

Tech Corner

Right Ventricular Autothreshold (RVAT) in ICD/ CTR-D

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 pacing amplitude in order to ensure safety and to save energy.

AVAILABILITY

The Right Ventricular Autothreshold is available in the following single-chamber ICD, dual-chamber ICD and CRT-D models:

- EDIS VR & ULYS VR¹,
- EDIS DR & ULYS VR¹,
- GALI CRT-D, GALI SonR CRT-D, GALI 4LV CRT-D & GALI 4LV SonR CRT-D VR¹.

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

Notes:

- *RVAT function is also available in the previous MicroPort CRM range (ENO, TEO, OTO, KORA 250...) with a few differences in the functioning*
- *RVAT is available in the new pacemaker ranges (ALIZEA, BOREA, CELEA), see corresponding Tech Corner.*

INDICATIONS

Right Ventricular Autothreshold is indicated for any patient whose pacing threshold is within normal limits (< 5 V). RVAT is also indicated for patients equipped with Remote Monitoring system (the autothreshold is valuable information to know if a lead is working properly, as the lead impedance and the detection; RVAT gives information on the ventricular capture to evaluate if a lead is working properly).

CAPTURE DETECTION

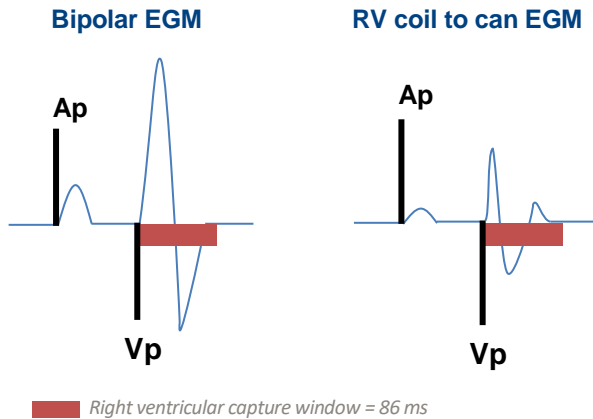
The ICD and CRT-D RVAT algorithm is based on the analysis of ventricular evoked potential response, i.e. ventricular amplitude.

During the test:

1. After right ventricular test spikes, both right ventricular bipolar EGM (Bipolar) and right ventricular coil to can EGM (Coil-Can) signals are analysed within a 86 ms capture window. The bipolar ECG is also called near-field EGM and the RV coil-can EGM is also called far-field

EGM.

2. The combined analysis of the two EGMs allows to conclude if the RV spike did capture or not.
3. In the 86 ms window, the device measures the peak-to-peak amplitude for both Bipolar and RV Coil-Can EGM. Capture is confirmed
 - when the amplitude on the Bipolar EGM is higher than 30 mV (≥ 30 mV), OR
 - when the amplitude on the RV Coil-Can EGM is higher than 1,5 mV ($\geq 1,5$ mV).



Right ventricular capture window on near-field EGM (Bipolar EGM) and far-field EGM (Coil-Can EGM)

DESCRIPTION OF THE FUNCTIONING

The right ventricular autothreshold is launched 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 test max amplitude (5V); discard fusion and definition of starting amplitude
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 check phases 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 or SafeR.
- No atrial or ventricular arrhythmia are ongoing,
- 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 step by step according to the programmed pacing mode , and
- Checks for 100% of right ventricular pacing.

Operation

This phase can encompass up to 3 steps:

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

If the pacing mode is AAI(R) of SafeR, 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 RV amplitude is set to 5 V with programmed pulse width.

3. Calibration phase

Aim

The aim is:

- to verify that ventricular spike at the test max amplitude (5 V) captures,
- to discard fusion, and
- to define the starting amplitude of the step-down threshold search phase (see “**Erreur ! Source du renvoi introuvable.**” section).

Operation

This phase takes place over three or four cycles and encompass 3 steps:

1. Evaluation of capture at test max amplitude (5 V)

In order to know if the pacing threshold is within normal limits, the device check first the capture at test max amplitude (5 V). Remember that capture analysis is based on peak-to-peak amplitude measurement of the EGM over the capture window. Capture is declared if the signal amplitude is above the capture detection threshold on at least 1 of the 2 EGM signals (see “Capture detection” section). If capture at test max amplitude (5 V) is confirmed, the Fusion evaluation will take place just after. If capture at 5 V is not established (RV pacing threshold is upper than 5 V), the device applies a back-up spike at 5V/1ms, interrupts the RVAT and retries 15 min after (if the total number of retry has not been reached yet, see “Definitions of interruption, retry and abortion” section).

2. Fusion evaluation

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.

During the cycle of fusion evaluation (without RV pacing), the device opens the 86 ms fusion window and measures the ventricular amplitude (see “Capture detection” section). Then a back-up spike of 5 V / 1 ms is applied at the end of the fusion window.

- If the device identifies spontaneous ventricular depolarisation during the fusion window similar to ventricular “capture”, (fusion beats could be suspected), the fusion test is then repeated one more time. If fusion is still suspected after this second fusion-test, the device interrupts the RVAT and retries 15 min after (if the total number of retry has not been reached yet, see “Definitions of interruption, retry and abortion” section).

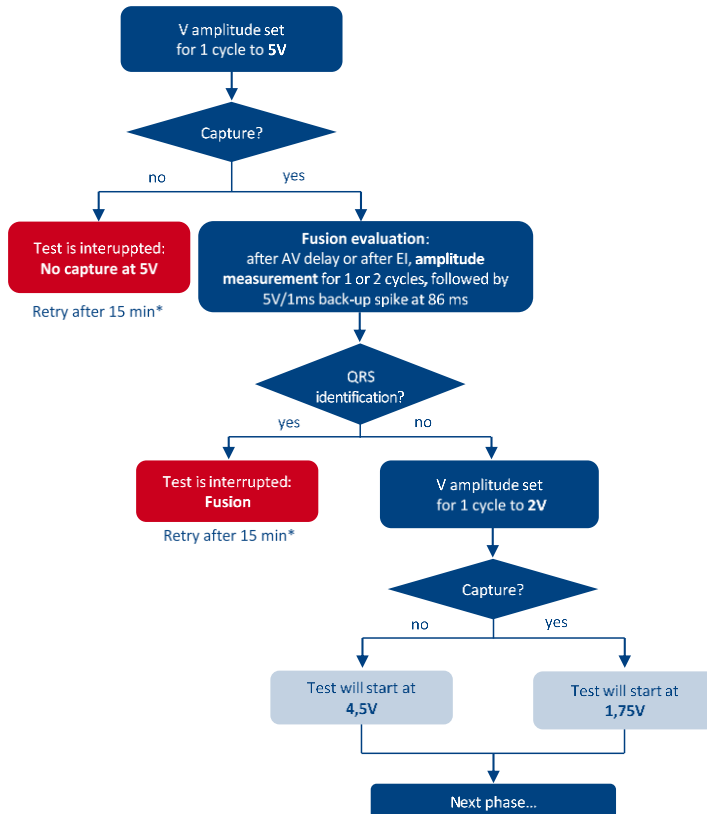
- If no fusion is suspected, the next step starts (identification of starting amplitude).

3. Identification of starting amplitude for pacing threshold test

The device needs to know if the pacing threshold is lower than 2 V to reduce the test duration and thus reduce the number of the test spikes (from 14 to 7).

The device applies a 2 V test spike and verifies the capture (see “Capture detection” section):

- If capture at 2 V is confirmed, the test starts at 1,75 V with maximum 7 test spikes (step-down threshold search phase).
- If no capture at 2 V, the device applies a back-up spike at 5V/1ms and the test starts at 4.5 V with maximum 14 test spikes.



RVAT calibration phase: 5 V test, fusion evaluation, identification of starting amplitude for pacing threshold test
EI: Escape Interval

4. Threshold search phase

Aim

The goal of this phase is to find RV threshold value, by analysing of ventricular evoked potential response.

Operation

The threshold test phase starting amplitude is 4,5V or 1,75V according to the results of the calibration phase. The device is progressively decreasing the test spike amplitude, verifying capture. It stops when the capture is lost or at 0,25 V. For each amplitude tested, the peak-to-peak signal amplitude on both EGM is analysed. Loss-of-capture is declared once the capture detection criteria are no longer met (see “Capture detection” section) and a back-up spike is applied at 5 V/1 ms, 86 ms after the non-captured spike.

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

Cycle number	1	2	3	4	5	6	7	8	9	10	11	12	13	14
If pacing threshold starts at 4.5 V	4.5	4	3.5	3	2.5	2,25	2	1,75	1.5	1.25	1	0.75	0.5	0.25
If pacing threshold starts at 1.75 V	1.75	1.5	1.25	1	0.75	0.5	0.25							

Reminder of capture detection criteria:

- Amplitude on the Bip EGM is higher than 30 mV (≥ 30 mV), or
- Amplitude on the RV coil-Can EGM is higher than 1,5 mV ($\geq 1,5$ mV).

The device stores the voltage of the last captured 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

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[®]). 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 if the interruption occurs during the 5 V test of the calibration phase. In this case, the amplitude is set to “Max Amplitude”, 6 V (not programmable).

Examples of events leading to an interruption

- AV delay or escape interval is modified by another algorithm
- Pacing rate is reaching 100 bpm
- PARAD is detecting a tachycardia majority (among SVT/ST, VT, VTLC or VF majorities)
- No capture is identified in 5 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 right ventricular amplitude is set to the maximum value between the current RV amplitude and the programmable “Safety Amplitude” until the next RVAT.

Examples of events leading to abortion

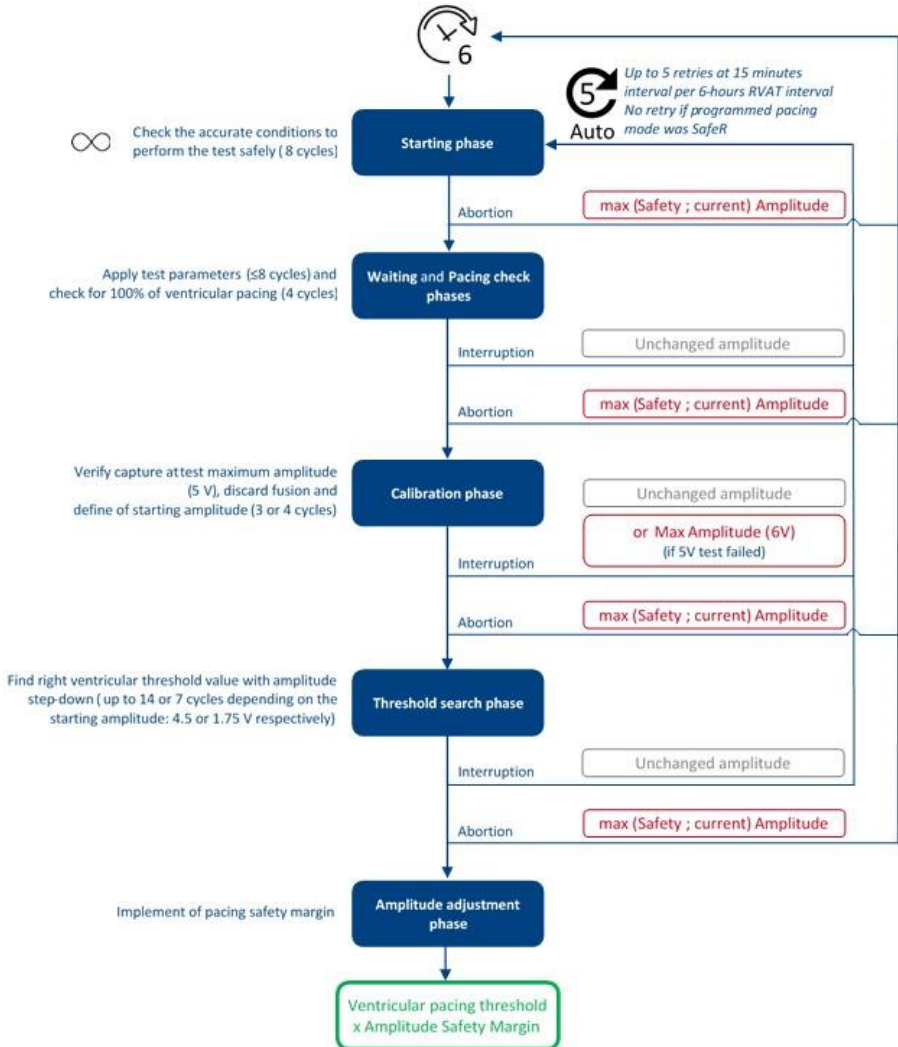
- The maximum number of available tests is reached, or
- Launch of RVAT while the previous one still in Starting phase.

Note: Retry is not performed in the in-clinic RVAT.

¹ When SafeR 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.

PROGRAMMING

The RVAT is available when DDD(R), SafeR(R), DDI(R), VVI(R) or DDD/DDIR 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 and stored but 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: 6 V.

When RVAT is interrupted, the current right ventricular pacing amplitude remains the same except in case of the interruption for non-capture at the test maximum amplitude (5 V). In this particular case, the right ventricular amplitude is forced to the non-programmable “RV Max Amplitude” (6V).

When RVAT is aborted, the current 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. 6 hours later).

For safety reasons, the RVAT will never lead to a pacing rate 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 RVAT in AIDA).

PROGRAMMING CONSTRAINTS

When RVAT is programmed:

- 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) or VOO (in-clinic RVAT), and
- The “RV Minimum Amplitude” is lower than the “RV Safety Amplitude”.

RIGHT VENTRICULAR AUTOTHRESHOLD IN AIDA

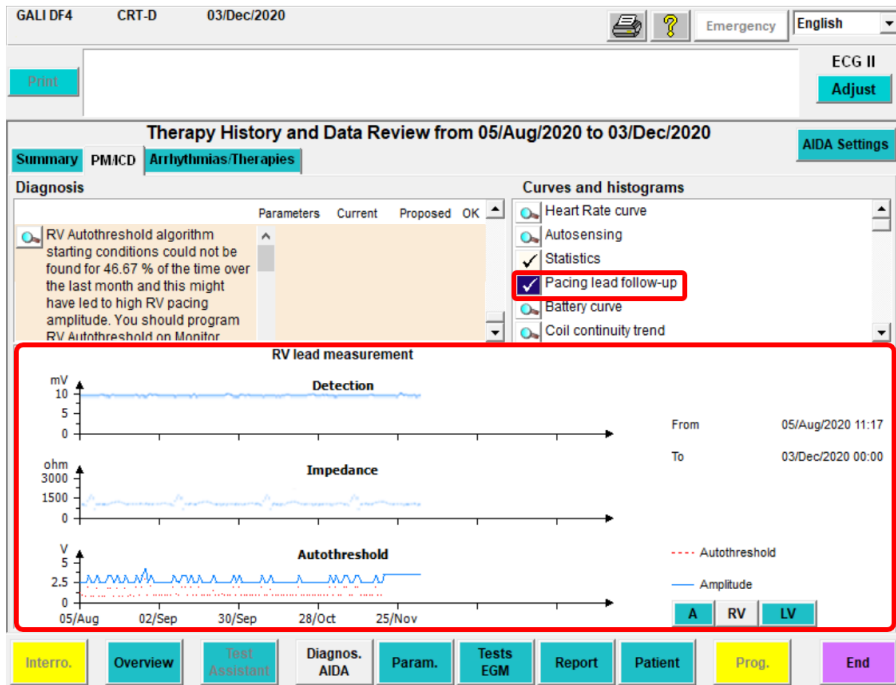
All programmer screens with data on RVAT are available when RVAT is programmed to “AUTO” or “MONITORING”.

Detailed statistics

Available statistics are:

- Numbers of successful RVAT in DDD and VVI pacing mode, and
- Numbers 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

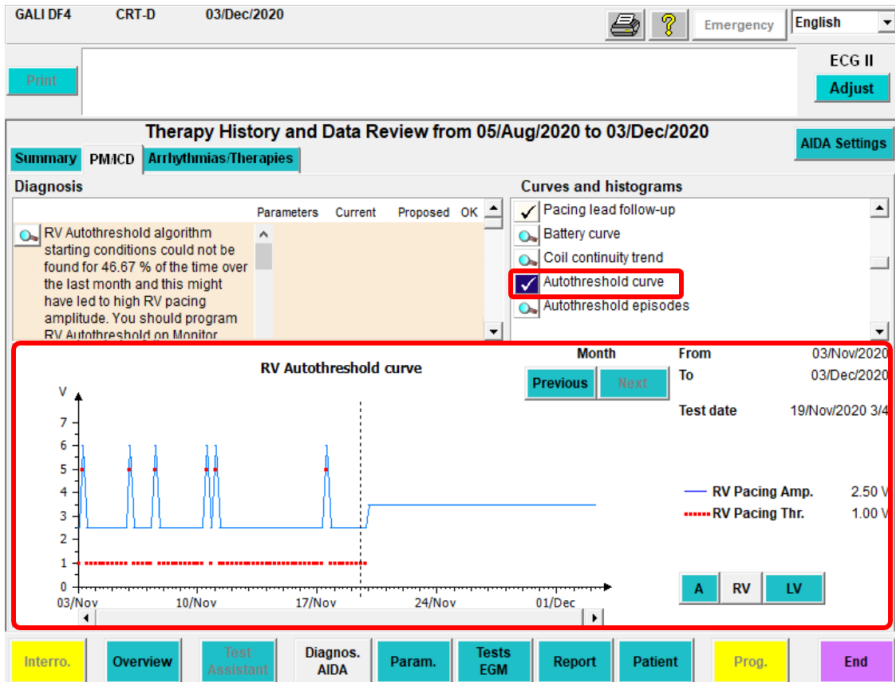


PM/ICD programmer screen with RV lead measurement trends when RV Pacing lead follow-up is selected.

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 (red dots) the daily mean of RV pacing thresholds (calculated on up to 4 measurements) and the adjusted RV pacing amplitude (blue curve).

Autothreshold curves

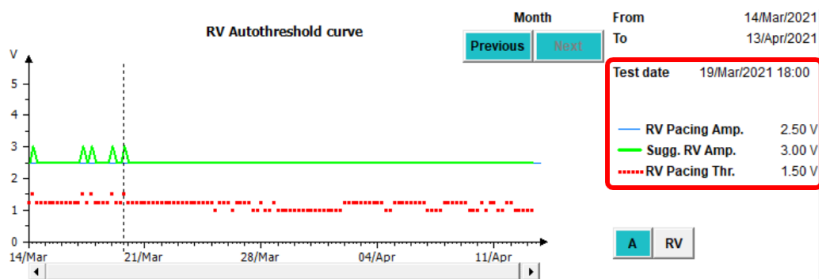


PM/ICD programmer screen with RV Autothreshold Curve when RV Autothreshold curve is selected and RVAT was programmed to "AUTO".

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.

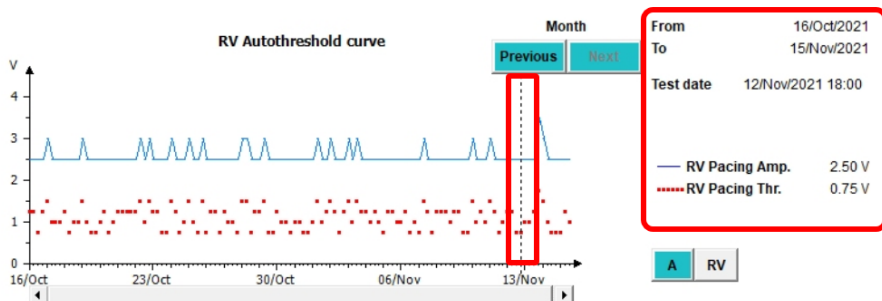
When RVAT was programmed to "AUTO" or "MONITORING", the "Autothreshold" curve displays the RV measured pacing thresholds (red dots, up to 4 per day) and the adjusted RV pacing amplitude (blue curve).

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

When clicking on curves, the exact value of the measured RV pacing threshold (or the reason for failure) 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/ICD programmer screen with RV Autothreshold Curve when RV Autothreshold 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 Autothreshold episodes magnifying glass to display detailed episodes, including markers and EGMs (RV bipolar, RVcoil-CAN by default). 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).

Therapy History and Data Review from 05/Aug/2020 to 03/Dec/2020

Diagnosis

RV Autothreshold algorithm starting conditions could not be found for 46.67 % of the time over the last month and this might have led to high RV pacing amplitude. You should program RV Autothreshold on Monitor

Curves and histograms

- ☒ Pacing lead follow-up
- ☐ Battery curve
- ☐ Coil continuity trend
- ☒ Autothreshold curve
- ☒ Autothreshold episodes

Type	Date
RVAT	19/Nov/2020 16:5
RVAT	19/Nov/2020 10:5
RVAT	19/Nov/2020 04:5
LVAT	19/Nov/2020 00:5
RAAT	19/Nov/2020 00:0
RVAT	18/Nov/2020 22:5
RVAT	18/Nov/2020 16:5
RVAT	18/Nov/2020 10:5
RVAT High Thr.	18/Nov/2020 04:5

RVAT 1.00 V

RV

RV coil-CAN

As

Vn

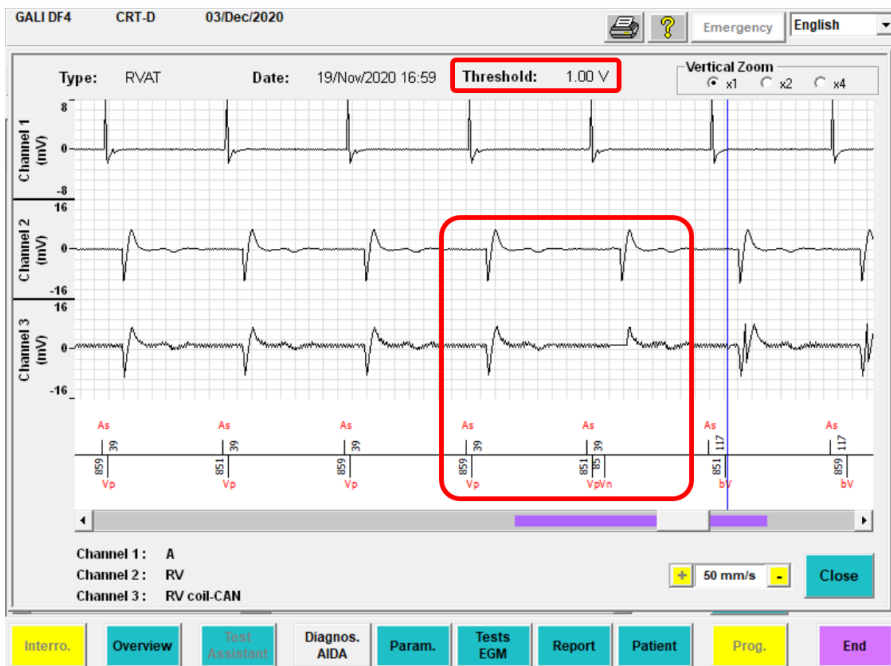
Vp

bV

Zoom

Interro. **Overview** **Test Assist.** **Diagnos. AIDA** **Param.** **Tests EGM** **Report** **Patient** **Prog.** **End**

PM/ICD programmer screen with RVAT episodes when Autothreshold episodes is selected.



PM/ICD programmer screen with RVAT episodes when Autothreshold episodes and zoom are selected (for accurate analysis).

Refer to user's manual furnished with the device for complete instructions for use (www.microportmanuals.com).

¹ Available in Europe

Note : all programmer screenshots were captured from SmartView 3.06.