RECOVER BP

IABP/VAD System

Operator's Manual

ABIOMED®

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IMPORTANT NOTICE: Read this ***entire*** manual before using the RECOVER BP IABP/VAD System. The RECOVER BP IABP/VAD System is to be used only in accordance with this manual and in conjunction with the *RECOVER BP Intra-Aortic Balloon Catheter Instructions for Use ****[document number]*.

Information contained in this document is subject to change without notice.

Contents

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Introduction

This manual provides instructions for operating the RECOVER BP IABP/VAD System (RECOVER BP System or System). It is intended to be used in conjunction with the *RECOVER BP Intra-Aortic Balloon Catheter Instructions for Use ****[add document number]*.

The following information summarizes the contents of each section:

- **Section 1 (Warnings and Cautions)** lists the warnings and cautions pertaining to the use of the RECOVER BP System.
- **Section 2 (Indications, Contraindications, and Potential Adverse Events)** discusses indications for use of the System and potential adverse events that may be associated with it.
- **Section 3 (The RECOVER BP IABP/VAD System)** provides an overview of the System and associated products.
- **Section 4 (Using the RECOVER BP Console)** describes the features, connections, and layout of the RECOVER BP Console (Console).
- **Section 5 (System Status and Settings)** describes the handling of tasks common to both IABP and VAD support.
- **Section 6 (IABP Support)** describes the procedures for providing IABP support.
- **Section 7 (VAD Support)** describes the procedures for providing VAD support.
- **Section 8 (Emergency System Operation [ESO])** describes Emergency System Operation for both IABP and VAD support.
- **Section 9 (Installation and Maintenance)** provides information on installation, cleaning, and preventive maintenance.
- **Section 10 (Abbreviations and Symbols)** explains the symbols and abbreviations used on the System.
- **Section 11 (System Specifications)** provides technical information pertaining to the System.

1 Warnings and Cautions

Contents

Warnings

NOTE: A ***warning*** indicates a situation that could result in injury or death.

- The RECOVER BP System is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. It is also not suitable for use in an oxygen-enriched atmosphere.

- The RECOVER BP Console does not contain any user-serviceable parts. To reduce the risk of electric shock, do ***NOT*** attempt to remove the Console housing or to replace the Console Battery.

- Do ***NOT*** connect items to the RECOVER BP System that are not specified as part of the System. All equipment intended for connection to signal input, signal output, or other connectors must comply with the relevant IEC standard (IEC 60950 for IT equipment and IEC 60601 series for medical electrical equipment).

  In addition, all such combinations (systems) must comply with IEC 60601-1-1, *Safety requirements for medical electrical systems.* Equipment not complying with IEC 60601-1 must be kept at least 1.5 m outside the patient environment, which is defined in the standard and in the System Specifications section of this manual.

- Do ***NOT*** simultaneously touch the patient and any part of the RECOVER BP System exposed by removal, without the use of a tool, of a connector or cover. In addition, do ***NOT*** simultaneously touch the patient and any other equipment.

- Power the Console using its internal battery if the integrity of the protective earth conductor is questionable.

- Per IEC 60601-1-1: Enclosure leakage current measured from or between parts of the RECOVER BP System within the patient environment must ***NOT*** exceed 0.1 mA. Enclosure leakage current in the event of interruption of any non-permanently installed protective earth conductor must ***NOT*** exceed 0.5 mA.

- Per IEC 60601-1-1: Patient leakage current must ***NOT*** exceed 0.01 mA.

- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the Electromagnetic Compatibility (EMC) information provided in the accompanying documents.

- Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

- The Equipment or System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Equipment or System should be observed to verify normal operation in the configuration in which it will be used.

- A patient monitor ***must*** be provided and used to ***continuously monitor*** patient physiological parameters. Do ***NOT*** rely solely on the System alarms to notify you of life-threatening conditions.

- Be sure to follow the warnings and cautions on the high-pressure gas (helium) cylinder. Observe all DOT and IATA regulations for Dangerous Goods/Hazardous Materials when transporting a Console containing a helium cylinder. Only personnel trained in the handling of high-pressure gas cylinders should install or replace the helium cylinder.

- Use only original accessories and replacement parts supplied by ABIOMED. Use of any other accessories or parts can endanger the patient.

- Do ***NOT*** reuse single-use devices.

- The RECOVER BP System is intended for use only by personnel trained in accordance with the ABIOMED® Training Program.

- Do ***NOT*** operate the RECOVER BP System near a Magnetic Resonance Imaging (MRI) machine.

- If the pressure trigger threshold is changed, evaluate inflation and deflation timing and make adjustments if necessary.

- Do ***NOT*** use Internal trigger source while the patient is producing cardiac output.

- If the heart rate varies by more than 10 beats per minute (bpm) within X seconds, evaluate inflation and deflation timing and make adjustments if necessary.

- Pumping an IAB that has a leak can result in: (1) a blood clot in the IAB that may require surgical removal of the IAB, and (2) air embolism.

- Due to the potential for thrombus formation, an IAB must ***NOT*** remain dormant.

- Do ***NOT*** place an IAB patient in a hyperbaric chamber.

- Do ***NOT*** use Auto timing when the patient's heart rate is greater than 200 bpm.

- Be extremely careful when a defibrillator is used on a patient. Dangerous high voltage is present during defibrillation. Do ***NOT*** touch the Console, patient, table, accessories, cables, or any connected equipment.

- Do ***NOT*** use pressure triggering while arrhythmia is present.

- When pressure triggering is used, adjust deflation to be complete at the upstroke of systole.

- Do ***NOT*** leave an IABP patient unattended.

Cautions

NOTE: A ***caution*** indicates a situation in which equipment may malfunction, be damaged, or cease to operate.

- The RECOVER BP Console must be plugged into AC power to maintain a charged battery.
- To remove all AC power from the Console, unplug the power cord from the AC outlet.
- Be sure to route the power cord and all cables, including the keypad/display extension cable, in a manner which prevents tripping hazards and equipment damage.
- Do ***NOT*** lean or place any objects on the Console keypad or on the screen.
- Do ***NOT*** pour liquid, including cleaning solution, directly on any part of the Console. Doing so can cause electrical malfunction.

  If liquid is accidentally spilled on the Console, be sure to thoroughly dry the affected area. Wait at least 15 minutes, after drying, before turning the Console ON. Verify that the Self-Test runs and indicates that the unit is operating properly.
- Minimize exposure of RECOVER BP System components to sources of electromagnetic interference (EMI). Exposure to sources of EMI, such as cell phones and two-way radios, may cause operational interference. To clear interference, either increase the distance between RECOVER BP System components and the EMI source or turn off the EMI source.
- Operation of RECOVER BP System components may interfere with the operation of other devices. If interference occurs, increase the distance between the device and RECOVER BP System components.
- Avoid activities that may build up static charges on the Console or on personnel contacting the Console. Avoid brushing bed sheets across the Console or touching the Console immediately after performing activities likely to build static charge. If electrostatic discharge interrupts operation of the Console, cycle the Power ON/OFF switch.

- Do ***NOT*** power the RECOVER BP System using Multiple Portable Socket Outlets (MPSO) or an extension cord.
- Do ***NOT*** allow the conductive parts of electrodes and associated connectors to contact any conductive parts and/or earth ground.
- Do ***NOT*** use a RECOVER BP System if any part of the System is damaged.
- Do ***NOT*** use damaged or contaminated connector cables.
- To prevent overheating and improper operation, do ***NOT*** block the RECOVER BP Console cooling vents while the Console is operating.
- The Console and cables should be disposed of according to all local, state, federal, and country regulations. The Console battery is a sealed lead-acid unit and should be reclaimed.
- Close the helium cylinder supply valve when the Console is not in use.

2 Indications, Contraindications, and Potential Adverse Events

Contents

Indications

IABP

- Cardiogenic shock
- Unstable angina
- Acute myocardial infarction (AMI)
- Complications following MI
- Adjunct to **** (PTCA)
- Adjunct to cardiac catheterization
- Bridge to transplant
- Hemodynamic support pre-, intra-, and post-operatively
- Bridge to other therapies
- Intractable arrhythmias

VAD

ABIOMED® RECOVER BP Circulatory Support System (CSS) therapy is intended to treat patients suffering from reversible ventricular dysfunction. Typical patients have undergone successful cardiac surgery and subsequently developed low cardiac output, or have suffered from acute cardiac disorders leading to hemodynamic instability.

The intent of the RECOVER BP System therapy is to provide circulatory support, restore normal hemodynamics, reduce ventricular work, and allow the heart time to recover adequate mechanical function.

Appropriate patient groups include those that are likely to recover cardiac function after the myocardium is permitted to rest on ventricular support. Examples include, but are not limited to:

- Patients who fail to wean from cardiopulmonary bypass (CPB) following heart surgery.
- Failed transplant patients who require ventricular assist following heart transplantation.
- Patients who require right ventricular assist device (RVAD) support while on implantable left ventricular assist device (LVAD) support.
- Patients suffering from acute cardiac disorders such as viral myocarditis.

A patient is a candidate for mechanical assistance with the RECOVER BP System if she/he meets all of the following criteria:

- Patient has a body surface area > 1.3 m^2 and is ≤ 75 years of age.
- Patient is in relatively good health other than the cardiovascular problem for which surgery was undertaken.
- All appropriate measures have been attempted to correct low arterial pH, arterial blood gas abnormalities, electrolytes, hypovolemia, hypervolemia, inadequate cardiac rate, dysrhythmias, and residual hypothermia.
- Cardiac resuscitation employing pharmacologic agents has been attempted. While the use of an Intra-Aortic Balloon Pump (IABP) is recommended prior to RECOVER BP System assistance, its use may not always be appropriate (e.g., fibrillating heart, peripheral atherosclerosis).
- Patient is unable to be weaned from CPB or is unable to maintain acceptable hemodynamics in the immediate postoperative period (< 6 hours after the first attempt to wean from CPB), or patient is unable to maintain acceptable hemodynamics following a significant cardiac event despite the measures cited above.

Contraindications

IABP

- Significant aortic valve insufficiency
- Thoracic or abdominal aortic aneurysm
- Severe **** (PVD)
- Occluded aorta

VAD

- Major cardiac or extracardiac catastrophes occurring during operation or in the postoperative period that preclude survival such as uncontrolled hemorrhage, massive air embolization, interstitial pulmonary hemorrhage with inability to maintain adequate ventilation, pump oxygenator or perfusion difficulties, or massive transfusion reaction, hemolysis during bypass, or inadequate cannulation.
- Central nervous system damage resulting in fixed and dilated pupils.

Potential Adverse Events

IABP

- Limb ischemia
- Aortic dissection
- Thrombosis
- Vascular injury
- Balloon rupture
- Infection
- Thrombocytopenia
- Hemorrhage

VAD

****[clinical]

3 The RECOVER BP IABP/VAD System

Contents

Overview

The RECOVER BP IABP/VAD System (RECOVER BP System) is a versatile cardiac assist device that combines IABP and VAD support capability within one Console (described in Section 4). This mobile System uses a laptop-style interface.

Figure 1 RECOVER BP Console

Disposables and Accessories

WARNING: Do ***NOT*** reuse single-use devices.

IABP

For IABP support (described in Section 6), the following items are used with the RECOVER BP System:

- 8F 40 cc IAB Catheter Kit (see Figure 2)

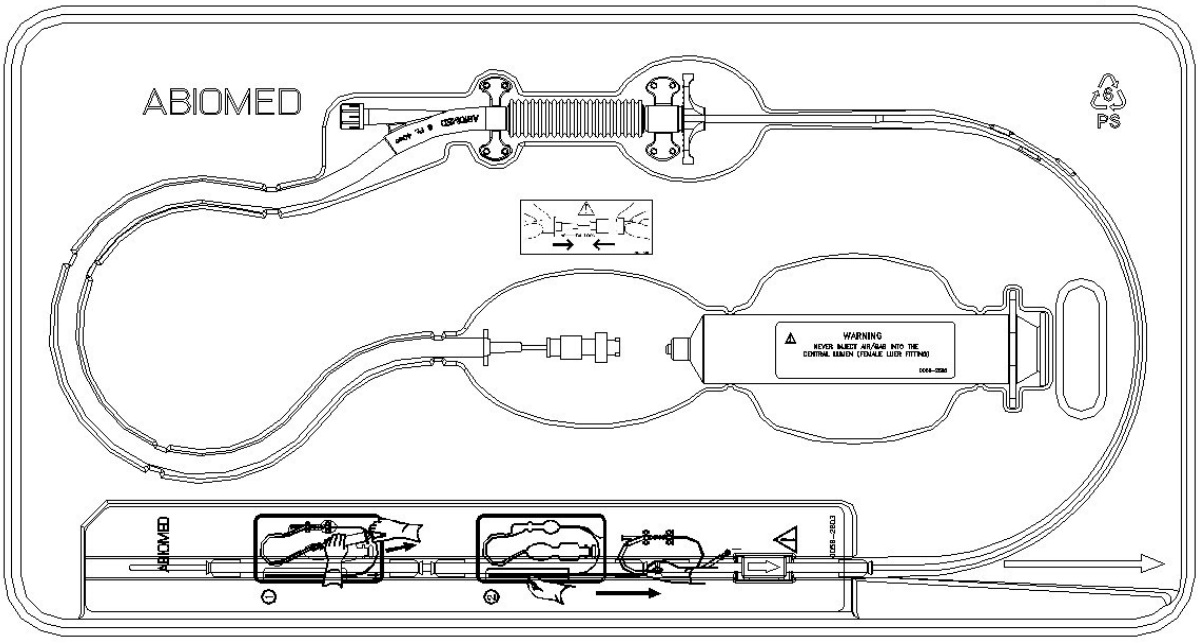


Figure 2 IAB Catheter Kit

- IAB Insertion Kit (see Figure 3)

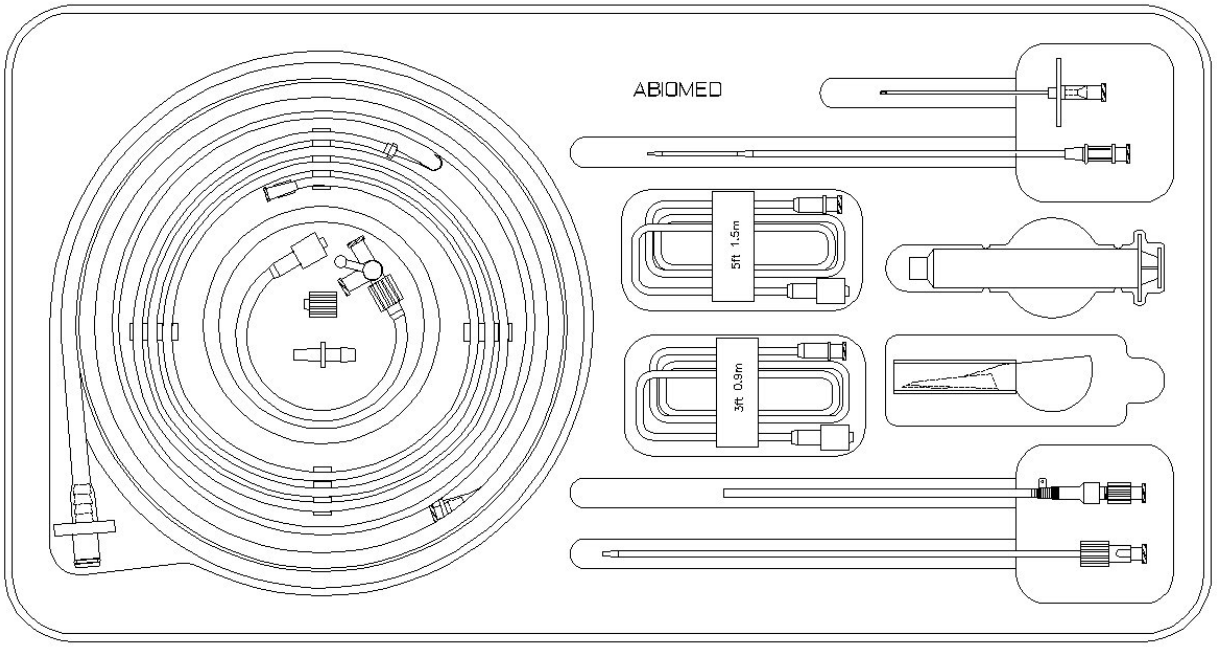


Figure 3 IAB Insertion Kit

- Patient Cable Set
- Helium Cylinder
- Chart Recorder Paper
- Adapter for Datascope® 8F (40 cc) IAB Catheter

VAD

For VAD support (described in Section 7), the following items are used with the RECOVER BP System:

- AB5000™ Ventricle (Ventricle) – a pneumatically driven device that provides pulsatile, hemodynamic support (see Figure 4). The single-chamber Ventricle provides circulatory support in the presence of left-, right-, or both-sided heart failure. It uses vacuum assist technology to operate either horizontally or vertically.

Figure 4 AB5000™ Ventricle

- BVS® Blood Pump (BVS Pump) – a pneumatically driven device that provides pulsatile, hemodynamic support (see Figure 5). The dual-chamber BVS Pump provides circulatory support in the presence of left-, right-, or both-sided heart failure. It can operate either vertically or horizontally and its atrial chamber fills passively.

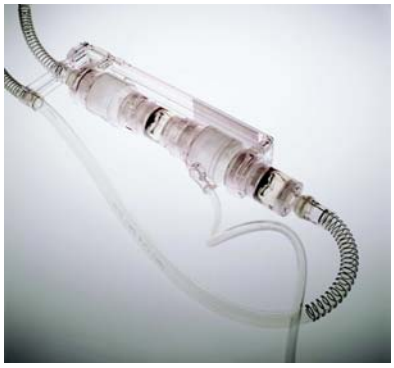


Figure 5 BVS® Blood Pump

- BVS® 5000 Atrial Cannula (32F, 36F, and 42F)
- BVS® 5000 Arterial Cannula (42F)
- BVS® Pump Mount Set (includes BVS® IV Pole Mount and BVS® Bed Mount)
- Aircraft Mounting Plate

4 Using the RECOVER BP Console

Contents

Overview

The following pages present a general overview of Console features, electrical connections, and interface layout.

For operating instructions, refer to IABP Support (Section 6) and VAD Support (Section 7). These sections contain detailed instructions and task-specific information.

Key Features

The key mechanical features of the Console are shown in Figures 6, 7, and 8. Tables 1, 2, and 3 describe the function of each feature.

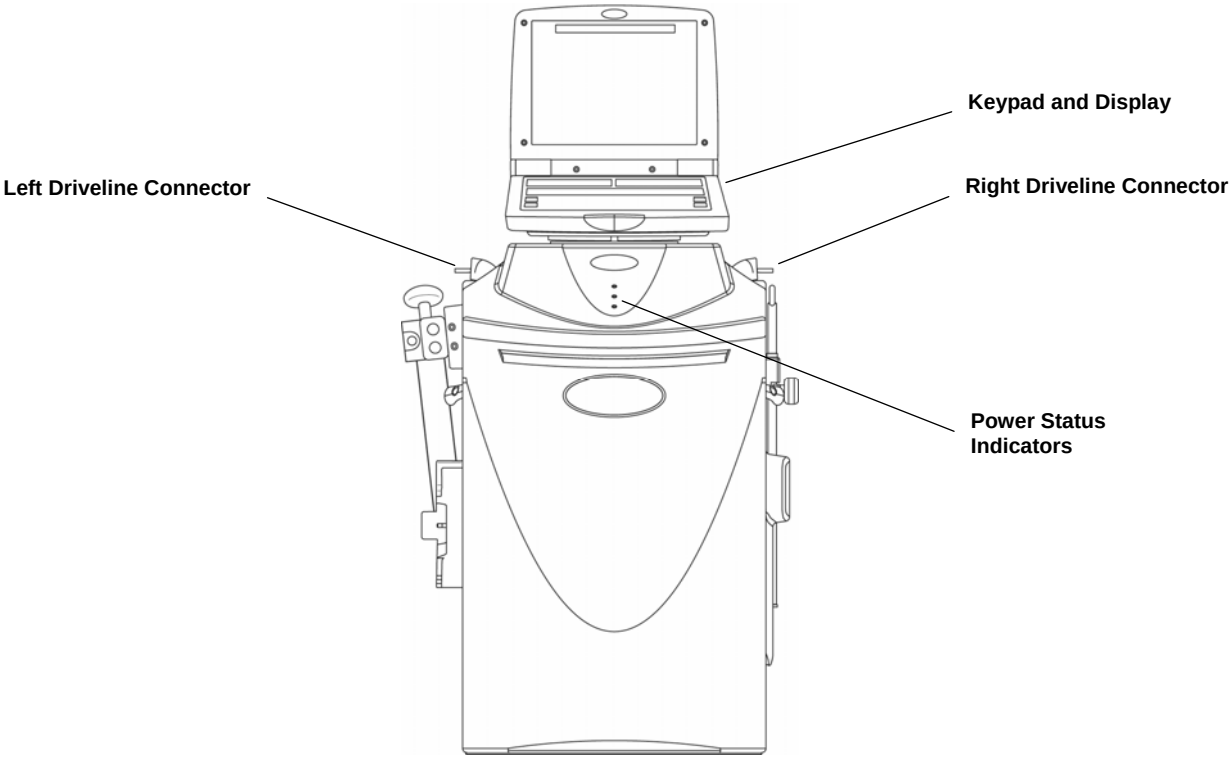


Figure 6 Console Features: Front View

Table 1 Console Feature Descriptions: Front View

Feature	Description
Keypad and Display	Laptop-style user interface used to monitor and control both VAD and IABP functions.
Left and Right Driveline Connectors	Connection points for driveline of an AB5000™ Ventricle or a BVS® Blood Pump.
Power Status Indicators	Lights that indicate Console battery status and whether the Console is currently operating on AC or battery power. See "Checking Console Power Status" later in this section for further information.
Cooling Vents	Allow cooling air to circulate through the Console.

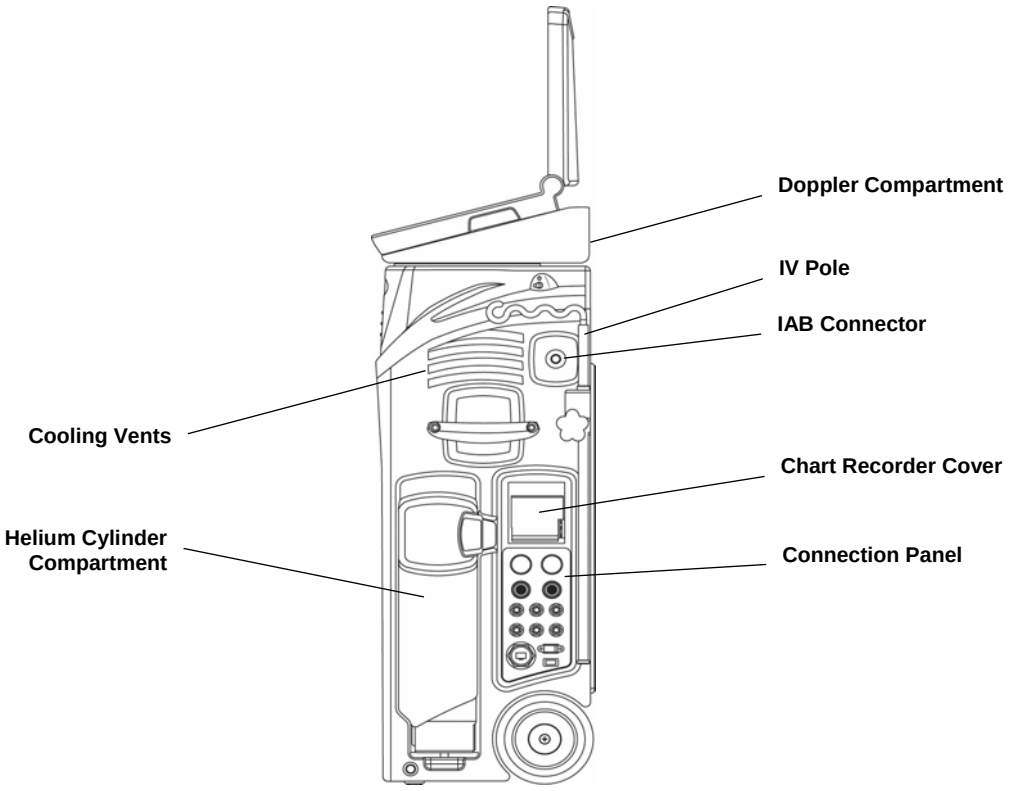


Figure 7 Console Features: Right-Side View

Table 2 Console Feature Descriptions: Right-Side View

Feature	Description
Doppler	Detects arterial blood flow.
IV Pole (for BVS® Blood Pump only)	Provides support for 2 BVS Blood Pumps.
IAB Connector	Connection point for the IAB Catheter extender.
Chart Recorder	Provides a printout of ECG, arterial pressure, and balloon pressure waveforms. See "Using the Printer" later in this section for further information.
Connection Panel	Used to make electrical connections to the Console.
Helium Cylinder	Storage tank for helium shuttle gas that is used to inflate the balloon.
Cooling Vents	Allow cooling air to circulate through the Console.

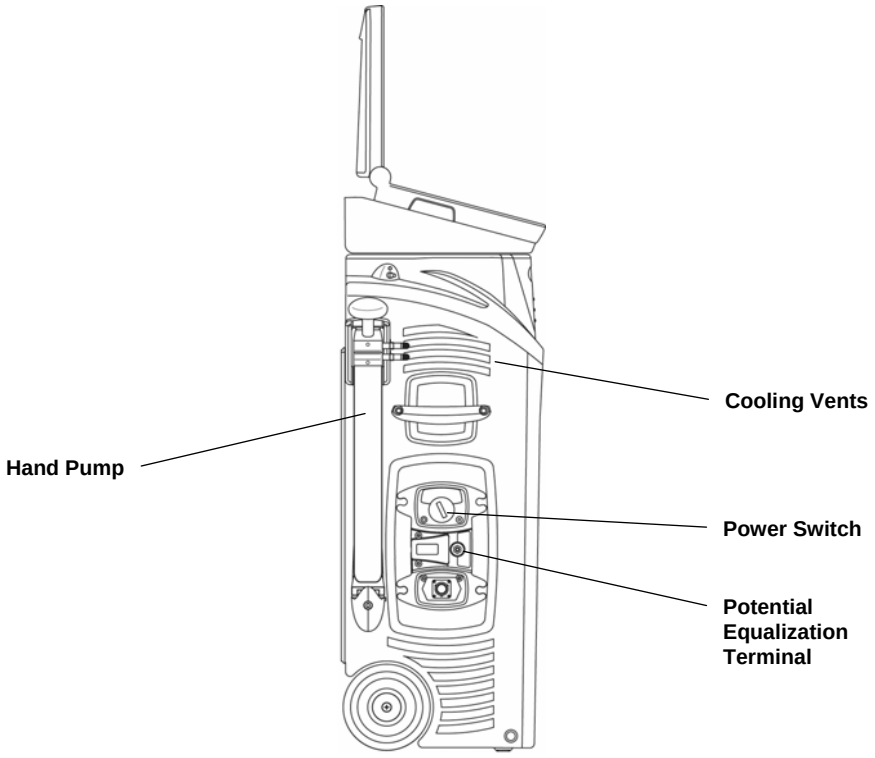


Figure 8 Console Features: Left-Side View

Table 3 Console Feature Descriptions: Left-Side View

Feature	Description
Power Switch	Switch to turn the Console ON or OFF.
Potential Equalization Terminal	Conductor for providing connection to the potential equalization busbar of the installation.
Hand Pump	Allows manual operation of an AB5000 Ventricle or a BVS® Blood Pump.
Cooling Vents	Allow cooling air to circulate through the Console.

Console Electrical Connections

Electrical connections to the Console are made at the right-side panel. The connections are shown in Figure 9 and briefly described in Table 4. Each connector is unique and keyed to ensure that connections are made correctly.

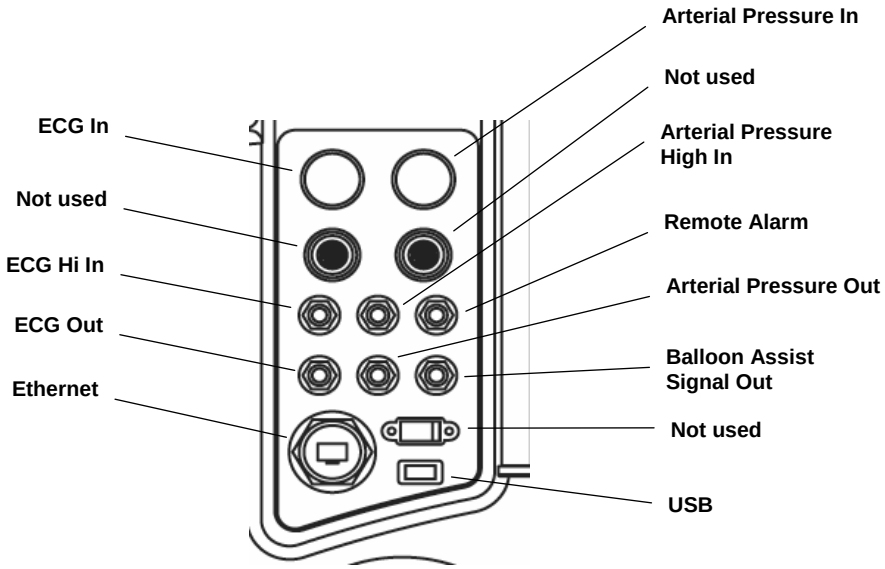
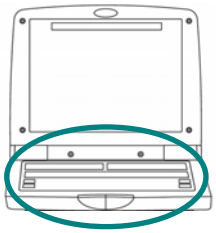


Figure 9 Console Electrical Connections

Table 4 Electrical Connection Descriptions

Connection	Description
Arterial Pressure In	Red 12-pin connector; connects to patient; 0–X VDC.
Arterial Pressure High In	¼-inch phone jack; connects to an external patient monitor; can be used by Console as a trigger; 0–5 VDC.
Remote Alarm	¼-inch phone jack; allows external monitoring of alarms; max. 40 VDC; normally open contacts.
Arterial Pressure Out	¼-inch phone jack; connects to an external patient monitor; 0–5 VDC.
Balloon Assist Signal Out	¼-inch phone jack; output timing signal for inflation; 0–5 VDC.
USB	1.1 or higher.
Ethernet	RJ45 connector; 100/10BaseT.
ECG Out	¼-inch phone jack; connects to an external patient monitor; ± 2.5 VDC.
ECG High In	¼-inch phone jack; connects to an external patient monitor; can be used by Console as a trigger; ± 2.5 VDC.
ECG In	Green 12-pin connector; connects to patient; ± X mVDC; ± X mVAC.

Keypad Layout



The keypad is used in conjunction with the display to control and monitor the IABP and VAD functions of the Console.

The keypad is divided into three sections (see Figure 10):

- Intra-Aortic Balloon Pump – for performing IABP support (see Section 6 for detailed descriptions of key functions).
- System – for handling tasks common to both IABP and VAD support (see Section 5).
- Ventricular Assist – for performing VAD support (see Section 7).

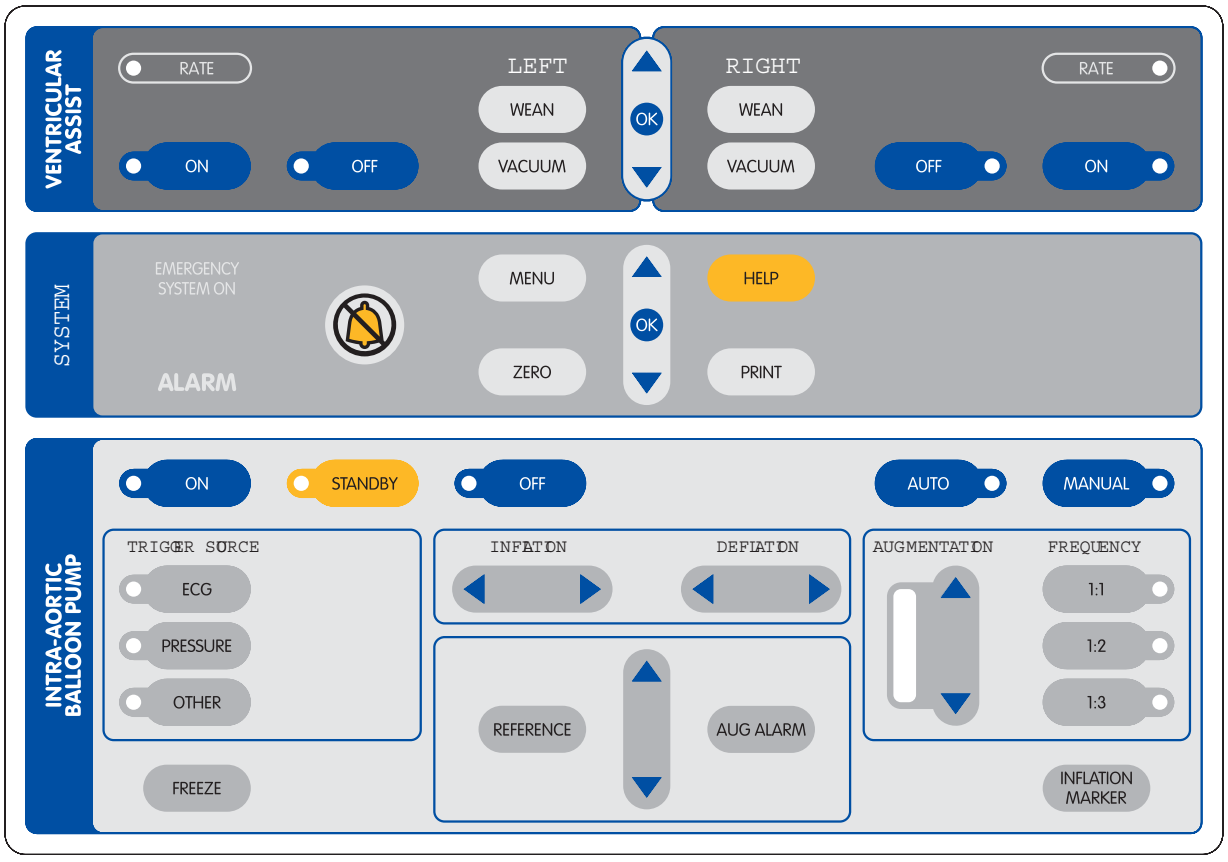


Figure 10 Console Keypad

Display Layout

The Console display is a color LCD monitor that can be tilted to achieve a comfortable viewing angle. You can swivel the keypad and display unit in either direction, and the entire keypad/display unit detaches for portable use while remaining connected to the Console by a coiled cable.

The Console uses separate menus and screens for IABP and VAD support.

Menus

Pressing the **MENU** key in the System section of the keypad (see Figure 11) displays the menu for the current function (either IABP or VAD).

The complete menu structure is shown in Table 5.

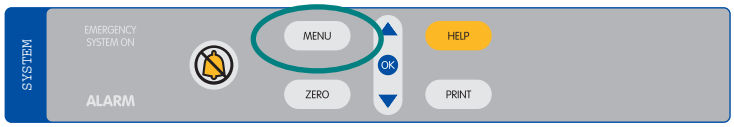


Figure 11 MENU Key

Table 5 Menu Structure

IABP Menu (see Section 6 for more information)
ECG Source (I, II, III, aVR, aVL, aVF, External)
ECG Gain (Auto, 0.5X, 0.75X, 1.0X, 1.25X, 1.5X, 2.0X, 3.0X)
AP Source (Direct, External)
Augmentation Alarm (Off, On)
System Menu
Print Menu
Waveforms (ECG/AP, ECG/BP, AP/BP, ECG, AP, BP)
Speed (25 mm/sec, 50 mm/sec)
Strip Length (8 sec, 60 sec)
Auto Print (Off, 1 min, 5 min, 30 min, 1 hr, 2 hr)
Console Mode
Brightness Control (1–10)
Audio Level (High, Medium, Low)
Date & Time (MM/DD/YY)(HH:MM)
Language (English)
IP Address (nnn.nnn.nnn.nnn)
Field Service
Left Compressor Run-Time (nn hr)
Right Compressor Run-Time (nn hr)
Software Version Main Unit (A mnb)
Software Version Keypad (A mnb)
Close

(continued on next page)

Table 5 Menu Structure (continued)

VAD Menu (see Section 7 for more information)
Left Low Flow Alarm Threshold
Right Low Flow Alarm Threshold
BSA
System Menu
Print Menu
Waveforms (ECG/AP, ECG/BP, AP/BP, ECG, AP, BP)
Speed (25 mm/sec, 50 mm/sec)
Strip Length (8 sec, 60 sec)
Auto Print (Off, 1 min, 5 min, 30 min, 1 hr, 2 hr)
Console Mode
Brightness Control (1–10)
Audio Level (High, Medium, Low)
Date & Time (MM/DD/YY)(HH:MM)
Language (English)
IP Address (nnn.nnn.nnn.nnn)
Field Service
Left Compressor Run-Time (nn hr)
Right Compressor Run-Time (nn hr)
Software Version Main Unit (A mnb)
Software Version Keypad (A mnb)
Close

Sample Screens

Figure 12 (IABP) and Figure 13 (VAD) show samples of Console screens.

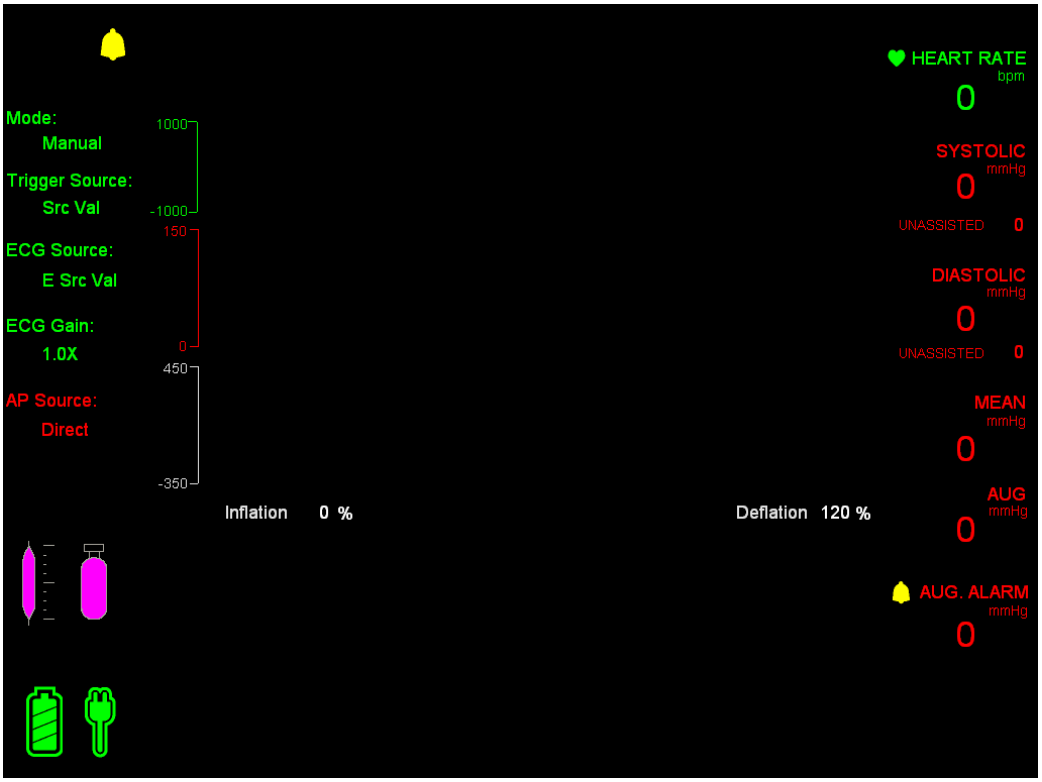


Figure 12 Sample IABP Screen

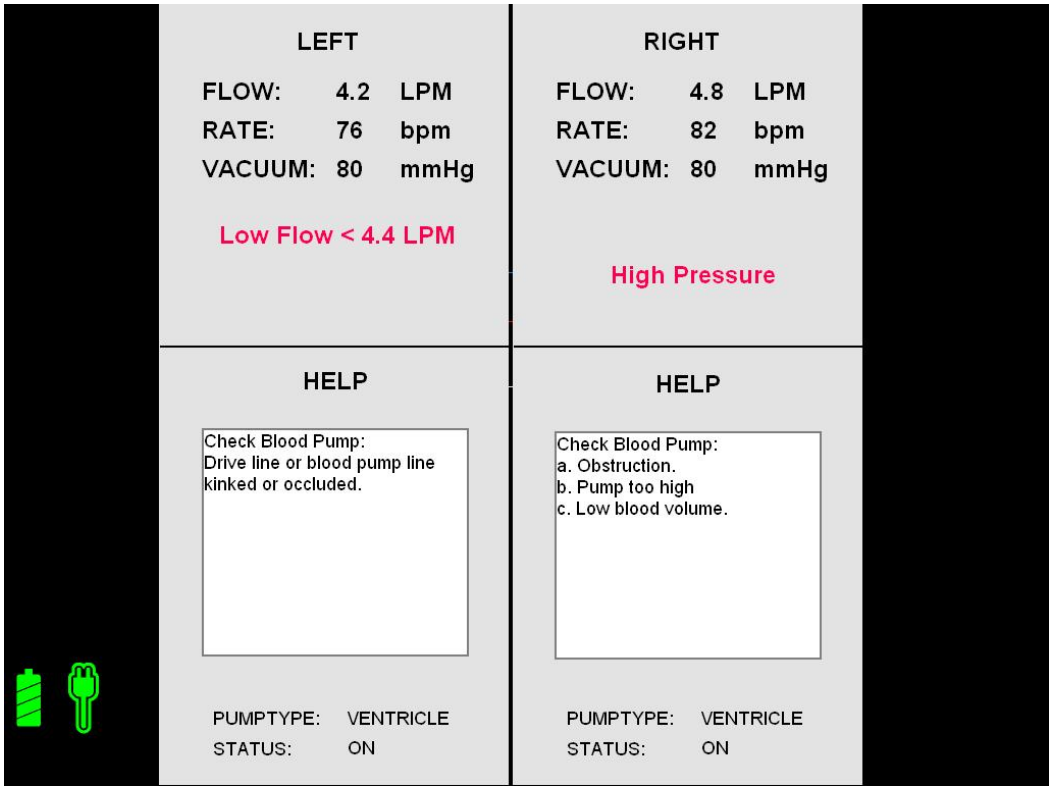


Figure 13 Sample VAD Screen

5 System Status and Settings

Contents

Using the Interface

The System section of the keypad (see Figure 14) is used for handling tasks common to both IABP and VAD support. These indicators and controls are described in Table 6.

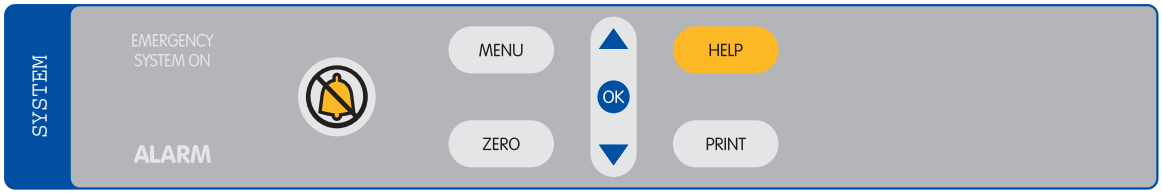


Figure 14 System Keypad

Table 6 System Keypad Functions

Feature	Use
Indicator Lights	
EMERGENCY SYSTEM ON	***Red*** light flashes when the Emergency System is operating. Refer to Section 8 for more information.
ALARM	***Red*** light flashes when any alarm is active.
Controls	
	Silences the alarm for approximately 1 minute.
MENU	Displays the menu for the current function (IABP or VAD).
ZERO	Zeroes the arterial pressure (AP) transducer.
HELP	Displays help text for handling VAD alarms.
PRINT	Prints per the current Print settings.
	Navigates through the selected function.
	Selects the highlighted function.
	Navigates through the selected function.

****[*SYSTEM* label]

System Menu

The System menu (see Figure 15) is located on both the IABP menu and the VAD menu. The menu structure is shown in Table 7.

Table 7 System Menu Structure

System Menu	
	Print Menu
	Waveforms (ECG/AP, ECG/BP, AP/BP, ECG, AP, BP)
	Speed (25 mm/sec, 50 mm/sec)
	Strip Length (8 sec, 60 sec)
	Auto Print (Off, 1 min, 5 min, 30 min, 1 hr, 2 hr)
	Console Mode (IABP, VAD)
	Brightness Control (0–10)
	Audio Level (High, Medium, Low)
	Date & Time (MM/DD/YY)(HH:MM)
	Language (English)
	IP Address (nnn.nnn.nnn.nnn)
	Field Service
	Left Compressor Run-Time (nn hr)
	Right Compressor Run-Time (nn hr)
	Software Version Main Unit (A mnb)
	Software Version Keypad (A mnb)

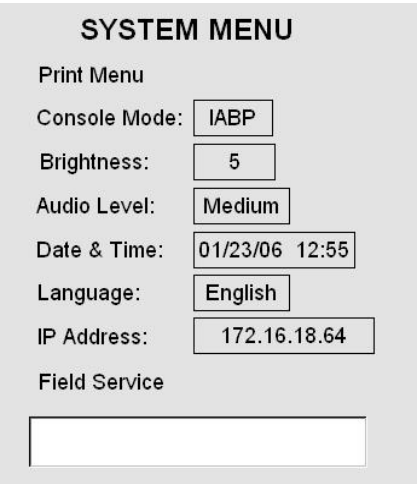


Figure 15 System Menu

Checking Console Power Status

The Console runs on either AC power or its internal battery. It continuously charges the battery, which requires approximately 16 hours to recharge after depletion, while it is plugged into AC power. A fully charged battery will power the Console for one hour.

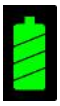
You can check on Console power status in two places:

- Two power status icons in the lower left corner of the IABP and VAD screens.

- Three power status indicator lights on the front of the Console just below the keypad ****[see Figure x].

Tables 8 and 9 describe the information provided in these two locations.

Table 8 Power Status Indicated by the IABP and VAD Screens

Battery Icon	AC Power Icon	Meaning
		Console is using AC power (halo showing). Console Battery is fully charged (all segments filled) but not in use (no halo).
		Using Battery power. Battery is fully charged. AC power is unplugged.
		Using Battery power. Battery is about ¾ charged. AC power is unplugged.
		Using AC power. Battery is about ½ charged.
		Using Battery power. Battery charge is low (icon flashes). AC power is unplugged.
		Using Battery power. Battery charge is critically low (icon flashes). AC power is unplugged.

****[1 hour VAD, 2 hours IABP?]

Table 9 Power Status Shown by the Power Status Indicators

Power Status Indicator and Condition	Meaning
AC Power – green	Console is using AC power.
Battery – amber	Console is unplugged from AC power and has automatically switched to battery power.
Battery – red	Approximately 30 minutes of battery power remaining.
AC Power – green ***and*** Charging – amber	Console is using AC power. Battery charge level is at approximately 80%.
AC Power – green ***and*** Battery – red	Possible battery fault.

6 IABP Support

Contents

Using the Interface

IABP Keypad

The IABP section of the keypad (see Figure 16) contains controls and indicators for handling the tasks involved in IABP support. The functions of these keys are described in Table 10.

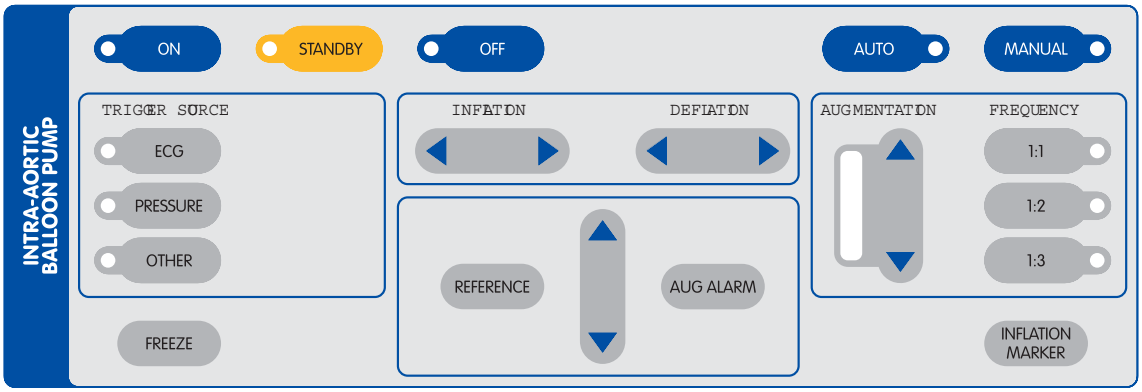


Figure 16 IABP Keypad

Table 10 IABP Keypad Functions

Feature	Use
Control Keys	
ON	Purges the pneumatic system and starts pumping.
STANDBY	Pauses pumping but keeps the Console ready to immediately resume pumping. Pumping resumes when ON is pressed.
OFF	Stops pumping when pressed twice within 13 seconds.
AUTO	Automatically selects optimal ECG source, ECG gain, AP source, trigger source, inflation timing, and deflation timing.
MANUAL	Allows you to select ECG source, AP source, trigger source, inflation timing, and deflation timing.
ECG	Selects ECG signal as the trigger source.
PRESSURE	Selects AP signal as the trigger source.
OTHER	Allows you to select Apace, Vpace, or Internal as the trigger source.
FREEZE	Freezes or unfreezes the display.
INFLATE	In MANUAL mode, the left and right arrows adjust the inflation interval. Inactive in AUTO mode.
DEFLATE	In MANUAL mode, the left and right arrows adjust the deflation interval. Inactive in AUTO mode.
REFERENCE	Up and down arrows select the reference line.
AUG ALARM	Up and down arrows set the augmentation alarm level.
AUG	Up and down arrows set the augmentation level.
FREQ	Selects assist frequency (1:1, 1:2, or 1:3).
INFLATION MARKER	Turns inflation marker on or off.
Indicator Lights	
ON	Green light when ON is pressed.
STANDBY	Amber light when STANDBY is pressed.
OFF	***Red*** light flashes when OFF is pressed once (pumping does not stop). Light ***stays red*** when OFF is pressed twice within 13 seconds (pumping stops).
AUTO	Green light when AUTO is pressed.
MANUAL	Amber light when MANUAL is pressed.
ECG	Green light when ECG is selected as the trigger source.
PRESSURE	Green light when AP is selected as the trigger source.
OTHER	Green light when Apace, Vpace, or Internal is selected as the trigger source.
AUGMENTATION	Green light bar indicates augmentation level.
FREQ	Green light indicates the selected assist frequency (1:1, 1:2, or 1:3).

****[INTRA-AORTIC BALLOON PUMP label]

IABP Screen

The IABP screen (see Figure 17) enables you to monitor all aspects of IABP operation. This screen also supplies patient information. These display elements are described in Table 11.

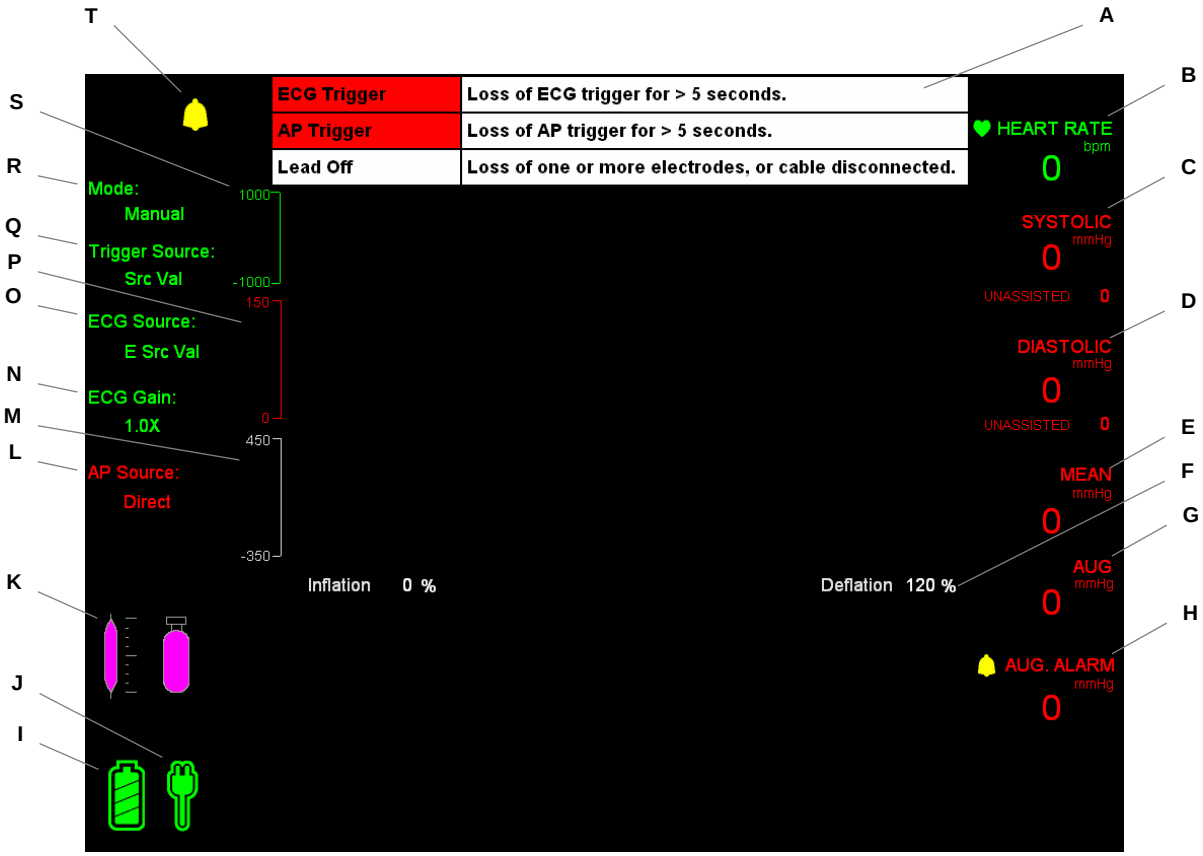


Figure 17 IABP Screen

Table 11 IABP Screen Descriptions

Item	Display Element	Description
A	Alarm Messages	Highest priority active alarms (3 maximum). Highest priority alarm is at the top of the list. Refer to "IABP Alarms" in this Section for more information.
B	Heart rate	Current heart rate in beats per minute (bpm); green text.
C	Systolic pressure	Red text; unassisted below in smaller text; mmHg.
D	Diastolic pressure	Red text; unassisted below in smaller text for 1:2 and 1:3 ratios only; mmHg.
E	Mean	Red text; mmHg.
F	Inflation/Deflation timing	White text (%); Inflation text not shown (located behind Help text).
G	Augmentation	Red text; mmHg.
H	Augmentation alarm	Red text; gray icon is crossed out when alarm is silenced; mmHg.
I	Battery power icon	Color of segments indicates battery status. Refer to Table 8 in Section 5 for more information.
J	AC power icon	Color indicates AC power status. Refer to Table 8 in Section 5 for more information.
K	Helium supply icon	Gray icon; also numeric value in pounds per square inch (psi).
L	AP source	Red text. Options: Direct, External.
M	Balloon Pressure	White trace.
N	ECG gain	Green text. Options: Auto, 0.5x, 0.75x, 1.0x, 1.25x, 1.5x, 2.0x, 3.0x.
O	ECG source	Green text. Options: I, II, III, V, aVR, aVL, aVF, External.
P	AP	Red trace (automatically scaled). White inflation marker indicates inflation period.
Q	Trigger source	White text. Options: ECG, AP, A-Pacer, V-Pacer, Internal.
R	Operation mode	White text; Auto or Manual.
S	ECG	Green trace; automatically scaled (optional gain levels are available). White inflation marker indicates inflation period. Green vertical line indicates pacer trigger.
T	Alarm indicator	Indicates an alarm condition exists; icon is crossed out when alarm is silenced.

Initial Setup

WARNING: Do ***NOT*** power the RECOVER BP System using Multiple Portable Socket Outlets (MPSO) or an extension cord.

WARNING: Pumping an IAB that has a leak can result in: (1) a blood clot in the IAB that may require surgical removal of the IAB, and (2) air embolism.

WARNING: A patient monitor ***must*** be provided and used to ***continuously monitor*** patient physiological pressure. Do ***NOT*** rely solely on the System alarms to notify you of life-threatening conditions.

1 Plug the Console power cord into an AC outlet.

2 Turn the Console ON using the AC power switch on the left side. The Console goes through a Self-Test and is ready to use in approximately 25 seconds. ***Verify*** that the audible alarm indicator is operating properly by listening for the ***alarm tone*** during the Self-Test.

NOTE: Upon power-up, the Console displays the same type of screen (IABP or VAD) used at shutdown. If necessary, change to IABP mode by pressing the **MENU** key and selecting **System Menu > Console Mode > IABP**.

3 Open the cover of the helium cylinder compartment. Turn the cylinder supply valve one-half turn counterclockwise to open the valve. Make sure the helium cylinder pressure reading on the left side of the display is at least ****[X] psi. Close the compartment cover.

NOTE: If the helium cylinder pressure is less than ****[X] psi, change the cylinder by following the steps in "Replacing the Helium Cylinder" in this Section.

Acquiring an Electrocardiograph (ECG) Waveform

WARNING: Do ***NOT*** allow the conductive parts of electrodes and associated connectors to contact any conductive parts and/or earth ground.

Acquiring a high-quality electrocardiograph (ECG) waveform is an important factor in achieving optimal triggering. An ECG waveform can be obtained using either skin electrodes or the output of an external monitor.

Using Skin Electrodes

1. Using the supplied patient ECG cable, connect each patient lead wire to a skin electrode. Use only high-quality electrodes.

2. Attach electrodes to the patient as shown in the figures below.

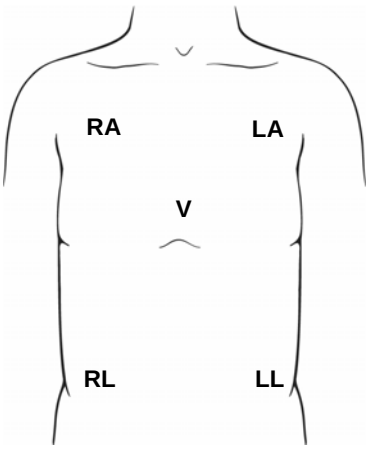


Figure 18 Electrode Locations (AHA)

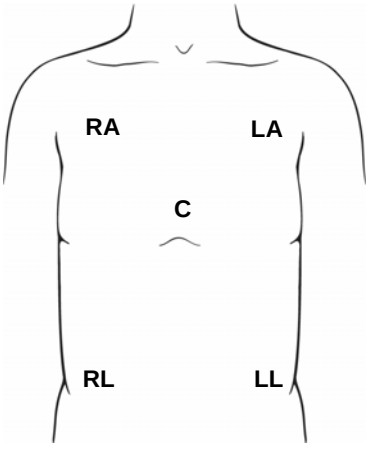


Figure 19 Electrode Locations (IEC)

3 Connect the patient ECG cable to the green ECG input connector on the side panel of the Console.

4 Press the **INFLATION MARKER** key.

5 Check that the ECG waveform and heart rate are shown on the display.

Using an External Monitor

1 Connect the interface cable to the ECG high-level patient monitor input on the side panel.

2 Check that the heart rate is shown on the upper right side of the display.

3 Press the **INFLATION MARKER** key.

4 Check that the ECG waveform and the heart rate are shown on the display.

Acquiring an Arterial Pressure (AP) Waveform

An arterial pressure (AP) waveform can be obtained using either a pressure transducer or the output of an external monitor.

Using a Pressure Transducer

NOTE: Refer to the Edwards Lifesciences Instructions for Use for important information on using the TruWave Disposable Pressure Transducer. Also refer to this document for volumetric displacement information.

The inner lumen of the IAB is the preferred location for the placement of a pressure transducer. This location results in the best waveform for optimal triggering and timing. If this approach cannot be used, use the radial artery per standard protocol.

1 Place a pressure catheter at the chosen location.

2 Connect the pressure catheter to the pressure transducer.

3 Zero the pressure transducer by pressing **ZERO** on the System keypad.

4 Check that the peak and mean systolic/diastolic pressures are displayed.

5 Check that the arterial pressure waveform is displayed after the IAB is inserted.

****[mention heparin?]

Using an External Monitor

1 Connect the AP high-level input interface cable between the external patient monitor and the high-level AP input on the side panel. Make sure that ****[X] is selected on the display.

2 Check that the arterial pressure waveform is properly displayed.

Connecting the IAB to the Console

1 Remove the plug from the IAB extender input connector.

2 Connect the Console extension tubing to the IAB.

3 Connect the Console extension tubing to the Console IAB connector.

4 Verify that the correct IAB size is shown on the left side of the display.

5 Verify that the augmentation level is set at maximum.

Initiating Support

WARNING: Due to the potential for thrombus formation, an IAB must ***NOT*** remain dormant.

You can initiate support in either ***Auto*** or ***Manual*** mode. The appropriate mode depends on whether ease-of-use or flexibility is needed.

In ***Auto*** mode (the default mode), the Console automatically chooses the best option for the following settings:

- ECG source and ECG gain
- AP source
- Trigger source
- Inflation and deflation timing

The Console continuously monitors system parameters to adjust settings as patient conditions change.

In ***Manual*** mode, you have the flexibility to choose from options for the above settings.

To Initiate Support in Auto Mode:

1 Make sure "AUTO" is selected on the IABP keypad.

2 Press the **ON** key on the IABP keypad. The Console purges the IAB Catheter, fills the Catheter with helium, and begins pumping on the IAB.

NOTE: The Console automatically empties and refills the IAB every two hours, after which support automatically resumes.

— This completes the steps for initiating support in Auto mode. —

To Initiate Support in Manual Mode:

WARNING: Due to the potential for thrombus formation, an IAB must ***NOT*** remain dormant.

1 Select "Manual" on the IABP keypad.

2 Refer to the following text to choose the desired option for each of the following settings:

- ECG source and ECG gain
- AP source
- Trigger source
- Inflation and deflation timing

Setting the ECG Source and ECG Gain

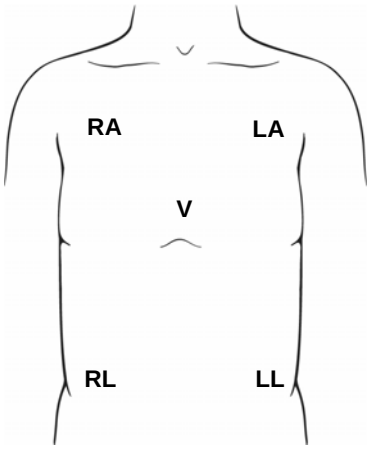
WARNING: Do ***NOT*** allow the conductive parts of electrodes and associated connectors to contact any conductive parts and/or earth ground.

Acquiring a high-quality electrocardiograph (ECG) waveform is an important factor in achieving optimal triggering. An ECG waveform can be obtained using either skin electrodes or the output of an external monitor.

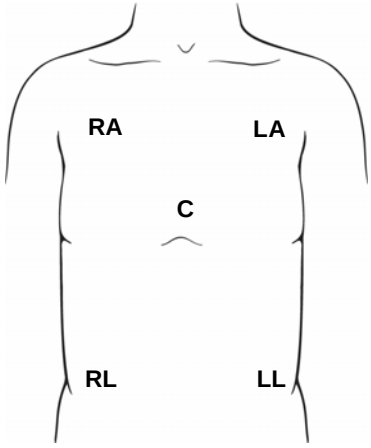
Using Skin Electrodes

1 Using the supplied patient ECG cable, connect each patient lead wire to a skin electrode. Use only high-quality electrodes.

2 Attach electrodes to the patient as shown in the figures below.



Electrode Locations (AHA)



Electrode Locations (IEC)

3 Connect the patient ECG cable to the green ECG input connector on the side panel of the Console.

4 Press the **MENU** key and select **ECG Source** from the IABP menu. Select the desired ECG source (see Figure 20). The left side of the display shows the selected source.

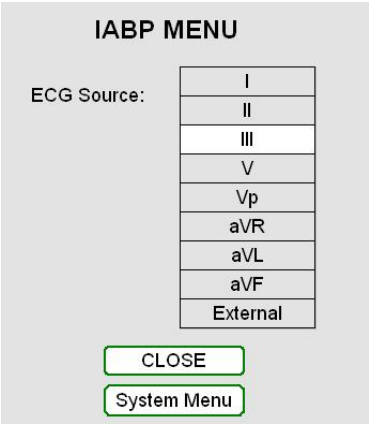


Figure 20 Selecting the ECG Source

5 Press **MENU** and select **ECG Gain**. Select the desired gain (see Figure 21). The left side of the display shows the selected ECG gain.

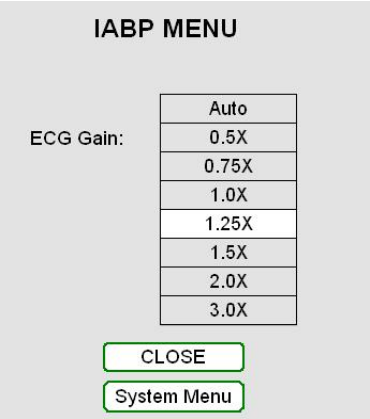


Figure 21 Selecting the ECG Gain

6 Check that the ECG waveform and heart rate are shown on the display.

Using an External Monitor

1 Connect the interface cable to the ECG monitor input on the side panel.

2 Press the **MENU** key and select **ECG Source**. Select the desired ECG source. The left side of the display shows the selected source.

3 Press **MENU** and select **ECG Gain**. Select the desired gain. The left side of the display shows the selected ECG gain.

4 Check that the ECG waveform and heart rate are shown on the display.

Setting the AP Source

Using a Pressure Transducer

NOTE: Refer to the Edwards Lifesciences Instructions for Use for important information on using the TruWave Disposable Pressure Transducer. Also refer to this document for volumetric displacement information.

1 Connect the transducer cable to the red AP connector on the side panel.

2 Press the **MENU** key and select **AP Source > Direct** (see Figure 22). The left side of the display shows the selected AP source.

****[delete AP Source white background]

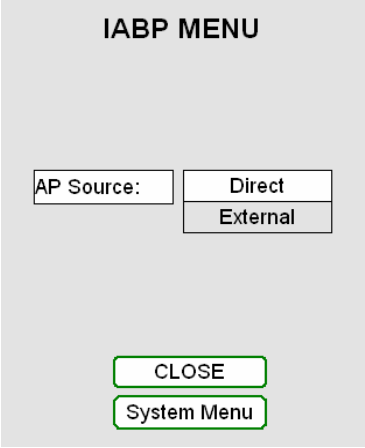


Figure 22 Selecting the AP Source for a Transducer

3 Check that the arterial pressure waveform is displayed.

Using an External Monitor

1 Connect the AP high-level input interface cable between the external patient monitor and the high-level AP input on the side panel. Make sure that ****[X] is selected on the display.

2 Press the **MENU** key and select **AP Source > External** (see Figure 23). The left side of the display shows the selected AP source.

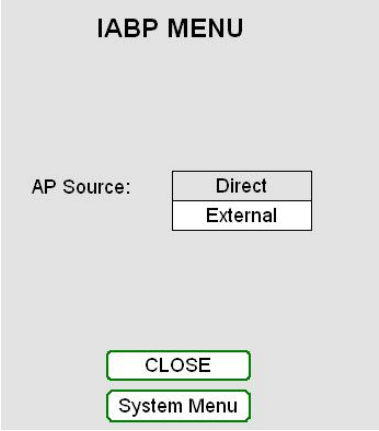


Figure 23 Selecting the AP Source for an External Monitor

3 Check that the arterial pressure waveform is properly displayed.

Selecting the Trigger Source

ECG

Using this setting, the Console triggers on the QRS and ignores pacemaker pulses. Select this option under TRIGGER SOURCE on the keypad.

Pressure

WARNING: When pressure triggering is used, adjust deflation to be complete at the upstroke of systole.

WARNING: Do ***NOT*** use pressure triggering while arrhythmia is present.

The Console triggers on the arterial pressure waveform. Select this option under TRIGGER SOURCE on the keypad.

Apace

The Console triggers on a pacer. Select this option by choosing Other (under TRIGGER SOURCE) and then selecting **Apace** from the Trigger Source Other Selection menu.

Figure 24 Selecting Apace as the Trigger Source

Make sure that the pacemaker pulses are being detected by ****[X]. The Apace signal must have an amplitude of ****[X] µV minimum and a pulse duration of ****[X] ms minimum.

Vpace

The Console triggers on the ventricular waveform of the pacer. You can choose this option by selecting Other (under TRIGGER SOURCE) and then selecting **Vpace** from the Trigger Source Other Selection menu.

Make sure that the pacemaker pulses are being detected by ****[X]. The Vpace signal must have an amplitude of ****[X] µV minimum and a pulse width of ****[X] ms minimum.

Internal

WARNING: Do ***NOT*** use Internal trigger source while the patient is producing cardiac output.

Use this setting when there is no cardiac cycle. Choose this option by pressing **Other** (under TRIGGER SOURCE) and selecting **Internal**.

If an ECG signal is detected while the internal trigger is in use, the system sounds an alarm, at which time the trigger source should be changed to ECG for optimal triggering.

NOTE: Check that the selected trigger source is shown on the left side of the display.

Setting Inflation and Deflation Timing

WARNING: If the heart rate varies by more than 10 beats per minute (bpm) within ****[X] seconds, evaluate inflation and deflation timing and make adjustments if necessary.

1 Press the **ON** key on the IABP keypad. The Console purges the IAB Catheter, fills the Catheter with helium, and begins pumping on the IAB.

2 ****[Initial timing procedure and graphic]

NOTE: The Console automatically empties and refills the IAB every two hours, after which support automatically resumes.

Inflation Timing

Use the left and right **INFLATE** keys to adjust the inflation timing until the highlighted segment of the arterial pressure trace begins at the dicrotic notch.

****[Timing graphic]

Deflation Timing

Use the left and right **DEFLATE** keys to adjust the deflation timing until the end of the highlighted segment of the arterial pressure trace is just prior to ventricular ejection.

****[Timing graphic]

— ***This completes the steps for initiating support in Manual mode.*** —

IABP Alarms

The Console monitors various functions to determine whether its operating parameters are within expected limits. When a parameter goes outside of its limits, the Console displays an alarm message and sounds an alarm tone. The severity of the alarm is indicated by the color of the alarm message and by the characteristics of the alarm tone.

Levels of Severity

Alarms are divided into three levels of severity:

- Life-Threatening – Red
- Serious – Yellow
- Advisory – White

A maximum of three alarms are displayed on the IABP screen (see Figure 27). Alarms are listed in order of importance, with the highest priority alarm at the top of the list. Each alarm is accompanied by descriptive text to help you with resolving the alarm.

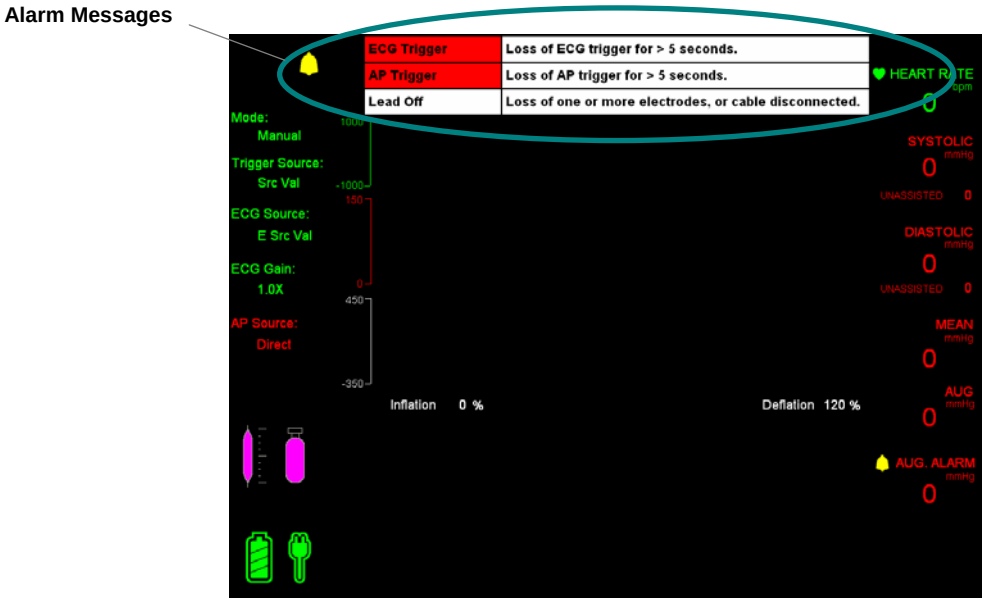


Figure 25 Alarm Messages on the IABP Screen

Alarm Messages

Table 12 shows all IABP alarm messages.

Table 12 IABP Red Alarm Messages

RED ALARMS Category: Life-Threatening		
Alarm Message	**Possible Cause**	**Action**
SYSTEM FAILURE Change to Backup Console	• System failure. • Keypad not working/connected.	1. Change to backup Console. 2. Check keypad connection. 3. Call for service.
PRESSURE LOW Leak in Catheter / Driveline	• Balloon rupture. • Loose driveline connection. • Fluid in driveline.	1. Inspect Catheter for blood or fluid. 2. Inspect Catheter/driveline connection.
PRESSURE LOW Fill Failure	• Loose driveline connection. • Possible System failure.	1. Inspect Catheter/driveline connection. 2. Change to backup Console.
PRESSURE LOW Disconnected Driveline	• Disconnected driveline.	Inspect Catheter/driveline connection.
PRESSURE HIGH Catheter / Driveline Occlusion	• Kink in Catheter or driveline. • Balloon failed to unwrap.	1. Assess patient position. 2. Inspect Catheter and driveline for kinks. 3. Inspect balloon for unwrap failure.

Table 12 IABP Red Alarms (continued)

RED ALARMS Category: Life-Threatening		
Alarm Message	**Possible Cause**	**Action**
TRIGGER No Trigger Source	• Unable to detect ECG or AP signal.	1. Check ECG leads/connection. 2. Check AP transducer/connection.
TRIGGER No ECG Signal Detected	• Unable to detect ECG signal. • Noise on ECG signal.	1. Check ECG leads/connection. 2. Limit movement of ECG cables. 3. Switch to Auto or AP mode.
TRIGGER No AP Signal Detected	• Unable to detect AP signal. • Low pulse pressure.	1. Check AP transducer/connection. 2. Check position of AP transducer valve. 3. Flush and re-zero AP transducer. 4. Change to Auto mode or ECG trigger source.
TRIGGER No Pacer Signal Detected	• Intermittent pacing. • No pacer signal spike. • Unable to detect ECG signal.	1. Change to Auto mode. 2. Check ECG leads/connection.

Table 13 IABP Yellow Alarm Messages

YELLOW ALARMS Category: Serious		
Alarm Message	**Possible Cause**	**Action**
TRIGGER Erratic Trigger Source	• Noise on ECG or AP signal.	1. Check ECG leads/connection. 2. Limit movement of ECG leads. 3. Change to Auto or AP mode.
TRIGGER ECG Detected	• ECG activity detected.	Change to Auto mode or ECG trigger source.
AUGMENTATION Below Set-Limit	• Patient hemodynamics. • Timing. • Augmentation alarm limit set too high.	1. Assess the patient. 2. Adjust timing. 3. Adjust augmentation alarm limit.
STANDBY Prolonged Time	• Console in Standby for more than 3 minutes.	1. Resolve active alarms. 2. If appropriate, resume pumping.
HELIUM SUPPLY Empty	• Helium cylinder valve closed. • Helium cylinder empty. • Helium supply leak.	1. Open helium cylinder valve. 2. Replace helium cylinder. 3. Check helium supply connection.

Table 14 IABP White Alarm Messages

WHITE ALARMS Category: Advisory		
Alarm Message	**Possible Cause**	**Action**
LEAD OFF ECG Electrode	• ECG lead off.	1. Check ECG leads. 2. Limit movement of ECG leads.
HELIUM SUPPLY Low	• Low helium cylinder pressure.	Replace helium cylinder.
SYSTEM Chart Recorder	• Out of paper. • Door open.	1. Check paper. 2. Close door. 3. Call for service.

Alarm Tone Characteristics

The Console signals life-threatening and serious alarms using unique sounds (see Table 15).

Table 15 Alarm Tone Characteristics

Severity Level	Description of Alarm Tone
Life-Threatening	Continuous beeps (4 times per second)
Serious	4 beeps within 1 second; repeats every 5 seconds

Alarm Silence Key

Pressing the alarm silence key on the System keypad (see Figure 26) silences the alarm tone for approximately 1 minute. The alarm sounds again if the alarm condition is still present after 1 minute.

The alarm sounds immediately, whether the alarm silence key has been pressed or not, if a new alarm condition occurs.

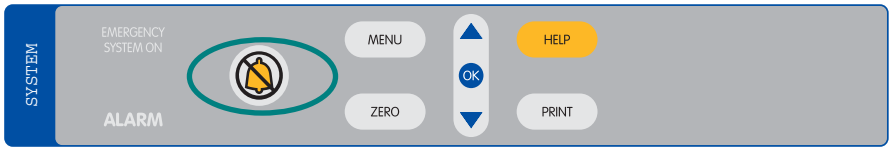


Figure 26 Alarm Silence Key

Weaning

The patient should be weaned from IABP support per hospital protocol.

Using the Doppler

The Doppler unit used with the RECOVER BP System is the Koven EchoSounder™ ES-101EX. It is stored in a compartment at the back of the keypad base.

To use the Doppler, follow these steps:

1. Open the compartment door and lift out the Doppler unit, which is tethered to the Console.
2. Turn the unit ON by pressing the power/freeze button.
3. Apply ultrasonic gel to the patient's skin or to the transducer.
4. Place the transducer on the artery to be checked. Move the unit slowly to find the location at which the unit generates the loudest sound. The optimal probe angle is approximately 60 degrees.
5. Adjust the sound volume by pressing the volume/mode button for less than 1 second.

NOTE: Refer to the Koven EchoSounder™ ES-101EX Instructions for Use for more information on the Doppler unit.

Using the Printer

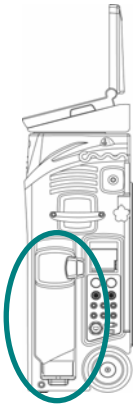
You can access various printing options by pressing the **MENU** key in the System section of the keypad and selecting **System Menu > Print Menu**. The following options are available:

- Waveforms – ECG/AP, ECG/BP, AP/BP, ECG, AP, BP
- Speed – 25 mm/sec, 50 mm/sec
- Strip length – 8 sec, 60 sec
- Auto Print – Off, 1 min, 5 min, 30 min, 1 hr, 2 hr

Replacing the Helium Cylinder

WARNING: Be sure to follow all warnings and cautions on the high-pressure gas (helium) cylinder. Observe all Department of Transportation (DOT) and International Air Transport Association (IATA) regulations for Dangerous Goods/Hazardous Materials when transporting a Console containing a helium cylinder. Only personnel trained in the handling of high-pressure gas cylinders should install or replace the helium cylinder.

CAUTION: Close the helium cylinder supply valve when the Console is not in use.



When either the HELIUM SUPPLY EMPTY or HELIUM SUPPLY LOW alarm message is displayed, change the helium cylinder by following the steps below:

1 Open the helium cylinder compartment (see Figure 27).

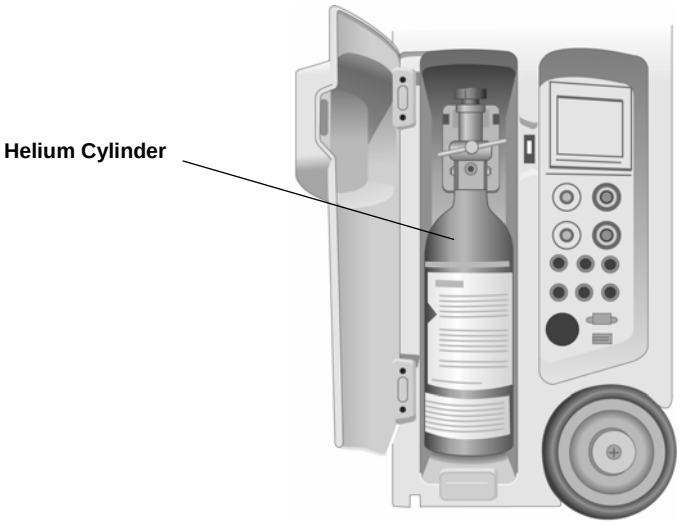


Figure 27 Helium Cylinder Compartment

2 Turn the supply valve handle fully clockwise to close the cylinder valve (see Figure 28).

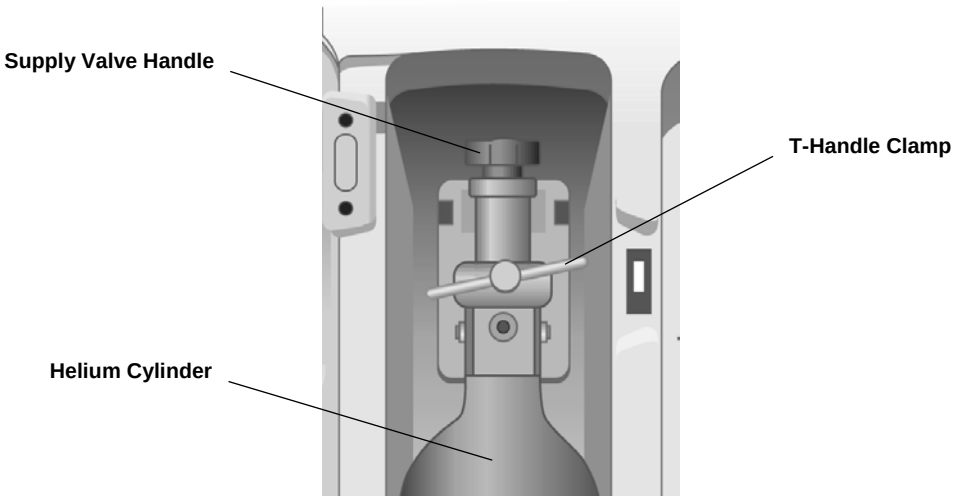


Figure 28 Helium Cylinder Components

3 Tilt the cylinder at a slight angle (see Figure 29). Support the cylinder and slowly turn the T-handle clamp (see Figure 28) counterclockwise to loosen it.

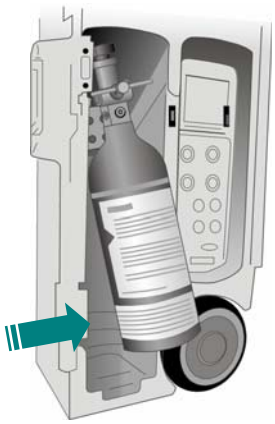


Figure 29 Tilting the Helium Cylinder

4 Slowly remove the cylinder. Remove the sealing washer, inspect the washer for damage (replace it with a new one if necessary), and place it back on the regulator.

5 Install the new cylinder and hand-tighten the T-handle clamp. Gently push the cylinder back into the compartment.

6 Open the supply valve by turning the handle counterclockwise one-half turn.

7 Close the cylinder compartment.

7 VAD Support

Contents

Using the Interface

VAD Keypad

The elements of the Ventricular Assist section of the keypad (see Figure 30) are described in Table 16.

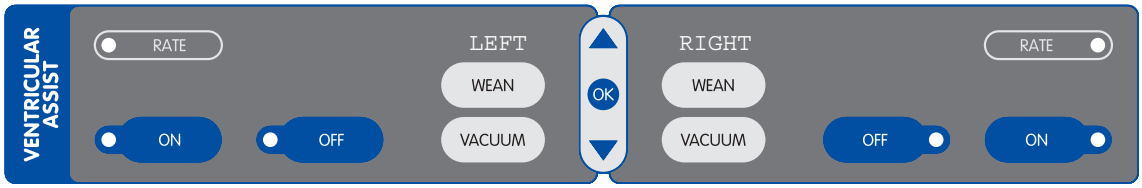


Figure 30 VAD Keypad

Table 16 VAD Keypad Functions

Feature	Use
Indicator Lights (LEFT and RIGHT)	
RATE	Amber light flashes with each beat.
ON	Green light when ON is pressed.
OFF	***Red*** light flashes when OFF is pressed once (pumping is not stopped). Light stays **red** when OFF is pressed twice within 13 seconds (pumping is stopped).
Controls (LEFT and RIGHT)	
ON	Starts pumping.
OFF	Stops pumping when pressed twice within 13 seconds.
WEAN	Displays weaning menu.
VACUUM	Displays vacuum menu.
Navigation Controls	
▲	Navigates through the selected function.
OK	Selects the highlighted function.
▼	Navigates through the selected function.

****[VENTRICULAR ASSIST label]

VAD Screen

The VAD screen (see Figure 31) allows you to monitor all aspects of VAD operation. These display elements are described in Table 17.

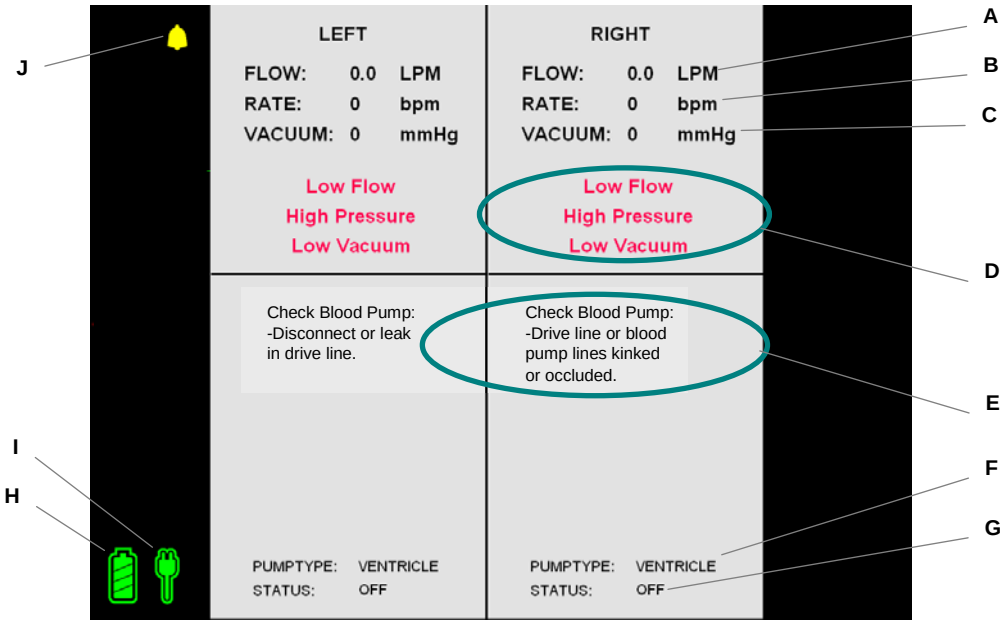


Figure 31 VAD Screen

Table 17 VAD Screen Descriptions

Item	Display Element	Description
A	Flow	Black text in normal operation; green text in wean mode. Blood flow rate in liters per minute (L/min).
B	Rate	Black text in normal operation; green text in wean mode. Beat rate in beats per minute (bpm).
C	Vacuum	Black text in normal operation; green text in wean mode. User-adjustable vacuum level in millimeters of mercury (mmHg).
D	Alarm Messages	Red text; highest priority active alarms (3 maximum for each side). Highest priority alarm is at the top of the list. For more information, refer to "VAD Alarms" in this Section.
E	Help text	Lists action(s) to take to resolve an alarm.
F	Blood pump type	BVS® Blood Pump or AB5000™ Ventricle.
G	Blood pump status	Indicates whether blood pump is ON or OFF.
H	Battery power icon	Color of segments indicates battery status. Refer to Table 8 in Section 5 for more information.
I	AC power icon	Color indicates AC power status. Refer to Table 8 in Section 5 for more information.
J	Alarm icon	Indicates an alarm condition exists; icon is crossed out when alarm is silenced.

The RECOVER BP System provides VAD support capability using either the AB5000™ Ventricle (Ventricle) or the BVS® Blood Pump (BVS Pump).

The following sections describe the procedures for using each blood pump type.

WARNING: A patient monitor ***must*** be provided and used to ***continuously monitor*** patient physiological pressure. Do ***NOT*** rely solely on the System alarms to notify you of life-threatening conditions.

Using the AB5000™ Ventricle

WARNING: Do ***NOT*** power the RECOVER BP System using Multiple Portable Socket Outlets (MPSO) or an extension cord.

Console Preparation

1. Plug the Console power cord into an AC outlet.

2. Turn the Console ON using the AC power switch on the left side. The Console goes through a Self-Test and is ready to use in approximately 25 seconds. ***Verify*** that the audible alarm indicator is operating properly by listening for the ***alarm tone*** during the Self-Test.

NOTE: Upon power-up, the Console displays the same type of screen (IABP or VAD) used at shutdown. If necessary, change to VAD mode by pressing the **MENU** key and selecting **System Menu > Console Mode > VAD**.

AB5000 Ventricle Preparation

Refer to the *AB5000™ Ventricle Instructions for Use (0055-9001)* and *AB5000™ Ventricle Training Guide (0055-9002)*.

Recommended Cannulation Method

Refer to the *Cannula Instructions for Use (0506-9110)*.

Pump Type Verification

Be sure that "Ventricle" is displayed as the pump type.

Initiating Support

1. Initiate support as described in the AB5000 Ventricle Instructions for Use and the AB5000 Ventricle Training Guide.

2. Begin pumping by pressing the **ON** key for the appropriate side (Left or Right). If both sides are being supported, press the ***Left*** **ON** key ***first***.

Optimizing AB5000 Ventricle Filling

When the Console is operating in normal (full flow) mode, flow rate should be greater than 2 L/min and typically ranges from 3 to 6 L/min.

To optimize blood flow, be sure that the patient is appropriately hydrated, with filling pressures within normal ranges. If the patient is hypovolemic, administer fluids according to hospital protocol.

The Ventricle is filled via vacuum assist. However, avoid raising the Ventricle above the heart to view it, because this could result in lower flow.

Adjusting Vacuum Level

Overview

The Console applies a default level of 100 mmHg (1.9 psi) of vacuum during diastole ***unless the vacuum level has been adjusted.*** You can adjust the vacuum level from 35 to 100 mmHg (0.7 to 1.9 psi) (in 5 mmHg (0.1 psi) steps) whether pumping is ON or OFF.

Reducing the vacuum level to 35 mmHg (0.7 psi) reduces the flow rate by as much as 2 L/min from the level achieved at 100 mmHg (1.9 psi). Reducing the vacuum level also changes the vacuum alarm limits.

Flow rate reduction for weaning can be performed using the weaning controls alone, by reducing the vacuum level alone, or by using both means of flow reduction simultaneously.

If an increase in flow rate is desired, increasing the vacuum level increases the flow rate, provided that there are no conditions limiting the flow through the device such as:

- Obstructions in the inflow cannula, outflow cannula, or driveline.
- Inadequate blood volume.
- Mispositioning of the AB5000 Ventricle.
- Disconnection or leak in the driveline.

Increasing the vacuum level to increase the flow rate can be used in response to activation of the low flow alarm during normal operation, or during weaning operation when the target flow level cannot be maintained at a reduced level of vacuum.

NOTE: If an inadvertent key stroke is made, allow the Console display to stabilize for about 5 seconds before proceeding. The display may take several seconds to update after an adjustment is made.

Adjusting the Vacuum Level with Pumping Off

Upon power-up (after completing its Self-Test), the Console displays the following screen:

****[Figure]

The... indicate that the vacuum level is set to the default level of 100 mmHg (1.9 psi). Press the pump ON button if no reduction in vacuum level is needed.

****[vacuum level adjustment]

In the following example, the vacuum level has been set to 50 mmHg (1.0 psi):

****[Figure]

Adjusting the vacuum level on one side does not affect the vacuum level on the other side.

The user-set vacuum level is applied to the Ventricle after its electrical/pneumatic connector is attached to the Console and the pump ON button is pressed.

If pumping is inadvertently started before plugging in the Ventricle electrical/pneumatic connector, an alarm is generated instructing you to "Turn Pumping OFF and then ON" to recognize that a Ventricle is attached. User-set vacuum levels are saved during these transitions and applied to operation of the Ventricle.

Adjusting the Vacuum Level with Pumping ON

If no vacuum level is set by the user during startup, the default vacuum level of 100 mmHg (1.9 psi) is automatically selected (after the Ventricle electrical/pneumatic connector is attached to the Console and the pump ON button is pressed).

In the following example, a Ventricle is pumping on the left side. The vacuum setting is at the default 100 mmHg (1.9 psi) level.

****[Figure]

****[vacuum level adjustment]

In the following example, a Ventricle is pumping on the left side with the vacuum level set to 35 mmHg (0.7 psi):

****[Figure]

To Stop Pumping

To stop pumping, press the appropriate **ON** button ***twice within 13 seconds***. You must press the button twice to stop the pump (see Figure ****X). This is a safety feature to prevent accidental operation.

****[Figure]

Weaning

When the patient is to be weaned, the Ventricle output may be set at any desired flow from 2.0 L/min to full flow (in 0.1 L/min. increments). ****[Selecting desired flow rate]

****[Figure]

During the weaning operation, the Console's ***displayed*** flow may vary for several beats from the selected flow setting. This may occur when patient conditions change and/or when the Console periodically adjusts Ventricle ejection duration to optimize flow. However, actual Ventricle flow will correspond to the selected flow setting.

Adjusting the Low Flow Alarm Level

The low flow alarm level can be adjusted when pumping is ON. It can be set to any level (in 0.1 L/min steps) between the current flow rate and 1.8 L/min during normal operation or 1.5 L/min in the weaning mode.

Remote Alarm Output

The remote alarm output allows you to connect the Console to a remote call system. The remote alarm output jack is located on the right side of the Console and accepts a standard phone plug. The switch is normally open, but closes when an alarm is generated. This switch closure can be used to trigger an alarm via the remote call system.

Preparing the Console for Intrahospital Transport

Unplugging the power cord automatically activates battery operation. When ready for transport, unplug the power cord and wind it around the cord wrap.

The Console can be either transported on its cart or removed from its cart and transported separately. To remove the Console from the cart, disengage the Console latch (located on the bottom rear of the cart) by ***lifting*** and ***then pulling*** the latch handle. Lift the Console by its side handles, with one person on each side, clear of the cart. Place the Console on the floor.

Drivelines and driveline connectors should be protected from tension during transport. Roll the Console carefully to avoid kinking or disconnecting the driveline.

To carry the Console over obstacles, grasp the side handles, with one person on each side, and lift.

Using the BVS® Blood Pump

WARNING: Do ***NOT*** power the RECOVER BP System using Multiple Portable Socket Outlets (MPSO) or an extension cord.

Console Preparation

1 Plug the Console power cord into an AC outlet.

2 Turn the Console ON using the AC power switch on the left side. The Console goes through a Self-Test and is ready to use in approximately 25 seconds. ***Verify*** that the audible alarm indicator is operating properly by listening for the ***alarm tone*** during the Self-Test.

BVS Pump Preparation

Refer to the *BVS Blood Pump Instructions for Use (0505-9000)*.

Recommended Cannulation Method

Refer to the *Cannula Instructions for Use (0506-9110)*.

Pump Type Verification

Be sure that "BVS Pump" is displayed as the pump type.

Initiating Support

1 Initiate support as described in the BVS Blood Pump Instructions for Use (0505-9000).

2 Begin pumping by pressing the **ON** key for the appropriate side (Left or Right). If both sides are being supported, press the ***Left*** **ON** key ***first***.

Optimizing BVS Pump Filling

When the Console is operating in normal (full-flow) mode, flow rate should be greater than 2 L/min and typically ranges from 3 to 6 L/min.

To optimize blood flow:

1. Be sure that the patient is appropriately hydrated, with filling pressures within normal ranges. If the patient is hypovolemic, administer fluids according to hospital protocol.

2. Observe the filling and emptying of the upper bladder. The bladder should just barely fill the plastic chamber during Pump systole, and just empty during Pump diastole. If the bladder is too full, move the Pump higher to reduce inflow pressure. If the bladder is too empty and the patient is sufficiently hydrated, lower the Pump to increase inflow pressure.

3. Position the top of the upper bladder 0 to 14 in. (35 cm) below the patient's atria. Flow rate may decrease if the Pump is positioned above or below this range.

4. After adjusting Pump height, observe bladder filling for 2 minutes (to allow the system to stabilize) before making another adjustment.

Mounting the BVS Pump to the Accessory Mounts

Three types of accessory mounts are available to mount the BVS Pump for transport.

- BVS® IV Pole Mount – attaches to a standard IV pole.

- BVS® Bed Mount – slips under the patient's mattress and accepts a BVS IV Pole Mount.

- BVS® Blood Pump Sling – allows the BVS Pump to be mounted horizontally for transport.

Attaching the BVS® IV Pole Mount to the IV pole

1. Unscrew the screw clamp enough to fit the clamp around the IV pole.
2. Tighten the screw clamp onto the IV pole by turning the black knob clockwise.
3. Adjust the height of the Pole Mount by turning the central adjustment lever counterclockwise one-half turn to loosen it, while holding the handle (the adjustment lever is now pointing up towards the 12 o'clock position).
4. Move the Pole Mount up or down with the handle to the desired position.
5. Turn the central adjustment lever clockwise, back to its original position, to secure the Pole Mount in place.

Attaching the BVS® IV Pole Mount to the BVS® Bed Mount

1. Hold the Bed Mount so the metal post faces up.
2. Slide the Bed Mount under the head of the mattress (between mattress and bed) so that the metal post is facing up next to the mattress. The weight of the mattress and the patient will hold the Bed Mount in place.
3. Hold the Pole Mount by the handle.
4. Unscrew the screw clamp enough to fit the clamp around the metal post.
5. Tighten the screw clamp onto the metal post by turning the black knob clockwise.
6. Adjust the height of the Pole Mount by turning the central adjustment lever counterclockwise one-half turn to loosen it, while holding the handle. Instead of pointing down, the central adjustment lever is now pointing up towards 12 o'clock.
7. Move the Pole Mount up or down with the handle to the desired position.

8 Turn the central adjustment lever clockwise, back to its original position, to secure the Pole Mount in place.

Attaching the BVS Pump to the BVS® IV Pole Mount

A long plastic plate is attached to the back of the BVS Pump. At the top of this plate, slightly above the upper inflow bladder, is a square back plate designed to slide into the Pump bracket.

1 Hold the BVS Pump securely so the inflow and outflow tubing is at the top of the Pump and the driveline is at the bottom.

2 Slide the back plate into one of the Pump brackets from the top down.

3 Make sure that both edges of the Pump bracket fully engage the Pump back plate to ensure that it is attached securely.

****[Adjusting the Pump height]

Attaching the BVS Pump to the BVS® Blood Pump Sling

1 Always hold the BVS Pump below the patient's heart.

2 Lay the Pump into the Sling. Be careful not to kink or bend the blood or air tubing.

3 Close the Sling around the Pump by joining the two hook-and-loop fastening ends.

4 Attach the Sling to the bed or stretcher by fastening the mounting straps around the bed rail.

****[Adjusting the Pump height]

Adjusting the Low Flow Alarm Level

The low flow alarm level can be adjusted when pumping is ON. It can be set to any level (in 0.1 L/min steps) between the current flow rate and 1.8 L/min during normal operation (1.5 L/min in the weaning mode).

****[Adjusting the alarm level]

To Stop Pumping

To stop pumping, press the appropriate **OFF** button ***twice within 13 seconds***. You must press the button twice to stop the pump (see Figure ****X). This is a safety feature to prevent accidental operation.

Weaning

When the patient is to be weaned, the BVS Pump output may be set at any desired flow from 2.0 L/min to full flow (in 0.1 L/min. steps).
****[Selecting desired flow rate]

[Figure]

During the Weaning operation, the Console's ***displayed*** flow may vary for several beats from the selected flow setting. This may occur when patient conditions change and/or when the Console periodically adjusts BVS Pump ejection duration to optimize flow. However, actual BVS Pump flow will correspond to the selected flow setting.

Remote Alarm Output

The remote alarm output allows the user to connect the Console to a remote call system. The remote alarm output jack is located on the right side of the Console and accepts a standard phone plug. The switch is normally open, but closes when an alarm is generated. This switch closure can be used to trigger an alarm via the remote call system.

Preparing the Console for Intrahospital Transport

Unplugging the power cord automatically activates battery operation. When ready for transport, unplug the power cord, and wind it around the cord wrap.

The Console can be transported on its cart or removed from its cart and transported separately. To remove the Console from the cart, first disengage the Console latch (located on the bottom rear of the cart) by ***lifting*** and ***then pulling*** the latch handle. Lift the Console by its side handles, with one person on each side, clear of the cart. Place the Console on the floor.

Drivelines and driveline connectors should be protected from tension during transport. Roll the Console carefully to avoid kinking or disconnecting the driveline.

To carry the Console over obstacles, grasp the side handles, with one person on each side, and lift.

VAD Alarms

The Console monitors various functions to determine whether its operating parameters are within expected limits. When a parameter goes outside of its limits, the Console displays an alarm message and sounds an alarm tone. The severity of the alarm is indicated by the color of the alarm message text and by the characteristics of the alarm tone ****[verify details].

Levels of Severity

Alarms are divided into two levels of severity:

- Life-Threatening – Red
- Serious – Yellow

A maximum of six alarms (three Left and three Right) are displayed on the VAD screen (see Figure 32). When an alarm condition occurs, pressing HELP on the System keypad opens a help window that describes the action(s) to take to resolve the alarm.

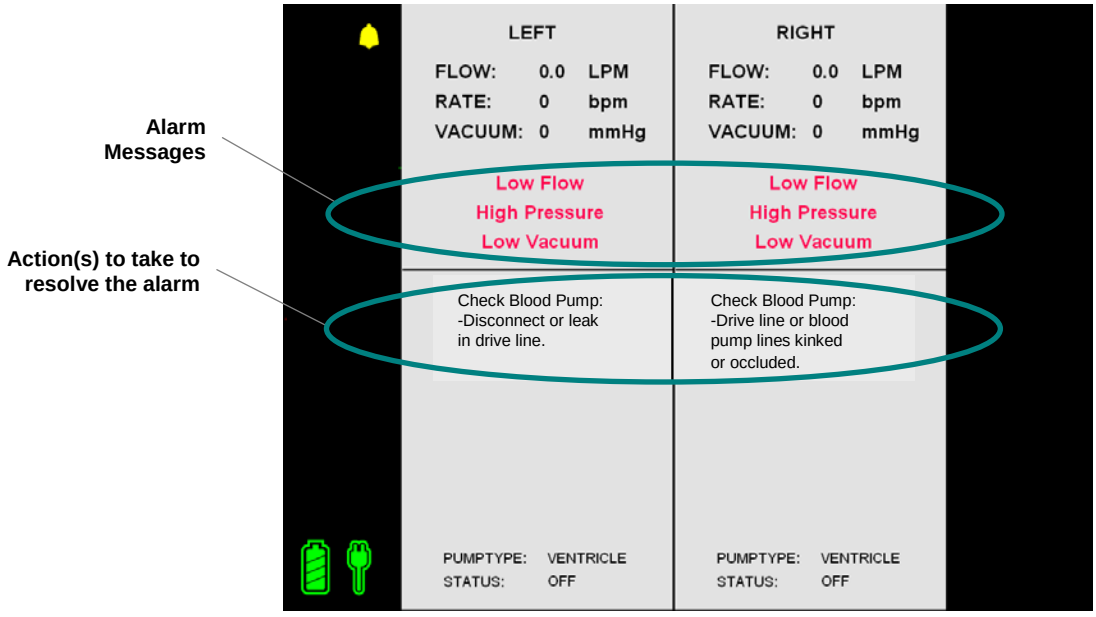


Figure 32 VAD Alarm Messages and Help Text

VAD Alarm Messages and Help Text

Tables 17 and 18 show all VAD alarm messages and help text.

Table 18 VAD Red Alarm Messages and Help Text

RED ALARMS Category: Life-Threatening	
Alarm Message	**Action**
LOW FLOW	Check Blood Pump: 1. Obstruction of blood lines. 2. Blood Pump placed too high relative to atrium. 3. Inadequate blood volume.
HIGH PRESSURE	Internal pressure problem: 1. Obtain backup Console.
LOW PRESSURE	Internal pressure problem if indicated when not pumping: 1. Obtain backup Console.
HIGH VACUUM	Internal vacuum problem: 1. Obtain backup Console.
LOW VACUUM	Internal vacuum problem: 1. Obtain backup Console.
SYSTEM FAILURE Keypad Failure - Change to Backup Console (Displayed in Help window)	Keypad not working/connected: 1. Check keypad connection. 2. Switch to backup Console. 3. Call for service.

Table 19 VAD Yellow Alarm Messages and Help Text

YELLOW ALARMS Category: Serious	
Alarm Message	**Action**
PUMP ID Pump ID Disconnected (displayed in help window)	Re-attach Ventricle electrical/pneumatic connector to Console.
PUMP ID New Pump ID Detected (displayed in help window)	Check Ventricle electrical/pneumatic connector: 1. Turn pump OFF and then ON again to change pump type selected by Console.

Using the Hand Pump

If the Console fails (stops pumping), the supplied RECOVER BP Hand Pump allows manual operation of the Ventricle or the BVS® Pump. The Hand Pump is stored on the side of the Console.

The Hand Pump may be operated while mounted on the Console, or it may be removed and held during operation.

Transferring to the Hand Pump

1 Turn off and unplug the Console.

2 Remove the Ventricle or BVS Pump driveline(s) from the Console connector.

3 Connect the driveline(s) to the Hand Pump. The Left pump driveline goes to the Left connector, and the Right pump driveline goes to the Right connector.

4 Set the Hand Pump shuttle mechanism to the position appropriate for the blood pump in use.

5 Pull the Hand Pump handle until it stops.

6 Push the handle to fully return it to its original position.

7 Continue pumping at a rate of 30 to 60 times per minute.

8 Observe the Ventricle or BVS Pump for proper filling and emptying.

Transferring from the Hand Pump to a Backup Console

1 Plug the backup Console power cord into an AC outlet.

2 Turn the Console ON and allow the Self-Test to run.

3 Transfer the driveline(s) from the Hand Pump to the backup Console.

4. Begin pumping by pressing the **ON** key for the appropriate side (Left or Right). If both sides are being supported, press the ***Left*** **ON** key ***first***.

5. If necessary, return the Hand Pump to the Console holder.

6. Contact service personnel as soon as possible to repair the failed Console.

8 Emergency System Operation (ESO)

Contents

The RECOVER BP Console monitors its operating parameters and automatically enables the Emergency System Operation (ESO) mode if a serious problem is detected. The effects on Console operation are dependent on whether IABP or VAD support is in progress.

ESO Enabled During IABP Support

When ESO is enabled, the Console performs the following actions:

- Stops IAB pumping.
- Deflates and vents the IAB.
- Activates an alarm.
- Turns on the ESO indicator light on the System keypad (see Figure 33).

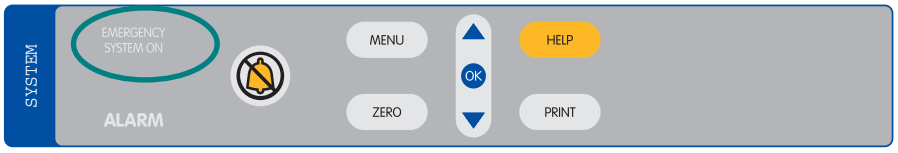


Figure 33 Emergency System Operation (ESO) Indicator

ESO Enabled During VAD Support

When ESO is enabled, the Console performs the following actions:

- Changes to a fixed-rate control system and continues pumping at approximately 75 bpm.
- Activates an alarm.
- Turns on the ESO indicator light on the System keypad (see Figure 33).

9 Clinical Considerations

Contents

Effects of Electrosurgical Equipment

The RECOVER BP Console may exhibit the following effects during the use of electrosurgical equipment:

- Display becomes blank or distorted
- Alarm sounds
- Pumping stops or becomes erratic

The display and the pumping function will resume normal operation within 10 seconds after the completion of electrosurgery.

Effects of Defibrillation Equipment

WARNING: Be extremely careful when a defibrillator is used on a patient. Dangerous high voltage is present during defibrillation. Do ***NOT*** touch the Console, patient, table, accessories, cables, or any connected equipment.

The Console is classified as Type CF defibrillation-proof (IEC 60601-1) equipment.

The following effects may occur during defibrillation:

- Display becomes blank or distorted
- Alarm sounds
- Pumping stops or becomes erratic

The display and the pumping function will resume normal operation within 10 seconds after the completion of defibrillation.

10 Installation and Maintenance

Contents

Installation

Prior to clinical use, installation and testing of the Console shall be performed by an authorized ABIOMED® Service Representative.

CAUTION: The RECOVER BP Console must be plugged into AC power to maintain a charged battery.

CAUTION: To remove all AC power from the Console, unplug the power cord from the AC outlet.

Checking the Console Before Each Use

WARNING: The RECOVER BP Console does not contain any user-serviceable parts. To reduce the risk of electric shock, do ***NOT*** attempt to remove the Console housing or to replace the Console Battery.

Prior to each clinical use, perform the following checks to determine that the Console is working properly and is ready to use:

1. Visually inspect for physical damage to the equipment housing, display, and power cord. Be sure that all required parts of the System, such as cables and the Hand Pump, are present.

2. Turn the Console ON using the AC power switch on the left side.

3. Allow the Console to complete the Self-Test. Verify that all indicator lights work and air audibly vents from the left and right driveline connectors. Verify that the audible alarm indicator is operating properly by listening for the alarm tone during the Self-Test.

NOTE: The audible alarm indicator can be tested during Console operation by pressing any **ON** or **OFF** key whose indicator light is on.

Periodic Testing of Backup Systems

Regularly test the Console's backup systems, which are the Hand Pump and the Emergency System Operation (ESO) feature.

Testing the Hand Pump

Operate the Hand Pump handle through its full range of motion and verify that air audibly vents from the left and right driveline connectors.

Testing ESO

1. Turn the Console ON. Within 30 seconds, simultaneously press both **WEAN** keys for at least 3 seconds.

2. Verify that a continuous audible alarm sounds and the ESO indicator light flashes.

3. Press the left and right Ventricular Assist **ON** keys. Check that the Rate indicator lights blink and that air vents from the driveline connectors as the Console pumps.

4. Turn the Console OFF to deactivate ESO.

Cleaning

CAUTION: Do ***NOT*** pour liquid, including cleaning solution, directly on any part of the Console. Doing so can cause electrical malfunction.

If liquid is accidentally spilled on the Console, be sure to thoroughly dry the affected area. Wait at least 15 minutes, after drying, before turning the Console ON. Verify that the Self-Test runs and indicates that the unit is operating properly.

Console

It is recommended that the Console be cleaned after each use. Turn the Console OFF before you clean it.

To clean the display/control panel area, use cotton and 70% isopropyl alcohol, or a soft cloth with soap and water.

To clean the housing, use a damp cloth and a mild detergent solution.

Patient ECG Cable

Clean and disinfect the patient ECG cable after each use by performing the procedure described in the Instructions for Use supplied with the cable or by following hospital operating procedures.

Preventive Maintenance

The following preventive maintenance items are to be performed only by an authorized ABIOMED® Service Representative.

Table 20 Preventive Maintenance Intervals

Component/Subsystem	Interval
Battery	One calendar year
Solenoid Valve	5000 hrs. operating time
Proportional Valve	2500 hrs. operating time
Compressor	2500 hrs. operating time
IABP	5000 hrs. operating time

Ordering Information

Table 21 Ordering Information for RECOVER BP Console

Catalog No.	Language	Nominal Voltage
0036-0000	English	120 VAC
****[?]	English	230 VAC

Table 22 Ordering Information for Parts

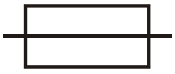
Catalog No.	Description	Contents
0036-0030	Cart	1 per box
0015-0040	Aircraft Mounting Plate	1 per box
0050-3200	BVS® Blood Pump Sling	1 per box
0005-0090	BVS® IV Pole Mount	1 per box
0005-0080	BVS® Bed Mount	1 per box
0005-0060	BVS® Pump Mount Set	1 per box
0036-2754	Patient Cable Set	****[?]
****[?]	Edwards Lifesciences TruWave Disposable Pressure Transducer (supplied sterile)	****[?]
0036-6300	*Helium Cylinder, 93 L	****[?]
2500-0133	*Helium Yoke Sealing Washer	****[?]
2000-0009	Chart Recorder Paper, Thermal, 2-inch Roll	****[?]
****[?]	Adapter for Datascope® 8F (40 cc) IAB Catheter	****[?]
****[?]	RECOVER BP IABP/VAD System Operator's Manual	1 per box
****[?]	RECOVER BP IABP/VAD System Service Manual	1 per box

* This is a refillable cylinder. Ownership of this cylinder has been established by sale to the purchaser. Refill may be arranged by contacting your local gas supplier or by contacting Linde Specialty Gas Customer Service at 1-800-837-7226. Refiller is required to relabel this product with their own label. Do not refill without properly labeling.

This cylinder may also be recycled by following the instructions below:

1. Using a properly installed regulator, slowly vent residual gas until empty.
2. Vent gas slowly into a well ventilated area, preferably outdoors.
3. Remove the regulator, let valve open. Write "EMPTY" on cylinder.
4. Deface any hazardous materials information labels.
5. Cylinder may be discarded as scrap metal or solid waste.
6. Check with local solid waste authority to ensure local regulatory compliance.
7. Questions? Contact Linde Specialty Gas Customer Service at 1-800-837-7226.

11 Symbol Descriptions

Symbol	Description	Symbol	Description
	"ON" (power)	**IPX1**	Protected against dripping water
	Alarm silence		Attention, consult instructions
	Equipotentiality		Year of manufacture
	Remote alarm output	**SN**	Serial number
	Fuse	**REF**	Part number
	"OFF" for a part of equipment	**LOT**	Lot number
	Type CF Equipment defibrillator-proof		Alternating current

12 System Specifications

Contents

Console Mechanical

****[reformat]

Attribute	Specification		
Temperature	Operating: Storage:	10°C to 40°C (50°F to 104°F) -15°C to 50°C (5°F to 122°F)	
Relative Humidity	Operating: Storage:	30% to 75% 10% to 95%, noncondensing	
Atmospheric Pressure	Operating: (1050 hPa) Storage: (1050 hPa)	8000 ft (750 hPa) to -1000 ft 18,000 ft (500 hPa) to -1000 ft	
Dimensions – Transport & Hospital Configuration		Transport (w/o Cart)	Hospital (w/ Cart)
	Height:	34 in. (86.4 cm)	41 in. (104.1 cm)
	Width:	23 in. (58.4 cm)	28 in. (71.1 cm)
	Depth:	11 in. (27.9 cm)	18 in. (45.7 cm)
Dimensions – Packaged Configuration		Console	Cart
	Height:	24 in. (61.0 cm)	28 in. (71.1 cm)
	Width:	30 in. (76.2 cm)	33 in. (83.8 cm)
	Depth:	38 in. (96.5 cm)	45 in. (114.3 cm)
Weight – Transport & Hospital Configuration		Transport (w/o Cart)	Hospital (w/ Cart)
	Maximum:	126 lb (57.2 kg)	190 lb (86.2 kg)
Weight – Packaged Configuration		Console	Cart
	Maximum:	****[X] lb	****[X] lb
Left-Side Flow Rate	Under normal operation, the Console must produce a minimum blood flow through the VAD for both pumps as follows: Minimum: 4.8 L/min at outflow pressure of 90 mmHg (1.7 psi) and inflow pressure > 10 mmHg (0.2 psi) for 42 Fr Atrial Cannula used with 42 Fr or 10 mm Arterial Cannula. Minimum: 4.0 L/min at outflow pressure of 90 mmHg (1.7 psi) and inflow pressure > 10 mmHg (0.2 psi) for 32 Fr and 36 Fr Atrial Cannula used with 42 Fr or 10 mm Arterial Cannula. Method: Blood flow rate calculated based on integration of airflow signal.		
Right-Side Flow Rate	Under normal operation, the Console must produce a minimum blood flow through the VAD as follows: Minimum: 4.8 L/min at outflow pressure of 40 mmHg (0.8 psi) and inflow pressure > 10 mmHg (0.2 psi) for 42 Fr Atrial Cannula used with 42 Fr or 10 mm Arterial Cannula. Minimum: 4.0 L/min at outflow pressure of 40 mmHg (0.8 psi) and inflow pressure > 10 mmHg (0.2 psi) for 32 Fr and 36 Fr Atrial Cannula used with 42 Fr or 10 mm Arterial Cannula Method: Blood flow rate calculated based on integration of airflow signal.		

Console Mechanical (continued)

****[reformat]

Attribute	Specification
Displayed Flow Accuracy	At altitudes between min/max range, flow accuracy is as follows: Left Side: ± 15% over the following ranges: Inflow Pressure 5 to 25 mmHg (0.1 to 0.5 psi) Outflow Pressure 60 to 90 mmHg (1.2 to 1.7 psi) Right Side: ± 15% over the following ranges: Inflow Pressure 5 to 15 mmHg (0.1 to 0.3 psi) Outflow Pressure 30 to 40 mmHg (0.6 to 0.8 psi) At elevations greater than maximum specified altitude range, flow rates displayed on Console may underreport flows by as much as 1.0 L/min.
Beat Rate	The Console must determine and display the VAD beat rate. Range: 0 – 150 bpm Resolution: 1 bpm Accuracy: ± 3 bpm or ± 3 %, whichever is greater
Timing	AUTO Mode Automatically and continually optimizes inflation & deflation timing. MANUAL Mode Allows the user to manually adjust inflation / deflation timing. Method: Percentage based on 4-beat average of beat-to-beat interval (ECG, AP, A-Pacer, V-Pacer). Percentage based on 4-beat average of 80 bpm Heart Rate (Internal). Inflation Range: 20 – 80 % (ECG, A-Pacer, V-Pacer, Internal) 0 – 35 % (AP) Inflation Default: 45 % (ECG, A-Pacer, V-Pacer, Internal) 10 % (AP) Deflation Range: 30 – 100 % (ECG, Internal) 35 – 75 % (AP) 30 – 120 % (A-Pacer, V-Pacer) Deflation Default: 80 % (ECG, A-Pacer, V-Pacer) 40 % (AP) 80 % (Internal)
Heart Rate	The Console must determine and display the heart rate. Range: 30 – 200 bpm Resolution: 1 bpm Accuracy: ± 3 bpm or ± 3% whichever is greater Display Update Rate: 2 ± 0.5 sec

Console Electrical

****[reformat]

Attribute	Specification
Console	AC operation: 100 – 230 VAC (nominal); 50/60 Hz; 4 A Internal battery operation: 24.0 VDC (nominal); sealed lead-acid
ECG	Lead Input Support: 5 Lead Cable (AAMI or IEC) Electrodes: RA, LA, LL, RL, V Sampled Leads: I, II, V' Derived Leads: III, aVR, aVL, AVF, V Range: ± 300 mV (DC) ± 80 mV (AC) Frequency Response: 0.4 – 100 Hz (-3dB) ****[TBD] 0.6 – 85 Hz Minimum Input Impedance: 2.5 MΩ Pacer Pulse Detection: On each sampled Lead Pacer Sensitivity: down to 1.54 V/s per AAMI EC13-2002 4.1.4.3 Lead Fault Detection: When any active electrode open Defibrillator Protection: compliance to IEC601-2-27 Defibrillator Recovery Time: compliance to IEC601-2-27 Electrosurgical Interference Suppression: Operation of an Electrosurgical Unit must not cause an unrecoverable malfunction. Default Waveform Sweep Speed: 25 mm/sec
Arterial Pressure	The Console must determine and display Arterial Pressure. Parameters: assisted systole, unassisted systole, assisted end diastole, unassisted end diastole, mean, augmented diastole, and AP waveform. Nominal Sensitivity: 5 μV / V / mmHg Range: 0 – 300 mmHg (5.8 psi) Resolution: 1 mmHg (.02 psi) Frequency Response: 0 – 40 Hz (-3dB) Accuracy: ± 2 mmHg (.04 psi) or ± 2% whichever is greater (not including transducer) Display Update Rate: 2 ± 0.5 sec Default Waveform Sweep Speed: 25 mm/sec
Doppler	Tethered and retractable 8 MHz hand-held non-directional probe. Minimum Length: 6 ft (1.8 m), uncoiled Audible Output: Integral speaker with volume control Minimum Audible Level: 73 dB @ 1 ft (0.3 m) Power Source: Battery Powered

Equipment Design

The RECOVER BP System is designed to comply with the requirements of the following standards:

- IEC 60601-1: 1988 + A1:1991 + A2:1995
- IEC 60601-1-1: 2000
- IEC 60601-2-27: 1994 (First Edition)
- IEC 60601-2-34: 2000 (Second Edition)

Equipment Classifications

Type of protection against electric shock	IEC 60601-1: Class I and internally powered. Relies not only on basic insulation against shock but also includes additional protection. Accomplished by providing means for connecting the equipment to the protective earth conductor of the fixed wiring of the installation in a way that prevents ***accessible metal parts*** from becoming ***live*** if basic insulation fails.
Degree of protection against electric shock	
Console	IEC 60601-1: Type CF defibrillation-proof
IAB	IEC 60601-1: Type CF defibrillation-proof
Pressure transducer	IEC 60601-1: Type CF defibrillation-proof
ECG	IEC 60601-1: Type CF defibrillation-proof
Mode of Operation	Continuous.
Degree of protection against explosion hazard	Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. Also not suitable for use in an oxygen-enriched atmosphere.
Degree of protection against harmful ingress of water	IEC 60529: IPX1 protected against dripping water.
Cleaning Methods	
Console	Display/control panel: 70% isopropyl alcohol, or soap and water. Housing: mild detergent.
Patient ECG Cable	Per manufacturer's Instructions for Use or per hospital operating procedures.

Federal Communications Commission (FCC) Notice

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED, Inc. could void the user's authority to operate this device.

Electromagnetic Compatibility

WARNING: Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the Electromagnetic Compatibility (EMC) information provided in the accompanying documents.

WARNING: Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

WARNING: The Equipment or System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Equipment or System should be observed to verify normal operation in the configuration in which it will be used.

NOTE: The EMC tables and other guidelines that are included in the Operator's Manual provide information to the customer or user that is essential in determining the suitability of the Equipment or System for the Electromagnetic Environment of Use, and in managing the Electromagnetic Environment of Use permit the Equipment or System to perform to its intended use without disturbing other Equipment and Systems or non-Medical Electrical Equipment.

TABLE 201

Guidance and Manufacturer's Declaration – Emissions All Equipment and Systems

The RECOVER BP Console is intended for use in the electromagnetic environment specified below. The customer or user of the RECOVER BP Console should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Enforcement – Guidance
RF Emissions CISPR 11	Group 1	The RECOVER BP Console uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The RECOVER BP Console is suitable for use in all establishments other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

TABLE 202

Guidance and Manufacturer's Declaration – Immunity All Equipment and Systems

The RECOVER BP Console is intended for use in the electromagnetic environment specified below. The customer or user of the RECOVER BP Console should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 61000-4-4	±2 kV Mains ±1 kV for input/output lines	±2 kV Mains ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential ±2 kV Common	±1 kV Differential ±2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	> 95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles > 95% dip for 5 seconds	> 95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles > 95% dip for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RECOVER BP Console requires continued operation during power mains interruptions, it is recommended that the RECOVER BP Console be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical location in a typical commercial or hospital environment.

TABLE 204

Guidance and Manufacturer's Declaration – Emissions Equipment and Systems that are NOT Life-Supporting

The RECOVER BP Console is intended for use in the electromagnetic environment specified below. The customer or user of the RECOVER BP Console should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V1 = 3 Vrms	Portable and mobile RF communications equipment should be separated from the RECOVER BP Console by no less than the recommended separation distances calculated/listed below: $D = (3.5/V1)\sqrt{P}$ $D = (3.5/E1)\sqrt{P}$ 80 to 800 MHz $D = (7/E1)\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum power rating in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E1 = 3 V/m	

TABLE 206

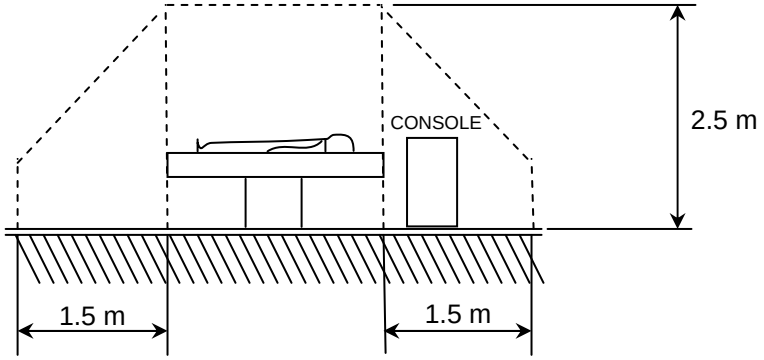
Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the RECOVER BP Console Equipment and Systems that are NOT Life-Supporting

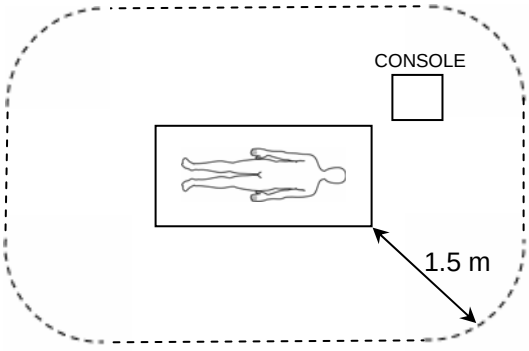
The RECOVER BP Console is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the RECOVER BP Console can help prevent electromagnetic interference by maintaining a minimum distance between Portable and Mobile RF Communications Equipment and the RECOVER BP Console as recommended below, according to the maximum output power of the communications equipment.

Maximum Output Power (Watts)	Recommended Separation Distances for the RECOVER BP Console		
	150 KHz to 80 MHz $d = 1.1667\sqrt{P}$	80 to 800 MHz $d = 1.1667\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3333\sqrt{P}$
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

Patient Environment

The RECOVER BP Console and the components of the RECOVER BP System are the only items approved for use within the patient environment defined in IEC 60601-1-1 and in the figure below.





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