ZOLL

User Guide

AutoPulse™ Resuscitation System Model 100

P/N. 11016-001 Rev. January 7, 2005

Notice

About this Guide

The information in this *User Guide* applies to the Revivant Corporation AutoPulse™ Resuscitation System Model 100.

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Preface

This document describes the operating steps and maintenance requirements for the AutoPulse™ Resuscitation System Model 100 (also known as the *AutoPulse System*).

Proper use of the AutoPulse System requires a thorough understanding of the System, and appropriate training and practice using the System.

Please read the entire *User Guide* before operating the AutoPulse System.

Who Should Read this Guide

This document should be read by personnel who will use this product and who are trained in Basic Life Support (BLS) and/or Advanced Life Support (ALS) techniques. This includes emergency medical technicians, paramedics, nurses, physicians, police, and fire rescue personnel, and people certified to administer cardiopulmonary resuscitation (CPR).

General Warnings and Precautions

Warning:

- The AutoPulse System is ***not*** intended for pediatric use.
- The AutoPulse System is ***not*** intended for patients with traumatic injury (wounds resulting from sudden physical injury or violence).
- Manual cardiopulmonary resuscitation (CPR) should start immediately and should not be postponed by deployment of the AutoPulse System.
- The AutoPulse System must be used ***only*** in cases that manual CPR would normally be initiated. Personnel certified in manual CPR must always be present during the AutoPulse System operation.
- The AutoPulse Platform is ***not*** intended for carrying a patient. The AutoPulse Platform should be secured to the top of a backboard or other equipment used to carry or transport the patient, if necessary. During transport, regular checks of the patient's alignment should be performed.
- Failure to properly position the LifeBand™ Chest Compression Assembly (CCA) at the patient's armpit line may cause injury to the patient.
- Do not place or position the patient on the AutoPulse Platform in either a facedown orientation or on the patient's side.
- If a system error occurs during active operation, immediately revert to manual CPR.

Warning:

- If a user advisory or fault cannot be cleared or a system error occurs during active operation, immediately revert to manual CPR.
- Do not strap across, or otherwise constrain, the LifeBand chest bands. Constraining the movement of the LifeBand chest bands can damage or break the LifeBand CCA.
- Do not touch the patient while the AutoPulse Platform is analyzing the patient's size.
- Failure to properly position a patient, both vertically and laterally with respect to the AutoPulse Platform, may cause injury to the patient.
- If you must move or realign the patient, you must press the Stop/Cancel button before adjustment.
- Do not place your hands or any other objects on or under the LifeBand chest bands while the AutoPulse System is analyzing the patient or during active operation.
- Operating the AutoPulse System on a patient for extended periods of time may result in minor skin irritation to the patient.
- Check the patient's chest rise during ventilation during active operation.

Caution: United States federal law restricts this device to sale by or on the order of a licensed physician.

Caution: The AutoPulse System is designed to be used only with Revivant Corporation-approved accessories. The AutoPulse System will perform improperly if non-approved accessories are used.

Caution: Only use Revivant Corporation Batteries specifically designed for use with the AutoPulse System. The use of other batteries may cause permanent damage to the AutoPulse Platform and will void the warranty.

Caution: Make sure that the LifeBand chest bands are ***not*** twisted before automatic compressions begin.

Caution: Do ***not*** submerge the AutoPulse Platform in liquid.

Caution: Use care while using sharp instruments around the LifeBand CCA.

Caution: Do not block the vents of the AutoPulse Platform.

Caution: Do not use the AutoPulse Platform alone as a patient transportation aid.

Caution: Straps or restraints used for transportation purposes *must not interfere* with the operation of the AutoPulse Platform. Specifically, straps across the patient's chest may restrict the compression/decompression of the chest. In general, strapping schemes must not alter the alignment of the patient to the AutoPulse Platform.

Caution: Motion can cause the patient to shift and restraints to loosen, so care should be given to the initial strapping for alignment of the patient to the AutoPulse Platform. Regular checks of patient alignment to the AutoPulse Platform and alignment of the LifeBand CCA to the patient's mid-axillary line should be made if the AutoPulse is performing active compressions, or before active compressions are restarted.

Caution: Remove the protective plastic cap from the Battery before attempting to charge the Battery.

Symbols

The symbols below may be found in this *User Guide*, on the AutoPulse Platform, or on the AutoPulse LifeBand CCA.

	Attention: Consult Accompanying Documents
	Date of Manufacture
	Manufacturer
SN	Serial Number
	Defibrillation Protected, Type BF Patient Connection
IP22	Degree of Protection Provided by Enclosure Per IEC 60529
	Do Not Reuse—Single Use Only
	Charging
	Ready
?	Fail
	Start Test

	Power

1 Introduction of the AutoPulse™ Resuscitation System

For years, a variety of attempts have been made to overcome the limitations of manual cardiopulmonary resuscitation (CPR). Revivant Corporation has developed a practical solution as an adjunct to the method used by medical professionals to perform CPR chest compressions. The AutoPulse™ Resuscitation System Model 100 (also known as the *AutoPulse System*) is the resulting product.

1.1 Indication for Use

The AutoPulse Resuscitation System Model 100 is used by trained personnel as an adjunct to manual CPR on adult patients in cases of clinical death, as defined by a lack of spontaneous breathing and pulse.

1.2 Description of the System

The AutoPulse Resuscitation System is an automated, portable, battery-powered chest compressor, which provides chest compressions as an adjunct to performing manual CPR (see Figure 1-1). Use of the AutoPulse System is intended to reduce the impact of rescuer fatigue and will enable the rescuer to address additional patient needs.

The AutoPulse System has the following operating parameters:

- Chest displacement: Equal to 20% reduction in anterior-posterior chest depth.
- Consistent compression rate and depth.
- Physiological duty cycle: Fixed at 50 ± 5%.
- Standardized 15:2 compressions (15 compressions followed by two consecutive 1.5 second ventilation pauses) or continuous compressions (user selectable).

Table 1-1 provides the patient/AutoPulse System operating parameters.

Table 1-1 Patient/AutoPulse System Operating Parameters

Patient Parameter	AutoPulse System Specification
Patient chest circumference permitted	29.9 to 51.2 in. (76 to 130 cm)
Patient chest width permitted	9.8 to 15 in. (25 to 38 cm)
Maximum patient weight permitted	300 lbs.(136 kg)

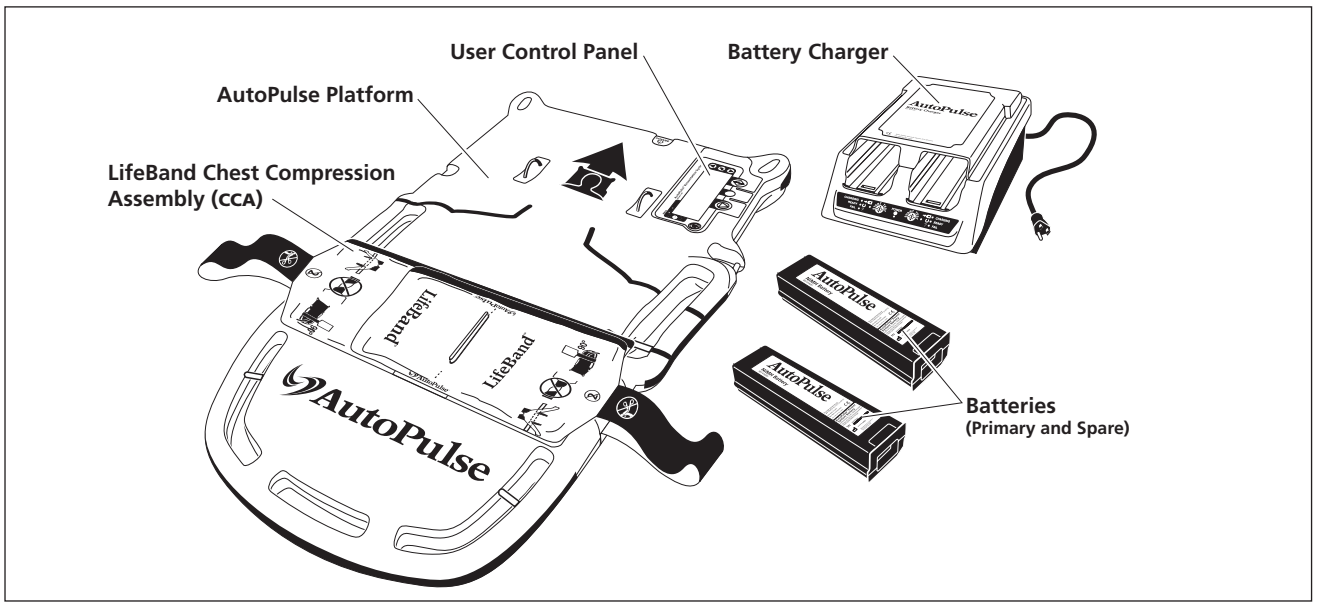


Figure 1-1 AutoPulse System

1.3 System Components

Figure 1-1 shows the main components of the AutoPulse System.

The AutoPulse System consists of the following:

- AutoPulse Platform
- LifeBand™ Chest Compression Assembly (CCA)
- AutoPulse Power System Battery
- AutoPulse Power System Battery Charger

1.3.1 AutoPulse Platform

The AutoPulse Platform contains the mechanical drive mechanism, control system, and electronics necessary to generate and control the force required to perform mechanical chest compressions. User controls and indicators are contained in the User Control Panel.

Figure 1-2 shows the patient surface (front) and back surface details of the AutoPulse Platform. The AutoPulse Platform features carry handles to facilitate transporting it to the scene of the arrest.

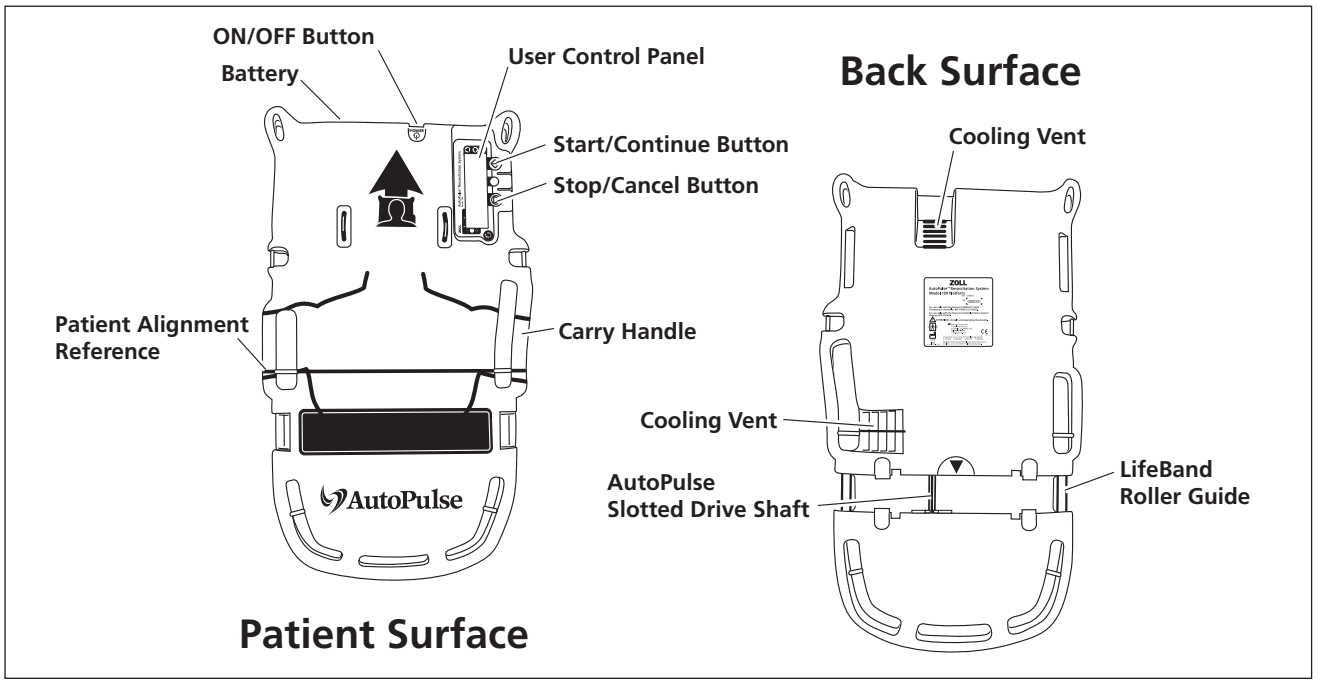


Figure 1-2 AutoPulse Platform (Patient and Back Surfaces)

1.3.2 LifeBand™ Chest Compression Assembly (CCA)

The LifeBand CCA consists of a cover plate and two bands integrated with a compression pad with a Velcro® fastener. Attached to the AutoPulse Platform, the LifeBand CCA is automatically adjusted to the patient by the AutoPulse Platform and provides compressions to the patient's chest in the region of the heart. The LifeBand CCA is a single-use component that is attached to the AutoPulse Platform before each use.

The latex-free LifeBand CCA is for single-patient use only.

1.3.3 AutoPulse Power System Battery

The AutoPulse Power System Battery (also known as the *Battery*) is a removable component that supplies power for the AutoPulse Platform operation. The Battery is a proprietary, rechargeable, nickel-metal hydride (NiMH) battery that is the exclusive power source for the AutoPulse Platform.

The Battery is mechanically keyed to the AutoPulse Platform and Battery Charger to facilitate correct installation. The Battery's back end contains connections for power and communications to the Battery Charger and to the AutoPulse Platform. A Battery Status Check button illuminates the Battery's status light-emitting diodes (LEDs).

For more information on the Battery, refer to the *AutoPulse Power System User Guide*.

1.3.4 AutoPulse Power System Battery Charger

The AutoPulse Power System Battery Charger (also known as the *Battery Charger*) is a stand-alone unit intended to charge and test-cycle the Batteries. The Battery Charger has two charging bays; each with its own indicators. The Battery Charger automatically maintains both the state of charge and tests and maintains the Battery to its highest possible capacity. Batteries should always be fully charged and ready for use before deploying the AutoPulse Platform.

For more information on the Battery Charger, refer to the *AutoPulse Power System User Guide*.

1.4 User Controls and Indicators

1.4.1 ON/OFF Button

The ON/OFF button is located adjacent to the Battery on the AutoPulse Platform (see Figure 1-3). Pressing the ON/OFF button once powers up the AutoPulse Platform and initiates a self-test. The User Control Panel's green Power LED lights up. Pressing the ON/OFF button again powers down the AutoPulse Platform.

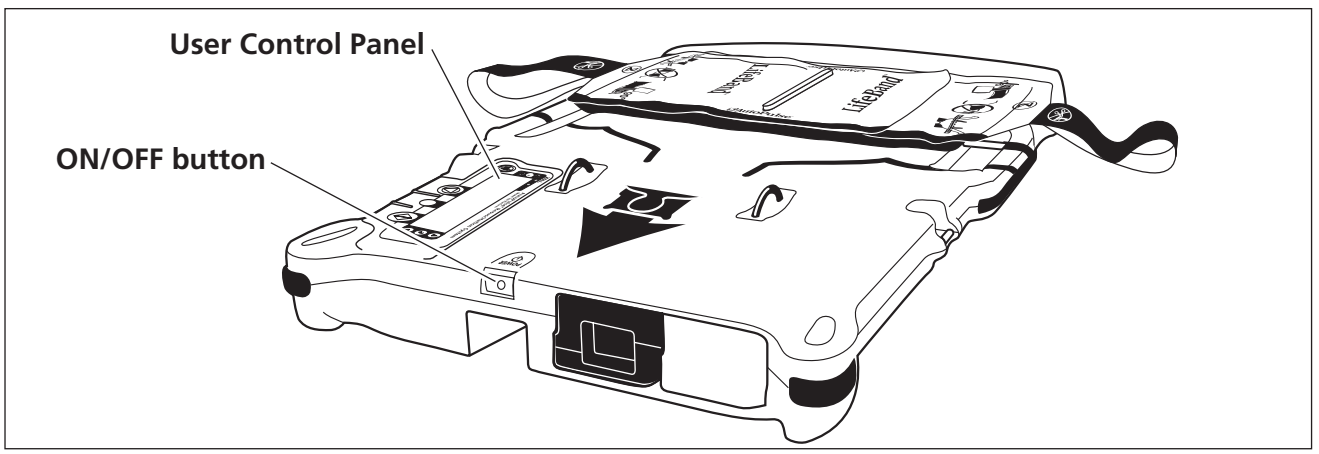


Figure 1-3 ON/OFF Button Location

1.4.2 User Controls

All user controls and indicators (except the ON/OFF button) are contained in User Control Panel (see Figure 1-4).

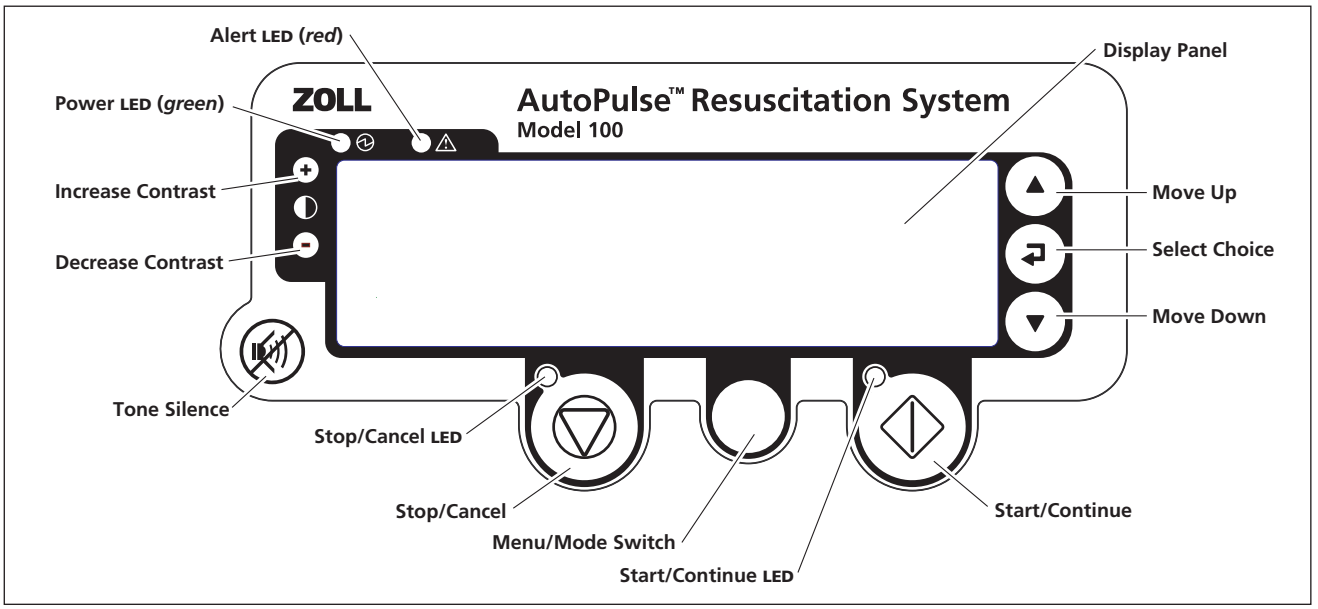
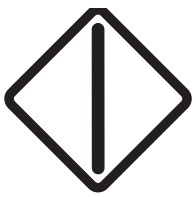


Figure 1-4 User Control Panel

1.4.2.1 Start/Continue Button



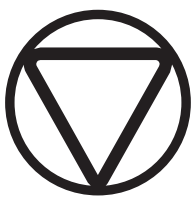
The Start/Continue button is active when “Start” or “Continue” appears on the display panel above the button and its green LED is illuminated.

Use the Start/Continue button to start or continue:

- Analyzing patient size
- Chest compressions

This button is green.

1.4.2.2 Stop/Cancel Button



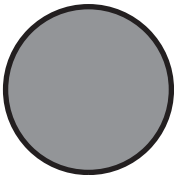
The Stop/Cancel button is active when “Stop”, “Quit”, “No Realign” or “Cancel” appears on the display panel above the button and its orange LED is illuminated.

Use the Stop/Cancel button to stop or cancel:

- Analyzing patient size (see Figure 3-9)
- Chest compressions (the AutoPulse Platform releases the tension on the LifeBand CCA) (see Figure 3-11)
- Hold state (see Figure 3-15)

This button is orange.

1.4.2.3 Menu/Mode Switch Button



On initial power-up this button functions as the Menu button. Pressing the Menu/Mode Switch button allows you to access information about:

1. The last patient session
2. The AutoPulse Platform
3. The AutoPulse Platform Battery

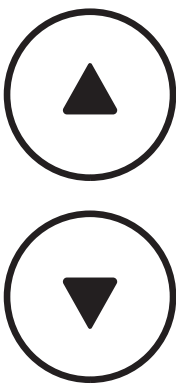
For a complete description of the available information and how to access it, refer to section Section 3.7, "Viewing AutoPulse Platform Information," on page 3-15.

While the AutoPulse is actively doing compressions this button may function as the Mode Switch button. The Mode Switching feature is only active when the "15:2 or Continuous" option has been set in Mode section of the Administration Set-up (refer to section Section 2.3, "Administrative Menu: user pre-set options," on page 2-9). If the "15:2 or Continuous" option has been set, the Mode Switch button will allow you to switch *on-the-fly* between 15:2 and Continuous compression modes.

The current mode (either "15:2" or "CONTINUOUS") is displayed on the upper left portion of the User Display.

This button is gray.

1.4.2.4 Move Up/Move Down Button



These buttons allow you to highlight for selection different menu or list items.

Pressing the Move Up button (upward pointing triangle) moves up to the next menu item.

Pressing the Move Down button (downward pointing triangle) moves down to the next menu item.

1.4.2.5 Select Choice Button

Pressing the Select Choice button selects the currently highlighted menu or list item.

1.4.2.6 Tone Silence Button

Selecting the Tone Silence button will disable or enable audio (tone) feed back generated by the AutoPulse System. When the audio feedback is on, pressing the Tone Silence button will turn it off. When the audio feedback is off, pressing the Tone Silence button will turn it back on. If ventilation and/or pause tones have been disabled in the Administration Menu the Tone Silence button will not re-enable them (refer to section Section 2.3, “Administrative Menu: user pre-set options,” on page 2-9).

Once audio feedback has been disabled with the Tone Silence button, it will automatically be re-enabled when one of the following occurs:

1. You press the Tone Silence button again.
2. You press the Start/Continue button to begin compressions.
3. You press the Stop button during compressions.
4. A low battery condition is reached (refer to section Section 1.4.3, “Low Battery Warning,” on page 1-9).
5. You switch between compression modes (refer to section Section 3.2, “Mode Change Confirm Display Panel Screen,” on page 3-11).

The icon displayed on the User Control Panel display when tones are enabled (on).

The icon displayed ion the User Control Panel display when tones are disabled (off).

1.4.2.7 Increase/Decrease Contrast Button

Pressing the Increase Contrast button (plus sign) increases the contrast of the display panel screen. Each key press increases the contrast of the display panel screen by one level.

There are a total of eight contrast levels.

Pressing the Decrease Contrast button (minus sign) decreases the contrast of the display panel screen. Each key press decreases the contrast of the display panel screen by one level.

You can adjust the contrast of the display panel screen at any time the AutoPulse Platform is powered up.

1.4.2.8 Power (Green LED)

The green Power LED lights whenever the AutoPulse Platform is powered on and able to respond to user input.

1.4.2.9 Alert (Red LED)

The red Alert LED lights whenever a user advisory, fault or system error condition exists for the AutoPulse Platform. For a list of advisory, fault and error conditions, refer to Chapter 5, "Troubleshooting Procedures".

1.4.3 Battery Charge Status

The User Control Panel displays the battery charge status. The Battery charge status icon only appears when the AutoPulse Platform is powered up.

Indicates the level of charge of the Battery. A graphic battery icon indicating four proportional levels of battery charge is displayed.

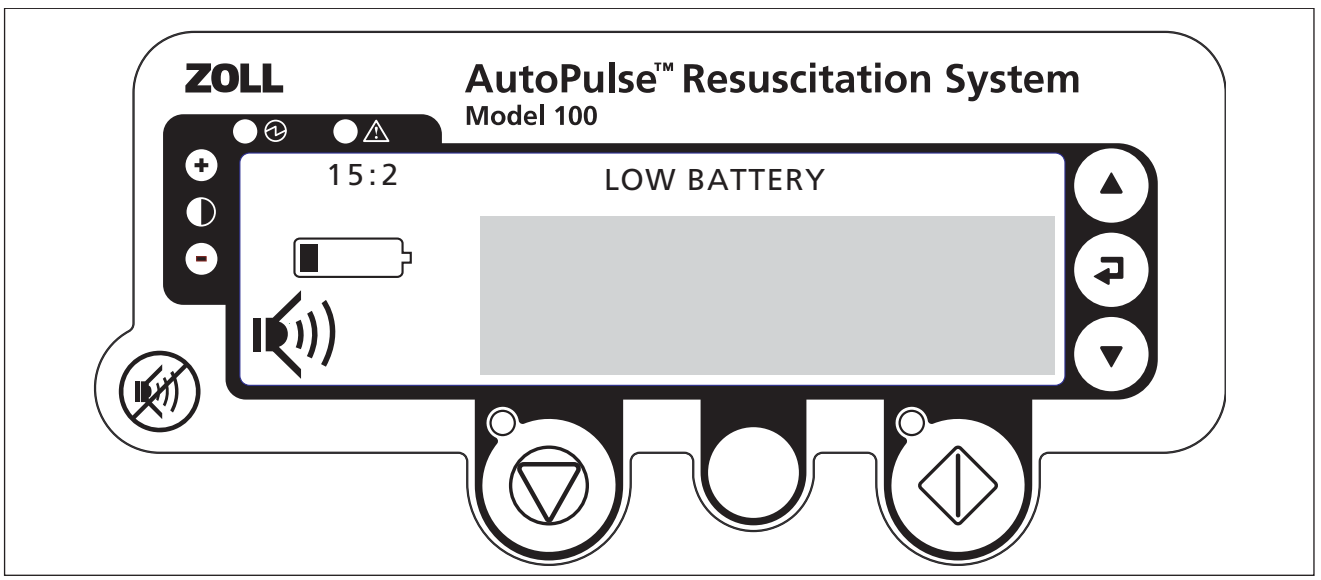


Figure 1-5 Low Battery Warning

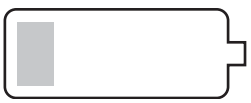
When at least five minutes of active operation remain on a Battery, the User Control Panel will give a "Low Battery" indication (see Figure 1-5). The "Low Battery" indication will remain on until the Battery is replaced or depleted. The Low Battery warning display will be accompanied with an audio warning of four rapid beeps which will be followed by two beeps every 30 seconds until the battery is replaced or depleted. It is recommended that a fully-charged Battery be exchanged for the Battery with the low charge (if available).

To exchange Batteries:

1. Press the Stop/Cancel button.
2. Press the ON/OFF button.
3. Remove the Battery (refer to Section 2.2, "Battery Installation and Removal" for more information).
4. Install the fully-charged Battery (refer to Section 2.2, "Battery Installation and Removal" for more information).
5. Resume chest compressions (refer to Section 3.2, "Starting Chest Compressions" for more information).

Table 1-2 describes the battery charge status indicator specifics. The Battery, when fully charged, has the capacity for a minimum run time of 30 minutes on a patient of nominal size and nominal resistance to compressions (a *nominal patient*). This is referred to in Table 1-2 as the *nominal run time*.

Table 1-2 Battery Charge Status Indicator Specifics

Battery Charge Icon	Bars Showing	Charge Level
	No bars showing.	The Battery has been depleted. Replace the Battery immediately.
	One bar showing.	The Battery's capacity is less than one-third of its nominal run time. Be prepared to exchange this Battery with a fully-charged Battery.
	Two bars showing.	The Battery's capacity is between 33% and 66% of its nominal run time.
	Three bars showing.	The Battery's capacity is between 66% and 100% of its nominal run time.
	All bars showing.	The Battery's capacity is at least 100% of its nominal run time.

1.4.4 Performance Characteristics

The basic operating characteristics of the AutoPulse Platform are shown in Table 1-3. All performance characteristics are factory preset. No adjustments are necessary.

Table 1-3 Operating Characteristics

Operating Performance	Specification
Compression rate	80 (± 5 compressions per minute)
Compression Modes (user selectable)	• 15:2 (15 compressions with two 1.5 second ventilation pauses) • Continuous compressions
Duty cycle	50 (± 5%)
Compression depth	20% of chest depth, +0.25/-0.5 inch

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2 Preparing the AutoPulse System for Use

The AutoPulse System is delivered fully assembled, except for the LifeBand Chest Compression Assembly (CCA) and the AutoPulse Power System Battery.

2.1 LifeBand Chest Compression Assembly (CCA) Installation and Removal

2.1.1 Installing the LifeBand CCA

1. Place the AutoPulse Platform with the patient surface facing down on a smooth, flat surface.

   Note: The drive shaft should be oriented so that the slot faces directly upward.

2. 1 Insert the head end of the LifeBand band clip into the drive shaft slot. The correct direction is towards the LifeBand plate alignment arrow seen on the Platform (see Figure 2-1).

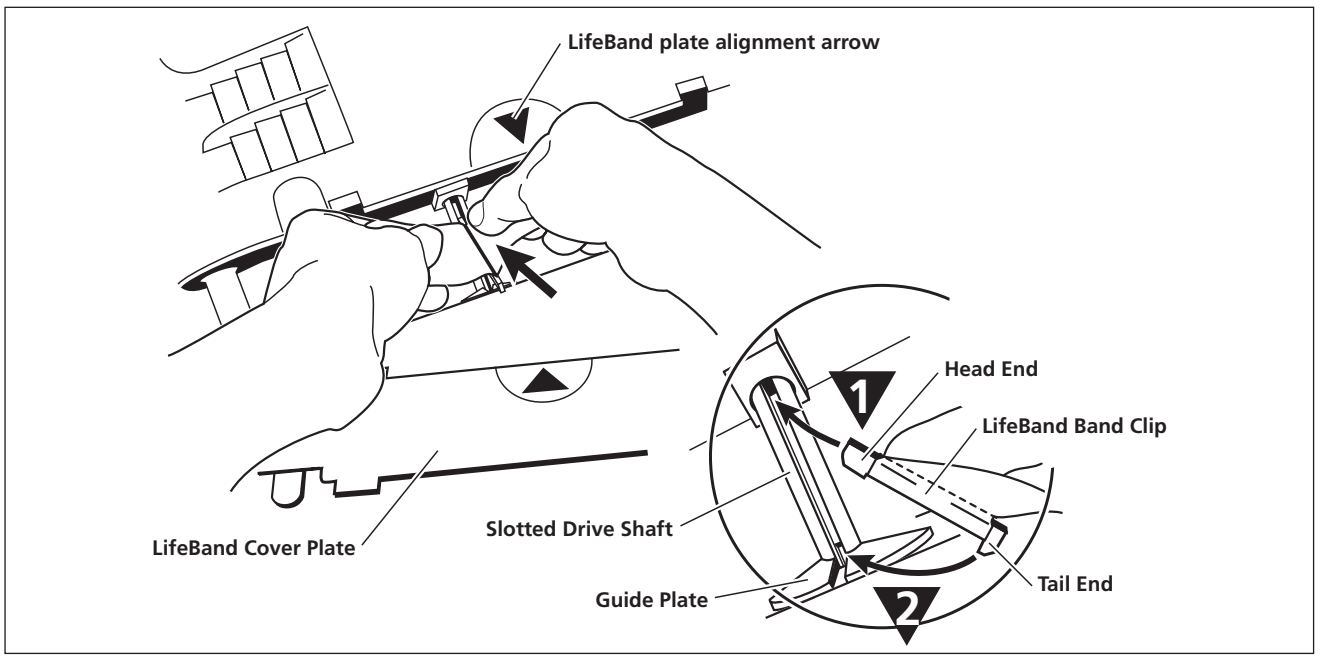

Figure 2-1 Sliding the LifeBand Band Clip into the Drive Shaft Slot

3. 2 Once the head end of the LifeBand band clip is positioned into the slot, press the tail end of the band clip into the slot of the guide plate until the band clip is fully seated in the drive shaft. You should feel it lock into place.

4. Make sure that the band clip is seated properly and fully into the slot on the drive shaft (see Figure 2-2).

   Note: If the band clip is properly seated, you should be able to easily turn the drive shaft in each direction by hand.

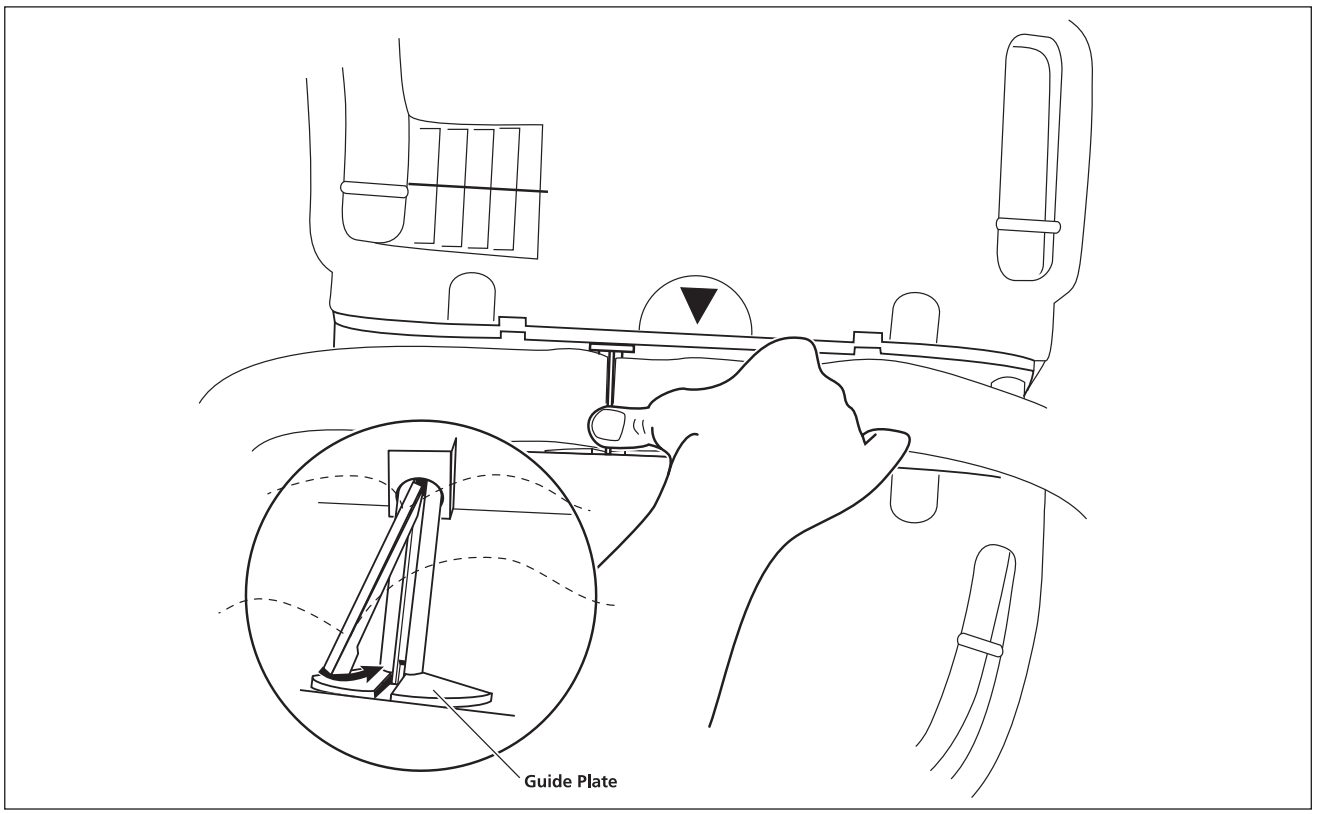

Figure 2-2 Seating the LifeBand Band Clip Properly into the Drive Shaft Slot

5. Ensure that both free ends of the LifeBand chest band are oriented flat (not twisted) and away from the AutoPulse Platform. Inspect the LifeBand CCA for any cuts or tears. Do not use the LifeBand CCA if cuts or tears are present.
6. Line up the arrow on the LifeBand cover plate with the matching arrow on the Platform.

7. Snap the LifeBand cover plate in place by fully inserting the locking tabs into the slots on the AutoPulse Platform (see Figure 2-3).

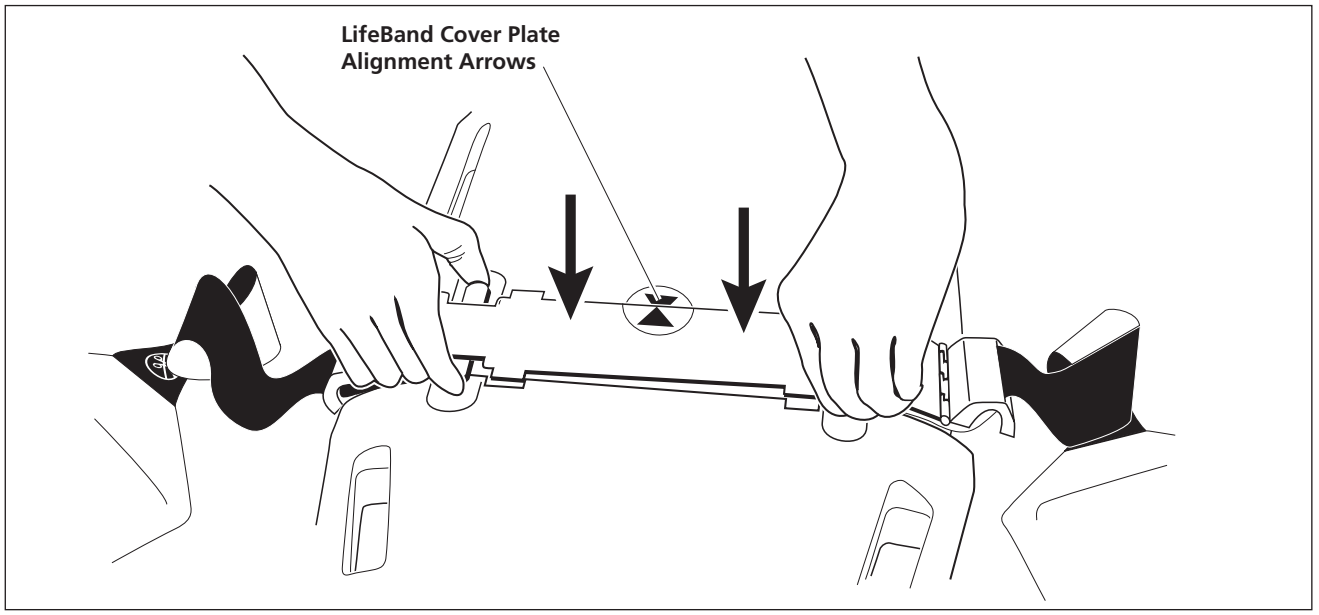

Figure 2-3 Snapping the LifeBand Cover Plate into Place

8. Flip down and snap into place the hinged skirts of the LifeBand cover plate to engage the LifeBand chest bands to the rollers (see Figure 2-4).

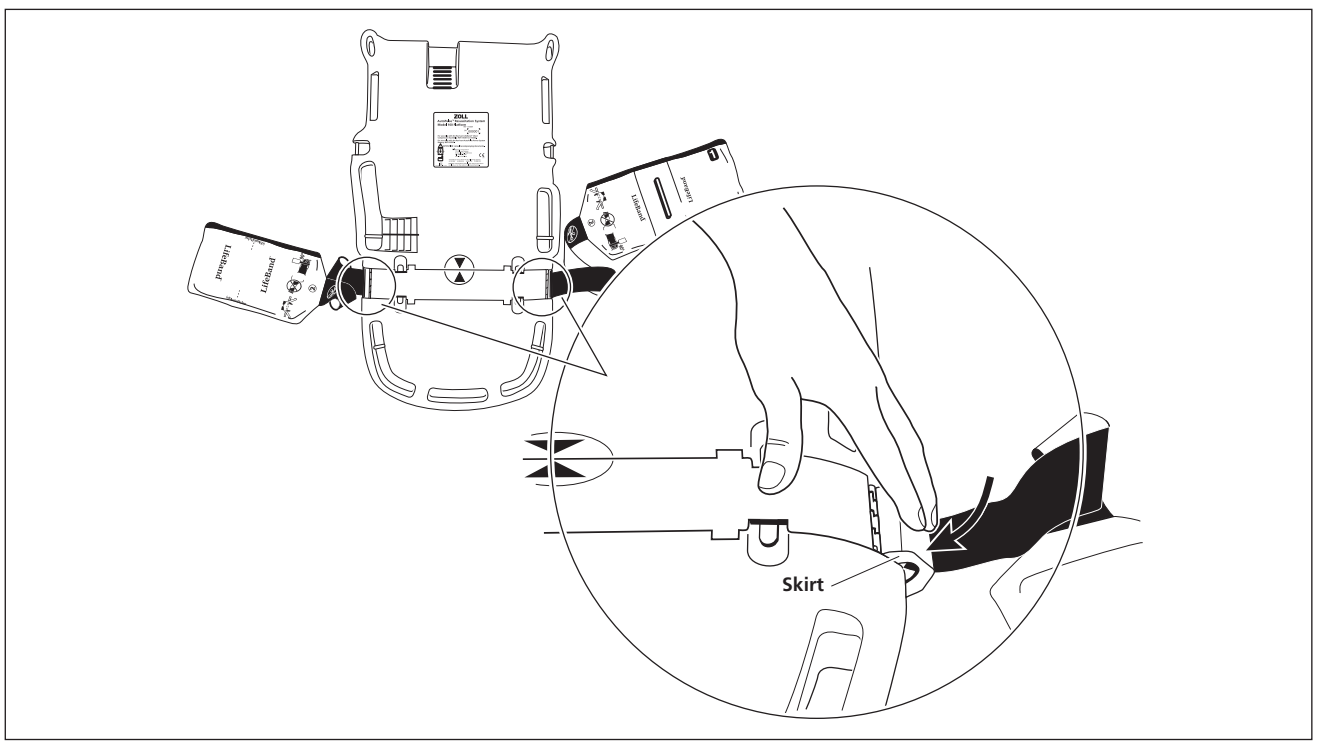

Figure 2-4 Flip Down the Hinged Skirts of the LifeBand CCA

9. Turn the AutoPulse Platform over and press the ON/OFF button to power it up. If the User Control Panel reports a user advisory, check the installation of the LifeBand band clip into the slot in the drive shaft.

2.1.2 Removing the LifeBand CCA

1. Place the AutoPulse Platform with the patient surface facing down on a smooth, flat surface.
2. Flip up the hinged skirts of the LifeBand cover plate to disengage the LifeBand chest bands from the rollers (see Figure 2-5). You will hear the skirt "snap." This is normal.

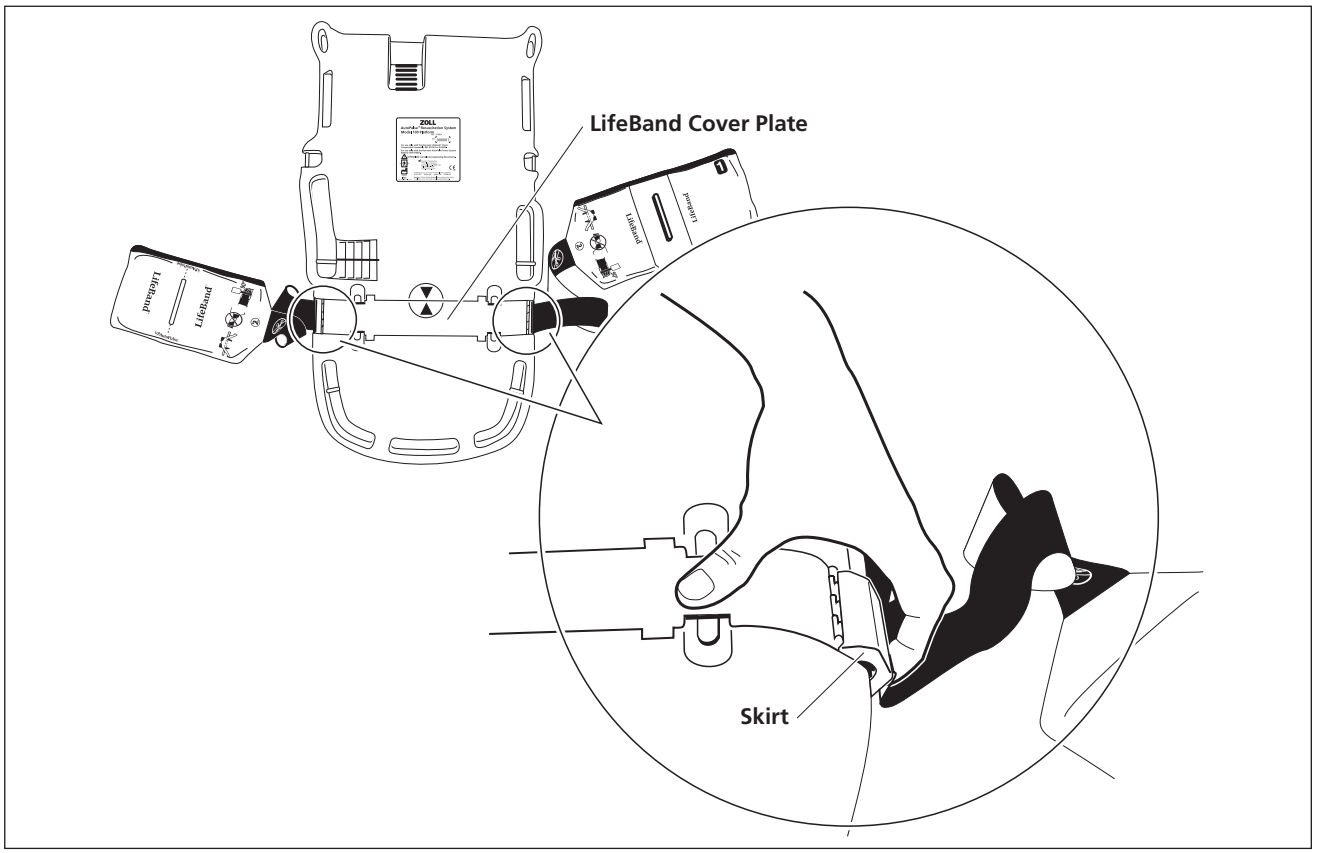

Figure 2-5 Flip Up the Hinged Skirts of the LifeBand CCA

3. Using both hands, pinch together the locking tabs of the LifeBand cover plate and firmly pull the plate straight up and away from the AutoPulse Platform (see Figure 2-6).

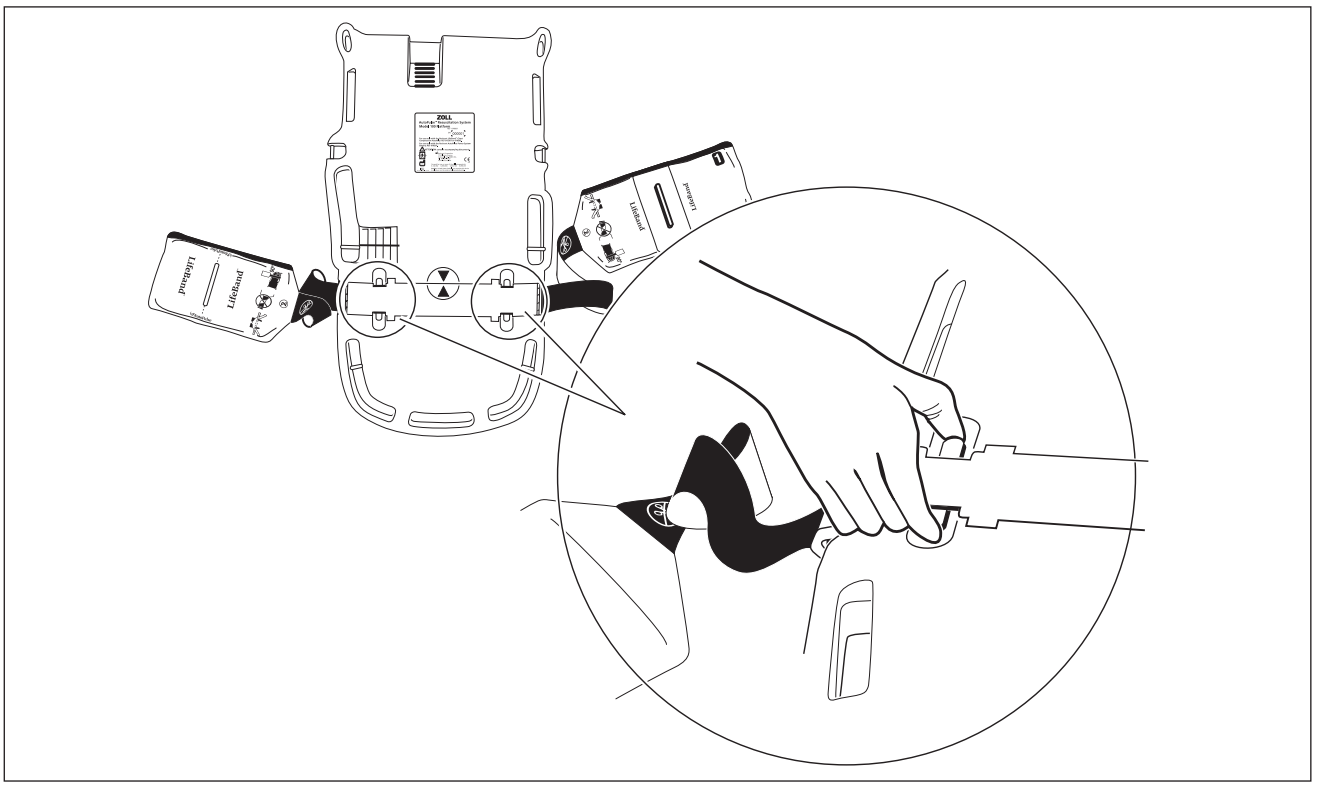

Figure 2-6 Pinching the Locking Tabs of the LifeBand CCA

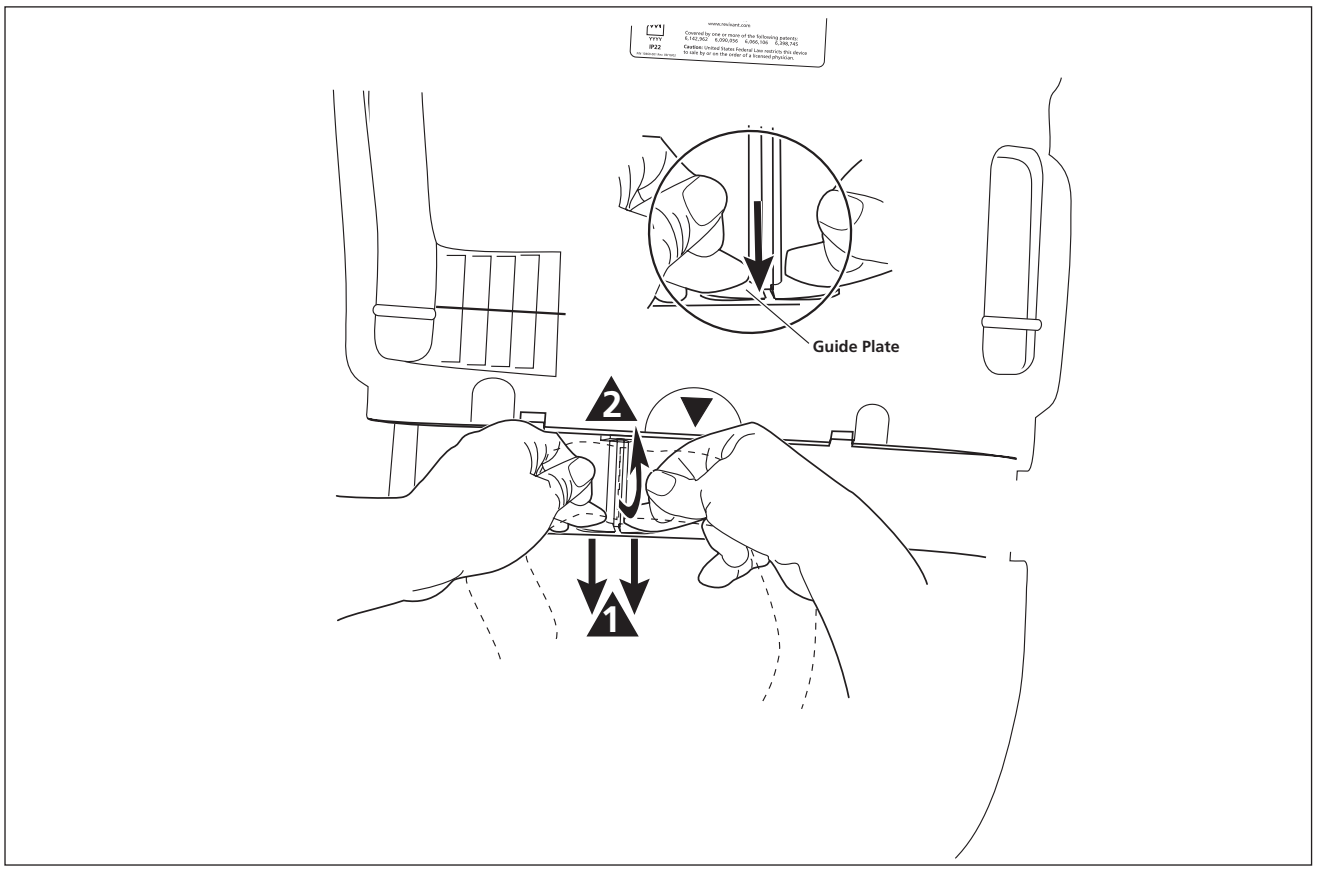

Figure 2-7 Removing the LifeBand Chest Band from the AutoPulse Platform

4. Remove the LifeBand chest bands from the AutoPulse Platform by grasping the LifeBand chest band with the thumb and index finger of both hands, on either side of the LifeBand band clip.

   1 Push in the guide plate, using both middle fingers. Keeping the guide plate pushed in,

   2 pull up the band to remove the clip from the shaft (see Figure 2-7).

5. **Discard the LifeBand CCA as it is a single-use component after patient use. Treat the LifeBand CCA as contaminated medical waste and dispose of it accordingly. There are no user-serviceable parts.**

6. Inspect the new, replacement LifeBand CCA for cuts or tears.

7. Replace the LifeBand CCA following the procedures in Section 2.1.1, “Installing the LifeBand CCA”.

2.2 Battery Installation and Removal

For more information on the AutoPulse Power System and its components, refer to the *AutoPulse Power System User Guide*.

Press the Status Check button on the Battery to ensure it is fully charged before insertion into the AutoPulse Platform and before patient use (refer to the "Performing a Battery Status Check" section in the *AutoPulse Power System User Guide* for more information). You should only use batteries that illuminate the green status light-emitting diode (LED).

Caution: Remove the protective plastic cap from the Battery before attempting to charge the Battery.

Batteries remaining in the AutoPulse Platform should be checked regularly for appropriate charge status. Low Batteries should be replaced with charged Batteries.

To install the Battery, slide the Battery into the Battery compartment in the AutoPulse Platform. The Battery should snap into place and mount flush with the AutoPulse Platform.

The Battery is mechanically keyed so that it can only be inserted in one orientation. Do not force or slam the Battery into the Battery compartment. If resistance is met, check for appropriate orientation, and check to insure there are no obstructions to Battery insertion.

Ensure that the Battery is securely latched (snaps into place) before moving the AutoPulse Platform or initiating chest compression.

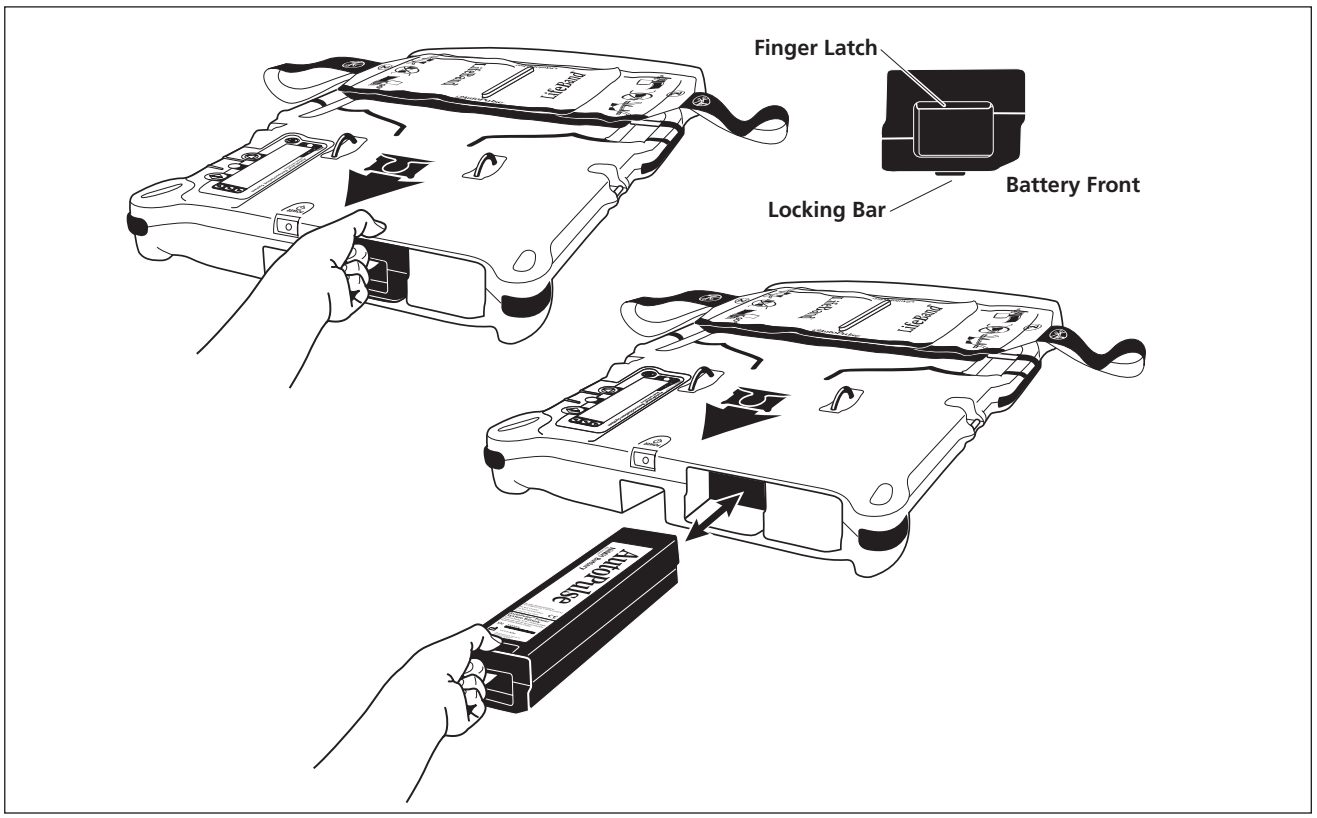

Figure 2-8 Battery Installation and Removal

To remove the Battery, hold the AutoPulse Platform firmly and grip the Battery while pressing the finger latch upwards to disengage the locking bar (see Figure 2-8), then pull the Battery straight out until it fully clears the Battery compartment.

Caution: Only use Revivant Corporation Batteries specifically designed for use with the AutoPulse System. The use of other batteries may cause permanent damage to the AutoPulse Platform and will void the warranty.

2.3 Administrative Menu: user pre-set options

There are several options that may be pre-set by the user prior to deployment of the AutoPulse Platform. These options are:

- Compression mode
- Ventilation tone on/off
- Pause alert tone interval
- Tone volume

Additionally the Administrative Menu allows you to access the following information (refer to section Section 3.7, “Viewing AutoPulse Platform Information,” on page 3-15):

- The last patient session
- The AutoPulse Platform
- The AutoPulse Platform Battery

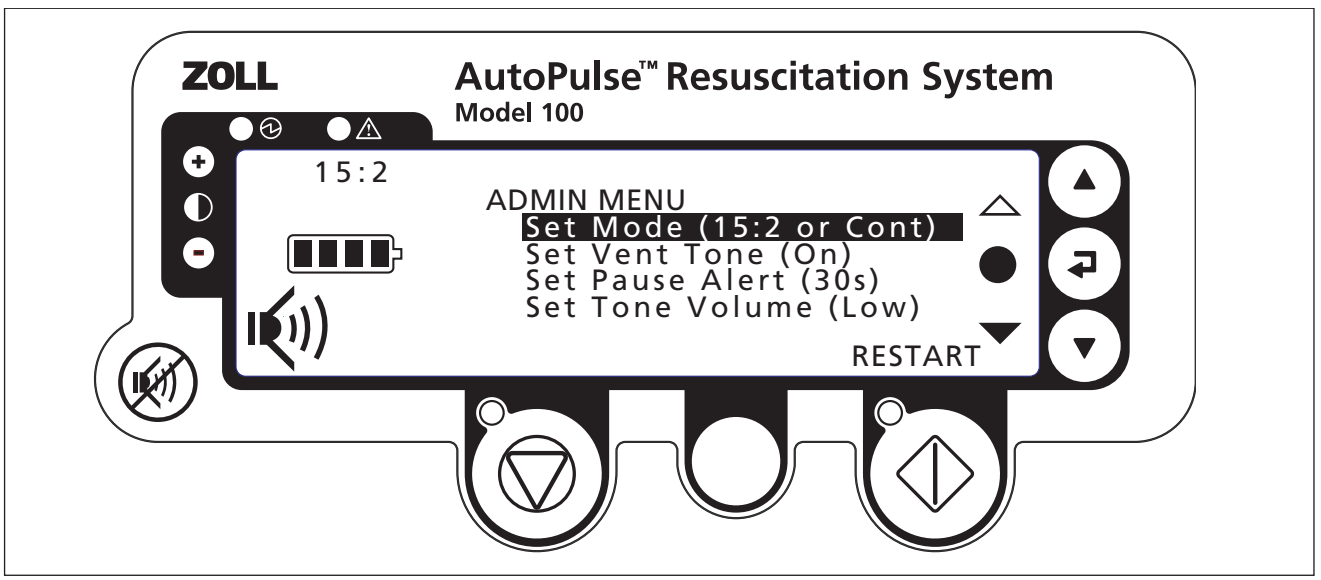

Figure 2-9 Administrative Menu

To access the Administrative Menu the AutoPulse Platform must be powered off. The Administrative Menu is activated by pressing the ON/OFF switch while both the Stop (orange) and Start (green) buttons are being depressed. Once the Administrative Menu is active use the Move Up and Down arrow buttons to highlight the desired menu item and the Select Choice Button to select it.

To exit from the Administrative Menu, press the "START" (green) button under the word "RESTART." The AutoPulse System will restart and place you into the idle state, ready for patient alignment or for system power-down.

Note: The current setting is displayed in the parenthesis after the main menu item.

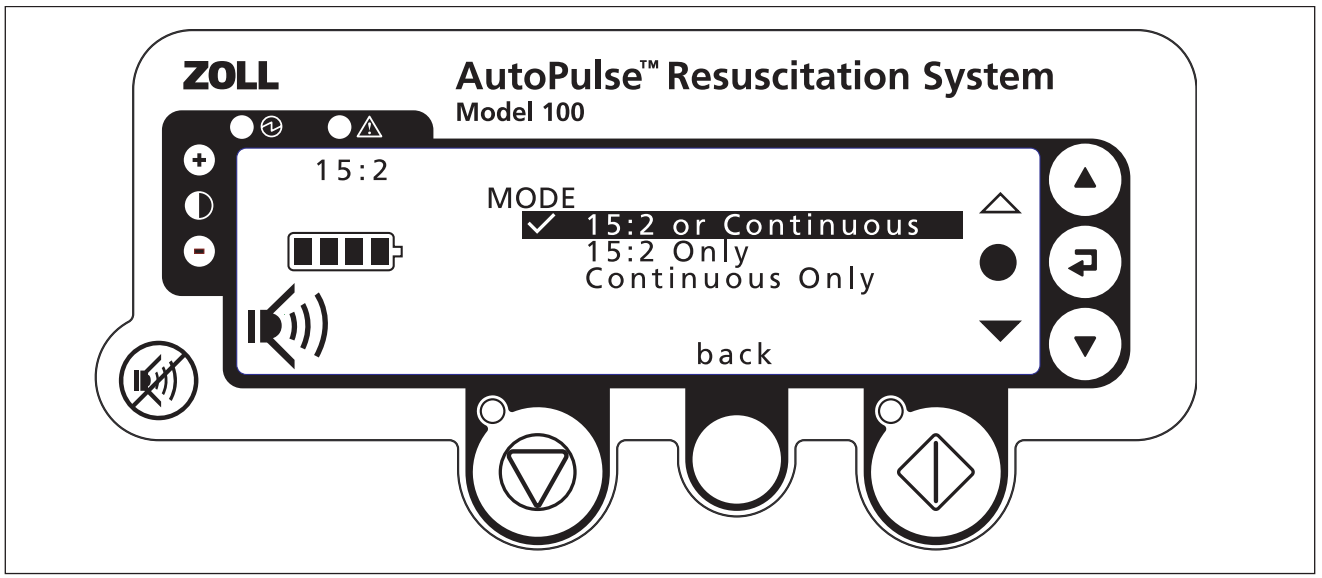

Figure 2-10 Compression Mode menu

The "Set Mode" menu item allows you to restrict the AutoPulse Platform operation to a single compression mode or to allow *on-the-fly* mode switching. Selecting "15:2 or Continuous" will allow *on-the-fly* mode switching between 15:2 and continuous compressions while the system is actively doing compressions. Selecting "15:2 Only" will restrict the system operation to the 15:2 mode. Selecting "Continuous Only" will restrict the system operation to continuous compressions. Highlight the desired setting using the Move Up and Down arrow buttons, press the Select Choice Button to select it (a check will appear beside the selected item) and then press the gray Menu/Mode switch button under the word "back" to return to the main Administrative Menu.

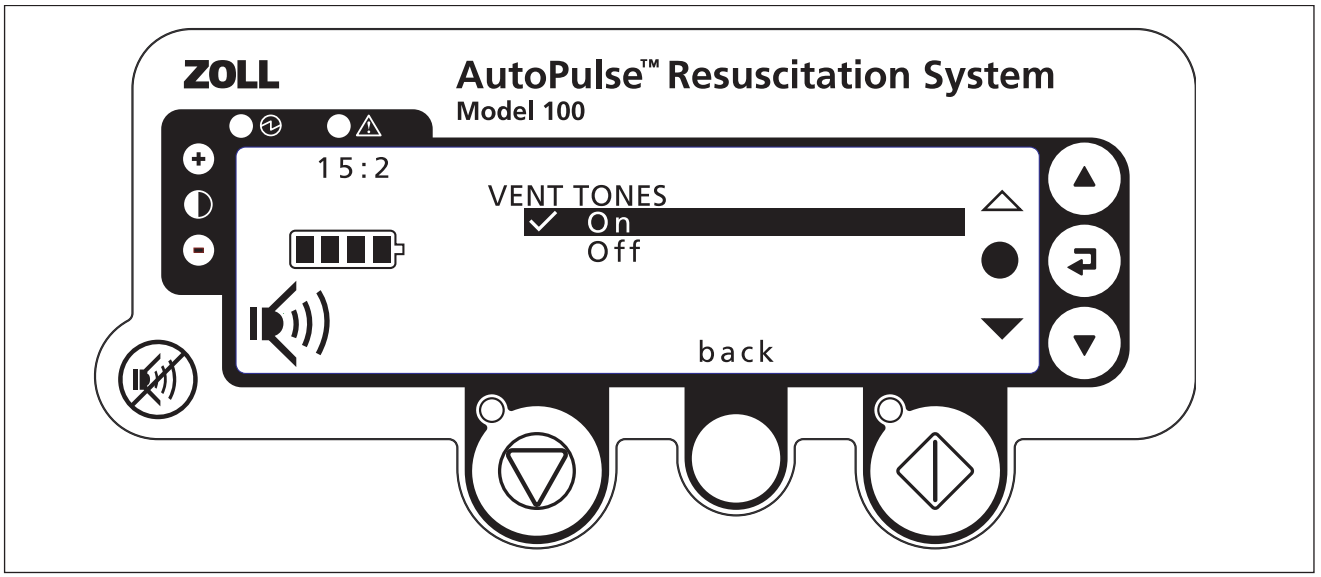

Figure 2-11 Ventilation Tones menu

The "Set Vent Tones" menu item allows you to enable or disable the audible tone sequence that is used to cue the ventilation phase in the 15:2 compression mode and to sound a ventilation cue during the 6th of each set of 7 compressions during continuous mode. Highlight the desired setting using the Move Up and Down arrow buttons, press the Select Choice Button to select it (a check will appear beside the selected item) and then press the gray Menu/Mode switch button under the word "back" to return to the main Administrative Menu.

Note: If the ventilation tone is disabled here it cannot be re-enabled, during operation, by using the Tone Silence button (refer to section Section 1.4.2.6, "Tone Silence Button," on page 1-7).

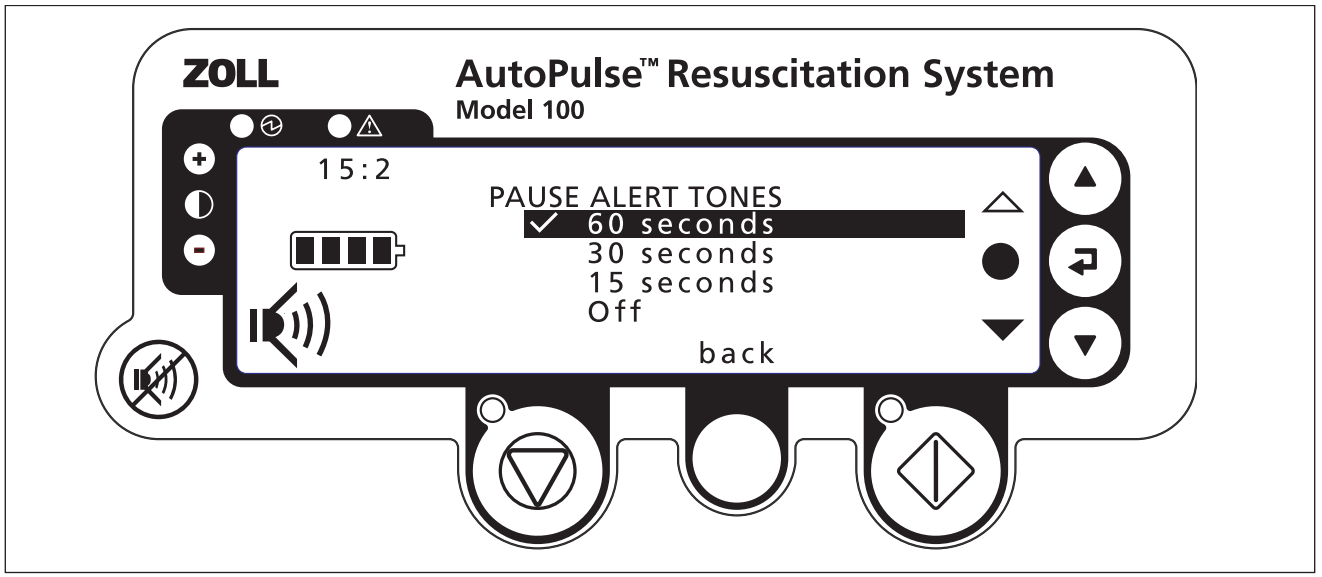

Figure 2-12 Pause Alert Tones menu

The "Set Pause Alert Tone" menu item allows you to set the frequency or disable the tone sequence used to alert that the system has been deliberately stopped (paused) while actively doing compressions. The options are to set the system to beep once every "60 seconds" (one minute), "30 seconds" or "15 seconds." Highlight the desired setting using the Move Up and Down arrow buttons, press the Select Choice Button to select it (a check will appear beside the selected item) and then press the gray Menu/ Mode switch button under the word "back" to return to the main Administrative Menu.

Note: If the pause alert tone is disabled here it cannot be re-enabled, during opperation, by using the Tone Silence button (refer to section Section 1.4.2.6, "Tone Silence Button," on page 1-7).

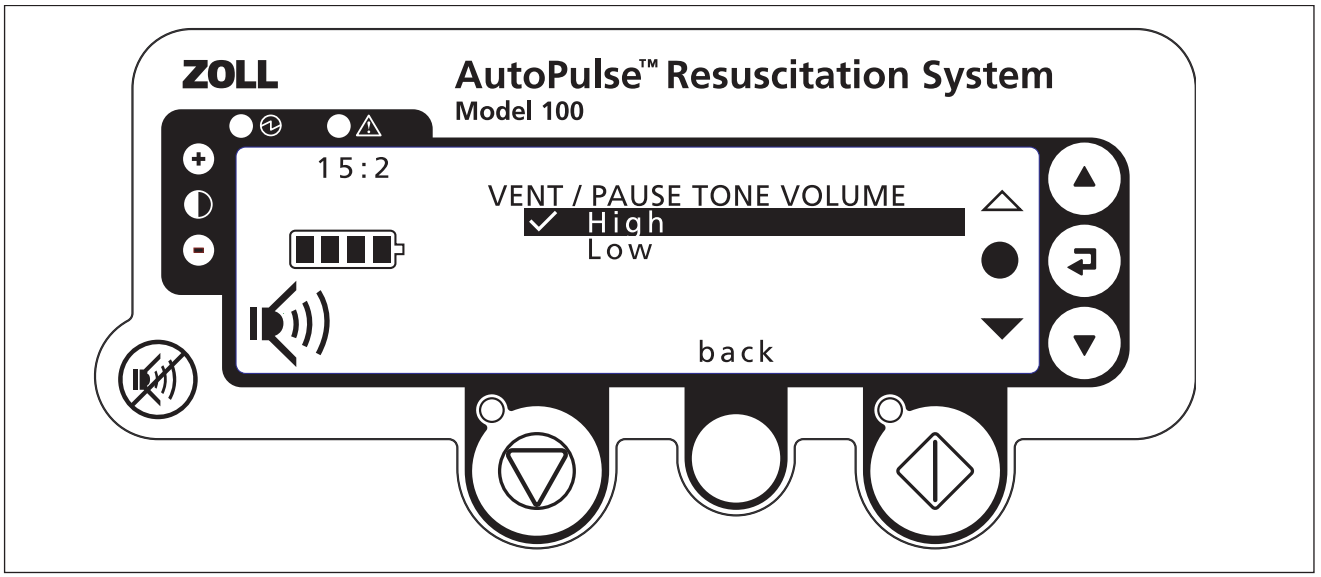

Figure 2-13 Ventilation/Pause Tone Volume menu

The "Set Tone Volume" menu item allows you to select the volume of the audible tone sequence that is used to cue for ventilation during active compressions and to alert the operator that the system has been deliberately stopped (paused) while actively doing compressions. Choices are "High" and "Low." Highlight the desired setting using the Move Up and Down arrow buttons, press the Select Choice Button to select it (a check will appear beside the selected item) and then press the gray Menu/Mode switch button under the word "back" to return to the main Administrative Menu.

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3 Using the AutoPulse System

This chapter describes how to use the AutoPulse System in an emergency situation. The AutoPulse Platform User Control Panel automatically provides display prompts to guide you.

Before deploying the AutoPulse System, note the following warnings and precautions:

Warning:

- The AutoPulse System is ***not*** intended for pediatric use.
- The AutoPulse System is ***not*** intended for patients with traumatic injury (wounds resulting from sudden physical injury or violence).
- Manual cardiopulmonary resuscitation (CPR) should start immediately and should not be postponed by deployment of the AutoPulse System.
- The AutoPulse System must be used ***only*** in cases that manual CPR would normally be initiated. Personnel certified in manual CPR must always be present during the AutoPulse System operation.

Caution: Use care while using sharp instruments around the LifeBand Chest Compression Assembly (CCA).

Caution: Do not block the vents of the AutoPulse Platform.

3.1 Deploying the AutoPulse System

Once you have arrived upon the scene and determined that use of the AutoPulse System is appropriate, prepare the AutoPulse Platform for use.

1. Power up the AutoPulse Platform. The ON/OFF button is located on the top (“head”) edge of the AutoPulse Platform (see Figure 3-1).

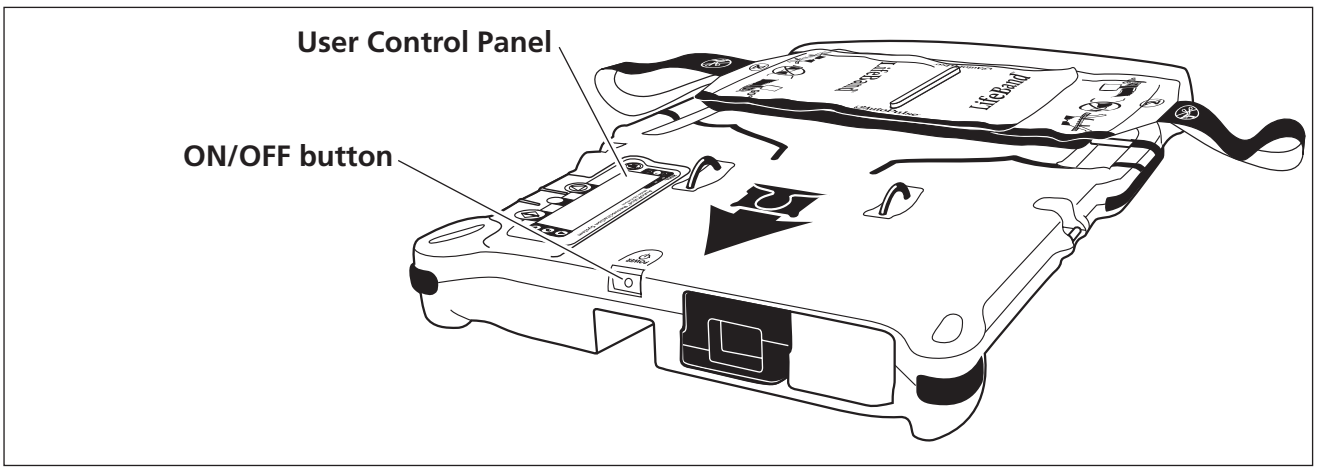

Figure 3-1 ON/OFF Button Location

2. The AutoPulse Platform illuminates the green Power light-emitting diode (LED) on the User Control Panel and performs its self-tests (see Figure 3-2). Refer to the User Control Panel and its display panel during the operation of the AutoPulse Platform. All operating information is available on the User Control Panel.

   Note: Make sure that no user advisory, fault or system error messages display.

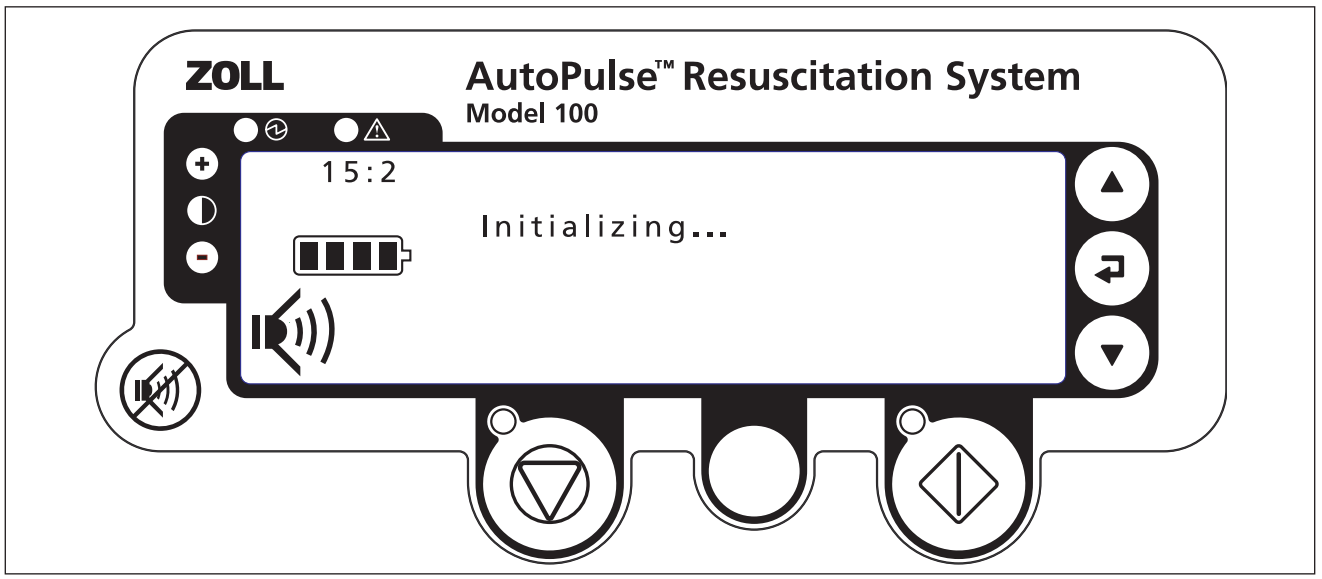

Figure 3-2 Self-Test Display Panel Screen

3. The AutoPulse Platform indicates that it is ready for use (see Figure 3-3).

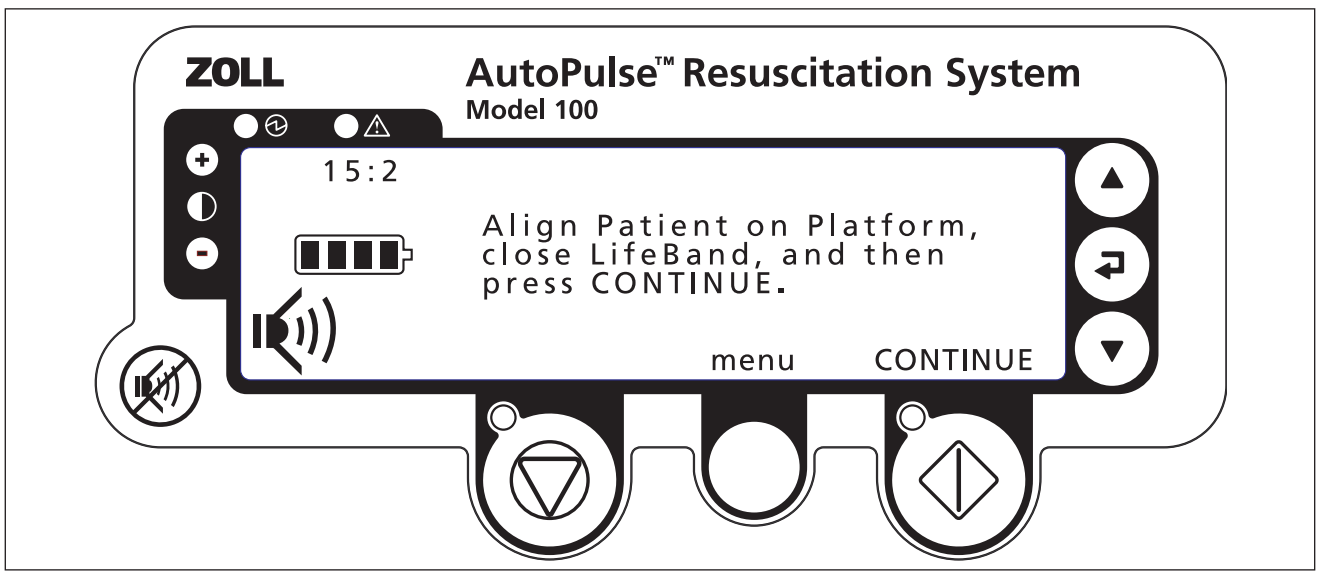

Figure 3-3 Patient-Readiness Display Panel Screen

4. After assessing the patient's condition, sit the patient up and make a single cut down the back of the patient's clothing (see Figure 3-4).
5. Slide the AutoPulse Platform into position behind the sitting patient and lay the patient down onto the Platform.

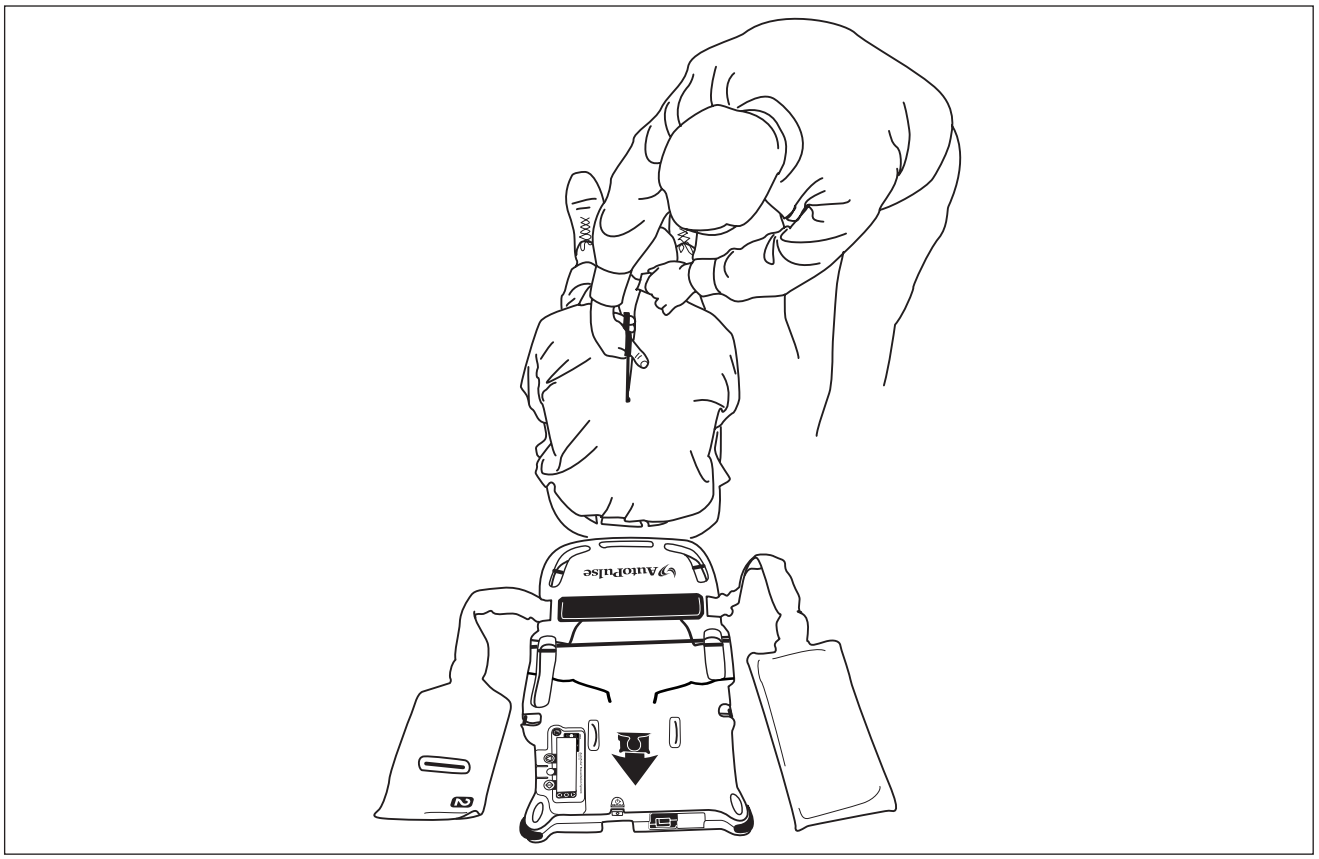

Figure 3-4 Cutting Patient Clothing and Positioning of AutoPulse Platform

6. Grasp the clothing by the sleeves and pull down toward the ankles to remove all of the clothing from both the front and back of the torso. (see Figure 3-5).

Figure 3-5 Removal of all Clothing from the Torso

7. Position the patient so that the patient is centered laterally (from left to right) and that the patient's armpits are aligned with the AutoPulse Platform using the yellow line positioning guides on the AutoPulse Platform as shown in Figure 3-6.

Warning: Do not place or position the patient on the AutoPulse Platform in either a facedown orientation or on the patient's side.

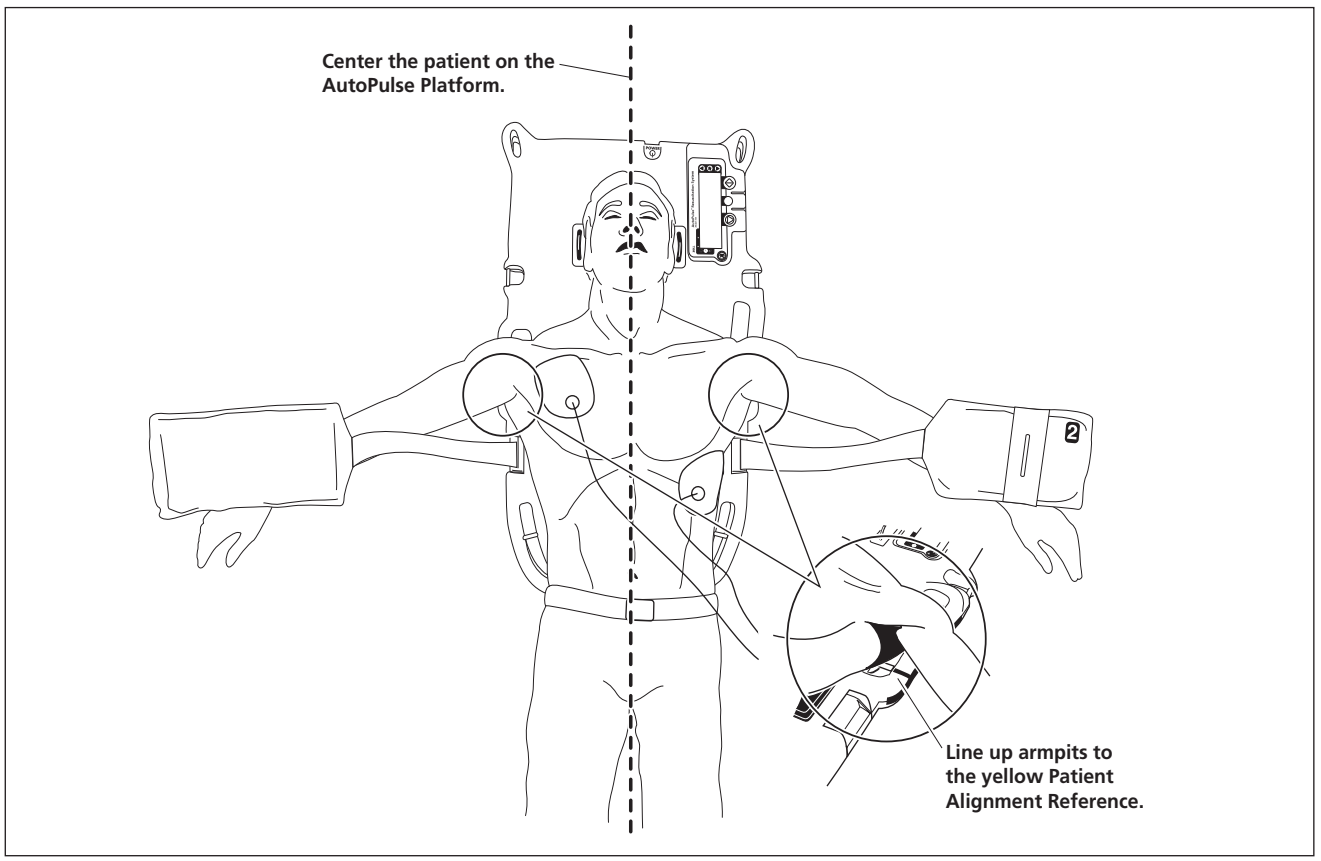

Figure 3-6 Patient Alignment

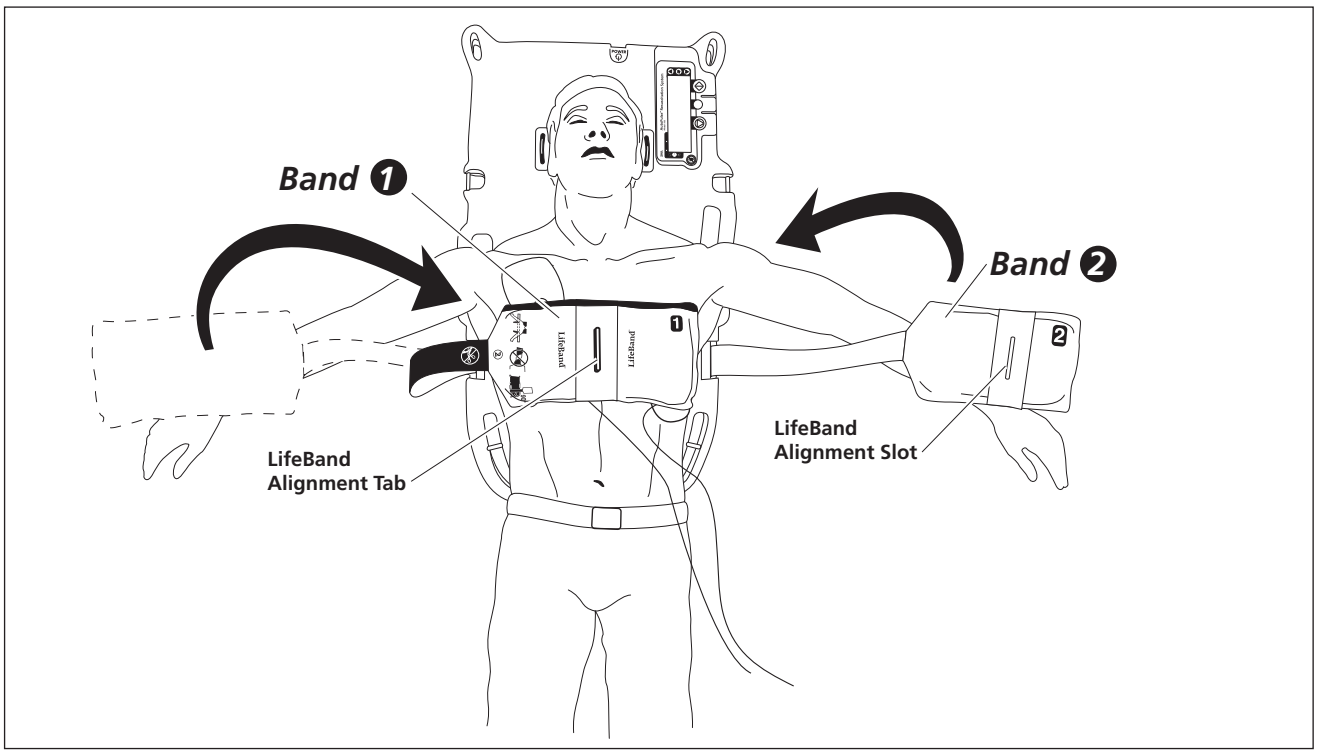

Figure 3-7 Aligning the LifeBand Chest Bands

8. Close the LifeBand chest bands around the patient's chest.

   Note: AED or defibrillation pads are ***not*** components of the AutoPulse System.

   To properly align the bands:

   a) Place band ❶ on top of patient's chest (see Figure 3-7).

   b) Locate mating slot of band ❷ over the alignment tab ❶ (see Figure 3-7).

   c) Press the bands together to engage and secure the Velcro® fastener (see Figure 3-8).

   Caution: Make sure that the bands are ***not*** twisted before automatic compressions begin.

   Note: If the bands cannot be closed, use manual CPR.

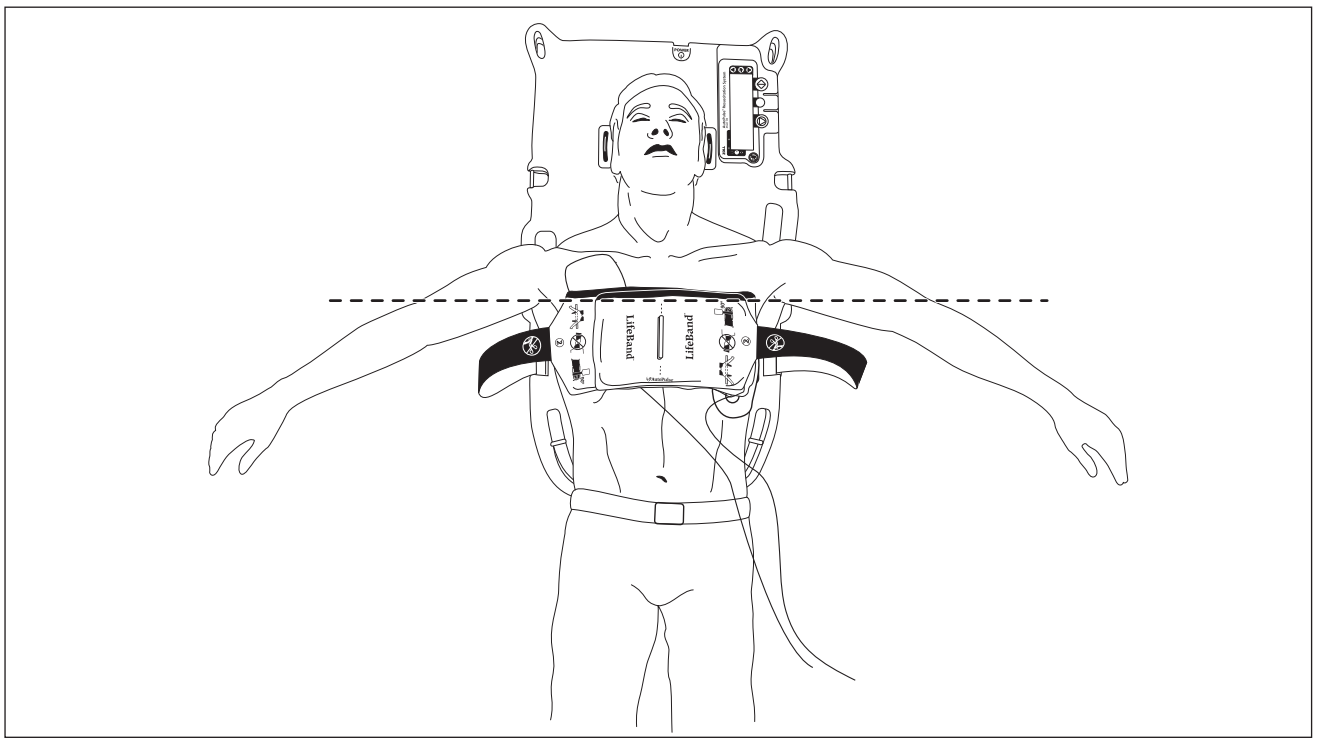

Figure 3-8 Fastening the LifeBand Chest Bands

3.2 Starting Chest Compressions

1. Make sure that the yellow upper edge of the LifeBand chest bands are aligned with the patient's armpits, and is directly over the yellow line on the AutoPulse Platform. Also make sure that there are no obstructions, such as clothing, straps or equipment, with the bands.

Warning:

- Failure to properly position the LifeBand Chest Compression Assembly (CCA) at the patient's armpit line may cause injury to the patient.
- Failure to properly position a patient, both vertically and laterally with respect to the AutoPulse Platform, may cause injury to the patient.
- Do not strap across, or otherwise constrain, the LifeBand chest bands. Constraining the movement of the bands can damage or break the LifeBand CCA.
- Operating the AutoPulse System on a patient for extended periods of time may result in minor skin irritation to the patient.

2. Press and release the Start/Continue button once. The AutoPulse Platform automatically adjusts the bands to the patient's chest (see Figure 3-9) and determines the appropriate compression.

   Note: Do not touch the patient or the LifeBand CCA while the AutoPulse Platform is analyzing the patient's size.

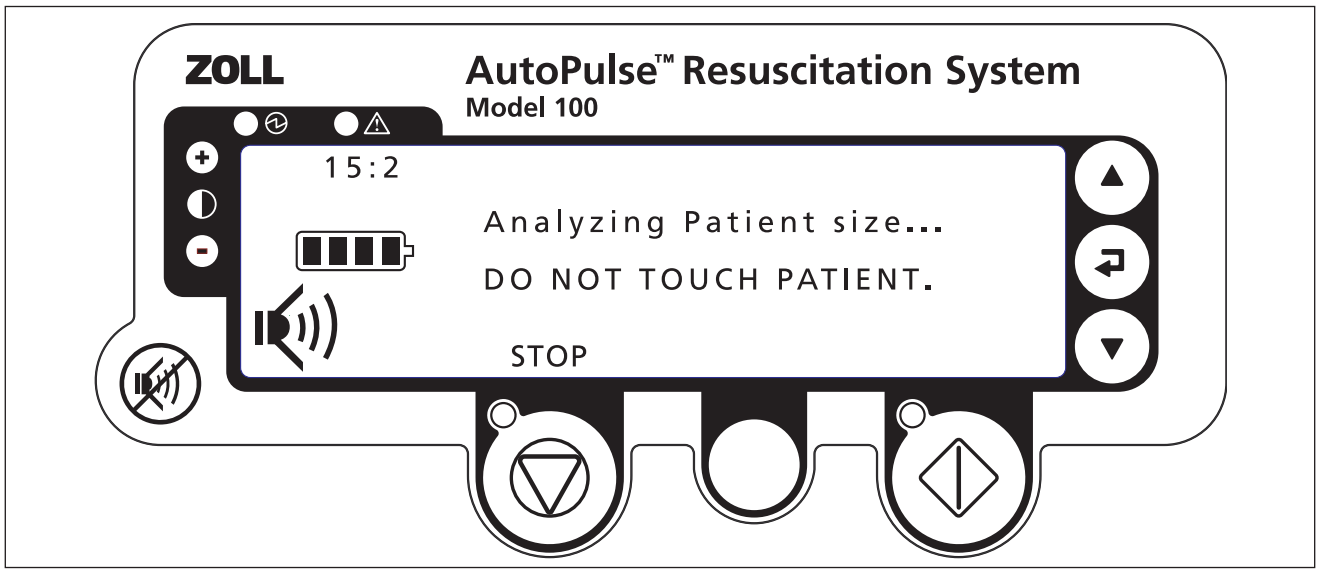

Figure 3-9 Analyzing Patient Size Display Panel Screen

3. Verify that the patient is properly aligned and that the LifeBand CCA has taken up any slack in the bands (see Figure 3-10).

Note: If the patient is not properly aligned, press the Stop/Cancel button, realign the patient, and begin compressions again with step 1 on page 3-7.

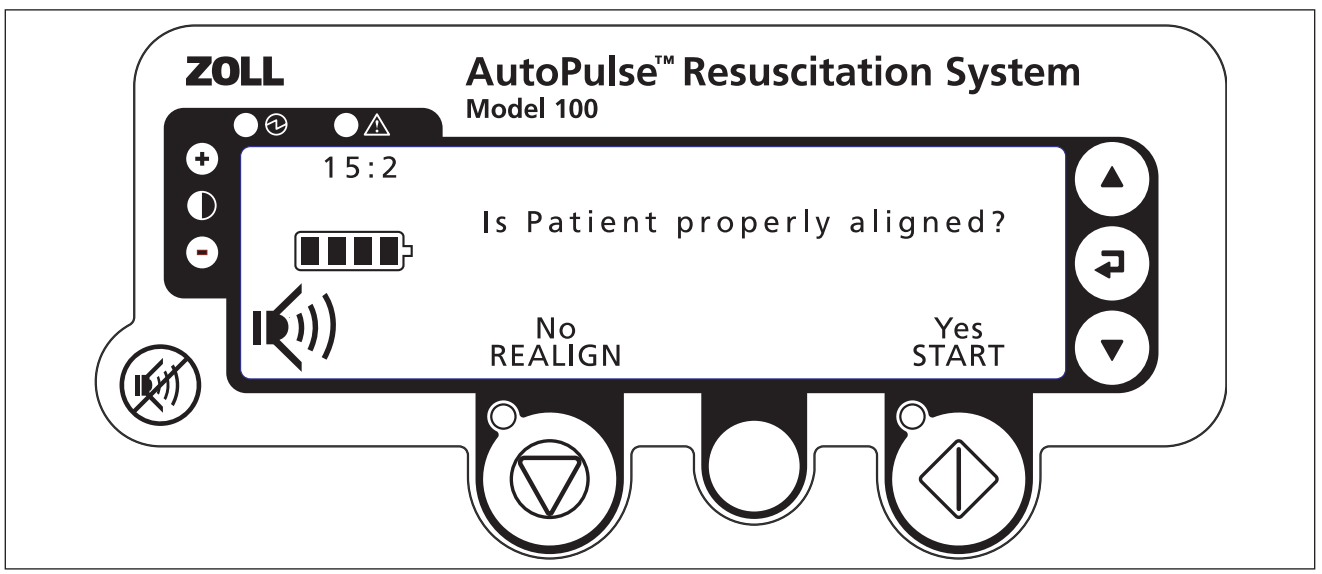

Figure 3-10 Verifying Patient Alignment Display Panel Screen

4. Press the Start/Continue button a second time to start compression cycles. The AutoPulse Platform begins chest compression cycles (see Figure 3-11).

   Note: Do not lean on the patient after pressing the Start/Continue button.

Warning:

- If you must move or realign the patient, you must press the Stop/Cancel button before adjustment.
- Do not place your hands or any other objects on or under the LifeBand chest bands while the AutoPulse System is analyzing the patient or during active operation.

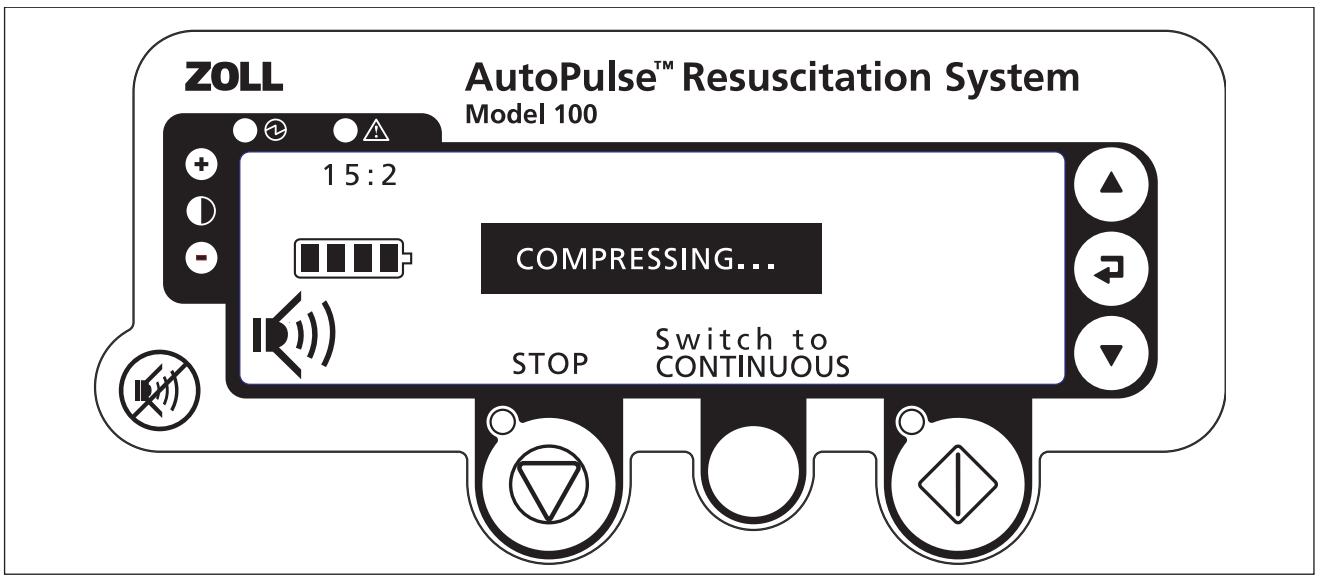

Figure 3-11 Chest Compression Display Panel Screen

5. Depending on the Mode setting in Administrative Menu (refer to section Section 2.3, "Administrative Menu: user pre-set options," on page 2-9), the AutoPulse Platform will perform 15:2 or Continuous compressions. In 15:2 mode the Platform performs 15 compressions and then pauses for three seconds to permit the user to ventilate the patient before automatically resuming compressions (see Figure 3-12). In Continuous mode the Platform performs continuous compressions. If *on-the-fly* mode switching has been enabled (in the Mode setting within the Administrative Menu) then the AutoPulse Platform will perform in the mode (either 15:2 or Continuous) that was used last until powered down; on power up 15:2 will be the initial selection.

   In 15:2 mode three audio cue tones will sound prior to the ventilation pause: one during each of the 13th, 14th, and 15th compressions. In Continuous mode, in every 7 compressions, one audio cue tone will sound—on the 6^{th} compression. The tones can be temporarily disabled (and re-enabled) by pressing the Tone Silence button (refer to section Section 1.4.2.6, "Tone Silence Button," on page

1-7). If there are no tones present they have been disabled in the Administrative Menu (refer to section Section 2.3, “Administrative Menu: user pre-set options,” on page 2-9) and the Tone Silence button will have no effect.

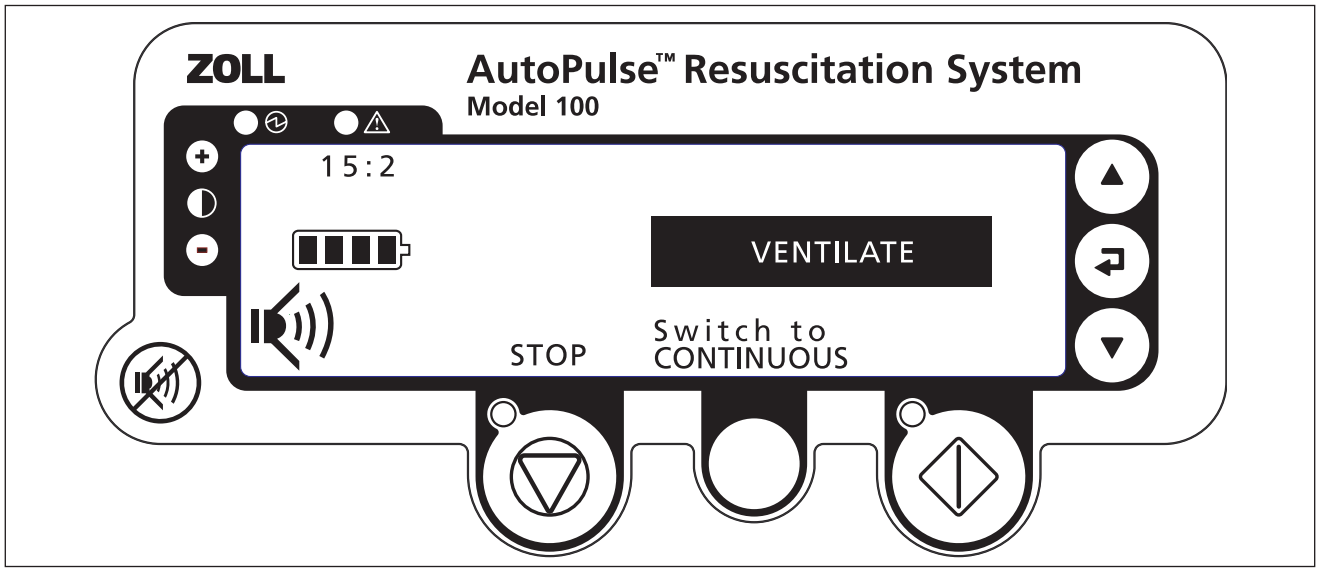

Figure 3-12 Ventilation Pause Display Panel Screen

Note: Positive pressure ventilation can be performed synchronous with any decompression and/or during the ventilation pause.

Warning:

- Check the patient’s chest rise during ventilation during active operation.

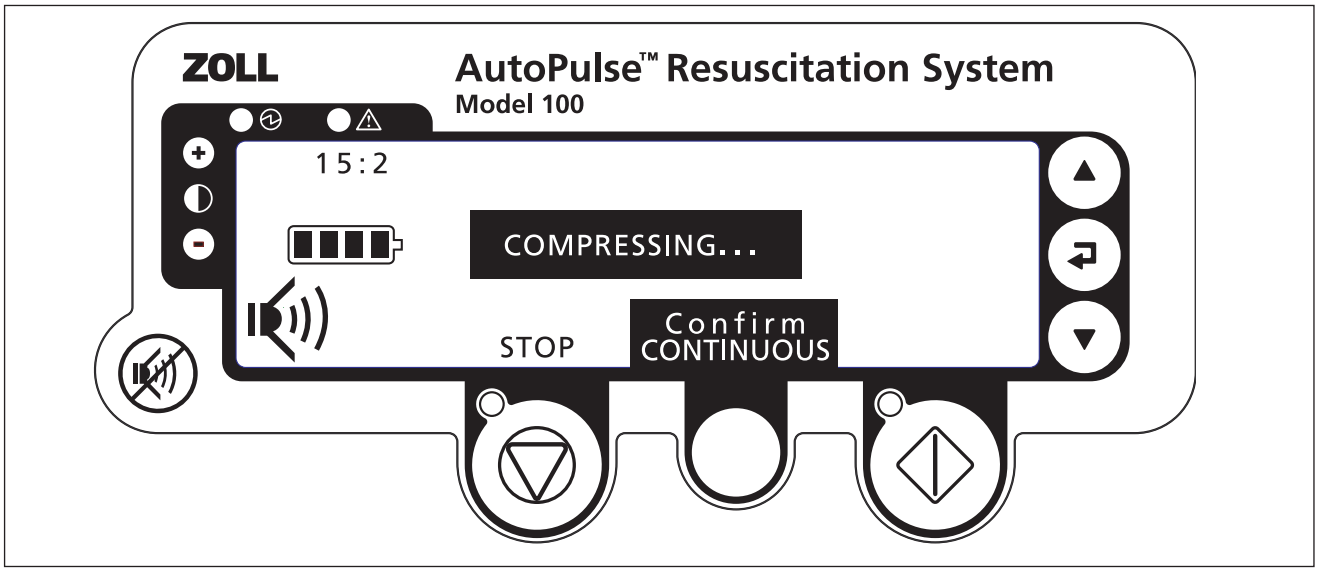

Figure 3-13 Mode Change Confirm Display Panel Screen

6. If *on-the-fly* mode switching has been enabled you may press the gray Menu/Mode switch button to switch between 15:2 and continuous compressions. The current mode is displayed in the upper left corner of the screen. The words above the gray Menu/Mode switch button indicate the alternate mode that the Platform will switch to. If there are no words above the gray button then *on-the-fly* mode switching in not enabled, and the Platform will only operate in the current mode and pressing the gray button will have no effect.

   Once the gray Menu/Mode switch button has been pressed you will be asked to confirm the mode switch (see Figure 3-13) by pressing the gray Menu/Mode switch button twice in rapid secession. A single tone will sound to confirm that the mode change has been accepted.

7. If access to the patient is required or to pause the AutoPulse Platform for any reason, press the Stop/Cancel button. The AutoPulse Platform releases the tension on the LifeBand chest bands allowing the user to pull out the bands to the maximum extended position. 30 seconds after the Stop/Cancel button has been pressed a single audio alert tone will sound. Following that initial tone the system will beep once every 60 seconds (one minute), 30 seconds or 15 seconds, according to the setting in the "Set Pause Alert Tone" menu item in the Administrative Menu. The tones can be temporarily disabled (and re-enabled) by pressing the Tone Silence button (refer to section Section 1.4.2.6, "Tone Silence Button," on page 1-7). If there are no tones present they have been disabled in the Administrative Menu (refer to section Section 2.3, "Administrative Menu: user pre-set options," on page 2-9) and the Tone Silence button will have no effect.

Note: Alternatively, opening the bands during active operation will cause the AutoPulse Platform to stop operation immediately. To restart compressions, re-fasten the Velcro® fastener and follow the normal operating steps beginning with step 1 on page 3-7.

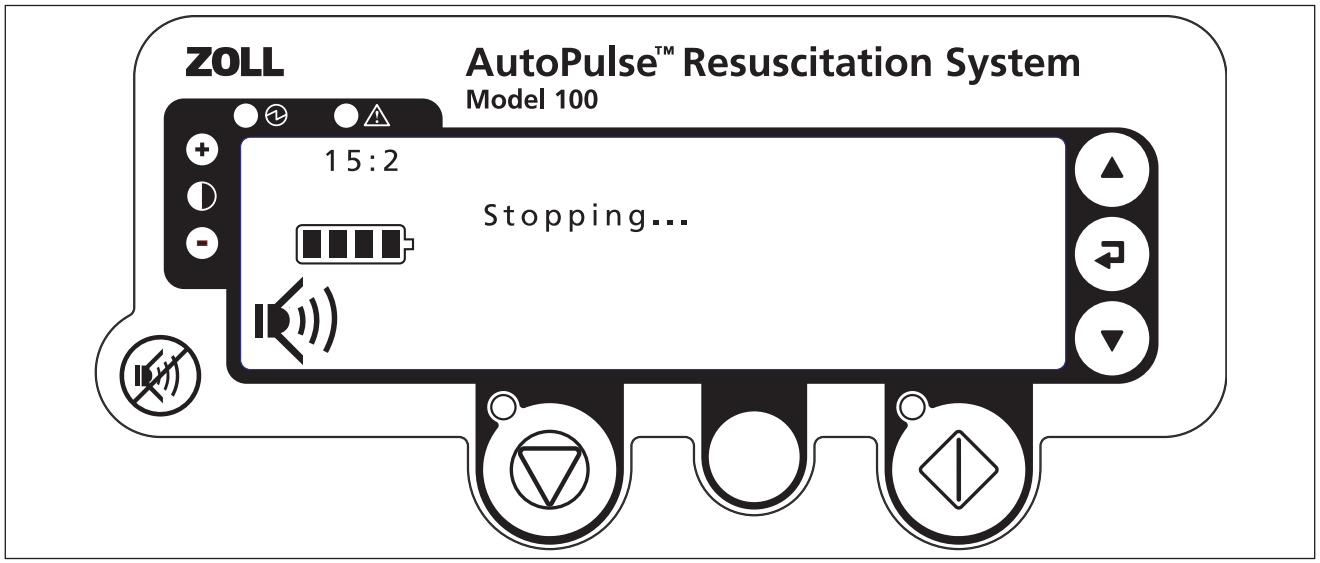

Figure 3-14 Stopping Compressions Display Panel Screen

8. To restart compressions, repeat procedure starting at step 1 on page 3-7 (see Figure 3-15).

Warning: If a user advisory or fault cannot be cleared or a system error occurs during active operation, immediately revert to manual CPR.

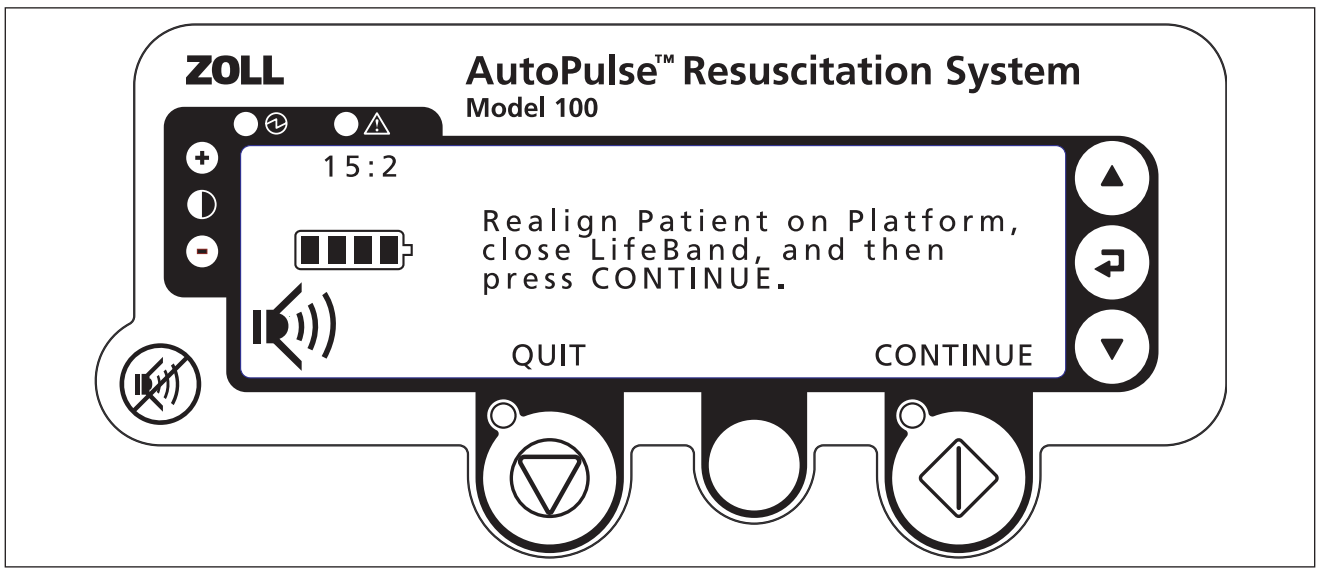

Figure 3-15 Restart/Continue Compressions Display Panel Screen

3.3 Ending Active Device Use

1. After either successful resuscitation or termination of activities, press the Stop/Cancel button followed by the ON/OFF button. The Stop/Cancel button action will cease the compression cycles and relax the LifeBand CCA (see Figure 3-14). The ON/OFF button action will power down the AutoPulse Platform.
2. Open the Velcro® fastener and lift or log roll off the patient from the AutoPulse Platform, as necessary.

3.4 Preparing the AutoPulse System for Its Next Use

1. Remove the LifeBand CCA from the AutoPulse Platform. Refer to Section 2.1.2, "Removing the LifeBand CCA" for more information.
2. **Discard the LifeBand CCA as it is a single-use component. Treat the LifeBand CCA as contaminated medical waste and dispose of it accordingly since there are no user-serviceable parts.**
3. Clean the AutoPulse Platform before its next use. Refer to Section 4.2, "Cleaning the AutoPulse Platform" for more information.
4. Replace the LifeBand CCA before returning the AutoPulse System to service. Refer to Section 2.1.1, "Installing the LifeBand CCA" for more information.
5. Remove the AutoPulse Power System Battery.

   Note: Ensure that the AutoPulse Platform is powered down before removing and replacing the Battery.
6. Replace the Battery with a fully charged Battery before returning the AutoPulse System to service.
7. Recharge the used Battery as necessary for future use.

3.5 Periodic Electrocardiogram (ECG) Monitoring and/or Defibrillation

When the AutoPulse System is used in conjunction with automatic external defibrillators (AEDs) or with other therapeutic devices that must monitor an ECG signal, interruption of the compression cycles may be required to avoid ECG motion artifact associated with mechanical chest compressions.

Note: Follow the manufacturer's instructions when using ECG monitor patches.

To interrupt the AutoPulse System's active operation, press the Stop/Cancel button.

To restart the AutoPulse Platform, follow the procedures in Section 3.2, "Starting Chest Compressions".

3.6 Patient Alignment and Securing for Transport

Warning: The AutoPulse Platform is **not** intended for carrying or transporting a patient. The AutoPulse Platform should be secured to the top of a backboard or other equipment used to carry or transport the patient, if necessary. During transport, regular checks of the patient's alignment should be performed.

The AutoPulse System does not require any patient restraints to perform compressions while the patient is lying on a flat surface. However, patient restraints should be used to maintain alignment of the patient to the AutoPulse Platform:

- If the AutoPulse System cannot be set on a flat level surface
- If the AutoPulse System is used during extrication or during transport

The AutoPulse Platform is designed to accept standard restraints to maintain patient alignment. The rescuer can secure a patient of up to **300 pounds** to a backboard and maneuver the patient as necessary while the AutoPulse is performing active compressions.

Caution: Motion can cause the patient to shift and restraints to loosen, so care should be given to the initial strapping for alignment of the patient to the AutoPulse Platform. Regular checks of patient alignment to the AutoPulse Platform and alignment of the LifeBand CCA to the patient's mid-axillary line should be made if the AutoPulse is performing active compressions, or before active compressions are restarted.

When transporting the patient, lift by supporting the patient and the AutoPulse Platform onto the transportation device (for example, a gurney or backboard) and place the AutoPulse Platform and patient within the vehicle during AutoPulse System operation. Securely strap the AutoPulse Platform and patient to the transportation device.

The AutoPulse Platform can be used in conjunction with a transportation device during transport to hospital (a gurney or backboard). However, care must be taken to ensure that the patient is properly strapped to the transportation device using locally-approved procedures for safe transport.

Caution: Straps or restraints used for transportation purposes **must not interfere** with the operation of the AutoPulse Platform. Specifically, straps across the patient's chest may restrict the compression/decompression of the chest. In general, strapping schemes must not alter the alignment of the patient to the AutoPulse Platform.

For more information about strapping and patient restraint options, contact Revivant Customer Service at 1-800-321-4CPR (or 1-408-524-3500).

3.7 Viewing AutoPulse Platform Information

On initial power-up, pressing the Menu/Mode Switch button allows you to access the information about:

1. The last patient session
2. The AutoPulse Platform
3. The AutoPulse Platform Battery

The same information may also be accessed from the Administrative Menu (refer to section Section 2.3, "Administrative Menu: user pre-set options," on page 2-9).

Once the Menu or Administrative Menu is active use the Move Up and Down arrow buttons to highlight the desired menu item and the Select Choice Button to select it.

Information presented about the Last Patient session is:

- Total compressions
- Total active time (min:sec)
- Total pause time (min:sec)

The last patient session data is updated after the AutoPulse is power cycled and one complete compression occurs.

Information presented about the AutoPulse Platform is:

- Model number
- Serial number
- Software version
- Name of manufacturer
- Manufacturer location (city, state, country)

Information presented about the AutoPulse Platform Battery is:

- Battery serial number
- Number of charge cycles performed (refer to the *AutoPulse Power System User Guide* for more information).

From any of the information displays, press the gray Menu/Mode Switch button under the word "back" to return to the main Menu or Administrative Menu.

To exit from the menu, press the gray Menu/Mode Switch button under the word “back,” The AutoPulse System returns to the idle state, ready for patient alignment.

To exit from the Administrative Menu, press the “START” (green) button under the word “RESTART.” The AutoPulse System will restart and place you into the idle state, ready for patient alignment.

4 Maintaining the AutoPulse System

4.1 Charging the Power System Battery

For more information on the AutoPulse Power System and its components, refer to the *AutoPulse Power System User Guide*.

To charge a Battery, follow these steps:

1. Slide the Battery into an available charging bay (see Figure 4-1). Make sure that the Battery locks into place (locking bar engaged).

   Caution: Remove the protective plastic cap from the Battery before attempting to charge the Battery.

   Note: For optimal charging, make sure that the Battery is at room temperature before insertion into the Battery Charger.

   Note: Do not slam the Battery into the Battery Charger because doing so may cause damage to the Battery's connector.

   Note: The Battery is mechanically keyed so that it can only be inserted in one orientation. Do not force the Battery into the charging bay. If resistance is met, check for appropriate orientation, and check to ensure that there are no obstructions to Battery insertion.

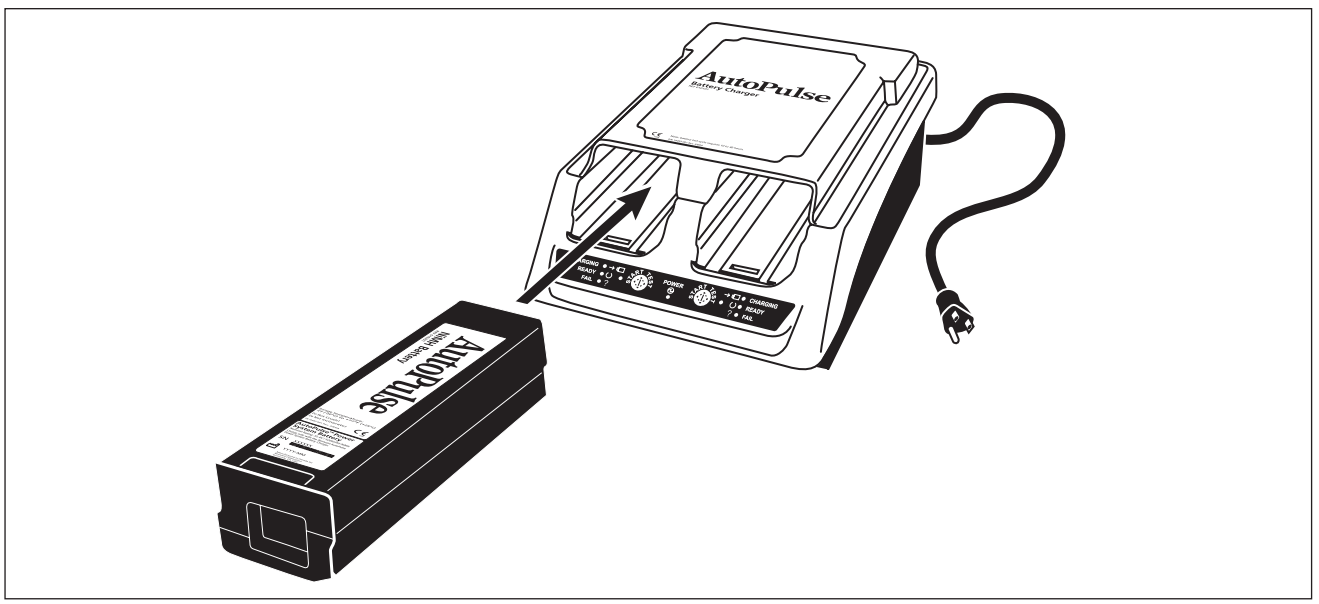

Figure 4-1 Battery Charger with Charging Bay

2. The Battery Charger automatically detects the presence of an AutoPulse Battery.
3. The Battery Charger's status will be indicated on the control panel (see Figure 4-2).

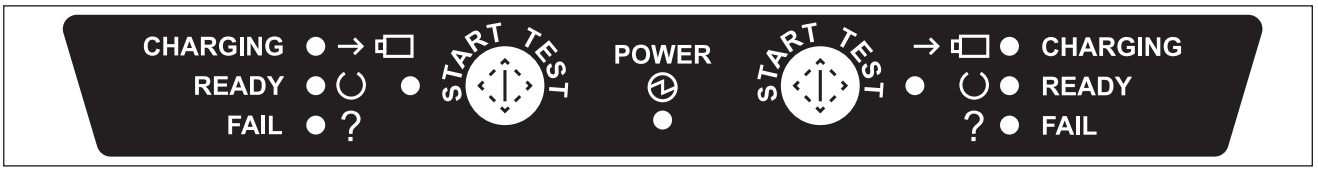

Figure 4-2 Battery Charger Control Panel

4. To manually run a test-cycle on a Battery, simply press the Battery Charger's Start Test button at any time that the Battery Charger is in Charge mode.

   Note: Do not remove a Battery from the Battery Charger until its charging completes or the Battery's runtime will be reduced.

   Note: Do not remove a Battery during a test-cycle or the Battery's runtime will be unknown. Removing a Battery during a test-cycle may cause the Battery Charger to automatically enter a test-cycle mode the next time a Battery is inserted into it.

5. Remove the Battery from the Battery Charger by gripping the Battery while pressing the finger latch to disengage the locking bar. Pull the Battery straight out until it fully clears the charging bay.

   Note: Recently-charged Batteries can be warm to the touch. This is a consequence of normal operation.

4.2 Cleaning the AutoPulse Platform

1. Remove and dispose of the LifeBand Chest Compression Assembly (CCA).
2. Wipe all the surfaces of the AutoPulse Platform free of foreign matter and spills with a disinfectant or bactericidal wipe. Check the vents to ensure that they are free and clear of any obstructive matter.

   Caution: Do ***not*** submerge the AutoPulse Platform in liquid.

3. Ensure that the AutoPulse Platform is dry before storing.

4.3 Storing the AutoPulse Platform

1. The AutoPulse Platform should be powered down before it is stored.

   Note: The AutoPulse Platform will automatically power down after 10 minutes of inactivity.

2. The AutoPulse Platform should be returned to its storage case, or a dust cover used, before being stored.
3. The AutoPulse Platform should be stored in a cool, dry place.

4.4 Maintenance

There are no user-serviceable parts in the AutoPulse Platform. In case of repair or service, contact the manufacturer.

5 Troubleshooting Procedures

In the event of a user advisory, fault or system error, the User Control Panel Alert light-emitting diode (LED) illuminates (refer to Section 1.4, "User Controls and Indicators"). Consider the information in this chapter.

Warning: If a persistent fault or system error occurs during active operation, immediately revert to manual cardiopulmonary resuscitation (CPR).

5.1 Troubleshooting Batteries

If a Battery's charge falls too low, a Low Battery warning will appear on the Control Panel Display. The Low Battery warning display will be accompanied with an audio warning of four rapid beeps which will be followed by two beeps every 30 seconds until the battery is replaced or depleted. If operation continues without changing the Battery, a Replace Battery screen will appear (see Figure 5-1 and Figure 5-2). If this is the case:

- Press the ON/OFF button to power down the AutoPulse Platform.
- Replace the AutoPulse Power System Battery with a new, fully-charged Battery. Press the ON/OFF button followed by the Start/Continue button again.

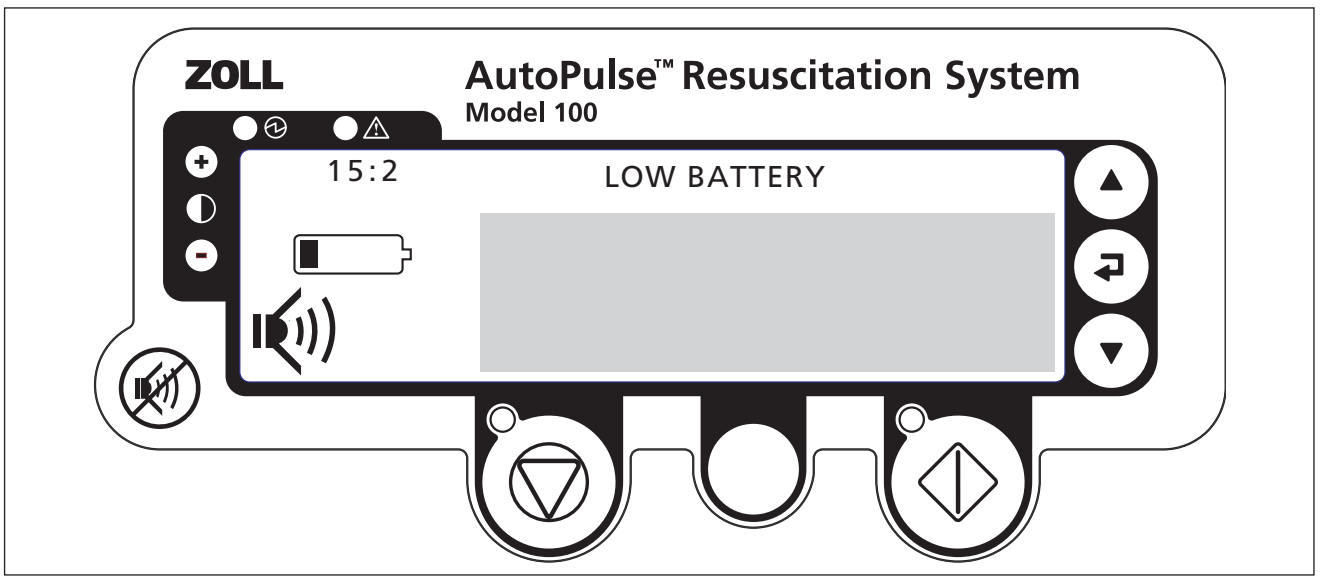

Figure 5-1 Low Battery Warning

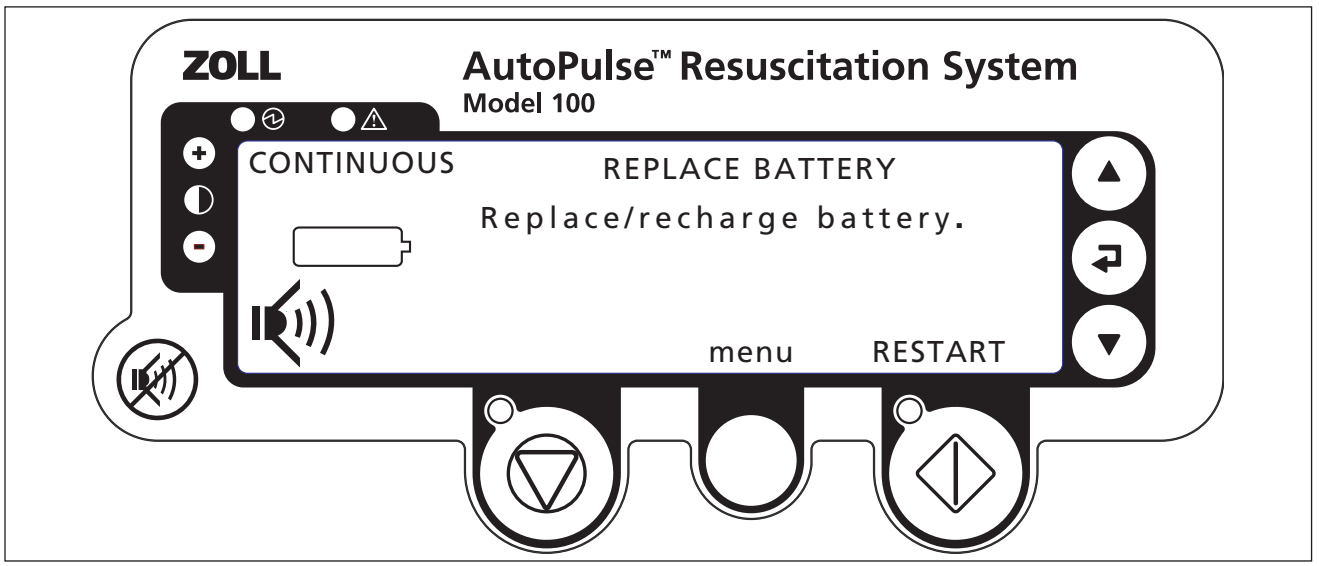

Figure 5-2 Replace Battery Screen

5.2 Troubleshooting User Advisories and Faults

The AutoPulse System enters a User Advisory state (see Figure 5-3) or the Fault State (see Figure 5-4) when one of several conditions is detected. A User Advisory generally indicates that a misalignment or inappropriate movement of the patient or the LifeBand CCA has occurred. A Fault generally indicates that the AutoPulse has detected an inappropriate internal condition. Both conditions are typically correctable by the operator. Follow the instructions on the screen and then attempt to RESTART active operation by pressing the Start/Continue button. If that does not work you should follow these general steps to troubleshoot Advisories and Faults:

1. Check for correct patient alignment (refer to Section 3.1, "Deploying the AutoPulse System" for more information), fully extend both LifeBand chest bands and attempt to RESTART active operation by pressing the Start/Continue button.
2. If the user advisory or fault persists:

   • Remove the LifeBand CCA assembly from, and fully re-insert into, the AutoPulse Platform (refer to Section 2.1, "LifeBand Chest Compression Assembly (CCA) Installation and Removal") and then press the Start/Continue button again.

   • Remove and replace the LifeBand CCA with a new LifeBand CCA and then press the Start/Continue button again.

   • Check the AutoPulse Platform for blocked vents.
3. If any Fault indicator cannot be rectified, contact the manufacturer.

In either User Advisory state or the Fault State, pressing the gray Menu/Mode Switch button, under the word “menu” allows you to access the AutoPulse Platform information menu (refer to section Section 3.7, “Viewing AutoPulse Platform Information,” on page 3-15).

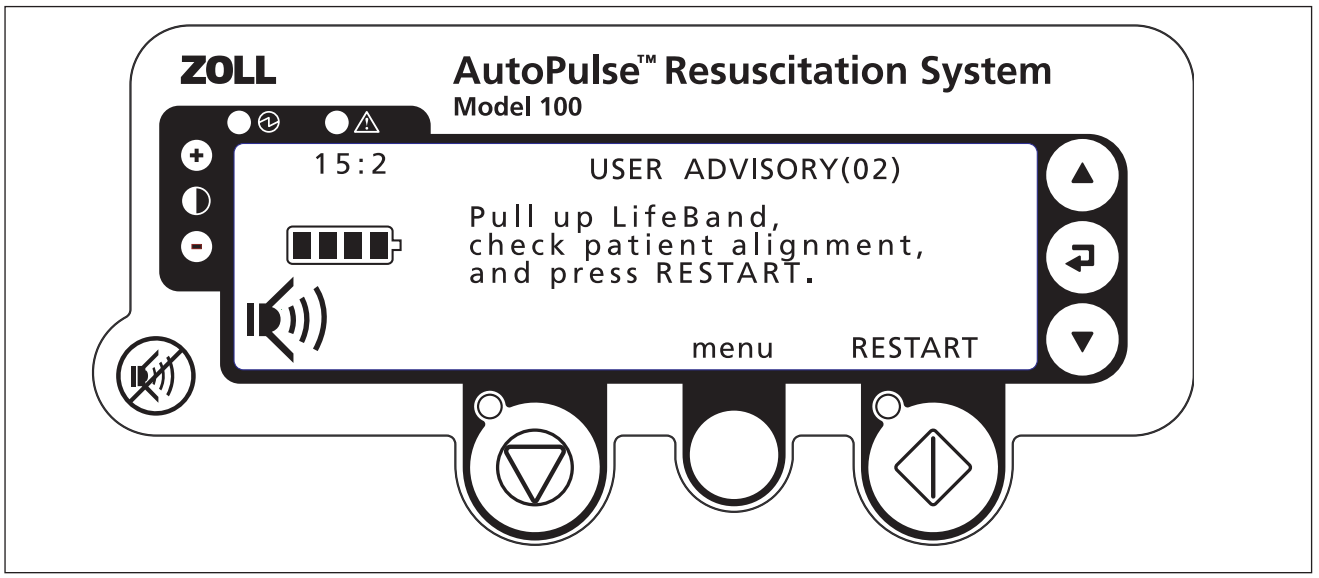

Figure 5-3 A User Advisory Screen

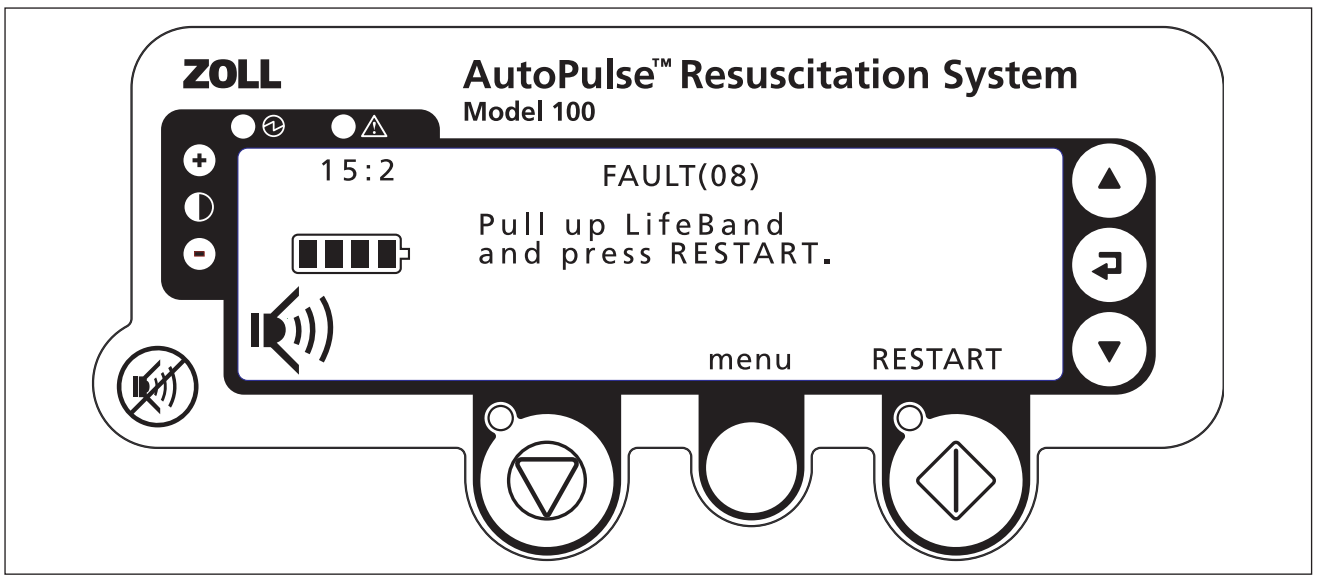

Figure 5-4 A Fault Screen

5.3 Troubleshooting Errors

In the event of a system error (see Figure 5-5), **you can take no steps** to return the AutoPulse System to normal operation. The AutoPulse System has detected an unrecoverable problem and cannot be restarted. Therefore, you must:

1. Begin manual CPR immediately.
2. Contact the manufacturer.

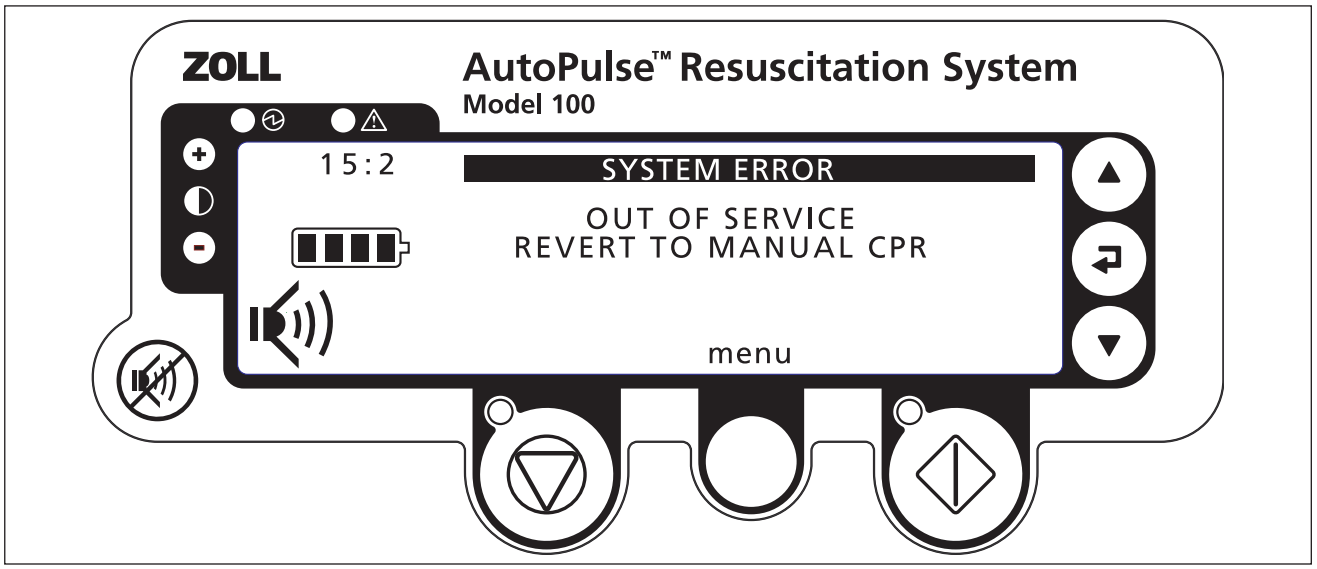

Figure 5-5 System Error Screen

Appendix A Technical Specifications

The specifications provided in this chapter apply to the AutoPulse Resuscitation System Model 100.

A.1 Patient Parameters

The AutoPulse System is designed for adults with weight of no more than 300 lbs. (136 kg) with chest circumference of 29.9 to 51.2 in. (76 to 130 cm) and chest width of 9.8 to 15 in. (25 to 38 cm).

Warning: The AutoPulse System is ***not*** intended for pediatric use.

A.2 LifeBand Chest Compression Assembly (CCA)

The latex-free LifeBand CCA is for single-patient use only. The LifeBand CCA consists of a cover plate and two bands integrated with a patient liner and compression pads with a Velcro® fastener.

A.3 Operating Parameters

Table A-1 Operating Parameters

Category	Specifications
Chest displacement	Equal to 20% reduction in anterior-posterior chest depth.
Physiological duty cycle	50 ± 5%.
Compression rate	80 ± 5 compressions per minute.
Compression modes (user selectable)	• 15:2 (15 compressions with two 1.5 second ventilation pauses) • Continuous compressions
Ventilation pause (15:2 mode)	Two pauses of 1.5 seconds.

A.4 Platform Physical

Table A-2 Physical Specifications

Category	Specifications
Size (L×W×H)	32.5 in. by 18.2 in. by 3.3 in. (82.5 cm by 46.2 cm by 8.4 cm).
Weight (excluding AutoPulse Power System Battery)	22 lbs. (10 kg).
Display	Dot matrix liquid crystal display (LCD), actively backlit, adjustable contrast.

A.5 Platform Environmental

Table A-3 Environmental Specifications

Category	Specifications
Operating temperature	+32º to +104ºF (0º to +40ºC).
Storage temperature	-4º to +149ºF (-20º to +65ºC).
Relative humidity	5% to 95%, non-condensing.
Atmospheric pressure	0 to 15,000 feet above sea level (760 to 428 mmHg).
Water resistance	Splash resistant as defined by IP22 per International Electrotechnical Commission (IEC) 60529.
Safety classification	Meets IEC 60601 – internally powered equipment, Type BF-Defibrillation Protected, movable, short-time operation, Class III.
Electromagnetic susceptibility	IEC61000-4-3, 4, 5, and 6 – level 2 (80 MHz to 2 GHz, 3V/m).
Electrostatic discharge	Meets IEC 61000-4-2 – 6 KV Contact, 8 KV Air.
Electromagnetic emissions	Meets CISPR 11/EN55011, Group 1, Class A.
Patient contacting materials	Meets ISO 10993-1 Biological evaluation of medical devices.
Shock	Meets IEC 60068-2-27 Basic Environmental Testing – Shock (50g, 11ms pulse, half sine wave).
Vibration	• Meets IEC 60068-2-64 Basic Environmental Testing – Random Vibration Broad Band (f1:20-f2:2000, ASD: 0.05). • Meets IEC 60068-2-6 Environmental Testing – Vibration (sinusoidal), (10 to 150 Hz, 10m/s^2).
Drop	Meets IEC 60068-2-32 Basic Environmental Testing – Free Fall – Procedure 1.
Corrosion resistance	External components are non-corrosive.
Operating classification	Short-time per IEC 60601-1 (30 minutes).

A.6 Battery Physical

Table A-4 Battery Specifications

Category	Specifications
Size (L×W×H)	11.5 in. by 3.2 in. by 2.2 in. (29.2 cm by 8.1 cm by 5.7 cm).
Weight	5.1 lbs. (2.3 kg).
Type	Rechargeable Nickel-Metal Hydride (NiMH)
Battery voltage (nominal)	32.4V
Capacity	3200 mAh (typical)
Initial Battery runtime (nominal patient)	30 minutes (typical)
Maximum Battery charge time	Less than $4^1/_4$ hours at 77ºF (25ºC)
Battery test-cycle time	Less than 10 hours per test-cycle session; up to three consecutive sessions possible.
Required replacement interval	100 full charge/discharge cycles. **Note:** The Battery will not operate after 100 full charge/discharge cycles.

A.7 Battery Environmental

Table A-5 Battery Specifications

Category	Specifications
Operating temperature	+32º to +113ºF (0º to +45ºC) ambient installed in device
Charge temperature	+41º to +95ºF (5º to +35ºC) ambient (68º to 77ºF [20º to 25ºC] preferred)
Storage temperature	• -4º to +77ºF (-20º to +25ºC) ambient for less than six months (may require test-cycle to meet performance characteristics) • +77º to +95ºF (+25º to +35ºC) ambient for less than two months (may require test-cycle to meet performance characteristics)
Operating altitude	0 to 15,000 ft. (0 to 4,572 m)
Enclosure protection	Meets IP22 per IEC 60529
Shock	Meets IEC 60068-2-27 Basic Environmental Testing Procedures – Shock (50g, 11ms pulse, half sine wave)
Vibration	Meets IEC 60068-2-6 Basic Environmental Testing Procedures (10 to 150 Hz, 10 m/s^2) Meets IEC 60068-2-64 Basic Environmental Testing Procedures – Random Vibration Broad Band – General Requirements (f1:20, f2:2000, ASD 0.05)
Free fall	Meets IEC 60068-2-32 Basic Environmental Testing Procedures – Free Fall – Procedure 1.

Table A-6 Battery EMI/EMC Specifications

Title	Standard
Electrostatic discharge	IEC 61000-4-2, Level 3
Radiated emissions	CISPR 11/EN55011, Group 1, Class A FCC part 15, Class A

A.8 Battery Charger Physical

Table A-7 Battery Charger Physical Specifications

Category	Specifications
Size (L×W×H)	15 in. by 9.75 in. by 9.1 in. (38 cm by 25 cm by 23 cm).
Weight	10 lbs. (4.5 kg)
Operating input voltage	100 to 240V AC
Operating input frequency	50/60 Hz
Input current	2.0 Amps (maximum)
Maximum Battery charge time	Less than $4^1/_4$ hours (at 77ºF [25ºC])
Fuses	User-replaceable, T2.0A 250V AC (2 required)

A.9 Battery Charger Environmental

Table A-8 Battery Charger Environmental Specifications

Category	Specifications
Operating temperature	+41º to +95ºF (5º to +35ºC) (68º to 77ºF [20º to 25ºC] preferred)
Storage temperature	-40º to +158ºF (-40º to +70ºC)
Relative humidity	5% to 95%, non-condensing.
Operating altitude	0 to 10,000 ft. (0 to 3,048 m)
Enclosure protection	Meets IP22 per IEC 60529
Shock (non-operational)	Meets IEC 60068-2-27 Basic Environmental Testing Procedures – Shock (50g, 11ms pulse, half sine wave)
Vibration (non-operational)	Meets IEC 60068-2-6 Basic Environmental Testing Procedures 10 to 150 Hz, 10 m/s^2 Meets IEC 60068-2-64 Basic Environmental Testing Procedures – Random Vibration Broad Band – General Requirements (f1:20, f2:2000, ASD 0.05)
Free fall (non-operational)	Meets IEC 60068-2-32 Basic Environmental Testing Procedures – Free Fall – Procedure 1.
Safety requirements	Safety certified to UL2601, CSA 22.2 No. 601.1-M90, EN60601-1

Table A-9 Battery Charger EMI/EMC Specifications

Title	Standard
Electrostatic discharge	IEC 61000-4-2, Level 3
RF electromagnetic fields immunity	IEC 61000-4-3, Level 2
EFT/burst	IEC 61000-4-4, Level 2
Surge immunity	IEC 61000-4-5, Level 2
Conducted RF disturbances immunity	IEC 61000-4-6, Class A
Dips, interruptions, and variations	IEC 61000-4-11
Harmonics current emissions	IEC 61000-3-2, Class A
Radiated emissions	CISPR 11/EN55011, Group 1, Class A FCC part 15, Class A

A.10 Limited Warranty for AutoPulse Resuscitation System

Revivant warrants to the initial Purchaser only that the "Warranted Product" purchased hereunder will be free from defects in workmanship or materials, when given normal, proper, and intended usage, for a specified period ("Warranty Period") from the date of its initial shipment to Purchaser. "Warranted Products" consist solely of those products whose description in this price list expressly states that the product includes a warranty for a specified time period (the Warranty Period for the product). Excluded from this warranty are expendable components and supply items such as the LifeBand™ Chest Compression Assembly.

Warranty Period: The AutoPulse Resuscitation System Platform, Battery, and Battery Charger (collectively and individually referred to as "Product") are sold with a one year warranty period to the end-user. The warranty period begins at delivery.

Revivant's sole obligations under this warranty are to repair or replace, at its option, any Warranted Product (or part thereof) that Revivant reasonably determines to be covered by this warranty and to be defective in workmanship or materials provided that the Purchaser has given notice of such warranty claim within the Warranty Period and the Purchaser has complied with Revivant's Return Material Authorization ("RMA") procedures. Repair or replacement of Products under this warranty does not extend the Warranty Period.

To request repair or replacement under this warranty, Purchaser should contact Revivant at 775 Palomar Avenue Sunnyvale, CA 94085, 1-800-321-4CPR or 1-408-524-3500. Revivant will inform purchaser of its then-current RMA procedure. Revivant shall determine whether to repair or replace Products and parts covered by this warranty and all Products or parts replaced shall become Revivant's property. In the course of warranty service, Revivant may but shall not be required to make engineering improvements to the Warranted Product or part thereof.

Exclusions

This warranty does not extend to any Warranted Products or parts thereof that have (a) been subject to misuse, neglect or accident; (b) been damaged by causes external to the Warranted Product, including but not limited to failure of or faulty electrical power; (c) not been used in accordance with Revivant's instructions; (d) been affixed to any nonstandard accessory attachment; (e) had the serial number removed or made illegible; (f) been modified by anyone other than Revivant; (g) been used with any software not provided by Revivant; or (h) been disassembled, serviced, or reassembled by anyone other than Revivant, unless authorized by Revivant. Revivant shall have no obligation to make repairs, replacements, or corrections which result, in whole or in part, from normal wear and tear.

Revivant makes no warranty (a) with respect to any products that are not Warranted Products, (b) with respect to any products purchased from a person other than Revivant or a Revivant-authorized distributor or (c) with respect to any product sold under a brand name other than Revivant.

THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY FOR REVIVANT'S PRODUCTS, EXTENDS ONLY TO THE PURCHASER AND IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. REVIVANT'S MAXIMUM LIABILITY ARISING OUT OF THE SALE OF THE PRODUCTS OR THEIR USE, WHETHER BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE, SHALL NOT EXCEED THE ACTUAL PAYMENTS RECEIVED BY REVIVANT IN CONNECTION THEREWITH. REVIVANT SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE (INCLUDING WITHOUT LIMITATION LOST PROFITS) DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, INABILITY TO SELL, USE OR LOSS OF USE OF ANY PRODUCT (HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY), EVEN IF REVIVANT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS. THE FOREGOING LIMITATIONS SHALL NOT APPLY TO ANY CLAIMS FOR BODILY INJURY OR DEATH TO THE EXTENT THAT LIMITATION OF DAMAGES FOR SUCH CLAIMS ARE UNENFORCEABLE OR AGAINST PUBLIC POLICY UNDER ANY APPLICABLE STATUTE OR RULE OF LAW.

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Appendix B AutoPulse System Parts and Accessories

Table B-1 AutoPulse System Parts and Accessories

Product Name	Description	Catalog No.
AutoPulse Resuscitation System Model 100 Platform	Provides automated chest compressions at a consistent rate and depth. Includes *User Guide, AutoPulse Resuscitation System Model 100*. Does not include LifeBand Chest Compression Assembly, AutoPulse Power System Battery, or AutoPulse Power System Battery Charger.	010001
AutoPulse Power System Battery Charger, U.S.	AutoPulse Battery Charger. Charges and conditions up to two Batteries and automatically assesses Battery charge level. Includes *User Guide, AutoPulse Power System*, and power cord.	010101
AutoPulse Power System Battery	Original equipment Nickel-Metal Hydride (NiMH) Battery for use with the AutoPulse Platform. The Battery, when fully charged, is intended to provide a minimum of 30 minutes of operation for a nominally-sized patient.	010201
LifeBand™ Chest Compression Assembly, 1 pack	Single-use LifeBand Chest Compression Assembly. (1 per package)	010301
LifeBand Chest Compression Assembly, 3 pack	Single-use LifeBand Chest Compression Assembly. (3 per package)	010302
LifeBand Trainer Chest Compression Assembly	Re-usable LifeBand CCA designed for training. Not for human use.	010303
AutoPulse Power System power cord	U.S. standard power cord, 3-way (replacement). Contact Revivant Corporation for International Power Cord configurations.	010701
User Guide, AutoPulse Resuscitation System Model 100	Describes the operating steps and maintenance requirements for the AutoPulse Platform.	010901
User Guide, AutoPulse Power System	Describes the operating steps and maintenance requirements for the AutoPulse Power System.	010902
Soft Carry Case, AutoPulse System	Soft-sided carrying case holds AutoPulse Platform, spare Battery, spare LifeBand CCA and Patient Restraints.	010601
AutoPulse Resuscitation System, 1 Year Extended Warranty	Extended warranty for 1 year beyond the initial warranty period, on AutoPulse Platform, Charger and Batteries; includes 1 preventative maintenance per year.	020001
AutoPulse Resuscitation System, 2 Year Extended Warranty	Extended warranty for 2 years beyond the initial warranty period, on AutoPulse Platform, Charger and Batteries; includes 1 preventative maintenance per year.	020002

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