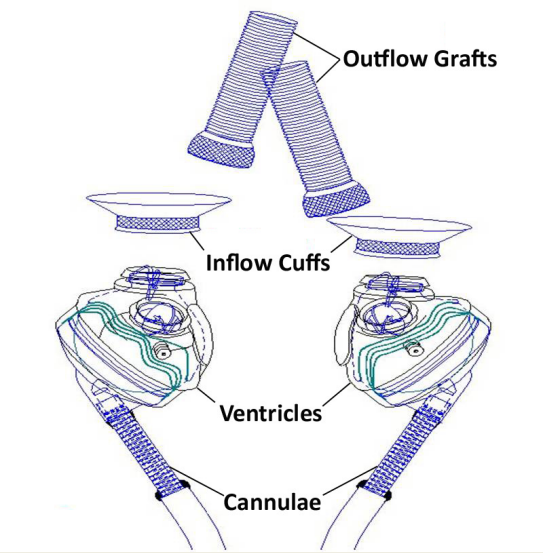
BUMCP ARTIFICIAL HEART & MCS PROGRAM S-TAH EDUCATION FOR OUT PT HD CENTER

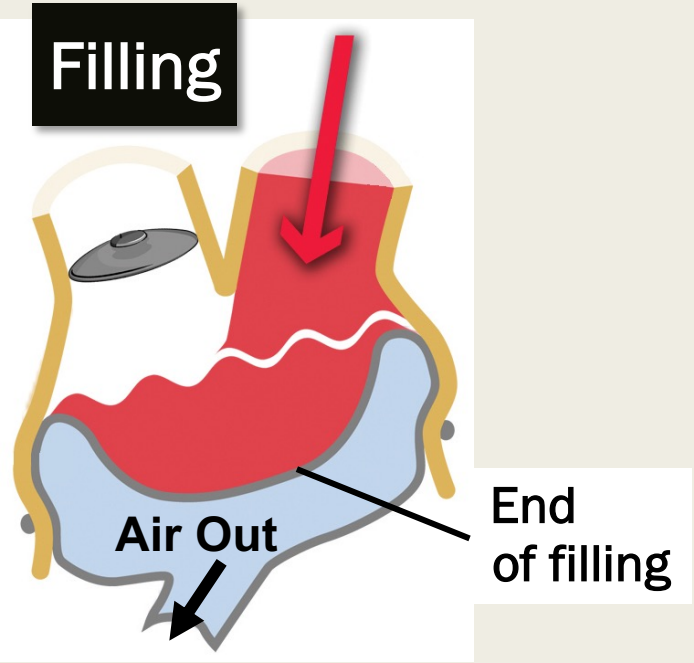
01/2020

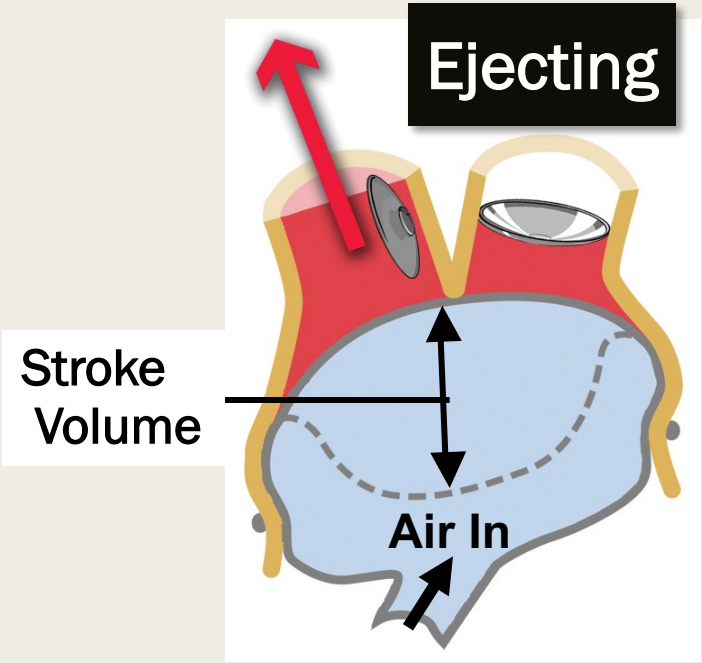
Overview and Operation



	70cc TAH-t	50cc TAH-t
Stroke Volume	70 mL	50 mL
Inflow Valve Diameter	27 mm	25 mm
Outflow Valve Diameter	25 mm	23 mm
Diaphragms	four (4) flexible polyurethane	
Maximum Output	10.5 LPM	7.5 LPM

Increasing venous return increases the stroke volume

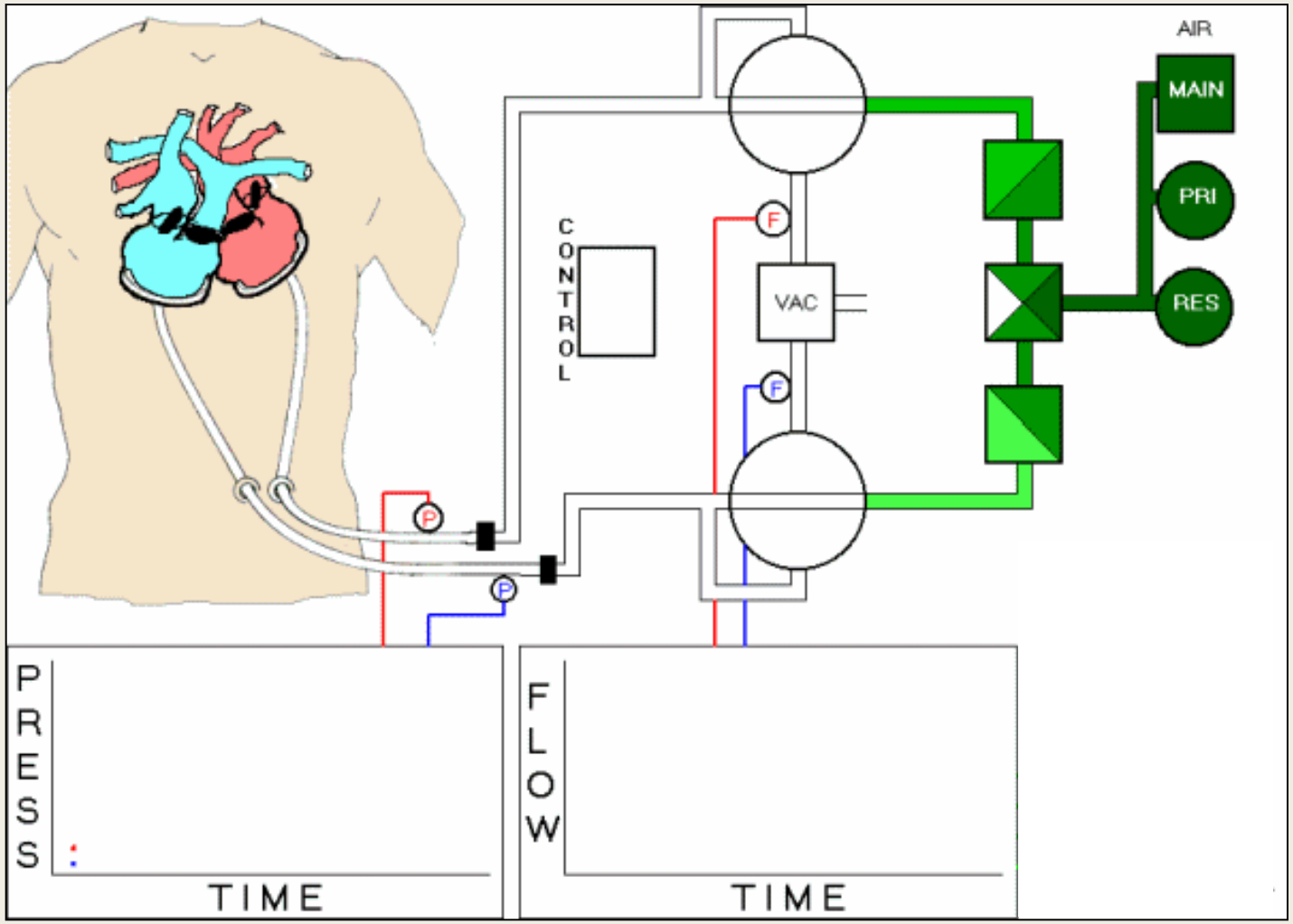




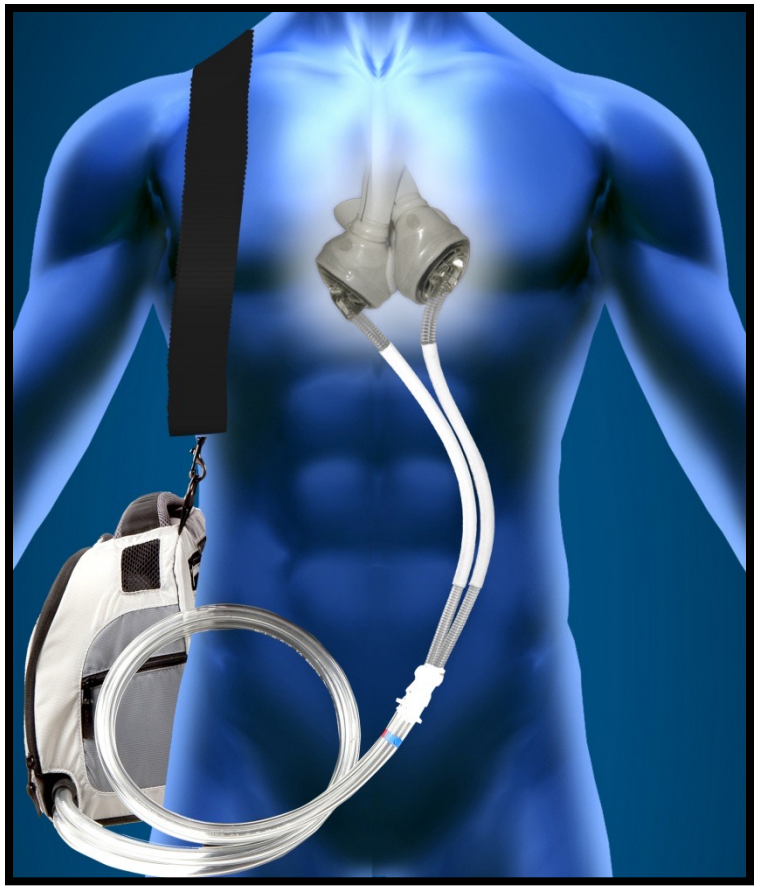
Adjust beat rate to achieve partial filling.

Adjust pressure to achieve full ejection of each ventricle.

Operating the TAH-t – Waveforms

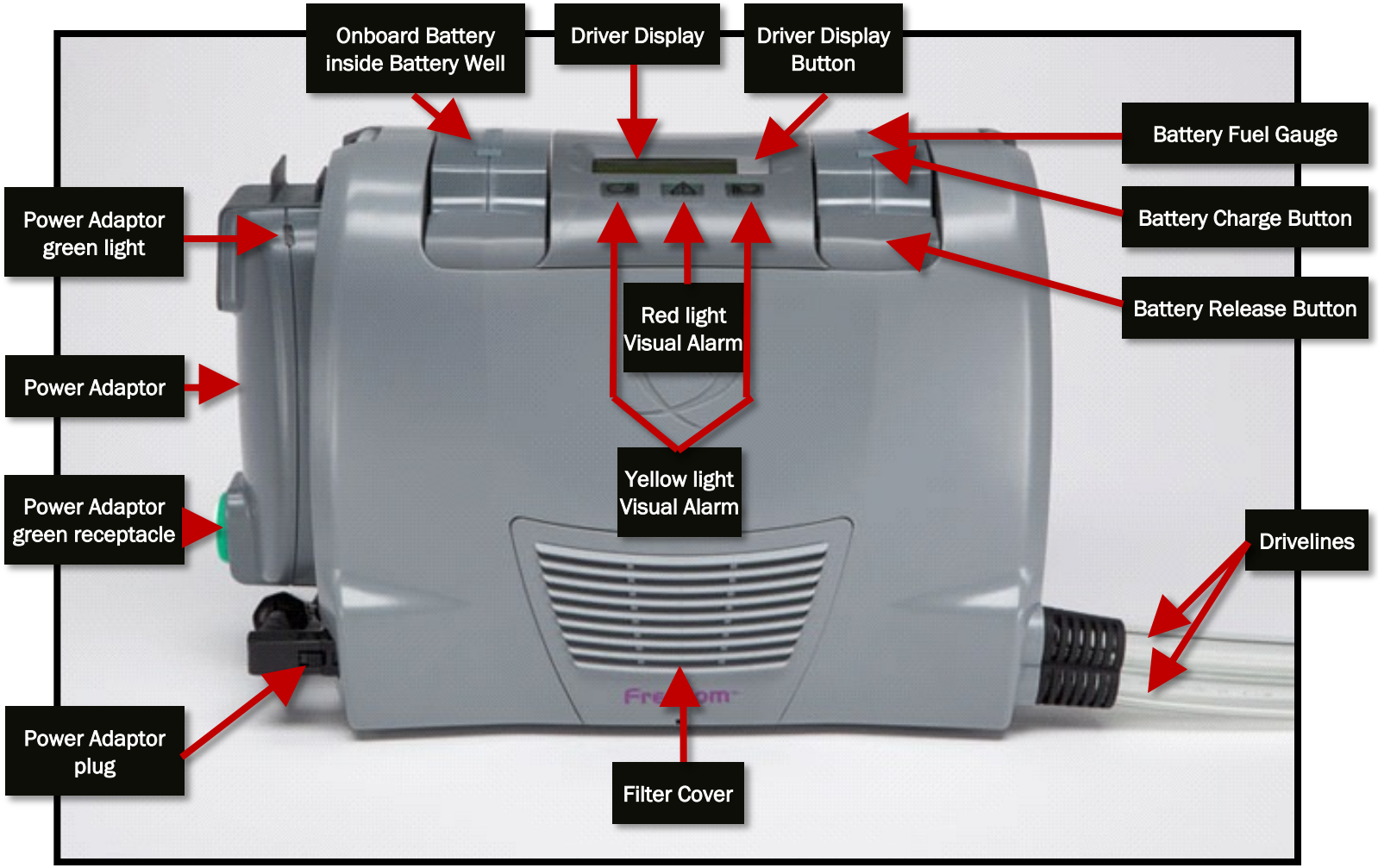


TAH-t with the Freedom Driver



- The Freedom Driver System is a multi-component electro-mechanical unit designed to provide pneumatic power to the implanted TAH-t.
- The Freedom Driver is the primary component of the Freedom Driver System
- Drivelines 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 Driver).
- The only adjustable setting in the Freedom Driver is the driver operating rate (Beat Rate).

Freedom Driver Parts



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Primary Freedom Driver

The **primary** Freedom Driver is the driver
connected to the implanted TAH-t.

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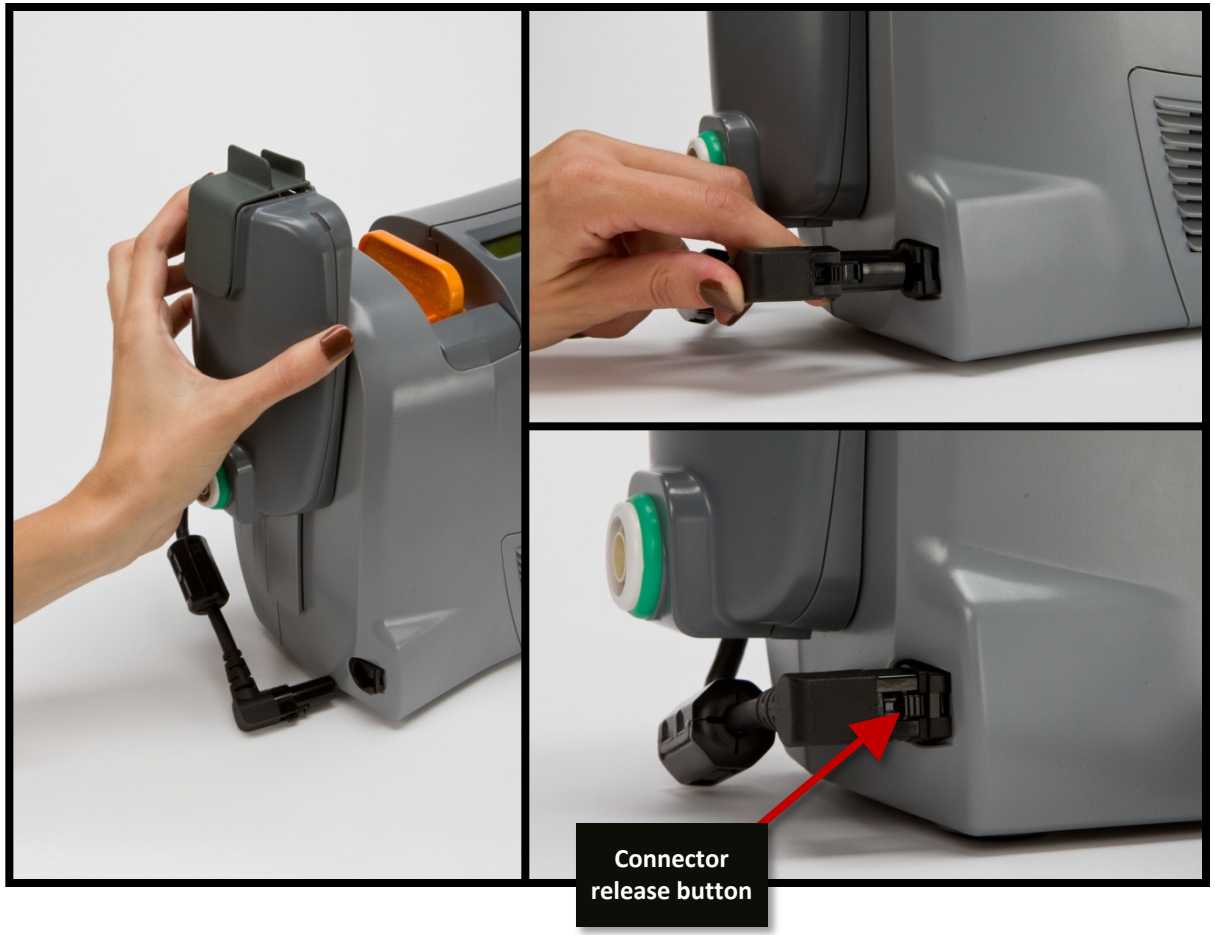
Power Adaptor

To attach the Power Adaptor to Driver, slide down onto rails and insert black connector.

To remove, press connector release button and pull away from Driver. Slide up off of rails.



Onboard Battery

- Four to six Onboard Batteries total
- Two fully charged Onboard Batteries provide approximately 2 hours of support
  (may vary according to Driver settings)
- Patient must always carry additional fully charged Onboard Batteries

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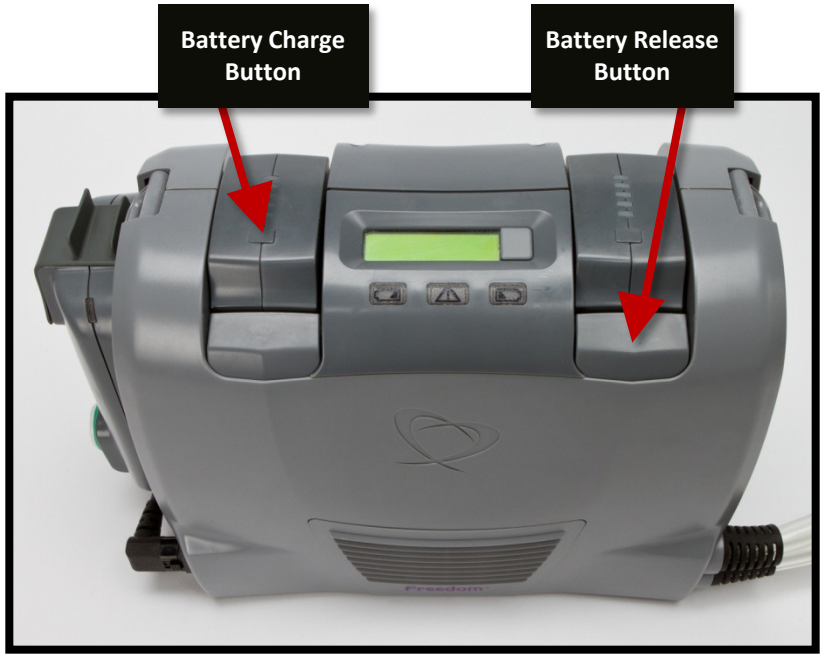
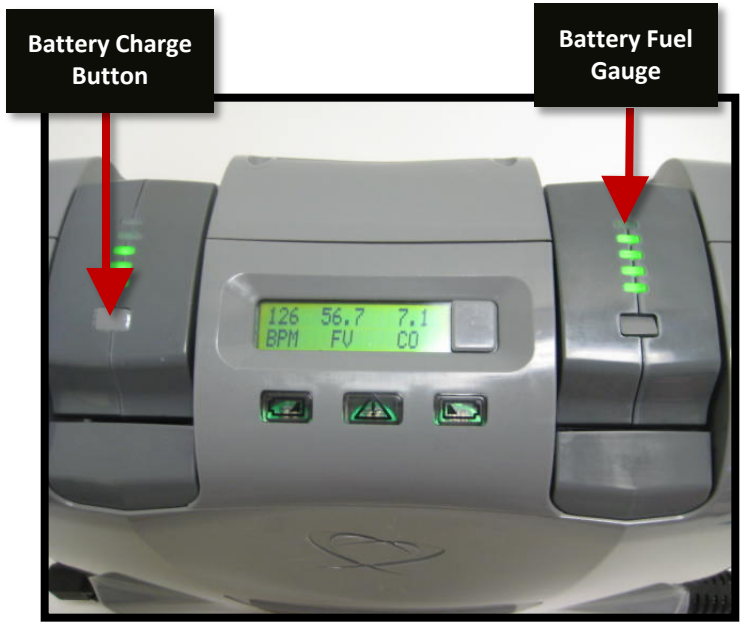
Onboard Battery Insertion and Removal



Only one battery can be removed at a time.

- To Insert charged Onboard Battery:
  - *Battery Charge Button and Battery Release Button must be next to each other*
  - *Push down on the Onboard Battery until the battery is locked in place*
- To remove Onboard Battery:
  - *Plug the Driver into an External Power source (wall power outlet or 12V vehicle power outlet)*
  - *Push down on the Battery Release Button and lift it out of the Battery Well*

Checking Onboard Battery Charge



- Press the Battery Charge Button.
- The Battery Fuel Gauge will show green lights on top of the Onboard Battery.
- Each light illuminated represents approximately 20% charge.
- All five lights illuminated indicate approximately 81% to 100% charge.

Battery Charger

- Plug the green connector from the AC Power Supply into the Battery Charger.
- Plug the other end of the AC Power supply into 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.
- 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 fully charged.

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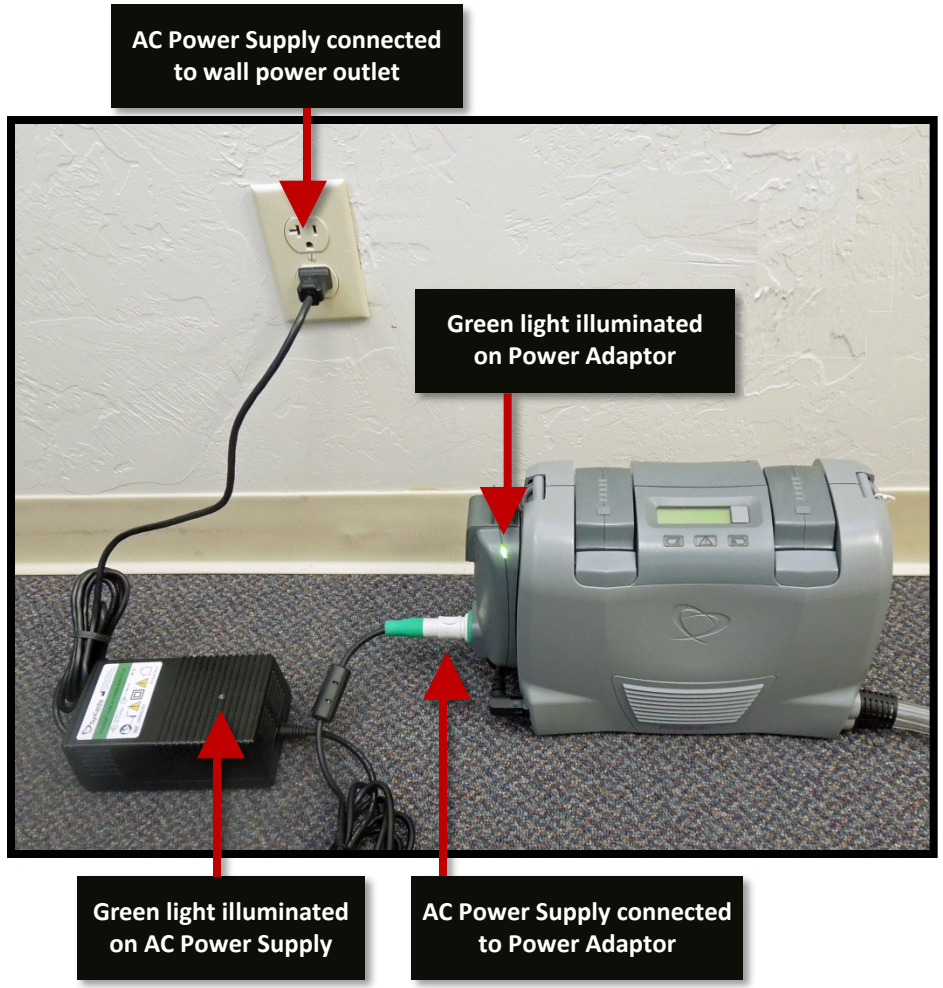
Hospital & Home AC Power Supplies

Home AC Power Supply

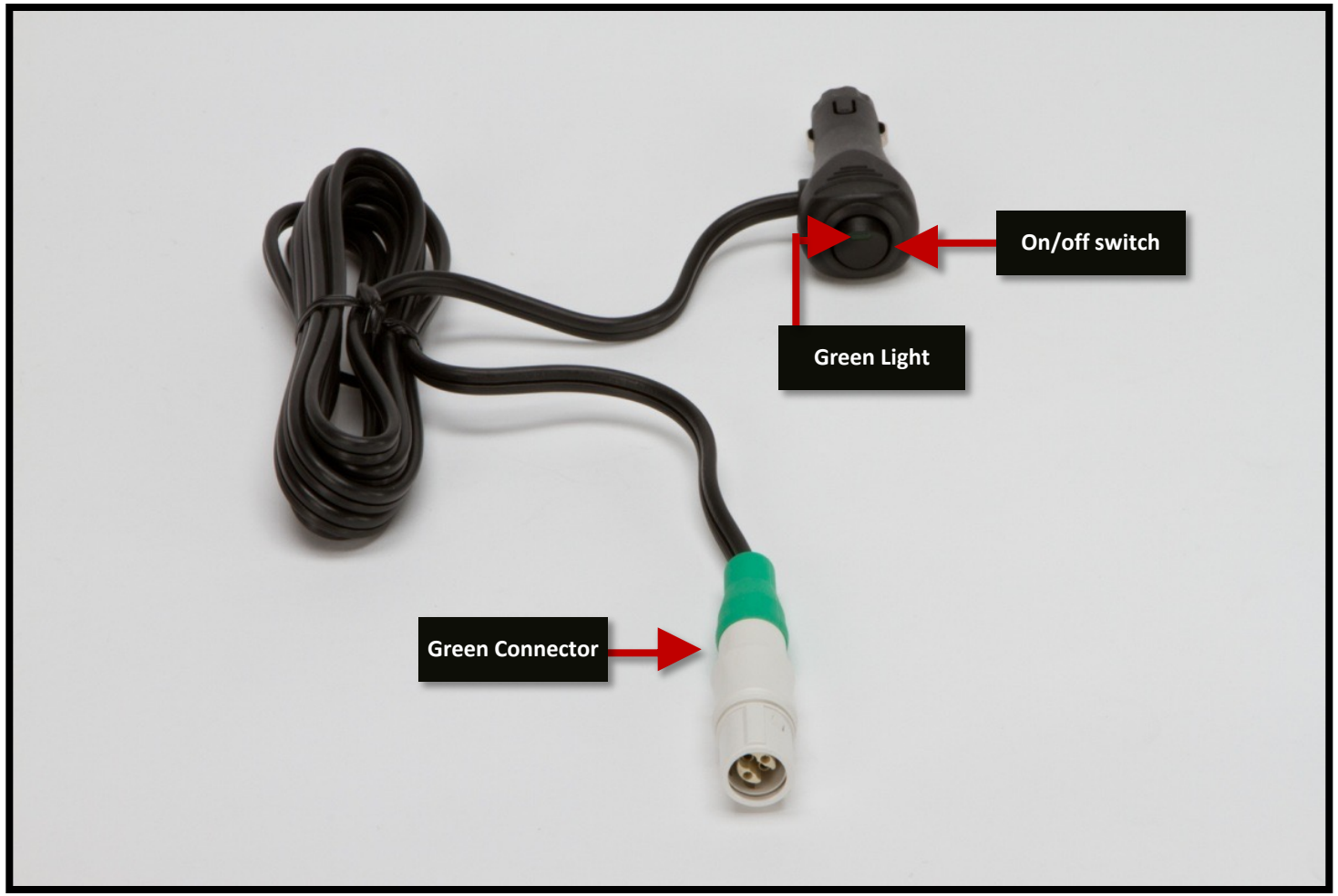
- Two Home AC Power Supplies are provided to the patient for Out-of-Hospital use.
- Whenever possible, connect the Freedom Driver to an External Power source to keep the Onboard Batteries fully charged.
- The Freedom Driver must be plugged into an External Power source and the connection verified to be secure and the indicator lights on the Power Supply and Power Adaptor must be illuminated solid green before the patient goes to sleep.

Connecting to External Power via the AC Power Supply

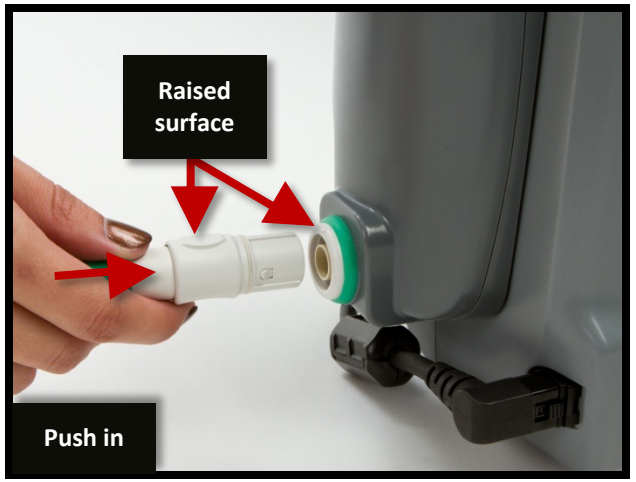


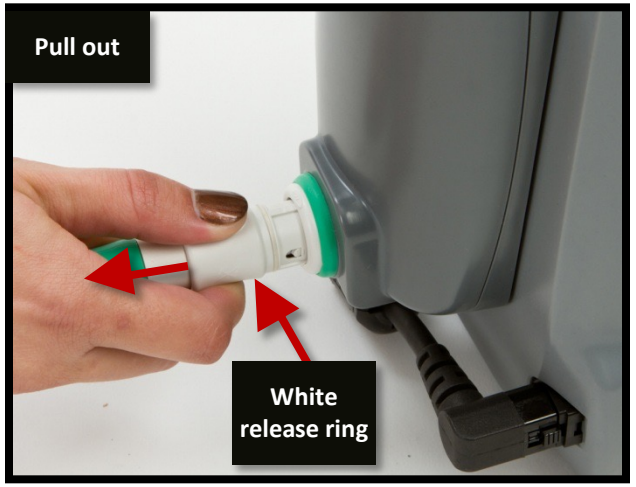
- Plug the green connector from the AC Power Supply into the Power Adaptor green receptacle.
- Plug the other end of the AC power supply into a wall power outlet.
- Confirm that the green light on the AC Power Supply **and** the Power Adaptor is illuminated.

Car Charger



Green Connector from AC Power Supply and Car Charger





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*
- *Push in the connector*

To remove the green connector:

- *Pull away the white release ring and remove the connector*

Shoulder Bag

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Backpack

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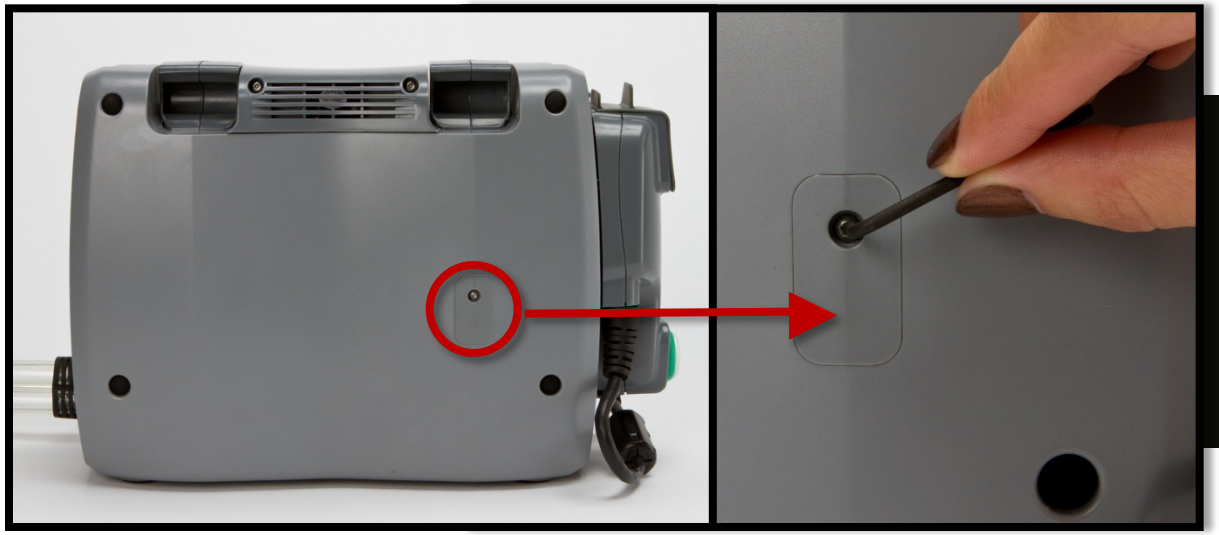
Patient Tool Kit

- White Wire Ties
  - *Inserted under the metal release button of the CPC connector to prevent accidental disconnection of the TAH-t Cannulae to the Freedom Drivelines*
- Wire Cutter Tool
  - *Used to cut the Wire Tie around the metal release button when switching from the primary to the backup Freedom Driver*
  - *Fits in the side pocket of the Shoulder Bag and Backpack*
- Black Hook and Loop Cable Ties
  - *May be used to attach the Drivelines to the Shoulder Bag or Backpack to minimize hanging of the Drivelines*

Adjustment of Beat Rate



Unscrew Setting Dial Cover with L Torx Wrench

Adjust Beat Rate with Slotted Screwdriver

To increase rate, turn Setting Dial clockwise

To decrease rate, turn counter-clockwise

Setting Dial

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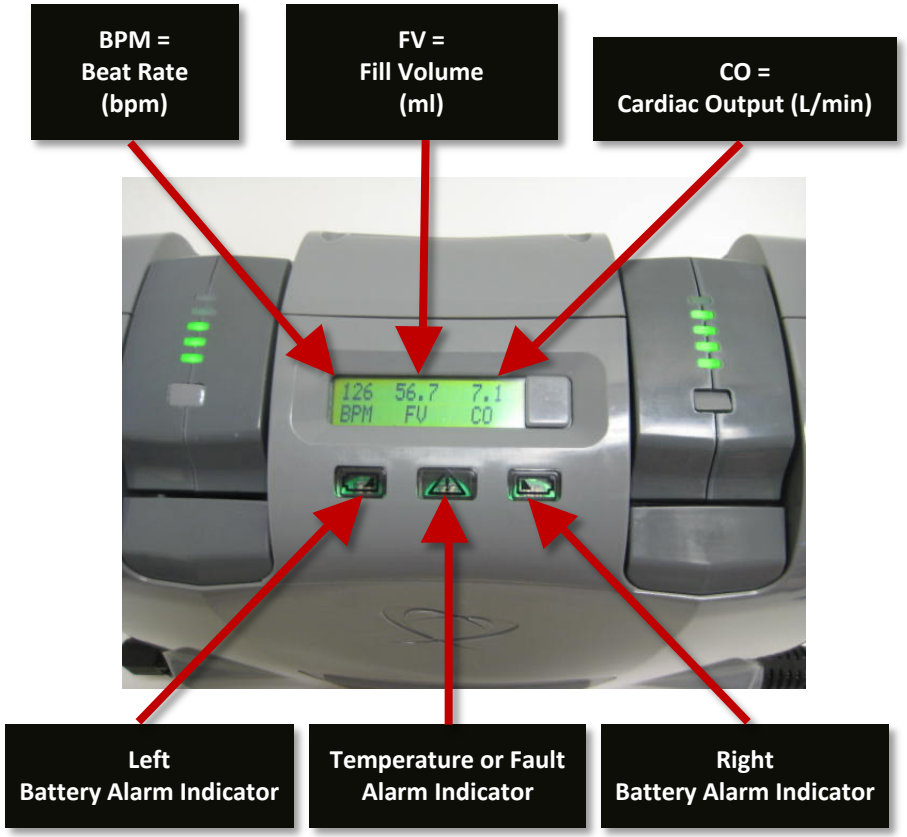
Driver Display and Visual Alarm Indicators



- The patient should check the Driver Display several times every day, to make sure that the values displayed on the screen are correct as recommended by the Hospital Contact Person.
- It is important that the patient and caregivers understand all the Alarms and what they need to do in each alarm situation.
- The patient must call their Hospital Contact Person for any problems with the Freedom Driver System.

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Freedom Driver Alarms

- Three Types of Alarms
  - *Battery Alarm*
  - *Temperature Alarm*
  - *Fault Alarm*
- Each Alarm indicated by:
  - *Visual Alarm* ***and***
  - *Audible Alarm*
- If two or more alarms are occurring at the same time, the highest priority alarm will take precedence.
- Do not ignore Alarms
- No way to mute Alarms
- The issue that caused the alarm must be **immediately** addressed

Battery Alarm

Indicated

- Beeping
- Blinking

Click on speaker icon to hear Battery Alarm

Battery Alarm

ALARM	HEAR	SEE	MEANING	WHAT YOU SHOULD DO
Battery Alarm	Loud **Intermittent** Tone	Yellow Battery LED **flashing**	One or both of the Onboard Batteries have less than 35% remaining charge (only two green lights display on the Battery Fuel Gauge)	Replace each low Onboard Battery, one at a time, with a charged Onboard Battery or connect to external power (NOTE: Once the batteries are charged above 35% the Battery Alarm will stop)
			Onboard Battery is incorrectly installed	Reinsert Onboard Battery until locked in place. If Battery Alarm continues, insert a new Onboard Battery
			One Onboard Battery is missing	Insert a charged Onboard Battery into Freedom Driver until locked in place

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Temperature Alarm

Indicated

- Beeping
- Blinking

Click on speaker icon to hear Temperature Alarm

Temperature Alarm

ALARM	HEAR	SEE	MEANING	WHAT YOU SHOULD DO
Temperature Alarm	Loud **Intermittent** Tone	Red Alarm LED **flashing**	The internal temperature of the Driver is too hot	Remove any objects that are blocking the Filter Cover and / or Fan and check filter
			The temperature of the Onboard Batteries is too hot or too cold	Replace each Onboard Battery, one at a time, with a charged Onboard Battery. Move the Freedom Driver to a cooler or warmer area

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Fault Alarm

Indicated

- Constar
- Solid re

Click on speaker icon to hear Fault Alarm

Fault Alarm

ALARM	HEAR	SEE	MEANING	WHAT YOU SHOULD DO
Fault Alarm	Loud **Continuous** Tone	Red Alarm LED **solid**	Low cardiac output potentially caused by Valsalva Maneuver: • Laughing • Strenuous coughing • Straining during a bowel movement • Lifting a heavy weight • Vomiting	Relax/interrupt valsalva maneuver
			Low cardiac output potentially caused by elevated systolic blood pressure	Manage as directed by physician and notify Hospital Contact Person.

Fault Alarm Table continues on next slide.

Fault Alarm continued

ALARM	HEAR	SEE	MEANING	WHAT YOU SHOULD DO
Fault Alarm	Loud **Continuous** Tone	Red Alarm LED **solid**	Kinked or disconnected drivelines	Straighten or connect drivelines
			Driver is connected to External Power without at least one correctly inserted Onboard Battery	Insert a charged Onboard Battery into Freedom Driver until locked in place
			One or both of the Onboard Batteries have less than 30% remaining charge	Replace each low Onboard Battery, one at a time, with a charged Onboard Battery or connect to external power. (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)
			Malfunction of the Driver	If the above steps do not stop the Fault Alarm, switch to Backup Freedom Driver. Return to hospital for a new Backup Freedom Driver.

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Backup Mode

- Backup Mode is the mode of operation that provides support to the implanted TAH-t if there is a malfunction in the primary Freedom Driver.
- Allows the Driver to continue to provide biventricular support to the TAH-t while maintaining pressures, vacuums and rates for both the left and right ventricles.
- Backup Mode happens automatically and starts a Fault Alarm that cannot be resolved.
- The patient must switch to the backup Freedom Driver immediately.

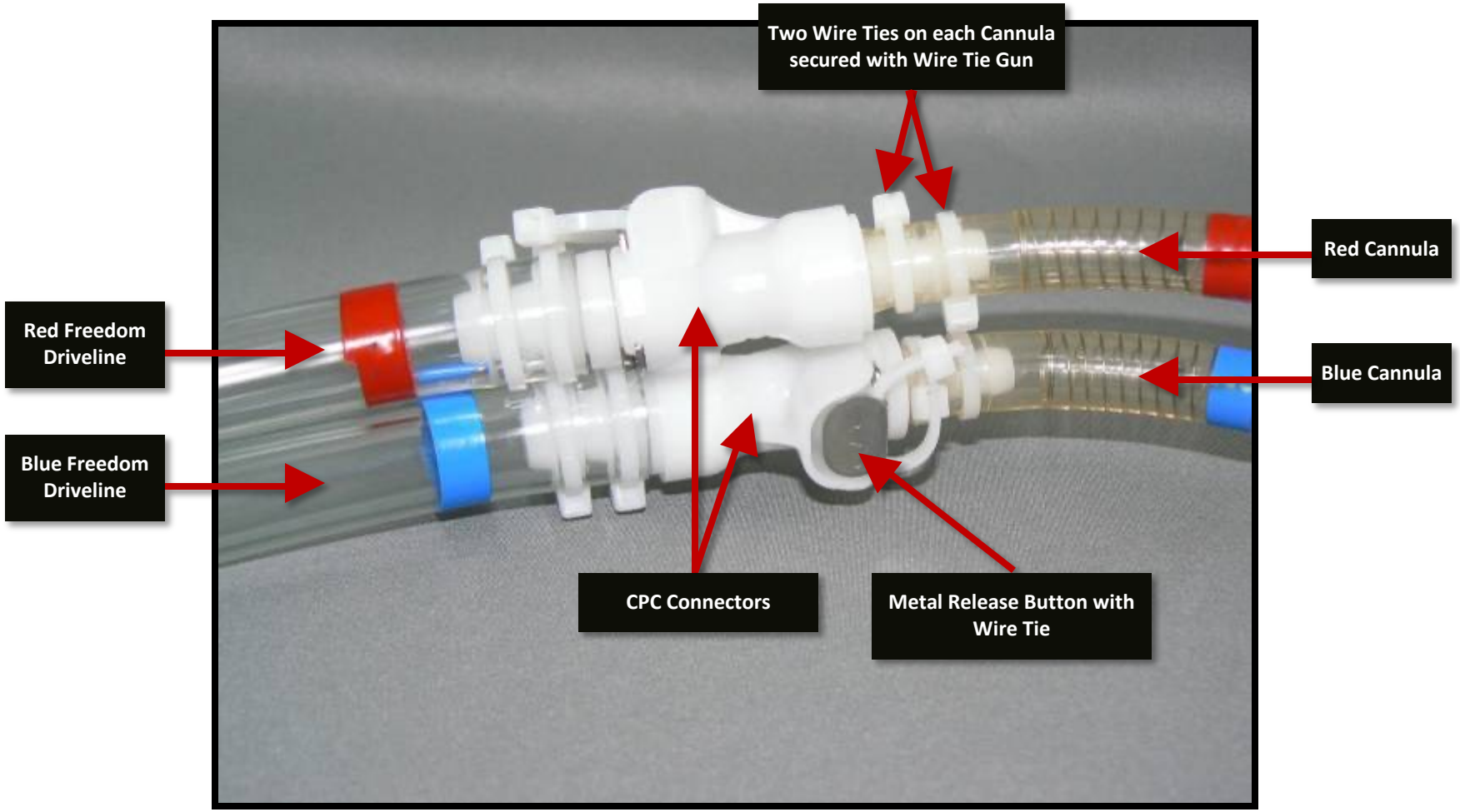
15 Minute Fault Alarm Delay

- No Fault Alarm for low Cardiac Output for first 15 minutes after Driver has been initially turned on

- If the Fault Alarm comes on immediately upon powering up the Driver:
  - *Check the charge of both Onboard Batteries and confirm that the Battery Fuel Gauge illuminates more than two green lights on each battery*
  - *If the Onboard Batteries are low on charge, connect to external power and charge the batteries*
  - *If the Onboard Batteries are not low on charge, then there is a malfunction of the driver*
    - Do not connect the patient to the faulty Freedom Driver
    - Contact SynCardia immediately

- When connecting to the Freedom Driver:
  - *Make certain Drivelines are connected to TAH-t Cannulae*
  - *Do not kink the Drivelines*

Freedom Drivelines Connected to Cannulae
via the CPC Connectors



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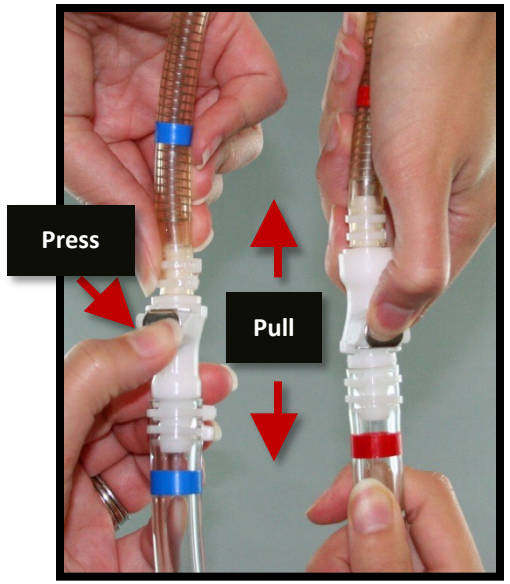
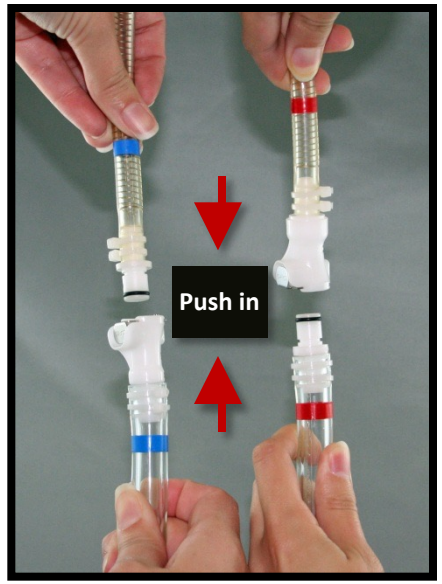
Switching from Primary to Backup Freedom Driver

- It is strongly recommended to have two people (patient and trained caregiver) exchange the primary Freedom driver for the backup Freedom Driver.

- Power on the Backup driver:
  - *Remove the driveline caps from the ends of the Drivelines*
  - *Insert one charged Onboard Battery*
  - *Remove the Dummy Battery*
  - *Insert the second charged Onboard Battery*
  - *If possible, connect the backup Driver into a wall power outlet*
  - *Verify that the backup Driver starts*

Switching from Primary to Backup Freedom Driver





- Cut the Wire Tie from the metal release button on the CPC connectors.
- Simultaneously blue to blue and red to red:
  - *Disconnect the Drivelines of the primary Driver from the TAH-t Cannulae*
  - *Immediately connect the drivelines of the backup Driver to the TAH-t Cannulae*
- Loop a new Wire Tie under the metal release button on the CPC connectors.
- Patient must notify Hospital Contact Person of the switch and return to hospital for a new backup Freedom Driver.
- The Hospital should notify SynCardia Systems that the Driver has been switched and return the faulty Driver.

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Monitoring

- EKG?- NONE
- Pulse?- YES, but rate is determined by TAH Driver and is fixed
- Blood pressure?- Yes, can be taken by automated cuff.
  - *Goal SBP 100-130 typically*
  - *Hypertension can cause decreased cardiac output if device cannot overcome systemic pressure to eject*
  - *If SBP decreased during HD run- assess patient, have patient/caregiver assess device parameters and call ON CALL MCS Coordinator*
  - *If any device alarms- call MCS Coordinator*
- Line placement: central lines must be placed under fluoroscopy to ensure tip of line is not approaching mechanical valve in ventricle
  - *Catheter can get caught in device and cause it to stop*

Monitoring

- Anticoagulation:
  - *Warfarin, asa and sometime additional antiplatelet medication (persantine)*
  - *Goal INR 2-3, asa dosed based on TEG monitoring*
- H/H- typically lower, acceptable 6/20 unless concern for bleed or symptomatic
- Blood products:
  - *SHOULD NEVER BE GIVEN WITHOUT SPEAKING WITH MCS TEAM!!*
- Drivelines:
  - *Should NEVER be kinked or disconnected*
  - *Sterile dressing changes done at home, dressings should remain in place*
    - Do not open dressing, if concerned- call MCS Coordinator
- Medications- SHOULD NEVER BE STARTED/STOPPED/CHANGED WITHOUT SPEAKING WITH MCS TEAM
- Lab work- standard weekly lab work and INR done by MCS team.
  - *If additional labs are required, please consult with MCS Team.*

Risk

- Stroke
- Infection- EVERY EFFORT SHOULD BE MADE TO REDUCE RISK OF INFECTION
- Device malfunction
- Fluid imbalance

Other considerations

- NO MRI
- NO CHEST COMPRESSIONS
- NO DEFIBRILLATION
- CALL 24HR CALL NUMBER WITH ANY QUESTIONS, CONCERNS, CHANGES

BUMCP Artificial Heart & Mechanical Circulatory Support Program

Office (non-urgent calls) 602-839-9300

24hr ON CALL RN MCS COORDINATOR Cell 602-819-7910