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THORATEC VAD SYSTEM

Introduction

Since its first clinical use in 1982, the Thoratec Ventricular Assist Device (VAD) system has proven to be a versatile and reliable surgical option to effectively support circulation in patients with left, right, or biventricular heart failure.

This system is appropriate for short or long-term support and is FDA approved for use with bridge-to-transplant and post-cardiotomy recovery patients. The Paracorporeal VAD (PVAD), is easily implanted and removed because the pump lies outside the body, allowing support of a wide range of patient sizes.

The Thoratec Implantable Ventricular Assist Device (IVAD), first used clinically in 2001, is the only implantable device that offers left, right and bi-ventricular support to patients. It can be placed pre-peritoneally, intra-abdominally or paracorporeally depending on patient size and duration and type of support required. Like the PVAD, it is appropriate for short or long-term support and FDA approved for bridge-to-transplant and post-cardiotomy recovery.

Program Description

The purpose of this manual and corresponding inservice program is to provide critical information to core members of the clinical team who care for Thoratec VAD recipients - from admission, to the time of transplantation or device removal. Nurses, perfusionists, physical therapists, respiratory therapists and other clinical personnel can benefit from this inservice program as well.



Program Objectives

At the completion of this inservice program, participants should be able to:

- Identify the components of the Thoratec VAD System, its functions, and the theory of device operation.

- Describe the path that blood follows with an LVAD and RVAD.
- List two potential complications associated with the Thoratec VAD.
- Identify the purpose and function of each of the buttons on the Dual Drive Console (DDC).
- Identify the components of the TLC-II Portable Driver system, its function, and operation.
- Describe the interventions appropriate in the event of an emergency (e.g., AC mains power failure or device malfunction).
Note: This includes both DDC and the TLC-II emergency procedures.
- List potential post-operative complications.

System Components

There are three main system components:

- 1 VAD blood pump - Paracorporeal (PVAD) or Implantable (IVAD)
- 2 Inflow and outflow cannulae
- 3 Dual Drive Console (DDC) or TLC-II Portable VAD Driver

The VAD Blood Pump

The central part of the system is the blood pump, which can be used for left ventricular (LVAD), right ventricular (RVAD), or biventricular (BiVAD) assistance. The pump has a rigid case that contains a blood-pumping sac composed of Thoralon[®], a proprietary polyurethane multi-polymer. Silicon oil lubricates the outside of the blood sac. Inside the VAD, two mechanical tilting disc valves maintain unidirectional flow. The blood pump has an effective stroke volume of 65cc; and, depending on various conditions, can generate flows up to 7.1 L/min at a rate of 110 beats per minute (bpm).

PVAD Pump

The PVAD (**Figure 1**) has a rigid plastic housing through which small bubbles in the silicon oil lubricant can be observed during pumping. A small magnetic switch (called the Hall effect switch) is mounted on the upper case. This switch is triggered when the PVAD is full of blood, sending a “full” signal via the electrical lead to the Dual Drive Console (DDC) or TLC-II. The Hall effect switch is attached to an electrical lead and is bundled with the pneumatic lead on the PVAD. The two leads are separated at a connector

approximately 2" from the blood pump. The pneumatic and electrical leads come in two lengths (5-foot and 7-foot extensions) and are attached to the DDC or the TLC-II Driver.

Note: Alternatively, 12-foot leads can be used for centers that only use the DDC.

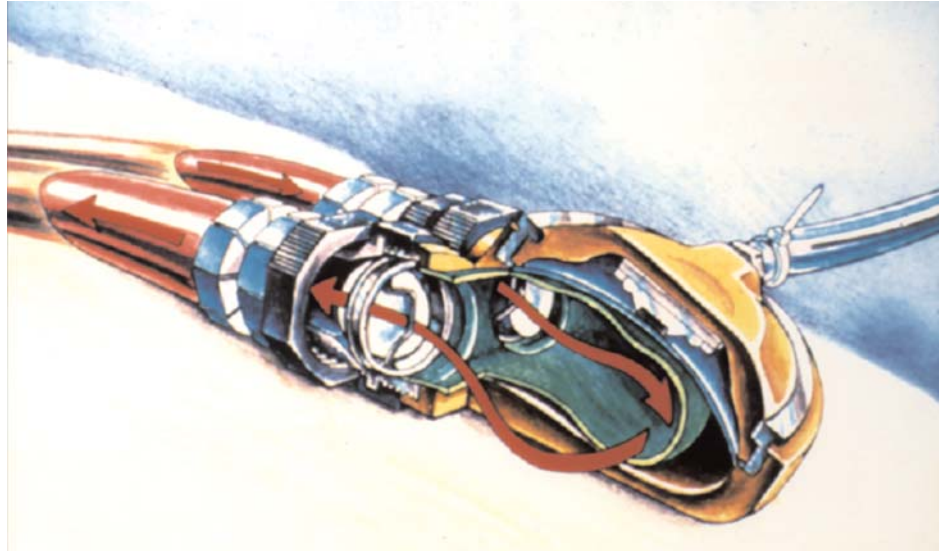


Figure 1 Cross section of PVAD Blood Pump

IVAD Pump

The IVAD (**Figure 2**) has a titanium alloy case with an optic sensor located on the upper housing. Using light reflection, the optic sensor sends a "full" signal via the signal processor lead to the DDC or TLC-II. When the IVAD is empty, a green indicator light illuminates on the signal processor. The percutaneous line, composed of wire reinforced Thoralon wrapped in velour, contains the optic sensor and pneumatic leads. The leads are separated at the Y connector. The 5-foot pneumatic lead attaches directly to the TLC-II Driver or, using the 7-foot extension lead, to the DDC. The signal processor lead connects directly to the TLC-II. If a DDC is used, the 5 foot electrical lead connects to the signal processor lead as well as the DDC adaptor lead.



Figure 2 IVAD Blood Pump

How the VAD Pump Works

A complete VAD cycle is as follows:

- 1 Blood fills the 65cc blood sac by pre-load pressures.
- 2 The PVAD Hall effect switch or IVAD optic sensor is triggered by the full blood sac.
- 3 A signal is transmitted via the gray electrical lead or signal processor lead to either the DDC or TLC-II.
- 4 Air pressure is sent to the pump via the pneumatic lead to compress the blood sac and eject the blood from the pump into the outflow cannula (systole). The air pressure is applied for a pre-determined amount of time, usually 300 msec.
- 5 Vacuum is applied to the pneumatic lead to remove the air to assist the pre-load pressure to fill the pump (diastole).

Inflow and Outflow Cannulae

The cannulae are Thoralon polyurethane tubes with a smooth blood-contacting surface. The arterial cannula is attached to a low-porosity woven polyester graft. The cannulae used for paracorporeal pump placement, are reinforced with wire to prevent kinking where they pass through the skin. In addition, the reinforced portion is covered with velour to encourage tissue ingrowth, which provides an effective barrier to infection.

Warning: Never clamp the wire-reinforced portion of the cannulae.

Cannulae can be inserted in the left or right atrium or placed in the left ventricular apex or right ventricle to provide inflow to the VAD blood pump. Blood is returned to the patient with an arterial cannula attached to the ascending aorta or the main pulmonary artery, depending on whether the left or right ventricle is being assisted. The PVAD and connections to inflow and outflow cannulae are shown in **Figure 3**.

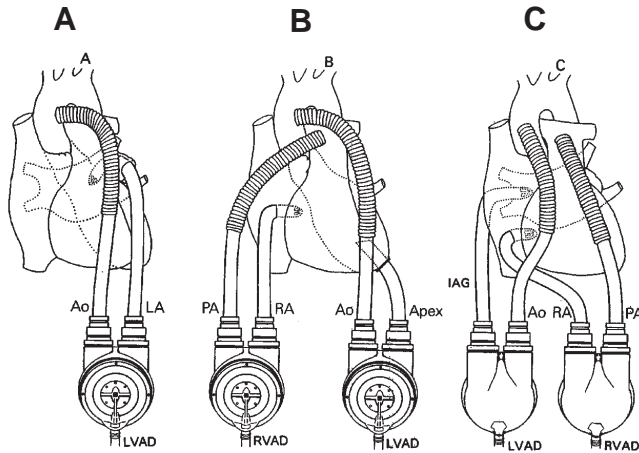


Figure 3 Thoratec PVAD and three cannulation approaches for univentricular left heart support (Panel A) and biventricular support (Panels B and C). Ao=aorta, LA=left atrial appendage, PA=pulmonary artery, RA=right atrium, Apex=left ventricular apex, IAG=cannula inserted via the interatrial groove and directed towards LA roof. Note that the VADs in Panel C are turned over and are on the sides of the chest that are opposite of those in Panel B.

The cannulae used when the pump is implanted are shorter, slightly curved with flared ends. The curved portions are wire reinforced to prevent kinking and velour covered to promote tissue ingrowth for anchoring. The IVAD and connections to inflow and outflow cannulae are shown in **Figure 4**.

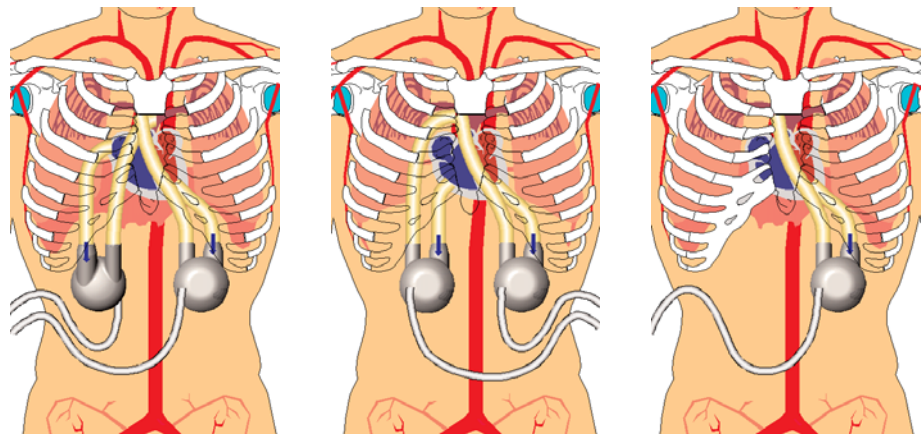


Figure 4 Thoratec IVAD: Biventricular IVAD with left ventricular and right atrial cannulation (left), biventricular IVAD with left ventricular and right ventricular cannulation (middle), and left IVAD with left ventricular cannulation (right).

Dual Drive Console (DDC)

The Dual Drive Console (DDC) has two independent drive modules for left and/or right ventricular support. Patients with BiVADs require both modules and patients with a single VAD (LVAD or RVAD) require one module.

The driver supplies pulses of pneumatic pressure to the blood pump to eject blood from the pump into the pulmonary artery (RVAD) or the ascending aorta (LVAD). Each ejection period alternates with a filling period in which blood, assisted by a slight vacuum, fills the VAD. A full 65cc stroke volume is possible from 20 to 110 beats per minute (bpm), providing outputs of 1.2 to 7.1 liters per minute (l/min). The console calculates VAD output automatically. For example, VAD rate 60 bpm x 65 ml stroke volume = 3.9 l/min.

Dual Drive Console Mechanisms

Modes of Operation

Three mode control keys (**Figure 5**) are located on the lower left corner of the module. Mode changes occur by pressing a key.

ASYNC The ASYNC mode allows the clinician to set a fixed VAD rate, which is asynchronous to the heart rate. This mode is useful for initiating VAD support in the operating room and weaning from the device.

VOLUME The VOLUME mode is the recommended mode of operation. In the VOLUME mode, the VAD rate automatically responds to changes in the patient's physiological condition. Once the pump fills completely with blood, the PVAD fill switch or IVAD optic sensor signals the console to eject the blood from the pump. Therefore, VAD rate and output varies with changes in pre-load to the pump. If pre-load pressure increases, the pump fills faster and VAD rate and output increases. Conversely, VAD output and rate decreases as pre-load decreases.

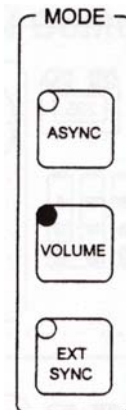


Figure 5 Mode Control Keys

EXT SYNC Thoratec does not currently recommend the EXT SYNC mode of operation.

Set Value

The Set Value section (**Figure 6**) allows the clinician to make changes to basic VAD functions.

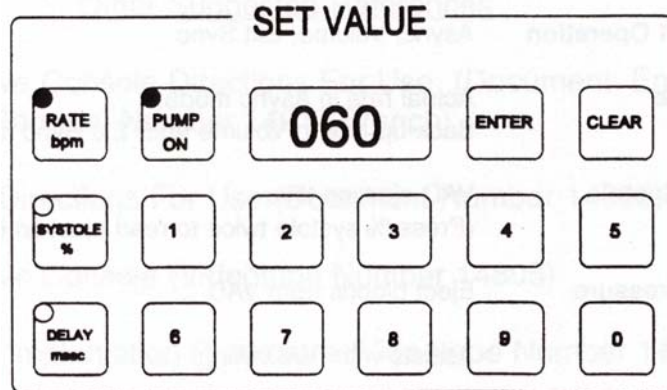


Figure 6 Set Value Section

Pump On	Initiates VAD pumping.
Pump On & Enter	Stops VAD pumping.
Rate bpm	VAD rate for the ASYNC mode. Back-up rate (minimum VAD rate allowed) for the VOLUME mode.
% Systole	VAD ejection time (percentage of VAD cycle used for ejection).
Delay msec	Thoratec does not recommend using this button, as it is only used with the EXT SYNC mode.
Clear	Used to silence audible alarms indefinitely. Used to clear incorrect Set Value Rate or Set Systole % entries.
Enter	Used to confirm changes for Set Value Rate and Systole % values.

Caution: Pressing CLEAR does not correct the alarm condition. There will be no additional audible alarm unless a new alarm condition occurs.

Changing Set Values

To Change Set Value Rate (actual or back-up)

- 1 Press RATE bpm.
- 2 Enter new Set Rate using the numbered key pads 0-9 (i.e., 60).
- 3 Press Enter once the new number is displayed.

To Change Percentage of VAD Systole (ejection time)

- 1 Press SYSTOLE %.
- 2 Enter a new Set % Systole using the numbered key pads 0-9 (i.e., 30).
- 3 Press Enter once the new number is displayed.

If an incorrect number is pressed while entering a new Set Rate or Set % Systole, press Clear and try again.

An EEE appears if entered numbers fall outside the acceptable range (Set Rate 20-140 bpm and Set % Systole 20-70%). If an EEE appears after Set Rate or Set % Systole entry, console operation remains unchanged and defaults to the previous Set Rate or Set % Systole.

Display Monitors

There are six display monitors that give current information about VAD operation (**Figure 7**). The keys above each display allow for the selection of data to be displayed. The values displayed are updated every fourth beat. Display monitors cannot be used to change VAD parameters.



Figure 7 Display Monitors

Display Information Generated

Rate (bpm)	VAD pumping rate in beats per minute (bpm).
Systole %	VAD ejection time as a percentage of the VAD pump cycle spent in systole (ejection). Press % systole twice for eject time in milliseconds (msec).
Stroke Volume (mL)	Programmed value of 65ml. Complete VAD filling and ejection equals a 65cc stroke volume.
VAD Output (L/min)	Displays the calculated blood flow (L/min) from the VAD (VAD rate x Stroke Volume (65ml) = VAD Output). Again, this value is accurate only if the VAD is filling and emptying completely.
Eject (mmHg)	Drive pressure in mmHg delivered for complete VAD ejection.
Fill (mmHg)	Vacuum in mmHg delivered to assist VAD in filling.

Caution: A 65cc stroke volume will always be displayed, even if the actual stroke volume is lower due to incomplete ejection. This value is accurate only if the VAD is filling and emptying completely.

Making Changes to Pressure and Vacuum

To Change Pressure:

- 1 Turn regulator knob (located below the Pressure Gauge) **(Figure 8)** *clockwise* to *increase* eject pressure.
- 2 Turn regulator knob *counter-clockwise* to *decrease* eject pressure.
- 3 Observe Eject display monitor to identify adequate pressure levels.

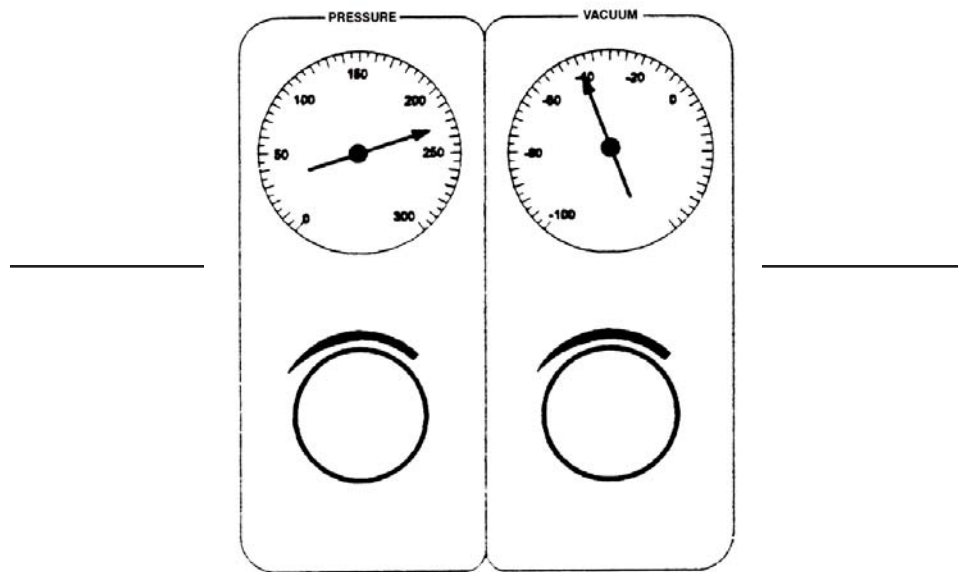


Figure 8 Pressure and Vacuum Gauges

To Change Vacuum:

- 1 Turn regulator knob (located below the Vacuum Gauge) (**Figure 8**) *clockwise* to *increase* vacuum.
- 2 Turn regulator knob *counter-clockwise* to *decrease* vacuum.
- 3 Observe Fill display monitor to identify adequate vacuum levels.

Thoratec does NOT recommend using the analog pressure and vacuum gauges to determine adequate pressure and vacuum levels, as they are not as accurate as the digital displays.

Recommended Settings

Mode of Operation Volume

Set Rate	50 to 60 bpm
Set % systole	25% to 30% (1/2 Set Rate = 300msec)
Drive Pressure	140 to 160 mmHg (RVAD) 230 to 245 mmHg (LVAD)
Vacuum	-25 to -40 mmHg

Indicators

The Status, Alarm, and Power indicators (**Figure 9**) provide specific information about console operation.

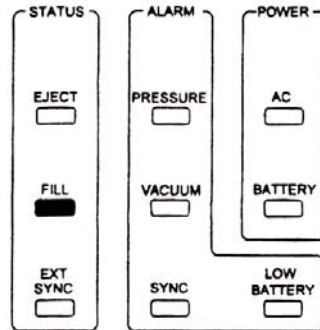


Figure 9 Status Alarm Indicators

Status Indicator

Eject light

Not used in the VOLUME or ASYNC modes.

Fill light

Indicates when the VAD is filling completely (green light illuminates when a signal is received from the electrical lead or signal processor lead).

Ext Sync

Not used in the VOLUME or ASYNC modes.

Alarm Panel

An alarm panel on each module alerts staff to possible console or patient problems. An alarm condition is accompanied by continuous beeping and a red light illuminated in the alarm section. Action is required to correct alarm conditions. There are four possible alarms: Pressure, Vacuum, Sync, and Low Battery.

Console Alarms & Troubleshooting

Pressure

Pressure alarms occur when the eject pressure is below 100 mmHg or above 250 mmHg. Once eject pressure is adjusted within an acceptable range, the alarm stops and the red light disappears.

Potential causes include:

- Pressure changed by staff - *Adjust eject pressure to an acceptable range.*
- Compressor and/or UPS failure - *Change to back-up console.*
- Pneumatic lead kinks - *Check the lead.*

Vacuum

Vacuum alarms occur when the vacuum is less than +4 mmHg (i.e., +5) or greater than -99 mmHg (i.e., -100). Once vacuum is adjusted within the acceptable range, the alarm stops and the red light disappears. Potential causes include:

- Vacuum changed by staff - *Adjust fill vacuum to acceptable range.*
- Compressor and/or UPS failure - *Change to backup console.*

Sync

The Sync Alarm occurs only in Volume Mode (due to loss of the fill signal), during which an “-E-” is displayed for VAD output and the VAD rate drops to the Set Rate (back-up rate). When a Sync Alarm occurs:

- 1 Observe PVAD pump. If filling completely, check electrical lead connections and, if necessary, change the lead.
- 2 Check IVAD electrical, signal processor and DDC adapter lead connections or kink in the percutaneous line.
- 3 Check for kinks in the paracorporeal cannula and pneumatic lead.
- 4 Check vacuum level, Set Rate, and Set % Systole
- 5 Assess patient for:
 - Arrhythmia · Vasodilation
 - Hypovolemia · Inadequate pharmacological support
 - Bleeding · Right heart failure (LVAD only patients)
 - Tamponade · Recovery of native ventricle
- 6 Change IVAD electrical, signal processor and/or DDC adapter leads.

Note: A Sync Alarm for loss of fill signal will NOT occur in the Asynchronous Mode; an “-E-” is displayed for VAD output.

VAD Filling

Complete VAD filling can be determined by either the green fill light or with the PVAD, visual inspection. The console changes include the following steps:

- 1 Increase vacuum (not to exceed -50 mmHg)
- 2 Decrease Set Rate (until fill signal appears)
- 3 Decrease Set % Systole (250 msec to 300 msec)

VAD Ejection

With the PVAD, the "Flash Test" will verify that the pump is emptying completely. To perform a flash test, shine a flashlight at an angle through the top (fill switch side) of the VAD. A flash of white light is visible on the opposite side of the VAD when ejecting completely.

With the IVAD, complete emptying of the pump can be determined by the green empty light on the signal processor lead flashing with each VAD cycle.

Note: Absence of the green fill light on the DDC console will result in loss of the green empty light on the signal processor even when the pump is emptying completely.

Note: IVAD Signal Processor Lead with continuous, rapid flashing: Disconnect and reconnect lead to initiate self check indicated by long, steady green light. If unresolved, replace lead.

Reasons for Incomplete VAD Ejection

- Outflow cannula kinked
- Eject pressure too low
- Set % systole too low (<300 msec)
- Systolic pulmonary pressure or systolic BP too high

Troubleshooting for Incomplete VAD Ejection

- 1 Assess paracorporeal cannula for kinks.
- 2 IVAD - check for presence of fill signal (required to detect empty on signal processor).
- 3 Check IVAD percutaneous line for kinks.
- 4 Increase drive pressure:
(LVAD 250 mmHg - maximum)
(RVAD 170 mmHg - maximum)

- 5 Increase Set % Systole until VAD emptying.
- 6 Lower patient's systolic pressure if hypertensive.

Explanations for the -E-

The causes for an -E- displayed in the VAD output monitor are:

- Loss of fill signal
- Eject time less than 250 msec
- Eject pressure <100 mmHg or >250 mmHg

Low Battery

A low battery alarm occurs when the battery that powers the module computer board has 30 minutes (or less) of power remaining. The alarm for the UPS is on the front panel of the DDC. Note: This battery is NOT the Uninterruptible Power Source that supplies power to the compressors when unplugged from main power.

Action: Plug console into AC power outlet.

Power Section

The AC light (yellow) comes on when the console is plugged into an electrical outlet. During patient transportation or ambulation, the flashing yellow battery illuminates and an audible alarm sounds every five seconds.

The Uninterruptible Power Supply (UPS) Status panel is displayed on the lower front console and provides approximately 40 minutes of battery time to the compressors. As the battery loses its charge, the five green battery lights disappear one at a time. A red battery light and continuous audible alarm indicates less than 5 minutes of battery power remains. Note: It takes 24 hours to fully charge the battery.

Action: Plug console into AC power outlet.

EMERGENCY SITUATIONS

Mechanical Failure

The console has an alarm system, and back-up mechanisms for device malfunction or failure.

An alarm is not necessarily a mechanical failure. If an alarm sounds:

- 1 Assess patient's appearance and tolerance.
- 2 Listen to and/or observe VAD.
- 3 Observe console and identify alarm.

Hand Pumps

Hand pumps can be used to maintain blood flow to the patient during drive console failure. Always keep two (2) hand pumps with the DDC. For console failure:

- 1 Disconnect the VAD pneumatic lead(s) from the back of the DDC.
- 2 Connect lead(s) to the hand pump(s).
- 3 Squeeze the hand pump(s) firmly, about once per second (60 bpm), to empty and fill the VAD. Note: Use your foot to squeeze the hand pump if necessary.
- 4 Switch to back-up module or console.

Caution: Do NOT pump the RVAD faster than the LVAD because this may cause pulmonary edema.

Emergency Selector Valve

The emergency selector valve is an alternative to manual support. The selector valve (Red), found inside on the console's back door, is for short-term emergency use. Using this valve allows one module to pump both VADs. The valve has three potential positions: **1**) the **Center** position is for normal operation (each drive module operates independently), **2**) the **Out** position allows the top module to drive both VADs; and, **3**) the **In** position allows the bottom module to drive both VADs.

Caution: If the LVAD module fails and the RVAD module is required to drive both VADs, increase the drive pressure to completely eject blood from the LVAD and prevent pulmonary edema. Always have a back-up system available.

For univentricular support, the second module can serve as a back up for mechanical failure of the operating module. Settings (Set Rate, Set % Systole, drive pressure, and vacuum) for the second module should be the same as the operating module. For mechanical failure, turn on the compressor, then switch the pneumatic lead and electrical lead.

Start Up Procedure in the Operating Room

- 1 Power switch On (back door).
- 2 UPS On (open back door).
- 3 Turn top and bottom module Power switches to On and verify that Calibration switches are Off (module back panel - **Figure 10**).
- 4 Turn Compressor switches ON for top and bottom modules.
- 5 Ensure that Emergency Selector Valve (red) (located on inside back door) is in the Center (Normal) position.

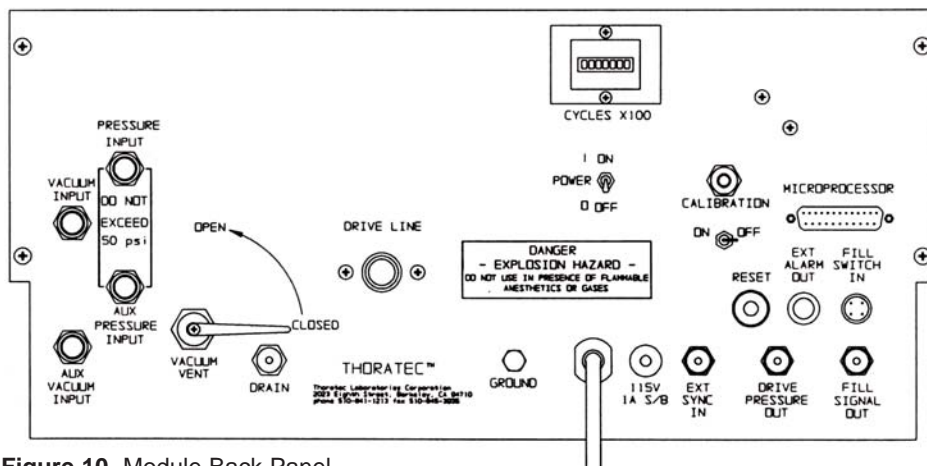


Figure 10 Module Back Panel

- 6 Set initial console settings:

Mode of Operation	Async
Set Rate	40 bpm
Set % systole	20%
Eject Pressure	150 mmHg
Vacuum	-20 mmHg
- 7 Pressure calibration is recommended before attaching to the VAD (see *Console Calibration*).
- 8 Initiate VAD pumping (Pump On) after de-airing completed.
- 9 Observe PVAD and transesophageal ECHO for air, and check for intact suture lines, then:
 - a. Gradually increase eject pressure to over 230 mmHg (LVAD) and 140 mmHg (RVAD).
 - b. Check for adequate pump emptying.
 - c. Apply vacuum to approximately -10 to -25 mmHg.
- 10 Change to volume mode once VAD is filling and ejecting completely.

Caution: Failure to turn off the calibration switch results in erroneous calibration values if the Set Value Rate or Systole % is changed. Modules must be recalibrated when this occurs.

Console Calibration

For accurate pressure management, calibrate the pressure transducers inside the drive modules *before* attaching to the VAD pump. Note: Routine calibration during device operation is not recommended and not required.

- 1 Turn “On” the calibration switch (module back panel).
- 2 Verify that the pressure eject/fill indicator light flashes (front panel).
- 3 Press Clear and Enter in the Set Value section (front panel).
Note: The Eject-Fill display should read 000 ± 2 . If not, press 000 on the keyboard and then press Enter.
- 4 Turn “Off” the calibration switch.
- 5 Verify that the pressure eject/fill indicator light stops flashing (the pressure transducers are now calibrated).
- 6 Repeat Steps 1-4 for the second drive module.

Recommended Console Storage

When storing the console, ensure that:

- Console is connected to an electrical outlet while in storage.
- Power switch is On (back door of console).
- UPS switch is On (charges batteries; inside console).
- AC Power light is On, the UPS status panel should display:

Load	No lights
Battery	1 to 5 green lights
Alarm	Off
Inverter	On
AC	On

- Both module power switches are in Off position.
- Both compressor switches are in Off position.

TLC-II Portable Driver

The TLC-II VAD Portable Driver is a lightweight, portable, pneumatic VAD driver that is powered by batteries or from external (AC) power. It is designed to provide portable pneumatic drive power for ambulatory patients supported with the Thoratec VAD.

Do NOT use the TLC-II VAD Portable Driver on VAD patients requiring > 160 mmHg drive pressure and > 350 msec of ejection time for complete RVAD ejection when using the Dual Drive Console. Also, never attempt to use the TLC-II as an intra-aortic balloon pump or for any use other than that specifically indicated in the *Instructions for Use*.

System Components

The TLC-II Portable Driver System consists of the following components:

- TLC-II Portable Driver (with vented, nylon carrying case)
- Batteries
- AC Adapter
- Car Power Adapter
- Battery Charger
- Mobility Cart
- Hand Pumps
- Docking Station with the Heart Touch Computer
- Mobile Computer

TLC-II Driver

The TLC-II VAD Portable Driver consists of a pneumatics assembly, an electronics assembly, two removable rechargeable lithium-ion batteries, and one additional rechargeable battery for emergency use. All of these components fit inside a vented, nylon carrying case (**Figure 11**).

Each rechargeable battery provides at least 55 (BiVAD) to 80 (RVAD or LVAD) minutes of power to the TLC-II. The TLC-II Driver discharges one battery at a time



Figure 11 TLC-II Portable Driver inside nylon carrying case

before automatically switching to the other battery. To reduce driver weight, the battery charger is a separate component (usually located on the docking station).

- The TLC-II Driver provides power to pump the VAD, stores events (data), uses symbols, messages, and alarms to report information and indicate situations requiring attention.
- The symbols and message display on the TLC-II Driver's front panel indicates corrective actions to be taken when alarms occur .
- 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 is water resistant, not water-proof.
- The carrying case front pocket is used for carrying the AC adapter with cable, car power adapter, spare batteries, and two hand bulbs. It includes a hook for holding the driver key.
- Always carry two emergency hand pumps in the carrying case pocket.

Note: The ports and connectors for leads and cables are on the top of the driver, next to the control panel.

Description of Leads and Cables

Connection	Color Code	Characteristics
LVAD electrical lead	Red	LVAD full signal (PVAD only)
LVAD pneumatic lead	Red	Pneumatic drive for LVAD
RVAD electrical lead	Blue	RVAD full signal (PVAD only)
RVAD pneumatic lead	Blue	Pneumatic drive for RVAD
Signal processor lead (stickers provided)	Red (LVAD)/ Blue (RVAD)	LVAD & RVAD full & empty signals (IVAD only)
Computer cable	Green	Cable to connect portable driver to computer
External power cable	Yellow	Cable to connect portable driver to external power such as AC adapter, car power adapter, or Docking Station power supply

Note: See **Figure 12** for location of color-coded connectors.

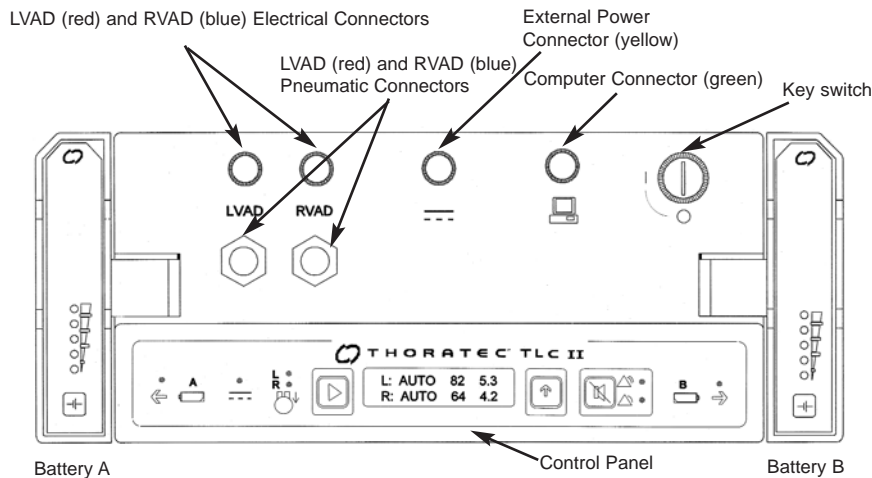


Figure 12 TLC-II Driver; top interface and Control Panel

The **control panel** (**Figure 13**) on top of the TLC-II driver provides information about TLC-II function.

On the sides of the control panel are two yellow **change battery lights (a)**, battery A on the left side and battery B on the right side. These lights illuminate when the batteries are depleted and need to be replaced. The green **EXT POWER** light (**b**) illuminates when the TLC-II is using external power. Two green **FULL** lights (**c**) indicate when the LVAD (L) and RVAD (R) are completely full of blood, as detected by the Hall effect switch in the PVAD or optic sensor in the IVAD blood pumps. By pressing the **MODE** button (**d**), the TLC-II toggles between the two modes for the VADs: **1**) either fixed rate pumping (FIXD) at a preset fixed rate, or **2**) automatic rate pumping (AUTO) as triggered by the VAD full signal. This button can be overridden or de-activated by settings on the TLC-II HeartTouch computer.

In the middle of the control panel is a **message display (e)** showing status information on the LVAD (top row) and RVAD (bottom row). The main display shows the pumping mode (AUTO or FIXD), the rate in beats per minute, and the flow in liters per minute. Also shown on this display are: driver serial number, driver usage time (hours), and alarm messages. The **scroll button (f)** can be pressed to toggle between multiple messages, which otherwise are automatically displayed for three (3) seconds each before reverting to the status information display.

The vacuum regulator (**Figure 14**) is located on the side of the TLC-II and is protected by a Velcro® flap.

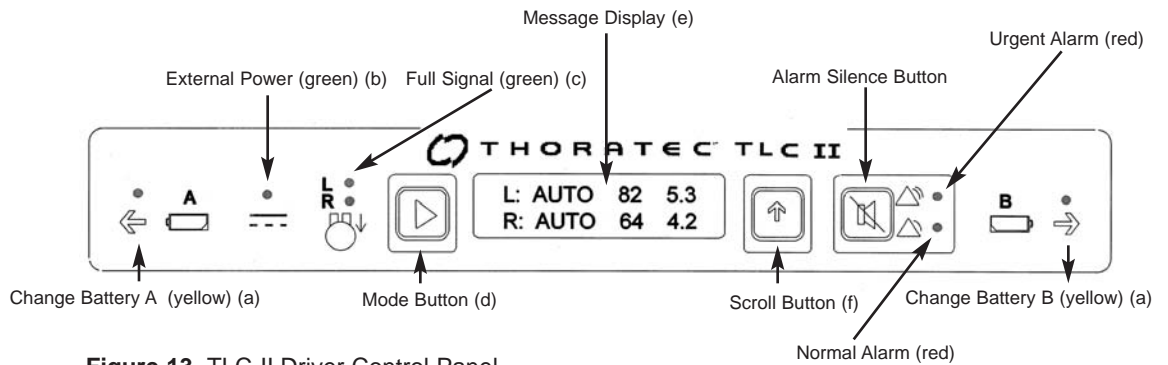
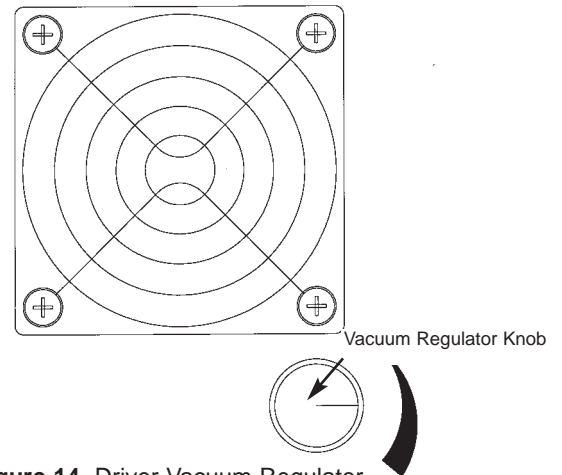


Figure 13 TLC-II Driver Control Panel

Note: Normal and urgent alarms are discussed elsewhere in this manual.

Maximum vacuum is achieved by turning the knob fully *clockwise*. When starting a patient on the TLC-II, the vacuum regulator should be set at the minimum vacuum (fully *counter-clockwise*) and gradually increased until fill signals and desired rate are achieved.



Directly above the vacuum regulator is the air intake filter and grill. Regularly check the grill to assure that it is free from all dust **Figure 14** Driver Vacuum Regulator and obstructions.

Modes of Operation

The TLC-II has two timing modes:

Fixed Mode

In this mode, the operator sets a rate and the driver maintains that pumping rate until the operator changes it. This mode is often used for start-up in the operating room or to wean the patient from the VAD after recovery of the natural ventricle. This is the default mode unless another mode is chosen or when no full signal is received in the Auto mode.

Auto Mode

This mode is used in most clinical cases because of the automatic changes in VAD flow that occur in response to changes in physiological conditions. The instant the blood pump is full of blood, the PVAD Hall effect switch or IVAD optic sensor, signals the driver to begin ejection. The rate varies with changes in preload to the pump. If the preload (or venous return) increases, the pump fills faster and thus ejection begins sooner, which increases the rate. In the same way, the rate decreases as preload decreases.

VAD flow is determined by the VAD rate times the pre-set stroke volume; for example, 60 bpm times 65cc equals 3.9 LPM. The maximum flow is achieved when using the Auto mode because the blood pump fills and empties completely, with no time lost between phases of the cycle.

Power Sources

The TLC-II is designed to operate with at least two power sources: **1)** either two batteries or **2)** one battery and external power. It can operate with one power source but will sound a warning beep every 30 seconds until a second power source is connected. A continuous alarm sounds when approximately 10 minutes of battery power remain. This indicates that the batteries must be replaced.

If all power sources are removed, the driver switches to the emergency backup system and the urgent alarm sounds. If the emergency battery is depleted, an alarm sounds and it must be replaced with a fully charged battery. The emergency battery is located inside the bottom of the driver and is accessed by

WARNING: Do NOT change emergency battery while patient is connected to the Driver.

unscrewing the Philip's head screws on the bottom plate.

Batteries

- Each side of the TLC-II Driver has a slot for a battery.
- Each battery provides at least 55 minutes (BIVAD) to 80 minutes (LVAD or RVAD) when fully charged (**Figure 15**).
- Pressing the test button illuminates the green battery lights.
- There are five battery lights; each light represents approximately 20% of battery time. When a battery is fully charged, all five lights illuminate.
- To insert a battery, slide it into its slot with the indicator lights visible. A “click” indicates that it is properly seated in the slot.
- To remove a battery, pull the battery clip medially and withdraw the battery from the slot.
- Batteries can be charged only by using the Battery Charger.

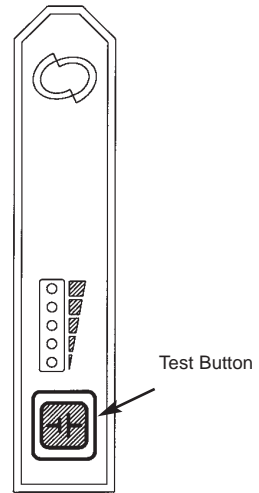


Figure 15 TLC-II Battery

Battery Charger

- The battery charger can recharge two batteries in two hours. Batteries should not be left in the charger for more than 14 days.
- The charger power switch should always be on and connected to an electrical outlet.
- The battery charger (**Figure 16** following page) has three (3) lights for each battery:
 - 1 A **yellow light** indicates the battery is charging.
 - 2 A **green light** indicates the battery is fully charged and ready to use.
 - 3 A **steady red light** indicates the battery cannot be charged. A **flashing red light** indicates that the battery temperature is too hot or cold.

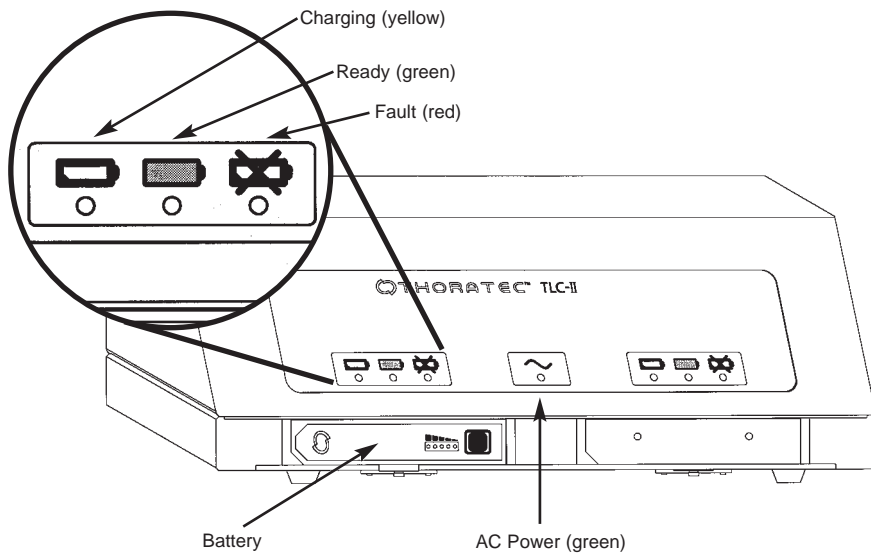


Figure 16 Battery Charger

AC Adapter

The AC Adapter (**Figure 17**) can be used to preserve battery life. Plug the yellow cable on the AC adapter into the yellow external power connector on the TLC -II Driver. Plug the AC power cable into an electrical outlet and verify that the green external power indicator lamps on the TLC-II and adapter are illuminated. If it is not illuminated, the TLC-II is drawing power from the batteries. A short beep indicates that external power has been connected.

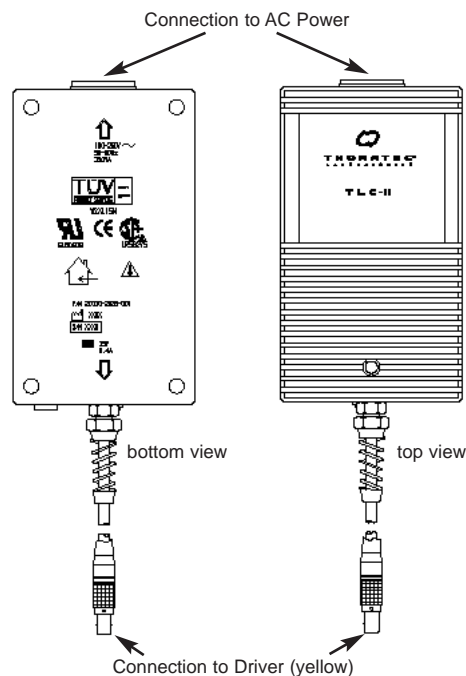


Figure 17 AC Power Adapter

Car Power Adapter

The Car Power Adapter (**Figure 18**), like the AC Adapter, does not charge the batteries in the TLC II Driver but can be used to preserve battery life. Insert the Car Power Adapter cigarette lighter plug into the automobile cigarette lighter socket or power outlet, start the car engine and verify the green indicator lights on the cigarette adapter plug and end of the car power adapter illuminate.

Note: Power may not be available unless the car key is in the ON position or until the engine is started. If the indicator lights do not illuminate after the engine is started, do not use the car power adapter.

Plug the yellow cable into the yellow external power connector on the TLC-II Driver. Verify a short beep and green external power indicator lamp illuminated on the TLC-II Driver.

Note: The TLC-II Driver requires 2 power sources at all times. When using the car power adapter, another power source must be available, i.e. charged battery in A and B battery slots.



Figure 18 Car Power Adapter

Docking Station

When the TLC-II Driver is not in ambulatory use, the Docking Station (**Figure 19**) provides a convenient central station for the TLC-II and accessories. It also contains the HeartTouch computer, the battery charger, an accessory drawer, and room for storing two TLC-II Drivers.

Power to the docking station is obtained by connecting AC power to the plug on the lower back door of the unit (**Figure 20**). This receptacle also contains the main on-off power switch. The top drawer of the docking station contains two bays for holding two TLC-II drivers in their carrying cases. On the side of both bays are external power connections. Connect the yellow power cable from the TLC-II external power connector to the yellow connector on the bay. To interface the TLC-II to the computer, connect the green computer cable from the TLC-II computer connector to the green connector on the front bay.

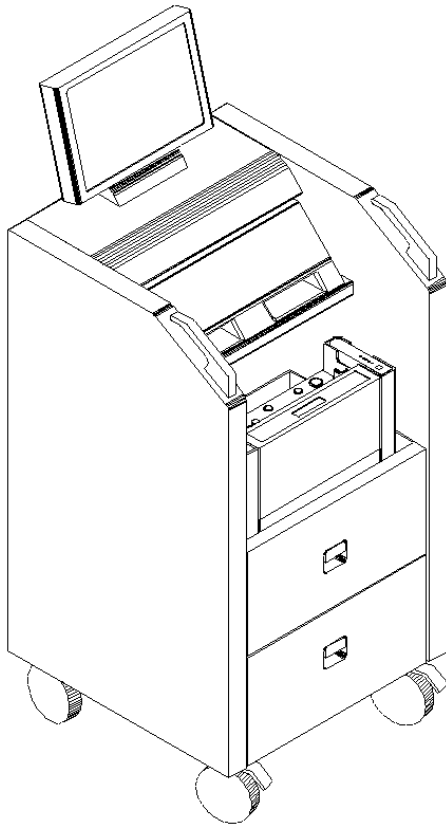


Figure 19 TLC-II Docking Station

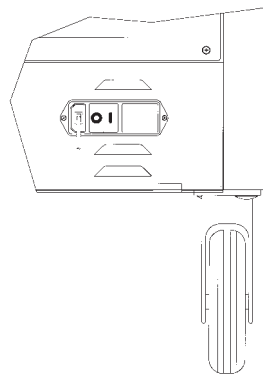


Figure 20 Docking Station Main Power Receptacle and On-Off Switch

HeartTouch Computer

The HeartTouch computer runs an interface monitoring program that is specifically designed to communicate with the TLC-II Driver. This computer is required only during start-up to select or change settings and for diagnostic purposes. Since the TLC-II Driver has its own internal microprocessor that controls all TLC-II functions, once it is in ambulatory use on a stable patient, the TLC-II does not need to be connected to the HeartTouch computer. The computer and touchscreen are located on the top of the docking station. There is a power on-off switch on the back upper corner of the Docking Station for turning on/off the computer and touchscreen.

The HeartTouch computer contains six screens that can be accessed by touching the indicated tab:

- 1 Main
- 2 Plots
- 3 List
- 4 VAD Settings
- 5 General
- 6 Technical

The first three screens and the technical screen are solely for displaying information. No changes to control parameters can be made from these screens. The remaining two screens contain control buttons that can change information or settings stored in the TLC-II Driver.

Main Screen

The Main Screen (**Figure 21**) displays basic information about the TLC-II driver: VAD rate, flow, and mode for each VAD in use,

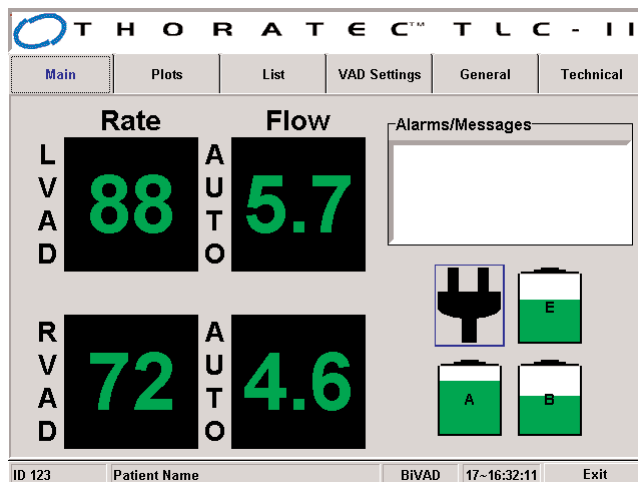


Figure 21 Main Screen

status of all power sources, alarm information, and patient identification. When the TLC -II is not connected to the HeartTouch computer, the following message is displayed: NO RESPONSE FROM THE TLC-II. The main screen appears on the bottom half of all the other screens.

Plots Screen

Real-time plots of pneumatic eject and vacuum pressure waveforms for the LVAD (red) and/or RVAD (blue) are added to the top window for the last 5-second period (**Figure 22**). Pressure is displayed in millimeters of mercury (mmHg) versus time in seconds.

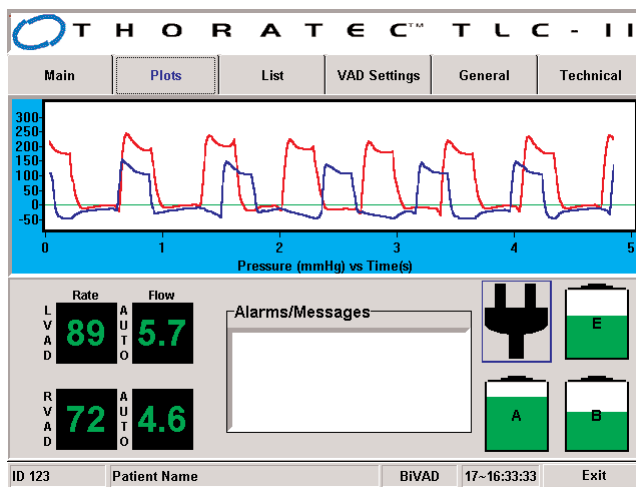


Figure 22 Plot Screen

List Screen

The top shaded row of information in the List Screen (**Figure 23**) shows the most current status of the TLC-II. The subsequent rows display saved event records. An event is recorded during any

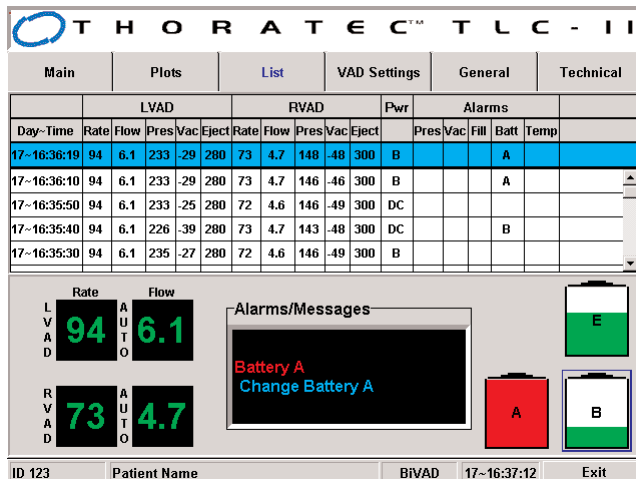


Figure 23 List Screen

alarm condition, with any changes to the operating parameters or power source, and at routine time intervals as programmed in the General screen (**Figure 25**).

In the first column of the List Screen, the day and time of the event is displayed. Next, five parameters are displayed for each VAD:

- Rate** average VAD rate in bpm
- Flow** average VAD blood flow in L/min
- Pres** average peak eject (drive) pressure in mmHg during ejection
- Vac** average minimum vacuum during filling
- Eject** ejection time in msec

The **power source** (Pwr) in use is displayed as follows:

- DC** external DC power
- A** battery A
- B** battery B

Alarm information is also shown as follows (see pages 40-41 for alarm troubleshooting):

- Pres** pressure alarms (L for LVAD; R for RVAD)
- Vac** vacuum alarms (L for LVAD; R for RVAD)
- Full** full signal alarms (L for LVAD; R for RVAD)
- Batt** battery alarms (A, B, or E for battery A or B, or the emergency battery)
- Temp** Compressor temperature alarms (HI for high; LO for low)

VAD Settings Screen

This screen (**Figure 24**) shows the current VAD operating settings and allows changes to be made to those settings. The *Instructions*

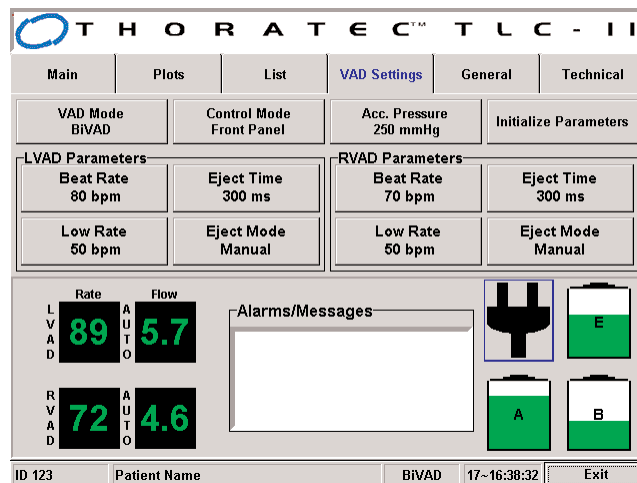


Figure 24 Settings Screen

for Use Manual should be consulted before using this screen. Setting changes may include: VAD mode, control mode, accumulator pressure, beat rate, low rate, and eject time. Eject mode is always manual.

Recommended Settings

Control Mode	Automatic (front panel disabled).
Accumulator Pressure	250-270 mmHg for BiVAD & LVAD (RVAD pressure is NOT adjustable).
Beat Rate	5 beats below average VAD rate during normal activity. For example, if VAD rate is 80-90, set beat rate at 75 bpm.
Low Rate	5 - 10 beats below lowest VAD rate (usually occurs during sleep).
Vacuum	-10 to -20 mmHg
Eject Time	270-330 msec
Eject Mode	Manual

General Screen

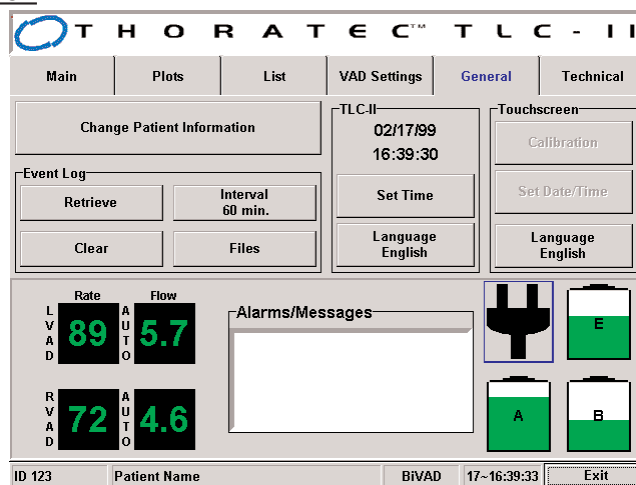


Figure 25 General Screen

Options available from the General Screen (**Figure 25**) include: changing patient information, setting the interval between routine event recordings, retrieving and clearing the event log, accessing patient files, and setting the date, time and language on the TLC-II and the Touch screen computer. The *Instructions for Use* should be consulted before using this screen.

Technical Screen

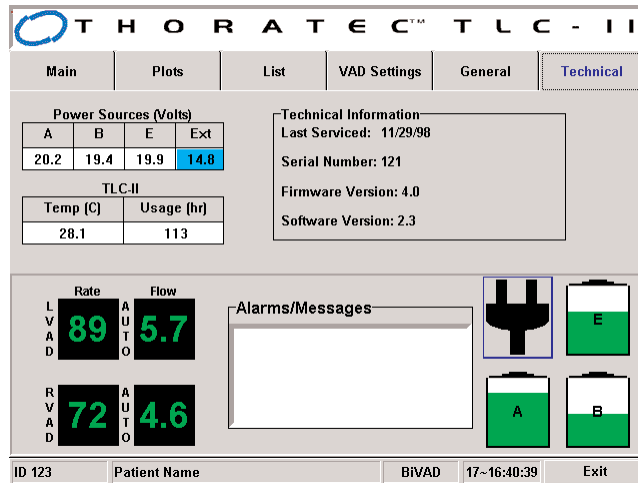


Figure 26 Technical Screen

The Technical Screen (**Figure 26**) is used only for observing the following TLC-II diagnostic information: power source voltage, compressor temperature, usage hours, date the TLC-II was last serviced, TLC-II serial number, firmware and software versions.

Mobile Computer

The Mobile Computer (**Figure 27**) is a light weight tablet computer that performs the same functions as the HeartTouch computer utilizing the same software. The external floppy disk drive allows storage of data log files.

The Mobile Computer is powered with an internal battery or with the TLC II AC Adapter connected to the yellow computer power adapter cable plugged into the DC input port. The power button is located on the top right corner. When using battery power, the computer will shut off if it is not used for 10 minutes.

To interface with the TLC II Driver, connect the Data Cable to the serial port and the green connector to the green computer port on the TLC II Driver. The stylus is used to access the six screens and input instructions to the computer. Refer to the previous section on the HeartTouch computer for further information on the six computer screens. The *Instructions for Use* should be consulted before using the Mobile Computer.

Note: Mobile Computer is to be used by trained medical personnel, not for use by the patient.

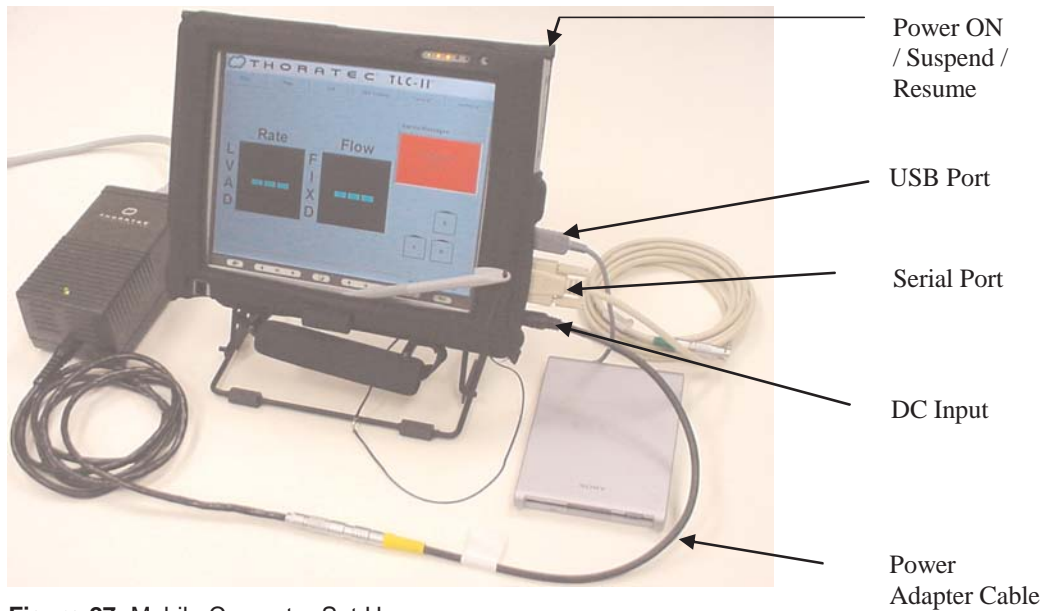


Figure 27 Mobile Computer Set Up

Start Up Procedure (Before Connecting to the Patient)

- 1 Insert a fully-charged battery into the emergency battery slot (located on the bottom of the TLC-II Driver).
- 2 Place TLC-II Driver in the Docking Station.
- 3 Turn on power to Docking Station and HeartTouch computer.
- 4 Connect power cable (yellow) and computer cable (green) to Docking Station and TLC-II Driver. If using mobile computer, connect the Date cable (green) to the TLC-II Driver.
- 5 Place fully-charged batteries into the A and B battery slots (located on top of the TLC-II Driver).
- 6 Press the battery test button and note the status.
Note: With a fully-charged battery, all five green lights turn on.
- 7 Insert occluder plugs into the LVAD and RVAD pneumatic ports.
- 8 Turn on system with key switch, then remove key and place it on the hook inside the carrying case pocket.
- 9 Verify that all indicator lights on top of the driver illuminate and audible tones for normal and urgent alarms are present.
- 10 With occluder plugs in place, check for occlusion and/or hi pressure alarm.
- 11 Check for Lo Pressure Alarm by removing Occluder Plug from either pneumatic port.
- 12 Remove both occluder plugs and insert the set-up plugs into the pneumatic ports (inserting set-up plugs prevents the Occlusion and Pressure Alarms during set up).
- 13 Press and hold the alarm silence button for 10 seconds to indefinitely silence the No Full Signal Alarm during set up.
- 14 Go to the VAD Settings Screen to program the TLC-II Driver using the recommended VAD settings that appear below.
- 15 Enter patient information on the General screen.

VAD Setting	Function
CONTROL MODE	Automatic (front panel disabled).
ACCUMULATOR PRESSURE	250-270 mmHg for BiVAD and LVAD mode. RVAD pressure NOT adjustable (changing LVAD accumulator pressure will NOT affect RVAD pressure).
VACUUM	-10 to -20 mmHg
LOW RATE	5 to 10 beats below lowest VAD rate (usually occurs during sleep).
BEAT RATE	5 beats below average VAD rate during normal activity. <i>Example: If VAD rate is 80-90, set beat rate to 75 bpm.</i>

TLC-II Troubleshooting Full & Empty

The TLC-II Driver has one compressor that provides eject pressures and vacuum to both LVAD and RVAD pneumatic ports. For patients on BiVAD support, pressure and vacuum are set for the LVAD. The RVAD eject pressure is not adjustable as it is set internally by a step-down regulator. Therefore, troubleshooting for loss of full signal and incomplete emptying may differ depending on which VAD is involved.

Complete VAD Filling

Complete VAD filling is dependent on the patient's preload.

Assessment includes presence of the green full signal(s) and, with the PVAD, visual inspection of the pump(s). If the full signal is absent:

- 1 Observe the PVAD pump. If filling fully, check electrical lead connections, and if necessary change the lead.
- 2 Check IVAD signal processor lead connections or kink in the Percutaneous line.
- 3 Check for kinks in the Paracorporeal cannulae & pneumatic lead.
- 4 Check vacuum level, eject duration, and beat rate setting.
- 5 Assess patient for:
 - Arrhythmia · Vasodilation
 - Hypovolemia · Inadequate pharmacological support
 - Bleeding · Right heart failure (LVAD only patients)
 - Tamponade · Recovery of native ventricle
- 6 Change IVAD signal processor lead.

Troubleshooting incomplete VAD filling:

- 1 If patient-related, correct cause.
- 2 Lower beat rate.
- 3 Increase vacuum.
- 4 Decrease eject time.

Complete VAD Ejection

With the PVAD, complete ejection is assessed by the "flash" test and is performed by shining a flashlight at an angle through the top (fill switch side) of the pump. A flash of white light is visible on the opposite side of the pump when ejecting completely.

With the IVAD, complete ejection is assessed by presence of the

green empty light on the signal processor lead or empty flag (figure 28) on the Plots Screen.

Troubleshooting Incomplete VAD Ejection:

- 1 Assess paracorporeal cannulae for kinks.
- 2 Check IVAD signal processor lead connections and percutaneous line for kinks.
- 3 Increase accumulator pressure (affects LVAD only).
- 4 Increase eject time until a flash appears with PVAD or green empty light on IVAD signal processor.
- 5 Lower patient's systolic pressure if hypertensive.

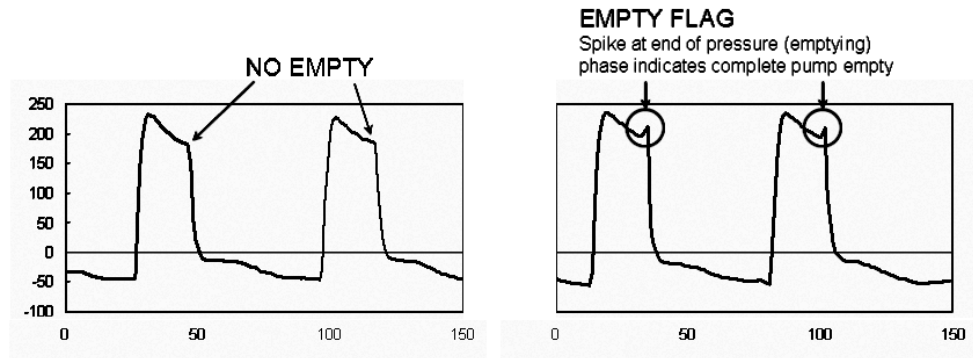


Figure 28 Empty flag on Plots Screen

Emergency Response Procedures

Hand Pumping

Two hand pumps (**Figure 29**) 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 emergency hand pumps. To maintain blood flow by hand pumping:

- 1 Disconnect the pneumatic lead(s) from the TLC-II Driver and connect to the hand pump(s).
- 2 Squeeze the hand pump(s) completely, about once per second (60 times per minute) to empty and fill the VAD(s). Use your foot to squeeze the hand pump(s) if necessary.
- 3 Switch to the backup TLC-II Driver or Dual Drive Console as soon as possible.

CAUTION: Do NOT pump the RVAD faster than the LVAD because this may cause pulmonary edema.



Figure 29 Hand Pumps

Switching to Backup TLC-II Driver

Before a backup driver can be used, it must be programmed to the appropriate settings using the HeartTouch computer or Mobile Computer. Once programmed, proceed with the following steps to switch to a backup driver:

- 1 Place a fully charged battery in the emergency battery slot.
- 2 Place two fully charged batteries in the TLC-II Driver.
- 3 Turn on the TLC-II Driver.
- 4 Optional: Press the silence button (several alarms will sound because no VAD is connected to the driver).
- 5 Verify battery power or external power to the TLC-II Driver.
- 6 Disconnect the pneumatic lead(s) (red for LVAD, blue for RVAD) and immediately attach to the back-up driver pneumatic connector of the same color (remove the occluder from the port prior to connecting the pneumatic lead).
- 7 Disconnect the PVAD electrical lead(s) or IVAD signal processor lead(s) (red for LVAD, blue for RVAD) and connect to the back-up driver electrical connector of the same color.
- 8 Verify no alarms.
- 9 If alarms are present, perform the appropriate troubleshooting.
- 10 Verify complete emptying.
- 11 Remove key and store it on the hook in the carrying case pocket.

Changing Pneumatic or Electrical Leads

It is unlikely that these leads will require replacement. If there is a severe air leak you will be able to hear the air escaping. In addition, the TLC-II driver indicates a low-pressure alarm, there may be no “full” signal, and with the PVAD you will be able to see that the VAD is not pumping.

To Change the Pneumatic Lead:

- 1 Disconnect the leaking pneumatic lead from the Y-connector on the VAD pump and from the TLC-II Driver's pneumatic connector port.

WARNING: If the patient has a BiVAD, when a pneumatic lead is removed from either port, both VADs will depressurize.

- 2 Attach the new pneumatic lead to the Y-connector and the TLC-II Driver's pneumatic connector. The metal fitting on the pneumatic lead attaches to the TLC-II Driver.
- 3 Verify VAD pumping, complete emptying, and no alarms.

To Change the Electrical Lead or Signal Processor Lead:

- 1 Disconnect the electrical lead or signal processor lead from the Y-connector on the VAD pump and the TLC-II Driver's electrical connector port.
- 2 Next, attach the metal fitting of the new lead to the Y-connector on the VAD pump by aligning the red dots.
- 3 Attach the gray end of the new lead to the TLC II Driver's electrical connector port.
- 4 Verify green full signal on TLC-II Driver control panel.

Troubleshooting Alarms








Alarms alert you to potential problems with the TLC-II Driver or VAD. Each alarm situation includes:








- **Written Message** - The written message is found in the message display and describes the alarm and action you need to take. "L" means LVAD and "R" means RVAD.
- **Visible Alarm** - The visible alarm is a light that illuminates to indicate an urgent alarm, normal alarm, or need to change battery condition.
 - a. Urgent alarm turns red when the emergency system is in operation.
 - b. Normal alarm turns red for all other alarms.
 - c. Change battery alarm turns yellow when a battery should be replaced with a fully charged battery.
- **Audible Alarm** (beep) - The audible alarm beeps intermittently or continuously for all alarm situations.
 - a. The audible alarm can be silenced for 30 seconds during normal alarm situations by pressing the silence button. Silencing the alarm does not correct the problem.

- b. The full signal is the only alarm that can be silenced indefinitely. This is accomplished by pressing and holding the alarm silence button for 10 seconds. When the full signal returns or the electrical lead is removed and reinserted, the alarm resets itself.
- c. The urgent alarm cannot be silenced.

Alarm Messages and Responses

There are seven alarm types that include batteries, loss of full signal, pressure and vacuum, temperature, service interval, internal alarms, and emergency backup. Alarms are summarized in the tables on the following pages.

Written Message	Visual Alarm	Audible Alarm (beep interval)	Meaning	Action Required
CHANGE BATTERY A <<<A OR CHANGE BATTERY B >>>B	Yellow light for change Battery A or Battery B 	Every 30 seconds	Battery A or Battery B has no power	Replace Battery A or Battery B with 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 tone	One Battery has NO power and the remaining Battery has less than 10 minutes of power left. If both Batteries lose their power, the TLC-II will run on the Emergency Battery system. The Emergency Battery can power the Driver only for a limited amount of time.	Replace the Battery with a fully-charged Battery. Note: Change the Battery next to the yellow Change Battery light.
EMERGENCY BATT REPLACE	Red Normal Alarm 	Continuous tone	Ten minutes or less of Emergency Battery power remains.	Immediately replace primary TLC-II Driver with backup TLC-II Driver.
NO L FULL SIGNAL CHECK LEADS; VAD or NO R FULL SIGNAL CHECK LEADS; VAD	Red Normal Alarm light; green LVAD and/or RVAD full indicator light is absent 	5 seconds	TLC-II Driver has been unable to detect a Full signal for at least 8 seconds. Message Display shows "..." instead of VAD flow. VAD will switch to fixed mode & pump at the beat rate.	Verify VAD pumping. Check leads for kinks and proper connections. Visually inspect PVAD for filling and if filling completely, change electrical lead. If PVAD is not filling or with IVAD, assess patient and adjust settings. Change IVAD signal processor lead.
HI L PRESSURE REPLACE or HI R PRESSURE REPLACE	Red Normal Alarm 	Continuous tone	The pressure in the TLC-II Driver is too high to operate properly.	Verify VAD pumping. Check leads for kinks and proper connections. If not resolved, replace TLC-II Driver with backup Driver.
LO L PRESSURE CHECK; REPLACE or LO R PRESSURE CHECK; REPLACE	Red Normal Alarm 	Continuous tone	The pressure in the TLC-II Driver is too low to operate properly.	Verify VAD pumping. Check pneumatic lead(s). If not resolved, replace TLC-II Driver with backup Driver.
HI L VACUUM REPLACE or HI R VACUUM REPLACE	Red Normal Alarm 	Continuous tone	The vacuum is too high.	Verify VAD pumping (occluder cap on unused pneumatic port). Check pneumatic lead(s). If not resolved, replace TLC-II Driver with backup Driver.

Written Message	Visual Alarm	Audible Alarm (beep interval)	Meaning	Action Required
LO L VACUUM REPLACE or LOW R VACUUM REPLACE	Red Normal Alarm 	Continuous Tone	The vacuum is too low.	Verify VAD pumping; check pneumatic lead(s). Adjust vacuum. If not resolved, replace the TLC-II Driver with backup Driver.
RVAD OCCLUSION CHECK LEADS; VAD or LVAD OCCLUSION CHECK LEADS; VAD	Red Normal Alarm 	Continuous tone	Pneumatic lead or cannula kinked or obstructed or the TLC-II Driver is ejecting a VAD partially filled with blood.	Verify VAD pumping. Check pneumatic lead(s) and cannulae for kinking.
HI TEMPERATURE REPLACE	Red Normal Alarm 	Continuous tone	The compressor temperature is too high.	Check the intake air filter for dust or blockages and clean it. Replace the primary TLC-II Driver with the backup Driver if alarm continues.
LO TEMPERATURE WAIT	Red Normal Alarm 	Once per second	The compressor temperature is too low.	Wait for the TLC-II Driver to warm up before using.
SERVICE INTERNAL REPLACE	Red Normal Alarm 	Once every 10 seconds.	Preventative maintenance is required to prevent driver malfunctions. Service must be performed by Thoratec.	Replace TLC-II Driver as soon as possible.
ALARM 18-22 REPLACE	Red Normal Alarm 	Once per second	One of the internal test situations has failed to operate within specifications.	Immediately replace primary TLC-II Driver with backup Driver.
[No written message] or EMER SYSTEM ON; REPLACE	Red URGENT Alarm 	Continuous tone	The TLC-II Driver is operating on the emergency system and battery. Silencing the alarm is NOT possible.	If no message is displayed, change Batteries or connect to AC Adapter. If message is displayed, replace primary TLC-II Driver with backup Driver.

Preparing for Excursions

The patient and patient's caregiver must be trained before taking excursions. Training and training checklists are included in the Thoratec TLC-II VAD Portable Driver and System *Instructions For Use* (document number 50010-006-002). The following equipment is required for excursions away from the hospital:

- One (1) Primary TLC-II Driver (with emergency battery)
- One (1) Back-up TLC-II Driver (with emergency battery)
- Four (4) Hand pumps (2 for each driver)
- At least four (4) fully charged spare batteries (used in A and B battery slots of primary and back-up drivers)
- One (1) AC Adapter with cable
- One (1) Car Power Adapter
- One (1) Mobility Cart (**Figure 30**) (optional)



Figure 30 Mobility Cart

Equipment Care and Maintenance

- Do NOT expose the TLC-II Driver to temperatures higher than 104° F or lower than 50° F for prolonged periods of time.
- To prevent high temperature alarm, do NOT block the air intake filter on the TLC-II Driver Carrying Case.
- Keep the TLC-II Driver dry. Protect it from shower spray, rain, and liquid spills.
- Avoid the following as they can be hazardous to, or interfere with, the operation of the VAD system:
 - Paint, paint remover, fingernail polish remover, adhesive tape remover, or other solvents containing acetone (PVAD only)
 - High power cellular phones (greater than 1 Watt) within 12 feet and cellular phones (less than or equal to 1 Watt) within 2 feet
 - Satellite phones (within 12 feet)
 - Radio transmitters or walkie-talkies (within 12 feet)

Post-Operative Patient Management

Patient Assessment

Assessing Pump Function

- Observe green full light on the driver for complete filling.
- Observe pump for complete ejection:
 - PVAD “flash test”
 - IVAD green empty light on signal processor

Assessing VAD Parameters

- Mode of Operation
- Pump rate
- Eject time
- VAD flow/output
- Eject Pressure
- Vacuum

Hemodynamics

- Atrial pressures
- Pulmonary pressures
- Blood pressure
- Intake/output

Potential Post-Implant Complications

Hypovolemia

Assessment: VAD filling is preload-dependent and must have adequate volume to fill the pump.

Management: Give volume replacement agents (i.e., colloids).

Bleeding

Assessment: Chest tube drainage >200 ml/hr
Check PTT, PT, fibrinogen, platelets, hemoglobin, and hematocrit
Decreased VAD output/flow

Management: Completely reverse heparin in the OR
Correct coagulopathies
Do NOT begin anti-coagulation protocol until

bleeding has stopped
Re-exploration

Tamponade

Assessment: Can be confused with right ventricular failure
No VAD response to fluid challenges
Increased atrial pressures
Decreased VAD rate and output/flow
Decreased blood pressure
Transesophageal echocardiogram

Management: Volume and vasopressor support
Reexploration

Right Ventricular Failure with Isolated LVAD Support

Assessment: Increased central venous pressure
Possibly increased pulmonary artery systolic pressure
Decreased VAD output/flow

Management: Inotropic drug therapy, diuretics
Nitric oxide or vasodilators for pulmonary hypertension
RVAD insertion

Arrhythmias

Assessment: Check rhythm on EKG
Decreased VAD output/flow

Management: For isolated LVADs, treat atrial/ventricular arrhythmias with drugs and/or cardioversion.
For BiVADs, arrhythmias may not require treatment.

Note: Most ventricular arrhythmias are short and convert spontaneously, and the incidence of V-fib and asystole is low. Many patients tolerate ventricular arrhythmias (LVADs or BiVADs) without hemodynamic compromise and remain asymptomatic.

Thromboembolism

Risk Factors: Inadequate anti-coagulation
Incomplete VAD ejection (negative flash test or loss of green empty signal)
Low VAD output/flow (< 3.0 L/min)
Cannula, pneumatic lead, or percutaneous line kinking
Sepsis

- Assessment:** Mental changes
Weakness, paralysis, blurred vision, slurred speech
Abnormal computerized tomography (CT) scan
- Management:** Adequate anti-coagulation
Prevent cannulae, pneumatic leads and/or percutaneous line from kinking
Verify complete VAD ejection
Maintain adequate VAD output/flow

Note: This device contains ferro-magnetic metal components. Do NOT perform MRI procedures on patients with the Thoratec VAD.

Recommended Anti-Coagulation Regimen

PHASE I (low dose heparin administration 12-72 hours after VAD insertion)

Heparin at 10 units/kg/hr

Begin low dose heparin when chest tube drainage falls to approximately 50 ml/hr for 2 or 3 hours, with stable hematocrit and hemoglobin levels and coagulation factors (PT, PTT, fibrogen and platelet count) approaching normal.

Note: Several centers use low molecular weight dextran at 25ml/hr in the first 12-72 hours post-op, instead of heparin. However, the use of dextran is controversial because its effectiveness and mechanism of action in VAD patients is unclear.

PHASE II (Heparin administration >72 hours post-operatively)

Increase heparin dose to maintain the PTT approximately 1.5 times control. Increase heparin after the risk of bleeding is diminished by the healing of raw surfaces and the repair of hemostatic abnormality associated with cardiopulmonary bypass.

PHASE III (Warfarin Administration)

International Normalization Ratio (INR) Range 2.5 to 3.5

Once the patient is extubated and tolerating oral medications, start warfarin (overlapping with heparin or dextran). Warfarin administration is similar to patients with mechanical heart valves. After obtaining an acceptable INR, discontinue heparin or dextran.

Note: Several centers administer aspirin (80mg/daily) for patients supported > 30 days or for platelet counts > 300 (Th/mm³) to help prevent platelet aggregation on the artificial surfaces.

CAUTION: Significant drops in the hematocrit (Hct) and hemoglobin (Hgb) levels, possibly requiring blood transfusions or the inability to stabilize Hct and Hgb levels, may require modification of anti-coagulation (e.g., lowering heparin or warfarin dosage or discontinuing aspirin administration).

Infection

Assessment: High VAD output
Erythema, drainage at cannulae exit sites
Fever
Positive cultures

Management: Prophylactic antibiotics per hospital protocol.
Early extubation and patient mobilization.
Remove all invasive lines and indwelling catheters as soon as medically indicated.
Rapid restoration of oral nutrition.
Strict aseptic technique for exit site dressing changes.

Use a binder to immobilize VAD(s) to promote tissue in-growth at the cannula/percutaneous line exit site(s).

VAD Exit Site Care

- Good hand washing technique.
- Sterile dressing changes ALWAYS (antibacterial agent or Betadine *solution*).
- Occlusive, dry dressing ALWAYS.
- VAD dressing change every 24 hours and PRN.
- Do NOT use povidone-iodine ointment (Betadine) for dressing changes because this may cause paracorporeal cannula or IVAD driveline degradation. Betadine™ *solution* is acceptable.
- Do NOT use products containing acetone because this may cause housing stress cracks in the PVAD.
- Do NOT use any petroleum-based ointments, bleach solutions, products containing silver (e.g., Silvadene™ cream) or hydrogen peroxide.

Major paracorporeal cannulae site infections are not common. However, cannulae site infections require aggressive therapy. For cannulae redness or purulent drainage, culture the site and increase the frequency of VAD dressing changes.

Note: Telemetry pouches can be used to support the VAD during patient ambulation (immobilized cannula allow for tissue in-growth).

Antibiotic irrigation may be used to treat “tracking” along the cannula site. “Tracking” is an infection along the cannula, resulting in poor tissue in-growth and infectious drainage. For tracking greater than one inch, irrigate with vancomycin (100mg/1000 ml sterile normal saline) or a diluted antibiotic solution specific to the infection. A 12 French suction catheter can be used for irrigation. Irrigate wound along tracking until return drainage is clear or bloody. **Note:** Several centers have had excellent results using antibiotic irrigation for cannulae site infections, often avoiding intravenous or oral antibiotic therapy.

Post Test

- 1 How can you determine if the Paracorporeal VAD (PVAD) pump is filling completely:
 - a. Green "fill" light on the Dual Drive Console (DDC) or TLC II Portable Driver.
 - b. Look at the pump.
 - c. Check stroke volume on console.
 - d. a & b

- 2 What assures you the Implantable VAD (IVAD) pump is emptying completely?
 - a. "Empty" light on signal processor
 - b. Flash test
 - c. VAD output is reasonable, i.e. 2.5 to 7.1 liters per minute

- 3 On the DDC, the "% systole" should be:
 - a. $\frac{1}{2}$ the set rate
 - b. $\frac{1}{4}$ the set rate
 - c. Will be automatically calculated by the console.

- 4 The inflow cannula to the LVAD is inserted:
 - a. In the apex of the left ventricle.
 - b. In the left atrium.
 - c. In the pulmonary vein.
 - d. a & b

- 5 It is recommended that the PVAD plastic housing be cleaned with acetone.
 - a. True
 - b. False

- 6 Anti-coagulation should be started within the first 24 hours.
 - a. True
 - b. False

- 7 What is the recommended mode of operation for stable patients on the DDC?
 - a. ASYNC
 - b. VOLUME
 - c. EXT SYNC

- 8 What is the recommended mode of operation for stable patients on the TLC II?
 - a. Fixed
 - b. Automatic

- 9 In case of mechanical failure of the DDC or TLC II, what should be used to power the VAD?
 - a. Standard Ambu bag.
 - b. Intra Aortic Balloon Pump Console.
 - c. Hand pump 60 times per minute.

- 10 The "clear" button on the DDC has two functions:
 - a. Silence the audible alarm indefinitely and will clear incorrect Set Rate or Set % systole entries.
 - b. Silence the audible alarm for 5 minutes and will clear incorrect Set Rate or Set % systole entries.
 - c. Will return all parameters to factory set defaults.
 - d. Removes all patient data from memory.

- 11 For IVAD supported patients, loss of the fill signal will result in loss of the empty signal when using:
 - a. The DDC
 - b. The TLC II Driver
 - c. Both DDC and TLC II Driver
 - d. Neither DDC or TLC II Driver

- 12 The TLC II Driver requires at least two power sources: either ___ batteries or ___ battery and the AC Adapter.
 - a. 3,1
 - b. 2,2
 - c. 2,1
 - d. None of the above.

- 13 Every 30 seconds a brief alarm sounds and the alarm displayed is *Replace Battery B*. What action is required?
 - a. Replace Battery A with a fully charged battery.
 - b. Replace Battery B with a full charged battery.
 - c. Replace Batteries A and B with fully charged batteries.

- 14 The green lamp on the Battery Charger indicates that the battery is:
 - a. Charging
 - b. Fully charged

- c. A fault has been detected and the battery should not be used.
- 15** While sleeping or relaxing your patient should use which power source?
- a. Batteries
 - b. AC Adapter
- 16** An audible alarm sounds every 5 seconds and No L Full Signal is displayed. What do you do?
- a. Check batteries.
 - b. Check AC Adapter.
 - c. Switch to the back-up TLC-II Driver.
 - d. Check electrical lead for proper connection and PVAD for complete filling and adequate pumping.
 - e. Replace the electrical lead if indicated.
 - f. d & e
- 17** If supported with an LVAD only, the occluder cap should always remain on the RVAD pneumatic port.
- a. True
 - b. False
- 18** The exit site dressing should be:
- a. Changed daily and PRN.
 - b. Done using Dakin's solution and polyethylene glycol-based or petroleum-based ointments.
 - c. A sterile procedure.
 - d. All of the above.
 - e. a & c
- 19** The signs of an infection include:
- a. High VAD output
 - b. Erythema and drainage at the cannulae exit sites
 - c. Fever
 - d. All of the above.
 - e. b & c
- 20** The VAD should be supported with an abdominal binder:
- a. While ambulating.
 - b. ALWAYS
 - c. During cannula site infection.

Dual Drive Console (DDC) Competency Assessment

Name: _____
print

Name: _____ **Date:** _____
signature

<u>Competency Criteria</u>	<u>Check When Verified</u> <input checked="" type="checkbox"/>
1 Explain the difference between Async and Volume Modes	<input type="checkbox"/>
2 Verify flash test and explain importance of test.	<input type="checkbox"/>
3 Explain the function of the IVAD signal processor and interaction with the fill signal.	<input type="checkbox"/>
4 Show location of battery indicators and describe amount of available battery time.	<input type="checkbox"/>
5 Turn on console for VAD function.	<input type="checkbox"/>
6 Change set rate to 70 bpm; adjust % systole appropriately.	<input type="checkbox"/>
7 Adjust Eject Pressure and Fill Vacuum to normal ranges.	<input type="checkbox"/>
8 Display VAD Rate, % Systole, Eject time in milliseconds, VAD Output, Eject Pressure, and Fill Vacuum.	<input type="checkbox"/>
9 Understand the meaning of alarms and appropriate responses for each type of alarm condition.	<input type="checkbox"/>
10 Demonstrate silencing of an audible "alarm."	<input type="checkbox"/>
11 Demonstrate changing to backup module.	<input type="checkbox"/>
12 Describe procedure for changing BiVAD patient to backup console while hand pumping.	<input type="checkbox"/>

TLC-II Competency Assessment

Name: _____
print

Name: _____ **Date:** _____
signature

<u>Competency Criteria</u>	<u>Check When Verified</u> <input checked="" type="checkbox"/>
1 Name three differences between the DDC and TLC-II.	<input type="checkbox"/>
2 Explain the differences between Fixed and Auto Modes.	<input type="checkbox"/>
3 Describe beat rate and low rate.	<input type="checkbox"/>
4 Verify flash test and explain importance of test.	<input type="checkbox"/>
5 List two methods to identify complete IVAD emptying	<input type="checkbox"/>
6 Interpret icons on battery changer and explain how long it takes to fully recharge a discharged battery.	<input type="checkbox"/>
7 Turn on driver and explain key storage.	<input type="checkbox"/>
8 Assess approximate time remaining on battery A.	<input type="checkbox"/>
9 Change from battery power to AC power adapter and identify indicator that shows driver is getting power.	<input type="checkbox"/>
10 Identify scroll button and explain service interval.	<input type="checkbox"/>
11 Understand the meaning of alarms and appropriate responses for each type of alarm condition.	<input type="checkbox"/>
12 Explain two reasons for driver switching into Emergency Mode.	<input type="checkbox"/>
13 Demonstrate procedure for changing to backup Driver.	<input type="checkbox"/>

Notes

Program Evaluation

Program Title: Thoratec VAD Clinical Operation & Patient Management

Program Date: _____

Presenter: _____

Location: _____

Program Evaluation:

Excellent Good Fair Poor N/A

1. Program met stated objectives.
2. Content covered topic adequately.
3. Rate overall this program.
4. Rate the program facilities.

Speaker Evaluation:

Excellent Good Fair Poor N/A

5. Rate overall quality of speakers.
6. Speaker was organized & effective
7. Speaker was qualified.
8. Speaker held interest.

The most useful part of this presentation was:

The least useful part of this presentation was:

Additional Suggestions:
