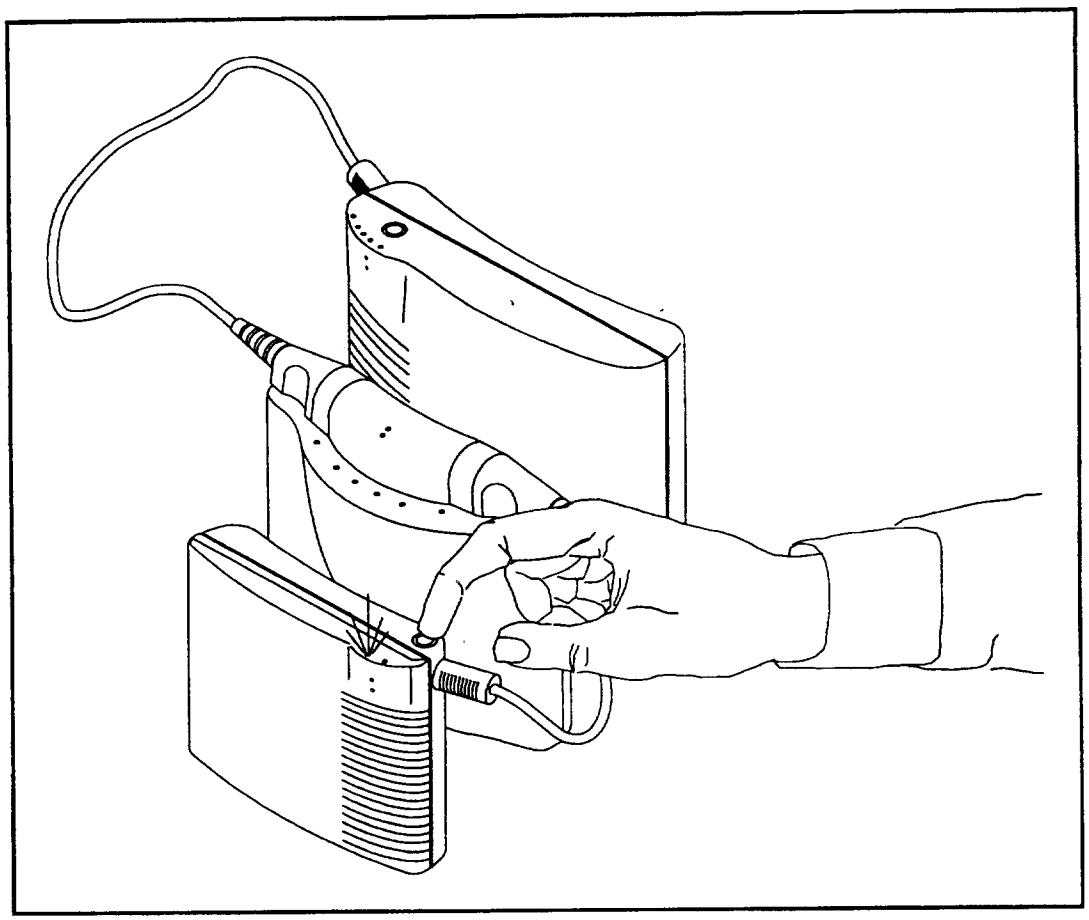
Recipient's Guide

Novacor® LVAS



Baxter

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Table Of Contents

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General Warnings And Precautions

Warnings

- You, the recipient, should not undergo MRI (magnetic resonance imaging) procedures. MRI may interfere with the action of the Pump/Drive Unit solenoid, resulting in irregular pumping. It could also cause the Pump/Drive Unit to move, possibly unseating the conduits and resulting in severe injury.
- Do not use the LVAS within an oxygen-enriched environment, such as a hyperbaric chamber. As with all equipment of this type, an oxygen-enriched environment increases the flammability of materials (such as plastics and metals) which increases the risk of fire. **This does not apply to the use of conventional oxygen therapy via mask or nasal tubes.**

Precautions

- Avoid sharp bends of the Percutaneous Lead. Excessive bending can damage the wiring. Damage to the wiring can result in abnormal pump operation.
- Contact Novacor before starting any therapeutic radiation treatment. Radiation treatment may damage some of the implanted components.

Note: Do not service this equipment yourself. Only qualified personnel can service this equipment. If service is required, contact your technical support personnel, listed on the inside front cover.

When and Whom Should I Call For Help?

Call your technical support personnel, listed inside the front cover, for the following conditions:

- A "Check" or "Replace" alarm occurs (see page 12-7 for more information)
- A Compact Controller "Temp" alarm lasts for more than five minutes (see page 12-7 for more information)
- The Compact Controller or Personal Monitor alarm doesn't sound when you do the daily alarms test.
- Pump/Drive Unit rate is less than 60 beats per minute, or greater than 140 beats per minute when you are resting.
- You want help with using or understanding the equipment

Note: **If the "Replace" light comes on the Compact Controller, replace the Compact Controller immediately. Do not wait for support personnel to arrive.**

Call the medical staff, listed inside the front cover, for any of the following conditions:

- Numbness, tingling or weakness in your arm or leg, or in your hand or foot
- Blurred vision or speech problems
- Shortness of breath or dizziness
- Any pain, including unrelieved headache, chest pain, or abdominal pain
- Oral temperature greater than 100.4° F or 38° C
- Any redness, swelling or drainage around the exit site (the spot where the Percutaneous Lead comes through the skin)
- Unusual bleeding or bruising
- Any condition where you feel unwell

Dial 911 (or your local emergency number) for any of the following conditions:

- Seizure or convulsion
- Loss of consciousness
- Awake but unresponsive
- Sudden collapse
- Unable to talk or move body parts
- The Pump/Drive Unit stops and cannot be restarted within two minutes

Call the medical/technical support personnel after you or your caregiver has called for emergency medical help.

1. Introduction To The Manual

This manual gives you and your caregiver the information that you need to use and care for the Novacor® LVAS (referred to as the LVAS), from Baxter Healthcare Corporation. It covers normal use, and also tells you how to handle emergencies. Please read the whole manual before using the LVAS without supervision.

Following is a brief description of the kind of information you will find in each section. For more information, go to the appropriate section. The alphabetized index at the back of the manual and the Table of Contents at the front will also help you find information.

General Warnings And Precautions

What are some general things that I should know about my device? When should I call for help?

1 Introduction to The Manual

How is the manual arranged? What information is presented in each section?

2 Introduction to The Device

Why do I need the LVAS? What does it do?

3 Description

What are the names of the pieces of the LVAS? What do they look like?

4 Environmental Conditions That Affect Use

What kind of temperatures can I use it in? Are there some conditions that I should avoid?

5 System Setup

How do I set up the LVAS equipment? Are there any special requirements?

2. Introduction To The Device

You and your doctor have chosen to use the Novacor® LVAS to help support your body's blood circulation. Since your heart can't pump strongly enough to adequately circulate the blood, the LVAS will take over the pumping function of the left ventricle, the main pumping chamber of the heart.

This manual gives you and your caregiver information about the LVAS, tells you what it does, and explains how to care for it. The technical support staff has received the technical manual for this equipment.

Note: You should always have access to someone trained in the use of the LVAS, and you should be trained in its use as well. Your medical care should be monitored by a qualified doctor and/or medical staff trained in the operation of the LVAS.

Three Major Groups of LVAS Components

1. The **implanted components,** shown in Figure 1 on page 3-1.

- A Pump/Drive Unit (often called simply "the Pump")
- Conduits that carry the blood from your heart to the Pump and from the Pump to the aorta
- The Percutaneous Lead

The Pump/Drive Unit is typically put between the muscle layers in the abdomen, and automatically adjusts to match changes in your circulation. The Percutaneous Lead goes from the implanted Pump/Drive Unit through your skin to the external Compact Controller.

2. The **Compact Controller,** shown in Figures 2 and 3 on pages 3-2 and 3-3.

- Regulates the flow of power to the Pump/Drive Unit
- Monitors how the Pump/Drive Unit is performing
- Uses lights and sounds to tell you when something is wrong

3. Two different types of **power sources,** the Power Packs and the Personal Monitor, shown on pages 3-3 to 3-6.

   Power Packs (Figures 4 and 5):

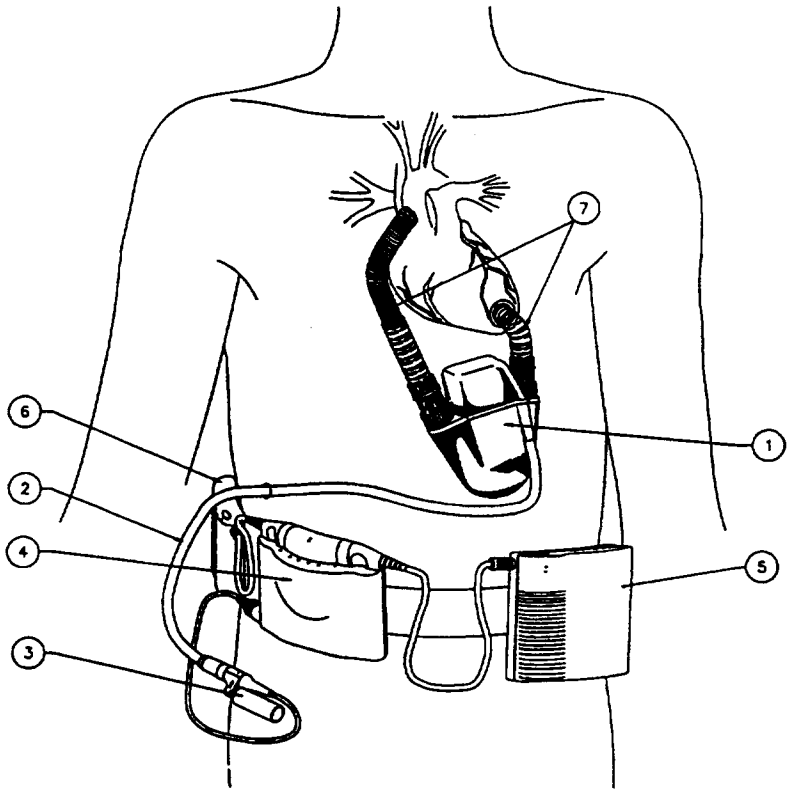
   - Can be carried with you when you are active ("Untethered" mode)
   - Have a limited charge
   - Must be monitored to make sure that another power source (more Power Packs or the Personal Monitor) is available when the Power Pack runs low.

   The **Personal Monitor** (Figure 7):

   - Plugs into a grounded wall outlet
   - Has a backup power source called the Standby Power Source
   - Is used normally when you are sleeping, watching TV, etc. ("Tethered" mode)
   - Makes the alarms from the Compact Controller louder
   - Displays alarm information on the Personal Monitor Display. This information is used with the alarm response tables in this manual (see pages 12-9 and 12-10) to tell you what to do if there is an alarm.

3. Description

Figure 1 The LVAS in Untethered Configuration (picture not to scale)



Components shown:

① Pump/Drive Unit (implanted)

② Percutaneous Lead (implanted)

③ Vent Filter

④ Compact Controller

⑤ Primary Power Pack

⑥ Reserve Power Pack

⑦ Blood-carrying conduits

The following items are also used with the LVAS:

- Personal Monitor with power cord and Personal Monitor/Controller cable (see page 3-5)
- Standby Power Source (see page 3-5)
- Power Pack Charger and power cord (see page 3-4)
- Support Accessories to carry components (see page 3-6)

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3.1 Pump/Drive Unit

The Pump/Drive Unit (see Figure 1) is typically implanted between muscle layers in the left side of your abdomen. It includes a pumping chamber and an electrical driver that provides the pumping action to circulate the blood through your body. Conduits carry the blood between your heart, the Pump, and your aorta. Tissue valves in the conduits direct the flow of blood.

3.2 Percutaneous Lead

The Percutaneous Lead is the tube that comes through your skin at about waist level (see Figure 1). It carries the electrical wires that lead from the Compact Controller to the Pump/Drive Unit. It also serves as an air vent for the Pump/Drive Unit.

A Vent Filter protects the vent in the Percutaneous Lead from lint and debris. You can unscrew and replace this air filter if necessary (see **Replacing the Vent Filter**, page 8-9). Keep all fluid away from the Vent Filter. If liquid enters the Vent Filter, it may go into the Percutaneous Lead, damaging the Pump/Drive Unit and possibly causing it to stop.

3.3 Compact Controller

The Compact Controller controls the Pump/Drive Unit rate by controlling the delivery of power. The Compact Controller also detects alarm conditions and alerts you with its alarms. When plugged into the Personal Monitor, it sends alarm and performance information for the Personal Monitor display.

The Compact Controller has six status lights on top. See **Status Lights and Meanings**, page 11-1, for more information. The Compact Controller also has two connectors for power sources at the top and a connector for the Percutaneous Lead at the bottom.

Figure 2 Top View of Compact Controller

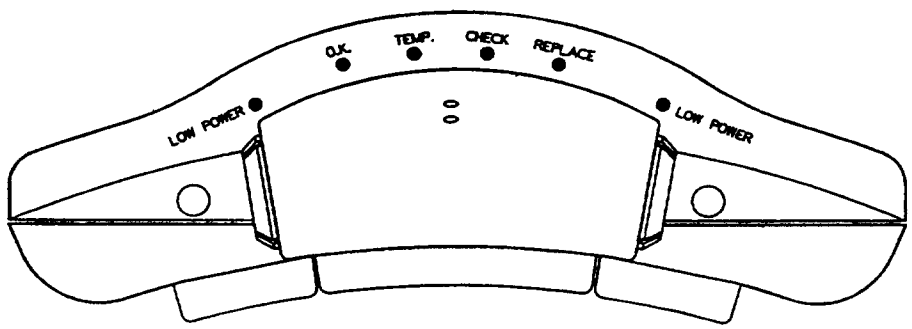
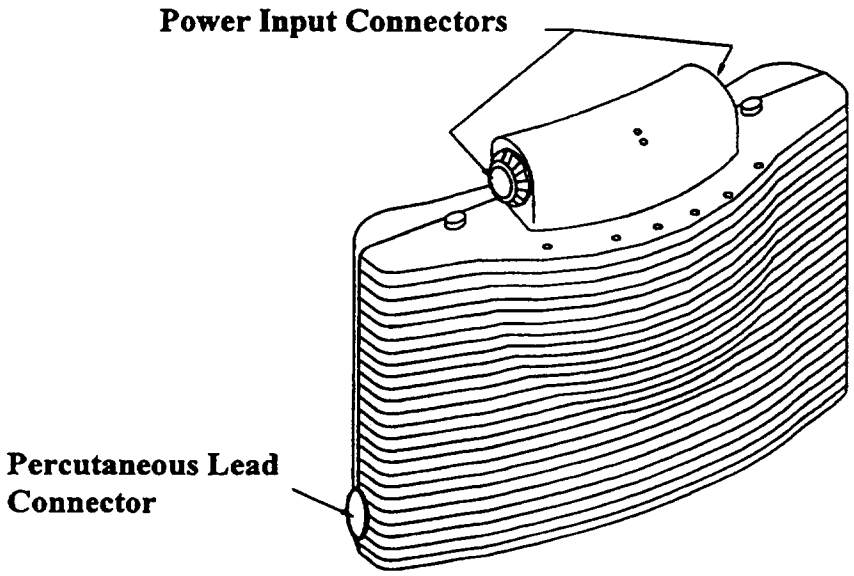


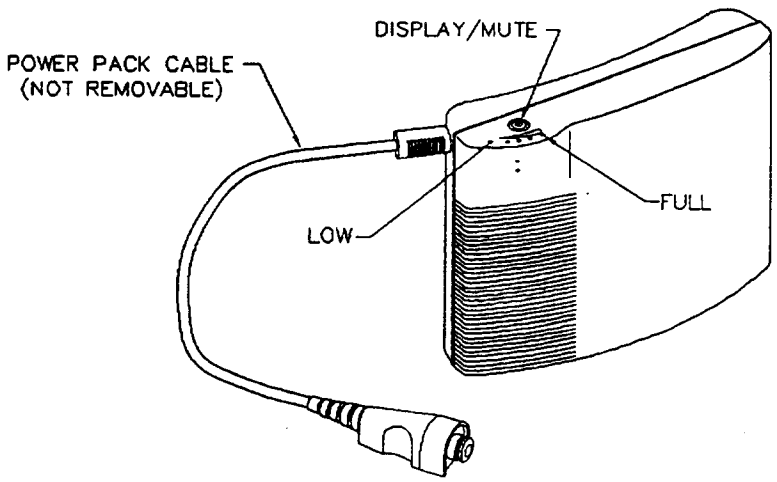
Figure 3 Front View of Compact Controller



3.4 Primary Power Pack

The Primary Power Pack is the larger of two rechargeable Power Packs. The Primary Power Pack has five charge-indicator lights and a Display/Mute Button. See **Power Packs**, page 11-3, for more information. The Primary Power Pack can run the LVAS for about 4 hours when fully charged, depending on your size and activity level.

Figure 4 Front View of Primary Power Pack

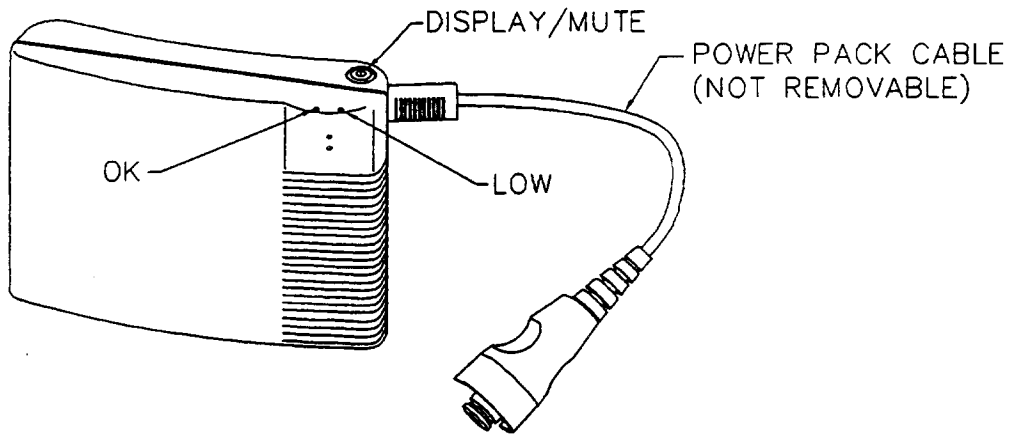


3.5 Reserve Power Pack

The rechargeable Reserve Power Pack is smaller and lighter than the Primary Power Pack. The Reserve Power Pack has two charge indicator lights and a Display/Mute Button. See **Power Packs**, page 11-3, for more information.

The Reserve Power Pack is a backup for the Primary Power Pack or Personal Monitor. It provides power when the Primary Power Pack or Personal Monitor is unplugged or is not supplying power. The Reserve Power Pack can run the LVAS for about one hour when fully charged.

Figure 5 Front View of Reserve Power Pack



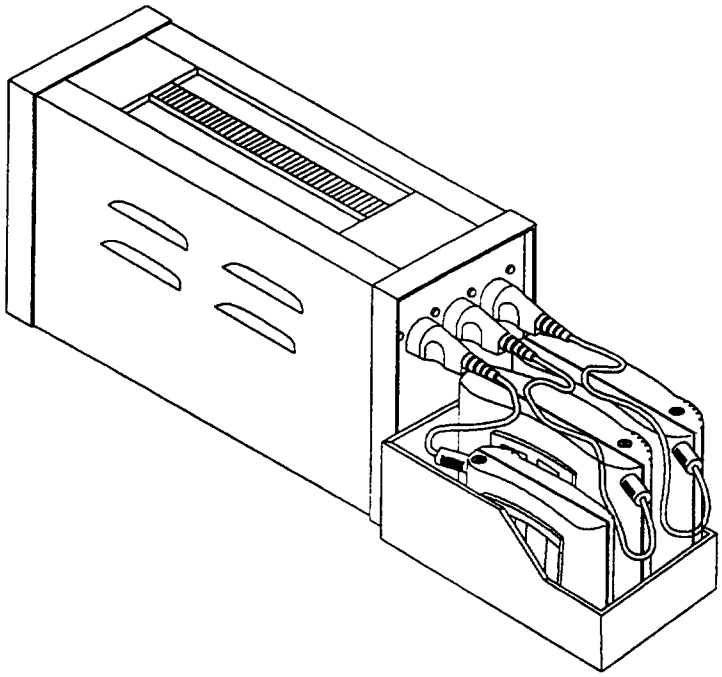
3.6 Power Pack Charger

The Power Pack Charger recharges the Primary and Reserve Power Packs. It can charge up to three Power Packs at once, including any combination of Primary and Reserve Power Packs.

Do not connect the Power Pack Charger to the Personal Monitor.

For more information see **System Setup,** page 5-8, and **Power Pack Charging,** page 10-3.

Figure 6 Power Packs Charging on Power Pack Charger



3.7 Personal Monitor

The Personal Monitor provides power to the Compact Controller when connected. It also tells you about Pump/Drive Unit performance, based upon information it receives from the Compact Controller.

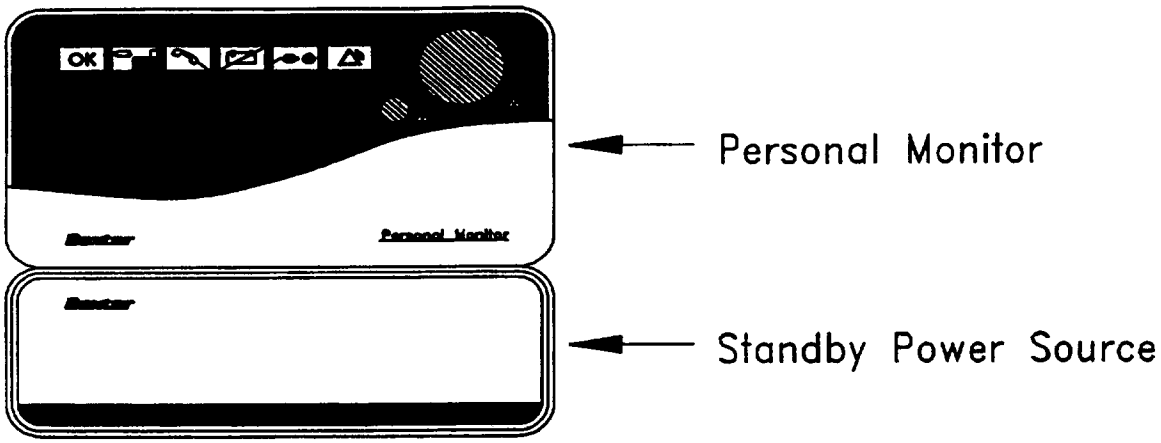
The Personal Monitor uses symbols, messages, and tones to let you know about conditions needing your attention. Using the message displayed on the Personal Monitor front panel with the Alarm Table will tell you what to do. See **Personal Monitor**, pages 11-4 and 11-5, for information about the symbols, and **Personal Monitor Alarms**, pages 12-9 and 12-10, for more information.

3.8 Standby Power Source

The Standby Power Source is a large battery that provides power to the Personal Monitor during a power outage. The Standby Power Source, when new, can power the system for about 12 hours (7 hours at temperatures below 64°F).

The Standby Power Source is not rechargeable.

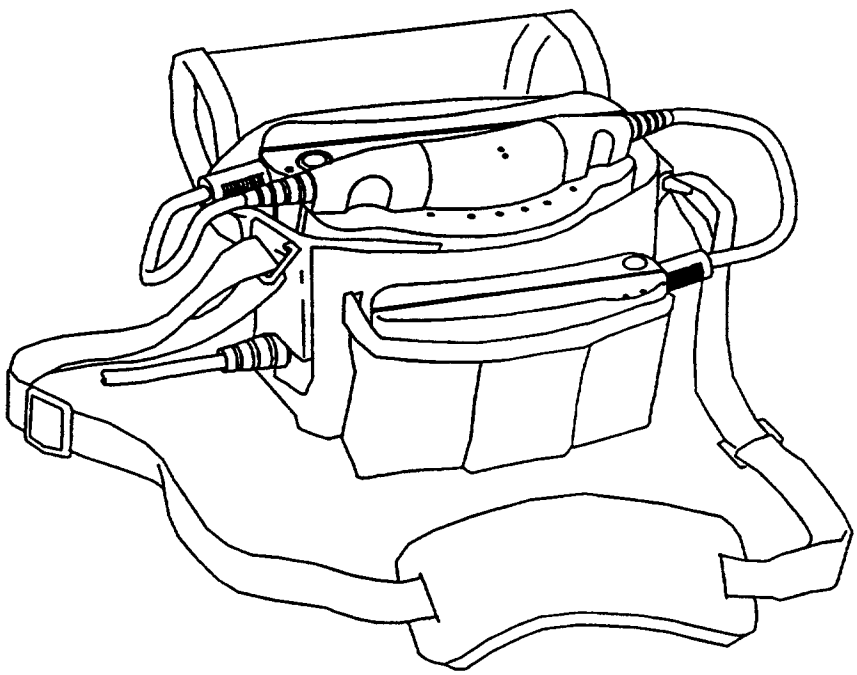
Figure 7 Front View of Personal Monitor and Standby Power Source



3.9 Support Accessories

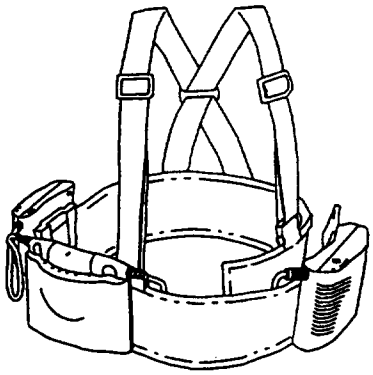
The Shoulder Bag can carry the Compact Controller along with Primary and Reserve Power Packs.

Figure 8 Shoulder Bag



The Support Belt is another way to carry the Compact Controller and Power Packs. It distributes the weight of these components evenly around your waist. The support belt is available in five sizes.

Figure 9 Support Belt



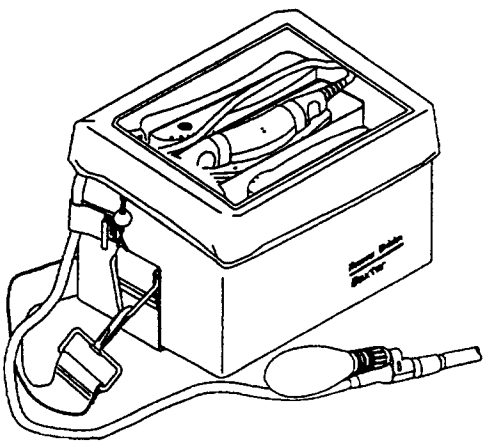
Talk to your healthcare provider about other support accessories that may be available.

3.10 Shower Accessories

A Shower Bag must be used to protect the external components of the LVAS during showers.

Caution: The shower accessories contain natural rubber latex which may cause allergic reactions.

Figure 10 Shower Bag



4. Environmental Conditions That Affect Use

The LVAS equipment is made of tough, durable materials, but it does require some basic care as described below. In addition, technical support personnel should perform periodic safety and function checks of the LVAS equipment.

See **Equipment Care and Maintenance**, Section 10, for information on cleaning your LVAS.

Temperature Conditions

Do not expose the equipment to temperatures higher than 120°F/50°C, or lower than 32°F/0°C for periods longer than approximately 20 minutes. If you are going to be exposed to such temperatures briefly, provide adequate ventilation/warmth to the components. This can be done by changing the number of layers of clothing over the components.

When you bring something from a cold place into a warm, humid one, water can condense on it. To lower the chance of this happening to your equipment, keep the Compact Controller and Power Packs under your outerwear when you go outside during cold weather. Also, if you are bringing stored equipment out of a cold location to a warmer one, allow it to sit for a few hours before using it.

Do not put the equipment in extremely hot or extremely cold locations, such as near or over a radiator, in direct sunlight, or in a very cold room.

Contact with Liquids

Caution: Keep all liquids away from equipment to avoid accidental spills. Do not put any of this equipment underwater or in other liquids. Contact with liquids increases the risk of shock and of damaging the equipment.

Electromagnetic Interference

Laboratory testing suggests that there is no risk from the effects of most devices that may produce electromagnetic interference (such as metal detectors, department store security devices, microwave ovens, cellular phones). However, the LVAS has not been tested with every brand of such devices, and the possibility of electromagnetic interference may exist from some of them.

Caution: If you experience unexpected changes in the rate of the LVAS, or irregular rhythms, see if there is a potential source of electromagnetic

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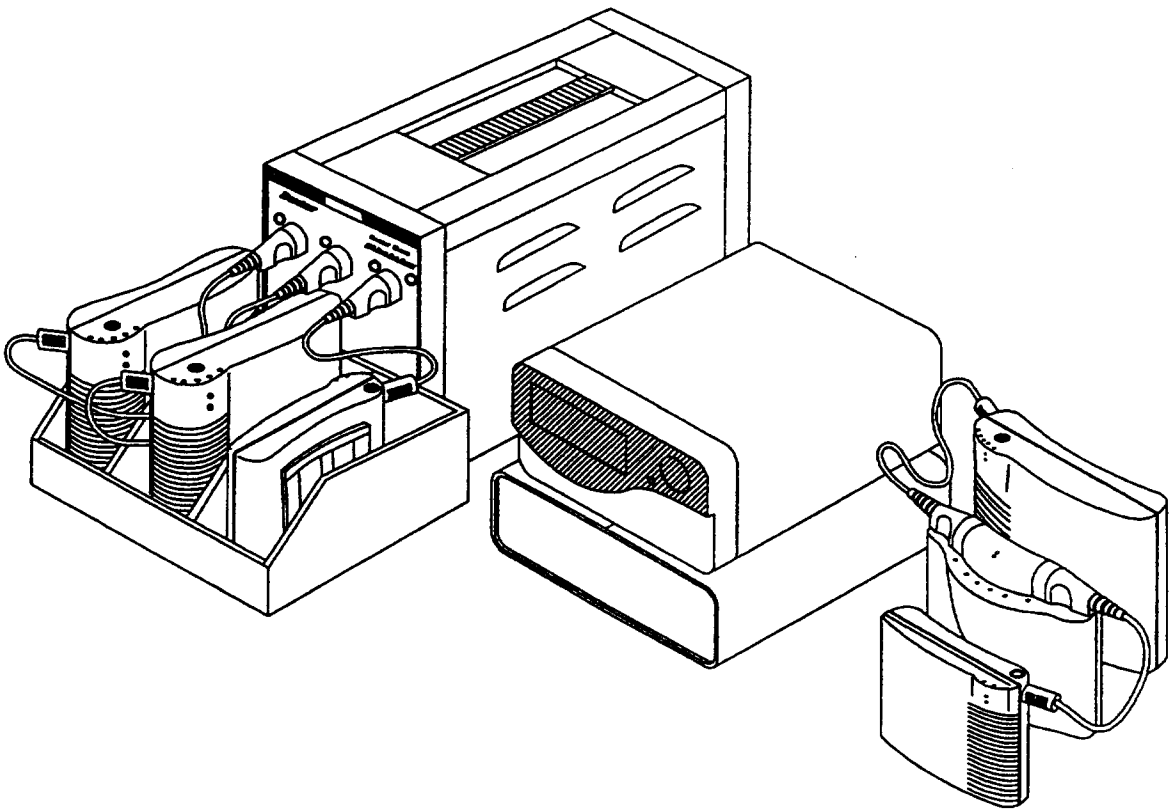
interference (for example, cell phones, radio transmitters, microwave ovens) within a few feet. If there is, move away from the potential source and see if the LVAS operation returns to normal. If it does not return to normal, contact your technical support personnel.

5. System Setup

You should practice setting up the system with your Technical support personnel before setting it up on your own. This lets you become familiar with each part of the system, how they connect, and what they do. If you have any questions during the system setup, please contact your Technical support personnel (listed inside the front cover) for more information. The system components are pictured below.



5.1 General Considerations

This equipment has alarm sounds and flashing lights to let you know about important system conditions. It has a message display to tell you what to do about the conditions.

If hearing the alarms or reading the messages is difficult for you, you may need help from someone who can hear the alarms and read the messages.

Protect the power cords and equipment cables. **Do not** put them where people walk. **Do not** allow anything heavy to rest on top of or roll over the cables. To avoid the possibility of electric shock, replace frayed or damaged cords and plugs. Contact your technical support personnel, listed inside the front cover, for equipment replacements.

Use only the power cord supplied with this system. A properly grounded extension cord may be used **only** if approved by the technical support personnel.

Do not use an extension cord with the Personal Monitor if you have a urinary or intravenous catheter. Doing so may increase your risk of shock.

Do not use a two-prong adapter plug or otherwise attempt to defeat the ground circuit. Doing so increases the risk of shock to you and your caregiver.

All units should sit on a hard, flat, stable surface. Do not place them on surfaces that could allow them to tip over or slip out of place. If you put any of the equipment on the carpet, place a flat, solid material (for example, a board or tile) on top of the carpeting first.

Caution: Plug this equipment into grounded power outlets only. This reduces the risk of shock.

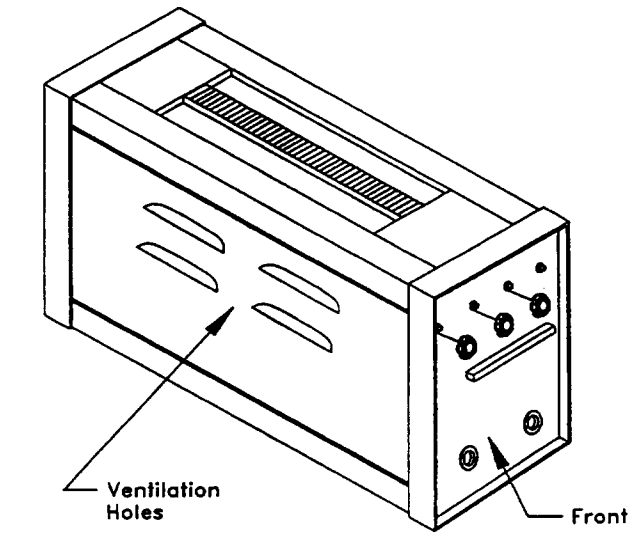
Caution: To avoid accidentally switching off the power to your LVAS, these outlets must not be connected to any wall switches. Set up your equipment near outlets that meet these requirements.

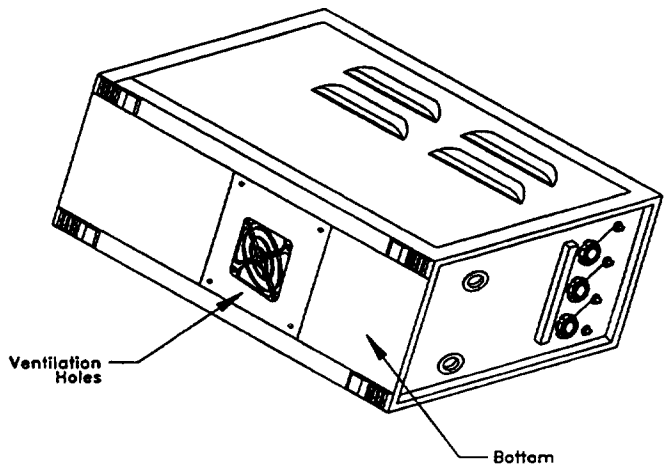
Note: If the power outlets are not grounded, an electrician will need to install grounded outlets before you can use this equipment.

Caution: Do not block ventilation holes. Blocking these openings can cause heat to build up inside and damage the equipment. This may cause the equipment to fail.

Make sure you have all of your LVAS equipment on hand before you begin the setup process.

Figure 11 Location of Ventilation Holes on the Power Pack Charger
Intended use position showing side vents
On side to show bottom vent





5.2 Setting Up The Compact Controller

The Compact Controller was adjusted for you. No further setup is necessary.

5.3 Setting Up The Personal Monitor

The Personal Monitor and the Standby Power Source can be stacked together, with the Personal Monitor on top of the Standby Power Source. Or, the Personal Monitor may be placed on a nearby bedside stand or tabletop, and the Standby Power Source on the floor beneath it or under the bed.

The Personal Monitor comes with one short cable [10.5 in. (27 cm.)] to connect to the Standby Power Source. A longer cable is available. Ask your technical support personnel for more information.

1. Set up and plug in the Personal Monitor

The Personal Monitor comes with one power cord to plug into the wall, one cable to connect to the Standby Power Source and one cable to plug into the Compact Controller.

Figure 12 Front View of the Personal Monitor and Standby Power Source in the Stacked Position

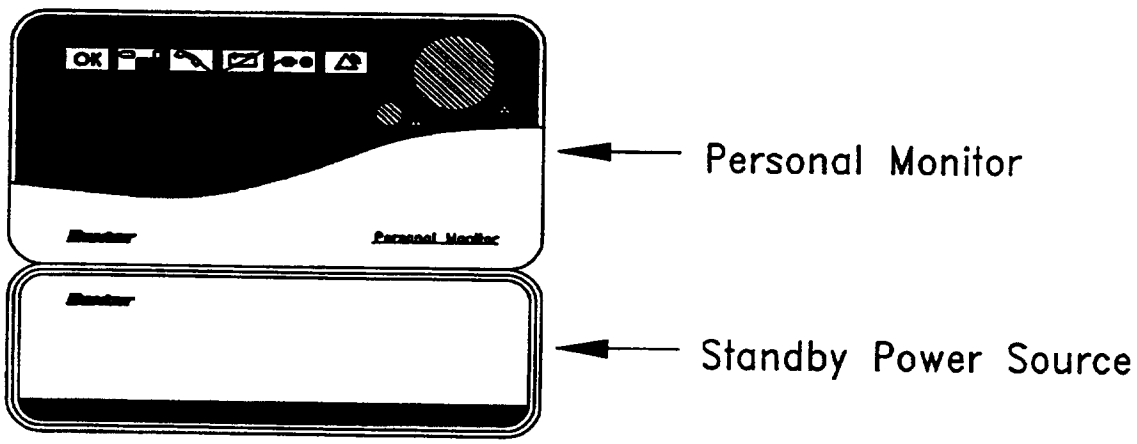
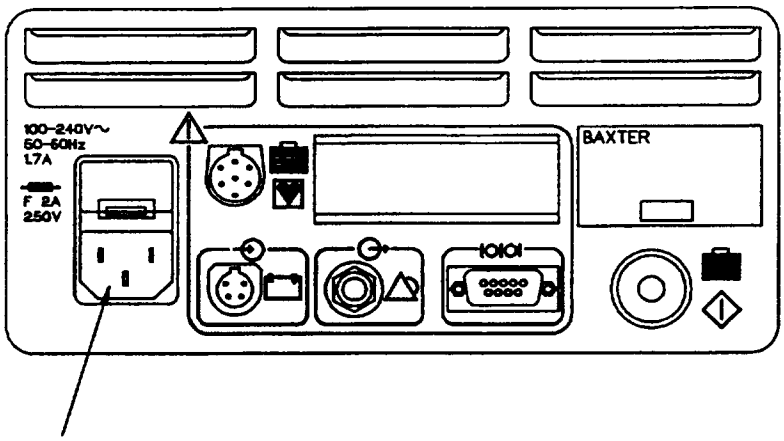


Figure 13 Connecting the Personal Monitor Power Cord



a. Plug the smaller, prongless end of the power cord into the back panel of the Personal Monitor.

b. Then, plug the larger end with prongs into a nearby grounded wall outlet.

Caution: Plug this equipment into grounded power outlets only. This reduces the risk of shock.

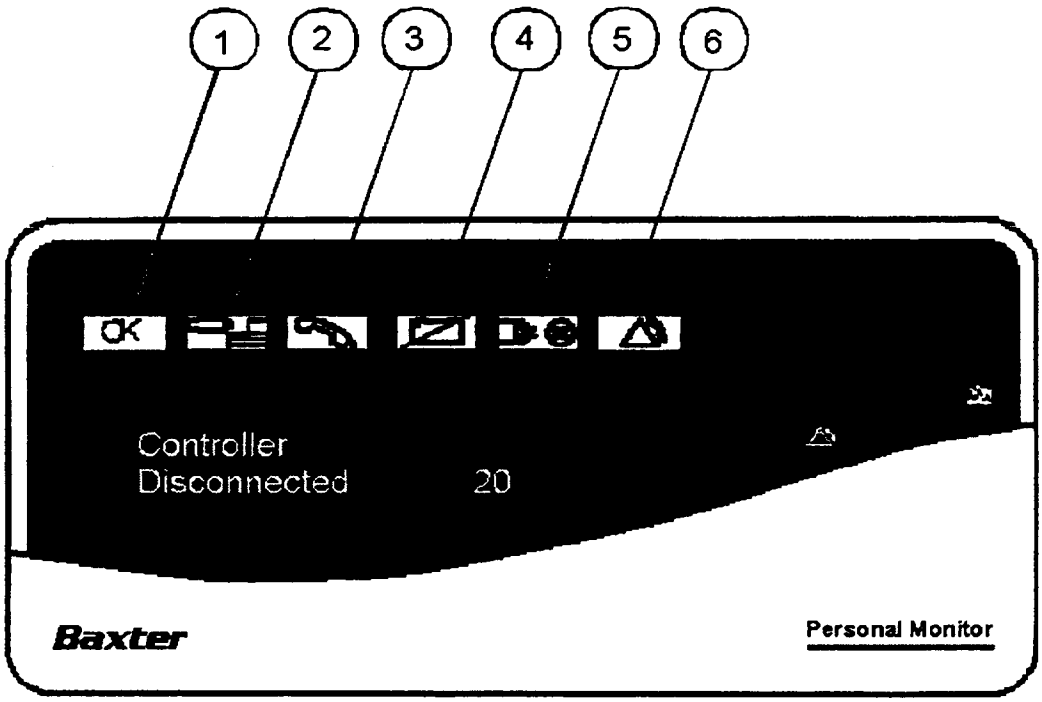
Caution: To avoid accidentally switching off the power to your LVAS, these outlets must not be connected to any wall switches. Set up your equipment near outlets that meet these requirements.

There is no on/off button on the Personal Monitor. It will be on as long as it is getting power from the Standby Power Source or the wall outlet.

When you plug the Personal Monitor into the wall outlet, the Personal Monitor will show a copyright message on its screen. Since you have not connected the Standby Power Source, it will show a message that reads "Standby Power Source Disconnected" and light the Standby Power Source symbol. Because you haven't connected the Compact Controller yet, the Controller Disconnected symbol will also light.

These symbols will go off and the "OK" symbol will light when you plug the Compact Controller and the Standby Power Source into the Personal Monitor.

Figure 14 Personal Monitor with Description of Symbols



①	"OK" (green)	④	"Standby Power Source" (yellow)
②	"Controller Disconnected" (yellow)	⑤	"Electric Power Disconnected" (yellow)
③	"Call" for assistance (yellow)	⑥	"Urgent Alarm" (red)

2. Connect the Standby Power Source to the Personal Monitor

The Standby Power Source comes with one cable that plugs only into the Personal Monitor.

a. Put the Personal Monitor on top of the Standby Power Source. Plug the gray end of the Standby Power Source cable into the gray socket in the back of the Standby Power Source.

b. Plug the black end of the Standby Power Source cable into the black socket in the back panel of the Personal Monitor.

Figure 15 Connecting the Personal Monitor to the Standby Power Source

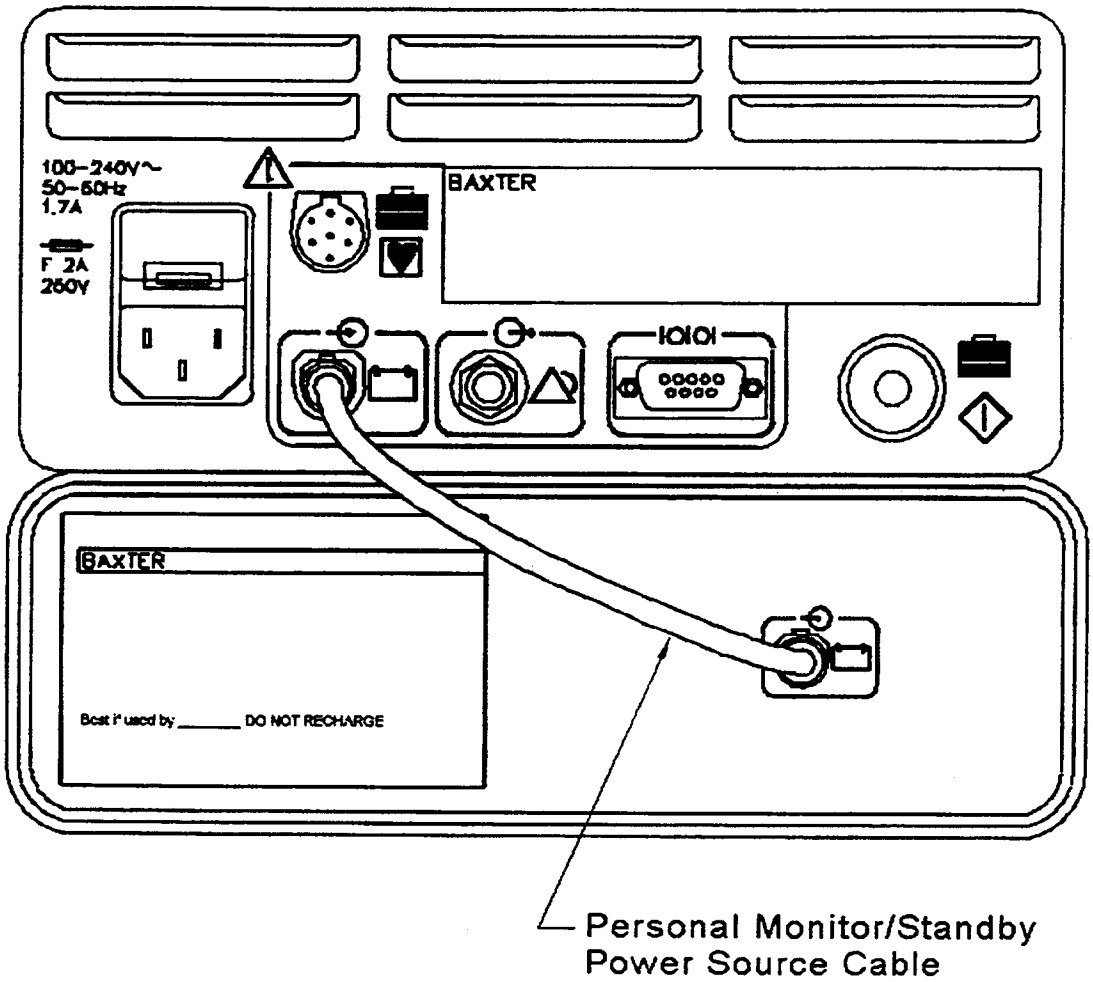
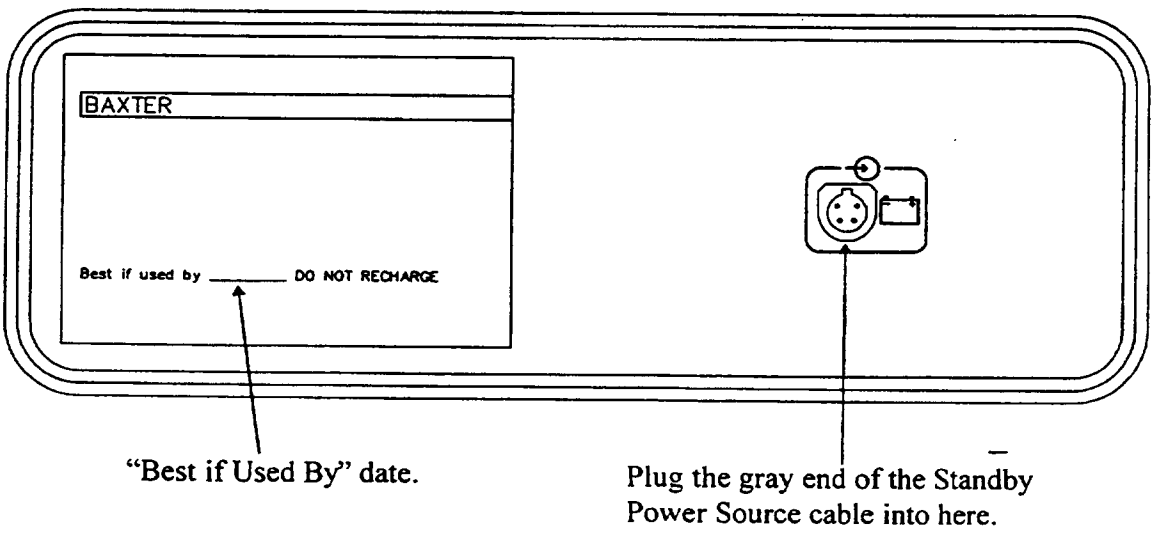


Figure 16 Date Label and Cable Connector on Standby Power Source



The "Standby Power Source" symbol will go out on the Personal Monitor because you have connected the Standby Power Source.

Caution: You must always have the Standby Power Source plugged into the Personal Monitor while you are sleeping. The Personal Monitor cannot operate or sound alarms when the power goes out unless it gets power from the Standby Power Source. The Compact Controller will alarm for "low power," but if you don't hear that alarm, your Reserve Power Pack could run low and your Pump/Drive Unit could stop.

Caution: Plug only the Standby Power Source to the Standby Power Source input connection. Other devices may interfere with Personal Monitor operation or cause Personal Monitor damage.

5.4. Setting Up the Power Pack Charger

The Power Pack Charger plugs into a **grounded** wall outlet.

Caution: Plug this equipment into grounded power outlets only. This reduces the risk of shock

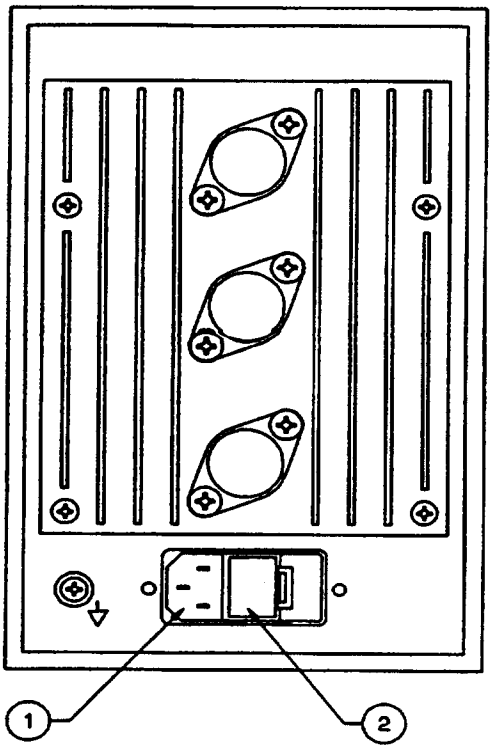
Caution: To avoid accidentally switching off the power to your LVAS, these outlets must not be connected to any wall switches. Set up your equipment near outlets that meet these requirements.

a. Plug the prongless end of the Power Pack Charger power cord into the back panel of the Power Pack Charger.

b. Plug the other end of the power cord into a **grounded** wall outlet.

c. Press the Power Switch on the back panel to the "On" position.

Figure 17 Connections on the Power Pack Charger



① AC/Mains connection
② Power switch

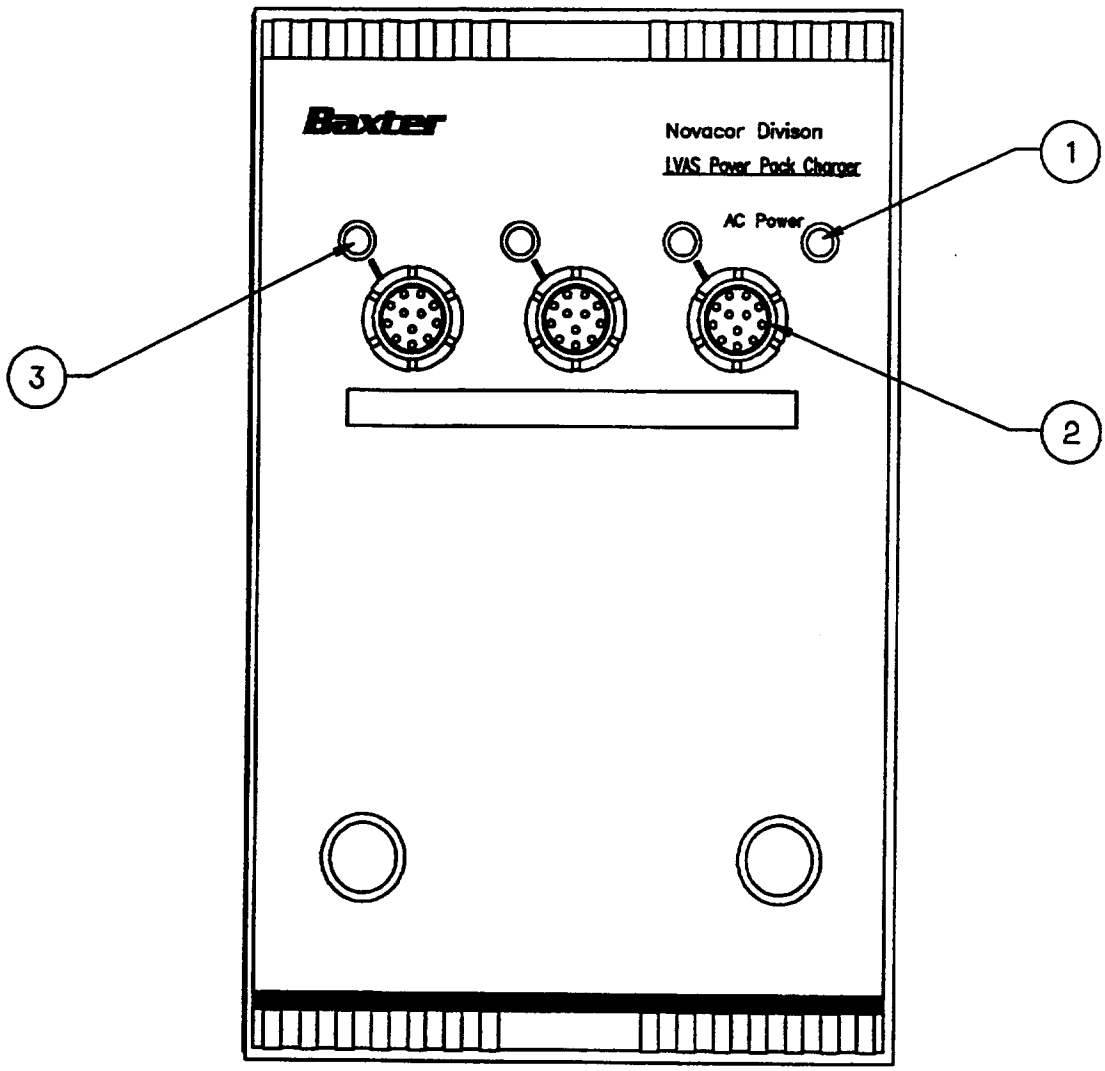
d. The green "AC Power" light is on when the Power Pack Charger is on.

e. Plug in the Power Packs for charging and storage.

f. The charging indicators will be yellow while charging and green when the Power Packs are full.

For more information on charging and storing the Power Packs, see **Power Pack Charging**, page 10-3.

Figure 18 Front View of the Power Pack Charger



① Power light (green) ② Power Pack connectors ③ Charging indicators (Yellow when charging, green when Power Pack is full)

6. Summary Of Use

This section provides a **quick reference only!** For detailed information, see the pages indicated.

Alarms

Power Packs (See page 12-8)

Compact Controller Alarms (See page 12-7)

Personal Monitor Alarms (See pages 12-9 and 12-10)

Emergency Contacts and Contact Situations (See inside front cover and page **iv** at the front of the manual)

Indicator Lights

Power Packs (See page 11-3)

Compact Controller Lights (See page 11-1)

Personal Monitor Indicators (See pages 11-4 and 11-5)

Replacing The Compact Controller (See pages 12-2 through 12-5)

Warning: The pump will stop briefly while the Compact Controller is being replaced. Make sure that the Compact Controller needs to be replaced before beginning.

1. Make sure that you (the recipient) are sitting or lying down before stopping the pump.
2. Be sure that both Power Packs are charged.
3. Unplug a Power Pack from the Compact Controller and plug it into the Replacement Compact Controller.
4. Unplug the other Power Pack, stopping the Pump/Drive Unit.
5. Unplug the Percutaneous Lead from the Compact Controller.
6. Plug the Percutaneous Lead into the Replacement Compact Controller. The Pump/Drive Unit should begin pumping automatically.
7. Plug the other Power Pack into the Replacement Compact Controller.
8. Call your technical support personnel, listed inside the front cover, as soon as possible.

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Changing From Untethered To Tethered (See pages 8-1 to 8-4)

1. Be sure that the Personal Monitor has power.
2. Check the power level in the Reserve Power Pack; replace if necessary before continuing.
3. Unplug the Primary Power Pack.
4. Plug the Compact Controller to the Personal Monitor.
5. Plug the Primary Power Pack to the Charger.

Changing From Tethered To Untethered (See pages 8-5 to 8-8)

1. Remove a fully charged Primary Power Pack from the Charger.
2. Check the power level in the Reserve Power Pack; replace if necessary before continuing.
3. Unplug from the Personal Monitor.
4. Plug the Primary Power Pack.

Power Management (See pages 10-2 through 10-4)

1. **Always** have two power sources plugged into the Compact Controller.
2. Rotate use of all of your Power Packs.
3. Store extra Power Packs plugged into the Charger at room temperature.
4. **Do not** let any objects or moisture near the electrical connectors.
5. **Do not** leave Power Packs in direct sunlight.
6. Check your Reserve Power Pack every day and replace it when the red "Low" light appears.

Daily Checks

1. Check that the Personal Monitor is plugged in with the "OK" light or "Controller Disconnected" light on.

2. Do Alarm Test (Personal Monitor and Compact Controller) (See Section 7.1)

   Press Alarm Test and Power Status on Personal Monitor

   Watch for indicator lights and alarm sounds on Personal Monitor and Compact Controller.

   Replace component with backup if it does not alarm properly, and notify your LVAS Operator.

3. Check that the Power Pack Charger is plugged in and turned on with Power Packs plugged in and charging.

4. Test Power Packs (see Section 7.1)

   Test Reserve Power Pack by pressing the Display/Mute button (at least once a day, and before disconnecting any power sources).

   Test Primary Power Pack by pressing the Display/Mute button (before use).

5. Inspect Percutaneous Lead for nicks, cuts, and tears. If you find any, contact your technical support personnel. (See Section 9.1)

   Inspect the vent filter and replace if needed. (See Section 8.5)

6. Do exit-site care. Contact your LVAS Operator or medical professional if there are signs of infection. (See Section 9.1.)

7. Follow your doctor's recommended medical schedule (for example, frequency of medication and monitoring of physical indicators such as weight, temperature, etc.) (See Section 9.)

Call your technical support personnel if you find any problems or have any questions.

Note: Your technical support personnel will periodically check the system and spare equipment.

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7. Daily Checks

Check your Compact Controller, your Primary and Reserve Power Packs, your Personal Monitor and Standby Power Source **every day** as described below.

Caution: Replace the Compact Controller, Power Packs, or Personal Monitor if any of their alarms are not working. If something serious happens and the alarm is not working, you may not be able to respond correctly. Test the alarms every day and contact your technical support personnel if you have any problems.

Personal Monitor And Compact Controller

1. When you first wake up in the morning, check the front panel of the Personal Monitor for lighted symbols and messages. The "OK" symbol should be lit and there should be no message. If there are alarms and messages, go to **Alarm Messages and Responses**, pages 12-9 and 12-10, to find out how to handle them.
2. Press the small button on the front panel of the Personal Monitor to test the alarm sounds and lights in the Personal Monitor and the Compact Controller. The Personal Monitor will then also show a message telling you how much power remains in the Standby Power Source. (A power outage during the night may have affected the remaining power in your Standby Power Source.) After 30 seconds, the Personal Monitor will return to the standard display.

   The alarms will sound in order, first the Personal Monitor and then the Compact Controller alarms. Listen carefully to be sure you hear each of them so you know that they are both working. If you can't hear one of the alarms, you must contact your technical support personnel for advice and to obtain a replacement. See page 12-2 for instructions on how to replace the Compact Controller if necessary.

Power Packs

See page 12-8 for a description of the Power Pack alarms.

1. Press the Display/Mute button on the Primary Power Pack to test the alarms and display the remaining power level. The Primary Power Pack typically can be used for one hour per green light. A red light indicates that the Primary Power Pack needs to be recharged.
2. Press the Display/Mute button on top of the Reserve Power Pack to test the alarms and display the remaining power level. If the red light comes on, replace it with a fully charged one and recharge the old Reserve Power Pack.
3. Replace **any** Power Pack that gives the "Low" alarm with a full one.

8. Daily Operation

Always connect the Compact Controller **to two power sources.** It draws power from only one source at a time. The second source provides an important backup. Check the remaining charge every hour when using the Primary Power Packs.

While you are relaxing or sleeping you should use the Personal Monitor and Reserve Power Pack in the Tethered mode of operation.

Most of the time that you are active you will use one Primary and one Reserve Power Pack in the Untethered mode of operation. You will not be connected to the Personal Monitor.

8.1 Tethered Operation

During times of little activity, such as when you are sleeping or relaxing, we recommend that you use your Personal Monitor. This is called the Tethered mode of operation. You should use the Tethered mode whenever you think you might fall asleep, or if you do not have a charged Primary Power Pack available.

When you use the Personal Monitor, the Compact Controller uses power from the grounded wall outlet. The Personal Monitor also can get power from the Standby Power Source, which can supply power to run the LVAS for several hours. Because of these backups, the only time you should need to change the Reserve Power Pack during the night is if there is an exceptionally long power outage.

To Switch From Untethered To Tethered Operation

1. Be sure that the Personal Monitor is ready to be used.

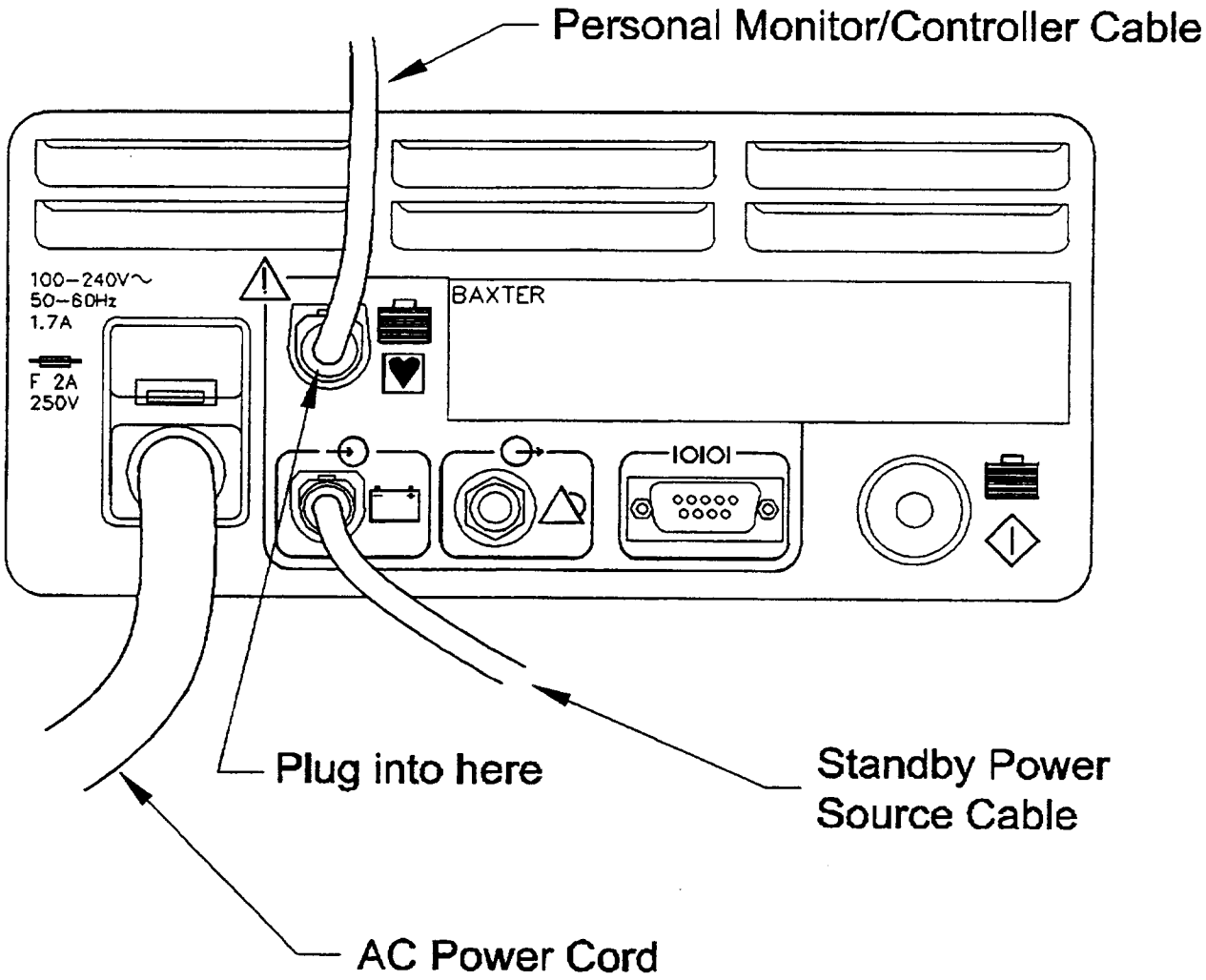
   a) The Personal Monitor should be on.

   b) The yellow "Controller Disconnected" symbol should be lit.

   c) The Personal Monitor/Controller cable should be plugged into the back panel of the Personal Monitor.

      Note: You can leave the Personal Monitor/Controller cable plugged into the Personal Monitor at all times.

Figure 19 Plugging in the Monitor/Controller Cable

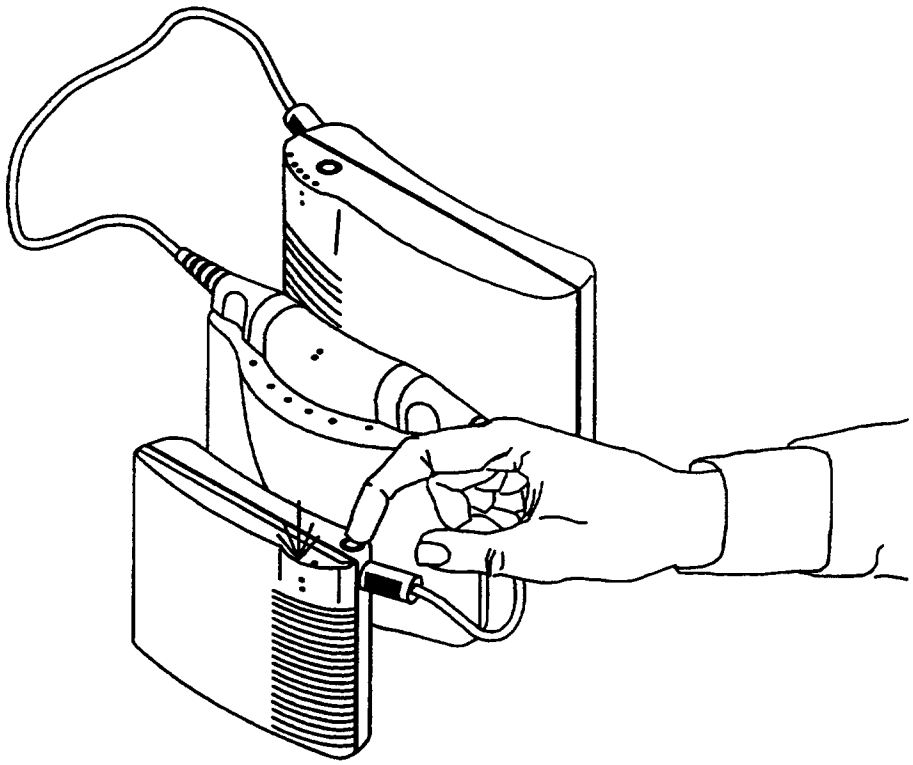


2. Be sure that the Reserve Power Pack is charged.

   a) If the red "Low Power" light is lit on top of the Reserve Power Pack or on the Compact Controller, replace the Reserve Power Pack with a fully charged one.

   b) Press the Display/Mute button on top of the Reserve Power Pack. If the red light comes on when you press the button, replace the Reserve Power Pack with a fully charged one. If the green "OK" light comes on, go to the next step.

Figure 20 Checking Reserve Power Pack Charge



3. Unplug the Primary Power Pack from the Compact Controller.

   Warning: Unplugging both power sources from the Compact Controller at the same time will cause the Pump/Drive Unit to stop. Plug in either power source to restart the Pump/Drive Unit.

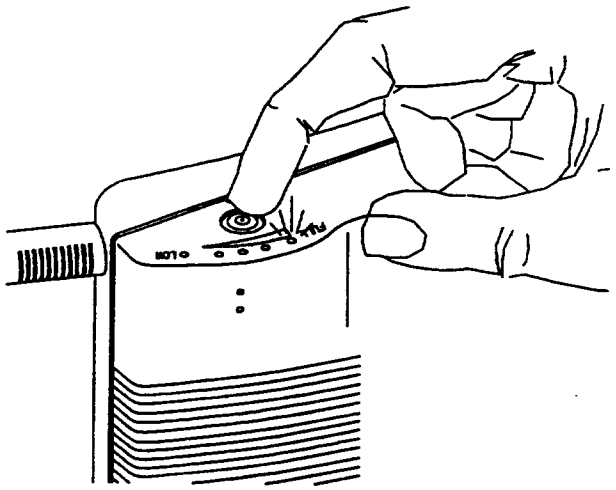
   a) Firmly hold the Compact Controller with one hand. Be careful not to accidentally loosen the Reserve Power Pack with this hand.

   b) With your other hand, firmly hold the hard plastic connector at the end of the Primary Power Pack cable. **Do not** pull on the cord itself. Pulling on the cord could damage the cord and the connector.

   c) Pull the Primary Power Pack connector from the Compact Controller. This connection may be tight, and may take some force to pull it loose.

   d) Press the "Display/Mute" button on top of the Primary Power Pack so that it will not alarm.

Figure 21 Pressing the Display/Mute Button to Prevent Power Pack Alarm



Note: If you don't press the "Display/Mute" button on the Primary Power Pack, the Power Pack will sound an alarm after 3 seconds to tell you it is unplugged. Press the button to silence the alarm.

Note: When you unplug a power source from the Compact Controller, the Compact Controller lights the "Low Power" light next to the empty power connector, and sounds an alarm if a power source is not plugged in within 30 seconds. The alarms tell you that the Compact Controller needs two power sources at all times. These alarms will stop when you plug in a power source.

4. Connect the Compact Controller to the Personal Monitor.

   a) Plug the Monitor/Controller cable into the vacant power input connector on the Compact Controller.

   b) If any other connections are loose, you will see messages on the Personal Monitor display that will tell you what to do next.

   c) If all connections are tight and all components are working properly, there will be no alarm message on the screen and no beep or tone alarms. The "O.K." lights on the Compact Controller and on the Personal Monitor will be lit.

5. Recharge the Primary Power Pack.

   a) Plug the Primary Power Pack into the Power Pack Charger for charging.

8.2 Untethered Operation

You will probably want to use the Power Packs, instead of the Personal Monitor, while you are active. This is called Untethered operation.

You must use one Primary Power Pack and one Reserve Power while you are in Untethered mode. The Compact Controller will draw power from the Primary Power Pack before drawing from the Reserve Power Pack. This design helps makes sure that the Reserve Power Pack will have energy remaining if the Primary Power Pack becomes empty. It also means that there is a series of alarms to allow you to respond before the Power Pack runs out of power.

Note: Do **not** plug two of the same type of Power Packs into the Compact Controller.

If plugged to two of the same type of Power Packs, the Compact Controller will use power from both at the same time. Both packs will become low and give a low power alarm. If you do not replace the Power Packs at the low power alarm, eventually both packs will become empty at the same time.

The amount of time that you can stay in Untethered operation depends on the amount of power remaining in your Power Packs. Each green light on your Primary Power Pack indicates about one hour of charge remaining. Carry enough fully charged Power Packs with you to meet both your planned and unplanned needs.

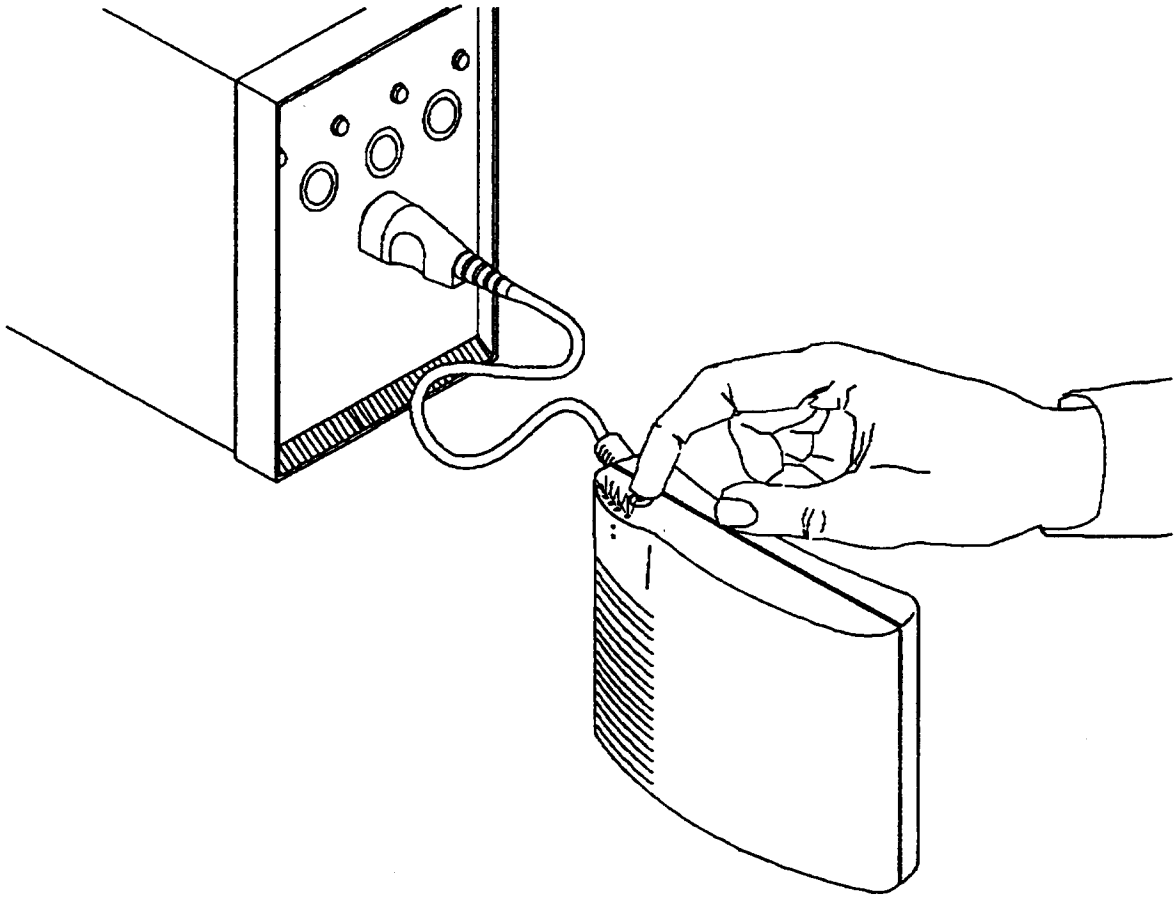
To Switch From Tethered To Untethered Operation

Before disconnecting from the Personal Monitor:

1. Remove a fully charged Primary Power Pack from the Power Pack Charger. Unplug the Primary Power Pack by pulling on the connector, not the cord. Pulling on the cord could damage the cord and the connector.

   Press the "Display/Mute" button on the Power Pack to determine its charge. A **fully charged** Primary Power Pack displays **four green lights** above the button.

Figure 22 Checking Power Pack Status before taking it off the Charger



2. Check the power level in the Reserve Power Pack.

   a) If the red "Low Power" light is lit on top of the Reserve Power Pack or on the Compact Controller, replace the Reserve Power Pack with a fully charged one.

   b) Press the Display/Mute button on top of the Reserve Power Pack. If the red light comes on when you press the button, replace the Reserve Power Pack with a fully charged one before going to the next step. If the green "OK" light comes on, you may go to the next step.

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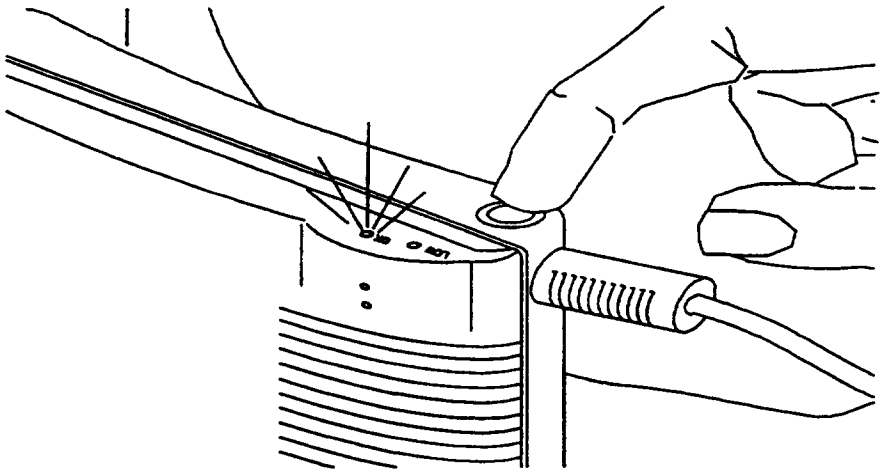
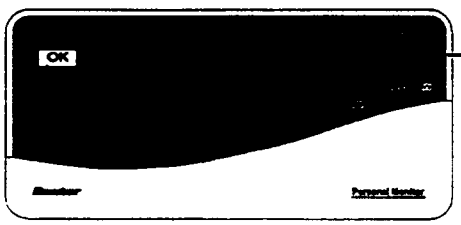
Figure 23 Press the Display/Mute Button to Check Reserve Power Pack Charge



3. Disconnect the Compact Controller from the Personal Monitor.

   a) Press the **large** button on the front of the Personal Monitor. Then, within 15 seconds, unplug the Personal Monitor/Controller cable from the Compact Controller.

Figure 24 Press the Large Button to Prevent Alarm



Note: If you do not press the large button first, the Personal Monitor will sound an alarm and display a message saying "Reconnect Controller." You cannot silence the alarm by pressing the large button on the front of the Personal Monitor. You must plug the Compact Controller back in and repeat this step. Unplug the Monitor/Controller Cable within 15 seconds **after** pressing the large button to avoid the alarm.

After unplugging the Personal Monitor/Controller cable from the Compact Controller, the red "Low Power" light on the Compact Controller next to that connection will light and the Compact Controller will beep once.

The Reserve Power Pack beeps every 15 seconds to tell you that it is the only source of power to the Compact Controller. The Compact Controller will sound an alarm after 30 seconds unless you plug in a second power source.

4. Connect the Primary Power Pack.

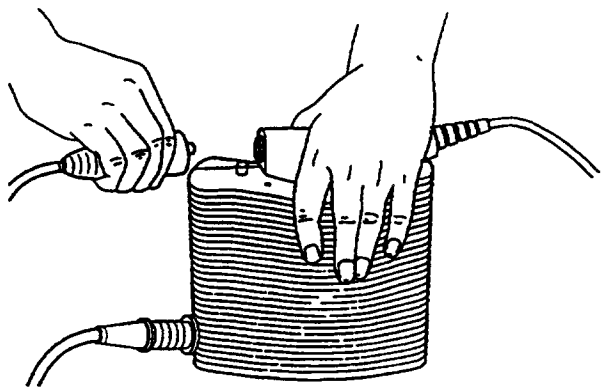
   Plug the Power Pack's cable into the vacant power connector on the Compact Controller. The cable connector should lock with a noticeable click.

   The red "Low Power" light on the Compact Controller next to that connector will go out.

   Be sure that the connector locks by gently pulling on the Power Pack cable, not the plastic connector shell. You should not be able to pull the cable connector away from the power input connector by pulling on the cable.

   During Untethered operation, check the power level of your Primary Power Pack every hour to be sure that enough power is available.

Figure 25 Plugging in the Primary Power Pack



8.3 Replacing The Reserve Power Pack

The Reserve Power Pack slowly uses energy internally. It will become low in approximately four to five days, even when the Compact Controller is connected to a Personal Monitor or Primary Power Pack. If the "Low" indicator comes on when you press the Display button, replace the Reserve Power Pack with a fully charged one. Follow the same procedure as for the Primary Power Pack. See pages 8-3 and 8-4, steps 3 and 5.

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8.4 While Traveling

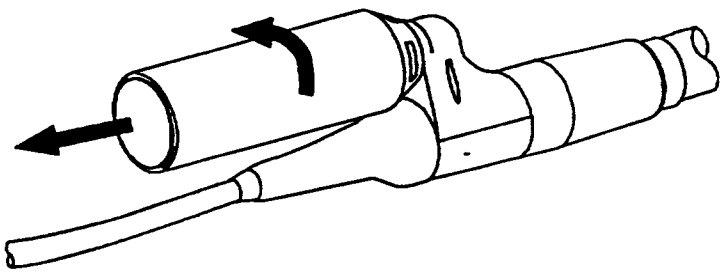
Always travel with fully charged Power Packs and carry extra Power Packs as well as an extra Compact Controller. You may need these components in an emergency.

When on extended trips, take your Personal Monitor, Standby Power Source, and Power Pack Charger. Follow the set-up guidelines provided in the **System Setup**, Section 5.

8.5 Replacing the Vent Filter

The vent filter protects the Percutaneous Lead from lint and debris. If you see a buildup in your vent filter when you do your daily inspection, or if the vent filter gets wet, you may replace the filter. Simply unscrew the old vent filter, discard it, and screw on a new one. You can discuss how often you need to change the filter with your Technical support personnel.

Figure 26 Unscrewing the Vent Filter



8.6 Showering Instructions

Warning: Do not allow liquid to enter the Percutaneous Lead. Keep liquids away from the Filter. If liquid enters the Filter, it may go into the Percutaneous Lead, damaging the Pump/Drive Unit and possibly causing it to stop.

Water in the Percutaneous Lead could damage the Pump/Drive Unit. If you see more than a few drops of water in the Percutaneous Lead, keep it pointing down below the level of the exit site, and call your technical support personnel.

Caution: Do not shower with the LVAS in Tethered Mode. Operating in Untethered mode (in other words, with the Power Packs) reduces the risk of shock.

Caution: **Keep the Shower Bag upright during and after shower. This will help prevent water from entering the Percutaneous Lead or the Compact Controller connections.**

Caution: **Do not put the Shower Bag in standing water. Do not submerge the Shower Bag or Vent Cover. This will help prevent water from entering the Percutaneous Lead or the Compact Controller connections.**

Caution: **If using a hand shower, keep the direction of the spray pointed nearly downward (no more than 45° away from vertical). This will help prevent water from entering the Percutaneous Lead or the Compact Controller connections.**

Note: Check Power Pack capacity before showering.

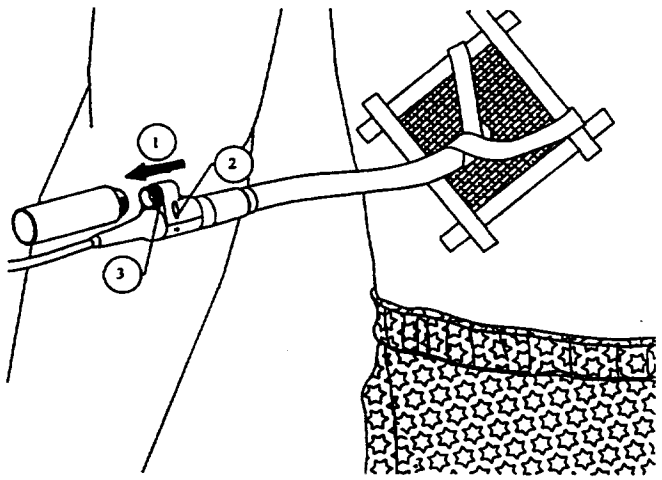
Note: Follow your doctor's instructions regarding the exit site before, during and after showering.

Before The First Shower

1. Your doctor will provide instructions for exit-site care before, during and after a shower.

2. A technical support person will make sure that the vent filter fitting is correctly placed on the Percutaneous Lead.

Figure 27 Removing the Vent Filter



1 Orientation of vent filter fitting 2 Vent filter fitting screws 3 O-ring

a) The fitting must be placed with the threaded connector toward the Compact Controller (away from the exit site).

b) The two pieces of the fitting must fit together tightly, with both screws tight and no gap between the two pieces. Tighten the screws using the wrench supplied with the shower accessories.

c) The O-ring must be in place and undamaged.

3. To be performed under the guidance of technical support:

a) Perform a dry run (dress rehearsal) of the shower procedure. Follow the showering instructions below, but without turning on the water. (Clothes may be left on for this dry run.) Practice until you are comfortable that you understand the instructions for all steps and can perform them properly, and have reviewed the list of precautions.

b) Make sure that the Shower Bag works for your particular shower. First take a brief (three-minute) shower following the showering instructions. (Technical support personnel do not have to be in shower room during the shower.) After this first shower, the technical support person should inspect the Percutaneous Lead and Shower Bag for water. There should be no water in the Percutaneous Lead and no more than 5 ml (1 teaspoon) in the Shower Bag. If there is more than this amount, the cause must be determined and eliminated before any more showers are taken. If these limits are met, routine showers may be 10 to 15 minutes.

For Each Shower

Before Turning on Water or Entering Shower:

1. Look at the Percutaneous Lead for holes or damage. **Do not** shower if you find or suspect any damage. Immediately contact your technical support personnel.

2. Prepare the exit site according to your doctor's instructions.

3. The Vent Cover should provide a tight seal when correctly installed to prevent water from entering the Percutaneous Lead.

Warning: Do not allow liquid to enter the Percutaneous Lead. Keep liquids away from the Filter. If liquid enters the Filter, it may go into the Percutaneous Lead, damaging the Pump/Drive Unit and possibly causing it to stop.

a) Look at the Vent Cover balloon for holes, cracking or brittleness. It may be leak tested by gently blowing into it by mouth and checking that it holds air. If it is not in good condition, or you are not sure, **do not** use that Vent Cover. Throw it away and use a new Vent Cover for showering.

b) Use a new Vent Cover every month. Throw away the old one.

c) Unscrew the Vent Filter and put it in a dry spot away from the shower. Make sure that the O-ring on the vent fitting is in place and undamaged. Contact your technical support personnel if it is missing or damaged. See Section 8.5, **Replacing the Vent Filter**, for detailed instructions on replacing the vent filter.

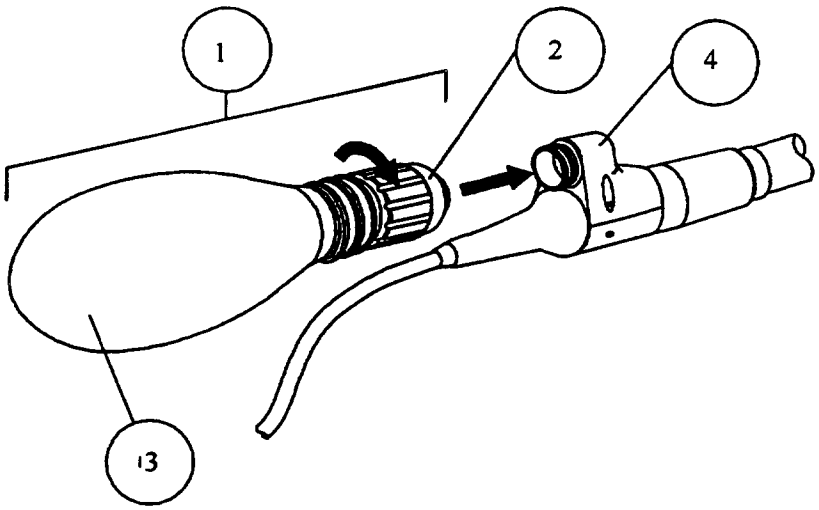
4. Screw on the Vent Cover:

a) Handle the Vent Cover only by its plastic part.

Caution: Do not squeeze the balloon while installing or while in place. Doing so could impair Pump/Drive Unit operation.

b) Bring the Vent Cover up to the vent fitting on the Percutaneous Lead. Move slowly the last few millimeters (1/8 inch) before making contact. Then screw the Vent Cover onto the fitting and tighten firmly.

Figure 28 Putting on the Vent Cover



1 Vent Cover 2 Vent Cover coupling 3 Vent Cover balloon 4 Vent fitting

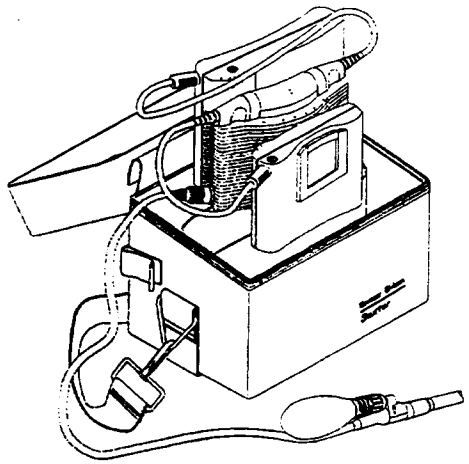
c) Check that the Pump/Drive Unit is operating normally (no change in sound or rhythm when the Vent Cover is installed).

5. Put the Compact Controller and Power Packs in Shower Bag:

a) Be sure that Power Packs are adequately charged (green lights when checked).

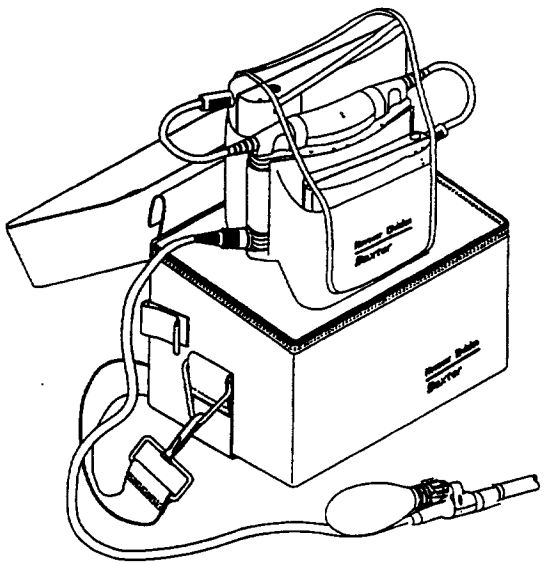
b) If the Compact Controller and Power Packs are carried on a belt, remove them and put them into the Shower Bag.

Figure 29 Placing the LVAS External Components in the Shower Bag



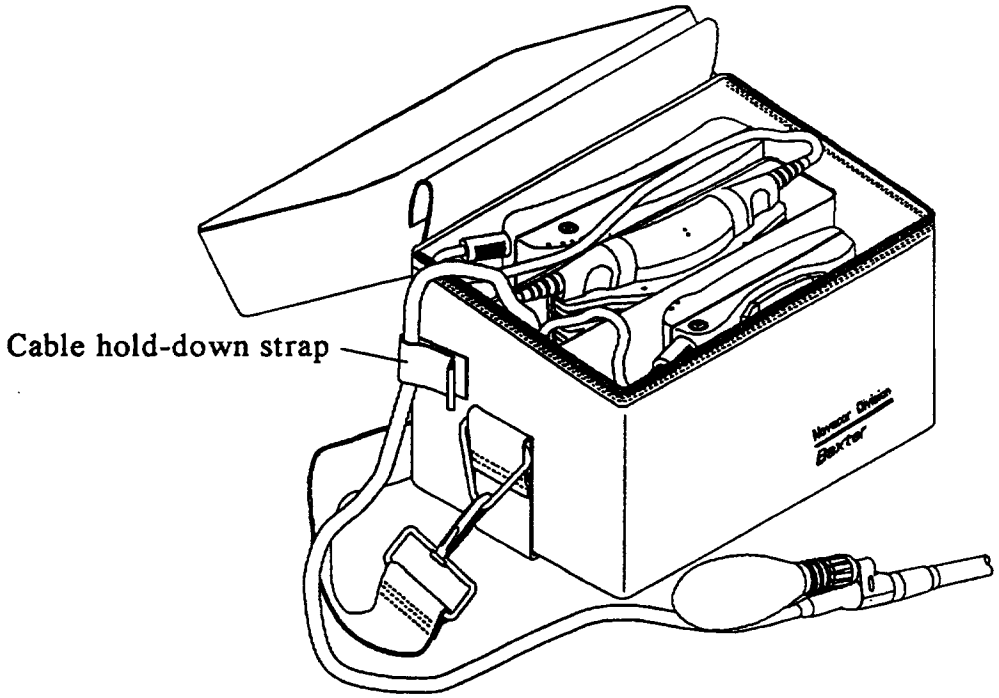
6. If the Support Bag is used to carry the Compact Controller and Power Packs, remove the divider from the Shower Bag, and place the Support Bag into the Shower Bag. Tuck the Support Bag's shoulder strap behind or under the Support Bag.

Figure 30 Placing the Support Bag in the Shower Bag



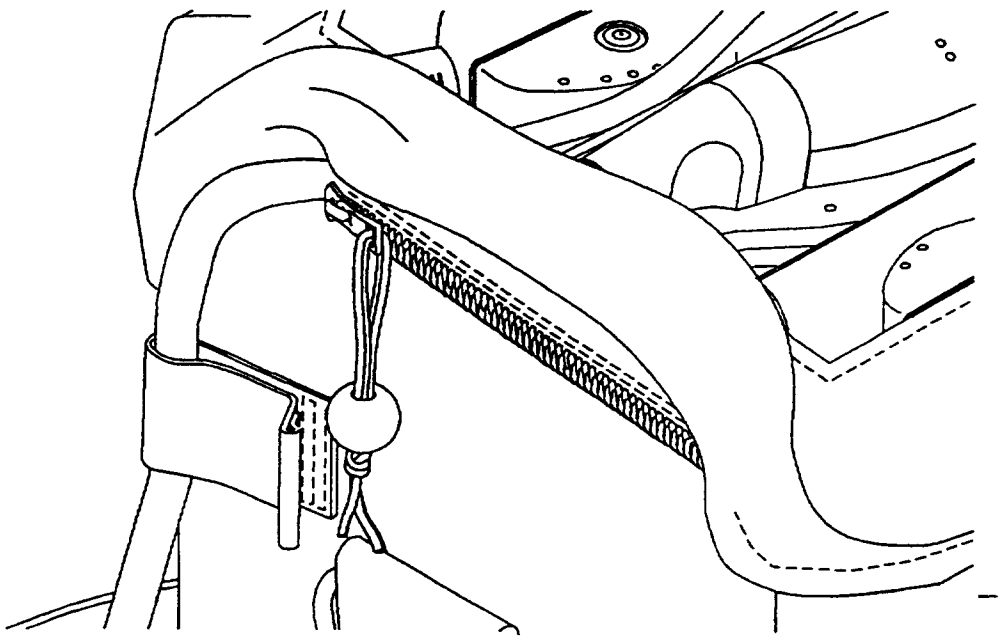
7. Position the Percutaneous Lead at the end of the zipper, fold it downward outside the bag and secure it with the cable hold-down strap.

Figure 31 Positioning the Percutaneous Lead



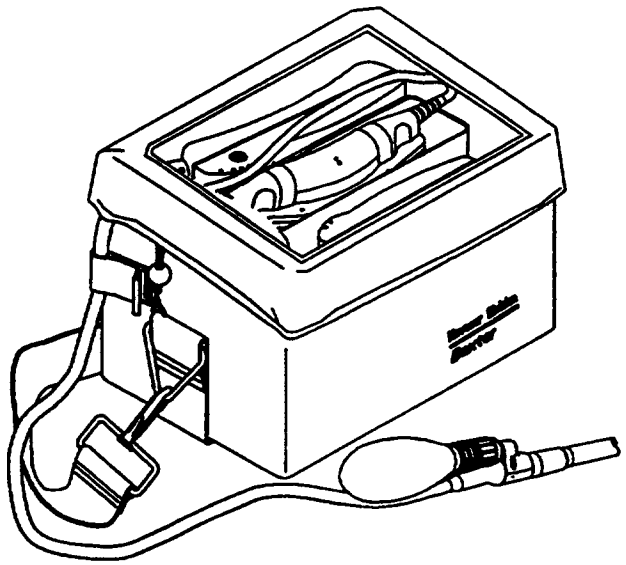
8. Close the zipper as far as possible: the zipper's slide should be right next to the Percutaneous Lead.

Figure 32 Proper Position of the Zipper



9. Fold the zipper flap down to cover the zipper. Make sure that the zipper flap covers the zipper completely, and that the Percutaneous Lead is secured under the cable hold-down strap.

Figure 33 Shower Bag Showing the Zipper Flap in its Final Position



10. Pick up the Shower Bag, hang it across your body, and proceed with shower.

After Shower

1. Dry yourself, and then dry off the Percutaneous Lead, vent fitting and the solid coupling of the Vent Cover. Wipe off the Shower Bag.
2. Release the cable hold-down strap, unzip the Shower Bag and remove the Compact Controller and Power Packs.
3. Check for water in the Shower Bag: a small amount is OK. If there is more than approximately 1 teaspoon (5 ml), contact your technical support personnel.
4. Look for water in the Percutaneous Lead. If there is any, keep it pointing down below the level of the exit site to prevent the water from entering the Pump/Drive Unit, and call your technical support personnel.
5. Unscrew the Vent Cover. Keep the Vent Cover below the level of the vent fitting during removal to prevent water from dripping into the vent fitting.
6. Put the Vent Filter back on the vent fitting and tighten.
7. Perform exit-site care according to doctor's instructions.
8. Set the Shower Bag and Vent Cover aside to dry. Store the Vent Cover out of direct sunlight. The Shower Bag can hang upside down to dry when empty.

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8.7 Limits Of Daily Living

The LVAS lets you move around and be active. However, there are some restrictions associated with the device.

The following activities are **always prohibited** for your safety and for the good function of your LVAS:

Absolutely NO	Comments
Total body submersion (for example, bathing, swimming)	The filter that connects to the Percutaneous Lead is not waterproof. If water enters the Percutaneous Lead, it could damage the Pump/Drive Unit and cause it to stop.
Steam bath or dry saunas	Moisture may go into the Percutaneous Lead. If water enters the Percutaneous Lead, it could damage the Pump/Drive Unit and cause it to stop. The temperature may also cause the Temperature alarm to sound.
Participation in contact sports	Hard, physical contact with other people or objects could damage the external LVAS hardware, injure internal organs, or interfere with tissue healing at the exit site.

Talk to your doctor before participating in the following types of activities:

Consult Your Doctor Regarding	Comments
Showering	Prior approval of your doctor and a special protective bag are required. See page 8-9.
Driving an automobile or other vehicle (for example, a tractor)	You must first get approval from your doctor. In addition, check your state laws before operating a moving vehicle.
Flying	You must first get approval from your doctor. In addition, talk to the airline about any special requirements that they may have.
Potentially strenuous sports (for example, golfing, jogging, tennis)	You and your doctor can determine together whether participation in a certain sport may pose a danger to either yourself or your LVAS equipment.

The following activities have **no known risk** to you or your LVAS equipment:

No Known Risk
Careful sponge baths
Sexual relations
Housework
Moderate exercise (for example, walking, gardening)
Shopping

9. Self-Care

The Percutaneous Lead (tube coming out of your skin) contains wires that connect the Pump/Drive Unit and the Compact Controller and allow them to communicate. The Percutaneous Lead also serves as a vent for the air displaced by the pump when it relaxes after pumping. The air is between the outer shell of the pump and the pumping chamber, and cannot get into the pumping chamber.

The area where the Percutaneous Lead comes out of your skin is the exit site. It needs a protective bandage or dressing to help prevent infection. Keep this dressing dry.

In addition to a protective dressing, your doctor or nurse may recommend an antiseptic cleanser for cleaning the Percutaneous Lead and the exit site. Use only water-based cleansers. Oil-based cleansers and lotions may slow healing.

When you clean the exit site, look for damage to the Percutaneous Lead. Notify your technical support personnel if there are cracks, nicks, or holes in the outer tubing of the Lead. The Lead can be repaired by your technical support personnel.

9.1 Exit-Site Care

Dressing

Every day, as you clean the exit site, you should look for signs of infection. This can include one or more of the following:

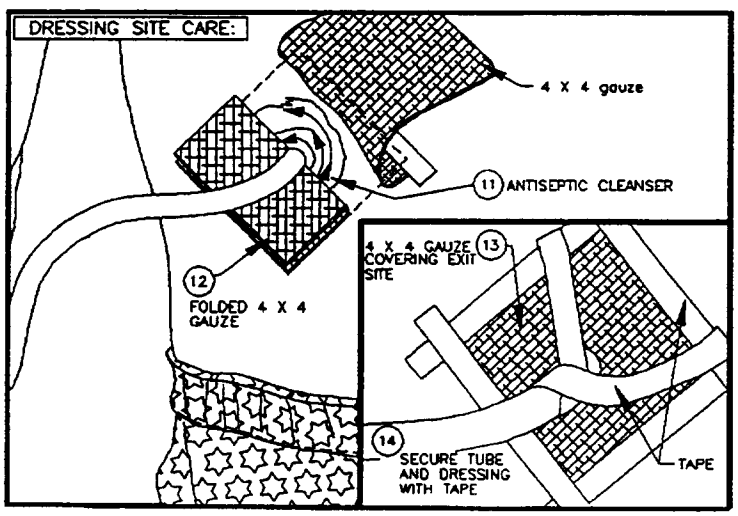
- Redness
- Drainage
- Pain
- Swelling
- Presence of an open sore or ulcer
- Warm to the touch

Note: If there are any signs of infection at the exit site, call your medical support team as soon as possible.

How To Change Your Exit-Site Dressing

1. Assemble materials (1 pair of sterile gloves, 1 pair of non-sterile gloves, sterile saline, antiseptic cleanser, 5 sterile 4x4 gauze packages and tape)
2. Wash your hands with soap and water
3. Put on a pair of non-sterile gloves
4. Remove old dressing
5. Dispose of soiled dressing and non-sterile gloves
6. Re-wash hands as Step #2 above
7. Open five sterile 4x4 gauze packages and sterile saline
8. Pour saline on four 4x4 gauze (2 packages) still on sterile wrapping
9. Put on a pair of sterile gloves
10. Using the wetted 4x4 gauze, clean exit-site area in a circular fashion, beginning close to the Percutaneous Lead and working outward
11. If instructed by your doctor or nurse, clean exit site with antiseptic cleanser, again in an outward circular pattern
12. Place two (1 package) folded dry 4x4 gauze underneath the Percutaneous Lead as a cushion against your skin
13. Place four (2 packages) 4x4 gauze over Percutaneous Lead and exit site
14. Secure dressing with tape

Figure 34 Exit-Site Care



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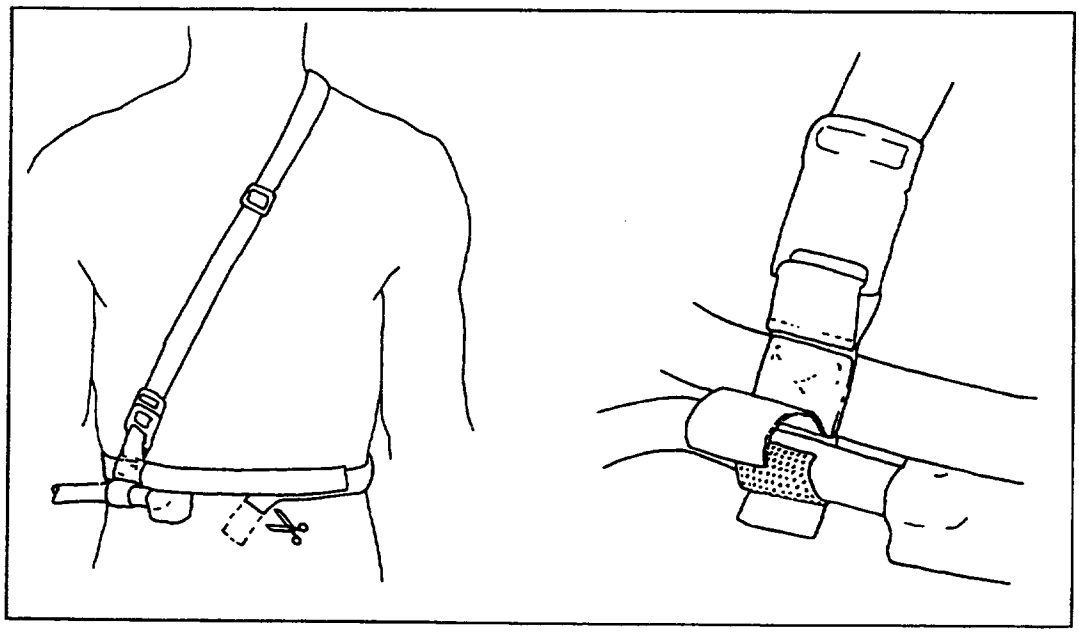
Strain Relief

Within the first few days of the surgery to implant the LVAS, your skin begins to grow around the Percutaneous Lead at the exit site. This is a natural and beneficial action called ingrowth or adhesion. It helps to prevent bacteria from entering your body along the Percutaneous Lead.

Do not pull, tug, bend, or excessively move the Percutaneous Lead. This could interfere with tissue ingrowth or cause the Percutaneous Lead to break away from the skin. Also, excessive bending or pulling of the Percutaneous Lead could damage it or the wires within it.

There are ways to help reduce movement of the Percutaneous Lead at the exit site, reducing the possibility of sores and infection. Ask your technical support personnel about a strain-relief belt, available in 4 sizes, to help immobilize the Percutaneous Lead. You can also use surgical tape for this purpose, or place a gauze cushion against your skin beneath the Percutaneous Lead. Your doctor may recommend other types of strain relief measures. Also, your doctor may recommend using an abdominal binder to provide support to the stomach muscles and incision during your recovery from surgery.

Figure 35 Strain Relief Belt



9.2 Medications

Your doctor will likely prescribe medications to help thin your blood to reduce the risk of blood clots. Take your blood-thinning medications according to your doctor's instructions.

If you forget to take your blood-thinning medications, you should call your doctor to determine what to do.

Note: Do not take extra blood thinning pills to make up for missed doses. Doing so could result in severe bleeding or other side effects.

Note: If you were taking medication before LVAS implant (for example, blood pressure pills), you may still need to take the medication after LVAS implant. Discuss your medication requirements with your doctor.

9.3 Routine Checkups

You, your doctor, and your technical support personnel will decide when and how often you need to be seen by the staff. This will depend on your specific condition, and may change during the course of your treatment.

Some of the things that might occur at your checkups include:

- Vital sign monitoring (blood pressure, heart rate and temperature)
- Inspection of the exit site
- Pump/Drive Unit rate and Pump/Drive Unit output reading
- General physical assessment
- Adjustment of medication dosages
- Blood draws

Note: If you have any questions about LVAS equipment or electrical safety, please call your technical support personnel.

10. Equipment Care And Maintenance

10.1 Equipment Care and Cleaning

Dust the equipment periodically.

Unplug equipment from the wall before cleaning.

Clean all of the equipment periodically by wiping with a clean, damp cloth. Make sure that the cloth is not dripping wet to prevent water from getting inside the equipment.

Caution: Keep all liquids away from equipment to avoid accidental spills. Do not put any of this equipment under water or other liquids. Contact with liquids increases the risk of shock and of damaging the equipment.

The Power Pack Charger has a foam filter on the bottom panel to protect an air intake fan. You should periodically clean this foam either with a vacuum or by gently brushing with a clothes brush or soft toothbrush.

Caution: Do not block ventilation holes. Blocking these openings can cause heat to build up inside and damage the equipment, and may result in failure of the equipment.

Note: If you put the equipment on the carpet, place a flat, solid material (for example, board or tile) on top of the carpeting first.

10.2 Storage

Store all equipment away from extreme temperatures and humidity.

Store spare Power Packs plugged into a Power Pack Charger. If that is not possible, recharge them at least once per week.

10.3 Compact Controller Care

Keep your spare Compact Controller with you at all times.

Do not drop or bump the Compact Controller.

Keep the Compact Controller away from liquids.

10.4 Power Pack Care

Your Power Packs include many features to make them safe and dependable. However, you must care for them properly and avoid exposing them to severe conditions. Otherwise, they may not last as long when you use them, and they may need to be recharged more frequently.

You will get the most use from your Power Packs if you use them until they alarm, rather than frequently recharging them. If you're switching to Untethered mode, always start with a fully charged Primary Power Pack.

Do:

- Store Power Packs fully charged. If you won't be using a Power Pack, store it plugged into the Power Pack Charger. Power Packs may be damaged if they are fully discharged when stored.
- Charge **only** on the Power Pack Charger.
- Keep stored Power Packs and the Power Pack Charger in a cool place. The ideal temperature range is 60°-80°F (15-25°C).
- Rotate use of your Power Packs. If they are not used regularly, they may not last as long, even if they have been stored on the Power Pack Charger.
- If you take a fully charged Power Pack from the Power Pack Charger and don't use it, put it back on the Charger. The Power Pack will recharge briefly. This brief charging won't count as a charge cycle.
- Always protect the Power Pack connectors from dirt and metal. Use the plastic connector cap if you put the Power Packs anywhere that might be dusty, or where metal objects could touch the connector. If metal or dirt gets into the connector, it could cause the Power Pack to short-circuit. This cannot be fixed, and you will have to replace the Power Pack.

Do Not:

- **Do not** let small metal objects near the connector of an unplugged Power Pack. Metal touching the connector pins will blow the Power Pack's internal fuse, making the Power Pack useless. This fuse is sealed inside and cannot be changed.
- **Do not** try to straighten a bent connector pin. Return damaged Power Packs or cables to your technical support personnel.
- **Do not** leave Power Packs in direct sunlight. The temperature can easily reach 140°-150°F (60°-65°C), which can damage the Power Packs.

- **Do not** charge a Power Pack when it is warm to the touch, or cold enough to condense moisture. Charging them at room temperature (normally around 60°-80°F, which is equal to 15-25°C), puts much less stress on them.
- **Do not** drop the Power Packs or let them hit hard objects. This can cause hidden damage that can develop even weeks after a severe blow.
- **Do not** let the Power Pack swing by its cord. This could cause the wires in the cord to break.

Recommended combinations of power sources are:

- Personal Monitor with a Reserve Power Pack (Tethered)
- Primary Power Pack with a Reserve Power Pack (Untethered)

The Compact Controller draws power from the Reserve Power Pack only when the Primary Power Pack is depleted, when the Personal Monitor has lost power, or when either of these is unplugged from the Compact Controller.

Note: Do not connect two of the same type of Power Packs to the Compact Controller.

If plugged into two of the same type of Power Packs, the Compact Controller will use power from both at the same time. Both packs will become low and give a low power alarm. If you do not replace the Power Packs at the low power alarm, eventually both Packs will become empty at the same time.

10.5 Power Pack Charging

You can recharge Power Packs approximately 200 times before you must replace them with new Power Packs. When plugged into the Power Pack Charger, the Power Pack will let you know that it has reached this limit by rapidly flashing its lights and beeping. Replace the Power Pack shortly after this happens.

When plugged into the Charger, a Power Pack will periodically cause the green light on the Charger to blink yellow. This is normal, and tells you that the Power Pack's charge is being maintained.

Leave the Power Pack plugged into the Charger until charging is complete. If you remove the Power Pack from the Charger before it charges fully, the Power Pack may say that it is "Low" before it really is.

Note: When not plugged into the Power Pack Charger, the Power Packs will slowly lose some charge. Try to keep any Power Packs you are not using plugged into the Power Pack Charger.

10.6 Getting The Most From The Standby Power Source

The Standby Power Source can run the Novacor® LVAS about three times as long as a fully charged Primary Power Pack. However, you can recharge a Primary Power Pack and reuse it many times, but the Standby Power Source is not rechargeable.

Because you cannot recharge the Standby Power Source, you need to minimize unintentional discharge. Here is how to get the longest life from the Standby Power Source:

- During storage, keep it in the coolest part of the room and out of sunlight. Heat shortens the Standby Power Source storage life.
- Use the Standby Power Source at room temperature. Using it at colder temperatures will decrease the amount of time that it can power the system.
- When you do the alarm test, the Personal Monitor tells you the length of time that the Standby Power Source can provide power.

Replace the Standby Power Source soon after the "Best If Used By" date on the back panel.

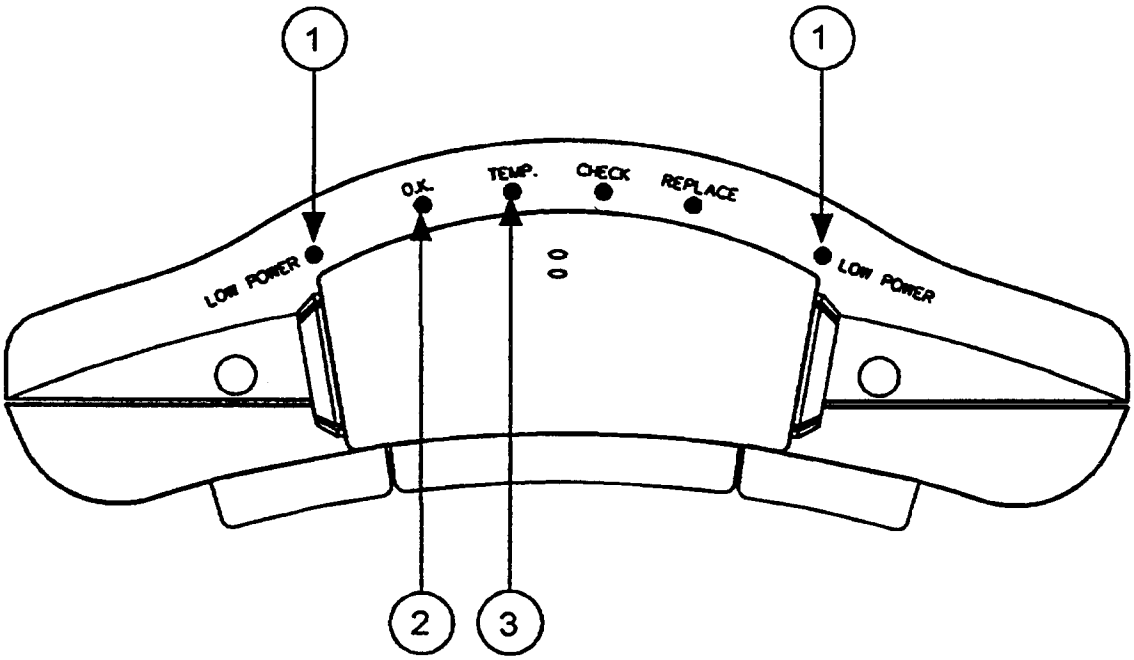
Call your technical support personnel to obtain a replacement Standby Power Source, or if you have concerns about the remaining capacity of the Standby Power Source.

11. Status Lights And Meanings

11.1 Compact Controller

The Compact Controller has six status lights on the top. If there is no power to the Compact Controller, the lights and alarms will not come, and the Pump/Drive Unit will stop.

Figure 36 Status Lights on the Compact Controller

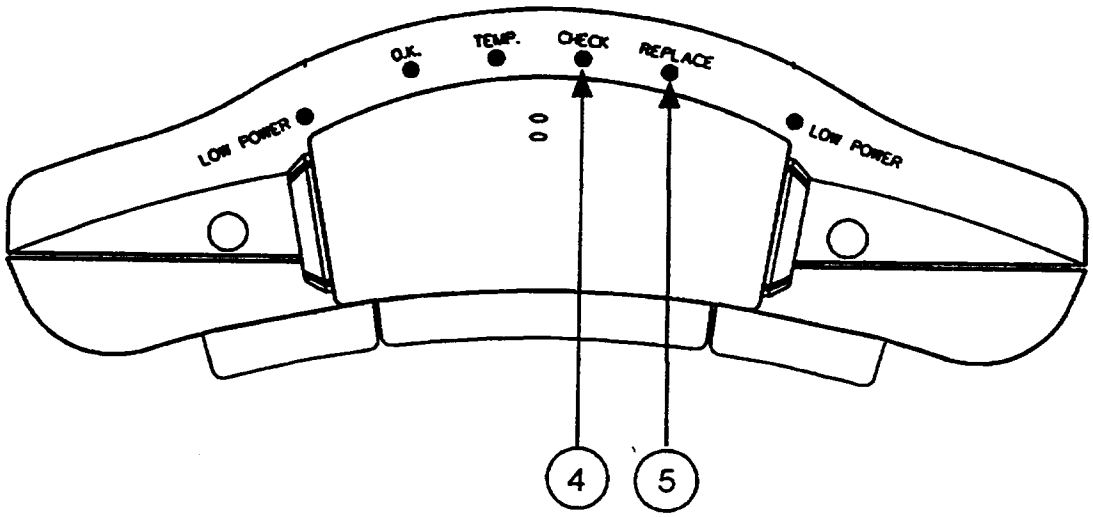


① "Low Power" (two lights)
A red light near each of the two power connectors. "Low Power" lights when a power source is not plugged into that connector, or when the power source connected is too low. A single, continuous alarm will sound after the light is lit for more than 30 seconds

② "O.K."
This green light means that the Compact Controller is receiving power and the Pump/Drive Unit is operating normally.

③ "Temp."
This yellow light means that the Compact Controller is very warm. There will be a single beep alarm every 15-20 seconds. The Compact Controller still works during and after a "Temp." alarm.

Figure 37 Status Lights on the Compact Controller



④ "Check"
This yellow light means there is an alarm condition in the implanted components or in the Compact Controller. It can also be a sign of a medical problem. A continuous tone means the alarm is urgent and should be taken care of immediately. A pattern of beeps means the alarm is not urgent. You can connect to the Personal Monitor to determine the cause.

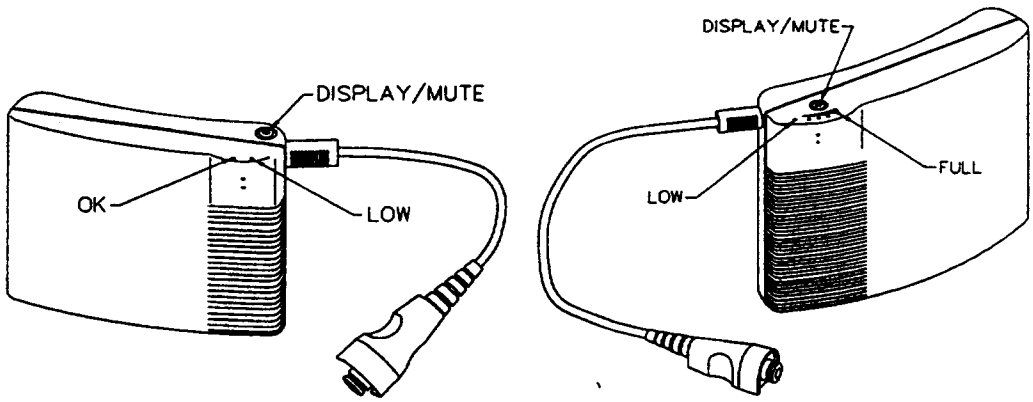
⑤ "Replace"
This red light means there is a potentially serious condition. A continuous tone will sound with the Replace light.

Note: The "OK" light should be lit when power is connected unless one of the other three indicators (Temp, Check or Replace) is lit.

11.2 Power Packs

Each Power Pack has a Display/Mute button. This button will display the charge level of the pack and/or silence an alarm when pressed.

Figure 38 Location of Status Lights and Controls on Power Packs
Reserve Power Pack (left) and Primary Power Pack (right)



Status Lights

Green Lights

- Will only light when you push the Display/Mute button.
- Tell you the remaining charge.
- Tell you the Reserve Power Pack is O.K. and has an acceptable charge level.
- Tell you how long the Primary Power Pack can be used. Each light is typically about an hour. For example, 3 lights mean that you can use it approximately 3 hours, 2 lights would mean 2 hours, etc.
- The Power Packs will sound a **Single Beep** every time you press the button and when you plug in to either the Charger or the Compact Controller.

Any Red Light means you need to check, and possibly replace, your Power Pack immediately. See "Responding to Power Pack Alarms", page 12-8.

Power Pack Run-Time

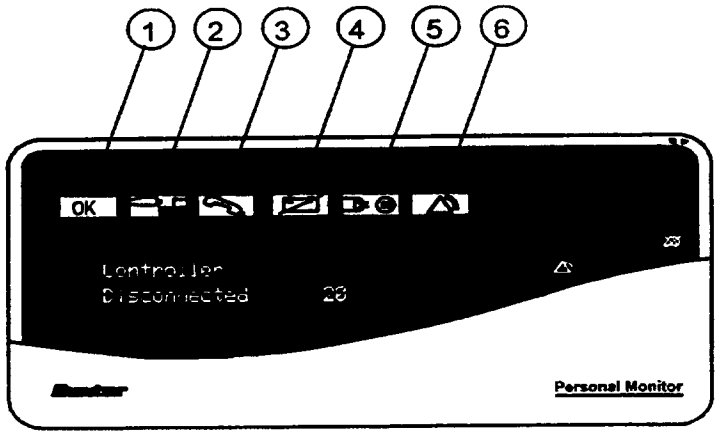
Power Pack	Typical Run-Time	"Low" Alarm	Time Remaining With "Low" Alarm
Primary Pack	4 hours - fully charged	Red light with double beep	Approximately 1 hour
Reserve Pack	1 hour - fully charged	Red light with double beep	15 - 30 minutes (Replace immediately!!)

11.3 Personal Monitor

A row of symbols on the front panel of the Personal Monitor tells you the general condition of the LVAS. A loud alarm from the Personal Monitor will alert you to conditions that require immediate attention.

The message display, a small screen on the front panel, provides additional information and will tell you what to do about alarms.

Figure 39 The Personal Monitor Indicator Lights



The **Personal Monitor indicator lights** are:

① OK **"OK"** -- The system is operating normally.

② **"Controller Disconnected"** -- The Personal Monitor is not plugged into the Compact Controller, or there is a fault in the Monitor/Controller cable.

③ **"Call"** -- Call your technical support personnel.

④ **"Standby Power Source"** -- The Standby Power Source is low, discharged or unplugged.

⑤ **"AC Power Disconnected"** -- The AC power cord is unplugged from the wall socket, or there is a power failure.

⑥ **"Urgent Alarm"** -- A serious condition exists. Immediate attention required.

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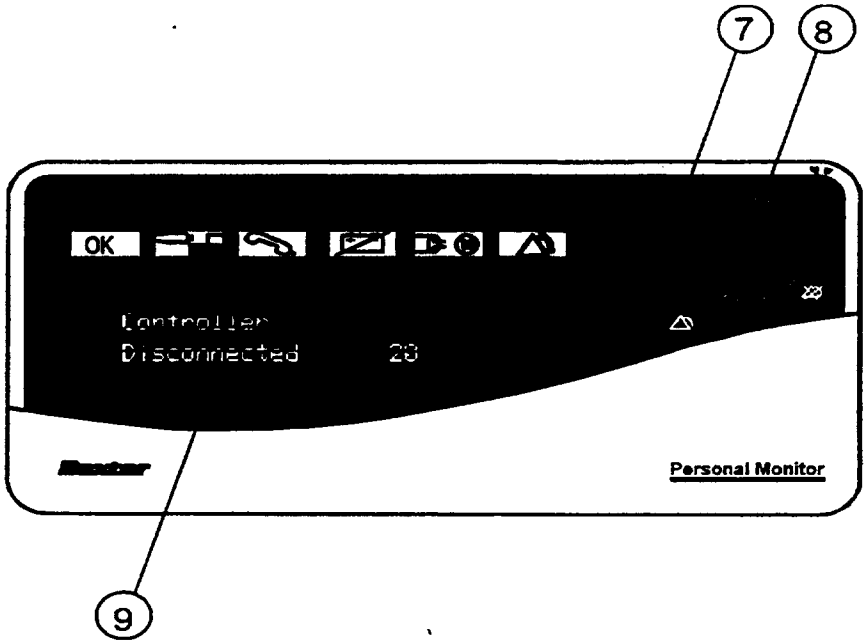
Figure 40 The Personal Monitor Buttons and Display Screen



⑦ **"Alarm Test and Power Status"** - Pushing the smaller button once will test the Personal Monitor and Compact Controller alarms and display the power status of the Standby Power Source. In turn:

1. The Personal Monitor symbols will light and the alarm will sound.
2. Following that, the Compact Controller indicators will light and the alarm will sound.
3. At the end of the alarm test, the remaining amount of time that the Standby Power Source can supply power will be displayed in the Message Display (⑨ in Figure 40), as in the following example:

```
Standby Power Source:
8-10 hours
```

⑧ **"Alarm Mute and Scroll"** - Pushing the larger button will turn off the alarm sound and scroll through any messages:

1. The first push will turn off the alarm sound, while displaying the alarm message, such as the "Controller Disconnected" message shown in the Message Display, number ⑨, in Figure 40.
2. Each push after that will bring up a new message, until the last one is reached.
3. The last message displayed will be the LVAS Status message, shown on the next page.

LVAS Status Message

The current LVAS status will be displayed as in the example below:

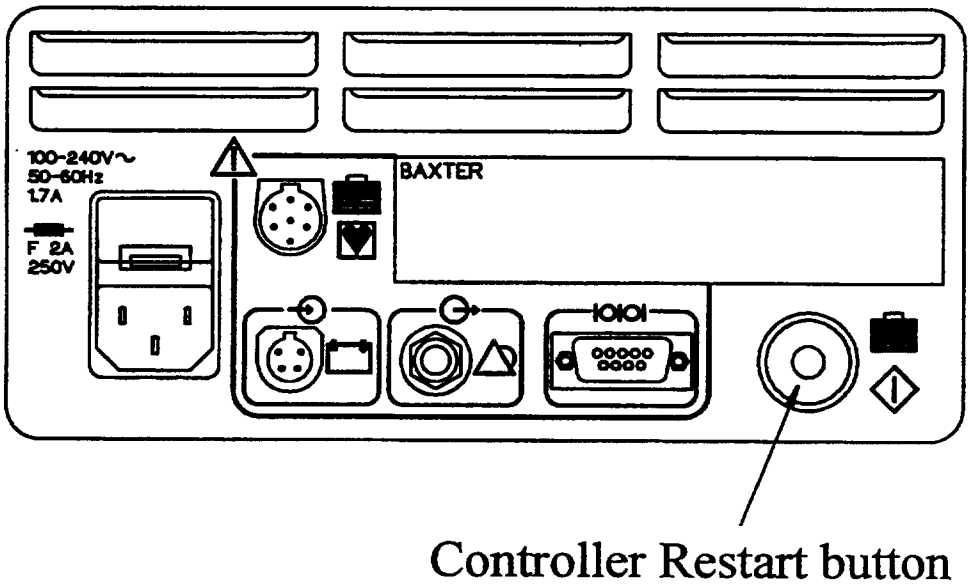
PO:	6.6	PR:	102	SV:	65
RV:	05	FR:	322	ER:	410

If you call a member of the technical support personnel in response to an alarm, they may ask you to read the numbers on the screen to them over the phone.

The Controller Restart Button

The **"Controller Restart"** button is located on the Personal Monitor back panel. Press Controller Restart only if directed to do so by the Personal Monitor message display or by your technical support personnel.

Figure 41 The Location of the Controller Restart Button



12. Emergency Response And Troubleshooting

12.1 Emergency Response

An emergency situation may be caused by conditions requiring medical care (see page iv) or by a mechanical problem that interferes with the pumping ability of the LVAS. It is important to learn how to identify and respond to an emergency. The most important action is to restore power and function to the LVAS system.

If there is a question in an emergency, or if your pump stops and cannot be restarted within 2 minutes, **contact your technical support personnel. If necessary, dial 911 (or your local emergency number) for medical assistance**. Keep a list of emergency numbers with your extra equipment.

Respond to the following alarms or messages **immediately**:

Personal Monitor Messages

- Low Pump Output
- Reconnect Controller
- Replace Controller Now

Compact Controller Alarms

- Low Power
- Replace
- Check

Keep extra components on hand and in good condition. Always carry an extra Compact Controller and two Primary Power Packs. If there is a problem with your system, you may need to quickly replace some of the components, particularly the Compact Controller (see next page).

Replacing The Compact Controller

If the "Replace" light on the Compact Controller comes on, there is a potentially serious condition within the Compact Controller.

Replace the Compact Controller **immediately:**

- If the "Replace" light comes on
- If the Pump/Drive Unit stops and does not restart

Never wait more than two minutes before replacing the Compact Controller if the Pump/Drive Unit has stopped. Call technical support as soon as possible after replacing the Compact Controller.

If the Pump/Drive Unit has stopped, check the following:

1. The status lights on the Compact Controller
   A "Replace" light or "Check" light with a continuous tone means that the Compact Controller should be replaced **immediately!**

2. Connections
   A loose connection could cause the pump to stop.

3. Power Packs
   An empty or malfunctioning Power Pack cannot supply energy to operate the Pump/Drive Unit.

If these steps do not restart the Pump/Drive Unit, immediately follow the steps on the next pages to replace the Compact Controller.

Caution: **The pump will stop briefly while the Compact Controller is being replaced. Make sure that the Compact Controller needs to be replaced before beginning.**

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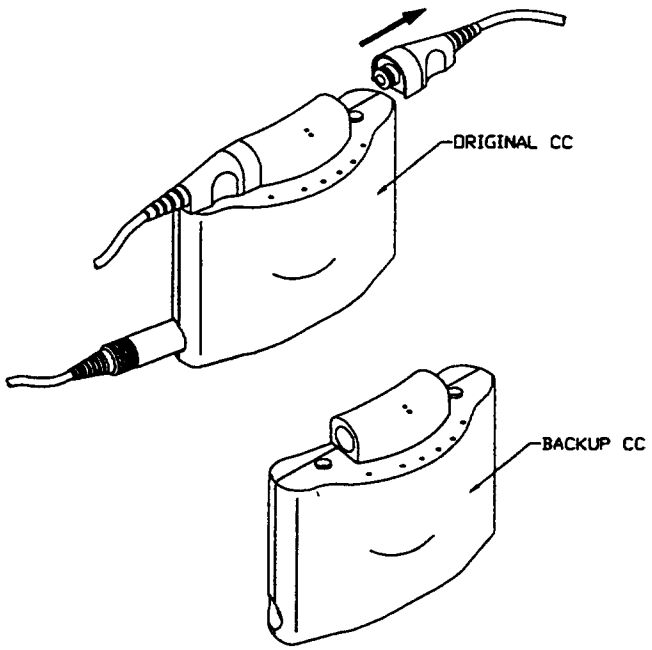
1. Have the backup Compact Controller next to you before you begin.
2. Unplug one power source from the Compact Controller.

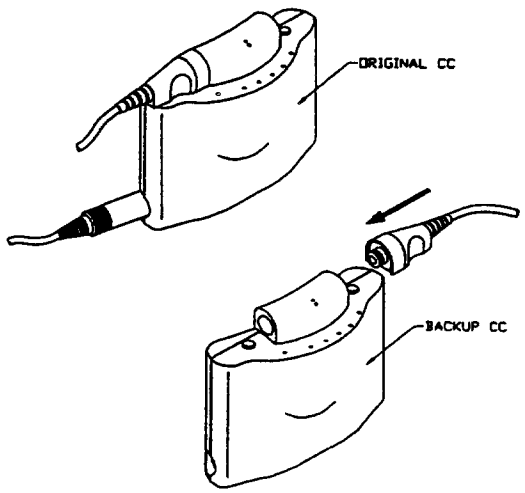
Figure 41 Unplugging a Power Source



3. Plug it into the backup Compact Controller.

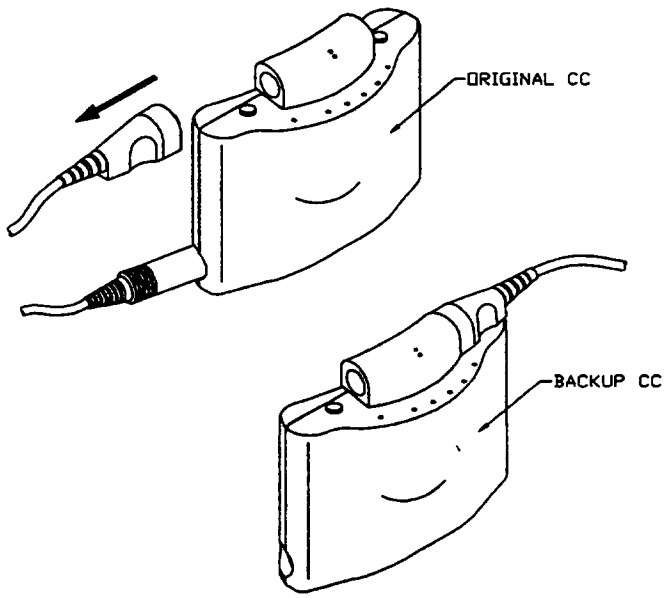
   Since the Percutaneous Lead is not connected yet, the backup Compact Controller will sound a continuous tone and light the "Check" light. One "Low Power" light will light, indicating there is only one power source.

Figure 42 Plugging the Power Source into the Backup Compact Controller



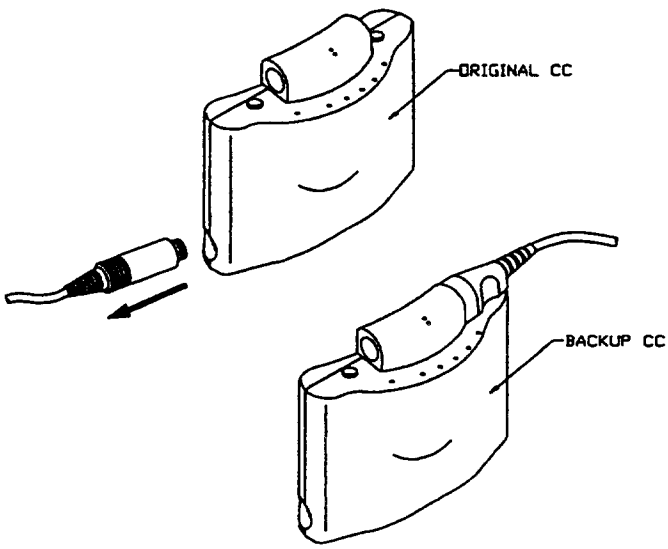
4. Unplug the other power source from the original Compact Controller. **This will stop the Pump/Drive Unit.** Make sure that you (the recipient) are sitting or lying down before stopping the pump.

Figure 43 Unplugging the Other Power Source



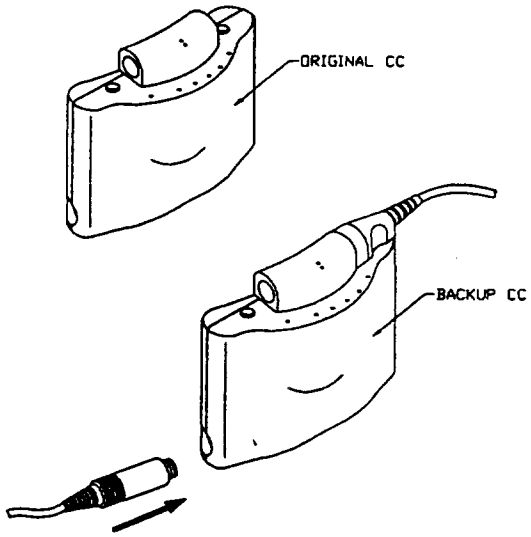
5. Disconnect the Percutaneous Lead from the original Compact Controller.

Figure 44 Disconnecting the Percutaneous Lead



6. Connect the Percutaneous Lead to the new Compact Controller. The Pump/Drive Unit should begin pumping within 3 seconds. If so, go to step 6. If the Pump/Drive Unit does not start pumping, check all connections.

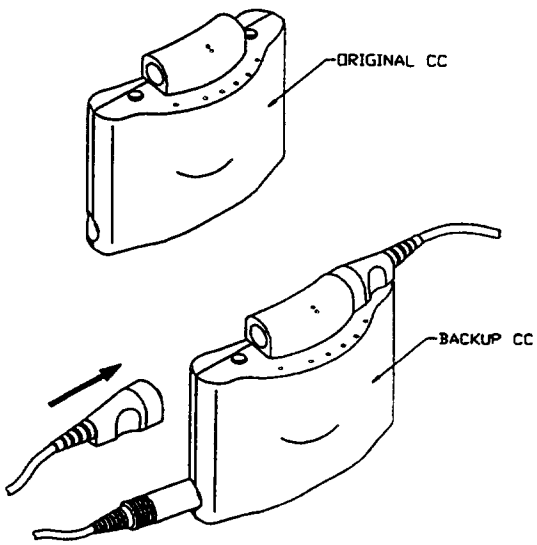
Figure 45 Connecting the Percutaneous Lead to the Backup Compact Controller



7. Plug a second power source into the new Compact Controller. The second power source may be either a Power Pack or the Personal Monitor.

   If you are in Untethered operation and get any alarms, connect to the Personal Monitor as soon as possible to determine the cause of the alarm.

Figure 46 Plugging Other Power Source to Backup Compact Controller



8. Contact technical support as soon as possible.

Power Outages

Caution: **You must always have the Standby Power Source plugged into the Personal Monitor while you are sleeping. The Personal Monitor cannot operate or sound alarms when the power goes out unless it gets power from the Standby Power Source. The Compact Controller will alarm for "low power," but if you don't hear that alarm, your Reserve Power Pack could run low and your Pump/Drive Unit could stop.**

Power outage information

Plan ahead. The power may go out at any time.

- Always have a working flashlight nearby.
- Have a phone that will work when the power is out.
- Always keep one or more extra Primary Power Packs fully charged and ready to use in case power doesn't return for several hours and you must leave the area of the power outage.
- Your local power company may have a priority list for reestablishing power after an outage. Contact your local power company to be added to this list.
- The Standby Power Source will supply power to the Personal Monitor.
- If you get a "Low Power" alarm on the Compact Controller while connected to the Personal Monitor, the Personal Monitor probably is not supplying power. This will happen during a power outage if the Standby Power Source is not plugged in or becomes empty. In this case, the Compact Controller draws power from the Reserve Power Pack. You should replace the Standby Power Source with a spare, if possible. If a spare one is not available, plug a Primary Power Pack into the Compact Controller in place of the Personal Monitor.

Standby Power Source Management

- The Personal Monitor will show the estimated remaining run time of the Standby Power Source when you press the small button on the front panel.
- If the run time on the Standby Power Source is very low, the Personal Monitor will sound an alarm and show a message. You should replace the Standby Power Source soon after getting this message. It is a good idea to keep an extra Standby Power Source on hand. Call your technical support personnel

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(listed on the inside front cover) for details on ordering a spare Standby Power Source.

- The Standby Power Source is not rechargeable. Use only when necessary, such as during a power outage. If you have at least three fully charged Primary Power Packs, you may want to use one to supply power to the Compact Controller during the power outage. This will let you save the power in the Standby Power Source. Do not use your last two charged Primary Power Packs. Save these in case it is necessary to move to a place where emergency power is available.

Note: If the Standby Power Source power level is low and you do not have a spare during a power failure, you should move to the nearest spot where emergency generators are available.

12.2 Troubleshooting

Responding To Compact Controller Alarms

The lights of the Compact Controller are the primary indication of LVAS condition. Connect the Compact Controller to the Personal Monitor and press the large alarm mute button to page through the alarm message display. Writing down the alarm message number will help you to monitor the performance of your LVAS, and will help the technical support personnel find the cause of problems. See page 12-9 and 12-10 for more information on how to handle the alarm.

"O.K."	No alarms
"LOW POWER"	Connect a fully charged power source to the power input connector next to the indicator
"TEMP."	Provide good air cooling for the Compact Controller
"CHECK"	Connect the Compact Controller to the Personal Monitor for more information and instructions. Record the message number.
"REPLACE"	The Compact Controller should be replaced immediately. Record the situation that seemed to cause the alarm.

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Responding to Power Pack Alarms

The information in this section helps you use your Power Packs safely while getting the most service from them.

The lights and alarms of the Power Packs provide information about the charge level of the pack. The Power Pack will also alarm each time you disconnect it from the Compact Controller or from the Charger.

Red Lights

- Tell you about a warning. The conditions that most frequently cause warnings are low power or disconnection.
- Red Lights may appear automatically or when you press the Display/Mute button.

Any Red Light means you need to check, and possibly replace, your Power Pack immediately.

The Red Lights have the following alarm sounds:

- **Single Beep (every 15 seconds, no red light)** = the Reserve Power Pack is supplying power to the Compact Controller. You need to attach another power source in addition to the Reserve Power Pack.
- **Double Beep Pattern** = Power Pack is low and should be replaced as soon as possible.
- **Triple Beep Pattern** = Power Pack is not functioning or is unplugged. Check connections and/or replace.
- **A Single Beep and flashing of all lights, repeated three (3) or more times** when a Power Pack is plugged into the Power Pack Charger. = The Power Pack has been recharged more than 200 times and should be replaced. If the Power Pack is hot to the touch, it may be giving an over-temperature alarm. Let the Power Pack cool and try to recharge it. If it still alarms, replace the Power Pack.

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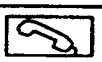
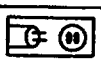
Responding to Personal Monitor Alarms

The Compact Controller alarms are the primary source of information about the LVAS. The messages below provide more information about the specific Compact Controller alarms and possible causes. Read the table by **first** looking for the Compact Controller status light that is currently lit, **then** for the Personal Monitor symbol and message currently shown. In the Alarm column, PM stands for Personal Monitor, and CC for Compact Controller. Recording the number associated with the message will help your technical support personnel find the cause of the alarm.

CC Status Light	PM Symbol Light	Personal Monitor Display	Alarm	Possible Message Number	Suggested Response
"OK"		(None)	No	None	None required
"OK"		Replace Controller Now	No	01	Check Personal Monitor/Controller Cable.
"REPLACE"		Replace Controller Now	CC	01, 02, 03, 05	Replace the Compact Controller immediately.
"CHECK"		Replace Controller Now	CC	06, 09	Quickly check all connections to the Controller. Replace Controller immediately if checking connections does not restore normal operation.
"CHECK"		Check Pump Cable Connection	CC	04	Check all connections between Pump/Drive Unit and Compact Controller.
"CHECK"		Press Rear button once	CC	08	Press "Restart" button on back of Personal Monitor. Call technical support personnel.
"CHECK"		Low Pump Output: Call Doctor	CC	07	Check Pump/Drive Unit connections and call for medical assistance.
"CHECK"		Press Rear button once	CC	31, 32	Press "Restart" button on back of Personal Monitor. Call technical support personnel.

CC Status Light	PM Symbol Light	Personal Monitor Display	Alarm	Possible Message Number	Suggested Response
"CHECK"		Replace Controller not urgent	CC	08, 09, 31, 32, 35, 36, 37	Check connections between Pump/Drive Unit and Compact Controller. Replace Compact Controller (with assistance and in a controlled environment) within 1 day if condition is not resolved. Call technical support personnel.
"LOW POWER"		Check Controller Power Inputs	CC	11	Check Monitor/Controller Cable, Reserve Power Pack.
"TEMP"		Uncover Controller: Too Hot	CC	10	Ensure good ventilation around Compact Controller.

The following alarms tell you about problems with the Personal Monitor or Standby Power Source. They can happen at the same time as any of the Compact Controller alarms, or without a Compact Controller alarm. If there is a Compact Controller alarm, consult the previous table **first**.

PM Symbol Light	Personal Monitor Display	Alarm	Possible Message Number	Suggested Response
	Replace Personal Monitor	PM	91, 92, 93, 94, 95, 98	Replace the Personal Monitor.
	Replace Controller Cable	PM	13	Check, replace Personal Monitor/ Controller Cable.
	Reconnect Controller	PM (can't be silenced)	14	Reconnect the Compact Controller (connection to the Controller is required to silence this alarm).
	Controller Disconnected	No	20	Plug a Primary Power Pack into Compact Controller's free input connector for Untethered operation.
	Check Power Cord: No AC/Mains Power	PM (after 5 minutes)	12	Check power cord, AC/mains power.
	Standby Power Source Disconnected	PM	17	Reconnect the Standby Power Source.
	Standby Power Source Very Low: Replace	PM	19	Replace the Standby Power Source with a new unit.

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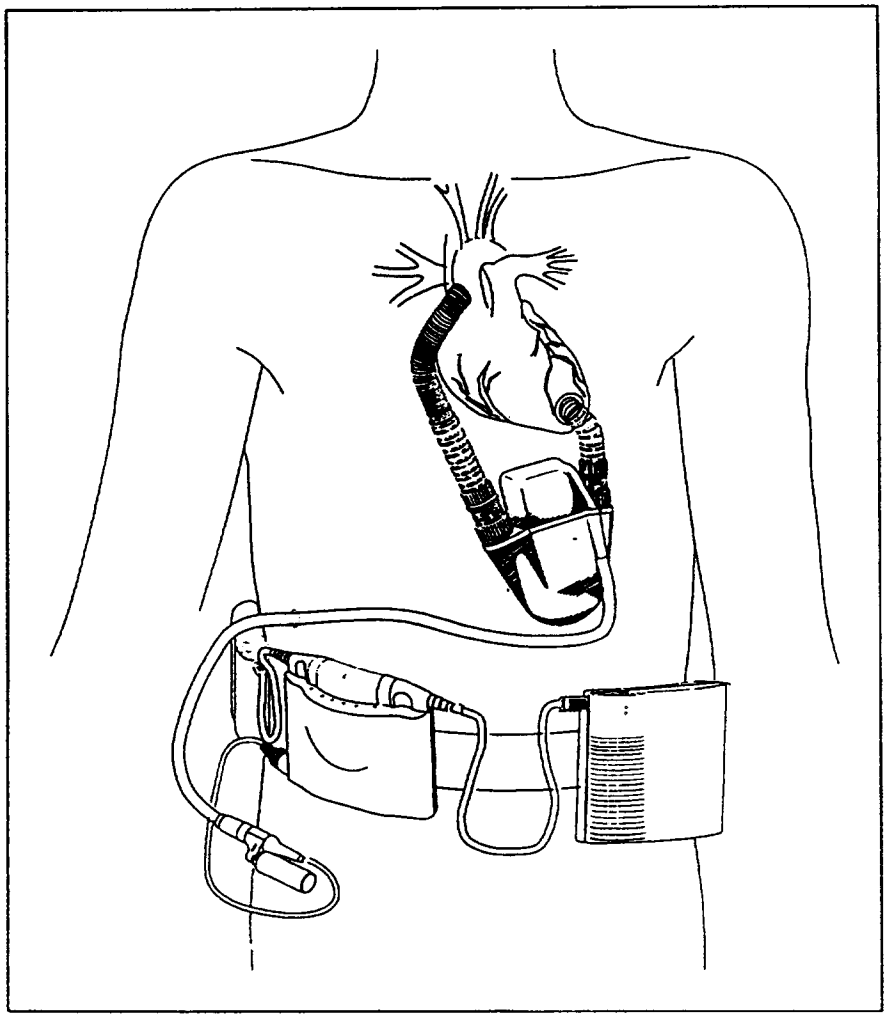
Physician's Manual

Novacor® LVAS



Baxter

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Technical Support And Service

Any suspected problems should be immediately evaluated by a trained LVAS Operator. Phone numbers of personnel trained to troubleshoot the system should be available to the clinical staff. For additional assistance, or to report any device problems, contact Novacor technical support at the location below:

Baxter Healthcare Corporation
Novacor Division
Technical Support Department
7799 Pardee Lane
Oakland, California 94621 USA

1-510-568-8338
Fax: 1-510-633-0467

Cellular phone (24 hours):
1-510-414-9186
1-888-THE LVAS

Emergency pagers (24 hours):
1-510-633-8389
1-510-633-8364

Baxter Healthcare Corporation
Novacor® Division
7799 Pardee Lane
Oakland, California 94621

Specification Number
GCP 9105-1097
Revision A

Catalog Number
N20072

Table Of Contents

Device Description

The Novacor® LVAS (also referred to as the LVAS), an implanted electronic left ventricular support device, provides circulatory support in patients with end-stage heart failure.

Intended Use/Indications

The LVAS is intended for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from nonreversible left ventricular failure. The LVAS is indicated for use both inside and outside the hospital.

Individualization of Treatment

Clinical experience has shown that successful LVAS support depends on correct patient selection and timing of implantation.

The safety and effectiveness of the LVAS has not been demonstrated in pregnant or nursing women.

Contraindications

The LVAS is contraindicated in patients with primary coagulation or platelet disorder, or with a body surface area less than $1.5m^2$ or greater than $2.5m^2$.

Warnings

Do not use this device without proper training. Ensure that all people who will be involved with this device have been properly trained. This includes doctors, nurses, patients, and family members.

Maintaining Device Effectiveness

Periodic functional and safety tests must be performed in accordance with the Operator's Manual.

Patient Counseling Information

Risks associated with use of the LVAS include the possibility of: infection, bleeding, thromboembolism and resultant CNS ischemic injury and neurological deficit, hemolysis, device failure, or reduced flow that could result in a cardiac index of less than 2.0 $L/min/m^2$, any of which might result in ineligibility for heart transplantation and/or death.

How Supplied

The implantable components of the LVAS, e.g. the Pump/Drive Unit, are supplied sterile and non-pyrogenic. The external Compact Controller and monitors/power supplies are supplied non-sterile.

1. About This Manual

This manual describes the operation and use of the Novacor® LVAS (also referred to as the LVAS) from Baxter Healthcare Corporation. Refer to the Operator's Manual for detailed information. This manual consists of the following sections:

1 **About This Manual**
Briefly describes the information presented in each section of the manual.

2 **Brief Device Description**
Briefly describes the LVAS, how it functions, and its significant physical and performance characteristics. More detailed information about the LVAS is found in Section 14, Device Description.

3 **Indications**
Describes the functional capability of the LVAS and the patient population in which the LVAS can be used without unreasonable risk of illness or injury associated with the LVAS.

4 **Contraindications**
Describes the conditions under which the device should not be used because the risk of use clearly outweighs any benefit.

5 **Warnings And Precautions**
Informs about hazards other than those that are contraindications to LVAS use. Warnings concern potential serious outcomes, such as death or serious injury. Cautions alert the user to exercise special care for the safe and effective use of the device.

6 **Adverse Events**
A list of the adverse events observed during clinical trial of the Novacor® LVAS.

7 **Clinical Study**
Describes the clinical study performed to support the indicated use. Includes the study design and endpoints, description of the patients studied, the methodology involved in gathering the data, and the results.

8 **Patient Selection and Individualized Treatment**
Provides guidance on determining the suitability of the device in a particular patient and on determining the appropriate timing of implantation.

9 **Patient Counseling Information**
Provides points to consider in counseling the patient about the LVAS.

10 **Conformance To Standards**
References standards and specifications used in the design, manufacture, or evaluation of the LVAS.

11 **How Supplied**
Information about how the LVAS is supplied, the additional equipment required for safe use, and such relevant information as sterility information.

12 **Operator's Manual**
Describes the contents of the Operator's Manual, the maintenance schedule for the device, a complete description of the device, and a summary of the directions for use.

13 **Recipient's Guide**
Provides a synopsis of the information provided to the LVAS recipient in the Recipient's Guide.

14 **Device Description**
Gives a detailed description of the device, its operating modes and controls.

15 **Directions for Use**
Tells how to use the LVAS Monitor, Compact Controller, and Personal Monitor. Includes LVAS setup and the Implant and Explant Procedures.

16 **Maintaining Device Effectiveness**
Lists the maintenance required to ensure optimal performance.

2. Brief Device Description

The Novacor® LVAS, an implanted electronic left ventricular assist system from Baxter Healthcare Corporation, operates in series with the left ventricle (LV) to provide circulatory support by taking over most of the work of the native LV. There are five major components that, when integrated, form the Novacor® LVAS: the Implant, Compact Controller, Power Packs (Primary and Reserve), LVAS Monitor and Personal Monitor.

The Implant, the implanted portion of the LVAS, consists of an integrated Pump/Drive Unit with a percutaneous lead carrying the control and power leads, bioprosthetic Valved Conduits, an Inflow Conduit and an Outflow Conduit. The device is implanted anteriorly within the left upper quadrant of the abdomen. The pump Inflow Conduit pierces the pericardial portion of the diaphragm to receive blood from a cannula inserted, via the apex, into the left ventricular cavity. The Outflow Conduit is anastomosed to the aorta.

Typically, during systole, the LV contracts and fills the pump. During diastole, the LV relaxes and fills with blood from the left atrium, while blood in the pump is ejected into the aorta. Thus, the LV only has to work against a very low pressure to fill the pump, and the pump takes over the major work of the LV by pumping blood against systemic blood pressure in the aorta. Further description is found in Section 14.

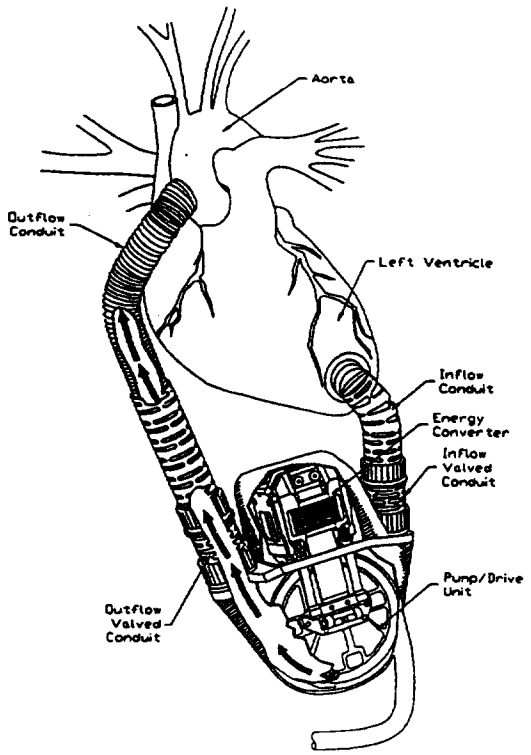


Figure 2-1 The Novacor® LVAS Within The Circulatory System

3. – Indications

The LVAS is intended for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from nonreversible left ventricular failure. The LVAS is indicated for use both inside and outside of the hospital.

4. Contraindications

The LVAS is contraindicated for use in patients with:

- Primary coagulation or platelet disorder
- Body surface area less than 1.5m^2 or greater than 2.5m^2.

5. Warnings And Precautions

General Considerations

Warnings

- Do not use this device without proper training. Ensure that all people who will be involved with this device have been properly trained. This includes doctors, nurses, patients, and family members.

- Do not recommend this device for a recipient with a mechanical prosthetic aortic valve. Flow through the aortic valve will be reduced because of the flow to the LVAS, increasing the risk of fibrin deposition on the mechanical valve, potentially resulting in emboli.

- Do not use this device in a patient with primary right ventricular failure and/or fixed pulmonary hypertension without concomitant therapy to reduce the hemodynamic consequence of these conditions. Both of these conditions (either individually or in combination) have the potential to cause reduced filling of the LVAS.

- Do not use this device in a patient that needs to undergo magnetic resonance imaging (MRI) procedures. MRI may interfere with the action of the Pump/Drive Unit solenoid, resulting in irregular pumping. It could also cause the Pump/Drive Unit to move, possibly unseating the conduits and resulting in severe injury.

- Do not use the LVAS within an oxygen-enriched environment, such as a hyperbaric chamber. As with all equipment of this type, an oxygen-enriched environment increases the flammability of materials (such as plastics and metals) which increases the risk of fire. **This does not apply to the use of conventional oxygen therapy via mask or nasal tubes.**

Precautions

- Do not resterilize any component of the LVAS.

During Implant

Warnings

- Use care in deairing the pump in order to avoid the possibility of air emboli.

Precautions

- Do not implant the Valved Conduits directly. They are to be used only as a component of the LVAS.
- Rinse the Valved Conduits according to the instructions in this manual before installing them into the LVAS. This will remove the glutaraldehyde solution in which they are stored.

Post-Implant Care

Warnings

- Do not disconnect both power sources from the Compact Controller at the same time. This will cause the Pump/Drive Unit to stop. Reconnect either power source to restart the Pump/Drive Unit.

Precautions

- Contact Novacor before starting any therapeutic radiation treatment. Radiation treatment may damage some of the implanted components.
- Use only water-soluble antiseptic cleansers around the exit site. Ointments may delay tissue ingrowth into the Percutaneous Lead.

6. Adverse Events

Table 6-1 provides a detailed summary of the adverse events observed during the clinical trial of the Novacor® LVAS. The table provides adverse event data for both the LVAS and CONTROL patients. The total event category includes, in addition to device related events, those events attributed to pre-existing patient conditions, surgical procedures (e.g., events known to be related to cardiopulmonary bypass), patient management (e.g., related to the use of other mechanical assist devices [RVAD], embolism or infection secondary to indwelling catheter or monitoring line), and disease progression. Within each category there are three columns: the first column lists the number of patients who experienced each adverse event, the second column lists the percentage of patients who experienced each event, and the third column lists the total number of events that occurred during the trial.

Please note that the data presented in the table is based on comprehensive definitions developed specifically for this study. Therefore, comparisons with other devices, or other studies, may not be appropriate.

Table 6-1 Summary of Adverse Event Data

	LVAS Patients (156)			Control Patients (35)		
	Total Events			Total Events		
Adverse Event Type	# of Patients	% Patients (95% CI)	# of Events	# of Patients	% Patients (95% CI)	# of Events
Bleeding	62	39.7% (32.0%, 47.9%)	102	0	0.0% (N/A)	0
Blood Pump/Drive Failure	1	0.6% (0.0%, 3.5%)	1	N/A	N/A (N/A)	N/A
Cardiac Tamponade	26	16.7% (11.2%, 23.5%)	31	0	0.0% (N/A)	0
Cardiovascular Dysfunction	53	34.0% (26.6%,42.0%)	69	26	74.3% (56.7%, 87.5%)	50
Control System Failure	0	0.0% (N/A)	0	N/A	N/A (N/A)	N/A
Embolism (CNS)	42	26.9% (20.1%, 34.6%)	61	0	0.0% (N/A)	0
Embolism (Non-CNS)	23	14.7% (9.6%, 21.3%)	39	8	22.9% (10.4%, 40.1%)	11
Hemolysis	1	0.6% (0.0%, 3.5%)	1	0	0.0% (N/A)	0
Hepatic Dysfunction	59	37.8% (30.2%, 45.9%)	63	8	22.9% (10.4%, 40.1%)	8
Infection	103	66.0% (58.0%, 73.4%)	195	16	45.7% (28.8%, 63.4%)	26
Neurologic Deficit	64	41.0% (33.2%, 49.2%)	96	3	8.6% (1.8%, 23.1%)	5
Other[1]	47	30.1% (23.1%, 38.0%)	68	6	17.1% (6.6%, 33.6%)	13
Renal Dysfunction	42	26.9% (20.1%, 34.6%)	47	15	42.9% (26.3%, 60.6%)	15
Reoperation	74	47.4% (39.4%, 55.6%)	146	10	28.6% (14.6%, 46.3%)	11
Respiratory Dysfunction	53	34.0% (26.6%, 42.0%)	63	14	40.0% (23.9%, 57.9%)	22
Right Ventricular Dysfunction	16	10.3% (6.0%, 16.1%)	16	5	14.3% (4.8%, 30.3%)	5

1 The "other" category includes all other adverse events not specifically defined in this study. Some examples are adverse drug reactions, chest tube insertion, wound debridement, slow continuous ultrafiltration for volume removal, ischemic bowel unrelated to embolism, elevated panel reactive antibodies and pulmonary edema.

7._ Clinical Study

The Novacor® LVAS was studied as a bridge to cardiac transplantation in a multicenter, non-randomized, concurrent control clinical trial.

Objectives: The primary objective of the clinical trial was to show an improved survival, with acceptable neurological function, and improved hemodynamics, at 30 days post-transplant.

Patients Studied: Between March, 1996, and June, 1998, a total of 191 patients were enrolled in the study (156 patients implanted with the device and 35 CONTROL patients). Patients with New York Heart Association (NYHA) Functional Class IV heart failure who were United Network for Organ Sharing (UNOS) Status I candidates for cardiac transplantation, 14 to 68 years old, were included in the study. Of the 156 patients implanted with the device, 129 were subsequently found to have met all inclusion/exclusion criteria and were designated as **CORE LVAS** patients. Implant duration for the **CORE LVAS** patients ranged from 1 to 657 days with a mean of 80 ± 83 days (mean ± S.D.). The other 27 patients were designated as **non-CORE LVAS** patients. CONTROL patients met the same inclusion/exclusion criteria as CORE LVAS patients, but were treated with conventional medical therapy because either a device was not available or they chose not to accept a device.

Methods: To be considered a **trial success**, a patient, at 30 days after transplantation, must have survived with acceptable neurological function, be NYHA Functional Class III or better, and have had an average pump index of 2.0 L/min/m^2 or greater during the period of LVAS support.

Results: Of the 129 CORE LVAS patients, 104 had reached trial endpoint at the time of this evaluation. Most (81 of 104) of the CORE LVAS patients survived to transplant and trial success was achieved in 70 of 104 patients. These results are compared to the control patients in Table 7-1.

Table 7-1 Survival to Transplant and Trial Success
Patients evaluable at 30 days post-transplant, N=139

Endpoint	Core LVAS (N=104)	Control (N=35)	Difference [95% CI]
Transplant	78% (81/104)	37% (13/35)	41%* [23%, -59%]
Trial success	67% (70/104)	34% (12/35)	29%* [15%, -51%]

CI = 95% confidence interval by normal approximation

* Difference statistically significant (p<0.001) by Fisher's Exact Test

The hemodynamic performance of the LVAS was assessed through a comparison of pre- and post-implant values of cardiac index, mean systemic arterial pressure, and pulmonary artery diastolic pressure. For the CORE LVAS population, the cardiac index (obtained by averaging each individual patient's averaged pump index) was 2.8 ± 0.04 L/min/m^2, compared to the pre-implant cardiac index of 2.0 ± 0.05 L/min/m^2. Mean systemic arterial pressure increased from 69 ± 1.0 mmHg to 83 ± 0.8 mmHg, while pulmonary artery diastolic pressure decreased from 28 ± 0.6 mmHg to 19 ± 0.5 mmHg as early as one day post implantation. These results are presented graphically in Figures 7-1, 7-2 and 7-3.

For the CORE LVAS patients, the measured indices for renal and hepatic function (serum creatinine, blood urea nitrogen, total bilirubin) and the liver transaminases (SGOT and SGPT), returned to within normal limits during LVAS support. These results are presented graphically in Figures 7-4, 7-5, 7-6, 7-7 and 7-8.

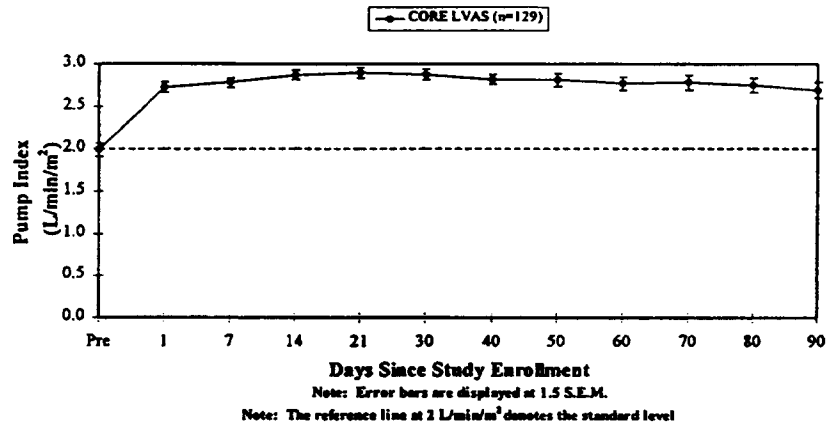
The actuarial survival (Kaplan-Meier estimate) for survival at one-year post transplantation for CORE LVAS patients is 78% [66%, 90%] and 85% [65%, 100%] for the CONTROL patients with a difference and [95% CI] of 7% [-30%, 16%]. Of the 104 CORE LVAS patients, 81 were transplanted. Of the 81, 33 survived to one year, 12 did not survive and 36 are alive but have not reached the one-year endpoint. Of the 35 CONTROL patients, 13 were transplanted, of the 13, 11 survived to one year, 2 did not survive.

Table 7-2 Actuarial Survival Post-Transplant
Patients evaluable at one year, N=94

Kaplan-Meier Survival	Core LVAS (N=81)	Control (N=13)	Difference [95% CI]
30 days post-transplant	90%	92%	2% [-13%, 17%]
1 year post-transplant	78%	85%	7% [-30%, 16%]

Adverse events were monitored and recorded throughout the study for all LVAS and CONTROL patients. Bleeding, cardiac tamponade, embolism (Central Nervous System [CNS]), and neurologic deficit were reported more frequently, statistically, in the LVAS patients than the CONTROL patients. In contrast, cardiovascular dysfunction was reported more frequently, statistically, in the CONTROL group. For further detail please refer to Table 6-1.

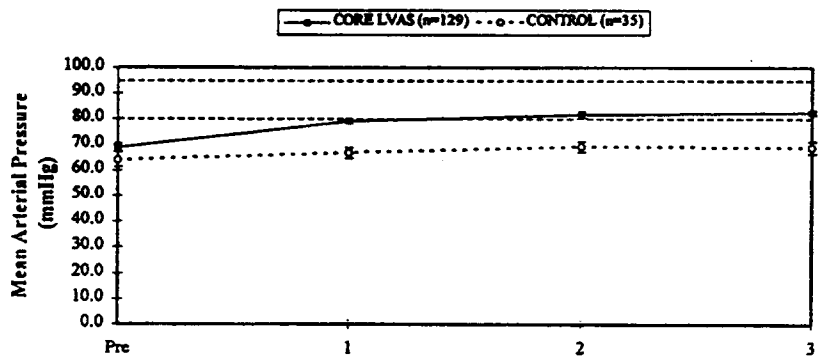
Figure 7-1 Pump Index



Note: Error bars are displayed at 1.5 S.E.M.

Note: The reference line at 2 L/min/m² denotes the standard level

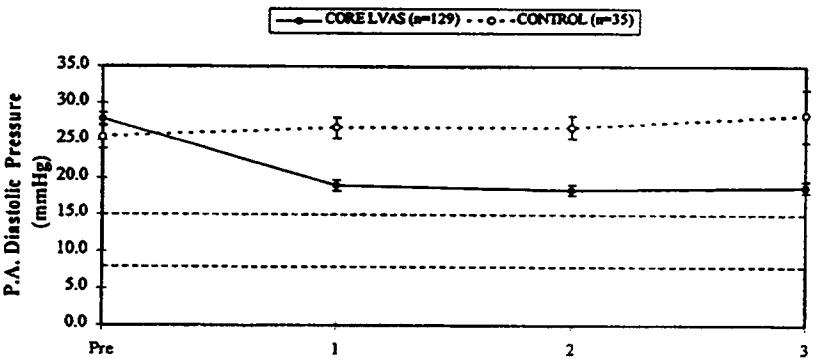
Figure 7-2 Mean Arterial Pressure



Note: Error bars are displayed at 1.5 S.E.M.

Note: The reference lines at 80 and 95 mmHg denote the normal range

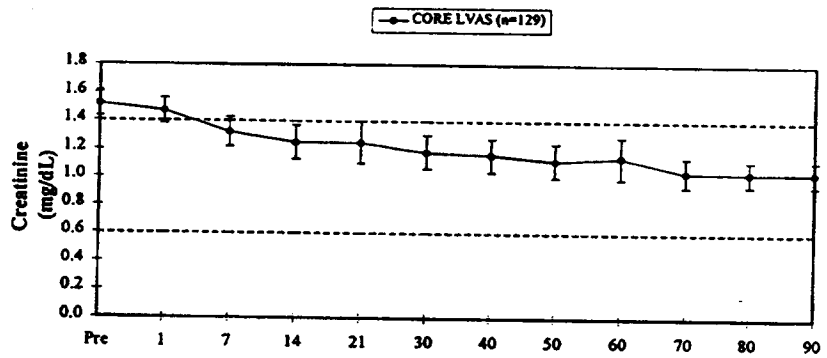
Figure 7-3 P.A. Diastolic Pressure



Note: Error bars are displayed at 1.5 S.E.M.

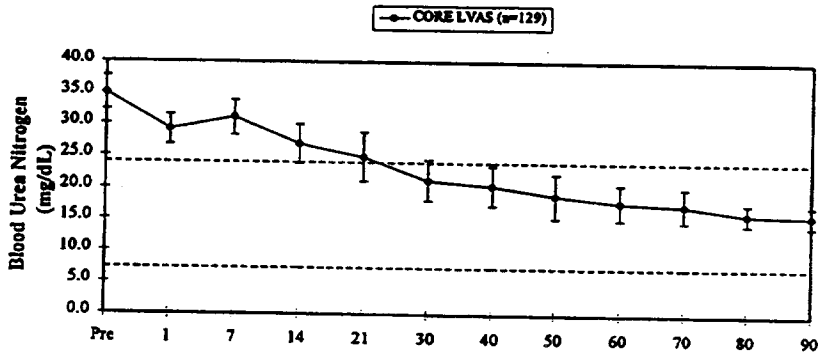
Note: The reference lines at 8 and 15 mmHg denote the normal range

Figure 7-4 Creatinine



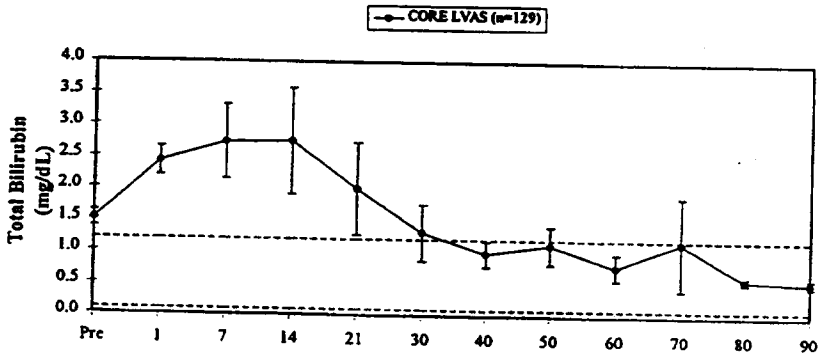
Note: Error bars are displayed at 1.5 S.E.M.
Note: The reference lines at 0.6 and 1.4 mg/dL denote the normal range

Figure 7-5 Blood Urea Nitrogen



Note: Error bars are displayed at 1.5 S.E.M.
Note: The reference lines at 7.4 and 24 mg/dL denote the normal range

Figure 7-6 Total Bilirubin



Note: Error bars are displayed at 1.5 S.E.M.
Note: The reference lines at 0.1 and 1.2 mg/dL denote the normal range

Figure 7-7 SGOT

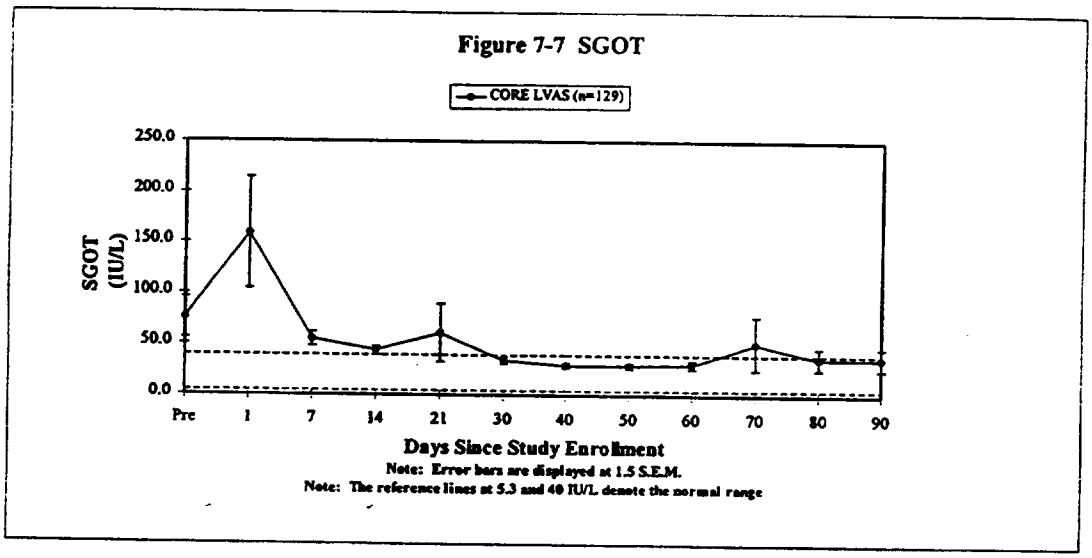
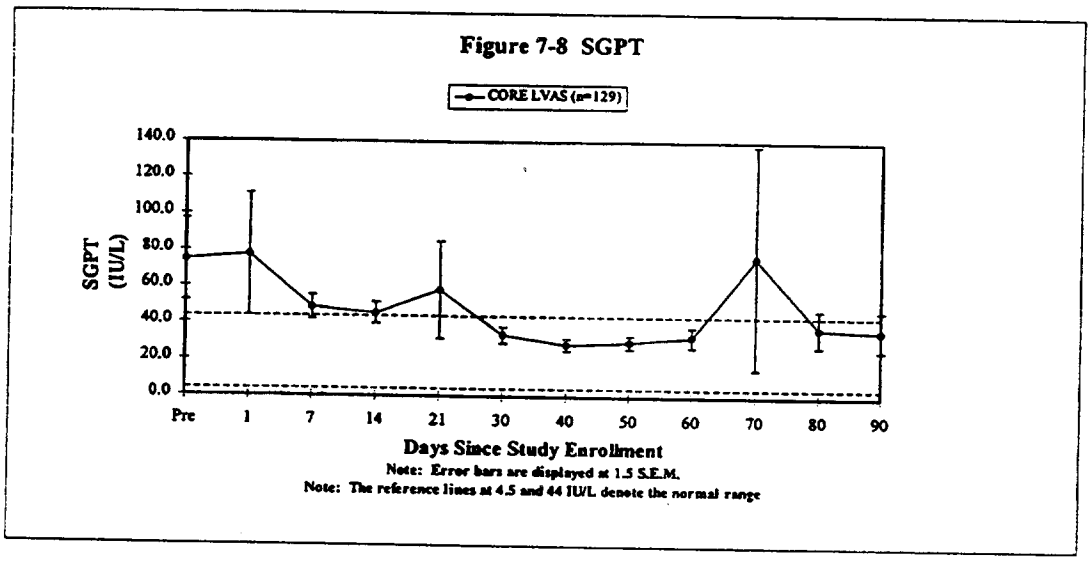


Figure 7-8 SGPT



Note: The elevation observed at 70 days results from a single patient (SGOT = 829 IU/L, and SGPT = 1939 IU/L). The patient experienced hepatic dysfunction which subsequently resolved.

Out-of-Hospital Patients: Of the 156 LVAS patients, 55 (35%) were discharged from the hospital and/or took excursions while awaiting transplantation [defined as Out-Of-Hospital (OOH)], the remaining 101 patients did not leave the hospital [defined as In-Hospital (IH)].

Of the 101 IH patients, 24 had not reached a trial endpoint at the time of this analysis, leaving 77 patients for the calculation of survival and success. Of the 77 patients, 51 (66%) survived to transplant and 39 (51%) met all success criteria.

To be considered for discharge and/or excursion during the trial, a patient must have:

- recovered from the disabling effects of the implant surgery and the morbid effects of congestive heart failure
- demonstrated that they were emotionally, intellectually and socially prepared for discharge
- demonstrated an understanding of the LVAS and an ability to manage the equipment
- identified a caregiver to provide assistance and support where necessary

Among the 55 OOH patients, 45 (82%) were discharged and 10 (18%) took occasional excursions but were not discharged. On average, these patients began taking excursions at 49.2 days postimplant. Of the 55 patients, 7 had not reached a trial endpoint at the time of this analysis, leaving 48 for the calculation of survival and success. Of the 48, 42 (88%) survived to transplant and 36 (75%) met all success criteria.

Table 7-3 summarizes the survival and success rates for both the OOH and the IH patients.

Table 7-3 Transplant and Trial Success for IH and OOH Experience
Core patients evaluable at 30 days post-transplant, N=125

Endpoint	IH Patients (N=77)	OOH patients (N=48)	Difference [95% CI]
Transplanted	66% (51/77)	88% (42/48)	-21% [-35%, -7%]
Trial success	51% (39/77)	75% (36/48)	-24% [-41%, -8%]

CI = 95% confidence interval by normal approximation

Of the 16 adverse event types collected during the trial, all but blood pump/drive failure (1 event) had lower rates in the OOH patients as compared to the IH patients. This data is presented in Table 7-4. As the OOH patients were on the device longer (mean 4.5 months) than the IH patients (mean 1.6 months), the appropriate method of data comparison is linearized rates for adverse events.

The apparent difference between the OOH and IH patient populations may be based, in part, on selection bias toward the discharge of healthier patients.

Table 7-4 IH and OOH Adverse Events

Adverse Event Type	IH (101)				OOH[1] (55)			
	% of Patients	Linearized Rate (event/month)	Upper One-tailed 95% CL	# of Events	% of Patients	Linearized Rate (event/month)	Upper One-tailed 95% CL	# of Events
Bleeding	36.6%	0.341	0.426	55	1.8 %	0.006	0.033	1
Blood Pump/Drive Failure	0.0%	0.000	0.019	0	1.8 %	0.006	0.033	1
Cardiac Tamponade	15.8%	0.112	0.164	18	0.0 %	0.000	0.019	0
Cardiovascular Dysfunction	31.7%	0.260	0.336	42	14.5 %	0.051	0.091	8
Control System Failure	0.0%	0.000	0.019	0	0.0 %	0.000	0.019	0
Embolism (CNS)	16.8%	0.174	0.237	28	27.3 %	0.121	0.176	19
Embolism (Non-CNS)	3.0%	0.019	0.048	3	0.0 %	0.000	0.019	0
Hemolysis	0.0%	0.000	0.019	0	0.0 %	0.000	0.019	0
Hepatic Dysfunction	33.7%	0.217	0.287	35	1.8 %	0.006	0.033	1
Infection	60.4%	0.688	0.804	111	30.9 %	0.172	0.235	27
Neurologic Deficit	37.6%	0.316	0.398	51	29.1 %	0.165	0.228	26
Other	26.7%	0.223	0.294	36	10.9 %	0.038	0.075	6
Renal Dysfunction	27.7%	0.192	0.258	31	1.8 %	0.006	0.033	1
Reoperation	47.5%	0.570	0.677	92	14.5 %	0.076	0.123	12
Respiratory Dysfunction	32.7%	0.248	0.322	40	5.5 %	0.019	0.049	3
Right Ventricular Dysfunction	3.0%	0.019	0.048	3	0.0 %	0.000	0.019	0

1 Presents events occurring after first discharge and/or excursion

Device Reliability

In vitro testing has demonstrated that the Novacor® LVAS has a multi-year reliability of 99.9% at one year, 98% at two years and 86% at three years as shown in Table 7-5.

An *in vitro* study was performed on the Novacor® LVAS to demonstrate system reliability and durability. Twelve units, submerged in normal saline at body temperature, were subjected to varying simulated load conditions using mock circulatory loops. The 12 units have all exceeded 3 years of test without failure. Testing is ongoing. To date, the cumulative test duration is 48.96 years with an average system duration of 4.08 years (with a range of 3.04 to 4.87 years). A reliability analysis using a Weibull model resulted in a reliability of 99.9% at one year, 98% at two years and 86% at three years (80% confidence). The results of this analysis are presented in Table 7-5.

Table 7-5 In Vitro Reliability (80% confidence)

1 Year	2 Year	3 Year
99.9%	98%	86%

The results of the *in vitro* testing are consistent with clinical experience. There were 156 LVAS patients enrolled in the clinical trial. The cumulative implant duration for the CORE LVAS patients was 10,374 days (28.4 years) with a mean duration of 80.4 ± 83.3 days (± S.D.) and a range of 1 - 657 days. As noted in Table 6-1, there was a single pump/drive failure and no control system failures. The pump/drive unit failure resulted from damage to the external portion of the Percutaneous Lead, after an implant duration of 465 days.

8. Patient Selection And Treatment

8.1 Individualization of Treatment

Successful patient support starts with initial patient evaluation and focuses on survival to transplant and the post-transplant course. Management and coordination of LVAS support requires a **multidisciplinary team**-oriented focus. The team should include cardiologists, surgical/heart transplant specialists, nursing staff, nutrition services, and cardiac rehabilitation specialists.

The results of the clinical studies suggest that patients with end-stage heart failure benefit from early intervention, based on key objective measures of cardiac failure including:

- Pulmonary capillary wedge pressure > 18 mmHg
- Mean systemic blood pressure < 65 mmHg
- Cardiac index of < 2.0 L/min/m^2 or LVEF < 25%
- Risk of sudden death

In the early postoperative period, the LVAS should be operated in *fill-to-empty* mode. During this period, the patient's heart rate may be irregular and their stroke volume highly variable. Therefore, *fill-to-empty* operation simplifies pump management by providing a pump output which is responsive to preload, ignoring beat-to-beat variation.

8.2 Anticoagulation Used During The Trial

The anticoagulation management approach used during the trial was similar to that used for patients with mechanical heart valves. The strategy was to focus on platelet protection as well as anticoagulation while the patient is on LVAS support.

- Low molecular weight dextran IV (10% dextran 40 at 25 ml/hr) was used in the early postoperative period (usually within the first 12 hours).
- Heparin (unfractionated IV) was used when the chest tube drainage fell below 30 ml/hr to maintain PTT at 1.5 to 2.0 times normal (adjusting the dose to maintain this level).
- Aspirin was used at 80 mg NG/PO QD was used for the duration of LVAS support. Ticlopidine, dipyridamole or similar antiplatelet agents were used in cases of aspirin intolerance (e.g., GI bleed).
- Coumadin® was used when oral administration of agents was tolerated (after about two weeks post implant) to maintain an International Normalized Ratio (INR) of 2.5 to 3.5 for the duration of LVAS support.

8.3 Specific Patient Populations

The safety and effectiveness of this device has not been demonstrated in nursing or pregnant women.

9. Patient Counseling Information

Serious complications may develop while a recipient is supported on the LVAS, and may make the patient an unsuitable transplant candidate and lead to death. A full explanation of the benefits and risks should be given to each prospective recipient before surgery. Potential recipients should also be provided a copy of the Recipient's Guide, Cat. # N20074.

Some of the risks include the possibility of thromboembolism and resultant CNS ischemic injury and neurological deficit, infection, bleeding, mechanically induced damage to cellular or humoral blood components resulting in hemorrhagic complications or hemolysis, device failure, or reduced flow that could result in a pump index of less than 2.0 L/min/m^2, any of which might result in ineligibility for heart transplantation and/or death.

A recipient who is being discharged from the hospital with the device will require 2 Compact Controllers, 2 Personal Monitors, 1 Standby Power Source, 2 Power Pack Chargers, 3 Primary Power Packs, and 2 Reserve Power Packs. A Shower Bag, and replacement vent filters will be needed if the recipient will be showering, and a backup Standby Power Source is recommended.

10. Conformance To Standards

The LVAS conforms to the applicable requirements of:

- IEC 60601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2, Medical electrical equipment - Part 1: General requirements for safety - 2. Collateral Standard: Electromagnetic compatibility -Requirements and tests.

11. How Supplied

The LVAS is comprised of the following:

Implant Kit

Catalog # N05224

Contains Pump/Drive Unit (sterile), Valved Conduits (sterile), Inflow Conduit (sterile), Outflow Conduit (sterile), Compact Controller (nonsterile)

Power Packs

Primary (nonsterile) Cat. # N10006

Reserve (nonsterile) Cat. # N10005

LVAS Monitor (nonsterile) Cat. # N15106

Personal Monitor (nonsterile) Cat. # N15105

Standby Power Source (nonsterile) Cat. # N15003

The Pump/Drive Unit, inflow conduit, outflow conduit, and apical fixation ring are provided sterile and non-pyrogenic in thermoformed trays, one "nested" inside the other. The trays are individually sealed and labeled. The valved conduits are provided sterile and non-pyrogenic in sealed plastic jars.

The external electronics and power sources are provided nonsterile.

Note: Certain components of this device may have been reprocessed. Reprocessed components meet all product specifications.

All sterilized components, including tools and accessories, are packaged in double aseptic transfer packages. System components, including the sterile primary packages, are placed into a secondary transport and storage container. This container consists of a suitcase with custom foam inserts that provide protection for the primary packaging and help organize the various components of the system. A peak impact load ("g level") indicator and temperature indicators are included in each suitcase and are used to notify the receiving inspector of extreme shipping conditions. Do not use the suitcase if the indicators have been activated. Contact Novacor for information on obtaining a replacement.

The Operator's Manual, Cat. # N20073, contains detailed information on the setup, operation, and troubleshooting of the LVAS. A brief description of the contents is given as a reference. For further information, see the appropriate section.

1	**Description**	Describes the LVAS system, its controls, connections, status indicators, function, and operating modes.
2	**System Components, Controls, and Displays**	Gives more detailed information on the LVAS components, the various control screens, and the controls functions.
3	**Setup and Operation**	Describes the implantation of the pump, the initial settings for the LVAS, and covers the time from implantation through transport to the Cardiac Care Unit.
4	**Continuing Operation**	Describes the different trigger modes, how to select them, and how to adjust them.
5	**Alarms and Troubleshooting**	Describes the alarms and alarm conditions and how to respond to them.
6	**Additional Functions and Operations**	Provides information on saving control parameter settings, backup modes, security features, optional connections, virus protection, and data files that the LVAS creates.
7	**Upon Receipt**	Describes the initial tests to be done upon receipt of the LVAS, and storage requirements.
8	**Maintenance**	Describes the various tests and procedures to maintain LVAS functioning. It also includes cleaning instructions.
9	**Safety**	Describes the warning symbols and the periodic safety inspection procedures.
10	**System Specifications**	Describes the LVAS physical and performance specifications.
11	**Summary**	Provides a brief reference of the information presented in other parts of the manual.

13. Recipient's Guide

Patients must be trained on the care and maintenance of the LVAS! The Recipient's Guide is intended to supplement this training, not replace it.

The Recipient's Guide, Cat. # N20074, gives the LVAS recipient and caregiver information on the proper use and maintenance of the LVAS external components. It also describes the limitations of normal activity that must be followed. A brief description of the contents is provided as a reference.

1	**Introduction To The Manual**	Describes the layout of the manual and the location of information.
2	**Introduction To The Device**	Tells why the LVAS was prescribed and what it does.
3	**Description**	Describes the LVAS and its components.
4	**Environmental Conditions That Affect Use**	Describes the storage and use environments, and warns against using the device outside certain environmental limits.
5	**System Setup**	Tells how to set up the various components of the LVAS.
6	**Summary Of Use**	A quick reference to the use of the LVAS, with page references for further information.
7	**Daily Checks**	Describes how to monitor the system for proper functioning, and what to do if there is a problem with a component.
8	**Daily Operation**	Describes what the recipient can do on a standard basis, including switching from Tethered to Untethered mode and back and showering.
9	**Self-Care**	Describes proper exit-site care and allowed activities, including taking blood-thinning medicine.
10	**Equipment Care And Maintenance**	Describes how to best take care of the LVAS and its components.
11	**Alarm Messages And Response**	Describes the alarms and how to respond to them.
12	**Emergency Response**	Describes how to replace the Compact Controller and what to do if the power goes out

14. Device Description

There are five major components that, when integrated, form the Novacor® LVAS: the Implant, Compact Controller, Power Packs (Primary and Reserve), LVAS Monitor and Personal Monitor.

The Implant, the implanted portion of the LVAS, consists of an integrated Pump/Drive Unit with a percutaneous lead carrying the control and power leads, bioprosthetic Valved Conduits, an Inflow Conduit and an Outflow Conduit. The device is implanted anteriorly within the left upper quadrant of the abdomen. The pump Inflow Conduit pierces the pericardial portion of the diaphragm to receive blood from a cannula inserted, via the apex, into the left ventricular cavity. The Outflow Conduit is anastomosed to the aorta.

The implanted components are illustrated below in Figures 14-1 and 14-2.

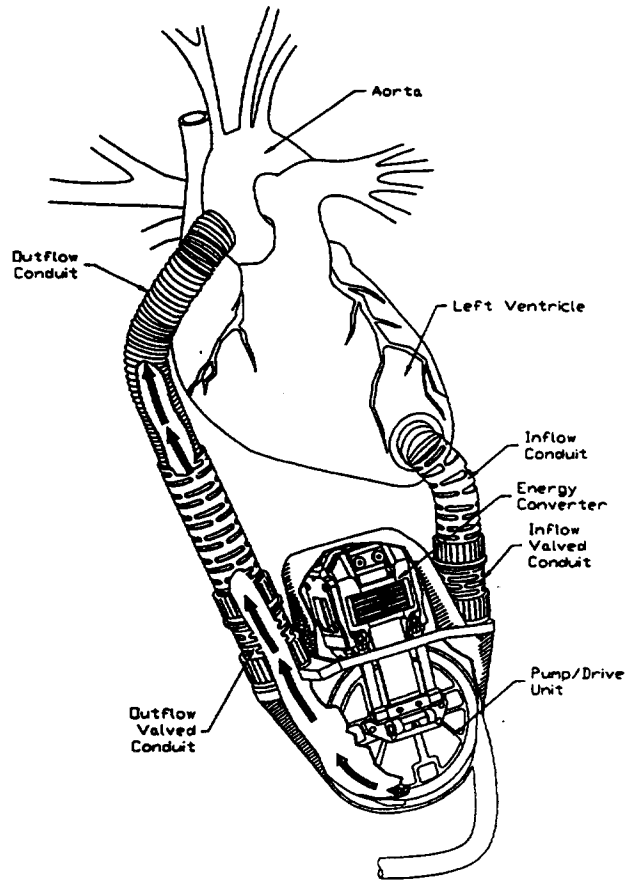


Figure 14-1 Illustration Of The Novacor® LVAS Within The Circulatory System

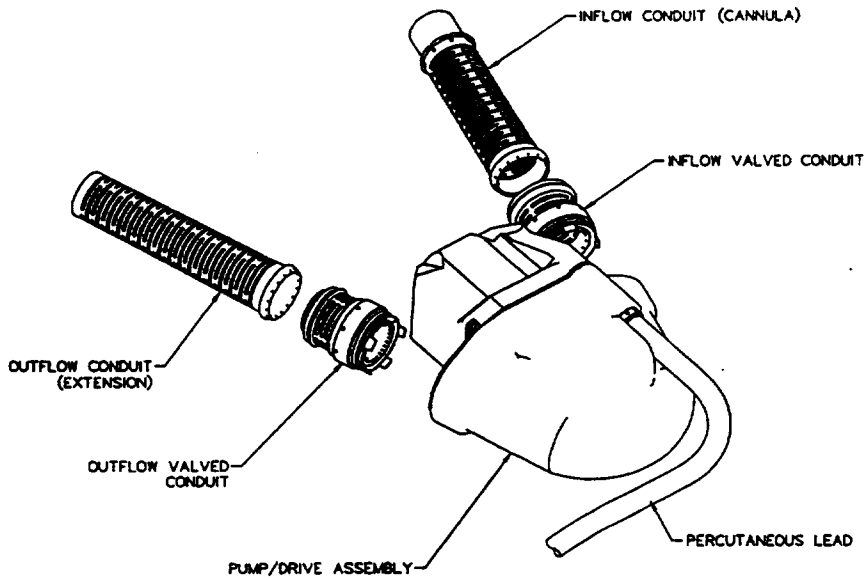
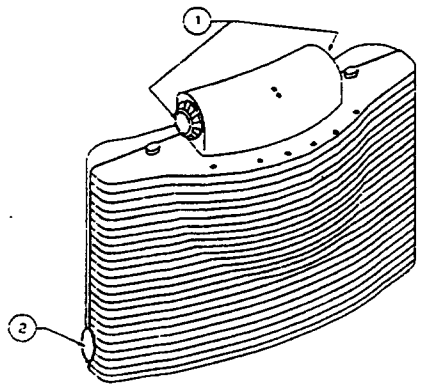


Figure 14-2 Implant Components: Pump/Drive Unit With Percutaneous Lead, Inflow And Outflow Valved Conduits, Inflow Conduit And Outflow Conduit

The Compact Controller (Figures 14-3 and 14-4) located extracorporeally, controls the timing of pump operation based on preprogrammed control algorithms and adjustable control parameters detailed below. In addition, the Compact Controller monitors LVAS operation, and activates alarms for defined fault conditions. It is intended to be worn on a belt around the recipient's waist, or carried in a shoulder bag or in the pockets of a special vest.



① Power Input Connectors
② Percutaneous Lead Connector

Figure 14-3 Side View

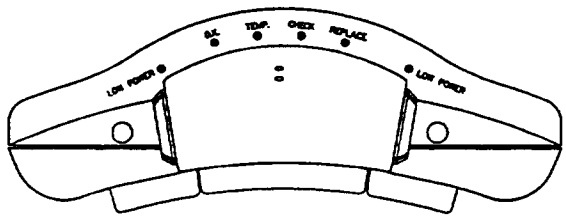


Figure 14-4 Top View

System Description

Solenoid Driver

The driving mechanism for the implanted Pump/Drive Unit is a solenoid, a device that acts as a magnet when electricity is applied. The pivoting solenoid is coupled, through springs, to the blood pump. Pump ejection occurs in three steps:

1. The solenoid rapidly pivots and closes when a large pulse of electrical energy is applied. The springs are flexed by the motion of the solenoid. A second smaller pulse of energy helps to capture and hold the solenoid closed. This is called the latch pulse.

2. The springs apply pressure to the blood pump, and ejection begins. The Compact Controller automatically reduces the energy to the solenoid as the springs relax during ejection.

3. Energy to the solenoid is stopped at the end of ejection, and the solenoid again becomes nonmagnetic. The pump is then free to passively fill from the left ventricle.

Pump Position Sensors

The implanted Pump/Drive Unit contains two sets of position sensors. These sensors monitor the position of elements of the Pump/Drive Unit throughout filling and ejection.

The solenoid sensor monitors the solenoid pivot angle. This information describes the pump volume and flow rate during the pump's filling.

The spring sensor monitors spring deflection. This information describes the pump volume and flow rate during ejection, and the pump residual volume.

The position sensor signals are used to determine when some of the timing thresholds are met in each of the three trigger modes. This infomation is also used to create the volume and flow waveform displays on the LVAS Monitor, and to calculate the energy to deliver to the solenoid.

Control Algorithms

Adjustment of the control algorithms is only available while the Compact Controller is connected to the LVAS Monitor.

- Fill Rate Trigger Mode: triggering of pump ejection is based on a drop in pump fill rate (typically accompanying the end of LV systole).

- ECG Trigger Mode: triggering of pump ejection is based on the recipient's ECG (available only when connected to the LVAS Monitor).
- Fixed Rate Trigger Mode: each pump ejection is triggered at a preset interval from the previous ejection.
- Failsafe: a backup mode that provides limited, fixed rate, full-fill operation.

Together, the Implant and the Compact Controller form the core of the Novacor® LVAS.

Power to the Compact Controller, hence to the Implant, is provided from two power sources: a main power source (Primary Power Pack, LVAS Monitor or Personal Monitor) and a secondary power source (Reserve Power Pack).

Therefore, the Novacor® LVAS may be considered to consist of three configurations as illustrated below:

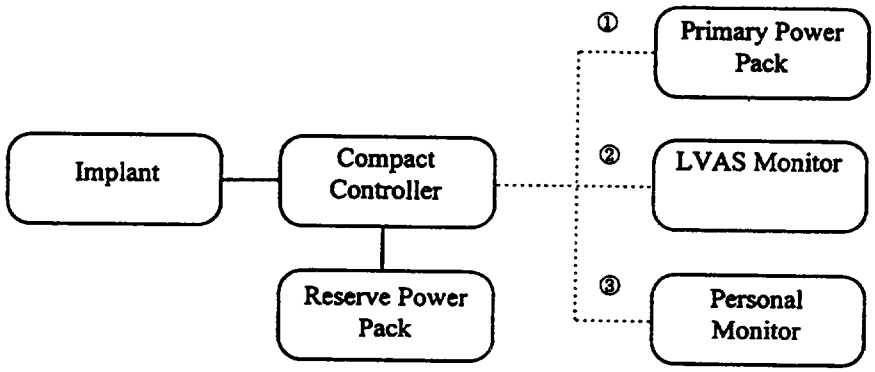


Figure 14-5 LVAS Configurations

In the first ("Untethered") configuration, power to the Compact Controller is provided by the Primary Power Pack, via an internal rechargeable battery. This configuration provides the recipient with a lightweight, ambulatory power supply allowing them the freedom to move around without restriction.

In the second ("Tethered") configuration, power to the Compact Controller is provided by the LVAS Monitor. The LVAS Monitor is intended primarily for use in the early postoperative period and provides power to the Compact Controller from the AC line or from an internal rechargeable transport battery. The LVAS Monitor also displays information on LVAS operation, allows an operator to change control parameters and alarm limits stored within the Compact Controller, and provides expanded alarm and diagnostic functions.

The LVAS Monitor has connections for the Compact Controller, recipient ECG leads and AC mains input. LVAS Monitor connections to the Compact Controller include the Compact Controller power connection, serial input and output data connections and a

lead sense connection. All of these connections are isolated from ground and other LVAS Monitor circuits.

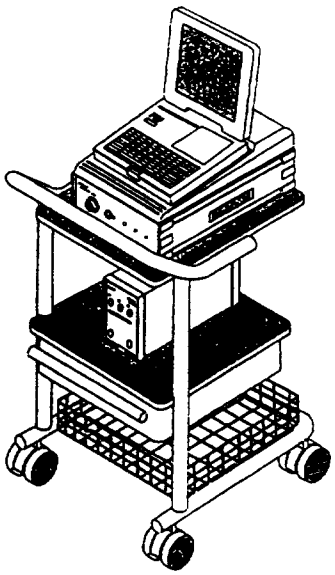


Figure 14-6 LVAS Monitor On Cart

In the third (also "Tethered") configuration, power to the Compact Controller is provided by the Personal Monitor. The Personal Monitor is smaller than the LVAS Monitor and is intended to support LVAS operation when the recipient has stabilized postoperatively and diagnostics/adjustments aren't needed. It provides power to the Compact Controller from the AC line or from the Standby Power Source during AC power outages. The Personal Monitor also displays basic information on LVAS operation and augments the Compact Controller alarm functions.

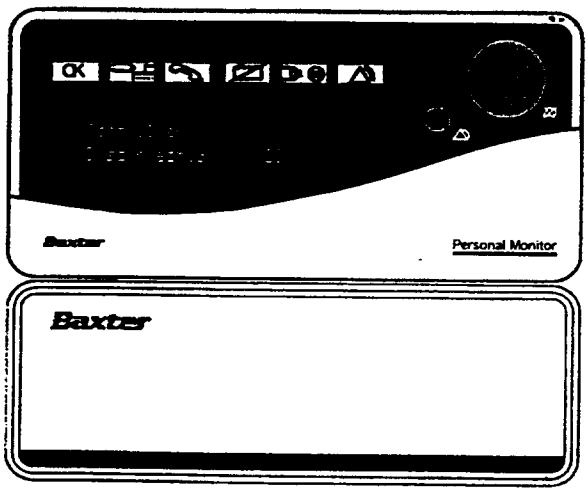


Figure 14-7 Personal Monitor With Standby Power Source

Switching between configurations involves changing from one main power source to another. The Reserve Power Pack provides power to the Compact Controller during the switch, maintaining uninterrupted LVAS operation.

Warning: **Disconnecting both power sources from the Compact Controller at the same time will cause the Pump/Drive Unit to stop. Reconnect either power source to restart the Pump/Drive Unit.**

Note: Do not connect two of the same type of Power Packs to the Compact Controller. If connected to two of the same type of batteries, the Compact Controller will use power from both at the same time. Both packs will become low and give a low power alarm. If you do not replace the batteries at the low power alarm, eventually both packs will become empty at the same time.

Physical Characteristics

The dimensions and weights of the major components are given in the following table.

	Dimensions	Weight
Pump/Drive Unit	16.5 x 13.2 x 6.1 cm (6.5 x 5.2 x 2.4 in)	1.0 kg (2.2 lb.)
Compact Controller	15.8 x 13.6 x 4.9 cm (6.2 x 5.4 x 1.9 in)	0.7 kg (1.5 lb.)
Primary Power Pack	17.3 x 14.2 x 4.7 cm (6.8 x 5.6 x 1.8 in)	2.0 kg (4.4 lb.)
Reserve Power Pack	12.9 x 10.6 x 3.7 cm (5.1 x 4.2 x 1.5 in)	0.7 kg (1.5 lb.)

Implant Procedure

Warning: **Use care in deairing the pump in order to avoid the possibility of air emboli.**

Caution: **A backup Compact Controller, LVAS Monitor, and Power Packs must be on hand and in good condition in case of emergency. Quick replacement of some of the components, particularly the Compact Controller, may be needed in order to keep the system operating properly.**

The information provided in this section is not intended to replace proper training.

The LVAS may be assembled in a different order than that given if the physician prefers. However, the Valved Conduits must be rinsed before attaching to the Pump/Drive Unit, and the Pump/Drive Unit must be deaired before removing the clamp on the Outflow Conduit.

1. **Perform Sternotomy, Fashion Pocket For Pump/Drive Unit**

   a) Create a standard median sternotomy incision with extension to umbilicus.

   b) Fashion a pocket in the left abdominal wall, anterior to posterior rectus sheath, between costal margin and iliac crest.

2. **Institute Cardiopulmonary Bypass**

   a) If patient is stable, initiation of bypass may be delayed until after the Outflow Conduit is anastomosed to the aorta and the Pump/Drive Unit is placed in the pocket.

   b) Explore for possible patent foramen ovale and repair if necessary.

3. **Perform Anastomosis Of Pump Outflow Conduit To Aorta**

   a) Trim the Outflow Conduit to the correct length, anastomose end-to-side to the ascending aorta and cross clamp near aorta.

   b) Tunnel conduit anteriorly through diaphragm right of midline.

   Note: Do not allow tissue or particulate matter to contaminate the inside of the conduit.

4. **Assemble Assist Device**

   a) Place trochar adaptor onto connector end of the Percutaneous Lead to lessen the chance of fluid entering the connector.

   Caution: Do not submerge the Percutaneous Lead. The sheath that covers the air vent is not watertight.

   b) Fill the pump with warm heparinized saline.

   c) Insert blue inflow Valved Conduit into pump fitting (see Figure 15-1) and rotate until keys seat. Tighten nut until it bottoms firmly.

   d) Connect Inflow Conduit to inflow Valved Conduit. Tighten conduit nut until it bottoms firmly while preventing conduit rotation.

   e) Insert gold outflow Valved Conduit into pump fitting (see Figure 15-1) and rotate until keys seat. Tighten nut until it bottoms firmly.

   f) Inspect Outflow Conduit for creases. If any creases have formed, smooth these creases with gentle pressure from the inside of the conduit using a blunt tool.

   g) Connect Outflow Conduit to outflow Valved Conduit. Tighten conduit nut until it bottoms firmly while preventing conduit rotation.

   h) Periodically refill pump with warm heparinized saline through the Inflow Conduit to keep inflow and outflow valve tissue moist.

5. **Tunnel Percutaneous Lead, Place Device In Pocket, Tunnel Inflow Conduit**

   Note: Do not allow tissue or particulate matter to contaminate the inside of the conduits or the pump, especially when tunneling through the diapraghm.

   Note: If desired, antibiotic lavage of the pump pocket may be performed.

   a) Using trochar, tunnel Percutaneous Lead (subcutaneously) to exit near right iliac crest.

   b) Place pump in pocket.

   c) Tunnel Inflow Conduit through diaphragm (at costal margin) and pericardium to left ventricle apex.

   d) Inspect Inflow Conduit for creases. If any creases have formed, smooth these creases with gentle pressure from the inside of the conduit using a blunt tool.

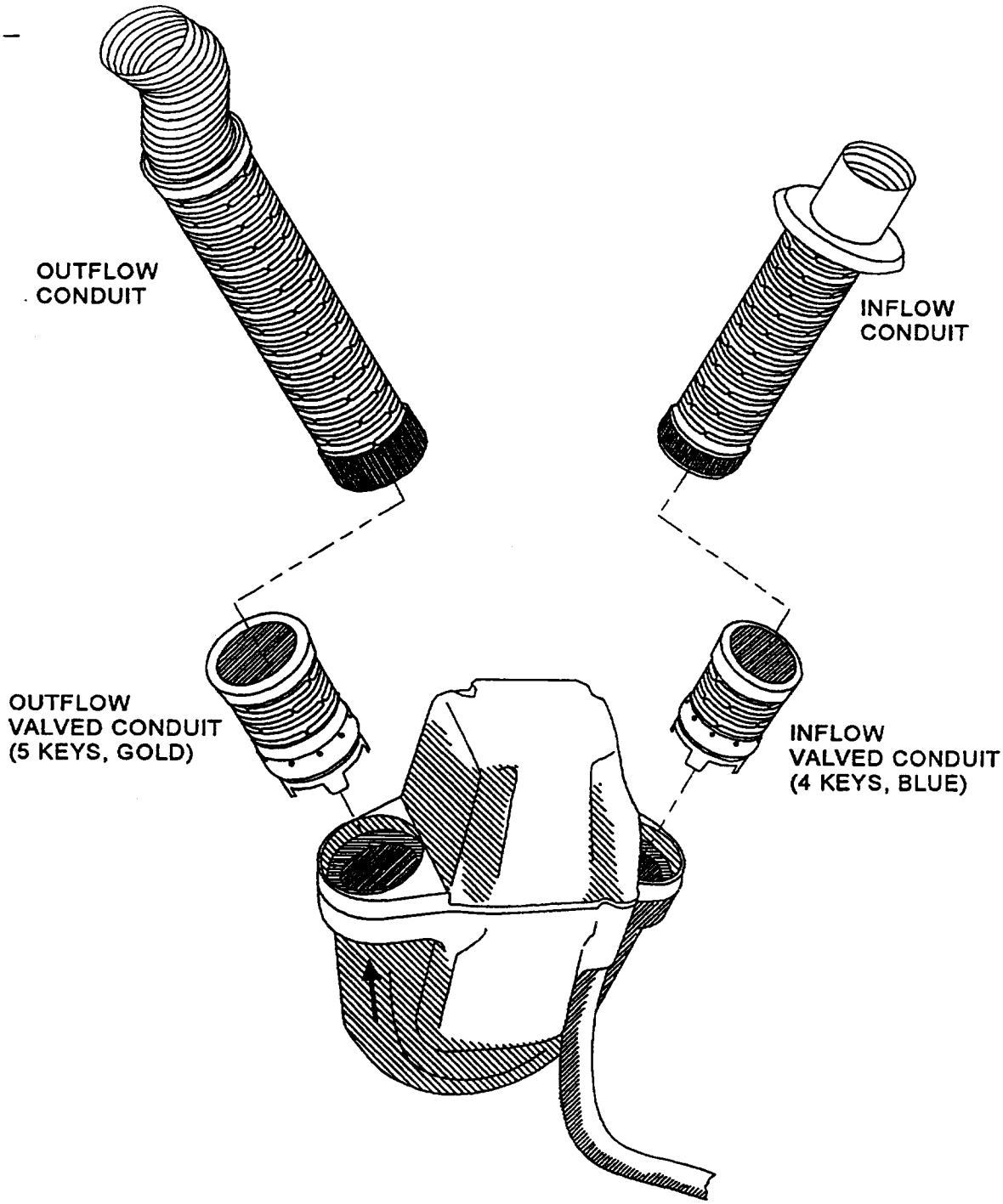


Figure 15-1 Valved Conduit Assembly

6. **Install Filter (See Figure 15-2)**

   a) Remove sheath and gauze from opening on Percutaneous Lead.

   b) Install filter assembly with hexdrivers (with screws). Filter assembly should point away from the recipient.

Note: Align the front edge of the silver connector with the back edge of the cable leading to the Compact Controller.

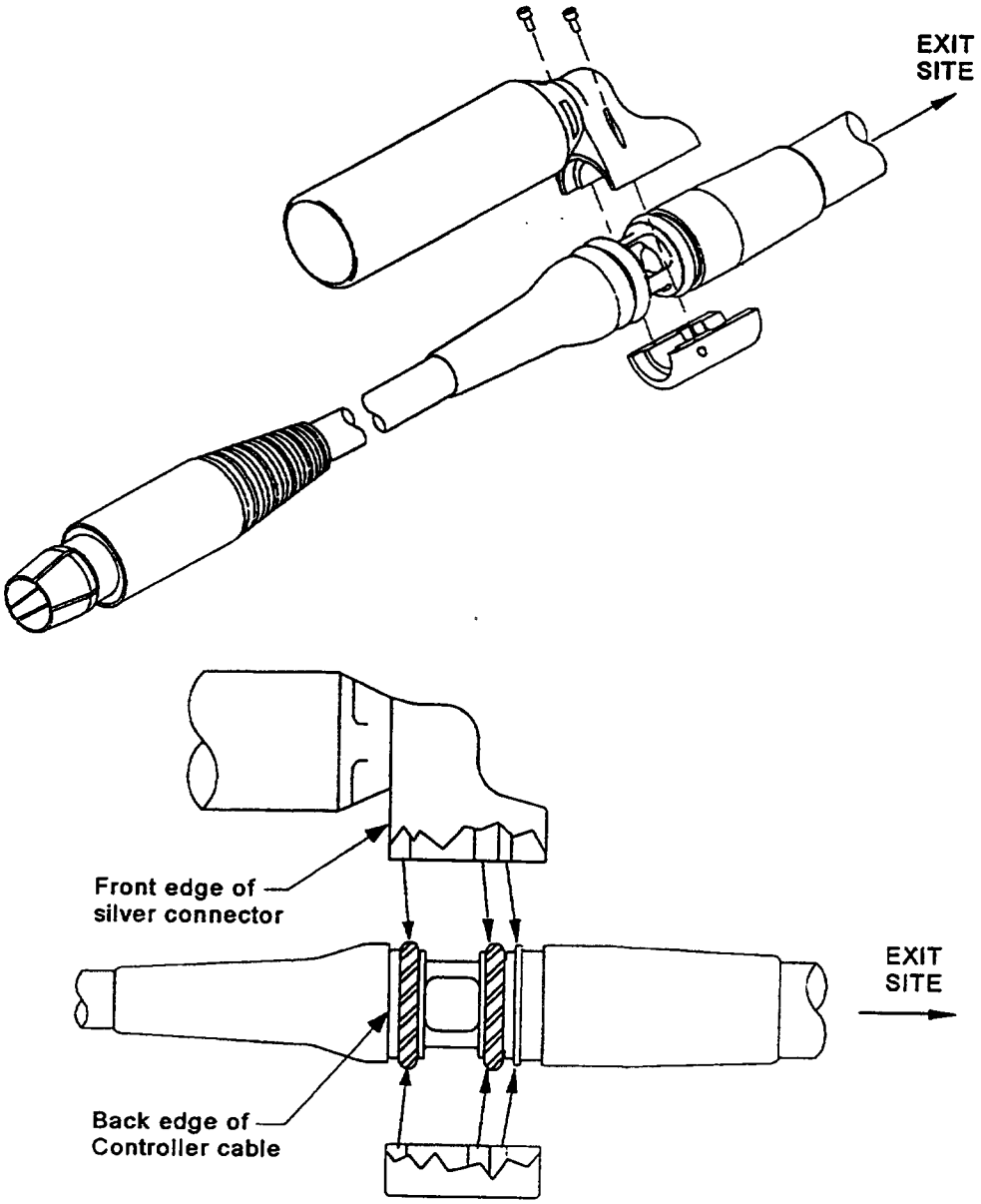


Figure 15-2 Filter Assembly

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7. **Connect And Check Compact Controller**

Warning: During implant Autostart must be DISABLED in Compact Controllers BEFORE connecting Percutaneous Lead. If Autostart is enabled, disable it before connecting. Otherwise the Pump/Drive Unit will start immediately when it is connected.

a) Make sure the Compact Controller is connected to the LVAS Monitor, is not alarming and the "OK" light is on.

b) Make sure "Autostart Disabled" appears on the LVAS Monitor Home screen. This confirms that Autostart is disabled.

c) Connect Percutaneous Lead to Compact Controller when it is handed out of the sterile field. Make sure an audible "click" is heard to confirm proper connection.

8. **Attach Apical Fixation Ring**

a) Elevate cardiac apex, ring with 12 pledgeted mattress sutures (3-0 Tevdek® or similar).

b) Attach fixation ring (using provided holder to ensure shape); remove holder by cutting retaining suture at groove.

Note: Position the apical fixation ring so that the ventriculotomy does not result in occlusion of the Inflow Conduit by the septum.

9. **Prime The Pump And Remove Residual Air**

a) Place needle vent at highest point of elevated Outflow Conduit.

b) Fill pump with warm heparinized saline through the Inflow Conduit.

c) Execute several single pump strokes (<F2>) to move trapped air to the needle vent. Refill the pump with heparinized saline after each stroke.

10. **Cannulate Left Ventricle**

a) Perform ventriculotomy within the apical ring at left ventricular apex.

Note: When performing ventriculotomy, be careful not to involve the septum. Ensure that the positioning of the ventriculotomy does not result in occlusion of the Inflow Conduit by the septum.

Note: Carefully remove any mural thrombus.

b) Insert Inflow Conduit into ventricle; secure in position with clamps, pursestring, then sutures.

11. Evacuate Air From Left Ventricle And Pump

a) Use needle aspiration of left ventricle and Inflow Conduit.

b) Execute several single strokes (<F2>) (with Outflow Conduit still clamped, elevated and vented).

c) Remove clamp from Outflow Conduit and perform additional single strokes with the graft elevated and vented.

12. Begin Continuous Pumping (Refer To Operator's Manual, Section 3.2, For Greater Detail)

An initial rate of 30 beats per minute in Fixed Rate trigger mode (<F5>) is recommended.

a) Keep the Outflow Conduit elevated and continue venting until all air has been purged.

b) Control the pump rate to avoid completely emptying the left ventricle. Observe the left atrium and the left ventricle to confirm that they remain at least partially filled. If a rate of less than 30 bpm is appropriate, operate the pump using a series of single strokes.

c) Increase the pump rate only when the volume waveform shows the pump is at or near full-fill on most cycles.

Note: Air entrainment is possible if the following 4 conditions exist:

- There is active LVAS pumping
- There is poor flow to the left atrium
- There is low arterial pressure (usually less than 60 mmHg)
- The conduits are exposed to air during the surgical procedure

These conditions have infrequently been reported during weaning from cardiopulmonary bypass or during anaphylactic shock.

d) When a fixed rate of greater than 70 bpm with near-full filling is reached, switch to fill-to-empty operation (Fill Rate Trigger mode, with the End-of-Fill Threshold set to 90% and the Eject Delay set to 0 msec).

e) After 24 hours and when the pump output is greater than 5 L/min, the system may be adjusted for synchronous operation. Return to fill-to-empty operation if synchronous operation results in pump stroke volumes less than 40 ml.

Rinsing Instruction for Valved Conduits

Store between 10°C to 25°C. The Valved Conduits must be used before the expiration date on the label.

The Valved Conduits are packaged sterile in individual plastic jars with screw-cap closures and seals. Before opening, the jars should be carefully examined for evidence of damage (e.g., a cracked jar or lid), leakage, and broken or missing seals. As long as the jars and their seals remain intact, the Valved Conduits will remain sterile.

Caution: **It is strongly recommended that the Valved Conduits not be opened unless it is reasonably certain that they will be needed shortly thereafter. This reduces the risk of contamination.**

Caution: **Valved conduits from containers found to be damaged, leaking, missing intact seals and/or without adequate glutaraldehyde must not be used.**

Caution: **The Valved Conduits and glutaraldehyde storage solution are sterile. The outside of the jar is not sterile and must not be placed in the sterile field.**

Caution: **The Valved Conduits and container should never be subjected to sterilization procedures. Resterilization could result in damage to the valves.**

The valved conduits can be rinsed while the surgeon is preparing the pump pocket.

1. After opening, the contents of the jar should be inspected. The jar should contain a sufficient quantity of buffered glutaraldehyde storage solution to completely cover the Valved Conduits in order to prevent the tissue from drying out.

2. To remove the Valved Conduits from the jar, remove the seal and screw cap. Handle the contents of the jar in an aseptic manner to prevent contamination. Transfer the Valved Conduits to a sterile rinse basin containing sterile 0.9% sodium chloride solution for irrigation.

   Caution: Do not use unprotected forceps in handling these Valved Conduits.

3. The Valved Conduits must be rinsed to reduce the glutaraldehyde concentration. To rinse the Valved Conduits, place each in a minimum of 500 ml of sterile 0.9% sodium chloride solution for irrigation. Be sure the solution is sufficient to completely submerge the prosthesis. With the Valved Conduits submerged, slowly agitate the conduit for a minimum of one minute. Leave the Valved Conduit in this solution for a further nine minutes. Discard the rinse solution. Repeat this process at least three additional times using new saline solution each time. The Valved

Conduits should be left in the final rinse solution until needed to prevent the tissue from drying out.

Caution: Do not allow leaflet tissue to contact other objects.

Caution: Do not place other objects in the rinse basin.

Caution: During the installation of the Valved Conduits into the LVAS and subsequent assembly of the LVAS, the Valved Conduits should be irrigated frequently on both sides with sterile 0.9% sodium chloride solution for irrigation to keep the tissue moist. Drying of the tissue may result in permanent damage to the valves.

Caution: Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat, and may also cause skin sensitization. Avoid prolonged breathing of the vapor. Use only adequate ventilation. In the event of contact, immediately flush the affected area with water. In event of contact with the eyes, seek medical attention.

4. Due to the biological nature of these valves, and their sensitivity to physical handling and environmental conditions, **open but unused Valved Conduits cannot be returned.**

Summary of Novacor® LVAS Setup And Operation

A summary of the directions for use is provided. For greater detail, refer to the Operator's Manual, Cat. # N20073.

Refer to the Operator's Manual for detailed system setup, operation, alarms, troubleshooting and safety information.

1. **Setup In The Operating Room (See Operator's Manual, Section 3.2)**

   a) Set up and initialize LVAS Monitor

   If desired, connect ECG input (use high level signal from OR patient monitor and ECG Cable Adapter, or connect patient leads).

   b) Set up Compact Controller

   Verify that the "Autostart Disabled" message appears in the lower right portion of the LVAS Monitor's Home screen. The indicated run mode should be "Halt."

2. **Initial Operation (See Operator's Manual, Section 3.3)**

   a) Plug the Percutaneous Lead into Compact Controller when passed off from the operative field. Pump volume waveform should indicate approximately 70 ml;

pump values (Pump Rate, etc.) should be zero; otherwise check connections, Compact Controller.

b) At surgeon's request, execute Single Strokes (<F2> from Operating Mode screen (<F8>)) to help purge air from pump.

c) When requested, begin pumping in Fixed Rate Trigger mode (<F3>). Adjust mode and control parameters as necessary.

d) Enable the Autostart function (<Alt-A>) when the chest is closed; "Halt" and "Single Stroke" boxes will disappear from screen.

e) Check for alarm conditions; if necessary, adjust physiology alarms to accommodate an initial period of low output.

f) Write control parameters and alarm limits to nonvolatile memory (<Alt-W>). Only those control values currently displayed will be saved (all parameters will be saved from Control Summary screen).

3. Dealing With Alarms

a) If the LVAS alarms during the implant procedure, check the recipient's condition. Many alarms are related to the recipient's physiological condition. The safety features and backup modes of the LVAS will usually provide the opportunity to first check the patient's physiologic status. The physiology alarms are adjusted from the Alarm Setup screen in the LVAS Monitor, and should be set with consideration given to the recipient's current condition.

b) If the alarm does **not** appear to be related to the recipient's condition:

- Check the alarm indicators.
- Check the Compact Controller connections. If they are connected, go to the next step.
- Replace the Compact Controller.
- Consider surgical intervention, if necessary.

4. Set Up The Compact Controller (Refer To Operator's Manual, Section 3.1, For Greater Detail)

a) Enable the Autostart function (<Alt-A>) when the chest is closed.

b) Verify that there are no alarm conditions.

c) Write the control parameter and alarm limit values to nonvolatile memory by pressing <Alt-W> from the Operating Mode or Control Summary screens.

Explant Procedure

1. If The Patient Is Alive At LVAS Explant

a) Connect the patient's Compact Controller to an LVAS Monitor.

b) Prepare and drape the patient's chest and abdomen.

c) Reopen the original incision, exposing the Pump/Drive Unit and the Inflow Conduit and Outflow Conduit.

d) Institute cardiopulmonary bypass.

e) Disable the "Autostart" function, halt the LVAS and disconnect from the LVAS Monitor.

f) Transect the Inflow Conduit and Outflow Conduit reinforcements, then crossclamp and transect the grafts. There can be significant tissue ingrowth on the plastic reinforcements of the conduits, requiring intricate dissection.

g) Place a drape under the Percutaneous Lead near the Pump/Drive Unit. Transect the lead and seal each end with a sterile cap, filled with providone iodine ointment such as Betadine®. Tie the lead caps securely in place, as shown in Figure 15-3.

Note: The lumen of the Percutaneous Lead is not sterile. Do not allow the Percutaneous Lead or its contents to enter the sterile field.

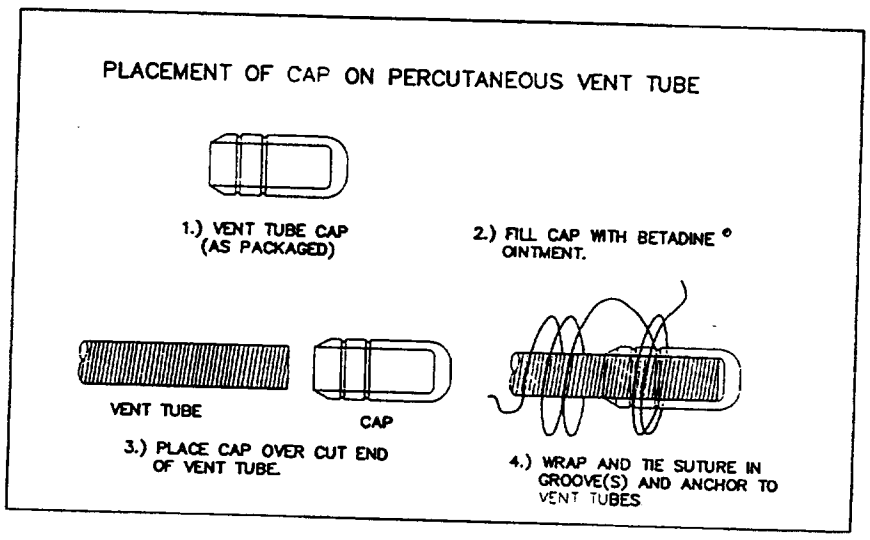

Figure 15-3 Capping Cut Percutaneous Lead

® Betadine is a registered trademark of Purdue Frederick.

h) Remove the Pump/Drive Unit (with sections of the Inflow Conduit and Outflow Conduit attached) from the operative field. As soon as practical, the interior of the Pump/Drive Unit should be rinsed with saline. This will ensure that residual blood does not clot on the pump chamber surface.

i) Dissect and extract the remaining portion of the lead through the skin exit site.

j) Proceed with cardiac transplantation.

k) Preserve and prepare the device for shipment to Baxter according to the instructions in Step 3.

2. If The Patient Died Before LVAS Explant

a) The patient should be fully anticoagulated before halting LVAS operation, to prevent postmortem thrombus formation within the pump.

b) It is preferable that a member of the LVAS team is present at autopsy and device explant. If this is impractical, a member of the team should brief the prosector as to the method of device explant and means of preparation for return of the explanted device to Novacor.

c) Remove the vascular connections near their insertion points, i.e., the left ventricular apex for the Inflow Conduit and the anastomotic site for the Outflow Conduit.

d) Remove the Pump/Drive Unit with Percutaneous Lead intact.

The filter assembly should be left on the lead to prevent accidental entry of fluid.

Do not cut the lead.

3. Preserve And Prepare The LVAS For Shipment To Baxter

Note: An Explant Kit (one designed for shipping all explanted components) is supplied to all centers and should be used to return components.

a) All centers should use 10% buffered formalin solution for shipping explanted components.

b) Refer to the graphical instructions included in the Explant Kit for the packaging of the individual components.

c) Disconnect the inflow and Outflow Conduit conduits from the inflow and outflow Valved Conduits by disengaging the threaded coupling nuts.

d) Disconnect the inflow and outflow Valved Conduits from the pump by disengaging the threaded coupling nuts. Remove the Valved Conduits and gently rinse with 0.9% sodium chloride solution for irrigation. Photographs may be taken for clinical center documentation records.

e) Remove the Inflow Conduit from the ventricular apex, leaving the minimal amount of tissue around the Conduit. Rinse with 0.9% sodium chloride solution for irrigation. The graft may be cut longitudinally and photographed for clinical center documentation records.

f) Remove Outflow Conduit at the anastomosis and gently rinse with 0.9% sodium chloride solution for irrigation. The graft may be cut longitudinally and photographed for clinical center documentation records.

g) If the Percutaneous Lead has been cut, cover the end with a vent tube cap to prevent fluids from entering the pump internal mechanisms. **Failure to cover the end will result in corrosion of the energy converter internal mechanisms and interfere with engineering explant analysis at Novacor.**

h) Empty the blood contained in the pump and gently rinse with 0.9% sodium chloride solution for irrigation. Fill the pump with 10% buffered formalin and seal the pump with the pump caps. Using soap and scrubbing pad, clean the exterior of the pump of all adherent tissue and blood. After washing, gently dry the exterior surface and wipe with alcohol.

i) Send the Explant Kit by overnight courier to Novacor, Baxter Healthcare Corporation.

16. Maintaining Device Effectiveness

The regular schedule of periodic maintenance and testing is outlined below.

Summary Of Periodic Checks

	Upon Receipt	While in Storage		While in Use		Upon Conclusion
		Every 3 Months	Every 6 Months	Daily	Weekly	
Functional check of LVAS Monitor	X		X			
Electrical safety checks	X		X			
Visual check, Implant Kit	X					
Power Pack check, on Power Pack Tester	X	X				
Run-down test, LVAS Monitor internal battery			X			
Alarms check, visual and audible	X		X	X		
Personal Monitor alarm and SPS check				X		
Visual inspection of cables and connectors					X	X
Vent filter check					X	
Inventory of spares					X	X
Review of Alarm Log					X	

* Perform test at interval specified by local regulations and hospital policy.

Refer to the Operator's Manual for detailed instructions on maintenance and testing.