

Tech Corner

Left Ventricular Autothreshold (LVAT) in CRT-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.

NOT AVAILABLE FOR DISTRIBUTION OR SALE IN THE USA.

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THE LEFT VENTRICULAR AUTOTHRESHOLD

The Left Ventricular Autothreshold (LVAT) feature allows automatic adjustment of the left ventricular pacing amplitude, according to a threshold test performed automatically by the device at regular intervals. The aim is to automatically and periodically maintain the left ventricular capture to patient's evolving needs and to adapt the left ventricular pulse amplitude in order to ensure safety and save energy.

AVAILABILITY

The Left Ventricular Autothreshold (LVAT) is available in the following CRT-D models¹:

- GALI CRT-D,
- GALI SonR CRT-D,
- GALI 4LV CRT-D, and
- GALI 4LV SonR CRT-D.

LVAT algorithm is available in automatic (periodic threshold search) and also in-clinic.

INDICATIONS

LVAT is indicated for any CRT-D patient whose left ventricular pacing threshold is inferior (<) to 6V. LVAT is also indicated for patients equipped with Remote Monitoring system: as the lead impedance, LVAT gives information on the ventricular capture to evaluate if a lead is working properly.

CAPTURE DETECTION

LVAT is based on:

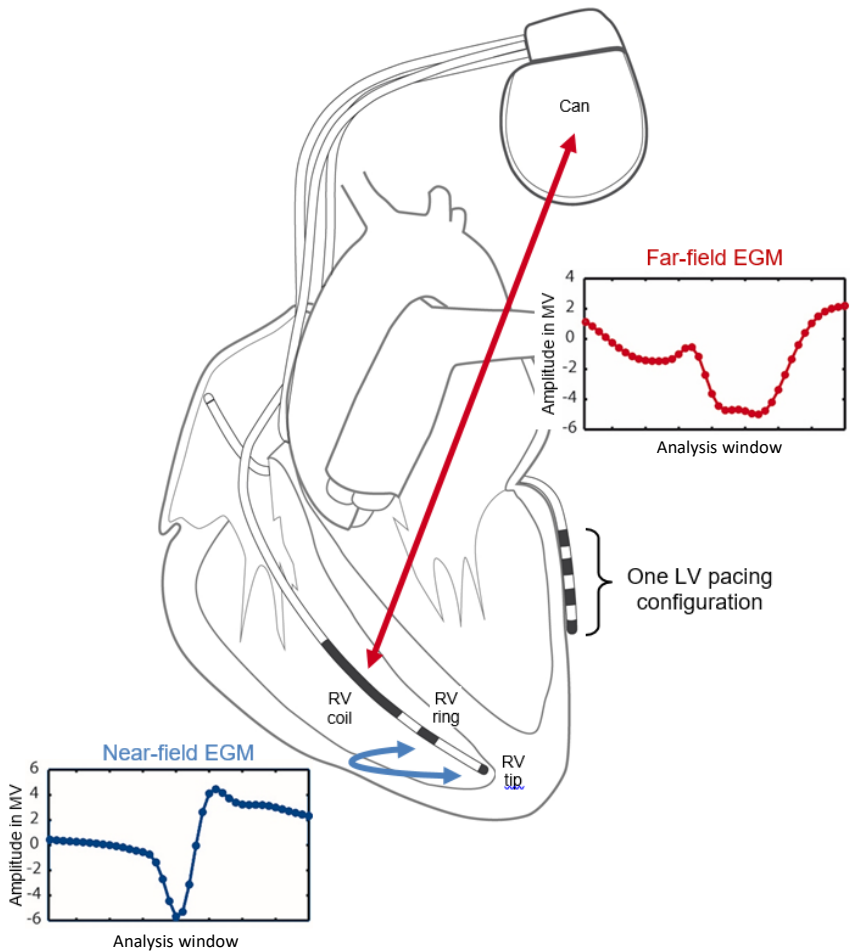
- the measurement, after LV pacing, of the ventricular Evoked Potential Response (EPR) on the near-field and the far-field EGMs of the **right** ventricular defibrillation lead, and
- the morphological analysis of these responses.

The morphological analysis is a multidimensional representation of the ERPs from 2 EGMs (far-field and near-field) during a period of time after LV pacing. The resulting representation is a RV coil to can amplitude (far-field) versus RV bipolar amplitude (near-field) curve.

This representation helps to distinguish a specific pattern of an efficient LV pacing amplitude (capture) from pattern of an inefficient LV pacing amplitude (no capture).

Ventricular ERP

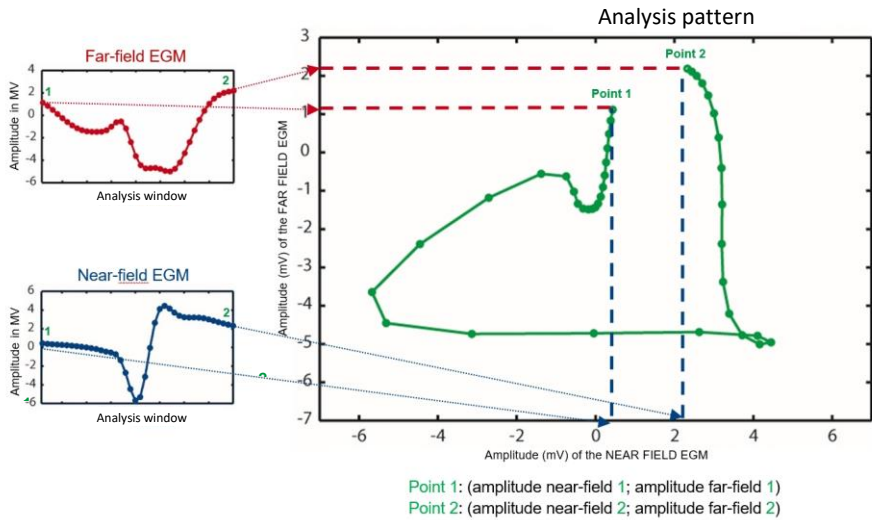
One ventricular ERP comes from the far-field EGM and the other one comes from the near-field EGM during the analysis window.



The right ventricular EPRs are detected on the near-field EGM and the far-field EGM after LV pacing.

Creation of a morphological pattern (curve)

To create the morphologic pattern, the device “plots” the amplitude of the far-field EGM versus the amplitude of the near-field EGM with time as a parameter. The temporal information is therefore preserved between the 2 EGM amplitudes.



Each point of the morphological pattern is defined by a pair of amplitudes: the amplitude of the near-field EGM and the one of the EGM far-field at a given time during the analysis window.

Comparison of the 2 morphological patterns

To distinguish the capture from the non-capture of LV pacing: the morphological analysis uses a reference pattern after LV pacing that captures and compares it to a pattern obtained after LV pacing with a tested pacing amplitude.

This comparison leads to 2 possible conclusions:

- Capture because the tested amplitude morphological pattern is similar to the reference pattern, or
- No capture because the tested amplitude morphological pattern is different from the reference pattern.

The in-clinic LVAT is available but its execution differs mainly from what is described below in this document.

DESCRIPTION OF THE FUNCTIONING

The left ventricular autothreshold is launched at 1:00 AM (as-shipped value, programmable) on the programmed left pacing vector configuration.

When Multipoint LV Pacing (MP) is activated, another LVAT is launched 15 min later on the 2nd programmed pacing vector.

LVAT is made of 5 phases; the objectives of each phase are described below.

1. Starting phase
Check of the accurate conditions to perform the test safely (slow and stable rhythm)
2. Waiting phase
Apply test parameters according to the pacing mode
Confirm the short AV delay (AVD) is applied (for DDD mode only)
3. Calibration phase
Discard high threshold value and fusion
Elaborate and validate a reference
4. Threshold search phase
Find left ventricular threshold value through LV amplitude step-down
5. Amplitude adjustment phase
Adjust the left pacing amplitude by applying the pacing amplitude safety margin

Note: Upon cardiac rhythms variation, interactions with other algorithms, etc. LVAT can be interrupted or aborted as these events could prevent the proper functioning of LVAT (see Definitions of interruption, retry and abortion section).

1. Starting phase

Aim

This aim of the starting phase is to ensure that rhythm conditions are met to perform the LVAT safely (slow and stable rhythm) and that no other test function is in progress.

Operation

Before performing the test on the programmed left pacing vector configuration, the device checks the following conditions at 1:00 AM (as-shipped, programmable). If one or several of these conditions are not fulfilled, the device continues to search cycle by cycle until midnight and will launch the LVAT as soon as they are fulfilled.

Conditions to start

The main conditions are:

- The cardiac rhythm is lower than (<) 85 bpm (with as-shipped values), or
- No ventricular arrhythmia is detected,
- No therapy or post-shock mode is ongoing,
- No other algorithms are running (such as for example: algorithms which modify AV delay, escape intervals), or
- No other test is ongoing.

2. Waiting phase

Aim

The device:

- Applies the test parameters according to the programmed pacing mode,
- Confirms the short AVD (39ms) is applied in DDD pacing mode to increase the probability of LV capture and avoid spontaneous conduction.

Operation

The LVAT pacing mode depends on the pacing mode just before LVAT.

- DDD pacing mode just before: the LVAT is performed in DDD
- VVI, DDI or DDI of MS pacing mode just before: the LVAT is performed in VVI

The device paces in bi-ventricular (with a VV delay of 0 ms):

- RV output is set to the programmed amplitude and pulse width
- LV output is set to the LV threshold + 1V (limited to LV Max Amplitude), if the previous threshold run properly
- LV output is set to LV Max Amplitude (5V by default) in particular cases, such as:
 - The first calibration failed for no capture at LV threshold + 1V
 - The LV Threshold is not found in the last 7 days

The pacing rate increase is required:

- In VVI, the ventricular pacing interval is overdriven by 100 ms. The waiting phase lasts only 1 cycle.
- In DDD, the ventricular pacing interval is overdriven by 100 ms. The waiting phase lasts up to 8 cycles to reach the required AVD (39 ms).

3. Calibration phase

Aim

The aim is:

- to discard a high pacing threshold value and to elaborate a morphological reference pattern of capture (phase 1), and
- to discard fusion and so to validate the morphological reference pattern of capture (phase 2) before entering the step-down threshold search phase (see “**Erreur ! Source du renvoi introuvable.**” section).

Operation

Up to 2 calibration attempts might be necessary. Each calibration encompasses two phases:

Phase 1: (1 to 5 cycles)

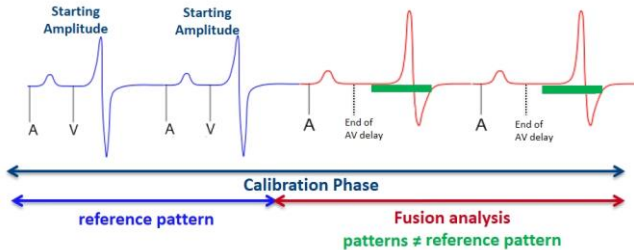
The objective is to elaborate the reference pattern of capture by obtaining 2 cycles with similar patterns when pacing at the starting amplitude.

To do so, the device starts by pacing LV at the starting amplitude. The starting amplitude is the current LV threshold+1V (limited to LVAT Max Amplitude) or LVAT Max Amplitude in the events described in "Waiting phase" section. As soon as 2 consecutive cycle patterns are similar, the capture reference pattern is elaborated and the device switches to phase 2.

Phase 2: (1 to 2 cycles)

The objective is to validate that the reference pattern of capture found in Phase 1 was a capture due to LV pacing and not spontaneous AV conduction (fusion beat).

To do so, the device will have to ensure that the capture reference pattern found in Phase 1 cannot be found at the end of the AV delay or Escape Interval (EI) in absence of LV pacing. If the comparison between these two patterns reveals a difference, the fusion is discarded and the capture reference pattern is validated. Thus, the morphological analysis is now able to distinguish fusion (due to spontaneous AV conduction) from true LV capture thanks to the reliable capture reference.



Calibration in case of spontaneous AV conduction. Validation of SPOT pattern reference and fusion discarding.
■ Analysis window

The device can then switch to the step-down threshold search phase.

Note: The calibration leads to the next phase (step-down threshold search) or to the LVAT interruption in case of no capture at LVAT Max Amplitude or fusion.

4. Threshold search phase

Aim

The aim of the threshold search phase is to find the LV threshold value by analysing the EPR on the near-field and far-field EGMs thanks to the morphological analysis following LV pacing of decreasing amplitude.

Operation

The threshold test phase starts at the LV starting amplitude (the current LV threshold+1V (limited to LVAT Max Amplitude) or the LVAT Max Amplitude). Then, the device progressively decreases the LV amplitude.

Test amplitudes (up to 17) during the threshold search phase (step-down):

Cycle number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Test amplitude	7	6	5	4,5	4	3,5	3	2,5	2,25	2	1,75	1,5	1,25	1	0,75	0,5	0,25

For a given tested amplitude (see “Capture detection” section):

- The capture is identified if the pattern following the LV tested amplitude is similar to reference pattern of capture. Then, the device decreases the LV amplitude (next step-down).
- The loss of capture is identified if the pattern following the tested LV amplitude is different from the reference pattern of capture.

The device needs to confirm the identified loss of capture within the 2 next cycles (with same given tested amplitude).

- If one more event of capture loss is identified again within these 2 cycles, the loss of capture is confirmed. The LV threshold is found, i.e. the amplitude of the previous tested step.
- If NO event of capture loss is identified within these 2 cycles, the loss of capture is NOT confirmed. Then, the device decreases further the LV amplitude (next step-down).

Below is an example of threshold search phase with identification/confirmation of capture loss. The device stores the voltage of the last capturing spike as the left ventricular pacing threshold.



Threshold search phase in DDD (simulation). Left ventricular pacing threshold measured at 2,25V.

■ Analysis window

5. Amplitude adjustment phase

Aim

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

Operation

Once the left ventricular automatic threshold test successfully ends, the device reprograms the left ventricular amplitude to the found left ventricular threshold + 1V (as-shipped, programmable). This amplitude is limited: higher than (\geq) the LV Min Amplitude and lower than (\leq) the LV Max Amplitude (both programmable).

Note: When LVAT is programmed on MONITORING, the LV threshold and the suggested amplitudes are stored in the device memories but the amplitude is not adjusted.

DEFINITIONS OF INTERRUPTION, RETRY AND ABORTION

LVAT disturbances may occur following events (for example cardiac rhythm variations) or interactions with other algorithms which could disrupt the proper functioning of LVAT.

Interruption, retry and abortion could occur during any phase once the starting phase is completed.

Interruption

An interruption means that LVAT is stopped and the device relaunches (“retries”) LVAT from the starting phase 15 min later. Up to 5 retries are allowed for each LVAT (i.e. 6 attempts in total). When MP is activated, up to 5 retries are authorized for LV MP1 and up to 5 retries are authorized for LV MP2.

Between 2 retries of LVAT, the current left ventricular amplitude remains unchanged until the next retry, except if the reason is the capture failure at “LV Max Amplitude” (programmable) during the calibration phase. In this case, the current left ventricular amplitude is set to the programmable “LV Max Amplitude” until next retry.

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 at LV Max Amplitude
- Fusion beats are identified in “Fusion Evaluation” test

Abortion

An abortion means that LVAT is stopped and no retry is performed. A new LVAT will be performed at next LVAT launch time.

When there is an abortion, the left ventricular amplitude remains unchanged until the new performed LVAT.

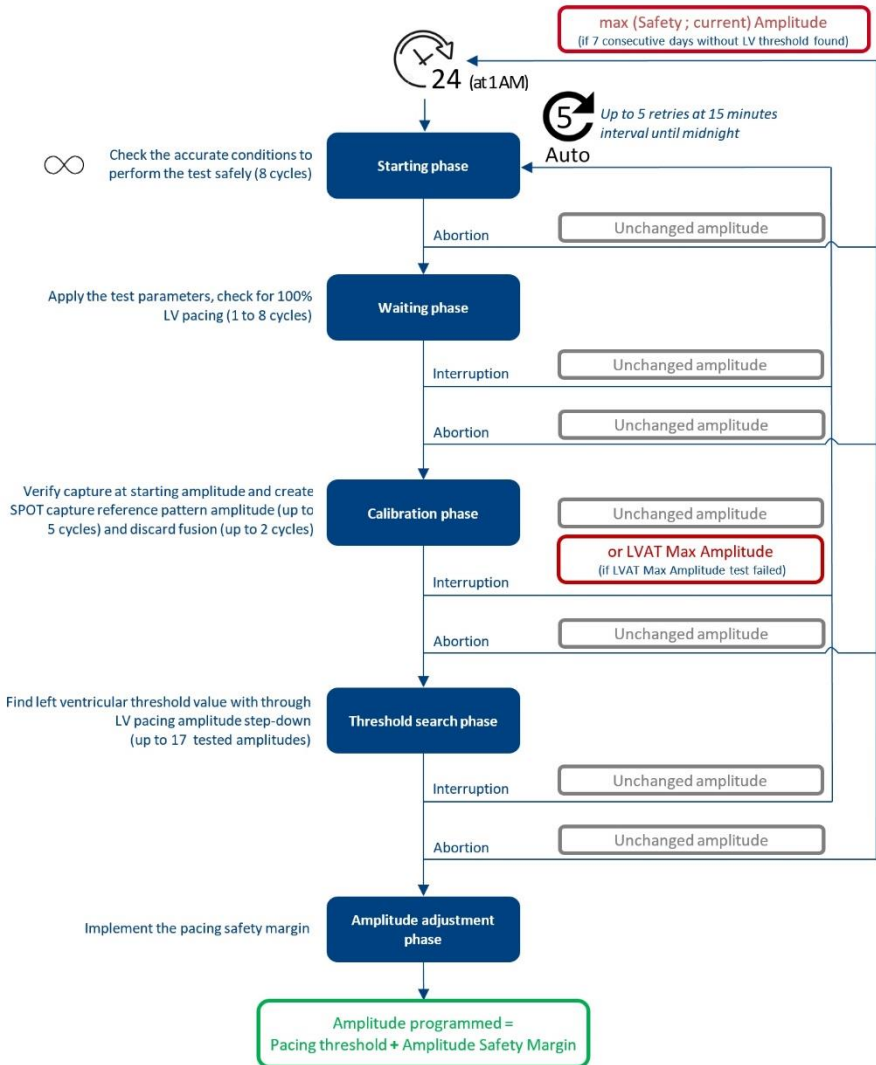
Examples of events leading to abortion

- The maximum number of available tests is reached, or
- Starting conditions are not found until midnight.

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

SUMMARY OF LEFT VENTRICULAR AUTOTHRESHOLD

Below is a summary of LVAT functioning when programmed “AUTO”.



Summary of LVAT process: description, aim, number of cycles, amplitude adjustment following LVAT success/interruptions/abortions.

PROGRAMMING

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

If programmed to “AUTO” or “MONITORING”, the device performs the LVAT automatically at the programmable “**Start Time**”: 00:00 AM, 1:00 AM (default), 2:00 AM and 12:00 AM. The LVAT is performed only on the programmed “LV Paced Polarity(ies)”.

When the LVAT function is programmed to “MONITORING”, the LV pacing threshold is measured and stored but the LV programmed pacing amplitude remains unchanged.

When the LVAT function is programmed to “AUTO”, the LV pacing threshold is measured, stored and the LV pacing amplitude is automatically adjusted to the measured left ventricular threshold + the “**LV Amplitude Safety Margin**”. The “LV Amplitude Safety Margin” is a programmable parameter: +0.5 – +1 (default) – +1.5 – +2 – +2.5 (V). The LV adjusted ventricular pacing amplitude is always higher than (\geq) the “LV Min Amplitude” and lower than (\leq) the “LV Max Amplitude”.

The “**LV Min Amplitude**” is a programmable parameter: 1 – 1.5 (default) – 2 – 2.5 – 3 – 3.5 (V).

The “**LV Max Amplitude**” is a programmable parameter: 2 – 2.5 – 3 – 3.5 – 4 – 4.5 – 5 (default) – 6 – 7 (V).

In case of LVAT interruption, the current left ventricular pacing amplitude remains the same except in case of the interruption for non-capture at the “LV Max Amplitude” test. In this particular case, the left ventricular amplitude is set to programmable “**LV Max Amplitude**”.

In case of LVAT abortion, the current left ventricular amplitude remains unchanged until the next LVAT is performed (the next day). Thus, in the case of an abortion, if the current amplitude is already at the “LV Maximum Amplitude”, the automatic amplitude adjustment will maintain the high LV pacing amplitude until the next LVAT is performed.

When LVAT cannot be performed for 7 consecutive days the current left ventricular pacing amplitude is set to the maximum value between the current programmed left ventricular amplitude and the programmable “**LV Safety Amplitude**” 2 – 2.5 – 3 – 3.5 (default) – 4 – 4.5 – 5 (V) until the next follow-up. Thus, in this situation, if the current amplitude is already at the “LV Maximum Amplitude”, the automatic amplitude adjustment will maintain the high LV pacing amplitude until the next LVAT is performed.

Notes:

1. When “LV Amplitude Safety Margin”, “LV Min Amplitude”, “LV Max Amplitude”, “LV Safety Amplitude” are reprogrammed, the device does not immediately apply changes to the left ventricular pacing amplitude. The new programmed value(s) will be taken into account from the next performed LVAT.
2. At the beginning of a follow-up, on parameter screen, when LVAT is programmed to “AUTO”, the “LV Amplitude” corresponds to the current LV pacing amplitude (applied by LVAT algorithm).

For safety reasons, the LVAT will never lead to a pacing rate above the non-programmable “**LV Max Rate**” (100 min⁻¹).

When LVAT is programmed to “MONITORING”, the “LV Amplitude Safety Margin”, “LV Min Amplitude”, “LVAT Safety Amplitude” and “LVAT Max Amplitude” parameters are not applied. They are only used for the calculation of the “suggested LV amplitude” within the LV Autothreshold curve (see Left Ventricular Autothreshold in AIDA).

After MP activation, most of the programming parameters are independent for LV MP1 and LV MP2. Most of them have same range of values, default value, interactions, behaviour and constraints.

“Start Time” parameter is common for LVAT MP1 and LVAT MP2 because LVAT with the programmed LV MP1 Paced Polarity is followed by LVAT with the programmed LV MP2 Paced Polarity 15 minutes later.

PROGRAMMING CONSTRAINTS

The LVAT is available when DDD(R), DDI(R) or VVI(R) pacing mode is programmed.

The LVAT is NOT available when:

- DOO, VOO, OOO or SafeR(R) pacing mode is programmed,
- “LV Paced Polarity” is LVtip1-RVring or LV3-RVring (for a given LVAT) in order to avoid anodal stimulation, or
- Pacing cavity is programmed to Right Ventricular pacing only.

When LVAT is programmed:

- Basic Rate is ≥ 35 bpm,
- The “LV Min Amplitude” is always lower than (\leq) the “LV Safety Amplitude” (for a given LVAT),
- The “LV Safety Amplitude” is always lower than (\leq) the “LV Max Amplitude” (for a given LVAT).

LEFT VENTRICULAR AUTOTHRESHOLD IN AIDA

LVAT data are available in the programmer when LVAT is programmed to “AUTO” or “MONITORING”.

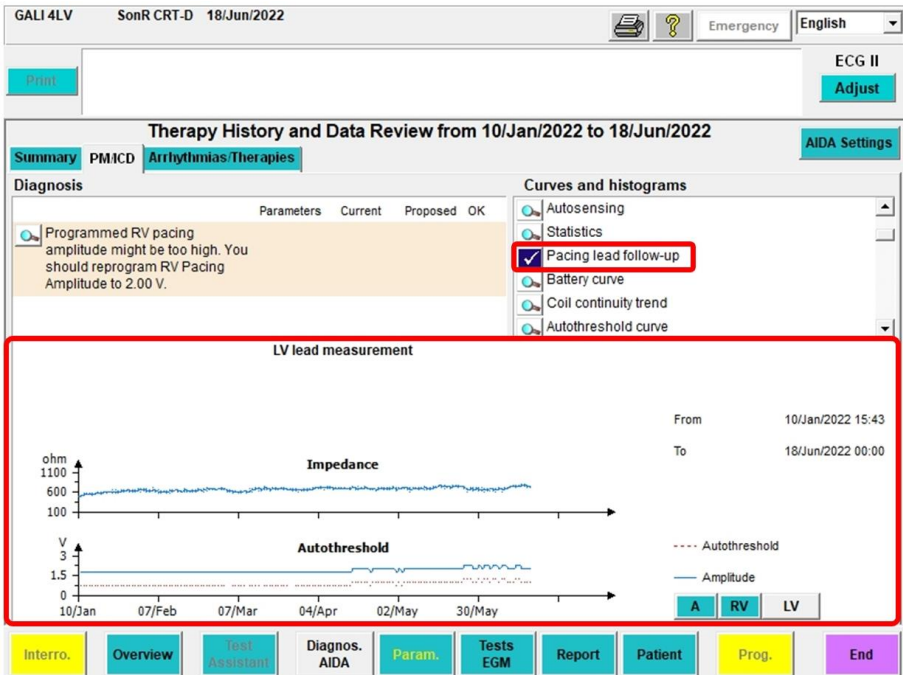
Detailed statistics

LVAT detailed statistics are available on AIDA Diagnos. screen, in PM/ICD tab and in Statistics and Detailed statistics sections.

Available statistics are:

- Numbers of LVAT success in DDD and VVI pacing mode, and
- Numbers of LVAT failures due to maximum number of retries reached (5 retries, i.e. 6 attempts in total) and due to starting conditions not conditions not found until midnight.

Lead follow-up curves

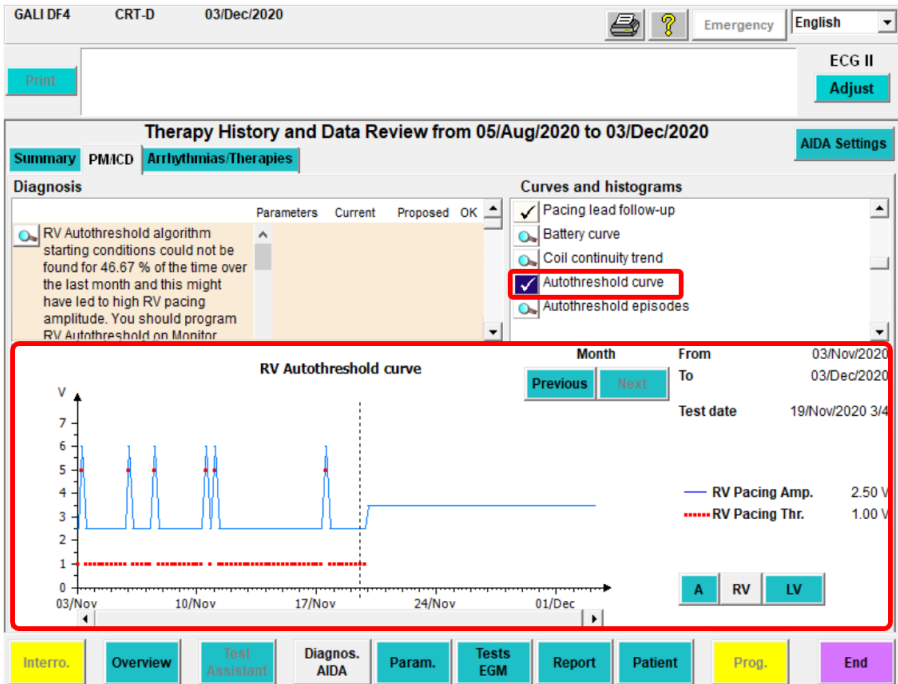


PM/ICD programmer screen when Pacing lead follow-up and LV chamber are selected.

In the PM/ICD tab on the Diagnos. AIDA screen, click on Pacing lead follow-up magnifying glass to display trends of 6 months lead measurements. By selecting the LV chamber (LV when MP is set to “OFF” or LV MP1 or LV MP2 when MP is set to “ON”), the trends of the programmed left ventricular pacing vector are displayed.

When LVAT was programmed to “AUTO” or “MONITORING”, the “Autothreshold” curve displays the daily LV pacing thresholds (red dots) and adjusted LV pacing amplitude (blue curve) in addition to the LV lead impedance curve.

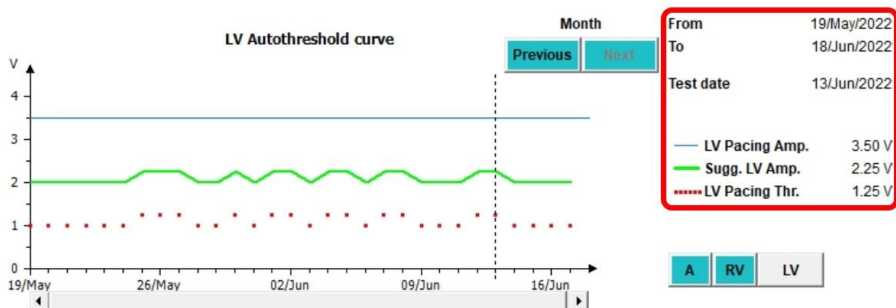
Autothreshold curves



PM/ICD programmer screen when Autothreshold curve and LV chamber are selected and LVAT was programmed to “AUTO”.

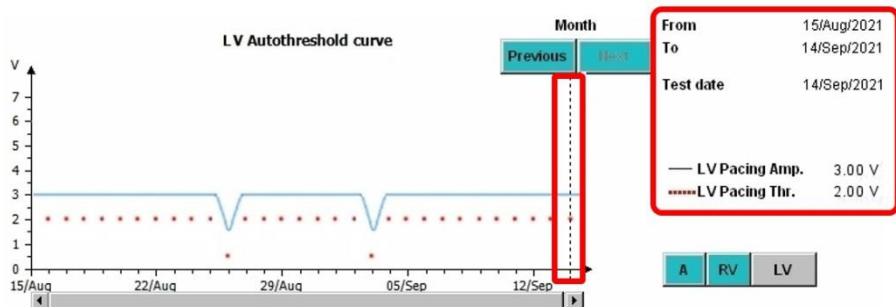
In the PM/ICD tab on Diagnos. AIDA screen, click on Autothreshold curve magnifying glass to display the detailed Autothreshold curves over the last months. By selecting the LV chamber (LV when MP is set to “OFF” or LV MP1 or LV MP2 when MP is set to “ON”), the trends of the programmed left ventricular pacing vector are displayed.

When LVAT was programmed to “AUTO” or “MONITORING”, the LV Autothreshold curve displays the daily LV measured pacing thresholds (red dots) and adjusted LV pacing amplitude (blue curve). When LVAT was programmed to “MONITORING”, an additional green curve “Sugg. LV Amp.” (suggested LV amplitude) is displayed showing how the amplitude would have been programmed if LVAT have been programmed to “AUTO”.



PM/ICD programmer screen when Autothreshold curve and LV chamber are selected and LVAT was programmed to “MONITORING”.

When clicking on curves, the measured LV pacing threshold or the failure reason and the value of the adjusted LV pacing amplitude for the selected day are displayed on the right part of the screen.



PM/ICD programmer screen when Autothreshold curve and LV chamber are selected and LVAT was programmed to “AUTO”.

Diagnosis

LVAT automatic interpretations are available on AIDA Diagnos. screen, in PM/ICD tab and in the Diagnostic section when the follow-up period with LVAT programmed to “AUTO” or “MONITORING” is superior or equal (\geq) to 1 month.

Below is the list LVAT automatic diagnosis available:

1. Low successfulness of LVAT
2. Overestimation of LVAT
3. Too low "LV Safety Amplitude"
4. Too high "LV 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 on RV bipolar and RVcoil-CAN channels. Episodes can be filtered by type and date. When an LVAT episode is selected, the measured pacing threshold or "Thr.>Start Amp.*" is displayed at the top of the strip. Thanks to the "Zoom" button, each LVAT episode can be zoomed in and a third EGM channel (A channel) is displayed for a more accurate analysis.

*: Threshold is upper than the Starting Amplitude. The starting amplitude is the current LV threshold+1V (limited to LVAT Max Amplitude).

Therapy History and Data Review from 10/Jan/2022 to 18/Jun/2022

Summary PMICD **Arrhythmias/Therapies** AIDA Settings

Diagnosis Parameters Current Proposed OK

Programmed RV pacing amplitude might be too high. You should reprogram RV Pacing Amplitude to 2.00 V.

Curves and histograms

- Coil continuity trend
- Autothreshold curve
- Autothreshold episodes

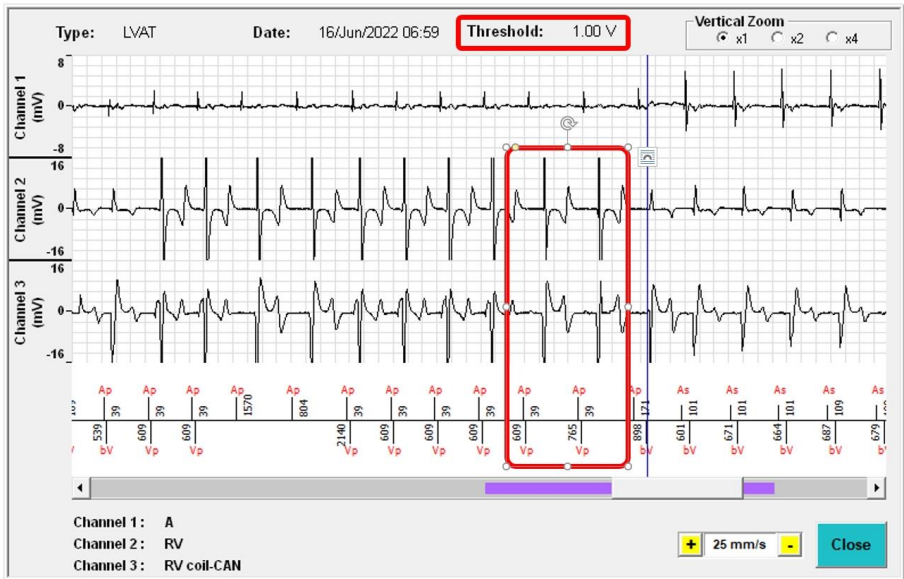
LVAT 1.00 V

Type	Date
RVAT	17/Jun/2022 12:3
LVAT	17/Jun/2022 11:2
RVAT	17/Jun/2022 06:2
RVAT	17/Jun/2022 04:5
RVAT	16/Jun/2022 18:2
RVAT	16/Jun/2022 12:4
LVAT	16/Jun/2022 06:5
RVAT	16/Jun/2022 06:2
RAAT	15/Jun/2022 11:2

Zoom

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

PM/ICD programmer screen when Autothreshold episodes and LVAT episode are selected



PM/ICD programmer screen when Autothreshold episodes, LVAT episode 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 only

Note: all programmer screenshots were captured from SmartView 3.06.