The Role of Information Technology in Disease Management: A Case for Heart Failure

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Quotes From Yesterday

“We need to focus on the people who have the disease and not on the disease people have.”

“How many patient lives did you touch today?”

“We have opportunities to have a more complete picture of the patient.”
Population Management

Level 1 – Chronic Care Management
With the right support patients can take active care in their treatment to prevent complications and disease progression.

Level 2 – High Risk Patient Care Mgt
Disease/care management using evidence-based care protocols for specific disease.

CHF Patients

Level 3 – Highly Complex Pt Case Mgt
Patient co-morbidities require special case management, usually by a nurse.
It is important to have the right information and knowledge in order to be able to identify those who are at most risk.

Information is power when it is accessible and actionable by those who need it – when they need it.
What programs will help deliver good chronic disease management?

- Better integration of health and social care
  - Multi-disciplinary team approach *
- Quality outcomes framework
  - JCAHO Core measures *
- Development in IT
  - Remote monitoring *
- Developing new roles and new ways of working
  - Integration of HF & EP Clinics *
- Role of Allied Health Professionals
  - NPs, Pas, RNs, VNA *
- Practitioners with special interests & expertise
  - HF cardiologists, nurses *

* CHF application
Essential Components of good disease management

• Use of information systems to access key data on individuals and population
  – HF Registries
  – Integrated information systems (Paceart, CareLink, CardioSight, EMR)
• Stratifying patients at risk
  – ACC/AHA Stages of HF
  – Risk stratification protocols
    • ADHERE Registry, Seattle Heart Model
• Involving patients in their own care
• Coordinating care (case managers, special clinics)
Essential Components of good disease management…cont’d

• Integrating specialist and generalist care
• Integrating care across organizational boundaries
• Reduce healthcare utilization
  – Minimize unnecessary visits and admissions
  – Provide care in the least intensive setting
Good chronic disease management can make a REAL DIFFERENCE

- Help prevent disease progression / deterioration
- Help prevent crises
- Help patient attain a good quality of life
Burden of Heart Failure Disease
Heart Failure Defined

“Heart failure is a complex clinical syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood.”

Hunt SA et al. Circulation. 2001;104:2996
Epidemiology of Heart Failure in the United States

- 4.79 million patients\(^1\); estimated 10 million in 2037\(^2\)
- Incidence: about 550,000 new cases each year\(^1\)
- Prevalence is 2% in persons aged 40 to 59 years, progressively increasing to 10% for those aged 70 years and older\(^3\)
- Sudden cardiac death is 6 to 9 times higher in the heart failure population\(^1\)

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Heart Failure Hospitalizations

The Number of Heart Failure Hospitalizations Is Increasing in Both Men and Women

CDC/NCHS: hospital discharges include patients both living and dead.

Outcomes in Patients Hospitalized with Heart Failure

Hospital Readmissions
N = 38,702

- 20% within 30 Days
- 50% within 6 Months

Mortality
N = 38,702

- 12% within 30 Days
- 33% within 12 Months
- 50% within 5 Years

Median length of hospital stay: 6 days

We have better interventions but have a long way to go

References:
Causes of Hospital Readmission for HF

- Diet Nonadherence: 24%
- Drug Nonadherence: 24%
- Inappropriate Drug: 16%
- Failure to Seek Care: 19%
- Other: 17%

Estimated Direct and Indirect Costs of Heart Failure in the US

- Low productivity/mortality* $2.6
- Home healthcare $2.2
- Drugs/other medical durables $2.9
- Physicians/other professionals $1.9
- Nursing home $3.6
- Hospitalization $14.7

Total cost: $27.9 Billion

* Lost future earnings of persons who will die in 2005, discounted by 3%.

### Top Five Medicare DRGs: On Average, Hospitals Lose Money

<table>
<thead>
<tr>
<th>DRG Description</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
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<tbody>
<tr>
<td>Heart failure and shock</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>–</td>
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<tr>
<td>Simple pneumonia and pleurisy</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>–</td>
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<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>–</td>
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<tr>
<td>Major joint and limb reattach (low extremity)</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>Intracranial hemorrhage and stroke with infarction</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

+ Reimbursement is greater than cost
– Reimbursement is less than cost
Hospital Visits for Congestive Heart Failure

Emergency Department Presentations

- Initial Episodes*: 21%
- Repeat Visits: 79%

Approximately 80% of ED visits for HF result in hospitalizations

*Requires full evaluation for reversible causes of heart failure.

JCAHO Core Measures

Hospital Core Performance Measures/ORYX

- Complete discharge instructions in the medical record
- Appropriate use of ACE inhibitors at discharge
- LVEF evaluated before or during admission or planned after discharge
- Smoking cessation advice/counseling

Disease Progression of HF: ACC/AHA HF Stages

- **High Risk:** Hypertension, coronary artery disease, diabetes, family history of cardiomyopathy
- **Asymptomatic LVD:** Previous MI, LV systolic dysfunction, asymptomatic valvular disease
- **Symptomatic HF:** Known structural heart disease, shortness of breath and fatigue, reduced exercise tolerance
- **Refractory End-Stage HF:** Marked symptoms at rest despite maximal medical therapy
**ACC / AHA Heart Failure Guidelines**

### At Risk for Heart Failure

**Stage A**
- At high risk for HF but without structural heart disease or symptoms of HF.

**Emphasis:** Patients with:
- Hypertension
- Atherosclerotic disease
- Diabetes
- Metabolic syndrome
  - Patients using cardiotonics
  - With HFx CM

**Therapy Goals**
- Treat hypertension
- Encourage smoking cessation
- Treat lipid disorders
- Encourage regular exercise
- Discourage alcohol intake, illicit drug use
- Control metabolic syndrome

**Drugs**
- ACEI or ARB in appropriate patients (see text)
- For vascular disease or diabetes

### Heart Failure

**Stage B**
- Structural heart disease but without symptoms of HF.

**Emphasis:** Patients with:
- Previous MI
- LV remodeling including LVH and low EF
- Asymptomatic valvular disease

**Therapy Goals**
- All measures under stages A and B

**Drugs**
- ACEI or ARB in appropriate patients (see text)
- Beta-blockers in appropriate patients (see text)

**Devices in Selected Patients**
- Implantable defibrillators

**Stage C**
- Structural heart disease with prior or current symptoms of HF.

**Emphasis:** Patients with:
- Known structural heart disease
- And shortness of breath and fatigue, reduced exercise tolerance

**Therapy Goals**
- All measures under stages A, B, C

**Drugs in Selected Patients**
- Aldosterone antagonist
- ARBs
- Digitalis
- Hydralazine/nitrates

**Devices in Selected Patients**
- Biventricular pacing
- Implantable defibrillators

**Stage D**
- Refractory HF requiring specialized interventions.

**Emphasis:** Patients who have marked symptoms at rest despite maximal medical therapy (e.g., those who are recurrently hospitalized or cannot be safely discharged from the hospital without specialized interventions)

**Therapy Goals**
- Appropriate measures under stages A, B, C
- Decision re: appropriate level of care

**Options**
- Compassionate end-of-life care/hospice
- Extraordinary measures
- Heart transplant
- Chronic inotropes
- Permanent mechanical support
- Experimental surgery or drugs
The Role of Registries in Heart Failure
Acute Decompensated Heart Failure National Registry (ADHERE®)
ADHERE® Registry

• ADHERE Core Module
  – Largest US HF registry
  – Multicenter
  – Observational
  – Open label
  – Web based

• Registry of US patients treated in hospitals for ADHF

Goals of ADHERE® Registry

- Describe demographics and clinical characteristics of patients hospitalized with ADHF
- Characterize current management of hospitalized patients with ADHF
- Define treatment strategies associated with best clinical outcomes and most efficient use of resources
- Assist in evaluating and improving quality of care

Impact of ED vs In-patient Initiation of IV Vasoactive Therapy on LOS

History of HF and LVEF Documented and $\leq 0.40^*$

Outpatient HF Medication

- **ACE Inhibitor**: 50.8%
- **ARB**: 12.8%
- **β-Blocker**: 57.4%
- **Diuretic**: 80.8%
- **Digoxin**: 41%

*Excludes patients with documented contraindications

2300/7883 patients hospitalized with HF; prior known dx of systolic dysfunction HF; outpatient medical regimen

### ADHERE® Quality of Care
Conformity to JCAHO HF Performance Indicators

<table>
<thead>
<tr>
<th></th>
<th>All Patients (N = 105,381)</th>
<th>Patients at Academic Hospitals (n = 34,346)</th>
<th>Patients at Non-Academic Hospitals (n = 71,035)</th>
<th>P value</th>
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<tbody>
<tr>
<td>HF-1 (%)</td>
<td>32.3</td>
<td>21.9</td>
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<td>Discharge Instruction</td>
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<tr>
<td>HF-2 (%)</td>
<td>82.7</td>
<td>84.0</td>
<td>82.0</td>
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<tr>
<td>LV Function</td>
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<tr>
<td>HF-3 (%)</td>
<td>66.1</td>
<td>70.3</td>
<td>63.7</td>
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<tr>
<td>Discharge ACE-I Rx</td>
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<tr>
<td>JCAHO HF-4 (%)</td>
<td>40.0</td>
<td>33.1</td>
<td>44.0</td>
<td>&lt;0.0001</td>
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<tr>
<td>Smoking Cessation Counseling</td>
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</tbody>
</table>

All Enrolled Discharges (N = 105,388) October 2001–January 2004
Clinical Status at Time of Discharge

All Enrolled Discharges* (N = 105,388) October 2001–January 2004

- Asymptomatic: 52%
- Improved (but still symptomatic): 37%
- No Mention: 11%

49% of patients discharged from the hospital are still symptomatic or have no mention of improvement of symptoms.

*Who were discharged home (including home with additional and/or outpatient care)
OPTIMIZE HF REGISTRY

• Web-based registry
  – Data on medications on admission, hospitalization progress, discharge
  – JCAHO Core Measures
• Process of Care Improvement
Objectives of OPTIMIZE HF

• Improve medical care and education of hospitalized HF patients
• Increase and speed up adoption of HF guidelines by initiating therapies prior to discharge
• Increase understanding to barriers to utilization of ACE inhibitors and Beta-blockers in HF patients
OPTIMIZE-HF: Abridged Version of In-hospital HF Management Algorithm

Patient presents with symptoms of HF (ACC/AHA Stage C or D)
History & Physical (special considerations: HTN, DM, CAD, anemia, infection)

Helpful diagnostic findings

Assess ECG: Evaluate for ischemia, arrhythmias

Determine left ventricular functional status

Systolic dysfunction (EF < .40)
Valvular: evaluate for surgery
CAD (angina/ischemia/previous Hx of CAD)
Evaluate for revascularization

Determine etiology

ETOH
Primary cardiomyopathy
Restrictive cardiomyopathy
Consider infiltrative & storage diseases, HTN, hypertrophic cardiomyopathy

Heart failure with preserved systolic function (EF ≥ .40)

Pharmacologic management

Discharge instructions
- Activity level
- Diet
- Complete list of discharge medications
- Follow-up appointment
- Weight monitoring
- What to do if symptoms worsen
- Smoking cessation advice/counseling/aid for all smokers
OPTIMIZE-HF: A Cycle of Quality Improvement

1. **Find and Support a Champion**
2. **Assess HF Treatment Rates**
   - Measure current treatment rates and process-of-care indicators
3. **Implement Refined Protocol**
   - Hospital team coordinates implementation of refined protocols
4. **Refine Protocol**
   - Hospital team identifies areas for improvement
5. **Assessment**
   - Hospital team reviews summary reports and current protocols
The Challenge….
Data Access
Data interpretation
Making Clinical Decision
Documentation
Information should be part of the Solution

iSolutions offer simple, elegant means for accessing and organizing cardiac device data for optimal and efficient patient care.
Rising complexity

Today’s EP clinic is more complex than ever before:

- Escalating patient volumes
- Calls for Electronic Medical Records (EMRs) and other technological advances
- Increasing device complexity
- Staff constraints (e.g., nursing shortages)
- Competitive pressures
- Unscheduled and missed appointments
- Patients (and families) who demand convenience and continuity of care

MEDTRONIC CARELINK® NETWORK
Remote Monitoring. Closer Connections.
Complex clinic environments

- Device patients at home or away, for routine follow-up or symptomatic episodes
- Programming, thresholds, etc.
- On-going patient management
  - Collaboration with other healthcare providers
  - Interaction with patient and caregivers
Complex clinic environments

Medtronic iSolutions

- Device patients at home or away for routine follow-up or symptomatic episodes
- Remote monitoring and follow-up
- Programming, thresholds, etc.
- In-clinic arrhythmia data management
- Electronic medical records
- Co-management

Home

Implant

Clinic
The Need

Multiple Access Options

Gap: Access to valuable HF data

Electrophysiologist
Implants & follows device, arrhythmias

Programmer CareLink

HF Physician/Cardiologist
Manages patient’s HF disease

No (or limited) access
Medtronic CareLink® Network
Taking remote monitoring to the next level
Customer Presentation
What is the Medtronic CareLink® Network?

The nation’s leading remote monitoring service, serving over 1000 clinics and 110,000 patients around the country

A work flow efficiency tool that has been shown to reduce ICD follow-up time by as much as 65%.

Remote follow-up system that provides comprehensive device data comparable to an in-office interrogation

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1 Falk D., Straub K. Practice efficiency improvements resulting from the use of Medtronic CareLink® Network remote monitoring service, Fairfield, Iowa: Human Factors International, July 2004

MEDTRONIC CARELINK® NETWORK
Remote Monitoring. Closer Connections.
The Medtronic CareLink Monitor

Portable monitor used by patients to send data for:

- Routine follow-up
- Symptomatic episodes
- Post-shock events

Extremely user-friendly

- One-button operation
- Sound and light cues are intuitive
- A standard telephone line is the only requirement
- Connect from home or while traveling (within the United States)
- Now offering “hands-free” wireless capability on new ICD and CRT-D devices
Introduction to Medtronic CareLink Network

Pacemaker follow-up on the Medtronic CareLink Network

Wireless devices on the Medtronic CareLink Network

Reimbursement

Pricing

Summary

Home

Medtronic CareLink Network

1. While at home, work, or traveling in the United States, the patient holds the mouse-like antenna of the Medtronic CareLink Monitor over the implanted cardiac device.

2. Data are transferred from the patient’s implanted device to the monitor. Data are sent from the Medtronic CareLink Monitor to a secure server via a standard phone line.

3. The clinician reviews the patient’s device data on the Medtronic CareLink Clinician Website.
“Before I had the monitor, I would have been quite concerned about traveling far from home and my clinic. Having the monitor with me and knowing I could be ‘connected’ with my clinic within minutes made me feel much better. **We’ve been to Disney, and Palm Springs, and the Medtronic CareLink Monitor always comes along.**”

**Dawn Yasik, age 34**  
InSync Maximo® patient on the Medtronic CareLink Network since 2003
“The Medtronic CareLink® Network reassures our patients that we are doing everything possible to keep in touch with them, even when they’re at home.”

Regina Owen, RN
The Stern Cardiovascular Center,
Memphis, Tennessee
CareLink for Pacemakers

CARELINK™ FOR PACEMAKERS.
It’s the office visit without the office visit.

✓ Full Parameter Summary
✓ Battery Voltage and Longevity
✓ Lead Impedance and Trends
✓ Automatic Capture Thresholds
✓ Episodes
✓ Percent Pacing
✓ Histograms
✓ Real-Time and Magnet EGMs
✓ Stored EGMs
✓ Arrhythmia Summary with Mode Switch Duration
The advent of wireless...

Routine device follow-up occurs while the patient sleeps, and continual automatic monitoring assures confidence for clinicians and patients.

- "Hands-free transmissions" for the patient
- Alleviates compliance issues
- Streamlines workflow by eliminating scheduling headaches
Medtronic CareLink® Wireless Programmer with High Speed Connectivity

**Wireless communication enabled programmer**
- Uses an RF band designated for medical device communication
- High-speed access to up-to-date device software
- All the functionality of the previous 2090 programmer

**Seamless connection to Paceart Systems**
- Seamlessly and automatically transfers data into the Paceart data management system
- May eliminate errors related to manual data entry

The Medtronic CareLink Programmer is a wireless communication-enabled programmer that provides technological solutions for customizing patient care and data management.
Advantages of wireless

**Better able to accommodate changing needs** and schedules of both patients and of clinicians.

**Easier for clinician** to set up a scheduling routine that fits into current practice methods. Scheduling becomes automated, saving time for the clinic.

**Automatic prescheduled checks** may improve patient care and convenience while reducing compliance issues.

**Medtronic CareAlert monitoring** may provide early detection and the opportunity to intervene sooner with proactive care.
Automatic Follow-Up (wireless)

1. Using the secure Medtronic CareLink Clinician Website, clinic staff can preschedule up to six automatic device checks for each patient—without having to make appointments or coordinate calendars with patients.

2. The device automatically “wakes up” at the scheduled time and communicates with the Medtronic CareLink Monitor, which is plugged into a standard phone line and an electrical outlet. Data are transmitted wirelessly from the device to the monitor as the patient sleeps.

3. Data are sent automatically from the Medtronic CareLink Monitor via the phone line.

4. The clinician reviews the patient’s device data on the secure website.
The implanted cardiac device detects a problem such as AT/AF or a device integrity issue. If the patient’s device is programmed to notify the clinician of Medtronic CareAlert status, the heart device automatically establishes wireless communication with the Medtronic CareLink Monitor, which is plugged into a standard phone line.

Device data are sent automatically from the monitor to a secure server via the phone line.

The clinician receives the alert via pager or voice message and checks the Medtronic CareLink Clinician Website for detailed information.

The clinician reviews the Medtronic CareAlert information and calls the patient to provide further instructions.
Medtronic CareAlert Monitoring (wireless)

Available Medtronic CareAlert Monitoring:

Programmable Alerts:
1. Daily AT AF Burden > Threshold
2. Fast Ventricular Rate during AT/AF
3. Number of Shocks delivered in an episode
4. All Therapies in a Zone Exhausted
5. VF Detection Therapy Off
6. Low Battery Voltage Recommend Replacement
7. Excessive Charge Time (End of Service)
8. Atrial Pacing (Impedance out of range)
9. RV Pacing (Impedance out of range)
10. LV Pacing (Impedance out of range)
11. Ventricular Defib (Impedance out of range)
12. SVC (HVX) Defib (Impedance out of range)

Non-Programmable Alerts:
1. Electrical Reset
2. Pacing Mode DOO VOO AOO
3. Active Can Off without SVC
4. Charge Circuit Timeout

888-70-CAREALERT (toll-free number)
Message ID number
8887022732-1234567

Hand-held pager
Proven efficiency gains

A study conducted by Human Factors International\(^1\) showed that device checks with the Medtronic CareLink\(^{\circledR}\) Network can be done in under 8 minutes—**one-third the time** of a typical in-office device check.

Committed to privacy and security

Medtronic has taken extensive measures to ensure that Medtronic CareLink® Network conforms to HIPAA regulations pertaining to both privacy and security of electronic Personal Health Information (ePHI)
Tachycardia counters

Clinical Status

Treated
- VF: 0
- FVT: 1
- VT: 0
- AT/AF: 0

Monitored
- VT (Off)
- VT-NS (>4 beats, >150 bpm): 5
- SVT: VT/VF Rx Withheld: 0
- AT/AF: 0

Time in AT/AF: <0.1 hr/day (<0.1%)

Functional
- Patient Activity: Last Week: 0.7 hr/day

Therapy Summary
- VT/VF: 1 of 1
- AT/AF: 0

Observations:
- Night heart rate over 85 bpm for 7 days.
- Patient Activity less than 2 hr/day for 14 weeks.
- Higher battery drain; Pre-arrhythmia EGM is set to On Continuous.
### Therapy Summary

<table>
<thead>
<tr>
<th>Parameter</th>
<th>VT/VF</th>
<th>AT/AF</th>
<th>Pacing</th>
<th>(% of Time Since 19-Aug-2005)</th>
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</thead>
<tbody>
<tr>
<td>Pace-Terminated Episodes</td>
<td>1 of 1</td>
<td>0</td>
<td>AS-VP</td>
<td>28.0%</td>
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<tr>
<td>Shock-Terminated Episodes</td>
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<td>AS-VP</td>
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<tr>
<td>Total Shocks</td>
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<td>AF-VP</td>
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<td>Aborted Charges</td>
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<td>0</td>
<td>AF-VP</td>
<td>0.4%</td>
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<tr>
<td>battery status</td>
<td></td>
<td></td>
<td>MVP</td>
<td>0%</td>
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</tbody>
</table>

### Observations (3)
- Night heart rate over 85 bpm for 7 days.
- Patient Activity less than 2 hr/day for 14 weeks.
- Higher battery drain: Pre-arrhythmia EGM is set to On Continuous.

### Device Status (Implanted: 04-Feb-2005)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Measured on:</th>
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<tbody>
<tr>
<td>Battery Voltage (ERI=2.61 V)</td>
<td>3.14 V</td>
<td>10-Nov-2005</td>
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<tr>
<td>Last Full Energy Charge</td>
<td>7.3 sec</td>
<td>19-Aug-2005</td>
</tr>
<tr>
<td>Pacing Impedance</td>
<td>432 ohms</td>
<td></td>
</tr>
<tr>
<td>Defibrillation Impedance</td>
<td>472 ohms</td>
<td></td>
</tr>
<tr>
<td>Programmed Amplitude/Pulse Width</td>
<td>2 V / 0.6 ms</td>
<td></td>
</tr>
<tr>
<td>Measured P/R Wave</td>
<td>4.8 mV</td>
<td>10-Nov-2005</td>
</tr>
<tr>
<td>Programmed Sensitivity</td>
<td>0.45 mV</td>
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</table>

### Parameter Summary

- **Mode**: AAI=>DDDR
- **Mode Switch**: 171 bpm
- **Lower Rate**: 70 bpm Paced AV 180 ms
- **Upper Track**: 120 bpm Sensed AV 150 ms
- **Upper Sensor**: 120 bpm

#### Detection
- **AT/AF**: On (1 zone)
- **VF**: On
- **FVT**: via VF
- **VT**: On

#### Rates
- **AT/AF**: >171 bpm
- **VF**: >188 bpm
- **FVT**: 188-250 bpm
- **VT**: 150-188 bpm

#### Therapies
- **AT/AF**: Burst*, Ramp, CV Off
- **VF**: 20J, 30J x 5
- **FVT**: Burst (1), 20J, 30J x 4
- **VT**: Burst (6), 20J, 30J x 4

*Enhancements: On: AF/AFl, Sinus Tach*
For VT/VF what should be viewed/printed?

<table>
<thead>
<tr>
<th>Patient</th>
<th>Device</th>
<th>Last Send</th>
<th>Print?</th>
<th>Event Summary</th>
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<tbody>
<tr>
<td>Smith, Clyde</td>
<td>EnTrust D153ATG</td>
<td>11/10/2005</td>
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<td>1 VT/VF, 1 second in AT/AF Since Last Session</td>
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<tr>
<td>Smith, John</td>
<td>InSync Sentry</td>
<td>12/23/2004</td>
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<td>1 Shock, 1 VT/VF, 7 SVT/NST</td>
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<td>Wijesokera, Marypat</td>
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<td>Nguyen, Aimee</td>
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<td>10/29/2005</td>
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Heart Failure Management Report

ICD Model: InSync Sentry 7297  Serial Number:  Date of Visit:

Date of Birth:  EF, on:  Hospital History:  Implant:  Physical:

Clinical Status (Aug 30, 2005 to Sep 09, 2005)

VT/VF: 0 episodes  V. Pacing (V. beats): 99.5 %
AT/AF: 0 episodes  Atrial Pacing: 49.5 %
Time in AT/AF: 0.0 hrs/day (0.0 %)

Observations (1) (Aug 30, 2005 to Sep 09, 2005)

- Patient activity averaged < 2 hrs/day last week.

OptiVol Fluid Trends (Feb 2005 to Sep 2005)

OptiVol fluid index is an accumulation of the difference between the daily and reference thoracic impedance values.

P = Program
I = Interrogate

Thoracic impedance (ohms)
- Daily
- Reference

Mar 2005  May 2005  Jul 2005  Sep 2005
Heart Failure Management Report

ICD Model: InSync Sentry 7297
Serial Number: 
Date of Visit: Jul 22, 2005

Date of Birth: 
History: Heart Failure
EF, on 20 % Dec 1.
Implant Mar 2, 2005

Clinical Status (Jun 21, 2005 to Jul 22, 2005)
- VT/VF 0 episodes V. Pacing (V. beats)
- AT/AF 0 episodes Atrial Pacing
- Time in AT/AF 0.0 hr/day (0.0 %)

Observations (3) (Jun 21, 2005 to Jul 22, 2005)
- Possible fluid accumulation, Jul 21, 2005.
- V. Pacing (V. beats) less than 90%.
- Patient activity averaged < 2 hr/day last week.

OptiVol Fluid Trends (Mar 2005 to Jul 2005)
OptiVol fluid index is an accumulation of the difference between the

P = Program
I = Interrogate

OptiVol fluid index

V. rate during AT/AF
(max/day +avg/day)

Patient activity
hours/day

Avg V. rate (bpm)
Day
Night

Heart rate variability (ms)

% Pacing/day
Atrial
Ventricular

Thoracic impedance
(ohms)

Daily
Reference

- Required fluid index threshold
- >200

- 0


Establish standard frequency for follow-up

- Monthly for routine Optivol HF monitoring?
- Increased transmissions for symptomatic or those patients with frequent fluid overload events

Develop protocol for communicating the frequency guidelines between HF and EP staff

Decide how the HF patient will be informed of the CareLink transmission frequency.
CardioSight™ Service

CardioSight Service offers heart failure clinics with direct access to exclusive, device-derived information tailored to the management of heart failure.

Timely, direct access designed for clinicians who treat heart failure to enable them to respond quickly to significant clinical events.

Unique insights to help guide patient care
- Simple one touch operation
- Secure report delivery in minutes

CardioSight Service provides access to exclusive 90-day trended information in the Heart Failure Management or Cardiac Compass® Trends Report for many of Medtronic's ICD and CRT-D devices.
CardioSight Reader

- Simple, one-touch operation
- Read-only access
- Clinic-based
- Reader works with multiple patients
- Requires standard telephone line
CardioSight Core Value: Direct Access, Unique Insight

Direct Access

Tool designed for the cardiology clinician to access relevant data for improved care and clinic efficiency

Unique Insight

Clinically relevant trend data, aligned across time. Indicators of the progression of heart failure include:

• OptiVol™ Fluid Trends
• AT/AF burden
• Heart rate variability
• Day and night heart rate
CardioSight Service Overview

1. Under a clinician’s instruction at the clinic, the patient places the mouse-like antenna of the CardioSight Reader over the implanted device. Data are transferred to the reader.

2. The reader transfers device data to a secure server via a standard analog phone line. The server then generates a Heart Failure Management or Cardiac Compass® Trends report. The report is sent to the clinician via fax with a privacy cover page.

3. The clinician reviews the cardiac trends (including OptiVo™ Fluid Trends if the device supports this feature) to help assess the patient’s status.
Fax Machine

- Compatible with standard fax machines
- Each report comes with a privacy cover sheet and back sheet
- Fax can be sent to computer by using fax software
Paceart is the leading in-clinic arrhythmia data management system.

Paceart System organizes relevant information:
- Stores programmed device parameters
- Summarizes patient session data into concise, convenient reports.
- Offers advanced TTM technologies.
- Creates key correspondence.
- Schedules patient follow-ups.
- Speeds records processing.
- Assists in charge and billing management

Adaptable solutions
- One system, many devices
- EMR Interoperability

Today, Paceart systems are installed in over 1,000 clinics managing more than 1.5 million patients with implanted cardiac devices.
Many Information Systems May Co-Exist Due To Complex Information Needs in Healthcare Provider Settings

An **Electronic Health Record (EHR)** is an electronic record of patient health information in multiple encounters and can combine multiple specialties, e.g. immunization, labs, radiology, etc. with key features including orders, prescription writing, charting, workflow management, clinical alerts, and decision support.

A **Practice Management System (PMS)** is a specialized system for scheduling and billing which may be part of the HER or a separate system.
Remote device follow-up systems such as Medtronic CareLink Network store a patient’s device data collected remotely. **Medtronic Paceart System** is a specialized device clinic workflow and information management application that complements other healthcare information systems. **Health Level Seven (HL7)** is the name of an organization that has developed a messaging standard (also known as HL7) which facilitates sharing of data across healthcare information systems.
HL7 CONNECTS DEVICE DATA TO THE EHR

- Implanted Device
- Conexus™ Wireless Technology
- CareLink™ Home Monitor
- Medtronic Programmer
- SessionSync™
- CareLink™ Server
- Paceart System
- HL7
- Electronic Health Record

Medtronic
Alleviating Pain - Preserving Health - Exercising Life

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ANSI Accredited
Standards Developer
### DATA INTEGRATION ENHANCES WORKFLOW

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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<tbody>
<tr>
<td>Eliminate Duplicate Data</td>
<td>Eliminates Double Registration and Scheduling in Paceart and PMS</td>
</tr>
<tr>
<td>Reduce Data Entry Burden</td>
<td>Reduces amount of scanning</td>
</tr>
<tr>
<td>Data Access</td>
<td>Reduces manual entry of data and potential for errors</td>
</tr>
<tr>
<td>Database Development</td>
<td>Make vital device information more widely available to clinicians in the EHR, including ER, anesthesiology, surgery, etc.</td>
</tr>
<tr>
<td>Workflow Coordination</td>
<td>Getting discrete data elements into the EHR makes the transition from “document management” to a “data management” model</td>
</tr>
<tr>
<td></td>
<td>Improve coordination of Paceart based device clinic workflow with other aspects of clinic workflow in PMS and EHR</td>
</tr>
</tbody>
</table>
PATIENT RECORD OF JAMES JONES IN PACEART HAS BEEN POPULATED BY INFORMATION RECEIVED VIA HL7

- Having a single source for demographic information frees clinicians from managing the administrative task of adding and updating demographics.
NEW APPOINTMENT FOR JAMES JONES IS AUTOMATICALLY CREATED IN PACEART VIA HL7

- A new appointment for James Jones is created in the Practice Management System
- Paceart receives an HL7 message from the Practice Management System about this appointment
The data exported includes patient identifiers, implanted device information, and detailed device data and a Paceart report summarizing the data.

Both discrete data and a Paceart PDF report or a link to it can be exported.
For the “constellation of caregivers”...

With Medtronic devices, information flows to wherever it is needed, whenever it is needed, and in formats customized to the user.
In summary

Access to remote device data helps both the Device clinic and the Heart failure clinic. Establishing workflow protocols to provide sharing of data will benefit all. Providing excellent, coordinated and timely care to the patient is key.
Thank You For Your Attention!