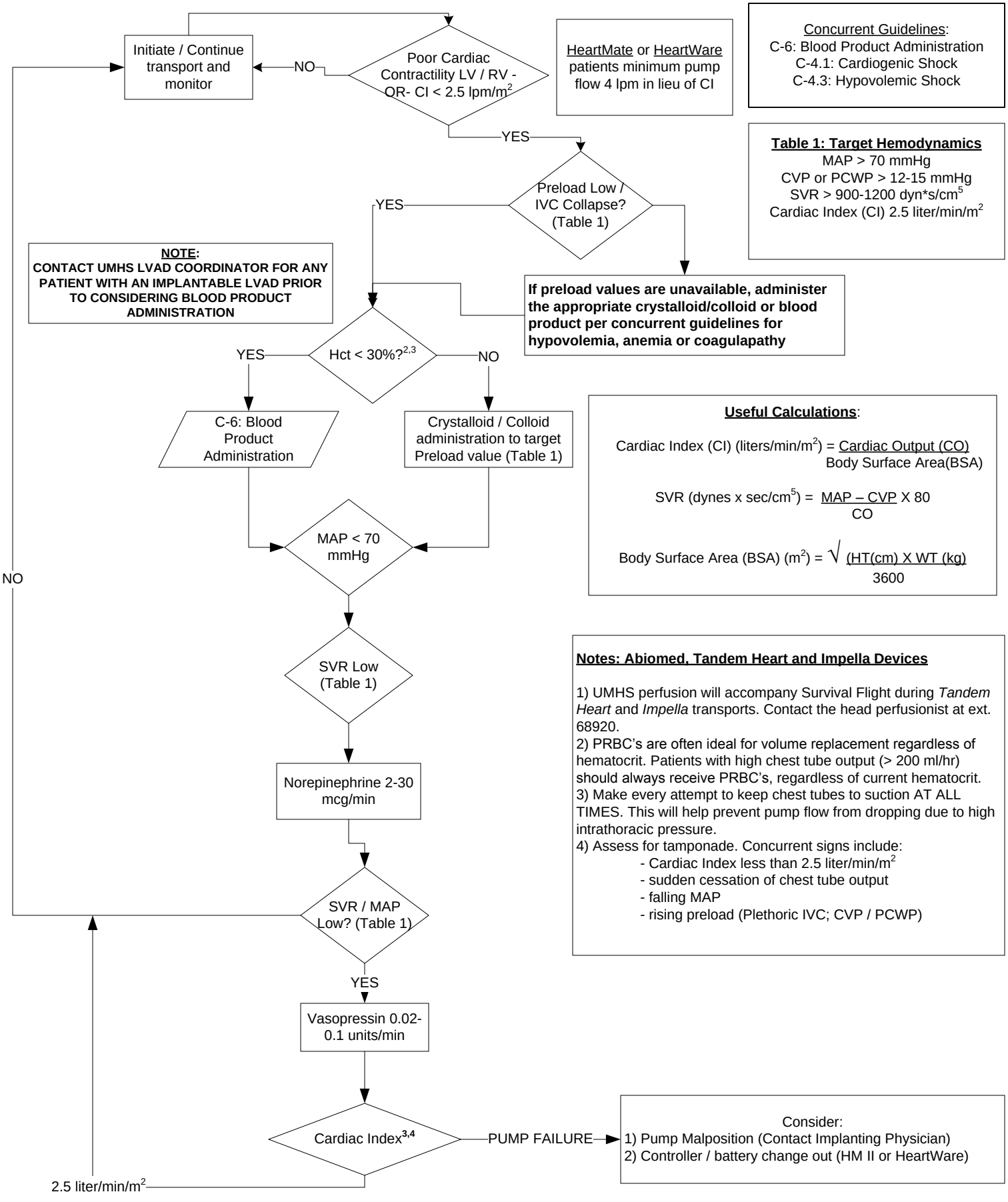
University of Michigan Survival Flight Clinical Guideline: C-2

Cardiac Assist Device Transports

A Cardiac / Ventricular Assist Device can augment function of the left ventricle, right ventricle or provide *Bi-ventricular* support. It temporarily and artificially aids the natural pumping action of the heart, depending on which side of the heart has failed. The purpose of this protocol is to ensure optimal care and a controlled environment during transport with the appropriate equipment and appropriate medical crew configuration.



Concurrent Guidelines:
C-6: Blood Product Administration
C-4.1: Cardiogenic Shock
C-4.3: Hypovolemic Shock

Table 1: Target Hemodynamics
MAP > 70 mmHg
CVP or PCWP > 12-15 mmHg
SVR > 900-1200 dyn*s/cm^5
Cardiac Index (CI) 2.5 liter/min/m^2

NOTE:
CONTACT UMHS LVAD COORDINATOR FOR ANY PATIENT WITH AN IMPLANTABLE LVAD PRIOR TO CONSIDERING BLOOD PRODUCT ADMINISTRATION

Useful Calculations:

Cardiac Index (CI) (liters/min/m^2) = Cardiac Output (CO) / Body Surface Area(BSA)

SVR (dynes x sec/cm^5) = (MAP – CVP) / CO X 80

Body Surface Area (BSA) (m^2) = $\sqrt{\frac{\text{HT(cm) X WT (kg)}}{3600}}$

Notes: Abiomed, Tandem Heart and Impella Devices

1) UMHS perfusion will accompany Survival Flight during *Tandem Heart* and *Impella* transports. Contact the head perfusionist at ext. 68920.
2) PRBC's are often ideal for volume replacement regardless of hematocrit. Patients with high chest tube output (> 200 ml/hr) should always receive PRBC's, regardless of current hematocrit.
3) Make every attempt to keep chest tubes to suction AT ALL TIMES. This will help prevent pump flow from dropping due to high intrathoracic pressure.
4) Assess for tamponade. Concurrent signs include:
- Cardiac Index less than 2.5 liter/min/m^2
- sudden cessation of chest tube output
- falling MAP
- rising preload (Plethoric IVC; CVP / PCWP)

Consider:
1) Pump Malposition (Contact Implanting Physician)
2) Controller / battery change out (HM II or HeartWare)

Implemented 2004; Revised February 2017 (PMM/CS)

Troubleshooting Pump Flow Problems

NOTE: PATIENT COMPLAINTS OF DIZZINESS OR FEELING OF IMPENDING DOOM SHOULD PROMPT THE CLINICIAN FOR IMMEDIATE EVALUATION OF PATIENT AND SYSTEM

Inflow Side of the Pump

1. Hypovolemia
2. Right Heart Failure (Left Heart Failure addressed with VAD)
    a. Inotropic support to augment right cardiac contractility
    b. Volume resuscitation
    c. Manipulation of Pulmonary Vascular Resistance (PVR)
        1. EtCO2 manipulation (an inverse relationship exists between CO2 and PVR)
        2. Pulmonary vasodilators (e.g., nitric oxide)
3. Cardiac tamponade
    a. if this is suspected, ensure chest tubes (if applicable) are patent and attached to suction
    b. Contact medical control for further guidance
4. Arrhythmias
    a. Tachy- and bradyarrhythmias addressed per current ACLS guidelines
    b. Heart Mate patients:
        1. disconnect device from power source and work toward patient
        2. After cardioversion reconnect starting from the patient, working back toward the power source
5. Pulmonary Hypertension
    a. Manipulation of PVR (see above)

Outflow Side of the Pump

1. Centrifugal pumps (eg., DuraHeart, HeartWare) are *afterload* sensitive. Flow will tend to decline as systemic vascular resistance (SVR) increases.
2. Consider afterload reduction agents for a MAP > 80 mmHg

Impella® 2.5

General Information:

-Inserted percutaneously (2.5)
-Catheter positioned across aortic valve
-Actively moves blood from LV to Ao

Max mean flow rate with no native output is 2.5 lpm

-With no native cardiac output this will be inadequate to sustain life for most patients
-Utilize SF Protocol C-9.1 (Cardiogenic Shock), Management Algorithm and "Troubleshooting Pump Flow" sections in order to maximize patient's native cardiac output

Catheter Migration

-Slack in catheter and screw pump momentum causes catheter to migrate down in to the LV (like a "boat motor")
No pressure change in pump head
-If malpositioned in the Aorta (Ao)
-Flat sine wave indicating a narrow pulse pressure

NOTE: **If LV not pumping, sensors will think that the catheter / pump is out of position and will indicate this on the console**

LV Migration:
-Wide pulse pressure
-Interventions to prevent malposition:
-Minimize excessive patient leg movement
-HOB less than 30 degrees

Transport Considerations:

-No synchronization with ECG required
-Pump not affected by altitude changes
-Equipment components small, making it ideal for transport
-Battery life < 1 hour

Patient assessment:

-Puncture site
-Pump position
-Check lower extremity pulses

Heart II Mate Considerations

1. The Heart Mate II is an "axial flow" device. It is non-pulsatile and therefore pulses may not be palpable on clinical exam. Since pulse pressure will more than likely be narrow, a mean arterial pressure may be all that is obtainable. Keep MAPs 70-90 mmHg
2. When not connected to the Power Module (formerly Power Base Unit (PBU)) fully charged batteries provide approximately 6 hours of untethered support.
3. Determine the need to contact 4C (x 66500 or 66501) in order to obtain spare systems controller or batteries.
4. Before disconnecting patient from the Power Module, document pump rate, flow and stroke volume.
5. Heart Mate Patients are to receive **LEUKOCYTE POOR, TYPE AND SCREEDNED BLOOD ONLY!!**
6. **Prior to liftoff, it is helpful to ascertain whether or not the patient has their Power Module, spare batteries and spare systems controller**
7. Chest compressions (CPR) on someone that has a Heart Mate is a FINAL RESORT option. Contact Medical Control in CVCICU (X66514) for consultation.

PARAMETERS TO ANNOTATE FOR A PATIENT WITH A HeartMate II and THEIR MEANING
(Ascertain the patient's normal values)

Pump Speed: This is **fixed** and set during implantation. A suction event (or drop in preload) will precipitate a drop in speed to the lower set pump speed limit. Large changes in speed may indicate pump problems or changes in patient volume status.
(NORMAL RANGE 8800-10,000 rpm)

Pump Power: A direct measurement of motor voltage and current. Changes in pump speed, flow or physiologic demand can affect pump power. Gradual power increases (over hours or days) may signal a deposition or thrombus.
(NORMAL RANGE 6-7 WATTS)

Pump Flow: This is an extrapolated value based upon pump power. Inaccuracies may occur in this value with changes in power based upon thrombus formation (an inaccurately high flow reading may occur). Conversely, an occlusion of the flow path will decrease flow and cause a corresponding decrease in power.
(NORMAL RANGE 4-5 lpm)

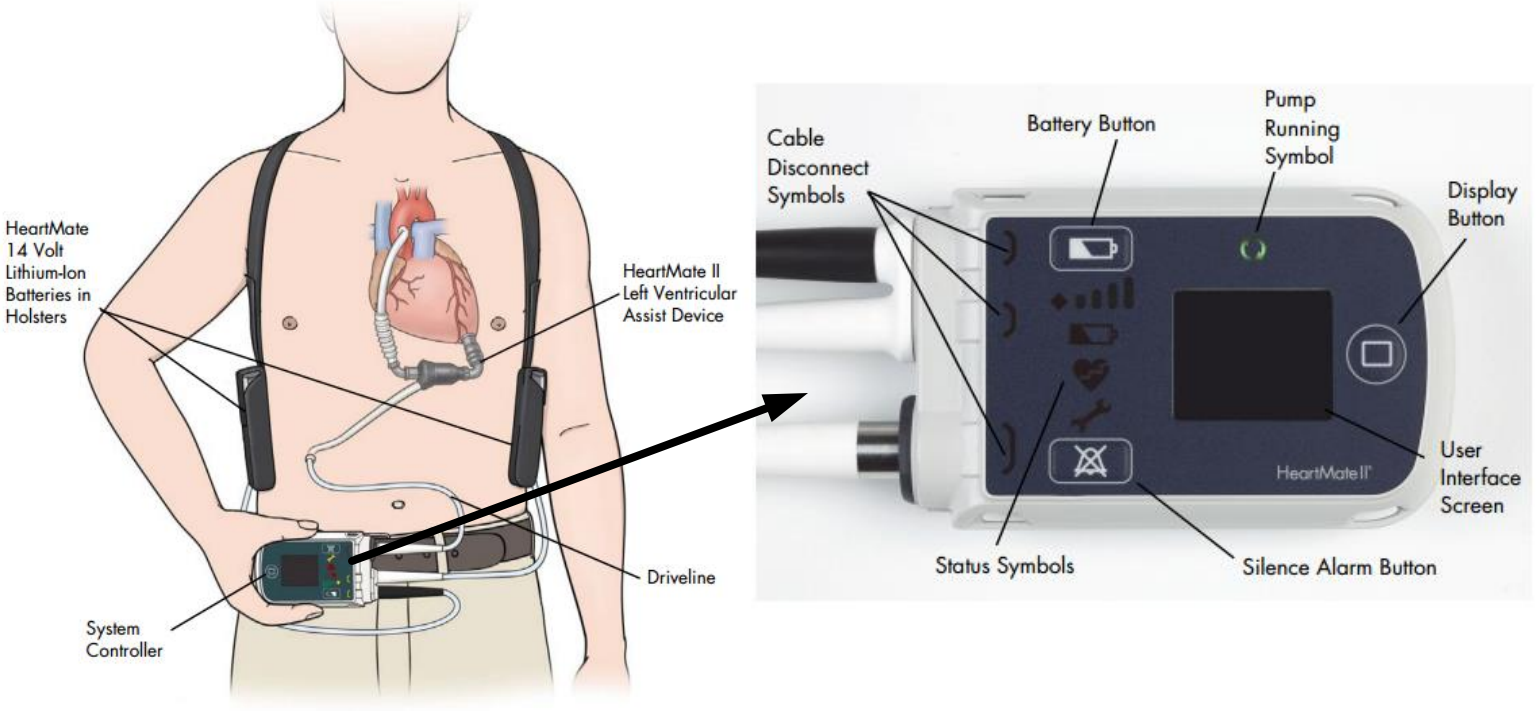
In cases where the right heart is not feeding blood in to the left ventricle fast enough, the pump will lower its inflow pressure (left ventricle), increasing the pump differential pressure and reducing flow to match right heart floe.

Should flow delivered by the right heart exceed the capacity of the pump, the pump inflow pressure will rise. This will cause the pump differential pressure to decrease and the flow generated by the pump to increase.

Pulsatility Index (PI): Represents cardiac pulsatility (range 1 to 10). The magnitude of this value is related to the amount of assistance provided by the LVAD.
(NORMAL VALUE 5)

Higher values indicate more ventricular filling (pump providing LESS support to the LV).

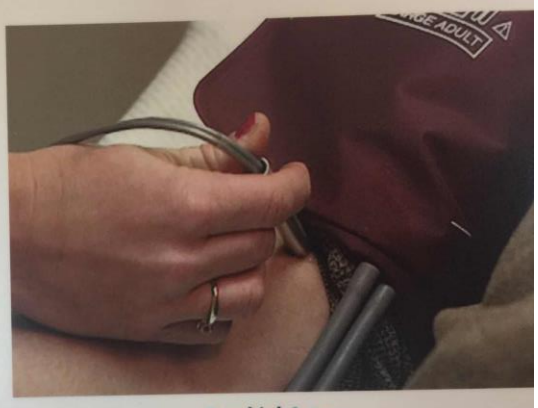
Lower values indicate less ventricular filling and lower pulsatility (pump providing MORE support)



Blood Pressure Assessment in a HeartMate II Patient

Note: *Due to the continuous flow of the HeartMate II, it may be difficult to obtain a blood pressure without a doppler.*

- Place the blood pressure cuff on the upper arm and apply transmission gel to the skin over the brachial artery.
- Position the probe over the artery until pulse is heard. Keep the pressure light enough so that the artery is not compressed.
- Inflate the blood pressure cuff until the arterial pulse is no longer audible.
- Slowly deflate the cuff until the first sound can be heard.
- Document this single number as the blood pressure.
- Recommended range for HeartMate II patients is 70 to 80 mmHg, not to exceed 90 mmHg.
- Review patient's history log to assure doppler pressure is not > 90 mmHg.



Brachial Artery

HeartMate II®
Left Ventricular Assist System

Pump Parameter Overview

There are four parameters monitored on the HeartMate II: **Speed**, **Flow**, **Power** and **Pulsatility Index**. No single parameter is a surrogate for monitoring a patient's clinical status. It is important to consider trends. Each patient's values are specific to their pump.

SPEED

- Speed can only be changed using the system monitor
  - **If speed is turned up, more blood is pulled from the LV = ↓LV chamber size**
  - **If speed is turned down, less blood pulled from the LV = ↑LV chamber size**
- The System Monitor displays the pump speed in revolutions per minute (rpm). This value matches the actual speed within ±100 rpm under normal conditions

POWER

- Device power is a direct measurement of pump motor voltage and current. Changes in pump speed, flow, or physiological demand can affect pump power

Look at trends over days (patient daily log)	*Report trend increases & decreases of 2.0 Watts*	*Report double digit power demands ≥10.0 watts*

FLOW

- Flow is an **estimate** that is derived from a calculation of fixed speed and power
- Flow and power have a linear relationship: **↑Power = ↑Flow estimate** **↓Power = ↓Flow estimate**
  - If the flow estimate falls outside the expected operational range or acceptable linear region, "+++" or "- - -" is displayed. This prevents the display of inaccurate flow information
  - If flow falls below 2.5 L/min, the HM II will alarm "low flow"
- **Afterload Sensitive:** If afterload (blood pressure) is high, the pump will not increase speed to overcome the high outflow pressure. Because power demand is not increased, the displayed flow read out may not change or, potentially decrease, even though the true flow out of the pump is hindered by the high aortic pressure
- **At any given speed, increased blood pressure will decrease flow**

PULSATILITY INDEX

- Pulsatility Index (PI) is the left ventricle's (LV) pulsatile contribution to the pump:

LV full → greater stretch → greater contractility = ↑Pulsatility Index
LV empty → less stretch → little contractility = ↓Pulsatility Index

- PI as it relates to changes in patient's status:
  - Indicative of changes in volume status due to altered preload
  - Indicative of changes to the natural heart's contraction
- PI as it relates to changes in pump speed:
  - As pump speed is increased, the PI goes down
  - As pump speed is decreased, the PI goes up

PI EVENT

- A PI event occurs when there is a 45% + or – change from the previous 15 second running average. Possible causes of events:

Suction event: the inflow cannula is obstructed	*Dehydration, bleeding, increased diuretic dosage*	*Arrhythmia, Vasovagal response*	*Right heart failure Increased PA pressure*

- If a PI event is detected, the pump speed will automatically reduce to the low speed limit and then gradually ramps back up at 100rpm/sec to the fixed speed

Clinical Considerations

CONT. FLOW PUMP

Continuously unloads left ventricle, narrowing pulse pressure

VITALS

Blood Pressure: Manual cuff with a doppler

- ❑ Locate brachial or radial pulse with Doppler
- ❑ Inflate BP cuff. Slowly release at 2mmHg per second
- ❑ First sound heard is "return to flow". Document this number as the MAP
- ❑ MAP goal: 70 – 90mmHg

Pulse: May be thready or absent

Oxygen Saturations: Unable to obtain due to poor capillary bed pulsatility

EKG

Pump does not affect the EKG

ACLS/CPR

ACLS per protocol

- Defibrillation, cardioversion, external pacing okay
- Do not place pads over the implanted HeartMate II LVAD or implanted ICD
- Contact implanting center to discuss CPR guidelines

PUMP ASSMT

Assess if pump is running:

- Auscultate over the left upper quadrant to assess if pump is running
- Report unusual sounds

INSPECT EQUIP

- When changing power sources, inspect pins in the connectors of controller power leads, patient cable, and battery clips
- Any issues with System Controller Operation

DRIVELINE

Report any signs of infection including increased WBC or + cultures

- Sterile dressing change per implant center protocol
- Ask care provider if concerns with exit site
- Review frequency of site care

Report any tears or separations in the silicone on driveline

Ensure patient is using an anchoring system to prevent tugging at exit site

INR

Goal: 2.0 to 2.5

INR goal will vary for each patient. Contact implanting center for patient specific INR goal

MONITOR REVIEW & DOCUMENTATION

Clinical Screen.....Review and Record: Speed, Flow, PI, Power
Settings Screen....Review and Record: Fixed Speed, Low Speed Limit
Alarms Screen.....Review and Record: Active Alarms
History Screen.....Review Event Log
Document the serial number of the system controller in use

EMERGENCY BAG

Patient should always carry emergency bag with backup controller, spare batteries and clips, and implanting center contact information

PATIENT QUESTIONS

- Any concerns with pump function?
- Changes in how pump feels or sounds?
- Any alarms?
- Trauma to driveline site?
- Concerns with equipment?
- Decreased battery life?
- Feelings of heart failure returning?
- Any bloody stool or nosebleeds?
- Is urine dark in color?
- Any weight gain or trouble breathing?
- Any lightheadedness or dizziness?
- Any returning symptoms of heart failure?

DAILY LOG

Review and assess for trends

THORATEC CORPORATION for Life

Thoratec Corporation, 6035 Stoneridge Drive, Pleasanton, CA 94588 1-925-847-8600 1-800-528-2577 www.thoratec.com

Changing the Heart Mate II System Controller

1. Place replacement System Controller within easy reach.

2. Ensure power supply connected to replacement System Controller.

3. Unlock Drive Line **(Fig. 1 and Fig.2)**

4. Disconnect the current System Controller from the LVAD by pressing the release button on the System Controller **(Fig. 3)**.

5. Connect the LVAD to the new System Controller by: aligning the dot on the drive line **(aka percutaneous lead)** to the black arrow above the connection port on the System Controller **(Fig. 4).**

6. Once aligned, fully insert percutaneous lead into system controller connector and push the latch guard to the "locked" position **(Fig. 5).**

7. Ensure that the pump running indicator on the system controller illuminates, the pump is running and all alarms are cleared. Assess patient LOC and perfusion status.

8. Check the percutaneous lead connection by gently tugging on metal end of percutaneous lead to ensure proper attachment. **WARNING! Do not pull on white portion of percutaneous lead.**

Fig. 1


Fig. 2


Fig. 3


Fig. 4


Fig. 5

Heart Mate II: Changing Batteries

When batteries have about 15 minutes of power left, the System Controller's YELLOW BATTERY (The POCKET CONTROLLER has a YELLOW DIAMOND) symbol will come on and a BEEP will sound about once every 4 seconds. This means it's time to change the batteries.

How to Change Batteries

1 Remove the battery clips and attached batteries from your holsters or carrying case.
2 Remove spare (fully-charged) batteries from your travel case or from the Power Module.
3 Turn over the Velcro circles on these batteries so you won't get confused about which batteries need to be recharged later.

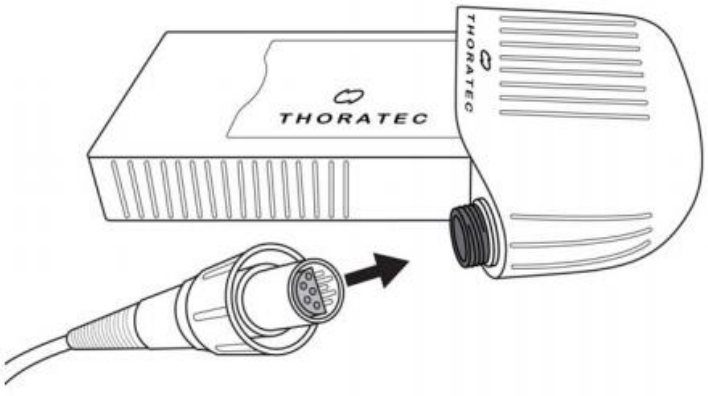
Note: Consider turning over the Velcro circles right after charging the batteries and just before putting them into the battery clips. This way you won't forget to turn them over later or get confused about which batteries need recharging.

4 Take out only 1 battery from its battery clip by pressing its battery release button
An alarm will sound one beep per second, the green power symbol will flash rapidly, and the 4 green battery fuel gauge lights will flash.

Note: You must press the battery release button to remove a battery from its clip.

WARNING ! .

At least 1 System Controller power lead must be connected to a power source (battery, Power Module, or EPP) at all times. Disconnecting both Controller power leads at the same time will cause the pump to stop.



HeartWare Components

HVAD® Pump

- Continuous flow VAD
- Weight = 160g
- Device design allows for pericardial placement, eliminating the need for abdominal surgery and device pockets
- Provides up to 10 L/min blood flow

Impeller

- Magnetically and hydrodynamically suspended
- Wide-bladed

Driveline

- Percutaneously connects the HVAD pump to an external controller
- Constructed with conductor wires similar to those used in pacemakers

HeartWare® Controller

- Provides feedback on pump operation through text, lights and sounds
- Requires 2 power sources at all times
- Contains an internal battery to run an audible "No Power" alarm

HeartWare® Battery

- Lithium Ion battery used to power the pump
- Each battery provides 4-6 hours of operation when fully charged

Driveline Cover

- Protects the pump/ controller connection and keeps it clean

Alarm Adapter

- Silences the "No Power" alarm when power is removed from a controller no longer in use

HeartWare® Monitor

- Touch screen tablet PC
- Used by clinicians to set and change pump parameters
- Displays adjustable real-time and historical pump information and alarm conditions

HeartWare® Controller AC Adapter

- Uses power from an electrical wall outlet to power the controller

HeartWare® Controller DC Adapter

- Uses power from an electrical outlet in an automobile to power the controller

HeartWare® Battery Charger

- Charges and tests up to 4 batteries simultaneously

Patient Pack

- Designed to support an ambulatory lifestyle
- Patient worn controller and batteries weigh approx. 3.5 pounds (1.59 kg)

HeartWare® Shower Bag

- Designed to allow patients to shower (with clinician approval)
- Protects the controller and batteries from direct water spray and moisture

HeartWare Considerations

Changing Heartware Controller:

•Attach power source to new controller. Wait for new controller to start alarming before moving driveline from original controller. (New controller will not work until it is alarming.)

•Pull back the white Driveline Cover from the original Controller's silver connector. (White Driveline Cover is a static guard).

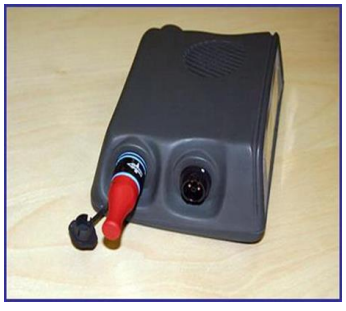
•Disconnect the Driveline from the original Controller by pulling the silver connector away from the Controller. Do not disconnect by pulling on the Driveline cable. When disconnecting the driveline, make sure you are gripping the ridges of the connector only – it will no disconnect if you hold past the ridges.

•Connect the Driveline to the new Controller (align the two red marks and push together)

•Insert the Alarm Adapter into the Blue Connector on the original Controller. (If you do not place alarm adaptor into original controller before disconnecting power source – it will continue to alarm.)

•Remove power source from original controller.

•Slide white Driveline cover over driveline on new controller.



Changing HeartWare Battery:

To Connect:

Grasp the power cable near its connector. Leave the connector free to rotate

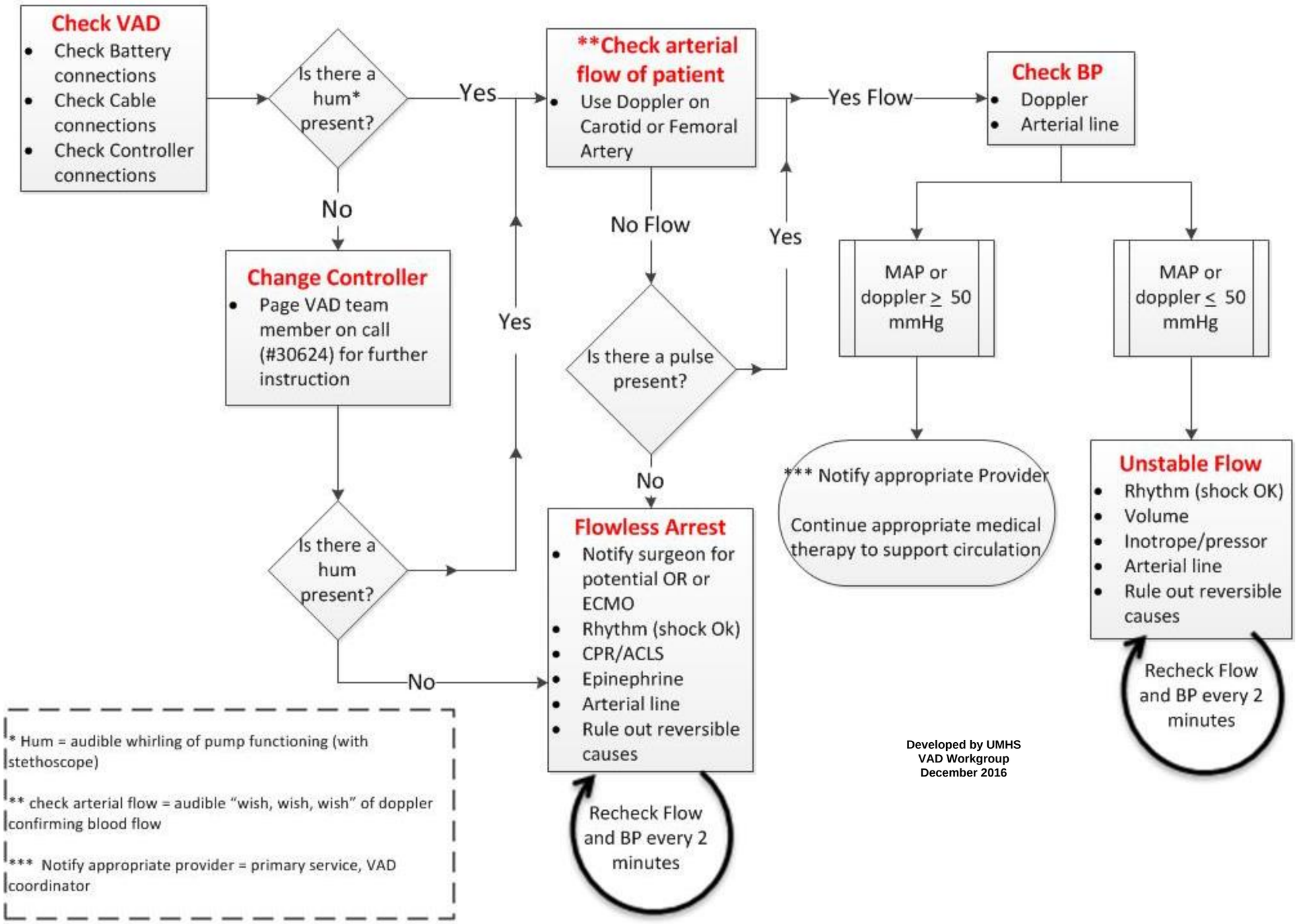
Line up the solid white arrow on the cable connector with the white dot on the Controller

Push the cable firmly onto the Controller until it locks in place

Confirm that the power cable is properly locked on the Controller by gently pulling on the cable near the connector.

Repeat above for second power source

Emergency Management Algorithm for Unresponsive VAD Patient



Developed by UMHS
VAD Workgroup
December 2016

Guidance and Additional IABP TIPS:

1. Verify balloon position by chest x-ray (CXR) or flouroscopy. Balloon tip should be 2-3 cm distal to the left subclavian artery or at the level of the carina on CXR.

2. Clinically, balloon position should be verified by presence and strength of the left radial pulse and urine output.

3. Obtain a balloon and arterial waveform strip from the outside hospital's IABP. Additionally, obtain waveform strips before, during and after transport.

4. IABP Set Up (Utilize the "**HEART**" Pneumonic)

H-Turn on IABP and ensure adequate helium level.
E- Connect to ECG cable with new electrodes. Ensure clean, dry skin contact to promote artifact-free signal. Referring hospital pump should be triggering off of the R-wave.
-NOTE: IABP interface dependent on patient. Ensure BEST ECG Lead selected.
A- Connect IABP Arterial Line (augmentation will still occur off of referring pump if trigger is from the R-wave). Zero transducer. Ensure IABP Select is selected to "transducer" instead of "monitor" mode. If a TeleFlex FOS is available for use, refer to the next page for setup.
R- Ensure trigger for transport pump is set for HR ("R-wave") and ECG is selected for "skin"
-Choose correct IABP tubing adapter after checking balloon volume (at insertion site).
T- Timing. Transfer referring hospital balloon tubing to IABP. Press "Assist" (the IABP will self-purge with helium). Press "autopilot" and set timing ratio.

5. Evaluation of augmentation and afterload reduction should be in a 1:2 timing ratio

6. Poor Augmentation:
   a. address hypovolemia and issues with SVR (Hypotension reduces aortic space which can also affect occlusivity and augmentation).
   b. ensure proper balloon placement

7. Balloon Occlusivity: Assessed by looking at the balloon pressure waveform. Using the screen cursor, measure the augmented diastolic pressure and the plateau ("chair seat") portion of the balloon pressure wave. The two pressures should read approximately 25 mmHg of each other. Less than 25 mmHg can mean occlusivity too high (Decrease balloon volume by 5 ml at a time to a MINIMUM % Fill of 66% - i.e., never take out > 1/3 and always keep balloon at least 2/3).

8. An IABP DOES NOT augment blood pressure. An IABP augments coronary artery perfusion, afterload reduction and cardiac output.

9. CPR: If augmentation is lost (AEB "normal" looking arterial pressure waveform with the pump still running), briefly place the IAB in standby and assess patient pulse. This could indicate a PEA arrest.

During CPR, the IABP augments best to change to an AP pressure source. This is most quickly accomplished by disconnecting the ECG cable. The pump will then augment off of the pressure generated by chest compressions

10. AutoCat II battery life 1 HOUR!!

11. Manual timing should be off of Arterial Pressure. Auto timing off of the "R-WAVE."

12. IABP arterial line is preferred for transducing and timing.

13. Pump failure during transport necessitates manual inflation and deflation of the balloon with a 60 ml syringe. Before manually inflating the balloon, the clinician should assess the line for blood. If no blood is present, attach the syringe **as close to the insertion site as possible** to the gas line connection and aspirate the balloon. If the line is clear, disconnect the syringe from the tubing, pull the plunger back to the size of the balloon volume, reconnect the syringe to the gas line and rapidly inflate and deflate. This should be done 1-2 times every 5 minutes. The maximum "idle" time for a balloon in the aorta is 30 minutes. Clot formation on an idle balloon may lead to a "showering" of emboli when pumping resumes.

14. **DISCONTINUE PUMPING ANYTIME BLOOD IS FOUND IN THE HELIUM LINE AS THIS INDICATES BALLOON RUPTURE. CLAMP THE CATHETER UPON FIRST INDICATION OF THIS!!**

15. The IABP may alarm during altitude change. The system may need to be re-purged. Press "Standby," then "Autopilot," and the system will self-purge.

16. Make every attempt not to attach more than 1 length of helium line on a TeleFlex IABP for transport as the added dead space will not be made up for by the pump and this can greatly affect augmentation.

Arrow®

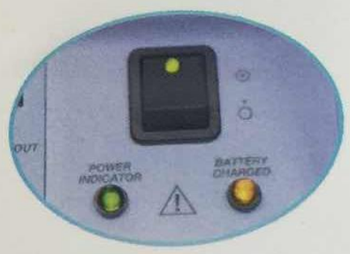
AutoCAT2WAVE® IABP

With FiberOptix® Sensor Technology

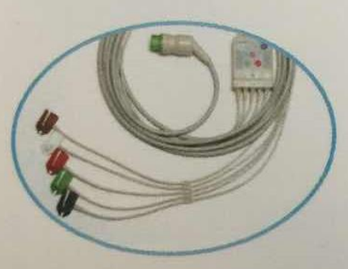
Quick Startup Guide

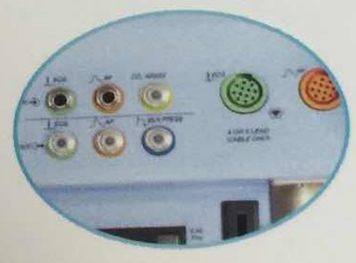
Counterpulsation Initiation Steps

1. Power On



2. Establish ECG Connection





3. Connect fiber optic sensor and calibration value key **before insertion**

4. Verify auto-zero via presence of green light bulb and audible alert

5. Insert IAB (per IFU)

Arrow®

AutoCAT2WAVE® IABP

With FiberOptix® Sensor Technology

Quick Startup Guide

Light Bulb Icon Legend

Black light bulb with blue square
Fiber optic IAB not connected

Blue light bulb
Fiber optic IAB attached but not yet zeroed.
* If the zero is not complete prior to insertion, manual calibration may be performed.

Green light bulb
Fiber optic IAB zeroed prior to insertion

White light bulb
Fiber optic IAB calibration value manually adjusted

To calibrate fiber optic source (if sensor was not zeroed prior to insertion and MAP value is erroneous):

a. Press AP select to highlight fiber optic
b. Press soft key under "FOS MAP CAL"
c. Adjust FOS MAP to actual MAP (from another accurate AP source such as a radial a line, central lumen, etc.)