How to Use This Guide

This guide summarizes two years of experience using OptiVol® Fluid Status Monitoring in the clinical setting. It intends to be a practical tool to help clinicians understand, interpret, and use the monitoring trends captured in Medtronic’s implantable cardiac defibrillator (ICD) and resynchronization therapy (CRT-D) devices. This information provides additional insight into the patient’s status, it does not replace current assessment tools but it may aid in the proactive monitoring and management of these patients.

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Considerations in this Clinicians Practical Guide are courtesy of Lisa Rathman, MSN, CRNP; Roy Small, MD, FACC; and Jill Repoley, MSN, CRNP. The Heart Group and Lancaster General Hospital, Lancaster, PA.
Heart Failure, Congestion, and Hospitalizations
Heart failure affects 5 million Americans and 550,000 new diagnoses are made every year. Further, heart failure is the primary reason for over 1 million hospital admissions each year.¹ For patients, the prognosis is poor once he or she has been hospitalized. For clinicians, the challenge is identifying and managing those patients at risk for clinical decompensation and the resulting hospitalization.

Fluid congestion is the major reason for heart failure hospital admissions. Typically, clinicians use signs and symptoms to evaluate patients for fluid build-up but these signs and symptoms may occur relatively late in the process of developing congestion. Some patients may develop sub-clinical congestion days or even weeks before the onset of clinical symptoms and signs.² Other cardiac physiologic parameters may also change in advance of the presentation of signs and symptoms.³

By monitoring changes in these physiologic parameters clinicians may be able to improve clinical outcomes.² The ability of implantable devices to continuously monitor cardiac trends and intrathoracic fluid may provide early warning of changes in cardiac status, including impending fluid overload, and subsequently may help clinicians identify patients at risk for decompensation.

Key Concepts
• Congestion is the primary cause of heart failure hospital admissions and predicts readmissions
• Congestion is often difficult to recognize, delaying appropriate interventions
• Clinical congestion often lags behind rising filling pressures
• Congestion contributes to progression of heart failure
There are three different ways to access the data that is provided on the Heart Failure Management Report or the Cardiac Compass® Reports. They are listed below.

**Medtronic CareLink® Network**
Medtronic CareLink Network is the nation’s leading remote monitoring service. Patients can connect to their clinic from home or away, providing peace of mind and freedom to LIVE LIFE. Clinicians have 24/7 access to device data on a secure Internet website.

Conexus® Wireless Telemetry for Medtronic’s newest devices takes remote monitoring to the next level, paving the way to true cardiac disease management. The Medtronic CareLink Network with Conexus Wireless Telemetry offers automatic data transmissions of 14 months of data and customizable alert notifications, new features to enable improved patient care.

With wireless device interrogation, routine follow-ups occur automatically while the patient sleeps, alleviating patient compliance issues. Using the Medtronic CareLink Clinician website, clinic staff can pre-schedule up to six automatic device checks for each patient, minimizing time spent rescheduling missed appointments and playing phone tag.

**CardioSight®**
CardioSight provides referring cardiologists easy access to device information tailored to the management of heart failure, helping clinicians identify problems before symptoms occur. It enables clinicians treating heart failure to better understand, appreciate, and communicate with electrophysiologists about cardiac device therapy. Access to the reports provides 90-day trended information from the Heart Failure Management Report or the Cardiac Compass Trends Report. Temporal alignment of trended information allows clinicians to easily assess changes across multiple dimensions.

The CardioSight Reader – based on proven Medtronic CareLink technology – is quick and easy to use, providing flexibility in clinic workflow. Much like existing tools for measuring patients’ vital signs, the CardioSight Reader can be used to conveniently obtain important details on patient status. Within minutes of downloading device information using the reader, a Heart Failure Management Report or Cardiac Compass Trends Report is faxed to the clinic and can be added to the patient chart before the physician consults with the patient.

The CardioSight Reader gives insight into a patient’s condition without using a device programmer. It provides simple, one-touch operation, enabling access to read-only information without the possibility of changing device parameters.

**Medtronic CareLink Programmer**
Medtronic CareLink Programmer is used in the clinic or operating room to manage device therapies and parameters. Enabled with Conexus Wireless Telemetry, the new generation programmer provides follow-up and implant efficiencies for Medtronic’s latest CRT-Ds and ICDs. Additionally, a version of the trended reports is available via the programmer.
Heart Failure Trend Data
Clinicians can review device trends via the Cardiac Compass or Heart Failure Management Reports. Both provide up to 14 months of temporally aligned information on potential fluid status and other heart failure parameters, including:

- OptiVol Trends*
- AT/AF
- Ventricular Rate during AT/AF
- Patient Activity
- Resting Night Rate
- Heart Rate Variability
- Percentage Pacing

In addition, the reports also provide programming and interrogation annotations as follows:

- Evaluation during an office visit: “I”
- Evaluation during a home monitor session: “I”
- Device parameters change: “P”

The OptiVol Trends and the Heart Failure Management Report (HFMR) as a whole should be used with the clinical assessment of the patient to provide the diagnostic picture.5-8

If “I” and “P” values are recorded for a day, only the “P” is displayed on the report. Reports from CardioSight do not provide these values.

Key Concept

- The trend data reports provide clinicians with a multi-dimensional perspective of the patient
Clinical Utility

Thoracic impedance and OptiVol can be a useful tool. Some of the utility includes:

- An assessment tool that provides essential insight into the patient’s clinical status
- Better disease management by assisting therapy titration and disease stabilization through continuous monitoring of patient status
- An educational tool for patients on medication and dietary adherence

The results of MID-HeFT, a feasibility study, indicated that intrathoracic impedance:

- Correlates with physiologic measures of heart failure such as pulmonary capillary wedge pressures (PCWP)
- Precedes patient’s symptoms and weight gains by two weeks

Clinicians using OptiVol trends have indicated the following:

- Detection of clinically relevant events including:
  - Pulmonary congestion/heart failure decompensation
  - Onset of atrial fibrillation
  - Pneumonia
  - Lead dislodgement
- OptiVol trends have shown clinical utility in association with other device data such as heart rate variability, night heart rate, activity level, and tachycardias.

Key Concepts

- OptiVol is adjunctive to existing evaluation and assessment tools
- It is not subjective to patient compliance
- It can serve as an educational tool to improve patient adherence to a prescribed treatment plan
Many times during the day, electrical impulses travel from the lead in the right side of the heart to the implanted device.

Using this electrical impulse vector, OptiVol Fluid Status Monitoring measures impedance across the thoracic cavity.

With less fluid in the thoracic cavity, patient’s intrathoracic impedance increases.

Electrical Impedance Increases

As fluid accumulates in the patient’s lungs, intrathoracic impedance decreases.

Electrical Impedance Decreases

Continuous and Automatic Fluid Status Monitoring with OptiVol

OptiVol is a monitoring tool that objectively tracks fluid changes in heart failure patients using intrathoracic impedance. Thoracic impedance, a technology originally developed by NASA in the 1960s, is based on the principle that water is a relatively good conductor of electrical current. Thus, electric conductance through body tissues varies according to the water content of the tissue. When a very low electric current is passed through the thorax, water content should be directly related to electric conductance and inversely related to impedance.

Key Concepts

- Thoracic impedance tracking with fluid is a proven concept
- OptiVol continuously tracks fluid changes
- If fluid retention goes up, impedance goes down; if fluid retention goes down, impedance goes up
**Key Concepts**

- Thoracic impedance is a representation of the patient’s impedance status. It should always be reviewed first.
- The OptiVol fluid index should be interpreted within the context of the Daily impedance and Reference impedance.

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*An Event is defined in the MID-HeFT study as the OptiVol fluid index crossing 60 ohms which may be related to a relevant clinical occurrence.*

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**OptiVol Trends**

The OptiVol Trends are displayed in two separate graphs:

The *thoracic impedance graph* plots the raw data measured from the right ventricular coil to the device can pathway. **It is best to review this graph first** as it represents the status of the patient’s impedance.

The OptiVol fluid index indicates that an *event* may occur or has occurred. It is only a graphical representation of the data captured and plotted by the thoracic impedance algorithm and should not be used in isolation.

The next few pages will go into more detail regarding OptiVol Trends.
Key Concepts

- OptiVol is sensitive to multiple etiologies of fluid accumulation in the thoracic cavity\textsuperscript{5,7-12,15-17}
- The OptiVol algorithm starts 34 days after implant to allow time for pocket and lead maturation\textsuperscript{15}
- The Reference impedance works as the patient’s own control\textsuperscript{4,5}

How OptiVol Is Measured\textsuperscript{4,5}

- Impedance is measured from RV coil to device can
- Average Daily impedance is an average of measures taken several times a day (12 noon to 5 pm every 20 minutes)
- Reference impedance trend starts 34 days post-implant
  - It is a moving standard that works as the patient’s own control
- Programmable parameter
  - OptiVol Threshold (nominal at 60 Ω)

Any thoracic fluid can result in impedance decline regardless of pathology\textsuperscript{5,7-12,15-17}.
Non-thoracic fluid is excluded. Thoracic fluid may include: Vascular, Interstitial, Alveolar\textsuperscript{15}.

As fluid accumulates in the patient’s lungs, intrathoracic impedance decreases and the OptiVol fluid index increases.
When Evaluating the OptiVol Data, Follow These Two Steps⁴,⁵,⁷,⁸:

1A. Review Thoracic Impedance

Review the thoracic impedance graph first. It shows the raw impedance and indicates the severity of an event. It is an accurate representation of the patient’s impedance status. Observe on the image above how the Daily impedance and Reference impedance track over time. Fluid may be accumulating in the thoracic cavity if the Daily impedance consistently tracks below the Reference impedance.

Reference impedance initializes 34 days post-implant. It adapts slowly to changes in Daily impedance and acts as the patient’s own control.¹⁵

Magnitude and duration of impedance reduction below the Daily impedance represent the severity of fluid accumulation.⁷

<table>
<thead>
<tr>
<th>Changes in Intrathoracic Impedance</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Declining impedance</strong> may be the result of:</td>
<td><strong>Rising impedance⁷</strong> may be the result of:</td>
</tr>
<tr>
<td>• HF congestion (with or without symptoms)⁵,⁸,¹⁵</td>
<td>• Volume depletion⁵</td>
</tr>
<tr>
<td>• Appropriate reduction of diuretics in the dehydrated patient⁶</td>
<td>• Diuretics (increases)¹⁶</td>
</tr>
<tr>
<td>• Pneumonia⁷</td>
<td>• Dehydration⁴</td>
</tr>
<tr>
<td>• Pleural effusion¹⁷</td>
<td>• Dialysis/ultrafiltration¹⁸</td>
</tr>
<tr>
<td>• Wound fluid from pocket revision or infection¹⁷</td>
<td>• Positive pressure ventilation¹⁵</td>
</tr>
<tr>
<td>• Pocket/lead revision⁷,⁹,¹⁰,¹⁷</td>
<td>• Pneumothorax¹⁷</td>
</tr>
<tr>
<td>• Lead dislodgement⁹,¹⁰</td>
<td></td>
</tr>
<tr>
<td>• IV fluids/blood transfusion¹⁵</td>
<td></td>
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<tr>
<td>• Blood volume¹⁶</td>
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</tbody>
</table>

† Note: It is normal for the Daily impedance to generally increase after implant. This is likely due to maturation of the device pocket and the resolution of the pocket fluid accumulation post-implant.

* Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.
18. Review OptiVol Fluid Index\textsuperscript{4,5,7,*}

Review the OptiVol fluid index graph. It is a graphical representation of the accumulation of consecutive day-to-day differences between the Daily and Reference impedance reviewed on step 1. When the OptiVol crosses the physician programmable threshold it may signal an EVENT of clinical relevance. The severity of this EVENT can only be assessed by reviewing the thoracic impedance graph and other device diagnostics and clinical assessment. The fluid index is reset when the Daily impedance increases above the Reference impedance for a sustained period of three days.

A common misconception is that the height of the fluid index indicates the severity. However, the fluid index is a better gauge of a possible event occurring.

Key Concepts
- A threshold crossing indicates only that a clinical event may have occurred\textsuperscript{4,5}
- Upward trend indicates the beginning of fluid build-up\textsuperscript{4,5}

* Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.
2. Evaluate Other Device Trend Data
Evaluate all trends for changes over time; typically interrelationships can be seen across multiple trends as the patient’s condition changes. The lists on the next page reflect some of the more common trend changes that may be observed as a patient’s status changes.

Evaluate Other Device Trend Data\textsuperscript{4,15}

- New onset AF
- Increasing/decreasing AF frequency
- Total burden

- Effectiveness of rate control during AF episodes

- Trended data of patient’s activity level

- Day/night HR trends
- Separation between day/night HR

- Trended data of HR variability

- Percentage A. pacing
- Percentage V. pacing
OptiVol Fluid Status Monitoring

Cardiac Compass Report

VT/VF Episodes/Day4,19,*

Clinical Use
• Changes in number of episodes may indicate effects of medication changes or compliance
• Patterns or clusters of episodes may correlate to the patient’s medical condition

Details
• This graph provides daily information about the number of spontaneous VT/VF episodes (treated or aborted)
• VT monitored episodes are not counted. Induced episodes are not counted (episodes that are detected within 120 seconds of the end of a manual temporary operation are termed as induced).
• VT and VF episodes are combined

One or More Shocks/Day4,19,*

Clinical Use
• Changes in number of episodes and patterns of shocks (clustering) may provide information about changes in patient’s medical condition

Details
• This graph uses a vertical line to represent a day where at least one shock therapy (Defib or CV) was being delivered during a spontaneous episode

Non-Sustained VT Episodes/Day4,19,*

Clinical Use
• May be useful to correlate patient symptoms to NSVT
• May trigger further investigation (for example, an increasing trend in NST may prompt a clinician to check patient’s electrolytes)

Details
• This graph is similar to the VT/VF episodes/day graph. Non-sustained episodes are those in which five consecutive beats are less than the TDI (or FDI, if VT is OFF or Monitor), but detection is not satisfied
• Induced episodes are not included (using same criteria as VT/VF episodes)

V. Rate During VT/VF4,19,*

Clinical Use
• Information about rate during VT/VF may be useful in evaluating effects of medication and identifying new arrhythmias

Details
• This graph shows the median ventricular rate during each episode, displayed as a point. Multiple points on the Y-axis may indicate different ventricular arrhythmia episodes with different rates that occurred on the same day. The dotted, dashed, and solid horizontal lines indicate the programmed detection rates for VT, FVT, and VF (i.e., VTDI, VFTI, and VFDI respectively).
• The median ventricular rate is calculated from 12 beat RR Median at the time of detection (same as is stored in the Episode Log)

Other Device Trends

Note: Available on Cardiac Compass Report only

Patient results may vary; not every response is the same.

* Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.

Considerations in this document do not replace a physician’s expert judgment. The physician’s knowledge of the patient’s medical condition should be considered, and clinical and device intervention considerations may be tailored to fit the patient.
OptiVol Fluid Status Monitoring

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Intervention Considerations

If A T/AF is observed, consider:
- Reviewing stored episodes, if not available, reprogram the device to store episodes
- A T therapies especially if atrial flutter is identified
- Adjusting rhythm control therapy
- Adjusting anticoagulation therapy
- Cardioversion
- Referral for surgery

If higher V. rates during A T/AF are observed, consider:
- Changes in rate control therapy (surgical procedure)
- Program Mode Switch “ON,” if not already
- Program Conducted AF Response “ON” in CRT-D devices (Concerto), if not already

AT/AF Total Hours/Day
Provides information about the patient’s A T/AF burden. Information may be useful in:
- Rhythm control: identifying new arrhythmias
- Rhythm control: evaluating efficacy of antiarrhythmic drugs
- Risk control: assessing potential risk for stroke and need to anticoagulate

V. Rate During AT/AF
Provides average and maximum ventricular rate during AT/AF. The maximum V. rate is the fastest sensed RR median during AT/AF. Information may be useful in:
- Rate control: correlating ventricular rate to patient symptoms
- Rate control: assessing potential risk for stroke and need to anticoagulate

Other Device Trends

Evaluate trend for:
- New onset AF
- Increasing/decreasing AF frequency
- Total burden
- Effectiveness of rate control during AF episodes

Patient results may vary; not every response is the same.

* Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.

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Patient Activity\textsuperscript{4,6,7}

Provides trends of patient activity determined using the accelerometer sensor. Information may be useful in:

- Monitoring heart failure (decreased activity may be an indicator of progression of heart failure symptoms)
- Monitoring patient’s exercise regimen
- Monitoring changes in activity following changes in therapy

Patient results may vary; not every response is the same.

\textsuperscript{*} Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.

Considerations in this document do not replace a physician’s expert judgment. The physician’s knowledge of the patient’s medical condition should be considered, and clinical and device intervention considerations may be tailored to fit the patient.

\textbf{Intervention Considerations}\textsuperscript{*}

If decrease in patient activity is observed\textsuperscript{6-8,11-15,17,21}:

- Assess for etiology of decreased activity
- Assess for association with OptiVol fluid index
- Further assess for volume overload/depletion to determine if heart failure symptoms changed
- Promote exercise as stated in AHA Guidelines
- Assess rate response programming
**Average V. Rate (Day and Night)**

Provides trends of day heart rate and night rate calculated using ventricular events (not in AT/AF) occurring between 8 am and 8 pm, and between 12 am and 4 am, respectively.

Information may be useful in:
- Monitoring decompensation due to heart failure (increasing trend in night heart rate may be an indicator of autonomic dysfunction)

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**Intervention Considerations**

If high night heart rate or increasing trend in night heart rate is observed, consider:

- Assessing efficacy of drugs, such as beta blockers
- Correlating patient symptoms with heart rate trends
- Adjust heart failure medications (e.g., ACE-I, BB, diuretics, etc.) to achieve optimal management
- Further assess for volume overload/depletion to determine if heart failure symptoms changed

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Patient results may vary; not every response is the same.

* Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.

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Heart Rate Variability (HRV)\(^4\)
Provides trend of 24-hour based measure of heart rate variability approximating the standard deviation of all NN intervals (SDNN) and standard deviation of the five-minute averages of NN intervals (SDANN). Information may be useful in:

- Monitoring heart failure (decreasing HRV may be an indicator of autonomic imbalance due to heart failure)\(^3\)
- Decline in HRV has been shown to be an early predictor of heart failure hospitalization\(^3\)
- Monitoring effects of therapy (HRV increases due to appropriate heart failure medications)\(^3\)
- HRV is not available when atrial fibrillation or pacing in the atrium is present\(^4\)

Intervention Considerations\(^*\)
If persistently low HRV (< 50 ms) or persistent HRV decline is observed, consider\(^1,2,\#\):

- Adjusting heart failure medications (e.g., ACE-I, BB, diuretics, etc.) to achieve optimal management
- Further assessing for volume overload/depletion to determine if heart failure symptoms changed

Patient results may vary; not every response is the same.

\(^*\) Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.

Considerations in this document do not replace a physician’s expert judgment. The physician’s knowledge of the patient’s medical condition should be considered, and clinical and device intervention considerations may be tailored to fit the patient.
Intervention Considerations*  
**CRT-D: Ventricular pacing below 90% observed, consider**21,22,25;  
- Full programmer interrogation to evaluate why  
- Repeat echo A/V optimization  
- Rule out lead dislodgement  
- Maximize V. pacing to ensure optimal CRT therapy  
**Dual Chamber ICD: If RV pacing is higher than desired, assess for worsening AV nodal conduction status. Consider modifications to the following**23,24:  
- Programming4  
- AV delay  
- MVP® Mode4  
- Decrease rate response settings4

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**Percent Pacing/Day**4  
Provides trended information about percentage of paced events (atrial and ventricular). Information may be useful in:  
- Assessing patient’s level of pacemaker dependence  
- Ensure nearly 100% pacing in the ventricle for effective CRT therapy22  
- Ensure minimal ventricular pacing in ICD devices (non-CRT)23,24

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* Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.

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OptiVol Fluid Status Monitoring

**AT/AF Diagnostics**

**The Problem of AF**

Atrial fibrillation is a common problem in patients with heart failure. In fact, heart failure increases a person’s risk of developing atrial fibrillation by up to six times.\(^{26}\) The prevalence of AF is associated with the severity of heart failure which increases and approaches nearly 50% in NYHA Class IV patients.\(^{27-30}\)

The negative consequences of atrial fibrillation in the heart failure patient can be many:\(^{31,32}\)
- Worsening HF
- More frequent hospitalizations
- Inappropriate ICD shocks
- Loss of CRT therapy
- Increased sympathetic tone
- Hemodynamic compromise

**The Challenge of Managing**

Detecting atrial fibrillation and quantifying the burden is a clinical challenge. Episodes are often asymptomatic and patient symptoms are poorly associated with atrial arrhythmias.\(^{33}\) Further, intermittent monitoring (i.e., ECG, Holter) fail to capture the occurrence of AT/AF episodes and accurately quantify the burden.\(^{34}\) The importance of accurately identifying atrial fibrillation and quantifying the burden is paramount as episodes lasting longer than one day in duration are independently associated with embolic events.\(^{35}\)

Rate control during atrial fibrillation can be equally problematic. Poor ventricular rate control during atrial fibrillation has demonstrated an association with an earlier time to the first heart failure hospitalization.\(^{36}\) Further, poor rate control during atrial fibrillation is the most common cause of inappropriate ICD shocks and reduced CRT pacing.\(^{37}\)

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**Intervention Considerations*\(^{*}\)**

If AT/AF is observed, consider:\(^{20}\):
- Adjust rhythm control therapy
- Adjust anticoagulation therapy
- Cardioversion
- Referral for surgery

If higher V. rates during AT/AF are observed, consider:\(^{20}\):
- Changes in rate control therapy
- Program Mode Switch “ON,” if not already\(^{4}\)
- Program Conducted AF Response “ON” in CRT-D devices (Concerto), if not already\(^{4}\)

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* Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.

Patient results may vary; not every response is the same.
Benefits

The AT/AF diagnostic trends provide valuable information which may help guide clinical decision making.\(^4\)

The atrial tachycardia/atrial fibrillation burden trend plots the total time spent in AT/AF on a daily basis. The trend view is self adjusting and will present the data in minutes or hours depending upon the total daily burden.\(^4\)

The ventricular rate during AT/AF trend displays the daily average and maximum ventricular rates occurring during AT/AF.\(^4\)

AT/AF Trends provide the clinician with information that may allow\(^4,6,20\):

- Detection of silent AF
- Documentation of paroxysmal episodes
- Quantification of total AF burden
- Evaluation of rate/rhythm control strategies
- Guidance for anticoagulation therapy
- Ruling out AF as a cause of symptoms

Patient results may vary; not every response is the same.

Considerations in this document do not replace a physician’s expert judgment. The physician’s knowledge of the patient’s medical condition should be considered, and clinical and device intervention considerations may be tailored to fit the patient.
Three Easy Steps to Evaluate the Patient Using the Trend Data*

**STEP 1**: Review Impedance and OptiVol Trend data

**STEP 2**: Evaluate Other Device Trend Data

**STEP 3**: Evaluate Patient and Correlate Findings to Make Clinical Decision

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a) Assess patient current status (signs and symptoms), past medical history, and physical exam. Assess for recent changes in patient overall clinical status (volume/anemia, pneumonia, dehydration, hospitalizations)

b) Review for medication changes (prescribed and over-the-counter [OTC])

c) Assess for changes in patient adherence (medication, diet)

d) Review other diagnostic variables (labs, x-rays)

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* Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.

Considerations in this document do not replace a physician’s expert judgment. The physician’s knowledge of the patient’s medical condition should be considered, and clinical and device intervention considerations may be tailored to fit the patient.
Background
85-year-old male with past medical history of CHF with ICM EF 20%. He has CAD, Hyperlipidemia, Type 2 Diabetes Mellitus, Atrial Flutter ablation in September 2003. He had an InSync Sentry device implant in February 2005.

Medications
Amiodarone, Bumetanide, Warfarin, Lisinopril, and Metoprolol.

STEP 1: Review Impedance and OptiVol Trend Data
Look for:
- Impedance trends up/down
- Fluid index reset

Patient results may vary; not every response is the same.
**STEP 2: Evaluate Other Device Trend Data**

- Note the correlation between the declining impedance and onset of AFib, reduced CRT pacing, and fast ventricular response
- April 26: AF begins, impedance starts declining
- Patient activity is stable
- No HRV data due to AFib

Patient results may vary; not every response is the same.
2a. Check for Trend Changes Over Time

Condition improving:

- Patient activity increasing\(^\text{7,12,13}\)
- HR variability increasing\(^\text{13,38}\)
- Separation between day/night HR increased\(^\text{39}\)
- CRT pacing maximized\(^\text{22,25}\)
- Ventricular rate with AF controlled\(^\text{40}\)
- Average day/night HR decreasing\(^\text{3,39}\)
- Atrial fibrillation burden decreasing

Condition worsening:

- Atrial fibrillation burden increasing\(^\text{21}\)
- Average day/night HR increasing\(^\text{3,39}\)
- High RV pacing in ICD patient\(^\text{23,24}\)
- Ventricular rate with AF uncontrolled\(^\text{31,32}\)
- CRT pacing below 100\(^\text{\%}\)\(^\text{22,25}\)
- Patient activity declining\(^\text{7,12,13}\)
- HR variability decreasing\(^\text{6,13,38,39}\)

* Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.
### 2b. Clinical and Device Intervention Considerations

Daily impedance is changed, consider possible cause:
Although the most common cause, thoracic fluid accumulation is not the only reason thoracic impedance might change. Nevertheless, a thoracic impedance change may indicate a clinically relevant event that may require medical attention.

<table>
<thead>
<tr>
<th>Heart failure-related event:</th>
<th>Clinically relevant event:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary edema⁵,⁸</td>
<td>Pocket infection⁴</td>
</tr>
<tr>
<td>Volume retention⁵,⁸</td>
<td>Pleural/pericardial effusion⁵</td>
</tr>
<tr>
<td>Pulmonary Congestion⁵,⁸</td>
<td>Diuretic therapy changes⁵,¹⁶</td>
</tr>
<tr>
<td>Pocket or lead revision⁸⁻¹¹</td>
<td>Anemia¹³</td>
</tr>
<tr>
<td></td>
<td>Dialysis¹⁸</td>
</tr>
<tr>
<td></td>
<td>Respiratory infection⁵</td>
</tr>
</tbody>
</table>

Consider the following actions:
- Corroborate with other diagnostic trend findings⁴
- Educate patient, i.e., dietary and/or fluid, medication compliance⁶,¹⁴,²¹
- Adjust HF medications to achieve optimal management²¹
- Titrate diuretics and appropriately monitor electrolytes²¹
- Refer to electrophysiology for system-related issue²¹,²²

**AT/AF observed, consider²⁰:**
- Corroborating with other diagnostic trend findings⁴
- Cardioversion
- Adjusting rhythm control therapy
- Instituting of anticoagulation therapy
- Surgical procedures

**AF with rapid ventricular response observed, consider²⁰:**
- Corroborating with other diagnostic trend findings⁴
- Cardioversion
- Adjusting rate control therapy
- Program Conducted AF Response “ON” in CRT-D devices (Concerto)⁴
- Program Mode Switch “ON” – to a nontracking pacing mode⁴

**Decrease in patient activity, consider:**
- Corroborating with other diagnostic trend findings⁴
- Promoting regular exercise as indicated⁶,¹⁴,²¹

**Increasing day/night HR with poor separation, consider¹,²,¹⁹:**
- Corroborating with other diagnostic trend findings⁴
- Adjusting HF medications
- Atrial fibrillation
- Sleep apnea or nocturnal dyspnea

**Persistently low HRV (< 50 ms) or declining values, consider¹,²,¹⁹:**
- Corroborating with other diagnostic trend findings⁴
- Adjusting HF medications²¹
- Not measured if patient is in AF⁴
- Consider if patient is in AF or atrially paced

**Percent ventricular pacing below 100% in CRT patient, consider²¹,²²,²⁵:**
- Corroborating with other diagnostic trend findings⁴
- Atrial fibrillation with rapid ventricular response³,¹²
- Evaluating device settings, may necessitate electrophysiology consult²²
- AV optimization
- Lead dislodgement⁹

**Percent pacing higher than desired in dual chamber ICD patient, consider²³,²⁴:**
- Corroborating with other diagnostic trend findings⁴
- AV delay
- Atrial fibrillation
- Program MVP Mode “ON”⁴
- Reprogram rate response settings⁴

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*Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.

Considerations in this document do not replace a physician’s expert judgment. The physician’s knowledge of the patient’s medical condition should be considered, and clinical and device intervention considerations may be tailored to fit the patient.
STEP 3: Evaluate Patient and Correlate Findings to Make Clinical Decision

* Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.
The following cases are examples of common trends you will see while evaluating patients’ OptiVol Trends. Over time, it will become easier to understand what you are seeing the more OptiVol Trends you read and patients you talk to regarding their trends.

**Stable, Well-Managed Patient**

This OptiVol data resembles the profile of a stable heart failure patient. Note the steady increase in Daily impedance post-implant. This is indicative of pocket maturation.\(^{15}\)

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**Key Concept**

Stable, well-managed patient after implant.

Impedance has stabilized.
Medication Nonadherence Patient

The intrathoracic impedance decline led to OptiVol Threshold crossing which was associated with a worsening heart failure due to medication nonadherence.

Note the cyclical changes in impedance. Commonly, elapses in the medications regimen happen monthly. The root cause could be associated with financial inability to fill out prescriptions. These events are shown in the report as monthly impedance decline and fluid index rise (peaks). This is a good opportunity to probe the patient, educate on medication adherence, and find alternatives for medication access.

Key Concept

Medication nonadherence is often characterized by monthly changes in impedance.

Patient results may vary; not every response is the same.
Dietary Nonadherence Patient
Commonly, events such as dietary nonadherence due to vacation, holidays, and special occasions lead to a decrease in impedance and rise in the fluid index that resembles a trend like this. This is a good opportunity to probe the patient and educate on diet adherence.\textsuperscript{6,12,*}

\begin{figure}
\centering
\includegraphics[width=0.8\textwidth]{chart.png}
\caption{OptiVol fluid index and thoracic impedance (ohms) over time.}
\end{figure}

Key Concept
Isolated changes in impedance are commonly associated with dietary nonadherence. Look for these changes especially during the holiday season and summer.\textsuperscript{6,12,*}

Patient results may vary; not every response is the same.

\textsuperscript{*} Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.
Dehydrated Patient

This patient was dehydrated when the Reference line was initialized. When patient’s status improved, the Daily impedance dropped below the Reference line and the fluid index began to rise even though the patient was not congested. Dehydration will cause a rise in Daily impedance. Appropriate reductions in diuretic therapy will cause the Daily impedance to decline which may result in OptiVol Threshold crossing.

Key Concept

Fluid status of the patient at time of implant may impact the Reference impedance.15,*

Patient results may vary; not every response is the same.

* Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA.
Heart Failure Patient Care Using OptiVol

Courtesy of The Heart Group and Lancaster General Hospital, Lancaster, PA

This guideline is meant to assist in the management of heart failure patients using monitoring data from certain implanted Medtronic devices. It is not designed to replace clinical judgment or individual patient needs. It does not provide the full scope of heart failure services.
Indications for Virtuoso

Virtuoso DR/VR devices are indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias in patients with NYHA Functional Class II/III heart failure. The Virtuoso DR device is also indicated for use in the above patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias. Atrial rhythm management features, available on the Virtuoso DR, such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in ICD–indicated patients with atrial septal lead placement and an ICD indication. Due to the addition of the OptiVol® diagnostic feature, the Virtuoso indication is limited to NYHA Functional Class I/II heart failure patients who are indicated for an ICD. The clinical value of the OptiVol fluid monitoring diagnostic feature has not been assessed in those patients who do not have fluid retention related symptoms due to heart failure.

Contraindications

The InSync Sentry and Concerto are contraindicated in patients whose ventricular tachyarrhythmias may have transient or reversible causes; patients with incessant VT or VF; and patients who have a unipolar pacemaker.

Virtuoso DR/VR devices are contraindicated for patients experiencing any of the following conditions: tachyarrhythmias with transient or reversible causes, incessant ventricular tachycardia or ventricular fibrillation, present implant of a unipolar implantable pulse generator, and primary disorder or bradycardia. Virtuoso DR is also contraindicated for patients who have a primary disorder of chronic atrial tachyarrhythmia with no concomitant VT or VF. Additionally, Virtuoso VR is contraindicated for patients who have a primary disorder of atrial arrhythmia.

Warnings and Precautions

Changes in a patient’s disease and/or medications may alter the efficacy of the device’s programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillation paddles directly over the device. Certain programming and device operations may not provide cardiac resynchronization.

Potential Complications

Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate tachyarrhythmia episodes, acceleration of ventricular tachycardia, and surgical complications such as hematoma, infection, and thrombosis. See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic’s website at www.medtronic.com.

CardioSight® Reader

The 2020A CardioSight Reader is intended for use in a clinical setting and is indicated for the transfer of patient and device data from compatible Medtronic implantable devices to a clinician. There are no contraindications for the 2020A CardioSight Reader. The CardioSight Reader must only be used for interrogating compatible Medtronic implantable devices. Do not use a cellular phone while the antenna is positioned over the implanted device. The CardioSight Reader is designed for use in the continental United States, Alaska, and Hawaii. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic’s website at www.medtronic.com.

Medtronic CareLink® Monitor/Medtronic CareLink Network

The Medtronic CareLink Monitor and the Medtronic CareLink Network are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manual. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician. Do not use a cellular phone while the antenna is positioned over the implanted device. The Medtronic CareLink Network is currently available in the continental United States, Alaska, and Hawaii. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic’s website at www.medtronic.com.

2090 Programmer

The Medtronic/Vitatron CareLink Programmer system is comprised of prescription devices indicated for use in the interrogation and programming of implantable medical devices. Prior to use, refer to the Programmer Reference Guide as well as the appropriate programmer software and implantable device technical manuals for more information related to specific implantable device models. Programming should be attempted only by appropriately trained personnel after careful study of the technical manual for the implantable device and after careful determination of appropriate parameter values based on the patient’s condition and pacing system used. The Medtronic/Vitatron CareLink programmer must be used only for programming implantable devices manufactured by Medtronic or Vitatron.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic’s website at www.medtronic.com.

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