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OTHER SUGGESTED REFERENCES

a. Thoratec® Ventricular Assist Device (VAD) System Instructions for Use (Document No. 15003)
b. Thoratec® Ventricular Assist Device Console Operation with Illustrations (Document No. 14803)
c. Patient Management Manual (Document No. 14577)
d. Thoratec® Ventricular Assist Device Dual Drive Console (Videotape No. 14805)
e. Thoratec® VAD System Surgeon Implantation Procedure (Videotape No. C049-1001)
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INSTRUCTIONS FOR USE

1. GENERAL INFORMATION

1.1 INTRODUCTION TO THE THORATEC® VAD SYSTEM

The Thoratec® Ventricular Assist Device (VAD) System 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). 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 blood pumps are driven by a dual drive console providing alternating pulses of pressure and vacuum to empty and fill the blood pump.

![Figure 1.1 Cannulation Approaches for the Thoratec® VAD]

A. Univentricular left heart support; B & C. Biventricular support
( A0 = 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 the LA roof.)
1.1.1 Components

The Thoratec® VAD System consists of three major components (see Figure 1.1): (1) blood pump, (2) cannulae, and VAD dual drive console (shown in Figure 1.6). Each component is described in detail in the following sections.

Blood Pump

The VAD blood pump is a prosthetic ventricle consisting of a smooth, seamless pumping chamber made of Thoratec's Thoralon, a proprietary polyurethane multipolymer, enclosed in a rigid polysulfone case (Figure 1.2). Two mechanical valves maintain unidirectional flow through the blood pump. The pumping chamber is separated from the air chamber by a polyurethane diaphragm. The diaphragm serves as both a volume limiter and safety chamber. Silicone oil lubricates the surface to prevent abrasion where the diaphragm contacts the blood sac.

A small magnet is mounted on a small polyurethane diaphragm located on the side of the air chamber opposite the blood chamber. Movement of this magnet is monitored by a Hall effect switch built into the case of the VAD. This switch determines when the VAD is full of blood, sending a fill signal to the drive console. The Hall effect switch is attached to an electrical lead, which is bundled with the pneumatic lead. The two leads are separated at a connector approximately 2 inches from the blood pump.
The pneumatic lead is 1/2 inch outside diameter, 1/4 inch inside diameter, and is 12 feet long when used with the DDC. For DDC use, the electrical lead is also 12 feet long. The pneumatic and electrical leads are attached to the drive console.

**Cannulae**

Blood is pumped from the VAD to the patient by arterial cannulae which are Thoralon tubes with a smooth, blood-contacting surface attached to a low porosity woven polyester graft (Figure 1.3). 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 the cannula is covered with polyester velour.

![Figure 1.3 Sealed Arterial Cannula](image)

Blood is brought from the patient to the VAD blood pump by either an atrial cannula (Figure 1.4) or a ventricular apex cannula (shown in Figure 1.5). The atrial cannula is made from a 51 French polyvinylchloride cannula coated inside and out with the same Thoralon used in the blood pump and arterial cannulae. The atrial cannula has a cage at the tip, and the proximal end of the cannula, where it enters the atrium, is formed at a 90 degree angle.

![Figure 1.4 Atrial Cannula (Catalog #10075-2574-001 and #10075-2573-001)](image)
For bridge to cardiac transplantation, it is usually preferable to cannulate the patient's left ventricular apex. For this purpose, the VAD is attached to a ventricular apex cannula, which is also made of Thoralon. The metal sleeve reinforced apex tube is inserted into the patient's left ventricle. The cannula is covered with polyester velour at the point where it exits the patient's body.

See Appendix A of the Thoratec® VAD System Directions for Use for more detailed descriptions of the various cannula configurations.

Figure 1.5 Ventricular Cannula with Two Side Holes (Catalog #14111-2571-000)

**Dual Drive Console**

The Thoratec Dual Drive Console supplies air pressure to compress the blood sac and drive the blood into the arterial system during the ejection period. Air is supplied in cycles, with each ejection period alternating with a filling period. During the filling period, the drive console supplies a slight negative pressure (vacuum) to the air chamber. The range of acceptable beat rates is 20 to 150 beats per minute (bpm) while the normal operating range is approximately 50 to 100 bpm.

The Dual Drive Console has two independent drive modules, each of which is designed to drive one ventricle. There are four compressors in the drive console, two for each drive module. One compressor supplies air pressure to one module while another compressor supplies negative pressure. Outside sources of positive and negative pressure, such as hospital house air, may also be used in place of, or as backups to, the compressors. Each Dual Drive Console has a uninterruptible power supply ("UPS") System which is used to supply power to the compressors during patient transport and also serves as short-term emergency backup.
Positive and negative pressure levels are controlled by two pressure regulators on each module. Pressure gauges measure the pressure available from accumulator chambers in each module. In addition to these two analog monitors, there are a number of digital monitors. These monitors provide information on the rate, percent systole (percent of cycle length used for ejection), eject time (in milliseconds), stroke volume (which is estimated, not measured), blood pump output (calculated from the pumping rate times the estimated stroke volume), peak ejection air pressure, and lowest negative air pressure during filling.
Also providing information are a number of status lights. There are amber lights to indicate whether the system is operating from its batteries or from an alternating current source. There are green lights to indicate complete VAD filling (in any mode), to indicate reception of a valid external synchronization signal, and to indicate when the system is in the eject or fill portion of its cycle (when it is in the manual mode). Alarms are indicated with red lights which are set to notify the operator of inappropriate air pressure or vacuum, loss of a valid external synchronization signal, or low battery level. An audible alarm is activated whenever any of the appropriate alarm conditions occur.

A touchpad keyboard on the front of each module controls the following features: pump on, pump off, mode of operation, rate and ejection percentage in the asynchronous mode, millisecond delay in the external synchronization mode, the audible alarm, backup rate and ejection percentage, and calibration of the pressure monitor.

The drive console operates from alternating current supplied via an isolation transformer. In the event of AC power failure or during patient transport, self-contained battery subsystems provide the power necessary to operate the drive module electronics. In the event of a single module failure during patient use, there is an Emergency Selector Valve that allows one module to drive both Drive Lines (see Section 2.4, page 27).
1.1.2 Principles of Operation

The Thoratec® VAD System can provide pulsatile blood flow at normal circulatory pressures in patients who have acute cardiac failure. In clinical practice, a full 65 ml effective stroke volume is possible at any rate from 20 to 110 bpm (depending on the cannulae used and the size of the patient), which means an output ranging from 1.3 to 7.1 ℓ/min.

The Thoratec® VAD is designed to support the circulation of blood in the pulmonary and/or systemic circulation when the natural heart, with the help of standard drug therapy and intra-aortic balloon counterpulsation, 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 (set by the operator), the air chamber is either vented to atmosphere or to a vacuum source, which allows the air to escape from the air chamber and blood to fill the blood chamber.

Four different methods are used to control the VAD. These methods, or modes, of operation are described below.

Asynchronous. In this mode, the operator chooses a particular rate and percent systole and the drive console maintains that pumping rate until the operator changes it. This mode is often used to wean the patient from extracorporeal circulation to the VAD when starting a case, and is often used to wean the patient from the VAD after recovery of the natural ventricle. This method is a fixed rate, variable stroke volume mode of operation. The driver automatically uses this mode if none other is chosen.

Volume. 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. This mode is a variable rate, fixed stroke volume method of operation and is also referred to as the full-to-empty mode. The instant the blood pump is filled with blood, the VAD fill switch signals the driver to begin ejection. The rate varies with changes in preload to the pump. If the preload (atrial pressure in most cases) increases, the pump fills faster and thus ejection begins sooner, which increases the rate. In the same way, the rate decreases as atrial pressure decreases.

External synchronous. In this mode, any outside electrical signal can be brought in to the drive console to end ejection. Typically, this signal is an R-wave synchronization signal from the electrocardiogram. In this operating mode, the blood pump provides counterpulsation, including a programmable delay, similar in manner to an intra-aortic balloon pump. It can provide one beat of the blood pump for every beat of the natural ventricle, or for every second, third, or fourth
beat of the natural ventricle. This mode is a variable rate, variable stroke volume mode.

**Manual.** This method is only used for certain diagnostic procedures. In this mode, the operator of the VAD pneumatic drive console can use one key entry to change VAD operation from fill to eject at any time.

The VAD filling and ejection phases are illustrated in Figure 1.8, which shows schematically the relationship among blood pump volume and pressure from the left atrium, aorta, and drive line during one cycle. During the filling phase, the pressure driving flow into the blood pump is provided from the left atrium (around 10 to 15 mm Hg), usually assisted by vacuum set at -25 to -40 mm Hg on the drive console. Drive pressure during ejection is usually set to about 230 to 245 mm Hg to fully empty the blood pump during the allocated ejection time of 300 msec. Filling duration is longer than ejection duration (e.g., 30 percent ejection, 70 percent filling as shown in Figure 1.8) because it is harder to fill the blood pump than to empty it.

![Figure 1.8 Idealized VAD Volume and Pressure During Filling and Ejection. VAD drive pressure and vacuum (P_{VAD}) are set to provide a pressure gradient during filling from the left atrium (LAP) and during ejection to the aorta (AoP).](image)

Two approaches to achieve complete filling are: (1) to increase the inflow pressure gradient by applying more vacuum or by increasing the left atrial filling pressure, perhaps by volume loading the patient or by improving right ventricular flow output through the lungs to the left atrium; and (2) to lengthen the filling duration by slowing the set rate or decreasing the percentage of the cycle length used for ejection (however, as described in Section 2, to allow sufficient time for complete ejection it is recommended not to go below an eject time of 300 msec).

The net flow output of the VAD is determined by the VAD rate times the stroke volume; e.g. 60 bpm times 65 ml equals 3.9 L/min. Maximum flow is achieved...
when the blood pump fills and empties completely, with no time lost between phases of the cycle. The VAD can never pump more net flow than returns to it and, for that reason, biventricular assist devices are often needed to ensure adequate flow through both sides of the circulation.

During use, the VAD is generally controlled with the volume (full-to-empty) mode. Filling is aided by a negative pressure of about -25 mm Hg. Positive pressure is set at least 100 mm Hg above peak systolic arterial pressure, which will eject the blood from the pump in approximately 300 msec.

Implantation and removal of the Thoratec® VAD involves standard surgical procedures, which are described in the Thoratec® Ventricular Assist Device System Directions for Use.

1.2 **CAUTIONS**

**USE OF APPROVED COMPONENTS.** The Thoratec® VAD and Drive Console have been developed, tested, and approved as a System. Use of the Drive Console is authorized only in conjunction with related equipment described in this document and in the Thoratec® Ventricular Assist Device Directions for Use.

**AIR SUPPLY.** Air supplied to the driver through the Auxiliary Pressure inputs must be clean, dry, and at the proper pressure. See Section 1.4 for specifications. In any case, supply pressure must never exceed 50 psi (3.3 bar).

**ALARM.** Turning off or clearing the audible alarm has no effect on the condition causing the alarm. Investigate and correct the cause of any alarm.

**BACK-UP.** Each console contains two independent drive modules, and therefore contains adequate built-in back-up capability for univentricular support. For patients receiving biventricular support, a complete dual drive console must be available as a back-up to be used in the event of a failure of the primary console.

**CALIBRATION.** Turning the Calibration On/Off switch (on the module back panel) does not affect VAD pumping. The Calibration On/Off switch must be turned off after calibration to preserve new pressure calibrations and to return to normal keyboard function. Automatic switching from battery to AC or vice versa does not require recalibration.
ELECTRICAL SAFETY. The drive console is designed to meet AAMI/NFPA electrical safety requirements. Avoid potentially dangerous electrical shock hazard by always connecting the power cord to an approved, three-wire AC power receptacle. Never attempt to remove or defeat the electrical ground. The following table lists locations and sizes of the fuses and circuit breakers used in the console:

<table>
<thead>
<tr>
<th>Fuse or Circuit Breaker Location</th>
<th>Dual Drive Console Model No.</th>
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<tr>
<td>Console Rear Panel</td>
<td>15 A, 125 VAC circuit breaker</td>
</tr>
<tr>
<td>Module Rear Panel</td>
<td>1A, 250 V, 3AG slow blow fuse</td>
</tr>
<tr>
<td>Module Battery Charger</td>
<td>3/4A, 250 V fast blow fuse</td>
</tr>
<tr>
<td>Module Battery (on hold-down bracket)</td>
<td>8A, 32 V, 3AG</td>
</tr>
<tr>
<td>UPS (Uninterruptible Power Supply)</td>
<td>FNQ-R-10, 600V time delay</td>
</tr>
<tr>
<td>Uninterruptible Power Supply Battery Pack</td>
<td>KTK-R-30, 600V fast acting</td>
</tr>
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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.

EXPLOSION HAZARD. Do not operate the drive console in the presence of flammable anesthetics or other flammable gases.

PATIENT SAFETY. Verify that all VAD pneumatic and electrical connections are in place, secure, and connected to the drive module in use before attempting to operate the system. Open the vacuum vent (module back panel) when no vacuum is desired. If the vent is closed, it occludes the air exhaust path to allow the vacuum pump to create a negative pressure. Depending on the position of the vacuum regulator on the front panel, this may cause positive pressure in the VAD chamber and can limit filling and reduce blood flow. Do not apply excessive vacuum to the VAD while the patient's chest is open; it can result in air being drawn into the circulatory system.

EXTERNAL ALARMS. The VOLUME mode is the recommended control mode for most patients. This is the only control mode where both audible and visual alarms on the Dual Drive Console (triggering on the absence of the VAD fill signal) are present if the VAD were to cease to operate due to adverse scenarios such as blockage of the pneumatic drive or cannulae. Any patient supported with the VAD drive console in the ASYNC or EXT SYNC modes must have the external alarm output on the drive console connected to the hospital nurse call system, or other similar external alarm system. This alarm output will trigger the external independent alarm after an 8 second absence of the VAD fill signal, thus alerting the user to check the VAD and drive console to determine that they are operating properly. This alarm is available in all control modes, but is not required when using VOLUME mode since internal audible alarms are present in that mode.
PATIENT TRANSPORT. The transport systems are designed for short-term use only. The battery operated UPS will drive the compressors and vacuum pumps less than 40 minutes. An alarm sounds and a red light on the UPS status panel lights when the battery capacity is within about 3 to 5 minutes of shut-off. The electronic controls of the modules will operate for several hours if the on-board battery is in good condition and fully charged. The red Low Battery light on the console front panel indicates that there is only enough power to operate for about 30 minutes.

STORAGE. The Dual Drive Console must be connected to an active AC outlet during storage to ensure maximum battery life. The console main power switch located on the panel in the console rear door must be on, and the UPS power switch must be on. In addition, the module Power switch (Operation/Battery Charge on older units) on the back panel of each module should be in the OFF (Battery Charge) position, and both compressor/vacuum pump switches should be off.

Damage to the battery backup systems may result if the batteries are not kept fully charged. If this should occur, the console would be operational in the AC power mode only.

CLEANING. Exercise extreme care in cleaning the console. DO NOT soak any item during cleaning or disinfection. DO NOT allow water or solvent to come in direct contact with electrical connectors.

ENVIRONMENT. Keep the DDC dry. Protect from shower, baths, rain, and liquid spillage.

BATTERIES. Do not incinerate batteries. Explosion or rupture of battery may occur. Do not discard batteries. Return batteries to Thoratec for disposal. Used batteries are hazardous waste. Do not let batteries get wet. Do not drop batteries or subject them to shock. Batteries should not be disassembled or modified. Do not allow necklaces, chains, or other metallic items to come into contact with the terminals.

1.3 CONTRAINDICATION

Never attempt to use the drive console as an intraaortic balloon pump or for any use other than that specifically indicated in the operating instructions.
1.4 SYSTEM SPECIFICATIONS

These safety standards only apply to Models 2600, 2601, 2602:

IEC 60601-1: 1998
IEC 60601-1-2: 2001
EN 60601-1-2: 1993
CSA C22.2 No. 601.1; UL2601-1 and IEC 601-1

The DDC also complies with the following standards:

Emission: CISPR 11 Class B

Immunity: MIL-STD-461D RE 101
          MIL-STD-461D CS 114
          MIL-STD-461D RS 101
          IEC 801-2
          IEC 801-3
          IEC 801-4
          IEC 801-5

Special precautions are required for installing and using the DDC in environments without exceeding the levels specified above.

Dimensions
Length  76.2 cm (30 inches)
Width   59.7 cm (23.5 inches)
Height  129.5 cm (51 inches)
Weight  231 kg (450 pounds)

System Power Requirements
Model 2600 110-120 VAC, 60 Hz, 15 amps
Model 2601 230 VAC, 50 Hz, 7.5 amps

Environmental Conditions
Operating
Temperature  +10° to +40 °C
Pressure     700 to 1060 mBar (525 to 795 mm Hg)
Humidity     5 to 80 percent

Storage
Temperature  0° to +40 °C
Pressure     700 to 1060 mBar (525 to 795 mm Hg)
Humidity     5 to 80 percent
Output Range
- Drive Rate: 20 to 150 bpm
- Percent Systole: 20 to 70%
- Drive Line Pressure: -100 to 250 mm Hg
- Drive Line Air Flow: 24 ℓ/min maximum

Input/Output Signal Characteristics
- Ext. Sync In: Triggers on rising edge of a positive pulse amplitude of 1.0V to 12V, with a rate of 20 bpm to 150 bpm
- Fill Switch In: VAD Hall-effect switch
- Drive Pressure Out: 000 mm Hg = 1.0 VDC, 250 mm Hg = 3.5 VDC
- Fill Signal Out: VAD empty and filling = 5 VDC, VAD full = 0 VDC
- External Alarm Out: Maximum 30 VDC, 25 VAC rms, at 250 ma, resistive load; normally open or normally closed (switch selectable); alarms when no fill switch signals are received from the VAD for 8 seconds or longer.

External Pressure/Vacuum Connections
- External Pressure: 7 to 10 psi (0.5 to 0.7 Bar) (clean and dry)
- External Vacuum: -100 mm Hg (-0.15 Bar)

1.5 CLASSIFICATION OF DDC
- Class 1 Equipment
- Type CF Equipment
- Internal-powered Equipment when powered by UPS
- The DDC is intended for CONTINUOUS OPERATION
1.6 LIST OF SYMBOLS

Alternating current

Type CF equipment

Attention, consult ACCOMPANYING MANUAL

Protective Earth (ground)
2. DESCRIPTION

The Pneumatic Dual Drive Console has two independent drive modules. The modules share some internal systems, such as the compressor tray, the uninterruptible power supply, and the console back door panel.

2.1 SOFTWARE

All software necessary to operate the system is stored on EPROMs (IC chips). The software version number is displayed in the **Set Value** display upon pressing the hidden button between the **Async** mode button and the **Set Rate** button. Version 3.21 is the current software version.

2.2 MODULE FRONT PANEL

The drive module front panel has two main functions: data and status display, and operator input (Figure 2.1). The displays include digital information about pumping parameters and status indicators for verifying various modes of operation. To change pumping and mode parameters, depress the pressure sensitive keys on the panel. An audible signal sounds when you press any key. Look at the display to verify that your selection is correct before making a change by pressing "Enter" for **Set Value** changes. In addition, drive pressure and vacuum can be adjusted using the regulator knobs on the front panel while observing the drive pressure and vacuum on the analog gauges.

**NOTE:** **Mode** changes occur when pressing an unlit key. "Enter" is not required.

![Figure 2.1 Drive Module Front Panel](image-url)
The front panel is divided into five sections: **Modes, Set Value, Monitors, Indicators, and Pressure** and **Vacuum**.

### 2.2.1 Modes

The three mode control keys, outlined by a white rectangle, are in the lower left corner of the front panel. The three mode keys are **Async**, **Volume**, and **Ext Sync**. The light in each mode key lights when you select that mode, and the mode selected will react immediately.

**Async.** The asynchronous mode allows you to control VAD operation by entering the desired parameters in the **Set Value** section. In this mode, the VAD is not synchronized with the patient or any outside source. VAD rate and percent systole depend solely on the **Rate** and **Systole** values you enter or the default values of **Rate** = 60 beats/min and 30% **Systole**.

The driver automatically uses the **Async** mode if you do not select a mode. If the conditions required for operating in another mode are not met, the driver will automatically use the settings for the **Async** mode.

**Volume.** In the **Volume** mode, a variable rate, full-to-empty operation of the VAD is achieved. The Hall effect switch mounted on the VAD housing senses when the blood chamber is filled with blood and the signal from this fill switch triggers ejection. This end of fill is indicated by the green fill light indicator. Ejection duration is controlled by the set % **Systole** value, which is calculated as a percentage of the set rate cycle duration. Actual pumping rate and actual % **Systole** are then variable, depending on the length of time it takes the VAD to fill. If the actual pumping rate drops (fill time increases) to the **Set Value Rate**, the **Set Value Rate** becomes the minimum pumping rate and the audible alarm
sounds and the red sync alarm light comes on, indicating loss of fill. This automatic switching ensures a minimum (operator selected or default) pumping rate. The Volume mode will again control if the VAD fill time decreases, allowing a pumping rate higher than the Set Value Rate.

**Ext Sync.** The Ext Sync is a dual function key. In the Ext Sync (external synchronization) mode, the VAD operates in synchrony with the patient's R-wave of the electrocardiogram. To use this mode, you must supply the drive module with a QRS sync pulse from an EKG monitor. The system triggers on the leading edge of an input pulse of 1.0 to 12 volts. A loss of the external sync signal will result in the driver reverting to Async set rate, the audible alarm will sound, and the red sync alarm light will turn on. Time delays may be introduced in the Ext Sync mode using the Set Value Delay Key.

You can also use the Ext Sync mode to pump the VAD intermittently. The intermittent function allows the VAD to cycle with every R-wave from the patient, or every second, third, or fourth R-wave.

### 2.2.2 Set Value

The Set Value section contains keys that allow you to control basic VAD functions:

- **Pump On** — Pump start and stop
- **Enter** — Enter data
- **Rate bpm** — Pumping set rate
- **Systole %** — % of the Set Rate cycle length used for ejection
- **Delay** — Timing with respect to an R-wave
- **Clear** — To clear wrong entries or to silence audible alarm
- **1 through 0** — Number pad

![Set Value Area of Drive Module Front Panel](image)

Figure 2.3 Set Value Area of Drive Module Front Panel
Pump On. **Pump On** is a dual function key that allows you to start and stop VAD pumping. **Pump On** should come up in the "on" position when power is supplied to the module.

**Enter.** Use **Enter** to initiate a selected function or value. The system does not recognize any selections (except **Pump On**) until you press this key. This feature allows you to verify and, if necessary, correct your selections before initiating them. If values are entered outside of preprogrammed ranges, the **Set Value** display will show EEE.

**NOTE:** Although the pump responds immediately to entered selections, the monitor displays are updated on every fourth beat and are an average of the past four beats.

**Start Pumping**  
Check that the **Pump On** light is lit and that the pressure gauges are fluctuating.

**Stop Pumping**  
Press **Pump On**. The **Pump On** light should flash, indicating that the system is in the stop pumping mode, but still pumping. Press **Enter** to stop pumping. The light will go out, indicating that pumping has stopped.

**NOTE:** Pressing any key besides **Enter** aborts the stop pumping message, and the system continues pumping. (Pump on light stops flashing and stays on.)

**Manual Pumping**  
With pump off, press Set Value **Rate**, **Clear**, and **Enter**. Now each time **Enter** is pressed, the VAD alternately changes from the fill position to the empty position, as indicated by the **Eject** and **Fill** status lights. The eject position is also indicated by -E- in the **Set Value** display and the fill position is indicated by "---" in the **Set Value** display. To resume normal pumping, select the desired mode and press **Pump On**.

---

**CAUTION**

The module automatically switches to battery operation when AC power is removed, so the module remains on when the main power switch is turned off or the console is unplugged. Turn the module off by switching the **Power** switch to **Off** (or **Battery Charge** on older units), which turns off everything in the module except the battery charger. This allows the module battery to be recharged when the console is connected to an AC power source and the main power switch turned on.
Clear. Use **Clear** to delete information set in the keyboard, but not yet entered in the system. You can also use **Clear** to remove values shown in the **Set Value** display. A third use of **Clear** is to silence any alarms that sound.

**CAUTION**
Pressing **Clear** to silence the alarm does not correct the cause of the alarm.

Rate. Press **Set Value Rate**, the appropriate number keys, and **Enter** to change the VAD pumping rate. You can use values from 20 to 150 bpm. Values outside this range will be rejected, as indicated by an EEE in the display. An entry that results in an EEE display does not change the operating rate. The **Rate** you enter becomes the minimum rate of VAD pumping in the **Volume** mode and **Ext Sync** mode. If no rate is selected and entered, the module will run at the default rate (60). Note that in the **Volume** or **Ext Sync** modes, the actual monitored rate (see 2.2.3) can be greater than, but never less than, the set rate.

Systole. Use **Systole %**, the appropriate number keys, and **Enter** to change the percentage of the set rate cycle length used for emptying the VAD. You can enter values from 20 to 70 percent. Values outside this range are rejected by the system, as indicated by an EEE display. Entering a value that results in EEE does not change the operating value. If no value for **Systole** is entered, the system will use the default value of 30 percent. Note that in the **Volume** mode the monitored % systole can be greater than, but never less than, the set value % systole. For most cases, the % **Systole** should be one half of the **Set Rate** value, which will result in a constant 300 msec eject time.

Delay. **Delay** is a dual function key that allows you to delay from the end of ejection to the next R-wave, and allows the audible alarm to be delayed. In the **Ext Sync** mode, use **Delay**, the appropriate number keys, and **Enter** to set or change the delay time, in milliseconds, from the end of ejection to the next anticipated R-wave. You can use values from 0 to 250 milliseconds. Values above 250 will be rejected by the system and EEE will appear in the display. A value that causes an EEE display does not change the delay. If you do not enter a delay value, the system will use the default delay of 000.

**Delay** key can be used to delay the audible alarms produced from losing the fill signal in the **Volume** mode, or losing the external sync signal in **Ext Sync** mode. To use this feature, press **Delay**, 999, **Enter**, then the number of minutes (0-9) desired for alarm disable. The minutes remaining will count down in display. The default alarm delay is 0.
2.2.3 Monitors

The three digital monitors -- Rate and Systole, Stroke Volume and Output, and Eject and Fill -- give current information about VAD operation. The keys above each display allow you to select which data you want displayed. The light on each key lights to identify the information selected. All displays are updated every fourth beat.

![Figure 2.4 Front Panel Monitors](image)

Rate and Systole. This display provides information about the actual VAD rate in beats per minute (bpm) or the percentage (fraction) of the VAD cycle devoted to ejection. The display value represents data averaged over the past four beats.

NOTE: The actual rate can be higher than the set rate in the volume mode or sync mode.

![Figure 2.5 Percent Systole (left) and Eject Time in msec (right)](image)

Ejection Time Display. When Systole information is selected, pressing the Systole monitor key again will display ejection time, converted to msec, for the remainder of the display update period of four beats. A display of 000 indicates an eject period greater than 1 second (1,000 msec). The ejection time is also displayed when pressing the "hidden" button located between the Volume mode button and the Set Value Systole % button. If the eject period is greater than 1 second (1,000 msec), the "hidden" button displays only the last three digits (e.g. 1,500 msec is displayed as 500).
Stroke Volume and VAD Output. This display indicates the volume of blood in milliliters being ejected from the VAD during each cycle (Stroke Volume); or the flow rate of blood, in liters per minute, the VAD pumps each minute (VAD Output).

NOTE: With the Thoratec® VAD the stroke volume is estimated to be 65 ml, but this estimate is correct only if the VAD is filling and emptying completely. Accordingly, VAD Output is also an estimate which is based on the multiplication of stroke volume times rate. For example, in Figure 2.6, at a rate of 80 bpm, the calculated VAD output = 80 bpm X 65 ml = 5200 ml/min = 5.2 liters per minute.

A value for stroke volume and VAD output is displayed only if the console determines that the VAD is filling and emptying completely using the following criteria:

1. VAD fill switch signal received (Fill switch Status indicator on)
2. Maximum drive pressure greater than 100 mm Hg
3. Ejection time greater than 250 msec

If any of these conditions is not met, -E- will be displayed. However, pressing VAD Output a second time will display 65 ml times the rate for the remainder of the display update period of four beats.

Warning: The value displayed after pressing VAD output a second time does not represent an accurate VAD output if -E- is redisplayed.
Eject and Fill. This display provides information about the pressure and vacuum in millimeters of mercury (mm Hg) applied to the VAD to accomplish pumping action. **Eject** indicates the peak pressure during VAD ejection. **Fill** indicates peak vacuum during VAD filling. If the calibration switch, located on the module rear panel, is in the on position, then the **Eject** and **Fill** will display pressure values applied to **Calibration** port. The **Eject** or **Fill** indicator light will also flash as a reminder that the **Calibration** switch is on. In normal operation, the eject pressure should be at least 100 mmHg greater than systolic blood pressure.

**NOTE:** The values in this display are peak values averaged over four beats. Due to point of measurement near the drive line connector port, they are more indicative of pressures applied to the VAD than the analog gauges.

### 2.2.4 Indicators

The **Status**, **Alarm**, and **Power** indicators provide specific information about drive module operation.
Status. Fill status lights when the VAD is completely full and remains on for part of the eject cycle.

Eject status light is used in the manual mode to indicate the eject position.

The Ext Sync status light indicates when each valid pulse is detected.

Alarm. The red Pressure, Vacuum, Sync, and Low Battery alarms indicate specific alarm conditions. Immediately correct the condition causing the alarm. All alarms are accompanied by continuous beeping.

Pressure. The Pressure alarm, which is accompanied by continuous beeping, indicates that the pressure to the VAD is outside the operating range of 100 to 250 mm Hg. Action Required: Examine the pressure gauge and adjust the pressure regulator as necessary. The alarm will shut off automatically when the pressure is within the optimum range. Recalibrate the pressure transducer if required.

Vacuum. The Vacuum alarm, also accompanied by continuous beeping, indicates that the vacuum is outside the operating range of +4 to -99 mm Hg. Action Required: Check the vacuum gauge and adjust the vacuum regulator as necessary. The alarm will shut off automatically when the vacuum is within the optimum range. Rezero or recalibrate the pressure transducer if required.

Sync. When in Volume mode, the Sync alarm indicates that no fill switch signal was received in the allotted time for filling (-E- will be displayed instead of VAD output). Action required: Make sure the fill switch cable is connected correctly and is not broken. Consider increasing the vacuum or adding volume to the patient to improve filling. Try lowering the Set Rate to increase the cycle length and thus the allotted time for filling. Another possibility is that there is a cannula obstruction in the heart that could be relieved by readjustment.

In Ext Sync mode, the Sync alarm will indicate loss of Ext Sync signal, or a signal with a rate out of range (i.e., rate below the set rate or above 150).

Low Battery. This indicator means that the battery backup system will operate the drive module for less than 1/2 hour. Action required: The module battery may need to be recharged or replaced.

Power. AC -- This light is illuminated when the module is receiving electricity from standard alternating current utility power. Battery -- This light flashes when the module is receiving power from the internal rechargeable battery.
2.2.5 Pressure and Vacuum

The Pressure and Vacuum gauges indicate the regulated pressure and vacuum available in the accumulators to pump the VAD. They do not indicate the actual amount applied to the VAD. The gauges are a guide to setting approximate values. Use the regulator control knobs below the gauges to adjust pressure and vacuum.

![Figure 2.9 Pressure and Vacuum Gauges (top) and Regulators (bottom)](image)

2.3 MODULE BACK PANEL

The back panel of each drive module contains a number of electronic and pneumatic switches and connectors (Figures 2.10 and 2.11). Some of the connectors are connected during manufacture to external counterparts located on the drive console back door panel.

![Figure 2.10 Drive Module Back Panel](image)
Figure 2.11  Back Panel Pneumatics

CAUTION
Do not change or remove connections on Module Back Panel.

2.3.1 Pneumatics

The pressure and vacuum inputs are on the left side of the back panel. The two vacuum inputs are Vacuum Input and Aux Vacuum Input. The two pressure inputs are Pressure Input and Aux Pressure Input. Auxiliary inputs are used for connecting other pressure and vacuum sources, such as house vacuum or compressed air to the driver. Auxiliary inputs are in parallel with the main inputs and the driver automatically uses the strongest source.

Vacuum Inputs. The Vacuum Input is connected to the compressors inside the console. The Aux Vacuum Input is connected to the console back door.

Pressure Inputs. The Pressure Input is connected to the compressors located inside the console. Aux Pressure Input is connected to the console back door. Auxiliary pressure should be supplied clean and dry and regulated to 0.5 to 0.7 bar (7 to 10 psi). Thoratec's External Pressure and Vacuum Connector Set, Catalog #10025-2585-000, is available for this.

Vacuum Vent. The Vacuum Vent controls the application of vacuum to the VAD during implantation. When the vent is Open, air is exhausted into the interior of the console resulting in 0 vacuum applied to the VAD. When it is Closed, vacuum is applied to the VAD as adjusted by the regulator on the front panel.
CAUTION
If no vacuum is desired, the Vacuum Vent should be open. If the vent is closed and no vacuum is applied, the VAD has no path for exhausting air during filling. Trapped air in the VAD chamber may limit filling and reduce blood flow.

Drain. The small tube fitting below the Vacuum Vent is a drain to remove moisture from the drive module air filter. The drain is automatic and is controlled by the driver microprocessor, every 100 beats.

Drive Line. The Drive Line is the source of pressure and vacuum for driving the VAD. The Drive Line from each drive module is connected to an outlet on the console back door.

2.3.2 Electronics

Cycles. This counter records the number of driver cycles. Multiply the counter reading by 100 to determine the actual number of cycles.

Power On/Off Switch. This locking type switch (pulled out first, then up or down) must be moved to On for VAD use. When the drive module is no longer needed, move the switch to Off, which turns everything off in the module except the battery charger, and make sure the power cord is plugged into AC. This procedure ensures that the driver batteries are fully charged and ready for use. (On older units the Power On/Off switch is labeled Operation/Battery Charge.)
Calibration. The calibration components include an on-off toggle switch and a pressure port. Use these components to calibrate the digital pressure monitors each time you start the drive console. (Refer to Section 3.2.4 for Calibration Procedure.)

Microprocessor. Used to transmit driver status information to a peripheral computer for diagnostics.

Reset. Use the Reset switch to return the driver module to the start-up conditions of async mode, Rate at 60, % Systole at 30, with the Pump On.

**CAUTION**
Reset returns the drive control parameters to their default values.

External Alarm. This output is connected to the console back door and provides a signal to an external alarm system (e.g., a nurse call system) whenever there is no fill switch signal from the VAD for 8 seconds or longer. The output is switch selectable on the external alarm interface (EAI) board on the module inside back panel to work with either a normally closed or normally open external alarm system.

Fill Switch In. This input is connected to the console back door and provides an input for the VAD Hall-effect fill switch.

Ext Sync In. This input, which is connected to the console back door, is the input for the EKG signal needed to operate the VAD in the Ext Sync mode. The system triggers on the rising edge of an input pulse of 1.0 to 12 V.

Drive Pressure Out. You can use Drive Pressure Out, which is connected to the console back door, for monitoring the VAD drive line pressure. (1.00V DC = 000 mm Hg, 3.50 V DC = 250 mm Hg.)

Fill Signal Out. Fill Signal Out, connected to the console back door, is for your convenience in monitoring VAD filling status. This signal is 5 volts when the VAD is empty and while it is filling. The signal changes to 0 volts when the VAD is full.

Fuse. The drive module 1.0 amp 3AG fuse (1-1/4 x 1/4 inch, 250V, slow blow).

GND. The stud marked GND is a common ground point.
2.4 CONSOLE BACK DOOR

The console back door is the external access point for both the top and bottom drive module connections (Figure 2.13). Except for the circuit breaker and power switch, all connectors and pneumatic inputs are connected to the back panel of each drive module. The connectors are labeled top or bottom module, and the pneumatic inputs are common to both modules.

![Console Back Door Panel](image)

**Figure 2.13 Console Back Door Panel**

**Power.** The **Power** switch is an on-off pushbutton that lights when AC power is on. A spring-loaded cover protects it from accidental switching. Lift the cover to use the switch. During storage, the Power switch should remain on, with the AC power cable plugged in, to ensure battery charging.

**Circuit Breaker.** The circuit breaker is a current sensitive device that indicates actuation by an extended button in the center back into the device.

---

**CAUTION**

Correct the cause of the problem before resetting the breaker.

---

**Aux Pressure Input.** Can be used for connecting house air to the driver.

**NOTE:** Pressurized air supplied to the driver through the Auxiliary Pressure input must be clean and dry. The optimum pressure of this external air supply is 0.5 to 0.7 bar (about 7 to 10 psi), only slightly greater than the pressure supplied by the internal compressors. This minimizes changes to actual drive pressure as the air source is shifted from the internal compressors to the external source. Use of an air filter and pressure regulator on the external air source is recommended so that the supply pressure and quality can be controlled. This can be achieved with Thoratec's External Pressure and vacuum connector set, Catalog #10025-2585-000.
In any case, the air supply pressure must not exceed 50 psi (3.3 bar), even for short periods of time.

**Vacuum Input.** Can be used for connecting house vacuum to the driver.

**Emergency Selector Valve.** The Emergency Selector Valve inside the console back door is for short-term emergency use only. Use this valve, if necessary, to have one module pump both VADs while you connect the back-up console. The valve has three positions which are selected by a detented slide (Figure 2.14). The Out (fully extended) position allows the top module to drive both VADs. The In position allows the bottom module to drive both VADs. The center position is Normal and the driver modules operate independently.

![Emergency Selector Valve](image)

**Figure 2.14** Emergency Selector Valve. At the start of each case, make sure this valve is in the normal center position.

2.4.1 **Battery Backup for Pneumatics**

There are three battery systems in the Dual Drive Console for power during transportation or during a power outage. Batteries are installed in the top and the bottom drive modules, and the third battery-powered system, an Uninterruptible Power Supply, or UPS, drives the compressors and vacuum pumps. It consists of rectifiers that convert utility AC power to DC; batteries to store the DC power; an inverter to reconvert the DC power to 60 Hz AC power; and control, display, and power conditioning elements. It is an on-line UPS in that during normal operation all power is rectified to DC and inverted back to AC. On loss of utility power, power is automatically drawn from the batteries and inverted to AC.

The UPS batteries should be recharged as soon as possible after use for transportation or in an emergency. They are recharged whenever the UPS is receiving utility power and is turned on, even if power is being drawn from the UPS to run the compressors.

The UPS should normally be left connected to utility power and turned on during storage so that the batteries are fully charged. Compressors and vacuum pumps should be turned off using the switches on the compressor tray. If the UPS is to be disconnected from utility power during storage then it must be turned off since it would otherwise continue to run and deplete battery power.
The UPS controls are located on the rear panel of UPS, inside the back door of the drive console (Figure 2.15). Controls consist of the **Power** switch and a **Cold Start** switch. The **Cold Start** switch is used to turn on the UPS when it is not connected to utility power. This is done by turning **On** the **Power** switch and then depressing the **Cold Start** switch for a few seconds until the UPS starts. When connected to utility power, the UPS starts as soon as the **Power** switch is turned on, and the **Cold Start** switch is not needed.

A fuse holder and fuse are also located on the side panel of the UPS. A 10 amp fuse (FNQ-R-10, 600V, time delay) is used.

UPS status is displayed on a panel on the front of the **Drive Console** just below the lower drive module (Figure 2.16). The upper row of lights marked **Load** indicates the amount of power being supplied by the UPS. In normal operation with all compressors and vacuum pumps on, two or three green lights will be lit. When the UPS batteries are being charged and no load is applied, no lights will be lit.

The second row of lights marked **Battery** gives a rough indication of battery charge status. A greater number of green lights lighted indicates more fully charged batteries. However, when the batteries are being recharged and all five green lights are lighted, additional charging time may be required to reach full charge.

When the UPS is running on batteries during transportation or a power outage, the UPS gives a brief audible signal about every 3 seconds. As discharge of the batteries continues, the green battery lights go out one by one, starting with the top light. When the final green light goes out a red **Battery Alarm** light is lit and the audible alarm becomes continuous, indicating that less than 5 minutes of battery operation remains.

Battery operation of up to 40 minutes maybe achieved, depending on the state of charge, age, condition, and temperature of the batteries, and the load being driven.

The remaining lights on the UPS status panel are an **AC** light, indicating that utility AC power is available; an inverter light (**INV**), indicating that the inverter is operating; and an **Alarm** light, indicating an internal overload or malfunction.
Figure 2.15  Uninterruptible Power Supply ("UPS")

Figure 2.16  UPS Indicator
3. SYSTEM OPERATION

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<th>QUICK REFERENCE</th>
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</tr>
<tr>
<td>1. Verify that <strong>Power</strong> switch is <strong>On</strong> (on back door).</td>
<td></td>
</tr>
<tr>
<td>2. Open back door and verify that <strong>UPS</strong> is <strong>On</strong> (on rear surface of uninterruptible power supply, &quot;UPS&quot;).</td>
<td></td>
</tr>
<tr>
<td>3. Turn top and bottom module <strong>Power</strong> switches to <strong>On</strong> (to <strong>Operation</strong> on older units) and verify that <strong>Calibration</strong> switch is <strong>Off</strong> (on rear of drive modules).</td>
<td></td>
</tr>
<tr>
<td>4. Turn <strong>On</strong> compressor switches (on compressor tray) for top and bottom modules.</td>
<td></td>
</tr>
<tr>
<td>5. Check that <strong>Emergency Selector Valve</strong> is in <strong>Normal</strong> position (central position, located on inside of back door). Close back door.</td>
<td></td>
</tr>
<tr>
<td>6. Set initial console settings:</td>
<td></td>
</tr>
<tr>
<td>a. <strong>Mode</strong>: <strong>Async</strong></td>
<td></td>
</tr>
<tr>
<td>b. <strong>Set rate</strong>: 40 bpm</td>
<td></td>
</tr>
<tr>
<td>c. <strong>Set % systole</strong>: 20%</td>
<td></td>
</tr>
<tr>
<td>d. <strong>Pressure</strong>: 100 to 110 mmHg</td>
<td></td>
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<tr>
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</tr>
<tr>
<td><strong>B. INITIAL PUMPING IN THE OPERATING ROOM</strong></td>
<td></td>
</tr>
<tr>
<td>1. Connect VAD <strong>Drive Lines</strong> and <strong>Fill Switch In</strong> (<strong>Hall Switch</strong> on older units) cables to driver (on back door).</td>
<td></td>
</tr>
<tr>
<td>2. Initiate VAD pumping (<strong>Pump On</strong>) after VAD is de-aired</td>
<td></td>
</tr>
<tr>
<td>3. Observe for air, check for intact suture lines, then:</td>
<td></td>
</tr>
<tr>
<td>a. Gradually increase drive pressure to over 200 mmHg (LVAD) and over 140 mmHg (RVAD)</td>
<td></td>
</tr>
<tr>
<td>b. Apply vacuum carefully to approximately -10 to -25 mmHg. <strong>CAUTION:</strong> When the chest is open, excessive vacuum increases the risk of air embolism.</td>
<td></td>
</tr>
<tr>
<td>c. Wean patient from CPB</td>
<td></td>
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<tr>
<td>d. Increase set rate/% systole, or change to <strong>Volume</strong> mode once VAD is filling and ejecting completely</td>
<td></td>
</tr>
<tr>
<td>4. Troubleshooting for inadequate VAD filling and flow output</td>
<td></td>
</tr>
<tr>
<td>a. Increase drive pressure and/or vacuum (with caution)</td>
<td></td>
</tr>
<tr>
<td>b. If required, decrease set rate and % systole to allow more time for filling.</td>
<td></td>
</tr>
<tr>
<td>c. Administer fluids or blood products.</td>
<td></td>
</tr>
<tr>
<td>b. Provide inotropic support and vasodilators as needed</td>
<td></td>
</tr>
<tr>
<td>e. Insert RVAD for RV failure with high right atrial pressure and poor LVAD filling.</td>
<td></td>
</tr>
</tbody>
</table>
THORATEC DUAL DRIVE CONSOLE
QUICK REFERENCE

C. EASIEST SETTINGS FOR AUTOMATIC PUMPING:
1. Recommended settings:
   a. **Mode**: Volume (full-to-empty)
   b. **Set Value Rate**: 50 to 60 bpm
   c. **Set Value % systole**: 25% to 30% (use 1/2 of Set Value Rate)
   d. **Drive Pressures**
      - LVAD: 230 to 245 mm Hg
      - RVAD: 140 to 160 mm Hg
      - Vacuum: -25 to -40 mm Hg
2. Few or no adjustments should be required with a stable patient. No fine tuning is required.
3. If the sync alarm comes on (no fill signal), indicating that the VAD is not filling at this rate, lower the Set Value Rate to 40 bpm, and lower the Set Value % systole to 20%.
4. Refer to Detailed Descriptions in the Dual Drive Console Directions for Use for more information.

D. ALARMS AND TROUBLESHOOTING

**CAUTION**
For all alarm conditions - first assess the patient, then observe the VAD to insure that it is filling and emptying, then assess the console.

1. **SYNC alarm** in Volume mode (No fill signal received; VAD output displays -E-):
   - Check cables and connections, vacuum level, patient volume, and cannula position; if required, lower set (back-up) rate, set % systole, to allow more time for filling.
2. **Pressure alarm** (Drive pressure (Eject) is <100 mm Hg or >250 mm Hg):
   - Adjust regulator. Check compressors, pneumatic connections, transducer calibration.
3. **Vacuum alarm** (Drive pressure (Fill) is >+4 mm Hg or <-99 mm Hg):
   - Adjust regulator. Check compressors, pneumatic connections, transducer calibration.
4. **Low Battery alarm** (<30 min remaining on module battery):
   - Plug console into AC electrical outlet to recharge batteries; replace battery if required.
5. **External Alarm** Connect external alarm output (one for each VAD) to hospital remote alarm (nurse call) system. (Alarms when no fill signals received from VAD for 8 seconds or longer); same troubleshooting as Sync alarm.

ALWAYS KEEP HAND PUMPING BULBS WITH THE CONSOLE
In the event of console failure, disconnect pneumatic driveline from console and connect to hand bulb. Squeeze the hand bulb about once per second. Connect VAD to back-up console as soon as possible.
Two start-up procedures are given. The first (on the previous pages) is a very brief summary of start-up procedures and of the easiest settings for automatic pumping, and it is intended to be used as a memory aid by an operator already familiar with the operation of the console. The second is presented in the next section, which is a more complete and systematic description of the start-up and is part of the description of the overall operating procedure. In order to operate the device safety and effectively, the operator must have a thorough understanding of the driver and, as a minimum, must be familiar with the information presented in this section, Section 2, "Description," and Section 5, "Overview of Pneumatics and Electronics."

**WARNING**

**Danger: Explosion Hazard**

Do not operate the drive console in the presence of flammable anesthetics or other flammable gasses.

### 3.2 DETAILED START-UP PROCEDURES

Before attaching the VAD to a drive module, use the following start-up protocol to ensure proper drive module operation and calibration. Complete all steps in the start-up sequence, including either one or two point pressure transducer calibration.

References to items other than those on the module front panel will be noted.

#### 3.2.1 Storage with Batteries Charging

The following start-up procedure is based on the assumption that the console has been stored with batteries being charged. Console status is then as follows:

1. Power cord -- Connected to utility power.
3. Module Power switches -- Off (both modules) *(Battery Charge on older units)*.
4. UPS Power switch -- On.
5. Compressor and Vacuum Pump Switches, labeled Top and Bottom -- Off.

#### 3.2.2 Preparing to Move Driver from Storage

1. Turn UPS Power switch off.
2. Turn Main Power switch off.
3. Disconnect power cable from utility power.
3.2.3  **Turning on Driver and Preparing for Pressure Calibration**

1. Connect the console power cord to utility power using an appropriate hospital grade receptacle.

2. Press the **Power** switch on the console back door to turn on AC power.

3. Open the console back door.

4. Turn UPS **Power** switch on UPS back panel on.

5. Move the module **Power** switch on each module back panel to **On** *(Operation on older units).* This is a locking switch. Pull out before switching.

6. Use the switches labeled **Top** and **Bottom** on the compressor tray to turn on the compressors for the both modules.

7. Allow the system to operate for 5 minutes for temperature stabilization.

3.2.4  **Pressure Calibration**

The pressure transducer inside the drive module is electronically calibrated at the factory and usually no calibration is necessary. However, a transducer can sometimes drift from these factory settings.

Use the calibration components on the drive module back panel to calibrate the pressure transducer using one of the two procedures described below. If required, the procedure must be performed twice, once for each drive module. *(Note that a VAD can still function without an accurate pressure transducer, but that the pressure alarms and displays will be inaccurate.)*

**One point calibration (transducer zero):**

1. Move the **Calibration** switch on module back panel to **On**. Verify that the calibration port just above the switch is open. The pressure eject or fill indicator light on the front panel will flash, as a reminder that the calibration switch is on.

2. Press **Clear** on front panel. Check that the **Set Value** display reads 000 ± 1.

3. Press **Enter**. Verify that the **Eject-Fill** display reads 000 ± 1.
4. Turn the **Calibration** switch to off. The pressure eject or fill indication light will stop flashing.

**CAUTION**

Failure to turn off the **Calibration** switch results in erroneous calibration values if you attempt to change the **Set Value Rate** or **Systole**.

5. Repeat steps 1 through 4 for the second drive module.

The drive modules are now calibrated for 0 mm Hg and ready for VAD attachment.

**Two point calibration:**

1. Move the **Calibration** switch on module back panel to **On**. Verify that the **Calibration** port just above the switch is open to atmosphere. The pressure eject or fill indicator light on the front panel will flash, as a reminder that the calibration switch is on.

2. Press **Clear** on module front panel. Check that the **Set Value** display reads 000 ± 1.

3. Press **Enter**. Verify that the **Eject-Fill** monitor reads 000 ± 1.

4. Apply 250 mm Hg on a sphygmomanometer or other known pressure source to the calibration port.

5. Use the **Set Value** number keys to select 250. Verify that 250 appears in the **Set Value** display.

6. Press **Enter**. Note that the **Eject-Fill** display now reads 250 ± 1.

7. Remove the known pressure source from the calibration port. Note that the **Eject-Fill** display reads 000 ± 1.

8. Turn the **Calibration** switch to **Off**. The pressure eject or fill indication light will stop flashing.
9. Repeat steps 1 through 8 for the second drive module.

The pressure transducers in the drive modules are now calibrated.

3.2.5 Preadjust Pressure and Vacuum Settings

1. Make sure the Emergency Selector Valve on the inside of the console back door is in the Normal (center) position.

2. Turn the vacuum vent on the module back panel to the closed position to allow negative suction.

3. Before connecting the VAD to the driver, cap off the air connection to the VAD (with your finger, if necessary) and press the VAD "Pump On" button, if it is not already on.

4. Select a VAD pumping rate of 40 bpm. To do that, press Set Value Rate, 4, 0, and then Enter. Verify that the selected rate appears in the Set Value display. If it does not, check that the Calibration switch is Off.

5. Adjust the pressure to a starting value of about 100 to 110 mm Hg and adjust the vacuum to approximately 0 to -4 mm Hg (to avoid using excessive vacuum when vacuum is first applied).

3.2.6 VAD Pumping

After the VAD has been connected to the cannulas on the patient, follow these steps to attach the VAD to the drive module and begin pumping.

1. Before connecting the pneumatic drive line to the driver, place driver in the VAD off position by entering Pump On, followed by Enter.

2. Make sure that the Vacuum Vent on the module back panel is open (vertical) to disable active suction. After the vent is opened, do not adjust the vacuum regulator (this can change the preadjustments made in section 3.2.5).
3. Attach the pneumatic drive line to the Drive Line fitting on the console back door.

4. Plug the VAD electrical connector into Fill Switch In on the console back door (labeled Hall Switch In on older units), making sure to carefully align the keyed part of the plug with the keyed part of the jack. Make sure that the drive line and the electrical connector from the VAD are connected to the same drive module (top or bottom).

5. Press the Mode Async key. Set the rate at 40 beats per minute.

6. Recheck steps 1 through 5. If satisfactory, press Pump On to begin pumping.

7. Slowly turn the Pressure regulator knob clockwise to increase the pressure (to about 230 to 245 mm Hg for an LVAD and 140 to 160 mm Hg for an RVAD). Watch the VAD to make sure ejection is complete (VAD empty of blood). To assure complete VAD emptying the peak ejection pressure should be at least 100 mm Hg above systolic arterial pressure and ejection time is approximately 300 msec. The Eject monitor is the most accurate indicator of the peak ejection pressure.

8. Check that the Fill light lights with each pump cycle.

9. If the VAD is filling and emptying, the rate can be increased to 60 beats/minute and the % systole to 30% and then the system can be placed in the Volume (full-to-empty) mode by pressing the mode Volume key. Verify that the Fill light continues to light with each pump cycle. (For smaller patients a lower rate may be required.)

10. To allow the use of active suction to increase VAD filling rate, turn the Vacuum Vent on the module back panel to Closed (horizontal).

   **CAUTION**
   
   When the patient's chest is open, use extreme caution if pumping the VAD with the Vacuum Vent closed; excessive vacuum may cause air to be drawn into the patient's circulation.

11. With the chest opened, apply vacuum carefully to approximately -10 to -25 mm Hg by turning the Vacuum regulator knob clockwise. After the chest is closed, vacuum should usually range from -25 to -45 mm Hg, but watch the VAD to make sure it is pumping properly.
12. Guidelines for Settings on VAD Drive Console

Use the following settings as guidelines only:

1. LVAD Settings
   a. **Volume Mode** (full-to-empty)
   b. **Set Rate** = 50 to 60 bpm (small patients may require a lower rate)
   c. **Set % Systole** = 25% to 30% (use 2 of Set Rate value to achieve an eject time of 300 msec)
   d. Maximum drive pressure = 230 to 245 mm Hg (at least 100 above the patient's systolic pressure)
   e. Minimum drive pressure (i.e., vacuum) = -25 to -40 mm Hg

2. RVAD Settings
   (same as LVAD except maximum drive pressure)
   a. **Volume Mode** (full-to-empty)
   b. **Set Rate** = 50 to 60 bpm
   c. **Set % Systole** = 25% to 30% (1/2 set rate; i.e., 300 msec)
   d. Maximum drive pressure = 140 to 160 mm Hg
   e. Minimum drive pressure (i.e., vacuum) = -25 to -40 mm Hg

   (Note: LVAD output should always be equal to or greater than RVAD output).

3. Make sure that the **Set % Systole** is always kept at one-half of the **Set Rate** value, which will provide a 300 msec eject time:

   300 msec eject time: **Set % Systole** = $1/2$ **Set Rate**

4. Note: In the volume mode, when the VAD is completely filling, the actual rate will be greater than the set rate. The filling time will vary according to the preload, resulting in VAD rates usually in the 65 to 100 bpm range which corresponds to flow rates from approximately 4.0 to 6.5 ℓ/min.

5. If the sync alarm comes on (no fill signal), indicating that the VAD is not filling at this rate, lower the **Set Value Rate** to 40 bpm, and lower the **Set Value % Systole** to 20%.
13. In most patients, the volume mode is the recommended mode for VAD control. However, if external synchronization will be used, connect the patient's EKG monitor (R-wave sync pulse) to Ext Sync In on the console back door. The system triggers on the leading edge of an input pulse of 1.0 to 12 volts. Press the Ext Sync mode key. The VAD will now pump in synchrony with the patient.

Select a Set Value key, either 1, 2, 3, or 4, to program the driver for pumping with every patient QRS, every second, third, or fourth patient QRS, respectively. Press Enter. The VAD will now pump in synchrony with the patient and be moderated by the ratio selection.

NOTE: The set rate must be below that of the actual VAD rate for synchronization to work. For example, if the patient's heart rate is 100 and the VAD set rate is 60, the VAD can synchronize at 1:1 but not 1:2. To synchronize every other beat (1:2), the set rate would have to be lower than 1/2 of the patient's heart rate, or 50 bpm.

Press Delay and the correct number keys for the desired delay. The selected delay time will be shown in the Set Value display. Press Enter to initiate the delay in system operation.

NOTE: The delay default is 0 millisecond (from the end of VAD ejection to the R-wave sync pulse).

3.3 FILLING TIMES AND EJECTION TIMES

3.3.1 Async Mode and Volume Mode Examples

The drive console should be set up to empty the VAD in approximately 300 msec with a drive pressure of at least 100 mm Hg above the patient systolic pressure (see Figure 2.1 for an example of a set rate of 60, and a set % systole of 30, resulting in an eject time of 300 msec).

In the Async mode (Figure 2.1.A), the eject time is then fixed at 300 msec and the fill time is fixed at 700 msec, and the flow output is stroke volume x rate = 65 ml x 60 bpm = 3.9 ℓ/min. If the VAD fills early, the console still waits the full 700 msec before initiating the next eject cycle.

In the Volume mode (Figure 2.1.B), however, the Hall-effect switch in the VAD detects when the VAD is full, thus sending a fill signal to the driver which terminates the filling portion of the cycle early. In this example the VAD fills in 450 msec while the ejection time stays at 300 msec, thus the total cycle length is reduced to 750 msec. This is equivalent to an actual VAD rate of 80 bpm and a flow output of 65 ml x 80 bpm = 5.2 ℓ/min. The actual % systole is now 40% of
the total 750 msec cycle length (e.g., 300 msec eject/750 msec), whereas the set % systole remains at 30%.

![Diagram of cycle timings in Async and Volume Modes](image)

Figure 3.1 Examples of Cycle Timings in Async and Volume Modes

Note: These examples assume complete filling and emptying of the VAD. The eject time is the same in A and B. In B, the filling time is terminated as soon as the VAD is full, and thus the cycle length is shorter, and the rate and flow output are greater.
3.3.2 **Filling Times**

In the **Volume** mode, VAD rate varies as a function of the time it takes for the VAD to fill completely with blood from the body. These filling times vary with the type of cannula, the filling blood pressure, and vacuum in the pneumatic drive line. Figure 3.2 shows how applying vacuum decreases the time it takes the VAD to fill a stroke volume of 70 ml (allowing 5 ml for valve regurgitation) when tested on a mock circulatory loop under ideal conditions. Figure 3.3 illustrates faster filling times when the ventricular cannula is used compared to the atrial cannula at a constant -30 mm Hg vacuum. For example, if the filling pressure was 10 mm Hg and the vacuum was -30 mm Hg, the filling time would be approximately 350 msec for the ventricular cannula and 570 msec for the atrial cannula (Figure 3.3).

Therefore, decreased filling times and correspondingly greater flow rates can be achieved either by using a ventricular cannula (which has a larger internal diameter than an atrial cannula) or with more vacuum, which evacuates the air behind the VAD pumping diaphragm faster. If the filling pressure goes up, such as when there is increased venous return, then the filling time decreases, and in the volume mode, the VAD rate and flow increases. Conversely, when the filling pressure goes down, filling times also decrease and VAD rate decreases.

![Figure 3.2 Effect of Filling Pressures and Vacuum on Filling Times. Times shown are to fill 70 ml using the long ventricular cannula.](image-url)
3.3.3 Ejection Times

The Thoratec® VAD should be set up to run from completely full to completely empty. Complete ejection is important even early in the case to promote good washing of the surfaces of the VAD blood pump and valves to prevent thrombus formation. Experience has shown that the LVAD drive pressure should be kept well over 200 mm Hg in most patients (usually 230 to 245 mm Hg), and RVAD pressures approximately 140 to 160 mm Hg.

To determine how long it takes to eject a 70 ml stroke volume (allowing some for regurgitation), ejection characteristics measured on a mock circulatory loop with a standard arterial cannula into different arterial loads are shown in Figures 3.4 and 3.5. These data show that it takes approximately 100 mm Hg above systolic arterial blood pressure to ensure complete ejection of the VAD in 300 msec (0.300 sec). The lower the drive pressure, the longer it takes to empty the complete stroke volume (longer eject times). The greater the drive pressure the shorter the required eject time.

If the drive pressure is too low, or if the eject time is too low, then the VAD is probably not ejecting completely. When in the Volume mode, don't be fooled by the higher and probably inaccurate VAD output readings (estimated by assuming a complete net 65 ml stroke volume), which are displayed when there is underejection. For example, if the VAD ejects only 40 ml because of a low drive pressure, it also only has to fill 40 ml, which takes less time, and the VAD rate increases (when in the Volume mode).
These numbers give a quick guideline for setting up the driver for complete ejection, which can be confirmed by the "flash" technique. While shining a flashlight on the fill switch side of the VAD blood pump, complete ejection can be confirmed with a flash of light coming through the other side of the VAD.

Figure 3.4  Eject Time Versus Drive Pressure and Arterial Pressure. Times shown are to eject a stroke volume of 70 ml.
Figure 3.5  Eject Time Versus Drive Pressure Minus Systolic Pressure.
A single relationship emerges when the time to eject 70 ml is plotted against the difference between maximum drive pressure and systolic arterial pressure. With an eject time of 0.300 seconds, the drive pressure should be at least 100 mm Hg above systolic pressure to completely empty the VAD.

3.3.4 Flow Output

Under test conditions on a mock circulatory loop with the ejection time set at 300 msec and the vacuum at -30 mm Hg, the VAD flow output in the Volume mode is presented as a function of filling pressure (Figure 3.6). Note that under these conditions the flow is greater while using the ventricular cannula than the atrial cannula (because of the lower filling times discussed in Section 3.3.2), and that flow increases with greater filling pressures (also because of lower filling time).

Changes in VAD flow are also illustrated another way in Figure 3.7. In the Async mode, VAD flow changes linearly with stroke volume up to the maximum stroke volume of 65 ml. In the Volume mode, VAD flow varies with beat rate, as long as the stroke volume is kept at the ideal 65 ml maximum.
Dual Drive Console

Thoratec® VAD Instructions for Use

Figure 3.6  VAD Flow Output for the Atrial and Ventricular Cannula

![Graph showing VAD Flow Output for the Atrial and Ventricular Cannula.]

Vacuum = -30 mmHg
300 msec eject

FILLING PRESSURE (mmHg)

VAD FLOW (L/min)

Atrial cannula
Ventricular cannula

Figure 3.7  VAD Flow Output for the Async and Volume Modes.

Flow during the Async fixed rate control mode varies linearly with stroke volume ("SV") up to the maximum volume of 65 ml. VAD flow output during the Volume (full-to-empty) mode varies with rate, which changes due to changes in filling pressure gradient and filling time.
3.3.5 Conversion Between Ejection Times and % Systole

It is recommended that the **Set % Systole** always be kept at 1/2 of the **Set Rate** value, thereby keeping the ejection time at 300 msec, as illustrated in Table 3.1. For example, at a rate of 80 beats/min and 40% systole, the ejection time is 300 msec. Similarly, the ejection time is also 300 msec at a rate of 60 bpm and 30% systole.

**Table 3.1**

Conversion Table for Ejection Time and % Systole at Different Beat Rates
(For Reference Only.)
Ejection Time in Milliseconds

<table>
<thead>
<tr>
<th>RATE</th>
<th>20</th>
<th>25</th>
<th>30</th>
<th>35</th>
<th>40</th>
<th>45</th>
<th>50</th>
<th>55</th>
<th>% SYSTOLE</th>
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Shaded area indicates usual operating range to maintain an ejection time of 300 msec.
Note that the % systole is half of the rate in the shaded region.
3.4 ALARMS

An alarm panel can be found on each VAD module to alert staff to possible console or patient problems. An alarm condition is accompanied by continuous beeping, and a red light is illuminated in the alarm section. Correct the condition causing the alarm immediately. Four potential alarm conditions include:

1. PRESSURE
2. VACUUM
3. SYNC
4. LOW BATTERY

3.4.1 PRESSURE alarms when the drive (eject) pressure is below 100 mm Hg or above 250 mm Hg. Once the pressure is adjusted within an acceptable range, the alarm will stop and the red light will disappear.

**DRIVE PRESSURE (EJECT) < 100 mm Hg or > 250 mm Hg**

Possible reasons for a drive pressure < 100 mm Hg or above 250 mm Hg include:

- Drive pressure changed by staff
- Transducer failure or calibration incorrect
- Compressor failure
- UPS failure
- Hospital compressed air off or connected incorrectly
- Pneumatic leak

3.4.2 VACUUM alarms when the pneumatic drive pressure during filling is greater than +4 or less than -99 mm Hg. Once the vacuum gauge is adjusted within an acceptable range, the alarm will stop and the light will disappear.

**DRIVE PRESSURE (FILL) greater than +4 or less than -99 mm Hg**

Vacuum is required for VAD operation, however, vacuum will rarely need to be higher than -50 mm Hg. Possible reasons for vacuum alarm include:

- Vacuum changed by staff
- Compressor failure
- UPS failure
- Hospital compressed air off or connected incorrectly
- Pneumatic leak
3.4.3 **SYNC** alarms when the console does not receive a fill switch signal from the VAD when in the VOLUME mode, or does not receive an external sync signal when in the EXT SYNC mode. The console will automatically switch to the Set Rate (Back-up Rate). Trouble shooting is necessary to return the patient from the back-up rate to the automatic rates as determined in VOLUME mode or EXT SYNC mode.

-**E**- Occasionally seen instead of VAD output

At least one of three conditions has been met for the -**E**- to appear

1. Drive pressure < 100 mm Hg
2. No fill switch signal
3. Eject time (pump systole) ≤ 250 msec

**Possible explanations for the -**E**-**

- Poor VAD filling (i.e., hypovolemia, RV failure, vacuum too low, tamponade, cannula obstruction, etc.)
- Set Rate too high (Common)
- % Systole too low (< 250 msec)
- % Systole too high (not adequate time for filling)
- Electrical cable (grey wire) malfunction (keep spares readily available).
- Electrical cable disconnection
- Fill switch failure
- Module failure
- Irregular or high heart rate in Ext Sync mode resulting in poor VAD filling

3.4.4 **LOW BATTERY** alarms, in the top module or the bottom module occur when the batteries have less than 30 minutes of power remaining. The low battery alarm should never sound unless the console remains unplugged from an electrical outlet. The AC light (yellow) should always be on unless the console is unplugged from an electrical source during patient transportation, or ambulation. The battery light flashes when the module is unplugged from an electrical outlet.

In addition to the batteries in the top two modules is a third battery for the air compressors (Uninterruptible Power Supply, or UPS). A chirp sounds every few seconds when this battery is no longer connected to AC power. A continuous alarm sounds when there is 5 minutes remaining.

3.4.5 **EXTERNAL ALARM.** The **EXT ALARM OUT** jack on the console back door should be used to connect each module in use to an external alarm system (such as the hospital nurse call system). This signal will trigger the external alarm when there is no fill switch signal from the VAD for 8 seconds or longer. The
conditions and explanation for this alarm are identical to the sync alarm in Section 3.4.3. (The output is switch selectable on the external alarm interface board in each module to work with a normally open or normally closed external alarm system). The external alarm output is designed to be connected to nurse call with an external alarm cable (Thoratec Catalog #14820). During an alarm condition the outputs are switched closed (for a normally open system) or are switched open (for a normally closed system).

Set Up and Check Out: When setting up the connections to an external (nurse call) system while a patient is being supported, the alarm should be tested for proper operation. This can be achieved (assuming that regular VAD fill signals are being received) by temporarily disconnecting the VAD fill switch cable from the console back door and verifying that the external alarm turns on in approximately 8 seconds. Reconnect the fill switch cable and verify that no further triggering of the external alarm system occurs.

CAUTION

The VOLUME mode is the recommended control mode for most patients. This is the only mode where both audible and visual alarms on the Dual Drive console (triggering on the absence of the VAD fill signal) are present if the VAD were to cease to operate due to adverse scenarios such as blockage of the pneumatic drive or cannula. Any patient supported with the VAD drive console in the ASYNC or EXT SYNC modes must have the external alarm output on the drive console connected to the hospital nurse call system, or other similar external alarm system. This alarm output will trigger the external independent alarm after an 8 second absence of the VAD fill signal, thus alerting the user to check the VAD and drive console to determine that they are operating properly. This external alarm is available in all control modes, but is redundant when using VOLUME mode since internal audible alarms are present in that mode.

3.5 TROUBLE SHOOTING FOR FILLING AND EMPTYING

Complete VAD filling and complete VAD ejection are required to prevent stasis in the VAD and possible VAD thrombus formation. Also, VAD output displayed is accurate only if the VAD pump is filling and ejecting completely.

3.5.1 VAD FILLING

Complete VAD filling is indicated by the green fill light or the drive module front panel, and/or by visual inspection 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.
Reasons for Inadequate VAD Filling

- Hypovolemia
- Bleeding
- Right ventricular failure with isolated LVAD support
- Cardiac Tamponade
- Inadequate pharmacologic support
- VAD cannula position
- Insufficient vacuum
- Set Rate too high
- % Systole too high

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

1. **Decrease Set Rate** (Until fill signal is seen)
   and
   **Decrease % systole** (1/2 set rate or 300 msec)
   or
2. **Increase vacuum** (< -50 mm Hg).

3.5.2 **VAD EMPTYING**

LVAD or RVAD drive pressure should be at least 100 mm Hg above the systolic blood pressure with 300 msec VAD ejection time (**Set % Systole = 1/2 of Set Rate**).

Occasionally inspect the VAD pump with a flashlight for complete VAD emptying (white flash). Shine a flashlight through the fill switch side of the pump at an angle and look for a flash of light coming through the other side. The white flash will not always be seen in the same location.

Reasons for Inadequate VAD Emptying (**no white flash visible**)

- VAD drive pressures too low
- Set % Systole too low
- Systolic pulmonary pressure or systolic arterial blood pressure too high
- Outflow cannula kinked
- Emergency selector valve is not in correct position
Troubleshooting for inadequate ejection

1. **Increase VAD drive pressure**
   (LVAD < 250 mm Hg, RVAD < 170 mm Hg)
   and/or

2. **Increase % systole**
   (Increasing % Systole can decrease VAD output)
   and/or

3. **Lower patient's blood pressure** or pulmonary pressure
   (If patient is hypertensive)

### 3.5.3 HOW TO INCREASE VAD OUTPUT

In some cases, pump systole can be reduced below 300 msec to provide more time for VAD pump filling, thereby increasing VAD output. However, pump emptying should not be compromised. Therefore, inspect the VAD pump with a flashlight to insure complete VAD emptying.

1. **Decrease Systole %**
   (> 250 msec)

   and

   **Increase Drive Pressure**
   (LVAD < 250 mm Hg and RVAD < 160 mm Hg)

   and/or

2. **Increase Vacuum**
   (< -50 mm Hg)

### 3.6 PORTABLE OPERATION

The procedure for switching to portable driver operation and returning to utility power is as follows.

#### 3.6.1 For Portable Operation

1. Press main **Power** switch to turn off.

2. Note that the AC light on the front panel of both drivers has gone off and the **Battery** lights have come on and are flashing.

3. Note that the AC light on the UPS status panel has gone off and the intermittent (about every 3 to 10 seconds) audible alarm has come on and INV light (inverter) stays on.

4. Note that VADs are operating properly.
5. Unplug power cord from utility power outlet. Console and patient can now be transported to another location.

6. A new fully-charged uninterruptible power supply ("UPS") can provide power to the compressors for approximately 40 minutes. A new fully-charged module battery can provide power for approximately 3 hours.

CAUTION
A Low Battery alarm light on a module front panel indicates that the module battery will operate the module for only about 30 minutes. A red battery alarm light on the UPS status panel and continuous audible signal indicates that the UPS will continue operation for less than 5 minutes.

3.6.2 To Return to Utility Power

1. Connect power cord to utility power using an appropriate hospital grade receptacle.

2. Press on main Power switch.

3. Note that the AC lights on both modules and the UPS status panel are on.

4. Note that VADs are operating properly.

3.7 BACK-UP PROCEDURES

Back-up Console. Each console contains two independent drive modules, and therefore contains adequate built-in back-up capability for univentricular support. For patients receiving biventricular support, a complete dual drive console must be available as a back-up to be used in the event of a failure of the primary console.

House Air. The compressors in the drive console should be backed up by connecting house air and vacuum to the auxiliary pressure and vacuum inputs on the console. Use only clean and dry house air.

Emergency Selector Valve. In the event of a module failure in a patient with biventricular devices, the Emergency Selector Valve on the back door of current versions of the drive console can be pushed or pulled to drive two VADs with one module for the short period of time necessary to connect up the back-up drive console. This essentially works as a Y connector. Place the working module in the async mode to a fixed rate of approximately 60 bpm at 30% systole, and a drive pressure of approximately 200 mm Hg. Connect the back-up drive console as soon as possible (see Section 2.4 for more information).
Hand Pumping. Personnel should be trained how to hand pump a VAD in the event of a drive console failure. If for any reason there is a drive console failure, blood flow can be maintained to the patient and stasis prevented in the blood pump by disconnecting the VAD airline tube from the drive console and connecting it to the hand bulb, for the short period of time necessary to connect the back-up drive console. Squeeze the hand bulb about once per second to empty and fill the blood pump. Connect the back-up drive console as soon as possible. This procedure is for emergency use only. This part can be ordered from Thoratec as Part #14787-2589-000, Hand Pump (one needed per VAD).

3.8 CONSOLE SHUT DOWN, STORAGE, AND BATTERY CHARGING

3.8.1 Console Shutdown

When the console is no longer being used to support a patient, shut it down as follows:

1. Turn off the console internal compressors.
2. Turn off the UPS.
3. Turn the module Power switch on the back panel of each module to Off (Battery Charge on older units).
4. Press main console power switch to turn off.
5. Disconnect the main power cable from utility power.

The console can now be moved to a storage area.

3.8.2 Recommended Storage Mode

Leave the console connected to utility power and batteries on charge at all times as follows:

1. Connect power cable to utility power and press main console Power switch to turn on (on console back door).
2. Turn on UPS (necessary to charge batteries).
3. Make sure the **Power** switch light on the console back door is on and the UPS status panel displays the following:

<table>
<thead>
<tr>
<th>Feature</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Load</td>
<td>No lights on.</td>
</tr>
<tr>
<td>Battery</td>
<td>One to five green lights on.</td>
</tr>
<tr>
<td>Alarm</td>
<td>Off.</td>
</tr>
<tr>
<td>Inverter</td>
<td>On.</td>
</tr>
<tr>
<td>AC</td>
<td>On.</td>
</tr>
</tbody>
</table>

4. The module **Power** switch (**Operation/Battery Charge** switch on older units) on the back panel of each module should be left in the **Off (Battery Charge)** position, which turns everything off except the battery charger.

The console should be left in this mode at all times when not in use, under test, or being serviced.

### 3.8.3 Alternative Storage Mode

If continuous battery charging is not possible, store system as follows:

1. Charge batteries using Steps 1 to 4 in Section 3.8.2 for a minimum of 24 hours as soon after use as possible.

2. Turn off UPS, press main **Power** switch to turn off, and disconnect power cable from utility power. Leave the module switches in the **Off (Battery Charge)** position.

3. Recharge batteries as above at least every 30 days. This will normally occur at the conclusion of the Routine System Test, but the batteries must be recharged every 30 days, even if the Routine System Test is not performed.
4. ROUTINE SYSTEM TEST

4.1 INTRODUCTION

The test procedure described in this section must be performed approximately every 30 to 90 days to ensure that the driver will operate properly when needed. A data sheet is provided at the end of this section on which the results of the test can be recorded. It is suggested that photocopies of this data sheet be used to record the results of each test and that they be retained in an operating and test log. This ensures that the results of the latest test are always available and it provides the information to check for long-term changes in system performance. This procedure is based on the console being in the recommended storage mode for at least the preceding 24 hours: connected to utility power with the main power switch on, UPS on, and upper and lower compressor switches off, and UPS status lights as follows:

- Load: All lights off.
- Battery: All green lights on, red light off.
- Alarm: Off.
- Inverter: On.
- AC: On.

4.2 EQUIPMENT REQUIRED

- Stop watch
- Sphygmomanometer, 0 to 300 mm Hg
- Drive line occlusion device, 2 needed

4.3 FRONT PANEL FUNCTION TEST

NOTE: You must do steps 4.3.1 through 4.6.2 twice, once for each module.

4.3.1 Turn module Power (Operation/Battery Charge on older units) switch on module back panel to On (Operation). Leave compressors off.

4.3.2 Verify that the displays are immediate and that the system comes up with the pump on:

- Rate bpm: 060
- Stroke Volume: -E-
- Eject: variable
- Set Value: 060
Press Clear to shut off the audible alarm. Alarm Pressure light will remain on. Make sure the following indicators are lighted: Rate, Stroke Volume, Eject, Async, Set Value Rate, Alarm (pressure and/or vacuum), and Power (AC).

4.3.3 To determine which version software is installed, press the "hidden button" between the Async mode button and the Set Rate button. Displayed in the Set Value display should be 321 (V3.21 software).

4.3.4 Press each display readout key. Verify that beep sounds, light comes on, and proper number is displayed.

- Rate: 060 ± 1
- Systole: 030 ± 1
- Stroke Volume: 065 then -E-
- VAD Output: 3.9 then -E-
- Eject: variable
- Fill: variable

4.3.5 Press each Mode key -- Async, Volume, and Ext Sync. Make sure that beep sounds and associated light illuminates. Set Value Rate light goes out, and Set Value Display changes to 001 in Ext Sync mode.

4.3.6 Verify that the Pump On light is on and the solenoids are clicking (sometimes difficult to hear). Press each Set Value key in sequence given below. Check that beep sounds, indicator lights, and correct value is shown in Set Value display.

- Rate: 060 ± 1
- Systole: 030 ± 1
- Delay: 000 ± 1

Press the Pump On key and verify that the light flashes. Press any front panel key. Look at Pump On to make sure light has stopped flashing.

- Press Pump On again: light flashes
- Press Enter
- Observe Pump On: light off, solenoids quiet

4.3.7 Press each number key three times. Check that beep sounds and number is displayed three times in Set Value display.

4.3.8 On the back panel of the module press the Reset switch to reset the module. Verify that the system resets to the default settings with the pump on. Press Clear to shut off the audible alarm.
4.3.9 Try to enter rates of 010, 019, 151, and 200 bpm. Entries should be ignored and Set Value display should read EEE.

4.4 OPERATION TESTS

4.4.1 Connect drive line occlusion devices to both Drive Line outputs on back panel.

4.4.2 Open console back door and turn on compressors. Make sure the module is in the Async mode at a rate of 60 bpm.

4.4.3 Adjust module front panel Pressure Regulator until Pressure Gauge reads 200 mm Hg. Adjust Vacuum Regulator until Vacuum Gauge reads -30 mm Hg.

4.4.4 Move Calibration switch on module back panels to On. Verify that the pressure eject or fill indicator light flashes on the front panel.

4.4.5 Press Clear and then Enter. Check that Eject display reads 000 ± 1.

4.4.6 Connect manometer to module Calibration port and apply static pressure of 250 mm Hg.

4.4.7 Enter 2, 5, and 0 on keypad and press Enter. Check that Eject display reads 250 ± 1.

4.4.8 Remove manometer and turn Calibration switch to off.

4.5 PRESSURE AND VACUUM ALARM TESTS

4.5.1 Press Pump On and verify that module is pumping.

4.5.2 Decrease pressure slowly until alarm sounds and pressure alarm light remains on. Check that Eject display reads between 097 and 099.

4.5.3 Increase pressure until alarm and light turn off. Check that Eject display reads between 100 and 102.

4.5.4 Increase pressure until alarm sounds and light comes on. Check that Eject display reads between 250 and 252.

4.5.5 Reduce pressure until alarm and light turn off. Check that Eject display is between 247 and 249.

4.5.6 Reduce pressure to 200 mm Hg.

4.5.7 Decrease vacuum until alarm and light turn on. Check that Fill display reads between +5 and +7 (may have to change Set Value % Systole, Set Value Rate, and adjust Pressure Regulator).
NOTE: (1) The atypical conditions required for the low vacuum alarm (with positive pressure at +5 mm Hg or more) may not be achievable with all drivers. Failure to achieve the alarm condition does not indicate a defect in the driver; (2) this alarm condition may be easier to test when using a VAD on a mock loop.

4.5.8 Increase vacuum until alarm and light turn off. Check that Fill display reads between +3 and +4.

4.5.9 Increase vacuum until alarm and light turn on. Check that Fill display reads -99.

4.5.10 Decrease vacuum until light turns off. Check that Fill display reads between -097 and -099.

4.5.11 Reset Vacuum to -30 mm Hg.

4.5.12 Move Vacuum Vent on module back panel to Open. Check that Vacuum Gauge goes immediately to 0.

4.5.13 Close Vacuum Vent.

4.6 SYNC ALARM TESTS

4.6.1 Press the Volume mode key. Check that the audible alarm sounds and the red sync alarm light comes on within a few seconds.

4.6.2 Press the Ext Sync mode key. Check that the audible alarm sounds and the red sync alarm light comes on within a few seconds.

4.7 EMERGENCY SELECTOR VALVE TEST

4.7.1 Press Pump On on top module, and turn off bottom module by pressing Pump On, then Enter (or verify that the bottom module is not pumping).

4.7.2 With Emergency Selector Valve in normal position, check that top module Drive Line is pulsing and that there is no output pressure to bottom module Drive Line.

4.7.3 Pull Emergency Selector Valve out. Check that both Drive Lines are pulsing.

4.7.4 Push Emergency Selector Valve in to innermost position. Check that there is no output pressure to either Drive Line.
4.7.5 Press **Pump On** and **Enter** on top module to turn pump off.

4.7.6 Press **Pump On** on bottom module. Check that both **Drive Lines** are pulsing.

4.7.7 Pull **Emergency Selector Valve** out to outermost position. Check that there is no output pressure to either **Drive Line**.

4.7.8 Return **Emergency Selector Valve** to normal position. Check that **Drive Line** for bottom module only is pulsing.

4.8 PORTABLE OPERATION TEST

4.8.1 Ensure console has been in a battery charge condition for a minimum of 24 hours before continuing.

4.8.2 Ensure that both modules are on and pumping with the following settings:

<table>
<thead>
<tr>
<th>Setting</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mode:</strong></td>
<td>Async</td>
</tr>
<tr>
<td><strong>Set Value Rate:</strong></td>
<td>60 bpm</td>
</tr>
<tr>
<td><strong>Set Rate % Systole:</strong></td>
<td>30%</td>
</tr>
<tr>
<td><strong>Eject display:</strong></td>
<td>200 to 230 mm Hg</td>
</tr>
<tr>
<td><strong>Fill display:</strong></td>
<td>-15 to -35 mm Hg</td>
</tr>
</tbody>
</table>

4.8.3 Ensure that **AC** power light is lit on both modules.

4.8.4 Ensure that both sets of compressors are on.

4.8.5 Ensure that the UPS status panel displays the following:

<table>
<thead>
<tr>
<th>Setting</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Load</td>
<td>Two or three green lights on</td>
</tr>
<tr>
<td>Battery</td>
<td>Five green lights on</td>
</tr>
<tr>
<td>Alarm</td>
<td>Off</td>
</tr>
<tr>
<td>Inverter</td>
<td>On</td>
</tr>
<tr>
<td>AC</td>
<td>On</td>
</tr>
</tbody>
</table>

4.8.6 Unplug from AC outlet and start stopwatch. **AC** light must go off and **Battery light** must light on both modules. UPS status lights must be as follows:

<table>
<thead>
<tr>
<th>Setting</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Load</td>
<td>Two or three green lights on</td>
</tr>
<tr>
<td>Battery</td>
<td>Three to five green lights on</td>
</tr>
<tr>
<td>Alarm</td>
<td>Off</td>
</tr>
<tr>
<td>Inverter</td>
<td>On</td>
</tr>
<tr>
<td>AC</td>
<td>Off</td>
</tr>
</tbody>
</table>

Audible alarm must sound briefly about every 3 seconds.
4.8.7 Test the "cold start" function by performing the following steps within the first 10 minutes of the test described above in 4.8.6:

- Turn off UPS. Note that compressors stop.
- After about 5 seconds, turn UPS on.
- Note that compressors stay off.
- Press Cold Start switch for about 1 second and release.
- Verify that UPS and compressors have come back on.

4.8.8 Note and record the stopwatch time that each of the battery status lights goes out. Note that when the fifth green Battery light goes out the red Alarm light comes on and the audible alarm becomes continuous. Note and record the time that the UPS turns off. (Refer to UPS Removal and Replacement Section. UPS batteries must be replaced if the UPS operates less than 30 minutes.) Check alarm status on both modules. If at the end of the UPS test either Low Battery light is on, module battery must be replaced (refer to Section 7.3).

4.8.9 Recharge batteries for at least 24 hours with the driver configured as follows:

- Connected to utility power.
- Main Power switch on.
- Module Power On/Off switch turned Off (Battery Charge on older units).
- UPS power switch on.
- Both compressor switches off.

4.9 CLEAN FILTERS

4.9.1 Check and clean the front grill and rear door filters if dirty.
Data Sheet -- Routine System Test  
(To be Performed Every 30-90 days)

Control Serial No.:  

<table>
<thead>
<tr>
<th>Date</th>
<th>Top</th>
<th>Bottom</th>
<th>Top</th>
<th>Bottom</th>
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<th>Bottom</th>
<th>Top</th>
<th>Bottom</th>
</tr>
</thead>
</table>

### Front Panel Function Test

4.3.2 System comes up immediately with the pump on?

4.3.3 Software version displayed by hidden button?

4.3.4 Rate

  - Systole
  - Stroke volume
  - VAD output

  - Eject
  - Fill

4.3.5 Mode keys function correctly?

4.3.6 Set Value keys function correctly?

4.3.7 Pump On key functions correctly?

4.3.8 Number keys function correctly?

4.3.9 Reset switch operates correctly?

4.3.9 Out of range entries not accepted?

### Operation Tests

4.4.5 Eject display, mm Hg

4.4.7 Eject display, mm Hg

### Pressure and Vacuum Alarm Tests

4.5.1 Module pumping?

4.5.2 Eject display, low alarm on, mm Hg

4.5.3 Eject display, low alarm off, mm Hg

4.5.4 Eject display, high alarm on, mm Hg

4.5.5 Eject display, high alarm off, mm Hg

4.5.7 Fill display, low vac on, mm Hg

4.5.8 Fill display, low vac off, mm Hg
<table>
<thead>
<tr>
<th>Date</th>
<th>Top</th>
<th>Bottom</th>
<th>Top</th>
<th>Bottom</th>
<th>Top</th>
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<th>Top</th>
<th>Bottom</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.5.9</td>
<td>Fill display, high vac on, mm Hg</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>4.5.10</td>
<td>Fill display, high vac off, mm Hg</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>4.5.12</td>
<td>Vacuum vent functions correctly?</td>
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<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Sync Alarm Tests

| 4.6.1  | Volume mode sync alarm functions properly? |        |     |        |     |        |     |        |     |        |
| 4.6.2  | Ext sync mode alarm functions properly?   |        |     |        |     |        |     |        |     |        |

Emergency Selector Valve Test

| 4.7    | Emergency Selector Valve functions correctly? |        |     |        |     |        |     |        |     |        |

Portable Operation Test

| 4.8.1 through 4.8.4 | UPS and Module status before test OK? |        |     |        |     |        |     |        |     |        |
| 4.8.5              | UPS initial test status OK?           |        |     |        |     |        |     |        |     |        |
| 4.8.7              | "Cold Start" functions correctly?     |        |     |        |     |        |     |        |     |        |
| 4.8.8              | Time displays change (min)            |        |     |        |     |        |     |        |     |        |
|                    | Fifth battery status light out        |        |     |        |     |        |     |        |     |        |
|                    | Fourth battery status light out       |        |     |        |     |        |     |        |     |        |
|                    | Third battery status light out        |        |     |        |     |        |     |        |     |        |
|                    | Second battery status light out       |        |     |        |     |        |     |        |     |        |
|                    | Red light and alarm on                |        |     |        |     |        |     |        |     |        |
|                    | UPS off (min)                         |        |     |        |     |        |     |        |     |        |
|                    | Module battery alarm on?              |        |     |        |     |        |     |        |     |        |
| 4.8.9              | Batteries recharged at least 24 hours? |        |     |        |     |        |     |        |     |        |
| 4.9.1              | Console filters cleaned?              |        |     |        |     |        |     |        |     |        |
|                    | Front grill                          |        |     |        |     |        |     |        |     |        |
|                    | Rear door                            |        |     |        |     |        |     |        |     |        |
5. OVERVIEW OF PNEUMATICS AND ELECTRONICS

The functional overview of the drive console presented in this section is designed to provide you with an understanding of the processes that occur during system operation.

The console contains the electronic and pneumatic devices necessary to deliver alternating vacuum and pressure to the VAD through the drive line connected to the port on the console back door. This regulated and timed alternating pulses of vacuum and pressure operates the VAD. A VAD cycle consists of a filling phase during which blood flows into the VAD and an ejection phase where the blood is returned to the patient. Pressure is used during VAD ejection to empty blood from the VAD, and vacuum allows filling of the VAD.

5.1 MODULE PNEUMATICS

The drive module delivers alternating pressure and vacuum to the drive line port by means of supplied vacuum and pressure, and a variety of pneumatic components. Throughout this description, reference will be made to the labeled components (Figure 5.1).

**Pressure.** Pressure is supplied through the main or AUX pressure inputs. The pressure is then regulated into the pressure accumulator. Pressure is also regulated to keep a constant pressure applied to solenoid valves 1 and 2. Output pressure from the accumulator is connected to the diaphragm-operated three-way valve.

**Vacuum.** Vacuum is supplied through the main or AUX vacuum inputs. The vacuum is then regulated into the vacuum accumulator. The manual Vent Valve allows you to remove vacuum from the system. The two vacuum accumulator outputs connect to the three-way valve.

**Three-way valve.** A three-way diaphragm operated valve allows alternating vacuum and pressure to be delivered to the driveline port. When solenoid valve 1 is activated, pressure is applied to the diaphragm of the valve. During the portion of the cycle that valve 1 is activated, vacuum from the input vacuum is applied through solenoid valve 2 to the other diaphragm of the 3-way valve. Pressure from the accumulator is then delivered to the driveline port.

When the voltage is removed from solenoid valve 1 and applied to solenoid valve 2, pressure is applied to the opposite diaphragm. During the portion of the cycle that valve 2 is activated, vacuum from the input vacuum is applied through solenoid valve 1 to the other diaphragm of the 3-way valve. The valve diaphragms will then be positioned so that vacuum is delivered to the driveline port.

**Solenoid timing.** The VAD pumping rate and percent systole are controlled by the timing of activation and the length of time solenoid valves 1 and 2 are activated. For example, to achieve 60 bpm and 30 percent systole requires that solenoid 1 be activated for 300 msec and solenoid 2 for 700 msec. A complete cycle takes 1 second, so there are 60 cycles in 1 minute, resulting in 60 bpm. During one cycle, the pressure is delivered for 30 percent of the time, resulting in 30 percent ejection time (systole).
Figure 5.1  Drive Module Pneumatics
Pressure and vacuum monitors. Pressure and vacuum are monitored by gauges and a pressure transducer. Gauges are connected to their respective accumulators through snubbers. The pressure transducer on the analog board is connected to the drive line port. The transducer produces an analog voltage that is converted to digital by the computer board. The digital signal is then displayed on the front panel **Eject-Fill** display, where **Eject** represents pressure and **Fill** represents vacuum.

Calibration solenoid. The calibration solenoid and port are used for calibrating the transducer. The transducer is connected to the calibration solenoid and to its respective port. The transducer responds to pressure applied to the **Calibration** port when the calibration solenoid is energized (**Calibration** switch on). Thus, you can enter the correct reading when applied pressure is not equal to the displayed value.

Factory set components. Both the mini pressure regulator, which regulates pressure applied to the solenoid valves, and the needle valve are factory set. **Do not** change the adjustment.

5.2 CONSOLE PNEUMATICS

The drive console provides vacuum and pressure to the modules through interfaces with the console back door. Throughout this description, reference will be made to the labeled components (Figure 5.2).

5.2.1 Module Vacuum and Pressure Supply

The console uses both internal air pumps and external sources to supply the modules with vacuum and pressure. Each of the four identical pumps is connected to a separate module main input. Two of the air pumps produce vacuum and two produce pressure. External sources of vacuum and pressure can be supplied to the modules through the AUX input ports on the console back door. The AUX input ports on both modules share the corresponding AUX input port on the console back door by means of T fittings incorporated in the pneumatic system.

5.2.2 Emergency Selector Valve

The **Emergency Selector Valve** is connected to the drive line output so that you can use one module to drive both module drive line outputs on the console back door (for short-term emergency use only). This valve consists of a shaft and body. The body has channels that are routed to a cylinder where the shaft can slide. The shaft has three grooves for O-rings, which provide two separate sealed chambers within the cylinder.
Figure 5.2  Dual Drive System Pneumatics
When the shaft is in the **Normal** position, both chambers are in use allowing each drive line to connect to its corresponding output. When the shaft is positioned to drive two VADs, only one chamber is in use. The two **Drive Line** outputs and only one drive line input are connected to the chamber so that one module can pump two VADs. (The Routine System Test procedure includes a test of the **Emergency Selector Valve** -- Section 4.7.)

---

**CAUTION**

The **Emergency Selector Valve** is for emergency use only to allow time to switch to the back-up console. For normal operation, make sure the knob is in the correct, **Normal**, middle position.

---

5.3 **MODULE ELECTRONICS**

The pneumatic drive module uses integrated electronic circuitry to control the electromechanical devices necessary for module operation. The module electronics consist of five main circuits: DC power, analog board, computer board, front panel board, and external alarm interface (EAI) board. Figure 5.3 shows a generalized block diagram of this circuitry, which is discussed below.

---

![Generalized Block Diagram of Drive Module Electronics](image)

Figure 5.3  Generalized Block Diagram of Drive Module Electronics
5.3.1 **DC Power**

The DC power section consists of a 6.3 VDC power supply, 6.0 VDC rechargeable battery, and battery charger. During normal operation, the power supply converts 120 VAC into 6.3 VDC to provide raw DC power to the analog board. When AC power is removed, the battery subsystem is designed to supply DC power to the analog board without loss of power to the components.

5.3.2 **Analog Board**

The analog board is interfaced with the Computer board and provides circuitry for controlling various components. The analog board circuitry can be divided into five sections: power management, power conditioner, analog signal conditioner, digital signal conditioner, and buffers (Figure 5.4 below).

---

**Figure 5.4** Detailed Block Diagram of Drive Module Electronics

- **Power management.** The analog board power management circuitry allows the battery to provide raw DC power when the VAC input to the power supply is lost. The battery also supplies power to circuitry on the analog board to enable start up by battery power alone, provided the module power switch is in the **On** position.
Power conditioner. This circuitry converts the power supply voltage (6.3 VDC) or the battery voltage (6.0 VDC) into +5 VDC and ±12 VDC (voltages necessary to operate the module electronics). The +5 VDC is acquired by regulating the power supply or battery voltage. The ±12 VDC is acquired by use of a DC-to-DC converter.

Analog signal conditioner. The analog board signal conditioner circuitry receives and conditions analog signals from the transducer, power supply, and battery and sends them to the computer board. The transducer (see Module Pneumatics) receives varying pressure signals and, with analog board circuitry, converts them into analog voltage signals. These signals are then conditioned and sent to the computer board for further processing. The power supply and battery voltages are monitored, conditioned, and sent to the Computer Board.

Digital signal conditioner. This circuitry conditions digital signals to and from the computer board. The incoming signals sent to the computer board are: External Synch, Fill signal, and Calibration switch. Both the external synchronization and the Hall effect fill switch signals are conditioned, buffered, and then sent to the Computer Board. When the Calibration switch is turned on, a digital signal is conditioned and sent to the computer board. The computer board then allows the calibration solenoids to be energized and displays alarm condition pressure readings without issuing an alarm command. Digital signals received from the Computer Board control the following devices: solenoid valves 1 and 2, air filter solenoid, Cycle Counter, and beeper (for alarms). The Analog Board receives these signals, conditions them, and sends them to the appropriate device.

Buffers. All of the digital signals coming from the Computer Board are buffered before being sent out to control the appropriate device. The buffers ensure impedance matching between the Computer Board and the controlled devices.

5.3.3 Computer Board

The Computer Board plays an important role in controlling the system. It communicates with the Analog Board through the Mother Board (bus) and with the Front Panel Board through ribbon connectors. For this discussion, the Computer Board is divided into four sections: parallel I/O (input-output), data acquisition system, computer timers, and digital-analog conversion.

NOTE: All pots are factory set; do not touch.

Computer timers. The CPU 68B09 microprocessor is the heart of the control system. The CPU receives information from devices interfaced through the parallel I/O ports. The information is then processed and controlled. All operating instruction software developed for the system resides in EPROMs. Temporary locations and scratch pad space needed by the CPU are provided by RAM.
Parallel I/O. Versatile Interface Adapters (VIA) allow the computer to communicate with the keyboard, display, and conditioned digital signals from the Analog Board.

Data acquisition system. The data acquisition system consists of a multiplexer, A/D (analog to digital) converter, and one VIA. All the conditioned analog signals from the analog board are connected to the inputs of the 16 channel Multiplexer with sample and hold amplifier. Upon request from the CPU, the Multiplexer then selects the appropriate analog signal and sends it to the A/D converter. The A/D converter converts the analog signal into digital and sends it to a VIA where data is received by the CPU.

Digital to analog conversion. Currently, the only signal necessary for the computer to convert digital back to analog is the pressure transducer signal. The digital information is processed, filtered, converted to analog, and sent to the Drive Pressure Out port on the back panel where you can use the port to monitor the voltage of the transducer.

5.3.4 Front Panel

The Front Panel is the user's interface with the computer. The Front Panel consists of a Front Panel Display Board and a Keyboard. (See Figure 5.4).

Display board. The Front Panel Display Board provides the necessary circuitry for displaying system status and operating information. This information is updated every fourth beat. Circuitry for multiplexing Keyboard entries also resides on this board.

Keyboard. A 4 by 8 membrane Keyboard is connected to the Front Panel Display Board. All keyboard entries are sent to the Computer and to the Analog Boards, which produces a beep every time you press a key (see Figure 5.4).

5.3.5 Mother Board

The Mother Board provides parallel connection between the Computer and Analog Boards and also connects these boards to the front and back panels.

5.3.6 External Alarm Interface Board

The external alarm interface (EAI) board is mounted on the module back panel. It processes the fill switch signal from the VAD and creates a hardware-determined alarm signal in the absence of a fill switch signal for a duration of approximately 8 seconds or longer. This alarm signal is designed to interface with hospital remote call systems (e.g. nurse call). See section 3.4.5 for more information.

5.4 CONSOLE ELECTRONICS
The electrical components in the Drive Console consist of an isolation transformer, UPS, compressors, fans, and cables. An overall schematic diagram of the console AC power distribution is shown in Figure 5.5.

5.4.1 **Isolation Transformer**

The console AC power cord is connected to the input of the isolation transformer, and all of the electrical components in the console are connected to the output. The purpose of this transformer is to reduce the leakage current from the overall system to the patient.

For drive console Model 2601, the transformer steps down the 230 V line voltage to 115 V to run the air compressors and drive modules.

5.4.2 **Uninterruptable Power Supply**

The Uninterruptible Power Supply ("UPS") supplies 120 volt 60 Hz power to the compressors, vacuum pumps, and fans. It is physically located on the same tray as the isolation transformer and functionally it is between the isolation transformer and compressors, vacuum pumps, and fans.

The UPS is an on-line unit that continuously converts utility power to DC and then back to 60 Hz AC power using an inverter. The UPS has self-contained batteries that are used to supply power to the inverter which in turn drive the pumps and fans when utility power is not available. When utility power is available the batteries are automatically recharged as necessary.

The UPS provides significant brown-out protection for the pumps and fans in that it does not draw from the batteries until the utility voltage drops below 84 volts. Below that voltage, battery power is used and running time is limited.

5.4.3 **Compressors**

The compressors, located on the Compressor Tray, provide vacuum and pressure to the modules. The compressors are supplied with 120 VAC from the transformer, and manual on-off switches are connected to them (see Figure 5.5).

5.4.4 **Fans**

The two fans on the console back door are connected to the UPS output. These fans provide cooling for the compressors and modules.
5.4.5 **Cables**

All of the electronic connections on the module back panels are connected to their back door counterparts by appropriate cables.

5.4.6 **EMI Board**

On the console back door is a small circuit board that contains surge protection against electrostatic discharge before passing the fill switch signals to the modules and contains filtering for electromagnetic interference (EMI) on external alarm and fill switch signals.
Figure 5.5  Console Electrical Schematic
6. INITIAL SET-UP AFTER SHIPPING

CAUTION
Check the VAD drive console for shipping damage before turning on. A qualified biomedical equipment maintenance technician authorized by Thoratec must perform the following set-up instructions.

6.1 TOP DRIVER MODULE

The top drive module is accessible from the top of the drive console. Remove the four screws in the top panel of the console and lift off the panel. Carefully inspect the module for any signs of damage and loose parts, connectors, or circuit boards. Refer to Figure 6.1 for correct placement of module components.

6.2 BOTTOM DRIVER MODULE

You can reach the bottom module from the front of the console by pulling it out on its slides. Remove all back panel connections before attempting removal. For the pneumatic connections, use a 5/8 inch open-end wrench on the bulkhead fitting to prevent it from turning while removing the connection. Disconnect all electrical and pneumatic connections from the back panel of the bottom module. Grasp the handles on the front and carefully pull the module forward until it locks in the fully extended position. Examine the bottom module in the same manner as you did the top.

WARNING
If, for any reason, you need to remove either module from the console, handle it with care. The module weighs approximately 70 pounds (32 kg).

To remove a module, release the slide lock tabs and pull it out of the slide rails. Pay attention to the power cord as you remove the module to prevent the cord from catching on and perhaps damaging other components. After replacing a module in the console, make sure you completely reconnect it. Be careful not to overtighten the Swagelok® fittings.

6.3 SYSTEM TEST

Perform Routine System Test described in Section 4.
The circled numbers in Figure 6.1 refer to the following:

(1) Back panel
(2) Battery leads
(3) Front panel
(4) Computer board
(5) Analog power supply board
(6) Battery charger
(7) Keyboard decoder board
(8) Mother board
(9) 6.3 V power supply
(10) Calibration solenoid #1
(11) Calibration solenoid #2
(12) Vacuum regulator
(13) Vacuum accumulator
(14) Pressure regulator
(15) Pressure accumulator
(16) Air filter
(17) Diaphragm valve drive pressure regulator
(18) Needle valve
(19) Diaphragm valve
(20) External alarm interface (EAI) board
7. SYSTEM MAINTENANCE

The following paragraphs provide information about routine maintenance. Only qualified biomedical personnel authorized by Thoratec should perform maintenance other than cleaning and disinfection.

7.1 ROUTINE MAINTENANCE

The Pneumatic Dual Drive Console requires minimum maintenance. Maintenance consists of cleaning, disinfection, compressed air cylinder replacement, and battery charging.

7.1.1 Cleaning and Disinfection

Regularly clean the exterior of the console 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 module and console front and back panels.

**CAUTION**

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

Clean accessory items, cables, pneumatic tubing, and the VAD as follows.

- Remove blood stains by soaking the item in a blood solvent, such as Hemasol® or hydrogen peroxide. Soak item only as long as necessary to remove stain.

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

**NOTE:** Never immerse the electrical connector of any device or cables with perforated sheaths. Put cable connectors in a 3 mil thick polyethylene bag and tightly seal the opening around the cable. Examine the outer sheath of cables for perforations before immersion.

7.1.2 Sterilization

Accessories may be gas sterilized with ethylene oxide. Always observe the outgassing period established for that sterilization method.
7.2 SERVICING

The Pneumatic Dual Drive Console uses nine air filters that require service per air filter schedule. Replace the compressor filters and clean all others during servicing.

7.2.1 Air Filter Schedule

1. Console front grill -- clean annually -- check monthly.
2. Console rear door filters -- clean weekly.
3. Vacuum compressor exhaust filters -- clean annually.
4. Compressor intake filters -- replace annually.

7.2.2 Air Filter Maintenance

Front grill and pressure compressor filter service:

1. Remove the screws in the front grill and then remove the front grill and metal mesh screen filter (Figures 7.1 and 7.2).

2. Unscrew the butterfly bolt to remove the compressor air filter caps. Then remove the filter from the cap (Figure 7.3).

3. Insert new compressor filters and reassemble. It is important to make sure that the O-ring is in place on the compressor during installation of the filter cap (Figure 7.3).

4. Blow out metal filter with house air or vacuum. Replace metal filter and front grill.

Vacuum compressor filter service:

1. Open the console back door and disconnect the four pneumatic connections and the power cord on the compressor tray.

2. Remove the two tray mounting bolts and slide the tray out into its locked position.

3. Tilt the compressor and remove the filter cap the same way you did for the pressure compressor (Figure 7.4). Do not disturb the pneumatic connection at the vacuum output on the filter cap (Figure 7.5).
Figure 7.1  Front Grill

Figure 7.2  Exposed View of Grill and Metal Mesh Screen
Figure 7.3  Exposed View of Compressor Filter Cap and Filter

Figure 7.4  Vacuum Compressor Filter Removal
4. During the compressor filter replacement, the white filter covers for the vacuum compressors should be inspected. The covers have an air intake orifice drilled into the side of the cover. The orifice should be clean and not contain debris or dirt.

Use a #52 drill bit to carefully ream the orifice in the filter cap. **Do not** make the orifice larger than the diameter of the drill bit.

**Note:** Improper cleaning of the vacuum compressor orifice could cause the compressors to make a loud knocking noise. The orifice serves an important function in the proper operation of the vacuum compressors. To isolate the knocking problem on the compressor tray, have the top compressor switch on and the bottom switch off. Monitor the compressor for a few minutes or until the noise occurs. Repeat with the bottom switch on and the top switch off.
5. During the cleaning of the compressor tray and components, the polyflo tubing should be inspected. The tubing is translucent white, and over time it can turn a light to dark brown and become brittle at the point of the Swagelok connections. The tubing should be replaced if it is found to be dark brown and/or brittle.

6. Install new filters and reassemble.

Vacuum compressor exhaust filter service:

1. Press and twist the black cap at the exhaust end of vacuum compressor to remove the filter (Figure 7.6). Leave the plastic disc in place.

2. Remove filter and blow out with house air or vacuum.

3. Insert cleaned filter in cap and reassemble.

Figure 7.6 Exposed View of the Vacuum Compressor Exhaust Filter
Fan filter service:

1. Carefully remove the outer fan filter ring on the console back door (Figure 7.7).
2. Separate the three screens and blow out each one.
3. Configure the screens as shown in Figure 7.8.
4. Install the screens and outer ring.

Figure 7.7  Drive Console Back Door and Fan Filter Assembly
Figure 7.8  Fan Filter Screen Configuration
7.3 ROUTINE REPLACEMENT OF COMPONENTS

Components listed in the following table are recommended for routine replacement at the specified intervals.

<table>
<thead>
<tr>
<th>Components</th>
<th>Part Number</th>
<th>Replacement Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>6VDC - 36.0 AH Battery</td>
<td>41000-0000-001</td>
<td>Yearly</td>
</tr>
<tr>
<td>Battery Charger</td>
<td>41100-0000-001</td>
<td>5 Years</td>
</tr>
<tr>
<td>12VDC - 7.0 AH Battery or 72 VDC Battery Pack</td>
<td>41000-0000-003 or 20002-0000-062</td>
<td>Yearly</td>
</tr>
<tr>
<td>72 VDC Battery Pack</td>
<td>20002-0000-065</td>
<td></td>
</tr>
<tr>
<td>Compressor Filters</td>
<td>31675-0000-028</td>
<td>Yearly</td>
</tr>
<tr>
<td>Pilot Valve or Pilot Valve Assembly</td>
<td>31201-0000-012 or 20002-0000-054</td>
<td>Yearly</td>
</tr>
<tr>
<td>Solenoid Pilot (Clippard Valve)</td>
<td>31201-0000-010</td>
<td>2 Years</td>
</tr>
<tr>
<td>Hand Pumping Bulbs</td>
<td>14787-2589-000 or 14148-2588-000</td>
<td>2 Years</td>
</tr>
<tr>
<td>Vacuum Regulator</td>
<td>20002-0000-007 or 20002-0000-089</td>
<td>2 Years</td>
</tr>
<tr>
<td>Dessicating Filter</td>
<td>100059</td>
<td>1 Year</td>
</tr>
<tr>
<td>Poly Flo Tubing</td>
<td>60003-0000-008</td>
<td>5 Years</td>
</tr>
</tbody>
</table>

All replacement components must be ordered from your local Thoratec distributor and installed by a Thoratec-authorized agent. Information on service and service contracts may be obtained by contacting:

Customer Service
Thoratec Corporation
6035 Stoneridge Drive
Pleasanton, CA 94588
USA
HEARTLINE Toll-Free Telephone: (800) 456-1477
Facsimile: (925) 847-8624 or (925) 847-8571

Thoratec Europe Ltd.
Burnett House
3 Lakeview Court, Ermine Business Park
Huntingdon, Cambridgeshire
PE29 6UA
United Kingdom
Telephone: +44 (0) 1480 455200
Facsimile: +44 (0) 1480 454126
8. TROUBLESHOOTING

This section covers various techniques of fault isolation for the VAD Pneumatic Dual Drive Console. The troubleshooting chart provides suggested logical approaches for localizing problems to the suspected subassembly or to operator error. Corrective action that refers to replacement of components or assemblies should be performed only by qualified biomedical personnel authorized by Thoratec.
## Troubleshooting Chart

<table>
<thead>
<tr>
<th>Trouble</th>
<th>Condition</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
<th>Refer to Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improper Front Panel Display</td>
<td>No displays</td>
<td>No AC power</td>
<td>Verify that AC power is present</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Module Power switch is off</td>
<td>Turn module power on</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Console breaker</td>
<td>Reset console breaker (correct cause of the problem before resetting the breaker)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Module fuse</td>
<td>Replace module fuse (correct the cause of the fuse blowing before replacing)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Faulty power supply</td>
<td>Check power supply voltage; if unadjustable replace power supply</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Faulty analog board</td>
<td>If proper power supply voltage present with no ± 12V or 5V output on analog board, replace analog board</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Analog board or computer board not firmly seated in its socket</td>
<td>Re-seat the board completely</td>
<td>*</td>
</tr>
<tr>
<td>Dim displays</td>
<td>Excessive load on power supply (lower power supply output)</td>
<td>Find cause of load and remove; adjust power supply if necessary</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

* - Must be performed by a Thoratec authorized agent.
**Troubleshooting Chart**

<table>
<thead>
<tr>
<th>Trouble</th>
<th>Condition</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
<th>Refer to Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improper Front Panel Display (continued)</td>
<td>Dim displays during battery operation</td>
<td>Low battery voltage</td>
<td>Refer to Trouble: Low battery indication</td>
<td>8</td>
</tr>
<tr>
<td>Indicator out</td>
<td>Faulty LED</td>
<td>Replace LED</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Faulty display board</td>
<td>Replace display board</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Display segment of display out</td>
<td>Faulty display</td>
<td>Replace display board</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Faulty display board</td>
<td>Replace display board</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>No fill light when VAD is observed to be full</td>
<td>Module not receiving fill switch signal</td>
<td>Check cable connection</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Faulty fill switch cable (VAD to console)</td>
<td>Replace cable (VAD to console)</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Faulty fill switch cable (console back panel to module)</td>
<td>Replace cable (console rear panel to module)</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Faulty EAI board, or cables not plugged into EAI board</td>
<td>Check connections or replace board</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Faulty fill lamp</td>
<td>Replace fill lamp</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Faulty display board</td>
<td>Replace display board</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Faulty analog board</td>
<td>Replace analog board</td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

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<th>Corrective Action</th>
<th>Refer to Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improper Front Panel Display (continued)</td>
<td>Battery light on when connected to AC</td>
<td>No power supply output</td>
<td>Verify AC to module is present; if no AC, check module fuse</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Battery light on when connected to AC (continued)</td>
<td>Faulty power supply</td>
<td>Replace power supply</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Faulty computer board</td>
<td>Replace computer board</td>
<td></td>
</tr>
<tr>
<td></td>
<td>AC light on during battery operation</td>
<td>Faulty computer board</td>
<td>Replace computer board</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vol output display reads -E-</td>
<td>Pressure not above 100 mm Hg range, no fill switch signal received, msec eject not greater than 250 msec</td>
<td>Adjust as necessary</td>
<td>3</td>
</tr>
<tr>
<td>Improper Eject-Fill Display Readings</td>
<td>Eject-Fill display reads gross difference from gauge value (i.e., gauge reads 200 mm Hg and Eject reads 729 mm Hg)</td>
<td>Entries made after calibration while still in calibration mode (Calibration switch left on)</td>
<td>Recalibrate or press reset switch to reset with default calibrations.</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Faulty computer board</td>
<td>Faulty computer board</td>
<td></td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Improper Eject-Fill Display Readings (continued)</td>
<td>Eject-Fill display does not change with change in vacuum or pressure</td>
<td>Calibration switch on</td>
<td>Turn off Calibration switch; recalibrate module if parameter change entries were made after calibration</td>
<td>3</td>
</tr>
<tr>
<td>Eject-Fill display does not change with change in vacuum or pressure (continued)</td>
<td>Program lock up</td>
<td>Reset and calibrate module</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Faulty computer board</td>
<td>Replace computer board</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No transducer output, faulty analog board</td>
<td>Replace analog board</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Eject-Fill reads –99 mm Hg</td>
<td>Parameter change (rate change, etc.) performed with Calibration switch on</td>
<td>Recalibrate transducers and turn Calibration switch off</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Eject-Fill display does not read within 6 mm Hg of gauge peak</td>
<td>Module out of calibration</td>
<td>Recalibrate module</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Faulty gauge</td>
<td>Replace gauge</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Faulty transducer on analog board</td>
<td>Replace analog board</td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

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<th>Corrective Action</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Alarm Indication</strong></td>
<td><strong>Pressure alarm on (light and audible)</strong></td>
<td><strong>Eject display above 249 mm Hg or below 100 mm Hg</strong></td>
<td><strong>Adjust pressure. Note: Pressing Clear will silence alarm, but pressure alarm light will remain on until pressure is in proper range</strong></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td><strong>Vacuum alarm on (light and audible)</strong></td>
<td><strong>Fill display reads above –98 mm Hg or below +400 mm Hg</strong></td>
<td><strong>Adjust vacuum. Note: Pressing clear will silence alarm, but vacuum alarm light will remain on until vacuum is in proper range</strong></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td><strong>Module continues to alarm after clearing with all pressure sources removed</strong></td>
<td><strong>Fill display reads +400 mm Hg then drifts to +005 mm Hg sounding alarm</strong></td>
<td><strong>Calibrate module; verify Eject-Fill display; reads 000 ± 1 when all pressure sources are removed</strong></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td><strong>After adjusting pressure and/or vacuum alarm light goes out but audible still sounds</strong></td>
<td><strong>VAD output displays - E -</strong></td>
<td><strong>Adjust module to remove - E -</strong></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td><strong>Sync alarm on, when in volume mode</strong></td>
<td><strong>Fill light not lighting (not in sync with pump filling</strong></td>
<td><strong>Verify that VAD is filling</strong></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Faulty fill switch, electrical cable, or cable not completely plugged in</strong></td>
<td><strong>Check and/or replace cable</strong></td>
<td>3</td>
</tr>
</tbody>
</table>
### Troubleshooting Chart

<table>
<thead>
<tr>
<th>Trouble</th>
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<th>Possible Cause</th>
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<tbody>
<tr>
<td><strong>Alarm Indication (continued)</strong></td>
<td>Sync alarm on, when in volume mode (continued)</td>
<td>Allotted time for filling is too short</td>
<td>Reduce set rate to lengthen cycle length</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Increase vacuum and/or add volume to patient to improve filing</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>No fill switch signal when VAD is filling</td>
<td></td>
<td>Refer to Trouble: Display - no fill light when VAD is filling</td>
<td>8</td>
</tr>
<tr>
<td><strong>No audible alarm with no fill light in volume mode</strong></td>
<td>Alarm delay has remaining delay time</td>
<td></td>
<td>Check alarm delay; clear delay if audible is desired</td>
<td>3</td>
</tr>
<tr>
<td><strong>Sync alarm on, when in Ext Sync mode</strong></td>
<td>Loss of Ext Sync signal</td>
<td></td>
<td>Verify proper Ext Sync signal is present</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>External sync pulses have rate less than Async fixed rate</td>
<td></td>
<td>Change Async fixed rate or external sync frequency to obtain desired rate</td>
<td>3</td>
</tr>
<tr>
<td><strong>Sync alarm flashes when in Ext sync mode (no audible)</strong></td>
<td>External Sync frequency greater than (150 bpm) 2.5 Hz.</td>
<td></td>
<td>Reduce external sync frequency (module will remain in 1:2 operation until external sync frequency is reduced)</td>
<td>3</td>
</tr>
<tr>
<td><strong>No audible alarm when sync alarm light is on in Ext Sync mode</strong></td>
<td>Alarm delay has remaining delay time</td>
<td></td>
<td>Check alarm delay; clear delay if audible is desired</td>
<td>3</td>
</tr>
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<tbody>
<tr>
<td>Alarm indication (continued)</td>
<td>Audible sync alarm after setting sync alarm delay</td>
<td>Sync alarm delay has no time left</td>
<td>Check time left on sync alarm delay; add more time if desired</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Audible sync alarm after setting sync alarm delay (continued)</td>
<td>Sync alarm delay was set while module was already in sync alarm condition</td>
<td>Return module to Async mode or make proper adjustments to remove sync alarm condition then set sync alarm delay</td>
<td>3</td>
</tr>
<tr>
<td>Volume Output Display - E -</td>
<td>Pump not ejecting completely</td>
<td>Eject pressure below 100 mm Hg</td>
<td>Adjust eject pressure</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eject time less than 250 msec (check eject time by pressing systole display twice, if 000 time is above 1,000 msec)</td>
<td>Adjust rate and/or vacuum as necessary</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Pump not filling completely (no fill switch signal)</td>
<td>Improper amount of vacuum</td>
<td>Adjust as necessary, staying within proper desired vacuum range</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not enough time to fill pump (VAD)</td>
<td>Lower set rate and set % systole as necessary</td>
<td>3</td>
</tr>
</tbody>
</table>
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<tr>
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<tbody>
<tr>
<td>Low Battery Indication</td>
<td>Low battery light on during operation (battery or AC)</td>
<td>Low battery voltage</td>
<td>Test battery charger. If it tests positive, charge battery for 24 hours</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Low battery voltage after 24 hour charge</td>
<td>Faulty battery</td>
<td>Replace battery</td>
<td>*</td>
</tr>
<tr>
<td>Low Battery Indication (continued)</td>
<td>Battery charger test negative</td>
<td>No AC power to battery charger</td>
<td>Verify that AC power is present</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>No battery charger output with AC power present</td>
<td>Console breaker</td>
<td>Reset console breaker (determine cause of problem before resetting breaker)</td>
<td>1, 2</td>
</tr>
<tr>
<td></td>
<td>Module fuse</td>
<td></td>
<td>Replace fuse (determine cause of problem before replacing any fuse)</td>
<td>1, 2</td>
</tr>
<tr>
<td></td>
<td>Charger fuse</td>
<td></td>
<td>Replace fuse</td>
<td>1, *</td>
</tr>
<tr>
<td></td>
<td>Faulty battery charger</td>
<td></td>
<td>Replace battery charger</td>
<td>*</td>
</tr>
<tr>
<td>Improper Key Press Response</td>
<td>No response to key press</td>
<td>Faulty keyboard</td>
<td>Test keyboard; replace keyboard if test negative</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Faulty display board</td>
<td></td>
<td>Replace display board</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Faulty analog board</td>
<td></td>
<td>Replace analog board</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Faulty mother board</td>
<td></td>
<td>Replace mother board</td>
<td>*</td>
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<tbody>
<tr>
<td>Improper Key Press Response (continued)</td>
<td>Key press produces beep only (no change in function)</td>
<td>Program lock up</td>
<td>Reset module</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Faulty computer board</td>
<td>Replace computer board</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Other displays react to key press (i.e., press rate monitor key and modes change)</td>
<td>Faulty display board</td>
<td>Replace display board</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Faulty keyboard</td>
<td>Replace keyboard</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Unable to change parameters (Rate, Systole, etc.)</td>
<td>Calibration switch on</td>
<td>Recalibrate module and turn Calibration switch off</td>
<td>3</td>
</tr>
<tr>
<td>Improper Volume Mode Function</td>
<td>Pressure and/or vacuum adjustments do not change rate (in Volume mode)</td>
<td>Fill switch signal not received</td>
<td>Verify that VAD is filling</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>No fill light when VAD is filling</td>
<td>Refer to Trouble: Display – no fill light when VAD is filling</td>
<td>Refer to Trouble: Display – no fill light when VAD is filling</td>
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<tbody>
<tr>
<td>Improper Ext Sync Mode Function</td>
<td>Module does not respond to external R-wave signal</td>
<td>Module not receiving external R-wave signal</td>
<td>Test BNC cable connecting console back panel Ext Sync to module back panel Ext Sync</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Module does not respond to external R-wave signal (continued)</td>
<td>Improper R-wave sync signal</td>
<td>Use the QRS-sync pulse from an EKG monitor. The driver accepts an input pulse of 1.0 to 12.0 volts</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bad R-wave signal connected</td>
<td>Improve R-wave signal</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Faulty analog board</td>
<td>Replace analog board</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Faulty computer board</td>
<td>Replace computer board</td>
<td>*</td>
</tr>
<tr>
<td>No Pressure Reading on Module Pressure Gauge When Using Internal Pressure Source</td>
<td>Pressure present at module pressure input</td>
<td>Pressure regulator turned off</td>
<td>Adjust pressure regulator</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Faulty check valve</td>
<td>Replace check valve</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>No output pressure from corresponding compressor</td>
<td>No AC power to compressor</td>
<td>Verify that AC power is supplied to driver, UPS power switch is on, and compressor switch is on</td>
<td>*</td>
</tr>
</tbody>
</table>

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<th>Corrective Action</th>
<th>Refer to Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Vacuum Reading on Module Vacuum Gauge When Using Internal Vacuum Source</td>
<td>Vacuum present at module vacuum input</td>
<td>Vacuum regulator turned off</td>
<td>Adjust module vacuum regulator</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Vacuum vent lever on module back panel in the open position</td>
<td></td>
<td>Turn lever to the closed position</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Faulty check valve</td>
<td></td>
<td>Replace check valve</td>
<td>*</td>
</tr>
<tr>
<td>No output vacuum from corresponding compressor</td>
<td>No AC power to compressor</td>
<td></td>
<td>Verify AC power is supplied to compressor tray and that compressor switch is on</td>
<td>3</td>
</tr>
<tr>
<td>Compressor on with no output</td>
<td>Clogged orifice in filter cap</td>
<td></td>
<td>Ream orifice</td>
<td>7</td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Remote call (nurse call) alarm is on.</td>
<td>No fill switch signals occurring from VAD blood pump (no fill light on module front panel)</td>
<td>Allotted time for filling is too short, or not enough vacuum</td>
<td>Reduce set rate to lengthen cycle length.</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Increase vacuum and/or add volume to improve patient filling.</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Faulty fill switch, electrical cable, or cable not completely plugged in.</td>
<td></td>
<td>Check and/or replace cable.</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Module not receiving fill switch signal</td>
<td>Faulty external alarm cable, or cable not completely plugged in.</td>
<td>Review other probable causes under Trouble – Improper front panel display, Condition – no fill light</td>
<td>8</td>
</tr>
<tr>
<td>Fill switch signals are occurring (as noticed on module front panel.)</td>
<td></td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Normally open/normally closed switch is in wrong position.</td>
<td></td>
<td>Change switch position on EAI board to match hospital remote call.</td>
<td>3</td>
</tr>
</tbody>
</table>

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9. EXTERNAL PRESSURE AND VACUUM CONNECTOR SET

(Catalog #10025-2585-000)

NOTE: When operating the Thoratec® Dual Drive Console on an External Pressure/Vacuum source (House Air), it is recommended that both modules be powered ON at all times, even if supporting a LVAD patient.

Powering off the bottom (RVAD) module, when pressure and vacuum are supplied to the console via the External Pressure/Vacuum source, may lead to pressure and/or vacuum loss on the top (LVAD) module. The control valves, located in the module, are left in an uncontrolled state when the module is not powered on. This can allow pressure to backflow through the bottom module reducing the drive pressure and vacuum available for the top (LVAD) module.

When supporting a LVAD patient and operating on the Internal Compressors it is acceptable, but not required, to have both modules powered ON. When using the Internal Compressors with only one module powered on, the module's dedicated compressors prevent backflow.

9.1 INSTRUCTIONS

9.1.1 The external pressure and vacuum connector set includes quick connects for the back door of the console, 20 feet of high pressure tubing, a pressure regulator for adjusting the supply pressure, and a filter to clean the air source. Since the types of fittings vary from hospital to hospital, you will need to provide your own mating connectors to the Thoratec kit.

9.1.2 Attach the pressure regulator/filter to external pressure and adjust the pressure to 0.5 to 0.7 bar (7 to 10 psi), which is close to the 7 psi pressure output of the internal driver air compressors.

CAUTION
Too high a pressure or the use of dirty air sources can cause the check valves to stick and the module to not work properly.

9.1.3 Attach the vacuum end to external vacuum (about -100 mm Hg).

9.1.4 Push the quick connects for pressure and vacuum into the appropriate connectors on the Dual Drive Console back door. Make sure these are pushed all the way in.

9.1.5 Internal check valves in the modules allow the pressure source with the highest pressure to run the pneumatics.
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>9.1.6</strong></td>
<td>Check the automatic switching over to external sources by briefly turning off the internal compressors and verifying that the module is still pumping with adequate pressure and vacuum.</td>
</tr>
<tr>
<td><strong>9.1.7</strong></td>
<td>Check the automatic switching over to internal sources by disconnecting the external sources and verifying that the module is still pumping with adequate pressure and vacuum.</td>
</tr>
<tr>
<td><strong>9.1.8</strong></td>
<td>For maximum safety and automatic back-up, leave both the internal compressors and the external sources on. Then each source will back up the other. Repeat steps 9.1.6 and 9.1.7 every day.</td>
</tr>
</tbody>
</table>