

AB5000™

OPERATOR'S GUIDE

to the AB Portable™ Driver



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IMPORTANT NOTICE: Read this entire manual before using the ABIOMED® AB Portable Driver. The AB Portable Driver is to be used only in accordance with this manual.

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OPERATOR'S GUIDE TO THE AB PORTABLE™ DRIVER

Rx Only

ABIOMED, Inc.
22 Cherry Hill Drive
Danvers, MA 01923
978-777-5410 (voice)
978-777-8411 (fax)
clinical@abiomed.com (email)

ABIOMED Europe GmbH
Neuenhofer Weg 3
52074 Aachen, Germany
+49 (241) 8860-0 (voice)
+49 (241) 8860-111 (fax)
europe@abiomed.com (email)

www.abiomed.com

24-Hour Emergency Hotlines:

N. America 1-800-422-8666
Europe +49 7000 467 3552

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PURPOSE OF THE MANUAL

This manual describes the ABIOMED® AB Portable Driver and provides instructions for operating the Portable Driver to provide VAD support.

MANUAL OVERVIEW

The information in this manual is divided into 7 sections:

- **Section 1: Warnings and Cautions** lists the warnings and cautions pertaining to the use of the AB Portable Driver.
- **Section 2: Indications and Contraindications** presents the indications and contraindications for use of the AB5000™ System.
- **Section 3: AB Portable Driver Overview** describes the features and connections on the AB Portable Driver and lists AB5000 and AB Portable Driver accessories.
- **Section 4: AB Portable Driver Panes and Menus** describes the information displayed on the AB Portable Driver user interface.
- **Section 5: Using the AB Portable Driver for VAD Support** describes how to use the Portable Driver to provide VAD support and includes information about alarms, using the Hand Pump, Emergency System Operation (ESO), portable operation, and clinical considerations.
- **Section 6: Installation and Maintenance** provides information on installation, Portable Driver checkout, backup system testing, cleaning, preventive maintenance, and ordering parts.
- **Section 7: System Specifications** provides technical information and defines the patient environment.

The manual also contains three Appendices:

- **Appendix A: Symbol Descriptions** explains the symbols and abbreviations used on the System.
- **Appendix B: Alarm Table** describes the alarms that can occur when the VAD is pumping and identifies help text for each alarm.
- **Appendix C: AB Portable™ Driver Domestic Limited Service Warranty**

1 WARNINGS AND CAUTIONS

WARNINGS 1.1

CAUTIONS 1.2

WARNINGS



The AB Portable Driver 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 AB Portable Driver does not contain any user-serviceable parts. To reduce the risk of electric shock, do **NOT** attempt to remove the Portable Driver housing or replace the Portable Driver battery.



Do **NOT** connect items to the AB Portable Driver 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 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 meters 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 AB Portable Driver 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 Portable Driver using its internal battery if the integrity of the protective earth conductor is questionable.



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 System Specifications section of this manual.



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



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



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 AB Portable Driver is intended for use only by personnel trained in accordance with the ABIOMED Training Program.




Do **NOT** operate the AB Portable Driver near a Magnetic Resonance Imaging (MRI) machine.



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

Warnings

Warnings alert you to situations that can cause injury or death. The red symbol  appears before warning messages.

CAUTIONS

Cautions

Cautions indicate a situation in which equipment may malfunction, be damaged, or cease to operate. The yellow symbol ⚠ appears before caution messages.



The AB Portable Driver must be plugged into AC power to maintain a charged battery.



To remove all AC power from the Portable Driver, unplug the power cord from the AC outlet.



Be sure to route the power cord and all cables in a manner that prevents tripping hazards and equipment damage.



Do **NOT** lean or place any objects on the Portable Driver.



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

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



Minimize exposure of AB Portable Driver 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 AB Portable Driver and the EMI source or turn off the EMI source.



Operation of AB Portable Driver may interfere with the operation of other devices. If interference occurs, increase the distance between the device and AB Portable Driver.



Avoid activities that may build up static charges on the Portable Driver or on personnel contacting the Portable Driver. Avoid brushing bed sheets across the Portable Driver or touching the Portable Driver immediately after performing activities likely to build static charge. If electrostatic discharge interrupts operation of the Portable Driver, cycle the System off and back on using the Power switch.



Do **NOT** power the AB Portable Driver using Multiple Portable Socket Outlets (MPSO) or an extension cord.



Do **NOT** use an AB Portable Driver 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 AB Portable Driver cooling vents while the Portable Driver is operating.



The Portable Driver battery should be disposed of according to all local, state, federal, and country regulations. The Portable Driver battery is a lithium ion unit and should be reclaimed.

2 INDICATIONS AND CONTRAINDICATIONS

INDICATIONS.....2.1

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INDICATIONS

The AB5000 System is a mechanical circulatory support system for use in patients suffering from potentially reversible ventricular dysfunction. It can also be used to facilitate patient transport. Typical patients have undergone successful cardiac surgery and subsequently developed low cardiac output, or suffer from acute cardiac disorders leading to hemodynamic instability. The intent of therapy is to provide circulatory support, restore normal hemodynamics, reduce ventricular work, and allow the heart time to recover adequate mechanical function. The Driver is external to the patient and is intended for short-term use.

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 devices (LVADs)
- Patients suffering from acute cardiac disorders such as viral myocarditis

A patient **is a candidate** for mechanical assistance with the AB5000 System if he/she meets all of the following criteria:

- Patient has a body surface area $> 1.3 \text{ m}^2$ 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, arrhythmia, and residual hypothermia.
- Cardiac resuscitation employing pharmacologic agents has been attempted. While the use of the Intra-Aortic Balloon Pump (IABP) is recommended prior to AB5000 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

- 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.

3 AB PORTABLE DRIVER OVERVIEW

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- AB5000 AND AB PORTABLE DRIVER ACCESSORIES3.8

GENERAL DESCRIPTION

The AB Portable Driver is a Circulatory Support System that operates either one or two AB5000 Ventricle blood pumps. The system can be configured for right AB Ventricle support and/or left AB Ventricle support. It can be used in hospitals and step-down units as well as in transport environments.

The AB Portable Driver uses a microprocessor to control the systolic and diastolic intervals based on blood pump flow. Software algorithms calculate the flow and automatically adjust settings to the outputs of the natural heart. This allows the heart to contribute to the pumping function while providing it the necessary assistance to rest and recover.

The Portable Driver incorporates several systems to ensure safe operation:

- Internal and external batteries for back up power
- Visual message displays and audible alarms for abnormal operating conditions
- Hardware-based control system backup for control of systolic and diastolic intervals for Emergency System Operation (ESO)
- Manual hand pump for operating the blood pump in emergency situations

The Portable Driver was designed to be carried by the patient. It weighs 18.9 pounds and uses lightweight components including lithium ion batteries. In addition, it was designed to work with external batteries in addition to the internal battery. This allows extended cordless operation.

The Portable Driver can be placed in the AB Power Pack and carried over the shoulder or as a backpack. The Portable Driver can also be attached to a 2-wheel cart for transport. The portability of the AB Portable Driver facilitates patient ambulation and assists the recovery process. (Portable operation is described in more detail in *Section 5: Using the AB Portable Driver for VAD Support*.)

Figure 3.1 illustrates the AB Portable Driver. Table 3.1 describes the features of the Portable Driver. These are discussed in more detail in the pages that follow.

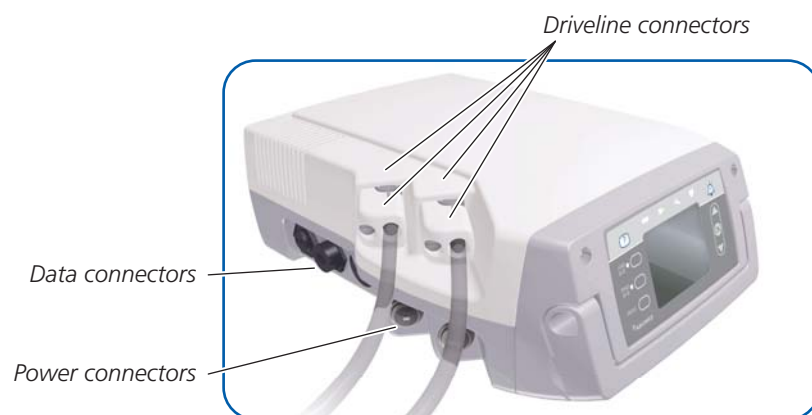


Figure 3.1 AB Portable Driver

Table 3.1 AB Portable Driver Features

Component	Function
Keypad	Enables user to control and monitor the AB Portable Driver and AB5000 Ventricle
Power connectors	Provide connections for the AB Portable Driver to be powered by external battery power or AC power
Driveline connectors	Connection points for AB5000 Ventricle drivelines
Data connectors	Provide Ethernet and USB connections for data transfer
Power switch (ON/OFF)	Main On/Off button for the AB Portable Driver

NOTE: For more information about operating the AB Portable Driver, refer to *Section 5: Using the AB Portable Driver for VAD Support* later in this manual.

For ordering information, refer to *Section 6: Installation and Maintenance*.

KEYPAD

The Keypad is used to control and monitor the AB Portable Driver. The Keypad contains eight integral membrane control buttons, four LED Status indicator lights across the top, two LED lights next to the LVAD ON/OFF and RVAD ON/OFF buttons, and a color LCD user interface display.

The user interface display shows the Left and Right Pump panes or various menus. (Panes and menus are described in *Section 4: AB Portable Driver Panes and Menus*).

Figure 3.2 illustrates the AB Portable Driver Keypad.

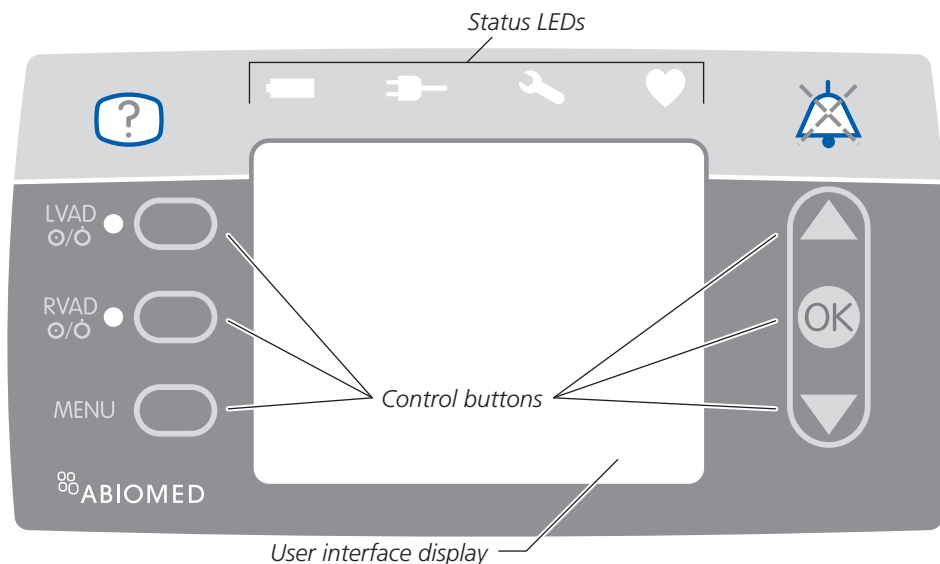


Figure 3.2 AB Portable Driver Keypad

Table 3.2 describes each of the buttons and Status LEDs on the Keypad.

Table 3.2 Keypad Functions


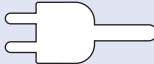










Feature	Description
STATUS LEDs	
Battery 	Indicates the status of the internal battery Illuminates GREEN when the Portable Driver is powered by the internal battery and no alarm conditions exist Illuminates AMBER for battery low alarms or when the internal battery is charging or when a low priority fault exists Illuminates RED if the battery is critically low or a high priority fault exists
AC Power 	Indicates the status of the external AC/DC power converter connection Illuminates GREEN when the Portable Driver is powered by external AC/DC power Illuminates RED when a fault is detected Is OFF when the Portable Driver is unplugged
Wrench 	Indicates the status of the AB Portable Driver Flashes RED at ESO beat rate with 50% duty cycle when ESO operation is active Flashes RED when any life-threatening alarm is active indicating a suspected problem with the Portable Driver
Heart 	Indicates the status of the AB Ventricle or cannula FLASHING RED when any life-threatening alarm is active, indicating a suspected problem with the AB Ventricle or cannula

Table 3.2 Keypad Functions – cont'd.

Safety Feature

The LVAD ON/OFF and RVAD ON/OFF buttons must be pressed twice within 13 seconds to turn OFF. This is a safety feature to prevent accidental operation.

Feature	Description
CONTROL BUTTONS	
Help 	Displays help text on the user interface display Pressing the Help button when there are no alarm conditions displays the help text for the current operational mode of the pump
Alarm Mute 	Silences audible alarms for approximately 1 minute Alarm remains muted for 1 minute unless a new alarm is issued before the 1-minute interval has expired The Alarm Mute icon (a bell with a cross through it) appears on the user interface display while the audio is muted
Left ON/OFF 	Starts pumping LED illuminates GREEN when the left side is pumping LED flashes RED when the button has been pressed once while the left side pump is on LED is off when the left side pump is off Stops pumping when pressed twice
Right ON/OFF 	Starts pumping LED illuminates GREEN when the right side is pumping LED flashes RED when the button has been pressed once while the right side pump is on LED is off when the right side pump is off Stops pumping when pressed twice
Menu 	Displays the menu functions on the user interface display Clears a displayed menu
Up Arrow 	Navigates up through the selected function Press the Up Arrow button to move up one item on the menu Note: Pressing the Up Arrow button when the top menu item is selected causes the selection to wrap around to the last menu item
OK 	Selects the highlighted function
Down Arrow 	Navigates down through the selected function Press the Down Arrow button to move down one item on the menu Note: Pressing the Down Arrow button when the last menu item is selected causes the selection to wrap around to the top menu item

*The various displays for the Battery and AC Power Status LEDs are presented in Table 4.2 in Section 4: AB Portable Driver Panes and Menus

POWER CONNECTORS

The AB Portable Driver operates on power from one of three sources:

- External AC/DC Converter
- Internal Battery
- AB Power Pack

Figure 3.3 shows the Battery (green) and AC/DC Converter (yellow) power connectors. Table 3.3 describes the power connectors.

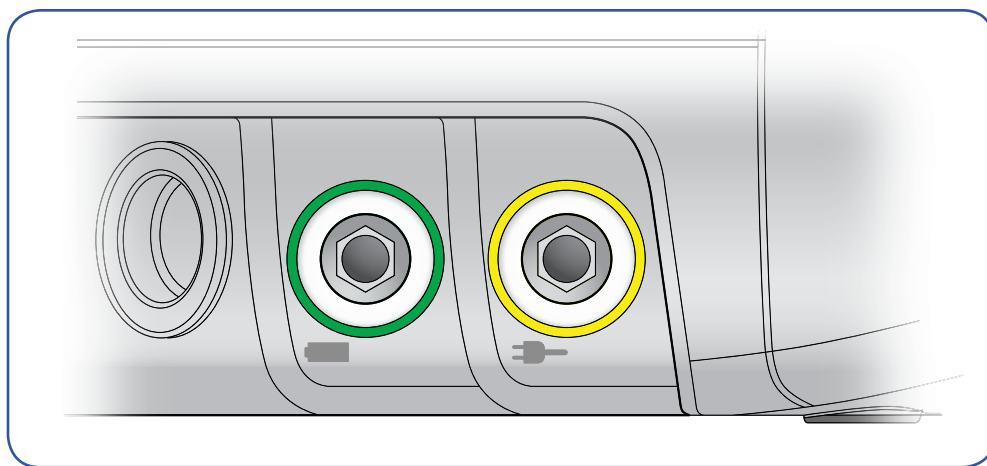


Figure 3.3 Power Connectors

Table 3.3 Power Connectors

Feature	Description
AC/DC Converter connector (yellow)	Connects to yellow External AC/DC Converter connector
Battery Connector (green)	Connects to green AB Power Pack connector

Battery Information

A fully charged internal battery will power the Portable Driver for 45 minutes. After depletion, the internal battery requires approximately 5 hours to recharge while it is plugged into AC power.

A fully charged Power Pack will power the Portable Driver for 3 hours and requires 8 hours to recharge.

DRIVELINE CONNECTORS

The AB Portable Driver can be configured for right AB Ventricle support (RVAD) and/or left AB Ventricle support (LVAD). Figure 3.4 illustrates the LVAD and RVAD connectors on the AB Portable Driver and the driveline connection points for driveline from the AB5000 Ventricle.

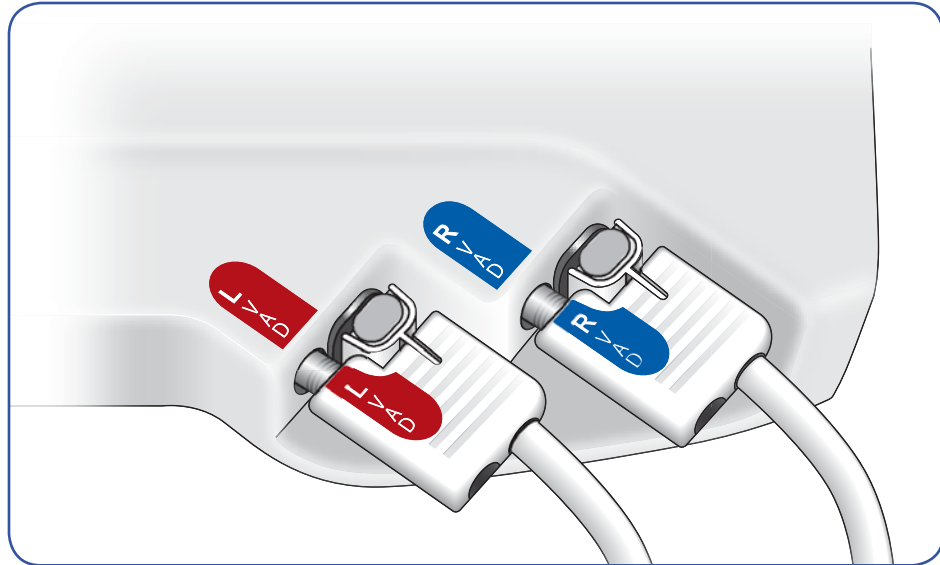


Figure 3.4 Driveline Connectors

Table 3.4 Driveline Connectors

Feature	Description
LVAD connector	Connection to left AB Ventricle driveline connector
RVAD connector	Connection to right AB Ventricle driveline connector

DATA CONNECTORS

The left side panel of the Portable Driver has two data connectors:

- Ethernet connection
- USB connection

Electrical connections to the Portable Driver are made at these connectors, which are shown in Figure 3.5 and described in Table 3.5. Each connector is unique and keyed to ensure that connections are made correctly.

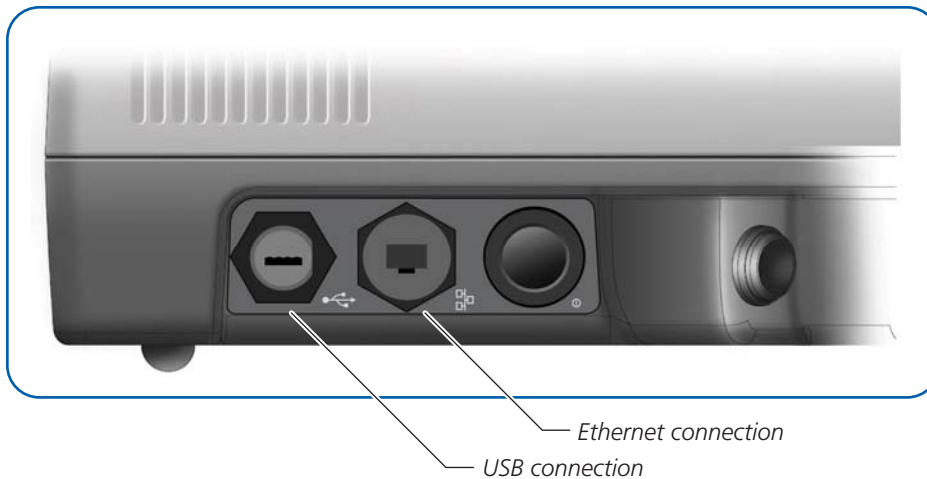


Figure 3.5 Data Connectors

Table 3.5 Electrical Connectors

Feature	Description
Ethernet connection	Service use only; RJ45 connector; 10/100BaseT
USB connection	Service use only; Standard USB Host Port Interface 1.1 or higher Functionality: USB Thumb drive

POWER SWITCH

The Power switch (ON/OFF) is a push button located on the left side of the AB Portable Driver next to the Ethernet and USB data connectors.

Turning the AB Portable Driver OFF

To turn the AB Portable Driver OFF, the user must press the Power switch and then press OK when prompted. This is a safety feature to prevent accidental operation.

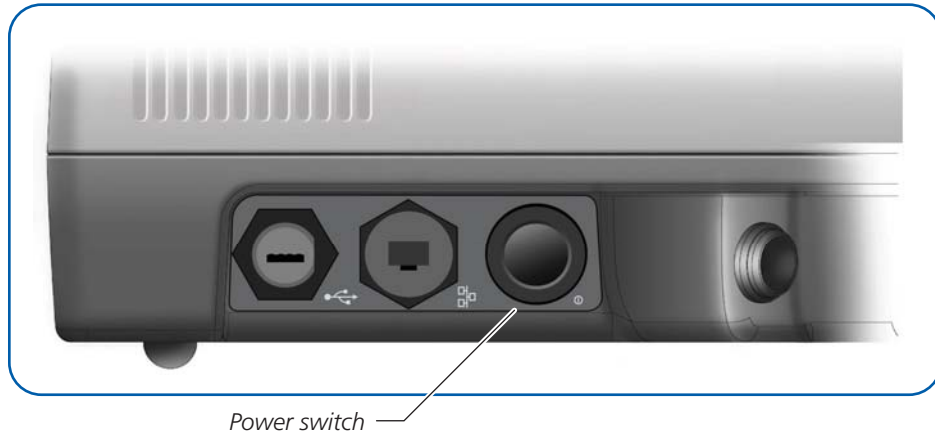


Figure 3.6 Power Switch

AB5000 AND AB PORTABLE DRIVER ACCESSORIES



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

The following items are used with the AB Portable Driver:

- AB5000 Ventricle—a pneumatically-driven device that provides pulsatile, hemodynamic support (see Figure 3.7). 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 3.7 AB5000 Ventricle

- BVS® 5000 Atrial Cannula (32F and 42F)
- BVS 5000 Arterial Cannula (10 mm and 12 mm)
- AB5000 Ventricle Holder
- External AC/DC Converter
- Hand pump
- Folding cart
- AB Power Pack



Figure 3.8 AB Portable Driver Accessories

4 AB PORTABLE DRIVER PANES AND MENUS

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OVERVIEW

The AB Portable Driver user interface consists of the following panes:

- Power On Self Test pane
- Left Pump pane
- Right Pump pane
- User pane
- Menu pane

This section describes the structure and function of each of these panes. The next section of the manual describes using the AB Portable Driver for VAD support.

POWER ON SELF TEST PANE

Turn on the AB Portable Driver by pressing the Power switch one time. The Power On Self Test display appears in the user interface display. The Power On Self Test display includes the message as seen in Figure 4.1 along with the software version.

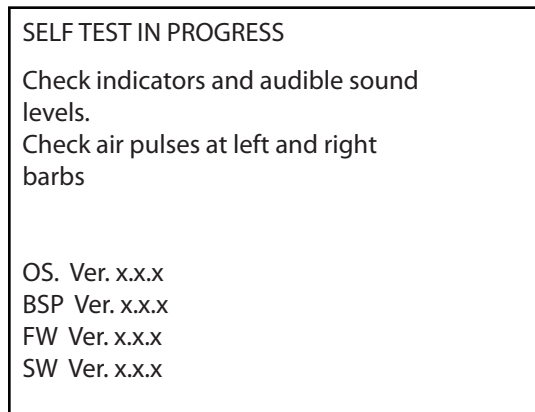


Figure 4.1 *Power On Self Test Pane*

LEFT AND RIGHT PUMP PANES

After the Power On Self Test, the Left and Right Pump panes appear in the user interface display within 60 seconds after turning the AB Portable Driver ON.

The Left and Right Pump panes are side-by-side panes that display similar types of information for each pump. Figure 4.2 shows these two panes with the left pump on and the right pump idle. The User pane appears below the Pump panes.

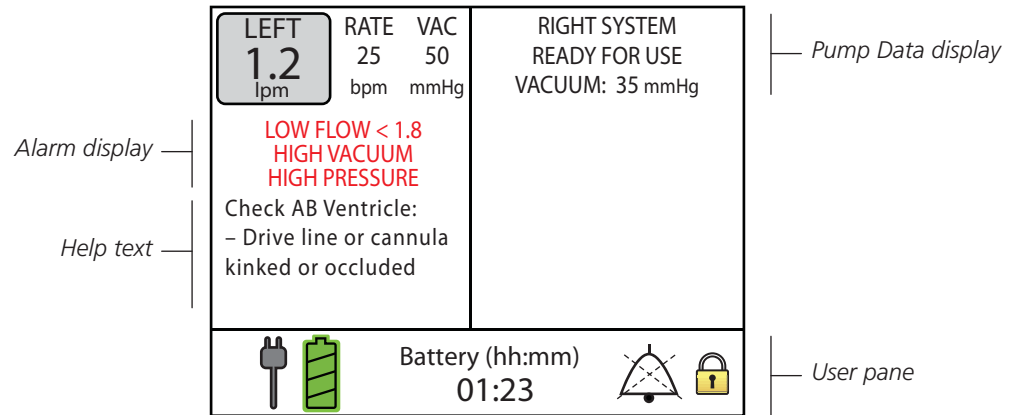


Figure 4.2 Pump Panes and User Pane

Table 4.1 identifies each display element of the Pump panes and User pane. Each element is discussed in more detail in the text that follows.

Table 4.1 Display Elements of the Pump Panes and User Pane

Display Element	Description
Flow	Black text in normal operation; green text in wean mode. Blood flow rate in liters per minute (lpm).
Rate	Black text in normal operation; green text in wean mode. Rate in beats per minute (bpm).
Vacuum	Black text in normal operation; green text in wean mode. User-adjustable vacuum level in millimeters of mercury (mmHg).
Alarm messages	Red text; discussed later in this section.
Help text	Lists action(s) to take to resolve an alarm or operational help information.
AC Power icon	Color indicates AC power status. (Refer to Table 4.2 for more information.)
Battery icon	Color of segments indicates battery status. (Refer to Table 4.2 for more information.)
Battery time remaining	Battery power time remaining.
Alarm Mute icon	Indicates alarm is muted (silenced).
Menu Lockout icon	Indicates that the Menu is locked and requires a password for access.

PUMP DATA DISPLAY

The top three lines of the Pump panes display pump data information:

- Flow rate
- Beat rate
- Vacuum level

Flow rate

When the pump is on and in normal mode, the word “LEFT” or “RIGHT” appears above the flow rate. When the pump is in wean mode, the label changes to “WEAN.” Flow is displayed in liters per minute (lpm).

Beat rate

The beat rate is displayed in beats per minute (bpm).

Vacuum level

Vacuum level is displayed in millimeters of mercury (mmHg). If the user has not adjusted the vacuum level since the unit was powered on, the vacuum level defaults to 35 mmHg. If the user has adjusted the vacuum level, the user-set vacuum level is displayed.

ALARM DISPLAY

Alarm messages are displayed immediately below the pump data. When the pump is on, these parameters are updated on the display once every four beats.

There are two categories of alarms:

- Alarms related to the operation of the pump
- Battery alarms

Alarms related to the operation of the pump are displayed below the pump data display. The alarm text is displayed in red while the alarm condition exists. As illustrated in Figure 4.2, there are three lines for displaying alarms:

- The top alarm field displays low flow alarm conditions
- The middle alarm field displays high or low vacuum alarms
- The bottom alarm field displays high or low pressure alarms

When an alarm is displayed, there is an audio annunciation of the alarm condition. This audio varies in duration and audible frequency, depending on the alarm category. (See *Appendix B: Alarm Table* for more information about alarms.) To mute the alarm audio, press the Alarm Mute button. The alarm will remain muted for 1 minute and will resound if the alarm condition is not resolved.

Audio Annunciation of Alarms

Life-threatening, high priority alarms sound 10 beeps every 6.7 seconds.

Serious, medium priority alarms sound 3 beeps every 15 seconds.

Advisory, low priority alarms sound 2 beeps every 30 seconds or only provide a visual image.

Alarm frequency is 800 ± 80 Hz.

The AB Portable Driver maintains the last displayed alarms for low flow, pressure, and vacuum alarms. Once resolved, these alarms are displayed in black text rather than red text. If an alarm is issued and the user has not pressed the Alarm Mute button before the alarm is resolved, the resolved alarm text will remain on the display until one of the following events occur:

- 20 minutes expire
- The Alarm Mute button is pressed
- An alarm of the same category (flow, vacuum, pressure) is issued

If more than one of the displayed alarms occurred and resolved simultaneously, the alarm with the higher priority will remain as the last displayed alarm. If two or more alarms resolve simultaneously, then the alarm that occurred most recently will be the last displayed alarm.

HELP TEXT DISPLAY

Up to five lines below the Alarm display are allocated to display help text for alarm conditions or general user assistance. When an alarm condition exists, help text is automatically displayed for the highest priority alarm. This text is cleared when the alarm condition clears.

Help text is also displayed when the user presses the Help button. If there are no alarm conditions when the user presses the Help button, the system displays the help text for the current operational mode of the pump. If non-alarm help is displayed when an alarm condition occurs, the Help text is replaced with the Alarm Help text.

USER PANE

The User pane spans the entire width of the bottom of the user interface display. (Refer back to Figure 4.2)

The User pane contains:

- AC Power icon
- Battery icon
- Remaining time on the battery
- Alarm Mute icon
- Menu Lockout icon

AC POWER ICON

The AC Power icon is in the shape of a plug and indicates whether the Portable Driver is plugged in and receiving power.

BATTERY ICON

The Battery icon, in the shape of a battery, indicates whether the Portable Driver is operating on internal battery power, and, if so, the approximate internal battery capacity, represented by the battery color and the number of filled-in quadrants. (See Table 4.2)

When the battery is charging, each quadrant of the battery icon is filled in sequentially with amber (yellow), and then unfilled all at once. This animation continues until the battery is fully charged.

BATTERY TIME REMAINING

When the system is operating on battery power and discharging, the remaining amount of battery time (from both the internal battery and, when applicable, external batteries) is displayed in the format HH:MM.

ALARM MUTE ICON

The Alarm Mute icon appears in the User pane when the Alarm Mute button has been pressed to silence an alarm.

Table 4.2 describes the information provided by the Battery and AC Power icons as well as the Battery and AC Power Status LEDs along the top of the Keypad (as described in the previous section of this manual).






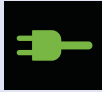




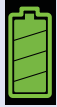



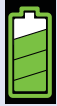



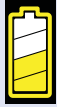


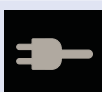






MENU LOCKOUT ICON

The Menu Lockout icon appears in the User pane when the Menu is locked and requires a password for access. Locking the Menu prevents accidental system setting changes. For more information, refer to the Menu Structure discussion that follows.

Battery Duration

A fully charged internal battery will power the AB Portable Driver for 45 minutes.

Table 4.2 Power Status Indicators

Keypad Display		Screen Display		Meaning / Required Action
Battery LED	Plug LED	Battery Icon	AC Power Icon	
				Using AC power. Battery is fully charged.
				Using AC power. Battery is charging.
				Using battery power. Battery is at approximately full charge. AC power unplugged.
				Using battery power. Battery is approximately 1/2 to 3/4 charged. AC power unplugged.
				Using battery power. Battery charge is low. Accompanied by 3 beeps repeated every 15 seconds. Plug the Portable Driver into AC power immediately or obtain a backup Portable Driver.
				Using battery power. Battery charge is critically low. Accompanied by 10 beeps repeated every 6.7 seconds. Plug the Portable Driver into AC power immediately or obtain a backup Portable Driver.
				Battery Fault. Do not unplug the Portable Driver. Obtain a backup Portable Driver.

MENU STRUCTURE

The AB Portable Driver menu structure consists of a Main Menu with six selectable items, many of which contain selectable submenu items. Table 4.3 illustrates the Menu Structure. Each menu selection listed in Table 4.3 is described in the text following the table.

Table 4.3 AB Portable Driver Menu Structure

Main Menu
Vacuum menu
Left
Right
Wean menu
Left
Right
Low flow alarm menu
Left
Right
Log view menu
Detailed view
Data download
System menu
Time
Date
Language
Screen brightness
Hour meter
Menu lockout

To display the Main Menu when there are no menus currently displayed, press the Menu button on the Keypad. Once the Main Menu is displayed, pressing the Menu button again closes the Main Menu and displays the Pump panes.

When a menu is opened, the first (or top) item in the menu is selected, that is, it is displayed in reverse video with white text on a black background. Use the Up and Down Arrow buttons on the Keypad to move through the current menu. Once the desired item is highlighted, press OK to confirm the selection and, when applicable, open the selection for edit. When an item is open for edit, pressing the Up and Down Arrow buttons increases or decreases the value of the item. Pressing OK confirms the change and pressing the Menu button cancels the adjustment, closes the menu, and returns to the previous menu (if there is one).

All menus have a display time-out value. If there are no user button presses for the time-out duration, the menu closes and the Pump panes are displayed. Unless otherwise specified, the menu time-out duration is 20 seconds.

Menu Navigation

The AB Portable Driver user interface is designed to provide a consistent method of navigating all menus. Unless otherwise noted, menu navigation, selection, adjustment, and time-out requirements are applicable to all menus of the AB Portable Driver user interface.

MAIN MENU

Main menu contains six selectable items:

- Vacuum menu
- Wean menu
- Low Flow Alarm menu
- Log View menu
- Data Download menu
- System menu

Figure 4.3 shows the Main Menu with the first item, Vacuum menu, selected.

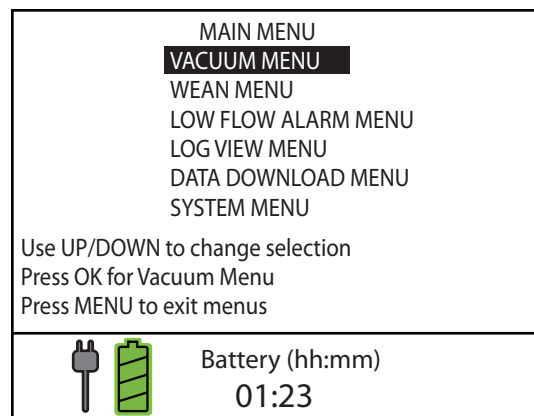


Figure 4.3 Main Menu

VACUUM MENU

The Vacuum menu allows users to adjust vacuum level. The menu has two selectable items:

- Left vacuum level
- Right vacuum level

Figure 4.4 illustrates the Vacuum menu with the left vacuum level selected.

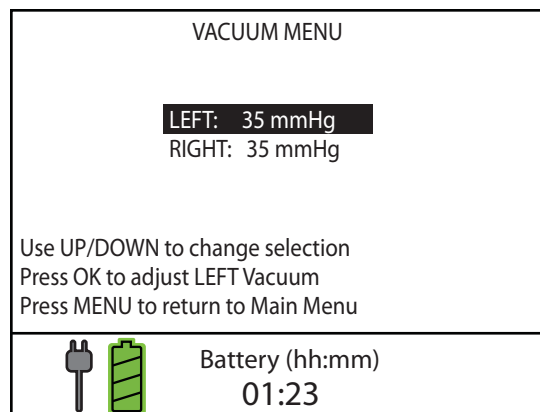


Figure 4.4 Vacuum Menu

The first time the Vacuum menu is displayed following a power cycle, the initial user-set value will be 35 mmHg, as shown in Figure 4.4. The vacuum level can be adjusted in 5 mmHg increments from 35 to 80 mmHg. Once the user changes the vacuum level and presses the OK button, the adjusted level is set, and the user-set level remains until the Portable Driver is power-cycled.

Adjusting vacuum level is discussed in more detail in *Section 5: Using the AB Portable Driver for VAD Support*.

WEAN MENU

The Wean menu allows users to select the flow rate for weaning. The menu contains two selectable items:

- Left flow
- Right flow

This menu is used to change the flow (assist) value of the left and right pumps and put the mode in and out of weaning.

The first time the Wean menu is displayed when the pump is in Normal On, the initial value is the current flow. Flow values can be increased and decreased in increments of 0.1 lpm between the current flow and 2.0 lpm.

Weaning is discussed in more detail in *Section 5: Using the AB Portable Driver for VAD Support*.

LOW FLOW ALARM MENU

The Low Flow Alarm menu allows users to adjust the low flow alarm limits. The menu contains two selectable items:

- Left low flow alarm limit
- Right low flow alarm limit

This menu enables the user to adjust limits on the left and right pumps independently. The user can adjust the low flow alarm limits when the pump is in run or wean mode, but not in idle or off-pending modes. Limits can be adjusted in increments of 0.1 liters per minute.

Adjusting low flow alarm levels is discussed in more detail in *Section 5: Using the AB Portable Driver for VAD Support*.

SYSTEM MENU

The System menu contains six selectable items:

- Time
- Date
- Language
- Screen brightness
- Hour meter
- Menu lockout

When the user selects an item from the System menu and presses OK, that menu item expands to allow the user to make changes within that menu item.

Figure 4.5 illustrates how to use the System menu to change the system time. After selecting TIME from the System menu and pressing OK, the HH:MM display appears with the hours highlighted. Use the Up and Down Arrow buttons to change the hour and then press OK. Then the minutes will be highlighted and can be changed using the Up and Down Arrow buttons. Press OK to accept the new Time setting and return to the System Menu.

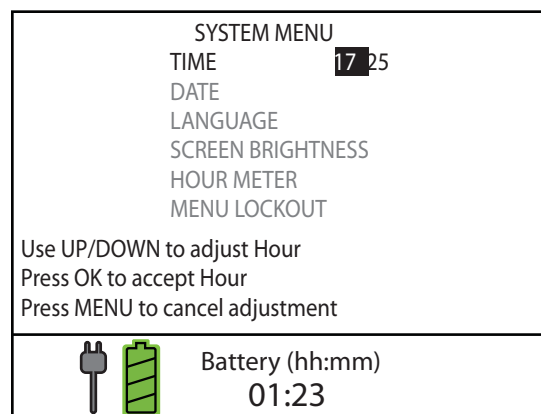


Figure 4.5 System Menu – Adjusting Time

All System menu items are changed in a manner similar to that described for changing the Time.

Time

The user can change the time. The format is a 24-hour clock displayed as: HH:MM.

Date

The user can change the date. The format of the date is MM/DD/YY.

Language

The default language is English. The user can change the language to German or French. (Spanish and Italian will be available with a later software update.) If the user changes the language, the new language will take effect immediately.

Screen Brightness

The screen brightness has 10 selectable levels, ranging from 1 (least bright) to 10 (brightest). The default screen brightness is 5. Users can change the screen brightness using the Up or Down Arrow buttons on the Keypad. Screen brightness updates immediately each time the level is changed.

Hour Meter

Selecting the hour meter allows users to view the number of hours on the Left and Right Compressors and on the total system.

System Menu Changes Maintained

All changes to the System menu are maintained when the system is power-cycled.

Menu Lockout

Selecting Menu Lockout allows users to lock and unlock the System Menu.

To lock the menu, select Menu Lockout. The Lockout Menu appears. The password is H-E-A-R-T. Use the Up and Down Arrow buttons to select the row in which each letter appears (eg, select the "FGHIJ" row for the letter "H"). Press OK after selecting each row until all 5 letters of the password have been entered. Then select "Submit Password" and press OK. The Menu Lockout icon appears in the User pane when the menu is locked.

To unlock the menu, use the Up and Down Arrow keys and OK button on the Lockout Menu to enter the password. Then select "Submit Password" and press OK. The Menu Lockout icon will no longer appear in the User pane after you unlock the menu.

5 USING THE AB PORTABLE DRIVER FOR VAD SUPPORT

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USING THE AB5000 VENTRICLE



Do **NOT** power the AB Portable Driver using Multiple Portable Socket Outlets (MPSO) or an extension cord.

The AB Portable Driver provides VAD support capability using the AB5000 Ventricle. This section describes how to prepare the Portable Driver and AB5000 Ventricle for use and how to initiate support and adjust settings during support. The remaining topics in this section include information about the hand pump, emergency system operation, portable operation, and other clinical considerations.

PORTABLE DRIVER PREPARATION

1. Plug the AB Portable Driver power cord into an AC outlet.
2. Turn the Portable Driver ON using the Power switch on the left side. The Portable Driver goes through a Self-Test and is ready to use in approximately 60 seconds. 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.

When the Portable Driver is plugged into AC power, it continuously charges the internal battery. A fully charged internal battery will power the Portable Driver for 45 minutes. After depletion, the internal battery requires approximately 5 hours to recharge while it is plugged into AC power. Fully charged AB Power Pack batteries can provide an additional 3 hours of battery power. Power Pack batteries require 8 hours to recharge after depletion.

Users can check the Portable Driver power status in two locations:

- The Battery and AC Power LEDs along the top of the Keypad
- The Battery and AC Power icons on the user interface display

AB5000 VENTRICLE PREPARATION

Refer to the *AB5000 Ventricle Instructions for Use (0055-9001)* and *BVS/AB Clinical Training Guide (0015-9003)*.

RECOMMENDED CANNULATION METHOD

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

INITIATING SUPPORT

1. Initiate support as described in the *AB5000 Ventricle Instructions for Use* and the *AB5000 Ventricle Training Guide*. Connect the left AB Ventricle driveline connector to the left AB Portable Driver connection and connect the right AB Ventricle driveline connector to the right AB Portable Driver connection as required.
2. Begin pumping by pressing the LVAD or RVAD ON/OFF button. If both sides are being supported, press the **LVAD ON/OFF** button **first**.

The system has a 13-second off-pending duration after the LVAD or RVAD ON/OFF button is pressed. Therefore, pressing the same ON/OFF button again within 13 seconds causes the pump to transition to idle. Pressing any other button before the 13-second off-pending interval has expired causes the pump to transition to On.

OPTIMIZING AB5000 VENTRICLE FILLING

When the Portable Driver is operating in normal (full-flow) mode, flow rate should be greater than 2 liters per minute (lpm) and typically ranges from 3 to 6 lpm.

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 decreased flow.

ADJUSTING VACUUM LEVEL

Overview

The AB Portable Driver applies a default level of 35 mmHg of vacuum during diastole **unless the vacuum level has been adjusted**. Users can adjust the vacuum level from 35 to 80 mmHg in 5 mmHg increments whether pumping is ON or OFF.

Maintaining a vacuum level of 35 mmHg reduces the flow rate by as much as 2 lpm from the level achieved at 80 mmHg. Adjusting the vacuum level also changes the vacuum alarm limits. Adjusting the vacuum level on one side does not affect the vacuum level on the other side.

Flow-rate reduction for weaning can be performed by adjusting flow rate using the Wean menu, 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

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

Adjusting Vacuum Level

1. Press the Menu button to access the Main Menu.
2. Use the Up and Down Arrow buttons on the Keypad to select Vacuum menu from the Main Menu.
3. Press the OK button.
4. Use the Up and Down Arrow buttons to select Left or Right.
5. Press the OK button to accept selection.
6. Use the Up and Down Arrow buttons to set the desired vacuum level. *(Each press increases or decreases the vacuum level by 5 mmHg)*
7. Press the OK button to accept the change.
8. Press the Menu button **twice** to return to the Left and Right Pump panes.

Figure 5.1 shows the Vacuum menu with the left vacuum level highlighted after five presses of the Up Arrow button changed the level from 35 mmHg to 65 mmHg

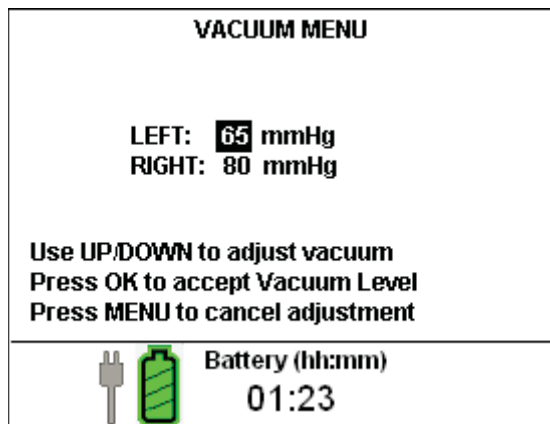


Figure 5.1 Adjusting Vacuum Level

WEANING

Overview

When the patient is ready to be weaned, the Ventricle output may be set at any desired flow rate from 2.0 liters per minute (lpm) to full flow (in 0.1 lpm increments). The current flow must be at least 2.0 lpm for the user to be able to adjust the wean flow rate. If the current flow is less than 2.0 lpm and the user selects the Wean menu, a message appears indicating that the flow must be at least 2.0 lpm to adjust the wean flow rate.

When the pump first enters wean mode, the target flow value to exit wean mode will be the current flow value before any adjustments were made. Flow values can be increased and decreased in increments of 0.1 lpm between the current flow (the flow at the time the Wean menu was opened) and 2.0 lpm.

The operational mode for the pump will be set to Weaning if the user adjusts the flow to a value *lower* than the current flow and presses the OK button. If the user adjusts the flow to the target flow value or a value that is *higher* than the value when the pump entered wean mode, and presses the OK button, the operational mode for that pump will be set to On Normal.

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

Setting the Weaning Flow Rate

1. Press the Menu button to access the Main Menu.
2. Use the Up and Down Arrow buttons to select the Wean menu from the Main Menu.
3. Press the OK button.
4. Use the Up and Down Arrow buttons to select Left or Right.
5. Press the OK button to accept selection.
6. Use the Up and Down Arrow buttons to set the desired flow rate. (*Each press increases or decreases the flow rate by 0.1 liters per minute*)
7. Press the OK button to accept the change.
8. Press the Menu button **twice** to return to the Left and Right Pump panes.

Figure 5.2 shows the right flow selected on the Wean menu.

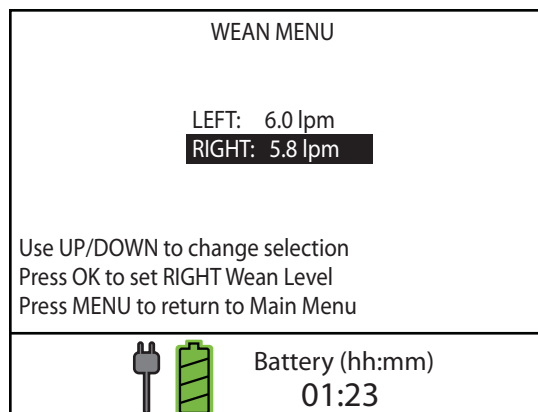


Figure 5.2 Adjusting the Weaning Flow Level

ADJUSTING THE LOW FLOW ALARM LEVEL

Overview

The low flow alarm level can be adjusted when pumping is ON in normal or wean mode, but not when the pump is in idle or off-pending modes. It can be set to any level (in 0.1 lpm steps) between the current flow rate and 1.8 lpm during normal operation (1.5 lpm in the wean mode).

The high limit is the current flow level. If the current flow level changes while the user is adjusting the low flow alarm limit, the high limit will change to the current flow. If the current flow is equal to or below the low limit, the system will not allow the alarm level to be adjusted and will display a message notification to the user.

The alarm settings are maintained through an AC mains power interruption since the system will continue to operate off its internal battery.

Adjusting Low Flow Alarm Level

1. Press the Menu button to access the Main Menu.
2. Use the Up and Down Arrow buttons to select the Low Flow Alarm menu from the Main Menu.
3. Press the OK button.
4. Use the Up and Down Arrow buttons to select Left or Right.
5. Press the OK button to accept the selection.
6. Use the Up and Down Arrow buttons on the Keypad to set the desired low flow alarm level. *(Each press increases or decreases the rate by 0.1 lpm)*
7. Press the OK button to accept the change.
8. Press the Menu button **twice** to return to the Left and Right Pump panes.

Figure 5.3 shows the Low Flow Alarm menu with the left side selected.

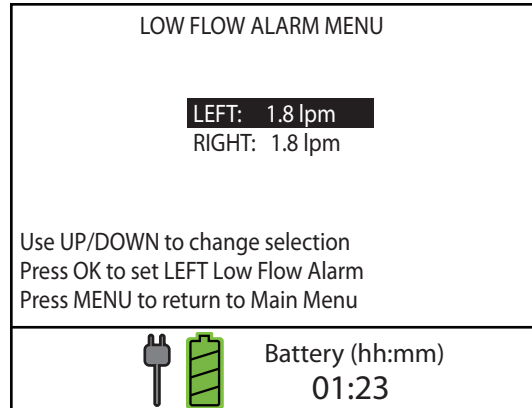


Figure 5.3 Adjusting the Low Flow Alarm Level

TO STOP PUMPING

To stop pumping, press the appropriate LVAD or RVAD ON/OFF button **twice within 13 seconds**. You must press the button twice to stop pumping. This is a safety feature to prevent accidental operation.

ALARMS

The AB Portable Driver monitors various functions to determine whether its operating parameters are within expected limits. When a parameter goes outside of allowed limits, the Portable Driver displays an alarm message and sounds an audible alarm.

When an audible alarm sounds, the operator will need to observe the front panel of the AB Portable Driver for alarm messages. If the operator is wearing the Driver on his or her back, he or she will need to take the Driver and Power Pack off the back to observe the Driver's front panel.

The AB Portable Driver monitors the flow of air that is used to drive the AB5000 Ventricle. This airflow is used to calculate the blood flow rate delivered to the patient. The blood flow is calculated every four beats and compared to the alarm threshold. The Driver issues an alarm when the four-beat average blood flow is below the low flow alarm limit. The alarm continues until the alarm condition is resolved and the four-beat average blood flow rises above the threshold.

The AB Portable Driver monitors the pressure and vacuum levels within the Driver. If the pressure measurements exceed the normal operating range for each beat of a four-beat cycle, then a High Pressure alarm is generated. The alarm continues until the pressure measurements are within the normal operating range for each beat of the four-beat cycle. The Low Pressure, High Vacuum, and Low Vacuum alarms operate in a similar manner.

The AB Portable Driver monitors the characteristics of the internal battery and the external batteries contained within the Power Pack. The batteries and battery chargers send information to the microprocessor in the AB Portable Driver. This information is used to calculate the cumulative battery run-time remaining for the system. If the battery run-time falls below the alarm threshold limits, an alarm is generated until the system is plugged into an AC power source. Alarms are also generated if communication with the battery or batteries is lost, if the temperature of the battery or batteries is too high, or if the battery or batteries require calibration.

Table 5.1 describes the audible indications for life-threatening and serious alarm conditions.

Table 5.1 Alarm Categories

Alarm Category	Audible Indication
Life-threatening, high priority	10 beeps every 6.7 seconds
Serious, medium priority	3 beeps every 15 seconds
Advisory, low priority	2 beeps every 30 seconds or no audible sound

A maximum of six alarms (three for the Left pump and three for the Right pump) are displayed in red text on the Left and Right Pump panes. If more alarm conditions are present than can be listed, the highest priority alarms are displayed first.

When an alarm condition occurs, help text is automatically displayed below the alarm messages. Help text describes the action(s) to take to resolve the alarm.

The system logs the occurrence and the identity of alarms generated. These logs are maintained when the Driver is powered down. The logs are only retrievable by ABIOMED service personnel.

Alarms may be delayed by as many as 7 beats after being triggered. The maximum delay time when operating at 60 bpm will be 7 seconds. The maximum delay time when operating at the minimum beat rate of 12 bpm will be 35 seconds.

Figure 5.4 shows 3 alarm conditions displayed for the Left pump and accompanying Help text.


LEFT	RATE	VAC	RIGHT	RATE	VAC
1.2 lpm	25 bpm	50 mmHg	6.6 lpm	72 bpm	35 mmHg
LOW FLOW < 1.8 HIGH VACUUM HIGH PRESSURE Check AB Ventricle: – Drive line or cannula kinked or occluded					
		Battery (hh:mm) 02:30			

Figure 5.4 Alarm Messages and Help Text

Appendix B: Alarm Table shows all alarm messages and the corresponding help text.

EMERGENCY SYSTEM OPERATION

The AB Portable Driver monitors its operating parameters and automatically enables the Emergency System Operation (ESO) mode if a serious problem is detected.

When ESO is enabled, the Portable Driver performs the following actions:

- Changes to a fixed-rate control system and the VAD continues pumping at approximately 50 bpm.
- Activates an audible alarm.
- Turns ON the Battery Status LED on the Keypad.
- Turns ON the Wrench Status LED on the Keypad.
- Turns ON the red AC status LED on the Keypad.
- Turns OFF the user interface display.

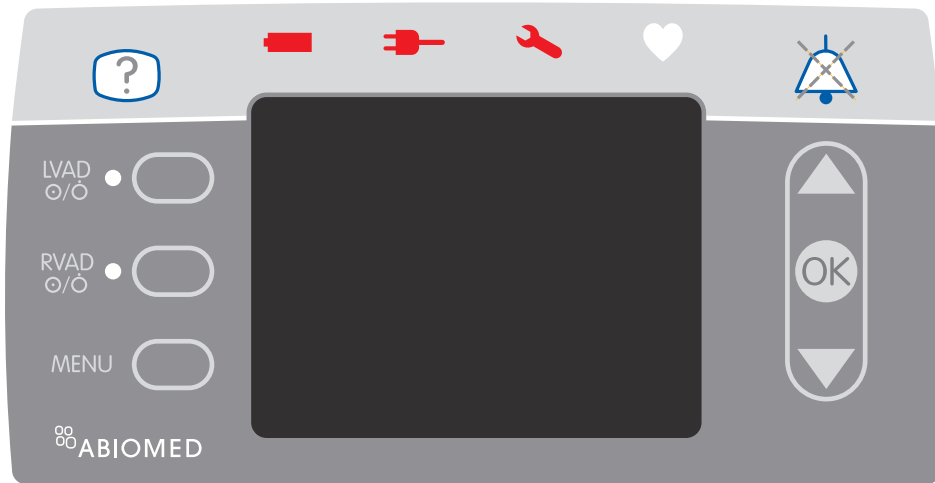


Figure 5.5 Emergency System Operation (ESO) Indicator

During ESO operation, no audible alarms other than the ESO alarm is active. Pressing the Alarm Mute button once permanently silences the ESO alarm.

USING THE HAND PUMP

If the Portable Driver fails (stops pumping), the supplied Hand Pump allows manual operation of the AB5000 Ventricle.

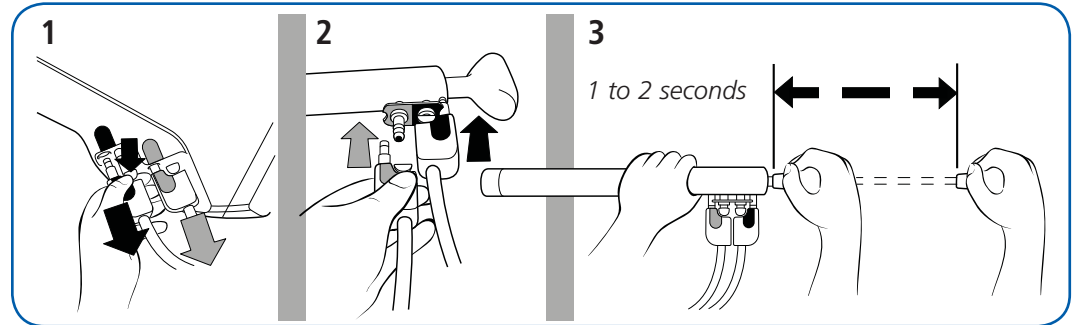


Figure 5.6 Manual Operation of the AB5000 Ventricle

TRANSFERRING TO THE HAND PUMP

1. Remove the AB5000 Ventricle driveline(s) from the Driveline connector(s).
2. Connect the driveline(s) to the Hand Pump. The LVAD driveline goes to the red LVAD connector and the RVAD driveline goes to the blue RVAD connector.
3. Pull the Hand Pump handle until it stops.
4. Push the handle to fully return it to its original position.
5. Continue pumping at a rate of 30 to 60 times per minute.
6. Observe the Ventricle for proper filling and emptying.

TRANSFERRING FROM THE HAND PUMP TO A BACKUP PORTABLE DRIVER

1. Plug the backup Portable Driver power cord into an AC outlet.
2. Turn the Portable Driver ON and allow the Self-Test to run.
3. Transfer the driveline(s) from the Hand Pump to the backup Portable Driver.
4. Begin pumping by pressing the LVAD or RVAD ON/OFF button for the appropriate side (Left or Right). If both sides are being supported, press the **LVAD ON/OFF** button **first**.
5. Contact service personnel as soon as possible to repair the failed Portable Driver.

PORTABLE OPERATION

The AB Portable Driver is designed for two types of portable operation:

- It can be carried using the Carrying Handle that is built into the Portable Driver.
- It can be placed in the AB Power Pack and carried or wheeled on a cart.

USING THE PORTABLE DRIVER CARRYING HANDLE

To carry the Portable Driver by the Carrying Handle, unplug the AC power (which automatically activates battery operation) and lift the Portable Driver by the built-in Carrying Handle. The internal battery provides 45 minutes of battery power. Plug the Portable Driver back into AC power as soon as feasible.

USING THE AB POWER PACK

The AB Power Pack enhances portability by providing extended battery runtime. The AB Power Pack incorporates four rechargeable batteries, battery charging circuitry, and an AC/DC power supply.

Additional convenient features of the AB Power Pack include:

- Convenient driveline connector access through a gap in the top zipper
- Front mesh pocket for driveline storage
- Easy access to the AC power cord
- Vents for AB Power Pack batteries
- Intake and outlet vents for the Portable Driver
- Storage space for extra items in a gusseted pocket
- Mesh pocket for the Hand Pump
- Padding to protect the Portable Driver during portable operation
- Built-in Carrying Handle
- Removable strap that can be connected for use as a shoulder strap or backpack style carrying
- Waist straps that store conveniently in pockets behind the back padding
- Securing straps for foldable cart
- Foldable 2-wheel luggage cart

Battery Power

The internal battery of the AB Portable Driver provides 45 minutes of battery power when fully charged.

When fully charged, the batteries in the Power Pack provide an additional 3 hours of battery power.



Figure 5.7 AB Power Pack

To use the AB Power Pack:

1. Unplug the Portable Driver from the AC power outlet if it is running on AC power. The Portable Driver will automatically switch to internal battery power until the new power source is connected.
2. Fully unzip the main compartment of the AB Power Pack and insert the Portable Driver with the Keypad facing the opening at the top of the compartment. The underside of the Portable Driver should rest against the AB Power Pack batteries. (See Figure 5.7)
3. Connect the power cable on the top of the AB Power Pack to the green power connector with the battery symbol on the Portable Driver. (See Figure 5.8.) A fully-charged AB Power Pack will provide 3 hours of battery power, in addition to the 45 minutes of battery power provided by the internal battery in the Portable Driver.

Charging the Portable Driver in the AB Power Pack

Whenever possible, plug the AC/DC power supply on the AB Power Pack into an AC Power source to charge the Portable Driver and the AB Power Pack batteries during use.

- To power the Portable Driver using AC power, plug the bottom of the AB Power Pack into an AC power source. (See Figure 5.8)

NOTE: When using the AB Power Pack, it is important to power the Portable Driver through the AC power source on the bottom of the AB Power Pack rather than plugging the Portable Driver directly into an AC power supply. Plugging the Portable Driver directly into an AC power supply will only charge the Portable Driver and the internal battery and not the AB Power Pack batteries.

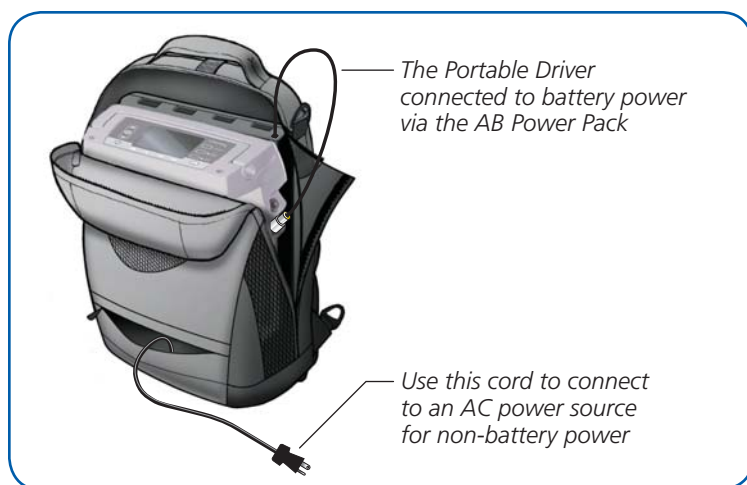


Figure 5.8 Powering the Portable Driver in the AB Power Pack

- Pass the drivelines through the gap in the top zipper as shown in Figure 5.7.
- To carry the AB Power Pack as a shoulder bag, clip the padded strap to the two D-rings on either side of the Handle on the top of the AB Power Pack. (See Figure 5.9)

To carry the AB Power Pack as a backpack, pass the strap on the top of the AB Power Pack through the D-ring on the padded strap. Remove the waist belt and strap anchors from behind the padding on the back of the AB Power Pack (See Figure 5.9) and clip the ends of the strap to the D-ring anchors.

To carry the AB Power Pack using the rolling cart, remove the padded strap (if attached). Clip the strap on the top of the AB Power Pack to the cart.



Figure 5.9 AB Power Pack Carrying Configurations

CLINICAL CONSIDERATIONS

EFFECTS OF ELECTROSURGICAL EQUIPMENT

The AB Portable Driver may exhibit the following effects during the use of electrosurgical equipment:

- Display becomes blank or distorted
- Alarm activates

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

6 INSTALLATION AND MAINTENANCE

- INSTALLATION 6.1**
- CHECKING THE PORTABLE DRIVER BEFORE EACH USE 6.1**
- PERIODIC TESTING OF BACKUP SYSTEMS 6.2**
 - Testing ESO 6.2
 - Testing the Hand Pump..... 6.2
- CLEANING THE PORTABLE DRIVER 6.2**
- PREVENTIVE MAINTENANCE 6.3**
- ORDERING INFORMATION 6.3**

INSTALLATION

Prior to clinical use, installation and testing of the Portable Driver must be performed by an authorized ABIOMED Service Representative.



The AB Portable Driver must be plugged into AC power to maintain a charged battery.



To remove all AC power from the Portable Driver, unplug the power cord from the AC outlet.

CHECKING THE PORTABLE DRIVER BEFORE EACH USE



The AB Portable Driver does not contain any user-serviceable parts. To reduce the risk of electric shock, do **NOT** attempt to remove the Portable Driver housing or to replace the Portable Driver battery.

Prior to each clinical use, perform the following checks to determine that the AB Portable Driver 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 Portable Driver ON using the Power switch on the left side of the Portable Driver.
3. Allow the Portable Driver 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 indicators are operating properly by listening for the audio alarm (three tones that increase in volume) as well as the power fail alarm (a series of rapid beeps).

PERIODIC TESTING OF BACKUP SYSTEMS

Regularly test the Portable Driver backup systems:

- The Hand Pump
- The Emergency System Operation (ESO) feature

TESTING ESO

1. Turn the Portable Driver ON. Within 20 seconds, simultaneously press the Up and Down buttons for at least 3 seconds.
2. Verify that a continuous alarm sounds and that the Wrench Status LED flashes.
3. Pumping starts automatically in 20 seconds. Verify that air vents from the driveline connectors as the Portable Driver pumps.
4. Turn the Portable Driver OFF to deactivate ESO.

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.

CLEANING THE PORTABLE DRIVER



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

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

The AB Portable Driver should be cleaned after each use. Turn the Portable Driver **OFF** before you clean it.

To clean the Keypad and user interface display areas, 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.

PREVENTIVE MAINTENANCE

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

Table 6.1 *Preventive Maintenance Intervals*

Component/Subsystem	Interval
Battery	1 year, calendar time
Solenoid Valves	5000 hours, operational time
Compressor	5000 hours, operational time

ORDERING INFORMATION

Table 6.2 *Ordering Information for the AB Portable Driver*

Catalog No.	Language	Nominal Voltage
0025-0010-E1S	English	120 VAC
0025-0010-G2S	German	230 VAC

Table 6.3 *Ordering Information for Parts*

Catalog No.	Description
0025-0050	Cart
0025-9000	OPERATOR'S GUIDE to the AB Portable Driver
0025-0020	AB Power Pack
0025-0030	AC/DC Power Supply
0025-0080	Hand Pump

7 SYSTEM SPECIFICATIONS

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PORTABLE DRIVER ELECTRICAL	7.2
EQUIPMENT DESIGN	7.3
EQUIPMENT CLASSIFICATIONS	7.3
ELECTROMAGNETIC COMPATIBILITY	7.4
PATIENT ENVIRONMENT	7.8

PORTABLE DRIVER MECHANICAL

Parameter	Specification
Temperature	Operating: 0°C to 40°C (32°F to 104°F) Storage: -20°C to 50°C (-4°F to 122°F)
Relative Humidity	Operating: 30% to 80%, noncondensing Storage: 10% to 80%, noncondensing
Atmospheric Pressure	Operating: 8000 ft (750 hPa) to -1000 ft (1050 hPa) Storage: 18,000 ft (500 hPa) to -1000 ft (1050 hPa)
Dimensions – Portable Configuration	Portable Driver Height: 5 ± 1 in Width: 11 ± 1 in Depth: 15 ± 1 in
Dimensions – Packaged Configuration	Portable Driver with Hand Pump, AC/DC power supply Height: 12 ± 1 in Width: 20 ± 1 in Depth: 25 ± 1 in
Weight – Portable Configuration	Portable Driver Maximum: 18.9 lbs
Weight – Packaged Configuration	Portable Driver with Hand Pump, AC/DC power supply Maximum: 44 lb
Left-Side Flow	Under normal operation, the Portable Driver produces a minimum blood flow through the VAD as follows: Minimum: 4.8 lpm at mean outflow pressure of 90 mmHg and inflow pressure > 10 mmHg for 42F Atrial Cannula used with 12 mm or 10 mm Arterial Cannula. Minimum: 4.0 lpm at mean outflow pressure of 90 mmHg and inflow pressure > 10 mmHg for 32F Atrial Cannula used with 12 mm or 10 mm Arterial Cannula. Method: Blood flow rate calculated based on integration of airflow signal.

Portable Driver Mechanical (continued)

Parameter	Specification
Right-Side Flow	<p>Under normal operation, the Portable Driver produces a minimum blood flow through the VAD as follows:</p> <p>Minimum: 4.8 lpm at mean outflow pressure of 40 mmHg and inflow pressure > 10 mmHg for 42F Atrial Cannula used with 12 mm or 10 mm Arterial Cannula.</p> <p>Minimum: 4.0 lpm at outflow pressure of 40 mmHg and inflow pressure > 10 mmHg for 32F Atrial Cannula used with 12 mm or 10 mm Arterial Cannula.</p> <p>Method: Blood flow rate calculated based on integration of airflow signal.</p>
Displayed Flow Accuracy	<p>Left Side: $\pm 15\%$ or ± 0.5 lpm, whichever is greater, over the following ranges:</p> <ul style="list-style-type: none">Inflow pressure 5 to 25 mmHgOutflow pressure 60 to 90 mmHg <p>Right Side: $\pm 15\%$ or ± 0.5 lpm, whichever is greater, over the following ranges:</p> <ul style="list-style-type: none">Inflow pressure 5 to 15 mmHgOutflow pressure 30 to 40 mmHg <p>over the range of specified operating pressures.</p>
Beat Rate	<p>Range: 0 to 150 bpm</p> <p>Resolution: 1 bpm</p> <p>Accuracy: ± 3 bpm or $\pm 3\%$, whichever is greater</p>

PORTABLE DRIVER ELECTRICAL

Parameter/Item	Specification
Portable Driver	<p>AC operation: 100–230 VAC (nominal); 47-63 Hz; 4 A</p> <p>Internal battery operation: 14.4 VDC (nominal); lithium ion</p>

EQUIPMENT DESIGN

The AB Portable Driver conforms to the applicable requirements of the following standards:

- UL 60601-1 (2003), 1st Edition *Medical Electrical Equipment, Part 1: General Requirements for Safety*
- CAN/CSA C22.2 No 601.1-M90 (1990; Reaffirmed 2005), 2nd Edition *Medical Electrical Equipment, Part 1: General Requirements for Safety*
- EN 60601-1 (1990), 2nd Edition *Medical Electrical Equipment, Part 1: General Requirements for Safety + A1(93) + A2(95) + A1.3(96)*
- IEC 60601-1 (1988), 2nd Edition *Medical Electrical Equipment, Part 1: General Requirements for Safety + A1(91) + A2(95)*
- IEC 60601-1-2 (2001), *Medical Electrical Equipment, Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests*
- IEC 60601-1-4 (2000), Edition 1.1 Consolidated Edition *Medical Electrical Equipment, Part 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems*

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 <i>accessible metal parts</i> from becoming live if basic insulation <i>fails</i> .
Degree of protection against electric shock for Portable Driver	Class I Equipment.
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. IEC 60529: IPX2 protected against direct sprays of water up to 15 from vertical for the AB Portable Driver when used with AB Power Pack
Cleaning Methods for Portable Driver	Keypad/Display: 70% isopropyl alcohol, or soap and water. Housing: mild detergent.

ELECTROMAGNETIC COMPATIBILITY



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.

NOTE: The EMC tables and other guidelines that are included in this 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 AB Portable Driver is intended for use in the electromagnetic environment specified below. The customer or user of the AB Portable Driver should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Enforcement – Guidance
RF Emissions CISPR 11	Group 1	The AB Portable Driver 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 B	The AB Portable Driver is suitable for use in all establishments, including 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 AB Portable Driver is intended for use in the electromagnetic environment specified below. The customer or user of the AB Portable Driver 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 AB Portable Driver requires continued operation during power mains interruptions, it is recommended that the AB Portable Driver be powered from an uninterruptible power supply or battery.

TABLE 204
Guidance and Manufacturer's Declaration – Emissions, Equipment and Systems that are Life-Supporting

The AB Portable Driver is intended for use in the electromagnetic environment specified below. The customer or user of the AB Portable Driver should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF	10 Vrms	V1 = 10 Vrms	Portable and mobile RF communications equipment should be separated from the AB Portable Driver by no less than the recommended separation distances calculated/listed below:
IEC 61000-4-6	150 kHz to 80 MHz		
Radiated RF	10 V/m	E1 = 10 V/m	$D = (3.5 / E1)\sqrt{P}$ $D = (3.5 / E1)\sqrt{P}$ 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.
IEC 61000-4-3	80 MHz to 2.5 GHz		

TABLE 206
Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the AB Portable Driver, Equipment and Systems that are Life-Supporting

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

Maximum Output Power (Watts)	Recommended Separation Distances for the AB Portable Driver (m)		
	150 KHz to 80 MHz	80 to 800 MHz	800 MHz to 2.5 GHz
	$d = 2.3333\sqrt{P}$	$d = 2.3333\sqrt{P}$	$d = 2.3333\sqrt{P}$
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 AB Portable Driver and the components of the AB Portable Driver System are approved for use within the patient environment defined in IEC 60601-1-1 and in the figure below.

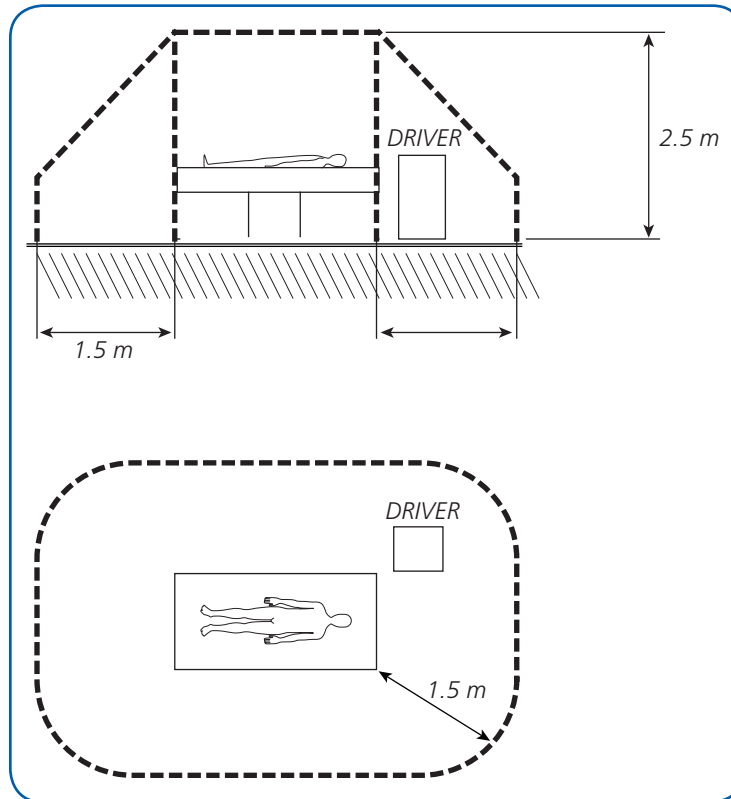


Figure 7.1 AB Portable Driver Patient Environment


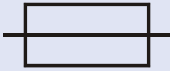










APPENDICES

APPENDIX A: SYMBOL DESCRIPTIONS A.1














APPENDIX B: ALARM TABLEB.1

**APPENDIX C: AB PORTABLE DRIVER DOMESTIC
LIMITED SERVICE WARRANTYC.1**

APPENDIX A: SYMBOL DESCRIPTIONS

Symbol	Description
	Alarm silence
	Fuse
	"ON" or "OFF" for a part of equipment
	"ON" or "OFF" for the LVAD and RVAD on the AB Portable Driver Keypad
IPX1	Protected against dripping water
IPX2	Protected against direct sprays of water up to 15 degrees from vertical for the AB Portable Driver when used with AB Power Pack
	Attention, consult instructions
	Year of manufacture
SN	Serial number
REF	Part number
LOT	Lot number
	Alternating current
	Direct current
	Help Key on the AB Portable Driver Keypad
	USB connection on the AB Portable Driver
	Ethernet connection on the AB Portable Driver
	Type B applied part

APPENDIX B: ALARM TABLE

Alarm Message Text	Visual Display ¹	Alarm Help Text	Notes	Priority ²	Relative Priority
HIGH PRESSURE	 (if High Barb Pressure)	Check AB Ventricle: - Drive line or Cannula kinked or occluded.	NOTE: Overrides low flow and vacuum alarms.	High	1
LOW PRESSURE	 (if Low Barb Pressure)	Check AB Ventricle: - Disconnect or leak in drive line.	NOTE: Overrides low flow and vacuum alarms.	High	2
HIGH VACUUM		Check AB Ventricle: - Drive line or Cannula lines kinked or occluded.	NOTE: Displays only if there is no low flow or low pressure alarm.	High	3
LOW VACUUM		Check AB Ventricle: - Disconnect or leak in drive line.	NOTE: Displays only if there is no low flow or high pressure alarm.	High	4
LOW FLOW < n.n (where n.n is the Low Flow Alarm Limit)		Check AB Ventricle: 1. Obstruction? 2. Low blood volume?	NOTE: Displays only if there are no pressure alarms.	High	5
N/A	 	Battery Critically Low - Plug Driver into AC Power Immediately!	NOTE: Displays in both Left and Right Help panes.	High	6
N/A	 	High Temperature 1. Plug into AC. 2. Unblock Vents. 3. Replace Driver (or Power Pack). 4. Call Service.	NOTE: Displays in both Left and Right Help panes.	High Medium	7-8 9-11
N/A	 	Battery Low - Plug into AC	NOTE: Displays in both Left and Right Help panes.	Medium	12
N/A	 	Battery Fault - Plug into AC - Call Service	NOTE: Displays in both Left and Right Help panes.	Low	13-16
N/A	N/A	Recalibrate Battery - Plug into AC - Call Service	NOTE: Displays in both Left and Right Help panes.	Low	17, 18

1. A physiological alarm condition exists when the Heart icon is displayed. A technical alarm condition exists when the Wrench icon is displayed or a Battery icon is displayed in yellow or red.

2. High, medium, and low priority alarms have a sound pressure of > 80 dBA

APPENDIX C: AB PORTABLE DRIVER WARRANTY

LIMITED SERVICE WARRANTY (US)

ABIOMED, Inc. warrants that, at the time of installation, all AB Portable Drivers (the “Goods”) sold will be free from defects in material and workmanship and remain free from defects under normal use and service for a period of one (1) year from the date of installation. Extended warranty and service may, at ABIOMED’s option, be offered for an additional charge, in which event separate or additional terms and conditions may apply.

This warranty does not cover routine Preventative Maintenance or replacement parts that are consumed per the Driver’s periodic maintenance schedule outlined in the Operator’s and Service Manuals.

The express warranty set forth on this page is the only warranty given by ABIOMED with respect to any goods furnished hereunder. ABIOMED makes no other warranty, express, implied or arising by custom or trade usage, and specifically makes no warranty of merchantability or of fitness for any particular purpose. Said express warranty shall not be enlarged or otherwise affected by ABIOMED’s rendering of technical or other advice or service in connection with the Goods.

ABIOMED shall not be liable for incidental or consequential losses, damages or expenses, directly or indirectly arising from the sale, handling or use of the Goods, or from any other cause relating thereto, and ABIOMED’s sole responsibility under this warranty will be, at its option, to 1) repair or replace the Goods or any components of the Goods found to be defective in workmanship or material during the foregoing warranty period, or 2) to refund the purchase price paid. All replaced components and Goods will become the property of ABIOMED. This warranty shall not apply if the Goods have been: (a) repaired or altered in any way by other than ABIOMED or ABIOMED authorized service personnel; (b) subjected to physical or electrical abuse or misuse; or (c) operated in a manner inconsistent with ABIOMED’s instructions for use of the Goods. If ABIOMED determines that a claim was not caused by ABIOMED or ABIOMED’s authorized service personnel, then Buyer shall pay ABIOMED for all related costs incurred by ABIOMED. This warranty is not transferrable without the express written consent of ABIOMED.

Under this warranty, ABIOMED will provide at no charge, updates or modifications which directly affect the safe operation of the Goods. ABIOMED is not obligated to provide updates or modifications which provide (a) product improvement or enhancement; (b) new product features, or (c) options to the Goods.

ABIOMED has no obligation to provide a loaner system during service or maintenance of the Goods. However, at ABIOMED’s sole discretion, ABIOMED may provide such loaner systems.

This warranty applies to the AB Portable Driver only and not to any disposable or other component of the AB Portable System. Specific items excluded from this warranty include, but are not limited to, Blood Pumps, cannula, and external tubing.

This warranty may not be amended without the express written consent of an authorized officer of ABIOMED, Inc.

LIMITED SERVICE WARRANTY (EUROPE)

Please contact your EU representative for warranty information.

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Clinical support 24 hours per day, 7 days a week:

1-800-422-8666 (US)

+49 (0) 7000 4673552 (EU)

www.abiomed.com

Abiomed, Inc.
22 Cherry Hill Drive
Danvers, Massachusetts 01923 USA
Voice: 978-777-5410
Facsimile: 978-777-8411
Email: marketing@abiomed.com

Abiomed Europe GmbH
Neuenhofer Weg 3
52074 Aachen, Germany
Voice: +49 (241) 8860-0
Facsimile: +49 (241) 8860-111
Email: europe@abiomed.com