SynCardia temporary Total Artificial Heart (TAH-t) with the Freedom® 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 Freedom 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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1 Device Description

1.1 General Device Information

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 Freedom Driver, that provides pneumatic power to the TAH-t (**Figure 1-1**).

NOTE: The Freedom Driver System should be operated only by people who have been trained and are being supervised by a doctor and Hospital staff who have been trained in the use of the TAH-t System and the Freedom Driver System. Data from the 70cc TAH-t and Freedom Driver clinical trial indicated that certain significant adverse events, such as Device Malfunction and Infection, occurred more frequently in the out-of-hospital environment. The Freedom Driver can be managed safely and effectively by trained patients and caregivers when the recommended guidelines for use and care are followed. Patients and caregivers should maintain a heightened level of care for their Freedom Drivers and accessories at all times. For additional information on out-of-hospital use, see **Section 2**.

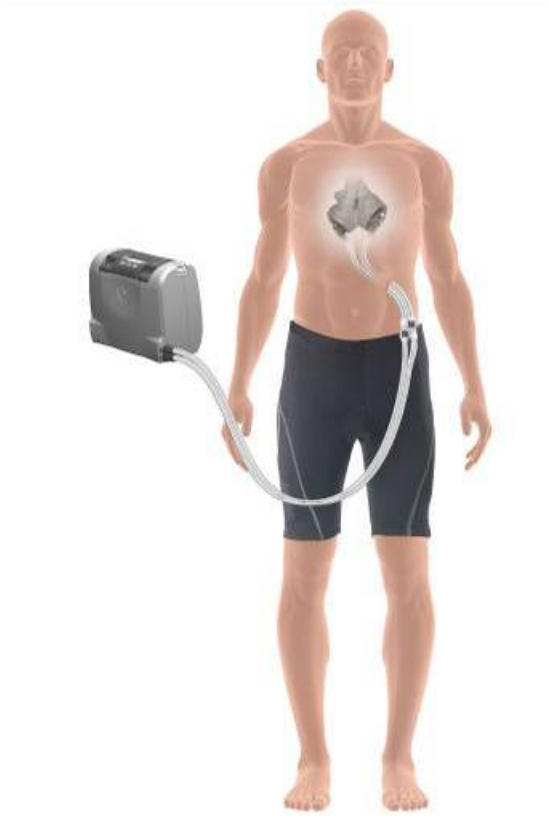


Figure 1-1 – 50cc or 70cc TAH-t with the Freedom Driver System

1.2 The TAH-t

NOTE: Throughout this manual, references to the TAH-t apply to both sizes of the implantable TAH-t (i.e. 50cc and 70cc), unless the size of the TAH-t is explicitly stated.

The SynCardia TAH-t **(Figure 1-2)** is an implantable pulsatile biventricular device that temporarily replaces a patient's native ventricles and valves and pumps blood to both the pulmonary and systemic circulation systems.

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**.

For more information on the TAH-t, please refer to the *SynCardia temporary Total Artificial Heart (TAH-t) Instructions for Use with the Companion 2 Driver System or CSS, for the 50cc or 70cc TAH-t,* as appropriate.

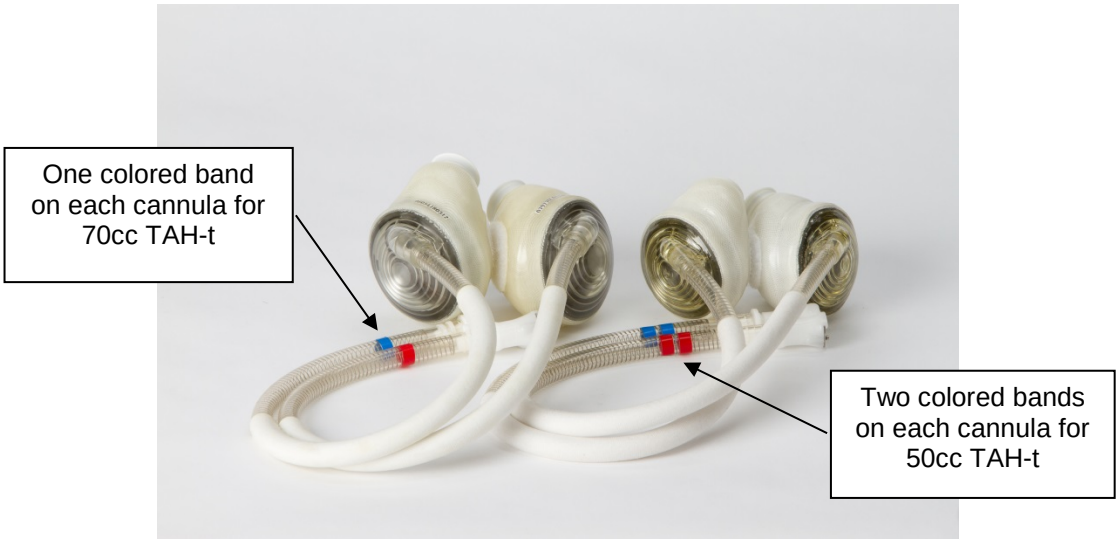


Figure 1-2 – The SynCardia 70cc TAH-t and 50cc TAH-t

1.3 The Freedom Driver System

The Freedom Driver System **(Figure 1-3)** is a multi-component electro-mechanical unit designed to provide pneumatic power to the implanted TAH-t.

Figure 1-3 – Freedom Driver with Attached Power Adaptor and Drivelines Connected to the Cannulae of a TAH-t

The Freedom Driver is the primary component of the Freedom Driver System. It supplies pulses of pneumatic pressure to the right and left Drivelines that are directly connected to the TAH-t Cannulae in a manner consistent with that accomplished by the implant driver (Circulatory Support System (CSS) Console or Companion 2 Driver). These pulses cause the diaphragms of the implanted TAH-t to distend, thereby ejecting blood from the right artificial ventricle into the pulmonary circulation, and from the left artificial ventricle into the systemic circulation.

The Drivelines are permanently connected to the Freedom Driver. The distal ends of the Drivelines are connected directly to the TAH-t Cannulae via CPC connectors.

The Freedom Driver uses visual indicators as well as visual and auditory alarms to give information about the state of the Driver. It is powered by two Onboard Batteries that are charged by means of a Power Adaptor that converts input power from external power sources to DC Power (For more information on the Power Management, see **Section 6.3**).

The Freedom Driver System uses materials that are commonly encountered in medical devices. These materials include Tygon, Lexan, Nylon and PVC.

The only adjustable setting in the Freedom Driver is the driver operating rate (Beat Rate). The Beats per Minute (BPM) can only be adjusted at the Hospital by a SynCardia trained medical professional with tools designed specifically for this purpose (provided in the Clinician Tool Kit). The Clinician Tool Kit should never be given to the patient and the patient should never adjust his/her Beat Rate.

The Freedom Driver System is designed to have the following advantages:

- Highly portable, allowing Hospitals to mobilize patients within the Hospital and discharge patients implanted with the TAH-t
- Simple user interface prevents patient manipulation of any functions, yet provides key information
- Lightweight, allows patients to leave home and enjoy activities outside of the Hospital and home environments

The Driver consists of a pneumatic assembly, electronic assemblies, interfaces to other components, a simple user interface and the ability to use multiple power sources.

1.3.1 Pneumatics

The pneumatics assembly consists of a compressor assembly and two fully redundant gearhead motors. The top portion of the cylinder compresses air routed to the right ventricle, while the bottom portion of the cylinder routes compressed air to the left ventricle.

The two stacked subassemblies are driven by a primary gearhead electric motor. The system includes a second gearhead motor that provides backup functionality in the event of a fault with the primary motor.

The gearhead motor drives the compressor assembly to provide the positive and negative air pressure for the left and right ventricles. The displacement of air occurs by the movement of the motor-driven pistons within the compressor assembly. Peak pressure and peak vacuum are controlled by a valve system within each chamber of the cylinder.

The pressurized air is routed through the Drivelines to the implanted TAH-t. Pressure and flow sensors connected to the pneumatic pathway provide performance information utilized to verify proper device operation and to calculate cardiac output.

During systole, the Driver supplies compressed air that is pressure regulated to actuate the left and right TAH-t ventricles, thereby expelling blood into the arterial and pulmonary systems. In

diastole, the compressors apply vacuum to the left and right ventricles to facilitate ventricular filling.

The compressor is driven by independent gearhead motors. The gearhead motors are governed by motor encoders and motor controllers. Only one gearhead motor is in use, and the other is used as a redundant backup.

In a gearhead motor fault condition in which the primary assembly detects current overload, the Driver will terminate operation of the faulted gearhead motor, and all functions will be performed by the remaining redundant gearhead motor. The Driver will then operate in Backup Mode.

Operation in Backup Mode signals a Fault Alarm condition, but allows the Driver to continue to provide biventricular support to the implanted TAH-t while maintaining pressures, vacuums and operation at the default rate of 125 BPM (+/- 5 BPM) for both the left and right ventricles. A Fault Alarm must be addressed immediately as described in **Section 10.3.**

While each driver has internal redundancy, each patient is issued a backup Freedom Driver. This backup Driver must accompany the patient at ALL times whether in the Hospital or out of the Hospital. It is critical that the backup Driver be available in the event that a Driver change is needed due to the primary Driver being dropped, exposed to liquid/debris, subjected to rough handling, or if a Fault Alarm cannot be resolved within three to four minutes.

1.3.2 Electronics

The electronics assemblies within the Driver route power to the subassemblies and actuate audible and visual alarm notifications.

Power management electronics automatically prioritize available power sources in the following order: External power (includes AC wall power or vehicle battery power) followed by the Onboard Batteries.

1.3.3 Interfaces

The color-coded TAH-t cannulae and Driveline CPC connectors are configured to connect only in one direction to ensure that the left and right ventricles are connected properly.

The Power Adaptor has a fixed power cord that connects to the Driver. The Power Adaptor cord is inserted into an outlet on the left side of the Driver.

The Power Adaptor has one input power outlet (green receptacle) that can be used for either the AC Power Supply or the Car Charger. The green receptacle is located at the left side of the Driver and is openly accessible. The Driver has a filter cover that

can be opened to allow the clinician or the patient to replace the filters.

The Driver has two battery well doors that conceal the battery wells when an Onboard Battery is not inserted. The Onboard Batteries are inserted into the battery wells to power the Driver.

1.3.4 Components of the Freedom Driver System

The Freedom Driver System consists of the following parts:

- One primary Driver with attached Power Adaptor
- One backup Driver with attached Power Adaptor
- One additional Power Adaptor
- Four to Six Onboard Batteries
- Two Hospital AC Power Supplies
- Two Home AC Power Supplies
- One Car Charger
- One Battery Charger (optional)
- Two Handle Straps (one attached to each Driver)
- Two Dummy Batteries (one inserted into each Driver)
- One Filter Pack including Screwdriver
- One Patient Tool Kit: Wire Ties, Wire Cutter Tool, Hook and Loop cable ties for Drivelines
- One Patient Information Card (**Appendix 1**) to be filled out by the Clinician
- One Shoulder Bag, one Backpack and one Accessory Bag
- One Pelican Case
- One Clinician Tool Kit: Slotted Screwdriver, L Torx Wrench, two Tamper Evident Labels, and one Driveline Retention Bag
- One Connector Kit: Male and Female CPC connectors for the Cannulae and ten Wire Ties
- One Permanent Center Tool Kit: one Battery Charger, one additional Dummy Battery, one additional Clinician Tool Kit, one Wire Cutter Tool, and spare screws for the Setting Dial Cover

	**CAUTION** **All of the above components of the Freedom Driver System are given to the patient upon Hospital discharge <u>except</u> the Freedom Hospital AC Power Supply, Clinician Tool Kit, the Permanent Center Tool Kit and the Dummy Battery that was inserted into the primary Freedom Driver.**

An exploded view showing the relationship of the main components of the Freedom Driver System is in **Figure 1-4**. The Freedom Driver System should only be operated with the system components and tools provided by SynCardia Systems, LLC.

If replacement components are needed, please contact SynCardia directly at +1 (866) 771-9437 or +1 (520) 545-1234 or your Distributor.

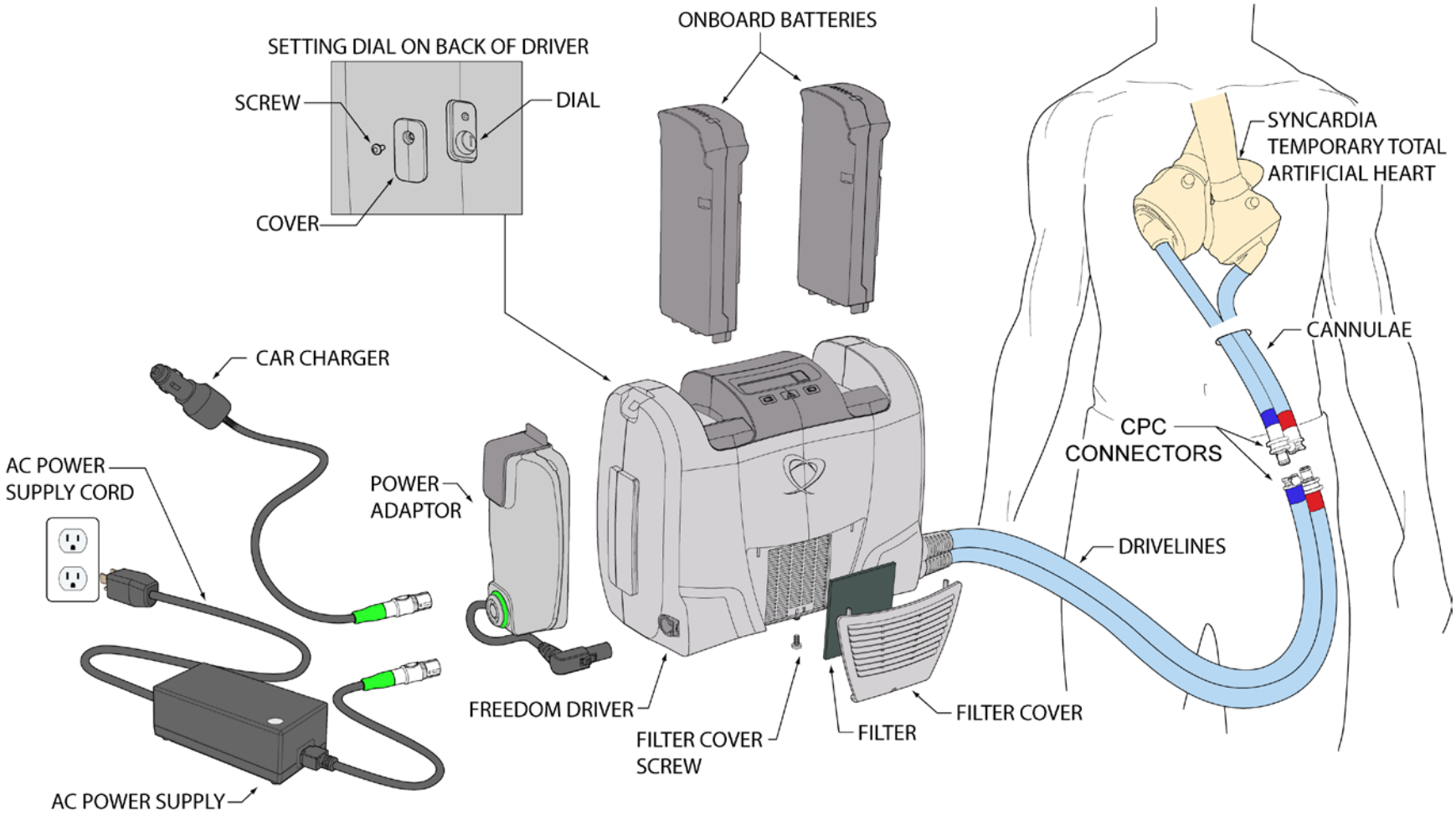


Figure 1-4 Exploded View of the Freedom Driver System

1.3.5 Primary Driver with attached Power Adaptor

The primary Freedom Driver **(Figure 1-5)** is the Driver connected to the implanted TAH-t.

- A Power Adaptor is attached on the side of the primary Freedom Driver and is needed to connect the Driver to an External Power source.

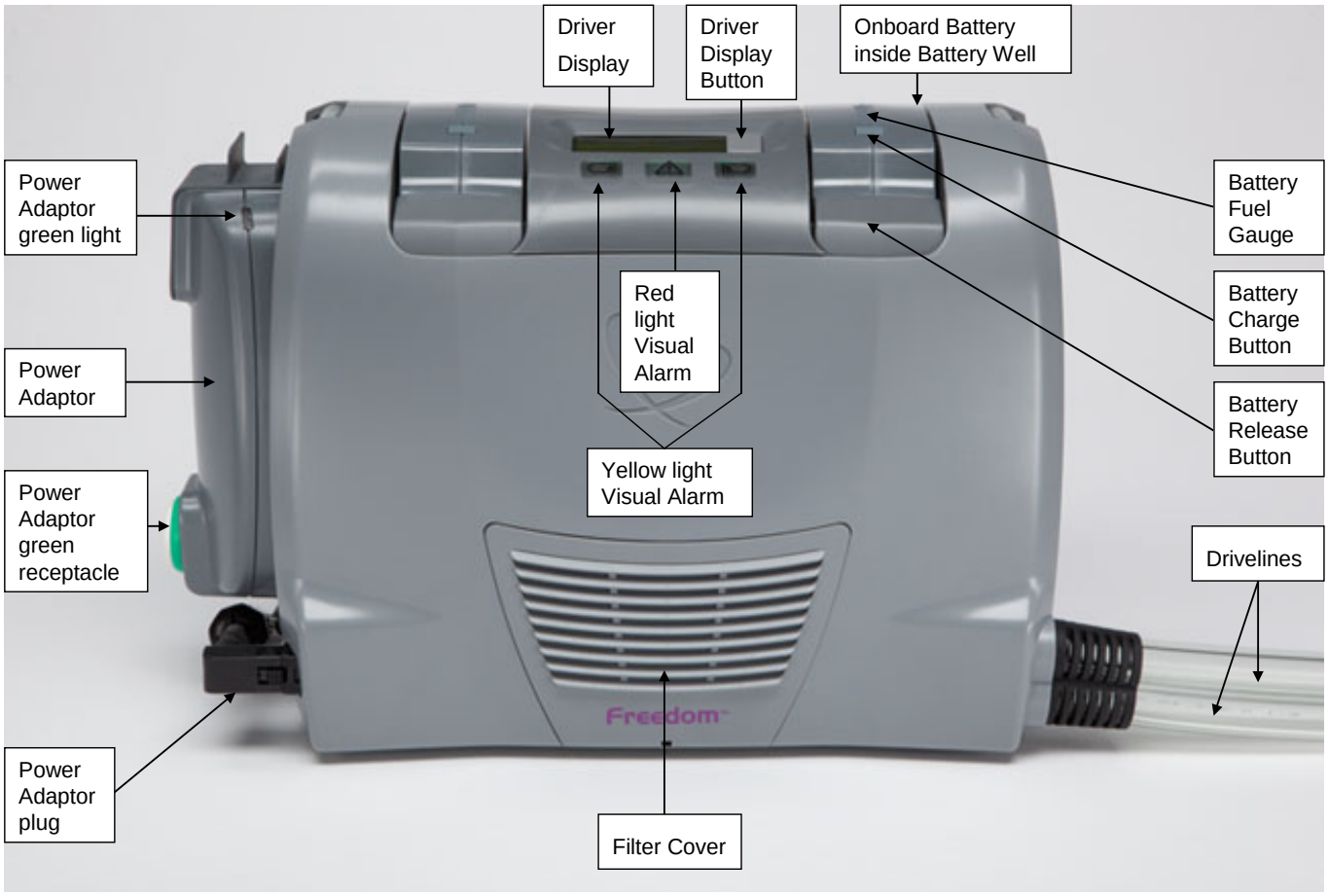


Figure 1-5 – Primary Freedom Driver with attached Power Adaptor and Two Inserted Onboard Batteries

The Freedom Driver has the following parts **(Figure 1-5)**:

- Driver Display: displays the Beats per Minute (BPM), Fill Volume (FV) and Cardiac Output (CO).
- Driver Display Button: when pressed, illuminates the Driver Display.
- Onboard Battery inside Battery Well: Onboard Batteries are the batteries that operate the Freedom Driver. They are inserted into

the compartments (Battery Wells) located on each side of the Freedom Driver.

- Battery Charge Button: when pressed firmly in the center, illuminates the Battery Fuel Gauge.
- Battery Fuel Gauge: indicates the amount of remaining charge for each Onboard Battery.
- Battery Release Button: when pressed, releases the Onboard Batteries out of the Battery Well.
- Drivelines: flexible tubes that are permanently connected to the Freedom Driver and connect to the TAH-t Cannulae through CPC Connectors
- Filter Cover: holds the Filter in place to prevent dirt and dust from entering the Freedom Driver.
- Yellow Light Visual Alarm: Indicates a Battery Alarm when lit. The alarm is accompanied by an audible tone.
- Red Light Visual Alarm: Indicates a Temperature Alarm (blinking light) or Fault Alarm (solid light). The alarm is accompanied by an audible tone.
- Power Adaptor: converts input power from External Power sources to DC power for use by the Freedom Driver.
- Power Adaptor green light: when lit, confirms proper connection of the Freedom Driver to External Power.
- Power Adaptor plug: transmits electrical power from the Power Adaptor to the Freedom Driver.
- Power Adaptor green receptacle: receptacle into which the green connector from the AC Power Supply or Car Charger are plugged in.

When the patient leaves the house, they must **always** take the backup Freedom Driver with them as well as all necessary accessories.

1.3.6 Backup Driver with Attached Power Adaptor

The backup Freedom Driver is provided to the patient in case the primary Freedom Driver is dropped, exposed to liquid/debris, subjected to rough handling or has a Fault Alarm that cannot be resolved.

Rough handling is defined as knocks, jolts, bumps and falls that may be received by the Freedom Driver during operational use. Examples of rough handling are:

- Banging the Freedom Driver against a hard surface (impact)
- Dropping and catching the Driver before it impacts a hard surface (jerking motion)

See **Section 10.3** for information on how to resolve Fault Alarms.

CAUTION

A backup Freedom Driver must always be available for the patient in the event that the primary Freedom Driver is dropped, exposed to liquid/debris, subjected to rough handling or has a Permanent Fault Alarm.

If the Freedom Driver is dropped, exposed to liquid/debris or subjected to rough handling, it may sustain damage that will not allow it to provide life-sustaining functions as designed.

If the primary Freedom Driver is dropped, exposed to liquid/debris, subjected to rough handling, or if the Fault Alarm cannot be resolved within three to four minutes, the patient must switch to the backup Freedom Driver.

The backup Freedom Driver **(Figure 1-6)** is given to the patient with an orange, nonfunctional Dummy Battery inserted in it.

- The Dummy Battery should only be removed from the backup Freedom Driver after inserting an Onboard Battery when switching from the primary Freedom Driver to the backup Freedom Driver because of a Fault Alarm that cannot be resolved.
- The Driver has an internal mechanism that locks one Battery in place, making it impossible for two Batteries to be removed at the same time. Insert an Onboard Battery to remove the Dummy Battery.
- A Power Adaptor is attached on the side of the backup Freedom Driver and is needed to connect the Driver to an External Power source.

Figure 1-6 – Backup Freedom Driver with attached Power Adaptor and Inserted Dummy Battery

1.3.7 Power Adaptor

The Power Adaptor **(Figure 1-7)** converts input power from External Power sources to DC power for use by the Freedom Driver.

Electrical power is transmitted from the Power Adaptor to the Freedom Driver by a power cord.

When External Power sources are connected to the Power Adaptor, it will simultaneously charge the inserted Onboard Batteries and power the Driver.

External power can come from an AC Power Supply connected to a wall power outlet, or from a Car Charger connected to a 12V vehicle power outlet.

The Power Adaptor has an indicator light that illuminates solid green when properly connected to External Power *and* the Freedom Driver.

Figure 1-7 – Power Adaptor

1.3.8 Onboard Batteries

The Onboard Batteries **(Figure 1-8)** power the Freedom Driver when inserted into either of the Battery Wells on top of the Driver. Each Driver comes with two Onboard Batteries.

When replacing an Onboard Battery, **promptly** insert another charged Onboard Battery correctly into the Freedom Driver.

Whenever possible, connect the Freedom Driver to an External Power source to keep the Onboard Batteries fully charged. The Freedom Driver MUST be connected to External Power and the connection verified to be secure and the indicator lights on the Power Supply and Power Adaptor must be illuminated solid green before the patient goes to sleep.

When External Power is removed, the Driver will automatically switch to Onboard Battery power.

Aside from the two Onboard Batteries that are inserted into the primary Freedom Driver, two additional fully charged Onboard Batteries must always be available to the patient.

Pressing the Battery Charge Button on top of the battery will illuminate the Battery Fuel Gauge and indicate how much battery charge is remaining.

It is recommended that the patient periodically rotates all of the Onboard Batteries. A serial number is located on each Onboard

Battery to help keep track of which Onboard Batteries have been used.

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

	CAUTION **The Onboard Batteries can only be used for a limited time when the Freedom Driver is not connected to External Power.** **When the Driver is not connected to external power, two fully charged Onboard Batteries provide approximately two hours of support before a Low Battery Alarm occurs. Actual support time may vary according to Driver Beat Rate setting.**

Figure 1-8 – Onboard Battery

1.3.9 AC Power Supply

1.3.9.1 Hospital AC Power Supply

The Freedom Hospital AC Power Supply is a Class I power supply unit which has an integrated, molded wall input power cord with a grounded plug **(Figure 1-9)**. The Hospital AC Power Supply connects the Power Adaptor to a grounded wall power outlet.

The Hospital AC Power Supply is intended to be used in a hospital environment only and should not be taken home by the patient. The patient will be able to take two Home AC Power Supplies for Out-of-Hospital-Use. See **Section 1.3.9.2.**

A green light on the Hospital AC Power Supply illuminates when it is connected to a wall power outlet. Whenever using the Hospital AC Power Supply, verify that all connections are secure and the indicator lights on the Power Supply and Power Adaptor are illuminated solid green.

The Hospital AC Power Supply is designed to accept electrical power input from 100VAC to 240VAC, and 50Hz/60Hz. Freedom Driver Systems will be shipped with region-appropriate AC Power Supplies.

Figure 1-9 – Hospital AC Power Supply

1.3.9.2 Home AC Power Supply

The Freedom Home AC Power Supply is a Class II power supply unit which has an integrated, molded wall input power cord **(Figure 1-10)**. The Home AC Power Supply connects the Power Adaptor to a wall power outlet.

The Home AC Power Supply is intended to be used in any environment outside of the hospital environment (e.g., residential areas). The Home AC Power Supply can be identified by the label with the green banner, as seen in **Figure 1-10.**

A green light on the Home AC Power Supply illuminates when it is connected to a wall power outlet. Whenever using the Home AC Power Supply, verify that all connections are secure and the indicator lights on the

Power Supply and Power Adaptor are illuminated solid green.

The Home AC Power Supply is designed to accept electrical power input from 100VAC to 240VAC, and 50Hz/60Hz. Freedom Driver Systems will be shipped with region-appropriate AC Power Supplies.

Figure 1-10 – Home AC Power Supply

1.3.9.3 AC Power Supply and Cord

Note: This AC Power Supply configuration is a previous model and the following information is for reference only.

The AC Power Supply with separate wall input cord **(Figure 1-11)** connects the Power Adaptor to a grounded wall power outlet.

The AC Power Supply has a green connector that plugs into the Power Adaptor and a Cord that plugs into the wall power outlet.

A green light on the AC Power Supply illuminates when it is connected to a wall power outlet. Whenever using the AC Power Supply, verify that all connections are secure and the indicator lights on the Power Supply and Power Adaptor are illuminated solid green.

The AC Power Supply is designed to accept input electrical power from 100VAC to 240VAC, and

50Hz/60Hz. Freedom Driver Systems will be shipped with the appropriate power cords.

Figure 1-11 – AC Power Supply and Cord

1.3.10 Car Charger

The Car Charger (**Figure 1-12**) connects the Power Adaptor to a 12V vehicle power outlet.

The Car Charger has an “on/off” switch on the end that plugs into the 12V vehicle power outlet.

Verify the switch is “on” after connecting the Car Charger. The Car Charger has a green light that only illuminates when it is connected to a 12V functional vehicle power outlet and the “on/off” switch is in the “on” position.

Figure 1-12 – Car Charger

1.3.11 Battery Charger

The Freedom Battery Charger (**Figure 1-13**) is a tabletop charger that can charge up to four Onboard Batteries that are not in use in the Driver. The Battery Charger uses the same AC Power Supply and Cord as the Freedom Driver. Do not connect the Car Charger to the Battery Charger.

Trained personnel should test the Battery Charger upon receipt and prior to distribution to patients according to the procedure described in the Freedom Battery Charger Operational Check Form (**Appendix 3**).

Figure 1-13 – Battery Charger

1.3.12 Handle Strap

Two Handle Straps are provided, one for the primary Freedom Driver and one for the backup Freedom Driver.

The Handle strap attaches to the Driver so that it can be carried without the Shoulder Bag or Backpack.

It is recommended to keep the Handle Strap attached to the Freedom Driver.

The Freedom Driver should be held by the Handle Strap when it is outside of the Shoulder Bag or Backpack.

The Handle Strap should be used to insert or remove the Freedom Driver into or out of the Shoulder Bag or Backpack.

1.3.13 Dummy Battery

The Dummy Battery **(Figure 1-14)** is a nonfunctional orange-colored insert that is placed in one of the Onboard Battery Wells of each Freedom Driver for shipping and storing.

- When not in use, the backup Freedom Driver is always stored and carried with one orange Dummy Battery.
- The Dummy Battery should only be removed from the backup Freedom Driver after inserting an Onboard Battery when switching the primary Freedom Driver to the backup Freedom Driver because of a Fault Alarm that cannot be resolved.
- The Driver has an internal mechanism that locks one Battery in place, making it impossible for two Batteries to be removed at the same time. Insert an Onboard Battery to remove the Dummy Battery.
- Hospitals should place the Dummy Battery that was shipped in the Primary Driver in the Permanent Center Tool Kit. A spare Dummy Battery is provided in the Permanent Center Tool Kit. The Dummy Battery is needed to turn off the Driver.

	**CAUTION** **The Dummy Battery should be left in the backup Freedom Driver. The only time the Dummy Battery should be removed is if the patient needs to switch from Primary Driver to Backup Driver (see Section 11).**

	CAUTION **The Dummy Battery should never be placed in the properly functioning primary Freedom Driver. Insert only into a faulted primary Driver after the patient is connected to a properly functioning backup Driver.** **If the Dummy Battery is inserted in the primary Freedom Driver, a condition is created in which accidental removal of all power is possible, resulting in the Driver ceasing to provide life-sustaining support.**

Figure 1-14 – Dummy Battery

1.3.14 One Filter Pack Including Screwdriver

A Filter **(Figure 1-15)** is a component made of thin foam located under the vent on the front of the Driver used to prevent dirt and dust from entering Driver.

Five replacement Filters are provided.

A Screwdriver **(Figure 1-15)** is provided to open the Filter Cover to replace the old Filter.

Three additional screws are provided in case the screw from the Filter Cover is misplaced.

Figure 1-15 – Filter Pack, Screwdriver and Screws

1.3.15 One Patient Tool Kit: Wire Ties, Wire Cutter Tool, Hook and Loop cable ties for Drivelines.

The Patient Tool Kit **(Figure 1-16)** contains the following:

Wire Ties

- Used to prevent accidental disconnection of the CPC Connectors that secure the TAH-t Cannulae to the Freedom Drivelines.
- They are inserted under the metal release button of the CPC connector.

Wire Cutter Tool

- Used to cut the Wire Tie around the metal release button when switching from the primary Freedom Driver to the backup Freedom Driver.

Hook and Loop Cable Ties

- May be used to attach the Drivelines to the Shoulder Bag or Backpack to minimize hanging of the Drivelines.

	**CAUTION** **Caution must be taken if Drivelines are looped using the Hook and Loop Cable Ties, since it decreases the available Driveline length. Care must be taken to avoid pulling on the Drivelines to avoid disturbance of the Cannulae exit sites.**

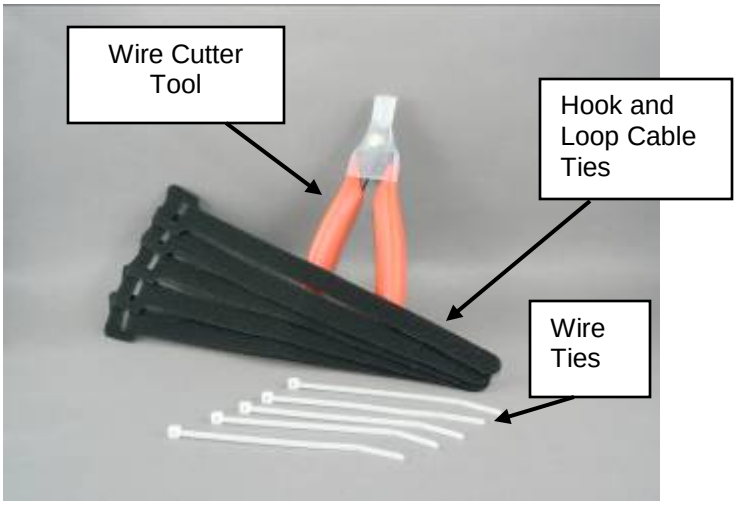


Figure 1-16 – Patient Tool Kit

1.3.16 Shoulder Bag and Backpack

The Shoulder Bag **(Figure 1-17)** and Backpack **(Figure 1-18)** are designed to contain the following items:

- The Freedom Driver with two inserted Onboard Batteries
- The Power Adaptor
- One Patient Tool Kit

It is recommended to carry the primary Freedom Driver inside the Shoulder Bag or Backpack. Clinicians should evaluate the patient strength and recovery status before having the patient carry the bags.

The backup Freedom Driver should also be carried inside the Shoulder Bag or Backpack.

The Shoulder Bag can be carried using the shoulder strap or by the handle.

The Backpack can be carried using the back straps or by the top-mounted handle. To help distribute weight, the Backpack straps have an adjustable chest strap.

Figure 1-17 – Shoulder Bag

Figure 1-18 – Backpack

Both the Shoulder Bag and the Backpack have similar features:

- The Freedom Driver with attached Power Adaptor is placed inside by unzipping the front flap.
- The interior has Velcro™ restraining straps to hold the Freedom Driver in place.

	**CAUTION** **Always secure the Freedom Driver with the Velcro™ restraining straps and make sure the zipper is fully closed, especially following Onboard Battery exchange. If the Freedom Driver is not properly secured inside the Freedom Shoulder Bag or Backpack, the Driver may fall and be damaged.** **If the Freedom Driver is dropped, exposed to liquid/debris or subjected to rough handling, it may sustain damage that will not allow it to provide life-sustaining functions as designed.** **If the Freedom Driver is dropped, exposed to liquid/debris or subjected to rough handling, it MUST be exchanged for the backup Freedom Driver.**

- The front flap has an opening to allow the Drivelines to come out on the right side.
- The front has a mesh window to view the yellow and red Visual Alarm indicator lights and Driver Display.
- In the front there is an Elastic Driveline Strap to attach the Drivelines to minimize hanging of the Drivelines.
- A clear window to insert the patient information/ emergency contact card **(Appendix 1)**
- The left side has a flap covered opening that allows direct access to the green connector receptacle of the Power Adaptor.
- The top has a mesh window to view the Power Adaptor green light to confirm connection to External Power.
- A rain cover is provided to **temporarily** protect the Freedom Driver from water (rain, sleet, snow, nearby shower/tub area, etc.) when the Driver is in the Shoulder Bag **(Figure 1-19)** or Backpack **(Figure 1-20)**. When the rain cover is used with the Freedom Driver inside the Shoulder Bag or Backpack, it provides water ingress protection for the system. Reference **Section 18.14** for water ingress protection.
- Mesh sides to allow air circulation

	**CAUTION** **Caution must be taken when Drivelines are looped using the Elastic Driveline Strap, since it decreases the available Driveline length. Care must be taken to avoid pulling on the Drivelines to avoid disturbance of the Cannulae exit sites.**

	**CAUTION** **Do not block the mesh windows on the Shoulder Bag and Backpack. This will cause the internal temperature of the Driver to increase and a Temperature Alarm will sound (See Section 10.2).**

	**CAUTION** **In rain (or other forms of precipitation) conditions, the Driver system must be used inside the Shoulder Bag or Backpack with the rain cover. The patient should immediately move to a dry area.**

Figure 1-19 – Shoulder Bag with Rain Cover

Figure 1-20 – Backpack with Rain Cover

1.3.17 Accessory Bag

The Accessory Bag (**Figure 1-21**) is provided to carry accessories.

The Accessory Bag is designed to contain the following items:

- Up to four Onboard Batteries
- The AC Power Supply
- The Car Charger
- One Filter Pack including Screwdriver
- An additional Power Adaptor
- One Patient Tool Kit

It is recommended that patients take all accessories in the Accessory Bag when leaving the house. The Accessory Bag can be carried using the shoulder strap or by the handle.

Figure 1-21 – Accessory Bag

1.3.18 Pelican Case

The Pelican case (**Figure 1-22**) is a large hard plastic case (box) with foam padding on the inside that holds the primary and backup Freedom Driver and accessories during shipping.

Figure 1-22 – Pelican Case

1.3.19 Standby Kit

The Standby Kit contains one Freedom Driver (with Power Adaptor, orange Dummy Battery and Handle Strap) inside of a hard plastic shipping case.

This kit is intended to stay at the transplant center until a patient needs a new backup driver due to scheduled service or a fault alarm.

After issuing the new Freedom Driver, the center should place the used driver in the kit and contact SynCardia for return instructions.

1.3.20 Clinician Tool Kit

The Clinician Tool Kit (**Figure 1-23**) contains the following:

Slotted Screwdriver and L Torx Wrench

- Used to set the Freedom Driver Beat Rate

Two Tamper Evident Labels

- Attached over the setting dial cover after adjustment of the Freedom Driver Beat Rate.

Driveline Retention Bag

- When the patient is switched from the implant driver to the Freedom Driver, the implant driver Drivelines are inserted into this large zip bag. The patient's name and the date of the switch are written on the bag and retained by the implant center to switch the patient back to the implant driver, if necessary.

Figure 1-23 – Clinician Tool Kit

1.3.21 Connector Kit

The Connector Kit is composed of CPC connectors and wire ties (**Figure 1-24**).

Male and Female CPC connectors for the Cannulae

- Inserted into the Cannulae during a CSS Console to Freedom Driver switch. Also provided as a spare in the event a connector needs to be replaced.

Ten Wire Ties

- Used to secure the CPC connectors to the Cannulae during a CSS Console to Freedom Driver switch and to prevent accidental disconnection of the Freedom Drivelines to Cannulae connections. Also used to prevent accidental disconnection of the Freedom Drivelines to Cannulae connections.

Figure 1-24 – Connector Kit

1.3.22 Permanent Center Tool Kit

The Permanent Center Tool Kit is provided inside a storage box with a lid. The Permanent Center Tool Kit contains duplicates of items provided with each Discharge Kit Case and is intended for use by the Clinicians in the event that the items from the Discharge Kit Case are not available. The Kit contains the following:

One Dummy Battery

- Provided to turn off a Freedom Driver, if necessary

Clinician Tool Kit

- Provided as a spare Tool Kit for use by Clinicians (see **Section 1.3.20** for contents)

Wire Cutter Tool

- Provided as a spare tool in the event the one from the Patient Tool Kit is not available

Additional Screws for Setting Dial Cover

- Provided as spares should the screw for the Setting Dial Cover get lost during setup

2 Indications for Use

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.

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.

Freedom Driver System Intended Use

The Freedom Driver System, used with the 50cc TAH-t or the 70cc TAH-t, is intended for in-hospital and out-of hospital use.

The TAH-t System with the SynCardia Freedom Driver is indicated for use as a bridge to transplantation in cardiac transplant candidates who are implanted with the TAH-t and are clinically stable.

Patients and caregivers should be mindful to keep the back-up Freedom Driver and recommended accessories with the patient at ALL times.

Additionally, the following precautions are important in the out-of-hospital environment. These measures will minimize known risks of managing the TAH-t supported by the Freedom Driver in the out-of-hospital environment.

- Avoid kinking and tugging of drivelines
- Examine cannulae exit sites during dressing changes and report changes in appearance to hospital personnel immediately
- Inspect cannulae regularly and report cracks and/or air leaks to hospital personnel immediately
- Practice proper power management. Assure that Onboard Batteries are fully charged at all times when not in use. Connect to wall power, if available, when responding to low battery alarms.
- Prior to excursions, assure that extra batteries and a backup driver are easily accessible to the patient
- When a Freedom Driver switch is necessary, calmly prepare the back-up driver and equipment prior to disconnecting the drivelines. The Freedom

Driver is designed to continue to provide its life-sustaining function when the driver is alarming

- Avoid activities that may result in fall or injury to the patient and/or Freedom Driver. **If the primary Freedom Driver is dropped or subjected to rough handling, the patient MUST switch to the backup Freedom Driver.**
- Avoid rough handling of drivers or placing drivers on uneven or unstable surfaces. **If the primary Freedom Driver is dropped or subjected to rough handling, the patient MUST switch to the backup Freedom Driver.**
- Change the filter weekly or more frequently, depending on environmental conditions
- Monitor the patient's blood pressure as recommended by hospital personnel and maintain healthy eating and exercise habits
- **If the Freedom Driver is exposed to liquid/debris, the patient MUST exchange it for the backup Freedom Driver**

2.1 Clinical Trial Results

A multi-center clinical study, the Freedom® Driver System Study, evaluated the use of the SynCardia Freedom Driver System in clinically stable patients implanted with the 70cc TAH-t in both the in-hospital and discharge (out-of-hospital) environments.

The FDA-approved Freedom Driver System Study was conducted:

- To demonstrate that the Freedom Driver System is a suitable pneumatic driver for clinically stable 70cc TAH-t patients, and
- To confirm that patients and lay caregivers can be trained to manage the Freedom Driver System safely outside the hospital.

The study enrolled 73 subjects and four compassionate use patients who were supported by the Freedom Driver System at 25 sites. Of the 77, 53 were supported on the Freedom Driver System in the out-of-hospital environment.

2.1.1 Suitable Pneumatic Driver

To be considered a suitable pneumatic driver for clinically stable 70cc TAH-t patients, the clinical results of the Freedom Driver System were required to meet three criteria.

- Cardiac Index

  Ninety-five percent of study subjects had to achieve an average cardiac index (CI) during Freedom Driver System support greater than or equal to 2.2 L/min/m^2.

  Result: Study results showed that all enrolled subjects met this criterion. The overall range was 2.7–4.5 L/min/m^2.

- Rate of Death and Preclusion from Transplant

The Freedom Driver In-Hospital Cohort was required to experience a rate of death or preclusion from transplant that was no more than 10% higher than the rate of death or preclusion from transplant for the clinically stable SynCardia temporary Total Artificial Heart (TAH-t) Postmarket Surveillance Study (PMSS) Cohort, who remained on Hospital (Implant) Driver support. The following *intermacs*® Registry key adverse events (AEs) were considered in this comparison:

- o Neurological Event: Ischemic or Cardiovascular Accident (CVA)
- o Major Infection: Internal Pump Component, Inflow or Outflow Tract Infection
- o Major Infection: Sepsis

Result: The rate of occurrence of these three key AEs was lower in the Freedom Driver In-Hospital Cohort than the rate of occurrence experienced by the clinically stable PMSS Cohort while in the hospital.

Table 2-1 summarizes the key AE comparison.

Table 2-1 – Key Adverse Event Comparison Stable PMSS to Freedom In-Hospital Cohort

Key Adverse Event Comparison							
Postmarket Surveillance Study Clinically Stable Cohort AEs [Hospital (Implant) Driver Support]				**SynCardia Freedom Driver System Study In-Hospital AEs**			
***intermacs*® Adverse Event**	**All Clinically Stable Subjects**			***intermacs*® Adverse Event**	**All In-Hospital Subjects on Freedom Driver Support**		
	Number of Events	**Number (%) of Subjects N=82**	**AEs per Subject Years N=13.5 yrs (4,937 days)**		**Number of Events**	**Number (%) of Subjects N=50 Number (%) of Subjects and Compassionate Use Patients N=77**	**AEs per Subject Years N=5.2 yrs (1,894 days)**
Internal Pump Component, Inflow or Outflow Tract Infection	1	1 (1%)	0.07	Internal Pump Component, Inflow or Outflow Tract Infection	0	0	0.00
Sepsis	8	8 (10%)	0.59	Sepsis	2	2 (3%)	0.39

Key Adverse Event Comparison							
Postmarket Surveillance Study Clinically Stable Cohort AEs [Hospital (Implant) Driver Support]				**SynCardia Freedom Driver System Study In-Hospital AEs**			
***intermacs*® Adverse Event**	**All Clinically Stable Subjects**			***intermacs*® Adverse Event**	**All In-Hospital Subjects on Freedom Driver Support**		
	Number of Events	**Number (%) of Subjects N=82**	**AEs per Subject Years N=13.5 yrs (4,937 days)**		**Number of Events**	**Number (%) of Subjects N=50 Number (%) of Subjects and Compassionate Use Patients N=77**	**AEs per Subject Years N=5.2 yrs (1,894 days)**
Ischemic or Hemorrhagic Cardiovascular Accident (CVA)	13	9 (11%)	0.96	Ischemic or Hemorrhagic Cardiovascular Accident (CVA)	3	3 (4%)	0.58

Adverse Event Profile:

- Clinically Stable In-hospital PMA approved Support (Post Market Surveillance/PMSS) vs. In Hospital Freedom Driver Support

Results: In some instances, subjects supported by the Freedom Driver System in the hospital showed increased rates of some adverse events in comparison to those patients supported by a Hospital Driver. However, the AE rate in every AE category experienced by subjects supported by the Freedom Driver System while in the hospital was either less than that of the AE rate experienced by the clinically stable PMSS Cohort or when there was an increase, the events did not have an adverse clinical impact on the patient (did not delay or preclude transplant). This comparison supports the conclusion that the Freedom Driver is safe for use in the hospital environment.

No subject deaths or preclusions from transplant occurred in subjects who remained in the hospital environment through their respective study endpoint. Therefore, the rate of death or preclusion from transplant experienced by the Freedom Driver Cohort while in the hospital environment was less than 10% higher than the rate of death or preclusion from transplant for the clinically stable PMSS Cohort and hospital safety was confirmed (see **Table 2-1 - Key Adverse Events**, above).

Table 2-2 compares AE to the Stable PMSS Cohort. The data show that the overall AE rate experienced by the patients

supported by a Hospital Driver is higher than that experienced by the subjects supported by the Freedom Driver System in the hospital.

Table 2-2 – Adverse Event Comparison Stable PMSS to Freedom In-Hospital Experience

Postmarket Surveillance Study Clinically Stable Adverse Events (AEs)				**SynCardia Freedom Driver System Study In-Hospital Adverse Events (AEs)**			
	All Clinically Stable Patients				**Results of In-Hospital AE Analysis**		
***intermacs*® Adverse Event**	**Number of Events**	**Number (%) of Subjects N=82**	**AEs per Subject Year N=13.5 yrs (4,937 days)**	***intermacs*® Adverse Event**	**Number of Events**	**Number (%) of Subjects and Compassionate Use Patients N=77**	**AEs per Subject Year N= 5.2 yrs (1,894 days)**
Any Adverse Event	137	47 (57%)	10.15	Any Adverse Event	48	26 (34%)	8.85
Major Bleeding	23	15 (18%)	1.70	Major Bleeding	4	4 (5%)	0.77
a. During First Seven days Post Implant	0	0	0.00	a. During First Seven days Post Implant	0	0	0.00
b. After Seven days Post Implant	23	15 (18%)	1.70	b. After Seven days Post Implant	4	4 (5%)	0.77
c. Re-Operation	0	0	0.00	c. Re-Operation	0	0	0.00
Cardiac Arrhythmias	0	0	0.00	Cardiac Arrhythmias	0	0	0.00
Pericardial Fluid Collection	1	1 (1%)	0.07	Pericardial Fluid Collection	0	0	0.00
Device Malfunction	3	3 (4%)	0.22	Device Malfunction	13	12 (16%)	2.50
a. Pump Failure	1	1 (1%)	0.07	a. Pump Failure	0	0	0.00
b. Pump Failure: Iatrogenic/ Recipient-Induced Failure	0	0	0.00	b. Pump Failure: Iatrogenic/ Recipient-Induced Failure	0	0	0.00
c. Non-Pump Failure	0	0	0.00	c. Non-Pump Failure	9	8 (10%)	1.73
d. Non-Pump Failure: Iatrogenic/ Recipient - Induced Failure	2	2 (2%)	0.15	d. Non-Pump Failure: Iatrogenic/ Recipient - Induced Failure	4	4 (5%)	0.77

Postmarket Surveillance Study Clinically Stable Adverse Events (AEs)				SynCardia Freedom Driver System Study In-Hospital Adverse Events (AEs)			
	All Clinically Stable Patients				Results of In-Hospital AE Analysis		
intermacs® Adverse Event	Number of Events	Number (%) of Subjects N=82	AEs per Subject Year N=13.5 yrs (4,937 days)	*intermacs*® Adverse Event	Number of Events	Number (%) of Subjects and Compassionate Use Patients N=77	AEs per Subject Year N= 5.2 yrs (1,894 days)
Hemolysis	10	10 (12%)	0.74	Hemolysis	6	5 (6%)	1.15
Hepatic Dysfunction	8	7 (9%)	0.59	Hepatic Dysfunction	1	1 (1%)	0.19
Hypertension	4	4 (5%)	0.30	Hypertension	5	5 (6%)	0.96
Major Infection	41	26 (32%)	3.04	Major Infection	9	7 (9%)	1.73
a. Localized Non-Device Infection	31	20 (24%)	2.30	a. Localized Non-Device Infection	6	5 (6%)	1.15
b. Percutaneous Site and/or Pocket Infection	1	1 (1%)	0.07	b. Percutaneous Site and/or Pocket Infection	1	1 (1%)	0.19
c. Internal Pump Component, Inflow or Outflow Tract Infection	1	1 (1%)	0.07	c. Internal Pump Component, Inflow or Outflow Tract Infection	0	0	0.00
d. Sepsis	8	8 (10%)	0.59	d. Sepsis	2	2 (3%)	0.39
Myocardial Infarction	0	0	0.00	Myocardial Infarction	0	0	0.00
Neurological Event	18	10 (12%)	1.33	Neurological Event	3	3 (4%)	0.58
a. Ischemic or Hemorrhagic Cardiovascular Accident (CVA)	13	9 (11%)	0.96	a. Ischemic or Hemorrhagic Cardiovascular Accident (CVA)	3	3 (4%)	0.58
b. Transient Ischemic Attack (TIA)	5	2 (2%)	0.37	b. Transient Ischemic Attack (TIA)	0	0	0.00
Psychiatric Episode	11	11 (13%)	0.81	Psychiatric Episode	2	2 (3%)	0.39
Renal Dysfunction: Acute	1	1 (1%)	0.07	Renal Dysfunction: Acute	1	1 (1%)	0.19
Renal Dysfunction: Chronic	1	1 (1%)	0.07	Renal Dysfunction: Chronic	0	0	0.00

Postmarket Surveillance Study Clinically Stable Adverse Events (AEs)				SynCardia Freedom Driver System Study In-Hospital Adverse Events (AEs)			
	All Clinically Stable Patients				Results of In-Hospital AE Analysis		
***intermacs*® Adverse Event**	**Number of Events**	**Number (%) of Subjects N=82**	**AEs per Subject Year N=13.5 yrs (4,937 days)**	***intermacs*® Adverse Event**	**Number of Events**	**Number (%) of Subjects and Compassionate Use Patients N=77**	**AEs per Subject Year N= 5.2 yrs (1,894 days)**
Respiratory Failure	5	4 (5%)	0.37	Respiratory Failure	2	2 (3%)	0.39
Right Heart Failure	0	0	0.00	Right Heart Failure	0	0	0.00
Arterial Non-CNS Thrombo-embolism	5	5 (6%)	0.37	Arterial Non-CNS Thrombo-embolism	2	1 (1%)	0.39
Venous Thrombo-embolism Event	2	2 (2%)	0.15	Venous Thrombo-embolism Event	0	0	0.00
Wound Dehiscence	1	1 (1%)	0.07	Wound Dehiscence	0	0	0.00
Other	3	2 (2%)	0.22	Other	0	0	0.00

Table 2-3 compares AE rates of the clinically stable PMSS Cohort (82 patients) to the cumulative Freedom Driver System Study experience (77 patients). The analysis includes the number of AEs in each AE category, the percentage of subjects/patients who experienced AEs, and the AE rate per subject year. This comparison supports the conclusion that the Freedom Driver System is safe for its intended use.

Table 2-3 – Adverse Event Comparison Stable PMSS to Cumulative Freedom Experience

Postmarket Surveillance Study Clinically Stable Adverse Events (AEs)				SynCardia Freedom Driver System Study Freedom Adverse Events (AEs)			
	All Clinically Stable Patients				All Subjects on Freedom Driver Support		
intermacs® Adverse Event	Number of Events	Number (%) of Subjects N=82	AEs per Subject Year N=13.5 yrs (4,937 days)	***intermacs***® Adverse Event	Number of Events	Number (%) of Subjects and Compassionate Use Patients N=77	AEs per Subject Year N=31.8 yrs (11,595 days)
Any Adverse Event	137	47 (57%)	10.15	Any Adverse Event	240	54 (70%)	7.55
Major Bleeding	23	15 (18%)	1.70	Major Bleeding	19	12 (16%)	0.60
a. During First Seven days Post Implant	0	0	0.00	a. During First Seven days Post Implant	0	0	0.00
b. After Seven days Post Implant	23	15 (18%)	1.70	b. After Seven days Post Implant	19	12 (16%)	0.60
c. Re-operation	0	0	0.00	c. Re-operation	0	0	0.00
Cardiac Arrhythmias	0	0	0.00	Cardiac Arrhythmias	0	0	0.00
Pericardial Fluid Collection	1	1 (1%)	0.07	Pericardial Fluid Collection	0	0	0.00
Device Malfunction	3	3 (4%)	0.22	Device Malfunction	101	42 (55%)	3.18
a. Pump Failure	1	1 (1%)	0.07	a. Pump Failure	1	1 (1%)	0.03
b. Pump Failure: Iatrogenic/ Recipient-Induced Failure	0	0	0.00	b. Pump Failure: Iatrogenic/ Recipient-Induced Failure	0	0	0.00
c. Non-Pump Failure	0	0	0.00	c. Non-Pump Failure	61	31 (40%)	1.92
d. Non-Pump Failure: Iatrogenic/ Recipient - Induced Failure	2	2 (2%)	0.15	d. Non-Pump Failure: Iatrogenic/ Recipient - Induced Failure	39	23 (30%)	1.23
Hemolysis	10	10 (12%)	0.74	Hemolysis	20	12 (16%)	0.63
Hepatic Dysfunction	8	7 (9%)	0.59	Hepatic Dysfunction	6	4 (5%)	0.19

Postmarket Surveillance Study Clinically Stable Adverse Events (AEs)				SynCardia Freedom Driver System Study Freedom Adverse Events (AEs)			
intermacs® Adverse Event	All Clinically Stable Patients			*intermacs*® Adverse Event	All Subjects on Freedom Driver Support		
	Number of Events	Number (%) of Subjects N=82	AEs per Subject Year N=13.5 yrs (4,937 days)		Number of Events	Number (%) of Subjects and Compassionate Use Patients N=77	AEs per Subject Year N=31.8 yrs (11,595 days)
Hypertension	4	4 (5%)	0.30	Hypertension	12	12 (16%)	0.38
Major Infection	41	26 (32%)	3.04	Major Infection	50	25 (32%)	1.57
a. Localized Non-Device Infection	31	20 (24%)	2.30	a. Localized Non-Device Infection	32	19 (25%)	1.01
b. Percutaneous Site and/or Pocket Infection	1	1 (1%)	0.07	b. Percutaneous Site and/or Pocket Infection	8	7 (9%)	0.25
c. Internal Pump Component, Inflow or Outflow Tract Infection	1	1 (1%)	0.07	c. Internal Pump Component, Inflow or Outflow Tract Infection	0	0	0.00
d. Sepsis	8	8 (10%)	0.59	d. Sepsis	10	8 (10%)	0.31
Myocardial Infarction	0	0	0.00	Myocardial Infarction	0	0	0.00
Neurological Event	18	10 (12%)	1.33	Neurological Event	11	7 (9%)	0.35
a. Ischemic or Hemorrhagic Cardiovascular Accident (CVA)	13	9 (11%)	0.96	a. Ischemic or Hemorrhagic Cardiovascular Accident (CVA)	10	7 (9%)	0.31
b. Transient Ischemic Attack (TIA)	5	2 (2%)	0.37	b. Transient Ischemic Attack (TIA)	1	1 (1%)	0.03
Psychiatric Episode	11	11 (13%)	0.81	Psychiatric Episode	4	4 (5%)	0.13
Renal Dysfunction: Acute	1	1 (1%)	0.07	Renal Dysfunction: Acute	2	2 (3%)	0.06
Renal Dysfunction: Chronic	1	1 (1%)	0.07	Renal Dysfunction: Chronic	0	0	0.00

Postmarket Surveillance Study Clinically Stable Adverse Events (AEs)				SynCardia Freedom Driver System Study Freedom Adverse Events (AEs)			
	All Clinically Stable Patients				All Subjects on Freedom Driver Support		
intermacs® Adverse Event	Number of Events	Number (%) of Subjects N=82	AEs per Subject Year N=13.5 yrs (4,937 days)	***intermacs***® Adverse Event	Number of Events	Number (%) of Subjects and Compassionate Use Patients N=77	AEs per Subject Year N=31.8 yrs (11,595 days)
Respiratory Failure	5	4 (5%)	0.37	Respiratory Failure	10	9 (12%)	0.31
Right Heart Failure	0	0	0.00	Right Heart Failure	0	0	0.00
Arterial Non-CNS Thrombo-embolism	5	5 (6%)	0.37	Arterial Non-CNS Thrombo-embolism	2	1 (1%)	0.06
Venous Thrombo-embolism Event	2	2 (2%)	0.15	Venous Thrombo-embolism Event	1	1 (1%)	0.03
Wound Dehiscence	1	1 (1%)	0.07	Wound Dehiscence	0	0	0.00
Other	3	2 (2%)	0.22	Other	2	2 (3%)	0.06

2.1.2 Patients and lay caregivers can be trained to manage the Freedom Driver System safely outside the hospital

To address the issue, the out-of-hospital AE profile had to be clinically comparable to the overall AE profile that occurred in the hospital during Freedom Driver System support. The intent of this analysis was two-fold:

- to demonstrate that the Freedom Driver can be used safely in the out-of-hospital environment, and
- to demonstrate that patients and lay caregivers can use the device safely.

Since patients and lay caregivers are the primary users of the Freedom Driver in the out-of-hospital environment, their ability to be trained to use the device safely is represented by the out-of-hospital AE profile.

Patients and caregivers should be mindful to keep the backup Freedom Driver and recommended accessories with the patient at ALL times.

Additionally, the following precautions are important in the out-of-hospital environment. These measures will minimize known risks of

managing the TAH-t supported by the Freedom Driver in the out-of-hospital environment.

- Avoid kinking and tugging of drivelines
- Examine cannulae exit sites during dressing changes and report changes in appearance to hospital personnel immediately
- Inspect cannulae regularly and report cracks and/or air leaks to hospital personnel immediately
- Practice proper power management. Assure that Onboard Batteries are fully charged when not in use. Connect to wall power, if available, when responding to low battery alarms.
- Prior to excursions, assure that extra batteries and a backup driver are easily accessible to the patient
- When a Freedom Driver switch is necessary, calmly prepare the back-up driver and equipment prior to disconnecting the drivelines. The Freedom Driver is designed to continue to provide its life-sustaining function when the driver is alarming
- Avoid activities that may result in fall or injury to the patient and/or Freedom Driver. **If the primary Freedom Driver is dropped or subjected to rough handling, the patient MUST switch to the backup Freedom Driver.**
- Avoid rough handling of drivers or placing drivers on uneven or unstable surfaces. **If the primary Freedom Driver is dropped or subjected to rough handling, the patient MUST switch to the backup Freedom Driver**
- Change the filter weekly or more frequently, depending on environmental conditions
- Monitor the patient's blood pressure as recommended by hospital personnel and maintain healthy eating and exercise habits
- **If the Freedom Driver is exposed to liquid/debris, the patient MUST exchange it for the backup Freedom Drive**r

Results: Two categories, Device Malfunctions and Percutaneous Site/Pocket Infections, showed a higher AE rate in the out-of-hospital environment. However, subjects remained stable during device malfunctions and the number of subjects experiencing percutaneous site and/or pocket infections was small, only one subject in-hospital (rate of 0.19 AEs per subject year) compared to three subjects out-of-hospital (rate of 0.32 AEs per subject year). None of these AEs precluded transplant. Although subjects experiencing these events in the study remained generally stable, device malfunctions and exit site infections could potentially be serious.

Table 2-4 compares the adverse event profiles for Freedom Driver System use in and out of the hospital. This comparison shows that the overall rate of adverse events experienced outside of the hospital is lower than that experienced in-hospital.

Table 2-4 – Freedom Adverse Event Comparison In-Hospital to Out-of-Hospital

SynCardia Freedom Driver System Study In-Hospital AEs				**SynCardia Freedom Driver System Study Out-of-Hospital AEs**			
***intermacs*® Adverse Event**	**Results of In-Hospital AE Analysis**			***intermacs*® Adverse Event**	**Results of Out-of-Hospital AE Analysis**		
	Number of Events	**Number (%) of Subjects and Compassionate Use Patients N=77**	**AEs per Subject Year N=5.2 years (1,894 days)**		**Number of Events**	**Number (%) of Subjects N=54**	**AEs per Subject Year N= 9.3 years (3,401 days)**
Any Adverse Event	48	26 (34%)	8.85	Any Adverse Event	64	34 (63%)	6.88
Major Bleeding	4	4 (5%)	0.77	Major Bleeding	4	4 (7%)	0.43
a. During First Seven days Post Implant	0	0	0.00	a. During First Seven days Post Implant	0	0	0.00
b. After Seven days Post Implant	4	4 (5%)	0.77	b. After Seven days Post Implant	4	4 (7%)	0.43
c. Re-operation	0	0	0.00	c. Re-operation	0	0	0.00
Cardiac Arrhythmias	0	0	0.00	Cardiac Arrhythmias	0	0	0.00
Pericardial Fluid Collection	0	0	0.00	Pericardial Fluid Collection	0	0	0.00
Device Malfunction:	13	12 (16%)	2.50	Device Malfunction:	36	22 (41%)	3.87
a. Pump Failure	0	0	0.00	a. Pump Failure	0	0	0.00
b. Pump Failure: Iatrogenic/ Recipient-Induced Failure	0	0	0.00	b. Pump Failure: Iatrogenic/ Recipient-Induced Failure	0	0	0.00
c. Non-Pump Failure	9	8 (10%)	1.73	c. Non-Pump Failure	22	16 (30%)	2.37

SynCardia Freedom Driver System Study In-Hospital AEs				SynCardia Freedom Driver System Study Out-of-Hospital AEs			
***intermacs*® Adverse Event**	**Results of In-Hospital AE Analysis**			***intermacs*® Adverse Event**	**Results of Out-of-Hospital AE Analysis**		
	Number of Events	**Number (%) of Subjects and Compassionate Use Patients N=77**	**AEs per Subject Year N=5.2 years (1,894 days)**		**Number of Events**	**Number (%) of Subjects N=54**	**AEs per Subject Year N= 9.3 years (3,401 days)**
d. Non-Pump Failure: Iatrogenic/ Recipient - Induced Failure	4	4 (5%)	0.77	d. Non-Pump Failure: Iatrogenic/ Recipient - Induced Failure	14	10 (19%)	1.50
Hemolysis	6	5 (6%)	1.15	Hemolysis	6	5 (9%)	0.65
Hepatic Dysfunction	1	1 (1%)	0.19	Hepatic Dysfunction	1	1 (2%)	0.11
Hypertension	5	5 (6%)	0.96	Hypertension	3	3 (6%)	0.32
Major Infection	9	7 (9%)	1.73	Major Infection	9	9 (17%)	0.97
a. Localized Non-Device Infection	6	5 (6%)	1.15	a. Localized Non-Device Infection	4	4 (7%)	0.43
b. Percutaneous Site and/or Pocket Infection	1	1 (1%)	0.19	b. Percutaneous Site and/or Pocket Infection	3	3 (6%)	0.32
c. Internal Pump Component, Inflow or Outflow Tract Infection	0	0	0.00	c. Internal Pump Component, Inflow or Outflow Tract Infection	0	0	0.00
d. Sepsis	2	2 (3%)	0.39	d. Sepsis	2	2 (4%)	0.22
Myocardial Infarction	0	0	0.00	Myocardial Infarction	0	0	0.00

SynCardia Freedom Driver System Study In-Hospital AEs				SynCardia Freedom Driver System Study Out-of-Hospital AEs			
***intermacs*® Adverse Event**	**Results of In-Hospital AE Analysis**			***intermacs*® Adverse Event**	**Results of Out-of-Hospital AE Analysis**		
	Number of Events	**Number (%) of Subjects and Compassionate Use Patients N=77**	**AEs per Subject Year N=5.2 years (1,894 days)**		**Number of Events**	**Number (%) of Subjects N=54**	**AEs per Subject Year N= 9.3 years (3,401 days)**
Neurological Event	3	3 (4%)	0.58	Neurological Event	0	0	0.00
a. Ischemic or Hemorrhagic Cardiovascular Accident (CVA)	3	3 (4%)	0.58	a. Ischemic or Hemorrhagic Cardiovascular Accident (CVA)	0	0	0.00
b. Transient Ischemic Attack (TIA)	0	0	0.00	b. Transient Ischemic Attack (TIA)	0	0	0.00
Psychiatric Episode	2	2 (3%)	0.39	Psychiatric Episode	1	1 (2%)	0.11
Renal Dysfunction: Acute	1	1 (1%)	0.19	Renal Dysfunction: Acute	0	0	0.00
Renal Dysfunction: Chronic	0	0	0.00	Renal Dysfunction: Chronic	0	0	0.00
Respiratory Failure	2	2 (3%)	0.39	Respiratory Failure	3	3 (6%)	0.32
Right Heart Failure	0	0	0.00	Right Heart Failure	0	0	0.00
Arterial Non-CNS Thrombo-embolism	2	1 (1%)	0.39	Arterial Non-CNS Thrombo-embolism	0	0	0.00
Venous Thrombo-embolism Event	0	0	0.00	Venous Thrombo-embolism Event	0	0	0.00
Wound Dehiscence	0	0	0.00	Wound Dehiscence	0	0	0.00
Other	0	0	0.00	Other	1	1 (2%)	0.11

2.1.3 Additional Analysis

Two centers that participated in the Freedom Driver System Study contributed approximately 40 percent of the subjects whose data were included in these results. This analysis includes four compassionate use patients. A comparison between the AE rate at these two centers to that at lower volume centers with less overall Freedom Driver System experience was conducted.

Results: The AE rates in some AE categories were greater in the low volume sites, but other AEs were greater in the high volume sites. Based on the overall AE rate, subjects supported with the Freedom Driver System at lower volume sites may experience approximately 1.5 more AEs per subject year than subjects at higher volume sites.

Table 2-5 compares the AE results between high volume centers and low volume centers.

Table 2-5 – Adverse Event Comparison Freedom Experience High Volume Sites to Low Volume Sites

SynCardia Freedom Driver System Study AEs High Volume Centers (N=2)				**SynCardia Freedom Driver System Study AEs Low Volume Centers (N=23)**			
***intermacs*® Adverse Event**	**Results of AE Analysis For High Volume Centers**			***intermacs*® Adverse Event**	**Results of AE Analysis For Low Volume Centers**		
	Number of Events	**Number (%) of Subjects N=29**	**AEs per Subject Year N=13.0 years (4763 days)**		**Number of Events**	**Number (%) of Subjects and Compassionate Use Patients N=48**	**AEs per Subject Year N= 18.7 years (6832 days)**
Any Adverse Event	87	18 (62%)	6.69	Any Adverse Event	153	36 (75%)	8.18
Major Bleeding	9	5 (17%)	0.69	Major Bleeding	10	7 (15%)	0.53
a. During First Seven days Post Implant	0	0	0.00	a. During First Seven days Post Implant	0	0	0.00
b. After Seven days Post Implant	9	5 (17%)	0.69	b. After Seven days Post Implant	10	7 (15%)	0.53
c. Re-operation	0	0	0.00	c. Re-operation	0	0	0.00
Cardiac Arrhythmias	0	0	0.00	Cardiac Arrhythmias	0	0	0.00

SynCardia Freedom Driver System Study AEs High Volume Centers (N=2)				SynCardia Freedom Driver System Study AEs Low Volume Centers (N=23)			
	Results of AE Analysis For High Volume Centers				Results of AE Analysis For Low Volume Centers		
***intermacs*® Adverse Event**	**Number of Events**	**Number (%) of Subjects N=29**	**AEs per Subject Year N=13.0 years (4763 days)**	***intermacs*® Adverse Event**	**Number of Events**	**Number (%) of Subjects and Compassionate Use Patients N=48**	**AEs per Subject Year N= 18.7 years (6832 days)**
Pericardial Fluid Collection	0	0	0.00	Pericardial Fluid Collection	0	0	0.00
Device Malfunction:	40	11 (38%)	3.08	Device Malfunction:	61	31 (65%)	3.26
a. Pump Failure	0	0	0.00	a. Pump Failure	1	1 (2%)	0.05
b. Pump Failure: Iatrogenic/ Recipient-Induced Failure	0	0	0.00	b. Pump Failure: Iatrogenic/ Recipient-Induced Failure	0	0	0.00
c. Non-Pump Failure	29	10 (34%)	2.23	c. Non-Pump Failure	32	21 (44%)	1.71
d. Non-Pump Failure: Iatrogenic/ Recipient - Induced Failure	11	6 (21%)	0.85	d. Non-Pump Failure: Iatrogenic/ Recipient - Induced Failure	28	17 (35%)	1.50
Hemolysis	9	5 (17%)	0.69	Hemolysis	11	7 (15%)	0.59
Hepatic Dysfunction	5	3 (10%)	0.38	Hepatic Dysfunction	1	1 (2%)	0.05
Hypertension	6	6 (21%)	0.46	Hypertension	6	6 (13%)	0.32

SynCardia Freedom Driver System Study AEs High Volume Centers (N=2)				SynCardia Freedom Driver System Study AEs Low Volume Centers (N=23)			
	Results of AE Analysis For High Volume Centers				Results of AE Analysis For Low Volume Centers		
intermacs® Adverse Event	Number of Events	Number (%) of Subjects N=29	AEs per Subject Year N=13.0 years (4763 days)	*intermacs*® Adverse Event	Number of Events	Number (%) of Subjects and Compassionate Use Patients N=48	AEs per Subject Year N= 18.7 years (6832 days)
Major Infection	13	8 (28%)	1.00	Major Infection	37	17 (35%)	1.98
a. Localized Non-Device Infection	9	5 (17%)	0.69	a. Localized Non-Device Infection	23	14 (29%)	1.23
b. Percutaneous Site and/or Pocket Infection	2	2 (7%)	0.15	b. Percutaneous Site and/or Pocket Infection	6	5 (10%)	0.32
c. Internal Pump Component, Inflow or Outflow Tract Infection	0	0	0.00	c. Internal Pump Component, Inflow or Outflow Tract Infection	0	0	0.00
d. Sepsis	2	2 (7%)	0.15	d. Sepsis	8	6 (13%)	0.43
Myocardial Infarction	0	0	0.00	Myocardial Infarction	0	0	0.00
Neurological Event	1	1 (3%)	0.08	Neurological Event	10	6 (13%)	0.53
a. Ischemic or Hemorrhagic Cardiovascular Accident (CVA)	1	1 (3%)	0.08	a. Ischemic or Hemorrhagic Cardiovascular Accident (CVA)	9	6 (13%)	0.48
b. Transient Ischemic Attack (TIA)	0	0	0.00	b. Transient Ischemic Attack (TIA)	1	1 (2%)	0.05
Psychiatric Episode	0	0	0.00	Psychiatric Episode	4	4 (8%)	0.21
Renal Dysfunction: Acute	0	0	0.00	Renal Dysfunction: Acute	2	2 (4%)	0.11

SynCardia Freedom Driver System Study AEs High Volume Centers (N=2)				SynCardia Freedom Driver System Study AEs Low Volume Centers (N=23)			
	Results of AE Analysis For High Volume Centers				Results of AE Analysis For Low Volume Centers		
***intermacs*® Adverse Event**	**Number of Events**	**Number (%) of Subjects N=29**	**AEs per Subject Year N=13.0 years (4763 days)**	***intermacs*® Adverse Event**	**Number of Events**	**Number (%) of Subjects and Compassionate Use Patients N=48**	**AEs per Subject Year N= 18.7 years (6832 days)**
Renal Dysfunction: Chronic	0	0	0.00	Renal Dysfunction: Chronic	0	0	0.00
Respiratory Failure	4	3 (10%)	0.31	Respiratory Failure	6	6 (13%)	0.32
Right Heart Failure	0	0	0.00	Right Heart Failure	0	0	0.00
Arterial Non-CNS Thrombo-embolism	0	0	0.00	Arterial Non-CNS Thrombo-embolism	2	1 (2%)	0.11
Venous Thrombo-embolism Event	0	0	0.00	Venous Thrombo-embolism Event	1	1 (2%)	0.05
Wound Dehiscence	0	0	0.00	Wound Dehiscence	0	0	0.00
Other	0	0	0.00	Other	2	2 (4%)	0.11

2.1.4 Conclusions

The results of the Freedom Driver System Study demonstrate that, while adverse events may occur in the out-of-hospital environment, the Freedom Driver System is appropriate for its intended use. When used in the clinically stable TAH-t patient population, the Freedom Driver System:

- Is a suitable pneumatic driver,
- Is safe and effective for use in the in-hospital environment, and
- Can be managed safely and effectively in the out-of-hospital environment by trained patients and caregivers when the recommended guidelines for use and care are followed.

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 m², 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.

The Freedom Driver System is contraindicated for use in TAH-t patients who are not clinically stable.

4 Warnings

CAUTION

Failure to adhere to the warnings listed below may cause the Freedom Driver System to malfunction or not perform the life-sustaining functions as designed.

4.1 TAH-t Warnings

- Setup and operation of the TAH-t System and the Freedom Driver System should be performed only by qualified personnel trained and certified in accordance with the SynCardia training program and in accordance with this Operator Manual and the TAH-t Instructions for Use. 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 or CSS, for the 50cc or 70cc TAH-t, as appropriate.
- No modification of this equipment should be performed by any clinician, caregiver, or patient.
- Safe use of this system has not been established in pregnant patients. Patients should not become pregnant while on the TAH-t System.
- Do not subject patients implanted with the TAH-t to magnetic resonance imaging (MRI) scans.
- 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.
- Do not allow the external Drivelines (or Cannulae) to become kinked. If there is a Fault Alarm, immediately inspect the Drivelines for kinks or damage.
- A reduction in the Fill Volume on the Freedom Driver Display to below 30 milliliters may indicate a failure of one of the diaphragms in an artificial ventricle of the 50cc TAH-t. It is recommended that the patient be switched to an implant driver for further evaluation.
- A reduction in the Fill Volume on the Freedom Driver Display to below 40 milliliters may indicate a failure of one of the diaphragms in an artificial ventricle of the 70cc TAH-t. It is recommended that the patient be switched to an implant driver for further evaluation.

- Do not administer CPR to TAH-t patients. Defibrillation, cardioversion, and CPR are ineffective on patients implanted with the TAH-t.
- Do not administer epinephrine to TAH-t patients experiencing hypertension.
- Flows should be kept at a reasonable output so that proper washing of the ventricles is established.

4.2 Driver System Warnings

- The Patient must use caution when entering and exiting vehicles to ensure that Drivelines do not get kinked.
- Do not submerge the Freedom Driver System or expose it to liquid/debris. Protect it from rain, showers, baths and liquid/debris.
  - Liquid/debris exposure is defined as any seepage of liquid or debris onto or into the Freedom Driver. Examples of liquid/debris exposure are:
    - Rain
    - Splash of water/soda/milk/soup
    - Paint
    - Household cleaners
    - Dirt/sand
- **If the Freedom Driver is exposed to liquid/debris, the patient must exchange it for the backup Freedom Driver.**
- **If the Freedom Driver is dropped or subjected to rough handling, it may sustain damage that will not allow it to provide life-sustaining functions as designed. If the Freedom Driver is dropped or subjected to rough handling, the patient MUST switch to the backup Freedom Driver.**
- If the Freedom Driver or any of the accessories are dropped, they must be brought back to the Hospital for replacement.
- Always keep the Freedom Driver System out of reach of infants, children and pets. The AC Power Supply cord and the Car Charger cable are strangulation/asphyxiation hazards.
- The AC Power Supply cord may be a tripping hazard. Make sure the cord is not lying in an open space where a person can trip over the cord.
- Always keep the Freedom Driver System away from open flame.
- **A backup Freedom Driver must always be available for the patient in the event that the primary Freedom Driver is dropped, exposed**

to liquid/debris, subjected to rough handling or has a Permanent Fault Alarm. If the primary Freedom Driver is dropped, exposed to liquid/debris, subjected to rough handling or if the Fault Alarm cannot be resolved within three to four minutes, the patient must switch to the backup Freedom Driver.

- The patient must always carry at least two additional fully charged Onboard Batteries as well as the Power Adaptor, AC Power Supply and Car Charger.
- Before the patient goes to sleep, the Driver **MUST** be plugged into External Power using the AC Power Supply. All connections must be verified to be secure and the indicator lights on the Power Supply and Power Adaptor must be illuminated solid green.
- The Onboard Batteries may take up to six hours to fully charge.

5 Precautions and Recommendations

CAUTION

Failure to adhere to the precautions and recommendations listed below may cause the Freedom Driver System to malfunction or not perform the life-sustaining functions as designed.

5.1 Precautions

- Measures should be taken to prevent infection. Use strict aseptic techniques while cleaning the exit site area.
- Use only water-soluble antiseptic cleaners around the exit site. Ointments may delay tissue in-growth into the Cannulae. Do not use cleaners on Drivelines, Cannula, Drivers or Driver Accessories.
- Whenever possible, connect the Freedom Driver to an External Power source to keep the Onboard Batteries fully charged. The Freedom Driver MUST be plugged into External Power and the connection verified to be secure and the indicator lights on the Power Supply and Power Adaptor must be illuminated solid green before going to sleep.
- The Freedom Driver and the Drivelines should always be worn over clothing and not be restricted by items such as a belt.
- Do not lift the Freedom Driver by the Drivelines or the Cannulae.
- After inserting an Onboard Battery, verify that it is properly inserted into the Freedom Driver by checking that the fuel gauge button is adjacent to the battery release button.
- Inspect the Drivelines and Cannulae daily. If a hole is detected in the Driveline or Cannulae, they should apply household tape to temporarily repair the hole. Then, immediately call the Hospital Contact Person to arrange for a hospital-based evaluation. The hospital should apply a self-fusing silicone tape to seal the hole. The hospital must contact SynCardia for possible further instructions.
- Avoid exposing the Freedom Driver System to extreme temperatures for more than brief periods of time.
- Do not block the Filter Cover and Fan of the Freedom Driver with any object that might block air flow.
- The patient must avoid being in loud environments (i.e. loud music, arenas, etc.) that might prevent them from hearing an Alarm from the Freedom Driver.
- The patient should avoid being in areas where the alarm cannot be heard by caregivers or others for more than brief periods of time.

- If the patient is sedated, they might not be able to hear and respond to the Driver alarms.
- After discharge, the patient's ability to drive is based on the discretion of the physician and any applicable local regulations.

5.2 Recommendations

- It is recommended to have two people (patient and trained caregiver) exchange the primary Freedom Driver for the backup Freedom Driver.
- It is recommended that the Freedom Driver has at least two sources of power to operate. Plug in the Freedom Driver to an External Power source when replacing an Onboard Battery. If connection to External Power is not available, make sure to promptly insert another charged Onboard Battery into the Freedom Driver.
- It is recommended to check proper function of a 12V vehicle power outlet and carry extra car fuses in the vehicle
- It is recommended to keep the Handle Straps attached to the primary and backup Freedom Drivers.
- Maintain the patient's systolic blood pressure under 140mmHg with anti-hypertensive medications and manage the patient's fluid status with diuretics, as appropriate.
- Monitor the patient's blood pressure and weight with timely medical intervention in response to changes reported by the patient or caregiver.
- Instruct the patient to seek immediate medical attention with the occurrence of intermittent low CO fault alarms and corresponding low cardiac outputs of less than 3.5 L/min shown on the Freedom display.
- It is recommended that the patient and trained caregiver receive refresher training at every clinic visit.

6 Operating Instructions

Only medical or technical support teams who have been trained in the use of the TAH-t System and the Freedom Driver System can make changes to the Freedom Driver settings.

All patients will be required to participate in hands-on training and demonstrate the ability to properly use and manage the equipment before they are allowed unsupervised use of the Freedom Driver System.

It is recommended that refresher training be provided to the patient and trained caregiver by hospital clinicians at every clinic visit. Refresher training may include, but may not be limited to:

- Switching Freedom Drivers
- Care and use of the Freedom Driver
- Warnings and Precautions
- Power Management

For their safety, patients must have all the necessary equipment when they leave the Hospital.

6.1 Equipment the Patient Needs to Leave the Hospital

The patient must go home with a primary *and* a backup Freedom Driver that have been checked out per the Test Protocol in **Appendix 2**. The Test Protocol must be conducted at the hospital by a trained hospital technical support team before connecting the patient to the Driver.

The backup Freedom Driver needs to be available at all times with the patient in case the primary Freedom Driver is dropped, exposed to liquid/debris, subjected to rough handling or has a Fault Alarm that cannot be resolved (as instructed in **Section 10.3**).

All Freedom Driver accessories will be provided to the patient before discharge from the hospital.

The following equipment is needed for Hospital discharge:

- One primary Driver with attached Power Adaptor
- One backup Driver with attached Power Adaptor
- One additional Power Adaptor
- Four to Six Onboard Batteries
- Two Home AC Power Supplies
- One Car Charger
- Optional Battery Charger
- Two Handle Straps (one attached to each Driver)
- One Dummy Battery (inserted into the backup Freedom Driver)

- One Filter Pack including screwdriver
- One Patient Tool Kit: Wire Ties, Wire Cutter Tool, Hook and Loop cable ties
- One Freedom Shoulder Bag, one Backpack and one Accessory Bag
- Quick Guide and Emergency Card

6.2 Equipment the Patient Needs to Leave the House

When the patient is home, it is recommended to keep the backup Freedom Driver and all accessories organized in the Backpack or Shoulder Bag and the Accessories Bag.

When the patient leaves the house, they must **always** take with them:

- The backup Freedom Driver with attached Power Adaptor and inserted Dummy Battery
- At least two additional fully charged Onboard Batteries,
- Home AC Power Supply
- Car Charger
- Patient Tool Kit
- Filter Pack
- Quick Guide and Emergency Card

CAUTION

A backup Freedom Driver must always be available in the event that the primary Freedom Driver is dropped, exposed to liquid/debris, subjected to rough handling or has a Permanent Fault Alarm.

If the Freedom Driver is dropped, exposed to liquid/debris or subjected to rough handling, it may sustain damage that will not allow it to provide life-sustaining functions as designed.

If the primary Freedom Driver is dropped, exposed to liquid/debris or subjected to rough handling, the patient MUST exchange it for the backup Freedom Driver.

If a Fault Alarm cannot be resolved within three to four minutes, it may become a Permanent Fault Alarm that requires switching to the backup Freedom Driver.

After an unscheduled Driver switch, the patient MUST go to the Hospital to return the faulted Driver, obtain a new backup Driver and get any necessary medical evaluations as determined by the clinician

6.3 Power Management

It is recommended that the Freedom Driver have at least **two** sources of power:

- Power from both Onboard Batteries, or
- Power from both Onboard Batteries and connection to an External Power source.

The Freedom Driver **requires** at least one source of power at all times:

- Power from at least one Onboard Battery (Battery Alarm will occur when one battery is missing), or
- Power from an external power source (Fault Alarm will occur if no Onboard Batteries are inserted)

Battery power can be used when the patient is ambulatory. The Onboard Batteries are a chargeable source of power that allows the Driver to operate without being connected to External Power. The use of Battery Power is described in **Section 6.5**.

CAUTION

The Onboard Batteries can only be used for a limited time when the Freedom Driver is not connected to External Power.

When the Driver is not connected to external power, two fully charged Onboard Batteries provide approximately two hours of support before a Low Battery Alarm occurs. Actual support time may vary based on Driver Beat Rate setting.

External Power provides power to operate the Freedom Driver and simultaneously charges the Onboard Batteries. External power sources include electrical power from a wall power outlet or a 12V vehicle power outlet. The use of External Power is described in **Section 6.4** below.

CAUTION

If Onboard Batteries are depleted of power or removed and the Driver is connected to external power, then the Fault Alarm will be activated (See Section 10.3 to address Fault Alarms).

One AC Power Supply and the Car Charger should be with the patient at all times. The other AC Power Supply should be plugged into the wall

outlet by the patient's bed and be transported when moving to a new sleeping place.

6.4 Using External Power through the Power Adaptor

Whenever possible (while reading, watching TV, sleeping, going on a vehicle trip, etc.), patients should use external power.

External Power provides power to operate the Freedom Driver and simultaneously charges the Onboard Batteries.

External power is provided to the Freedom Driver when the Power Adaptor is connected to wall power via the AC Power Supply or connected to a 12V vehicle power outlet via the Car Charger.

While connected to External Power, always keep two Onboard Batteries in the Freedom Driver in order to fully charge them.

CAUTION

The Freedom Driver should be plugged into grounded electrical wall power outlets with the Hospital AC Power Supply. The Home AC Power Supply can be used in any wall power outlet.

To avoid accidentally switching off the external electrical power to your Driver, DO NOT use any electrical outlets that are controlled by wall switches. If the external power is accidentally switched off, the Driver will stop operating after Battery Power is depleted.

CAUTION

Before going to sleep, the Driver MUST be plugged into External Power using the AC Power Supply. Verify that all connections are secure and the indicator lights on the Power Supply and Power Adaptor are illuminated solid green. If the external power is not connected, the Driver will stop operating after Battery Power is depleted.

Electrical power is transmitted from the Power Adaptor to the Driver by the Power Adaptor plug.

- The Power Adaptor is the device through which all External Power is routed to the Freedom Driver.

The Power Adaptor needs to be connected to an external power source in order to supply power to the Freedom Driver.

The Power Adaptor has a light on the upper right corner that illuminates solid green when it is connected to an External Power source:

- The Power Adaptor needs to be attached to the Freedom Driver,
- The green connector from either the AC Power Supply or Car Charger needs to be connected to the Power Adaptor, and
- The AC Power Supply or Car Charger must be plugged in to an External Power source (wall power outlet or 12V vehicle power outlet). The Car Charger toggle switch must be in the “on” position and the green light must be illuminated.

If the Power Adaptor light fails to illuminate or is blinking, recheck all connections and make sure that you are connected to a functional wall power outlet or vehicle 12V power outlet.

- If the light still fails to light up or is blinking, switch to the additional Power Adaptor provided.

6.4.1 Replacing the Power Adaptor in the Freedom Driver

The primary Freedom Driver and backup Freedom Driver come with the Power Adaptor attached to the Driver.

Make sure that the Power Adaptor **always** remains connected to the Freedom Driver to ensure quick access to External Power.

Should the Power Adaptor’s green Indicator Light on either the primary or backup Driver fail to light up or is blinking when power is properly connected, the patient should replace the Power Adaptor, following these steps:

- Unplug the Power Adaptor plug from the outlet on the left side of the Driver by pressing the button and pulling the cord **(Figure 6-1).**

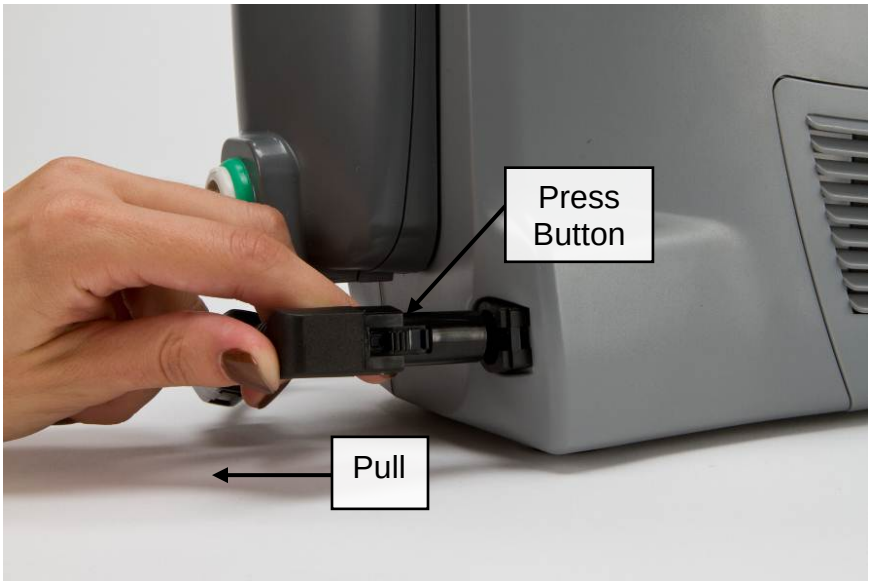


Figure 6-1 – Unplugging the Power Adaptor from the Freedom Driver

- Lift and remove the Power Adaptor from the connecting rails on the left side of the Driver **(Figure 6-2)**

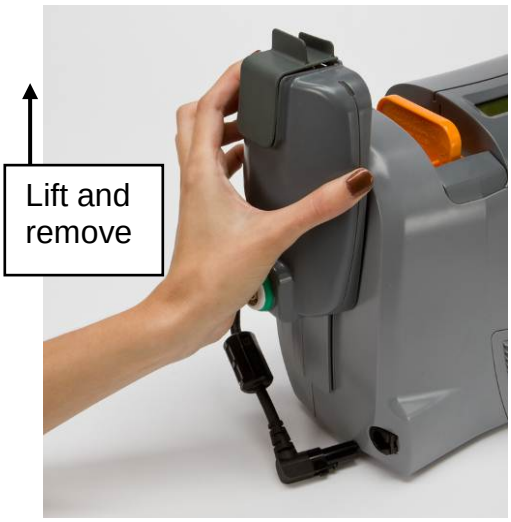


Figure 6-2 – Removing the Power Adaptor from the Freedom Driver

- Slide the additional Power Adaptor onto the connecting rails on the left side of the Driver
- Plug the Power Adaptor cord into the outlet on the left side of the Driver

6.4.2 Using Wall Power through the Power Adaptor

The Freedom Driver should be connected to a wall power outlet via the AC Power Supply whenever possible to ensure that the Onboard Batteries remain charged.

To connect the Freedom Driver to wall power, follow these steps:

- Plug the green connector from the AC Power Supply into the Power Adaptor green receptacle.

NOTE: To insert the green connector into the Power Adaptor, line up the raised surface on the green connector with the raised surface in the Power Adaptor green receptacle and push in the connector **(Figure 6-3)**.

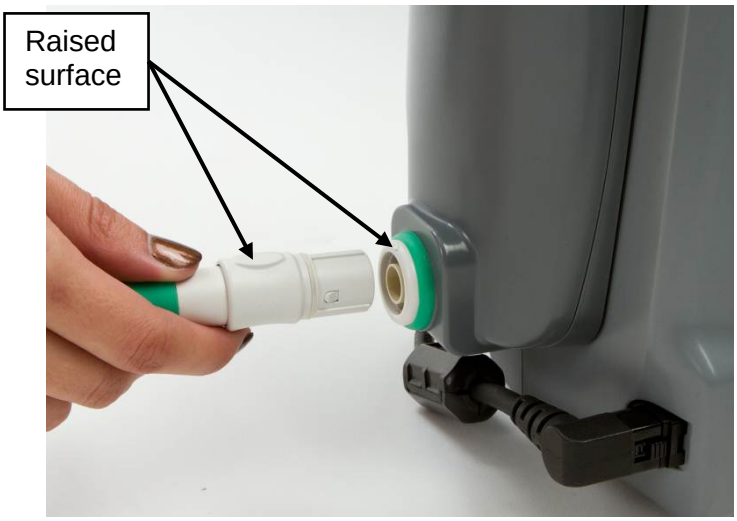


Figure 6-3 – Plugging the Green Connector into the Green Power Adaptor Receptacle

- Plug the other end of the AC Power Supply cord to a power outlet
- Confirm that the light on the Power Adaptor is illuminated solid green to ensure that a proper connection to External Power has been made.

The proper connection of the Freedom Driver to a wall power outlet is shown in **(Figure 6-4).**

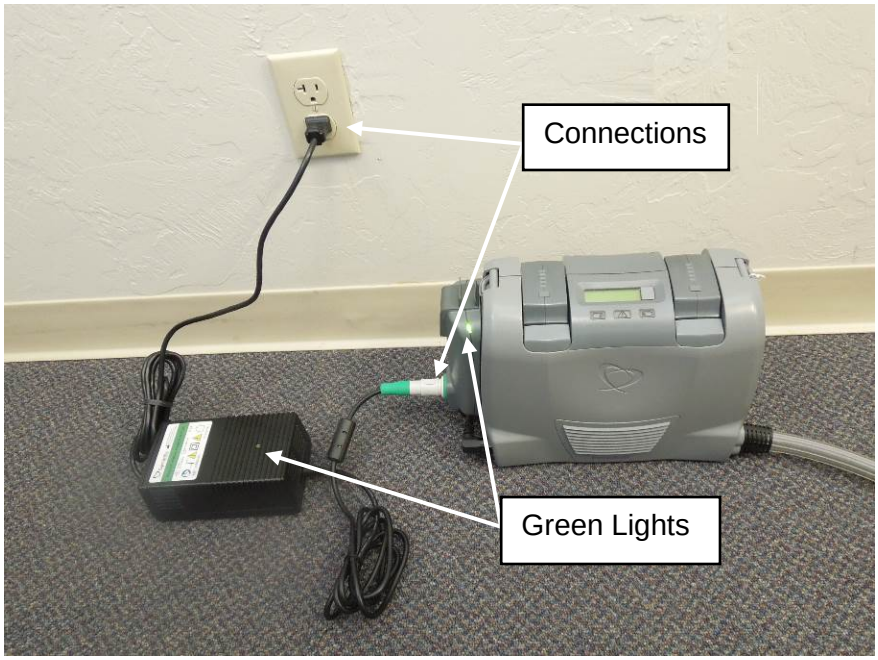


Figure 6-4 – Connection to External Power via the AC Power Supply

If the green light on the Power Adaptor is off, then the Freedom Driver is not properly connected to an External Power source and is using Onboard Battery power.

If the green light fails to light up on the Power Adaptor:

- Recheck all connections
- Make sure that you are connected to a functional wall power outlet
- Confirm that the green light on the AC Power Supply is illuminated.

If the green light on the Power Adaptor still fails to light up, switch to the additional Power Adaptor provided.

If the green light on the Power Adaptor is blinking, the Freedom Driver is receiving External Power, however the Power Adaptor should be replaced with the additional Power Adaptor provided.

6.4.3 Using Vehicle Power through the Power Adaptor

The Freedom Driver should be connected to a 12V power outlet via the Power Adaptor on vehicle trips to ensure that the Onboard Batteries remain charged. The External Power from a 12V vehicle power outlet can also be used in the event of loss of electricity in the patient's home.

	**CAUTION** **Do not connect the Car Charger to the Battery Charger.**

	**CAUTION** **The plug on the Car Charger and the tip of the plug may become hot while in use.**

Patients should be instructed to call their Hospital Contact Person in the event of any power outage lasting more than 30 minutes or sooner based on the remaining battery power.

Always make sure you turn the Car Charger off when leaving the vehicle, as it may drain the battery of your vehicle.

Patients should read their vehicle manual to determine the vehicle battery and outlet restrictions.

- It is recommended to check proper function of a 12V vehicle power outlet and carry extra fuses in the vehicle.

- This is a finite source of power and should not be relied upon for extended use.

To connect the Freedom Driver to a 12V vehicle power outlet, follow these steps:

- Start the vehicle engine.
- Plug the green connector from the Car Charger into the Power Adaptor green receptacle. Make sure the “on” switch on the Car Charger is turned on and is illuminated solid green.

NOTE: To insert the green connector into the Power Adaptor, line up the raised surface on the green connector with the raised surface in the green Power Adaptor receptacle and push in the connector.

- Plug the other end of the Car Charger into the 12V vehicle power outlet and flip the “on/off” switch on the Car Charger to the “on” position. Confirm that the green light on the Car Charger is illuminated.
- Confirm that the light on the Power Adaptor is illuminated solid green to ensure that a proper connection to External Power has been made.

If the green light on the Power Adaptor is off, then the Freedom Driver is not properly connected to an External Power source and is using Onboard Battery power.

If the green light fails to light up or is blinking on the Power Adaptor:

- Recheck all connections
- Make sure that you are connected to a functional vehicle 12V power outlet.
- Confirm that the green light on the Car Charger is illuminated indicating that the Car Charger is turned “on”.

If the light still fails to light up or is blinking, switch to the additional Power Adaptor provided.

6.4.4 Charging Onboard Batteries through the Power Adaptor

Onboard Batteries charge while inserted into a Freedom Driver connected to an External Power source.

To charge Onboard Batteries, follow these steps:

- Ensure that the Onboard Batteries are inserted into the Freedom Driver.
- Connect to an External Power source via wall power or a 12V vehicle power outlet as described in **Section 6.4.2** (Using Wall

Power through the Power Adaptor) and **Section 6.4.3** (Using Vehicle Power through the Power Adaptor).

- Confirm that the Onboard Battery is charging by pressing the Battery Charge Button on the top of the Onboard Battery. The Battery Fuel Gauge will illuminate and the last green light illuminated should blink within 15 seconds after the Driver has been connected to External Power.

NOTE: The Freedom Driver charges the battery with the lowest charge first. Only the charging battery will show a blinking green light when the Battery Fuel Gauge is illuminated. Batteries at the same charge level are charged alternately until both are fully charged.

If the last green light illuminated on the Onboard Battery does not blink and the Battery Fuel Gauge illuminates five green lights, then your Onboard Battery is fully charged.

If, while charging the Onboard Batteries, there is no blinking green light on either Onboard Battery and neither Onboard Battery is fully charged:

- Make sure that the Onboard Batteries are properly inserted in the Freedom Driver
- Make sure the Freedom Driver is properly connected to an External Power source.

Charging time when the Onboard Batteries are in the Freedom Driver depends on the Driver operating conditions.

- The Onboard Batteries may take up to six hours to fully charge.

6.4.5 Charging Spare Onboard Batteries through the Power Adaptor

It is recommended that only one spare Onboard Battery be charged in the Freedom Driver at a time to avoid a Battery Alarm from occurring.

To charge additional spare Onboard Batteries and to ensure continuous power to the Freedom Driver, follow these steps:

- Connect to an External Power source via wall power or a 12V vehicle power outlet as described in **Section 6.4.2** (Using Wall Power through the Power Adaptor) and **Section 6.4.3** (Using Vehicle Power through the Power Adaptor).
- Remove one Onboard Battery by depressing the Battery Release Button in front of the Onboard Battery.
- Insert spare Onboard Battery into empty Battery Well.
- Confirm that the Onboard Battery is charging by pressing the Battery Charge Button on top of the Onboard Battery. The

Battery Fuel Gauge will illuminate and the last green light illuminated should blink within 15 seconds after the Driver has been connected to External Power.

NOTE: The Freedom Driver charges the battery with the lowest charge first. Only the charging battery will show a blinking green light when the Battery Fuel Gauge is illuminated. Batteries at the same charge level are charged alternately until both are fully charged.

If the last green light illuminated on the Onboard Battery does not blink and the Battery Fuel Gauge illuminates five green lights then your Onboard Battery is fully charged.

If the last green light illuminated on the Onboard Battery does not blink and your Onboard Battery is not fully charged:

- Make sure that the Onboard Battery is properly inserted in the Freedom Driver
- Make sure you are properly connected to an External Power source.

Remain connected to External Power until the spare Onboard Battery is fully charged.

It is recommended that the patient periodically rotates all of the Onboard Batteries. A serial number is located on each Onboard Battery to help keep track of which Onboard Batteries have been used.

6.4.6 Removal of External Power

Before removing External Power from the Freedom Driver, make sure that two charged Onboard Batteries are correctly inserted in the Driver.

- Press the Battery Charge Button on the top of each Onboard Battery to verify that the Onboard Batteries are charged.
- If the last green light illuminated on the Onboard Battery does not blink and the Battery Fuel Gauge illuminates five green lights, then your Onboard Battery is fully charged.
- Make sure that at least four lights are illuminated on each Onboard Battery before disconnecting from External Power.
- Disconnect the green connector from the Power Adaptor and the AC Power Supply cord from the wall power outlet or the Car Charger from the 12V vehicle power outlet, and place them in the Accessory Bag.

NOTE: To remove the green connector, pull away the white release ring and remove the connector **(Figure 6-5)**. Do not rotate the white release ring.

- The Driver will automatically switch to Onboard Battery power.

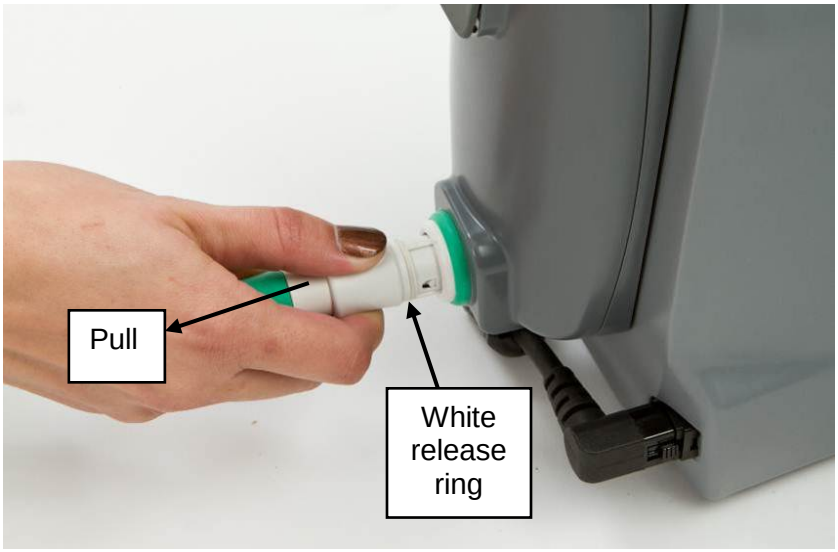


Figure 6-5 – Removing the Green Connector from the Green Power Adaptor Receptacle

6.5 Using Onboard Battery Power

Battery power can be used when the patient is ambulatory. The Onboard Batteries are a chargeable source of power that allows the patient to move freely in or out of the house.

Whenever possible, connect the Freedom Driver to an External Power source to keep the Onboard Batteries fully charged.

The patient must always carry at least two additional fully charged Onboard Batteries.

	CAUTION **The Onboard Batteries can only be used for a limited time when the Freedom Driver is not connected to External Power.** **When the Driver is not connected to external power, two fully charged Onboard Batteries provide approximately two hours of support before a Low Battery Alarm occurs. Actual support time may vary according to Driver Beat Rate setting.** **When the battery is 35% depleted, a Low Battery Alarm will occur. When the battery is 30% depleted, a Fault Alarm will occur which will continue until new batteries are inserted or until wall power is connected to the Driver. Reference Section 10 for addressing Low Battery and Fault Alarms.**

When the Driver is not connected to external power, two fully charged Onboard Batteries provide approximately two hours of support before a

Low Battery Alarm occurs. Actual support time may vary according to Driver Beat Rate setting.

The Driver will discharge both Onboard Batteries in an alternating sequence, automatically switching from Battery 1 to Battery 2 when not connected to external power.

When connected to external power, the Driver will first charge the Onboard Battery with the lowest charge. When both Batteries reach the same charge, the Driver will automatically alternate charging between Battery 1 and Battery 2.

Plug in the Freedom Driver to an External Power source when replacing an Onboard Battery.

- If connection to External Power is not available, make sure to **promptly** insert another charged Onboard Battery into the Freedom Driver.

The Driver is able to run with a single Onboard Battery, but this is not recommended, as a Battery Alarm will occur.

A Battery Alarm will occur if:

- One or both of the Onboard Batteries have less than 35% remaining charge (only two green lights display on Battery Fuel Gauge), or
- One of the Onboard Batteries is incorrectly installed, or
- One of the installed Onboard Batteries is removed.

There is no way to mute the Battery Alarm. Refer to **Section 10, *Visual and Audible Alarms*,** for instructions on how to resolve the Battery Alarm.

CAUTION

When there is a Battery Alarm, it is extremely important to connect to External Power from a wall power outlet or a 12V vehicle power outlet to charge the Onboard Batteries or replace the depleted Onboard Batteries, one at a time, with fully charged Onboard Batteries.

When the Driver is not connected to external power, two fully charged Onboard Batteries provide approximately two hours of support before a Low Battery Alarm occurs. Actual support time may vary according to Driver Beat Rate setting.

NOTE: Patients should notify their Hospital Contact Persons when their battery expiration date (if printed on label) is nearing. Newer versions of batteries do not have an expiration date printed on the label. However, they are tracked by the manufacturer and will be replaced before the expiration dates.

6.5.1 Checking Onboard Battery Charge

Determine the charge status of each Onboard Battery before it is installed into a Driver.

When the Battery Charge Button is pressed, the Battery Fuel Gauge **(Figure 6-6)** will show green lights on top of the Onboard Battery that indicate the amount of charge remaining in the battery. When running on Onboard Battery power, the remaining Battery Charge should be carefully monitored.

- Each light represents approximately 20% charge, with all five lights indicating approximately 81% to 100% charge.
- When the Driver is not connected to external power, two fully charged Onboard Batteries provide approximately 2 hours of support before a Low Battery Alarm occurs.

Figure 6-6 – Battery Fuel Gauge

6.5.2 Inserting the Onboard Batteries

The Onboard Batteries are designed to be inserted correctly into the Driver in only one direction. The Onboard Batteries must be inserted correctly into the Battery Well, as shown in **Figure 6-7,** in order to function properly and provide power to the Driver.

- Insert the Onboard Battery in the Onboard Battery Well, such that the Battery Charge Button and the Battery Release Button on the Freedom Driver are next to each other **(Figure 6-7)**.
- Push down on the Onboard Battery until the battery is locked in place.
- Confirm that the Onboard Battery is locked in place by trying to remove it without pressing the Battery Release Button. If

properly inserted, the Onboard Battery will stay in the Battery Well.

- If a Battery Alarm occurs, then there is an Onboard Battery related problem such as a low battery charge, removed battery, or inadequate connection of the battery.
- There is no way to mute the Battery Alarm. Refer to **Section 10, *Visual and Audible Alarms***, for instructions on how to resolve the Battery Alarm.

Figure 6-7 Correct Onboard Battery Insertion into Battery Well

6.5.3 Removing Onboard Batteries

The Freedom Driver has a mechanism that locks one Onboard Battery into the Driver at all times. This mechanism prevents the user from accidentally removing both Onboard Batteries at the same time.

- Plug the Driver into an External Power source (wall power outlet or 12V vehicle power outlet)
- Push down on the Battery Release Button in front of the Onboard Battery. This will release the Onboard Battery from the locking mechanism as long as another Onboard Battery is installed into the Driver.
- Grasp the unlocked Onboard Battery and lift it out of the Battery Well.

- When one Onboard Battery is removed, the internal mechanism will lock the other Onboard Battery in place, making it impossible for two Onboard Batteries to be removed at the same time.

6.6 Using the Battery Charger

The Freedom Battery Charger (Part Number 295054-001) is an accessory to the Freedom Driver System. The Battery Charger has four battery bays (**Figure 6-8**) that accommodate Freedom Onboard Batteries.

It is intended to be used as an alternative source of battery charging for the Onboard Batteries for the Freedom Driver System.

When connected to wall power using an AC Power Supply, the Battery Charger charges the Onboard Batteries. The back of the Battery Charger has a green power receptacle to connect the AC Power Supply (**Figure 6-9**). Do not connect the Car Charger to the Battery Charger.

The Freedom Battery Charger does not discharge the Freedom Onboard Batteries.

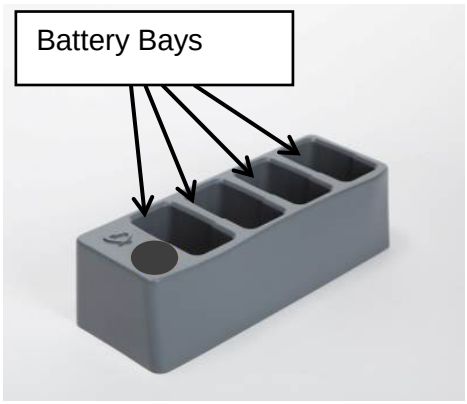


Figure 6-8 - Battery Charger and Bays

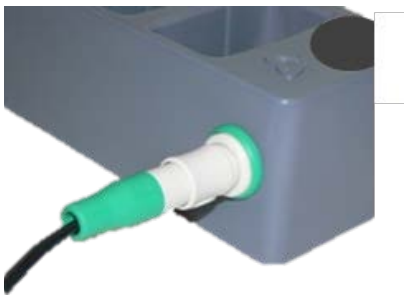


Figure 6-9 - Connect AC Power Supply and Battery Charger

6.6.1 To Charge Onboard Batteries

- Connect the AC Power Supply to the Battery Charger (**Figure 6-9**).
- Connect the AC Power Supply wall cord to a wall outlet. Check to see that the green light on the AC Power Supply is illuminated.
- Insert up to four Onboard Batteries into the Battery Charger bays (**Figure 6-8**). The bays are narrower in the front to align with the tapered front of the batteries.
- Confirm that the Onboard Batteries are charging by depressing the Battery Charge Button on the top of the battery. A charging battery will have a blinking light on the Battery Fuel Gauge.
- If you depress the Battery Charge Button and 5 lights illuminate with no blinking, the battery is 100% charged.
- To remove, lift the battery out of the bay. Always check the battery charge prior to inserting into the Freedom Driver.

6.6.2 If there is no blinking green light on an Onboard Battery and it is not already fully charged:

- Make sure that the Onboard Battery is properly inserted in the Battery Charger.
- Make sure the Battery Charger is properly connected to wall power and the green light is illuminated on the AC Power Supply.
- Make sure the wall outlet used is not controlled through a wall switch that is in the off position.
- If the Battery Charger is not functioning, patients should contact the implant center so they can coordinate a return with SynCardia Systems, LLC.
- If the Battery Charger is not functioning, the patient should charge the Onboard Batteries in the Driver as described in **Section 6.4.4.**

6.6.3 Battery Charger Warnings

- Only Onboard Batteries shall be placed into the battery bays. No other objects shall be placed into any battery bay.
- Do not use the Freedom Car Charger with the Battery Charger.
- It is important to keep the battery bays free of debris and liquid.
- If any objects or liquid get into the Battery Charger, the patient must call their Hospital Contact Person.

6.7 User Interface

The user interface consists of:

- One Driver Display (LCD screen),
- Two yellow lights on top of the Freedom Driver,
- One red light on top of the Freedom Driver,
- Battery Fuel Gauge on the top of each Onboard Battery,
- A Green light on the Power Adaptor, and
- Green Lights on the AC Power Supply and Car Charger

6.7.1 LCD Screen

When the button on the side of the Driver Display is pushed, the LCD screen will display Beats per Minute (BPM), left ventricle Fill Volume (FV) and Cardiac Output (CO) **(Figure 6-10)**.

The LCD screen (Driver Display) is the sole user interface when setting the Driver in a clinical environment. The SynCardia-trained operator will adjust the Beat Rate (BPM) of the Driver to accommodate the patient's TAH-t requirements.

It is important for the patient to check the Freedom Driver several times every day, to make sure that the values displayed on the screen are correct as recommended by the Hospital Contact Person.

If the LCD Screen ever fails to light up when the button is pushed, the patient should be switched to the backup Freedom Driver, and the primary Freedom Driver should be returned to SynCardia for service.

Figure 6-10 – Driver LCD Screen

For more information on setting the Driver, see **Section 7, *Preparing the Freedom Driver for Patient Use***.

6.7.2 Lights and Sounds

The yellow and red Indicator Lights for the Driver will not illuminate unless an alarm condition occurs. Each alarm includes a visible alarm (colored LED) and an audible alarm (sound).

There are three different kinds of Alarms:

- **Battery Alarm:** an intermittent tone audible alarm and an illuminated flashing yellow light,
- **Temperature Alarm:** a louder intermittent tone audible alarm and an illuminated flashing red light, and
- **Fault Alarm:** a loud continuous tone audible alarm and an Illuminated solid red light.

For detailed information regarding alarms, see **Section 10, *Visual and Audible Alarms*.**

6.7.3 LED Battery Fuel Gauge

The Indicator Lights on top of the Onboard Battery will be dark unless the Battery Charge Button is pressed.

When the Battery Charge Button is pressed, the Battery Fuel Gauge (**Figure 6-6**) will illuminate green lights on top of the Onboard Battery that indicate the amount of charge remaining in the battery.

- Each light represents approximately 20% charge, with all five lights indicating approximately 81% to 100% charge.
- When connected to External Power, the last green light illuminated on the Battery Fuel Gauge should blink within 15 seconds after the Driver has been connected to External Power.
- If the last green light illuminated on the Onboard Battery does not blink and the Battery Fuel Gauge illuminates five green lights, then the Onboard Battery is fully charged.
- When the Driver is not connected to external power, two fully charged Onboard Batteries provide approximately 2 hours of support before a Low Battery Alarm occurs.

6.7.4 Power Indicator Lights

The Freedom Power Adaptor has a solid green Indicator Light in the upper right corner which will illuminate when it is receiving power from either the AC Power Supply or the Car Charger and when the Power Adaptor is connected to the Driver.

- The solid green light on the Power Adaptor confirms proper connection of the Freedom Driver to External Power.

Green Indicator Lights on the AC Power Supply and Car Charger illuminate to indicate proper function of the equipment when connected to an electrical power source.

7 Preparing the Freedom Driver for Patient Use

7.1 General Shipping Information

The Freedom Driver System comes in a specialized shipping case (Pelican Case) that contains all the components for switching a TAH-t patient to the Freedom Driver System.

The trained Hospital staff will be responsible for unpacking and testing the Drivers and preparing them for patient use.

The Freedom Drivers and all accessories must be returned to SynCardia Systems, LLC in the Pelican Case.

The primary and backup Freedom Drivers are shipped with a Dummy Battery inserted into one of the Battery Wells.

Onboard Batteries are shipped with 40% charge.

7.2 Individual Shipping Units

The Pelican Case of the Freedom Driver System contains:

- One primary Driver with attached Power Adaptor in pink shipping bag
- One backup Driver with attached Power Adaptor in pink shipping bag
- One additional Power Adaptor
- Four to Six Onboard Batteries
- One Hospital AC Power Supply
- Two Home AC Power Supplies
- One Car Charger
- One Battery Charger
- Two Dummy Batteries (inserted into the each Freedom Driver)
- Two Handle Straps (one attached to each Driver)
- One Filter Pack including Screwdriver
- One Patient Tool Kit
- One Clinician Tool Kit
- One Connector Kit

In addition, the Hospital will receive a box containing an additional Hospital AC Power Supply, three bags (Shoulder Bag, Backpack, and Accessory Bag) that the patient will use to carry the Freedom Driver System. The trained Hospital staff will explain the use of the Freedom Bags and the use of the accessories to the patient.

The Hospital will also receive one Permanent Center Tool Kit.

7.3 Packing the Freedom Driver into the Freedom Bags

The trained Hospital staff is responsible for assuring that all the components are in the Backpack, Shoulder Bag and Accessory Bag. Consult with the patient to see which of the carrying options is preferred. Training will include how to switch from one carrying option to the other.

The Backpack and the Shoulder Bag will each contain one Freedom Driver. The preferred carrying method (Backpack or Shoulder Bag) will contain the primary Driver with two Onboard Batteries. The remaining bag will contain the backup Driver with one Dummy Battery installed into one of the Battery Wells.

Prior to patient discharge from the Hospital, the Handle Straps should be attached to the primary and backup Freedom Drivers.

Refer to the list below to check that all the components are in the Accessory Bag prior to discharge of the patient from the Hospital:

- At least two fully charged Onboard Batteries
- The AC Power Supply
- The Car Charger
- One Filter Pack including Screwdriver
- An additional Power Adaptor
- One Patient Tool Kit

7.4 Checking and Preparing the Driver

The primary and backup Freedom Drivers are shipped with fixed settings and are ready to run as soon as power is applied. The default Beat Rate is set at 125 BPM and, if necessary, must be adjusted as needed for the patient.

CAUTION

Both primary and backup Freedom Drivers must be tested at the Hospital prior to use, following the checklist for the Freedom Driver Test Protocol (Appendix 2).

If any of the Drivers do not pass the Protocol, do not connect the patient to the Freedom Driver System and contact SynCardia immediately. Drivers that do not pass the Protocol may not be able to provide life-sustaining functions as designed.

The completed checklist must be sent by FAX to SynCardia Systems, LLC at the fax number: 520-903-1782, also listed on the form.

In order to perform the Freedom Driver System Test Protocol (**Appendix 2**), the Driver must be connected to a 70cc TAH-t and to a Patient Simulator (also referred to as Mock Tank) set to normotensive settings, as specified in **Table 7-1**.

Table 7-1 - Normotensive Settings - Patient Simulator

Patient Simulator Normotensive Settings	
RAP	12 (± 5 mmHg)
AoP	95 (± 5 mmHg)
PAP	27 (± 5 mmHg)
LAP	12 (± 5 mmHg)

When connected to a 70cc TAH-t and to a Patient Simulator set to normotensive settings, the primary and backup Freedom Drivers should read on the Driver Display:

- Cardiac Output (CO) of 4.9 l/m to 9.7 l/m
- Beat Rate (BPM) of 125 ± 5 bpm

7.5 Initial Installation

For both the primary and backup Freedom Drivers perform the following prior to connecting to a patient:

- Remove the Freedom Driver from the Pelican Case
- Remove and discard the pink shipping bag
- Insert two Onboard Batteries into the Driver
- Connect the AC Power Supply to the Power Adaptor on the Driver
- Attach the Freedom Drivelines to the Patient Simulator
- Complete the Freedom Driver Test Protocol (**Appendix 2**)
- Fully charge the Onboard Batteries

After setup, the primary Driver should have two fully charged Onboard Batteries inserted into the Battery Wells before connecting it to a patient.

The additional Onboard Batteries should also be fully charged.

After setup, the backup Driver should be provided to the patient powered off and with one Dummy Battery inserted into a Battery Well.

7.6 Starting the Driver

To turn on the primary and backup Freedom Drivers and charge the Onboard Batteries perform the following:

- Remove the Driveline caps (**Figure 7-1)** from the ends of the Drivelines. DO NOT DISCARD THE DRIVELINE CAPS.
- Insert one Onboard Battery into the empty Battery Well
- Remove the Dummy Battery by pressing the Battery Release Button
- Insert another Onboard Battery into the empty Battery Well
- Verify that the Freedom Driver starts (you should hear the working motor inside of the Driver and feel air coming out of the Drivelines)
- Connect the Freedom Driver to a Patient Simulator to avoid alarms
- Connect the Freedom Driver into a wall power outlet using the AC Power Supply cord
- Fully charge the Onboard Batteries (refer to **Section 6.4.4** for instructions)

Figure 7-1 – Driveline Caps

7.7 Adjusting the Beat Rate of the Freedom Driver

The Beat Rate of the Driver is pre-set at 125 BPM when shipped to the Hospital. A setting dial on the back of the Driver is used to adjust the Beat Rate as necessary. The setting dial can be accessed by the clinician only by removing a small cover on the back of the Freedom Driver.

The tools to remove the protective cover and adjust the Beat Rate are sent to the Hospital in the Pelican Case as part of the Clinician Tool Kit and are to only be used by trained medical persons under the order of a

physician. These security type tools are intended to prevent tampering with the Freedom Driver Beat Rate by untrained persons.

	**CAUTION** **Do not give the Clinician Tool Kit to the patient. The Clinician Tool Kit must remain in the Hospital and must only be used by trained medical persons under the order of a physician.**

To adjust the beat rate on the Freedom Driver, follow these steps:

- Unscrew the setting dial cover on the back of the Driver by using the L Torx Wrench
- Use the provided Slotted Screwdriver to vary the Beat Rate to the appropriate setting **(Figure 7-2)**.
    - Clockwise rotation of the dial will increase Beat Rate
    - Counterclockwise rotation of the dial will decrease Beat Rate
- Press the Driver Display Button to monitor the Driver Beat Rate as it is adjusted.

Figure 7-2 – Beat Rate Setting Dial on the Back of the Freedom Driver

The Beat Rate of the Driver will typically be set to around 120-135 beats per minute. The rate may be varied to meet the need of the patient.

The Beat Rate of the backup Freedom Driver should be set to match the Beat Rate of the primary Freedom Driver.

	**CAUTION** **A Tamper Evident Label must be attached over the setting dial cover after adjustment of the Freedom Driver Beat Rate.**

Contact SynCardia Systems, LLC to order extra adjustment tools.

7.8 Switching to the Freedom Driver

If the Freedom Driver Beat Rate adjustment has been made in preparation to switch the patient to the Freedom Driver System, the Freedom Driver can be taken to the patient room to make the switch according to the instructions provided in this manual.

7.9 Moving the Freedom Driver

- Disconnect the Drivelines from the Patient Simulator and remove the AC Power Supply cord from the wall.
- Turn off the Freedom Driver while moving it to the patient's room: remove one Onboard Battery, replace it with the Dummy Battery and remove the second Onboard Battery.
- The Freedom Driver will terminate operation when it is disconnected from the wall outlet and both Onboard Batteries are removed.
- Put the Driveline caps on the ends of the Drivelines
- To restart the Freedom Driver, install both charged Onboard Batteries and connect the Driver to external power prior to switching the patient to the Freedom Driver.
- Patients should only receive one orange Dummy Battery (inserted into the backup Freedom Driver) upon Hospital discharge in order to ensure that they never insert two Dummy Batteries into the Driver at the same time.
- The second Dummy Battery must be kept by the Hospital so that when the Patient returns the Freedom Driver system it can be turned off after TAH-t explant and it can be shipped back to SynCardia with a Dummy Battery in each Driver.
- Follow the instructions in **Section 11**, ***Switch from the Primary Freedom Driver to the Backup Freedom Driver***, of this manual for connecting a patient to the Freedom Driver System.

7.10 Preparing and Storing the Backup Freedom Driver

To prepare the backup Driver, follow these steps:

- Set the Beat Rate of the backup Driver to the same rate as the primary Driver supporting the patient.

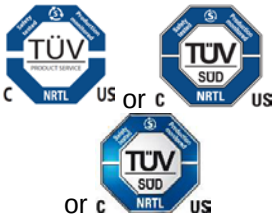
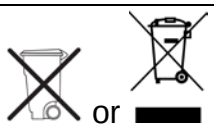
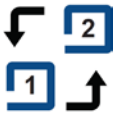
- After setting the Beat Rate and assuring that both Onboard Batteries are fully charged, unplug the Driver from external power and remove one Onboard Battery, replace it with the Dummy Battery, and then remove the second Onboard Battery to terminate operation of the Freedom Driver
- Make sure that the Driveline caps are attached to the ends of the Drivelines
- Place the items that will be going home with the patient in the Freedom bags.

Take the backup Driver, with the installed Dummy Battery, together with the loaded Accessory Bag, to the patient's room when switching a patient to the Freedom Driver System.

8 List of Symbols

Refer to **Table 8-1** for a description of the symbols used in Visual Alarms and in labels of the Freedom Driver System.

Table 8-1 –Symbols Used in the Freedom Driver System

Symbol	Description	Symbol	Description
	Temperature Alarm or Fault Alarm		Refer to instruction manual/ booklet
	Battery Alarm	**IP30**	Protected against objects ≥ 2.5mm; spraying water ; refer to **Table 18-7** and **Section 18.11** for IP rating descriptions
	Temperature Limitation		Safety Testing
	General Warning		Date of Manufacture
	Catalog Number		Manufacturer
	Batch Code		Direct Current/ External Power Status
	Serial Number		Alternating Current
	Use By Date		Do Not Dispose as Household Waste
	Do Not Incinerate		Input
	Keep Dry		Output
	Do NOT Drop		Exchange if Dropped, Subjected to Rough Handling or Exposed to Liquid/Debris
	Atmospheric Pressure Limitation		Humidity Limitation

Symbol	Description	Symbol	Description
	Protective Earth (ground)		Fragile
	Type BF Applied Part		Electrical Shock Hazard
	Do not use with Car Charger (Battery Charger only)		Not to be used in residential areas or any other area outside of a hospital environment
	Double Insulated		For use in any area including residential areas

Symbol	Description
4ICP6/65/96	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=Cobalt) P: Cell shape (P= Prismatic) 6: Maximum thickness of cell (in mm) 65: Maximum width of cell (in mm) 96: Maximum height of cell (in mm)

9 Freedom Driver Operating Cautions

9.1 Use of SynCardia-Approved Components Only

The Freedom Driver System and the TAH-t have been developed, tested and approved as a System. Use of the Freedom Driver is authorized only in conjunction with related equipment described in this document.

9.2 Tamper Evident Seal

Do not open the back panel of the Driver. If the Driver needs service, contact SynCardia Customer Service +1 (866) 771-9437 or +1 (520) 545-1234.

9.3 Observe Alarms

Alarms cannot be muted and must be immediately addressed.

For information on types of alarms and how to resolve each alarm, see **Section 10, *Visual and Audible Alarms*.**

9.4 Use of Backup Driver

A Freedom Driver with an attached Power Adaptor must be available as a backup to be used in the event the primary Freedom Driver is dropped, exposed to liquid/debris, subjected to rough handling or has a Permanent Alarm. It is also required that patients have the Power Adaptor, AC Power Supply, and Car Charger with them at all times to ensure that they can connect to external power. Two additional fully charged Onboard Batteries, the Wire Ties and the Wire Cutter Tool are needed to perform a switch from the primary Freedom Driver to the backup Freedom Driver.

9.5 Maintenance of Electrical Safety

Avoid potentially dangerous electrical shock hazards by always connecting the Hospital AC Power Supply cord to an approved, 3-wire grounded AC power receptacle. Never attempt to modify the equipment. The Home AC Power Supply is double insulated and is safe to use in grounded or ungrounded power outlets.

9.6 Reduction of Explosion Hazard

Do not operate the Freedom Driver System in the presence of flammable anesthetics or other flammable gases.

9.7 Maintenance of Patient Safety

- **If the Freedom Driver is dropped, exposed to liquid/debris or subjected to rough handling, it may sustain damage that will not allow it to provide life-sustaining functions as designed. If the Freedom Driver is dropped, exposed to liquid/debris or subjected to rough handling, exchange it for the backup Freedom Driver.**
- Verify that the Drivelines and electrical connections are in place, secure, and connected to the Freedom Driver before attempting to operate the System.
- Keep the Freedom Driver dry. Protect it from showers, baths, rain and liquid/debris. **If the Freedom Driver is exposed to liquid/debris, it must be exchanged for the backup Freedom Driver.**

9.8 Environment

- Do not operate the Driver beyond an ambient pressure of 525 mmHg to 795 mmHg (700hPa to 1060hPa), or at altitudes less than 1250 ft. below sea level or 8,000 ft. above sea level in an unpressurized cabin.
- A patient must get physician approval for airline travel.

9.9 Driver Storage Requirements

The backup Freedom Driver should always be stored unplugged in the backpack or shoulder bag (whichever is not in use with the Primary Driver in a cool, dry area. It is recommended to carry the primary and backup Freedom Drivers inside the Shoulder Bag and Backpack.

9.10 Freedom Driver System Maintenance

Refer to **Section 14, *Equipment Maintenance and Care*,** for maintenance and care instructions

9.11 Onboard Battery Maintenance

Refer to **Section 14.2.4, *Onboard Battery*,** for Onboard Battery maintenance and care instructions

9.12 Things to Do Before Switching the TAH-t Patient to the Freedom Driver System

- Before switching the TAH-t patient from the current driver system to the Freedom Driver System, complete the Freedom Driver Test Protocol **(Appendix 2)** for both the primary and backup Freedom Drivers.

- Confirm that the Handle Straps are attached to the primary and backup Freedom Drivers.
- The Beat Rate (BPM) on each Driver should be set for the particular patient if the default setting of 125 BPM is not appropriate.
- The backup Driver with attached Power Adaptor should be placed in the Shoulder Bag or Backpack and secured with Velcro™ straps. It should have an orange Dummy Battery inserted into one of the Battery Wells.
- The primary Driver should be placed in the Shoulder Bag or Backpack and secured with Velcro™ straps. It should have two charged Onboard Batteries inserted into the Battery Wells.
- Make sure that the Accessory Bag has been packed with the additional Power Adaptor, up to four charged Onboard Batteries, one AC Power Supply, the Car Charger, Wire Ties, Wire Cutter Tool, and the Filter Pack.
- The second AC Power Supply should be plugged into the wall outlet next to the patient's bed.
- The patient can now be switched from the Companion 2 Driver or CSS Console to the Freedom Driver.
- The serial numbers of the primary and backup Companion 2 Driver or CSS Consoles should be indicated on the Freedom Driver System Test Protocol (**Appendix 2**) along with the serial numbers of the primary and backup Freedom Drivers.
- The Freedom Driver System Test Protocol should be faxed to SynCardia Systems, LLC.

9.13 Patient Preparation for Excursions

Before the patient is taken on an excursion and leaves the Hospital, the following must be confirmed:

- The patient and caregiver(s) have been trained in emergency procedures.
- Optimal settings have been selected (check the Driver Display).
- There are no alarms in operation.
- Both Onboard Batteries in the Driver are fully charged.
- Fully loaded Accessory Bag and backup Driver are available.

Refer to the *Freedom Discharge Manual* for additional information in preparing the patient for discharge to home or intermediate facility.

When a patient leaves his/her house, he/she must **always** take:

- The backup Freedom Driver with attached Power Adaptor
- At least two additional fully charged Onboard Batteries,
- Home AC Power Supply
- Car Charger
- Wire Ties
- Wire Cutter Tool

	**CAUTION** **A backup Freedom Driver must always be available in the event that the primary Freedom Driver is dropped, exposed to liquid/debris, subjected to rough handling or has a Fault Alarm that cannot be resolved per the instruction in Section 10.3.** **If the backup Freedom Driver is not available and the primary Driver has a malfunction, the patient will not have a functioning life-supporting device.**

10 Visual and Audible Alarms

Alarms indicate potential problems with the Freedom Driver or the TAH-t. For the safety of the patient, it is important that all users (including the caregiver) understand the alarms and how to respond to them.

Each Alarm situation includes:

- A Visual Alarm (blinking or solid colored light), and
- An Audible Alarm (beeping or constant tone).

There are three kinds of Alarms that can occur with the Freedom Driver, listed in order of lowest to highest priority, they are:

- Battery Alarm,
- Temperature Alarm, and
- Fault Alarm.

If two or more alarms are occurring at the same time, the highest priory alarm will take precedence.

10.1 Battery Alarm

A Battery Alarm is indicated by a beeping tone Audible Alarm and a blinking yellow light Visual Alarm on the top of the Freedom Driver.
The volume of the Audible Alarm is in the range of 78 to 92 decibels (depending on the user's location with respect to the Driver).

The illuminated blinking yellow light on the top of the Freedom Driver will indicate which Onboard Battery (left or right) has caused the Battery Alarm **(Figure 10-1)**.

Figure 10-1 – Illuminated Flashing Yellow Battery Alarm Light

A Battery Alarm occurs if:

- One or both of the Onboard Batteries have less than 35% remaining charge (only two green lights display on Battery Fuel Gauge), or
- One of the Onboard Batteries is incorrectly installed, or
- One of the installed Onboard Batteries is removed, or
- One of the installed Onboard Batteries is not detected by the Driver.

There is no way to mute the Battery Alarm. The issue that caused the alarm must be **immediately** addressed by performing the following steps:

- Check the amount of charge remaining in both Onboard Batteries
  - Replace each low Onboard Battery (only two green lights illuminate on the Battery Fuel Gauge) with a charged Onboard Battery, or
  - Connect to External Power and leave both Onboard Batteries in place to charge.

    NOTE: Once the batteries are charged above 35% the Battery Alarm will stop.
- Reinsert incorrectly installed Onboard Battery until locked in place. If the Battery Alarm continues, insert a new Onboard Battery
- If an Onboard Battery is removed from the Freedom Driver, then insert a charged Onboard Battery into the Driver.

When connected to an External Power source:

- The Battery Alarm for the low charge Onboard Battery will continue until the Onboard Battery is charged above 35%.
- The Battery Alarm will continue for an incorrectly installed or removed Onboard Battery until the issue is addressed

CAUTION

When there is a Battery Alarm, it is extremely important to connect to External Power from a wall power outlet or a 12V vehicle power outlet to charge the Onboard Batteries or replace the depleted Onboard Batteries, one at a time, with fully charged Onboard Batteries.

The Onboard Batteries will eventually lose power and the Freedom Driver will not function if it is not connected to External Power.

	**CAUTION** **Before the patient goes to sleep, the Driver MUST be plugged into External Power using the AC Power Supply. All connections must be verified to be secure and the indicator lights on the Power Supply and Power Adaptor are illuminated solid green.** **When the Driver is not connected to external power, two fully charged Onboard Batteries provide approximately two hours of support before a Low Battery Alarm occurs. Actual support time may vary according to Driver Beat Rate setting. The Onboard Batteries will eventually lose power and the Freedom Driver will not function if it is not connected to External Power.**

	**CAUTION** **Do not ignore a Battery Alarm.** **A Battery Alarm will turn into a Fault Alarm if it is not addressed and one or both Onboard Batteries drop below 30% remaining charge. See Section 10.3 for resolving Fault Alarms.**

If the Battery Alarm changed into a Fault Alarm:

- Replace each low Onboard Battery (only two green lights illuminate on the Battery Fuel Gauge) with a charged Onboard Battery, or
- Connect to External Power and leave both Onboard Batteries in place to charge.

NOTE: The Fault Alarm will continue and will change into a Battery Alarm as the Onboard Batteries recharge. Once the Onboard Batteries are charged above 35%, the Battery Alarm will stop. If available, it is recommended that Batteries that are below 35% charge are recharged in the Battery Charger.

10.2 Temperature Alarm

A Temperature Alarm indicates that the internal housing of the Driver and/or the temperature of the Onboard Batteries is outside of the recommended operating range. The Drive Unit will continue to operate while in a Temperature Alarm, but the Temperature Alarm must be immediately addressed. The Temperature Alarm will stop when the temperature returns to recommended operating range.

If the Temperature Alarm continues for 30 minutes it will escalate to a Fault Alarm that will require a switch to the backup Driver.

A Temperature Alarm is indicated by a beeping tone Audible Alarm and a blinking red light Visual Alarm on the top of the Freedom Driver **(Figure 10-2)**.

The volume of the Audible Alarm is in the range of 82 to 93 decibels (depending on the user's location with respect to the Driver).

Figure 10-2 – Illuminated Flashing Red Temperature Alarm Light

A Temperature Alarm is caused if:

- The internal temperature of the Freedom Driver is too hot
- The temperature of the Onboard Batteries is too hot or too cold

There is no way to mute the Temperature Alarm. The issue that caused the alarm must be **immediately** addressed by performing the following steps:

- Replace each Onboard Battery, one at a time, with a charged Onboard Battery
- Remove any objects blocking the Filter Cover and Fan on the Freedom Driver
- Move the Freedom Driver into a climate controlled environment (a cooler or warmer area)

	**CAUTION** **Do not ignore a Temperature Alarm. An unresolved Temperature Alarm may become a Permanent Fault Alarm.**

	CAUTION **Do not block the Filter Cover and Fan. This will cause the internal temperature of the Driver to increase and a Temperature Alarm will sound.**

	CAUTION **Do not block the mesh windows on the Shoulder Bag and Backpack. This will cause the internal temperature of the Driver to increase and a Temperature Alarm will sound.**

10.3 Fault Alarm

A Fault Alarm **(Figure 10-3)** is indicated by a constant tone Audible Alarm and a solid red light Visual Alarm on the top of the Freedom Driver.

The volume of the Audible Alarm is in the range of 85 to 96 decibels (depending on the user's location with respect to the Driver).

	CAUTION **In the event of a Fault Alarm with a solid red light and a constant tone, immediately check that the Drivelines are not kinked and that the Drivelines are not disconnected from the Cannulae.**

Figure 10-3 – Illuminated Solid Red Fault Alarm Light

A Fault Alarm is caused if:

- The patient is experiencing low cardiac output (less than 3.5 L/min) potentially caused by:
  - A significant increase in thoracic pressure from a valsalva maneuver for more than 30 consecutive seconds. The following are typical valsalva maneuver conditions:
    - Laughing
    - Strenuous coughing
    - Sneezing
    - Straining during a bowel movement
    - Lifting a heavy weight
    - Vomiting
  - Elevated systolic blood pressure, or
  - Kinked Drivelines, or
  - Disconnected Drivelines and Cannulae, or
- The Battery Alarm was ignored and one or both Onboard Batteries have less than 30% remaining charge, or
- There is a malfunction of the primary Freedom Driver.

There is no way to mute the Fault Alarm. The issue that caused the alarm must be **immediately** addressed by performing the following steps:

- Relax/interrupt the valsalva maneuver, or
- Manage elevated systolic blood pressure as directed by your physician and notify Hospital Contact Person for additional instructions, or
- Undo any kinks on the Drivelines, or
- Reconnect Drivelines and Cannulae, or
- Check the amount of charge remaining in both Onboard Batteries. Replace each low Onboard Battery, one at a time, with a charged Onboard Battery or connect to External Power and leave both Onboard Batteries in place to charge.

NOTE: The Fault Alarm will continue and will change into a Battery Alarm as the Onboard Batteries recharge. Once the Onboard Batteries are charged above 35%, the Battery Alarm will stop.

If the patient has relaxed/interrupted the valsalva maneuver, there are no kinks or damage in the Drivelines, the Drivelines and Cannulae are connected, and the Battery Alarm has not been ignored, then a malfunction of the Freedom Driver exists and the patient must **switch to the backup Freedom Driver immediately**, following instruction in

Section 11, *Switch from Primary Freedom Driver to Backup Freedom Driver*.

	**CAUTION** **Do not ignore a Fault Alarm. If a Fault Alarm cannot be resolved within three to four minutes, it may become a Permanent Fault Alarm that requires switching to the backup Freedom Driver.**

11 Switch from Primary Freedom Driver to Backup 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 (patient and trained caregiver) exchange the primary Freedom Driver for the backup Freedom Driver.** **Make sure all items and accessories are closely available before exchanging Drivers.**

The switch from the Primary Freedom Driver to the Backup Driver can be performed by trained clinicians, and patients or caregivers who have been formally trained by the Hospital.

If the primary Freedom Driver is dropped, exposed to liquid/debris, subjected to rough handling or if the Fault Alarm cannot be resolved within three to four minutes, the patient must switch to the backup Freedom Driver.

The patient must switch to the backup Freedom Driver if a Fault Alarm (indicated by a constant tone Audible Alarm and a solid red Visual Alarm) occurs and cannot be resolved by performing the following:

- Relax/interrupt valsalva maneuver
- Make sure the Drivelines are not kinked
- Make sure both Drivelines and Cannulae are connected to each other
- If the Battery Alarm changed into a Fault Alarm:
    - Replace each low Onboard Battery (only two green lights illuminate on the Battery Fuel Gauge) with a charged Onboard Battery, or
    - Connect to External Power and leave both Onboard Batteries in place to charge.

NOTE: the Fault Alarm will continue and will change into a Battery Alarm as the Onboard Batteries recharge. Once the Onboard Batteries are charged above 35%, the Battery Alarm will stop.

	**CAUTION** **It is recommended that Batteries that are below 35% charge (i.e. are causing a Low Battery Alarm) are recharged in the Battery Charger.** **While recharging the Onboard Batteries in the Freedom Driver during a Fault Alarm, the patient must monitor their Cardiac Output (CO) on the primary Freedom Driver Display in order to assure that the Fault Alarm continues to be caused by the low Onboard Battery charge and that no other malfunction of the Driver exists during recharging of the Onboard Batteries.**

If the above does not resolve the Fault Alarm, then a malfunction of the primary Freedom Driver may exist and it may be operating in Backup Mode.

- Backup Mode is the mode of operation that provides support to the TAH-t if there is a malfunction in the primary Freedom Driver. Backup Mode happens automatically and starts a Fault Alarm that cannot be resolved by the steps listed in **Section 10.3**.
- The patient **must switch to the backup Freedom Driver immediately** by following the procedure described below.
- After switching, the patient must contact the Hospital to arrange for a new backup Driver.

11.1 Materials

To perform a switch from the primary Freedom Driver to the backup Freedom Driver, the following is needed:

- The backup Freedom Driver
- Two additional charged Onboard Batteries
- Wire Cutter Tool
- Wire Ties

It is recommended to have two AC Power Supplies and access to two functional wall power outlets in order to perform a switch from the primary Freedom Driver to the backup Freedom Driver.

11.2 Preparation to Perform Switch from Primary to Backup Freedom Driver

If possible, plug the primary Freedom Driver into a wall power outlet using the AC Power Supply. If connecting to wall power, confirm that the light on the Power Adaptor is illuminated solid green to ensure a proper connection.

To turn on the backup Freedom Driver:

- Remove the Driveline caps from the ends of the Freedom Driver Drivelines
- Insert one spare charged Onboard Battery from the Accessory Bag into the backup Freedom Driver
- Remove the orange Dummy Battery and install the second spare charged Onboard Battery from the Accessory Bag into the backup Freedom Driver
- If possible, connect the backup Freedom Driver into a wall power outlet using the AC Power Supply cord
- Verify that the backup 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 backup Freedom Driver, there is a malfunction of the Driver.

The patient must not switch from the primary Freedom Driver to the backup Freedom Driver.

The patient must call the Hospital Contact Person and go to the Hospital immediately to exchange the primary Freedom Driver.

CAUTION

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

11.3 Driver Switch

Refer to **Figure 11-1** for an image of the **red** and **blue** Freedom Driveline to Cannula connection via the CPC connectors.

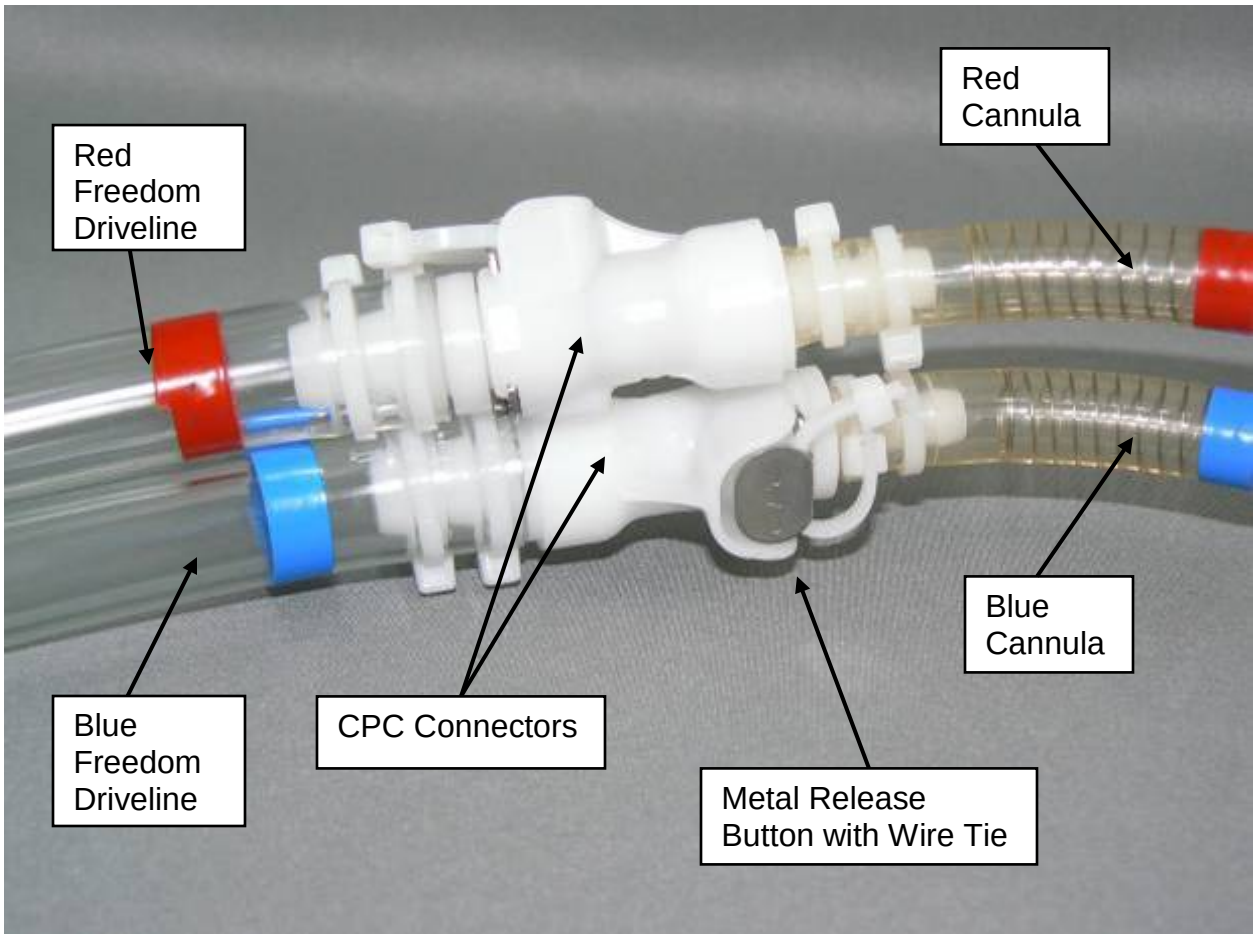


Figure 11-1 – Freedom Drivelines Connected to Cannulae via the CPC Connectors

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** Freedom Driveline **(Figure 11-2)**.

Gently pull to remove the Wire Tie and discard.

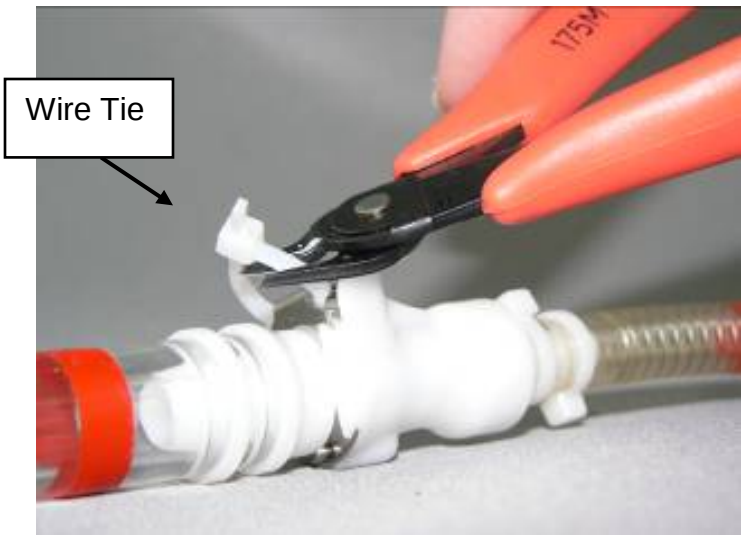


Figure 11-2 – Cutting the Wire Tie with the Wire Cutter Tool

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** Freedom Driveline.

Gently pull to remove the Wire Tie and discard.

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

3) **Perform steps 4 and 5 simultaneously** in order to disconnect the Drivelines of the primary Freedom Driver and connect the Drivelines of the backup Freedom Driver **(Figures 11-3 and 11-4)**.

4) Disconnect the **red** Cannula from the **red** Driveline of the primary Freedom Driver:

- Press *and* hold down the metal release button,
- Pull the **red** Cannula away from the **red** Driveline,
- **Immediately** insert the **red** Cannula into the new **red** Driveline from the backup Freedom Driver,
- 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 primary Freedom Driver:

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

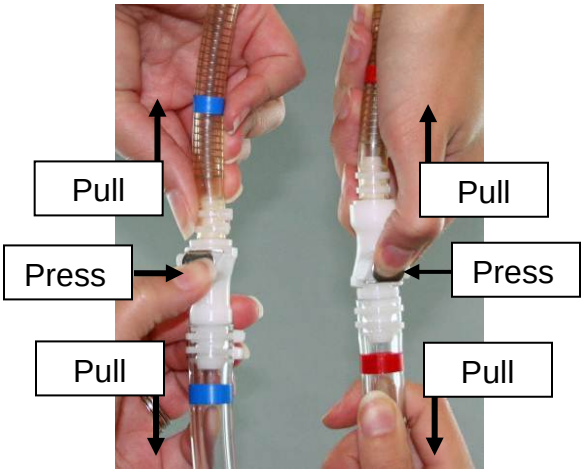


Figure 11-3 – Disconnecting the Drivelines from the Cannulae

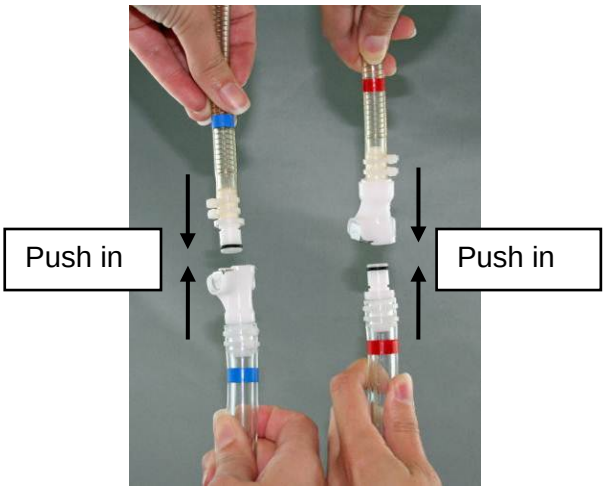


Figure 11-4 – Connecting the Drivelines to the Cannulae

6) Slide a Wire Tie under the metal release button of each CPC connector **(Figure 11-5)**.

- 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.

This wire tie is added to help prevent accidentally depressing the metal CPC connector and potentially disconnecting the CPC connectors.

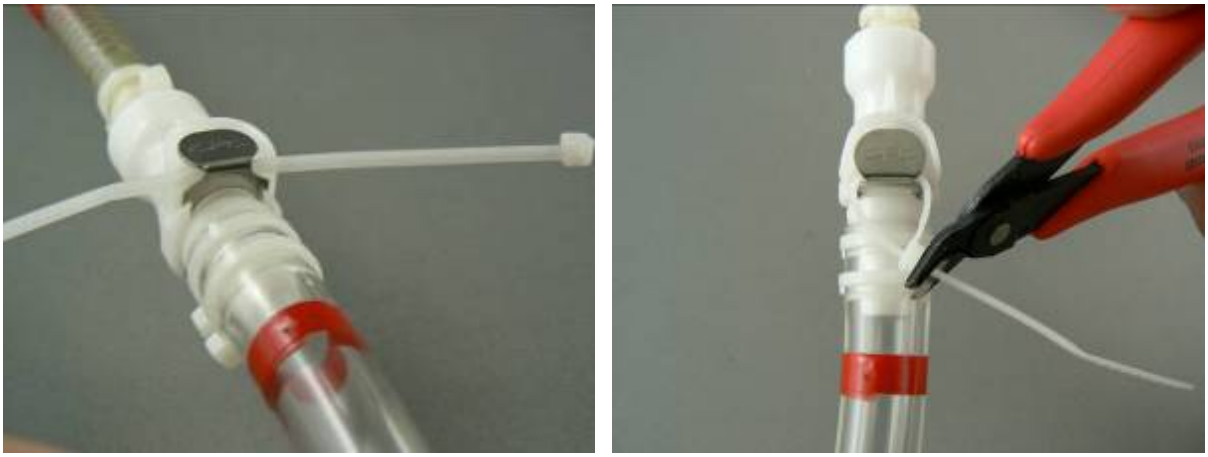


Figure 11-5 – Inserting Wire Tie under Metal Release Button of CPC connector

⚠	**CAUTION** **If a Wire Tie is unavailable, the patient must be careful NOT to accidentally disconnect the Drivelines from the Cannulae.** **The patient must go to the Hospital to return the faulted Freedom Driver and be issued a new backup Freedom Driver.** **Hospital personnel will then secure the connectors with a new Wire Tie.**

7) Remove one Onboard Battery from the faulted Freedom Driver and insert into the Accessory Bag.

- Insert the orange Dummy Battery removed from the backup Freedom Driver into the faulted Driver.

  Remove the second Onboard Battery from the faulted Freedom Driver and place it in the Accessory Bag.

- Unplug the faulted Freedom Driver from wall power and this will turn off the faulted Freedom Driver.

8) The patient must notify the Hospital Contact Person of the Driver switch.

- The connected backup Freedom Driver is now the primary Freedom Driver.
- Immediately after the Driver exchange, the patient must go to the Hospital to return the faulted Driver, obtain a new backup Driver and receive any necessary medical evaluations as determined by the clinician.

9) The Hospital should notify SynCardia Systems that the Driver has been switched and return the faulty Driver.

CAUTION

Some faults may cause the Freedom Driver to not charge the Batteries.

If the patient travels to the Hospital with a Freedom Driver with a Fault Alarm, they must plug the Driver into vehicle power to maintain the Onboard Batteries.

The patient must immediately notify the Hospital Contact Person that they are on the way so that the Hospital can prepare a backup Freedom Driver.

11.4 Exchange Driver at Hospital

After a Driver switch, the Hospital should inform SynCardia and SynCardia will issue a Return Material Authorization (RMA) to ship back the Driver and will send a replacement Driver to the Hospital.

12 Switch from CSS Console 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 to switch the patient from the CSS Console to the primary Freedom Driver.** **Make sure all items and accessories are closely available before exchanging Drivers.**

The switch from CSS Console to Primary Freedom Driver should be performed by trained clinicians only and should not be performed by patients.

12.1 Materials

Prior to switching the patient from the CSS Console to the Freedom Driver System, the following must be available:

- One prepared primary Freedom Driver
- One prepared backup Freedom Driver
- 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 (Not supplied by SynCardia. Used to tighten the wire ties)
- CPC Connectors from Permanent Center Tool Kit
- Heavy-duty scissors to cut Driveline tubing

12.2 Preparation to Perform Switch from CSS Console to Primary 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 (**Appendix 2**). If any of the Drivers do not pass the Protocol, do not connect the patient to the Freedom Driver System and contact SynCardia immediately.

The Freedom Driver comes with CPC connectors already attached onto each **red** and **blue** Driveline. You need to attach the respective mate CPC

connector provided in the Connector Tool Kit to each Driveline and then secure the connection with a Wire Tie under the metal release button as described below:

- Slide a Wire Tie under the metal release button of each CPC connector **(Figure 12-1)**.
- 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.

  This wire tie is added to help prevent accidentally depressing the metal CPC connector and potentially disconnecting the CPC connectors.

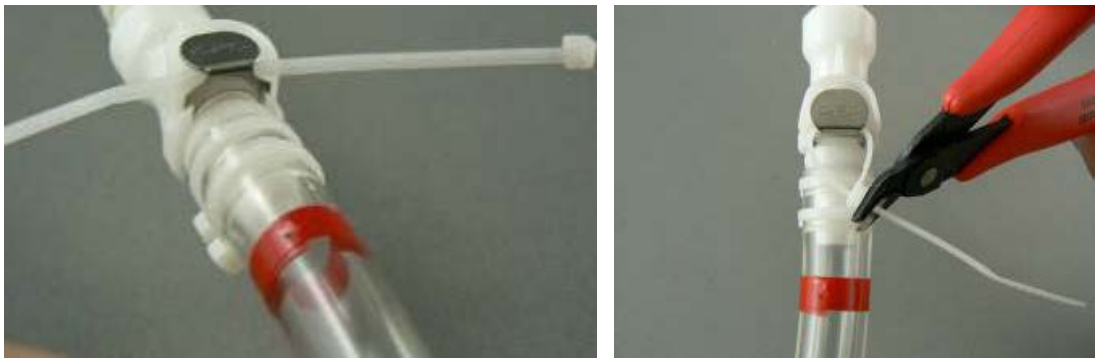


Figure 12-1 – Inserting Wire Tie under Metal Release Button of CPC Connector

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 CSS Console to the Freedom Driver.**

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

12.3 Driver Exchange

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 12-2**.

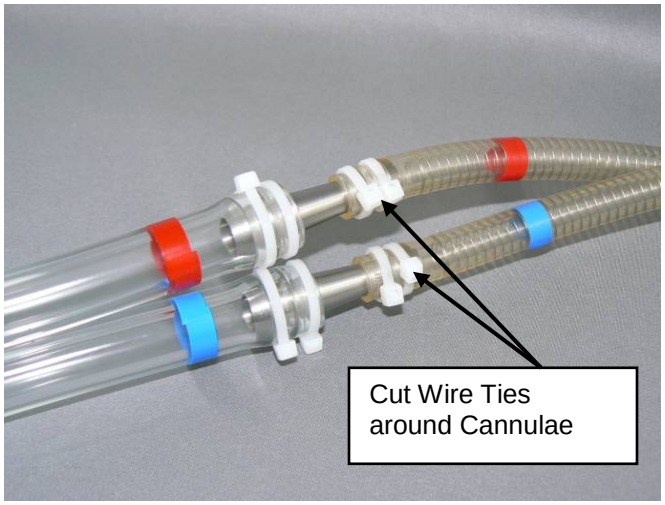


Figure 12-2 – Wire Ties around CSS Hose Barb Connectors

2) **DO NOT DISCONNECT OR REMOVE YET**

Loosen the metal hose barb connectors from the Cannulae as shown in **Figure 12-3**.

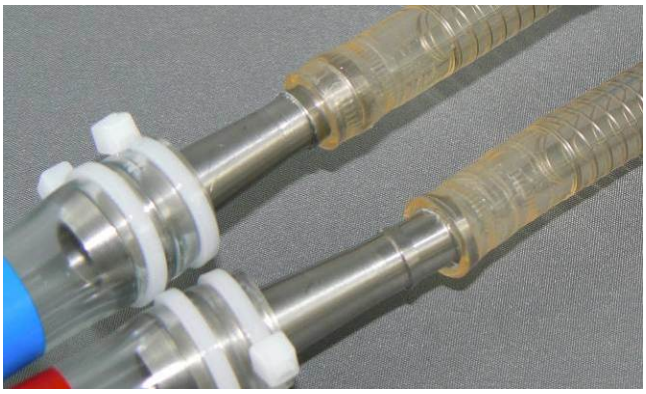


Figure 12-3 - Metal Hose Barb Connectors Loosened, But Still Connected, to the Cannulae

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

3) **Perform steps 4 and 5 simultaneously** in order to disconnect the Drivelines of the CSS Console and connect the Drivelines of the primary Freedom Driver.

4) Remove the metal hose barb from the **red** Cannula by pulling and then immediately insert the CPC connector of the **red** Freedom Driveline into the **red** Cannula (**Figure 12-4**).

5) Simultaneously, remove the metal hose barb from the **blue** Cannula by pulling and then immediately insert the CPC connector of the **blue** Freedom Driveline into the blue Cannula (**Figure 12-4**).

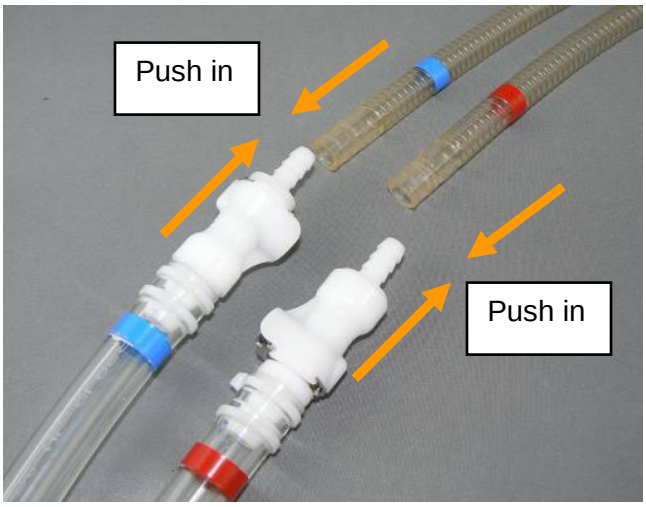


Figure 12-4 - Inserting the Freedom Drivelines into the Cannulae

6) Secure each Cannula to the CPC connectors with two Wire Ties, as shown in **Figure 12-5** below.

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

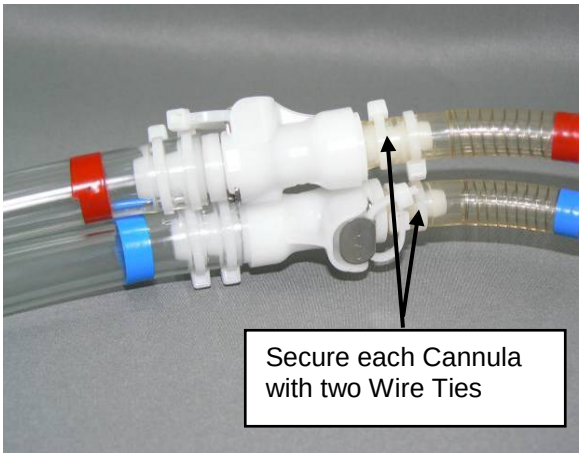


Figure 12-5 – Securing Cannulae to CPC Connectors with Wire Ties

7) Modify the CSS Console Drivelines for potential reuse:

NOTE: In order to modify CSS Console Drivelines for potential reuse with a Freedom patient, you will need special CSS Console Driveline CPC Connectors (the CPC Connectors in the Connector Kit cannot be used for this modification). If you would like to modify CSS Console Drivelines, please contact SynCardia Systems to obtain the proper connectors.

a) Remove Metal Hose Barb Connectors from the Driveline by cutting the Driveline tubing (**Figure 12-6**).

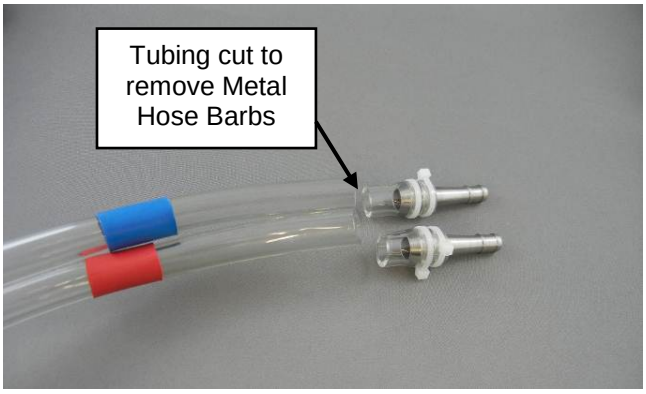


Figure 12-6 – Cut Driveline Tubing

b) Insert the male CSS Console Driveline CPC Connector into the red Driveline. Secure with at least two wire ties (**Figure 12-7**).

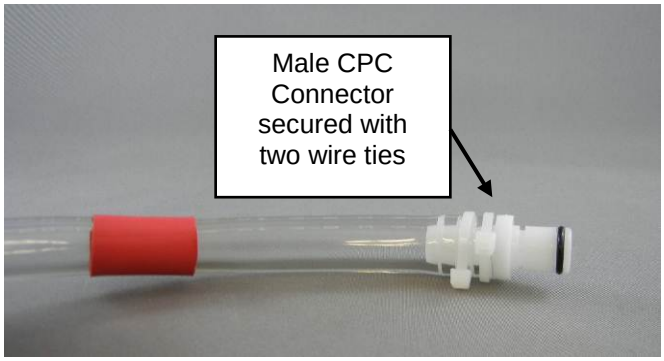


Figure 12-7 – Male CPC Connector

c) Insert the female CSS Console Driveline CPC Connector into the blue Driveline. Secure with at least two wire ties (**Figure 12-8**).

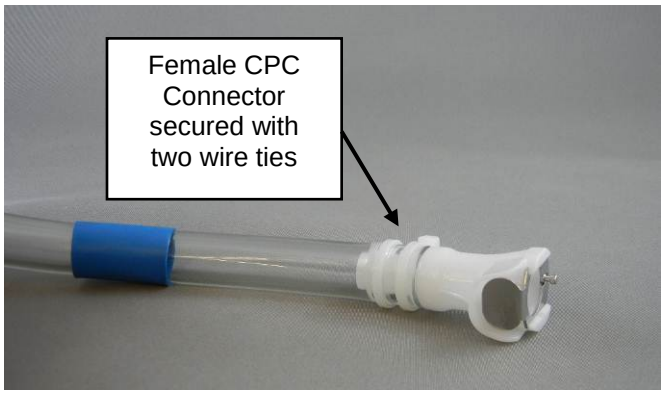


Figure 12-8 – Female CPC Connector

d) Inspect the modified-end of the Driveline to ensure that it matches the other end of the Driveline (**Figure 12-9**).

- Verify the **red** Driveline has the male CPC Connector on both ends
- Verify the **blue** Driveline has the female CPC Connector on both ends

The final Modified CSS Console Driveline is shown in **Figure 12-10**.

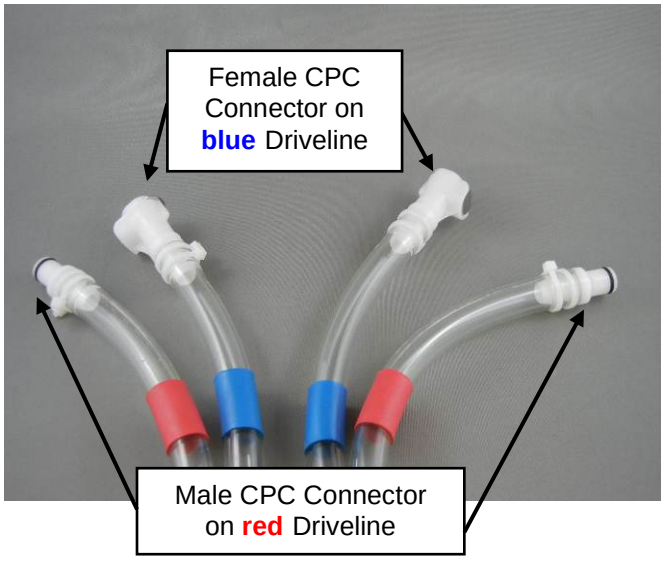


Figure 12-9 – Driveline End Comparison

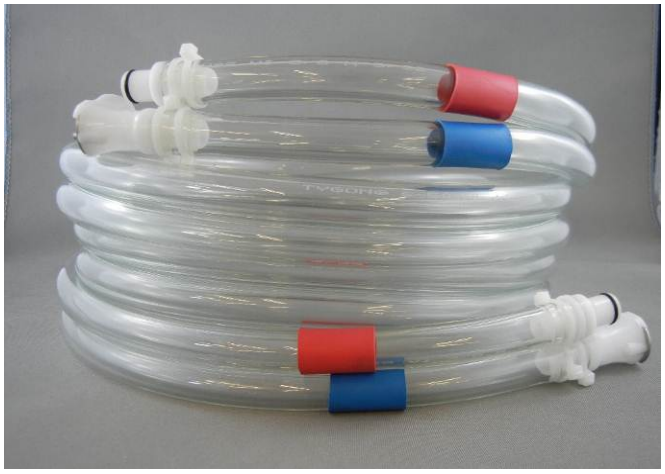


Figure 12-10 – Modified CSS Console Driveline

8) Insert the Modified CSS Console 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 a CSS Console, if necessary.

9) The Hospital should notify SynCardia Systems Clinical Support that the patient has been switched from the CSS Console to the Freedom Driver.

13 Switch from Freedom Driver to CSS Console

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 to switch the patient from the Freedom Driver to the CSS Console.** **Make sure all items and accessories are closely available before exchanging Drivers.**

The switch from a Freedom Driver to a CSS Console should be performed by trained clinicians only and should not be performed by patients.

13.1 Materials

Prior to switching the patient from the Freedom Driver System to the CSS Console, the following must be available:

- One prepared CSS Console
- Driveline Retention Bag with the Patient's Drivelines
- Wire Cutter tool from Freedom Patient Tool Kit
- Wire ties from the Freedom Patient Tool Kit
- Wire Tie Gun (Not supplied by SynCardia. Used to tighten the wire ties)

13.2 Preparation to Perform Switch from Freedom Driver to CSS Console

Prepare the CSS Console as indicated in Chapter 1 of the *SynCardia Circulatory Support System (CSS) User's Manual* using the Modified CSS Console Drivelines made in **Section 12.3***.*

13.3 Driver Exchange

Refer to **Figure 13-1** for an image of the **red** and **blue** Freedom Driveline to Cannula connection via the CPC connector.

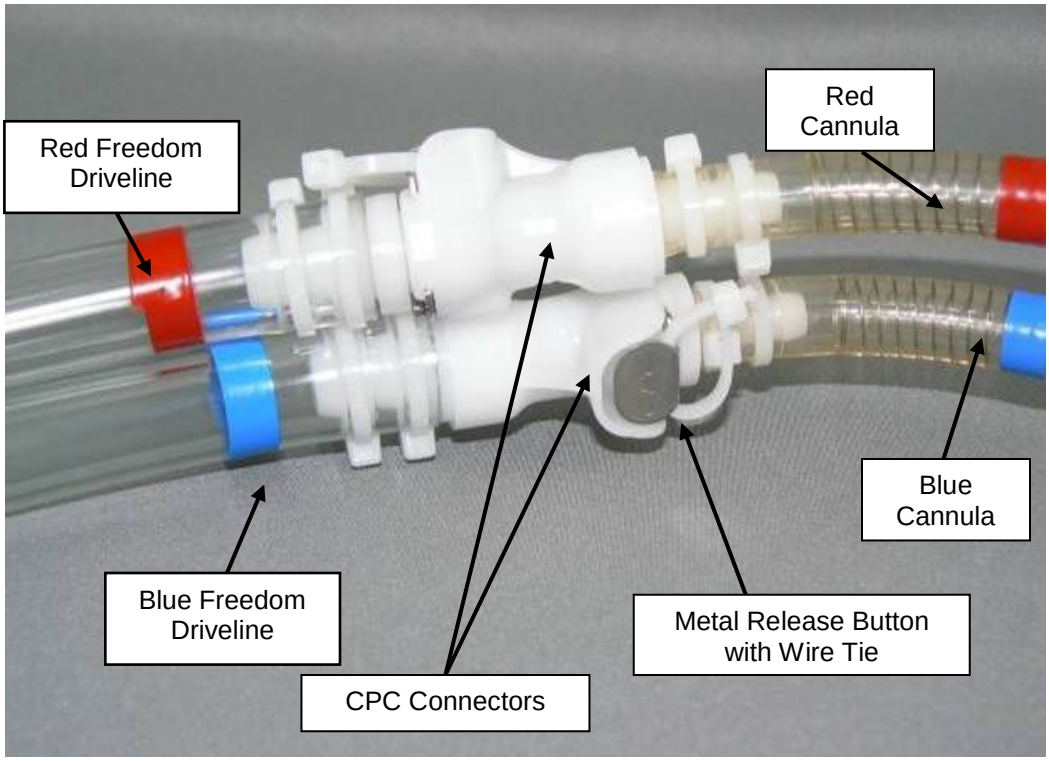


Figure 13-1 – Connection of Driver Connectors to Cannulae

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** Freedom Driveline **(Figure 13-2)**.

Gently pull to remove the Wire Tie and discard.

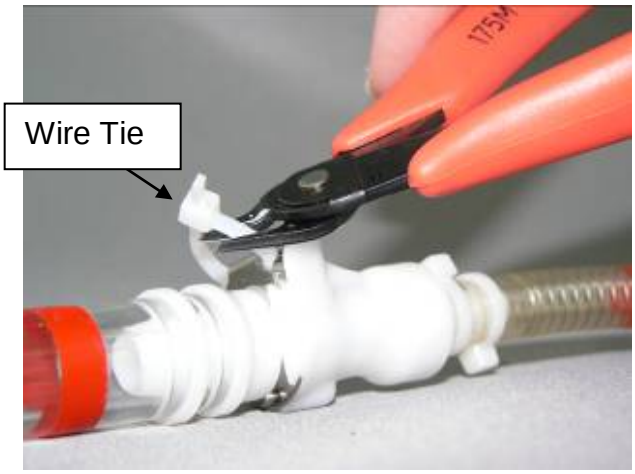


Figure 13-2 – Cutting the Wire Tie with the Wire Cutter Tool

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** Freedom Driveline.

Gently pull to remove the Wire Tie and discard.

CAUTION

Before disconnecting the Drivelines of the Freedom Driver, you must have the Modified Drivelines of the CSS Console within reach.

3) **Perform steps 4 and 5 simultaneously** in order to disconnect the Drivelines of the Freedom Driver and connect the Modified Drivelines of the CSS Console **(Figures 13-3 and 13-4)**.

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

- Press *and* hold down the metal release button,
- Pull the **red** Cannula away from the **red** Freedom Driveline,
- **Immediately** insert the **red** Cannula into the **red** Modified CSS Console 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 Freedom Driver:

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

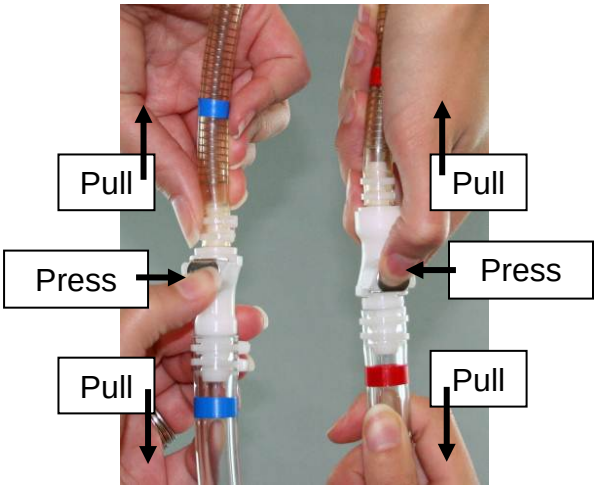


Figure 13-3 – Disconnecting Freedom Drivelines from the Cannulae

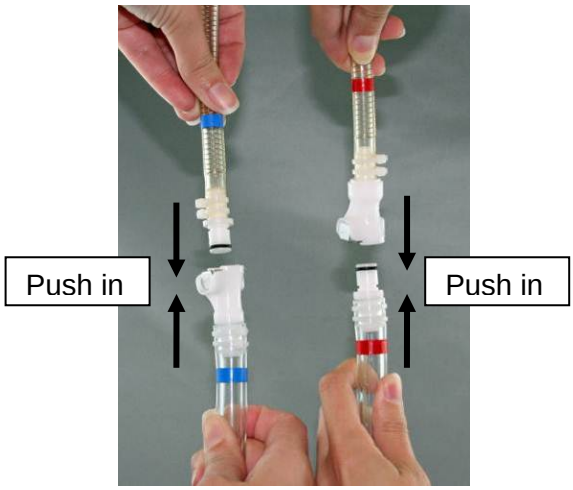


Figure 13-4 – Connecting the Modified CSS Console Drivelines to the Cannulae

6) Slide a Wire Tie under the metal release button of each CPC connector **(Figure 13-5)**.

- 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.

This wire tie is added to help prevent accidentally depressing the metal CPC connector and potentially disconnecting the CPC connectors.

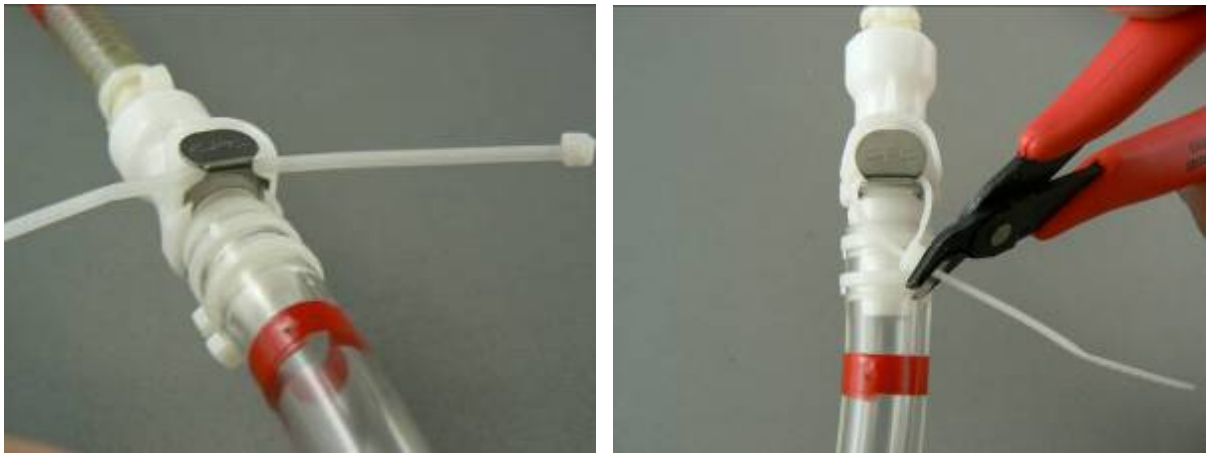


Figure 13-5 – Inserting Wire Tie under Metal Release Button of CPC Connector

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

14 Switch from CSS Console with Modified Drivelines to 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 to switch the patient from the CSS Console to the Freedom Driver.

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

The switch from a CSS Console to a Freedom Driver should be performed by trained clinicians only and should not be performed by patients.

14.1 Materials

Prior to switching the patient from the CSS Console with Modified Drivelines 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

14.2 Preparation to Perform Switch from CSS Console with Modified Drivelines 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 CSS Console to the Freedom Driver.**

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

14.3 Driver Exchange

Refer to **Figure 14-1** for an image of the **red** and **blue** Modified CSS Console Driveline to Cannula connection via the CPC connector.

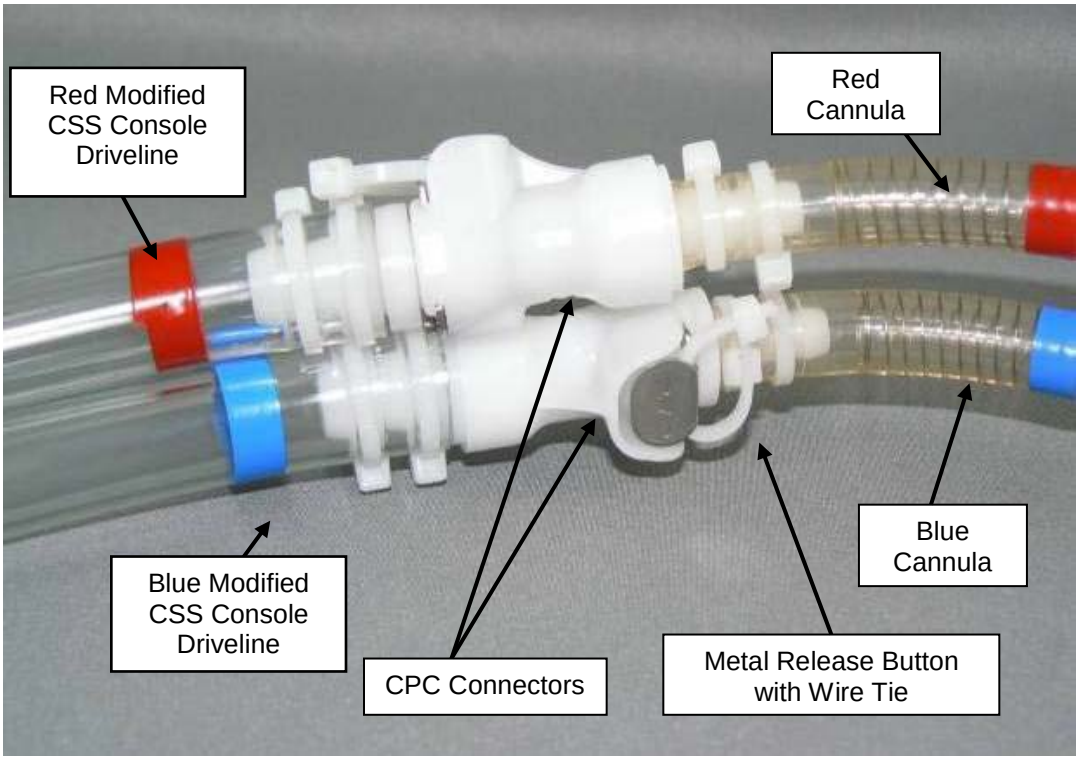


Figure 14-1 – Connection of Modified CSS Console Driveline to Cannulae

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** Freedom Driveline **(Figure 14-2)**.

Gently pull to remove the Wire Tie and discard.

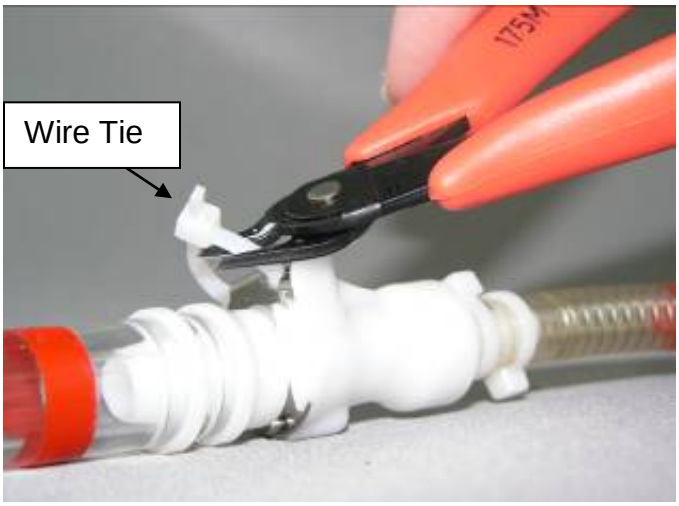


Figure 14-2 – Cutting the Wire Tie with the Wire Cutter Tool

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** Modified CSS console Driveline.

Gently pull to remove the Wire Tie and discard.

⚠	**CAUTION** **Before disconnecting the Modified Drivelines of the CSS Console, you must have the Drivelines of the operating Freedom Driver within reach.**

3) **Perform steps 4 and 5 simultaneously** in order to disconnect the Modified Drivelines of the CSS Console and connect the Drivelines of the Freedom Driver **(Figures 14-3 and 14-4)**.

4) Disconnect the **red** Cannula from the **red** Modified Driveline of the CSS Console Driver:

- Press *and* hold down the metal release button,
- Pull the **red** Cannula away from the **red** Modified CSS Console 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** Modified Driveline of the CSS Console:

- Press *and* hold down the metal release button,
- Pull the **blue** Cannula away from the **blue** Modified CSS Console 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.

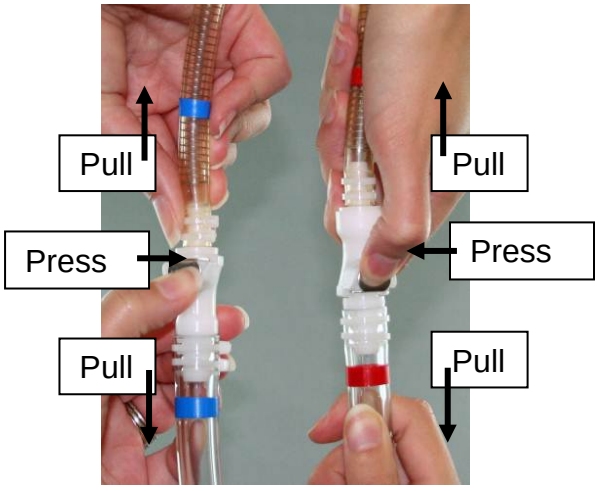


Figure 14-3 – Disconnecting Modified CSS Console Drivelines from the Cannulae

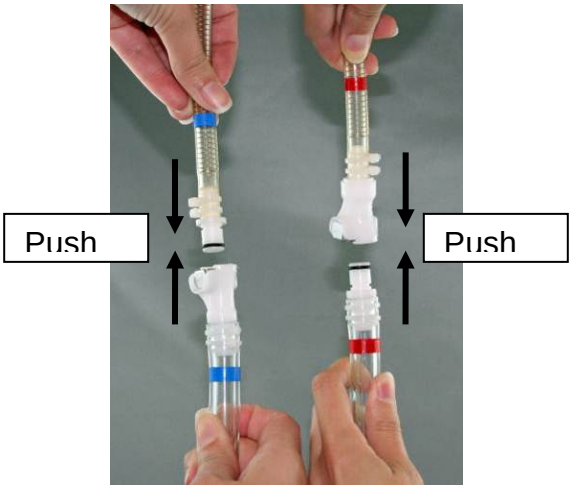


Figure 14-4 – Connecting the Freedom Drivelines to the Cannulae

6) Slide a Wire Tie under the metal release button of each CPC connector **(Figure 14-5)**.

- 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.

This wire tie is added to help prevent accidentally depressing the metal CPC connector and potentially disconnecting the CPC connectors.

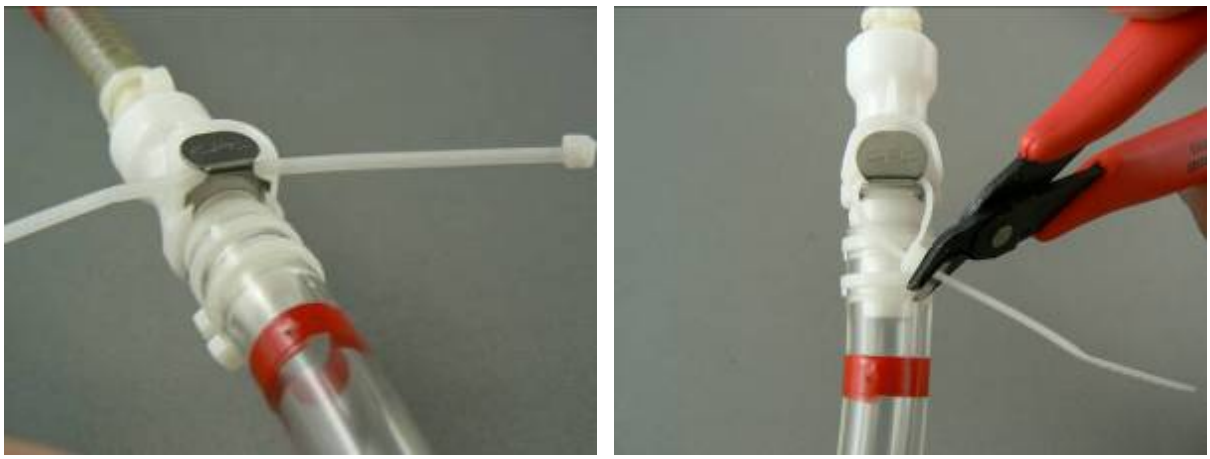


Figure 14-5 – Inserting Wire Tie under Metal Release Button of CPC Connector

7) Insert the Modified CSS Console 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 CSS Console, if necessary.

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

15 Switch from Companion 2 Driver to 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.**

The switch from a Companion 2 Driver to a Freedom Driver should be performed by trained clinicians only and should not be performed by patients.

15.1 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 Patient Tool Kit
- Male and Female CPC connectors and Wire Ties from Connector Tool Kit
- Driveline Retention Bag

15.2 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 (**Appendix 2**). 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.**

15.3 Driver Exchange

Refer to **Figure 15-1** for an image of the **red** and **blue** Companion Driveline to Cannula connection via the CPC connector.

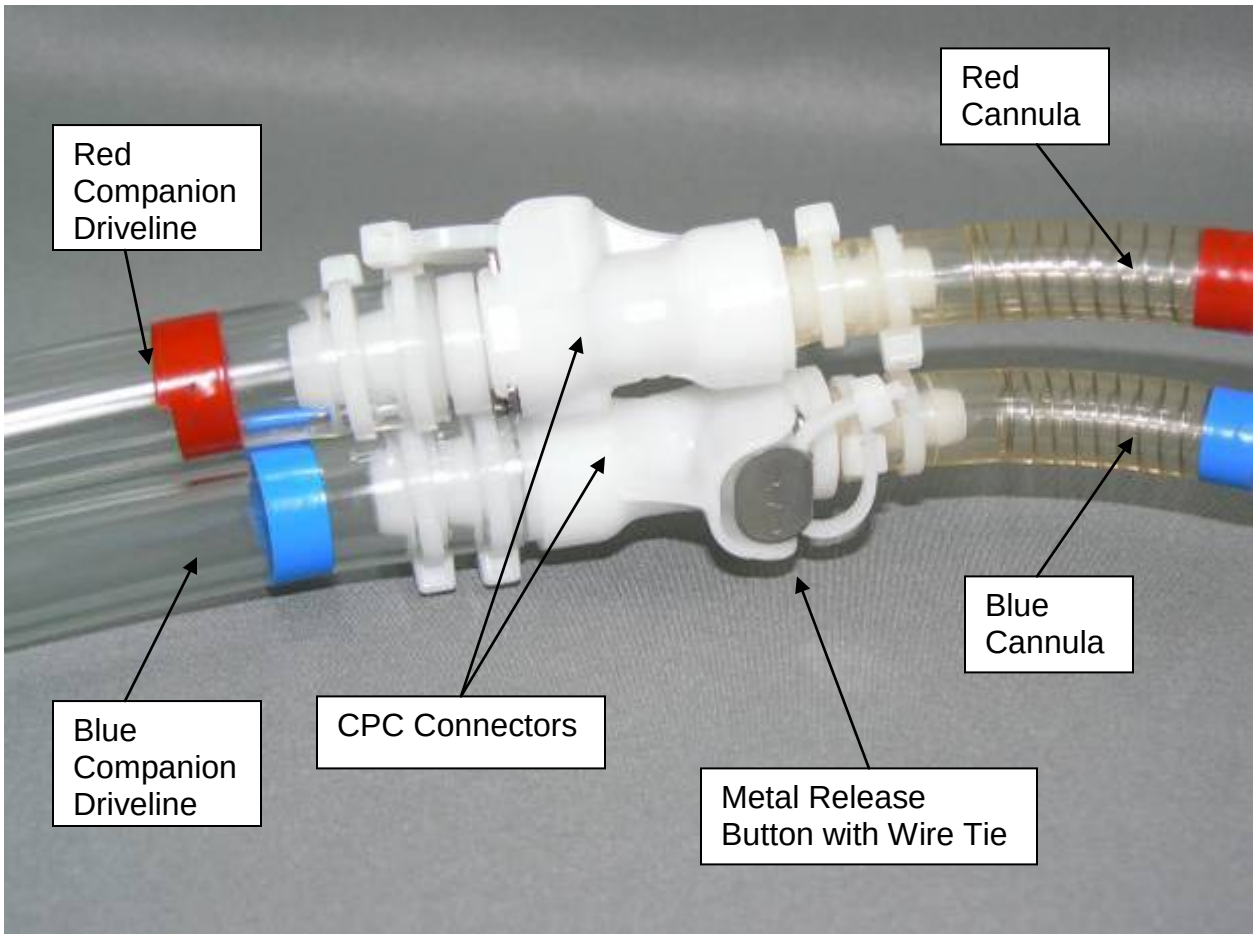


Figure 15-1 – Companion Drivelines Connected to Cannulae via the CPC Connectors

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 Driveline **(Figure 15-2)**.

Gently pull to remove the Wire Tie and discard.

Figure 15-2 – 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 15-3 and 15-4)**.

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 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 or Companion 2 Driver:

- Press *and* hold down the metal release button,
- Pull the **blue** Cannula away from the **blue** Companion 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.

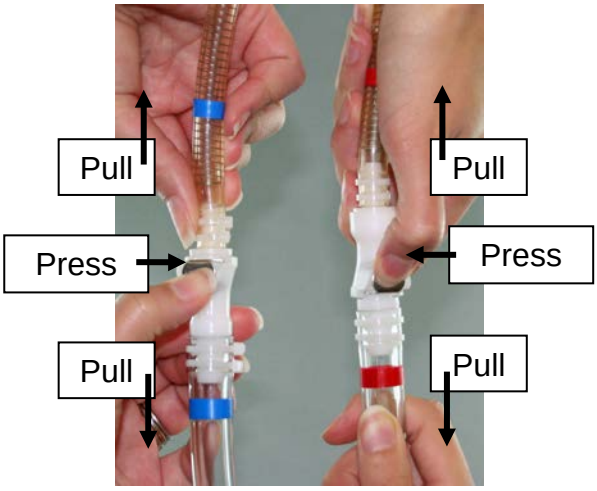


Figure 15-3 – Disconnecting the Companion Drivelines from the Cannulae

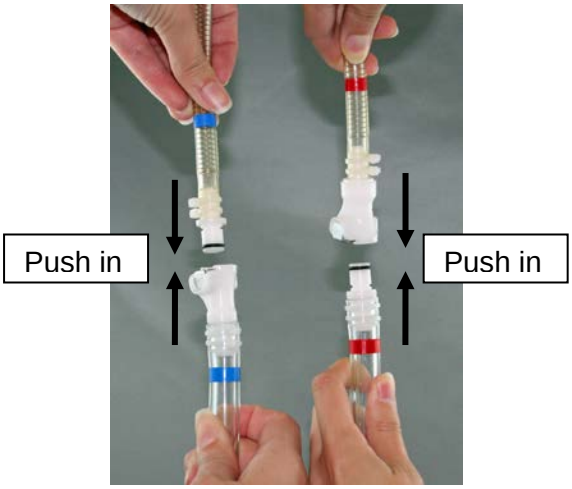


Figure 15-4 – Connecting the Freedom Drivelines to the Cannulae

6) Slide a Wire Tie under the metal release button of each CPC connector **(Figure 15-5)**.

- 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.

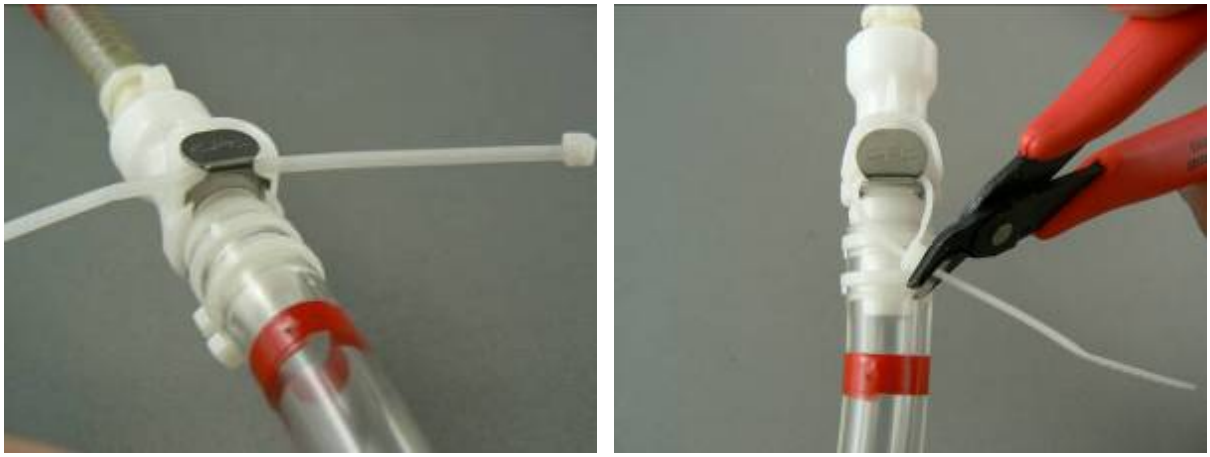


Figure 15-5 – Inserting Wire Tie under Metal Release Button of CPC Connector

7) Insert the Companion 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 from the Companion 2 Driver to the Freedom Driver.

16 Switch from Freedom Driver to a Companion 2 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 Freedom Driver to the Companion 2 Driver.

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

The switch from a Freedom Driver to a Companion 2 Driver should be performed by trained clinicians only and should not be performed by patients.

16.1 Materials

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

- One prepared Companion 2 Driver
- Wire Cutter tool from Patient Tool Kit
- Male and Female CPC connectors and Wire Ties from Connector Tool Kit
- Driveline Retention Bag with Patient's Drivelines

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

Prepare the Companion 2 Driver as indicated in the *SynCardia Companion 2 Operator Manual.*

16.3 Driver Exchange

Refer to **Figure 16-1** for an image of the **red** and **blue** Freedom Driveline to Cannula connection via the CPC connector.

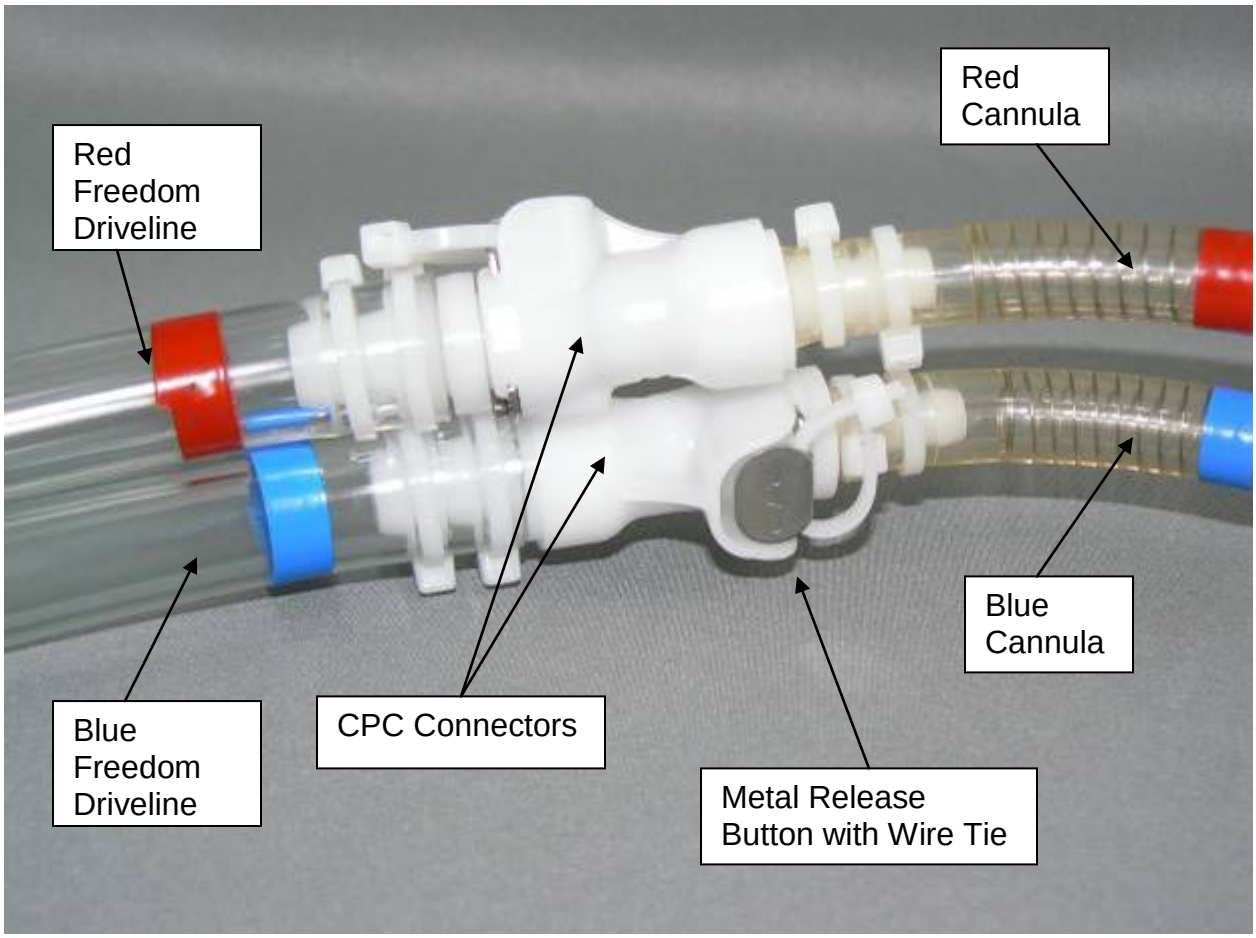


Figure 16-1 – Freedom Drivelines Connected to Cannulae via the CPC Connectors

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** Freedom Driveline **(Figure 16-2)**.

Gently pull to remove the Wire Tie and discard.

Figure 16-2 – 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** Freedom Driveline.

Gently pull to remove the Wire Tie and discard.

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

3) **Perform steps 4 and 5 simultaneously** in order to disconnect the Drivelines of the Freedom Driver and connect the Drivelines of the Companion 2 Driver **(Figures 16-3 and 16-4)**.

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

- Press *and* hold down the metal release button,
- Pull the **red** Cannula away from the **red** Freedom Driveline,
- **Immediately** insert the **red** Cannula into the **red** Companion 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 Freedom Driver:

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

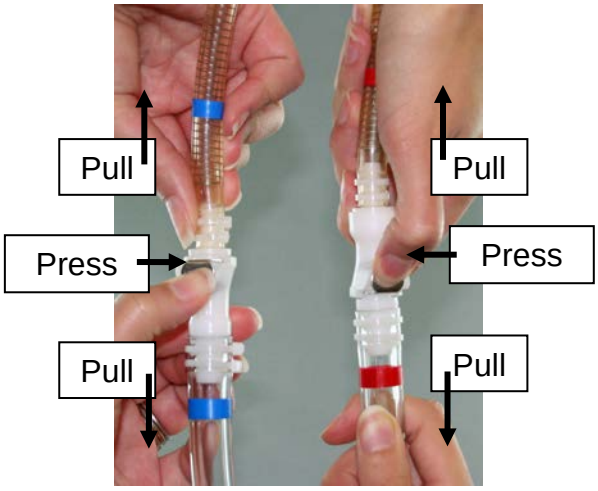


Figure 16-3 – Disconnecting the Freedom Drivelines from the Cannulae

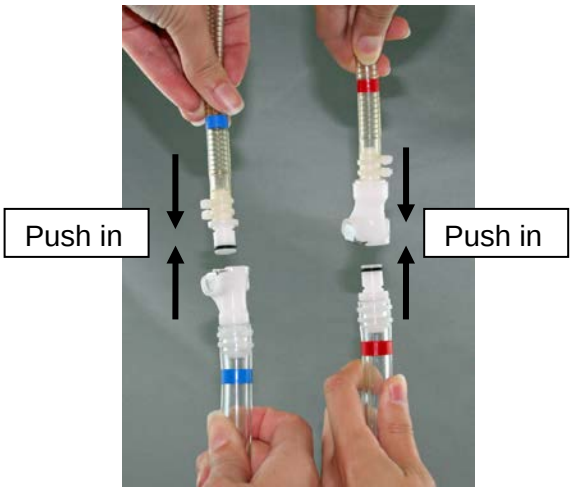


Figure 16-4 – Connecting the Companion Drivelines to the Cannulae

6) Slide a Wire Tie under the metal release button of each CPC connector **(Figure 16-5)**.

- 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.

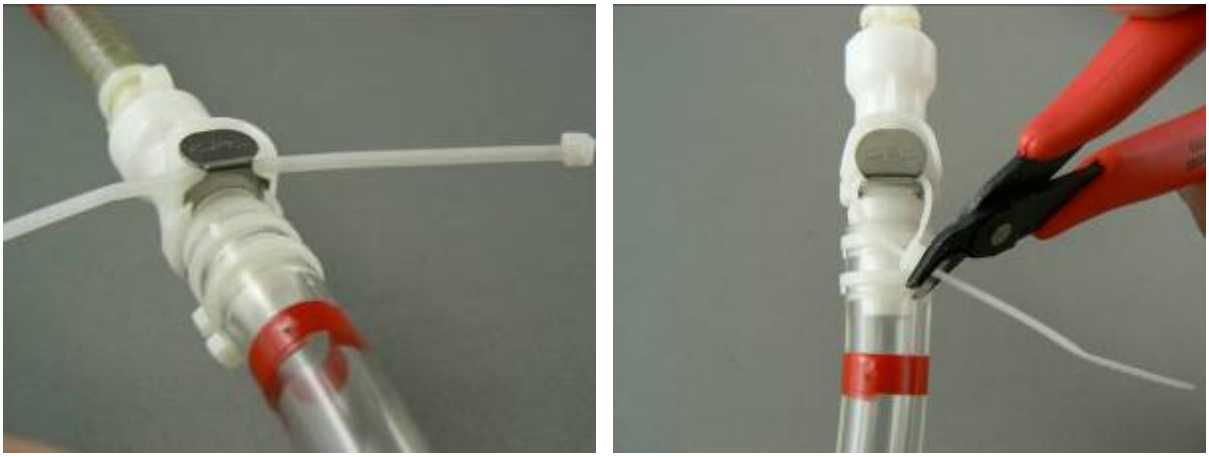


Figure 16-5 – Inserting Wire Tie under Metal Release Button of CPC Connector

7) The Hospital should notify SynCardia Systems that the patient has been switched from the Freedom Driver to the Companion 2 Driver.

17 Equipment Maintenance and Care

17.1 Service

Hospital personnel schedule the exchange of Freedom Drivers for servicing.

SynCardia performs complete service on the Freedom Drivers at regularly scheduled intervals. SynCardia will notify the Hospital to schedule the exchange of Freedom Drivers. When a patient is transplanted or is no longer using the Freedom Driver System, it should be returned to SynCardia for evaluation in the original Pelican case with all accessories.

Maintenance is required no later than every 120 days.

17.2 Maintenance and Cleaning Instructions

17.2.1 Freedom Driver

The Freedom Driver System must be maintained in order for it to work properly.

- Do not expose the Freedom Driver to temperatures higher than 40°C (104°F) or lower than 4.5°C (40°F) for long periods.
- To prevent a Temperature Alarm, do not block the Filter Cover and Fan on the Driver.
- Do not submerge the Freedom Driver or expose it to water.
- Do not expose the Freedom Driver to paint, paint remover, fingernail polish remover, or other solvents.
- Use extreme care when cleaning the equipment. Clean with a cloth lightly dampened ONLY with water.
- Dust the equipment periodically with a soft, clean cloth.

CAUTION

DO NOT soak any item of the Freedom Driver during cleaning.

DO NOT allow water to come in direct contact with the Freedom Driver electrical connections to avoid shock or electrocution.

If the Freedom Driver is exposed to liquid/debris, it MUST be exchanged for the backup Freedom Driver.

17.2.2 Drivelines

The Drivelines and Cannulae must be inspected daily to make sure they are intact and have no holes.

- The patient must inspect the Drivelines and Cannulae daily. If the patient detects a hole in the Driveline or Cannulae, they

should apply household tape to temporarily repair the hole. The patient must immediately call the Hospital Contact Person to arrange for a hospital-based evaluation. The hospital should apply a self-fusing silicone tape to seal the hole. The hospital must contact SynCardia for possible further instruction.

- To clean the Drivelines, wipe gently with a soft, clean, cloth, lightly dampened ONLY with water.

17.2.3 Filter

Filter inspection is necessary at least once a week and the filter should be replaced or cleaned as necessary. More frequent inspection is recommended for environments that are dusty or have contaminates such as pet hair.

The patient needs the Filter Pack with screwdriver in order to change the Filter.

To replace the filter, follow these steps:

- Open the Filter Cover **(Figure 17-1)** by removing the screw on the bottom with the screwdriver provided.
- Remove the old Filter and put in a new Filter.
- Put the Filter Cover back in place and secure it with the screw.

Filters may be rinsed for re-use if there are no holes or tears.

To clean the filter, rinse using cold water. Allow to air dry before use.

Additional Filter Packs can be reordered from SynCardia Systems, LLC.

Figure 17-1 – Filter Cover

17.2.4 Onboard Batteries

The Onboard Batteries must be cared for properly.

THINGS TO DO:

- Store the Onboard Batteries in a cool, dry place and within a temperature range of 0°C to 40°C (32°F to 104°F)
- Charge Onboard Batteries within a temperature range of 0°C to 40°C (32°F to 104°F)
- It is recommended that the patient periodically rotates all of the Onboard Batteries. A serial number is located on each Onboard Battery to help keep track of which Onboard Batteries have been used
- Make sure the Onboard Batteries are fully charged before storing them
- Protect the Onboard Battery connectors from moisture, dirt and metal at all times
- Patients should notify their Hospital Contact Persons when their battery expiration date (if printed on label) is nearing. Newer versions of batteries do not have an expiration date printed on the label. However, they are tracked by the manufacturer and will be replaced before the expiration dates.

NOTE: If the temperature of the batteries reaches 90°C (194°F), they will not recharge. Patients will need to call their Hospital Contact Person for replacements.

THINGS NOT TO DO:

- Do not disassemble or modify the Onboard Batteries.
- Do not use Onboard Batteries as a power supply for anything other than the Freedom Driver System.
- Do not charge an Onboard Battery using anything other than a Driver or other specified equipment.
- Do not incinerate Onboard Batteries, as explosion or rupture may occur.
- Do not discard Onboard Batteries - they are hazardous waste. Return Onboard Batteries to SynCardia for disposal.
- Do not leave the Onboard Batteries exposed to extreme heat or cold, especially in direct sunlight or in a closed vehicle in the sun. Extreme high and low temperatures can damage the Onboard Batteries
- Do not drop the Onboard Batteries or subject them to shock
- Do not submerge Onboard Batteries in liquid
- Do not allow necklaces, chains, or other metal items to come into contact with the Onboard Batteries

17.2.5 Battery Wells

It is important to keep the Battery Wells free of debris and liquid.

Each Battery Well has a door to prevent any small light weight objects from entering the Battery Well.

If any objects or liquid gets into the Battery Well, the patient must call their Hospital Contact Person.

CAUTION

Keep objects and liquids that could fall into the Battery Wells away from the Freedom Driver. Failure to do so may cause the Freedom Driver to malfunction.

17.2.6 Battery Charger

- Before cleaning, always disconnect the AC Power Supply from the Battery Charger.
- Use extreme care when cleaning the equipment. Dust the equipment periodically with a soft, clean cloth. To remove debris from the bays, invert the charger and shake gently.
- If you need to remove heavy dirt from the outside of the Battery Charger dampen a soft, clean cloth and wipe the exterior of the housing gently.
- Trained personnel should test the Battery Charger upon receipt and prior to distribution to patients according to the procedure described in the Freedom Battery Charger Operational Check Form (**Appendix 3**).
- The Battery Charger has an expected mission life of at least 1 year; however, the unit may remain in the field as long as it is operational.
- Patients should return a malfunctioning Battery Charger to the implant center so the center can coordinate the return and proper disposal with SynCardia Systems, LLC.
- No other maintenance needs to be performed on the Battery Charger.

17.3 Storage Instructions

The Discharge Kit, prior to patient assignment, and the Standby Kit should be stored in their Pelican Case(s) in a cool, dry area.

The backup Freedom Driver and accessories should be stored in the Backpack or Shoulder Bag (whichever is not in use with the Primary Driver) in a cool, dry area.

17.4 Return of the Freedom Driver System

When the patient receives a heart transplant, the patient must return the Freedom Driver and all accessories to the Hospital.

The Hospital must return the Freedom Driver and all accessories to SynCardia in the Pelican Case.

18 Freedom Driver System Specifications

18.1 Driver System Safety Standards

- The Freedom Driver, as part of the SynCardia TAH-t and Freedom Driver System, has been tested pursuant to the requirements of the following standards:
- IEC 60601-1: 1988, Medical electrical equipment – Part 1: General requirements for safety. Amendment No. 1 (1991) and Amendment No. 2 (1995)
- IEC 60601-1-2: 2007, Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-8:2006 General requirements for basic safety and essential performance – Collateral Standard: General Requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-6, General requirements for safety – Collateral Standard: Usability.
- IEC 60601-1-11:2010 Medical electrical equipment- Part 1-11: General requirements for basic safety and essential performance- Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

The IEC 60601-1 standard requires making the following declarations and stating the type and degree of protection for listed hazards.

Table 18-1 - Declaration Concerning General Safety Standards for the Freedom Driver

Type	Degree of Protection
Mode of Operation	Continuous
Type of protection against electrical shock	Class II (double insulated), and internally powered. Can be used with Class I Hospital AC Power Supply and Class II Home AC Power Supply.
Degree of protection against electric shock	Type BF Applied Part (Body Floating)
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Not suitable for use in the presence of flammable anesthetics

Type	Degree of Protection
Degree of protection against harmful ingress of water and foreign materials	IP30

	MEDICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH IEC 60601-1

The Freedom 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/ Freedom 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 Freedom Driver System.**

18.2 Battery Charger Safety Standards

- The Battery Charger, as part of the Freedom Driver System, has been tested pursuant to the requirements of the following standards:
  - o IEC 60601-1-2: 2007, Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

The IEC 60601-1 standard requires making the following declarations and stating the type and degree of protection for listed hazards.

Table 18-2 – Declaration Concerning General Safety Standards for the Battery Charger

Type	Degree of Protection
Mode of Operation	Continuous
Type of protection against electrical shock	Class I (grounded)
Degree of protection against electric shock	NA – Not an Applied Part
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Not suitable for use in the presence of flammable anesthetics
Degree of protection against harmful ingress of water and foreign materials	IP20

Table 18-3 – Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The Battery Charger is intended for use in the electromagnetic environment specified below. The customer or the user of the Battery Charger should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Battery Charger uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Battery Charger is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	IEC 61000-3-2 Class	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

The Freedom Battery Charger has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2007 - 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.
- Patients and caregivers should contact their hospitals for assistance.
- Hospitals should contact SynCardia Systems, LLC for assistance.

Declaration and Guidance Concerning Electromagnetic Immunity for The Freedom Battery Charger

The Freedom Battery Charger is intended for use in the electromagnetic environment specified below. The customer or the user of the Battery Charger should assure that it is used in such an environment.

Table 18-4 – Declaration and Guidance Concerning Electromagnetic Immunity for the Freedom Battery Charger for IEC 60601-1-2

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV Contact ±8 kV Air	± 6 kV Contact ±8 kV Air	Floors are to be wood, concrete, or ceramic tile. If floors covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0.5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	<5 % *U*T (>95 % dip in *U*T) for 0.5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Battery Charger requires continued operation during power mains interruptions, it is recommended that the Battery Charger be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	0.3 A/3	If image distortion occurs, it may be necessary to position the Battery Charger further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic fields should be measured in the intended installation location to assure that it is sufficiently low.

Declaration and Guidance Concerning Electromagnetic Immunity for the Freedom Battery Charger

The Freedom Battery Charger is intended for use in the electromagnetic environment specified below. The customer or the user of the Battery Charger should assure that it is used in such an electromagnetic environment.

Table 18-5 – Declaration and Guidance Concerning Electromagnetic Immunity for the Freedom Battery Charger for IEC 60601

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Freedom Battery Charger, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 80 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters 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 marked with the following symbol: 
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 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 can-not 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 Freedom is used exceeds the applicable RF compliance level above, Freedom 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. **b** Over the frequency range 150 kHz and 80 MHz, field strengths should be less than 3 V/m.			

18.3 Driver Dimensions (without carrying bag)

- Width: 27.94 cm (11 inches)
- Height: 22.23 cm (8.75 inches)
- Depth: 13.02 cm (5.125 inches)
- Weight: Driver with Power Adaptor and two Onboard Batteries is 6.12 kg (13.5 lbs)

18.4 Power Adaptor Dimensions

- Width: 9.525 cm (3.75 inches)
- Height: 15.24 cm (6 inches)
- Depth: 4.7 cm (1.85 inches)
- Weight: 0.22 kg (0.5 lbs)

18.5 Battery Charger Dimensions

- Width: 26 cm (10.25 inches)
- Height: 8.3 cm (3.25 inches)
- Depth: 9.2 cm (3.625 inches)
- Weight: 0.65 kg (1.44 lb)

18.6 Environmental Conditions

- Operating Temperature (Driver): 4.5° to 40°C (40° to 104°F)
- Operating Temperature (Accessories): 4.5° to 40°C (40° to 104°F)
- Transportation/Storage Temperature: -25° to 70°C (-13° to 158°F)
- Operating Pressure: 700 to 1060 hPa (525 to 795 mmHg) 8,000 ft. above sea level to 1250 ft. below sea level
- Transportation/Storage Pressure: 700 to 1060 hPa (525 to 795 mmHg)
- Operating Humidity: 10-95%RH
- Transportation/Storage Humidity: 10 – 95% RH (non-condensing)
- Vibration: 0.75 G peak, 5 Hz to 500 Hz (three orthogonal axes, sweep at 1 octave/min 5 min dwell at four major resonances)

18.7 Driver System Power Requirements

- Onboard Batteries (2): 14.8V rechargeable lithium-ion polymer Batteries, which each provide up to 60 minutes of power when fully charged.
- AC Power Supply: Input: 100-240 V, 50/60 Hz; Output: 16 V, 9.4 A

18.8 Battery Charger Power Requirements

- Onboard Batteries (Part Number 295025-001; sold separately): 14.8V rechargeable lithium-ion polymer Batteries
- AC Power Supply (Part Numbers 295400 and 295600): Input: 100-240 V AC, 350 V, 50/60 HZ. Output: 16V DC, 9.4 A
- Battery Charger (Part Number 295054-001): Input 16V DC; Output 12-17V DC 9A

18.9 Driver Operating Ranges

- Rate: 125 BPM ±15 BPM
- Left Drive Pressure (fixed): 205 mmHg
- Right Drive Pressure (fixed): 110 mmHg
- Diastolic Vacuum (fixed): -10 mmHg
- Systolic Duration (fixed): 50%

18.10 Input / Output Characteristics

Table 18-6 describes the input/output characteristics of the Freedom Driver System.

Table 18-6 – Input / Output Characteristics

Connection	Location	Characteristics
Drivelines	Driver (Right Side)	Fixed Drivelines
Power Adaptor Receptacle	Driver (Left Side)	Accepts power from the Power Adaptor
Covered Setting Dial	Driver (Back Side)	Concealed dial available for Beat Rate adjustment within a clinical environment

18.11 Classification for Freedom Driver System

- Class II Equipment; can also be used with Class I Hospital AC Power Supply
- Type BF Equipment
- Driver Ingress Protection:
  - Driver - IP30
  - Driver in Shoulder Bag/Backpack with Rain Cover – IP32
- Externally-Powered Equipment when connected to an AC power source

The Driver is intended for continuous operation for a period of 120 days.

18.12 Classification for Battery Charger

- Class I Equipment
- Ingress Protection: IP20
- Externally-Powered Equipment when connected to an AC/DC power source

18.13 Classification for Hospital AC Power Supply

- Class I Equipment
- Ingress Protection: IP21
- Externally-Powered Equipment when connected to an AC/DC power source

18.14 Classification for Home AC Power Supply

- Class II Equipment
- Ingress Protection: IP21
- Externally-Powered Equipment when connected to an AC/DC power source

Refer to **Table 18-7** for summary of IEC 60529, Ingress Protection (IP) Ratings.

- The two digits represent different forms of environmental influence
  - The first digit represents protection against ingress of solid objects
  - The second digit represents protection against ingress of liquids

Table 18-7 – IP Rating Classification

Number	First Digit: Ingress of Solid Objects	Second Digit: Ingress of Liquids
0	Non-protected	Non-protected
1	Protected against solid foreign objects of 50 mm Ø and greater	Protected against vertically falling water drops
2	Protected against solid foreign objects of 12,5 mm Ø and greater	Protected against vertically falling water drops when enclosure tilted up to 15°
3	Protected against solid foreign objects of 2,5 mm Ø and greater	Protected against spraying water
4	Protected against solid foreign objects of 1,0 mm Ø and greater	Protected against splashing water
5	Dust-protected	Protected against water jets
6	Dust-tight	Protected against powerful water jets
7	N/A	Protected against the effects of temporary immersion in water
8	N/A	Protected against the effects of continuous immersion in water
9	N/A	Protected against high pressure and temperature water jets

18.15 Firmware Versions

- Safety Monitor Firmware V1.14
- Display Firmware V1.02

Appendix 1

Patient Information Card Template

Appendix 1

Patient Information Card Template

PATIENT INFORMATION

Patient Name: Jane Doe

Patient Address: 1992 E. Silverlake Rd

Tucson, AZ 85713

Hospital Contact Person: John Smith

Contact Telephone # 555-555-5555

I have a temporary total artificial heart (TAH-t).

Do not administer CPR. Do not defibrillate. Do not administer epinephrine to TAH-t patients experiencing hypertension.

I am anticoagulated and on platelet inhibitors.

If I am having a medical emergency, please call the Hospital Contact Person immediately.

F-900035-EN Rev 005

Hospital	
Hospital Name	University Hospital
Address	555 East Main Street
Hospital Contact Person	John Smith
Contact Telephone #	555-555-5555
Doctor	
Name	John Doe, M.D.
Address	555 East Main Street
Telephone #	555-555-5556
Ambulance	
Company Name	Rapid Transit
Address	5556 East Main Street
Telephone #	555-555-5557
Emergency Services	
Contact Emergency Services and then call your Hospital Contact Person	

Appendix 2

Freedom Driver System Test Protocol

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

FREEDOM DRIVER SYSTEM TEST PROTOCOL

PRIMARY FREEDOM DRIVER SERIAL #: _____
BACKUP FREEDOM DRIVER SERIAL #: _____
HOSPITAL NAME: _____

NOTE: This procedure should be performed by trained persons only. Perform this test upon receipt of equipment and prior to patient use. Patient Simulator connected to a 70cc TAH-t should be Normotensive (RAP 12±5, AoP 95± 5, PAP 27± 5, LAP 12± 5 mmHg) with the RAP valve open.

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

BACKUP FREEDOM DRIVER CHECK

Remove Driveline caps and place one Onboard Battery into the Driver	YES ☐	NO ☐
Remove Filter Cover using supplied tools. Inspect filter for debris and clean as needed	YES ☐	NO ☐
Remove Dummy Battery from the Driver and insert second Onboard Battery into the Driver	YES ☐	NO ☐
Attach wall power and verify an illuminated solid green light on Power Adaptor and AC Power Supply	YES ☐	NO ☐
Verify that Onboard Batteries are charging (last green light illuminated on Battery Fuel Gauge blinks)	YES ☐	NO ☐
Connect Freedom Drivelines to Patient Simulator set to normotensive parameters	YES ☐	NO ☐
Verify Driver Display shows BPM, FV, and CO readings when Display Button is pressed	YES ☐	NO ☐
Verify Driver Display shows Cardiac Output (CO) of 4.9 – 9.7 l/m	YES ☐	NO ☐
Verify Driver Display shows Beats Rate (BPM) of 125 ± 5 bpm	YES ☐	NO ☐
Verify the Driver operates without alarms	YES ☐	NO ☐
Verify that Onboard Batteries are fully charged (five green lights illuminate on Battery Fuel Gauge)	YES ☐	NO ☐
Disconnect the Freedom Driver from Patient Simulator	YES ☐	NO ☐

POWER REMOVAL ON BACKUP DRIVER

Remove external power from the backup Freedom Driver	YES ☐	NO ☐
Remove one Onboard Battery from the Battery Well	YES ☐	NO ☐
Place the Dummy Battery into the available Battery Well	YES ☐	NO ☐
Remove the second Onboard Battery from the Battery Well and restore Driveline caps	YES ☐	NO ☐
Leave the Power Adaptor attached to the backup Freedom Driver	YES ☐	NO ☐

PRIMARY FREEDOM DRIVER CHECK

Remove Driveline caps and place one Onboard Battery into the Driver	YES ☐	NO ☐
Remove Filter Cover using supplied tools. Inspect filter for debris and clean as needed	YES ☐	NO ☐
Remove Dummy Battery from the Driver and insert second Onboard Battery into the Driver	YES ☐	NO ☐
Attach wall power and verify an illuminated solid green light on Power Adaptor and AC Power Supply	YES ☐	NO ☐
Verify that Onboard Batteries are charging (last green light illuminated on Battery Fuel Gauge blinks)	YES ☐	NO ☐
Connect Freedom Drivelines to Patient Simulator set to normotensive parameters	YES ☐	NO ☐
Verify Driver Display shows BPM, FV, and CO readings when Display Button is pressed	YES ☐	NO ☐
Verify Driver Display shows Cardiac Output (CO) of of 4.9 – 9.7 l/m	YES ☐	NO ☐
Verify Driver Display shows Beats Rate (BPM) of 125 ± 5 bpm	YES ☐	NO ☐
Verify the Driver operates without alarms	YES ☐	NO ☐
Verify that Onboard Batteries are fully charged (five green lights illuminate on Battery Fuel Gauge)	YES ☐	NO ☐
Connect the additional Power Adaptor and AC Power Supply to the primary Freedom Driver	YES ☐	NO ☐
Attach wall power and verify illuminated solid green light on additional Power Adaptor and AC Power Supply	YES ☐	NO ☐
Disconnect the Freedom Driver from Patient Simulator	YES ☐	NO ☐
Turn off primary Freedom Driver and restore Driveline caps while moving it to the patient's room	YES ☐	NO ☐

If any of the answers above are "No", do not connect the patient and call Clinical Support Hotline Number +49-700-796227342 or +1 866-771-9437 or +1-520-545-1234 for US.

Performed By (Print First and Last Name) _____**Date**:_____

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

FREEDOM DRIVER SYSTEM TEST PROTOCOL

PRIMARY FREEDOM DRIVER SERIAL #: _____
BACKUP FREEDOM DRIVER SERIAL #: _____
HOSPITAL NAME: _____

PATIENT PREPARATION

Indicate Patient number to be attached (eg:TAH-t Patient #35)……..Patient # _____

Driver System Currently on Patient: Type _____Primary Serial #_____ Secondary Serial # _____

Indicate Patient Beat Rate setting on primary Freedom Driver……..……_____BPM

BPM set on backup Driver to match BPM on primary Driver……YES ☐ NO ☐

Attach Tamper Evident Label over the setting dial cover of both primary and backup Freedom Drivers..YES ☐ NO ☐

Place Patient Info Card and Quick Guide into Shoulder Bag and Backpack……..YES ☐ NO ☐

Load the following items into the Accessory Bag:

2 to 4 fully charged Onboard Batteries... YES ☐ NO ☐		Additional Power Adaptor..... YES ☐ NO ☐	
Hospital AC Power Supply..... YES ☐ NO ☐		Filter Pack including Screwdriver..... YES ☐ NO ☐	
Car Charger..... YES ☐ NO ☐		One Patient Tool Kit..... YES ☐ NO ☐	

Load one Driver with Driveline caps in Shoulder Bag..... YES ☐ NO ☐

Load one Driver with Driveline caps and a Hospital AC Power Supply in Backpack..... YES ☐ NO ☐

Provide one Battery Charger to the patient..... YES ☐ NO ☐

Send a copy of this form to SynCardia Systems, LLC BY FAX to +1 520-903-1782..... YES ☐ NO ☐

NOTE: Two Home AC Power Supplies must be provided to the patient upon discharge from the hospital.

If any of the answers are "No", do not connect the patient and call Clinical Support Hotline Number +1 866-771-9437 or +1-520-545-1234

Performed By (Print First and Last Name) _____**Date**:_____

Appendix 3

Freedom Battery Charger Operational Check Form

Freedom Battery Charger Operational Check Form

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

Unit Serial Number: _____

Hospital: _____

- **Keep a copy of this form for your records.**
- **Note: This procedure should be performed by trained persons only. Perform this test upon receipt and prior to distribution to patients.**

SET UP

1. Perform a visual inspection of the Battery Charger. Do not proceed if the Battery Charger has visible damage or exposed internal parts.
2. Connect the AC Power Supply to the Battery Charger (**See Figure 1-1**).
3. Connect the AC Power Supply wall cord to a wall outlet. The green light on the AC Power Supply should be illuminated.

CHECK OUT

4. Insert a depleted Onboard Battery into the first Battery Charger bay (**See Figure 1-2**).
5. Confirm that the Onboard Battery is charging by depressing the Battery Charge Button on the top of the battery. A charging battery will have a blinking light on the Battery Fuel Gauge.

Does the Onboard Battery inserted in the first Battery Charger bay have a blinking light on the Battery Fuel Gauge?	YES ☐ NO ☐

6. If Yes, remove the battery from the bay, wait 20 seconds, and repeat for each bay:

Does the Onboard Battery inserted in the second Battery Charger bay have a blinking light on the Battery Fuel Gauge?	YES ☐ NO ☐
Does the Onboard Battery inserted in the third Battery Charger bay have a blinking light on the Battery Fuel Gauge?	YES ☐ NO ☐
Does the Onboard Battery inserted in the fourth Battery Charger bay have a blinking light on the Battery Fuel Gauge?	YES ☐ NO ☐

Note: If four (4) depleted Onboard Batteries are available, checkout steps 4 – 6 can be completed simultaneously.

7. If the response to any of these questions is “NO”, please see the Troubleshooting Instructions below. If the Troubleshooting Instructions do not correct the problem, please contact the SynCardia Systems, LLC Help Line at (866) 771-9437.

Send a copy of this form to SynCardia Systems, LLC by FAX to 520-903-1782

Performed By: _____ **Date:** _____

Freedom Battery Charger Operational Check Form

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

Unit Serial Number: _____

Hospital: _____

FIGURES

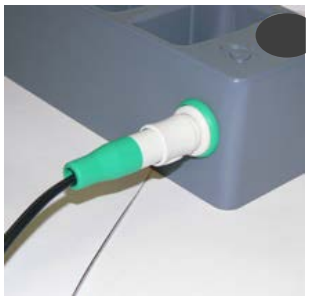


Figure 1-1
Connect AC Power Supply and Battery Charger

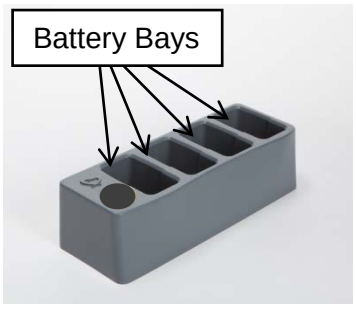


Figure 1-2
Battery Charger and bays

TROUBLESHOOTING INSTRUCTIONS

If there is no blinking green light on an Onboard Battery:

- The Onboard Battery may be fully charged already.
    - Remove it from the Battery Charger. Depress the Battery Charge Button. If 5 lights illuminate, the battery is fully charged.
- The Onboard Battery may not be fully inserted into the Battery Charger.
    - Make sure that the Onboard Battery is properly seated in the Battery Charger.
- The Battery Charger may not be receiving power.
    - Check to see if the AC Power Supply is properly connected to the Battery Charger (**See Figure 1-1**)
    - Check that the Wall Cord is connected to the AC Power Supply.
    - Check that the Wall Cord is not plugged into a wall outlet controlled through a wall switch that is in the off position.
- If these Troubleshooting Instructions did not correct the problem, please contact the SynCardia Systems, LLC Help Line at (866) 771-9437.