Start with the thoracic impedance trend and evaluate the patient’s Daily impedance.

The thoracic impedance trend is an accurate representation of the patient’s actual Daily impedance level. The Daily impedance trend may change as the patient’s status changes.

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

Review the OptiVol fluid index trend next . . .

The OptiVol fluid index trend is a graphical representation of the consecutive day-to-day difference between the Daily and Reference impedance. The OptiVol fluid index will rise as intrathoracic fluid level increases. Generally, the OptiVol trends will demonstrate the following patterns as the patient’s status changes.

- Consider reasons for changes in Daily impedance – possible elements that could impact impedance including but not limited to:
  - Pulmonary edema
  - Volume retention
  - Pulmonary congestion
- Consider non-heart failure explanations for changes in impedance:
  - Pocket or lead revision
  - Pocket infection
  - Respiratory infection
  - Pleural/pericardial effusion
  - Diuretic therapy changes
  - Anemia

Based on clinician experience using OptiVol trend data in practice and during clinical trials.

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.
Evaluate other device trend data

Evaluate trend for:

- 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

Condition improving:

- Patient activity increasing
- Average day/night HR increasing
- CRT pacing maximized
- Ventricular rate with AF uncontrolled
- Average day/night HR decreasing
- Patient activity declining
- Atrial fibrillation burden decreasing
- HR variability decreasing

Condition worsening:

- Atrial fibrillation burden increasing
- High RV pacing in ICD patient
- Ventricular rate with AF uncontrolled
- CRT pacing below 100%
- Patient activity declining
- Atrial fibrillation burden decreasing
- HR variability decreasing

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.
Upon completing review of the device-based diagnostics, the next step is to approach the patient. The patient evaluation should consist of your standard approach to patient assessment in the clinic. This step may include, but is not limited to, the following measures or order:

- Review medication list
  - Medications prescribed by HF clinicians
  - Medications prescribed by other: GP, IM, Nephrologist, etc.
- Over-the-counter medications
- Exercise

Review other diagnostic studies
- Labs
- X-rays
- Echocardiography
- Perfusion studies

Evaluate patient concerning salt and/or fluid restriction and compliance with medications
- Adjust HF medications (e.g., ACE-I, BB, etc.) to achieve optimal management
- Add/increase diuretic and appropriate monitoring of electrolytes

**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 for thoracic impedance might change. Nevertheless, a thoracic impedance change may indicate a clinically relevant event that may require medical attention.

**Heart failure-related event**: Clinically relevant event:
- Pulmonary edema
- Pocket infection
- Volume retention
- Pulmonary congestion
- Diuretic therapy changes
- Respiratory infection
- Anemia

**Pocket or lead revision**

**Corroborating with other diagnostic findings**
- Consider if patient is in AF or atrially paced
- Program Mode Switch "ON" – to a nontracking pacing mode
- Refer to electrophysiology for system-related issue
- Titrate diuretics and appropriately monitor electrolytes
- Adjust HF medications to achieve optimal management
- Educate patient concerning salt and/or fluid restriction and compliance with medications

**Assess patient's current status**
- Review chart for past medical history
- Interview patient
- Perform physical examination
- Assess patient compliance
- Medications
- Diet
- Exercise

**Review other diagnostic studies**
- Labs
- X-rays
- Echocardiography
- Perfusion studies

Consider the following actions:
- Corroborate with other diagnostic trend findings
- Evaluate patient, i.e., diet, exercise/or fluid, medication compliance
- Adjust HF medications to achieve optimal management
- Titrate diuretics and appropriately monitor electrolytes
- Refer to electrophysiology for system-related issue
- Consider if patient is in AF or atrially paced
- Program Mode Switch "ON" – to a nontracking pacing mode

**Decrease in patient activity, consider**
- Corroborating with other diagnostic trend findings
- Promoting regular exercise as indicated

**Incorporating day/night HR with poor separation, consider**
- Atrial fibrillation
- Sleep apnea or nocturnal dyspnea

**Persistently low HR (< 50) or declining values, consider**
- Corroborating with other diagnostic trend findings
- Adjusting rate control therapy
- Program Conducted AF Response "ON" in CRT-D devices (Concerto)
- Program Mode Switch to a nontracking pacing mode

**Decrease in ventricular pacing below 50% in CRT patient, consider**
- Corroborating with other diagnostic trend findings
- Atrial fibrillation with rapid ventricular response
- Evaluating device settings may assist electrophysiology consult
- AV optimization
- Lead dislodgement

**Potential complications**
- Inpatients and outpatients may experience thoracic fluid accumulation, hypoxia, fatigue, inadequate energy expenditure, and/or death. These complications may necessitate medical intervention and may include the use of surgical or medical intervention to correct the underlying cause.

**CROP AREA**

**Brief Statement**
Indyx® Sentry®, Models CDRHDN, and Virtuoso® Models D154AWG/D154VWC (DR/VR)

**Indications for Indyx Sentry and Concerto**: The Indyx Sentry and Concerto are intended for electrophysiology, antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular tachyarrhythmias in patients with NYHA Functional Class III or IV in those patients who remain symptomatic despite stable, optimal medical therapy, and have left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration.

**Indications for Virtuoso**: Virtuoso DR/VR devices are indicated to provide ventricular extracardiac pacing and ventricular defibrillation for automated treatment of life-threatening ventricular tachyarrhythmias in patients with NYHA Functional Class III/IV failure. The Virtuoso DR device is also indicated for use in the above population with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias. Atrial rhythm management features, available in the Virtuoso DR such as atrial rate, atrial rate stabilization (ARS), Atrial Performance Pacicking (APP), and atrial rate control therapy (ARRT), may be indicated for the suppression of atrial tachyarrhythmias in ICD-ventricle patients with atrial fibrillation or flutter and an ICD indication. Due to the addition of the Optivol® fluid monitoring diagnostic feature, the Virtuoso indication is limited to NYHA Functional Class III/IV 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 Indyx Sentry, Concerto, and Virtuoso are contraindicated in patients whose ventricular tachyarrhythmias may have transmural or reversible causes, patients with incessant VT or VF, and patients who have a pulmonary pseudoaneurysm.

**Warnings and Precautions**: Changes in patient’s diseases and/or medications may alter the efficacy of the device. Changes in drug delivery, tissue damage, induction of an arrhythmia, underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical stress, or device damage. Do not place transducers within 6 inches/15 cm of the ICD or AV lead. Certain programming and device operations may not provide cardiac resynchronization.

**Potential Complications**: Potential complications include, but are not limited to, rejection phenomena, erosions through the skin, muscle or nerve stimulation, oversensing, underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical stress, or device damage. Do not place transducers within 6 inches/15 cm of the ICD or AV lead. Certain programming and device operations may not provide cardiac resynchronization.

**See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/alternate avenue. For further information, please call Medtronic at (763) 582-2589 and/or visit Medtronic’s website at www.medtronic.com.

**Cautions**: Federal law (USA) restricts these devices to be sold by or on the order of a physician.