The Current Status of Cardiac Pacemaker Systems and On-going Design Innovations

Introduction

This article will discuss the current status of cardiac pacemaker devices, including material related to the ongoing development of pacemaker systems, such as the main cardiac pacemaker device, programming of current devices and pacemaker leads. The functioning of a cardiac pacemaker system is achieved through the use of a programming system. Each company has usually developed their own programming systems in order to verify the programming parameters, e.g. *Pulse Width (ms), Sensitivity (mV), refractory blanking period and amplitude* in order to modify specific pacemaker parameters as required. Any modifications in the cardiac pacing parameters are supervised by an EP cardiologist. A sample template for recording any pacemaker parameter modifications which I have developed is presented in the APPENDIX section.

One of Medtronic's programming system "The MyCareLink Monitor (model # 24950 and model number 24952) is used to wirelessly connect to the patient's implanted cardiac device and read the data stored on the device. The transmitter, located in the patient's home, sends the patient's data to his or her physician(s) by the CareLink Network using a continuous landline, cellular, or wireless (wi-fi) Internet connection." [1]

- "The first pacemaker implant took place in Sweden in 1958. Soon after, the first pacemaker implant in the United States occurred in 19601. Nearly one million people worldwide are implanted with implantable pacemakers each year. Implantable pacemakers are life-sustaining, life-supporting Class III devices" [2]
- "Historically, FDA has often required extensive pre-clinical and clinical data to be provided in a PMA in order to evaluate the safety and effectiveness of a pacemaker system" [1]
    - Bench data is used to "establish functional acceptability of hardware, software and feature design and manufacturing"

[1] https://www.fda.gov/medical-devices/safety-communications/cybersecurity-vulnerabilities-affecting-medtronic-implantable-cardiac-devices-programmers-and-home
[2] https://www.fda.gov/media/95842/download

  - Animal data is often required by the FDA to "support biocompatibility and durability of new materials"
  - And clinical data is obtained through clinical trials at various clinical settings in order to assess acute and chronic system-level performance including proper functioning at the biological interface (assessment of pacing capture threshold and sensing abilities)." [1]

- "Permanent cardiac pacemakers refer to a group of self-contained, battery operated, implanted devices that send electrical stimulation to the heart through one or more implanted leads".[3]

There are several current implantable cardiac device manufacturing firms including (Medtronic, Abbott, St. Jude Medical and BIOTRONIC USA), which are dedicated to improving the overall therapeutic effectiveness and safety of their cardiac pacemaker devices and programming systems for their patients.

The FDA has articulated that [4]

- "Pacemakers are surgically implanted medical devices which make use of use of low-energy electrical pulses that generate electrical impulses to treat irregular or stalled heart beats…"
- Approximately "1 million people worldwide are implanted with pacemakers each year." The leads in a traditional single chamber pacemaker run from the pacemaker, implanted under the skin near the collarbone, through a vein directly into the heart's right ventricle; the leads deliver electric pulses from the generator to the right ventricle and help coordinate timing of the chamber's contractions."

There will be a discussion of both cardiac pacemakers designed for adult use as well as devices specifically designed for pediatric patients.

[3] https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=267
[4] https://www.fda.gov/news-events/press-announcements/fda-approves-first-leadless-pacemaker-treat-heart-rhythm-disorders

Types of Current Pacemakers (permanent)

- Single Chamber Pacemakers
- Dual Chamber Pacemakers
- Biventricular Pacemakers
- Rate Responsive Pacemakers
- Antitachycardia Pacemakers

Types of Temporary Pacemakers

- Transcutaneous pacing
- Temporary epicardial pacing is used during open heart surgery
- Transvenous pacing (temporary)

Dual Chamber Devices:

- Dual chamber modes (DDD or DDDR):
- Ventricular Pacing: Fixed-Rate and Demand Pacemakers: cardiac performance of these individuals. In selected patients, dual-chamber pacing may allow an increase in ventricular rate during exercise.

Cardiac Pacemakers for the Pediatric Patient

Unmet Need(s) for pediatric cardiac pacemaker device with monitoring capabilities:

Additionally, heart rates result in increased battery utilization which can significantly impact the longevity of the pulse generators. Future pacemaker device technology could potentially provide for more efficient and individualized programming and therefore reduce battery power consumption and provide a more effective and therapeutic effect.

Quality and feasibility of future device technology for the pediatric patient:

- Smaller in size than current adult pacing devices
- Longer battery life

- Could potentially be designed to be compatible to the growth, anatomical and physiological considerations of the pediatric pacing patient
- Improved pacing lead compatibility to the clinical needs of the paced pediatric patient
- And enhanced programming capabilities that can cater to the demands of the young patients and ability to treat brady and tachyarrhythmias as well as heart failure.

Regulatory Issues

Cardiac pacemakers used clinically today are closed regulated and are considered as class III medical devices. [5]

- "Class III – These are devices that sustain or support life, are implanted, or present potential high risk of illness or injury. Examples of Class III devices include implantable pacemakers and breast implants. 9% of device types are Class III and require FDA review through premarket approval (PMA) or humanitarian device exemption (HDE)."

Current cardiac pacemaker leads are now designated as class II medical devices.[3]

- "The development of a guidance document for permanent cardiac pacemaker leads and adaptors is based on the Division of Cardiovascular and Respiratory Devices (DCRD) evaluation of numerous device applications, and the establishment of certain criteria necessary to conduct such evaluations. This is a dynamic document which will be reviewed periodically as device materials, designs and indications for any changes in the technology and or device improvements" [6]
- "The following series is intended to identify issues that need to be addressed to qualify a 'new' pacemaker lead and to identify some of the non-clinical tests which may be used to support a pacemaker lead submission."

[5] https://www.fda.gov/medical-devices/resources-you-medical-devices/consumers-medical-devices
[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-submission-research-and-marketing-applications-permanent-pacemaker-leads-and-pacemaker-lead

- "Pacemaker lead adaptors, which were pre-amendments Class III devices, are now Class II devices… It is the responsibility of the lead manufacturer to define a comprehensive testing methodology for a particular lead design." [3]
    - "Class II –These are devices that generally present a moderate risk of harm to the user. Examples of Class II devices include powered wheelchairs and some pregnancy test kits. 53% of device types are Class II, most of which require FDA review through premarket notification (510(k))." [2]

The electronics of the cardiac pacemaker has not dramatically changed over the year since it was used clinically. What has changed is the size, the lead configuration. The current on-going of pacemaker leads continues to increase the overall safety of therapeutic efficacy of the pacemaker systems.

Cardiac Pacemaker Devices as class III medical devices are "subject to premarket approval applications (PMAs), premarket notification (510(k)) or requests for De Novo designation are eligible for breakthrough device designation if both of the following criteria are met" [7]:

Criteria	**Description**	**Refer to Guidance**
First Criterion	The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions	Section III.B.1
Second Criterion	The device also meets **at least one** of the following:	
	a. Represents Breakthrough Technology	Section III.B.2.a

[7] https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program

Criteria	Description	Refer to Guidance
	b. No Approved or Cleared Alternatives Exist	Section III.B.2.b
	c. Offers Significant Advantages over Existing Approved or Cleared Alternatives	Section III.B.2.c
	d. Device Availability is in the Best Interest of Patients	Section III.B.2.d

Cybersecurity Issues

To date there have been no cyber security issues associated with the pacemaker devices but there have been some related issues in the programming systems as discussed in the next section [8] :

1. EXECUTIVE SUMMARY

CVSS v3 7.1

Vendor: Medtronic

Equipment: 2090 CareLink Programmer

--------- Begin Update B Part 1 of 5 --------

29901 Encore Programmer

--------- End Update B Part 1 of 5 --------

Vulnerabilities: Storing Passwords in a Recoverable Format, Relative Path Traversal, Improper Restriction of Communication Channel to Intended Endpoints

[8] https://www.us-cert.gov/ics/advisories/ICSMA-18-058-01

2. UPDATE INFORMATION

This updated advisory is a follow-up to the original advisory titled ICSMA-18-058-01 Medtronic 2090 CareLink Programmer Vulnerabilities (Update A) that was published June 28, 2018, on the NCCIC/ICS-CERT website.

3. RISK EVALUATION

Successful exploitation of these vulnerabilities may allow an attacker with physical access to a 2090 Programmer to obtain per-product credentials to the software deployment network. These credentials only grant access to the software deployment network access which is limited to read-only versions of device software applications.

Additionally, successful exploitation of these vulnerabilities may allow an attacker with local network access to influence communications between the Programmer and the software deployment network.

Cardiac Pacemaker Device Failures

Cardiac pacemakers as with any medical devices are prone to failure due to several factors, e.g. battery depletion; lead infection, movement of a pacing lead, improper programming of a device and or nMRI interferences which may affect the overall functioning of a device.

Battery Depletion Issues-

- The FDA became aware of three medical device reports in which a Medtronic implantable pacemaker or CRT-P battery had fully drained because of a crack in the device's capacitor, without any warning to the patient or health care provider. As of April 10, 2019, 131,889 of affected devices have been sold in the U.S. [9]

[9] https://www.fda.gov/medical-devices/safety-communications/fda-alerts-providers-and-patients-check-premature-battery-depletion-certain-medtronic-pacemakers-fda

- "If a capacitor in an implanted pacemaker or CRT-P is cracked can create an electrical short, which can cause a battery to drain earlier than expected. If the battery is completely drained, the device will no longer deliver pacing therapy. **Programming System Failure (s)** [10]

Class II Device Recall LATITUDE Patient Management System

Date Initiated by Firm	October 12, 2011
Date Posted	December 01, 2011
Recall Status[1]	Terminated [3] on December 04, 2012
Recall Number	Z-0333-2012
Recall Event ID	60244
PMA Number	P910077
Product Classification	Implantable cardioverter defibrillator (non-crt) - **Product Code** LWS
Product	LATITUDE¿ Patient Management System, Models 6441*, 6442*, 6465*, 6488 (USA). There are two software applications: the programmer software and the LATITUDE remote monitoring system software. The Model 2868 Software Application is loaded onto the Model 3120 programmers. These programmers are used during in-office follow-ups. The software version affected domestically is version 1.05 for COGNIS and TELIGEN and the affected software is version 2.04 for COGNIS, TELIGEN, and PUNCTUA, ENERGEN and INCEPTA. The PUNCTUA, ENERGEN, and INCEPTA are not currently approved in the US. The LATITUDE Patient Programming management system is intended to remotely communicate with a compatible Guidant or Boston Scientific pulse generator and transfer data to a central database. The LATITUDE Patient Management

[10] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=104862

	System software is web-based and therefore at any point in time, there is only one (1) released version for each model number. The current version is 7.1. Both the programmer software and the LATITUDE remote monitoring system software similarly display the shock lead impedance measurements.
Code Information	Models 6441*, 6442*, 6465*, 6488 (USA).
Recalling Firm/ Manufacturer	Boston Scientific CRM Corp 4100 Hamline Ave N Saint Paul MN 55112-5700
For Additional Information Contact	651-582-4000
Manufacturer Reason for Recall	Current Boston Scientific defibrillator systems measure shock lead impedances up to 200 ohms, and export results to the programmer and LATITUDE monitoring system via the Daily Measurements feature. A measured shock lead impedance that is greater than 125 ohms or less than 20 ohms will generate an alert message on programmer screens and a Red Alert within LATITUDE (if activated).
FDA Determined Cause [2]	Software design
Action	Boston Scientific sent an "IMPORTANT DIAGNOSTIC INFORMATION" letter dated October 2011 to all affected customers. The letter described the product, problem and actions to be taken by the customers.
Quantity in Commerce	25,300 (14,700 US; 10,600 OUS)
Distribution	Worldwide Distribution-USA (nationwide) including DC and Puerto Rico and the countries of AUSTRIA, BELGIUM, DENMARK, FINLAND, FRANCE, GERMANY, IRELAND, ITALY, NETHERLANDS, NORWAY, PORTUGAL, SPAIN, SWEDEN, SWITZERLAND, UNITED KINGDOM, CANADA, AUSTRALIA, NEW ZEALAND, CYPRUS,

	CZECH REPUBLIC, GREECE, GUADELOUPE, HUNGARY, BANGLADESH, CHINA, COCOS ISLAND, HONG KONG, INDIA, INDONESIA, KOREA, MALAYSIA, PHILIPPINES, SINGAPORE, SOUTH KOREA, SRI LANKA, THAILAND, RUSSIA, SAUDI ARABIA, SLOVAKIA, SLOVENIA, SOUTH AFRICA, NEW CALEDONIA, POLAND, PORTUGAL, QATAR, REUNION,IRAN, ISRAEL, JORDAN, KUWAIT, LATVIA, LEBANON, LUXEMBOURG, MONACO, MOROCCO, JAPAN, ARGENTINA, ARUBA, BAHAMAS, BARBADOS, BELIZE, BERMUDA, BRAZIL, CAYMAN ISLANDS, CHILE, COLOMBIA, COSTA RICA, DOMINICAN REPUBLIC, ECUADOR, EL SALVADOR, FALKLAND ISLANDS, HAITI, HONDURAS, JAMAICA, MEXICO, PANAMA, PERU, TRINIDAD & Tobago, URUGUAY, VENEZUELA, AND NETHERLANDS ANTILLES.
Total Product Life Cycle	TPLC Device Report

Recent Cardiac Pacemaker Device Developments

Several innovations have been recently approved for clinical use which are smaller; more therapeutically effective and safer for the patients. Some of these will be discussed in the following section, e.g. Medtronic's micra leadless pacemaker and the 510k approval for this device is shown below [11]:

Device	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM
Generic Name	Leadless Pacemaker
Regulation Number	870.3610
Applicant	MEDTRONIC Inc. 8200 Coral Sea Street Ne Ms Mv S11 Mounds View, MN 55112
PMA Number	P150033

Date Received	09/17/2015
Decision Date	04/06/2016
Product Code	PNJ
Docket Number	16M-1125
Notice Date	04/12/2016
Advisory Committee	Cardiovascular
Clinical Trials	NCT02004873
Expedited Review Granted?	Yes
Combination Product	Yes

PMA Approval for the Micra Transcatheter Pacemaker System (Pacemaker Model MC1VR01 and Programmer Application Software model SW022 Version 1.1).

The Micra pacemaker system is indicated for use in patients:

- Who have experienced one or more of the following conditions:
  - symptomatic paroxysmal or permanent high-grade AV block in the presence of AF
  - Symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy
  - symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy Rate-responsive pacing

is indicated to provide increased heart rate appropriate to increasing levels of activity.

- "As the first leadless pacemaker, Micra offers a new option for patients considering a single chamber pacemaker device, which may help prevent problems associated with the wired leads," said William Maisel, M.D., M.P.H., acting director of the Office of Device Evaluation at the FDA's Center for Devices and Radiological Health. Micra is intended for patients with a heart arrhythmia called atrial fibrillation or those who have other dangerous arrhythmias, such as bradycardia-tachycardia syndrome." [1]

Recently FDA approved cardiac pacemakers designed for use with patients undergoing nMRI exams shown in the following section:[11]

Device	Assurity MRI And Endurity MRI Pacemakers, Tendril MRI Lead, MRI Activator, Merlin PCS Programer Software
Generic Name	Implantable Pulse Generator, Pacemaker (Non-Crt)
Applicant	St. Jude Medical, Inc. 15900 Valley View Court Sylmar, CA 91342
PMA Number	P140033
Date Received	12/24/2014
Decision Date	01/31/2017
Product Codes	NVN LWP
Docket Number	17M-0661
Notice Date	03/10/2017
Advisory Committee	Cardiovascular
Clinical Trials	NCT01576016
Expedited Review Granted?	No
Combination Product	Yes

[11] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140033

Abbreviations

AF- Atrial fibrillation

ATP- Antitachycardia Pacing

CRT- Cardiac resynchronization therapy

LBBB- left bundle branch block

HR – heart rate

CCF – Cleveland Clinic Foundation

BPM – Beats per minute

Right bundle branch block

EKG/ECG- Electrocardiogram

EP- Electrophysiology

EF- Ejection Fraction

EPS- electrophysiological study

MI- myocardial infarction

HF – heart failure

CHD- Congenital Heart Disease

V - Ventricle

A – Atrium

NASPE - North American Society of Pacing and Electrophysiology

CRT-P - cardiac resynchronization therapy pacemaker

RA – right atrium

RV – right ventricle

P/S – pace and sense

Terminology (for cardiac pacemaker devices)

Programmable Functions:

T- Triggered

R - Rate Modulated

M- Multiprogrammable

D -Dual

T/I - Triggered/Inhibited

D - Dual (A&V)

P – chamber paced

S- chamber sensed

O – None (no chamber sensed or paced)

C – Communicating

VVIOO mode: a single chamber pacemaker is set to pace the ventricle when intrinsic cardiac activity is not sensed in the ventricle. Extra programs and anti-tachycardia functions are not set.

DDIRD mode: both the atrium and the ventricle may be paced when intrinsic cardiac activity is not sensed; the rate can be increased as required (for example, when the patient is exercising) and pacing and or an electrical shock will be delivered should the patient require this in the event of a life threatening intrinsic high heart rate.

AAIOO mode: atrial-only pacing when intrinsic cardiac activity is not sensed in the atrium. There is no ventricular sensing or pacing.

The five position NBG Pacemaker Code:

Position I of the code indicates the chamber (or chambers) paced

Position II of the code represents the chamber used for the second function of a pacemaker, namely, sensing for intrinsic signals

Position III of the code indicates the mode of response to sensing

Position IV indicates the programmable parameters of the device

Additional Note(s) related to position IV:

- R (rate response) in the 4th position only tells us that the device is capable of (and programmed to) a rate responsive function.
- C (communicating) indicates that the pacemaker is capable of transmitting and/or receiving data for informational or programming purposes.
- M (multiprogrammable) indicates that the device can be programmed in more than 3 parameters.

All DDD pacemakers are, also, multiprogrammable.

- P (simple programmable) usually indicates that the pacemaker is limited to 3 or fewer programmable parameters.
- O (none) is rarely encountered and indicates that the device has no programmable parameters.

Bibliography

https://www.fda.gov/media/95842/download

https://www.fda.gov/medical-devices/safety-communications/cybersecurity-vulnerabilities-affecting-medtronic-implantable-cardiac-devices-programmers-and-home

https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P150033

Yanulis, George E. A Novel Cardiac Pacing Paradigm for Atrial Fibrillation and Heart Failure Patients. Doctoral dissertation, Fenn College of Engineering, Cleveland State University. 2008 May; 1-106-link to my doctoral dissertation – link listed below:

https://etd.ohiolink.edu/!etd.send_file?accession=csu1216064065&disposition=inline

https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=267

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=104862

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-submission-research-and-marketing-applications-permanent-pacemaker-leads-and-pacemaker-lead

https://www.fda.gov/news-events/fda-brief/fda-brief-fda-warns-patients-providers-about-cybersecurity-concerns-certain-medtronic-implantable

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=81945

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P150033

https://www.fda.gov/medical-devices/safety-communications/fda-alerts-providers-and-patients-check-premature-battery-depletion-certain-medtronic-pacemakers-fda

https://www.fda.gov/medical-devices/resources-you-medical-devices/consumers-medical-devices

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140033

Additional Diagrams (related to cardiac pacing devices)

Position I	Position II	Position III	Position IV	Position V
Chamber(s)Paced	Chamber(s)Sensed	Response to Sensing	Rate Modulation	Multisite Pacing
O = None	O = None	O = None	O = None	O = None
A = Atrium	A = Atrium	T = Triggered	R = Rate Modulation	A = Atrium
V = ventricle	V = ventricle	I = Inhibited		V = ventricle
D = Dual (A+V)	D = Dual (A+V)	D = Dual (T+I)		D = Dual (A+V)

Position I: Chambers Paced ▪ Refers to chambers paced.

Position II: Chambers Sensed ▪ Refers to the location where the pacemaker senses native cardiac electrical activity.

Position III: Response to Sensing ▪ Refers to pacemaker's response to sensed native cardiac activity.

- ▪ T = Sensed activity results in triggering of paced activity
- ▪ I = Sensed activity results in inhibition of pacing activity

Position IV: Rate Modulation

▪ Indicates ability for rate modulation designed to altered heart appropriately to meet physiological needs e.g. physical activity. Sensors may measure and respond to variables including vibration, respiration, or acid-base status.

Position V: Multisite Pacing

▪ Allows indication of multiple stimulation sites within one anatomical area e.g. more than one pacing site within the atria or biatrial pacing

NOTE:

The following is a Cardiac Pacing Template which I developed. can be used for patient monitoring sessions -

Pacemaker Parameters DATE

Modes

Mode VVI

Mode Switch

Rates

Lower Rate (ppm)

Upper Tracking Rate (ppm)

ADL Rate (ppm)

Intrinsic/AV

Paced AV (ms)

Sensed AV (ms)

Search AV+ Off

Rate Adaptation AV On

Start Rate (ppm)

Stop Rate (ppm)

Maximum Offset

Refractory Blanking

PVARP (ms)

PVAB (ms)

Ventricular Refractory (ms)

VenL Blanking (after A. Pace) (ms)

PMT Intervention On

PVC Response On

Ventricular Safety Pacing On

Rate Response

Optimization On

ADL Response

Exertion Response

ADRL Percent

Activity Threshold Medium/Low

Activity Acceleration 30 sec

Activity Decelerations Exercise

High Rate Response 0.2%

ADL Rate Setpoint 5

Upper Sense Rate Setpoint 60

Atrial Lead

Amplitude (V)

Pulse Width (ms)

Sensitivity (mV)

Pace Polarity Unipolar

Sense Polarity Unipolar

Lead Monitor Monitor Only

Maximum Impedance (ohms)

Minimum Impedance (ohms)

Monitor Sensitivity

Amplitude Margin 2X

Minimum Adapted Amplitude

Atrial Lead

Capture Test Frequency Day at ___

Capture Test Time

Acute Phase Off

Acute Phase Complete 01/15/07

Ventricular Lead

Amplitude (V)

Pulse Width (ms)

Sensitivity

Sensing Assurance On

Pace Polarity Bipolar

Sense Polarity Bipolar

Lead Monitor Monitor Only

Maximum Impedance (ohms)

Minimum Impedance (ohms)

Monitor Sensitivity 8

Capture Management Monitor Only

Amplitude Margin 2X

Min. Adapted Amplitude (V)

Capture Test Frequency Day at Resl

Acute Phase Off

Acute Phase Complete 01/15/07

V. Sensing During Search Adaptive

Additional Features

RDR Detection Type Off

Sleep Off

Non-comp Atrial Pacing On

Transtelephonic Monitor Off

Extended Telemetry Off

Extended Marker Standard

Implant Detection Off/Complete

Atrial High Rate Episodes

Episode Trigger High rate

Detection Rate (ppm)

Detection Duration (sec)

Termination Beats

Episode Collection Method Rolling

Ventricular High Rate Episodes

Detection Rate (ppm)

Detection Beats

Termination Beats

SVT Filter On

Episode Collection Method Rolling

Battery Status (Date/Time)

Battery Status

Date of Implant 10/23/06 at 8:13 PM

Voltage

Current (micro-amps)

Impedance (ohms)

Remaining Longevity

Estimated at (months)	13
Minimum	7
Maximum	19

Based on Past History

Lead Status (Date/Time

	Atrial	Ventricular
Amplitude (V)		
Pulse Width (ms)		
Output Energy (micro-joules)		
Current (mA)		
Impedance (ohms)		
Pace Polarity	Unipolar	Bipolar