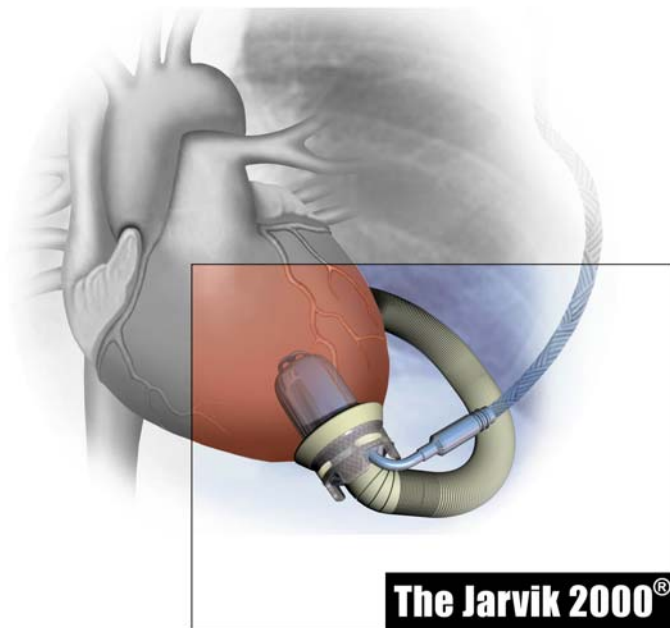












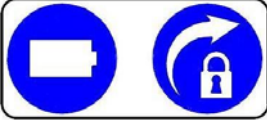




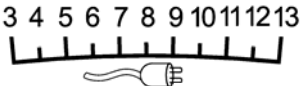

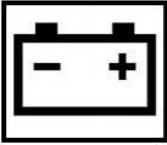

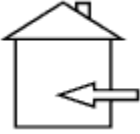



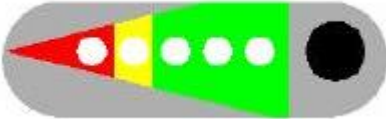



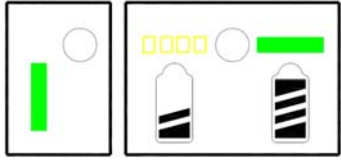
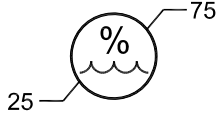
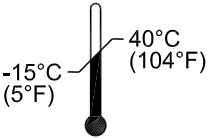



# Operator Manual Jarvik 2000<sup>®</sup> Adult Ventricular Assist System, Post-Auricular Cable



| Symbol   | Meaning   |
|--|---|
|               | <p>Refer to instruction manual / booklet.<br/>On Equipment: Follow Instructions for Use</p> |
|               | <p>Defibrillation-Proof Type CF Applied Part</p>  |
| <br>YYYY-MM   | <p>Date of Manufacture<br/>YYYY(year), MM(month)</p>  |
|               | <p>Caution</p>  |
|              | <p>Protect from Water</p>   |
|             | <p>Single Use Only</p>  |
| <br>YYYY-MM | <p>Use By date shown: YYYY(year), MM(month)</p>   |
|             | <p>Mark of conformity to applicable European Directives</p>                                 |
|             | <p>Reorder number</p>   |
|             | <p>Serial Number</p>  |
|             | <p>Lot Number</p>   |

| Symbol   | Meaning   |
|--|---|
|                   | Fragile   |
| <b>IP64</b>  | Enclosure protected completely from dust<br>Enclosure protected from water sprayed from any direction   |
|                   | Enclosure for Alarm Battery. Rotate knob clockwise to activate backup alarm.  |
|                   | Do not dispose in trash   |
|                  | Pump Stopped Alarm  |
|                 | The top panel of the FlowMaker® Controller has a symbol of a propeller to represent Jarvik 2000 Adult VAD speed. The large propeller with the arrow next to it indicates the direction to turn the knob to increase the speed. The higher the number on the dial, the faster the Jarvik 2000 Adult VAD speed.           |
|                 | The top panel of the FlowMaker® Controller has a symbol of a propeller with a line drawn across it. This symbol is called the underspeed indicator. If the underspeed indicator lights up yellow, this means that the speed that the Jarvik 2000 Adult VAD is actually running is lower than the speed set on the dial. |
|                 | The numbers 3 through 13 appear across the top of the FlowMaker® Controller with a picture of an electric plug below the numbers. These numbers indicate the electrical power (Watts) that the system is using.   |
| <b>1213</b><br> | If the FlowMaker® Controller measures 13 watts of power or more, this indicates a malfunction. The number 13 will light <b>yellow</b> .   |

| Symbol  | Meaning   |
|---|---|
|    | <p>When the battery powering the Jarvik 2000 Adult VAD is low (about 5-10 minutes of running time remaining with the Lithium-ion Battery), the low battery symbol on the FlowMaker® Controller lights <b>yellow</b> and the <b>alarm sound beeps</b>.</p> |
|    | <p>Recycle.</p>   |
|    | <p>For Indoor use only.</p>   |
|    | <p>Keep out of sunlight.</p>  |
|   | <p>Do not drop.</p>   |
|  | <p>Do not hit.</p>  |
|  | <p>Lithium-ion Battery has an indicator with five lights, which indicate how much power is remaining. Depress the black button to turn on the indicator lights.</p>   |
|  | <p>Denotes the item labeled is shipped non-sterile.</p>   |

| Symbol  | Meaning  |
|---|--|
|    | <p>The Li-ion Battery Charger has two status lights. A green light next to the vertical green bar indicates connection to wall power. The second light indicates charge status. The second light flashes yellow during charging, as represented by the dashed horizontal yellow bar above the half filled battery icon. This light is solid green when the Li-ion Battery is fully charged, as represented by the solid green horizontal bar above the completely filled battery icon. When the Li-ion Battery Charger is not connected to a Li-ion Battery, the second light will remain off.</p> |
|    | <p>Recommended humidity range for shipping is 25% to 75%.</p>  |
|    | <p>Recommended temperature range for shipping is -15°C (5°F) to 40°C (104°F).</p>  |
|   | <p>Keep this way UP.</p>   |
|  | <p>Pull here.</p>  |
|  | <p>Ethylene Oxide Sterilized.</p>  |
| <p><b>4ICR35/61</b></p>   | <p>Industry Code for Specified Lithium-ion Battery</p>   |

## Intended Use of this Operator Manual

The objective of the Operator Manual is to provide medical support staff who are responsible for Jarvik 2000<sup>®</sup> Adult VAS patient care and support with the necessary information regarding care and operation of the Jarvik 2000<sup>®</sup> Adult VAS.

**This manual is to be used by trained medical staff in conjunction with other documentation supplied with Jarvik 2000<sup>®</sup> Adult VAS.** It is important that all users study and thoroughly understand this Operator Manual and the accompanying Technical Information before attempting to use the Jarvik 2000<sup>®</sup> Adult VAS.


The Operator Manual is intended for staff with medical or nursing skills, biomedical engineering skills, or hospital personnel trained to work with medical equipment.

The Operator Manual is to be used in the context of a formal training program or as a reference document.

A separate manual entitled the Training Manual is designed to provide implant centers, physicians, and Jarvik 2000 Adult VAD support staff with the procedures for surgical implantation of the device. **In particular, the Training Manual is necessary for the surgical implantation of the Jarvik 2000<sup>®</sup> Adult VAD.**

It is recommended that all patients who are treated with the Jarvik 2000<sup>®</sup> Adult VAS receive anticoagulation medication. **A separate document entitled Anticoagulation Management Recommendations describes how the patient's anticoagulation medications should be managed. All staff who are responsible for managing the medication of patients treated with the Jarvik 2000<sup>®</sup> Adult VAS must study and thoroughly understand the Anticoagulation Management Recommendations before attempting to use the Jarvik 2000<sup>®</sup> Adult VAS.**

The table below describes documentation required for implantation and support of the Jarvik 2000<sup>®</sup> Adult VAS.

| Symbol   | Instructions for Use  | Description of Instructions for Use  |
|--|---|--|
|  | IU0329—Operator Manual  | The Operator Manual is designed to provide information for staff and users of the Jarvik 2000 <sup>®</sup> Adult VAS and its external equipment. [REF] JHI-001 and [REF] JHI-002.  |
|  | IU0330—Training Manual—Destination Study  | The Training Manual—Destination Study is designed to provide guidance exclusively for the implantation of Jarvik 2000 <sup>®</sup> Adult VAS, Post-Auricular Cable. [REF] JHI-001.   |
|  | IU0328—Patient Handbook—Jarvik 2000 Adult, Post-Auricular Cable—Destination Study   | The Patient Handbook—Jarvik 2000 Adult, Post-Auricular Cable is designed to provide information for patients being treated exclusively with the Jarvik 2000 <sup>®</sup> Adult VAS, Post-Auricular Cable. [REF] JHI-001.       |
|  | IU0165—Sterilization and Instructions for Use – Jarvik 2000 <sup>®</sup> Adult Coring Knife, 0.9”                                   | Provides sterilization and instructions for use for the Jarvik 2000 <sup>®</sup> Adult Coring Knife, 0.9” [REF] JHI-605- designed for the implantation of the Jarvik 2000 <sup>®</sup> Adult VAD. [REF] JHI-001.               |
|  | IU0166—Sterilization and Instructions for Use—Surgical Instruments for the Jarvik 2000 <sup>®</sup> Adult VAD—Pedestal Implantation | Provides sterilization and instructions for use for the Surgical Instruments designed for the implantation of the Jarvik 2000 <sup>®</sup> Adult VAD, Post-Auricular Cable. [REF] JHI-001.                                     |
|  | IU0331—Anticoagulation Management Recommendations   | Provides anticoagulation management recommendations for patients in the U.S. Destination Study implanted with the Jarvik 2000 <sup>®</sup> Adult VAD. [REF] JHI-001.   |
|  | IU0150—Field Sterilization Policy   | Provides list of all components of the Jarvik 2000 <sup>®</sup> Adult VAS, describes which components are shipped sterile, which are non-sterile, which can be re-sterilized and which cannot be re-sterilized. [REF] JHI-001. |
|  | IU0202—Surgical Instruments Required for Pedestal Implantation of the Jarvik 2000 <sup>®</sup> Adult VAD, Post-Auricular Cable      | Provides list of all surgical instruments required for Pedestal implantation of the Jarvik 2000 <sup>®</sup> Adult VAD, Post-Auricular Cable. [REF] JHI-001.   |
|  | IU0198—Decontamination Instructions   | Provides instructions on decontaminating the Jarvik 2000 Adult VAD in the event the Jarvik 2000 VAD needs to be shipped to Jarvik Heart, Inc. after use for evaluation.  |
|  | IU0332—Technical Information  | Provides Technical Information for all components of the Jarvik 2000 <sup>®</sup> Adult Ventricular Assist System.   |

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## Intended Use

The Jarvik 2000<sup>®</sup> Adult Ventricular Assist System (also referred to as the Jarvik 2000<sup>®</sup> VAS) is intended to augment blood flow in patients with insufficient hemodynamic function where there is an imminent risk of irreversible cardiac decompensation or death. It is intended for use both inside and outside the hospital.

The Jarvik 2000<sup>®</sup> VAS is indicated for use in patients with late stage heart failure who may be either bridge to transplant candidates or lifetime use recipients. The patient is considered suitable for implant if the body surface area (BSA) is at least 1.2 m<sup>2</sup>.

The Jarvik 2000<sup>®</sup> Adult Ventricular Assist Device (also referred to as the Jarvik 2000<sup>®</sup> VAD) may be implanted at heart surgery centers where cardiac surgeons and clinical staff have successfully completed the surgical training program for implantation of the Jarvik 2000<sup>®</sup> VAD.

## Device Description

The Jarvik 2000<sup>®1</sup> Ventricular Assist System (VAS) is an axial flow miniature rotary blood pump system. The Jarvik 2000<sup>®</sup> VAD (Ventricular Assist Device) is approximately 1 inch in diameter, weighs 90 grams and displaces a volume of 25 ml. The Jarvik 2000 VAD is silent and compact, approximately the size of a “C” cell flashlight battery and is positioned partially within the natural heart. The Jarvik 2000 VAD can pump blood in excess of 8 liters per minute (lpm).

The Jarvik 2000 VAS is available in two models: the Jarvik 2000 VAS, Post-Auricular Cable (JHI-001) and the Jarvik 2000 VAS, Abdominal Cable (JHI-002). This manual covers the operation of the Jarvik 2000 Adult VAS, Post-Auricular Cable only for the purpose of the U.S. study entitled the Evaluation of the Jarvik 2000<sup>®</sup> Left Ventricular Assist System with Post-Auricular Connector—Destination Therapy.

The Jarvik 2000 VAS is operated by a FlowMaker<sup>®2</sup> Controller which provides power to the implanted Jarvik 2000 VAD, provides user settable speeds at which the Jarvik 2000 VAD runs, and provides alarms and indicators. The rechargeable Lithium-ion Battery permits portable use in a comfortable, wearable configuration. The Reserve Battery/Charger powers the Jarvik 2000 VAD during sleep. Two fully charged Reserve Battery/Chargers provide over 2 days of backup power in the event of an emergency such as a local power blackout. Backup units for the FlowMaker Controller, batteries, cables and battery chargers are provided. A cable called the Y Cable is provided to allow battery changes without stopping the Jarvik 2000 VAD.

Each Jarvik 2000 VAD has a serial number which is marked on the implanted Jarvik 2000 VAD itself. The serial number can be read externally on the Pedestal.

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<sup>1</sup> Jarvik 2000 is a registered trademark of Jarvik Heart, Inc.

<sup>2</sup> FlowMaker is a registered trademark of Jarvik Heart, Inc.

## Contraindications

- The Jarvik 2000 VAS is contraindicated in patients who cannot tolerate anticoagulation medication.
- The Jarvik 2000 VAD incorporates a Hemashield Vascular Graft. This graft should not be implanted in patients with a known sensitivity to products of bovine origin.
- Although not an absolute contraindication, Jarvik Heart, Inc. recommends caution in the use of the Jarvik 2000 in cancer patients, especially patients with a history of chemotherapy, because of an elevated risk of cerebral hemorrhage. This increased risk has been noted in patients with a history of use of doxorubicin and tamoxifen and may also be increased in patients who have used other chemotherapy agents. The Jarvik 2000 should not be used in this group of patients unless no other treatment option is available and the risk of imminent death is very high.

## Precautions and Warnings

- This manual must be read in its entirety, and a thorough understanding of the device, its proper usage, and risks must be understood before use of the device.
- Before using any of the Jarvik 2000 VAS accessories and components, all users must be trained on the use of the equipment.
- A full set of back-up equipment must be carried with the user at all times.
- If the patient is dependent on the Jarvik 2000 VAD, a caregiver should be with the patient at all times.
- Magnetic resonance imaging (MRI) cannot be performed once the device has been implanted. The magnetic field may interfere with the function of the Jarvik 2000 VAD causing the Jarvik 2000 VAD to stop or injury to the patient. However, diagnostics such as x-rays, echocardiography, computed tomography (CT) scans, and ultrasound have no influence on the performance of the Jarvik 2000 VAD.
- Patients undergoing treatment by the Jarvik 2000 VAS should avoid areas with high concentrations of electromagnetic interference.
- If in an area of high electromagnetic interference, e.g. near an AM/FM broadcast tower, power transformer, etc. move to a location as far as practically possible from the source of interference.
- Patients under treatment by the Jarvik 2000 VAS should seek guidance prior to entering areas, which may affect the operation of the device (e.g. areas with high concentrations of radio frequency energy, high pressure, high humidity, etc.), including areas where a warning prevents entry by patients fitted with a pacemaker.
- Implanted components should not be exposed to therapeutic levels of ultrasound energy (e.g. ultrasound hearing and /or extracorporeal shockwave lithotripsy) used to alter or ablate tissue (this does not apply to diagnostic techniques such as echocardiography), as the device may inadvertently concentrate the ultrasound field and cause harm.
- Therapeutic ionizing radiation may damage the device and the damage may not be immediately detectable.
- Defibrillation, CPR, and cardiac massage may all be performed while the Jarvik 2000 VAS system is running. Confirm the system is operating properly after defibrillation is performed.
- Do not touch the drive cable exiting the body or any of the external components of the Jarvik 2000 VAS whenever external defibrillation is applied.

- In general, it is safe to operate an AICD or pacemaker with the Jarvik 2000 VAS; however, it is not possible to be certain that all combinations of devices will operate as intended or safely at the same time.
- The Jarvik 2000 VAD should not be implanted in a patient with a mechanical aortic valve. Tissue valves are generally considered to be at lesser risk.
- Hospital staff should remove the Pedestal Cable every three months, during follow up visits for inspection and cleaning.
- Do not attempt to clean the Pedestal site with any product which contains iodine such as Betadine. The iodine may cause the pins on the Pedestal to corrode.
- It is recommended that all patients who are treated with the Jarvik 2000 VAS receive anticoagulation medication. A separate document entitled Anticoagulation Management Recommendations describes how the patient's anticoagulation medications should be managed. All staff who are responsible for managing the medication of patients treated with the Jarvik 2000 VAS must study and thoroughly understand the Anticoagulation Management Recommendations before attempting to use the Jarvik 2000 VAS.
- The FlowMaker Controller contains electronic components which are subject to damage if dropped.
- The batteries are subject to damage if dropped.
- The cables and connectors can break or short-circuit if over stressed or pulled and should always be protected from catching on objects, or being kinked, twisted, or tangled. Never lift or hang the FlowMaker Controller or batteries by the cables.
- Patients using the Jarvik 2000 VAS should avoid environments where the air pressure is less than 10.2psi (70kPa) or greater than 15.4psi (106kPa), as these pressure extremes may cause damage to the equipment or cause it to function incorrectly and may put the patient at risk. Note that this does not prevent the patient from traveling in commercial aircraft, which are typically pressurized with the acceptable range.
- The FlowMaker Controller and batteries should be kept at temperatures above 32° F (0° C) and below 104° F (40° C). Do not leave these items in hot or cold environments, such as the inside of a car in the summer or winter.
- Patients using the Jarvik 2000 VAS should avoid environments where the ambient temperature is above 104°F (40°C) or below 32°F (0°C) as these temperature extremes may cause damage to the equipment or cause it to function incorrectly and put the patient at risk.
- If possible, always keep the equipment and back-up equipment at or near room temperature.
- If in an area where ambient temperature is below 32°F (0°C) move immediately to an area where the temperature is above 32°F (0°C) but below 104°F (40°C), e.g. a heated room or automobile.
- If in an area where ambient temperature is above 104°F (40°C) move immediately to an area where the temperature is below 104°F (40°C) but above 32°F (0°C), e.g. an air-conditioned room or automobile.
- The FlowMaker Controller and Lithium-ion Batteries are splash resistant but not waterproof. Any liquids spilled on them should be removed immediately with a clean dry cloth or paper towel.

- The user may shower with the Jarvik 2000 VAD implanted when approved by the physician after the surgical wound has healed. The FlowMaker Controller and Lithium-ion Battery must be placed outside the shower area and covered with a dry towel or bag.
- The Lithium-ion Battery Chargers are not splash resistant and must be kept dry and protected from spills.
- The Reserve Battery/Charger is not splash resistant and must be kept dry and protected from spills.
- The Alarm Battery in the FlowMaker Controller powers the alarms only and is not sufficient to run the Jarvik 2000 VAD.
- The patient must return to the implant center every three months so that staff can replace the Alarm Battery, test the new Alarm Battery, and check all the equipment. Staff must only use Alarm Batteries that are obtained from Jarvik Heart, Inc.
- Be sure that the Alarm Battery Cap holding the Alarm Battery in place on the FlowMaker Controller is screwed finger tight whenever the FlowMaker Controller is used. If the Alarm Battery Cap is not finger tight in place, the backup power for the alarms will not function.
- Do not insert a finger in the enclosure for the Alarm Battery to reduce the risk of low voltage shock.
- There is no implanted battery to run the Jarvik 2000 VAD. The Jarvik 2000 VAD will stop if the FlowMaker Controller is disconnected from the drive cable. It will also stop if the FlowMaker Controller is disconnected from the Y Cable or battery cable. If this occurs, reconnect the cables immediately to restart the Jarvik 2000 VAD.
- It is not possible to run the Jarvik 2000 VAS from wall power even if the Reserve Battery/Charger is plugged into wall power. It is also not possible to charge the Reserve Battery/Charger while the same Reserve Battery/Charger is being used to run the Jarvik 2000 VAD.
- The Reserve Battery and Reserve Charger are provided as a single unit (as the Reserve Battery/Charger) inside the fabric carrying case; however, they are not electrically connected to each other. If the Reserve Battery/Charger is plugged into wall power and the Reserve Battery/Charger is connected to the FlowMaker Controller, the FlowMaker Controller only operates from the Reserve Battery/Charger itself. At all times, the Jarvik 2000 VAD is run only from battery power.
- To avoid risk of electric shock, the Reserve Battery/Charger must only be connected to a supply mains with protective earth.
- Never charge the batteries from an ungrounded outlet. Do not use adapters to ground the outlet or power strips.
- Never charge the batteries from an outlet which is regulated by a light switch as the switch could be turned off resulting in a battery which is not charged when expected.
- Never use an extension cord or multiple portable socket outlet (power strips) or any other items not part of the system when charging the batteries.
- Do not attempt to service any of the equipment. Any servicing should be referred to Jarvik Heart trained service staff.
- Do not attempt to replace any of the equipment with any parts which are not provided by Jarvik Heart, Inc.
- The Lithium-ion Battery cannot be used without the Lithium-ion Battery Cable. Always ensure a Lithium-ion Battery Cable is attached to each Lithium-ion Battery after charging.

- All external cables should be replaced after 6 months of use. These cables include the following:
  - All external Extension Cables and Pedestal Cables which connect the Jarvik 2000 VAD to the FlowMaker Controller.
  - All Y Cables which connect the FlowMaker Controller to the Lithium-ion Battery Cable.
  - All Lithium-ion Battery Cables which connect the Y Cable to the Lithium-ion Battery.
- A warm cable close to the skull Pedestal indicates increased electrical resistance due to a damaged cable. If a patient reports a warm external Pedestal Cable, the Pedestal Cable should be replaced under the supervision of a health care professional and verified that this corrects the problem.
- Report premature replacements of all components to Jarvik Heart, Inc.
- At Time of Implant:
  - Do not implant the Jarvik 2000 VAD if it has been dropped.
  - Do not operate the Jarvik 2000 VAD in air even for a few seconds as this will cause the bearings to break. The Jarvik 2000 VAD must be submerged in fluid to run safely.
  - A complete back-up system including a back-up Jarvik 2000 VAD must be readily available on site when the device is implanted in case of an emergency.
  - Do not autoclave the Jarvik 2000 VAD. Doing so can damage the Jarvik 2000 VAD and attached graft.
  - Do not allow any foreign objects to be near the inflow of the Jarvik 2000 VAD. Foreign objects could migrate into the Jarvik 2000 VAD or graft resulting in damage to the Jarvik 2000 VAD or harm to the patient.

## Potential Complications

The possibility exists that serious potential complications may arise from the use of the Jarvik 2000<sup>®</sup> VAS.

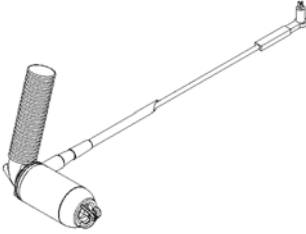
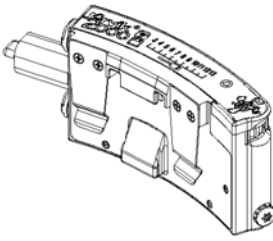
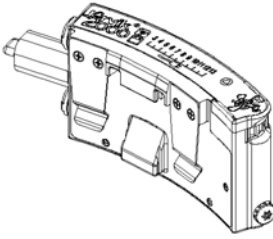
Potential complications associated with the use of the Jarvik 2000<sup>®</sup> VAS include:

- Death
- Excessive bleeding
- Reoperation
- Thromboembolism (blood clots that form and can travel to other parts of the body)
- Device thrombosis (blood clots around the device)
- Systemic hypotension (low blood pressure)
- Failure of the right side of the heart
- Cardiogenic shock (the heart and Jarvik 2000 VAD do not supply the proper amount of blood to the body)
- New myocardial infarction (heart attack)
- Cardiac mural thrombi (blood clots on the walls of the heart)
- Cardiac arrhythmia (irregular heart rhythm)
- Coagulopathy (a condition in which the blood cannot clot properly)
- Infection
- Hemolysis (the destruction of red blood cells)
- Liver dysfunction
- Kidney dysfunction
- Lung dysfunction
- Mechanical failure (the assist device or one of its components might fail to operate)
- Stroke or neurological dysfunction
- Air emboli (air entry into the vascular system)


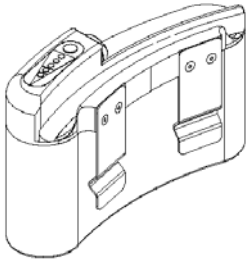
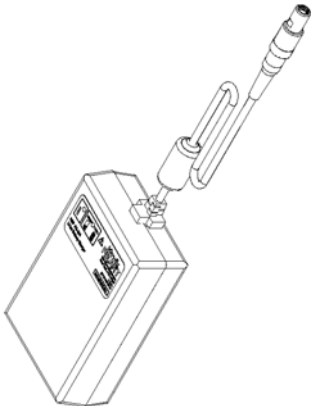
There may be additional risks that are presently unknown.

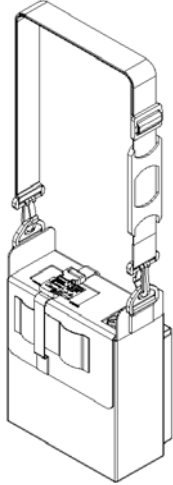
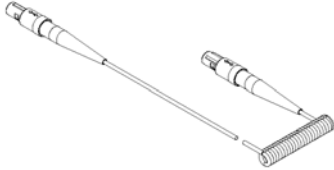

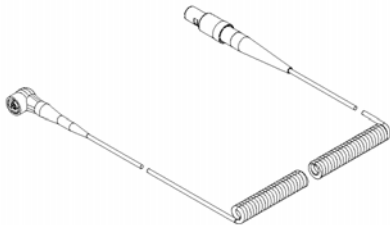
# List of Components

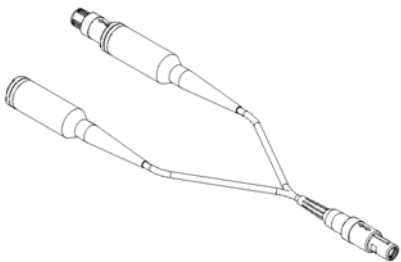
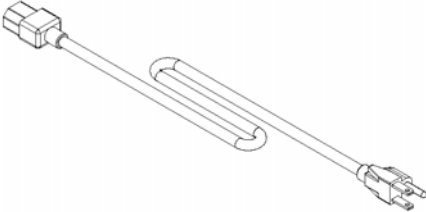
## Jarvik 2000 VAS, Post-Auricular Cable

| Component                                   | Part Number | Depiction   | Description  |
|---|-------------|---|--|
| Jarvik 2000 Adult VAD, Post-Auricular Cable | JHI-001     |    | Includes the implanted blood pump, the outflow graft and an internal cable, which exits the body behind the ear.   |
| ILS FlowMaker® Controller                   | JHI-102     |   | The ILS FlowMaker® Controller powers the Jarvik 2000® Adult VAD. The ILS FlowMaker Controller intermittently reduces the set speed for a few seconds approximately once per minute. It is connected to the Jarvik 2000® Adult VAD, Post-Auricular Cable via an external Pedestal Cable (JHI-201). An Extension Cable may be used in series between the Pedestal Cable and the FlowMaker® Controller. |
| Constant Speed FlowMaker® Controller        | JHI-101     |  | The Constant Speed FlowMaker® Controller powers the Jarvik 2000® VAD. It is connected to the Jarvik 2000® VAD, Post-Auricular Cable via an external Pedestal Cable (JHI-201). An Extension Cable may be used in series between the Pedestal Cable and the FlowMaker® Controller.   |



| Component                   | Part Number | Depiction  | Description  |
|-----------------------------|-------------|--|--|
| Alarm Battery               | PB0201      |   | <p>The FlowMaker® Controller has a 6V Alarm Battery which powers the back-up alarm if there is loss of power.</p>  |
| Lithium-ion Battery         | JHI-301     |   | <p>The portable Lithium-ion Battery provides power to the Jarvik 2000 VAD for 7-12 hours via the FlowMaker Controller. It connects to a Lithium-ion Battery Cable (JHI-202) which is connected to the FlowMaker Controller either directly or via a Y Cable (JHI-212).</p> |
| Lithium-ion Battery Charger | JHI-404     |  | <p>The Lithium-ion Battery Charger is used to recharge the portable Lithium-Ion Battery.</p>   |

| Component                 | Part Number | Depiction  | Description  |
|---------------------------|-------------|--|--|
| Reserve Battery/Charger   | JHI-303     |     | The Reserve Battery/Charger provides power to the Jarvik 2000 VAD for 24 hours. It is connected to the FlowMaker Controller directly or via a Y Cable (JHI-212). |
| Lithium-ion Battery Cable | JHI-202     |    | Connects to the Lithium-Ion Battery (JHI-301).   |
| Extension Cable           | JHI-204     |  | Acts as an Extension Cable between the FlowMaker Controller and the Pedestal Cable.  |
| Pedestal Cable            | JHI-201     |  | Connects to the internal cable which exits the body behind the ear.  |

| Component               | Part Number | Depiction  | Description   |
|-------------------------|-------------|--|---|
| Y Cable                 | JHI-212     |  | Connects the FlowMaker Controller to the Lithium-ion Battery via the Lithium-ion Battery Cable.     |
| Power Cord, U.S., 6 ft. | JHI-205     |  | Plugs into a wall unit. Is used on the Lithium-ion Battery Charger and the Reserve Battery/Charger. |
| Power Cord, U.S., 9 ft. | JHI-206     |  |   |

***List of Components for Surgical Implantation of the Jarvik 2000 VAD***

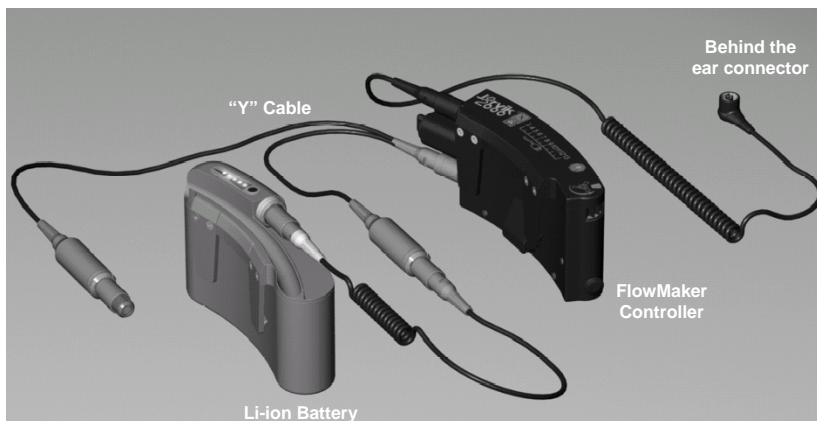
For a list of components provided by Jarvik Heart, Inc. for the surgical implantation of the Jarvik 2000 VAD, please see the Training Manual.

## Operating the Jarvik 2000<sup>®</sup> VAS

The Jarvik 2000 VAS includes a miniature rotary pump called an axial flow pump. The Jarvik 2000 VAD is approximately the size of a “C” cell flashlight battery and is surgically positioned partially within the natural heart. The Jarvik 2000 VAD is connected to an internal cable which exits the body behind the ear. An external cable is attached to the exit site of the internal cable. The external cable is then connected to the external FlowMaker Controller. The FlowMaker Controller receives electricity from the battery to run the Jarvik 2000 VAD at the selected speed.



Figure 1 Jarvik 2000<sup>®</sup> VAD



**Figure 2 External Equipment for Jarvik 2000® VAS, Post-Auricular Cable**

**Initial Set-Up**

- Plug the white and gray end of the Lithium-ion Battery Cable to a Lithium-ion Battery.
- Plug the gray strain relief end of the Lithium-ion Battery Cable (or the gray cable from the Reserve Battery/Charger) into either of the female receptacles of the Y Cable. The unused female receptacle should have the blank plug inserted to seal the receptacle.
- Connect the male plug of the Pedestal Cable to the FlowMaker Controller.
- Connect the female receptacle of the Pedestal Cable to the drive cable at the exit site.
- Screw on the Alarm Battery Cap finger tight.
- Connect the male plug of the Y Cable to the FlowMaker Controller.

**Changing a Battery**

If the battery is being changed, remove the blank plug on the free end of the Y Cable and plug in a fresh battery. If a Lithium-ion Battery is being used, a Lithium-ion Battery Cable will need to be connected as described in the Initial Set-Up above. If a Reserve Battery/Charger is being used, the gray cable is plugged into the Y Cable. After the fresh battery has been plugged into the open female connector of the Y Cable, remove the used battery from the other female connector. Place a blank plug in the open connector to seal it.

|              |   |
|--------------|---|
| <b>NOTE:</b> | It is possible to plug the battery cable directly into the FlowMaker Controller without the use of a Y Cable. However, without the Y Cable, the Jarvik 2000 VAD will stop each time the battery is changed. Unless there is an emergency and a Y Cable is not available or is damaged, the Y Cable should be used at all times. |
|--------------|---|

|  |  |
|--|--|
|  | The user must make sure to always connect a charged battery whenever making battery changes. In other words, make sure the battery being connected to the Jarvik 2000 VAS is not a discharged battery. |
|--|--|

|              |  |
|--------------|--|
| <b>NOTE:</b> | Always place the blank plug back in the end of the Y Cable that is not connected to a battery to protect the connector from dirt, dust, foreign matter, and water. |
|--------------|--|

## Removing Power from the Jarvik 2000 VAD

There is no on/off switch to power the Jarvik 2000 VAD. In general, the only time it is recommended to remove power from the Jarvik 2000 VAD is when the patient returns to the implant center for the replacement and test of the Alarm Battery which is described in a separate section in this manual. However, if power needs to be removed from the Jarvik 2000 VAD for any reason, change the speed setting on the FlowMaker Controller to setting 1 and simply disconnect the Lithium-ion Battery or the Reserve Battery/Charger from the Y Cable (and thus the FlowMaker Controller).

## Carrying the External Equipment

The Lithium-ion Battery and the FlowMaker Controller have been designed in such a way that they can be worn on a belt if the user wishes to do so. Both the Lithium-ion Battery and the FlowMaker Controller have belt clips which can be used to clip these items on a belt. If the user does not typically wear a belt or does not want to wear the components on a belt, the components can be placed in an over-the-shoulder type of bag.

|              |  |
|--------------|--|
| <b>NOTE:</b> | When choosing a carrying case for the external components, the user should ensure that all alarms can be heard when the components are in the case. Make sure the carrying case has ventilation. |
|--------------|--|

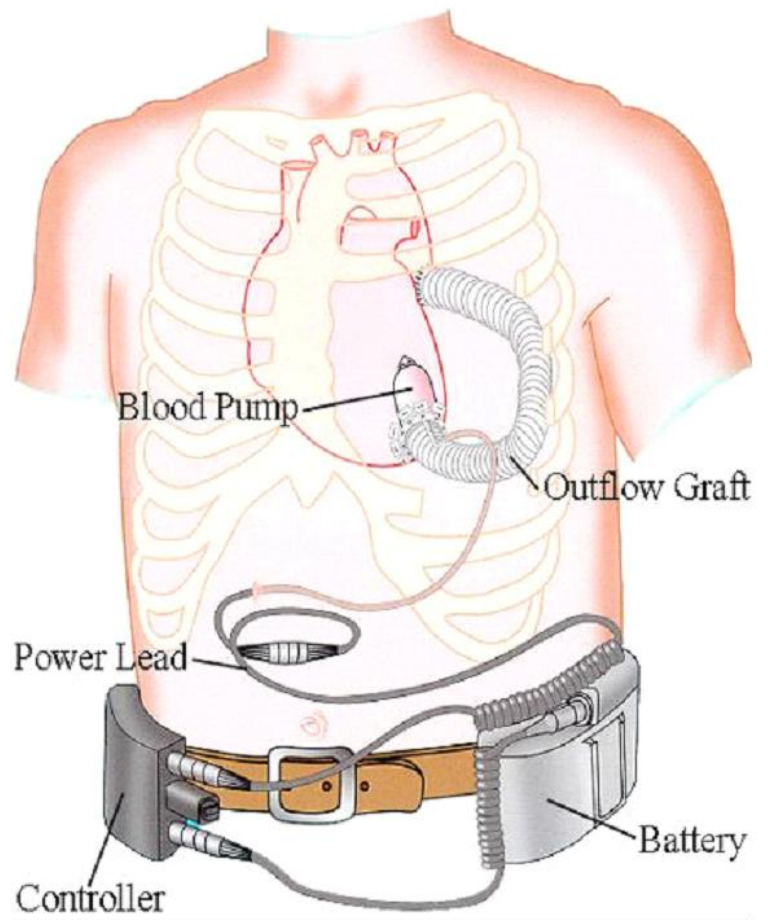


Figure 3 External Components Worn on a Belt

## Intermittent Low Speed FlowMaker® Controller

The Intermittent Low Speed (ILS) FlowMaker Controller provides power to the implanted Jarvik 2000 VAD and has five user settable speeds. The ILS FlowMaker Controller intermittently reduces the set speed for a few seconds approximately once per minute. By reducing the speed briefly each minute, the ILS FlowMaker Controller may reduce the risk of complications associated with prolonged closure of the aortic valve for certain patients.

The FlowMaker Controller should be replaced after 2 years of continuous use.



Figure 4 FlowMaker® Controller

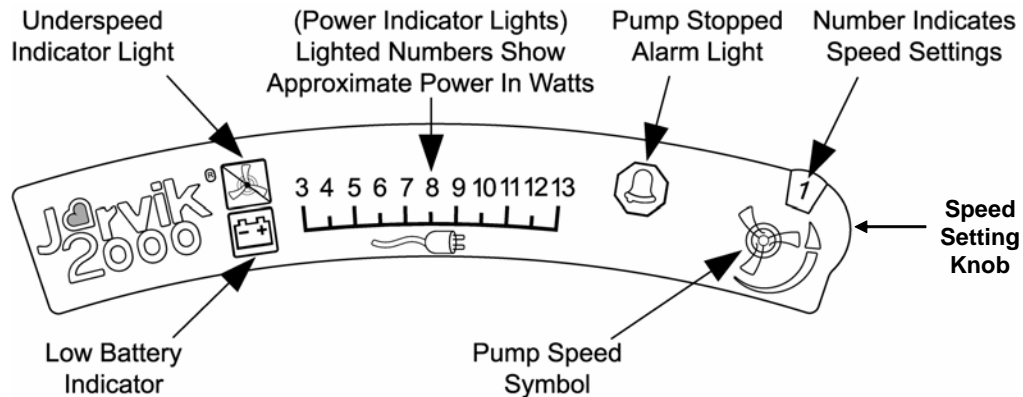


Figure 5 Diagram of FlowMaker® Controller Top Panel



Figure 6 ILS FlowMaker® Controller

### Setting the Speed of the Jarvik 2000 VAD

Only one control adjustment to the Jarvik 2000 VAS can be made, namely the **speed at which the Jarvik 2000 VAD is running**. The Jarvik 2000 VAD speed can be selected by turning the knob on the side of the FlowMaker Controller so that the selected setting number appears in the window on the top panel.

|  |   |
|--|---|
|  | <p>The top panel of the FlowMaker Controller has a symbol of a propeller to represent Jarvik 2000 VAD speed. The large propeller with the arrow next to it indicates the direction to turn the knob to increase the speed. The higher the number on the dial, the faster the Jarvik 2000 VAD speed.</p>   |
|  | <p>A different, smaller symbol of a propeller with a line drawn across it is called the underspeed indicator. If the underspeed indicator lights up yellow, this means that the speed that the Jarvik 2000 VAD is actually running is lower than the speed set on the dial. <b>See section entitled Alarms and Indicators for more details.</b></p> |

Figure 7 Speed Symbols Located on the FlowMaker® Controller

The Jarvik 2000 VAD runs at the following speeds according to the setting number on the dial:

| Setting Number | Approximate Jarvik 2000 VAD Speed |
|----------------|-----------------------------------|
| 1              | 8,000 RPM                         |
| 2              | 9,000 RPM                         |
| 3              | 10,000 RPM                        |
| 4              | 11,000 RPM                        |
| 5              | 12,000 RPM                        |

Figure 8 Setting Number and Approximate Jarvik 2000 VAD Speed



The FlowMaker Controller does not measure the actual blood flow that the heart is pumping. In general, the Jarvik 2000 VAD increases the blood flow pumped by the natural heart by approximately the following:

| Setting Number | Approximate Flow |
|----------------|------------------|
| 1              | 1-2 L/min        |
| 2              | 2-3 L/min        |
| 3              | 4-5 L/min        |
| 4              | 5-7 L/min        |
| 5              | 7-8.5 L/min      |

**Figure 9 Setting Number and Approximate Flow of Jarvik 2000 VAD**

However, if the patient is hypovolemic or becomes dehydrated (after a cold or flu, for example), turning the speed to the higher settings (4 or 5) may make the flow go down due to obstruction or suction. Other conditions, such as a kinked aortic graft, or thrombus occluding the device, can cause the flow through the Jarvik 2000 VAD to be less than otherwise expected at a given speed setting.

The speed setting selected should be based on the clinical condition of the patient and not on a presumed blood flow value.

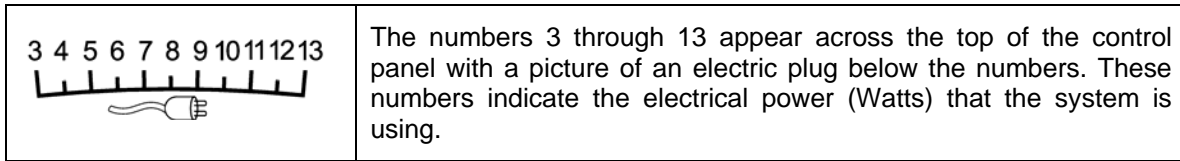
After the physician has evaluated the condition of the patient, the physician will determine the appropriate speed setting for the patient at any given time. In general, a lower speed may be selected during sleep, an intermediate speed may be used most of the day, and a higher speed may be used occasionally during exercise.



**If the Jarvik 2000 VAD speed is turned to setting 4 or 5 during exercise, always be sure to turn the setting back down to the proper number for rest when exercise is stopped.**

## Power Indicator Lights

The FlowMaker Controller measures the amount of electric power that the Jarvik 2000 VAS is using in watts and lights that number on the panel. The Power Indicator Lights are located on the top of the FlowMaker Controller.



**Figure 10 Power Indicator Lights**

When the number 3 is indicated, the Jarvik 2000 VAD is using 3 Watts or less. When the number 13 is indicated, the Jarvik 2000 VAD is using 13 Watts or more.

One, two, or three numbers may appear to be lit at any moment, and the lights may change rhythmically with the heartbeat of the natural heart. All lights are green except the number 13 which is yellow.

The amount of power used generally increases when the speed of the Jarvik 2000 is increased. The following are typical values:

| Setting Number | Approximate Power (Watts) |
|----------------|---------------------------|
| 1              | 3-4                       |
| 2              | 4-5                       |
| 3              | 5-6-7                     |
| 4              | 7-8-9                     |
| 5              | 8-9-10                    |

**Figure 11 Speed Setting and Approximate Wattage**

During the course of the patient's recovery the amount of power that the Jarvik 2000 VAS uses may change. For an initial period of time after the implant operation, the lights may not blink rhythmically. Later they may begin to blink which may indicate how fast the natural heart is beating. One may notice that exercise makes the lights blink faster. It may be useful for the patient to keep a record of this information. If the condition of the natural heart improves or deteriorates, this information may help the physician understand the changes that occurred. In addition, this information may also be helpful if a problem with the Jarvik 2000 VAS were to occur.

|              |   |
|--------------|---|
| <b>NOTE:</b> | Just prior to making any battery change, the user should look at the power indicator lights and check to make sure the power displayed is appropriate for the setting number on the FlowMaker Controller. If the wattage displayed is either too high or too low for the set speed, the user should contact the implant center immediately. |
|--------------|---|

## Connecting the FlowMaker® Controller

The FlowMaker Controller has two receptacles. The black receptacle is for the external Pedestal Cable. The gray receptacle is for the Y Cable.

The connectors are attached and removed by a **push-pull latch** mechanism, not by a screw thread.

The plugs and receptacles are keyed so that they cannot be connected improperly; they are also color coded for ease of use.

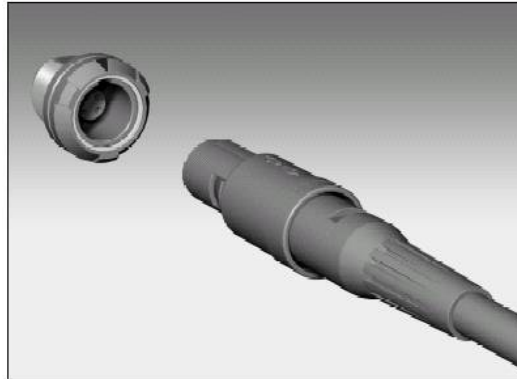


Figure 12 Diagram of Cable and Connector

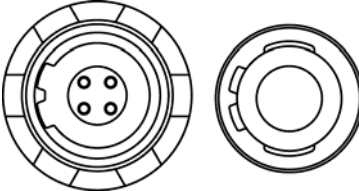
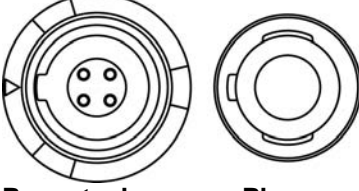
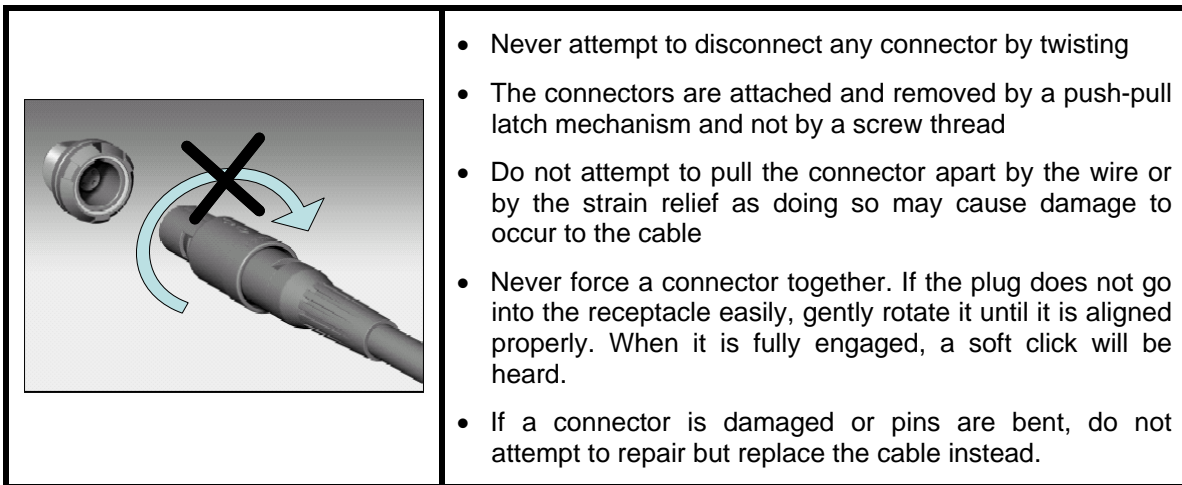
|   |  |
|---|--|
|  <p>Receptacle      Plug</p>  | <p>The <b>black</b> receptacle on the FlowMaker Controller is located above the housing for the small back-up Alarm Battery. This receptacle has <b>double key slots</b> for a black plug. The <b>Pedestal Cable</b> also has double key slots.</p>                    |
|  <p>Receptacle      Plug</p> | <p>The <b>gray</b> receptacle on the FlowMaker Controller is located below the housing for the small back-up Alarm Battery. This receptacle has a <b>single key slot</b> for the gray plug of the Y Cable, Lithium-ion Battery Cable, and Reserve Battery/Charger.</p> |

Figure 13 Diagrams of Key Slots in Receptacles and Plugs

Note that the single and double keys on the plugs and receptacles are easily visible and must be placed in the proper rotational position, with the arrows on receptacle and plug lined up, for the connectors to go together. Place the plug into the receptacle with slight pressure and gently rotate the plug until the key-way engages. Then push the connector together. The connector should **click into place** and should not come apart if the cable is tugged slightly. To remove the plug, hold the cable **close** to the receptacle, squeeze gently and pull.



**Figure 14 Cable Connector Use**

An Extension Cable may be used to allow the external components to be kept at distance. The Extension Cable connects the external Pedestal Cable to the FlowMaker Controller. The Extension Cable includes a retractable coil about a foot long which extends to about six feet. This facilitates domestic activities such as sleeping and showering. The retractable coil is intended to be partially stretched during normal use, but should not be over-stretched or it will not return to its original shape and may become tangled more easily. Do not use more than one Extension Cable with the Jarvik 2000 VAS, Post-Auricular Cable.

**All external cables should be replaced after 6 months of use.**

These cables include the following:

1. All Extension Cables and Pedestal Cables which connect the Jarvik 2000 VAD to the FlowMaker Controller.
2. All Y Cables which connect the FlowMaker Controller to the Lithium-ion Battery Cable.
3. All Lithium-ion Battery Cables which connect the Y Cable to the Lithium-ion Battery.

Ensure that each patient replaces all external cables after 6 months of use. Provide only new and unused cables to patients. Maintain a log recording external cable distribution and replacement.

**Constant Speed FlowMaker® Controller**

Certain patients may be intolerant to the eight second reduction in blood flow inherent to ILS. In such cases, a Constant Speed FlowMaker Controller (without ILS) may be requested. All other features of the Constant Speed FlowMaker Controller are identical to that of the ILS FlowMaker Controller.

## Batteries

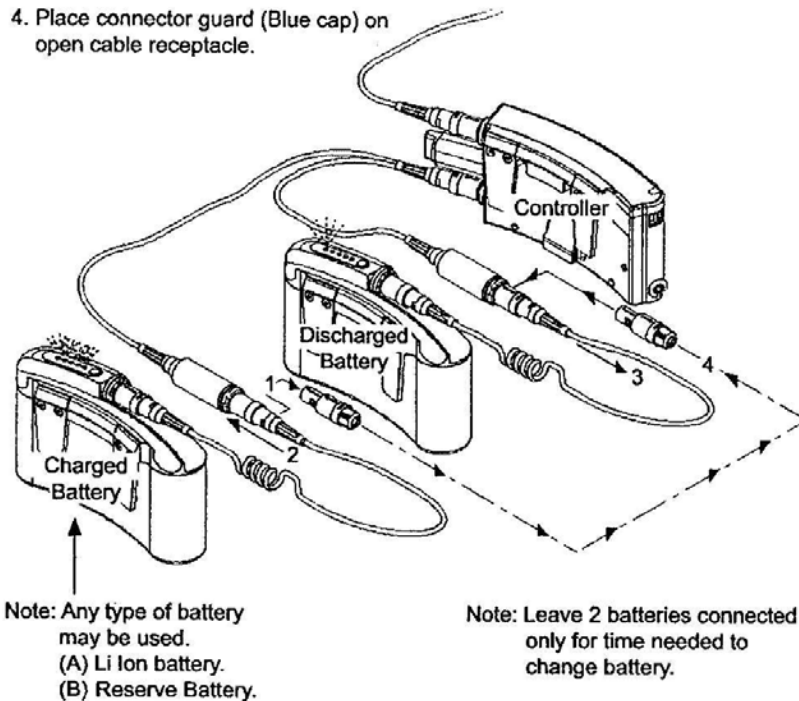
The Jarvik 2000 VAS operates with two types of batteries:

- 1) Each Lithium-ion Battery provides power for the Jarvik 2000 VAD for 7-12 hours under usual conditions.
- 2) Each Reserve Battery/Charger provides power for the Jarvik 2000 VAS for 24 hours under usual conditions.

When either of the two types of batteries being used to run the Jarvik 2000 VAS are low, the FlowMaker Controller will generate a low battery alarm by beginning to beep and simultaneously will display a yellow low battery indicator. Even after the low battery alarm begins to beep, the Jarvik 2000 VAS will continue to run for five to ten minutes. Take care to change the battery carefully in order to protect the cables and connectors from damage. If the Lithium-ion Battery is allowed to run for more than five to ten minutes it will shut off completely, and the Jarvik 2000 VAS will stop running.

### Instructions for battery change:

1. Remove connector guard. (Blue cap)
2. Plug the charged battery into the Y-Cable.
3. Unplug discharged battery from the Y-Cable.
4. Place connector guard (Blue cap) on open cable receptacle.



**Figure 15 Battery Change**

When the Y Cable is used, there is no reason to make the change quickly. Take time to avoid damaging the cables or connectors.



If the Jarvik 2000 VAD has been turned off for any reason and then is being turned on, the FlowMaker Controller should be set at speed setting 1 and gradually increased to the recommended speed. Power to the Jarvik 2000 VAD should be made between the FlowMaker Controller and the battery. However, if the battery is being changed with a Y Cable, there is no need to decrease the speed as the Jarvik 2000 VAD will not stop during the battery change.

### ***Lithium-ion Battery and Lithium-ion Battery Charger***



**Figure 16 Li-ion Battery**

The portable Lithium-ion Battery (also referred to as the Li-ion Battery) has enough power to run the Jarvik 2000 VAS for **7-12 hours under usual conditions**.


**NOTE:**

**When using the Li-ion Battery, the batteries should be alternated so each battery is used for approximately the same amount of time. Alternating the batteries helps assure that no battery is left for long periods of time without recharging, and that batteries are kept in the fully charged condition as much as possible. When alternating the batteries, check for Li-ion Batteries which last fewer than 7 hours and replace as needed.**

Each Li-ion Battery can be recharged hundreds of times. Eventually, as the number of times the Li-ion Battery has been recharged increases, fully charged Li-ion Batteries will power the Jarvik 2000 VAS for less than 7 hours. Although the Li-ion Battery still powers the Jarvik 2000 VAD and will continue to function properly over many additional recharge cycles, the amount of time it will last before requiring charging will continue to decrease.

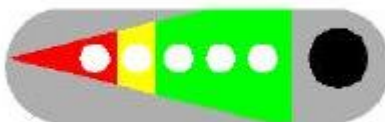
**Therefore, when a Li-ion Battery lasts less than 7 hours under usual use, from the time it is fully charged until the low battery alarm, the Li-ion Battery should be replaced with a new one.**

**Never dispose of a Li-ion Battery in the trash. Li-ion Batteries must be disposed of according to local law.**

|   |   |
|---|---|
|  | <p><b>A Lithium-ion Battery Cable (also referred to as a Li-ion Battery Cable) must be attached to the Li-ion Battery to plug the Li-ion Battery either into the Y Cable (which is then plugged into the FlowMaker Controller) or directly into the FlowMaker Controller without a Y Cable. The Li-ion Battery cannot deliver power without a Li-ion Battery Cable.</b></p> |
|---|---|

For the Jarvik 2000 VAD to operate, the Pedestal Cable must connect the FlowMaker Controller to the implanted Jarvik 2000 VAD.

Each Li-ion Battery has an indicator with five lights which indicates how much power is remaining. Depress the black button to turn on the indicator lights. Three lights are in the “green” zone, one light is in the “yellow” zone, and one light is in the “red” zone.



**Figure 17 Diagram of Li-ion Battery Indicator for Remaining Power**

The approximate amount of time remaining until low battery alarm for speed settings 1 to 3 are indicated below:

| Indicator** | Li-ion Battery - <b>NEW</b> | Li-ion Battery Ready for Retirement | Approximate Time Remaining Until Low Battery Alarm* |
|-------------|-----------------------------|-------------------------------------|---|
| ●●●●●       | ~ 8 – 12 hrs.               | < 7 hrs.                            | Operating range with <b>ALL</b> 5 LEDs lit          |
| ●●●●○       | ~ 6 – 10 hrs.               | -                                   | Operating range with 4 LEDs lit                     |
| ●●●○○       | ~ 5 – 8 hrs.                | -                                   | Operating range with 3 LEDs lit                     |
| ●●○○○       | ~ 3 – 5 hrs.                | -                                   | Operating range with 2 LEDs lit                     |
| ●○○○○       | ~ 5 min – 2 hrs.            | -                                   | Operating range with 1 LED lit                      |

\* Note: Actual operating times may vary depending on equipment, environment, and use conditions. Operating time decreases as the speed setting is increased from 1 to 5.

\*\* Note: All LEDs are green; however, the background zones are color coded.

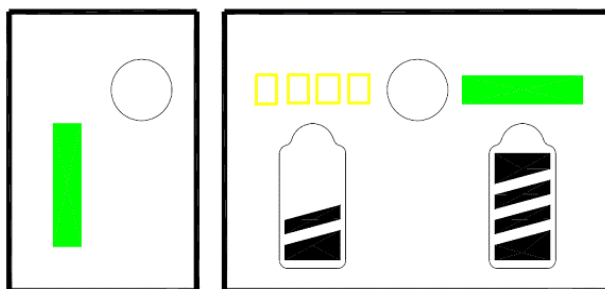
**Figure 18 Battery Life Indicator Lights**



**Figure 19 Lithium-ion Battery Charger**

The Lithium-ion Battery Charger (also referred to as the Li-ion Battery Charger) is used to charge the Li-ion Batteries. The Li-ion Battery Charger has a detachable power cable to plug into the wall, and a smaller fixed cable to plug into the Li-ion Battery. This smaller cable has a gray and white connector plug which fits into the gray and white receptacle on the Li-ion Battery.

The Li-ion Battery Charger has two status lights. A green light next to the vertical green bar indicates connection to wall power. The second light indicates charge status. The second light flashes yellow during charging, as represented by the dashed horizontal yellow bar above the half filled battery icon. This light is solid green when the Li-ion Battery is fully charged, as represented by the solid green horizontal bar above the completely filled battery icon. When the Li-ion Battery Charger is not connected to a Li-ion Battery, the second light will remain off.



**Figure 20 Lithium-ion Battery Charger Label**

|              |  |
|--------------|--|
| <b>NOTE:</b> | <p>When the Li-ion Battery Charger is first connected to wall power, the green light next to the vertical green bar will turn on. The second light will simultaneously turn on green for approximately 1-3 seconds, followed by the startup sequence below:</p> <ul style="list-style-type: none"> <li>• Flashing yellow for approximately 18-24 seconds</li> <li>• Solid green for approximately 1-3 seconds</li> <li>• Off</li> </ul> <p>The Li-ion Battery Charger is not required to go through the startup sequence each time it is connected to a Li-ion Battery. It will only occur when wall power is first applied to the Li-ion Battery Charger.</p> |
|--------------|--|





**Never connect the Li-ion Battery to the Li-ion Battery Charger while the second light is green. If a connection is made during this brief period of time, the Li-ion Battery will not charge.**

**When disconnecting the Li-ion Battery Charger from a fully charged Li-ion Battery, always wait for the second light to turn off before connecting another Li-ion Battery.**

Do not position the Li-ion Battery Charger in such a way that it is difficult for the user to detach the Li-ion Battery Charger from the power supply cord.



**Never use an extension cord or multiple portable socket outlet (power strips) or any other items not part of the system when charging the batteries.**

**Allow approximately five and a half hours to fully recharge a fully discharged Li-ion Battery.**

The Li-ion Battery and Li-ion Battery Charger can be left plugged into mains after charging. To remove power from the Li-ion Battery Charger, simply unplug the power cord from the wall outlet.

The Li-ion Battery may be damaged if it is dropped onto a hard surface. The indicator lights and the black button are also subject to damage and should be protected. Do not press the black button with pointed or hard objects. Protect the Li-ion Battery from impact.

If any of the indicator lights on the Li-ion Battery are damaged, they may not light up when the black button is depressed. The Li-ion Battery will still function properly and may be used until the battery can be exchanged for another battery; however, more careful attention must be paid to the amount of time the battery has been used since recharging.

The Li-ion Battery includes an attachment device to permit the FlowMaker Controller to be mounted onto it. Hold the Li-ion Battery and slide the “tongue” of the FlowMaker Controller into the “groove” on the Li-ion Battery. When these two components are joined in this way, never lift them by the FlowMaker Controller only. The Li-ion Battery could slide out of the “tongue and groove” attachment device and fall. Always directly hold the Li-ion Battery and FlowMaker Controller whenever handling the components.

**NOTE:**

- **Li-ion Batteries should be fully recharged before storage so that the battery is available for use.**
- **If it is necessary to store or shelve the Li-ion Battery, fully recharge the Li-ion Battery every 60 days.**

**Use only Li-ion Batteries and Li-ion Battery Chargers provided by Jarvik Heart. Inc.**

## **Reserve Battery/Charger**

The Reserve Battery/Charger is a single unit, which is provided in a fabric carrying case with a shoulder strap. The Reserve Battery/Charger provides power for times when the patient is not using the wearable Li-ion Battery, such as at night. Note that the Reserve Battery/Charger is quite heavy (approximately 15 lbs. or 7 kg). When practical, the Reserve Battery/Charger should be placed on the floor because then it is impossible for it to fall. If the battery must be placed on a table, be sure to place it on a clean, hard surface.



**Figure 21 Reserve Battery/Charger Connected to Y Cable then FlowMaker® Controller**

The Reserve Battery/Charger has a long cord with a gray plug that plugs into the Y Cable (which is then connected to the FlowMaker Controller) or plugs directly into the FlowMaker Controller without a Y Cable. The carrying case has two fabric loops to hold the clips on the FlowMaker Controller. When using the Reserve Battery/Charger, keep the FlowMaker Controller and Y Cable in place on these loops and connect the elastic retention strap to prevent the FlowMaker Controller from being accidentally pulled away. If the FlowMaker Controller is attached to the battery case, keep the long battery cable neatly coiled in the side pouch of the case. Be careful never to put stress on the battery cable.

|              |   |
|--------------|---|
| <b>NOTE:</b> | To avoid damaging the Reserve Battery/Charger, always lift using the strap. |
|--------------|---|



**Figure 22 Charging the Reserve Battery/Charger**

The Reserve Battery/Charger, as the name indicates, has both a battery and a charger built into a single unit. There is a clear plastic window on top of the fabric carrying case through which two lights are visible. These lights are marked Power and Charge. A gray cable and a gray receptacle are also located on top of the Reserve Battery/Charger. A detachable power cord is provided for connection of the charger section of the unit to wall power.

A green light next to the Power label on the top of the Reserve Battery/Charger indicates connection to wall power.

To charge the Reserve Battery/Charger, disconnect the gray plug from the Y Cable or FlowMaker Controller and plug it into the gray receptacle on the Reserve Battery/Charger. (This will appear that the Reserve Battery/Charger is being connected to itself. In actuality, the Reserve Battery is being connected to the Reserve Charger which is attached to the Reserve Battery inside the fabric case).

A yellow light next to the Charge label on the Reserve Battery/Charger will turn on to indicate charging. When the Reserve Battery/Charger is fully charged, the yellow light will turn off.

|              |  |
|--------------|--|
| <b>NOTE:</b> | <ul style="list-style-type: none"> <li>• The green light next to the Power label on the Reserve Battery only indicates that wall power is connected to the charger section of the unit. The green light does not indicate the Reserve Battery/Charger is fully charged.</li> <li>• The Reserve Battery/Charger is fully charged only if the Charge light is off <b>and</b> the gray cable is plugged into the gray receptacle on the unit.</li> <li>• <b>If the gray cable is not plugged into the receptacle on the Reserve Battery/Charger while the unit is also plugged into the wall, the Reserve Battery/Charger will not charge.</b></li> </ul> |
|--------------|--|

The Reserve Battery/Charger may remain connected to the wall plug indefinitely without damage to the Reserve Battery/Charger.



**It is not possible to run the Jarvik 2000 VAS from wall power even if the Reserve Battery/Charger is plugged into wall power. It is also not possible to charge the Reserve Battery/Charger while the same Reserve Battery/Charger is being used to run the Jarvik 2000 VAD.** The Reserve Battery and Reserve Charger are provided as a single unit inside the fabric carrying case; however, they are not electrically connected to each other. **At all times, the Jarvik 2000 VAD is run only from battery power.**

Do not position the Reserve Battery/Charger in such a way that it is difficult for the user to detach the Reserve Battery/Charger from the power supply cord.



**Do not attempt to charge the Reserve Battery with an external charger. Only use the Reserve Charger which is provided in a single unit with the Reserve Battery (the Reserve Battery/Charger) by Jarvik Heart, Inc.**

When fully charged, each of the Reserve Battery/Chargers has enough stored power to run the Jarvik 2000 VAS for over 24 hours. When the Reserve Battery/Charger is new and the Jarvik 2000 VAS is run at an average speed (setting 3) the Reserve Battery/Charger will power the Jarvik 2000 VAD for over 35 hours. If the Reserve Battery/Charger is used for under 12 hours and then recharged, it will last for more than 1000 recharge cycles. If it is not recharged until it is fully discharged and the low battery alarm sounds, it will last for fewer than 200 recharge cycles.

**Recommended normal use at 25°C (77°F) ambient conditions.**

**Use the Reserve Battery/Charger for less than 12 hours each night and recharge it each morning after switching to the Li-ion Battery. Alternate use of the Reserve Battery/Chargers by using one of the Reserve Battery/Chargers one night and the other Reserve Battery/Charger the following night.** Alternating the batteries this way assures that they will both be freshly charged (which is important if there is a power outage) and increases the service life of both batteries.

When it is **unavoidable** to store the Reserve Battery/Charger for 3 months or longer, periodically recharge the Reserve Battery/Charger at the following intervals depending upon ambient temperature.

| Storage Temperature        | Recharge Interval |
|----------------------------|-------------------|
| Below 68°F (20°C)          | 6 months          |
| 68°F (20°C) to 86°F(30°C)  | 4 months          |
| 86°F(30°C) to 104°F (40°C) | 2 months          |

**Figure 23 Recharging Stored Reserve Battery/Chargers**

**The Reserve Battery/Charger should be replaced after 3 years of normal use. Use only the Reserve Battery/Charger provided by Jarvik Heart, Inc.**

## Reserve Battery/Charger Handling Precautions



The Reserve Battery/Chargers are lead-acid batteries which contain strong sulphuric acid. If the Reserve Battery/Chargers are damaged by dropping or otherwise, the Reserve Battery/Chargers may leak, causing an acid exposure hazard.

The following information is provided in case of battery leakage:

### Emergency and first aid procedures

If exposed to sulphuric acid from the batteries by:

**Inhalation:** Remove to fresh air. Give oxygen or artificial respiration if needed. Get immediate medical attention.

**Eye Contact:** Flush with plenty of water for at least 15 minutes. Get immediate medical attention.

**Skin Contact:** Remove contaminated clothing and flush affected areas with plenty of water for at least 15 minutes.

**Ingestion:** Do not induce vomiting. Dilute by giving large quantities of water. If available give several glasses of milk. Do not give anything by mouth to an unconscious person. Give CPR if breathing has stopped. Get immediate medical attention.

### Precautions for Safe Clean Up

Steps to be taken in case of broken battery case or electrolyte leakage:

- Neutralize any electrolyte or exposed internal battery parts with soda ash (sodium bicarbonate / baking soda) until fizzing stops.
- Keep untrained personnel away from electrolyte and broken battery.
- Place broken battery and clean-up materials in a plastic bag or non-metallic container.
- Dispose of clean-up materials as a hazardous waste. Ventilate area as hydrogen gas may be given off during neutralization.

### Battery Disposal

**U.S. Federal and State laws prohibit the improper disposal of all lead acid batteries.** The battery end users (owners) are responsible for their batteries from the date of purchase through their ultimate disposal. The only legally acceptable method of disposal of lead acid batteries is to recycle them at a Resource Conservation and Recovery Act (RCRA) approved secondary lead smelter.

## Y Cable

The Y Cable for the Jarvik 2000 VAS is used to allow battery changes without removing power from the Jarvik 2000 VAD. Before unplugging a discharged battery, a recharged battery should be plugged into the Y Cable. If the battery cable is unplugged prior to attaching a charged battery to the other end of the Y Cable, the Jarvik 2000 VAD stops, but the natural heart continues to beat. If this occurs, the beeping tone of the alarm will change to a steady tone, indicating that the Jarvik 2000 VAD is stopped. After the used battery is replaced with a fresh one, always remove the discharged battery from the Y Cable.

When two batteries of the same type (either two Reserve Battery/Chargers or two Li-ion Batteries) are connected to Y Cable, and are being used to run the Jarvik 2000 VAS, the low battery alarm on the FlowMaker Controller will begin to beep when both of the batteries are low.

When different battery types (1 Reserve Battery/Charger and 1 Li-ion Battery) are connected to the Y Cable, and are being used to run the Jarvik 2000 VAS, the low battery alarm on the FlowMaker Controller will begin to beep when the Reserve Battery/Charger is low.

## Alarms and Indicators

The FlowMaker Controller monitors the Jarvik 2000 VAD speed, the power consumed, and the battery. The FlowMaker Controller also provides alarms and indicators to the user.

Alarms are communicated to the user by both a visual indicator and an audible alarm. **Alarms require immediate attention.**

Indicators are communicated to the user by a visual indicator only. Indicators require appropriate corrective action.


Below is a list of all alarms and indicators for the Jarvik 2000 VAS.


| Alarm or Indicator   | Alarm (audible)    | Visual Indicator |
|----------------------|--------------------|------------------|
| Pump Stopped Alarm   | steady tone        | steady red       |
| Low Battery Alarm    | Intermittent beeps | steady yellow    |
| High Power Indicator | -                  | steady yellow    |
| Underspeed Indicator | -                  | steady yellow    |

Figure 24 List of Alarms and Indicators

### *Pump Stopped Alarm*

The patient should not remove any components even for dressing unless under supervision. If power to the Jarvik 2000 VAD is interrupted, the Jarvik 2000 VAD will stop and the Pump Stopped Alarm will sound.

|   |   |
|---|---|
|  | <p>The Pump Stopped Alarm symbol is shaped like a stop sign with a bell inside it.</p> <p>If the Jarvik 2000 VAD stops or if the Jarvik 2000 VAD speed drops to below 5,000 RPM for any reason, a <b>steady alarm sound</b> is heard and the Pump Stopped Alarm symbol on the FlowMaker Controller lights <b>red</b>.</p> <p>The Pump Stopped Alarm will also sound if the intermittent low speed feature on the ILS FlowMaker Controller fails to function for any reason.</p> |
|---|---|

|   |   |
|---|---|
|  | <p><b>If the steady Pump Stopped Alarm sound is heard at any time other than when cables are disconnected, immediate attention is required.</b></p> |
|---|---|

## ***Procedure to Resolve Pump Stopped Alarm***

### ***- Jarvik 2000 VAS, Post-Auricular Cable***

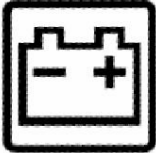

The most likely reason for the Jarvik 2000 VAD (pump) to stop is a completely **discharged battery** or a **disconnected** or **damaged cable**. If the cause of a component failure is clearly identifiable (i.e. low battery, physical damage, etc.) replace that cable or component **first**.

If the cause is unknown, follow these step-by-step instructions with the assistance of a support person. The patient should sit down or lie down. This procedure should be completed quickly. Back-up equipment must be immediately available.

1. Be sure the alarm is not an intermittent beeping which only indicates a low battery. If the alarm is beeping, change the battery as usual.
2. If the Jarvik 2000 VAD is stopped (steady alarm sounding, red light on):
  - a. **Disconnect the Pedestal Cable from the Pedestal at the skull, and set aside all the attached components.** Disconnect the Li-ion Battery Cable and also partially unscrew the Alarm Battery Cap on the FlowMaker Controller to silence the alarm.
  - b. Plug in a backup Pedestal Cable into a backup FlowMaker Controller. Make sure the FlowMaker Controller is set at speed setting 1. Make sure to tighten the Alarm Battery Cap on the backup FlowMaker Controller to activate the back-up alarm.
  - c. Using the backup Li-ion Battery Cable, plug a fully charged Li-ion Battery into the FlowMaker Controller.
  - d. If the Jarvik 2000 VAD now runs, and the patient is feeling well, red tag the original components that were set aside in step 2a.
  - e. Set the FlowMaker Controller back at the speed the user was using prior to the alarm.
3. **If the Jarvik 2000 VAD (pump) is still stopped call the medical emergency number immediately.**
4. Red tag all components of the system that were set aside before changing to the backup components in step 2a.
5. If the Jarvik 2000 VAD still has not started, the patient should lie down and the support person should double check batteries and connectors. Try changing batteries again. It is possible that a discharged battery was removed and the same discharged battery was accidentally plugged back into the system. It is possible that neither battery is charged. If no lights illuminate on either battery, use a third battery. It is also possible that one of the connectors is not fully plugged in and is not making contact. Recheck all connectors.
6. If all of the above steps have been followed and all cables and components have been replaced without successfully restarting the Jarvik 2000 VAD, **disconnect the power to the Jarvik 2000 VAD by unplugging the battery.** Also partially unscrew the Alarm Battery Cap on the FlowMaker Controller. **(The alarm should stop sounding)**. If the Li-ion Battery or Reserve Battery/Charger is not disconnected, the FlowMaker Controller will apply power to the Jarvik 2000 VAD which could be harmful. Disconnecting the battery reduces the chance of a clot forming inside the Jarvik 2000 VAD by allowing the rotor to spin as blood flows across it.

**Note: Return any failed or suspect component(s) to the Clinical Center for evaluation by Jarvik Heart, Inc.**



## Low Battery Alarm

| LOW BATTERY ALARM   |  |
|---|--|
|  | <p>When the battery powering the Jarvik 2000 VAD is low (about 5-10 minutes of running time remaining with the Li-ion Battery), the low battery symbol on the control panel lights <b>yellow</b> and the <b>alarm sound beeps</b>.</p> |
|  | <p>This condition requires attention as the Jarvik 2000 VAD will stop when the battery becomes fully discharged.</p>   |

Although the Li-ion Battery will have enough power to continue operating the Jarvik 2000 VAD for 5-10 minutes, recharged batteries should always be kept immediately at hand and the battery should be changed when the alarm sounds.



The Reserve Battery/Charger will continue to operate for approximately 15 minutes after the low battery alarm begins to sound. This time is longer than that for the Li-ion Battery.

## High Power Indicator

| HIGH POWER INDICATOR  |  |
|---|--|
|  | <p>If the FlowMaker Controller measures 13 watts of power or more, this indicates a malfunction. The number 13 will light <b>yellow</b>.</p>   |
|  | <p>This condition should receive prompt attention. Replace unit with back-up FlowMaker Controller and if the condition persists <b>immediate medical assistance is required</b>.</p> |



## Underspeed Indicator

|   |   |
|---|---|
|  | The underspeed indicator light will glow yellow when the FlowMaker Controller detects that the Jarvik 2000 VAD speed is slower than the dial setting selected. No alarm sounds.   |
|  | If the underspeed indicator stays on after taking all corrective actions, this indicates a problem with the cables, battery, FlowMaker Controller, or the implanted Jarvik 2000 VAD. This condition should receive prompt attention. <b>Immediate medical assistance is required.</b> |

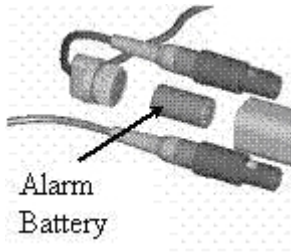
The underspeed indicator is intended as a method to confirm that the Jarvik 2000 VAD is running at the set speed. If the underspeed indicator is lit, this indicates that the Jarvik 2000 VAD is running slower than the speed indicated on the dial setting. If this occurs, and there are no clinical indications of a problem with the patient's condition, the most common reason is the battery voltage is too low.

In the case of low battery voltage, corrective actions are to:

- 1) Select a lower speed setting on the FlowMaker Controller and/or
- 2) Change the battery to a fully charged Li-ion Battery.

If the underspeed indicator light is still lit, then the cause may be a fault in the system. Replace all external components. If the underspeed light is still on after replacing all external components, then treat the situation as an emergency; the patient should seek immediate medical attention.

## Backup Power for the Alarms

|   |   |
|---|---|
|  | A small, non-rechargeable Alarm Battery is used to assure that the FlowMaker Controller has enough power for the alarms if the main battery fails, if the battery cable fails, or if the main battery becomes accidentally disconnected. This Alarm Battery is located in a small housing on the end of the FlowMaker Controller between the connectors for the external cable and the battery cable. |
|---|---|

**Figure 25 Location of Alarm Battery on FlowMaker® Controller**

Any time the main battery is disconnected, the Jarvik 2000 VAS will stop and the alarm will sound. The small Alarm Battery does not have enough power to run the Jarvik 2000 VAS for even a short time and is only used to power the alarms.

## Care and Maintenance of the Jarvik 2000 VAS

All external equipment should be inspected weekly at a minimum. Replace any cables or external equipment that appears damaged with a back-up component. Immediately contact the implant center to have the back-up component replaced as soon as possible. All damaged equipment should be returned to the implant center. The implant center should then contact Jarvik Heart, Inc. to return the equipment for inspection.

Never try to service or fix a damaged or broken component. Always replace the component with a back-up component and return the damaged or broken component to the implant center for return to Jarvik Heart, Inc.

**All external cables should be replaced after 6 months of use.** These cables include the following:

1. All external Extension Cables and Pedestal Cables which connect the Jarvik 2000 VAD to the FlowMaker Controller.
2. All Y Cables which connect the FlowMaker Controller to the Li-ion Battery Cable.
3. All Li-ion Battery Cables which connect the Y Cable to the Li-ion Battery.

All external cables, batteries and the FlowMaker Controller can be cleaned by wiping with a cloth moistened with 70% isopropyl alcohol. Use caution with the isopropyl alcohol as it is flammable.

All batteries including Li-ion Batteries, Reserve Battery/Chargers, and the Alarm Battery used to power the back-up alarm should only be replaced with batteries provided by Jarvik Heart, Inc.

### ***Replacing and Testing the Back-Up Power for the Alarms***



The patient must return to the implant center every three months so that staff can replace the Alarm Battery, test the new Alarm Battery, and check all the equipment. Staff must only use Alarm Batteries that are obtained from Jarvik Heart, Inc.

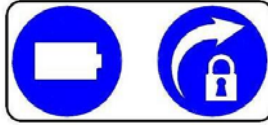
Every three months, staff at the implant center must perform the following steps:

1. Replace the Alarm Battery with a fresh Alarm Battery obtained from Jarvik Heart, Inc.
2. Be sure that the Alarm Battery Cap is screwed finger tight.
3. Briefly unplug the Y Cable from the Li-ion Battery or Reserve Battery/Charger powering the Jarvik 2000 VAD. The Jarvik 2000 VAD will stop while the battery is disconnected, and the Pump Stopped Alarm will sound.
4. Immediately plug the main battery back in. The Jarvik 2000 VAD will begin to run and the Pump Stopped Alarm will no longer be heard.
5. If the alarm does not sound when the Li-ion Battery or Reserve Battery/Charger is disconnected, reconnect the main battery. Change the Alarm Battery again for a new one and repeat the procedure.

The Alarm Battery may be placed into its housing with either the plus (+) or minus (-) side inserted first. The Alarm Battery Cap holding the Alarm Battery in place must be screwed all the way down in order for the Alarm Battery to operate properly.

**NOTE:**

**Whenever the Alarm Battery is replaced, the date should be written on the new Alarm Battery. This way it is clear when the Alarm Battery was last changed.**



**Figure 26 Alarm Battery Cap Must be Screwed on Finger Tight**

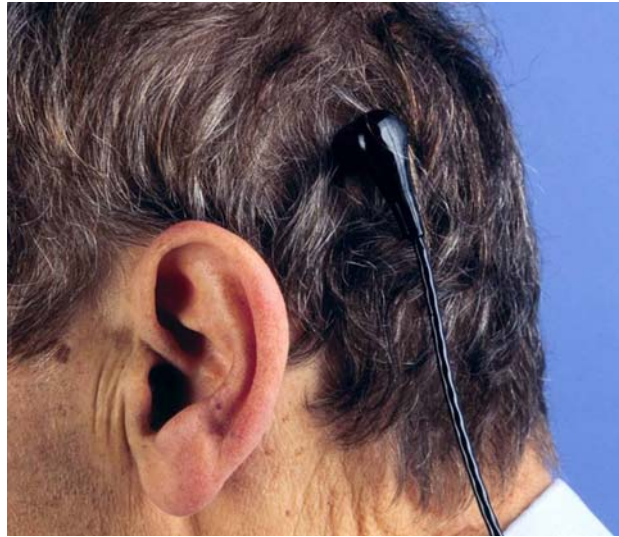
|  |  |
|--|--|
|  | <p>Be sure that the Alarm Battery Cap holding the Alarm Battery in place on the FlowMaker Controller is screwed on finger tight whenever the FlowMaker Controller is used. If the Alarm Battery Cap is not screwed finger tight in place, the backup power for the alarms will not function.</p> |
|--|--|

The patient must keep a backup FlowMaker Controller together with a backup Li-ion Battery and a complete set of backup cables with him/her at all times. The small battery in the backup FlowMaker Controller may be left in its housing and the Alarm Battery Cap loosened just until the alarm goes off. An O-ring, which seals the battery chamber from fluid spills, will keep the Alarm Battery Cap from coming off as long as it is not loosened too much.

|  |  |
|--|--|
|  | <p>A full set of back-up equipment must be carried with the user at all times.</p> |
|--|--|

|  |   |
|--|---|
|  | <p>If the backup FlowMaker Controller is needed, be sure to tighten the Alarm Battery Cap to activate the back-up Alarm Battery before connecting the main battery to the FlowMaker Controller.</p> |
|--|---|

## Care of the Pedestal-Skin Junction—Jarvik 2000 VAS, Post-Auricular Cable



**Figure 27 Pedestal Cable in Place**

After healing of the incision at the Pedestal site, no wound dressing is used over the Pedestal. The hair is allowed to grow back normally, and is not trimmed back from the Pedestal exit site. The skin should be cleaned daily with mild soap and water and may be cleaned occasionally with a dilute hydrogen peroxide solution.



**Do not attempt to clean the Pedestal site with any product, which contains iodine such as Betadine. The iodine may cause the pins on the Pedestal to corrode.**

The patient may shower or bathe normally. During showering or bathing, the inside of the connector must be kept dry.

If a small amount of sebaceous crusty material accumulates at the skin-to-Pedestal junction, this should be gently removed with a non-iodine based antiseptic under aseptic conditions.

The patient should not remove the external Pedestal, in order to avoid getting liquid or contaminating material into the connector. If the Pedestal Cable must be removed, use best efforts to avoid hair or other contaminants entering the Pedestal.



**Hospital staff should remove the Pedestal Cable every three months, during follow up visits for inspection and cleaning.**

The connector pins should be inspected under 5X magnification and good lighting (with a magnifying glass or loupe). If the pins appear wet, or if there is visible foreign contaminating material present this must be removed by rinsing with isopropyl alcohol and by use of a fine brush (such as an artist's brush) if necessary. After cleaning both the Pedestal and the end of the Pedestal Cable that attaches to the Pedestal, both parts should be blown dry with clean compressed air through a small tube, such as available in an aerosol can. The o-ring inside the Pedestal should be inspected and replaced if damaged.

When the cleaning and drying is complete, inspection should show clean dry gold pins with no surface residue. The cavity surrounding the pins and the groove around the o-ring should likewise be dry and free of residue. The cable connector end of the Pedestal Cable should also be dry and free of residue.

## **Disposal of Equipment**

The appropriate way to dispose of the Li-ion Battery and Reserve Battery/Charger has been discussed in the preceding sections about those components. All other components that are no longer needed may be disposed of in hospital industrial waste. The Alarm Battery should be disposed of according to local law for the disposal of batteries. Should the operator require evaluation of a Jarvik 2000 VAD which has been used, the Jarvik 2000 VAD should be decontaminated according to the protocol listed in Jarvik Heart Document Number IU0198 before packaging the Jarvik 2000 VAD. The Jarvik 2000 VAD should be packed in the same manner as it shipped to the operator to protect it from damage during return shipment. All other components which the operator would like evaluated, should be packaged appropriately to ensure the components will not be damaged during shipment and returned to Jarvik Heart, Inc. The operator should contact Jarvik Heart, Inc. before shipping the items so that the items can easily be identified upon arrival.