HeartMate 3™ Left Ventricular Assist Device

PUMP PARAMETER OVERVIEW

There are four parameters monitored on the HeartMate 3™ Left Ventricular Assist Device (LVAD): Speed, Power, Flow and Pulsatility Index. No single parameter is a surrogate for monitoring a patient's clinical status. It is important to consider trends. Pump parameter values are patient-specific.

SPEED

- The HeartMate 3 LVAD fixed speed range: 3,000–9,000 revolutions per minute (rpm)
- Speed can only be changed using the System Monitor or HeartMate Touch™
- The System Monitor displays the pump speed in rpm. This value matches the actual speed within ± 100 rpm under normal conditions
- Starting at 4,000 rpm, the HeartMate 3 LVAD has an artificial pulse that is activated every 2 seconds
- The ▲ icon beside the speed display on the system controller indicates Artificial Pulse mode is active

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

- **↑ Power may signal thrombus deposits inside the pump or aortic insufficiency**
- **Gradual power decreases may indicate obstruction of flow and should be evaluated**
- **Report double-digit power demands ≥ 10.0 Watts**

FLOW

- Flow is an **estimate** that is derived from a calculation of fixed speed, power and the patient's hematocrit value

- **↑ Speed – ↑ Flow**
- **↓ Speed – ↓ Flow**
- **If the flow estimate falls below a pre-set limit of either 2.5 LPM or 2.0 LPM, the HeartMate 3™ System Controller will alarm "low flow"**

- At any given speed, increased blood pressure (BP) will decrease flow through the pump

PULSATILITY INDEX

- During systole, the left ventricle (LV) contracts, increasing ventricular pressure that causes increases in pump flow
  - These flow pulses are measured and averaged over 15-second intervals
- The HeartMate 3 LVAD observed clinical Pulsatility Index (PI) range: 1–10
- PI values should be routinely monitored and should not vary significantly during resting conditions
- Under otherwise stable conditions, a significant drop in value may indicate a decrease in circulating blood volume

PI EVENT

- The HeartMate 3 LVAD employs PI detection to recognize and avert the LV collapse
- If a PI event is detected, the pump speed will automatically reduce to the low speed limit and then gradually ramp back up to the fixed speed
  - There are no audible alarms with a PI event

POSSIBLE CAUSES OF EVENTS: Sudden changes in power or pump speed, coughing/sneezing, arrhythmias, ventricular suction, beat-to-beat variations in LV volume and intra-aortic balloon pumps

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CLINICAL CONSIDERATIONS

CONTINUOUS-FLOW PUMP

- The HeartMate 3™ LVAD has an Artificial Pulse mode that "beats" 30 times per minute asynchronously with the heart
- Continuously unloads LV, narrowing pulse pressure
- The HeartMate 3 LVAD may create electromagnetic interference with electrocardiogram (EKG) monitoring
- Adjustment of EKG lead placement may reduce the level of interference

VITALS

BP:

- Automatic BP monitors may not be accurate
- Manual auscultation with a Doppler is recommended
  - The mean BP should be < 90 mmHg

Pulse: A palpable pulse may or may not be present

Oxygen saturations: May be unable to obtain as pulse oximeter technology is based on pulsatile flow

PUMP ASSESSMENT

Assess if pump is running:

- Auscultate over the left upper quadrant to assess whether the pump is running
- Any change in parameters should be evaluated with all clinical considerations taken into account
- One single pump parameter is not a surrogate for monitoring the overall clinical status of the patient

EMERGENCY CARE

- Defibrillation or cardioversion allowed, if necessary
- Chest compressions — Use clinical judgment; there may be risks associated with performing chest compressions

EQUIPMENT

- The System Controller must be connected to the Power Module, Mobile Power Unit or 14-volt lithium ion batteries at all times when connected to a patient
- Up to 10- to 17-hour battery life, per pair
- The patient must always connect to the Power Module or Mobile Power Unit for sleeping or when there is a chance of sleep
- A backup System Controller and charged batteries must remain with the patient at all times

DRIVELINE

- Sterile dressing change per implant center protocol
  - Report any signs of infection
- Report any tears or separations in the silicone or polyurethane on the driveline
- Ensure the patient is using an anchoring system to prevent pulling of the driveline
  - Do not twist, kink or sharply bend the driveline
- Verify the modular cable in-line connection is secure and that no yellow line is visible

INR

- Goal: 2.0 to 3.0
- International normalized ratio (INR) goal will vary for each patient

MONITOR REVIEW AND DOCUMENTATION

Clinical Screen — Review and Record: Speed, Flow, PI, Power
Settings Screen — Review and Record: Pulse Speed, Low Speed Limit and Hematocrit
Alarms Screen — Review and Record: Active Alarms
History Screen — Review Event and Periodic Logs

PATIENT QUESTIONS

- Any alarms?
- 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?

WARNINGS

- No magnetic resonance imaging
- Avoid static electricity
- No swimming

HeartMate Touch™ Communication System Overview: The HeartMate Touch™ Communication System is intended for use by clinicians in the hospital to wirelessly monitor a patient's HeartMate II™ Left Ventricular Assist System or HeartMate 3™ Left Ventricular Assist System. The HeartMate Touch Communication System is required during implant procedures and any time close monitoring of system operation is needed. It provides clinicians with the ability to program system parameters such as pump speed, assess and track alarm conditions, and view and save performance data.

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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

HeartMate 3™ LVAS Indications: The HeartMate 3™ Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in adult and pediatric patients with advanced refractory left ventricular heart failure and with an appropriate body surface area.

HeartMate 3™ LVAS Contraindications: The HeartMate 3 Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

HeartMate 3™ LVAS Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 Left Ventricular Assist System are: death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS) thromboembolism, pericardial fluid collection, pump pocket or pseudo pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) or pump thrombosis.

MAT-2007803 v2.0
Item approved for U.S. use only.

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