Tech Corner

SonR CRT Optimization

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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MicroPort™ CRM

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SonR CRT Optimization

Although cardiac resynchronization therapy (CRT) is widely used to treat many heart failure patients, around 30% of them do not benefit from the therapy.[1, 2] This limited response to the therapy can be reduced by optimizing the device programming, particularly the stimulation rate, paced and sensed atrioventricular (AV) delay, and the interventricular (VV) delay.[3, 4, 5, 6, 7]

Ideally, patients implanted with a CRT device should receive 100% ventricular pacing with effective ventricular capture, but the optimal pacing configuration will vary from patient to patient. The optimization of CRT systems, usually based on ultrasound imaging,[8,9,10,11] is time-consuming and the number of patients in need of multiple optimization procedures due to ventricular remodelling is growing rapidly.[12,13]

The mechanical effects of a more coordinated contraction result in a shortening of the isovolumetric contraction phase and the pre-ejection time, and an increase in LV dP/dt (change in left ventricular pressure over time).[6,7] The concept of measuring contractility with an implantable accelerometer was first clinically validated through a multicenter study[14, 15, 16] of a rate responsive pacing system (BEST – Living from SORIN Biomedica); the authors showed that changes in contractility through modulation of sympathetic activity (normal changes in daily living, and changes in response to physical or emotional stress) were detected using the implantable sensor. This study positively demonstrated that measurement of Peak Endocardial Acceleration signal (called PEA or SonR) is feasible and reliable in the long-term, both for use in rate responsive pacing, and possible broader use as a hemodynamic monitor of cardiac function. Moreover, it has been demonstrated that the signal information content is not dependent on the lead site.[17]

Subsequent clinical studies were conducted demonstrating that optimal VV and AV Delays determined using algorithms based on PEA/SonR signal analysis (SonR method) are correlated with the highest hemodynamic improvement and lead to significant clinical benefit for patients, in particular reducing the rate of non-responsiveness to CRT therapy.

Ritter et al.[18] validated that using the SonR signal to obtain a tailored AV delay in a pacemaker population provided AV delays that correlated ($r = 0.78$, $p < 0.01$) to AV delays as determined by direct echocardiographic measurement of left ventricular filling. In 2000, Bordachar[19] reported on the feasibility of extending SonR technology beyond pacemakers to a heart failure population requiring cardiac resynchronization therapy; the authors demonstrated a significant correlation between percent change in the Aortic Velocity Time Integral (AoVTI) and percent change in SonR ($r = 0.74$, $p < 0.001$). Also in 2000, Leung et al.[20] validated SonR AV delay optimization for use during exercise. The algorithm for selecting optimal AV delays was then improved; compared to the previous algorithm, Dupuis[21, 22] reported a similar correlation ($r = 0.79$, $p < 0.0012$), but a smaller difference between optimal AV delays (OAVDs) determined using the modified SonR algorithm vs. echocardiographic method ($\Delta = -9$ ms vs. $\Delta = -23$ ms [18]). In addition, the new algorithm allows the determination of the OAVD by the implanted device during daily activities and not only during in-office sessions.

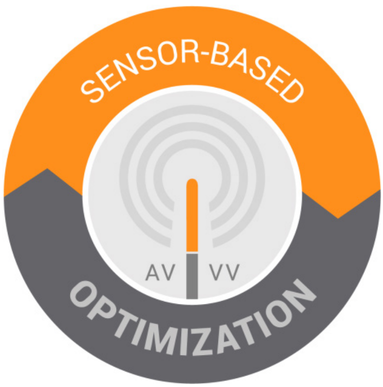
In order to validate the method of improving contractility (left ventricular pressure change, or LV dP/dt max) through adjustment of VV (LV vs. RV) timing in CRT patients, Delnoy et al[23, 24], measured LV pressure change in response to changing AV and VV paced intervals.

The authors reported that, in nine of 12 (75%) CRT responders tested, the SonR method and the method of directly measuring LV dP/dt max (greatest LV dP/dt max) resulted in the same recommended optimal VV configuration, supporting the introduction of SonR into clinical practice as new operator-independent method of VV interval optimization.

Most recently, the SonR CRT optimization method was evaluated in the RESPOND CRT study[25]. In this international, multicentre, randomized (2:1), prospective, double-blinded, non-inferiority study, the authors evaluated 1039 heart failure patients (NYHA III/IV, LVEF ≤ 35%, QRS ≥ 120 ms in LBBB, QRS ≥ 150 ms in non LBBB) optimized either automatically by SonR (n = 670), or by echocardiography (n = 328). Using a clinical composite endpoint, a CRT responder was defined as alive, no HF-related events, and improved based on either New York Heart Association Functional Class or European Quality of Life questionnaire. The RESPOND-CRT trial successfully met its primary end point with 75% of clinical responders in the SonR group versus 70% in the control group at 12 months.[26] ($p<0.001$). This trial also showed a 35% risk reduction in heart failure hospitalization for patients optimized with SonR.[26]

Therefore, frequent and automatic AV and VV delay optimization in patients with CRT-D devices could benefit both patients, through increasing the percent of CRT responders, and clinicians, through simplifying CRT optimization.

This document intends to clarify the SonR algorithm functioning mode, as present in the currently available MicroPort ICD SonR devices.



Objective

Optimizing CRT devices with an hemodynamic device-based sensor

Availability

The SonR™ AV and VV optimization algorithm is available in the following MicroPort CRT-D models, when implanted with the SonRtip lead:

- PLATINIUM™ 4LV SonR CRT-D 1844
- PLATINIUM SonR CRT-D 1811 and 1841,
- INTENSIA™ SonR CRT-D 184
- PARADYM™ RF SonR CRT-D 9770
- PARADYM 2 SonR CRT-D 8772
- PARADYM SonR CRT-D 8750

Definition

The SonR sensor consists of a micro-accelerometer embedded in the tip of the SonRtip™ atrial lead. SonR measures the vibrations generated by the myocardium during cardiac contractions, which are correlated to LV dP/dt max.[17, 27, 28]

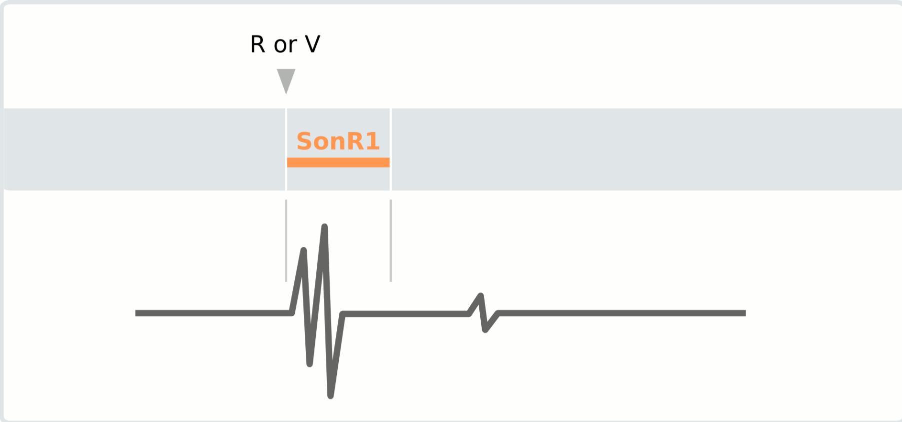
The SonR sensor continuously measures the contractility of the heart allowing for automatic optimization of AV and VV intervals. Optimization is performed on a weekly basis both at rest and during exercise. This allows for cardiac resynchronization therapy to be continuously adapted to the individual needs of each patient.

Measuring the SonR signal

For the CRT optimization, the SonR signal is measured as the Peak-to-Peak amplitude of the SonR1 component. This measurement is performed inside one window which is opened on a paced or sensed ventricular event. The opening of the window from the ventricular event depends:

- on the VV delay applied: if it is not 0 ms, the window opens on the second event
- on whether the ventricular event is paced or sensed (see table 1 below)

The closure of the window is always 250 ms after the ventricular event used for opening the window (see table 1).



Type of event	VV delay	Opening from the V event	Closure from the V event
Paced	VV delay ≠ 0	32 ms	250 ms
Paced	VV delay = 0	48 ms	250 ms
Sensed	NA	0 ms	250 ms
Paced	RV only or LV only	48 ms	250 ms

Table 1. SonR1 detection window according to the type of ventricular event (paced or sensed)

The SonR algorithm

Automatic/Manual mode

The SonR CRT optimization can work in 2 modes: automatic or manual.

Automatic mode: when programmed on "AV+VV", the algorithm calculates the optimal VV delay at rest and AV delays at rest and at exercise on a weekly basis in between follow-ups. Once activated, the first optimization starts at midnight of the same day, then every Monday at midnight.

Manual mode is used during an in-clinic follow-up, the optimization is launched through the programmer and the device will provide optimal VV and AV delays at rest.

When does the SonR optimization start?

SonR will try to optimize the VV and AV delays every week, starting from Monday midnight (0:00 am) with the VV delay optimization if programmed on “AV+VV” mode. The optimization will also be launched at midnight of the day the optimization has been activated.

VV and AV Delays optimization steps

For each VV or AV delay optimization, the following steps are performed:

a. Checking of the correct conditions to perform the test (rest or exercise).

b. Calculation of the PR or AR interval (except for AV delay optimization at exercise).

c. Determination of the AV delays to be tested based on the PR/AR.

d. Scan of the different AV delays and measure of the SonR amplitude.

e. Processing of the SonR amplitude measured for the calculation of the optimal VV/AV delays.

f. Processing and application of the results of the VV and AV delay optimization.

Description of the function

Automatic VV Delay optimization at rest

The following paragraphs on VV delay optimization are also applicable to the Automatic sensed and paced AV delay optimization at rest (see examples in the section “Annexes”, page 24):

- Rest conditions
- Abort conditions for PR/AR calculation and retry
- Excluded cycles

Rest conditions

In order to start the PR calculation for the VV delay test, the patient has to be at rest. All the following conditions have to be met for 10 consecutive cycles (in automatic mode[a]):

- pacing rate based on the rate response sensor ≤ Basic rate + 5 bpm (only if rate response is programmed),
- heart rate < 90 bpm over 8 atrial cycles (in automatic mode[b])
- no ventricular or atrial premature contractions (PVCs or PACs)
- no tachyarrhythmia detection

PR/AR interval calculation

PR interval calculation

For the calculation of the PR interval, in the presence of spontaneous atrial rhythm, the programming is temporarily changed to:

- an AVD of 300 ms,
- a 10 bpm hysteresis is applied to the basic rate or sensor rate if rate response is active (the lowest value allowed is 30 bpm),
- the escape interval is set to the one corresponding to the rate calculated at the step above (this escape interval will also be kept during the optimization test).

After these conditions are applied, the device will start the measurement of the PR interval. The first 3 cycles are not considered in the calculation for stabilization reasons.

Automatic mode: This setting will apply until the PR interval is found.

Manual mode: This setting will apply for 11 cycles or until 5 consecutive cycles with atrial pacing occur.

The PR interval will be then calculated as:

- equal to the minimum value between the mean value of the 8 measured PR and 224 ms
- equal to 224 ms in the event of absence of spontaneous ventricular conduction over 8 cycles (not necessarily consecutive)

If it is not possible to calculate the PR interval 5 consecutive times (see the paragraph below "*Abort conditions for PR/AR calculation and Retry*"), due to the lack of spontaneous atrial activity, the test will be performed in atrial paced conditions: the device starts the AR interval calculation.

[a] *Four consecutive cycles for the manual mode*

[b] *Manual mode: the cycle length of the last 8 atrial cycles has to be longer than the interval given by the cycle of the programmed Max rate + 47 ms. Example, Max rate = 120 bpm, the cycle length is 500 ms. The average cycle of the patient has to be longer than 500+47 = 547 ms, i.e. heart rate less than 110 bpm.*

AR interval calculation

The AR interval calculation will only be performed if the PR interval calculation has failed. For the calculation of the AR interval, the programming of the AV delay is temporarily set to 300 ms until the AR interval is found or until the presence of 5 consecutive cycles with atrial sensing.

The first 3 cycles are not considered in the calculation for stabilization reasons.

The AR interval will be then calculated as:

- equal to the minimum values between the mean value of the 8 measured AR and 264 ms
- equal to 264 ms in the event of absence of spontaneous ventricular conduction (complete AV block) over 8 cycles (not necessarily consecutive)

Abort conditions for PR/AR calculation and Retry

All cycles with PACs or PVCs or any tachyarrhythmia detected are excluded from the PR/AR calculation. If 3 consecutive or 5 non-consecutive cycles are excluded, then the PR/AR interval detection phase is aborted and the algorithm restarts the evaluation of the Rest conditions (see page 9).

In the event of an aborted first attempt, the device will immediately restart the search for the rest conditions and retry the PR or AR calculation. If the second attempt fails, the device will retry the PR or AR calculation one hour later, then 2 hours later, then 4 hours, 8 hours, etc... This retry phase will end at the start of a new week (new Monday), if the failure is recurrent[c].

VV Delay scan

AV Delays to be tested

After the PR or AR has been found, the device will calculate the 6 AV delays to be tested for each VV delay configuration. The shortest AV delay tested is always 32 ms, and the longest one is given by PR/AR – 47 ms, if the PR/AR interval is longer than 156 ms; otherwise the longest AV delay tested will be the PR/AR – 8 ms.

For the intermediate AV delays, they will be equally spaced between the two extremes; if it is not possible (due to the AVD values allowed), the interval between two consecutive AV delays will be bigger for the longest and shortest AV delays (the ones closest to the extremes).

See Example 1 in the section "*Annexes*", page 24.

[c] *For the manual optimization no retry is made*

VV Delays to be tested

The device will test the 6 AV delays defined above (always starting with the shortest one), in combination with 7 fixed VV configurations, starting from the one with the greatest delay in activation on the left side.

The tested configurations are, in the order:

- L+R 48 ms
- L+R 32 ms
- L+R 16 ms
- BiV0
- R+L 16 ms
- R+L 32 ms
- R+L 48 ms

Manual mode: one additional configuration with LV pacing only will be tested as well as the 7 configurations already described.

Definition of the optimal VV Delay (Area Index Method)

The average SonR values at different AV delays for a given VV delay configuration are taken as the contractility index, called the "Area Index".

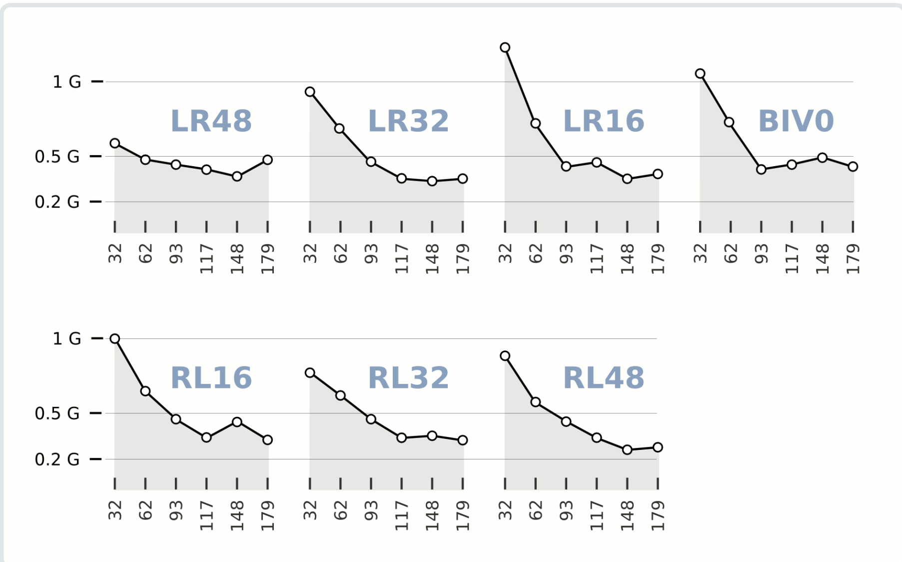


Figure 1A – Variation of the average amplitude of the SonR signal at each AV delay for the 7 VV delays

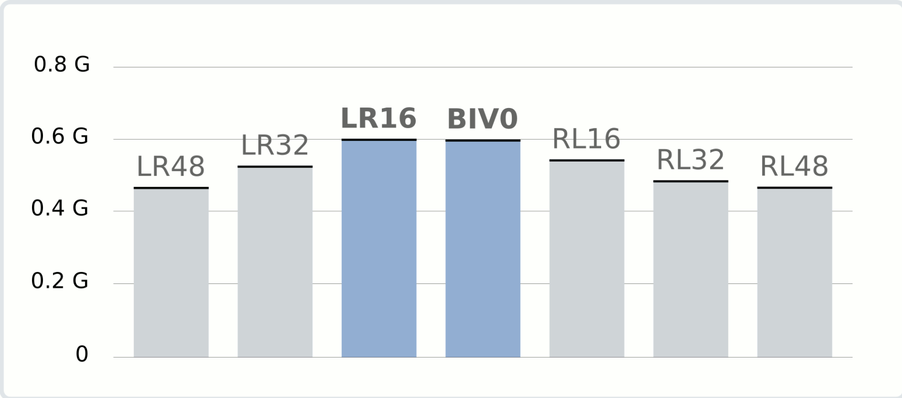


Figure 1B – Contractility index for each VV delay configuration according to the largest area under the curves from the graphic above (figure 1A)

By measuring different VV configurations, the device can determine the one with the maximum area, which corresponds to the best ventricular function, i.e. which can be considered as the optimal hemodynamic CRT configuration[24] (Figure 1B).

The first 3 cycles after the change of AV delay are not considered in the average; then for each AV delay tested with a given VV delay configuration, the sonR1 amplitude is measured and averaged over 6 cycles.

The Area Index, also called the contractility index, associated to a given VV delay configuration is the sum of the SonR amplitude calculated on the 6 AV delays tested. The optimal VV delay configuration is the one with the highest area index.

In Figure 1B, two VV delay optimizations have the same best Area Index (LR16 and BiV0), the one with shortest VV delay (i.e. BiV0) is the optimal one.

Other example:

- If LR 32 and RL16 have the same Area Index, the best one would be RL 16.

If the two VV delay configurations have the same distance from BiV0, the one which is further to the left is considered as the optimal one.

Example:

- If LR 32 and RL 32 have the same Area Index, the best one is LR 32.

<u>Excluded cycles</u>

Abnormal cycles will be excluded from the SonR signal average calculation. These cycles are sensed intrinsic R waves (including VT and VF cycles), PACs, PVCs, cycles in fallback mode, A or V channel noise.

Scan abort conditions and Retry

The scan will be aborted if:

- the average heart rate over 8 atrial cycles is above 100 bpm
- there is detection of a tachyarrhythmia
- the pacing programming is in post-shock mode
- interference (ventricular or atrial noise) within the same AV delay is present for more than 5 cycles

In the event of the scan being aborted at the first attempt, the device will immediately restart the search for the rest conditions and will immediately retry the PR or AR calculation. If the second attempt fails, the device will retry optimizing the VV delay 1 hour later, then 2 hours later, then 4 hours, 8 hours, etc … This retry phase will end at the start of a new week (new Monday), if the failure is recurrent[d].

VV Delay optimal value processing

Note: For the manual optimization no processing of the VV delay is made; the VV delay used for the AV delay optimization is the optimal one as defined by the Area Index method.

Once the optimal VV delay value has been determined, it will only be programmed if there is a significant improvement (≥ 14%) in the contractility Index compared to the previous programmed VV delay. Otherwise no change will be applied. The maximum variation allowed is 16 ms from the previously programmed VV delay. This VV delay will be used for the remaining steps of the optimization process. It will be programmed once the rest AV delay has been found.

See Example 2 in the section "*Annexes*", page 24.

Automatic sensed and paced AV Delay optimization at rest

The search for the PR and AR intervals for the AV delay optimization will start only if the optimal VV delay has been found.

It will not start before 1:00 am for the sensed AVD (PR interval calculation), and not before 2:00 am for the paced AVD (AR interval calculation).

PR and AR interval calculations are separated by 1 hour to avoid too many changes of the AV delay within a short time period.

[d] *For the manual optimization no retry is made.*

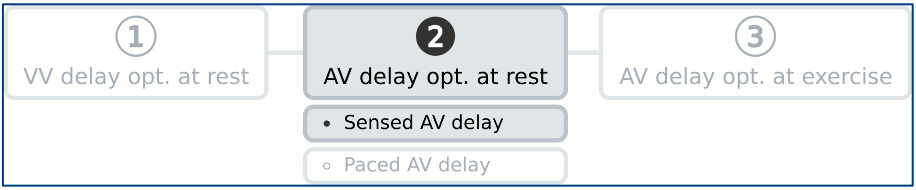
See Example 3 in the section “*Annexes*”, page 25.

Rest conditions

Same as in Automatic VV delay optimization at rest (see page 9).

PR/AR interval calculation

PR interval calculation



For the calculation of the PR interval, in the presence of spontaneous atrial rhythm, the programming is temporarily changed to:

- an AVD of 300 ms,
- the escape interval is set to the one given by the basic rate or by the accelerometer sensor if rate response is programmed (this escape interval ill be kept also during the optimization test)
- a 10 bpm hysteresis is applied to the average ventricular rate.

After these conditions are applied, the device will start the measurement of the PR interval. The first 3 cycles are not considered in the calculation for stabilization reasons.

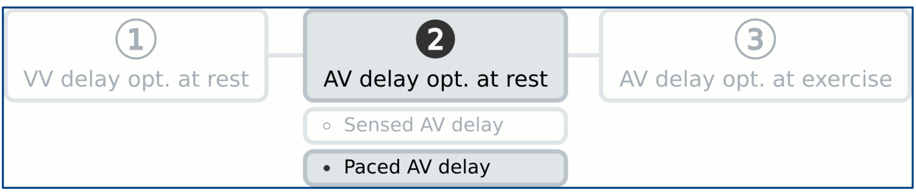
Automatic mode: This setting will apply until the PR interval is found.

Manual mode: This setting will apply for 11 cycles or until 5 consecutive cycles with atrial pacing occur.

The PR interval will be then calculated as:

- equal to the minimum value between the mean value of the 8 measured PR and 224 ms
- equal to 224 ms in the event of absence of spontaneous ventricular conduction over 8 cycles (not necessarily consecutive)

AR interval calculation



For the calculation of the AR interval, temporary programming is used depending on the patient's current atrial rhythm:

- In the event of a paced atrial rhythm, the escape interval is temporarily set to the one given by the basic rate or by the sensor if rate response is active (this escape interval will be kept also during the optimization test).
- In the event of spontaneous atrial rhythm, the rhythm will be increased by a positive hysteresis of 10 bpm.
- In any event, the AV delay is extended to 300 ms.

After these conditions are applied, the device will start the measurement of the AR interval. The first 3 cycles are not considered in the calculation for stabilization reasons.

This programming is applied as soon as 8 cycles with AR measurement are obtained (not necessarily consecutive) or until 5 consecutive cycles with atrial sensing are detected.

The AR interval will be then calculated as:

- equal to the minimum value between the mean value of the 8 measured AR and 264 ms
- equal to 264 ms in the event of absence of spontaneous ventricular conduction (complete AV block) over 8 cycles (not necessarily consecutive)

Abort conditions for PR/AR calculation and Retry

Same as in Automatic VV delay optimization at rest (see page 10).

Sensed/Paced AV Delays scan

Sensed/Paced AV Delays to be tested

After the PR/AR has been found, the device will calculate the 11 AV delays to be tested in combination with the already determined optimal VV delay. The shortest AV delay tested is always 32 ms, and the longest one is given by PR/AR – 47 ms, if the PR interval is longer than 156 ms, otherwise the last AV delay tested will be PR/AR – 8 ms.

For the intermediate AV delays, they will be equally spaced between the two extremes; if it is not possible (due to the AVD values allowed), the interval between two consecutive AV delays will be larger for the longest and shortest AV delays (the ones closest to the extremes). The steps will always be 8 and/or 16 ms.

See Example 4 in the section "*Annexes*", page 28.

Definition of the optimal sensed/paced AV delay at rest – SIGMOID method

During the evaluation of the optimal sensed/paced AV delay at rest, the device will apply the same AVD over 9 consecutive cycles. The first 3 cycles are not considered for stabilization reasons and the SonR signal average will be calculated over the last 6 cycles.

The SonR amplitude measured at each AV delay will be used for determining the optimal paced and sensed AV delay with the sigmoid method.

A 3-segment curve (upper or left plateau, linear part between both plateaus, lower or right plateau), composing a simplified sigmoid that best fits the curve obtained from the SonR amplitude during AV scan will be defined (Figure 2).

The optimal AV delay is one of the middle points of the linear part of the best fit 3-segment curve (the inflection point of the curve); the optimal AV delay defined is the shortest one, providing the longest ventricular filling time, without atrial wave truncation[22].

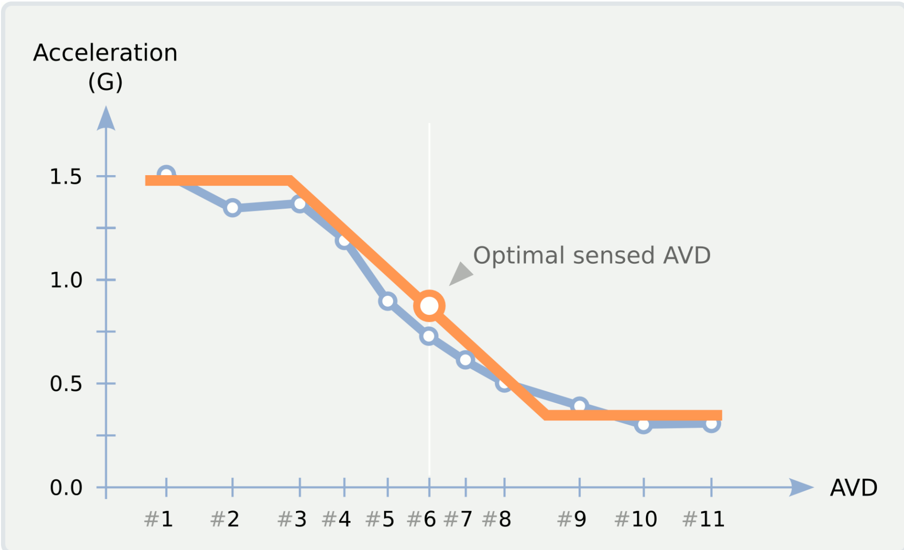


Figure 2: Average of the SonR amplitude for each of the 11 AVD vs. Sigmoid curve computed by the system.

<u>Excluded cycles</u>

Same as in Automatic VV delay optimization at rest (see page 8).

<u>Scan abort and Retry</u>

In the event of the scan being aborted at the first attempt, the device will immediately restart the search for the rest conditions and will immediately retry the PR or AR calculation. If the second attempt fails, the device will retry optimizing the AV delay 1 hour later, then 2 hours later, then 4 hours, 8 hours, etc … This retry phase will end at the start of a new week (new Monday), if the failure is recurrent[e].

See examples in the section "*Annexes*", page 25.

[e] *For the manual optimization no retry is made.*

Rest AV delay optimal value processing

After the determination of the optimal sensed (SAV) and paced (PAV) AV delays, through the sigmoid method, the values will be compared to the allowable range of parameters:

- for the SAV, the value has to be in the range between 60 and 180 ms
- for the PAV, the value has to be in the range between 90 and 240 ms.

If the values are not within these limits, they will be rounded to the upper or lower value of the allowable range.

The difference between these two values and the previous applied AV delays is evaluated to see if it is less than 20 ms, if not, the AV delays will be rounded to have a max difference of 20 ms. Also the difference between the PAV and the SAV (PAV-SAV) should be in the range 0-100 ms. In the event that the difference is higher, the last rest AVD found is considered invalid and a new attempt for this type of scan (sensed or paced) will be performed after the retry interval.

Manual optimization: In the event of a manual scan, the SAV has to be greater or equal to 60 ms and the PAV has to be greater than the SAV (the results are presented as AVD + Offset).

Application of the results of the CRT Optimization

Application of the optimal AV/VV Delays at rest

The results of the CRT optimization are applied after the optimal VV delay and at least one of the 2 AV delays at rest have been found. The values obtained are used for the calculation of the automatic AV delay applied according to the heart rate of the patient.

Calculation of the provisional AVD at exercise (before automatic optimization at 12:00 pm)

If the two optimal AV delays at rest are found, the optimized exercise AV delay is defined by applying the same difference as the rest and exercise AV delay of the previous week (calculated or programmed)to the optimal sensed rest AV delay found,.

If only one optimal AVD at rest is available (sensed or paced), the adapting curve will be determined by defining the missing optimal AVD at rest by using the same extension of the two rest AVD of the previous week. The missing exercise AV delay is found by applying the same difference to the optimal sensed rest AV delay as the rest and exercise AV delay of the previous week. The missing exercise rate is found by applying the same difference between the basic rate and Exercise rate of previous week.

Automatic AV Delay Optimization at exercise

1 VV delay opt. at rest | 2 AV delay opt. at rest | **3 AV delay opt. at exercise**

The AVD optimization at exercise is available only for the automatic mode.

Exercise conditions

The phase for the search of the exercise condition evaluation will start at 12:00 am on the day of activation of the optimization (Monday), every time that at least one of the two AV delays at rest has been found.

The trigger for the optimization will be the patient's heart rate. An exercise rate has to be defined in the programmer (nominal value is 90 bpm) and once the patient reaches this heart rate, the device will check that all the following conditions are met to start the scan: stable rhythm, no PACs, no PVCs or any other atrial or ventricular tachyarrhythmia.

AV Delay scan

<u>Exercise AV Delays to be tested</u>

If 5 consecutive atrial cycles end with a sensed atrial event, the test will be performed in atrial sensed conditions. The PR interval measured during the SAV delay scan will be used to define the AV delays to test.

If 5 consecutive atrial cycles end with a paced atrial event, the test will be performed in atrial paced conditions. The AR interval measured during the PAV delay scan will be used to define the AV delays to test.

In exercise conditions, only 5 AV delays will be tested:

- 2 AVD shorter than the last optimal AVD at exercise,
- the last optimal AVD at exercise
- 2 AVD longer than the last optimal AVD at exercise.

The length of the intervals will depend on the patient's PR/AR interval at rest:

- If the (PR/AR at rest – 47ms) > 96 ms, the AVD will be calculated in steps of 16 ms.
- In case the (PR/AR at rest – 47ms) < 96 ms, the AVD will be calculated in steps of 8 ms (Figure 3).

<u>Definition of the optimal AV delay at exercise</u>

During the evaluation of the optimal exercise AV delay, the device will apply the same AVD over 9 consecutive cycles. The first 3 cycles are not considered for stabilization reasons and the SonR signal average will be calculated over the last 6 cycles.

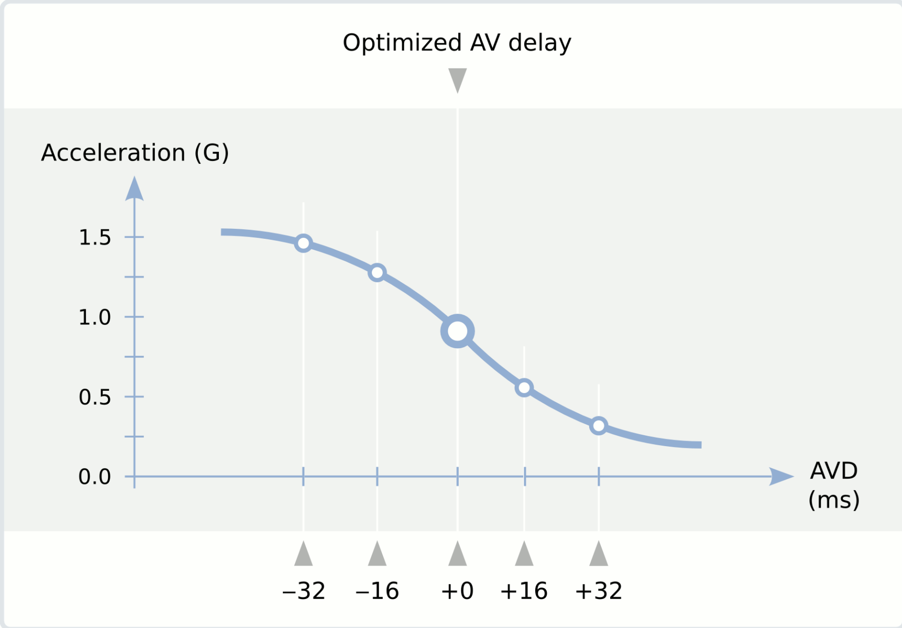


Figure 3: Exercise AVD scan, with the 5 tested AVD calculated in steps of 16 ms

The exercise scan rate is calculated as:

- the ventricular rate at the beginning of the scan in the event that the test is in atrial paced conditions or,
- in the event of an atrial sensed scan, the ventricular rate at the beginning of the scan minus 10 bpm if this is higher than the basic rate. Otherwise, at the ventricular rate at the beginning of the scan.

<u>Scan suspension conditions</u>

The evaluation of the SonR amplitude is not taken into account in the average calculation during AVD scan, for any cycle considered abnormal. This includes:

- any atrial pacing during test in atrial sensing conditions or P wave detection during the test in atrial paced conditions,
- R wave detections,
- PACs or PVCs,
- cycles in fallback mode
- noise in the atrial or ventricular channels.

Exercise AV Delay optimal value processing

After finding the optimal AVD at exercise, the device will check if the value found is within the range of programmable values:

- the optimal AVD should be longer than 32 ms

- the difference between the optimal AVD at exercise and the AVD at rest calculated in the same atrial conditions (sensed or paced) should be < 48 ms.

In the event that the value is within the defined range, the provisional AVD at exercise (calculated in 3b) will be replaced by this new value.

In the event that the result is not in the defined range, the interval will be programmed to the closest programmable value.

In the event that the scan is aborted at the first attempt, the device will immediately restart the search for the exercise conditions and will immediately retry the calculation of the optimized AV delay during exercise. If the second attempt fails, the device will retry optimizing the exercise AV delay 1 hour later, then 2 hours later, then 4 hours, 8 hours, etc … This retry phase will end at the start of a new week (new Monday), if the failure is recurrent.

Programmable parameters

In order to have access to the automatic SonR CRT optimization function, the “SonR” parameter need to be selected in the “Patient” screen, and the device has to be programmed in DDD, DDDR or DDD/DDIR.

Note: In the event of VVI programming (AF patients), only the manual VV scan is possible.

The Automatic “SonR CRT optimization” can be programmed in the “Brady” parameter screen. It can be programmed as:

Parameters	Explanation
OFF	The optimization is not active
Monitor	The device suggests the optimal VV/AV delay values every week, but the values are not automatically programmed
AV+VV	The device determines and programs the optimal VV/AV delay combination values every week
AV	The device determines and programs only the optimal AV delay values every week

The heart rate at which the optimization at exercise starts is programmable in the Advanced Parameters, from 70 bpm to 120 bpm, with steps of 5 bpm. The nominal value is 90 bpm.

The manual optimization can be launched in the “Test EGM screen”, in the “SonR CRT optimization” tab. It is possible to select which type of test can be launched on the screen. In the DDD or DDDR mode, VV + AV scan, only AV or only VV scan are available.

Studies and results

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Annexes

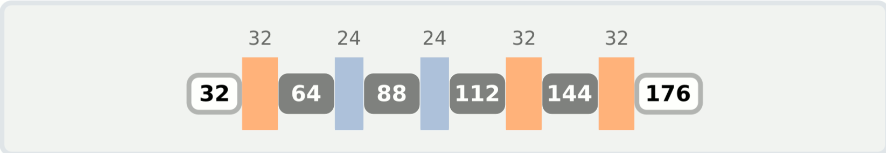
Example 1: Calculation of the 6 AV delays to be tested for VV delay scan

PR interval = 223 ms

First AVD = 32 ms

Last AVD = 223 - 47 = 176 ms

The final AV delay steps will be the following:



Example 2: VV delay optimal value processing

First optimization

- VV reference (programmed): BIV0
- Optimal VV delay: RL32, with Area Index higher than 14% of the reference BIV0; a change of configuration from the programmed one of one VV configuration is allowed, so the new VV configuration is RL16.

Second optimization

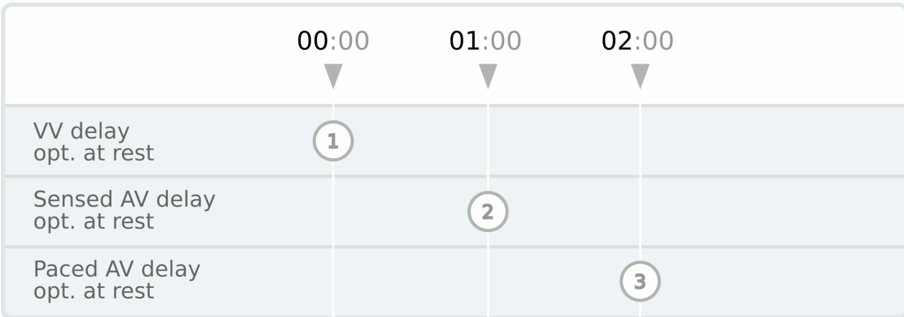
- VV reference: RL16,
- Optimal VV delay: LR32, with Area Index higher than 14% of the reference RL16; a change of configuration from the programmed one of one VV configuration is allowed, the new VV configuration is BIV0.
- BIV0 is the optimal configuration.

Third optimization

- VV reference: BIV0,
- Optimal VV delay: LR32, with Area Index less than 14% of the reference BIV0; no change of configuration from the programmed one is allowed, the new VV configuration is BIV0.
- BIV0 is the optimal configuration.

Examples 3: AV delay optimization at rest: timings

Example 3A



1 **Test successful. OK to start the AV delay optimization at rest:**

- starting at 1:00 for Sensed AV delay;
- starting at 2:00 for Paced AV delay.

2 **Test successful. OK to start the AV delay optimization at exercise:**

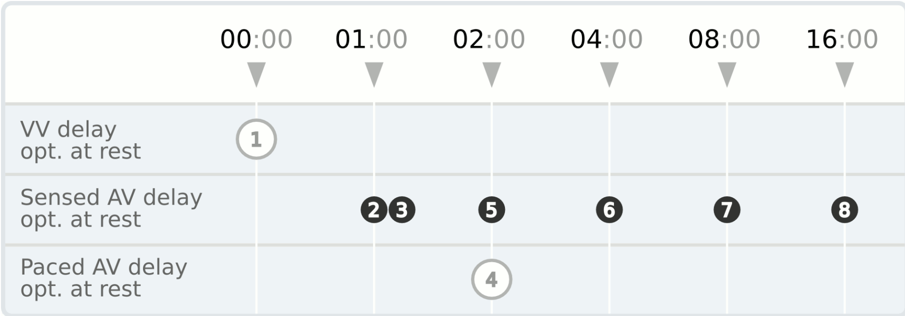
- will look for exercise conditions starting at 12:00;
- New VV delay and sensed AV delay at rest are applied.

3 **Test successful. New paced AV delay at rest is applied.**

Example 3B

1. Test failed. Retry just after.
2. Test failed. Retry 1 hour later.
3. Test failed. Retry 2 hours later.
4. **Test successful. OK to start the AV delay optimization at rest:**
   - starting at 1:00 for Sensed AV delay (time over);
   - starting at 2:00 for Paced AV delay (time over).
5. **Test successful. OK to start the AV delay optimization at exercise:**
   - will look for exercise conditions starting at 12:00;
   - New VV delay and sensed AV delay at rest are applied.
6. **Test successful. New paced AV delay at rest is applied.**

Example 3C



1 **Test successful. OK to start the AV delay optimization at rest:**

- starting at 1:00 for Sensed AV delay;
- starting at 2:00 for Paced AV delay

2 Test failed. Retry just after.

3 Test failed. Retry 1 hour later.

4 **Test successful. OK to start the AV delay optimization at exercise:**

- will look for exercise conditions starting at 12:00;
- New VV delay and paced AV delay at rest are applied.

5 Test failed. Retry 2 hours later.

6 Test failed. Retry 4 hours later.

7 Test failed. Retry 8 hours later.

8 Test failed. Retry 16 hours later. This retry phase will end at the start of a new week (new Monday) if the failure is recurrent.

Examples 4: Calculation of the 11 AV delays to be tested for AV delay scan

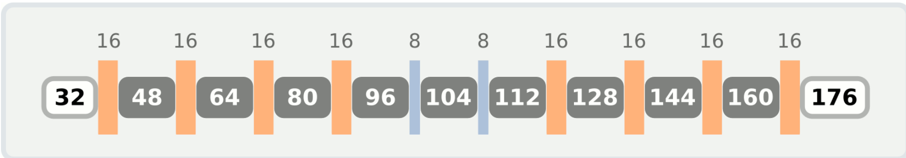
Example 4A

PR interval = 223 ms

First AVD = 32 ms

Last AVD = 223 - 47 = 176 ms

The final AV delay steps will be the following:



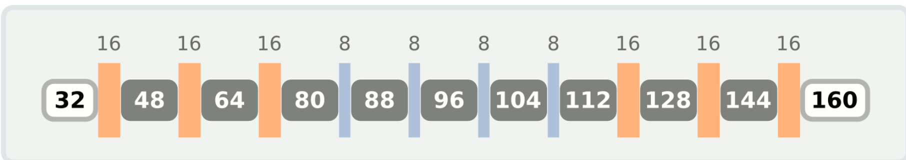
Example 4B

PR interval = 207 ms

First AVD = 32 ms

Last AVD = 207 – 47 = 160 ms

The final AV delay steps will be the following:



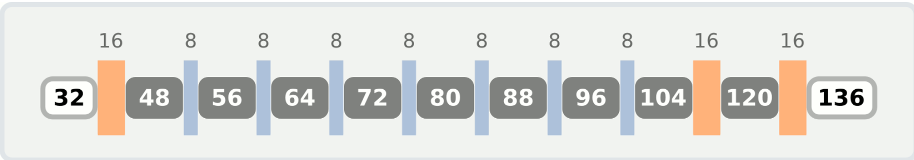
Example 4C

PR interval= 183 ms

First AVD = 32 ms

Last AVD = PR – 47 ms = 136 ms

The final AV delay steps will be the following:



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