

SYSTEM HIGHLIGHTS

Paceart
Optima™
System 1.8

CLINIC WORKFLOW MANAGEMENT

Flow Sheets

- New tab in Encounters showing data in a tabular format from the current encounter, plus four previous encounters
- Contains a selection of device data, including: bradycardia and tachycardia programming, device status, lead threshold and impedance measurements, episodes, and counters
- Patient Care Impact:
 - Quickly identify data trends, especially those that warrant additional attention (i.e., Battery Longevity, Threshold, Impedance, AF Burden, RV Shocks Delivered — lifetime, RV ATP Delivered — Lifetime, etc.)
 - Quickly identify missing or inconsistent data
 - Quickly view previous programming changes
- Practice Efficiency:
 - Quickly view significant encounter data in one location
 - Compare data elements across past encounters, without having to open each encounter

The screenshot displays a 'Flow Sheet' interface with a navigation menu at the top and a data table below. The table has five columns representing encounters: 3/2/2017, 6/3/2017, 9/7/2017, 12/9/2017, and 3/15/2018. The data is organized into sections: 'Brady Programming' (Modes and Rates), 'Device Status' (Battery, Pace/Sense Lead Impedance), and 'Defib Lead Impedance'. Callouts point to various features: 'Expand or collapse data elements' points to the left-hand navigation menu; 'Quickly view previous programming change' points to the 'Modes and Rates' section; 'Quickly identify missing or inconsistent data' points to a missing value in the 'Battery' section; and 'Quickly identify data trends, especially those that warrant additional attention' points to the 'Battery Longevity' data across the encounters.

Encounter Data	3/2/2017	6/3/2017	9/7/2017	12/9/2017	3/15/2018
Encounter Type	In-clinic	In-clinic	Remote	Remote	In-clinic
Brady Programming					
Modes and Rates					
Pacing Mode	AARx=>DDDR	DDDR	DDDR	DDDR	DDDR
Pacing Lower Rate	64 bpm	70 bpm	70 bpm	70 bpm	70 bpm
Pacing Upper Rate	140 bpm				
Pacing Upper Sens. Rate	140 bpm				
Device Status					
Battery					
Battery Voltage	3.12 V	3.11 V	3.10 V	3.08 V	3.07 V
Battery Longevity	6yr, 10mo	6yr, 7mo	6yr, 3mo	5yr, 10mo	5yr, 8mo
Pace/Sense Lead Impedance					
RA Primary Lead Impedance Polarity	Bipolar	Bipolar	Bipolar	Bipolar	Bipolar
RA Primary Lead Impedance Value	399 Ω		399 Ω	790 Ω	703 Ω
RV Primary Lead Impedance Polarity	Bipolar	Bipolar	Bipolar	Bipolar	Bipolar
RV Primary Lead Impedance Value	456 Ω				
LV Primary Lead Impedance Polarity	Bipolar	Bipolar	Bipolar	Bipolar	Bipolar
LV Primary Lead Impedance Pathway	LV-Tip to LV-Ring				
LV Primary Lead Impedance Value	437 Ω				
Defib Lead Impedance					

All patient and clinical data are fictitious and for demonstration purposes only.

The screenshot displays the Medtronic Paceart Optima™ System software interface. The top navigation bar includes 'HOME', 'SEARCH', 'TIMES', 'SCHEDULE', and 'ENCOUNTERS'. The main window is divided into several sections:

- Patient Information:** Shows patient details for Patricia, including Patient ID, Date of Birth, and Diagnoses.
- Device Details:** Displays device information for the Medtronic M11204 Pacemaker CRT-P, including Model Number, Serial Date, and Lead.
- Encounters:** Lists recent encounters with dates and times.
- Device Status:** A table showing device status over time.
- Brady Programming:** A detailed table of programming parameters for the device, including Pacing Mode, Pacing Lower Rate, Pacing Upper Rate, AV Delay, Pacing Amplitude, Pacing Pulse Width, Pacing Priority, and Sensitivity.
- Equations:** A section for mathematical equations related to the device's operation.

Advanced Search Usability

- Double-click an item in the search results to open the related item (e.g., patient, encounter, etc.)

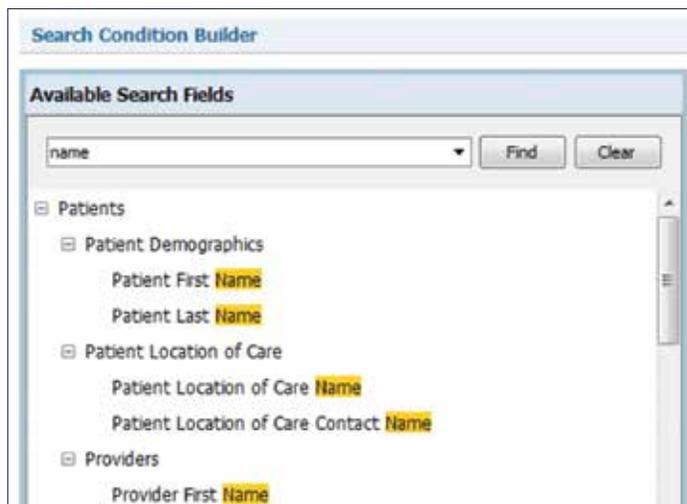
The screenshot illustrates the search results interface. On the left, a table titled 'Search Results' shows a list of patients. The 'Hart' entry is highlighted, and a mouse cursor is shown double-clicking on it. An arrow points from this entry to a detailed view of the patient's information on the right.

Patient Last Name	Patient First Name	Pat ID
Fuler	Bethany	MT
Hanson	Donna	URL
Hart	Shirley	PSS
Stafford	Kareem	67B
Rose	Teresa	2BM
Liu	Lindsey	8NB
Montgomery	Mathew	ZCP

The detailed view for Patient: Hart, Shirley shows the following information:

- Patient Information:** Patient ID: PSSLUQ, Date of Birth: 10/31/1942, Diagnoses:
- Navigation:** Patient Overview, Demographics, Diagnostics

- Find data fields using partial terms



- Multi-select from drop-down lists to quickly create "OR" conditions
- Search for Encounter Workflow History items, including a sample saved search
- The Search Conditions display is consistent between edit and view modes

IMPROVED EFFICIENCY

Spell-check Functionality

- Includes country-specific dictionaries for supported English locales (U.S., Canada, Australia, and New Zealand)

ENHANCEMENTS TO REPORTS & LETTERS

- Updated text on Doctor Letter from "Pacemaker Dependent" to "Pacing Dependent"

ENCYCLOPEDIA MANAGEMENT

Device Encyclopedia

- Quickly identify and remove unused devices that are not Paceart™-provided
- Merge manufacturer names that are not Paceart-provided with the Paceart-provided name (e.g., SJM -> St. Jude Medical)

DEVICE SUPPORT†

Import support has been added for selected models from the following device families:

Boston Scientific	ICD	CHARISMA™ EL, MOMENTUM™ EL, PERCIVA™ Mini, RESONATE™ EL, VIGILANT™ EL
	CRT-D	CHARISMA, MOMENTUM, RESONATE, VIGILANT
Medtronic	ICD	Primo MRI™, Mirro MRI™

†As of May 2018, not all models are available in every geography.

Brief Statement

Medtronic Paceart™ System

Intended Use: The Paceart system is intended for use as a 12-lead electrocardiograph, pacemaker artifact analyzer, and transtelephonic ECG receiving station. It also acts as a database for cardiac patients with or without pacemakers or implantable cardioverter defibrillators.

Contraindications: There are no known contraindications for the Paceart system.

IPGs, ICDs, and CRT ICDs

Indications: Implantable Pulse Generators (IPGs) are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Pacemakers are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include various degrees of AV block to maintain the atrial contribution to cardiac output and VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm. See device manuals for the accepted patient conditions warranting chronic cardiac pacing. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications. For the MR-conditional IPGs, a complete SureScan™ pacing system, which consists of an approved combination (see <http://www.mrisurescan.com>) MRI SureScan device with SureScan lead(s), is required for use in the MR environment. **Implantable cardioverter defibrillators (ICDs)** are indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. **Notes on some features in ICDs:** 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. **Additional notes for DR ICDs:** The use of the device has not been demonstrated to decrease the morbidity related to atrial tachyarrhythmias. The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 17%, and in terminating device classified atrial fibrillation (AF) was found to be 16.8%, in the VT/AT patient population studied. The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 11.7%, and in terminating device classified atrial fibrillation (AF) was found to be 18.2% in the AF-only patient population studied. CRT ICDs are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the following classifications: New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction \leq 35% and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration \geq 130 ms, left ventricular ejection fraction \leq 30%, and NYHA Functional Class II, NYHA Functional Class I, II, or III and who have left ventricular ejection fraction \leq 50% and atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure

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medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant. Some ICDs and CRT ICDs are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias. The RV Lead Integrity Alert (LIA) feature is intended primarily for patients who have a Medtronic ICD or CRT-D device and a Sprint Fidelis lead (Models 6949, 6948, 6931, and 6930), based on performance data. The RV LIA feature may not perform as well with a St. Jude Medical Riata™/Durata® lead or a Boston Scientific Endotak lead as it does when used with a Medtronic Sprint Fidelis lead. This is because different lead designs may have different failure signatures and conditions that may or may not be detected early by the RV LIA feature.

Contraindications: IPGs are contraindicated for concomitant implant with another bradycardia device and concomitant implant with an implantable cardioverter defibrillator. There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient's age and medical condition, however, may dictate the particular pacing system, mode of operation, and implant procedure used by the physician. Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate. Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms. Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance. Antitachycardia pacing (ATP) therapy is contraindicated in patients with an accessory antegrade pathway. **ICDs and CRT ICDs** are contraindicated in patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis; patients who have a unipolar pacemaker implanted, patients with incessant ventricular tachycardia (VT) or ventricular fibrillation (VF), and patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

Warnings/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. Additionally, for CRT ICDs, certain programming and device operations may not provide cardiac resynchronization. Use of the device should not change the application of established anticoagulation protocols. For MR-conditional IPG Systems, before performing an MRI scan, refer to the SureScan pacing system technical manual for additional information, patients and their implanted systems must be screened to meet the MRI Conditions of Use. Do not scan patients who do not have a complete SureScan pacing system consisting of an approved combination MRI SureScan device with SureScan lead(s); patients who have broken, abandoned or intermittent leads; or patients who have a lead impedance value of $<$ 200 Ω or $>$ 1,500 Ω .

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 arrhythmia episodes, and surgical complications such as hematoma, infection, inflammation, and thrombosis. An additional complication for ICDs and CRT ICDs is the acceleration of ventricular tachycardia. SureScan systems have been designed to minimize potential complications in the MRI environment. Potential MRI complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.

See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, MRI conditions for use, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

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

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