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Original Article

# Automatic atrial capture device control in real-life practice: A multicenter experience

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ABSTRACT

*Background:* Device-based fully automatic pacing capture detection is useful in clinical practice and important in the era of remote care management.

The main objective of this study was to verify the effectiveness of the new ACAP Confirm® algorithm in managing atrial capture in the medium term in comparison with early post-implantation testing.

*Methods:* Data were collected from 318 patients (66% male; mean age, 73 ± 10 years); 237 of these patients underwent device implantation and 81 box changes in 31 Italian hospitals. Atrial threshold measurements were taken manually and automatically at different pulse widths before discharge and during follow-up (7 ± 2 months) examination.

*Results:* The algorithm worked as expected in 73% of cases, considering all performed tests. The success rate was 65% and 88% pre-discharge and during follow-up examination ($p < 0.001$), respectively, in patients who had undergone implantation. We did not detect any difference in the performance of the algorithm as a result of the type of atrial lead used. The success rate was 70% during pre-discharge testing in patients undergoing device replacement.

Considering all examination types, manual and automatic measurements yielded threshold values of 1.07 ± 0.47 V and 1.03 ± 0.47 V at 0.2-ms pulse duration ($p=0.37$); 0.66 ± 0.37 V and 0.67 ± 0.36 V at 0.4 ms ($p=0.42$); and 0.5 ± 0.28 V and 0.5 ± 0.29 V at 1 ms ($p=0.32$).

*Conclusions:* The results show that the algorithm works before discharge, and its reliability increases over the medium term. The algorithm also proved accurate in detecting the atrial threshold automatically. The possibility of activating it does not seem to be influenced by the lead type used, but by the time from implantation.



## 1. Introduction

The development of a fully automatic pacing system [1,2] is becoming increasingly important in today's remote-control era and is driven by the need to both improve patient safety and ensure pacing therapy. Device-based capture detection enables stimulation parameters to be continually adjusted in the ambulatory setting. This allows narrower safety margins to be used and prolongs the life of the device. Many of the follow-up tasks of the pacemaker and

*Abbreviations:* ICD, implantable cardioverter defibrillator; AV, atrial–ventricular; PM, pacemaker; CRT, cardiac resynchronization therapy; SD, standard deviation; SJM, St. Jude Medical

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implantable cardioverter defibrillator (ICD) are performed routinely and reported automatically by the device itself on the first programmer screen (fast-path). These tasks include measuring battery voltage, lead impedance, and sensed electrogram amplitude. Automatic programming adjustments for rate response, mode switching, and atrial–ventricular (AV) interval adaptation are commonplace [3–6]. These data are useful for both in-clinical and remote follow up. This capability was first described by Funke [7] in 1972. Currently, various pacemakers are able to detect ventricular capture automatically, a feature that has yielded benefits [8,9].

Furthermore, software-based solutions for pacing the cardiac chamber of interest with the lowest feasible energy and good safety margin can increase the life of the device.

Both surface and endocardial atrial signals have low amplitude and can be difficult to process because they are difficult to distinguish from signals originating from other sources. However, the availability of remote-control systems that allow the home management of patients with implantable devices has prompted researchers to develop more reliable algorithms for the automatic management of atrial capture.

The methods used for this purpose are, substantially, the analyses of atrial potentials, evoked atrial potentials [10], and ventricular rhythm in cases of stable spontaneous AV conduction [11].

Recently, St. Jude Medical (SJM) has proposed an updated version of its algorithm of atrial capture without changing the name (ACAP Confirm®). The aim of the present multicenter study was to verify the reliability of this new algorithm.

## 2. Materials and methods

### 2.1. Objective

The main objective of this study was to verify the effectiveness of the new ACAP Confirm® algorithm in managing atrial capture both in new implants and in patients undergoing device replacements. Effectiveness was defined as the number (%) of patients in whom ACAP Confirm® could be activated successfully by means of the in-clinic automatic threshold test, which means that the ACAP Confirm® is recommended by the device at the end of the test, and a threshold has been identified.

The secondary objectives were (1) to investigate the relationship with pulse width (performed by considering the percentage of activations recorded by the ACAP Confirm® Merlin PCS programmer at the end of the test run) and (2) to check the clinical equivalence of automatic and manual threshold test results.

### 2.2. Patient population

Data from 318 patients were retrospectively collected in 31 Italian hospitals. Data were collected in accordance with institutional guidelines on ethics. Patients underwent their first implantation or device replacement with a St Jude Medical device (PM, ICD, CRT-P, CRT-D: list of devices in appendix A) installed with ACAP Confirm® algorithm features between May 2011 and March 2012. Zephyr DR pacemakers were excluded because they were equipped with the first version of the algorithm, which had yielded unsatisfactory results [12]. Data from the first routine ambulatory follow-up examination ($7 \pm 2$ months [range, 2–12 months]) were also collected from first-time device recipients.

### 2.3. Methods

In cases of new implants, data were collected after the implantation procedure and during follow-up examination; in cases of device replacement, data were collected from the box-change procedure before discharge only. Atrial capture thresholds were measured in automatic and manual modes with different pulse durations (0.2, 0.4, and 1.0 ms). If the algorithm could not return a threshold measurement, the reason was documented, and an “intention-to-treat” approach was adopted (the first attempt result was considered, although the result could easily be overcome by a second attempt, e.g., fusion could be prevented by increasing the threshold test rate).

The new version of ACAP Confirm® uses the morphology of the evoked response to determine capture versus non-capture by using a correlation score that compares the waveform shape independently from the absolute amplitude. This morphology template is stored during loss of capture and is not visible. The template is created before *each* threshold search both in-clinic and out-of-clinic. The threshold test will automatically be performed if ACAP Confirm® is recommended. Moreover, ACAP Confirm® out-of-clinic testing could be programmed every 8 or 24 h.

### 2.4. Statistical analysis

Categorical variables describing the patient population are expressed as absolute numbers and percentages, whereas continuous variables are shown as means (with standard deviations [SD]) or medians (with quartiles) for continuous variables. Non-continuous variables were compared by using Fisher's exact test. Normally distributed, continuous variables were compared by using two-sample t test for independent variables or paired t test for paired data. Non-parametric Wilcoxon signed rank (for paired data) tests were used for non-normally distributed variables. All P values were two sided, and a $P$ value of $< 0.05$ indicates statistical significance.

**Table 1**
Atrial leads: manufacturer and models.

| Brand | Number and frequency (%) | Models (*N* patients) |
|---|---|---|
| Boston Scientific | 3 (1%) | Fineline 2 4480 |
| Biotronik | 3 (1%) | PX53JBP |
| Ela-Medical | 3 (1%) | Stelid 2 |
| Medtronic | 33 (10%) | 5568 (1)<br>5076 (2)<br>4076-active (1)<br>5554 (4)<br>4574 (21)<br>4592-passive (3)<br>N/A (1) |
| St. Jude Medical | 269 (84%) | 1488-active (1)<br>1688-active (2)<br>1782-active (2)<br>1882-active (19)<br>1888-active (12)<br>1420-passive (1)<br>1421T-passive (1)<br>1474-passive (4)<br>1642-passive (42)<br>1944-passive (176)<br>N/A (8) |
| Sorin | 1 (0.3%) | 58JB |
| Vitatron | 3 (1%) | ICM09JB (2)<br>IMD49JB (1) |
| Not available | 3 (1%) | |