ST. JUDE MEDICAL: BI-VENTRICULAR AUTOCAPTURE

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by
Alexander Hristov Mihov
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COMMITTEE MEMBERSHIP

TITLE: St. Jude Medical: Bi-Ventricular Autocapture

AUTHOR: Alexander Mihov

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COMMITTEE CHAIR: Lily Laiho, BMED

COMMITTEE MEMBER: Kristen O'Halloran Cardinal, BMED

COMMITTEE MEMBER: Robert Crockett, BMED

ABSTRACT
St. Jude Medical: Bi-Ventricular Autocapture
Alexander Hristov Mihov

Bi-Ventricular Auto Threshold periodically and independently measures and trends the capture threshold of the right and left ventricles in order to determine the minimum pulse amplitude required to capture the heart. The BiVATH algorithm can operate in three modes: OFF, ON and MONITOR^[7].

The feature can be independently enabled in the right or left ventricle. It measures the capture thresholds one ventricle at a time. If Bi-Ventricular pacing is enabled, the chamber being tested will be paced first. If it is the right ventricle to be tested, the left ventricle pacing is temporarily turned off^[7]. If the right ventricular test pulse caused loss of capture (LOC), a backup pulse in the same chamber is issued with high output mode (HOM) amplitude to ensure capture in the right chamber. If it is the left ventricle to be tested, the right ventricular chamber is always pacing at HOM amplitude to ensure capture (CAP) in the right chamber. The threshold search is suspended in case of tachycardia or by other algorithms^[7].

A step-down, step-up threshold search is conducted on a regular basis. The pacing amplitude is incrementally lowered until loss of capture occurs, and then increased until capture is confirmed to determine the current pacing threshold^[7]. This is accomplished by a conventional method of stepping the pulse amplitude down in fixed voltage steps until Loss of Capture (LOC) is detected and then up in fixed voltage steps until Capture (CAP) is regained. The pacing amplitude is then set to a value equal to the found threshold plus the programmed safety margin to ensure Capture until the next threshold search is conducted^[7].

The algorithm also collects in-clinic and out-of-clinic diagnostics for analysis.

TABLE OF CONTENTS

TABLE OF FIGURES	VII
I. BACKGROUND AND CLINICAL IMPORTANCE	1
II. PROJECT OBJECTIVE.....	4
III. DESIGN AND IMPLEMENTATION.....	5
IV. RESULTS	9
V. DISCUSSION	11
VI. CONCLUSION AND FUTURE WORK.....	12
VII. REFERENCES.....	13
VIII. APPENDIX A: IMPLEMENTATION CODE	14
IX. APPENDIX B: UNIT TEST CODE.....	15
X. APPENDIX C: USER INTERACTION WORKFLOW	16

TABLE OF FIGURES

FIGURE 1: Strength-Duration Curve ^[10]	2
FIGURE 2: Figure removed by St. Jude Medical legal.....	5
FIGURE 3: Figure removed by St. Jude Medical legal.....	6
FIGURE 4: Figure removed by St. Jude Medical legal.....	7
FIGURE 5: Figure removed by St. Jude Medical legal.....	8
FIGURE 6: Step 1 - Bi-Ventricular Algorithm – Initial State ^[9]	16
FIGURE 7: Step 2 - Bi-Ventricular Algorithm – User Options ^[9]	17
FIGURE 8: Step 3 - Bi-Ventricular Algorithm – AutoCapture Selection ^[9]	18
FIGURE 9: Step 4 - Bi-Ventricular Algorithm – Initial Signal Gain Adjustment Selection ^[9]	19
FIGURE 10: Step 5 - Bi-Ventricular Algorithm – Gain Adjustment In Progress ^[9]	20
FIGURE 11: Step 6 - Bi-Ventricular Algorithm – Gain Adjustment End, AutoCapture Start ^[9] ..	21
FIGURE 12: Step 7 - Bi-Ventricular Algorithm – AutoCapture In Progress #1 ^[9]	22
FIGURE 13: Step 8 - Bi-Ventricular Algorithm – AutoCapture In Progress #2 ^[9]	23
FIGURE 14: Step 9 - Bi-Ventricular Algorithm – Threshold Determined (1.625 V) ^[9]	24
FIGURE 15: Step 10 - Bi-Ventricular Algorithm – Pacing Amplitude Programmed (1.625 V) ^[9]	25

I. BACKGROUND AND CLINICAL IMPORTANCE

Cardiac pacing involves the delivery of a polarizing electrical impulse from an electrode in contact with the myocardium with the generation of an electrical field of sufficient intensity to induce a propagating wave of cardiac action potentials^[3]. The stimulating pulse may be either anodal or cathodal in polarity, though with differing stimulation characteristics^[3]. In addition, the stimulation characteristics are related to the source of the stimulating pulse, with constant-voltage and constant-current generators exhibiting somewhat different stimulation properties. The minimum energy necessary to initiate a propagated depolarizing wavefront reliably from an electrode is defined as the stimulation threshold^[3].

The intensity of an electrical stimulus that is required to capture atrial or ventricular myocardium is dependent on the duration of the stimulating pulse – i.e., the pulse width^[3]. The stimulus amplitude for endocardial stimulation has an exponential relation to the duration of the pulse, with a rapidly rising strength-duration curve at pulse widths less than 0.25 msec and a relatively flat curve at pulse widths greater than 1.0 msec^[3].

A small change in pulse duration is associated with a significant change in the threshold amplitude at short pulse durations but a small change at longer pulse durations. Because of the exponential relationship between stimulus amplitude and pulse width, the entire strength-duration curve can be described relatively accurately by two points on the curve, *rheobase* and *chronaxie*.

Figure 1, part A, below shows *rheobase* defined as the flattened portion of the strength-duration curve indicating the point at which increasing pulse width is no longer associated with a corresponding fall in voltage (Figure 1, part B). Rheobase thus indicates the voltage (pulse amplitude) at which capture will not be improved by and increase in pulse width. *Chronaxie*, on the other hand, is defined as the threshold pulse width on the strength-duration curve at twice the rheobase value^[5].

FIGURE 1: Strength-Duration Curve^[10]

Rheobase of a constant-voltage strength-duration curve is defined as the least stimulus voltage that will eventually stimulate the myocardium at any pulse duration. For practical purposes, rheobase voltage is usually determined as the threshold stimulus voltage at a pulse width of 2.0 msec. The chronaxie pulse duration is defined as the threshold pulsed duration at the stimulus amplitude that is twice the rheobase voltage^[5].

The chronaxie pulse duration is important in the clinical application of pacing, as it approximates the point of minimum threshold energy on the strength-duration curve.

With pulse durations greater than chronaxie, there is little reduction in threshold voltage^[6]. Rather, the wider pulse duration results in the wasting of stimulation energy, without providing an increase in safety margin^[6]. At pulse durations less than chronaxie there is a steep increase in threshold voltage and stimulation energy. Thus, the chronaxie pulse duration is usually close to the point of minimal stimulation energy^[6].

An appreciation of the threshold strength-duration relation is important for the proper programming of stimulus amplitude and pulse width. Modern pulse generators offer two major methods for evaluating the stimulation threshold: either automatic determination of the stimulus voltage at a constant pulse duration or automatic decrementation of the pulse duration at a constant stimulus voltage^[6]. In order to provide an adequate margin of safety, when the stimulation threshold is determined by decrementing the stimulus amplitude, the stimulus voltage is usually programmed to approximately twice the threshold value^[6]. Similarly, for pulse generators that determine threshold by automatically decrementing pulse duration, the pulse duration is usually programmed to at least three times the threshold value. It should be recognized that the hyperbolic shape of the strength-duration curve has important implications for interpreting the results of threshold testing^[6].

Device longevity is a crucial issue for implantable pacing devices, as it improves the patients' comfort while decreasing the cost of pacing therapy^[6]. A relevant feature to improve pacemaker longevity is the capability to detect effective stimulation, and to adjust the pacing output by a small safety margin according to measured threshold. By this approach to cardiac stimulation, the pacing output is periodically tailored following threshold variability, which may depend on physiologic and pathologic factors, at no compromise with patients' safety^[6]. Indeed, a continuous "reprogramming" of the pacing output occurs without any intervention by the physician: optimizing the output below battery voltage has been proved to save considerably the device longevity^[6]. It is in fact reported that, despite pacing thresholds being measured at follow-up visits, pacemakers are rarely reprogrammed below the battery voltage to improve longevity because of misleading perceptions or safety concern.

II. PROJECT OBJECTIVE

The objective of this thesis is to implement an algorithm which automatically and periodically evaluates the minimum ventricular stimulation threshold, based on a trove of research done by St. Jude Medical earlier in the 1990's and outlined here.

The AutoCapture algorithm can be programmed into three different modes: ON, OFF, or CALIBRATE. When AutoCapture is programmed to CALIBRATE, the AutoCapture algorithm uses the slope of the ventricular IEGM to differentiate capture from non-capture. When AutoCapture is programmed to OFF, the ventricular pulse amplitude and width are set to fixed values and the AutoCapture algorithm is disabled. When AutoCapture is programmed to ON, then the AutoCapture algorithms are enabled as described below^[7].

The AutoCapture algorithm applies a capture criterion to the evoked response following every primary pacing pulse to determine whether the pulse resulted in ventricular depolarization. If the evoked response fails the capture criterion, then a backup pulse is delivered shortly after the primary V-pulse^[7]. The amplitude of the backup pulse is large enough to ensure capture. If two consecutive primary pulses fail to capture, then the pacer enters a Loss of Capture Recovery routine, thus re-establishing capture. Once capture is reestablished, the AutoCapture begins a threshold search, which may establish a new amplitude for the primary V-pulse.

III. DESIGN AND IMPLEMENTATION

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FIGURE 5: Figure removed by St. Jude Medical legal

IV. RESULTS

The development of the Bi-Ventricular AutoCapture Algorithm involved several separate Firmware development teams. Some of the functionality was developed as sub-modules interacting with the main threshold search determination algorithm. All engineers involved, including myself, wrote different parts of the code as part of the implementation. My specific assignments on this project involved writing some parts of low-level hardware interaction code, as well as the actual threshold search algorithm and high level interactions with other parts of the platform. Specifically, I produced the code which obtains samples from the analog-to-digital converter (ADC) on dedicated signal channels, and processes these samples, beat-by-beat. I authored the state machine design presented in Figure 5 above, as well as its implementation, including writing unit testing and bench testing code of the overall algorithm. In addition, I helped in the development of a piece of code which assures that there is proper pacing and sensing by the device before a threshold search can actually begin.

The implementation of the above pieces of the system can be seen in Appendices A and B.

User Interactions

The Bi-Ventricular Auto Capture algorithm's main purpose is to allow the physician to find and program the most appropriate pacing pulse amplitude for a given patient and program this value permanently while *in-clinic*. Additionally, the physician can allow the algorithm to run *out-of-clinic*. In both cases, the minimal pacing amplitude is found. Appendix C shows a pictorial sequence of the Steps involved in determining the minimal pacing amplitude from a user's perspective.

While *in-clinic*, the physician interrogates the patient's device (Step 1) and observes the current state of the device in real time with intrinsic atrial activity (AS makers) and ventricular paced activity (VP markers). A threshold of 0.25 V

indicates a search has never been performed on this device since FW download and lead connection^[9]. The user is then allowed to select a different temporary pacing mode, rate of pacing, and starting amplitude (Step 2). Additionally, the user can choose to perform threshold search manually, observe the amplitude at which capture is lost, and set the pacing threshold by selecting the AutoCapture algorithm as a method of determining the minimum pacing threshold (Step 3). After all selections are done, the physician has to perform signal gain adjustment, so that the measurement during the actual threshold search determination test is correct (Step 4). This step is mandatory for first-time capture threshold performance. If a threshold has already been found once, gain adjustment can be skipped (Step 5). The basic functionality of the Gain Adjustment step of the algorithm is to reduce signal strength to a level where no signal clip-off occurs. This will ensure that the PDI and/or DMAX methods used to determine capture on every beat perform correctly^[9].

Once the Gain Adjustment is complete, the actual Threshold Search commences (Step 6)^[9]. The progression of the Threshold Search follows a pattern of pulses issued at each test pulse amplitude. Capture or non-capture is determined, followed by reduction of the test pulse amplitude to the next test level (Step 7)^[9].

Once capture is lost at test pulse amplitude of 1.5V, loss of capture (LOC) markers are issued. An additional step up to 1.625 V is made, to ensure continued capture. Safety margin is added, and the algorithm flow is complete (Step 8)^[9]. Finally, the user is presented with a trend showing all thresholds found by the algorithm within the past one year. This is indicated by a number of green dots in the “RVCap Confirm Trend” plot, each dot corresponding to a successful threshold search (Step 9)^[9]. The physician has the option of selecting to use the threshold found by the algorithm or ignore it and pick a pacing amplitude based on other considerations (Step 10)^[9].

V. DISCUSSION

St. Jude Medical's Bi-Ventricular AutoCapture algorithm is a unique algorithm in its implementation, though the idea of automatically searching and re-setting a pacemaker's or ICD's pacing amplitude is common in today's implantable cardiac devices. The algorithm achieves two main goals – 1) it gives the patient and treating physician the peace of mind that pacing is optimal, and 2) it increases device longevity, by minimizing unnecessary battery drainage throughout the lifetime of the device. Additionally, it provides a historical record of the pacing threshold in the form of a trend plot, alerting the physician of any possible disease progression, chemical imbalance, or other side effects of the chosen treatment course in the long run.

Implementation of the Bi-Ventricular AutoCapture algorithm is possible on the St. Jude hardware platform through the availability of more data channels and the simultaneous usage of sampled data for numerous purposes at the same time. With the availability of left ventricular leads in recent years, the algorithm allows for independent measurement of threshold in both ventricles – a particularly important point from a disease progression point of view. The additional capability to perform selective pacing within each of the ventricles gives physicians a multitude of options. St. Jude Medical has received very positive feedback from physicians around the world regarding the usefulness of the algorithm in that respect.

Many similarities in the algorithm's low level functionality allow for modular re-use of code in applications concerning autocapture in the right atrium as well.

VI. CONCLUSION AND FUTURE WORK

Compared to older platforms, the St. Jude Medical's current platform is a major milestone which allows for better, faster, and more precise data collection, retrieval, and processing. Yet, future improvements of the current hardware platform may benefit the existing Bi-Ventricular AutoCapture algorithm by providing capabilities such as higher sampling rates, and greater memory size for more stored diagnostics. Additionally, improvement in microprocessor characteristics may result in optimizations to real-time, beat-by-beat calculations being faster, and more energy efficient, thus improving the algorithm's overall duty cycle as well.

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VIII. APPENDIX A: Implementation Code

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IX. APPENDIX B: Unit Test Code

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X. APPENDIX C: User Interaction Workflow

FIGURE 6: Step 1 - Bi-Ventricular Algorithm – Initial State^[9]

FIGURE 7: Step 2 - Bi-Ventricular Algorithm – User Options^[9]

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FIGURE 15: Step 10 - Bi-Ventricular Algorithm – Pacing Amplitude Programmed (1.625 V)^[9]