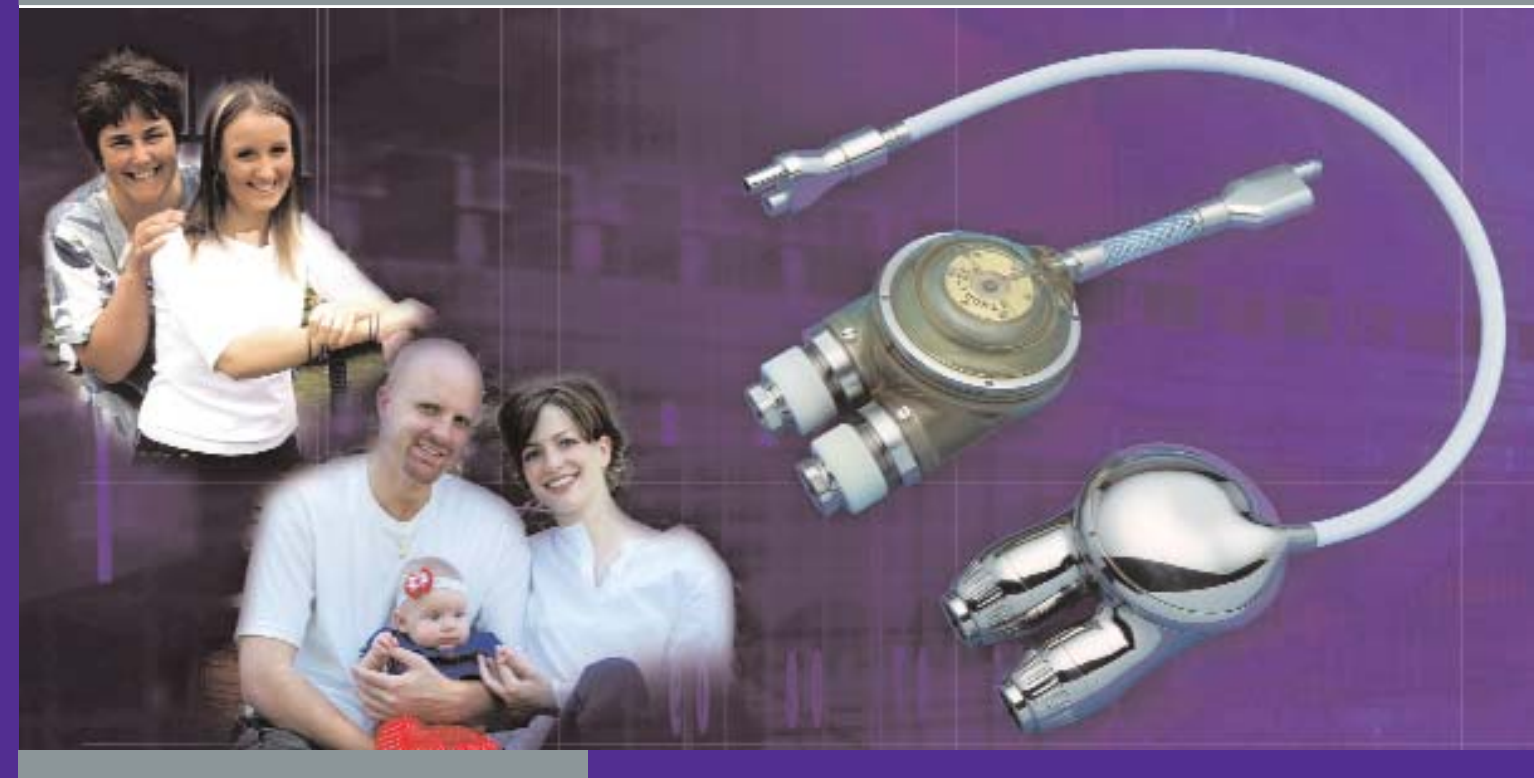


Thoratec® Ventricular Assist Device (VAD) & Implantable Ventricular Assist Device (IVAD™) Patient Handbook



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Thoratec Corporation continually strives to provide the highest quality products for mechanical circulatory support. Specifications may change without notice. Therefore, please refer to the *Thoratec VAD Instructions for Use* shipped with the Thoratec VAD for the most current information regarding indications, contraindications, warnings, and precautions. Thoratec and Thoralon are registered trademarks of Thoratec Corporation.

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Rx Only  0197
2003



PLEASE
Read this entire manual before operating the Thoratec VAD System at home or out of the hospital. It is not safe to leave the hospital before you read the entire manual.

Contact one of the individuals listed below if you have any questions.

All problems should be reported immediately to a qualified medical or technical support person.

Phone number of those people who are trained to help you with the Thoratec VAD System are listed below:

For VAD Team:

Name	Emergency phone () _____	Non-Emergency () _____
_____	_____	_____
_____	pager () _____	() _____

For Medical Assistance:

Name	Emergency phone () _____	Non-Emergency () _____
_____	_____	_____
_____	pager () _____	() _____

Call the hospital medical staff if you or your caregiver called Emergency Medical Services.

<p>Thoratec Corporation 6035 Stoneridge Drive Pleasanton, California 94588 USA (925) 847-8600 Toll Free: (800) 528-2577</p>	<p>Thoratec Europe Limited 5 Brunel Court, Burrell Road, St. Ives, Cambridgeshire, PE27 3LW UK 44-1480 461866</p>
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INDICATIONS FOR USE

The Thoratec Ventricular Assist Device is indicated for:

- Bridge to transplant patients who meet all of the following criteria:
 1. Candidate for cardiac transplantation.
 2. Imminent risk of dying before donor heart procurement.
 3. Dependence on, or incomplete response to, continued vasopressor support.
- Postcardiotomy recovery patients who are unable to be weaned from cardiopulmonary bypass.
- The TLC-II portable pneumatic driver is intended for use both inside and outside the hospital, or for transportation of VAD patients via ground ambulance, fixed wing aircraft, or helicopter.

GENERAL WARNINGS AND PRECAUTIONS – VAD SYSTEM

WARNINGS

1. Pulling, kinking, twisting, stepping on, or placing objects on pneumatic leads can cause loss of air which is necessary for VAD pumping.
2. There may be an increased risk of clot formation in the VAD if blood is not ejecting completely with each beat.
3. Take anticoagulation (blood thinning) medication as prescribed by your doctor. Failure to take this medication may lead to a stroke.
4. Do not take extra blood thinning pills to make up for missed doses.
5. Do not use solvents such as acetone, nail polish remover, paint thinner, or glues, near or on the external VAD because these agents may cause the VAD housing to crack.

PRECAUTIONS

1. Kinking, pulling or twisting cannulas or leads can interfere with tissue healing and increase the risk of infection at the exit site.
2. Total body submersion in water, steam bath or dry saunas, and participation in contact sports is prohibited.
3. Wash your hands with soap and water for 3 minutes before a VAD dressing change and use sterile technique.

4. Contact hospital staff for any of the following:
 - a. Numbness, tingling or weakness.
 - b. Feeling “unwell”.
 - c. Any pain, including chest pain, and unrelieved headache.
 - d. Redness, swelling, drainage at the “exit site(s)”.
 - e. Shortness of breath or dizziness.
 - f. Blurred vision or speech problems.
 - g. Temperature greater than 101°F (38.3°C).
 - h. Unusual bleeding or bruising.
5. Contact the Emergency Medical Services immediately for:
 - a. Loss of consciousness.
 - b. Seizure or convulsions.
 - c. Sudden fall or collapse.
 - d. Aware but unresponsive.
 - e. Inability to talk or move body parts.
 - f. VAD stops.
6. Always confirm a severe air leak before replacing the pneumatic lead. If there is a severe air leak you will hear the air escaping, the TLC-II® Driver will indicate a low pressure alarm and there will be no fill signal. In addition, if you have an external VAD you will see that the VAD is not pumping. If you have an implantable VAD, the empty signal will not light.

GENERAL WARNINGS AND PRECAUTIONS - TLC-II Driver

WARNINGS

1. A backup TLC-II Driver must always be available for potential driver problems or failure.
2. Always keep two emergency Hand Pumps with the TLC-II Driver.
3. Do not remove the occluder from the unused pneumatic connection because the TLC-II Driver will not operate properly.
4. Do not open the back panel of the TLC-II Driver. Only a qualified VAD technician can service this equipment. If the driver needs service, contact your doctor or VAD technician.
5. The TLC-II Driver can only be plugged into a grounded electrical outlet. To avoid accidentally switching off the power to your TLC-II, wall switches must not control the electrical outlets.
6. Use only the power cords and equipment supplied with the TLC-II Driver.
7. Keep the TLC-II dry. Protect it from showers, baths, rain, and liquid spillage. Do not immerse any of the equipment in water.

8. Keep spare components of your TLC-II System available and in good condition. You may need to quickly replace some of the components of your TLC-II System to keep it operating properly.
9. Do not change the Emergency Battery located inside the TLC-II Driver.

PRECAUTIONS

1. Avoid exposing the equipment to extremely hot or cold locations, such as placing the equipment near an oven, a radiator, in a closed vehicle, or in a very cold room.
2. Do not block ventilation holes. Blocking these openings can cause heat build-up that will damage the equipment.
3. Do not place the equipment on a sloping or unstable surface. Do not set any heavy object on top of the equipment. Replace any unstable cart, table or support. Move your equipment with care to avoid overturning or dropping it.
4. Exercise extreme care in cleaning the TLC-II Driver. DO NOT soak any item during cleaning. DO NOT allow water or solvent to come in direct contact with electrical connectors.
5. Do not use satellite phones, cell phones with power outputs greater than 1 Watt, or other radio transmitters (walkie-talkies) within 12 feet (3.6 meters) of the TLC-II Driver or IVAD Empty Signal. Such devices may interfere with the driver operation. *

*** Note: Cellular phones with power outputs of 1 Watt or less can be used at a distance of 2 feet or greater from the TLC-II and IVAD Empty Signal. Check your cell phone's instruction manual to determine its power rating.**

6. Do not operate the driver more than 10,000 ft. above sea level or 1,250 ft. below sea level, unless inside a pressurized cabin (e.g. airplane cabin).

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1 INTRODUCTION

You and your doctor have chosen to use the Thoratec Ventricular Assist Device (VAD) System to support your circulation until your heart recovers or a donor heart becomes available for transplantation.

The Thoratec VAD is a temporary system designed to help the heart pump enough blood to the body. To accomplish support, blood flows from the heart to the VAD (pump), and then back to the body. You have a left ventricular device (LVAD), right ventricular device (RVAD) or bi-ventricular device (BiVAD). One or two pump(s) are either resting on your abdomen (external) or implanted inside your body (implantable). The device type depends on your body size and your heart's requirements.

You and your doctor have agreed that you are ready for excursions away from the hospital or discharge from the hospital. The TLC-II Portable Driver (TLC-II Driver) will provide you with the opportunity to leave the hospital without medical supervision. First, however, you and/or your caregiver will need to complete a training course.

This manual gives you and your caregivers information about how to use and care for this equipment. Your physician and the technical support staff in the hospital have received the technical manual for this equipment.

NOTE: This equipment is intended for use only by individuals who have received the Thoratec VAD System, have been trained to operate the TLC-II Driver and are being supervised by a qualified physician and hospital staff trained in the operation of the Thoratec VAD System.

2 DESCRIPTION

2.1 THE THORATEC VAD SYSTEM

The Thoratec VAD System contains the following major components:

1. Ventricular Assist Device (VAD) Blood Pump
2. Cannulae
3. TLC-II Driver

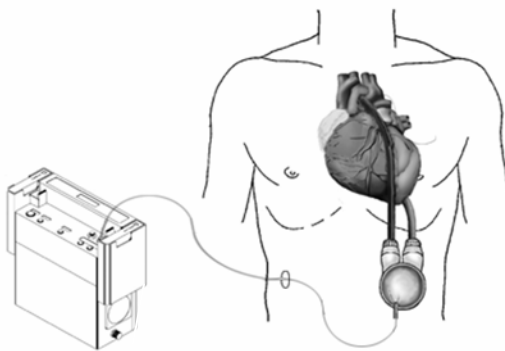


Fig. 1.1 Implantable ventricular assist device (IVAD)

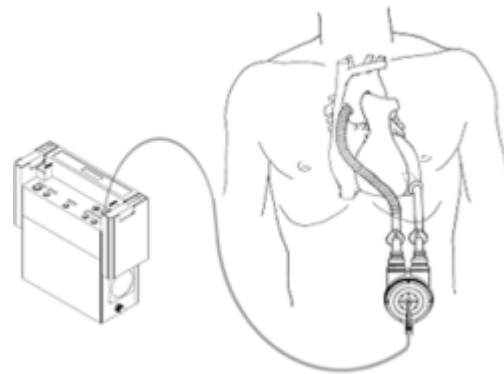


Fig. 1.2 Paracorporeal ventricular assist device (PVAD)

- One or two VADs (pumps) are placed in or on the abdomen and connect to the heart and great vessels with cannulae.
- The VAD(s) is(are) operated and controlled by the TLC-II Driver.
- Implantable VAD (Fig. 1.1). One lead from each VAD exits the body and connects to electrical and pneumatic leads.
- External VAD (Figure 1.2). Two cannulae exit the body and connect to the VAD. Each VAD connects to an electrical and pneumatic lead.
- The electrical and pneumatic leads connect the VAD to the TLC-II Driver. The electrical lead carries signals to and from the VAD, and notifies the Driver when the VAD is full of blood. The pneumatic lead is plastic and shuttles air between the Driver and VAD. The air is necessary for VAD pumping.

2.2 THE TLC-II DRIVER SYSTEM

You should have the following components in the TLC-II System:

- | | | |
|-------------------------------------|--------------------|----------------------|
| 1. TLC-II Driver with Carrying Case | 4. Battery Charger | 7. Car Power Adapter |
| 2. Batteries | 5. Mobility Cart | |
| 3. AC Adapter | 6. Hand Pumps | |

2.3 THE TLC-II DRIVER WITH COMPONENTS

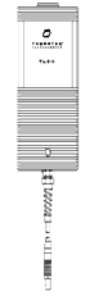
Figure 2



1. Carrying Case



2. Battery



3. AC Adapter



4. Battery Charger



5. Mobility Cart



6. Hand Pumps



7. Car Power Adapter

- The TLC-II Driver provides power to pump the VAD, and uses symbols, messages, and beeps to report information and alert you to situations requiring attention.
- The symbols and Message Display on the TLC-II Driver's front panel will indicate what you need to do.
- The TLC-II Driver should always be used in the Carrying Case, which can be carried by hand, the shoulder strap, or on the mobility cart.

- The Carrying Case can also hold the AC Adapter with Cables, two spare Batteries, and two Hand Pumps.



CAUTION

Do not block the air vent at the bottom of the Carrying Case. It can cause the TLC-II Driver to overheat and malfunction.

2.4 BATTERIES

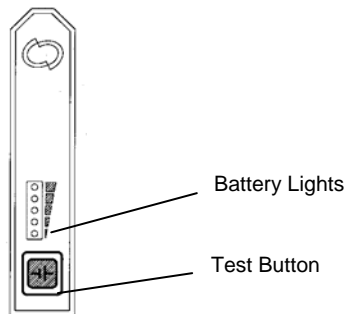


Figure 3

- Each side of the TLC-II Driver has a slot for each Battery.
- Each Battery provides at least 55 minutes (for 2 VADs) or 80 minutes (for 1 VAD) when fully charged.
- Pressing the test button will illuminate up to five green battery lights.
- If all five lights are lit, the battery is fully charged.
- Batteries can only be charged using the Battery Charger (see Section 2.6 on page 13).

2.5 AC ADAPTER

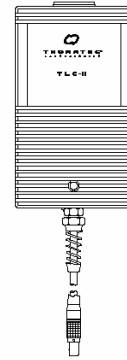


Figure 4

- The AC Adapter with cables can be connected to the TLC-II Driver and a grounded electrical outlet to preserve Battery life.
- The AC Adapter should be used when you are not mobile.
- The AC Adapter will not charge Batteries.

2.6 BATTERY CHARGER



Figure 5

- The Battery Charger can fully recharge up to two Batteries in two hours.
- The Charger power switch should always be ON and connected to a grounded electrical outlet.

2.7 MOBILITY CART



Figure 6

- The Mobility Cart can be used to transport the TLC-II Driver.
- The TLC-II Driver is attached to the Mobility Cart with Velcro straps found on the Carrying Case.
- The Cart can be folded up for convenient storage.

2.8 HAND PUMPS



Figure 7

- Two Hand Pumps should remain with the TLC-II Driver at all times.
- One Hand Pump is needed for each VAD.
- In the event of TLC-II Driver failure, blood flow can be maintained with the Hand Pumps.

2.9 CAR POWER ADAPTER



Figure 8

- The Car Power Adapter, like the AC Adapter, does not charge the batteries in the TLC-II Driver but can be used to preserve battery life.

2.10 IMPLANTABLE VAD EMPTY SIGNAL



Figure 9 Part of Implantable VAD Electrical Lead

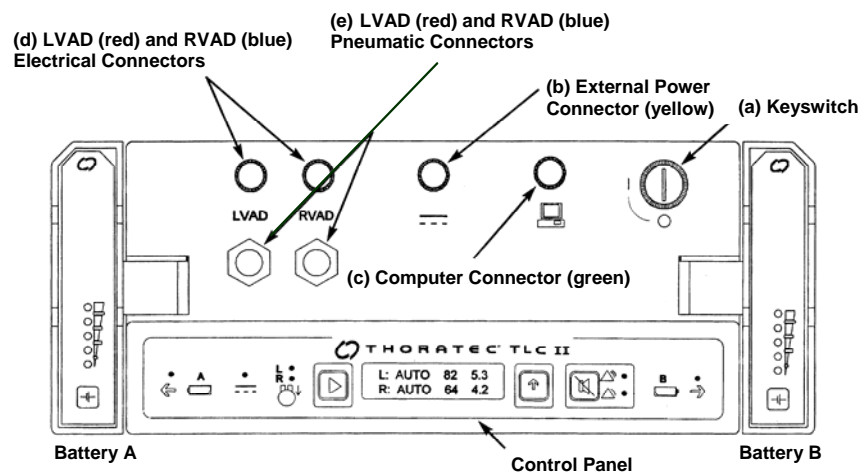
- For use with the Implantable VAD only.
- Each time blood is completely emptied from inside the VAD, the empty light will turn green.

3 DRIVER MESSAGES AND CONNECTIONS

Only medical or technical support teams should make adjustments to your TLC-II System. Adjustments are made by connecting your TLC-II Driver to the HeartTouch™ Computer. However, you and/or your caregiver should understand basic information about the system including appropriate action for all alarms.

3.1 TOP OF THE DRIVER

Figure 10 Located at the top of the TLC-II Driver are the connectors, a control panel, and two Batteries (Battery A and Battery B).



KEYSWITCH (a)

- The key to turn on the TLC-II Driver goes into the **Keyswitch**.
- Remove the key to avoid turning off the Driver, once the driver is ON.
- Store the key in the Carrying Case pocket.
- The key cannot be removed when the Driver is OFF.

EXTERNAL POWER CONNECTOR (b)

- The **External Power Connector** is color-coded **YELLOW**.
- To preserve battery life, the yellow AC Adapter with cables attaches to the External Power Connector and to a grounded electrical outlet.

COMPUTER CONNECTOR (c)

- Only for use by medical personnel.
- The **Computer Connector** is color-coded **GREEN** and connects to the HeartTouch Computer with a green cable.

ELECTRICAL (d) AND PNEUMATIC (e) CONNECTORS

- Color-coded electrical and pneumatic connectors are located above the message panel.
- The **LVAD** electrical and pneumatic leads are **RED** and connect to the **RED** electrical and pneumatic connectors.
- The **RVAD** electrical and pneumatic leads are **BLUE** and connect to the **BLUE** electrical and pneumatic connectors.


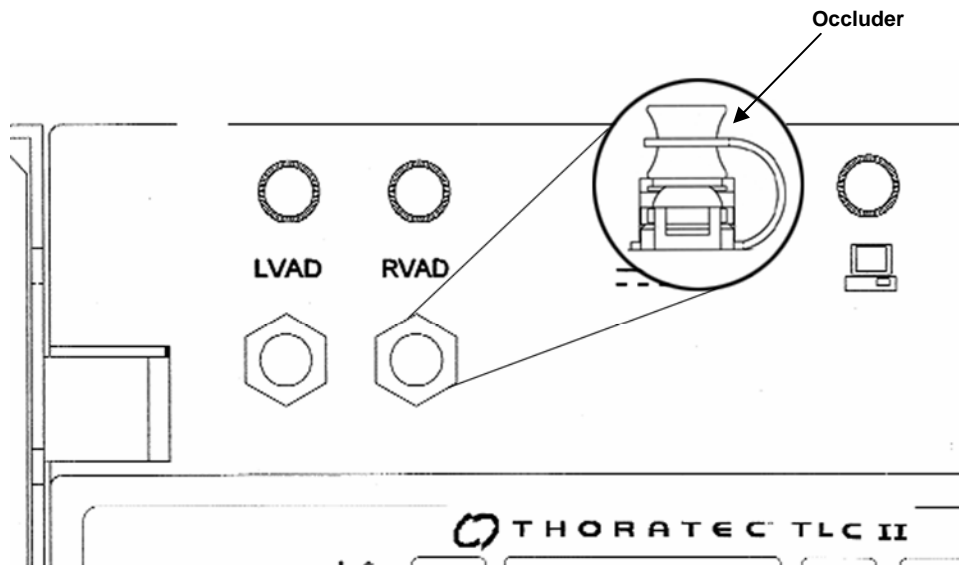
	<p>WARNING</p> <p>Do not remove the occluder from the unused pneumatic connection because this will cause the TLC-II Driver to lose pressure.</p>
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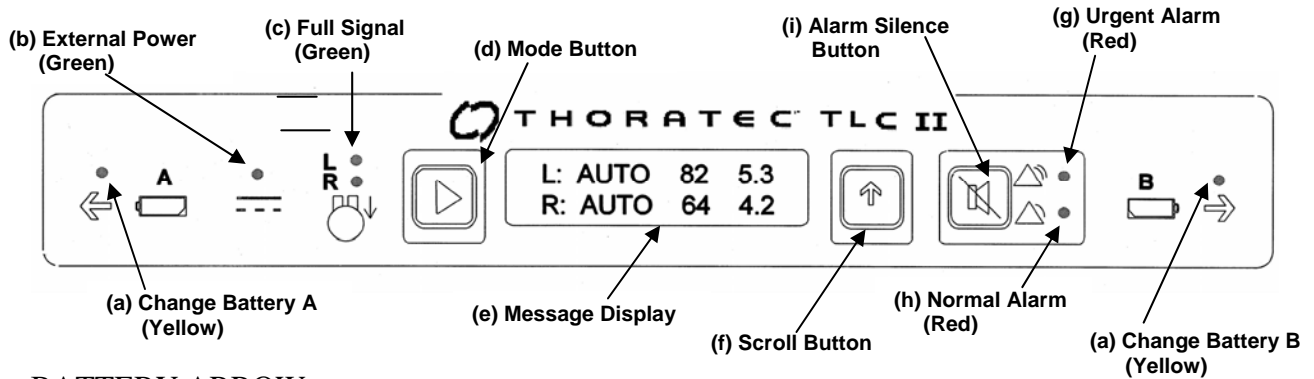
Figure 11 Occluder covering the unused RVAD pneumatic connector.



3.2 CONTROL PANEL

The **Control Panel** is located on top of the TLC-II Driver.

Figure 12 Control Panel



BATTERY ARROW $\leftarrow \Rightarrow$

- A **Change Battery** light (a) is found on each side of the Message Panel (Fig. 11).
- The Change Battery A light (left) turns yellow when battery A should be replaced with a fully charged battery.
- The Change Battery B light (right) turns yellow when battery B should be replaced with a fully charged battery.

EXTERNAL POWER \bullet

- The **External Power** light (b) will turn green when the TLC-II Driver is powered from an electrical outlet (external power source) instead of batteries.

FULL SIGNAL \bullet

- The **Full Signal** (c) turns green when the LVAD (L) and/or the RVAD (R) are full of blood, as detected by a sensor in the VAD.

MODE BUTTON

- Pressing the **Mode Button** (d) changes the mode of operation between a fixed rate (FIXD) or automatic rate (AUTO).
- The current mode is indicated on the **Message Display** (e).
- Only your physician, or a technician, can deactivate the Mode Button.


MESSAGE DISPLAY

L: AUTO	82	5.3
R: AUTO	64	4.2


- The **Message Display** (e) provides information about the LVAD and the RVAD.
- The top row displays LVAD information about the mode of operation (FIXD or AUTO), VAD rate, VAD output, and alarms.
- The bottom row displays RVAD information.

SCROLL BUTTON 

- The **Scroll Button** (f) can be pressed to read multiple alarm messages.
- If the button is not pressed, each alarm message will automatically display for three seconds.
- Pressing this button will also display the Driver’s serial number and total usage hours.

ALARMS  (g) Urgent (Red)
 (h) Normal (Red)

- The **Urgent Alarm** light (g) turns red and a continuous alarm sounds when the system is operating from the emergency backup battery.
- This alarm cannot be silenced.
- The **Normal Alarm** light (h) turns red and an alarm sounds for all other alarm situations.
- The audible alarm can be silenced for 30 seconds by pressing the **Silence Button** (i), and the alarm remains red.



WARNING
 Pressing the silence button does not correct the cause of the alarm.
 Investigate and correct the cause of any alarm condition.

The alarm type and required action is seen in the **Message Display**. More alarm information is found in Section 5.

3.3 BATTERY FRONT PANEL

- A **Battery** is located on each side of the TLC-II Driver.
- Pressing the **Test Button** on the Battery will illuminate up to five green **Battery Lights**, which show approximate battery charge.
- If all five lights are lit, the battery is fully charged.

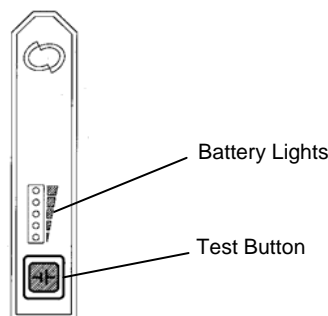


Figure 13 Battery

4 POWER MANAGEMENT

The TLC-II Driver requires at least two power sources to drive the VAD: either two Batteries, or one Battery and external power from a grounded electrical outlet. The Batteries are a rechargeable source of power that allows you to move freely in or out of the house. However, Batteries can only be used for a limited time. The external power can provide a continuous source of power, as long as the power cable is connected to the TLC-II Driver and a grounded electrical outlet.

4.1 USING EXTERNAL POWER

- While reading, watching TV or sleeping you should use external power by connecting to an electrical outlet because it provides power for an unlimited period of time. In fact, if you are relaxing and might fall asleep, you should switch from battery power to electrical power, in case you sleep longer than the time allowed by the remaining power in the Batteries.

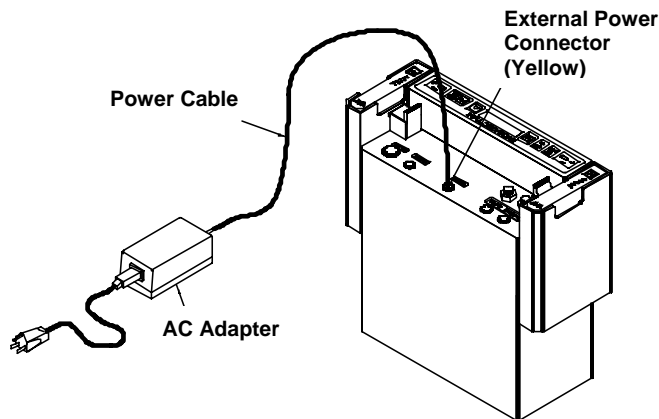


Figure 14 TLC-II Driver with Power Cable

- To use external power, plug the yellow plug on the power cable into the TLC-II Driver's yellow external power connector. Next, plug the AC cord into a grounded electrical outlet.
- Verify that the external power light on the TLC-II Driver turns green. If the light does not turn green, the TLC-II Driver is using battery power.
- Before switching back from external power to battery power, make sure that two charged batteries are in the TLC-II. Pressing the Test Button will provide information about battery power remaining. Next, disconnect the yellow power cable from the TLC-II and then the electrical outlet.
- A short beep will indicate a new power source.



WARNING

The TLC-II Driver should be plugged into grounded electrical outlets only. To avoid accidentally switching off the external electrical power to your Driver, wall switches must not control any electrical outlets.

4.2 USING THE CAR POWER ADAPTER

- Remove the cigarette lighter from its socket in the automobile.
- Insert the car power adapter plug into the cigarette lighter socket. **Note:** Power may be available without turning the car key to the ON position or having the engine started. The green light on the adapter plug and body illuminates when there is power.
- Start the car engine.
- Verify that the green lights on the car power adapter are illuminated. **Note:** Do NOT use the adapter if the lights are not illuminated.
- Plug the yellow color-coded cable of the car power adapter into the yellow external power connector on the TLC-II Driver.
- Verify that the external power light on the Driver turns green. **Note:** A short beep indicates that external power is connected. If there is no beep and the light does not turn green, the TLC-II is still drawing power from the batteries.
- Before switching from the car power adapter back to batteries, make sure that 2 charged batteries are in the TLC-II Driver. **Note:** Pressing the Test Button provides information about remaining battery power. The Car Power adapter should be used **ONLY** when fully charged batteries are available. Do not rely on it as the sole source of power.
- Disconnect the yellow color-coded external power cable from the TLC-II and then switch to battery power. **Note:** A short beep indicates disconnection of external power. The car power adapter and cables can be stored in the TLC-II accessory pocket.

4.3 USING BATTERY POWER

- Five green battery lights indicate a fully charged battery. When fully charged, each Battery provides at least 55 minutes for BiVAD support and 80 minutes for LVAD or RVAD support.
- When using battery power, the TLC-II Driver will use power from only one Battery. Once the power is gone from one Battery, the TLC-II will automatically start using power from the other battery.
- When a Battery loses all its power, a beep is heard and the light for Battery A or B will turn yellow. The beep will sound every 30 seconds and there will be the message “**CHANGE BATTERY A**” or “**CHANGE BATTERY B**” in the Message Display.
- If the battery is not changed and the second Battery has less than ten minutes of power remaining, a continuous alarm sounds. In this case both batteries are low.

You need to change the battery next to the Change Battery light (turns yellow). The Battery that should be changed is also indicated on the Message Display.

**CAUTION**

It is extremely important to change the battery; otherwise the second battery will eventually lose its power and emergency power becomes necessary.

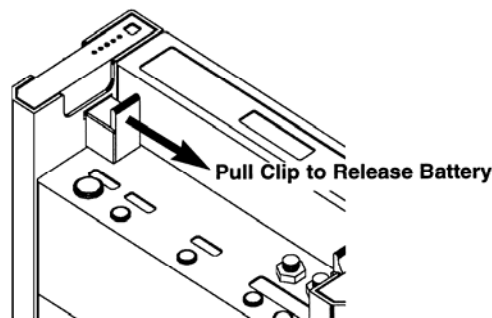
4.4 BATTERY REMOVAL

To remove a battery from the TLC-II, slide the clip and pull out the battery (see Figure 13). Slide a fully charged battery into the slot, pushing down until you hear it snap into place.

**CAUTION**

Do not use the leads as leverage when you remove the Battery. This could damage the leads and require replacement.

Figure 15 Battery Removal



4.5 CHARGING BATTERIES

The battery charger should always be ON and connected to a grounded electrical outlet. The switch is located on the back of the charger. Insert one or two Batteries into the charger. It can fully recharge up to two Batteries in two hours. It is best to leave the Batteries in the charger until charging is complete.

**CAUTION**


**Do not place the battery charger on a sloping or unstable surface.
Do not set any heavy objects on top of the equipment.**

The battery charger has three lights for each battery (see Figure 16):

Charging: Yellow light indicates that the Battery is charging.

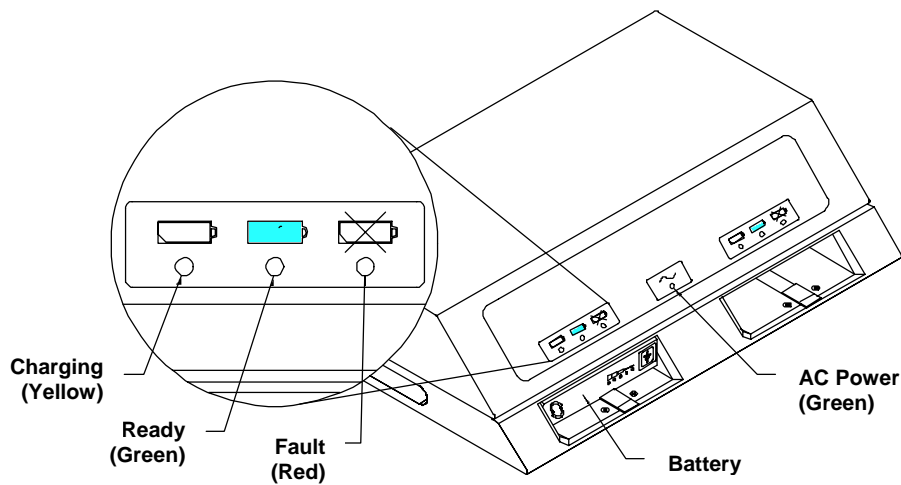
Ready: Green light indicates a fully charged battery ready for use.

Fault: Red light indicates a problem with the battery. This light will flash if the battery temperature is too high or too low. Remove the battery from the charger and wait for the battery to cool down or warm up and try again.



CAUTION
 Do not use a battery if a red light appears, because it may not work properly.
 Call your VAD technician.

Figure 16 Battery Charger



To remove a Battery from the charger, press the tab located under the Battery and remove the Battery.

4.6 CARE OF BATTERIES

Your Batteries include many features to make them safe and dependable. However, you must care for them properly.

Things to do:

- Store your Batteries and Battery Charger in a cool, dry place and within a temperature range of -4°F to 140°F (-20°C to 60°C).
- Charge Batteries within a temperature range of 10°C to 35°C (50°F to 95°F).
- Use all your Batteries. A serial number is located on each Battery.
- Store Batteries fully charged. Two Batteries may be stored in the battery charger for up to 14 days.
- Protect the Battery connectors from moisture, dirt and metal at all times.

Things NOT to do:

- Do not leave the Batteries exposed to extreme heat or cold, especially in direct sunlight or in a closed car in the sun. The temperature can easily reach 140°F to 150°F (60°C - 65°C) which can damage the Batteries.
- Do not drop the Batteries or let them hit hard objects.
- Do not let Batteries get wet.
- Do not store Batteries in the charger for more than 14 days.
- Do not allow necklaces, chains, or other metallic items to come into contact with the Batteries.
- Do not disassemble or modify the Batteries.
- Never use Batteries as a power supply for anything other than the TLC-II Driver.

5 ALARMS

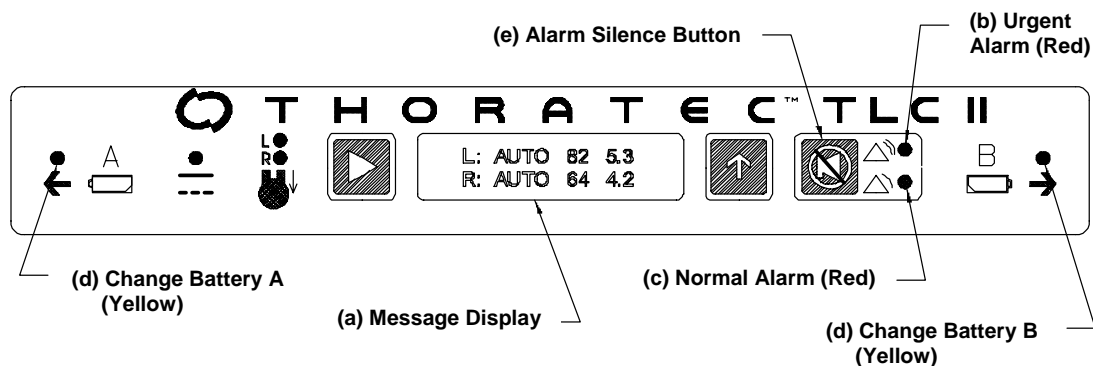
5.1 OVERVIEW

The alarms alert you to potential problems with the TLC-II Driver or VAD. For your safety, it is important that you and/or your caregiver understand all the alarms and appropriate action requirements.

Each alarm situation includes a 1) written message, 2) visible alarm and 3) audible alarm (beep).

- 1) The written message is found in the Message Display (a) and describes the alarm and action you need to take. “L” means LVAD and “R” means RVAD.
 - The Urgent Alarm turns red when the emergency system in operation.
 - The Normal Alarm turns red for all other alarms.
 - The Change Battery alarm turns yellow when a Battery should be replaced with a fully charged Battery.
- 2) The visible alarm is a light that illuminates to indicate an Urgent Alarm (b), Normal Alarm (c), or need to change a Battery (d).
 - The Urgent Alarm turns red when the emergency system in operation.
 - The Normal Alarm turns red for all other alarms.
 - The Change Battery alarm turns yellow when a Battery should be replaced with a fully charged Battery.
- 3) The audible alarm beeps intermittently or continuously for all alarm situations.
 - The audible alarm can be silenced temporarily for normal alarm situations by pressing the Silence Button (e). However, silencing the alarm does not correct the cause of the alarm.

Figure 17 Message Panel



CAUTION

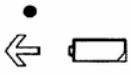
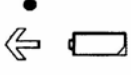



Pressing the Silence Button does not correct the alarm.
 Investigate and correct the cause of any alarm.










CAUTION


If you cannot hear alarms or read the messages,
 you need help from someone who can.

5.2 ALARM MESSAGES AND RESPONSES

There are seven alarm types that include batteries, loss of fill, pressure and vacuum, temperature, service interval, internal alarms and emergency backup. Alarms are summarized below. Written messages use “L” for LVAD and “R” for RVAD.

WRITTEN MESSAGE	VISUAL ALARM	AUDIBLE ALARMS (BEEP INTERVAL)	MEANING	ACTION REQUIRED
CHANGE BATTERY A <<<A OR CHANGE BATTERY B >>>B	Yellow light for change Battery A or Battery B 	30 seconds	Battery A or Battery B has no power .	Change Battery A or Battery B with a fully charged Battery.
CHANGE BATTERY A < 10 MINUTES LEFT OR CHANGE BATTERY B < 10 MINUTES LEFT	Yellow light for change Battery A or Battery B 	Continuous	One Battery has no power and the remaining Battery has less than 10 minutes of power. If both Batteries lose their power, the TLC-II will run on the emergency battery and emergency System. The emergency battery has a limited amount of time it can run the TLC-II Driver.	Change the battery with a fully charged Battery immediately. Change the battery next to the Change Battery light (yellow). The appropriate battery is also indicated on the Message Display.
EMERGENCY BATT REPLACE	Normal Alarm lights red 	Continuous	There is about 10 minutes or less of emergency battery power.	Replace TLC-II Driver with a back-up TLC-II Driver immediately.
NO L FULL SIGNAL CHECK LEADS; VAD OR NO R FULL SIGNAL CHECK LEADS; VAD	Normal Alarm lights red and the LVAD and/or RVAD green fill light no longer illuminates 	5 seconds	The TLC-II Driver has not detected a full signal for approximately 8 seconds. The pump may not be completely full. The Message Display shows a “_ _ _” instead of VAD rate. The VAD will pump at a previously set rate.	Verify VAD pumping. Check leads for proper connections or kinks.
HI L PRESSURE REPLACE OR NO R PRESSURE REPLACE	Normal Alarm lights red 	Continuous	The pressure in the TLC-II Driver is too high to operate properly.	Verify VAD pumping, check leads for kinks or blockage. Replace TLC-II Driver with back-up driver. Call VAD technician.

WRITTEN MESSAGE	VISUAL ALARM	AUDIBLE ALARMS (BEEP INTERVAL)	MEANING	ACTION REQUIRED
LO L PRESSURE CHECK; REPLACE OR LO R PRESSURE CHECK; REPLACE	Normal Alarm lights red 	Continuous	The pressure in the TLC-II Driver is too low to operate properly.	Verify VAD pumping, check leads for proper connections, and system for air leaks. Replace TLC-II Driver with back-up driver. Call VAD technician.
HI L VACUUM REPLACE OR HI R VACUUM REPLACE	Normal Alarm lights red 	Continuous	The vacuum is too high.	Replace TLC-II Driver with back-up driver. Call VAD technician.
LO L VACUUM REPLACE OR LO R VACUUM REPLACE	Normal Alarm lights red 	Continuous	The vacuum is low.	Replace TLC-II Driver with backup driver. Call VAD technician.
RVAD OCCLUSION CHECK LEADS; VAD OR LVAD OCCLUSION CHECK LEADS; VAD	Normal Alarm lights red 	Continuous	Pneumatic lead or cannula is kinked or obstructed or the TLC-II Driver is ejecting a VAD partially filled with blood.	Verify VAD pumping. Check leads and cannulas for kinking. Call VAD technician.
HI TEMPERATURE REPLACE	Normal Alarm lights red 	Continuous	The compressor temperature is too high.	Check the TLC-II Driver's air filter for dust or blockage. If necessary, remove the dust. If not blocked or resolved with dusting, replace the TLC-II Driver and call VAD technician.
LO TEMPERATURE WAIT	Normal Alarm lights red 	1 second	The compressor temperature is too low.	Wait for the TLC-II Driver to warm up before use.
SERVICE INTERVAL REPLACE	Normal Alarm lights red 	10 seconds	Preventive maintenance is required every 1500 hours of continuous use to prevent driver malfunctions. Thoratec must perform TLC-II Driver Service.	Replace TLC-II Driver as soon as possible. Call the VAD technician.
ALARM 18-24 REPLACE	Normal Alarm lights red 	1 second	One of the internal test situations has failed to operate within specifications.	Replace TLC-II Driver immediately. Call VAD technician.
<i>No written message</i> OR EMER SYSTEM ON	Urgent Alarm lights red 	Continuous	The TLC-II Driver is operating on the emergency battery system. The alarm cannot be silenced.	Verify power from the batteries or electrical outlet. Replace TLC-II Driver immediately. Call VAD technician.

WRITTEN MESSAGE	VISUAL ALARM	AUDIBLE ALARMS (BEEP INTERVAL)	MEANING	ACTION REQUIRED
<p><i>No written message</i></p>	<p>(Implantable VAD only) VAD Empty Signal</p> <ul style="list-style-type: none"> • Light flashing very quickly or flickering faster than VAD rate 	<p>No audible alarm.</p>	<p>Empty signal processor interruption or failure.</p>	<p>Check drive lines, all connections. Remove electrical lead and reconnect at TLC-II driver. Call VAD technician.</p>

Note: When the recommended action is to replace the TLC-II Driver, the emergency Hand Pumps can be used if no backup TLC-II Driver is immediately available.

6 EMERGENCY RESPONSE

A back-up TLC-II Driver and Hand Pumps must always be available for potential TLC-II Driver failures. This section will describe necessary steps to switch to a backup TLC-II Driver and proper use of the Hand Pumps.

6.1 SWITCHING TO BACK-UP TLC-II DRIVER

Before you leave the hospital, your doctor or VAD technician will program appropriate settings for your backup Driver. This is a precaution, in case your backup Driver is needed for emergency use. The following are the necessary steps for you to switch to your backup TLC-II Driver.

1. Place two fully charged **Batteries** in the TLC-II Driver.
2. **Turn on** the TLC-II Driver and remove key.
3. **OPTIONAL:** Press the SILENCE button (Several alarms will sound because no VAD is connected to the Driver).
4. **Verify** battery power or external **power** to the TLC-II Driver.
5. **Disconnect the pneumatic lead(s)** (red for LVAD or blue for RVAD) and immediately attach it to the back-up driver pneumatic connector of the same color (remove the Occluder for the lead being connected).
6. **Disconnect the electrical lead(s)** (red for LVAD or blue for RVAD) and connect it to the back-up driver electrical connector of the same color.
7. **Verify no alarms and call** your **VAD support team** immediately. (See page 2).
8. If alarms are present, perform the appropriate troubleshooting listed in Section 5.
9. **Store key** in carrying case.



CAUTION

Always change the LVAD first if supported with two pumps (BiVADs).



WARNING

Leave the Occluder on the unused pneumatic connector if supported with only one VAD pump. Otherwise the TLC-II System will not have enough pressure to operate properly.

6.2 USING THE HAND PUMP

In the event of a TLC-II driver failure, blood flow can be maintained with the emergency hand pumps. One pump is needed for each VAD.

1. Disconnect the pneumatic lead from the TLC-II Driver and connect it to the Hand Pump (Figure 18).
2. Squeeze the Hand Pump completely about once per second (60 times per minute) to empty and fill the blood pump(s). Use your foot to squeeze the Hand Pump, if necessary.
3. Switch to the backup TLC-II Driver as soon as possible.

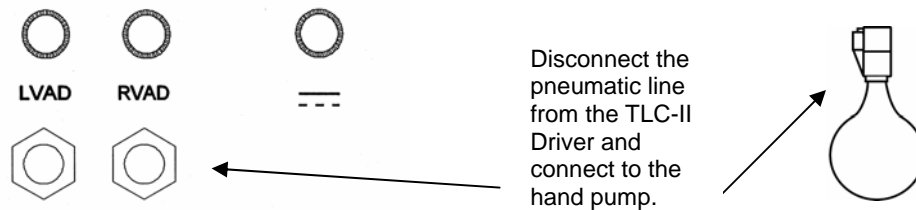


Figure 18 Hand Pump Connections



WARNING

For BiVAD support squeeze each Hand Pump at the same rate. Do not pump the RVAD faster than the LVAD because this can cause lung congestion.

6.3 SWITCHING TO BACK-UP PNEUMATIC OR ELECTRICAL LEAD

It is unlikely that these leads will require replacement and before you leave the hospital, your doctor or VAD technician will show you how to switch the pneumatic and electrical leads. The leads should never be replaced unless instructed to do so by a doctor or VAD technician.

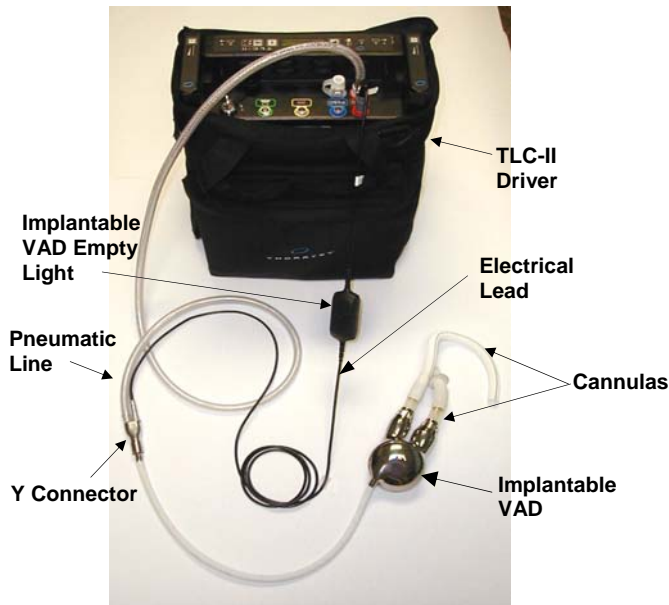


Fig 19.1 Implantable VAD System

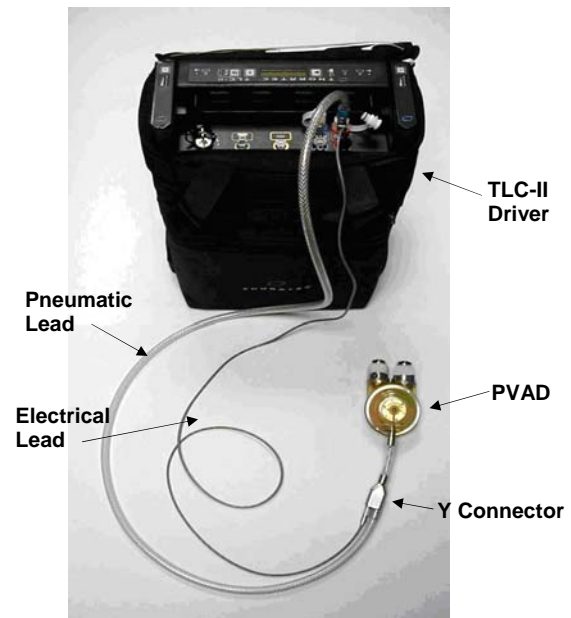



Fig 19.2 External VAD System

6.3.1 Switching the Pneumatic Lead

If there is a severe air leak you will be able to hear the air escaping, the TLC-II driver will indicate a low pressure alarm and there will be no full signal. In addition, if you have an external VAD you will be able to see the VAD is not pumping; if you have an implantable VAD the empty signal will not light.



CAUTION:

Always confirm a severe air leak before replacing the pneumatic line. If the source of the TLC-II alarms is uncertain, see Section 5.

Apply hand pressure to occlude the leak. Tape can also be used to seal the leak. If this resolves the air leak and eliminates the TLC-II alarms, call your VAD Technician or physician for additional instructions.

If the air leak cannot be resolved with hand pressure or tape, the TLC-II driver indicates a low pressure alarm and no full signal alarm, and the VAD is not pumping normally, replace the leaking pneumatic lead with a new pneumatic lead.

The following steps are necessary to switch the pneumatic lead:

1. Disconnect the leaking pneumatic lead from the Y-Connector and then from the TLC-II Driver's pneumatic connector (Figure 19.1 or 19.2).
2. Attach the new pneumatic lead to the Y-Connector and TLC-II Driver's pneumatic connector. The metal fitting on the pneumatic lead attaches to the TLC-II Driver.
3. Verify no alarms and VAD pumping.
4. Call your VAD support team immediately.

6.3.2 Switching the Electrical Lead

This lead should be replaced only under the guidance of the VAD support team. The lead may require replacement if it is suspected that the lead is faulty.

To replace, disconnect the electrical lead from the Y-Connector and TLC-II Driver's electrical connector (Figure 19.1 or Figure 19.2). Next, attach the new lead to the Y-Connector and TLC-II Driver's electrical connector.

6.4 EMERGENCY CONTACT SITUATIONS

If there is an urgent or life-threatening problem, call your local emergency medical services (911 for the USA).

NOTE: You should call the VAD technician or physician for any alarm situation other than the “Change Battery A” or “Change Battery B” alarm.

Contact the hospital medical staff for any of the following conditions:

- Numbness, tingling or weakness in any arm or leg
- Blurred vision or speech problems
- Shortness of breath or dizziness
- Any pain, including chest pain, unrelieved headache
- Temperature greater than 101°F (38.3°C)
- Any redness, swelling or drainage around the exit site(s)
- New, increased, or change in color of drainage from incision area
- Unusual bleeding or bruising
- Any condition where you feel “unwell”

Emergency Medical Services should be contacted immediately if any of the following occurs:

- Seizure or convulsion
- Loss of consciousness
- Awake but unresponsive
- Sudden fall or collapse
- Inability to talk or move body parts
- VAD stops

NOTE: Call the hospital medical staff after calling Emergency Medical Services.

See Page 2 for Contact Names and Numbers.

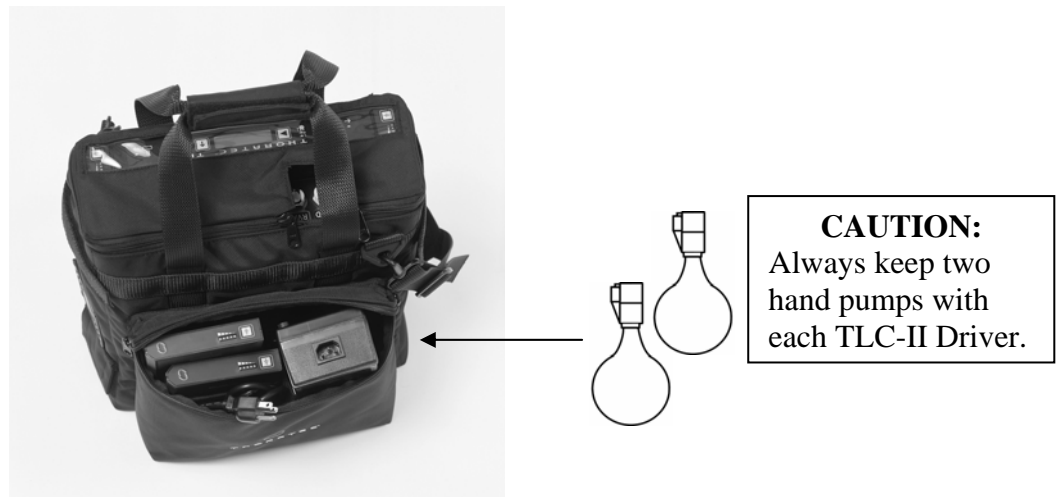
7 PREPARING FOR EXCURSIONS AND HOSPITAL DISCHARGE

For your safety, it is very important that you leave the hospital with all the necessary equipment. The following equipment is required for excursions away from the hospital or hospital discharge.

7.1 EQUIPMENT REQUIREMENTS

EXCURSIONS	HOSPITAL DISCHARGE
1 Primary TLC-II Driver	1 Primary TLC-II Driver
1 Back-up TLC-II Driver	1 Back-up TLC-II Driver
4 Hand Pumps	4 Hand Pumps
4 Fully charged spare Batteries (used in A and B battery slots of Primary and Back-up driver)	8 fully charged spare Batteries (used in A and B battery slots of Primary and Back-up driver)
1 AC Adapter with cables	2 AC Adapters with cables
1 Mobility Cart	1 Mobility Cart
1 Car Power Adapter	1 Battery Charger
	1 spare Pneumatic Lead
	1 spare Electrical Lead
	1 Car Power Adapter

Figure 20 TLC-II Driver with Accessories



7.2 USING THE MOBILITY CART

To mount the TLC-II on the Mobility Cart (Figure 20):

1. Unfold the Mobility Cart until it snaps into place.
2. Place the TLC-II Driver with carrying case firmly against the bottom of the cart.
3. Wrap the Velcro strips from each side of the carrying case through the cart's frame, then firmly re-attach it back to the case.
4. Pull up the cart handle until it firmly locks into place.

Figure 21 TLC-II Mobility Cart



8 EQUIPMENT MAINTENANCE AND CARE

8.1 MAINTENANCE

For your safety, a VAD technician will perform periodic safety checks of your TLC-II Drivers. In addition, Thoratec performs complete service on your TLC-II Driver at regularly scheduled service intervals.

The TLC-II Driver will automatically notify you when service is required. The message “Service Interval, Replace” will appear in the Message Display. The Normal Alarm lights red, and the audible alarm sounds every 10 seconds. You should replace your TLC-II Driver with the backup TLC-II Driver as soon as possible and notify your VAD coordinator or physician that the driver requires servicing.

8.2 EQUIPMENT CARE

You must take care of your equipment in order for it to work properly.

- Do not expose the TLC-II Driver to temperatures higher than 104°F (35°C) or lower than 50°F (10°C) for prolonged periods of time.
- To prevent a high temperature alarm, do not block the air filter on the TLC-II Driver Carrying Case.
- Keep the TLC-II Driver dry. Protect it from shower, baths, rain, and liquid spills.
- Avoid the following as they may be hazardous to, or interfere with the operation of, your Thoratec VAD System:
 - Paint, paint remover, finger polish remover or other solvents
 - High power cellular phones (greater than 1 Watt) within 12 feet
 - Satellite phones (within 12 feet)
 - Radio transmitters or walkie-talkies (within 12 feet)

Note: Cellular phones with power outputs of 1 Watt or less can be used at a distance of 2 feet or greater from the TLC-II and IVAD Empty Signal. Check your cell phone’s instruction manual to determine its power rating.

8.3 CLEANING THE EQUIPMENT

Use extreme care when cleaning your equipment. You can dust the equipment periodically. Regularly inspect the air filter and remove the dust with a cloth or vacuum. If removal of heavy dirt is necessary, use a soft, clean, moist cloth. Dampen the cloth with a mild soap and water solution.

**CAUTION**

DO NOT soak any item during cleaning.
DO NOT allow water to come in direct contact with electrical connectors.

9. ADVERSE EVENTS

Due to the severity of your illness and because of the open-heart operation that you had, you can have complications after the pump is implanted. The potential complications (which are also called “adverse events”) may include:

- Death
- Infection
- Neurological Dysfunction
- Thromboembolic Complication
- Bleeding
- Reoperation
- Hemolysis
- Hepatic Dysfunction
- Arrhythmias
- Respiratory Failure
- Hypertension
- Hypotension

You may be able to go home with your TLC-II driver. A study was done to compare how patients did who stayed in the hospital with the TLC-II and those patients that were able to go home. The complication results of this study are presented in the following table:

**Adverse Events Regardless of Cause
 In-Hospital and Home Discharge Patients**

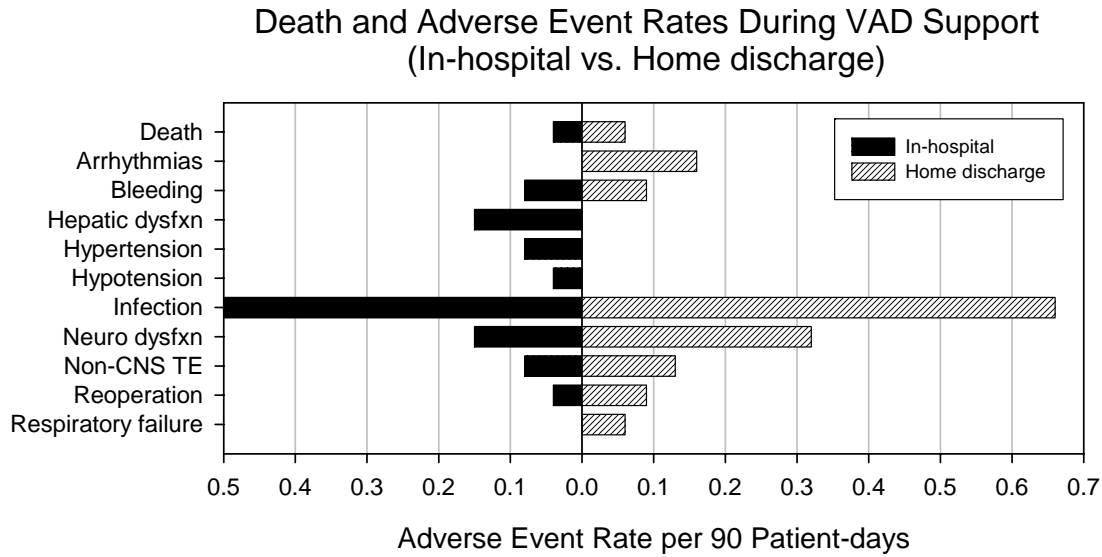
Event	Home Discharge Group After Initial Discharge (n=25*)					TLC-II In Hospital (n=31)				
	Patients	% of Pts	UCL†	LCL‡	Events	Patient	% of Pts	UCL	LCL	Events
Bleeding	3	12.0%	24.7%	0.0%	3	2	6.5%	15.1%	0.0%	2
Cardiac Tamponade	0	0.0%	0.0%	0.0%	0	0	0.0%	0.0%	0.0%	0
Hemolysis	0	0.0%	0.0%	0.0%	0	4	12.9%	24.7%	1.1%	4
Infection	13	52.0%	71.6%	32.4%	21	10	32.3%	48.7%	15.8%	13
Arrhythmias	3	12.0%	24.7%	0.0%	5	0	0.0%	0.0%	0.0%	0
Right Heart Failure	0	0.0%	0.0%	0.0%	0	0	0.0%	0.0%	0.0%	0
Left Heart Failure	0	0.0%	0.0%	0.0%	0	0	0.0%	0.0%	0.0%	0
Myocardial Infarction	0	0.0%	0.0%	0.0%	0	0	0.0%	0.0%	0.0%	0
Thromboembolic Complication (non-CNS)	4	16.0%	30.4%	1.6%	4	2	6.5%	15.1%	0.0%	2
Reoperation	3	12.0%	24.7%	0.0%	3	1	3.2%	9.4%	0.0%	1
Hepatic Dysfunction	0	0.0%	0.0%	0.0%	0	4	12.9%	24.7%	1.1%	4
Renal Failure	0	0.0%	0.0%	0.0%	0	0	0.0%	0.0%	0.0%	0
Neurological Dysfunction	8	32.0%	50.3%	13.7%	10	3	9.7%	20.1%	0.0%	4
Respiratory Failure	2	8.0%	18.6%	0.0%	2	0	0.0%	0.0%	0.0%	0
Hypotension	0	0.0%	0.0%	0.0%	0	1	3.2%	9.4%	0.0%	1
Hypertension	0	0.0%	0.0%	0.0%	0	2	6.5%	15.1%	0.0%	2
Death	2	8.0%	18.6%	0.0%	2	1	3.2%	9.4%	0.0%	1

† Upper Confidence Limit

‡ Lower Confidence Limit

* Patient 12-101 discharged 3 days before data freeze and is not included in this analysis (no adverse events reported)

Figure 22 Death and Adverse Event Rates During VAD Support



Your doctor can explain what the serious adverse event terminology means and also tell you more about the rates of complications. Be sure to ask your doctor if you have questions.

10 SELF-CARE OUT-OF-HOSPITAL

10.1 ACTIVITY

Recommended activity while supported on the TLC-II System depends on your rate of recovery and individual energy level. A gradual increase in activity will hasten your recovery because it will help loosen the secretions in your lungs, stimulate your appetite and improve your sleeping patterns, as well as increase your strength.


Your breastbone takes approximately two to three months to heal completely. During the first six weeks, you must avoid pushing, pulling or twisting movements, and lifting anything weighing more than five pounds (2.27 kg). This includes activities such as carrying groceries, vacuuming, mowing the lawn and walking your dog on a leash. You should check with your doctor before resuming more vigorous activities.

10.2 LIMITS OF DAILY LIVING

The TLC-II Driver is designed to allow you comfort and freedom to move around. However, there are some restrictions associated with the TLC-II System.

The following table lists activities that are ALWAYS PROHIBITED for your safety.

ABSOLUTELY NO:	REASON:
Total body submersion (e.g., swimming, bathing)	The TLC-II Driver and some of the lead connectors are not waterproof.
Steam Bath Or Dry Saunas	High temperature and moisture will interfere with the TLC-II Driver.
Participation In Contact Sports (e.g., tackle football, wrestling)	Hard, physical contact with other persons or objects could cause damage to the VAD, TLC-II Driver, and cause injury to internal organs, or interfere with wound healing at the exit sites.
Activities that may cause pulling, twisting, or kinking of cannulas or leads	Can interfere with tissue healing and increase your risk for infection at the site.

	<p>WARNING</p> <p>Do not kink, twist, step on, or place objects on pneumatic lead(s) or cannulas. This may cause loss of air which is necessary for VAD pumping.</p>
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Consult your doctor regarding:	Comments:
Driving an automobile	You must first get approval from your doctor. In addition, check with local laws and regulations before operating a moving vehicle.
Flying	You must first get approval from your doctor and airline.
Potentially strenuous activity (e.g., golfing, jogging, tennis)	You and your doctor can determine together whether participation in certain activities may pose a danger to either yourself or the TLC-II Driver.
Showering	Physician approval is required.


The following activities DO NOT pose a known risk to your TLC-II System and DO NOT need to be avoided:

No known risk:
<ul style="list-style-type: none"> • Careful sponge bath • Sexual relations • Housework • Moderate exercise (e.g., walking, shopping)

10.3 SELF-CARE

Take your temperature daily. Contact your doctor if your temperature is above 101°F (38.3°C).

Weigh yourself at the same time every day for the first month. Call your doctor if you gain more than 3 pounds (1.36 kg) in two days or if you notice swollen ankles, feet or fingers. If you do, you may be retaining fluid. This can be controlled by medication.

	<p>WARNING</p> <p>Do not use solvents such as acetone, nail polish remover, paint thinners, or glues near or on the external VAD because these agents may cause the VAD housing to crack.</p>
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See Section 6.3 (page 31) for emergency contact situations.

10.4 COMPLETE VAD EMPTYING

It is very important that your VAD(s) empty completely with each beat. Complete VAD emptying should be checked daily.

Implantable VAD. The Implantable VAD Empty Signal light will turn green when blood is completely emptied from inside the VAD. Due to interactions with the heart it is normal not to

have an empty signal appear on every beat. **If no light is noticed for prolonged periods of time, call your VAD technician.**

External VAD. Shine a flashlight at an angle through the VAD. A flash of light will be seen on the opposite side if the VAD is emptying completely. **If no flash of light is noticed with each VAD beat, call your VAD technician.**

**WARNING**

There may be an increased risk of clot formation in the VAD if the VAD is not emptying completely.

10.5 WOUND CARE AND INFECTION CONTROL

The area where the VAD lead or cannulas comes out of your skin is called the “exit site”. Check your incisions and VAD exit site(s) every day. The exit site(s) need a protective bandage or “dressing” to help prevent infection. This dressing should be kept dry.

In addition to a protective dressing, your doctor may recommend a germ fighting cleanser to be used to clean around the exit site(s). Your doctor will determine how frequently your dressing should be changed. As you clean the exit site(s), you should look for signs of infection that may include one or more of the following:

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

**CAUTION**

Call your doctor if there are any signs of infection at the exit site(s).

HOW TO CHANGE YOUR DRESSING

1. Assemble materials (sterile gloves, 1 pair of non-sterile gloves, sterile saline, germ fighting cleanser, and sterile 4x4 gauze packages)
2. Wash your hands with soap and water for 3 minutes
3. Put on a pair of non-sterile gloves
4. Remove old dressings
5. Dispose of soiled dressing and non-sterile gloves
6. Open sterile 4x4 gauze packages and sterile saline
7. Pour saline on 4x4s still on sterile wrapping
8. Put on a pair of sterile gloves
9. Using a wetted 4x4, clean exit site(s) in a circular fashion, beginning close to the tube and working your way outward
10. If instructed by your doctor or nurse, clean the exit site(s) with germ fighting cleanser, again in an outward circular pattern.

11. Place one or two folded 4x4s underneath the lead(s) or cannulas to act as a cushion against your skin
12. Place two to four 4x4s over each lead or cannula.
13. Secure dressing with tape

You may notice tissue healing around the exit site(s). This is a natural and beneficial body reaction. This healing acts as a barrier to infection. It is important to prevent too much movement of the lead(s) or cannulas because movement can interfere with tissue healing and increase your risk for infection at the site.

**CAUTION**

Wash your hands with soap and water for 3 minutes BEFORE a dressing change and use sterile techniques.

**CAUTION**

After many weeks or months, infections can develop at the exit site(s). Therefore, it is important to prevent pulling, tugging or excessive movement of the lead(s) or cannulas throughout VAD support.

10.6 MEDICATION

Your doctor will prescribe an anticoagulant such as warfarin (Coumadin®) and possibly an anti-platelet agent such as aspirin to take daily while supported with a VAD. These medications 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 take your prescribed dosage as soon as you remember and call your doctor.

**WARNING**

Take anticoagulation medication as prescribed by your doctor. Failure to take this medication may lead to a stroke.

**WARNING**

DO NOT take extra blood thinning pills to make up for missed doses.

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

Remember:

- ✓ Take your medications as directed at the same time(s) daily.
- ✓ Do not stop taking any medications unless told by your doctor to do so.
- ✓ Notify your doctor of any adverse reactions or unpleasant side effects.

- ✓ Check with your doctor before taking other prescriptions or non-prescription medications.
- ✓ Carry an updated medication identification card in your wallet.

10.7 ROUTINE CHECK-UP

You and your doctor will determine how often you will need to be seen by the physician, nurse, or VAD technician in your home or in the hospital.

You can expect the following to be done at your check-ups:

- ✓ General physical assessment
- ✓ Monitoring of blood pressure, heart rate, temperature, and weight
- ✓ Inspection of the exit site
- ✓ Pump rate, output and other pump assessments
- ✓ Review of completed data collection forms
- ✓ Blood work (if necessary)

11 SUMMARY

11.1 POWER MANAGEMENT

The TLC-II Driver requires at least two power sources to drive the VAD: either two Batteries, or one Battery and External Power. The Batteries should be used when you are mobile, and the External Power should be used when you are resting.

11.2 USING EXTERNAL POWER

Plug the yellow AC Adapter with cable into the Driver's yellow power connector. Next, plug the opposite end of the cable with the electrical prongs into a grounded electrical outlet.

Verify that the External Power light on the TLC-II Driver turns green.

11.3 USING BATTERY POWER

Before switching back from External Power to battery power, make sure that two charged Batteries are in the TLC-II Driver. Next, disconnect the yellow Power Cable from the TLC-II and then the electrical outlet.

Pressing the Test Button on the Battery gives you battery power information. Five green battery lights on the Battery indicate a fully charged battery. As the Battery loses its power, the green lights gradually disappear. Once power is completely gone from one Battery, the TLC-II automatically starts using the opposite Battery.

When fully charged, each Battery provides approximately 55 minutes for BiVAD support and 80 minutes for LVAD or RVAD support.

11.4 BATTERY REMOVAL

To remove a Battery from the TLC-II, slide the clip and pull out the battery. Slide a fully charged battery into the slot, pushing down until you hear it snap into place.

CAUTION: Do not push or pull the pneumatic or electrical leads when you remove the Batteries.

11.5 CHARGING BATTERIES

Insert one or two Batteries into the Battery Charger. It can fully recharge up to two Batteries in two hours. It is best to leave the Batteries in the Battery Charger until charging is complete.

The Battery Charger has three lights for each battery:

Charging: Yellow light indicates that the Battery is charging.

Ready: Green light indicates a fully charged battery ready for use.

Fault: Continuous Red light indicates a battery problem. Do not use the Battery and call your VAD technician. A flashing red light indicates that the Battery is too hot or too cold. Wait for the battery to cool down or warm up and try again.

11.6 ALARMS (QUICK REFERENCE)

ALARM MESSAGE	ACTION REQUIRED
CHANGE BATTERY A (or B) <<<A (>>>B)	Replace Battery A or B with a fully charged battery.
CHANGE BATTERY A (or B) < 10 MINUTES LEFT	Change battery indicated on the message display with a fully charged battery immediately. Look for yellow light next to the Battery that should be changed.
EMERGENCY BATT REPLACE	Replace TLC-II Driver with back-up TLC-II Driver immediately.
NO L OR R FULL SIGNAL CHECK LEADS; VAD	Check VAD cannulas, leads, all connections. Call for assistance.
HI L OR R PRESSURE REPLACE	Check VAD leads. Replace TLC-II Driver with back-up TLC-II Driver.
LO L OR R PRESSURE CHECK; REPLACE	Check VAD, leads, or for system air leak. Replace TLC-II Driver with back-up TLC-II Driver.
HI L OR R VACUUM REPLACE	Check VAD. Replace TLC-II Driver with back-up TLC-II Driver.
LO L OR R VACUUM REPLACE	Check VAD. Replace TLC-II Driver with back-up TLC-II Driver.
LVAD OR RVAD OCCLUSION CHECK LEADS; VAD	Check pneumatic leads, cannulas, VAD. Call for assistance.
HI TEMPERATURE REPLACE	Check TLC-II Driver filter and remove dust. Replace TLC-II Driver with back-up TLC-II Driver if alarm not resolved after removal of dust.
LO TEMPERATURE WAIT	Wait until TLC-II Driver is warmer.
SERVICE INTERVAL REPLACE	Replace TLC-II Driver with back-up TLC-II Driver immediately.
ALARM 18-22 REPLACE OR EMER SYSTEM ON	Replace TLC-II Driver with back-up TLC-II Driver immediately.
<i>No Written Message</i>	Check power.
(IMPLANTABLE VAD ONLY) EMPTY SIGNAL FLASHING FASTER THAN VAD RATE.	Check leads, drivelines, all connections. Remove electrical lead and reconnect at TLC-II Driver. Call for assistance.

NOTE: Back-up TLC-II Driver and Hand Pumps must always be available for potential driver failures. In all cases where the recommended action is to replace the TLC-II Driver, the Hand Pumps can be used if no backup TLC-II Driver is immediately available.

11.7 EMERGENCY RESPONSE (QUICK REFERENCE)

USING THE HAND PUMP

1. **Disconnect** the pneumatic lead from the TLC-II Driver **and connect** it to the **Hand Pump**.
2. **Squeeze** the **Hand Pump** completely about once per second (60 times per minute) to empty and fill the blood pump(s). Use your foot to squeeze the Hand Pump, if necessary.
3. Switch to the backup TLC-II driver as soon as possible.
4. For BiVADs, squeeze the Hand Pumps at the same rate.

SWITCHING TO THE BACK-UP TLC-II DRIVER

1. Place two fully charged **Batteries** in the TLC-II Driver.
2. **Turn on** the TLC-II Driver and remove key.
3. **OPTIONAL:** Press the SILENCE button (Several alarms will sound because no VAD is connected to the Driver).
4. **Verify** battery power or external **power** to the TLC-II Driver.
5. **Disconnect the pneumatic lead(s)** (red for LVAD or blue for RVAD) and immediately attach it to the back-up driver pneumatic connector of the same color (remove the Occluder for the lead being connected).
6. **Disconnect the electrical lead(s)** (red for LVAD or blue for RVAD) and connect it to the back-up driver electrical connector of the same color.
7. **Verify no alarms and call** your **VAD support team** immediately. (See page 2).
8. If alarms are present, perform the appropriate troubleshooting listed in Section 5.
9. **Store key** in carrying case.



CAUTION

Always change the LVAD first if supported with two pumps (BiVADs).



WARNING

Leave the Occluder on the unused pneumatic connector if supported with only one VAD. Otherwise the System will not have enough pressure to operate properly.

11.8 EMERGENCY CONTACTS AND CONTACT SITUATIONS

CONTACT THE VAD TEAM WHEN...
VAD rate is less than 40 beats per minute.
VAD is not emptying.
Any TLC-II alarm situation other than the “Change Battery A” or “Change Battery B”
Any Battery Charger or Battery problem that you don’t understand
Residence power outage lasting more than 30 minutes
After calling for emergency medical services

CONTACT THE HOSPITAL MEDICAL STAFF FOR...
Numbness, tingling or weakness
Feeling “unwell”
Any pain, including chest pain, unrelieved headache
Redness, swelling, drainage at the “exit sites”
Shortness of breath or dizziness
Blurred vision or speech problems
Temperature greater than 101°F (38.3°C)
Unusual bleeding or bruising

EMERGENCY MEDICAL SERVICES SHOULD BE CONTACTED IMMEDIATELY FOR...
Loss of consciousness
Seizure or convulsion
Sudden fall or collapse
Awake but unresponsive
Inability to talk or move body parts
VAD stops

12 SELF-CARE SUMMARY

WOUND CARE

VAD Wound Care Protocol:
Clean the exit site with _____
Cover the area with _____
Change the dressing every _____

MEDICATION

Medication	Dosage	Frequency	Additional Instructions

SCHEDULE

Requirement	Frequency	Description
Medication	Daily	Blood thinning medication
Dressing Change	As ordered	Refer to dressing change protocol
Temperature	Daily	Call doctor for temperature > 101°F (38.3°C)
Weight	Daily	Call doctor for > 3 pounds (1.36 kg.) in two days
VAD Emptying	Daily	Call VAD team for incomplete VAD emptying
Blood work	As ordered	Blood work and coagulation status