

Novacor Left Ventricular Assist Device

The Novacor Left Ventricular Assist System (LVAS) supports left ventricular function in patients with end-stage heart failure. The device is indicated for bridge-to-transplantation and has been approved for Destination Therapy in the United States. The Novacor LVAS is a pulsatile pump with an electromagnetic driver that compresses a polyurethane sac between 2 pusher plates.

Compact Controller

Description:

- Weight 0.68 kg
- Connects to driveline
- Runs the Novacor LVAS
- Requires external power to run the system
- Each patient has 1 primary and 1 back-up controller

Status Light Indicators:

OK Light	Green light displayed. Indicates the controller is receiving power and there are no active alarms.
Temp Light	Yellow light displayed. Single beep every 15 secs. Indicates the controller is experiencing excessive temperatures but will continue to function. ⇒ Action: Uncover controller and provide cooling.
Check Light	Yellow light displayed. Continuous tone, pattern of beeps. Indicates a non-urgent alarm. ⇒ Action: Uncover controller and provide cooling.
Replace Light	Red light displayed. Continuous tone Indicates an urgent alarm ⇒ Action: Replace controller.
Low Power Light	Red light displayed. Single beep every 3 seconds, continuous tone after 30 secs. ⇒ Action: Check power sources and change as necessary.

Modes of Operation

Fixed Rate

Operates the pump at a fixed rate between 30 and 150 bpm.

Used during start up in the OR.

Fill Rate Trigger

Preferred method of operation.

Pump detects decrease of ventricular filling at end-systole and signals the pump to eject.

Pump ejection coincides with native LV systole

ECG Trigger

Not recommended for use.

Failsafe

Provides a back-up mode of fixed operation at a pre-set rate.

Set on both controllers during set-up.

Autostart

- Autostart is enabled during pump start-up in the OR. Once enabled if power to the Compact Controller is interrupted, the Autostart function on either the main or the back-up controller will restart the pump in Fill Rate Trigger mode when power is restored.
- If Autostart has not been enabled, an alarm with a pop-up window will appear on the screen as a reminder.

POWER SOURCES

1. Primary Power Pack
 - Larger of 2 rechargeable batteries with a 4 hour capacity
 - Visual and audio alarms
 - Audio:
 - Triple beep – disconnected
 - Double beep - < 20% power remaining
 - Frequent double beep < 10% power remaining
 - Visual:
 - 5 indicator lights for battery capacity (20% each)
 2. Reserve Power pack
 - Smaller battery with 1 hour capacity
 - 2 capacity indicators
 - i. OK - > 80% capacity
 - ii. Low < 80% capacity
1. Compact controller will draw power from the largest power source.
 2. A "recharge cycle" is counted when at least 1 indicator light goes out – for best economy use the power pack until LOW indicator lights comes on.
 3. Power packs will alarm after reaching 200 recharge cycles.
 4. Power packs can be recharged in the POWER PACK CHARGER
 - Red light charging error
 - Yellow light charging
 - Green light fully charge

Instructions for changing Power Sources

Changing from LVAS/Personal Monitor to Power Packs:	Changing from Power Packs to LVAS/Personal monitor:
<ol style="list-style-type: none">1. Ensure Reserve Power Pack "OK" light is illuminated and the unit is fully charged.2. Disconnect LVAS Monitor/Personal Monitor cable.3. Connect replacement Power Pack.4. Silence Monitor disconnect alarms.	<ol style="list-style-type: none">1. Make sure the monitor is plugged in, turned on and the Patient cable is connected and within easy reach.2. Remove the battery clips from the vest/holster and place within easy reach.3. Disconnect primary power pack from controller.4. Connect controller cable to compact controller.

ALWAYS OPERATE WITH TWO DIFFERENT POWER SOURCES, THE RESERVE POWER PACK AND ANOTHER POWER SOURCE.

LVAS Monitor

The LVAS Monitor consists of a keyboard and display screen used primarily in hospital for evaluation of LVAS performance.

1. Monitor/controller cable connection
2. Front panel lights indicate:
 - I. AC Power
 - II. Monitor ON
 - III. Battery OK
 - IV. Transport battery (1 hour)
 - V. ECG Connection – not routinely used.

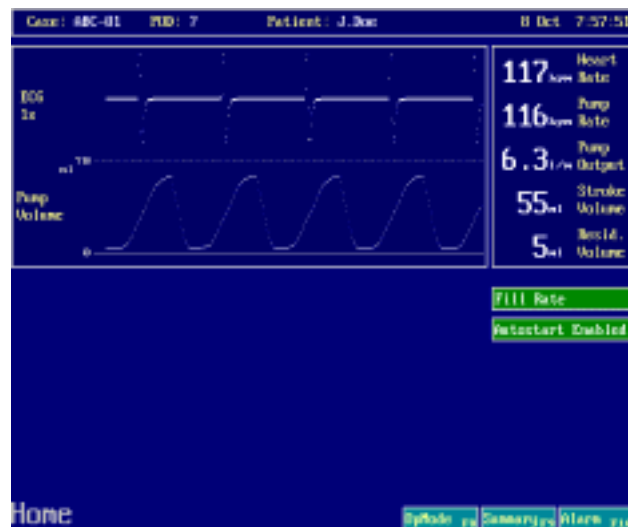
There are 4 different display screens

1. Case Information Screen (**ALT C**)

- Case ID
- Patient Name
- Implant Date

3. Home Screen (**Home from any screen**)

- Should be the screen on display when in Hospital.
- Displays ECG and pump volume waveforms.
- Displays heart rate, pump rate, pump output, stroke volume, residual volume.
- Displays patient name, ID, Mode, POD #, autostart.
- Press <F#> for access to other screens.



3. Operating Mode Screen (**F8 from Home Screen**)
 - Displays ECG waveform, pump volume and flow rate waveforms.
 - Displays pump parameters.
 - Allows adjustment of current pump run mode and timing options.
 - LVAS settings are stored on compact controller.

4. Control Summary Screen (**F9 from Home Screen**)
 - Displays all parameters.
 - Allows adjustment of parameters prior to pump initiation.
 - Used to adjust back-up controller.

Alarm Messages

Pop-up Alarm Messages:

- Displays alarm description at alarm onset with suggested response.
- Press Spacebar – mute x 2 minutes.
- Press Delete – will suspend alarm until next event.

1. Alarm Screen (**F10 from Home or Operating Screen mode**)

- All active alarm conditions are highlighted.

2. Alarm Test (**Alt T from Alarm Screen**)

- Tests system alarms
- Will be performed daily by VAD Coordinator.

3. Alarms set-up screen (**F2 from Alarms screen**)

- Physiology alarms – pump output, stroke volume, residual volume.
- Set parameters according to patient condition
- Press Alt W to save.

4. Alarm Log Screen (**F1 from alarms screen**)

- Displays anset and resolved time of EACH alarm and event.
- F1 allows search via date/time/page.

Do not adjust alarm parameters unless asked to by a member of the VAD Team

Novacor LVAS Emergency Procedures

Failsafe Mode: Automatic back-up mode of pump operation initiated when a system failure occurs.

- Starts after 5 incomplete ejections.
- Failsafe mode is pre-set by LVAD team.
- Failsafe rate is displayed on Control summary screen.
- Pump rate will be slower and sound louder than normal.

If Failsafe mode is enabled:

1. Check patient
2. Check alarm indicators
3. Check connections
4. Check filter for obstruction
5. Change Compact Controller if asked to by VAD Team.

If you are unable to resolve the Failsafe Mode condition – notify VAD team

Changing the Compact Controller

1. Ensure patient is sitting or lying down.
2. Disconnect 1 power source and connect to back-up controller.
3. Disconnect second power source from controller to stop pump.
4. Attach pump to new (back-up) controller. Pump should start immediately.
5. Connect second power source.

Daily Care

The Patient should always carry:

- ⇒ Autostart enabled back-up controller
- ⇒ Spare Power Packs
- ⇒ Spare Filter

A back-up LVAS Monitor should be available while patient in hospital.

System Checks to be done on every shift:

1. Verify Autostart is enabled.
2. Verify reserve power packs are >80% charged.
3. Check filter to ensure it is clear of obstruction.
4. Document q1h in CVICU and q4h on ward:
 - a. Heart rate
 - b. pump rate/output
 - c. stroke volume
 - d. residual volume
 - e. Mode of operation