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Clinical Application of the HF Diagnostic Trends

A three-step approach to patient management

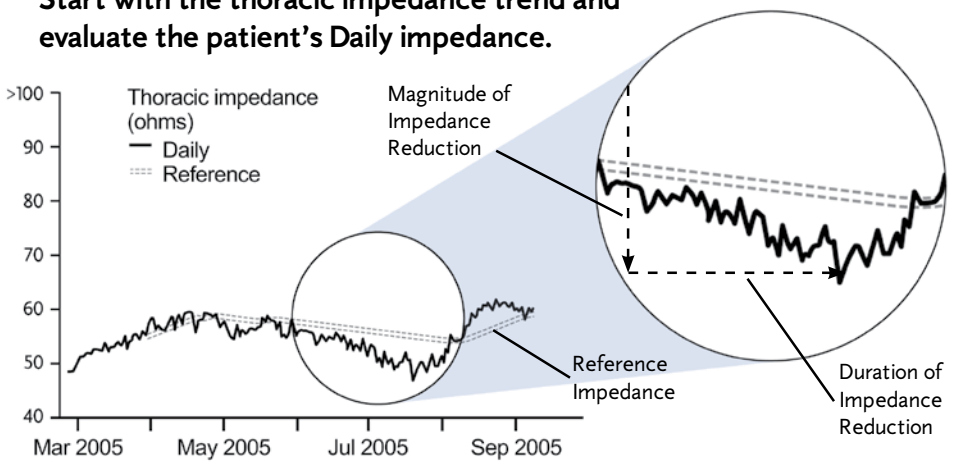
Trends:[1]

- *OptiVol® Impedance*
- *AT/AF Diagnostics*
- *Heart Rate Variability*
- *Percent Pacing*

1 REVIEW IMPEDANCE TREND AND OPTIVOL TREND DATA[1-3*]

Accessible on Medtronic CareLink® Programmer and CardioSight®

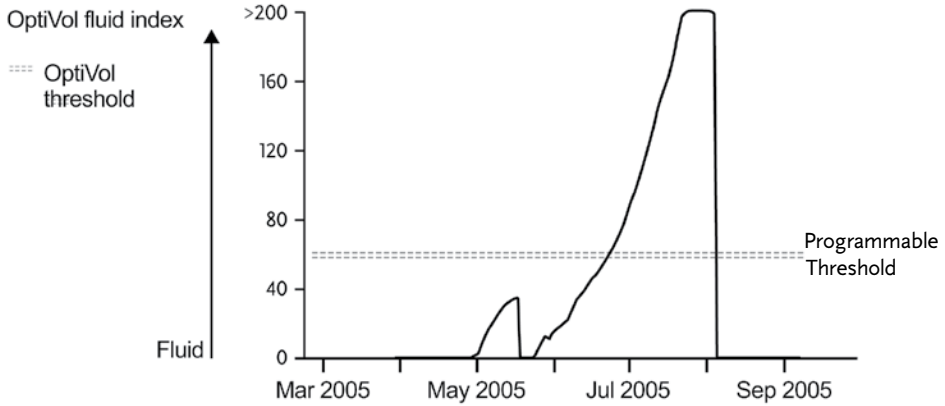
Start with the thoracic impedance trend and evaluate the patient's Daily impedance.



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.[3] It adapts slowly to changes in Daily impedance and acts as the patient's own control.[3]

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.[2-8]

*OptiVol Fluid Management is a feature in Concerto® and InSync Sentry® CRT-Ds and Virtuoso® DR/VR ICDs.

1a IMPEDANCE AND OPTIVOL TREND DATA[1]

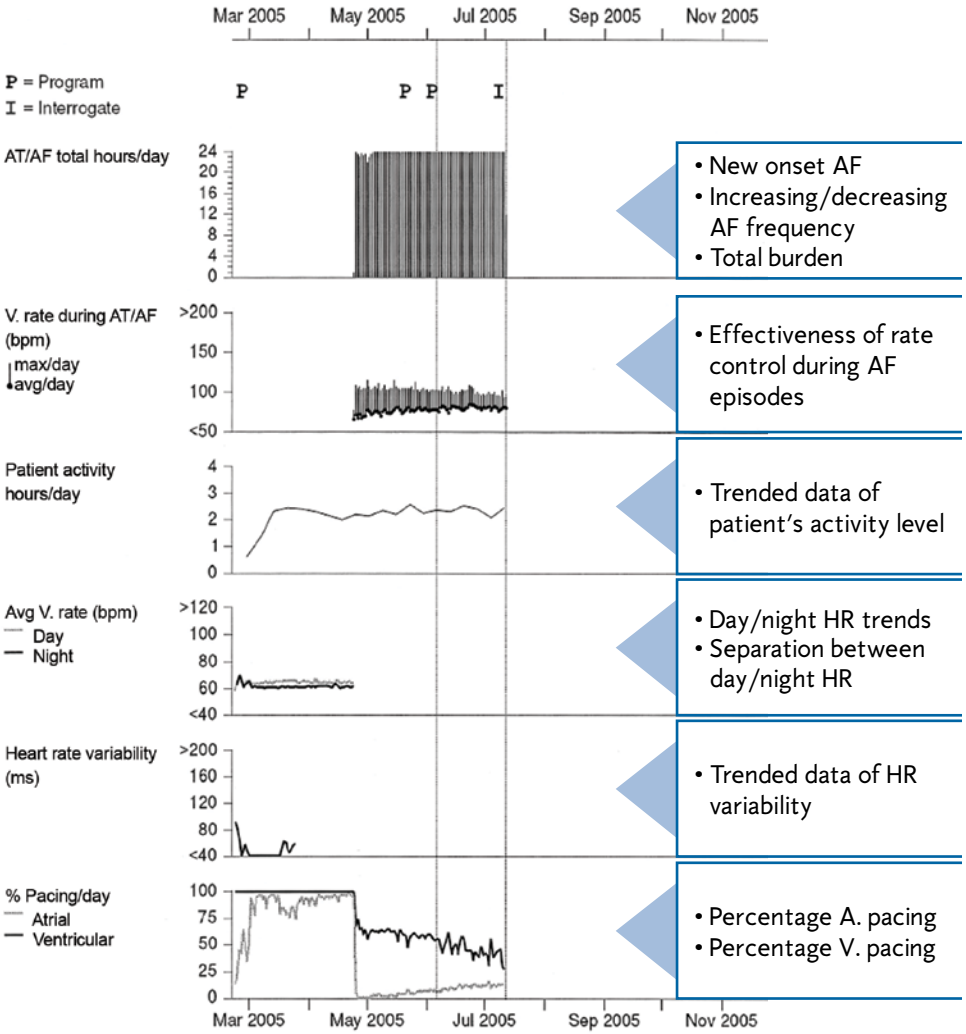
- Consider reasons for changes in Daily impedance – possible elements that could impact impedance including but not limited to:*
  - Pulmonary edema[2,4]
  - Volume retention[2,4]
  - Pulmonary congestion[2,4]
- Consider non-heart failure explanations for changes in impedance:*
  - Pocket or lead revision[4-7]
  - Pocket infection[2]
  - Respiratory infection[2]
  - Pleural/pericardial effusion[3]
  - Diuretic therapy changes[2,8]
  - Anemia[7]

*Based on clinician experience using OptiVol trend data in practice and during clinical trials.[2-8]

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.

2 EVALUATE OTHER DEVICE TREND DATA[1]

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

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.

2a CHECK FOR TREND CHANGES OVER TIME[1]

Condition improving:	Condition worsening:
Patient activity increasing[7,9,10]	Atrial fibrillation burden increasing[11]
HR variability increasing[10,12,13]	Average day/night HR increasing[12,13]
Separation between day/night HR increased[13]	High RV pacing in ICD patient[14,15]
CRT pacing maximized[16–18]	Ventricular rate with AF uncontrolled[19,20]
Ventricular rate with AF controlled[21]	CRT pacing below 100%[18,22]
Average day/night HR decreasing[12,13]	Patient activity declining[7,9,10]
Atrial fibrillation burden decreasing	HR variability decreasing[10,12,13,23]

Increasing Neutral Decreasing

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.[2-9]

Heart failure-related event:
- Pulmonary edema[2,4]
- Volume retention[2,4]
- Pulmonary congestion[2,4]
- Pocket or lead revision[4-7]

Clinically relevant event:
- Pocket infection[2]
- Pleural/pericardial effusion[3]
- Diuretic therapy changes[2,8]
- Anemia[7]
- Dialysis[24]
- Respiratory infection[2]

Consider the following actions:
- Corroborate with other diagnostic trend findings[1]
- Educate patient, i.e., dietary and/or fluid, medication compliance[25-27]
- Adjust HF medications to achieve optimal management[25]
- Titrate diuretics and appropriately monitor electrolytes[25]
- Refer to electrophysiology for system-related issue[18,25]

AT/AF observed, consider:[11]
- Corroborating with other diagnostic trend findings[1]
- Cardioversion
- Adjusting rhythm control therapy
- Instituting of anticoagulation therapy
- Surgical procedures

AF with rapid ventricular response observed, consider:[11]
- Corroborating with other diagnostic trend findings[1]
- Cardioversion
- Adjusting rate control therapy
- Program Conducted AF Response "ON" in CRT-D devices (Concerto)[1]
- Program Mode Switch "ON" – to a nontracking pacing mode[1]

Decrease in patient activity, consider:
- Corroborating with other diagnostic trend findings[1]
- Promoting regular exercise as indicated[25-27]

Increasing day/night HR with poor separation, consider:[12,13,23]
- Corroborating with other diagnostic trend findings[1]
- Adjusting HF medications[25]
- Atrial fibrillation
- Sleep apnea or nocturnal dyspnea

Persistently low HRV (< 50 ms) or declining values, consider:[12,13,23]
- Corroborating with other diagnostic trend findings[1]
- Adjusting HF medications[25]
- Not measured by device if patient is in AF[1]
- Consider if patient is in AF or atrially paced

Percent ventricular pacing below 100% in CRT patient, consider:[18,22,25]
- Corroborating with other diagnostic trend findings[1]
- Atrial fibrillation with rapid ventricular response[18,19]
- Evaluating device settings may necessitate electrophysiology consult[18]
- AV optimization
- Lead dislodgement[5,6]

Percent pacing higher than desired in dual chamber ICD patient, consider:[14,15]
- Corroborating with other diagnostic trend findings[1]
- AV delay
- Atrial fibrillation
- Program MVP® Mode "ON"[1]
- Reprogram rate response settings[1]

*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.

3 EVALUATE THE PATIENT AND CORRELATE FINDINGS TO MAKE CLINICAL DECISION[25]*

Upon completing review of the device-based diagnostics, the next step is to evaluate the patient. The patient evaluation should consist of your standard approach to patient assessment in the clinic. This step might 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

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
- Educate 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

*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.

Brief Statement

InSync Sentry® Models 7297/7299, Concerto® Model C154DWK, and Virtuoso® Models D154AWG/D154VWC (DR/VR)

Indications for InSync Sentry and Concerto: The InSync Sentry and Concerto are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias, and for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy, and have a 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 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 II/III 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, Concerto, and Virtuoso 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.

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, inflammation, 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.

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