

HEARTWARE™
HVAD™
WAVEFORM APP
INSTRUCTIONS



Medtronic

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WELCOME

The HVAD Waveform App and this booklet are provided for educational purposes only. The waveform scenarios herein are fictional and are also for educational purposes only. At all times, it is the professional responsibility of the practitioner to exercise independent clinical judgment in any particular situation. Changes in a patient's disease and/or medications may alter the efficacy of a device's programmed parameters or related features and results may vary. The device functionality and programming described in this instructional booklet are based on the HeartWare™ HVAD™ System and can be referenced in the HVAD System IFU.

This booklet is meant to accompany the HVAD Waveforms iPad app. Visit the iOS App Store on your iPad and search for 'HVAD Waveforms' to start learning.

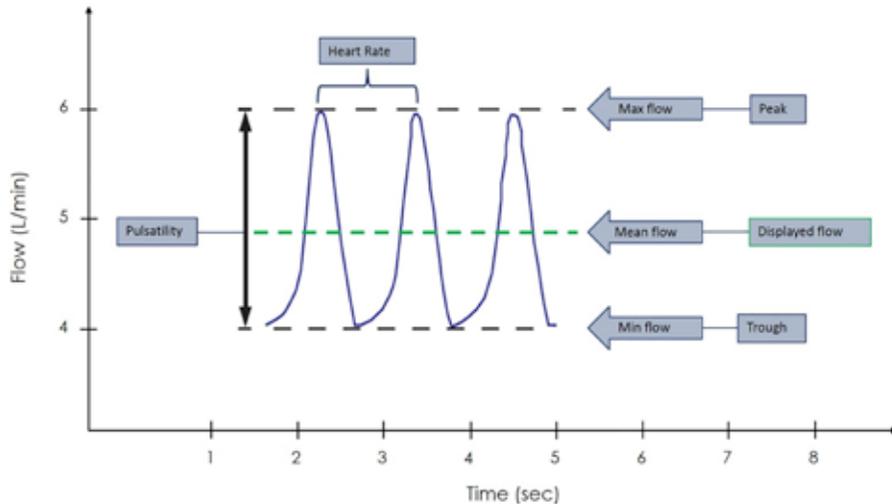


"The HVAD System has the unique feature among centrifugal VADs currently approved in the United States of providing an estimated instantaneous flow waveform, the characteristics of which provide significant insights into patient and device properties."¹

Jonathan Rich, MD
Northwestern University

HVAD WAVEFORMS

CHARACTERISTICS



Heart Rate: Peak-to-peak on the waveform. To determine the patient's heart rate count the number of peaks within a 10 second window and multiply by 6

Peak (Max flow): The top of the waveform – typically during systole

Trough (Min flow): The bottom of the waveform – typically during diastole

Pulsatility (L/min): Peak – Trough. Under normal conditions the pulsatility should be ≥ 2 L/min

Mean Flow: The mean flow through the pump. This is the number displayed on the controller and hospital monitor.

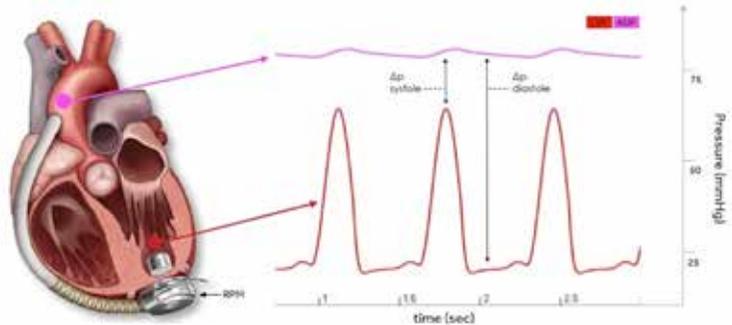
HVAD WAVEFORM

Theory of Operation

Blood flow through the HVAD is generated by 3 factors:

1. Pressure at the inflow of the pump (LVP) and
2. Pressure at the outflow of the pump (AoP)
3. Set speed (RPM)

The difference in pressure across the pump (Ao-LV) is Δp



5

Blood flow depends on the set RPM and the pressure difference (Δp) between the LV (red) and the Ao (pink). Flow decreases when Δp is large and flow increases when Δp is small.

PRO TIP:

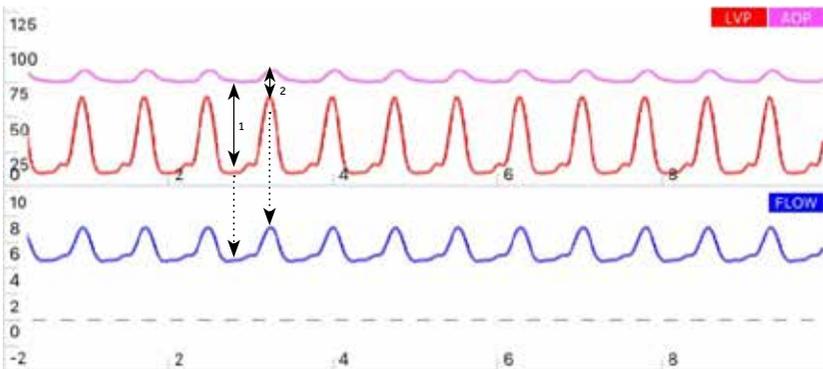
The spinning impeller (RPM) provides the energy (E) that allows the blood to flow from the lower pressure LV to the higher pressure aorta. Because the RPM is fixed, the amount of energy the pump provides remains constant for any given speed. The HeartWare™ HVAD™ Pump can then be thought of as providing the necessary energy to move blood up the pressure gradient from the LV to the aorta. Given adequate filling conditions, flow will

increase with increasing RPM. Because the pump is providing a fixed amount of energy to move blood up a pressure gradient, the flow will increase with a smaller pressure gradient (systole) and will decrease with a larger pressure gradient (diastole). Flow is proportional to the pump RPM and inversely proportional to the pressure gradient across the pump, or: $\text{Flow} \propto \frac{\text{RPM}}{\Delta p}$.

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HVAD WAVEFORM

Theory of Operation: Ao and LV Pressure Waveforms



HVAD flow is driven by the set RPM and the pressure difference between the LV (red) and Ao (pink) .

1. Pressure difference during diastole. Note that the HVAD flow (blue) is lowest during the portion with the largest pressure difference.
2. Pressure difference during systole. Note that the HVAD flow (blue) is highest during the portion with the smallest pressure difference.

Because the RPM is set at a fixed speed, the variation in the waveform is driven by the varying pressures throughout the cardiac cycle. The pressure difference can be thought to represent resistance to flow. The larger the pressure difference across the pump (and therefore the resistance), the lower the flow for any fixed speed and vice versa.

PRO TIP:

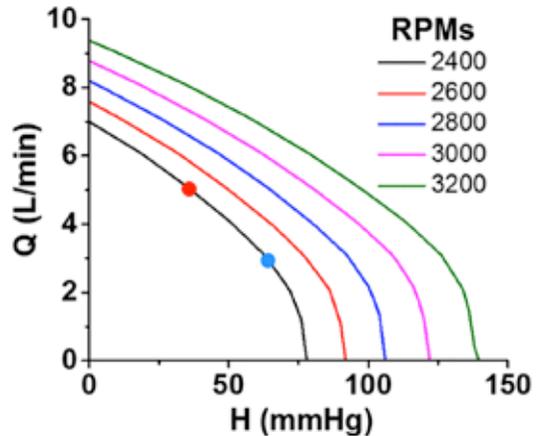
In this example, the LVP does not exceed AoP and this indicates the Ao valve is not opening.

HVAD WAVEFORM

Theory of Operation: The HQ Curve

LVAD pump flow is driven by the pressure difference across the pump. The amount of flow that results from any given Δp is dictated by the pump's HQ Curve.

This HQ curve depicts the flow (Q) along the y-axis, pressure differential (H) along the x-axis, and HQ curves for different set RPM. If we have an HVAD patient with pump RPM set at 2400 (black curve). The red dot is depicting systole and represents the moment when the pressure differential (H) is smallest and the flow (Q) is maximized. The blue dot is depicting diastole and represents the moment when the pressure differential (H) is largest and the flow (Q) is minimized. As long as the patient remains on speed 2400 and the pressures are stable, the flow (Q) will oscillate along the 2400 curve between the red and blue dots. This oscillation over time is how the waveform is generated.



PRO TIP:

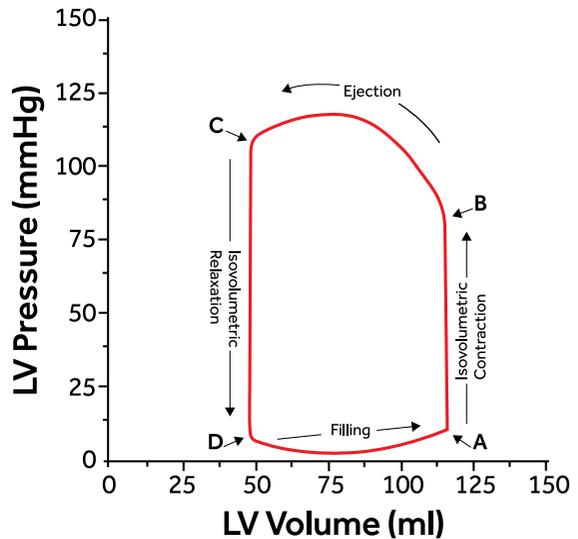
Every pump has a unique HQ relationship. For instance, the HQ curves for the Heartmate II® differ from that of HVAD. One should not assume LVAD behavior across pump types will remain constant for any given set of patient conditions. HQ curves are helpful when determining if a given flow is appropriate for a given set speed.

HVAD WAVEFORM

Theory of Operation: PV Loop

Pressure volume diagrams provide insight into the instantaneous pressure-volume relationship in each cardiac chamber.² Each loop represents one cardiac cycle. LV pressure is one of the factors that drive HVAD flow and observing how changes to the instantaneous pressure and volume in the LV affects the waveform further illustrates the relationship between the patient's cardiac physiology and the pump.

- A. Mitral valve closes
- B. Aortic valve opens
- C. Aortic valve closes
- D. Mitral valve opens

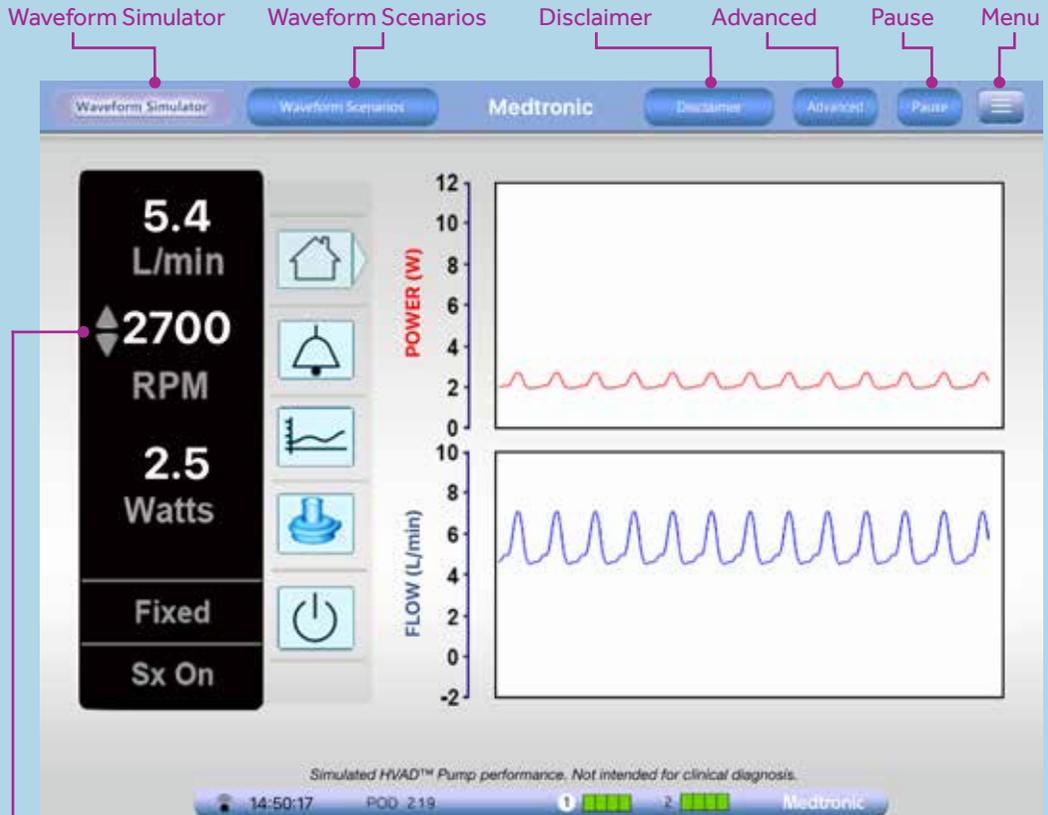


PRO TIP:

Left ventricular PV loops in the setting of LVADs result in a triangular-shaped PV loop because the LV is continuously unloaded throughout the cardiac cycle.²

HOME SCREEN

Interactive Buttons

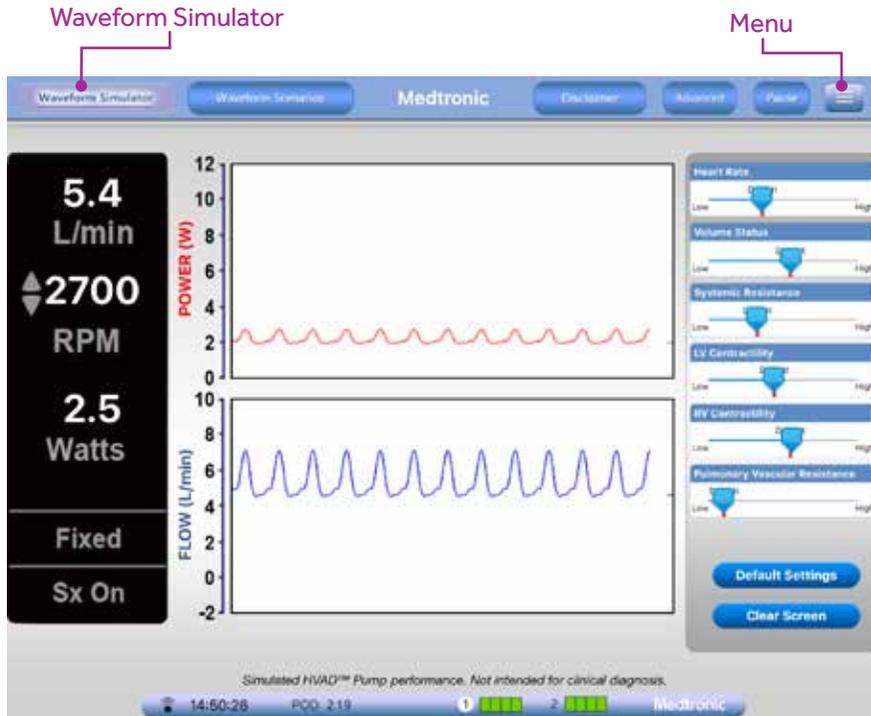


Adjustable Speed 1800 – 4000 RPM

HVAD waveforms do NOT conform to a single, classic appearance, and are not intended for diagnostic purposes. Waveforms represent pump performance.

WAVEFORM SIMULATOR

Interactive Buttons

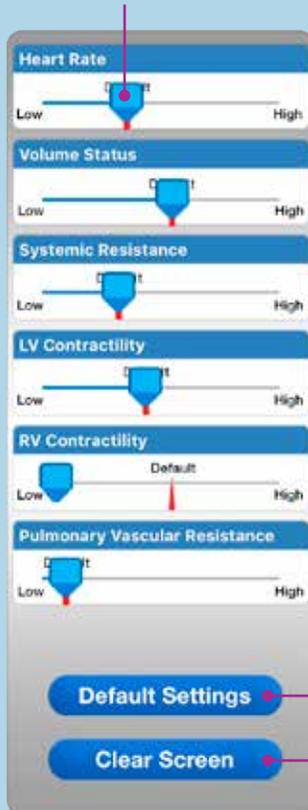


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WAVEFORM SIMULATOR

Clinical Parameters

Slide button: Slide from 'Low' to 'High' to see instant effects on the waveform.



The flow waveform represents the relationship between the pump and the patient. This can be seen by adjusting these 6 clinical parameters and seeing the instantaneous effect on the HVAD waveform.

These parameters can be adjusted independently or simultaneously.

Default Settings

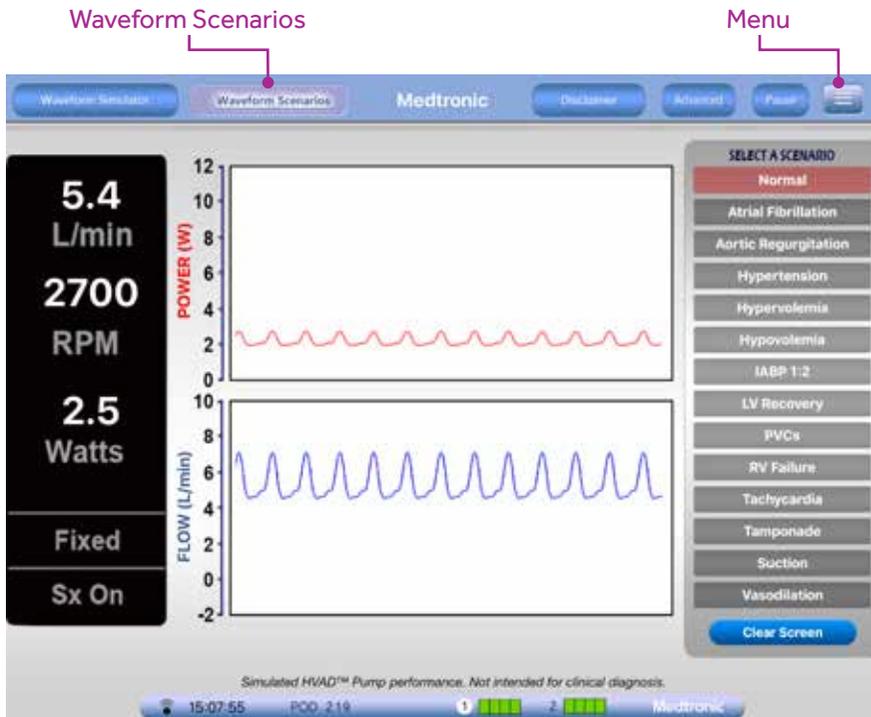
Tap to return clinical parameters to Default settings (red marker)

Clear Screen

Tap to clear dynamic waveform and run with new settings

WAVEFORM SCENARIOS

Interactive Buttons



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WAVEFORM SCENARIOS

Waveform Scenarios

Tap each scenario to observe waveform behavior in various clinical conditions

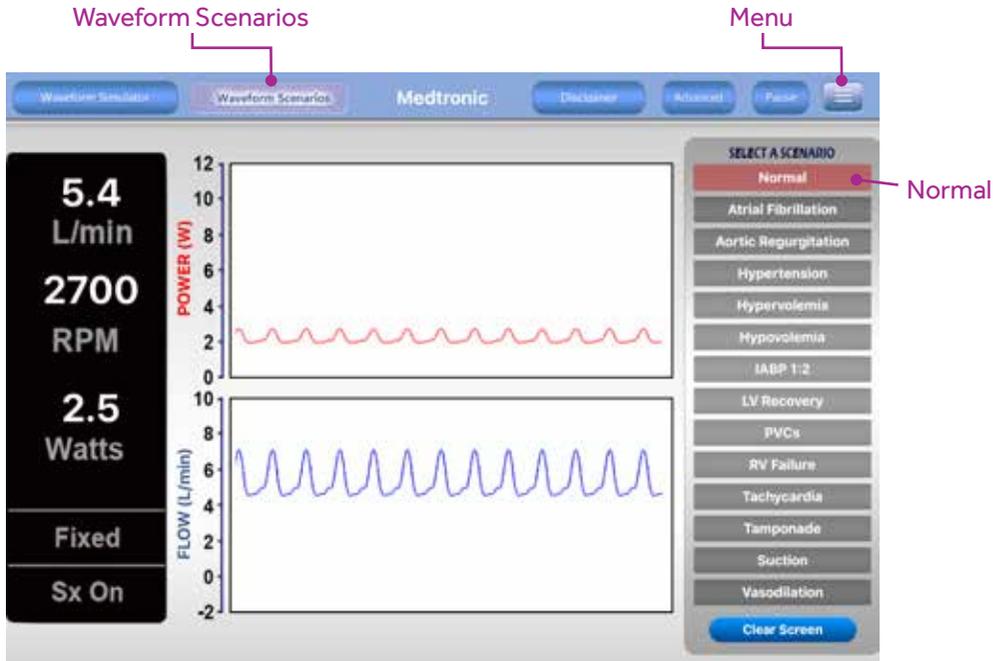


The flow waveform represents the relationship between the pump and the patient. This can be seen by selecting one of these clinical conditions and seeing the instantaneous effect on the HVAD waveform.

Tap to clear dynamic waveform and run with new settings

WAVEFORM SCENARIO

Normal



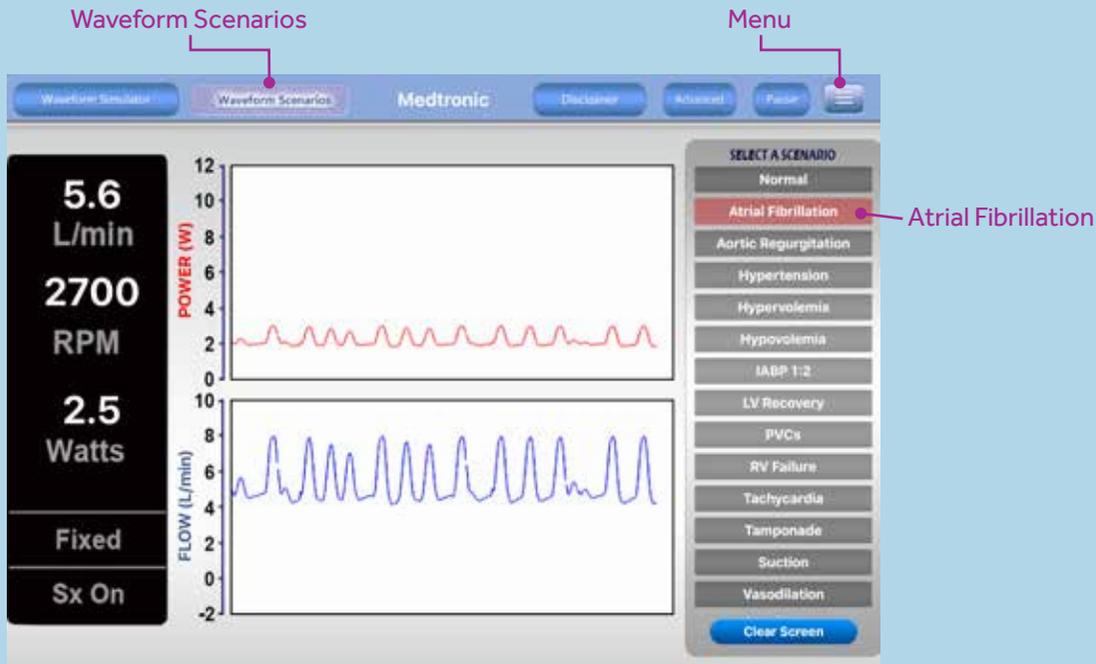
The normal HVAD waveform varies during the cardiac cycle between 4-5 L/min at the trough and 6-8 L/min at the peak*. Thus, the normal HVAD waveform has a pulsatility of 3-4 L/min. Generally, the trough should remain > 2 L/min and the pulsatility should remain ≥ 2 L/min.²

*This is a normative statement. Each patient should be assessed on an individual basis.

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WAVEFORM SCENARIO

Atrial Fibrillation

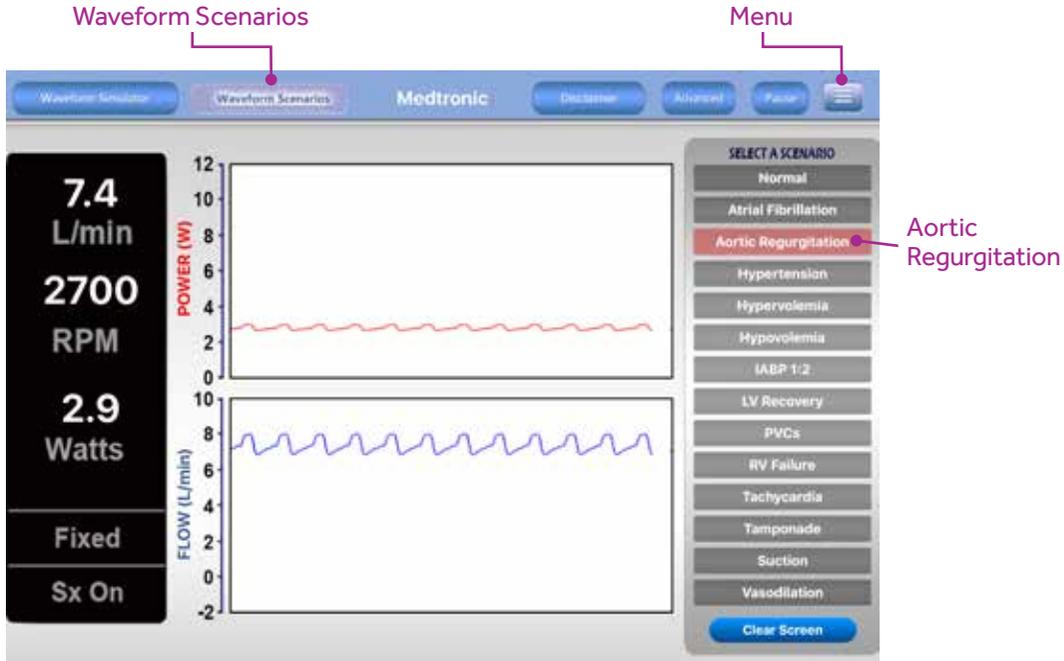


Atrial fibrillation is characterized by irregularly irregular time intervals between heart beats. This irregularity influences both ventricular filling and LV contractility and is visible on the waveform on a beat-to-beat basis with changes in pulsatility and rate.¹

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WAVEFORM SCENARIO

Aortic Regurgitation



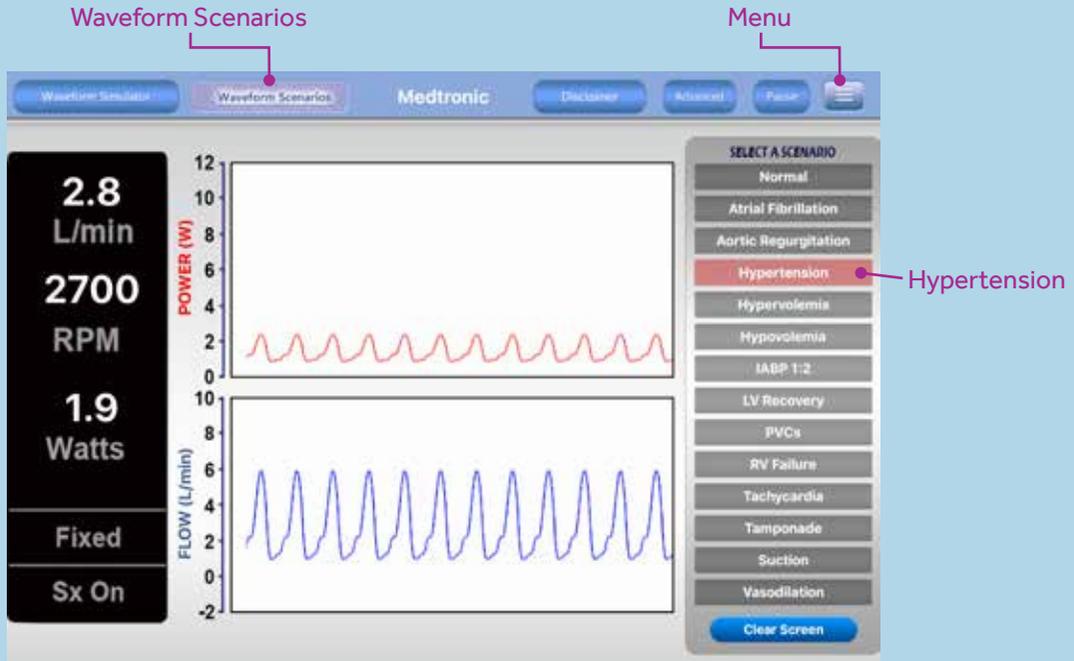
Aortic regurgitation causes rapid decline of aortic pressure during diastole which elevates the end diastolic pressure of the LV (LVEDP) and early aortic opening during systole. The elevated LVEDP results in a reduced Δp and increased flow in diastole. This is visible on the waveform with an elevated trough (shown here ~ 7lpm). The HVAD waveform in the presence of AR is characterized by high peak, mean and trough flows, and low pulsatility.¹

Note that the presence of AR, HVAD flow may not reflect flow to the body since some blood recirculates back through the AoV.¹

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WAVEFORM SCENARIO

Hypertension

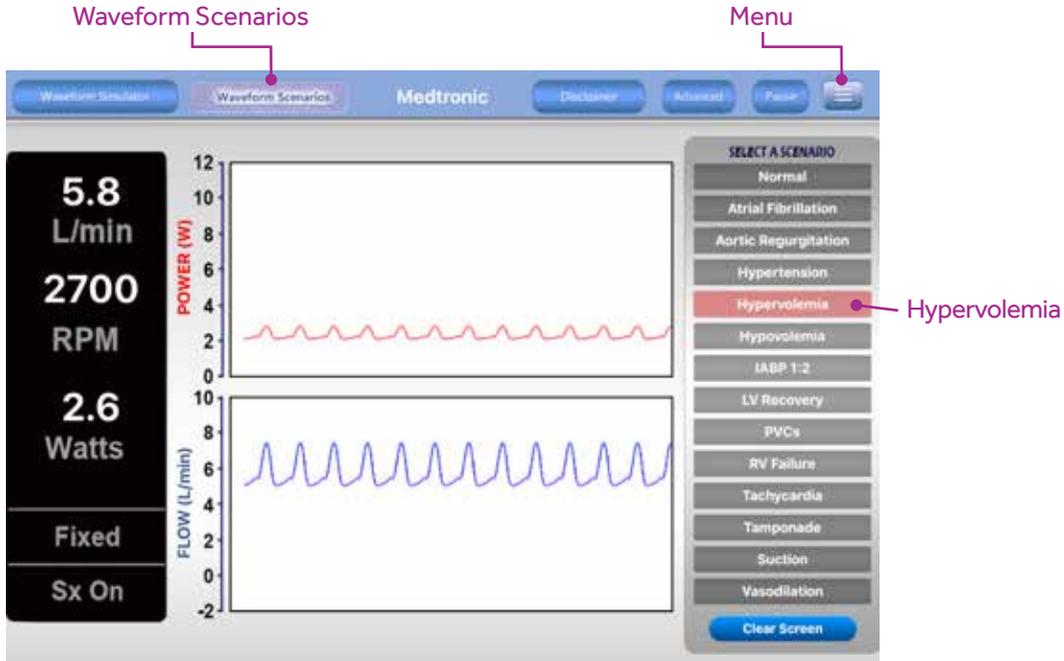


Hypertension is characterized by an increase in aortic pressure which may result in a greatly increased pressure differential across the HVAD, particularly in diastole.¹ This can be appreciated on the HVAD waveform where the effects of hypertension are most notable in the trough, as shown here with the trough nearly at 0 lpm. The HVAD waveform in the setting of hypertension is characterized by high pulsatility with low flow.

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WAVEFORM SCENARIO

Hypervolemia

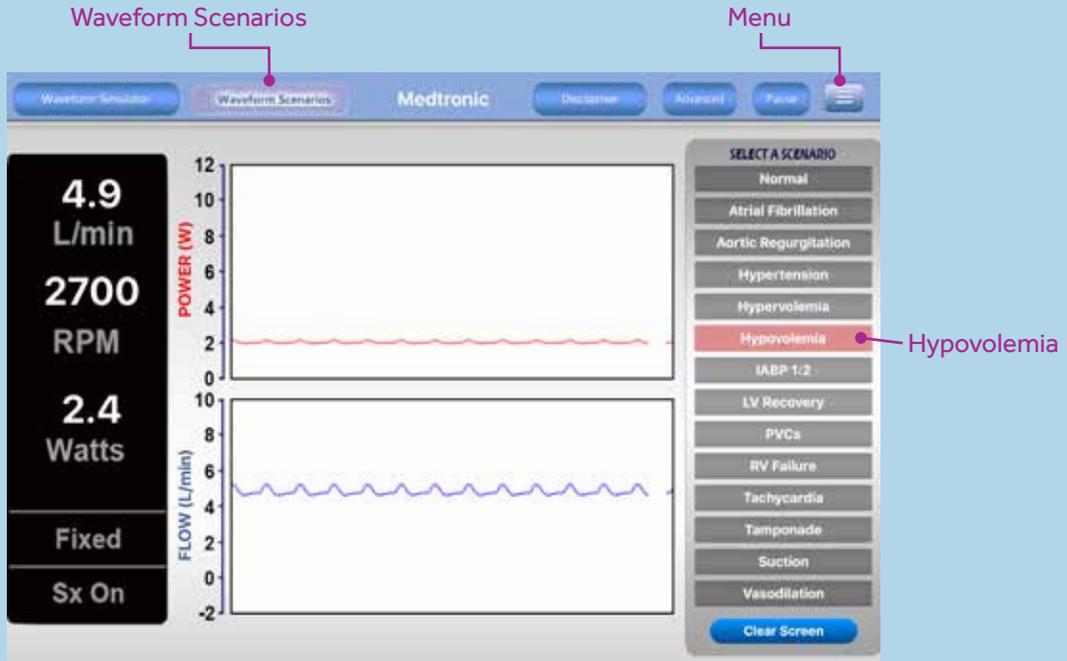


Hypervolemia is characterized by increased LV filling which results in higher diastolic and systolic LV pressures which decreases the pressure gradient across the pump throughout the cardiac cycle and results in higher pump flows.¹ The HVAD waveform in the setting of hypervolemia is characterized by high pulsatility in the setting of high flow.

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WAVEFORM SCENARIO

Hypovolemia

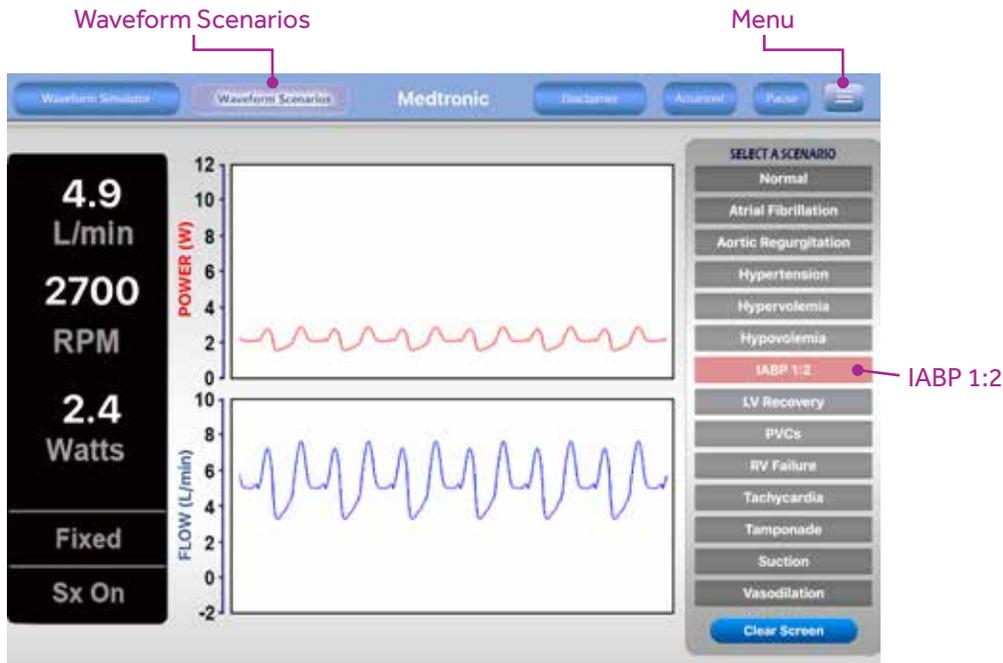


Hypovolemia is characterized by decreased LV filling which results in lower diastolic and systolic LV pressures which increases the pressure gradient across the pump throughout the cardiac cycle and results in lower pump flows. The HVAD waveform in the setting of hypovolemia is characterized by low pulsatility in the setting of low flow.

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WAVEFORM SCENARIO

Intra Aortic Balloon Pump

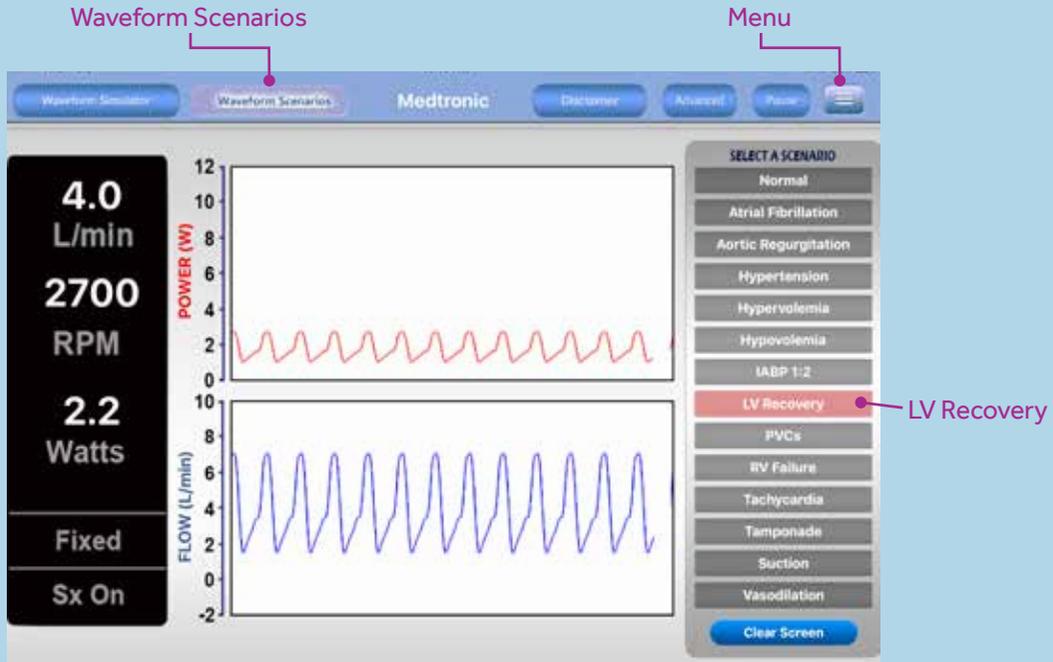


An IABP pump operates via the mechanism of counter-pulsation, inflating at the onset of diastole and deflating at the onset of systole. During IABP supported beats, an increase in flow occurs in systole (coinciding with IABP deflation) and flow decreases during diastole coinciding with IABP inflation. Thus, a marked increase in pulsatility is observed on the HVAD waveform in each cardiac cycle in which the IABP is triggered.¹

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WAVEFORM SCENARIO

Left-Ventricular Recovery

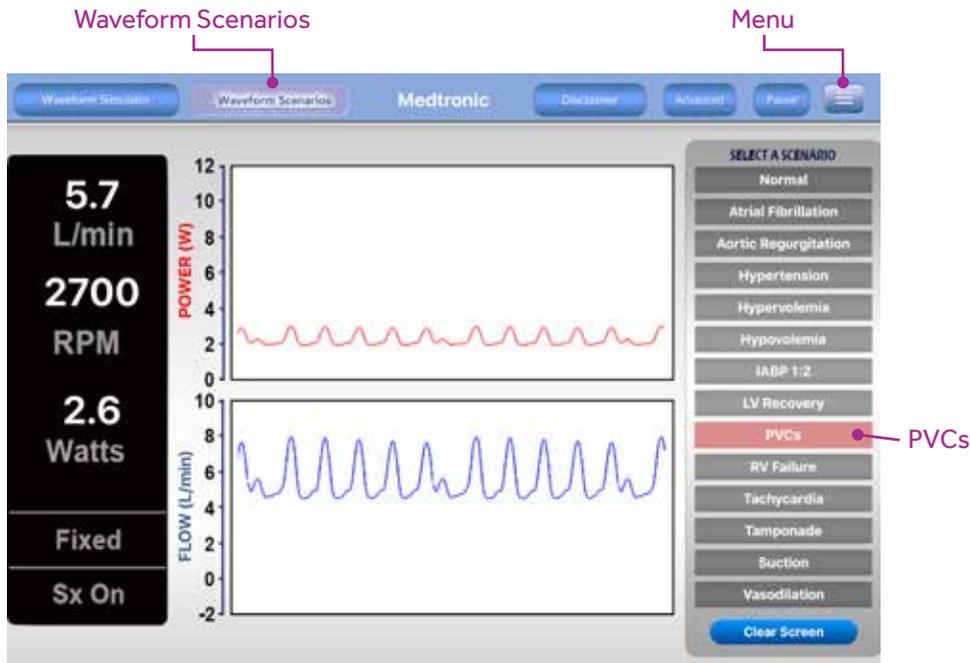


LV recovery is characterized by an increase in LV contractility which increases LV systolic pressure generation which may result in more consistent AoV opening and a decrease in end-diastolic pressure.¹ The combined effect is to decrease the pressure gradient in systole and increase the pressure gradient in diastole which may translate to a waveform with a substantial increase in pulsatility. Note that in the setting of LV recovery, HVAD flow may not reflect total cardiac output as some proportion of blood is being natively ejected through the AoV.

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WAVEFORM SCENARIO

Premature Ventricular Contractions (PVC)

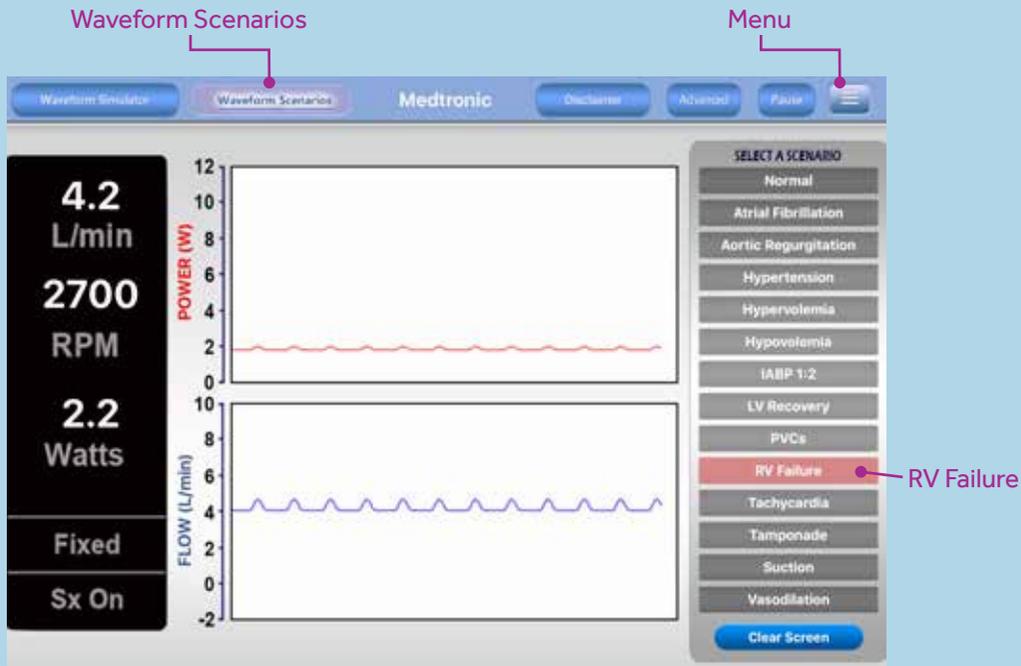


The heartbeat associated with a PVC may contribute to reduced left-ventricular filling time and contractility. This leads to a beat on the waveform that is low flow and low pulsatility. The hallmark of PVCs on the HVAD waveform is a normal appearing waveform with intermittent low pulsatility beats associated with the PVC. The post-PVC waveform typically demonstrates properties of the classic phenomenon of post-extrasystolic potentiation following a compensatory pause during which there is both increased ventricular filling and increased contractility. This results in a waveform 'beat' of greater pulsatility following the PVC 'beat'.¹

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WAVEFORM SCENARIO

Right Ventricular Failure

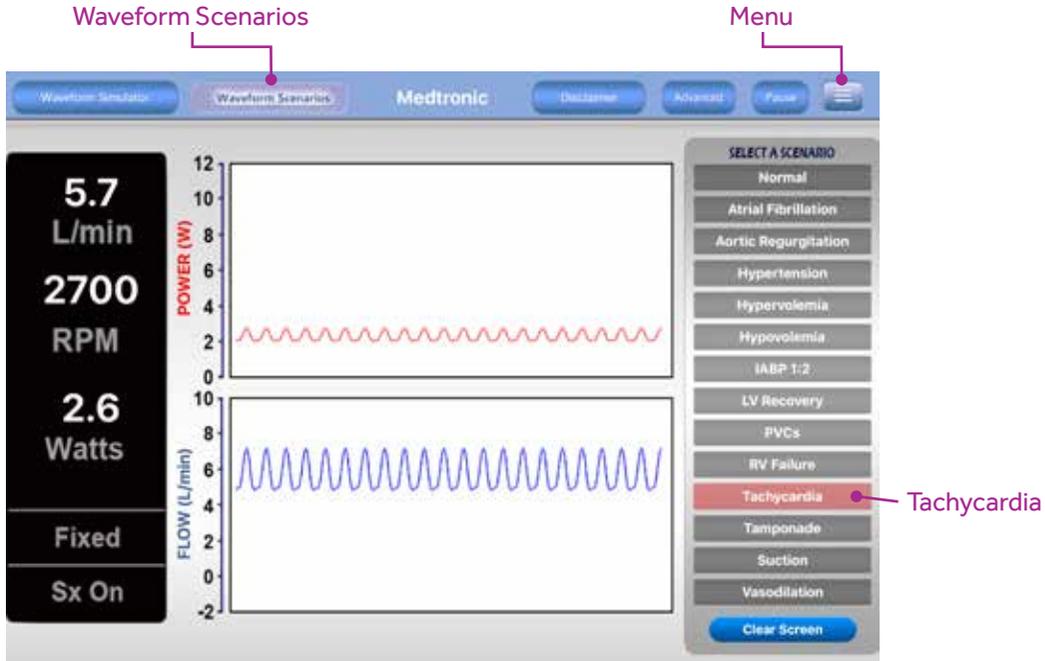


Right ventricular failure leads to decreased preload to the left ventricle resulting in a larger pressure gradient across the pump in both systole and diastole. In this regard, the HVAD waveform associated with RHF generally mimics that of a severe hypovolemic state with decreased peak flow, mean flow, and pulsatility. The differentiation of RHF from hypovolemia relies on the detection of clinical signs such as jugular venous distention, peripheral edema, echocardiographic evaluation and, when needed, invasive measurement of central venous pressure, PCWP and cardiac output.¹

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WAVEFORM SCENARIO

Tachycardia

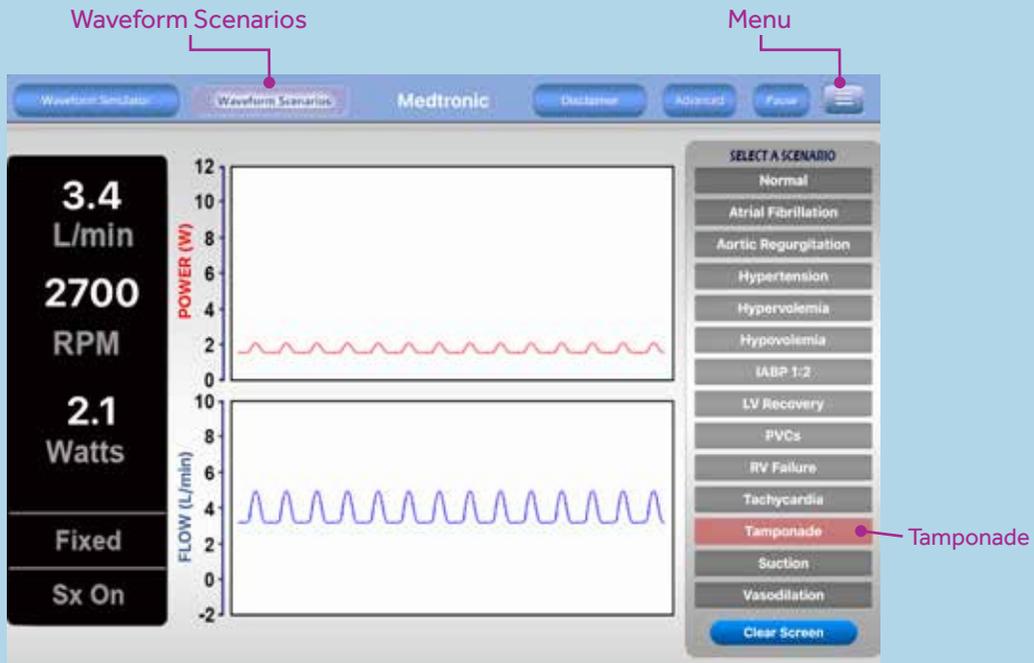


Tachycardia results in decreased LV diastolic filling time due to increased heart rate and this will often translate to a relatively low flow, low pulsatility waveform.¹ Note that the heart rate can be calculated by counting the number of peaks and multiplying by 6. Ensure that the time scale on the HVAD monitor is set to 10 s.

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WAVEFORM SCENARIO

Tamponade

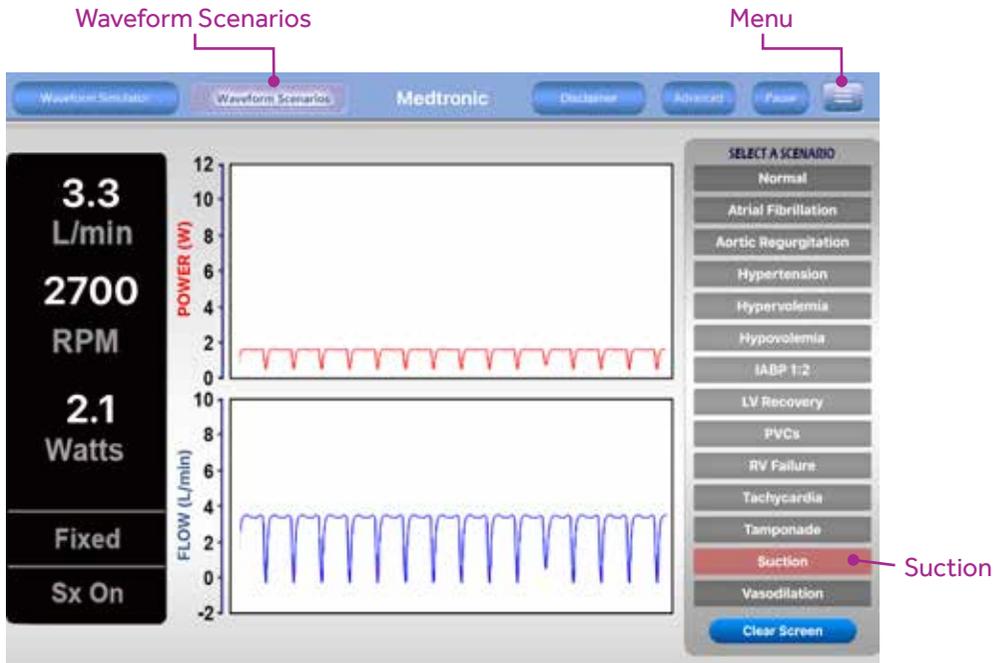


Cardiac tamponade results in an increase in pericardial pressure which restricts filling of both ventricles. As a consequence, there are relatively small increases in LV diastolic pressures and marked reductions in systolic pressures. The HVAD waveform in the setting of cardiac tamponade may result in a low flow, low pulsatility waveform and a broad differential diagnosis is needed as other common scenarios occurring in the early postoperative state, such as hypovolemia due to blood loss and right heart failure, may exhibit similar waveforms.¹.

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WAVEFORM SCENARIO

Suction

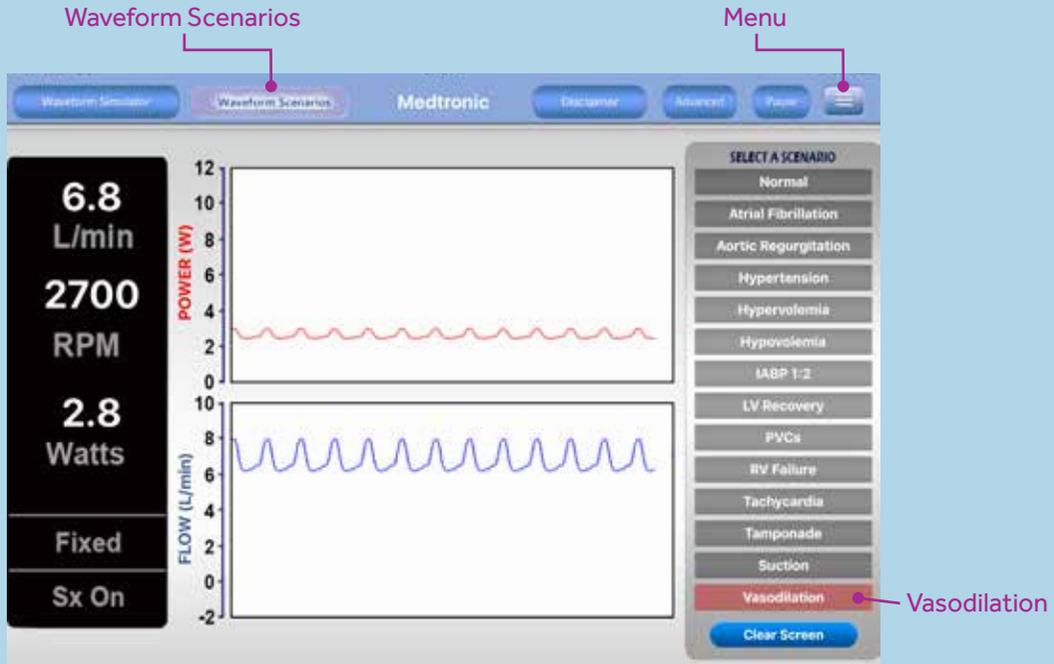


Suction results from either a suboptimal inflow position and/or a mismatch between left ventricular filling and the pump speed. Conditions that can lead to suction include hypovolemia, RV failure, arrhythmias, tamponade, and the HVAD RPM set too high. One of the most useful and easily recognizable features of the HVAD waveform is identification of suction events. The HVAD waveform in the setting of suction is characterized by relatively sharp downward deflections towards 0 L/min during systole.¹

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WAVEFORM SCENARIO

Vasodilation



Vasodilation is characterized by low afterload resistance and relative hypotension which results in a lower pressure gradient across the pump throughout the cardiac cycle. The HVAD waveform in the setting of vasodilation may result in a low pulsatility, high flow waveform.¹

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ADVANCED SCREEN

Advanced



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ADVANCED SCREEN

Hemodynamic Outputs

Outputs	
AoP mmHg	83/75 (78)
PAP mmHg	35/16 (20)
PCWP mmHg	14
CVP mmHg	11
CO L/min	0.00
Left Ventricle	
EDV ml	194
EDP mmHg	15

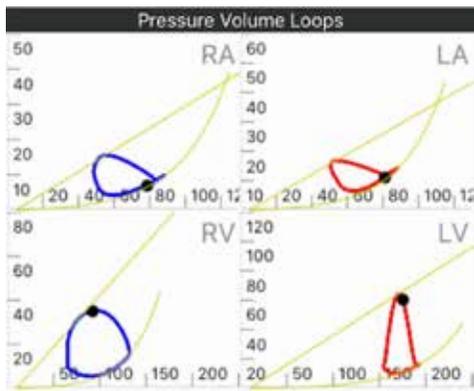
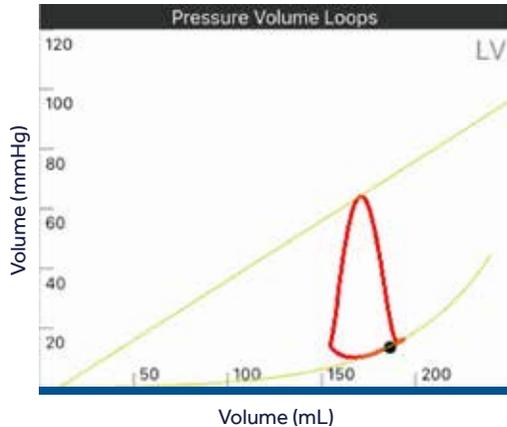
The hemodynamic output panel gives the outputs as well as definitions when tapped. The parameters here are the output based on the different scenarios the user chooses. One cannot input parameters here to see a corresponding change on the waveform.

It should be noted that the CO (L/min) is reflective of cardiac output through the aortic valve. If the aortic valve is closed throughout the cardiac cycle, the CO will be 0.00 (as shown).

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ADVANCED SCREEN

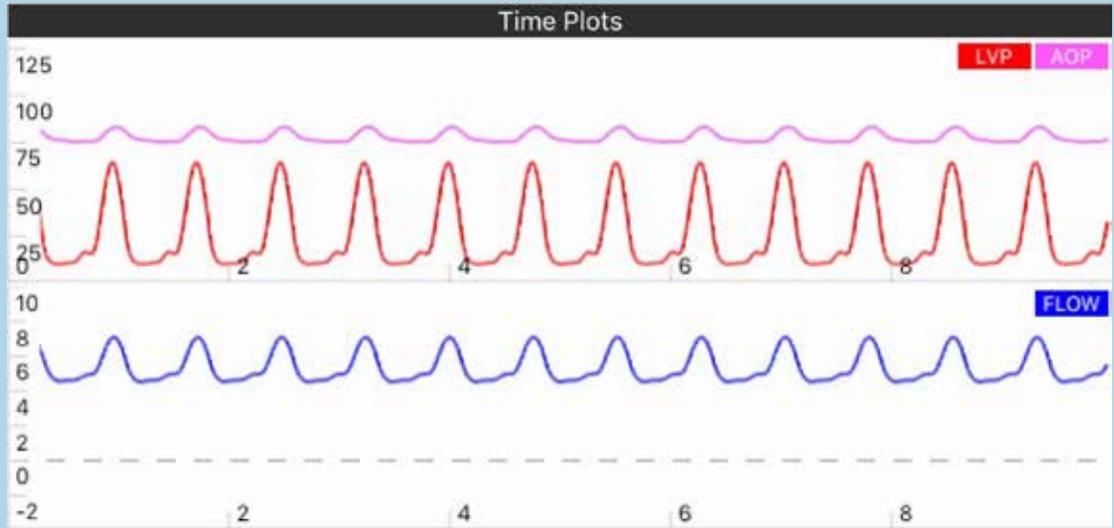
PV Loops



Tap the Pressure Volume Loops window to open the PV loops for all 4 cardiac chambers. Tapping any individual window will display that loop only.

ADVANCED SCREEN

LVP, AOP, Flow Waveforms

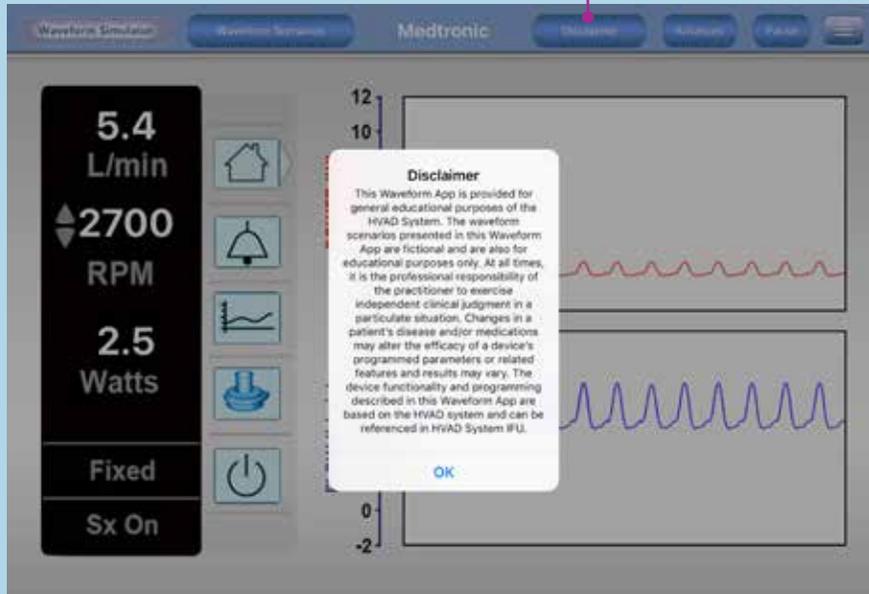


The AOP – LVP – HVAD waveforms window allows for simultaneous comparison of the AOP, LVP, and HVAD waveforms. This window is useful because it provides a visual representation of how the AOP and LVP change relative to each other under various clinical conditions along with the corresponding change to the HVAD waveform. Tap the screen to enlarge either the AOP-LVP waveforms or the HVAD waveform.

WAVEFORM SCENARIO

Disclaimer

Disclaimer



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WAVEFORM SCENARIO EXAMPLE

Explain waveform behavior in the setting of hypertension



A patient is supported on HVAD at 2700 RPM and flowing 5.6 lpm with a BP 83/75 (78). A short time later the flow has decreased to 2.8 lpm, the HVAD waveform pulsatility has increased, and it is noted that the BP has increased to 113/98 (103). Let's use the app's Advanced features to explain the change in waveform behavior.

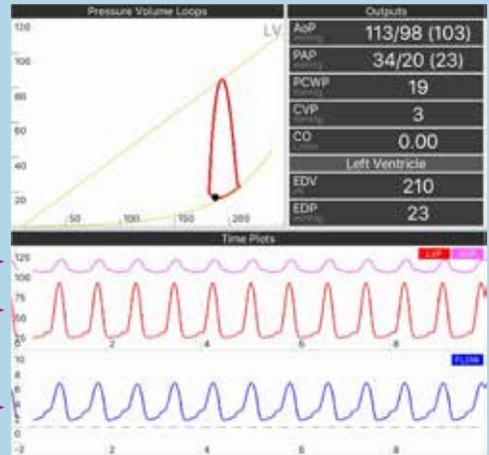
HVAD waveforms do NOT conform to a single, classic appearance, and are not intended for diagnostic purposes. Waveforms represent pump performance.

WAVEFORM SCENARIO EXAMPLE

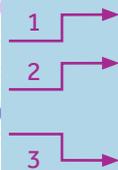
Explain waveform behavior in the setting of hypertension



Normal



Hypertension



1. Increased Ao pressure from 83/75 (78) mmHg to 113/98 (103) mmHg
2. LV pressure waveform increases from 70/15 (33) mmHg to 90/23 (45) mmHg
3. HVAD waveform decreases from 7/5 L/min (mean 5.4 L/min) to 6/1 L/min (mean 2.8 L/min)

So

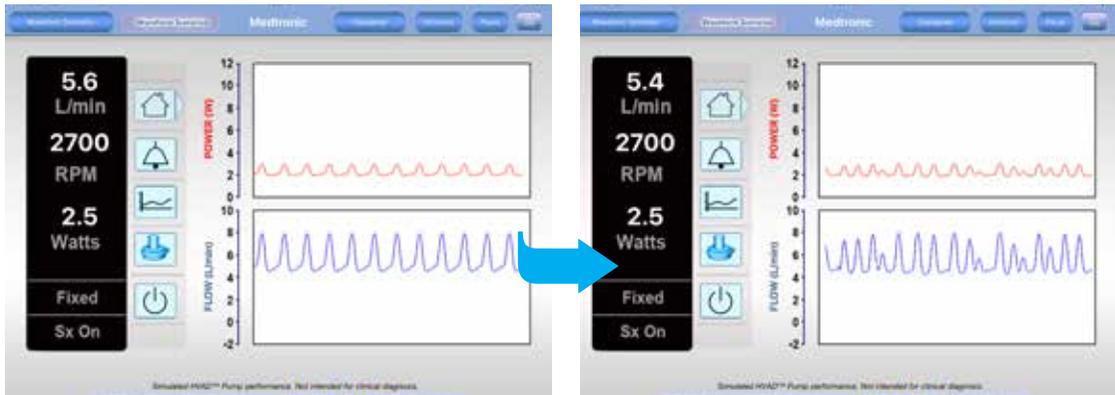
1. Δp increased by 10 mmHg in systole and increased by 15 mmHg in diastole
 - Recall Δp is analogous to resistance to flow

2. Therefore flow decreases by 1 lpm in systole and by 4 lpm in diastole for an overall decrease of 2.6 lpm

Hypertension is a clear example of the concept that flow through the pump is inversely proportional to the pressure difference across the pump. It is important to note that degree of pulsatility does not correlate with mean flow. In the clinical scenario of hypertension, the pulsatility increases while the mean flow decreases. There are other scenarios (such as volume overload) where pulsatility increases along with mean flow.

WAVEFORM SCENARIO EXAMPLE

Explain waveform behavior in the setting of atrial fibrillation

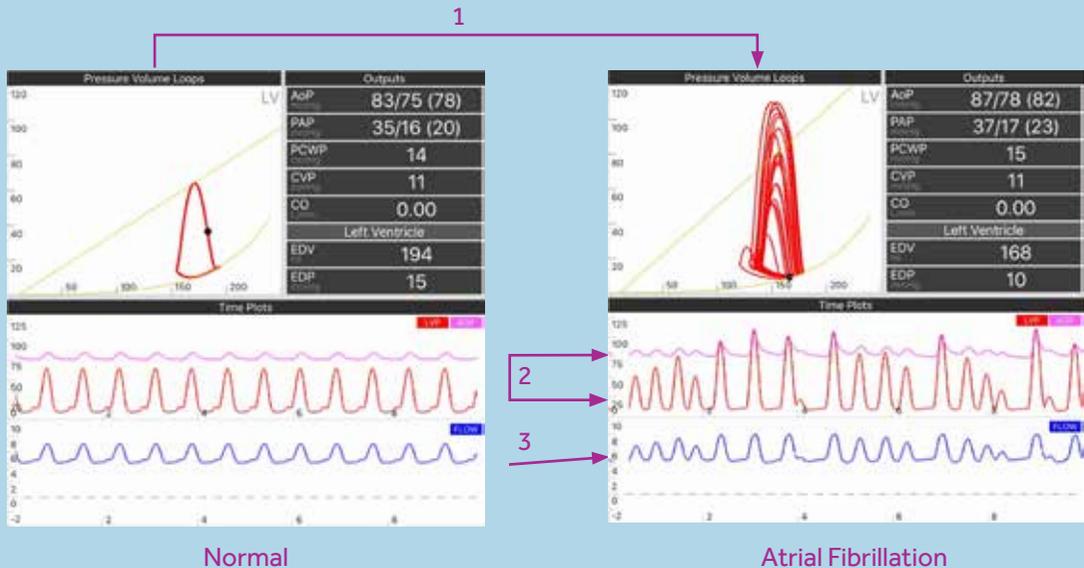


A patient is supported on HVAD at 2700 RPM and flowing 5.6 lpm with what seems to be a normal waveform. A short time later the flow has decreased to 5.4 lpm and the waveform has taken on an irregular morphology. Let's use the app's Advanced features to explain the change in waveform behavior.

HVAD waveforms do NOT conform to a single, classic appearance, and are not intended for diagnostic purposes. Waveforms represent pump performance.

WAVEFORM SCENARIO EXAMPLE

Explain waveform behavior in the setting of atrial fibrillation



1. Pressure volume loops demonstrate beat-to-beat changes in LV pressure and volume due to irregular filling secondary to Afib. Smaller loops indicate less filling and pressure.
2. Ao and LV pressure waveforms are also irregular. Note that LVP intermittently exceeds AoP, indicating occasional aortic valve opening.
3. Waveform behavior in the setting of atrial fibrillation is a good example of how waveforms relay patients' cardiac information in a way that is similar to commonly used modalities like pressure volume loops and aortic and LV pressure waveforms. For instance, given a small 'beat' during this afib example, the PV loop has a small area and is shifted to the left (reduced volume) and shifted down (reduced pressure). This can then be seen on the LV pressure waveform with a smaller peak reflecting lower LV pressure. Because this LV waveform 'beat' is reduced, the pressure gradient between the LV and the aorta at this moment in time is increased. This is then seen on the HVAD waveform as a reduced flow 'beat'.

Brief Statement: HeartWare™ HVAD™ System

Indications

The HeartWare™ Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The HeartWare System is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.

Contraindications

The HeartWare System is contraindicated in patients who cannot tolerate anticoagulation therapy.

Warnings/Precautions

Proper usage and maintenance of the HVAD™ System is critical for the functioning of the device. Never disconnect from two power sources at the same time (batteries or power adapters) since this will stop the pump, which could lead to serious injury or death. At least one power source must be connected at all times. Always keep a spare controller and fully charged spare batteries available at all times in case of an emergency. Do not expose batteries to excessive shock or vibration since this may affect battery operation. Do not grasp the driveline cable as this may damage the driveline. Do not pull, kink or twist the driveline or

the power cables, as these actions may damage the driveline. Special care should be taken not to twist the driveline including while sitting, getting out of bed, adjusting the controller or power sources, or when using the shower bag. Do not disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

Potential Complications

Implantation of a Ventricular Assist Device (VAD) is an invasive procedure requiring general anesthesia, a median sternotomy, a ventilator and cardiopulmonary bypass. There are numerous risks associated with this surgical procedure and the therapy including but not limited to, death, stroke, device malfunction, peripheral and device-related thromboembolic events, bleeding, infection, hemolysis and sepsis.

Refer to the "Instructions for Use" for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions and potential adverse events prior to using this device. The IFU can be found at www.heartware.com/clinicians/instructions-use.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

References

1. Rich, J.D., Burkhoff, D. HVAD flow waveform morphologies: Theoretical foundation and implications for clinical practice. ASAIO. 2017; 63(5):526-535.
2. Darshan, D., Burkhoff, D. Cardiovascular simulation of heart failure pathophysiology and therapeutics. Journ of Cardiac Failure. 2016; 22(4).
3. HVAD System Instructions for Use. HeartWare Inc., Framingham, MA, USA.01/17.

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