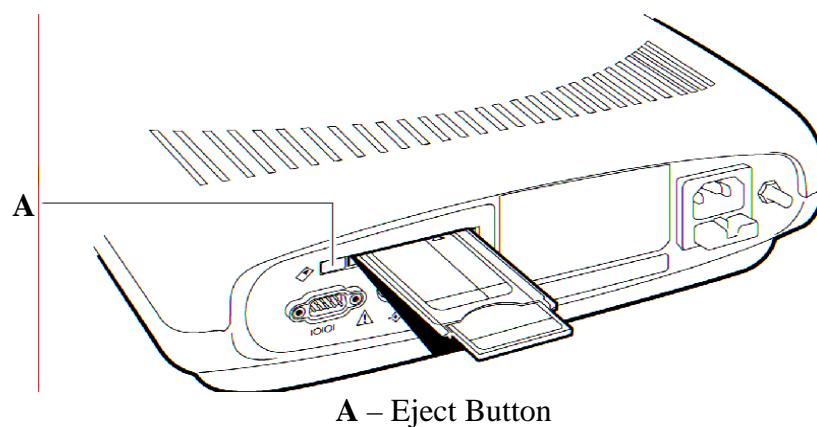


Figure 3-8 PCMCIA Card Eject Button

3.7 The BioZ Dx Display

The Cardiograph consists of a color display screen with four distinct areas:

A System Status Bar

C Waveform Area

B Patient Values

D Command Bar

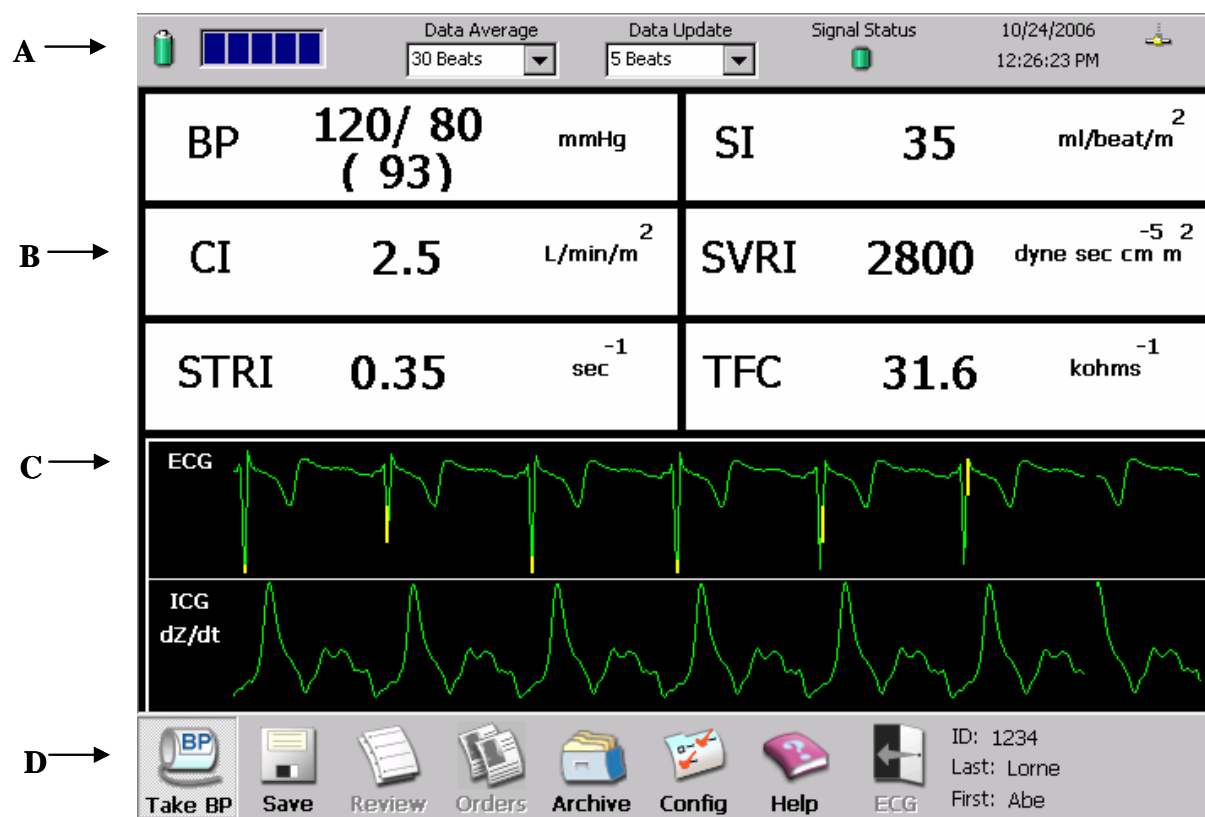


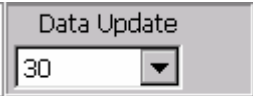
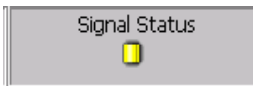
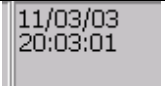



Figure 3-9 Monitoring Screen

GETTING STARTED

Status Bar

Button / Indicator	Description
	Battery Signal Status Indicator: Indicates Battery Level. Cycling progress Bar indicates Charging. Green battery icon indicates full charge.
	Data Average Indicator and Button: Provides Drop Down Menu to set, and indicator to display the number of beats to use when calculating Hemodynamic Patient values.
	Data Update Indicator and Button: Provides Drop Down Menu to set, and indicator to display the number of beats to use when updating the Hemodynamic Patient values on the screen
	<p>Signal Status Indicator: Green indicates that a sufficient number of acceptable ICG beats (5 out of 40) are present to display Hemodynamic values. Yellow indicates an insufficient number of acceptable ICG beats are available and Hemodynamic values are not calculated and/or updated.</p> <p>See Troubleshooting section for what to do when indicator is yellow.</p>
	System Date and Time: Displays current date and time. Date and Time may be formatted through the Config function.
	Network Status Indicator: Indicates when a network card is installed in the PCMCIA card slot in the back of the Cardiograph. Network functions may be accessed through the Config function.

Hemodynamic Values

The Main Screen displays up to six User Defined parameters at any given time. The User can define which parameters to display via the **Config** button on the Command Bar (See Section 7.1 Screen & Report Configuration Screen). During a Patient monitoring session, the User may also view the remaining Parameters via the **Review** button on the Command Bar.

The Hemodynamic Parameters are:

HR	Heart Rate	LCWI	Left Cardiac Work Index
SV	Stroke Volume	VI	Velocity Index
SI	Stroke Index	ACI	Acceleration Index
CO	Cardiac Output	STR	Systolic Time Ratio
CI	Cardiac Index	STRI	Systolic Time Ratio Index
SVR	Systemic Vascular Resistance	PEP	Pre Ejection Period
SVRI	Systemic Vascular Resistance Index	LVET	Left Ventricular Ejection Time
BP	Systolic (SBP), Diastolic (DBP) and Mean Arterial (MAP) Blood Pressure	TFC	Thoracic Fluid Content
TAC	Total Arterial Compliance	TFCI	Thoracic Fluid Content Index
TACI	Total Arterial Compliance Index	SSRI	Systemic Stroke Resistance Index
QC	Q-C Interval	LSWI	Left Stroke Work Index
HI	Heather Index	Z₀	Base Impedence

See Appendix A. HEMODYNAMIC PARAMETERS and Appendix B. GLOSSARY OF TERMS.





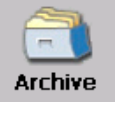

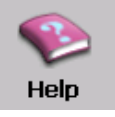
GETTING STARTED

Waveform Area

The BioZ Dx provides three waveforms of which two may be displayed at any given time. The User may select the waveforms for display via the **Config** button on the Command Bar.

Waveform	Description
ECG	<p>ECG: Displays the system selected optimum ECG vector. The ECG vector amplitude is auto scaled to fill the display and therefore may not be indicative of actual ECG amplitude and/or morphology.</p> <p>Note: The BioZ Dx ECG is <u>non-diagnostic</u> and is used only for the purpose of R and Q point detection. It is NOT intended to be used by the clinician to evaluate and/or make decisions regarding possible diagnosis, treatment, or causes for symptoms.</p> <p>Pacer Spikes are simulated and do not reflect actual and/or relative amplitude as related to the ECG signal. They are intended as a point of reference for timing purposes only.</p>
ICG	<p>ICG: Displays the inverted Delta Z waveform. The Delta Z waveform is the dynamic change of impedance due to pulsatile changes in thoracic blood volume that occurs with each heartbeat.</p>
dZ/dt	<p>dZ/dt: Displays the first derivative of the inverted Delta Z waveform.</p>

Command Bar

Button	Description
 Take BP	When button is pressed, the NIBP module inflates the cuff and takes a blood pressure measurement. De-selecting the button interrupts the blood pressure measurement and deflates the cuff.
 Save	When button is pressed, the current displayed patient data is saved in Archive as an ICG report. A Dialog box is displayed providing the User with the option of appending a label to the dataset.
 Review	When button is pressed, all of the datasets from the last twenty minutes of the current monitoring session are displayed. The User may then select any of the datasets to print and/or save to Archive. NOTE: Any datasets not Saved or Printed during the session will be lost once the Patient ID button is pressed or the power is turned off.
 Orders	When button is pressed, displays any orders that have been entered into the system. User may Add, Edit or Delete any order.
 Archive	When button is pressed, all of the Config Screen is displayed. The User may then print, delete, send to a PCMCIA Card, or load patient records into the memory of the cardiograph.
 Config	When button is pressed, the Config Screen is displayed.
 Help	When button is pressed, a Screen listing the basic steps required to perform an ICG test is displayed.
ID: Name:	When button is pressed, the cardiograph exits from the ICG monitoring mode and enters the ECG monitoring mode. For additional information on the ECG application refers to section 4 OPTIONAL ECG FEATURE. NOTE: The cardiograph cannot perform both ICG and ECG monitoring simultaneously. See Philips Getting Started Guide, M4992-91120, and ECG Learning Kit, M4992-91905, for ECG application instructions.
ID: Last: First:	Displays the current patient ID, Last, and First name.

GETTING STARTED

Navigation

Inactive toolbar buttons will all make the inactive beep when the user presses the **Trim Knob**.

Arrow Keys

The arrow keys will act like the default Windows action of the **Tab** and **Shift-Tab** key presses when navigating GUI items. In other words the **Down** arrow and the **Right** arrow acts as the **Tab** key press does and the **Up** arrow and the **Left** arrow acts as the **Shift-Tab** key press does.

Exceptions

If a drop list is expanded, the arrow keys will retain their default Windows actions. Also, if the cursor is in an edit field, the **Left** and **Right** arrows will retain their default Windows actions as well.

Radio Buttons

The **Arrow** keys, the **Trim Knob** and **Tab** and **Shift-Tab** key presses will cycle focus through all **Radio** button items instead of the normal Windows action (for **Tab** and **Shift-Tab**) of cycling focus through only one **Radio** button in a group. Arrowing, trimming or tabbing through a **Radio** button will not select the **Radio** button, only give it focus.

Radio buttons can only be selected by the **space bar** or **Trim Knob** press.

4 OPTIONAL ECG FEATURE

4.1 Intended Use

The intended use of the ECG Patient Interface Module (PIM) is to acquire multi-channel ECG signals from adult and pediatric patients from body surface ECG electrodes and to record, display, analyze, and store these ECG signals for review by the user. The cardiograph is to be used in healthcare facilities by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations, and interpretations for review by the user.

The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to review and validate (or change) the computer-generated ECG interpretation.

4.2 Indications

The ECG is to be used where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment, or to rule out causes for symptoms.

4.3 ICG / ECG Launch Screen

For Devices configured to run the optional Philips PageWriter Trim III ECG application the following Launch Screen will appear at system boot-up(Figure 4-1).

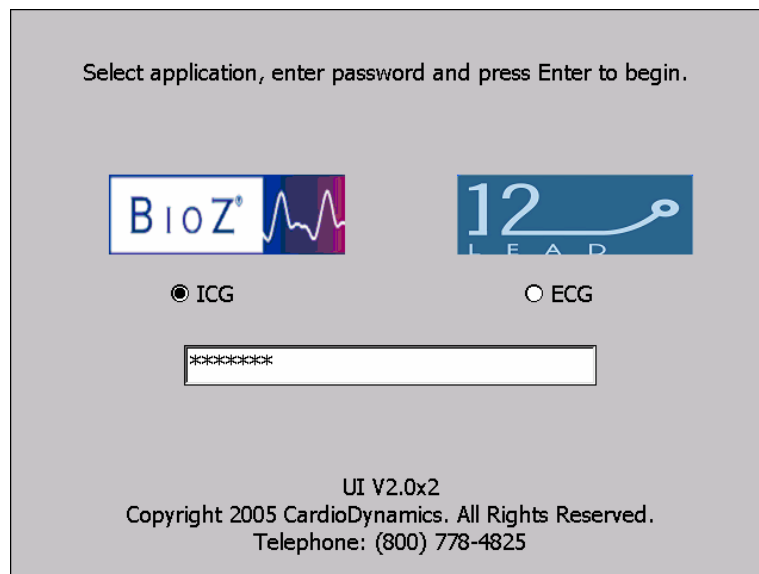


Figure 4-1 ICG / ECG Launch Screen

Select the desired application, enter password and press the Enter key to continue.

This manual provides information for the ICG application only, for information regarding the ECG application refer to the User documentation provided with the Philips PageWriter Trim III ECG system.

NOTE:	The cardiograph cannot perform both ICG and ECG monitoring simultaneously. Cardiographs configured to run both ICG and ECG also contain an additional command enabling the User to exit to ICG when operating the ECG application. (Figure 4-2 ICG Launch Icon)
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Figure 4-2 ICG Launch Icon

OPTIONAL ECG FEATURE

For systems that are configured for ICG only, the Launch Screen will only display the ICG application..

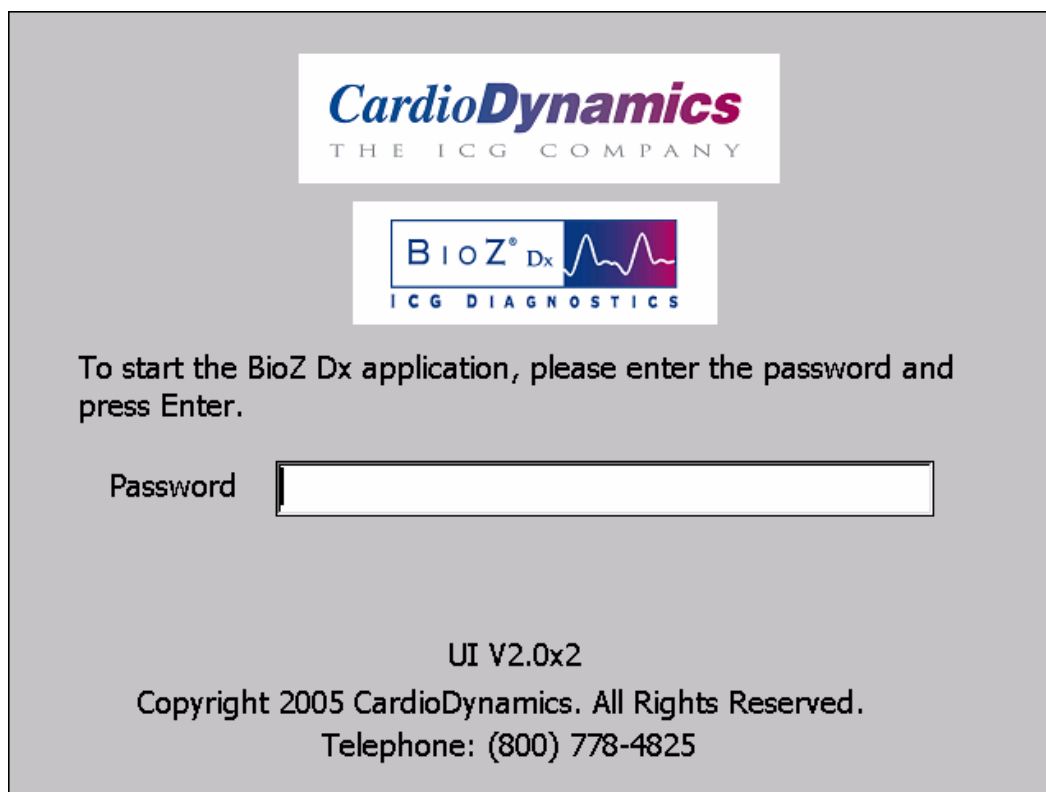


Figure 4-3 ICG Launch Screen

To start the BioZ Dx application, enter the password and press the Enter Key

5 PATIENT MONITORING

A patient monitoring session is initiated from the Main Screen. The ‘**Patient ID**’ Control Key, located on the front panel, is used to begin a “live” monitoring session.

The following sections will explain the steps necessary to monitor a patient.

5.1 Patient Preparation

Instructing the Patient

The first step in beginning a monitoring session is to explain the test to the patient. It is important that the patient is calm and in a relaxed state.

- Reassure the patient that the test is painless
- Ensure that the patient is comfortable and in a supine position

NOTE:	Hemodynamic normal ranges are established for a patient in the supine position only. Mean Arterial Pressure (MAP) related parameters are based on the assumption that MAP is constant throughout the arterial system. Due to gravitational forces this assumption is only valid when the arterial system is at the same level, i.e., when a patient is supine. Therefore the MAP, and MAP related parameters for SVR/SVRI/SSRI/TAC/TACI/LSWI and LCWI are invalid when the patient is not in the supine position.
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Once the Sensors, Cable and Blood Pressure cuff have been properly applied to the patient, instruct the patient to:

- Not move or talk
- Breathe normally
- Relax all muscles

ICG Sensors

To obtain accurate results with the BioZ Dx it is important to:

- Properly prepare the skin
- Use high quality ICG sensors with low skin-to-electrode impedance
- Ensure proper spacing between transmitting and receiving sensors
- Ensure good adhesive properties
- Only use sensors that have been recently removed from the sealed package. Sensors are single use disposable items. Check the package expiration date before use.

The ICG sensors distributed by CardioDynamics meet these requirements.

NOTE:	The algorithm used to determine the stroke volume by Impedance Cardiography is dependent on proper skin preparation, the ICG Sensor conductive gel/electrode type, spatial relationship between snaps, and site placement on the patient. Use of non-CardioDynamics' approved ICG sensors will affect the ability of the BioZ Dx to determine the patient's hemodynamic parameters.
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Skin Preparation

Proper skin preparation is very important in order to prevent artifact and obtain a strong ICG signal.

- Shave the hair over the sensor sites if necessary.
- Wash thoroughly with soap & water
- 'Dry prep' the sensor sites by mildly abrading the skin.

ICG Sensor Application

- Check the expiration date on the sealed pouch prior to opening. Open the sealed pouch and remove the four dual sensors.
- Prep the skin as listed above.
- Remove the four dual sensors from the backing material and apply each sensor, adhesive side down, to the proper sites as indicated on the diagram (Figure 5-1) and the package label. The wide rectangular shaped end with the heart label should be positioned closest to the heart. For the neck use the root of the neck as a reference for vertically locating the rectangular shaped, heart labeled detecting sensor with the corresponding circular shaped transmitting sensor being positioned directly superior and inline with the ear lobe. For the thorax use the xiphoid process as a reference for vertically locating the rectangular shaped, heart labeled detecting sensor with the corresponding circular shaped transmitting sensor being positioned directly inferior and along the mid-axillary line.
- Connect the right and left (**with respect to the patient's right and left**) lead wires (as indicated on the patient cable yoke and individual lead wire connectors) to their respective dual sensor sites.

The lead wires must be attached as follows:

- Blue left and right lead wire connectors (labeled as a **1** inside a circle) to the respective circular shaped transmitting sensors on the neck.
- Purple left and right lead wire connectors (labeled as a **2** inside a heart) to the respective rectangular shaped detecting sensors on the neck.
- Green left and right lead wire connectors (labeled as a **3** inside a heart) to the respective rectangular shaped detecting sensors on the thorax.

PATIENT MONITORING

- Orange left and right lead wire connectors (labeled as a 4 inside a circle) to the respective circular shaped transmitting sensors on the thorax.

NOTE:	Placing the ICG Sensors incorrectly will adversely affect the ability of the BioZ Dx to measure and process the bioimpedance signal, which can lead to inaccuracies in the hemodynamic parameters!
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- Both the neck and thorax ICG sensors must be positioned so that they are 180 degrees opposite each other. Should the patient have an invasive line, chest tube, etc. at the recommended locations, the ICG sensors may be rotated slightly as long as they remain 180 degrees opposite of each other.

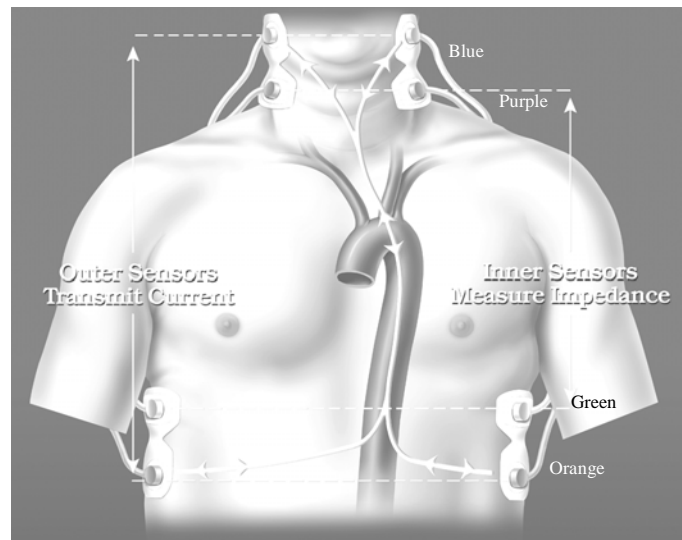
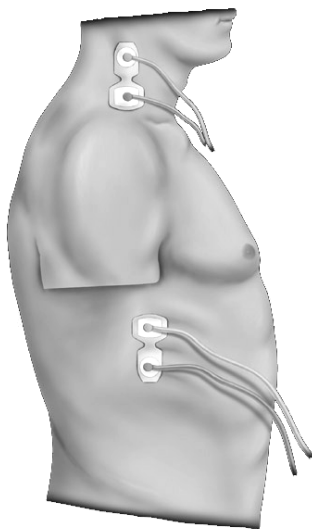


Figure 5-1 ICG Sensor Placement Diagram

5.2 Apply the Blood Pressure Cuff

The BioZ Dx NIBP module utilizes the oscillometric method in determining blood pressure values. The oscillometric method measures the pressure pulse within the cuff in incremental steps. This pressure pulse has a maximum value of approximately 1 mmHg that occurs at the MAP. A sophisticated algorithm is then applied to plot the oscillometric envelope of pulse pressure measurements vs. cuff pressure measurements. The cuff pressure at which the peak pressure pulse occurs is the MAP. The diastolic and systolic values are determined by the shape of the oscillometric envelope.

The shape of an actual patient oscillometric envelope varies from measurement-to-measurement and from individual-to-individual. Therefore it is quite possible to have different systolic and diastolic pressures for the same measured MAP as well as different MAPs for the same systolic and diastolic pressures.

To Use the NIBP Cuff:

- Wrap the cuff around the patient's upper arm (observe the precautions listed below). Ensure that the cuff is positioned so that the arrow aligns with the patient's Brachial artery.
- Connect the inflation tube to the NIBP Port on the front panel of the ICG PIM.

Once the monitoring session begins, the Cardiograph will automatically operate the blood pressure cuff to obtain the measurement.

In order to obtain an accurate blood pressure measurement and to ensure the safety of the patient it is essential that the following precautions be observed:

- **Use only the blood pressure cuff provided with the device.**
- **Use the proper size cuff for the patient's arm.**
- **Ensure that the cuff is evenly and snugly wrapped around the patient's arm.**
- **Ensure that the bladder within the cuff is not folded.**
- **Ensure that all connections are tight so as to prevent leakage.**
- **While making blood pressure measurements be sure to avoid any compression or restriction of the pressure tube leading to the cuff.**
- **The operator is advised to observe directly that inflation of the cuff does not result in prolonged impairment to the patient's circulation.**
- **The patient's arm should remain relaxed and still while the blood pressure cuff is inflating and deflating.**

PATIENT MONITORING

To Enter a Manual Blood Pressure

When **‘Manual Entry’** is the source for entering the systolic blood pressure (SBP) and diastolic blood pressure (DBP) the Cardiograph will estimate the mean arterial pressure (MAP) using the following equation:

$$\text{MAP} = \text{DBP} + (\text{SBP} - \text{DBP}) / 3$$

Note: SBP and DBP may be obtained by any method available to the clinician. For example, the auscultatory method via a sphygmomanometer may be used to obtain the SBP and DBP and then manually entered into the respective fields on the Patient ID screen.

5.3 Begin the Patient Monitoring Session

After the Lead Wires, Sensors and Blood Pressure Cuff have been properly connected to the patient, there is required demographic information that must be entered into the ICG BioZ Dx in order to begin the ICG test. There are two methods for entering this data: Enter new patient data or retrieve previously archived patient data.

New Patient Data (When performing an ICG test the first time)

To begin, Press the **Patient ID** Control Key. The Patient ID Screen will be displayed.

The screenshot displays the 'Patient ID' screen of the ICG BioZ Dx device. At the top, there is a status bar with a battery icon, 'Data Average' (30 Beats), 'Data Update' (5 Beats), 'Signal Status' (yellow light), and the date/time '10/24/2006 12:32:55 PM'. Below this is a blue header bar labeled 'Patient ID'. The main area contains several input fields: 'Patient ID(P)' with a tab for 'Retrieve Records(R)' and 'Orders(O)'; 'Patient ID' (1234), 'Last Name' (FIELDS), 'First Name' (DEBBY), and 'Add'l Name' (empty). 'Date Of Birth' is split into 'Month' (07), 'Day' (08), and 'Year' (1967) with a '(YYYY)' label. 'Height' has fields for feet and inches, and 'Weight' has a field for pounds. There are three sections: 'Gender' with radio buttons for 'Male' and 'Female' (Female is selected); 'BP Method' with radio buttons for 'Manual Entry' and 'Auto BP Cuff' (Auto BP Cuff is selected); and 'Blood Pressure' with 'SBP' and 'DBP' fields. At the bottom are 'Physician' (DR. SMITH) and 'Operator' (empty) dropdown menus. A bottom toolbar contains icons for 'Take BP', 'Save', 'Review', 'Orders' (highlighted), 'Archive', 'Config', 'Help', and 'ECG'. On the right side of the toolbar, there are labels for 'ID:', 'Last:', and 'First:'.

Figure 5-2 Patient ID Screen

Patient ID Screen

All required patient information must be entered by the User via the Patient ID screen if monitoring a patient for the first time

To navigate through the Patient ID screen, rotate the trim knob or press the **Tab** key to move the cursor to the desired entry field. Use the keyboard to enter information. If an incorrect entry is made, press the **Backspace** key and re-enter the correct value. Press down on the **Trim knob** to make a selection within a Radio Button Field, for example, to select Male or Female. Press **Enter** when all selections

PATIENT MONITORING

are complete. Pressing **Esc** will cause the ID screen to be closed and none of the entered data will be retained.

NOTE:	It is important to enter accurate height and weight in order to obtain accurate hemodynamic information. Be sure to take these measurements prior to beginning the ICG test.
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Field	Required	Description/ Size:
Patient ID	Yes*	All Characters Except for space / 40 Characters.
Last Name	Yes*	All Characters / 40 Characters.
First Name	Yes*	All Characters / 40 Characters.
Add'l Name	No	All Characters / 40 Characters
Date of Birth	Yes	Numeric. Month & Day: 2 Characters, Drop Down Menu. Year: 4 Characters, Text Box. (BioZ Dx system date must be set correctly in order to calculate patient's age correctly)
Height	Yes	Numeric. Feet: 1 Character. Inches: 2 Characters. Centimeters: 3 Characters. All Text Boxes.
Height Units	Yes	Alpha. Select English or Metric units.
Weight	Yes	Numeric. Pounds: 3 Characters. Kilograms: 5 Characters. Both Text Boxes.
Weight Units	Yes	Alpha. Select English or Metric units.
Gender	Yes	Radio Button. Select Male or Female
Blood Pressure	Yes	Radio Button. Manual or Auto BP Cuff. If Manual is selected then the User will input Numeric values up to 3 Characters in the SBP and DBP fields.
Physician	No	Alphanumeric. 32 Characters, Drop Down Menu.
Operator	No	Alphanumeric. 32 Characters, Drop Down Menu.

* Indicates either one or more of the following fields are required to begin an ICG test: Patient ID, Last Name, or First Name.

Should the operator enter data on the Patient ID Screen that is outside the **Operating Range** of the cardiograph, the value will be rejected. However, for values entered which are outside the **Recommended Range** that value may be accepted upon confirmation by the user.

Session Start-up Behavior

When a new patient session is started, updates will be displayed according to the selected **Data Update** rate. Until enough beats have been collected, data averaging will be based on the available beats. Once enough beats have been collected, data averaging will be based on the newest beats based on the selected **Data Average** period.

Re-Monitoring a Patient

If the patient has been monitored previously and their record was Archived, then the User may recall the previously stored Patient ID information via the Auto Patient ID

The user simply types the desired patient's ID into the Patient ID field, when the user moves the cursor out of the Pt ID field, the BioZ Dx will search its internal database for a patient with the same Pt ID.

If a patient is found, the BioZ Dx will automatically populate the Last Name, First Name, Add'l Name, Date of Birth, Height, Physician, and Operator fields with the data found in the most recent database record and the Weight field will be put into focus.

If the Pt ID field is blank or no match can be found, the fields will not be populated.

Additionally, the user may recall the previously stored Patient ID information via the Retrieve Records tab.

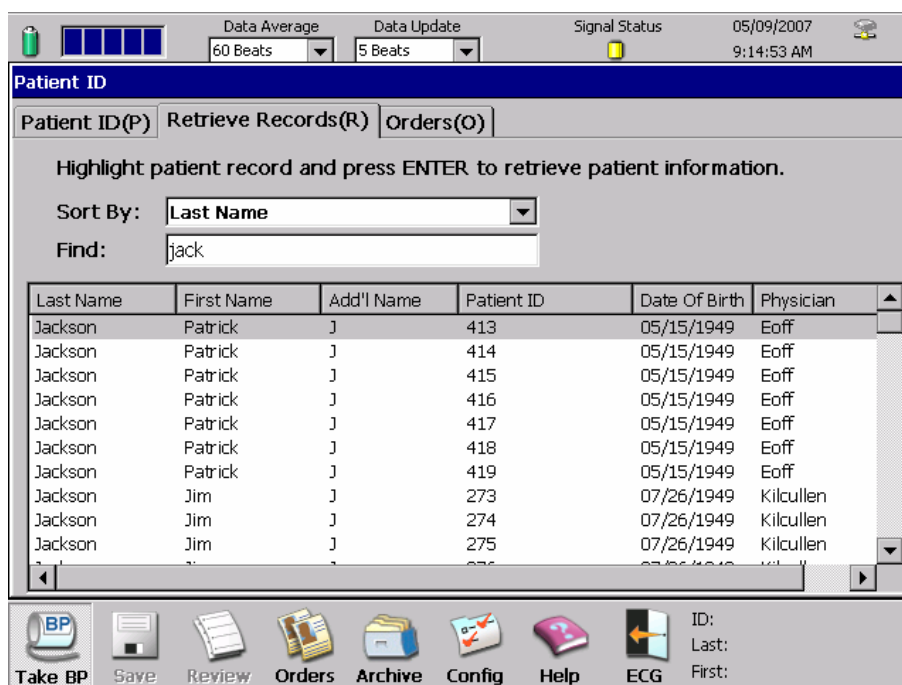


Figure 5-3 Retrieve Records Screen

PATIENT MONITORING

- Press **Alt & R** simultaneously to access the **Retrieve Records** Menu. The cursor will be placed in the **Sort By** field.
- Press the **Trim knob** to display the **Sort By** Drop Down Menu. Rotate **Trim Knob** or use the **Up/Down** Arrow keys to highlight the desired Sort by method. Press the **Trim knob** to Select desired **Sort By** method.
- Type in the Patient ID, Last Name or Date of Birth of the person to test. The Retrieve Records page shall dynamically search as characters are typed into the Find field when the selected Sort By is Last Name or Patient ID. The applicable Archived patient record will be displayed. If multiple records exist for the same Patient ID, Name, or DOB, the records will be sorted by the date and time of the archived patient record. Use the **Up/Down** arrows to scroll through the list and to highlight the desired patient record.
- Press the **Trim Knob** to retrieve the Patient ID information. The screen will revert to the Patient ID screen and all fields except weight and SBP/DBP will be filled in.
- Enter the current weight. Update the height if necessary. Select BP method and enter BP if necessary.
- After the required Patient ID fields have been entered, press the **Enter** key. The blood pressure cuff will inflate (if Auto BP is selected) and the Main Screen will be displayed.

The Cardiograph will automatically perform a **Leads Check** to determine patient cable and sensor integrity. Once proper lead connection has been established the system will begin “looking” for an ECG R wave. After the system has identified an ECG vector with acceptable R waves, it will evaluate the corresponding ICG beat. After a minimum number of ICG beats has been accepted (as determined by the **Data Average** setting) hemodynamic values will be displayed.

NOTE:	Please refer to the Troubleshooting Section of this manual if unable to obtain hemodynamic values.
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5.4 Saving Patient Information



Selecting the **Save** Command provides the User with the ability to save a patient ICG Report that may later be retrieved via the **Retrieve** Command. When the **Save** command is selected, a **Save** Dialog Box will be displayed. The User may then define a label to be appended to the data via an alphanumeric text entry up to 125 characters. Pressing **Enter** will then Save the ICG Report to the BioZ Dx Archive.

In addition to the **Save** Command, the **Print** Command also saves an ICG Report for later retrieval. Should the operator attempt to shut down the cardiograph or monitor the next patient without saving a status report, a message will automatically be displayed giving them the option to continue or to go back and save the status report.

NOTE:	Maximum storage capacity is 15,000 ICG Reports. The User should use the Archive function for instructions on deleting and transferring archived ICG Reports (see section 5.6 Archived Patient Information).
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Pressing **Esc** will return the User to the Main Screen.

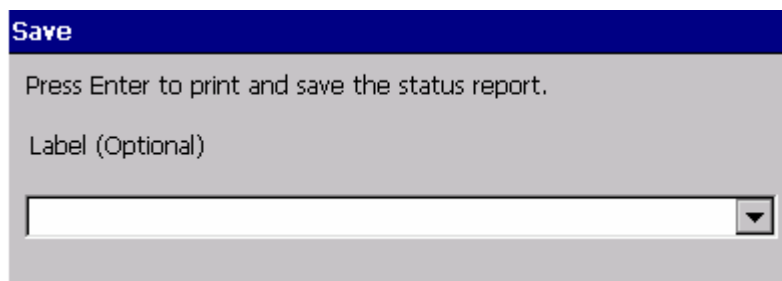


Figure 5-4 Save Dialog

5.5 Reviewing Patient Information



Selecting the **Review** Command provides the User with the ability to review all of the data sets that were displayed, saved and/or printed during the last 20 minutes of the most recent ICG session. The User may highlight a data set and then print and/or save to **Archive** should they desire. Press **Esc** to return to the ICG main screen.

The **Review** Command is active only after the **Stop Control Key** has been selected and the patient data will remain available only until the next time the Patient ID Screen is opened, or power is turned off.

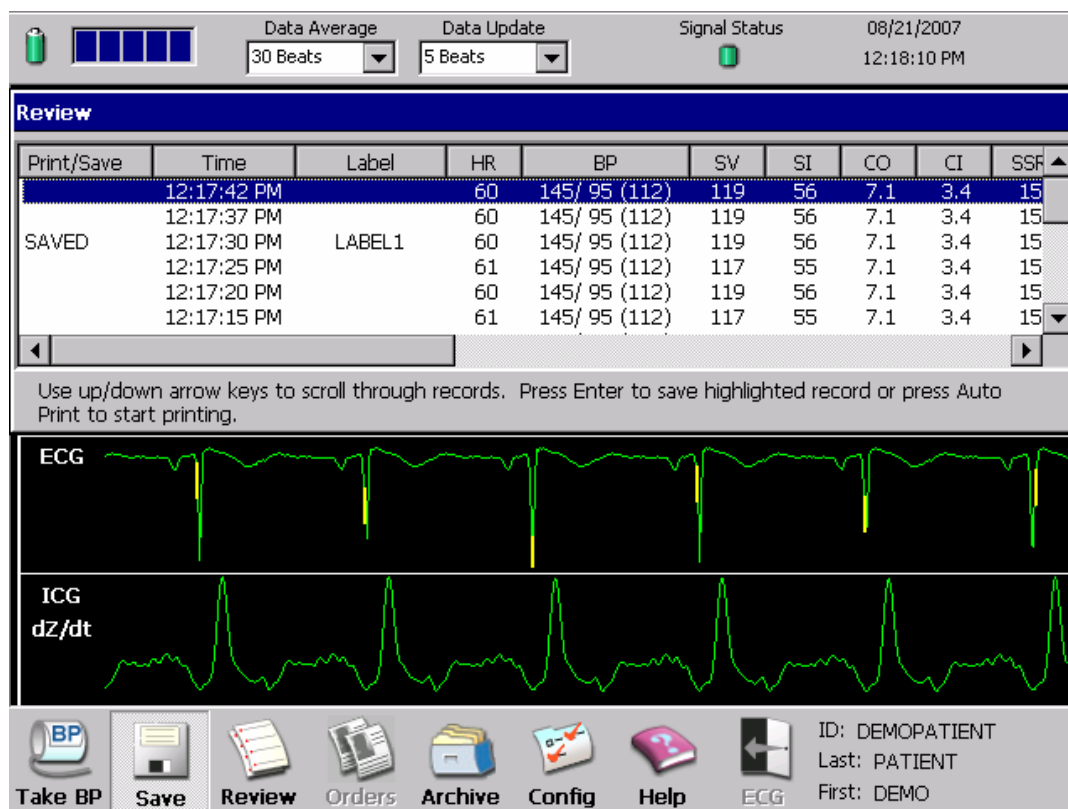


Figure 5-5 Review Screen

5.6 Archived Patient Information



Selecting the **Archive** Command provides the User with the ability to **Print**, **Delete**, or **Export** files from the ICG Cardiograph's database. The Archive is a database of all saved patient ICG Reports. The reports are sorted and retrievable by Date, Last Name, Patient ID, Date of Birth, or Physician.

Data Average: 30 Beats | Data Update: 5 Beats | Signal Status: | 08/21/2007 12:23:00 PM

Archive

Highlight saved ICG Status Report(s) to Print, Delete, Load, Send, or Export. Press spacebar to view.

Sort By: Last Name | Find:

Load | Select All
 Send | Delete
 Export | Auto Saves

Session Date	Session Time	Last Name	First Name	Add'l Name	Patient ID	Date Of
08/21/2007	12:17:30 PM	PATIENT	DEMO		DEMOPATIENT	01/29/:
08/17/2007	09:13:22 AM	PATIENT	DEMO		DEMOPATIENT	01/29/:
08/17/2007	09:13:07 AM	PATIENT	DEMO		DEMOPATIENT	01/29/:

Total Sessions: 19 | Total Sessions Last 30 days: 8

Take BP | Save | Review | Orders | Archive | Config | Help | ECG

ID: | Last: | First:

Figure 5-6 Archive Screen

PATIENT MONITORING

Total Number of Patient Sessions

The total cumulative number of patient monitoring sessions is displayed in the lower left of the Archive Screen. Additionally, the number of sessions performed within the last 30 days is also provided immediately to the right of the total sessions listing.

Sorting to Retrieve Patient ICG Reports

When the **Archive** Screen is displayed, the cursor will be in the **Sort By** field. Press down on the **Trim Knob** to display a list of sort methods - Last Name, Patient ID, DOB, Date and Physician. The sort method can be selected by rotating the **Trim Knob** or using the **Up/Down** Arrow keys. Once the desired sort method has been selected press down on the **Trim Knob** to accept it. Move the cursor to the **Find** field by rotating the **Trim Knob** and type in the appropriate information, i.e., Last Name, Patient ID, DOB, Date or Physician and move cursor to the table of reports. The closest matching record of the ICG Report will be highlighted. The archive dialog will dynamically search as characters are typed into the **Find** field when the selected Sort method is Last Name, Patient ID or Physician.

Selecting Multiple Records

Multiple records may be highlighted by holding down the **Ctrl** button, move to the next desired record using the **Up/Down** arrow keys, while still pressing the **Ctrl** button press the **Spacebar**.

Printing Archived ICG Reports

Once the desired ICG Report has been selected, press the **Auto Print** Control key to print the Archived ICG Report.

Deleting Archived ICG Reports

Once the desired ICG Report(s) have been selected, press the **Delete** button on the Archive Screen to delete the selected ICG Report(s).

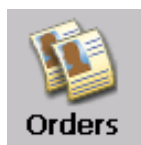
Transferring Archived ICG Reports

ICG Reports may be transferred to and from another ICG BioZ Dx via a PCMCIA Card.

- **Load** is used to transfer ICG Reports into the Cardiograph's ICG Patient database from the external PCMCIA media.
- **Send** is used to transfer ICG Reports from the Cardiograph's ICG Patient database and onto the external PCMCIA media.

NOTE:	Removing the PCMCIA Card while data transfer is in progress may corrupt the database. Contact Technical Support should you have questions on transferring archived ICG reports.
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5.7 Orders Entry



Selecting the **Orders** Command provides the User with the ability to schedule tests for specific patients for upcoming sessions.

The user may add up to **150** orders to the desired list.

The **Orders** page can be accessed by using the **Trim Knob** and navigating to the **Orders** icon and pressing down.

Once the **Orders** page has been selected, press **Alt & O** simultaneously to select the **Orders** tab and then navigate using the **Trim Knob** or the **Up/Down** Arrow keys to the desired field.

Patient ID

Patient ID(P) Retrieve Records(R) Orders(O)

Use up and down arrows to select an Orders entry. Press Enter to load order.

Patient ID	Last Name	First Name	Add'l Name	Gender	Physician
1234	FIELDS	DEBBY		Female	DR. SMITH
	KEIL	DAVID		Male	DR. PATTERS...
6757	ROLAND	AMY		Female	DR. JONES

Pending Orders List Loaded: 3
Available: 147 **Add** Edit Delete

Take BP Save Review **Orders** Archive Config Help ECG ID: Last: First:

Figure 5-7 Orders Entry

PATIENT MONITORING

The user may use the Trim Knob or the Up/Down Arrow keys to Add, Edit or Delete patients from the pending orders list..

When the Add button is selected, a dialogue window will appear for input of patient information.

- Rotate **Trim Knob** or use the **Up/Down** Arrow keys to the desired field and use the keyboard to enter the patient information. Press the **Trim knob** or the Enter key when done to automatically save the information and close the window.

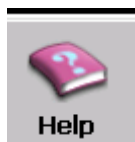
The screenshot shows the 'Orders Entry' dialog box overlaid on the main software interface. The dialog box has a title bar 'Orders Entry' and contains the following fields and controls:

- Patient ID: Text input field
- Last Name: Text input field
- First Name: Text input field
- Add'l Name: Text input field
- Date Of Birth: Form with three dropdown menus for Month, Day, and Year, followed by the text '(YYYY)'.
- Gender: Radio button controls for Male and Female.
- Physician: Dropdown menu
- Operator: Dropdown menu
- Instructions: 'Press Enter to add the order to the list or press Esc to cancel.'

The background interface shows a 'Patient' list on the left, a top status bar with 'Data Average', 'Data Update', 'Signal Status', and the date '10/24/2006', and a bottom toolbar with icons for 'Take BP', 'Save', 'Review', 'Orders' (highlighted), 'Archive', 'Config', 'Help', and 'ECG'.

Figure 5-8 Orders Entry

5.8 Help Command



The **Help** Command button opens screens that offer information for Taking an ICG Test, Button Identification, Command Toolbar, Basic Navigation and useful Tips..

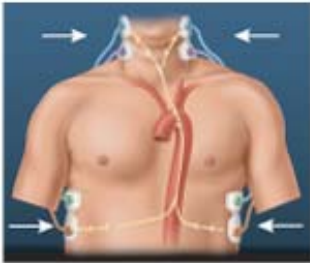


Once in the help screen, use the Trim Knob to scroll between screens.

Use the ESC key to exit from the help menu.

CardioDynamics
B I O Z Dx
Help

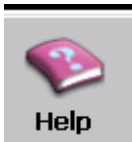
To Take an ICG Test:

1. Prepare patient and attach sensors and lead wires



2. Place NIBP Cuff if using automatic BP method (patient should be supine)
3. Press Patient ID button to enter required Patient ID information
4. Press  (Enter) to begin monitoring
5. Press Auto Print button once values appear and signal status is green
6. Press Stop after report has finished printing

Turn Trim Knob ➡ to go forward | Press ESC key to exit

Figure 5-9 Help Screen



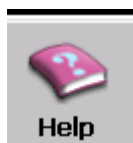
Help screen for Button Identification.

CardioDynamics
BIOZ[®] Dx
Help

Button	Press Button to...
A	Turn the cardiograph on/off or place in Standby
B Patient ID	Enter Patient ID information
C Auto Print	Print ICG Status Report
D ECG Rhythm	Not used for ICG
E Copy	Print a copy of the last ICG Status Report
F Page	Advance the printer paper to the top of the next page
G Stop	Stop the ICG test

Turn Trim Knob ◀ to go back | Turn Trim Knob ▶ to go forward | Press ESC key to exit









Figure 5-10 Help Screen



Help screen for the Command Toolbar.

CardioDynamics
B I O Z D_x
Help

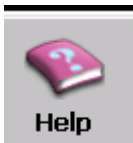
Command Toolbar

A	B	C	D	E	F	G	H	
								ID:
Take BP	Save	Review	Orders	Archive	Config	Help	ECG	Name:

Button	Select this Button to...
A	Start or stop a blood pressure measurement
B	Save an ICG Status Report to the Archive
C	Review the most recently monitored patient's hemodynamic data
D	Enter ICG Orders using the keyboard
E	<ul style="list-style-type: none"> Print an ICG Status report of a previously monitored patient Transfer ICG Status reports to and from the cardiograph
F	Change the Configuration settings on the cardiograph
G	Get help with using the cardiograph to take an ICG
H	To perform a 12-Lead ECG

Turn Trim Knob ◀ to go back
Turn Trim Knob ▶ to go forward
Press ESC key to exit

Figure 5-11 Help Screen



Help screen for Basic Navigation.

*Cardio***Dynamics**
B I O Z _{Dx}
Help

Basic Navigation

1. Turn the Trim Knob to scroll through buttons

2. Press the Trim Knob to select a button

3. Press the Enter key to accept changes and exit any screen

4. Press the Esc key to exit any screen without saving changes

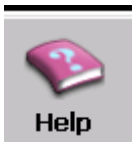
To select a Dialog Screen Tab:

1. Press and hold the Alt key
2. Press the letter key in parenthesis

Parameters	Screen	Report	Par
HR	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	VI
BP: SBP/DBP (MAP)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	ACI

Turn Trim Knob ◀ to go back
Turn Trim Knob ▶ to go forward
Press ESC key to exit

Figure 5-12 Help Screen



Help screen for useful Tips.

CardioDynamics **BIOZ** Dx **Help**

Tips for: Taking Blood Pressure <ol style="list-style-type: none">1. Use correct size cuff2. Place cuff 1" above elbow with arrow over the brachial artery3. Ensure the patient is relaxed, not talking, and motionless during cuff inflation and deflation	Tips for: Obtaining Good Signal Quality <ol style="list-style-type: none">1. Prep patient's skin:<ul style="list-style-type: none">• Shave if necessary• Clean with soap and water• Dry thoroughly with gauze2. Ensure lead wires are connected properly and sensors are making good contact with patient's skin3. Ensure patient is relaxed, not talking, and motionless during ICG test
--	--

Turn Trim Knob ◀ to go back | Press ESC key to exit

Figure 5-13 Help Screen

PRINTING THE ICG REPORT

6 PRINTING THE ICG REPORT

The BioZ Dx has an integrated printer. Pressing the **Print** Control Key during a “live” ICG test, **Review**, or **Archive** function will Print the ICG Status Report and Save a copy to the **Archive** for later review, printing, and/or transfer to external media.

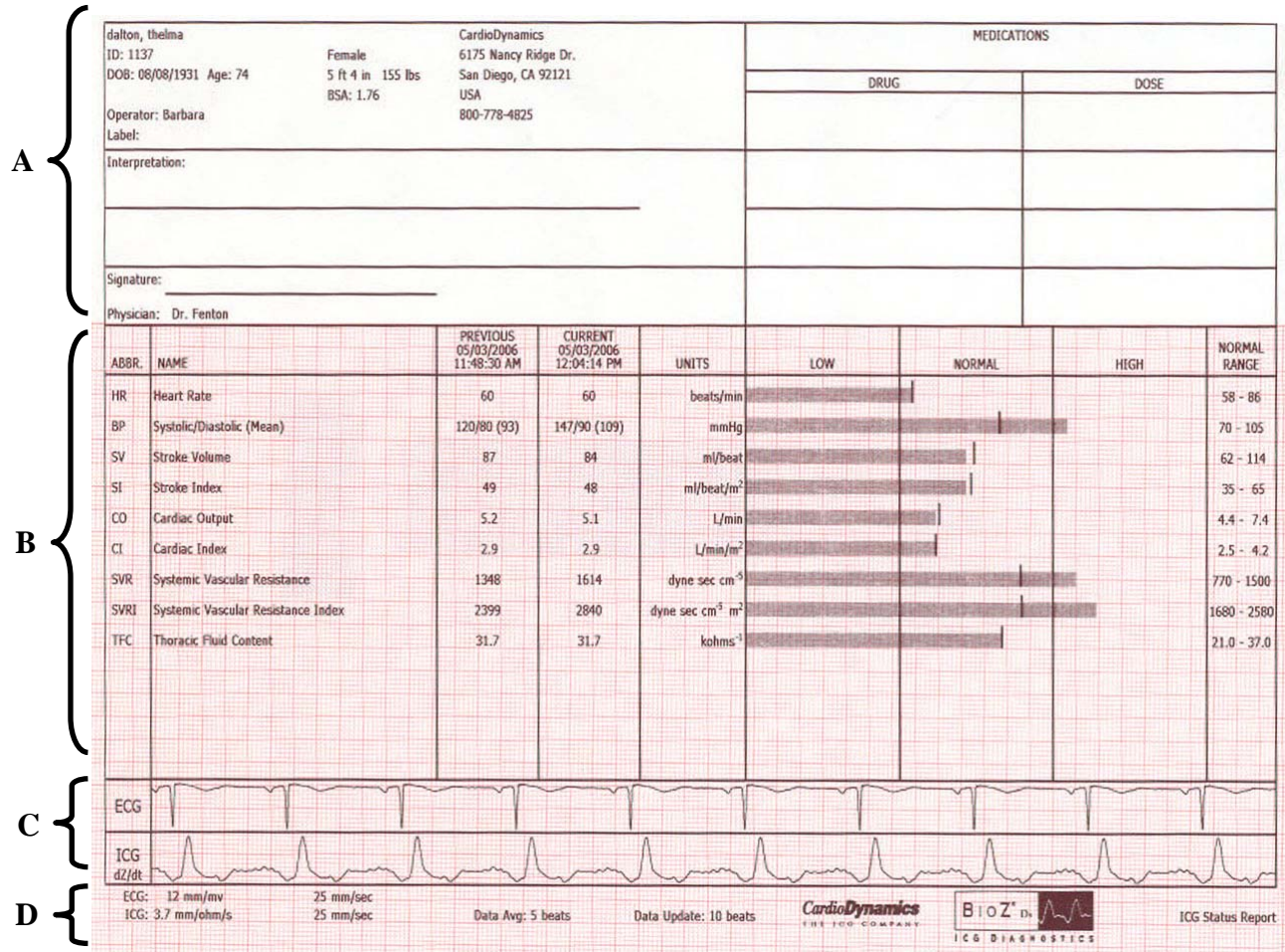


Figure 6-1 ICG Status Report

The ICG Status Report consists of four main sections: The **Header (A)**, **ICG Values (B)**, **Waveforms (C)**, and **Footer (D)** areas.

Note: For an explanation of parameters and their respective normal ranges, refer to Appendix A. Hemodynamic Parameters, and Appendix B. Glossary of Terms.

Note: Values that fall outside of the maximum and minimum limits will be displayed at their respective limits per Appendix A.

6.1 ICG Status Report Header

The **Header** contains all of the Patient, Physician and Facility information entered in the Patient ID and Facility screens for the particular ICG test. Also included is an area for the Physician to write their interpretation and list the status of any medication adjustments.

6.2 ICG Status Report Hemodynamic Parameter Value Section

The **ICG Hemodynamic Parameter Section** displays up to 13 of the current and most recent previously saved User defined ICG parameters in both numerical and Bar Graph format as related to their respective Low, Normal, and High ranges. The current data are indicated via the bar graph while the most recent previous saved data are indicated via a “tick” mark thus providing the clinician with a visual indication of visit-to-visit changes in ICG parameters.

6.3 ICG Status Report Waveform Display Section

The **ICG Waveform Section** displays two of the three available waveforms displayed by the BioZ Dx as defined by the User via the **Config** Command function.

NOTE:	These waveforms are auto scaled to vertically fill the waveform section. Please refer to the scale in the footer section in order to determine actual waveform amplitude.
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6.4 ICG Status Report Footer

The **Footer Section** displays the scale of the ECG and ICG Waveform amplitude and speed, ICG Data Average Period, Display Update, and Signal Status.

NOTE:	The BioZ Dx ECG is non-diagnostic and is used only for the purpose of R and Q point detection. It is NOT intended to be used by the clinician to evaluate and/or make decisions regarding possible diagnosis, treatment, or causes for symptoms.
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7 SYSTEM CONFIGURATION

The **Config** Command Button provides the User with the ability to configure various system defaults. There are three main areas for User Configurability: Screen & Report, Options, and Facility.

7.1 Screen & Report Configuration Screen

The **Screen & Report** Dialog Screen provides the User with the ability to configure which waveforms and parameters will be displayed on the ICG Main Screen and ICG Status Report. The user may choose one of two ICG waveforms, six parameters for the Main Screen, and 13 parameters for the ICG Status Report. Should the operator exceed the maximum number of displayed parameters a message will automatically appear to alert them.

Rotate **Trim Knob** or press the **Tab** key to move cursor to the desired parameter Screen or Report field and press the **Trim Knob** to either include or remove a parameter from the Screen or Report.

Press **Enter** to save and exit.

Configuration

Screen & Report(S) Options(O) Facility(F) Password(P) Network(N)

Parameters	Screen	Report	Parameters	Screen	Report
HR	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	VI	<input type="checkbox"/>	<input type="checkbox"/>
BP: SBP/DBP (MAP)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	ACI	<input type="checkbox"/>	<input type="checkbox"/>
SBP	<input type="checkbox"/>	<input type="checkbox"/>	STR	<input type="checkbox"/>	<input type="checkbox"/>
DBP	<input type="checkbox"/>	<input type="checkbox"/>	STRI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
SV	<input type="checkbox"/>	<input checked="" type="checkbox"/>	QC	<input type="checkbox"/>	<input type="checkbox"/>
SI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	HI	<input type="checkbox"/>	<input type="checkbox"/>
CO	<input type="checkbox"/>	<input checked="" type="checkbox"/>	TFC	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
CI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	TFCI	<input type="checkbox"/>	<input type="checkbox"/>
SSRI	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Zo	<input type="checkbox"/>	<input type="checkbox"/>
SVRI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	LCWI	<input type="checkbox"/>	<input type="checkbox"/>
TAC	<input type="checkbox"/>	<input type="checkbox"/>	LSWI	<input type="checkbox"/>	<input type="checkbox"/>
TACI	<input type="checkbox"/>	<input type="checkbox"/>			

RESTORE DEFAULT PARAMETERS

ICG Waveform

☐ ICG DeltaZ Waveform

☒ ICG dZ/dt Waveform

☒ Print TFC, TFCI and Zo Bar Graphs

☒ Display Pacer Spikes on ECG Waveform

Apply

Take BP Save Review Orders Archive Config Help ECG

ID: Last: First:

Figure 7-1 Screen & Report Screen

7.2 Options Configuration Screen

The **Options** Configuration Screen provides the User with the ability to set the default formats, units, and/or values for Date, Time, Height, Weight, CVP, PAOP, Standby Interval, Shutdown Interval and Paper size.

Pressing **Alt & O** simultaneously will access the **Options** screen.

Rotate the **Trim Knob** to move the cursor to the desired field, for fields containing radio buttons press down on the **Trim Knob** to make a selection. The fields for CVP, PAOP, Standby Interval and Shutdown Interval contain a drop down menu of choices, after accessing the field press down on the **Trim Knob** to display the drop down menu. Rotate the **Trim Knob** or use the **Up/Down** arrow keys make a selection within the drop down menu, press down on the **Trim Knob** to accept the selection and close the drop down menu.

Press **Enter** to save and exit.

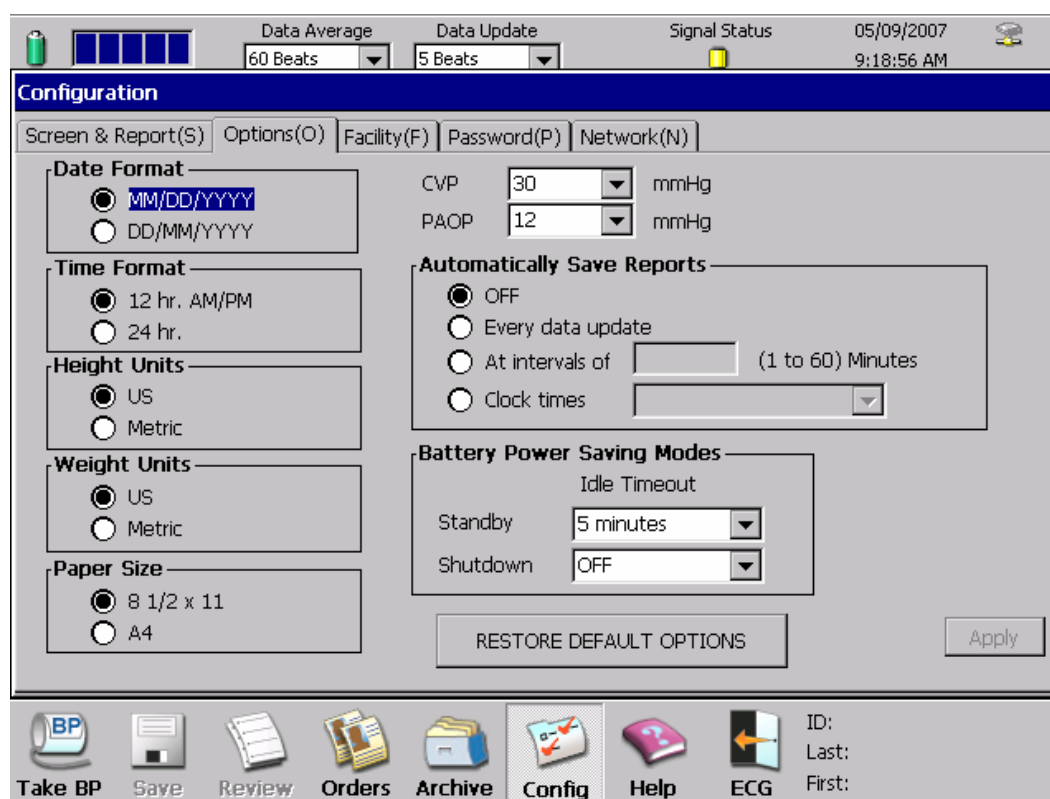


Figure 7-2 Options Screen

SYSTEM CONFIGURATION

Battery Power Saving Modes

When on Battery Power in ICG mode, the BioZ Dx will go to Standby and then complete Shutdown after a User configurable time interval when no keys/commands have been operated.

Standby and/or Shutdown will not occur while printing or during an active monitoring session.

When the unit enters Standby mode power to the LCD screen is turned off but the cardiograph itself remains on. Any key press will bring the system back from standby mode. When returning from standby, the screen shown will be the HIPAA screen if the HIPAA timeout was set and was exceeded. If the HIPAA timeout was not set or was not exceeded then the screen shown will be the last screen before entering Standby.

Shutdown differs from Standby in that the Cardiograph will actually shut itself off. The user must press the power button to turn the unit back on.

The system will go into Standby when the Standby idle time drop down list is set to a value between 5 and 30 minutes. Options available in the drop down list are: OFF, 5,10,15,20,25, and 30 minutes. The default for Standby is set to a timeout interval of 5 minutes and if the user selects OFF the system will not go into Standby mode.

The system will shut down when the Shutdown idle time drop down list is set to a value between 5 and 30 minutes. Options available in the drop down list are: OFF, 5,10,15,20,25, and 30 minutes. The default for Shutdown is set to a timeout interval of 10 minutes and if the user selects OFF the system will not go into Shutdown mode unless the battery power drops to a critical level.

7.3 Facility Configuration Screen

The **Facility** Configuration Screen provides the User with the ability to enter the ICG Report Header Facility information to include Name, Address, Ordering Physician, Operator, and Predefined Report Labels.

Pressing **Alt & F** simultaneously will access the **Facility** screen.

Rotate **Trim Knob** to move cursor to the desired field and enter the information via the keyboard. Press **Tab** or the **Trim Knob** to move to the next field. To enter a list of Ordering Physician(s), Operator(s), and Label Field(s), rotate the **Trim Knob** to select the **Add** button and press the **Trim Knob** to accept. The steps are identical to remove an entry via the **Remove** button.

Press **Enter** to save and exit.

The screenshot displays the 'Facility Configuration' window. At the top, there's a status bar with 'Data Average' set to '30 Beats', 'Data Update' set to '5 Beats', 'Signal Status' indicated by a yellow light, and the date/time '10/24/2006 12:43:27 PM'. Below this is a tabbed interface with 'Facility(F)' selected. The form contains the following fields and values:

- Institution Name: CardioDynamics
- Facility Name: Home Office
- Dept. Name*: Technical Services
- Cardiograph Location*: First Floor
- Street Address 1: 6175 Nancy Ridge Dr.
- Street Address 2: (empty)
- City: San Diego
- State or Province: CA
- Postal Code: 92121
- Country: USA
- Phone Number: (800) 778-4825
- Ordering Physician: (empty dropdown)
- Operator: (empty dropdown)
- Label: (empty dropdown)

For the last three fields, there are 'Add' and 'Remove' buttons. An 'Apply' button is located at the bottom right of the form area. A note on the right side states '* Not displayed on status report'. The bottom toolbar includes icons for 'Take BP', 'Save', 'Review', 'Orders', 'Archive', 'Config', 'Help', and 'ECG'. User information on the far right of the toolbar reads: ID: 1234, Last: FIELDS, First: DEBBY.

Figure 7-3 Facility Screen

SYSTEM CONFIGURATION

7.4 Password Configuration Screen

The **Password** Configuration Screen provides the User with the ability to set a unique password, as well as adjusting the **Screensaver timeout**.

Pressing **Alt & P** simultaneously will access the **Password** screen.

The cursor will automatically be placed in the **Please enter current password** field and the user is prompted for the current password.

Rotate **Trim Knob** to move cursor to the **Please enter new password** field and type in the desired password.

Rotate **Trim Knob** to move cursor to the **Please confirm new password** field and type in the new password.

Rotate **Trim Knob** to move to the **Change Password** button and press down on the **Trim Knob**, a pop-up window will confirm your password has been changed, press **Enter** to close the window.

Press **Enter** to save and exit.

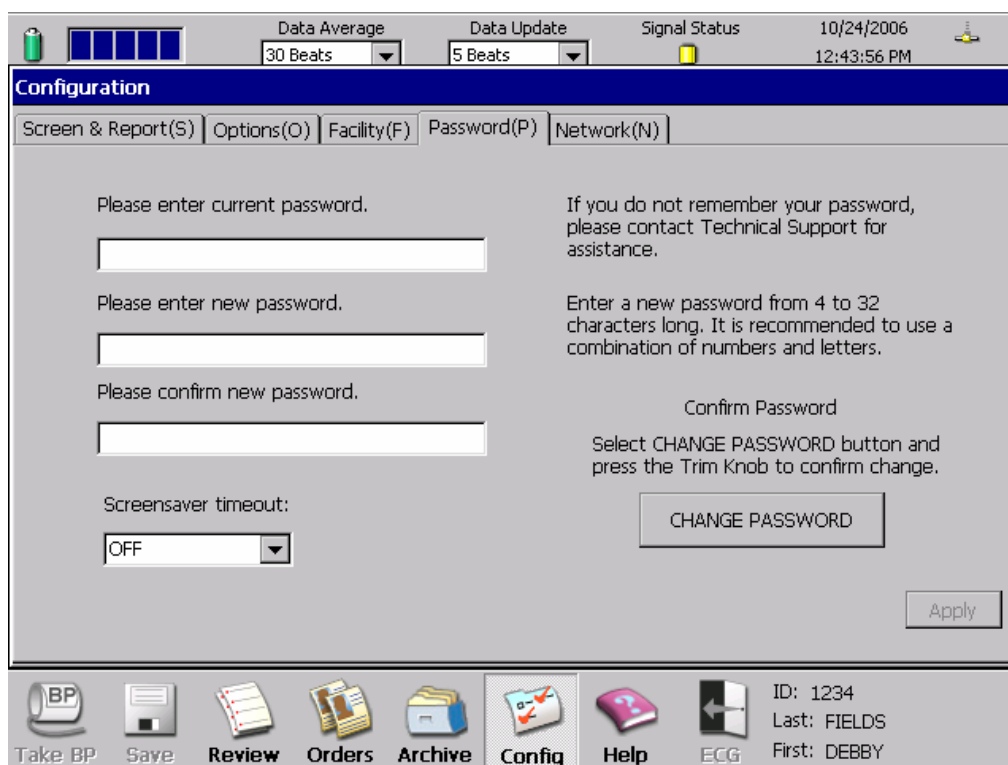


Figure 7-4 Password Screen

7.5 Network Configuration Screen

The **Network** Configuration Screen provides the User with the ability to change TCP/IP settings to either static or a fixed IP configuration.

Pressing **Alt & N** simultaneously will access the **Network** screen.

The cursor will be displayed in the Network ID field, by Rotating the **Trim Knob** the cursor will move to the desired field and the user can either select to **Obtain an IP Address Automatically** or **Specify an IP Address**.

*To Specify an IP Address, rotate the Trim Knob between fields for IP Address, Subnet Mask and Default Gateway and use the keyboard to enter the applicable domain information.

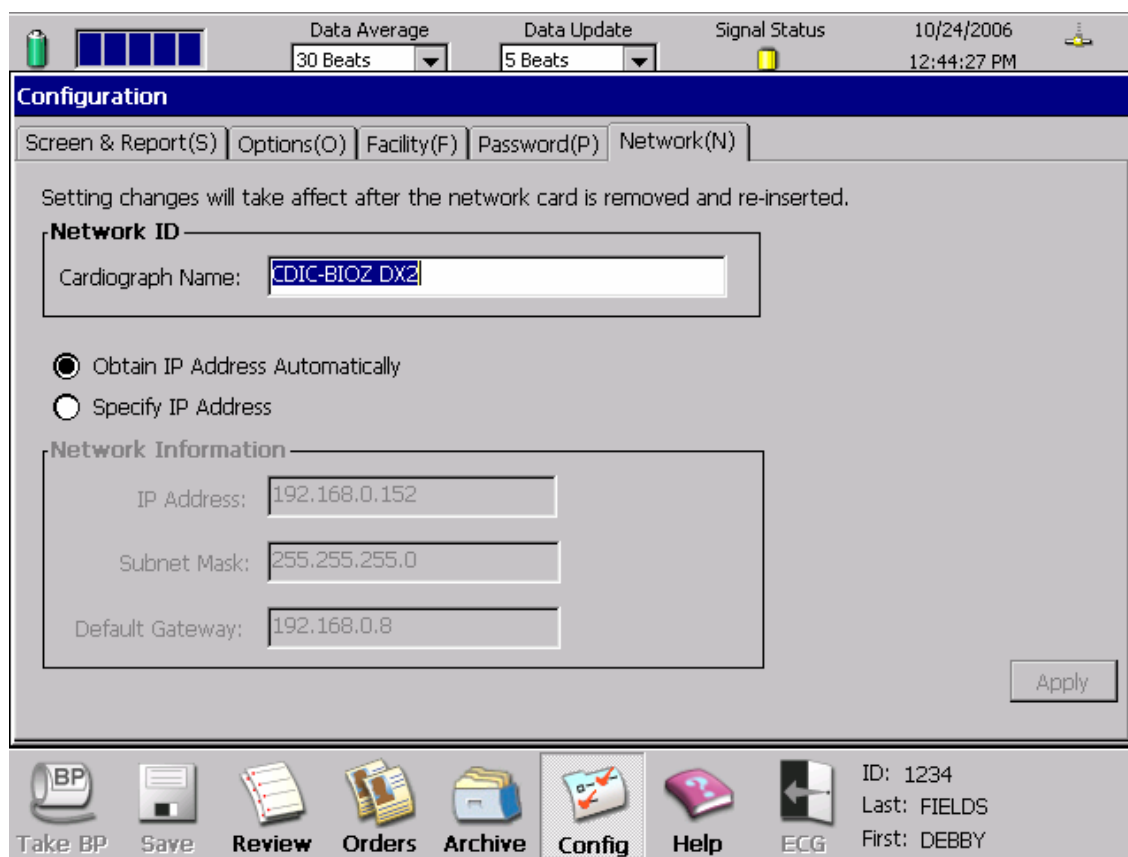


Figure 7-5 Network Screen

SYSTEM CONFIGURATION

*CardioDynamics suggests that a network professional assists in the setup when selecting a specific IP configuration.



NOTE:	To use XML files in an EMR system, the EMR developer MUST use the correct CDIC XML schema to extract data from the files. Transfer of data from the BioZ Dx into the EMR system must be fully validated by the EMR developer.
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7.6 HIPAA Screen

This screen is designed to assist customers in their compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

HIPAA included provisions designed to encourage electronic transactions and also required new safeguards to protect the security and confidentiality of health information

Whenever the Cardiograph is left idle for a User defined period of time, the HIPAA screen will be activated locking out access to patient information. The User can easily return to the operating mode by entering the User defined password and pressing the Enter key.



To return to the application, please enter the password and press Enter.

Password

Figure 7-6 HIPAA Screen

TROUBLESHOOTING

8 TROUBLESHOOTING

The ICG Cardiograph is designed for reliable operation. If you experience any problems with the cardiograph, ICG PIM, or performing an ICG, there are several things that you should verify prior to calling for service.

If you have any problems that you are unable to solve, please contact CardioDynamic's Technical Service Department at 800-778-4825 (option 3), or outside of the USA at 858-535-0202 (option 3), or by e-mail at tech-service@cdic.com. Emergency After Hours Technical Support is available, 7 days a week between the hours of 6 a.m. and 9 p.m., Pacific Time, by cell phone at 866-880-6674.

8.1 Blood Pressure Errors

Problem(s)	Possible Causes	Potential Solutions
Weak or No Oscillometric Signal Artifact / Erratic Oscillometric Signal Exceeded Retry Count Exceeded Measurement Time Limit	Cuff is in wrong position Cuff is loose on patient's arm Excessive clothing between cuff and patient's arm Cuff is the wrong size Patient is not motionless and relaxing their arm Patient has weak and/or low pulse	Reapply Cuff and retake BP ensuring that: The arrow on the cuff is located over the patient's artery just above the elbow joint The cuff is wrapped snugly There isn't excess clothing between the cuff and arm The size is correct for the patient's arm circumference The patient is motionless with their arm relaxed during the measurement cycle If error persists, contact Technical Support
Pneumatic Blockage	Hose, Cuff, and/or Fittings are blocked Hose or Cuff is crimped and/or folded	Clear Hose, Cuff or Fittings of any blockage Replace Hose and/or Cuff If error persists, contact Technical Support
Cuff Overpressure	Hose, Cuff, and/or Fittings are blocked Hose or Cuff is crimped and/or folded	Clear Hose, Cuff or Fittings of any blockage Replace Hose and/or Cuff If error persists, contact Technical Support

Problem	Possible Causes	Potential Solutions
Inflate Timeout, Air leak or Loose Cuff	Hose, Cuff, and/or Fittings have a leak Cuff is loose Hose, Cuff or fittings are not connected properly	Replace Hose, Cuff and/or fittings If error persists, contact Technical Support
BP reading Wait message	ICG PIM Does not have enough stored power to initiate Cuff inflation	Wait at least four minutes for sufficient power to be restored If error persists, contact Technical Support
Following msg is displayed: “No BP values. Are you sure you want to continue?”	Communicates to the user they have attempted to print or save without valid BP parameters	Correct the missing or invalid BP parameters and retry.
BP Cuff Communications Failure Power Supply / Hardware Failure Safety Override Fitted or Auto-zero Out of Range Transducer Out of Range ADC Out of Range EEPROM Calibration Data Failure	Damaged Equipment	Service Required. Contact Technical Support.

TROUBLESHOOTING

8.2 Printer / Printing Errors

Problem	Potential Solutions
Paper doesn't advance; "Paper jam detected" Error Message is Displayed	Replace Paper or clear paper jam If error persists, contact Technical Support
Paper moves then stops and displays error message, "Paper jam detected"	Make sure BioZ Dx is loaded properly with approved thermal paper Clean paper sensor lens If error persists, contact Technical Support
Printer does not feed paper, "Battery power too low for good printing" error message is displayed	Charge batteries Replace battery packs If error persists, contact Technical Support
Printer does not feed paper, "Printer drawer is open" error message is displayed	Close drawer If error persists, contact Technical Support
Paper moves but printing is faint, or blank	Ensure approved thermal paper is being used Clean paper sensor lens If error persists, contact Technical Support
Paper stops in the wrong place after pressing Page or Print control keys	Ensure approved thermal paper is being used Clean paper sensor lens If error persists, contact Technical Support
Printed data is garbled, dark on one side but faint on other.	If error persists, contact Technical Support

Problem	Potential Solutions
Paper does not tear off cleanly, or paper stops at the wrong spot	<p>Wrong paper size setting</p> <p>Wrong method is being used to tear off paper. Ensure that paper is torn horizontally in a steady, left to right motion. Do not tear paper in a rapid up or down motion.</p> <p>If error persists, contact Technical Support</p>
Blank pages printed after report	<p>Wrong paper size setting. Verify that the correct paper for the Paper size setting is properly loaded in the paper drawer.</p> <p>If error persists, contact Technical Support</p>

TROUBLESHOOTING

8.3 Monitoring Errors (ICG)

Problem(s)	Possible Causes	Potential Solutions
“There are no values to save or print. Please wait until the first update” message is displayed.	Communicates to the user they have attempted to print or save prior to values being displayed or while the signal status is bad.	<p>Wait until values are displayed</p> <p>Verify sensor and lead placement are correct</p> <p>Be sure patient is lying still. Motion such as coughing and talking will produce instability in the waveform</p> <p>Replace sensors with new set</p> <p>Perform ICG Maintenance Test to verify integrity of lead wires, replace any lead sets that fail the check</p> <p>If problem persists it is likely a patient related issue (such as a bundle branch block)</p>
“Unable to learn ECG” message is displayed.	There may be a problem with one of the lead sets, sensor application or patient related issue.	<p>Verify the lead sets are from CardioDynamics, the BioZ Dx will only operate with CardioDynamics leads</p> <p>Prep the patient’s skin with soap and water before applying sensors</p> <p>Make sure patient’s head is straightforward not turned to the left or right</p> <p>Be sure patient is lying still. Motion such as coughing and talking will produce instability in the waveform</p> <p>Remove any jewelry that may interfere with the leadwires</p> <p>Perform ICG Maintenance Test to verify integrity of lead wires, replace any lead sets that fail the check</p> <p>If the problem persists contact CardioDynamics Technical Services (800-778-4825 opt. #3) for additional assistance</p>

Problem(s)	Possible Causes	Potential Solutions
“Learning ECG Vector” message is displayed.	The cardiograph is programmed to automatically identify the best ECG vector, no input is required from the operator.	<p>If the message continues to appear, perform the following:</p> <p>Verify sensor and lead placement are correct</p> <p>Be sure patient is lying still, motion such as coughing and talking will produce instability in the waveform</p> <p>Perform ICG Maintenance Test to verify integrity of lead wires, replace any lead sets that fail the check.</p>
<p>“ECG Amplitude is too low”</p> <p>“ECG has excessive artifact”</p> <p>“ICG Amplitude is too low”</p> <p>“ICG has excessive artifact”</p> <p>“Intermittent leads failure detected”</p>	These error messages advise the operator that the BioZ Dx can not display data due to the poor quality of a specific signal.	<p>Prep the patient’s skin with soap and water before applying sensors.</p> <p>Make sure patient’s head is straightforward not turned to the left or right.</p> <p>Be sure patient is lying still, motion such as coughing and talking will produce instability in the waveform.</p> <p>Remove any jewelry that may interfere with the leadwires</p> <p>Perform ICG Maintenance Test to verify integrity of lead wires, replace any lead sets that fail the check.</p> <p>If the problem persists contact CardioDynamics Technical Services (800-778-4825 opt. #3) for additional assistance.</p>
“HR is out of the system range (40 – 250)	The patient’s heart rate is either below 40 or above 250 beats per minute.	The patient’s heart rate must be in a range between 40 and 250 beats per minute.

TROUBLESHOOTING

8.4 Communication and Data Errors

Problem(s)	Possible Causes	Potential Solutions
Message is displayed stating: “Not enough space on the media. Please insert a new disk and press Send again”	This message is displayed when the PCMCIA Card is full but there is still more information to be transferred.	Insert a new PCMCIA Card and press the OK button in the message box. When OK is pressed, the information shall continue to be transferred until all the selected reports have been copied or until the storage media is filled and the message is redisplayed.
ICG Communications Failure.	The BioZ Dx is unable to communicate with the Patient interface module.	<p>Check the USB cable connecting the cardiograph to the PIM, verify the connector ends are fully inserted in the receptacle.</p> <p>Replace the USB cable if any damage is noted on the connector ends or they will not lock into the receptacle.</p> <p>Perform the Version Control Check to verify the CRC.</p> <p>If the problem persists contact CardioDynamics Technical Services (800-778-4825 opt. #3) for additional assistance.</p>
“The BioZ Dx has detected a problem with the USB connection.”	The USB cable plugs into the rear of the cardiograph and connects the monitor with the ICG PIM.	<p>Verify the USB cable is plugged into the cardiograph and the ICG PIM.</p> <p>If the problem persists contact CardioDynamics Technical Services (800-778-4825 opt. #3) for additional assistance.</p>
“Cannot access database. Your database might be damaged”	A problem exists where the system can no longer read the information in the database.	The system will automatically move the corrupt database to a storage location and create a new database. The creation of the new database will allow the operator to continue using the cardiograph, however, the new database will not contain any previous patient data.

Problem(s)	Possible Causes	Potential Solutions
<p>“Cannot access database. Your load database might be damaged”</p> <p>“Cannot access database. Your send database might be damaged”</p>	<p>These messages may occur when an attempt to load or send the database fails.</p>	<p>Shut down the cardiograph, restart the system and retry the procedure.</p> <p>The external compact flash card may be faulty.</p> <p>The PCMCIA adapter may be faulty</p> <p>If the problem persists contact CardioDynamics Technical Services (800-778-4825 opt. #3) for additional assistance.</p>

TROUBLESHOOTING

8.5 System Reset

In the event the cardiograph does not respond to key presses and the display remains frozen for an extended period of time, follow the steps below to initiate a system reset:

- Gently press and release the system reset button using an ordinary paper clip or other slender object (refer to Figure 8-1).

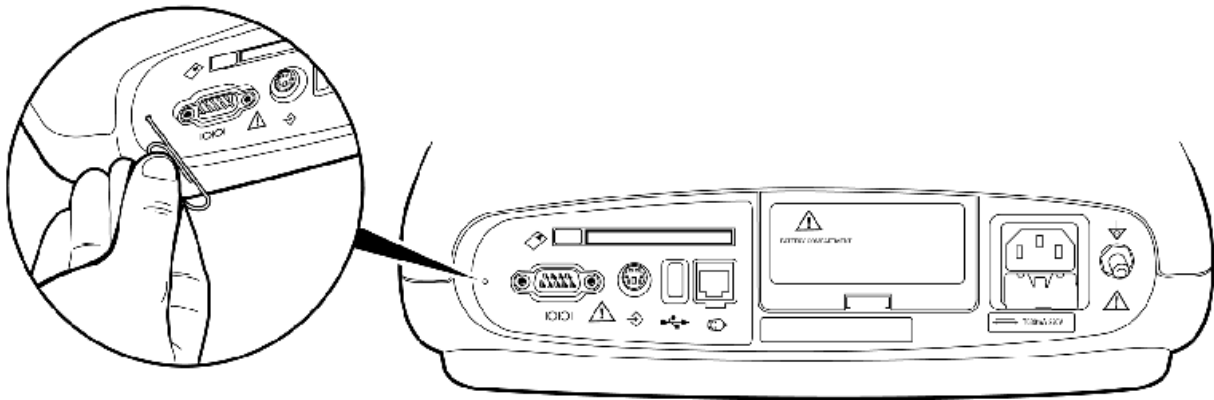


Figure 8-1 System Reset button

8.6 Software Installation Instructions

The process for installing software may vary depending on the version currently in use on your BioZ Dx and the version that is going to be installed. For this reason, it is important to follow the installation instructions that are included in the software upgrade kit. CardioDynamics includes installation instructions with every software upgrade kit that is sent out. If you experience difficulties or have questions regarding any of the steps please contact Technical Support at 800-778-4825, option 3 (USA), or if outside the USA, 1-858-535-0202, option 3.

8.7 Power Management

The system host processor controls several functions of the power system. These include:

- Activating sleep mode if the unit is on battery power and has been left on the launch screen for 5 minutes.
- Battery power saving modes (refer to section 7.2)
- Restricting the user from printing when the charge capacity reaches preset levels
- Alerting the user when maintenance is needed for the battery

Battery Discharging

When the battery is discharged to the 30% level, the Cardiograph disables printing, and continues to allow the battery to be discharged to a 20% level. When the 20% level is reached, the Cardiograph beeps to warn the user to plug in the AC power cord. If the AC power cord is not plugged in within three minutes, the Cardiograph automatically shuts down.

Accidental discharging of the battery may be avoided through the use of the battery power saving modes (refer to section 7.2)

Battery Charging

When the AC power cord is plugged in, the battery begins to charge. Check the charging status on the System Status Bar.

When the unit is in operating mode, the charge current is 580mA. When the unit is in sleep mode, the charge current depends on the battery. The initial charge current is approximately 580mA in bulk charger status. When the voltage is up to approximately 14.6V, the current is slowly reduced to approximately 100mA over time as it enters floating charging.

9 ICG BioZ Dx CARE AND MAINTENANCE

9.1 Cleaning External Surfaces

Note: Infection could occur from cross contamination of blood products. Use caution when disinfecting equipment that may come into contact with blood products.

Approved Cleaning Solutions:

- Mild soap and water
- Lysol® Disinfectant
- Lysol® Deodorizing Cleaner (may discolor the cable and/or lead wires)
- Dial® liquid antibacterial soap

Do Not:

- Use Isopropyl Alcohol, Acetone, Iodine, Phenol, Chlorine, or Ammonia based cleaners
- Autoclave, use ultrasonic cleaners, or ethylene oxide sterilization
- Immerse in any cleaning agents and/or apply cleaning agents directly to surfaces
- Use abrasive cleaners or cloths
- Wet the connectors

Do:

- Unplug the AC power cord
 - Avoid the lead wire connectors and patient data cable connectors
 - Wipe all external surfaces with a soft, nonabrasive cloth dampened with any of the approved cleaning agents
 - Let all components dry completely before using
 - Disconnect power cord prior to cleaning
 - Turn power switch to off / standby
-

9.2 Cleaning the Print Head

To Clean the Print Head:

- Open the paper door on front of cardiograph
- Wipe print head (A) lightly with a foam swab dipped in 90% alcohol
- Allow the print head to dry completely

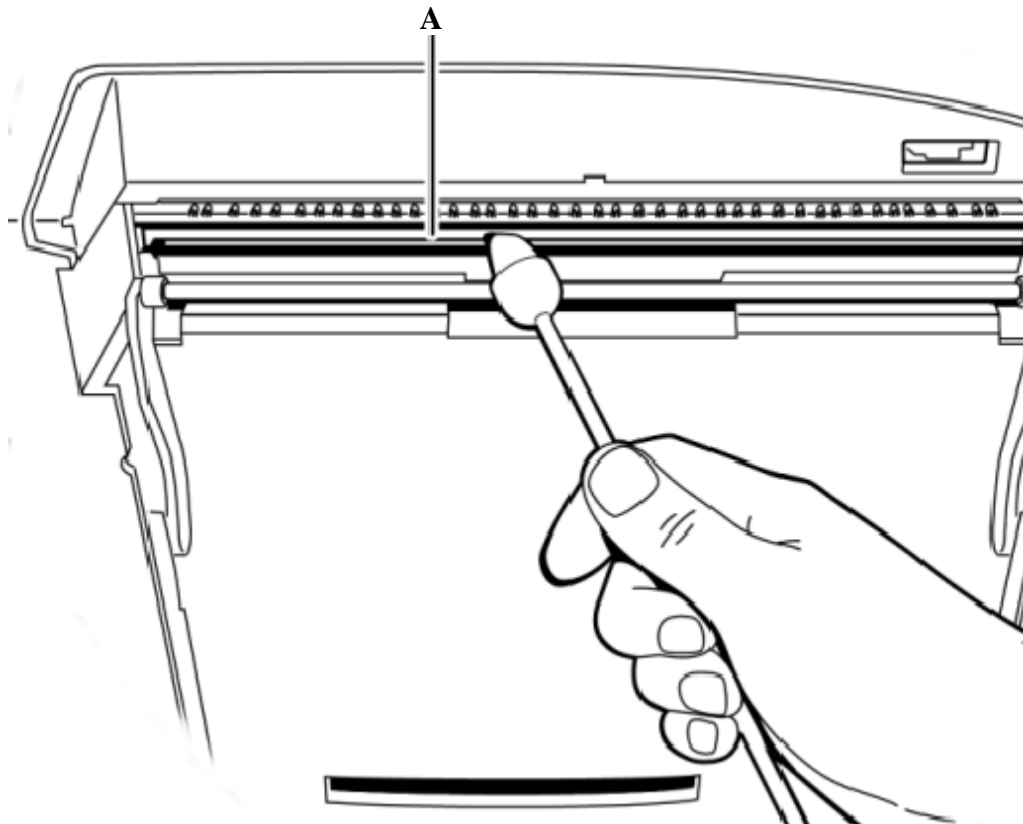


Figure 9-1 Cleaning the Print Head

9.3 Cleaning the Paper Sensor Lens

To clean the Paper Sensor:

- Open the paper door on front of cardiograph. The paper sensor lens is above and to the right of the print head.
- Wipe the paper sensor lens lightly with a **DRY** foam swab. Do **NOT** use alcohol

9.4 Replacing Printer Paper

Replace the printer paper when a red stripe appears on the printed ECG report. Always load less than 100 sheets of printer paper into the paper tray

- Ensure that the entire first page of the new paper roll is fully draped over the roller before closing the printer door
- Ensure that the paper size configured for the cardiograph is the same size paper being loaded into the paper drawer.

To Change the Printer Paper:

1. Open the paper drawer on the front of the cardiograph and remove any remaining sheets.
2. Lift up the paper bar. Insert a new pack of printer paper with the printed side facing up. Ensure that no more than 100 sheets are being inserted into the paper tray.

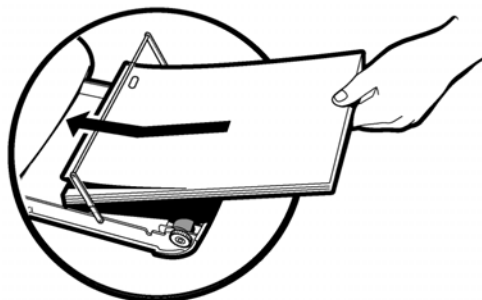


Figure 9-2 Inserting Paper

3. Ensure that the paper sensor hole (A) is positioned as shown.

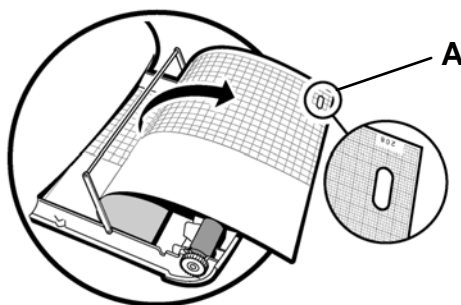


Figure 9-3 Paper Sensor Hole

4. Lower the paper bar. Drape the entire first sheet over the roller. Ensure that the perforated edge of the paper aligns with the edge of the paper drawer.

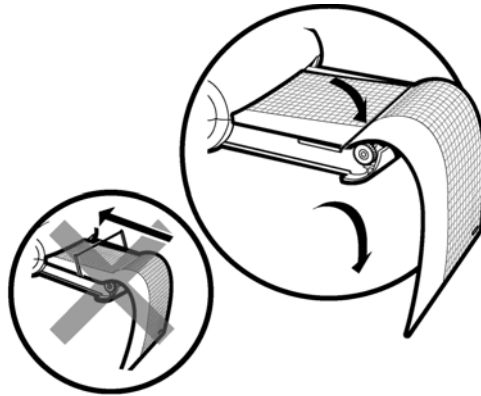


Figure 9-4 Lower Paper Bar

5. Close the paper drawer.
6. Press the **Page** button on the right side of the cardiograph.
7. Tear off the page a motion. Do not tear

. steady, left to right

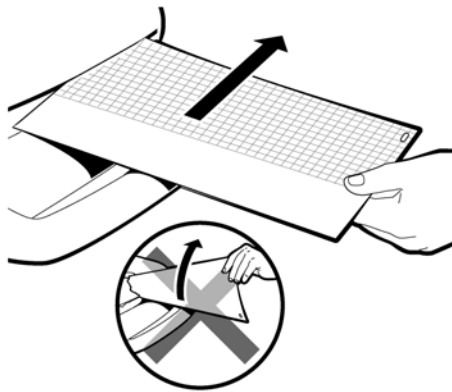


Figure 9-5 Tearing Off the Paper

9.5 Battery Maintenance and Care

The sealed lead-acid battery used in the cardiograph will provide optimum life when the unit is continuously connected to AC power and fully charged after each use. A depleted battery requires 16 hours of continuous charge time to fully charge. Because it is not always possible to allow a full charge cycle between uses, the Cardiograph was designed to charge a depleted battery to 90% of its capacity in approximately eight hours.

The battery must be installed for proper operation of the cardiograph. The BioZ Dx cannot print an ICG Status report without the battery, even if it is plugged into AC power.

The Cardiograph has one lead acid battery that supplies power to the BioZ Dx during mobile use, and to power the Cardiograph printer while it is connected to AC power.

With the batteries fully charged, the BioZ Dx can print up to 10 ICG Status Reports every 30 minutes. Use of the blood pressure feature (which draws power from the battery as well) may have an impact on the number of status reports that can be printed in this period of time.

Battery life varies depending on frequency of use and maintenance. For improved battery life, keep the Cardiograph plugged in when not in use. If the battery has been fully charged and requires recharging after a few Status reports, consider replacing it.

For Optimal Battery Performance:

- Fully charge batteries before AC or mobile use.
- Check the battery power indicator on the Status Bar.
- Configure the battery power saving modes as described in section 7.2
- Put the BioZ Dx into Standby mode when not in use.
- Always charge the batteries when the Cardiograph is not in use. Connect the BioZ Dx to an AC power source and make sure that the power switch is turned to the ON position with the green AC light on.
- The batteries automatically charge whenever the Cardiograph is connected to AC power. The batteries will charge while the BioZ Dx is in use on AC power, but will charge at a slower rate. It is recommended to charge the batteries while the Cardiograph is not in use.
- Operate the cardiograph, charge batteries, and store at room temperature (25 °C / 77 °F). Higher temperatures reduce battery life and degrade performance.
- If the BioZ Dx is not in use for more than six months, fully charge batteries prior to using the cardiograph.
- Repeated undercharging of the battery will damage the battery and reduce battery life.

- If the battery has been fully charged and requires recharging after a few ICG tests, consider replacing it.
- The battery should be removed from the unit and placed in storage if the Cardiograph will not be used for more than one month.
- The use of cardiograph accessories (bar code reader, magnetic card reader, PC card, modem) will deplete battery power at a faster rate. The battery will require more frequent charging if these accessories are used with the cardiograph.
- A fully charged battery stored outside the cardiograph will need to be recharged every three months. If the battery is not charged every three months it will be damaged. A depleted battery will not perform as expected after a full recharge and will eventually require replacement. See *Storing and Charging the Battery* for more information.

9.6 Storing and Charging the Battery

Remove the battery from the Cardiograph if it will be stored for more than 30 days without use. While in storage, the battery will require a full recharge every 3 months. Charge the battery for at least 16 hours. This will ensure that the battery does not completely discharge while in storage. A fully depleted battery will require replacement. The battery life will be prolonged when stored in cooler temperatures, but will be damaged if stored below freezing (0 °C/32°F). Store the battery at a temperature of 40°C (104°F) or lower.

To Store the Battery:

Charge the battery for 16 hours before removing it from the cardiograph. Ensure that the AC power cord is connected to the BioZ Dx and is plugged into a grounded AC power outlet. Check that the green AC power indicator light on the front of the Cardiograph is lit.

Remove the battery from the BioZ Dx and store it in a cool, dry location. For information about removing or replacing the battery, refer to *Replacing the Battery*.

Recharge the battery for 16 hours every 3 months that the battery is in storage.

Charging the Batteries

Charge the batteries whenever the Cardiograph is not in use. The batteries will charge when the BioZ Dx is in use and is connected to AC power, but will charge at a slower rate.

ICG BioZ Dx CARE AND MAINTENANCE

Battery Charge Rates:

If the BioZ Dx is ...	Time to fully charge batteries
Power off	480 minutes
Standby	575 minutes
Active Use	Variable

Check the battery level indicator on the Status Bar to verify that the batteries are fully charged.

9.7 Replacing the Batteries

How often the batteries need to be replaced depends on how well the battery is maintained and how much it is used. If the batteries are fully charged but lose significant power after only a few ICGs, consider replacement. Only use batteries supplied by CardioDynamics.

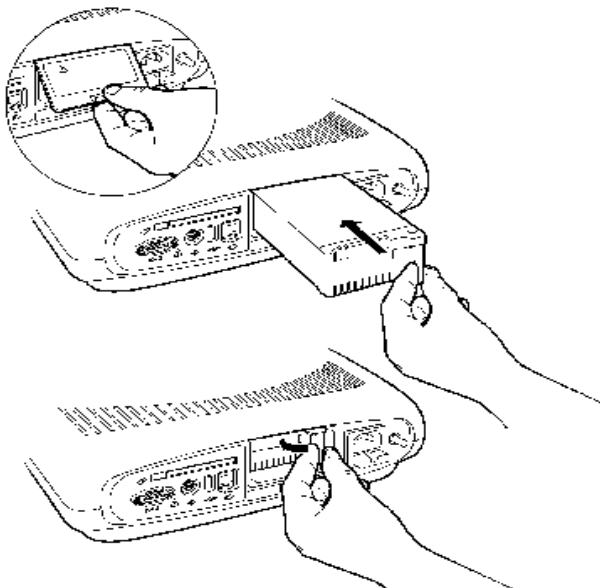


Figure 9-6 Replacing the Battery Packs

To Replace the Battery Packs:

- Disconnect the Cardiograph from AC power and turn the power switch to the OFF position.
- Lift the battery access panel.
- Pull on the batteries to remove.
- Insert the new batteries and replace the battery door.
- Connect the BioZ Dx to an AC power source and turn the power switch to ON. Verify that the green AC indicator is on.
- Set the correct date and time on the cardiograph.
- Charge for at least 24 hours prior to mobile use of the cardiograph.

WARNING:	Properly dispose of or recycle depleted batteries according to local regulations. Do not disassemble, puncture, or incinerate the disposed batteries.
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9.8 Removing and Replacing the AC Fuse

The AC fuse needs to be replaced when the Cardiograph is plugged into AC power, but the green AC power indicator light on the front of the BioZ Dx does not illuminate.

Only use replacement AC fuses with a 1.5 amp (250V) time-delay, the same size and configuration as the original fuse.

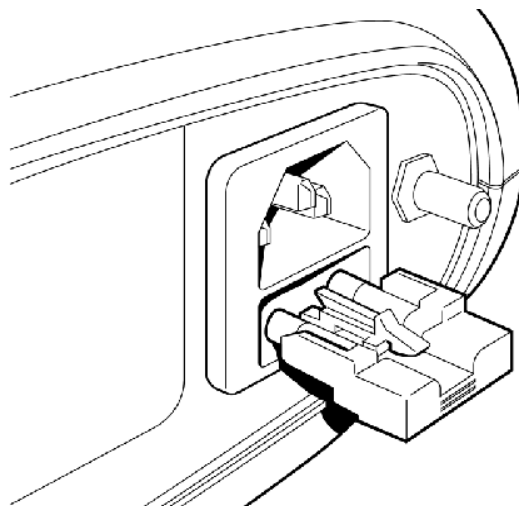


Figure 9-7 Replacing the AC fuse

To Replace the AC Fuse:

- Unplug the Cardiograph from AC power. Pull out the AC power cord from the AC power connector on the rear of the cardiograph.
- Locate the AC fuse, which is directly below the AC power connector.
- Push down on the center tab on the fuse and pull out the fuse from the fuse holder slot.
- Insert the new fuse using the same orientation, with the center tab facing up.
- Push the fuse all the way into the fuse holder slot. The fuse snaps into place.

9.9 Ordering replacement parts

To order replacement parts contact the CardioDynamics Technical Service department at 800-778-4825 and select option 3, or outside of the USA at 858-535-0202, option 3.

10 ICG BioZ Dx SUGGESTED MAINTENANCE SCHEDULE

There are two maintenance checks that should be performed on the Cardiograph, an ICG and NIBP check. See sections 10.1 and 10.2 for the procedure.

- ICG Maintenance Test should be performed **quarterly** or anytime the hemodynamic values are questioned by the Operator.
- NIBP Maintenance Test should be performed **annually** or anytime the blood pressure values are questioned by the Operator.

10.1 ICG Maintenance Test

The BioZ Dx is self-calibrating. The calibration may be verified via the built in ICG tester located in the ICG PIM.

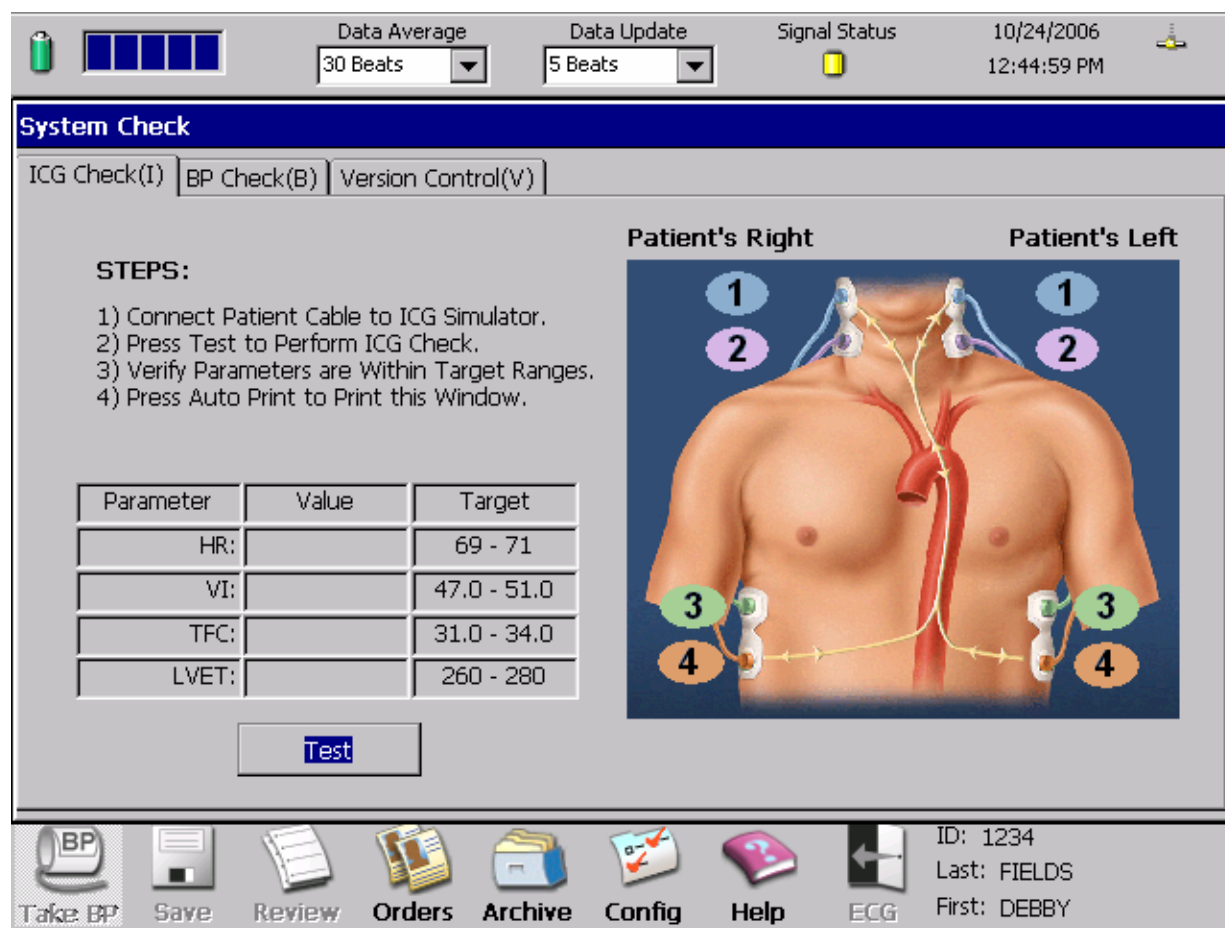


Figure 10-1 ICG Check Screen

To Verify System Calibration:

- Connect Patient Lead Wires to corresponding ICG PIM snap connectors, i.e., left lead wire array to left-sided snaps with the corresponding proper colored and numbered lead wire connector.
- Connect to AC power source and turn Cardiograph ON.
- Press the <Alt> and S keys simultaneously. The ICG Check Screen will be displayed. See Figure 10-1 ICG Check
- Rotate **Trim Knob** to select **TEST** and press **Enter** or the Trim Knob to begin the test
- Verify that the values are within the Target Range as indicated on the screen. Select **Print** button to print an ICG Test Report.

If values are out of target range, contact Technical Support.

10.2 NIBP Maintenance Test

The NIBP module should be tested on an annual basis at minimum. There are four (4) separate tests that require testing: Over Pressure Test, Leak Rate Test, Transducer Accuracy Test, and Blood Pressure Test.

In addition to a blood pressure cuff, the following equipment NOT supplied with the BioZ Dx is required in order to perform the tests: An external pressure tester such as a BioTek NIBP Analyzer, calibrated pressure gauge such as a mercury manometer, hoses and Tee fittings.

Assemble the NIBP Diagnostic Test Set-up as indicated in the following diagram:

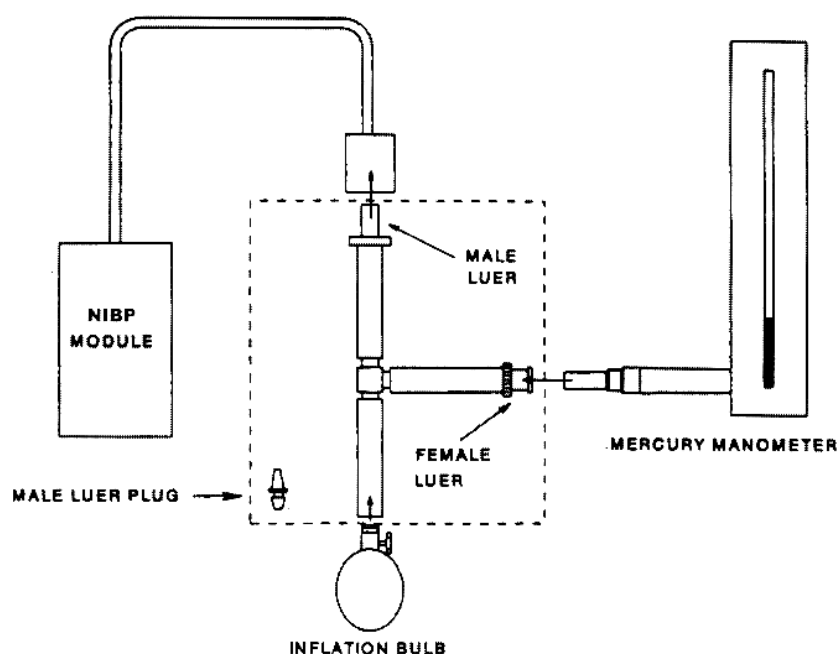


Figure 10-2 Example NIBP Test Set-up

NOTE:	The setup and procedures in this section represents only one way of performing the recommended maintenance checks of the blood pressure module. There are other automated testing devices and procedures that may be substituted for the equipment and/or procedures indicated in this manual.
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To Perform a BP Check:

- Press the **Alt** and **S** keys simultaneously to access the System Check Screen. Select the **BP Check** tab by pressing **Alt** and **B** keys simultaneously.

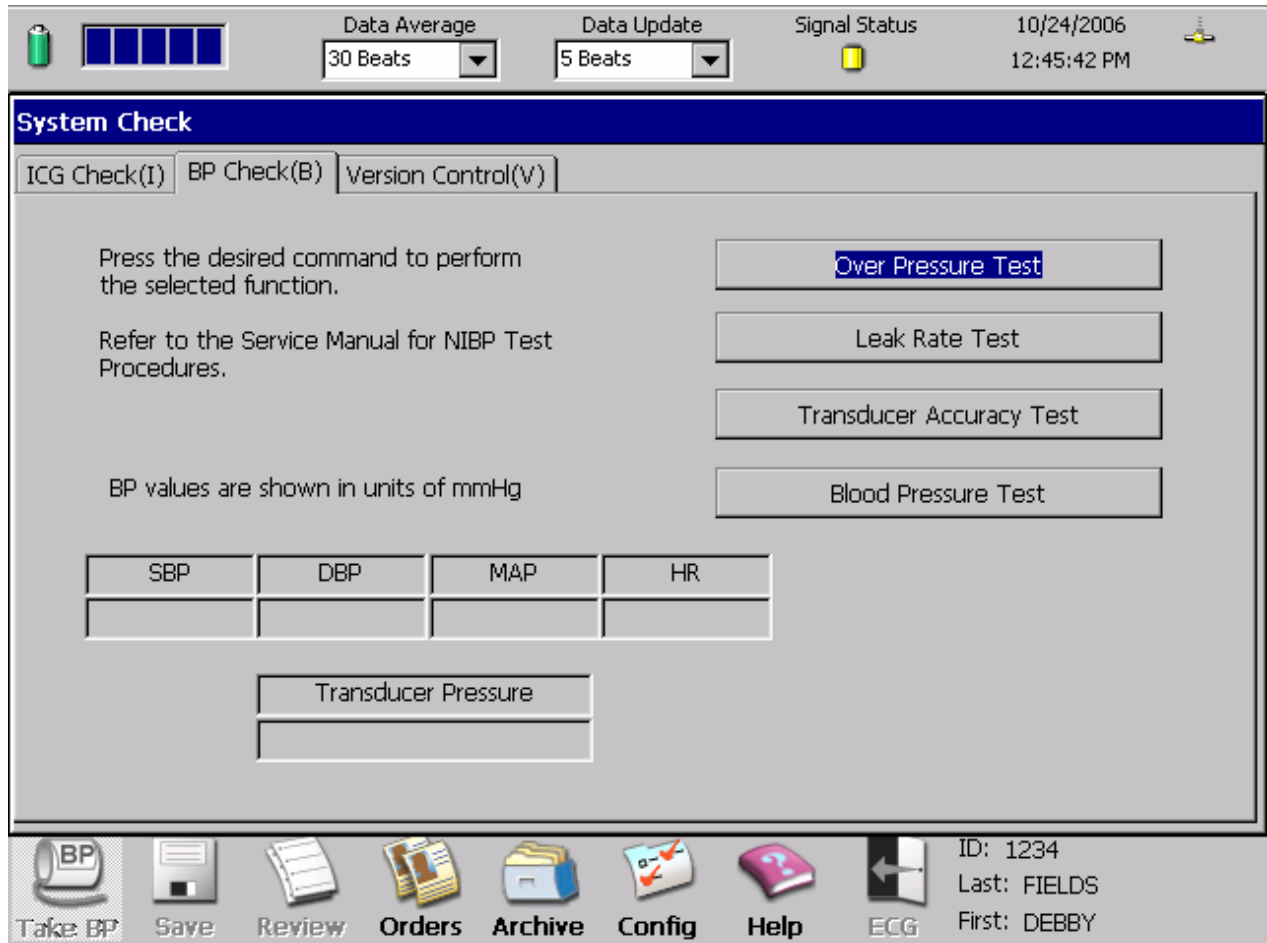


Figure 10-3 Blood Pressure Check Screen

- Specifications for these Blood Pressure Tests vary depending on the model Cardiograph and PIM your facility has. Contact CardioDynamics Technical Services (800-778-4825 opt. #3) to obtain specifications for your specific model

10.3 Version Control Check

It is recommended that the Version Control Check be performed after a software upgrade or if the operator is unable to resolve a PIM communication error. No input is required by the operator, simply pressing the “Version Control(V)” tab will initiate the check.

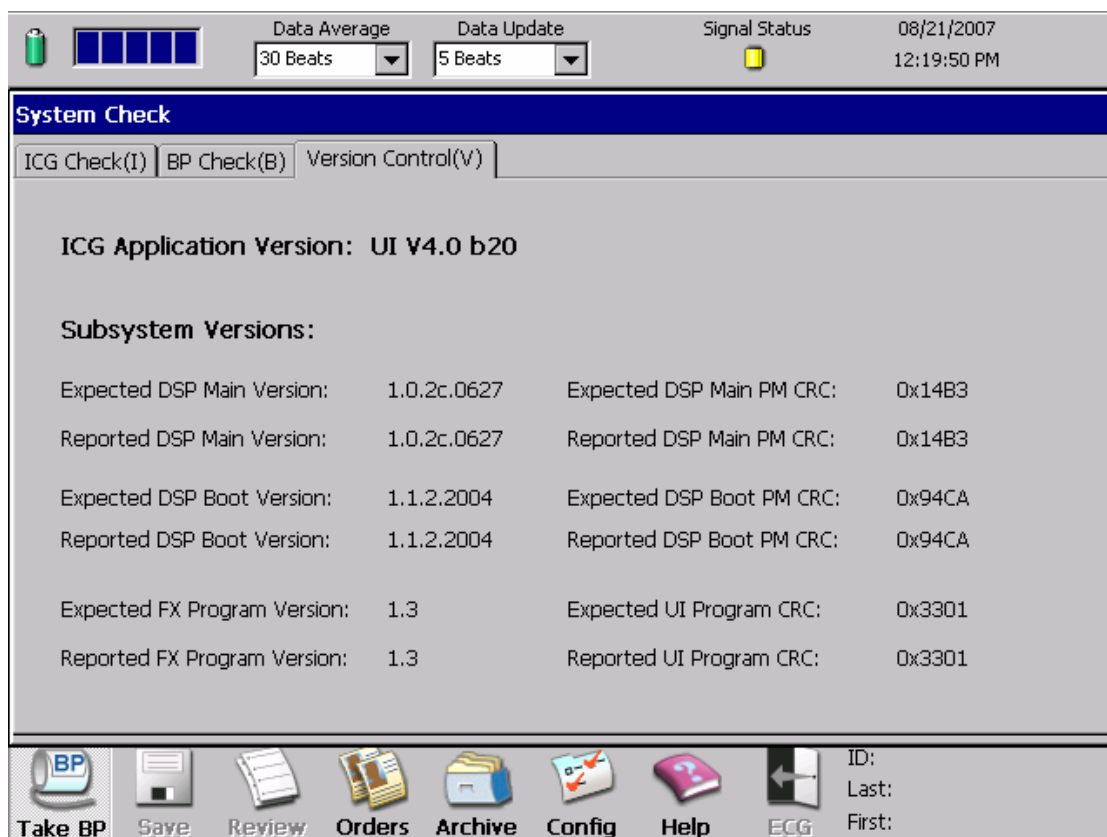


Figure 10-4 Version Control Check Screen

11 SAFETY TESTS

This section explains tests of the cardiograph's electrical safety. Use the procedures called out by the manufacturer of the safety analyzer in use.

- Test both Normal and Reverse polarity line connections for each test, and record the worst-case value.
- If a ground reference point is needed for the testing, use the metal grounding stud on the back of the cardiograph.

11.1 Safety Test S1 - Earth Leakage

To check for leaks in the ground wire for the AC power cord.

Normal Condition with both AC line connections intact:

- $\leq 300 \mu\text{A}$ (UL, 120 VAC)
- $\leq 500 \mu\text{A}$ (IEC, 240 VAC)

Single Fault Condition with one AC line connection open:

- $\leq 1000 \mu\text{A}$

11.2 Safety Test S2 - Protective Earth Resistance

Impedance of protective earth ground:

- $\leq 200 \text{ m}\Omega$

11.3 Safety Test S3 - Leads Leakage Current

Leakage from Source or into Sink patient leads (Applied Parts)

Source

Normal Condition with both AC line connections and earth ground intact:

- $\leq 10 \mu\text{A}$

Single Fault Condition with separate open neutral and open earth, each in turn:

- $\leq 50 \mu\text{A}$

Sink

Single Fault Condition with AC Mains voltage on Applied Parts (both AC line connections and earth ground intact).

- $\leq 50 \mu\text{A}$

NOMINAL SPECIFICATIONS

12 NOMINAL SPECIFICATIONS

The BioZ Dx has input protection against defibrillators and electro-surgical devices. The Cardiograph is designed to meet the following specifications. Contact Technical Support for information regarding use in conditions other than specified.

Component	Physical Specifications / Technical Information
<p>System: (ICG BioZ Dx and PIM)</p>	<p>Storage Temperature and Humidity Range: 0 °C to 50 °C (32 °F to 122 °F), 15% to 90% Relative Humidity (RH, non condensing)</p> <p>Storage Altitude: 15,000 ft. (4550 m)</p> <p>Operating Temperature and Humidity Range: 10 °C to 40 °C (50 °F to 104 °F) 15% to 80% Relative Humidity (RH, non condensing)</p> <p>Operating Altitude Range: -650 ft. (-198 m) to 5,350 ft (1,631 m)</p>
<p>Cardiograph</p>	<p>Physical Dimensions: 12.2 x 15.3 x 6.9 in (31.0 x 38.8 x 17.6 cm)</p> <p>Weight: 16.3 lbs. (7.4 kg)</p> <p>Display: 640 x 480 pixel resolution color TFT display</p> <p>Printer Type: High-resolution, digital-array printer using thermal-sensitive paper.</p> <p>Printer Resolution: 200 dpi (voltage axis) by 500 dpi (time axis)</p> <p>Battery Type: Rechargeable Lead-acid</p> <p>Battery Capacity: Typically 30 ICG report capacity</p> <p>Battery Charge time: 480 minutes (eight hours) to full capacity</p> <p>Power Requirements: 100-240 VAC, 50-60 Hz, 65 VA max</p> <p>Meets the following requirements for safety and performance:</p> <ul style="list-style-type: none"> • IEC 60601-1(Class I Type BF) • IEC 60601-1-2(CISPR 11, Group 1, Class A) • IEC 60601-2-25 • UL 2601 • CAN/CSA-C22.2 No. 601.1 • JIST 1202 • AAMI EC11

Component	Physical Specifications / Technical Information
ICG PIM	<p>Physical Dimensions: 7.638 x 4.528 x 2.677 in (19.4 x 11.5 x 6.8 cm)</p> <p>Weight: 1.8 lbs (0.82Kg)</p> <p>Measurement Current: 2.5mA, rms $\pm 10\%$; 70 kHz $\pm 10\%$.</p> <p>Meets the applicable sections of the following requirements for safety and performance:</p> <ul style="list-style-type: none"> • IEC 60601-1 (Defibrillation-proof Type BF applied parts) • IEC 60601-1-2 (CISPR 11, Group I, Class A) • IEC 60601-2-25 • UL 2601 • CAN/CSA – C22.2 No. 601.1
ICG Patient Cable and Lead Wires	<p>Patient Cable Length: 8 ft (2.44 m)</p> <p>Lead Wire(s) Length: 27-48 in. (69 – 122 cm)</p> <p>Integrated Patient Cable Defibrillation Protection</p> <p>Meets the applicable sections of AAMI EC-53</p>
Cart	<p>The cart has been tested for stability using the IEC 60601-1 test protocol.</p> <p>Dimensions: 16.37 inches (width) x 23.6 inches (depth) x 36.6 inches (height) (416 x 600 x 930 mm)</p> <p>Cart Weight 46.29 pounds (21 Kilograms)</p>

NOMINAL SPECIFICATIONS

Component	Physical Specifications / Technical Information
Noninvasive Integrated Blood Pressure Module	<p>Method of Measurement: Oscillometric. Diastolic values correspond to Phase 5 Korotkoff sounds</p> <p>Systolic Range: 40 – 260 mm Hg</p> <p>Diastolic Range: 20 – 200 mm Hg</p> <p>Mean Arterial Range: 27 – 220 mm Hg</p> <p>HR Range: 40 – 250 BPM (beats per minute)</p> <p>Cuff Deflate Rate: Deflation Step Rate varies with HR, cuff pressure, and cuff volume</p> <p>Initial Inflation Pressure: 160 mm Hg (default). Variable from 120 to 280 mm Hg</p> <p>Transducer Accuracy: ± 3 mm Hg under normal operating conditions (Possible slight reduction in accuracy for temperatures above 50 °C up to 60 °C.)</p> <p>Patient Safety:</p> <ul style="list-style-type: none"> • Maximum cuff inflation time is limited to 50 seconds • Duration of blood pressure reading is limited to 130 seconds <p>Additional redundant safety circuitry oversees normal operation and will override to abort a reading if:</p> <ul style="list-style-type: none"> • Cuff pressure exceeds 300 mm Hg • The cuff has been inflated for 180 seconds <p>The Module meets all relevant parts of the following safety standards:</p> <ul style="list-style-type: none"> • IEC-60601-1 • IEC-60601-2-30 • AAMI SP10 • EN1060-1 • EN1060-3 • UL 2601 • CAN/CSA – C22.2 No. 601.1

12.1 Electromagnetic Compatibility (EMC)

Electromagnetic compatibility with surrounding devices should be assessed when using the cardiograph.

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the Cardiograph according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

The BioZ Dx should not be used adjacent to, or stacked on top of other equipment. If the Cardiograph must be used adjacent to or stacked on top of other equipment, verify that the BioZ Dx operates in an acceptable manner in the configuration in which it will be used.

Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment.

13 Z Care® STANDARD WARRANTY

CardioDynamics International Corporation (“CDIC”) warrants that the BioZ Dx® System (“System”) and the System Software (“Software”) shall be free from errors / defects in materials, workmanship, and programming that cause the System not to function in accordance with the accompanying written specifications provided with the System at the time of installation. *CDIC will provide this Warranty for a period of sixty (60) months from the original CDIC date of shipment.*

This Warranty shall include all options and accessories purchased with the System except the external patient cable(s), power cords, data cables, PCMCIA memory cards, removable battery, the external inflatable blood pressure cuff(s) and hose(s), which shall be covered for ninety (90) days from the original CDIC invoice date.

If during the warranty period Buyer uses the Products as directed in the Operators Manual but the Products fail to conform to their specifications, CDIC will repair or replace the Products, at CDIC’s sole election. CDIC MAKES NO OTHER REPRESENTATIONS OR WARRANTY, WHETHER EXPRESS OR IMPLIED, AS TO MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ARISING FROM COURSE OF DEALING OR USAGE OF TRADE. CDIC SHALL NOT BE LIABLE TO BUYER OR ANY OTHER INDIVIDUAL OR ENTITY FOR ACTS OF GOD, PROPERTY DAMAGE, LOSS OF USE, INTERRUPTION OF BUSINESS, LOST PROFITS, LOST DATA OR ANY OTHER SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RELATING TO USE OF THE PRODUCTS, HOWEVER CAUSED, WHETHER FOR BREACH OF WARRANTY, CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE. IN NO EVENT SHALL CDIC’S LIABILITY IN CONNECTION WITH THE PRODUCTS EXCEED THE PRICE PAID THEREFOR BY THE BUYER. Warranty is made on original product purchase only and is not transferable. CDIC products are designed, tested and warranted as complete systems consisting of integrated hardware and consumables. As a result, CDIC cannot guarantee or warrant the accuracy or results of tests done with CDIC hardware products when third party consumables (such as sensors) are used to perform tests with such products. Any attempt to modify any CDIC product from its original condition as delivered to Buyer, or any use or integration with or into a CDIC product of parts or components not approved by CDIC will void the warranty for that product.

CDIC’s and/or its Distributors’ liability and obligation, and the End User’s sole remedy shall be, at CDIC’s option, to either repair or replace software and/or System or any part thereof. It is the responsibility of the End User to notify CDIC or CDIC’s Distributor (if CDIC requests the End User to notify its Distributor) by telephone or in writing of any problem experienced by the End User within the Warranty Period and no later than thirty (30) days after the expiration of the warranty period.

This Warranty does NOT apply to fuses and/or cardiograph paper used in conjunction with the System.

Warranty Coverage:

- Customer / Technical Support is available Monday through Friday, 7 a.m. to 4 p.m. Pacific Time, at 800-778-4825 or 858-535-0202, option 3.
- CDIC will provide a loaner or replacement unit (equivalent or similar to purchased unit) within two (2) business days (U.S. Customers only) after it has been determined that the purchased unit needs repair. This determination needs to be made before 3:00 p.m. Pacific Time in order for the

two (2) day loaner/replacement unit provision, and is dependent upon delivery services available to End User's location.

- CDIC will repair or replace any components of the System that cause the System to not function in accordance with the Operators/Service manual and/or instructions for use provided with the System at time of sale.
- CDIC will provide free shipping and freight charges for original and loaner/replacement unit exchanges (UPS Ground or equivalent).
- CDIC will provide subsequent operational software upgrade disks and installation instructions at no charge to the customer.

Warranty Coverage is void if:

- The System and/or Software has been maintained, repaired, modified or altered by any person other than an authorized CDIC representative or without prior approval from an authorized CDIC representative.
- The System and/or Software has not been properly operated or maintained in accordance with CDIC's then applicable written operating and maintenance manuals.
- The configuration of the System and/or Software has been altered by, but not limited to, the addition of any other computer software to the System.
- The failure of the System and/or Software has resulted from acts of God, accident, abuse, misapplication, or negligence.
- **Note:** There are no user-serviceable components in the BioZ Dx[®]. All units must be returned to CDIC for repair or replacement during the warranty period.

CDIC does not warrant (either expressed or implied) the correctness or validity of any output information or data provided by the System, including, but not limited to, any information relating to any medical diagnosis/treatment or to the health and safety needs of patients. CDIC does not warrant that any output of the System will meet the standards or requirements of the End User's medical practice. End User expressly acknowledges that End User is solely responsible for verifying that any results produced by the System are free from error and suitable for the applications for which they are to be used.

14 SOFTWARE LICENSE AGREEMENT

By this agreement, CardioDynamics International Corporation, a California Corporation (Hereinafter referred to as “Licensor” in this agreement) agrees to grant, and the end User (hereafter referred to as “Licensee” in this agreement), agrees to accept the following terms and conditions described in this agreement (including User documentation).

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15 Appendix A. HEMODYNAMIC PARAMETERS

Note 1: The normal/mid ranges defined in the BioZ are derived and/or obtained from one or more sources:

- 1) from the mean CI, HR, and MAP \pm 2 SD, as published by Milnor, William R., M.D. *Hemodynamics*. (1982). Baltimore: Williams & Wilkins.
- 2) Darovic, G.O. *Hemodynamic Monitoring: Invasive and Noninvasive Clinical Application*. 2nd Ed. (1995). W.B. Saunders Company.
- 3) Historical based on predicate ICG devices.

Therefore, values lying within the normal/mid range are not necessarily indicative of the optimal hemodynamic state for a given patient. Patients must be assessed based on their individual physiologic state.

Note 2: Displayed and printed parameter values that fall outside of the maximum and minimum limits will be displayed at their respective limits as defined in the table below under the column headings MIN and MAX.

Parameter (Abbrev)	Units	Normal/Mid Range (Note 1)	MIN (Note 2)	MAX (Note 2)
Heart Rate (HR)	beats /min	58 – 86	40	250
Systolic Blood Pressure (SBP)	mm Hg	100 – 140	40	260
Diastolic Blood Pressure (DBP)	mm Hg	60 – 90	20	200
Mean Arterial Blood Pressure (MAP)	mm Hg	70 – 105	27	220
Stroke Index (SI)	mL /m ²	35 – 65	5	125
Stroke Volume (SV)	mL	Variable depending on Body Surface Area (BSA)	5	250
Cardiac Index (CI)	L /min /m ²	2.5 – 4.2	1.4	15.0
Cardiac Output (CO)	L /min	Variable depending on Body Surface Area (BSA)	1.4	15.0
Systemic Vascular Resistance (SVR)	dynes sec cm ⁻⁵	770 – 1,500	1	3500
Systemic Vascular Resistance Index (SVRI)	dynes sec cm ⁻⁵ m ²	1,680 – 2,580	1	11000
Left Cardiac Work Index (LCWI)	kg m /m ²	3.0 – 5.5	0.1	25.0
Acceleration Index (ACI)	/100 /sec ²	Female: 90 – 170 Male: 70 – 150	0	400
Velocity Index (VI)	/1000 /sec	33 – 65	6	200

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Parameter (Abbrev)	Units	Normal/Mid Range (Note 1)	MIN (Note 2)	MAX (Note 2)
Thoracic Fluid Content (TFC)	/kOhms	Female: 21.0 – 37.0 Male: 30.0 – 50.0	15.0	143.0
Thoracic Fluid Content Index (TFCI)	/kOhms /m ²	Female: 12.0 – 21.0 Male: 15.0 – 25.0	5.0	150.0
Systolic Time Ratio (STR)	no units	0.30 – 0.50	0.10	1.50
Systolic Time Ratio Index (STRI)	/sec ¹	0.3 – 0.5	0.1	1.5
Systemic Stroke Resistance Index (SSRI)	dyne sec cm ⁻⁸ L min ⁻¹ m ²	110.1 – 165.1	1.0	1250.0
Pre Ejection Period (PEP)	msec	NA	70	300
Left Ventricular Ejection Time (LVET)	msec	NA	120	450
Total Arterial Compliance (TAC)	mL /mmHg ¹	13.0 – 28.0	0.1	80.0
Total Arterial Compliance Index (TACI)	mL / m ² /mmHg ¹	8.0 – 14.0	0.1	40.0
Left Stroke Work Index (LSWI)	g m /m ²	47.2 – 70.8	1.0	270.0
Heather Index (HI)	Ohms /s ²	NA	0.2	30.0
Q-C Interval (QC)	msec	NA	100	350
Base Impedance (Z ₀)	Ohms	Female: 27.0 – 48.0 Male: 20.0 – 33.0	7.0	67.0

16 Appendix B. GLOSSARY OF TERMS

ACCELERATION INDEX (ACI) [$100^{-1} \text{ sec}^{-2}$]: An index of the peak acceleration of aortic blood flow. The peak acceleration takes place approximately 15-30 msec after the opening of the aortic valve. ACI is a measure of the true inotropic state of the heart and is fairly independent of AFTERLOAD. The normal ranges for supine, resting adults are 70 – 150 x $100^{-1} \text{ sec}^{-2}$ for males and 90 – 170 x $100^{-1} \text{ sec}^{-2}$ for females.

$$\text{ACI} = 100 * (d^2Z/dt^2)/Z_o$$

ACI: See ACCELERATION INDEX.

AFTERLOAD: Represents the forces that the ventricle must overcome to deliver blood into the systemic vasculature during contraction. The primary component of afterload is vasoactivity, represented by Systemic Vascular Resistance (SVR). The secondary component of AFTERLOAD is blood viscosity. AFTERLOAD is a systolic phenomenon.

BASE IMPEDANCE (Z_o) [Ohm]: The mean electrical impedance of the thoracic cavity. Also known as THORACIC FLUID INDEX (TFI).

BODY SURFACE AREA (BSA) [m^2]: BSA is estimated by the DuBois and DuBois formula to be:

$$\text{BSA} = W^{0.425} \times H^{0.725} \times 0.007184$$

where H is the patient's height in cm, and W is their weight in kg.

BSA: See BODY SURFACE AREA.

CARDIAC INDEX (CI) [$\text{l min}^{-1} \text{ m}^{-2}$]: The value of CARDIAC OUTPUT (CO) indexed by the BODY SURFACE AREA (BSA). The normal range for supine, resting adults is 2.5-4.2 $\text{l min}^{-1} \text{ m}^{-2}$.

$$\text{CI} = \text{CO} / \text{BSA}$$

CARDIAC OUTPUT (CO) [l/min]: The total volume of blood pumped by the heart in one minute.

$$\text{CO} = \text{SV} * \text{HR}$$

CENTRAL VENOUS PRESSURE (CVP) [mmHg]: The pressure at the output of the systemic vasculature (filling pressure of the right heart). Normal mean value is 6 mmHg.

CI: See CARDIAC INDEX.

CO: See CARDIAC OUTPUT.

CONTRACTILITY: The rate of shortening of the myocardial muscle fibers in time. Contractility is a systolic phenomenon.

CVP: See CENTRAL VENOUS PRESSURE.

DIASTOLIC BLOOD PRESSURE (DBP) [mmHg]: The minimum arterial pressure (at the end of diastole).

DELTA Z (IMPEDANCE) WAVEFORM (deltaZ): The change in the thoracic base impedance due to the cardiac cycle.

dZ/dt [Ohms/sec]: The first derivative of the deltaZ waveform with respect to time. dZ/dt_{max} corresponds to the peak blood velocity in the aorta during systole.

d²Z/dt² [Ohms/sec²]: The second derivative of the deltaZ waveform with respect to time. d^2Z/dt^2_{max} corresponds to the peak blood acceleration in the aorta during systole.

ELECTRICAL BIOIMPEDANCE (EB): A noninvasive technique for converting the measurement of electrical conductivity of a body segment into the blood flow through the segment and the content of fluids within the segment.

HEART RATE (HR) [beats min⁻¹]: The number of beats performed by the heart in one minute.

HEATHER INDEX (HI) [Ohms /s²]: Ratio of maximum impedance change to the QC Interval.

$$HI = dZ / dt_{\max} * 1000 / (QC)$$

HEMODYNAMIC MODULATORS: The parameters that affect (modulate) blood flow and blood pressure.

HI: See HEATHER INDEX.

HR: See HEART RATE.

HYPERDYNAMIC STATE: The supernormal or abnormally high value for a specific condition.

HYPERTENSION: A state where the mean arterial pressure exceeds 100 mmHg (supine, resting adults).

HYPODYNAMIC STATE: The infranormal or abnormally low value for a specific condition.

HYPOTENSION: A state where the mean arterial pressure is lower than 84 mmHg (supine, resting adults).

INOTROPY: Myocardial contractility or, the force of contraction. Normoinotropy is an adequate (normal) inotropic state; hypoinotropy is an inadequate (infranormal) inotropic state [corrected therapeutically through the use of positive inotropic therapy/support]; hyperinotropy is an excessive (supranormal) level of inotropic state [corrected therapeutically through the use of negative inotropic therapy].

LCW: See LEFT CARDIAC WORK.

LCWI: See LEFT CARDIAC WORK INDEX.

LEFT CARDIAC WORK (LCW) [kg m]: The measure of work which the left ventricle must expend to pump blood; it is a product of the ventricular pressure contribution (MAP - PAOP), CO, and a constant (unit conversion factor). LCW is proportional to the myocardial oxygen consumption. The normal range for supine, resting adults is, 5.4 – 10.0 kg m.

$$LCW = (MAP - PAOP) * CO * 0.0144$$

LEFT CARDIAC WORK INDEX (LCWI) [kg m m⁻²]: A value of LEFT CARDIAC WORK (LCW) indexed by the BODY SURFACE AREA (BSA). LCWI is a product of the ventricular pressure contribution (MAP - PAOP), CI, and a constant. The normal range for supine, resting adults, 3.0 - 5.5 kg m m⁻².

$$LCWI = (MAP - PAOP) * CI * 0.0144$$

LEFT STROKE WORK INDEX (LSWI) [g m m⁻²]: The measure of work which the left ventricle must expend to pump blood per heart beat; it is a product of the ventricular pressure contribution (MAP - PAOP), SI, and a constant. The normal range for LSWI, based on the ideal hemodynamic state where, SI = 50 ml/m², MAP = 92 mmHg, PAOP = 10 mmHg is: 47.2 – 70.8 g m m⁻².

LEFT VENTRICULAR EJECTION TIME (LVET) [msec]: The time between the opening and closing of the aortic valve.

Appendix B. GLOSSARY OF TERMS

LSWI: See LEFT STROKE WORK INDEX.

MEAN ARTERIAL PRESSURE (MAP) [mmHg]: A measure of the average arterial perfusion pressure, which determines blood flow to the tissues.

NORMODYNAMIC STATE: When the CARDIAC INDEX (CI) is within its respective normal range (normodynamic = adequate global blood flow level for a specific condition).

NORMOTENSION: A state where mean arterial pressure (MAP) is within a normal range. The normal MAP range for supine, resting adults is 84 - 100 mmHg.

PAOP: See PULMONARY ARTERY OCCLUDED PRESSURE.

PEP: See PRE-EJECTION PERIOD.

PRE-EJECTION PERIOD (PEP) [msec]: The period of isovolumetric ventricular contraction.

PULMONARY ARTERY OCCLUDED PRESSURE (PAOP) [mmHg]: The filling pressure of the left heart. Normal, mean value is 10 mmHg.

Q-C INTERVAL (QC) [msec]: The interval from start of left ventricular depolarization to the point of maximum impedance change.

$$QC = (q_time - c_time) * 1000 / process_rate$$

QC: See Q-C INTERVAL.

SI: See STROKE INDEX.

SSRI: See STROKE SYSTEMIC RESISTANCE INDEX.

SSVRI: See STROKE SYSTEMIC RESISTANCE INDEX. Same as SSRI

STRI: See SYSTOLIC TIME RATIO INDEX.

STROKE INDEX (SI) [ml/m²]: STROKE VOLUME indexed by BODY SURFACE AREA.

$$SI = SV / BSA$$

STROKE SYSTEMIC RESISTANCE INDEX (SSRI) [dyne sec cm⁻⁸ L min⁻¹ m²]: A measure of afterload on a per beat basis. It is calculated by substituting SI for CI in the SVRI equation. [((MAP - CVP)/SI) x 80]. The normal range for SSRI, based on the ideal hemodynamic state where, SI = 50 ml/m², MAP = 92 mmHg, CVP = 6 mmHg is: 110 – 165. Note: Also referred to as Stroke Systemic Vascular Resistance Index (SSVRI).

STROKE VOLUME (SV) [ml]: The volume of blood delivered by the heart into the vasculature in one beat.

SV: See STROKE VOLUME.

SVR: See SYSTEMIC VASCULAR RESISTANCE.

SVRI: See SYSTEMIC VASCULAR RESISTANCE INDEX.

SYSTEMIC VASCULAR RESISTANCE (SVR) [dyne sec cm⁻⁵]: The vascular resistance of the systemic vasculature as seen by the left ventricle (afterload). Normal range for a supine, resting adult is: 770 – 1500 dyne sec cm⁻⁵.

$$SVR = 80 * (MAP - CVP) / CO$$

SYSTEMIC VASCULAR RESISTANCE INDEX (SVRI) [dyne sec cm⁻⁵ m²]: SVRI represents the primary component of afterload. The normal range of SVRI for a supine, resting adult is: 1680 to 2580 dyne sec cm⁻⁵ m².

$$SVRI = 80 * (MAP - CVP) / CI$$

SYSTOLIC BLOOD PRESSURE (SBP) [mmHg]: The highest level of arterial blood pressure reached with each heart beat.

SYSTOLIC TIME RATIO (STR): Calculated by the systolic time intervals (STI) of PRE-EJECTION PERIOD (PEP) and LEFT VENTRICULAR EJECTION TIME (LVET).

$$STR = PEP / LVET$$

SYSTOLIC TIME RATIO INDEX (STRI) [/sec¹]: The ratio of the STR to R-R Interval.

$$STRI = STR / R-R \text{ interval}$$

TAC: See TOTAL ARTERIAL COMPLIANCE.

TACI: See TOTAL ARTERIAL COMPLIANCE INDEX.

TEB: See THORACIC ELECTRICAL BIOIMPEDANCE.

TFC: See THORACIC FLUID CONTENT.

TFCI: See THORACIC FLUID CONTENT INDEX.

TFI: See THORACIC FLUID INDEX.

THORACIC ELECTRICAL BIOIMPEDANCE (TEB): The special utilization of Electrical Bioimpedance for thoracic measurements, producing a measurement of global blood flow (CO/CI, SV/SI), Thoracic Fluid Content (TFC), base impedance and the parameters of left ventricular performance – VI and ACI, (Velocity Index, Acceleration Index).

THORACIC FLUID CONTENT (TFC) [kOhm⁻¹]: The total conductivity of the thorax, representing parallel conductivity contributions of three compartments: intravascular, intra-alveolar and interstitial. The normal ranges are 30 – 50 for males and 21 – 37 for females. Excessive TFC value indicates an excess in thoracic fluids, however, it does not specify if the fluids are in the intravascular, intra-alveolar or interstitial compartment(s).

$$TFC = 1000 / Z_o$$

THORACIC FLUID CONTENT INDEX (TFCI) [kOhm⁻¹ / m²]:

$$TFCI = 1000 / (TFI * BSA)$$

THORACIC FLUID INDEX (TFI) [Ohm]: See BASE IMPEDANCE.

TOTAL ARTERIAL COMPLIANCE (TAC) [mL mmHg⁻¹]:

$$TAC = 10 * SV / (SBP-DBP)$$

TOTAL ARTERIAL COMPLIANCE INDEX (TACI) [mL m⁻² mmHg⁻¹]:

$$TACI = 10 * SI / (SBP-DBP)$$

VASOACTIVITY: Vasoactivity is a change in vessel diameter, controlling vascular resistance of the vessel's blood flow rate.

Appendix B. GLOSSARY OF TERMS

VELOCITY INDEX (VI) [$1000^{-1} \text{ sec}^{-1}$]: Is a measurement of normalized peak aortic flow. VI is a preload/volume-dependent measure of contractility. The normal range for supine, resting adults is: 33 – 65 x $1000^{-1} \text{ sec}^{-1}$.

$$VI = 1000 * (dZ/dt) / Z_o$$

VI: See VELOCITY INDEX.

WEDGE PRESSURE: A term that is often used simultaneously, although incorrectly, for Pulmonary Artery Occluded Pressure (PAOP). This term dates back to times before the introduction of the occlusive balloon. At that time, the catheter was actually ‘wedged’ into a small pulmonary artery in order to measure the filling pressure of the left heart.

Z₀: See BASE IMPEDANCE.

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