Thoratec® TLC-II® Portable Pneumatic Driver

Instructions for Use

THORATEC®
CORPORATION

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EC REP

Thoratec Corporation continually strives to provide the highest quality products for mechanical circulatory support. Specifications may change without notice. Therefore, please refer to the *Thoratec VAD Instructions for Use* shipped with the Thoratec VAD for the most current information regarding indications, contraindications, warnings, and precautions. Thoratec, the Thoratec logo, and TLC-II are registered trademarks of Thoratec Corporation. The Thoratec TLC-II was authorized to bear the CE Mark in 2003. Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

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Thoratec® TLC-II® Portable VAD Driver and System

INSTRUCTIONS FOR USE

50010-0006-002.L 06/05

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INDICATIONS FOR USE

The Thoratec Ventricular Assist Device (VAD) is indicated for:

Bridge-to-transplant patients who meet all of the following criteria:

1 Candidate for cardiac transplantation.
2 Imminent risk of dying before donor heart procurement.
3 Dependence on, or incomplete response to, continued vasopressor support.
4 Post-cardiotomy recovery patients who are unable to be weaned from cardiopulmonary bypass.

The TLC-II portable pneumatic driver is intended for use both inside and outside the hospital, or for transportation of VAD patients via ground ambulance, fixed-wing aircraft, or helicopter.

CONTRAINDICATIONS

- Uncontrolled hemorrhage.
- Central nervous system damage resulting in fixed and dilated pupils.
- Contraindications to cardiac transplantation contraindicate use of the device for bridge to transplant.

WARNINGS

Patient Population - General
VAD patients with prosthetic aortic valves may have increased risk of thromboembolism due to blood flow shunted away from the valve.

Patients with greater than 1.5+ aortic insufficiency should either not be considered a candidate for VAD support, or should be considered only after repair or replacement of the aortic valve.

Significant right-to-left shunting can occur in patients with a patent foramen ovale. Patency of the foramen ovale should be considered and corrected if necessary, prior to insertion of VADs.

Cannulae may be difficult to insert in patients with small hearts, in patients with congenital abnormalities, or in patients with previous cardiac reconstructive surgery. There are no detailed data available at this time regarding this issue.

Patient Population - Bridge to Transplant
Patients with hepatic and/or renal dysfunction may require 2 to 3 weeks of VAD support for major organ function to recover.

Patients with elevated levels in the panel of reactive antibodies (PRA) may require extensive duration of VAD support in order to locate a donor heart. Patients should be excluded if the expectation of finding a donor heart is not reasonable.

Patient Population - Postcardiotomy Recovery
There are no additional warnings other than those already listed for the general patient population specific to the use of the device pending postcardiotomy myocardial recovery.

Procedural Techniques - All Indications for Use
The VAD is provided sterile; caution must be taken in opening the package. Do NOT resterilize. Do NOT use if package is damaged. Store at 20 - 30°C.

Do not disassemble the VAD. Collet nuts and collets must be removed to attach cannulae to the VAD, and this can be performed by hand. Disassembly or attempts to loosen the cap ring, valve housing nuts, or any other component of the VAD may affect VAD function.

Do NOT use polar organic solvents, such as ketones, chlorinated hydrocarbons, and aromatic hydrocarbons, anywhere near the VAD. Such use has caused stress-cracking of the polysulfone and other damage to the VAD housing. These solvents include, but are not limited to, acetone, methyl ethyl ketone (MEK), methylene chloride, chloroform, trichloroethane, and benzene and its derivatives.

Do NOT use povidone-iodine (e.g., betadine) ointments, or other polyethylene glycol-based ointments in contact with the cannula for prophylactic care of the transdermal skin site. Such use over several months has caused cannula degradation at the end of the wire reinforced region. Povidone-iodine solution (not containing polyethylene glycol) is recommended.

PRECAUTIONS

Training of Personnel
Surgical, nursing, and perfusion staff responsible for the VAD program at each hospital should complete the Thoratec VAD Training program.

Required System Backup
Each Dual Drive Console contains two independent drive modules, and therefore contains adequate built-in back-up capability for univentricular support. For patients using the .... TLC-II or receiving biventricular support on the Dual Drive Console driver, an additional TLC-II or Drive Console must be available as a back-up to be used in the event of a failure of the primary driver.

Personnel should be trained how to hand pump a VAD in the event of a drive console or TLC-II failure. If for any reason there is a driver failure, blood flow can be maintained to the patient and stasis prevented in the blood pump by disconnecting the VAD airline tube from the driver and connecting it to the hand pump for the short period of time necessary to connect the back-up drive console. Squeeze the hand pump about once per second to empty and fill the blood pump. Alternatively place hand pump on floor and use your foot. Connect the back-up drive console or TLC-II as soon as possible. This procedure is for emergency use only.

Steps to Minimize the Risk of Thrombosis

At low beat rates there is an increased risk of thrombus formation in the VAD. Therefore it is recommended that the device be operated at rates above 40 bpm and with complete filling and ejection of the VAD blood pump in the VOLUME mode (Auto Rate mode on TLC-II). Pneumatic drive ejection pressures of at least 100 mmHg above the patient's systolic blood pressure are recommended for complete ejection. Complete VAD emptying can be verified by using a flashlight (see Section 12.7 of the *Thoratec Ventricular Assist Device Instructions for Use*, document number 15003 for details). During weaning the patient from the VAD, and or during other conditions that result in low flow or beat rates below 40 bpm, continuous infusion of heparin for anticoagulation to achieve a partial thromboplastin time of 1.5 times control is recommended. See Section 13.4 of the *Thoratec Ventricular Assist Device Instructions for Use*, document number 15003, for anticoagulation regimen.

Interaction with Magnetic Resonance Imaging

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

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OTHER SUGGESTED REFERENCES

a. Thoratec Ventricular Assist Device Instructions for Use (Document No. 15003)
b. Thoratec Ventricular Assist Device Console Operation with Illustrations (Document No. 14909)
c. Thoratec Patient Management Manual (Document No. 14910)
d. Thoratec Ventricular Assist Device Dual Drive Console (Videotape No. 14805)
e. Thoratec Ventricular Assist Device Implantation Procedure (Videotape No. 14804)
f. Thoratec Dual Drive Console Instructions for Use (Document 14025)

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1. GENERAL INFORMATION

1.1 INTRODUCTION

The Thoratec TLC-II Portable VAD Driver (TLC-II Driver) is a lightweight, portable, pneumatic VAD driver, powered by batteries or from external power. The TLC-II Driver is designed for use with the Thoratec Ventricular Assist Device (VAD) and Thoratec Implantable Ventricular Assist Device (IVAD). The Thoratec VAD is a paracorporeal pump and is referred to as the “PVAD” throughout this manual. The TLC-II Driver provides portable pneumatic driver power for ambulatory PVAD and IVAD patients and is completely interchangeable with the Thoratec Dual Drive Console (DDC). It is, therefore, possible to switch patients from the console driver to the portable driver and back depending on patient need. The system is designed to supply isolated LVAD support, RVAD support, or biventricular support (both LVAD and RVAD).

The TLC-II System consists of the TLC-II Driver, batteries, a portable AC adapter, a mobility cart, and a docking station. The docking station is the "home base" for the TLC-II and accessories, including the battery charger and the system computer. Use of each of these components is completely described in this document. Section 1 provides an overview of the Thoratec VAD System. A complete description of the TLC-II System is presented in Section 2, followed by Clinical Study Information in Section 3, System Operation in Section 4, Alarm Troubleshooting in Section 5, and Maintenance in Section 6.

1.2 OVERVIEW OF THE THORATEC VAD SYSTEM

The Thoratec TLC-II Portable VAD Driver is designed for use only with the Thoratec PVAD and IVAD. The Thoratec VAD Systems can be used for partial circulatory assistance or for total support of the right and/or left ventricles. The VADs are placed in a paracorporeal position on the anterior abdominal wall and connected to the heart and circulatory systems with cannulae crossing the chest wall.

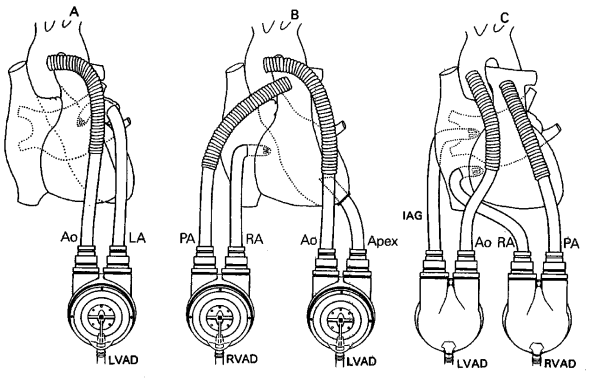


Figure 1.1 *Thoratec PVAD and three cannulation approaches for univentricular left heart support (Panel A), and biventricular support (Panels B and C).*
Ao = aorta, LA = left atrial appendage, PA= pulmonary artery, RA = right atrium, Apex = left ventricular apex, IAG = cannula inserted via the interatrial 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 those of Panel B. (Modified from Farrar DJ et al, New England Journal of Medicine 1988; 318: 333-340. Copyright 1988, Massachusetts Medical Society.)

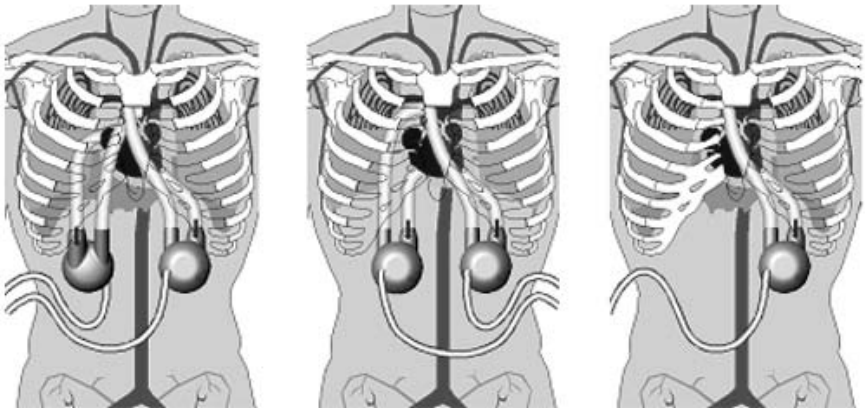


Figure 1.2 *Thoratec IVAD: Biventricular IVAD with left ventricular and right atrial cannulation (left), biventricular IVAD with left ventricular and right ventricular cannulation (middle), and left IVAD with left ventricular cannulation (right).*

For left heart support, cannulation can be achieved from either the left atrium or left ventricle with return to the aorta. For right heart support, atrial cannulation is used with return to the pulmonary artery. The VAD blood pumps are operated and controlled pneumatically by either the Thoratec Dual Drive Console or by the Thoratec TLC-II Portable VAD Driver. Both Drivers deliver alternating pulses of pressure and vacuum to empty and fill the VAD pumping chambers.

The Thoratec Systems consists of the following major components:

- Thoratec VADblood pump: Either a PVAD (Paracorporeal Ventricular Assist Device) or IVAD (Implantable Ventricular Assist Device)
- Selection of inflow and outflow cannulae
- Dual Drive Console or TLC-II Portable VAD Driver

Each component is briefly described in the following sections.

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).

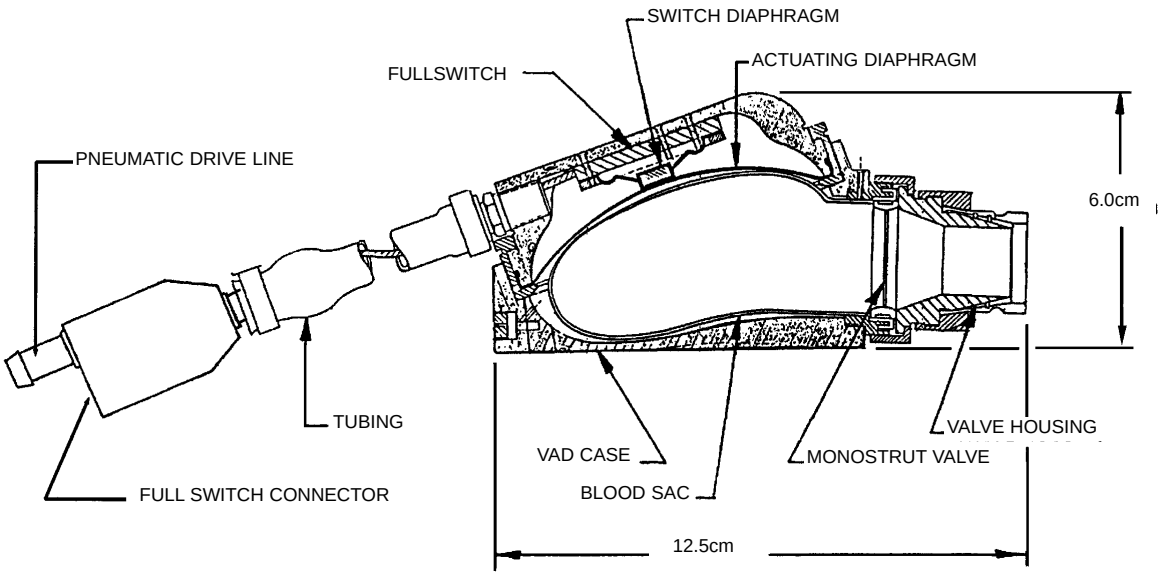


Figure 1.3 *VAD Blood Pump*

PVAD Pump

The PVAD (**Figure 1.1**) 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.

IVAD Pump

The IVAD (**Figure 1.2**) 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

Cannulae
Blood is brought from the patient to the VAD blood pump by either a ventricular apex cannula or an atrial cannula. For bridge to cardiac transplantation, it is usually preferable to cannulate the patient's left ventricular apex.

Blood is pumped from the VAD to the patient through arterial cannulae which are Thoralon polyurethane tubes with a smooth, blood-contacting surface attached to a low porosity woven polyester graft The end of the Thoralon tube is reinforced with wire to prevent deformation of the cannula where it passes through the patient's ribs and skin. The reinforced portion of each cannula is covered with polyester velour to encourage tissue ingrowth.

See **Appendix A** of the *Thoratec Ventricular Assist Device Instructions for Use*, document number 15003, for more detailed descriptions of the various cannulae configurations.

Dual Drive Console
The Thoratec VADs can be controlled with either the TLC-II or the Thoratec Dual Drive Console. These drive systems are designed to be interchangeable and both provide univentricular or biventricular pneumatic control of the pumps.

More detailed information on the Dual Drive Console is contained in *Thoratec Dual Drive Console Instructions for Use*, document number 14025.

1.3 TLC-II DRIVER PRINCIPLES OF OPERATION

Both the Thoratec PVAD and IVAD Systems can provide pulsatile blood flow at normal circulatory pressures in acute cardiac failure patients. In clinical practice, a 65 ml stroke volume is possible at any rate from 30 to 110 bpm (depending on the cannulae used and the size of the patient), which means an output ranging from 1.9 to 7.1 l/min.

They are designed to support the circulation of blood in the pulmonary and/or systemic circulation when the natural heart, with the help of conventional therapy, is unable to maintain normal flows and pressures in those vascular beds. To accomplish this support, blood is shunted from the natural ventricle by way of a cannula in the left ventricle, or the right or left atrium, to a VAD blood pump. Once the VAD is full of blood, compressed air is pulsed to start ejection. The air moves a diaphragm that squeezes the blood out of the blood sac, through the arterial cannula, and into either the pulmonary artery or the ascending thoracic aorta. After a time sufficient to eject the blood from the pump the air chamber is either vented to atmosphere or to a vacuum source, which allows air to escape from the air chamber and blood to fill the blood chamber.

The TLC-II has two timing modes: **Fixed** and **Auto:**

Fixed: In this mode, the operator chooses 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. Both the TLC-II and the Dual Drive Console automatically use this mode (which is called "Asynchronous" on the Dual Drive Console) if another mode is not chosen.

Auto: This mode is used in most clinical cases because of the automatic changes in flow output that occur in response to changes in physiological conditions. The instant the blood pump is filled with blood, the PVAD Hall Effect switch or IVAD optical 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 output is determined by the VAD rate times the stroke volume; for example, 60 bpm times 65 ml equals 3.9 l/min. The maximum flow is achieved when the blood pump fills and empties completely, with no time lost between phases of the cycle.

Implantation and removal of the Thoratec VAD involves standard surgical procedures, which are described in the *Thoratec Ventricular Assist Device Instructions for Use*, document number 15003.

1.4 CAUTIONS 

USE OF THORATEC-APPROVED COMPONENTS ONLY. The Thoratec TLC-II Driver and the Thoratec VAD have been developed, tested, and approved as a System. Use of the TLC-II is authorized only in conjunction with related equipment described in this document and in the *Thoratec Ventricular Assist Device Directions for Use*, document number 15003.

TAMPER EVIDENT SEAL. Do not open the back panel of the TLC-II Driver. If the driver needs service, contact Thoratec Customer Service.

INVESTIGATE THE CAUSE OF ALARMS. Turning off or clearing an audible alarm has no effect on the condition causing the alarm. Investigate and correct the cause of any alarm.

USE OF BACK-UP DRIVER. A TLC-II Driver or Dual Drive Console must be available as a back-up to be used in the event of a failure of the primary driver.

CELLULAR PHONES. Do not use satellite phones, cell phones with power outputs greater than 1 watt, or other radio transmitters (walkie-talkies) within 12 feet (3.6 meters) of the TLC-II Driver. Such devices may interfere with the driver operation.

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

MAINTENANCE OF ELECTRICAL SAFETY. The TLC-II System is designed to meet AAMI/NFPA electrical safety requirements. Avoid potentially dangerous electrical shock hazard by always connecting the power cord to an approved, 3-wire AC power receptacle. Never attempt to remove or defeat the electrical ground or EMI shielding. The following table lists locations and sizes of the fuses and circuit breakers used in the TLC-II Driver.

Fuse or Circuit Breaker Location	**Thoratec TLC-II Driver**		
	Size	**Fuse Type**	**Location**
AC Adapter	3½ Amps, 2 Pole	5 x 20 mm IEC 127 Time Lag	Internal (on PC board)
Docking Station	5 Amps for 120VAC 2.5 Amps for 230VAC	5 x 20 mm IEC 127 Time Lag	At power entry module
Battery Charger	4 Amps	5 x 20 mm IEC 127 Time Lag	At power entry module

If any of these safety features are activated for any reason, determine the cause of the problem before resetting the breaker or replacing the fuse.

REDUCTION OF EXPLOSION HAZARD. Do NOT operate the TLC-II in the presence of flammable anesthetics or other flammable gases.

MAINTENANCE OF PATIENT SAFETY. Verify that all VAD pneumatic and electrical connections are in place, secure, and connected to the driver in use before attempting to operate the system.

ENVIRONMENT. Keep the TLC-II dry. Protect from shower, baths, rain, and liquid spillage. Do NOT operate the TLC-II driver below an ambient pressure of 525 mmHg (700 mBar) or above an altitude of 10,000 feet in an unpressurized cabin.

PATIENT AMBULATION CHECKLIST. Before undertaking any excursions away from the primary care area, ensure that:

- The system operation checklist has been followed
- The patient and/or caregiver are trained in emergency procedures
- Optimal settings have been selected using the system computer
- There are no alarms in operation
- Both batteries on the TLC-II are fully charged
- Additional fully charged spare batteries are available
- A functional TLC-II AC adapter is available
- Two emergency hand pumps are available.

REMOVE KEY DURING OPERATION. The key should be removed from the keyswitch when the TLC-II is in operation and placed in the pocket of the carrying case. It cannot be removed when the unit is switched off.

TLC-II DRIVER STORAGE. The TLC-II Driver should always be connected to an active AC outlet at anytime when the patient is not ambulating in order to conserve battery power. Batteries need to be recharged in the Battery Charger which is a separate component from the TLC-II Driver.

TLC-II DRIVER CLEANING. Exercise extreme care in cleaning the TLC-II Driver. DO NOT soak any item during cleaning or dis-infection. DO NOT allow water or solvent to come in direct contact with electrical connectors. See Section 5 for more information.

BATTERIES

1. Store batteries in a cool, dry place—in particular, avoid storing batteries at high temperature.
2. Batteries should not be left in vehicles, direct sunlight, or other places where the temperature may rise above 60°C (140°F).
3. Store and discharge batteries only within the specified range: -20° to 60°C (-4° to 140°F).
4. Charge batteries within the specified temperature range: 10° to 35°C (50° to 95°F).
5. Do not let batteries get wet.
6. Do not drop batteries or subject them to shock.
7. Batteries should not be disassembled or modified.
8. Do not allow necklaces, chains, or other metallic items to come into contact

with the terminals.

9. Never use TLC-II batteries as a power supply for anything other than the TLC-II driver.
10. Never charge a TLC-II battery using anything other than the TLC-II charger.
11. Do not leave batteries in charger for longer than 14 days. Remove batteries from driver for storage.
12. Do not incinerate batteries. Explosion or rupture of battery may occur.
13. Do not discard batteries. Return batteries to Thoratec for disposal. Used batteries are hazardous waste.

1.5 CONTRAINDICATIONS

Never attempt to use the TLC-II as an intra-aortic balloon pump or for any use other than that specifically indicated in the operating instructions.

Do not use on VAD or IVAD patients requiring >160 mmHg drive pressure and >350 msec of ejection time for complete RVAD ejection when using the Dual Drive Console.

1.6 TLC-II SYSTEM SPECIFICATIONS

1.6.1 Safety Standards

The TLC-II Portable VAD Driver, as part of the Thoratec VAD and IVAD System, has been thoroughly tested and classified by Underwriters Laboratories (UL) to fire, casualty, and electric shock hazard requirements of UL 2601-1. In addition, both devices meets the following European EN safety standards: EN 60601-1: 1987, Amendment 1:1993, and Amendment 2:1995. These standards require making the following declarations and stating the type and degree of protection for listed hazards. See the following pages for more specific safety and testing classification information.

1.6.1.1 Declaration Concerning General Safety Standards

Type	Degree of Protection
Mode of Operation	Continuous
Method of Sterilization	100% EtO for blood pump and all sterile accessories
Type of protection against electrical shock	Class I (grounded) and internally powered
Degree of protection against electric shock	Type CF (Cardio Floating)
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Degree of protection against harmful ingress of water	Docking Station with External AC Adapter and Battery configurations: IPX1

Medical Electrical Equipment with respect to shock, fire, mechanical and other specified hazards only in accordance with UL 2601-1 and CAN/CSA C22.2 No. 601-1 7D72

1.6.1.2 Declaration and Guidance Concerning Electromagnetic Emissions

The TLC-II and VAD/IVAD System are intended for use in the electromagnetic environment specified below. The customer or the user of either device should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11 EN 55011	Group 1	The TLC-II and VAD/IVAD System use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The TLC-II and VAD/IVAD System are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
Radiated emissions, magnetic field MILSTD-461E	RE101	The TLC-II and VAD/IVAD System generate magnetic fields due to the presences of RF energy created by its internal function. Therefore, its magnetic field emissions are very low and are not likely to cause any interference in nearby electronic equipment.

1.6.1.3 Declaration and Guidance Concerning Electromagnetic Immunitry for all Thoratec PVAD and IVAD Equipment

The TLC-II and VAD/IVAD System are intended for use in the electromagnetic environment specified below. The customer or the user of either device should assure that it is used in such an environment. See following table.

Declaration and Guidance Concerning Electromagnetic Immunity for all Thoratec PVAD and IVAD Equipment			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	min. ±6 kV contact min. ±8 kV air	TLC-II on a Docking Station [±6] kV contact [±8] kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic discharge (ESD) IEC 61000-4-2	min. ±6 kV contact min. ±8 kV air	TLC-II with AC power or battery power [±8] kV contact [±15] kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5% U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. The TLC-II contains 2 batteries (1 primary and 1 backup), which will provide uninterruptible power for a minumum of 55 minutes for BiVAD and 80 minutes for uni-VAD support. **Note:** U_T is the AC mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If disturbance occurs, it may be necessary to position the device further from sources of power frquency magnetic fields or install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

1.6.1.4 Declaration and Guidance Concerning Electromagnetic Immunity for Life-Sustaining Thoratec PVAD and IVAD Equipment, including VAD, Driver, and Batteries

The TLC-II and VAD/IVAD System are intended for use in the electromagnetic environment specified below. The customer or the user of either device should assure that they are used in such an electromagnetic environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Thoratec PVAD or IVAD systems than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended Separation Distances			
Conducted RF IEC 61000-4-6	Min. 3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	[3] Vrms	$d = \left[\frac{3.5}{3}\right] / P$
	Min. 10 Vrms 150 kHz to 80 MHz in ISM bands[a]	[10] Vrms	$d = \left[\frac{12}{10}\right] / P$
Radiated RF IEC 61000-4-3			$d = \left[\frac{12}{10}\right] / P$ 80 MHz to 800 MHz
	Min. 10 V/m 80 MHz to 2.5 GHz	[10] V/m	$d = \left[\frac{23}{10}\right] / P$ 800 MHz to 2.5 GHz
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.
			Interference may occur in the vicinity of equipment that is marked with the IEC symbol for non-ionizing radiation.
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.95 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.77 MHz.

b Compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into the patient areas. For this reason, an additional factor of (*min. 10/3*) is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TLC-II is used exceeds the applicable RF compliance level above, TLC-II should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device

The TLC-II and VAD/IVAD System have been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2001 Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. These devices generate, use and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase separation between equipment.
- Connect equipment into an outlet on a circuit different from that to which the other device(s) is/are attached.
- Consult Thoratec Corporation for assistance.

Note: Special precautions are required for installing and using the TLC-II and VAD/IVAD System within portable and RF communication environments.

WARNING: Use of equipment and supplies other than those specified in this manual or sold by Thoratec for replacement parts may result in increased emission or decreased immunity of the Thoratec TLC-II and VAD/IVAD System.

WARNING: The TLC-II and the Thoratec PVAD and IVAD should not be used adjacent to other equipment or in a stacked configuration with other equipment. The normal operation of the devices must be verified when used in these configurations.

1.6.2 Dimensions (without carrying case)

Width: 34.1 cm (13.5 inches)
Height: 34.0 cm (13.5 inches)
Depth: 13.5 cm (5.3 inches)
Weight: 7.5 kg (16.5 lbs) without removable batteries or carrying case
9.8 kg (21.6 lbs) with two removable batteries and carrying case)

1.6.3 Environmental Conditions

Operating Temperature (Driver, AC Adapter, Mobile Computer Docking Station):	10° to 40°C (50° to 104°F)
Operating Temperature (Charger, Car Power Adapter):	10° to 35°C (50° to 95°F)
Transportation/Storage Temperature:	-20° to 60°C (-4° to 140°F)
Operating Pressure:	700 to 1060 mBar (525 to 795 mmHg) 10,000 ft. above sea level to 1250 ft. below sea level
Transportation/Storage Pressure:	500 to 1060 mBar (375 to 795 mmHg)
Operating Humidity:	30% to 75%
Transportation/Storage Humidity:	10% to 100% (non-condensing)
Transportation/Storage Humidity (Mobile Computer):	8% to 80% (non-condensing)
Vibration:	0.75 G peak, 5 Hz to 500 Hz (three orthogonal axes, sweep at 1 octave/min 5 min dwell at four major resonances)

1.6.4 System Power Requirements

Removable Batteries (2):	Rechargeable lithium-ion batteries, which each provide at least 55 minutes (BiVAD support) to 80 minutes (LVAD or RVAD support) of power when fully charged. 20.8V
Emergency Battery (1):	Same as removable battery; rechargeable lithium-ion cells, providing up to 45 minutes of support when fully charged. 20.8V
AC Adapter:	Input voltage 90 VAC to 240VAC, 50-60 Hz Output voltage 15 VDC

Docking Station:	Input voltage 100 to 240 VAC, 50-60 Hz. Voltage is key selectable to 100, 120, 220 and 240 VAC. Output voltages Computer power output 12 & 5VDC Two power outputs for drivers 15 VDC each Battery charger power 120 VAC, 50-60 Hz
Mobile Computer and Accessories:	Input voltage: 16 VDC, 3.36 A
Car Power Adapter:	Input Voltage: 12 to 16 VDC, 8 A(max) Output Voltage: 16 VDC, center pin positive 4.5 A max

1.6.5 Output Range

VAD Rate:	30 to 110 bpm
Ejection Time:	230 to 370 msec
Peak Drive Pressure:	200 to 250 mmHg (LVAD) 120 to 170 mmHg (RVAD)
Vacuum:	0 to -50 mmHg

1.6.6 Battery Charger

Operates over a voltage range of 100 VAC to 240 VAC, 50 or 60 Hz. Charges two lithium-ion batteries simultaneously in approximately 2 hours. Battery Charger recommended for use in the Docking Station and for use by the patient who is ambulating either in-hospital or in a step-down facility/apartment with nursing care.

1.6.7 Input/Output Characteristics

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 and empty signals (IVAD only)
Computer	Green	Serial line interface for connection only to TLC-II HeartTouch system computer on Docking Station or Mobile Computer.
External Power	Yellow	For connecting TLC-II to external power, such as AC Adapter, Car Power Adapter, or Docking Station.

1.6.8 Classification of Docking Station

- Class 1 Equipment
- Type CF Equipment
- Drip-Proof Equipment (IPX 1)
- Internally-Powered Equipment when powered by battery
- The TLC-II is intended for CONTINUOUS OPERATION

1.7 LIST OF SYMBOLS

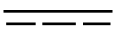
Off (power: disconnect from the mains)

On (power: connect to the mains)

Alternating Current

Type CF Equipment

Attention, consult ACCOMPANYING MANUAL



External Power (Direct Current)

Protective Earth (ground)

2. DESCRIPTION

This chapter describes all of the features of the TLC-II System. Read this chapter first, and then follow the instructions in Chapter 4 for proper set-up and operation of the system.

The Thoratec TLC-II Portable VAD System (TLC-II System) consists of three major components:

- TLC-II Portable Driver and Batteries
- TLC-II Mobility Cart
- TLC-II Docking Station, containing:
  - Battery Charger
  - HeartTouch System Computer with Touchscreen

2.1 TLC-II Portable VAD Driver

The Thoratec TLC-II portable VAD Driver is a lightweight, portable, pneumatic VAD driver, powered by batteries or from external power. It is designed to provide

portable pneumatic drive power for ambulatory patients supported with the Thoratec Ventricular Assist Device.

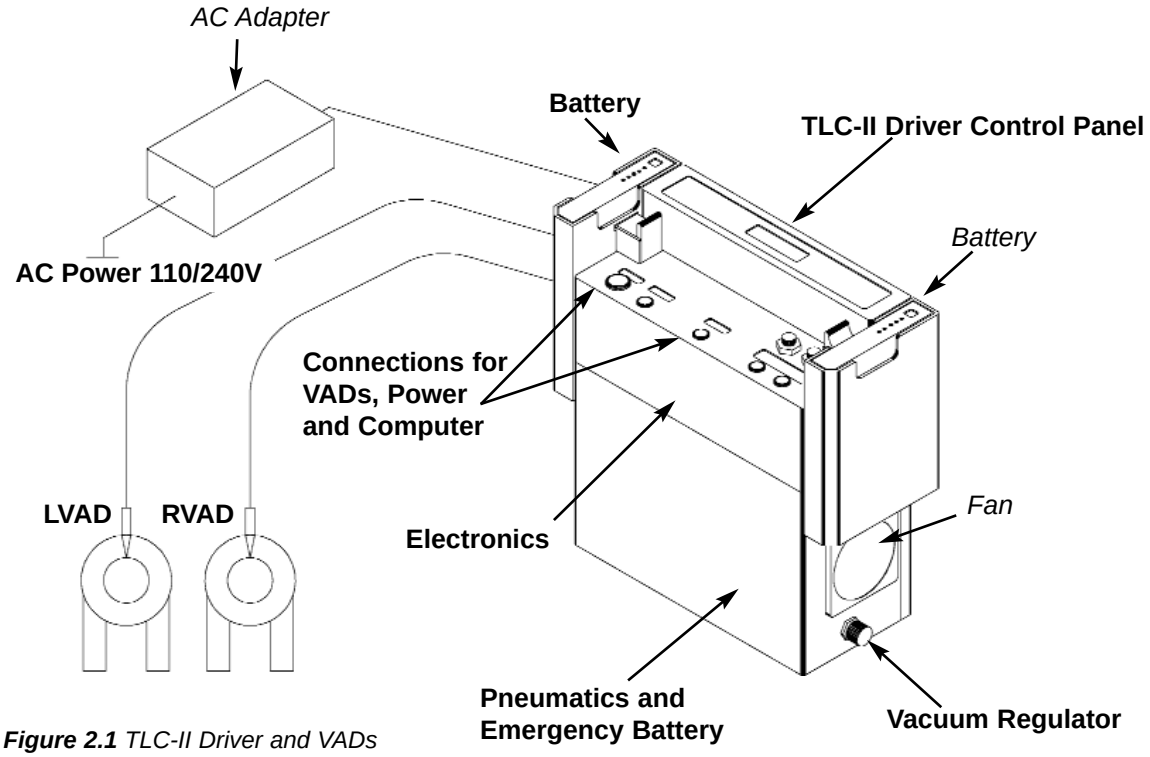


Figure 2.1 *TLC-II Driver and VADs*

The Thoratec TLC-II Portable Driver (**Figure 2.1**) consists of a pneumatics assembly, an electronics assembly, 2 removable rechargeable lithium-ion batteries and 1 additional rechargeable battery for emergency use, all of which are contained in a vented, nylon carrying case. Each rechargeable battery will provide at least 55 (BiVAD) to 80 (LVAD or RVAD) minutes of power to the TLC-II. The TLC-II Driver discharges 1 battery at a time before automatically switching to the other battery. To reduce driver weight, the battery charger is a separate component, located on the docking station.

2.1.1 Pneumatics

The **pneumatics assembly** consists of a mini air compressor which provides both positive and negative air pressures for both the LVAD and RVAD, solenoid valves for switching between VAD ejection and filling phases, and a vacuum regulator for setting the level of negative pressure used during VAD filling.

During VAD ejection, the TLC-II Driver supplies air pressure to compress the blood pumping sac and drives the blood into the arterial system. Air is supplied in cycles, with each ejection period alternating with a filling period. During the filling period, the driver supplies a slight negative pressure (vacuum) to the air chamber of the VAD. The air pressure for

the LVAD is controlled to an average supply pressure adjustable from 200 to 280 mmHg, and is stepped down with a regulator to 180 mmHg for supply pressure to the RVAD.

Pressure sensors are located on each VAD driveline which monitor both positive and negative pressures during the cycle. The actual drive pressure for each VAD side will vary depending on patient conditions. An adjustable vacuum regulator, located in the lower part of the driver below the fan grill, can be accessed through a small opening in the carrying case. This is a three turn knob providing adjustment of negative pressure available for assisting both LVAD and RVAD filling over the approximate range of 0 (fully counterclockwise) to -50 mmHg (fully clockwise). The actual amount of vacuum varies depending on whether one or two VADs are in use, on the inflow cannula used, and on patient conditions.

2.1.2 Electronics

The electronics assembly contains all electronic controls of TLC-II functions, including LVAD and RVAD control, battery and external power switching and control, and communication with the external HeartTouch computer on the docking station. There is also an independent emergency backup system consisting of a redundant motor drive, solenoid drive electronics, and audible alarm. These are powered by an independent lithium-ion battery located in the lower half of the driver. The TLC-II has internal non-volatile memory that stores all programmed control parameters and event log information at routine time intervals.

2.1.3 Interfaces

At the top of the TLC-II driver are the system interfaces, the control panel, and the two rechargeable batteries (**Figure 2.2**). Above the control panel are the color-coded pneumatic and electrical lead connections providing interfaces with the VADs, external power, and the external HeartTouch computer. The LVAD pneumatic and electrical full switch leads are color-coded red (representing the systemic circulation) and the RVAD connections are color coded blue (representing the pulmonary circulation). When univentricular support is desired, always cap off the unused port with the supplied occluder.

WARNING: Do not remove the occluder from the unused pneumatic port during univentricular support. This will depressurize the VAD in use.

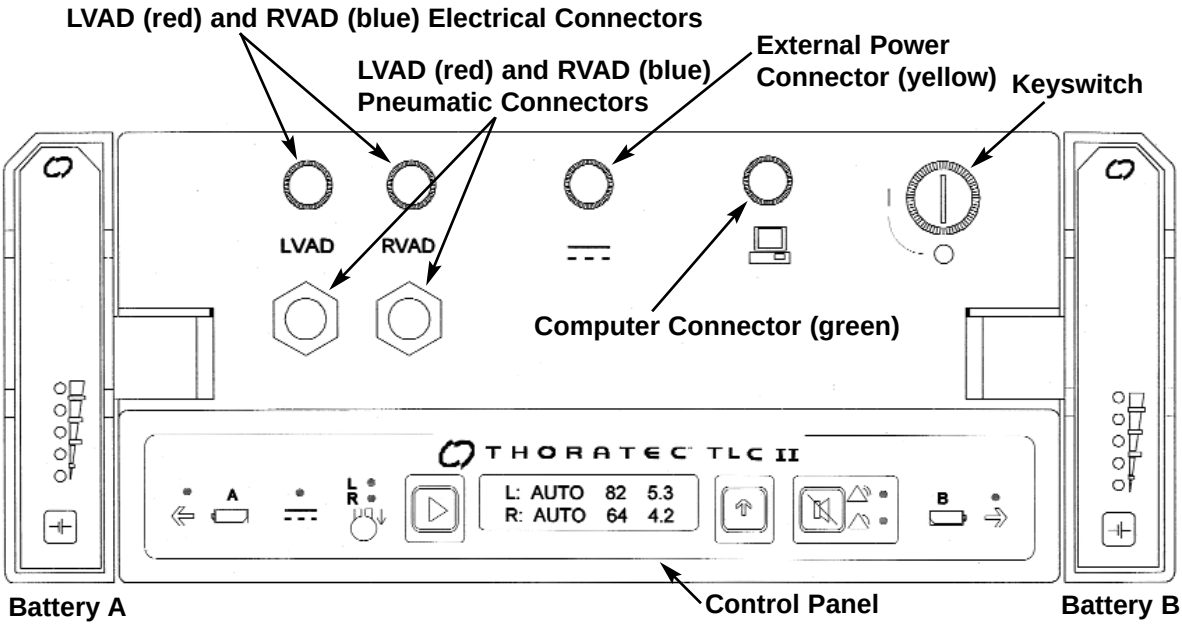


Figure 2.2 *TLC-II Driver Top Interface and Control Panel*

The **EXTERNAL POWER** connector (color coded yellow) is for external 15 VDC power provided from external power sources:

1 The TLC-II Portable AC Adapter
2 The power connector on the TLC-II Docking Station.
3 The Car Power Adapter

The **COMPUTER** connector is color coded green and provides interface with either the external HeartTouch computer located on the TLC-II Docking Station or Mobile Computer. Making this connection automatically establishes communication with the HeartTouch computer.

WARNING: Only connect the TLC-II Driver's Computer Interface to the HeartTouch computer or Mobile Computer. Do not attempt to connect this output to any other computer.

2.1.4 Control Panel

On the top of the TLC-II Driver (**Figure 2.3**) is the **control panel** (a) in **Figure 2.3**, which provides information about TLC-II function. On the sides of the control panel are 2 yellow **change battery** lights (b), 1 for battery A (on the left side) and battery B (on the right side), each of which illuminates when the rechargeable battery needs to be replaced with a fully charged battery. The green **EXT POWER** light (c) illuminates when the TLC-II is receiving external power. Two (2) green **FULL** lights (d) are provided to indicate when the LVAD (**L**) and RVAD (**R**) are completely full of blood, as detected by the full switch sensor in the VAD

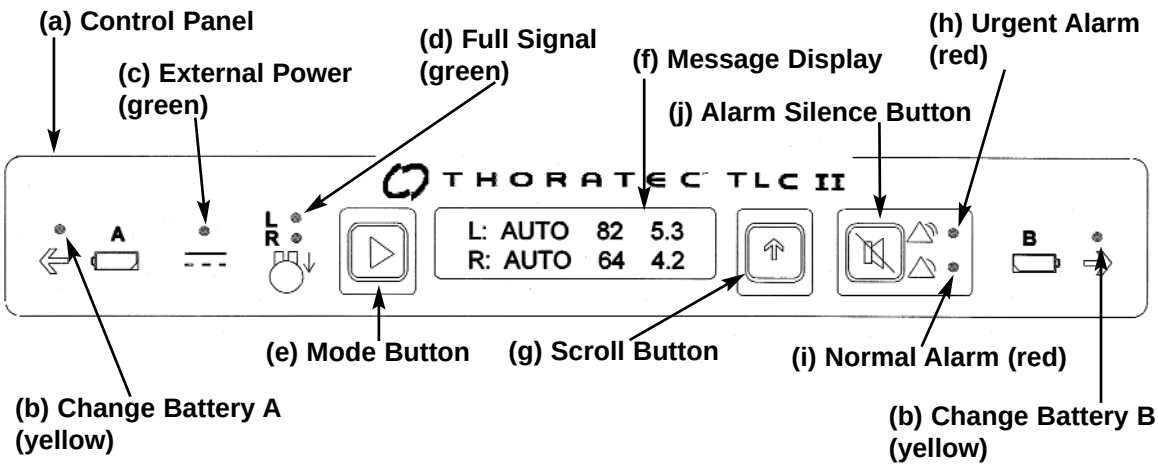


Figure 2.3 *TLC-II Driver Control Panel*

blood pumps. The **MODE** button (e) if activated, toggles between two user-selected timing modes for the VADs: either fixed rate pumping (**FIXD**) at a preset fixed rate, or automatic rate pumping (**AUTO**) as triggered by the VAD full switch. Pressing this button once toggles between the two timing modes. The current mode selected is indicated on the message display. Auto mode requires the presence of regular full signals from the VAD. Note that this switch can be overridden or de-activated by settings on the TLC-II HeartTouch computer, described later.

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

All alarms are audible and indicated by either of 2 red alarm lights:

The **URGENT ALARM** (h) light is lit and a continuous audible alarm sounds when the system is operating from the emergency backup electronics. This alarm cannot be silenced. The emergency backup system is a completely independent electronic module, consisting of compressor motor control, solenoid control, and an independent audible alarm, all powered by an independent emergency battery. When first turning on power to the TLC-II, the emergency backup system and the audible and visual **URGENT ALARM** lights come on for approximately 3 seconds, before the main electronics take over.

WARNING: If the URGENT ALARM stays on, change over to a backup TLC-II Driver or a Thoratec Dual Drive Console as soon as possible.

The red **NORMAL ALARM** (i) indicator light and audible alarm turn on when other alarm conditions occur which do not involve the emergency backup system. The type of alarm and action required is displayed in the message display. The audible alarm can be silenced for 30 seconds by pressing the **ALARM SILENCE** button (j); however the red **ALARM** light (i) will remain lit. The audible full alarm can be silenced indefinitely (see Section 4.1.2.6).

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

Initialize: Simultaneously holding down the **MODE** (e), **SCROLL** (g) and **SILENCE** (j) keys for 5 seconds will initialize settings in the TLC-II to the following default values:

BiVAD mode	
Accumulator Pressure	250 mmHg
Fixed rate of pumping	LVAD: 80 beats per minute RVAD: 70 beats per minute
Eject time	300 msec (both RVAD and LVAD)
Low rate	50 bpm (both RVAD and LVAD)
Patient name and ID are blank	[blank]

2.1.5 Power

The TLC-II is designed to operate with at least 2 power sources: either two batteries, or one battery and external power. It will operate with one power source, but after the number of power sources is reduced to one, a warning sounds every 30 seconds until a second power source is connected. A continuous alarm sounds when approximately 10 minutes of battery time remain, indicating that the batteries need to be replaced.

If all power sources are removed, the system operation will switch to the emergency backup system, and the emergency alarm sounds. This circuit is powered by an independent battery. If this battery is depleted it must be replaced with a fully charged battery. Emergency battery status is monitored by the main TLC-II system, and an alarm occurs when the emergency battery must be replaced.

The power sources (AC adapter and batteries) should be periodically checked for functionality.

2.1.5.1 **Rechargeable Batteries** (Part No. 101568 or 20010-2815-000)

On each side of the TLC-II are slots for 2 TLC-II lithium-ion rechargeable batteries (**Figure 2.4**). The battery on the left side is referred to as **Battery A,** and the battery on the right side is referred to as **Battery B**. Each battery provides at least 55 minutes (BiVAD support) to 80 minutes (LVAD or RVAD support), of battery power to the TLC-II.

The actual time depends on other conditions of use, including the VAD beat rate and the state of the battery.
When the TLC-II is operating on two batteries, it uses one until it is depleted and then automatically switches to the other. The **change battery** light (b in **Figure 2.3**) next to the depleted battery lights up and a warning will sound every 30 seconds until the used battery is replaced or until an external power source is connected. A message is displayed on

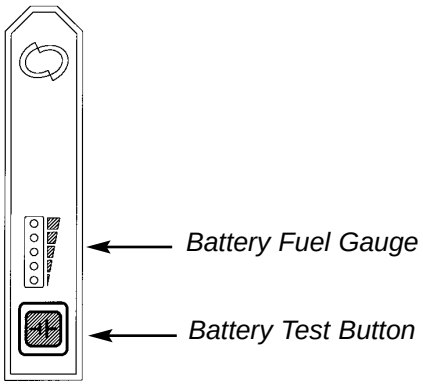


Figure 2.4 *TLC-II Battery*

the control panel indicating which battery to replace.
Pressing the **battery test** button on the front panel of the battery will illuminate up to 5 lights, representing approximate capacity remaining. Five (5) lights indicates a fully charged battery, with each light representing roughly 20% capacity.

2.1.5.2 **AC Adapter** (Part No. 20010-2815-001)

The TLC-II **AC Adapter** can be connected to the TLC-II driver and to an electrical outlet to preserve battery life. External power is preferentially used by the TLC-II when it is available. The power adapter provides 15 VDC input to

the TLC-II and operates over a wide range of input voltages (90-240 VAC, 50-60 Hz). This power adapter has two cables. The yellow end plugs into the **external power** (**Figure 2.5**) connector on the TLC-II and the AC power end plugs into an electrical outlet.

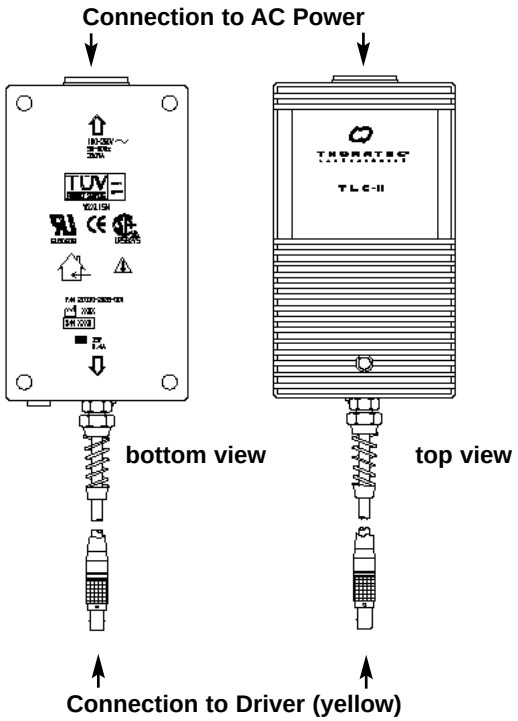


Figure 2.5 *TLC-II AC Adapter*

2.1.5.3 Emergency Battery

An independent rechargeable lithium-ion battery, identical to those used to power the main system, is used as the emergency back-up battery providing power to the emergency backup system. If fully charged, this battery should run the emergency backup system for up to 45 minutes of continuous use, but since it is not anticipated that the emergency system is needed for continuous operation, this battery should last several months before requiring replacement with a fully charged battery. When approximately 10 minutes of battery power remain, an alarm will sound indicating that the battery needs to be replaced with a fully charged battery. This battery is located in the bottom left corner of the TLC-II, accessed after removing the TLC-II from its carrying case (**Figure 2.6**). See Chapter 5 for instructions on replacing this battery.

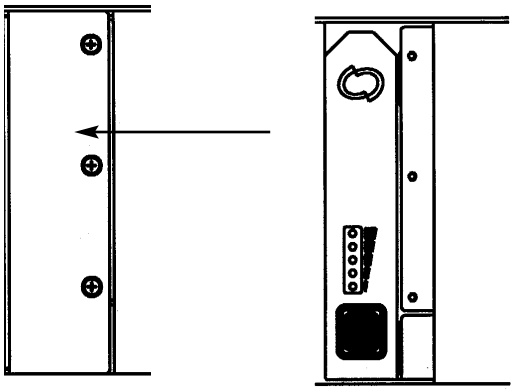


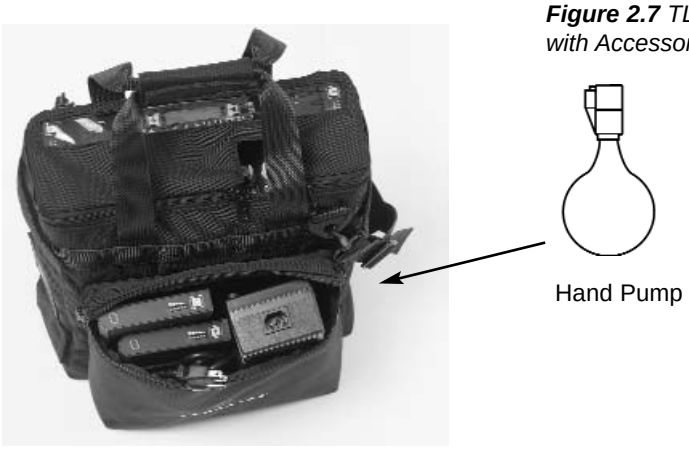
Figure 2.6 *TLC-II Driver Emergency Battery Access*

2.1.6 Carrying Case

The TLC-II is designed to be used at all times in its black nylon carrying case, which allows the TLC-II driver to be carried either by hand, with the shoulder strap, or by placing it on the mobility cart. The carrying case provides an accessory pocket large enough for one TLC-II External Power Adapter, two spare batteries, and two emergency hand pumps (**Figure 2.7**).

WARNING: Always carry two emergency hand pumps in the pocket.

Figure 2.7 *TLC-II Driver in Carrying Case with Accessory Pocket*



2.2 Docking Station

When the TLC-II Driver is not in ambulatory use, the TLC-II Docking Station (**Figure 2.8**) provides a convenient central station for the TLC-II and accessories. It contains the TLC-II HeartTouch computer, a battery charger, room to hold two TLC-II Drivers, and an accessory drawer.

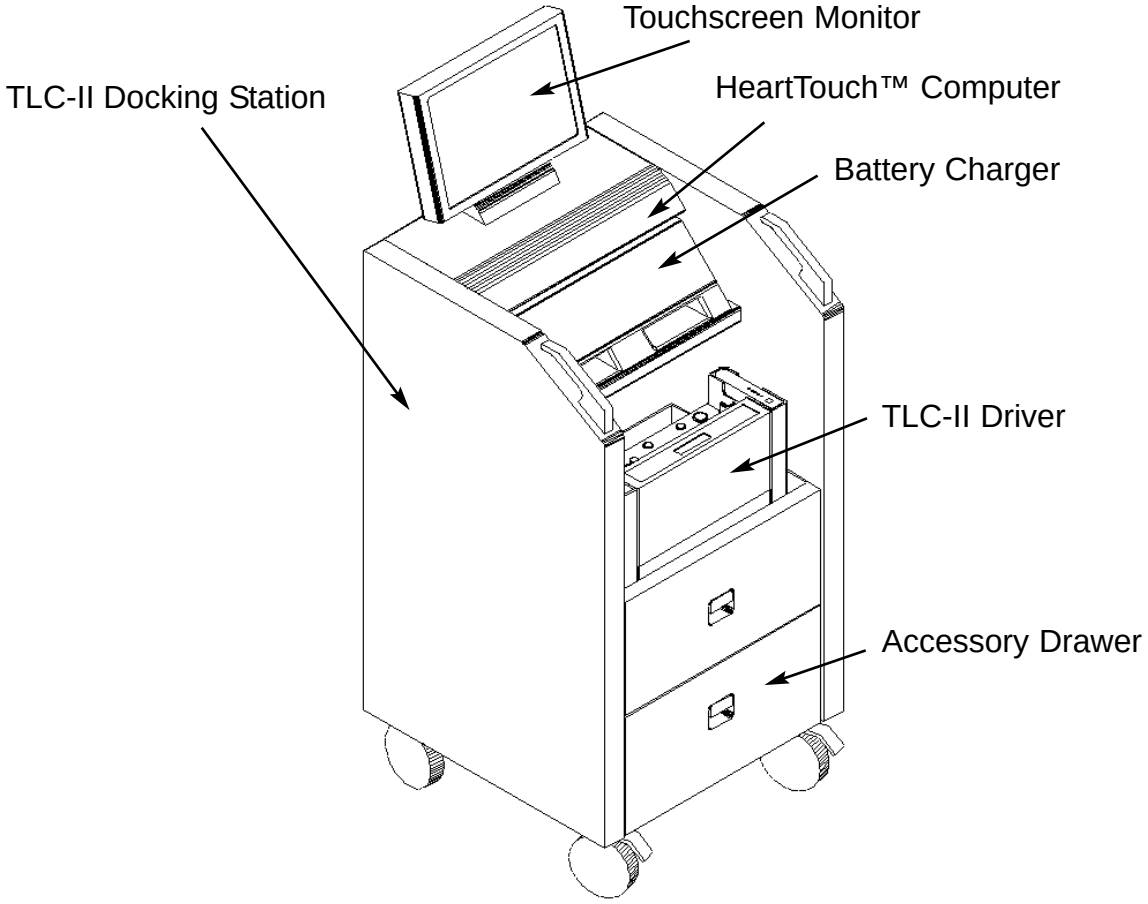


Figure 2.8 *TLC-II Docking Station*

2.2.1 Docking Station Interfaces and Power

Power to the docking station is obtained by connecting AC power (selectable from 100 to 240 VAC, 50 or 60 Hz) to the plug on the lower back door of the unit (**Figure 2.9**). This receptacle also contains the main on-off power switch for the docking station. AC power is connected through an isolation transformer to the battery charger and up to three internal DC power supplies: one 15 VDC power supply for each of the TLC-II drivers, and a separate power supply for the HeartTouch computer.

The top drawer of the docking station contains two bays for holding 2 TLC-II drivers in their carrying cases. The front bay is for the driver in use, and the back bay provides room for a backup driver. On the side of the drawer (**Figure 2.10**) are 2 external power connections, color coded yellow, one for each of the TLC-II drivers, and one computer connection (color coded green). Connect the yellow power lead from the TLC-II external power connector to the yellow connector on the drawer. Connect the green computer cable from the TLC-II computer connector to the green connector on the drawer.

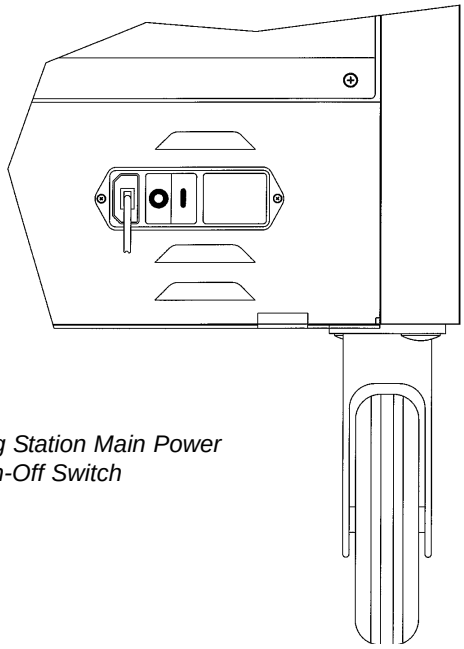


Figure 2.9 *Docking Station Main Power Receptacle and On-Off Switch (lower rear panel)*

2.2.1.2 Shutting Off the Docking Station

1. Select and highlight “exit” located in lower right corner of screen.
2. When the shut off symbol appears, select yes to confirm that you want to shut off Docking Station computer.
3. Turn off the power by pressing the power switch located on top rear of Docking Station.
4. Unplug Docking Station. **Note**: To avoid potential hard disk failure, do not unplug the Docking Station until *after* completing steps 1 - 3 above.

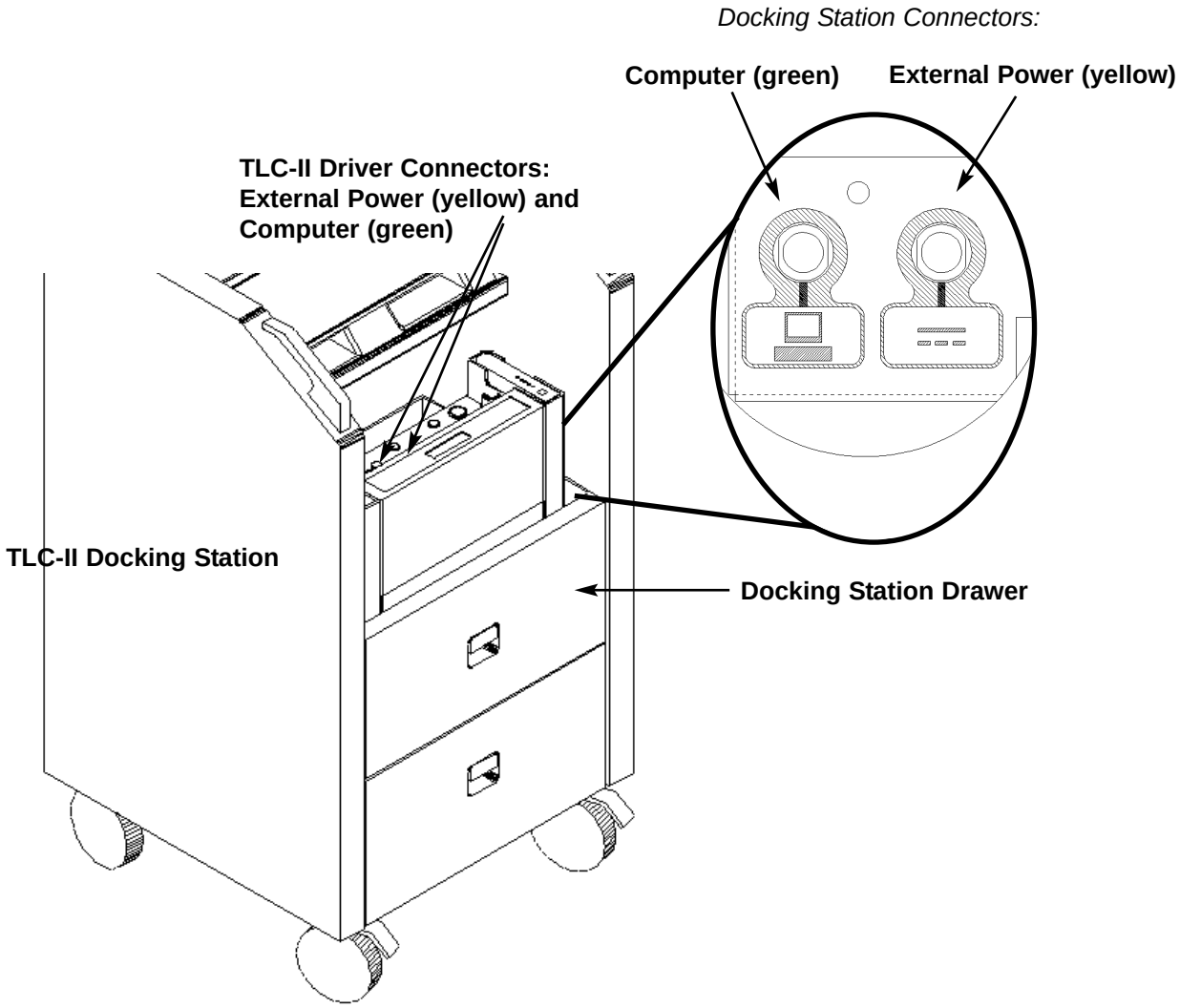


Figure 2.10 *Connection between Docking Station and TLC-II Driver.*

2.3 Battery Charger

The TLC-II battery charger (**Figure 2.11**) is connected to the docking station power through a plug in the back, automatically adjusting to 100 to 240 VAC, 50 or 60 Hz. When used in the docking station, the battery charger power switch is always left in the on position, since all power in the Docking Station is controlled by the main docking station on-off switch. The battery charger can also be used as a stand-alone device.

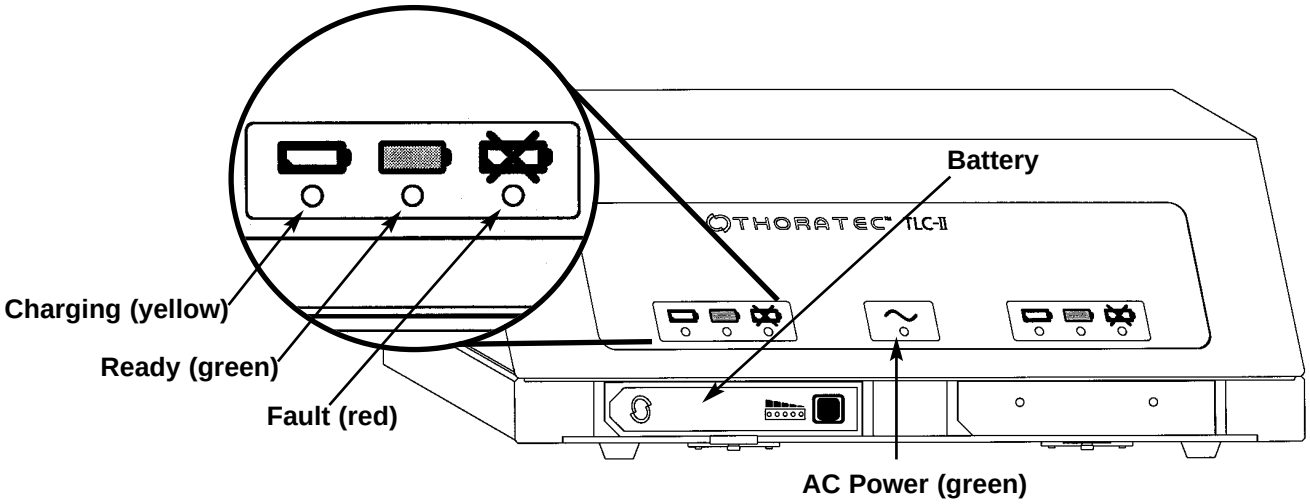


Figure 2.11 *TLC-II System Battery Charger*

The TLC-II battery charger can fully recharge one or two TLC-II batteries in approximately 2 hours. There are 3 status indicator lights for each battery:

Charging: indicates that the battery is charging (yellow).

Ready: indicates that the battery is fully charged and is ready for use (green).

Fault: indicates that the charger is unable to charge the battery. This light will flash if the battery temperature is too high or too low. Wait until the battery is within the range of temperatures to allow charging (10° - 35° C, 50° - 95° F). If the light is steady, the battery should be inserted into a TLC-II Driver that is not on a patient to determine the battery voltage level. If the unloaded battery voltage, as shown on the technical screen on the HeartTourch computer, is above 20 V then the battery is acceptable for use. Otherwise, do not use the battery.

2.4 HEARTTOUCH™ COMPUTER

The TLC-II System 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 and for diagnostic purposes. Since the TLC-II driver has its own internal microcontroller that controls all TLC-II functions, once it is in ambulatory use in a stable patient, the TLC-II does not need to be connected to the HeartTouch computer.

2.4.1 Computer Interface

The computer and touchscreen are located on the top of the docking station (**Figure 2.8**). There is a power on-off switch on the back of the computer for power to the computer and touchscreen. The Docking Station must be connected to AC power and the docking station main power switch turned on for the computer to work.

The TLC-II connects to the computer by connecting the green color coded cable from the green connector on the TLC-II driver to the green connector on the Docking Station drawer. All user interface to the HeartTouch computer is accessed via a touchscreen.

The TLC-II Driver and the HeartTouch computer communicate through a special protocol that includes several levels of automatic hand shaking and error checking, as well as user confirmation of all parameter changes. The TLC-II Driver ignores any command that does not follow the correct sequence of commands in the protocol. Similarly, if the HeartTouch computer does not receive the correct error-checked information from the TLC-II, it displays a "NO RESPONSE FROM THE TLC-II" message.

2.4.2 Software

The HeartTouch computer contains six screens accessible by touching the indicated tab:

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

The first 3 screens and the technical screen only display information. No changes to control parameters can be made from these screens. The other 2 screens contain control buttons that can change information or settings stored in the TLC-II.

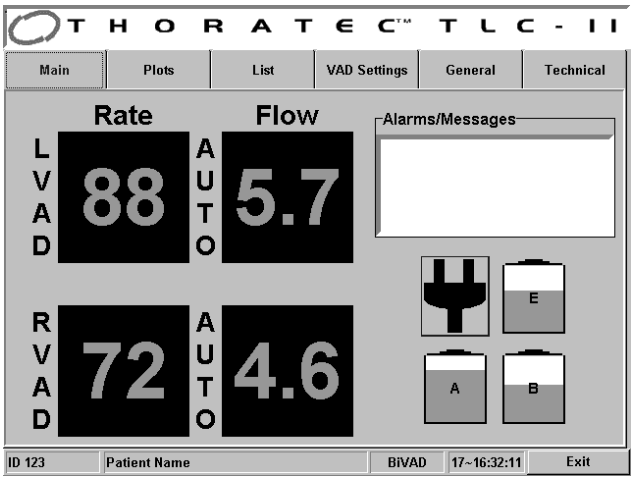


Figure 2.12 *HeartTouch Computer "Main Screen"*

2.4.2.1. Main Screen

The main screen (**Figure 2.12**) displays the most basic information in the TLC-II: VAD rate and flow for each VAD in use, status of all power sources, and alarm information. If no information is received from the TLC-II Driver, or if the TLC-II is not connected to the HeartTouch computer, then a message is displayed: NO RESPONSE FROM THE TLC-II.

Rate shows the current rate of the LVAD and/or the RVAD in beats per minute (bpm). **Flow** shows the current flow in liters per minute (L/min). If no full signal is received, then no flow information is displayed. These values are also displayed on the control panel of the TLC-II driver itself.

The timing mode is shown for each VAD, between the Rate and Flow displays: "AUTO" for the automatic rate mode, and "FIXD" for the fixed rate mode.

The Alarms/Messages presents current alarms from the TLC-II and action required. Multiple alarm messages toggle automatically. In the lower right quarter of the main screen the available power sources are presented schematically. **A, B** = battery A and battery B; **E** = emergency battery; and a power plug symbol = external power. The current power source being used is indicated by a blue box around the appropriate symbol. The estimated level of battery charge is indicated by a green bar graph indicator for each battery. Red indicates a battery that has low capacity or needs replacement. A more accurate indicator of battery status is provided on the battery itself by pressing the test button on the battery front panel.

A **status row** of information is displayed on the bottom row of the screen. This contains the patient identification number, patient name, VAD mode (LVAD, RVAD or BiVAD), and the current day and time, and an **EXIT** button.

The **EXIT** button should always be used before turning off power to the touchscreen computer. This will close down all system resources in a safe manner. When the confirmation arrow appears, it is safe to turn off the computer or docking station. **Note**: You must properly shut off the computer before unplugging the Docking Station to avoid potential hard drive failure. Follow the directions for shutting off the Docking Station computer found in section 2.2.1.2 to assure proper system shut down.

2.4.2.2 Plots Screen

When the plots screen (**Figure 2.13**) is selected, information from the main screen is reduced in size and is displayed in the bottom half of this screen. Real-time plots of pneumatic drive pressure waveforms from the LVAD and/or RVAD are added to the top window for the last 5 second period. The

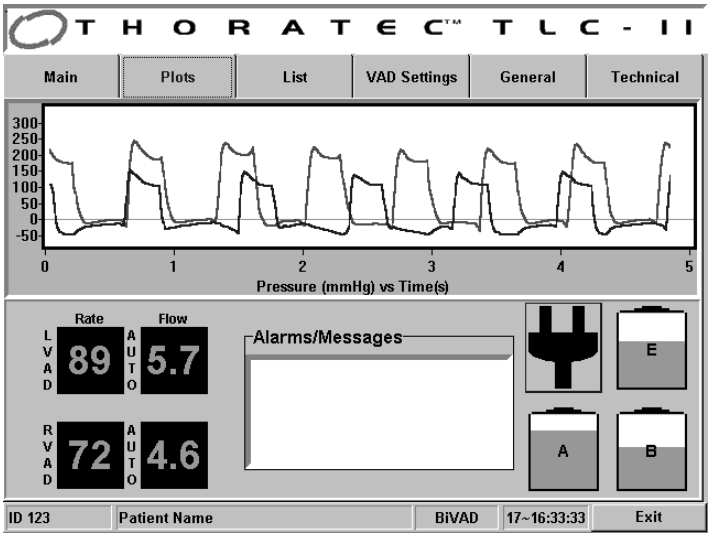


Figure 2.13 *HeartTouch Computer "Plot Screen"*

drive pressure for the LVAD is plotted in red, and the drive pressure for the RVAD is plotted in blue. Pressure is displayed in millimeters of mercury (mmHg) versus time in seconds. The trace can be frozen by touching the screen. The waveforms can be saved to disk by touching "Save Display"; plotting continues by touching "Resume". Plotting also resumes automatically after 10 seconds.

To store a waveform log file use the following procedure:

1. Access the plots screen
2. Touch the plot when desired waveforms are visible
3. Note the time and date for future reference when reviewing the stored data.
4. The plot will freeze and two buttons will appear in the upper corners of the plot. SAVE DISPLAY will initially be inactive and RESUME DISPLAY will be active.
5. Touch the SAVE DISPLAY button when it becomes active.
6. Three sets of waveforms, each five seconds in duration, will be saved, and a confirmation message will appear. The sets saved are the 3 five second periods before, during, and after the plot was touched.
7. If a patient name or ID has not been entered, an error message will appear and the data will not be saved.
8. Press RESUME DISPLAY to cancel the save function at any time.
9. The waveform files, when copied to disk (see Section 2.4.2.5.5), will contain tab delimited data with the following columns; date, time, sequence number, LVAD pressure, RVAD pressure, L full/empty signal, L solenoid signal, R full/empty signal, R solenoid signal, serial number, total usage hours, LVAD usage hours, RVAD usage hours, BiVAD usage hours and service interval.

2.4.2.3 List Screen

The list screen (**Figure 2.14**) displays lists of monitored information from the TLC-II in the top half of the screen. The

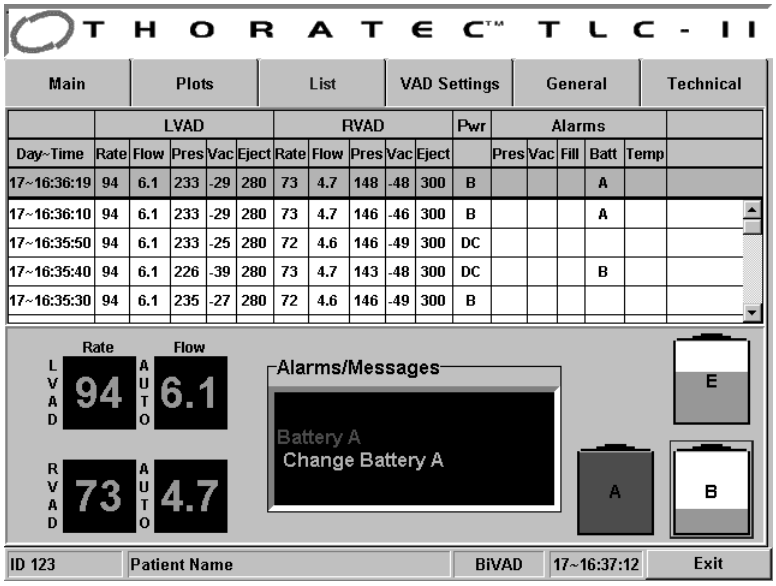


Figure 2.14 *HeartTouch Computer "List Screen"*

monitoring information from the main screen is displayed in the bottom half of the screen. The top shaded row of information shows the most current status of the TLC-II. The subsequent rows display previous event records. An event record is stored in the TLC-II during any alarm condition, during any change made to operating parameters, battery or power source, or at routine log intervals set in the General Settings screen. Up to 660 event records can be stored in the TLC-II. When the HeartTouch computer is connected to the TLC-II, event record information is transferred to the HeartTouch computer and stored on the hard disk.

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

Rate: average beat rate of the VAD in bpm
Flow: average VAD blood flow in L/min
Pres: average peak 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:

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: high or low compressor temperature

2.4.2.4 VAD Settings Screen

The VAD Settings screen (**Figure 2.15**) shows the current VAD operating settings and allows changes to be made to those settings. By touching the desired parameter, a dialog box is displayed, which allows changes to the current selection within certain allowed limits or choices.

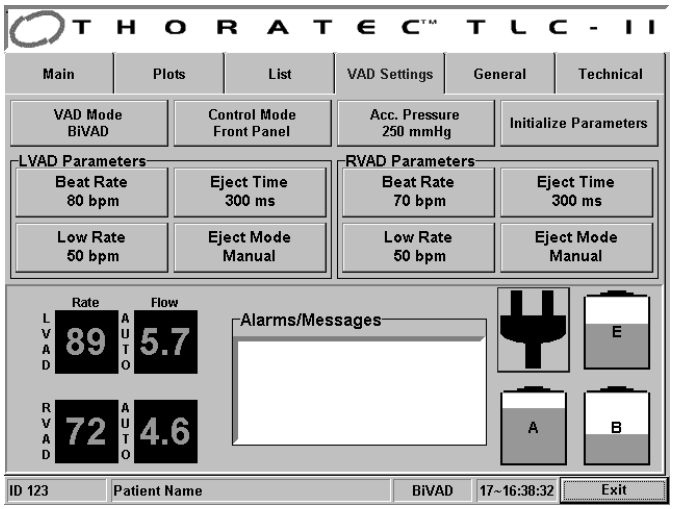


Figure 2.15 *HeartTouch Computer "VAD Settings Screen"*

All changes to driver settings undergo several layers of communication handshaking and error checking between the HeartTouch computer and the TLC-II. All changes also require user confirmation of the requested change. Once the change is made to a control parameter, it is stored in the TLC-II memory and is used. When the TLC-II is turned off, these most recent parameters are used the next time the TLC-II is turned on.

To make a change, touch the parameter and a dialog box will appear. Select the desired value and then confirm by touching **Change,** and confirming yes, or touch **Cancel.**

VAD Settings and allowed selections include the following:

2.4.2.4.1 VAD Mode

LVAD: only the LVAD operates
RVAD: only the RVAD operates
BiVAD: both LVAD and RVAD operate

2.4.2.4.2 Control Mode

Two control modes are used for timing (fixed rate and auto rate) and there are three options for selecting these modes from the external computer:

Front panel selectable (mode button on the front panel of the TLC-II driver toggles between the two timing modes: fixed or auto. This is the default selection option).

With the **front panel selectable** option the front panel mem-

brane **Mode button** (**Figure 2.3**) is used to choose fixed rate timing mode or auto rate timing mode. Upon pressing this button one short beep is emitted to verify the button was pressed. This switch is inactive unless "front panel selectable" is chosen from the external computer.

Fixed rate (front panel disabled). When this option is chosen from the external computer, the front panel mode switch is disabled.

Auto rate (front panel disabled). When this option is chosen from the external computer, the front panel mode switch is disabled and the system will always attempt to use the auto rate mode whenever full signals are present.

Description of Timing Modes

Fixed rate
In this timing mode, the LVAD and/or RVAD operate at a specified VAD fixed rate setting. This mode is also used if no fill signal is received in the auto mode. If the Fixed Rate mode is selected for a patient with biventricular support, then both LVAD and RVAD operate in fixed rate mode. The allowed range for the fixed rate mode is 30 to 100 bpm.

Auto rate
In the auto rate timing mode, the LVAD and/or RVAD rate are variable and respond to preload. That is, they respond to the blood flow filling rate from the body into the VAD blood pump. The Auto mode requires full signals from the VAD to the TLC-II. Filling of the blood sac during a cycle is terminated by the VAD full signal and ejection begins immediately. Therefore, when the VAD fills faster, the VAD rate and, thus, the flow output increase in response to increased preload. If preload decreases, the VAD takes longer to fill, and the VAD rate and output decrease. The valid range for the auto rate mode is between the **low rate** set value and 110 bpm. If no full signal is detected, the TLC-II pumping rate slows down to the **low rate** value in an attempt to locate a full signal and reestablish the auto mode. If no full signals are present, the TLC-II reverts to the FIXED rate value, turns on the alarm lamp and sounds an alarm, and displays “No L Full Signal” or “No R Full Signal” in the message display.

If the Auto Mode is selected for a patient with biventricular support, the system will run both VADs in the auto mode, assuming full signals are present for both VADs. Without full signals, both VADs will run in Fixed Rate. If the LVAD loses its full signal, then both VADs revert to Fixed Rate Mode. If

the RVAD loses its full signal, the RVAD reverts to Fixed Rate, with the LVAD still in Auto Mode.

The actual LVAD and RVAD mode (**"FIXD"** or **"AUTO"**) are presented on the top and bottom rows of the message display on the TLC-II.

2.4.2.4.3 Accumulator Pressure

Valid range:	200 to 280 mmHg
Default Settings:	
LVAD:	250 mmHg
RVAD:	220 mmHg
BiVAD:	250 mmHg

This sets the average supply pressure in the LVAD accumulator, which is automatically maintained by the TLC-II. The average supply pressure in the RVAD accumulator is stepped down to 180 mmHg with an internal regulator. The resulting drive pressures used to empty the LVAD and the RVAD are related to accumulator pressures but will vary depending on patient conditions. The peak LVAD and RVAD drive pressures are presented on the List screen (**Figure 2.14**).

2.4.2.4.4 Initialize Parameters

With this option all control parameters are returned to their default values. The default parameters are defined as:

VAD Mode:	BiVAD
Timing Mode:	Front Panel Selectable, Fixed Rate
LVAD Beat Rate:	80 bpm
RVAD Beat Rate:	70 bpm
LVAD Eject Time:	300 msec
RVAD Eject Time:	300 msec
LVAD Low Rate:	50 bpm
RVAD Low Rate:	50 bpm
Accumulator Pressure:	250 mmHg
Patient Name and ID:	blank

2.4.2.4.5 LVAD and RVAD Beat Rate

Valid range: 30 to 100 bpm
Default settings
- LVAD: 80 bpm
- RVAD: 70 bpm

This sets the rate at which the LVAD or RVAD operate when in the fixed rate timing mode. The default values are 80 bpm for the LVAD and 70 bpm for the RVAD. The allowed range is 30 to 100 bpm.

WARNING: Selection of beat rates less than 40 bpm is not recommended except for start-up or for weaning. Therefore, if a rate less than 40 bpm is selected, a warning is issued: "Warning: VAD beat rates below 40 bpm are not recommended."

2.4.2.4.6 Low Rate

Valid in auto rate mode only.
Valid range: 30 -100 bpm
Default settings:
LVAD: 50 bpm
RVAD: 50 bpm

This sets the lowest allowed VAD rate when in the auto rate mode. Thus the VADs are allowed to pump as low as the low rate while waiting for a full signal. If no full signal can be detected at this low rate, then the VAD reverts to the Fixed Beat Rate value.

2.4.2.4.7 Eject Time

Valid range: 230 - 370 msec
Default value: 300 msec for both LVAD and RVAD
This sets the time allowed for VAD ejection.

2.4.2.4.8 Eject Mode

Manual: Ejection time used is the selected eject time.
Automatic: For future use

2.4.2.5 General Settings Screen

Options available from this screen (**Figure 2.16**) are the following:

2.4.2.5.1 Change Patient Information

When this option is selected, an alpha-numeric keyboard is shown to allow entry of patient ID number, name, or initials if desired. This information is stored in the TLC-II along with the appropriate TLC-II settings for a given patient. The patient ID and patient name are also displayed on the bottom status bar of the HeartTouch computer Screen. The HeartTouch computer will not be able to store retrieved data if patient ID or name is not entered.

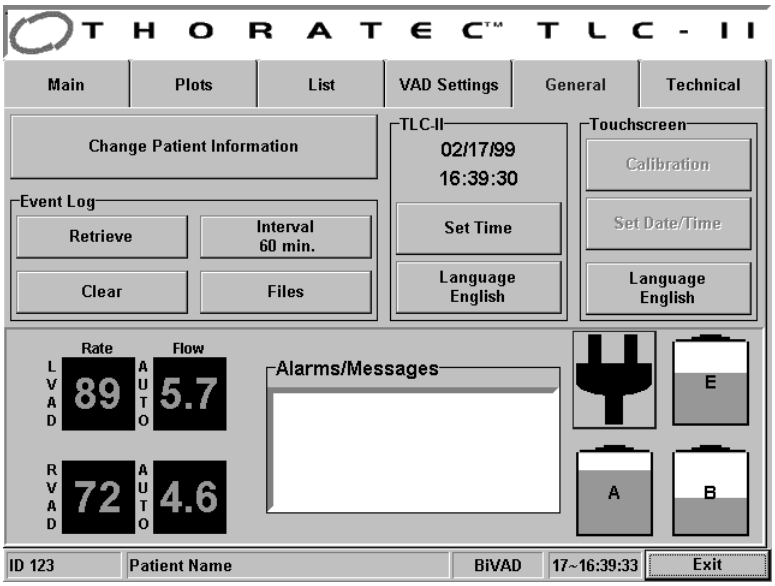


Figure 2.16 *HeartTouch Computer "General Settings Screen"*

2.4.2.5.2 EVENT Log Interval

Allowed range: (10 to 120 minutes)
Default: 60 minutes

This value sets the interval in minutes between event records that are routinely logged into TLC-II memory. Additional event records are recorded if parameter values are changed or if alarms occur. The TLC-II has memory for 660 event records. Once this memory is full, it starts writing over the oldest record. With a log interval of 10 minutes, up to 110 hours of monitoring can be logged. See **Table 2.1** for list of parameters stored upon each event.

2.4.2.5.3 RETRIEVE Event Log

This button retrieves all history event log information stored in memory in the TLC-II. During normal use, history event entries are automatically retrieved a few at a time. Use of this button is the fastest way to update all of the history events at one time.

2.4.2.5.4 CLEAR Event Log

With this option all values stored in the TLC-II are cleared from memory. All new logging starts from the current time. This is useful when starting a new patient.

2.4.2.5.5 Event Log Files

This is used to copy event log files and waveform files to the floppy disk drive. Event log files contain the information listed in **Table 2.1** and are written as delimited text files for import into commercial spreadsheet programs.

Table 2.1 Stored Parameters in the Event Log Files

Item	Parameter
	CURRENT TLC-II INFORMATION
1	Log Time
2	Serial Number
3	Sequence Number
4	VAD Configuration (LVAD, RVAD or BiVAD)
5	LVAD Current Timing Mode (auto or fixed)
6	LVAD Current Beat Rate
7	LVAD Current Flow Rate
8	LVAD Current Max. Pressure
9	LVAD Current Mean Eject Pressure
10	LVAD Current Eject Time
11	LVAD Current Max. Vacuum
12	LVAD Current Mean Fill Vacuum
13	LVAD Cycles w/o Full/8
14	LVAD Cycles w/o Empty/8
15	RVAD Current Timing Mode (auto or fixed)
16	RVAD Current Beat Rate
17	RVAD Current Flow Rate
18	RVAD Current Max. Pressure
19	RVAD Current Mean Eject Pressure
20	RVAD Current Eject Time
21	RVAD Current Max. Vacuum
22	RVAD Current Mean Fill Vacuum
23	RVAD Cycles w/o Full/8
24	RVAD Cycles w/o Empty/8
25	Current Power Source (Battery A, B or DC)
26	External DC Voltage
27	Battery A Voltage
28	Battery B Voltage
29	Battery E Voltage
30	Total Usage Time (Hours)
31	LVAD Usage Time (Hours)
32	RVAD Usage Time (Hours)
33	BiVAD Usage Time (Hours)
34	Service Interval
35	Compressor Temperature (C)
	SET VALUES
36	Set Accumulator Pressure (mmHg)
37	LVAD Set Control Mode (front panel, auto, or fixed)
38	LVAD Set Eject Beat Rate (manual)
39	LVAD Set Fixed Beat Rate
40	LVAD Set Low Beat Rate
41	LVAD Set Fixed Eject Time
42	RVAD Set Control Mode (front panel, auto, or fixed)
43	RVAD Set Eject Mode (Manual)
44	RVAD Set Fixed Beat Rate
45	RVAD Set Low Beat Rate
46	RVAD Set Fixed Eject Time
47	Regular Log Interval (minutes)
	ALARMS (0 = NO; 1 = YES)
48	High LVAD Pressure
49	High LVAD Vacuum
50	Low LVAD Pressure
51	Low LVAD Vacuum
52	LVAD Occlusion
53	Low LVAD Rate
54	No LVAD Full Signal
55	High RVAD Pressure
56	High RVAD Vacuum
57	Low RVAD Pressure
58	Low RVAD Vacuum
59	RVAD Occlusion
60	Low RVAD Rate
61	No RVAD Full Signal
62	Battery A is Low
63	Battery B is Low
64	Emergency Battery in Use
65	Low Temperature
66	High Temperature
67	Alarm 18
68	Alarm 19
69	Emergency Battery
70	Service Interval
71	Alarm 20
72	Alarm 21
	EVENTS
73	Power Up TLC-II
74	TLC-II Serviced
75	Service Interval Changed
76	Scheduled Event Recording
77	Unscheduled Event Recording
78	New Patient
79	VAD Configuration Changed
80	LVAD Timing Control Changed
81	RVAD Timing Control Changed
82	LVAD Timing Mode Changed
83	RVAD Timing Mode Changed
84	LVAD Fill Mode Changed
85	RVAD Fill Mode Changed
86	LVAD Eject Mode Changed
87	RVAD Eject Mode Changed
88	Preferred Battery Changed
89	Power Source Changed
90	Event Buffer Overflowed
91	LVAD Fixed Beat Rate Changed
92	RVAD Fixed Beat Rate Changed
93	LVAD Auto Low Beat Rate Changed
94	RVAD Auto Low Beat Rate Changed
95	LVAD Fixed Eject Time Changed
96	RVAD Fixed Eject Time Changed
97	Motor Voltage Changed
98	Recording Interval Changed
99	Serial Number Changed
100	Current Time Changed

Also available are general settings for the TLC-II and for the touchscreen:

TLC-II:

2.4.2.5.6 Set Time

The current time and date stored in the TLC-II are displayed in this box. The current time on the HeartTouch computer is displayed on the bottom status row. The **Set Time** option is used to change the time and date on the TLC-II driver to equal the time and date on the HeartTouch computer.

2.4.2.5.7 Language

The current language used for messages on the TLC-II control panel is shown here. Press this button to select a different language.

Touchscreen:

2.4.2.5.8 Calibration

Choose this option to adjust the position of the touchscreen cursor.

2.4.2.5.9 Set Date/Time

Choose this option to set the date and time on the HeartTouch computer. The current date and time are displayed on bottom status row.

2.4.2.5.10 Language

The current language used on the HeartTouch computer is shown here. Press this button to select a different language.

2.4.2.6 Technical Screen

The technical screen (**Figure 2.17**) is used only for observing certain TLC-II diagnostic information. The following information is displayed.

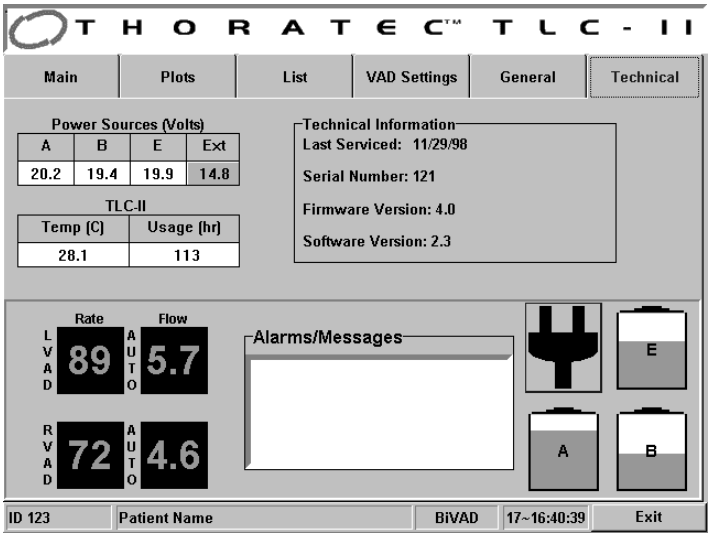


Figure 2.17 *HeartTouch Computer "Technical Screen"*

2.4.2.6.1 Power Sources (Volts)

The voltages of the four TLC-II power sources are continuously monitored by the TLC-II and are displayed on this screen when the TLC-II is connected to the HeartTouch computer. Battery A, Battery B and the emergency battery (E) range from 20.8V (when fully charged) to 13.5V (when fully discharged). After removal of the TLC-II load, voltages of a fully discharged battery rise to over 17V. Therefore, battery voltage alone is not an accurate measurement of the charge available. Use the battery test button on the front of each battery for a more accurate determination of remaining life. The voltage of the external power source (EXT) is also displayed. The Thoratec TLC-II AC adapter, Car Power Adapter, and the power supply in the TLC-II Docking station provide at least 14.5V.

2.4.2.6.2 Compressor Temperature and Usage

The temperature of the air compressor is continuously monitored by the TLC-II and is displayed here when the TLC-II is connected to the HeartTouch computer. A high temperature alarm occurs on the TLC-II if the temperature exceeds 60°C. The compressor usage is recorded by the TLC-II in hours. The TLC-II sounds an alarm when preventive maintenance is required.

2.4.2.6.3 Technical Information

Several items are displayed here:

- Date that the TLC-II Driver was last serviced
- TLC-II serial number
- Firmware version for the TLC-II micro-processor
- Software version for the HeartTouch computer

2.5 MOBILITY CART

In addition to being able to carry the TLC-II by hand or by using the shoulder strap, the TLC-II can be used with the TLC-II mobility cart (**Figure 2.18**). This cart has 2 wheels, a telescoping handle and can be folded up for convenient storage.

The TLC-II driver is attached to the mobility cart with Velcro straps on the TLC-II carrying case.

WARNING: Do not start on ambulatory use without first testing each battery. A fully charged battery has five lights on.

Figure 2.18 *TLC-II Mobility Cart and Driver*

2.6 MOBILE COMPUTER

The Mobile Computer provides the same functionality as the HeartTouch Computer, but in a smaller, portable format. The Mobile Computer is intended for clinicians' use only and should never accompany a patient out of the hospital when he or she is discharged. For details on the use and operation of the Mobile Computer, please refer to *Section 4.7*.

2.7 CAR POWER ADAPTER

The Car Power Adapter is required for all discharged patients and should accompany patients during excursions.

For details on the use and operation of the Car Power Adapter, please refer to *Section 4.8*.

3. CLINICAL STUDY

3.1 Study Overview

A clinical study was performed to evaluate the safety and effectiveness of the TLC-II Portable Driver in the home environment in patients implanted with a Thoratec Paracorporeal VAD (PVAD). The patients in this study were patients implanted with the PVAD (LVAD, RVAD or Bi-VAD support) under the currently approved indications of bridge to transplantation or postcardiotomy myocardial recovery. The patients were hemodynamically stable, without medical complications and had a desire for home discharge.

The primary endpoints of the study were effectiveness and safety of the VAD System in the home environment. The study was a prospective, non-randomized study. Patients in the study were followed until their outcome of transplantation, VAD explant (in the case of recovery) or death, and hospital discharge after these events.

3.2 Patient Population

A total of 29 patients were enrolled into the TLC-II Home Discharge study at 12 investigational centers in the United States between February 22, 2001, and June 5, 2003. For a summary of patient enrollment and outcomes, please refer to **Figure 3.1** (flow diagram).

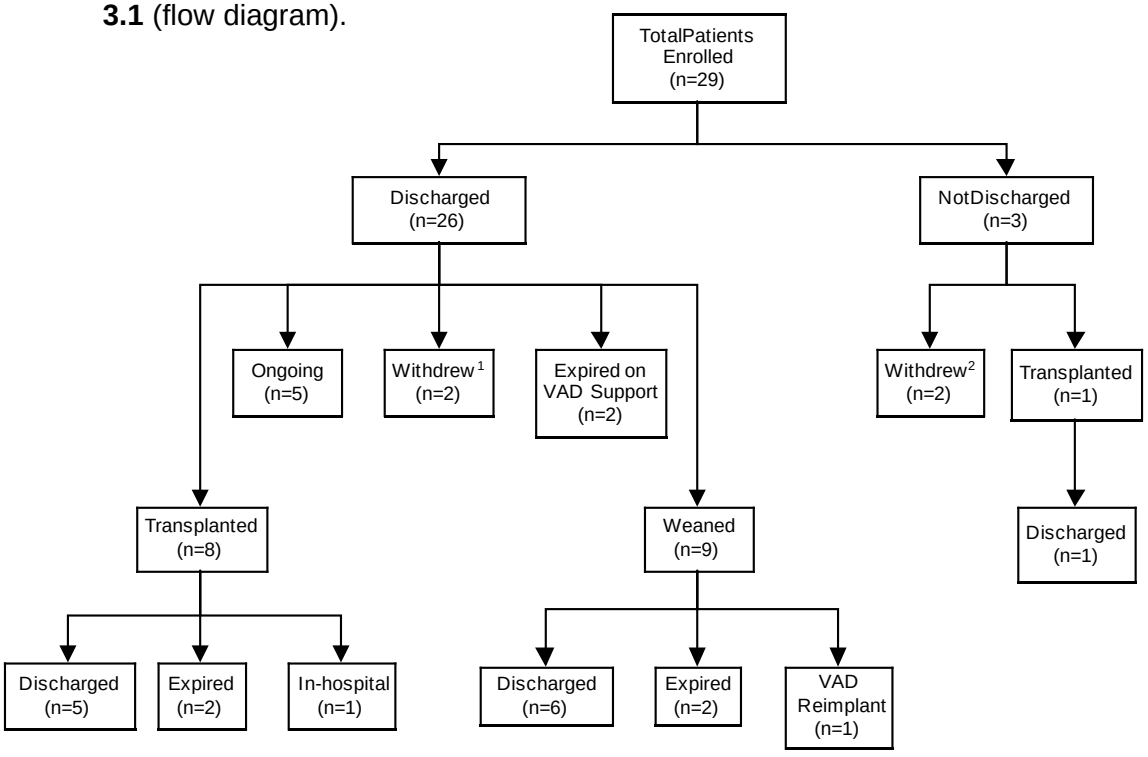


Figure 3.1 *Enrollment and Follow Up of Home Discharge Patients*

1. One patient was withdrawn from the study due to signs of right heart failure. The second patient was withdrawn due to CVA.

2. One patient was withdrawn from the study due to recurrent pleural effusions. The second patient was withdrawn due to a change in medical status, which made the patient ineligible for discharge (ie, patient was unable to be weaned from respiratory support, had persistent infections, and was required to stay in bed).

Of the 29 patients enrolled, 26 patients were discharged home. The median age of these patients was 50 years (range 21 to 73) with the majority of patients being male (69%). Sixty-two percent (62%) of the patients were implanted with a LVAD, 38% with a Bi-VAD and 0% with only an RVAD.

The In-Hospital study included 31 patients that were enrolled at 10 investigational centers in the United States between February 5, 1999, and June 4, 2001. The baseline demographics for these patients were similar to the TLC-II Home Discharge patient cohort.

3.3 Effectiveness: VAD Flow Index and Patient Outcomes

VAD Flow Index
The TLC-II Driver successfully maintained VAD flows > 2.0l/min/m2 in the home environment.

Patient Outcomes
Twenty-six (26) patients were studied, of which 2 withdrew from the study, 19 achieved an outcome, and 5 were ongoing at the time of data analysis. Of the 19 patients with known outcomes, 42% (8/19) were transplanted and 47% (9/19) of the patients were weaned with subsequent VAD explant. Two (2) patients withdrew from the study and 5 of the patients remained on VAD support at the time of data analysis.

The majority, 73% (11/15), of the patients that were transplanted or weaned from VAD support, and for whom post-VAD outcome is known, were discharged alive.

3.4 Adverse Events

Tables 3.1 and **3.2** present data on the rates and frequency of adverse events between the 2 groups. The first table presents the number of patients experiencing adverse events regardless of cause. This information is also displayed graphically in **Figure 3.2**. **Table 3.2** presents the data normalized per 90 patient days. All of the adverse events presented in the tables occurred after discharge to the home environment.

No new adverse events were observed in the Home Discharge Study that have not occurred in previous studies with the VAD System.

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

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

Table 3.1 *All Cause Adverse Events*

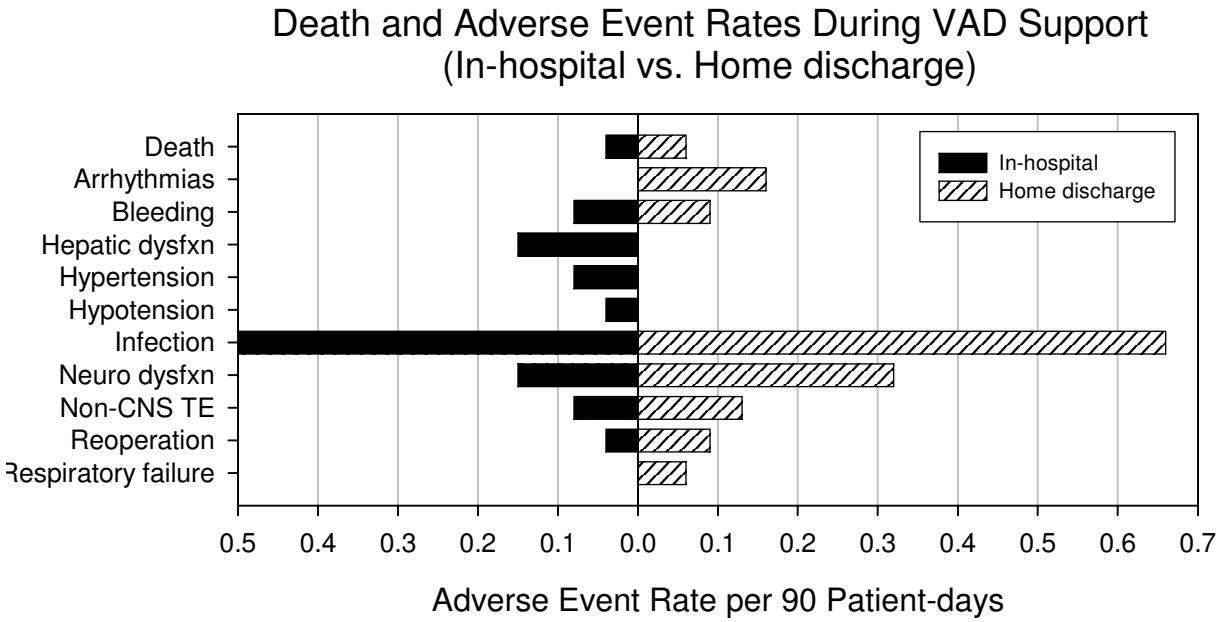


Figure 3.2 *Death and Adverse Event Rates During VAD Support*

Event	Home Discharge (n=25[a]) Events / 90 pt days	TLC-II In Hospital (n=31) Events / 90 pt days	Risk Ratio (95% Confidence Limits)
Total days in study	2843[b] (7.8 yrs)	2361.0 (6.5 yrs)	
Bleeding	0.09	0.08	1.24 (0.21 - 7.46)
Cardiac Tamponade	0.00	0.00	----
Hemolysis	0.00	0.15	----
Infection	0.66	0.50	1.34 (0.67 - 2.68)
Arrhythmias	0.16	0.00	----
Right Heart Failure	0.00	0.00	----
Left Heart Failure	0.00	0.00	----
Myocardial Infarction	0.00	0.00	----
Thromboembolic Complication (non-CNS)	0.13	0.08	1.66 (0.30 - 9.08)
Reoperation	0.09	0.04	2.49 (0.26 - 23.97)
Hepatic Dysfunction	0.00	0.15	----
Renal Failure	0.00	0.00	----
Neurological Dysfunction	0.32	0.15	2.07 (0.65 - 6.63)
Respiratory Failure	0.06	0.00	----
Hypotension	0.00	0.04	----
Hypertension	0.00	0.08	----
Death	0.06	0.04	1.66 (0.15 - 18.33)

a. Patient 12-101 discharged 3 days prior to data freeze and not included in analysis

b. Days in study after initial discharge

Table 3.2 *All Cause Adverse Events per 90 Patient Days*

4. SYSTEM OPERATION

In this chapter, system operation is presented. Section 4.1 should be referred to for quick reference only. Section 4.2 should be followed for appropriate TLC-II set-up for a new patient and Section 4.3 should be followed once the TLC-II has already been set up for a patient.

4.1 Thoratec TLC-II Portable Driver Quick Reference Guide

The following are “quick references” for start-up, switch to back-up, or to handle alarm situations. Please refer to Section 4.2 for more detailed information.

I. START-UP PROCEDURE

1. Place TLC-II in docking station.
2. Connect power and computer cables.
3. Insert fully charged batteries (press test button: fully charged battery has 5 lights) in each battery holder.
4. Turn on key switch and remove key. Place key in pocket of driver for storage.
5. Insert set-up plug in ports to eliminate pressure alarms during set-up. Press Silence button to silence alarms, if necessary.
6. Configure VAD settings for patient using VAD settings screen
7. Enter Patient Information using General Screen.
8. Connect patient to TLC-II using 5-foot pneumatic lead and the appropriate electrical or signal processor lead (i.e., use 5’ electrical lead for PVAD or 7’ signal processor lead for IVAD).
9. Press mode button for AUTO mode if desired and verify VADs filling and ejecting.
10. Adjust VAD settings if necessary to attain VAD ejection.
11. Adjust vacuum as necessary to attain full signals and desired rate.

 ***ALWAYS KEEP HAND PUMPS WITH DRIVER!***

In case of driver failure, disconnect pneumatic lead(s) from driver and connect hand pump(s). Squeeze hand pump(s) once per second. Connect to back-up as soon as possible.

II. SWITCHING TO BACK-UP TLC-II (Already set up for patient)

1. Insert fully charged batteries (press test button: fully charged battery has 5 lights) in each battery holder.
2. Connect to External Power if available.
3. Turn on key switch and remove key.
4. Remove occluder(s) from appropriate pneumatic port (red LVAD, blue RVAD) of TLC-II. If BiVAD, switch LVAD first.
5. Disconnect pneumatic lead(s) from primary TLC-II or hand pump and connect to back-up TLC-II port of same color.
6. Disconnect the PVAD elelctrical lead(s) or IVAD signal processor lead(s) (red for LVAD, blue for RVAD) and then connect to the back-up Driver’s electrical connector of the same color.
7. Press mode button for AUTO mode if necessary.
8. Verify full signals are being received from VAD(s) and VAD(s) are ejecting.
9. Place key in pocket of driver for storage.

ALARM MESSAGE	ACTION REQUIRED
CHANGE BATTERY A or B <<<A (>>>B)	Replace Battery A or B with a fully charged battery.
CHANGE BATTERY A or B < 10 MINUTES LEFT	Immediately replace the battery next to the illuminated yellow change battery light with a fully charged battery.
EMERGENCY BATT REPLACE	Replace TLC-II Driver with back-up driver immediately.
NO L or R FULL SIGNAL CHECK LEADS; VAD	Check VAD, cannula, leads, and all connections. Call for assistance.
HI L or R PRESSURE REPLACE	Check VAD and leads. Replace TLC-II Driver with back-up driver.
LO L or R PRESSURE CHECK; REPLACE	Check VAD and leads for system air leak. Replace TLC-II Driver with back-up driver.
HI L or R VACUUM REPLACE	Check VAD. Replace TLC-II Driver with back-up driver.
LO L or R VACUUM REPLACE	Check VAD. Replace TLC-II Driver with backup driver.
LVAD or RVAD OCCLUSION CHECK LEADS; VAD	Check pneumatic leads, cannulas, VAD. Call for assistance.
HI TEMPERATURE REPLACE	Check Driver air filter. If required, replace TLC-II Driver with back-up driver.
LO TEMPERATURE WAIT	Wait until TLC-II Driver is warmer.
SERVICE INTERVAL REPLACE	Replace TLC-II Driver with back-up driver immediately
ALARM 18-22 REPLACE or EMER SYSTEM ON	Replace TLC-II Driver with back-up driver immediately
NO MESSAGE	Check power

4.2 Setting up the TLC-II for a Patient for the First Time, Using the HeartTouch Computer

A. Connections and Power

4.2.1 Place the TLC-II Driver in the Docking Station (or next to the Docking Station).

4.2.2 Connect the TLC-II Docking Station to AC power and turn on the main power and the power to the computer (**Figure 4.1**).

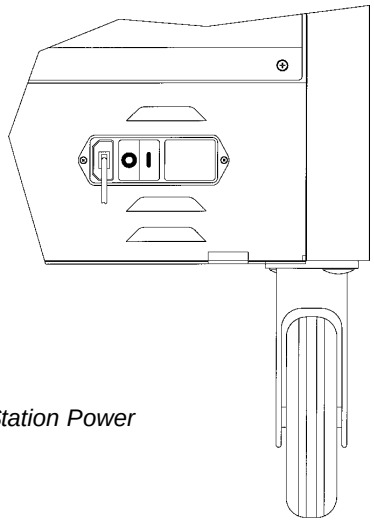


Figure 4.1 *Docking Station Power Switch*

4.2.3 Connect the power cable (color coded yellow) from the TLC-II to the Docking Station connector (**Figure 4.2**).

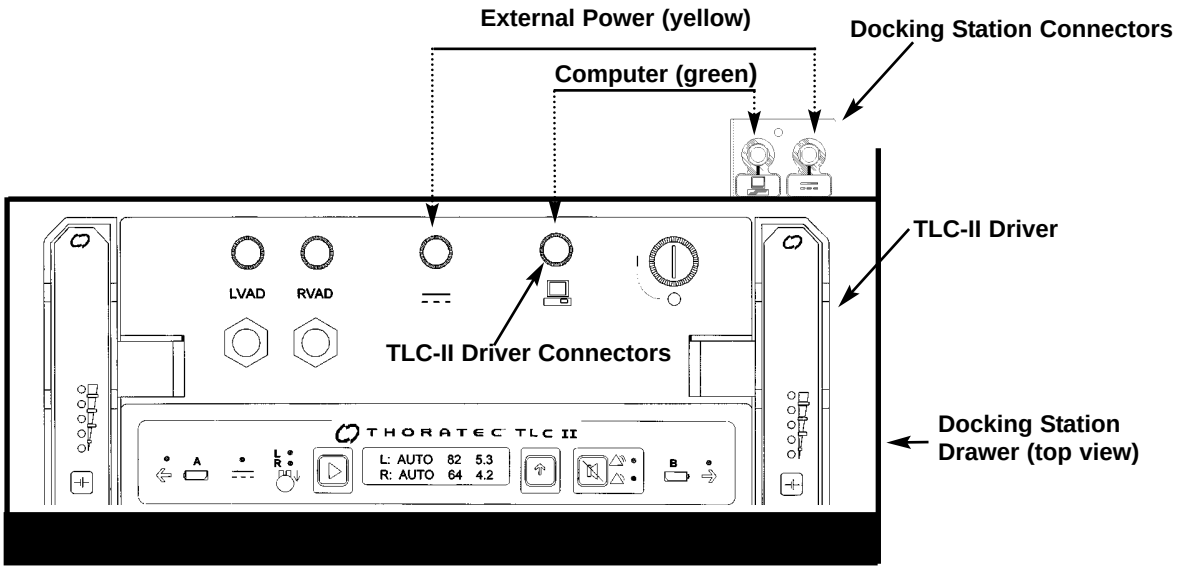


Figure 4.2 *TLC-II Driver and Docking Station Connectors (see also Figure 2.10)*

4.2.4 Connect the computer cable (color coded green) from the TLC-II to the Docking Station connector (**Figure 4.2**).

4.2.5 Place a fully charged battery in each of the 2 TLC-II battery holders.

4.2.6 Press the battery test button and note the status. With a fully charged battery all 5 green lights turn on (**Figure 4.3**).

WARNING: Do not start an ambulatory use without first testing each battery. A fully charged battery has 5 lights on.

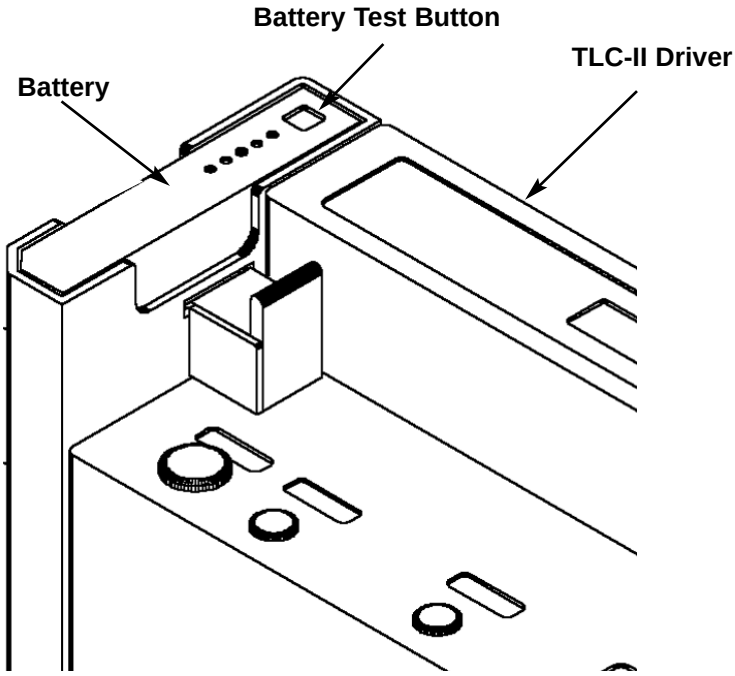


Figure 4.3 *TLC-II Driver, Battery, and Battery Test Button*

4.2.7 Remove the port occluders and insert set-up plug, if available, into the active VAD port (**Figure 4.4**). These will simulate the appropriate drive pressures and eliminate pressure and vacuum alarms during the set-up procedure.

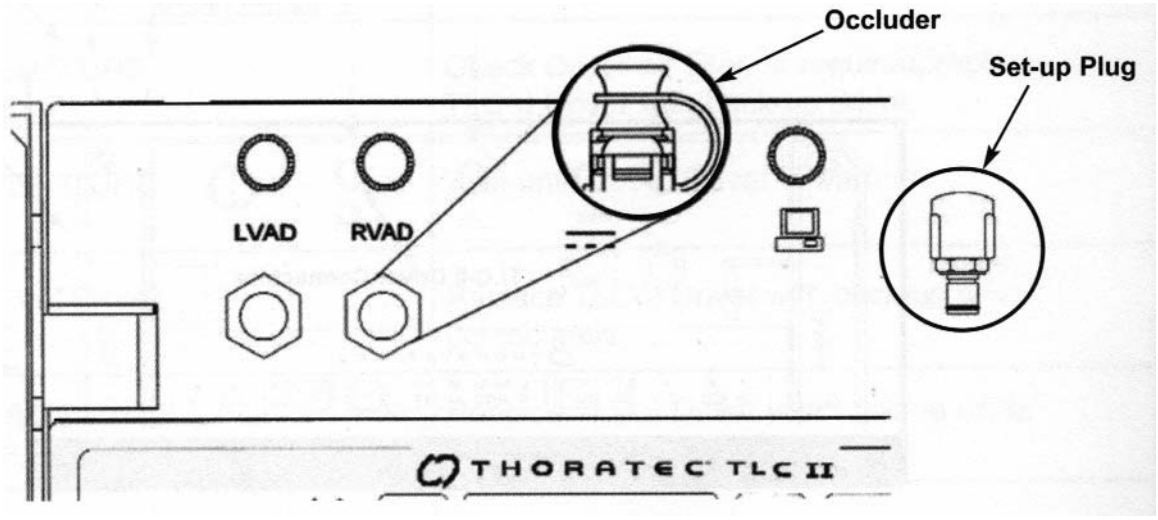


Figure 4.4 *TLC-II Driver Top Interface Showing Port Occluder and Set Up Plug*

4.2.8 Turn on the TLC-II with the keyswitch. Note that the emergency backup system turns on for about 3 seconds and the control panel on the TLC-II Driver briefly displays "INITIALIZING" and the software version number and date (**Figure 4.5**).

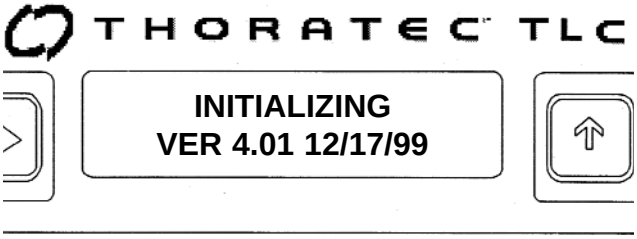


Figure 4.5 *TLC-II Control Panel Display During Initialization*

4.2.9 When the keyswitch is turned on, the key should be removed to avoid accidentally turning off the TLC-II. When the keyswitch is turned off, the key cannot be removed.

4.2.10 The main TLC-II system now takes over control and displays the timing mode, beat rate and flow for LVAD (top row) and/or RVAD (bottom row) (**Figure 4.6**). When no VAD is connected, or when there is no full signal present, "- - -" is displayed instead of a flow value.

4.2.11 Since no VADs are connected, several alarms may also become active, including PRESSURE and NO L (or R) FULL SIGNAL. Press the SILENCE button to silence the audible alarm for 30 seconds. Use set-up plugs to eliminate pressure and vacuum alarms during set-up. Press the SCROLL BUTTON to view all ALARM MESSAGES.

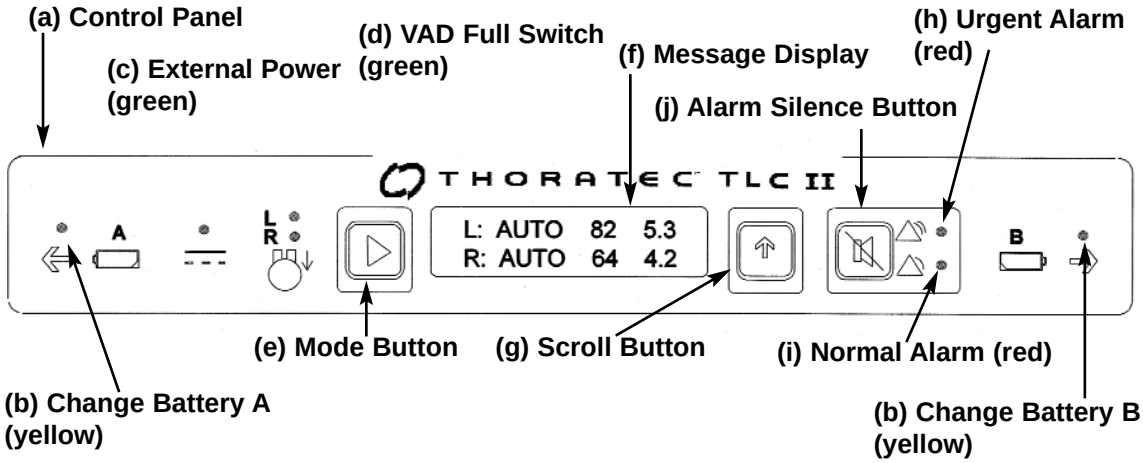


Figure 4.6 *TLC-II Control Panel*

4.2.12 Verify that the TLC-II is receiving power through the external power input, and the external power indicator lamp is illuminated. If the External Power indicator light is not illuminated then the TLC-II is using the rechargeable batteries.

B. Using the HeartTouch Computer

4.2.13 Verify that the TLC-II is communicating with the HeartTouch computer by noting that the display for VAD rate on the touchscreen monitor shows a numeric rate value, and the power source indicators are illuminated on the touchscreen (**Figure 4.7**).

4.2.14 Note that "- - -" is displayed instead of flow when no VAD is connected or when no full signal is detected.

4.2.15 If the TLC-II is not communicating with the computer, then a message appears in the **Alarms/Messages** box: **"No response from TLC-II".** If this message appears, check the connections of the green color coded computer cable.

4.2.16 Note that there are six main Tabs for each of the screens: Main, Plots, List, VAD Settings, General, and Technical.

4.2.17 To change the language on the HeartTouch computer, press the General Tab, and press the **Language** button on the Touchscreen. Select a different language and confirm.

4.2.18 Touch the **VAD Settings** Tab and examine the existing settings for the TLC-II (**Figure 4.7**).

4.2.19 To initialize all settings in the TLC-II to their default values, and to clear the patient name and ID, press **Initialize Parameters** and confirm **Yes**.

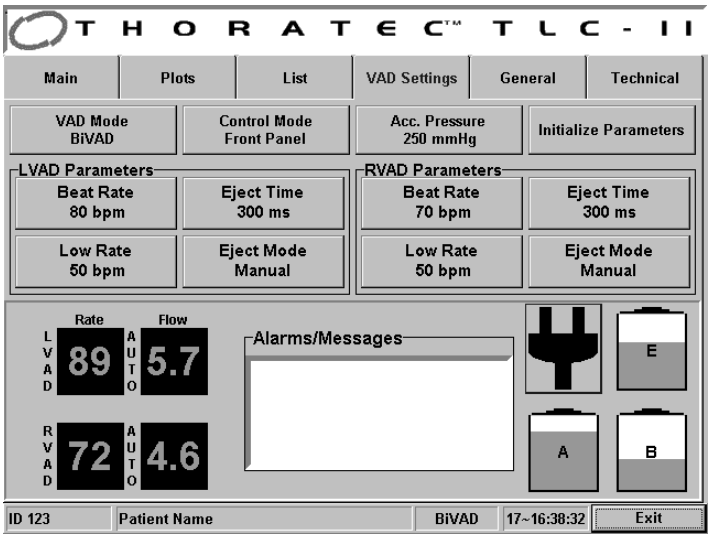


Figure 4.7 *HeartTouch Computer "VAD Settings Screen"*

This is the recommended start up for a new patient.

Default values upon initialization:

VAD Mode:	BiVAD
Accumulator Pressure:	250 mmHg
Control Mode:	Front Panel selectable, fixed rate
LVAD Beat Rate:	80 bpm
LVAD Low Rate:	50 bpm
LVAD Eject Time:	300 msec
RVAD Beat Rate:	70 bpm
RVAD Low Rate:	50 bpm
RVAD Eject Time:	300 msec
Patient Name:	[Blank]
Patient ID:	[Blank]

4.2.20 Verify that the correct VAD configuration (LVAD, RVAD, or BiVAD) is chosen for the **VAD Mode**. To change, touch the **VAD Mode** button on the HeartTouch computer and a dialog box appears. Touch the correct mode to match the VADs on the patient and then touch **Change.** A dialog screen will ask for confirmation of the change. Touch **YES** to confirm the change, or **Cancel** (**Figure 4.8**).

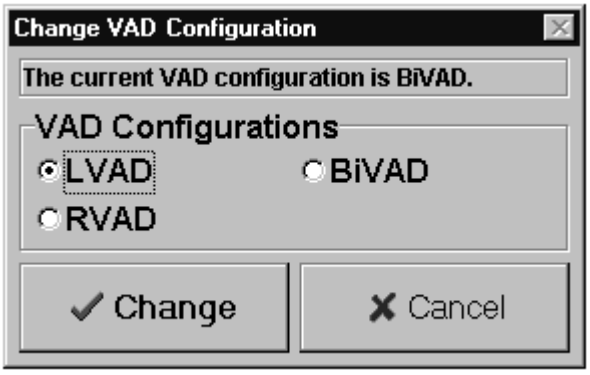


Figure 4.8 *HeartTouch Computer "VAD Configuration Dialog Box"*

4.2.21 Verify that the desired **Control Mode** is chosen for VAD timing. Choose **front panel selectable** to allow choice of auto rate or fixed rate from the TLC-II front panel.

4.2.22 Next, confirm that the **beat rate** values for the LVAD and/or RVAD (both for BiVAD operation) for use in fixed rate operation are the desired values for the patient. If switching a patient from the Dual Drive Console, typically the beat rate values on the TLC-II should be approximately equal to the actual pumping rate being used on the Dual Drive Console.

4.2.23 To change the TLC-II rate, touch **Beat Rate,** and a dialog box appears with arrows allowing the rate to be increased (up arrow) or decreased (down arrow). After choosing the desired rate, touch **Change** to accept and **Yes** to confirm, or **Cancel** to not accept (**Figures 4.9** and **4.10**).

WARNING: If a beat rate value less than 40 bpm is chosen, a warning message appears: "VAD beat rates below 40 bpm are not recommended."

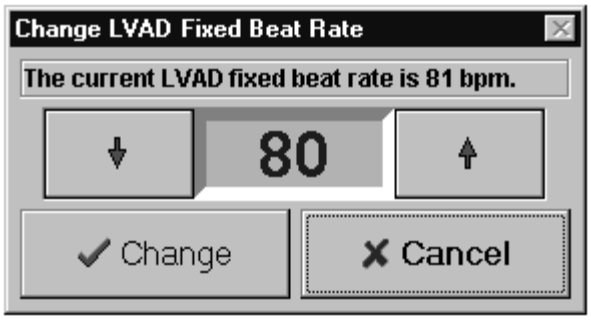


Figure 4.9 *HeartTouch Computer "Beat Rate Dialog Box"*

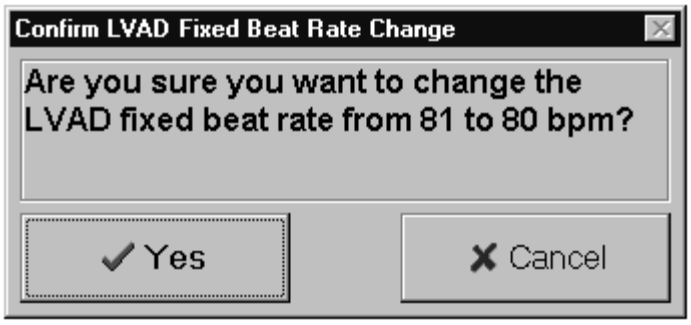


Figure 4.10 *HeartTouch Computer "Confirmation Dialog Box"*

4.2.24 Confirm that the **Low Rate** is the desired value for the patient. This is the lowest rate that is used in the auto rate mode while waiting for a full signal from the VAD. If no full signal is detected at this rate, the TLC-II switches to the fixed rate mode. Typically **Low Rate** is kept at the default

value of 50. Alternatively use 20 to 30 bpm below the beat rate value. To change this value touch **Low Rate** and the change value dialog box appears. Select the desired value and press **Change**, then touch **Yes** to confirm.

4.2.25 Confirm that the **Eject Time** is the desired value for each VAD being used. Typically 300 msec is used to empty the LVAD and RVAD. To change, touch **Eject Time** and select the desired value and confirm.

4.2.26 Confirm that the **Eject** mode is the manual mode.

4.2.27 Confirm that the accumulator pressure is at the desired level. Typically, the default value of 250 mmHg is used. To change, touch **Acc**. **Pressure,** select the desired value, and confirm. Increase the accumulator pressure or increase Eject Time to assure complete emptying of the VAD.

4.2.28 Touch the **General** tab and then touch **Change Patient Information** to enter the patient name and ID. A keyboard touchscreen is displayed. Touch each key to spell the patient's name (or initials) and ID number, then press **Change** and **Yes** to accept. The patient's name is then displayed on the touchscreen monitor and is used to set up file names and folders for event logs on the HeartTouch computer (**Figure 4.11**).

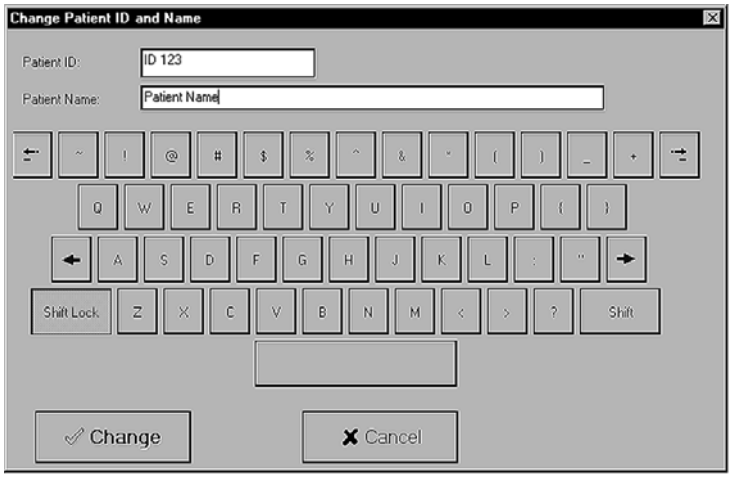


Figure 4.11 *HeartTouch Computer "Patient Information Screen"*

4.2.29 Touch the **Main** Screen Tab for routine monitoring.

4.2.30 Use the **Plots** screen to monitor drive pressure waveforms for the LVAD and/or RVAD.

4.2.31 Use the **List** screen to view a tabular history of values.

4.2.32 Verify that the pneumatic outputs to the VAD are operating.

4.2.33 With the pneumatic occluders in place verify that **OCCLUSION** or **HI PRESSURE** alarms come on (or with the small hole covered when using the set-up plug).

4.2.34 Next, temporarily remove the occluders and verify that the **LO PRESSURE** alarms come on.

4.2.35 Also verify that the LVAD and/or RVAD full alarms are on (**NO L FULL SIGNAL, NO R FULL SIGNAL**). Press the **Silence** button to silence audible alarms for 30 seconds.

4.2.36 The TLC-II is now ready to control a VAD on a patient.

4.2.37 Note that the TLC-II driver is now programmed with the chosen settings. These settings are stored in memory even if the TLC-II is turned off, and is used the next time the TLC-II is turned on.

4.2.38 To switch a patient from the Dual Drive Console to the TLC-II, skip to Section 4.4.

WARNING: Always use the EXIT button before turning off the HeartTouch computer to avoid problems with the Windows operating system.

4.3 Setting up the TLC-II without the HeartTouch Computer

4.3.1 If the TLC-II has been previously set-up for the same patient (with steps 4.2.1 - 4.2.37), then the stored settings can be used without needing the HeartTouch computer. These settings are stored in memory even when the TLC-II is turned off.

4.3.2 Place a fully charged battery in each of the 2 TLC-II battery holders.

4.3.3 Press the battery test button and note the status. With a fully charged battery all 5 green lights are turned on (**Figure 4.3**).

WARNING: Do not use the instructions in this Section 4.3 unless all the instructions in section 4.2 have previously been successfully completed. Repeat Section 4.2 if necessary.

4.3.4 Remove the port occluders and insert set-up plug, if available, into the active VAD port. These will simulate the appropriate drive pressures and eliminate pressure and vacuum alarms during the set-up procedure.

4.3.5 Turn on the TLC-II with the keyswitch. Note that the emergency backup system turns on for about 3 seconds and the control panel on the TLC-II Driver briefly displays "INITIALIZING" and the software version number and date (**Figure 4.5**).

4.3.6 Then the main TLC-II system takes over control and displays the timing mode, beat rate and flow for LVAD (top row) and/or RVAD (bottom row) (**Figure 4.6**). When no VAD is connected, or when there is no full signal present, "- - -" is displayed instead of a flow value.

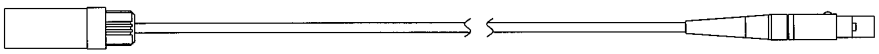
4.3.7 Since no VADs are connected, several alarms may also become active, including PRESSURE and NO L (or R) FULL SIGNAL. Press the SCROLL BUTTON to view all ALARM MESSAGES. Press the ALARM SILENCE button to silence the audible alarm for 30 seconds (**Figure 4.6**). Use set-up plugs to eliminate pressure and vacuum alarms during set-up (**Figure 4.4**).

4.3.8 The TLC-II is now ready to control a VAD on a patient.

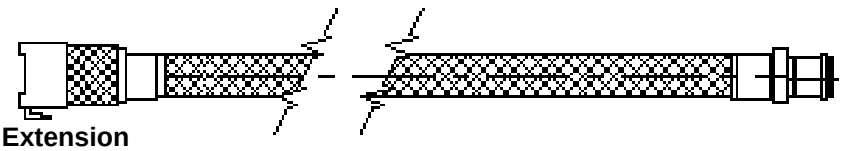
4.4 Switching a Patient from a Dual Drive Console to a TLC-II

4.4.1 Verify that the TLC-II is properly set-up and operating correctly, and that all steps in Section 4.2 or 4.3 have been completed. Leave the TLC-II keyswitch turned on.

4.4.2 Verify that each VAD on the patient is connected to the Dual Drive Console with the Console/TLC-II Extension Set for the pneumatic and electrical leads (color coded red for the LVAD and blue for the RVAD). This extension set allows a 1.5 m (5 ft.) pneumatic and electrical lead to be used on the TLC-II and a 2 m (7 ft.) extension (for a total of 3.5 m) when using the Dual Drive Console (**Figure 4.12**).



Electrical Lead Extension



Pneumatic Lead Extension

Figure 4.12 *Dual Drive Console/TLC-II Extension Set*

4.4.3 For LVAD support, remove the occluder or set-up plug on the TLC-II from the red LVAD pneumatic connector.

4.4.4 Disconnect the LVAD pneumatic lead (color coded red) from the end of the Console/TLC-II Extension Set and connect it immediately to the TLC-II LVAD pneumatic connector (color coded red) (**Figure 4.4**).

WARNING: For univentricular support, always completely occlude the unused port with the occluders. Do not use set-up plugs. (For example: with an LVAD patient, leave the occluder in the RVAD port.) Failure to do so will depressurize the system.

4.4.5 For LVAD support, disconnect the LVAD electrical lead (color coded red) from the Console/TLC-II Extension Set and connect it to the TLC-II LVAD electrical connector (color coded red).

4.4.6 For RVAD support, remove the occluder or set-up plug on the TLC-II from the blue RVAD pneumatic connector.

4.4.7 Disconnect the RVAD pneumatic lead (color coded blue) from the Console/TLC-II Extension Set and connect it immediately to the TLC-II RVAD pneumatic connector (color coded blue).

4.4.8 For RVAD support, disconnect the RVAD electrical lead (color coded blue) from the Console/TLC-II Extension Set and connect it to the TLC-II RVAD electrical connector (color coded blue).

4.4.9 Verify that full signals are being received from the VADs by examining the L and R full lights.

4.4.10 Adjust the vacuum regulator on the bottom side of the TLC-II, inside the opening in the TLC-II carrying case (**Figure 4.13**). Start with minimum vacuum (fully counterclockwise) and gradually increase until full signals and desired rate are achieved. Do not use more vacuum than necessary to fill the VAD. Maximum vacuum is fully clockwise.

WARNING: Insufficient VAD blood flow may occur if too little vacuum is applied.

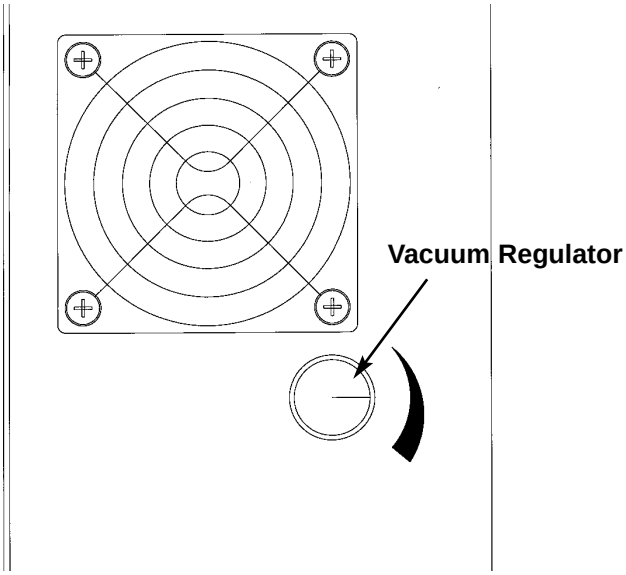


Figure 4.13 *TLC-II Driver Vacuum Regulator (lower side of driver)*

4.4.11 Press the mode button to select the automatic rate mode for automatic control of VAD rate based on VAD filling. Verify that the words AUTO appear on the main TLC-II display for each VAD. Each time the mode button is pressed, the mode switches between auto and fixed rate modes of pumping (**Figure 4.14**).

4.4.12 Make sure that no alarms are active before proceeding with support.

WARNING: Always investigate and correct the cause of any and all driver related alarms. If driver related alarms cannot be corrected immediately, then switch the patient to a backup TLC-II driver or a Dual Drive Console.

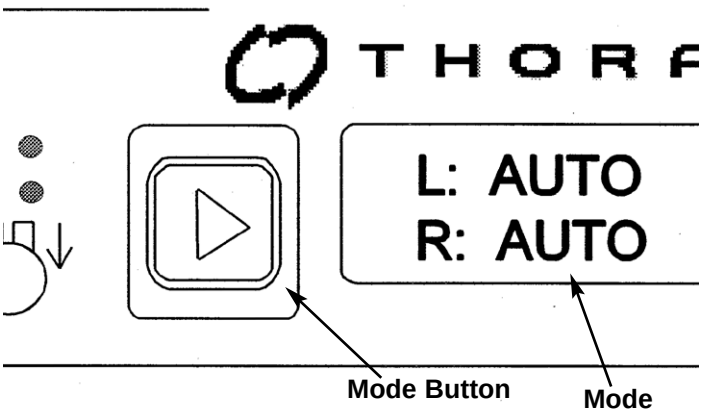


Figure 4.14 *Mode Button on TLC-II Control Panel*

4.5 Using the TLC-II Driver with the TLC-II AC Adapter

4.5.1 To use electrical outlets at locations away from the TLC-II Docking station, connect the TLC-II Driver to the TLC-II AC Adapter. To preserve battery life, use external power when available.

4.5.2 Plug the yellow color coded cable on the AC adapter into the yellow external power connector on the TLC-II Driver.

4.5.3 Plug the AC power cable into an electrical outlet (**Figure 4.15**).

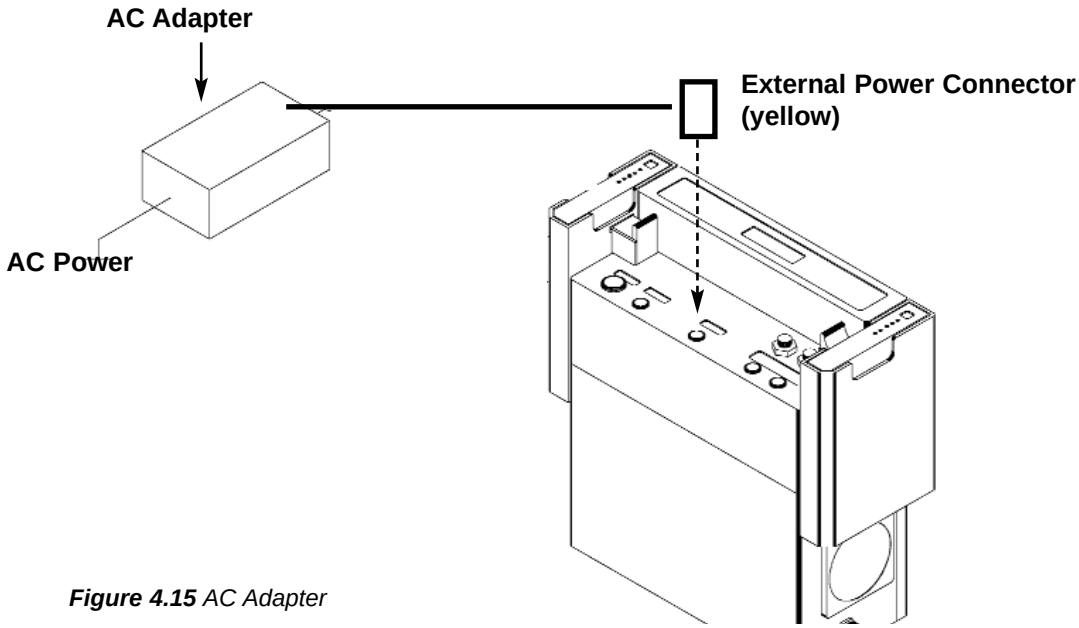


Figure 4.15 *AC Adapter*

4.5.4 Verify that the external power indicator lamp on the TLC-II is 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.

4.5.5 Before disconnecting external power to switch to battery power, assure that fully charged batteries are installed in the TLC-II; then disconnect the yellow color-coded external power cable from the TLC-II and disconnect the AC adapter from AC power. **Note**: A short beep indicates disconnection of external power. The AC adapter and cables can be stored in the TLC-II accessory pocket.

4.6 Using Battery Power and Preparing for Ambulatory Use

4.6.1 The TLC-II is designed to operate from at least two power sources: either two batteries, or one battery and external power. The driver operates with one power source but an alarm sounds until the second power source is installed.

4.6.2 Assure that there are two fully charged batteries in the TLC-II, one inserted in the slot for battery A and one in the slot for Battery B. Make sure that each battery is fully inserted into the slot, pushing all the way down until it snaps into place.

4.6.3 For each battery, determine the approximate state of charge by pressing the test button (**Figure 4.16**) on the front of each battery and observing the number of status lights: All 5 lights illuminated indicates the battery is fully charged, and each of the 5 green lights indicates the approximate capacity remaining (see Section 2.1.5.1). Depending on conditions, each battery when fully charged can run the TLC-II for at least 55 (BiVAD) to 80 (LVAD or RVAD) minutes (**Figure 4.16**).

WARNING: Do not start on ambulatory use without first testing each battery. A fully charged battery has five (5) lights on.

4.6.4 Assure that the following equipment is in the accessory pocket of the carrying case:

a. **Spare Batteries.**
Always carry spare fully-charged batteries. Press the battery test button of each battery. A fully charged battery has all five lights on (**Figure 4.16**).

b. **Two (2) emergency hand pumps.**

c. **AC Adapter.**
This is needed only if it is intended to run the TLC-II from electrical outlets away from the docking station (**Figure 4.15**).

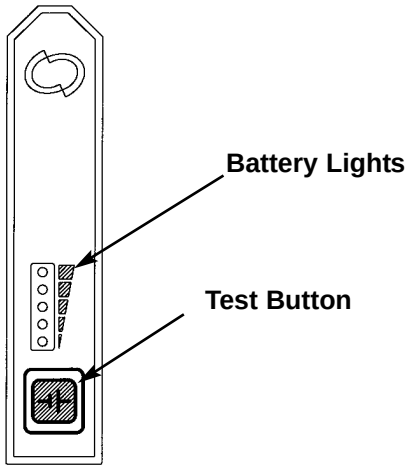


Figure 4.16 *Battery Test Button and Battery Lights*

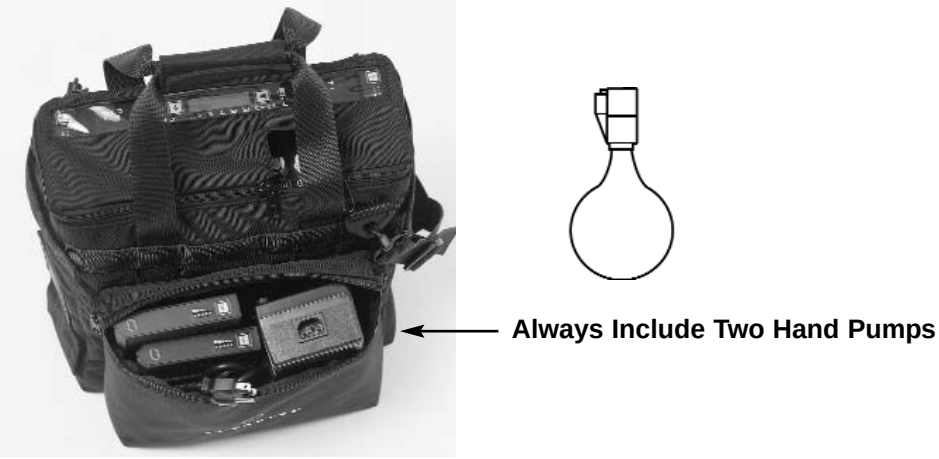


Figure 4.17 *TLC-II Driver Accessory Pocket with Accessories*

4.6.5 When 1 battery has been depleted, power automatically switches to the other battery. When this occurs a single audible chirp sounds and the yellow indicator light for Battery A or Battery B will illuminate. A single beep will sound every 30 seconds and a message will be displayed to replace the battery: "Change Battery A" or "Change Battery B". When there is less than approximately 10 minutes remaining, the alarm sound will change to a continuous tone.

If the TLC-II is connected to the HeartTouch computer, a similar message is displayed on the touchscreen monitor.

4.6.6 To remove a depleted battery from the TLC-II, slide the retaining clip (as shown on diagram) and remove the battery. Slide a fresh battery into the slot, pushing all the way down until it snaps into place (**Figure 4.18**).

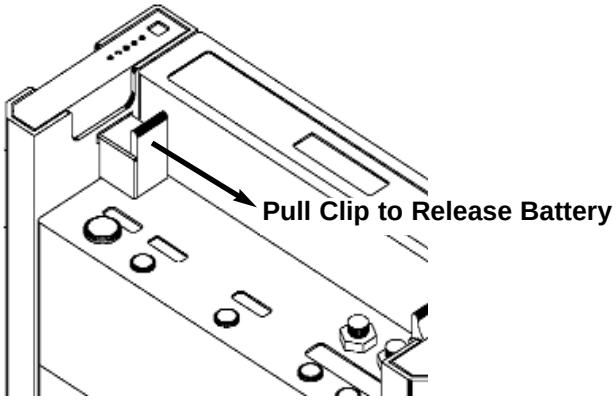


Figure 4.18 *TLC-II Driver Battery Removal*

4.6.7 When a fresh battery has been installed, the battery alarms are silenced, assuming that there are two valid power sources available (2 batteries, or 1 battery plus external power).

WARNING: If the battery alarm persists, check all battery connections and status before proceeding with ambulatory use.

4.7 Mobile Computer and Accessories

The mobile computer is a lightweight tablet computer that is used for data log file retrieval and for changing the operating parameters of the TLC-II driver (beat rate, accumulator pressure etc.). The accessories include the folding stand, floppy disk drive, data cable, power adapter cable, slip case and travel case.

The Mobile Computer uses the same software as the Heart Touch Computer. Refer to Section 2.4 for detailed HEART software instructions.

WARNING: The mobile computer may be used ONLY to run the Thoratec HEART software. Attempts to use the mobile computer to run any other programs may affect the functioning of the computer. Running of unauthorized programs on the mobile computer will invalidate the warranty.

Figure 4.19 *Mobile Computer*

4.7.1 Setup

Connect the Power Adapter Cable to the TLC-II AC Adapter (part number 20010-2825-001) with the red dots on the connectors indicating alignment. Plug the other end of the cable to the Mobile Computer DC input socket. **Note**: When using the Mobile Computer with a TLC-II Driver on a patient, power the Mobile Computer ONLY with internal battery or the TLC-II AC adapter.

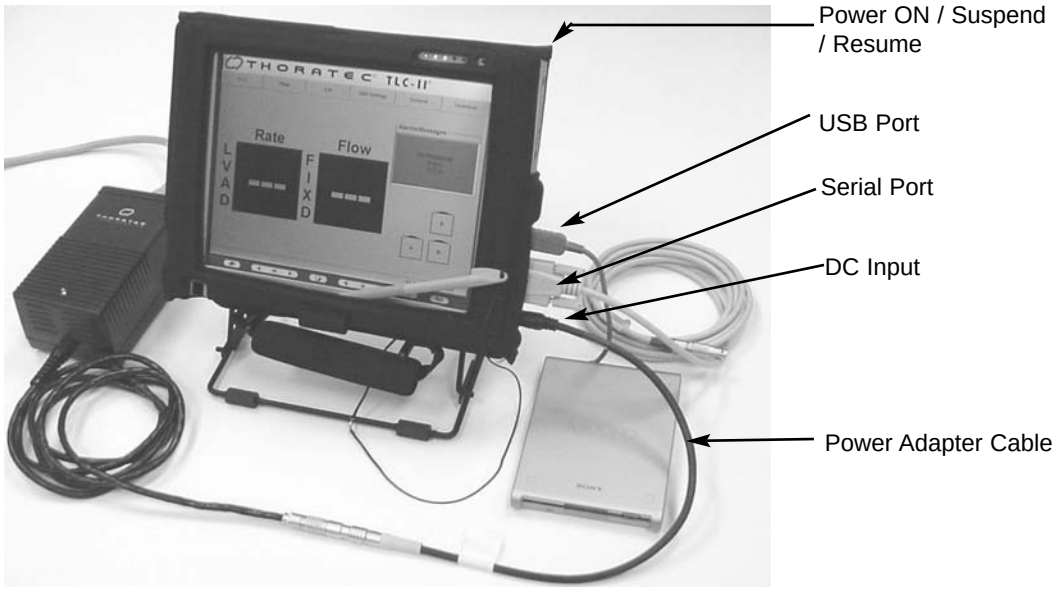


Figure 4.20 *Mobile Computer Set up*

4.7.2 Quick Start

1 Turn on the computer by pressing the 'Power ON / Suspend / Resume' button, located on the top right corner. Wait for the HEART software interface screen to appear.

2 Connect the Data Cable to the serial port and the TLC-II computer connector (green).

3 Use the Stylus provided to input instructions to the computer.

4 Connect the Floppy Drive to the USB port if download of log file data to floppy is desired.

Note: The computer can be hand held by putting one's palm through the straps at the back of the slip case or placed on the folding stand on a table top.

Note: When the computer is powered by the AC adapter, the screen will not turn off. When powered by battery, the screen will turn off after 10 minutes if there is no input. Touching the screen with the Stylus provided causes the screen to reappear.

4.7.3 System States*

On state
The system is running and the display screen is on. The power icon (see section 4.7.4) is displayed continuously.

Idle state
Some system functions are regulated or turned off to conserve power when operating from batteries. The display screen may be turned off. The system returns to the On state when Stylus activity or other input is detected. The power icon is displayed continuously.

Suspend-to-RAM mode
The power icon display is blinking. System operation is suspended. Most system functions are turned off to conserve power. Power to memory is on, maintaining data in programs that were running before system operation was suspended. The system does not respond to the Stylus or other input when in Suspend-to-RAM mode. To return to the ON state, press the 'Power ON/ Suspend / Resume' button.

Off state
The Power icon is not displayed. All system functions are turned off to conserve power. The system does not respond to the Stylus or other input. The system boots at the next system power-on.

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4.7.4 Status Indicators*

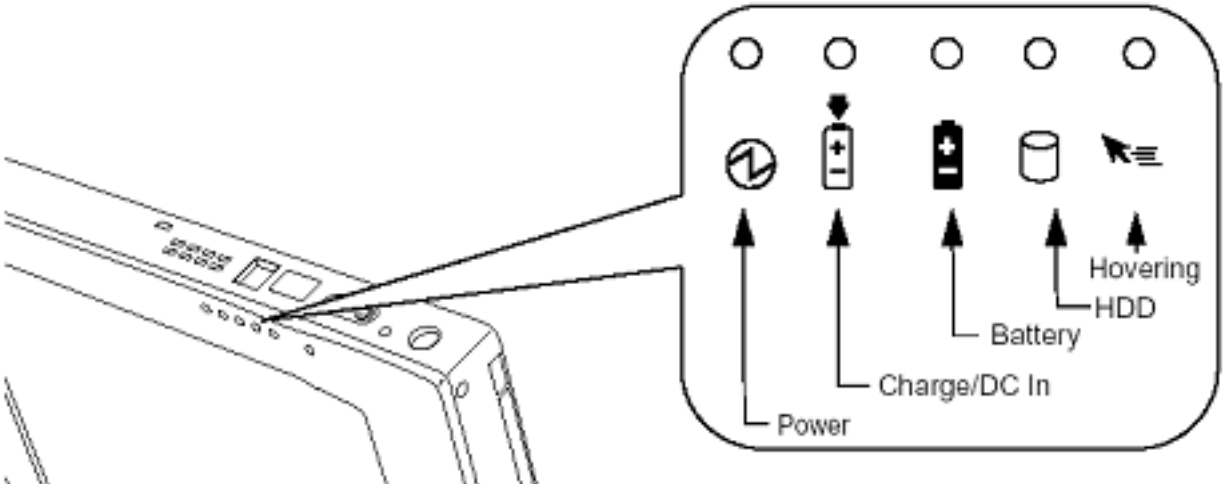

Figure 4.21 *Status Indicators*

The meanings of the icons are listed in the table below*.

Icon	Mode/State	LED State	Remarks
Power 	- On State - Idle State	Green, continuous	
	- Suspend-to-RAM	Green, blinking	
	- Off State	Off	
Charge/DC Input 	- On State - Idle Mode - Suspend-to-RAM - Off State-	Amber	AC adapter and battery pack are available and system is charging.
		Green	- AC adapter and battery pack are available and system is NOT charg ing (battery fully charged). - AC adapter is available but battery pack is not present.
		Amber, blinking	AC adapter and battery pack are available and waiting to charge (bat-tery pack is out of thermal range).
		Off	AC adapter is NOT available.
Battery 	- On State - Idle Mode - Suspend-to-RAM with AC adapter - Off State	Green, continuous	Battery pack charge between 50% - 100%
		Amber, continuous	Battery pack charge is between 13% - 49%
		Red, continuous	Battery pack charge is between 0% - 12%
		Red, blinking	There is a battery error.
		Off	Battery pack is NOT installed.
	- Suspend-to-RAM without AC adapter	Green, blinking slow	Battery pack charge is between 50% - 100%
		Amber, blinking slow	Battery pack charge is between 13% - 49%
		Red, blinking slow	Battery pack charge is between 0% - 12%
	Off State	Off	If battery is inserted during power off, LED blinks amber for 4 seconds to detect battery. Battery status is dis-played for 5 seconds after that.
HDD Access 	- On State (or flashing) - Idle Mode	Green	Displayed when hard disk drive is accessed.
	- Suspend-to-RAM - Off State	Off	Hard disk drive is NOT being accessed.
Hovering** 	- On State (hovering enabled)	Green	Hovering mode is enabled.
	- On State (hovering dis abled	Off	Hovering mode is disabled.
	- Suspend-to-RAM - Off State	Off	

** This function is NOT used in current HEART software.

4.7.5 Hotpad

Hotpads are located at the bottom of the screen for brightness adjustments. The other hot pads are not used in this computer. To use a hotpad, tap directly on it with the Stylus. Press and hold will repeat the hotpad function.

Figure 4.22 *Hotpad*

4.7.6 Peripheral Connector / Interfaces*

Connector/ Peripheral	Icon	Purpose
DC input connector		Connect an external power source, such as the AC adapter.
Serial Port		Connect to TLC-II Driver system using laptop data cable.
USB Port		Connect universal serial bus (USB) floppy drive.

Note: Other Interfaces are not used by the HEART software.

4.7.7 Charging the Battery

When DC power remains connected to the computer, the charging process continues until the battery pack reaches 100%. Approximate charging times are shown in the table below*.

Battery Pack Charge Level Reached	Approximate Charge Time (computer NOT in use)	Approximate Charge Time (computer in use)
90%	3 hours	6 hours
100%	4 hours	8 hours

With a fully charged battery, the computer can operate continuously for approximately 2.5 hours without the screen saver on.

Note that even when the computer is in the Off state, the battery is still supplying power to some system components.

4.7.8 Care and Maintenance*

Protecting the Display Screen

The computer is designed to provide you with years of service. Using a screen protector will help ensure that the screen remains as clear as possible. When installed, the screen protector becomes a durable, replaceable writing surface that protects the display screen from abrasion.

WARNING: During normal use of the computer, small particles from the environment can become embedded in the Stylus tip and scratch the screen. To prevent scratching the screen, ensure that a screen protector is installed before using your computer. The warranty does NOT cover a screen that is scratched as a result of not using a screen protector.

To install a new screen protector on your computer:

1 If a screen protector is already installed on the display screen, remove it before installing the new screen protector. **Note**: The screen protector is held onto the display screen surface by a thin strip of adhesive around the edges. A notch in one corner of the screen protector allows you to slide your fingernail under the screen protector for easy removal.

2 Clean the display by wiping the screen surface gently using a soft cotton cloth dampened with isopropyl alcohol. Ensure that all residues have been removed from the screen before applying a new screen protector.

WARNING: The Computer is NOT waterproof. Do NOT pour liquids on the Computer or wash the Computer with a heavily soaked cloth.

3 Remove the protective coating from the adhesive side of the screen protector first.

4 Apply the screen protector to the display screen surface. **Note**: Orient screen protector with the adhesive side of the screen protector facing the display screen and the notched corner facing toward the lower left corner of the display screen.

5 Apply pressure to the screen protector with your finger using a continuous wiping motion along the edges. **Note**: To ensure a good seal between the screen protector and the display, do not lift the screen protector from the display once it has been applied. The adhesive sets completely within 48 hours.

6 Remove the protective plastic cover from the face of the screen protector.

7. Clean any residue left behind by the protective coating from the exposed surface of the screen protector by wiping gently with a soft cotton cloth dampened with isopropyl alcohol. Wipe the screen protector with a soft dry cloth to remove any low-tack adhesive; this will help prevent the Stylus tip from squeaking. The screen protector is now installed.

Storing the Computer

WARNING: Do NOT store your Computer with the screen side down, otherwise damage to the display may occur. Keep computer in the Slip Case provided and store in the Travel Case to avoid damage.

Store the Computer in the Off state with a fully charged battery pack installed. You can store the computer in the Off state for about 30 days with a fully charged battery pack installed. After this period, the battery pack should be recharged. If you intend to store the Computer for a longer period of time, the small battery that maintains system time may need to be replaced. Replacement of the clock battery should only be performed by authorized technicians.

Avoiding Overheating

The computer monitors its internal temperature. As the internal temperature approaches the tolerable limits of heat-sensitive components, system functions are automatically limited or turned off to prevent damage. To avoid overheating the computer, do not obstruct the air vents on the top and bottom edges of the computer.

Cleaning the Display Screen

To clean the computer display screen, wipe the screen surface gently using a soft cotton cloth slightly dampened with water or isopropyl alcohol.

4.7.9 Troubleshooting

Problem: *System Will Not Resume Operation*

If the system will not resume operation after system operation has been suspended, check the following possible causes:

- The battery pack may either be defective, or discharged to the critically low level. When the battery pack reaches the critically low level, the system is forced into Suspend-to-RAM mode to avoid a total system power failure. To correct this problem, connect an external power supply (such as the AC adapter) to the Computer.
- The system may be at the critical thermal limit. To avoid damage to heat-sensitive components, the system enters Suspend-to-RAM mode when it gets too hot. System operation cannot be resumed until the Computer cools off to a tolerable temperature. Move the Computer to a cooler location.

Problem: *Display Screen Is Blank or Difficult to Read*
If the display screen on your computer appears blank or is unreadable, confirm that the system is running (the Power icon is displayed continuously on the Status display), and check the following:

- The system brightness may be set too low, causing the screen to appear too dark. Use the brightness hotpad to adjust the screen brightness (section 4.7.5).
- The video timeout may have expired. Tap on the display screen to reactivate the display. Note that this is a normal, power-saving feature.

Problem: *Cursor Is Not Tracking Stylus*
If the cursor on the screen appears to be misaligned with the Stylus or is not accurately tracking the computer, calibrate the computer touch screen using the calibration button on the General screen of the Heart Software.

Problem: *Computer Is Not Responding to the Stylus*
If the system doesn't respond to the Stylus, the application or system may have crashed, and it may be necessary to reset the system. Turn off and turn on the computer again. If the system still does not respond to the Stylus after reset, contact Thoratec at the addresses shown in the last page for further assistance.

4.7.10 Unpacking

The Mobile Computer and its accessories are packaged in a carrying case. Simply unpack it from the shipping box.

4.8 Car Power Adapter

The Car Power Adapter provides extra mobility to the patient by adding another source of power to the TLC-II driver. The Car Power Adapter uses the power from an automobile's cigarette lighter socket and converts it to a voltage that is appropriate to power the TLC-II driver. There are two cables with the Car Power Adapter. The yellow end plugs into the external power connector of the TLC II while the cigarette lighter adapter plug goes to the automobile cigarette lighter socket. Indicator LEDs (green) are visible on the cigarette lighter adapter plug and on one end of the Car Power Adapter (**Figure 4.23**).

Note: The Car Power Adapter is required for all discharged patients and should accompany patients during excursions.

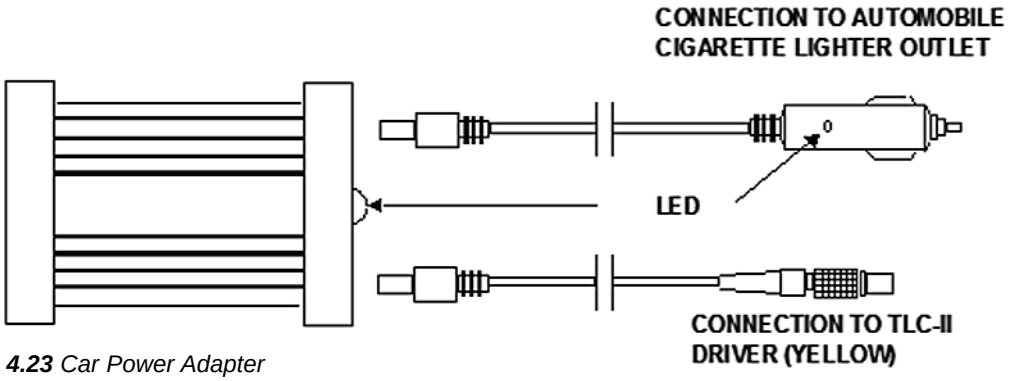

Figure 4.23 *Car Power Adapter*

4.8.1 Operation

To preserve battery life, use external power when available.

WARNING: The Car Power Adapter should be used ONLY when fully charged batteries are available. Do NOT rely on it as the sole source of power.

Note: The Car Power Adapter uses a snap-in connector for the output cable (yellow). Ensure the output cable audibly snaps into place when connecting the output cable to the adapter body.

1 Remove the cigarette lighter located in the automobile.

2 Insert the Car Power Adapter cigarette lighter plug into the cigarette lighter's socket. Power may be available without turning the car key to the ON position or having the engine started. The LEDs on the plug and the adapter body will be illuminated when there is power.

3 Start the car engine.

4 Verify that the LEDs of the Car Power Adapter are illuminated. Do NOT use the adapter if the LEDs are not illuminated.

5 Plug the yellow color-coded cable of the Car Power Adapter into the yellow external power connector on the TLC-II Driver.

6 Verify that the external power indicator lamp on the TLC-II is illuminated. **Note**: If it is not illuminated, the TLC-II is still drawing power from the batteries. A short beep indicates that external power has been connected.

Note: Before disconnecting external power to switch to battery power, assure that fully charged batteries are installed in the TLC-II; then disconnect the yellow color-coded external power cable from the TLC-II. A short beep indicates disconnection. The Car Power Adapter and cables can be stored in the TLC-II accessory pocket.

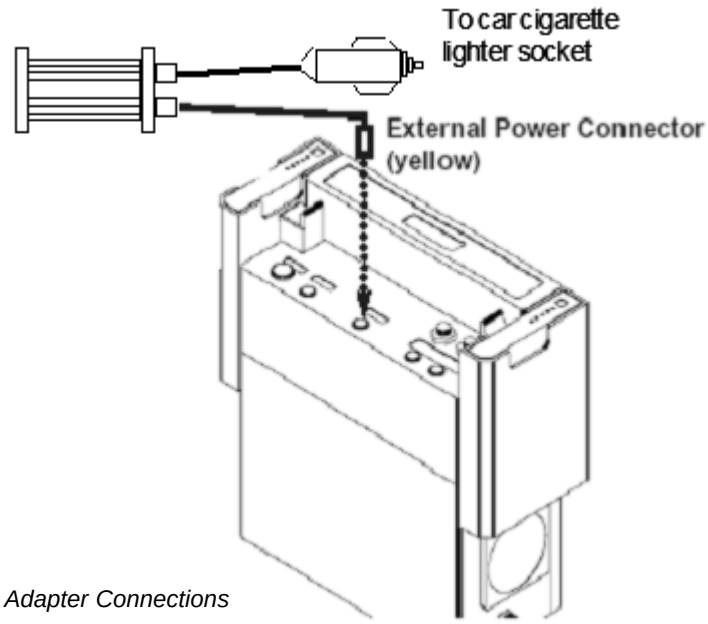

Figure 4.24 *Car Power Adapter Connections*

4.8.2 Care and Maintenance

WARNING: Do NOT allow liquids to come in contact with the Car Power adapter.

4.8.3 Trouble Shooting

No Output (TLC-II External Power Indicator is not ON). Check the following in the order listed:

Symptom	Action
No voltage from cigarette lighter socket.	Make sure car engine in ON. Make sure cigarette lighter plug is completely inserted into car socket. Make sure fuse to cigarette lighter socket is not blown.
LED on cigarette lighter plug is not illuminated.	Unscrew the tip of the plug and check the fuse inside. If it is blown, replace with 3AG (1/4" X 1 1/4") Slo-Blo, 8A, 250V fuse.
LED on Power Adapter is not illuminated.	Make sure output connector (yellow) audibly snaps into connector on Car Power Adapter. Check the voltage output with a multimeter. If there is no voltage, replace adapter.

4.8.4 Unpacking and Assembly

1 Remove the Car Power Adapter from the shipping box. Untie the cables.

2 Insert the input and output cables into the adapter. The input cable has a male plug on one end and a cigarette lighter plug on the other. The output cable has a female plug on one end and the yellow external power plug on the other.
Note: To assure proper connection, the output cable must audibly snap into place on the Car Power Adapter body.

3 Place the Car Power Adapter in the accessory pocket together with other components.

Figure 4.25 *TLC-II Driver in Carrying Case with Accessory Pocket*

Note: When unpacking the Car Power Adapter for the first time, you will find the Input and Output cables already connected to the adapter.

4.9 Recharging Batteries

4.9.1 Insert one or two depleted batteries into a Thoratec TLC-II Battery Charger. There is one battery charger on the TLC-II Docking Station and additional battery chargers can be used at other locations (**Figure 4.26**).

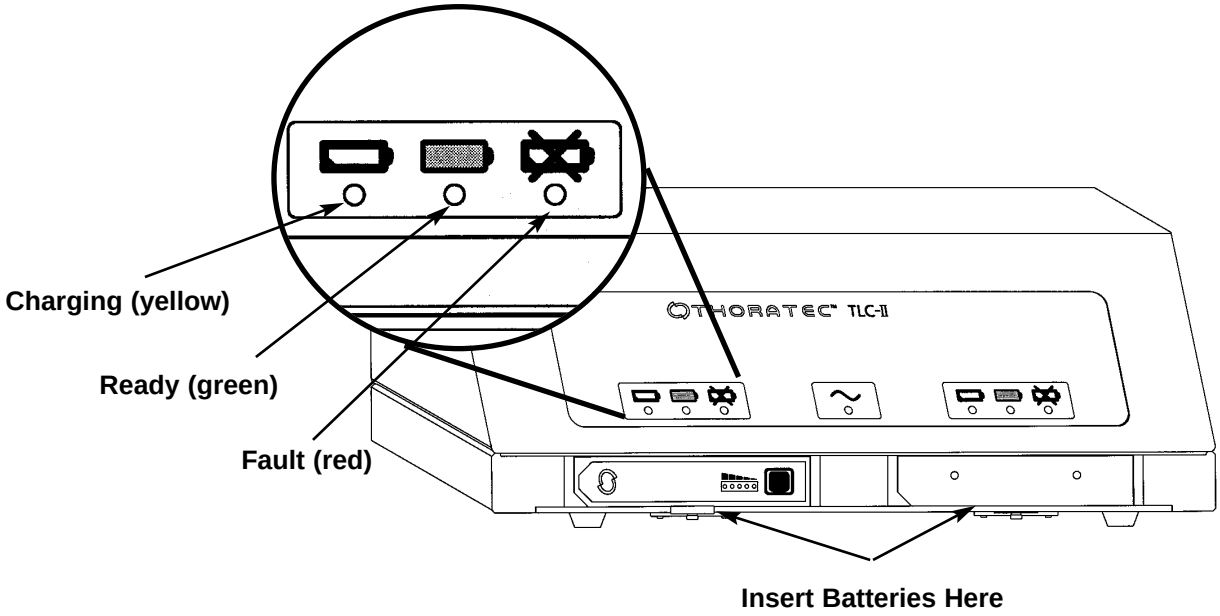

Figure 4.26 *TLC-II System Battery Charger and Indicator Lights*

4.9.2 The yellow charging light flashes when in the pre-charge mode, and will revert to a steady illumination when in normal charge mode. Approximately 2 hours are required to fully recharge each battery.

4.9.3 The green ready lamp illuminates when charging is complete. At this time the battery is fully charged and is ready for use.

4.9.4 The red battery fault light indicates that the charger is unable to charge the battery. This light will flash if the battery temperature is too high or too low. Wait until the battery is within the range of temperatures to allow charging (10° - 35° C, 50° - 95° F). If the light is steady, the battery should be inserted into a TLC-II Driver that is not on a patient to determine the battery voltage level. If the unloaded battery voltage, as shown on the technical screen, is above 20 V then the battery is acceptable for use. Otherwise, do not use the battery.

4.10 Using the TLC-II Carrying Case and Mobility Cart

4.10.1 The TLC-II is designed to be used at all times in the nylon carrying case. The mobility cart provided is a convenient cart with wheels allowing movement of the TLC-II in its carrying case.

Figure 4.27 *TLC-II Driver with Shoulder Strap*

Figure 4.28 *Mobility Cart with TLC-II Driver*

4.10.2 To carry the TLC-II, either the handles or the optional shoulder strap can be used. To use the shoulder strap make sure that the shoulder strap is firmly attached to the side clips on the case (**Figure 4.27**).

4.10.3 To mount the TLC-II on the mobility cart, unfold the bottom bracket of the cart until it snaps into place (**Figure 4.28**).

4.10.4 Place the TLC-II carrying case firmly against the bottom of the mobility cart.

4.10.5 Unhook the Velcro strips from each side of the carrying case and thread through mobility cart frame. Firmly re-attach back to the TLC-II case and make sure that both sides of the carrying case are firmly attached to the mobility cart.

4.10.6 Pull the telescoping handle up until it firmly locks into place.

4.10.7 The TLC-II in the mobility cart is now ready for ambulatory use.

5. ALARMS AND TROUBLESHOOTING

5.1 Alarms

There are several alarms that warn of existing or potential problems in the TLC-II or VADs. Alarm conditions are accompanied by audible beeps, and a red alarm light is illuminated. Always observe the patient first, and then correct the condition causing the alarm immediately.

Alarms fall into the following categories:

Pressure and Vacuum
Full Signal
Batteries
Temperature
Service Interval
Internal Alarms
Emergency Backup

5.1.1 Pressure and Vacuum Alarms

These alarms occur when the drive pressure during ejection or vacuum during filling are above or below specified values. There are high and low alarms for pressure and vacuum for both the LVAD and RVAD. An audible alarm sounds and the red normal alarm light illuminates (**Figure 5.1**).

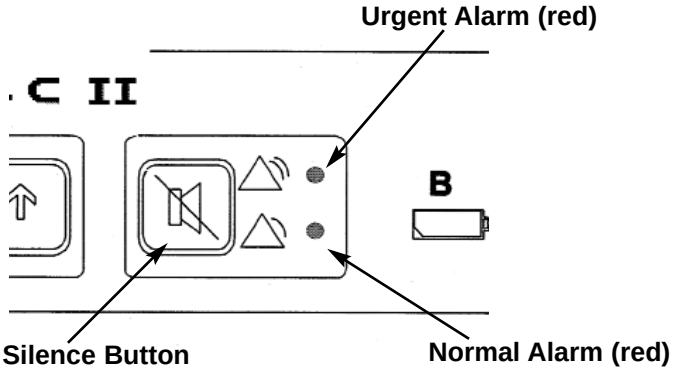

Figure 5.1 *TLC-II Control Panel Urgent and Normal Alarm Lights*

5.1.1.1 One or more of the following messages are displayed in the TLC-II control panel (and on the HeartTouch Computer), indicating an alarm from the LVAD (L) or RVAD (R):

"HI L PRESSURE"
"LO L PRESSURE"
"LVAD OCCLUSION"
"HI L VACUUM"
"LO L VACUUM"
"HI R PRESSURE"
"LO R PRESSURE"
"RVAD OCCLUSION"
"HI R VACUUM"
"LO R VACUUM"

In addition, a second message is displayed, either

"CHECK LEADS, VAD"
"REPLACE"
or
"CHECK; REPLACE"

This is a reminder to check all connections, the pneumatic lead and the VAD pump itself, and to verify the operation of the TLC-II driver. "Replace" indicates to replace the device with a back-up driver as soon as possible.

5.1.1.2 Possible causes of **High Pressure** alarms include:

- Pneumatic lead occluded
- Transducer error or failure
- Cannula occluded or kinked

5.1.1.3 Possible causes of **Low Pressure** alarms include:

- Pneumatic lead disconnected
- Compressor failure
- System air leak

5.1.1.4 Possible causes of **Occlusion** alarms include:

- Pneumatic lead occluded
- Cannula occluded or kinked
- Attempting to empty a partially full VAD

5.1.1.5 Possible causes of **High Vacuum** alarms include:

- Transducer error or failure
- Compressor or vacuum relief valve occlusion

5.1.1.6 Possible causes of **Low Vacuum** alarms include

- Compressor failure
- Solenoid failure
- System leak

5.1.2 Full Signal Alarms

If no full signal is detected by the TLC-II from the LVAD (L) or RVAD (R) for a period of approximately 8 seconds, an audible alarm sounds and the red alarm light illuminates. These alarms occur in the AUTO or the FIXED rate modes. In addition, the L (or R) VAD green full light no longer illuminates with each beat.

5.1.2.1 An error message is displayed on the TLC-II control panel and on the HeartTouch Computer (when connected to the TLC-II):

"NO L FULL SIGNAL", or
"NO R FULL SIGNAL"

In addition, a second message is also displayed:

"CHECK LEADS; VAD"

This is a reminder to check all VAD electrical lead connections, and to check the VAD to observe that it is pumping correctly.

5.1.2.2 When a full signal is not present, "- - -" is displayed instead of a numeric value for VAD blood flow (**Figure 5.2**).

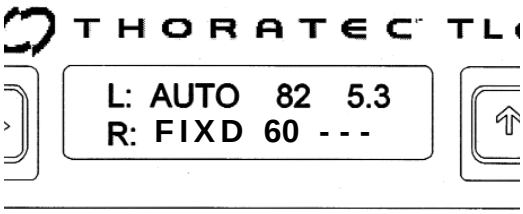

Figure 5.2 *Example of Display Showing "---" for Invalid Flow Measurement*

5.1.2.3 If the TLC-II is running in the auto rate mode when a full signal is lost, the TLC-II pumping rate slows down to the low rate value in an attempt to locate a full signal. If no full signal is present it then automatically runs in fixed rate timing at the fixed beat rate setting.

5.1.2.4 The TLC-II does not automatically revert to auto rate mode when full signals are re-established, in front panel selectable configuration. Press the mode button on the control panel to resume operation in the auto rate mode once full signals are present.

5.1.2.5 Possible explanations for a full signal alarm include the following:

- Poor VAD filling (i.e., hypovolemia, tamponade, cannula obstruction, RV failure, vacuum too low, etc)
- Electrical lead malfunction (keep spares readily available)
- Electrical lead disconnection
- Full switch failure
- Pneumatic lead disconnected
- Driver malfunction

5.1.2.6 If necessary, the audible full signal alarm can be silenced indefinitely (until another full signal is received) by holding down the silence button for 10 seconds. The red alarm light and messages are unaffected.

5.1.3 Battery Alarms

5.1.3.1 The status of all batteries (Battery A, Battery B, and the emergency battery) are continuously monitored by the TLC-II. Additionally, the status of any battery, whether or not it is installed in the driver, can be determined by pressing the battery test button on the front of each battery.

5.1.3.2 The low battery alarm occurs when the battery voltage drops below a fixed threshold value. The alarm is cleared when the battery voltage rises above a higher fixed threshold voltage.

5.1.3.3 No audible alarm sounds as long as there are two power sources available (in addition to the emergency battery). During change from one battery to another, a single audible beep sounds

5.1.3.4 When either Battery A or Battery B are depleted the following messages are displayed:

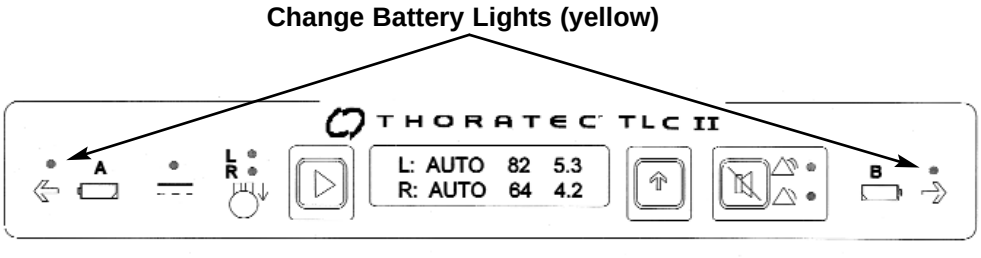

Figure 5.3 *TLC-II Control Panel Change Battery Lights*

"CHANGE BATTERY A"
<<< A

or

"CHANGE BATTERY B"
B>>>

In addition, the yellow change battery light for Battery A or Battery B illuminates. (**Figure 5.3**)

5.1.3.5 If there is only one power source available (in addition to the emergency battery), an audible alarm turns on at 30 second intervals.

5.1.3.6 The audible alarm changes to a continuous alarm when there is approximately 10 minutes, or less, of battery life remaining. An additional message is displayed:

"< 10 MINUTES LEFT"

5.1.3.7 When the emergency battery requires replacement, an audible alarm sounds, the red alarm light illuminates, and the following messages are displayed:

"EMERGENCY BATT"
"REPLACE"

The alarm indicates that approximately 10 minutes, or less, of emergency battery power is remaining. The emergency battery is the same Thoratec rechargeable lithium-ion battery as used for battery A and B. See section 6 for instructions on replacing the battery. Under normal use, the emergency battery should last several months before replacement is required.

WARNING: Always replace the emergency battery with a fully charged TLC-II battery. Press the test button. A fully charged battery has 5 lights on.

5.1.4 Temperature Alarms

5.1.4.1 An audible alarm, and the red alarm light turns on if the temperature of the air compressor is greater than, or less than, a fixed threshold value. The main cause of this alarm is a dirty air intake filter. Keep this filter clean. See Section 6.1.4.

5.1.4.2 The following messages for high temperature are displayed:

"HI TEMPERATURE"
"REPLACE"

WARNING: Do not use a TLC-II Driver if the HI TEMPERATURE alarm is on. Replace this TLC-II with a backup driver as soon as possible.

WARNING: Failure to keep the air intake clean and free from obstruction can cause overheating of the TLC-II. See Section 6.1.4.

5.1.4.3 The following messages for low temperature are displayed:

"LO TEMPERATURE"
"WAIT"

This indicates that the driver is too cold to use. Wait for it to warm up before use.

5.1.4.4 Possible causes of a temperature alarm include:

- Fan malfunctioning or is blocked
- Vents or air intake are blocked
- Motor or compressor malfunction
- Unit still cold from storage in winter conditions
- Thermistor malfunction

5.1.5 Service Interval Alarm

5.1.5.1 Preventive maintenance is required with the TLC-II to achieve the highest reliability. The TLC-II stores the cumulative number of hours the TLC-II Driver has been used since the last service. An alarm is based on the cumulative usage time.

5.1.5.2 To display the current usage hours, press the scroll button once. The driver serial number and the cumulative usage hours are displayed briefly. This information is displayed after any existing alarm messages have been displayed.

5.1.5.3 An audible alarm and the red alarm light are turned on if the air compressor has been used for longer than a defined period, and it is time for preventive maintenance. The following messages appear:

"SERVICE INTERVAL"
"REPLACE"

WARNING: Do not use a TLC-II driver if the service interval alarm is on. Replace with a back-up driver as soon as possible.

5.1.6 Internal Alarms

5.1.6.1 The TLC-II continuously monitors the status of various internal test conditions.

5.1.6.2 An audible alarm and the red alarm light turns on if any of these fail to operate within predetermined specifications.

5.1.6.3 A message is displayed indicating the type of error:

"ALARM 18-22"

In addition, a second message is also displayed:

"REPLACE"

WARNING: Do not use a TLC-II Driver if any of the internal alarms are on. Replace this TLC-II with a backup driver as soon as possible.

5.1.7 Emergency Backup Alarms

5.1.7.1 Whenever the emergency backup system is activated, an audible alarm turns on, and the urgent alarm light turns on. This alarm cannot be silenced. These audible and visual indicators are independent of the main control system.

5.1.7.2 The emergency backup system automatically takes over the electronic control of the TLC-II compressor and VAD operation when all 3 main power sources (battery A, battery B, and External Power) are removed, if the solenoid drive electronics fail, or if the motor drive electronics fail to deliver sufficient air pressure.

5.1.7.3 Although a fully charged battery in the emergency battery compartment can drive the TLC-II for up to 45 minutes, this

should not be relied upon. The emergency backup system is designed for temporary use only. If the problem cannot be quickly resolved, and the emergency backup system and alarms persist, replace with a backup driver as soon as possible.

WARNING: Do not use a TLC-II Driver if the emergency backup system remains on and does not switch over to normal system control. Replace this TLC-II with a backup driver as soon as possible.

5.2 Alarm Thresholds and Indicators

The definition of alarm thresholds that trigger and clear an alarm are delineated in **Table 5.1**, along with the messages displayed on the control panel. "Replace" indicates that the driver should be replaced with a back-up unit as soon as possible.

5.3 Troubleshooting for VAD Filling and Emptying

Complete VAD filling and complete VAD emptying minimize stasis in the VAD and possible VAD thrombus formation. Also, VAD output displayed is accurate only if the VAD pump is filling and emptying completely.

5.3.1 VAD Filling

Complete VAD filling is indicated by the green full light on the TLC-II control panel. For the PVAD, complete filling can also be confirmed by visual inspection of the VAD as a backup method. VAD filling is dependent on adequate preload. Volume loading to increase atrial pressure (preload), or improvement of RV output to the LVAD with medication, may be needed to improve VAD filling.

5.3.1.1 Possible Reasons for Inadequate VAD Filling:

- Hypovolemia
- Bleeding
- Right ventricular failure with isolated LVAD support
- Cardiac tamponade
- Inadequate pharmacologic support
- VAD cannula position
- Insufficient vacuum
- Fixed beat rate too high
- Ejection time too long

Table 5.1 Description of Alarms

Condition	Alarm On	Alarm Clear	Audible Interval	Messages
High L Pressure	≥ 300 mmHg	≤280 mmHg	Continuous	HI L PRESSURE REPLACE
Low L Pressure	≤180 mmHg	≥ 190mmHg	Continuous	LO L PRESSURE CHECK; REPLACE
LVAD Occlusion	Occlusion detected	No occlusion detected	Continuous	LVAD OCCLUSION CHECK LEADS, VAD
Low L Vacuum	≥ +30 mmHg	≤ +25 mmHg	Continuous	LO L VACUUM REPLACE
High L Vacuum	≤ -70 mmHg	≥ -60 mmHg	Continuous	HI L VACUUM REPLACE
No L Full Signal	LVAD full signals missing	LVAD full signal received	Silence during first 8 seconds (approx); then 5 seconds	NO L FULL SIGNAL CHECK LEADS; VAD
High R Pressure	≥ 220 mmHg	≤ 210 mmHg	Continuous	HI R PRESSURE REPLACE
Low R Pressure	≤ 110 mmHg	≥ 115 mmHg	Continuous	LOW R PRESSURE CHECK; REPLACE
RVAD Occlusion	Occlusion detected	No occlusion detected	Continuous	RVAD OCCLUSION CHECK LEADS, VAD
Low R Vacuum	≥ +30 mmHg	≤ +25 mmHg	Continuous	LO R VACUUM REPLACE
High R Vacuum	≤ -70 mmHg	≥ -60 mmHg	Continuous	HI R VACUUM REPLACE
No R Full Signal	RVAD full signals missing	RVAD full signal received	Silence during first 8 seconds (approx); then 5 seconds	NO R FULL SIGNAL CHECK LEADS; VAD
Change Battery A	Low battery A voltage	Acceptable battery A voltage	When only 1 power source, 1 beep every 30 secs. Continuous alarm if 1 power source and less than 10 minutes left	CHANGE BATTERY A <<<A <10 MINUTES LEFT
Change Battery B	Low battery B voltage	Acceptable battery B voltage	When only 1 power source, 1 beep every 30 secs. Continuous alarm if 1 power source and less than 10 minutes left	CHANGE BATTERY B B>>> < 10 MINUTES LEFT
Replace emergency battery	Low emergency battery voltage; approximately 10 minutes remaining	Acceptable emergency battery voltage	Continuous	EMERGENCY BATT REPLACE
High compressor temperature	>= 60 degrees Celsius	< 58 degrees Celsius	Continuous	HI TEMPERATURE REPLACE
Low compressor temperature	<= 0 degrees Celsius	> 2 degrees Celsius	1 second	LO TEMPERATURE WAIT
TLC-II Service	Exceeded recommended Interval hours of usage	Factory or maintenance reset	10 seconds	SERVICE INTERVAL REPLACE
Internal Alarms 18-22	Error condition occurs	Factory or maintenance reset	1 second	ALARM 18-22 REPLACE
Emergency System On	Immediately	Main control system takes over	Continuous (hardware alarm, independent of main system)	EMER SYSTEM ON REPLACE

5.3.1.2 Trouble shooting for poor VAD filling with no hypovolemia, no cardiac tamponade, no right ventricular failure, and adequate pharmacologic support:

- Connect TLC-II to HeartTouch Computer or Mobile Computer and then decrease fixed beat rate until full signal is seen.
- Increase vacuum (maximum vacuum is achieved in fully clockwise position).
- Reduce ejection time, but without compromising complete emptying.

5.3.2 VAD Emptying

The TLC-II accumulator pressures are controlled at fixed values to achieve complete VAD emptying in approximately 300 msec at normal physiological pressures. Should longer or shorter ejection times be required, adjust the ejection times with the HeartTouch Computer or Mobile Computer using the VAD setting screen.

With the PVAD, complete ejection is assessed by the “flash” test. Occasionally inspect the PVAD pump with a flashlight for complete VAD emptying (white flash). Shine a flashlight through the full switch side of the pump at an angle and look for a flash of light coming through the other side. The white flash is not always in the same location.

With the IVAD, complete ejection is assessed by the green light on the signal processor lead or by an “empty” flag on the plot screen (**Figure 5.4**).

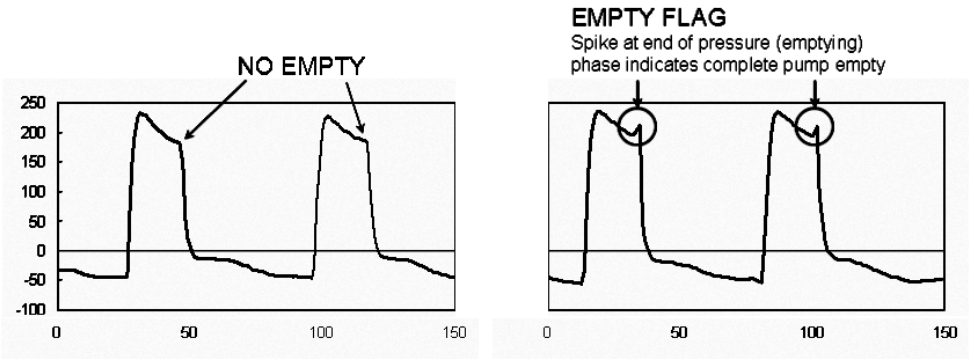

Figure 5.4 *Empty flag on plot screen*

5.3.2.1 Possible reasons for inadequate VAD emptying *(no white flash visible)*

- Systolic pulmonary or arterial blood pressure too high
- Outflow cannula kinked
- Ejection Time too short
- Drive pressure too low

5.3.2.2 Troubleshooting for inadequate emptying:

- Increase ejection time or accumulator pressure. Connect TLC-II to HeartTouch Computer or Mobile Computer and increase eject time and/or pressure. Observe for complete ejection.
- Lower patient's arterial blood pressure or pulmonary pressure (if patient is hypertensive).
- Examine paracorporeal cannulae for kinks.
- Check IVAD signal processor lead connections.
- Examine percutaneous line for kinks.

5.4 Back-Up Procedures

5.4.1 Back-up Driver

A complete Thoratec driver (TLC-II or Dual Drive Console) must be available as a back-up to be used in the event of a failure of the primary driver.

5.4.2 Hand Pumping

Personnel should be trained how to hand pump a VAD in the event of a driver failure. Make sure that there are always 2 hand pumps available in the TLC-II accessory pocket at all times.

If for any reason there is a TLC-II driver failure, blood flow can be maintained to the patient and stasis prevented in the blood pump by disconnecting the VAD pneumatic lead from the TLC-II and connecting it to the hand pump. Squeeze the hand pump about once per second to empty and fill the blood pump. Use your foot if necessary. Connect the VAD to the back-up driver as soon as possible. This procedure is for emergency use only. This part can be ordered from Thoratec as Part Number 14787-2589-000 Hand Pump (one needed per VAD).

6. SYSTEM MAINTENANCE

There is minimal routine maintenance required of the TLC-II, which consists mainly of changing emergency batteries, inspecting filters, and cleaning. The TLC-II also requires preventive maintenance at regularly scheduled service intervals. This consists of refurbishment of the compressor and pneumatics.

6.1 Routine Maintenance

6.1.1 Changing emergency batteries

6.1.1.1 When the emergency battery requires changing, an alarm sounds and a display on the TLC-II front panel shows "EMERGENCY BATT". Alternatively, emergency battery status can be determined by connecting the driver to the docking station and observing a bar graph representing an emergency battery status on the computer screen. A fully charged emergency battery can run the TLC-II system for up to 45 minutes; therefore since the emergency system is not in use during normal operation of the TLC-II, it should last several months before requiring replacement.

6.1.1.2 If the TLC-II is connected to a patient, switch the patient over to a back-up driver (TLC-II or Dual Drive Console).

WARNING: Do not attempt to change emergency batteries while the TLC-II is connected to a patient.

6.1.1.3 To change the emergency battery, make sure the key switch is turned off and that the yellow external power cable is removed from the external power jack.

6.1.1.4 Remove the TLC-II Driver from its nylon carrying case.

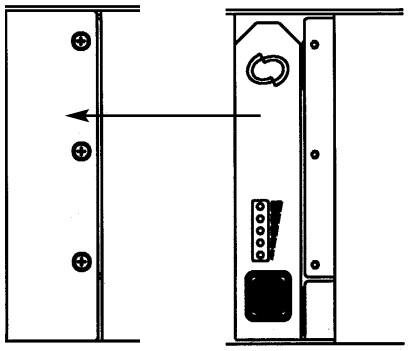

Figure 6.1 *TLC-II Driver Emergency Battery Access*

6.1.1.5 Remove the 3 screws on the bottom of the TLC-II Driver and open the emergency battery compartment (**Figure 6.1**).

6.1.1.5.1 Remove the depleted emergency battery and install a fully charged battery (the connection pins should be inserted into the driver with the status panel showing). Battery should slide easily into slot. If not, check for proper orientation.

WARNING: Install only a fully charged Thoratec TLC-II battery in the emergency battery slot. Press the battery test button on the front of the battery. Five lights indicates the battery is fully charged. Do not attempt to use any other type of battery.

6.1.1.6 Replace the emergency battery cover and tighten the three screws.

6.1.1.7 Replace the TLC-II Driver in the carrying case.

6.1.1.8 Turn the driver on and verify that the Replace Emergency Battery Alarm is now inactive.

6.1.1.9 Recharge the depleted battery in the TLC-II Battery Charger.

6.1.2 Cleaning and Disinfecting

Regularly clean the exterior of the TLC-II Driver, charger, batteries, and docking station with a soft dampened cloth. Dampen the cloth with a mild soap and water solution or a disinfecting agent. Approved disinfecting agents are: carbolic acid solution (Lysol®), methyl or isopropyl alcohol, pHisoHex, and benzalkonium-type detergents. Avoid hard rubbing on driver and charger panels or on the Docking Station Touchscreen.

Caution: Do not use acetone, phenol, ether, or high concentrations of formaldehyde (e.g., Formalin). These agents may damage the equipment or paint.

Disinfect accessory items by a cold soak in Sephiran Chloride according to the manufacturer's directions.

Caution: Never immerse a battery pack or electrical connectors of any device. Also never immerse cables with perforated sheaths.

6.1.3 Cleaning the Touchscreen

Use care when cleaning the touchscreen to avoid scratching or otherwise damaging the screen. Use a non-abrasive household or commercial window cleaner, such as Windex®. Spray on sparingly and wipe off with a clean and dry cloth or paper towel. Disinfect using a clean cloth dampened with isopropyl alcohol.

6.1.4 Cleaning the Air Intake Filter

6.1.4.1 Regularly check the grill on the side of the TLC-II carrying bag to assure that it is free from all dust or obstructions.

6.1.4.2 Look through the grill on the carrying case and inspect the air intake grill on the side of the TLC-II Driver.

6.1.4.3 If required, remove the driver from the carrying case and clean off any dust collecting on the fan intake with a vacuum.

WARNING: Failure to keep the air intake clean and free from obstruction can cause overheating of the TLC-II.

6.2 Servicing

6.2.1 The TLC-II compressor and pneumatics require regular preventive maintenance. When it is time to service the driver, an alarm will sound and the following message is displayed:

"SERVICE INTERVAL"
"REPLACE"

6.2.2 To display the driver cumulative usage time, press the scroll button once on the TLC-II control panel, and the driver serial number and usage hours are displayed:

"S/N XXX"
"USAGE XXXX HR"

Alternatively, connect the TLC-II to the HeartTouch Computer and observe Usage hours on the Technical screen.

6.2.3 Service must be performed only by Thoratec or a Thoratec authorized agent.

6.2.4 To obtain factory authorized service, place the TLC-II Driver into the padded shipping suitcase and return to Thoratec.

6.2.5 The air compressor will be replaced with a refurbished unit, the solenoid valves will be checked and/or replaced, and internal filters will be replaced. The whole system is then retested and returned.

6.2.6 To obtain service, contact Thoratec at the address on the last page of this manual.

7. UNPACKING AND SYSTEM ASSEMBLY

7.1 Docking Station

7.1.1 Remove docking station from shipping crate and remove protective plastic cover.

7.1.2 Remove upper back panel from docking station.

7.1.3 Remove computer from shipping container and remove protective packing.

7.1.4 Place computer on top shelf of docking station and secure it in place with four captive screws.

7.1.5 Open docking station back door, locate the two electrical cables that connect to the computer, insure that they run through the grommeted holes provided, and connect them to the bottom of the computer.

7.1.6 Remove battery charger from shipping box and place on second docking station shelf below the computer. Locate line power cord from docking station and connect to battery charger.

7.1.7 Turn on power switch on back of battery charger.

7.1.8 Re-attach docking station upper back panel.

7.1.9 Close and secure back door of docking station.

7.1.10 Check docking station power inlet module for proper voltage and correct if necessary. Check fuse values if changing voltage selector. For 100 and 120V, use a 5 amp fuse. For 220 and 240V, use a 2.5 amp fuse.

7.2 Charger and Batteries

7.2.1 Follow steps 4.9.1 - 4.9.4 in Section 4.9 (Recharging Batteries) to check out the operation of both sides of the battery charger.

7.2.2 Verify that batteries are being charged and the green ready light comes on at the end of charging.

7.2.3 Press the test button on each charged battery and verify that the battery lights turn on. A fully charged battery has five lights on.

7.3 Driver

7.3.1 Remove TLC-II Driver from shipping case. Save shipping case for future use to ship driver back to manufacturer for preventive maintenance.

7.3.2 Install a fully charged Thoratec TLC-II battery as the emergency battery, following the instructions in Section 6.1.1.

7.3.3 Place driver in nylon carrying case, making sure the control panel can be seen through the window on the top flap.

7.3.4 Place driver in outer bay of the top drawer of docking station.

7.3.5 Install two batteries in driver battery holders, observing proper orientation.

7.3.6 Install power (yellow) and computer (green) cables from docking station to driver.

7.3.7 Make sure two emergency hand pumps are always available in the accessory pocket.

7.3.8 The system should now be ready to be used. Follow instructions in Section 4 for system operation.

7.4 System Check-Out

7.4.1 To check-out the TLC-II Driver and system, follow all steps in section 4.1, which are the steps used when setting up the TLC-II for a patient for the first time.

7.4.2 Simulate different patient settings and verify that the TLC-II responds accordingly.

7.4.3 The TLC-II is now ready for use.

7.4.4 If there are any problems while performing the check-out of any part of the TLC-II System, contact your Thoratec representative immediately.

APPENDIX A
TLC-II TRAINING CHECKLIST FOR STAFF

- ❑ Understands requirements for excursions away from the hospital.
- ❑ Understands patient teaching requirements.
- ❑ Understands the components of the TLC-II System.
- ❑ Able to set up the TLC-ll using the HeartTouch Computer.
- ❑ Able to switch from the Dual Drive Console to TLC-II.
- ❑ Identifies slots for two rechargeable batteries, and successfully replaces the batteries as indicated.
- ❑ Able to successfully recharge batteries with the battery charger.
- ❑ Can accurately estimate the remaining usage time on each battery.
- ❑ Identifies the external power connector and successfully connects the AC adapter to the TLC-II Driver and electrical outlet.
- ❑ Able to appropriately connect the TLC-II Driver to the mobility cart.
- ❑ Able to hear audible alarms, and identify alarm messages on the TLC-II Driver.
- ❑ Understands the meaning of alarms and demonstrates appropriate responses to alarm conditions.
- ❑ Able to successfully switch from the primary TLC-II Driver to back-up driver.
- ❑ Able to successfully use the Hand Pumps for 5 minutes.
- ❑ Able to verify complete VAD ejection.
- ❑ Local emergency medical services notified regarding study.

TLC-II TRAINING CHECKLIST FOR PATIENT/CAREGIVER (Applicable to In-Hospital and Home Discharge Patients)

- ❑ Basic understanding of structure and function of the heart and rationale for VAD implantation.
- ❑ Identifies slots for two rechargeable batteries, and successfully replaces the batteries as indicated.
- ❑ Able to successfully recharge batteries with the battery charger.
- ❑ Can accurately estimate the remaining usage time on each battery.
- ❑ Identifies the external power connector and successfully connects the AC adapter to the TLC-II Driver and electrical outlet.
- ❑ Able to appropriately connect the TLC-II Driver to the mobility cart.
- ❑ Able to hear audible alarms, and identify alarm messages on the TLC-II Driver.
- ❑ Understands the meaning of alarms and demonstrates appropriate responses to alarm conditions.
- ❑ Able to successfully switch from the primary TLC-II Driver to back-up driver.
- ❑ Able to successfully use the Hand Pump(s) for 5 minutes.
- ❑ Able to successfully use and operate the Car Power Adapter.

Signature (patient): _____ Date: _____

Signature (caregiver): _____ Date: _____

Trainer's Signature: _____ Date: _____

HAND PUMP TRAINING

OBJECTIVE: To demonstrate ability to successfully use the Hand Pumps on the TLC-II Portable VAD Driver.

EQUIPMENT: TLC-II Portable VAD Driver
Two (2) Hand Pumps with Quick Connects
Mock Loop

MOCK LOOP SETUP:

1. Connect TLC-II driver to VAD on mock loop. Set driver to fixed rate of 60 bpm with a 300 msec eject time.
2. Adjust mock loop pressures to attain arterial pressures of 90-110 mmHg and atrial pressures of 10-20 mmHg. Follow mock loop operating instructions as necessary.

INSTRUCTIONS: Follow the instructions in Section 5.4.2 of the *TLC-II Instructions for Use Manual* (or Section 6.2 of the *TLC-II Patient Guide Manual*).

SUCCESSFUL COMPLETION OF TRAINING:

1. Disconnect pneumatic lead(s) from TLC-II Driver and connect to Hand Pump(s).
2. Maintain a VAD pump rate of approximately 60 bpm for five minutes.
3. Reconnect pneumatic lead(s) from Hand pumps to the TLC-II Driver.

NOTE: Clinical and technical staff must complete training with two hand pumps (BiVAD support). Patients and caregivers must complete training with one or two hand pumps, depending on patient VAD support.

TRAINING CHECKLIST FOR TLC-II HOME DISCHARGE PATIENTS/CAREGIVER

- ❑ Completed all checklist items for TLC-II Training (Applicable to In-Hospital and Home Discharge patients).
- ❑ Able to change dressings at cannulae exit sites using sterile technique.
- ❑ Understands prohibitions against total body submersion (swimming, bathing), steam or dry sauna baths, and participation in contact sports.
- ❑ Understands prohibitions against the use of solvents and other chemicals on or around the VAD and the possible consequences.
- ❑ Understands the care of the VAD pneumatic and electrical leads and cannulae.
- ❑ Able to successfully change the electrical lead between TLC-II Driver and VAD.
- ❑ Able to successfully change the pneumatic lead between TLC-II Driver and VAD.
- ❑ Understands how to perform the "flash test" to confirm complete ejection of the VAD.
- ❑ Understands importance of taking medications as prescribed.
- ❑ Knows when to contact hospital staff and/or emergency medical services.

Signature (patient): _____ Date: _____

Signature (caregiver): _____ Date: _____

Trainer's Signature: _____ Date: _____

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