

Thoratec Ventricular Assist Device

The Thoratec Ventricular Assist Device (VAD) is a paracorpeal system that supports right, left or both ventricles in patients with end-stage heart disease. The device is indicated for both bridge-to-recovery and bridge-to-transplantation.

System Components

1. VAD Blood Pump

The VAD blood pump has a rigid plastic case containing a blood sac. A full blood sac triggers the Hall effect switch that transmits a signal via an electrical lead to the DDC or TLC II. The blood sac is compressed by air from a pneumatic driver to eject blood from the sac into the outflow cannulae (systole). Vacuum is applied to the pump to remove the air pressure so blood can fill the pump (diastole). The blood pump has a volume of 65cc and can pump up to 6.5L/min.

Contact with Acetone will cause the VAD housing to crack.

2. Inflow and Outflow Cannulae

Cannulae may be inserted in the left or right atrium or placed in the left ventricular apex or right ventricle to provide inflow to the pump. Blood returns to the patient with an arterial cannula attached to the ascending aorta or the main pulmonary artery. Cannulae are reinforced with wire to prevent kinking where they pass through skin.

3. Dual Drive Console (DDC)

The DDC has 2 independent drive modules for left and/or right ventricle support. Patients with BiVADs require both modules and patients with a single VAD require one module.

The DDC alternates air pressure with vacuum to allow for effective filling and ejection of the blood sac. The DDC has an internal battery that can supply up to 40 minutes of power when disconnected from AC power.

The DDC must be plugged in at all times.

Dual Drive Console

Modes of Operation

3 mode control keys are located on the lower left corner of the module. Pressing a key changes the mode of operation.

- | | |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ASync | <ul style="list-style-type: none">▪ Fixed rate asynchronous to the patient's intrinsic heart rate.▪ Used when initiating VAD support in the operating room and when weaning the device. |
| VOLUME | <ul style="list-style-type: none">▪ Recommended mode of operation.▪ VAD automatically responds to changes in patient's physiological condition.▪ If pre-load pressure increases, pump fills faster and VAD rate increases. If pre-load decreases, VAD output and rate decreases. |
| EXT SYNC | <ul style="list-style-type: none">▪ EXT SYNC is not recommended as a mode of operation. |

Set Value

Set Value allows for changes to VAD operation.

Pump On	Initiates VAD pumping.
Pump On and Enter Rate bpm	Stops VAD pumping. 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	Not recommended for use as it is associated with the EXT SYNC mode.
Clear	Used to silence audible alarms indefinitely. Once pressed, there will be no additional audible alarm unless a new alarm condition occurs.
Enter	Used to confirm changes for Set Value Rate and Systole % values.

Changing Set Values

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

1. Press RATE bpm
2. Enter new Set Rate using numbered key pad and press enter.

To Change percentage of VAD Systole (ejection time)

1. Press %Systole.
2. Enter the new value using numbered keypad and press enter.

If an incorrect number is pressed while entering a value press Clear and try again.

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

Display Screens

6 display screens provide information about VAD operation. The keys above each display allow for selected data to be displayed. The values displayed are updated every fourth beat. Display screens cannot be used to change VAD parameters.

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)	A set value of 65 cc. 65 cc of stroke volume is always 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.
VAD Output (L/min)	Automatically calculated blood flow in L/min from the VAD (VAD rate x stroke volume (65cc) = VAD output). Value is accurate only if the VAD is filling and emptying completely.
Eject (mmHg)	Drive pressure in mmHg delivered for complete VAD ejection (is a preset value of between 230-245 – usually 100 mmHg above patient's systolic blood pressure)
Fill (mmHg)	Vacuum in mmHg delivered to assist VAD in filling.

Making Changes to Pressure and Vacuum

Use digital displays to determine accurate pressure and vacuum levels.

To change pressure:

1. Turn regulator knob, located below the pressure gauge, **clockwise to increase** eject pressure and **counter-clockwise to decrease** eject pressure.
2. Observe eject display monitor to identify adequate pressure levels.

To change vacuum:

1. Turn regulator knob, located below the vacuum gauge **clockwise to increase** vacuum and **counter-clockwise to decrease** vacuum.
2. Observe fill display monitor to identify adequate vacuum levels.

Recommended Settings:

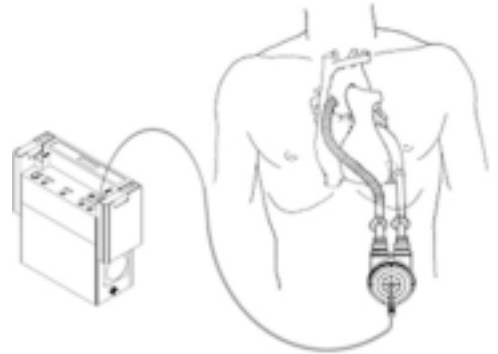
Mode of Operation	Volume
Set Rate	50-60 bpm
Set % systole	25% to 30% (1/2 Set Rate = 300 msec)
Drive Pressure	140 to 160 mmHg (RVAD) 230 to 245mmHg (LVAD)
Vacuum	-25 to -40 mmHg

TLC-II Portable Driver (TLC driver)

The TLC driver is a portable VAD driver powered by batteries or external AC power. The TLC driver should not be used on VAD patients who require > 160 mmHg drive pressure and > 350 msec of ejection time for complete RVAD ejection when using the Dual Drive Console.

The driver consists of a pneumatics assembly, an electronics assembly, two removable rechargeable lithium-ion batteries, one rechargeable battery for emergency use. All these components fit inside a nylon carrying case.

- The TLC driver provides power to pump the VAD, stores data, uses symbols, messages and alarms to report information and indicate situations requiring attention.
- The symbols and message display on the TLC driver's front panel indicates corrective actions to be taken when alarms occur.
- Always carry 2 emergency hand pumps and the Driver key in the carrying case pocket.



Description of Leads and Cables

Connection	Colour Code	Characteristics
LVAD electrical lead	Red	LVAD full signal
LVAD pneumatic lead	Red	Pneumatic drive for LVAD
RVAD electrical lead	Blue	RVAD full signal
RVAD pneumatic lead	Blue	Pneumatic drive for RVAD
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 or Docking Station power supply

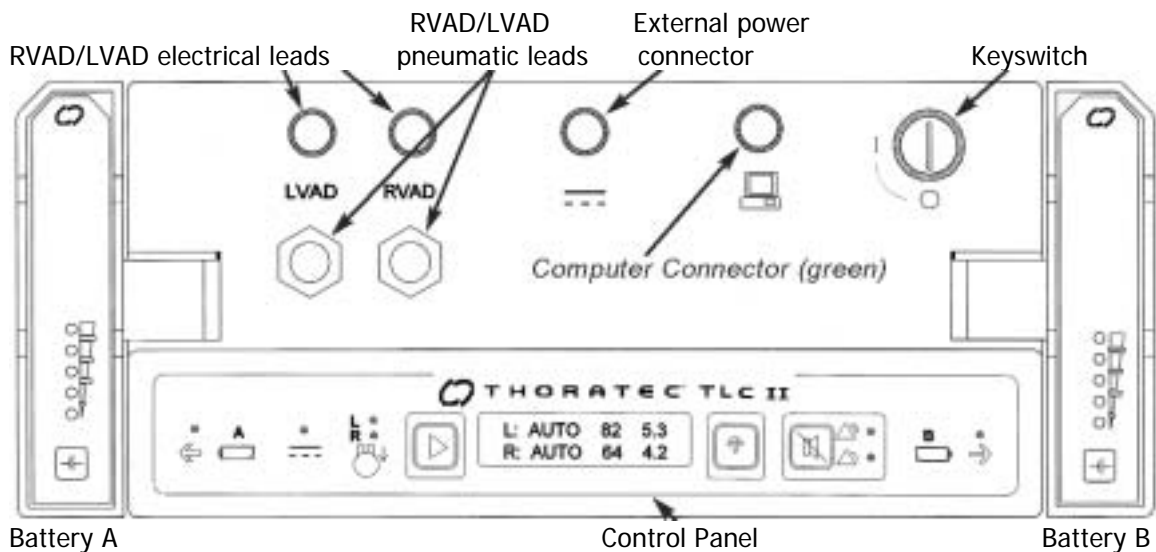
The TLC II driver operates in two modes:

Fixed

- Asynchronous mode.
- Default mode when Auto has not been selected or when no fill signal is received in Auto mode.

Auto

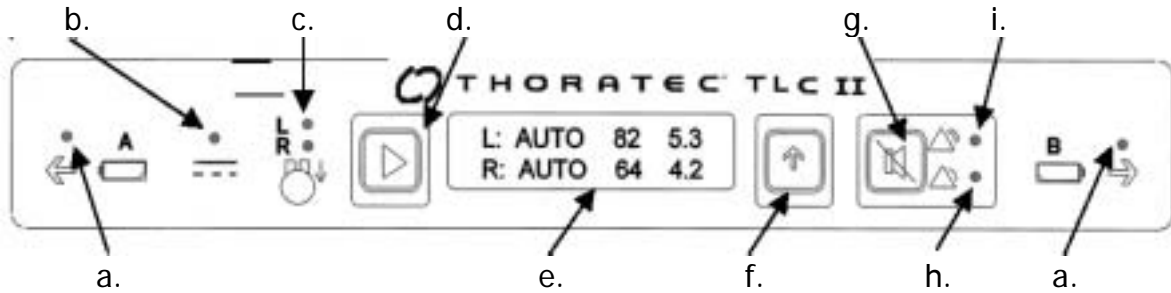
- Volume mode
- Most frequent mode of operation.



Starting the TLC II Portable Driver

1. Turn on power to the Docking Station and computer.
2. Connect power cable (yellow) and computer cable (green) to Docking Station and TLC driver.
3. Place fully-charged batteries into A and B battery slots.
4. Insert occluder plugs into LVAD and RVAD pneumatic ports.
5. Turn on system with key; remove key and place on hook inside the carrying case pocket.
6. Verify that all indicator lights on top of the driver illuminate and audible tones for normal and urgent alarms are present.
7. With occluder plugs in place, check for occlusion and/or hi pressure alarm.
8. Check for Lo Pressure Alarm by removing occluder plug from either pneumatic port.
9. 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).
10. Press and hold the alarm silence button for 10 seconds to indefinitely silence the No Full Signal Alarms during set up.
11. Go to the VAD Setting Screen to program the TLC driver using the recommended VAD settings that appear below
12. Enter patient information on the General Screen.
13. Enter settings.

TLC II Control Panel Indicators



Change battery A (a) – yellow	Illuminated when batteries are depleted and need to be replaced
External power (b) - green	Illuminates when the TLC driver is using external power
Full signal (c) – green	Two green Full lights indicate when the LVAD (L) and RVAD (R) are completely full of blood
Mode button (d)	Pressing MODE button switches from fixed rate to automatic rate. This button can be overridden or de-activated by settings on the TLC Heart Touch computer.
Message display (e)	Shows status info on the LVAD (top row) and RVAD (bottom row). The main display shows mode, rate, and flow. Alarm messages appear in this screen. Messages are displayed for 3 seconds before reverting to status info.
Scroll button (f)	Pushing button allows user to scroll between alarm code messages and status info.
Alarm silence (g)	Silence alarm for 30secs during normal alarm conditions.
Normal alarm (h)	Red light for all alarm conditions
Urgent alarm (i) – red	Red light for Emergency alarms when emergency system is in operation. Cannot be silenced.
Change battery B (a) – yellow	Illuminated when batteries are depleted and need to be replaced

Vacuum Regulator Knob:

Vacuum regulator knob is located on side of TLC driver, protected by a Velcro flap.

Air intake filter and grill is above the regulator and needs to be kept free of dust and obstructions.

Maximum vacuum is achieved by turning the knob fully clockwise.

When starting a patient on the TLC driver: set vacuum regulator to minimum (fully counter clockwise) and gradually increase until Fill signals and desired rate are achieved.

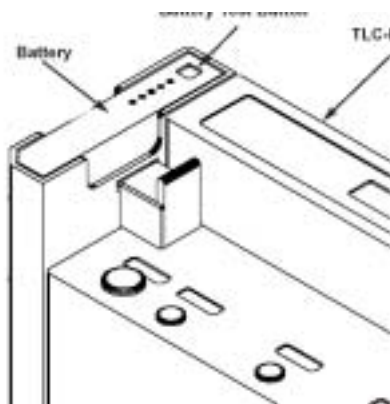
Power Sources:

The TLC driver is designed to operate with either 2 batteries or one battery and the external power source. It can operate with 1 power source but will sound a warning beep every 30 seconds until a second power source is connected. A continuous alarm sounds when there is approximately 10 minutes of battery power remaining.

An Emergency battery is located inside the bottom of the driver and can be accessed by unscrewing the Philip's screws on the bottom plate. This battery serves as an Emergency back-up system and will support pump function if all other power sources fail.

If the Emergency battery is depleted, an urgent alarm will sound until the Emergency battery has been changed. Do not change the Emergency Battery when the patient is connected to the Portable Driver.

Batteries



- Each rechargeable battery provides power for 80 minutes (LVAD/ RVAD) or 55 minutes (BiVAD) when fully charged.
- To insert a battery into the TLC II, slide it into its slot with the indicator light visible. A "click" indicates that it is properly inserted in the slot.
- To remove a battery, pull the battery clip towards you and withdraw the battery from the slot. Place depleted battery into battery charger.
- 5 green power indicator lights are located on each battery. Each light represents approximately 20% of battery time. Pressing the test button illuminates the green battery lights.

Battery Charger

- The charger should always be plugged into an electrical outlet and turned "on".
- Batteries can fully recharge in 2 hours and should never be left in the charger for more than 14 days.
- Indicator lights:
 - *Green* light indicates the battery is fully charged and ready to use.
 - Yellow light indicates the battery is charging.
 - *Steady* red light indicates the battery cannot be charged.
 - *Flashing* red light indicates that the battery temperature is too hot or cold

AC Adapter

The Thoratec VAD can be connected to an electrical outlet with the AC Adapter.

- Plug the yellow cable on the AC adapter into the yellow external power connector on the TLC driver.
- Plug the AC power cable into an electrical outlet. A beep indicates that external power has been connected
- Verify that the green external power indicator lamps on the TLC driver and adapter are illuminated. If it is not illuminated, the TLC driver is drawing power from the batteries.



TLC II Docking Station

The TLC II Portable Driver can be attached to a "docking station" when the driver is not in ambulatory use. The docking station contains the HeartTouch computer, battery charger, accessory drawer, and room for storing 2 TLC drivers. Plug the docking station into an electrical outlet and turn it on.

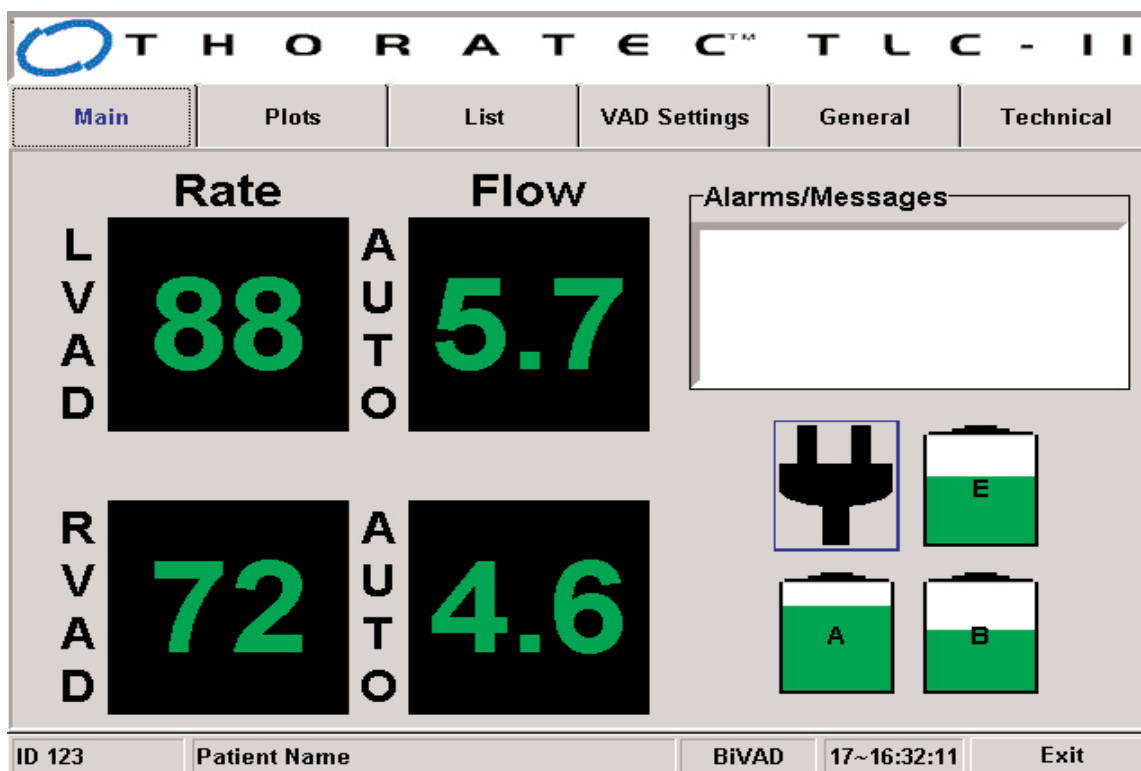
- Place the TLC II driver into the docking station.
- Connect the yellow power cable from the TLC driver to the yellow connector on the bay.
- To interface the TLC driver to the HeartTouch computer, connect the green computer cable from the TLC driver to the green connector on the front bay.

HeartTouch Computer

The Heart Touch computer is required during start-up, to change settings, and for diagnostic purposes. The computer and touchscreen are located on top of the docking station. Once the patient is stable and ambulatory the TLC driver does not need to be connected to the HeartTouch computer. The Heart Touch computer contains six screens to allow for the visualization of information and setting changes.

Main Screen

- Displays VAD rate, flow and mode for each VAD in use.
- Status of all power sources, alarm info and patient ID.
- Should be the default screen when patient is attached to the computer.



Plots Screen

- Shows real-time waveforms of air and vacuum pressure.

List Screen

- Shows the current status of the TLC driver.
- Alarm condition will trigger an event, which is recorded in the list.
- Changes to operating parameters, power source and routine time intervals are recorded.

VAD Settings Screen

Shows current VAD operating settings and allows changes to be made to those settings.

Recommended Settings

Control Mode	Automatic (front panel disabled)
Accumulator Pressure	250-270 mmHg for BiVAD and LVAD (RVAD pressure is NOT adjustable)
Beat Rate	5 beats below average VAD rate during normal activity. 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	270-300 msec
Eject Mode	Manual

General Screen

- Set the date, time and language on the TLC II and HeartTouch computer.
- Access, input or change patient information.
- Set the interval between routine event recordings, retrieve and clear information from the event log.

Technical Screen

- Diagnostic information such as power source voltage, compressor temperature, usage hours, date the TLC driver was last serviced, TLC serial number, firmware and software versions.

Alarms & Troubleshooting

Status, Alarm and Power indicators provide specific information about console operation.

1. Status Indicators:

Eject light	Not used in 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)
Ext Sync	Not used in VOLUME or ASYNC modes

2. Alarm Indicators:

Alarm indicators alert staff to possible console or patient problems. An alarm condition is accompanied by a red light and a continuous beeping sound. Alarm conditions must be corrected. The 4 possible alarms are: Pressure, Vacuum, Sync, and Low Battery.

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.

Cause	Correction
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 +4mmHg (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:

Cause	Correction
Vacuum changed by staff	Adjust fill vacuum to acceptable range
Compressor and/or UPS failure	Change to backup console

Sync

The Sync alarms occur 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, look at the pump to see if it is filling completely. If the pump is filling completely, check the electrical lead connections and if necessary, change the electrical leads. If the pump is not filling completely, follow steps 1 to 3 below:

1. Check for kinks in the cannula and pneumatic lead
2. Check vacuum level, Set Rate, and Set % Systole
3. Assess patient for:

Arrhythmia	Vasodilation
Hypovolemia	Recovery of native ventricle
Bleeding	Inadequate pharmacological support
Tamponade	Right heart failure or arrhythmias with isolated VAD

A Sync Alarm for loss of fill signal will NOT occur in the Asynchronous mode; an "-E-" is displayed for VAD output.

3. Power indicators:

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 Uninterrupted Power Source (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.**

AC Power

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 sound every 5 seconds.

UPS Indicator

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**

4. VAD Filling

Complete VAD filling can be determined by either the green fill light or visual inspection. If you do not have complete VAD filling console changes include the following steps:

For complete VAD filling try to	Note
Increase vacuum	Should not exceed -50mmHg
Decrease Set Rate	Until fill signal appears
Decrease Set % Systole	To 250msec to 300 msec

5. VAD Ejection

The "flash test" will verify that the VAD 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.

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 cannula
- 2 Increase drive pressure: LVAD 250 mmHg maximum
RVAD 170 mmHg maximum
- 3 Increase Set % systole until a flash appears
- 4 Lower patient's systolic pressure (if hypertensive).

Explanations for the -E-

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

1. Loss of fill signal
2. Eject time less than 25 msec
3. Eject pressure < 100 mmHg or > 250 mmHg

Damaged Pneumatic or Electrical Leads

Changing Pneumatic Leads

1. Disconnect the leaking pneumatic lead from y-connector on pump and from connector port on driver.
2. Attach new pneumatic lead to the y-connector on pump and connector port on driver.
3. Verify VAD pumping and complete emptying with Flash test.
4. If alarm states exist, follow necessary troubleshooting to resolve alarm state.

Changing Electrical Leads

1. Disconnect the electrical lead from the y-connector on the VAD pump and from the connector port on the driver.
2. Attach new electrical lead to the y-connector on pump and connector port on the driver.
3. Verify VAD pumping and complete emptying with Flash test.
If alarm states exist, follow necessary troubleshooting to resolve alarm state.

Emergency Situations

Mechanical Failure

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

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

In the event of a mechanical failure, use either the hand pumps or the Emergency Selector valve to provide short-term support and switch to the back-up system as soon as possible.

1. Hand Pumps

Always have 2 hand pumps with the DDC.

In the event of console failure:

1. Disconnect the VAD pneumatic lead(s) from the back of the DDC.
2. Connect lead(s) to the hand pump.
3. Squeeze the hand pump(s) firmly, about once per second to empty and fill the VAD.
4. Switch to back-up module or console.

Caution: If the patient has BiVAD, do not pump the RVAD faster than the LVAD as this will put the patient into pulmonary edema.



2. Emergency Selector Valve

The emergency selector valve is a short-term alternative to manual support. The Red selector valve is found inside the console's back door. Using this valve allows one module to pump both VADs. The valve has three potential positions:

1. Center position is for normal operation. (each drive module operates independently).
2. Out position allows the top module to drive both VADs.
3. In position allows the bottom module to drive both VADs.

Caution:

For BiVAD support, 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. Switch to the back-up system as soon as possible.

For univentricular support, the second module can serve as a back up for mechanical failure of the operating module. Setting (Set Rate, Set % Systole, drive pressure and vacuum) for the second module should be the same as the operating module.

Switching Operation to a Backup System

- Turn back-up system on and follow start-up procedures to input current VAD settings for required drives.
- Disconnect pneumatic leads and immediately re-attach to appropriate ports on the back-up system.
- Disconnect electrical leads and connect to the appropriate ports of back-up system.
- Verify that no alarm states exist. If alarms are present, complete necessary troubleshooting.
- Verify complete emptying by performing a "Flash" test.

Alarm Messages and Responses

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 driver will run on the emergency battery system. The emergency battery can power the driver 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 driver with back-up 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 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 VAD for filling. If VAD is filling completely, change electrical lead. If VAD is not filling, assess patient and adjust settings.
HI L PRESSURE REPLACE Or HI R PRESSURE REPLACE	Red Normal Alarm	Continuous tone	The pressure in the TLC driver is too high to operate properly	Verify VAD pumping. Check leads for kinks and proper connections. If not resolved, replace TLC driver with back- up driver
LO L PRESSURE CHECK; REPLACE Or	Red Normal alarm	Continuous tone	The pressure in the TLC driver is too low to operate properly	Verify VAD pumping. Check pneumatic lead(s). If not resolved, replace TLC driver

LO R PRESSURE CHECK; REPLACE				with back-up driver.
Written Message	Visual Alarm	Audible Alarm (beep interval)	Meaning	Action Required
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 driver with back-up driver.
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 TKLC driver with back-up 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 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 driver with back-up driver if alarm continues.
LO TEMPERATURE WAIT	Red Normal Alarm	Once per second	The compressor temperature is too low	Wait for the TLC 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 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 driver with back-up driver.
[No written message] or EMER SYSTEM ON; REPLACE	Red Urgent Alarm	Continuous tone	TLC 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 driver with back-up driver.