EXPANDED SEARCH CAPABILITY

- Dive deeper into your database with new Saved Advanced Searches to help track remote utilization, lost to follow-up, CRT pacing, percent pacing, tachy detections, ICM/ILR patients, AF burden, and infection control usage.
- Advanced Searches can now search and report on device data fields, including (but not limited to): programming, counters, percent pacing, and lead impedance.
- Multi-select options in basic searches for Device, Encounter, Appointment searches.

IMPROVED EFFICIENCY

- Improved handling of Visit IDs with EMR workflow: Visit ID values for appointments associated to an encounter will be updated automatically and documented in a workflow history.
- Tasks screen convenience and improved provider workflow: View attachments and export directly from the Tasks screen.
- Task Due Date and Priority can be set or updated along with task recipient when routing a task.
- Attaching files to an encounter allows selecting multiple files at once.
- Flow Sheets now display the Billable Encounter field from Encounter Info, and up to 10 encounters are loaded.
- EGM Waveforms will now display Mode Switch markers above the marker line.
ENHANCEMENTS TO REPORTS & LETTERS

- Doctor Letter reports show the Electronic Signature user and date/time instead of provider name for signed encounters (configurable in Administration -> User Preferences).

HL7 INTERFACE ENHANCEMENTS

- Export can be configured to create a single, combined PDF containing Paceart™ reports and all encounter PDF attachments.
- Appointments added or updated from HL7 will include a note on the Modify screen: “This appointment is linked to an external system.”

MANAGING YOUR SYSTEM

- Mainspring status and connectivity information are included on the System Health screen.
- A new Device Cleanup function helps find and replace user-created devices in the encyclopedia with Paceart-provided devices as new devices are added (Encyclopedia -> Manage ...).
ADDED DEVICE SUPPORT

- Optima 1.9 device support includes the Paceart Simplified Device Update 2 release, which includes device support for new Boston Scientific and Medtronic devices.
- Future device update releases will continue to update device support as new devices are released.
- Device update version is now listed in the About dialog under Help (e.g., Device Encyclopedia version 2).

IMPORTANT NOTES

- Optima 1.9 no longer includes the ability to record ECG data from any source (ECG module, USB modem, CardioVoice™, or TTM).
- ECG strips recorded in previous versions of Optima can still be viewed and included on reports.
- Upgrade to Optima 1.9 will clear the MR Compatibility field in the device encyclopedia for all Paceart-provided devices. This was done since the information provided was not specific to the customer region. If you update devices with MR Compatibility information applicable to your region after the Optima 1.9 upgrade, this information will be kept across future upgrades.
**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. Antiarrhythmia 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 antiarrhythmia 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 V-TAT 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 antiarrhythmia 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 ≤ 35% and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration ≥ 130 ms, left ventricular ejection fraction ≤ 30%, and NYHA Functional Class II. NYHA Functional Class I, II, or III and who have left ventricular ejection fraction ≤ 50% and atioventricular 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 medical therapy that is needed 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 indicated 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 bradyarrhythmia 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. Antiarrhythmia 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 or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset or device damage. Do not place transsthoracic 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 IPGs, 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 MR 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.

---

Medtronic and the Medtronic logo are trademarks of Medtronic. **Third party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company.**

**Medtronic**

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

UC202013502 EN ©2020 Medtronic.
Minneapolis, MN. All Rights Reserved.
Printed in USA, 04/2020

---