Heart failure and devices: the remote patient management perspective

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Introduction

- Cardiovascular diseases are the leading cause of death and the fifth most common cause of illness worldwide.
- Among cardiovascular diseases, the most common clinical picture is the heart failure.
- Over the last 30 years, the prevalence of cardiovascular diseases has declined. By contrast, the prevalence of HF has risen.
- Epidemiological data show that almost 50% of patients die within five years

Disease Management: Major Elements/Goals

- Maximize evidence-based, high quality care through standardized algorithms
- Multi-disciplinary team approach
- Patient education (empowerment)
- Seemless integrated care
  - Close patient follow-up
  - Frequent incremental treatment titrations
- Triage need for advanced therapies

Main issues

- The delay in implementing a process of integration between the hospital sector and that of General Practitioners
- The poor communication among hospital specialists
- The lack of continuity in the diagnostic-therapeutic pathway

explain the:

- variability in the clinical approach to HF patients,
- the risk of inappropriate use of hospitalization (unwarranted admissions)
- the resulting burden on healthcare budgets

The objective of containing hospital healthcare expenditure, as expressed in the National Health Service plan, can only be achieved through the reorganization and integration of in-hospital/out-of-hospital services and by outsourcing therapy

ACC/AHA Guidelines

2005 ACC/AHA Guidelines: Class 1 Indications[1]	
Initial Clinical Assessment	*Serial* Clinical Assessment
"… Initial examination of patients presenting with HF should include… measurement of weight …and calculation of body mass index …"	**"Assessment should be made at each visit of the:** •ability of a patient with HF to perform routine and desired activities of daily living. – volume status and weight of the patient

"Short-term changes in fluid status are best assessed by measuring changes in body weight …" [2]

[1] Hunt, SA *ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult,* http://www.acc.org/qualityandscience/clinical/guidelines/failure/update/index.pdf, pp 9.
[2] Ibid. pg. 14.

Remote Patient Management

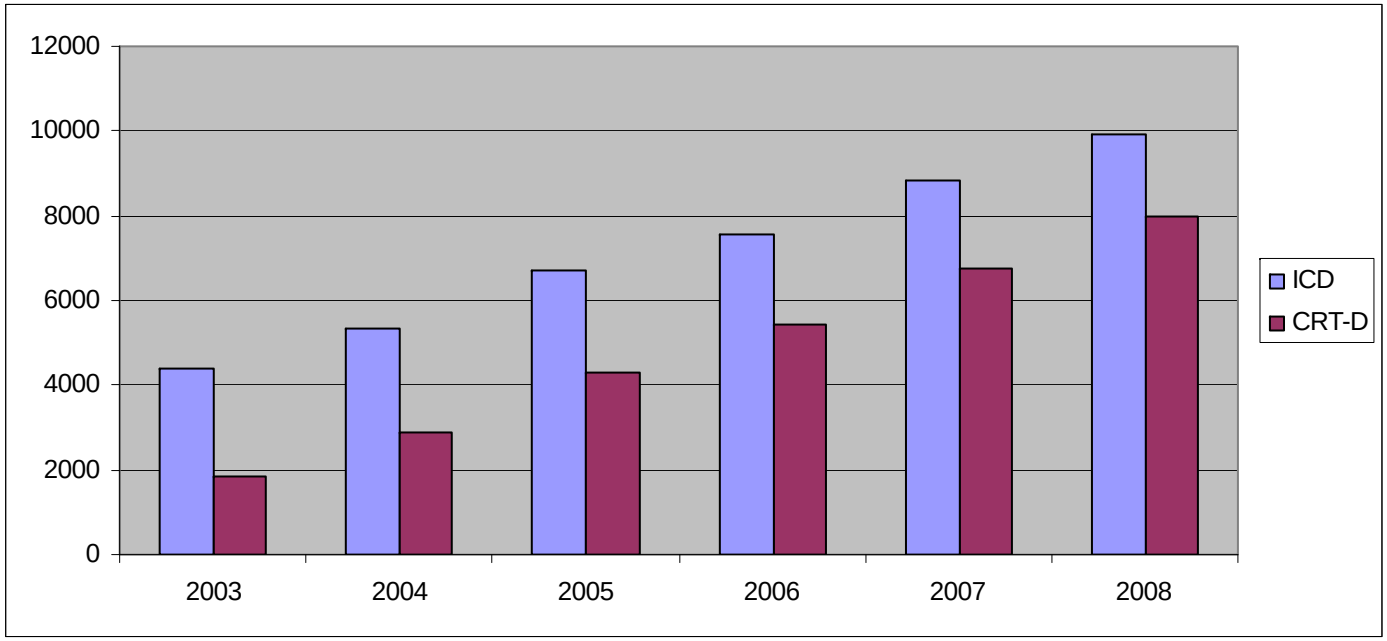
Heart rhythm society recommends that Cardiac Rhythm Management (CRM) device manufacturers develop and utilize wireless and remote monitoring technologies to:

- identify abnormal device behavior as early as possible;
- reduce underreporting of device malfunctions by determining the functional status of an implanted device more frequently and more accurately

In the last years, the biomedical industry has focused its research and development efforts in the development of ICD and CRT-D devices that can be controlled remotely.

This new Disease Management tool allows distant monitoring of the implanted patient (with ICD or CRT-D)

Number of implants in Italy: From Eucomed



Italy:

- The number of ICD implantations increased 5-fold in 6 years (AIAC data, 2005)
- Life expectancy is increasing
- Number of follow-ups: every 3 months for each patients

Today’s Device Clinic is Paper Based

- A patient may return up to 4 times per year.
- Clinician checks patient and device.
- Physician prints information on kinds of therapy delivered and when.
- Reports are in several formats or sizes and are stored in the patient’s record (folder of paper documents in the physician’s office).

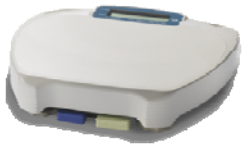
Challenges with Paper-Based Device Data

- Provides no method of easily searching or comparing historical device information.
- Data not easy to collect, track, or retrieve.
- Data not easy to forward to other physicians for analysis.

Remote Patient Management

New generations of RPM system also focus in the control of vital clinical parameter of the patient such as

-blood pressure (BP) and
-body weight (BW)
-QoL Questionnaire



Summary | Events | Settings | Health | Configure Patient

Health Summary | Patient Symptom Report | Heart Rate Variability

PATIENT SYMPTOM REPORT

Question	07 Mar 2005 09:12 PM	14 Mar 2005 08:10 PM	21 Mar 2005 08:15 PM	28 Mar 2005 06:30 PM	04 Apr 2005 08:00 PM
Are you feeling unusually fatigued?	yes	yes	no	no	yes
Have you felt faint or dizzy over the past few days?	several times	twice	once	no	several times
Describe the swelling in your ankles, legs, or abdomen over the past few days	increased noticeably	remained about the same	decreased noticeably	I had no swelling	increased noticeably
Describe your ability to walk or climb stairs over the past few days	decreased noticeably	remained about the same	decreased noticeably	no difficulty	decreased noticeably
How many pillows did you sleep with last night?	slept sitting up	3 or more	2	none or 1	slept sitting up
How often did you wake up breathless last night?	more than a few times	a few times	once	none	more than a few times

- Today the Latitude®system is the only remote patients management system linked to an ICD or CRT-D device that is able to monitor both device functionality and patient clinical parameters.

Casa del paziente

ICD or CRT-D

Communicator

Website

Health Following Physician

Objectives

Device Battery Management
Patient's Weight Management
Compliance with Guidelines

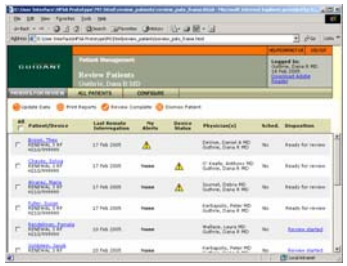
Device managing physician

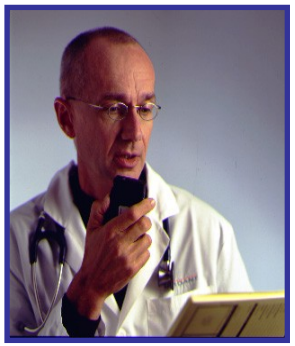
Objectives

Device management
Arrhythmia management

Connecting Multiple Physicians

LATITUDE® allows multiple physicians to participate in the care of the patient





- Heart Failure Specialist
- Implanting Physician

- Both physicians have access to the same patient record in LATITUDE®
- Each physician maintains their own schedule and alert “subscriptions”
- Physician will ***only*** be notified of alert conditions that they have selected

LATITUDE® Patient Management consists of 4 key capabilities

Remote Follow-Up

- Device interrogation that may replace some in-clinic follow-ups
- Full interrogation, including 10-second EGM
- Designed to drive clinic efficiency

Remote Monitoring

- Additional device and patient monitoring between scheduled follow-ups
- Checks specific device information and heart health
- Designed to impact patient outcomes

Patient-Initiated Interrogation (PII)

- On-demand interrogation of device *(Clinic enables feature via website)*
- Full interrogation, including 10-second EGM
- Designed to impact both efficiency and patient outcomes

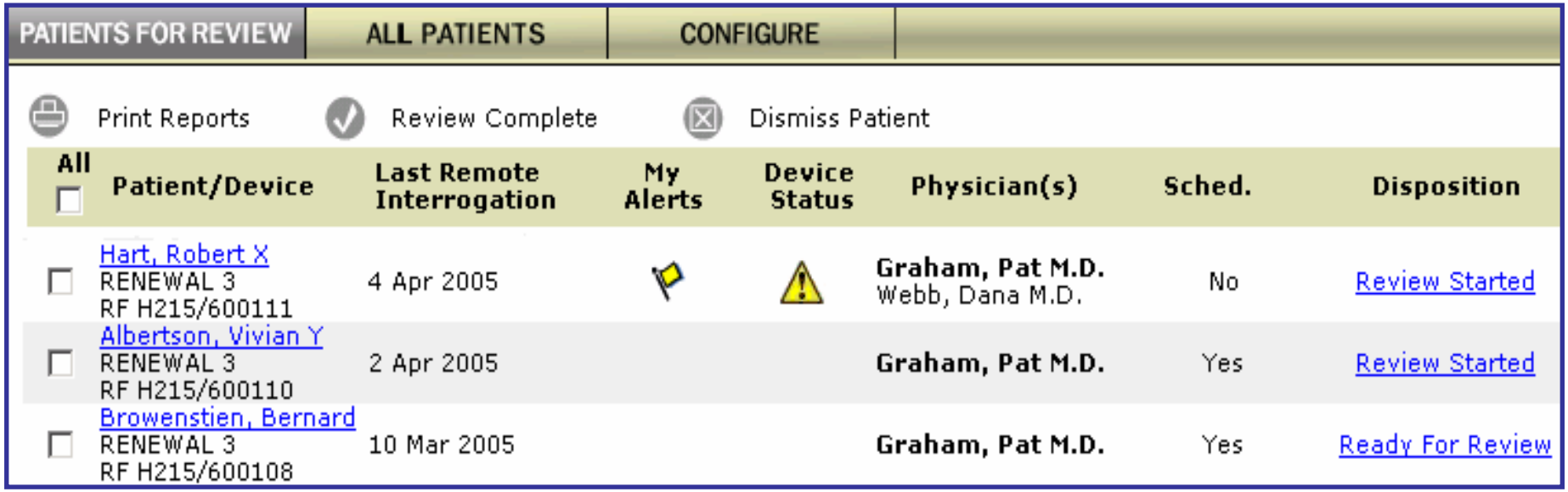
Heart Failure Management

- Allows EPs & Heart-following physicians to work together
- Wireless weight scale and blood pressure monitor (aligned with ACC/AHA Guidelines)
- Symptom self-report questions (QOL)

Advantages

Patient	Electrophysiologist	Attending cardiologist	Clinic/ hospital
			
•Improvement in health: the system is adapted to the patient's condition. •Tranquility. •No unnecessary examinations. •Greater participation in therapy choices.	• Practical efficiency. • Greater contact with attending cardiologist. • Availability of significant information. • Better management of information.	• Ability to personalize therapy. • Better, more precise information. • Better patient management. • Better management of information.	Better health and management of patients, leading to: •fewer hospital admissions; •fewer adverse events; •shorter hospitalization; •lower HF-related costs

View of scheduled interrogations



- Patients with scheduled interrogations appear on the “Patients for Review” page, which serves as clinician’s work queue
- Comprehensive data, similar to data from the ZOOM programmer
- Patient reports are PDF documents. Thus, they can be printed, faxed, e-mailed or saved to your computer or EMR

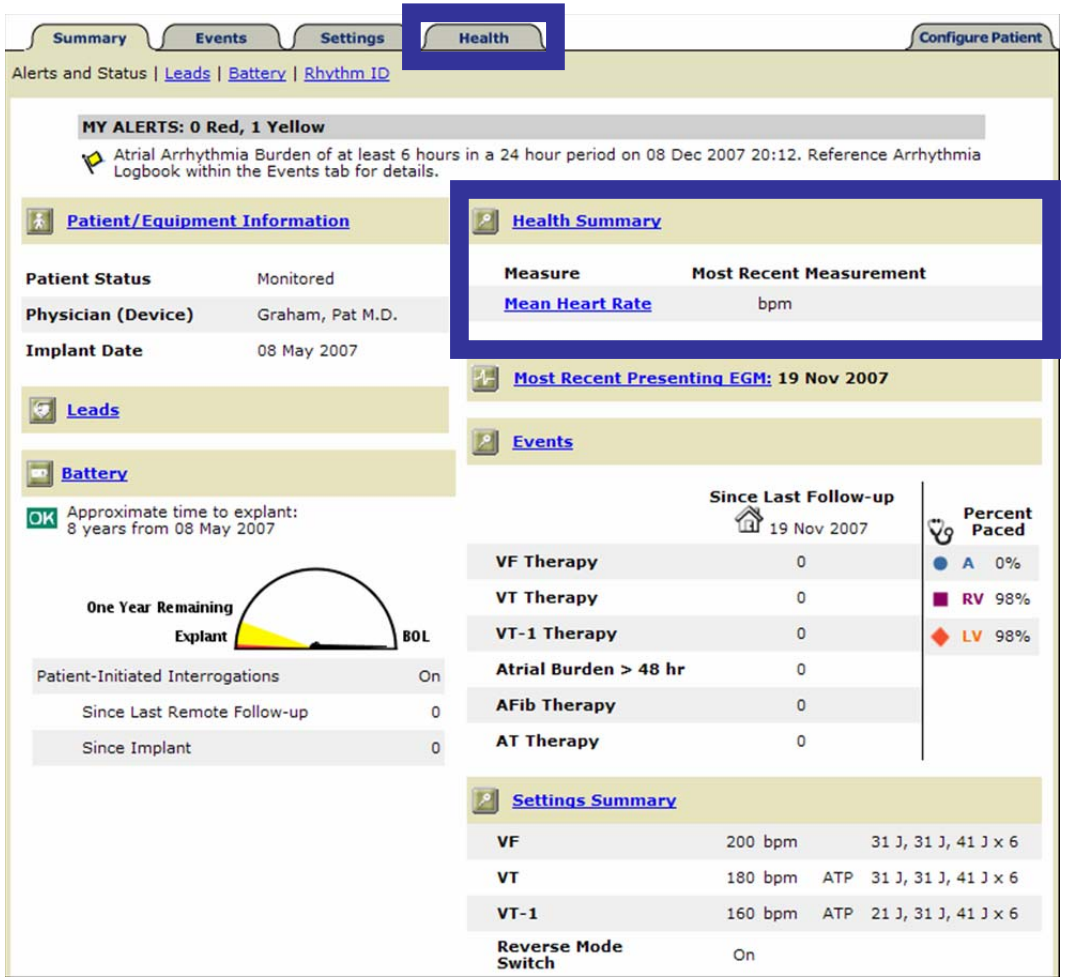
Online Follow-up — Health Summary

View information about the patient and patient's device

Review Summary

Available Links and Tabs

- Alerts
- Most recent EGM
- Events
- Battery
- Leads
- Settings Summary
- Patient Information
- **Health Summary**



RED ALERTS:

Urgent clinical event notifications

- Device battery has reached end of life (EOL)
- High or low shock lead impedance
- High or low shock lead impedance detected when attempting to deliver a shock
- High or low right ventricular pacing lead impedance
- High voltage detected on shock lead during charge
- Tachy mode change due to magnet
- Tachy mode set to value other than Monitor + Therapy
- Possible device malfunction
- Device parameter error

YELLOW ALERTS:

Non-urgent alerts- Provides notification of potential health or device problem

- **Battery**
  - Voltage was too low for projected remaining capacity
  - Explant indicator reached
- **Ventricular Pacing Leads**
  - Low right ventricular intrinsic amplitude
  - High right ventricular intrinsic amplitude
  - Low left ventricular intrinsic amplitude
  - High left ventricular intrinsic amplitude
  - Low left ventricular pacing lead impedance
  - High left ventricular pacing lead impedance
- **Atrial Pacing Leads**
  - Low atrial intrinsic amplitude
  - High atrial intrinsic amplitude
  - Low atrial pacing lead impedance
  - High atrial pacing lead impedance
- **Arrhythmias**
  - Shock therapy delivered to convert arrhythmia (Ventricular)
  - Accelerated arrhythmia episode (Ventricular)
  - Atrial Arrhythmia Burden in a 24 hour period (>0, 0.5, 1, 3, 6, 12, 18, 24 hours)
  - Patient triggered event stored

YELLOW ALERTS:

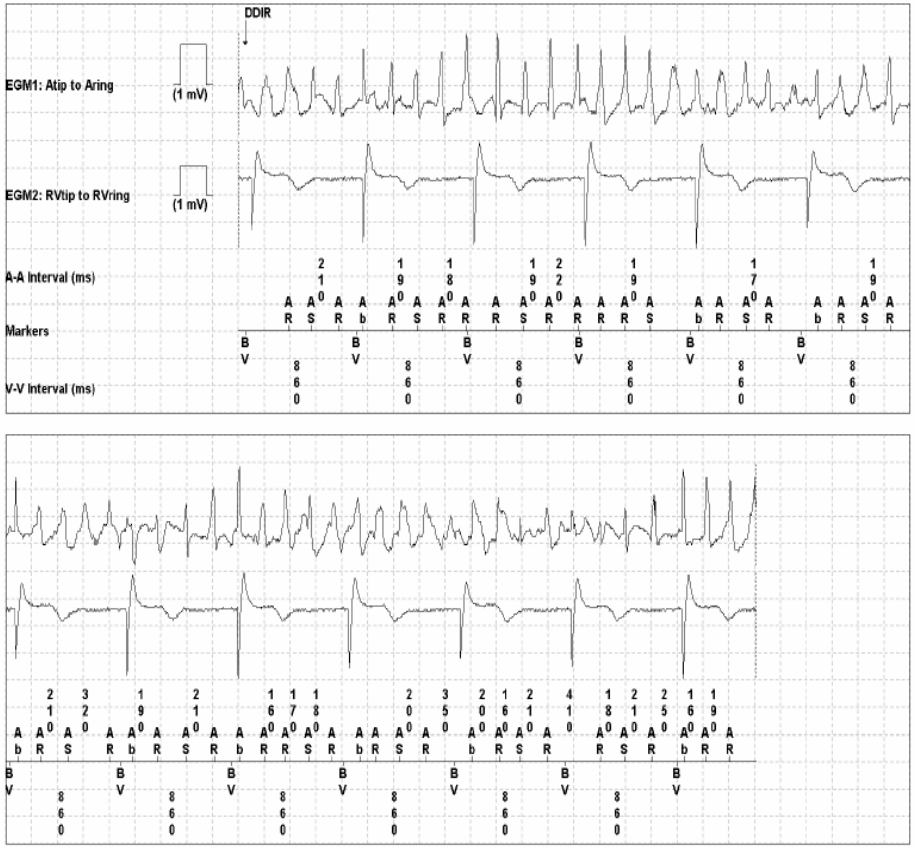
Non-urgent alerts- Provides notification of potential health or device problem

- **Pacing**
  - Cardiac Resynchronization Therapy pacing (<50, 60, 70, 80, 85, 90, 95 %)
  - Right Ventricular Pacing (>10, 20, 30, 40, 50 %)
- **Weight (for patients with LATITUDE Weight Scales)**
  - Weight gain of at least 2.27 kilogram or greater change within 7 days or at least .91 kilogram or greater per day average change over multiple days

AF Alert

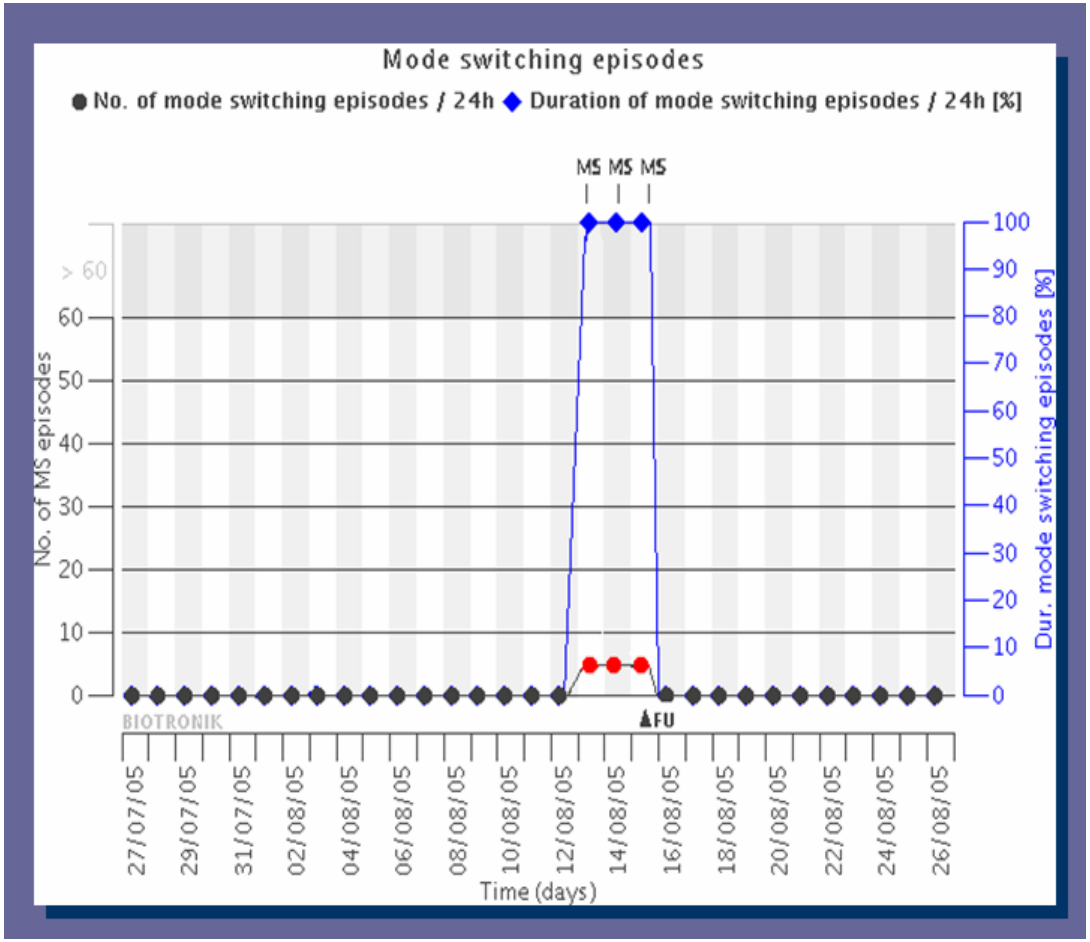
Policlinico Casilino

- **Male,**
- **Age: 58 aa**
- **CMPD,**
- **EF 32 %,**
- **Primary Prevention**
- **QRS 130 ms**
- **Short breathing**



Early identification of AFib

Daily mode switching episodes monitoring

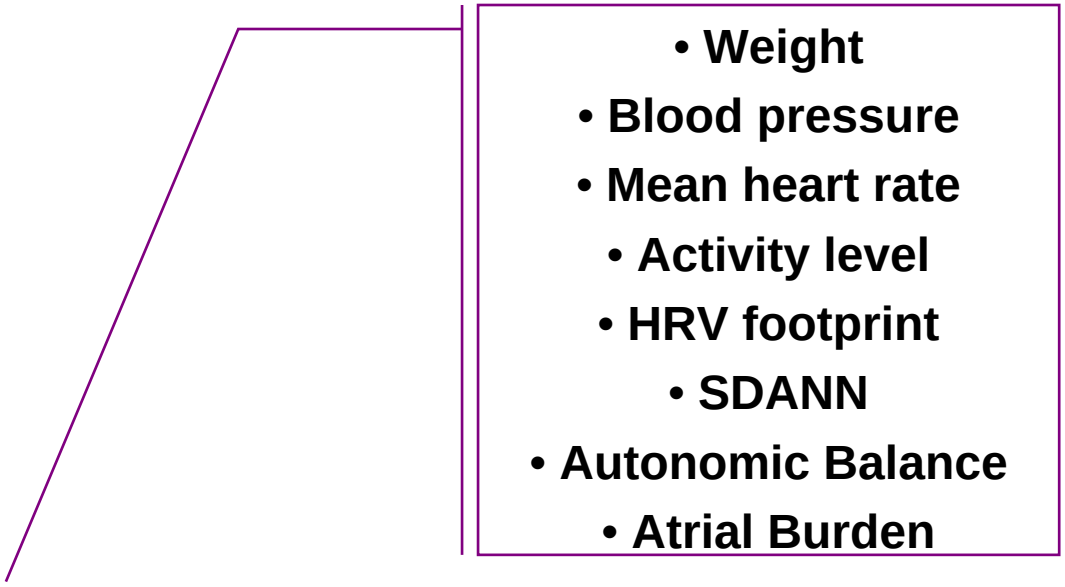


Online Follow-up — Health Summary

Review Summary

Available Links and Tabs

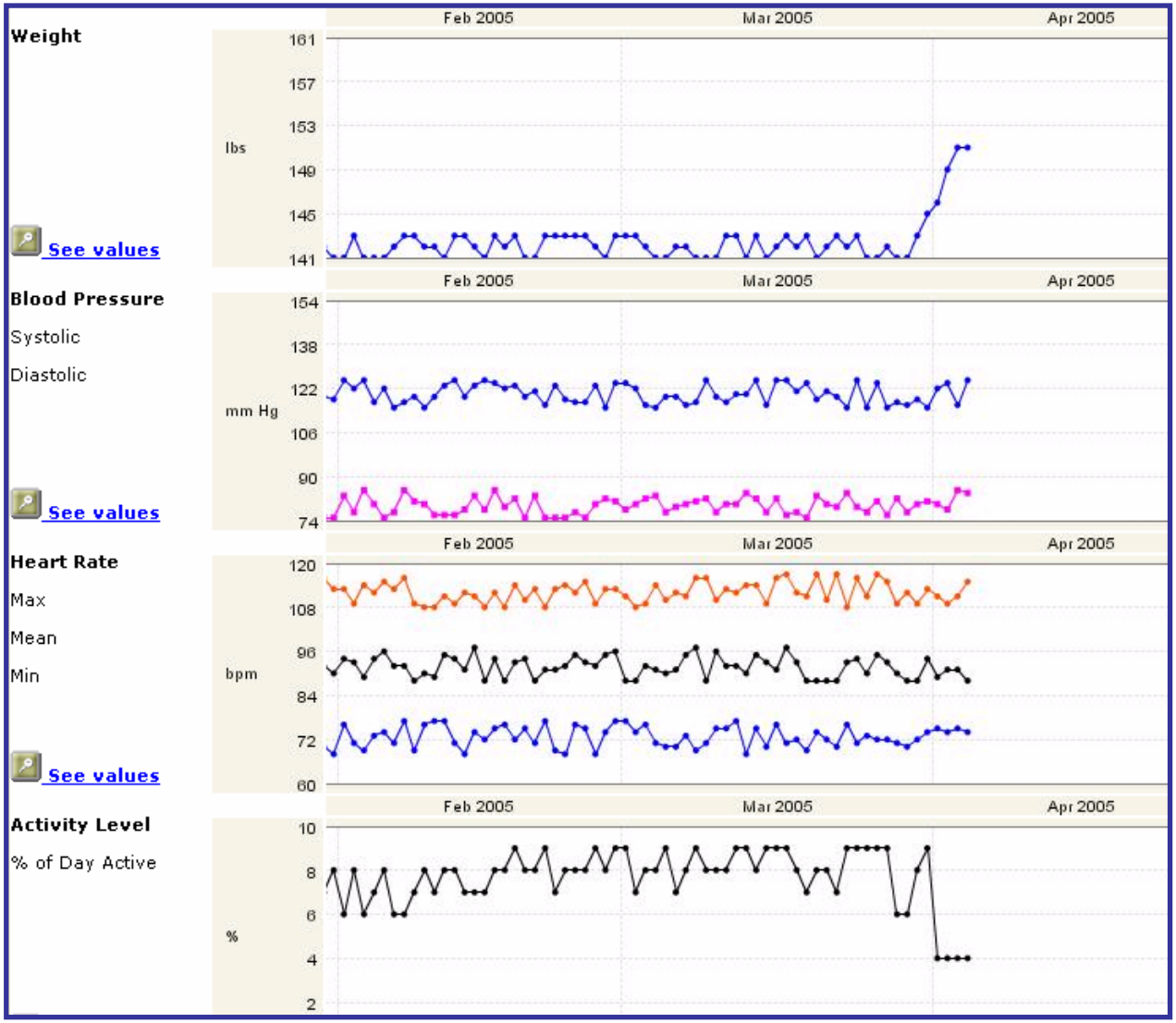
- Alerts
- Most recent EGM
- Events
- Battery
- Leads
- Settings Summary
- Patient Information
- **Health Summary**



Online Follow-up — Heart Failure

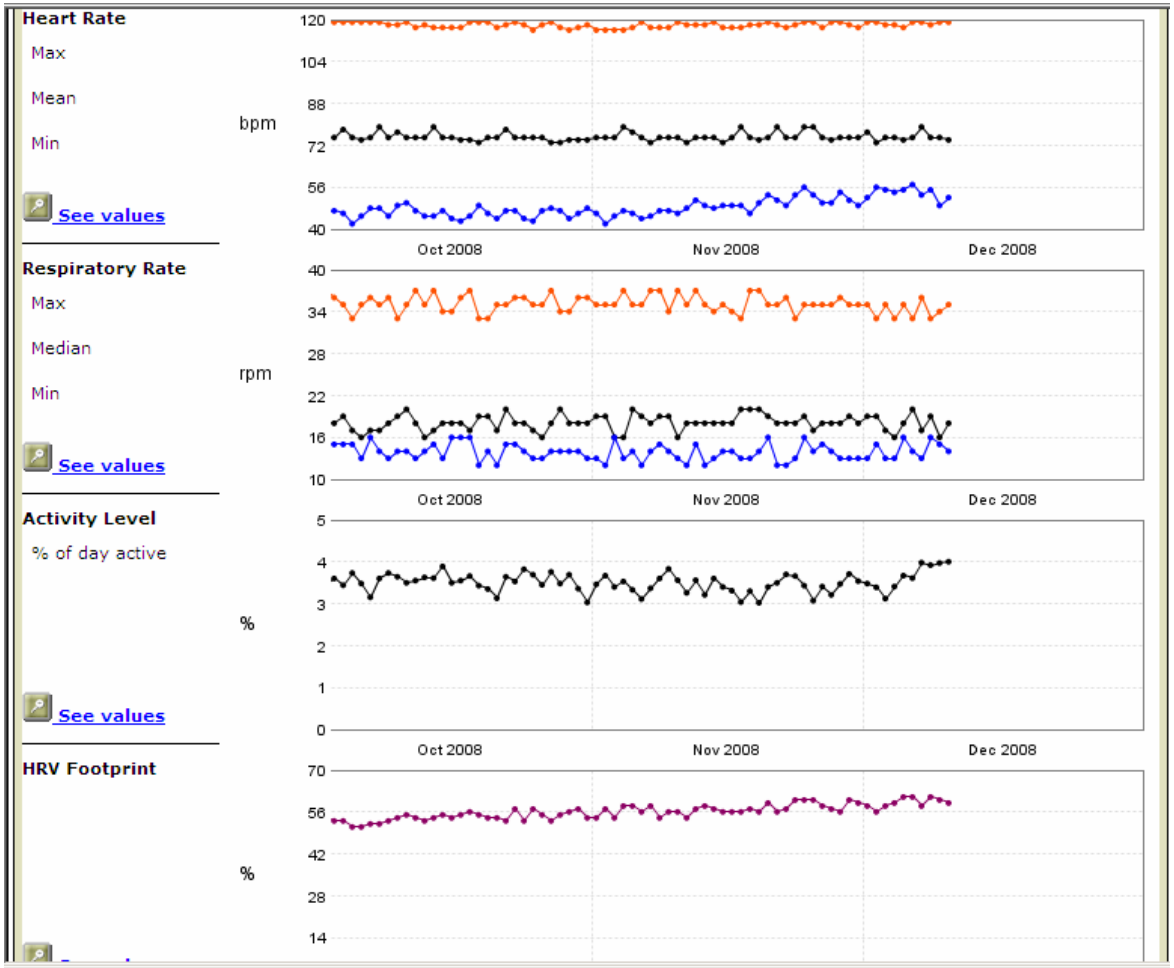
Question	06 Nov 2007 09:12 PM	13 Nov 2007 08:10 PM	20 Nov 2007 08:15 PM	27 Nov 2007 06:30 PM	04 Dec 2007 08:00 PM
Feeling unusually fatigued?	Yes	Yes	No	No	Yes
Faint or dizzy over past few days?	Several times	Twice	Once	No	Several times
Swelling over past few days	Increased	Remained same	Decreased	No swelling	Increased
Ability to walk or climb past few days	Increased	Remained same	Decreased	No difficulty	Increased
Pillows used last night?	Slept sitting up	3 or more	2	None or 1	Slept sitting up
Woke up breathless last night?	More than few times	Few times	Once	None	More than few times

LATITUDE® Heart Failure Management



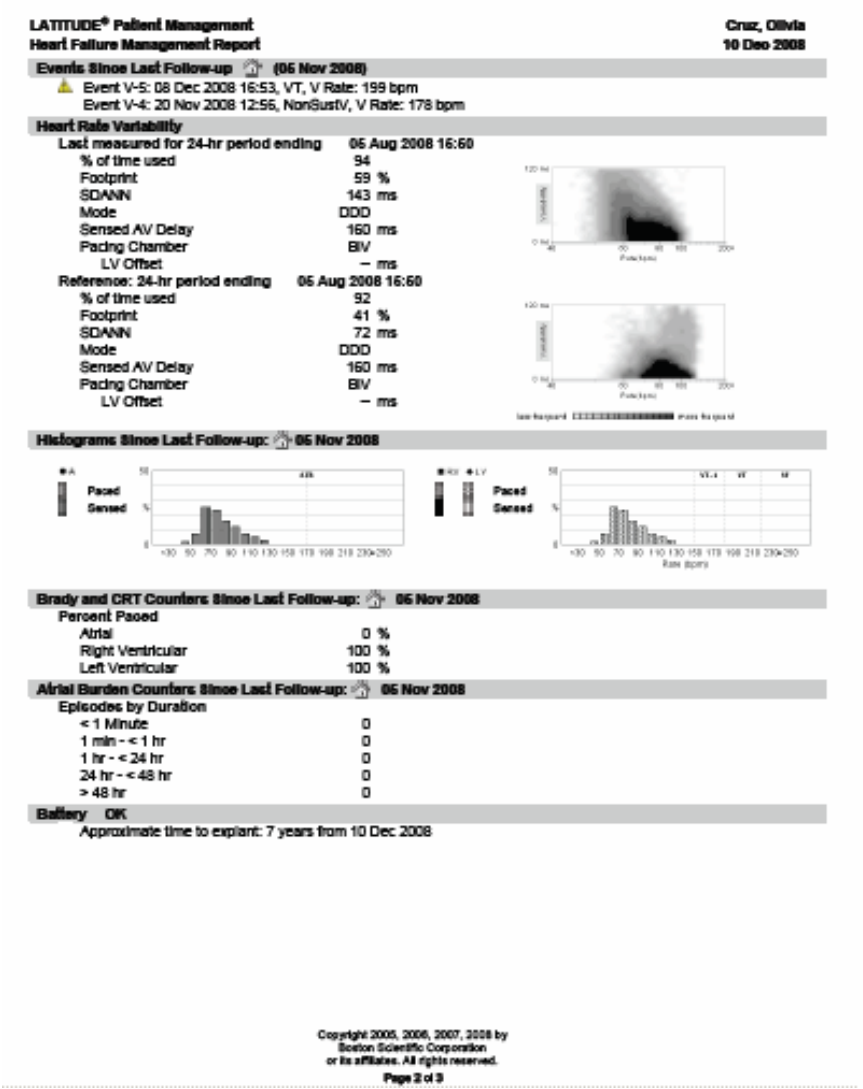
Online Follow-up — Heart Failure

Health status review



Heart Failure Management Report

- **Heart Failure Management Report**
  - My Alerts
  - Trends
    - Events
    - Weight
    - Blood Pressure
    - Activity Log
    - Heart Rate
    - SDANN
    - HRV Footprint
    - Autonomic Balance Monitor
  - Events
  - Heart Rate Variability
  - Histograms
  - Brady and CRT counters
  - Battery settings



LATITUDE® Patient Management — Cruz, Olivia
Heart Failure Management Report — 10 Dec 2008

Events Since Last Follow-up (06 Nov 2008)

Event V-5: 08 Dec 2008 16:53, VT, V Rate: 199 bpm
Event V-4: 20 Nov 2008 12:56, NonSustV, V Rate: 178 bpm

Heart Rate Variability

Last measured for 24-hr period ending	06 Aug 2008 16:60	
% of time used	94	
Footprint	59	%
SDANN	143	ms
Mode	DDD	
Sensed AV Delay	160	ms
Pacing Chamber	BiV	
LV Offset	–	ms
Reference: 24-hr period ending	06 Aug 2008 16:60	
% of time used	92	
Footprint	41	%
SDANN	72	ms
Mode	DDD	
Sensed AV Delay	160	ms
Pacing Chamber	BiV	
LV Offset	–	ms

Histograms Since Last Follow-up: 06 Nov 2008

Brady and CRT Counters Since Last Follow-up: 06 Nov 2008

Percent Paced

Atrial	0 %
Right Ventricular	100 %
Left Ventricular	100 %

Atrial Burden Counters Since Last Follow-up: 06 Nov 2008

Episodes by Duration

< 1 Minute	0
1 min - < 1 hr	0
1 hr - < 24 hr	0
24 hr - < 48 hr	0
> 48 hr	0

Battery OK
Approximate time to explant: 7 years from 10 Dec 2008

Activity Log

Activity Log is a measure of the patient's activity automatically gathered by the device using the data provided by the accelerometer sensor (piezoelectric)

Does not need to be in an adaptive-rate mode (DDDR or VVIR) to gather information

Activity Log Report

Activity Log - Table

Date	Percent active (%)
27-JUN-2002	10.20
26-JUN-2002	8.73
25-JUN-2002	10.56
24-JUN-2002	6.55
23-JUN-2002	10.68
22-JUN-2002	8.59
21-JUN-2002	14.21
26-JUN-2002	9.87
19-JUN-2002	8.68
12-JUN-2002	9.23
05-JUN-2002	8.26
29-MAY-2002	11.04
22-MAY-2002	8.71
15-MAY-2002	7.56
08-MAY-2002	9.26
01-MAY-2002	14.72
24-APR-2002	8.28
17-APR-2002	9.88
10-APR-2002	9.77
03-APR-2002	8.32
27-MAR-2002	7.60
20-MAR-2002	10.43
13-MAR-2002	9.77
06-MAR-2002	9.38
27-FEB-2002	8.10
20-FEB-2002	9.25
13-FEB-2002	8.80
06-FEB-2002	10.69
30-JAN-2002	7.16
23-JAN-2002	7.22
16-JAN-2002	8.00
09-JAN-2002	6.45
02-JAN-2002	5.90
26-DEC-2001	4.44
19-DEC-2001	2.19
12-DEC-2001	1.51

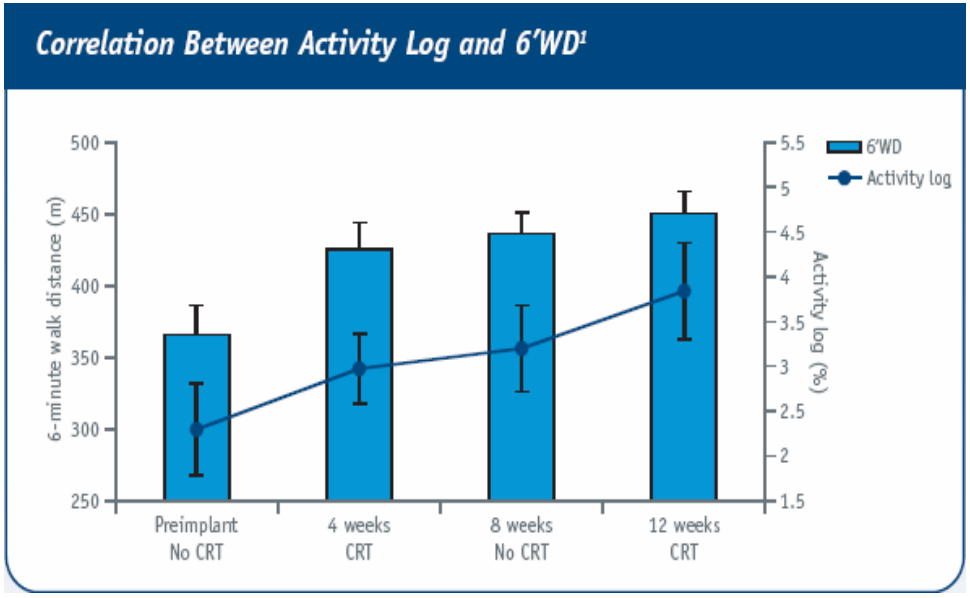
Any force of 50 milligravities (equivalent to standing from a seated position) or greater will be counted in the TOTAL "Percent of Day Active"

Activity Log: clinical value

A Novel Method—The Activity Log Index—for Monitoring Physical Activity of Patients With Heart Failure

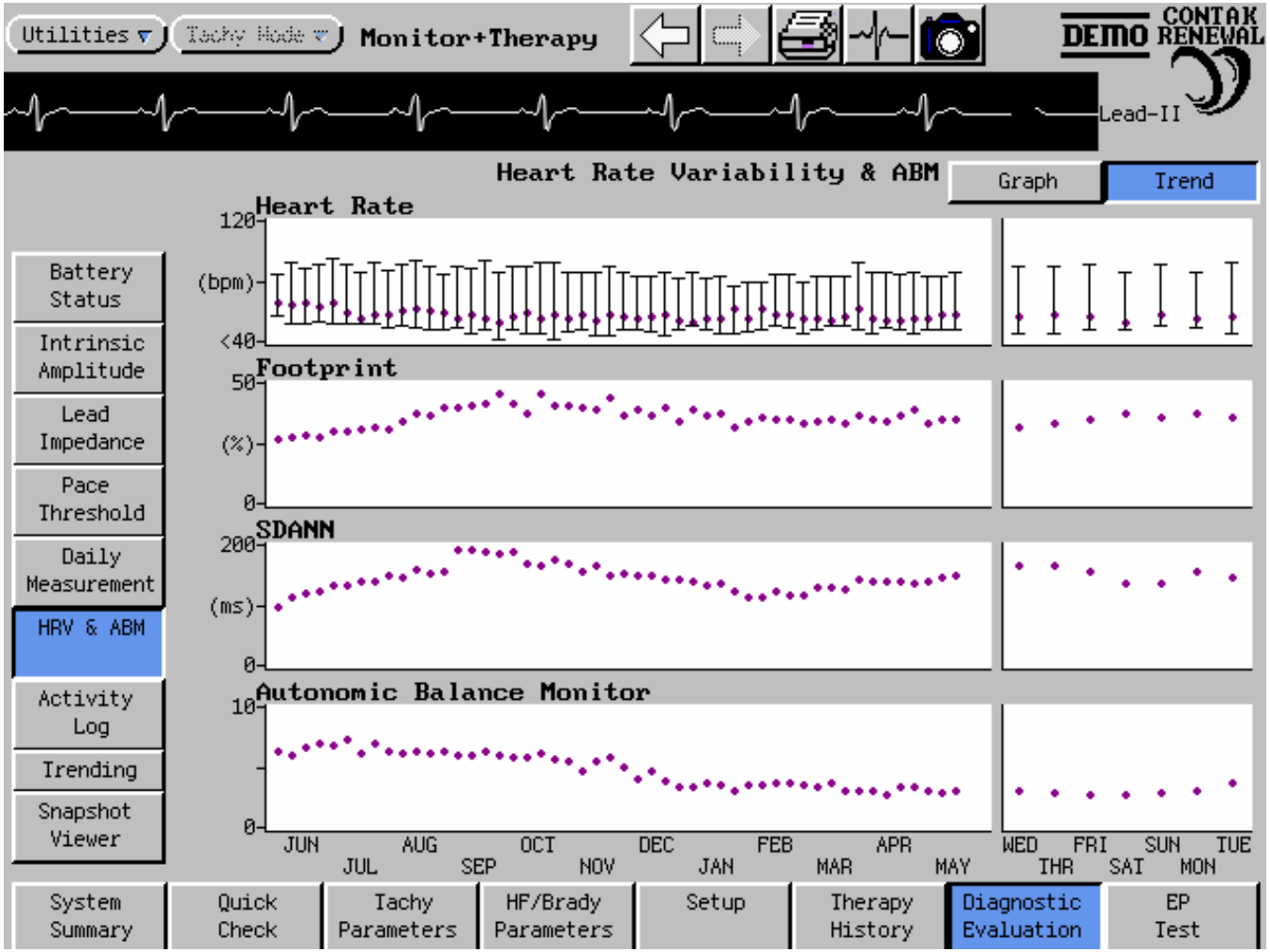
Veerichetty A. Kadhiresan, PhD, Joseph Pastore, PhD, Angelo Auricchio, MD, PhD, Stefan Sack, MD, Annette Doelger, BS, Steven Girouard, PhD, and Julio C. Spinelli, PhD, for the PATH-CHF Study Group*

The American Journal of Cardiology Vol. 89 June 15, 2002



- Activity log is highly sensitive and specific in detecting the physical activity of patients[2]
- Furthermore, activity log increased substantially when CRT was administered to patients in a blinded fashion
- The magnitudes of activity log change largely correlated with change in 6'WD
- This correlation was independent of whether CRT was active or not

Six-months HRV trends



Max
Average Heart Rate
Min

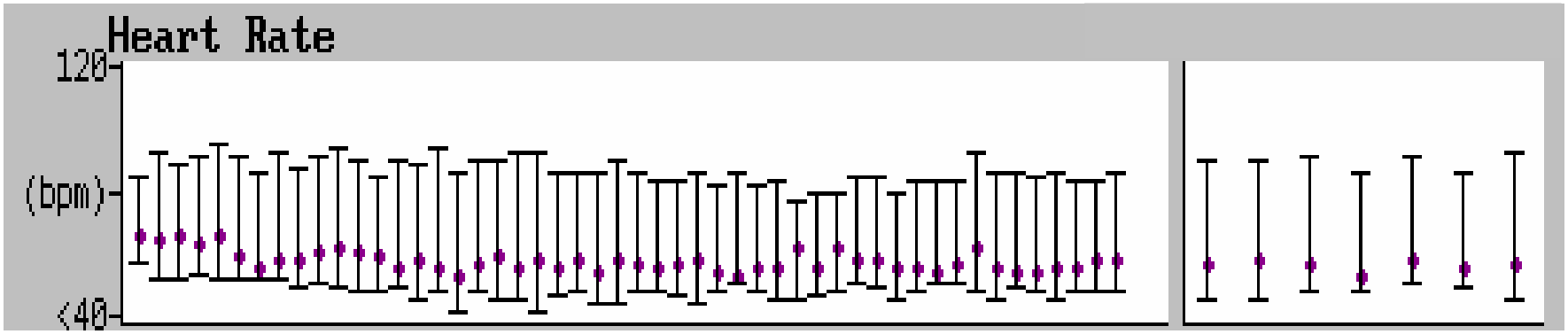
Cardiac working area

R-R Variability

Balance
Symp/Parasymp
(LF/HF)

Clinical valuation of patient
CRT efficacy

Average Heart Rate

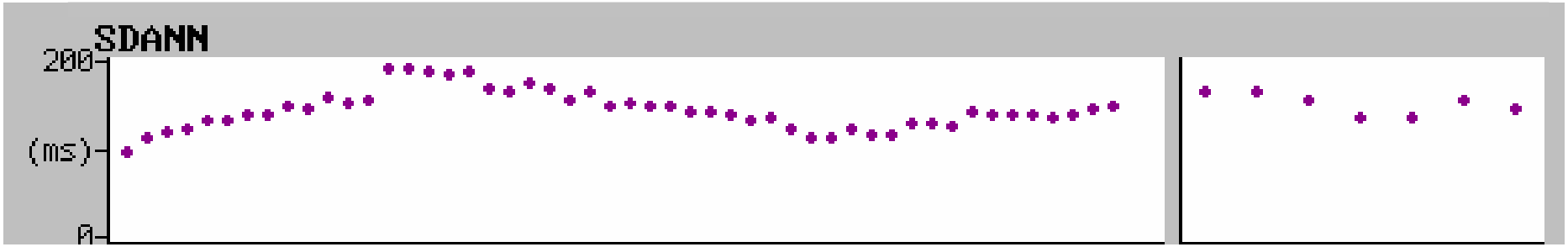


CRT Efficacy is indicated by

a decrease of Average Heart Rate

Clinical valuation of patient
CRT efficacy

Cardiac R-R Variability

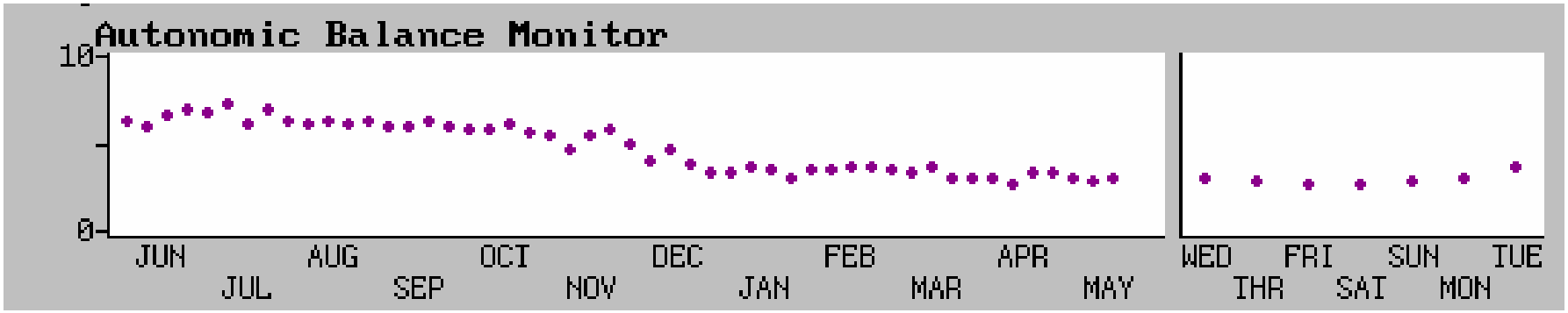


CRT Efficacy is indicated by an increase of Variability

- SDANN is a way of measuring variability
- The biggest SDANN value is, the better it is for the patients

Clinical valuation of patient
CRT efficacy

Balance Sympath/Parasymp



Autonomic Balance functions as a surrogate measurement for LF/HF ratio

Low Frequency = sympathetic-parasimpathetic tone
High Frequency = parasympathetic tone

CRT Efficacy is indicated by a decrease of Automatic Balance Monitor

Experience in US

The LATITUDE™ system is the most rapidly-adopted remote monitoring system in the U.S.[1] and represents a unique experience.

To date, 124,787[2] patients in the United States have been followed up by means of the LATITUDE™ system.

Throughout the world-class service offered to 2,174 clinics, representing 71,029 monitoring years[3] in 2008.

[1] Data based on number of patients reported at three years post launch. Data of file.
[2] Active Patients with Wanded Devices: 63,578; Active Patients with RF Enabled Devices: 35,554. Analysis of aggregate de-identified LATITUDE™ Patient Management system patient enrollments as of 03/10/09. Data on file.
[3] Patient Monitoring Years is defined as the total number of days each patient was active in LATITUDE™ in 2008, converted into years.
[

Trials of home monitoring

A randomized trial of home telemonitoring in a typical elderly heart failure population in North West London: results of the Home-HF study

Aims Heart failure chiefly affects the elderly, with frequent emergency admissions. Telemonitoring can identify worsening heart failure but previous randomized trials have enrolled selected patient populations. The Home-HF study examined the impact of home telemonitoring on typical heart failure patients discharged from three acute hospitals in North West London, UK.

Methods and results Patients hospitalized with heart failure were randomized to telemonitoring or usual specialist care. Primary outcome measures were days alive and out of hospital. Secondary outcome measures were number and duration of heart failure hospitalizations, clinic visits, and quality of life. We recruited 182 patients. There was no difference in the primary outcome measure in the two groups, but there were significantly fewer unplanned hospitalizations for heart failure decompensation, and a reduction in clinic and emergency room visits in the telemonitoring group. There was no statistically significant difference in the mean direct health service costs.

Conclusion Home telemonitoring in a typical elderly population of heart failure patients produces a similar outcome to 'usual' specialist care, but reduces clinic and emergency room visits and unplanned heart failure rehospitalizations at little additional cost. This method of disease monitoring may allow specialist services to increase the number of patients under their care.

EUROPEAN SOCIETY OF CARDIOLOGY®

European Journal of Heart Failure (2009) **11**, 319–325
doi:10.1093/eurjhf/hfn050

Trials of home monitoring

Home telemonitoring in heart failure patients: the HHH study (Home or Hospital in Heart Failure)

Aims The Home or Hospital in Heart failure (HHH) study was a European Community-funded, multinational, randomized controlled clinical trial, conducted in the UK, Poland, and Italy, to assess the feasibility of a new system of home telemonitoring (HT). The HT system was used to monitor clinical and physiological parameters, and its effectiveness (compared with usual care) in reducing cardiac events in heart failure (HF) patients was evaluated. Measurements were patient-managed.

Methods and results From 2002 to 2004, 461 HF patients (age 60 ± 11 years, New York Heart Association class 2.4 ± 0.6, left ventricular ejection fraction 29 ± 7%) were enrolled at 11 centres and randomized (1:2) to either usual outpatient care or HT administered as three randomized strategies: (i) monthly telephone contact; (ii) strategy 1 plus weekly transmission of vital signs; and (iii) strategy 2 plus monthly 24 h recording of cardiorespiratory activity. Patients completed 81% of vital signs transmissions, as well as 92% of cardiorespiratory recordings. Over a 12-month follow-up, there was no significant effect of HT in reducing bed-days occupancy for HF or cardiac death plus HF hospitalization. *Post hoc* analysis revealed a heterogeneous effect of HT in the three countries with a trend towards a reduction of events in Italy.

Conclusion Home or Hospital in Heart failure indicates that self-managed HT of clinical and physiological parameters is feasible in HF patients, with surprisingly high compliance. Whether HT contributes to a reduction of cardiac events requires further investigation.

EUROPEAN SOCIETY OF CARDIOLOGY®

European Journal of Heart Failure (2009) **11**, 312–318
doi:10.1093/eurjhf/hfp022

Estimation of the economic benefits Clinical efficiency

In the management of heart failure patients, remote patient management has been shown to impact positively on clinical and economic endpoints.

•Patients followed up by means of RPM have a 32% lower risk of hospital readmission than those followed up in accordance with current standards(1).

•Mean at-rest heart rate and mean 24-hour heart rate in 70% of patients undergoing hospital readmission increase during the week before hospitalization(2).

•Monitoring body weight has also proved useful in preventing readmissions(3).

1.Fleishman V, David IS. Remote Physiological Monitoring: Innovation in the Management of Heart Failure. New England Healthcare Institute, 2004.
2. Ellery S, PakrashiT, Paul V, Sack S. Predicting mortality and rehospitalizationin heart failure patients with home monitoring--the Home CARE pilot study. ClinRes Cardiol. 2006;95 Suppl3:III29-35. Review.
3. ChaudhrySI, Wang Y, ConcatoJ, Gill TM, KrumholzHM.Patternsof weight change preceding hospitalization for heart failure.Circulation. 2007 Oct 2;116(14):1549-54. Epub2007 Sep 10.

CONCLUSION

Remote patient management of HF patients implanted with CRTD can help electrophysiologist and clinicians by several features

Latitude system - in pts with HF - gives us the possibility to have many data about clinical status of our pts
(symptoms, weight, blood pressure, mean HR, HRV, activity log, etc.)
other than the classical informations about the occurrence of arrhythmias (supraventricular and ventricular) and the device status