DuraHeart™System®

1. Can I do external CPR?

- · Only if necessary; treat per physician discretion.
- · Closed chest CPR is contraindicated
- May be performed as needed at the discretion of the attending physician
- External chest compressions may cause the dislocation/damage of pump Inflow/Outflow conduits
- External defibrillation any be performed on a patient with the DuraHeart[™] System[®] without disconnecting any of the system components
- 2. If not, is there a "hand pump" or external device to use? No.
- 3. If the device slows down (low flow state), what alarms will go off?

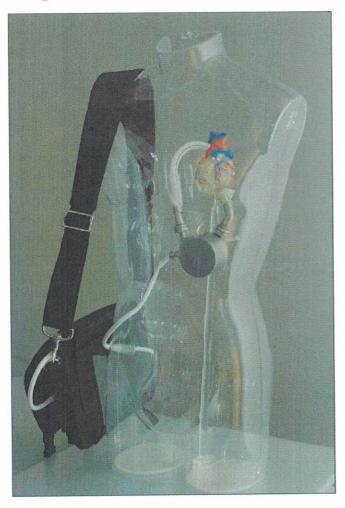
 An emergency alarm will sound and the emergency alarm indicator (RED LIGHT) will light up.
- 4. How can I speed up the rate of the device? The rate of the device can only be modified in a hospital setting. For low flow rates, check for hypovolemia or RHF and treat accordingly.
- Do I need to heparinize the patient if it slows down?Call the accepting VAD facility for guidance.
- Can the patient be defibrillated while connected to the device? Yes.
- 7. If the patient can be defibrillated, is there anything I have to disconnect before defibrillating?
 No, defibrillate per protocol.
- 8. Does the patient have a pulse with this device?
 If the patient's own heart has some residual function, you may be able to feel a pulse.
- What are acceptable vital sign parameters? Mean Arterial Pressure (MAP) 80-90 mm Hg.
- 10. Can this patient be externally paced? Yes, as needed.

January 2015

DuraHeart™System®

The DuraHeart™ LVAS is the latest-generation rotary blood pump designed for long-term patient support. The system incorporates a centrifugal flow rotary pump with an active magnetically levitated impeller featuring three position sensors and magnetic coils that optimize blood flow. The impeller's magnetic levitation is designed to eliminate friction by allowing a wide gap between blood contacting surface areas, enabling blood to flow through the pump unimpeded in a smooth non-turbulent fashion.

The DuraHeart™ System consists of an implantable Pump and several components that support the function of the Pump. The system is made up of seven main components (see photo below) which include:





External Batteries

Li-ion batteries provide power tot the pum for untethered operation for up to 3-1/2 hours per battery. Each battery can be recharged up to 200 times.

"Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport .ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010

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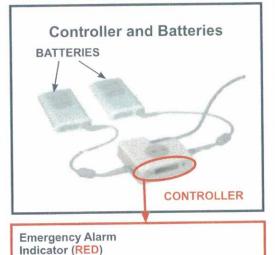
URPLE PURPLE PURPLE PURPLE

URPLE

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DuraHeart[™]**System**[®]

CONTROLLER



Display

Caution Alarm

Indicator (YELLOW)

MUTE Button

MENU Button

and Power Light

- Communicates with console for system set up, monitoring and troubleshooting
- Controls and monitors pump function, stores system data
- Interfaces with external power sources (Console, Batteries, Charger, Emergency Backup Battery)
- Displays system status Pump Flow Rate
 - Pump Rate
 - Motor Current
 - System alarms and Alerts
 - Power Supply Status

• Emergency Alarms

- High Priority.
- Flashing RED light and continuous Emergency Alarm tone.
- Requires immediate care by medical specialist and controller exchange.



EMERGENCY ALARMS

1000 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
PROBLEM	
The Pump may not be rotating	
The Pump cable is disconnected	
Possible serious problem with the controller	
Pump motor may have serious problem	
The impeller may not be levitated	

SILENCING ALARMS

Emergency Alarms

- Mute button silences audible alarm for 2 minutes
- · Audible alarm returns after 2 minutes

Caution Alerts

Mute button silences audible alarm for 5

ANTICOAGULATION

Patients will be on Coumadin with this deviceTarget INR range should be between 2.0 to 3.0 Combination antiplatelet therapy of ASA 81mg daily and Persantine 25-75 mg TID

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