Integrating Monitoring into the Infrastructure and Workflow of Routine Practice: OptiVol®

Roy S. Small, MD, FACC

Heart Failure Clinic, The Heart Group; Heart Failure Service, Lancaster General Hospital, Lancaster, PA

New cardiac resynchronization devices that monitor intrathoracic impedance may be utilized to monitor intravascular fluid status in chronic heart failure patients. Incorporating these devices into a heart failure medical practice requires the integration of heart failure medical services and electrophysiology. These devices must be interrogated and the data analyzed if the diagnostic information is to be useful in the care of heart failure patients. Device generated time aligned trends should be interpreted in the context of clinical findings. Systems must be well designed to deal with the results of solicited and unsolicited data.

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There are presently more than 5 million Americans living with heart failure, with 550,000 new cases diagnosed each year.[1] This disease will reach epidemic proportions as the number of affected patients is expected to double by the year 2030. Advances in cardiology are at least in part responsible for this increase with fewer fatalities from acute myocardial infarction and the more widespread use of prophylactic defibrillators.

Patients with heart failure are a challenge to manage. Typically their course is marked by episodes of acute decompensation (ADHF) requiring intensification of therapy and oftentimes hospitalization. Congestion is the most common cause of decompensation; however, it can be difficult to detect at an early stage.[2] The signs and symptoms of congestion do not necessarily reflect hemodynamic status and daily weights are helpful but often inconsistent.[3] Currently available noninvasive measures (transthoracic impedance) or serum markers (B-type natriuretic peptide) of congestion correlate poorly with measured filling pressures.[4] Device diagnostics may offer one more piece of the puzzle in treating these complex patients.

Whereas the onset of ADHF symptoms typically occurs over hours to days, the fluid accumulation that causes this decompensation develops more insidiously.[5,6] If the intrathoracic fluid content could be routinely monitored, then it may be possible to detect incipient fluid retention before the onset of fulminant symptoms and possibly abort hospitalization. The potential savings to the healthcare system are likely to be enormous.

Intrathoracic impedance is inversely correlated with the pulmonary capillary wedge pressure.[7] This principle has been utilized to design an algorithm that may provide an early warning of impending decompensation.[8] Although there is limited clinical experience with this algorithm, it has been approved by the US Food and Drug Administration (FDA) as a diagnostic feature within a cardiac resynchronization defibrillator.[9]

The diagnostic fluid index is automatically derived by comparing the measured average daily impedance value against the previously established baseline. Consecutive negative deviations in the actual daily measured impedance from the calculated reference value result in a higher fluid index. Fluid index values greater than the programmed threshold constitute a device classified event and correspond to thoracic fluid congestion. The sensitivity and specificity of this diagnostic algorithm for indicating the likelihood of ADHF episodes is still uncertain. The InSync Sentry® cardiac resynchronization therapy device and defibrillator (CRT-D) (Medtronic, Inc., Minneapolis, MN) with automated intrathoracic fluid status monitoring (OptiVol® fluid index monitoring; Medtronic, Inc.) provides standard cardiac resynchronization therapy and incorporates this fluid management algorithm allowing routine monitoring of intrathoracic impedance.

The first InSync Sentry CRT-D with OptiVol was implanted in a patient in Lancaster, Pennsylvania in December 2004. There have been over 180 implants to date at our institution. Our retrospective review indicates a sensitivity of 82% for detecting clinically relevant events. Most of these patients have been followed regularly in our congestive heart failure clinic. This has encouraged us to examine how this device might be used in a clinical practice.

Incorporating device monitoring into a standard heart failure medical practice is a challenge and requires re-examination of our current treatment protocols. The first issue to consider is which patients would be appropriate for hemodynamic monitoring.

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The current recommended selection criteria for cardiac resynchronization therapy (CRT) identify a population of patients who are at high risk of developing ADHF (Table 1, Column A).[10] The CARE-HF was an open labeled randomized trial that compared CRT pacing with optimal medical therapy in 813 CRT eligible patients (New York Heart Association class III or IV heart failure, wide QRS duration > 120 ms, and left ventricular ejection fraction [LVEF] ≤ 35%). The primary endpoint of all-cause mortality or

Table 1
Selection Criteria for Hemodynamic Monitoring

A	B
Recommended Selection Criteria for CRT*	**Practice Criteria for Hemodynamic Monitoring**
• EF ≤ 35%	• The patient will be recognized
• QRSd > 120 ms	• The device will be interrogated
• NYHA Class III or IV	• The information will be interpreted
• Worsening heart failure despite optimal medical therapy	• The results will be applied

CRT, cardiac resynchronization therapy; EF, ejection fraction; QRSd, QRS duration; NYHA, New York Heart Association. *Data from American College of Cardiology/American Heart Association Guidelines.[10]

unplanned hospitalization for major cardiovascular events was reached by 39% of the CRT-P patients at a mean of 29 months follow-up versus 55% in the control group.[11] Thus, the event rate for CRT patients remains high despite optimal medical management and cardiac resynchronization. These patients may be considered for intrathoracic impedance monitoring provided that certain practice criteria are satisfied (Table 1, Column B). If the patient with heart failure is followed in a setting in which the device diagnostics are not likely to be utilized then implantation of an impedance monitoring CRT-D does not seem justified. Intrathoracic fluid status monitoring is now available in non-CRT defibrillators. The patient selection criteria will probably remain the same, other than the requirement for a prolonged QRS duration. Large scale clinical trials will be necessary to confirm the utility of intrathoracic impedance monitoring if it is going to gain wide acceptance.

There are a number of modifications a medical heart failure practice might make to assure proper device utilization.

Step 1: Integrating Heart Failure Management and Electrophysiology

To create an environment in which device diagnostics will be properly managed, it is advantageous to integrate the heart failure medical practice and electrophysiology (EP) (Figure 1). The traditional approach to the patient with heart failure has been to separate the "electrical" from the "medical" management. This seems ill suited to the current environment in which resynchronization therapy is an integral part of the management of chronic heart failure. Collaboration between EP and "medical" heart failure managers is critical when determining which device should be implanted in which patient and at what time. The proper evaluation of CRT nonresponders requires both EP (lead location and device related issues) and heart failure (noncardiac and cardiac, nondevice issues) input. Successful A-V and V-V optimization can only be achieved by the coordination of the EP and heart failure services.

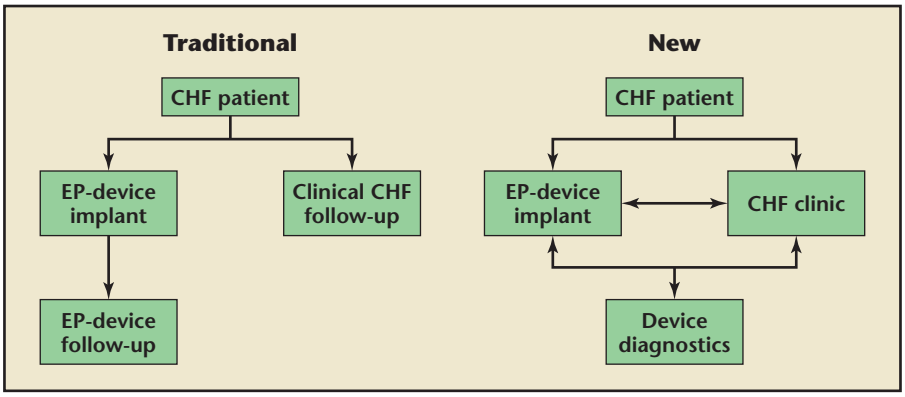


Figure 1. *Approaches to the congestive heart failure (CHF) patient. EP, electrophysiology.*

Electrical abnormalities frequently precipitate heart failure (for example the development of atrial fibrillation) and heart failure follow-up may detect device malfunction or inappropriate programming. Regular meetings, common educational opportunities, and an open line of communication will facilitate resolution of these issues.

Although it may seem obvious that a patient has a CRT device, the exact nature of the device and its diagnostic capabilities must be clear to all care providers.

Step 2: Recognize the Device and Download the Data

To successfully use device diagnostics there must be a system to recognize the device and download the data. Although it may seem obvious that a patient has a CRT device, the exact nature of the device and its diagnostic capabilities must be clear to all care providers. The entire heart failure management team (heart failure physician, nurse practitioner, physician's assistant, and nurse) must be familiar with these devices. Downloading the data must be quick and easy if it is to be incorporated into the clinical flow of the practice.

The InSync Sentry CRT-D with OptiVol can be interrogated 3 ways. Although the Medtronic programmer (model 2090) can generate a Heart Failure Management Report, it is unlikely (and potentially unsafe) that ancillary personnel outside of the EP clinic will feel comfortable using a device that can reprogram the electrical parameters of the defibrillator.

The CardioSight® service (Figure 2) facilitates direct access to the device diagnostics with read-only capabilities and simple one-touch operation. It generates a Heart Failure Management Report that is faxed to the clinician's office within 10 minutes over a standard telephone line. The Heart Failure Management Report includes the OptiVol fluid index trends with the "raw" impedance data and the threshold graph (Figure 3). In addition,

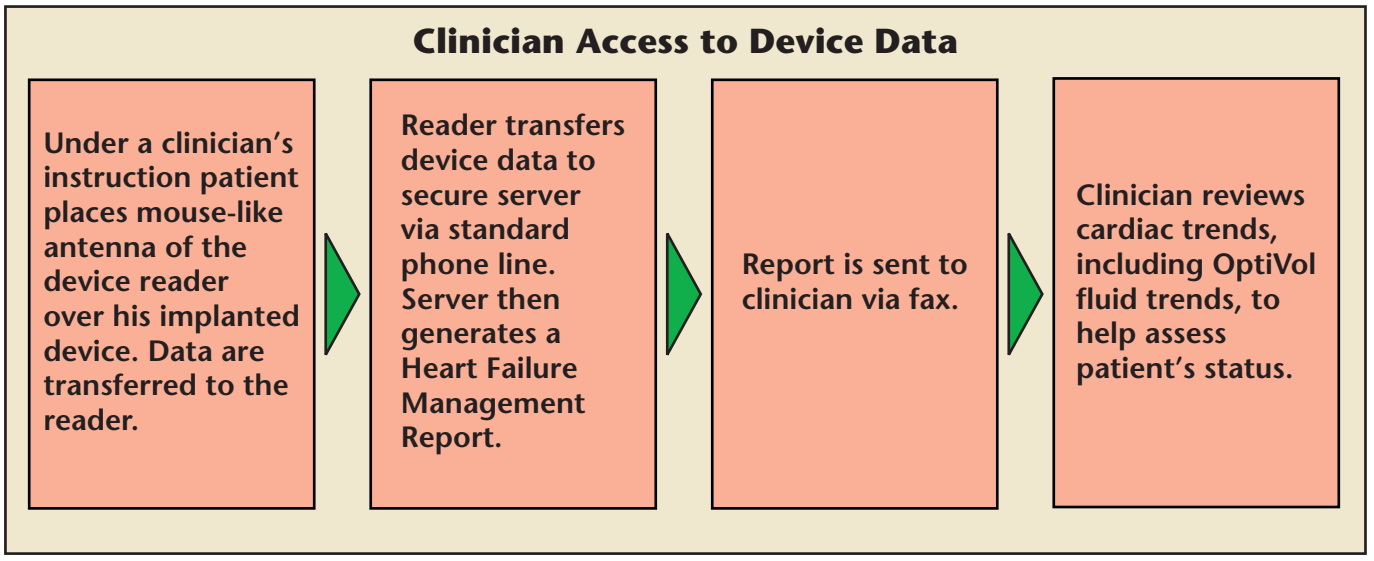
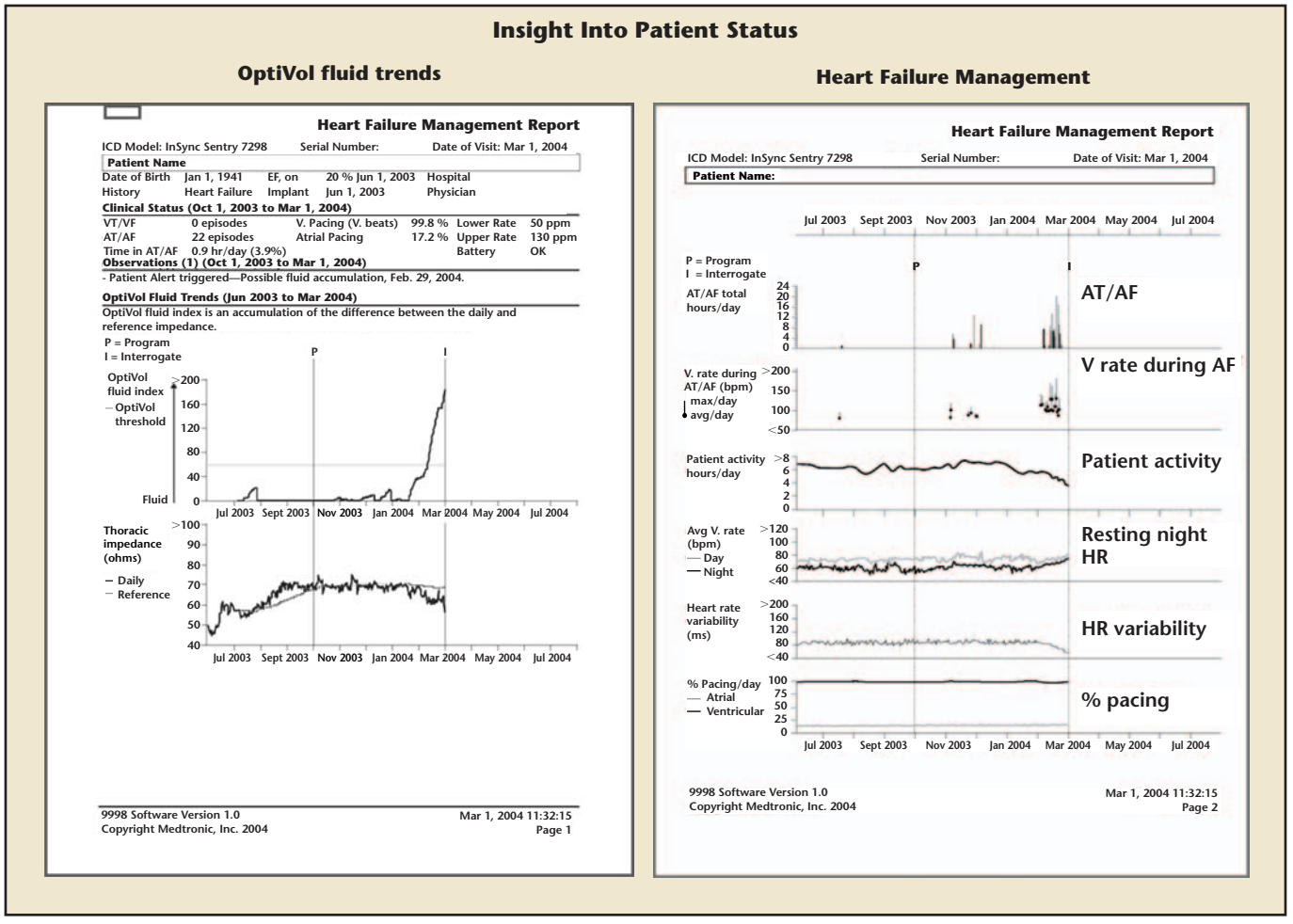


Figure 2. *Utilizing the CardioSight Service in the heart failure clinic. Reprinted with permission from Medtronic, Inc.*

Figure 3. *Heart Failure Management Report with OptiVol Fluid Trends. EF, ejection fraction; VT/VF, ventricular tachycardia/ventricular fibrillation; AT/AF, atrial tachycardia/atrial fibrillation; HR, heart rate. Reprinted with permission from Medtronic, Inc.*



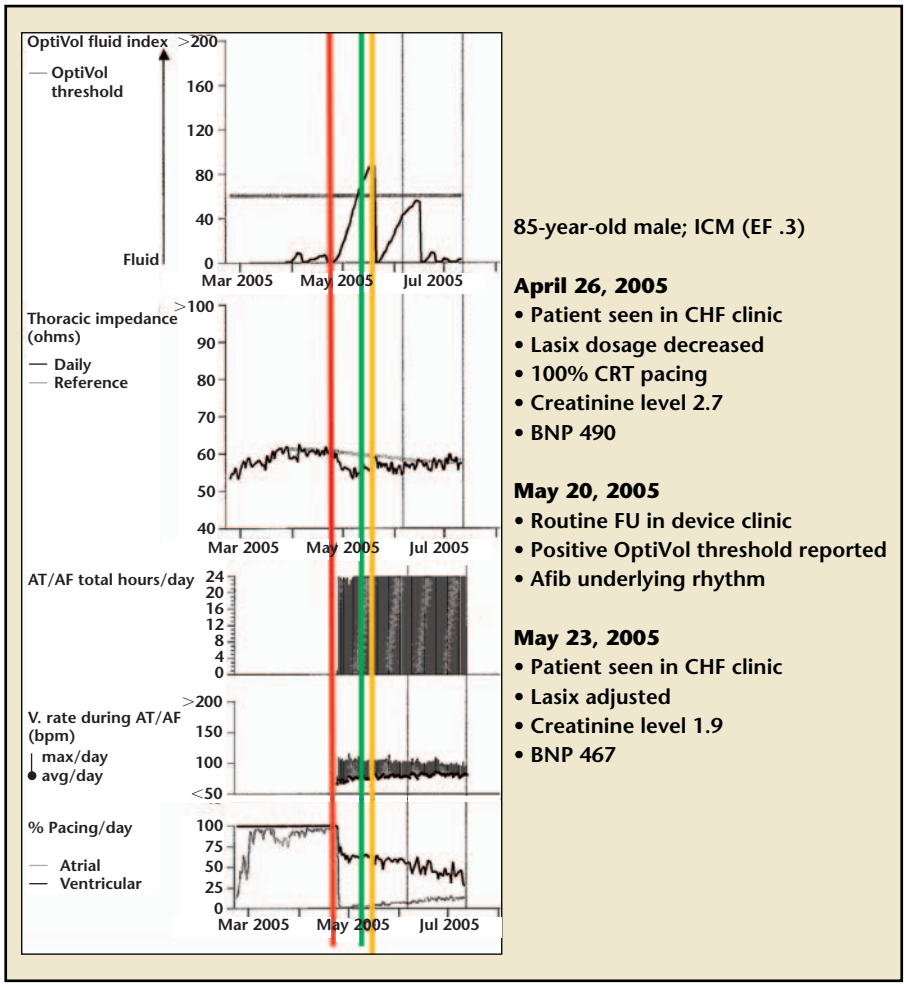


Figure 4. *An episode of fluid retention following the development of atrial fibrillation. ICM, ischemic cardiomyopathy; EF, ejection fraction; CHF, congestive heart failure; CRT, cardiac resynchronization therapy; BNP, B-type natriuretic peptide; FU, follow-up; AT/AF, atrial tachycardia/atrial fibrillation. Reprinted with permission from Medtronic, Inc.*

other useful diagnostic information is included in the Heart Failure Management Report including atrial arrhythmias, ventricular response rate during atrial arrhythmias, patient activity index, average night heart rate, heart rate variability, and percent atrial and ventricular pacing. These trends are aligned across time, which facilitates the recognition of their interrelationships. Heart rate variability itself has important prognostic implications.[12] The loss of cardiac resynchronization (manifest as a decrease in percent ventricular pacing) due to an increase in the heart rate following the development of atrial fibrillation frequently precipitates an episode of fluid retention (Figure 4). Thus each parameter of the Heart Failure Management Report should be reviewed in the ADHF patient as they may offer clues as to why a patient has decompensated.

The Heart Failure Management Report can also be generated from the Medtronic CareLink® Network (Figure 5). The Cardiac Compass® Report generated from a CareLink download includes the Heart Failure Management Report, ventricular arrhythmias, and device therapy. OptiVol fluid trend data have been available since

Figure 5. *Utilizing the CareLink Network in the home. Reprinted with permission from Medtronic, Inc.*

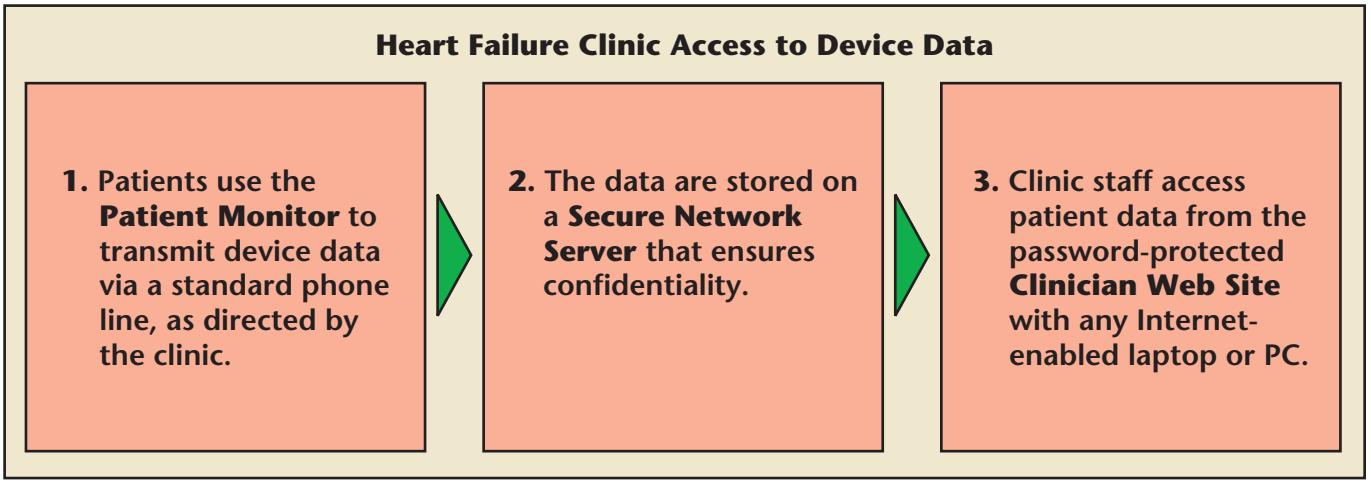


Table 2
CareLink or CardioSight

CareLink	CardioSight
• Potentially "billable"*	• Not yet "billable"
• Download over phone from home	• Interrogate in office
• Weekly impedance trends (ability to "zoom")	• 90-day summary with daily impedance averages
• Heart Failure Management Report and Cardiac Compass	• Heart Failure Management Report
• No OptiVol threshold line	

*A fee may be charged if download is requested for specific indications (ie, symptoms).

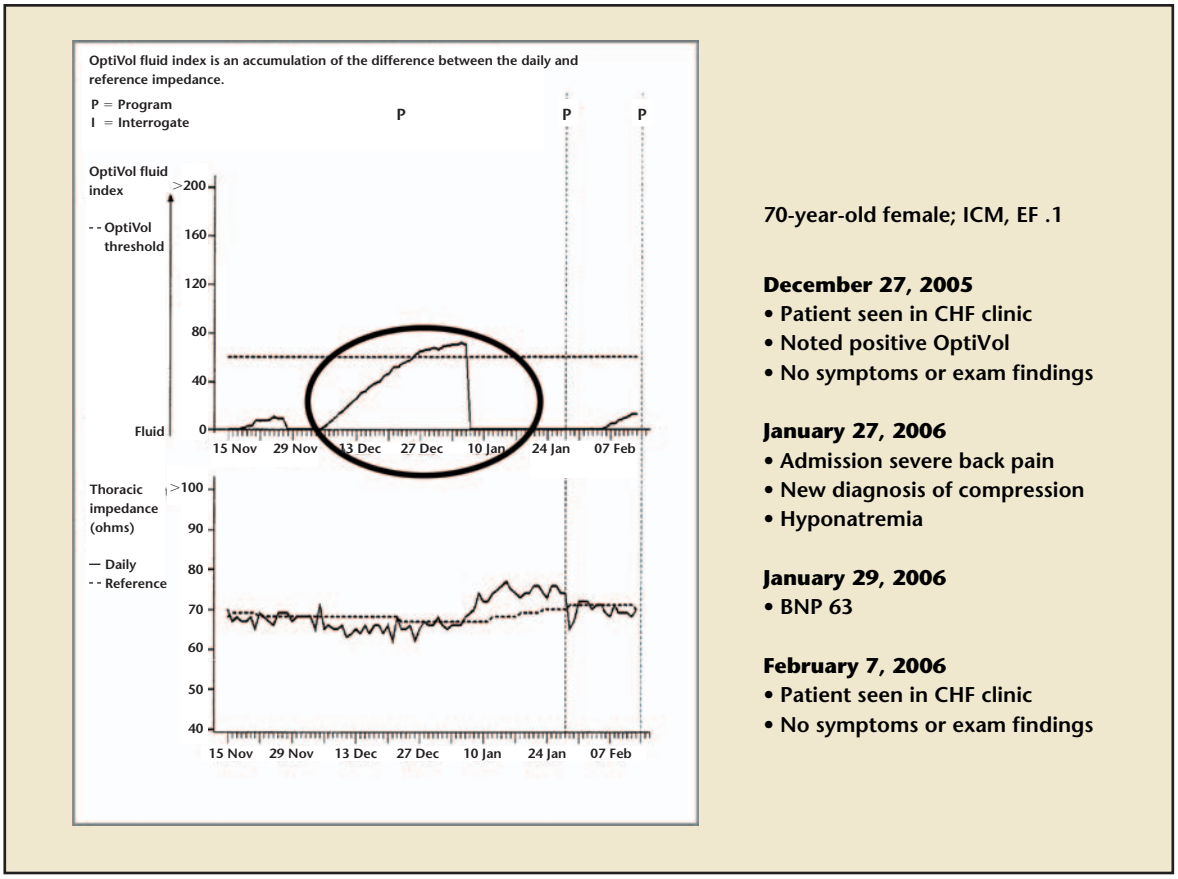
February 2006 on the CareLink Network. The standard format is presented as a weekly summary but the software has the ability to "zoom" to daily measurements over a 90-day period, similar to the CardioSight download. CardioSight and CareLink are compared in Table 2.

A coordinated and integrated heart failure and EP service facilitates the utilization of the device data that might be generated in the EP clinic (CareLink) but that require clinical heart failure management (intrathoracic impedance data). The "Alert Option" (not yet available in the United States) will notify patients with an audible tone when the OptiVol threshold is crossed. Patients might then be instructed to download their device via the CareLink Network or to arrange for an office evaluation. A systematic approach to this device will be essential when this option becomes available.

Step 3: Analyze the Data

Intrathoracic impedance should be considered a "vital sign" and downloaded at each follow-up appointment. The patients implanted with

Figure 6. *False positive. Impedance fall and index crossing unrelated to fluid retention. ICM, ischemic cardiomyopathy; EF, ejection fraction; CHF, congestive heart failure; BNP, B-type natriuretic peptide.*



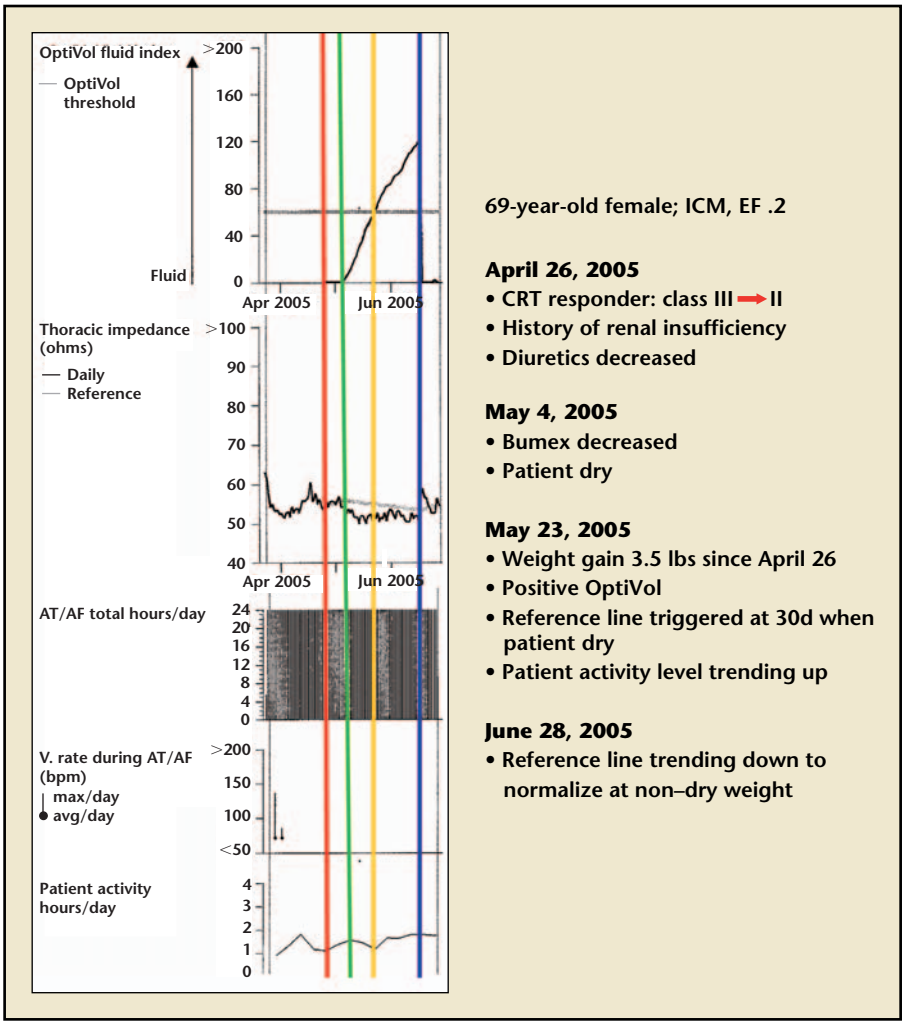


Figure 7. *Fall in impedance and fluid index crossing an appropriate reduction in diuretic dose. ICM, ischemic cardiomyopathy; EF, ejection fraction; CRT, cardiac resynchronization therapy; AT/AF, atrial tachycardia/atrial fibrillation.*

these devices are often marginally compensated and the signs and symptoms of fluid retention are often imprecise. There is currently no fee for an individual CardioSight download; it can be safely performed by ancillary personnel and the impedance data are available within minutes. There is no disruption in the flow of patients.

The sensitivity and specificity of the impedance data are still uncertain. Our preliminary analysis has yielded a significant number of false-positive events, which we have defined as fluid index threshold crossings that occur without the development of signs or symptoms of heart failure. Whereas some of these crossings may reflect mild or subclinical congestion, others are not readily explained. Therefore, a clinical evaluation of the patient should be performed before therapeutic adjustments based upon impedance data. False-positive results may occur for clinically obvious reasons (hematoma, pneumonia, or pocket revisions) or for unapparent causes. A reflex response to a threshold crossing is not appropriate (Figure 6). For example, a patient with a recent CRT implant who has responded to resynchronization therapy might appropriately require less diuretic in the ensuing months. Decreasing the diuretic dose may precipitate a threshold crossing but yet reflect the re-establishment of more appropriate intravascular volume status (Figure 7).

It is a common misconception that the size of the threshold crossing is proportional to the degree of fluid retention and that the "raw" impedance data can be ignored. On the contrary, a decrease in the "raw" impedance indicates fluid retention and the degree of change is proportional to the severity of congestion. The height of the threshold crossing indicates only that an event has occurred. Once a fluid index crossing has occurred, it takes time for the baseline to re-establish even if appropriate treatment is initiated. During this interval, examination of the "raw" impedance data may help guide additional therapy. If the "raw" impedance data demonstrate increasing values, then the patient may be improving despite a persistent positive fluid index. There is currently no re-set option for the established baseline.

Step 4: Utilize the Data

The fluid index baseline is not established for 34 days following device implantation to allow for pocket healing. Indeed pocket revisions will characteristically cause a dramatic fall in impedance measurements and are a known cause of a "false positive" fluid index crossing.

Impedance data should be interpreted in the context of the clinical findings. Whereas the cause of a "false-positive" threshold crossing may be obvious there are also instances when the threshold is exceeded for no apparent reason. Systems must be designed to react appropriately to unsolicited data

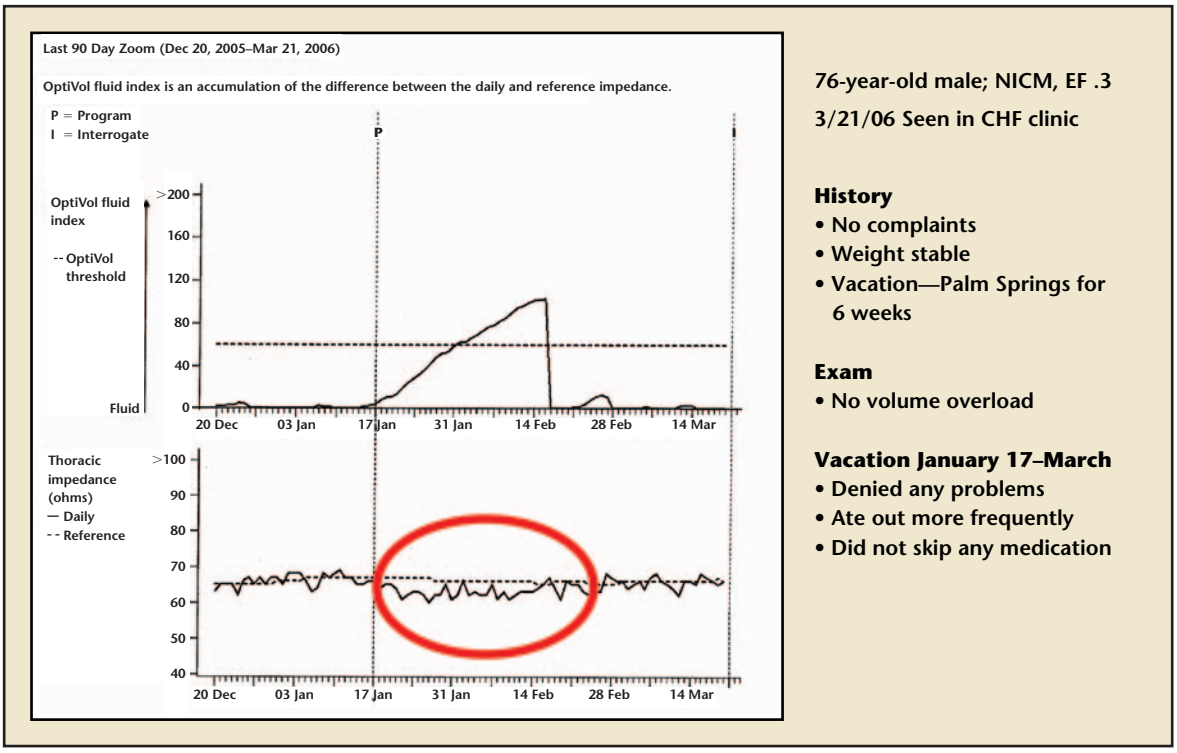


Figure 8. *Fall in impedance and fluid index crossing due to dietary noncompliance. NICM, nonischemic cardiomyopathy; EF, ejection fraction; CHF, congestive heart failure.*

whether generated by the device itself (the "Alert Option") or part of the routine follow-up of an ancillary function (CareLink). If the impedance data are not used, then a potentially valuable disease management tool has been wasted. Patient lapses with drug or diet therapy are a frequent cause of decompensation.[13] Impedance data may be useful in facilitating patient compliance by providing the heart failure management team with specific examples of fluid retention related to drug withdrawal or dietary indiscretion (Figure 8).

In summary, intrathoracic impedance measured by the InSync Sentry CRT-D with OptiVol fluid monitoring is highly sensitive to fluid changes. Intrathoracic impedance is helpful as a tool for managing chronic heart failure when used in conjunction with other diagnostic information. Impedance data should be available to the physician and interpreted in the context of clinical findings. Systems must be designed to coordinate, distribute, and interpret information generated by device diagnostics. ■

Main Points

- The signs and symptoms of congestive heart failure do not necessarily reflect hemodynamic status, and daily weights are helpful but often inconsistent.
- If the intrathoracic fluid content could be routinely monitored, then it may be possible to detect incipient fluid retention before the onset of fulminant symptoms and possibly abort hospitalization.
- Intrathoracic impedance measured by the InSync Sentry CRT-D with OptiVol fluid monitoring is highly sensitive to fluid changes.

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