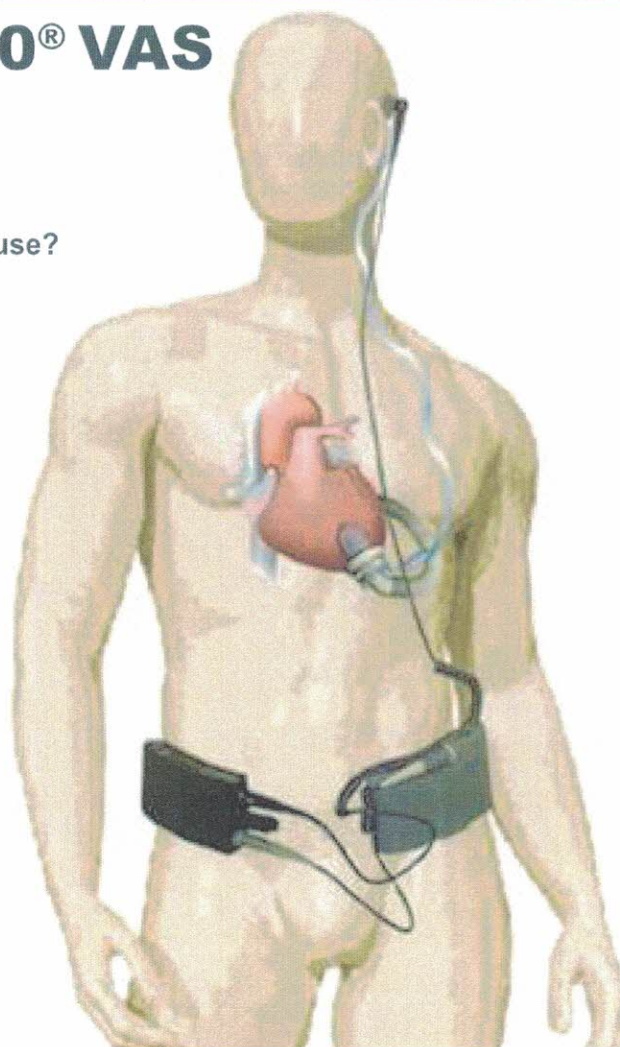
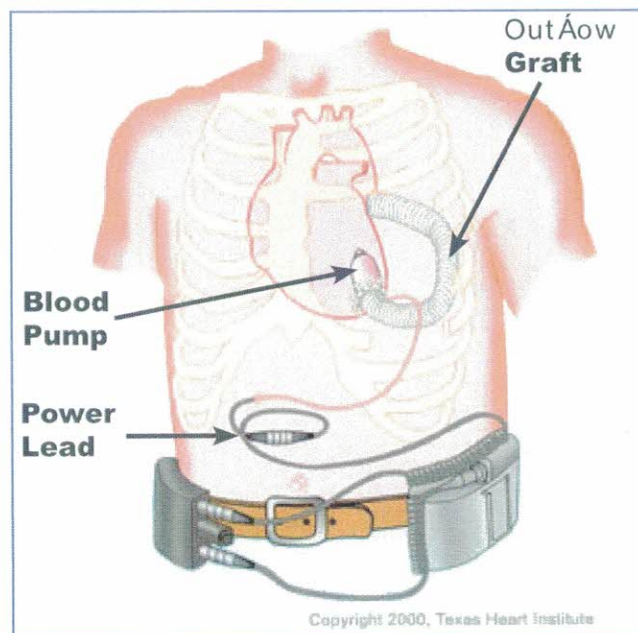


Jarvik 2000® VAS

1. **Can I do external CPR?**
Yes, only as a last resort.
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?**
No alarm for low flow. If pump is off, the red "Pump Stop" symbol will light with a continuous alarm.
4. **How can I speed up the rate of the device?**
There is a speed dial on the side of the controller (see picture on next page). Turning the dial in the direction of the arrow increases the speed. Each increment is 1,000 RPM. It is recommended not to change the speed without consulting the implanting center.
5. **Do I need to heparinize the patient if it slows down?**
Typically yes, if the pump is stopped (red "Pump Stop" alarm). Check with the implanting center.
6. **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.
8. **Does the patient have a pulse with this device?**
Most patients have a faint palpable pulse. If the controller is marked "ILS" (see below), the speed is automatically reduced every minute for 8 seconds & the patients pulse may increase during this time.
9. **What are acceptable vital sign parameters?**
MAP 65 - 80mm Hg.
10. **Can this patient be externally paced?**
Yes.



Jarvik 2000 with Post-Auricular exit site.



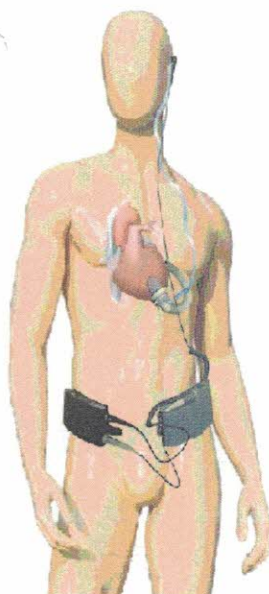
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Jarvik 2000 with Abdominal exit site.

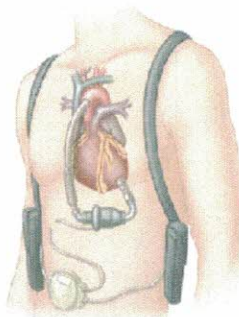
Adapted from Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport in ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010 in press. This guide does not supersede manufacturer instructions. Copy with permission only. March 2015 Jarvik 2000®

JANUARY 2015

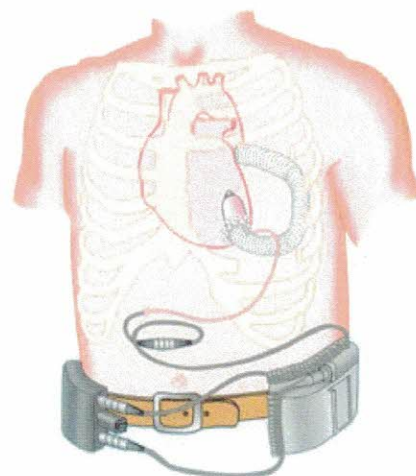
Jarvik 2000® VAS



**Jarvik 2000® VAS,
Post-Auricular Cable.**

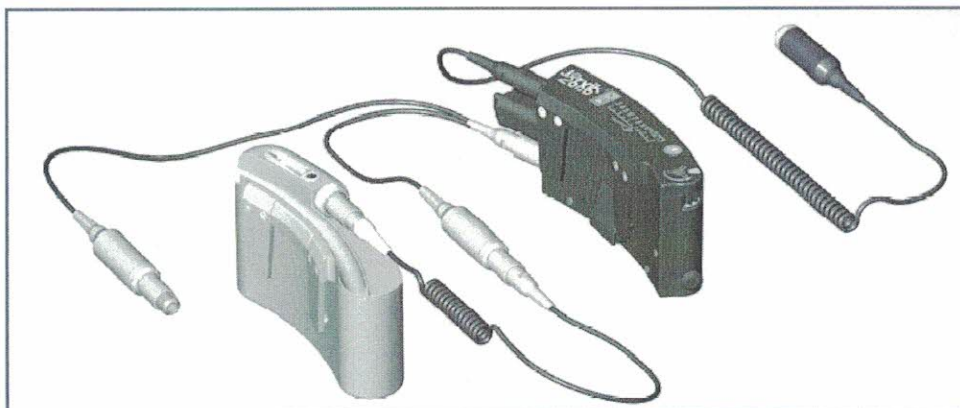


The Jarvik 2000® VAS is available in two models: the Jarvik 2000® VAS, Post-Auricular Cable (JHI-001) and the Jarvik 2000® VAS, Abdominal Cable (JHI-002). The main difference between the two models is the exit site of the drive cable. The drive cable of the Jarvik 2000® VAS, Abdominal Cable exits the abdomen and the drive cable of the Jarvik 2000® VAS, Post-Auricular Cable exits at a Pedestal surgically attached to the skull behind the ear.

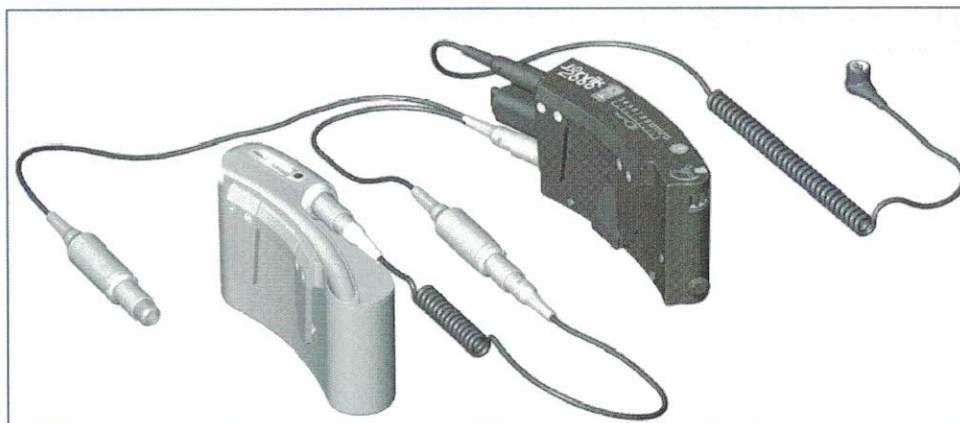


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**Jarvik 2000® VAS,
Abdominal Cable.**



External Equipment for Jarvik 2000® VAS, Abdominal Cable.



External Equipment for Jarvik 2000® VAS, Post-Auricular Cable.

NOTE: This Field Guide is NOT intended to replace the Operator Manual and Patient Handbook.

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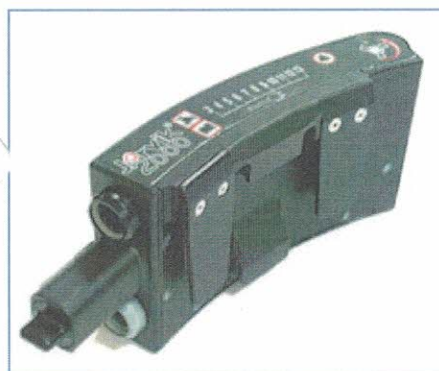
Jarvik 2000® VAS



Li-ion Battery.



Reserve Battery/Charger.



FlowMaker® Controller.

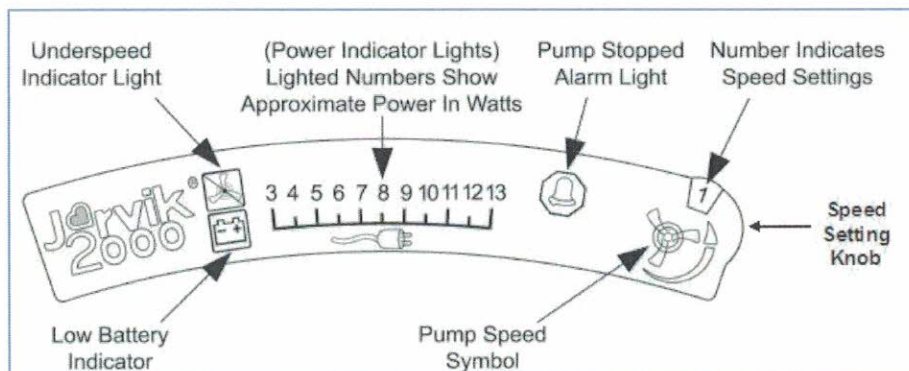


Diagram of FlowMaker® Controller Top Panel.

Dial Setting	Speed Rpm	Flow L/min	Power Watts
1	8,000	1-2	3-4
2	9,000	2-3	4-5
3	10,000	4-5	5-6-7
4	11,000	5-7	7-8-9
5	12,000	7-8.5	8-9-10

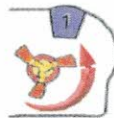
The FlowMaker Controller provides:

1. power to the implanted blood pump,
2. user settable speeds at which the pump runs, and
3. alarms and warnings.

The **FlowMaker®** Controller does not monitor the actual blood flow that the **Jarvik 2000® Ventricular Assist Device (VAD)** is pumping. In general, the higher the setting number the more blood the Jarvik 2000 VAD will pump. The tabulated flow estimates are based on research measurements in healthy animals. The actual blood flow may vary and will depend on several factors including blood pressure and the condition of the natural heart.

Jarvik 2000® VAS

Speed Setting, Alarms, and Warnings



Only one control adjustment to the **Jarvik 2000® VAD** can be made. The **Jarvik 2000® VAD speed** can be selected by turning the knob on the side of the **FlowMaker® Controller**. The setting number appears in the window on the top panel. The arrow indicates the direction to turn the knob to increase the speed.



Power Indicator Lights The numbers indicate the electrical power (Watts) that the VAD is using. One, two, or three numbers may be lit at any moment, and the lights may change rhythmically with the heartbeat of the natural heart. A power measure of 13 watts or more indicates malfunction. The High Power Indicator, number 13, will light yellow. This condition should receive prompt medical attention.



When the battery powering the **Jarvik 2000® VAD** is low, the **Low Battery Alarm** on the **FlowMaker® Controller** lights **yellow** and the alarm sound beeps. Remaining running time with the portable Li-ion Battery is about 5-10 minutes; with the Reserve Battery/Charger for approximately 15 minutes



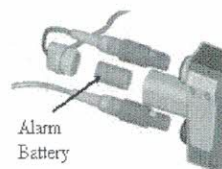
If the **Jarvik 2000® VAD** stops or if the VAD speed drops to below 5,000 RPM for any reason, a steady alarm sound is heard and the **Pump Stopped Alarm** on the **FlowMaker® Controller** lights **red**. The **Pump Stopped Alarm** will also sound if the intermittent low speed featured on the ILS **FlowMaker® Controller** fails to function for any reason. Immediate attention is required. **Follow the Pump Stopped Alarm procedure for the appropriate Jarvik 2000® VAS model (Post-Auricular Cable or Abdominal Cable)** which is included in this Field Guide.



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. The most common reason is the battery voltage is too low.

In this case, 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; and if the underspeed light is still on after replacing all external components, treat the situation as an emergency and seek immediate medical attention. *See Patient Handbook and Operator Manual for more details.*



A 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 cables. 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. Every time the **Alarm Battery Cap** is tightened, the Controller's back-up Alarm needs to be tested. With a caregiver present, briefly disconnect the main battery (Li-ion Battery or Reserve Battery/Charger) to be sure the Pump Stopped Alarm sounds. The disconnection should be brief and the main battery should be reconnected almost immediately. If the Pump Stopped Alarm does not sound, retighten the Alarm Battery Cap and repeat the test.

Contact the implant center immediately if the alarm does not sound during this test.



Jarvik 2000® VAS

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 the Pedestal and 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 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. This should be done with the assistance of a medical support person if possible.
5. It is possible that one of the connectors is not fully plugged in and is not making contact. Recheck all connectors.
6. 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.
7. 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 your Clinical Center for evaluation by Jarvik Heart, Inc.



Jarvik 2000® VAS

Procedure to Resolve Pump Stopped Alarm Jarvik 2000® VAS, Abdominal 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.

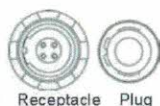
1. Be sure the alarm is not an intermittent beeping which only indicates a low battery. If the alarm is beeping, change the battery as usual.
2. If the Jarvik 2000® VAD is stopped (steady alarm sounding, red light on):
 - a. **Disconnect the Extension Cable from the drive cable at the abdomen, and set 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 the drive cable (the cable exiting the skin at the abdomen) directly into the backup FlowMaker® Controller (eliminating the Extension Cable). 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 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 your 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. Be sure that all external cables and connectors have been changed and check to see if the connector at the end of the drive cable exiting the skin at the abdomen is broken. If it is broken and has come apart – try to put it back together where it is broken. If the Jarvik 2000® VAD does not run, take the connector apart again – rotate the parts 90° and put the connector back together again. Repeat three times. The Jarvik 2000 VAD may start. The connector may then be held together with tape while the patient is transported to the hospital for it to be repaired.
6. It is possible that one of the connectors is not fully plugged in and is not making contact. Recheck all connectors.
7. 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.
8. 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 your Clinical Center for evaluation by Jarvik Heart, Inc.



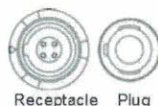
Jarvik® 2000

Jarvik 2000® Adult Ventricular Assist System—Quick Reference Guide



Receptacle Plug

Connection from Jarvik 2000 VAD to FlowMaker Controller: The black receptacle on the FlowMaker Controller is located above the housing for the small back-up Alarm Battery. The receptacle has double key slots for a black plug. The Extension Cable and the Pedestal Cable (depending on the model of the device used) also have double key slots.



Receptacle Plug

Connection from FlowMaker Controller to Y Cable or battery: The gray receptacle on the FlowMaker Controller is located below the housing for the small back-up Alarm Battery. This receptacle has a single key slot for the gray plug of the Y Cable, Li-ion Battery Cable, and Reserve Battery/Charger.

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. The connectors are attached and removed by a push-pull latch mechanism, not by a screw thread. 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. To remove the plug, hold it close to the receptacle and pull.

- Never attempt to disconnect any connector by twisting.
- Do not attempt to pull the connector apart by the wire or by the strain relief.
- Never force a connector together. If the plug does not go into the receptacle easily, gently rotate it until it is aligned properly. When it is fully engaged, a soft click can be heard.
- If a connector is damaged or pins are bent, do not attempt to repair but replace the cable instead.

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.



The portable Li-ion Battery will run the Jarvik 2000 VAS for 7-12 hours under usual conditions. The Li-ion Battery has an indicator with 5 lights that indicates how much power is remaining. Depress the black button to turn on the indicator lights:

Indicator	Approximate Remaining Time
All 5 LEDs lit	8-12 hours
4 LEDs lit	6-10 hours
3 LEDs lit	5-8 hours
2 LEDs lit	3-5 hours
1 LED lit	5 minutes - 2 hours

Li-ion Battery Charger

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:

- Flashing yellow for approximately 18-24 seconds
- Solid green for approximately 1-3 seconds
- Off

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.

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.

The Reserve Battery/Charger has both a battery and a charger built into a single unit; however, they are not electrically connected to each other.

Reserve Battery Use:

1. Unplug the gray cable from the battery charger and plug it into the gray connector of the Y cable or the FlowMaker Controller.
2. Unplug the black power cord from the Reserve Battery/Charger and the wall plug.
3. 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 (>24 hrs capacity) and the low battery alarm sounds, it will last for fewer than 200 recharge cycles.
4. Use the Reserve Battery/Charger for less than 12 hours each night and recharge it each morning after switching to the Li-ion Battery.



Reserve Battery Use



Charging the Reserve Battery

Charging the Reserve Battery:

Disconnect the gray plug from the Y Cable or FlowMaker Controller and plug it into the gray receptacle on the Reserve Battery/Charger.

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 near fully charged, the yellow light will turn off and automatically start to safely slow charge the battery. Continue charging the battery after the yellow light goes out and whenever the battery is not in use.

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.

The Reserve Battery/Charger is near fully charged only when the Charge light turns off and the gray cable is plugged into the gray receptacle on the unit.

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.

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. At all times, the Jarvik 2000 VAD is run only from battery power.