

Review Article

Perioperative Interrogation of St. Jude Cardiovascular Implantable Electronic Devices: A Guide for Anesthesiologists



Brett Cronin, MD^{*†}, Michael K. Essandoh, MD, FASE[†]

^{*}Department of Anesthesiology, University of California, San Diego, San Diego, CA

[†]Cardiovascular Anesthesiology, Department of Anesthesiology, The Ohio State University Medical Center, Columbus, OH

Feelings of trepidation or uncertainty regarding cardiovascular implantable electronic devices (CIEDs) in the perioperative period can often be mitigated by a thorough knowledge of societal recommendations, recommended management options, and familiarity with CIEDs. Given that effective interpretation of an interrogation report is vital to determining perioperative management options and applying societal recommendations, the creation and interpretation of St. Jude CIED interrogation reports are discussed. In an effort to increase the familiarity with St. Jude transvenous CIEDs amongst anesthesiologists, basic programming of a St. Jude pacemaker and implantable cardioverter defibrillator (ICD) also are described.

Published by Elsevier Ltd.

Key Words: pacemaker; cardiovascular implantable electronic device; implantable cardioverter defibrillator; anesthesia; device programming; St. Jude Medical; interrogation

AS CARDIOVASCULAR implantable electronic device (CIED) technology continues to improve and indications for implantation expand, the likelihood of encountering a patient with a CIED in the perioperative period will increase. Despite their pervasiveness, the prospect of managing these devices frequently is associated with trepidation and uncertainty amongst anesthesiologists. However, possessing a thorough knowledge of current societal recommendations, understanding perioperative management options, and familiarity with CIEDs can mitigate these feelings.

Effectively interpreting a CIED interrogation report is pivotal to determining perioperative management options, and further guides the application of societal recommendations to perioperative patient care. As a result, some tertiary institutions have developed CIED teams that provide

guidance for the management of patients with CIEDs undergoing surgery; however, hospitals with limited resources may not have designated CIED teams. When anesthesiologists in centers without CIED teams encounter patients with CIEDs, device representatives are often consulted, which may delay surgery. It is important to note that device representatives cannot provide independent care but rather only provide support to the requesting physician. Therefore, the medico-legal responsibility rests with the requesting physician. Further complicating anesthesia care is the variety of CIEDs available for commercial use requiring knowledge on the intricacies of each manufacturer's devices. Educating anesthesiologists about CIED interrogation for each manufacturer may avoid the limitations above. Therefore, this series will review CIED interrogations of the four most common device companies in the United States (ie, St. Jude Medical, Boston Scientific, Medtronic, and Biotronik) one at a time.

To start, the production of a St. Jude Medical (St. Paul, MN) interrogation report (ie, the device programmer) and basic

¹Address reprint requests to Brett Cronin, MD, Department of Anesthesiology, University of California, San Diego, UCSD Medical Center, 200 W Arbor Drive #8770, San Diego, CA 92103.

E-mail address: bcronin@ucsd.edu (B. Cronin).

Table 1

St. Jude Medical Devices - Potential Responses to Magnet Application.

Pacemakers	
Device Setting	Response to Magnet Application
Battery test (default)	Asynchronous pacing at 100 bpm (98.6 bpm in older models) with the rate gradually decreasing to 86.3 at ERI
OFF	NO response to magnet application
Data collection	NO change in pacemaker settings but the device collects event snapshots
Data collection and battery test	Magnet application of 2 seconds results in no change in pacemaker settings but the device stores an electrogram. Magnet application of ≥ 5 seconds the battery test mode results in asynchronous pacing

Defibrillators	
Device Setting	Response to Magnet Application
Normal (default)	Tachyarrhythmia therapies are disabled and pacemaker settings are left unaltered
OFF	Magnet application has NO effect on tachyarrhythmia therapies or pacemaker settings

Abbreviations: bpm, beats per minute; ERI, elective replacement indicator.

programming of a CIED will be discussed. Much of the information presented can be gleaned from textbooks and St. Jude manuals; however, this review attempts to concisely present the material relevant to the perioperative period that is contained within lengthy texts. While a precedent has already been set in some large academic centers for anesthesiology-run perioperative CIED services, the authors are not advocating for all anesthesiologists to assume total responsibility for CIEDs, but rather suggest that basic programming can be completed by anesthesiologists after some formal training and that better patient care will come from increased knowledge and familiarity with CIED interrogation.^{1,2}

Cardiovascular Implantable Electronic Devices and Societal Recommendations

In order to interpret a device interrogation report and preoperatively prepare a patient with a CIED for surgery, one must have a basic understanding of devices, the North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group Generic code, the North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group Generic Defibrillator

code, and the American Society of Anesthesiologists (ASA) and Heart Rhythm Society (HRS) recommendations.^{3–7} Given that the basics of CIEDs and perioperative management recommendations have been extensively published, they will not be repeated in detail here, but rather readers are encouraged to review this information as needed.^{8–19} However, specific key points as they relate to the perioperative management of St. Jude pacemakers and defibrillators will be discussed.

St. Jude Medical CIEDs

In order to determine the potential responses to magnet application (Table 1), contact the company representative (1-800-722-3423 or 1-800-PACE-ID), or obtain an interrogation with the appropriate device programmer (ie, Merlin

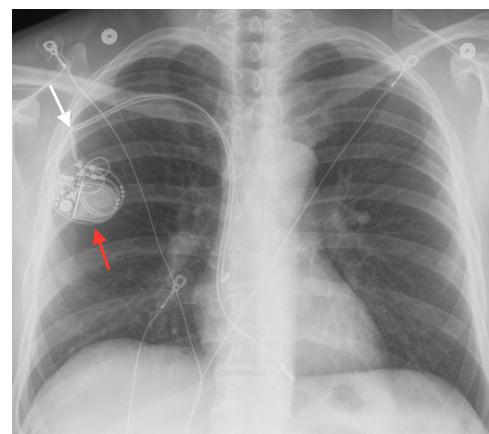


Fig 1. Chest radiograph - an example of a St. Jude transvenous dual chamber pacemaker (Assurity with magnetic resonance imaging compatible leads) with the generator in the right pectoral location (red arrow) and leads in the right atrium and right ventricle, as well as a potential site of lead damage (white arrow).

Table 2

St. Jude Medical Devices

St. Jude CIEDs	
Pacemaker	Accent, Accent RF, Assurity, Endurify, Identity, Microny, Zephyr
ICD	Current, Ellipse, Fortify Assura, Fortify
CRT-P	Allure, Quadra Allure, Anthem
CRT-D	Promote, Quadra Assura, Unify Assura, Unify Quadra, Unify

Abbreviations: CIED, cardiovascular implantable electronic devices; CRT-D, cardiac resynchronization therapy - defibrillator; CRT-P, cardiac resynchronization therapy - pacemaker; ICD, implantable cardioverter defibrillator.

Patient Care System); a practitioner must first correctly identify the device (Table 2).¹⁵ In the absence of patient history, a wallet card, or medical records, a chest radiograph can often be used to identify the device manufacturer.¹³ Given the variability in generator placement (ie, left versus right pectoral region), a chest radiograph also can be useful to determine the feasibility of intraoperative interrogation or magnet application days prior to a procedure. The location of the generator may influence a practitioner's perioperative management (ie, magnet application versus interrogation) and facilitate coordination with a CIED team member prior to the day of surgery. In addition, a chest radiograph may identify potential causes of device malfunction (Fig 1).

Merlin Patient Care System

Before discussing the interpretation of a report or programmable features that are applicable to anesthesiologists, it is important to become familiar with the Merlin Patient Care System (PCS) (St. Jude Medical, St. Paul, MN). The Merlin PCS is a portable programming system specifically designed to

interrogate, program, display information, and test St. Jude Medical implantable devices and leads through a 15-inch touch screen display. Therefore, the Merlin PCS cannot be used to interrogate devices manufactured by other companies. In addition to communicating with St. Jude devices via a telemetry wand, the Merlin PCS is capable of radiofrequency (RF) communication within 6 feet of RF capable implanted devices (eg, Accent RF and Assurity) after an initial connection is made with inductive telemetry and the antenna is connected.²⁰ While familiarity with the capabilities of the Merlin PCS can be lifesaving, one must first be able to turn the device on.

The power cable, which is frequently in the storage compartment with the telemetry wand in the top right of the programmer, inserts into the power receptacle on the back left. Once connected, locate the on/off switch on the left side and then open the screen display via the latch on the front right. The telemetry wand can be connected via the port located in the storage compartment or the alternate port on the right side of the Merlin PCS. Place the wand over the St. Jude CIED and select interrogate on the touch screen display (Fig 2). Interrogation of a device should produce a surface

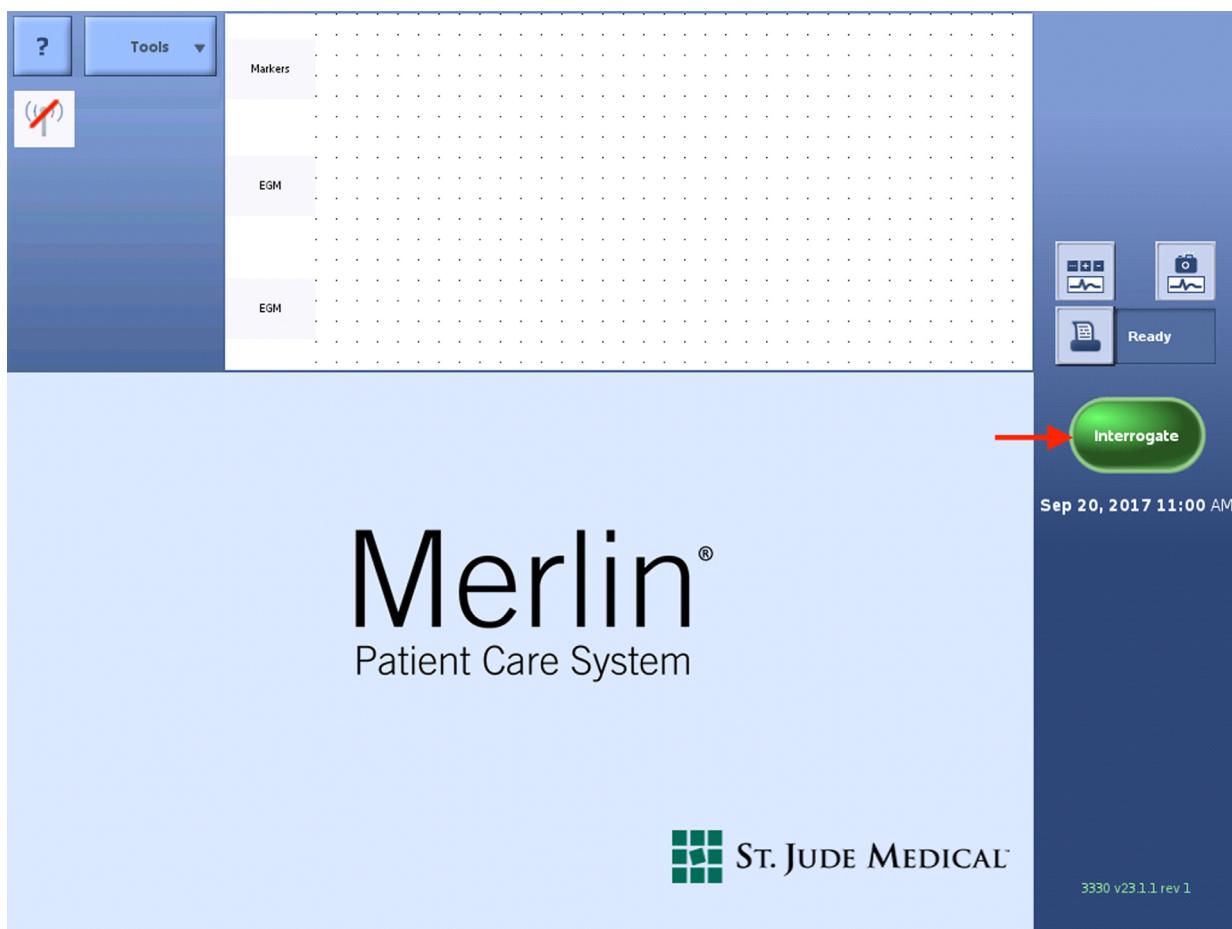


Fig 2. Merlin Patient Care System screenshot displaying the interrogate button (red arrow).

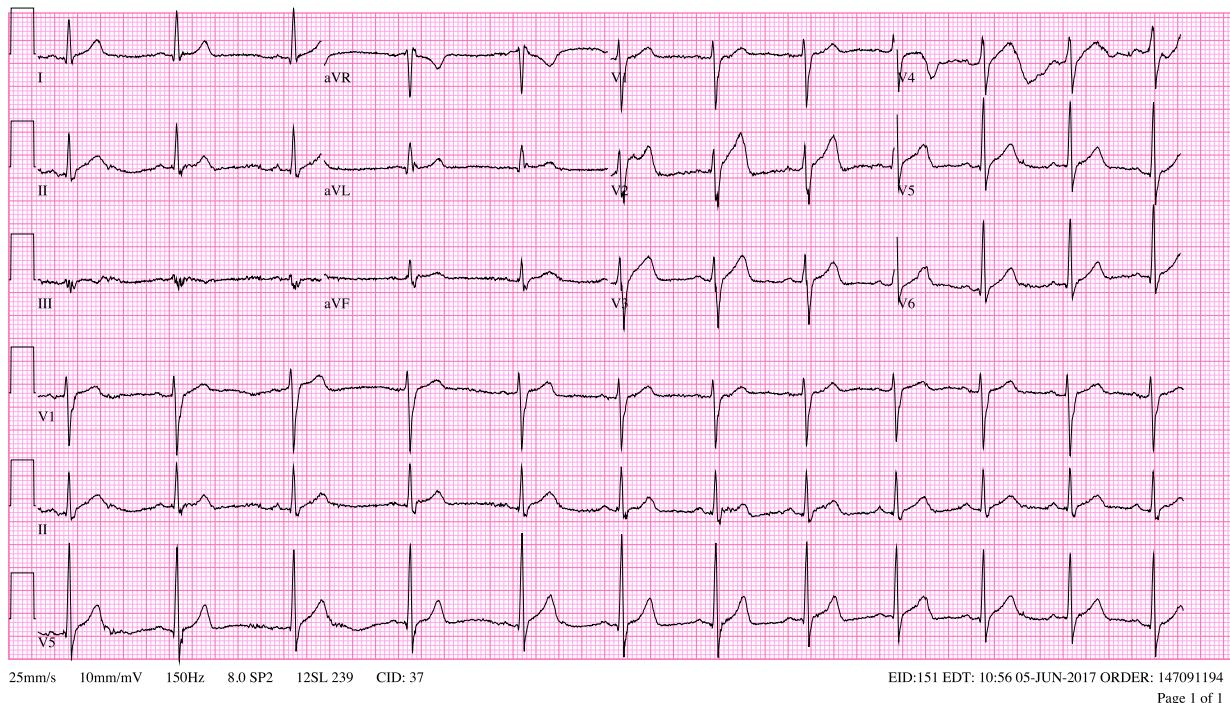


Fig 3. Twelve-lead ECG from the patient/device displayed in Figure 1 demonstrating sinus rhythm with sinus arrhythmia.

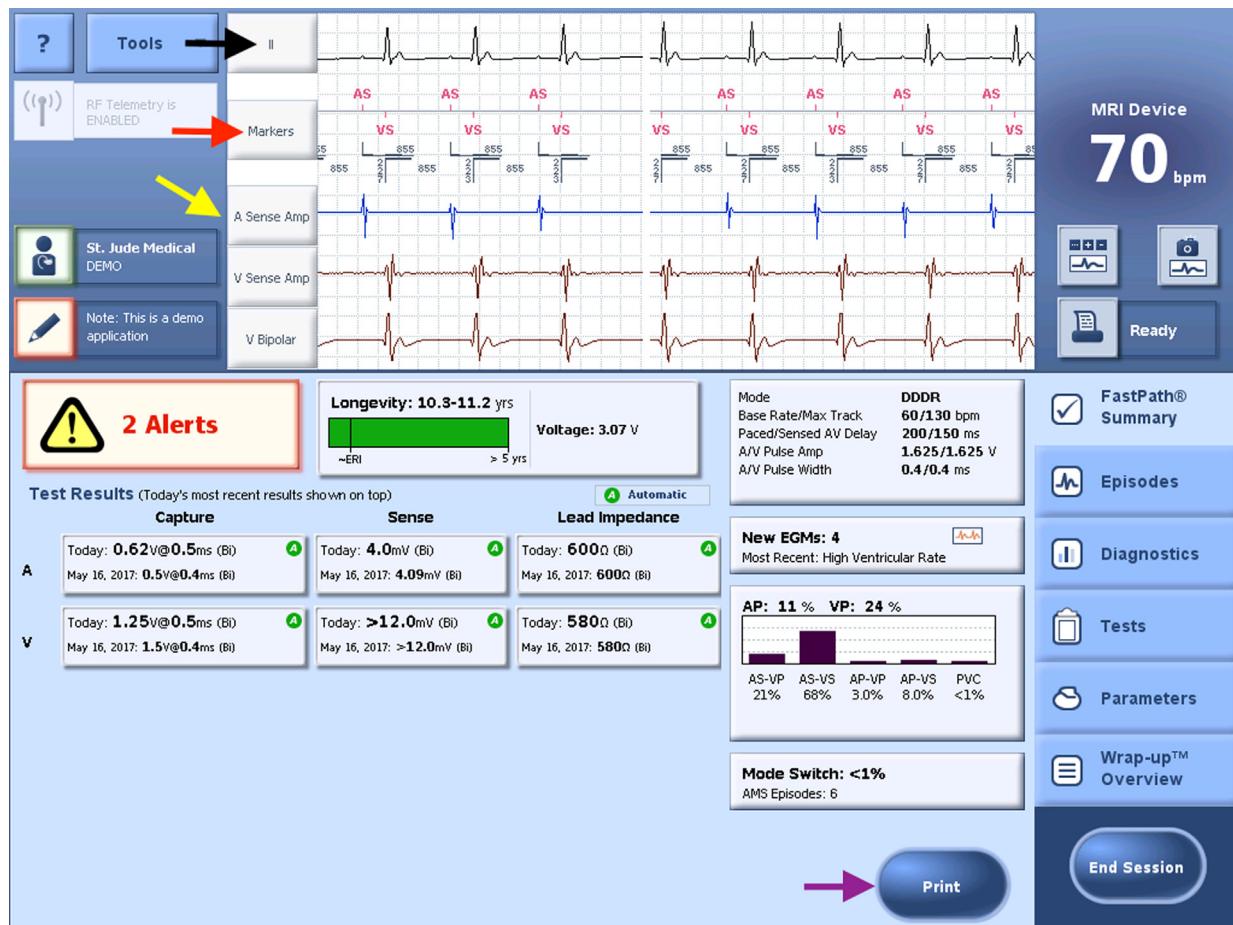


Fig 4. Merlin Patient Care System summary screen from a dual-chamber pacemaker (Assurity) displaying the surface ECG lead II (black arrow), marker channel (red arrow), electrograms (yellow arrow), and print button (purple arrow).

electrocardiogram (ECG) that resembles the patient's pre-operative 12-lead ECG (Fig 3), a marker channel, and electrograms (Fig 4). While the information contained in an interrogation report can be obtained by navigating the touch screen display, an interrogation report should be printed (Fig 4) to document the device settings, which may facilitate subsequent interrogations and programming.

Interrogation Report (St. Jude Assurity Pacemaker)

The data conveyed in a device interrogation report is vast. Although this information is vital to industry representatives, credentialed programmers, electrophysiologists, and those advanced programmers certified by or testamurs of the International Board of Heart Rhythm Examiners (IBHRE), it

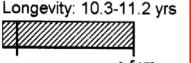
A

ST. JUDE MEDICAL

**DEMO PATIENT
Assurity MRI™ 2272 Pacemaker DEMO**

**Sep 13, 2017
10:29 am
In-Clinic**

FastPath® Summary ⚠ 2 Alerts Page 1 of 1

Battery Longevity: 10.3-11.2 yrs 	Implant Date: Sep 8, 2016
Voltage Magnet Rate Battery Current Remaining Capacity to ERI	3.07 V 100.0 ppm 9 uA >95%

Test Results Sep 13, 2017 ⌚ Automatic

Capture	Sense	Lead Impedance
A 0.625V @ 0.5ms (Bi) 4 0.5V @ 0.4ms (Bi) May 16, 2017	4.0mV (Bi) 4 4.1mV (Bi) May 16, 2017	600 Ω (Bi) 4 600 Ω (Bi) May 16, 2017
V 1.25V @ 0.5ms (Bi) 4 1.5V @ 0.4ms (Bi) May 16, 2017	>12.0mV (Bi) 4 >12.0mV (Bi) May 16, 2017	580 Ω (Bi) 4 580 Ω (Bi) May 16, 2017

Parameters

Mode	DDDR
Base Rate	60 bpm
Max Track Rate	130 bpm
Paced AV Delay	200 ms
Sensed AV Delay	150 ms

Capture & Sense

A	A
ACap® Confirm/V. AutoCapture	On
Pulse Amplitude	1.625 V 4
Pulse Width	0.4 ms
AutoSense	Off
Sensitivity (Safety Margin)	0.5 mV (7:1)
V	V
On	On
1.625 V 4	1.625 V 4
0.4 ms	0.4 ms
Off	Off
2.0 mV (6:1)	2.0 mV (6:1)

Diagnostics Summary Since Sep 8, 2016 Episodes Summary Since Sep 8, 2016

AP	11 %	Counts	EGMs
VP	24 %	6	6

AMS Episodes	6
Mode Switch	<1%
AT/AF Burden	<1%

Note
This is a demo application.

Alerts ⚠ Device cybersecurity upgrade is available
High Ventricular Rate detected (!)

► Manual-programmed ↳ Auto-programmed

Assurity MRI™ 2272 Pacemaker (DEMO pr14.07.75)
Merlin® PCS (#26664 3330 v23.1.1 rev 1)

FastPath® Summary Page 1 of 1
Sep 13, 2017 10:29 am

Fig 5. Selected pages—(A) FastPath Summary and (B) Parameters—from a sample interrogation report of an Assurity pacemaker. Important information—as described in the manuscript—is highlighted by red boxes.

B
DEMO PATIENT
Assurity MRI™ 2272 Pacemaker DEMO
Sep 13, 2017
10:29 am
In-Clinic

Parameters

Page 1 of 2

Patient	Date of Birth EF %	Aug 15, 1948 30 %	Indications for Implant	SSS			
Device	Manufacturer	Model	Serial	Implant Date			
Pacemaker	St. Jude Medical	Assurity MRI™ 2272	DEMO	Sep 8, 2016			
A Lead	St. Jude Medical	Tendril MRI™ LPA1200M / 46 cm		Sep 8, 2016			
V Lead	St. Jude Medical	Tendril MRI™ LPA1200M / 52 cm		Sep 8, 2016			
Additional Cardiac Hardware - Not Present							
Basic Operation		Refractories & Blanking					
Mode	DDDR	PVARP	275 ms				
V. Triggering	Off	Post-Vent. Atrial Blankning	150 ms				
Magnet Response	Battery Test	Rate Responsive PVARP/V Ref	High				
V. Noise Reversion Mode	DOO	Shortest PVARP/V Ref	175 ms				
Sensor	On	A/V Pace Refractory	190/250 ms				
Threshold (Measured Avg.)	Auto (+0.0) (2.0)	A/V Sense Refractory	93/250 ms				
Slope (Measured Auto)	Auto (+2) (8)	Ventricular Blankning	Auto				
Max Sensor Rate	130 bpm	Ventricular Safety Standby	On				
Reaction Time	Fast	PVC Response	Off				
Recovery Time	Medium	PMT Response	Atrial Pace				
		PMT Detection Rate	110 bpm				
Rates							
Base Rate	60 bpm	AT/AF Detection & Response					
Rest Rate	Off	Auto Mode Switch	DDIR				
Max Sensor Rate	130 bpm	A. Tachycardia Detection Rate	180 bpm				
Max Track Rate	130 bpm	AMS Base Rate	80 bpm				
Hysteresis Rate	Off	AF Suppression™	Off				
2:1 Block Rate	216 bpm						
Delays							
Paced AV Delay	200 ms						
Sensed AV Delay	150 ms						
Rate Responsive AV Delay	Medium						
Shortest AV Delay	100 ms						
Ventricular Intrinsic Preference (VIP®)	On						
VIP® Extension	200 ms						
Search Interval	1 min						
Search Cycles	1						
Negative AV Hysteresis/Search	Off						
Capture & Sense							
ACap® Confirm/V. AutoCapture	A	V					
Backup Pulse Configuration	On	On					
Search Interval	Bipolar	Bipolar					
Paced/Sensed AV Delay	8 hours	8 hours					
Pulse Amplitude	50/25 ms	50/25 ms					
Pulse Width	1.625 V	1.625 V					
AutoSense	0.4 ms	0.4 ms					
Sensitivity (Safety Margin)	Off	Off					
	0.5 mV (7.8:1)	2.0 mV (6:1)					
Last Programmed: May 16, 2017 10:18 am	Bold values were changed this session (See Wrap-up™ Overview report for details)			► Manual-programmed Automatic			
Parameters that are "n/a" are not shown				↳ Auto-programmed			
Assurity MRI™ 2272 Pacemaker (DEMO pr14.07.75) Merlin® PCS (#26664 3330 v23.1.1 rev 1)							
Parameters Page 1 of 2 Sep 13, 2017 10:29 am							

Fig 5. (continued)

is not necessary for anesthesiologists to interpret all the information prior to a routine anesthetic. In fact, much of the basic information required is conveyed on two pages of the report—the FastPath Summary and Parameters pages (Figs 5A and B).

Patient/Device Identification

First, it is important to confirm that the report is correctly associated with the patient. The patient information as well as

the type of device can be found at the top of the FastPath Summary (Fig 5A).

Indication

Additional patient specific information such as the indication for implantation and last programmed date is located on the Parameters page (Fig 5B). The indication for implantation (ie, pacemaker dependence), device type (ie, potential magnet responses), magnet rate, and mode aid the practitioner in

formulating a tentative perioperative plan; however, additional information is required. For example, in this demo patient, the indication for implantation is sick sinus syndrome and does not display a paced rhythm on preoperative 12-lead ECG (Fig 3). Therefore, the percentage paced—found under diagnostics summary on the FastPath Summary (Fig 5A)—can be used to guide perioperative management. A high percentage of atrial- or ventricular-paced events combined with a procedure that possesses an elevated risk of electromagnetic interference favors asynchronous pacing via programming or magnet application.

Magnet Application

Magnet application in St. Jude pacemakers merits special attention. St. Jude devices have a programmable response to magnet application (Table 1). Therefore, the magnet response must be confirmed prior to a practitioner relying upon magnet application for asynchronous pacing in the perioperative period. This important piece of information, located on the Parameters page under basic operation (Fig 5B), also is

dependent upon the interrogation report being recent and accurate. It is recommended by the HRS that a pacemaker be interrogated within 12 months and ICD/CRT (cardiac resynchronization therapy) devices within 6 months of elective surgery.⁹ Therefore, the date the interrogation report was generated, located at the top right of the FastPath Summary (Fig 5A) or Parameters page (Fig 5B), should be considered when formulating a perioperative management plan in the days prior to an elective procedure.⁹

Assuming magnet application results in asynchronous pacing, the heart rate response to a magnet also is dependent upon battery life (Table 1). Consequently, the magnet rate as well as the battery life should be confirmed on the FastPath Summary page (Fig 5A) and compared with the HRS recommendation—battery longevity greater than 3 months.⁹ While it would be preferable for the generator to be recently implanted and battery life long (ie, > 3 months), leads are preferably mature at the time of surgery; the ASA/HRS recommends that leads be mature (ie, > 3 months old) prior to an elective procedure. Information regarding the implant date of leads as well as the generator can be located on the Parameters page (Fig 5B).

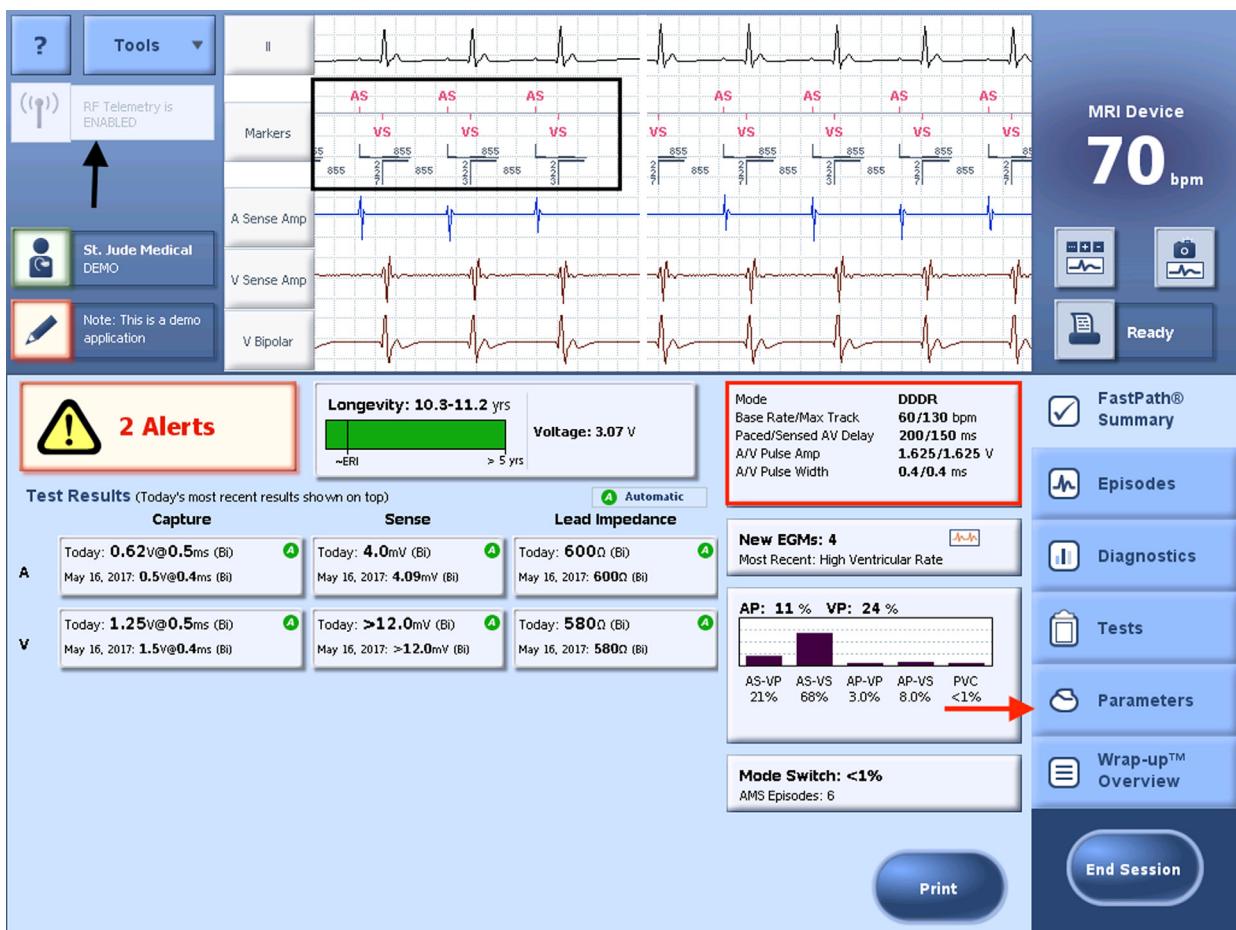


Fig 6. Merlin Patient Care System summary screen from a dual chamber pacemaker (Assurity) highlighting the RF telemetry status (black arrow), marker channel (black box), mode settings (red box), and parameters (red arrow). AS, atrial-sensed event; RF, radiofrequency; VS, ventricular-sensed event.

Pacing Threshold, Lead Impedance, and Sensitivity

While knowledge of lead impedances, sensitivities, and thresholds may not seem to apply to anesthesia, they impact lead function and capture. Hence, a basic understanding is necessary. In fact, the HRS and ASA recommend that an adequate pacing threshold safety margin be documented prior to proceeding with elective surgery.⁹ Information related to lead impedance, capture threshold, and sensitivity can be found on the FastPath Summary page as well as the Parameters page (Figs 5A and B).

Pacing Threshold

The capture threshold, or threshold, is the least amount of electrical stimulus required to consistently depolarize the myocardium and result in contraction. The threshold is typically displayed as a voltage threshold in volts (V) because permanent pacemakers have a battery with a limited voltage. The threshold also is displayed with a specific pulse width in milliseconds (ms)—typical pulse

widths are 0.4 to 0.6 ms. Most modern pacemakers are able to automatically assess the threshold and optimize the voltage and/or pulse width to maximize the battery life of the device. With autocapture enabled in this Assurity dual-chamber pacemaker, the thresholds are constantly being assessed and the output being adjusted accordingly to maintain a safety margin in the right atrium and ventricle.^{21,22} For example, in this demo, the automatic bipolar pacing threshold is 0.625 V at 0.5 ms in the atrial lead and 1.25 V at 0.5 ms in the ventricular lead (Fig 5A under test results). Therefore, the pacing voltage for this patient is programmed at 1.625 V at 0.4 ms for both the atrial and ventricular leads, which is displayed under capture and sense. These voltages are well above the lowest possible pacing threshold but not excessively high, which would be at the cost of battery life. In general, commonly accepted chronic threshold measurements (at a pulse width of 0.5 ms) are < 3.0 V.¹² In older pacemakers without autocapture, which is designated as an "A" near the pulse amplitude, a fixed output would be programmed (eg, 2.0 V at 0.4 ms). This is important because when a fixed output is programmed an acceptable safety

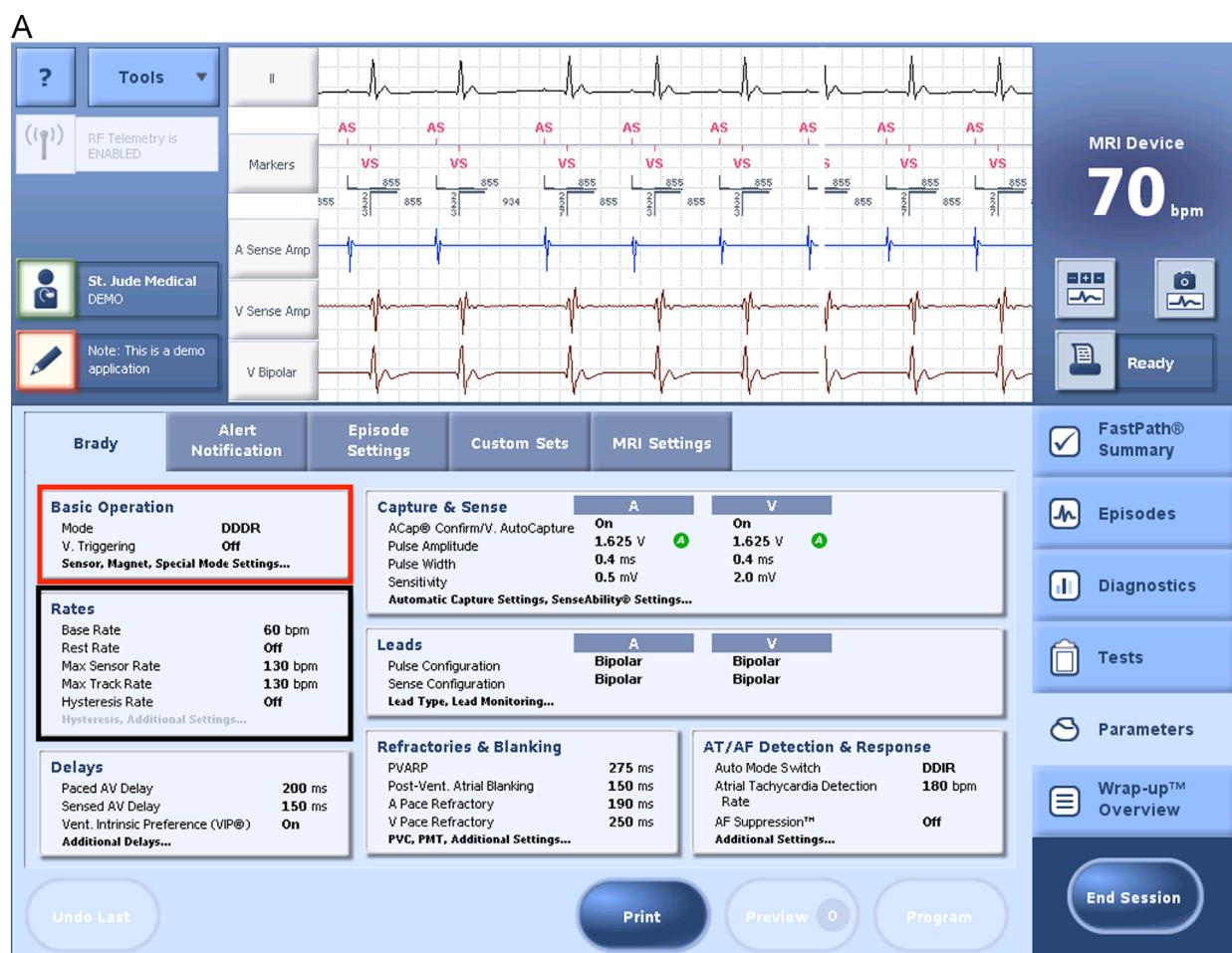


Fig 7. (A) Merlin Patient Care System parameters screen from a dual chamber pacemaker (Assurity) highlighting the basic operation tab (red box) and rates tab (black box). (B) Merlin Patient Care System parameters screen from a dual chamber pacemaker (Assurity) displaying the basic operation expanded tab, which includes the current mode (red box), magnet response (black box), rate adaption sensor (black arrow), and program button (red arrow).

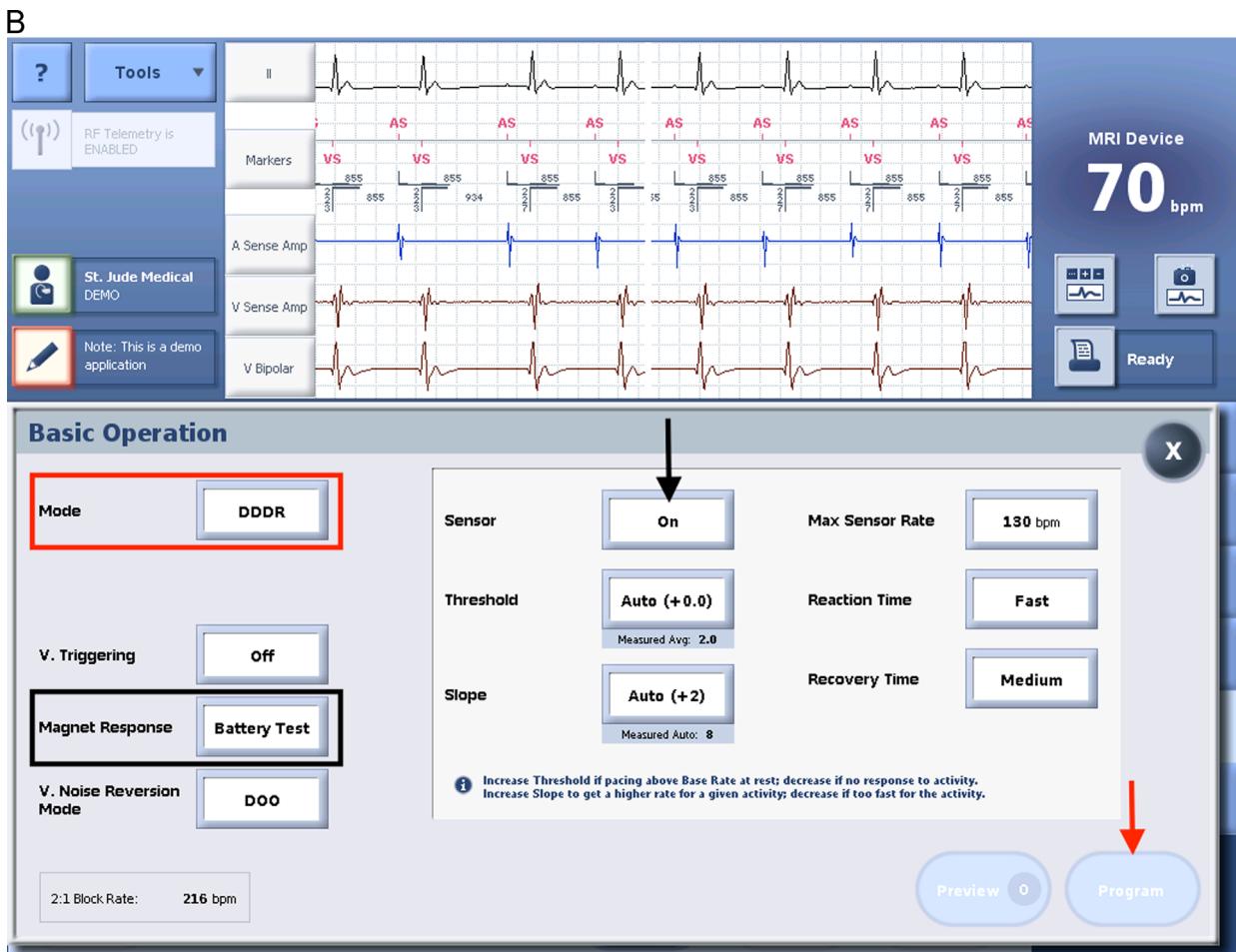


Fig 7. (continued)

margin needs to be maintained in order to guarantee capture. An accepted safety margin for a fixed output to threshold is 2:1.¹²

Lead Impedance

Closely related to voltage by Ohm's Law ($V = IR$), where V = Voltage, I = current, and R = resistance, is the concept of impedance or resistance. While slightly counterintuitive, the ideal impedance is actually in the range of 300 to 1,200 ohms (when measured at a pulse width of 0.5 ms). Low impedance would result in wasted current or signify a lead insulation breach. Alternatively, elevated impedance would make pacing impossible due to an inability to capture the myocardium or signal the presence of a lead fracture or poor connection. This demo patient demonstrates acceptable impedances in both the bipolar atrial and ventricular leads at 600 and 580 ohms, respectively (Fig 5A under test results).¹²

Sensitivity

A device's sensitivity is its ability to detect the patient's intrinsic rhythm. This directly affects the appropriate function of the pacemaker and pacemaker inhibition due to

electromagnetic interference. The amplitude, or total height (ie, positive and negative deflection), of the sensed complex (eg, QRS) is denoted in millivolts (mV). Overall, the greater the amplitude, the more likely the patient's own complex is to be sensed. Acceptable chronic measurements for a P wave are > 1.5 mV and for an R wave > 4 mV. This demo patient displays acceptable sensitivities of both the bipolar atrial (4.0 mV) and ventricular leads (> 12 mV) under test results (Fig 5A).

The level detector of the pacemaker can then be programmed to be less sensitive (ie, block the recognition of weaker signals) or more sensitive (ie, allow weaker signals to be detected).^{12,23} Excessive sensitivity may result in inappropriate pacemaker inhibition. This Assurity pacemaker has an atrial sensitivity of 0.5 mV, which offers a safety margin of almost 8:1, and a ventricular sensitivity of 2.0 mV, which results in a safety margin of 6:1 (Fig 5A under capture and sense).¹²

Additional Parameters

As previously mentioned, device interrogation reports contain a large amount of information regarding device function and modifiable parameters. For example, sensitivity, pulse

amplitude, refractory periods, blanking periods, delays, hysteresis, and mode switching are all modifiable. While these variables are important to the function of a CIED they either do not commonly influence perioperative management and/or should not be modified by practitioners with only basic education. Therefore, even in emergency situations these parameters should be deferred to practitioners with advanced training or certification.

Basic Programming (St. Jude Assurity Pacemaker)

Familiarity with basic programming of a St. Jude pacemaker can be educational for anesthesiologists. After some formal education and institution support, basic programming (ie, mode, rate, rate adaption, and magnet response changes) by anesthesiologists also could be useful in situations where a CIED team member or device representative is not

A

ST. JUDE MEDICAL®

DEMO PATIENT
Ellipse™ DR 2311-36 ICD DEMO

Sep 18, 2017
5:52 am
In-Clinic

FastPath® Summary

7 Alerts

Battery
Longevity: 6.4-6.9 yrs
Implant Date: Mar 27, 2016

Test Results Sep 18, 2017

Automatic

Capture	Sense	Lead Impedance
A 1.0V @ 0.5ms (Bi) A 0.875V @ 0.5ms (Bi) Jul 20, 2017	4.0mV (Bi) A 4.0mV (Bi) Jul 20, 2017	600 Ω (Bi) A 580 Ω (Bi) Aug 19, 2017
V 1.0V @ 0.5ms (Bi) A 1.0V @ 0.5ms (Bi) Jul 20, 2017	>12.0mV (Bi) A >12.0mV (Bi) Jul 20, 2017	580 Ω (Bi) A 580 Ω (Bi) Aug 19, 2017
HV		42 Ω (RV to SVC & Can) A 41 Ω (RV to SVC & Can) Aug 19, 2017

Parameters

Mode	DDDR	Zone Configuration	VT-1	VT-2	VF
Base Rate	65 bpm	Detection Criteria	150 bpm	181 bpm	214 bpm
Max Track Rate	110 bpm	Therapy (ENABLED)	Monitor	15.0 J	ATP x1
Paced AV Delay	200 ms		25.0 J		15.0 J
Sensed AV Delay	150 ms			30.0 J	30.0 J
				36.0 J x2	36.0 J x4

Capture & Sense

A	V
ACap® Confirm/V. AutoCapture On	On
Pulse Amplitude 2.0V A	1.25V A
Pulse Width 0.5 ms	0.5 ms
AutoSense On	On
Sensitivity Auto A	Auto A

Diagnostics Summary Since Sep 23, 2016

VT/VF Episodes: 4 Since Jul 20, 2017

VT-1	VT-2	VF
Episodes 0	2	2
ATP Delivered 0	0	0
Shocks Delivered 2	0	0

SVT Episodes: 0
Non-sustained Episodes: 0

Note
This is a demo application

Alerts

- SecureSense™ is On, and it inhibited therapy due to V lead noise.
(Patient Notifier triggered Aug 19, 2017 at 6:21 am)
- SecureSense™ is On, and it detected V lead noise and inhibited therapy until timeout expired.
(Patient Notifier triggered Aug 19, 2017 at 6:21 am)
- SecureSense™ is On, and it detected Non-sustained V Oversensing

► Manual-programmed ► Auto-programmed

More Alerts on next page

Ellipse™ DR 2311-36 ICD (DEMO pr12.0E.94)
Merlin® PCS (#26664 3330 v23.1.1 rev 1)

FastPath® Summary Page 1 of 2
Sep 18, 2017 5:52 am

Fig 8. Selected pages—(A) FastPath Summary and (B) Parameters—from a sample interrogation report of an Ellipse ICD. Important information—as described in the manuscript—is highlighted by red boxes.

B


DEMO PATIENT
Ellipse™ DR 2311-36 ICD DEMO
Sep 18, 2017
5:52 am
In-Clinic

Parameters

Page 1 of 4

Patient		Indications for Implant		
Date of Birth	Feb 26, 1946	Atrial Fibrillation (AF), Congestive Heart Failure, Dilated Cardiomyopathy		
EF %	35 %	(CHF/DCM), Ischemic Cardiomyopathy		
Device	Manufacturer	Model	Serial	Implant Date
ICD	St. Jude Medical	Ellipse™ DR 2311-36	DEMO	Mar 27, 2016
A Lead	St. Jude Medical	OptiSense® 1999		Mar 27, 2016
V Lead	St. Jude Medical	Riata i 1590		Mar 27, 2016
Basic Operation				
Mode	DDDR	Refractories & Blanking		
Magnet Response	Normal	PVARP	275 ms	
V. Noise Reversion Mode	Pacing Off	Post-Vent. Atrial Blanking	60 ms	
Episodal Pacing Mode	DDI	Rate Responsive PVARP/V Ref	Low	
Sensor	On	Shortest PVARP/V Ref	225 ms	
Threshold (Measured Avg.)	Auto (+0.0) (2.0)	A/V Pace Refractory	190/250 ms	
Slope	8	A/V Sense Refractory	93/125 ms	
Max Sensor Rate	110 bpm	Ventricular Blanking	52 ms	
Reaction Time	Fast	Ventricular Safety Standby	On	
Recovery Time	Medium	Arrhythmia Unhiding	3 intervals	
		PVC Response	Off	
		PMT Response	Atrial Pace	
		PMT Detection Rate	110 bpm	
Rates				
Base Rate	65 bpm	AT/AF Detection & Response		
Rest Rate	Off	Auto Mode Switch	DDIR	
Max Sensor Rate	110 bpm	A. Tachycardia Detection Rate	180 bpm	
Max Track Rate	110 bpm	AMS Base Rate	80 bpm	
Hysteresis Rate	Off	AF Suppression™	Off	
2:1 Block Rate	164 bpm			
Delays				
Paced AV Delay	200 ms			
Sensed AV Delay	150 ms			
Rate Responsive AV Delay	Medium			
Shortest AV Delay	100 ms			
Ventricular Intrinsic Preference (VIP®)	Off			
Negative AV Hysteresis/Search	Off			
Capture & Sense				
ACap® Confirm/V. AutoCapture	A	V		
Backup Pulse Configuration	On	On		
Search Interval	Bipolar	Bipolar		
Paced/Sensed AV Delay	8 hours	8 hours		
Pulse Amplitude	2.0V	1.25V		
Pulse Width	0.5 ms	0.5 ms		
AutoSense	On	On		
Sensitivity	Auto	Auto		

Last Programmed: Mar 26, 2017 4:30 pm Bold values were changed this session (See VWrap-up™ Overview report for details)
 Parameters that are "n/a" are not shown Manual-programmed Automatic
 Auto-programmed

Ellipse™ DR 2311-36 ICD (DEMO pr12.0E.94)
 Merlin® PCS (#26664 3330 v23.1 rev 1)

Parameters Page 1 of 4
 Sep 18, 2017 5:52 am

Fig 8. (continued)

immediately available. In order to interrogate and program a device, follow the previously described steps to turn on the Merlin PCS and connect with the CIED (Figs 2 and 4).

Patient/Device Identification, Capture Threshold, Impedance, and Sensitivity

Once a connection has been established, the summary page (Fig 4) will display the information contained in an

interrogation report as previously discussed (ie, identification, capture threshold, impedance, sensitivity, etc). Additional information displayed includes the RF telemetry status, which may be extremely useful if the patient is positioned or draped such that the wand is unable to be placed over the generator, as well as a live surface electrogram and marker channel. The marker channel communicates to the practitioner if the patient is atrial- or ventricular-paced. Alternatively, the device may be sensing native atrial or ventricular events.

Magnet Response, Mode, and Programmed Rate

Given the frequent reliance on magnet application in the perioperative period, the ability to interrogate and reprogram a St. Jude device is particularly important. As previously stated, the response to magnet application in St. Jude devices is programmable (Table 1); therefore, in order to assure asynchronous pacing with magnet application on the day of surgery, one would require a recent interrogation report (Fig 5B). Alternatively, asynchronous pacing can be confirmed on the day of surgery via magnet application or the Merlin PCS (Fig 7B).

A magnet response, mode change (eg, asynchronous pacing), or rate change can be accomplished by selecting the displayed mode on the touch screen display (Fig 6). An alternative route is following prompts under the parameters tab located in the right lower corner of the screen, followed by the basic operation and rates tab (Figs 7A and B). Please note that after a rate, mode, or magnet response change is made one must program the device (Fig 7B) and confirm the change on the surface ECG and marker channel.

Rate changes can be used to investigate underlying activity and thus determine pacemaker dependency by temporarily

reprogramming a pacemaker to VVI at 30 bpm (or lowest programmable rate) or to augment cardiac output intraoperatively through an increase in heart rate.

Rate Adaptation

In addition to basic rate or mode changes, anesthesiologists commonly request that rate adaptation, a pacemaker's ability to automatically change the heart rate in response to certain monitored parameters, be disabled in the perioperative period.⁶ Continuation of rate adaptive therapy in the perioperative period may result in inappropriate heart rate changes.^{16,24,25} Therefore, the authors and anesthesiologists who follow the ASA and HRS recommendations prefer that rate adaptation be disabled.⁹ This can be accomplished by changing the mode (eg, DDDR to DDD) or turning the sensor—St. Jude devices rely upon acceleration as the monitored parameter for rate adaptive therapy—off (Fig 7B). Irrespective of what changes are made, a post-interrogation/programming report should be printed to document any changes.

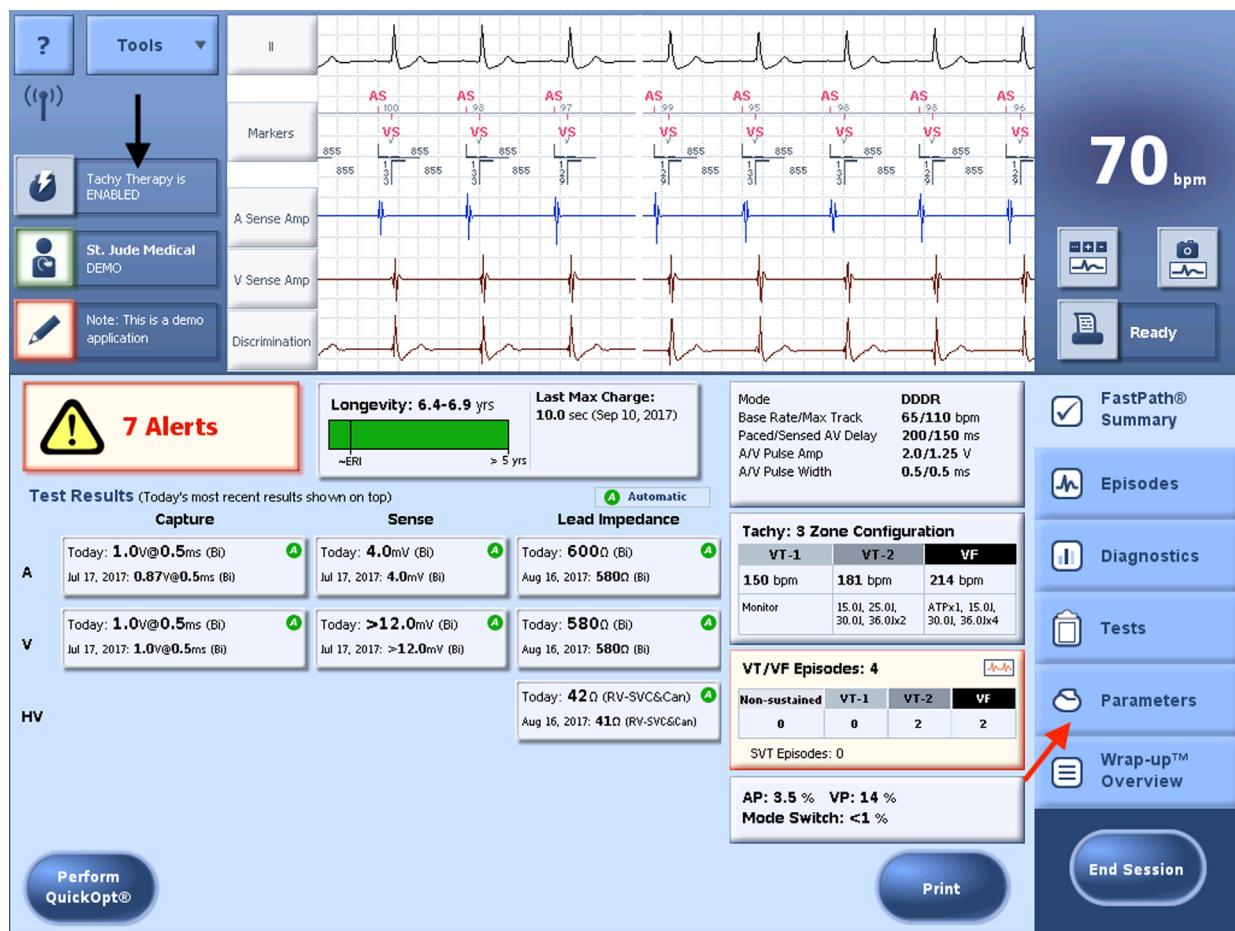


Fig 9. Merlin Patient Care System summary screen from an ICD (ellipse) displaying the parameters tab (red arrow) and tachy therapy status (black arrow).

Interrogation Report (St. Jude Ellipse Implantable Cardioverter Defibrillator)

Interpretation of a St. Jude implantable cardioverter defibrillator (ICD) report is very similar to that previously described for a pacemaker. Important concepts such as the indication for placement, number of leads, date of implantation for the leads and generator, battery life, lead impedances, lead sensitivities, mode, rate, rate modulation, and pacemaker dependency should be investigated. However, an ICD also contains one or more high voltage (HV) coils. The presence of these high voltage coils provides for tachyarrhythmia therapies in the form of low energy cardioversion or high-energy defibrillation.

High Voltage Lead Impedance

The impedance of these high voltage coils is provided on the FastPath Summary page under test results (Fig 8A). For St. Jude ICDs, 25 to 125 ohms is considered normal. However, an acute rise (eg, an increase from 30 ohms to 100 ohms over a

12-month period) may be indicative of a dysfunctional HV coil and should be investigated.

Antitachycardia Pacing

Modern ICDs also are capable of providing antitachycardia pacing (ATP) for tachyarrhythmia management. ATP involves termination of a tachyarrhythmia circuit by rapid or overdrive pacing. Most modern ICDs will attempt to terminate a tachyarrhythmia by ATP for lower rate ventricular tachycardia (VT) or while charging for a shock because it is less painful for the awake patient and utilizes less energy, which optimizes device life. As seen in the FastPath Summary page under the parameters heading (Fig 8A) this demo Ellipse ICD has 3 zones—VT-1, VT-2, and VF—each with different treatment algorithms. In this demo patient, the VT-1 zone, which has the lowest rate cut off of 150 beats per minute, results only in monitoring and electrogram storage. Interestingly, the VT-2 zone does not have ATP as a treatment modality but rather starts with low-energy (15.0 Joules [J]) cardioversion and progresses to high-energy defibrillation (36 J) if previous therapies are ineffective. In this demo patient, the diagnosis

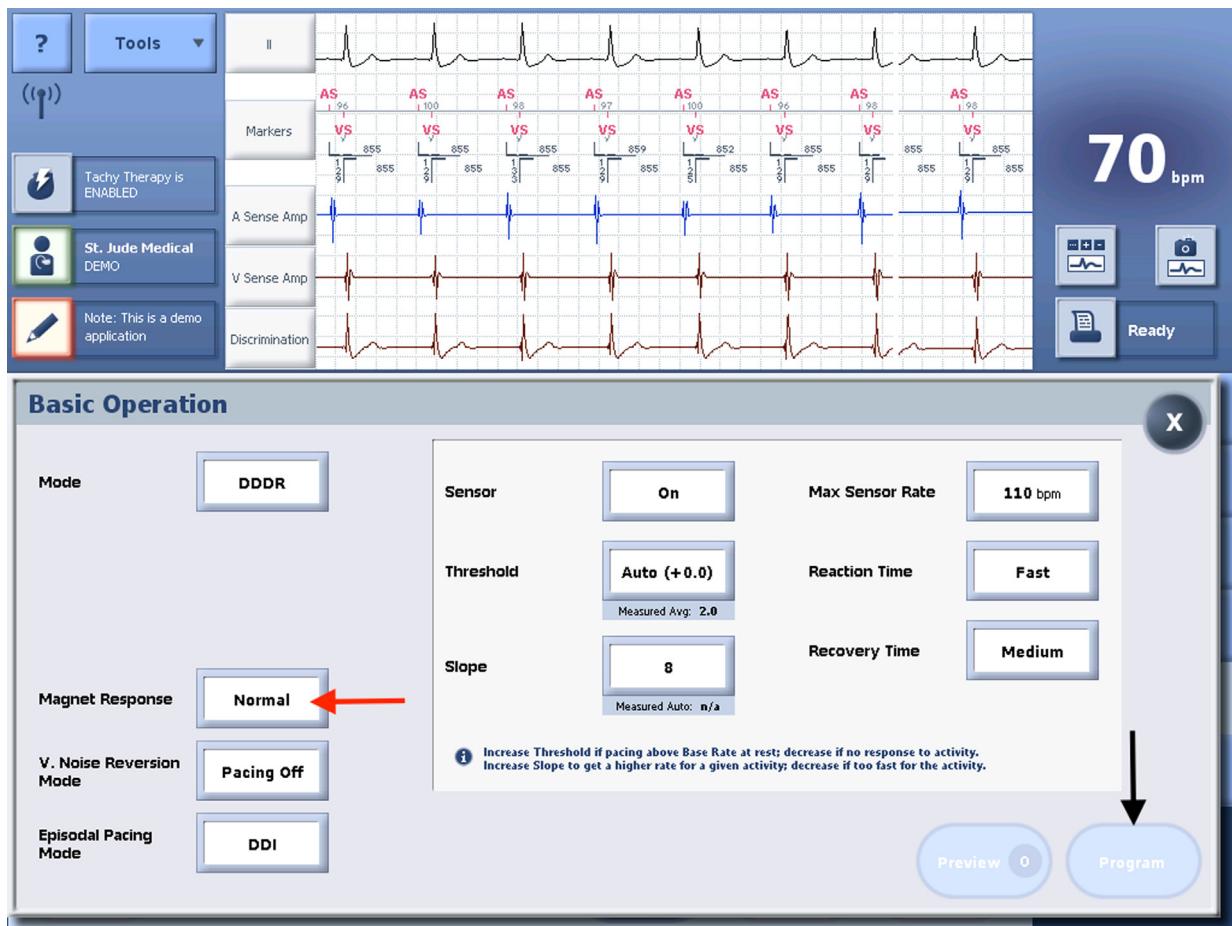


Fig 10. Merlin Patient Care System parameters screen from an ICD (ellipse) highlighting the basic operation tab and magnet response (red arrow) and program button (black arrow).

of ventricular fibrillation results in ATP while the capacitor is charged for defibrillations of increasing energy. While this basic understanding of the treatment algorithms is likely adequate for an anesthesiologist, additional information regarding diagnostic criteria and device delivered therapies can be located on the additional Parameters pages (not provided) contained in a typical report.

Tachyarrhythmia History

The FastPath Summary page (Fig 8A) also will inform the practitioner as to how many events (ie, VT or VF) the patient has had since the last interrogation under the diagnostic summary heading. This information may influence whether or not the practitioner relies upon the ICD for therapies perioperatively (ie, removes the magnet intraoperatively if a tachyarrhythmia is diagnosed) or requires additional monitoring.

Magnet Application

The magnet response for St. Jude ICDs is also programmable (Table 1) with the device responding to magnet

application by either disabling tachyarrhythmia therapies (ie, normal) or having no effect (ie, off). The magnet response can be confirmed on the Parameters page of the interrogation report under basic operation (Fig 8B).

Basic Programming (St. Jude Ellipse ICD)

Given the dual function of transvenous ICDs, many of the basic modifiable parameters (ie, mode, rate, and rate adaption) of St. Jude ICDs are the same. Therefore, programming ICDs to an asynchronous mode in pacemaker-dependent patients can be completed as previously described for pacemakers.

Magnet Application

The application of a magnet to an ICD is only expected to disable tachyarrhythmia therapies and have no effect on bradycardia-pacing function. Thus, the ability to reprogram pacemaker-dependent patients to an asynchronous mode in the perioperative period is extremely valuable.

The response to magnet application is modifiable in St. Jude ICDs (Table 1). In order to verify that magnet application will

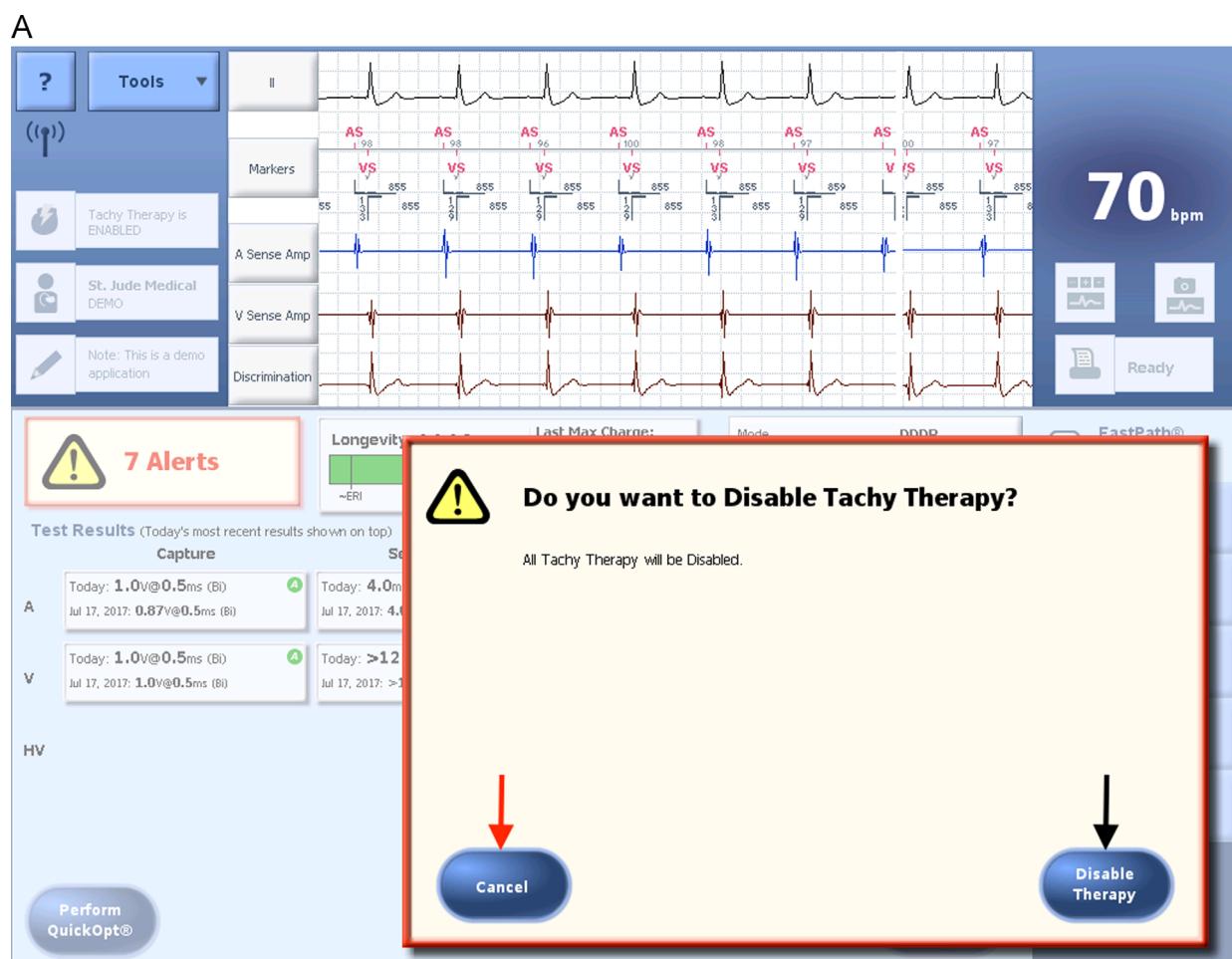


Fig 11. Merlin Patient Care System summary screen: (A) after the selection of tachy therapies with the disable therapy button (black arrow) and cancel button (red arrow) highlighted, (B) after tachy therapies have been disabled (red and black arrows), and (C) after the selection of tachy therapies with the enable therapy button (black arrow) and cancel button (red arrow) displayed.

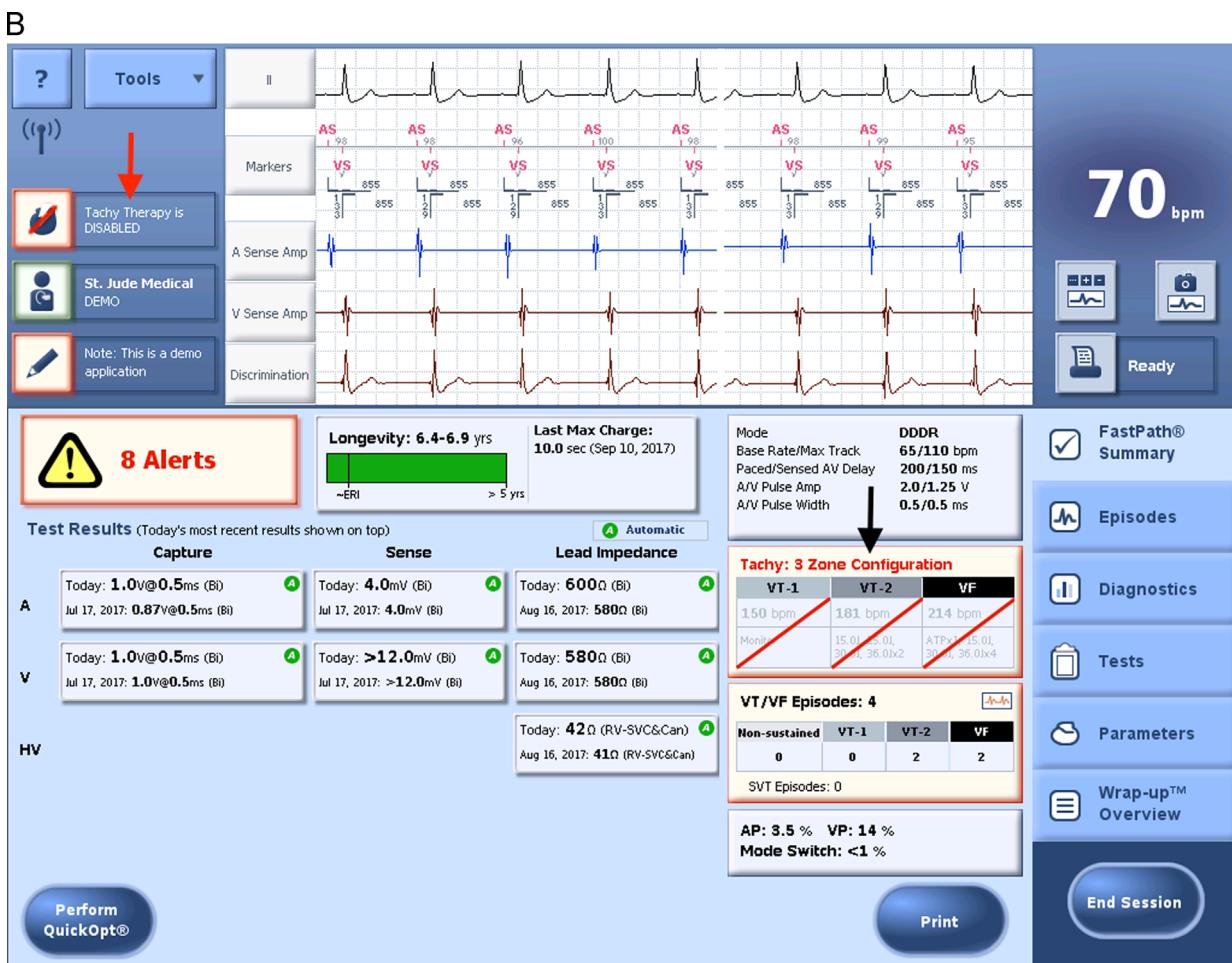


Fig 11. (continued)

suspend tachyarrhythmia therapies a recent interrogation report is needed. Alternatively, one can confirm the magnet response via the Merlin PCS. After establishing a connection with the ICD, the magnet response can be confirmed or changed (ie, normal versus off) via the parameters (Fig 9) and then basic operation (Fig 10) tabs.

Disabling Tachyarrhythmia Therapies

If disabling tachyarrhythmia therapies is preferred to magnet application for perioperative management, this also can be accomplished after some formal training via the summary screen (Fig 9). Once “tachy therapies” is selected, the practitioner will be prompted to either disable therapy or cancel (Fig 11A). If tachy therapies are disabled, this can be confirmed on the summary page in 2 places (Fig 11B). It is worth mentioning that alternative means for the treatment of a malignant arrhythmia (ie, external pads and a defibrillator) should be readily available whenever tachyarrhythmia therapies are disabled. At the conclusion of the procedure, “tachy therapies” can be re-enabled via the summary screen (Fig 11C). Once again, a report should be printed and placed

in the patient’s chart any time changes are made to a device’s settings.

Pacemaker Dependency

Even though a preoperative 12-lead ECG, paced rhythm on telemetry, indication for placement, or percentage paced can aid in determining pacemaker dependence, it is often useful to re-confirm pacemaker dependence on the day of surgery. The underlying rhythm and rate can be assessed by temporarily reprogramming the mode and rate to VVI at 30 bpm. This can be easily accomplished via the tests and temporary pacing tab (Fig 12). Temporary pacing allows one to identify the underlying rhythm without changing the bradycardic pacemaker settings.

Summary - St. Jude CIEDs for Anesthesiologists

In summary, CIED basic principles and perioperative management recommendations apply to St. Jude CIEDs as well. However, anesthesiologists should be cognizant of the fact that the magnet response in this subset of devices is programmable. In addition to other vital pieces of information

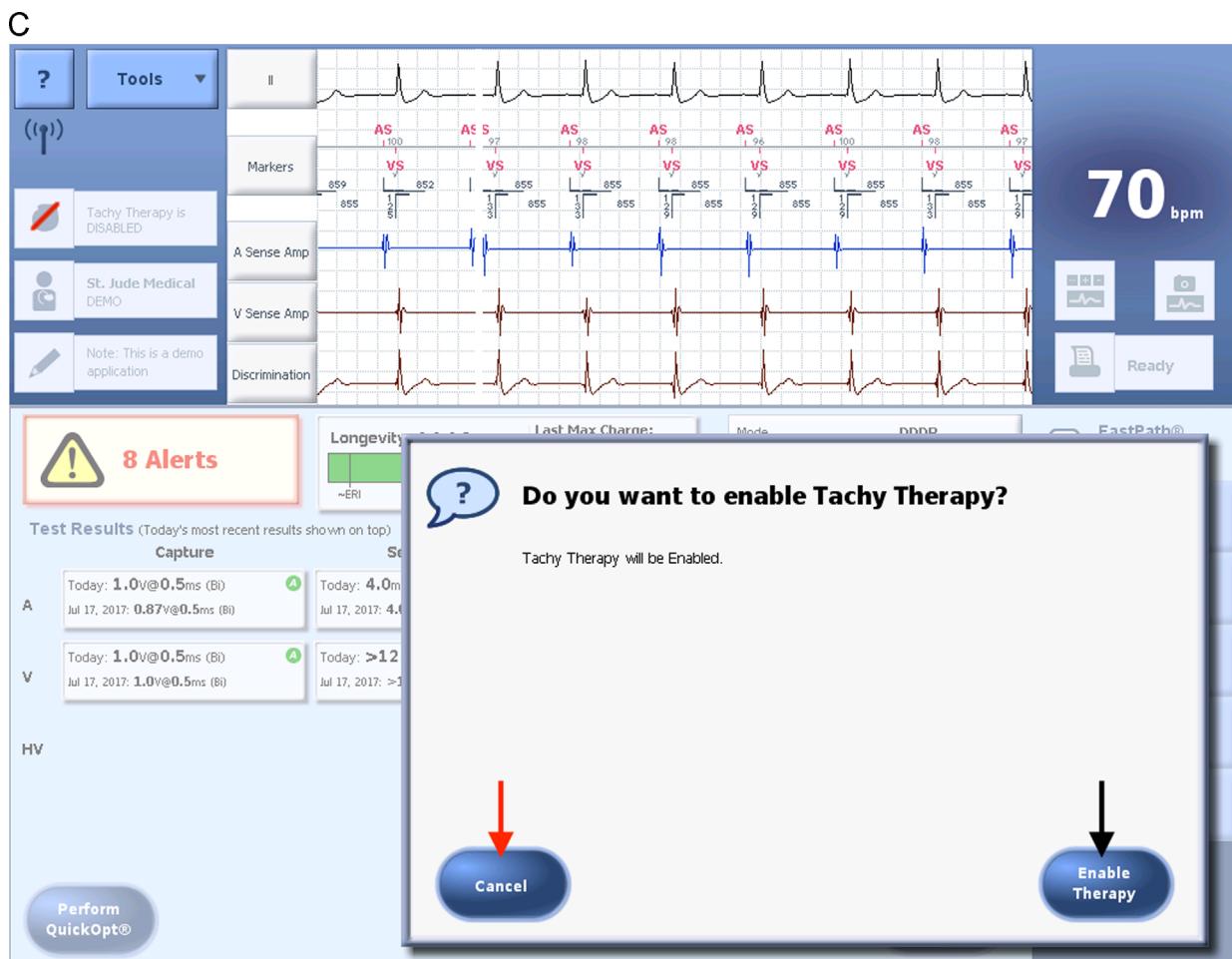


Fig 11. (continued)

the response to magnet application must be confirmed in the preoperative period in order to develop an appropriate management plan (Table 3). This is especially important in St. Jude ICDs as inappropriate therapy can result in significant morbidity and even mortality.¹⁵ Once the prerequisite information is obtained then observation, a magnet, or interrogation can be utilized for intraoperative management (Fig 13); however, societal recommendations favor interrogation and programming.

While the societal recommendations are not specific to cardiac surgery, the close proximity of the surgical site to CIEDs and intraoperative cardiac manipulation favors preoperative as well as postoperative interrogation. Alternatively a sterile magnet or RF communication could be utilized during cardiac surgery.

As a rule, perioperative device programming mandates interrogation in the postoperative period. However, the HRS and ASA recommendations advocate for interrogation in the postoperative period even in the absence of preoperative device programming.

The authors contend that the basic programming frequently required in the perioperative period and described in this review (ie, mode, rate, rate adaption, magnet response, and

tachyarrhythmia therapies) can be safely completed by anesthesiologists after some formal education and institutional support.

Conclusions

While the authors are not advocating for uncertified or uncredentialed anesthesiologists to assume total responsibility for CIEDs in the perioperative period, this is a potential area for increased involvement by anesthesiologists in the near future. Akin to the evolution of intraoperative transesophageal echocardiography for cardiac surgery, the perioperative management of CIEDs may one-day rest in the hands of anesthesiologists. While there is an avenue to formal certification offered by the IBHRE, this requires a significant investment of time and money on the part of the practitioner. Furthermore, the test and certification offered by the IBHRE is not focused on perioperative management. Alternatively, some institutions have created anesthesiology-run CIED services supported by electrophysiologists or under the instruction of 1 senior anesthesiologist with IBHRE testamur status.^{1,2,26} At the author's institution, industry representatives in conjunction with electrophysiologists have led a number of classes to



Fig 12. Merlin Patient Care System tests screen displaying the temporary pacing tab, which can be found under tests, with the mode (red arrow), base rate (black arrow), and start temporary (red box) buttons highlighted.

Table 3
Summary - St. Jude CIED Perioperative Considerations for an Elective Procedure

Preoperative	
Recent interrogation	Pacemaker within 12 months ICD/CRT within 6 months
Battery life	> 3 months
Leads	> 3 months since implantation
Capture threshold (chronic)	< 3.0 V
Safety margin	Autocapture - 1 V (atrial lead), 0.375 V (ventricular lead) Fixed output - 2:1 ratio (pulse amplitude:capture threshold) 300-1,200 ohms
Lead impedance (ideal)	25-125 ohms
High voltage lead impedance (ICDs only)	P wave > 1.5 mV R wave > 4 mV
Sensitivity (chronic)	
Magnet response	Confirm the device response to magnet application
Rate adaptation	Consider disabling for perioperative period
Pacemaker dependency	Determine dependency via history, ECG, or interrogation
EMI risk	Determine by the type, location, and nature of the procedure
Tachyarrhythmia history (ICDs only)	Determine the number and type of events recorded
Tachyarrhythmia treatment algorithm	Determine the programmed parameters for the diagnosis and treatment of tachyarrhythmias
Intraoperative	
ICDs	Lack confirmation of proper magnet application (ie, tone emission) An alternative means of malignant arrhythmias treatment (ie, external defibrillator) is required if "tachy therapies" are disabled
Pacemakers	The magnet induced asynchronous pacing rate is 100 bpm and decreases to 86.1 at ERI
Postoperative	
Perioperative programming mandates postoperative interrogation Societal recommendations favor interrogation in the postoperative period	

Abbreviations: bpm, beats per minute; CIED, cardiovascular implantable electronic device; CRT, cardiac resynchronization therapy; ECG, electrocardiogram; EMI, electromagnetic interference; ERI, elective replacement interval; ICD, implantable cardioverter defibrillator; mV, millivolts; V, volt.

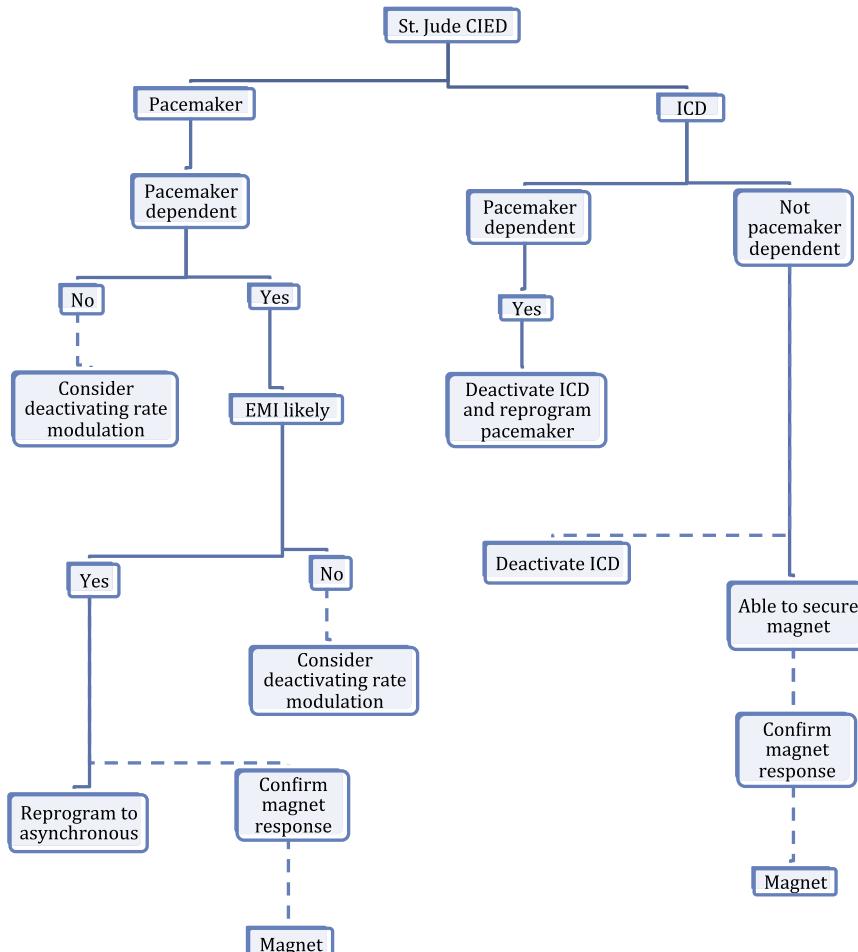


Fig 13. General algorithm for St. Jude CIED intraoperative management. Please note that this is a simplified diagram and management also depends upon the likelihood of encountering electromagnetic interference. CIED, cardiovascular implantable electronic device; EMI, electromagnetic interference; ICD, implantable cardioverter defibrillator.

educate cardiac anesthesiologists on perioperative CIED management and provide support as needed. If anesthesiologists become more involved in the perioperative management of these devices, there likely will be a need for perioperative-focused education and certification. In the authors' opinion, perioperative CIED management by anesthesiologist is an area for expansion that will not only lead to greater collaboration with electrophysiologists and device companies but also a reduction in operating room delays and improved patient care.

References

- Ellis MKM, Treggiari MM, Robertson JM, et al. Process improvement initiative for the perioperative management of patients with a cardiovascular implantable electronic device. *Anesth Analg* 2017;125:58–65.
- Rooke GA, Lombaard SA, Van Norman GA, et al. Initial experience of an anesthesiology-based service for perioperative management of pacemakers and implantable cardioverter defibrillators. *Anesthesiology* 2015;123:1024–32.
- Bernstein AD, Daubert JC, Fletcher RD, et al. The revised NASPE/BPEG generic code for antibradycardia, adaptive-rate, and multisite pacing. North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group. *Pacing Clin Electrophysiol* 2002;25:260–4.
- Epstein AE, DiMarco JP, Ellenbogen KA, et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol* 2013;61:e6–75.
- Epstein AE, Dimarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for device-based therapy of cardiac rhythm abnormalities. *Heart Rhythm* 2008;5:e1–62.
- American Society of Anesthesiologists. Practice advisory for the perioperative management of patients with cardiac implantable electronic devices: Pacemakers and implantable cardioverter-defibrillators: An updated report by the american society of anesthesiologists task force on perioperative management of patients with cardiac implantable electronic devices. *Anesthesiology* 2011;114:247–61.
- Bernstein AD, Camm AJ, Fisher JD, et al. North American Society of Pacing and Electrophysiology policy statement. The NASPE/BPEG defibrillator code. *Pacing Clin Electrophysiol* 1993;16:1776–80.
- Atlee JL, Bernstein AD. Cardiac rhythm management devices (part I): Indications, device selection, and function. *Anesthesiology* 2001;95:1265–80.
- Crossley GH, Poole JE, Rozner MA, et al. The Heart Rhythm Society (HRS)/American Society of Anesthesiologists (ASA) Expert Consensus Statement on the perioperative management of patients with implantable defibrillators, pacemakers and arrhythmia monitors: Facilities and patient management this document was developed as a joint project with the

- American Society of Anesthesiologists (ASA), and in collaboration with the American Heart Association (AHA), and the Society of Thoracic Surgeons (STS). *Heart Rhythm* 2011;8:1114–54.
- 10 Essandoh M, Daoud EG. Perioperative considerations for patients with subcutaneous implantable cardioverter-defibrillators undergoing noncardiac surgery. *J Cardiothorac Vasc Anesth* 2016;30:756–61.
 - 11 Hayes DL, Friedman PA. Cardiac pacing, defibrillation and resynchronization: A clinical approach, 3rd ed. Chichester, West Sussex, UK. Hoboken, NJ: Wiley-Blackwell; 2013.
 - 12 Moses HW. A Practical guide to cardiac pacing, 6th ed. Boston, MA: Little, Brown; 2007.
 - 13 Jacob S, Shahzad MA, Maheshwari R, et al. Cardiac rhythm device identification algorithm using X-Rays: CaRDIA-X. *Heart Rhythm* 2011;8: 915–22.
 - 14 Mahlow WJ, Craft RM, Misulia NL, et al. A perioperative management algorithm for cardiac rhythm management devices: The PACED-OP protocol. *Pacing Clin Electrophysiol* 2013;36:238–48.
 - 15 Rozner MA. Cardiac implantable electrical devices. In: Kaplan JA, editor. *Kaplan's Cardiac Anesthesia: For Cardiac and Noncardiac Surgery*. Philadelphia, PA: Elsevier; 2016. pp 1663.
 - 16 Schulman PM, Rozner MA, Sera V, et al. Patients with pacemaker or implantable cardioverter-defibrillator. *Med Clin North Am* 2013;97: 1051–75.
 - 17 Stone ME, Apinis A. Current perioperative management of the patient with a cardiac rhythm management device. *Semin Cardiothorac Vasc Anesth* 2009;13:31–43.
 - 18 Stone ME, Salter B, Fischer A. Perioperative management of patients with cardiac implantable electronic devices. *Br J Anaesth* 2011;107(Suppl 1):i16–26.
 - 19 Thompson A, Mahajan A. Perioperative management of cardiovascular implantable electronic devices: What every anesthesiologist needs to know. *Anesth Analg* 2013;116:276–7.
 - 20 St Jude Medical. MerlinTM Patient Care System - user manual. Available at: <https://manuals.sjm.com/Search-Form?re=North-America&cc=US&ln=EN&qry=Merlin%20Patient%20Care%20System&ipp=102017h>. Accessed September 14, 2017.
 - 21 St. Jude Medical. Bradycardia and tachycardia devices (Merlin Patient Care System) help manual. Available at: <https://manuals.sjm.com>. Accessed September 14, 2017.
 - 22 St. Jude Medical. Bradycardia devices reference manual. Available at: <https://manuals.sjm.com>. Accessed September 14, 2017.
 - 23 Hayes DL, Asirvatham SJ. Dictionary of cardiac pacing, defibrillation, resynchronization, and arrhythmias. Minneapolis, MN: Cardiotext Publishing; 2007.
 - 24 Schwartzenburg CF, Wass CT, Strickland RA, et al. Rate-adaptive cardiac pacing: Implications of environmental noise during craniotomy. *Anesthesiology* 1997;87:1252–4.
 - 25 Rozner MA. The patient with a cardiac pacemaker or implanted defibrillator and management during anaesthesia. *Curr Opin Anaesthesiol* 2007;20:261–8.
 - 26 Rozner MA, Schulman PM. Creating an anesthesiologist-run pacemaker and defibrillator service: Closing the perioperative care gap for these patients. *Anesthesiology* 2015;123:990–2.