

VIRTUOSO™ ICD

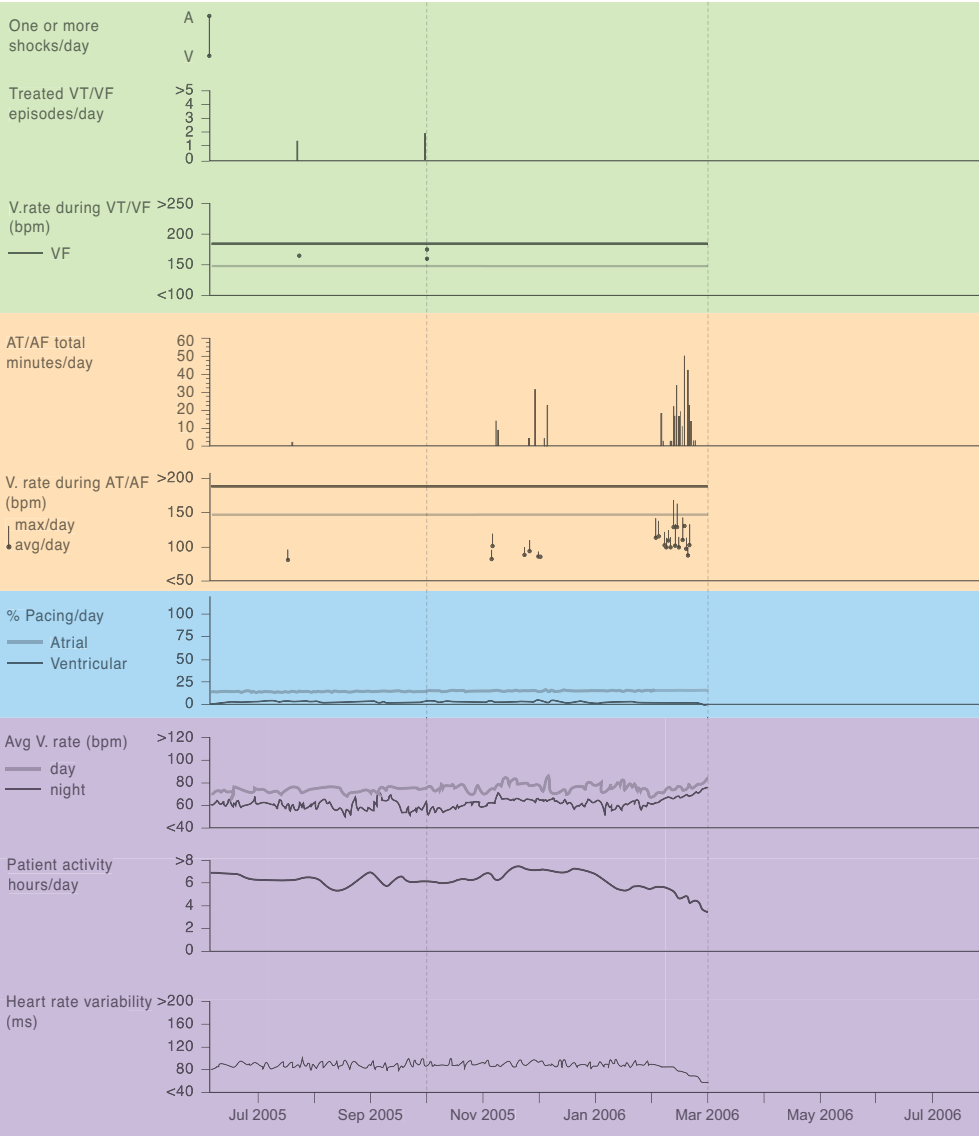
Cardiac Compass® Trends

Cardiac Compass Report

Device: **Virtuoso D154AWG** Serial Number: _____ Date of Visit: _____
 Patient: _____ ID: _____ Physician: _____

Jul 2005 Sep 2005 Nov 2005 Jan 2006 Mar 2006 May 2006 Jul 2006

P = Program
 I = Interrogate
 — = Remote



Clinical Concerns/Questions

VT/VF Arrhythmias

- Are episodes present?
- Is there more than one episode in a day?
- What is average rate/interval of the episodes?
- Are episodes related to AT/AF?
- Are episodes affecting HF status?

AT/AF Arrhythmias

- Are previously undiagnosed episodes present?
- What is the burden and frequency?
- Has rhythm-control therapy increased the amount of time spent in sinus rhythm?
- Is there adequate ventricular rate control during AT/AF episodes?
- Is there an increased risk for stroke due to long durations?
- Are atrial episodes affecting VT/VF frequency?
- Are atrial episodes affecting HF status?

Pacing Percentages/Rate Response Information

- Is atrial pacing maximized if overdrive pacing is desired?
- Is atrial pacing minimized for patients with competent sinus nodes?

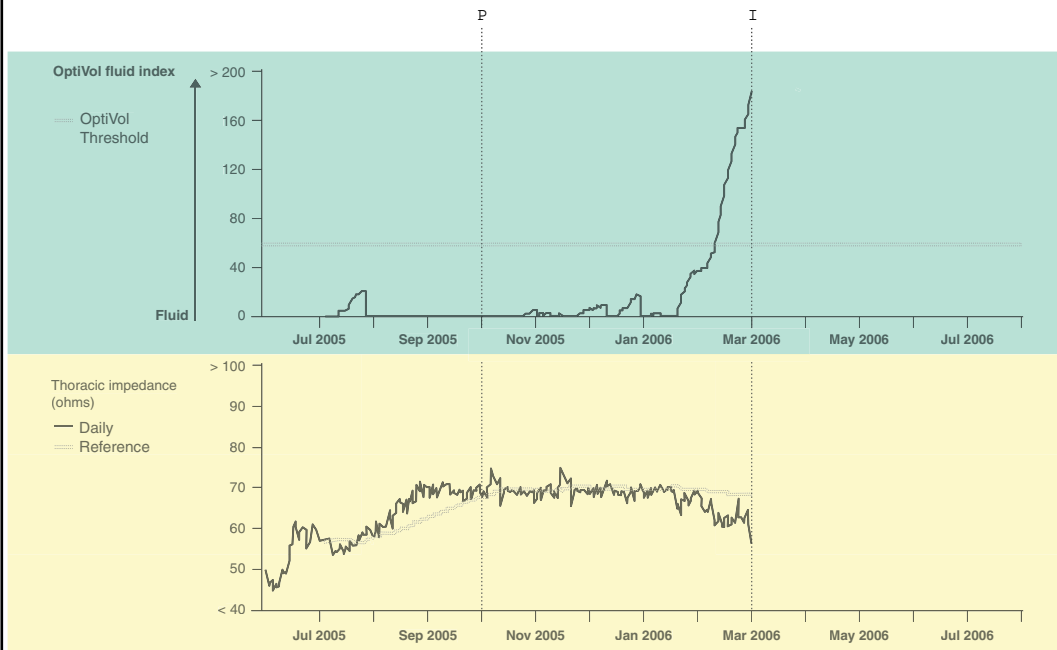
Heart Failure Status Indicator Trends

- Is patient presenting with recent signs of worsening HF?
- Are the worsening HF symptoms related to a ventricular or atrial arrhythmia?
- Are average day/night heart rates increasing, decreasing, or stable?
- Is patient activity level increasing, decreasing, or stable?
- Does heart rate variability appear to be increasing, decreasing, or stable?

Cardiac Compass Report

Device: **Virtuoso D154AWG**

Serial Number:



OptiVol fluid index is an accumulation of the difference between the Daily and Reference impedance.

Clinical Concerns/Questions

OptiVol® Fluid Index

- Has the OptiVol Threshold been crossed/when?
- Does the crossing of the OptiVol Threshold agree with patient symptoms?
- Is medical intervention required?

Thoracic Impedance Trend

- Is the Reference impedance consistent with the Daily impedance measurements?

Cardiac Compass Report – Data Collection and Measurement

OptiVol Fluid Status Monitoring

OptiVol Index Trend: This trend is the accumulated changes between the Reference impedance measurements and Daily impedance measurements. This includes a physician programmable (30-180) OptiVol Threshold.

Thoracic Impedance Trend: A plot of Daily impedance values and the Reference impedance

VT/VF Arrhythmia Information

Episodes/day (frequency): Vertical lines report daily number of combined VT/VF episodes; "monitor-only" and/or induced episodes not counted

Shocks/day: Each vertical line corresponds to episode(s) that required at least one Defib or CV therapy to terminate

V. rate during VT/VF: Horizontal lines reflect programmed detection zones; solid dots match to recorded episode median V. rate; multiple points reflect multiple episodes of varying median rates

AT/AF Arrhythmia Information

AT/AF hours/day (rhythm-control): Vertical lines report total time spent in AT/AF on daily basis; based upon total time spent in mode switch

V. rate during AT/AF (rate-control): Solid dot reflects average V. rate and vertical line reflects maximum sensed V. rate (highest of 12 beat medians)

Pacing Information

% Pacing/day: Horizontal lines connect individual points that reflect 24-hour percentage totals calculated at midnight

Heart Failure Information

Avg. V. rate: Day rate measured between 8 am and 8 pm; night rate measured between 12 am and 4 am; calculated as the sum of V. intervals divided by the number of V. intervals; beats occurring during VT/VF, AT/AF not included

Patient Activity: Based upon accelerometer information (even if rate response OFF); lines reflect hours/day patient activity exceeds 60-70 steps/minute walk level; daily activity averaged over 7-day period and plotted

HR Variability: Calculated as standard deviation of 5-minute medians of normal sensed *atrial* intervals; atrial intervals during AT/AF or VT/VF not included; points plotted daily and connected horizontally. HR Variability is calculated in pacing modes, including those with rate response.

Brief Statement

Virtuoso Models D154AWG/D154VWC (DR/VR)

Indications: 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:** Virtuoso DR/VR devices are contraindicated for patients experiencing any of the following conditions: tachyarrhythmias with transient or reversible causes, incessant ventricular tachycardia or ventricular fibrillation, present implant of a unipolar implantable pulse generator, and primary disorder or bradyarrhythmia. Virtuoso DR is also contraindicated for patients who have a primary disorder of chronic atrial tachyarrhythmia with no concomitant VT or VF. Additionally, Virtuoso VR is contraindicated for patients who have a primary disorder of atrial arrhythmia. **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 device manuals 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.

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