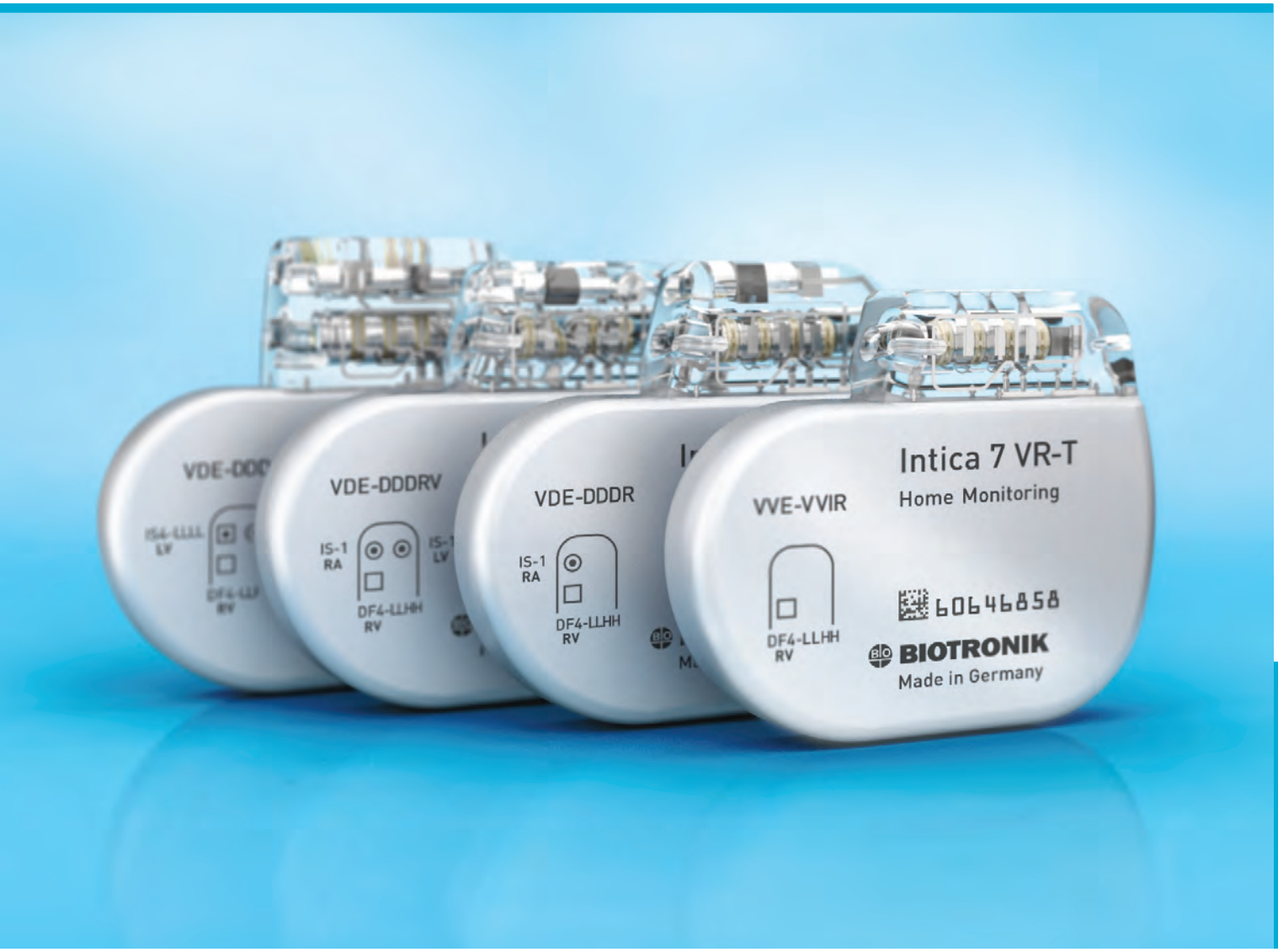
Intica 5/7

Function Manual

ProMRI®



BIOTRONIK
excellence for life

Intica 5/7
Function Manual

Intica ICD Family

Doc. Id.: 422209--B

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I Characteristics of the Intica 5/7 ICD Families

What's in this part?

Overview You will find a description of the Intica 5/7 ICD families in part I of the function manual.

1 Product Description

What's in this chapter?

Intended Medical Use

Intended use

Intica belongs to a family of implantable cardioverter-defibrillators (ICD). The primary objective of the therapy is to prevent sudden cardiac death. Furthermore, the device is capable of treating bradycardia arrhythmias and cardiac resynchronization therapy with multisite ventricular pacing.

The implantation of an ICD is a symptomatic therapy with the following objectives:

- Termination of spontaneous ventricular fibrillation (VF) through shock delivery
- Termination of spontaneous ventricular tachycardia (VT) through antitachycardia pacing (ATP); in case of ineffective ATP or hemodynamically not tolerated VT, with shock delivery
- Cardiac resynchronization through multisite ventricular pacing (triple-chamber devices)
- Compensation of bradycardia through ventricular (single-chamber devices) or AV sequential pacing (DX, dual- and triple-chamber devices).

  VR-T DX and HF-T/HF-T QP devices types with DX functionality are only indicated for patients not requiring atrial pacing.

Diagnosis and therapy forms

The device monitors the heart rhythm and automatically detects and treats cardiac arrest resulting from ventricular tachyarrhythmia. All major therapeutic approaches from the field of cardiology and electrophysiology are included. 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 and the operation conditions of a device system.

- Only qualified medical specialists having this required special knowledge are permitted to use implantable devices.
- If users do not possess this knowledge, they must be trained accordingly.

Indications

Intica can treat life-threatening ventricular arrhythmias with antitachycardia pacing and defibrillation.

Generally approved differential diagnostics methods, indications, and recommendations for ICD therapy apply to BIOTRONIK devices. See the current guidelines of cardiology associations for guidance.

We recommend observing the indications published by the German Cardiac Society (Deutsche Gesellschaft für Kardiologie, Herz- und Kreislaufforschung, (DGK)) and the European Society of Cardiology (ESC). This also applies to the guidelines published by the Heart Rhythm Society (HRS), the American College of Cardiology (ACC), the American Heart Association (AHA), and other national cardiology associations.

Single-chamber and dual-chamber

Single-chamber and dual-chamber ICDs are indicated for patients with the following risk:

- Sudden cardiac death caused by ventricular arrhythmias

Triple-chamber

Triple-chamber ICDs are indicated for patients with the following risks:

- Sudden cardiac death caused by ventricular arrhythmias
- Congestive heart failure with ventricular asynchrony

Contraindications

Known contraindications:

- Tachyarrhythmia caused by temporary or reversible irritation, e.g. poisoning, electrolyte imbalance, hypoxia, sepsis or acute myocardial infarction
- Such frequent VT or VF that the therapies would cause an unacceptably rapid depletion of the device batteries
- VT with few or without clinically relevant symptoms
- VT or VF treatable by surgery
- Concomitant diseases that would substantially limit a positive prognosis
- Accelerated intrinsic rhythm

System Overview

Device family

The complete Intica 5/7 ProMRI device family consists of several device types with a DF-1/IS-1 or DF4/IS-1 connection or with DF4/IS-1 or DF4/IS4/IS-1 connection.

- Single-chamber: VR-T and VR-T DX (device type with only a DF-1/IS-1 connection)
- Dual-chamber: DR-T
- Triple-chamber: HF-T and HF-T QP

Note: Not all device types are included in every device family.

Note: Not all device types are available in every country.

Note: Not all device types are approved in every country.

Note: Not all functions and parameters mentioned in this technical manual are featured by each device type of each device family.

Device

The device's housing is made of biocompatible titanium, welded from outside and thus hermetically sealed. The ellipsoid shape facilitates implantation in the pectoral muscle area.

The connections for bipolar pacing and sensing (and unipolar connections for the triple-chamber device) as well as for shock delivery are found in the device header.

The housing serves as a potential antipole during shock delivery or in the case of unipolar lead configuration.

Lead connectors

BIOTRONIK offers ICDs with headers for different standardized lead connections:

- DF-1/IS-1 and DF-1/IS-1/IS4
- DF4, DF4/IS-1 and DF4/IS-1/IS4

Note: Suitable leads must comply with the norms:

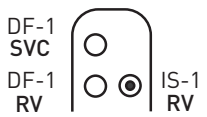
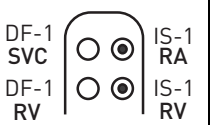
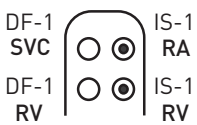
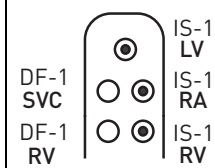
- A device's DF-1 connector port may only be used for connecting leads with a DF-1 connector that conform to ISO 11318.
- A device's IS-1 connector port may only be used for connecting leads with a IS-1 connector that conform to ISO 5841-3.
- A device's DF4 connector port may only be used for connecting leads with a DF4 connector that conform to ISO 27186.
- A device's IS4 connector port may only be used for connecting leads with a IS4 connector that conform to ISO 27186.

Note: The device and leads have to match.

- Only DX type leads by BIOTRONIK may be connected to the device type VR DX with DF-1/IS-1.
- Only quadripolar leads may be connected to the device type HF QP with IS4.
- When working with DX functionality, the device type HF (QP) with DF-1 may be connected to DX type leads by BIOTRONIK.

DF-1/IS-1

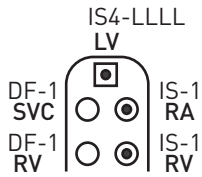
The labeling on each device provides information pertaining to the connector port assignment in the header.

VR	VR DX	DR	HF
			

Connector port	Lead connector	Configuration	Implantation site	Device type
RA	IS-1	Bipolar	Atrium	VR DX, DR, HF
RV	IS-1	Bipolar	Right ventricle	VR, VR DX, DR, HF
RV	DF-1	Shock coil	Right ventricle	VR, VR DX, DR, HF
SVC	DF-1	Shock coil	Superior vena cava	VR, VR DX, DR, HF
LV	IS-1	Unipolar, bipolar	Left ventricle	HF

DF-1/IS-1/IS4

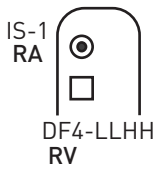
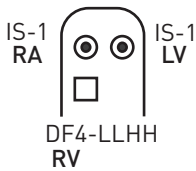
The labeling on each device provides information pertaining to the connector port assignment in the header.

HF QP


Connector port	Lead connector	Configuration	Implantation site	Device type
RA	IS-1	Bipolar	Atrium	HF QP
RV	IS-1	Bipolar	Right ventricle	HF QP
RV	DF-1	Shock coil	Right ventricle	HF QP
SVC	DF-1	Shock coil	Superior vena cava	HF QP
LV	IS4	Unipolar, bipolar	Left ventricle	HF QP

DF4/IS-1

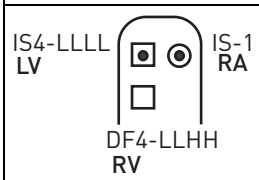
The labeling on each device provides information pertaining to the connector port assignment in the header.

VR	DR	HF
		

Connector port	Lead connector	Configuration	Implantation site	Device type
RA	IS-1	Bipolar	Atrium	DR, HF
RV	DF4	Bipolar and shock coil	Right ventricle	VR, DR, HF
LV	IS-1	Unipolar, bipolar	Left ventricle	HF

DF4/IS-1/IS4

The labeling on each device provides information pertaining to the connector port assignment in the header.

HF QP


Connector port	Lead connector	Configuration	Implantation site	Device type
RA	IS-1	Bipolar	Atrium	HF QP
RV	DF4	Bipolar and shock coil	Right ventricle	HF QP
LV	IS4	Unipolar, bipolar	Left ventricle	HF QP

Leads

BIOTRONIK leads are sheathed with 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 sliding properties for the lead. Leads with steroids reduce inflammatory processes. The fractal design of the electrodes provides for low pacing thresholds. 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 radio frequency (RF) telemetry in the programmer. BIOTRONIK calls this function SafeSync.

Programmer

Implantation and follow-up are performed with BIOTRONIK's portable programmer: Software PSW as of version 1505.

There are programmers with integrated or external SafeSync Module for RF telemetry.

Leadless ECG, IEGM, markers and functions are displayed simultaneously on the color display.

The programmer allows you to determine the thresholds and to perform all tests during an in-office follow-up; in addition, you can change the permanent program and send it to the implanted device.

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.

Modes

Note: Not all functions and parameters mentioned in this technical manual are featured by each device type of each device family.

The mode setting depends on the individual diagnosis:

Device type	Modes
VR	VVI; VVIR; VOO; OFF 7 series: VVI-CLS
VR DX	VDD; VDDR; VDI; VDIR; VVI; VVIR; V00; OFF 7 series: VVI-CLS
DR, HF (QP)	DDD; DDDR; DDI; DDIR DDDR-ADIR; DDD-ADI VDD; VDDR; VDI; VDIR VVI; VVIR; AAI; AAIR; VOO; DOO; OFF 7 series: VVI-CLS; DDD-CLS

NBD and NBG codes

VVE is the NBD code for the antitachycardia mode of the single-chamber, dual-chamber, and triple-chamber devices without atrial therapy:

V	Shock in the ventricle
V	Antitachycardia pacing (ATP) in the ventricle
E	Detection via IEGM analysis

VDE is the NBD code for the antitachycardia mode of the dual-chamber and triple-chamber devices with atrial therapy:

V	Shock in the ventricle
D	Antitachycardia pacing (ATP) in the atrium and ventricle
E	Detection via IEGM analysis

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

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 devices:

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

VDDR is the NBG code for the antibradycardia mode of the single-chamber type DX device:

V	Ventricular pacing
D	Sensing in the atrium and ventricle
D	Pulse inhibition and pulse triggering
R	Rate adaptation

VVIR is the NBG code for the antibradycardia pacing modes of the single-chamber device:

V	Ventricular pacing
V	Sensing in the ventricle
I	Pulse inhibition in the ventricle
R	Rate adaptation

BIOTRONIK Home Monitoring®

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

- With Home Monitoring, diagnostic and therapeutic information as well as 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 heart or in the device are forwarded immediately.
- A test message can be initiated at any time using the programmer to immediately check the Home Monitoring function.

Intica order numbers

Not all device types are available in every country:

	Intica 5 ProMRI			
	DF-1/IS-1	**DF4/IS-1**	**DF-1/IS4/IS-1**	**DF4/IS4/IS-1**
VR-T	404689	404690	—	—
VR-T DX	404688	—	—	—
DR-T	404686	404687	—	—
HF-T	404683	404684	—	—
HF-T QP	—	—	406932	404685

	Intica 7 ProMRI			
	DF-1/IS-1	**DF4/IS-1**	**DF-1/IS4/IS-1**	**DF4/IS4/IS-1**
VR-T	404634	404635	—	—
VR-T DX	404633	—	—	—
DR-T	404631	404632	—	—
HF-T	404627	404628	—	—
HF-T QP	—	—	404629	404630

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 container includes the following:

- Device, blind plugs (if applicable)
- Screwdriver

Therapeutic and Diagnostic Functions

Diagnostic functions

- Data from implantation and the most recent interrogations and follow-ups are recorded as well as arrhythmia episodes; they are stored together with other data to assess both the patients' and the device's state at any time.
- To check the lead for proper functioning, an automatic impedance measurement using subthreshold pacing pulses is performed in the device.
- Leadless ECG function: For all device types, far-field derivation can be measured without external leads between the right ventricular distal shock coil and housing, which, depending on the implantation site, corresponds to ECG derivation II or III (Einthoven).
- Once a telemetry connection has been established during a test procedure in an in-office follow-up, the leadless ECG and the IEGM are displayed with markers.

Antitachycardia pacing

- The ICD can treat ventricular tachycardia with antitachycardia pacing (ATP); ATP can also be delivered in the VF zone (ATP One Shot) when the stability criterion (monomorphic rapid VTs) is met before shock delivery.
- The ICD can also respond to atrial tachycardia with antitachycardia pacing (ATP) in case of stable heart rates or with high-rate pacing (HF bursts) in case of unstable heart rates.
- Depending on the device type, the device software contains not only the ICD functions but also all pacemaker functions for 1, 2 or 3 chambers. The heart rhythm is continuously monitored; each arrhythmia is classified according to the heart rate and the adjustable detection criteria. Depending on the preset values, antibradycardia as well as antitachycardia therapy is inhibited or delivered.

Cardioversion, defibrillation

- The ICD can treat ventricular tachyarrhythmia with cardioversion and/or defibrillation. Shock polarity and energy can be programmed individually. Shock energies between 2.0 J and 40 J are possible. Before delivery of the shock, the ICD can be set to only deliver a shock when ongoing tachyarrhythmia is confirmed; during this time period the device can identify spontaneous conversion of the tachyarrhythmia and cancel the charging process if necessary.
- The shock paths can be set between the different shock coils (SVC/RV) and/or the housing.

Antibradycardia pacing and CRT

- Rate hystereses, automatic sensor functions, and a night program promote the patient's intrinsic rhythm, avoid overdrive pacing, and facilitate adaptation of the device to the individual needs of the patient.
- Both atrial and ventricular thresholds are determined automatically in the device. For the 5 and 7 series , capture control is used to set the pulse amplitudes so that pacing is performed with the optimum atrial and ventricular amplitude for the patients with each change of the pacing threshold.
- Setting an upper tracking rate for the atrium prevents unspecific atrial pacing, thus reducing the risk of pacemaker-mediated tachycardia.
- Positive AV hysteresis functions support intrinsic conduction and thus the natural contraction sequence. Negative AV hysteresis functions support the cardiac resynchronization therapy by maintaining pacing in stress situations.
- For resynchronization of the ventricles, triple-chamber devices have functions for multisite ventricular pacing with possible VV delays in either direction.
- 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 12 vectors can be used with the HF QP device type.

- With the HF QP device of the 7 series: Two stimuli can be configured for the left ventricle to improve the resynchronization of the ventricles. The stimuli can be delivered sequentially or simultaneously.
- Additional, special form of rate adaptation with devices from the 7 series: an increased cardiac output requirement is detected using physiological impedance measurement. The measuring principle is based on contractile changes (ionotropy) of the myocardium (CLS function: Closed loop stimulation). Rate adaptation is automatically initialized and optimized in CLS mode.
- Ventricular pacing suppression with devices from the 5 and 7 series : unnecessary ventricular pacing is avoided by promoting intrinsic conduction (Vp suppression function). The device can thereby adapt to conduction changes and switch between an ADI(R) and a DDD(R) mode.

Storing programs

There are different therapy programs:

- Parameter settings effective for the most common indications in pre-configured programs (Program Consult) are offered.
- For special indications, individual parameter settings can be stored in up to three therapy programs.

ProMRI devices recognize magnetic resonance imaging devices

Intica has a sensor which can reliably recognize a magnetic resonance imaging device. 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 imaging device and automatically activates the preset MRI program. Reprogramming to the permanent program occurs also automatically when the imaging device is left.

Home Monitoring functions

- The device automatically sends information to the transmitter once a day. It also sends messages related to events, which are immediately forwarded to the Service Center. In addition to this, test messages can be initiated using the programmer.
- Appointments for Home Monitoring-supported follow-ups can be scheduled via the HMSC.
- Important medical information in the device messages include the following:
  - Atrial and ventricular arrhythmias
  - Parameters relevant to leads in the atrium and ventricle: pacing thresholds, sensing amplitudes, impedances
  - Current statistics
  - IEGM online HD with up to 3 high definition channels

Replacement Indications

Possible battery levels

- BOS: Beginning of Service: > 90% charge
- MOS 1: Middle of Service: 90% to 40% residual charge
- MOS 2: Middle of Service: < 40% residual charge
- ERI: Elective Replacement Indication (i.e. RRT: Recommended Replacement Time)
- EOS: End of Service

Elective Replacement Indication (ERI)

Elective Replacement Indication can be detected by Home Monitoring.

CAUTION
Temporally limited therapy If ERI occurs shortly after follow-up and is only detected during the subsequent follow-up, then the remaining service time can be much less than 3 months. • Replace device soon.

- The device can monitor the heart rhythm for at least 3 more months.
- At least 6 maximum energy shocks can be delivered until EOS occurs.
- The set parameters in the device do not change.

EOS replacement indication

End of Service can be detected by Home Monitoring.

WARNING
Patient at risk of death If EOS replacement indication occurs before replacement of the device, then the patient is without therapy. • Replace device immediately. • Monitor patient constantly until immediate replacement of the device!

- VT and VF detection and all therapies are deactivated!
- The antibradycardia function remains active in the VVI mode:
  - Ventricular pacing: RV; basic rate 50 bpm; without special pacemaker functions such as hysteresis, etc.
  - Pulse amplitude of 6 V; pulse width of 1.5 ms
  - Cycle duration for BIOTRONIK Home Monitoring: 90 days

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 Sensing Functions

What's in this chapter?

Sensing Concept

Function

The device continuously analyzes the heart rate in order to be able to initiate suitable therapy when necessary.

In order to do this, the leads in the atrium and ventricle sense P and R waves.

The scan rate is 128 Hz.

The device uses various criteria to determine whether or not an arrhythmia has to be treated (detection). For example, sinus tachycardias or supraventricular tachycardias are arrhythmias that do not require therapy. This prevents exposing the patient to inadequate therapy.

- Sensing in the atrium: devices of type VR-T DX, DR and HF
- Sensing in the right ventricle: devices of type VR, VR-T DX, DR and HF
- Sensing in the left ventricle: HF devices

Note: Proper sensing by the ICD is required for safe and effective implementation. Measurement of the P and R amplitudes should be performed again subsequent to each modification of the input stage settings. This ensures that the signals suffice for adequate detection of tachycardias.
It may be necessary to carry out another DFT test to verify the effectiveness of the modified sensing settings.

Note: If no atrial or left ventricular lead is connected, then sensing must be deactivated in these chambers.
If atrial or left ventricular sensing is deactivated, then IEGM transmission and recordings are also deactivated in these chambers.

Left ventricular sensing

Left ventricular sensing is only evaluated for:

- IEGM recordings
- LV T-wave protection
- Event statistics

Left ventricular sensing is not utilized for VT/VF detection and timing of pacemaker functions.

Automatic Sensitivity Control

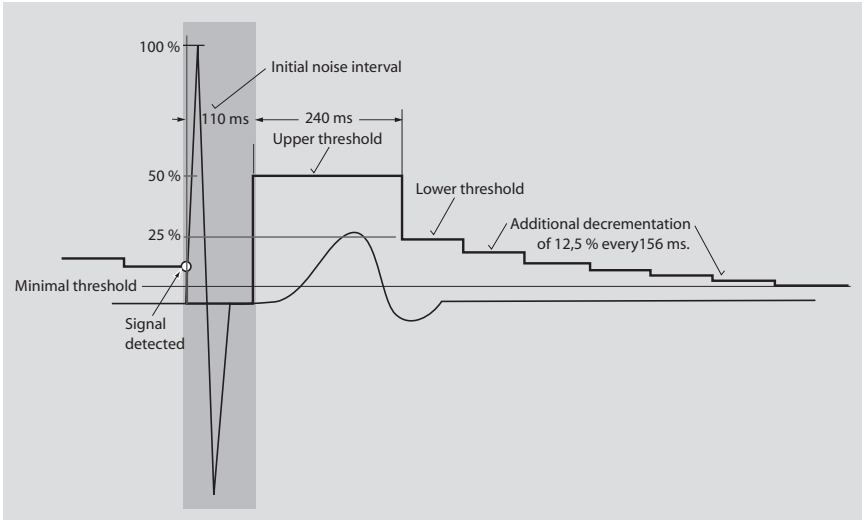
The input stages of the ICD are adjusted to signal sensing in the range between sinus rhythm, atrial fibrillation and ventricular fibrillation. Noise is suppressed during signal sensing.

Sensitivity in the atrium, the left ventricle and the right ventricle can be adjusted separately.

The standard settings are adequate for most signals experienced in practice.

If the standard settings are not sufficient for sensing and assessing signals adequately, then fine tuning can be carried out for each chamber using the **[Show sensing expert parameters]** function.

Automatic sensitivity control



Technical principle

Automatic sensitivity control is based on the principle of having two adaptive thresholds.

As part of the standard settings, the upper threshold is calculated as 50% of the R-wave amplitude and the lower threshold is calculated as 25% of the R-wave amplitude in the ventricle based on a sensed R-wave.

After a sensed event the upper threshold, 50% of the previous R amplitude, is active for the upper threshold duration of 350 ms following a sensed event and 400 ms following a paced event so that no T-waves are sensed in the ventricle. A lower sensitivity is effective during the waiting period of the T-wave following delivery of pace.

After the upper threshold duration of 350 ms after a sensed event and 400 ms after a paced event, the signal sensing is switched with increased sensitivity to the lower threshold at 25% of the previous R amplitude so that a subsequent fibrillation event with a low amplitude can be sensed.

In beat-to-beat adjustment, each sensed amplitude is measured again and the upper and lower thresholds are set again accordingly.

A minimum threshold can be set to prevent signal noise, if sensitivity is too high. This limits a decrease in the threshold in the case of low amplitudes and thus prevents noise.

Settings

When clinically applied, it is easy to have sensitivity controlled automatically by selecting predefined settings:

- Standard
- Enhanced T-wave suppression
- Enhanced VF sensitivity

Sensing can be individually adjusted when a parameter is reprogrammed in the **[Show sensing expert parameters]** screen.

Standard

This setting is recommended for patients, for whom an R-wave amplitude over 3 mV has been measured with the device in the standard setting.

Enhanced T-wave suppression (TWS)

Note: Set enhanced T-wave suppression only if T-wave oversensing occurs frequently and regularly.

Enhanced T-wave suppression is especially effective due to more narrowly defined values. At the same time, the upper threshold is increased to 75% of the measured R-wave.

Enhanced T-wave suppression is less suitable in cases of sinus rhythm with low signal amplitudes (< 3 mV) or cases of ventricular fibrillation signals with highly fluctuating signal amplitudes, because R amplitudes that are too low accompanied by low-frequency signal components can additionally be restricted due to the stricter filter range.

For patients with long QT syndrome, the upper threshold duration after sensing can be extended from 350 ms to 500 ms. This serves to prevent switching to the lower threshold too early during the escape time of the delayed T-wave.

Enhanced VF Sensitivity (VFS)

The enhanced VF sensitivity setting enhances VF detection, especially in cases of highly fluctuating VF signal amplitudes.

This setting is recommended if the VF detection time exceeds 5 – 6 seconds due to intermittent marker failures.

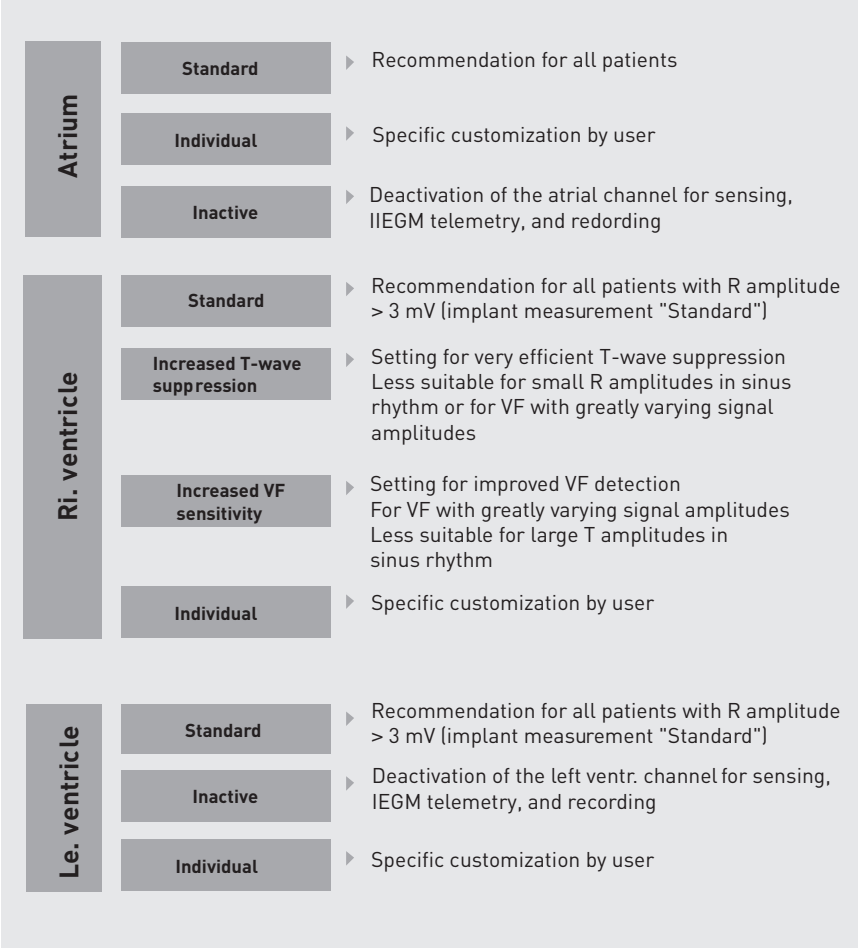
This setting is less suitable for patients with large T-waves. Enhanced VF sensitivity is achieved by way of a shortened upper threshold duration after detection and pacing as compared to the standard setting. Thus, the upper threshold is left prematurely.

Detection features

The input stage is effective due to the following features:

- High resolution of amplitudes up to 25 mV
- Fast adaptation of sensitivity due to non-linear decrement

Parameter sets Predefined parameter sets for sensing



Far-field Protection

Function Far-field protection prevents spontaneous or paced ventricular events from being incorrectly sensed in the atrium.

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

The following functions determine the blanking periods in the atrium:

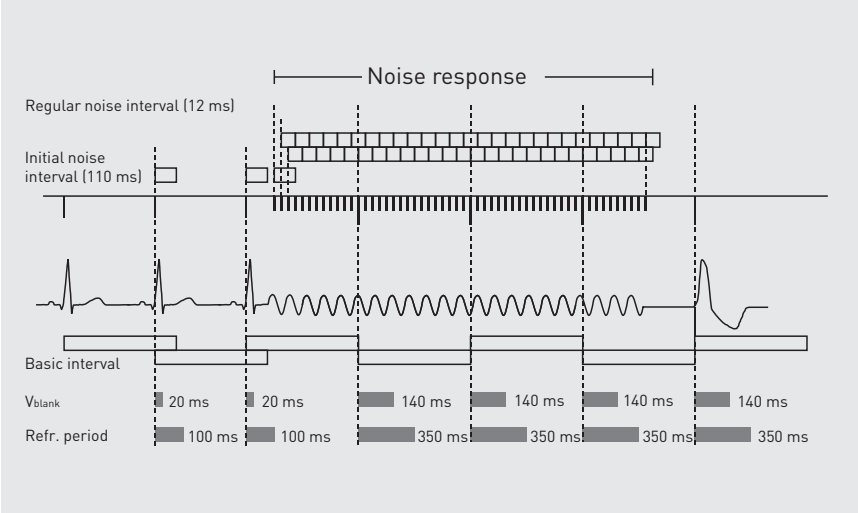
- Far-field protection after Vp (VA crossblank after Vp)
- Far-field protection after Vs (far-field blanking)
- Blanking after atrial pacing

Far-field sensing from the ventricular channel can cause problems with mode switching and during rhythm evaluation by SMART. Therefore, preventing far-field sensing is especially important.

A blanking period is also initiated in the ventricle after atrial pacing to prevent far-field sensing in the ventricle. The user can adjust the value for the right ventricle and the value for the left ventricle as fixed.

Note: Sensed events within a noise interval are not evaluated as tachycardia rates. If a sensed event occurs in an initial noise interval (110 ms), the regular noise interval (12 ms) is subsequently started. The noise interval can be retriggered. Constantly restarting the interference interval leads to asynchronous pacing.

Noise response



Setting Sensing Parameters

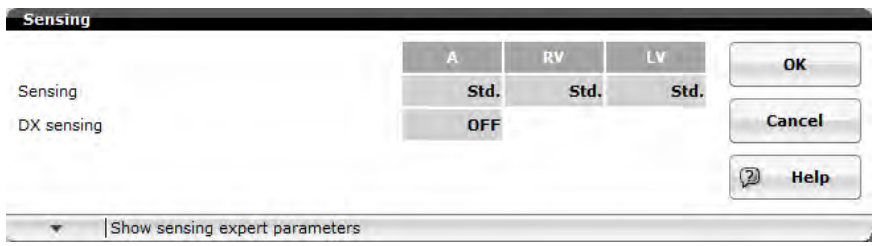
Navigation: Parameters → Bradycardia/CRT → Sensing

Objective

Differentiated setting of the sensing function serves the following purposes:

- Setting the input stage sensitivity of the respective channel
- Activating or deactivating sensing in the respective channel, e.g. in the left ventricle
- Setting the minimum sensing threshold

User interface



Sensing in the atrium

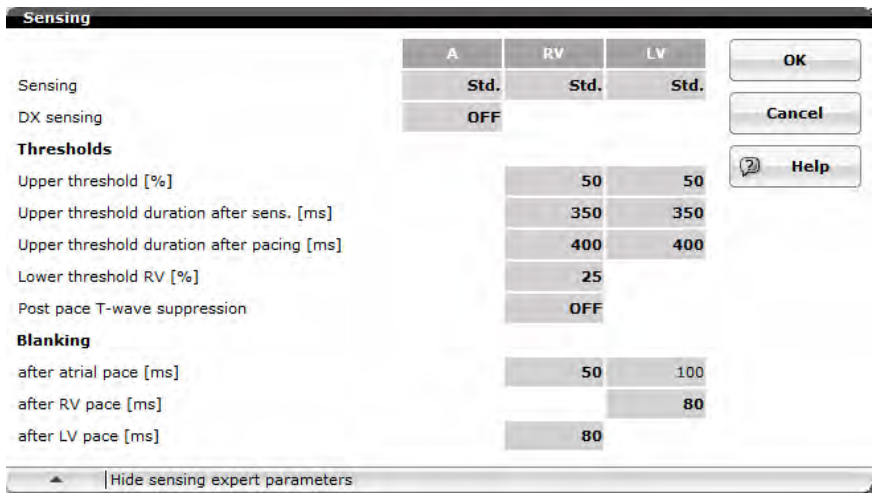
The following parameters can be set for sensing in the atrium:

Channel	Setting	Description
Atrium	Standard (`Std.`)	The standard setting for sensing in the atrial channel has been selected.
	Disabled (**OFF**)	This setting disables sensing, real-time IEGM and recording in the atrial channel for diagnostic purposes.

Sensing in the ventricle

The following parameters can be set for sensing in the ventricle:

Channel	Setting	Description
Right ventricle	Standard (`Std.`)	The standard setting for sensing in the right ventricular channel has been selected.
	Enhanced T-wave suppression (`TWS`)	This setting causes T-wave sensing to be severely suppressed. However, this setting is not particularly beneficial for a sinus rhythm with low signal amplitudes and a VF with strongly fluctuating signal amplitudes.
	Enhanced VF sensitivity (`VFS`)	This setting enhances VF detection, especially in cases of strongly fluctuating signal amplitudes. However, this setting is less suitable for a sinus rhythm with high T wave amplitudes.
	Individual (`Ind.`)	This setting is displayed by the system if the parameters for the sensing function differ from standard settings – or in other words have been changed individually.
Left ventricle	Standard (`Std.`)	The standard setting for the left ventricular lead has been selected.
	Individual (`Ind.`)	This setting is displayed by the system if the parameters for the sensing function differ from standard settings – or in other words have been changed individually.
	Disabled (`OFF`)	In this setting, sensing and recording for diagnostic purposes are disabled in the left ventricular channel. However, real-time IEGM is displayed.



Parameters for thresholds

The following parameters can be set for sensing thresholds:

Parameter	Description
`Upper threshold`	The relationship expressed as a percentage of the upper threshold with the maximum measured amplitude; amplitudes below this threshold are not evaluated.
`Upper threshold duration after sens.`	The interval within which the upper threshold is retained as the sensing threshold; amplitudes below this threshold are not evaluated.
`Upper threshold duration after pacing`	
`Lower threshold RV`	The relationship expressed as a percentage of the lower threshold with the maximum measured amplitude; amplitudes below this threshold are not evaluated.
`Post pace T-wave suppression`	Altered sensitivity for the defined time period.

Parameters for blanking times

The following parameters can be set for the blanking periods:

`Blanking ...`	Description
`after atrial pace`	After atrial pacing, sensing of signals in the RV and LV is suppressed.
`after RV pace`	After right ventricular pacing, the sensing of signals in the right ventricle (in-channel blanking) is suppressed, and also for the left ventricle (cross channel blanking) in the case of triple-chamber devices.
`after LV pace`	For triple-chamber devices, after left ventricular pacing, the sensing of signals in the left (in-channel blanking) and also in the right ventricle (cross channel blanking) is suppressed.

DX sensing

A DX lead can be connected to triple-chamber devices. To do this, DX sensing must be switched on.

Note: Before switching on `DX sensing`, make sure that a DX lead is connected to the device.

Minimum threshold

The set value determines the minimum sensitivity at which signals are sensed. The minimum threshold is the absolute lower limit. The upper and lower thresholds are the boundaries for evaluating P and R waves from beat to beat, between maximum amplitude and minimum threshold. See also: Parameters for thresholds, p. 29 and Parameters for blanking times, p. 29.

3 Tachyarrhythmia Detection

General Functional Principles

What's in this chapter?

The ICD differentiates between sinus rhythm, atrial fibrillation and ventricular fibrillation as well as fast and slow tachycardias in the ventricle depending on the assessed rate.

Each arrhythmia zone has an adjustable rate range. This range extends from the lower rate of a zone to the lower rate of the next-highest zone; as a result, the arrhythmia zones are joined seamlessly. Each zone is allocated a therapy sequence.

A VT1 zone can also be programmed without therapy, so that the episodes in this rate range are recorded only for diagnostic purposes (monitoring zone).

In addition to the ventricular arrhythmia zones, the ICD can also set an atrial AT/AF arrhythmia zone to which atrial therapy zones can be assigned.

Ventricular detection always has precedence over atrial detection.

3.1 Detection Algorithms

What's in this section?

Ventricular Tachycardia Detection

The ICD classifies an RR interval as tachycardic using the criteria for rate limit (bpm) or frequency limit (ms) in the VT zones.

The ICD checks the validity of this classification using five adjustable functions that can also be combined:

- Detection/redetection counter
- Onset
- Stability
- Sustained VT
- SMART detection or MorphMatch for devices of type DR-(T), HF-(T) and VR-(T) DX

Detection counter

The following features are used especially to avoid unnecessary shock deliveries:

- Large range of values for the X-out-of-Y counters for the VF range to enable longer detection times
- Large range of values for the forward/backward counters for zones VT1 and VT2
- Exclusive counting for the VT and VF zones to clearly discriminate tachy-arrhythmia
- Separately adjustable redetection parameters for the VF zone
- Standard values for all counters

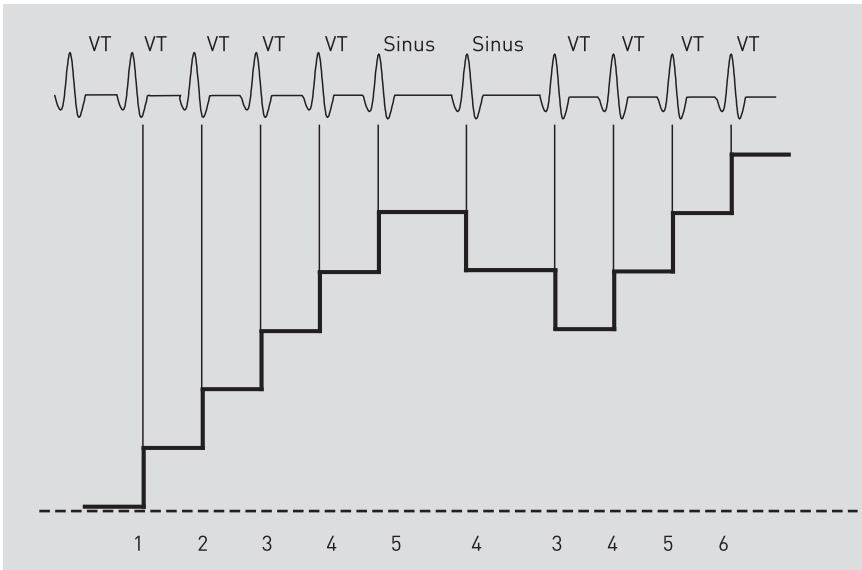
A tachycardic RR interval starts counting within a VT zone.

The ICD detects a tachycardia when the number of tachycardic RR intervals has reached the set value of the detection counter.

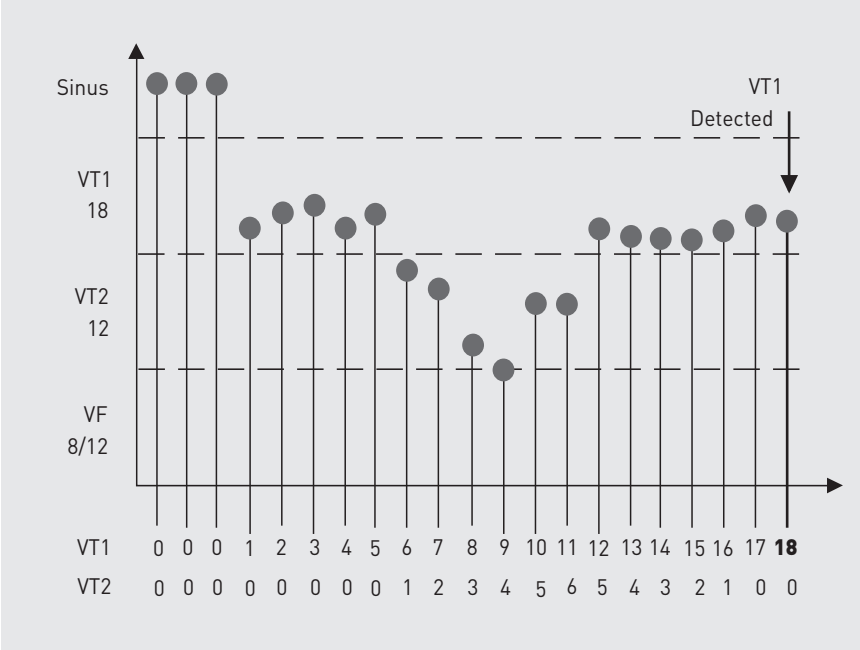
Each RR interval that is not tachycardic sets the counter back a value (forward/backward counter). If five successive intervals prior to initial detection are not tachycardic, then the detection counter is reset and restarted.

The ICD distinguishes between individual short intervals (extrasystoles, couplets, runs) and a tachycardia using the detection counter.

Example of VT counter



Example of detection counting within the VT and VF zone

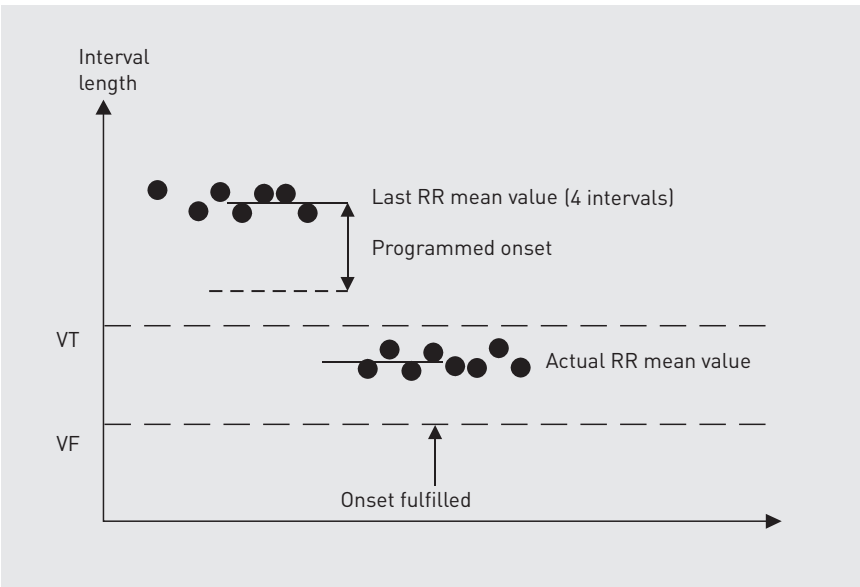


Onset If the onset criterion is switched on, then it has to be fulfilled in addition to the detection counter criterion.

The ICD enhances rhythm evaluation using the onset criterion and excludes signals of gradually accelerating tachycardias like sinus tachycardias from the decision for therapy. To do this, it forms a sliding RR mean value from the last four measured RR intervals.

The criterion is considered fulfilled if the difference between the last RR mean value and the current RR interval is larger than the onset parameter and this is confirmed by comparing the last RR mean value with the current RR mean value. Onset is set in [%] as a value relative to the RR mean value.

Onset criterion



Onset is also an integral feature of the SMART detection algorithm.

Stability

If the stability criterion is switched on, then it has to be fulfilled in addition to the detection counter criterion.

The stability criterion is another factor that serves to enhance rhythm evaluation. Signals from irregularly conducted atrial tachycardia, such as atrial fibrillation, are excluded from detection and distinguished from stable ventricular reentry tachycardia.

If fluctuation between the durations of the last three tachycardia intervals remains within the set range of fluctuation, the stability criterion is considered to have been met for the current interval. The range of fluctuation can be specified in [ms] or [%].

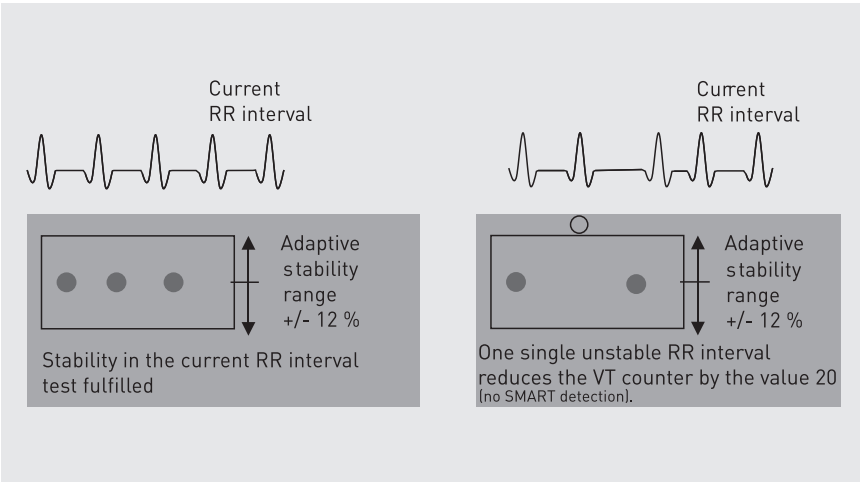
The percentage of the stability criterion refers to the heart rate. The interval is considered stable if the value set for stability is ±12% and none of the last 3 RR intervals deviate from the current interval by more than ±12%.

If SMART detection is switched off, an unstable RR interval reduces the VT counter by a value of 20. If the value of the VT counter is less than 20, the counter is set to 0.

If SMART detection is switched on, detection of an unstable RR interval reduces the VT counter by the value provided by the SMART decision pathway.

The stability criterion is checked for each interval.

Stability criterion



Stability is also an integral feature of the SMART detection algorithm.

With and without SMART detection, the stability criterion is programmed as a percentage [%]. The stability criterion thus adjusts adaptively to the current heart rate. Additionally, when SMART is deactivated, the stability criterion can be programmed in [ms].

Sustained VT

The ICD uses the sustained VT criterion to detect and deliver therapy for sustained ventricular tachycardias that do not meet the onset or stability criterion, or do not meet a combination of the two.

The sustained VT function has a timer, which starts within one of the VT zones with two consecutive RR intervals. Once the timer has been started, it can only be reset by fulfilled termination detection, magnet application or initial detection with immediate therapy delivery.

If no termination detection occurs during the duration programmed for sustained VT, then redetection is initiated. Upon redetection the additional inhibiting criteria onset and stability do not take effect.

The sustained VT function cannot be switched on if SMART detection is activated. The function can be implemented if the following conditions apply:

- Sustained VT for devices of type VR(-T), VR(-T) DX, DR(-T), and HF(-T): use of onset and stability

Due to increased dependency of tachyarrhythmia detection on the onset and/or stability criteria in the case of VT detection without SMART, all individual conditions have to be met to achieve detection.

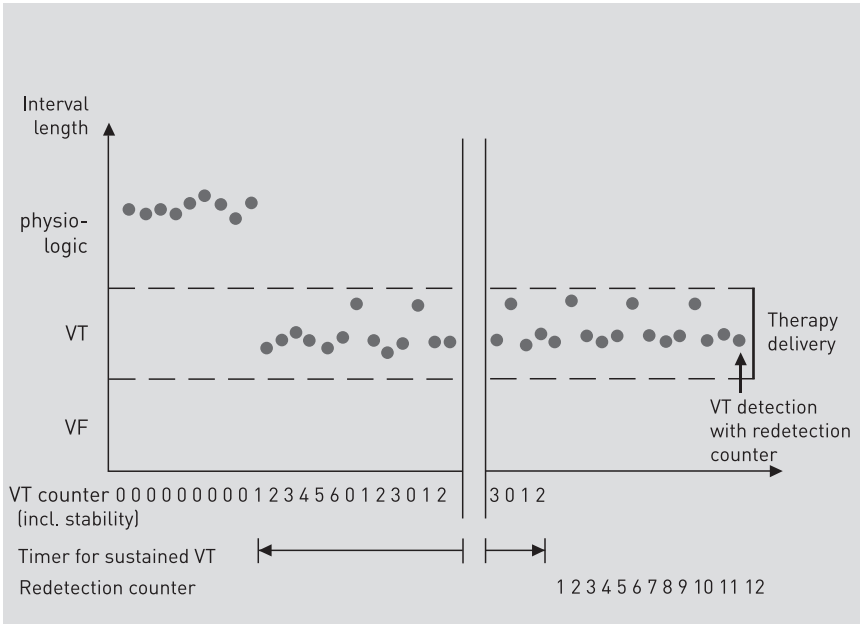
Therefore:

This results in the risk of non-detection. If one criterion is only not fulfilled because, for example, a disadvantageous limit has been programmed for stability, then no therapy is delivered even though the tachycardic rhythm continues.

The sustained VT function can be used to override the checking of logically AND-linked criteria and to introduce therapy.

- SMART = OFF
- Onset and/or stability = ON

Detection of a sustained VT



Recording of non-sustained tachycardia (short interval/ nsT counter)

The device family has the ability to count and record non-sustained ventricular tachycardia as well as very short intervals to detect lead failures, connection failures between the device and lead, and other sources of interference.

1. Counter of short intervals

What is counted?

- Short intervals are recorded only on the RV lead (tip ring).
- All events occurring in a time window (standard value: 110 – 140 ms) of 30 ms after noise interval are counted.

What is recorded in the device?

- Daily trend recording of short intervals that occur
- Cumulative counter since implantation
- Triggering of an IEGM recording if 30 short intervals are reached within 24 hours. This is followed by transmission via Home Monitoring.
- The IEGM recording can be accessed on the programmer (follow-up) and in the Home Monitoring Service Center.

The data is accessible in the Recordings (Episodes tab) and Diagnostics (More diagnostics tab) windows as well as in the Home Monitoring Service Center.

Possible causes of short intervals are:

- Interference due to lead failures
- Interference due to incorrect connection of leads to the device
- External sources of interference
- Recording of individual VF sensings in the sensing window

The short intervals counter cannot be deactivated. There is no special alarm when numerous short intervals are reached. However, a new IEGM will be available in the HMSC and on the follow-up page of the programmer.

2. nsT (non sustained tachycardia)

What is counted?

- Non-sustained tachycardia that are too short to be counted by the VT/VF detection counter
- Each interval that is not sensed in the programmed tachycardia zones decrements the counter by a value of one.
- nsT events are recorded only if no tachycardia detections occurred within this episode.

How are nsTs detected?

- Each interval sensed in the programmed tachycardia zones increments the counter by a value of one.
- If five consecutive slow intervals are sensed outside the programmed tachycardia zones and the counter value is still one or higher, this is detected as nsT.
- A distinction is made between slow and fast nsTs.
  - Criterion for fast nsTs: the smallest weighted mean value of four consecutive intervals is less than 220 ms.
  - Criterion for slow nsTs: the weighted mean value of four consecutive intervals is always greater than 220 ms.

What is recorded in the device?

- Daily trend recording of nsTs that occur
- Cumulative counter of nsTs
- Triggering of an IEGM recording when an nsT occurs. This is followed by transmission via Home Monitoring.
- The IEGM recording can be accessed on the programmer (follow-up) and in the Home Monitoring Service Center.
- When the for nsT parameter is set to OFF in the Parameters window (Diagnostics tab), then IEGM recording and the associated counters and statistics will also be switched off.

The data is accessible in the Recordings (Episodes tab) and Diagnostics (More diagnostics tab) windows as well as in the Home Monitoring Service Center.

Possible causes of nsTs are:

- Interference due to lead failures
- Interference due to incorrect connection of leads to the device
- External sources of interference
- Recording of individual VF sensings in the sensing window
- Non-sustained tachycardia that are too short to be counted by the detection counter

SMART Detection

The SMART detection algorithm should use atrial rhythm evaluation to differentiate between ventricular tachycardias and supraventricular tachyarrhythmias, for which therapy from the device is not required or desired.

SMART detection is a discrimination algorithm that uses both atrial and ventricular signals to classify tachyarrhythmias. The classification of heart rhythms is accomplished by utilizing several main tests within the SMART detection algorithm. These are:

- Atrial and ventricular rate
- Rate stability
- Multiplicity (numeric ratio of atrial to ventricular signals)
- Stability of AV conduction
- Sudden changes in ventricular rate (onset)

Scope of validity

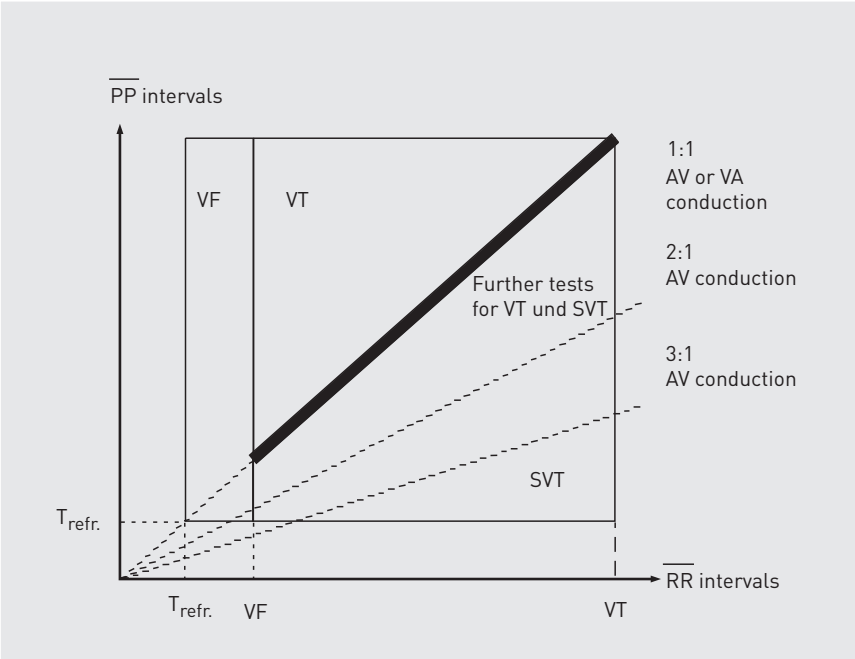
SMART detection is only applied to the VT1 and VT2 arrhythmia zones. If a ventricular rhythm meets the VT1 or VT2 criteria, then the SMART detection algorithm provides an additional detection test. If the corresponding tachycardia originates in the atrium, then ventricular therapy delivery is inhibited. If an arrhythmia fulfills the VT criteria, however, then therapy is delivered.

Conditions

SMART detection can be applied selectively to the VT1 and VT2 arrhythmia classes:

- If SMART is only set in the VT1 zone, then the counter is increased for VT1 once an interval falls within the VT1 zone and the SMART decision is VT.
- If SMART is only set in the VT2 zone, then the counter is increased for VT2 once an interval falls within the VT2 zone and the SMART decision is VT.
- If SMART is set in the VT1 zone and the VT2 zone, then the counter is increased for VT1 once an interval falls within the VT1 or VT2 zone and the SMART decision is VT.
- If SMART is set in the VT1 zone and the VT2 zone, then the counter is increased for VT2 once an interval falls within the VT2 zone and the SMART decision is VT.

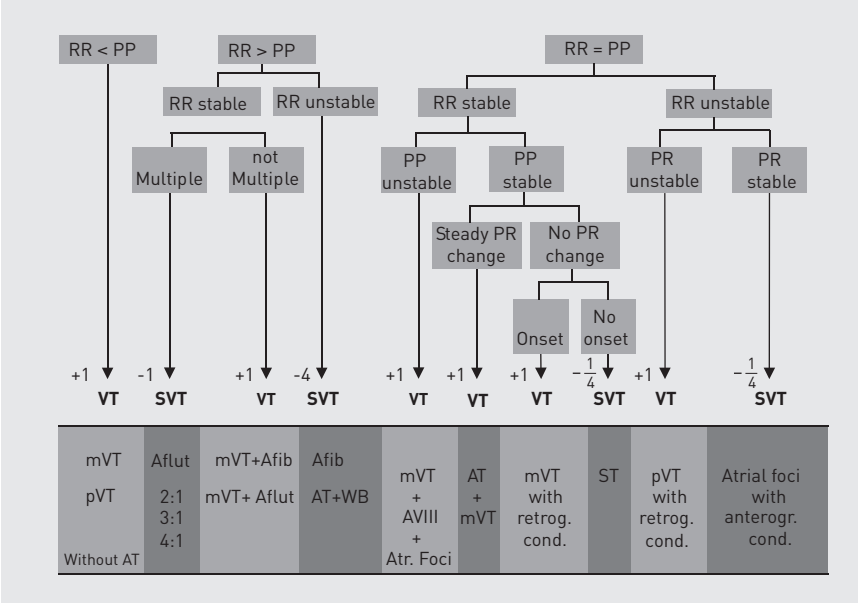
SMART AV discrimination



SMART detection algorithm functioning

The SMART detection algorithm is based on ongoing comparison of averaged atrial and ventricular intervals. These are calculated using four separate intervals in each case.

SMART decision tree



If the ventricular rate is higher than the atrial rate, then the ICD increments the VT counter forward without further tests and delivers VT therapy.

If the atrial rate is higher than the ventricular rate and no exceptions apply, then the ICD assumes a supraventricular cause. For the exception rule, the ICD also tests RR stability and atrioventricular multiplicity.

If the averaged intervals in the atrium and ventricle are equal, then corresponding 1:1 decision trees are available, which include tests of the onset criterion as well as PP and PR stability.

The discrimination algorithm determines whether each RR interval within the VT zone is of supraventricular or ventricular origin.

In the case of ventricular origin, the VT counter is increased by 1. In the case of atrial origin, the VT counter is decremented by 0.25, 1 or 4.

Note: SMART onset is preset to: 20%
SMART stability is preset to: 12%

MorphMatch

Overview

The MorphMatch function employs an analysis algorithm to discriminate between ventricular tachycardia and supraventricular tachyarrhythmia for which device intervention is not necessary or desired.

MorphMatch can be used in both VT zones but not in the VF zone.

Since ventricular tachycardia (VT) originates in the ventricle, there is a significant difference between VT, sinus and SVT morphology. The function makes use of this fact by evaluating the morphological characteristics of all intrinsic QRS complexes below the VF zone.

Classification of QRS complexes

The QRS complexes are classified by evaluation of certain morphological characteristics consisting of the following elements:

- A QRS complex is any sensed RVs that is slower than the defined VF zone. This is evaluated morphologically in the far-field channel. In addition, a time window of 250 ms triggered by the near-field channel (RV tip – RV ring) is evaluated. This time window extends across a time 100 ms prior to sensing and 150 ms after sensing of the QRS complex.

  Note: Due to the observation window of 250 ms, the setting for the upper value of the VF zone is limited to a maximum of 231 bpm.
- Calculation of three morphological characteristics for each QRS complex
  - Normalized area: Areas under the morphology curves are calculated and divided by the value of the maximum amplitude, which normalizes them.
  - Normalized vector: A vector is composed of four peaks on the morphology curve and is divided by the value of the highest peak.
  - Maximum peak: determination of the maximum peak.
- From the three morphological characteristics for the individual QRS complexes below 100 bpm, a reference is formed for each morphological characteristic and provides an average reference value. This reference value represents the average QRS morphology in the sinus rhythm. By also taking into account the natural variance between the individual sinus morphologies, MorphMatch determines the morphology threshold. The reference value and the morphology threshold are updated on a beat-to-beat basis.
- Valid for intervals of the VT zone:

  Each of these three morphological characteristics of the current QRS complex is compared (beat-to-beat) with the corresponding reference value, which corresponds to the average sinus QRS complex morphology. The differences in these three morphological characteristics are then summed and then compared to the VT morphology threshold.
- An integrated, permanent signal check ensures that any artifacts and signal distortions are filtered out.
- The reference curve is reset after termination of the episode or every 24 hours.

VT morphology counter

The VT morphology counter evaluates every sensed event and adds or subtracts every event as follows:

- Counter + 1: Morphology difference ≥ morphology threshold in the VT zones
- Counter ± 0: Morphology difference < morphology threshold in the VT zones or event in the VF zone
- Counter – 1: Rate slower than defined VT zones, RVp
- Reset: VT counter reset or counter number = 0

VT therapy decision

For VT therapy decision MorphMatch uses two different counters:

- VT counter
- VT morphology counter

Once the VT counter meets the defined criterion, the VT morphology counter checks whether a VT or a SVT has occurred. This is done according to the following criteria:

- VT morphology counter ≥ 50% VT counter = VT is confirmed and the therapy is delivered
- VT morphology counter < 50% VT counter = SVT is confirmed and therapy is withheld

VT and SVT counters are reset after MorphMatch confirms an SVT.

A VT detection following immediately thereafter is not a redetection but rather still a detection using valid initial detection counters.

Limitations of the morphology criterion

The morphology criterion is limited in the following cases:

- Use in triple-chamber devices unless left ventricular pacing is deactivated
- Use in patients with intermittent or rate-dependent bundle branch block
- If MorphMatch has made the VT decision and a therapy has been delivered, the function is deactivated for the redetection time and is only available again after termination of the episode.

Recordings of MorphMatch decisions

MorphMatch decisions are stored in episode details where they can be accessed. These can be used to change the value of the MorphMatch threshold parameter, if necessary.

The result of the morphology counter is shown in %. See the VT therapy decision above for the meaning of the value.

MorphMatch threshold parameter

The MorphMatch threshold parameter is used to adjust the parameter in case of incorrect MorphMatch decisions, MorphMatch – Details, p. 52.

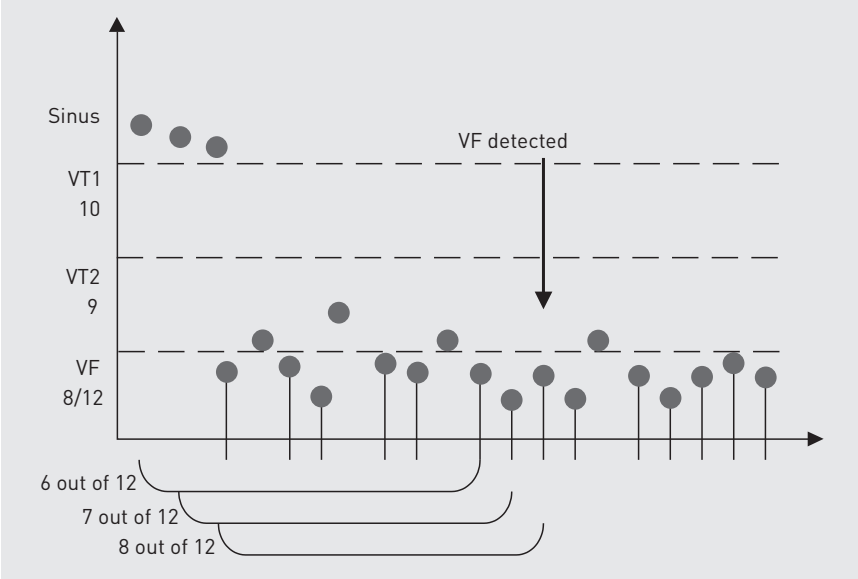
Ventricular Fibrillation Detection

VF detection

The ICD classifies a heart rate as fibrillation if a minimum number X of a number Y of successive RR intervals is lower than the set VF interval. The unit in this case is milliseconds [ms]. If [bpm] has been selected instead of [ms] for the rate limit, then a minimum number X of the number Y of successive signals has to be above the set limit [bpm].

VF detection uses this X-of-Y algorithm. No inhibiting criterion can be programmed for the VF zone, because ventricular fibrillation always requires therapy.

VF detection



Hysteresis after VF detection

VF detection has a hysteresis function that extends the VF zone limit by 60 ms.

Mode of functioning

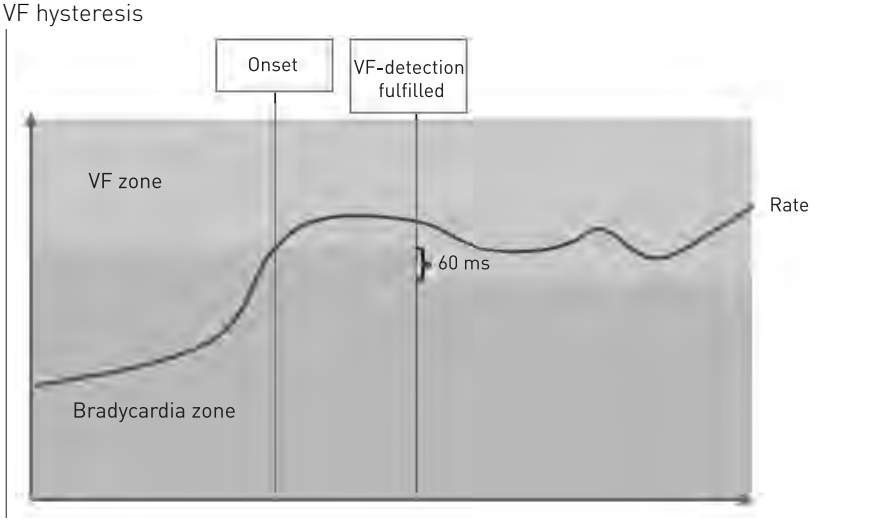
- Tachyarrhythmia rates oscillating around the VF zone limit no longer cause shocks with confirmation to be canceled during the capacitor charging phase.
- This function is effective only during the charging phase for shocks with confirmation.

Example

- VF zone limit: 200 bpm = 300 ms
- VF was detected

Shock with confirmation is canceled only if 3 out of 4 intervals are smaller than 360 ms = 167 bpm.

VF hysteresis



Ventricular Redetection and Termination

Redetection

Redetection begins as soon as a detected tachyarrhythmia episode has been delivered therapy but not terminated. A tachycardic RR interval then starts the counting. The parameters can be adjusted separately in the VT/VF zones.

Therapy is delivered again if the number of tachycardic RR intervals reaches the set value in the redetection counter function. Each RR interval that is not tachycardic reduces the counter by a value of one.

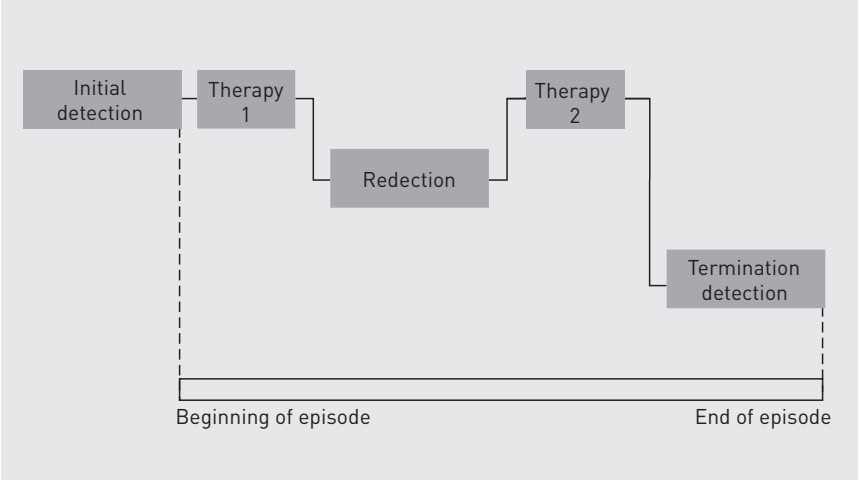
If the stability criterion is switched on, then this also applies to redetection.

If SMART detection is activated in the respective VT zone, then the SMART redetection algorithm is automatically activated. SMART redetection cannot be switched off separately.

Termination detection

The ICD classifies a tachyarrhythmia episode as terminated if at least 12 of 16 consecutive RR intervals are greater than the VT/VF interval of the lowest VT/VF zone (X-of-Y not programmable).

Redetection and termination detection



Note: If VT1 is set up as a monitoring zone and initial detection is carried out in VT2 or VF, then the limit for termination is not VT1, but VT2 or VF.

Forced termination

If supraventricular tachycardia continues after successful VT/VF therapy, then it has to be ensured that therapy is made available again in the case of repeated VT or VF.

An episode with sustained atrial fibrillation and tachycardic ventricular rate is considered terminated after the set duration has passed.

An episode with forced termination is saved in **[Recordings]**. The Forced termination parameter is preset and functions as a hidden parameter that is not visible on the user interface.

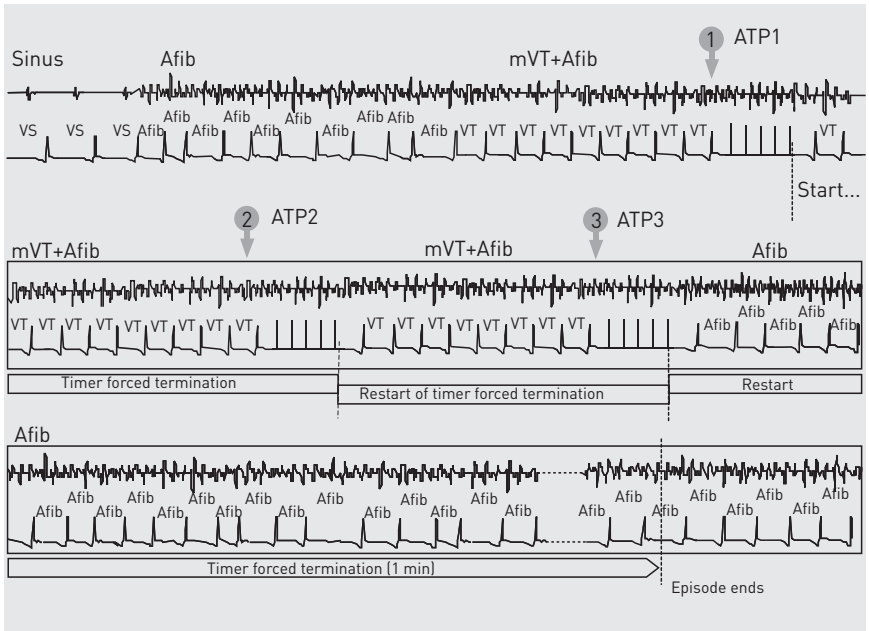
The following settings are required for an episode with sustained atrial fibrillation to be considered terminated:

- SMART = ON
- Forced termination = 1 min (fixed, not programmable)

or

- SMART = OFF
- Onset and/or stability have to be activated in a VT zone.
- Sustained VT = OFF

Forced termination



Atrial Rate Classification

AT/AF rate classification

If the AT/AF rate is set, then the ICD continuously classifies each PP interval. An atrial episode starts when at least 36 of 48 consecutive PP events have a higher rate than the set AT/AF rate. An atrial episode is considered terminated if 20 of 24 consecutive PP events have a lower rate than the set AT/AF rate.

AT/AF event message via Home Monitoring

A timer is started at the beginning of an atrial episode. If no termination of the atrial episode occurs during this time, then a device message is transmitted pertaining to the sustained atrial episode.

Supraventricular tachycardia episodes

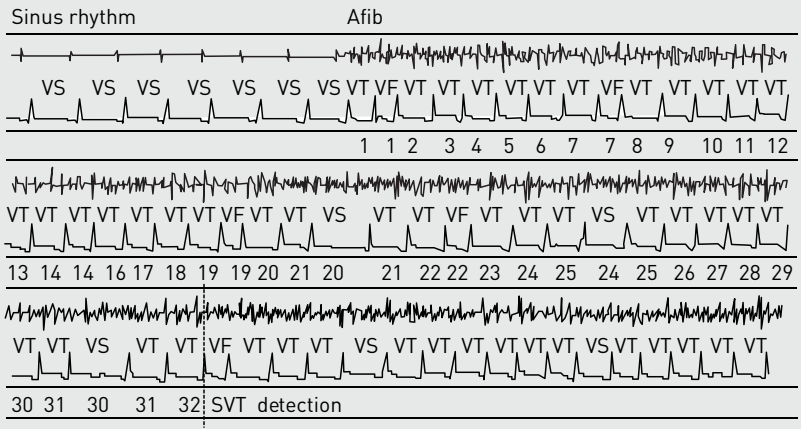
The supraventricular tachycardia counter cannot be set. This counter is defined as double the value of the VT1 counter. The VT1 counter can be set. If the VT1 counter has been set to 16, then a value of 32 automatically applies to the supraventricular tachycardia counter.

Supraventricular tachycardia episodes are saved. A detection criterion is specified, which classifies an episode as a supraventricular tachycardia.

Supraventricular tachycardia detection is based on a forward-backward counter principle. All RR rates that are higher than the rates of the lowest VT zone are counted. Classification using inhibiting additional criteria such as onset or SMART is not carried out here.

A supraventricular tachycardia episode is considered fulfilled if the supraventricular tachycardia counter has reached the specified counter number but the VT counters are not fulfilled in any VT zone.

SVT detection



The example shows sudden atrial fibrillation. Upon activating the onset and stability criteria, the VT counter does not reach the required 16 events even if SMART is activated due to lack of stability of the RR intervals. The VT counter is repeatedly reset or repeatedly counted backwards by SMART.

The supraventricular tachycardia counter, on the other hand, reaches 32 intervals despite several minus counter steps due to individual slower sinus intervals. Individual VF intervals interrupt supraventricular tachycardia counting.

The time of fulfilled supraventricular tachycardia detection is the trigger event used to store the IEGM. SVT episodes are not only stored in dual- and triple-chamber ICDs but also in single-chamber ICDs.

There is a second method for detecting SVT episodes, MorphMatch, p. 40.

3.2 Detection Parameters

What's in this section?

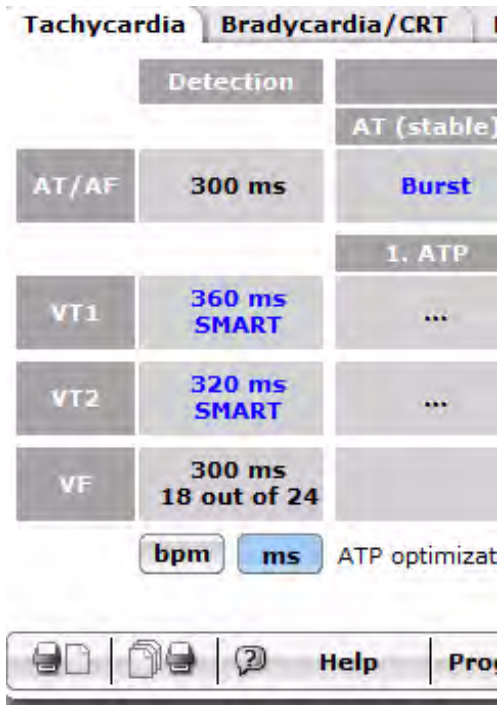
Purpose Detection parameters are used to classify arrhythmias according to the atrial (AT/AF) or ventricular arrhythmia zones (VT1 ... VF) and decide on therapy options.

Detection Parameters

Navigation: Parameters → Tachycardia → Detection

Objective Detection parameters are used to allocate arrhythmias to an atrial (AT/AF) or ventricular arrhythmia zone (VT1 ... VF) and if necessary, decide on therapeutic options.

Item



WARNING
Inactive detection and therapy in static magnetic fields If the device's magnetic sensor detects magnetic fields beyond a magnetic flux density of approx. 1.5 mT, VT and VF detection and the respective therapies are deactivated. If the magnetic sensor detects magnetic fields below 1 mT, VT and VF detection and the respective therapies are activated again.

Note: If VT/VF detection and therefore ICD therapy has been deactivated by applying a magnet or by the use of static magnetic fields in the 8 hours previous to the interrogation for more than 5 min, an information message indicates that ICD therapy has been deactivated temporarily. You can then set the status of ICD therapy in the same dialog window in which the message text appears.

Description of detection parameters

Parameter	Description
`Interval` (`bpm`) or `Rate` (`ms`)	Sets the limits of an arrhythmia zone; for more information see: Interval – Details, p. 48.
`Detection counter`; `Redetection counter`	Distinguishes individual short intervals (extrasystoles, couplets, runs, etc.) from tachycardia; for more information see: Detection and Redetection Counter – Details, p. 49.
`SMART detection`	Differentiates between ventricular and supraventricular tachyarrhythmia: ICD intervention is not necessary or desirable for the latter; for more information, see: SMART Detection – Details, p. 49.
`Onset`	Differentiates between gradually accelerating tachycardias and sudden tachycardias; for more information, see: Onset – Details, p. 50.
`Stability`	Makes a distinction between conducted supraventricular tachycardias (atrial fibrillation, for example) and ventricular tachycardias that require therapy; for more information see: Stability – Details, p. 50.
`Sustained VT`	Increases sensitivity, in case inhibiting criteria prevent detection of sustained VT; for more information see: Sustained VT – Details, p. 51.
`Forced termination`	The time period after which a detection or re-detection counts as terminated so that any new detection will have all therapies available; for more information see: Forced Termination – Details, p. 51.
`MorphMatch`	Helps to distinguish between supraventricular tachycardias and ventricular tachyarrhythmias through the morphological evaluation of the QRS complex; for more information see: MorphMatch – Details, p. 52.

Interval – Details

Navigation: Parameters → Tachycardia → Detection -> VT1, VT2 or VF

Effect of PP intervals

The parameter Interval (or Rate) has the following effect on PP intervals:

- If a PP interval is shorter (or a PP rate greater) than the parameter value programmed for an arrhythmia zone (AT, AF), the PP interval is assigned to the respective arrhythmia zone.
- A PP interval is limited by either an As, Ars or Ap.

Effect of RR intervals

The parameter Interval (or Rate) has the following effect for RR intervals:

- If an RR interval is shorter (or an RR rate greater) than the parameter programmed for an arrhythmia zone (VT1, VT2 or VF), the RR interval is assigned to the respective arrhythmia zone.
- An RR interval is limited by either a Vs or a Vp.
  The following are Vs:
  — RVs
  — PVC
  — RVrs
  The following are Vp:
  — RVp (with right ventricular or biventricular pacing)
  — LVp (with left ventricular pacing)
- If the value **OFF** is programmed, the ICD does not detect in the relevant arrhythmia zone.
- The parameter value also applies for redetection.

Detection and Redetection Counter – Details

Navigation: Parameters → Tachycardia → Detection -> VT1, VT2 or VF

Effect The detection counter and redetection counter parameters have the following effect:

- For AT/AF detection:
  - If 36 of 48 consecutive tachycardia PP intervals are smaller than or equal to the programmed value of the AT/AF interval parameter, the rhythm is considered AT or AF.
  - The Stability parameter differentiates between AT and AF; for more information see: Stability – Details, p. 50.
- For VT detection:
  - The criterion is met if the number of tachycardiac RR intervals is greater than or equal to the programmed value of the detection or redetection counter parameter.
  - Every RR interval that is greater reduces the counter by one. The smallest value is 0.
  - Different values can be programmed for detection and redetection.
- For VF detection:
  - If a minimum number (X) of the total number of consecutive RR intervals (Y) is greater than or equal to the programmed value of the detection or redetection counter parameter VF (X out of Y), the rhythm is considered VF.
  - Different values can be programmed for detection and redetection.

SMART Detection – Details

Navigation: Parameters → Tachycardia → Detection -> VT1, VT2 or VF

Description

- SMART detection can be set separately for VT1 and VT2.
- By classifying the atrial rhythm, the SMART detection algorithm is designed to discriminate between ventricular tachycardias and a variety of supraventricular tachyarrhythmias (SVTs) for which device intervention is not required.
- If the RR interval is within VT1 or VT2, SMART detection checks whether an SVT is the cause of the tachycardia according to the following criteria:
  - Stability
  - Onset
  - Multiplicity
  - Comparison of atrial and ventricular rates

Effect The SMART detection algorithm is based on a continuous comparison of the mean atrial and ventricular intervals obtained. These are calculated using four separate intervals in each case.

- If the ventricular rate is higher than the atrial rate, then the ICD increments the VT counter forward without further tests and delivers VT therapy.
- If the atrial rate is higher than the ventricular rate and no exceptions apply, then the ICD assumes a supraventricular cause. For the exception rule, the ICD also tests RR stability and atrioventricular multiplicity.
- If the averaged intervals in the atrium and ventricle are equal, then corresponding 1:1 decision trees are available, which include tests of the onset criterion as well as PP and PR stability.

DX devices If the ICD assumes that there is under-sensing in the atrium, then SMART detection is not deployed and Onset/Stability is used instead to distinguish between SVT and VT.

Onset – Details

Navigation: Parameters → Tachycardia → Detection -> VT1, VT2 or VF

Effect

The Onset parameter has the following effects:

- The programmed percentage relates to the difference between the following measurements:
  - Mean value from the last four RR intervals after onset
  - Mean value from the last four RR intervals before onset
- The criterion is met when the difference is greater than the programmed value.
- In order to be effective, the onset criterion must be met in addition to the Detection counter criterion.
- The criterion is only effective for initial detection. Onset is always considered fulfilled for redetection.
- For onset, there is only one common value for VT1 and VT2.

Stability – Details

Navigation: Parameters → Tachycardia → Detection -> VT1, VT2 or VF

Effect on atrial detection

The Stability parameter has the following effect on atrial detection:

- Prerequisite: Of 48 consecutive tachycardia PP intervals, 36 are greater than or equal to the programmed value of the AT/AF interval parameter.
- If 5 of the last 8 tachycardia PP intervals differ by 40 ms or less from the preceding intervals for these 8 tachycardia PP intervals, the atrial tachycardia is considered stable and therefore as AT.
- If 3 of the last 8 tachycardia PP intervals are smaller than 200 ms (interval) or faster than 300 bpm (rate), the atrial tachycardia is considered unstable and therefore as AF.

Effect on ventricular detection

The Stability parameter has the following effect on ventricular detection:

- If the current interval remains within the defined range (range of fluctuation) of the previous three tachycardia intervals' fluctuations, this criterion is considered met for the current interval.
- Detected instability affects detection or redetection counters as follows:
  - If SMART Detection is switched off: The VT counter for detections and redetections is reduced by 20.
    If less than 20, the counter is rounded to zero.
  - If SMART Detection is switched on: The counters are adjusted individually, depending on the SMART decision pathway.
- If SMART detection is activated for VT1 and VT2, the programmed value for Stability applies both to VT1 and to VT2.
- The value programmed for Stability is effective for initial detection and redetection.

Sustained VT – Details

Navigation: Parameters → Tachycardia → Detection -> VT1, VT2 or VF

Effect The Sustained VT parameter works as follows:

- The counter is started by an initial VT1, VT2, or VF interval.
- The following events will stop and return the set time to zero:
  - VT or VF initial detection
  - Termination detection
  - Sequence for the set time
- If no VT, VF or termination is detected during the set sustained VT time, the following happens when the time expires:
  - Redetection with the respective parameter values is started.
  - Onset, stability and MorphMatch are not effective.
- The programmed value always applies uniformly to VT1 and to VT2.

Forced Termination – Details

Navigation: Parameters → Tachycardia → Detection -> VT1, VT2 or VF

Effect

Note: The parameter value for Forced termination cannot be set individually. It is preset to 1 min by the system.

The parameter value sets the time limit after which the episode is terminated:

- Prerequisites:
  - SMART detection is switched on.
  - For single-chamber modes: Stability is switched on for detection and redetection.
- In this case, the episode is forced to terminate after 1 min so that the entire range of therapy is available in the event of a new VT/VF.
- Response without forced termination: If a VT has ended but an underlying SVT is still going on, then no termination detection takes place, but neither is any redetection made.

MorphMatch – Details

Navigation: Parameters → Tachycardia → Detection -> VT1, VT2 or VF

Effect

Prerequisite:

- The detection counter, onset and stability criteria are fulfilled.

If Morphology = ON, the criterion functions as follows:

If ...	Then ...
50% or more of the evaluated VT intervals show VT morphology,	the episode is classified and treated as VT, followed by a redetection or termination detection.
less than 50% of the evaluated VT intervals show VT morphology,	the episode is classified as an SVT episode. Therapy is withheld, the counter for VT, SVT and MorphMatch are restarted, followed by redetection or termination detection.

- If `MorphMatch` = `Monitoring`, then the criterion works as follows:
  - The details, evaluation and course of the tachycardia are recorded.
  - The evaluation does not have an effect on therapy decisions.
- The evaluation based on the MorphMatch function is saved in the Episode details data (`MorphMatch counter [%]`; See also:).Evaluating episode details, p. 180

Restrictions

- It cannot be used for redetection after an initial VT or VF detection.
- Only if `SMART detection` is switched off
- Triple-chamber devices: in dual-chamber mode only (with no biventricular pacing)
- In `VT2` only if `VT1 MorphMatch` = `ON`

MorphMatch

For `VT1` and `VT2` the following can be set individually:

Parameter value	Effect
`ON`	Classification and therapy
`Monitoring`	Classification only The assessment is stored in the episode details, the decision on therapy options is not affected.

MorphMatch threshold

Parameter values and their effect:

Parameter value	Effect
`Std.` `Standard`	Standard value for the compliance level between the current QRS complex and the Morphology reference upon which the decision on VT morphology is based.
`High`	Larger morphological difference required for classification as a VT morphology
`Low`	Smaller morphological difference required for classification as a VT morphology

Note: Observe the following possible effects of the parameter values:

- The `High` setting can reduce the number of VTs detected.
- The `Low` setting can increase the number of undetected SVTs.

4 Tachyarrythmia Therapy

What's in this chapter?

4.1 Status of ICD Therapy

What's in this section?

Activating and Deactivating ICD Therapy

Objective

In the `ICD therapy` group box, you can enable or disable the detection and therapeutic functions of the ICDs by clicking once on the **[ON]** or **[OFF]** button.

Activating the function will make the settings made in the `Tachycardia` tab effective.

WARNING
If ICD therapy [OFF] = Status: `Disabled`, then no VT or VF therapy
If ICD therapy is switched off, the ICD does not perform any VT/VF therapy, regardless of the set values shown as detection and therapy parameters.
• When the ICD therapy is switched on, ensure that arrhythmia zones and therapies are programmed effectively.

Messages

The following messages can be displayed after interrogating the device:

Message	Meaning
`Enabled`	ICD therapy is active. Arrhythmia zones and therapies will work as programmed.
`Disabled`	ICD therapy is inactive. No VT/VF therapies can be delivered, regardless of the set and displayed values for detection and therapy parameters.
`Temporarily active`	ICD therapy is temporarily active. For DFT testing, the therapies set in the **DFT** tab are temporarily enabled. After the DFT test, the ICD can only begin delivering regular tachyarrhythmia therapies once the temporary program has been closed.
`Temporarily inactive`	ICD therapy is temporarily inactive. This is the case with tests on the follow-ups that are executed as a temporary program without enabling ICD therapy and with the DFT test when all temporary therapies have already been delivered.
`Unknown`	The status of the ICD therapy could not be detected during device interrogation.

Programming Head and Magnet Application

General considerations

The detection and therapy behavior of an ICD is different when the programming head (PGH) or the permanent magnet is applied.

Detection and therapy when programming head applied

If ...	Then ...
the PGH is applied, connection with the programmer is established and ICD therapy is activated,	detection and therapy are both active and: • Temporarily inactive: during diagnostic tests • Temporarily active: during the DFT test
the PGH is applied, connection with the programmer is established and ICD therapy is not activated,	detection and therapy are both inactive
the PGH is applied for an interrogation or to establish RF telemetry contact,	detection and therapy are always temporarily inactive. The last programmed state of ICD therapy is activated after the interrogation.

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 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.

Detection and therapy when magnet applied

Note: Use the BIOTRONIK M-50 permanent magnet.

If ...	Then ...
a permanent magnet is applied,	detection and therapy of tachycardia events are interrupted.
a permanent magnet is applied for more than 8 hours,	the device automatically reactivates detection and therapies to prevent accidental permanent deactivation.

If you intend to actively interrupt detection and therapy for longer than eight hours, the permanent magnet must be raised before the eight hours have elapsed in order to restart the time window again.

WARNING

Inactive detection and therapy in static magnetic fields

If the device's magnetic sensor detects magnetic fields beyond a magnetic flux density of approx. 1.5 mT, VT and VF detection and the respective therapies are deactivated.
If the magnetic sensor detects magnetic fields below 1 mT, VT and VF detection and the respective therapies are activated again.

Note: If VT/VF detection and therefore ICD therapy has been deactivated by applying a magnet or by the use of static magnetic fields in the 8 hours previous to the interrogation for more than 5 min, an information message indicates that ICD therapy has been deactivated temporarily. You can then set the status of ICD therapy in the same dialog window in which the message text appears.

4.2 Parameters for Tachyarrhythmia Therapy

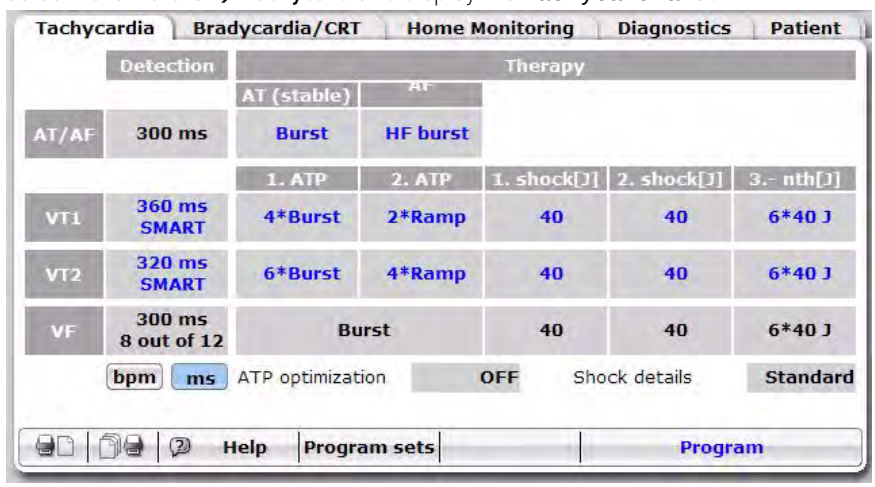
What's in this section?

Purpose

The ICD uses therapy sequences programmed by means of the tachyarrhythmia therapy parameters to terminate tachyarrhythmia in the zones AT, AF, VT1, VT2 and VF.

Navigation

Select **Parameters** → **Tachycardia** to display the `Tachycardia` tab:



Description

The therapy parameters are set on the user interface:

Therapy Parameters	Description of parameters
AT/AF	Used to terminate atrial tachyarrhythmia: • 1 therapy attempt
VT1 and VT2	Used to terminate ventricular tachyarrhythmia up to: • 2 ATP attempts • 8 therapy shocks
VF	Used to terminate ventricular fibrillation up to: • 1 ATP attempt • 8 therapy shocks

Therapy Sequence Pattern

General functional principles

The ICD uses the following functions to treat atrial and ventricular tachyarrhythmias:

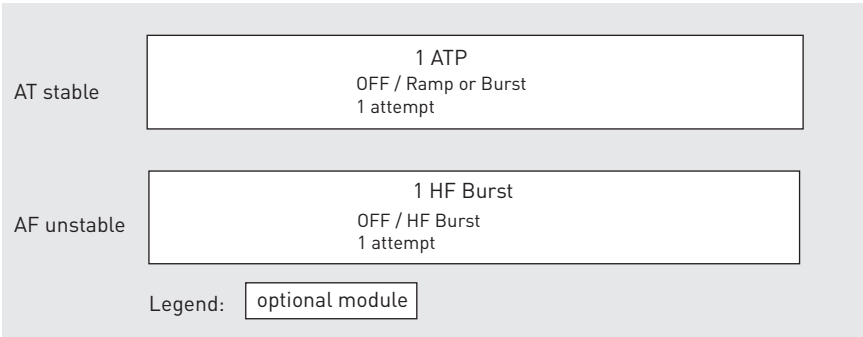
- Atrium: pacing by antitachycardia pacing (ATP) or HF burst
- Ventricle: pacing by antitachycardia pacing (ATP) followed by one or more shocks in some cases
- Ventricle: Defibrillation with adjustable energy, polarity and shock form with or without confirmation

Atrial therapies

A therapy can be programmed for each of the arrhythmia zones AT or AF:

The following therapies are available in the AT/AF zones:	
1st AT zone (stable)	An ATP with selectable ATP type (ramp or burst)
2nd AF zone (unstable)	An HF burst

Atrial therapies



Note: Atrial therapy rules

- Atrial therapy is successful if the episode is terminated within one minute. One therapy attempt is possible per episode.

  In case of failure, the function is blocked for the current episode.
- A maximum of 5 therapy attempts can be made per day
- Apply the stability criterion (40 ms) to discriminate between stable and unstable atrial tachycardia
- Ventricular backup stimulation is possible (standard value = OFF)
- Automatic shut-off until next in-office follow-up if an atrial episode lasts ≥ 48 h or atrial therapy results in accelerated rhythm within one minute (VT-VF detection).

Ventricular therapy sequences

A therapy sequence consisting of scaled-strength therapies can be set up for each of the arrhythmia zones VT1, VT2 and VF.

VT1/VT2 therapy sequence

The therapy sequence for VT1 and VT2 consists of a combination of antitachycardia pacing sequences and/or shocks:

The following therapy sequences are available in the VT zones:	
1.	One ATP with adjustable number of therapy deliveries and selectable ATP form
2.	Two consecutive ATPs with independently adjustable number of therapy deliveries and selectable ATP form
3.	A shock with adjustable energy, polarity, shock waveform and confirmation
4.	Two shocks with independently adjustable energy. Polarity, shock waveform and confirmation are programmable, but are identical for both shocks.
5.	Two shocks with independently adjustable energy and up to six additional shocks with maximum energy. Polarity, shock waveform and confirmation are programmable, but are identical for all shocks.
6.	Combinations of one or two ATPs and up to eight subsequent shocks

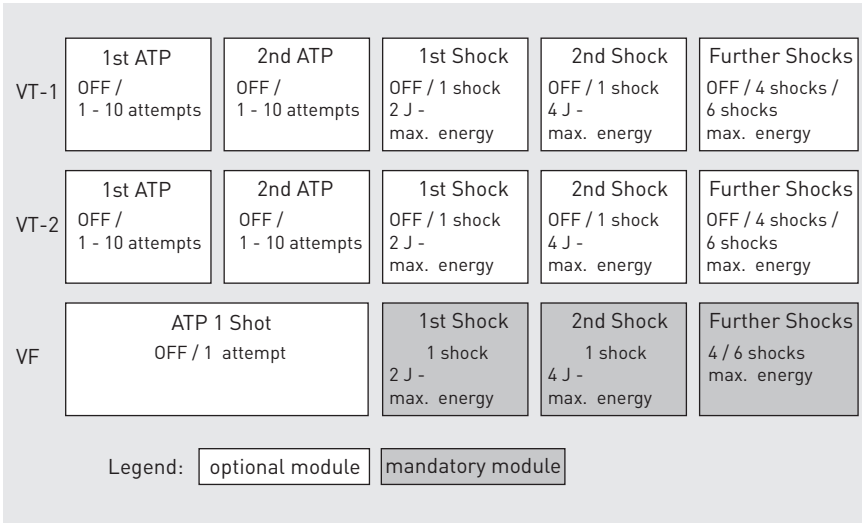
VT monitoring zone: The VT1 zone can also be used solely as a monitoring zone even without a therapy sequence.

VF therapy sequence

The therapy sequence for VF consists of one ATP One Shot as a therapy option and/or forced shocks:

The following therapy sequences are available in the VF zone:	
1.	ATP One Shot as an attempt to terminate a stable VF without pain and is followed by a shock sequence if not successful.
2.	Therapy sequence with two shocks with adjustable energy. Polarity, shock waveform and confirmation are programmable, but are identical for both shocks.
3.	Therapy sequence as in item 2 with up to six additional shocks with maximum energy

Ventricular therapy sequences

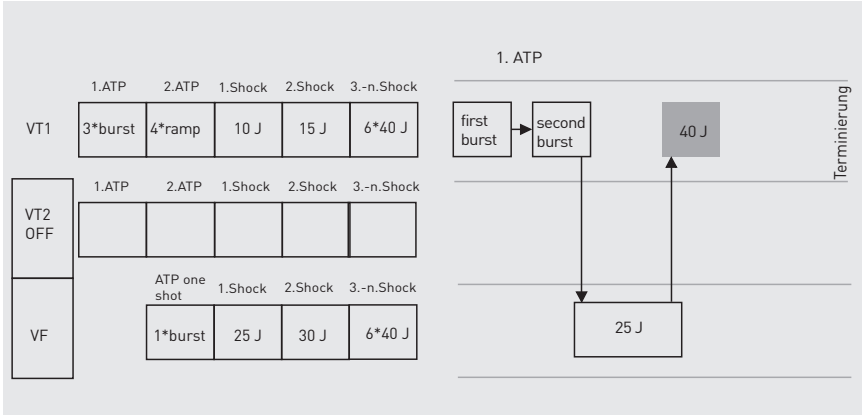


Progressive course of therapy

This function is a fixed setting in all arrhythmia zones. During the course of an episode, if redetection occurs in another arrhythmia zone, then only the therapies with a higher energy than the last delivered shock or the last ATP are still delivered.

The ICD blocks every ATP for the current episode if a shock has already been delivered during its course.

Progressive course of therapy



If no shock has been set in the VT1 zone, but an ineffective shock has been delivered in another zone, the progressive course of therapy results in no therapy being able to be delivered in the case of redetection in the VT1 zone. The VT1 zone is then only effective as a monitoring zone.

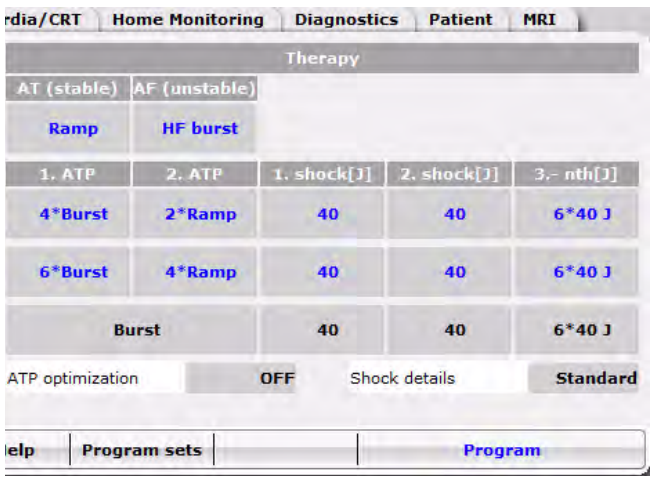
Tachycardia Therapy Parameters

Objective

With the help of the parameters for tachycardia therapy, the therapy sequences to be used in the ICD are set in order to terminate tachycardias in the AT, AF, VT1, VT2 and VF zones. The following therapy sequences are possible:

- ATP and burst therapies for AT/AF
- ATP and shock therapies for VT
- ATP One Shot and shock therapies for VF

Item



Note: You must have activated detection parameters before you can set therapy parameters.

Meaning of therapy parameters

Parameter	Description
`AT (stable)`, `AF (unstable)`	Therapy runs: • Per detection: 1 • Per day: 5 For more information see: AT and AF Therapies – Details, p. 62
`ATP optimization`	The higher the rate of success of an ATP therapy, the earlier in the sequence it should be placed. For more information see: ATP Optimization – Details, p. 69
`Shock details`	Set the shock waveform, polarity and path in detail to achieve optimal effectiveness. For more information see: Therapy Shock Parameters: Configuring Zones Separately , p. 79
ATP One Shot	ATP One Shot can be used as an initial low-energy therapy for VF. For more information see: ATP One Shot, p. 70
[ATP help...]	Displays the course of the ATP therapy sequences graphically. For more information see: Display ATP Therapies Graphically (ATP Help), p. 68
Progressive course of therapy	If a shock has been delivered in the course of a tachyarrhythmia episode, then the system blocks the delivery of ATP therapies (including ATP One Shot) for the remaining duration of the episode. The emission of further shocks always either requires a higher level of energy than the previous one or the maximum energy.
Surge guard	This function prevents detections caused by ineffective therapies from swinging to and fro between the arrhythmia zones. For more information see: Surge Guard – Details, p. 80

AT and AF Therapies – Details

Navigation: Parameters → Tachycardia → Therapy -> AT or AF

Therapy concept

The following therapies can be used:

- For atrial tachyarrhythmia (AT): ATP (for more information see: ATP parameters, p. 71)
- For atrial fibrillation (AF): HF burst (for more information see: HF burst parameters, p. 71)

The following applies during the course of the therapies:

- If an atrial therapy that has not subsequently been terminated led to the detection of a VT or VF (tachycardiac rhythm in the ventricle), then atrial therapies are blocked until the next follow-up.
- For the follow-up, the physician will receive a corresponding message and actively decide whether to reactivate atrial therapies.

4.3 ATP Therapy

What's in this section?

Antitachycardia Pacing (ATP)

Overview

The ICD can use various forms of antitachycardia pacing to deliver therapy of ventricular tachyarrhythmias. ATP can be configured individually so as to allow for creating ATP therapy sequences of various agressiveness levels and integrating these in the therapy sequence.

Up to two ATP therapy sequences can be set up in the VT1 and VT2 zones.
ATP One Shot can be set as a one-time therapy option in the VF zone.

Antitachycardia pacing (ATP)

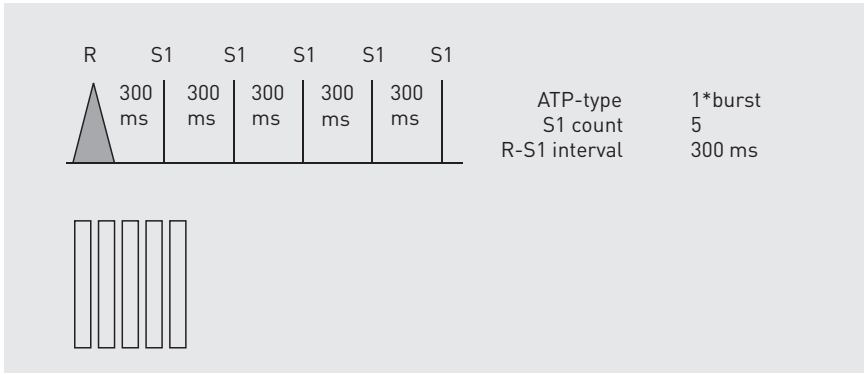
Numbers and forms can be specified for each ATP. Two different ATP forms, each with up to 10 therapy deliveries, can be selected:

- Burst
- Ramp

Note: The bars in the following graphics are also displayed in the ATP help in the user interface.

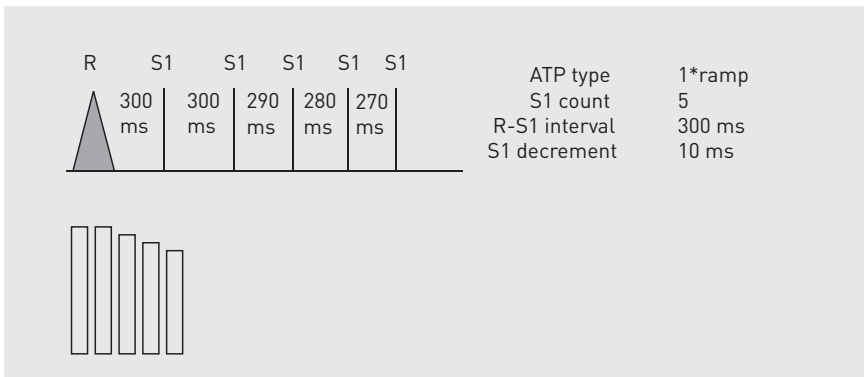
Burst

A number of S1 follows the R-S1 coupling interval at equal intervals.



Ramp

Pulses whose intervals change constantly follow the R-S1 coupling interval. The S1 decrement is critical to these changes.



ATP Parameters

Setting the ATP parameters

The various different antitachycardia pacing parameters are defined as adaptive to the last RR mean value or as an absolute value. Depending on the set ATP type, the ICD changes the corresponding parameters from one delivery to the next.

Note: The ventricular pacing parameter can be used for triple-chamber ICDs to specify whether ATPs are only delivered to the right ventricle, the left ventricle or both ventricles.

S1 count: The number S1 defines the number of stimuli of an ATP.

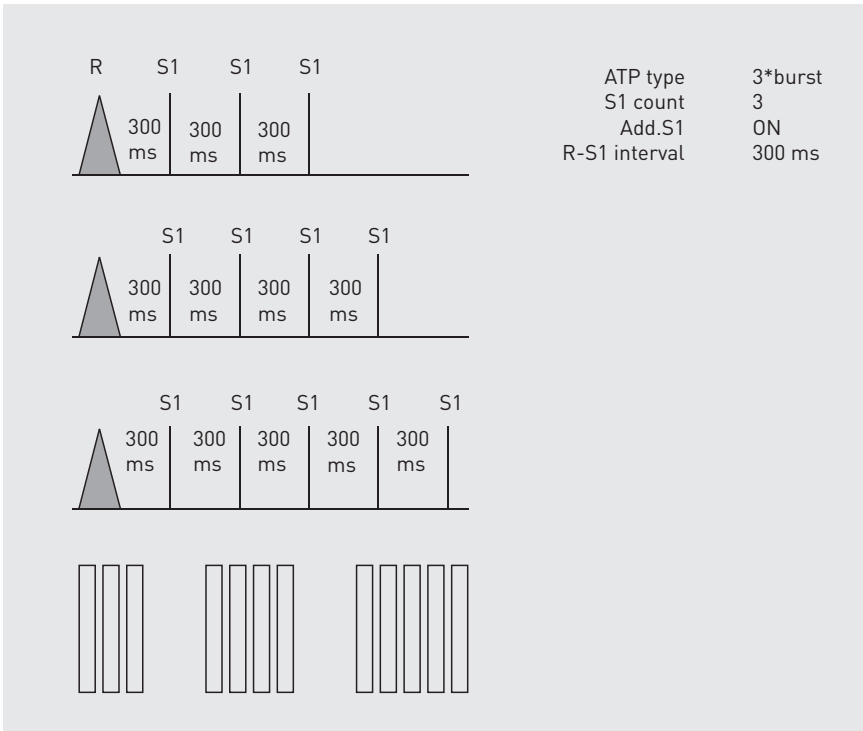
Add. S1: Add. S1 causes the second and each following ATP to be extended by one stimulus each.

R-S1 interval: The coupling interval R-S1 is at the beginning of each ATP. It defines the interval between the last R-wave and the first stimulus S1. The second stimulus always follows the first at the same interval. This parameter can be set as a percentage value of the last RR interval or in ms.

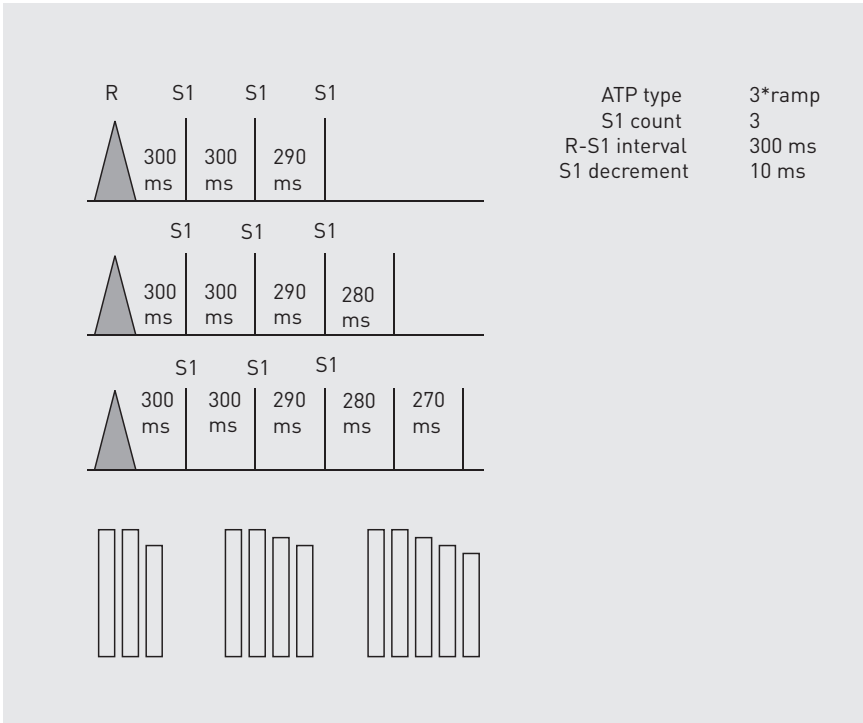
S1/S2 decrement: The S1 decrement continuously reduces the pacing interval within an ATP beginning after the second stimulus. This parameter generates the ATP form ramp.

Scan decrement: Scan decrement is used to specify shortening of the R-S1 interval with each additional pulse delivery.

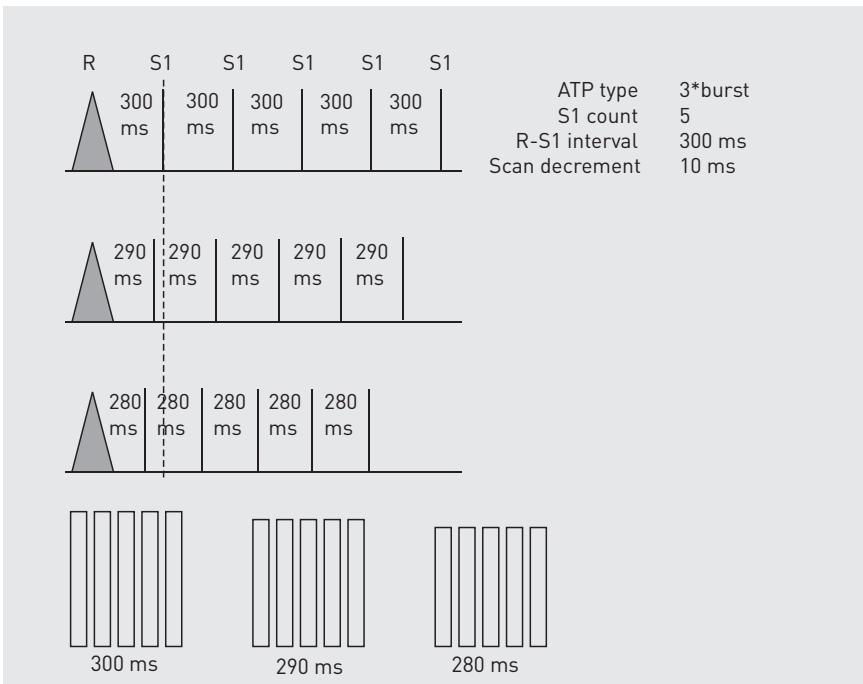
Burst with Add S1



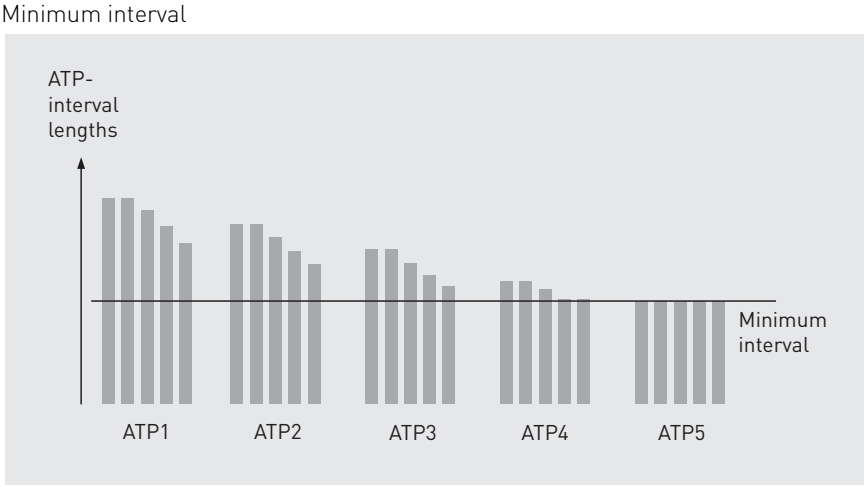
Ramp with Add S1



Burst with scan decrement



Minimum interval: This parameter specifies the minimum possible interval duration for ATP. This prevents a shorter interval, which could theoretically result from applying S1 decrement or scan decrement. The minimum interval applies to both ATP sequences. The minimum interval is set to a fixed value of 200 ms.



ATP optimization

In order to optimize future therapies, the ICD saves ATP settings that have resulted in termination in the VT1 or VT2 zone. ATP sequences start future therapy sequences with these settings. In the background, a counter stores the success or failure of each ATP therapy with the value +1 or +1 and sets the order of the ATP therapies according to their stored success counters. Effective ATP therapies are delivered first and ineffective ones are delivered last.

Upon later detection in a VT zone, in which a successful ATP sequence is already stored, this is delivered first. If not successful, the counter for this ATP is reset for the corresponding zone and the therapy sequence in the same zone begins with the next successful therapy. The sequence of ATP therapies is thus continuously optimized by the use of the dynamic ATP therapy memory, which sorts and delivers the ATP therapies according to their success.

Upon detection in another arrhythmia zone, the therapy sequence is started with an ATP therapy that has been optimized and stored there.

ATP optimization is activated or deactivated for the VT1 and VT2 zone.

The ATP surge guard runs in the background and ensures that rhythm-accelerating ATP therapy sequences are permanently blocked for the current episode and until the next ATP reprogramming.

ATP One Shot

ATP One Shot is intended to attempt one-time painless termination of a stable VF and thus reduce the number of delivered shocks.

In the VF zone an attempt to terminate fibrillation using ATP can be made once before shock delivery.

The ATP is only delivered if the VF fulfills the fixed stability criterion of 12% of the VT zone.

The shock following the ATP is always delivered with shock confirmation so that shock delivery can be prevented in the case of successful ATP.

If the ATP One Shot is not successful, then the first shock in the VF zone is delivered without waiting for redetection.

ATP One Shot: Early ATP delivery

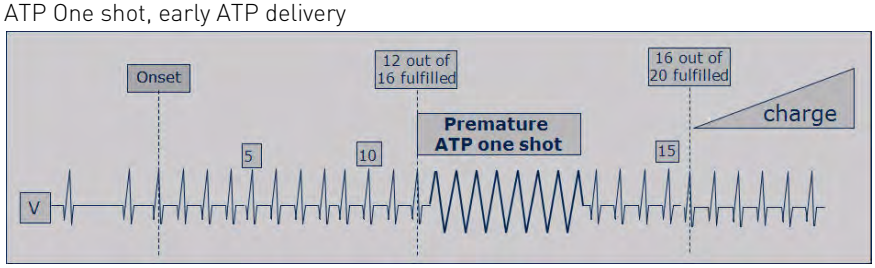
With the additional ATP One Shot function, early ATP delivery is likewise intended to attempt one-time painless termination of a stable VF and thus reduce the number of delivered shocks.

For detection conditions in the VF zone, see Early ATP delivery, p. 70.

If ATP One Shot – early delivery – is unsuccessful, the VF counter for arrhythmia detection continues to run. Delivery of the ATP is not counted towards counting/ fulfilling the VF counters, i.e. after ATP delivery in the example given below it would continue to count after 13. This first fulfillment of the programmed VF counters is marked as redetection, though it is actually the initial detection and causes delivery of the first shock.

Together with the shorter detection times, this is the main difference from ATP One Shot without early ATP delivery.

ATP One shot, early ATP delivery



Display ATP Therapies Graphically (ATP Help)

Navigation: Parameters → Tachycardia → Therapy

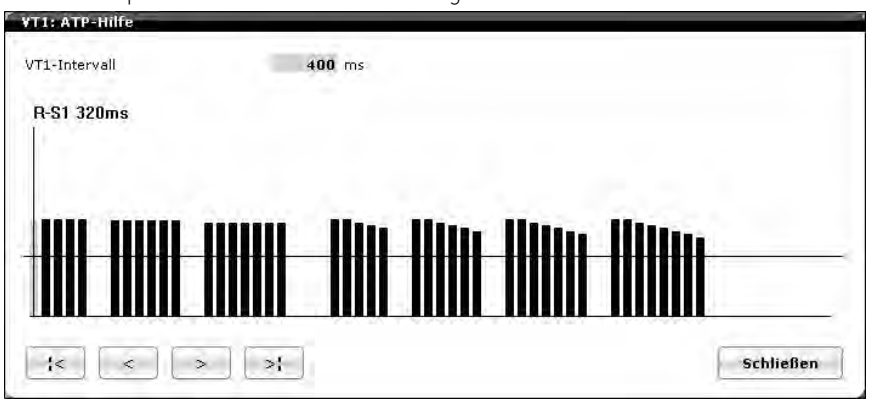
Displaying the ATP help window

To open the ATP help window, proceed as follows:

Step	Action
1	Select in the **VT1**, **VT2** or **VF** tab: **[ATP help...]**.

ATP therapy display

The ATP help window contains the following information:



- The graph displays the course of the ATP therapy sequences for the respective VT zone as groups of bars.
- The bars are grouped as follows:
  - Two blanks on the X axis mark the change to the next ATP attempt.
  - Four spaces on the X axis mark the changeover to the 2nd ATP in the sequence.
- Each bar represents an interval, portraying its relative size. The types and numerical sizes of an interval are entered into a caliper, which you can move from bar to bar using the arrow keys.

Related topics

See: ATP Types – Details, p. 69 and ATP and HF Burst Parameters – Details, p. 71

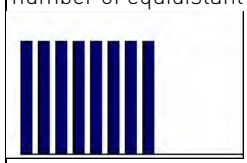
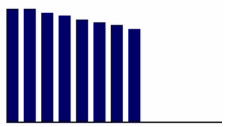
ATP Optimization – Details

Function

- To optimize future therapies, the ICD continuously evaluates the success achieved by an ATP therapy in terminating a tachyarrhythmia in a therapy sequence in the VT1 or VT2 zone. In the background, the ICD automatically reconfigures the position of ATP therapy in the sequence according to its success rate: The higher the success rate, the farther ahead the particular therapy is placed in the sequence.
- The effective parameter setting of the therapy (e.g., `Burst`; `Ventricular pacing`: BiV; `Number S1`: 5; `R-S1 interval`: 320 ms, etc.) is also used in the new position (if applicable) in the sequence.
- ATP therapies that accelerate a tachyarrhythmia into a higher zone are blocked until the next follow-up.
- Reprogramming the ATP therapies resets ATP optimization.

ATP Types – Details

Process ATP types are subjected to the following process:

ATP type	Description
`Burst`	The R-S1 interval is followed by a programmed number of equidistant S1 pulses. 
`Ramp`	The R-S1 interval is followed by pulses with constantly changing intervals. The S1 decrement is critical to these changes: 

Related topics See: ATP and HF Burst Parameters – Details, p. 71

ATP One Shot

Navigation: Parameters → Tachycardia → Therapy

ATP One Shot

ATP One Shot works as follows (if `Early ATP delivery` = `OFF`):

- If VF has been detected and the stability criterion has been met, ATP One Shot is used once prior to a shock.
- The capacitors are charged immediately after delivery of the ATPs. If the ATPs were delivered successfully, the capacitor charging is interrupted and shock delivery is prevented.

Early ATP delivery

Early ATP delivery is employed under the following premises:

- `Early ATP delivery` = `ON`
- The value programmed for the detection counter is 16 out of 20 or greater.
- The stability criterion is met.
- The detection counter has classified 12 out of 16 intervals as VF according to the stability criterion.

Under the above-listed preconditions ATP is delivered on a one-off basis with the following further progression:

The shock capacitors are not charged immediately after ATP delivery, and the ICD continues to detect.

If the following occurs after delivery of ATP ...	Then ...
termination is detected	• the capacitors are not charged. • for the time being, there is no therapy delivery.
• VF is still detected. • Detection counters are met.	• the capacitors are charged and the programmed shock therapies are delivered. • the first shock requires a confirmation.

Medium-term impact assessment

If ATP One Shot remains ineffective for 4 consecutive tachyarrhythmias and the tachyarrhythmias were terminated without ATP employment, then ATP One Shot is automatically deactivated until the next follow-up. The function is then automatically reactivated at the next follow-up.

ATP and HF Burst Parameters – Details

ATP parameters

The parameters mean the following:

Parameter	Description
`Attempts`	Defines the number of ATP attempts
`ATP type`	Defines the type or form of stimuli: burst or ramp.
`Ventricular pacing`	Defines the pacing location of a triple-chamber device: • Right ventricle • Left ventricle • Biventricular
`Number S1`	Defines the number of stimuli of an ATP sequence.
`Add S1`	Number S1 increases by 1 with every ATP. The interval to the additional pulse depends on the size of the S1 decrement and the scan decrement.

`P-S1 interval`
or
`R-S1 interval`
	Programmable coupling interval at the beginning of every ATP. It defines the interval between the last sensed P or R wave and the first stimulus (S1). The second stimulus always follows the first one with the same interval.

`S1 decrement`	Continuously reduces the pulse interval of the ATP from the second stimulus on, so that the ATP type takes on the form of a ramp.
`Scan decrement`	Reduces the R-S1 interval from scan to scan after redetection.

HF burst parameters

The parameters mean the following:

Parameter	Description
`Therapy`	Therapy with AF: `HF burst` (high-rate burst)
`Rate`	HF burst rate
`Duration`	HF burst duration

Parameters for backup pacing

Taken individually, the parameters for AT and AF therapy mean the following:

Parameter	Description
`Backup stimulation`	Basic rate of backup pacing
`Mode` (not programmable)	Mode of backup pacing

4.4 Defibrillation Therapy

What's in this section?

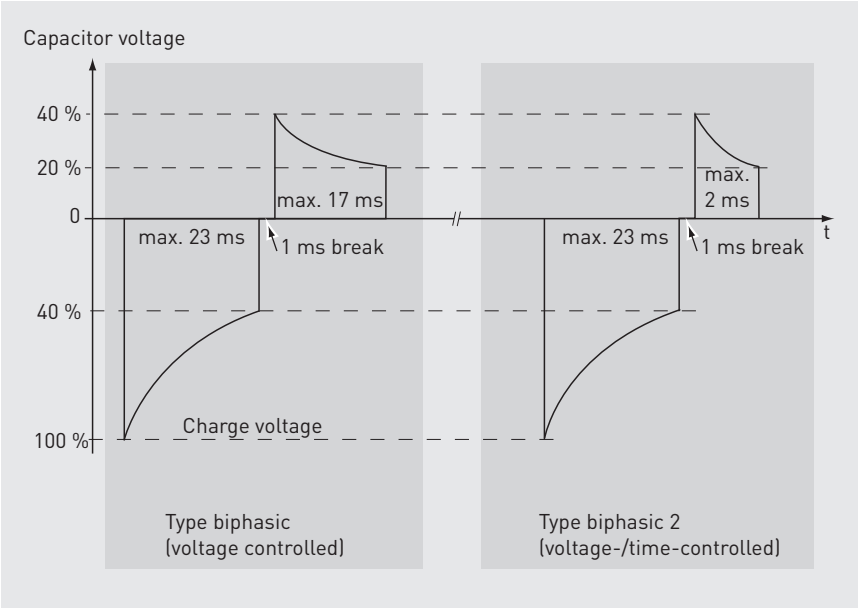
Shock Therapy

For VT and VF therapy, the ICD can deliver defibrillation shocks. A maximum of eight shocks with various different shock energies can be set for each VT and VF zone. Polarity, shock form, confirmation, and shock path are also adjustable, but these then have the same settings for all shocks in a zone.

Shocks

Shocks are delivered based on voltage and time. Switching and cut-off voltages as well as phase duration of the shocks are values that have been optimized within the course of clinical testing and cannot be modified. The energies of the first and second shocks can be set between two Joules and maximum energy. All shocks following the second shock in a particular zone are delivered with the maximum energy.

Shock form with normal polarity



The shock form can be set to biphasic, biphasic 2 or alternating beginning with biphasic or biphasic 2, and selection can be made between normal, reverse or alternating polarity beginning with normal or reverse polarity. The ICD automatically limits the duration of the shock phases.

The parameters for the VT1, VT2 or VF zone can be configured individually by checking the box under **Standard → Configure zones separately**.

Configuration options:

- Therapy Shock Parameters: Confirmation, p. 76
- Therapy Shock Parameters: Polarity and Shock Form, p. 77
- Therapy Shock Parameters: Shock path, p. 78
- Therapy Shock Parameters: Configuring Zones Separately , p. 79

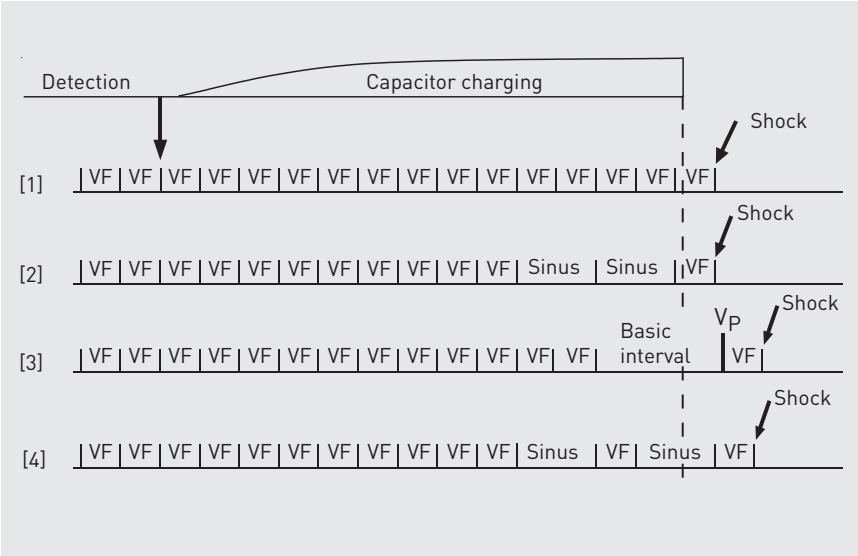
Charging process

If the ICD evaluates a cardiac rhythm as VF or VT, and if shock therapy has been programmed for these zones, the capacitors are charged.

Defibrillation with confirmation

For defibrillation with confirmation, the ICD evaluates the cardiac rhythm even while the capacitors are charging. The device does not deliver a shock if it detects an intrinsic rhythm below the VT1 zone or a bradycardia during the charging period. In all other cases, it will attempt to synchronize the defibrillation shock with the first tachycardic event after charging is complete. If no tachycardic intervals have been detected after charging is complete, shock delivery is inhibited.

Shock confirmation



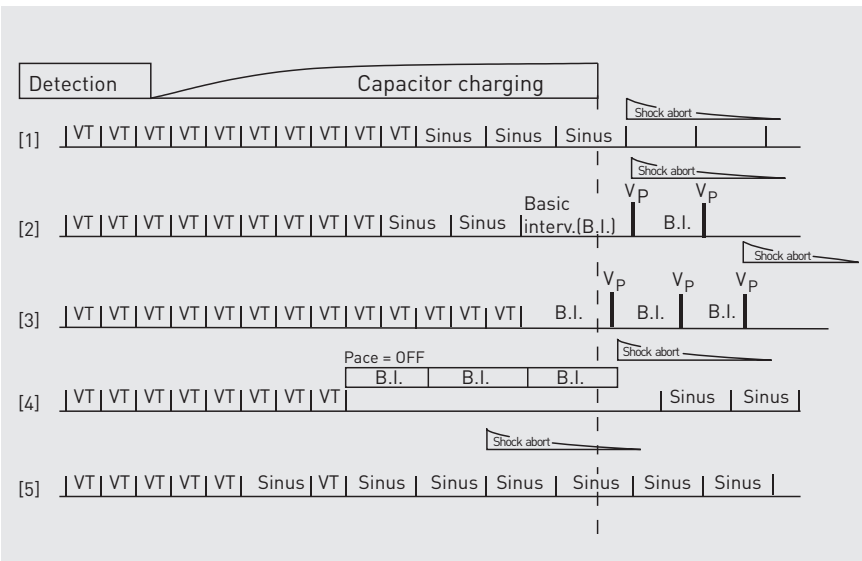
The diagram includes examples of defibrillation with confirmation based on different events of rhythm evaluation.

The abort criterion requires that three of four consecutive intervals show a sinus rhythm while charging. In these examples, the abort criterion is not fulfilled.

The shock is always delivered at the first tachycardic event after charging is completed. If an interval below the VT1 zone is detected at this time and the abort criterion is not fulfilled, then the shock is delayed. The following intervals are subsequently classified.

The shock is delivered as soon as an interval is detected within a VT1 zone. Otherwise the shock is inhibited. However, the maximum duration between the end of charging and the shock is 2 seconds.

Shock abort



The diagram above shows the shock abort criteria of defibrillation with confirmation based on various events of rhythm evaluation.

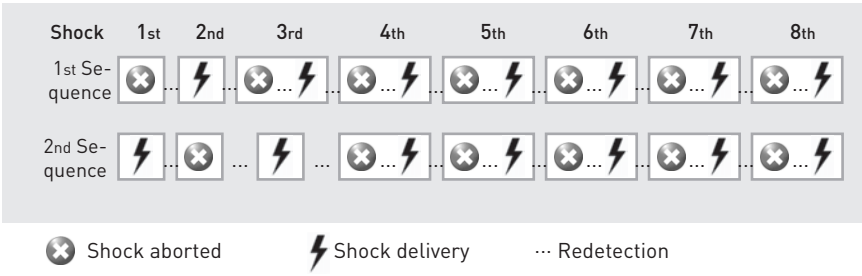
The abort criterion requires that three of four consecutive intervals show a sinus rhythm.

The rhythm is evaluated during the charging procedure. In the examples, the abort criterion is fulfilled. If, at the end of the charging period, the interval is not within the VT1 zone, then the device waits for a tachycardia interval and the shock is delayed by up to two seconds maximum.

If the abort criterion has already been fulfilled before charging is completed, then the charging process is stopped prematurely. The charged shock energy is then discharged through an internal resistance.

Note: Shocks with confirmation that were aborted after the charge are available again in the respective VT or VF zone, so that, after aborting (for example) 8 programmed shocks, 7 remain available.

Shocks that the function skipped due to lack of confirmation are delivered from the third programmed shock at the same location after redetection:



When shocks with confirmation are performed, in a VT or VF zone two sequences of shock deliveries can result that are influenced by the starting behavior on shock delivery. In sequence 1, the 1st shock was aborted, while in sequence 2 the 1st shock was delivered.

Defibrillation without confirmation

If the ICD is set to defibrillation without confirmation, it will deliver a defibrillation shock after charging. The cardiac rhythm is not re-evaluated while the capacitor is charging. The ICD attempts to synchronize the defibrillation shock with an R wave. If synchronization does not succeed within two seconds, then the ICD delivers the shock without synchronization.

Post-shock pacing

Post-shock blanking: during post-shock blanking, the ICD will not evaluate the cardiac rhythm. This will suppress interference signals from post-shock potentials.

Post-shock pacing: if the cardiac rhythm is bradycardia or asystole following a shock, the ICD paces according to the post-shock pacing parameter. At the same time, the cardiac rhythm is evaluated again.

If the episode has not been terminated, the ICD will initiate further therapy. The therapy sequence will be concluded only once termination or the maximum number of set therapies has been reached, Parameters for Post-shock Pacing, p. 79.

Progressive course of therapy

The progressive course of therapy function works in the background and cannot be switched off. This function has the following effect:

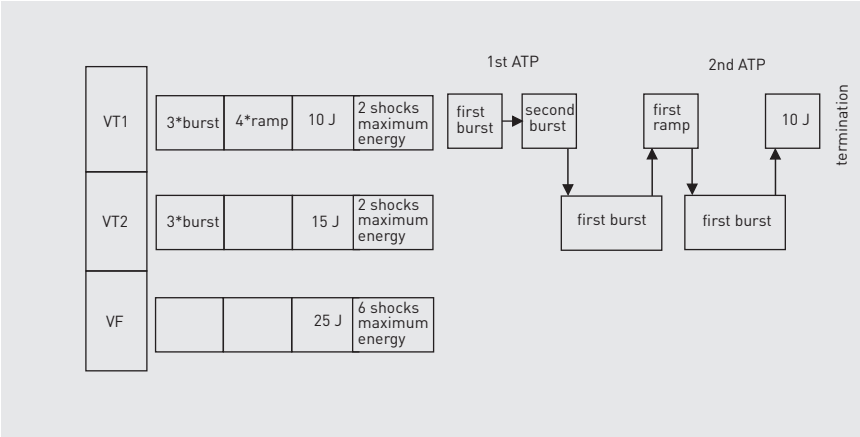
- The ICD prevents further shocks from being delivered with lower energy after a shock. Instead, only shocks with higher energy are delivered.
- The ICD blocks all ATP therapies for the current episode if a shock has already been delivered during its course.

Surge guard

The ICD uses this function to prevent the heart rhythm from fluctuating between the respective arrhythmia zones without achieving termination due to alternating accelerating and decelerating therapies. A therapy that causes acceleration is no longer used during an episode.

The surge guard function cannot be programmed, Surge Guard – Details, p. 80.

Surge guard VT1/VT2



Therapy Shock Parameters: Confirmation

Navigation: Parameters → Tachycardia → Shock details

Confirmation parameters

The parameter settings are defined as follows:

Parameter value	Description
ON	• The ICD continues to evaluate the cardiac rhythm while the capacitors are charging. — The ICD does not deliver any shock when it detects a non-tachycardia rhythm during charge time. — Otherwise, the ICD tries to synchronize the defibrillation shock with an R wave. — If synchronization is unsuccessful, or if no tachycardiac intervals are detected after charging, shock delivery is withheld.
OFF	• The cardiac rhythm is not evaluated while the capacitors are charging. • The ICD attempts to synchronize the defibrillation shock with an R wave. If synchronization is not possible, the ICD will deliver an asynchronous shock.

Therapy Shock Parameters: Polarity and Shock Form

Navigation: Parameters → Tachycardia → Shock details

Polarity

`Normal`:

	1st phase	2nd phase
RV shock coil	Negative	Positive
SVC shock coil or active housing	Positive	Negative

`Reversed`:

	1st phase	2nd phase
RV shock coil	Positive	Negative
SVC shock coil or active housing	Negative	Positive

Polarity, alternating

`Normal → alternating`:

- The shock sequence starts with `Normal` polarity.
- With the second maximum energy shock, the polarity changes to `Reversed` and in the course of all subsequent shocks alternates between `Reversed` and `Normal`.

`Reversed → alternating`:

- The shock sequence starts off with `Reversed` polarity.
- With the second maximum energy shock, the polarity changes to `Normal` and in the course of all subsequent shocks alternates between `Normal` and `Reversed`.

Shock waveform

The parameter settings are defined as follows:

`Shock waveform`	`Biphasic`	`Biphasic 2`
Pause duration	1 ms	1 ms
Energy	Variable	Variable
End voltage 1st phase	40%	40%
Time 1st phase	Max. 23 ms	Max. 23 ms
End voltage 2nd phase	20%	Variable
Time 2nd phase	Max. 17 ms	2 ms

Shock waveform, alternating

`Biphasic → alternating`:

- The shock sequence starts with `Biphasic`.
- With the second maximum energy shock, the shock waveform changes to `Biphasic 2` and in the course of all subsequent shocks alternates between `Biphasic 2` and `Biphasic`.

`Biphasic 2 → alternating`:

- The shock sequence starts with shock waveform `Biphasic 2`.
- With the second maximum energy shock, the shock waveform changes to `Biphasic` and in the course of all subsequent shocks alternates between `Biphasic` and `Biphasic 2`.

Polarity and shock form alternate

When both `Polarity` and `Waveform` are programmed as alternating, then the shock sequence starts with the set primary values, and then the polarity changes first, changing the shock waveform in its turn only after that.

For example, if `Polarity` = `Normal → alternating` plus `Waveform` = `Biphasic → alternating`:

1.	`Normal`	`Biphasic`
2.	`Reversed`	`Biphasic`
3.	`Normal`	`Biphasic 2`
4.	`Reversed`	`Biphasic 2`

After 4. the shock sequence restarts with 1.

Therapy Shock Parameters: Shock path

Navigation: Parameters → Tachycardia → Shock details

Shock path parameters

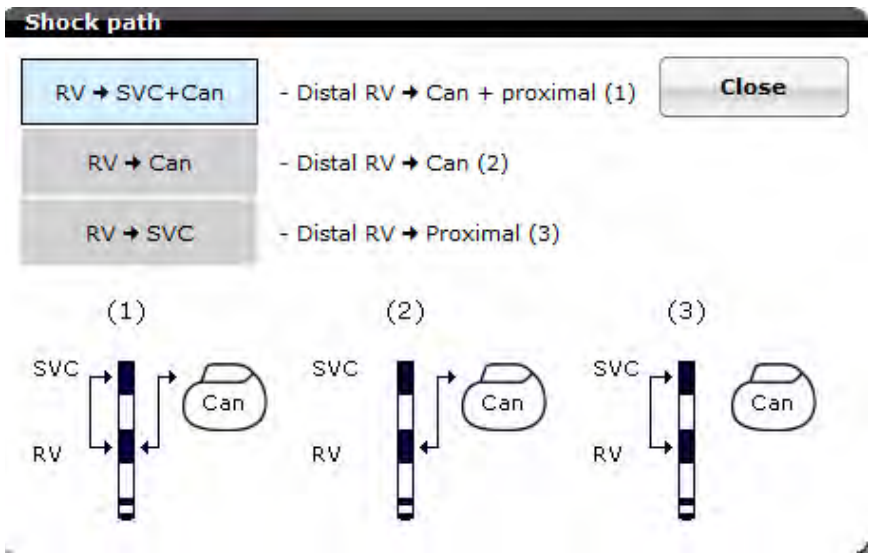
Note: Make sure that the implanted lead model has two shock coils before setting one of the following values in the `Shock path` window.

- `RV → Can+SVC`
- `RV → SVC`

The parameters have the following meanings:

Shock path	Meaning
`RV → Can+SVC`	Distal RV -> housing + proximal (1)
`RV → Can`	Distal RV -> housing (2)
`RV → SVC`	Distal RV -> Proximal (3)

The `Shock path` window:



Therapy Shock Parameters: Configuring Zones Separately

Navigation: Parameters → Tachycardia → Shock details

Configuring zones separately

Select **[Configure zones separately]** to enable you to set different values for each individual arrhythmia zone separately.

If different values have been set for each arrhythmia zone and you undo your selection, then the values of **VF** will be entered for **VT1** and **VT2**.

Parameters for Post-shock Pacing

Navigation: Parameters → Bradycardia/CRT → Post-shock pacing

Objective

After the termination of a ventricular arrhythmia by a therapy shock, the implanted device should not immediately begin pacing according to the permanent program, but should be able to respond to a possible temporary increase in threshold or to a higher required rate.

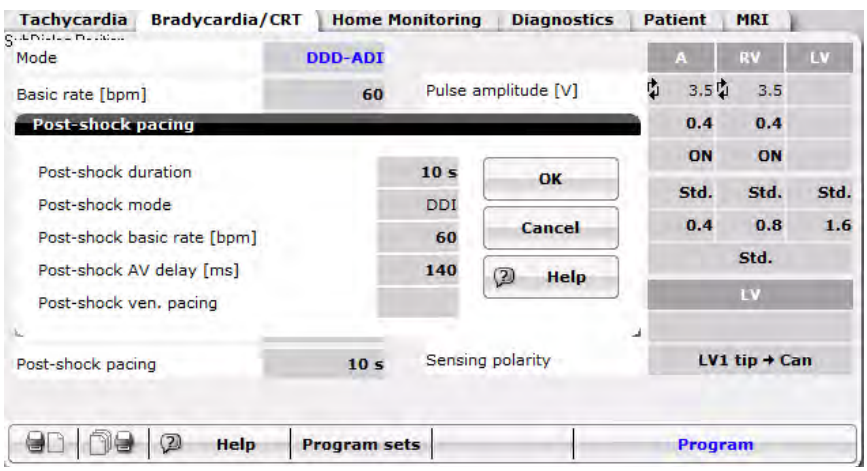
To do this you can program your own post-shock pacing. The duration of use and parameters of this program are temporary and can be set independently.

Pacing parameters

The pacing mode for the post-shock mode automatically arises out of the permanent program as follows:

Permanent program mode	Post-shock mode
DDD(R)	DDI
DDD-ADI(R)	DDI
DDI(R)	DDI
DDI-CLS	DDI
VVI-CLS	VVI
VDD(R)	VDI
VDI(R)	VDI
AAI(R)	DDI
VVI(R)	VVI
OFF	VVI

- A, RV:
  - Pulse amplitude: 7.5 V
  - Pulse width: 1.5 ms
- LV:
  - Pulse amplitude: Permanent program
  - Pulse width: Permanent program



Surge Guard – Details

Function If a tachyarrhythmia is accelerated by an ATP therapy into a higher arrhythmia zone and after the initial detection is redetected after a deceleration in that zone, then this ATP therapy is blocked for the remaining course of the episode.

5 Bradycardia and Resynchronization Therapy

What's in this chapter?

5.1 ProgramConsult – Bradycardia Therapy

What's in this section?

Objective

- The **[ProgramConsult]** function provides numerous programs with preset parameters for the most common bradycardia 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 shown in blue in the `Bradycardia/CRT` window and can be transmitted directly to the device as a new permanent program.
- Before programming, the parameters can be adjusted to fit the patient's individual needs.

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]**.

5.2 Pacing Modes

What's in this section?

Mode (Pacing Mode)

Navigation: Parameters → Bradycardia/CRT

WARNING
No protection against tachyarrhythmia in asynchronous modes Asynchronous modes can only be set when tachyarrhythmia detection is switched off. Consequently, the implanted device will not detect or treat any tachyarrhythmias. • Monitor the patient continuously and always keep external defibrillation equipment available on standby.

Single-chamber Modes

AAI mode, VVI mode

Single-chamber AAI and VVI 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. If an event occurs within the basic interval, pulse delivery is inhibited. Otherwise, pacing takes place at the end of the basic interval.

Dual-chamber Modes

DDD mode

In the DDD mode, the basic interval starts either with an atrial sensed event As, an 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 and AV delay are restarted. However, if an atrial sensed event occurs within the basic interval but outside the atrial refractory periods, atrial pacing is inhibited and the basic interval and the AV delay are restarted.

If no ventricular sensed event occurs during the AV delay, the device delivers a pacing pulse in the ventricle at the end of the AV delay. If a ventricular sensed event occurs during the AV delay, the ventricular pulse delivery is inhibited.

A ventricular sensed event without a previous atrial event (PVC) results in restart of the basic interval. The AV delay is not restarted in this case. Atrial and ventricular pulse delivery is inhibited.

DDI mode

In contrast to the DDD mode, the basic interval in DDI mode is not restarted by atrial sensed or paced events (P waves), but rather by ventricular sensed or paced events. The VA interval (basic interval minus the AV delay) is started together with the basic interval.

If no atrial or ventricular sensed event occurs 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 then occurs, the atrial pacing delivery is inhibited. However, the AV delay does not start with this sensed event, but rather starts after the VA interval has elapsed. Therefore P waves do not trigger ventricular events in the DDI mode.

VDD mode

The VDD mode is derived from the DDD mode. The difference is that no atrial pacing takes place in the VDD mode. If the atrial sensed event does not take place, then the basic interval starts with a premature ventricular contraction or with the end of the preceding basic interval.

The AV block is the only indication for the VDD mode.

VDI mode

The VDI mode is derived from the VVI mode. Both modes enable recording of atrial events. The VDI mode was originally designed for measuring retrograde conduction with the IEGM and/or the marker function. Retrograde conduction time can be determined directly in the programmer or in an additional ECG recorder, as the length of time between a ventricular paced or sensed event and the subsequent atrial sensed event.

Triple-chamber Modes

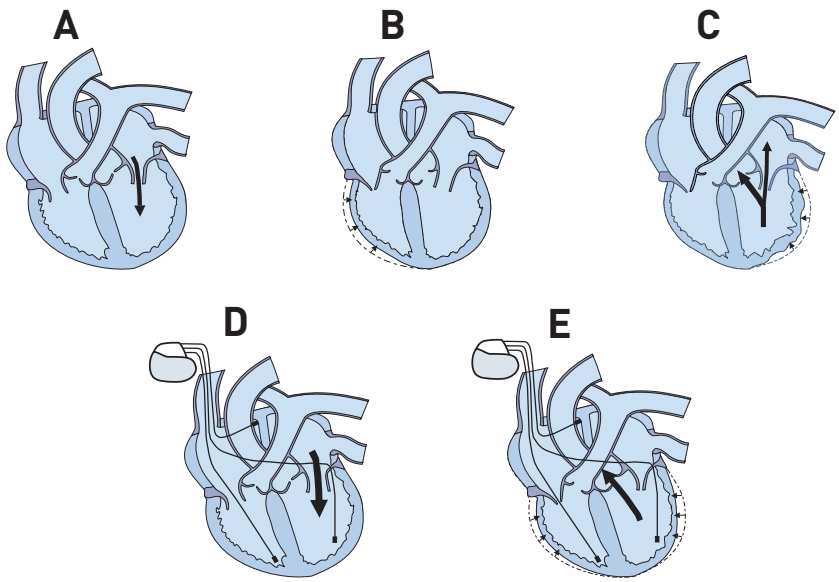
Triple-chamber devices

For triple-chamber devices, 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. Ventricular multisite 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:



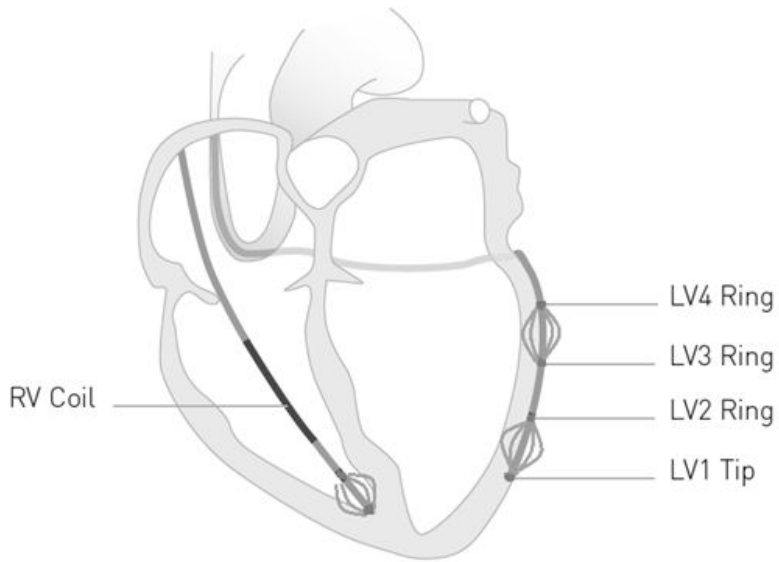
- A. Shortened diastoles result in incomplete left ventricular filling
- B. Delayed left ventricular contraction
- C. Septal diskenesia and pumping blood back through the mitral valve
- D. Atriosequential biventricular pacing with extended diastole and increased left ventricular filling
- E. Synchronized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

MultiPole Pacing: HF-T QP devices can deliver 2 LV paces in the left ventricle and one pace in the right ventricle sequentially or synchronously. The pacing sites can be configured individually and offer the following options:

- 2 LV paces during each cardiac cycle
- 1 RV pace during each cardiac cycle
- 0 – 50 ms delay between LV1 and LV2 pacing sites
- Both LV paces require different polarities
- The following configurations are possible:
  - LV1 – LV2 – RV
  - RV-LV1 -LV2
- Simultaneous or delayed pacing (0 – 50 ms)



Note: Cardiac resynchronization in a triple-chamber device 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 device 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 following programs and functions; it is not automatically adopted:

- Permanent program
- Mode switching
- Post-shock pacing

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 of the R modes (accelerometer) 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 paced 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.

Special Modes

OFF mode

In the OFF pacing mode, all functions relevant to the pacemaker are deactivated in the permanent program. Sensing can only take place in the right ventricle, which is used for detection classification of the tachyarrhythmia therapy. If the OFF pacing mode is activated and ICD detection is programmed to OFF, then the ICD is completely switched off.

V00 mode

In the V00 pacing mode, the pacing pulses are delivered asynchronously in the ventricle.

Note: When programming the V00 mode, you should consider the risks associated with asynchronous ventricular pacing.
No VT and VF detection are allowed in V00 mode.

D00 mode

Asynchronous AV sequential pulses are emitted in the D00 pacing mode.

Note: When programming the D00 mode, you should consider the risks associated with asynchronous ventricular pacing.
No VT and VF detection are allowed in D00 mode.

5.3 Resynchronization Therapy

What's in this section?

Resynchronization Therapy Settings

Multisite or MultiPole left ventricular pacing polarity

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. Different pacing polarities can be programmed with a bipolar or quadripolar LV lead; see the following pages.

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 quadripolar LV lead is required for the use of all multisite or MultiPole 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 (+ RVES).

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 + RVES). 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 (LVES). The LVES 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 has no impact on timing in triple-chamber devices.

Sensing polarity

The triple-chamber device offers different configurations for the left ventricular sensing function: 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 two poles along the lead.

The quadripolar sensing polarity offers the following configuration options using a quadripolar lead:

- LV1 tip => LV2 ring
- LV1 tip => housing
- LV2 ring => LV3 ring
- LV2 ring => housing
- LV3 ring => LV4 ring
- LV3 ring => housing
- LV4 ring => housing

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.

The Concept of LV Lead Polarity

Navigation: Parameters → Bradycardia/CRT → LV

Objective

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

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

Note:

- An effective cardiac resynchronization therapy requires continuous multisite ventricular pacing. Patients cannot tolerate phrenic nerve stimulation.
- Phrenic nerve stimulation can be prevented by programming the lead configuration.

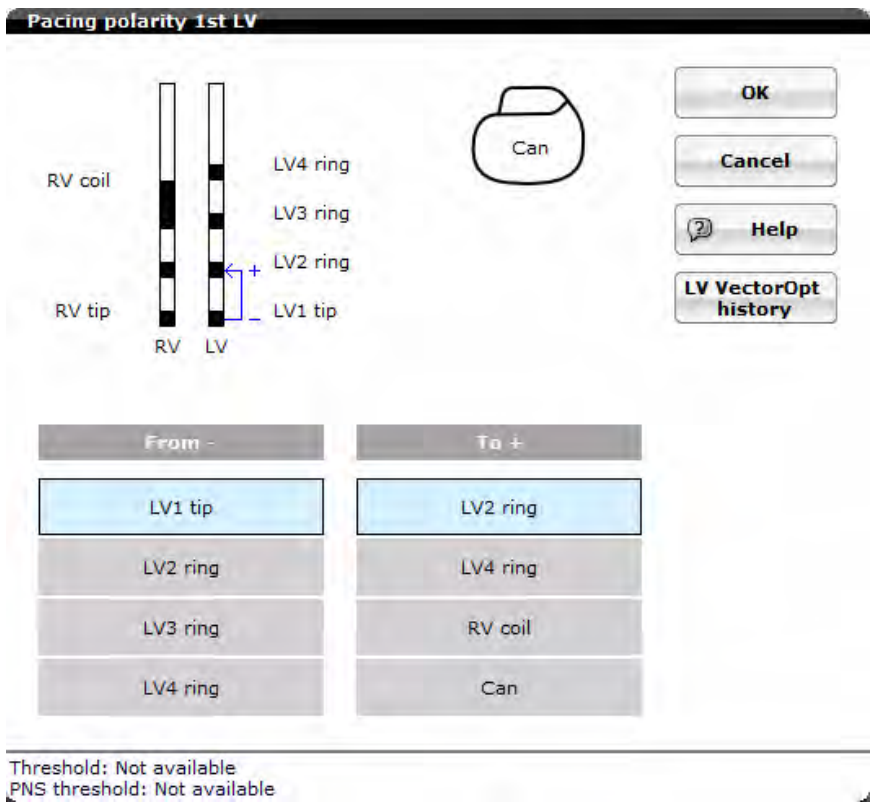
Lead polarity configurations

The following polarities for pacing and sensing are possible, depending on the type of lead being used (unipolar, bipolar or quadripolar).

Lead polarity	Number of polarities in LV	
	Pacing	Sensing
UP	2	1
BP	5	2
QP	12	7

User interface

Example of HF-T-QP device with quadripolar LV lead



Parameters for 2nd LV Stimulus

Navigation: Parameters → Bradycardia/CRT → LV

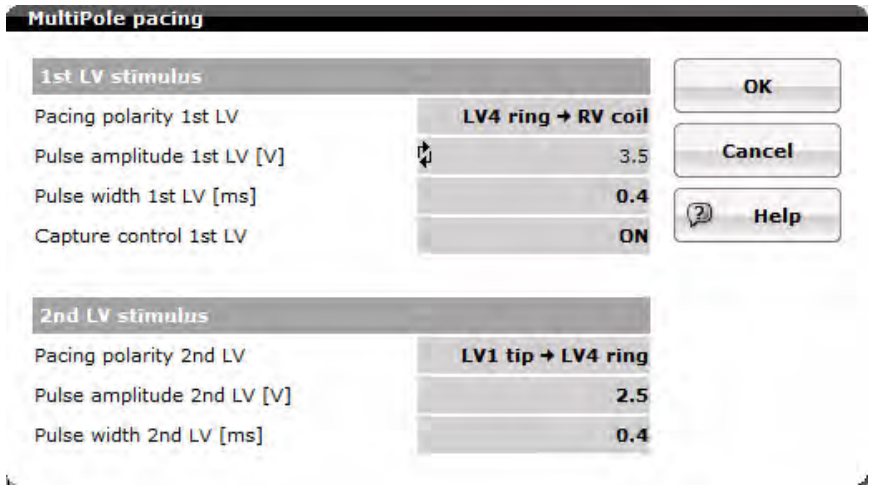
Set parameters for LV pacing

Proceed as follows:

Step	Action
1	In the `2nd LV stimulus` group box, click on `Pacing polarity 2nd LV`.
2	Select the pacing polarity for the 2nd left ventricular pacing path.
3	Then you can set the parameters for pulse amplitude and width.

User interface

Example of MultiPole Pacing 2nd LV stimulus



LV Pacing and Sensing Polarity

Navigation: Parameters → Bradycardia/CRT → LV

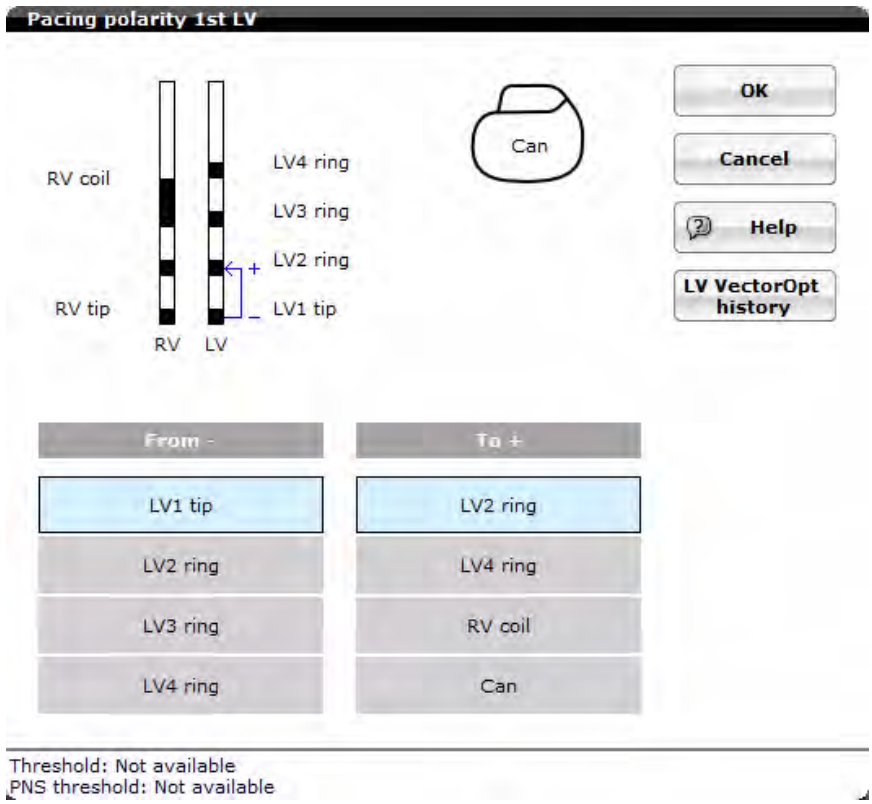
Concept: from minus to plus

Proceed as follows:

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

User interface

Example of HF-T-QP device with quadripolar LV lead



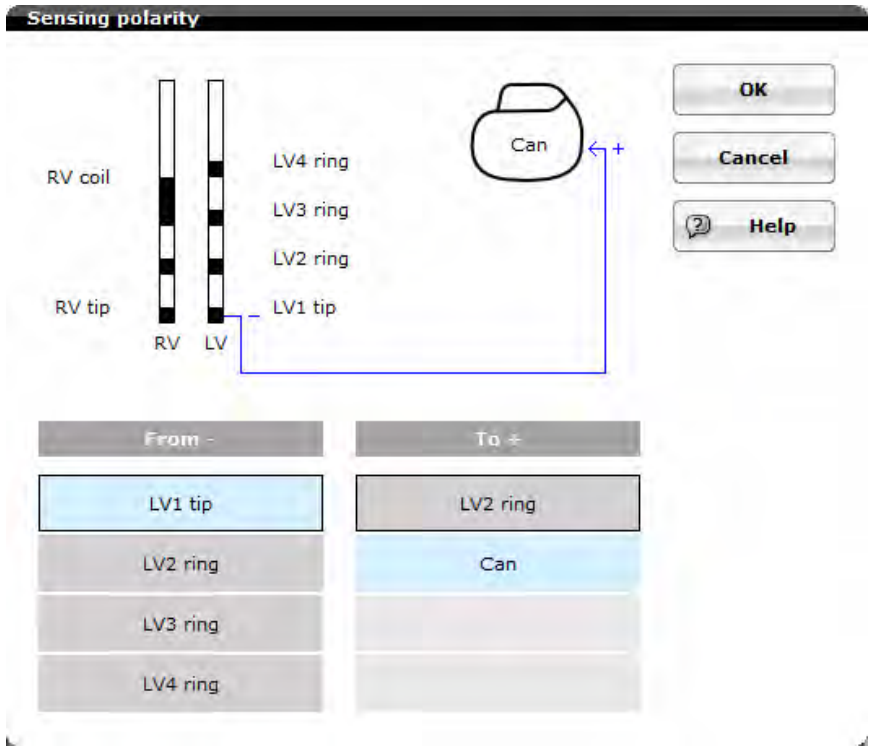
From (–) to ... (+)

The poles selected in each case are shown in the **[From -]** and **[To +]** columns with a blue background. The display of the anodes available to the selected cathode is dynamically adjusted in the **[To +]** column. Proceed as follows to set the left ventricular polarity.

Step	Action
1	In the **[From -]** column, select the pole you want as the cathode for the pacing or sensing path.
2	In the **[To +]** column select the pole you want as the anode for the pacing or sensing path.
3	Confirm by pressing **[OK]**. The path set for the left ventricular configuration is displayed on the user interface in the following field: **Parameters → Bradycardia/CRT → LV/MultiPole pacing**

User interface

Example of HF-T-QP device with quadripolar LV lead



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.

The archive can be selected from the fields for LV pacing polarity. In triple-chamber devices this is possible both in the field for the 1st LV pacing polarity and in the field for the 2nd LV pacing polarity.

Proceed as follows:

- Select **Parameters → Pacing polarity 1st LV** or **Pacing polarity 2nd LV**
- The window for setting the polarity is opened.
- Select the **[LV VectorOpt history]** option.

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

The device gives you the option of providing cardiac resynchronization therapy (CRT) using multisite ventricular and MultiPole Pacing.

Accordingly, the following pacing sites can be set:

- Right ventricular
- Biventricular
- Exclusively left ventricular
- Biventricular MultiPole Pacing

Multisite 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 with the 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).
`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 after Vp`	Interventricular latency period; The VV delay after Vp can be set, while the VV delay after Vs is fixed at 0 ms. This value 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 and ATP therapy

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.

MultiPole Pacing

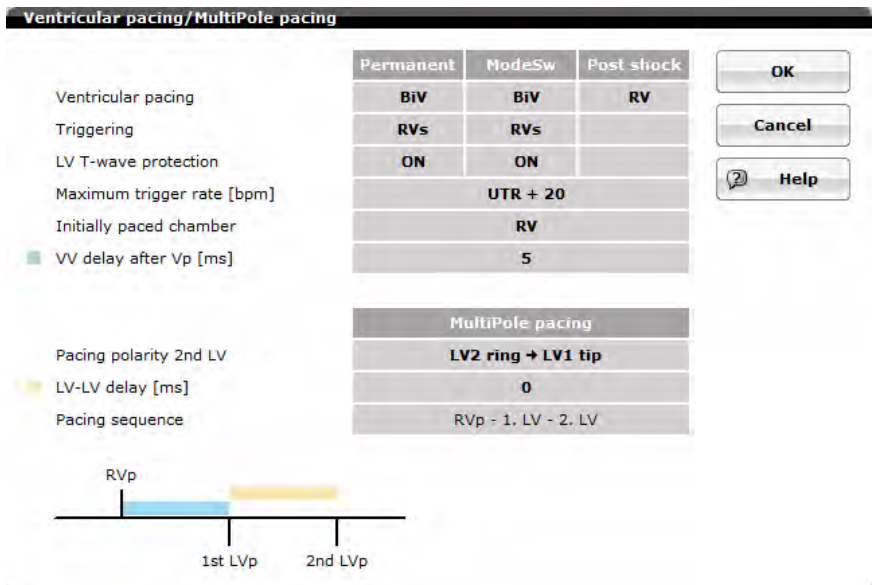
MultiPole Pacing is an additional pacing option in cardiac resynchronization therapy, with which 2 paces can be delivered to the left ventricle and 1 to the right ventricle during the cardiac cycle.

Note: MultiPole Pacing requires a large amount of energy and reduces the longevity of the active device.

The following parameters with the following functions are set for MultiPole Pacing:

Parameter	Function
`Pacing polarity 2nd LV`	The selection of this parameter leads you to the dialog with the programming system, in which you can set parameters for MultiPole Pacing.
`LV-LV delay`	Latency period between LV1 and LV2
`Pacing sequence`	Stimulation sequence as governed by the initially paced chamber. • LV1 – LV2 – RV • RV – LV1 – LV2

User interface



5.4 Rate Adaptation

What's in this section?

5.4.1 Pacing Modes

What's in this section?

Rate-Adaptive Modes

Rate adaptation principles

The device uses two 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:

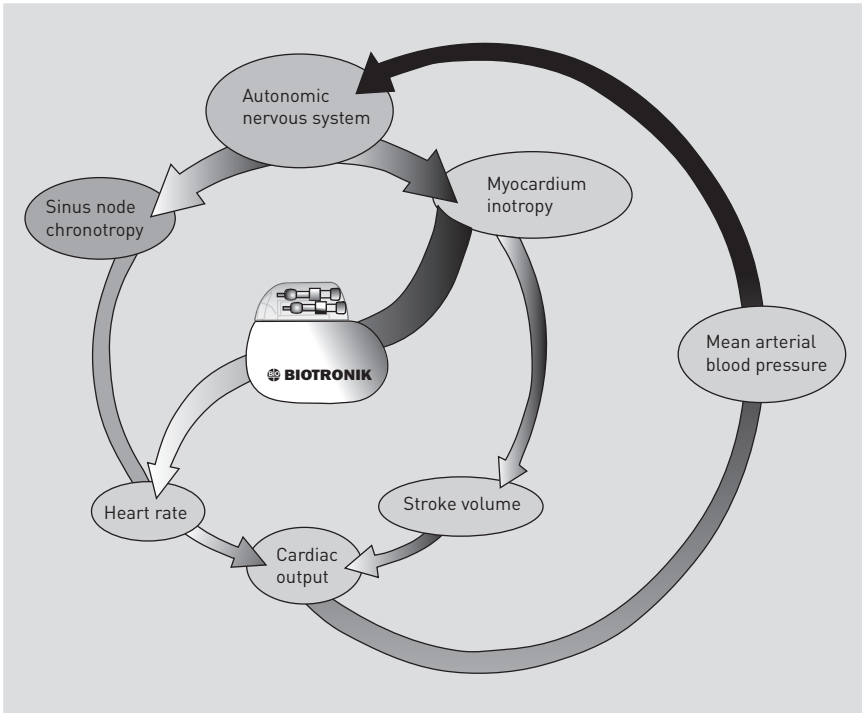
Rate adaptation	
Closed loop stimulation	**Accelerometer**
DDD-CLS VVI-CLS	DDDR DDIR DOOR DVIR DDDR-ADIR VDDR VVIR VVTR VDIR V00R AAIR AATR AOOR

5.4.2 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 device 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 device 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 device.

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:

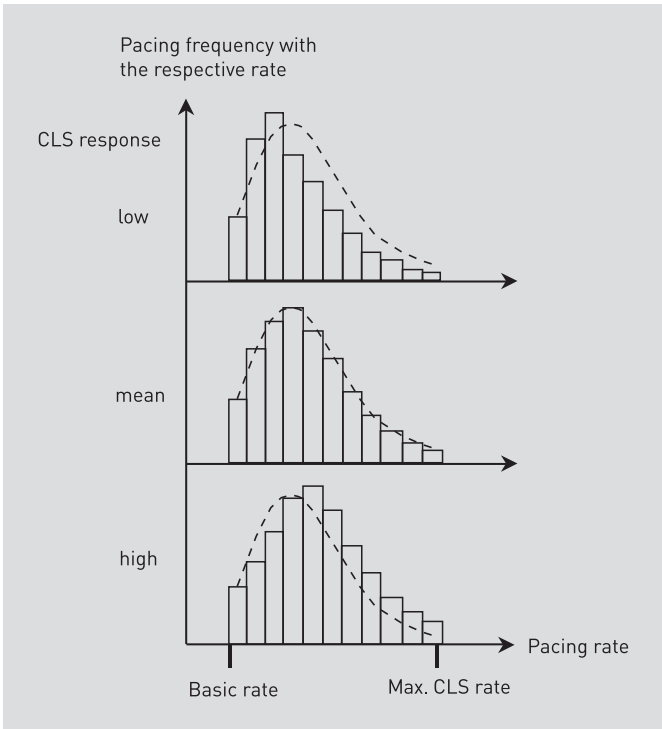
- Vp required
- CLS response
- Resting rate control (dynamic rate limit)

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 device 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.

5.4.3 Rate Adaptation using the Accelerometer

What's in this section?

Rate Adaptation (R Modes)

Purpose

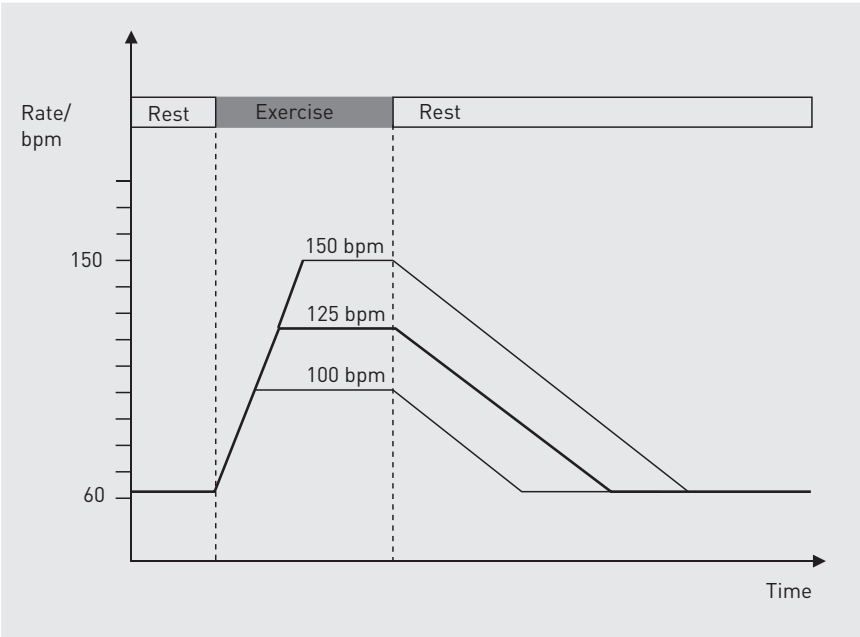
Sensor-controlled rate adaptation adapts the pacing rate to changing metabolic requirements at rest and under stress conditions. With increasing activity, the pacing rate rises to the rate determined by the sensor and then slowly drops back to the programmed basic rate when no further activity is detected.

This is implemented technically through an accelerometer integrated into the circuitry. Under physical activity, the accelerometer generates an electrical signal that is continually evaluated.

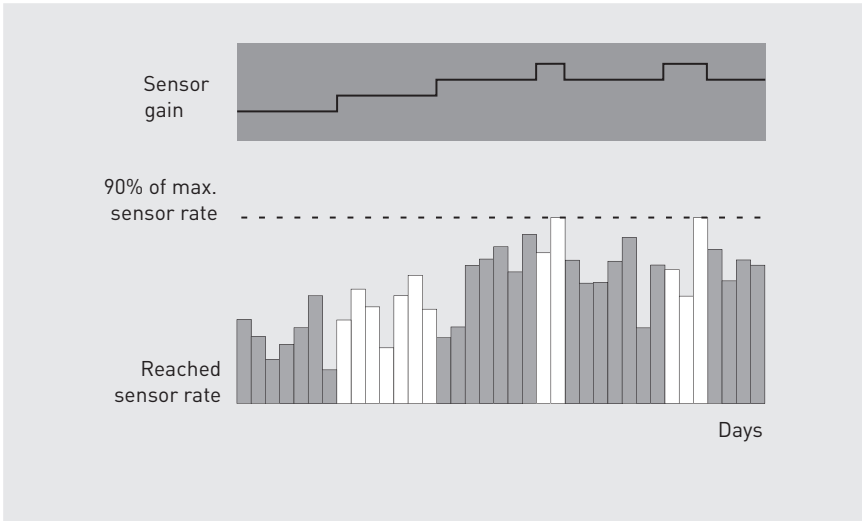
The following parameters characterize rate-adaptive pacing:

- **Sensor gain** – Defines the factor that correlates a certain level of activity with a defined rate.
- **Automatic sensor gain** – When automatic gain is switched on, the gain parameter is influenced as follows:
  - If 90% of the maximum sensor rate is not reached for the duration of 1 hour within a week, gain is incremented by one step.
  - If 90% of the maximum sensor rate is reached for 1 hour within 24 hours, gain is reduced by one step.

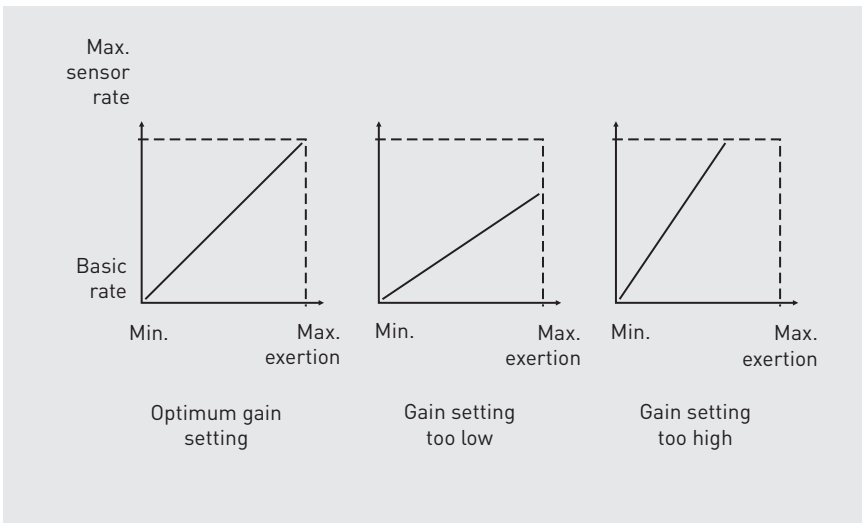
Maximum sensor rate for various settings during physical activity



Automatic adjustment of sensor gain with a 7:1 algorithm

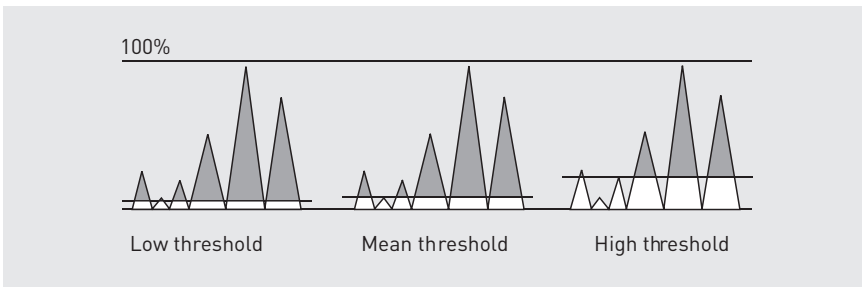


Impact of sensor gain on rate adaptation



The **sensor threshold** defines the value for the minimum level of activity triggering a defined rate above the hysteresis rate.

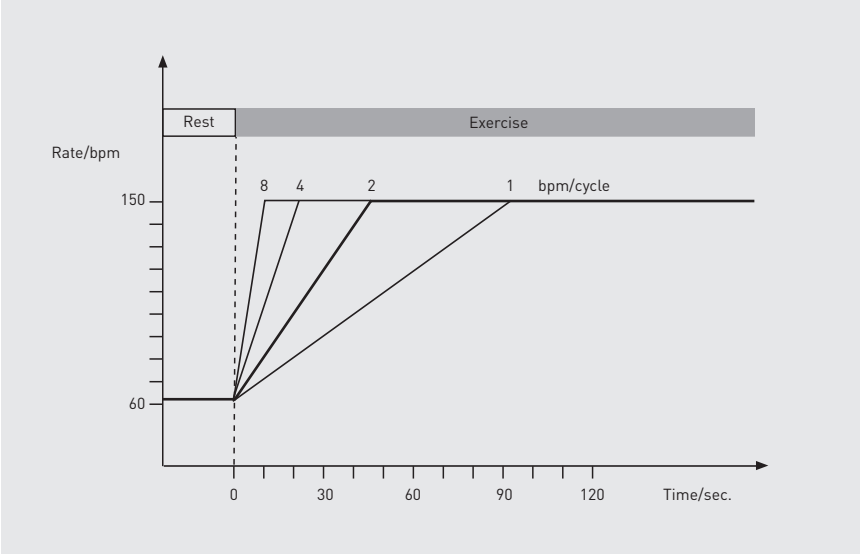
Only signals above the programmed threshold influence rate adaptation.



The maximum sensor rate defines the maximum pacing rate (bpm) permitted by the sensor. This parameter is also used as a criterion for the automatic gain function.

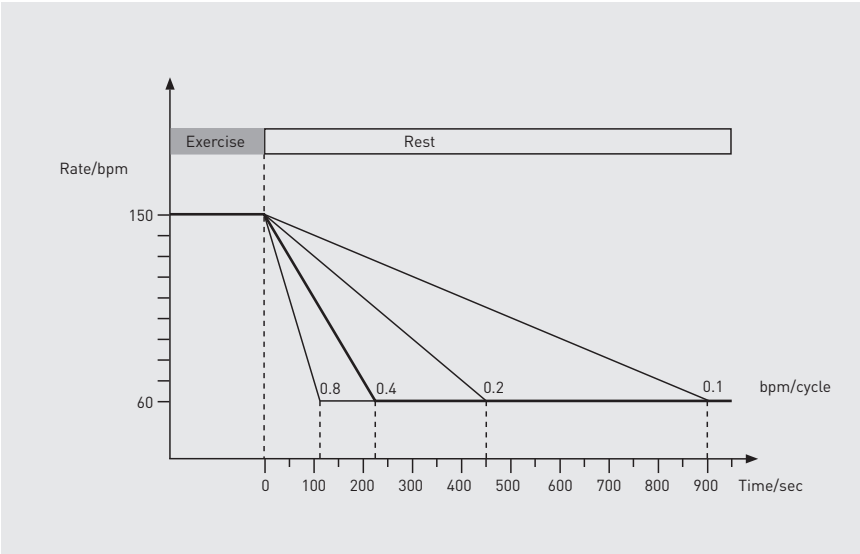
The maximum rate increase defines the maximum rate of increase in the pacing rate (bpm/cycle) required to follow the sensor rate.

Rate increase during exertion



The maximum rate decrease defines the maximum rate of decrease in the pacing rate (bpm/cycle) required to follow the sensor rate.

Rate decrease following exertion



Rate fading Rate adaptation of the device is carried out via rate fading. Modified rates are gradually adapted to the new values. This serves to prevent erratic rate changes. Adaptation is carried out using the maximum rate increase and maximum rate decrease parameters of the accelerometer.

Rate Fading – Rate Smoothing – Rate Stabilization

Modes

The device provides three functions that control an increase or decrease of the pacing frequency in a way tolerable for the patient in case of sudden rate changes. The rate fading and rate stabilization functions are used with mode switching in the modes listed below if these functions were previously activated. The rate fading function is automatically active and cannot be deactivated:

DDD(R), DDD(R)-ADI(R), DDI(R), VDD(R), VDI(R), VVI(R), AAI(R)

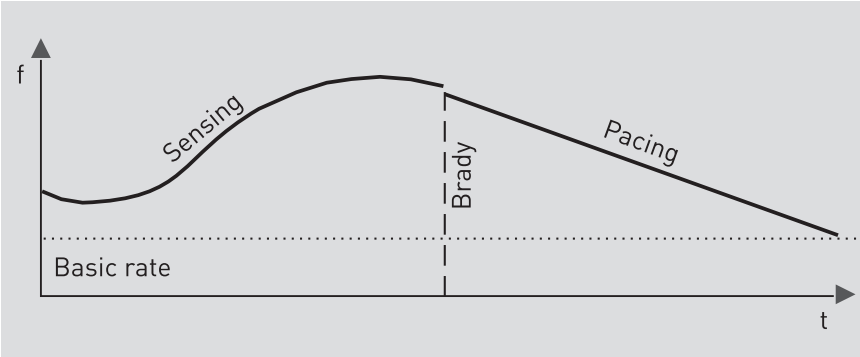
Rate smoothing

Applications of rate smoothing using the same rate increase/decrease as rate fading in order to provide a tolerable transition between different pacing rates.

- Switching from basic rate => night rate => basic rate
- Beginning and end of mode switching
- At the end of post mode switching duration
- At the end of post-shock pacing

Rate fading

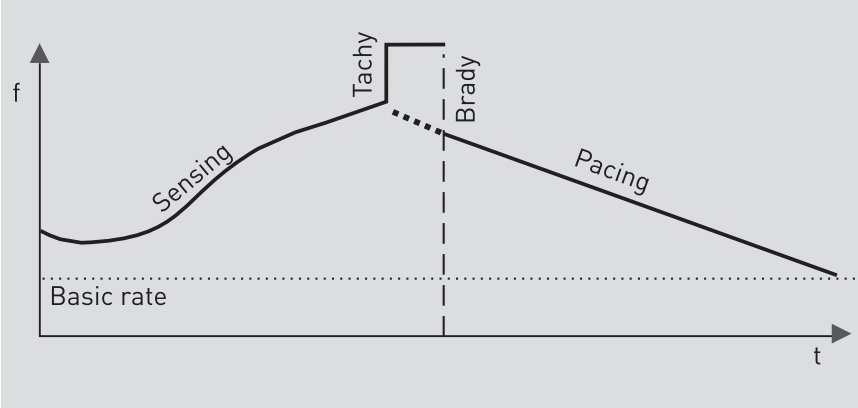
Rate fading results in improved adjustment of the device pacing rate to the patient's intrinsic rhythm in the case of sudden bradycardia.



After four 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.

If rate fading is activated, then the device calculates the backup rate, which is always active in the background. As soon as the heart rate decreases, the device 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.

Rate stabilization with mode switching

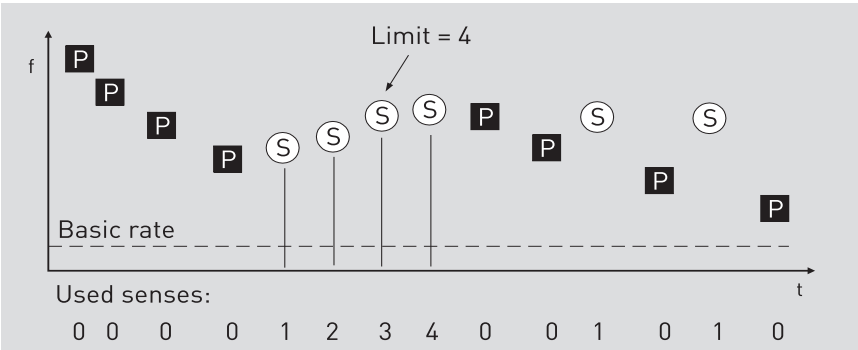


In cases of atrial tachycardia, which result in mode switching, the target rate is set to the sensor or basic rate. The current pacing rate in the ventricle results from the current value of the backup rate.

If rate stabilization is activated with mode switching, then the device calculates the backup rate, which is always active in the background. As soon as the rate decreases, the device 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 stabilization with mode switching.

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

This way, rate stabilization is continued during intermittent sensed events.



Four consecutive sensed events are required to activate the function. Individual sensed events have no impact.

Table 2: Backup rate and target rate

Backup rate	Rate at which the device paces in the case of sudden rate decrease. This is 10 bpm lower than the heart rate and follows the target rate upwards at 1 ... 10 bpm per cycle or falls at 0.1 ... 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/basic rate. The backup rate follows the target rate at the programmed rate increase or decrease.

Sensor/Rate Fading – 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.

5.5 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.

5.6 Timing Functions

What's in this section?

5.6.1 Rates and Rate Hystereses

What's in this section?

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 device is automatically adjusted to the clock of the programmer at every interrogation. Ensure that the time displayed on the programmer is correct.

Rate Hysteresis

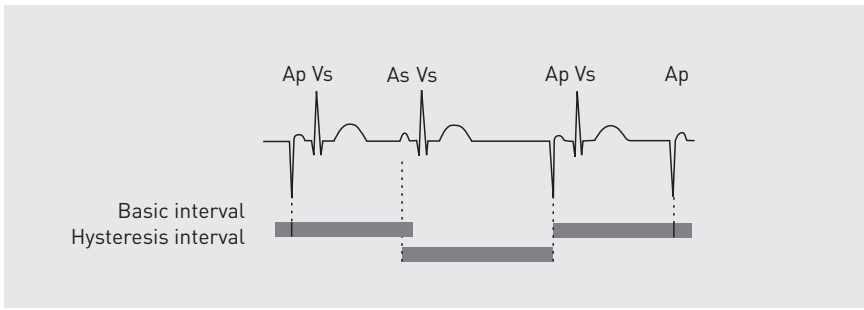
Promotion of intrinsic rhythm

Rate hysteresis can be set to promote the patient's intrinsic rhythm. In this case, after a sensed event, the device not only waits for the duration of the basic interval for a new sensed event, but also for the duration of the longer hysteresis interval before pacing occurs.

The device tolerates an intrinsic rhythm whose rate lies below the basic rate. However, the intrinsic rate 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 interval or the interval determined by the sensor.

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 device paces at the hysteresis rate instead of the basic rate even in the absence of intrinsic activity.

Rate hysteresis

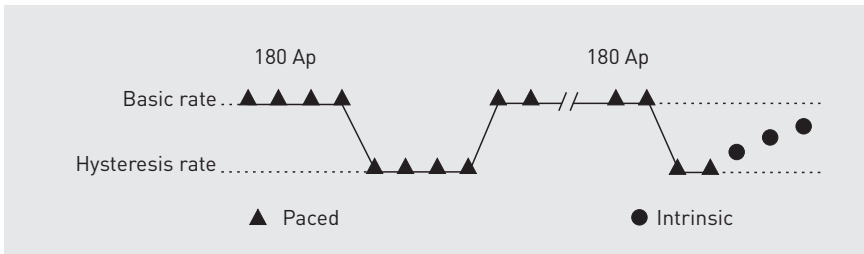


Rate scan hysteresis

This function is a sub-feature of rate hysteresis and promotes the intrinsic rhythm after long periods of pacing. The function is always switched on in combination with the repetitive rate hysteresis.

After 180 successive pacing cycles, the ICD reduces its rate to the hysteresis rate for 10 cycles with the purpose of either sensing an intrinsic event in this time and thus inhibiting its own effects, or continuing pacing at the basic rate after this event.

Rate scan hysteresis

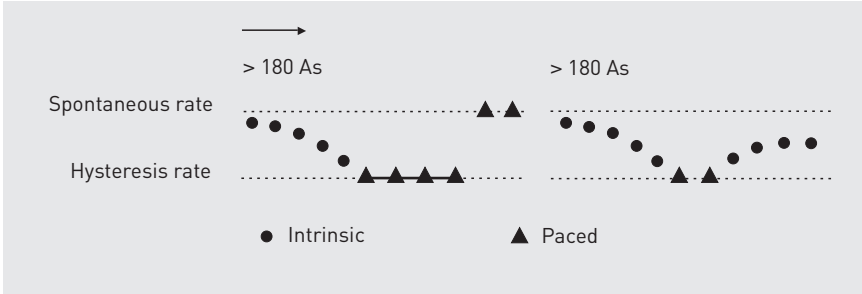


Repetitive rate hysteresis

This function is a sub-feature of rate hysteresis and is always switched on in combination with rate scan hysteresis.

When the intrinsic rhythm falls below the hysteresis rate, or ceases entirely, the device then paces at the hysteresis rate for 10 cycles, allowing the ICD to be inhibited in case of onset of a faster intrinsic rhythm.

Repetitive rate hysteresis



Rate hystereses

Navigation: Parameters → Bradycardia/CRT

Objective

Hysteresis functions inhibit stimulation in favor of the intrinsic rhythm of the heart.

Rate hysteresis

If the intrinsic rhythm is lower than the basic rate, but higher than the hysteresis rate, stimulation is inhibited.

Repetitive hysteresis

Repetitive hysteresis contributes to the prevention of unnecessary pacing in cases in which conventional hysteresis can be overcome – using post-extrasystolic pausing, for example.

Scan hysteresis

Scan hysteresis helps the production of an intrinsic rhythm during longer phases of pacing:

- If scan hysteresis is enabled, the device regularly reduces the pacing rate to the hysteresis rate for 10 cycles after 180 successive pacing events in order to search for intrinsic events.
- If no intrinsic event is sensed during the scan intervals, pacing at the basic rate is resumed (at the sensor rate in rate-adaptive mode).

5.6.2 Functions of the Dynamic AV Delay

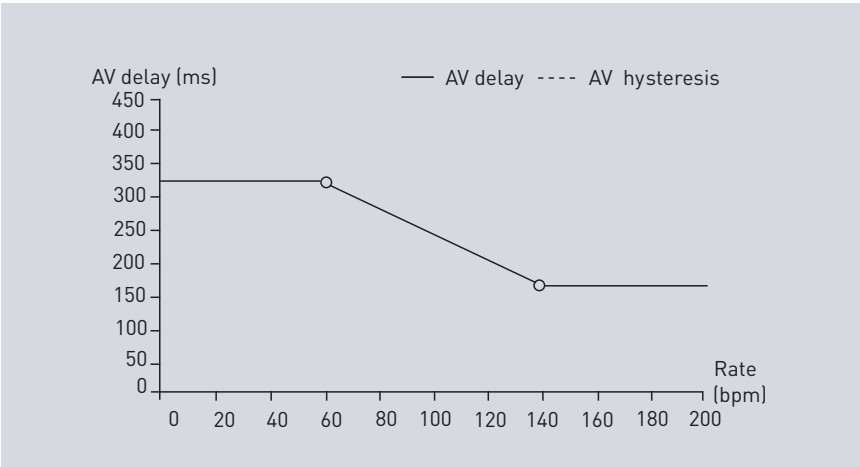
What's in this section?

Dynamic AV Delay

The AV delay defines the interval between an atrial paced or sensed event and the ventricular pacing pulse. If the ICD is programmed in dual-chamber mode, an intrinsic ventricular event falling within the AV delay will inhibit the ventricular pacing pulse. If not contraindicated, a longer AV delay can be selected to increase the probability of ventricular pulse inhibition.

An AV delay is dynamic when it varies depending on the intrinsic atrial rhythm. The dynamic AV delay provides an independent selection of AV delays for two rate points. The ICD calculates and sets the dynamic AV delay between these two points linearly. The incline of the AV delay curve can be positive or negative here, which provides the possibility of triggering long AV delays with slow rates and short AV delays with fast rates or vice versa.

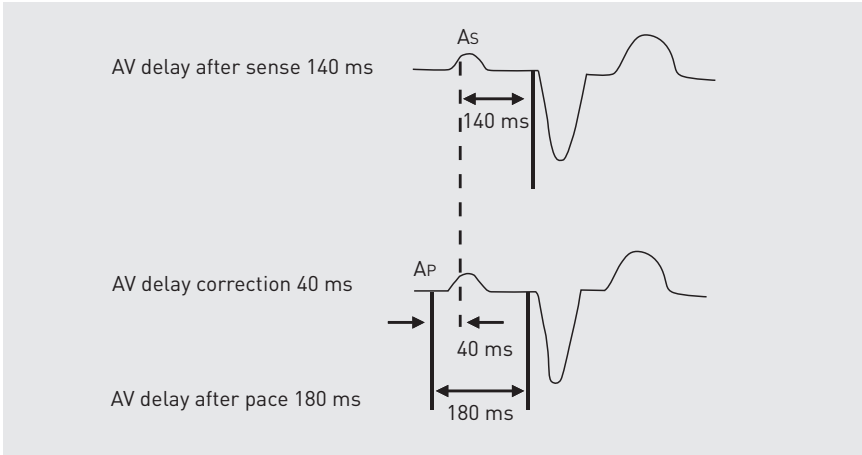
AV delay



In addition to selecting the preset values (low, medium and high) for the dynamic AV delay, the dynamic AV delays may be programmed individually or to a fixed AV delay.

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

Sense compensation



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 reduce it in length.

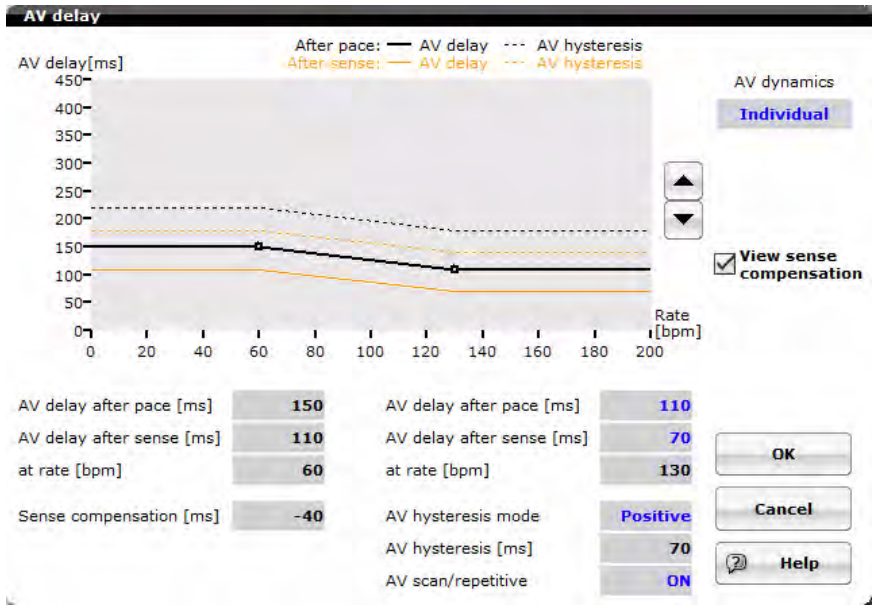
For more information see: Setting AV Hystereses, p. 121

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 the relevant specific physiological conditions.

Procedure Proceed as follows:

Step	Action
1	Select 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 AV delay



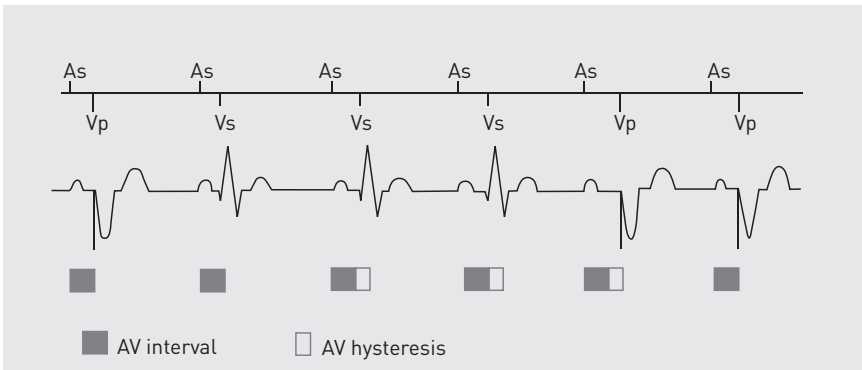
AV Hysteresis

Positive AV hysteresis

AV hysteresis can be programmed to promote spontaneous AV conduction.

In doing so, the AV delay is extended by a defined range of values after sensing an intrinsic ventricular event. The long AV delay remains intact as long as an intrinsic ventricular rhythm is measured. The short AV delay without extension by the hysteresis value follows after ventricular pacing.

Positive AV hysteresis

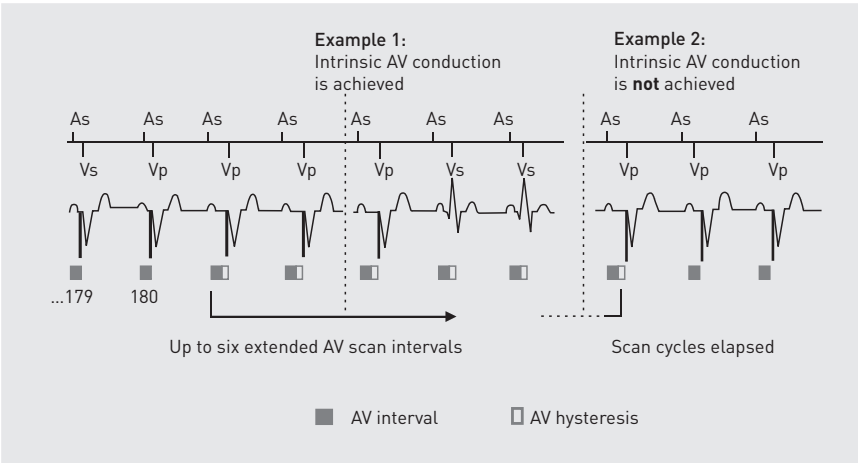


AV scan hysteresis

This function is a sub-function of positive AV hysteresis and promotes spontaneous AV conductions even during longer phases of pacing. The function is always switched on in combination with AV repetitive hysteresis.

After 180 successive pacing cycles, the ICD will extend the AV delay for five cycles to the time extended by the AV hysteresis. If the ICD detects spontaneous AV conduction during this time, pacing is withheld until it is needed again. Otherwise, the ICD switches to the short AV delay and repeats the described process after 180 successive pacing cycles.

AV scan hysteresis

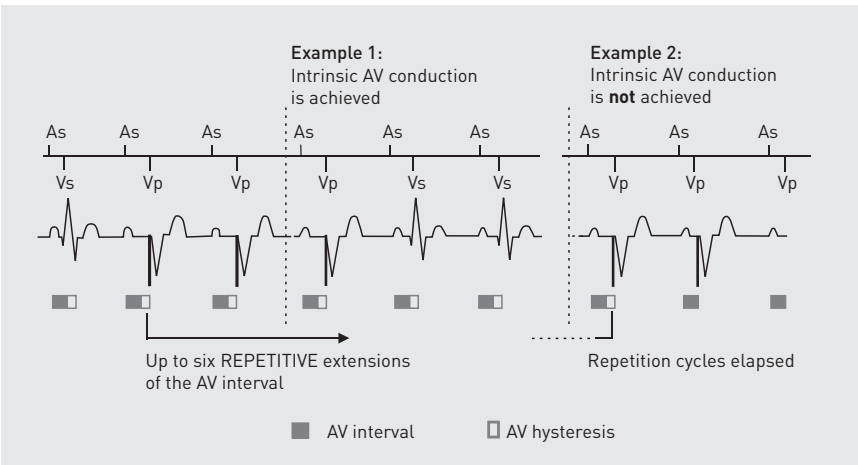


AV repetitive hysteresis

This function is a sub-function of positive AV hysteresis, thereby further improving the chances of successful spontaneous AV conduction. The function is always switched on in combination with AV scan hysteresis.

The extended AV delay after a ventricular paced event remains with the AV repetitive hysteresis for five cycles in addition to the AV hysteresis. If spontaneous AV conduction occurs during one of these cycles, then the extended AV delay remains intact. If not, then the ICD reverts to the short AV delay.

AV repetitive hysteresis

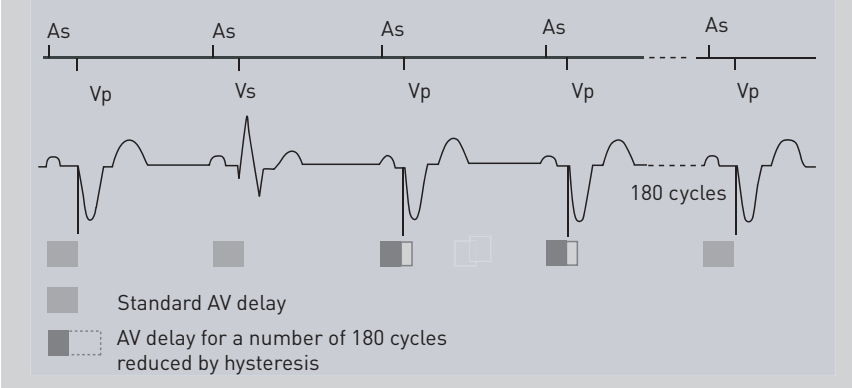


Negative AV hysteresis

This function is intended to suppress intrinsic excitation conduction and promote pacemaker stimulation in the ventricle. This is required for patients with hypertrophic obstructive cardiomyopathy (HOCM) for example or can be considered within the context of cardiac resynchronization therapy for congestive heart failure patients.

The function shortens the AV delay upon occurrence of a sensed ventricular event. The AV delay is shortened by the set value after sensing an intrinsic ventricular event. Following ventricular pacing with short AV delay, the permanently programmed AV delay takes effect without shortening by the hysteresis value.

Negative AV hysteresis



Setting AV Hystereses

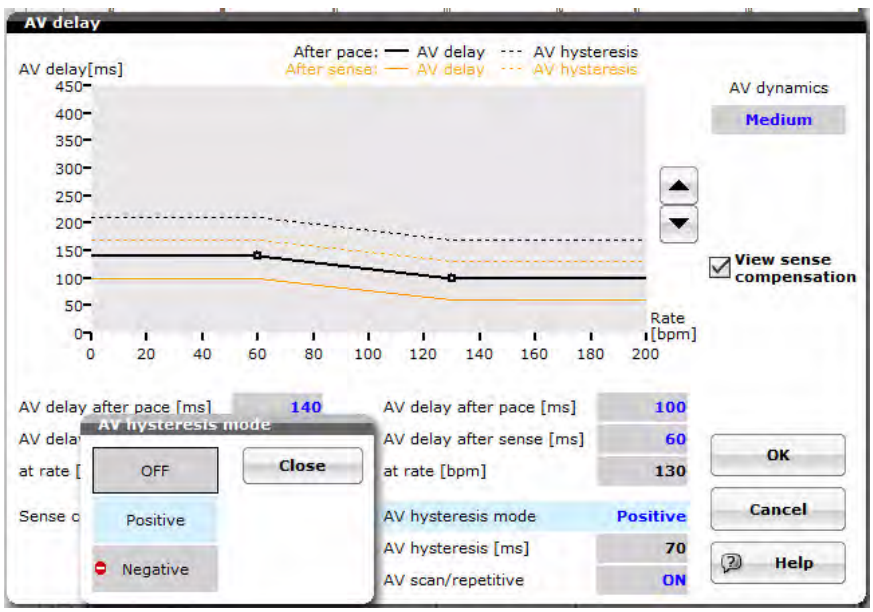
Navigation: Parameters → Bradycardia/CRT

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; e.g. 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 increased/decreased by the defined hysteresis value after sensing an intrinsic ventricular event.

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

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.
- Hence, the AV repetitive hysteresis reduces pacing when an existing intrinsic event within the extended AV delay does not occur for a variety of reasons.
- This behavior is possible for 5 cycles in positive AV repetitive hysteresis.

Negative

- The repetitive cycles occur with the decreased AV delay. When the preset 180 cycles are completed, the programmed AV delay is restored (increased). 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 cycles (5). 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 zero.
- Hence, AV scan hysteresis reduces pacing in situations in which intrinsic conduction exists but does not fall within the programmed AV delay.

AV Safety Delay

Protection against pulse inhibition

If an atrial pace triggers ventricular oversensing due to crosstalk, undesired pulse inhibition in the ventricle can result. Sensing of atrial pulse delivery in the ventricular channel during the AV delay can be incorrectly interpreted as an intrinsic ventricular event. Therefore the AV safety delay (100 ms) is started after atrial pacing in the DDD(R) and DDI(R) modes.

If ventricular sensing (RVs) occurs after the cross blanking has elapsed but still within the AV safety delay, then the pacemaker paces at the end of the AV safety delay in the ventricle with Vp. This ventricular stimulus after 100 ms (deviating from the regular AV delay) is a back-up pulse. The back-up pulse serves as protection from undesired impulse inhibition after crosstalk.

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 sensing 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.

Note: In HF-T device, the pacing configuration BiV causes an AV back-up pulse to be delivered first in the chamber that has been programmed as the chamber to be paced first (RVp or LVp). The programmed VV delay is automatically reset to 0 ms in the case of AV safety pacing. However, a VV delay of 20 ms can occur for technical reasons.

5.6.3 Refractory and Blanking Times

What's in this section?

Refractory and Blanking Periods

Refractory periods

Refractory periods serve to depict the physiological timing of the heart in the device, in which no pacing pulses are to be expected normally.

Sensed events that occur during the refractory period have no effect on device timing. Exceptions are mode switching and tachycardia detection. With these functions, sensing events within the refractory period are utilized for arrhythmia detection.

Blanking periods

Blanking serves to suppress sensing events which have most likely occurred not physiologically, but due to interferences in the signal path.

Atrial refractory behavior

The **ARP** is the atrial refractory period after an atrial sensed event (225 ms + sense compensation) or pace (225 ms or AV delay, whichever is longer). ARPs are not programmable. They are automatically set.

An atrial, non-refractory sensed or paced event starts the atrial refractory period (ARP). It is not retriggerable by atrial sensing events. Atrial sensed events that occur within the atrial refractory period, but outside the blanking periods (atrial refractory sensing events, Ars) have no influence on pacemaker timing.

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 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)
- In all R-synchronous modes (e.g., DDI), a PVARP starts in the case of the following events: Vp, VES, Vs

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

If no pacemaker-mediated tachycardia (PMT) is detected within 7 days, the Auto PVARP function automatically reduces PVARP and PVARP after PVC by 50 ms. Once a value that does not trigger a PMT has been found, the PVARP is no longer automatically shortened.

Ventricular refractory behavior

The **VRP** is the ventricular refractory period after ventricular pacing and a ventricular sensed event.

A ventricular sensed event restarts the ventricular refractory period (VRP). It is not retriggerable by ventricular sensing events. PVC starts a ventricular refractory period after a ventricular sensing event. The VRP after sensing is set to a fixed value of 200 ms.

A ventricular refractory period (VRP) after ventricular paced events is always exactly as long as the ventricular blanking period.

A ventricular stimulus starts the ventricular refractory period (VRP) after pacing delivery. No ventricular pulse is delivered during the ventricular refractory period. Triggered ventricular paces and safety paces can be delivered during this period. Sensing events outside the ventricular refractory period (Vs) have an impact on pacemaker timing. Ventricular sensed events within the ventricular refractory period (Vrs) do not affect pacemaker timing.

Ventricular refractory periods are not programmable.

Atrial blanking periods

If the atrial channel is blanked, then all incoming atrial sensing events will be suppressed. They do not affect the rhythm and noise evaluation or the device behavior. An atrial sensed event does not retrigger the atrial blanking period. An atrial sensing event starts the blanking period in its own channel. An atrial pace starts the blanking period. After a ventricular pace, the atrial channel is blanked for the duration of cross blanking. The atrial triggered blanking periods are not affected by this.

Note: Additional atrial blanking periods can be an effective means of suppressing ventricular far-field sensing in the atrium (see far-field protection).

Ventricular blanking periods

If the ventricular channel is blanked, then all incoming ventricular sensing events will be suppressed. They do not affect the rhythm and noise evaluation or the device behavior. A ventricular sensing event does not retrigger the ventricular blanking period.

A ventricular sensing event starts the blanking period in its own channel. A ventricular pace starts the ventricular blanking period. After an atrial pace, the ventricular channel is blanked for the duration of cross blanking. The ventricular triggered blanking periods are not affected by this. Atrial sensing events have no impact on ventricular blanking periods.

PMT Protection (Description)

Overview

- Description of the PMT detection
  - Criteria of the detection algorithm
  - Terminating the PMT
- Setting PMT protection
- Details of PMT confirmation

Purpose

Based on an algorithm, PMT protection inhibits triggering of pacemaker-mediated tachycardia (PMT).

In the atrial-controlled dual-chamber device modes (DDD, VDD), the device starts PMT protection after the following events:

- Ventricular stimulus
- Ventricular extrasystoles

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.

Criteria of the detection algorithm

A pacemaker-mediated tachycardia is recognized by the sensing algorithm when the following criteria are satisfied:

Criterion	Description
1	The mean value of the last eight sequential Vp-As intervals is shorter than the programmed VA criterion.
2	The mean value of the Vp-As intervals is subtracted from each of the eight individual Vp-As intervals. The result is compared with an internal PMT stability criterion and evaluated with respect to a particular margin of fluctuation that can be tolerated. If stability (+/- 25 ms) exists, a confirmation phase follows.

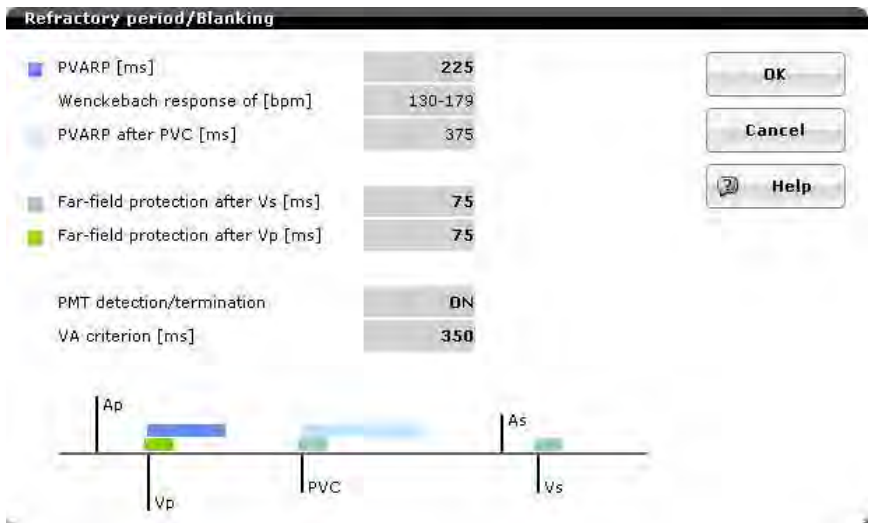
Terminating the PMT

If ...	Then ...
these two criteria are met,	the device automatically changes the AV delay by a defined value.
the following Vp-As interval remains constant,	the PMT is considered to be confirmed.
the PMT is confirmed,	the algorithm for terminating the PMT is initiated with an automatic extension of the PVARP interval for the duration of a cardiac cycle.

Setting PMT protection

Set the PMT protection as follows:

Step	Action
1	Select `Refractory period/Blanking` to access the function.
2	Select `PMT detection/termination` and `ON` to activate the function.
3	Select `VA criterion` and enter the desired value.
4	Select **[OK]** to accept the settings. The activated PMT protection function is accepted and displayed on the program screen.
5	Select **OFF** if you want to deactivate PMT protection.



Details of PMT confirmation

If a PMT is detected based on the VA criterion and the stability of the last eight cycles, the PMT is confirmed by a displacement of the ventricular stimulus before the atrial event and an examination whether the subsequent atrial event exhibits an adequate displacement.

The test method is based on the length of the pacing interval or the AV delay. UTI is the interval corresponding to the upper tracking rate.

Interval length	AV delay	Test method
> UTI	⩽ 200 ms	Increase of the AV delay by 50 ms
> UTI + 50 ms	> 200 ms	Decrease of the AV delay by 50 ms
⩽ UTI	⩽ 200 ms	Increase of the AV delay by 50 ms
⩽ UTI	> 200 ms	Increase of the AV delay by 50 ms
> UTI and ⩽ UTI + 50 ms	> 200 ms	Length of UTI = AV delay plus PVARP + 50 ms

Setting Refractory Periods, Blanking Periods and PMT Protection

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

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 set for PMT protection, refractory and blanking periods:

- PVARP, Auto (PVARP), PVARP after PVC
- Far-field protection after Vs, Vp
- PMT protection

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 (RPVC) 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.
  - — After a PMT has first been detected, the PVARP is increased 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

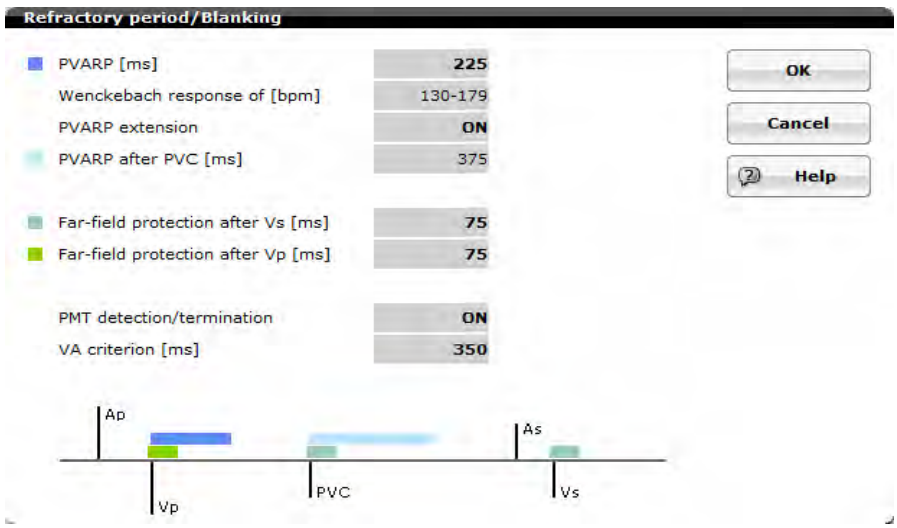
  Events that occur during the refractory period and are sensed by the device have no effect on device timing. This does not include algorithms used for prevention in the case of atrial tachyarrhythmia (e.g., automatic mode switching).

- Far-field protection
  - Far-field protection prevents atrial leads in dual-chamber modes from detecting ventricle potentials (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.
  - Far-field protection always has a 16-ms time lead over the ventricular event.

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.



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, the PVARP is extended automatically if a PMT has been confirmed.

In the dual-chamber device's atrial 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. If PMT has occurred, this means there is coupling between the Vp interval and the subsequent As interval (VA interval). The detection algorithm is based on a constant for the length of the VA interval.

In case of a confirmed PMT, the device will attempt to interrupt it by extending the PVARP.

5.6.4 Ventricular Pacing Suppression

What's in this section?

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 device type is suitable for which underlying disease?

A device with AAI function is sufficient for patients with intact AV conduction.

However, dual-chamber devices 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 devices 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 seconds 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.

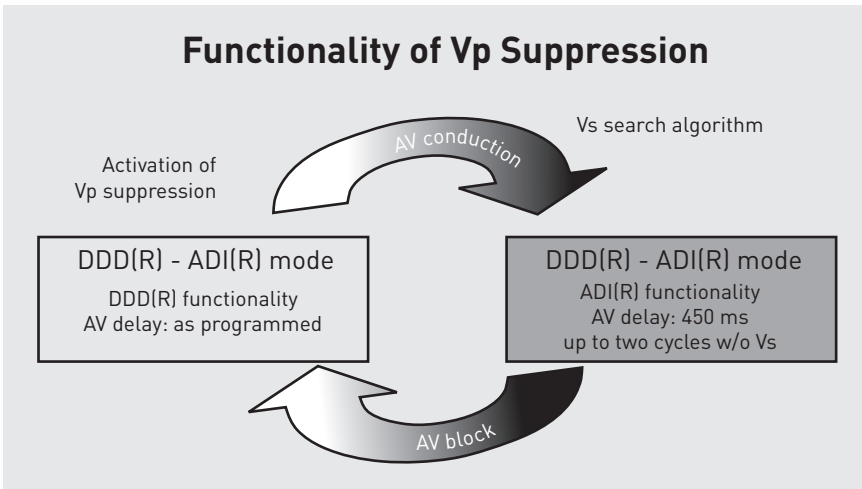
If there is intrinsic AV conduction, the function works in a mode similar to ADI(R).

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.

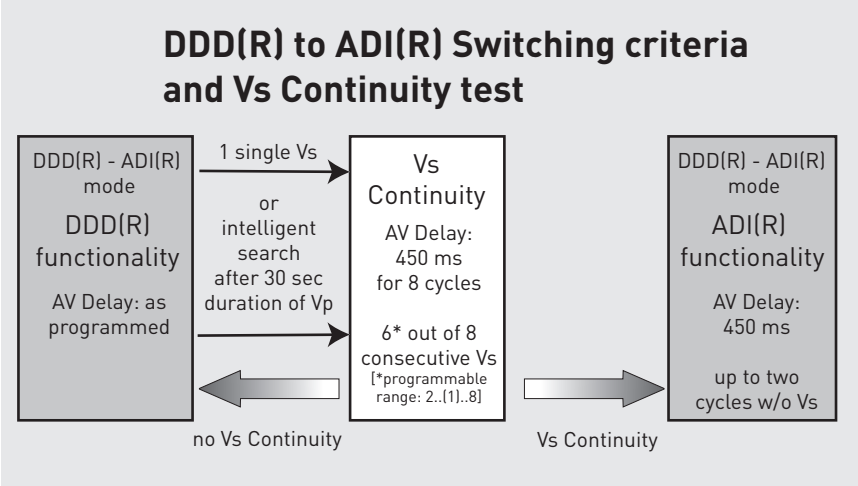
The search for an intrinsic ventricular rhythm can be triggered by two different events:

- 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

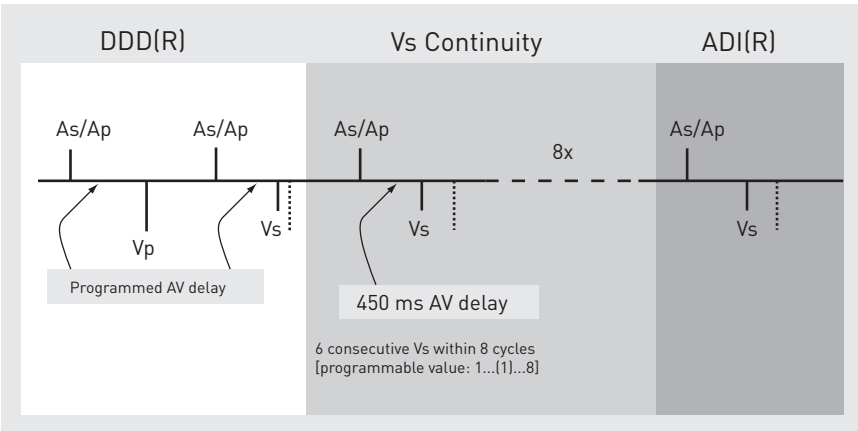
In order to prevent constant switching between DDD(R) and ADI(R), an additional test is performed to verify the stability of the intrinsic ventricular rhythm.

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.



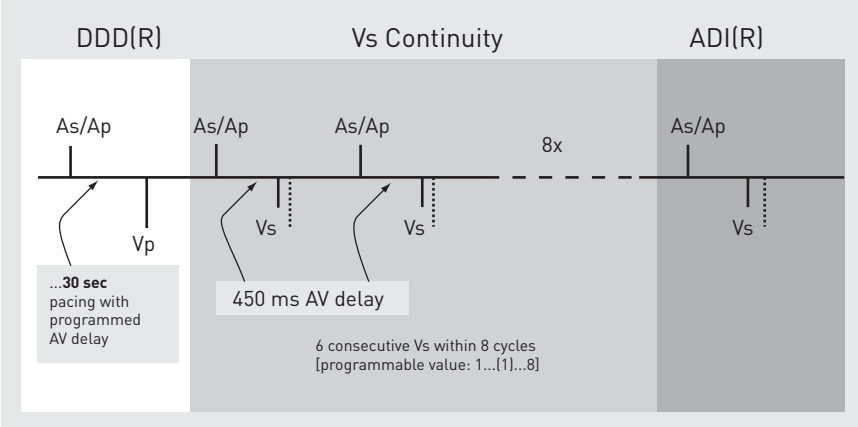
The search is successful if the set number of cycles has been sensed consecutively within 8 cycles. If no Vs was sensed except for the initial Vs, then the device paces for 8 cycles with an AV delay of 450 ms.

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 hours for intrinsic AV conduction. The scan interval is set to 20 hours instead of every 24 hours 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 two cardiac cycles or within 2 seconds, 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 four different criteria which result in switching and they all work independently:

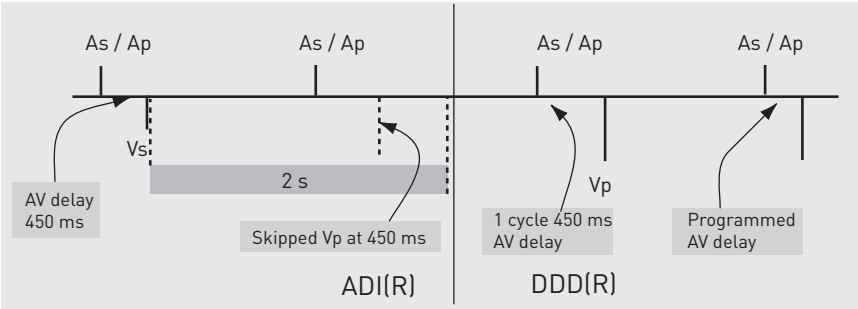
- No Vs for 2 seconds
- 2 consecutive cycles without Vs
- Pacing support for X out of 8 cycles without Vs (programmable number, default setting: 3 out of 8)
- 15 switches per hour permanently switches to DDD(R) until 24:00 h of the same day.

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 seconds 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 seconds because the ventricular stimulus is AV-synchronous. In this example, the ventricular pause is about 3 seconds. 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.

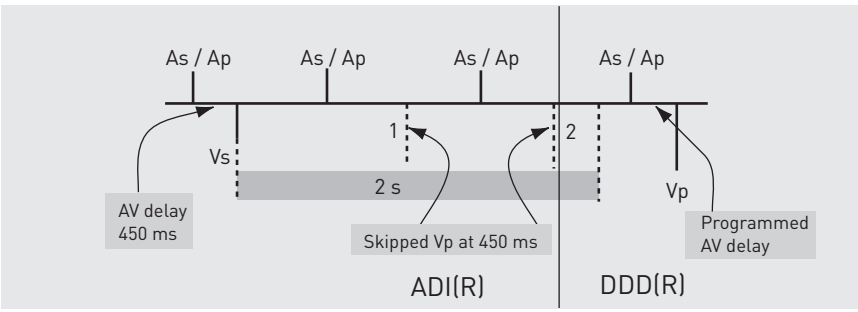
Example: Ventricular pause at 40 bpm



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).

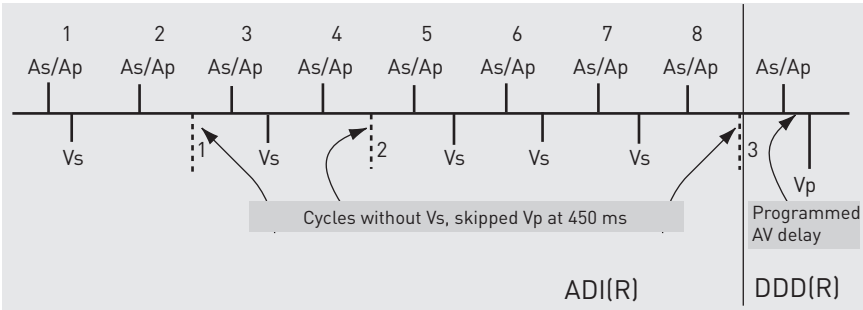
Example: Ventricular pause at 70 bpm



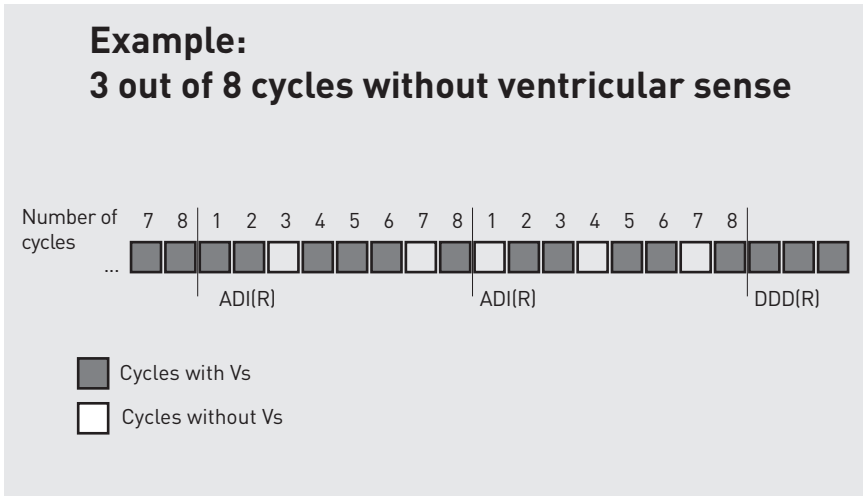
Switching criterion: programmable number X-out-of-8 cycles without Vs

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.

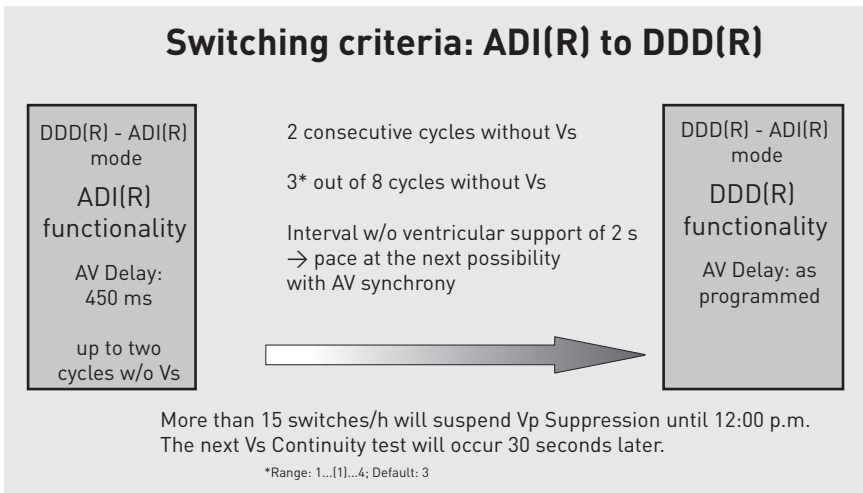
Example: 3 out of 8 cycles without Vs



The 8-cycle interval is fixed and is not flexible like the X-out-of-Z criterion in mode switching.



Summary



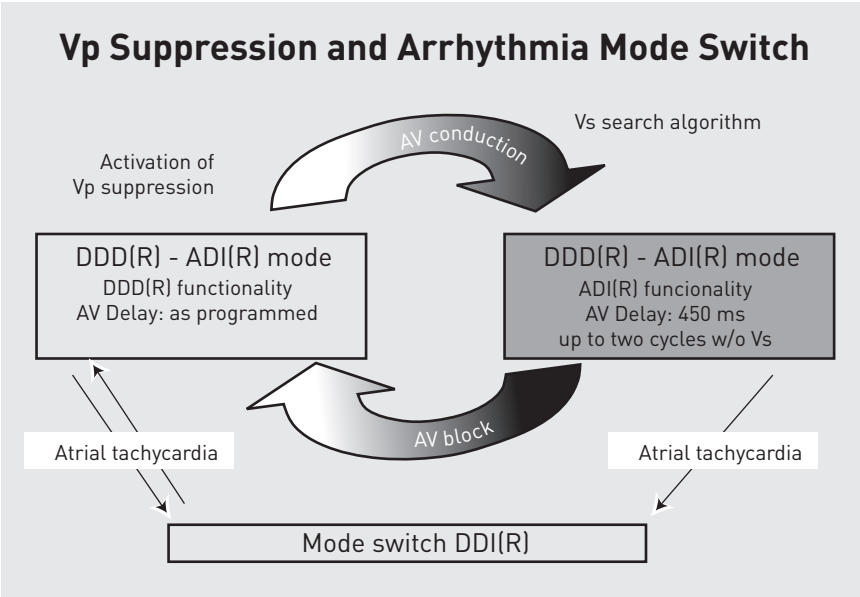
Vp suppression and mode switching

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.



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 pacemaker 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.

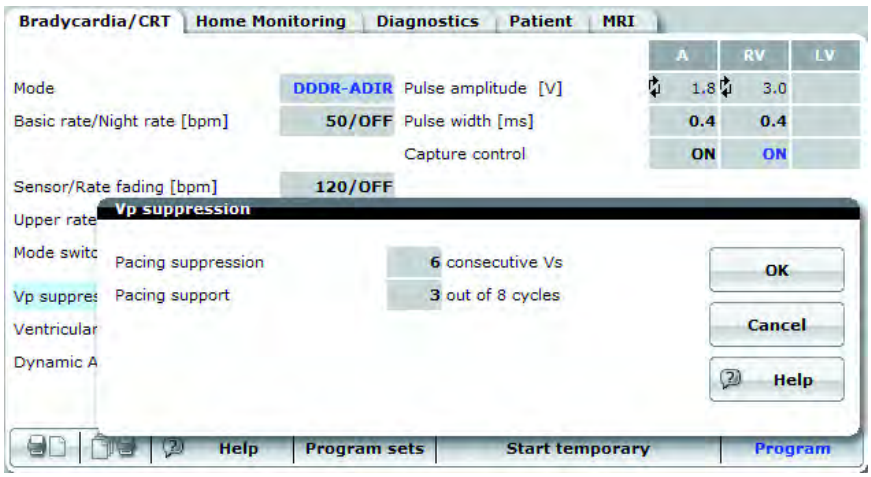
Activate the function

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** window.

User interface

Vp suppression



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.

5.7 Atrial and Ventricular Capture Control

What's in this section?

5.7.1 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

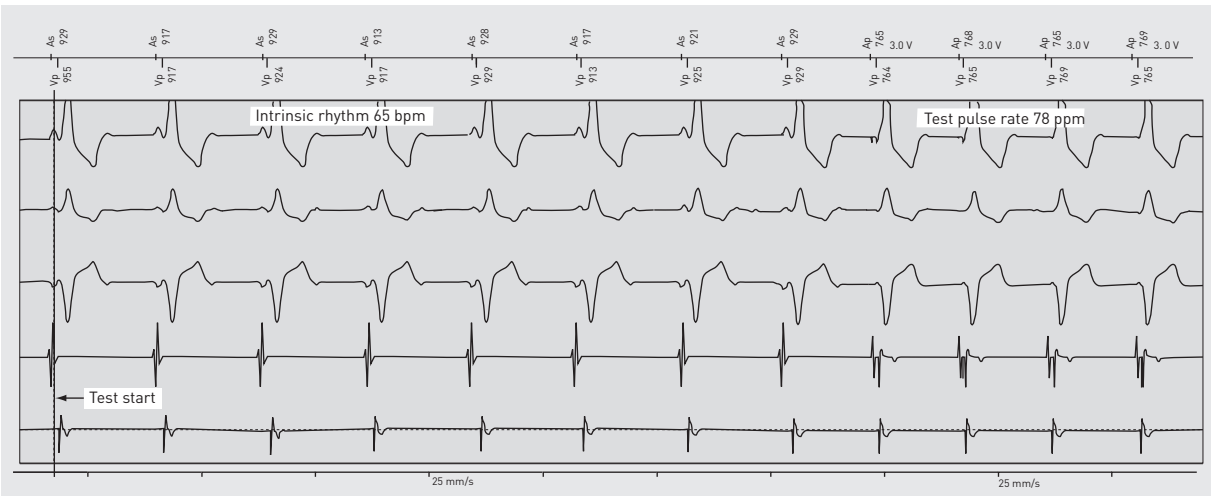
The atrium is paced in order to be able to identify the loss of stimulus response at a certain amplitude.

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 ...
the average atrial rate is higher than the programmed pacing rate	the atrial pacing threshold test is carried out at a rate which corresponds to the average intrinsic rhythm + 20%.
the average atrial rate is lower than the programmed pacing rate	the atrial pacing threshold test is carried out at the pacing rate + 20%.
the average atrial rate lies above 108 beats per minute	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 with the far-field blanking (FFB) value.

Pacing threshold search using amplitude reduction

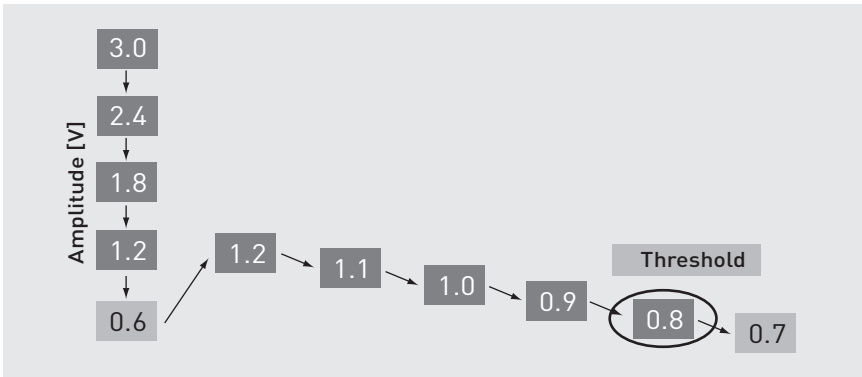
- The pacing threshold search begins at the programmed start amplitude (default setting: 3.0 V). The amplitude is reduced here in 0.6 V increments, until 2 intrinsic atrial events are sensed within 5 cycles (2 of 5).
- After the first loss of stimulus response (2 of 5), the device switches back to the 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

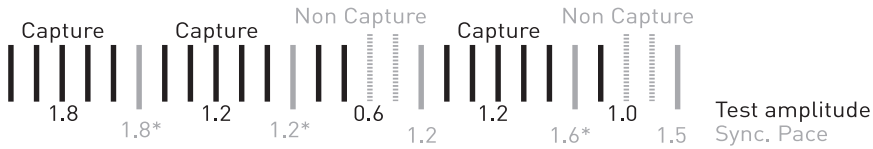
- Each test amplitude is delivered and analyzed 5 times with the same pacing energy for the duration of 5 cycles.
- After two sensed events within 5 cycles, the test sequence is likewise terminated prematurely, because ineffective pacing has occurred and the value has fallen below the pacing threshold.

- 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.

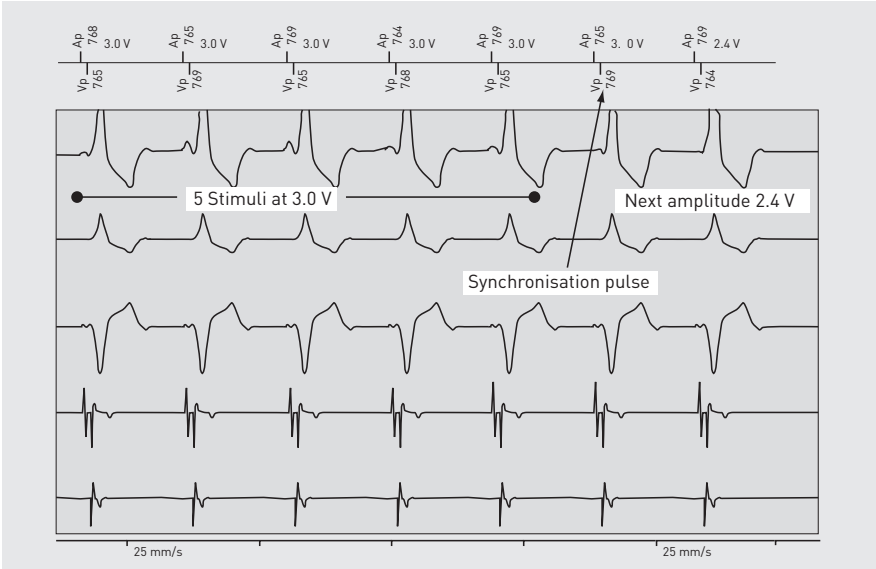
  For technical reasons, the synchronization pulse is even delivered without a loss of capture response.
  If no capture response occurs, the synchronization pulse has a pacing energy 0.6 V greater than the unsuccessful test pulse.
  If a capture response occurs, the synchronization pulse has the same 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

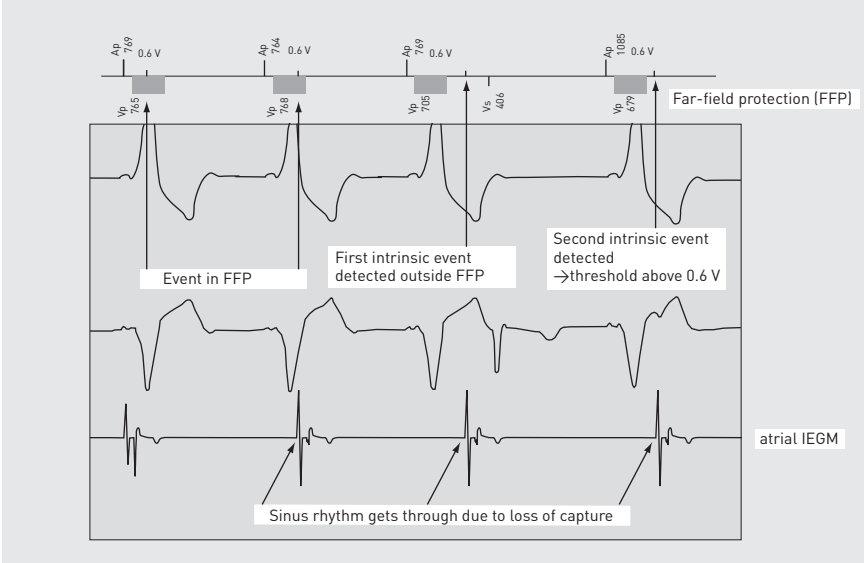
Diagram of the test and synchronization pulses with capture response (capture) and with loss of capture response (non-capture)



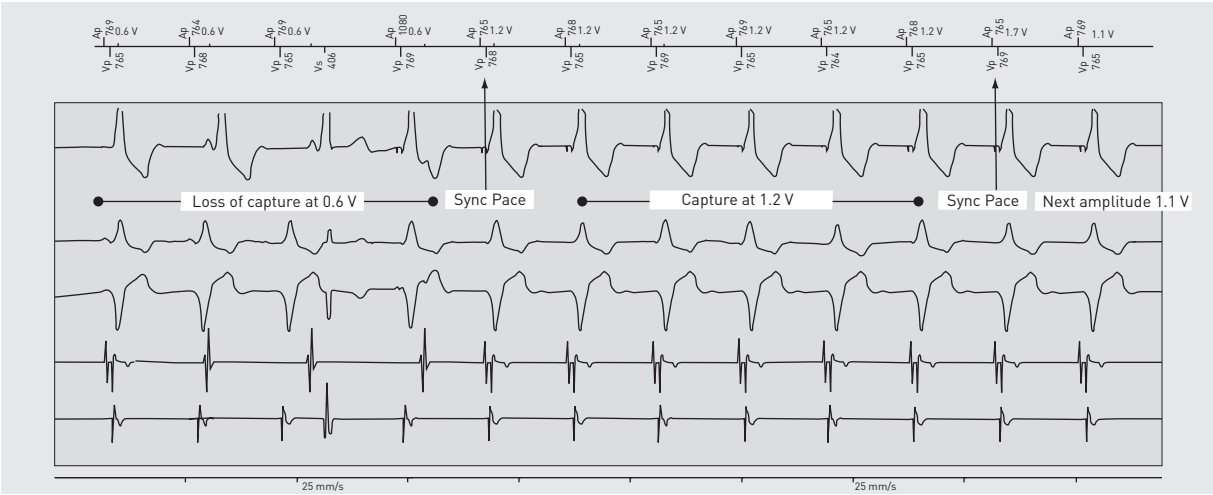
Example: Synchronization pulse, 5 stimuli at 3 V and a synchronization pulse



Example: Loss of capture at 0.6 V; only atrial markers outside the programmed far-field protection value 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.

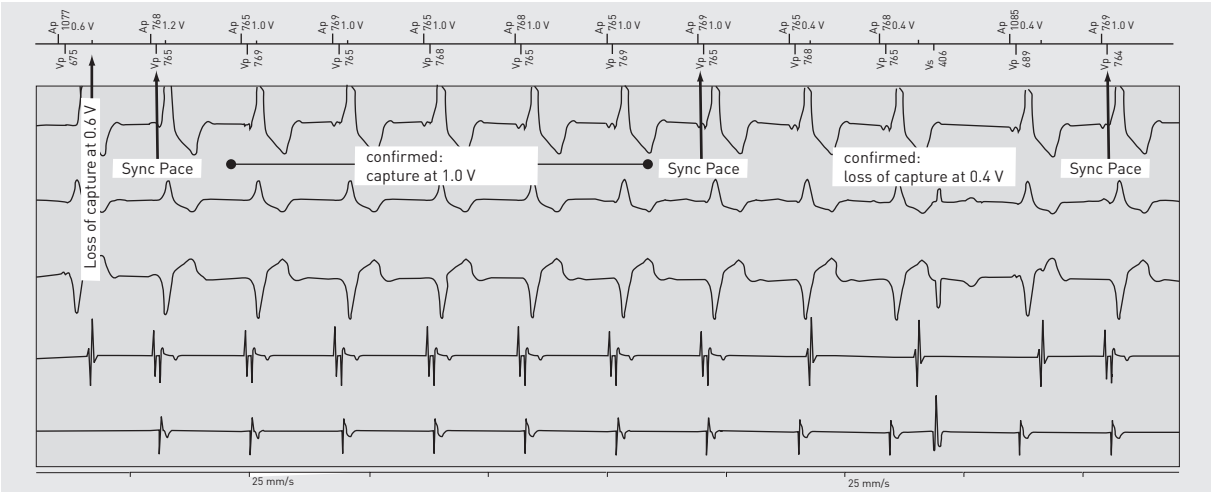
- 2nd step:

  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.

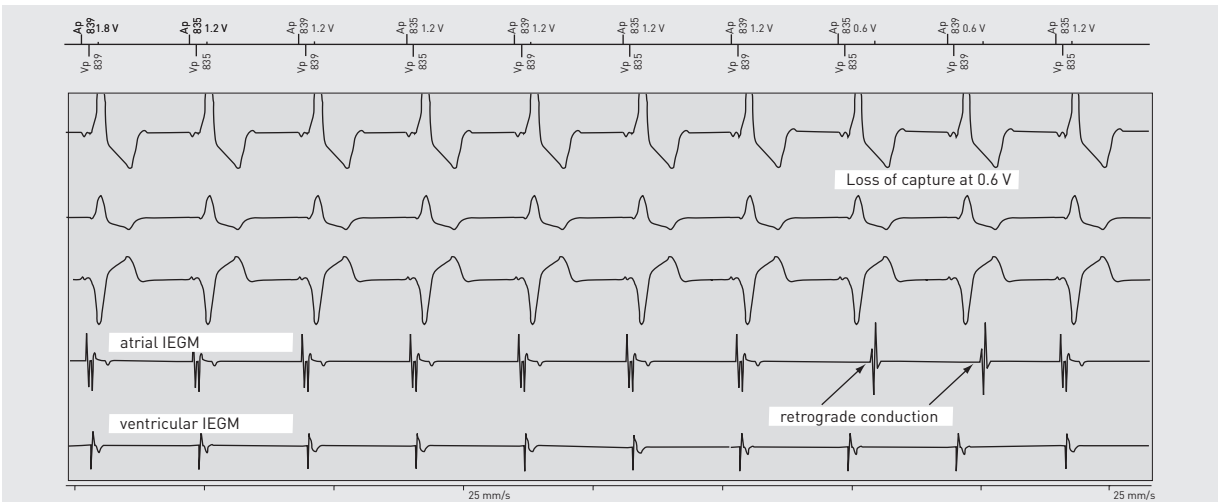
Example verification test: capture response at 0.7 V (= pacing threshold), loss of the capture response at 0.6 V, (pacing threshold +/-0.3 V)



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, 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.

5.7.2 Ventricular Capture Control

What's in this section?

Ven. Active Capture Control – Overview

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

Purpose

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 automatically adjust the pulse amplitude via a change in the pacing threshold.

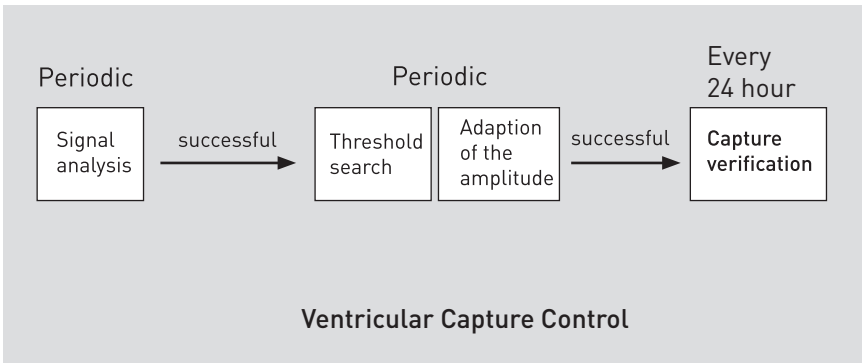
Components of the algorithm

The algorithm is comprised of 3 components:

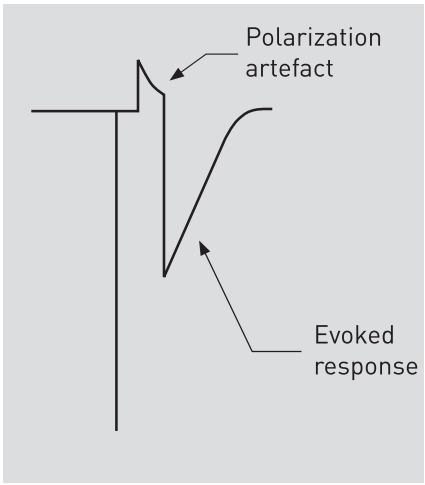
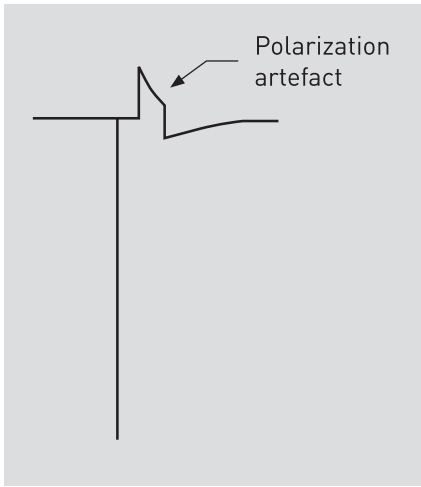
- Signal analysis
- Measurement of the pacing threshold with amplitude setting
- Verification of stimulus response

All components occur periodically. If the entire ventricular capture control mode is set to ON, all 3 components will run one after the other.

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 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.
- An automatic method which checks the efficiency of pacing and periodically determines the pacing threshold (every 24 hours) can manage with a smaller safety margin, since the pulse amplitude is 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	The evoked response is an 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	A polarization artifact is noise which arises between the pacing 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	Signal analysis is a component of the function which 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.

Term	Description
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 stimulus response	A component of the function which classifies a stimulus as effective or ineffective
Ineffective stimulus	A single ineffective, ventricular stimulus without depolarization (non-capture)
Safety margin	The difference between the pacing threshold and the programmed impulse amplitude is referred to as the safety margin.
Loss of capture	The function detects a loss of capture if a series of ventricular stimuli at different AV delays cannot depolarize the tissue (2 of 3 successive ineffective stimuli).
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

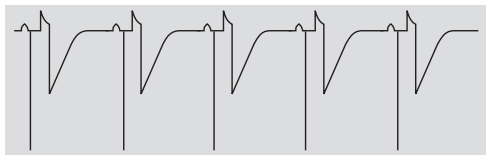
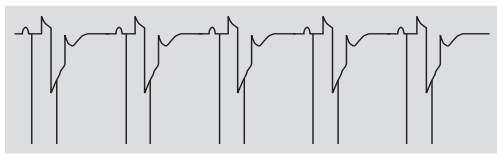
Purpose

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 110 bpm.

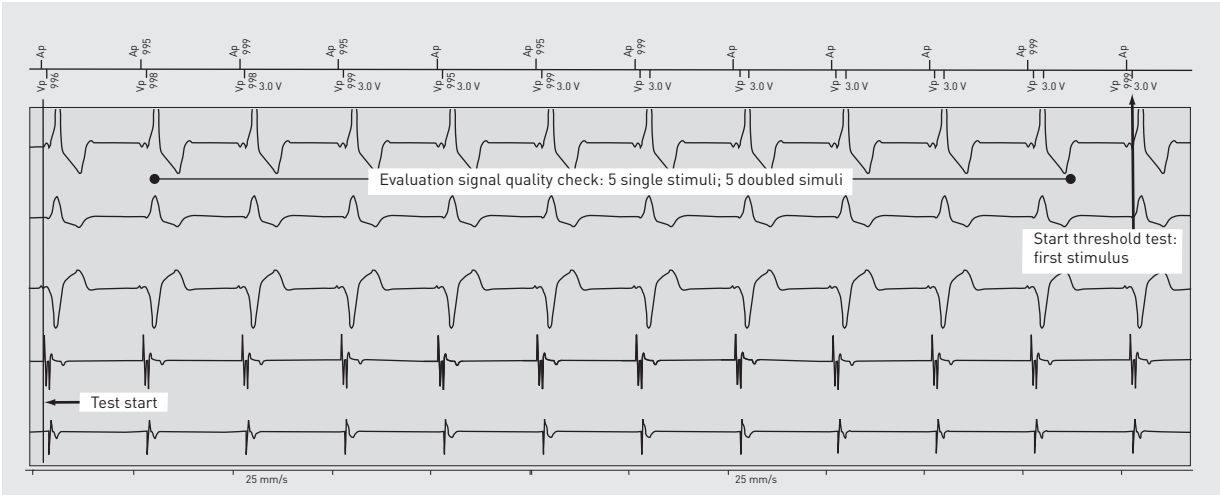
How signal analysis works

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 safety pacing until a successful measurement can be conducted.
The signals (evoked response and polarization artifact) can be changed by changing the pacing polarity and pulse amplitude under **Parameters → Capture control → Threshold test start** so that the signal quality is possibly sufficient.
The automatic pacing threshold search only functions at a constant pulse width of 0.4 ms.

Example: Checking signal quality, analysis of evoked responses



Possible scenarios during signal analysis

If...	Then...
after initial activation, signal analysis is completed successfully, but subsequently completed without success,	the pulse amplitude is set to a safe value. This value consists of the most recently measured pacing threshold + a maximum safety margin of 1.2 V if the measured value is greater than half of the start amplitude. If the measured value is less than half of the start amplitude, then the value of the start amplitude is set. Signal analysis is conducted again at the next programmed time.

Automatic Threshold Measurement

Purpose

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.

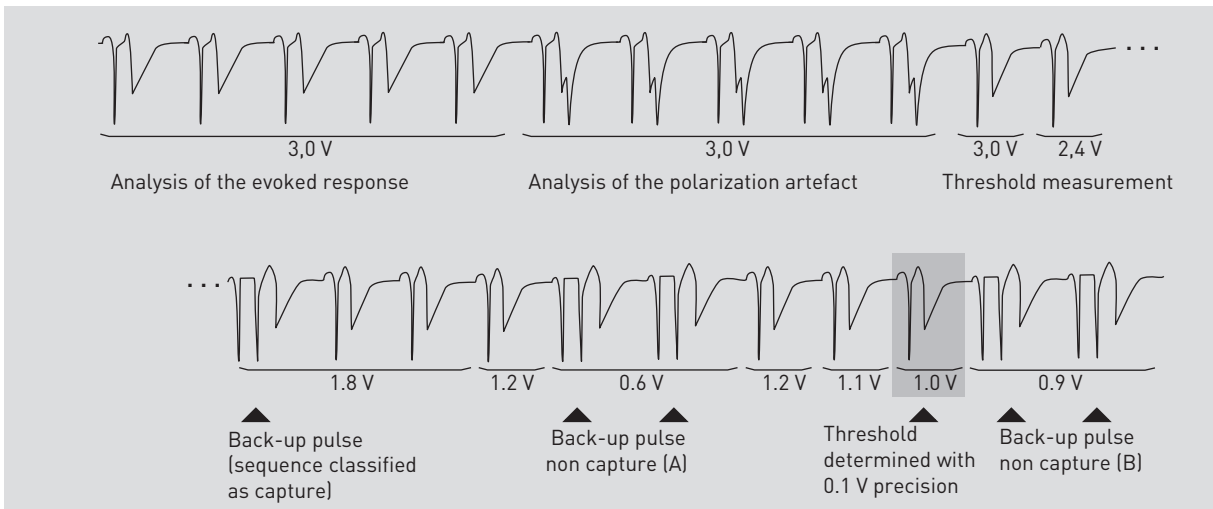
Prerequisite

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 reduced, 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 0.6 V and 1 ms is delivered after each ineffective ventricular stimulus. This leads to continuous effective pacing.

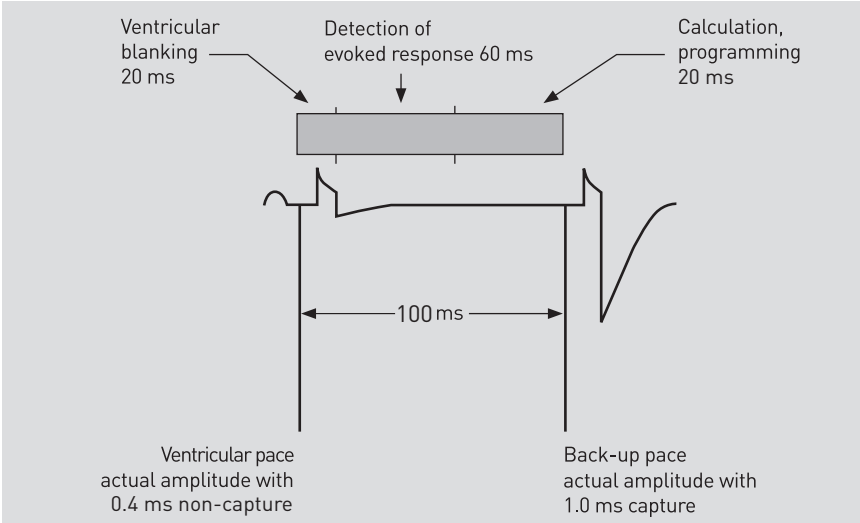


Backup pulse

The algorithm checks the effectiveness of every single ventricular stimulus during the threshold test. If an ineffective stimulus is detected, a backup pulse with more energy will be delivered within 100 ms. The energy of this stimulus is increased in that the pulse width is increased to 1.0 ms and the pulse amplitude is increased by 0.6 V.

Thus, the energy of the back-up pulse is higher than the energy of the previous ineffective stimulus.

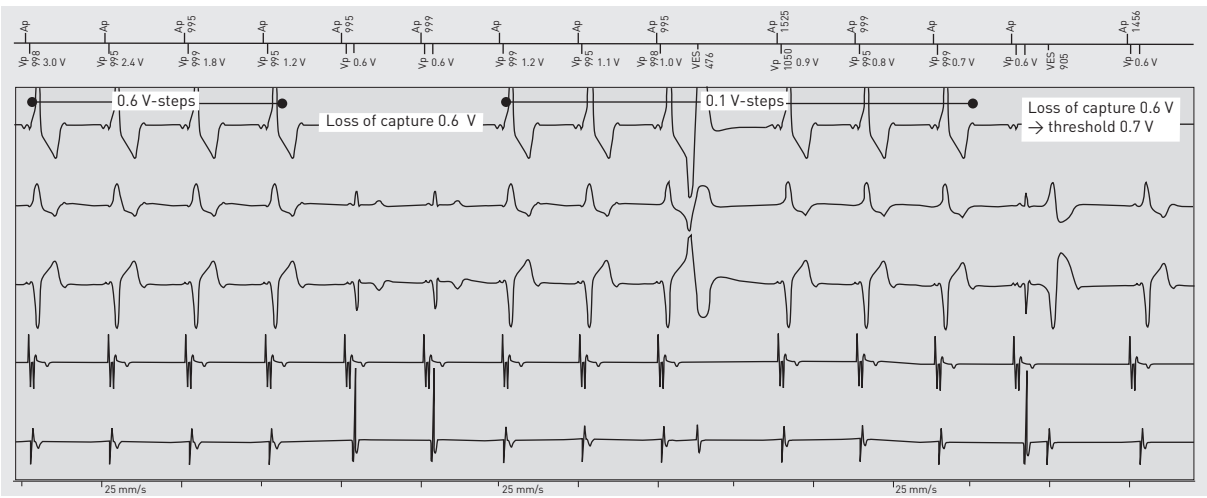
Diagram of the signal analysis when the stimulus is not effective



Automatic determination of the pacing threshold

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



Settings The standard value for the start of the threshold test is 3.5 V and 2.5 with ATM. The pulse width is fixed at 0.4 ms and cannot be changed.

The scan mode is carried out at night just prior to the time of Home Monitoring transmission. This serves to minimize the impact that a highly fluctuating intrinsic rate has on the algorithm.

5.7.3 Configuring Capture Control, Parameters

What's in this section?

Capture Control

Navigation: Parameters → Bradycardia/CRT → Capture control

Atrial capture control

Atrial capture control is based on event markers in the atrium and on their daily statistical evaluation. Atrial capture control consists of the following sub-functions:

- Periodic and automatic measurement of the pacing threshold
- Confirmation of the found pacing threshold
- Adaptation of the amplitude if ATM has not been set

Ventricular capture control (RV, LV)

Ventricular capture control is based on an algorithm that checks the response evoked between the stimuli on a daily basis and adjusts the pacing energy if fluctuations in the pacing threshold occur.

- Ventricular capture control consists of the following sub-functions:

Signal analysis
  — This function analyzes the signal quality of the ventricular-evoked capture response (when pacing is effective) and polarization artifacts (when pacing is ineffective). The function ensures that only undisturbed suitable signals are evaluated. The pacing threshold search and testing of the capture response functions can only be executed after the signal quality has been successfully tested.

Pacing threshold search
  — This function automatically and periodically determines the pacing threshold as well as the resulting pacing parameters.

Adjustment of the amplitude if ATM has not been set:
  — This function continuously adapts the pulse amplitude to the results of the pacing threshold measurement. Automatic increase of the pulse amplitude by an adjustable safety margin guarantees safe pacing.

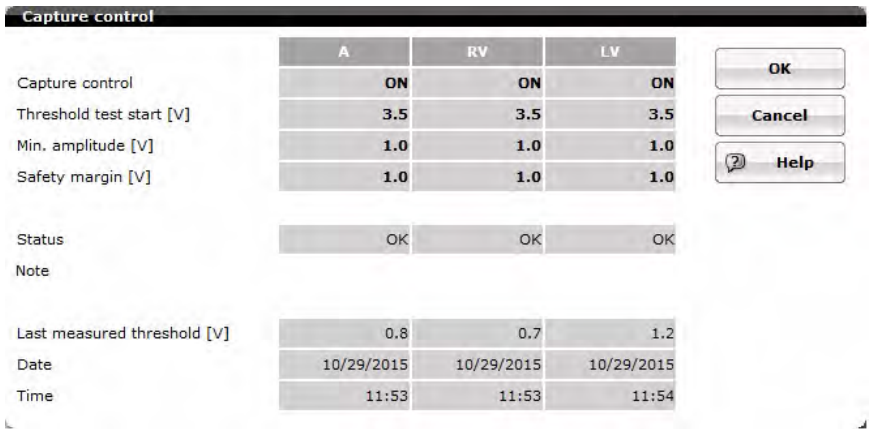
Setting parameters

Setting Capture Control, p. 152

Setting Capture Control

Navigation: Parameters → Bradycardia/CRT → Capture control

User interface



Note: Capture control is available only for the RV and BiV ventricular pacing modes.

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.

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.
`Status`	Display capture control status, p. 153
`Last measured threshold`	

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.
Determining the right ventricular pacing threshold	Ventricular pacing is temporarily set to right ventricular.
Determining 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.
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
Active capturecontrol	ON; OFF; ATM (monitoring only)
Minimum amplitude (atrial)	0.5 ... (0.25) ... 4 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.
Threshold test start (maximum ventricular and atrial amplitude)	2.5... (0.5)... 5 V
Minimum ventricular amplitude	1 ... (0.25) ... 4 V 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.
Safety margins of the ventricular and atrial pulse amplitudes	Atrial safety margin: 0.5, 1.0, 1.2 V Ventricular safety margin: 1.0, 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
Active capturecontrol	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.

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 beat-to-beat measurements 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 2.5 V increases the chances of success because the polarization artifacts are smaller in the leads. In addition to this, it makes the test faster.

5.8 Antitachycardia Functions

What's in this section?

Behavior Upon Reaching the Upper Tracking Rate

Upper tracking rate

In the atrial-controlled dual-chamber modes, the upper tracking rate (UTR) along with the atrial refractory period and the PVARP determines the maximum ventricular rate triggered by P waves.

The upper tracking rate must be set to a value tolerable by the patient for an extended period of time. The upper tracking rate determines the minimum interval between a sensed or paced event and the subsequent atrial or ventricular paced event.

A reduction of the pacing interval to correspond to that of the upper tracking rate may also be initiated at rest (e.g., upon sensing atrial extrasystoles, myopotentials, or other interference). Therefore, programming of a low upper tracking rate may be indicated for patients with increased vulnerability.

Wenckebach or 2:1

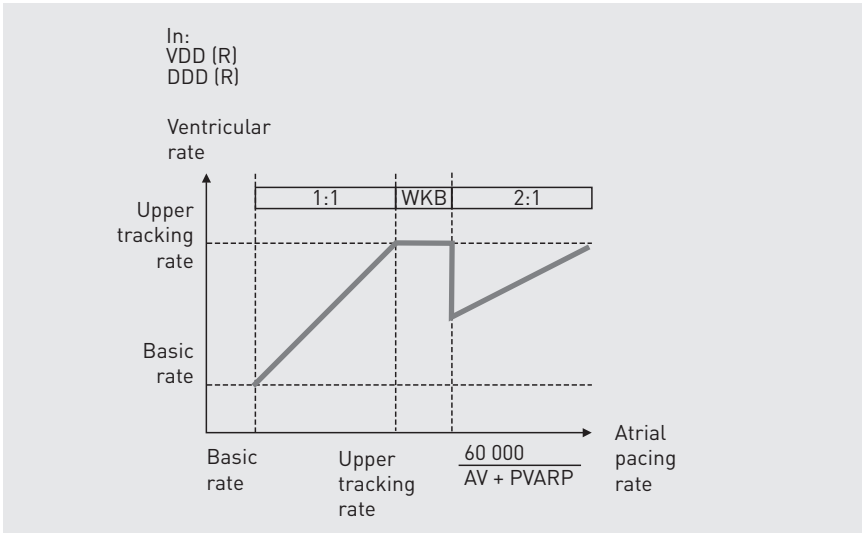
In the modes DDD(R) and VDD(R), either Wenckebach response or 2:1 response is available depending on the programming of the AV delay, the PVARP and the upper tracking interval.

Wenckebach response

- If the end of the AV delay falls in the upper tracking rate interval, ventricular pacing occurs at the end of the upper tracking rate interval.

2:1 response

- The high-rate atrial event occurs in the ARP, the FFB or the PVARP. The AV delay is not started.



Special characteristics of the Wenckebach response

As part of the Wenckebach response, the device switches to ventricular timing in addition to atrial timing. A VA interval starts after a ventricular event (Vs, Vp) to avoid extension of the Wenckebach response due to atrial timing.

The timing in the device ensures that the Vp following the VA delay and atrial pacing can be emitted at the end of the AV delay. This enables a defined exit from the Wenckebach response at any time.

In the Wenckebach response, the device counts the number of consecutive Wenckebach cycles. If more than four Wenckebach cycles are detected, a shortened VA interval is started after Vp to guarantee the constancy of the ventricular rate (rate fading).

The short VA delay in this instance is calculated from the ventricular interval of the upper tracking rate minus the AV delay (or the AV safety interval). Once the Wenckebach response has come to an end, the device counter is reset.

Upper tracking rate in the atrium

The upper tracking rate in the atrium is intended to prevent atrial pacing from being carried out during the vulnerable period after an atrial sensed event during the post-ventricular atrial refractory period. This function is intended to assure that the next atrial stimulus is delivered outside of the heart's natural atrial refractory period.

Therefore, an upper rate is started in the atrium with values of 175, 200 or 240 bpm following an AsPVARP.

The atrial intervals have the following values with four possible settings:

- OFF
- 175 bpm = 342 ms
- 200 bpm = 300 ms
- 240 bpm = 250 ms

The next Ap can only be delivered after the atrial interval has passed.

This means that atrial pacing is delayed especially in cases in which sensor rates are high.

To guarantee the stability of the ventricular rate as best possible, the AV delay can be shortened to the AV safety delay (at the most) when the basic interval is extended.

Note: If mode switching is activated, no right atrial stimulus takes place in DDI mode with activated atrial upper rate at the end of the sensor or basic interval.

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 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.

Mode Switching – Concept

Purpose The conduction of high atrial rates and atrial tachycardias to the ventricle can be effectively suppressed with a device algorithm.

This function is especially suited for patients with irregular atrial signals (atrial flutter, atrial fibrillation), thus preventing conduction of the fast atrial rate.

Description When a tachycardia episode occurs, the device automatically switches from an atrial-controlled to a ventricular-controlled mode.

Sensing is based on the continuing evaluation of the last 8 atrial intervals. When X-out-of-8 intervals reveal an atrial rate that is above the programmed intervention rate, then the onset criterion is fulfilled and mode switching automatically follows.

Atrial-controlled mode	Ventricular-controlled mode after mode switching
DDD(R), DDD-CLS, DDD(R)-ADI(R)	DDI(R)
VDD(R)	VDI(R)

The device offers algorithms that effectively suppress the conduction of high atrial rates and atrial tachycardias into the ventricle:

- Mode switching with X/Z-out-of-8 algorithm

Resynchronization The device runs in the programmed non-atrial mode as long as the deactivation criterion (Z-out-of-8) is satisfied.

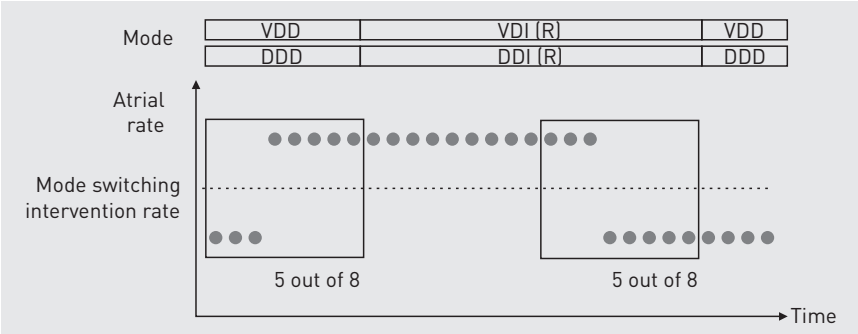
When Z out of 8 intervals lie below the programmed intervention rate, the atrial tachycardia is considered to be over, and the pacemaker automatically switches back to the originally programmed atrial-controlled mode.

The X or Z counter is reset to zero after each completed switching.

The X-out-of-8 criterion prevents unnecessary mode switching in cases of atrial extrasystoles or unstable atrial signals for example.

Furthermore, this algorithm can be employed to determine the speed at which a de- and resynchronization with ventricular depolarization takes place. The intervention rate is programmable.

Mode Switching



Post mode switching: rate and duration

In order to avoid reentry of atrial tachyarrhythmias after mode switching, DR-T and HF-T devices provide the option of pacing at a higher basic rate following resynchronization of mode switching.

The required parameters are as follows:

- Post mode switching rate
- Post mode switching duration

The ICD then generally uses the permanent program parameters for the post mode switching duration. Only the basic rate parameter corresponds to the set post mode switching rate.

Rate stabilization with mode switching

The rate stabilization with mode switching parameter uses the same algorithm as the rate fading parameter to increase and decrease the pacing rate relative to the intrinsic rhythm, Rate Fading – Rate Stabilization, p. 107.

Mode Switching

Navigation: Parameters → Bradycardia/CRT → Mode switching

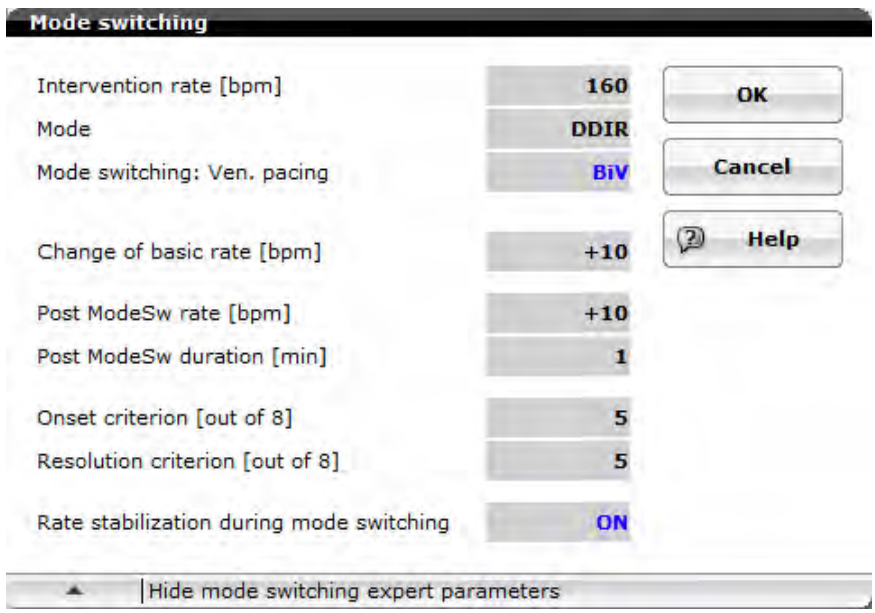
Objective

The conduction of high atrial rates and atrial tachycardias in the ventricle is prevented through the use of mode switching; e.g. from DDD to DDI on the basis of X/Z-out-of-8 detection.

Description

- An atrial tachycardia is considered detected if 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 ventricular-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 automatically into the atrial-controlled mode originally programmed.

User interface



Meaning of parameters The mode switching parameters that you need to set include the following:

Parameter	Meaning
`Intervention rate`	Rate at which an atrial tachycardia is detected.
`Mode`	The ventricular-controlled mode into which the device is required to switch.
`Mode switching: Ven. pacing`	Configuration of ventricular pacing for mode switching Set the CRT parameters: Setting Ventricular Pacing, p. 97
`Change of basic rate`	Rate for the duration of mode switching
`Post ModeSw rate`	Rate at which pacing is required after mode switching ends. This rate is higher than the basic rate and should therefore prevent any relapse of the previous atrial arrhythmias.
`Post ModeSw duration`	Duration of the post mode switching rate
`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`	Prevents any rapid fall in the ventricular rate: • To set the required ventricular rate, the sensed atrial rate is not used. Instead of the sensed atrial rate, 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.

5.9 Patient Data, Diagnostics and Home Monitoring

What's in this section?

Setting Home Monitoring

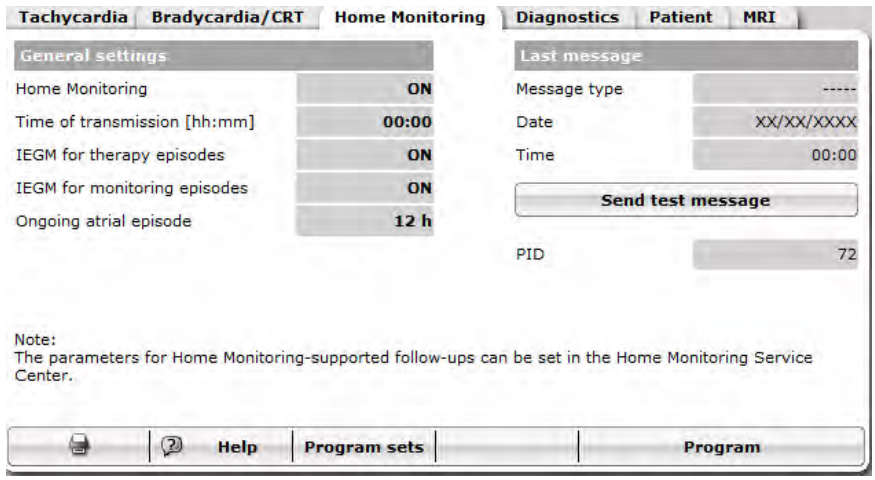
Navigation: Parameters → Home Monitoring

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 following parameters, among others, can be set in the `General settings` group box:

Parameter	Description
`Time of transmission`	Time of day at which the message from the device to the CardioMessenger and from there to the BIOTRONIK Service Center is sent. `Std.` = to a default time in the early hours of the morning – which will depend on the serial number of the device
`IEGM for therapy episodes`	Determine whether the IEGM of a therapy episode should be transmitted to the Service Center.
`IEGM for monitoring episodes`	Determine whether the IEGMs of the monitoring episodes should be transmitted to the Service Center. Monitoring episodes are episodes that are not treated with therapy, e.g. SVT, atrial episodes or VT monitoring episodes.
`Ongoing atrial episode`	Determine whether an atrial tachycardia should be considered a sustained atrial episode, and, if so, after how much time. If the system has classified an episode as sustained, this information is transmitted to the Service Center with an event message.

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 Service Center.

Setting Diagnostics Parameters

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

Recordings The following parameters, among others, can be set in the `Recording episodes` group box:

Parameter	Description
`For AT/AF`	Determine whether AT/AF episodes are to be recorded. The `Advanced ON` parameter value extends the time window for medical history.
`For SVT`	Determine in this field whether episodes classified as SVT are to be recorded.
`For nsT`	In this field, define whether or not non-sustained tachycardia (nsTs) should be counted and represented in IEGMs even when they do not fulfill the VT or VF detection criterion. For more information on nsTs see: Non-sustained Tachycardia (nsT), p. 164
`For CRT pacing interrupt`	Determine in this field whether interruptions of CRT pacing are represented in IEGMs.
`Periodic recording` [`days`]	If `Home Monitoring` = `OFF` (Setting Home Monitoring, p. 162), you can use this field to set the cycle duration of periodic IEGM recordings. The recordings are displayed under: **Recordings → Episodes**.
`IEGM configuration`	For triple-chamber devices, set the channels for recordings. `FF` indicates the far-field derivation between the RV shock coil and the housing.

Statistics In the `Statistics` group field, you can 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 so that intrinsic signals can be detected. • `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. 164

Thoracic Impedance

Navigation: Parameters → Diagnostics → Thoracic impedance (TI)

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. 192.

Details: Thoracic Impedance Measurement – Details, p. 164

Thoracic Impedance Measurement – Details

Navigation: Parameters → Diagnostics → Thoracic impedance (TI)

Technical implementation of impedance measurement

- The function is synchronized with R-waves and is based on a shock impedance measurement with sub-threshold stimuli.
- The measurement is made between the housing and the distal shock coil.
- The following is performed daily: 1024 measurement cycles per hour for 24 measurement intervals.
- The average daily impedance measurement values are stored in the ICD.
- 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. 192

Non-sustained Tachycardia (nsT)

Details

- Non-sustained tachycardia (nsT) consist of a total number of VT intervals that are shorter than the value programmed for the detection counter, and which therefore do not generate a detection.
- The nsT detection counter takes in all intervals that fall within one of the programmed tachyarrhythmia zones.
- An nsT is detected when in case of short termination (5 out of 5 non-tachycardia intervals) the nsT detection counter is greater than or equal to 1.
- Any detected nsT triggers an IEGM recording and is counted by the nsT counter.
- The total number of nsTs that have occurred during the monitoring interval is displayed as a trend.
- In this trend a distinction is made between slow and fast nsTs. For this purpose, a running mean value is created from 4 successive intervals. If the shortest mean value is less than 220 ms, then the associated nsT is considered a fast nsT and otherwise as a slow nsT.
- Counter and IEGM are transmitted to the BIOTRONIK Home Monitoring Service Center.
- When the `For nsT` parameter is set to `OFF`, then IEGM recording and the associated counters and statistics will also be switched off.
- The nsT detection counter will be reset on detection (of VT, VF, SVT, VT1 monitoring) and not incremented during the episode.

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 implanted device (e.g., 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 prior implanted 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 prior implanted device was registered with the Home Monitoring Service Center, the HMSC recognizes the device change and shows this to the HMSC user.

6 Home Monitoring

What's in this chapter?

Introduction

Patients may be followed even more effectively using BIOTRONIK's Home Monitoring function. All Home Monitoring devices are equipped with a small transmitter and are designated with the letter "T" (VR-T, VR-T DX, DR-T, HF-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.

When using BIOTRONIK Home Monitoring, the information transmitted from the device can be viewed in the Home Monitoring Service Center and printed there as a status report (PDF file). This keeps you permanently informed of your patient's cardiac status.

A transmitter receives messages from the device and transmits them to the Home Monitoring Service Center. The data is processed and made available via a secure Internet connection.

The 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 device, the transmitter, and the Home Monitoring Service Center.

Device

The power of the device's transmitter is very low so as not to affect the patient's health in any way. The resulting limited 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 at regular intervals. 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).

The device can send three different types of messages:

- Test message (triggered by the programmer)
- Trend message (daily message and Home Monitoring-supported follow-up)
- Event message

In addition, periodically recorded IEGMs can be transmitted at configurable times for Home Monitoring-supported follow-up:

- Appointments for Home Monitoring-supported follow-ups can be scheduled via the HMSC.

  For more information, see Setting Home Monitoring, p. 162, Home Monitoring-supported follow-up, p. 170

Transmitter

The transmitter (CardioMessenger® II and CardioMessenger®SMART as a mobile device or CardioMessenger® II-S as a stationary device) functions like a cellular phone and transmits the messages received from the device via the cellular phone network to the Home Monitoring Service Center. The batteries integrated in CardioMessenger® II and CardioMessenger®SMART enable battery-operated usage for 15-24 hours depending on the model. The CardioMessenger® II and CardioMessenger®SMART can, of course, also be used with the included charging station. The CardioMessenger® II-S is operated as a stationary device and is connected to the mains supply.

The Home Monitoring Service Center

At the Home Monitoring Service Center, the device messages transmitted by the transmitter are analyzed. 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 as monitoring findings on the secure Internet platform. They can trigger notifications about the receipt of the device message which are sent to the attending physician via fax, SMS or e-mail.

Internet platform

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

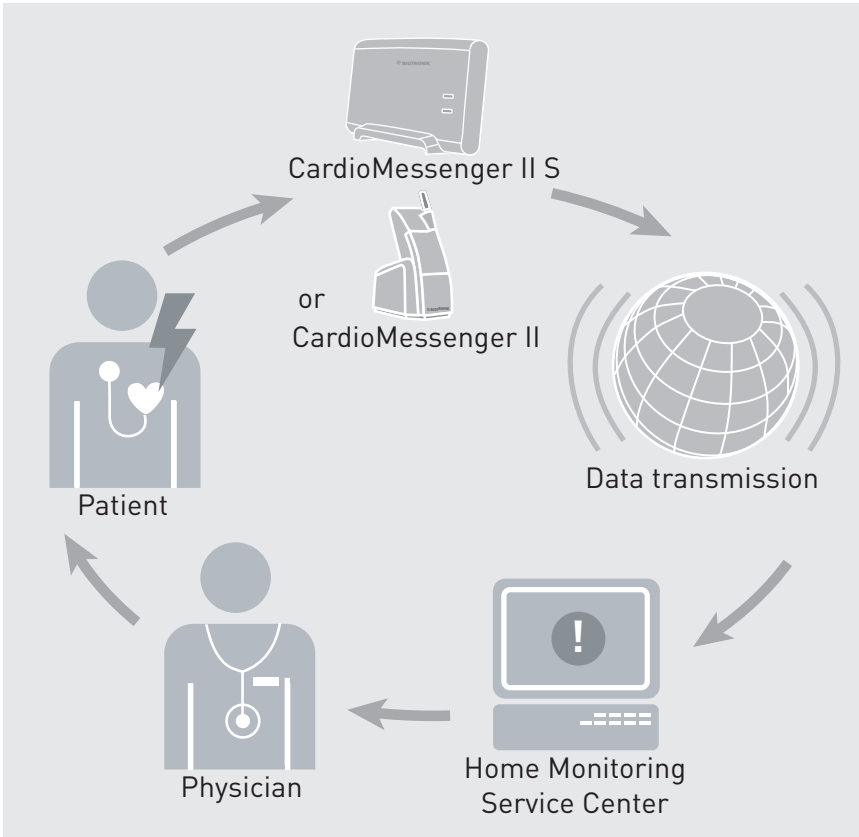
Programmer

You must activate the BIOTRONIK Home Monitoring function in the programmer and register the device with the BIOTRONIK Home Monitoring Service Center.

For more information about activating Home Monitoring on the programmer, see the technical manual of the respective programmer.

For information about registering Home Monitoring, see the technical manual for the BIOTRONIK Home Monitoring Service Center. For information about registering a device, see the online help for the Home Monitoring Service Center.

Home Monitoring concept



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 battery service time (ERI or EOS).

Contraindications

There are no contraindications for the use of the Home Monitoring Service Center 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 Internet 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

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 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 must 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, the 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 must be carried out by the physician using the programmer (in-office follow-up) approximately 3 months after implantation following the lead ingrowth phase.
- 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
- Shock impedance

Bradycardia and tachycardia rhythm and therapy monitoring:

- Sensed event and paced event counter
- Detected episodes
- Delivered therapies
- Success of ATPs and shocks

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.

Home Monitoring Parameters

Parameters: Description and settings

The meanings and settings of the Home Monitoring parameters can be found under: Setting Home Monitoring, p. 162

Types of Device Messages

Devices with the Home Monitoring function send device messages at fixed times or after certain events have occurred. Message transmission can be triggered as follows:

- Trend message
  - The time of day (daily) triggers the message.
- Event message
  - The event triggers the message.
- Message with periodic IEGM for Home Monitoring-supported follow-up

Trend message

In the programmer, you can configure the time at which the daily device message is transmitted to the patient device. The standard setting is a time during which the patient is sleeping because the patient will then be near the patient device.

This setting usually should not be changed.

The length of the time interval (monitoring interval) is not programmable, but is preset to daily. A data set is generated in the device for each monitoring interval.

Event message

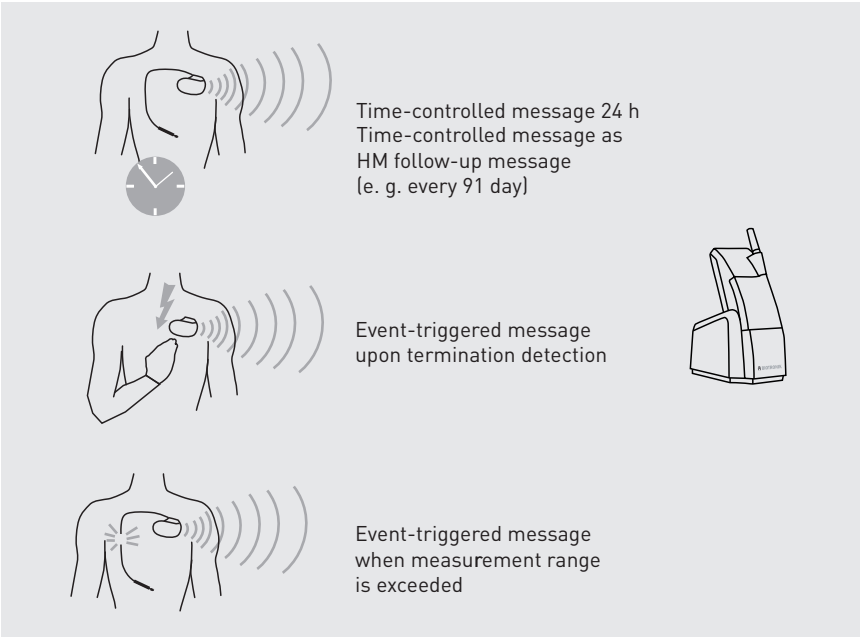
When the device detects certain cardiac and technical events, an event message is sent to the patient device. The triggering events are adjusted to the specific device. You can go to the Home Monitoring Service Center on the Internet and configure whether these events should trigger a notification and to which address the notifications are sent via e-mail, SMS or fax.

Events can trigger monitoring findings. For many events, you can select whether a red, yellow or no finding is triggered. Color coding is applied to the findings in the Home Monitoring Service Center (Internet platform). Some events (e.g., ERI) are always coded red. Notifications are sent if communication channels have been stored (e-mail, SMS, fax) and the event is coded accordingly. A notification is always sent for a red monitoring finding. With yellow monitoring findings, it depends on whether the HMSC user has set whether to receive a notification for this particular type of event.

Message with periodic IEGM for Home Monitoring-supported follow-up

This message type sends a periodically recorded IEGM and additional data from the device so that a Home Monitoring-supported follow-up can be performed. The time for this message is set either in the Home Monitoring Service Center or on the programmer's interface.

Message transmission



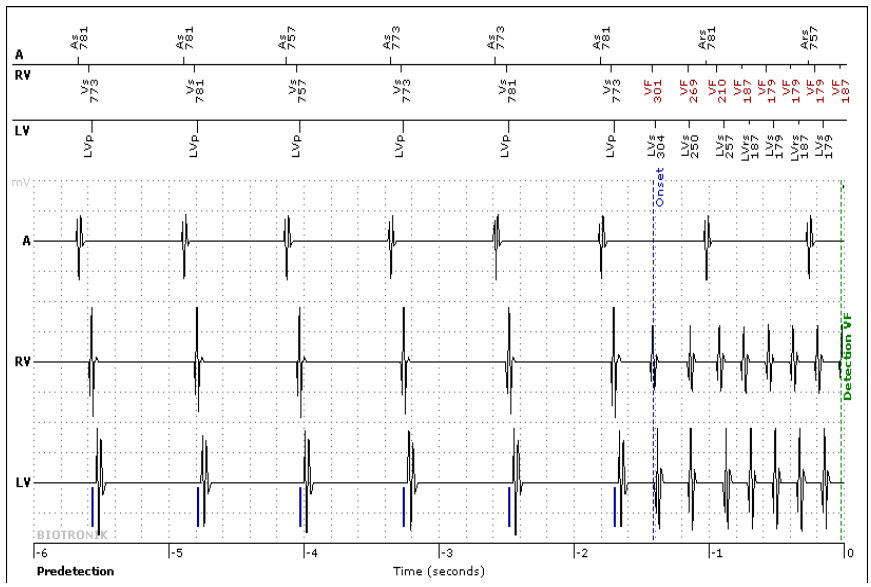
IEGM-Online® HD

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

- Episode details
- Right atrial marker channel
- Right ventricular marker channel
- Left ventricular marker channel
- Right atrial morphology
- Right ventricular morphology
- Left ventricular morphology
- Far-field (FF) ECG as a leadless ECG in place of an external ECG (recording between the housing and the shock coil) together with RA and RV morphology or RV and LV morphology.
- Transmission of up to four IEGMS daily (up to two IEGMs each for monitoring and therapy episodes with extended recording of pre-episode history)

Up to three channels are transmitted depending on the selection.

IEGM and marker channel



7 Recordings

What's in this chapter?

Objective

The Recordings function is a long-term memory that supports the therapy monitoring of ICDs with the following features:

- Storage of tachycardia events with differing origins, with IEGM recording and marker channels
- Storage of periodic IEGMs and marker channels
- Visualization of the complete shock history:
  - Shock energies and impedances
  - Charge time of all charging cycles
- Numerical list of all detections and therapies since implantation and the last follow-up

Recordings, Basics

Navigation: Recordings → Episodes

Interrogation and display

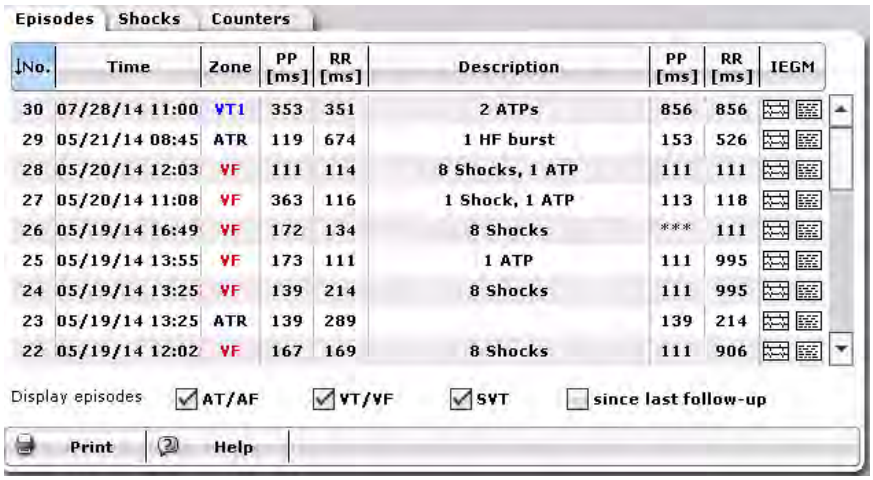
When you select **[Recordings]** the system interrogates the implanted device. The `Episodes` tab displays the result of the interrogation.

Highlighted events

Episodes or IEGMs which have not yet been opened or read are indicated in bold type in the Episodes tab.

User interface

The Episodes tab



Memory management

The recordings are summarized in a single list, which is populated from 5 separate memory segments with the following events:

- VT and VF episodes with therapy
- AT and AF episodes with therapy
- VT1 monitoring, SVT, AF and AT monitoring
- Periodic IEGM, technical recordings
- nsT

For more information see: Memory Management – Details, p. 176

When the maximum capacity of a memory segment is reached, the oldest entry is overwritten with the newest.

Memory Management – Details

Memory segment capacity

The total memory capacity is spread among the segments as follows:

Memory segment	Number of episodes	Duration (min)
VT and VF episodes with therapy	60	40
AT and AF episodes with therapy	10	4
VT1, AT, AF monitoring, SVT	20	8
Periodic IEGM, technical recordings	40	6
nsT	20	2

Technical recordings

- Between two follow-ups, the following events (only the first in case of several) trigger a recording:
  - `RV amplitude low` (= less than 1.5 x minimum threshold)
  - `Atr. pacing impedance out of range`
  - `RV pacing impedance out of range`
  - `LV pacing impedance out of range`
  - `Shock impedance out of range`
  - `Atr. threshold test unsuccessful`
  - `RV threshold test unsuccessful`
  - `LV threshold test unsuccessful`
  - `Start of RV pacing`: Applies only at basic rate, but not where there is a rate increase due to rate adaptation or where rate fading is occurring
  - > 30 short intervals within 24 h
- The following event (only the first in case of several) for the day triggers a recording:
  - `CRT pacing interrupt` Loss of BiV pacing (triple-champer devices) due to maximum ventricular trigger rate

Evaluating Episodes

Navigation: Recordings → Episodes

Sorting the displayed data

- Default setting: The entries are in chronological order. The most recently saved entry is displayed at the top of the table.
- Sort the listed entries either in ascending or descending order by clicking on the field showing the relevant column heading. An arrow next to the column header indicates the direction of sorting.

Filtering the display

Filter the episode display with the help of the check boxes in the table footer.

Information relating to episodes

Taken individually, the entries in the `Episodes` tab mean the following:

Column header	Description
`No.`	Ordinal number of the episodes in the order of occurrence
`Time`	Date and time of detection
`Zone`	Arrhythmia zone which was identified during initial detection.
`PP [ms]` (before/after therapy)	PP interval in milliseconds based on the sliding mean value of the last four PP intervals

Column header	Description
RR [ms] (before/after therapy)	RR interval in milliseconds based on the sliding mean value of the last four RR intervals
Description	• Monitoring Episode: No therapy was set for the respective zone. • Periodic recording: IEGM recording for Home Monitoring • Regular episode with therapies: — n Shocks: Number of shocks — n ATP: Number of ATPs — OFF: Magnet was applied during episode • Details on technical recordings Between two follow-ups, the following events (only the first in case of several) trigger a recording: — RV amplitude low (= less than 1.5 x minimum threshold) — Atr. pacing imp. out of range — RV pacing imp. out of range — LV pacing imp. out of range — Shock impedance out of range — Atr. threshold test unsuccessf. — RV threshold test unsuccessful — LV threshold test unsuccessful — RV lead monitoring — Start RV pacing: Applies only at basic rate, but not where there is a rate increase due to rate adaptation or where rate fading is occurring • The following event (only the first in case of several) for the day triggers a recording: — CRT pacing interrupt Loss of BiV pacing (triple-champer devices) due to maximum ventricular trigger rate

Column header	Symbol	Description
IEGM		An IEGM has been saved for the episode: Click on the icon to display the IEGM; see also: Evaluating the Episode IEGM, p. 178.
		Details have been saved for the episode: Click on the icon to display the details; see also: Episode List, Evaluating Details, p. 180.

Evaluating the Episode IEGM

Navigation: Recordings → Episodes → IEGM

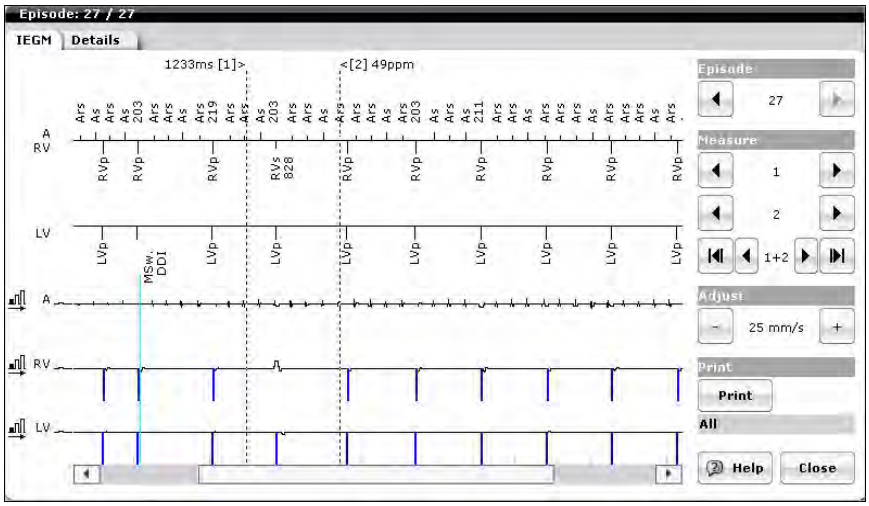
Displaying the episode IEGM

Proceed as follows:

Step	Action
1	Select the IEGM symbol in the `Episodes` tab:  .

User interface

Display of episodes – IEGMs



Legend

The IEGM shows the following information for an analysis:

Event	Marker channel	IEGM
Initial detection, redetection	• Type of detection • Detected arrhythmia zone	Vertical, dotted, green bar through all IEGM channels
Charging phase of capacitors	–	Solid, horizontal black bar above the IEGM channels
Shock	• Energy value • Impedance value	Vertical red bar in the respective IEGM channel
Paced event	• Marker • Pacing and ATP type with interval size in ms	Blue bar in the lower half of the IEGM channel (also ATP)
Sensed event (used for timing)	• Marker that is half as long as other bars • Interval size	–
Refractory sensed event (not used for timing)	• Marker that is one quarter as long as other bars • Interval size	–

Marker texts

For an explanation, see Episode List, IEGM Marker Texts, p. 179

Episode List, IEGM Marker Texts

Marker text legend The following information is displayed for an evaluation:

Group	Abbreviation	Marker
Atrium	As	Atrial sensed event
	Ars	Atrial refractory sense
	As (PVARP)	Atrial sensed event in PVARP
	Ap	Atrial paced event
	AT/AF	Detection of atrial tachycardia or atrial fibrillation
Right ventricle	RVs	Right ventricular sensed event
	RVrs	Right ventricular refractory sensed event
	RVp	Right ventricular paced event
	PVC	Premature ventricular contraction
Left ventricle	LVs	Left ventricular sensed event (LVs)
	LVp	Left ventricular paced event (LVp)
VT/VF	VT1	VT1 episode
	VT2	VT2 episode
	VF	VF episode
	AFib, AFlut, SinusT, 1:1	SVT episode
	• Det. VT1 • Det. VT2 • Det. VF • Det. SVT • Rdt. VT1 • Rdt. VT2 • Rdt. VF	VT/VF episode: • Detection • Redetection
	Term	Termination of an episode
ATP therapy	• Burst • Ramp	ATP type
Mode	Perm. + mode	Mode of permanent program
	MSw + mode	Mode after Mode Switching
	PSh + mode	Mode of post-shock program
ECG/IEGM	FF	Far-field ECG/IEGM
	A	Atrium
	RV	Right ventricle
	LV	Left ventricle

Episode List, Evaluating Details

Navigation: Recordings → Episodes

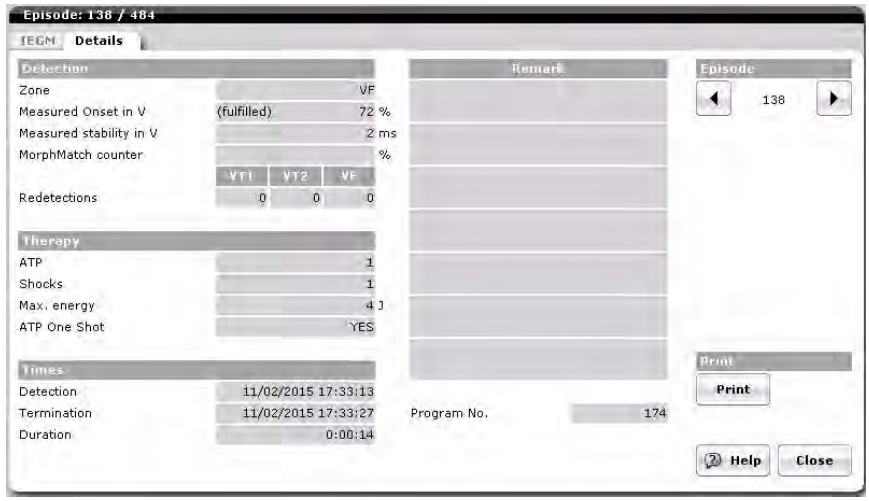
Displaying episode details

Proceed as follows:

Step	Action
1	In the episode list, select the symbol:  (See: Evaluating Episodes, p. 176).

Evaluating episode details

Display of the episode details:



The tab shows the following information for an evaluation:

Episode	Description of episode
`Zone`	Arrhythmia zone
`Measured Onset in V`	Difference in percentage between the RR interval leading to detection and the last RR mean value (calculated from the four preceding RR intervals)
`Measured stability in V`	Fluctuations of the last four tachycardia intervals
`MorphMatch counter`	Percentage of events with VT morphology out of all evaluated events in this episode
`Redetections`	Number of redetections in the arrhythmia zones
`ATP`	Number of delivered ATPs
`Shocks`	Number of delivered shocks
`Max. energy`	Maximum energy charged for therapy shocks
`ATP One Shot`	Number of ATPs delivered in VF
`Detection`	Time of detection
`Termination`	Time of termination
`Duration`	Duration of episode (between detection and termination)
`Remark`	• `Induced`: Arrhythmia triggered manually • `canceled`: Episode canceled by magnet application • Explanation of the classification of an SVT • Reference to errors detected in the IEGM recording • Details on technical triggers

Evaluating the Shock List

Navigation: Recordings → Shocks

Evaluating the shock list

Proceed as follows:

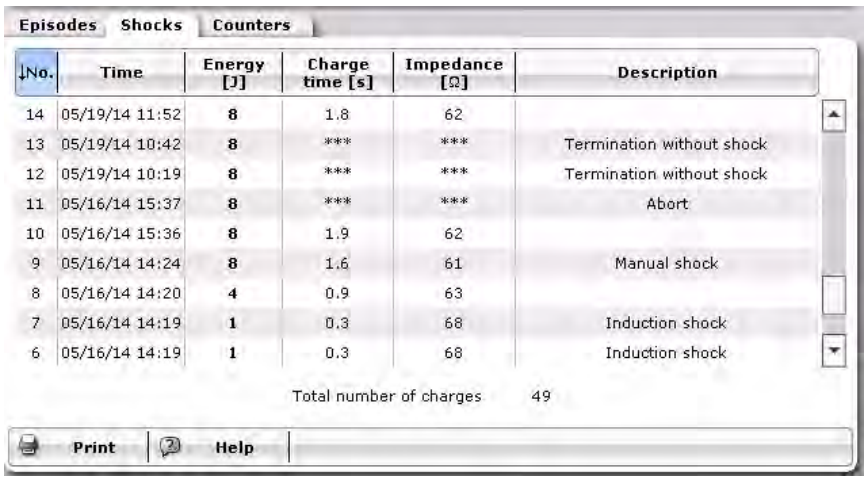
Step	Action
1	Select the Shocks tab.

Sorting the displayed data

- Default setting: The entries are in chronological order. The most recently saved entry is displayed at the top of the table.
- Sort the listed entries either in ascending or descending order by clicking on the field showing the relevant column heading. An arrow next to the column header indicates the direction of sorting.

User interface

The Shocks tab



Shock list

The displays in the shock list mean the following:

Column header	Description
No.	Ordinal number of the shocks and charges in the order of delivery
Time	Date and time of delivery
Energy	Programmed energy (in Joules)
Charge time	Capacitor charge time (in seconds)
Impedance	• Shock impedance measured during shock delivery (in Ω) • If the measured impedance is greater than 150 Ω or less than 25 Ω, the system indicates: — > 150 — < 25 • *** indicates one of the following: — Impedance invalid — Reform — Charge canceled, e.g. due to termination

Column header	Description
`Description`	• `Termination without shock`: spontaneous termination detected upon shock confirmation • `Manual shock`: The shock was triggered manually (during an electrophysiological examination) • `Induction shock`: The shock was delivered for tachycardiac induction (during an electrophysiological examination) • `Emergency shock`: Emergency shock delivered • `Automatic cap reform`: automatic capacitors loaded for maintenance • `Manual reform`: manual capacitors loaded for maintenance • `Reversed`: Shock delivered with reverse polarity • `Abort`: Shock delivered or reforming aborted

Total number of charges The total number of charges is indicated in the table footer: `Total number of charges`.

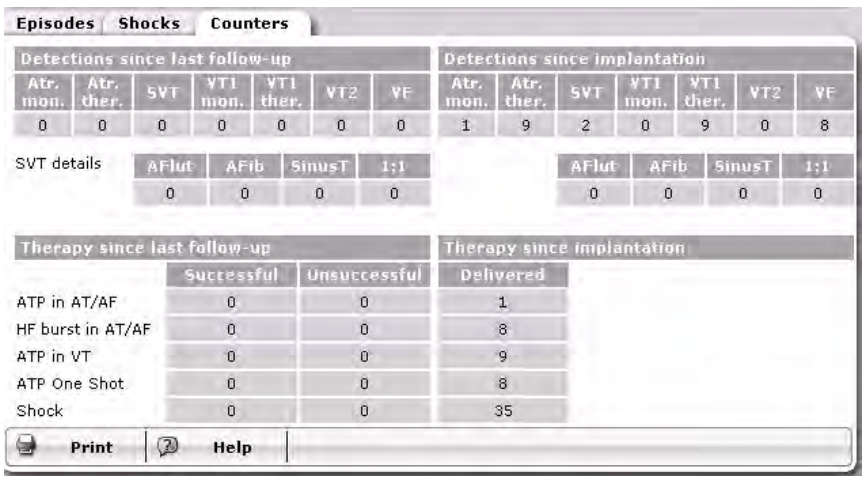
Evaluating the Counter

Navigation: Recordings → Counters

Objective Use the `Counters` tab to get an overview of the frequency and numerical distribution of the various detections and therapies.

Description The table shows counters for all detections and therapies separately for the time periods `Detections since last follow-up` and `Detections since implantation`.

User interface The `Counters` tab



The information displayed in **Detections since last follow-up** and in **Detections since implantation** as well as in the **Therapy since last follow-up** and **Therapy since implantation** have the following meaning:

Field	Classification
Zone	Arrhythmia detected in: • **Atr. mon.**: atrial tachycardia without therapy • **Atr. ther.**: atrial tachycardia • **SVT**: supraventricular tachycardia without therapy • **VT1 mon.**: ventricular tachycardia in VT1 without therapy • **VT1 ther.**: ventricular tachycardia in VT1 • **VT2**: ventricular tachycardia in VT2 • **VF**: ventricular fibrillation
SVT details	SVT diagnosed as: • **AFlut**: atrial flutter • **AFib**: atrial fibrillation • **SinusT**: sinus tachycardias • **1:1** 1:1: conductions at a ratio of 1:1
Therapy since last follow-up and **Therapy since implantation**	Delivered therapies: • **ATP in AT/AF** • **HF burst in AT/AF** • **ATP in VT** • **ATP One Shot** • **Shock** Therapy success: • **Successful**: with therapeutic success • **Unsuccessful**: without therapeutic success • **Delivered**: total

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.
- These statistics are submitted where a ventricular tachycardia episode occurs

Transmitting statistics

All statistical data are transmitted to the programmer and saved on it upon first interrogation.

General Considerations

Common features of statistics

All statistics share the following features:

- Interrogate statistics
  - The statistics memories are read when the device is initially interrogated.
- Start statistics
  - When statistics are restarted, this deletes the statistics memories in the device. However, data transmitted to the programmer beforehand remain saved there until the end of the session.
- Start and duration
  - Long-term trends have a maximum recording duration of 240 days. The first recorded data is then overwritten. The start date in all long-term trend graphs can be read on the left side. Histograms are automatically restarted with each new interrogation of the programmer. The histogram duration is displayed only in the window title on **Follow-up → Details**.
- Caliper function
  - A caliper function is provided in the statistics windows to help interpret trends and histograms. Along the displayed calipers, the absolute and percentage values of the respective statistics for the selected time or histogram class are displayed.

Recording duration of the statistics

The displayed recording duration of statistics can include the following time period:

- The time span between the start of recording and the time of interrogation

Some event counter data is recorded for the entire statistics recording period.

General notes regarding all trend statistics

The axes of the trend statistics are automatically scaled by the programmer.

The legends of the trend statistics and the histograms are automatically annotated depending on the device and the configured functions.

48-hour recordings are always up-to-date recordings of the past 48 hours:

- The oldest data is overwritten after 48 hours.

Selecting Statistics for Diagnostics

Navigation: Parameters → 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 for 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 48 h • Short-term trends (note: neutral phrasing) • 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: Parameters → 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

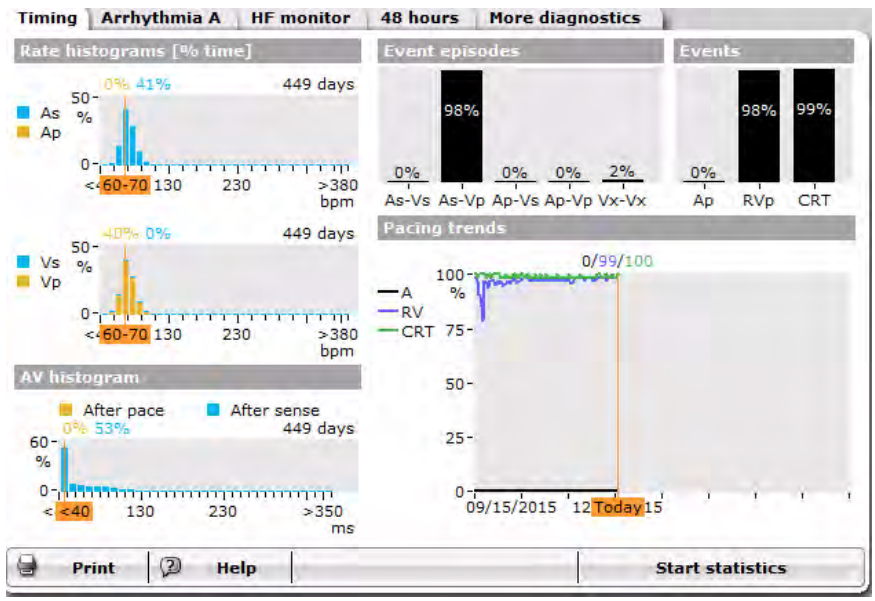
Using the histograms

A vertical auxiliary line (caliper) and, on some statistics, two 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 (caliper) 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:

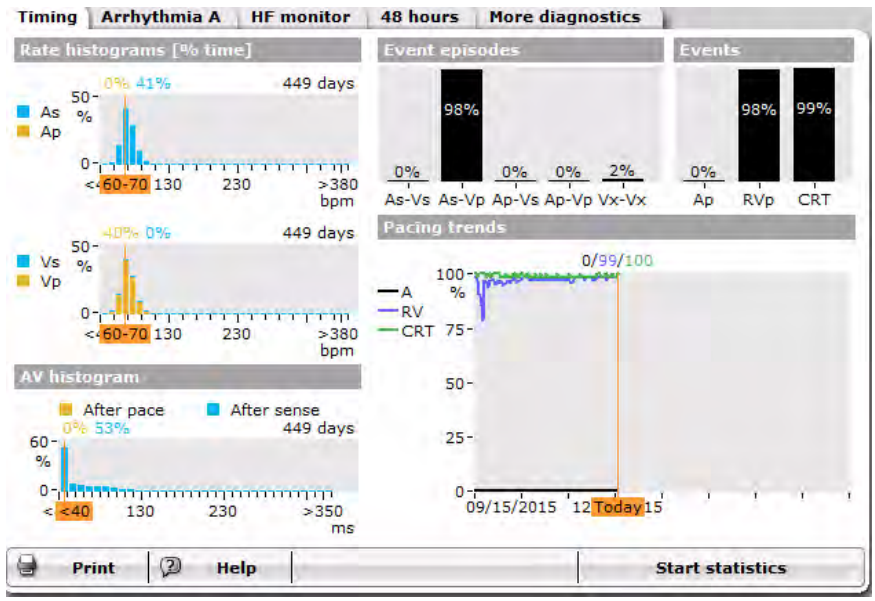
- Rate histograms
- Event episodes and events;
  see also **Follow-up → Details**: `Event episodes`
- Pacing trends as long-term trends over 240 days;
  see also **Follow-up → Details**: `Long-term trends`
- AV histograms

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:

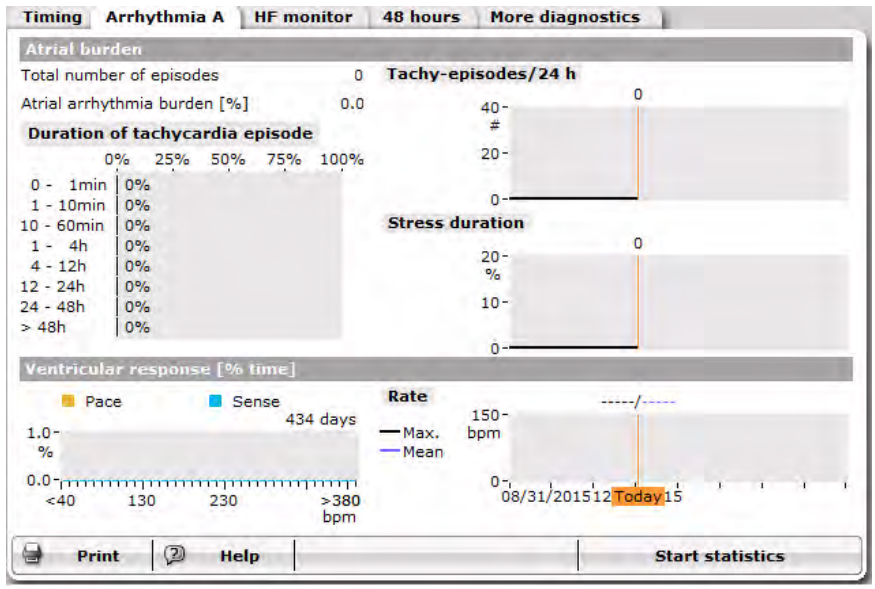
- Arrhythmia burden
  - Total number of episodes since starting the statistics
  - Accumulated arrhythmia burden expressed as a percentage since starting the statistics
  - Duration and distribution over time of episodes of tachyarrhythmia within the last follow-up period
  - Number of atrial tachyarrhythmia episodes per day
  - 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:

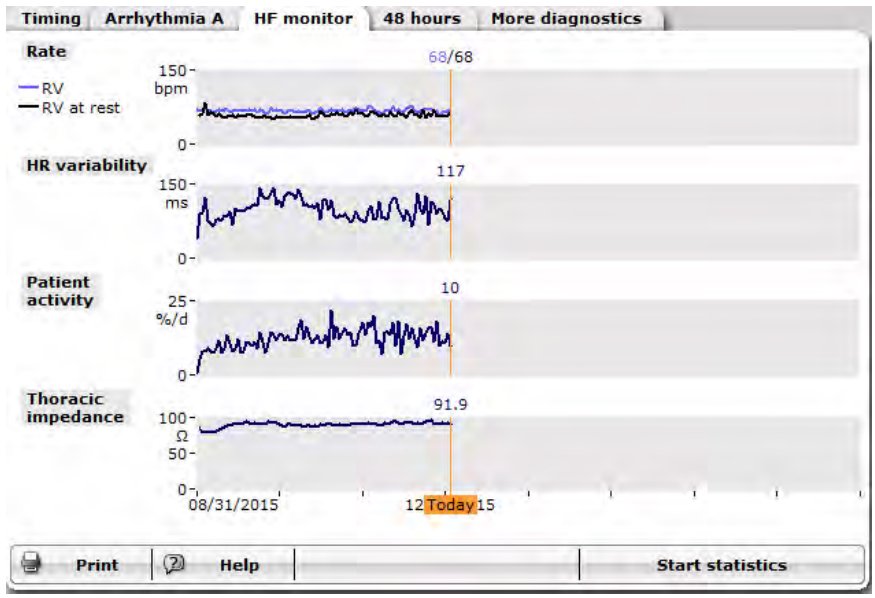
- Mean heart rate
- Mean heart rate at rest
- Variability of the mean heart rate
- Patient activity
- Thoracic impedance

Activating HF monitor statistics

Setting Diagnostics Parameters, p. 163

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.
  - Vs, Vp and Vrs (ventricular event sensed in the refractory period) recording
- 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 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 and DX).
- 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 48 Hours

Navigation: Diagnostics → 48 hours

Objective

These statistics provide important data recorded in the last 48 hours.

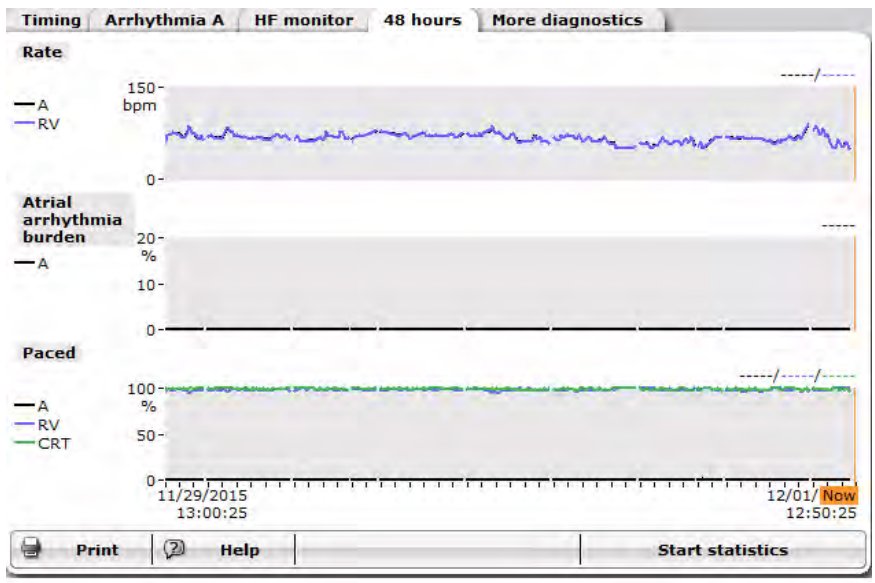
This makes it possible evaluate a summary of important data from the individual statistics (timing, atrial arrhythmia) at a glance.

The following statistics are displayed in the form of short-term trends.
- Rate trend (see also: **Diagnostics → Timing**)
- Atrial burden (see also: **Diagnostics → Arrhythmia A**)
- Percentage of pacing (see also: **Diagnostics → Timing**)

Note: The short-term trends continuously store the data from the last 48 hours. The oldest data is then overwritten.
The parameters are recorded every 10 minutes.

User interface

Short-term trends for statistics from the last 48 h



Displaying Further Statistics

Navigation: Diagnostics → More diagnostics

Overview

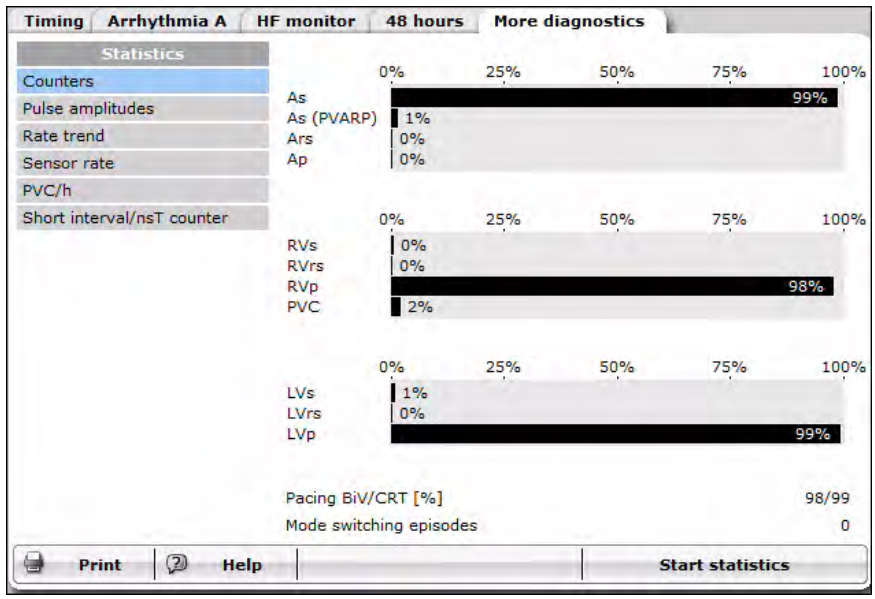
After selecting **Diagnostics → More diagnostics**, the following statistics are shown with their histograms and trends in the `Statistics` group box:

- Event counters
- Pulse amplitudes
- Rate trend with percentage of pacing
- Sensor rate
- Long-term trend PVC/h
- A counter for short intervals and a counter for nsT (non-sustained tachycardia)

  The development of both counters is displayed as a trend.

Example of event counters

The `More diagnostics` tab showing the event counter



Sensor statistics, details

The recording of the sensor rate does not depend on whether the respective pacing rate was active or whether pacing did not occur due to intrinsic events.

The sensor rate thus also shows how the device would have paced had pacing not been inhibited.

- The frequency with which the sensor rate occurs in certain rate ranges is recorded. The rate range between < 40 and > 180 bpm is subdivided into 16 equi-distant rate classes.
- The graph shows the percentages of the individual classes in the form of a bar chart as well as the total number of events.

Note: The sensor histogram is displayed whether or not a rate-adaptive pacing mode has been set.

9 System Functions

What's in this chapter?

Name of the device

The tab with the name of the implanted device being interrogated contains device-specific default settings and functions:

- Synchronizing system times
- Read ICD data
- Activate RF telemetry
- Measure the battery voltage
- Firmware version

Tab with Device Name

Navigation: More -> [Name of device]

Synchronizing the time

Where necessary, synchronize the system time for the implanted device with the time as set in the programmer.

Selecting RF or PGH telemetry

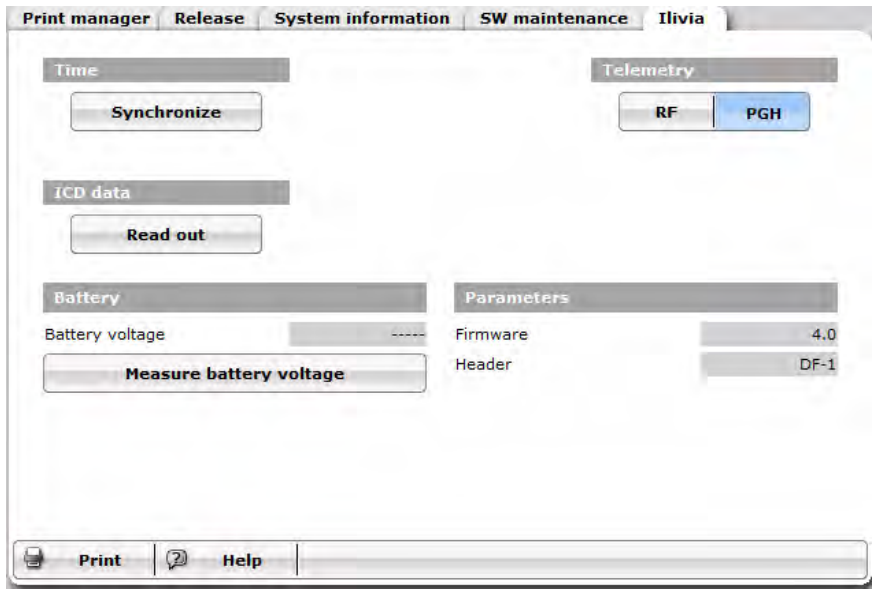
- Always apply the programming head before setting the telemetry type.
- The selected telemetry type becomes active after two seconds.

Reading ICD data (memory dump)

- Transfer the entire contents of the data storage of the device to the programmer for analysis.
- The data are saved on the programmer. From there they can be transferred onto an external storage medium (USB stick).
- The saved data can only be evaluated by BIOTRONIK employees.

User interface: Example

Ilivia tab



Measuring the battery voltage

Note: After shock delivery or capacitor reforming the battery will need some time (battery recovery time) to develop a new residual voltage. This process will modify the measured value.

- For this reason, battery voltage should be measured only at least 24 hours after the last shock delivery or capacitor reforming. Check the entries in: **Recordings → Shocks**.

Printing

By pressing **[Print]** you will obtain the following printed information:

- `Battery voltage`
- Battery ID (numbers 3 and 6)
- Details on the group box `Parameters`

III Follow-up

What's in this part?

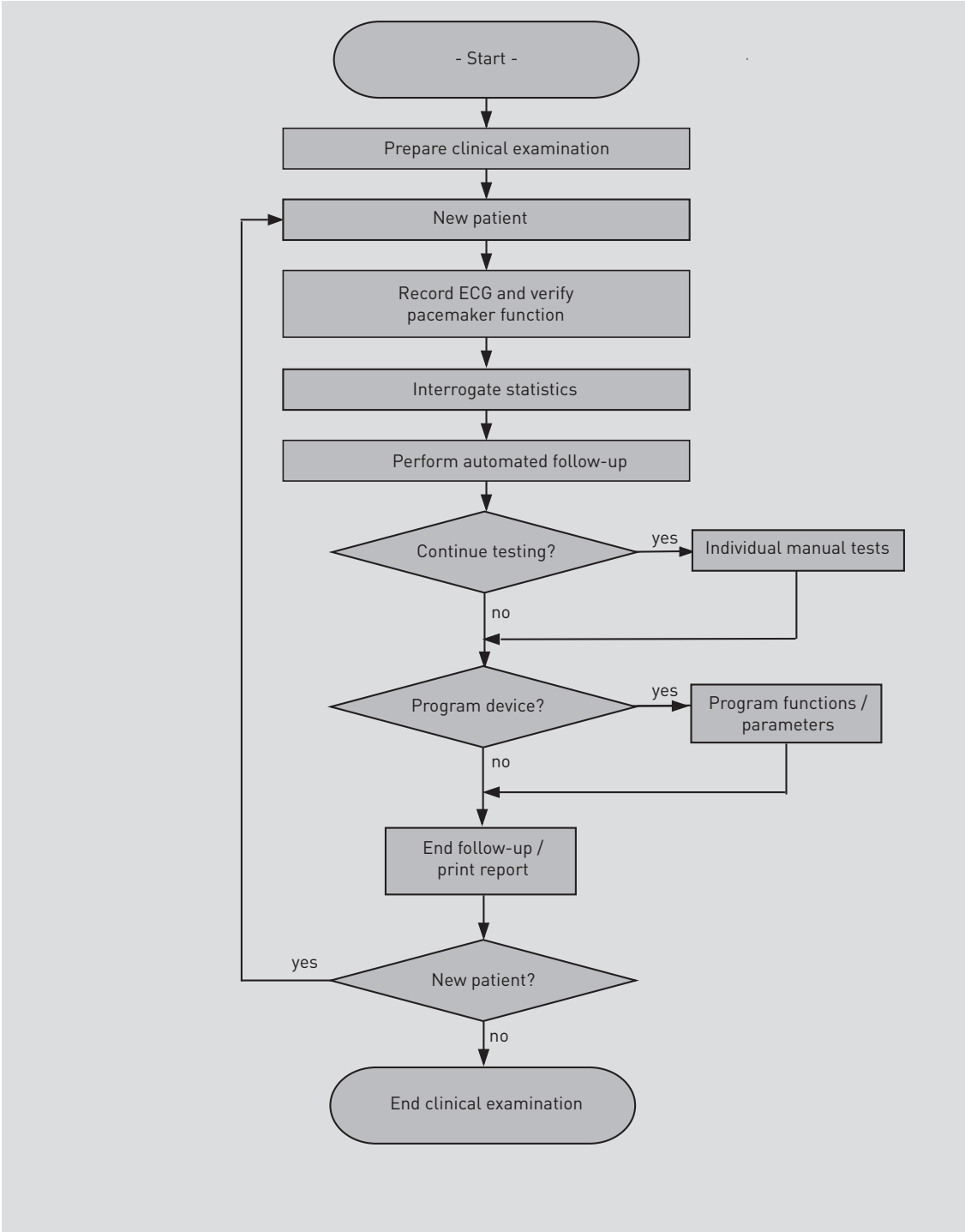
See part III of the function manual for further information on all topics related to follow-up.

10 Preparing for Follow-up

What's in this chapter?

Performing a Patient Follow-up

Recommended sequence for follow-up



Overview

Recommended sequence of steps for patient follow-up:

Sequence	Description
1	Interrogate the device.
2	Record and evaluate the ECG.
3	Check the pacing function of the device.
4	• Evaluate the status of the device and follow-up window. • As needed: — Evaluate diagnostics. — Evaluate recordings and episodes.
5	Automatically perform standard tests or alternately: initiate all the follow-up tests manually.
6	Customize the program functions and parameters (depending on the follow-up results).
7	Transmit the program permanently to the device.
8	Print (print report) and document follow-up data.
9	Finish the follow-up for this patient.

Interrogating the device

Proceed as follows:

Step	Action
1	Place the programming head of the programmer directly above the patient's device and establish RF or PGH telemetry. When using RF telemetry, you can remove the programming head again after two seconds.
2	Make sure that telemetry contact with the device has been established. When telemetry contact has been established, the following processes are performed automatically: • The device is identified. • The current (permanent) device program is interrogated. • All data stored in the device are transmitted to the programmer.

Recording and evaluating the ECG

Proceed as follows:

Step	Action
1	Connect the patient to the ECG cables in the usual manner. As an alternative, you can also use the far-field ECG function, in which the ECG is acquired wirelessly between the shock coil and housing.
2	Record the ECG and print it as needed.
3	Evaluate the ECG.

Checking the pacing function of the device

Proceed as follows:

Step	Action
1	Check the pacing function of the device.

Checking the device

After transmitting the device data, the Follow-up window is displayed on the programmer. Proceed as follows:

Step	Action
1	The events that have taken place are displayed in the `Episodes` group box on the Follow-up page in a list with the statistics symbol.
2	Select the displayed event by clicking on it. Then the statistics class, to which the displayed event belongs, is displayed. The statistics contain detailed information on the corresponding results.

Starting follow-up tests automatically

Selected follow-up tests can be started automatically and, in part, be executed automatically. The follow-up tests selected in the follow-up preferences are specially marked. Proceed as follows:

Step	Action
1	Start the tests. The sequence of the tests depends on the options offered by the device: either completely automated running in the background or partially automated as a follow-up assistant. The values measured in the individual tests are displayed in the `Test results` group field.
2	Print the contents of the Follow-up window.

Manually running follow-up tests

In addition to the standard tests that are automatically started, all follow-up tests can also be executed manually. Proceed as follows:

Step	Action
1	Select one of the tests for follow-up, start the tests, and perform the measurements.
2	As needed, select other tests and functions.
3	Evaluate the tests.

Adapting the program parameters

If the tests and measurements indicate the need to adjust program functions and parameter values, then it is necessary to change the current program and transmit it to the device. Proceed as follows:

Step	Action
1	Change the necessary parameter values and activate or deactivate the relevant program functions.
2	Transmit the new program to the device so that your chosen settings can take effect. This can also be done temporarily for test purposes.
3	Transmit the new program to the device as a permanent program by selecting **[Program]** . Successful transmission is confirmed by a message.

Printing follow-up data

Proceed as follows:

Step	Action
1	Select **[More]**. The Print/Export window will be opened.
2	Print the report of the entire follow-up **(Print/Export).**

Completing the follow-up

Proceed as follows:

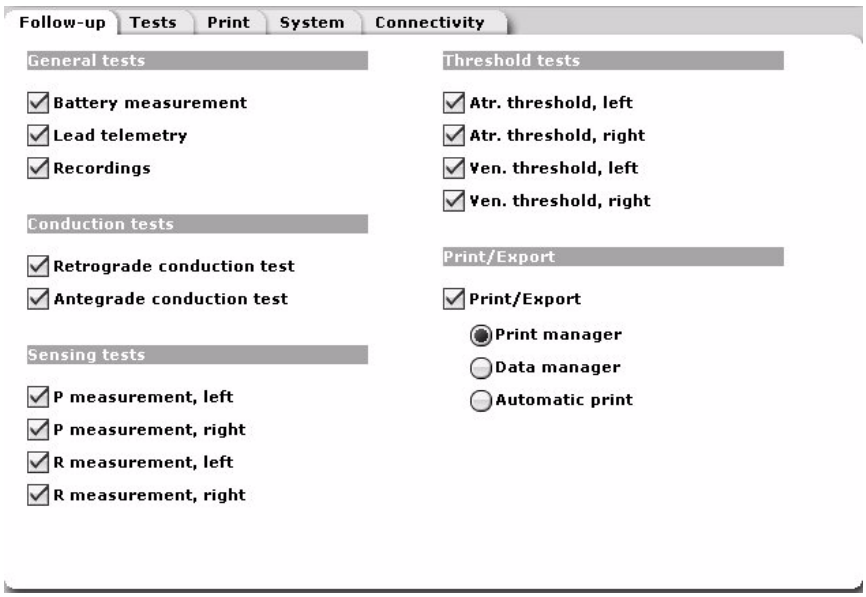
Step	Action
1	Stop the follow-up session and wandless telemetry by clicking on **[End]**.
2	The patient may now leave the follow-up session.
3	Interrogate the device of your next patient. The follow-up for the next patient is ready.
4	Proceed in the same manner as described above.

Setting a Follow-up Sequence

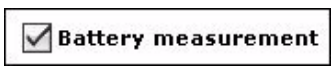
Navigation Preferences → Follow-up

Purpose Defining default settings for the follow-up sequence helps simplify implementation and supports the customer-specific process. This is possible because the customer-specific settings take effect immediately when performing the different follow-up tests and functions. This eliminates the need to configure the individual tests separately in each follow-up.

User interface Configure settings in the `Follow-up` tab:



Setting the sequence The respective check boxes are used to configure which measurements and tests (see Function of the Tests , p. 203) are performed automatically during follow-up:



The respective radio buttons are used to configure how the follow-up results are automatically output (see Setting Follow-up Results Output, p. 203)

Note: The selected option for issuing follow-up results only works if `Print/Export` is selected.

Information pertaining to the respective function of the tests Function of Parameters that Can be Set, p. 205

Function of the Tests

Function of the tests

The tests have the following functions:

Test	Function
`Battery measurement`	Measures the remaining voltage of the implanted device battery
`Lead telemetry`	Measures impedance to assess lead integrity
`Recordings`	Read recorded data
`Retrograde conduction test`	Measures the duration of the stimulus conduction from ventricle > atrium
`Antegrade conduction test`	Measures the duration of the stimulus conduction from atrium > ventricle
`P measurement, left`	Measures sensing in left atrium
`P measurement, right`	Measures sensing in right atrium
`R measurement, left`	Measures sensing in left ventricle
`R measurement, right`	Measures sensing in right ventricle
`Atr. threshold, left`	Measures pacing threshold in left atrium
`Atr. threshold, right`	Measures pacing threshold in right atrium
`Ven. threshold, left`	Measures pacing threshold in left ventricle
`Ven. threshold, right`	Measures pacing threshold in right ventricle

Function of Parameters that Can be Set, p. 205

Setting Follow-up Results Output

Navigation

Preferences → Follow-up

Requirements

The selected option for issuing follow-up results only works if `Print/Export` is selected.

Function of the options

The options have the following function:

Option	Function
`Print manager`	The results are displayed for printing in the print manager after the follow-up is completed.
`Data manager`	The results are displayed for export in the data manager after the follow-up is completed.
`Automatic print`	The follow-up results are printed out automatically after completion.

Setting defaults for provision of the results

Proceed as follows:**[Automatic print]**

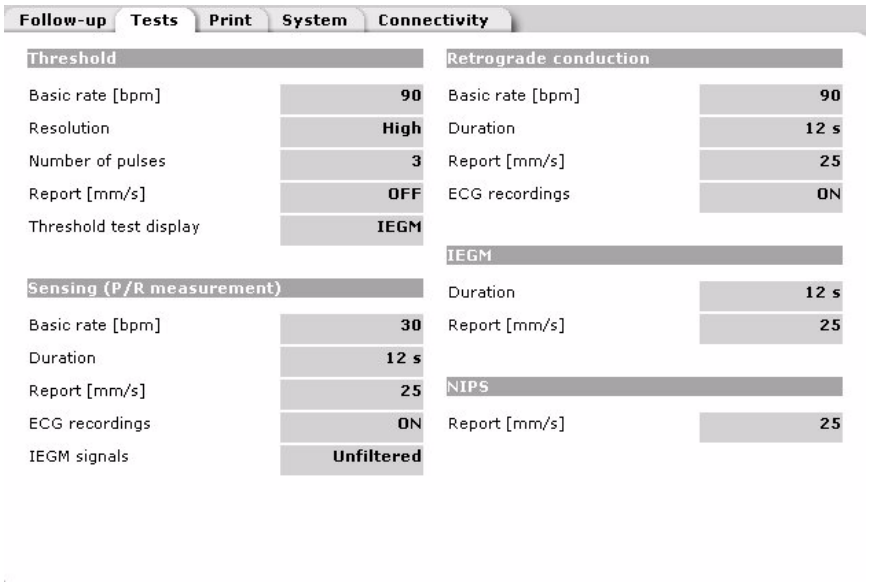
Step	Action
1	Select the radio buttons.

Setting Default Parameters for Tests

Navigation Preferences → Tests

Purpose To simplify follow-ups using system default settings

User interface The `Tests` tab:



Sequence Set:

Sequence	Description
1	Select parameter
2	Select value from window

The selected value is immediately applied and is set as the default setting for the next system startup.

Further details Information about the parameters in detail: Function of Parameters that Can be Set, p. 205

Function of Parameters that Can be Set

Function of the parameters

Parameter	Function
`Basic rate`	The rate at which the device delivers pulses in the absence of sensed intrinsic events or if the sensing function is deactivated. To run the test effectively, the pacing rate of the threshold test must be higher than the patient's intrinsic rate.
`Resolution`	Range of values: `Low`, `Medium`, `High`
`Number of pulses`	The parameter determines the number of test pulses triggered. When activated, this function ensures that the patient will remain without pacing for no longer than the set number of test pulses after falling below the pacing threshold. After each of the programmed number of test pulses, the pacemaker automatically returns to a safe start amplitude.
`Print setup`	The parameter controls automatic printing of ECG and IEGM as well as the paper speed while performing the respective tests.
`Threshold test display`	Displays the ECG or IEGM
`Duration`	Period in which certain implanted devices use IEGM for measurement.
`ECG recordings`	It is possible to record the last 60 seconds of the ongoing IEGM, save it as a file and then archive it using the Freeze function. Markers and surface ECGs are also stored together with the IEGM.
`IEGM signals`	Range of values: `Filtered`, `Unfiltered`

11 Follow-up Assistant

What's in this chapter?

Objective

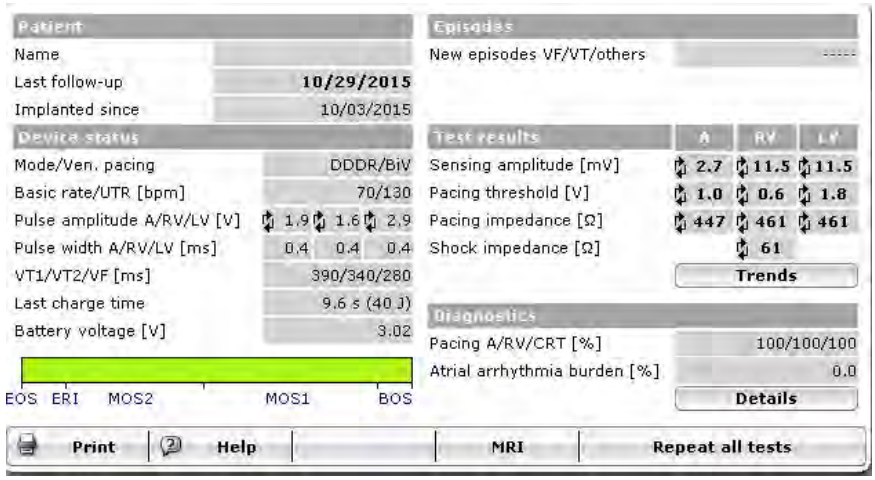
The follow-up assistant helps the user to conduct follow-ups effectively. The system can execute the following actions from the dialog:

- Provide an overview of patient and implant status
- Display episodes and events from previous follow-up periods and open the relevant linked program page by clicking
- Display test results and trends
- Display important diagnostic information and details
- Start tests
- Navigate to the MRI program
- Print a follow-up report

Follow-up Window

Navigation: Follow-up

Display 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. 208

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 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 **[Repeat all 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. 210

Diagnostics: Details Details of Diagnostics, p. 213

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
MOS1	Middle of Service 1: • 90% to 40% residual charge
MOS2	Middle of Service 2: • < 40% residual charge
ERI	Elective Replacement Indication (i.e., RRT: Recommended Replacement Time): • indicates 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 following symbols mean the following:

Symbol	Meaning
	Values for the last 24 hours have been automatically measured and updated.

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.

Display event details

Click on the event being displayed to review its details.

Event messages

Meaning of Event Messages, p. 209

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.

Priority	Event text	Meaning
1	`EOS occurred`	End of service: Service life of the device has ended
2	`Device error`	Device error has occurred; contact BIOTRONIK.
3	`Elev. power consumpt.`	Elevated power consumption has occurred. Check impedances and leads.
4	`Shocks in backup mode`	Backup mode is operated with a limit in the VF zone of 150 bpm, or 400 ms, which may under some circumstances deviate from the originally programmed limit in the zone.
5	`Low shock impedance detected. Shock path integrity can no longer be guaranteed. Please contact BIOTRONIK.`	Low shock impedance was detected. The integrity (reliability) of the shock path can no longer be ensured. Contact BIOTRONIK.
6	`Check shock impedance`	Critical concern regarding measured shock impedance: Check the lead and review if necessary.
7	`Check pacing impedance`	Critical concern regarding pacing impedance: Check the lead(s) and revise if necessary.
8	`ERI occurred`	Elective replacement indication: indicates device must be replaced.
9	`Very low RV sense amplitudes`	Critical concern regarding signal amplitude: Check the leads and reposition if necessary.
10	`Ineffective max. energy shock`	Maximum energy shock had no effect: Check DFT.
11	`Episode with multiple shocks`	Critical episode: Check recordings and modify programming if necessary.
12	`Ven. episode with ven. acceleration`	Critical episode: Check recordings and modify programming if necessary.
13	`Ven. episode with atr. acceleration`	Critical episode: Check recordings and modify programming if necessary.
14	`Ven. episode (> 1 min)`	Ventricular episode lasted longer than 1 min.
15	`Ven. episode (> 3 in 24 h)`	More than three ventricular episodes occurred within 24 h.

Priority	Event text	Meaning
16	`Atr. therapies blocked due to VT/VF`	An atrial therapy may possibly have increased the ventricular rate in a VT or VF zone. Therefore, AT therapies have been deactivated. During follow-up: Decide on the reactivation of AT therapies.
17	`SVT episode (> 10 min)`	Supraventricular episode lasted longer than 10 min.
18	`Atr. therapies blocked due to Afib > 48h`	An atrial therapy took longer than 48 h and increased the risk of cerebrovascular stroke significantly. Therefore, AT therapies have been deactivated. During follow-up: Decide on the reactivation of AT therapies.
19	`> 48 h Afib since start of statistics`	Sustained atrial episode > 48 h detected since start of statistics.
20	`Shipment mode active`	The manufacturer has set the device to shipment mode to conserve energy. Deactivate shipment mode before completing the implantation procedure.

Evaluate Trends in Measured Values

Navigation: Follow-up → Trends

Display trends

The Trends function provides a structured overview of important measured values, which are displayed as graphic trends since the last follow-up.

- Pacing thresholds
- P/R amplitudes
- Pacing impedance in the atrium and ventricle
- Shock impedance in the ventricle

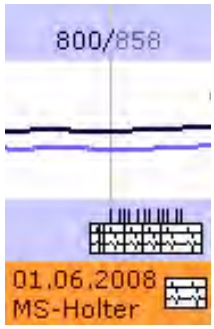
You can use the Trends function to navigate and to take a focused look at particular individual events.

Events from the event list are shown directly under the cursor in the `Trends` window, together with a comment and the date upon which they occurred.

- 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 recording of long-term trends to restart recording here: **Diagnostics → Start statistics**.

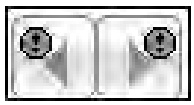
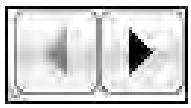
Results icons

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

Impedance Trends – Details, p. 211

Pacing Thresholds, P and R Wave Amplitudes – Details, p. 212

Impedance Trends – Details

Navigation: Follow-up → Trends

Time window and resolution

The following impedance trends are displayed for up to 240 days with a preset resolution of 24 hours:

- Atrial impedance trend
- Right ventricular impedance trend
- Left ventricular impedance trend
- Shock impedance trend

Details

- Impedances are measured automatically. Measurement cannot be turned on or off.
- The daily value shown is the mean value from 4 measurements taken automatically on the device within a 24 h period.
- Sub-threshold shock impedance measurement is performed with the set lead polarity.
- If any measurement result taken within the recording period of 24 h is lying 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.

Pacing Thresholds, P and R Wave Amplitudes – Details

Navigation: Follow-up → Trends

Pacing threshold trends

Enable the function for recording threshold trends here: **Parameters → Bradycardia/CRT → Capture control → ON** or -> **ATM** (for 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 → Follow-up

Objective

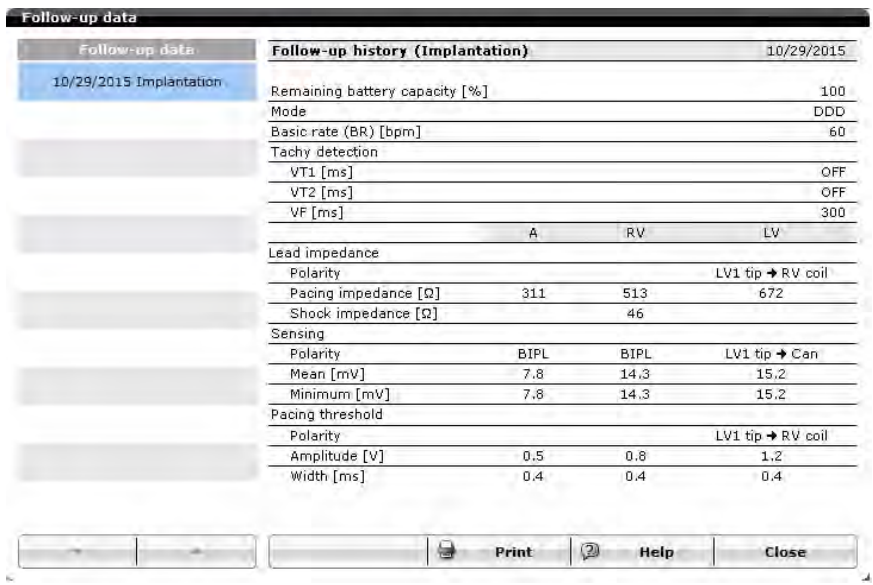
The archive offers you a structured overview of the chronological development of lead measurement values and the left ventricular polarity set for triple-chamber devices since implantation.

In addition, the data is shown for:

- Remaining battery capacity
- Modes
- Basic rate
- Arrhythmia zones

User interface

The `History` window



- The values determined upon implantation and those of the 11 subsequent follow-ups are displayed.
- When 11 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.

Details of Diagnostics

Navigation: Follow-up → Diagnostics

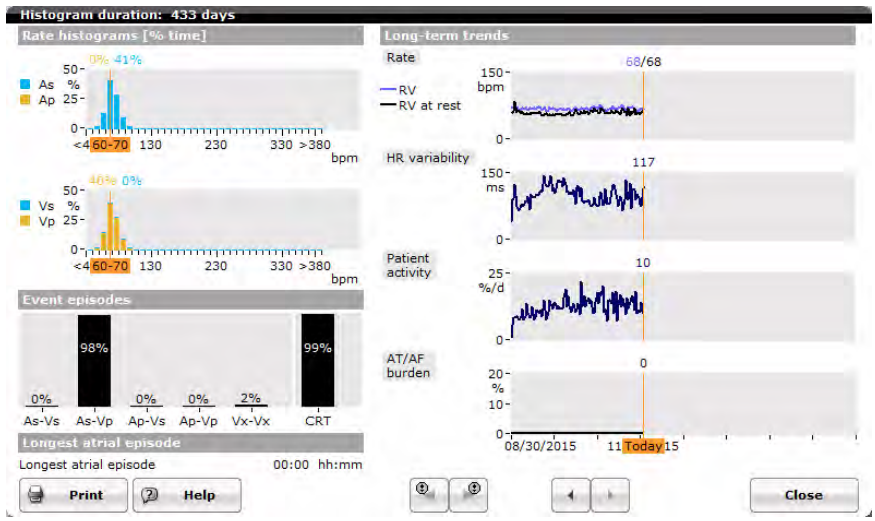
Objective

In the `Follow-up` window in the `Diagnostics` group box 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.

Note: The long-term trends save the data continuously and, unlike all histograms of the statistics, are not reinitialized each time the device is interrogated.

User interface

Details of diagnostics; histograms and trends



Display details

In the `Follow-up` window select from the `Diagnostics` group box: **[Details]**.

12 Performing Manual Follow-up

What's in this chapter?

12.1 Test Function Overview

What's in this section?

Electrophysiological Tests

You can use the electrophysiological tests to determine and test effective detection and therapy parameters.

During the course of the various tests, the intrinsic events of the patient and the detection of the ICD can be monitored continually via IEGM and marker texts.

Impedance Test

The pacing impedance measurement is used to determine the electrical resistance of the lead system. This value serves to check the condition and position of the lead (e.g. in case of lead fracture) for effective pacing.

Automatic:

The device automatically measures the pacing impedance in the programmed pacing configuration four times per day in each active channel (A, RV, LV). Measurement is carried out after the episode in cases of tachyarrhythmia (VT, VF). The measurement is performed using below-threshold pulses regardless of whether pacing is being performed.

Results of automatic measurement of pacing impedance (200 to 3000 Ohm) are presented in the impedance statistics and transmitted via Home Monitoring. In the case of invalid measurement values, an event message is sent via Home Monitoring.

Manual:

The pacing impedance can also be measured manually in each follow-up using the programmer's test function. The programmer shows the current measured value of the last measurement cycle in each case.

Sensing test

The sensing test determines the current P and R-wave amplitudes of the intrinsic events in all active channels. This lead position information provides the requirements for further system tests.

Automatic:

The device automatically measures the P and R-wave amplitudes in each active channel (A, RV, LV) four times each day. Measurement is carried out after the episode in cases of tachyarrhythmia (VT, VF).

Valid results of automatic measurement of unfiltered amplitudes (P wave: 0.5 to 8 mV; R-wave amplitude: 2 to 20 mV) are presented in the sensing statistics and transmitted via Home Monitoring. In the case of invalid measurement values, an event message is sent via Home Monitoring. In biventricular and left ventricular mode, the right ventricular sensed events are not triggered. This allows only intrinsic events to be considered for the sensing test.

Manual:

P/R wave amplitudes can also be measured manually in each follow-up using the programmer's test function. Six sensed events are evaluated in the manual and automatic sensing test. The display is updated with every new measured value. The programmer indicates if no sensed events occur.

Threshold test

The threshold test determines the lowest pacing energy needed to pace the heart in all active channels. In the threshold test, either the pulse amplitude or the pulse width is reduced until pacing no longer triggers a response from the heart. The next highest value that effectively paces the heart is the threshold. Low values for the pulse width or the pulse amplitudes increase the device's longevity.

DFT test

The defibrillation threshold is the least required shock energy to successfully terminate a tachyarrhythmia.

The DFT test is used to determine the patient's defibrillation threshold.

During the DFT test, a temporary program is started for VF therapy that can be configured with different detection and therapy parameters than the permanent program.

Programmed bursts or T-wave synchronized shocks are delivered for inducing VT or VF. Manually or automatically delivered therapies (ATP or shock) are then tested for terminating the induced arrhythmias. If necessary, you can specifically deliver an emergency shock at maximum energy.

Painless shock impedance test

Measurement of shock impedance determines the electrical resistance between the shock coil and housing. This value serves to check the condition (in case of lead fracture) of the lead for effective shock therapy.

Automatic painless shock impedance measurement:

The device automatically measures the shock impedance four times per day. Measurement is carried out after the episode in cases of tachyarrhythmia (VT, VF). Measurement is carried out with below-threshold electrical pulses of 1 mA and is synchronized with a ventricular event. A measurement cycle consists of three measurements so that an average can be determined to compensate for the impact of IEGM signals.

Painless shock impedance measurement is carried out automatically four times per day. A daily mean value is formed from the four measurement values.

Results of automatic shock impedance measurement (25 to 150 Ω) are presented in the impedance statistics and transmitted via Home Monitoring.

Manual:

Shock impedance can also be measured manually in each follow-up using the programmer's test function. The programmer shows the current measured value of the last measurement cycle in each case.

Test of conduction times

Determining and evaluating conduction times forms a foundation for setting timing parameters that affect sensing and pacing between the right atrium and right ventricle as well as between the right and left ventricles. Change the timing parameters in order to prevent pacemaker-mediated tachychardias and to optimize patient hemodynamics.

12.2 Impedance Test

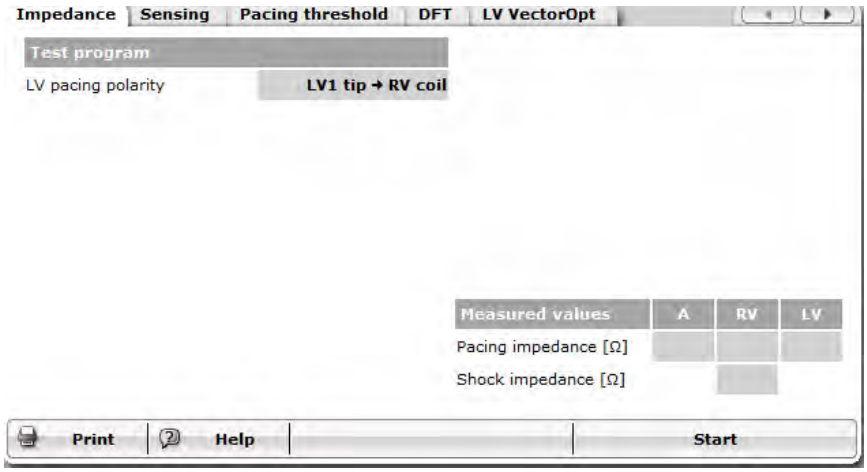
What's in this section?

Objective

- The impedance measurement is used to determine the electrical resistance for the pacing impedance and shock impedance of the implanted leads.
- The measured values serve to check the leads (e.g., 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 A communication error 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.

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 shock impedance • Measuring the pacing impedance • Displaying measured values

Results Evaluate the results and reposition the leads if necessary.

12.3 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
- Creation of good prerequisites for additional electrophysiological tests
- Determination of optimal sensitivity for the device

WARNING
Interrupted telemetry can cause incorrect data display A communication error 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.

Note: Switch on sensing for the relevant chamber: **Parameters → Bradycardia/ CRT → Sensing**.

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 the **[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	Conclude the intrinsic rhythm test by releasing the **[Intrinsic rhythm]** button.	The permanent program is active again.

Details: Sensing Test – Details, p. 222

Sensing Test – Details

Navigation: Tests → Sensing

Measurement of R amplitudes

During manual sensing testing, an evaluation is made either once for each channel or for a maximum of 6 detected events with a maximum duration of 5 sec. 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

12.4 Threshold Test

What's in this section?

Conducting the Threshold Test

Navigation: Tests → Pacing 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

A communication error 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.

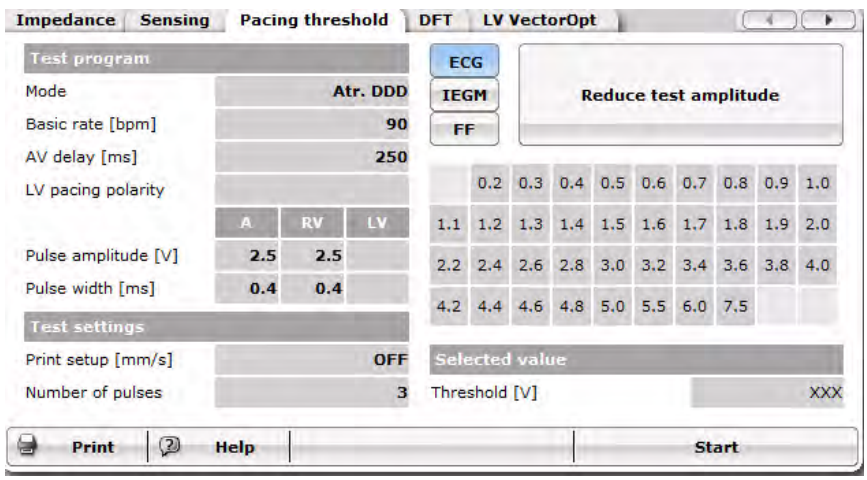
WARNING

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 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 text, observe the ECG monitor to obtain the pacing threshold and to modify the test amplitude if a particular pacing pulse is no longer effective. See also: Select test amplitude, p. 225
4	Press the **[Stop]** button when you want to stop the test.
5	Accept the measured pacing threshold by selecting the value in the `Threshold` window.

Note: Set the derivation for the test signal required specifically in each case by **[ECG]**, **[IEGM]** and **[FF]** for Far-field ECG (leadless ECG).

Select test amplitude

Choose from the following options:

Select a test amplitude from the table	The selected test amplitude will be applied.
Reduce the test amplitude one step at a time	Briefly press the **[Reduce test amplitude]** button: • The test amplitude is decreased by one step. As long as the test pulses are active, they are displayed for test pulses under the ECG Flash window. See also: Show and hide Flash windows, p. 225
Reduce test amplitude automatically	Hold down **[Reduce test amplitude]**: • The test amplitude will be reduced automatically as long as you continue to hold the button down. The reduction process is controlled by the `Number of pulses` parameter. • Release the button as soon as the value is lower than the pacing threshold: The safe start amplitude will become active immediately.

Show and hide Flash windows

In the ECG windows, Flash 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 → Pacing 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.
Number of pulses	• After each of the programmed number of test pulses, the pacemaker automatically returns to a safe start amplitude. • Where the threshold is not reached, the patient is left without effective pacing for the set number of test pulses at most. • Where the (∞) function is disabled, the set test pulse remains active until the next value is set or the threshold test is completed.
Print setup mm/s]	Feed velocity for printout of ECGs
[ECG] (with Flash window = ON)*	Conventional Einthoven-based ECG
[IEGM] (with Flash window = ON)*	Intracardiac electrogram
[FF] (with Flash window = ON)*	Far-field ECG: wireless far-field derivation between distal shock coil and housing; for left-side implantation of the ICD this corresponds to Einthoven's Derivation III

*** Flash window**

Show and hide Flash windows, p. 225

12.5 Determining the Defibrillation Threshold (DFT Test)

What's in this section?

Definition

The defibrillation threshold is the lowest required energy to successfully terminate a tachyarrhythmia.

Objective

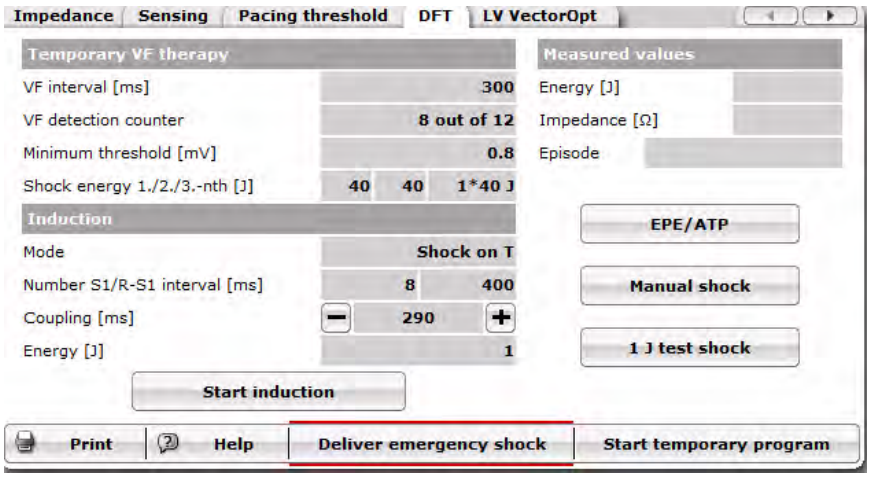
You can obtain the defibrillation threshold with the help of the DFT (defibrillation threshold) test.

The results of the DFT test can be used to program the ICD so that it can usually terminate VT/VF episodes requiring therapy with the first shock and with optimal energy utilization.

In addition to this, it is possible to conduct electrophysiological examinations (EP studies)

User interface

The **DFT** tab



Preparation of the DFT Test

Evaluating the system integrity of the shock coil

The painless shock impedance measurement is available as an alternative to the 1 J test shock.

To conduct the measurement, select **Tests → Impedance → Start**. The measured values for shock impedance and pacing impedance are displayed in the `Measured values` group box.

VT/VF Induction

Navigation: Tests → Induction

Objective

A VF is induced for the DFT test in order to test the effectiveness of therapy parameters for detection and termination of tachyarrhythmias.

Mode

The following modes are available for VF induction:

Induction modes	Description
`HF burst`	Burst with high rate
`Shock on T`	Shock at the end of a burst, synchronized with a T-wave

HF burst

The following parameters are available for the HF burst:

Parameter	Description
`Duration`	HF burst duration Alter the duration of the HF burst interactively: • To extend it: Hold down the **[Deliver HF burst]** button • Complete the change: Release the **[Deliver HF burst]** button
`Rate`	HF burst rate

Shock on T

The following parameters are available for the shock on T:

Parameter	Description
`Number S1`	Number of S1 stimuli for the burst
`R-S1 interval`	Start interval with which the system couples the burst to the R-wave
`Coupling`	Interval with which the system couples the shock on T without confirmation to the last S1 stimulus of the burst
`Energy`	Total energy that the shock on T is to emit; when set to **OFF** , a burst can be delivered without a shock in order to first locate the T-wave in the IEGM.

Evaluate DFT

Navigation: Tests → DFT

Prerequisites

The following prerequisites must be met in order to carry out a DFT test:

Tested positive:

- Sensing (see Performing the Sensing Test, p. 221)
- Impedance (see Measuring Impedance, p. 219)
- Shock impedance (see Measuring Impedance, p. 219)

Parameters set for:

- Detection (see Detection Parameters, p. 47)
- ATP and therapy shock (see Tachycardia Therapy Parameters, p. 61)
- `Induction`
- `Temporary VF therapy`
- Manual shock (see Setting a Manual Shock, p. 231)

Note: The following applies to detection and therapy during the DFT test:

- Parameter values in the group box `Temporary VF therapy` are effective only temporarily, in other words, only when the temporary program has been started and for as long as it remains active.
- As soon as the DFT test has ended or the temporary program has been actively stopped, the parameters for the permanent program become effective again.
- During execution of the DFT test, ICD therapy is activated temporarily in order to test the effectiveness of the therapy.

WARNING

Increased risk of ventricular arrhythmia

During testing, the risk of inducing ventricular arrhythmia is high.

- Keep an external defibrillator at hand.

WARNING

DFT Test: Ventricular arrhythima does not terminate

If ventricular arrhythmia continues uncontrolled it will become a threat to the patient's life.

- Stop the DFT test by clicking on the following button: **[Stop temporary program]**.

  The parameters set for the permanent program will begin to apply immediately and can terminate the ventricular arrhythmia.
- If the ventricular arrhythmia continues, escalate the measures to terminate it as necessary in the following manner:
  - **Manual shock → Deliver manual shock**
  - **[Deliver emergency shock]**
  - Use an external defibrillator.

Conducting the DFT test

Step-by-step instructions: Conducting the DFT Test, p. 230

Episode details

Details on the induced episode are displayed in the `Measured values` group box in the `Episode` field:

a)	The last episode is identified by the time it occurred.	
b)		Click on the symbol to display the IEGM.

Conducting the DFT Test

Navigation: Tests → DFT

Instruction To test the DFT, proceed as follows:

Step	Action
1	Evaluate the shock impedance values measured automatically: **Follow-up → Test results → Shock impedance**. Or measure shock impedance using the 1-J test shock: **Tests → 1 J test shock → Deliver 1-J test shock**.
2	Evaluate the default settings in the `Induction` and `Temporary VF therapy` group boxes, and adjust the settings if necessary.
3	Use **[Start temporary program]** to start the temporary program.
4	Induce the tachyarrhythmia using **[Start induction]**.
5	Use **[Stop temporary program]** to stop the temporary program.
6	Evaluate the induced episode in the `Measured values` group box.

Setting Parameters for EP Studies/ATP

Navigation: Tests → DFT → EPE/ATP

Objective For EP (electrophysiological) study, you can start ATP manually for test purposes independently of whether you are using implanted device detection.

WARNING
Increased risk of ventricular arrhythmia During testing, the risk of inducing ventricular arrhythmia is high. • Keep an external defibrillator at hand.

Setting EP study/ATP Select **[EPE/ATP]** to set the parameters for ATP.

Meaning of parameters The following parameters are available for EP study/ATP:

Parameter	Description
`Type`	Burst, ramp, burst + PES
`Ventricular pacing` (Triple-chamber devices only)	The chamber in which you want pacing to take place
`Number S1`	Number of S1 stimuli of ATP
`R-S1 interval`	Start interval with which the system couples the burst to the R-wave

`S1 – S2`
`S2 – S3`
`S3 – S4`
	Intervals of extrastimuli (PES) to be coupled to the basic interval.

`S1 decrement`	Continuously reduces the pulse interval of the ATP from the second stimulus on, so that the ATP type takes on the form of a ramp.

Setting a Manual Shock

Navigation: Tests → DFT → Manual shock

Objective The manual shock is used in order to test the effectiveness of a therapy shock independently of detection by the device.

WARNING
Increased risk of ventricular arrhythmia During testing, the risk of inducing ventricular arrhythmia is high. • Keep an external defibrillator at hand.

Polarity `Normal`:

	1st phase	2nd phase
RV shock coil	Negative	Positive
SVC shock coil or active housing	Positive	Negative

`Reversed`:

	1st phase	2nd phase
RV shock coil	Positive	Negative
SVC shock coil or active housing	Negative	Positive

Shock waveform The parameter settings are defined as follows:

`Shock waveform`	`Biphasic`	`Biphasic 2`
Pause duration	1 ms	1 ms
Energy	Variable	Variable
End voltage 1st phase	40%	40%
Time 1st phase	Max. 23 ms	Max. 23 ms
End voltage 2nd phase	20%	Variable
Time 2nd phase	Max. 17 ms	2 ms

Rapid Pacing

Navigation: Tests → DFT → EPE/ATP → Rapid pacing

Objective

Rapid pacing of the ventricle is used to support particular individual paces of a transcatheter heart valve implantation.

Description

- The rate range of rapid pacing is between 150 and 300 bpm.
- You can enable or disable rapid pacing by clicking once on **[Start]** or **[Stop]**.
- The maximum duration of fast overdrive pacing can be set in advance (to a maximum of 50 s). After this time has elapsed the overdrive pacing ceases.

Note: In order to further extend the duration of overdrive pacing within 10 s of the end of the current action by an additional 10 s, press the **[+ 10 s]** button.

Note: Before you conduct rapid pacing, disable ICD therapy temporarily. Otherwise, rapid pacing will not be possible.

WARNING

Increased risk of ventricular arrhythmia

During testing, the risk of inducing ventricular arrhythmia is high.

- Keep an external defibrillator at hand.

WARNING

Critical pressure-free state of the heart

A pressure-free state of the heart is not well tolerated by patients.

- Continuously check with an ECG if the patient tolerates fast overdrive pacing.
- Expose the patient to fast overdrive pacing as briefly as possible.
- Before terminating overdrive pacing, complete the TAVI procedure.
- If needed, extend the duration of overdrive pacing.
- Reactivate ICD therapy at a clinically suitable point in time. Activating and Deactivating ICD Therapy, p. 55

12.6 NIPS – Non-Invasive Programmed Stimulation

What's in this section?

NIPS – Select Therapy

Navigation: Tests → Atr. NIPS

Objective

Pulse delivery of the device can temporarily be controlled using the programmer for the acute therapy of atrial arrhythmias.

Burst and programmed pacing is possible on the `Atr. NIPS` tab only in the atrium with multi-chamber devices.

WARNING
Triggering arrhythmias Depending on the type of high-frequency 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 A communication error 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.

Selecting the form of therapy

Proceed as follows:

If ...	Then ...
you want to trigger a pulse train with fixed or variable rate,	select the `Burst pacing` form of therapy.
you want to trigger a full electro-physiological stimulation program with up to three extrastimuli,	select the `Programmed stimulation` form of therapy.

Starting the backup program

Proceed as follows in order to ensure backup pacing:

Step	Action
1	Select **Tests → Atr. NIPS**.
2	Select `Backup stimulation` and the pacing rate you want to achieve. Backup pacing is performed in VVI mode as a temporary program with the selected rate. Select **[Start backup program]**.
3	Select **OFF** if you want to carry out NIPS without backup pacing.

Cancel backup program

The rate of backup pacing cannot be changed during burst stimulation. This is only possible if burst pacing is previously switched off.

Step	Action	Remark
1	Select **[Stop backup program]**.	NIPS is cancelled and the permanent program is transmitted to the device.

Note: Running follow-ups by applying the programming head
Independently of the option of aborting backup, external pacing can be stopped at any time by raising the programming head (at least 30 cm). The device then switches back to its permanent program.

Switching the report ON and OFF

An automatic report is offered for NIPS. If it is activated, the ECG is printed automatically.

NIPS – Description of Burst Pacing

Navigation: Tests → Atr. NIPS

Description

Using burst pacing it is possible deliver a pulse sequence with a fixed or variable rate as long as you keep the **[Burst]** button pressed down.

The parameters for burst pacing are located on the right-hand side of the NIPS window.

Parameter	Description
`Start`	Initial rate for burst stimulation
`Min.`	Minimum rate with decreasing ramp
`Max.`	Maximum rate with increasing ramp
`Burst rate` (Ramp)	The step size for increases or reductions in the ramp function is permanently fixed at 10 bpm/s.

NIPS – Executing Burst Pacing

Navigation: Tests → Atr. NIPS

Starting/stopping burst pacing

Proceed as follows:

Step	Action	Result
1	Select **[Start backup program]**.	NIPS is activated as a temporary program in the device. The status bar displays: `NIPS backup program is active.` Backup pacing is ensured and controlled by the backup program.
2	Press the middle section of the **[Burst]** button and hold down the button for the duration of the burst.	As long as the button remains pressed, burst pacing at the specified rate will accompany safety pacing. When the button is released, only backup pacing is active.
3	Select **[Stop backup program]**.	NIPS is cancelled and the permanent program is transmitted to the device.

Varying the burst rate during pacing

The burst rate can be gradually changed during pacing (ramp function). This ramp function is facilitated by a three-part button.

If ...	Then ...
you wish to increase the burst rate,	press the right-hand **[+]** section of the **[Burst]** button and hold down the button for the duration of the burst. Based on the preset value, the burst rate is increased incrementally until the specified maximum has been reached. When the button is released, backup pacing is active.
you want to decrease the burst rate,	press the left-hand **[-]** section of the **[Burst]** button and hold down the button for the duration of the burst. Based on the preset value, the burst rate is decreased incrementally until the specified minimum has been reached. When the button is released, backup pacing is active.
you want to cancel burst stimulation,	release the **[Burst]** button. After releasing the button, the burst pacing is automatically ended. Backup pacing remains active.

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.

NIPS – Description of Programmed Stimulation

Navigation: Tests → Atr. NIPS

With programmed stimulation, it is possible to trigger a full electrophysiological pacing program with up to three extrastimuli.

Programmed stimulation is used in the ventricle using the **EPE/ATP** function. See the **DFT** tab: **Tests → DFT → EPE/ATP**.

Description

The following parameters can be set for programmed stimulation:

Parameter	Description
`S1-S1 interval`	Basic interval for programmed stimulation
`S1 cycles`	The basic interval is repeated for the specified number of cycles before the extrastimuli are added. If the value 0 is specified, the extrastimuli become effective immediately after the start of the basic interval.
`S1-S2 interval`, `S2-S3 interval`, `S3-S4 interval`	Intervals of the extrastimuli that are coupled to the basic interval. The method is described below and applies to all intervals of the extrastimuli.

Couple the pacing intervals

The extrastimuli are coupled to the basic interval as follows:

If ...	Then ...
pacing is to be carried out without the first extrastimulus (`S1-S2 interval` = `None`),	all further extrastimuli are not coupled, either.
a numerical interval value is selected for the `S1-S2 interval`,	the first extrastimulus is coupled after the set cycles of the basic interval are complete. Stimulation takes place at the end of the S1 – S2 interval.
pacing is to be carried out without the second extrastimulus (`S2-S3 interval` = `None`),	all further extrastimuli are not coupled, either.
a numerical value is selected for the `S2-S3 interval`,	the first extrastimulus and then the second extrastimulus is coupled after the set cycles of the basic intervals are complete. Pacing occurs at the end of the S1-S2 and S2-S3 intervals respectively.
a numerical value is selected for the `S3-S4 interval`,	the first extrastimulus, then the second extra-stimulus, and finally the third extrastimulus is coupled after the set cycles of the basic intervals are complete. Pacing occurs at the end of the S1-S2, S2-S3, and S3-S4 intervals respectively.

NIPS – Executing Programmed Stimulation

Navigation: Tests → Atr. NIPS

Executing programmed stimulation

Proceed as follows:

Step	Action	Result
1	Select **[Start backup program]**.	NIPS is activated as a temporary program in the device. The status bar displays: `NIPS backup program is active.` Backup pacing is ensured and controlled by the backup program.
2	Select **[Start programmed stimulation]**	NIPS is activated as a temporary program in the device. Programmed stimulation commences in addition to backup pacing. This remains active until the set sequence has been carried out in full or until the function is ended manually. After this, only backup pacing is active.
3	Select **[Stop backup program]**.	External pacing is canceled and the permanent program is transmitted to the device.

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.

12.7 Retrograde Conduction Test

What's in this section?

Conducting the Retrograde Conduction Test

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 A communication error 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.

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 five conductions or ten 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. 240

Test for Retrograde Conduction – Details

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.

IV ProMRI

What's in this part?

Overview See part IV for further information on conditions and instructions for the MR scan.

13 Basic Information

What's in this chapter?

13.1 Preparing the MRI Scan

What's in this section?

MRI Program – Device Preparation

ProMRI manual

Note: Always observe the information given in the ProMRI manual by BIOTRONIK:

- 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: on
OFF	MRI program: off
AUTO	MRI program = automatic on upon detection of an MRI 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 MRI field sensor will then be enabled during the set period.
3	Select an MRI mode: • OFF – recommended for patients who are not pacemaker-dependant • 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. 245

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 Home Monitoring-supported follow-up is performed and transmitted 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. 245

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.

MRI Manual

Note: The following information applies to software version PSW xxxx.A (/x) [M] exclusively.

You can find a technical manual with detailed information on how to safely conduct an MR scan on patients with an implanted MR conditional device system from BIOTRONIK on the Internet by clicking the following link:

- manuals.biotronik.com
- -> Product group: ProMRI -> Product: ProMRI

You can also use the following QR code:

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: Not all functions and parameters mentioned in this technical manual are featured by each device type of each device family.

Note: Unless described separately, information for device type HF also applies to device type HF QP.

Bradycardia / CRT

General ICD therapy

Parameter	Range of values	Standard	VR	DX	DR	HF
ICD therapy	OFF; ON	ON	x	x	x	x
Programs	Display standard program; Display safe program; Display first interrogated program; Individual 1, 2, 3; ProgramConsult	—	x	x	x	x

Timing: Basic rate day/night and rate hystereses

Parameter	Range of values	Standard	VR	DX	DR	HF
Basic rate	30 ... (5) ... 100 ... (10) ... 160 bpm	40 bpm	x	x		
		60 bpm			x	x
Night rate	OFF; 30 ... (5) ... 100 bpm	OFF	x	x	x	x
Night begins	00:00 ... (00:01) ... 23:59 hh:mm	22:00 hh:mm	x	x	x	x
Night ends		06:00 hh:mm				
Rate hysteresis	OFF; -5 ... (-5) ... -25 ... (-20) ... -65 bpm	OFF	x	x	x	x
Scan/repetitive	OFF; ON	ON	x	x	x	x

Timing: AV delay

Parameter	Range of values	Standard	VR	DX	DR	HF
AV dynamics	Low; Medium; High; Fixed; (Individual)	Low		x	x	x
AV delay (1 or 2) after:						
– Pacing	40 ... (5) ... 350 ms Only for Fixed, also: 15	–			x	x
– Sensing	Either automatic: AV delay after pacing + sense compensation Or: 15; 40 ... (5) ... 350 ms	–		x	x	x
– At rate 1	50 ... (10) ... 130 bpm	60 bpm				
– At rate 2	60 ... (10) ... 140 bpm	130 bpm				
Sense compensation	OFF; -5 ... (-5) ... -120 ms	-40 ms			x	x
AV hysteresis mode	OFF; Positive; Negative; IRSplus	OFF		x	x	
	OFF; Positive; Negative	OFF				x
AV hysteresis (positive)	70; 110; 150; 200 ms	70 ms		x	x	x
7 series, CLS modes: AV hysteresis (positive)	70; 110; 150 ms	110 ms		x	x	x
AV hysteresis (negative)	10 ... (10) ... 150 ms	50 ms		x	x	x
AV scan and repetitive (positive)	OFF; ON	ON		x	x	x

Timing: Post-shock pacing

Parameter	Range of values	Standard	VR	DX	DR	HF
Post-shock duration	OFF; 10 s; 30 s; 1 min; 2 min; 5 min; 10 min	10 s	x	x	x	x
Post-shock basic rate	30 ... (5) ... 100 ... (10) ... 160 bpm	60 bpm	x	x	x	x
AV delay post shock	50 ... (10) ... 350 ms	140 ms			x	x
Ventricular post-shock pacing	RV; BiV	RV				x

Timing: Upper rate

Parameter	Range of values	Standard	VR	DX	DR	HF
Upper rate	90 ... (10) ... 160 bpm	130 bpm		x	x	x
Atrial upper rate	OFF; 175; 200; 240 bpm	200 bpm			x	x

Timing: Mode switching

Parameter	Range of values	Standard	VR	DX	DR	HF
Intervention rate	OFF; 120 ... (10) ... 200 bpm	160 bpm		x	x	x
Onset criterion	3 ... (1) ... 8 (out of 8)	5		x	x	x
Resolution criterion						
Modification of basic rate	OFF; 5 ... (5) ... 30 bpm	10 bpm		x	x	x
Mode	After mode VDD(R): VDI(R)	VDIR		x	x	x
	After mode DDD(R), DDD-ADI(R): DDI(R) 7 series, after mode DDD-CLS: DDI(R)	DDIR			x	x
After mode switching:						
– Rate	OFF; 5 ... (5) ... 50 bpm	10 bpm		x	x	x
– Duration	1 ... (1) ... 30 min	1 min				
– Rate stabilization with mode switching	ON; OFF	OFF		x	x	x

Timing: Ventricular pacing suppression

Parameter	Range of values	Standard	VR	DX	DR	HF
Vp suppression	OFF; ON	OFF			x	x
Pacing suppression after consecutive Vs	1 ... (1) ... 8	6			x	x
Pacing support after X-out-of-8 cycles	1; 2; 3; 4	3			x	x

Timing: Ventricular pacing

Parameter	Range of values	Standard	VR	DX	DR	HF
Permanent	RV; BiV; LV	BiV				x
Triggering	OFF; RVs; RVs+PVC	RVs				x
LV T-wave protection	OFF; ON	ON				x
Maximum trigger rate:						
– DDD(R) and VDD(R)	UTR + 20; 90 ... (10) ... 160 bpm	UTR + 20				x
– DDI(R), VDI(R) and VVI(R)	90 ... (10) ... 160 bpm	130 bpm				
Initially paced chamber	RV; LV	LV				x
VV delay after Vp	0 ... (5) ... 100 ms	0 ms				x

Timing: Ventricular MultiPole pacing

The following parameters apply for devices of the 7 series, HF QP type:

Parameter	Range of values	Standard	HF QP
Pacing polarity 2nd LV	OFF; LV1 tip -> LV2 ring LV1 tip -> LV4 ring LV1 tip -> RV coil LV1 tip -> housing LV2 ring -> LV1 tip LV2 ring -> LV4 ring LV2 ring -> RV coil LV3 ring -> LV2 ring LV3 ring -> LV4 ring LV3 ring -> RV coil LV4 ring -> LV2 ring LV4 ring -> RV coil	OFF	x
LV-LV delay	0 ... (5) ... 50 ms	0 ms	x
Pulse amplitude LV 2nd LV	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V	2.5 V	x
Pulse width LV 2nd LV	0.4; 0.5 ... (0.25) ... 1.5 ms	0.4 ms	x

Timing: Refractory periods and blanking periods

Parameter	Range of values	Standard	VR	DX	DR	HF
PVARP	AUTO; 175 ... (25) ... 600 ms	225 ms		x	x	x
PVARP extension	OFF; ON	ON		x	x	x
Blanking RV after atrial pacing	40 ... (10) ... 100 ms	50 ms			x	x
LV blanking after RV pacing	50 ... (10) ... 100 ms	80 ms				x
RV blanking after LV pacing						
Far-field protection after Vs	OFF; 25 ... (25) ... 225 ms	75 ms		x	x	x
Far-field protection after Vp	50 ... (25) ... 225 ms	75 ms		x	x	x

Timing: PMT protection

Parameter	Range of values	Standard	VR	DX	DR	HF
PMT detection/ termination	OFF; ON	ON		x	x	x
VA criterion	250 ... (10) ... 500 ms	350 ms		x	x	x

Timing: Rate adaptation via accelerometer

Parameter	Range of values	Standard	VR	DX	DR	HF
Maximum sensor rate	80 ... (10) ... 160 bpm	120 bpm	x	x	x	x
Sensor gain	AUTO; Very low; Low; Medium; High; Very high	Medium	x	x	x	x
Sensor threshold	Very low; Low; Medium; High; Very high	Medium	x	x	x	x
Rate increase	1; 2; 4; 8 bpm/cycle	2 bpm/ cycle	x	x	x	x
Rate decrease	0.1; 0.2; 0.5; 1.0 bpm/ cycle	0.5 bpm/ cycle	x	x	x	x
Rate fading	OFF; ON	OFF	x	x	x	x

Timing: Rate adaptation via CLS

The following parameters apply to devices of series 7:

Parameter	Range of values	Standard	VR	DX	DR	HF
Maximum sensor rate	80 ... (10) ... 160 bpm	120 bpm	x	x	x	x
CLS response	Very low; Low; Medium; High; Very high	Medium	x	x	x	x
CLS resting rate control	OFF; +10 ... (+10) ... +50 bpm	+20 bpm	x	x	x	x
Vp required	Yes; No	No	x	x	x	
	Yes	Yes				x

Pacing: Pulse amplitude and pulse width

Parameter	Range of values	Standard	VR	DX	DR	HF
Pulse amplitude A	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V	AUTO			x	x
Pulse amplitude V/RV			x	x	x	x
Pulse amplitude LV						x
Pulse width A	0.4; 0.5 ... (0.25) ... 1.5 ms	0.4 ms			x	x
Pulse width V/RV			x	x	x	x
Pulse width LV						x

Pacing: Atrial capture control

Parameter	Range of values	Standard	VR	DX	DR	HF
Atrial capture control	OFF; ATM; ON	ON			x	x
Threshold test start	with ATT: 2.5 ... (0.5) ... 5.0 V with ATM: 3.5 V	3.5 V			x	x
Minimum amplitude	0.5 ... (0.25) ... 4.0 V	1.0 V			x	x
Safety margin	0.5; 1.0; 1.2 V	1.0 V			x	x

Pacing: Ventricular capture control

Parameter	Range of values	Standard	VR	DX	DR	HF
Ventricular capture control RV + LV	OFF; ATM; ON	ON	x	x	x	x
Threshold test start	with ATT: 2.5 ... (0.5) ... 5.0 V with ATM: 3.5 V	3.5 V	x	x	x	x
Minimum amplitude	1.0 ... (0.25) ... 4.0 V	1.0 V	x	x	x	x
Safety margin	1.0; 1.2 V	1.0 V	x	x	x	x

Lead configuration LV on IS-1 connection

Parameter	Range of values	Standard	VR	DX	DR	HF
Pacing polarity LV (IS-1)	LV tip -> LV ring LV tip -> RV coil LV ring -> LV tip LV ring -> RV coil UNIP	LV tip -> RV coil				x
Sensing polarity LV (IS-1)	UNIP; BIPL	UNIP				x

Lead configuration LV on IS4 connection

Parameter	Range of values	Standard	HF QP
Pacing polarity LV (IS4)	LV1 tip -> LV2 ring LV1 tip -> LV4 ring LV1 tip -> RV coil LV1 tip -> housing LV2 ring -> LV1 tip LV2 ring -> LV4 ring LV2 ring -> RV coil LV3 ring -> LV2 ring LV3 ring -> LV4 ring LV3 ring -> RV coil LV4 ring -> LV2 ring LV4 ring -> RV coil	LV1 tip -> LV2 ring	x
Sensing polarity LV (IS4)	LV1 tip -> LV2 ring LV1 tip -> housing LV2 ring -> LV3 ring LV2 ring -> housing LV3 ring -> LV4 ring LV3 ring -> housing LV4 ring -> housing	LV1 tip -> LV2 ring	x

MRI program

MRI program

Parameter	Range of values	Standard	VR	DX	DR	HF
MRI program	OFF; AUTO; ON	OFF	x	x	x	x
Expiration date	Today ... (1) ... Today + 14 days	Today + 14 days	x	x	x	x
Mode	VOO; OFF	OFF	x	x		
	VOO; DOO; OFF				x	
	V00; V00-BiV; D00; D00-BiV; OFF					x
Basic rate	70 ... (5) ... 100 ... (10) ... 160 bpm	90 bpm	x	x	x	x
Pulse amplitude LV	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V	As in permanent program				x
Pulse width LV	0.4; 0.5 ... (0.25) ... 1.5 ms					x
Pacing polarity LV	IS-1: LV tip -> LV ring LV ring -> LV tip IS4: LV1 tip -> LV2 ring LV1 tip -> LV4 ring LV2 ring -> LV1 tip LV2 ring -> LV4 ring LV3 ring -> LV2 ring LV3 ring -> LV4 ring LV4 ring -> LV2 ring					x

Tachycardia

Detection

Parameter	Range of values	Standard	VR	DX	DR	HF
Interval AT/AF	240 ... 600 ms	300 ms		x	x	x
Interval VT1	OFF; 270 ... (10) ... 600 ms	OFF	x	x	x	x
Interval VT2	OFF; 270 ... (10) ... 500 ms					
Interval VF	OFF; 240 ... (10) ... 400 ms	300 ms				
Detection counter VT1	10 ... (2) ... 100	28	x	x	x	x
Detection counter VT2	10 ... (2) ... 80	20				
Detection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30; 30 out of 40	18 out of 24				
Redetection counter VT1	10 ... (2) ... 50	20	x	x	x	x
Redetection counter VT2	10 ... (2) ... 40	14				
Redetection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30	8 out of 12	x	x	x	x
SMART detection VT1/VT2	OFF; ON	ON		x	x	x
SMART detection ON:						
– Onset VT1/VT2	4 ... (4) ... 32%	20%		x	x	x
– Stability VT1/VT2	8 ... (4) ... 48%	12%				
SMART detection OFF:						
– Onset VT1/VT2	OFF; 4 ... (4) ... 32%	20%	x	x	x	x
– Stability VT1/VT2	OFF; 8 ... (4) ... 48 ms 8 ... (4) ... 48%	12%				
MorphMatch	OFF; Monitoring; ON	OFF	x	x	x	x
MorphMatch threshold	Low; Std; High	Std.	x	x	x	x
Sustained VT	OFF; 1; 2; 3; 5; 10; 20; 30 min	OFF	x	x	x	x

Therapy: Atrial therapy

The following parameters apply to devices of series 7:

Parameter	Range of values	Standard	VR	DX	DR	HF
Atrial therapy in the presence of stable atrial flutter:						
ATP type	OFF; Burst; Ramp	OFF			x	x
Number S1	2 ... (1) ... 10	5			x	x
P-S1 interval	70 ... (5) ... 95%	80%			x	x
S1 decrement	5 ... (5) ... 40 ms	10 ms			x	x
Backup stimulation	OFF; 70; 90;	OFF			x	x
Atrial therapy in the presence of unstable atrial fibrillation:						
Therapy	OFF; HF (high frequency) burst	OFF			x	x
Rate	10 ... (5) ... 40 Hz	40 Hz			x	x
Duration	2 ... (1) ... 10	3 s			x	x
Backup stimulation	OFF; 70; 90;	OFF			x	x

Therapy: Ventricular ATP

Parameter	Range of values	Standard	VR	DX	DR	HF
For VT1/VT2: Attempts	OFF; 1 ... (1) ... 10	OFF	x	x	x	x
ATP type for VT1/VT2	Burst; Ramp	Burst	x	x	x	x
ATP type for VF	OFF; Burst; Ramp	Burst	x	x	x	x
ATP optimization	OFF; ON	OFF	x	x	x	x
Number S1 for VT1/VT2	1 ... (1) ... 15	5	x	x	x	x
Number S1 for VF		8				
S1 decrement for VT1/VT2 and for VF	5 ... (5) ... 40 ms	10 ms	x	x	x	x
Scan decrement for VT1/VT2	OFF; 5 ... (5) ... 40 ms	OFF	x	x	x	x
Add S1 for VT1/VT2	OFF; ON	ON	x	x	x	x
Ventricular pacing	RV; LV; BiV	RV				x
R-S1 interval for VT1/VT2	70 ... (5) ... 85; 88; 90; 95%	80%	x	x	x	x
R-S1 interval for VF		88%				
Early ATP delivery for VF	OFF; ON	OFF	x	x	x	x

Therapy: Shock

Parameter	Range of values	Standard	VR	DX	DR	HF
Number of shocks VT1/VT2	0; 1; 2; 6; 8	8	x	x	x	x
Number of shocks VF	6; 8	8	x	x	x	x
1st Shock for VT1/VT2	OFF; 2 ... (2) ... 20 ... (5) ... 40 J	40 J	x	x	x	x
2nd Shock for VT1/VT2	OFF; 4 ... (2) ... 20 ... (5) ... 40 J	40 J	x	x	x	x
3rd - nth shock for VT1/VT2	OFF; 4*40 J; 6*40 J	6*40 J	x	x	x	x
1st Shock for VF	2 ... (2) ... 20 ... (5) ... 40 J	40 J	x	x	x	x
2nd Shock for VF	4 ... (2) ... 20 ... (5) ... 40 J	40 J	x	x	x	x
3rd - nth shock for VF	4*40 J; 6*40 J	6*40 J	x	x	x	x
For shock in VT1/VT2 and VF:						
– Confirmation	OFF; ON	ON	x	x	x	x
– Polarity	Normal; reverse; Normal -> alternating; reverse -> alternating	Normal				
– Shock form	Biphasic; Biphasic 2; Biphasic -> alternating; biphasic 2 -> alternating	Biphasic				
– Shock path	RV -> housing + SVC RV -> housing RV -> SVC	RV-> ICD+SVC	x		x	x
		RV -> ICD		x		

Sensing

Sensitivity and thresholds

Parameter	Range of values	Standard	VR	DX	DR	HF
Sensing A	STD; OFF	STD		x	x	x
Sensing RV	STD; TWS; VFS; IND	STD	x	x	x	x
Sensing LV	STD; OFF; IND	STD				x
DX sensing	ON; OFF	OFF				x
Upper threshold RV	50; 75%	50%	x	x	x	x
Upper threshold LV	50; 75%	50%				x
Upper threshold duration RV after detection	110; 150 ... (50) ... 500 ms VFS: 110 ms	350 ms	x	x	x	x
Upper threshold duration RV after pace		400 ms				
Lower threshold RV	25; 50%	25%	x	x	x	x
T-wave suppression after pacing	OFF; ON	OFF	x	x	x	x
Minimum threshold A	0.2 ... (0.1) ... 2.0 mV	0.4 mV		x	x	x
Minimum threshold RV	0.5 ... (0.1) ... 2.5 mV	0.8 mV	x	x	x	x
Minimum threshold LV	0.5 ... (0.1) ... 2.5 ... (0.5) ... 5.0 mV	1.6 mV				x

Diagnostics

The following can be set:

Parameter	Range of values	Standard	VR	DX	DR	HF
For AT/AF	OFF; ON 7 series: Extended ON	ON		x	x	x
For SVT	OFF; ON	ON		x	x	x
For nsT	OFF; ON	ON	x	x	x	x
For CRT pacing inter-ruption	OFF; ON	ON				x
Periodic recording	When Home Monitoring is deactivated: OFF; 30 ... (30) ... 180 days	90 days	x	x	x	x
IEGM configuration	RA, RV, LV RA, RV, FF FF; RV; LV	RA, RV, LV				x
Start resting period	00:00 ... (1:00 AM) ... 23:00 hh:mm	2:00 AM hh:mm	x	x	x	x
Duration of resting period	0.5 ... (0.5) ... 12 h	4 h	x	x	x	x
AV delay adjustment in sensing test	OFF; 300 ms	300 ms		x	x	x
Thoracic impedance (TI)	OFF, ON	OFF	x	x	x	x

Home Monitoring

Parameter	Range of values	Standard	VR	DX	DR	HF
Home Monitoring	OFF; ON	OFF	x	x	x	x
Time of transmission	STD; 00:00 ... (1:00 AM) ... 23:00 hh:mm	STD	x	x	x	x
IEGM for therapy episodes	OFF; ON	ON	x	x	x	x
IEGM for monitoring episodes						
Ongoing atrial episode	OFF; 6; 12; 18 h	12 h		x	x	x
Configurable in the HMSC:						
Transmission date	XX.XX.XXXX	Follow-up + 91 days	x	x	x	x
Cycle duration	20 ... (1) ... 366 days	91 days	x	x	x	x

15 Technical Data

What's in this chapter?

Mechanical Characteristics

Housing Devices with header for DF-1 and DF4 connector:

Type	Lead connector	W x H x D in mm	Volume [cm³]	Mass g
VR	DF-1	65 x 55 x 11	33	82
	DF4	65 x 54 x 11	31	81
VR DX	DF-1	65 x 55 x 11	33	82
DR	DF-1	65 x 55 x 11	33	82
	DF4	65 x 56 x 11	32	82
HF	DF-1	65 x 58.5 x 11	34	83
	DF4	65 x 56 x 11	33	82
HF QP	DF-1	65 x 60.5 x 11	36	86
	DF4	65 x 58.5 x 11	36	87

Materials in contact with body tissue

- Housing: Titanium
- Header: epoxy, polysulfone; DF4 seal: silastic
- Silicone plugs and blind plugs (if applicable): Silopren or silastic

X-ray identification NK

Electrical Characteristics

Standards The specifications are made according to EN 45502-2-2:2008.

Measuring conditions If not indicated otherwise, all specifications refer to the following conditions:

- Ambient temperature: 37°C ± 2°C
- Pacing/sensing: 500 Ω ±1%
- Shock: 50 Ω ± 1%

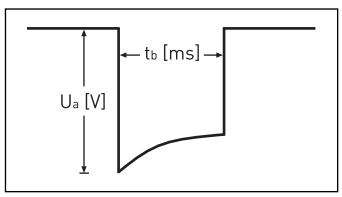
Factory settings

- Arrhythmia zones VT1, VT2, VF: OFF
- Antibradycardia pacing: OFF
- Home Monitoring: OFF

Telemetry data for Home Monitoring:

- MISC frequencies: 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

- Note on device type VR DX (only devices with a DF-1/IS-1 connection): The EMC requirements are met as long as atrial sensitivity is set to 1.0 mV (factory settings) or values ⩾ 1.0 mV. Measures must be taken to assure interference-free therapy if more sensitive values are set.
- Note on device type HF and HF QP: In the case of unipolar sensing, the requirement for interference voltages of ⩽ 0.3 mV (peak to peak) is met.

Common mode rejection ratio

*Devices with a DF-1/IS-1 connection only; ** Information for device type HF also applies to device type HF QP.

Rate	Common mode rejection ratio			
	Atrium: DX*	Atrium: DR, HF**	V right: VR, DR, HF**	V left: HF**
16.6 Hz	76 dB	72 dB	58 dB	55 dB
50 Hz	73 dB	72 dB	65 dB	55 dB
60 Hz	75 dB	71 dB	66 dB	62 dB

ATP amplitude

A burst was measured at 500 Ω, an amplitude of 7.5 V (tolerance ± 1.5 V), pulse width of 1.5 ms, R-S1 interval of 300 ms and an S1 count of 5:

ATP amplitude	Measured minimum	Measured maximum	Mean value
RA	7.23 V	7.27 V	4.93 V
RV	7.26 V	7.52 V	5.04 V
LV	7.51 V	7.54 V	5.07 V

Automatic sensitivity control

Measurement of actual values and test signal wave shape: standard triangle. For the device type VR DX, the programmed atrial sensitivity is intensified by a factor of 4.

Sensitivity	Value	Tolerance	Measured value
A: positive	0.2 mV	0.2 ... 0.5	0.27 mV
A: negative			0.26 mV
DX: A: positive	0.2 mV	0.2 ... 0.52 (0.05 to 0.13)	0.11 mV
DX: A: negative			
RV: positive	0.5 mV	0.3 ... 0.7	0.53 mV
RV: negative			0.57 mV
LV: positive	0.5 mV	0.3 ... 0.7	0.53 mV
LV: negative			

Shock energy / peak voltage

With shock path: RV to housing + SVC

Shock energy (Tolerance)	Tolerance Peak voltage	Measured value Shock energy	Measured value Peak voltage
1 J (0.7 ... 1.18)	90 ... 120 V	0.83 J	98.1 V
20 J (15.9 ... 21.6)	440 ... 480 V	17.4 J	462 V
40 J (33.8 ... 41.4)	620 ... 690 V	36.7 J	659 V

Battery Data

Battery characteristics

The following data is provided by the manufacturers:

Manufacturer	**GREATBATCH, INC. Clarence, NY 14031**	**LITRONIK Batterie-technologie GmbH 01796 Pirna, Germany**
Battery type	GB 2992	LiS 3410 RR
System	Li/SVO/CFx	LiMnO2
Battery ID number shown on the programmer	3	6
Device type	VR, VR DX, DR, HF, HF QP	
Battery voltage at ERI	2.5 V	2.85 V
Charge time at BOS	8 s	8 s
Charge time at ERI	10 s	10 s
Usable capacity until ERI 5 series: VR, VR DX, DR, HF, HF QP 7 series: VR, VR DX, DR	1390 mAh	1390 mAh
Usable capacity until ERI: 7 series: HF, HF QP	1600 mAh	—
Usable capacity until EOS	1730 mAh	1520 mAh

Storage period

The storage period affects the battery service time.

- Devices should be implanted within 19 months between the manufacturing date and the use by date (indicated on the package).
- If the ICD is implanted shortly before the use by date, the expected service time may be reduced by up to 17 months.

Calculation of service times

- The services times have been calculated as follows – in all chambers depending on the device type:
  - Pulse amplitude: 2.5 V
  - Pulse width: 0.4 ms
  - Pacing impedance: 500 Ω
  - Basic rate: 60 bpm
  - Home Monitoring: ON, 1 device message each day and 24 IEGM online HD transmissions per year
  - Diagnostic functions and recordings: permanently set
- Capacitor reforming is performed 4 times per year and therefore at least 4 maximum charges for shocks have to be assumed per year even if less than 4 are delivered.

Calculation of the number of shocks

Calculation of the number of shocks: Service time [in years] x number of shocks per year

Intica 5/7 VR-T Service times with GB 2992 or LiS 3410 RR battery:

Pacing	Service time [in years] at number of shocks per year				
	4	8	12	16	20
0%	10.3	8.3	7.0	6.0	5.3
15%	10.1	8.1	6.8	5.9	5.2
50%	9.5	7.8	6.6	5.7	5.0
100%	8.8	7.3	6.2	5.4	4.8

Intica 5/7 VR-T DX Service times with GB 2992 or LiS 3410 RR battery:

Pacing	Service time [in years] at number of shocks per year				
	4	8	12	16	20
0%	9.4	7.7	6.5	5.7	5.0
15%	9.2	7.6	6.4	5.6	4.9
50%	8.7	7.2	6.2	5.4	4.8
100%	8.1	6.8	5.9	5.2	4.6

Intica 5/7 DR-T Service times with GB 2992 or LiS 3410 RR battery:

Pacing	Service time [in years] at number of shocks per year				
	4	8	12	16	20
0%	9.4	7.7	6.5	5.7	5.0
15%	9.0	7.4	6.3	5.5	4.9
50%	8.1	6.8	5.9	5.2	4.6
100%	7.1	6.1	5.3	4.7	4.3

Intica 5 HF-T (QP) Service times with GB 2992 or LiS 3410 RR battery:

Pacing	Service time [in years] at number of shocks per year				
	4	8	12	16	20
0%	8.9	7.4	6.3	5.5	4.9
15%	8.3	7.0	6.0	5.2	4.7
50%	7.2	6.1	5.4	4.8	4.3
100%	6.0	5.3	4.7	4.2	3.9

Intica 7 HF-T (QP) Service times with battery GB 2992 without multipolar pacing:

Pacing	Service time [in years] at number of shocks per year				
	4	8	12	16	20
0%	10.1	8.4	7.2	6.3	5.5
15%	9.4	7.9	6.8	6.0	5.3
50%	8.2	7.0	6.1	5.5	4.9
100%	6.9	6.0	5.4	4.8	4.4

Service times with battery GB 2992 with multipolar pacing:

Pacing	Service time [in years] at number of shocks per year				
	4	8	12	16	20
0%	10.1	8.4	7.2	6.3	5.5
15%	9.2	7.8	6.7	5.9	5.3
50%	7.7	6.6	5.9	5.2	4.7
100%	6.2	5.5	5.0	4.5	4.1

Legend for the Label

Label on the package

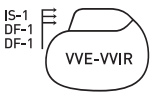
The label icons symbolize the following:

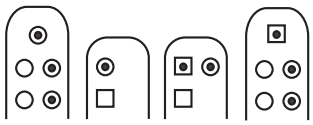
	Manufacturing date		Use by
	Storage temperature		Order number
	Serial number		Product identification number
	Dangerous voltages!		European approval mark
	Contents		Consult the instructions for use

 Sterilized with ethylene oxide			
	Do not resterilize		Single use only. Do not reuse!
	Do not use if packaging is damaged		Non-sterile

	Transmitter with non-ionizing radiation at designated frequency
Label icon on devices with ProMRI®: 	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	Compatibility with telemetry protocol version 2 of BIOTRONIK Home Monitoring

 Example	Device: NBG code and compatible leads
 Example	Factory settings for therapy: OFF
	Screwdriver

 Examples of the connector allocation: DF-1/IS-1, DF4/IS-1, DF-1/IS4/IS-1, DF4/IS4/IS-1
 Bipolar IS-1 connector
 Unipolar IS-1 connector
 Unipolar DF-1 connector
 IS4 connector, DF4 connector

Intica 5/7
Function Manual

Revision: B (2020-11-05)

422209

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