Tech Corner

Right Ventricular Autothreshold (RVAT) in ALIZEA BOREA CELEA pacemakers

NOTE: PLEASE NOTE THAT THE FOLLOWING INFORMATION IS A GENERAL DESCRIPTION OF THE FUNCTION. DETAILS AND PARTICULAR CASES ARE NOT DESCRIBED IN THE ARTICLE. FOR ADDITIONAL EXPLANATION PLEASE CONTACT YOUR SALES REPRESENTATIVE.

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THE RIGHT VENTRICULAR AUTOTHRESHOLD

The Right Ventricular Autothreshold (RVAT) function allows automatic adjustment of the ventricular pacing amplitude, according to a threshold test performed automatically by the device at regular intervals (every 6 hours). The aim is to maintain automatically and periodically the ventricular capture and to adapt the ventricular pulse amplitude in order to ensure safety and to save energy.

AVAILABILITY

The Right Ventricular Autothreshold algorithm is available in the following pacemaker models:

- ALIZEA DR, SR[1]
- BOREA DR, SR[1,2]
- CELEA DR, SR[1,2]

RVAT algorithm is available in automatic, periodic threshold search and also in-clinic.

Notes:

- *RVAT function is also available in the previous MicroPort CRM pacemaker ranges (ENO, TEO, OTO, KORA 250…) with a few differences in the functioning.*
- *RVAT is available in the ICD/CRT-D range (ULYS, EDIS, GALI) with a different functioning (more details in the corresponding Tech Corner).*

INDICATIONS

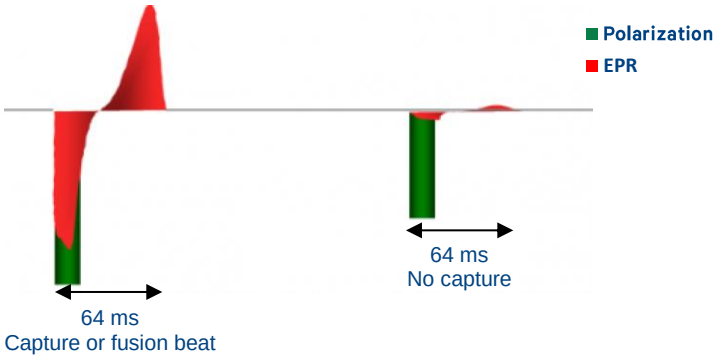
Ventricular Autothreshold is indicated for any patient whose pacing threshold is within normal limits (< 2 V). RVAT is also indicated for patients equipped with Remote Monitoring system: as the lead impedance and the detection; RVAT gives information on the ventricular capture to evaluate if a lead is working properly.

CAPTURE ANALYSIS

The capture analysis is performed during a capture window of 64 ms on the far-field EGM (RVring-Can EGM).

The main challenge for any ventricular autothreshold algorithm is to distinguish between the myocardial Evoked Potential Response (EPR) and the post-pacing polarization on the lead, which is due to the electric current flowing through the fluid at the tissue-electrode interface.

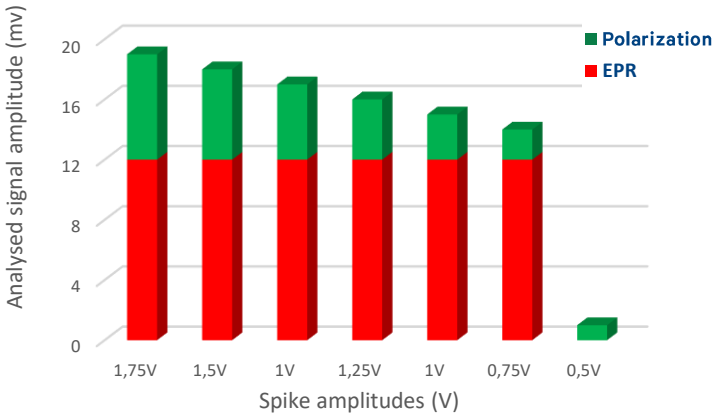
[1] *Not available for distribution or sale in the USA*
[2] *Not available for distribution or sale in Japan*



RV capture window of 64 ms. On the left side: the spike captures the ventricle. On the right side: the spike does not capture the ventricle, but there is still a signal measured by the lead: this is the post-pacing polarisation

In order to differentiate between the two signals (EPR and polarization), a calibration phase is required prior to each threshold test. The illustration above shows the theoretical difference between the measured EPR with polarization, and a non-capture beat with only the polarization present during the 64 ms capture window.

Another way to graphically represent the EPR/polarization is seen in the graph below.



Repartition between EPR and polarization through pacing amplitude step-down.

As the graph shows, during the threshold process the EPR remains constant whatever the delivered voltage of the spike. On the other hand, the polarization decreases progressively, as the voltage decreases.

DESCRIPTION OF THE FUNCTIONING

The right ventricular autothreshold in ALIZEA, BOREA and CELEA is launched every 6 hours, at 0 AM, 6 AM, 12 PM and 6 PM, fixed and non-programmable times.

RVAT is made of 5 phases; the objectives of each phase are described here after.

1. Starting phase
   Check of the accurate conditions to perform the test safely
2. Waiting phase
   Apply DDD mode (DR models) or VVI mode (SR models), apply test parameters and check for 100% of ventricular pacing
3. Calibration phase
   Verify capture at 4 V and 2 V; discriminate between evoked potential response (ERP) and post-pacing polarization and discard fusion.
4. Threshold search phase
   Find right ventricular threshold value through amplitude step-down
5. Amplitude adjustment phase
   Adjust the pacing amplitude by applying the pacing safety margin

Notes:

1. *The starting phase, waiting phase and amplitude adjustment phase are not applicable to the in-clinic RVAT.*
2. *RVAT disturbances may occur following events (for example cardiac rhythm variations) or interactions with other algorithms, which could disrupt the proper functioning of RVAT (see Definitions of interruption, retry and abortion section below).*

1. Starting phase

Aim

This phase ensures that the rhythm conditions are met to start the RVAT and that no other test functions are in progress.

Operation

At 00:00 AM, 6:00 AM, 12:00 PM and 6:00 PM, the device checks the following conditions.

If one or several of these conditions are not fulfilled, the device continues to search them cycle by cycle between two RVAT tests and will launch the RVAT as soon as they are fulfilled.

Conditions to start

The main conditions are:

- The cardiac rhythm should be lower than (<):
  - 85 bpm, if pacing mode is VVI or DDI, or Fallback Mode Switch is running, or
  - 100 bpm, if pacing mode is DDD, SafeR or Dplus.
- No atrial arrhythmia is starting or ending,
- No other algorithms are running (such as for example: algorithms which modify AV delay or escape intervals).

2. Waiting phase

Aim

The device:

- Applies the test parameters and
- Checks for 100% of right ventricular pacing.

Operation

This phase can encompass up to 3 steps:

1. AAI(R)→DDD(R) transition (SafeR or Dplus pacing modes)

   If the pacing mode is AAI(R) of SafeR or pseudo AAI of Dplus, the device switches first to DDD (one cycle).
2. AV delay reduction to reach the test AV delay

   The algorithm may add transitional cycles to enable progressive reduction of the AV delay from the current AV delay to the test AV delay (in case of long initial AV delay).
3. Pacing check

   The device checks for 100% of ventricular pacing under RVAT test configuration:
   - AV delay shorten to 63 ms (after A paced) or 39 ms (after A sensed) in DDD(R)
   - Escape interval is reduced by 102 ms in VVI(R) or DDI(R) or DDI(R) of Mode Switch

During this phase the RV amplitude is set to 5 V with programmed pulse width.

3. Calibration phase

Aim

The aim is:

- to verify that the ventricular spike captures at 4 V and 2 V,
- to discriminate between (Evoked Potential Response) EPR and post-pacing polarization, and
- to discard fusions.

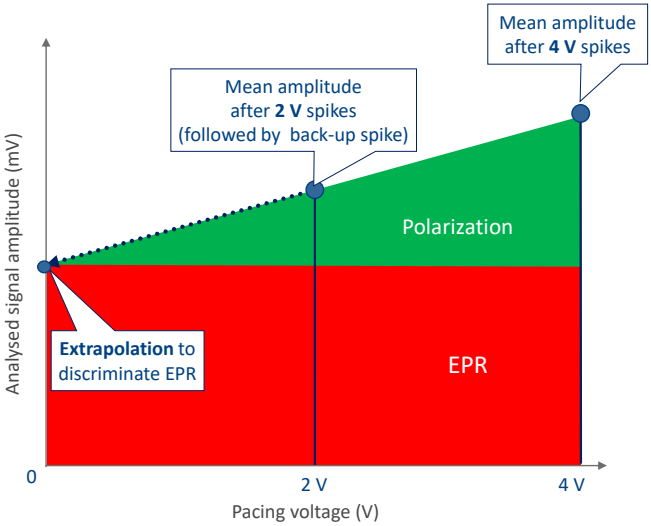
Operation

The calibration process includes the following steps:

1. Check of the 4 V and 2 V capture (6 cycles)
   - 3 pulses at 4 V at programmed pulse width: the device verifies that the signal measured after each spike is consistent, and averages the values.
   - 3 pulses at 2 V at programmed pulse width: the device verifies that the signal measured after each spike is consistent, and averages the values. These 3 pulses at 2 V are followed 64 ms later by a back-up pulse at 4 V/1 ms in order to ensure ventricular capture (as the device does not know yet if the threshold is lower or higher than 2 V).

2. Discrimination between EPR and post-pacing polarization (same 6 previous cycles)

   To estimate the EPR, the device extrapolates the EPR value at "0 V", based on these last two signal averages (one after 2 V spikes and the other after 4 V spikes).



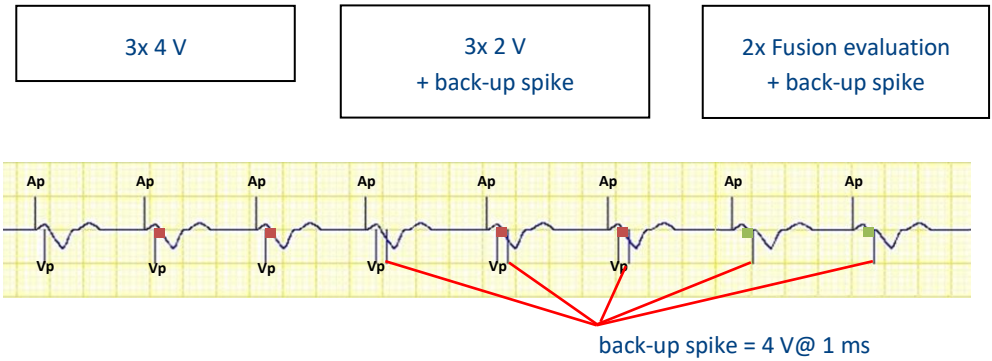
   In the event of interruption during the capture verification at 4/2 V or the discrimination between EPR/post-pacing polarization, the device interrupts the RVAT and retries later (see "Definitions of interruption, retry and abortion" section).

3. Fusion evaluation (2 cycles)

   The evaluation of the fusion during the calibration phase aims to identify if spontaneous ventricular depolarisation occurs at the time of ventricular stimulation (this is what is called fusion beats). This situation is not suitable to perform the RV pacing threshold because the ventricular capture cannot clearly be assessed.

   To check for fusion beats, the device opens the 64 ms "fusion window" and measures the ventricular amplitude (see "Capture Analysis" section). Then a back-up spike of 4 V/1 ms is applied at the end of the fusion window.

- If the device identifies spontaneous ventricular depolarisation during the fusion window (fusion beats could be suspected), then the device interrupts the RVAT and retries later (see "Definitions of interruption, retry and abortion" section)
- If no fusion is suspected, the next step starts (Threshold search phase).



Successful calibration phase in DOO (simulation).
Capture window
Fusion window

4. Threshold search phase

Aim

The goal of this phase is to find the RV threshold value, by checking if the measured ventricular signal is higher or lower than the ventricular evoked potential response.

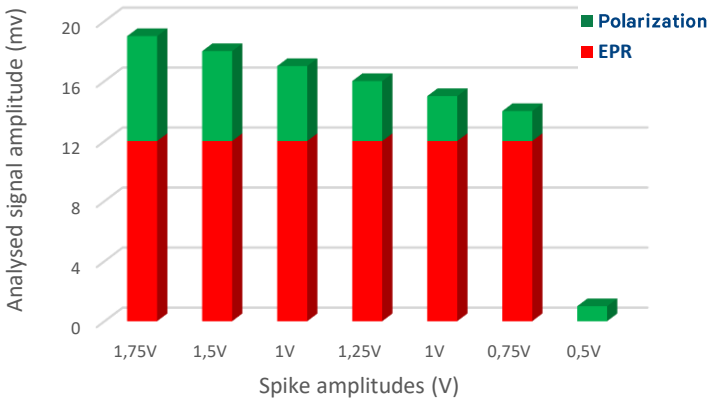
Operation

The device decreases the amplitude of test spikes progressively, starting at 1.75 V, with 0.25 V decrements, with capture analysis. It stops when the capture is lost (i.e. when the measured signal is lower than the EPR) or at 0.25 V. A 4 V/1 ms back-up pulse will follow the non-capture spike, at the end of the capture window.

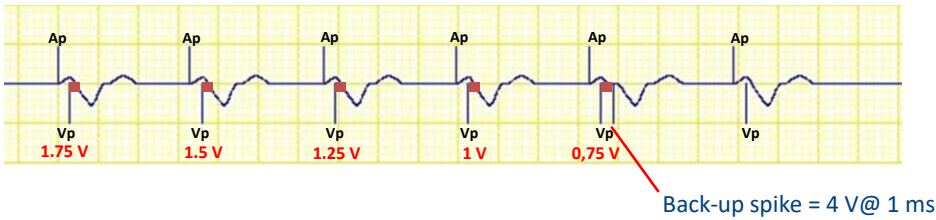
Test amplitudes during the threshold search phase (step-down):

Cycle number	*1*	*2*	*3*	*4*	*5*	*6*	*7*
Amplitude (V)	1.75	1.5	1.25	1	0.75	0.5	0.25

The figure below illustrate the functioning of the test: when the measured signal is lower than the EPR, it corresponds to post-pacing polarization only and the device concludes that the spike is inefficient (0,5 V). The threshold (0,75 V) is the previous spike, the last one higher than the EPR.



The figure below shows a threshold search phase.



Threshold search phase in DOO (simulation). Ventricular pacing threshold measured at 0.75 V.
Capture window

The device stores the voltage of the last capturing spike as ventricular pacing threshold.

5. Amplitude adjustment phase

Aim

The amplitude adjustment phase aims to adjust the pacing amplitude by applying the pacing safety margin.

Operation

Once the right ventricular automatic threshold test successfully ends, the device reprograms the right ventricular amplitude by multiplying the RV threshold by the programmed safety margin: x 2 by default (see Programming & Programming constraints).

Note: When RVAT is programmed on MONITORING, the RV threshold and the targeted amplitude are stored in the device memories but the amplitude is not adjusted.

DEFINITIONS OF INTERRUPTION, RETRY AND ABORTION

RVAT disturbances may occur following events (for example cardiac rhythm variations) or interactions with other algorithms, which could disrupt the proper functioning of RVAT.
Interruption, retry and abortion could occur during any phase except during the Starting phase where only abortion could occur.

Interruption / Retry

An interruption means that RVAT is stopped, whatever the phase, and the device relaunches ("retries") RVAT from the starting phase 15 min later (except if the device is programmed on SafeR or Dplus[3]). Up to 5 retries are allowed for each RVAT (*i.e.* 6 attempts in total).
Between 2 retries of RVAT, the current right ventricular amplitude remains unchanged until the next retry, except for one specific event described in the "Programming" section.
Examples of events leading to an interruption

- AV delay or escape interval is modified by another algorithm
- Pacing rate is reaching 100 bpm in DDD, Dplus, VDD,DDT, VVI, DDI or DDI of Mode Switch pacing mode
- No capture is identified in 4 V or 2 V tests
- Fusion beats are identified in" Fusion Evaluation" test

Abortion

An abortion means that RVAT is stopped, whatever the phase, and no retry is performed. A new RVAT will be performed at the next RVAT launch time (00:00 AM, 6:00 AM, 12:00 PM or 6:00 PM). When there is an abortion, the current right ventricular amplitude is set to the maximum value between the current right ventricular amplitude and the programmable "Safety Amplitude" until the next RVAT (see the "Programming" section).

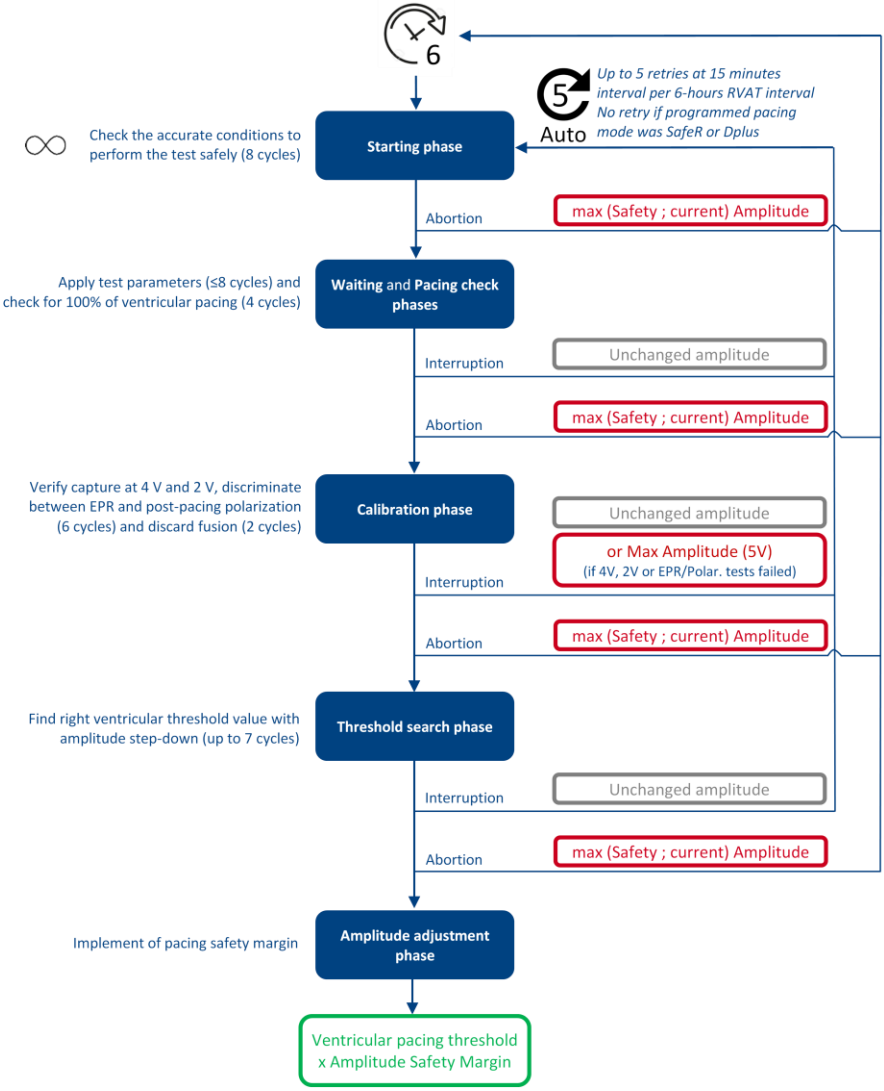
Example of events leading to an abortion

- The maximum number of available tests is reached
- Launch of RVAT while the previous one is still in the Starting phase

[3] When SafeR or Dplus mode is programmed, no retry is performed, because the ventricular pacing shall be minimized when the device is programmed in this mode.

SUMMARY OF RIGHT VENTRICULAR AUTOTHRESHOLD

Here after a summary of RVAT functioning when programmed “AUTO”.



Summary of RVAT process: description, aim, number of cycles, interruptions/abortions might leading right ventricular amplitude changes for each phase. EPR: Evoked Potential Response; Polar.: Polarization

PROGRAMMING

The RVAT is available when DDD(R), SafeR(R), Dplus(R), DDI(R), VVI(R), DDD/DDIR, SafeR/DDIR, Dplus/DDIR, VDD(R), VVT(R) or DDT(R) pacing mode is programmed.

"**Autothreshold**" is programmable and can be set on: AUTO, MONITORING or OFF.

If programmed to "AUTO" or to "MONITORING", the device performs the RVAT automatically at the non-programmable "**Start Time**": 00:00 AM, 6:00 AM, 12:00 PM and 6:00 PM (every 6 hours).

When the RVAT function is programmed to "MONITORING", the RV pacing threshold is measured, stored and the RV programmed pacing amplitude remains unchanged.

When the RVAT function is programmed to "AUTO", the RV pacing threshold is measured, stored and the RV pacing amplitude is automatically adjusted to the ventricular pacing threshold multiplied by the "**RV Amplitude Safety Margin**" in order to face potential small variations.

The "RV Amplitude Safety Margin" is a multiplier coefficient and a programmable parameter: x1.5 – x2 (default) – x2.5 – x3.

The RV adjusted ventricular pacing amplitude is always higher than the "**RV Min Amplitude**" and lower than the "**RV Max Amplitude**". The "RV Min Amplitude" is a programmable parameter: 1 – 1.5 – 2 – 2.5 (default) – 3 – 3.5 (V). The "RV Max Amplitude" is not a programmable parameter: 5 V.

When RVAT is interrupted, the current right ventricular pacing amplitude remains the same until the next retry except in case of the interruption due to failure during one of two first step of the calibration phase (capture verification at 4/2 V and the discrimination between EPR/post-pacing polarization). In this particular case, the right ventricular amplitude is forced to the programmable "**RV Max Amplitude**" (5V).

When RVAT is aborted, the right ventricular pacing amplitude is forced to the maximum value between the current programmed amplitude and the programmable "**RV Safety Amplitude**": 2 – 2.5 – 3 – 3.5 (default) – 4 – 4.5 – 5 – 6 (V) until new performed RVAT.
Thus, in the case of an abortion, if the current amplitude is already at the "Maximum Amplitude", the automatic amplitude adjustment to the maximum between the current right ventricular amplitude and the "Safety Amplitude" will set the current amplitude to the "Maximum Amplitude".

Note: When "RV Amplitude Safety Margin", "RV Min Amplitude", "RV Safety Amplitude" are reprogrammed, the device does not immediately apply changes to the right ventricular pacing amplitude. The new programmed value(s) will be taken into account at the next RVAT test (i.e. maximum 6 hours later).

For safety reasons, the RVAT will never lead to a pacing rate rhythm above the non-programmable "**RV Max Rate**" (100 min^{-1}).

When RVAT is programmed to “MONITORING”, the “RV Amplitude Safety Margin”, “RV Minimum Amplitude”, “RV Safety Amplitude” and “RV Maximum Amplitude” parameters are not applied. They are used only for the calculation of the “Suggested RV Voltage output” curve (see RIGHT Ventricular Autothreshold in AIDA
).

PROGRAMMING CONSTRAINTS

When RVAT is programmed:

- The ventricular sensing is bipolar
- Right ventricular pulse width is ≤0.5 ms,
- Rest AVD is ≥ 110 ms,
- Basic Rate is ≥35 bpm,
- Basic Rate is ≤ 80 min^{-1} when pacing mode is DDI(R), VVI(R), VVT or VOO (in-clinic RVAT), and
- The “RV Minimum Amplitude” is lower than the “RV Safety Amplitude”.

Notes:

1. *In the event of VVT pacing mode, RVAT is only done on non-triggered V paced events.*
2. *If Automaticity at implantation is activated with default settings, the as-shipped Autothreshold configuration “OFF” is automatically programmed to “Monitor” (as-shipped, programmable), 20 minutes after the confirmation of the implantation.*

RIGHT VENTRICULAR AUTOTHRESHOLD IN AIDA

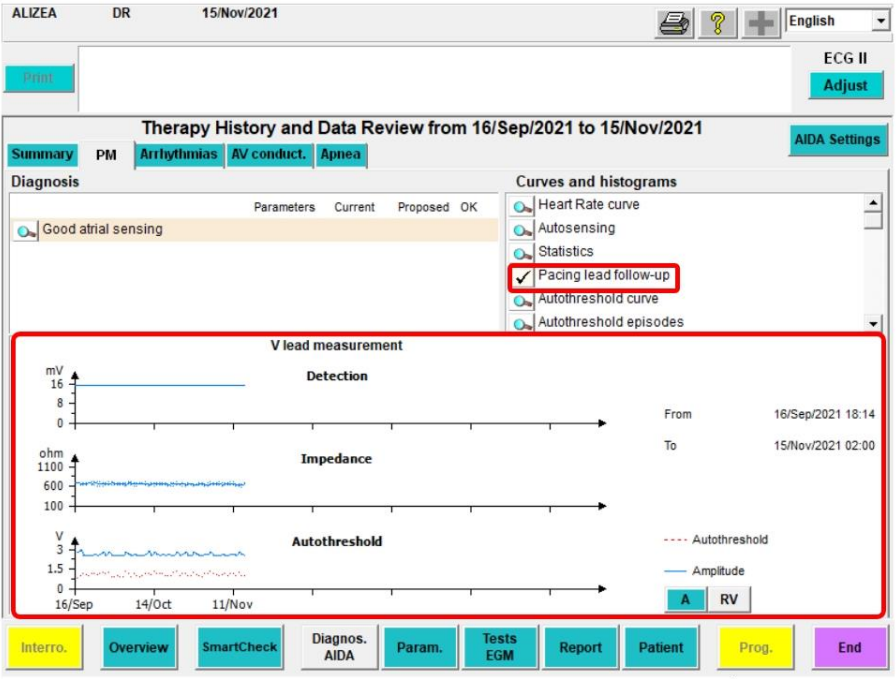
All programmer screens with data on RVAT are available when RVAT is programmed to “AUTO” or “MONITORING”.

Detailed statistics

Available statistics are:

- Number of successful RVAT in DDD and VVI pacing mode, and
- Number of RVAT failures due to maximum number of retries reached (5 retries, i.e. 6 attempts in total) and due to starting conditions not met until the next RVAT is launched.

Lead follow-up curves

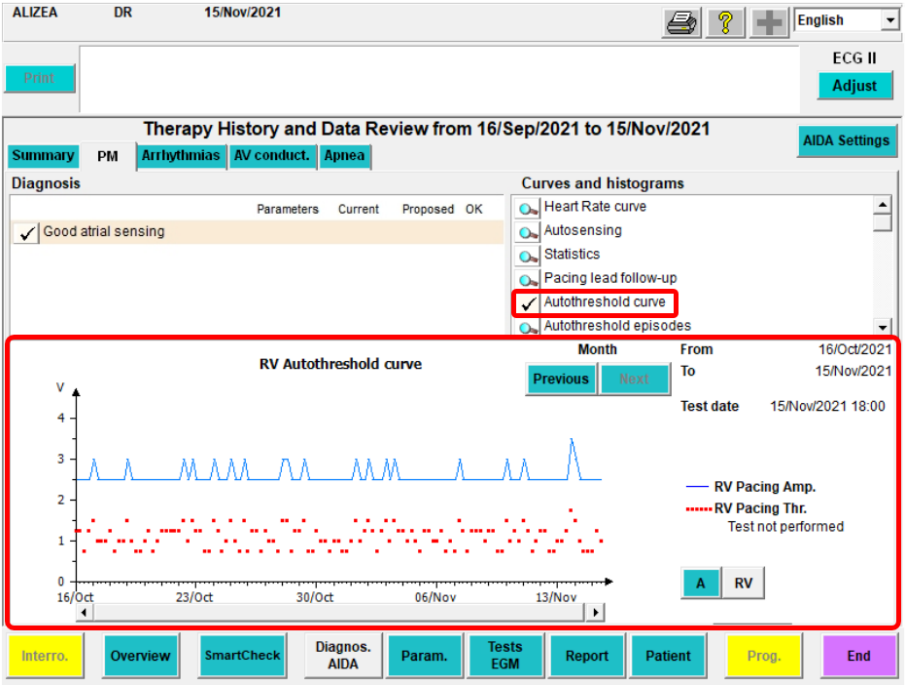


PM programmer screen with RV lead measurement trends when RV Pacing lead follow-up is selected.

On Diagnos. AIDA screen, in PM tab, click on “Pacing lead follow-up” magnifying glass to display 6 months lead measurements trends. By selecting the RV chamber, the right ventricular lead trends are displayed.

When RVAT was programmed to “AUTO” or “MONITORING”, the “Autothreshold” curve displays the daily mean of RV pacing thresholds (red dots), calculated on up to 4 measurements and the adjusted RV pacing amplitude (blue curve).

Autothreshold curves

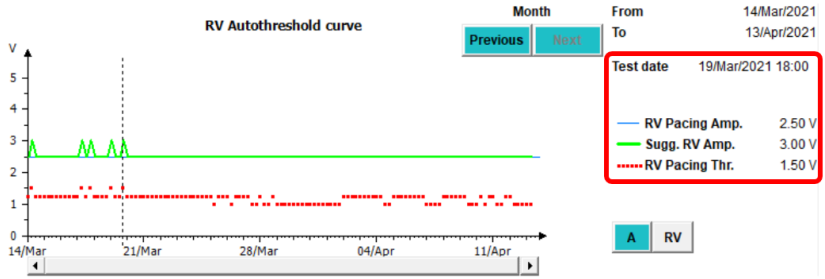


PM programmer screen with RV Autothreshold Curve when RV Authothreshold curve is selected and RVAT was programmed to "AUTO".

In "Diagnos. AIDA" screen, on PM tab, click on Autothreshold curve magnifying glass to display the detailed Autothreshold curves over the last month. By selecting the RV chamber, the right ventricular lead trends are displayed.

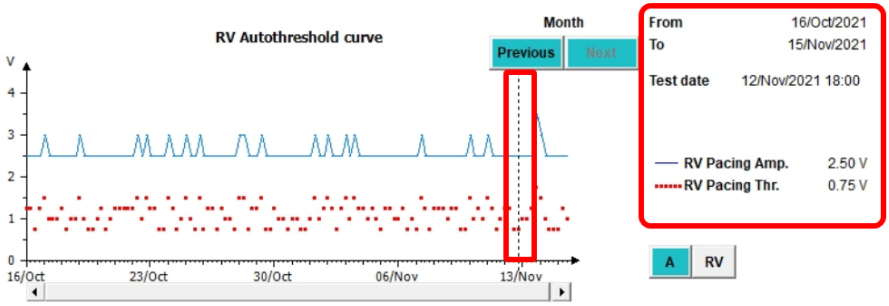
When RVAT was programmed to "AUTO" or "MONITORING", the "Autothreshold" curve displays the RV measured pacing thresholds (red dots, up to 4 per day) and the adjusted (AUTO) or fixed (MONITORING) RV pacing amplitude (blue curve).

When RVAT was programmed to "MONITORING" the additional green curve is displayed showing how the amplitude would have been programmed if RVAT was programmed to "AUTO".



PM programmer screen with RV Autothreshold Curve when RV Authothreshold curve is selected and RVAT was programmed to "MONITORING".

When clicking on curves, the exact value of the measured RV pacing threshold (or the failure reason) and the adjusted RV pacing amplitude are displayed on the right part of the screen for the selected test at the selected date (up to 4 detailed measurements per day). In the example below: test 3/4 (12:00 AM) on 20/Nov/2020).



PM programmer screen with RV Autothreshold Curve when RV Authothreshold curve is selected and RVAT was programmed to "AUTO".

Diagnosis

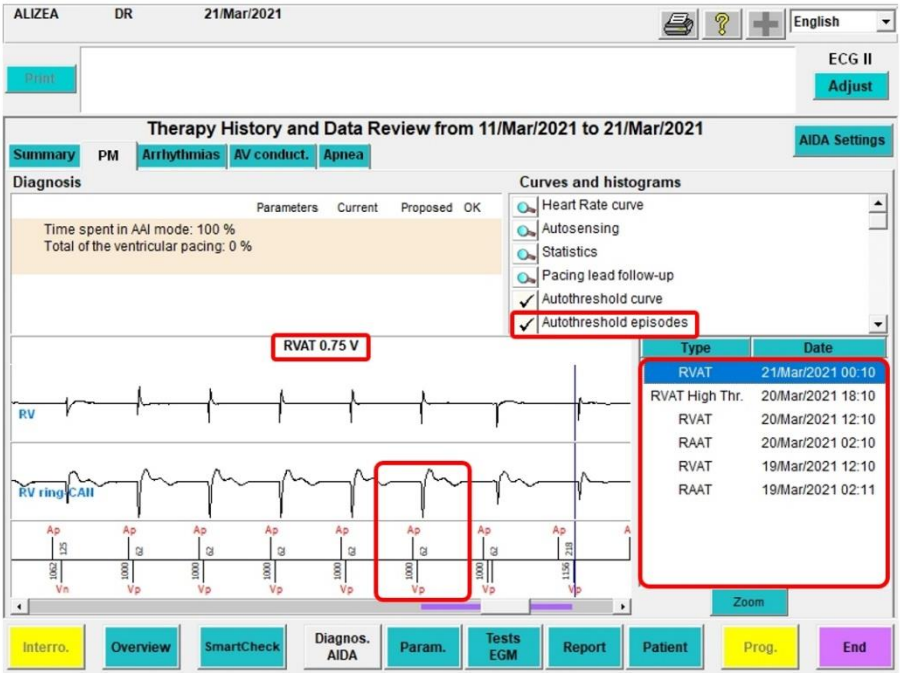
RVAT automatic interpretations are available when the follow-up period with RVAT programmed to "AUTO" or "MONITORING", is above 1 month.

Hereafter, the list of topics related to RVAT automatic diagnosis available:

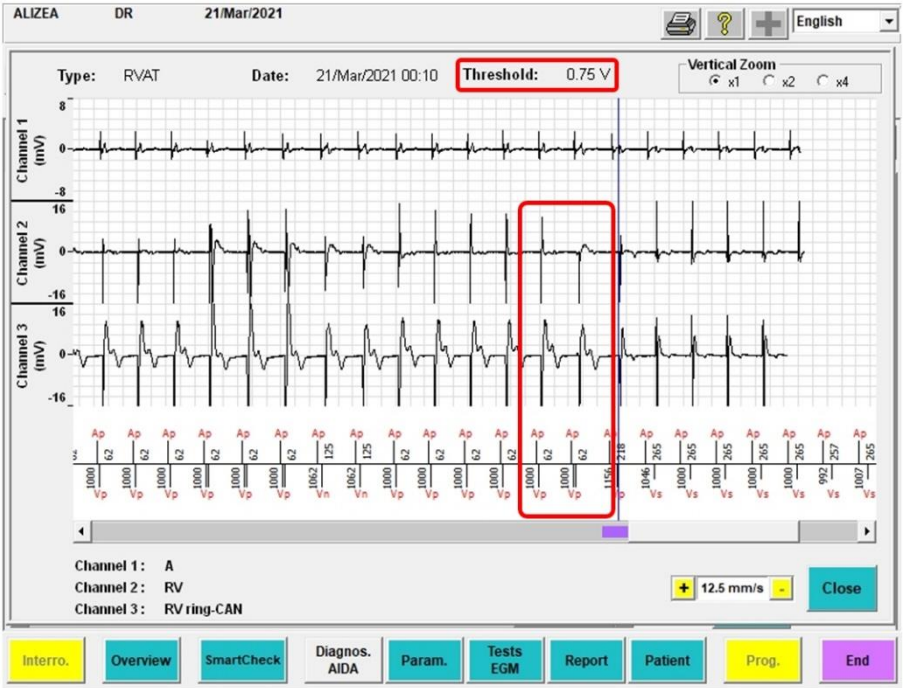
1. Low successfulness of RVAT
2. Overestimation of RVAT
3. Too low "RV Safety Amplitude"
4. Too high "RV Min Amplitude"

Stored Autothreshold episodes

On Diagnos. AIDA screen, in PM tab, click on the Autothreshold episodes magnifying glass to display detailed episodes, including markers and EGMs (RV bipolar, RVring-CAN). Episodes can be filtered by type and date. When an RVAT episode is selected, the measured pacing threshold is displayed on the top of the strip. Thanks to the "Zoom" button, each RVAT episode can be zoomed in, and atrial EGM channel is displayed for a more accurate analysis (for DR models only).



PM programmer screen with RVAT episodes when Authothreshold episodes is selected.



PM programmer screen with RVAT episodes when Autothreshold episodes and zoom are selected for accurate analysis

Refer to user manual for complete instructions for use available at www.microportmanuals.com.

Note: all programmer screenshots were captured from SmartView 3.06.