SynCardia
Companion 2 Driver System
Operator Manual

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CAUTION: The 50cc temporary Total Artificial Heart (TAH-t) is an Investigational Device - Limited by United States Law to Investigational Use.

CAUTION: In the United States, the use of the SynCardia 70cc TAH-t for destination therapy is investigational.

CAUTION: In the United States, the use of the Companion 2 Driver System with the 70cc TAH-t for the destination therapy indication or with the 50cc TAH-t is investigational.

CAUTION: Federal (USA) law restricts this device to sale by or on order of a physician.

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Chapter 1. Device Description

The SynCardia temporary Total Artificial Heart (TAH-t) System is comprised of an implantable TAH-t (50cc or 70cc) and an external driver, such as the Companion 2 Driver (**Figure 1-1**) which includes a Hospital Cart and/or Caddy.

Figure 1-1 – 50cc or 70 cc TAH-t with Companion 2 Driver System

The 50cc and 70cc TAH-ts (**Figure 1-2**) are implantable pulsatile biventricular devices that temporarily replace a patient's native ventricles and valves, and pump blood to both the pulmonary and systemic circulation. For more information on the TAH-t, see the *SynCardia temporary Total Artificial Heart (TAH-t) Instructions for Use with the Companion 2 Driver System,* for the 50cc or 70cc TAH-t, as appropriate.

The 50cc TAH-t is a smaller version of the PMA approved 70cc TAH-t and is an Investigational Device Limited by United States Law to investigational use.

The TAH-t cannulae have colored bands on them. The cannula with the red band is connected to the left ventricle and the cannula with the blue band is connected to the right ventricle. After implantation, the 50cc TAH-t and 70cc TAH-t can be differentiated by these colored bands on the cannulae. The 50cc TAH-t cannulae have two colored bands on each cannula whereas the 70cc TAH-t cannulae have one colored band on each cannula, as shown in **Figure 1-2**.

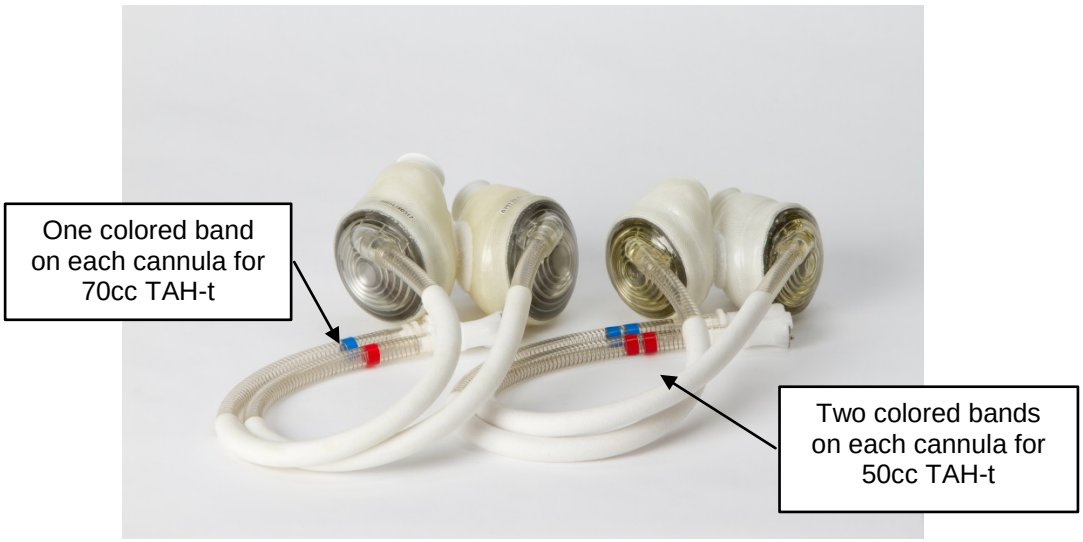


Figure 1-2 – 70cc TAH-t and 50cc TAH-t

The implantable 50cc or 70cc TAH-t consists of two artificial ventricles. The cannula from each artificial ventricle is tunneled through the chest wall. The cannulae of the right and left artificial ventricles are attached to seven-foot pneumatic Drivelines that connect to the Companion 2 Driver System.

The Companion 2 Driver System (**Figure 1-3**) is a multi-component electro-mechanical unit designed to provide pneumatic power to the implanted 50cc or 70cc TAH-t. The Companion 2 Driver System operates and monitors the 50cc or 70cc TAH-t throughout the implantation, surgical recovery phase and ambulatory phase of patient support. The Companion 2 Driver System includes a Driver, a Hospital Cart, and a Caddy and an optional Hand Pump.

Figure 1-3 – Companion 2 Driver System Major Components

1.1 Companion 2 Driver

The Driver (**Figure 1-4**) powers the TAH-t and docks into the Hospital Cart or the Driver Caddy. The TAH-t is monitored non-invasively by the Driver so there are no electrical connections to the patient.

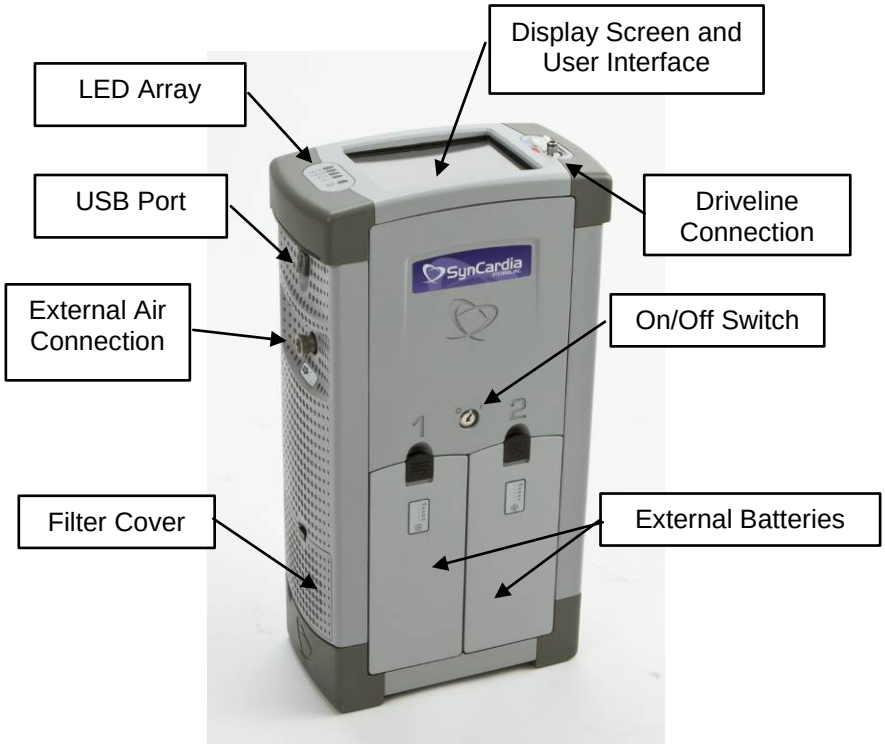


Figure 1-4 – Companion 2 Driver

1.2 Hospital Cart

The Hospital Cart (**Figure 1-5**) is a large cart with wheels, into which the Driver docks. It is intended for use in the hospital during the TAH-t implant procedure and subsequent recovery phase.

- The Driver docks into the Hospital Cart by placing the Driver straight into the center of the Hospital Cart so the docking connectors mate. The Driver must always be put into the Hospital Cart with the External Batteries facing outward.
- To remove the Driver from the Hospital Cart, simply lift the Driver straight up out of the Hospital Cart.

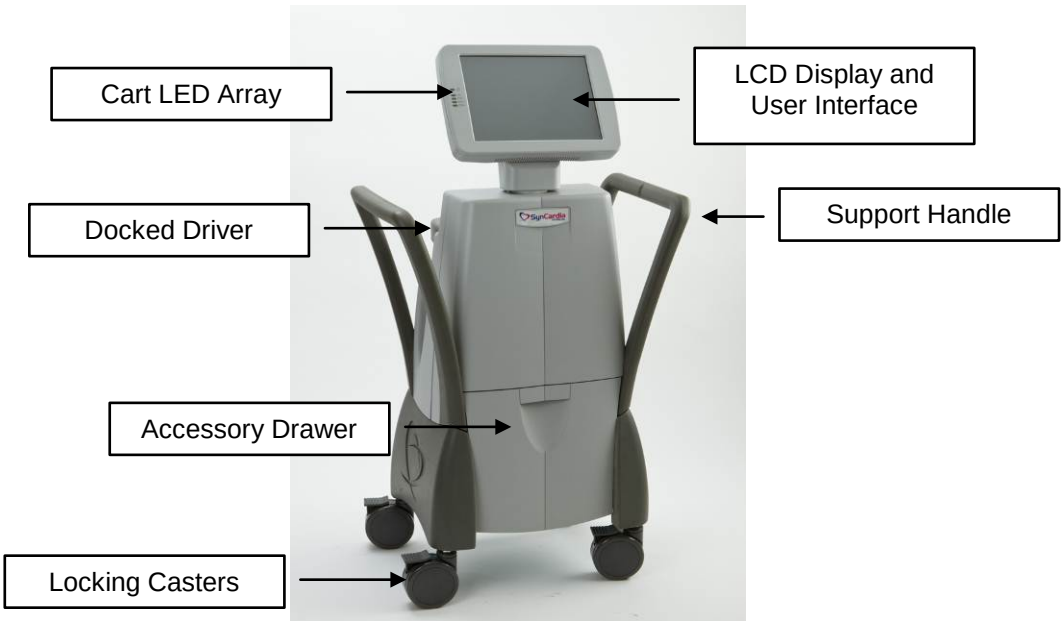


Figure 1-5 – Hospital Cart

1.3 Caddy

The Driver Caddy (**Figure 1-6**) is a small cart with wheels, into which the Driver docks. It is designed to facilitate mobility of ambulatory patients within the hospital. A tire pump is included in the attached pouch for inflating the pneumatic tires.

- The Driver docks into the Caddy by placing the Driver straight into the center of the Caddy so that the docking connectors mate. The Driver must always be put into the Driver Caddy with the External Batteries facing outward.
- The Driver is removed from the Caddy by depressing the Driver Release Button found at the back of the Caddy. Once the Driver Release Button is depressed, the Driver can be removed from the Caddy by lifting straight up.

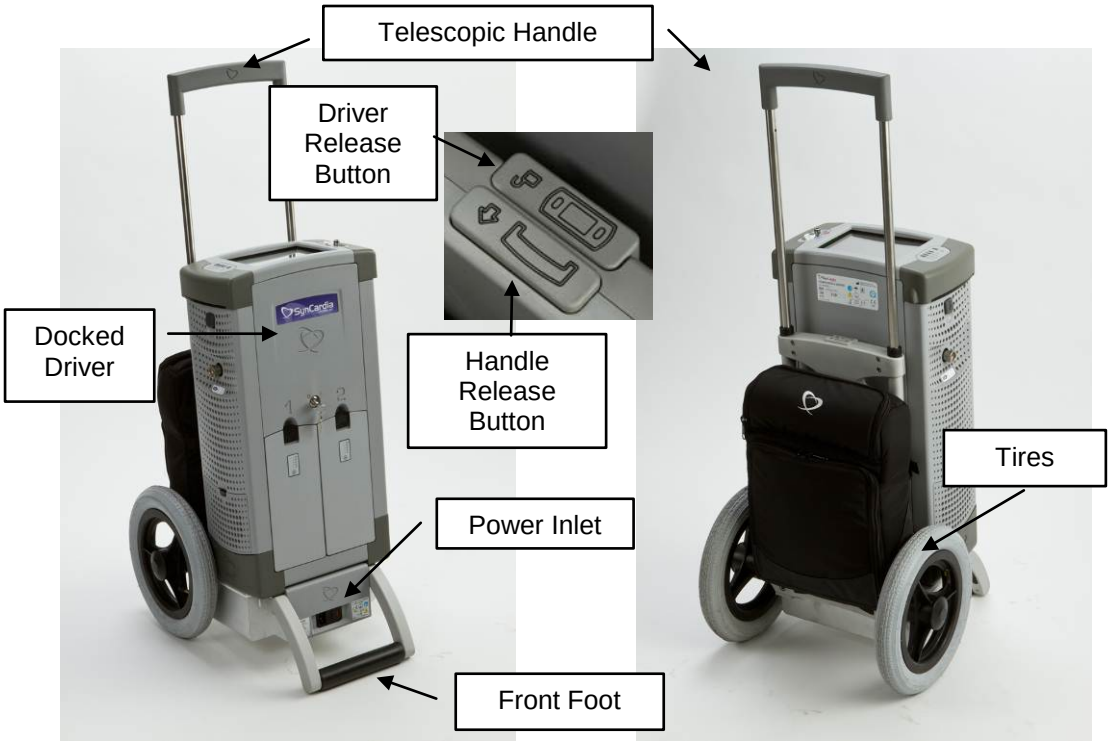


Figure 1-6 – Driver Caddy

1.4 Hand Pump

The optional Hand Pump (**Figure 1-7**) is a manually-operated driver that is intended to provide pulses of pneumatic pressure through the right and left Drivelines. The Hand Pump is designed for emergency use when a backup Driver is not immediately available. The Companion Drivelines connect to the CPC connectors on the Hand Pump. Clinical operators should pump at 110 strokes per minute to provide adequate Cardiac Output. See the *SynCardia Hand Pump Operator Manual* for additional details.

Figure 1-7 – Optional Hand Pump

Chapter 2. Indications for Use

2.1 70cc TAH-t Indication for Use

The SynCardia 70cc temporary Total Artificial Heart (TAH-t) is indicated for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from non-reversible biventricular failure.

The use of the SynCardia 70cc TAH-t for destination therapy (for patients who are ineligible for cardiac transplantation and for whom clinical indices indicate a remote likelihood of becoming eligible for a transplant) is investigational.

2.2 50cc TAH-t Indication for Use

The SynCardia 50cc temporary Total Artificial Heart (TAH-t) is indicated for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.

2.3 Companion 2 Driver System Intended Use

The Companion 2 Driver System, used with the 50cc TAH-t or the 70cc TAH-t, is intended for use inside the hospital and on the hospital grounds.

Chapter 3. Contraindications

The 70cc TAH-t System is contraindicated for use in:

- Patients who do not have sufficient space in the chest area vacated by the natural ventricles. Generally this includes patients who have body surface areas < 1.7 m^2, or who have a distance between the sternum and the 10th anterior vertebral body measured by computed tomography imaging (CT scan) < 10 cm.
- Patients who cannot be adequately anticoagulated on the 70cc TAH-t.

The 50cc TAH-t System is contraindicated for use in:

- Patients who are not cardiac transplant eligible.
- Patients who do not have sufficient space in the chest area vacated by the natural ventricles.
- Patients who have a body surface area (BSA) of > 1.85 m^2.
- Patients who cannot be adequately anticoagulated on the 50cc TAH-t.

Chapter 4. Warnings

4.1 Setup and operation of the 50cc or 70cc TAH-t System should only be performed by personnel certified in accordance with the SynCardia certification program. A thorough understanding of the technical principles, clinical applications, and risks associated with the device is necessary. Prior to use, refer to the *SynCardia temporary Total Artificial Heart (TAH-t) Instructions for Use with the Companion 2 Driver System* for the 50cc or 70cc TAH-t.

4.2 The Drivelines are sterile components and are intended for single use only. Do not use if package is opened or damaged. Do not re-sterilize or reuse.

4.3 Safe use of this system has not been established in pregnant patients.

4.4 Do not subject patients implanted with the 50cc or 70cc TAH-t to magnetic resonance imaging (MRI) scans.

4.5 Do not use the TAH-t System if the implantable artificial ventricles cannot fit in the chest area vacated by the natural ventricles. Compression of the inferior vena cava and left pulmonary venous are possible consequences.

4.6 Do not allow any catheter to get near the inflow valves of the TAH-t. If a catheter migrates into an inflow valve, the valve could become stuck, limiting flow. Confirm the position of the catheter by x-ray after catheter insertion and repeat an x-ray immediately if any unexplained sudden drop in cardiac output occurs. A percutaneously inserted central catheter may migrate into the inflow valve when the patient raises his or her arm.

4.7 There is a potential for air embolism. De-air the artificial ventricles to minimize the possibility of air inadvertently entering the device.

4.8 Do not allow the external Drivelines to become kinked. If there is any low cardiac output alarm, inspect the external Drivelines for kinking.

4.9 A reduction in the maximum stroke volume on the external driver monitoring computer to below 30 milliliters may indicate a failure of one of the diaphragms in a ventricle of the 50cc TAH-t.

4.10 A reduction in the maximum stroke volume on the external driver monitoring computer to below 40 milliliters may indicate a failure of one of the diaphragms in a ventricle of the 70cc TAH-t.

4.11 Do not administer CPR to TAH-t patients. Defibrillation, cardioversion, and CPR are ineffective on patients implanted with the 50cc or 70cc TAH-t.

4.12 The graphical user interface software on the Companion 2 Driver requires two minutes to fully load after the power is turned on with the key switch. No Driver alarms are active during this time.

4.13 If the Driver is started while undocked from a Hospital Cart and the touch screen is non-responsive after the graphical user interface is presented on the display, dock the Driver into the Hospital Cart to recalibrate the Driver

touch screen. This is performed through driver touch screen calibration procedure (see **Section 8.1.10**).

4.14 Always keep the Companion 2 Driver System away from any ignition source including open flame and smoldering cigarettes.

4.15 If a docked Driver user interface displays the following in the Power Status Window:

- Both External Batteries Missing
- and no AC Power Icon
- and there are External Batteries and/or AC power applied

remove the External Batteries and AC power. Reconnect AC Power and reinsert the External Batteries.

4.16 Preliminary data on the use of the Companion 2 Driver versus the Circulatory Support Console (CSS) with the TAH-t for patients who received circulatory rescue intervention (*e.g.*, extracorporeal membrane oxygenation [ECMO] or intra-aortic balloon pump [IABP]) prior to implant suggest a higher mortality for the Companion 2 Driver compared to the CSS. A mortality difference was not observed among patients not initially treated with a pre-implant circulatory intervention.

4.17 If upon docking the Driver into a Hospital Cart or Caddy, the Driver screen flickers, flashes black and white, or turns off, immediately undock the Driver and DO NOT attempt to dock the Driver again into the same Hospital Cart or Caddy. A malfunction of the Hospital Cart or Caddy may exist and it must be returned to SynCardia for evaluation. The Driver should be docked into another Hospital Cart or Caddy.

Chapter 5. Precautions

5.1 Surgical, nursing, and perfusion staff responsible for the SynCardia TAH-t program at each hospital must complete the SynCardia Certification program.

5.2 The SynCardia TAH-t and Drivelines are provided sterile; caution must be taken in opening the package. Do NOT resterilize. Do NOT use if package is damaged. Storage temperature for the Drivelines is 10 - 50°C.

5.3 Measures should be taken to prevent infection or sepsis. Use strict aseptic techniques during implantation.

5.4 The outflow grafts must be pre-clotted before use.

5.5 Do not use an antifibrinolitic agent like Amicar with an active clotting agent like FEIBA.

5.6 Each Companion 2 Driver contains two independent compressor subassemblies, each capable of providing independent support for operation of the TAH-t. Hospitals, and patients supported with the Companion 2 Driver, must have an additional Companion 2 Driver available as a backup to be used in the event of a failure of the primary Companion 2 Driver.

Always program the correct settings for the backup Driver when the primary Driver is programmed.

Train personnel how to exchange the primary Companion 2 Driver with a backup Companion 2 Driver in the event of system failure. Connect the backup Companion 2 Driver as quickly as possible. This procedure is for emergency use only. See Chapter 15 in this manual, Switching from Primary Companion 2 Driver to Backup Companion 2 Driver.

5.7 It is recommended that the external air pressure for the Companion 2 Driver be maintained between 50 to 80 PSI (3.5 to 5.5 Bar). If the external air pressure is below this range it will not impact the Driver functionality, however, it may result in a System Malfunction Alarm. If a System Malfunction Alarm is displayed while on external air, remove the external air connection from the Driver and verify that the alarm clears. If the external air pressure is above the specified range it will not impact the Driver functionality, however, the internal compressor may activate intermittently. When the compressor activates, the external air icon on the display will not be illuminated.

5.8 The TAH-t System contains ferro-magnetic metal components. Do NOT perform MRI imaging procedures on patients implanted with the TAH-t.

5.9 Manage the exit site in accordance with hospital procedures.

5.10 Use only water-soluble antiseptic cleaners around the exit site. Ointments may delay tissue in-growth around the cannulae.

5.11 Monitor cardiac output when closing the chest. A reduction in TAH-t output while closing the chest may indicate inflow obstruction. Reposition

the TAH-t ventricles by anchoring to a rib or moving it into the left pleural space.

5.12 A sudden reduction in TAH-t flow may be caused by a kink in the pneumatic Drivelines (check for and correct), or some inflow obstruction to the TAH-t, such as tamponade (surgical intervention may be required).

5.13 Flows should be kept at a reasonable output so that proper washing of the ventricles is established.

5.14 The level of anticoagulation will vary depending on the patient's coagulation status. Clinical experience has shown that typically, patients supported with the 70cc TAH-t require systemic antithrombotics similar to those used for patients with mechanical valves.

5.15 The user (Clinical Engineer/Nurse) should install the Driver into the Cart or Caddy with assistance from another trained user if necessary.

5.16 To facilitate Hospital Cart movement over an obstacle that is 20 mm in height (approximately 0.8") it is recommended that the user (Clinical Engineer/Nurse) and an assistant, if needed, pull upwards on the Hospital Cart Support Handles.

Chapter 6. Companion 2 Driver

The Driver is designed to operate as a stand-alone unit or can be docked into the Hospital Cart or Driver Caddy during use. The Driver functions with either external air or compressor-generated air. The primary mode of function of the Driver is operation with external air. The Driver should always be connected to external air when available. Compressor-generated air is a secondary mode of function.

6.1 Pneumatics

The pneumatics system is comprised of a regulated connection to external air, as well as two fully redundant compressor subassemblies connected to a common buffer tank. The two independent compressor subassemblies, A and B, are driven by separate motors and separate controllers to provide positive air pressure to the buffer tank, and thus to left and right ventricle.

The two independent scroll compressors act as primary and backup compressors to pressurize the buffer tank common to all sources of air (hospital supplied or compressor supplied).

During systole, the Driver supplies compressed air that is regulated to cause the left and right TAH-t ventricle diaphragms to move upward and expel blood into the arterial and pulmonary systems. In diastole, vacuum is applied by speed regulated vacuum blowers. Pressure sensors are located on each pneumatic pathway and monitor both positive and negative pressures during the cycle so that adjustments can be made by the operator to change pressure and vacuum.

The compressors act independently; one as primary and the other as an internal backup. If the primary compressor fails, the internal backup compressor starts and an alarm sounds, indicating that the Driver must be exchanged.

6.2 Electronics

The electronics assemblies within the Driver route power to the subassemblies, monitor pressure and flow signals, actuate audible and visual alarm notifications, display the user interface and respond to user inputs.

Power management electronics automatically prioritize available power sources in the following order: external power, external Batteries and internal, Emergency Battery. When any higher priority power source is available, the power management electronics will seamlessly switch support to the higher priority source.

The power management electronics assembly is designed to continue to route power to the motor assemblies in the event of a loss of one power channel.

The integrated computer electronics assembly displays and records information and transmits user interface inputs into commands to adjust the Driver parameters to the user selected value.

There are two controllers that are independent of the computer, which monitor the computer status and are capable of maintaining user settings in the event of a computer malfunction.

The Driver has internal non-volatile memory that stores all programmed control parameters and event log information at routine time intervals.

6.3 Interfaces

The TAH-t Driveline connector is keyed to connect the Driver in one direction only, to ensure that the left and right ventricles are connected properly.

A USB port on the side of the Driver accepts connections to USB 1.0 and 2.0 devices to retrieve stored information from the Driver. No information can be loaded onto the Driver through this unidirectional USB interface.

A Key Switch on the front panel of the Driver allows the device to be manually stopped and started. When the Driver Key Switch is turned to the OFF position, the key cannot be removed to ensure that the key is always available to turn on the Driver.

When the Driver Key Switch is turned to the ON position, the Driver will begin operation at default settings, prior to complete initialization of the software. Once the application software load process is complete, the Driver will operate at the last user settings.

When the Driver is ON, the key must be removed from the Driver to prevent unintended interruptions to Driver operation. Once removed, the key may be stored in a location determined by the clinical staff.

The Docking Connector is on the bottom panel of the Driver. This connector automatically makes the required connections for power and for audible and visual signal transmission when the Driver is placed in the Hospital Cart or Driver Caddy.

There is a port on the right side of the Driver for connecting to External air.

6.4 Display Screen / User Interface

The display screen of the Driver provides non-invasive diagnostic and monitoring information to the user. Beat rate, dynamic stroke volumes, calculated cardiac outputs and hourly average cardiac outputs are displayed on a beat-to-beat basis. Left and right drive pressures and flow waveforms, along with cardiac output trends, are provided on the Driver display and Hospital Cart display (when the Driver is docked into the Hospital Cart).

Patient-related alarms (*e.g.*, low cardiac output) are also displayed on the display panel and LED indicators of the Driver. An alarm is indicated by an audible sound, visual indicators and a written message.

6.4.1 Display Screen

The color LCD display and touch screen is the mechanism by which all adjustable device operating parameters may be adjusted and device outputs monitored and displayed. The primary I.C.U. Mode screen is shown in **Figure 6-1**.

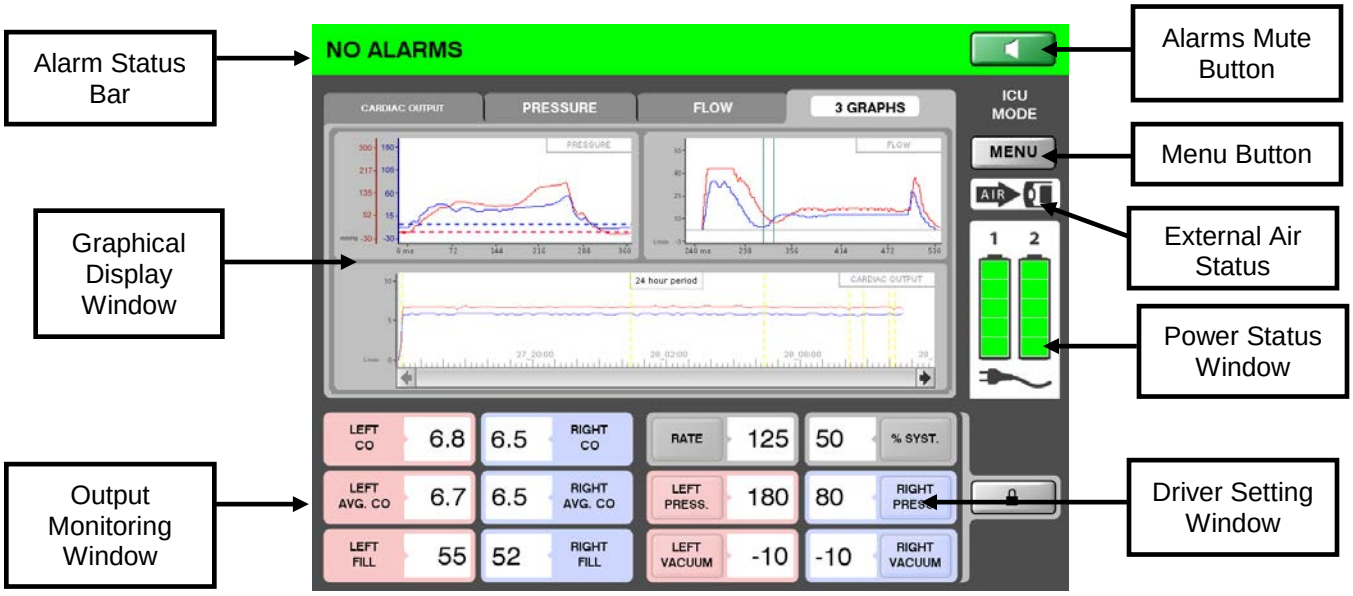


Figure 6-1 – Display Main Screen in Primary ICU Mode

The Alarm Status Bar displays the system alarm level. The color and text in the Alarm Status Bar will change colors as alarm states change. Alarms may be muted by pressing Alarm Mute Button. Pressing the Alarm Mute button does not resolve the alarm condition and does not affect the visual alarm indicator LED displays. **Chapter 14,** *Alarms and Notifications,* contains additional information.

The Graphical Display Window shows pressure and flow waveforms on a beat-to-beat basis and the cardiac output trend

data for both the left and right TAH-t ventricles. Selection of the tabs labeled CARDIAC OUTPUT, PRESSURE and FLOW will display a zoomed view of the desired waveform of interest.

The Output Monitoring Window displays the measured fill volume, the calculated cardiac output and cardiac output hourly trends for both the left and right TAH-t ventricles. Fill volume and cardiac output are updated on a beat-to-beat basis.

The Menu Button allows users with sufficient device access rights to navigate to submenus to review further information, setup new patients, copy information, and other related activities as described more fully in **Chapter 8,** *Operating Modes – Surgical (O.R.) Environment,* **Chapter 9,** *Operating Modes – I.C.U. Environment, and* **Chapter 10,** *Operating Modes – Ambulatory Mode*.

The Power Status Window displays battery charge status for both external Batteries and shows a plug icon when the device is powered by an external power source (i.e., line current). The plug icon changes to a counter when the Driver is powered by Batteries to communicate the remaining battery support time. After disconnecting from wall power, the Companion 2 Driver display (counter) will take approximately one minute to update the estimated battery support time based on Driver settings.

The Driver Settings Window is the area where TAH-t parameters such as rate and pressure may be adjusted. Operating limits and methods to implement changes depend on the set operating mode of the device, as described in **Chapters 8 – 10,** *Operating Modes – Surgical (O.R.) Environment, Operating Modes – I.C.U. Environment, and Operating Modes – Ambulatory Mode,* respectively.

The Air Icon indicates if the Driver is connected to external air or is powered by the compressors.

6.4.2 Alarm and Power Status LED Array

The Driver contains a redundant LED array (**Figure 6-2**) that communicates information about Alarm Status and Power Status in the event of a display screen failure.

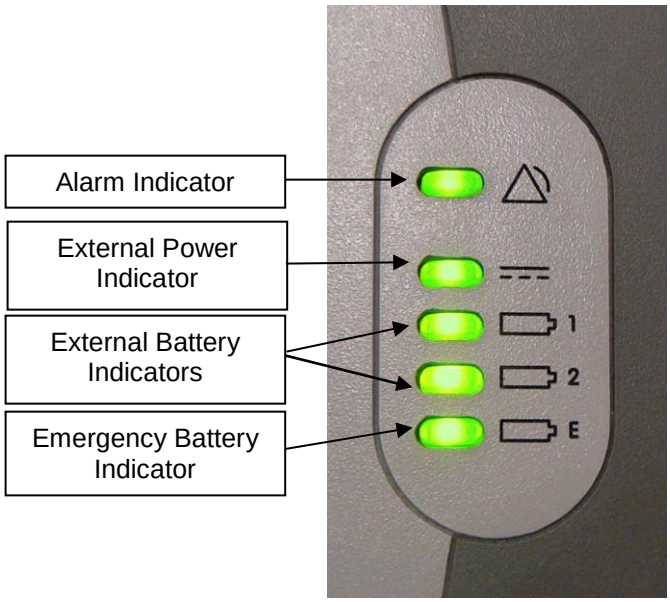


Figure 6-2 – Driver Alarm and Power Status LED Array

The Alarm LED: Solid green indicates there is no alarm. Solid yellow, flashing yellow, red and flashing red all indicate alarms with each color indicating an alarm of different severity.

External Power LED: Solid green indicates external power is applied to the Driver. A yellow external power LED indicates the Driver is operating from battery power.

Battery LED: Solid green indicates the battery is charged and has at least 20% of capacity. The LEDs flash green when the batteries are being charged. A yellow Battery LED indicates the remaining capacity is low (less than 30 minutes). A flashing yellow Battery LED indicates the remaining battery capacity is very low (less than 10 minutes) or there is a battery fault condition.

Emergency Battery LED: Solid green indicates the Emergency Battery is not in use. A flashing green emergency LED indicates the Emergency Battery is being charged. Flashing red indicates a very high alarm state.

6.5 Power

The Driver is designed always to be connected to two power sources - the internal Emergency Battery and either of the two external Batteries and/or an external AC power source. If all power sources are removed or depleted, an audible buzzer will sound. If the Driver is operating on one power source the Driver will be in a very high alarm state. See **Chapter 14,** *Alarms and Notifications,* for full description.

The Driver will display a power plug icon when an external wall power source is provided to the docked Driver. The plug icon is replaced with the remaining estimated battery support time when the Driver is operating from the external Batteries or the internal, Emergency Battery. After disconnecting from wall power, the Companion 2 Driver display (counter) will take approximately one minute to update the estimated battery support time based on Driver settings.

6.5.1 Connection to External Power

The Driver should be connected to external (wall) power via the Hospital Cart or Driver Caddy when available.

CAUTION

If upon docking the Driver into a Hospital Cart or Caddy, the Driver screen flickers, flashes black and white, or turns off, immediately undock the Driver and DO NOT attempt to dock the Driver again into the same Hospital Cart or Caddy. A malfunction of the Hospital Cart or Caddy may exist and it must be returned to SynCardia for evaluation. The Driver should be docked into another Hospital Cart or Caddy.

The Emergency Battery and two external Batteries are charged when the Driver is docked in the Hospital Cart or Driver Caddy with the power cord attached to external wall power. Completely depleted External and Internal Batteries may require up to 11 hours to charge.

The Hospital Cart and the Driver Caddy are designed to accept input from both European (220VAC/50Hz) and US (110VAC/60Hz) external power sources.

	**CAUTION** **The Companion 2 Driver should be plugged into grounded electrical outlets only.** **To avoid accidentally switching off the AC power to a docked Driver, do not plug the Driver into any electrical outlet controlled by a wall switch.**

6.5.2 External Batteries

Two external lithium ion Batteries (**Figure 6-3**) are installed in the front panel of the Driver. The Battery on the left side is Battery 1. The Battery on the right side is Battery 2.

Two fully charged Batteries provide a minimum of 60 minutes of support, with each Battery providing a minimum of 30 minutes of support. Actual support time varies according to driver settings. The remaining estimated External Battery support time is shown on the Display when the Driver is operating from external Batteries. After disconnecting from wall power, the Companion 2 Driver display (counter will take approximately one minute to update the estimated battery support time based on Driver settings.

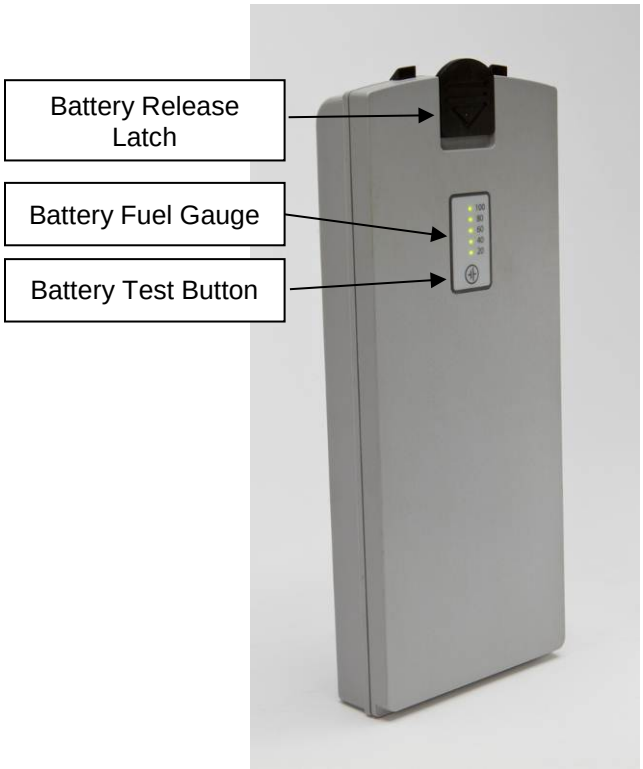


Figure 6-3 – Driver External Battery

When the Driver is operating on battery power, the Batteries are depleted together. Audible alarms will sound every 3.5 minutes when the remaining capacity is low (less than 30 minutes).

The alarm frequency changes to every 30 seconds when the external Batteries are very low (less than 10 minutes) and must be exchanged, or the Driver must be plugged into external wall (AC) power.

Battery capacity can be assessed independently of the Driver by depressing the Battery Test button on the External Battery.

Five illuminated lights indicate a fully charged Battery, with each light representing approximately 20% capacity.

6.5.3 Emergency Battery

The Emergency Battery is an independent, internal, rechargeable lithium-ion battery that does not require routine service or replacement.

It provides power to the Driver when no other power source is provided. When fully charged, the Emergency Battery will provide support for a minimum of 10 minutes.

Since operation on the Emergency Battery indicates no other power sources are provided, the Driver will actuate a very high alarm status, sounding a 10-beep audible burst at 70-80 dB until an alternate power source is connected.

As with all rechargeable batteries, the full capacity of the External Batteries and Emergency Battery will decrease as a result of battery age and charge/discharge cycling.

Chapter 7. Air Supply

There are two sources of air supply to the Companion 2 Driver: external air and internal compressors.

The primary source of air supply to the Companion 2 Driver is external air. Whenever available, the Driver must be connected to external air (**Figure 7-1**). In times of patient transport, the compressors may be used, but the Driver should be reconnected to external air when available.

It is recommended that the external air pressure for the Companion 2 Driver be between 50 to 80 PSI (3.5 to 5.5 Bar). If the external air pressure is below this range, it will not impact the Driver functionality; however, it may result in a System Malfunction Alarm. If a System Malfunction Alarm is displayed while on external air, remove the external air connection from the Driver and verify that the alarm clears. If the external air pressure is above the specified range it will not impact the Driver functionality, however, the internal compressor may activate intermittently. When the compressor activates, the external air icon on the display will not be illuminated.

Figure 7-1 – External Air Connection

Chapter 8. Operating Modes – Surgical (O.R.) Environment

There are three distinct operating modes that enable the Driver to provide users with appropriate controls and monitoring information for use in the:

- Surgical environment (O.R. Mode)
- I.C.U. (I.C.U. Mode)
- Hospital Grounds (Ambulatory Mode).

All modes display a similar primary screen (**Figure 8-1**) but differ in operating range and ability to modify settings.

The O.R. Mode is intended for use ONLY in the surgical environment, as audible alarms are muted in this mode and the rate can be adjusted to OFF.

In the O.R. Mode, all driver functions are accessible, and the full range of Driver Settings is available.

8.1. Preparation for Use – O.R. Mode

8.1.1. Dock the Driver without External Batteries into the Hospital Cart. If necessary, this may be done with the help of another trained user.

8.1.2. Connect the Hospital Cart to a wall AC power source.

8.1.3. Insert two External Batteries into the Driver.

8.1.4. Connect the Driver to external air. If external air is not available, the Driver will operate with its internal compressors.

8.1.5. Turn the Driver ON by rotating the key clock-wise.

8.1.6. Remove the key from the Driver and should be stored in a location determined by the clinical staff.

8.1.7. The Driver will begin operating at default settings when power is applied and the key switch is set to the ON position. Once the Driver software has loaded, the system will show the Ambulatory Mode Screen (**Figure 8-1**).

	**CAUTION** **Do not rapidly rotate the key between the ON setting and OFF setting.**

	**CAUTION** **If a docked Driver user interface displays the following in the Power Status Window:** - **Both External Batteries Missing** - **And no AC Power Icon** - ***and* there are External Batteries and/or AC power applied** **Remove the External Batteries and AC power. Reconnect AC Power and reinsert the External Batteries.**

	**CAUTION** **If the Driver is started while undocked from a Hospital Cart and the touch screen is non-responsive after the graphical user interface is presented on the display, dock the Driver into the Hospital Cart to recalibrate the Driver touch screen. This is performed by following the touch screen calibration procedure (see Section 8.1.9).**

	**CAUTION** **If upon docking the Driver into a Hospital Cart or Caddy, the Driver screen flickers, flashes black and white, or turns off, immediately undock the Driver and DO NOT attempt to dock the Driver again into the same Hospital Cart or Caddy. A malfunction of the Hospital Cart or Caddy may exist and it must be returned to SynCardia for evaluation. The Driver should be docked into another Hospital Cart or Caddy.**

8.1.8. Change the operating mode to O.R. Mode by completing the following steps:

(1) Press the MAXIMIZE SCREEN icon on the display.

(2) Select MENU, then O.R. MODE (**Figure 8-1**).

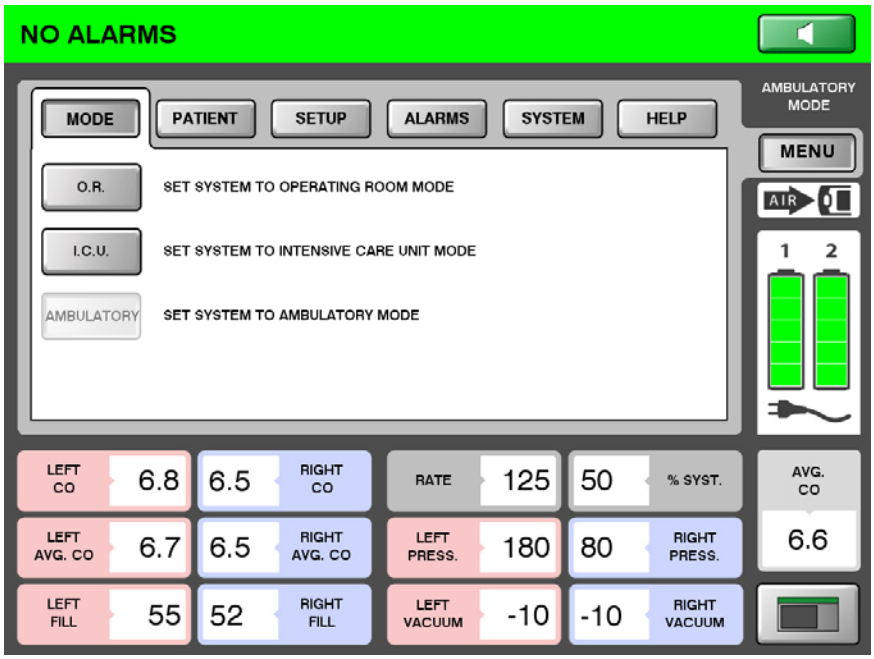


Figure 8-1 – Menu Selection in Ambulatory Mode

(3) A dialogue box called ENTER PASSWORD will request that you enter the O.R. Mode password (3228) and press CONFIRM to change to O.R. Mode. This can be verified by the Mode Change temporary confirmation window displayed for two seconds and the O.R. Mode descriptor in the upper right corner of the display (**Figure 8-2**).

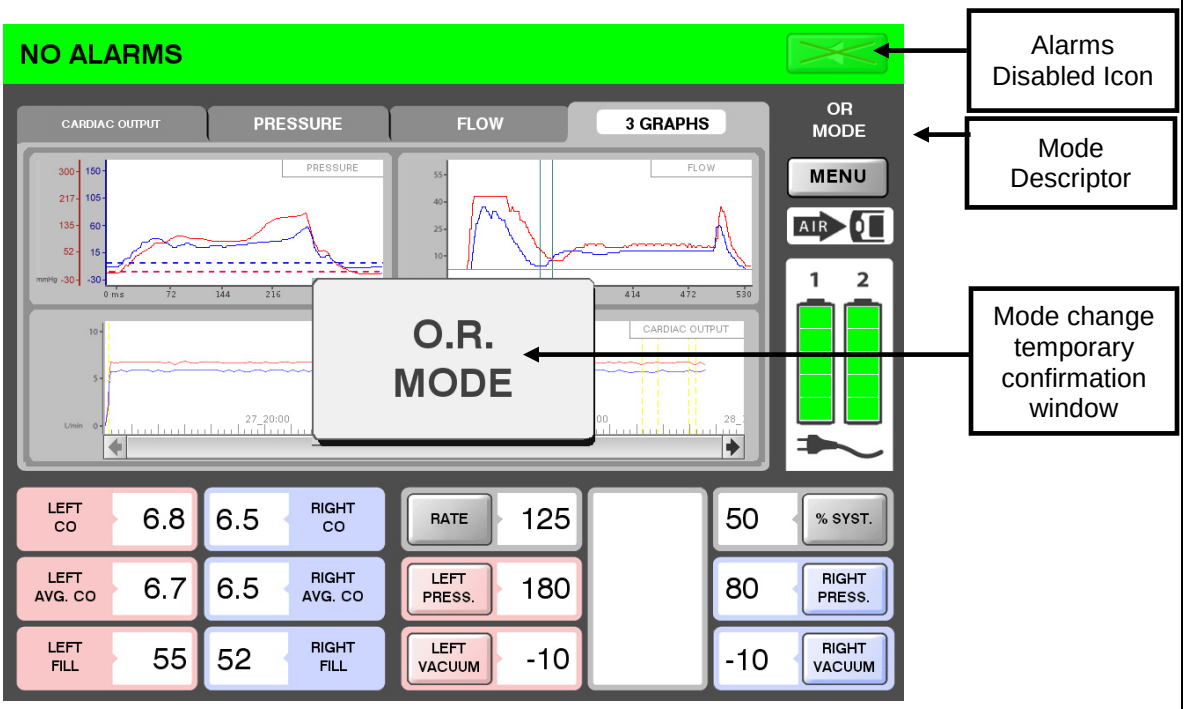


Figure 8-2 – O.R. Mode Entry Screen

(4) The Audible Alarm indicator has a solid “X” over the speaker to indicate that audible alarms are muted. A reminder audible signal will be generated every two hours to indicate that the system is in O.R. Mode. All visual alarm indicators will continue to function

8.1.9. Set System Language.

(1) To set the System Language, from the main O.R. Screen, select MENU, SETUP, and then LANGUAGE.

(2) Select the desired language and press CONFIRM to accept the change, as shown in **Figure 8-3**.

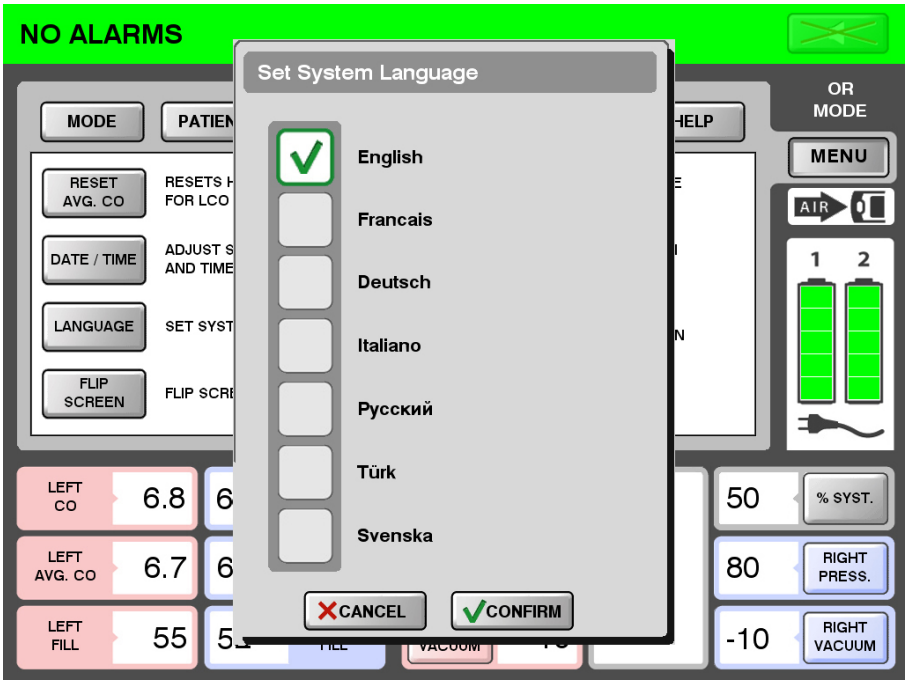


Figure 8-3 – Language Selection Screen

8.1.10. Calibrate the Screen

(1) The touch screen interface on the Driver and the Hospital Cart can be calibrated, if necessary

(2) To calibrate a touch screen, select MENU, SETUP and either DRIVER SCREEN CALIBRATION or CART SCREEN CALIBRATION.

(3) The onscreen prompts will direct you to touch four places in succession on the screen to be calibrated. You must touch the bullseye for approximately 2 seconds to be prompted to touch the next place on the screen.

Note: If the “Calibration Complete-OK” button does not engage on the Driver or Cart display due to a touch screen calibration error, the touch screen calibration will return to the previous settings within 30 seconds allowing continuous interfacing with the Driver. The calibration procedure can be repeated as necessary to improve the touch screen performance.

8.1.11. Perform System Check

(1) The System Check is a combination of automated and manual test of Driver operation. Results are to be recorded on the System Check form, located in **Appendix A**.

(2) Document the Driver Serial Number and Hospital/ Facility name in the header portion of the System Check form.

(3) Verify that two External Batteries with at least a partial charge are installed in the Driver.

(4) Turn the Driver key to the ON position and note the time required from initial power-on to when the system begins to run at the default start-up settings.

(5) Verify that that the Driver compressors began to run within 10 seconds and note the results on the form.

(6) Change from Ambulatory Mode to OR Mode by selecting the maximize screen icon, MENU, MODE, OR Mode. Enter the password, 3228, to complete the change.

(7) Once OR Mode is active, change Rate to single pulse mode by selecting RATE, followed by the "-" icon until the displayed rate is "- -", indicating that the compressors are off and operating in single pulse mode.

(8) Begin the automated portion of the System Check by navigating to the System Check icon in the menu. Select MENU, SYSTEM then SYSTEM CHECK (**Figure 8-4**).

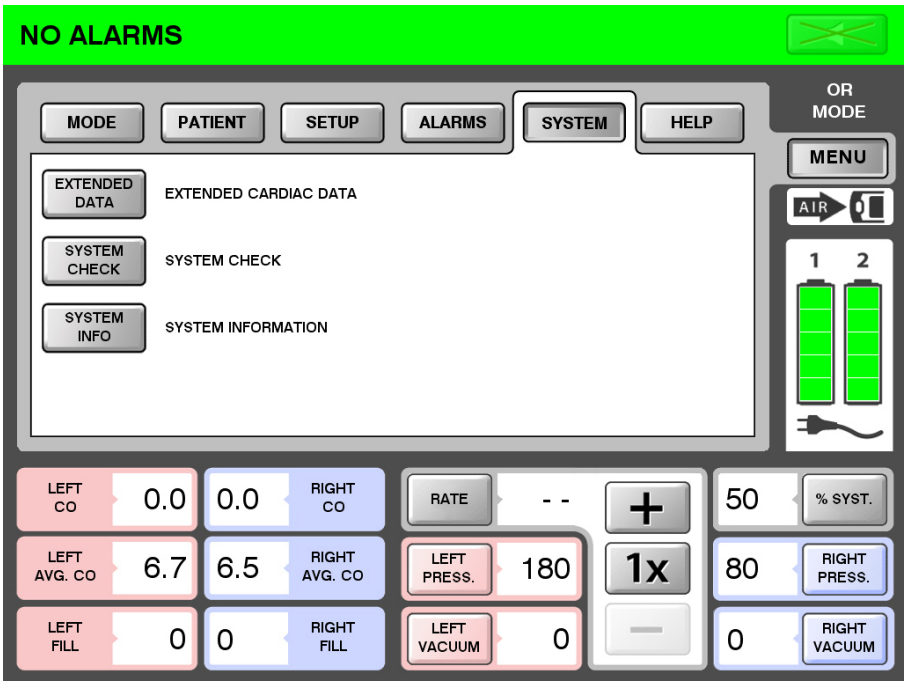


Figure 8-4 – System Check Menu Screen

(9) System Check performs a variety of tests related to power management, system communication, sensors, pressure measure, flow measurement, and audible and visual alarm systems operation.

(10) System Check requires user interaction to complete and prompts will indicate when user action is required. A progress bar is displayed during the test.

(11) Record System Check test results on the Companion 2 Driver System Check form.

Note: The power icons and external air icons do not update during System Check. They remain as they were when the System Check process was started.

(12) The power management system and indicators are manually verified. Complete the steps and document the results on the System Check Form. See **Chapter 13**, *Power Management,* for any additional information.

(13) Turn the Driver off and sign and date the Companion 2 Check Form.

(14) If any tests above are not successful, contact SynCardia Systems, LLC. Obtain the backup Driver and prepare it for use as indicated in this section.

(15) Send a copy of the completed form to SynCardia Systems, LLC by fax at the number indicated on the form.

8.1.12. Set Date and Time

(1) When System Check is successfully completed, set the Date and Time for the Driver, if needed, by pressing MENU, SETUP, ADJUST SYSTEM DATE/TIME (**Figure 8-5**).

(2) Select each item that requires modification and use the “+” or “-” button to change to the desired value.

(3) Select CONFIRM to accept the change.

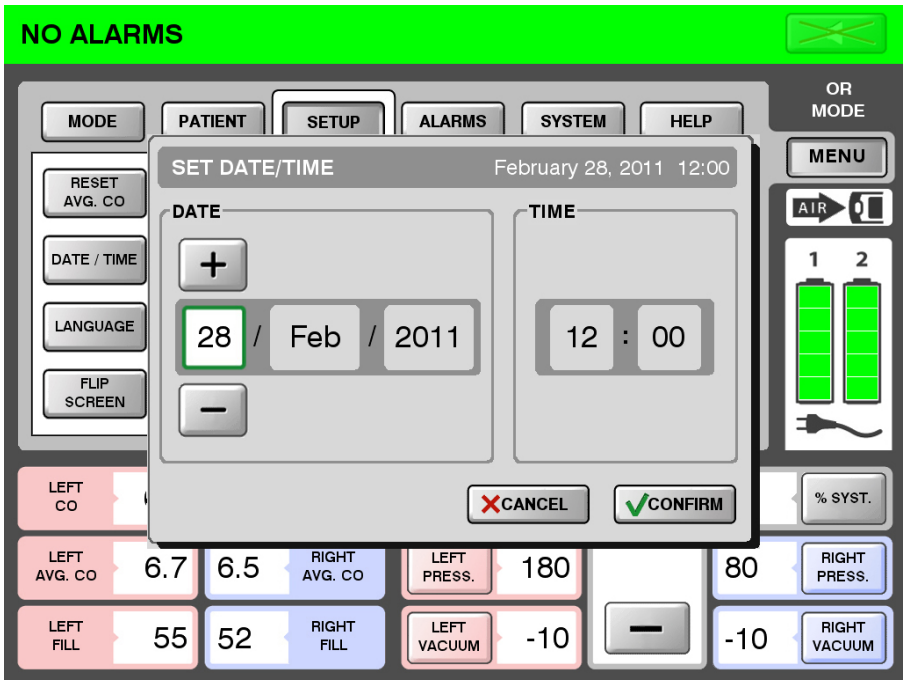


Figure 8-5 – Set Date/Time

8.1.13. Set up a New Patient File

Starting a new patient file will overwrite prior information. To enter a profile for a new patient:

(1) Select MENU.

(2) Select PATIENT tab.

(3) Select NEW button to create a new patient profile.

(4) The operator will be notified that a new patient file will overwrite any previous data and will be asked if the previous patient data should be downloaded. Press CANCEL if you would like to exit the new patient file screen.

(5) Enter the patient information in the pop-up window using the touch keyboard that appears. Select the white box next to PATIENT ID, TAH-t SERIAL NUMBER and EMERGENCY CONTACT # to enter the requested alpha numeric information.

(6) It is recommended that the hospital call-in number be included in the EMERGENCY CONTACT # box. The data entered in this patient screen will also appear on the Help Screen displayed when selecting MENU, HELP in order to provide users with access to any contact numbers entered in this screen.

(7) Select CONFIRM when entry is completed.

(8) A warning is displayed indicating that setting up a new patient overwrites existing prior patient information (**Figure 8-6**). Select YES to complete the new patient file creation or NO to exit to the PATIENT screen to copy the patient data.

(9) Patient file information may be edited by selecting EDIT.

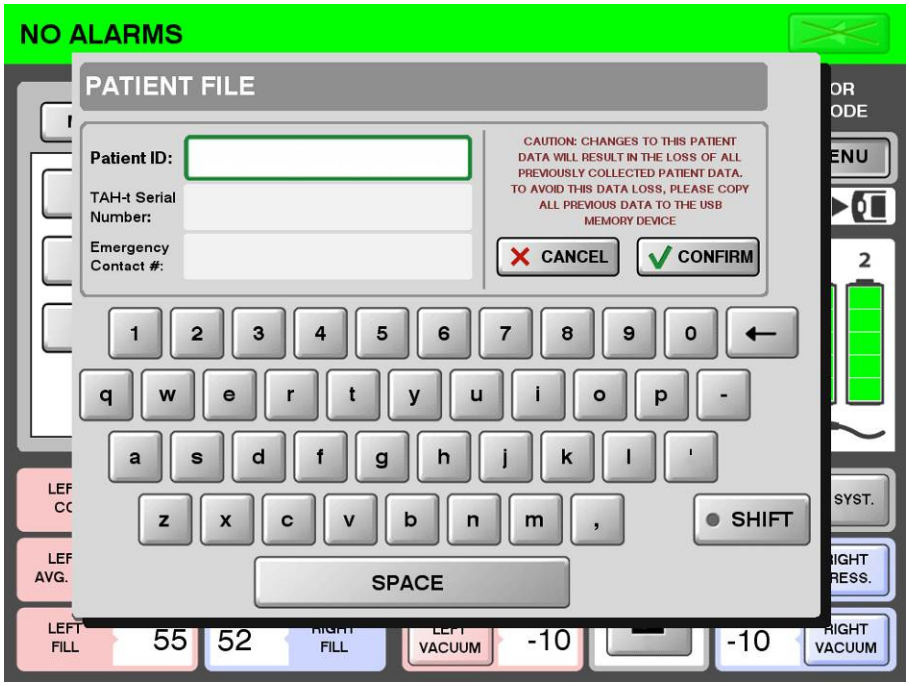


Figure 8-6 – New Patient Setup Screen

(10) Patient File Information

Patient data log files record information pertaining to the operation of the Driver and any alarms that occurred, in a comma-separated file (CSV) that can be opened with most spreadsheet applications. The Patient File information includes performance data, pressure and flow waveforms and alarm history data. The following performance information is recorded in the data log files:

- Patient ID
- TAH-t Serial Number
- Hospital

The following measured or calculated values are recorded in the log file(s):

- Time
- Rate

- Percent Systole
- Left Cardiac Output
- Right Cardiac Output
- Left Hourly Cardiac Output Average
- Right Hourly Cardiac Output Average
- Left Fill Volume
- Right Fill Volume
- Left Peak dP/dt
- Right Peak dP/dt
- Left Vacuum
- Right Vacuum
- Left Pressure
- Right Pressure

The following user-set values are recorded in the log file:

- Rate
- Percent Systole
- Left Maximum Pressure
- Right Maximum Pressure
- Left Vacuum
- Right Vacuum

Alarm occurrences and duration are recorded in the Alarm log. This information remains stored even if power to the Driver is removed. See **Chapter 14,** *Alarms and Notifications,* for additional information on alarms.

(11) Copy Patient File. The steps for copying files to any 8GB or larger USB 1.0/2.0 compliant mass memory device are described below and depicted in **Figure 8-7**. The patient file is in comma-separated values (CSV) format and can be imported into many spreadsheet and database programs.

- Select the MENU option.
- Select the submenu PATIENT option.
- A screen displays and instructs the operator to:
  - Insert a USB storage device into the USB port.
  - Press COPY to start.
  - Copying will take a few seconds.
  - Press DONE, then remove USB device.
  - To exit at any time, select CANCEL.

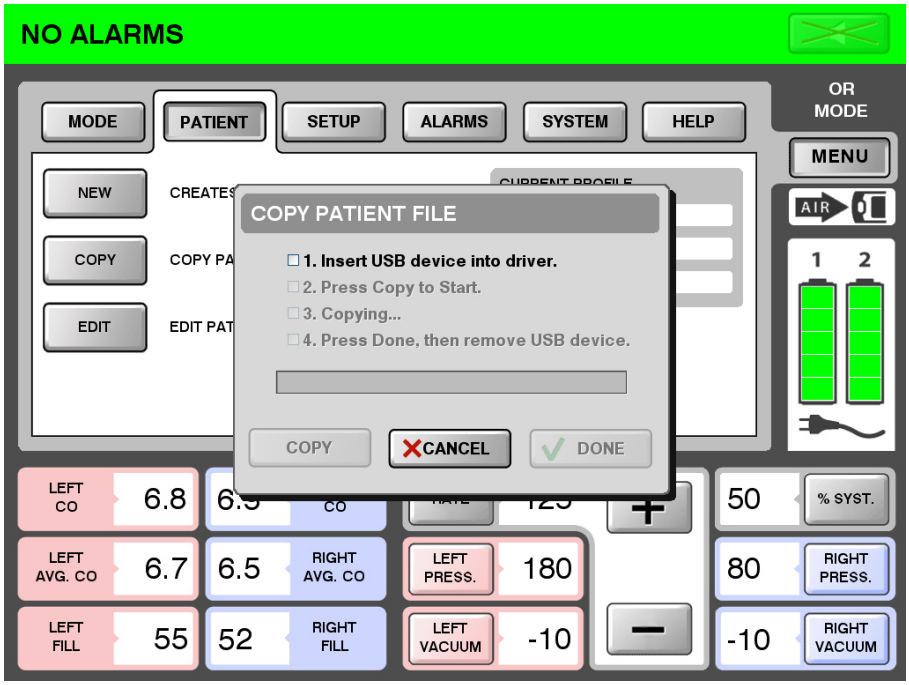


Figure 8-7 – Patient File Copy Screen

8.2. Prepare for Implant Procedure

Once the Driver is set up for the new patient, the surgical team may request certain actions during the procedure. The following actions may be required during the procedure.

8.2.1. Adjustment of Operation Parameter

The Parameter Adjustment Window of the user interface is shown in **Figure 8-8** below.

Figure 8-8 – Parameter Adjustment Window

(1) To adjust any parameter, touch the parameter name, such as PRESSURE.

(2) Select “+” to increase the setting and “-” to decrease the setting.

(3) Pressing the “+” or “-” button once will change the value by increments of one.

(4) Holding the “+” or “-” button for two seconds may cause the parameter to immediately change by different increments, as shown in **Table 8-1.**

Table 8-1 – O.R. Mode Parameter Adjustment Range and Increments

Parameter	Units	Minimum	Maximum	Single Press Increment	Press and Hold Increment
Rate	Beats per minute (BPM)	40 (<40 is single pulse mode)	150	1	10
% Systole	Percent (%)	40	60	1	1
Left Pressure	mmHg.	120	280	1	5
Right Pressure	mmHg.	40	150	1	5
Left Vacuum*	mmHg.	0	-30	1	5
Right Vacuum*	mmHg.	0	-30	1	5

* Actual vacuum achieved is dependent on the patient systemic pressures and resistance and the Driver parameter settings. In general, increasing vacuum increases fill volumes and decreases in vacuum decrease fill volume.

(5) All adjustments in O.R. Mode occur without delay when the “+” increase or “-” decrease button is selected.

(6) The background for the “+” and “-” buttons encapsulates the selected parameter to indicate the parameter that will be adjusted when the increment or decrement button is selected, as shown in **Figure 8-9** below.

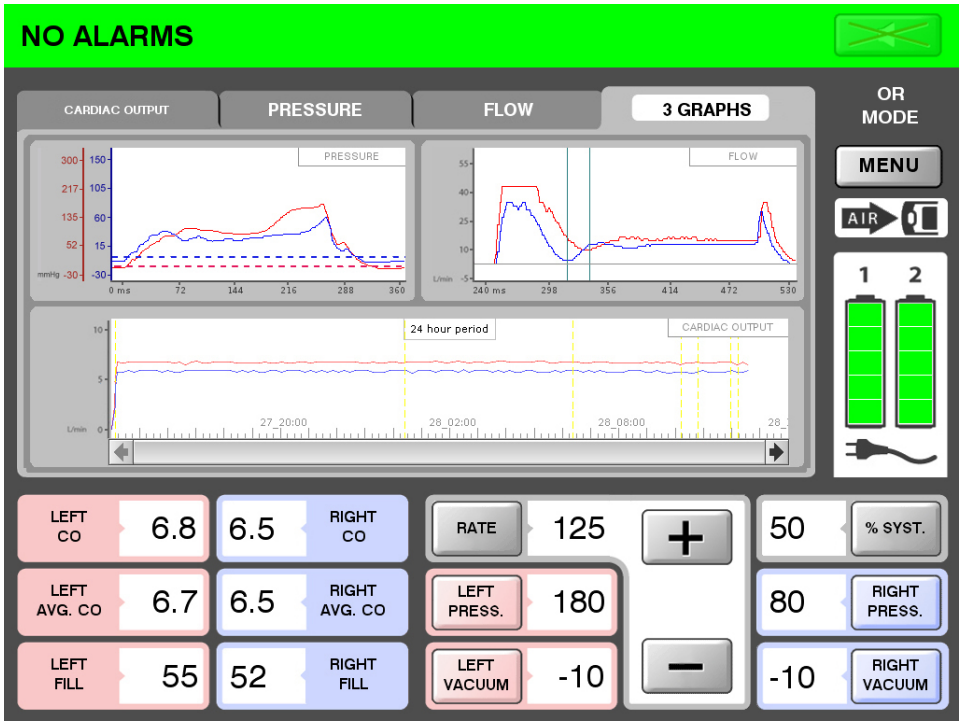


Figure 8-9 – Adjustment of Parameters in O.R. Mode

8.2.2. Single Pulse Mode

The Driver rate can be adjusted down to 40 in O.R. Mode. Turning the rate down any further suspends pumping action and allows single-pulse actuations to be used, which are helpful in de-airing the TAH-t.

(1) To set the Driver to single pulse mode, select RATE then select the “-” button to decrease rate.

(2) Pressing the “-” button once decreases the Rate by one BPM per selection.

(3) Holding down the button will reduce the Rate in increments of ten.

(4) When the Rate is below 40, “- -” is shown for the Rate and single pulse actuation becomes an option.

(5) Select the One Time icon, “1X” (beneath the “+” button) to perform a single pulse actuation (**Figure 8-10**).

(6) When the increment button (“+”) is selected, the rate starts at 40 BPM. Multiple alarms will be displayed when transitioning out of single pulse mode. These alarms will clear as the beat rate is increased to the ICU operating beat rate range of 90 to 150 BPM and the cardiac output levels stabilize at the final settings.

Figure 8-10 – Main O.R. Screen Showing Single Pulse Mode Button

8.2.3. Transfer Support

(1) When directed by the surgical team to increase the Rate, select RATE and press and hold the “+” increment button to increase the Rate to 120 BPM. Multiple alarms will be displayed when transitioning out of single pulse mode. These alarms will clear as the beat rate is increased to the ICU operating beat rate range of 90 to 150 BPM and the cardiac output levels stabilize at the final settings.

(2) If the surgeon requests that the TAH-t be turned off, the drivelines can be disconnected from the Driver using the single connector to immediately cease TAH-t pneumatic support , or the rate “-” button can be held down to decrease the rate until single pulse mode is enabled and the TAH-t rate is zero.

(3) The stroke volumes will be low until the patient is completely off bypass.

(4) During initiation of pump operation, no vacuum is to be applied.

	**CAUTION** **When applying vacuum, always start with the left side first, then the right.** **Always assure partial filling of the ventricles by observing the fill volume of the ventricles on the screen.** **The fill capacity of each 70cc ventricle is 70cc; acceptable partial fill is between 50 and 60 cc.** **The fill capacity of each 50cc ventricle is 50cc; acceptable partial fill is between 30 and 40 cc.**

8.2.4. Flip Screen

The surgeon may request to see the cardiac output from the Driver. The Hospital Cart display can be rotated to face the surgical team while the device settings are adjusted from the Driver.

(1) The display on the Driver can be flipped 180° by selecting MENU, SETUP, FLIP SCREEN (**Figure 8-11**).

(2) This will change the orientation of the Driver display only and will not affect the Hospital Cart display.

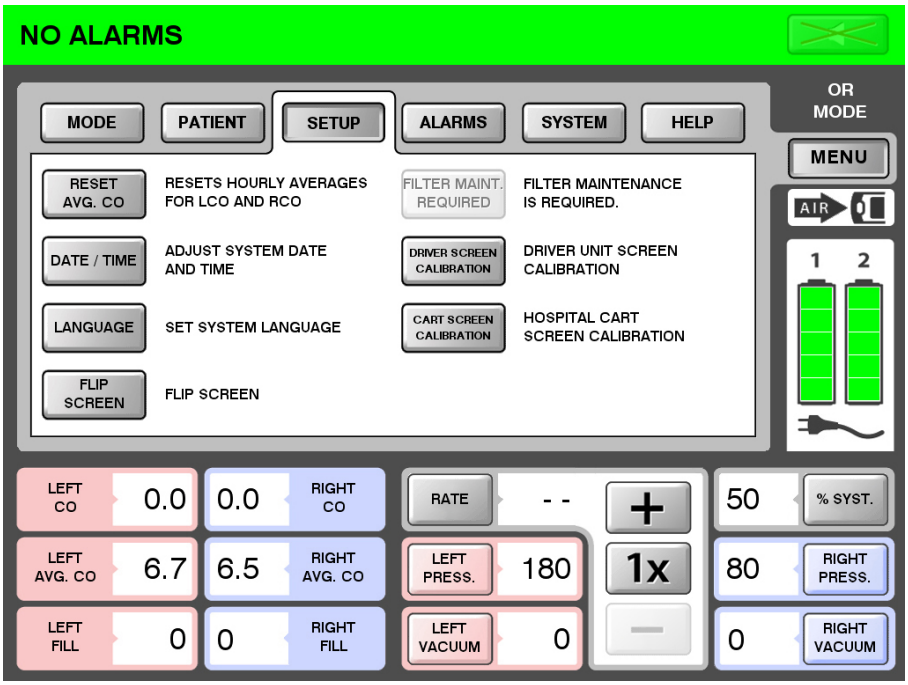


Figure 8-11 – Flip Screen Menu

8.2.5. Optimization of Adjustments

Once the Rate has increased to 120 BPM, pressures, systolic duration and vacuum can be adjusted to ensure that the TAH-t is operating at a partial fill/full eject.

(1) Full Eject Adjustment

Left and Right pressure waveforms are shown on the main O.R. Screen in the 3 GRAPHS tab. If needed, the PRESSURE tab can be selected on the main screen display to view a larger pressure waveform graph. The left pressure is shown with a red line, and the right pressure waveform is shown with a blue line.

It may be necessary to increase or decrease left and right pressures to obtain a clear full eject flag for both ventricles. Ideally, the full eject flag should be approximately 10 to 20% of the total pressure waveform, as shown in **Figure 8-12**. The full eject flag can be identified as a change in slope; where the pressure waveform begins to increase, in the later part of the waveforms.

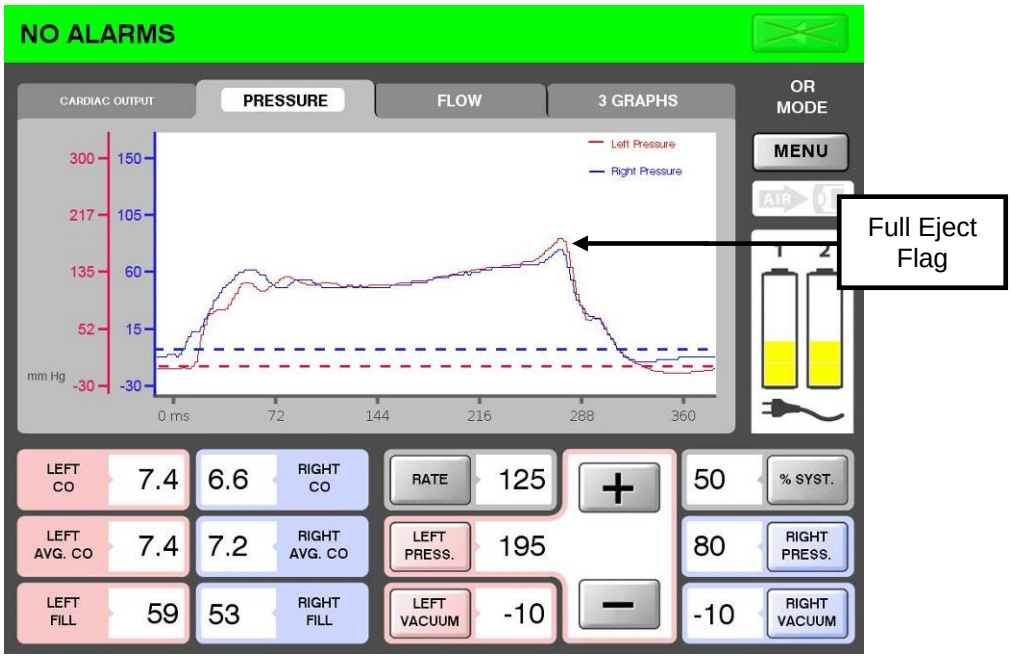


Figure 8-12 – Zoomed View of Pressure Waveform Showing Full Eject Flag

	**CAUTION** **Always assure full emptying of the ventricles by observing where the full eject markers are on the pressure waveforms.** **The full eject markers are the second rise near the latter part of the waveform** (**Figure 8-12**).

(2) No Full Eject Flag Observed

If there is no readily observable full eject flag, increase pressure for the affected ventricle until the full eject flag is 10 to 20% of the pressure waveform or a clear change in slope is observed.

(3) Full Eject Flag > 20% of Waveform

If the full eject flag is biased to the left, decrease pressure for either the left or the right ventricle until the full eject flag is reduced to approximately 10 to 20% of the pressure waveform length.

(4) Partial Fill Adjustment

The TAH-t is intended to operate with a partial fill. An acceptable partial fill for the 70cc TAH-t is fill volume between 50 and 60 cc. An acceptable partial fill for the 50cc TAH-t is fill volume between 30 and 40 cc. Rate, Vacuum and Systolic Duration settings affect whether the TAH-t is at partial or full fill and may require adjustment to resolve the issue.

(5) Identification of Full Fill Condition

When the Driver is connected to a 70cc TAH-t and a Full Fill condition exists, the background color for the Fill Volume icon in the lower left corner of the display screen turns from red (for the left ventricle) and blue (for the right ventricle) to yellow when the fill volume is 65mL or greater (**Figure 8-13**). An acceptable partial fill for the 70cc TAH-t is fill volume between 50 and 60 cc.

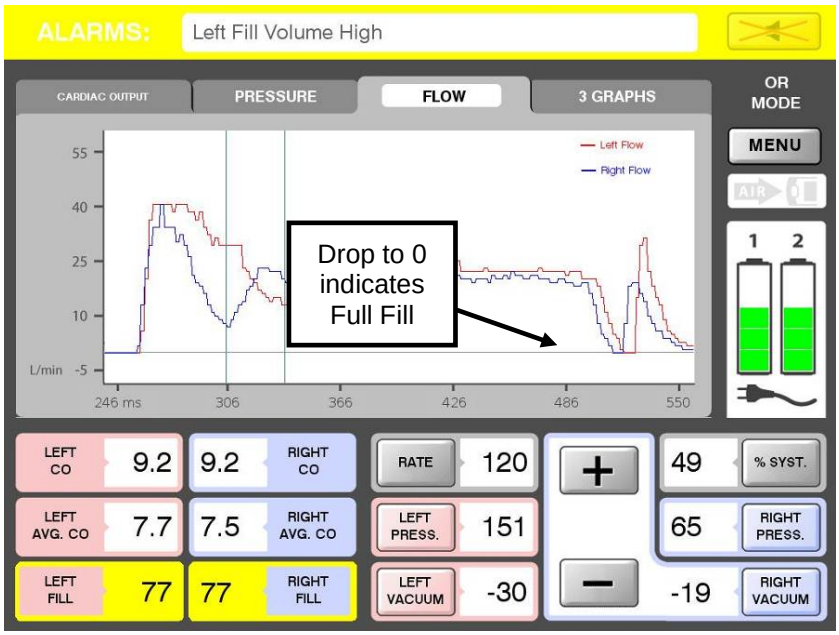


Figure 8-13 – Screen Showing Full Fill on the Left and Right Ventricle for a 70cc TAH-t

When the Driver is connected to a 50cc TAH-t and a Full Fill condition exists, the background color for the Fill Volume icon in the lower left corner of the display will NOT change to yellow, but will remain red (for the left ventricle) and blue (for the right ventricle). Always assure partial filling of the ventricles by observing the displayed fill volume of the ventricles and flow waveform on the screen. An acceptable partial fill for the 50cc TAH-t is fill volume between 30 and 40 cc.

CAUTION

The following alarms will not occur when the Companion 2 Driver is being used with the 50cc TAH-t:

- **Left Fill Volume High**
- **Right Fill Volume High**

Fill volume for the 50cc TAH-t should be monitored and Driver settings adjusted if the patient is experiencing or approaching a full fill condition (> 40cc)

(6) Flow Waveform

The flow waveform indicates the return air flow from the TAH-t to the Driver that is caused by the filling of the ventricle with blood. When the diaphragm stops moving, the flow rate drops to zero. If the diaphragm stops moving before systole starts, the flow waveform will approach zero, indicating that the diaphragm has maximized its movement and is full filling (See **Figure 8-13**). If the flow remains above zero, as shown in **Figure 8-14**, the device is operating in a partial fill condition.

Note: If the Flow Waveform indicates a full fill condition, the Fill Volume High alarm may not occur because the full eject flag is not present on the Pressure Waveform.

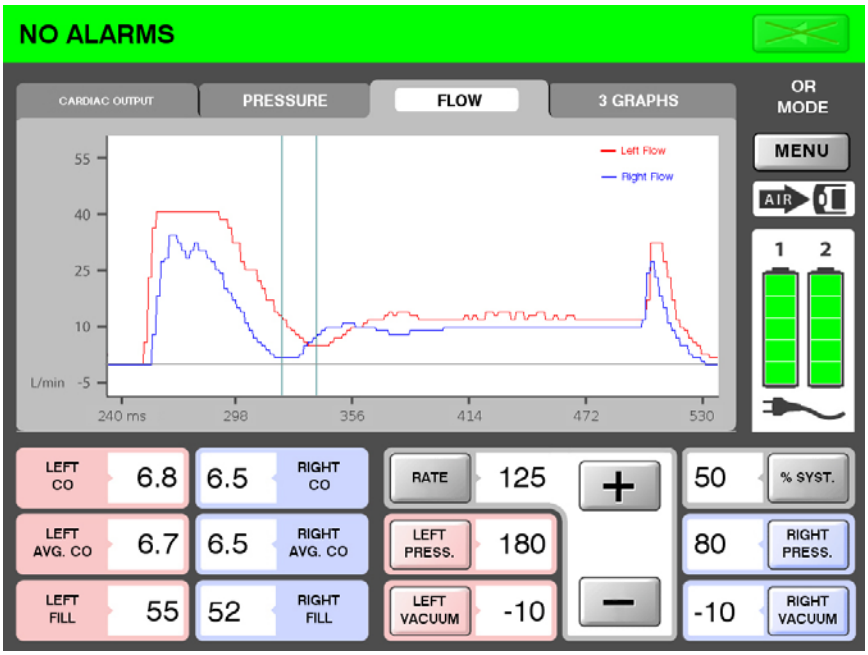


Figure 8-14 – Partial Fill Flow Waveform

(7) Resolve Full Fill Condition

To resolve a full fill condition, adjust the following parameters, one at a time, until the TAH-t is operating at a partial fill condition. It may not be necessary to adjust all parameters to resolve the issue.

- Increase rate
- Decrease vacuum
- Increase systolic duration

Once the TAH-t is confirmed to be running in a partial fill, full eject mode, Alarm settings may be modified as indicated in **Chapter 14,** *Alarms and Notifications,* to be specific for the patient.

Once the TAH-t is fully supporting a patient, the average Cardiac Output (Avg. CO) can be reset to display only relevant information by selecting MENU, SETUP, and RESET AVG CO and confirming the change (**Figure 8-15**). The Avg. CO number is useful for comparison to the instantaneous Cardiac Output display to see if the current Cardiac Output is greater than or less than the hourly average cardiac output.

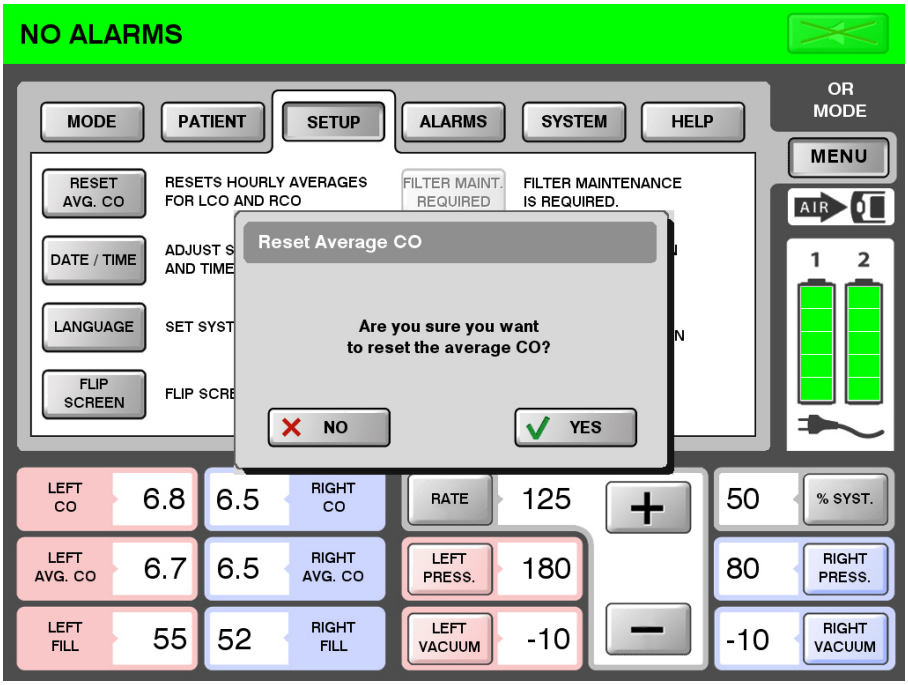


Figure 8-15 – Reset Average Hourly Cardiac Output

8.2.6. Change to I.C.U. Mode

(1) Once the surgery is complete and the Driver parameters have been properly adjusted to achieve partial fill, full eject, the Driver MUST be changed to I.C.U. Mode.

(2) Select MENU, MODE, and I.C.U. MODE.

(3) Changing to I.C.U. Mode activates the audible alarms, limits the minimum rate to 90 BPM and provides additional protection against accidental adjustment of operating parameters.

(4) No password is required to change from O.R. Mode to I.C.U. Mode because there are more restrictions in I.C.U. Mode than in O.R. Mode.

8.2.7. Change to Ambulatory Mode

(1) Once the patient is hemodynamically stable, the Driver may be changed to Ambulatory Mode.

(2) Select MENU, MODE, and Ambulatory Mode.

(3) Ambulatory Mode restricts access to all adjustments other than:

- Copy Patient File
- Set Date and Time (if necessary)

(4) No password is required to change from O.R. Mode to Ambulatory Mode because there are more restrictions in O.R. Mode than in Ambulatory Mode.

8.2.8. Setup of Backup Driver

The Driver will begin operating at default settings when power is applied and the key switch is set to the ON position. The Driver will begin to pump as soon as the key switch is set to the ON position.

Once the Driver software has loaded (will take approximately 2 – 3 minutes), the system will show the Ambulatory Mode Screen. Once the Driver settings for a given patient are defined, follow the steps below to set up the backup Driver.

(1) Power on the backup Driver. (**Note:** Alarms are disabled for the first 2 minutes).

(2) Once the Driver software has loaded, the system will show the Ambulatory Mode Screen (**Figure 8-16**).

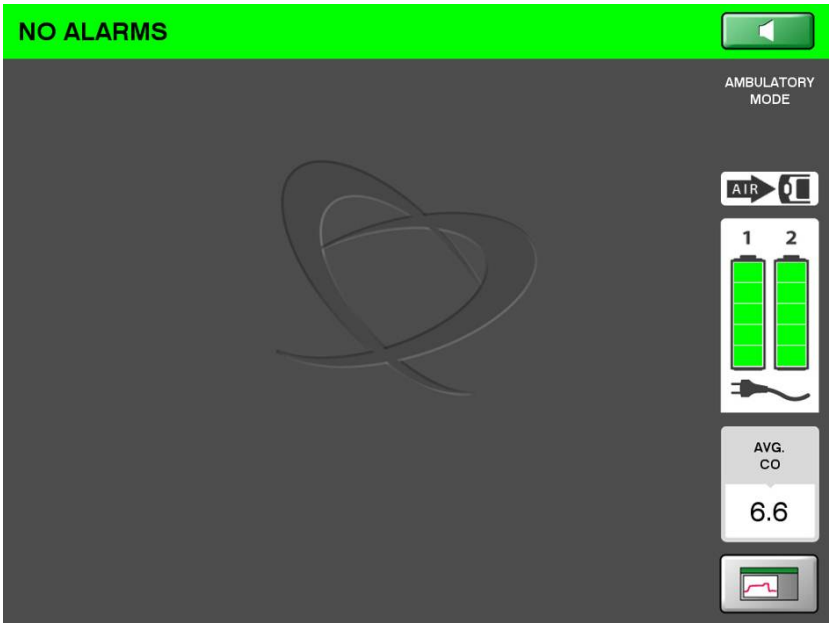


Figure 8-16 – Ambulatory Mode

(3) Change to I.C.U. Mode by selecting MENU, I.C.U. MODE and enter the password, 9722.

(4) Press the LOCK Icon in the lower right corner to unlock the touch screen.

Chapter 9. Operating Modes – I.C.U. Environment

The I.C.U. Mode is intended for in-hospital use only. This mode allows for adjustment of alarm limits, changing date and time, set-up of patient data and adjustment of parameters such as rate, pressure, vacuum and percent systole.

This mode is intended to be used by trained hospital personnel who have a need to modify device operation to respond to potential changes in patient conditions, such as decreasing pressure when patient edema decreases.

Although O.R. Mode allows for real-time adjustment of operating parameters, the I.C.U. Mode provides controls against accidental changes that may be caused by inadvertent contact with the touch screen.

9.1. Adjustment Locked/Unlocked

The default condition for the I.C.U. Mode is “locked,” which is indicated by the LOCK Icon (**Figure 9-1**).

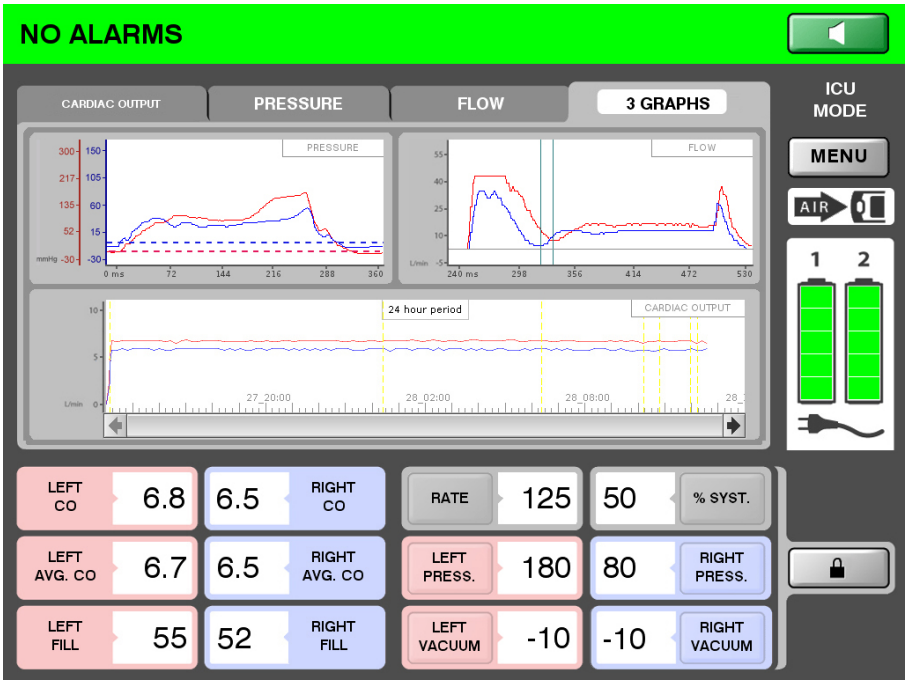


Figure 9-1 – I.C.U. Mode Screen – Locked

In order to change parameters, it is necessary to select this button to unlock the screen (**Figure 9-2**). Unlocked screens revert to locked status after 30 seconds of no activity.

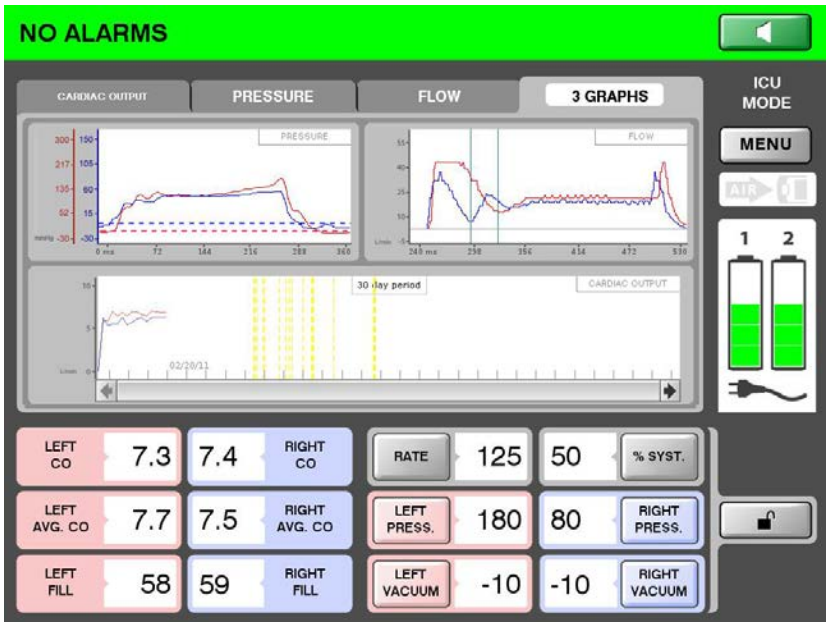


Figure 9-2 – I.C.U. Mode Screen – Unlocked

9.2. Adjustment of Parameters

9.2.1. Operating parameters can be adjusted once the screen is unlocked. The adjustment window in I.C.U. Mode shows both the current setting and the new setting, as shown in **Figure 9-3**.

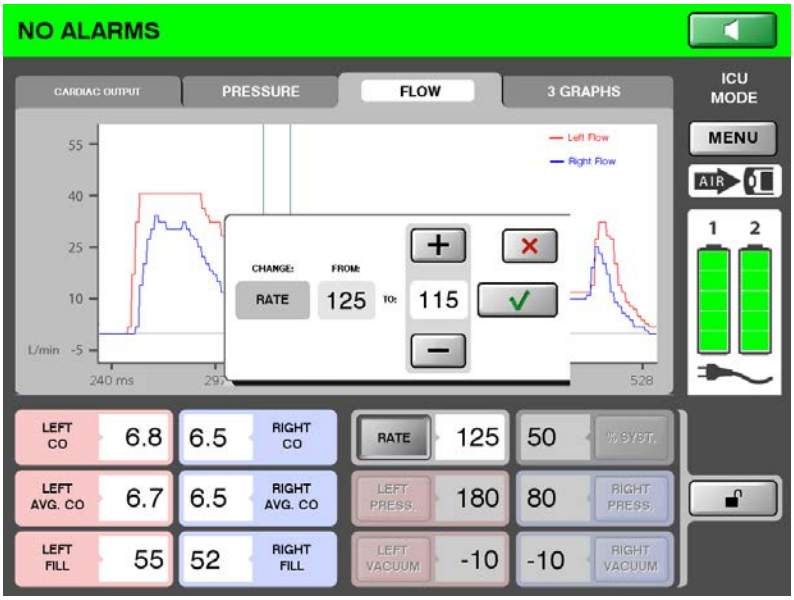


Figure 9-3 – I.C.U. Mode Parameter Adjustment

Verify that the TAH-t continues to operate in a partial fill/full eject condition, as described in **Section 8.2.5**, *Optimization of Adjustments*.

9.2.2. The following parameters may be changed:

- Rate
- % Systole
- Left Pressure
- Right Pressure
- Left Vacuum
- Right Vacuum

9.2.3. The general instruction to change each of the operating parameters is the same. Using RATE as the example, the operating parameters are adjusted as follows:

(1) Unlock the LOCK icon by selecting it.

(2) Press the RATE button on the LCD screen.

(3) Select "+" or "-" to increase or decrease the rate.

(4) Select "√" to enter the change or "X" to cancel the change.

(5) A confirmation screen will appear asking: "Are you sure you want to change?"

(6) Select "√ YES" to confirm the change or "X NO" to cancel the change.

(7) Once you select "√ YES", your change is immediately initiated.

(8) After making changes to any of the parameters, select the UNLOCKED icon to return to the locked position.

9.2.4. Holding the "+" or "-" button for two seconds will cause the parameter to immediately change by increased increments, as shown in **Table 9-1**.

Table 9-1 – I.C.U. Mode Parameter Adjustment Range and Increments

Parameter	Units	Minimum	Maximum	Single Press Increment	Press and Hold Increment
Rate	Beats per minute (BPM)	90	150	1	10
% Systole	Percent (%)	40	60	1	1
Left Pressure	mmHg	120	280	1	5
Right Pressure	mmHg	40	150	1	5
Left Vacuum*	mmHg	0	-30	1	5
Right Vacuum*	mmHg	0	-30	1	5

* Actual vacuum achieved is dependent on the patient systemic pressures and resistance and the Driver parameter settings. In general, increasing vacuum increases fill volumes and decreases in vacuum decrease fill volume.

Chapter 10. Operating Modes – Ambulatory Mode

Ambulatory Mode is intended for patients who are hemodynamically stable while in the hospital. This Mode restricts access to all adjustments other than:

- Copy Patient File
- Set Date and Time (if necessary)

Any other changes of device settings require that the Operating Mode be changed to I.C.U. Mode or O.R. Mode.

When power is applied and the key switch is set to the ON position, the Driver will begin operating at the factory default settings.

Once the Driver software has loaded, the system will show the Ambulatory Mode Screen (**Figure 10-1**).

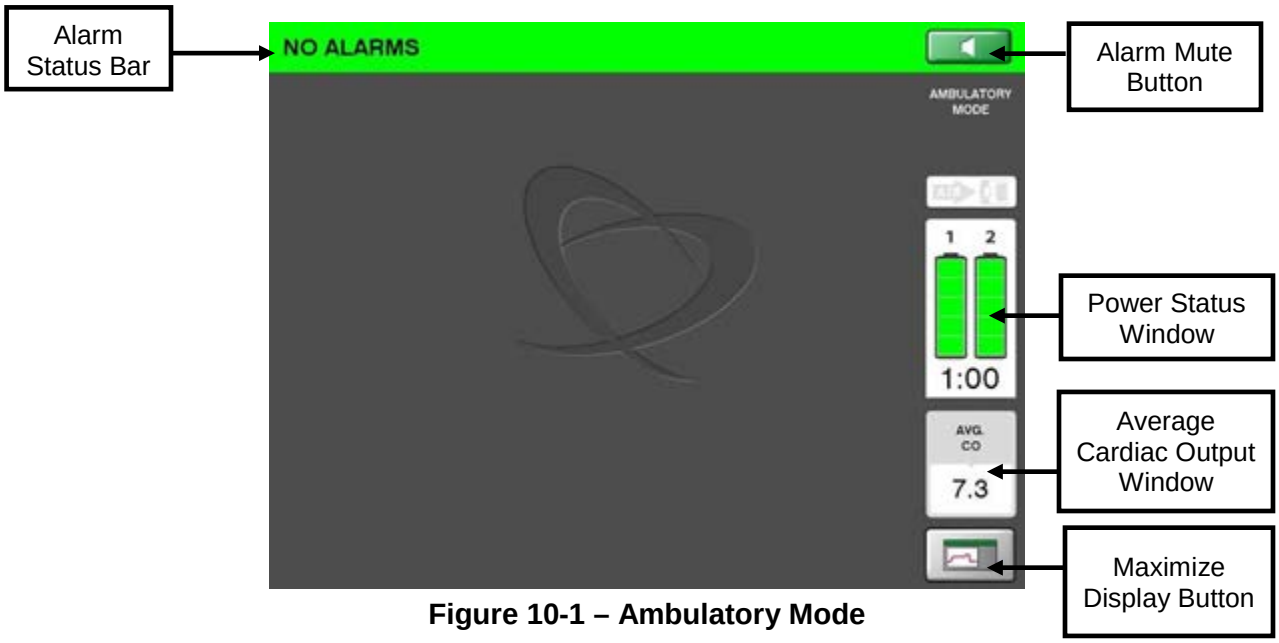


Figure 10-1 – Ambulatory Mode

When selected, the Maximize Display Button (**Figure 10-1**) provides graphical display information and allows the Menu button to be accessed, as shown in **Figure 10-2.**

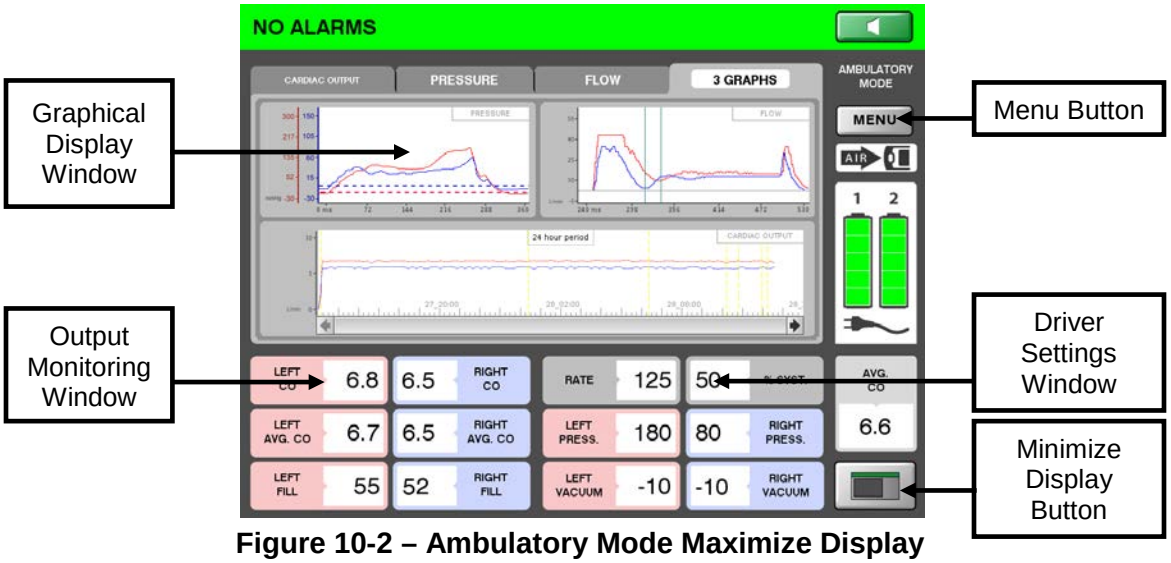


Figure 10-2 – Ambulatory Mode Maximize Display

10.1. Patient File Information

Patient data log files record information pertaining to the operation of the Driver and any alarms that occurred, in a comma-separated file (CSV) that can be opened with most spreadsheet applications. The Patient File information includes performance data, pressure and flow waveforms and alarm history data. The following performance information is recorded in the data log files:

- Patient ID
- TAH-t Serial Number
- Hospital

The following measured or calculated values are recorded in the log file(s):

- Time
- Rate
- Percent Systole
- Left Cardiac Output
- Right Cardiac Output
- Left Hourly Cardiac Output Average
- Right Hourly Cardiac Output Average
- Left Fill Volume

- Right Fill Volume
- Left Peak dP/dt
- Right Peak dP/dt
- Left Vacuum
- Right Vacuum
- Left Pressure
- Right Pressure

The following user-set values are recorded in the log file:

- Rate
- Percent Systole
- Left Maximum Pressure
- Right Maximum Pressure
- Left Vacuum
- Right Vacuum

Alarm occurrences and duration are recorded in the Alarm log. This information remains stored even if power to the Driver is removed. See **Chapter 14,** *Alarms and Notifications,* for additional information on alarms.

10.2. Adjustments

10.2.1. Copy Patient File

The steps for copying files to any 8GB or larger USB 1.0/2.0 compliant mass memory device are described below and depicted in **Figure 10-3**. The patient file is in comma-separated values (CSV) format and can be imported into many spreadsheet and database programs.

(1) Select the MENU option.

(2) Select the submenu PATIENT option.

(3) Select COPY PATIENT FILE.

(4) A screen displays and instructs the operator to:

- Insert a USB storage device into the USB port.
- Press COPY to start.
- Copying will take a few seconds.
- Press DONE, then remove USB device.
- To exit at any time, select CANCEL.

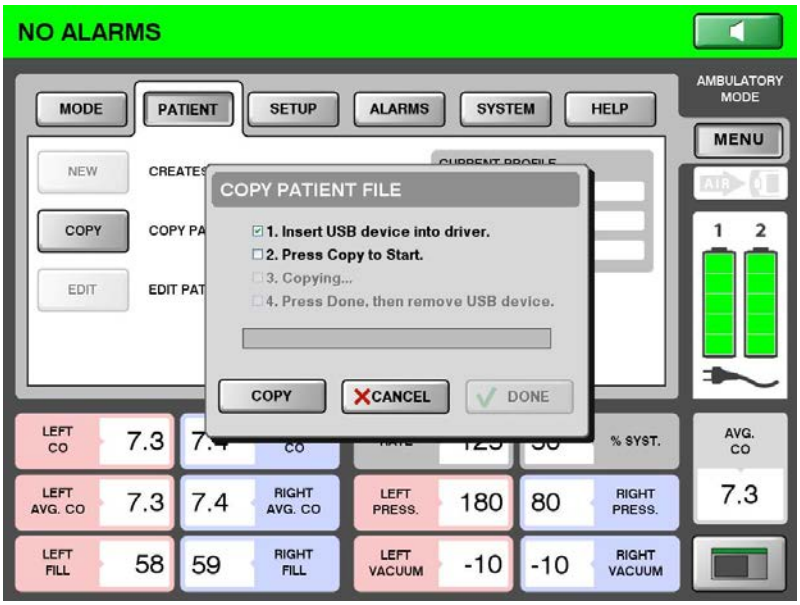


Figure 10-3 – Patient File Copy Screen

10.2.2. Set Date and Time

Set the Date and Time for the Driver, if needed, by pressing MENU, SETUP, DATE / TIME. Select each item that requires modification and use the "+" or "-" button to change to the desired value. Select ENTER to accept the change (**Figure 10-4**).

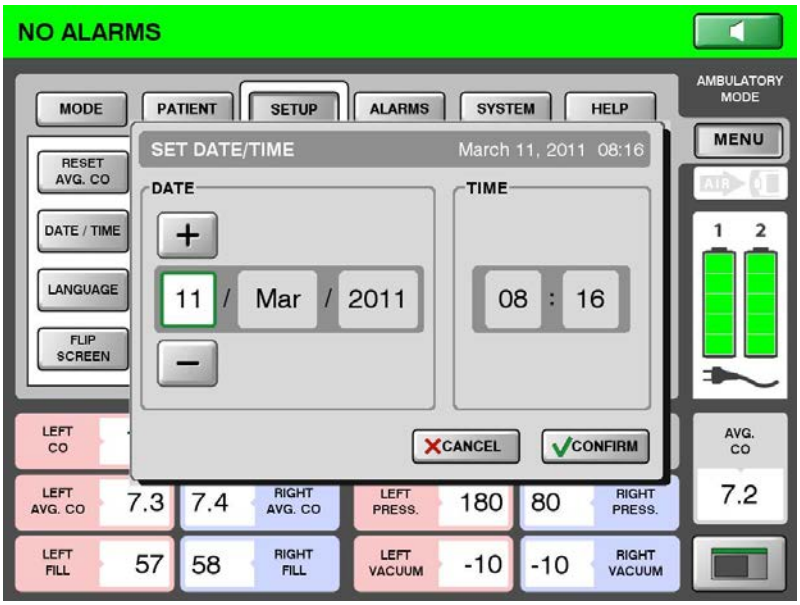


Figure 10-4 – Set Date/Time

10.2.3. Change to O.R. Mode

Change the operating mode to O.R. Mode by completing the following steps:

(1) Select MENU, MODE, and O.R. MODE.

(2) Enter the O.R. Mode password (3228) and press CONFIRM to change to O.R. Mode.

10.2.4. Change to I.C.U. Mode

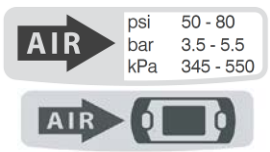
Change the operating mode to I.C.U. Mode by completing the following steps:

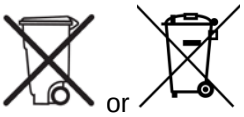
(1) Select MENU, MODE, and I.C.U. MODE.

(2) Enter the I.C.U. Mode password (9722) and press CONFIRM to change to I.C.U. Mode.

Chapter 11. List of Symbols

Table 11-1 – Symbols Used in Companion 2 Driver System Labeling

Symbol	Description	Symbol	Description
I	"ON" (power)	O	"OFF" for a part of equipment
	Temporary Audible Alarm silenced		Audible Alarm Disabled
	Refer to instruction manual/ booklet	**IP30**	Protected against objects ≥ 2.5mm; dripping water at 15° tilt
	External Battery 1		Year of manufacture
	External Battery 2	**SN**	Serial number
	Emergency Battery	**REF**	Part number
	Type BF Equipment	**LOT**	Lot number
	Alternating Current		Direct current/ external power status
	External Power Connected Icon		Alarm LED
	External air		Caution
	Use By Date		Warning, dangerous voltage
	Manufacturer		Temperature limitation

Symbol	Description	Symbol	Description
	Protective earth (ground)		Atmospheric pressure limitation
	Fragile, handle with care		Keep dry
	Humidity limitation		Do not use if package is damaged
	Sterilized using ethylene oxide		Safety Testing
	Do not re-sterilize		Do Not Dispose as Household Waste
	Do Not Incinerate		Do Not Crush
4ICR19/65-5	IEC 61960 battery designation. The alpha and numeric characters represent the following: 4: Number of cell packs connected in series in the battery I: Battery cell chemistry (I = Lithium Ion) C: Metal basis for the positive electrode (C=Colbalt) R: Cell shape (R = Cylindrical) 19: Maximum diameter of cell (in mm) 65: Maximum overall height of the diameter (in mm) 5: Number of battery cells connected in parallel within a cell pack		Slide red tab to release AC Power Cord connector from Hospital Cart or Driver Caddy

Chapter 12. Companion 2 Driver Operation Cautions

12.1. Use of SynCardia-Approved Components Only

The Companion 2 Driver and the TAH-t have been developed, tested and approved as a System. Use of the Companion 2 Driver is authorized only in conjunction with related equipment described in this document and in the *SynCardia 70cc temporary Total Artificial Heart (TAH-*t*) Instructions for Use with the Companion 2 Driver System* and *SynCardia 50cc temporary Total Artificial Heart (TAH-t) Instructions for Use with the Companion 2 Driver System*.

12.2. Investigating the Causes of Alarms

Turning off or muting an audible alarm has NO effect on the condition causing the alarm. Investigate and correct the cause of any alarm.

12.3. Use of Backup Driver

A SynCardia approved Driver must be available as a backup to be used in the event of a failure of the primary Driver.

12.4. Maintenance of Electrical Safety

The Companion 2 Driver System is designed to meet AAMI/NFPA electrical safety requirements. Avoid potentially dangerous electrical shock hazards by always connecting the power cord to an approved, 3-wire AC power receptacle. Never attempt to remove or defeat the electrical ground or EMI shielding. **Table 12-1** lists locations and sizes of the fuses and circuit breakers used in the Companion 2 Driver Accessories.

Table 12-1 – List of Locations and Sizes of Fuses

Fuse or Circuit Breaker Location	Companion 2 Driver System Accessories		
	Size	Fuse Type	Location
Hospital Cart	10 Amp, 250V	MDA-10 31.75 X 6.35mm Time Lag	At power entry module
Driver Caddy	10 Amp, 250V	MDA-10 31.75 X 6.35mm Time Lag	At power entry module

12.5. Fuses

Fuses are user replaceable.

12.6. Reduction of Explosion Hazard

Do NOT operate the Companion 2 Driver System in the presence of flammable anesthetics or other flammable gases.

12.7. Maintenance of Patient Safety

Verify that all pneumatic and electrical connections are in place, secure, and connected to the Driver in use before attempting to operate the System.

12.8. Environment

Keep the Driver dry. Protect it from showers, baths, rain, and liquid spillage. DO NOT operate the Driver beyond an ambient pressure of 525 mmHg to 795 mmHg (700 to 1060 mBar), or at altitudes less than 2000 ft. below sea level or above an altitude of 8,000 ft. above sea level. Driver displayed Cardiac Output is accurate to within 10% throughout this range. Above 4000 ft Driver displayed Cardiac Output is accurate to within 15% for hypertensive patient conditions.

12.9. Removal of Key During Operation

Remove the key from the Key Switch when the Driver is in operation. The key cannot be removed when the Driver is switched OFF.

12.10. Driver Storage Requirements

Always store Companion 2 Drivers in a Hospital Cart or Caddy that is connected to external (wall) power. Storing the Driver without external (wall) power may cause the Emergency Battery to deplete and may render the Driver unusable for patient support.

The Driver should always be connected to an active wall outlet at any time when the patient is not ambulating in order to conserve battery power. Batteries in the Driver are charged when wall power is applied. The Driver does not have to be set to the ON position to charge Batteries. Additional Batteries may be charged in the backup Driver. Do not store the Companion External Batteries in a Companion 2 Driver that is not connected to external (wall) power. This may render the External Batteries unusable. External Batteries can be stored separately from the Driver or in a Companion 2 Driver docked into a Hospital Cart or Caddy that is connected to external (wall) power.

12.11. Companion 2 Driver System Cleaning

Exercise extreme care in cleaning the Companion 2 Driver System. DO NOT soak any item during cleaning or disinfection. DO NOT allow water or solvent to come in direct contact with electrical connectors. See **Chapter 20,** *Equipment Maintenance and Care,* for more information.

12.12. Batteries

Things to do:

- Do store Batteries in a cool, dry place - in particular, avoid storing Batteries at high temperatures.
- Do store Batteries only within the specified range: 0° to 40°C (32° to 104°F).
- Do discharge Batteries only within the specified range: 4.5° to 40°C (-4° to 104°F).
- Do charge Batteries within the specified temperature range: 10° to 35°C (50° to 95°F).

Things NOT to do:

- Do not leave Batteries in vehicles, in direct sunlight, or in other places where the temperature may rise above 40°C (104°F).
- Do not let Batteries get wet.
- Do not drop Batteries or subject them to shock.
- Do not disassemble or modify the Batteries.
- Do not allow necklaces, chains, or other metallic items to come into contact with the terminals.
- Do not use Companion Batteries as a power supply for anything other than the Companion 2 Driver System.
- Do not charge a Battery using anything other than a Companion 2 Driver.
- Do not incinerate Batteries. Explosion or rupture of Batteries may occur.
- Do not discard Batteries. Used Batteries are hazardous waste. Return Batteries to SynCardia for disposal.

12.13. Patient Ambulation Checklist

Before undertaking any excursions away from the primary care area, ensure that:

- Clinical Staff is trained in emergency procedures.
- Optimal settings have been selected using the touch screen display user interface.
- There are no alarms in operation.

- Both external Batteries in the Driver are fully charged.
- Additional fully-charged External Batteries are available.
- The Companion 2 Driver is docked in either a Hospital Cart or Driver Caddy.
- A backup Driver is available that has successfully completed System Check.

Chapter 13. Power Management

The Driver requires at least one source of power:

- Wall power from a grounded wall outlet (external power), or
- Power from one or both External Batteries

External power provides a continuous source of power. The Driver uses external power when docked into the Hospital Cart or Driver Caddy, and the power cord is plugged into the power inlet and the wall outlet.

The Driver cannot use external power when not docked into the Hospital Cart or Driver Caddy.

The Batteries provide a rechargeable source of power that allow the patient to move freely. However, Batteries can only be used for a limited time. When fully charged, each Battery provides a minimum of 30 minutes of support. Two fully charged Batteries provide a minimum of 60 minutes of support.

The External Batteries will charge while installed in a Driver that is docked into a Hospital Cart or Driver Caddy connected to a wall outlet.

13.1. Using External Power

13.1.1. Unless the patient is on an excursion within the hospital or on hospital grounds, it is advisable to plug the Hospital Cart or Driver Caddy with the installed Driver into a wall outlet using the power cord. This provides power for an unlimited amount of time.

13.1.2. To connect external power:

- Plug the locking connector (**Figure 13-1**) from the power cord into the Hospital Cart or Driver Caddy power inlet and make sure the connection is secure. **Figure 13-2** and **Figure 13-3** show where the power inlet is located on the Hospital Cart and Driver Caddy.
- Connect the plug end of the power cord into a grounded wall outlet.
- Make sure that the External Power Indicator on the Driver turns green. If the light does not turn green, the Driver is using battery power.

Figure 13-1 – Locking Connector on the Power Cord

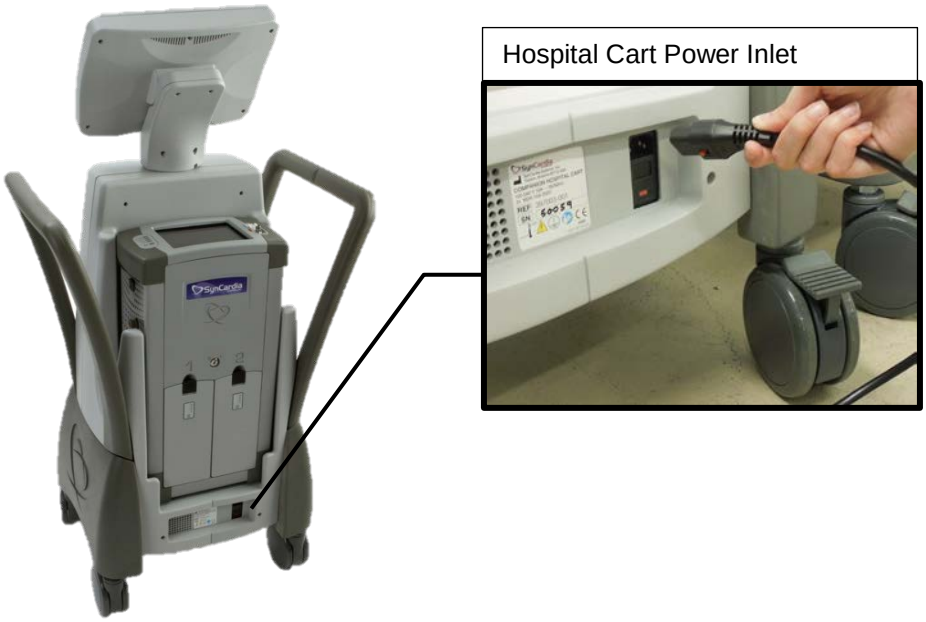


Figure 13-2 – Connecting External Power with the Hospital Cart

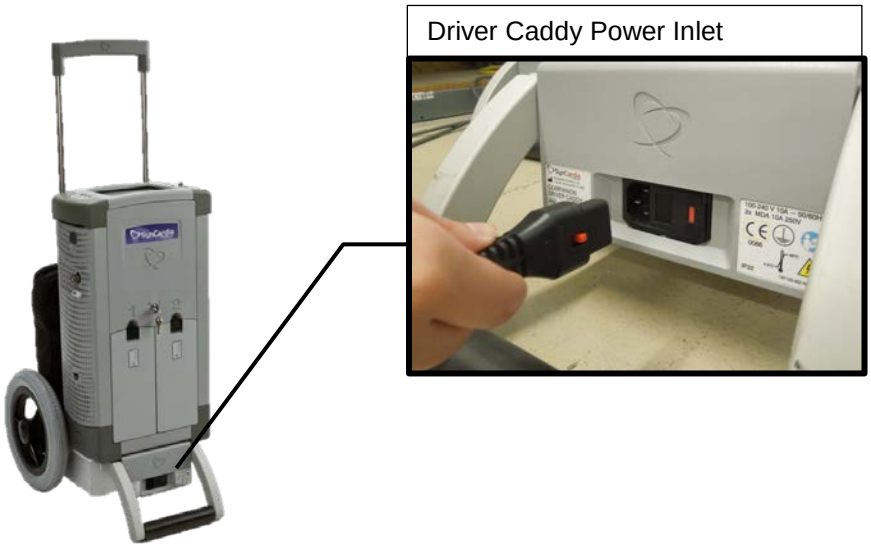


Figure 13-3 – Connecting External Power with the Companion Driver Caddy

	CAUTION **If upon docking the Driver into a Hospital Cart or Caddy, the Driver screen flickers, flashes black and white, or turns off, immediately undock the Driver and DO NOT attempt to dock the Driver again into the same Hospital Cart or Caddy. A malfunction of the Hospital Cart or Caddy may exist and it must be returned to SynCardia for evaluation. The Driver should be docked into another Hospital Cart or Caddy.**

	CAUTION **The Driver should be plugged into grounded electrical wall outlets only.** **To avoid accidentally switching off the external electrical power to the Driver, do not use any electrical outlets that are controlled by wall switches.**

13.1.3. Disconnecting external power and switching to battery power:

- Make sure that two charged Batteries are inserted into the Driver. Pressing the Battery Test Button on each Battery shows how much battery power is remaining.
- Disconnect the power cord from the power inlet on the Driver Caddy or Hospital Cart and the wall outlet. To disconnect the locking connector, slide the red tab to release (**Figure 13-4**).
- The time remaining for each Battery will be shown on the Driver Touch Screen Display Panel (**Figure 13-5**). After disconnecting from wall power, the Companion 2 Driver display (counter) will take approximately one minute to update the estimated battery support time based on Driver settings.

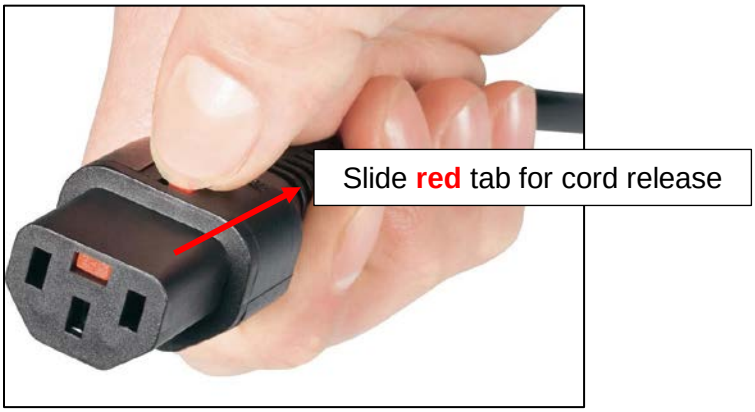


Figure 13-4 – Releasing the Locking Connector on the Power Cord

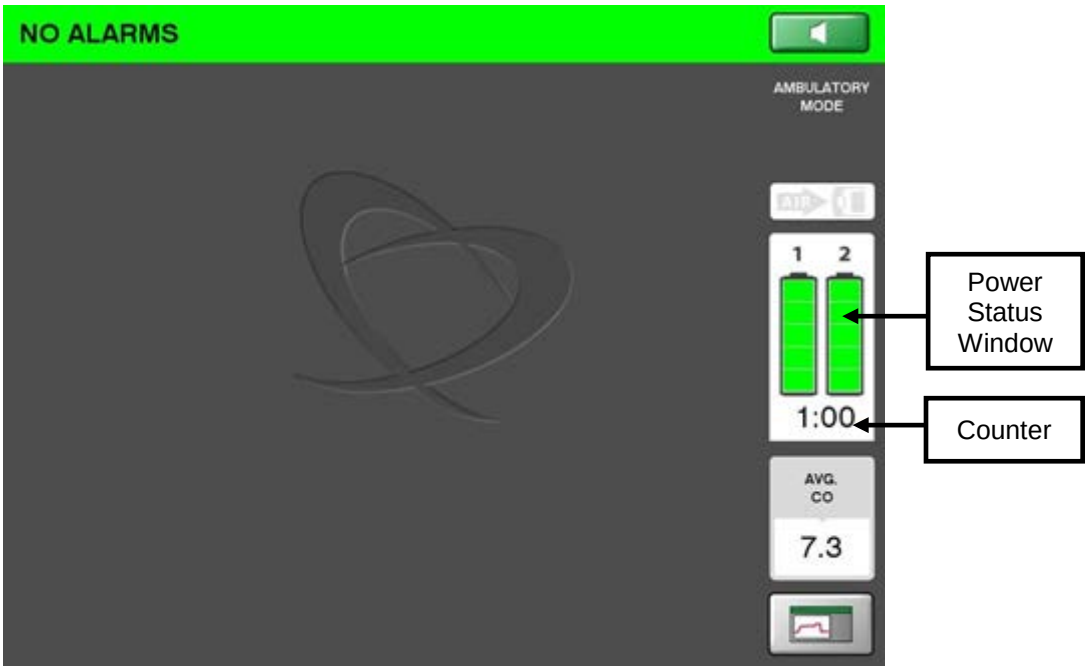


Figure 13-5 – Battery Power Status Window

13.2. Using Battery Power

Battery power can be used when the patient is ambulatory.

13.2.1. Determine the charge status of each External Battery before it is installed into a Driver. Five green battery lights signify that the Battery is fully charged. When fully charged, each Battery provides a minimum of 30 minutes of support. Two fully charged Batteries provide a minimum of 60 minutes of support.

13.2.2. When using battery power, the Driver uses power from both External Batteries. The Driver is able to run with a single External Battery, but this is not recommended.

13.2.3. When a Battery has less than 30 minutes of support time remaining, an alarm sounds and the indicator light for Battery 1 or Battery 2 will turn yellow. The alarm will sound every 3.5 minutes. The display in the Power Status Window will show the Battery with yellow bars.

13.2.4. If the Battery is not replaced and there is less than 10 minutes of support time remaining, the Battery Indicator begins flashing yellow and an alarm sounds every 30 seconds. The Battery symbol in the Power Status Window on the display shows a red battery.

	CAUTION **When there is a red battery shown in the Power Status Window, it is extremely important to change the External Batteries or to connect to external power from a grounded wall outlet; otherwise, the Batteries will eventually lose power and emergency power will become necessary.**

13.3. Battery Removal

When the External Batteries are in use, the Power Status Window shows the Battery Symbols and the remaining support time is displayed, as shown in **Figure 13-6**. After disconnecting from wall power, the Companion 2 Driver display (counter) will take approximately one minute to update the estimated battery support time based on Driver settings.

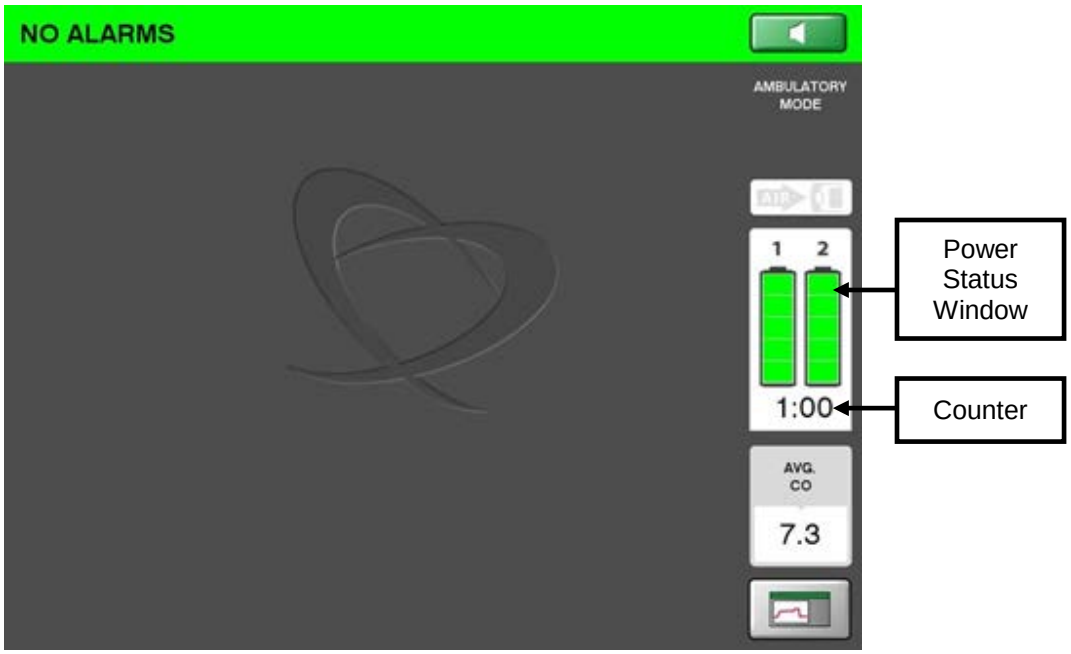


Figure 13-6 – Battery Power Status Window

13.3.1. To remove a Battery from the Driver, push the Battery Release Latch down towards the Battery Fuel Gauge LED indicators and lift the top of the battery out of the Driver (**Figure 13-7**).

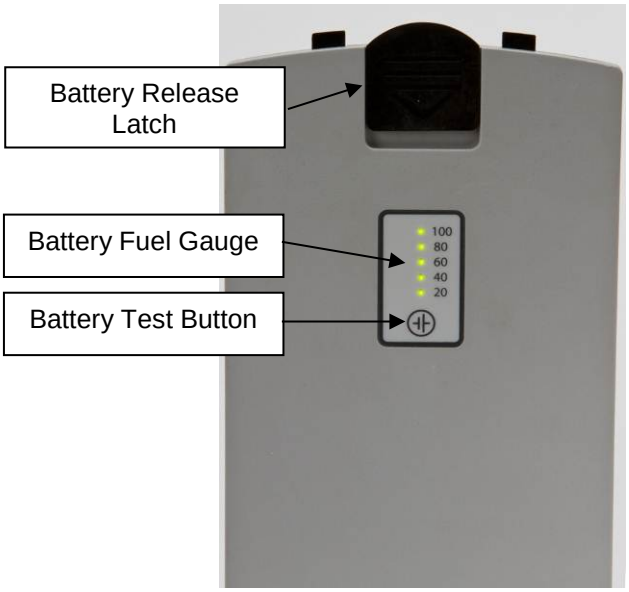


Figure 13-7 – Battery Latch

13.3.2. The Power Status Window indicates that a Battery has been removed or is not functioning correctly by showing the Battery Symbol with an "X" (**Figure 13-8**).

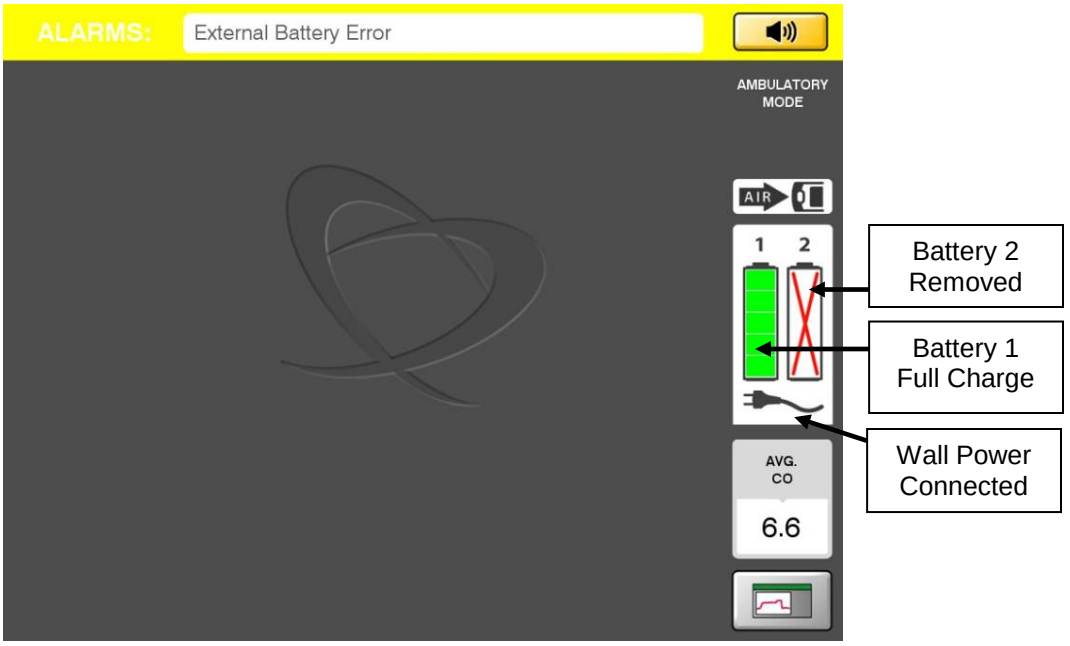


Figure 13-8 – Battery Power Status Window with One Battery Removed

13.3.3. Verify that the display shows that the Battery is properly installed. If the Battery Power Status Window looks like **Figure 13-8** after installing the Battery, remove and reinsert the Battery. If the problem occurs again, replace the Battery with a spare Battery.

13.3.4. To insert a Battery, put the bottom of the Battery into the Driver and push the Battery towards the Driver. An audible “snap” indicates that the latch has secured the Battery to the Driver. Correct battery installation can be verified by the Batteries appearing as shown in **Figure 13-6** and by pulling the Release latch (without depressing it) (**Figure 13-7**) away from the Driver (the Battery will remain in place).

13.3.5. The Battery Indicator LED in the Driver Power Status LED Array, **Figure 13-9**, flashes green when the batteries are being charged.

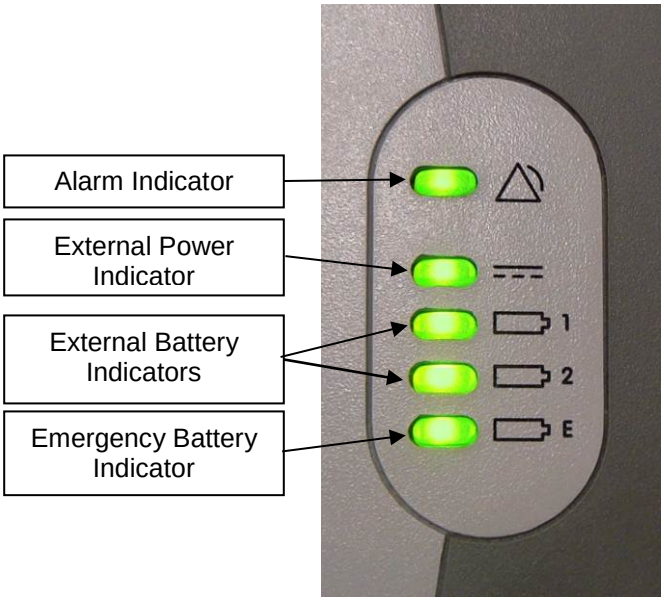


Figure 13-9 – Driver Power Status LED Array

13.3.6. The internal Emergency Battery will provide a minimum of 10 minutes of additional support in the event that no other power source is connected to the Driver. The Driver alarms when the Emergency Battery is in use and will show a red battery in the Power Status Window as shown in **Figure 13-10**.

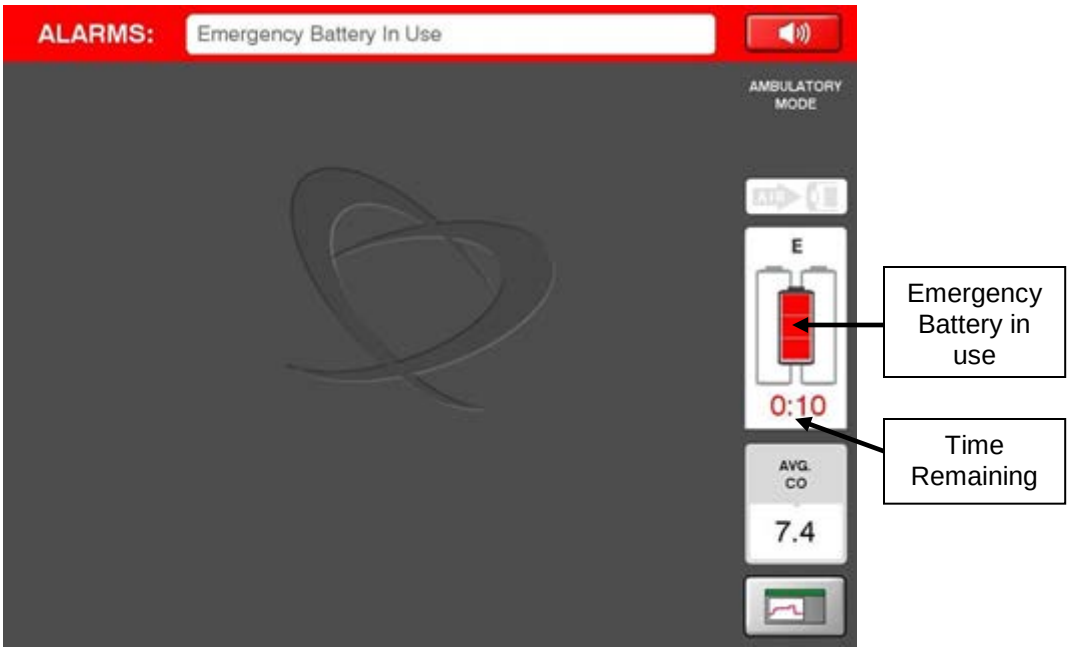


Figure 13-10 – Battery Power Status Window Showing Emergency Battery in Use

13.3.7. If no power sources are connected to the system and the Emergency Battery is depleted, a unique buzzer sound will be generated, indicating that no power is connected to the system. The system must be reconnected immediately to an alternate power source, such as the wall power or External Batteries or the patient must be switched to a SynCardia approved Backup Driver.

Chapter 14. Alarms and Notifications

14.1. Alarm Messages and Responses

14.1.1. There are five different alarm levels: Very High, High, Medium, Low and Very Low. If an alarm occurs while the Driver is supporting the patient, refer to **Table 14-1** for alarms and their corrective actions. For alarms observed while the Driver is not supporting a patient, contact SynCardia for additional information. If more than one alarm occurs, the highest priority alarm message is shown first in the Alarm Bar.

Very High, High, Medium and Low Alarms are accompanied with an audible notice between 70-80 decibels. They vary in occurrence and frequency as shown in **Table 14-1.** Very low alarms do not have an audible notice.

The graphical user interface software requires two minutes to fully load after the power is turned on with the key switch. No Driver alarms are active during this time.

Table 14-1 – Alarm Messages and Responses

Alarm Message	Visual Indicators	Audible Signal	Corrective Action
Dual Compressor Malfunction	Alarm Bar: Flashing Red Alarm Indicator LED: Flashing Red	10 beeps every 2½ seconds 70-80 dBA	Replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Very Low Left Cardiac Output	Alarm Bar: Flashing Red Alarm Indicator LED: Flashing Red	10 beeps every 2½ seconds 70-80 dBA	Make sure the Driveline is connected and has no kinks. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Very Low Right Cardiac Output	Alarm Bar: Flashing Red Alarm Indicator LED: Flashing Red	10 beeps every 2½ seconds 70-80 dBA	Make sure the Driveline is connected and has no kinks. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
System Malfunction	Alarm Bar: Flashing Red Alarm Indicator LED: Flashing Red	10 beeps every 2½ seconds 70-80 dBA	Replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**

Alarm Message	Visual Indicators	Audible Signal	Corrective Action
Low Left Cardiac Output	Alarm Bar: Red Alarm Indicator LED: Red	10 beeps every 5 seconds 70-80 dBA	Make sure the Driveline is connected and has no kinks. Verify Driver settings are achieving full eject/partial fill conditions from Driver displayed wave forms. Assess patient conditions that may contribute to a low Cardiac Output. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Low Right Cardiac Output	Alarm Bar: Red Alarm Indicator LED: Red	10 beeps every 5 seconds 70-80 dBA	Make sure the Driveline is connected and has no kinks. Verify Driver settings are achieving full eject/partial fill conditions from Driver displayed wave forms. Assess patient conditions that may contribute to a low Cardiac Output. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Single Compressor Malfunction	Alarm Bar: Flashing Red Alarm Indicator LED: Flashing Red	10 beeps every 2½ seconds 70-80 dBA	Replace Driver with a SynCardia approved backup Driver. While not on a patient, cycle power on the Driver that displayed the alarm. If alarm persists, return the Driver to SynCardia. **Notify SynCardia at 1-866-771-9437**
Emergency Battery Error	Alarm Bar: Flashing Red Alarm Indicator LED: Flashing Red Emergency Battery Indicator: Flashing Red	10 beeps every 2½ seconds 70-80 dBA	Replace Driver with a SynCardia approved backup Driver. While not on a patient, charge the Driver that displayed the alarm for up to 11 hours. Cycle power on the Driver. If alarm persists, return the Driver to SynCardia. **Notify SynCardia at 1-866-771-9437**

Alarm Message	Visual Indicators	Audible Signal	Corrective Action
Emergency Battery In Use and Low	Alarm Bar: Flashing Red Emergency Battery Indicator: Flashing Red	10 beeps every 2½ seconds 70-80 dBA	Verify Driver is connected to an external power source (wall outlet) and External Power indicators are displayed. Replace External Batteries with fully charged Batteries. If condition persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Emergency Battery In Use	Alarm Bar: Flashing Red Emergency Battery Indicator: Flashing Red	10 beeps every 2½ seconds 70-80 dBA	Verify Driver is connected to an external power source (wall outlet) and External Power indicators are displayed. Replace External Batteries with fully charged Batteries. If condition persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Cardiac Output Imbalance (low)	Alarm Bar: Red Alarm Indicator LED: Red	10 beeps every 5 seconds 70-80 dBA	Make sure the Driveline is connected and has no kinks. Verify Driver settings are achieving full eject/partial fill conditions from Driver displayed wave forms. Assess patient conditions that may contribute to a low Cardiac Output. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Cardiac Output Imbalance (high)	Alarm Bar: Red Alarm Indicator LED: Red	10 beeps every 5 seconds 70-80 dBA	Make sure the Driveline is connected and has no kinks. Verify Driver settings are achieving full eject/partial fill conditions from Driver displayed wave forms. Assess patient conditions that may contribute to a high Cardiac Output. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**

Alarm Message	Visual Indicators	Audible Signal	Corrective Action
Low Left Pressure	Alarm Bar: Red Alarm Indicator LED: Red	10 beeps every 5 seconds 70-80 dBA	Make sure the Driveline is connected and has no kinks. Verify Driver settings are achieving full eject/partial fill conditions from Driver displayed wave forms. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Low Right Pressure	Alarm Bar: Red Alarm Indicator LED: Red	10 beeps every 5 seconds 70-80 dBA	Make sure the Driveline is connected and has no kinks. Verify Driver settings are achieving full eject/partial fill conditions from Driver displayed wave forms. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
High Internal Temperature	Alarm Bar: Red Alarm Indicator LED: Red	10 beeps every 5 seconds 70-80 dBA	Make sure that the Driver is not close to a heat source and that the sides of the unit are not blocked. Check air filters and replace/clean as needed. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Emergency Battery Low	Alarm Bar: Red Alarm Indicator LED: Red	10 beeps every 5 seconds 70-80 dBA	Verify Driver is connected to an external power source (wall outlet) and External Power indicators are displayed. Replace External Batteries with fully charged Batteries. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Left Ventricle Over Pressure	Alarm Bar: Red Alarm Indicator LED : Red	10 beeps every 5 seconds 70-80 dBA	Verify the Over Pressure alarm setting is 20 mmHg higher than the active Driver pressure settings. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**

Alarm Message	Visual Indicators	Audible Signal	Corrective Action
Right Ventricle Over Pressure	Alarm Bar: Red Alarm Indicator LED: Red	10 beeps every 5 seconds 70-80 dBA	Verify the Over Pressure alarm setting is 20 mmHg higher than the active Driver pressure settings. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Very Low External Battery	Alarm Bar: Flashing Yellow Alarm Indicator LED: Flashing Yellow Battery 1 and/or 2 Indicator: Flashing Yellow	3 beeps every 30 seconds 70-80 dBA	Verify Driver is connected to an external power source (wall outlet) and External Power indicators are displayed. Replace External Batteries with fully charged Batteries and verify Batteries indicate near full charge on battery fuel gauge. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Rate Incorrect	Alarm Bar: Flashing Yellow Alarm Indicator LED: Flashing Yellow	3 beeps every 30 seconds 70-80 dBA	Verify Driver Rate Incorrect alarm settings are appropriate (**Section 14.4**). If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Left Pressure Incorrect	Alarm Bar: Flashing Yellow Alarm Indicator: Yellow	3 beeps every 30 seconds 70-80 dBA	Verify Driver Left Pressure Incorrect alarm settings are appropriate (**Section 14.4**). If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Right Pressure Incorrect	Alarm Bar: Flashing Yellow Alarm Indicator: Yellow	3 beeps every 30 seconds 70-80 dBA	Verify Driver Right Pressure Incorrect alarm settings are appropriate (**Section 14.4**). If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**

Alarm Message	Visual Indicators	Audible Signal	Corrective Action
Computer Malfunction	Alarm Bar: Red Alarm Indicator LED: Red	10 beeps every 5 seconds 70-80 dBA	Computer Malfunctions are intended to notify the user of software communication errors. This alarm may recover automatically; however, if the alarm persists, the Driver should be replaced with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Left Vacuum Incorrect	Alarm Bar: Yellow Alarm Indicator LED: Yellow	2 beeps every 3½ minutes 70-80 dBA	Verify Driver Left Vacuum Incorrect alarm settings are appropriate (**Section 14.4**). If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Right Vacuum Incorrect	Alarm Bar: Yellow Alarm Indicator LED: Yellow	2 beeps every 3½ minutes 70-80 dBA	Verify Driver Right Vacuum Incorrect alarm settings are appropriate (**Section 14.4**). If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
External Battery Error	Alarm Bar: Yellow Alarm Indicator LED: Yellow Battery Indicator: Yellow	2 beeps every 3½ minutes 70-80 dBA	Verify Driver is connected to an external power source (wall outlet) and External Power indicators are displayed. Replace External Batteries with charged Batteries and verify Batteries indicate a charge on battery fuel gauge. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Low External Battery	Alarm Bar: Yellow Alarm Indicator LED: Yellow Battery Indicator: Yellow	2 beeps every 3½ minutes 70-80 dBA	Verify Driver is connected to an external power source (wall outlet) and External Power indicators are displayed. Replace External Batteries with charged Batteries and verify Batteries indicate a charge on battery fuel gauge. If alarm persists, replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**

Alarm Message	Visual Indicators	Audible Signal	Corrective Action
Left Fill Volume High	**NOTE:** this alarm only applies to Driver use with the 70cc TAH-t (this alarm is not present with the 50cc TAH-t) Left fill volume: Background is yellow. Alarm Bar: Flashing Yellow Alarm Indicator LED: Flashing Yellow	3 beeps every 30 seconds 70-80 dBA	Verify Driver settings are achieving full eject/partial fill conditions from Driver displayed wave forms. Assess patient conditions that may contribute to a Left Fill Volume High alarm. If alarm persists, certified clinical staff may make adjustment to device rate or vacuum.
Right Fill Volume High	**NOTE:** this alarm only applies to Driver use with the 70cc TAH-t (this alarm is not present with the 50cc TAH-t) Right fill volume: Background is yellow. Alarm Bar: Flashing Yellow Alarm Indicator LED: Flashing Yellow	3 beeps every 30 seconds 70-80 dBA	Verify Driver settings are achieving full eject/partial fill conditions from Driver displayed wave forms. Assess patient conditions that may contribute to a Right Fill Volume High alarm. If alarm persists, certified clinical staff may make adjustment to device rate or vacuum.
Incorrect Percent Systole	Alarm Bar: Yellow Alarm Indicator LED: Yellow Percent Systole Background is: Yellow	2 beeps every 3½ minutes 70-80 dBA	Replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Configuration Data Lost	Alarm Bar: Yellow Alarm Indicator LED: Yellow	2 beeps every 3½ minutes 70-80 dBA	Replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**
Filter Maintenance Required	Alarm Bar: Yellow Alarm Indicator LED: Yellow	No audible signal.	Using the finger access groove, replace/clean filter.
Driver Requires Service	Alarm Bar: Yellow Alarm Indicator LED: Yellow	2 beeps every 3½ minutes 70-80 dBA	Replace Driver with a SynCardia approved backup Driver. **Notify SynCardia at 1-866-771-9437**

14.2. Alarm Status

The current status of alarms can be viewed on the Alarm Status Screen (**Figure 14-1**).

Multiple alarms may be active simultaneously. The highest priority alarm will be displayed in the Alarm Bar and be highlighted in the Alarm Status Screen. Any active lower priority alarms will also be highlighted in the Alarm Status Screen. For instance, a low cardiac output alarm may be accompanied by a high pressure alarm resulting from a Driveline kink.

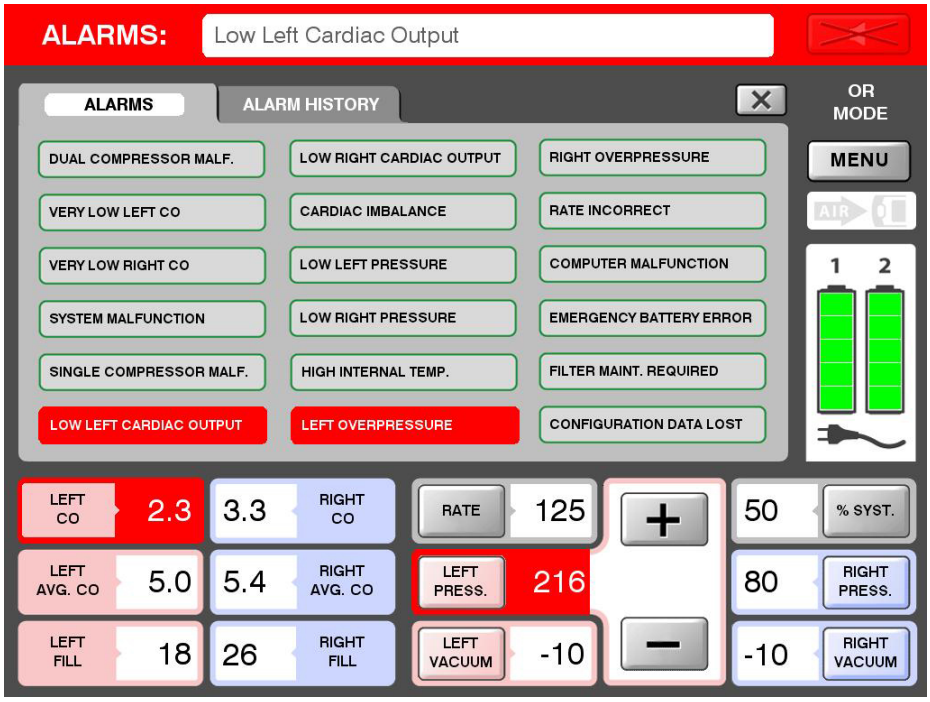


Figure 14-1 – Alarm Status Screen

The Alarm Status Screen may be accessed by pressing MENU, ALARMS or by pressing on the alarm bar anywhere other than the Alarm Mute Button.

14.3. Alarm History

The Alarm History Log will indicate the dates and times of alarm events (**Figure 14-2**).

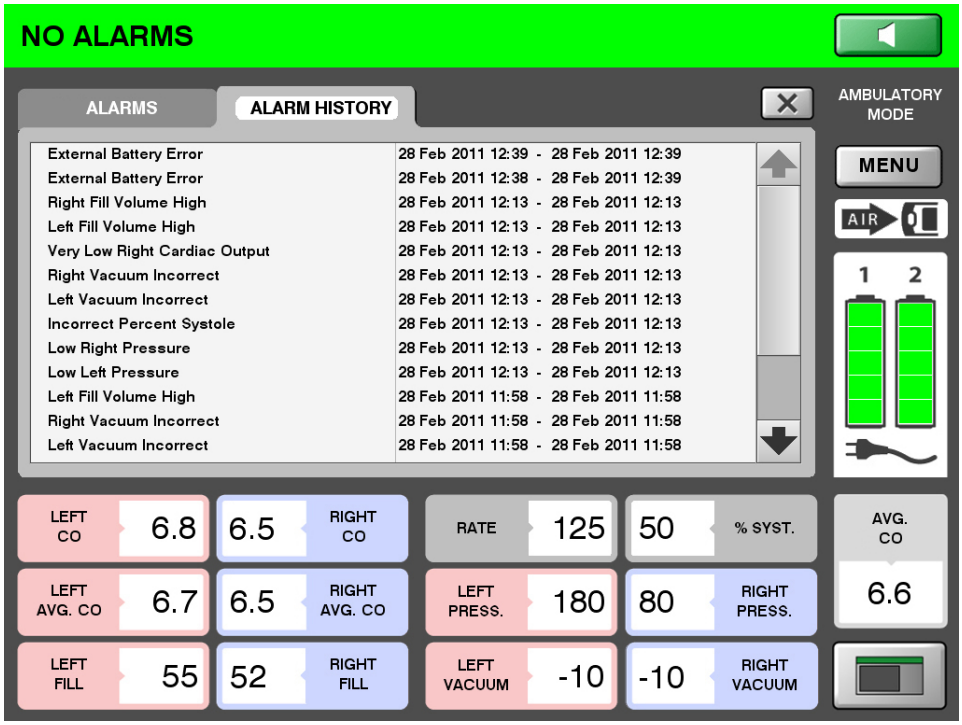


Figure 14-2 – Alarm History Screen

The Alarm History can be viewed by touching the Alarm Status Bar and then selecting the Alarm History Tab or by pressing MENU, ALARMS, and ALARM HISTORY.

14.4. Alarm Settings

The Driver alarm settings are adjusted to default values by the factory, but may be adjusted for individual patients. The Alarm settings may be accessed from the O.R. Mode and I.C.U. Mode by selecting MENU, ALARMS and ALARM SETTINGS (**Figure 14-3**).

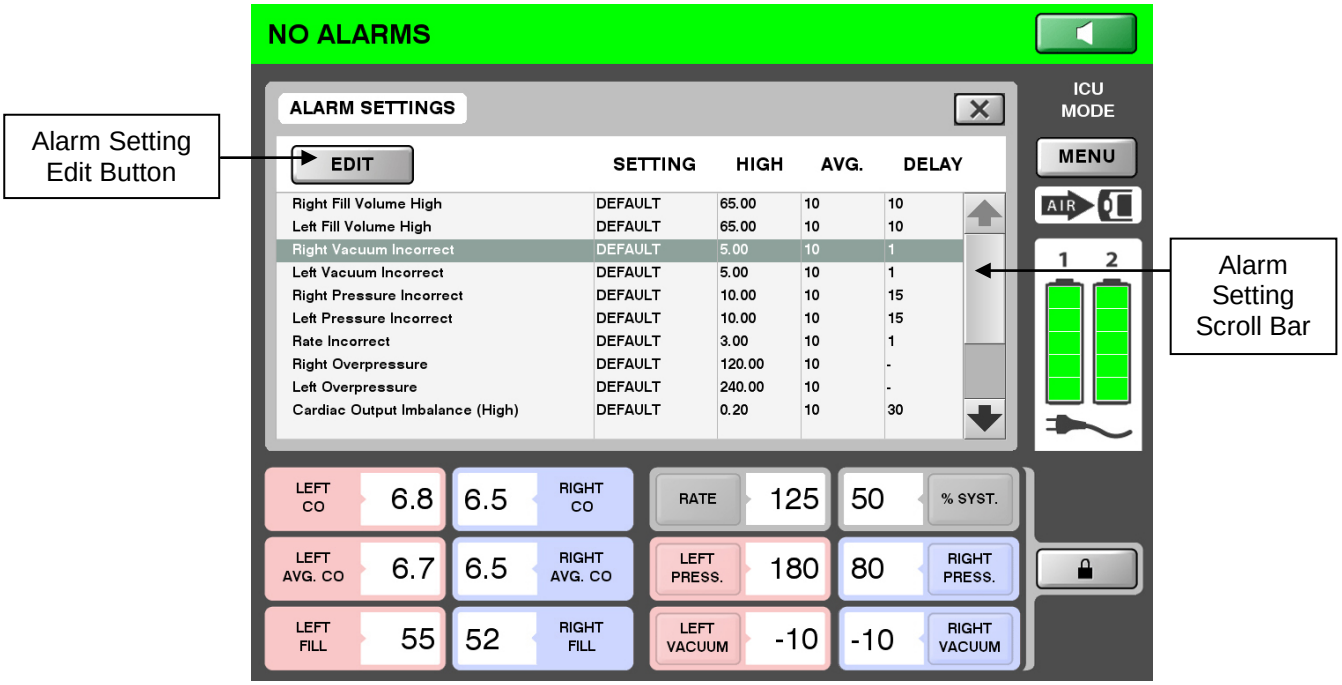


Figure 14-3 – Alarm Settings Screen

Alarm settings can be adjusted by scrolling up or down, selecting the alarm name and pressing the EDIT button.

A secondary window will open to allow the alarm limits to be adjusted. Settings that cannot be configured will be gray and cannot be selected (**Figure 14-4**).

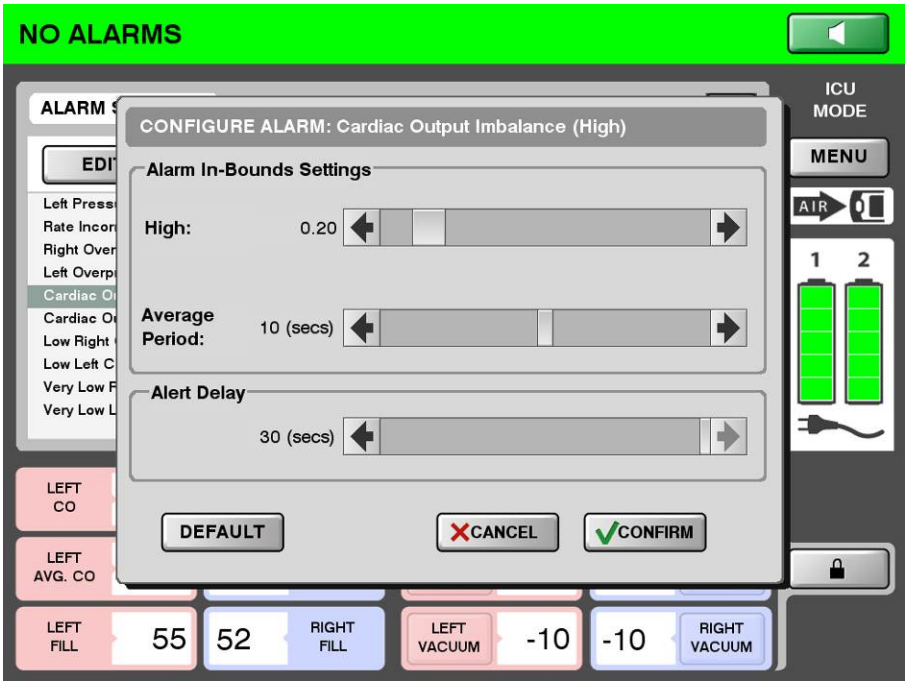


Figure 14-4 – Alarm Configuration Screen

The alarms adjustment ranges and default, preset values are shown in **Table 14-2**, in descending priority order. Alarms are prioritized based on the potential harm to a patient and the time, or delay, in which that harm would be experienced based on the detected fault.

Where the alarm limits are user adjustable, the ranges present prevent the operator from setting the limits to extreme values that could render the alarm useless.

Alarm limits and settings are stored in the Driver and persist during short or extended power interruptions. This allows the user to configure alarm settings on the backup Driver as directed in **Section 8.2.8**, *Setup of Backup Driver*.

Table 14-2 – Alarm Configuration Default Settings and Ranges

Multiple Alarm Priority	Alarm/Screen Message	Averaging Period Range (Seconds)	Default Averaging Period (Seconds)	Active Low Limit Range	Active High Limit Range	User Step Value	Default Setting	Enunciation Delay (Seconds)	Default Delay (Seconds)
1	Dual Compressor Malfunction	N/A	N/A	N/A	N/A	N/A	N/A	0	0
2	Very Low Left Cardiac Output	N/A	N/A	1.5 L/min	N/A	N/A	1.5 L/min	0 to 30	1
3	Very Low Right Cardiac Output	N/A	N/A	1.5 L/min	N/A	N/A	1.5 L/min	0 to 30	1
4	System Malfunction	N/A	N/A	N/A	N/A	N/A	N/A	0	0
5	Low Left Cardiac Output	0 to 30	10	1.5 L/min	5 L/min	.1	3.5 L/min	0 to 90	60
6	Low Right Cardiac Output	0 to 20	10	1.5 L/min	5 L/min	.1	3.5 L/min	0 to 90	60
7	Single Compressor Malfunction	N/A	N/A	N/A	N/A	N/A	N/A	0	3
8	Emergency Battery Error	N/A	N/A	N/A	N/A	N/A	N/A	0	0
9	Emergency Battery in Use and Low	N/A	N/A	N/A	N/A	N/A	N/A	0	0
10	Emergency Battery in Use	N/A	N/A	N/A	N/A	N/A	N/A	0	0
11	Cardiac Output Imbalance (low)	0 to 20	10	0%	10%	1%	0%	0 to 30	30
12	Cardiac Output Imbalance (high)	0 to 20	10	10%	100%	1%	20%	0 to 30	30
13	Low Left Pressure	N/A	N/A	90 mmHg	N/A	N/A	N/A	0	0
14	Low Right Pressure	N/A	N/A	20 mmHg	N/A	N/A	N/A	0	0
15	High Internal Temperature	N/A	N/A	59˚C	70˚C	N/A	N/A	0	0
16	Emergency Battery Low	N/A	N/A	80%	N/A	N/A	N/A	0	0
17	Left Ventricle Overpressure	0 to 20	10	210 mmHg	300 mmHg	1	240 mmHg	0	0
18	Right Ventricle Overpressure	0 to 20	10	90 mmHg	170 mmHg	1	120 mmHg	0	0
19	Very Low External Battery	N/A	N/A	10 minutes	N/A	N/A	N/A	0	0

Multiple Alarm Priority	Alarm/Screen Message	Averaging Period Range (Seconds)	Default Averaging Period (Seconds)	Active Low Limit Range	Active High Limit Range	User Step Value	Default Setting	Enunciation Delay (Seconds)	Default Delay (Seconds)
20	Rate Incorrect	0 to 20	10	1 BPM	3 BPM	1	3 BPM	0 to 30	1
21	Left Pressure Incorrect	0 to 20	10	1 mmHg	40 mmHg	1	10 mmHg	0 to 30	15
22	Right Pressure Incorrect	0 to 20	10	1 mmHg	40 mmHg	1	10 mmHg	0 to 30	15
23	Computer Malfunction	N/A	N/A	N/A	N/A	N/A	N/A	0	0
24	Left Vacuum Incorrect	0 to 20	10	1 mmHg	5 mmHg	1	5 mmHg	0 to 30	1
25	Right Vacuum Incorrect	0 to 20	10	1 mmHg	5 mmHg	1	5 mmHg	0 to 30	1
26	External Battery Error	N/A	N/A	71˚C	N/A	N/A	N/A	0	0
27	Low External Battery	N/A	N/A	30 minutes	N/A	N/A	N/A	0	0
28	Left Fill Volume High *See Note below	0 to 20	10	65mL	N/A	N/A	N/A	0 to 30	10
29	Right Fill Volume High *See Note below	0 to 20	10	65mL	N/A	N/A	N/A	0 to 30	10
30	Incorrect Percent Systole	N/A	N/A	2%	N/A	N/A	N/A	0	0
31	Configuration Data Lost	N/A	N/A	N/A	N/A	N/A	N/A	0	0
32	Filter Maintenance Required	N/A	N/A	30 days	N/A	N/A	N/A	0	0
33	Driver Requires Service	N/A	N/A	730 days	N/A	N/A	N/A	0	0

***NOTE**: Left Fill Volume High alarm and Right Fill Volume High alarm only applies to Driver use with the 70cc TAH-t (this alarm is not present with the 50cc TAH-t).

14.5. Notifications

The Driver provides audible and visual notifications (**Table 14-3**) that do not represent alarm conditions. These notifications are intended to improve communication of events or actions.

Table 14-3 – Notifications

Event	Visual Indicators	Audible Signal	Corrective Action
External Power Source Connection	External Power Indicator: Solid Green Power Status Window: Plug Icon	Two rising tones in succession	No action required
External Power Source Disconnect	External Power Indicator: Yellow Power Status Window: Remaining battery support time	Two falling tones in succession	No action required unless other power related alarm conditions exist, e.g., low External Battery power
External Battery in Use	Numerical display of the estimated remaining battery support time.	No audible signal	No action required
Emergency Battery in Use	Power Status Window: Icon overlays the External Battery Icon Numerical display of the estimated remaining battery support time	10 beeps every 2.5 seconds	Connect Driver to an external power source (wall outlet). Replace External Batteries with fully charged Batteries. If alarm continues, replace Driver with backup Driver.
Emergency Battery Low	External Power Indicator: Solid Green Emergency Battery Indicator: Flashing Red Power Status Window: Plug Icon	No audible signal	No action required. Emergency Battery is charging. Emergency Battery Low Alarm will clear when charged to adequate level.
OR Mode Notification	Display shall indicate it is in OR Mode	Two beep audible reminder signal every 2 hours	No action required if the device is in use during a surgical procedure, otherwise change to I.C.U. Mode or Ambulatory Mode to activate audible alarms
Audible Alarms Disabled in O.R. Mode Reminder	Solid “X” over the Alarm Mute Button	Two beep audible reminder signal every 2 hours	No action required if the device is in use during a surgical procedure, otherwise change to I.C.U. Mode or Ambulatory Mode to activate audible alarms

Event	Visual Indicators	Audible Signal	Corrective Action
ICU Mode Notification	Display shall indicate it is in ICU Mode	No audible signal	No action required if the device is in use in the I.C.U., otherwise change to OR Mode if in use during a surgical procedure or Ambulatory Mode to activate audible alarms
Ambulatory Mode Notification	Display shall indicate it is in Ambulatory Mode	No audible signal	No action required if the device is in use on an Ambulatory patient, otherwise switch to OR Mode if in use during a surgical procedure or I.C.U Mode if in use in an I.C.U.
External Battery Charging	Power Status Window: Charge bars will appear in the Battery Icon	No audible signal	No action required
External air Connected	External air Connection Icon enabled (black)	No audible signal	No action required
External air Disconnected	External air Connection Icon disabled (grey)	No audible signal	No action required

Chapter 15. Switching from Primary Companion 2 Driver to Backup Companion 2 Driver

A backup implant Driver (CSS or Companion 2) must always be available in the event the primary Driver fails. This section describes how to switch to a backup Companion 2 Driver.

Always program the correct settings for the backup Driver when the primary Driver is programmed.

NOTE: The procedure described below to switch drivers is the same for both the 50cc TAH-t and 70cc TAH-t.

15.1. Preparation for the Driver Exchange

Turn the backup Driver key switch to the ON position. The Driver will operate on internal battery power.

Note: **The backup Driver will begin operating at the previously set settings while the software starts. It is safe to use the backup Driver during this process. Even though the display will remain dark, the alarm indicator LEDs will show alarm status. The display will remain dark until the software is completely operational.**

15.2. Driver Exchange

15.2.1. Disconnect the Driveline connector from the primary Driver by depressing the tab on the side of the Driveline connector. Attach the Driveline connector to the connection on the backup Driver in the same direction (as shown in **Figure 15-1**).

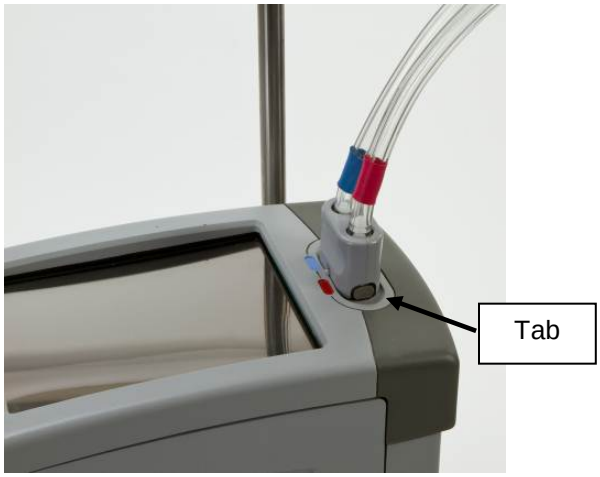


Figure 15-1 – Properly Connected Drivelines

15.2.2. Verify that the backup Driver that is now connected to the TAH-t has both External Batteries installed. If not, insert the Batteries.

15.2.3. Make sure that the External Batteries that have been installed are fully charged. If not, connect the backup Driver to wall power.

15.2.4. Determine if there are any alarms. If there are alarms, see **Chapter 14**, Alarms and Notifications, to correct them.

15.2.5. Remove the key from the backup Driver and insert it into the primary Driver. Turn off the primary Driver. The key will lock into place when the primary Driver is set to the OFF position.

15.2.6. Notify SynCardia Systems that the Driver has been switched. Report any alarms or problems at this time.

Chapter 16. Switching from CSS Console to Companion 2 Driver System

NOTE: The procedure described below to switch drivers is the same for both the 50cc TAH-t and 70cc TAH-t.

16.1. Materials

Prior to switching from the CSS Console to the Companion 2 Driver System, assemble the following materials:

- One set of Companion Drivelines. This includes the male and female CPC Connectors and corresponding mate attached to the left and right Drivelines, respectively.
- Companion 2 Driver with power ON
- Wire Tie Cutter tool
- Wire Ties
- Wire Tie Gun

Note: The female CPC connector is <u>always</u> inserted into the blue Driveline. The male CPC connector is <u>always</u> inserted into the red Driveline.

16.2. Preparation for the Driver Exchange

16.2.1. Prepare the Companion 2 Driver as indicated in **Section 8.2.8**, *Setup of Backup Driver,* including the System Check. If the driver does not pass the Setup, do not connect the patient to the Companion 2 Driver and contact SynCardia immediately.

16.2.2. Connect the Companion Drivelines to the Driver, using the single Driveline connector. Check that air is pulsing from the free ends of the Driveline. The Companion 2 Driver comes with CPC connectors already attached onto each **red** and **blue** Driveline.

16.2.3. Position the Driver that is ON next to the patient.

16.2.4. Ensure that the drive parameters are set appropriately for the patient

16.3. Driver Exchange

16.3.1. With the Wire Cutter Tool provided in the Tool Kit, cut the Wire Ties that secure the CSS metal hose barb connectors to the **red** and **blue** Cannulae, as shown in **Figure 16-1**.

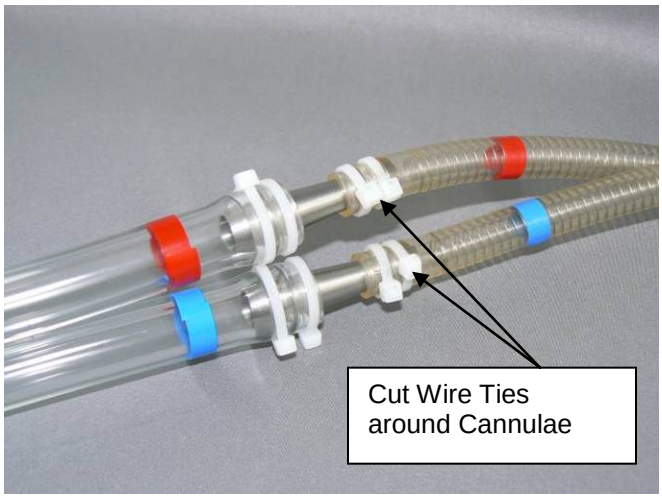


Figure 16-1 – Wire Ties around CSS Hose Barb Connectors

16.3.2. Loosen the metal hose barb connectors from the Cannulae as shown in **Figure 16-2**. DO NOT DISCONNECT OR REMOVE YET.

Figure 16-2 – Metal Hose Barb Connectors Loosened, but Still Connected, to the Cannulae

⚠	**CAUTION** **Before disconnecting the Drivelines of the CSS Console you must have the Drivelines of the Companion 2 Driver within reach.**

16.3.3. **Perform steps 16.3.4 and 16.3.5 simultaneously** in order to disconnect the Drivelines of the CSS Console and connect the Drivelines of the Companion 2 Driver.

16.3.4. Remove the metal hose barb from the red Cannula by pulling and then immediately insert the CPC connector of the red Companion 2 Driveline into the red Cannula (**Figure 16-3**).

16.3.5. Simultaneously, remove the metal hose barb from the **blue** Cannula by pulling and then immediately insert the CPC connector of the **blue** Companion 2 Driveline into the blue Cannula (**Figure 16-3**).

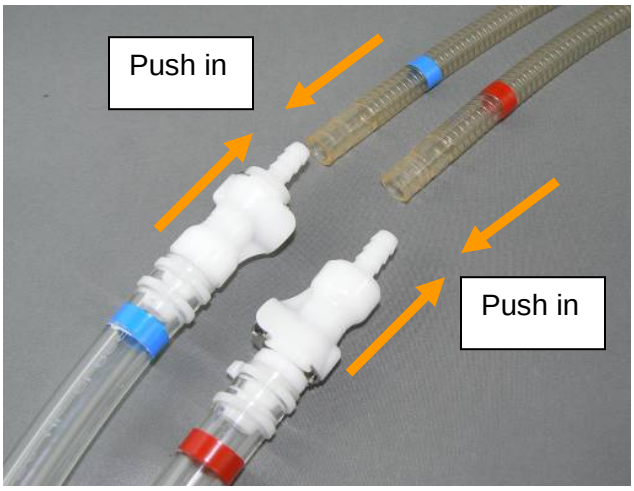


Figure 16-3 – Inserting the Companion 2 Drivelines into the Cannulae

16.3.6. Secure each Cannula to the CPC connectors with two Wire Ties, as shown in **Figure 16-4** below.

⚠	**CAUTION** **The Wire Ties around the Cannulae and CPC connectors must be secured using a Wire Tie Gun.**

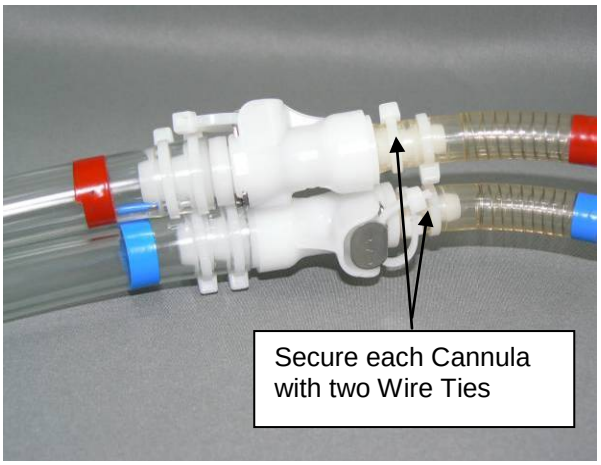


Figure 16-4 – Securing Cannulae to CPC Connectors with Wire Ties

16.3.7. It is recommended that the CSS Console Drivelines be retained or disposed of in accordance with hospital procedures.

Chapter 17. Switching from Companion 2 Driver System to CSS Console

NOTE: The procedure described below to switch drivers is the same for both the 50cc TAH-t and 70cc TAH-t.

17.1. Materials

Prior to switching from the Companion 2 Driver System to the CSS Console, assemble the following materials:

- One set of CSS Console Drivelines
- CSS Console with power ON
- CPC connectors (male and female)
- Male 3/8 connector, part number: 170088-003
- Female 3/8 connector, part number: 170087-003
- Locking ties
- Scissors

Note: The female CPC connector is <u>always</u> inserted into the blue marked Driveline. The male CPC connector is <u>always</u> inserted into the red marked Driveline.

17.2. Preparation for of the CSS Console and Drivelines for Driver Exchange

17.2.1. Prior to switching to the CSS Console, the Console should be prepared in the following manner:

- Ensure that the drive parameters are set appropriately for the patient.
- Turn on the CSS Console and alarm panel.
- Attach the CPC connector to the CSS Console Drivelines (follow instructions below) and ensure that air is pulsing from the free ends of the Driveline.

17.2.2. When switching from the Companion 2 Driver System to the CSS Console, change the Driveline connections that connect to the CSS Console:

- Remove the hose barb connectors from the CSS Drivelines.
- Insert a 3/8” female CPC connector (P/N 170087-003) into the **blue** marked Driveline. This is the connector that has the lock on it.
- Insert a 3/8” male CPC connector (P/N 170088-003) into the **red** marked Driveline. This is the connector that does not have the lock on it.

17.3. Driver Exchange

Two people are required to change support from the Companion 2 Driver to the CSS Console. One person has the **blue** marked Driveline and the other person has the **red** marked Driveline. Perform the next steps together:

17.3.1. Remove locking ties from under the metal release button on the CPC connectors.

17.3.2. Simultaneously, disconnect the CPC connectors from each of the Companion Drivelines that mate with the CPC connectors of the cannulae of the TAH-t.

17.3.3. Immediately insert the CPC connectors of the CSS Console Drivelines into the CPC connector of the respective color marked cannulae of the TAH-t. Assure that the **red** marked CSS Console Driveline is attached to the **red** marked cannula of the TAH and the **blue** marked CSS Console Driveline is attached to the **blue** marked cannula of the TAH-t.

17.3.4. Reinsert a locking tie under the metal release button on the CPC connections to prevent inadvertent disconnect.

Note: The TAH-t is now connected to the CSS Console via CPC connectors.

Chapter 18. Switching from Companion 2 Driver to Primary Freedom Driver

NOTE: The procedure described below to switch drivers is the same for both the 50cc TAH-t and 70cc TAH-t.

CAUTION

It is recommended to have two people switch from the Companion 2 Driver to the Freedom Driver.

Make sure all items and accessories are available before exchanging Drivers.

18.1 Materials

Prior to switching the patient from the Companion 2 Driver to the Freedom Driver System, the following must be available:

- One prepared primary Freedom Driver
- One prepared backup Freedom Driver
- Wire Cutter tool from the Freedom Patient Tool Kit
- Driveline Retention Bag from the Freedom Tool Kit

18.2 Preparation to Perform Switch from Companion 2 Driver to Freedom Driver

Both primary and backup Freedom Drivers must be tested at the Hospital prior to use, following the checklist for the Freedom Driver Test Protocol in the Freedom Operator Manual. If any of the Drivers do not pass the Protocol, do not connect the patient to the Freedom Driver System and contact SynCardia immediately.

To turn on the Freedom Driver:

- Remove the driveline caps from the ends of the Freedom Driver Drivelines
- Insert two charged Onboard Batteries into the Freedom Driver
- Connect the Freedom Driver into a wall power outlet using the AC Power Supply and Cord
- Verify that the Freedom Driver starts (you should hear the working motor inside of the Driver and feel air coming out of the Drivelines)

NOTE: The Freedom Driver is set up not to activate a Fault Alarm for low Cardiac Output for 15 minutes after it has been initially turned on, to allow time to connect to a TAH-t.

	**CAUTION** **If the Fault Alarm comes on immediately upon powering up the Freedom Driver, there is a malfunction of the Driver.** **The patient must not be switched from the Companion 2 Driver to the Freedom Driver.**

	**CAUTION** **When performing a switch from the Companion 2 Driver to the Freedom Driver, make certain the Drivelines are properly connected to the TAH-t Cannulae, and do not kink the Drivelines.**

18.3 Driver Exchange

Refer to **Figure 18-1** for an image of the **red** and **blue** Companion 2 Driveline to Cannula connection via the CPC connector.

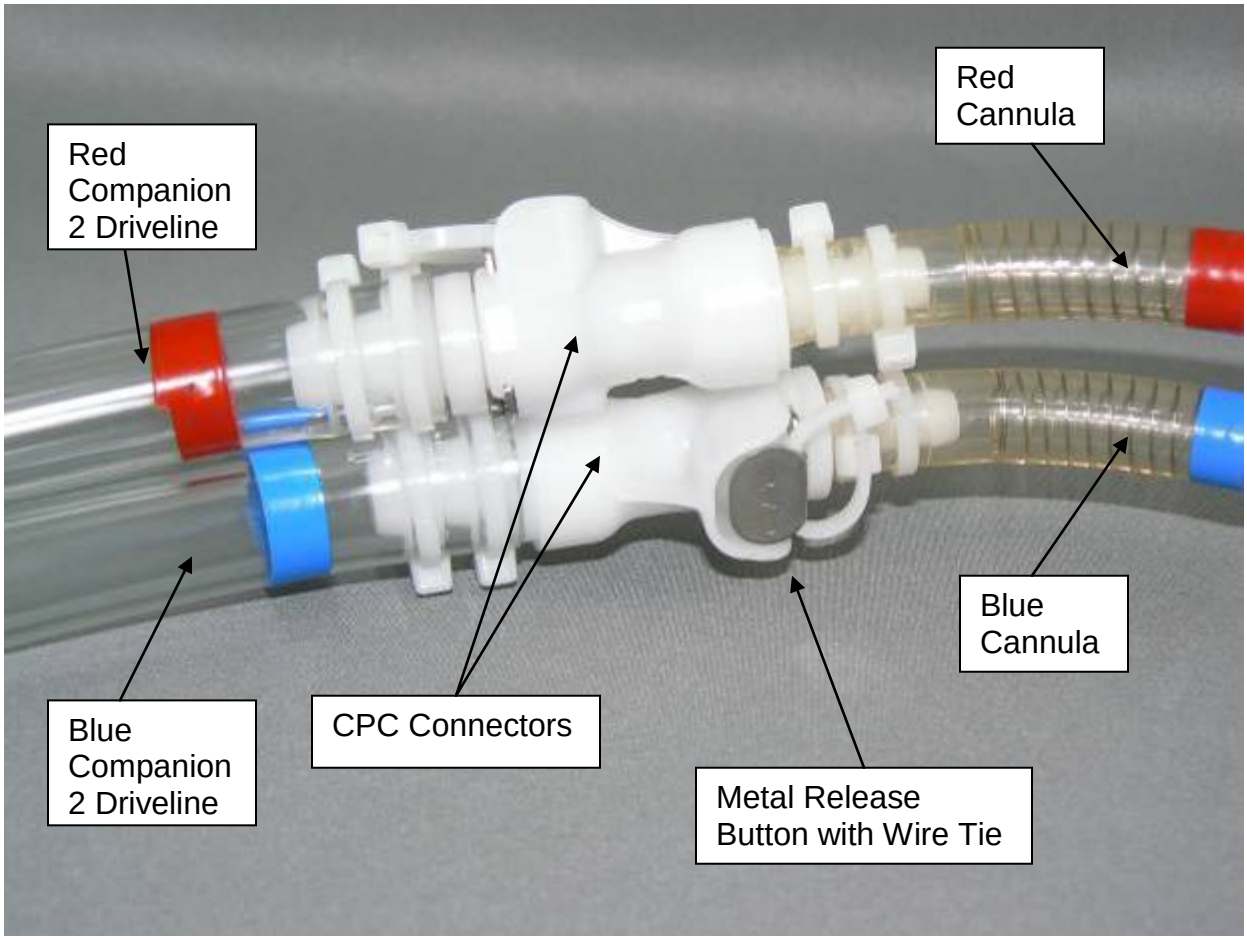


Figure 18-1 – Companion 2 Drivelines Connected to Cannulae via the CPC Connectors

1) **DO NOT DISCONNECT THE CANNULA FROM THE DRIVELINE YET.**

With the Wire Cutter Tool provided in the Tool Kit, cut the Wire Tie under the metal release button of the CPC Connector that secures the **red** TAH-t Cannula to the **red** Companion 2 Driveline **(Figure 18-2)**.

Gently pull to remove the Wire Tie and discard.

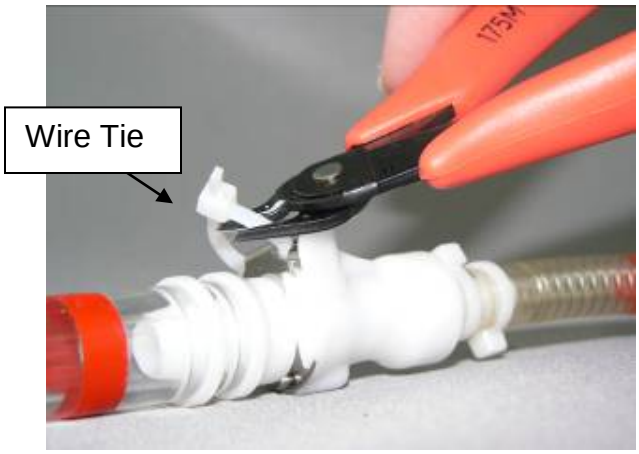


Figure 18-2 – Cutting the Wire Tie with the Wire Cutter Tool

2) **DO NOT DISCONNECT THE CANNULA FROM THE DRIVELINE YET.**

With the Wire Cutter Tool provided in the Tool Kit, cut the Wire Tie under the metal release button of the CPC Connector that secures the **blue** TAH-t Cannula to the **blue** Companion Driveline.

Gently pull to remove the Wire Tie and discard.

⚠	**CAUTION** **Before disconnecting the Drivelines of the Companion 2 Driver, you must have the Drivelines of the Freedom Driver within reach.**

3) **Perform steps 4 and 5 simultaneously** in order to disconnect the Drivelines of the Companion 2 Driver and connect the Drivelines of the Freedom Driver **(Figures 18-3 and 18-4)**.

4) Disconnect the **red** Cannula from the **red** Driveline of the Companion 2 Driver:

- Press *and* hold down the metal release button,
- Pull the **red** Cannula away from the **red** Companion 2 Driveline,
- **Immediately** insert the **red** Cannula into the **red** Freedom Driveline,
- Insert until a click is heard.
- Lightly tug on the connection to make sure that it is secure.

5) **Simultaneously**, disconnect the **blue** Cannula from the **blue** Driveline of the Companion 2 Driver:

- Press *and* hold down the metal release button,
- Pull the **blue** Cannula away from the **blue** Companion 2 Driveline,
- Immediately insert the **blue** Cannula into the **blue** Freedom Driveline,
- Insert until a click is heard,
- Lightly tug on the connection to make sure that it is secure.

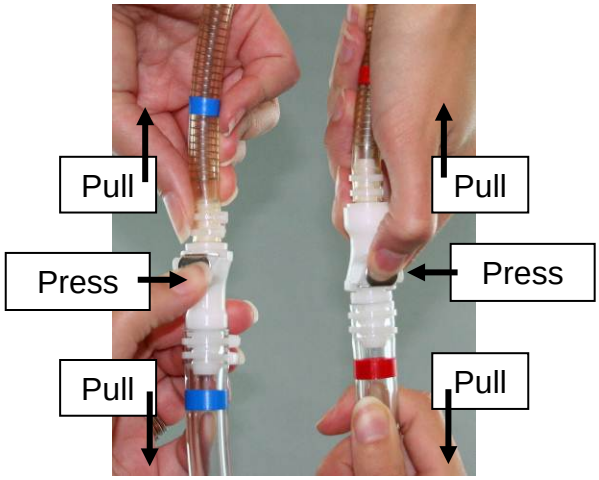


Figure 18-3 – Disconnecting Companion 2 Drivelines from the Cannulae

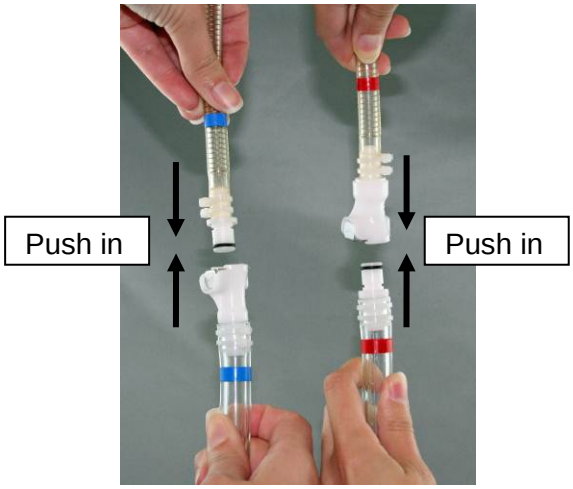


Figure 18-4 – Connecting the Freedom Drivelines to the Cannulae

6) Slide a Wire Tie under the metal release button of each CPC connector **(Figure 18-5)**.

- Create a loose loop in the tie, taking care not to depress and disconnect the connectors.
- Cut off the excess length of both Wire Ties.

The loop in the Wire Tie makes it easier to cut if it is necessary to change to another Driver.

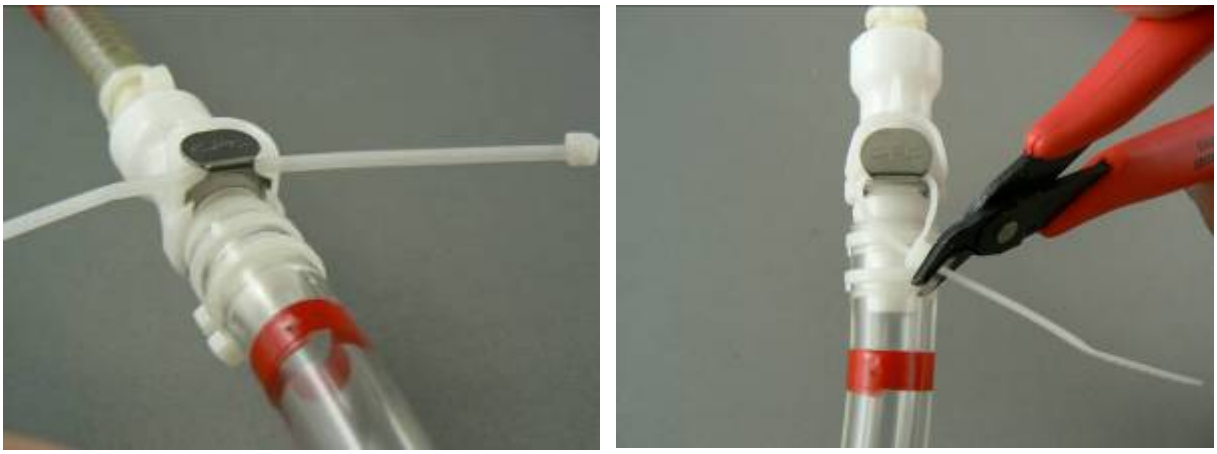


Figure 18-5 – Inserting Wire Tie under Metal Release Button of CPC Connector

7) Insert the Companion 2 Drivelines into the Driveline Retention Bag. The patient's name and the date of the switch must be written on the bag and retained by the Hospital to switch the patient back to the Companion 2 Driver, if necessary.

8) The Hospital should notify SynCardia Systems that the patient has been switched.

Chapter 19. Switching from Freedom Driver to Companion 2 Driver System

NOTE: The procedure described below to switch drivers is the same for both the 50cc TAH-t and 70cc TAH-t.

CAUTION

It is recommended to have two people switch from the Freedom Driver to the Companion 2 Driver.

Make sure all items and accessories are available before exchanging Drivers.

19.1 Materials

Prior to switching from the Freedom Driver to the Companion 2 Driver System, assemble the following materials:

- Companion 2 Driver with power ON
- Velcro
- Scissors
- Wire Cutter tool from Patient Tool Kit
- Male and Female CPC connectors and Wire Ties from Connector Tool Kit
- Driveline Retention Bag
- Wire Tie Gun

Note: The female CPC connector is always inserted into the blue Drivelines. The male CPC connector is always inserted into the red Drivelines.

19.2 Preparation for Driver Exchange

19.2.1 Prepare the Driver as indicated in **Section 8.2.8**, *Setup of Backup Driver,* including the System Check.

19.2.2 Connect the Companion Drivelines to the Driver using the single Driveline connector.

19.2.3 Position the Driver that is ON next to the patient.

19.3 Driver Exchange

Two people are required to change from the Freedom Driver to the Companion 2 Driver. One person has the **blue** Driveline and the other person has the **red** Driveline.

19.3.1 Cut the Wire Ties that prevent depressing the Quick Connects that join the Freedom Driver Drivelines and the TAH-t cannulae together.

19.3.2 Simultaneously:

19.3.2.1 Unplug the **red** Cannula from the Freedom Driver Driveline and connect the Quick Connect to the Companion 2 **red** color-coded Driveline Quick Connect.

19.3.2.2 Unplug the **blue** Cannula from the Freedom Driver Driveline and connect the Quick Connect to the Companion 2 **blue** color-coded Driveline Quick Connect.

19.3.3 Attach a Wire Tie around each cannula so that it covers the connectors and prevents the connections from coming loose. Squeeze tightly.

19.3.4 Cut off the excess ties and cover with Velcro.

19.3.5 The cannulae from the TAH-t are now connected to the Drivelines on the Companion 2 Driver.

Chapter 20. Equipment Maintenance and Care

20.1 Maintenance

Hospital personnel should complete the Companion 2 Driver System Check (**Appendix A**) upon receipt, prior to use, and every 6 months if the Driver is not in use.

In addition, SynCardia will track the Driver runtime and notify the center when a Driver is due for scheduled service.

The Driver Caddy may require air to be added to the tires periodically.

CAUTION

DO NOT modify this equipment without authorization of the manufacturer.

20.2 Equipment Care

The equipment must be maintained in order for it to work properly.

20.2.1 Do not expose the Driver to temperatures higher than 40°C (104°F) or lower than 4.5°C (40°F) for long periods of time.

20.2.2 To prevent a high temperature alarm, do not block the air inlets on the sides of the Driver.

20.2.3 Do not submerge the Driver or expose it to excessive water. Protect it from showers, baths, and liquid spills.

20.2.4 Do not use paint, paint remover, finger polish remover, or other solvents anywhere near the Companion 2 Driver System.

20.3 Cleaning the Equipment

20.3.1 Use extreme care when cleaning the equipment. Dust the equipment periodically with a soft, clean cloth.

20.3.2 If heavy dirt needs to be removed from the outside of the Driver, Hospital Cart or Driver Caddy, use cloth and mild soap and wipe.

CAUTION

DO NOT soak any item of the Driver during cleaning.

DO NOT allow water to come in direct contact with the Driver electrical connectors.

20.4 Filter Maintenance

20.4.1 The Companion 2 Driver will alarm at preset intervals to notify the user to replace the Air Filters. This alarm will appear in a yellow banner as “Filter Maintenance Required” (**Figure 20-1**).

Figure 20-1 – Yellow Banner Alarm for Filter Maintenance Required

20.4.2 To access the filter, press the Filter Cover Latch (**Figure 20-2**) and pull the Filter Cover away from the Driver body.

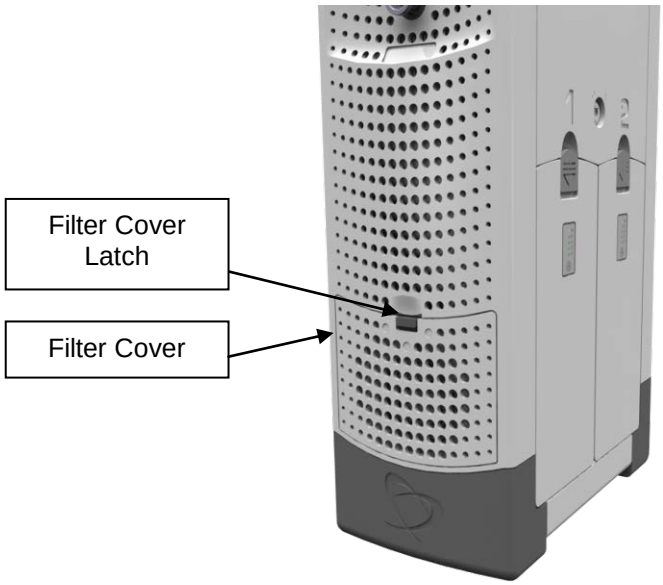


Figure 20-2 – Driver Side Panel and Filter Cover

20.4.3 Once the cover is removed, remove the filter from the Driver housing (see **Figure 20-3**)**.** Filters can be rinsed, air dried and re-used.

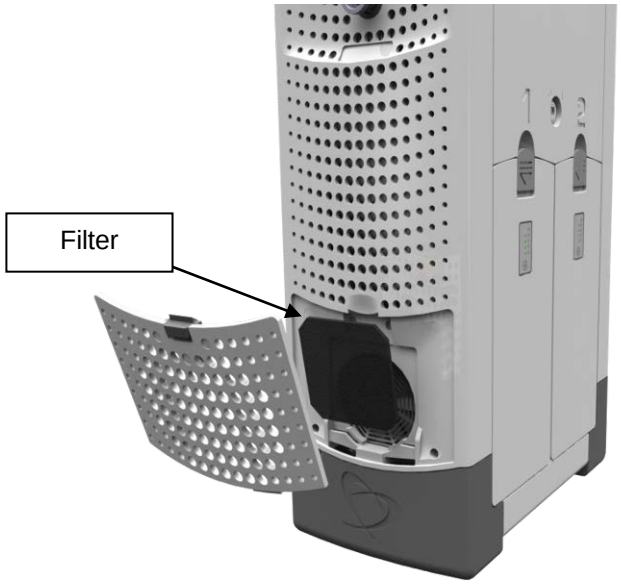


Figure 20-3 – Driver Side Panel with Filter Cover Removed

	**CAUTION** **Do not touch the moving fan.**

20.4.4 Place a clean filter over the fan opening and reinstall the Filter Cover. Repeat this process on the opposite side of the Driver.

20.4.5 After cleaning or replacing the filter, follow these steps to clear the alarm:

(1) Select MENU

(2) Select SETUP

(3) The FILTER MAINT. REQUIRED button should be active (see **Figure 20-4**)

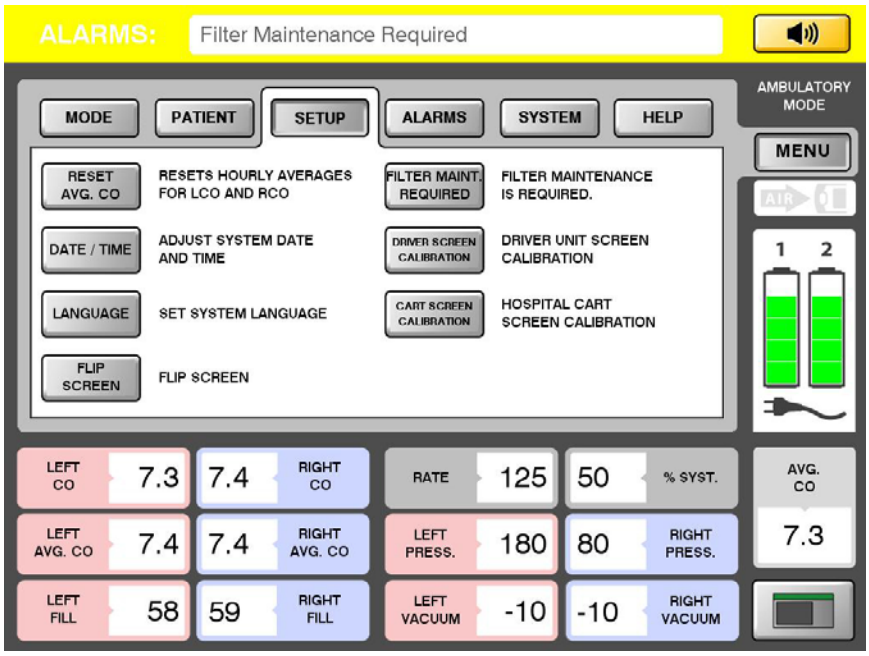


Figure 20-4 – SETUP Menu

(4) Select the FILTER MAINT. REQUIRED button

(5) This will bring up a verification screen asking “Has the filter maintenance been completed” (see **Figure 20-5**). Select YES.

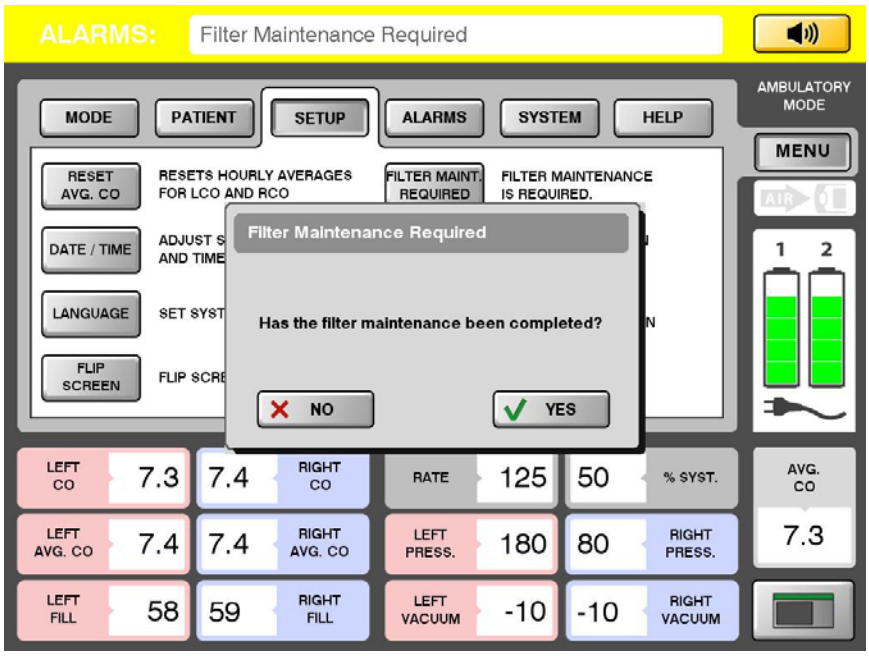


Figure 20-5 – Verification Screen

(6) Once the alarm has been cleared, the FILTER MAINT. REQUIRED button will be grayed out (see **Figure 20-6**).

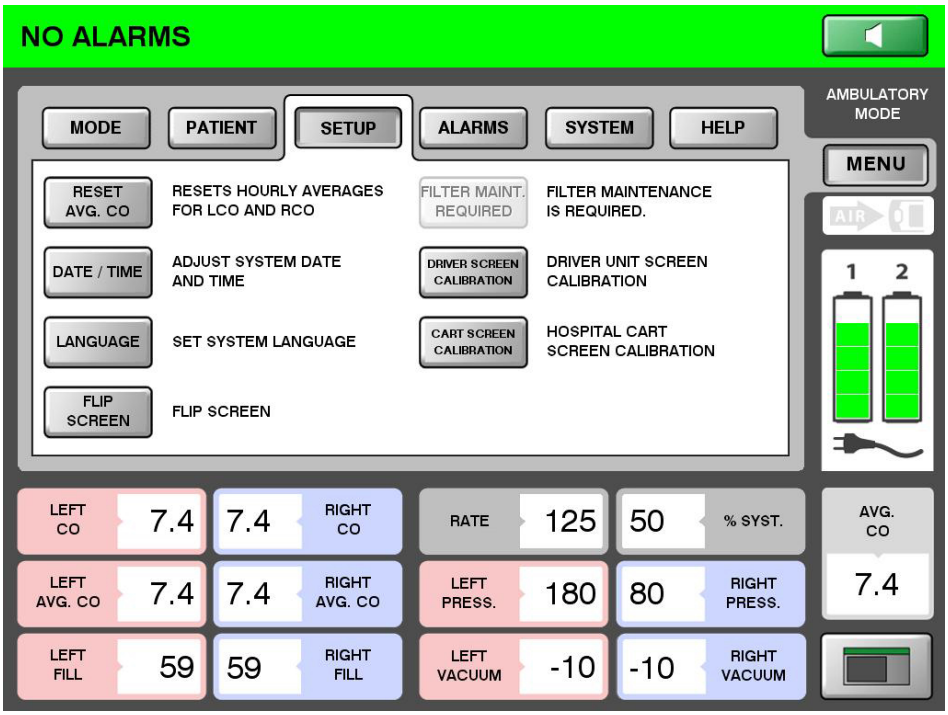


Figure 20-6 – SETUP Menu with Filter Maintenance Alarm Cleared

Chapter 21. Unpacking and System Setup

21.1 Driver

The Driver ships in a hard shell case with foam inserts. Retain all packing materials.

21.1.1 Immediately upon receipt of any Companion 2 Driver:

- Unpack the Driver
- Dock the Driver (without External Batteries) into a Hospital Cart or Caddy. If necessary, this may be done with the help of another trained user.
- Connect the Hospital Cart or Caddy to an external (wall) power source to charge the Driver internal Emergency Battery, which may be partially or fully depleted upon receipt. A Driver with a depleted internal Emergency Battery will not pass the System Check (**Section 21.1.7**) and may not properly support a patient.

21.1.2 Install two external Batteries into the Driver.

21.1.3 Connect the Driver to external air. If external air is not available, the Driver will operate with its internal compressors.

21.1.4 Turn the Driver ON by rotating the key clock-wise.

21.1.5 Remove the key from the Driver. It should be stored in a location determined by the clinical staff.

21.1.6 The Driver will begin operating at default settings when power is applied and the key switch is set to the ON position. Once the Driver software has loaded, the system will show the Ambulatory Mode Screen.

21.1.7 Perform the System Check and complete the System Check form, as described in **Section 8.1.11**. If the system does not pass the System Operation Check, contact SynCardia immediately.

21.1.8 Once the internal Emergency Battery and External Batteries are charged, the system is ready for clinical use.

	**CAUTION** **Do not rapidly rotate the key between the ON setting and OFF setting.**

	**CAUTION** **If upon docking the Driver into a Hospital Cart or Caddy, the Driver screen flickers, flashes black and white, or turns off, immediately undock the Driver and DO NOT attempt to dock the Driver again into the same Hospital Cart or Caddy. A malfunction of the Hospital Cart or Caddy may exist and it must be returned to SynCardia for evaluation. The Driver should be docked into another Hospital Cart or Caddy.**

21.2 Hospital Cart

The Hospital Cart is shipped in a large crate. The front door of the crate can be opened and a ramp lowered while the crate remains on the pallet.

21.2.1 Unlock the casters and slowly roll the Hospital Cart out of the crate.

21.2.2 Return all packaging materials to the crate and contact SynCardia for instructions for returning the crate.

21.3 Driver Caddy

The Driver Caddy is shipped with disposable packaging materials.

21.3.1 Remove the Driver Caddy with the attached pouch from the shipping package.

21.3.2 The Driver Caddy is now ready for use.

Chapter 22. Companion 2 Driver System Specifications

22.1 Safety Standards

The Companion 2 Driver System, as part of the SynCardia TAH-t Companion 2 Driver System, has been thoroughly tested pursuant the requirements of European safety standard IEC 60601-1: 2006. This standard requires making the following declarations and stating the type and degree of protection for listed hazards. See the following pages for more specific safety and testing classification information.

Table 22-1 – Declaration Concerning General Safety Standards

Type	Degree of Protection
Mode of Operation	Continuous
Method of Sterilization	100% EtO for TAH-t and all sterile accessories (e.g., Drivelines)
Type of protection against electrical shock	Class I (grounded) and internally powered
Degree of protection against electric shock	Type BF (Body Floating)
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Degree of protection against harmful ingress of water and foreign materials	Driver: IP30 Driver Caddy: IP32 Hospital Cart: unrated

TÜV SÜD NRTL C US	MEDICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH IEC 60601-1

22.1.1 Declaration and Guidance Concerning Electromagnetic Emissions

The Companion 2 Driver System components are intended for use in the electromagnetic environment specified in **Table 22-2**. The customer or the user of the device should assure that it is used in such an environment.

Table 22-2 – Declaration and Guidance Concerning Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11 EN 55011	Group 1	The SynCardia TAH-t Companion 2 Driver System creates RF energy only as an incidental outcome of its internal electrical and electronic functions. RF emissions are very low and are unlikely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	SynCardia Companion 2 Driver docked in the Hospital Cart SynCardia Companion 2 Driver docked in Driver Caddy SynCardia Companion 2 Driver in stand-alone configuration
Harmonic emissions IEC 61000-3-2	Class A	The SynCardia TAH-t Companion 2 Driver System is suitable for use in institutional, commercial and domestic establishments and directly connects to the public low-voltage power distribution system that supplies buildings used for institutional, commercial or domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Companion 2 Driver with Hospital Cart, Caddy or Docking Station. Mains power applied. No change in functional operation.	

22.1.2 Declaration and Guidance Concerning Electromagnetic Immunity for all Companion 2 Driver System

The Companion 2 Driver System components are intended for use in the electromagnetic environment specified in **Table 22-3**. The customer or the user of the components should assure that they are used in such an environment. See the following table.

Table 22-3 – Declaration and Guidance Concerning Electromagnetic Immunity for Companion 2 Driver System

Declaration and Guidance Concerning Electromagnetic Immunity for Companion 2 Driver System			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Contact discharge: ±2, 4 and 6 kV. Air discharge: ±2, 4 and 8 kV.	Companion 2 Driver as a standalone or with Hospital Cart or Caddy. Mains AC power or battery power applied. No change in functional operation.	Floors are to be wood, concrete, or ceramic tile. Alternatively, the Companion 2 Driver System on floors covered with synthetic material shall comply if the relative humidity is at least 30%.
Electrical fast transient/burst IEC 61000-4-4	Mains fast transient of ± 2 kV.	Companion 2 Driver with Hospital Cart or, Caddy. Mains power applied. No change in functional operation.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Mains surge of ± 1 kV differential mode ± 2 kV common mode	Companion 2 Driver with Hospital Cart or Caddy. Mains power applied. No change in functional operation.	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0.5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	Companion 2 Driver with Hospital Cart or Caddy. Mains power applied. No change in functional operation. <5% *U*T (>95 % dip in *U*T) for 0.5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. The Companion 2 contains 3 Batteries (2 external Batteries and 1 internal backup Battery), which will provide uninterruptible power for a minimum of 70 minutes. **Note:** *U*T is the AC mains voltage prior to application of the test level.

Declaration and Guidance Concerning Electromagnetic Immunity for Companion 2 Driver System			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Companion 2 Driver with Hospital Cart or Caddy. Mains power applied. No change in functional operation.	If the Companion 2 Driver System is to be operated near equipment generating high magnetic field such as an NMR, the magnetic fields should be measured in the intended installation location to assure safe operation.

22.1.3 Declaration and Guidance Concerning Electromagnetic Immunity for Life-Sustaining Companion 2 Driver System, including the TAH-t, Companion 2 Driver and Batteries

The Companion 2 Driver System components are intended for use in the electromagnetic environment specified in Table 22-4. The customer or the user of either device should assure that they are used in such an electromagnetic environment.

Table 22-4 – Declaration and Guidance Concerning Electromagnetic Immunity for Life-Sustaining Companion 2 Driver System, including the TAH-t, Companion 2 Driver and Batteries

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Companion 2 Driver System than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter
Recommended Separation Distances			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6	Mains conducted RF. 150 kHz to 80 MHz outside ISM bands	3 Vrms Companion II Driver with Hospital Cart or Caddy. Mains power applied.	$d = \left[\frac{3.5}{3}\right] / p$ Distance for compliance test & for minimum installation

Recommended Separation Distances			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
	Mains conducted RF. 150 kHz to 80 MHz in ISM bands	10 Vrms Companion II Driver with Hospital Cart. Mains power applied.	$d = \left[\frac{12}{10}\right] / p$ Distance for compliance test & for minimum installation
Radiated RF IEC 61000-4-3	Susceptibility to radiated RF 80 MHz to 2.5 GHz	10 V/m Companion 2 Driver as a standalone or with Hospital Cart or Driver Caddy. Mains power or battery power. No change in functional operation	$d = \left[\frac{12}{10}\right] / p$ 80 MHz to 800 MHz Distance for compliance test & for minimum installation
		10 V/m Companion 2 Driver as a standalone or with Hospital Cart or Driver Caddy. Mains power or battery power. No change in functional operation	$d = \left[\frac{23}{10}\right] / p$ 800 MHz to 2.5 GHz Distance for compliance test & for minimum installation
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
			Interference may occur in the vicinity of equipment that is marked with the IEC symbol for non-ionizing radiation.
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

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

[b] Compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into the patient areas. For this reason, an

additional factor of (*min. 10/3*) is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Companion 2 is used exceeds the applicable RF compliance level above, Companion 2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device

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

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

Note: Special precautions are required for installing and using the SynCardia TAH-t/Companion 2 Driver System within portable and RF communication environments.

	**CAUTION** **Use of equipment and supplies other than those specified in this manual or sold by SynCardia for replacement parts may result in increased emission or decreased immunity of the Companion 2 Driver System.**

22.2 Driver Dimensions (without carrying case)

- Width: 33 cm (13 inches)
- Height: 61 cm (24 inches)
- Depth: 17 cm (6.7 inches)
- Weight: Approximately 25.8 kg (57 lbs) without External Batteries, Approximately 28.1 kg (62 lbs) with two External Batteries

22.3 Hospital Cart Dimensions

- Width: 68.5 cm (27 inches)
- Height: 127 cm (50 inches)
- Depth: 43.2 cm (17.5 inches)
- Weight: 84 kg (185 lbs)

22.4 Driver Caddy Dimensions

- Width: 53.3 cm (21 inches)
- Height: 71.1/109.2 cm (28/43inches handle lowered/raised)
- Depth: 45.7 cm (18 inches)
- Weight: 6.8 kg (15 lbs)

22.5 Environmental Conditions

22.5.1 Operating Conditions

- Operating Temperature (Driver, Driver Caddy): 4.5° to 40°C (40° to 104°F)
- Operating Temperature (Hospital Cart): 10° to 40°C (50° to 104°F)
- Operating Pressure: 700 to 1060 mBar (525 to 795 mmHg) 10,000 ft. above sea level to 2000 ft. below sea level
- Operating Humidity: 10-95% RH

22.5.2 Transportation/Storage

- Driver Transportation/Storage Temperature: -20° to 60°C (-4° to 140°F)
- Battery Transportation Temperature: 0° to 60°C (32° to 140°F)
- Battery Storage Temperature: 0° to 40°C (32° to 104°F)
- Transportation/Storage Pressure: 700 to 1060 mBar (525 to 795 mmHg)
- Transportation/Storage Humidity: 10 – 100% RH (non-condensing)

- Vibration: In accordance with ASTDM D-4169 Distribution Cycle 13: Acceptance Level II: 2008

22.6 System Power Requirements

- External Batteries (2): Rechargeable lithium-ion Batteries, which each provide at least 30 minutes of power, for a total of 60 minutes of power, when fully charged. 16.4V
- Internal Emergency Battery (1): Rechargeable lithium-ion cells, providing a minimum of 10 minutes of support when fully charged. 16.8V
- Hospital Cart, Driver Caddy: Input voltage 100 VAC to 240 VAC, 50-60 Hz Output voltage 18 VDC

22.7 Operating Ranges

- Rate: 40 to 150 bpm (single pulse in O.R. Mode)
- Systole: 40% to 60%
- Left Driver Pressure: 120 to 280 mmHg
- Right Driver Pressure: 40 to 150 mmHg
- Left Vacuum: 0 to -30 mmHg
- Right Vacuum: 0 to -30 mmHg

22.8 Input / Output Characteristics

Table 22-5 describes the input/output characteristics of the Companion 2 Driver System.

Table 22-5 – Input / Output Characteristics

Connection	Location	Characteristics
Drivelines	Driver top	Single Connector keyed to prevent misconnection to connect Driver to TAH-t
Docking Connector	Driver bottom	Multiple connection pins and guide pins to ensure orientation during connection and transmission of power, display and audible signals
USB Port	Driver side panel	Unidirectional USB port protected with a rubber cap that allows information to be copied from the Driver

Connection	Location	Characteristics
AC Power	Hospital Cart rear panel Driver Caddy front panel	Standard 3 prong power connection socket
DC Power	Driver Cover Battery wells	Keyed battery insertion to prevent misconnection to battery terminals
External air	Driver Side Panel	Quick disconnect pneumatic connection

22.9 Classification Companion 2 Driver System

- Class 1 Equipment
- Type BF Equipment
- Driver Ingress Protection: IP30
- Driver Caddy Ingress Protection: IP32
- Hospital Cart: unrated
- Externally-Powered Equipment when connected to an external AC (wall) power source

The Driver is intended for CONTINUOUS OPERATION.

22.10 Software Versions in the Companion 2 Driver System

- Embedded Supervisor: v1.25
- Graphical User Interface: v1.0.2160

Appendix A – Companion 2 Driver System Check Form

SynCardia Systems, LLC
1992 E Silverlake Rd.
Tucson, AZ., USA 85713
Office Phone: 520-545-1234; FAX 520-903-1782
Clinical Support: (866) 771-9437

Companion 2 Driver System Check Form

Driver S/N: _____

Hospital Name: _____

Keep a copy of this form for your records. See the Operator Manual for details on procedure.

Note: This procedure should be performed by trained persons only using a Patient Simulator connected to a 70cc TAH-t. Perform this test upon initial receipt, prior to use, and every 6 months if the device is not in use. Reference **Chapter 21**, *Unpacking and System Setup*, as needed.

Driver Set Up and Check Out

1. Attach Driver to Patient Simulator (connected to a 70cc TAH-t) using Companion Drivelines.

2. Place two external batteries into the driver and turn on the driver.

Verify system starts pumping within 10 seconds Note: If Driver or Batteries have been stored for an extended period, there may be an active low battery alarm.	Pass ☐ Fail ☐

3. To access Driver serial number, press “Menu,” navigate to “System,” “System Info.” Record Driver serial number and hospital name at the top of this form.

4. Optimize the view and navigate to the OR Mode by pressing “Menu,” “Mode” then “OR Mode” and enter the password (3228).

5. Set the Driver parameters to:

Beat Rate	125
Left Pressure	180
Right Pressure	80
Left Vacuum	-10
Right Vacuum	-8

6. Verify Patient Simulator is set to Normotensive (RAP 12±5, AoP 90± 5, PAP 27± 5, LAP 12± 5 mmHg).

7. Change the Rate to zero (- -) and navigate to the test console screen by pressing “Menu” then “System” and then “System Check.”

8. Follow the on screen system prompts for System Check:

Verify the system passed all Tests	Pass ☐ Fail ☐

9. Upon completion of System Check, press “Close”

10. Proceed to Battery Tests on Page 2.

Comments: _____

_____

Companion 2 Driver System Check Form

SynCardia Systems, LLC
1992 E Silverlake Rd.
Tucson, AZ., USA 85713
Office Phone: 520-545-1234; FAX 520-903-1782
Clinical Support: (866) 771-9437

Driver S/N: _____

Hospital Name: _____

Battery Tests

1. Prepare the Driver for the Battery Test:
   - Reattach the Drivelines and return to rate of 125 beats per minute
   - If not already docked, dock the Driver into a Hospital Cart or Caddy,
   - Change Driver from “OR Mode” to “ICU Mode”
2. Remove external power connection.

Verify the display shows estimated time below the battery icons	Pass ☐ Fail ☐

3. Remove Battery #1 from the battery docking port.

Verify that the display and LED lights indicate that the battery is removed	Pass ☐ Fail ☐

4. Replace Battery #1.

Verify that the Driver recognizes the replaced battery	Pass ☐ Fail ☐

5. Remove Battery #2 from the battery docking port.

Verify that the display and LED lights indicate that the battery is removed	Pass ☐ Fail ☐

6. Replace Battery #2

Verify that the Driver recognizes the replaced battery	Pass ☐ Fail ☐

7. Remove both batteries

Verify that the Driver runs on the Emergency Battery and the display and audible alarms are functioning	Pass ☐ Fail ☐

8. Replace the external batteries

Verify restoration to normal operation (no battery alarms present)	Pass ☐ Fail ☐

9. Connect the system to wall power

Verify the driver displays and LED lights indicate that the wall power is connected	Pass ☐ Fail ☐

10. Turn the system off. **If the Driver failed any of the above steps, contact SynCardia Systems, LLC Help Line at (866) 771-9437.**
11. Sign, date and fax form to **520-903-1782**
12. Store the Driver (with batteries installed) docked into a Hospital Cart or Caddy connected to Mains Power.

Comments: _____

Performed By: _____ **Date:** _____