Enitra 6/8

Function Manual

ProMRI®

BIOTRONIK
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Enitra 6/8
Function Manual

Enitra Pacemaker Family

Doc. Id.: 429316--C

Table of Contents

I Characteristics of the Device Family

What's in this part?

Overview You will find a description of the characteristics of the device family in part I of the function manual.

1 System Description

What's in this chapter?

Intended Medical Use

Intended use

Enitra is a family of implantable pacemakers that can be implanted for all bradycardia arrhythmia indications. The primary objective of the therapy consists of improving patients' symptoms that can be clinically manifested. The implantation of the pacemaker is a symptomatic therapy with the following objective:

- Compensation of bradycardia by atrial, ventricular, or AV sequential pacing
- Additional triple-chamber features: Resynchronization of ventricular chamber contraction via biventricular pacing

Diagnosis and therapy forms

The cardiac rhythm is automatically monitored and bradycardia arrhythmias are treated. All major therapeutic approaches from the field of cardiology and electrophysiology are unified in this pacemaker family. BIOTRONIK Home Monitoring® enables physicians to perform therapy management at any time.

Required expertise

In addition to having basic medical knowledge, the user must be thoroughly familiar with the operation of a device system.

- Only qualified medical specialists having the special knowledge required for the proper use of implanted devices are permitted to use them.
- If users do not possess this knowledge, they must be trained accordingly.

System Overview

Device family

This device family consists of single-chamber, dual-chamber and triple-chamber devices with or without Home Monitoring. Not all device types are available in every country.

The following device variants are available:

Device type	Variant with Home Monitoring	Variant without Home Monitoring
Single-chamber	Enitra 6 SR-T, Enitra 8 SR-T	Enitra 6 SR
Dual-chamber	Enitra 6 DR-T, Enitra 8 DR-T	Enitra 6 DR
Triple-chamber	Enitra 8 HF-T, Enitra 8 HF-T QP	—

Device

The device's housing is made of biocompatible titanium, welded from the outside and therefore hermetically sealed. The ellipsoid shape facilitates ingrowth into the pectoral muscle area. The housing serves as an antipole in the case of unipolar lead configuration.

Lead connections

BIOTRONIK provides pacemakers with headers for different standardized lead connections:

- IS-1
- IS-1/IS4

Note: Suitable leads must comply with the norms:

- A device's IS-1 connector port must only be used for connecting leads with an IS-1 connector that conform to ISO 5841-3.
- A device's IS4 connector port must only be used for connecting leads with an IS4 connector that conform to ISO 27186.

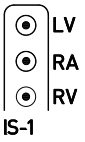
Note: The device and leads have to match.

- Only quadripolar leads must be connected to the IS4 connector on device type HF QP with IS4.

Note: Use only adapters approved by BIOTRONIK for leads with different connections.

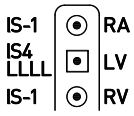
- If you have any questions concerning the compatibility of other manufacturers' leads, please contact BIOTRONIK.

IS-1 The device labeling provides information pertaining to the connection assignment:

SR	DR	HF
VVIR/AAIR IS-1	DDDR  IS-1	DDDRV  IS-1

Connector port	Lead connector	Configuration	Implantation site	Device type
A/RA	IS-1	Unipolar, bipolar	Atrium	DR, HF
V/RV	IS-1	Unipolar, bipolar	Right ventricle	SR, DR, HF
LV	IS-1	Unipolar, bipolar	Left ventricle	HF

IS-1/IS4 The device labeling provides information pertaining to the connection assignment:

HF QP
DDDRV 

Connector port	Lead connector	Configuration	Implantation site	Device type
RA	IS-1	Unipolar, bipolar	Atrium	HF QP
RV	IS-1	Unipolar, bipolar	Right ventricle	HF QP
LV	IS4	Unipolar, bipolar	Left ventricle	HF QP

Leads BIOTRONIK leads are sheathed in biocompatible silicone. They can be flexibly maneuvered, are stable long-term, and are equipped for active or passive fixation. They are implanted using a lead introducer set. Some leads are coated with polyurethane which is known to increase the gliding properties for the lead. Leads with steroids reduce inflammatory processes. The fractal design of the leads allows for low pacing thresholds, high pacing impedance, and a low risk of oversensing.

BIOTRONIK provides adapters to connect already implanted leads to new devices.

Telemetry Telemetric communication between the device and the programmer can be carried out following initialization either by applying the programming head (PGH) to the device or by using wireless wandless telemetry in the programmer.

Programmer Using the programmer, the pacing thresholds can be determined and all tests can be performed during implantation and in-office follow-up. In addition to this, the programmer is used to set mode and parameter combinations, as well as for interrogation and saving of data from the device. Leadless ECG, IEGM, markers and functions are displayed simultaneously on the color display.

Modes The mode setting depends on the individual diagnosis:

Device type	Modes	Standard
SR	• VVI-CLS (8 series only) • VVIR, V00R, AAIR, A00R • VVI, VVT, V00, AAI, AAT, A00 • OFF	VVIR
DR	• VVI-CLS; DDD-CLS (8 series only) • DDD-ADI, DDDR-ADIR (6 and 8 series) • DDDR, DDIR, DVIR, D00R, VDDR, VDIR • VVIR, V00R, AAIR, A00R • DDD, DDT, DDI, DVI, D00, VDD, VDI • VVI, VVT, V00, AAI, AAT, A00 • OFF	DDDR
HF (QP) (8 series)	• VVI-CLS, DDD-CLS • DDD-ADI, DDDR-ADIR • DDDR, DDIR, DVIR, D00R, VDDR, VDIR • VVIR, V00R, AAIR, A00R • DDD, DDT, DDI, DVI, D00, VDD, VDI • VVI, VVT, V00, AAI, AAT, A00 • OFF	DDDR

Note: Home Monitoring is possible in all modes.
The OFF mode only functions temporary, i.e. during a test.

NBG codes AAIR or VVIR is the NBG code for the antibradycardia mode of the single-chamber device:

A/V	Pacing in the atrium or ventricle
A/V	Sensing in the atrium or ventricle
I	Pulse inhibition in the atrium and ventricle
R	Rate adaptation

DDDR is the NBG code for the antibradycardia mode of the dual-chamber device:

D	Pacing in the atrium and ventricle
D	Sensing in the atrium and ventricle
D	Pulse inhibition and pulse triggering
R	Rate adaptation

DDDRV is the NBG code for the antibradycardia mode of the triple-chamber device:

D	Pacing in the atrium and ventricle
D	Sensing in the atrium and ventricle
D	Pulse inhibition and pulse triggering
R	Rate adaptation
V	Multisite pacing in both ventricles

BIOTRONIK Home Monitoring®

In addition to effective pacing therapy, BIOTRONIK provides a complete therapy management system:

- With Home Monitoring, diagnostic and therapeutic information and technical data are automatically sent to a stationary or mobile transmitter via an antenna in the device header. The data are encrypted and sent from the transmitter to the BIOTRONIK Service Center via the cellular phone network.
- The received data are deciphered and evaluated. Each physician can set the criteria for evaluation to be used for each patient and can configure the time of notification via e-mail, SMS or fax.
- A clear overview of the results of this analysis is displayed for the attending physicians on the protected internet platform Home Monitoring Service Center (HMSC).
- Data transmission from the device is performed with a daily device message.
- Device messages, which indicate special events in the patient's heart or in the device, are forwarded with the following message.
- A test message can be initiated at any time using the programmer to immediately check the Home Monitoring function.

Order numbers for Enitra

The devices can be obtained as follows:

Enitra 6 SR	407165	Enitra 8 SR-T	407159
Enitra 6 SR-T	407162	Enitra 8 DR-T	407147
Enitra 6 DR	407153	Enitra 8 HF-T	407142
Enitra 6 DR-T	407150	Enitra 8 HF-T QP	407141

Package contents

The storage package includes the following:

- Sterile packaging with device
- Serial number label
- Patient ID card
- Warranty booklet

Note: The technical manual pertaining to the device is either included in hard copy form in the storage package or in digital form on the internet.

The sterile packaging includes the following:

- Device
- Screwdriver

Diagnostic and Therapy Functions

General overview

All the systems have extensive features that allow quick diagnosis and delivery of safe therapy for bradycardia conditions.

- Automatic functions make it easy and fast to implant, configure, and check the pacemaker.
- Auto-initialization after implantation: The device recognizes the implanted leads autonomously and sets the polarity. The automatic functions of the software are activated after 10 min.

Diagnostic functions

- Data from the last interrogations and follow-ups are recorded as well as arrhythmia episodes; they are stored together with other data to assess the state of both the patient and the device at any time.
- Continuous automatic below-threshold impedance measurements are performed in the device independent of the pacing pulse in order to check the lead for proper functioning.
- Once a telemetry connection has been established during a test procedure in an in-office follow-up, the IEGM is displayed with markers.

Antibradycardia pacing

- Sensing: The amplitudes of the P and R waves are measured in the implanted device fully automatically and permanently to record varying amplitudes. The sensitivity for the atrium and ventricle is adapted automatically on an ongoing basis. The measurement data are averaged and the trend can be displayed.
- Pacing thresholds: Pacing thresholds are automatically identified in the device: In single-chamber devices the right ventricular, in dual-chamber devices the atrial and right ventricular, in triple-chamber devices the atrial, right and left ventricular pacing thresholds. Capture control adjusts the pulse amplitudes in such a way that every change of the pacing threshold results in the patient being paced at an optimal amplitude.
- Timing: Pacing in the atrium is checked particularly carefully in dual and triple-chamber devices by an automatic adaptation of the atrial refractory period in order to avoid pacemaker-mediated tachycardia (Auto PVARP function: The postventricular atrial refractory period is adapted automatically).
- Additional, special form of rate adaptation with devices from the 8 series: An increased cardiac output requirement is detected using physiological impedance measurement. The measuring principle is based on contractile changes (inotropy) of the myocardium (CLS function: Closed Loop Stimulation). Rate adaptation is automatically initialized and optimized in CLS mode.
- Ventricular pacing suppression: Unnecessary ventricular pacing is avoided by promoting intrinsic conduction (Vp suppression function). The device can adapt itself to conduction changes. In the case of intrinsic conduction, the device switches from a DDD(R) to an ADI(R) mode.
- 8 series: In the course of the follow-up, an automatic test of the AV delay is performed to improve the heart performance. AV delays are calculated; the optimum values can be applied.

Resynchronization therapy

Triple-chamber devices have functions to configure different VV delays in order to resynchronize the ventricles.

- Capture Control is also available for the left ventricle with automated tracking of the pacing threshold or automatic threshold monitoring (ATM) for trend analysis.
- To ensure that no additional surgery is necessary in case of a left-sided increase of pacing threshold or undesired phrenic nerve stimulation, different pacing polarities can be set for the left ventricular lead with a triple-chamber device. Up to 13 vectors can be used with the HF QP device type.
- 8 series: With the QP device type, the LV vector test provides a fast measurement of the pacing threshold, the phrenic nerve pacing threshold and the pacing impedance. The relative influence on the service time is also displayed. The measurement results are evaluated automatically so that the optimal pacing polarity can be set.

  The short RV-LV conduction test also supports the selection.
- An additional diagnostic function with biventricular pacing: Variability of the heart rate, patient activity, and thoracic impedance are monitored on a continual basis.

Programs

There are two types of therapy programs:

- Default parameters are offered for the most common indications (ProgramConsult function).
- Individual settings can be saved in 3 individual therapy programs.

ProMRI devices recognize magnetic resonance imaging devices

The static magnetic field of magnetic resonance imaging devices is reliably recognized with the aid of a sensor. This sensor can be activated for a maximum of 14 days using the MRI AutoDetect function during an interrogation.

If the patient comes near a magnetic resonance imaging device within the time set, the implanted device recognizes the static magnetic field and automatically activates the preset MRI program. Reprogramming to the permanent program occurs also automatically after leaving the imaging device.

Home Monitoring functions

The device automatically sends information to the transmitter once a day.
In addition to this, test messages can be initiated using the programmer.
Important medical information includes, among others, the following:

- Ongoing atrial and ventricular arrhythmia
- Parameters relevant to leads in the atrium and ventricle: Thresholds, sensing amplitudes, impedances
- Current statistics on bradycardia therapy
- Individually adjustable timing interval for device messages which provide additional information pertaining to the device messages
- IEGM online HD® with up to 3 high definition channels
- Transmission of these IEGM recordings with device messages

Replacement Indications

Possible charging status

The time span from the beginning of service (BOS) to elective replacement indication (ERI) is determined by, among others, the following:

- Battery capacity
- Lead impedance
- Pacing program
- Pacing to inhibition ratio
- Pacemaker circuit properties

The following are the defined pacemaker operational statuses:

- BOS: Beginning of Service: > 90%
- ERI: Elective Replacement Indication (i.e., RRT: Recommended Replacement Time)
- EOS: End of Service

ERI activation

ERI detection is automatically activated after the following events:

- Successful auto-initialization

ERI display

ERI is displayed as follows:

- On the programmer after interrogation of the pacemaker
- By a defined decrease in the basic rate as well as the magnet rate

Rate decrease

The decrease of basic rate and magnet rate is defined as follows:

- In the following modes, the pacing rate decreases by 11%:
  DDD(R); DDT; D00(R); VDD(R); VDI(R); VVI(R); VVT; AAI(R); AAT; A00(R)
- In the modes DDI(R) and DVI(R), only the VA interval is extended by 11%. This reduces the pacing rate by up to 11%, depending on the configured AV delay.

Change of the mode with ERI

This change depends on the mode which is set. It is displayed on the programmer.

- Single-chamber modes: VVI
- Dual-chamber modes: VDD
- Triple-chamber modes: Dual-chamber pacing, one biventricular setting is kept

Deactivated functions with ERI

The following functions are deactivated:

- Atrial pacing
- Night program
- Rate adaptation
- Atrial and ventricular capture control
- Rate fading
- Atrial overdrive pacing
- IEGM recordings
- Statistics
- Home Monitoring
- Rate hysteresis
- Ventricular pacing suppression

Magnet response at ERI

After reaching ERI, pacing is performed as follows after applying the magnet or programming head:

Magnet response	Cycles 1 to 10	After 10th cycle
Automatic	Asynchronous with 80 bpm	Synchronous with basic rate reduced by 11%
Asynchronous	Asynchronous with 80 bpm	Asynchronous with 80 bpm
Synchronous	Synchronous with basic rate reduced by 11%	Synchronous with basic rate reduced by 11%

Expected service times after ERI

The information is based on the following:

- Lead impedance of 500 Ω or 600 Ω
- 100% pacing
- Interval from ERI to EOS for the single-chamber device in AAI(R)/VVI(R) mode, for the dual and triple-chamber device in DDD(R) mode
- Standard program with both high and low pacing energy
- Data of the battery manufacturer (see the battery data)

110 bpm 4.6 V 1.5 ms 500 Ω	30 bpm 0.2 V 0.1 ms 500 Ω	70 bpm 2.5 V 0.4 ms 500 Ω	70 bpm 5.0 V 0.4 ms 500 Ω	60 bpm 2.5 V 0.4 ms 600 Ω	60 bpm 5 V 0.4 ms 600 Ω
Mean value: 8 months Minimum value: 6 months		— Minimum value: 6 months		— Minimum value: 6 months	

II Functional Description and Handling

What's in this part?

Overview Please see part II of the function manual for a description of the device functions and how to use them.

2 Auto-initialization

What's in this chapter?

Auto-Initialization of the Device

Purpose

The auto-initialization function automatically puts the device into operation.

Functional principle

Auto-initialization starts once a lead is connected to the device for the first time and lead impedance < 2500 Ω is measured.

The device begins normal operation if stable impedances are measured in a confirmation phase lasting up to 10 minutes (up to 20 minutes with two unipolar leads) and the lead polarities are confirmed.

The standard values for pacing and sensing are applied during the confirmation phase. The automatic functions are disabled.

Confirmation phase

A confirmation phase begins following initial lead detection.

This normally lasts up to 10 minutes. If two unipolar leads are connected, it can last up to 20 minutes.

The device checks whether conditions are stable for lead polarity and lead impedance.

Automatic termination of auto-initialization

When the confirmation phase has successfully ended, the device begins the standard program with automatic functions to adapt various parameters if no other permanent program has been transferred.

After the end of auto-initialization, the Follow-up window is displayed.

Programming the device prior to auto-initialization

If the device was programmed prior to auto-initialization, the programmed settings will be applied in the confirmation phase when automatic functions are deactivated.

After a successful testing phase, the automatic functions are also available.

Manual termination of auto-initialization

Auto-initialization is canceled if a permanent program taking immediate effect is transmitted during the testing phase.

Note: Once auto-initialization is canceled manually, it cannot be restarted or repeated!

3 Lead Configuration and Monitoring

What's in this chapter?

Automatic Lead Impedance Measurement

Navigation: Parameters → Diagnostics → Enable lead check

Objective

The automatic lead check function can be used to quickly detect technical failures in the system (device and lead) resulting from a defective lead or faulty connection of the leads.

The function is required for auto-initialization (see: Auto-Initialization of the Device, p. 19).

Automatic lead impedance measurement provides constantly up-to-date measured impedance values via Home Monitoring or for interrogation with the programmer.

Functional description

The function is activated as part of the factory settings and is already active while in the package.

Automatic lead impedance measurement works constantly.

Provided corresponding leads are connected, the system measures lead impedance in the atrium and the ventricle for the bipolar and the unipolar configuration.

Switch the function on or off via: **Parameters → Diagnostics → Enable lead check**.

The function is automatically deactivated in the following situations:

- During programming head application
- During data collection for Home Monitoring (a few minutes per transmission)

If a permanent program is transferred to the device, all present lead error messages are deleted.

Physical measuring principle

The device delivers a low-level (far below the pacing threshold) measuring pulse especially for the impedance measurement. The impedance is calculated based on the voltage drop measured in this process.

The energy of the pulse for measuring the lead impedance is very low:

- Pulse amplitude: 100 µA
- Pulse width: 30 µs

Synchronization with the heart rhythm

The measuring pulse is delivered synchronously to the heart rhythm 90 ms after a ventricular sensed event or paced event in each case.

At most, one measuring pulse is delivered for each cardiac cycle.

Time sequence

With multi-chamber devices, the lead impedances are measured in 6 consecutive cardiac cycles in the following order:

- Atrial, bipolar
- Atrial, unipolar
- Right ventricular, bipolar
- Right ventricular, unipolar
- Left ventricular, bipolar
- Left ventricular, unipolar

With single-chamber devices, this sequence is shortened accordingly.

The measurement sequence automatically repeats every 30 s.

Automatic lead check

The automatic lead check verifies whether the measured values are within a range from 100 to 2500 ohms, which is defined as acceptable.

If a measurement result is outside this impedance range, the measurement is repeated in the next two cardiac cycles.

Error message for bipolar lead configuration

If the measurement results are outside the acceptable range for three consecutive measurements during bipolar lead check, then the system responds as follows:

- The system generates a message which is displayed in the event list in the follow-up window and in the TrendView during the next device interrogation or follow-up.
- Devices with the Home Monitoring function activated can immediately transmit this information automatically to the Home Monitoring Service Center.
- The system automatically switches to the unipolar configuration.
- The system performs an automatic pacing threshold test (provided this function is activated).
- The maximum sensitivity of automatic sensitivity control is adapted.

Error message for unipolar lead configuration

If the measurement results are outside the acceptable range for three consecutive measurements during unipolar lead check, then the system responds as follows:

- To prevent false lead error messages from being triggered by electromagnetic interference (EMI), the system starts a 90-minute verification period.
- Then three successive measuring cycles are run again.
  - If all three measured values are within the accepted impedance range, the device returns to normal mode.
  - If at least one of the three measured values is outside the accepted impedance range, the lead error is considered verified.
- The system generates a message which is displayed in the event list in the follow-up window and in the TrendView during the next device interrogation or follow-up.
- Devices with the Home Monitoring function activated can immediately transmit this information automatically to the Home Monitoring Service Center.

Displaying the measurement results on the programmer

After successful interrogation, the programmer software displays the most recently measured values before the application of the programming head.

Impedance measurement is temporarily interrupted while the programming head is being applied.

In the `Follow-up` window, the impedance values are displayed for the active lead configuration.

You can press the **[TrendView]** button to display the lead impedance history.

In the `Tests` window in the `Impedance` tab, measured values are also displayed for the inactive lead configuration.

Lead Configuration

- In a unipolar configuration, the negative pole (the cathode) is situated in the heart, while the positive pole (the anode) is formed by the housing of the device.
- In a bipolar configuration, both poles of the leads are situated in the heart. The devices allow for programming separate lead polarities for pacing and sensing.

Advantages and disadvantages

- Compared with bipolar pacing, unipolar pacing has the advantage of being clearly identifiable on the surface ECG and has slightly lower energy consumption.
- With unipolar pacing, the device housing represents one pole; therefore, high pulse amplitudes can cause muscle stimulation in this area.
- Because of its lower susceptibility to interference signals, i.e., due to skeletal myopotentials, bipolar sensing offers a much better "signal-to-noise-ratio" than unipolar sensing. Therefore it is possible to program higher sensitivities (lower values).

CAUTION
If a unipolar lead is used in the atrium or ventricle, the corresponding lead configuration has to be programmed to `unipolar`. Otherwise entrance and/or exit block will result.

Setting Lead Polarity

Navigation: Parameters → Bradycardia/CRT

WARNING
Unipolar pacing can interfere with a co-implanted ICD. If an ICD is implanted at the same time as a pacemaker and a lead failure occurs, it is possible to switch to unipolar pacing after a pacemaker reset or using the automatic lead check function. This can falsely inhibit or trigger delivery of tachyarrhythmia therapy from the ICD. • For pacemaker patients with a co-implanted ICD a unipolar lead configuration is not permitted.

Objective/description

You can program different lead configurations for pacing and sensing using the following parameters:

- `Sensing polarity`
- `Pacing polarity`

If bipolar leads are connected, both a bipolar and unipolar lead configuration can be set.

Advantages:

- Bipolar lead configuration: Higher sensitivities can be programmed.
- Unipolar lead configuration: The pacing pulse is easier to identify in the ECG; less energy is required.

Default setting

The device automatically sets the lead polarity according to the connected leads during auto-initialization.

If a specific polarity has been programmed prior to auto-initialization, then this has priority.

Permissible configurations

All combinations are permitted.

4 Sensing Functions

What's in this chapter?

Sensing Concept

Background

Sensing thresholds of leads usually remain steady for an extended period of time. Typical values are 3 - 4 mV for the atrium and about 12 mV for the ventricle.

Development of the automatic sensitivity control function

Early generations of pacemakers used the sensing of atrial events even during atrial flutter or fibrillation for pacemaker timing and thus often induced ventricular tachyarrhythmias. Mode switching algorithms prevented this undesirable behavior by switching over to ventricular timing.

The development of implantable cardiac defibrillators provided functions for automatic sensitivity control for the right ventricle and the right atrium, which can correctly capture particularly small and varying signal amplitudes during flutter or fibrillation. This function automatically adapts sensitivity to the occurring signal amplitudes and provides for proper therapy by the device due to correct signal processing.

Application for automatic atrial sensitivity control

Recent studies have shown that approximately 50% of patients develop episodes of atrial fibrillation even if they were previously without pathological findings.

This device family offers the complete automatic sensitivity control for all chambers. Diagnostics and mode switching have been optimized by proper capturing of atrial flutter or fibrillation.

Automatic Sensitivity Control

The input filters of the device are aligned with signal sensing in the range between the sinus rhythm, atrial fibrillation and ventricular fibrillation. Noise is suppressed during signal sensing.

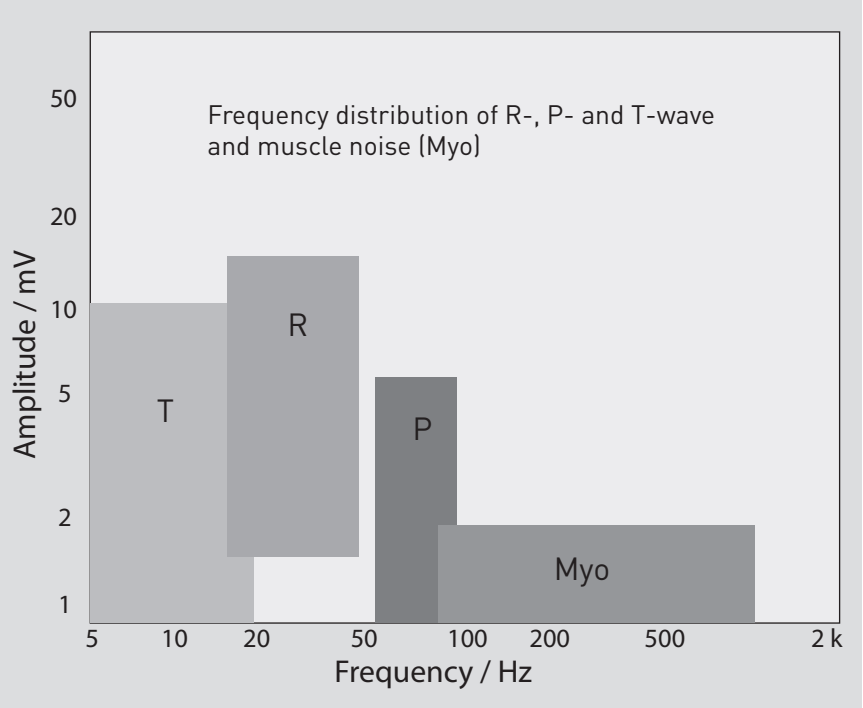
The sensitivity values in the atrium and right ventricle are dynamically adapted independently of each other with each cardiac activity (beat-to-beat).

Signal recording and filtering

The IEGM signal is recorded at the lead tip and converted into a digital signal. The digitized signal passes through a bandpass filter, which allows signal frequencies between 18 and 100 Hz to pass. T waves (≤ 18 Hz) and myopotentials (≥ 100 Hz) are thus excluded as sources of interference for sensing.

Signal processing is carried out for fixed sensitivity values as well as for automatic sensitivity control.

Filter characteristics



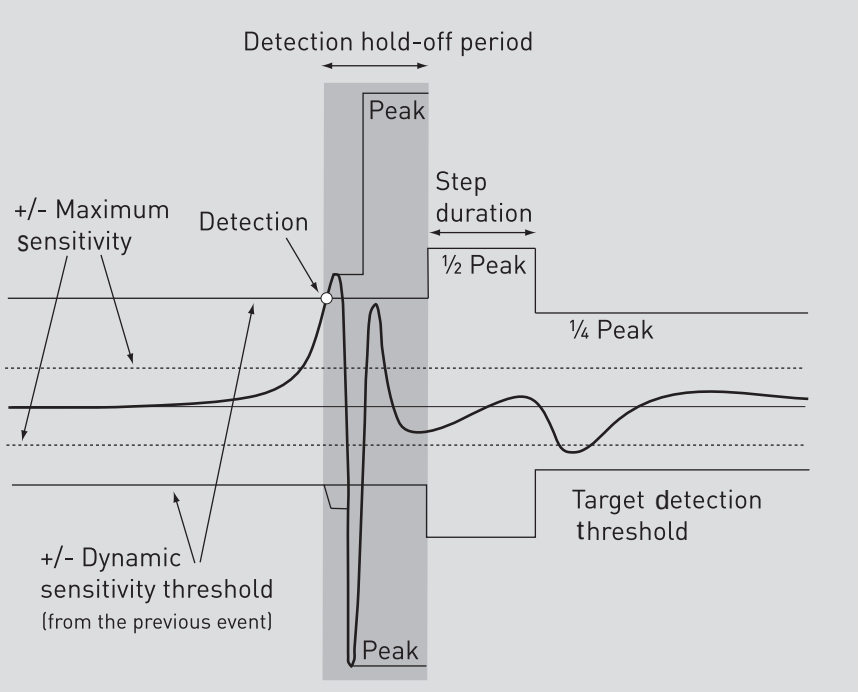
The automatic sensitivity control principle

When using automatic sensitivity control, the function automatically measures the amplitude peak and adapts the sensing threshold automatically as shown in the illustration below. After every sensed event, the function starts the detection hold-off period and measures the peak value of the amplitude. After this initial stage, the sensitivity is initially decreased to 50% of the measured peak value of the amplitude. At the end of the step duration, sensitivity is decreased to 25% of the measured peak values of the amplitude, but never below the minimum adjustable value for sensitivity.

This function automates setting of sensitivity and relieves the physician of having to make the setting manually.

Amplitudes with highly variable and small peak values are recorded reliably. The signal-to-noise ratio of 1:4 suppresses undesired noise.

Automatic sensitivity control in the ventricle in the case of sensing, functions the same way in the atrium



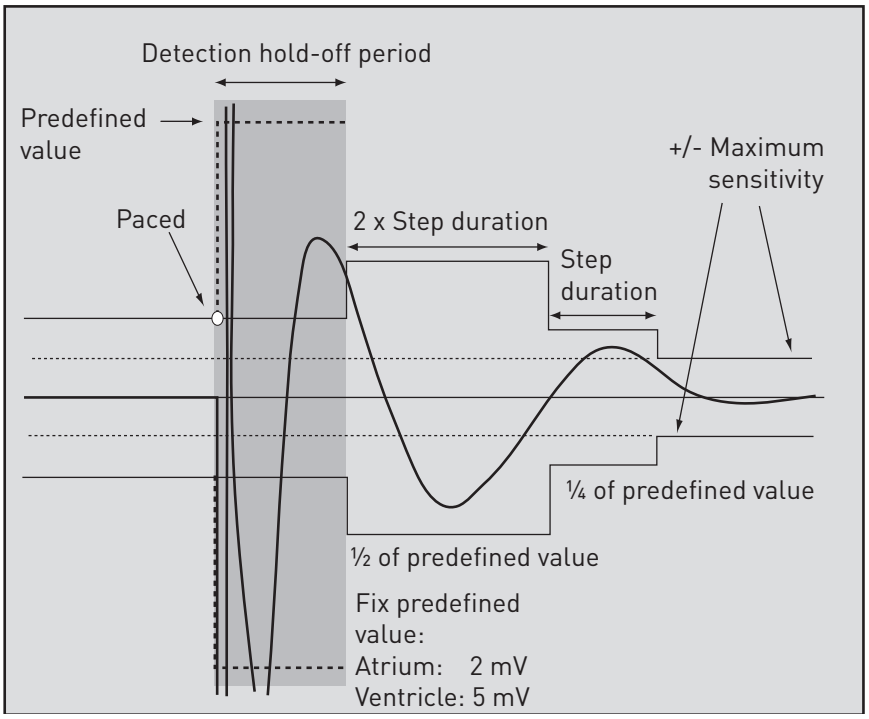
Phases of automatic sensitivity control

The timing intervals for periodic adaptations of the sensitivity in the case of a sensed event are specified in different ways for the atrium and the ventricle:

- Atrium
  - Detection hold-off period: 100 ms
  - Step duration: 80 ms
  - The decrease limit is equal to the maximum sensitivity: 0.2 mV bipolar, 0.5 mV unipolar.
- Ventricle
  - Detection hold-off period: 120 ms
  - Step duration: 125 ms
  - The decrease limit is equal to the maximum sensitivity: 2 mV, unipolar or bipolar

Note: After a pause of ≥ 1 s without sensing, the maximum sensitivity is adjusted.

Automatic sensitivity control in the ventricle in the case of pacing, functions the same way in the atrium



Phases of automatic sensitivity control

In the case of a paced event, the sensitivities are adjusted to fixed values for atrium and ventricle at the start.

The timing intervals for periodical adaptations of the sensitivity in the case of a paced event are specified in different ways for the atrium and the ventricle:

- Atrium
  - Detection hold-off period: 120 ms
  - Step duration: 80 ms
  - Initial sensitivity value: 2 mV
- Ventricle
  - Detection hold-off period: 200 ms
  - Step duration: 125 ms
  - Initial sensitivity value: 5 mV

Interference Interval as Interference Protection

Function

The interference interval prevents intrinsic events or paced events in the ventricle from being incorrectly sensed in the atrium and vice versa.

Therefore, the blanking periods following atrial and ventricular events guarantee adequate sensing.

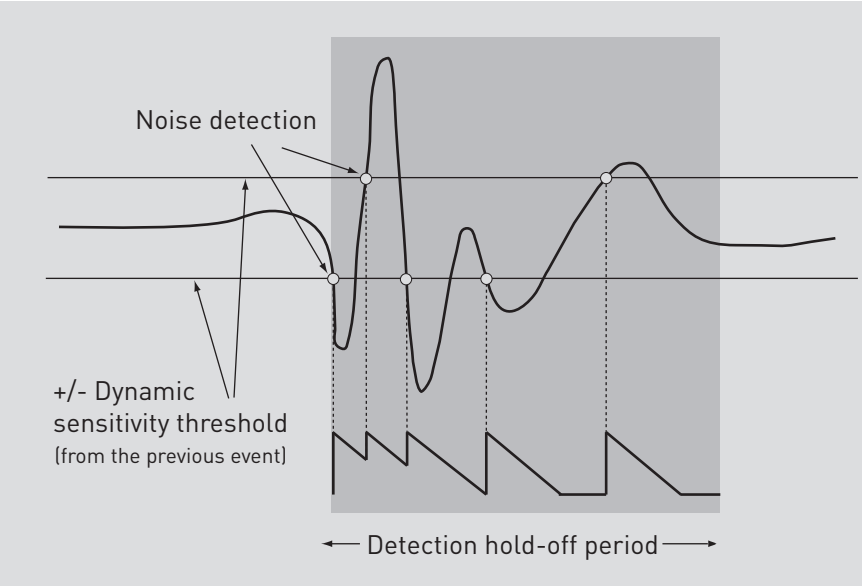
Far-field sensing from the ventricular channel can cause problems with mode switching and during rhythm classification. Therefore, it is particularly important that far-field sensing from the ventricular channel be prevented.

Likewise, a blanking period is initiated in the ventricle after an atrial pace to prevent far-field sensing in the ventricle.

Sensed events within an interference interval are not evaluated as tachycardia rates. A sensed event within an interference interval (50 ms) restarts the interference interval (50 ms). The interference interval can be retriggered.

Constantly restarting the interference interval leads to asynchronous pacing.

Sensing of noise



The interference interval is 50 ms and starts after the following events:

- Sensing
- Detection hold-off period

No sensing takes place during the interference interval.

Manual or Automatic Sensitivity Control

Navigation: Parameters → Bradycardia/CRT → Sensing

Objective

The sensitivity of the device's sensing function is either dynamically updated by the automatic sensitivity control or it is manually programmed to a set value.

An optimally configured sensing threshold guarantees reliable sensing of intrinsic events, but at the same time ignores electromagnetic interference and other interference signals.

Automatic

In the factory settings, the automatic sensitivity control is active immediately after auto-initialization of the device.

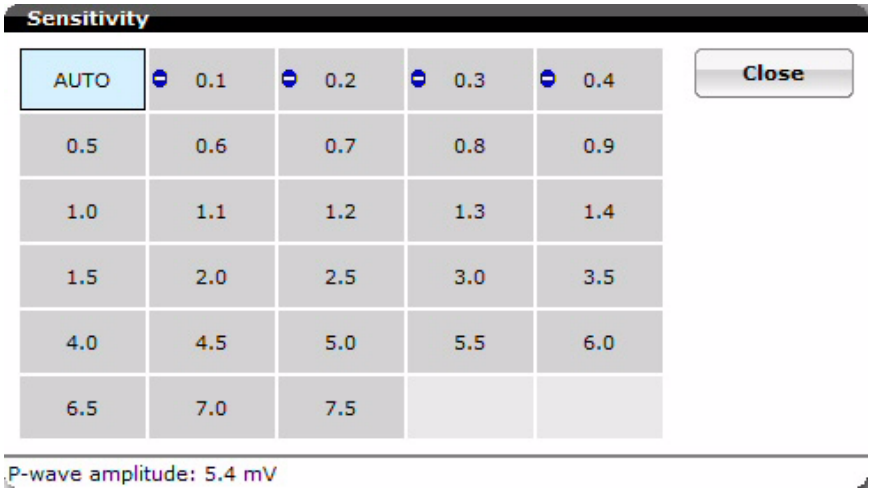
Manually

Proceed as follows to disable automatic sensitivity control and manually specify sensitivity:

Step	Action
1	Open **Parameters → Bradycardia/CRT**.
2	Select the required chamber (A, VR, LV) for the `Sensitivity` parameter.
3	Select a suitable value for the sensing threshold in the opened window. The value window displays the amplitude value measured last (A, RV, LV) in the bottom line.

User interface

Value window for adjustment of the sensing threshold



Automatic sensitivity control

The automatic sensitivity control measures the amplitude of the R- or P-wave and adapts the sensing threshold for every cardiac cycle each time (beat-to-beat).

- The maximum automatically adjustable sensitivity (lowest sensing threshold) for the ventricle is 2.0 mV.
- With multi-chamber devices: The maximum automatically adjustable sensitivity for the atrium is 0.2 mV with bipolar sensing or 0.5 mV with unipolar sensing.

If no new signal is sensed within one second after sensing, the control algorithm sets itself to the maximum sensitivity.

5 Bradycardia Therapy

What's in this chapter?

5.1 Pacing Modes

What's in this section?

Mode (Pacing Mode)

Navigation: Parameters → Bradycardia/CRT

WARNING
Unphysiological rhythm changes during magnet application! During asynchronous magnet response, unphysiological rhythm changes can occur. • Implement countermeasures if necessary!

Standard Pacing Modes

Overview

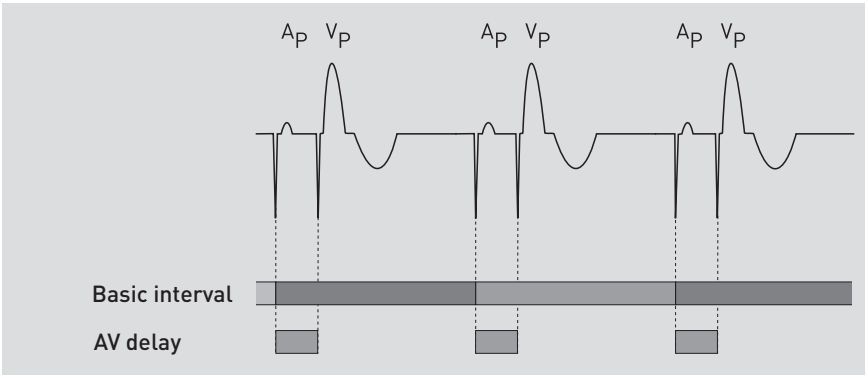
The following pacing modes will be described:

- DDD, DDI, DVI, VDD
- AAI, VVI
- A00, V00, D00
- Triggered modes
- OFF (only possible temporarily during follow-up for diagnostic purposes)

DDD mode

In the DDD mode, the basic interval starts with an atrial sensed (As) or atrial paced event (Ap) or a ventricular sensed event without a preceding atrial event (PVC = premature ventricular contraction). If no atrial sensed event occurs within the basic interval, atrial pacing takes place at the end of the basic interval and the basic interval is restarted.

AV sequential pacing in the DDD mode in the case of missing intrinsic cardiac events

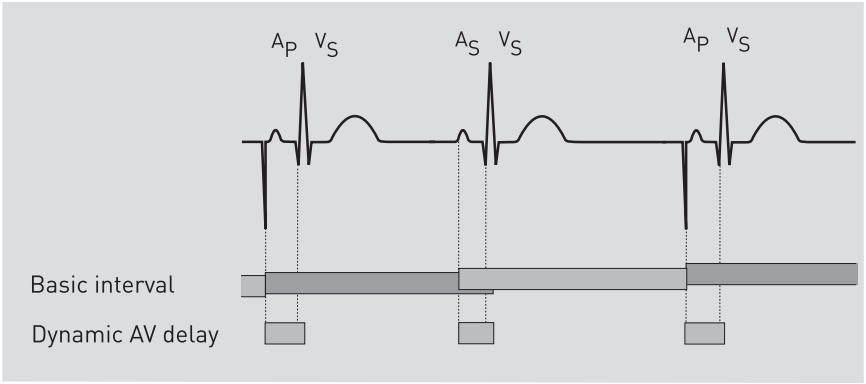


Atrial/ventricular events

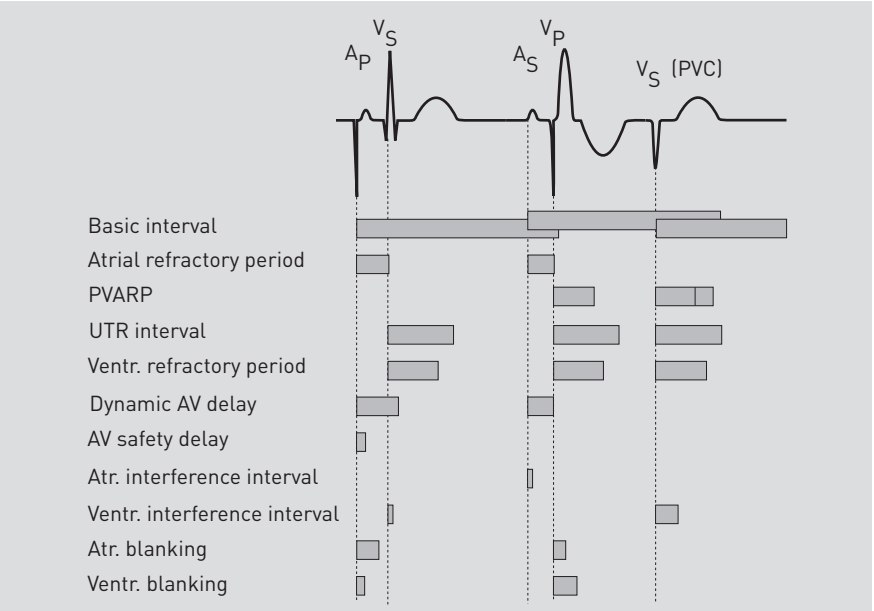
Atrial/ventricular sensed events have the following impact in DDD mode:

If ...	Then ...
If an atrial sensed or paced event takes place,	Then the AV delay starts with the basic interval.
If no ventricular sensed event occurs during the AV delay,	Then the pacemaker delivers a pacing pulse in the ventricle at the end of the AV delay.
If a ventricular sensed event (Vs) occurs during the AV delay,	Then the ventricular pacing (Vp) is inhibited.
If an atrial sensed event takes place,	Then atrial pacing is inhibited and the basic interval is restarted.

An atrial sensed event restarts the basic interval.



Start of timing intervals in DDD mode depending on the occurring events



The chart above shows the timing intervals initiated by sensing or pacing. The above chart distinguishes between pacing at the end of the AV delay (Vp) or pacing at the end of the AV safety delay (Vsp) and between sensing within the AV delay (Vs) or sensing outside the AV delay (PVC).

VDD mode

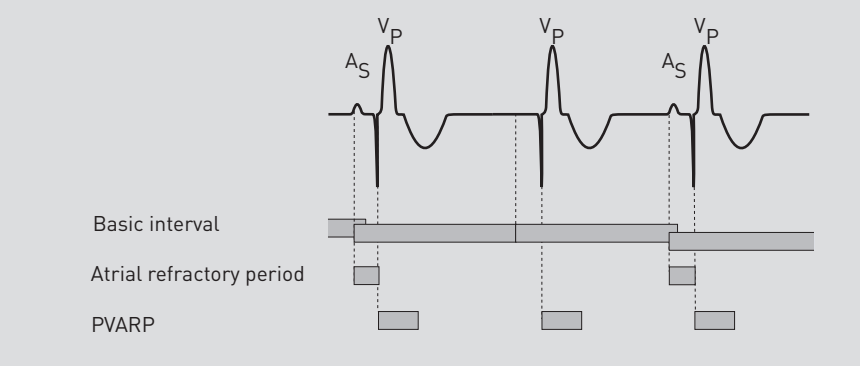
The VDD mode is derived from the DDD mode. The difference is that no atrial pacing takes place.

Sensed events

Absence of sensed events has the following impact in VDD mode:

- If the sensed event does not take place, then the basic interval starts with an atrial sensed event, a premature ventricular contraction or with the end of the preceding basic interval.

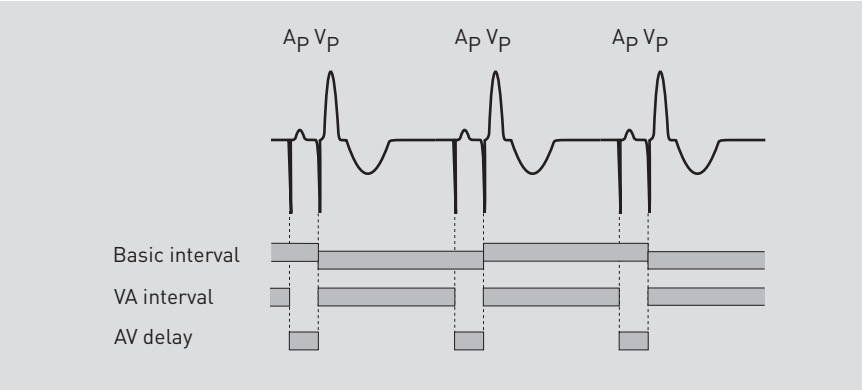
Prevention of pacemaker-mediated tachycardias in VDD mode



DDI mode

In contrast to the DDD mode, the basic interval in DDI mode does not start with a P wave, but rather with ventricular sensed or paced events. The VA interval is started together with the basic interval.

AV sequential pacing in the DDI mode in the case of missing intrinsic cardiac events

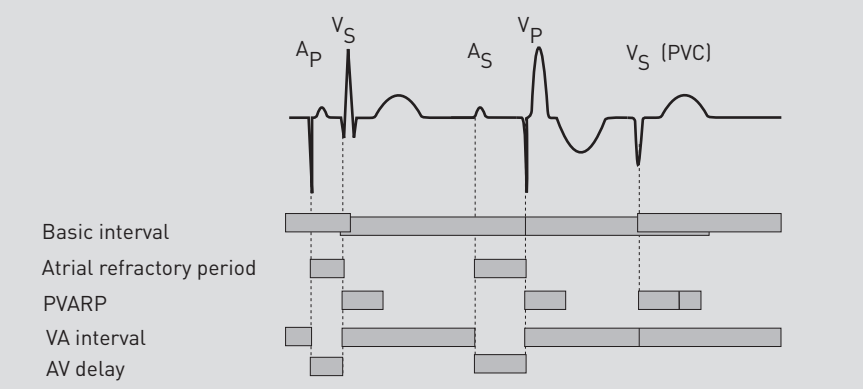


Atrial/ventricular events

Atrial/ventricular sensed events have the following impact in DDI mode:

If ...	Then ...
If no atrial or ventricular sensed events occur during the VA interval,	Then atrial pacing takes place at the end of the VA interval. The AV delay is restarted together with the pacing.
If a sensed event occurs,	Then atrial pulse delivery is inhibited, however the AV delay does not start with the sensed event, but rather after the VA interval has elapsed. Therefore P waves do not trigger ventricular events in the DDI mode.

Inhibition of atrial pacing in DDI mode by an atrial sensed event occurring within the VA interval. At the end of the VA interval, the atrial refractory period restarts.



DVI mode

The DVI mode is derived from the DDI mode. In contrast to the latter, atrial sensing does not occur in DVI mode. Therefore, atrial pacing is forced at the end of the VA delay.

Ventricular events

Ventricular sensed events have the following impact in DVI mode:

- If a ventricular sensed event occurs during the VA interval, then atrial and ventricular pulse delivery are inhibited.

AAI and VVI modes

The AAI and VVI single-chamber pacing modes are used for atrial or ventricular demand pacing. In each case, pacing and sensing only occur in either the atrium (AAI) or the ventricle (VVI). The basic interval is started by a sensed or paced event.

Sensed events

Sensed events have the following impact in the AAI and VVI modes:

- If a sensed event is recognized within the basic interval, then pulse delivery is inhibited. Otherwise, pacing takes place at the end of the basic interval.

A00 and V00 modes

In these pacing modes, pulses are emitted asynchronously in the atrium (A00) or ventricle (V00).

Note: When programming the V00 or A00 modes, you should consider the risks associated with asynchronous ventricular pacing.

D00 mode

Asynchronous AV sequential pulses are emitted in this pacing mode (D00).

Note: When programming the D00 mode, you should consider the risks associated with asynchronous ventricular pacing.

Triggered pacing

The triggered pacing modes correspond to the respective demand pacing modes with the following distinction: No pulse inhibition takes place upon sensing of an atrial/ventricular event outside of the refractory period. Instead, pacing is carried out immediately in the respective chamber.

The corresponding pacing modes are:

Pacing mode						
Demand pacing mode	DDD	VDD	DDI	DVI	AAI	VVI
Triggered	DDT	-	-	-	AAT	VVT

The pacing mode DDT does not feature an AV safety delay. This is not necessary, as ventricular pulse inhibition in cases of crosstalk (ventricular sensing of the atrial pacing pulse) cannot occur in this mode.

Sensed events

Sensed events have the following impact in the triggered pacing modes:

If ...	Then ...
If atrial/ventricular events are sensed outside of the refractory period,	Then no pulse inhibition occurs, but a pulse is delivered immediately out in the respective chamber.

VDI mode

The VDI mode is derived from the VVI mode. In contrast to the latter, the VDI mode enables registration of intraatrial events. However, the timing corresponds to that of the VVI mode.

Retrograde conduction measurement

The VDI mode is designed for measuring retrograde conduction with the IEGM and/or the marker function.

- If there is retrograde conduction, it can be measured as the time interval between a ventricular paced or sensed event and the subsequent atrial sensed event. This measurement can be achieved using the programming device or an additional ECG recorder.

OFF mode

No pacing pulses are delivered in the OFF mode. External pacing (NIPS) represents one exception to this.

Objective

Without external pacing, the OFF mode is used for detection and morphological evaluation of the intrinsic rhythm.

- With external pacing, the OFF mode is used for electrophysiological studies and to combat tachycardia.
- The pulse and control parameters remain adjustable in the OFF mode because the external pacing function of the programmer can be used to trigger pacing pulses and to transmit sensed events to the programmer. Note that sensing is limited by the refractory period, whereas pacing is not.

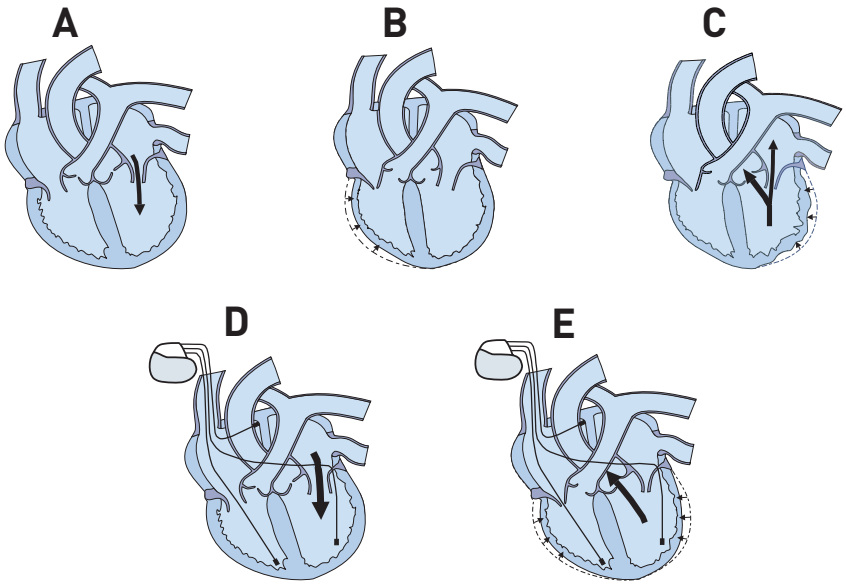
Triple-chamber modes

The device with HF-T added to its name is the triple-chamber model in the pacemaker family. The NBG code is DDDRV. Triple-chamber pacing can be carried out using two leads in a single ventricle or in each of the two ventricles. Multisite ventricular pacing is the primary function of cardiac resynchronization therapy.

Both ventricles are paced synchronously. This prevents blood from being pumped back into the atrium through the mitral valve.

At the same time, the ventricle filling time and therefore the cardiac output is increased (see illustration).

The diagram shows how multisite ventricular pacing functions in patients with heart failure and cardiomyopathy:



- A. Shortened diastoles result in incomplete left ventricular filling
- B. Delayed left ventricular contraction
- C. Septal diskenesia and pumping blood back through the mitral valve
- D. Atriosequential biventricular pacing with extended diastole and increased left ventricular filling
- E. Synchronized ventricular contraction with increased cardiac output

The following ventricular pacing configurations are available for multisite ventricular pacing:

- BiV (pacing in both ventricles or in two locations within one ventricle)
- LV (pacing only in the left ventricle)
- RV (conventional single-chamber or dual-chamber pacing)

Note: Cardiac resynchronization can be disabled by switching to RV pacing.

The ventricular pacing configuration BiV can be combined with dual-chamber and single-chamber modes with ventricular participation (DDD, VDD, DDI, VDI, VVI) and the ventricular pacing configuration LV can be combined with the atrial-controlled dual-chamber modes (DDD, VDD). The timing of the pacemaker is carried out in accordance with the rules of the configured single-chamber or dual-chamber modes. Only pulse delivery in the ventricles is additionally affected by the ventricular pacing configuration.

Note: The ventricular pacing configuration is to be programmed separately in the permanent program and in mode switching. It is not automatically adopted.

Summary of the Functions and Time Intervals of the Pacing Modes

About this table

The table summarizes the functions and time intervals that apply to the various pacing modes. Not included are rate-adaptive parameters and parameters that can be programmed in all pacing modes.

The sensitivity can always be programmed during pulse inhibition and/or pulse triggering.

Table 1: Functions and timing intervals of the different pacing modes

Parameters	Pacing modes											
	DDD	DDD-CLS	DDD-ADI	DDT	DDI	DVI	VDD	VDI	AAI	AAT	VVI	VVT
Basic rate	x	x	x	x	x	x	x	x	x	x	x	x
Rate hysteresis	x		x	x	x		x	x	x	x	x	x
Repetitive rate hysteresis	x		x	x	x		x	x	x	x	x	x
Rate scan hysteresis	x		x	x	x		x	x	x	x	x	x
Upper tracking rate (UTR)	x	x	x	x			x	x				x
Pulse width/amplitude A	x	x	x	x	x	x			x	x		
Pulse width/amplitude	x	x	x	x	x	x	x	x			x	x
As inhibits Ap	x	x	x		x				x			
As triggers Ap				x						x		
As triggers Vp	x	x	x	x			x					
Vs inhibits Vp	x	x	x		x	x	x	x			x	x
Vs triggers Vp				x								x
Refractory period A	x	x	x	x	x		x	x	x	x		
Refractory period V	x	x	x	x	x	x	x	x			x	x
Dynamic AV delay	x	x	x				x					
AV hysteresis	x	x					x					
AV repetitive hysteresis	x	x					x					
AV scan hysteresis	x	x					x					
AV safety delay	x	x	x		x	x						
Sense compensation	x	x	x	x								
Ventricular blanking period	x	x	x	x	x	x						
Wenckebach possible	x	x	x				x					

Table legend:

- x = present
- A = atrium, atrial
- V = ventricle, ventricular
- A_p = atrial paced event
- A_s = atrial sensed event
- V_p = ventricular pace event
- V_s = ventricular sensed event

Rate-Adaptive Modes

Rate adaptation via CLS

The device achieves physiological rate adaptation with closed loop stimulation. The closed loop modes are functionally identical to the non rate-adaptive modes, but differ in that the basic rate increases if the device senses patient stress or exertion. The closed loop modes are indicated by CLS.

Rate adaptation via accelerometer

Rate-adaptive modes are marked by an R (for rate) in the device code. The rate-adaptive modes function in the same way as the corresponding non-rate-adaptive modes except that the basic rate increases when patient exertion is sensed by the motion sensor.

Note: Take into account that in rate-adaptive modes (DDD-CLS, VVI-CLS, DDDR, DDIR, DVIR, VDDR, VVIR, AAIR), it is possible that the atrial or ventricular refractory period can comprise a major portion of the basic interval at high rates, so that sensing of intrinsic events is limited or completely suspended.

Note: Automatic switching to DDI or DDIR mode is performed when using mode switching.

Pacing when Exposed to Interference

Objective

The pacemaker is equipped with interference protection to protect the patient against undesired inhibition by non-cardiac signals.

Description

An interference interval is started at the same time as the refractory period. The interference interval corresponds to a resettable refractory period of 50 ms. If an event is sensed in one of the two chambers during the interference interval, the interference interval in the corresponding channel is restarted. In case of a coupled rate exceeding 1200 bpm, the interference interval is continually restarted, so that the channel remains refractory throughout the entire basic interval. The pacemaker will then pace asynchronously at the programmed basic rate in that particular chamber as long as the interference (e.g., electrical or electromagnetic interference) persists.

Interference mode

Depending on whether the interference is sensed in the atrium or the ventricle, the pacing modes will change for the duration of the interference as shown below:

Mode	Pacing mode during interference		
	Atrium	Ventricle	Atrium and ventricle
DDD-CLS	DVI-CLS	DAD-CLS	D00(R)
DDI(R)	DVI(R)	DAI(R)	D00(R)
DVI(R)		D00(R)	
VDD(R)	VVI(R)	VAT(R)	V00(R)
VVI-CLS		V00(R)	
VVI(R)		V00(R)	
DDT(R)	DVT(R)	DAT(R)	D00(R)
VDI(R)	VVI(R)	V00(R)	V00(R)
VVT(R)		V00(R)	

Setting the Magnet Response

Navigation: Parameters → Bradycardia/CRT → Basic rate/Night rate → Show magnet response parameters

Objective

Magnet responses are used to check the device's pacing functions.

Description

When the magnet is applied, the reed switch in the device closes.

The device's response to magnet application is programmable with the following settings:

- Asynchronous magnet response
- Synchronous magnet response
- Automatic magnet response

The following functions are deactivated in the asynchronous mode by application of a magnet:

- Capture control
- Vp suppression
- Atrial overdrive pacing
- Rate adaptation via accelerometer
- Rate adaptation via CLS
- Rate fading
- Arrhythmia classification
- Recording of statistics
- AV hystereses
- Night program
- Rate hystereses
- Measuring of thoracic impedance
- IEGM recordings

WARNING
Unphysiological rhythm changes during magnet application! During asynchronous magnet response, unphysiological rhythm changes can occur. • Implement countermeasures if necessary!

Asynchronous magnet response

- Sensing is deactivated.
- Pacing: Asynchronous with rate at 90 bpm
- Upon transmission of changed parameters, the magnet response is set to synchronous for the duration of magnet application (see below).

Synchronous magnet response

The synchronous magnet response is used for follow-up and recording of IEGMs by the patient.

- Sensing is active.
- Pacing: The programmed basic or sensor rate is active.

Automatic magnet response

- During the first 10 cycle after magnet application: Asynchronous pacing (see above).

  The AV delay is reduced to 100 ms if a longer interval has been set.
  This avoids ventricular fusion beats when AV conduction is intact and makes it easier to sense the effectiveness of ventricular pacing.
- Then: Synchronous pacing

5.2 Resynchronization Therapy

What's in this section?

Special Settings

Multiple left ventricular polarity pace

The special complex location of the left ventricular lead results in extracardiac pacing (e.g. phrenic nerve stimulation) more often than right ventricular leads do in practice. Ideally, the LV lead is placed in a lateral or posterolateral coronary sinus vein and thus very close to the left-side phrenic nerve and to its area of stimulation as well. The undesired phrenic nerve stimulation can be eliminated by means of the programmable left ventricular pacing polarities that make another operation unnecessary. Six pacing polarities with a bipolar LV lead and thirteen pacing polarities with a quadripolar LV lead can be programmed.

In addition to the location of LV leads, passive fixation in the vein on the outside cardiac wall is an indication that LV leads often have poorer pacing thresholds than do RV leads. Polarity paces can also be used in this case to avoid surgical intervention.

Note: Use of a bipolar or a quadripolar LV lead is required for the use of all multiple pacing polarities.

Triggering and maximum trigger rate

Triggering in combination with cardiac resynchronization in the triple-chamber devices should ensure synchronous ventricular contraction in cases of nonspecific exertion (e.g., sinus tachycardia) because this makes an essential contribution to cardiac output for patients with congestive heart failure.

A ventricular sensed event would cause inhibition of the stimulus in the ventricle by definition because the rules for the single-chamber and dual-chamber modes also apply to the triple-chamber modes. However, this would counteract cardiac resynchronization because it is based on synchronous pacing in the ventricle. Therefore triggering should cause forced left ventricular pacing after right ventricular sensing. The trigger pulse is processed as defined in the NBG code, but it is limited solely to the left ventricle and only in combination with one of the ventricular pacing configurations BiV or LV.

As a consequence of triggering, left ventricular pacing is delivered immediately following a right ventricular sensed event RVs (+ RPVC).

Triggering can be activated solely for right ventricular sensed events (RVs) or for a combination of right ventricular sensed events and right ventricular sensed extrasystoles (RVs + RPVC). Triggering can also be switched off entirely, in which case the device again functions in conventional DDD mode with a multisite ventricular pacing configuration.

Note: Even though premature ventricular contraction does not have a hemodynamic effect due to its special properties for resynchronization of the ventricle, there are some rare conditions (e.g. Chagas disease) that require triggering of these events. Premature ventricular contractions do not normally have to be triggered.

Note: Triggering has to be set both for the permanent program and for mode switching. The setting from the permanent program is not automatically adopted.

In addition to the general option of switching off triggering, it is also possible to limit triggering for right ventricular sensed events using the maximum trigger rate. This parameter represents an upper limit for triggering, up to which the device triggers left ventricular stimulus based on right ventricular sensed events.

The maximum trigger rate can be set between 90 and 160 bpm. However, due to the greater affinity to the upper tracking rate (UTR), the maximum trigger rate can also be automatically programmed with the upper tracking rate using the setting UTR + 20 bpm.

WARNING

Right ventricle triggering

In patients with intact AV conduction, intrinsic atrial tachycardia can be conducted into the right ventricle at a rate of up to 160 bpm. In such cases, deactivate triggering or reduce the maximum trigger rate.

LV T-wave protection

For protection against pacing in the vulnerable phase of the left ventricle, triple-chamber devices have a function that is controlled by sensed left ventricular events. This is intended to protect the left ventricle against triggered stimuli during the vulnerable period, which could be caused by a left ventricular extrasystole (LPVC). The LPVC is conducted into the right ventricle and used here as RVs to trigger left ventricular stimuli (see Triggering). The left ventricular pulse that is triggered immediately following the sensed RVs could then occur in the vulnerable period of the left ventricle.

The duration of the interval to protect against undesired pacing of the left ventricle is calculated based on the maximum trigger rate. The safety interval is started after each LVs.

Note: Left ventricular sensing is only used for the function described above and for diagnostic purposes. It is insignificant for timing in triple-chamber devices.

Polarity sense

The triple-chamber device offers two configurations for the left ventricular sensing function: unipolar or bipolar. This makes it possible to connect unipolar or bipolar left ventricular leads. In the unipolar configuration, the electrical signal is received between the left ventricular tip electrode and the device housing. The bipolar configuration measures signals between the poles of the lead.

VV delay

During biventricular pacing, either the right (RV) or the left ventricle (LV) can be set as the chamber that is paced first. This can be used to set interventricular conduction times to match the condition optimally. Interventricular conduction times between 0 and 100 ms are available only after ventricular pacing (LVp or RVp).

In the case of a right ventricular sensed event, conduction is either carried out immediately or upon reaching the maximum trigger rate or deactivated triggering is inhibited. If LV T-wave protection is activated, a left ventricular sensed event would start the interval to protect the left ventricle and possibly prevent pacing in the left ventricle or, if LV T-wave protection is deactivated, there would be no effect.

HF(-T) / QP devices: Setting the Lead Polarity for the Left Ventricle

Navigation: Parameters → Bradycardia/CRT → LV

Objective

The goal of left ventricular pacing is to do the following:

- Optimize hemodynamics
- Suppress phrenic nerve stimulation
- Reduce excessive left ventricular pacing thresholds
- The variety of possible settings allows you to set optimal values without having to reposition any leads.

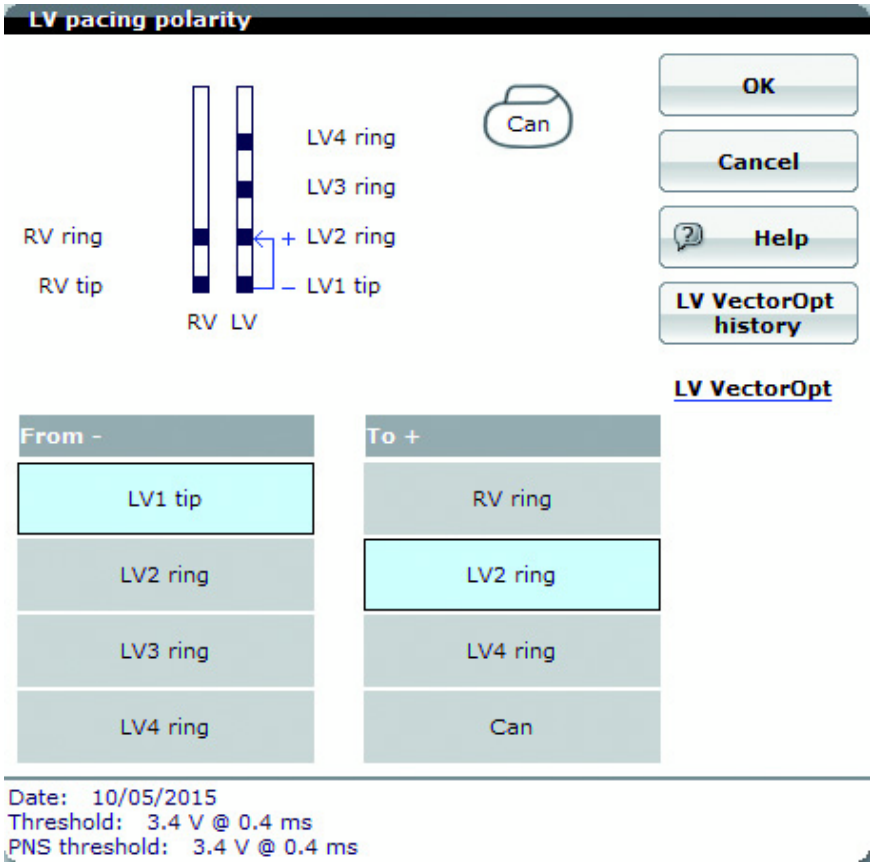
Lead polarity configurations

The following configurations for pacing and sensing are possible:

Lead polarity	Number of configurations in LV	
	Pacing	Sensing
Bipolar	6	2
Quadripolar (only HF-T QP devices)	13	2

User interface

Example of the user interface for configuring the pacing of a quadripolar left ventricular lead:



Phrenic nerve stimulation

Note:

- Resynchronization therapy can be effective only with continuous biventricular pacing. Patients cannot tolerate phrenic nerve stimulation.
- Phrenic nerve stimulation can be prevented by programming the lead configuration.

Concept: from minus to plus

Proceed as follows:

If ...	Then ...
you want to set a pacing polarity,	use the `From –` / `To +` schema. The **[From -]** column shows the possible cathode poles, while the **[To +]** shows the possible anode poles.

Setting the lead polarity for the left ventricle

Proceed as follows to set the left ventricular lead polarity:

Step	Action	Remark
1	Select **Parameters → Bradycardia/ CRT**.	The `Parameters (permanent)` window opens.
2	Select the desired polarity for pacing for the left ventricle in the `LV pacing polarity` field.	Take into consideration the type of the implanted left ventricular lead (unipolar or bipolar).
3	Select one of the pacing polarity configurations.	The selection must be confirmed once with a release to select the bipolar lead configuration. The selected value is accepted as the parameter and displayed.

Call and display LV pacing history

You can make the software display LV configuration and the measured values for the left ventricular pacing as a history.

Proceed as follows:

- Select the **[LV VectorOpt history]** option.

  The window for setting the polarity is opened.

The archive shows the following:

- Polarity of the LV pacings
- Pacing threshold with details on pulse amplitude and width
- Pacing threshold of the PNS pacing with details on the pulse amplitude and width
- Lead impedance
- Date of measurement

Setting Ventricular Pacing

Navigation: Parameters → Bradycardia/CRT

Objective

Configure ventricular pacing for cardiac resynchronization therapy (CRT), etc.:

- Right ventricular
- Biventricular
- Exclusively left ventricular

Biventricular pacing

In the case of biventricular pacing, you can pace either the right or the left ventricle first.

With the help of the interventricular conduction time (VV delay) you can set biventricular pacing optimally to the specific medical condition of the patient.

You can set the following parameters by using the following functions in accordance with medical indication and individual needs of the patient:

Parameter	Function
`Triggering`	Ensures that ventricular contractions are synchronous: • Under stress, e.g. in cases of sinus tachycardia • In cases of premature ventricular contraction
`LV T-wave protection`	During the protection interval of the vulnerable phase for the left ventricle, no stimulus is delivered to that ventricle.
`Maximum trigger rate`	• Maximum rate to be used for resynchronization. • The setting `UTR + 20` derives the maximum trigger rate from the upper rate. • The safety interval for the left ventricle is calculated from the maximum trigger rate (LV T-wave protection) to avoid pacing in the vulnerable period.
`Initially paced chamber`	The chamber to be stimulated first controls the primary pulse. VV delays can be set after Vp depending on RV and LV.
VV delay	Interventricular latency period: • `VV delay after Vp` can be programmed. • `VV delay after Vs` is fixed at 0 ms and cannot be changed.

WARNING

Ineffective pacing when only left ventricular pacing occurs

If only left ventricular pacing is set and lead dislodgement occurs, the following risks arise:

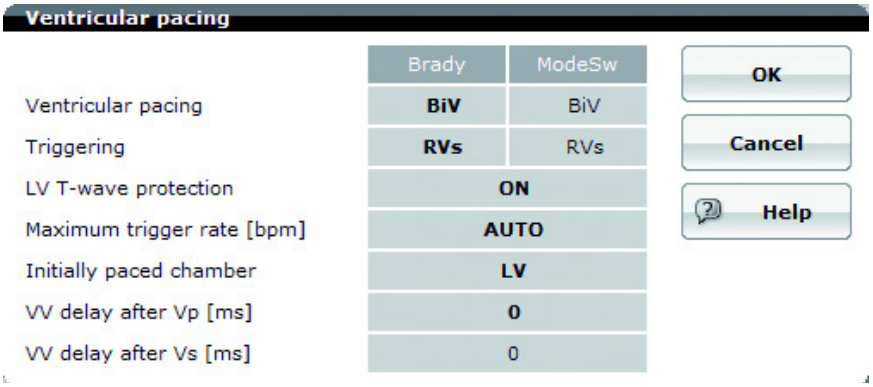
- Loss in effectiveness of ventricular pacing

Reduce the risk:

- Consider the pacing parameters carefully.
- The exclusive use of left ventricular pacing is not recommended for pacemaker-dependent patients.

WARNING
Triggering the ventricle: Conduction of atrial tachycardias For patients with intact AV conduction, intrinsic atrial tachycardias can be conducted to the ventricle to a maximum of 160 bpm. • In such cases, deactivate triggering or reduce the maximum trigger rate.

User interface



5.3 Pacing Parameters

What's in this section?

Setting Pulse Amplitude and Pulse Width

Navigation: Parameters → Bradycardia/CRT

Objective

Optimized pulse amplitude and pulse width values ensure effective and reliable pacing. The lower the parameter values (fine tuning without safety margin for the pulse amplitudes), the longer the service time of the device.

Safe and regular pulse amplitudes and widths

The pulse amplitude and pulse width values are continuously maintained during the entire service time of the device. This applies to pulse amplitude values up to 7.5 V. Thus the safety margin is maintained even when the battery voltage decreases at the end of the device's service time.

Setting pulse amplitude and pulse width

The pulse amplitude and the pulse width can be independently programmed for all channels.

Evaluate the default parameter values and adjust them if necessary.

Basic Rate during the Day and at Night

Basic rate during the day

A sensed or paced event starts the basic interval. If a sensed event does not occur during the basic interval, the device emits a pulse at the end of the basic interval. A sensed event inside the basic interval and outside the set refractory period inhibits pacing and restarts the basic interval. Asynchronous modes such as V00 and D00 are excluded.

In the atrial-controlled modes, the basic interval is started by an atrial event. In the atrial-controlled dual-chamber modes, the basic interval is also started by a premature ventricular contraction.

In the ventricular-controlled modes, the basic interval is started by a ventricular event.

Night rate

If the night rate parameter is activated, the device paces at the set night rate during the night. This makes it possible to adapt the pacing rate to the patient's reduced metabolic needs during this time.

Furthermore, VVI and V00 pacing may prevent the possible worsening of hemodynamics.

The night rate as well as the beginning and end of the night can be set.

At the beginning of the night period, the basic rate and the hysteresis rate are reduced to the night values.

If rate adaptation is enabled, the sensor threshold during the night is increased by one increment (less sensitive). This prevents undesirable rate increases – even in patients who do not sleep soundly.

After the night has ended, the device resumes the basic rate.

Note: Please take into consideration that the patient may travel to other time zones. If this is expected, the night duration should be programmed accordingly shorter or even deactivated.

Note: The internal clock of the pacemaker is automatically adjusted to the clock of the programmer at every interrogation. Ensure that the time displayed on the programmer is correct.

Setting the Basic Rate for Day and Night

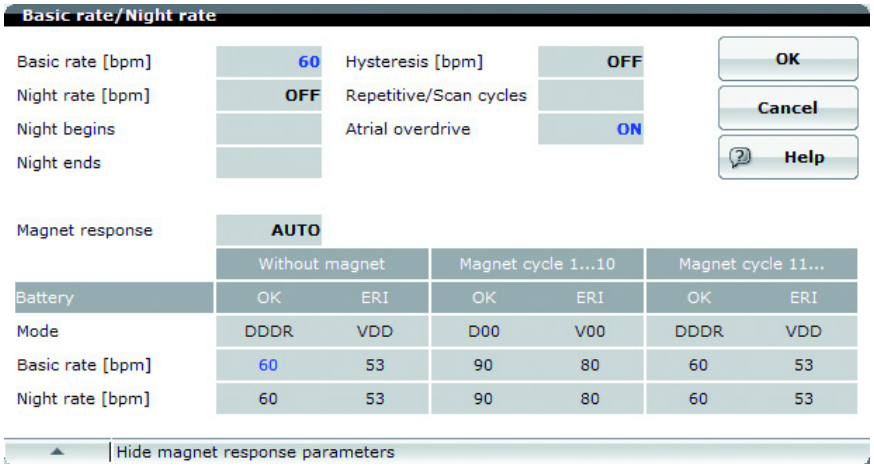
Navigation: Parameters → Bradycardia/CRT → Basic rate/Night rate

Objective The basic rate serves as the device's pacing rate, which can be adapted to meet the patient's individual needs.

Description The basic rate is the lower rate limit, at which the device paces the heart if the intrinsic rhythm is irregular or no longer present.

In addition to the basic rate during the day, a night rate can be set to account for a patient's lower metabolic needs at night. The beginning and end of the night rate can be set separately.

User interface



Rate hystereses Setting Rate Hystereses, p. 60

Atrial overdrive pacing Atrial Overdrive Pacing, p. 130

Magnet response Setting the Magnet Response, p. 41

5.4 Timing Functions

What's in this section?

5.4.1 Programs and Parameters

What's in this section?

Setting and Transmitting Parameters

Objective Use the parameters to adjust the device to individual patient requirements.

Sequence

- Setting parameters
- Transmitting parameters to the device

Prerequisites The device must be interrogated first.

If interrogation is successful, the device data is transmitted to the programmer and displayed.

Setting parameters Proceed as follows:

Step	Action	Result
1	Select **[Parameters]**.	The window opens and shows the status in the status bar: `Parameters (permanent)`.
2	Set the parameters.	The values are displayed in the window. The status bar shows the status: `Parameters (edited)`.

Transmitting parameters Select **[Program]** to transmit the changed parameters to the device.

Note: After transmission, the changed parameters are immediately effective as a new permanent program of the device.

Note: For more information on configuring the program functions, see the technical manual: `Handling Basics (online help on the programmer)` or `Programmer SW PSW` (PDF file in the Manual Library).

ProgramConsult - Selecting Programs by Indication

Navigation: Parameters → Bradycardia/CRT → Program sets

Objective

The ProgramConsult function provides a number of programs with default parameters for the most common pacemaker indications.

By selecting a program suggestion for a specific indication, a number of default parameters are loaded which have shown to be effective for these indications.

- These parameters are displayed in blue in the program's tabs and windows.
- They are shown unchanged in black if the already set parameters have the same values as the programmed suggestions.

The parameters can be adjusted to the individual needs of the patient and transmitted directly to the device as a new permanent program.

Using ProgramConsult

Proceed as follows:

Step	Action
1	Select **Parameters → Program sets → ProgramConsult**.
2	Select a program with the applicable indication.
3	Adjust the parameters to the patient's needs.
4	Transmit the program to the implanted device by pressing **[Program]**.

Creating and Using Individual Therapy Programs

Overview It is possible to create up to three individually configured therapy programs. To do this, the therapy parameters can be set as needed and stored under a name of your choice.

Purpose This function serves to provide frequently required parameter configurations at the push of a button.

Creating a therapy program Perform the following steps:

Step	Action
1	Select **[Parameters]**.
2	Set the parameters for the planned therapy in the `Bradycardia` tab.
3	Select **[Program sets]**.
4	Select **[Store]** for `Individual1`, `Individual2` or `Individual3` (free memory).
5	Name the program using the virtual keyboard and complete your entry by pressing Enter.
6	The individually created therapy program is available for all patients with applicable indications.

Using a therapy program Perform the following steps:

Step	Action
1	Interrogate the device.
2	Select **[Parameters]**.
3	Select **[Program sets]**.
4	Select your individually stored program by pressing the stored name. The preset parameters are loaded.
5	Select **[Program]** to transmit the program to the device.
6	The preset parameters are activated.

Note: Pay attention to the individual conflict rules of the preset parameters. In cases of conflict, adjust individual parameters.

5.4.2 Functions of Rate Hysteresis

What's in this section?

Rate Hysteresis

Definition

The rate hysteresis is specified as the difference from the basic rate. In rate-adaptive pacing, the hysteresis remains constant while the hysteresis rate follows the variable (sensor-controlled) basic rate.

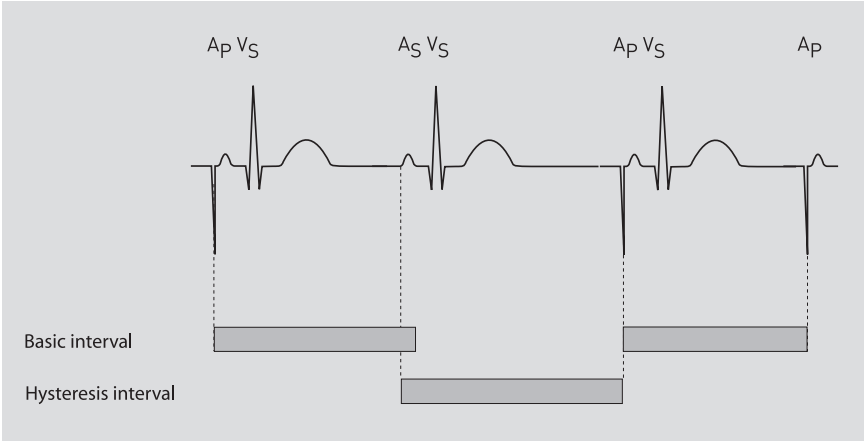
Description

To preserve a spontaneous rhythm once it occurs, a rate hysteresis can be programmed in the modes DDD(R), DDT(R), DDI(R), VDD(R), VDI(R), VVI(R), VVT(R), AAI(R) and AAT(R).

In this case, after a sensed event, the pacemaker not only waits for the duration of the basic interval for a new sensed event, but for the duration of the longer hysteresis interval before pacing occurs.

This means that the pacemaker tolerates a spontaneous rhythm whose rate lies below the basic rate. However, the intrinsic rhythm must be higher than the rate that corresponds to the hysteresis interval.

If a sensed event does not occur within the hysteresis interval, a pacing pulse is delivered at the end of the hysteresis interval. The next interval then corresponds to that of the basic rate or the interval determined by the sensor.



Starting events

- In the pacing modes DDD(R), DDT(R), VDD(R), AAT(R) and AAI(R), the hysteresis interval starts with an atrial sensed event.
- In the pacing modes DDI(R), VVI(R), VVT(R), and VDI(R), it starts with a ventricular sensed event.
- In the pacing modes DDD(R), DDT(R) and VDD(R), it also starts with a premature ventricular contraction.

Note: If rate hysteresis is to be used in the DDI mode, the AV delay must be programmed shorter than the intrinsic conduction time. Otherwise, the pacemaker paces at the hysteresis rate instead of the basic rate even in the absence of spontaneous activity.

Repetitive Rate Hysteresis

Objective

The repetitive rate hysteresis helps to maintain the intrinsic rhythm and avoid unnecessary pacing in situations that exceed the basic hysteresis, such as post-extrasystolic pauses.

The repetitive rate hysteresis can only be used in conjunction with the rate scan hysteresis.

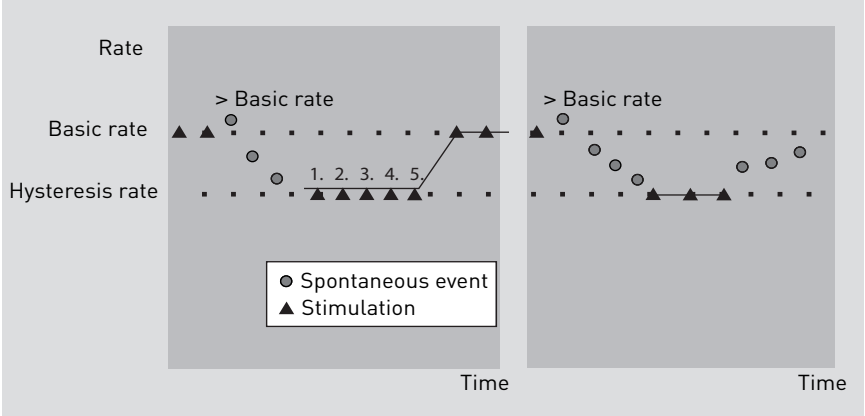
Description

If such a pause occurs, the pacemaker continues to pace at the hysteresis rate for a fixed number of five cycles instead of immediately reverting to the basic rate.

An existing intrinsic rhythm is thus once again able to inhibit the pacemaker. This prevents any worsening of the hemodynamics, as might otherwise occur in modes such as VVI pacing.

With DDD or DDDR pacing the intrinsic atrial rhythm is supported and stabilized. This prevents the undesirable suppression of the intrinsic rhythm through overdrive pacing, especially during resting periods.

Repetitive rate hysteresis is only activated in the presence of an intrinsic rhythm, when at least one single inhibition by the intrinsic rhythm has occurred.

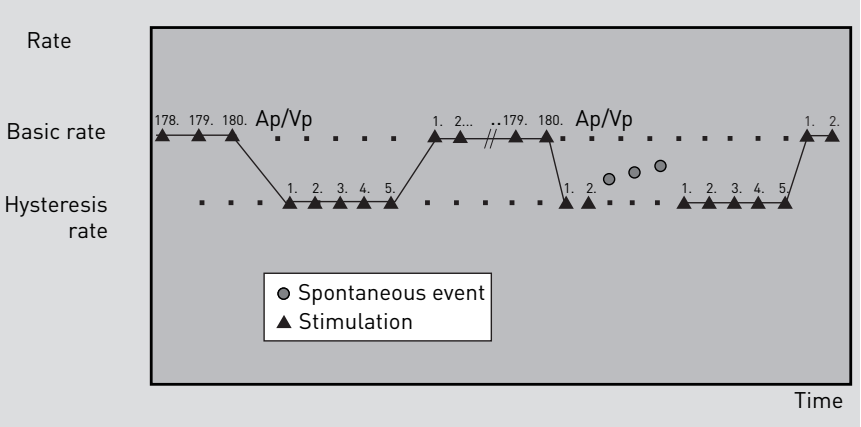


Rate Scan Hysteresis

Definition The rate scan hysteresis scans an intrinsic rhythm during longer phases of pacing.

Description If the scan hysteresis is activated, the pacemaker will temporarily reduce the pacing rate to the hysteresis rate after every 180 consecutive paced events.

If no intrinsic event is sensed during these five scan intervals, pacing at the basic rate is then resumed (at the sensor rate in rate-adaptive mode). Scanning for an intrinsic rhythm is repeated after an additional 180 uninterrupted pacing cycles.



Reaction to vasovagal syncope and carotid sinus syndrome The rate scan hysteresis can be used only in conjunction with the repetitive rate hysteresis to treat patients with vasovagal syncope and carotid sinus syndrome of a primarily cardioinhibitory type.

The following programming is recommended for this purpose:

Parameter	Recommended programming
Basic rate	Increased value (e.g., 70 bpm)
Rate hysteresis	Always program the hysteresis rate at rest so that it is lower than the intrinsic rhythm (e.g., -15 bpm).
Repetitive / scan cycles	ON

This program will inhibit the pacemaker until bradycardia episodes occur. If the rate drops due to an attack, the pacemaker will pace at the hysteresis rate for the set number of five fixed repetition cycles (the confirmation period).

The pacemaker will switch to the higher basic rate to prevent possible syncope only if an intrinsic rhythm does not occur during the confirmation period.

The pacemaker will scan for an intrinsic rhythm every 180 cycles (rate scan hysteresis) to avoid long pacing phases. If the attack has been terminated by that time, the pacemaker will be inhibited; otherwise, it will repeat the scan after 180 cycles with continuous pacing.

Note: Patients with carotid sinus syndrome and a tendency to syncopes should only be treated with a DDD(R) device to exploit the contribution of the atrium to ventricular filling and to overall hemodynamics as much as possible during such attacks.

Setting Rate Hystereses

Objective

The device has a hysteresis function intended to maintain and support the patient's intrinsic heart rhythm for as long as possible. In addition to the conventional hysteresis function, additional hysteresis functions (repetitive/scan cycles) can be activated.

Selecting parameters

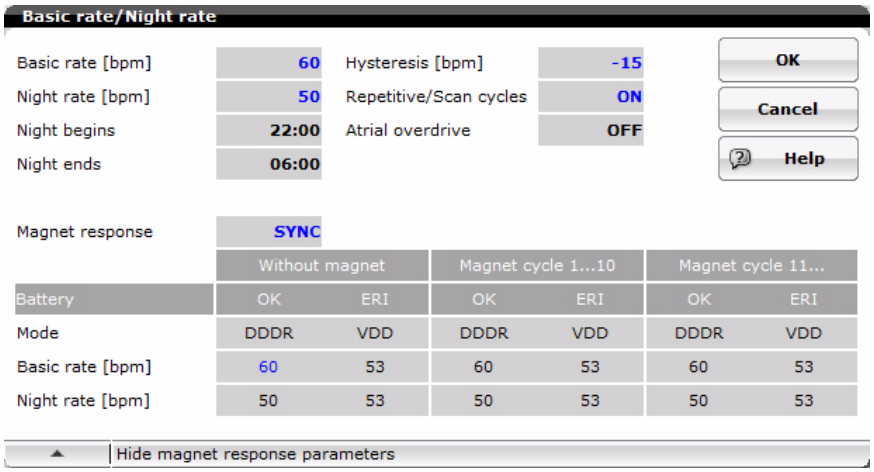
- Select **Parameters → Bradycardia/CRT** to choose the parameters.

Setting rate hystereses

Proceed as follows:

Step	Action
1	Select `Basic rate/Night rate`. The window contains the following parameters among others: • `Hysteresis` • `Repetitive/Scan cycles`
2	Select `Hysteresis` and set the required hysteresis rate. You can select the additional hysteresis only after activating the hysteresis function.
3	`Repetitive/Scan cycles` Select ON to activate this hysteresis function. The number of repetitive / scan cycles is fixed. Confirm the settings with **[OK]** to accept the values.

Parameters: `Hysteresis`



5.4.3 Functions of the Dynamic AV Delay

What's in this section?

Dynamic AV Delay

Description

The AV delay defines the period of time between an atrial event and the subsequent ventricular stimulus. The dynamic AV delay allows independent selection of AV delays in five atrial rate ranges. The AV delay selected for this rate is then effective depending on the current atrial rate. The dynamic AV delay is started after atrial sensing and after sensor-driven atrial pacing. In the following rate ranges, the AV delay can be selected as required. Basic rate:

- 40 – 60 bpm
- 61 – 80 bpm
- 81 – 100 bpm
- 101 – 120 bpm
- 121 – 140 bpm

In the non-rate-adaptive pacing modes, an AV delay may be separately selected for AV sequential pacing at the basic rate. The AV delays in the four other atrial rate ranges are only active after atrial sensing.

In addition to the option of setting the AV delay individually for these ranges, the programmer also offers four pre-set options (low, medium, high and fixed). Refer to the table below for details.

The optimization feature can be deactivated and fixed AV delays can be selected. In non-rate-adaptive modes, the AV delay after atrial paced events is different from the AV delay after atrial sensed events.

Preset dynamic AV delays

Preset dynamic AV delays in the DDDR mode (standard program)

Frequency range	AV delay (in ms) for programming the dynamic AV delay to		
	Low	Medium	High
At 60 bpm	150	150	150
At 80 bpm	140	130	120
At 100 bpm	130	120	100
At 120 bpm	120	100	75
At 140 bpm	120	75	50
Fixed for all rate ranges	150		

Preset dynamic AV delays in the DDD-CLS mode (standard program)

Frequency range	AV delay (in ms) for programming the dynamic AV delay to		
	Low	Medium	High
At 60 bpm	150	150	150
At 80 bpm	140	130	120
At 100 bpm	130	120	100
At 120 bpm	120	100	75
At 140 bpm	120	75	50
Fixed for all rate ranges	150		

Between the values 61 - 80 bpm is interpolated.

The values for the dynamic AV delay in the DDD-CLS mode are set to these values to prevent competitive stimulation.

Setting AV Delay

Navigation: Parameters → Bradycardia/CRT

Objective

Dynamic AV delay simulates natural AV conduction in various stress situations.

Description

The AV delay is the interval between an atrial event and the subsequent ventricular pace. If AV delay is programmed dynamically, it adjusts itself automatically using a rising pacing rate.

AV hystereses

A positive hysteresis will extend the AV delay and a negative one will shorten it.

For more information see: Setting AV Hystereses, p. 67

Sense compensation

Sense compensation shortens the AV delay after an atrial sensed event to improve the stability of the patient's hemodynamics and in accordance with that patient's specific physiological conditions.

Optimize AV delay

The AV delay can be optimized with the following functions:

- IRSplus:
  - Intrinsic Rhythm Support can support the heart's intrinsic rhythm. The objective is to maintain spontaneous AV conduction of the heart as long as possible.
    For more information see: IRSplus - Promoting Intrinsic AV Conduction, p. 77
- AV Optimization by Testing:
  - Optimized AV delays are determined on the basis of P-wave measurements. The test results are displayed and can be adopted for pacing and sensing.
    For more information see: AV Optimization by Testing, p. 190

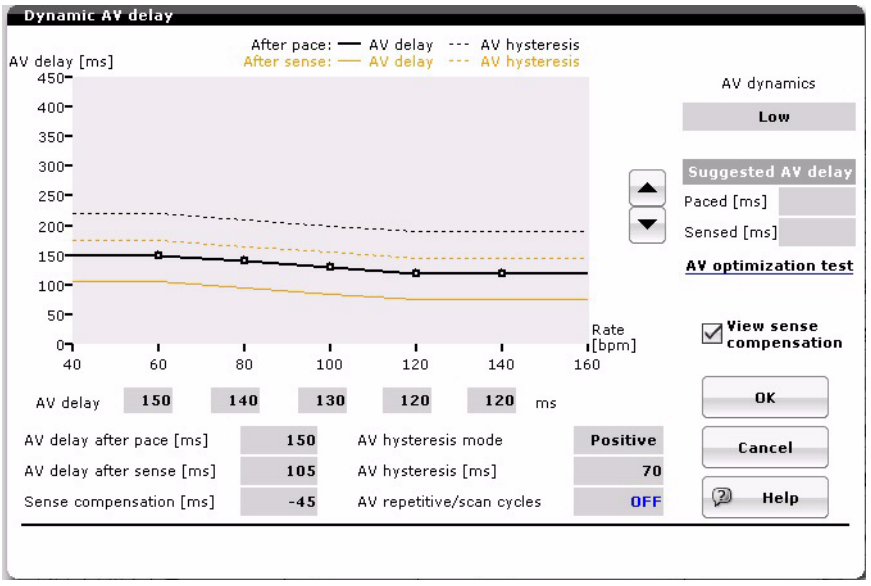
Procedure

Proceed as follows:

Step	Action
1	Select `Dynamic AV delay`.
2	Select one of the default settings in the `AV dynamics` field. The dynamics of the AV delay are interpolated in the selected rate range.
3	Where appropriate modify the settings by selecting a numerical value, by changing settings with the arrow keys or in the diagram by moving the upper and lower rate points using the stylus. The setting is now considered individual.
4	To show sense compensation in the diagram, if applicable, activate the **[View sense compensation]** check box.
5	Select **[OK]** to accept the values.

User interface

`Dynamic AV delay`



AV Safety Delay

Protection against pulse inhibition

If an atrial pace triggers ventricular oversensing through crosstalk, undesired pulse inhibition in the ventricle can result. Sensing of the atrial pulse delivery in the ventricular channel during the AV delay can be incorrectly interpreted as intrinsic ventricle excitation.

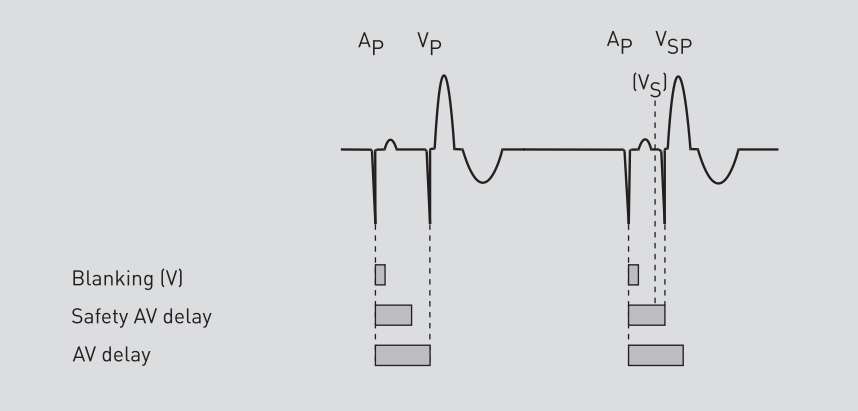
Description

In the DDD(R), DDI(R), and DVI(R) pacing modes, the AV safety delay is started with atrial pacing. If a ventricular sensed event occurs within the AV safety interval, the pacemaker paces in the ventricle at the end of the interval (Vsp = ventricular safety pace). If the AV delay is shorter than the AV safety delay, pacing occurs at the end of the AV delay.

This prevents ventricular pulse inhibition through ventricular sensed events of atrial pacing (crosstalk).

If AV sequential pacing is observed with an AV delay corresponding to the AV safety delay, this may be evidence of ventricular crosstalk (sensing of atrial pulse delivery).

In order to avoid crosstalk, you can define a lower atrial pulse energy, a lower ventricular sensitivity (higher numerical value) and/or a longer ventricular blanking period.



The AV safety delay is not programmable and lasts 100 ms.

Sense Compensation

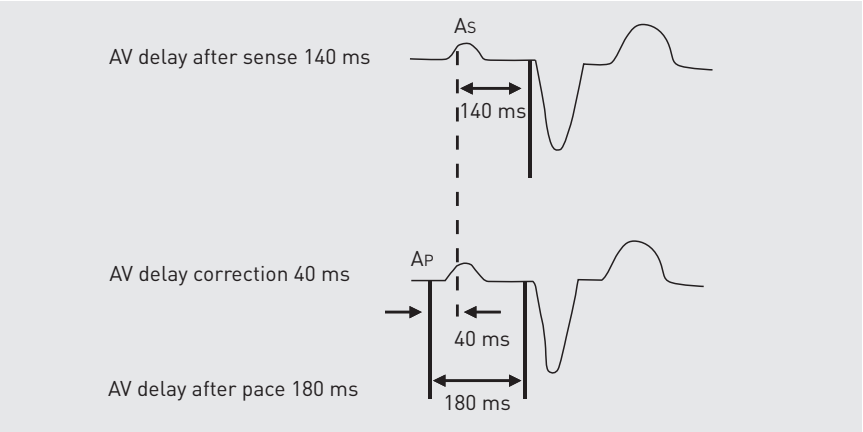
Objective

For hemodynamic reasons, it is desirable to maintain a constant period between an atrial and a ventricular contraction and to adjust it to physiologic conditions. For this purpose, sense compensation can be used to shorten the AV delay after an atrial sensed event.

Description

You can program values of -10 to -120 ms for the sense compensation. In this case, the AV delay after an atrial sensed event is shorter by the programmed value than the delay after an atrial paced event. The AV delay after an atrial paced event then corresponds to the programmed AV delay.

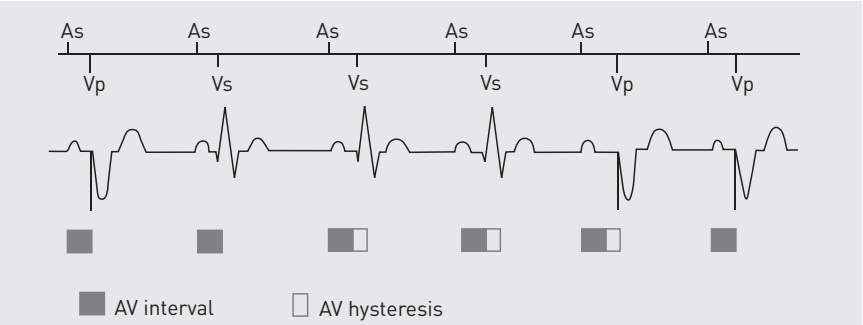
Sense compensation



AV Hysteresis

Objective

AV hysteresis can be programmed to a low, medium, or high setting to promote intrinsic AV conduction.



Description

When AV hysteresis is activated, the AV delay is extended by the defined range of values after sensing an intrinsic ventricular event. The extended AV delay remains intact as long as an intrinsic ventricular rhythm is sensed. The short AV delay interval without extension by the hysteresis value then takes effect after repeated ventricular pacing.

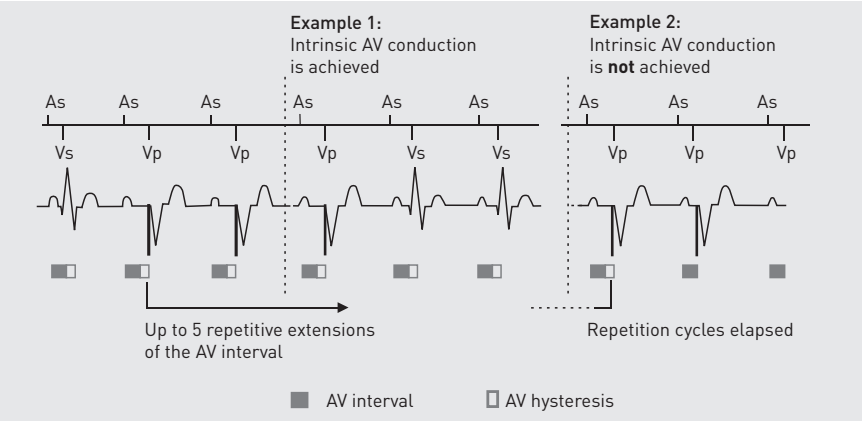
CAUTION
If AV hysteresis is enabled along with the algorithm for detecting and terminating pacemaker-mediated tachycardias (PMT management), the variance in the AV delay for detection and termination of a PMT have priority over any possible simultaneous activation of the AV hysteresis.

AV Repetitive Hysteresis

Objective The AV repetitive hysteresis reduces pacing when existing intrinsic activity within the extended AV delay is suppressed by occasional paced events.

Description Even when AV repetitive hysteresis is activated, the AV delay is extended by the defined hysteresis value after sensing an intrinsic ventricular event.

In contrast to normal AV hysteresis, once the ventricular paced event occurs, the extended AV delay remains intact for a set number of cycles. If an intrinsic rhythm occurs during one of these repetitive cycles, the long AV delay remains intact. Only when the repetitive cycles have elapsed without spontaneous AV conduction does the pacemaker switch back to the short AV delay.



AV Scan Hysteresis

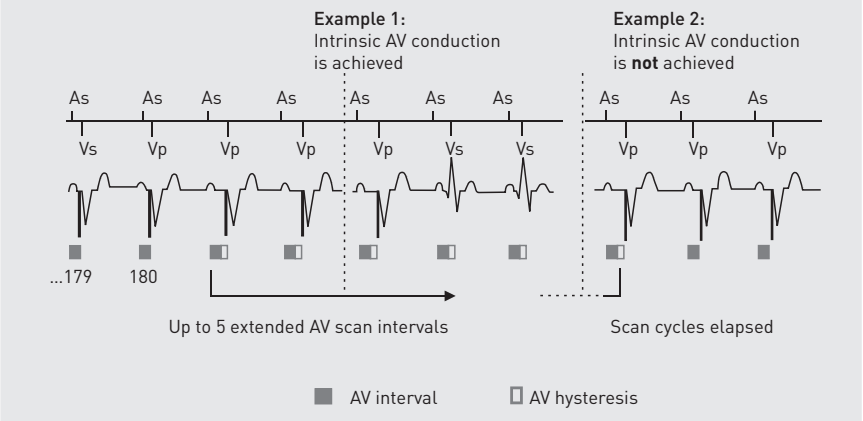
Objective The AV scan hysteresis reduces pacing in situations in which intrinsic conduction exists but does not take place within the defined AV delay.

Description With AV scan hysteresis, the AV delay is switched to the interval extended by the AV hysteresis after 180 consecutive cycles in which a paced event has occurred without any intrinsic ventricular activity. The long AV delay remains intact for a defined number of cycles.

If an intrinsic AV conduction occurs within the defined number of cycles, the AV hysteresis remains intact.

The short AV delay is resumed only when no ventricular event has been sensed within the defined number of cycles and instead every one of these cycles ends with a pacing. The cycle counter begins counting the consecutive paced cycles again.

Ventricular sensed events (excluding PVC) reset the counter to zero and activate AV hysteresis.



Negative AV Hysteresis

Objective

In individual cases, it may be necessary to support ventricular pacing and allow the least possible conduction of the atrial intrinsic rhythm. This may be necessary particularly for patients with hypertrophic obstructive cardiomyopathy (HOCM).

Description

With a ventricular sensed event (Vs), the function decreases the AV delay and thereby promotes ventricular pacing. As opposed to this, in conventional positive AV hysteresis, the AV delay is extended to support intrinsic rhythms.

Negative AV hysteresis is optional. It is possible to program the negative AV hysteresis function in combination with the negative AV repetitive hysteresis. This ensures that pacing is carried out upon occurrence of a sensed event for a programmable number of cycles with shorter AV delay.

Setting AV Hystereses

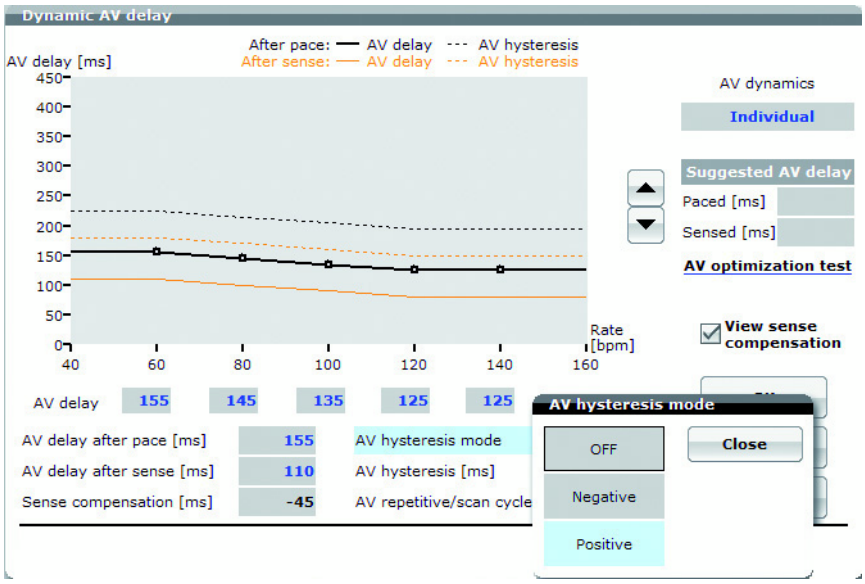
Navigation: Parameters → Bradycardia/CRT

Objective

- A positive AV hysteresis aims to contain a patient's spontaneous AV conduction for as long as possible, thus ensuring that the contraction sequence is natural. All unnecessary pacing of the ventricle should be avoided.
- A negative AV hysteresis aims to encourage ventricular pacing and allow as little as possible conduction of the intrinsic atrial rhythm, for example, in cases of hypertrophic obstructive cardiomyopathy (HOCM) or in support of resynchronization therapy.

User interface

AV hystereses



AV repetitive hysteresis

When AV repetitive hysteresis is activated, the AV delay is extended/shortened by the defined hysteresis value after sensing an intrinsic ventricular event.

- If a ventricular paced event occurs, the modified interval for AV delay remains unchanged, in contrast to the case of a normal AV hysteresis.

Positive

- If an intrinsic activity occurs during one of these repetitive cycles, the long AV delay remains intact. Only when the repetitive cycles have elapsed without spontaneous AV conduction does the pacemaker switch back to the short AV delay.
- The AV repetitive hysteresis reduces ventricular pacing, when an intrinsic ventricular event occurs within the extended AV delay.
- The AV repetitive hysteresis maintains the extended AV delay for 5 successive cycles.

Negative

- The repetitive cycles occur with the shortened AV delay. When the preset 180 cycles are completed, the programmed AV delay is restored (extended). An intrinsic ventricular event shortens the AV delay again.

AV scan hysteresis

In case of an AV scan hysteresis, after 180 successive cycles in which one paced event and no ventricular sensed event has taken place, the AV delay switches to the interval extended by the AV hysteresis.

- The long AV delay remains intact for a preset number of (5) cycles. If an intrinsic AV conduction occurs within these cycles, the AV hysteresis remains intact.
- The short AV delay interval resumes only when no ventricular event has been sensed within the number of cycles and instead every one of these cycles ends with a paced event. The counter starts to count successive paced cycles over again from zero. Intrinsic ventricular events (excluding PVC) reset the counter to 0.
- Hence, AV scan hysteresis reduces pacing in situations in which intrinsic conduction exists but does not fall within the programmed AV delay.

The Concept of Ventricular Pacing Suppression

Why should right ventricular pacing be avoided?

Right ventricular pacing evokes an asymmetrical contraction of the ventricle due to the unphysiological activation of the cardiac conduction system.

Various randomized studies performed with pacemaker and ICD patients have shown that frequent ventricular pacing is connected with an increased risk of congestive heart failure and atrial fibrillation as long-term effects.

Therefore, pacing should only be performed if it is clinically necessary.

Based on this new knowledge, it is widely accepted that pacemaker therapy should avoid unnecessary right ventricular pacing.

This particularly applies to patients with sick sinus syndrome (SSS) and/or intermittent AV block.

Which pacemaker type is suitable for which underlying disease?

AAI pacemakers are sufficient for patients with intact AV conduction.

However, dual-chamber pacemakers are still indicated in most cases for safety reasons if the patient develops an AV block, bradycardia-induced atrial fibrillation or drug-induced bradycardia.

According to the German heart registry, this happens in 83% of the cases. The device should be able to be programmed in such a way that unnecessary right ventricular pacing can be avoided.

Dual-chamber pacemakers are always indicated for patients with AV block. For patients with intermittent AV block, right ventricular pacing should cease in phases of intrinsic AV conduction.

In cases of intermittent or permanent first-degree AV block, a decision has to be made between delayed atrioventricular conduction and pacing with a short AV delay, which is hemodynamically more effective.

Vp suppression: option for avoiding right ventricular pacing

- In phases of intact AV conduction, pacing is performed in a mode similar to AAI.
- In phases when there is no AV conduction, the mode is switched back to DDD pacing and the right ventricle is paced.

The Vp suppression function enables the device to toggle between these two modes according to the patient's needs.

Functioning of Ventricular Pacing Suppression

Overview

The following topics are described within this segment:

- Activation of Vp suppression
- Mode of functioning
- Switching from DDD(R) to ADI(R)
- Switching criterion and Vs continuity search
- Vs continuity search triggered by a single Vs
- Vs continuity search triggered by a timing interval
- Intelligent search
- ADI(R) mode
- Switching from ADI(R) to DDD(R)
- Switching criterion: 2 s without Vs
- Switching criterion: 2 consecutive cycles without Vs
- Switching criterion: programmable number X-out-of-8 cycles without Vs
- Summary
- Vp suppression and mode switching
- Statistics recordings of Vp suppression
- Vp suppression and high rates
- Vp suppression interactions with other functions and actions

Activation of Vp suppression

The Vp suppression function is activated if the mode DDD-ADI or DDDR-ADIR is selected.

Mode of functioning

Vp suppression supports intrinsic AV conduction by only pacing in the ventricle if intrinsic AV conduction becomes unstable or stops.

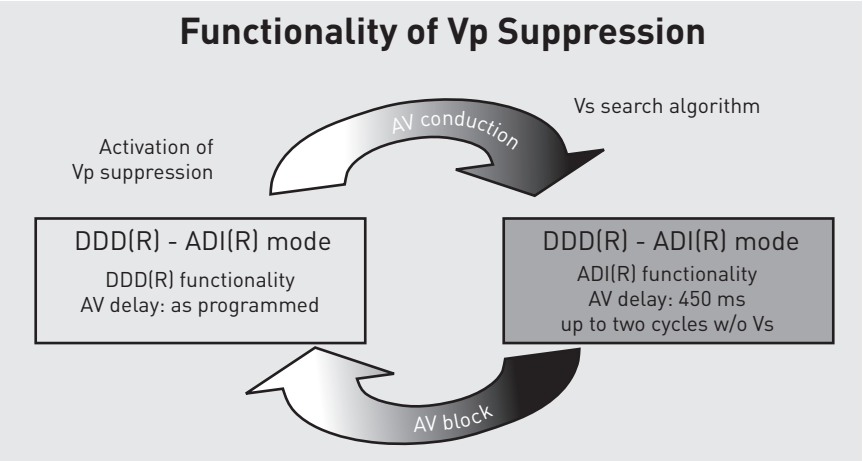
If there is intrinsic AV conduction, the function works in a mode similar to ADI(R).

If intrinsic AV conduction stops or becomes unstable, the function paces in DDD(R) mode with the programmed AV delay in the ventricle.

Automatic mode switching between these two modes provides for maximum intrinsic optimization without doing damage to the patient.

Scan algorithms with a programmed schedule test intrinsic AV conduction and the AV delay is extended to 450 ms.

The ADI(R) mode - according to the NBG pacemaker code - describes precisely what the device does in this state. Thus, as opposed to the AAI(R) mode, sensing is also possible in the ventricle in order to switch to the DDD(R) mode and pace in the ventricle in the case of ventricle pauses or unstable rhythms.



Switching from DDD(R) to ADI(R)

If Vp suppression is activated by switching on the DDD(R)-ADI(R) mode, the function initially works in DDD(R) mode, so that a ventricular pace is triggered at the end of the AV delay.

In DDD(R) mode, the device systematically scans to determine whether there is an intrinsic ventricular rhythm.

If no activity is sensed for 30 s within the AV delay, the function starts a continuous scan algorithm called the Vs continuity search.

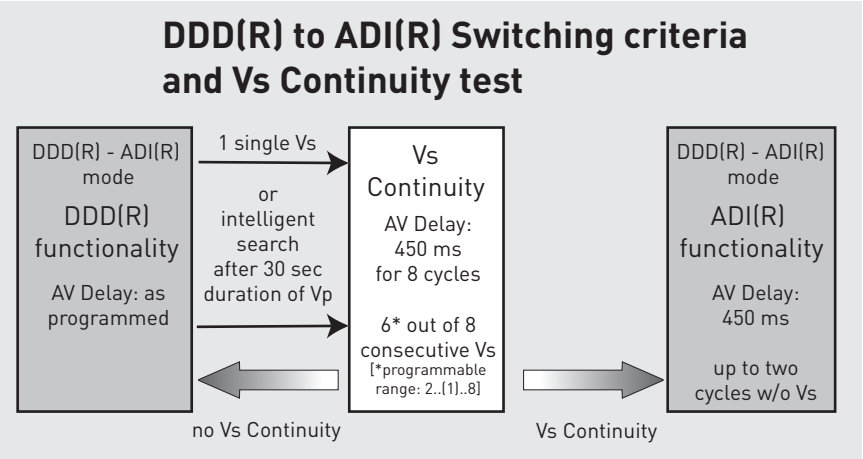
The search for an intrinsic ventricular rhythm can be triggered by 2 different events:

- Sensing of a single Vs event within the AV delay (even PVC)
- No ventricular sensed events within a certain time (intelligent search, at least 30 s)

Switching criterion and Vs continuity search

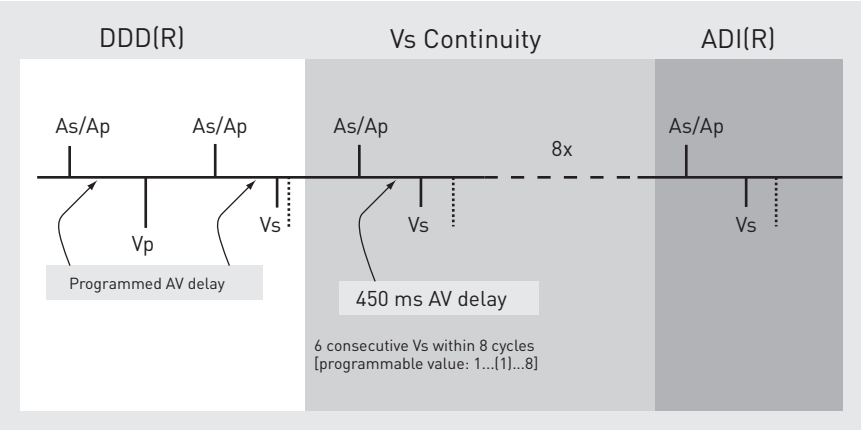
In order to prevent constant switching between DDD(R) and ADI(R), an additional test is performed to verify the stability of the intrinsic ventricular rhythm.

The device only switches to ADI(R) if a stable Vs activity is verified.



The Vs continuity search triggered by a single Vs

If the device paces in the DDD(R)-ADI(R) mode according to the set AV delay and senses a single Vs within the AV delay, then the Vs continuity test is started.



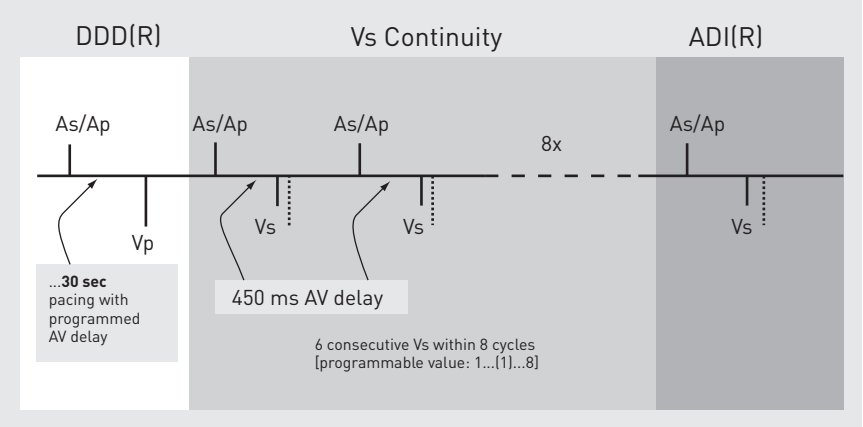
The search is successful if the set number of cycles has been sensed consecutively within 8 cycles. If no Vs was sensed except for the initial Vs, then the device paces for 8 cycles with an AV delay of 450 ms.

As a result, the device will work in the DDD(R) mode with the programmed AV delay until the next Vs continuity test.

If the search was successful and the number of programmed consecutive Vs was sensed, it switches to the ADI(R) mode.

Vs continuity search triggered by a timing interval

If the DDD(R)-ADI(R) mode has been set and the device paces with the programmed AV delay in the ventricle, then the initial Vs continuity search begins 30 s after removing the programming head.



The Vs continuity search runs in the same way within the programmed AV delay as the search triggered by a single Vs.

The condition for switching to the ADI(R) mode is met if the programmed number of Vs is consecutively sensed within 8 cycles.

Intelligent search

The intelligent search serves to avoid frequent scan cycles for patients who have no intrinsic rhythm.

The reason for this is that some patients become symptomatic if the device paces with a long AV delay.

Every time the Vs continuity search is unsuccessful, the timing interval for starting the search is doubled until a limit of 128 min is reached. Then the Vp suppression function will only search every 20 h for intrinsic AV conduction. The scan interval is set to 20 h instead of every 24 h so that the search is initialized at different times of day. The search is carried out at different times of day and night in a 6-day cycle.

The Vp suppression function does not deactivate itself entirely on its own.

Intelligent search time schedule

30 sec → 1 min → 2 min → 4 min → .... → 128 min → 20 h

ADI(R) mode

The device always works in ADI(R) mode if there is a stable intrinsic rhythm.

If the device works in ADI(R) mode according to NBG nomenclature, then pacing is only performed in the atrium **(A)**. Sensing takes place in both chambers **(D)** but atrial pacing is inhibited **(I)** if the intrinsic rhythm is higher than the basic rate or the rate specified by the sensor **(R)** .

While working in ADI(R) mode, no ventricular pacing is carried out. If no ventricular sensing occurs within 2 cardiac cycles or within 2 s, then it switches to DDD(R) mode.

While the device is working in the ADI(R) mode, sensing is performed in the atrium and ventricle. The AV delay is 450 ms and is not followed by a ventricular stimulus.

Switching from ADI(R) to DDD(R)

If an intrinsic ventricular rhythm is no longer sensed, it switches to DDD(R) mode.

In order to safely account for all situations, there are 4 different criteria which result in switching and they all work independently:

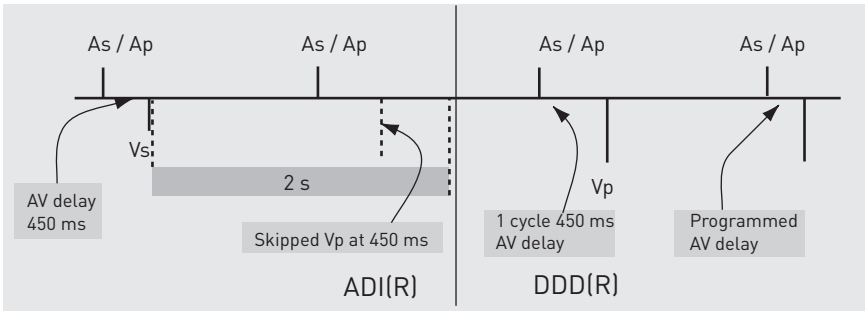
- No Vs for 2 s
- 2 consecutive cycles without Vs
- Pacing support for X out of 8 cycles without Vs (programmable number, default setting: 3 out of 8)
- 15 switches per hour permanently switches to DDD(R) until 24:00 h of the same day.

The criterion which is met first triggers the switch. Regardless of the criterion, switching is AV-synchronous. The ventricle is always paced either using the programmed AV delay or with the AV delay of 450 ms depending on the situation and especially depending on the rate.

Switching criterion: 2 s without Vs

In the example shown below, the 2-second criterion is met first. The two-second timer always starts at the sensed ventricular event. The ventricular pause is greater than 2 s because the ventricular stimulus is AV-synchronous. In this example, the ventricular pause is about 3 s. Due to the fact that the rate is low (1500 ms), the 2-second criterion is met earlier than the 2-cycles-without-Vs criterion.

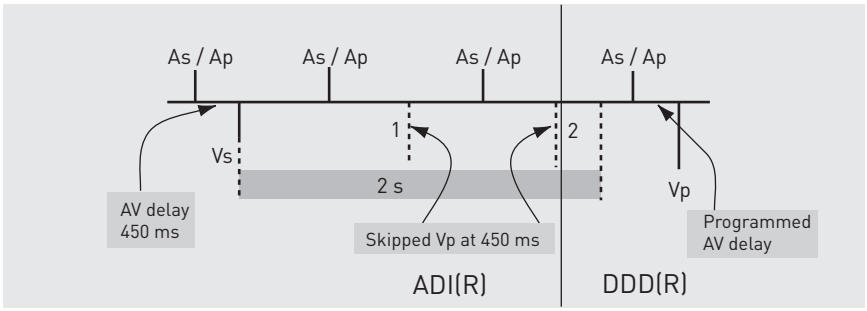
Example: Ventricular pause at 40 bpm



Switching criterion: 2 consecutive cycles without Vs

In the example shown below, the 2-cycles-without-Vs criterion is met earlier than the 2-second criterion because the cycle length is 857 ms (70 bpm).

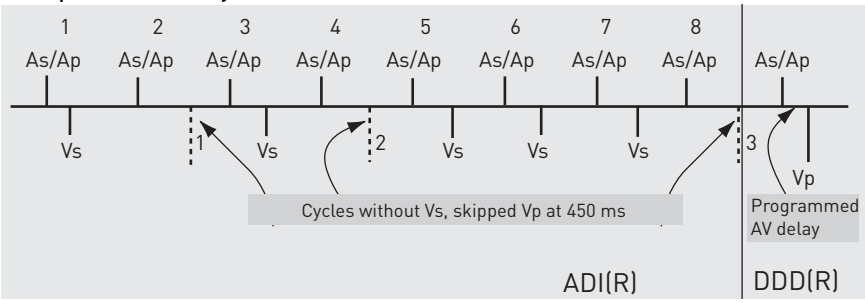
Example: Ventricular pause at 70 bpm



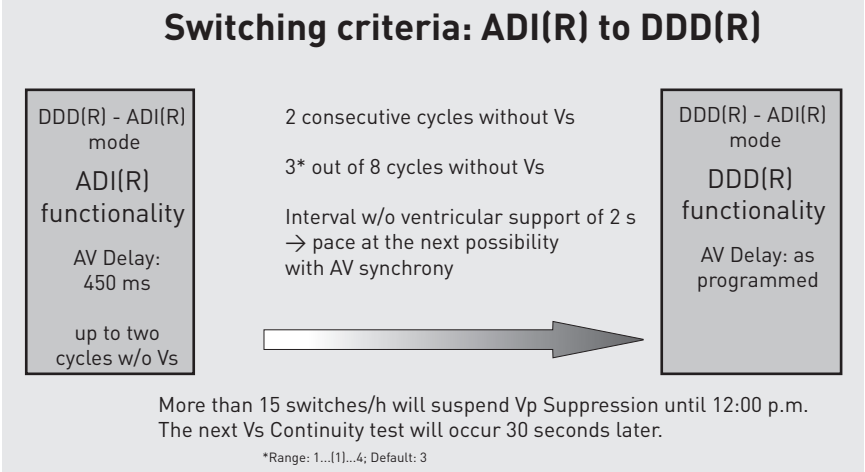
Switching criterion: programmable number X-out-of-8 cycles without Vs

In order to avoid irregular ventricular rhythms while in ADI(R) mode, only a programmable number of cycles is permissible without an intrinsic event. The default setting is 3 out of 8 cycles. If this criterion is met, it switches to DDD(R) mode.

Example: 3 out of 8 cycles without Vs



Summary



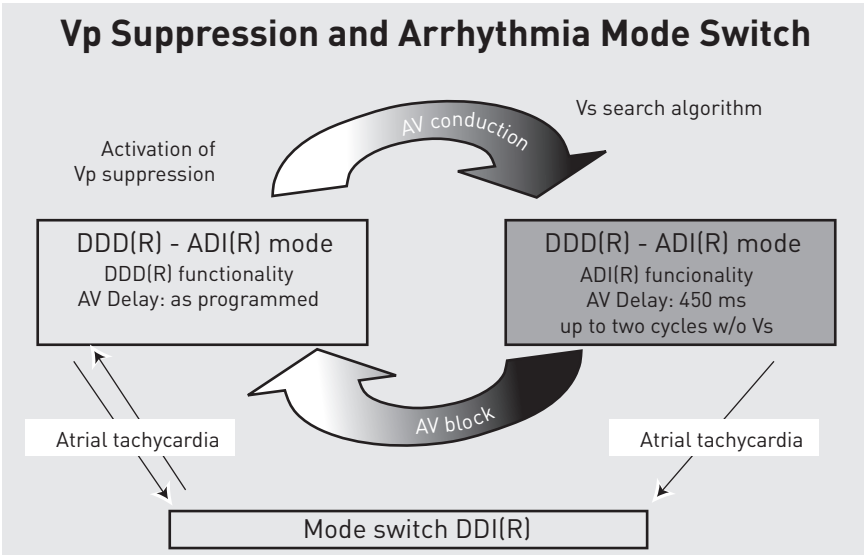
Vp suppression and mode switching

Every time the DDD(R)-ADI(R) mode is activated, mode switching is automatically activated with the possibility of switching to DDI(R) mode. Mode switching is available in the background regardless of the current Vp suppression mode function in order to protect the patient against high ventricular rates. The function is deactivated for the duration of mode switching.

Whenever the mode switching criterion is met, the algorithm switches to the DDI(R) mode regardless of the current functioning of the DDD(R)-ADI(R) mode.

The algorithm remains in DDI(R) mode until the resynchronization criterion is met.

Subsequent to resynchronization from within mode switching, the algorithm always switches to DDD(R) and not to ADI(R) mode to work with defined conditions after a tachycardia.



Diagnostics recordings of Vp suppression

You will find the diagnostics for Vp suppression under **Diagnostics → More diagnostics → Vp suppression**

The Vp suppression diagnostic function records the actions of these functions numerically and chronologically:

- 240-day trend for the duration of ADI(R). Like all long-term trends, this is a rolling recording in which one data point is recorded per day. The portion is shown as a percentage of one day for the ADI(R) mode. The earliest recordings are overwritten if recording continues for more than 240 days.
- Counter for successful switching to the ADI(R) mode. All successful Vs continuity searches since the last transmission of the permanent program are counted.
- Counter of Vs continuity searches. The absolute number of scan cycles since the last permanent program transmission is counted.

It has to be taken into consideration that there are several functions with higher priority than Vp suppression. After switching back, Vp suppression starts in the DDD(R) mode with a new Vs continuity search.

This is the reason why the number of Vs continuity searches and successful switches can be unexpectedly high in the case of 100% sensing spread throughout the day.

Vp suppression and high rates

Vp suppression is not connected to specific rate limits like, for example, capture control.

In the case of high rates, the AV delay would be longer than the VA interval if the AV delay is set to a maximum of 450 ms.

Therefore, the AV delay of 450 ms is reduced depending on the rate to avoid unfavorable hemodynamic situations in the case of high rates.

The exact AV delay dependent on the rate when Vp suppression is activated can be viewed in the diagram of the dynamic AV delay function.

The maximum AV delay is still 450 ms at 100 bpm and is reduced incrementally, reaching a base of 300 ms at 140 bpm, which remains set even at higher rates.

Vp suppression interactions with other functions and actions

As already mentioned above, there are functions with a higher priority than Vp suppression.

The Vp suppression function is interrupted if a function with higher priority starts. After automatic reactivation of Vp suppression, the function always initially works in DDD(R) mode regardless of which mode was active when the Vp suppression was interrupted.

The following algorithms, partial functions and actions interrupt the Vp suppression function:

- Pacing threshold search of atrial and ventricular capture control
- Mode switching
- PMT detection
- Programming head application
- Long-term deactivation when ERI is reached

Setting Ventricular Pacing Suppression

Navigation: Parameters → Bradycardia/CRT → Vp suppression

Objective

The ventricular pacing suppression function serves to promote the intrinsic ventricular rhythm with AV conduction.

Description

The Vp suppression function supports intrinsic AV conduction. The function can only be set in DDD(R)-ADI(R) mode. In cases of intrinsic conduction, the device works in a mode similar to AAI.

The device switches back to the DDD(R) mode under the following conditions:

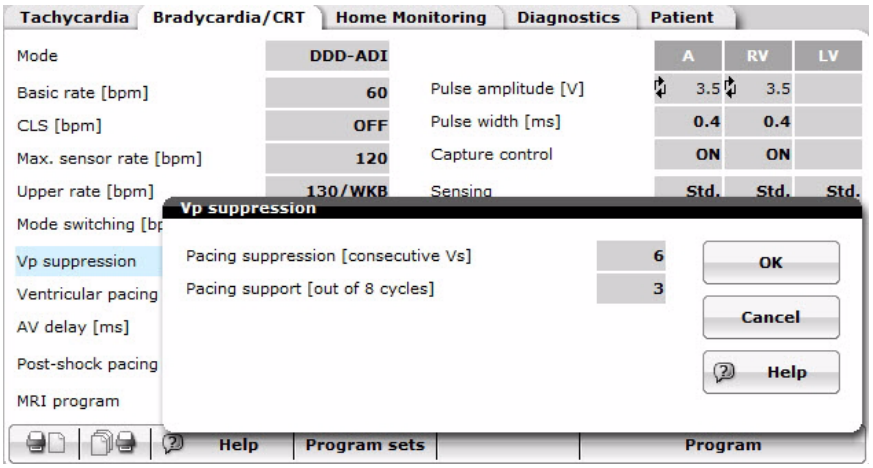
- 2 consecutive cycles without Vs
- X (1 - 4) of 8 intervals without ventricular support
- Interval without ventricular support for 2 s
- More than 15 conversions per hour deactivate the function for 20 hours

Activate the function

Proceed as follows:

Step	Action
1	Select **Parameters → Bradycardia/CRT**.
2	Select the mode DDD-ADI or DDDR-ADIR. The Vp suppression function is now activated and shows the value `ON` in the `Bradycardia/CRT`.

User interface



Effect

Over the long term, right-ventricular pacing has been shown to cause asymmetrical ventricular contraction due to the unphysiological cardiac conduction. In the long term, this serves to prevent loss of ventricle synchronization and development of congestive heart failure.

IRSplus - Promoting Intrinsic AV Conduction

Navigation: Parameters → Bradycardia/CRT

Objective

The IRSplus (Intrinsic Rhythm Support) function is intended to support the heart's intrinsic rhythm. All parameters of the AV hysteresis functions are set simultaneously in a single step. The objective is to maintain spontaneous AV conduction of the patient's heart as long as possible. This causes a natural contraction procedure and prevents unnecessary pacing of the ventricle.

Note: IRSplus and AV hystereses cannot be activated if Vp suppression has been activated. IRSplus cannot be activated if LV or BiV is set for ventricular pacing in triple-chamber devices.

IRSplus range of values

The value range is preconfigured as follows after activating the IRSplus function:

Function	IRSplus	Standard
AV hysteresis	400* ms	OFF
AV scan	5 cycles	–
AV repetitive	5 cycles	–

* At high rates of over 100 bpm, the AV hysteresis interval is shortened to 300 ms maximum at rates of over 140 bpm.

Note: IRSplus allows for long AV delays. Therefore, turn on PMT protection in order to avoid tachycardias, which may be induced by the device.

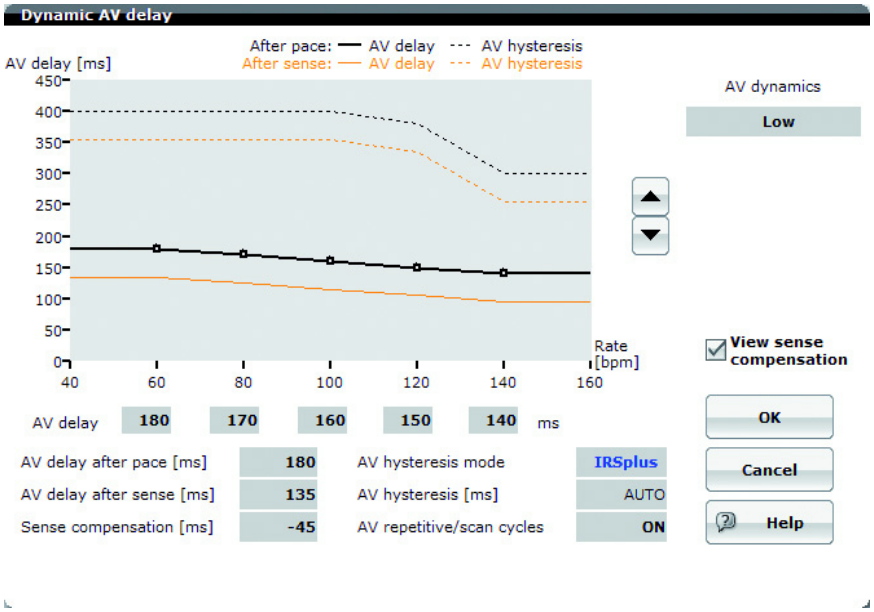
Activating IRSplus

To activate the IRSplus function and automatically activate AV hystereses in the dynamic AV delay, proceed as follows:

Step	Action
1	Make sure PMT protection is activated to prevent pacemaker-mediated tachycardias. Select **Parameters → Bradycardia/CRT → Refractory period/Blanking → PMT protection → ON**.
2	Select **Parameters → Dynamic AV delay → AV hysteresis mode → IRSplus**. The AV hystereses are automatically set in the dynamic AV delay.
3	Confirm the settings with **[OK]** to accept the values.

Graphic display of AV hysteresis

In the `Dynamic AV delay` window, the AV hysteresis is displayed in the AV delay diagram as a dotted line.



5.4.4 Refractory and Blanking Times

What's in this section?

Timing of the Atrial Refractory Periods (ARP, PVARP)

Abbreviations

Abbreviations and their meanings in graphics and text:

Abbreviation	Meaning
BI	Basic interval
AV	AV delay
As	Atrial sensed event
Ap	Atrial paced event
ARP	Atrial refractory period
AUR	Atrial upper rate interval
Vs	Ventricular sensed event
Vp	Ventricular pace event
VRP	Ventricular refractory period
PVARP	Post-ventricular atrial refractory period
PVARP(ext).	Extended post-ventricular atrial refractory period
FFPp	Far-field protection after pacing
UTI	Upper tracking interval
Vp(WKB)	Ventricular pace delayed by Wenckebach response
Vp(SW)	Ventricular back-up pace in the safety interval
Vp(BU)	Ventricular pace as backup pacing
Vs(AVC)	Ventricular sensing in the "PVC discrimination after As" window

Definition: Physiologic refractory period

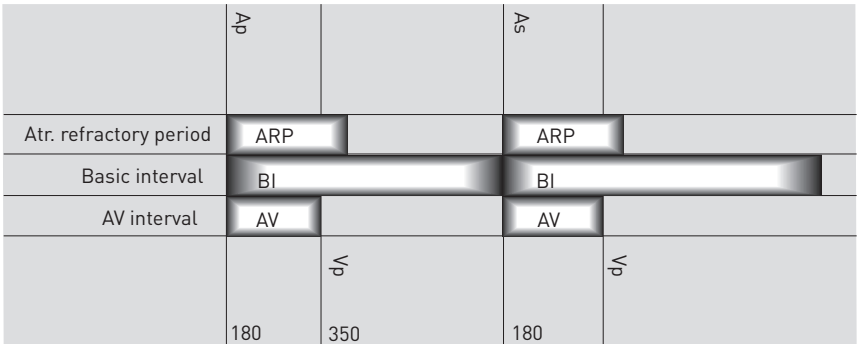
Time period after depolarization in which a heart cell is in the refractory state and cannot be depolarized again:

- 150 to 220 ms depending on the heart rate

Definition: Atrial refractory period in the device's timing

- The atrial refractory period (ARP) starts with a sensed or paced event.

Each of the following atrial events (As, As(AV), Ap, Ap(AUR) and As(PVARP)) starts an atrial refractory period (ARP).



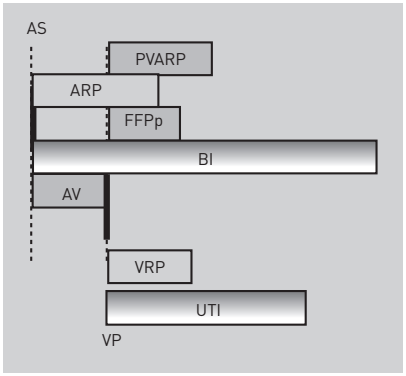
Mode-controlled atrial refractory period setting

Setting	Mode
AUTO	DDD(R), DDD-CLS, DDI(R), VDI(R), VDD(R), DDD(R)-ADI(R)
300 ... (25) ... 775 ms	AAI(R), AAT, DDT

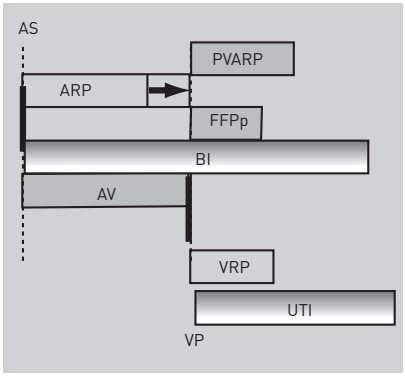
Timing with the atrial refractory period setting AUTO

- The atrial refractory period (ARP) is automatically configured in addition to the AV delay.
- The atrial refractory period (ARP) is 225 ms minimum. It is also used after As(PVARP).

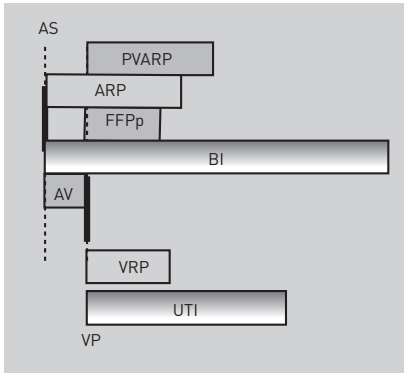
225 ms-FFP < AV delay < 225 ms



AV delay > 225 ms



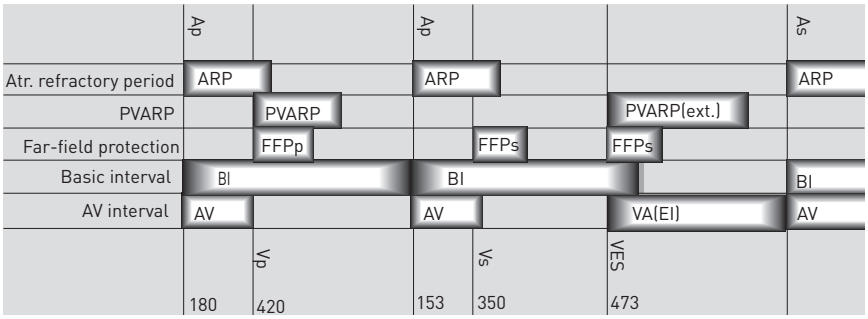
225 ms-FFP > AV delay



Post-ventricular atrial refractory period (PVARP)

The post-ventricular atrial refractory period function prevents atrial pacing from being triggered directly after a ventricular event. This prevents a pacemaker-mediated tachycardia (PMT).

- In all P-synchronous modes (e.g., DDD), a PVARP starts in the case of the following events: Vp, Vp(WKB), Vp(SW), Vp(BU)
- In all R-synchronous modes (e.g., DDI), a PVARP starts in the case of the following events: Vp, Vp(SW), Vp(BU), VES, Vs and Vs(AVC).



Auto PVARP

After ending a pacemaker-mediated tachycardia (PMT), PVARP and PVARP after PVC are automatically extended by 50 ms.

The limit for PVARP is:

- Value of the VA criterion + 50 ms.
- Minimum automatic setting: 175 ms

Setting Refractory Periods, Blanking Periods and PMT Protection

Navigation: Parameters → Bradycardia/CRT → Refractory period/Blanking

Objective

Blanking and refractory periods can prevent false inhibition of the device by interference potentials. The following interference potentials may inhibit the device:

- Retrograde conductions
- Far-field sensing
- Afterpotentials

Overview

The following parameters can be configured for PMT protection, refractory and blanking times:

- PVARP, Auto (PVARP), PVARP after PVC
- Far-field protection after Vs, Vp
- PMT protection
- Ventricular blanking after Ap
- VA criterion

PVARP - Description of the parameters

The PVARP lengthens the atrial refractory period (ARP) after a ventricular event (PV = post-ventricular). The total atrial refractory period is divided into the atrial refractory period (ARP) and two other safety intervals - the far-field blanking (FFB) and PVARP. A right ventricular extrasystole (RVES) triggers the prolonged PVARP.

- Automatic PVARP
  - If pacemaker-mediated tachycardia (PMT) is confirmed, the post-ventricular atrial refractory period is automatically extended by 50 ms.
  - This value remains "frozen" and is not further reduced by the absence of PMTs.
  - If PMTs should occur again, then the PVARP is increased further.
- Automatic atrial refractory period
  - The atrial refractory period (ARP) is automatically coupled to the AV delay.
  - The ARP does not drop below 225 ms.
- Refractory periods

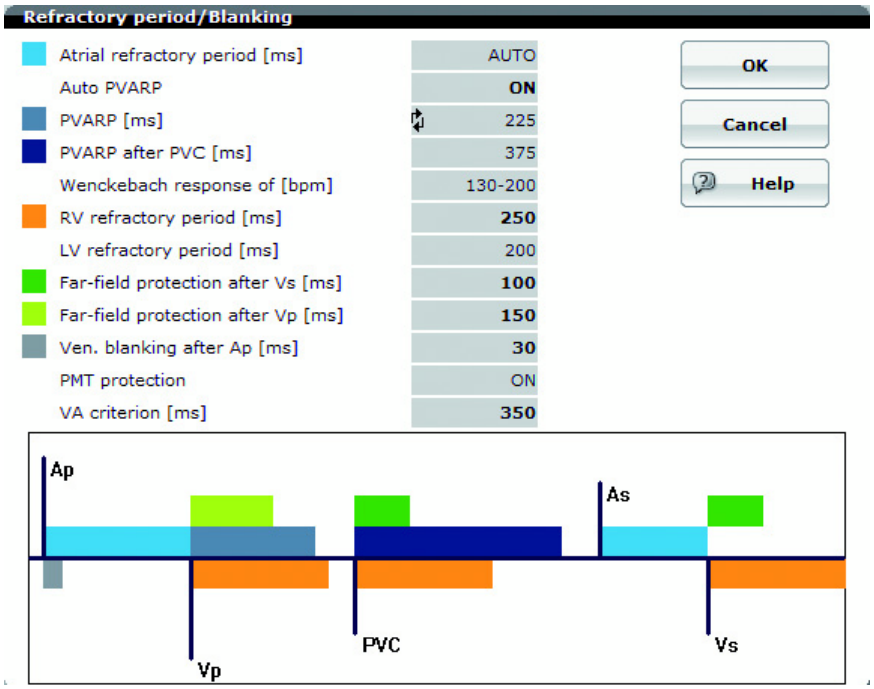
  Events that occur during the refractory period and are sensed by the device have no effect on device timing. This does not include algorithms used for prevention in the case of atrial tachyarrhythmia (for example, automatic mode switching).
- Far-field protection
  - Far-field protection prevents atrial leads in dual-chamber modes from detecting events in the ventricle (far-field sensing) and interpreting them incorrectly as events in the atrial channel.
    Events that are sensed in the far-field protection interval do not affect device timing.

Events and safety intervals

The following events trigger the safety intervals:

- Atrial events start the ARP.
- All ventricular events start the far-field protection.
- Ventricular stimuli start the PVARP interval.
- Premature ventricular contractions (PVCs) increase the value of PVARP by 150 ms.

User interface



Purpose of PMT protection

With its basic algorithm, PMT protection can interrupt the persistance of a pacemaker-mediated tachycardia (PMT).

When the AUTO (PVARP) parameter value is set, where a PMT has been confirmed, the PVARP is extended automatically, see also: PVARP - Description of the parameters, p. 81.

In the dual-chamber device's atrially controlled modes (DDD, VDD), the device will start PVARP after the following events:

- Ventricular stimulus
- Premature ventricular contractions

PMT detection

In principle, PMT is detected with the absence of coupling between a ventricular pace and the following atrial sense event during sinus rhythm. When PMT is present, there is coupling between the Vp interval and the subsequent As interval (which is known as the VA interval). The detection algorithm is based on a constant for the length of the VA interval.

Where a confirmed PMT has occurred, the device will attempt to interrupt it by extending the PVARP.

5.5 Atrial and Ventricular Capture Control

What's in this section?

Overview

The functions of atrial capture control are designed as follows:

- Continuous monitoring of effective atrial pacing
- Periodic determination of the atrial pacing threshold
- Verification of capture response
- Periodical adaptation of the pulse amplitude

The functions of ventricular capture control are designed as follows:

- Continuous monitoring of effective ventricular pacing
- Periodic determination of the ventricular pacing threshold
- Verification of capture response
- Beat-to-beat adaptation of the pulse amplitude

Objective

Because the pulse amplitude is periodically (atrial) or continuously (ventricular) being adjusted to the threshold, it is possible to optimally apply the energy reserves of the pacemaker and thus ensure reliable patient care.

Note: Leads that generate high polarization artifacts are not suitable for ventricular capture control.

5.5.1 Atrial Capture Control

What's in this section?

Atrial Capture Control - Overview

Overview

- Objective of atrial capture control
- Function
- Advantages

Objective of atrial capture control

Lead aging, changes to the medication, lead dislodgement and pathological changes can result in changes to the pacing threshold.

Automatic algorithms permit follow-ups to be carried out as efficiently as possible. Automatic measurement of the ventricular threshold and the corresponding automatic adaptation of the ventricular pulse amplitude are functions that have already been used for many years in clinical practice.

This type of automatic algorithm is thus advantageous for measurement of the atrial threshold and the corresponding adaptation of the atrial amplitudes.

Function

The dual-chamber and triple-chamber devices in this device family have an algorithm for atrial capture control that is based on periodic observation and differentiation of atrial signals. The algorithm automatically measures the atrial threshold at a defined time and adapts the pulse amplitude when needed.

Advantages

The following advantages arise from the use of atrial capture control:

- **Home Monitoring-supported follow-up:**

  The follow-up examination can be accomplished as a Home Monitoring-supported follow-up. One of the requirements for this is presence of the atrial capture control function.

- **Safety:**

  The atrial amplitude is automatically adapted to increased atrial thresholds, so that atrial exit blocks are avoided.

- **Longevity:**

  The lowest atrial pulse amplitude value is determined by atrial capture control. It is automatically adapted to the current atrial threshold in each case and a safety margin is added. Low values for the atrial pulse amplitude increase the service life of the device.

Automatic Threshold Measurement

Overview

- Testing principle
- Determining the intrinsic rate and performing overdrive pacing
- Searching for the pacing threshold
- Confirming the pacing threshold
- Automatic active capture control
- Programming suggestions

Testing principle

When measuring the atrial threshold, the pulse amplitude is reduced until pacing in the heart no longer triggers a response. As soon as there is no atrial stimulus response, the intrinsic atrial rate takes over and generates a sensing marker, which can be produced using possible retrograde conduction if there is no intrinsic atrial rate.

Therefore, the atrial threshold can also be identified in the case of sinus arrest (no intrinsic atrial rate) by means of retrograde conduction.

Determining the intrinsic rate and performing overdrive pacing

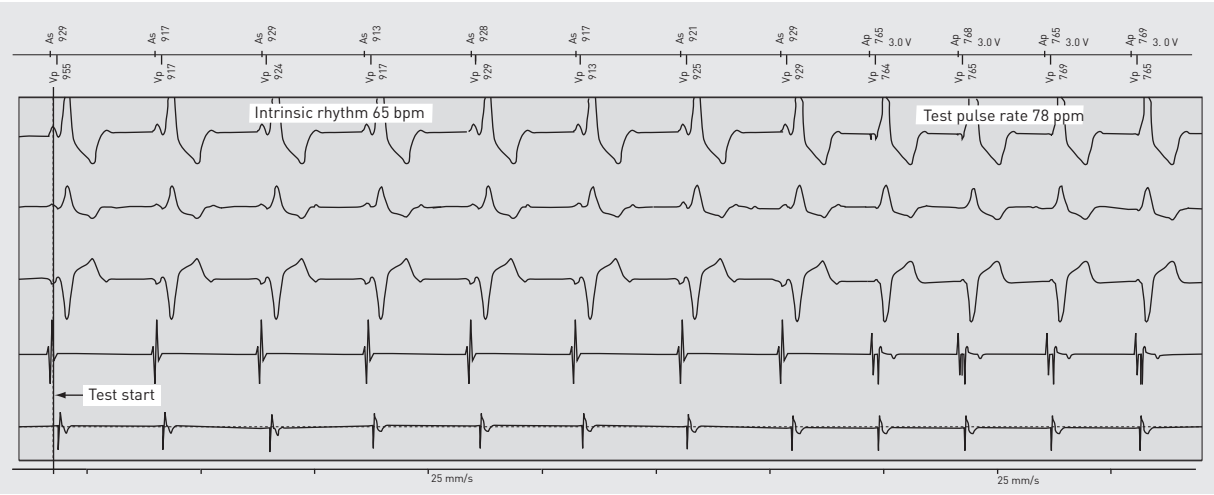
The atrium is paced in order to be able to identify the loss of stimulus response at a certain amplitude.

Therefore, the intrinsic rate is subjected to overdrive pacing amounting to 20% to ensure the atrium is being paced artificially. The intrinsic rate is identified using the average rate of the last 4 cycles in each case.

Conditions for overdrive pacing

If ...	Then ...
If the average atrial rate is higher than the programmed pacing rate	Then the atrial pacing threshold test is carried out at a rate which corresponds to the average intrinsic rhythm + 20%.
If the average atrial rate is lower than the programmed pacing rate	Then the atrial pacing threshold test is carried out at the pacing rate + 20%.
If the average atrial rate lies above 108 beats per minute	Then the test cannot be carried out at the present time and the atrial pulse amplitude remains at the current value.

Intrinsic rhythm 65 bpm + 20% = test pulse rate of 78 bpm



Searching for the pacing threshold

Mode and AV delay during the test

- DDI mode:

  Pacing in DDI mode prevents tracking of retrograde conducted P waves, which can occur if the atrial paced response is lost during the pacing threshold test. In DDD mode, retrograde conducted P waves can trigger pacemaker-mediated tachycardias. Therefore, the test is carried out in DDI mode.

- AV delay = 50 ms

  After the AV delay of 50 ms, ventricular pacing is carried out, starting an atrial blanking of 150 ms. During blanking, the cardiac pacemaker does not evaluate the atrial signals for the test.
  To allow sensing of the intrinsic atrial rhythm as early as possible and prevent retrograde conduction, the AV delay has to be as short as possible. This ensures that an intrinsic atrial rhythm event will not be blanked in the atrial channel.

Pacing threshold search using amplitude reduction

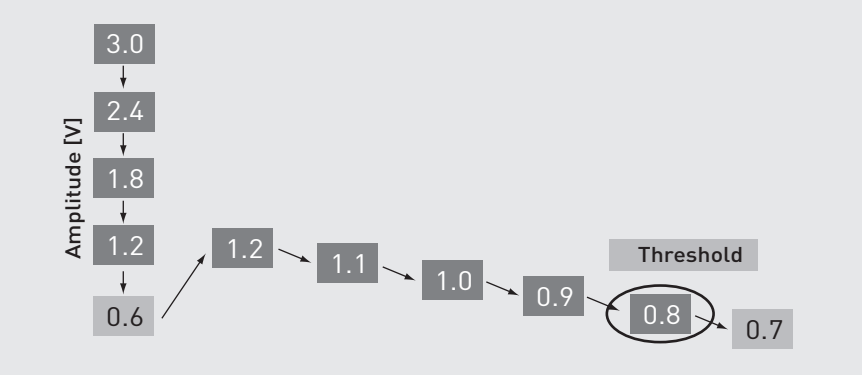
- The pacing threshold search begins at the programmed start amplitude (default setting: 3.0 V). The amplitude is reduced here in 0.6 V increments, until 2 intrinsic atrial events are sensed within 5 cycles (2 of 5).
- After the first loss of stimulus response (2 of 5), the device switches back to the amplitude, at which the last stimulus response took place, in order to perform a more detailed search.
- The test amplitude is decreased in increments of 0.1 V until the device detects a loss of 2 of 5 possible stimulus responses for the second time.

  This completes the pacing threshold search.

Below 0.6 V, the search is always performed in 0.1 V increments.

The criterion 2 of 5 was selected because, statistically, at least 2 events within 5 cycles can be sensed outside the far-field protection interval.

Start amplitude: 3.0 V; amplitude reduction: 0.6 V increments; loss of stimulus response at 0.6 V; beginning of detailed search at 1.2 V; amplitude reduction: 0.1 V increments; loss of the capture response at 0.7 V; **pacing threshold at 0.8 V**



Amplitude rate per test amplitude, analysis algorithm and synchronization pulse

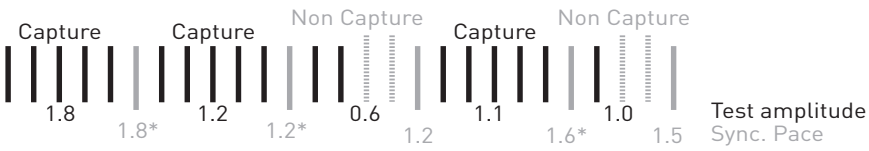
- Each test amplitude is delivered and analyzed 5 times with the same pacing energy for the duration of 5 cycles.
- After two sensed events within 5 cycles, the test sequence is likewise terminated prematurely, because ineffective pacing has occurred and the value has fallen below the pacing threshold.

- After each test pulse sequence with the same pacing energy, a synchronization pulse is delivered to ensure that the AV synchrony is restored after possible loss of pacing.

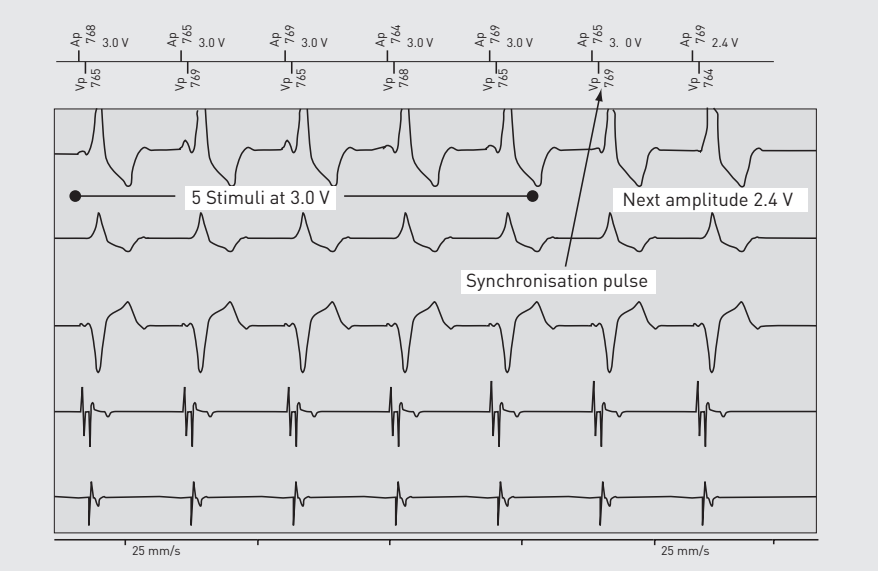
  For technical reasons, the synchronization pulse is even delivered without a loss of capture response.
  If there is no capture response, the synchronization pulse has a pacing energy of 0.6 V. This is delivered additionally in the test sequence with the larger step size (0.6 V).
  If a capture response occurs, the synchronization pulse has the same pacing energy as the test pulse.
  In the test sequence with smaller increments (0.1 V), the pacing energy of the synchronization pulse is increased by 0.5 V.
- Premature ventricular contractions have no impact on the test.

Test sequence	Amplitude of the synchronization pulse
Decrease in increments of 0.6 V with capture response	Pacing energy the same as test amplitude
Decrease in increments of 0.6 V without stimulus response	Pacing energy the same as test amplitude + 0.6 V
Decrease in increments of 0.1 V with and without capture response	Pacing energy the same as test amplitude + 0.5 V

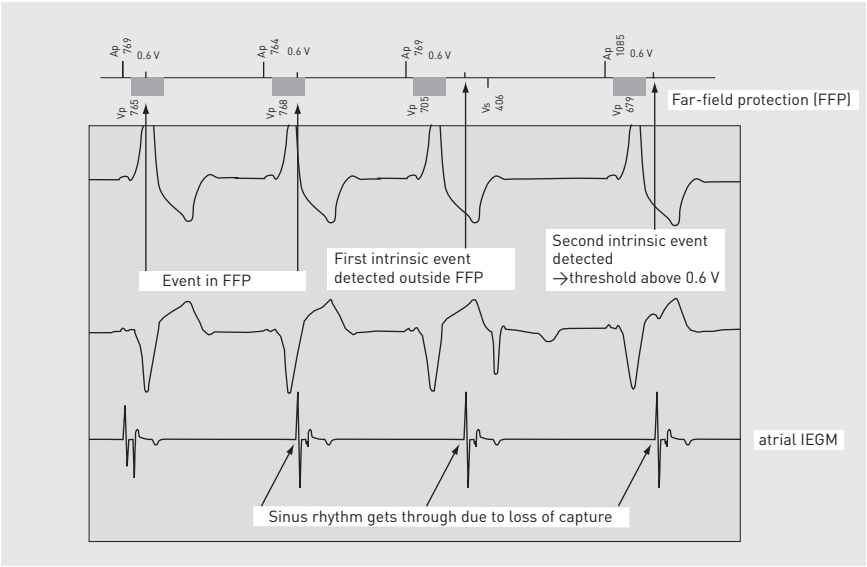
Diagram of the test and synchronization pulses with capture response (capture) and with loss of capture response (non-capture)



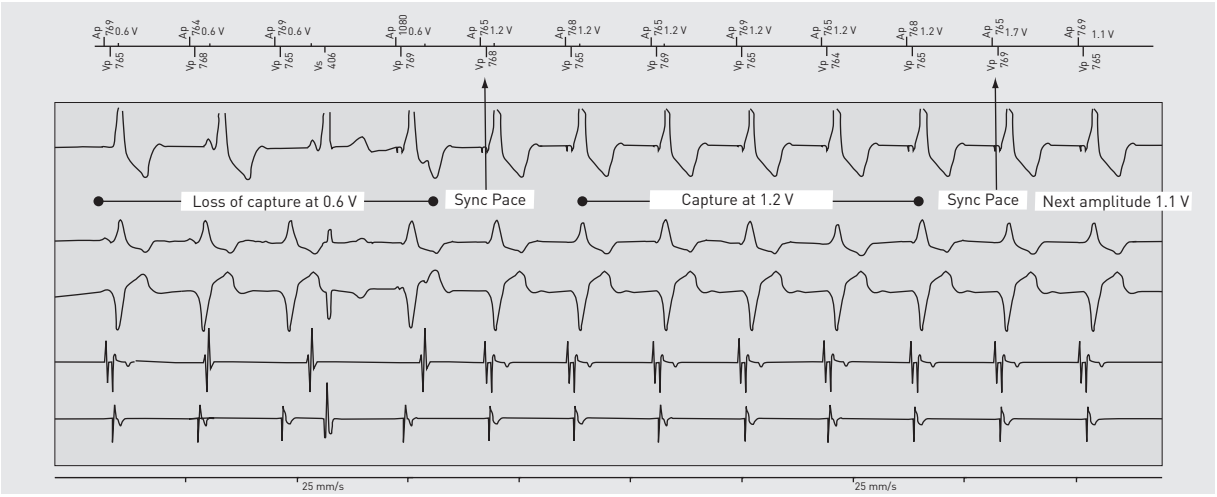
Example: Synchronization pulse, 5 stimuli at 3 V and a synchronization pulse



Example: Loss of capture at 0.6 V; only atrial markers outside the far-field protection interval (150 ms after Vp) are evaluated.



Example: Beginning of the detailed search in 0.1 V increments, switching from 0.6 V to 0.1 V increments of decrementation



The threshold determined at the beginning is confirmed as follows:

- 1st step:

  Pacing pulses of 0.3 V above the pacing threshold are delivered within a testing period of 5 atrioventricular pacing intervals.

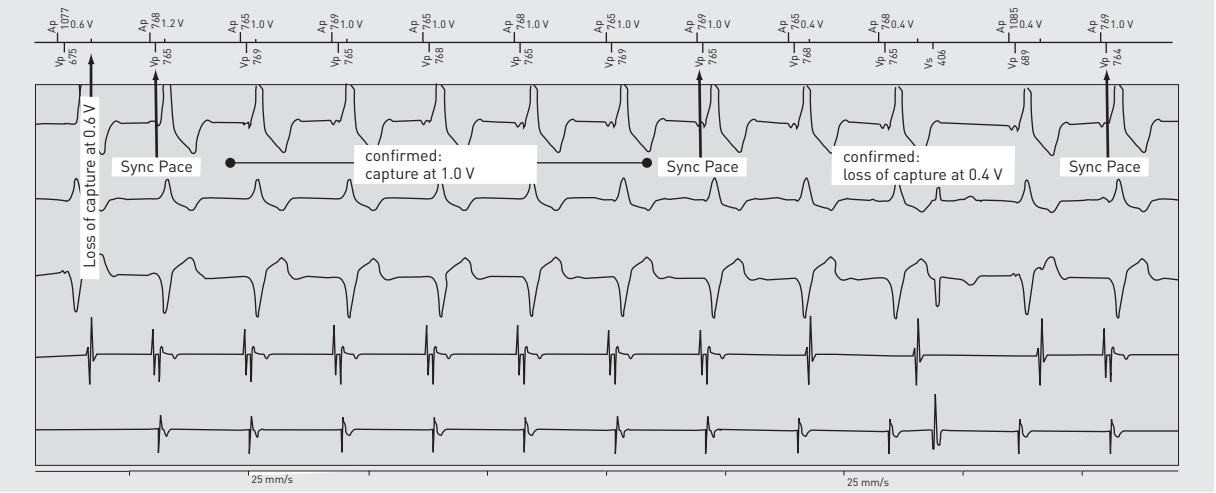
- 2nd step:

  Another test cycle of 5 atrioventricular pacing intervals is carried out at 0.3 V below the pacing threshold.

- The pacing threshold is considered verified if a capture response is identified in the first step and loss of the capture response is confirmed in the second step.

Note: If the pacing threshold is ≤ 0.3 V, pacing markers of 0 V are set in the IEGM.

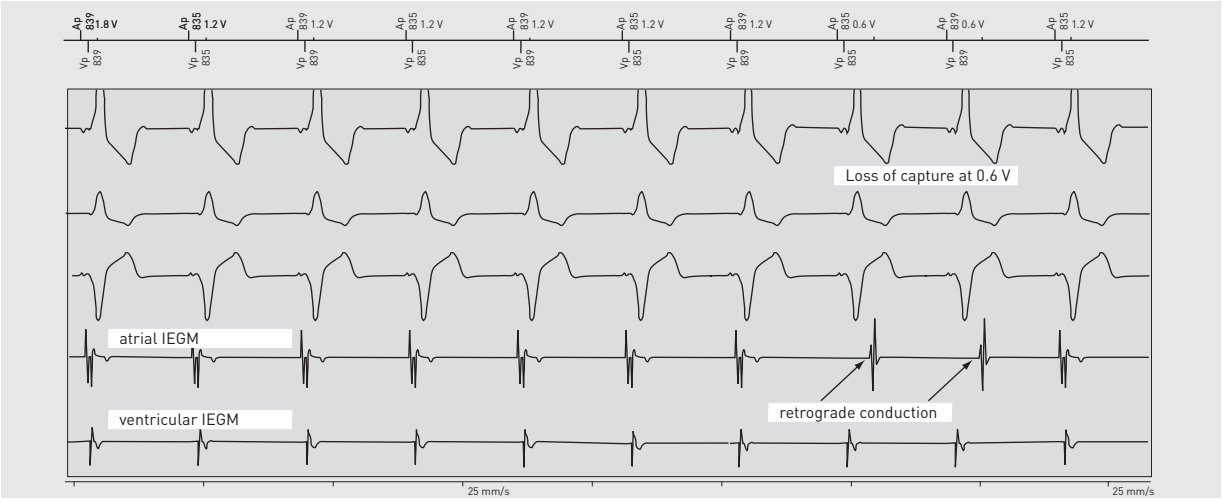
Example verification test: capture response at 0.7 V (= pacing threshold), loss of the capture response at 0.6 V, (pacing threshold +/-0.3 V)



Pacing threshold measurement using retrograde conduction in the case of sinus arrest

- Atrial capture control also works if there is no atrial intrinsic rate.
- Retrograde conducted P waves, which are caused by ventricular pulses if there are no intrinsic atrial events, suffice for analysis.

Example: Sinus arrest with retrograde conduction time of 220 ms



Automatic active capture control

- The atrial pulse amplitude is adapted by adding the programmed safety margin (default setting 1.0 V, adjustable) to the measured pacing threshold.
- If no atrial pacing threshold test could be carried out (e.g., at an intrinsic rate > 108 bpm), the current atrial amplitude remains valid.
- If atrial capture control is deactivated (e.g., in the case of interferences of a unipolar lead), the atrial amplitude is calculated by adding the test output amplitude and the safety margin. Default setting: 3.0 V + 1.0 V = 4.0 V.

Note:
If atrial capture control is deactivated, an error message is displayed in the Follow-up window and an event message is generated for BIOTRONIK Home Monitoring. Unsuccessful measurements of atrial capture control are shown in the Home Monitoring statistics as gaps.

Programming suggestions

- The value of the "Threshold test start" parameter does not influence the success of the test (as opposed to ventricular capture control), but decrementing makes it several seconds faster.
- The test is repeated daily at the programmed time.

Note: Make sure there is a sufficient difference between the threshold and the value of the threshold test start parameter, so that pacing threshold changes can be monitored following implantation.

5.5.2 Ventricular Capture Control

What's in this section?

Ventricular Capture Control – Overview

- Components of the algorithm
- Characteristics
- Manual/automatic determination of the pacing threshold
- Terms

Objective

During implantation and follow-up, the necessary pulse amplitude required to depolarize the myocardial tissue is usually measured. This minimum pulse amplitude is identified as the pacing threshold. The impulse amplitude is set twice as high as the measured pacing threshold as standard. The purpose of ventricular capture control is to adjust the pulse amplitude via a change in the pacing threshold.

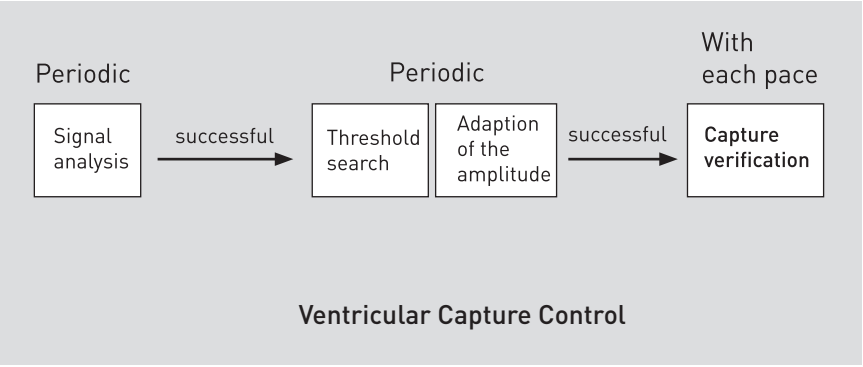
Components of the algorithm

The algorithm is comprised of 3 components:

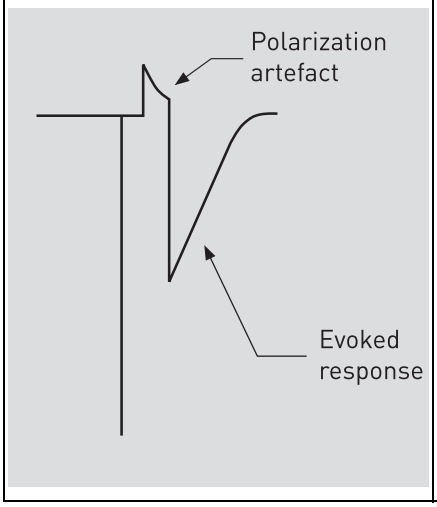
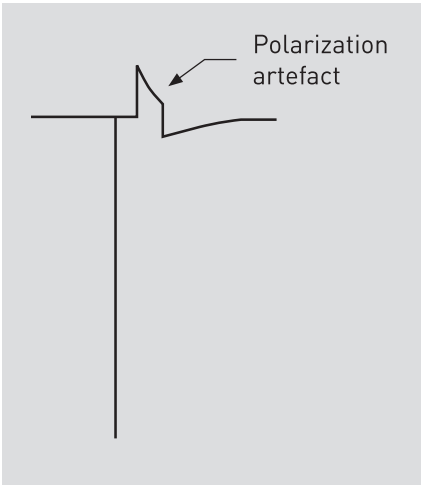
- Signal analysis
- Measurement of the pacing threshold with amplitude setting
- Verification of capture response

The first 2 components occur periodically. Verification of the capture response occurs with every pace. If the ventricular capture control parameter is activated with ON, all 3 components are performed one after another.

Overview of the algorithm's components



The algorithm is based on the comparison of the signals from the evoked response and the polarization artifact.

Successful pacing	Unsuccessful pacing
	

Characteristics

The function comprises of the following characteristics:

- The function periodically measures the pacing threshold, automatically adjusts the pulse amplitude and offers a programmable safety margin.
- The function checks the effectiveness of every ventricular pacing pulse on a beat-to-beat basis and implements a backup pulse in the case of an ineffective pace.
- The differences in the signal morphology and the evoked response and the polarization artifact are used to differentiate between effective and ineffective pacing.

Manual/automatic determination

- As the manual method of determining the pacing threshold occurs at long intervals (e.g. every 12 months), a large safety margin must be selected in order to ensure an effective pacing.
- A smaller safety margin is acceptable for the automatic method, which continually checks the effectiveness of pacing and periodically determines the pacing threshold (e.g., every 24 h), as the pulse amplitude is continuously adjusted to the demand. A smaller safety margin may lead to less power consumption and an extended service time of the device.

Terms The following table lists and describes all terms that are used in connection with ventricular capture control.

Term	Description
Evoked response	Intracardiac signal which arises through the excitation of the myocardium tissue. The evoked response is independent from the pulse amplitude and the pacing threshold.
Polarization artifact	Noise that arises between the lead and the myocardial tissue after delivery of the pacing pulse. The polarization artifact is dependent on the pulse amplitude, the structure of the lead tip, and the manner of the implantation.
Signal analysis	A component of the function that periodically determines whether the evoked response has been correctly recognized and whether the polarization artifact's amplitudes are small enough. If the signal analysis determines that the signal is not useable, then the other components of the function cannot be activated.
Pacing threshold search:	A component of the function which periodically determines the pacing threshold. The pacing threshold search can only be performed after a successful signal analysis.
Verification of capture response	A component of the function which classifies every stimulus (beat-to-beat) as effective or ineffective.
Ineffective stimulus	A ventricular stimulus without stimulus response
Safety margin	The difference between the pacing threshold and the programmed impulse amplitude is referred to as the safety margin.
Threshold test start	The set amplitude at which signal analysis and pacing threshold measurement start. The signal analysis is also carried out for every amplitude.
Backup pulse	Pacing pulse of increased energy following an ineffective stimulus

Signal Analysis

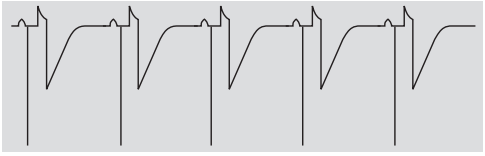
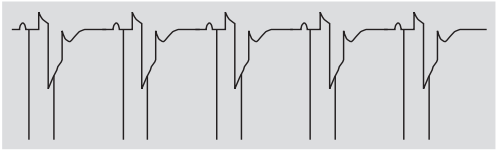
Purpose

This sub-function analyzes the signal quality of the ventricular evoked stimulus response when the stimulus is effective, and the polarization artifacts when the stimulus is ineffective.

The function ensures that only undisturbed and suitable signals are evaluated. The signal analysis function works up to a ventricular rate of 100 bpm.

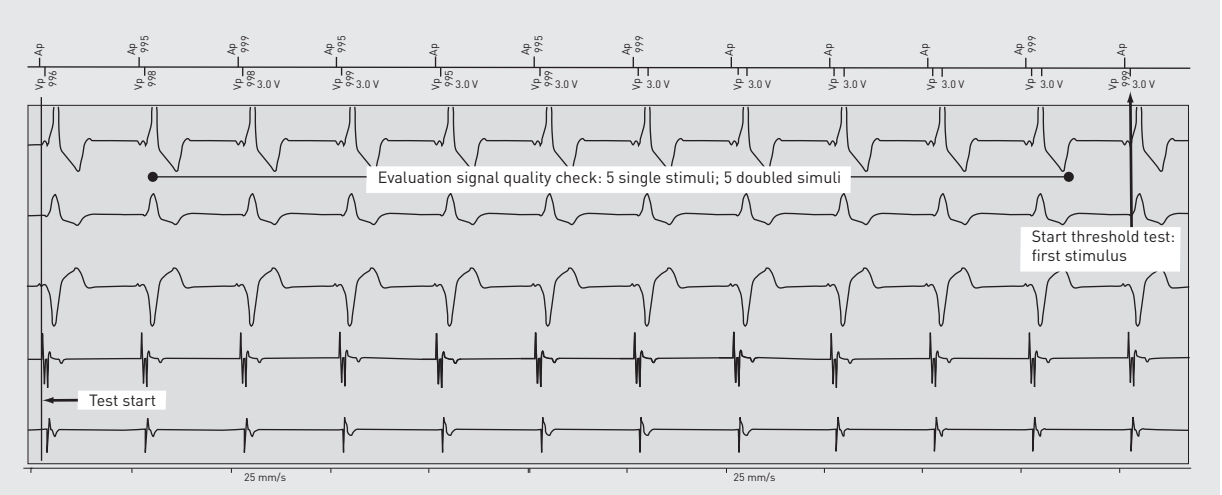
How signal analysis works

The signal analysis sub-function works in the following way:

Sequence	Description
1	The device measures with a constant, maximum pulse amplitude (Threshold test start) for a duration of 5 cycles. The AV delay is shortened to 50 ms after pacing and to 15 ms after sensing. 
2	After another 5 cycles, a second pulse is delivered with the same amplitude 100 ms after the effective stimulus. This pacing reaches refractory tissue and thus does not evoke a stimulus response. This makes it possible to determine the sole polarization artifacts of the lead. 
3	The average signal from the 5 measurements is used to compare the effectiveness of the pacing pulse (signal morphology) and to classify it as effective or ineffective.

Note: If the signal quality is classified as insufficient, then the pacemaker temporarily and automatically switches to backup stimulation until a successful measurement can be conducted.
If insufficient signal quality is measured repeatedly, then the function is deactivated and the pacemaker switches to permanent safety pacing.
The signals (evoked response and polarization artifact) can be changed by changing the pulse width, the pacing polarity and the pulse amplitude under **Ventricular Capture Control → Threshold test start [V]** so that the signal quality is possibly sufficient.

Example: Checking signal quality, analysis of evoked responses



Possible scenarios during signal analysis

If...	Then...
If after initial activation of ventricular capture control, signal analysis is not completed successfully	Then the function is immediately deactivated. The pulse amplitude is set to the value of the "Start threshold test" amplitude. By changing parameters, the signal quality can be changed so that analysis is permanently successful.
If after initial activation, signal analysis is completed successfully, but subsequently completed without success,	Then the function is suspended and the pulse amplitude is set to a safe value. This value is composed of the last measured threshold + maximum safety margin of 1.2 V. Signal analysis is performed again at the next programmed time. The procedure is carried out up to 3 times.
If the third consecutive signal analysis remains unsuccessful,	Then the function is deactivated and the pulse amplitude is set to a safe value (threshold test start amplitude + 1.2 V). Afterwards, the ventricular capture control can only be manually reactivated with the programmer.

Automatic Threshold Measurement

Objective

The sub-function Pacing threshold measurement enables the pacing threshold with the resulting stimulus to be automatically determined. The ventricular threshold is periodically measured and the pulse amplitude is adjusted if necessary.

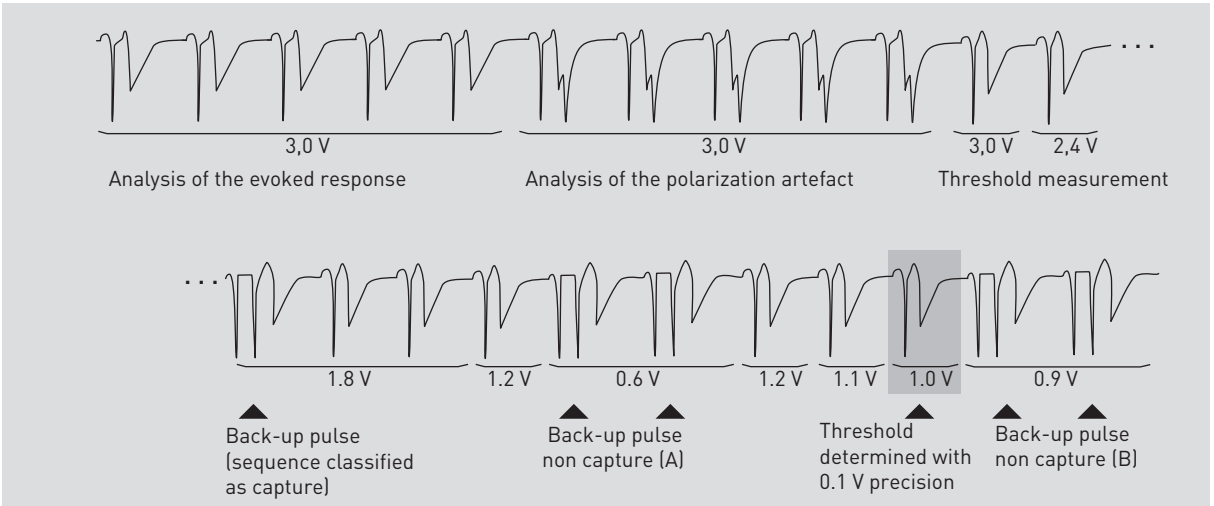
Prerequisite

Only after the signal quality has successfully been checked can the pacing threshold measurement and capture control functions be executed.

How the pacing threshold measurement works

The threshold is determined as follows:

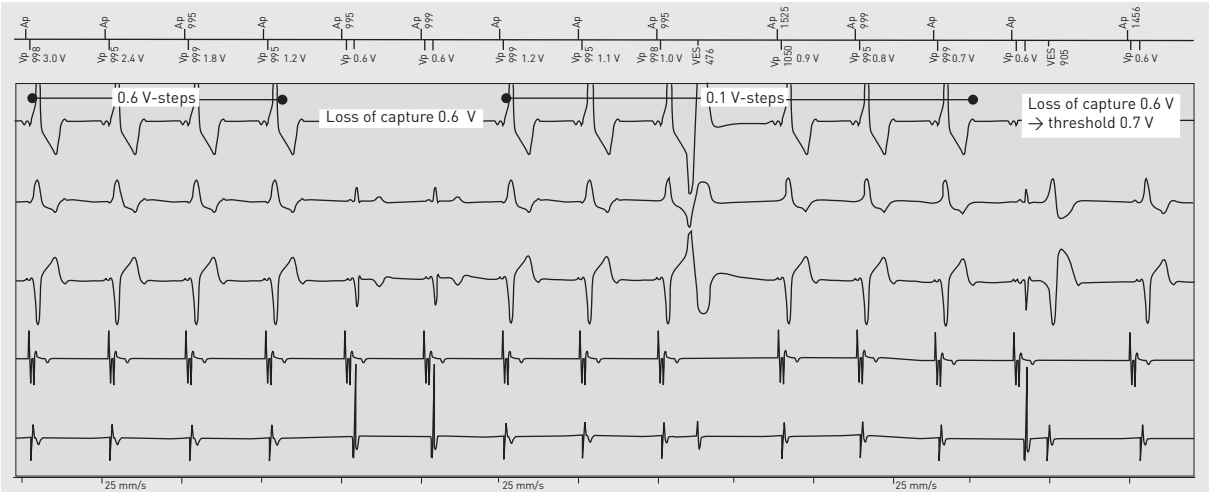
Sequence	Description
1	After successful verification of the signal quality, the pulse amplitude is incrementally decreased with each pace. • The amplitude is decreased, first in larger increments (0.6 V), then in smaller increments (0.1 V). • Each amplitude is tested with 1 stimulus. • The AV delay is shortened to 50 ms after pacing and to 15 ms after sensing.
2	The incremental decrease of the pulse amplitude continues until a loss of stimulus response (ineffective stimulus) is measured. The last effective pulse amplitude that is measured is accepted and saved as the pacing threshold value.
3	A safety pulse with an increased pulse width energy of 1.0 ms is delivered after each ineffective ventricular stimulus. This leads to continuous effective pacing.



Automatic determination of the pacing threshold

If ...	Then ...
If a single ineffective pace is sensed during the first pulse amplitude decrement (0.6 V),	Then the pacing value is set at the previous value minus 0.1 V and the amplitude is then reduced by 0.1 V in order to determine the pacing threshold.
If a single ineffective pace is sensed during the second pulse amplitude decrement (0.1 V),	Then the preceding measured value is taken to be the pacing threshold.
If an ineffective pace is sensed again,	Then up to 2 more stimuli are delivered with the same pulse amplitude.
If 2 of 3 stimuli are ineffective,	Then the preceding measured value is taken to be the pacing threshold. The pulse amplitude is then set to the pacing threshold plus the programmable safety margin.

Example: the pacing threshold test was carried out in less than 20 seconds.



Programming suggestions

The standard value to start the threshold test is 3.0 V. To further increase the likelihood that the test will be successful, this value can be lowered to 2.4 V. Also, in case of a low pacing threshold, the pulse width can be reduced from 0.4 ms to 0.3 ms.

The search type is set to time of day and 00:30 h in the night by default in the software. This serves to minimize the impact that a highly fluctuating intrinsic rate has on the algorithm.

Verification of Capture Response

Overview

- Functionality (verification of the capture response)
- Backup pace
- Algorithm for fusion discrimination
- Fusion discrimination in 3 stages

Objective

This sub-function allows the pulse amplitude to be continuously verified. Verification of the capture response is possible up to a ventricular rate of 110 bpm.

Functionality

The pacing effectiveness is checked after each ventricular stimulus.

Sequence	Description
1	When pacing is effective, the current settings are retained.
2	When pacing is ineffective, then a backup pulse with increased energy is delivered after a maximum of 130 ms. This is carried out at the same amplitude and an increased pulse width.
3	If a series of 3 consecutive ventricular paces, even after the AV delay has been changed (with atrial-controlled pacing modes or the basic rate in ventricular-controlled pacing modes), does not produce effective pacing, the signal analysis function is started first and a new threshold search is executed.
4	If pacing continues to be ineffective, the pulse amplitude is increased in order to secure effective pacing. Due to this automatic capture control, it is possible to select a small safety margin, which can combine lower energy consumption with safe pacing.
5	After the monitoring interval has elapsed, the threshold search function is automatically executed. The pulse amplitude is set to the threshold value plus the safety margin.

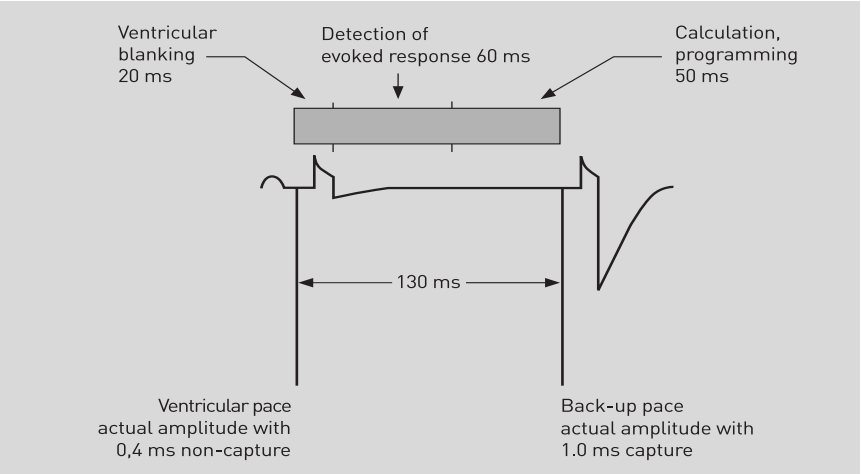
Note: The verification of capture response function does not work when the programming head or magnet is applied.

Backup pace

The algorithm checks the effectiveness of every single ventricular stimulus. If an ineffective stimulus is sensed, a backup pace with more energy will be delivered within 130 ms. The energy of this pace is increased in that the pulse width is increased to 1.0 ms.

The maximum pulse width that can be programmed with capture control is 0.4 ms, which causes the backup pulse to provoke a depolarization. Thus, the energy of the backup pace is 150% higher than the energy of the previous ineffective stimuli.

Diagram of the signal analysis when the stimulus is not effective



Algorithm for fusion discrimination

Fusion beats can significantly compromise signal morphology, which, in some cases, may cause such fusion beats to be classified as ineffective pacing.

A fusion beat occurs when the spontaneous depolarization could still not be sensed before the stimulus delivery from the pacemaker. An overlay of the spontaneous complex with the stimulus thus results.

Fusion discrimination is important during the pacing monitoring phase. During the signal check and the pacing threshold measurement, the AV delay is always reduced to 50 ms in order to avoid fusion beats.

Fusion beats do not compromise the safety of the algorithm but trigger backup pulses which would otherwise not be necessary. During capture response verification, ineffective pacing may be sensed for two reasons:

- Actual ineffective pacing
- Fusion beat

Fusion discrimination in 3 stages

Apart from the signal analysis and the threshold measurement, fusion discrimination is started with each case of ineffective pacing. Fusion discrimination occurs in three stages:

Sequence	Description
1	If an AV hysteresis is programmed, then the AV delay is prolonged to the value of the programmed AV hysteresis when an ineffective pace is sensed. If no AV hysteresis is programmed, the AV delay is prolonged for one cycle using the average AV hysteresis (+110 milliseconds). Extension of the AV delay serves to support the intrinsic rhythm and effectively discriminate a fusion beat. The AV delay remains extended as long as ventricular events are being sensed. If no intrinsic event is sensed, the pacemaker paces after the extended AV delay.
2	Return to the normal AV delay. If the stimulus is effective after the extended AV delay, the pacemaker returns to the normal AV delay. If an ineffective stimulus is sensed in the normal AV delay, the pacemaker switches to the third stage of fusion beat discrimination.
3	Reduction of the AV delay to 15 or 50 ms after As or after Ap. If effectiveness is sensed in two stimuli, the pacemaker reverts to regular pacing verification. If pacing was detected as ineffective even after the shortened AV delay, a new signal analysis with threshold measurement is initiated.

5.5.3 Configuring Capture Control, Parameters, and FAQ

What's in this section?

Setting Capture Control

Navigation: Parameters → Bradycardia/CRT → Capture control

WARNING
Pacing may become ineffective where an increase in the pacing threshold occurs if `Capture control` **=** `OFF` **or** `ATM` Where `ATM` or `OFF` is set, the pulse amplitude is not automatically adjusted. • When the setting is switched to `ATM` or `OFF`, make sure that there is sufficient safety margin when setting the pulse amplitude.

Note: Ventricular capture control is only available for RV and BiV pacing.

Parameters for capture control

The parameters have the following functions:

Parameter	Description
`Threshold test start`	Initial value for the pacing threshold measurement.
`Min. amplitude`	Prevents the pulse amplitude from falling below a particular value.
`Safety margin`	After successfully making automatic threshold measurements, if capture control = ON, the pulse amplitude is made up of the pacing threshold plus a safety margin.
`Search type`	Select `Search type`to determine the times or intervals during which the automatic pacing threshold search is executed continuously. Intervals or times can be alternately selected.
`Interval`	If you have selected Interval, then enter the period in which the pacing threshold measurement is performed in h.
`Time of day`	If you have selected Time of day, then enter the time of the pacing threshold measurement. Then the intervals are 24 h each.

Setting parameters

Proceed as follows:

Step	Action
1	Select **[Threshold test start]**, to set the initial value of the pacing threshold measurement.
2	Select **[Min. amplitude]** to prevent the minimum amplitude from falling below a particular value.
3	Select **[Safety margin]**, to adjust the safety margin. After successfully making automatic threshold measurements, if capture control = ON, the pulse amplitude is made up of the pacing threshold plus a safety margin.
4	Confirm your entries by pressing **[OK]**.

Capture control for triple-chamber devices

Capture control for triple-chamber devices works as follows:

Option	Explanation
Activation of capture control for both ventricles	The pacing threshold is determined first for the right ventricle and then for the left ventricle.
Fixing of the right ventricular pacing threshold	Ventricular pacing is temporarily set to right ventricular.
Fixing of the left ventricular pacing threshold	This happens under biventricular pacing where the left ventricle is first paced and the VV delay is set to 50 ms. Immediately after measuring the pacing threshold, permanent programmed ventricular pacing is set.

Display capture control status

Display	Description
`OK`	The capture control or ATM function is activated and operates without errors.
`Disabled`	Atrial and ventricular capture control are deactivated when the replacement indication ERI is reached or when lead impedance goes outside the permitted range of values (200 to 3000 Ω).
`Pending`	The device could not yet determine a valid pacing threshold.

Ventricular and Atrial Capture Control - Programmable Parameters

Parameter overview

Parameter	Range of values and explanations
Capture control	ON; OFF; ATM (monitoring only)
Minimum amplitude (atrial)	0.5 ... (0.1) ... 4.8 V The minimum amplitude and threshold test start (maximum atrial amplitude) parameters prevent a certain value of the ventricular amplitude from being exceeded or undershot during the threshold search.
Minimum amplitude (ventricular)	The value 0.7 V is a fixed preset. It is not programmable and is not displayed for ventricular capture control. The minimum ventricular amplitude and threshold test start (maximum ventricular amplitude) parameters prevent a certain value of the ventricular amplitude from being exceeded or undershot during the threshold search.
Threshold test start (maximum ventricular and atrial amplitude)	2.4; 3.0; 3.6; 4.2; 4.8 V
Search type	Interval; time of day The search type parameter determines the times or intervals during which the signal quality is continuously verified and the automatic threshold search is executed. Intervals or times can be alternately selected.
Interval	0.1; 0.3; 1; 3; 6; 12; 24 hours
Time of day	00:00 to 24:00 h, min. time unit of 10 min.
Safety margins of the ventricular and atrial pulse amplitudes	Atrial safety margin: 0.5 ... (0.1) ... 1.2 V Ventricular safety margin: 0.3 ... (0.1) ... 1.2 V The value of the pulse amplitudes, which is set by the function, is made up of the most recently measured pacing threshold plus the configured safety margin or the programmed initial amplitude + 1.2 V for the ventricle and 1 V for the atrium if the pacing threshold is higher than the initial amplitude (Threshold test start).

Function options The following options are available for the capture control function:

Options	Explanations
Capture control	ON; OFF; ATM (monitoring only)
ON option	This option activates all sub-functions: The pacing threshold is monitored and recorded; the pacing energy is adapted continuously for the ventricle and periodically for the atrium. This is done with the following: • Signal analysis (ventricle only) • Automatic pacing threshold search • Verification of capture response (ventricle only)
OFF option	This setting deactivates the entire capture control function.
Automatic threshold monitoring (ATM) option	The pacing threshold is monitored and recorded at programmable time intervals. This is done with the following: • Signal analysis (ventricle only) • Automatic pacing threshold search Accordingly, **no** continual adaptation of the pulse amplitude is performed.

CAUTION
When selecting the ATM or OFF options, make sure that a sufficient safety margin is selected when setting the pulse amplitude since there is no automatic tracking of the pulse amplitude for these options.

FAQ - Frequently Asked Questions

Overview

The following questions regarding the behavior of capture control in particular situations will be answered:

- When are the atrial and ventricular thresholds measured?
- Which atrial and ventricular events cause temporary deactivation of capture control?
- What is the response to magnet and programming head application?
- How does the capture control function behave on reaching ERI?
- How do fusion beats affect ventricular capture control?
- What should be observed when pacing with single-chamber devices?

When are the atrial and ventricular thresholds measured?

In addition to the pacing threshold search after loss of capture response, the following measurements are carried out as follows:

- At a defined time of day

The pacing threshold measurement is conducted, in order to ensure an exact safety margin also in the case of slow changes in the pacing threshold.

If the pacing threshold measurement is initiated by a sudden loss of capture response, the counter causing the next periodical measurement is reset.

Which atrial and ventricular events cause temporary deactivation?

During the following events, automatic adaptation of the amplitude and verification of the capture response are temporarily turned off and automatically reactivated after the end of the event:

- Mode switching
- Sustained noise response
- Rates > 110 bpm
- The last measured pacing threshold plus safety margin is greater than the maximum amplitude (Threshold test start)

For the duration of the event, the amplitude is set at the last measured pacing threshold plus 1.2 V (highest safety margin). If the algorithm is temporarily interrupted, then the status OK is displayed during interrogation.

What is the response to magnet and programming head application?

The process is momentarily interrupted by magnet and programming head application during the signal analysis or the pacing threshold measurement and is restarted after 3 – 4 cycles following application if magnet response is set to SYNC (synchronous).

Monitoring of pacing success is interrupted during magnet application if magnet response is set to ASYNC (asynchronous).

During communication with the programming head, the function is disabled and is reactivated when the programming head is removed.

How does the capture control function behave on reaching ERI?

When ERI is reached, capture control is deactivated. The amplitude is set to the most recent automatically measured pacing threshold plus 1.2 V in the ventricle, while the amplitude in the atrium is set to the most recent automatically measured pacing threshold plus 1 V.

How do fusion beats affect ventricular capture control?

If pacing is classified as ineffective because of a fusion beat, a backup pace is delivered. Fusion beats do not compromise safety, however, they lead to unnecessary backup pacing. In the following cycles the AV delay can be extended or shortened to 15/50 ms (after As/Ap) in order to avoid fusion beats and to prevent the sensing of loss of capture response (3 consecutive ineffective Vp) because of fusion beats.

Which status messages are displayed?

Status description:

Display	Description
`OK`	The capture control or ATM function is activated and operates without errors.
Ventricular capture control `Disabled`	After implantation, the implanted device attempts to permanently activate ventricular capture control. The device disables the ventricular capture control permanently if 24 measurements have failed per day. Possible reasons for this status are: • If a polarization artifact that is too large or ineffective pacing at maximum amplitude is sensed during signal analysis after programming, then the device sets the amplitude to the value programmed for threshold test start and indicates the status deactivated. • Reaching the replacement indication ERI • Lead failure (lead impedance outside the permitted range of values 200 to 2500 ohm) • If loss of capture is detected 24 times within 24 h, then the amplitude is set to the value programmed for threshold test start plus 1.2 V and the function is deactivated.
Atrial capture control `Disabled`	The device disables the atrial capture control permanently if the following events have occurred: • Reaching the replacement indication ERI • Lead failure (lead impedance outside the permitted range of values 100 to 2500 ohm) • If loss of capture is detected, then the amplitude is set to the value programmed for threshold test start plus 1.0 V and the function is deactivated.
`Pending`	The device could not yet determine a valid pacing threshold. Further measurements will be made.

What actions can be taken in the case of an inactive ventricular status?

If insufficient signal morphology is the reason for unsuccessful measurement, then it can be remedied by changing the following parameters:

- Amplitude (Threshold test start, e.g. 2.4 V)
- Pulse width (e.g. 0.3 ms)
- Polarity (from unipolar to bipolar)

Changing these parameters can result in successful measurement.

Note: Activation of capture control via auto-initialization or manual activation sometimes fails during implantation because the implantation damage causes the pacing thresholds to increase. In the first weeks following implantation, the pacing threshold drops again so that the capture control can be activated either automatically or manually.

What should be observed when pacing with ventricular single-chamber devices?

In order to ensure pacing in single-chamber devices during signal analysis and verification of stimulus response, the device paces at a rate that is 10 bpm higher than the intrinsic rhythm.

Comparison of Atrial and Ventricular Capture Control

A comparison of differences between atrial and ventricular capture control

Atrial capture control	Ventricular capture control
The pacing threshold is determined using sensing markers	The pacing threshold is determined by the beat-to-beat measurement of evoked responses.
Reduction of the start amplitude of the pacing threshold test (Threshold test start) has no impact on the test result and makes the test faster.	Reduction of the start amplitude of the pacing threshold test (Threshold test start) from 3.0 V to 2.4 V increases the chances of success because the polarization artifacts are smaller in the leads. In addition to this, it makes the test faster.
Safety margin: 1.0 V (default setting)	Safety margin: 0.5 V possible because of beat-to-beat monitoring with backup pacing in the case of ineffective pacing
Switching on using auto-initialization. The first measurement is performed at the programmed time (default setting: 00:30 h).	Switching on using auto-initialization. The first measurement is performed at the programmed time (default setting: 00:30 h).

5.6 Rate Adaptation

What's in this section?

5.6.1 Pacing Modes

What's in this section?

Rate-Adaptive Modes

Rate adaptation principles

The device uses 2 independent principles for rate adaptation:

- Physiological rate adaptation via Closed Loop Stimulation
- Rate adaptation using the accelerometer

An overview of rate adaptation

The programmable rate-adaptive modes can be categorized as follows:

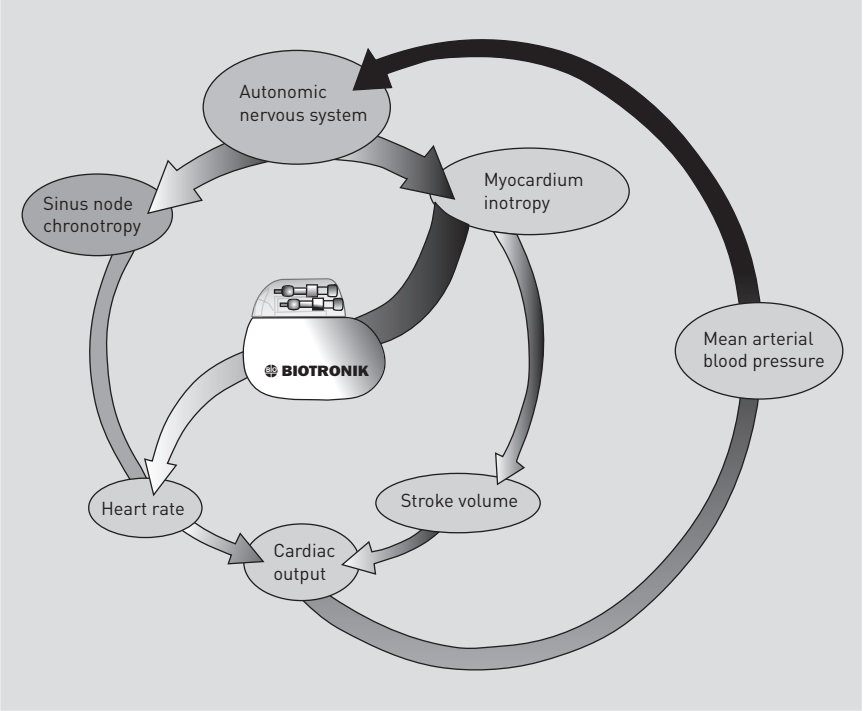
Rate adaptation	
Closed loop stimulation	**Accelerometer**
DDD-CLS VVI-CLS	DDDR DDIR D00R DVIR DDDR-ADIR VDDR VVIR VDIR V00R AAIR A00R

5.6.2 Physiological Rate Adaptation (CLS Function)

What's in this section?

The Closed Loop Stimulation Principle

The contraction dynamics of the myocardium vary depending on the patient's exertion. The changes are characteristic and closed loop stimulation uses these to generate a physiological pacing rate specific to the patient. This also applies to the patient's mental stress.



The pacemaker evaluates the dynamics of the contraction of the myocardium (inotropy) in a short time period after the beginning of ventricular excitation. Impedance measurement is carried out with a ventricular lead and is primarily dependent on the specific conductivity of a small volume surrounding the lead tip.

The impedance changes are characteristic for the ventricular contraction procedure and directly proportional to the stress on the heart. The pacemaker calculates the required pacing rate using a reference measurement with a reference impedance curve recorded at rest. The CLS responds immediately at the beginning of stress by using contractility as input information for rate adaptation. Therefore, the combination with rate adaptation by accelerometer is not necessary.

Closed loop stimulation is self-calibrating and automatically adjusts to the patient's situation within just a few minutes. Typically, there is no need to manually fine-tune the system. Automatic fine-tuning is active during the entire service time of the pacemaker.

Among other things, pacing cycles with extended or shortened AV delays update the reference impedance curves at regular intervals.

However, some individual cases (e.g. if the patient is extremely active or extremely inactive) may require adjustment of the CLS.

Individual Adjustment of CLS Parameters

Overview The following parameters can be individually adjusted in the **CLS → Show CLS expert parameters** window:

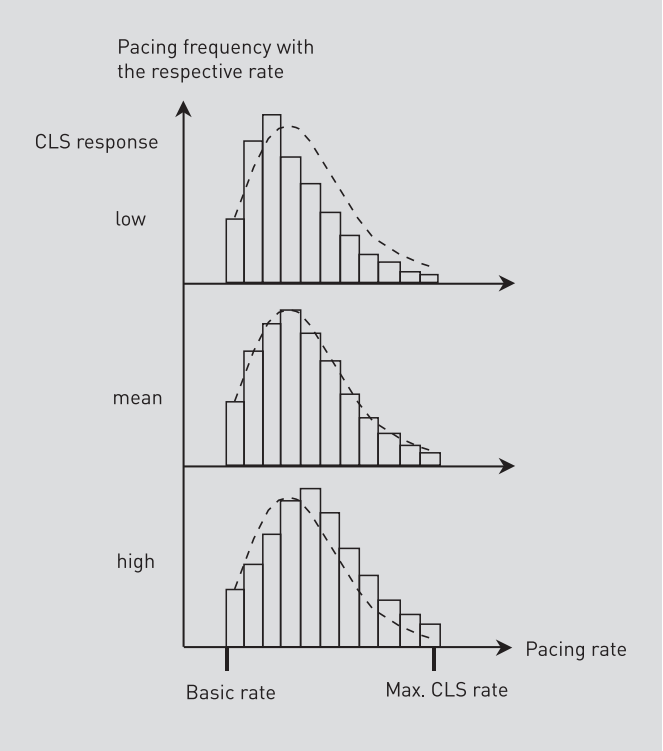
- Vp required
- CLS response
- Resting rate control (dynamic rate limit)

Vp required In the mode DDD-CLS, an AV hysteresis is set by default to support existing adequate intrinsic AV conduction. For patients with inadequate or non-existent intrinsic AV conduction, it may be necessary to deactivate the AV hysteresis. The [Vp required] parameter is activated for this.

CLS response The factory settings for closed loop stimulation are made so as to ensure that the majority of patients receive optimum rate dynamics. Adjustment is not usually required.

However, the rate profile resulting from closed loop stimulation can vary greatly from patient to patient. In individual cases, the rate dynamics can be optimized if the rate distribution is inadequate.

The parameter [CLS dynamics] affects an internal device target rate, which depends on the preset basic and maximum closed loop rate parameters. The device internally controls rate adaptation so that 20% of the pacing events are always above the internal target rate. If the CLS dynamics parameter is reprogrammed, then increasing setting values result in rate distribution towards higher middle rates and lower setting values result in rate distribution with lower rates.



Resting rate control

This parameter limits the pacing rate attainable at rest to the programmable value of, e.g., 20 bpm above the set basic rate. This serves to suppress unspecific rate excursions at rest without limiting rate adaptation in cases of mental stress. This can be switched off if a high rate limit is not desired from the clinical perspective.

The exact value depends on the relationship between the basic rate and the maximum closed loop rate.

CLS Safety Feature

The pacemaker regularly checks the requirements for correct closed loop stimulation internally. If one of the requirements is not met, then closed loop stimulation is interrupted. The accelerometer takes on rate adaptation for the duration of the interruption. Once all requirements have been met, closed loop stimulation is automatically activated again. The following events interrupt closed loop stimulation:

- Automatic initialization of CLS
- Mode switching
- Ventricular fusion beats
- Inadequate impedance values
- Hardware and software errors

Setting Closed Loop Stimulation

Navigation: Parameters → Bradycardia/CRT

Objective

Closed loop stimulation creates a physiological adjustment of the pacing rate specifically for the patient for periods of physical or mental stress.

Description of closed loop stimulation

The contraction dynamics of the myocardium vary depending on the patient's exertion. The device evaluates the dynamics of the contraction of the myocardium in a short time period after the beginning of ventricular excitation. The device creates a stress-specific pacing rate based on characteristic impedance changes. Closed loop stimulation is self-calibrating and adjusts itself automatically to the particular circumstances of the patient.

Note: There is usually no need to manually fine-tune the system.

Description of CLS expert parameters

Parameter	Description
`CLS response`	The rate profile resulting from closed loop stimulation can differ widely depending on individual requirements. In individual cases, the rate dynamics can be optimized if rate distribution is not adequate. CLS response determines how the profile of rate distribution can be changed. The setting `Very high` moves the rate profile to higher values, while the setting `Very low` moves the rate profile to lower values.
`CLS resting rate control`	The resting rate control serves to limit the pacing rate possible during resting and hence enables stable rate adaptation.
`Vp required`	In the pacing mode DDD-CLS, an AV hysteresis is entered as a default value to support existing adequate intrinsic AV conduction. If ventricular pacing is necessary, then when this parameter is activated, AV hysteresis is switched off and ventricular pacing is encouraged. **Note:** If the patient has intermittent sufficient intrinsic AV conduction, then this parameter should not be activated.

5.6.3 Rate Adaptation using the Accelerometer

What's in this section?

The Principle of Rate Adaptation via Accelerometer

Objective

Sensor-controlled rate adaptation allows an adjustment of the pacing rate to changing metabolic needs at rest and during exertion.

Technical realization

The pacemakers are equipped with an accelerometer that is integrated into the hybrid circuit. This sensor produces an electric signal which is constantly processed by analog and digital signal facilities.

If a rate-adaptive mode is programmed, then this results in an adjusted increase of the basic rate, depending on the exertion level of the patient.

Due to the integration of the sensor in the hybrid circuit, it is not sensitive to static pressure on the housing.

Description

The pacing rate increases at the onset of exercise to the sensor determined rate. It slowly returns to the basic rate when exercise is no longer sensed.

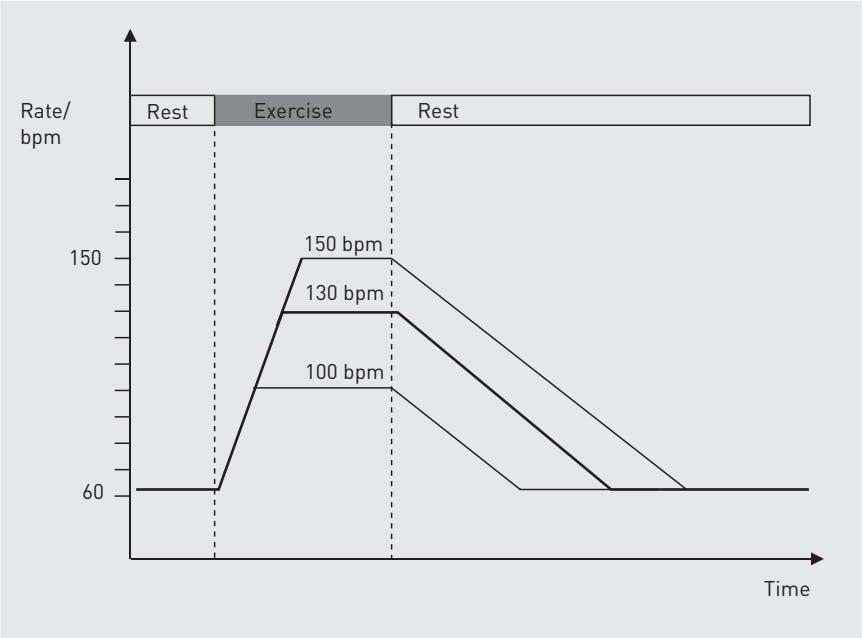
The sensing and inhibition function remains active during sensor-controlled operation. In case of high pacing rates, however, the refractory period may potentially cover a majority of the basic interval, resulting in asynchronous pacing.

Maximum Activity Rate

Description Regardless of the sensor's sensed signal amplitude, the pacing rate will not exceed the programmed maximum activity rate.

The programmed value applies only to the maximum pacing rate during sensor-controlled operation and is independent of the upper tracking rate.

Note: In the DDIR and DVIR modes, lower maximum sensor rates result than those indicated here, depending on the selected AV delay. The respective values are indicated by the programmer.
The shorter the selected AV delay is, the higher the maximum sensor rates can become.



Sensor Gain

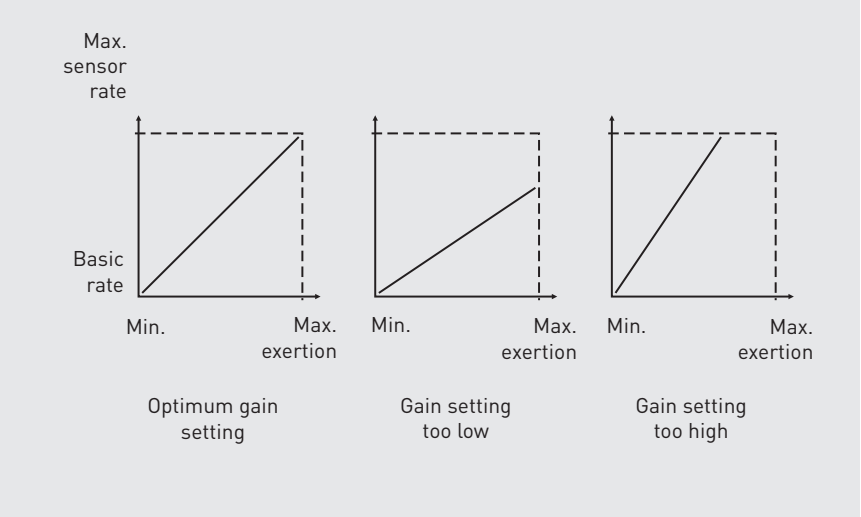
Definition The sensor gain designates the factor by which the electric signal of the sensor is amplified before subsequent signal processing occurs.

Objective The programmable sensor gain permits adaptation of the desired rate adaptation to the individually variable signal strengths.

Description The optimal parameter setting is achieved when the desired maximum pacing rate is reached during maximum exertion.

Before adjusting the sensor gain, the rate increase, rate decrease, and maximum sensor rate parameters must be checked for their suitability with respect to the individual patient.

If the rate increase is not sufficient during high levels of physical exertion, the sensor gain should be increased. On the other hand, the sensor gain should be reduced if high rates are obtained at low levels of exertion.



Note: Automatic sensor gain complements the manual sensor gain adjustment option; see Automatic Sensor Gain, p. 114.

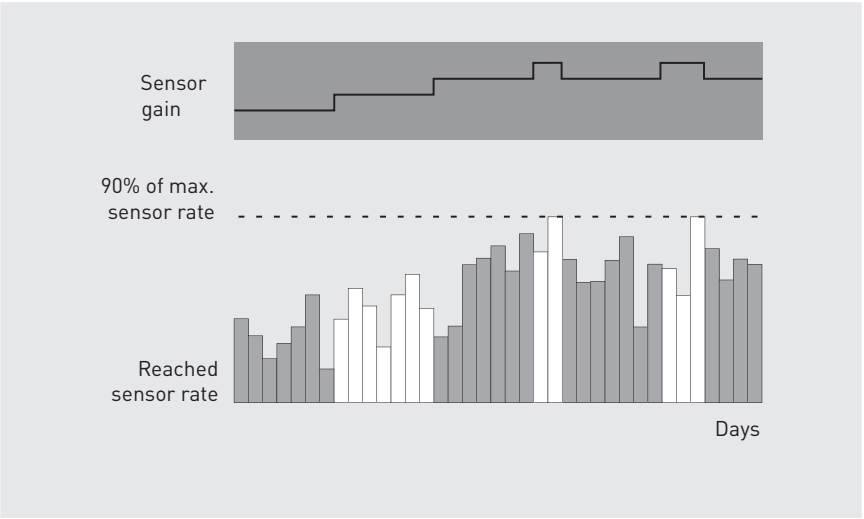
Automatic Sensor Gain

Description

The manually programmable sensor gain is supplemented by an automatic sensor gain function. When the function is enabled, the pacemaker continuously checks whether sensor gain optimally corresponds to the patient's needs and makes adjustments if necessary.

The automatic sensor gain function checks daily whether 90% of the set maximum activity rate has been reached for a total of 90 seconds. If this occurs, it decreases the sensor gain by one increment.

If the maximum activity rate is not reached, the current setting remains initially unchanged. If the MAR is not reached within a period of 7 days, sensor gain is increased by one increment.



Sensor Threshold

Definition

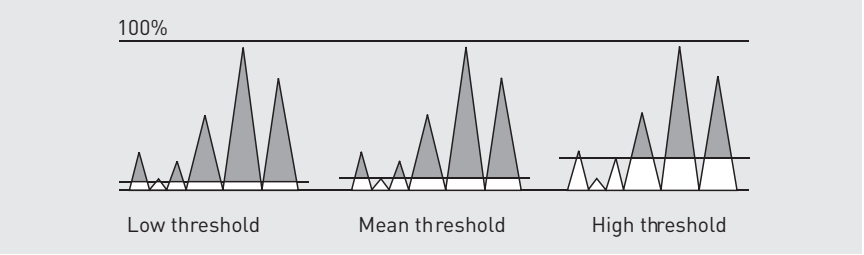
The minimum strength of the signals used for rate adaptation is determined with the programmable sensor threshold. Sensor signals below this threshold do not affect rate adaptation.

Purpose

With the programmable sensor threshold, a stable rate can be achieved when the patient is at rest by ignoring low-amplitude signals that have no relevance to increased levels of physical exertion.

Setting the sensor threshold

If the pacing rate at rest is unstable or reaches values that are above the basic rate, the sensor threshold should be increased. On the other hand, the sensor threshold should be reduced if a sufficient rate increase is not observed with slight exertion. The sensor gain should be adjusted before setting the sensor threshold.



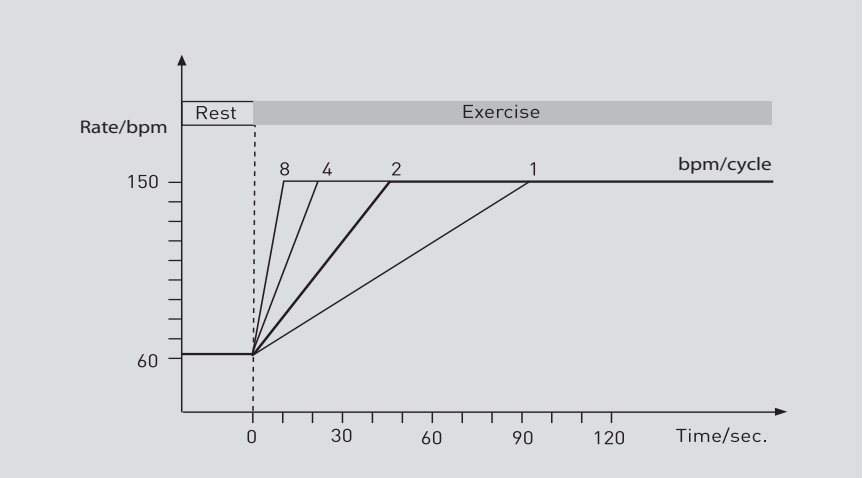
Rate Increase

Description

The rate increase parameter determines the maximum speed at which the pacing rate rises if the sensor signal indicates increasing exertion.

For example, setting the rate increase to 2 bpm per cycle means that the rate increases from 60 bpm to 150 bpm in 45 cycles.

The programmed rate increase applies only to sensor-controlled operation and does not affect the rate changes during atrial-controlled ventricular pacing.



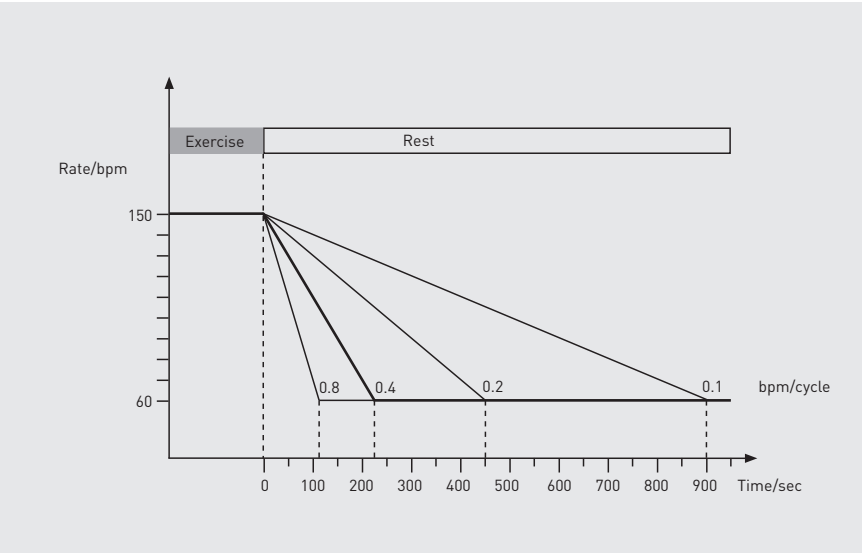
Rate Decrease

Description

The programmed rate decrease parameter determines the maximum speed by which pacing is reduced if the sensor signal indicates decreasing exertion.

For example, setting the rate decrease to 0.5 bpm per cycle means that the rate decreases from 150 bpm to 60 bpm in 180 cycles.

In the modes DDIR and DVIR, the rate decrease is slightly slower than indicated here (partly depending on the programmed AV delay).



Sensor Simulation

Definition Even when a non-rate-adaptive mode is programmed, the sensor response is recorded without being effective. In other words, the sensor simulation indicates how the sensor would have responded if a rate-adaptive mode had been programmed.

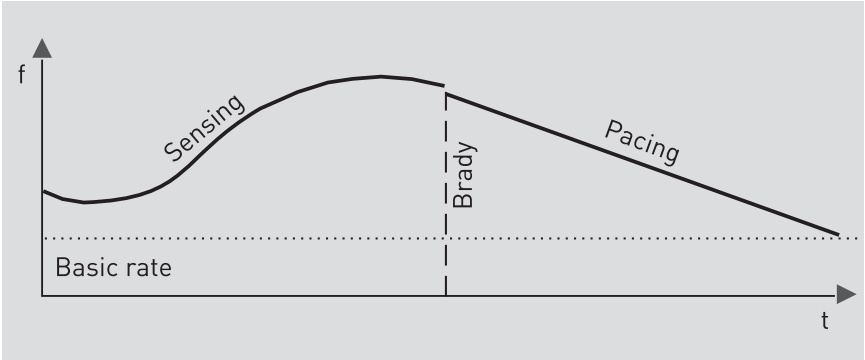
Purpose This function is helpful to find the optimum sensor settings and to compare the sensor rate with the intrinsic rhythm.

Thus, sensor information is available prior to the activation of the rate adaptation, which can be used to evaluate the sensor response; Displaying Other Statistics, p. 159.

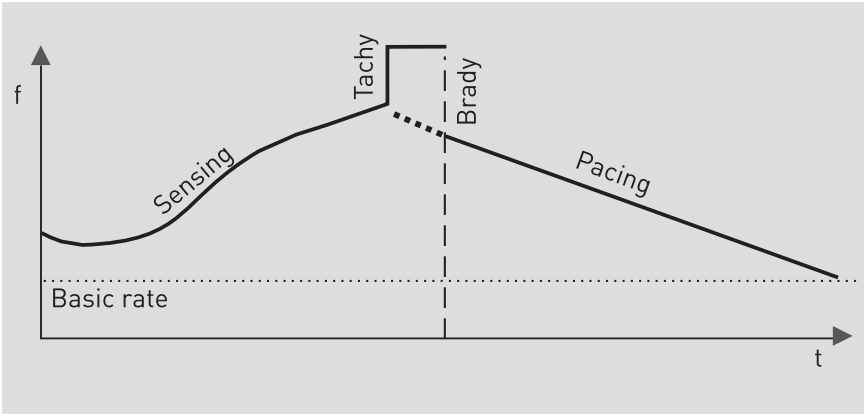
Note: In the sensor simulation, you can only select sensor threshold values that are greater than those used in the permanent program.

Rate Fading

Rate fading results in improved adjustment of the pacemaker's pacing rate to the patient's intrinsic rhythm in the case of sudden bradycardia.



If rate fading is activated, then the pacemaker calculates the backup rate, which is always active in the background. As soon as the rate decreases, the pacemaker paces with the backup rate. With a certain delay, the backup rate follows the heart rate according to the programmable rate increase (1... 10 bpm/cycle) and the programmed rate decrease (0.1; 0.2; 0.5; 1.0 bpm/cycle). These settings determine the sensitivity of the controlled rate fading.

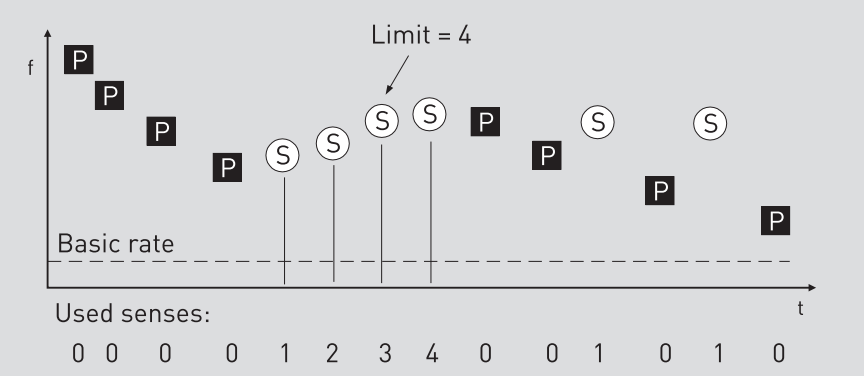


After 4 consecutive As, the target rate for the backup rate is calculated from the current atrial rate minus 10 bpm. AES and Ap set the target rate to the value of the basic or sensor rate.

In cases of sudden atrial tachycardia, which result in mode switching, the target rate is set to the sensor or basic rate. The current pacing rate in the ventricle results from the current value of the backup rate prior to the mode switching event.

If the pacing rate reaches the heart rate upon rate decrease, then at least 4 consecutive intrinsic cycles above the pacing rate are required to adjust the pacing rate to the last intrinsic event.

This way rate fading is continued during intermittent sensed events.



4 consecutive sensed events are required to activate rate fading. Individual sensed events have no impact on rate fading.

Table 2: Backup rate and target rate

Backup rate	Rate at which the pacemaker paces in the case of sudden rate decrease. It can be up to 10 bpm (maximum) lower than the heart rate and follows the target rate upwards at the set value (1; 2; 4; 8 bpm) per cycle or falls at the set value (0.1; 0.2; 0.5; 1 bpm) per cycle if the target rate is lower than the current backup rate.
Target rate	The target rate is either the current rate minus 10 bpm or the sensor or basic rate. The backup rate follows the target rate at the programmed rate increase or decrease.

Sensor Functions – Details

Navigation: Parameters → Bradycardia/CRT → Sensor/Rate fading

Maximum sensor rate

Regardless of the sensor's detected signal amplitude, the pacing rate will never exceed the programmed maximum sensor rate. The programmed value refers to the maximum pacing rate in sensor control and must be less than the upper rate.

Note: The shorter the selected AV delay, the higher the maximum sensor rates can become. The respective values are displayed on the programmer but not in DDIR mode.

Sensor gain

The programmable sensor gain designates the factor by which the electric signal of the sensor is amplified. This allows the rate adaptation to be modified for individually variable signal strengths. The optimal setting is achieved when the desired maximum sensor rate is reached during maximum exertion. Before adjusting the sensor gain, the rate increase, rate decrease, and maximum sensor rate parameters must be checked for their suitability with respect to the individual patient.

Automatic gain

The programmable sensor gain is supplemented by the automatic sensor gain function. Every day, the device checks whether 90% of the set maximum sensor rate has been reached for a certain total duration (for at least 90 s (cumulative) within one day).

If ...	Then ...
90% of the set maximum sensor rate is reached	the sensor gain decreases by one increment.
90% of the set maximum sensor rate has not been reached within 7 days,	the sensor gain increases by one increment.

Sensor threshold

The minimum signal strength used for rate adaptation is determined using the programmable sensor threshold. Sensor signals below this threshold do not affect rate adaptation. With the sensor threshold, a stable rate can be achieved when the patient is at rest by ignoring low-amplitude signals that have no relevance for increased levels of physical exertion. If the pacing rate at rest is unstable or reaches values that are above the basic rate, the sensor threshold should be increased. On the other hand, the sensor threshold should be reduced if a sufficient rate increase is not observed with slight exertion. The sensor gain should be adjusted before setting the sensor threshold.

Rate increase

The programmed rate increase value determines the maximum speed at which the pacing rate rises if the sensor signal indicates increasing exertion. A setting of the rate increase of 2 bpm per cycle, for example, means that the rate increases from 60 bpm to 150 bpm in 45 cycles. The programmed rate increase applies only to the rate analyzed by the sensor.

Rate decrease

The programmed rate decrease value determines the maximum speed by which pacing is reduced if the sensor signal begins decreasing. A setting for rate decrease of 0.5 bpm per cycle, for example, means that a rate of 150 bpm will fall to 60 bpm within 180 cycles.

Note: In DDIR mode, the actual rate decrease is sometimes slower, depending partly on the programmed AV delay.

Sensor simulation

Even when a non-rate-adaptive mode is programmed, the sensor response is recorded without being effective. As a result, when rate adaptation is activated there will already be data according to which the sensor response can be evaluated in the histogram.

Rate fading

In all pacing modes, the rate fading function can, in cases of sudden rate decreases, lead to a controlled adjustment of the pacing mode of the device to the patient's intrinsic rhythm, to the programmed basic rate or to the sensor rate.

If rate fading is activated, the device calculates the backup rate, which is always active in the background. When a sudden decrease of the heart rate occurs, the device immediately begins to pace at the backup rate and regulates the process of rate decrease guided by the backup rate and the rate fading settings.

5.7 Antitachycardia Functions

What's in this section?

Upper Rate

Navigation: Parameters → Bradycardia/CRT → Upper rate

Description

In all of the triggered pacing modes, the upper rate limits the pacing rate triggered by atrial sensing.

The settings help prevent the conduction of atrial tachycardias to the ventricle.

WARNING
Triggering the ventricle: Conduction of atrial tachycardias Intrinsic atrial tachycardias can be transmitted to the ventricle from the device at a rate of up to 160 bpm. • Reduce the upper rate. • Adjust the mode switching parameters. • Program a ventricular-controlled mode (DDI, VVI, VDI or sim.)

Device response

The response of the implanted device at the upper rate (Wenckebach (WKB) or 2:1) is pre-set via a combination of several parameters – including AV delay and PVARP. They cannot be set directly.

- **Wenckebach response** occurs when the intrinsic rhythm exceeds the upper rate.
- **2:1 response** occurs when the intrinsic rhythm exceeds the rate resulting from the following: 60,000 divided by AV delay plus PVARP.

Displaying results

The display in the `Wenckebach response of` field (from n to m bpm) is the rate range in which the implanted device exhibits Wenckebach response.

Atrial upper rate

The upper rate in the atrium should prevent atrial pacing from occurring in the vulnerable period of the atrium after an atrial sensed event during PVARP. The upper rate in the atrium should therefore ensure that the next atrial stimulus is delivered outside the natural atrial refractory period of the heart.

Atrial Upper Rate

Abbreviations

Abbreviations and their meanings in graphics and text:

Abbreviation	Meaning
Intrin. atr. refr.	Intrinsic atrial refractory period
BI	Basic interval
AV	AV delay
As	Atrial sensed event
Ap	Atrial paced event
ARP	Atrial refractory period
AUR	Atrial upper rate
Vs	Ventricular sensed event
Vp	Ventricular paced event
VRP	Ventricular refractory period
PVARP	Post-ventricular atrial refractory period
As (PVARP)	As in the PVARP starts the AUR (atrial upper rate)
FFPp	Far-field protection after pacing

Problem: Atrial tachycardias triggered by PAC

A premature atrial contraction (PAC) which occurs within the PVARP interval depolarizes the atrium.

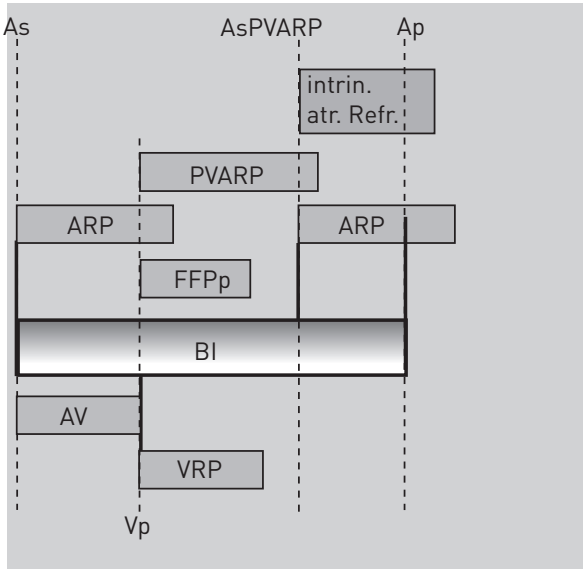
As a consequence, the atrial tissue is refractory for 150 - 220 ms.

Pacing in the vulnerable period depends on the following factors:

- PVARP configuration
- Current heart rate

Pacing in the atrium at the end of the refractory period can trigger an atrial tachycardia.

Atrial pacing at the end of the PVARP in the vulnerable phase:



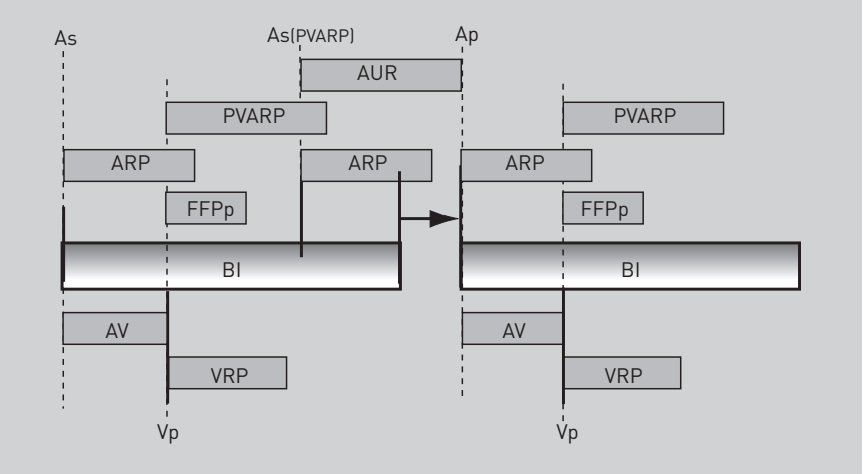
Atrial upper rate as safety interval

This function protects against atrial tachycardias. The safety interval functions as follows:

- Each sensed atrial event during the PVARP (As(PVARP)) starts the atrial upper rate (AUR).
- During a sustained episode of AUR, an intended atrial pace (Ap) is shifted to the end of the AUR.

The standard value for the atrial upper rate is 240 bpm (250 ms).

Shifting of the atrial stimulus to the end of AUR:



Mode Switching

Navigation: Parameters → Bradycardia/CRT → Mode switching

Objective The conduction of high atrial rates and atrial tachycardias to the ventricle is prevented through the use of mode switching, for example, from DDD to DDI on the basis of X/Z-out-of-8 algorithm.

Description

- An atrial tachycardia is considered detected where the X-out-of-8 onset criterion is fulfilled. The 8 currently most recent atrial intervals are evaluated for detection purposes.
- During detection the device switches into ventricularly controlled mode. This mode remains active until the resolution criterion (Z-out-of-8) is fulfilled.
- If Z out of 8 intervals are below the programmed intervention rate, the device switches off automatically into the atrially controlled mode originally programmed.

Meaning of parameters The mode switching parameters have the following meanings:

Parameter	Meaning
Intervention rate	Rate at which an atrial tachycardia is detected.
Switch to	The ventricularly controlled mode into which it is intended to switch the device.
Ventricular pacing	Configuration of ventricular pacing for mode switching Set the CRT parameters: Setting Ventricular Pacing, p. 48
Change of basic rate	Rate for the duration of mode switching
Onset criterion	Total atrial intervals **above** the intervention rate (**X-**out-of-8): leads to mode switching
Resolution criterion	Total atrial intervals **below** the intervention rate (**Z-**out-of-8): terminates mode switching
Rate stabilization during mode switching	This prevents any rapid fall in the ventricular rate: • To configure the required ventricular rate, the sensed atrial rate is not used. Instead, the mean sensed ventricular rate minus 10 bpm is used as the pacing rate. If no ventricular rate is sensed, then the basic rate is used for mode switching.
2:1 Lock-in protection	• During high atrial rates (atrial flutter) in combination with a relatively long AV delay, every second P wave can occur regularly in the atrial far-field protection interval. The device's timing behavior is then similar to a 2:1 block: when atrial flutter is sensed at 280 bpm, the ventricle is paced at 140 bpm. In order to terminate this block using 2:1 lock-in, the AV delay is extended by the value of far-field protection and switched to a ventricular-controlled pacing mode. • 2:1 lock-in protection in combination with mode switching prevents mode switching from not starting or from only starting at very high rates.

2:1 or Wenckebach Response

Description

The resulting mode, either 2:1 or Wenckebach (WKB), is automatically displayed, depending on the combination of selected parameters. The parameters that affect this are:

- Upper tracking rate (UTR)
- Atrial refractory period

Wenckebach response

A response similar to Wenckebach block (Wenckebach response) results if the selected upper tracking rate is lower than the rate corresponding to the atrial refractory period.

If the upper tracking rate is exceeded in Wenckebach response, the AV delay is continually prolonged so that the ventricular pacing rate does not exceed the programmed upper tracking rate.

If the selected upper tracking rate exceeds the rate corresponding to the atrial refractory period, the maximum P-wave-triggered ventricular rate results exclusively from the atrial refractory period, not from the programmed upper tracking rate.

Note: The extended AV delay in Wenckebach response and the associated decoupling of the atrium and ventricle rhythms increase the likelihood of sensing retrograde P waves. This should especially be considered if the dynamic AV delay is to be used for preventing or terminating (pacemaker-mediated) tachycardia, since the Wenckebach response deactivates the dynamic AV delay when the upper rate is exceeded.

2:1 behavior

If the length of the atrial cycle is shorter than the programmed atrial refractory period, a 2:1 block, then a 3:1 block, etc., will result before the upper tracking rate is reached in the ventricle (DDD mode, 2:1 response).

Resulting pacing rate

If the resulting length of the spontaneous atrial cycle is shorter than the upper rate interval in a rate-adaptive mode, the resulting pacing rate will depend on whether the 2:1 rate has been exceeded. If this is the case, the sensor rate will be used as the pacing rate.

If the 2:1 rate is not exceeded, the pacemaker will use a rate that lies between the sensor rate and the rate determined by the atrial refractory period. In the latter case, the cycle length switches between the sensor-defined interval and a shorter interval, which is at least the amount of the ARP. Response then depends on the response of the atrial rate to sensor rate and on the atrial refractory period.

2:1 Lock-In Management

Description

In cases of high atrial rates (atrial flutter) in combination with a relatively long AV delay, it is possible that every second P wave regularly occurs in the atrial far-field blanking. In this case, the device detects only half of the present atrial rate.

Therefore the behavior of the device is similar to a 2:1 block. The device paces in the ventricle at a rate corresponding to half the atrial rate. At very high atrial rates, this can cause physiologically unsuitable high ventricular rates.

If atrial fibrillation is sensed at a rate of 280 bpm, then pacing is performed at a ventricular rate of 140 bpm.

This phenomenon is called 2:1 lock-in and can cause the patient serious discomfort in cases of prolonged atrial tachyarrhythmias.

Impact on mode switching

It is possible that, in a 2:1 situation such as this, the Mode Switching function will not be started or will only be started at very high rates even though this would be necessary. Therefore this function is intended to ensure effective application of Mode Switching.

In order to terminate this behavior (2:1 lock-in), the AV delay is extended by the value of the far-field blanking and it can be switched to a ventricular-controlled pacing mode. The algorithms of the 2:1 lock-in behavior are designed as follows:

- Suspicious phase
- Confirmation
- Termination

Suspicious phase

The following criteria have to be met to fulfill the conditions of the 2:1 situation:

- 8 consecutive VpAs intervals have to occur.
- The actual ventricular rate must exceed 100 bpm.

If these conditions are met, then the 2:1 lock-in situation is considered confirmed.

Confirmation

Detection is initiated as follows:

- The AV delay is extended for a cycle of up to 300 ms to confirm the 2:1 lock-in situation. Therefore events that were previously within the blanking period are detected by the device as atrial refractory events.

Termination

Termination is initiated as follows:

- If the As-Ars interval reaches the mode switching rate, then the device immediately switches to the previously selected ventricular mode (without previously evaluating the criteria for X/Z-out-of-8 mode switching).
- If the rate corresponding to the As-Ars interval is greater than the mode switching rate, then the AV delay is reduced to the current value in 50 ms increments.

Programmable parameters

The following parameter is displayed in the mode switching window and can be set there.

2:1 lock-in protection	ON; OFF

PMT Prevention

Purpose

PMT prevention

PMT occurrence

- Pacemaker-mediated tachycardia is generally triggered by ventricle depolarization that is asynchronous with atrial depolarization, e.g., as would be the case in premature ventricular contractions (PVC).
- The tachycardia is maintained retrogradely by VA conduction of paced ventricle depolarization and antegradely by P-wave-triggered ventricular pacing.

PMT prevention measures

In the case of ventricular detection without previous atrial event, the following intervals are restarted to prevent a PMT:

- Basic interval
- Post-ventricular atrial refractory period (PVARP)
- Extending the atrial refractory period after a PVC

Result

A retrograde P wave with a VA conduction time shorter than the PVARP cannot initiate a ventricular pace and hence cannot trigger a PMT.

Extending the atrial refractory period through PVARP

Subsequent to a ventricular event, the atrial refractory period is extended through PVARP (if set) by the programmed value if the following events occur:

- A ventricular sensed event without a preceding atrial event (PVC); pacing modes: DDD(R), DDT(R), VDD(R)
- A ventricular pace event that has not been triggered by a P-wave; pacing modes: VDD(R)

Note: An atrial refractory period extension through PVARP might be necessary in the case of a short atrial refractory period in conjunction with a long VA conduction period in order to prevent the triggering of a PMT by asynchronous ventricular depolarizations.

PMT protection

Overview

- PMT detection
- PMT termination

Objective

Pacemaker-mediated tachycardias can also be caused by artifacts and atrial extrasystoles. In such cases, the PMT protection algorithm offers functions to provide both reliable detection as well as termination of PMTs. In this way, the hemodynamically more favorable AV synchronization can rapidly be re-established.

PMT detection using the VA criterion

The period between a ventricular event and the sensing of a retrograde P wave is designated as the VA interval or retrograde conduction:

Vp-As interval (Vp = ventricular paced event, As = atrial sensed event).

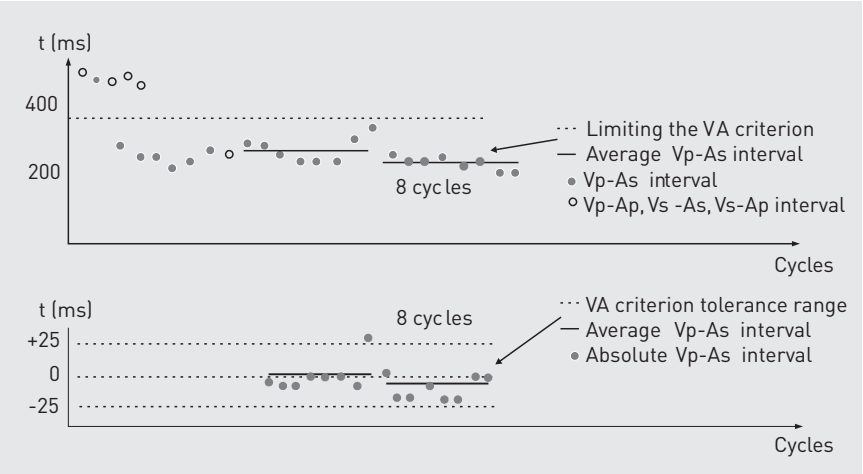
The VA delay is a programmable parameter (VA criterion) and can be set between 250 and 500 ms.

Detection algorithm

A pacemaker-mediated tachycardia is recognized by the detection algorithm when the following conditions are met:

If ...	Then ...
If eight consecutive Vp-As intervals are shorter than the programmed VA interval and the average standard deviation for the eight Vp-As intervals is within the tolerance limit of the PMT stability criterion,	Then the device automatically extends or shortens the AV delay by a defined value.
If the resulting Vp-As interval remains constant,	Then the PMT is considered to be confirmed. The algorithm for terminating the PMT is automatically started.

Note: In cases where a low upper tracking rate and long AV delays have been programmed, pacing rates slightly above the UTR may occur for a few cycles.



Termination algorithm

The algorithm for terminating PMTs becomes effective as follows:

Sequence	Description
1	The PMT is terminated by extending PVARP by one pacing cycle.
2	This interrupts the retrograde conduction and hence the PMT. Consequently the PVARP must be longer than the retrograde conduction period after ventricular pacing or sensing.
3	Auto PVARP: After ending a pacemaker-mediated tachycardia (PMT), Auto PVARP automatically extends the PVARP and the PVARP after PVC by 50 ms. The limit for the PVARP extension is: • Value of the VA criterion + 50 ms. After the parameter is programmed, the Auto PVARP function automatically shortens the PVARP extension and the PVARP after PVC by 50 ms.

PVC Discrimination after As

PVC discrimination after atrial sensed events

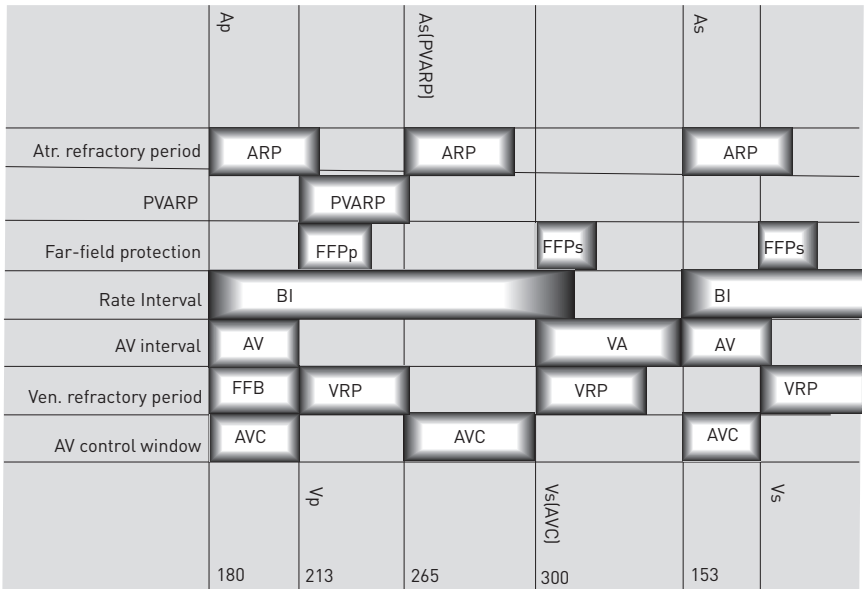
Pacemaker timing (programming) can cause a situation in which the device senses ventricular events as extrasystoles that are not physiologic premature ventricular contractions (PVC). If this takes place systematically for each cycle, then the situation is referred to as PVC lock-in.

The "PVC discrimination after As" interval prevents the device from entering a PVC lock-in situation. By starting the "PVC discrimination after As" interval for each As and each As(PVARP), the device can make a distinction between real and false premature ventricular contractions. An As(PVARP) is a refractory atrial event that occurs outside of blanking but within the PVARP.

Distinction is made between PVC and antegrade conduction by allocating the subsequent ventricular event (inside or outside the "PVC discrimination after As" interval).

"PVC discrimination after As" interval

- The "PVC discrimination after As" interval starts in all dual-chamber modes with atrial sensing if the following events occur:
  — As, As(AV), Ap, Ap(AUR), As(PVARP)
- The "PVC discrimination after As" interval is identical to the programmed AV delay (up to 350 ms).
- The "PVC discrimination after As" interval is limited by the following events:
  — As, As(PVARP), Ap, Ap(AUR)
  — RVs, RVs(AVC), RVp, RVp(SW), RVp(WKB)



Atrial Overdrive Pacing - Concept

Description

Atrial overdrive pacing is used as a preventive measure to reduce the number of atrial tachycardia incidences. Numerous clinical examinations and publications provide information as to reducing the risk of forming atrial tachycardia. The overdrive algorithm causes atrial overdrive pacing and ensures pacing at a rate slightly above the intrinsic rhythm. Atrial overdrive pacing thus minimizes the number of sensed atrial events. The overdrive pacing function is available in the modes DDD(R), DDD(R)-ADI(R) (Vp suppression), AAI(R) and AAT(R) in the device variants DR, DR-T, HF and HF-T.

Increasing and decreasing the rate incrementally

Each time an atrial event is sensed, the pacing rate is increased by a specified value. This rate increase is preset to 8 bpm and is limited by high rate protection.

High rate protection can be set by the maximum activity rate parameter in the sensor/rate fading function (range of values 80 ... 10 ... 180 bpm).

If the heart rate does not continue to increase, then the overdrive rate is reduced in increments of 1 bpm. The rate decrease occurs in each case at the end of a fixed number of 20 cycles.

The pacing rate is reduced until an atrial event is sensed again. Then the overdrive pacing cycle starts again with rate increase.

Protective function of the algorithm

Atrial overdrive pacing has various protective functions, which take effect at high atrial rates:

- When exceeding the programmed maximum activity rate, as is the case with atrial tachycardia for example, the algorithm is automatically deactivated. If the rate drops below the maximum activity rate again, then the overdrive algorithm is activated again.
- The function is also deactivated if the mean value of the atrial rate of the last 64,000 cycles exceeds an average safety rate. In this case, the pacing rate is reduced to the basic rate incrementally. The safety rate depends on the programmed basic rate and the maximum activity rate. If the average atrial rate drops below the safety rate, then preventive overdrive pacing is activated again.

The 4th time the function is deactivated because the safety rate is exceeded, overdrive pacing is switched off permanently. Atrial overdrive pacing can only be activated again the next time the pacemaker is interrogated.

CAUTION
When programming atrial overdrive pacing, a check should be performed to determine whether pacemaker-mediated tachycardia can be triggered based on the selected pacemaker program and whether atrial overdrive pacing results. If so, it is recommended that the maximum activity rate for atrial overdrive pacing in the Sensor/Rate fading function be programmed at a value that is lower than the expected rate of pacemaker-mediated tachycardia.

Atrial Overdrive Pacing

Navigation: Parameters → Bradycardia/CRT → Basic rate/Night rate

Available for the following devices

- 6 and 8 series
- DR, DR-T and HF, HF-T

Objective

Atrial overdrive pacing is intended to reduce the occurrence of atrial tachycardias by means of atrial overdrive pacing above the sinus rhythm.

Description

The device paces just above the sinus rhythm with the objective of limiting the amount of intrinsic atrial events to an average of less than 4%.

Algorithm

- After each sensed atrial event (except for PAC), the pacing rate is increased according to the `Rate increase` parameter.
- If the intrinsic rhythm decreases, the pacing rate is reduced according to the `Rate decrease` parameter until a new atrial event is sensed.
- The function is deactivated as soon as the intrinsic rhythm exceeds the value of the `Max. activity rate` parameter. It is reactivated when the sinus rate again falls below this rate.
- The function is deactivated if the average atrial rate exceeds an internal safety value within 12 h. It is reactivated when the average atrial rate again falls below this safety value. After the fourth deactivation,the function can only be reactivated manually during the follow-up.

Pacing modes for overdrive pacing

- DDD(R)
- AAI(R)
- AAT(R)
- DDD(R)-ADI(R)

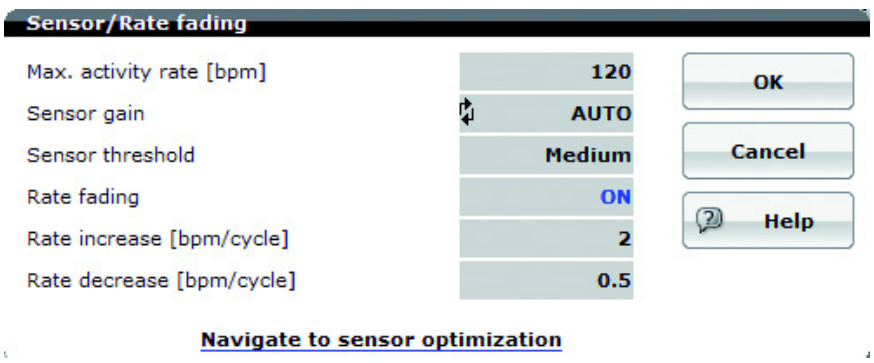
Programming

The following 3 parameters control the function:

- Rate increase
- Rate decrease
- Max. activity rate

  The maximum activity rate can be programmed. To do so, select the following: **Parameters → Sensor/Rate fading → Max. activity rate**

User interface



5.8 Patient Data, Home Monitoring, Diagnostics

What's in this section?

Setting Home Monitoring

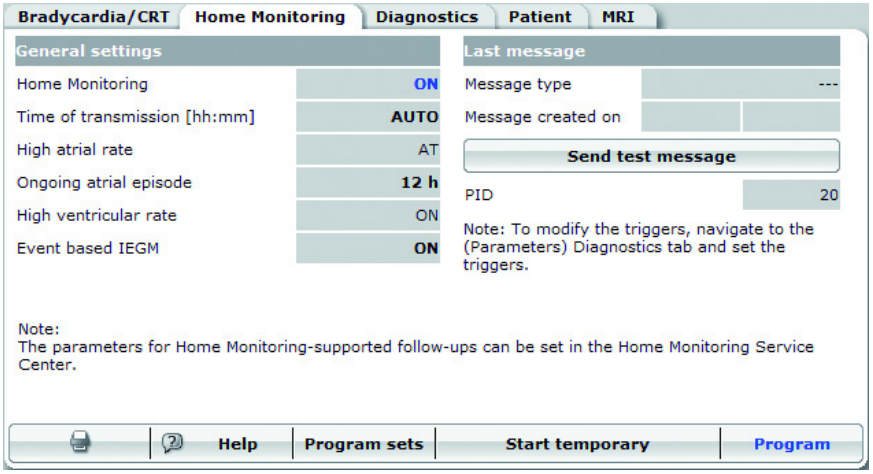
Navigation: Parameters → Home Monitoring

Objective

In the `Home Monitoring` tab you can make the settings for data transmission for the Home Monitoring function.

User interface

The Home Monitoring window



General settings group box

The parameters in detail:

Parameter	Description
`Time of transmission`	Time of day at which the message from the device to the CardioMessenger and from there to the BIOTRONIK Home Monitoring Service Center (HMSC) is sent. `AUTO` = at a default time in the early hours of the morning – which will depend on the serial number of the device
`High atrial rate`	Controls sending of messages at high atrial rates (HAR). Values are adopted from the IEGM recordings setting. 8 series: The IEGM is sent via Home Monitoring. Setting: automatically adopted from the `Recording triggers` group box and high atrial rate (HAR).
`Ongoing atrial episode`	Time period for which an atrial episode is defined as sustained. If the set duration is exceeded, then the next device message informs about the occurrence of this episode.
`High ventricular rate`	Controls sending of messages at high ventricular rates (HVR). Values are adopted from the IEGM recordings setting. An IEGM is sent via Home Monitoring. Setting: automatically adopted from trigger for recordings and high ventricular rate (HVR).
`Event-based IEGM`	Controls sending of messages at recorded event-based IEGMs Values are adopted from the IEGM recordings settings. An IEGM is sent via Home Monitoring. Setting: ON; OFF

Last message group box

The following data, among others, can be found in the `Last message` group box:

Parameter	Description
[Send test message]	Checks the data transmission function
`PID`	PID is the ID number for the device and is required to initialize Home Monitoring at the BIOTRONIK HMSC.

Setting Diagnostic Functions

Navigation: Parameters → Diagnostics

Objective

Make your settings for the various parameters for statistics and IEGM recordings in the `Diagnostics` tab.

Triggers for recordings

Set the following parameters for IEGM recordings in the `Recording triggers` group box:

Parameter	Description
`High atrial rate`	Select whether exceeding a high atrial rate should trigger an IEGM recording. Meaning of parameter values: • `ModeSw`: Exceeding the upper rate for mode switching triggers recording. • `AT`: Detecting a high atrial rate (`HAR limit`triggers recording.
`High ventricular rate`	Select whether detection of a high ventricular rate (see parameter set `High ventricular rate (HVR)`) should trigger an IEGM recording.
`Patient triggering` (only: Edora 8, Evity 8, Enitra 8, Enticos 8)	Select whether the patient should be able to trigger IEGM recording by applying a magnet. When the function is switched on, the magnet effect will be automatically set to synchronous during transmission for safety reasons. Please instruct your patient.
`Pre-trigger recording`	Specify the duration of the entire recording time (10 s) which passes before the triggering event.
`IEGM signal`	Select the characteristics of the IEGM signal.

Statistics

In the `Statistics` group field, set the following parameters:

Parameter	Description
`Start resting period` and `Resting period duration`	The resting period is a daily time period in which the minimum intrinsic heart rate is recorded as the resting rate. The results can be seen under: **Diagnostics → HF monitor**.
`AV delay adj. sensing test`	• In the pacing modes DDD(R) or VDD(R), an AV delay can be fixed for the automatic P/R wave measurement in order to be able to sense intrinsic signals. • `OFF`: The AV delay is assumed from the permanent program for the duration of the automatic P/R measurement.

Setting thoracic impedance

Thoracic Impedance, p. 134

Patient and Device Data

Navigation: Parameters → Patient

Objective

The following can be done in this tab:

- In case of a new implantation:

  Enter the patient data to transmit it to the device and store it there permanently.
- In case of a follow-up:

  View the patient data interrogated by the device, correct errors if necessary, and print out for the report.
- In case of a device change:

  Import the data from the prior device (for example, name, date of birth, and information on the leads) into the new device.

This data is used for unique patient identification and the allocation of follow-ups stored in the programmer. It has no impact on the therapeutic or diagnostic functions of the device.

Save data in the implanted device

Select **[Program]** in order to save these data permanently in the implanted device and to make it available for follow-up care.

Importing data

Proceed as follows:

Step	Action
1	Select **[Import]**.
2	Select the patient data that you want to import.
3	Select **[OK]**.

Note: The serial number of the previous device is also imported. It is sent to the Home Monitoring Service Center (HMSC) with a message from the new device. If the patient's previous device was registered with the Home Monitoring Service Center, the HMSC recognizes the device change and shows this to the HMSC user.

Thoracic Impedance

Navigation: Parameters → Diagnostics → Thoracic impedance

Objective

Thoracic impedance measurements may be useful for patients with a risk of decompensated heart failure.

Usually decompensated heart failure is accompanied by edemas, which can be detected effectively via a reduction in thoracic impedance. The devices in this product family can measure thoracic impedance and transmit this information to the BIOTRONIK Service Center via Home Monitoring. In addition, the impedance trend can also be displayed on the programmer: Display HF Monitor Statistics, p. 156.

Details

Thoracic Impedance Measurement – Details, p. 135

Thoracic Impedance Measurement – Details

Navigation: Parameters → Diagnostics → Thoracic impedance

Technical implementation of impedance measurement

- The measurement is synchronized with R waves and is based on an impedance measurement with sub-threshold stimuli.
- The measurement is made between the housing and the ring electrode.
- The average daily impedance measurement values are stored in the device.
- Via the daily transmission made using Home Monitoring, the data are sent to the BIOTRONIK Home Monitoring Service Center, where they are evaluated.
- The impedance measurements are displayed as thoracic impedance trend. Display HF Monitor Statistics, p. 156

6 Home Monitoring

What's in this chapter?

Introduction

About the Home Monitoring function

With BIOTRONIK's Home Monitoring function, patients can be treated even more effectively. All Home Monitoring devices are equipped with a small transmitter and are designated with the letter "T" (e.g., DR-T, SR-T).

All functions and features of the basic device, such as pacing and sensing functions, preset parameters, or memory functions, are unaffected by the Home Monitoring function.

With Home Monitoring, you can view the data transmitted by the device in a clear form in the Internet and thus always be informed of your patient's cardiac status.

A patient device receives messages from the device and transmits them to the BIOTRONIK Service Center. At the Center, the data are processed and are made available via a secure Internet connection.

The device's Home Monitoring function can be used for the entire service time of the device or for shorter periods, such as several weeks or months.

The most important components of Home Monitoring are the implanted device, the patient device, and the Internet platform Home Monitoring Service Center.

Device

The power of the device's transmitter is very low, so that the patient's health is not affected in any way. The resulting small transmission range requires the use of a special transmitter to forward the device data to the BIOTRONIK Service Center.

The patient's device data are sent to the transmitter once a day (usually at night). With Home Monitoring, the distance between the device and the transmitter should not be less than 20 centimeters (6 inches) and not more than two meters (6 feet).

Transmitter

The transmitter collects the data sent by the device and transmits the information via the cellular phone network to the BIOTRONIK Service Center.

The stationary transmitter (e.g. CardioMessenger II-S) is usually placed on the patient's bedside table. The patient can take it on trips and also set it up and connect it to the power supply while on vacation.

BIOTRONIK Home Monitoring Service Center

The BIOTRONIK Service Center receives the data sent by the transmitter and evaluates them. The analysis criteria are specific to the particular device and can additionally be individually customized for each patient. The results of the analysis are presented both in diagram and table form on the secure Internet platform. If the value of a transmitted parameter is outside the defined limits, a monitoring finding is created if the system is configured to do so. Monitoring findings can automatically trigger notifications that are sent to the attending physician via fax, SMS or E-mail.

The BIOTRONIK Home Monitoring Service Center is the Internet platform where patients' current monitoring findings are presented clearly and accessibly. The Detail view contains specifics about monitoring findings and medical histories for every patient.

Programmer

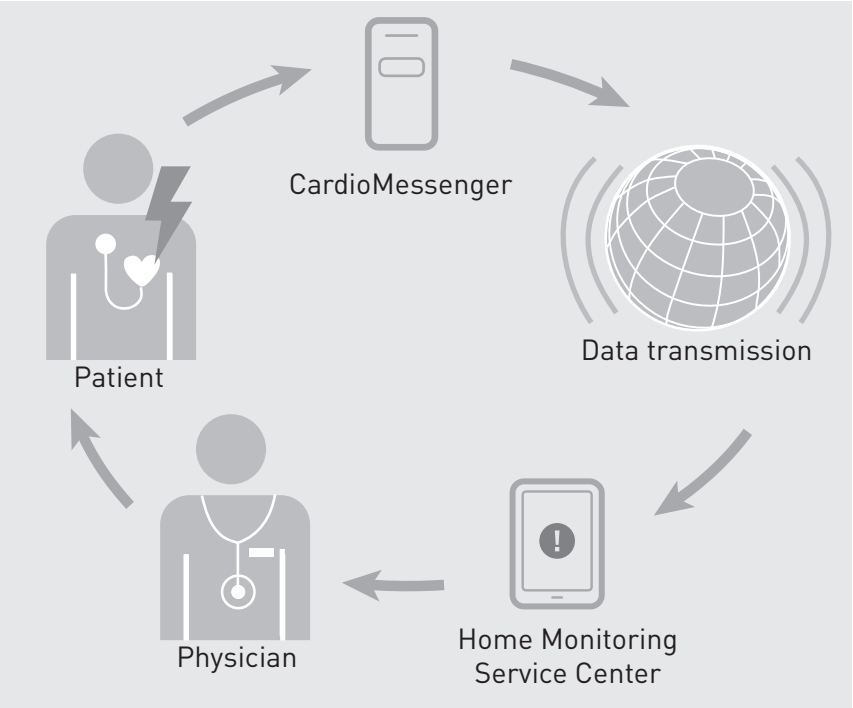
You must activate the BIOTRONIK Home Monitoring function in the programmer and create a patient profile in the Home Monitoring Service Center.

For information about activating Home Monitoring on the programmer, see the manual for the programmer.

For information about registering as a user in the Home Monitoring Service Center, see the technical manual for the Home Monitoring Service Center.

For information on creating a new profile for a new patient in the Home Monitoring Service Center, refer to the online help for the Home Monitoring Service Center.

Home Monitoring concept



Home Monitoring Parameters

Home Monitoring OFF, ON

You can activate or deactivate the Home Monitoring function using the programming device. The additional sub-functions can only be used if Home Monitoring has been activated. When the function is switched on, all other parameters are automatically reset to the default settings.

Time of transmission AUTO, 0:00...23:50 h

Set a time between 0:00 and 11:50 PM for the device message. It is recommended to set a time between 0:00 and 4:00 when the patient is usually sleeping.

The default time of transmission [AUTO] is a time of transmission between 1 and 2 o'clock.

High atrial rate Controls sending of messages at high atrial rates (HAR). Values are adopted from the IEGM recording settings. An IEGM is sent via Home Monitoring only if the `Event-based IEGM` parameter has been activated.

Ongoing atrial episode 6, 12, 18 h

Set the minimum duration here, which an atrial episode has to have to be evaluated as a persistent atrial episode. Device messages which indicate a persistent atrial episode are transmitted to the Home Monitoring Service Center.

High ventricular rate Controls sending of messages at high ventricular rates (HVR). Values are adopted from the IEGM recording settings. An IEGM is sent via Home Monitoring only if the `Event-based IEGM` parameter has been activated.

Event-based IEGM Event-based IEGMs are transmitted to the BIOTRONIK Service Center if you have activated this parameter. These events include high atrial and ventricular rates as well as lead failures.

Periodic IEGM Configure the interval or date for generating and transmitting the periodic IEGM in the Home Monitoring Service Center. You can find further information pertaining to periodic IEGM in the section Periodic and Event-based IEGM, p. 142.

Types of Device Messages

Types of device messages Devices with the Home Monitoring function send the device message daily at a specified time. The device message can contain varying amounts of data:

- Each message contains the results of daily measurements and statistics.
- The first message after implantation and every message after reprogramming (e.g., as part of follow-up) also contain all information on the current device settings.
- The periodic IEGM message also contains the current device settings and the periodic IEGM.

Device messages which indicate specific events in the patient's heart or in the device are forwarded immediately.

Test message A test message can be triggered with the programmer to test the connection to the Home Monitoring Service Center. The test message is sent immediately. If it is received by a transmitter, then it immediately forwards the test message to the BIOTRONIK Service Center.

You can view the test message just a little later on the protected Internet platform, if data has been entered for the patient. Therefore you should make sure the data for the patient has been entered in the Home Monitoring Service Center before sending the test message.

Event message When the device detects certain cardiac and technical events, an event message is sent to the patient device. The triggering events are adjusted to the specific device. You can go to the Home Monitoring Service Center on the Internet and configure whether you also want to receive event reports for these events.

A range of events, e.g., when the battery reaches ERI, cannot be deselected. For more information about the events, see the online help for the Home Monitoring Service Center.

Criteria for the Use of Home Monitoring

Intended use

The general intended medical use is to make diagnostic information available to physicians. The Home Monitoring Service Center is a diagnostic tool. It can be consulted for decisions on further therapeutic actions. The therapeutic effect of devices that transmit data is not affected because the Home Monitoring Service Center has no direct effect on the device. Patient review via Home Monitoring has no effect on the therapy of concomitant cardiovascular diseases. This must still be performed according to guidelines.

The specific intended medical use is to make data available for the following purposes:

- Diagnostics of rhythmologic functions
- Analysis of the effectiveness of therapies delivered by the device
- Monitoring of the technical status of the device and the lead(s)
- Assessment of further therapeutic measures, especially regarding follow-ups

Prerequisites

The technical prerequisites for access to the functions are described in the manual for the BIOTRONIK Home Monitoring Service Center.

Indications

The approved indications and contraindications for pacemakers and ICDs are identical, regardless of whether or not the Home Monitoring function is available. There is no absolute indication for the use of the Home Monitoring Service Center.

However, every patient with an indication for a pacemaker or ICD could benefit from using Home Monitoring and its individualized therapy options. The Home Monitoring Service Center can be used as a diagnostic tool for all patients who have a BIOTRONIK implanted device with Home Monitoring function and who have been equipped with a corresponding transmitter by their physician. The indication for using the Home Monitoring Service Center can include, but is not limited to the following:

- The patient must be monitored in the post-operative phase.
- The patient has a history of paroxysmal or intermittent atrial arrhythmias.
- The patient has an exceptionally high incidence of ventricular tachycardias.
- The patient has marginal sensing thresholds and/or pacing thresholds. Lead impedances are outside of the normal range.
- The patient's medication has been changed.
- The patient resides in a remote location.
- The patient has transportation issues.
- The device is nearing the end of its service time (ERI or EOS).

Contraindications

There are no contraindications for the use of the Home Monitoring as a diagnostic tool because it has no effect on the diagnostic or therapeutic functionality of the device. However, proper use of Home Monitoring requires the complete cooperation of the patient. A further prerequisite is that the physician has access to the Home Monitoring Service Center. The Home Monitoring system is not recommended for use in the following situations:

- The patient is unable to correctly operate the system due to physical and/or mental conditions.
- There is no cellular phone network roaming partner of T-Mobile available in the patient's vicinity.
- The clinic or practice has no Internet access that is regularly maintained.
- The physician is unable to use the Internet, or there is no personnel qualified to analyze the collected Home Monitoring data.
- The clinic or practice is unable to contact the patient if therapeutic measures are required.

Home Monitoring-supported follow-up

Home Monitoring does not serve to replace regular in-office appointments with the physician required for other medical reasons.

Follow-up supported by Home Monitoring can be used to functionally replace in-office follow-up under the following conditions:

- The patient was informed that the physician must be contacted if symptoms worsen or if new symptoms arise despite the use of the Home Monitoring function.
- Device messages are transmitted regularly.
- The physician decides whether the data transmitted via Home Monitoring with regard to the patient's clinical condition as well as the technical state of the device system are sufficient. If not, an in-office follow-up has to be carried out.

Possible early detection due to information gained via Home Monitoring may necessitate an additional in-office follow-up. For example, the data may indicate at an early stage lead problems or a foreseeable end of service time (ERI). Furthermore, the data could provide information about previously unrecognized arrhythmias or necessary modification of the therapy by reprogramming the device.

For devices whose programmed parameters cannot be displayed or adequately displayed in the Home Monitoring Service Center, documentation of the programming should be used as a reference.

Follow-up intervals

Follow-ups must be performed at regular, agreed intervals.

- The first follow-up (approximately 3 months after implantation when the lead ingrow phase is concluded) should be carried out in-office using the programmer.
- The next in-office follow-up should be carried out once a year, at least 12 months after the last in-office follow-up.

Scope of Home Monitoring functions

Monitoring of system integrity:

- Battery status, battery voltage
- Detection and therapy activation

Monitoring of lead integrity:

- Impedance in the atrium and ventricle

Bradycardia and tachycardia rhythm and therapy monitoring:

- Sensed event and paced event counter
- Detected episodes

Warnings and precautions

Recognized warnings and precautions for pacemakers and ICDs are applicable and are independent of Home Monitoring. However, there are specific precautions for Home Monitoring.

Please follow the specific warnings and precautions for Home Monitoring in the BIOTRONIK Home Monitoring Service Center manual and the patient device manual.

Periodic and Event-based IEGM

The device can record the following IEGM types:

- Periodic: Recording is time-controlled at regular intervals and is transmitted together with the daily device message.
  - The periodic IEGM is deleted following transmission. Therefore, it can only be viewed in the Home Monitoring Service Center and not with the programmer.
- Event-based: Recording is event-based including high atrial and ventricular rates as well as lead failures.
  - The event-based IEGM is stored on the device and transmitted to the Home Monitoring Service Center. It can, therefore, be viewed in the Home Monitoring Service Center and viewed on the programmer after interrogation of the device.

The attending physician can thus gain comprehensive insight into the patient's cardiovascular condition and decide whether to have the patient come in for follow-up.

Depending on the device type, the IEGM sent by Home Monitoring consists of the following:

- Right atrial marker channel
- Right ventricular marker channel
- Left ventricular marker channel
- Right atrial IEGM
- Right ventricular IEGM
- Left ventricular IEGM

Periodic IEGM

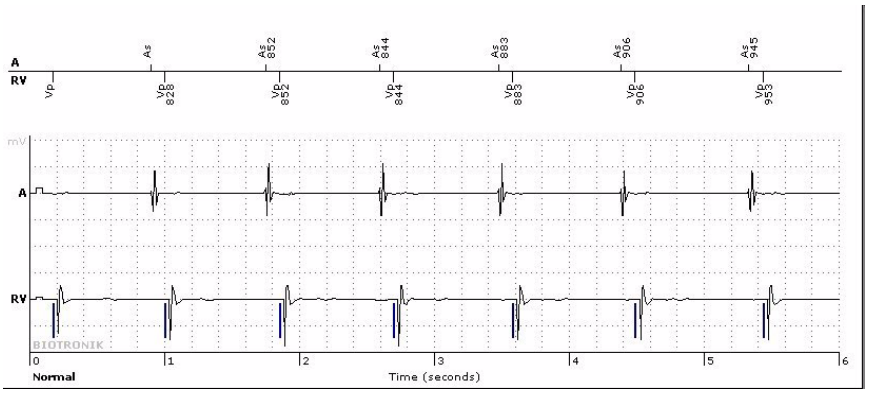
The IEGM is subdivided into 3 recorded sequences of approximately 10 seconds duration:

- Normal
  - Recording with the current device settings
- Forced sensing
  - Modes: AAI(R), VVI(R), VVI-CLS, DDD(R), DDD-CLS, VDD(R)
  - Recording with programmed AV hysteresis and rate hysteresis
  - If the hystereses are switched off, the programmed AV delay + 70 ms is effective.
  - Basic rate -10 bpm if the rate is > 40 bpm
    Basic rate -5 bpm if the rate is 35 - 40 bpm
  - No rate change if the rate is < 35 bpm
- Forced pacing
  - Modes: AAI(R), VVI(R), VVI-CLS, DDD(R), DDD-CLS, VDD(R)
  - In the modes DDD(R), DDD-CLS and VDD(R), increase of the atrial rate by 12.5% with an AV delay of 100 ms
  - In the mode AAI(R), increase of the atrial rate by 12.5%
  - In the modes VVI(R) und VVI-CLS, increase of the ventricular pacing rate by 12.5%

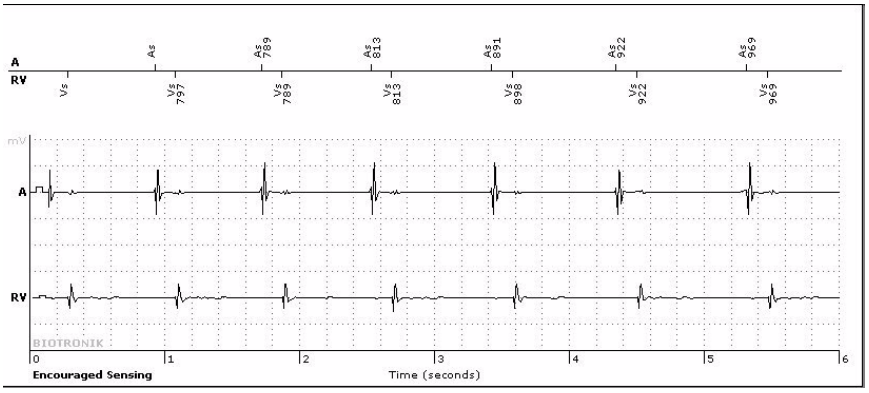
Note: The average rate is determined during intrinsic IEGM registration. If the rate increase is limited by the upper rate, no encouraged sensing or encouraged pacing are performed in DDI mode.

The following diagrams are excerpts. About 10 seconds of each IEGM type are recorded and sent.

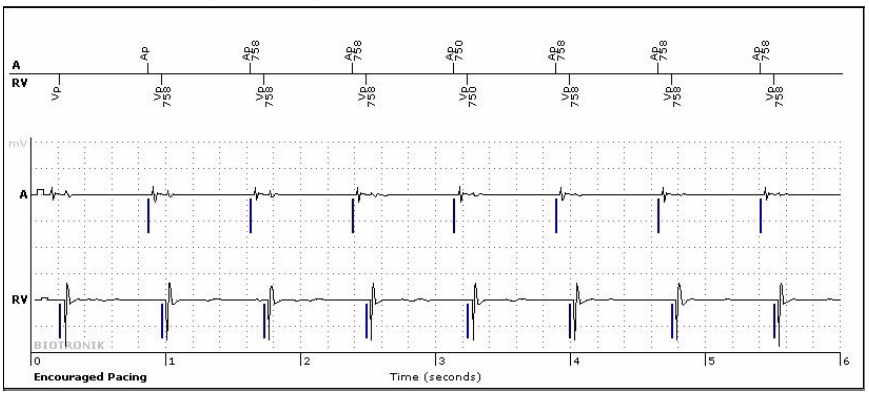
IEGM type: normal



IEGM type: encouraged sensing



IEGM type: encouraged pacing



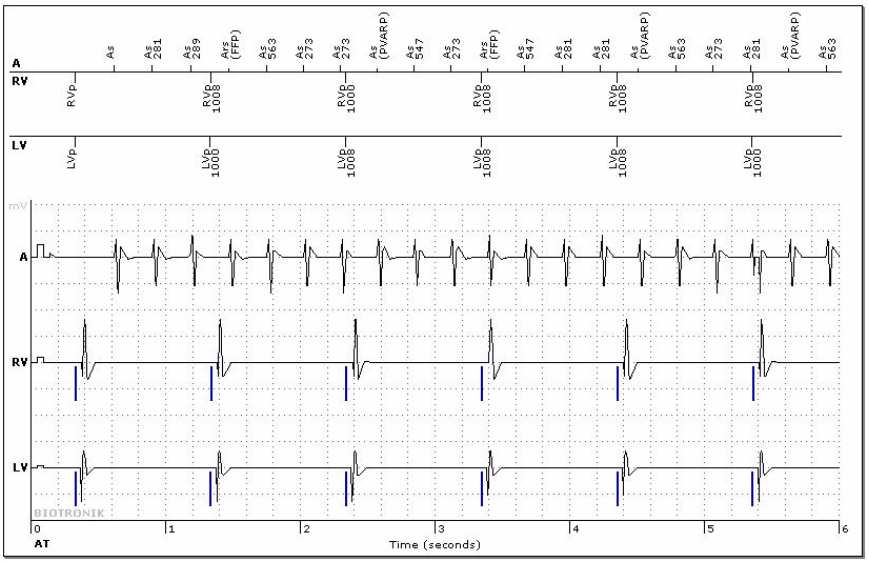
Event-based IEGM

The IEGM is recorded and transmitted to the Home Monitoring Service Center are performed if the following events occur:

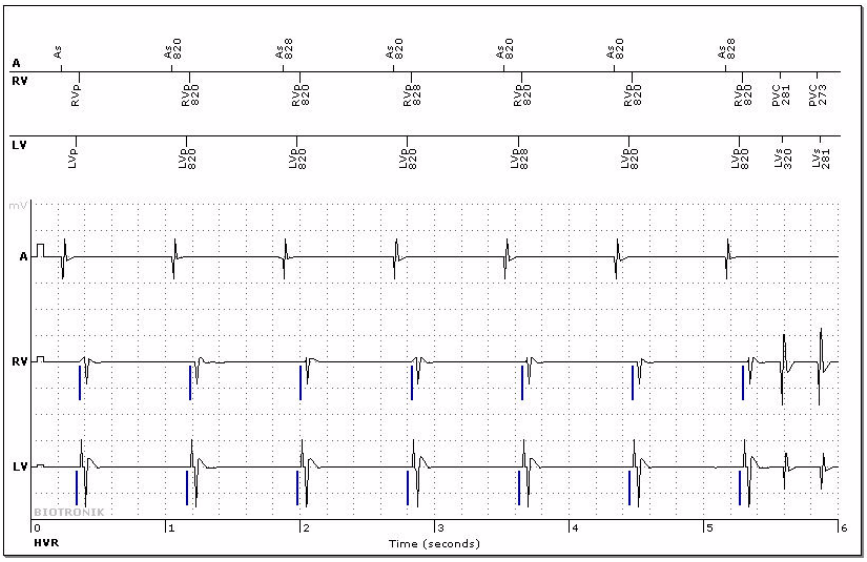
- High atrial rates
- High ventricular rates
- Lead failures

The following diagrams are excerpts. Approximately 10 seconds of each IEGM type are recorded and sent.

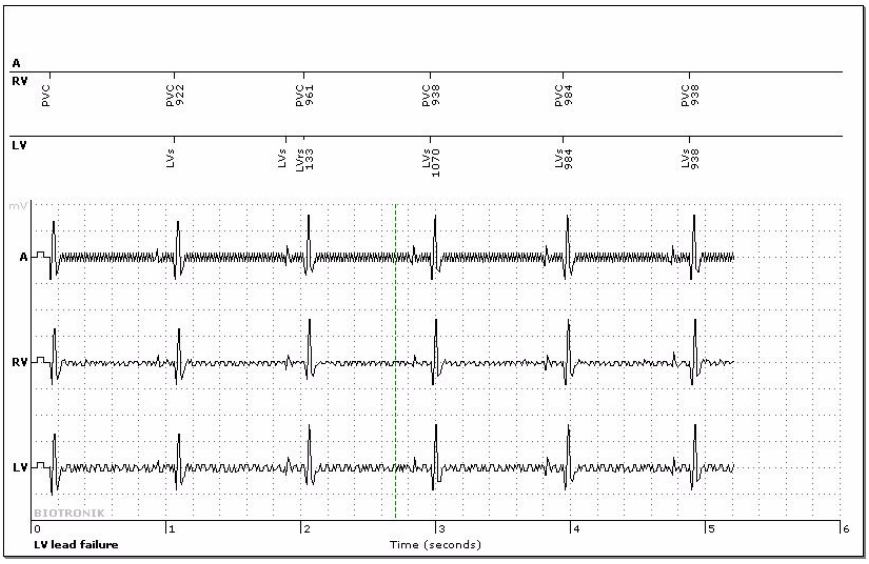
IEGM type: high atrial rates



IEGM type: high ventricular rates



IEGM type: lead failure



7 Evaluate Recordings

What's in this chapter?

IEGM Recordings

Recording capacity

Each IEGM recording has a duration of approximately 10 s.

Device family	Maximum amount of recordings
Edora 8, Evity 8, Enitra 8, Enticos 8	20
Evity 6, Enitra 6	12
Enticos 4	4

Showing the graphic display of an IEGM recording

Proceed as follows:

Step	Action	Result
1	Select **[Recordings]**.	The respective window is opened and displays the saved types of IEGM recordings.
2	Select the desired IEGM recording from the displayed list by clicking on it.	After selecting the desired IEGM recording from the list, the device is interrogated. The data are read from the device and displayed in the associated window as a graph.

Interrogating all data sets

If you interrogate all data sets, then all IEGM recordings can be displayed on the programmer screen without delay.

The following procedures are triggered with the **[Interrogate]** button:

- All recorded data sets of the device are transmitted to the programmer.
- The duration of this procedure depends on the scope of the data:
  The real-time IEGM is not available during this time. The information line shows: `Interrogation...`
- After all data sets have been transmitted, the information line shows:

  `Interrogation was successful.`

High rate with single-chamber devices

For single-chamber devices, set the following parameters in the `High rate` group box:

Parameter	Description
`High rate limit`	Set the upper rate (150 ... 200 bpm) that triggers an IEGM recording if it is exceeded.
`High rate counter`	This counter determines the number of intervals to be recorded. These are the intervals that are above the high rate limit. Select the maximum number of recorded events. Values: 4; 8; 12; 16

Setting IEGM recording parameters

The parameters for the IEGM recording of the device can be set as follows:

Parameters → Diagnostics → Recording triggers

Set limits for high atrial and ventricular rates as well as the number of ventricular events in the group boxes.

With multi-chamber devices:

- `High atrial rate (HAR)`
- `High ventricular rate (HVR)`

Additional single-chamber features:

- `High rate limit`
- `High rate counter`

Displaying, evaluating, saving, and printing the IEGM

Proceed as follows to display an IEGM with the programmer from the list of recordings:

Step	Action
1	Click on the IEGM symbol of the desired recording in the `View` column. The programmer opens an IEGM display window with an expressive signal display, comprehensive remarks, options for adapting the display, and buttons for printing and saving.

Note: Reprogramming parameters deletes any IEGM recordings in the device. To prevent this from happening, retrieve the IEGMs prior to programming and store them in the programmer.

8 Statistics (Diagnostics)

What's in this chapter?

8.1 Statistics Classes

What's in this section?

The numerous statistics functions that save the data and the special events occurring between follow-ups in the device are assigned to various statistics classes according to content.

Objective

To transmit the data saved in the device to the programmer in order to evaluate it and to use it in optimizing diagnostics and therapy.

Description

- The counters for statistics functions are activated after transmitting a program.

Transmitting statistics

All statistical data are transmitted to the programmer and saved on it upon first interrogation.

Selecting Statistics for Diagnostics

Navigation: Diagnostics

Overview

The following actions can be performed with the Diagnostics function:

- Interrogate statistics:
  Statistics are always interrogated during initial interrogation of the device.
- Displaying statistics
- Selecting statistics
- Evaluating statistics
- Update statistics by reinterrogation of the device
- Delete statistics by restarting

Interrogating statistics

On first interrogation from the start screen, all statistical data on the device (except data from the `More diagnostics` tab) are transmitted to and saved on the programmer.

Selecting statistics

Select a statistic as follows:

Step	Action
1	Select **[Diagnostics]** to call the function. The various classes of statistics available are shown under the associated tabs in the `Diagnostics` window: • Timing • Atrial arrhythmia • HF monitor (long-term trends for diagnostics of cardiac resynchronization therapy) • Short-term trends for the last 24 h • More statistics for diagnostics
2	Select the statistics class that you want to look at, for example, `Timing`. All corresponding statistics are displayed in a window as histograms and trends.

Selecting and displaying other statistics

Select the other statistics as follows:

Step	Action
1	Select **Diagnostics → More diagnostics** to access the function. The various statistics summarized in the `More diagnostics` tab are shown in the group box with the same name.
2	Press one of the buttons, for example, `Pulse amplitudes`. The corresponding histogram or the trend is displayed.
3	Touch the buttons to switch between the various functions of the statistics. The corresponding data is displayed.

Update statistics by device reinterrogation

The statistical data is updated when it is reinterrogated. This reinterrogation will replace the device values previously displayed on the programmer with the current device values.

Step	Action
1	Select **[End]**, to return to the start screen and confirm your action with **[OK]**.
2	When telemetry contact (RF or programming head application) has been established, the device is reinterrogated and the statistics are updated. The updated data are displayed in the `Diagnostics` window.

Delete statistics by restarting

To completely delete available statistics from the device, proceed as follows:

Step	Action
1	Select **[Start statistics]** to reinitialize all statistical counters (i.e., to reset them to 0). The current display is not deleted by pressing the **[Start statistics]** button. The new statistical data are first shown when the device is reinterrogated.

Note: Trends are not deleted by interrogation. The oldest recordings are overwritten after 240 days.
Histograms and counters are restarted after each follow-up.

Using the Statistics

Navigation: Diagnostics

Displaying the statistics

The statistics feature shows recorded data such as events, event sequences, and classifications as follows:

- Graphical display as histogram
- Numerical (absolute) quantity
- Occurrence expressed as a percentage
- Graphical display as trend curve

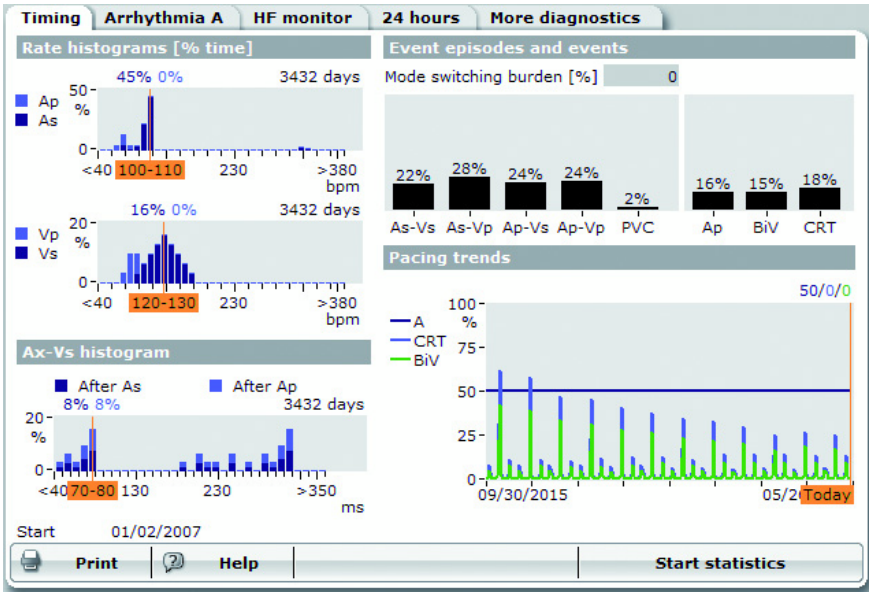
Using the histograms

A vertical auxiliary line and, on some statistics, two additional arrow keys allow you to navigate (to the right and to the left) through certain histograms. The corresponding values of the histogram are displayed at the location of the auxiliary line. Proceed as follows:

Type	Action
1	Press on an area of the histogram on the screen. A vertical auxiliary line will appear, displaying the respective values.
2	Some statistics can also be navigated using arrow keys. Press the arrow keys [**>>**] and [**<<**]. The auxiliary line is moved gradually.

Example

Timing tab with statistics



8.2 Evaluating Statistics

What's in this section?

Displaying Timing Statistics

Navigation: Diagnostics → Timing

Overview

The following trends and histograms are available for use in statistics:

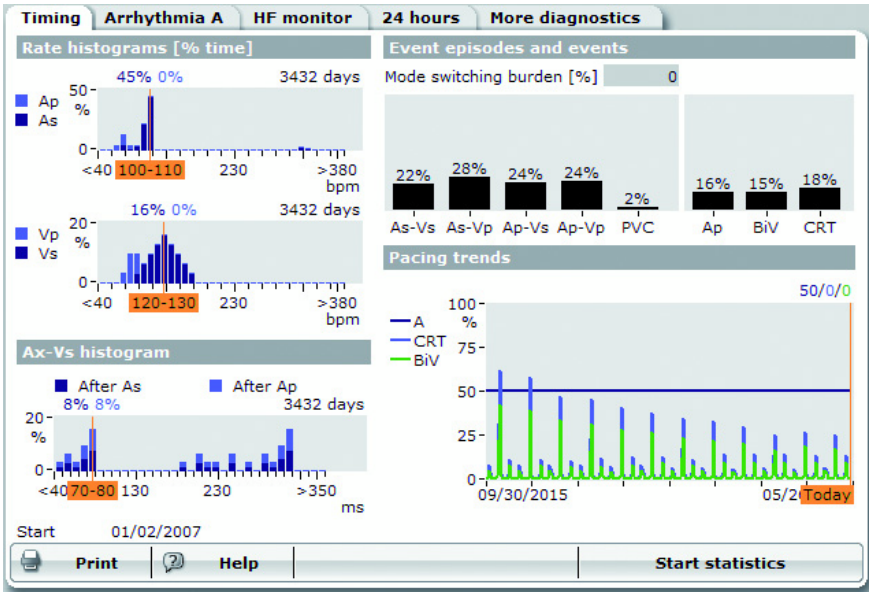
- Rate histograms
- Event episodes and events;
  see also **Follow-up → Details**: `Event episodes`
- Pacing trends as long-term trends over 240 days;
  see also **Follow-up → Details**: `Long-term trends`
- AV histograms

When a statistic function is selected, the statistic function opened last is displayed. This applies to the complete device follow-up.

Note: The histograms of the statistics are reinitialized (set to 0) each time the device is interrogated.

Displaying timing statistics

Timing tab with statistics



Displaying Atrial Arrhythmia Statistics

Navigation: Diagnostics → Arrhythmia A

Overview

The following statistics are available for atrial arrhythmias:

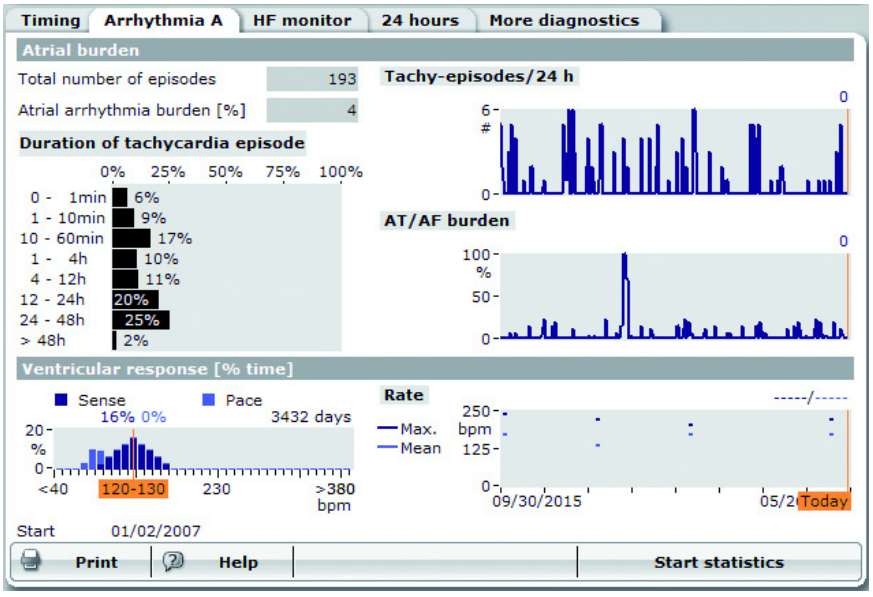
- Arrhythmia burden
  - Total number of episodes since starting the statistics
  - Accumulated arrhythmia burden expressed as a percentage since starting the statistics
  - Duration and distribution over time of episodes of tachyarrhythmia within the last follow-up period
  - Number of atrial tachyarrhythmia episodes per day
  - AT/AF activity duration trend per day in %
- Ventricular reaction
  - Histogram of rates with percentages of pacing and detection
  - Maximum and mean rate trend

The recording duration usually begins with the initial start of the statistics after implantation. When the Statistics function is restarted during a follow-up – by pressing **[Start statistics]** – all previous statistical data are deleted and recordings are restarted from the beginning.

Note: The histograms of statistics are reinitialized (set to 0) each time the device is interrogated.

User interface

Atrial arrhythmia tab



Display HF Monitor Statistics

Navigation: Diagnostics → HF monitor

Overview

The following HF monitor statistics are displayed as a long-term trend:

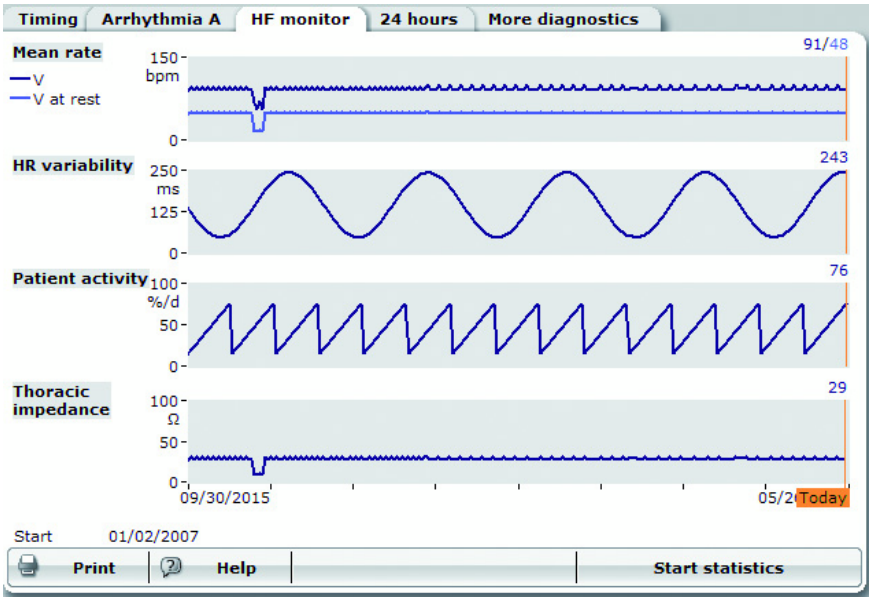
- Mean heart rate
- Mean heart rate at rest
- Variability of the mean heart rate
- Patient activity
- Thoracic impedance

Activating HF monitor statistics

Setting Diagnostic Functions, p. 133

Example

HF Monitor tab



Displaying HF monitor statistics

Note the following details of the HF monitor statistics:

- Mean heart rate

  The mean heart rate per day is specified as follows:
  - Display of the mean heart rate at rest in bpm
  - Recording as long-term trend for a maximum of 240 days, each consisting of 24 hours, with a resolution of 1 bpm within a recording range of 30 - 250 bpm. The trend is then updated, beginning with the oldest value.
  - Recording of Vs, Vp and Vrs (ventricular event sensed in the refractory period)

- Ventricular heart rate at rest

  The ventricular heart rate at rest is recorded for the duration of the set resting period and indicated as follows:
  - Display of the mean ventricular heart rate at rest in bpm. Mean values are calculated by dividing the set resting period into 10-minute intervals. The minimum averaged value of the 10-minute intervals per day is shown.
  - Recording as a long-term trend for a maximum of 240 days, with a resolution of 1 bpm in a recording range of 30 - 250 bpm; after that, the trend is updated beginning with the oldest value.
  - Recording of Vs, Vp and Vrs (ventricular event sensed in the refractory period)

- For each separate trend the display shows the mean values on all days for which valid values are present.
- Variability of the mean heart rate

  The variability of the heart rate is recorded in bpm according to the SDANN algorithm, as a long-term trend for up to 240 days with a resolution of one day. The corresponding heart rate is measured in the atrium (multi-chamber devices).
- Patient activity

  Patient activity is measured as the time during which the device's motion sensor delivers a rate higher than the device's basic rate. The resolution for patient activity is 2 s. The data is converted into % per day. For example, 2.4 h of patient activity are indicated as 10%/day in the trend.
  - There has been activity wherever the current sensor signals are greater than or equal to the sensor threshold.
  - A daily value of 0%/day means that no patient activity was detected. 24 h means that the device detected activity continuously throughout the day.
- Thoracic impedance
  - The thoracic impedance measurements are displayed as a thoracic impedance trend and can thus be evaluated diagnostically on the programmer.

Statistics for the Last 24 Hours

Purpose These statistics provide important data recorded in the last 24 hours.

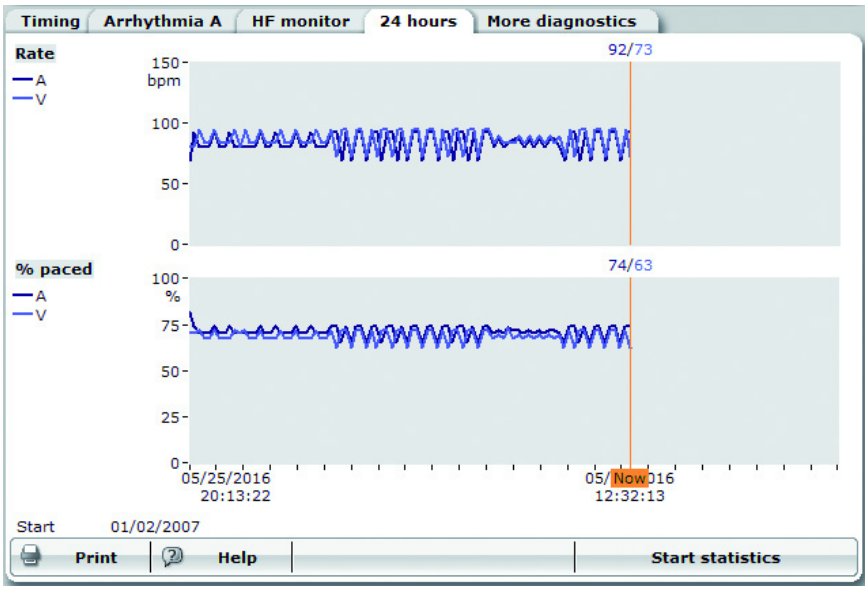
You can evaluate a summary of important data from the individual statistics (timing, atrial arrhythmia) at a glance.

The following statistics are displayed as short-term trends:

- Rate trend; see also
  Diagnostics → Timing
- Percentage of pacing; see also
  Diagnostics → Timing

Note: The short-term trends continuously store the data from the last 24 hours. The oldest data is then overwritten.

Short-term trends for statistics 24 h



The parameters are recorded every 10 minutes.

Displaying Other Statistics

Navigation: Diagnostics → More diagnostics

Overview The following statistics are shown with histograms and trends in the `Statistics` group box:

- Event counters: As, As (PVARP), Ars, Ars (FFP), Ap, RVs, PVC, RVrs, RVp, LVs, LVrs, LVp
- Event episodes and events
- Pulse amplitudes of the threshold trend (A, RV, LV)
- Distribution of the Ax-Vs intervals
- Sensor rate: percentage in rate classes
- Atrial arrhythmia with mode switching events, duration, longest atrial episode
- Ventricular arrhythmia with PVC sequences: Single PVC, couplets, triplets, runs
- P/R wave trend (A, RV, LV)
- Trend of lead impedance (A, RV, LV)
- Far-field histogram with intervals Vp-As, Vs-As
- Vp suppression

9 System Functions of the Device

What's in this chapter?

Transmitting Device Data

Navigation: More -> [Name of device]

Objective

To be able to export device data to an external data medium, the data must first be transmitted to the programmer.

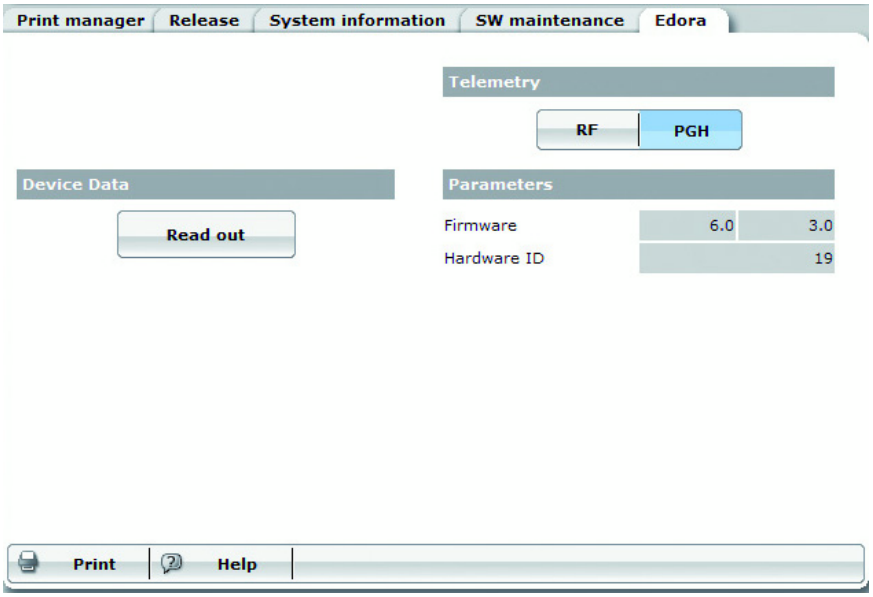
Transmitting data

To apply this function, proceed as follows:

Step	Action
1	Select **[More]** and click on the tab with the name of the device, e.g., **[Edora]**.
2	In the group box `Device Data`, select the **[Read out]** button. The data are transmitted via device interrogation. The duration of the interrogation is displayed as a percentage. Successful transmission is indicated in the information line: `Interrogation was successful.`
3	Proceed according to the instructions: • Technical manual for the programmer's software, Handling Basics part, ECG chapter

Edora as example

Device data read-out (export)



Activating RF Telemetry

Navigation: More -> [Name of device]

Definition and description of RF telemetry

The RF telemetry function is also referred to as SafeSync RF telemetry. In this manual, the function is referred to in the short form, RF telemetry.

RF telemetry enables permanent wireless communication between the programmer and the device over a distance of up to three meters.

Prerequisites for RF telemetry

The Renamic programmer contains an internal module for establishing RF telemetry.

The SafeSync Module accessory is available for the ICS 3000 to enable the RF telemetry function. The SafeSync Module connects to the ICS 3000 via the USB interface. Refer to the technical manual of the SafeSync Module for further information.

Permanently activating or deactivating RF telemetry

RF telemetry can be switched on or off globally for all follow-ups and temporarily for the current follow-up.

Step	Action	Remark
1	Select **Preferences → Connectivity → RF Telemetry → Interrogation → ON**.	RF telemetry is automatically established within two seconds after the programming head is applied. After this point, the programming head is no longer needed to maintain communication between the device and the programmer.

Activating RF telemetry at the beginning of the follow-up

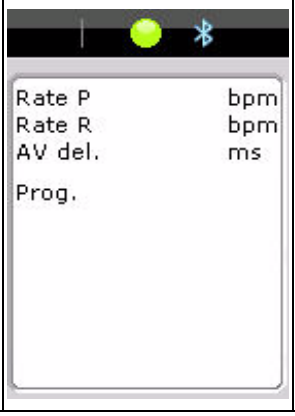
If you have not permanently activated RF telemetry, you can also initialize this function at the start of the follow-up.

Step	Action	Remark
1	Place the programming head on the patient over the implanted device.	
2	Select More => Device name => Telemetry => RF, to activate RF telemetry.	RF telemetry is active after two seconds and you can remove the programming head.

Note: If you want to switch from RF telemetry back to telemetry using the programming head (PGH), you first need to place the programming head on the patient over the device.
Select More => Device name => Telemetry => RF.

Telemetry control indicators

The control indicators for PGH and RF telemetry are shown in the following table:

Telemetry	Illustration	Remark
Active RF telemetry		The RF telemetry status is shown in five increments: from 1 bar = 20% to 5 bars = 100%. Depending on the quality of the telemetry contact (signal strength), the individual bars are shown in green. A weak contact shows only one bar in green, whereas all five bars are shown in green when there is optimal contact. The bars are shown in gray if RF telemetry is lost. The display should have at least three green bars. Otherwise, you should reposition the programmer until an adequate signal strength is achieved. Additionally, an icon depicting a device with radio waves is shown in the field at the right above the navigator.
Active PGH telemetry		The telemetry status between the programming head and the device is shown as a green circle when there is optimal telemetry contact. In case of malfunctions, the circle is shown in red. The circle is shown in gray if telemetry is lost. In case of malfunctions, locate the source of interference using an EMI test and turn off the source.

RF telemetry and economy mode

Telemetry switches to economy mode if the programmer is not used for 3 minutes during a follow-up. Additionally, the patient name is displayed in the `Economy mode` window. RF telemetry is fully reactivated when the window is closed.

RF telemetry and safety

The RF telemetry function can only establish a connection to the device of one patient at a time so that there is no possibility of confusion.

When the programming head is applied to start the session, a device is explicitly assigned to a programmer during initialization of RF telemetry.

Note: Consider power consumption and service time
RF telemetry requires somewhat more power than does PGH telemetry. The power consumption during a single implantation corresponds to approximately 10 days of service time. The consumption during a 20-minute follow-up corresponds to approximately 5 - 7 days of service time. Do not establish unnecessary RF telemetry. Check the battery capacity of the device at regular intervals.

Note: Transmitting the safe program does not negatively impact the stability of RF telemetry.

Note: If RF or PGH telemetry is lost, the device always automatically switches back to the permanent program after a certain time, including when a test is being performed.

WARNING

Risk to patient from programmer interference or interrupted telemetry!

Programmer interference or interrupted telemetry during performance of temporary programs (follow-up tests) can result in inadequate pacing of the patient. This is the case if the programmer can no longer be operated due to a program error or a defective touch screen and you cannot terminate the temporary program.
To ensure patient safety, the temporary program is also terminated when telemetry is canceled.
To terminate the temporary programming by canceling telemetry, proceed as follows:

- Telemetry using PGH

Lift the programming head 30 cm. The device automatically switches to the permanent program.

- RF telemetry

Switch the programmer off or move it out of the range of the implanted device. The device automatically switches to the permanent program.

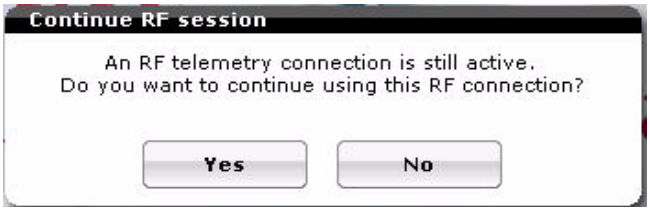
Restore RF telemetry by restarting

Restore RF telemetry after a connection loss by restarting the programmer.

If the programmer is restarted and an RF telemetry connection was present within the preceding five minutes, the programmer displays a dialog box to restore the session. This function is useful if the programmer needs to be restarted and the device is already in the sterile field.

The session must not have been inactive for longer than five minutes, as the device's RF telemetry times out after five minutes.

In this case, the programming head must be reapplied to reinitialize RF telemetry.



Automatic deactivation of RF telemetry

The connection between the device and the programmer is lost if the programmer or device switches off RF telemetry.

The device automatically switches RF telemetry off if the connection is interrupted for longer than five minutes (programmer out of range).

The programmer likewise drops the connection after five minutes without contact to the device. Contact via RF telemetry is automatically disconnected after 30 minutes without user action.

Stopping RF telemetry

RF telemetry is completely deactivated 5 minutes after the interrogation ends.

III Follow-up

What's in this part?

See part III of the function manual for further information on all topics related to follow-up.

10 Performing Automatic Follow-Up

What's in this chapter?

The follow-up concept at a glance

The follow-up is virtually fully automated since all relevant data is measured periodically.

When the device is interrogated, the measurement data including pacing threshold, P/R amplitude and lead impedance, for example, are available because they are saved periodically.

Therefore, it will not be necessary to carry out additional manual measurements in many cases.

In addition to the saved measurement data, which indicate automatically measured values with two white arrows, all important data for medical evaluation are displayed at a glance.

Hyperlinks, which are indicated in bold lettering, lead to more menus and serve to make navigation very convenient.

If required, follow-up tests can be started right from this page for manual implementation. A real-time IEGM is displayed with all relevant markers when the programmming head is applied.

Other convenient functions on the follow-up page are:

- Follow-up history of the implantation and the 9 most recent follow-ups can be accessed directly
- Patient implantation data
- Device status with the most important permanent program parameters
- Error messages and episodes
- Archive of the measurement trend and Holter recordings, diagnostics data (statistics)
- Battery status and replacement indication

Interrogating the Device Automatically

Objective

You must interrogate the device in order to conduct a follow-up. Upon interrogation, the data stored in the device is transmitted to the programmer.

The following steps describe how to interrogate a device from the `Device list` screen.

Interrogating

Proceed as follows:

Step	Action
1	Place the programming head directly over the device.
2	Make sure that telemetry contact with the device has been established.

Description of the process sequence

Upon telemetry contact, the following steps are automatically performed:

Sequence	Description
1	The device is identified.
2	The current (permanent) pacemaker program is interrogated.
3	All data stored in the device are transmitted to the programmer.
4	A message on the screen confirms successful transmission.
5	Evaluate the data and perform the follow-up.

Follow-up

Follow-up intervals

Follow-ups must be performed at regular, agreed intervals.

- Following the lead ingrowth phase, approximately 3 months after implantation, the first follow-up should be carried out by the physician using the programmer (in-office follow-up).
- The next in-office follow-up should be carried out once a year and no later than 12 months after the last in-office follow-up.

Follow-up with BIOTRONIK Home Monitoring®

Monitoring using the Home Monitoring function does not serve to replace regular in-office appointments with the physician required for other medical reasons.

Follow-up supported by Home Monitoring can be used to functionally replace in-office follow-up under the following conditions:

- The patient was informed that the physician must be contacted if symptoms worsen or if new symptoms arise despite the use of the Home Monitoring function.
- Device messages are transmitted regularly.
- The physician decides whether the data transmitted via Home Monitoring with regard to the patient's clinical condition as well as the technical state of the device system are sufficient. If not, an in-office follow-up has to be carried out.

Possible early detection due to information gained via Home Monitoring may necessitate an additional in-office follow-up. For example, the data may indicate at an early stage lead problems or a foreseeable end of service time (ERI). Furthermore, the data could provide indications of previously unrecognized arrhythmias or regarding modification of therapy by reprogramming the device.

Follow-up with the programmer

Use the following procedure for in-house follow-up:

1	Record and evaluate the ECG.
2	Interrogate the device.
3	Evaluate the status and automatically measured follow-up data.
4	Check the sensing and pacing functions.
5	Manually perform standard tests if necessary.
6	Possibly evaluate statistics and IEGM recordings.
7	Possibly adjust program functions and parameters.
8	Transmit the permanent program to the implanted device.
9	Print and document follow-up data (print report).
10	Finish the follow-up for this patient.

Follow-up Window

Navigation: Follow-up

Objective

The most important interrogated data and measured values are summarized in groups in the `Follow-up` window.

Abbreviations and symbols

Legend for the Follow-up Window , p. 170

Prerequisites

Note: The following requirements must be met for an automatic follow-up:

- Telemetry contact between the device and programmer has been established.
- The device was successfully interrogated automatically, the information line shows the message: `Interrogation was successful.`.
- There is enough printer paper in the programmer paper tray (if printing is to be carried out with the programmer's internal printer).

The pacing threshold test is automatically performed at a specific time of day if capture control has been activated.

Repeat all tests

You can repeat the follow-up test sequence at any time, for example, if measured values do not appear plausible: Select **[Start tests]**.

Start up tests individually

You can start up tests individually by clicking on the appropriate measured value. The system then switches to the tab for the relevant test: Select **[Start]** from there.

Test results: Trends

Evaluate Trends in Measured Values, p. 176

Diagnostics: Details

Details of Diagnostics, p. 178

Legend for the Follow-up Window

Navigation: Follow-up

Battery charging status

The various abbreviations mean the following:

Abbreviation	Meaning
BOS	Beginning of Service: • > 90% charge
ERI	Elective Replacement Indication (i.e., RRT: Recommended Replacement Time): • indicates that the device must be replaced
EOS	End of service: • Service life of the device has ended

WARNING
Battery charging status = EOS: patient not being treated If the battery status is EOS (end of service), the active device is out of service and cannot provide any therapy. • Replace the implanted device immediately.

Symbols

The symbol has the following meaning:

Symbol	Meaning
	Values have been automatically measured and updated in the last 24 hours.

Real-Time IEGM on the User Interface

Real-time IEGM display

While the magnet is being applied or when the wandless telemetry is activated, a real-time IEGM of the data transferred from the device is displayed on the programmer screen.

The IEGM is produced simultaneously for the relevant channels with a scan rate of 256 Hz.

At the same time a marker channel and a surface ECG channel are displayed.

Availability and temporary exceptions

This real-time monitoring of the current IEGM data is constantly available during the follow-up. The only times the IEGM is not updated is during initial interrogation of the device and during transmission of recordings and statistical data.

Further information

Detailed explanations of IEGM display adaptation and handling of the programmer's Holter function are available in the technical manual Handling Basics.

Real-time IEGM during tests

The following measured values are displayed in the real-time IEGM window while the various tests are being conducted:

- During the sensing test: the amplitudes of the sensed signals
- During the threshold test: the pulse amplitudes
- During the retrograde conduction test: the conduction times

Recording the IEGM

The Freeze button can be used to have the software display a recording of the IEGM in another window. Detailed markers and entries of measured values are displayed in this window.

Marker overview The following marker symbols and labels are displayed in the IEGM window and in the Freeze window.

Channel	Display in the IEGM marker channel	Display in the Freeze window	Event, meaning
Atrium	Marker up, long, label: P	Marker up, label: Ap	Atrial pace
Atrium	Marker up, short, label: S	Marker up, label: As	Atrial sensing
Atrium	Marker up, very short, no label	Marker up, label: As (PVARP)	Atrial sensing during PVARP
Atrium	Marker up, very short, no label	Marker up, label: Ars	Atrial sensing of a refractory or interference signal
Atrium	Marker up, very short, no label	Marker up, label: Ars (FFP)	Atrial refractory sensing during the period of far-field protection
Ventricle	Marker down, long, label: P	Marker down, label: Vp	Ventricular pacing, ventricular triggered pacing, pacing in the ventricular safety window, ventricular stimulation after UTI (Wenckebach), ventricular backup stimulus
Ventricle	Marker down, short, label: S	Marker down, label: Vs	Ventricular sensing, ventricular sensing during the AV delay
Ventricle	Marker down, very short, no label	Marker down, label: Vrs	Ventricular sensing of a refractory or interference signal
Ventricle	Marker down, short, label: S	Marker down, label: PVC	Premature ventricular contraction

Configuring and Performing Automatic Follow-up

Automatic functions at a glance Follow-ups for the devices are largely automated. As soon as interrogation is performed for the follow-up, measured value data are available in the `Test results` group box for the following tests:

- `P/R wave amplitude`
- `Threshold`
- `Lead impedance`

> **Note:** The measured values for the parameters `P/R wave amplitude` and `Threshold` are displayed when the follow-up tests have been conducted using **[Start tests]**.

The pacing threshold test is automatically performed at specific times of day or at hourly intervals if the `Capture control` function has been activated or the `ATM` parameter has been set in the `Parameters (permanent)` window.

Prerequisites The following requirements must be met for an automated follow-up:

- Telemetry contact between the device and the programmer has been established.
- It was possible to automatically interrogate the device.
- The programmer confirms the process with the following message in the information line:
  `Interrogation was successful.`
- There is enough printer paper in the programmer paper tray (if printing is to be carried out with the programmer's internal printer).

WARNING
Patient endangered by interrupted telemetry! Interruptions in telemetry between the programmer and the device during follow-up tests may result in inadequate pacing. • Telemetry using PGH Lift the programming head 30 cm; the device switches automatically to the permanent program. • RF telemetry When using RF telemetry, stop the temporary program in the user interface. The permanent program is then immediately active. If this is not successful, turn off and reposition the programmer then restart the programmer.

Results of automatic follow-up

The automatic follow-up displays the following results in the `Follow-up` window:

Display	Result
For the entire last follow-up period	• Total number of episodes • Number of ATs, mode switches, HVRs • IEGMs triggered by the patient
For the last 24 hours, all automatically measured values of the following tests	• Pacing impedance in RA, RV and LV • Average P/R amplitudes • Pacing threshold in RA, RV and LV
All automatically determined measurement values in the `Test results` group box	Black double arrows next to measured values or parameters indicate that these values have been measured or set automatically.

Results of the automatic follow-up tests

The results of the automatic follow-up can be found as follows:

- An overview of the follow-up test results can be found in the `Test results` group box in the `Follow-up` window.
- During follow-up, the automatic test functions generate an IEGM display with test markers in real-time and a print file with a short IEGM sequence. This short IEGM sequence can be displayed and printed with the set parameters via **More → Print manager → Preview**.
- The follow-up results are electronically archived:

  The archived follow-up results can be displayed by clicking on the **[Last follow-up]** button in the `Patient` group box. See: Archiving Follow-up Results, p. 175

Repeating the automatic tests

The tests can be repeated at any time.

Step	Action	Remark
1	Select **[Start tests]**.	
2	The `P/R wave amplitude` is determined.	The IEGM is displayed in real-time. P and R amplitudes are displayed with markers.
3	The `Threshold` is determined.	The IEGM of the pacing threshold test is transferred in real-time.
4	The `Lead impedance` is measured.	The lead impedance is always measured automatically and continuously by the device.

Canceling the automatic follow-up

An ongoing automatic follow-up can be canceled by pressing **[Stop]**.

11 Archive - Events - Measured Value Trends

What's in this chapter?

Display Events

Navigation: Follow-up

Display The `Follow-up` window shows the events that have been saved in the device since the last follow-up.

Detail of user interface

- New episodes  **20 recording(s)**

Display event details Click on the event being displayed to review its details.

Event messages Meaning of Event Messages, p. 174

Meaning of Event Messages

Navigation: Follow-up

WARNING
Battery charging status = EOS: patient not being treated If the battery status is EOS (end of service), the active device is out of service and cannot provide any therapy. • Replace the implanted device immediately.

Event messages

Note: The following table shows all possible event messages and explains their meaning. The precise messages shown will depend on the device type.

Event text	Meaning
`Device error`	Device error has occurred; contact BIOTRONIK.
`ERI occurred`	Elective replacement indication: indicates device must be replaced
`Lead status / lead error`	The device has been switched to unipolar pacing. You will find further information under **Diagnostics → More diagnostics → Lead impedance trend**.
`Ventricular episodes (> 3 in 24 h)`	More than three ventricular episodes occurred within 24 h.
`> 48 h Afib since last follow-up`	Sustained atrial episode > 48 h detected since the last follow-up.

Pacing Thresholds, P and R Wave Amplitudes – Details

Navigation: Follow-up → TrendView

Pacing threshold trends

Enable the function for recording threshold trends here:

- **Parameters → Bradycardia/CRT → Capture control → ON** or -> `ATM` (monitoring only).

Trends in P and R wave amplitudes

Note: If no value can be obtained, for example, due to permanent pacing, then no value is entered for that day.

- All trends record amplitudes from 0.2 to 20 mV.
- The P and R wave amplitudes are only displayed in the trend if sensing has been switched on for the relevant channel.

Archiving Follow-up Results

Navigation: Follow-up → Last follow-up

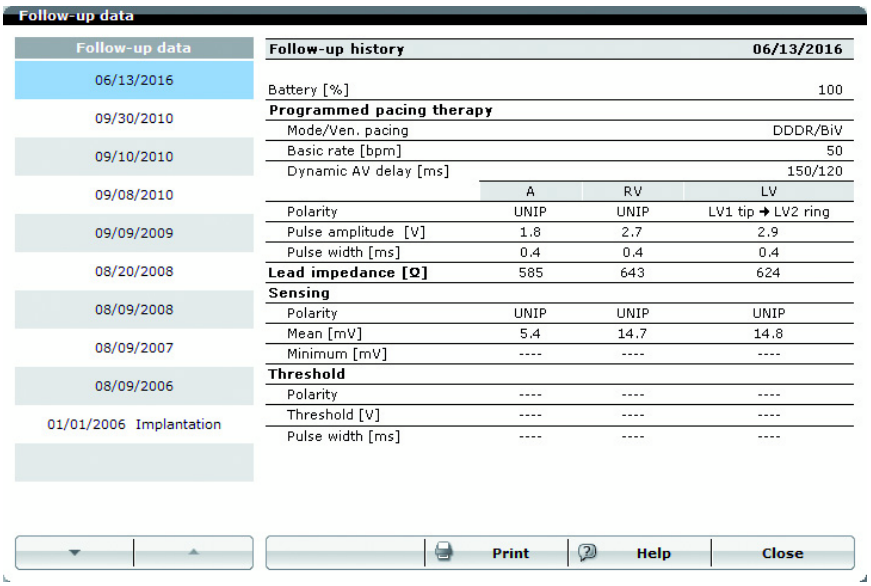
Objective

The archive offers you a structured overview of the chronological development of lead measurement values and the left ventricular polarity set for triple-chamber devices since implantation.

In addition, the data is shown for:

- Remaining battery capacity
- Modes
- Basic rate

User interface



Follow-up history			06/13/2016
Battery [%]			100
Programmed pacing therapy			
Mode/Ven. pacing			DDDR/BiV
Basic rate [bpm]			50
Dynamic AV delay [ms]			150/120
	A	RV	LV
Polarity	UNIP	UNIP	LV1 tip → LV2 ring
Pulse amplitude [V]	1.8	2.7	2.9
Pulse width [ms]	0.4	0.4	0.4
Lead impedance [Ω]	585	643	624
Sensing			
Polarity	UNIP	UNIP	UNIP
Mean [mV]	5.4	14.7	14.8
Minimum [mV]	----	----	----
Threshold			
Polarity	----	----	----
Threshold [V]	----	----	----
Pulse width [ms]	----	----	----

- The values determined upon implantation and those of the 9 subsequent follow-ups are displayed.
- When 10 follow-ups have been recorded, the system overwrites the oldest record beginning with the first follow-up. However, the data set recorded at implantation remains saved.

Evaluate Trends in Measured Values

Navigation: Follow-up → TrendView

Display trends

The Trends function provides you with a structured overview of important measured values, which are displayed as graphic trends since the last follow-up.

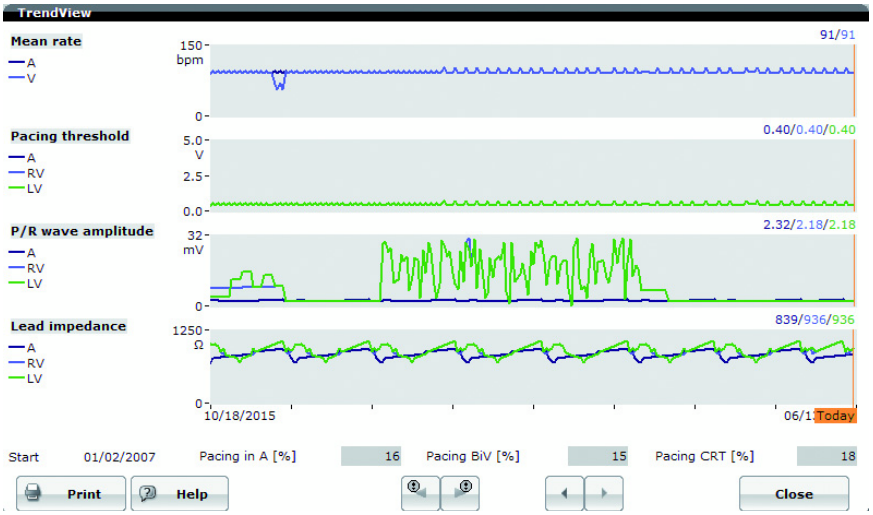
- Mean atrial and ventricular rate
- Pacing thresholds
- P/R amplitudes
- Pacing impedance in the atrium and ventricle

You can use the Trends function to navigate and to take a focused look at particular individual events.

Events from the event list are displayed directly beneath the caliper in the window **[TrendView]** with a comment and the date.

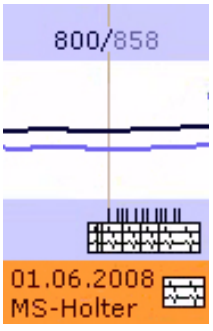
- Data for long-term trends are saved on a continuous basis. Recordings are not reinitialized every time the device is interrogated.
  - If required, initialize the restart for long-term recordings here: **Diagnostics → Start statistics**.

User interface



Results icons

The icons have the following meanings:

Icon	Meaning
	Event with details on data, time and type
	Event plus icon; Display details: click on the area shown in color

Arrow keys for navigation

The arrow keys have the following functions:

Icon	Functions
	Arrow keys with event icon: navigate to the left or right to the next event.
	Simple arrow keys: move the cursor to the right or left from one day to the next one.

Related topics

TrendView – Details, p. 177

Pacing Thresholds, P and R Wave Amplitudes – Details, p. 175

Automatic Lead Impedance Measurement, p. 21

TrendView – Details

Navigation: Follow-up → TrendView

Time window and resolution

The following trends are displayed for up to 240 days with a preset resolution of 24 h:

- Atrial, right and left ventricular pacing impedance
- Threshold trend in the atrium, left and right ventricle
- P/R wave amplitudes

Details

- Impedances are measured automatically. Measurement cannot be turned off.
- The daily value shown is the mean value which is determined automatically by the device within a 24 h period.
- If any measurement result taken in the recording period of 24 h should be outside the measurement range, then it will be shown in the trend.
- The 24 h recording period ends 2 min before the following time:
  - Message transmission for Home Monitoring
- The data are sent daily to the Home Monitoring Service Center if Home Monitoring is enabled.

Details of Diagnostics

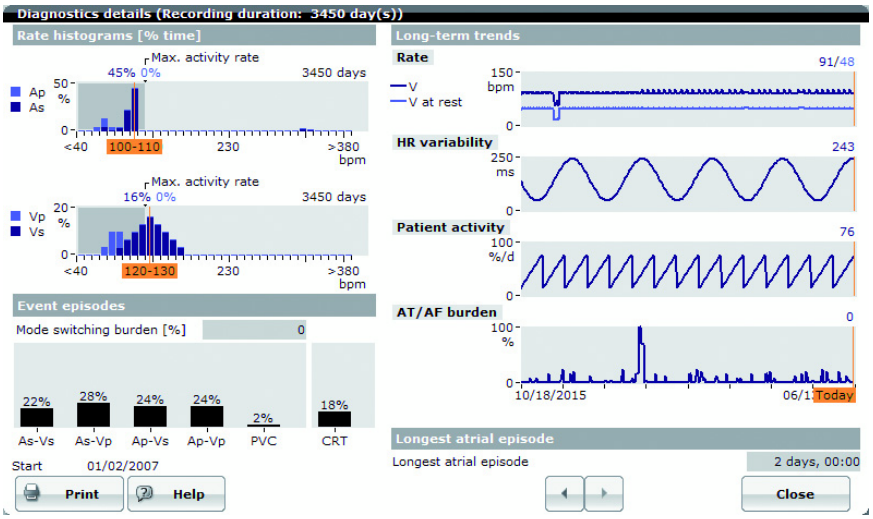
Navigation: Follow-up

Objective

In the `Diagnostics` group box in the `Follow-up` window you can display selected statistical data for diagnostic purposes all together in a single window. Here, you can evaluate the most important data from the individual statistics at a glance.

User interface

Details of diagnostics; histograms and trends



Display details

In the `Diagnostics` group box in the window `Follow-up` select: **[Details]**.

12 Performing Manual Follow-up

What's in this chapter?

12.1 Impedance Test

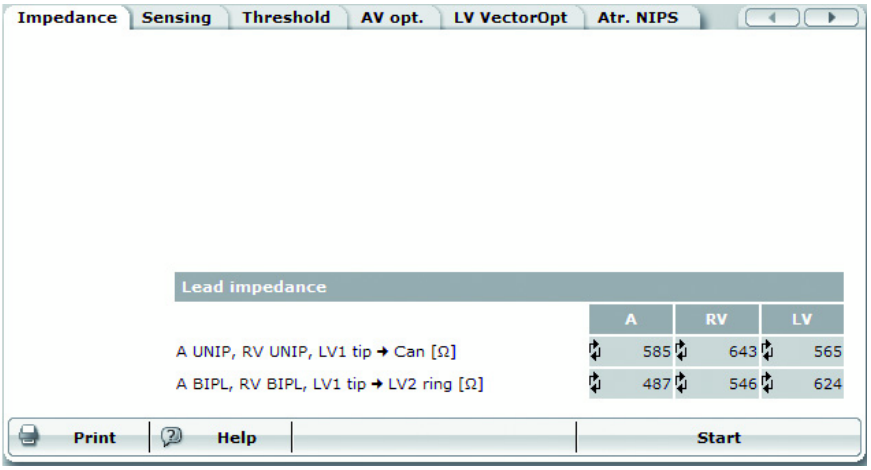
What's in this section?

Objective

- The impedance test measures the following conductor resistances of the implanted leads:
  - Pacing impedance
- The measured values serve to check the leads (for example, in case of lead fracture) and to evaluate the lead position.

User interface

The `Impedance` tab



Measuring Impedance

Navigation: Tests → Impedance

WARNING
Interrupted telemetry can cause incorrect data display Interrupted telemetry between the device and the programmer can cause false data to be displayed on the programmer. • In order to continuously monitor the effectiveness of pacing and the plausibility of the test results at any time, use an external ECG device during tests.

WARNING
Patient endangered by interrupted telemetry! Telemetry interference between programmer and implanted device can lead to inappropriate pacing of the patient. • In the case of telemetry with PGH: — Raise the programming head by at least 30 cm; the device will switch automatically to the permanent program. • In the case of RF telemetry: — Stop the temporary program using the user interface of the programmer: The permanent program will become active immediately. • If these measures do not work, turn the programmer off, restart it and, if necessary, reposition the programming head.

Note: Stop the temporary program
• In the case of telemetry with PGH: — Raise the programming head by at least 30 cm; the device will switch automatically to the permanent program. • In the case of RF telemetry: — Stop the temporary program using the user interface of the programmer: The permanent program will become active immediately. • If these measures do not work, turn the programmer off, restart it and, if necessary, reposition the programming head.

Measuring impedances

Step	Action
1	Evaluate the default parameter values for the test program and adjust them if necessary.
2	Select **[Start]**. The following processing actions are executed by the system: • Measuring the pacing impedance • Displaying measured values

Results Evaluate the results and reposition the leads if necessary.

12.2 Sensing Test

What's in this section?

Performing the Sensing Test

Navigation: Tests → Sensing

Objective The sensing test has the following clinical benefits:

- Evaluation of the position of the leads
- Check of prerequisites for additional electrophysiological tests
- Determination of optimal sensitivity for the device

WARNING

Interrupted telemetry can cause incorrect data display

Interrupted telemetry between the device and the programmer can cause false data to be displayed on the programmer.

- In order to continuously monitor the effectiveness of pacing and the plausibility of the test results at any time, use an external ECG device during tests.

WARNING

Patient endangered by interrupted telemetry!

Telemetry interference between programmer and implanted device can lead to inappropriate pacing of the patient.

- In the case of telemetry with PGH:
  - Raise the programming head by at least 30 cm; the device will switch automatically to the permanent program.
- In the case of RF telemetry:
  - Stop the temporary program using the user interface of the programmer: The permanent program will become active immediately.
- If these measures do not work, turn the programmer off, restart it and, if necessary, reposition the programming head.

Note: Stop the temporary program

- In the case of telemetry with PGH:
  - Raise the programming head by at least 30 cm; the device will switch automatically to the permanent program.
- In the case of RF telemetry:
  - Stop the temporary program using the user interface of the programmer: The permanent program will become active immediately.
- If these measures do not work, turn the programmer off, restart it and, if necessary, reposition the programming head.

Performing the sensing test

To perform the sensing test, proceed as follows:

Step	Action	Remark
1	Evaluate the default parameter values for the test program and adjust them if necessary.	--
2	Select `Basic rate` and reduce the basic rate to a value less than the intrinsic rhythm.	Display of measured values: • Current measured value: to the right of the IEGM • Mean measured values: in the `Measured values` group box
3	Evaluate the mean measured values.	Optimization options: • Reposition the leads. • Change the parameter values.

When the test is completed, the permanent program is automatically reactivated.

Conducting the intrinsic rhythm test

Step	Action	Remark
1	Select **[Intrinsic rhythm]** and hold down the button.	The intrinsic rhythm test starts: • Backup pacing is deactivated. • The P and R amplitudes are measured and displayed.
2	End the intrinsic rhythm test by releasing the **[Intrinsic rhythm]** button.	The permanent program is active again.

Details

Sensing Test – Details, p. 184

Sensing Test – Details

Navigation: Tests → Sensing

Measurement of R amplitudes

During manual sensing testing, an evaluation is made either once for each channel for 5 seconds or for a maximum of 6 detected events. The display is updated with every new measured value. In manual sensing tests, if no sensed event occurs then the programmer will show a corresponding message.

Results

Depending on the test mode and the set parameters, the sensing test provides the following results:

- Display of minimum, mean and maximum signal amplitudes of the P/R waves in every chamber
- Display of mean rate if atrial sensed events occur

12.3 Threshold Test

What's in this section?

Conducting the Threshold Test

Navigation: Tests → Threshold

Objective The threshold test determines the lowest value of pacing energy needed to pace the heart. Low values for pulse width and pulse amplitudes increase the service time of the implanted device.

In the course of the threshold test, the pulse amplitude is reduced until a stimulus no longer triggers a response from the heart. The next highest value that effectively paces the heart is the threshold.

WARNING

Interrupted telemetry can cause incorrect data display

Interrupted telemetry between the device and the programmer can cause false data to be displayed on the programmer.

- In order to continuously monitor the effectiveness of pacing and the plausibility of the test results at any time, use an external ECG device during tests.

WARNING

Patient endangered by interrupted telemetry!

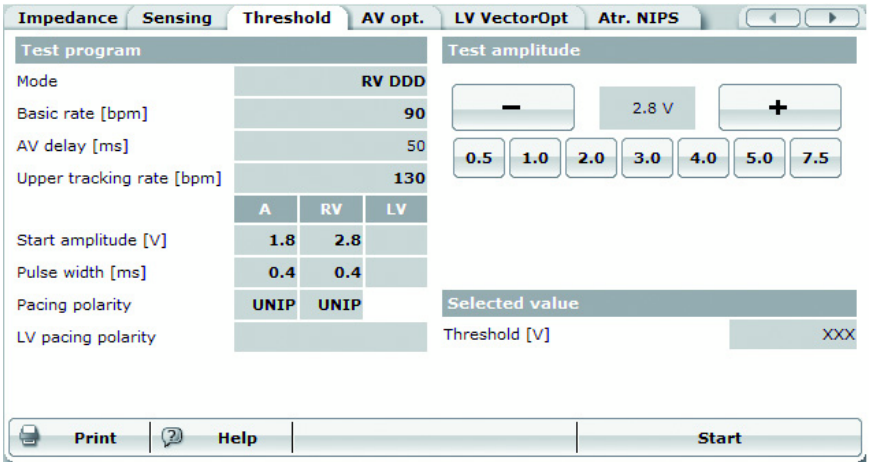
Telemetry interference between programmer and implanted device can lead to inappropriate pacing of the patient.

- In the case of telemetry with PGH:
  - Raise the programming head by at least 30 cm; the device will switch automatically to the permanent program.
- In the case of RF telemetry:
  - Stop the temporary program using the user interface of the programmer: The permanent program will become active immediately.
- If these measures do not work, turn the programmer off, restart it and, if necessary, reposition the programming head.

Note: Stop the temporary program

- In the case of telemetry with PGH:
  - Raise the programming head by at least 30 cm; the device will switch automatically to the permanent program.
- In the case of RF telemetry:
  - Stop the temporary program using the user interface of the programmer: The permanent program will become active immediately.
- If these measures do not work, turn the programmer off, restart it and, if necessary, reposition the programming head.

User interface



Conducting the threshold test

If you want to run the threshold test using the default settings or adjusted parameters in the `Test program` group box, then proceed as follows:

Step	Action
1	Evaluate the default parameter values for the test program and adjust them if necessary.
2	Select **[Start]**.
3	During the test, observe the ECG monitor to obtain the pacing threshold and to modify the test amplitude if a particular pacing pulse is no longer effective.
4	To end the test, press the following button: • **[Stop and Save]**
5	Accept the measured pacing threshold by selecting the value in the `Threshold` window.

Select test amplitude

Proceed as follows:

Select a test amplitude from the table	The selected test amplitude will be applied.
Increase or reduce test amplitude	Choose from the following options: • Either select the desired test amplitude from the table • Or select **[+]** or **[-]** As long as the test pulses are active, capture wave windows are displayed under the ECG to highlight the test pulses. See also: Show and hide capture waveform windows, p. 187

Show and hide capture waveform windows

In the ECG windows, capture waveform windows show extracts from the ECG for test pacing. From here you can show or hide these windows permanently: **Preferences → Tests → Capture waveform window**.

Evaluating and adopting the results

Accept the threshold value in the `Threshold` window. You can print out the results if required.

WARNING
Ineffective pacing due to modified pacing threshold The values determined by the threshold test can vary from follow-up to follow-up. • Always ensure a sufficient safety margin in the values for pulse amplitude and pulse width.

Adjusting the permanent program

Adjust the permanent program if required: **Parameters → Bradycardia/CRT** and transmit your settings to the device using the **[Program]** button.

Threshold Test – Parameters

Navigation: Tests → Threshold

Setting the parameters of the test program

In most cases, the factory settings of the test program are suitable for the threshold test. You can change the parameters if necessary.

Meaning of parameters

The meaning of selected parameters:

Parameter	Meaning
`Mode: ...-AUTO`	The threshold test is executed automatically.

12.4 AV Optimization Test

What's in this section?

AV Optimization by Testing

Navigation: Parameters → Dynamic AV delay → AV optimization test

> **Note:** Stop the temporary program
> - In the case of telemetry with PGH:
> — Raise the programming head by at least 30 cm; the device will switch automatically to the permanent program.
> - In the case of RF telemetry:
> — Stop the temporary program using the user interface of the programmer: The permanent program will become active immediately.
> - If these measures do not work, turn the programmer off, restart it and, if necessary, reposition the programming head.

Objective

The test is helpful for optimizing the AV delay. Optimized AV delays are determined on the basis of P-wave measurements. These values are displayed for pacing and sensing and can be applied for the `Dynamic AV delay`.

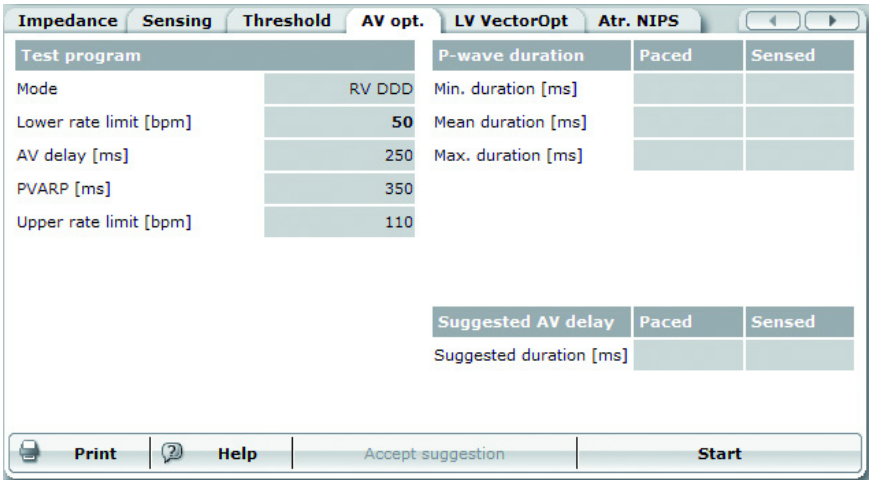
Performing AV optimization test

Proceed as follows:

Step	Action
1	Select **Tests → AV opt.** You can alternately access the test: Select **Parameters → Bradycardia/CRT → Dynamic AV delay → AV optimization test**.
2	Begin the test immediately with the preset values or edit the parameter beforehand: `Lower rate limit` Once it starts, the test is performed by measuring the P waves.
3	Various intervals and the optimized AV delay are shown in the field: `Suggested AV delay`.
4	Select **[Accept suggestion]**. The optimized values are applied for `Dynamic AV delay`, displayed there and are available for further editing of the AV delay.

User interface

AV optimization test



Parameters for AV optimization test

The following parameters control the test:

Parameter	Meaning
Mode RV DDD	The test is performed in DDD mode and determines the perceived and paced duration of P-waves. RV indicates that pacing is only performed in the right ventricle.
Lower rate limit	Can be selected within the rate range.
AV delay	Fixed preset
PVARP	Fixed preset
Upper rate limit	Fixed preset

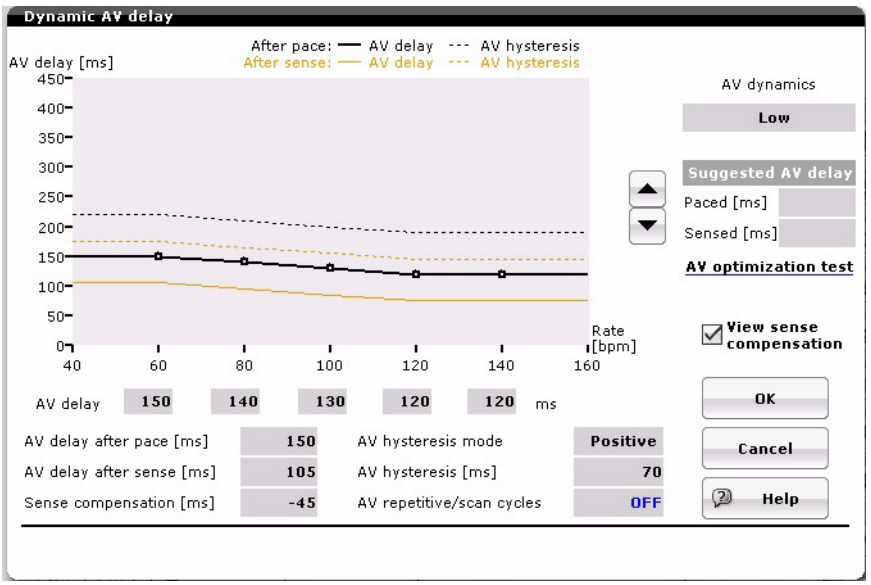
Using optimized values

The values determined for the AV delays have been applied and are displayed in the window: Dynamic AV delayin the field: Suggested AV delay.

The AV delay can be further edited using these optimized values.

User interface

Suggested AV delay



12.5 LV VectorOpt

What's in this section?

Test LV Pacing

Navigation: Tests → LV VectorOpt

Note: Stop the temporary program

- In the case of telemetry with PGH:
  - Raise the programming head by at least 30 cm; the device will switch automatically to the permanent program.
- In the case of RF telemetry:
  - Stop the temporary program using the user interface of the programmer: The permanent program will become active immediately.
- If these measures do not work, turn the programmer off, restart it and, if necessary, reposition the programming head.

Testing and setting the parameters for LV VectorOpt

It is possible to test LV polarities and their parameters in the `LV VectorOpt` tab, and to transfer these settings directly into the permanent program.

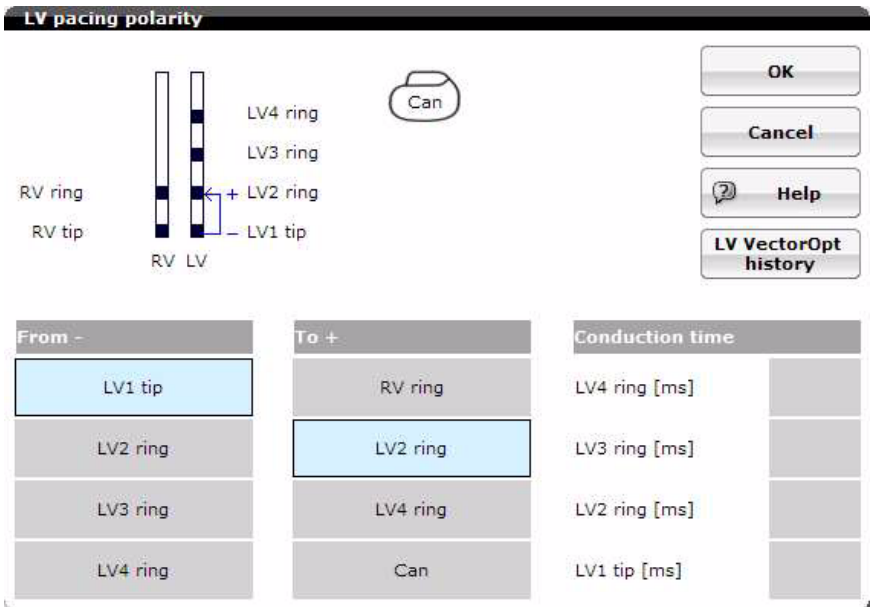
The following parameters can be displayed, tested and set:

- Polarities of LV pacing – pacing paths
- LV pacing threshold

  with the values for Pulse amplitude and Pulse width
- Pacing threshold for phrenic nerve stimulation (PNS) with information on pulse amplitude and width
- Lead impedance
- Conduction times from RVp to LVs

Set LV test polarity

LV polarity with 13 possible configurations can be selected directly with the forward and backward arrows. LV polarity can also be set in the `LV pacing polarity` dialog window.



Setting additional parameters

The parameters for the LV threshold test and the phrenic nerve stimulation can be set directly:

- Pulse amplitude:
  - Change the amplitude using **[-]** and **[+]** in a number of preset step sizes
  - Direct selection of amplitude buttons with numeric values
- `Pulse width`
- `Start amplitude`

Saving measured values

The measured values can be saved separately for LV pacing threshold and phrenic nerve stimulation.

- Select **[Save threshold]**, to save the pacing threshold obtained.
- Select **[Save PNS threshold]**, to save the PNS threshold obtained.

Display of measured values

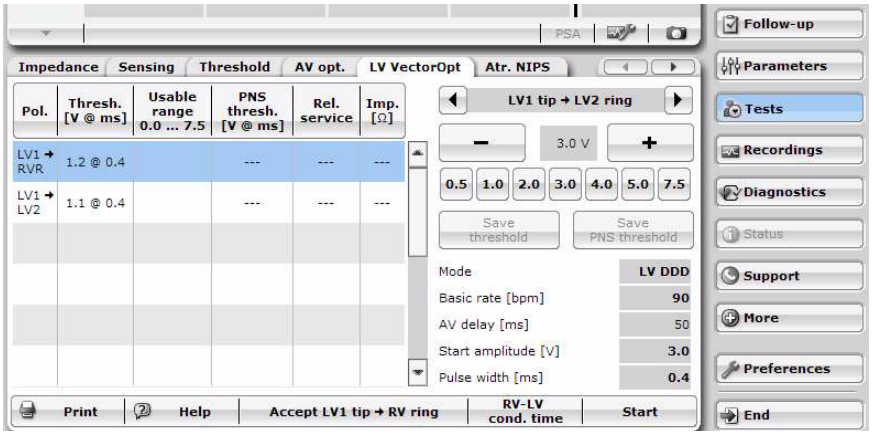
The measured values are displayed in the table on the left of the window.

Accept all settings

You can accept the suitable polarity directly into the permanent program:

- To do this, select the relevant row in the table.
- Select **[Accept]**.

  The selected setting is accepted into the Parameters tab and is made effective through being sent as the permanent program.



Measuring the RV-LV Conduction Time

Navigation: Tests → LV VectorOpt

Note: Stop the temporary program

- In the case of telemetry with PGH:
  - Raise the programming head by at least 30 cm; the device will switch automatically to the permanent program.
- In the case of RF telemetry:
  - Stop the temporary program using the user interface of the programmer: The permanent program will become active immediately.
- If these measures do not work, turn the programmer off, restart it and, if necessary, reposition the programming head.

Measuring the RV-LV conduction time

This function serves to measure and evaluate the conduction time between an RV pace and the various LV poles.

Select **Tests → LV VectorOpt → RV-LV cond. time**.

The measurement can be performed with the following parameters:

- Available modes: RV DDD; RV VVI
- Basic rate
- AV delay

Conduction times to the available LV poles are measured and displayed based on the RV pace (lead tip and ring).

Measuring the RV-LV conduction time

This function serves to measure and evaluate the conduction time between an RV pace and the various LV poles.

- Select **[RV-LV cond. time]** and **[Measure]**, in order to measure conduction time.

The measured conduction times are displayed in the window of the same name.

12.6 NIPS - Non-Invasive Programmed Stimulation

What's in this section?

NIPS - Non-Invasive Programmed Stimulation

Navigation: Tests → Atr. NIPS

WARNING
Triggering arrhythmias Depending on the type of high-rate stimulation and the predispositions of the patient, dangerous arrhythmias, including ventricular fibrillation, may be triggered. • External pacing may only be performed by physicians familiar with high-rate stimulation procedures. • During electrophysiological examinations, observe the usual precautionary measures.

Objective

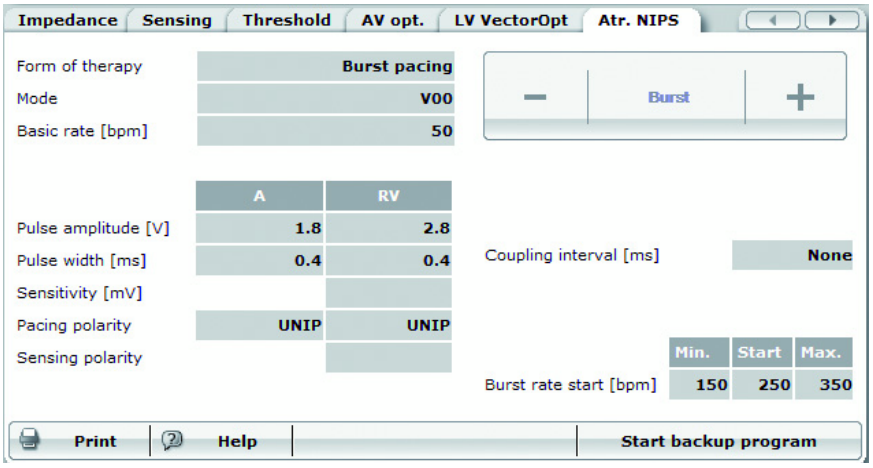
NIPS is used for the acute treatment of atrial arrhythmia. The device delivers high frequency pulse sequences that are triggered manually on the programmer. No additional external device is required.

Description

NIPS includes the following features:

- Backup pacing (backup program)
- The following therapies:
  - Burst pacing: Pulse sequence with fixed or variable rate; details: NIPS - Executing Burst Pacing, p. 198
  - Programmed pacing: electrophysiological pacing program with up to three extrastimuli; details: NIPS - Executing Programmed Stimulation, p. 200

User interface



Switching the Print setup ON and OFF

When the automatic Print setup is switched on, the ECG and the parameters for the permanent program are printed automatically.

NIPS default settings

Permanently save the preference for the report paper speed in the programmer: **Preferences → Tests → Print setup**. This setting will be used the next time the function is activated.

NIPS - Executing Burst Pacing

Navigation: Tests → Atr. NIPS

WARNING

Triggering arrhythmias

Depending on the type of high-rate stimulation and the predispositions of the patient, dangerous arrhythmias, including ventricular fibrillation, may be triggered.

- External pacing may only be performed by physicians familiar with high-rate stimulation procedures.
- During electrophysiological examinations, observe the usual precautionary measures.

WARNING

Interrupted telemetry can cause incorrect data display

Interrupted telemetry between the device and the programmer can cause false data to be displayed on the programmer.

- In order to continuously monitor the effectiveness of pacing and the plausibility of the test results at any time, use an external ECG device during tests.

WARNING

Reduced pulse amplitude due to a drop in battery voltage

If the rate and amplitude are set very high and the pulse width is set too long at the same time, the battery voltage can temporarily drop so low that the actual pulse amplitude drops well below the selected level.

- Continuously check the pacing efficiency using ECG monitoring.

WARNING

Loss of capture

If the pulse amplitude is not large enough to provide effective pacing, the patient may experience a hemodynamically critical condition.

- Therefore, continuously monitor the ECG and the patient's condition.

Note: Stop the temporary program

- In the case of telemetry with PGH:
  - Raise the programming head by at least 30 cm; the device will switch automatically to the permanent program.
- In the case of RF telemetry:
  - Stop the temporary program using the user interface of the programmer: The permanent program will become active immediately.
- If these measures do not work, turn the programmer off, restart it and, if necessary, reposition the programming head.

Backup pacing

Preparation:

- For `Backup stimulation` select the pacing rate (or `OFF` if NIPS is to be performed without safety pacing).

Start:

- Select **[Start backup program]**:
  - Safety pacing is performed in VVI mode as a temporary program with the selected rate.
  - The information line displays the following: `NIPS backup program is active.`

Change backup rate:

- The rate of backup pacing cannot be changed during programmed pacing or burst pacing. Select **[Stop backup program]** (see below).

Stop:

- Select **[Stop backup program]**: NIPS is canceled and the permanent program is activated in the device.

Parameter

NIPS - Description of Selected Parameters, p. 202

Burst stimulation

Start:

- Press the **[Burst]** button and keep it pressed for the duration of pacing.

Increase/decrease burst rate:

- On the **[Burst]** button: press and hold **[+]** / **[-]** for the duration of the burst.
- The burst rate is increased/decreased incrementally from the preset value until the programmed burst maximum/minimum has been reached.

Stop:

- Release the **[Burst]** button:
  - Burst pacing is ended.
  - Backup pacing remains active.

NIPS - Executing Programmed Stimulation

Navigation: Tests → Atr. NIPS

WARNING

Triggering arrhythmias

Depending on the type of high-rate stimulation and the predispositions of the patient, dangerous arrhythmias, including ventricular fibrillation, may be triggered.

- External pacing may only be performed by physicians familiar with high-rate stimulation procedures.
- During electrophysiological examinations, observe the usual precautionary measures.

WARNING

Interrupted telemetry can cause incorrect data display

Interrupted telemetry between the device and the programmer can cause false data to be displayed on the programmer.

- In order to continuously monitor the effectiveness of pacing and the plausibility of the test results at any time, use an external ECG device during tests.

WARNING

Reduced pulse amplitude due to a drop in battery voltage

If the rate and amplitude are set very high and the pulse width is set too long at the same time, the battery voltage can temporarily drop so low that the actual pulse amplitude drops well below the selected level.

- Continuously check the pacing efficiency using ECG monitoring.

WARNING

Loss of capture

If the pulse amplitude is not large enough to provide effective pacing, the patient may experience a hemodynamically critical condition.

- Therefore, continuously monitor the ECG and the patient's condition.

Note: Stop the temporary program

- In the case of telemetry with PGH:
  - Raise the programming head by at least 30 cm; the device will switch automatically to the permanent program.
- In the case of RF telemetry:
  - Stop the temporary program using the user interface of the programmer: The permanent program will become active immediately.
- If these measures do not work, turn the programmer off, restart it and, if necessary, reposition the programming head.

Backup pacing

Preparation:

- For `Backup stimulation` select the pacing rate (or `OFF` if NIPS is to be performed without safety pacing).

Start:

- Select **[Start backup program]**:
  - Safety pacing is performed in VVI mode as a temporary program with the selected rate.
  - The information line displays the following: `NIPS backup program is active.`

Change backup rate:

- The rate of backup pacing cannot be changed during programmed pacing or burst pacing. Select **[Stop backup program]** (see below).

Stop:

- Select **[Stop backup program]**: NIPS is canceled and the permanent program is activated in the device.

Parameter

NIPS - Description of Selected Parameters, p. 202

Programmed stimulation

Start:

- Select **[Start programmed stimulation]**.

  The programmed stimulation remains active until the set sequence has been carried out in full or is ended manually (see below).

Stop:

- **[Stop progr. stimulation]**Select **[Stop progr. stimulation]**:
  - Programmed stimulation is ended.
  - The device uses the permanent program.
  - Backup pacing remains active.

NIPS - Description of Selected Parameters

Burst pacing

Form of therapy = burst pacing:

Parameter	Description
Coupling interval	• Burst pacing is started after the coupling interval has passed. • The coupling interval synchronizes burst pacing with the first paced or sensed event. • If the value for Coupling interval is set to None then burst pacing is started asynchronously.

Programmed stimulation

Form of therapy = programmed stimulation:

Parameter	Description
S1 - S1	Basic interval for programmed stimulation
S1 cycles	The basic interval is repeated in n cycles before the extrastimuli are coupled. If the value 0 is specified, extrastimuli may be delivered immediately after the basic interval S1 - S1 .
S1 - S2 ... S3 - S4	• If > 0: Intervals of the extrastimuli that are coupled to the basic interval and possibly preceding extra-stimuli. • If = 0: no coupling of extrastimuli
Decrement	• If > 0: The last interval of extrastimuli is reduced by the set value after the pause with each sequence. • If = 0: No decrement of the last interval
Pause	The parameter Pause becomes effective after a stimulation sequence. • If > 0: After the pause has elapsed, the complete sequence is automatically repeated until the programmed stimulation is canceled. • If = Stop: The sequence is not repeated automatically.

Field name	Description
Current	The field shows the last active extrastimulus as calculated from the settings for the respective extra-stimulus interval and the decrement.

12.7 Retrograde Conduction Test

What's in this section?

Conducting the Retrograde Conduction Test

Navigation: Tests → Retrogr. conduct.

Objective Starting from the measured conduction times, you can set the temporal control parameters in order to optimize hemodynamics and prevent pacemaker-mediated tachycardia.

WARNING

Interrupted telemetry can cause incorrect data display

Interrupted telemetry between the device and the programmer can cause false data to be displayed on the programmer.

- In order to continuously monitor the effectiveness of pacing and the plausibility of the test results at any time, use an external ECG device during tests.

WARNING

Patient endangered by interrupted telemetry!

Telemetry interference between programmer and implanted device can lead to inappropriate pacing of the patient.

- In the case of telemetry with PGH:
  - Raise the programming head by at least 30 cm; the device will switch automatically to the permanent program.
- In the case of RF telemetry:
  - Stop the temporary program using the user interface of the programmer: The permanent program will become active immediately.
- If these measures do not work, turn the programmer off, restart it and, if necessary, reposition the programming head.

Note: Stop the temporary program

- In the case of telemetry with PGH:
  - Raise the programming head by at least 30 cm; the device will switch automatically to the permanent program.
- In the case of RF telemetry:
  - Stop the temporary program using the user interface of the programmer: The permanent program will become active immediately.
- If these measures do not work, turn the programmer off, restart it and, if necessary, reposition the programming head.

Conducting the test

Step	Action
1	Evaluate the default parameter values for the test program and adjust them if necessary.
2	In the `Basic rate` field, select the rate with which stimulation is required during testing. The rate must be above the intrinsic rhythm.
3	Start the test by pressing **[Start]**. The test ends automatically after 5 conductions or 10 seconds. During measurement, the system displays the following on the screen: • On the IEGM display: the current measured conduction time • Under `Measured values`: the minimum, mean and maximum conduction time measured over a number of periods, as well as the mean rate.
4	Use **[Cancel]** to abort the test if necessary.

Details Test for Retrograde Conduction – Details, p. 205

Test for Retrograde Conduction – Details

Navigation: Tests → Retrogr. conduct.

Description This test determines whether retrograde conduction occurs and, if so, how long latency is.

The following latencies are measured:

- Right ventricle (pacing) and atrium (dual-chamber devices)
- Left or right ventricle and atrium (triple-chamber devices)

Prerequisites The test can be performed only under the following conditions:

- The device was successfully interrogated.
- Pacing is possible in the right or left ventricle.
- Sensing is possible in the right atrium.

Process sequence

- The system updates the display with each new measurement, shows a progress bar on the information line and displays the **[Cancel]** button instead of the **[Start]** button.
- The user can print out the measurements and parameters.
- The user can select a different chamber, change parameters if necessary and start a new measurement process.

12.8 Sensor Optimization

What's in this section?

Sensor Optimization

Navigation: Tests → Sensor opt.

Objective

Sensor optimization adjusts the sensor function in the device to the patient's needs during the exercise test.

Description

For the duration of sensor optimization, create a rate profile of the patient by performing exercise tests. To do this, a fixed short-term trend of 16 min. is recorded, which documents the function of the sensor in the device during this exercise test.

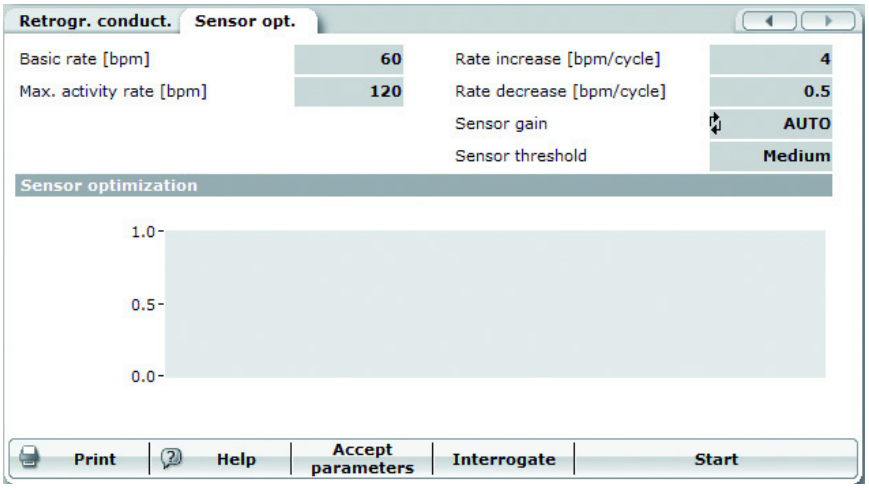
After the exercise test, interrogate the device again and suggestions for setting the sensor parameters in the `Sensor opt.` window will be provided. The parameters can be changed and further optimized.

Then adopt the suggestion and check to make sure that the changed parameters do not result in conflicts with other parameters. If they do not, adopt the settings in the permanent program.

Performing sensor optimization

The device was successfully interrogated for the first time. The standard statistics were are also interrogated in this process. Proceed as follows to perform sensor optimization:

Step	Action
1	Select **Tests → Sensor opt.** to access the sensor optimization function. The statistics are empty the first time sensor optimization is called.
2	Select **[Start]**. A message indicates that a fixed short-term trend has to be set for sensor optimization. Confirm the notification with **[OK]** to start the fixed short-term trend.
3	Have the patient complete the exercise test and then interrogate the device again by positioning the programming head.
4	Change the parameters for rate adaptation until the preview curve of the trend chart meets your expectations. Select **[Accept parameters]** to check the changed settings in the parameters window with regard to possible parameter conflicts. Transmit the changed parameter settings to the device using the **[Program]**button.



Details on the simulation preview

The sensor optimization window also includes the parameters for rate adaptation. These correspond to the settings that are valid while the trend is being recorded.

Note: If sensor optimization has been performed with a pacing mode without rate adaptation, then the corresponding rate-adaptive program is shown as a parameter suggestion.

IV ProMRI

What's in this part?

Overview See part IV for further information on conditions and instructions for the MR scan.

13 Preparing the MRI Scan

What's in this chapter?

MRI Program - Device Preparation

MRI Manual

Note: Always observe the information given in the MRI manual by BIOTRONIK: • It can be found at: manuals.biotronik.com/ Product Group: ProMRI -> Product: ProMRI

Selecting a program

Select your program setting with the **MRI → MRI program** function:

Parameter setting	Program
ON	MRI program: activate
OFF	MRI program: deactivate
AUTO	MRI program = automatic activation upon detection of a magnetic field: The default MRI program remains active for as long as the MRI scan continues.

Device preparation

Step	Action
1	Group box MRI checklist: • Make sure that all the preconditions for an MRI scan are fulfilled. • Tick the **[Patient is approved for MRI scan]** check box.
2	Only when Program = AUTO: • Select Expiration date: Enter a date that is not more than two weeks in the future. The magnetic sensor will then be enabled during the set period.
3	Select an MRI mode: • OFF - recommended for patients who are not pacemaker-dependant • A00, D00, V00 - recommended for pacemaker-dependent patients depending on the particular indication • D00/BiV or V00/BiV - recommended for patients dependent on their pacemaker with a triple-chamber device for biventricular pacing
4	You can use the **[Test MRI]** button to test whether the pacing settings are suitable for the patient before sending the MRI program.
5	Select **[Program]** to transmit the settings to the device.

Patient Information

Radiological Information for the Patient, p. 212

MRI Programs - Details

MRI program: AUTO

Note: Using the MRI AutoDetect function requires a bipolar sensing polarity in the permanent program.

- With the MRI AutoDetect function, the device has a sensor which recognizes the fields of an MRI scanner and switches automatically into the predefined MRI mode. 1 minute after leaving the MRI scanner, the device automatically switches back to the permanent program.
- The MRI AutoDetect function is active for a maximum of 14 days from the day it is programmed and allows for an indefinite number of MRI scans during this period. The programming expires at 23:59h of the selected day.
- Thus – even as early as the day of the preliminary examination – the device can be set to an automatic MRI mode as long as the planned MRI session is to take place within the next 2 weeks. The device will not need to be reprogrammed after the MRI scan.
- When Home Monitoring is activated, a follow-up is performed during the night after the MRI scan.

MRI program: ON

- With devices containing MRI AutoDetect, you can also switch on the MRI program manually.
- Switch off the MRI program after the MRI scan.

Patient Information

Radiological Information for the Patient, p. 212

Radiological Information for the Patient

Display and print information

By using the **[Radiological information]** button, you can view radiological information and print it out to pass it on to the patient for MR scanning if required.

V Technical Data

What's in this part?

Overview The technical data is documented in part V.

14 Parameters

What's in this chapter?

Note: Unless described separately, information for device type HF also applies to device type HF QP.

Timing

Basic rate day/night

Parameter	Range of values	Standard	SR	DR	HF
Basic rate	30 ... (5) ... 100 ... (10) ... 200 bpm	60 bpm	x	x	
		50 bpm			x
Night rate	OFF; 30 ... (5) ... 100 ... (10) ... 200 bpm	OFF	x	x	x
Night begins	00:00 ... (10 min) ... 23:50 hh:mm	—	x	x	x
Night ends					

Rate hystereses

Parameter	Range of values	Standard	SR	DR	HF
Hysteresis	OFF; -5 ... (-5) ... -25 ... (-20) ... -65 bpm	OFF	x	x	x
Repetitive/ search cycles	OFF; ON	OFF	x	x	x

AV delay

Parameter	Range of values	Standard	SR	DR	HF
AV delay	Low; Medium; High; Fixed; Individual	Low		x	x
	20 ... (5) ... 350 ms (in 6 rate ranges)	180-170-160-150-140 ms		x	
	CLS and all HF modes: 20 ... (5) ... 350 ms (in 6 rate ranges)	150-140-130-120-120 ms		x	x
Sense compensation	OFF; -10 ... (-5) ... -120 ms	-45 ms		x	x

AV hystereses

Parameter	Range of values	Standard	SR	DR	HF
AV hysteresis mode	OFF; Positive; Negative HF when setting RV: IRSplus	OFF		x	x
Positive modes: AV hysteresis	70; 110; 150; 200 ms	70 ms CLS modes: 110 ms		x	x
Negative modes: AV hysteresis	10 ... (10) ... 150 ms	50 ms		x	x
AV repetetive / scan cyles	OFF; ON	ON		x	x

Ventricular pacing

Parameter	Range of values	Standard	SR	DR	HF
Ventricular pacing	BiV, RV; LV	BiV			x
Triggering	OFF; RVs; RVs + PVC	RVs			x
LV T-wave protection	ON; OFF	ON			x
Maximum trigger rate	AUTO; 90 ... (10) ... 160 bpm	AUTO			x
Initially paced chamber	RV; LV	LV			x
VV delay after Vp	0 ... (5) ... 80 ... (10) ... 100 ms	0 ms			x
VV delay after Vs	0 ms	0 ms			x

Upper rate

Parameter	Range of values	Standard	SR	DR	HF
Upper rate SR: in VVT mode	90 ... (10) ... 200 bpm	130 bpm	x	x	x
Wenckebach response/ 2:1 rate	Automatically set	—		x	x
Atrial upper rate	OFF; 175; 200; 240 bpm	240 bpm		x	x

Mode switching

Parameter	Range of values	Standard	SR	DR	HF
Mode switching	OFF; ON	ON		x	x
Intervention rate	100 ... (10) ... 250 bpm	160 bpm		x	x
Switch to mode	DDI; DDI(R) when permanent DDD(R) VDI; VDI(R) when permanent VDD(R)	DDI(R)		x	x
Ventricular pacing	RV; BiV	BiV			x
Onset criterion	3 ... (1) ... 8 (out of 8)	5		x	x
Resolution criterion				x	x
Change of the basic rate with mode switching	OFF; +5 ... (5) ... +30 bpm	+10 bpm			
Rate stabilization with mode switching	OFF; ON	OFF		x	x
2:1 lock-in protection	OFF; ON	ON		x	
	When setting RV: OFF; ON	ON			x

Ventricular pacing suppression

Parameters valid for devices in DDD-ADI or DDDR-ADIR modes:

Parameter	Range of values	Standard	SR	DR	HF
Vp suppression	OFF; ON	OFF		x	x
Pacing suppression after consecutive Vs	1 ... (1) ... 8	6		x	x
Pacing support after x cycles	1 ... (1) ... 4 (out of 8)	3		x	x

Refractory periods

Parameter	Range of values	Standard	SR	DR	HF
RV refractory period	200 ... (25) ... 500 ms	250 ms	x	x	x
Atrial refractory period	AUTO	AUTO		x	x
Atrial refractory period in the modes AAI(R); AAT(R); DDT	300 ... (25) ... 775 ms	350 ms		x	x
LV refractory period	200 ms	200 ms			x
AUTO PVARP	OFF; ON	ON		x	x
PVARP	175 ... (25) ... 600 ms	225 ms		x	x
PVARP after PVC	PVARP + 150 ms (max: 600 ms)	Automatically set		x	x

Blanking periods

Parameter	Range of values	Standard	SR	DR	HF
Far-field protection after Vs	100 ... (10) ... 220 ms	100 ms		x	x
Far-field protection after Vp	100 ... (10) ... 220 ms	150 ms		x	x
Ventricular blanking period after Ap	30 ... (5) ... 70 ms	30 ms		x	x

PMT protection

Parameter	Range of values	Standard	SR	DR	HF
PMT protection	OFF; ON	ON		x	x
VA criterion	250 ... (25) ... 500 ms	350 ms		x	x

Pacing and Sensing

Pulse amplitude and pulse width

Parameter	Range of values	Standard	SR	DR	HF
Pulse amplitude A/RV/LV	0.2 ... (0.2) ... 6.0 ... (0.5) ... 7.5 V	3.0 V	x	x	x
Pulse width A/RV/LV	0.1 ...(0.1) ... 0.5 ... (0.25) ... 1.5 ms	0.4 ms	x	x	x

Sensitivity

Parameter	Range of values	Standard	SR	DR	HF
Sensitivity	AUTO; 0.5 ... (0.5) ... 7.5 mV	AUTO	x		
Sensitivity A	OFF; AUTO; 0.1 ... (0.1) ... 1.5 ... (0.5) ... 7.5 mV	AUTO		x	x
RV sensitivity	AUTO; 0.5 ... (0.5) ... 7.5 mV	AUTO	x	x	x
LV sensitivity	OFF; AUTO; 0.5 ... (0.5) ... 7.5 mV	AUTO			x

Atrial capture control

Parameter	Range of values	Standard	SR	DR	HF
Atrial capture control	ATM (monitoring only); ON; OFF	ON		x	x
Minimum amplitude	0.5 ... (0.1) ... 4.8 V	1.0 V		x	x
Threshold test start	2.4 ... (0.6) ... 4.8 V	3.0 V		x	x
Safety margin	0.5 ... (0.1) ... 1.2 V	1.0 V		x	x
Search type	Interval; time of day	Time of day		x	x
Interval	0.1; 0.3; 1; 3; 6; 12; 24 h	24 h		x	x
Time of day	00:00 ... (00:10) ... 23:50 hh:mm	00:30 hh:mm		x	x

Ventricular capture control

Parameter	Range of values	Standard	SR	DR	HF
Capture control RV	ATM (monitoring only); ON; OFF	ON	x	x	x
Capture control LV					x
Minimum amplitude RV	0.7 V	0.7 V	x	x	x
Minimum amplitude LV					x
Threshold test start	2.4 ... (0.6) ... 4.8 V	3.0 V	x	x	x
RV safety margin	0.3 ... (0.1) ... 1.2 V	0.5 V	x	x	
LV safety margin	1.0; 1.2 V	1.0 V			x
Search type	Interval; time of day	Time of day	x	x	x
Interval	0.1; 0.3; 1; 3; 6; 12; 24 h	24 h	x	x	x
Time of day	00:00 ... (00:10) ... 23:50 hh:mm	00:30 hh:mm	x	x	x

Atrial overdrive pacing

Parameter	Range of values	Standard	SR	DR	HF
Atrial overdrive pacing	OFF; ON With ON: maximum over-pacing rate 120 bpm, mean rate increase approximately 8 bpm, rate decrease after 20 cycles	OFF		x	x

Lead configuration

Parameter	Range of values	Standard	SR	DR	HF
Sensing polarity A	Unipolar; bipolar	Unipolar	x	x	x
Sensing polarity RV	Unipolar; bipolar	Unipolar	x	x	x
Sensing polarity LV	Unipolar; bipolar	Unipolar			x
Pacing polarity A	Unipolar; bipolar	Unipolar	x	x	x
Pacing polarity RV	Unipolar; bipolar	Unipolar	x	x	x
Pacing polarity LV	Device type HF: LV1 tip -> LV2 ring LV1 tip -> RV ring LV2 ring -> LV1 tip LV2 ring -> RV ring LV1 tip -> housing LV2 ring -> housing	LV1 tip –> housing			x
	Device type HF QP LV1 tip -> LV2 ring LV1 tip -> LV4 ring LV1 tip -> RV ring LV1 tip -> housing LV2 ring -> LV1 tip LV2 ring -> LV4 ring LV2 ring -> RV ring LV2 ring -> housing LV3 ring -> LV2 ring LV3 ring -> LV4 ring LV3 ring -> RV ring LV4 ring -> LV2 ring LV4 ring -> RV ring	LV1 tip –> LV2 ring			x

IEGM recordings

Parameter	Range of values	Standard	SR	DR	HF
Number of recordings (each max. 10 s)	6 series: 12 8 series: 20	—	x	x	x
High atrial rate (HAR)	OFF; AT; mode switching	AT	x	x	x
High ventricular rate (HVR)	OFF; ON	ON	x	x	x
8 series: Patient triggering (triggered by patient)	OFF; ON	OFF	x	x	x
Pre-trigger recording	0; 25; 50; 75; 100%	75%	x	x	x
IEGM signal	Filtered; Unfiltered	Filtered	x	x	x

Rates for statistics

Parameter	Range of values	Standard	SR	DR	HF
HAR limit	100 ... (10) ... 250 bpm	200 bpm		x	x
HVR limit	150 ... (5) ... 200 bpm	180 bpm	x	x	x
HVR counter	4; 8; 12; 16 events	8 events	x	x	x
Start resting period	00:00 ... (1:00) ... 23:00 hh:mm	2:00 hh:mm	x	x	x
Duration of resting period	0.5 ... (0.5) ... 12 h	4 h	x	x	x
Lead check	OFF; ON	ON	x	x	x

Rate Adaptation

CLS modes: closed loop stimulation

Parameters valid for 8 series devices:

Parameter	Range of values	Standard	SR	DR	HF
Maximum CLS rate	80 ... (10) ... 160 bpm	120 bpm	x	x	x
CLS response	Very low; Low; Medium; High; Very high	Medium	x	x	x
CLS resting rate control	OFF; +10 ... (10) ... +50 bpm	+20 bpm	x	x	x
Vp required	Yes; No	No When BiV is set: Yes	x	x	x

R modes: Accelerometer

Parameters valid for devices with R modes:

Parameter	Range of values	Standard	SR	DR	HF
Sensor gain	AUTO; Very low; Low; Medium; High; Very high	AUTO	x	x	x
Max. activity rate	80 ... (10) ... 180 bpm	120 bpm	x	x	x
Sensor threshold	Very low; Low; Medium; High; Very high	Medium	x	x	x
Rate fading	OFF; ON	OFF	x	x	x
Rate increase	1; 2; 4; 8 bpm/cycle	2 bpm/cycle	x	x	x
Rate decrease	0.1; 0.2; 0.5; 1.0 bpm/cycle	0.5 bpm/cycle	x	x	x

MRI Program

MRI modes

Modes valid for devices marked ProMRI:

Mode	Range of values	Standard	SR	DR	HF
MRI program	ON; OFF; AUTO	OFF	x	x	x
Expiration date	Today's date ... (1 day) ... today's date + 14 days	Today's date + 14 days	x	x	x
MRI mode	OFF; A00; V00	Dependent on permanent program	x		
	OFF; D00; A00; V00			x	
	OFF; D00; A00; V00; D00-BiV; V00-BiV				x

MRI parameters

Preset parameters in the MRI program:

Parameter	Range of values	Standard	SR	DR	HF
Basic rate	70 ... (10) ... 160 bpm	90 bpm	x	x	x
AV delay	110 ms	110 ms		x	x
VV delay	0 ms	0 ms			x
Pulse amplitude A/RV	4.8 V	—	x	x	x
Pulse width A/RV	1.0 ms				
Pulse amplitude LV	0.2 ... (0.2) ... 6.0 ... (0.5) ... 7.5 V	As in permanent program			x
Pulse width LV	0.1 ... (0.1) ... 0.5 ... (0.25) ... 1.5 ms				

Preset Programs

Standard and safe program

Mode after auto-initialization:

Parameter	Factory setting	Standard	Safe program	SR	DR	HF
Mode	VVI	VVIR	VVI In the AAI mode, the safe program is also AAI.	x		
Mode	DDD	DDDR	VVI		x	x

Lead configuration, determined and set immediately after connection (auto lead check):

Parameter	Factory setting	Standard	Safe program	SR	DR	HF
Pacing polarity A/RV	Unipolar	Unipolar	Unipolar	x	x	x
Pacing polarity LV	TCUP	TCUP	—			x
Sensing polarity A/RV	Unipolar	Unipolar	Unipolar	x	x	x
Sensing polarity LV	Unipolar	Unipolar	—			x
Automatic lead check	ON	ON	—	x	x	x

Parameters after auto-initialization:

Parameter	Factory setting	Standard	Safe program	SR	DR	HF
Basic rate	60 bpm	60 bpm	70 bpm	x	x	
	50 bpm	50 bpm				x
Night rate	OFF	OFF	OFF	x	x	x
Rate hysteresis	OFF	OFF	OFF	x	x	x

Parameter	Factory setting	Standard	Safe program	SR	DR	HF
Upper rate	130 bpm	130 bpm	—		x	x
AV dynamics	Low	Low	—		x	x
AV hysteresis mode	OFF	OFF	—		x	x
Sense compensation	-45 ms	-45 ms	—		x	x
AV safety delay	100 ms	100 ms	—		x	x
VV delay	0	0	—			x
LV T-wave protection	ON	ON	—			x
Far-field protection after Vs	100 ms	100 ms	—		x	x
Far-field protection after Vp	150 ms	150 ms	—		x	x
Ventricular blanking period after Ap	30 ms	30 ms	—		x	x
PMT protection	ON	ON	—		x	x
VA criterion	350 ms	350 ms	—		x	x
Magnet response	AUTO	AUTO	AUTO	x	x	x
Pulse amplitude A	3.0 V	3.0 V	—		x	x
Pulse amplitude RV	3.0 V	3.0 V	4.8 V	x	x	x
Pulse amplitude LV	3.0 V	3.0 V	—			x
Pulse width A	0.4 ms	0.4 ms	—		x	x
Pulse width RV	0.4 ms	0.4 ms	1.0 ms	x	x	x
Pulse width LV	0.4 ms	0.4 ms	—			x
Sensitivity A	AUTO	AUTO	—		x	x
Sensitivity RV	AUTO	AUTO	2.5 mV	x	x	x
Sensitivity LV	AUTO	AUTO	—			x
Refractory period A	AUTO	AUTO	—		x	x
Refractory period RV	250 ms	250 ms	300 ms	x	x	x
Refractory period LV	200 ms	200 ms	—			x
Mode switching	ON	ON	—		x	x
Onset criterion	5-out-of 8	5-out-of 8	—		x	x
Resolution criterion	5-out-of 8	5-out-of 8	—		x	x
Intervention rate	160 bpm	160 bpm	—		x	x
Switches to	DDIR	DDIR	—		x	x
The basic rate with mode switching	+10 bpm	+10 bpm	—		x	x
Rate stabilization with mode switching	OFF	OFF	—		x	x
PVARP	AUTO (Start 250 ms)	225 ms	—		x	x
PVARP after PVC	400 ms	Automati-cally set	—		x	x
Capture control A	ON	ON	OFF	x	x	x
Capture control RV	ON	ON	OFF		x	x
Capture control LV	ON	ON	OFF			x
Atrial overdrive pacing	OFF	OFF	—		x	x
Vp suppression	OFF	OFF	—			x
IEGM recording (HAR)	ON	AT	OFF	x	x	x
IEGM recording (HVR)	ON	ON	OFF	x	x	x
Home Monitoring	OFF	OFF	OFF	x	x	x

Tolerances of Parameter Values

Parameter	Range of values	Tolerance
Basic rate	30 ... (5) ... 100 ... (10) ... 200 bpm	± 20 ms
Basic interval	1000 ms	± 20 ms
Magnet rate (magnet interval)	90 bpm (664 ms)	± 20 ms
Pulse amplitude	0.2 ... 7.5 V	The greater value of ±50 mV or +20/-25%
Pulse width	0.1 ... 1.5 ms	The greater value of ±20 µs or ±10%
Sensitivity A EN 45502-2-1 triangle pulse	0.1 ... 0.2 mV	The greater value of ±0.1 mV or ±20%
	0.3 ... 7.5 mV	
Sensitivity RV/LV EN 45502-2-1 triangle pulse	0.5 ... 7.5 mV	±20%
Refractory period	200 ... 500 ms	± 20 ms
Maximum activity rate	80 ... 180 bpm	± 20 ms
Lead impedance	100 ... 200 Ω	±50 Ω
	201 ... 2500 Ω	±10%

15 Technical Data

What's in this chapter?

Mechanical Characteristics

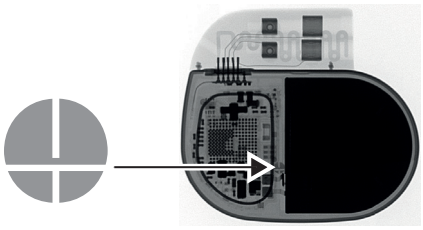
Measurements for the housing

Device	W x H x D [mm]	Volume [cm³]	Mass [g]
Single-chamber SR(-T)	48 x 40 x 6.5	10	20.8
Dual-chamber DR(-T)	48 x 44 x 6.5	11	23.2
Triple-chamber HF-T	53 x 52 x 6.5	14	26.9
Triple-chamber HF-T QP	53 x 53 x 6.5	15	31.2

Note: D = housing without header

X-ray identification

All device types receive the BIOTRONIK logo for X-ray identification. It can be found centrally between the circuitry and the battery inside the housing and is visible on the X-ray image.



Materials in contact with body tissue

- Housing: Titanium
- Header: Epoxy, polysulfone; IS4 seal: Silastic
- Silicone plug: Silopren or silastic

Electrical Characteristics

Components and input values

Electrical characteristics determined at 37°C, 500 Ω:

Circuit technology	Dycostrate
Input impedance	> 10 kΩ
Pulse form	Biphasic, asymmetric
Polarity	Cathodic

Electrically conductive surface

The device housing has the form of a flattened ellipsoid. The electrically conductive area is for:

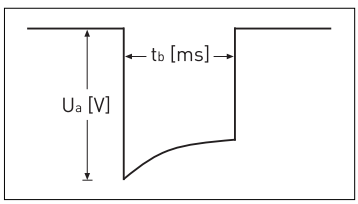
- Single and dual-chamber devices: 30 cm^2
- Triple-chamber devices: 33 cm^2

Telemetry data

- MICS frequency: 402 - 405 MHz
- Maximum power of transmission: < 25 µW (-16 dBm)

Pulse form

The pacing pulse has the following form:



The pulse amplitude reaches its maximum value at the beginning of the pulse (Ua). With increasing pacing duration (tb), the pulse amplitude is reduced dependent on the pacing impedance.

Resistance to interference

All variants of BIOTRONIK devices comply with the requirements of EN 45502-2-1: 2003, § 27.5.1 at the highest sensitivity.

Battery Data

Battery characteristics

The following data is provided by the manufacturers:

Manufacturer	Wilson GREATBATCH, INC. Clarence, NY 14031	LITRONIK GmbH 01796 Pirna Germany	
Battery type	GB 3193	LiS 2650MK	LiS 3150MK
System	QMR® Li-CFX/SVO	$LiMn0_2$	$LiMn0_2$
Device type	SR; DR	SR; DR	HF; HF QP
Battery voltage at BOS	3.3 V	3.1 V	3.1 V
Open-circuit voltage	3.3 V	3.1 V	3.1 V
Nominal capacity	1010 mAh	950 mAh	1200 mAh
Usable capacity until EOS	971 mAh	880 mAh	1066 mAh
Remaining capacity at ERI	39 mAh	70 mAh	134 mAh

Shortening of the service time after long storage period

In case of implantation after an average storage period – about 1 year before the end of the use by date – the average service time decreases by about 1%.

Devices should be implanted within 19 months between the manufacturing date and the use by date (indicated on the package).

Power consumption

- BOS, inhibited: SR(-T), DR(-T) 6 µA; HF-T (QP) 7 µA
- BOS, 100% pacing: SR(-T) 8 µA; DR(-T) 11 µA; HF-T (QP) 14 µA

Calculation of service times

Mean service times pre-estimated from the following and other data:

- Storage for 6 months
- Technical data of the battery manufacturer
- Basic rate of 60 bpm in AAIR/VVIR modes (single-chamber devices) or DDDR modes (dual-chamber and triple-chamber devices)
- Home Monitoring configuration: OFF
- No wandless telemetry
- Configuration of different pulse amplitudes and lead impedances

Mean service times SR

For single-chamber devices the following times result when set to AAIR or VVIR, with a basic rate of 60 bpm and a pulse width of 0.4 ms at an impedance of 500 Ω:

Amplitude	Pacing	Average service time
2.5 V	100%	13 years
	50%	14 years, 9 months
3.0 V	100%	11 years, 3 months
	50%	13 years, 7 months
5.0 V	100%	5 years, 6 months

Mean service times DR

For dual-chamber devices, the following times result when set to DDDR with a basic rate of 60 bpm and a pulse width of 0.4 ms at an impedance of 500 Ω:

Amplitude	Pacing	Average service time
A: 2.5 V RV: 2.5 V	100%	9 years, 4 months
	50%	11 years, 4 months
A: 3.0 V RV: 3.0 V	100%	7 years, 8 months
	50%	10 years
A: 5.0 V RV: 5.0 V	100%	3 years, 2 months

Mean service times HF

For triple-chamber devices of the 8 series, the following times result when set to DDDR with a basic rate of 60 bpm, 100% biventricular pacing and a pulse width of 0.4 ms at an impedance of 500 Ω:

Amplitude	Pacing	Average service time
A: 2.5 V	10%	9 years, 8 months
RV: 2.5 V LV: 2.5 V	100%	
A: 3.0 V	10 %	8 years
RV: 3.0 V LV: 3.0 V	100%	
A: 5.0 V RV: 5.0 V LV: 5.0 V	100%	2 years, 6 months

Legend for the Label

The label icons symbolize the following:

	Manufacturing date		Use by
	Storage temperature	REF	Order number
SN	Serial number	PID	Product identification number
CE	CE mark		
	Contents		Follow the instructions for use!

STERILE EO	Sterilized with ethylene oxide		
	Do not resterilize		Single use only, do not reuse
	Do not use if packaging is damaged	NON STERILE	Non-sterile

	Transmitter with non-ionizing radiation at designated frequency
Label icon on devices with ProMRI®: MR	MR conditional: Patients having a device system implanted whose components are labeled with this symbol on the packaging can be examined using an MR scan under precisely defined conditions.

TP2	Compabiltiy with telemetry protocol version 2 of BIOTRONIK Home Monitoring

IS-1 VVIR/AAIR Example	Uncoated device: NBG code and compatible leads
	Screwdriver
Examples of the connector allocation: IS-1, IS-1/IS4	

Enitra 6/8

Function Manual

Revision: C (2021-01-11)

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