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Introduction

Cylos is a line of pacemakers that may be used for all indications of bradycardic arrhythmias. There are three pacemakers in the Cylos product group. There are single- and dual-chamber pacemakers that achieve physiological rate adaptation using Closed Loop Stimulation,[1] and a third pacemaker that permits external monitoring via a Home Monitoring feature.[2]

The myocardium contracts differently under different states of load. Closed Loop Stimulation (CLS) uses these variations to provide the patient with a physiologic pacing rate that is specific to his or her needs. The dynamics of the cardiac contractions are evaluated by unipolarly measuring the intracardiac ventricular impedance. Changes in the impedance curves over time are directly proportional to the state of load. By evaluating these changes, the pacemaker then sets the pacing rate. Closed Loop Stimulation uses ventricular sense (V_S) and ventricular pace (V_P) events in calculating the pacing rate.

A traditional accelerometer is another way Cylos can adapt the pacing rate. With the accelerometer, which is integrated into the hybrid circuit, any patient movement generates an electrical signal. This signal is used as input for controlling how the pacing rate is adapted.

Cylos DR

The dual-chamber pacemaker has separate atrial and ventricular leads and is suited for patients who need AV-synchronous pacing.

Cylos VR

The single-chamber pacemaker needs just one lead and is only suited for ventricular pacing.

Cylos DR-T

Cylos DR-T features the complete functionality of Cylos DR and is also equipped with the Home Monitoring function. For more information, please see the "Home Monitoring" section.

[1] Pacing in a closed loop.
[2] An extended telemetry option available in Cylos DR-T

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All the systems have extensive features that allow quick diagnosis and delivery of safe therapy for cases of bradycardic arrhythmia. The guided follow-up functions have been largely automated. Initialization and optimization of Closed Loop Stimulation is also automated. This saves the physician time and eliminates problems in verifying and adjusting the pacemaker.

Even during implantation, the implant can detect any connected leads – one of the key aspects of Auto-initialization.

Cylos features numerous special functions:

- The amplitude control function (which is referred to as ACC, Active Capture Control) continuously monitors the effectiveness of ventricular pacing and continuously adjusts the pacing amplitude to the pacing threshold.
- Closed Loop Stimulation (CLS) is automatically initiated and optimized.
- Statistics tracking intrinsic AV conduction help optimize the programmed AV delay and AV hysteresis.
- Antitachycardia functions provide the patient significant protection from the consequences of tachycardias. Automatic mode conversion or automatic mode switching prevent atrial-controlled pacing in the case of atrial tachycardias.
- A preventive overdrive mode reduces the occurrence of atrial tachycardias by using minimal overdrive pacing of the patient's intrinsic rate.
- Extensive algorithms help to prevent, recognize, and terminate tachycardia induced by the pacemaker.

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- Innovative rate hysteresis promotes the patient's own cardiac rhythm and avoids unnecessary overdrive pacing.
- AV hysteresis features support intrinsic conduction and hence the natural contraction process.
- The night program adjusts the pacing rate to the reduced metabolic needs of the patient while resting at night.
- The regular automatic lead impedance check triggers the switch from a bipolar to unipolar pacing mode when values outside the normal range occur.
- Automatic sensor features make it easier to adjust pacemaker parameters to the individual needs of the patient.
- The Rate Fading function ensures that the heart rate does not drop abruptly when the intrinsic rate suddenly decreases. Rather, the rate is gradually reduced until the basic or sensor rate has been reached.
- IEGM recordings provide insight into the events before a tachycardic phase.
- Extensive memory functions (such as the histogram, rate trend, activity chart, etc.) facilitate evaluation of the state of the patient and the pacemaker.
- Atrial and ventricular extrasystoles as well as atrial tachycardias can be analyzed and classified with respect to their complexity and when they occur.
- An external pulse control function is available for terminating atrial tachycardias and for use during electrophysiologic studies. Burst stimulation, with realtime control of the burst rate, and programmed stimulation, with up to 4 extrastimuli, are available.

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- Automatic functions and the storage of follow-up data in the implant simplify and accelerate the follow-up process.

Note: This technical manual describes all the features of the Cylos line of pacemakers.
A special note of any features that apply only to specific Cylos models will be made in the text or margins.

NBG Code

DDDR is the NBG code[1] for **Cylos DR/DR-T**:

D Pacing in both chambers
D Sensing in both chambers
D Inhibition and triggering of pulses
R Rate adaptation

VVIR is the NBG code[2] for **Cylos VR**:

V Pacing in the ventricle
V Sensing in the ventricle
I Inhibition and triggering of pulses
R Rate adaptation

Programmer and Software

The pacemakers can only be programmed with appropriate BIOTRONIK programmers, e.g., ICS 3000 or PMS 1000, along with the current software version. The range of functions and available parameters depend on the software module being used. Therefore, the operation and availability of certain functions can differ from the description in this manual. Specific information pertaining to the programmable options is provided in the user manual of the respective software module.

[1] See Bernstein et al., The Revised NASPE/BPEG Generic Code for Antibradycardia, Adaptive-Rate, and Multisite Pacing. PACE 2002, Vol. 25, No. 2: 260-264
[2] See Bernstein et al., The Revised NASPE/BPEG Generic Code for Antibradycardia, Adaptive-Rate, and Multisite Pacing. PACE 2002, Vol. 25, No. 2: 260-264

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Indications and Contraindications

Indications for Closed Loop Stimulation

Closed Loop Stimulation uses ventricular sense (Vs) and ventricular pace (Vp) events in calculating the pacing rate. The indications for Closed Loop Stimulation are summarized in the following:

— Patients with intermittent AV conduction disorders or intact AV conduction. The algorithm is based on an AV hysteresis that can be turned off for patients with high-degree AV blocks.
— Patients with a permanent AV block can be paced in the ventricle with the required V_P parameter set to “yes”.
— Patients with vasovagal syncope can be optimally supported with the programmable “dynamic runaway protection” parameter.
— Patients who would benefit from a constant AV delay are better treated when the “CLS dynamics” parameter is turned off.

The following information includes general indications and contraindications for the use of cardiac pacemakers. Please refer to the appropriate medical literature for detailed information. The guidelines of the American College of Cardiology (ACC),[1] the American Heart Association (AHA), and the German Society for Cardiology and Cardiovascular Research[2] are particularly good sources of information.

[1]Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices, Gregoratos et al., ACC/AHA Task Force Report, Circulation 2002; 106: 2145-2151, October 15, 2002

[2]Richtlinien zur Herzschrittmachertherapie; Indikationen, Systemwahl, Nachkontrolle. [Guidelines for Cardiac Pacemaker Therapy; Indications, System Selection, Follow-up Care]. Reports by the Commission for Clinical Cardiology at the German Society for Cardiology - Cardiovascular Research] (DGK), B. Lemke, W. Fischer, H. K. Schulten, Steinkopff Verlag 1996

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General Indications

The following conditions are regarded as general indications for pacemaker implantation when they occur together with symptoms such as syncope, dizziness, reduced physical capacity, or disorientation:

- Sinus node arrest and symptomatic bradycardia with or without an AV conduction disorder.
- Intermittent or complete AV block.
- Brady-/tachycardia syndrome or other symptoms of sick sinus syndrome that result in symptomatic bradycardia.
- Supraventricular reentry tachycardias that can be suppressed by chronic AV-sequential pacing.
- Atrial and ventricular ectopic arrhythmias that can be suppressed by permanent AV-sequential pacing.

In contrast to a single-chamber pacemaker, a dual-chamber pacemaker is indicated for patients who require increased cardiac output. This includes active patients and patients who have experienced, or are likely to experience, pacemaker syndrome.

An atrial-controlled dual-chamber mode (DDD and VDD) is indicated for patients who have an intact spontaneous atrial rhythm. Ventricular-controlled, AV-sequential dual-chamber pacing modes (DDI, DVI and VDI) are indicated for patients in whom ventricular pulse triggering due to spontaneous atrial events is not required or desired. Rate-adaptive pacing is indicated for patients who exhibit chronotropic incompetence and require increased pacing rates with physical activity.

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The functions "Automatic Mode Conversion" and "Mode Switching" in connection with the pacing modes DDD(R) and VDD(R) are useful in cases of paroxysmal atrial tachyarrhythmia to interrupt any atrial synchronization of ventricular pulses during the phases of atrial tachyarrhythmia. The DDD(R) mode with Mode Conversion is an alternative to the DDI(R) or DVI(R) mode in this case.

The AAI mode is indicated in the presence of symptomatic sinus node dysfunction as long as adequate AV conduction exists. The VVI mode is indicated in cases of symptomatic bradycardia when there is no (longer) significant atrial contribution to hemodynamics.

The demand modes as well as the asynchronous DOO, AOO, and VOO modes (with reduced sensing functions) are indicated in cases of medical/technical complications (e.g., electromagnetic interference, sensing errors, lead fractures, detection of myopotentials, muscle stimulation, etc.).

The triggered pacing modes DDT, DDI/T, VDT, DVT, AAT, and VVT as well as the VDI and OFF modes are indicated for diagnostic purposes.

General Contraindications

There are no known contraindications for the use of multiprogrammable and multifunctional dual-chamber pacemakers, provided that implantation is preceded by an adequate diagnosis, and no parameter combinations inappropriate for the patient’s condition are programmed. In individual cases, it is recommended that the tolerance and effectiveness of parameter combinations are checked by observing the patient for some time after programming. The following are contraindicated:

- Operating modes with atrial control (DDD, VDD, AAI) are contraindicated in the presence of chronic atrial tachycardia as well as chronic atrial fibrillation or flutter.

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- If slow retrograde conduction is encountered after ventricular pacing, a longer atrial refractory period and/or a shorter AV delay may have to be programmed to prevent pacemaker-mediated tachycardia. Programming DDI, DVI, or VVI modes is rarely required in these instances.
- If elevated rates above the basic rate are not well tolerated by the patient (e.g., the patient has chest pain as a result), a low “upper rate” and lower “maximum sensor rate” should be programmed. In these cases, atrial-controlled modes and rate-adaptive modes may even be contraindicated.
- If a case of pacemaker syndrome has been observed or is likely to develop, the modes VDD, VVI and VOO are contraindicated. The DDI mode is contraindicated in cases of pacemaker syndrome where sinus rates are above the basic rate.
- Atrial single-chamber pacing is contraindicated in the presence of existing AV conduction disorders or if failing AV conduction can be demonstrated by suitable tests.
- In the presence of competing spontaneous rhythms, modes without sensing and inhibition ability in the chamber affected are contraindicated.
- Unipolar pacing is contraindicated for patients who also have an implanted cardioverter-defibrillator (ICD). There is a risk of ICD inhibition or accidental delivery of pacemaker pulses.

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Home Monitoring

Introduction

Cylos DR-T

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

The Home Monitoring function has no effect on any functions and features of the basic implant, such as pacing and sensing functions, preset parameters, or memory functions.

With Home Monitoring, you as the physician can view the data transmitted by the implant in a comprehensive report called a Cardio Report, allowing you to always be informed about your patient's cardiac status.

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

The implant’s Home Monitoring function can be used for the entire operational life of the implant or for shorter periods, just a few weeks or months.

The most important components of Home Monitoring are the implant, the patient device, and the BIOTRONIK Service Center.

The Implant

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

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The patient's implant data are sent to the patient device at regular intervals. With Home Monitoring, the distance between the implant and the patient device should not be less than 20 centimeters (8 inches) and not more than two meters (6 feet).

The implant can send three different types of messages: trend messages, event messages and patient messages (for pacemakers only). For more information about the message types, see "Types of Implant Messages," on page 17.

Patient Device

The RUC or CardioMessenger® patient device works similarly to a cellular phone and transmits the messages received from the implant as short messages (SMS) to the BIOTRONIK Service Center via the cellular phone network. The integrated batteries enable battery-operated usage for 15-24 hours, depending on the model. The patient device can, of course, also be used with the included charging station.

BIOTRONIK Service Center

At the BIOTRONIK Service Center, the implant messages transmitted by the patient device are processed and then made available to you via the Internet or a fax in the form of a concise report called the Cardio Report.

Cardio Report

In the Cardio Report, the transmitted implant data are displayed in graphs and tables. With the online option, you can individually configure the Cardio Report graphs for each patient. For certain events, the Cardio Reports are also sent to you by fax, e-mail, or SMS, in addition to being available for viewing on the Internet.

The title of the Cardio Report indicates the report type. There are three types of Cardio Reports:

- Trend reports
- Event reports
- Patient reports (for pacemakers only)

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On event reports, the title tells you which event triggered that Cardio Report, e.g., Event report – ERI detected.

Programmer

You must set up the Home Monitoring function in the programmer and register with the BIOTRONIK Customer Service Center.

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

For information about signing up for Home Monitoring, see the manual for the BIOTRONIK Home Monitoring® Service.

Types of Implant Messages

Implants with the Home Monitoring function send implant messages at set times or when certain events have occurred. Message transmission can be triggered as follows:

- Trend message –
  every day, at a certain time, the message is triggered
- Event message –
  an event triggers the message
- Patient message –
  the pacemaker patient triggers the message with a special magnet

Trend Message

Using the programmer, you decide the time at which the daily implant message is transmitted to the patient device. It is recommended that a time be chosen during which the patient is sleeping because the patient will then be close to the patient device.

The length of the time interval (the monitoring interval) is not programmable: it is preset to "daily." For each monitoring interval, a data set is generated in the implant and the transmission is triggered.

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Event Message

When the implant detects certain cardiac and technical events, an event message is sent to the patient device. For each implant, you decide what kinds of events will trigger a message. You can go to the Home Monitoring Service Center on the Internet and configure whether you also want to receive event reports for these events.

Certain events, e.g., when the battery reaches ERI, can never be omitted. You can find more information about events in the online help section for the Home Monitoring Service Center.

Patient Message

Pacemaker patients can apply a special magnet over the pacemaker and trigger a message. Please provide your patient with comprehensive information about how to handle the magnet and for which physical symptoms you consider it appropriate for your patient to trigger a message.

Caution! The special magnet may only be distributed to pacemaker patients.

A patient-triggered message does not affect any trend message transmission settings.

For more information about programmer settings with the patient message, see the manual of your programmer.

Home Monitoring Parameters

Home Monitoring

Off, On

You can activate (ON) or deactivate (OFF) the Home Monitoring function with your programmer. Any other partial functions can only be used if Home Monitoring has been previously activated.

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Monitoring Interval

1 day

When you activate the Home Monitoring function, the (daily) interval of the trend message transmission is automatically activated.

Transmission Time of the Periodic Report

Between 0:00 (12:00 a.m.) and 23:50 (11:50 p.m.)

For the trend message, program a time between 0:00 (12:00 a.m.) and 23:50 (11:50 p.m.). Selecting a time between 0:00 (12:00 a.m.) and 4:00 (4:00 a.m.) is recommended as that is a time when the patient is usually asleep.

Event Message

Off, On

The implant detects certain cardiac and technical events that trigger an automatic message transmission. As a default setting, this option is activated.

Patient Message

Off, On

The patient-triggered message can also be programmed. This option is not activated for the default settings.

Criteria for the Use of Home Monitoring

Intended Use

The fundamental medical objective is to make diagnostic information available to physicians. The therapeutic effect of implants that transmit data is not affected because the Home Monitoring Service Center has no direct effect on the implant.

For a specific description of the objective of the Home Monitoring system, see the manual for the BIOTRONIK Home Monitoring® Service.

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Prerequisites

The technical prerequisites for access to Cardio Reports are described in the manual for the BIOTRONIK Home Monitoring® Service.

Indications and Contraindications

The known indications and contraindications for pacemakers and ICDs are applicable regardless of Home Monitoring. There is no absolute indication for the use of the Home Monitoring Service Center.

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 implant. However, proper use of Home Monitoring requires the complete cooperation of the patient. Moreover, a prerequisite is that the physician has access to the Home Monitoring data (per fax and/or Internet) in order to be able to use the Home Monitoring Service Center.

Warnings and Precautions

The known warnings and precautions for pacemakers and ICDs are applicable regardless of Home Monitoring. However, there are specific precautions for Home Monitoring.

Please observe the specific warnings and precautions for Home Monitoring in the manual of the BIOTRONIK Home Monitoring® Service and in the manual of the patient device.

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Pacing Types – Modes

Closed Loop Modes

Valid for Cylos DR and Cylos VR

Cylos achieves physiologic rate adaptation using Closed Loop Stimulation. Closed Loop Modes work the same way as non-rate-adaptive modes. The only difference is that the basic rate is increased when Cylos senses that the patient is under stress. Closed Loop modes are identified by the designation "CLS."

In the DDD-CLS and VVI-CLS modes, the atrial and/or ventricular refractory period can cover a larger portion of the basic interval with high closed loop pacing rates. As a result, the sensing of spontaneous events may be prevented or impossible.

Rate-Adaptive Modes

Valid for Cylos DR-T

Rate-adaptive modes are marked by an "R" (for "rate") in the pacemaker code. Rate-adaptive modes function identically to corresponding non-rate-adaptive modes, with the exception that the basic rate increases when patient exertion is detected by the motion sensor. The non-rate-adaptive modes are described below. In rate-responsive demand modes (DDDR, DDTR/A, DDTR/V, 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 sensor-modulated rates. As a result, sensing of intrinsic actions is limited or completely suspended. For more information, see the "Rate Adaptation" section.

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Overdrive Modes

Overdrive modes reduce the probability of atrial tachycardias. In this case, the pacing rate always lies slightly above the intrinsic atrial heart rate. Preventive overdrive is available in modes DDD(R)+, DDT/(R)A+, DDT/V(R)+, AAI(R)+ and AAT(R)+. For a detailed functional description, see the "Preventive Overdrive Pacing" section.

DDD Mode

In the DDD mode, the basic interval starts with an atrial sense (A_S) or atrial pace event (A_p) or a ventricular sense event not preceded by an atrial event (VES = "ventricular extrasystole"). If no atrial sense event occurs within the basic interval, atrial pacing takes place at the end of the basic interval (See Figure 1), and the basic interval is restarted.

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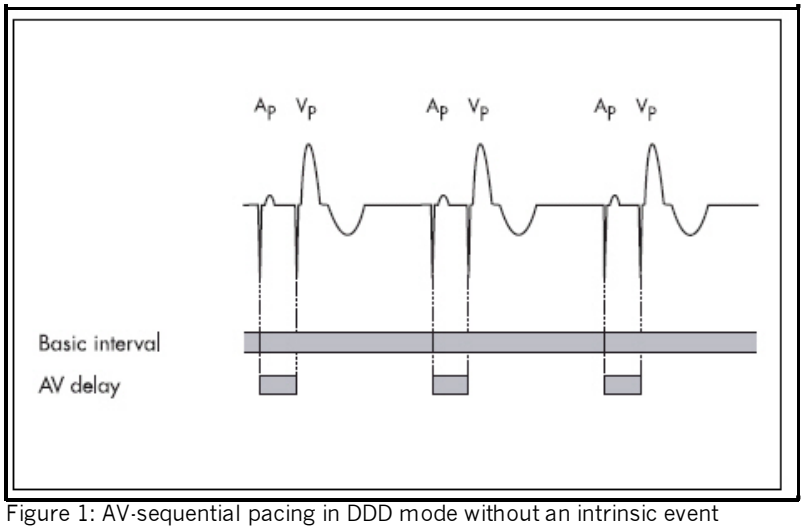

Figure 1: AV-sequential pacing in DDD mode without an intrinsic event

In the case of an atrial sensed or paced event, the AV delay starts together with the basic interval. If a ventricular sensed event does not occur within the AV delay, ventricular pacing is triggered at the end of the AV delay. If ventricular sensing (V_S) occurs within the AV delay, the ventricular pulse delivery (V_P) is inhibited.

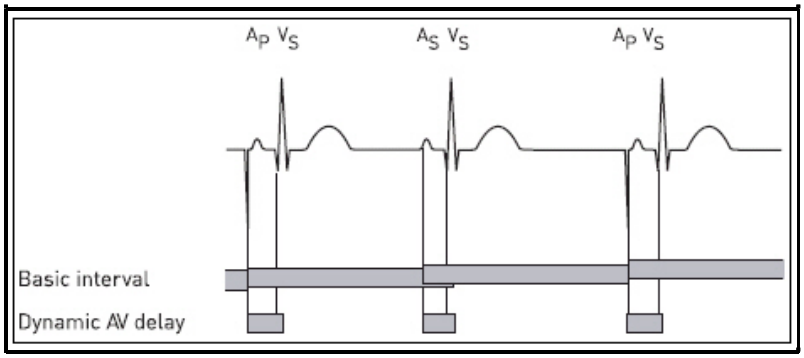

Figure 2: An atrial sensed event restarts the basic interval

If atrial sensing occurs, atrial pacing is inhibited and the basic interval is restarted (See Figure 2).

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Figure 3 and Table 1 summarize the timing intervals initiated by sensing or pacing. The table distinguishes between pacing at the end of the AV delay (V_P) or pacing at the end of the AV safety delay (V_{SP}) and between sensing within the AV delay (V_S) or sensing outside the AV delay (VES).

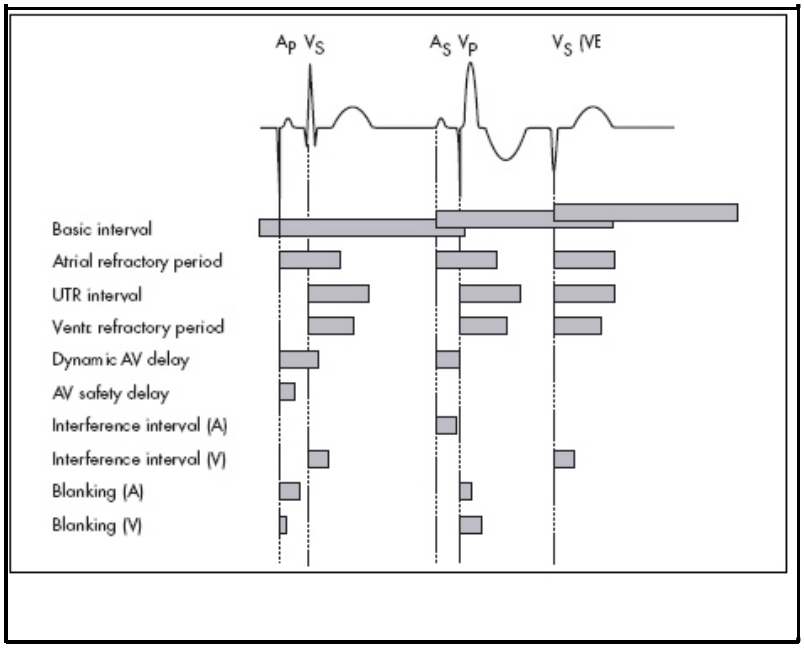

Figure 3: Start of timing intervals in the DDD mode depending on the events that occur

Timing Interval	Event					
	A_p	A_s	V_p	V_{sp}	V_s	VES
Basic Interval (DDD)	•	•				•
Basic Interval (DDI)			•	•	•	•
Atrial Refractory Period	•	•				•
Atrial Refractory Period - Extension						•
Upper Tracking Rate Interval			•	•	•	•
Ventricular Refractory Period			•	•	•	•

Table 1: Timing intervals initiated by pace and sense events in DDD and DDI modes (V_{sp} = ventricular safety pacing)

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Timing Interval	Event					
	A_p	A_s	V_p	V_{sp}	V_s	VES
(Dynamic) AV Delay	•	•				
AV Safety Delay	•					
Interference Interval (A)		•				
Interference Interval (V)					•	•
Blanking Period (A)	•		•	•		
Blanking Period (V)	•		•	•		

Table 1: Timing intervals initiated by pace and sense events in DDD and DDI modes (V_{sp} = ventricular safety pacing)

DDI Mode

In contrast to the DDD mode, the basic interval in the DDI mode does not start with a P wave, but rather with ventricular sensed or paced events. The VA interval is started together with the basic interval. If no atrial or ventricular sensing occurs within the VA interval, atrial pacing takes place at the end of the VA interval (See Figure 4).

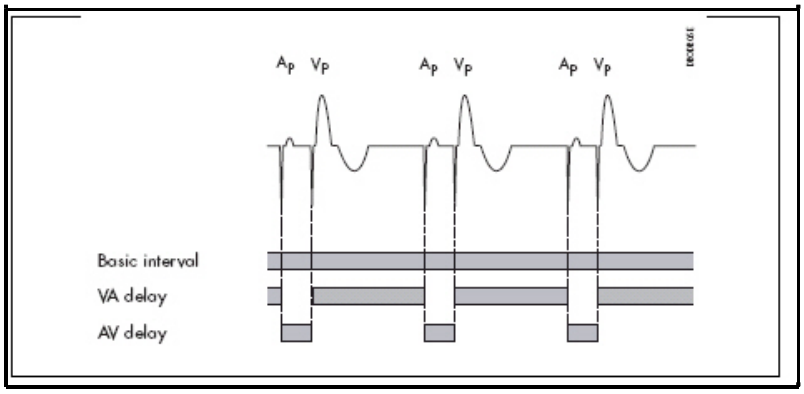

Figure 4: AV-sequential pacing in DDI mode without an intrinsic event

Upon pacing, the AV delay is restarted. If sensing occurs, atrial pacing is inhibited (See Figure 5). The AV delay does not start with this sense event, but again at the end of the VA interval. Thus, P waves in DDI mode do not trigger ventricular events.

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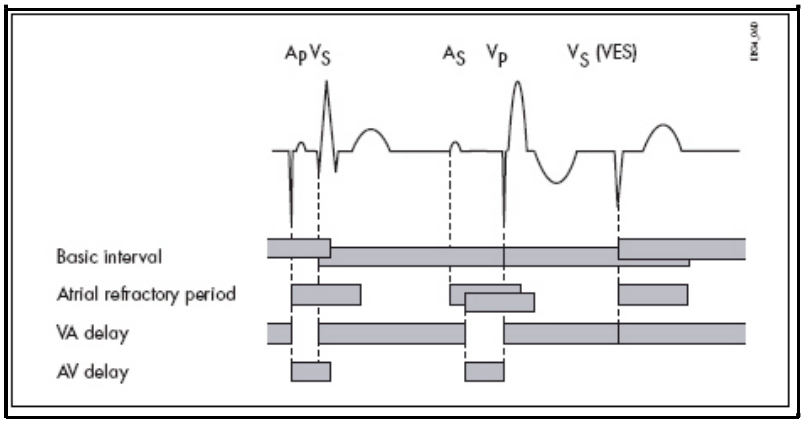

Figure 5: Inhibition of atrial pacing in DDI mode by an atrial sensed event occurring within the VA interval. The atrial refractory period restarts at the end of the VA interval.

DVI Mode

The DVI mode is based on the DDI mode. In contrast to the latter, atrial sensing does not occur in DVI mode. Therefore, atrial pacing is forced at the end of the VA delay. Ventricular sensing within the VA interval inhibits both the atrial and the ventricular pulse. Ventricular sensing within the AV delay inhibits the ventricular pulse.

VDD Mode

The VDD mode is derived from the DDD mode. In contrast to the latter, no atrial pacing takes place. Therefore, the basic interval starts at an atrial sense event, a ventricular extrasystole, or at the end of the preceding basic interval if no sense event occurs.

To prevent pacemaker-mediated reentry tachycardia, the atrial refractory period is also started by ventricular paced events that were not triggered by atrial sensed events (See Figure 6).

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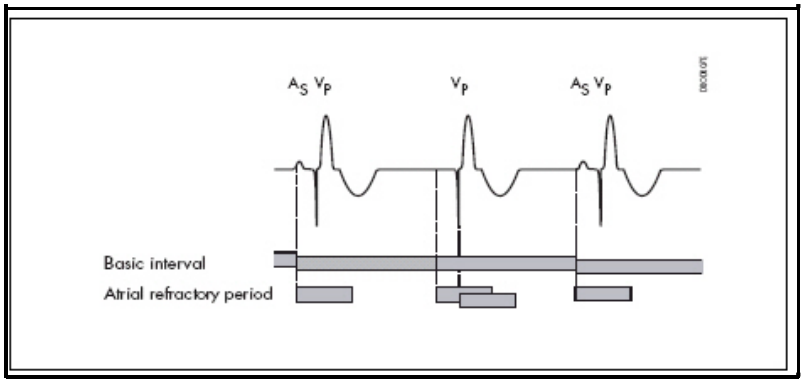

Figure 6: Prevention of pacemaker-mediated tachycardia in VDD mode

AAI Mode, VVI Mode

The AAI and VVI single-chamber pacing modes are used for atrial or ventricular demand pacing. In each case, pacing and sensing only occur in either the atrium (AAI) or the ventricle (VVI).

The basic interval is started by a sense or pace event. If there is a sense event before the end of the basic interval, pulse delivery is inhibited. Otherwise, pacing takes place at the end of the basic interval.

AOO Mode, VOO Mode

In these pacing modes, pulses are emitted asynchronously in the atrium (AOO) or ventricle (VOO). When using VOO or AOO mode, the risks associated with asynchronous ventricular pacing must be considered.

DOO Mode

Asynchronous AV-sequential pulses are delivered in this pacing mode. When using DOO mode, the risks associated with asynchronous ventricular pacing must be considered.

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Triggered Pacing

Triggered pacing modes correspond to the respective demand modes, the difference being that detection of an atrial/ventricular event outside the refractory period does not cause pulse inhibition, but rather triggers immediate pulse delivery to the respective chamber.

The corresponding pacing modes are:

Demand:	DDD	VDD	DDI	DVI	AAI	VVI
Triggered:	DDT DDT/A DDT/V	VDT	DDI/T	DVT	AAT	VVT

However, the following differences do occur: There is no AV safety delay in the DDT, DDI/T and DVT pacing modes. It is not necessary since ventricular pulse inhibition because of crosstalk (ventricular sensing of the atrial pacing pulse) cannot occur in these modes.

In the DDI/T and DVT pacing modes, the basic interval is not restarted if ventricular sensing occurs within the AV delay.

DDT/A Mode, DDT/V Mode

The DDT/A and DDT/V modes are derived from the DDT mode. In DDT/A mode, the pacemaker delivers a pulse in the atrium after every sensed atrial event and inhibits pacing in the ventricle if required. Similarly, in DDT/V mode, an immediate pulse in the ventricle, and if required pulse inhibition in the atrium, follows every sensed ventricular event.

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VDI Mode

The VDI mode is derived from the VVI mode. In contrast to the latter, the VDI mode allows intra-atrial events to be recorded. The timing corresponds to the VVI mode, however. The VDI mode is designed for measuring retrograde conduction with the IEGM and/or the marker function. Retrograde conduction time can be determined directly on the programmer, or on an additional ECG recorder, as the length of time between a ventricular pace or sense event and the subsequent atrial sense event.

OFF Mode

In the OFF mode, pacing pulses are not delivered, except when used with external pulse control. Without external pulse control, the OFF mode is used for detection and morphological evaluation of the intrinsic rhythm. With external pulse control, the OFF mode is used for electrophysiologic studies and to combat tachycardia. The OFF mode is only programmable as a temporary program. The pulse and control parameters remain adjustable in the OFF mode. With the use of the external pulse control function, the programmer triggers pacing pulses and sensed events can be transmitted to the programmer. Note that sensing is limited by the refractory period, whereas pacing is not.

Magnet Effect

Placing a magnet (or the programming wand) over the pacemaker causes the built-in magnetic switch in the pacemaker to close. The pacemaker response to magnet application is adjustable.

Note: The following functions are deactivated by magnet application:

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— Recording of statistics
— Mode switching
— Automatic lead check
— AV hysteresis and rate hysteresis
— Rate adaptation
— Overdrive
— PMT protection
— VES lock-in termination
— Active capture control (ACC)
— Rate fading

Automatic Magnet Effect

During the first 10 cycles after magnet application the pacemaker paces asynchronously at 90 ppm (at 80 ppm upon reaching the replacement indication). Thereafter, synchronous pacing at the programmed basic rate occurs (or at the night rate, if one has been programmed). During asynchronous pacing, the AV delay is reduced to 100 ms if a longer interval was programmed. This avoids ventricular fusion beats when AV conduction is intact and makes it easier to detect the effectiveness or ineffectiveness of ventricular pacing.

Asynchronous Magnet Effect

The sensing function of the pacemaker is deactivated for the duration of the external magnet application. During this time, the pacemaker paces asynchronously at 90 ppm (at 80 ppm upon reaching the replacement indication).

Synchronous Magnet Effect

The sensing and pacing behavior of the pacemaker remains unchanged when a magnet is placed over the pacemaker. The basic rate also remains intact (except after the replacement indication has been reached). The synchronous magnet effect is only important for the follow-up and if you want IEGM recordings to be triggered by the patient. This guarantees that the sensing function remains enabled when the programming wand or magnet is applied, and that the replacement indication can be monitored.

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Summary of the Functions and Timing Intervals of the Modes

Table 2 summarizes the functions and time intervals that apply to the various demand pacing modes. Not included are rate-adaptive parameters and parameters that can be programmed in all pacing modes.

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

Parameter	Pacing Modes														
	DDD	DDT	DDT/A	DDT/V	DDI	DDI/T	DVI	DVT	VDD	VDT	VDI	AAI	AAT	VVI	VVT
Basic rate	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Rate hysteresis	•	•	•	•	•				•	•	•	•	•	•	•
Repetitive rate hysteresis	•	•	•	•	•				•	•	•	•	•	•	•
Scan rate hysteresis	•	•	•	•	•				•	•	•	•	•	•	•
Upper tracking rate	•	•	•	•		•		•	•	•	•				•
A pulse duration/ amplitude	•	•	•	•	•	•	•	•				•	•		
V pulse duration/ amplitude	•	•	•	•	•	•	•	•	•	•	•			•	•
A_s inhibits A_p	•			•	•							•			
A_s triggers A_p		•	•			•							•		
A_s triggers V_p	•	•	•	•					•	•					
V_s inhibits V_p	•		•		•		•		•		•			•	
V_s triggers V_p		•		•		•		•		•					•
A refractory period	•	•	•	•	•	•			•	•	•	•	•		
V refractory period	•	•	•	•	•	•	•	•	•	•	•			•	•
Dynamic AV delay	•		•	•					•						
AV hysteresis	•			•					•						
AV repetitive hysteresis	•			•					•						

Table 2: Functions and timing intervals of the different pacing modes

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Parameter	Pacing Modes														
	DDD	DDT	DDT/A	DDT/V	DDI	DDI/T	DVI	DVT	VDD	VDT	VDI	AAI	AAT	VVI	VVT
AV scan hysteresis	•			•					•						
AV safety delay	•		•	•	•		•								
Sense compensation	•	•	•	•											
V blanking period	•	•	•	•	•	•	•	•							
Wenckebach possible	•		•	•					•						

Table 2: Functions and timing intervals of the different pacing modes

• = present
A = atrium, atrial
V = ventricle, ventricular
A_p = atrial pace event
A_s = atrial sense event
V_p = ventricular pace event
V_s = ventricular sense event

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Timing Functions

Basic Rate

The basic rate is the rate at which the pacemaker delivers pulses in the absence of a spontaneous rhythm or if sensing is deactivated. The corresponding interval is called the "basic interval" - the interval between two pacing pulses.

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 ventricular extrasystole.

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

Rate Hysteresis

To preserve a spontaneous rhythm once it occurs, a rate hysteresis can be programmed in the modes DDD(R), DDT(R), DDT(R)/A, DDT(R)/V, DDI(R), VDD(R), VDT(R), VDI(R), VVI(R), VVT(R), AAI(R) and AAT(R). In this case, the pacemaker, after detecting a sense event, “waits” not only for the duration of the basic interval for a new sense event, but also for the duration of the longer hysteresis interval before pacing occurs. This means that the pacemaker tolerates a spontaneous rhythm whose rate lies below the basic rate. However, the intrinsic 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 conforms to that of the basic rate or the interval determined by the sensor (See Figure 7).

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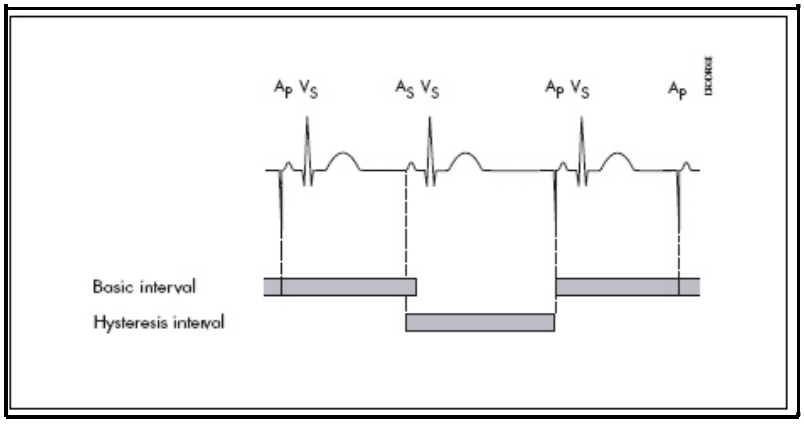

Figure 7: Basic rate and rate hysteresis in DDD mode

In pacing modes DDD(R), DDT(R)/A, DDT(R)/V, DDT(R), VDD(R), VDT(R), AAT(R), and AAI(R) the hysteresis interval starts with an atrial sense event. In the modes DDI(R), VVI(R), VVT(R) and VDI(R) it starts with a ventricular sense event. In modes DDD(R), DDT(R)/A, DDT(R)/V, DDT(R), VDD(R) and VDT(R) it also starts with a ventricular extrasystole.

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

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

Repetitive Rate Hysteresis

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

If such a pause occurs, the pacemaker continues to pace at the hysteresis rate for a programmable number of cycles instead of immediately reverting to the basic rate (See Figure 8).

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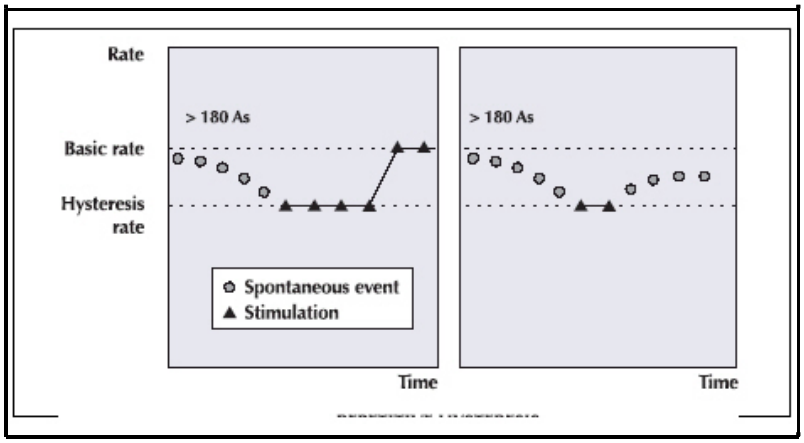

Figure 8: Repetitive rate hysteresis

An existing spontaneous rhythm is thus once again able to inhibit the pacemaker. This prevents any worsening of the hemodynamics, as might otherwise occur in modes such as VVI pacing. The pacemaker supports and stabilizes the spontaneous atrial rhythm in DDD or DDDR modes. This prevents the undesirable suppression of the spontaneous rhythm through overdrive, especially during periods of rest. Repetitive rate hysteresis is only activated in the presence of a stable intrinsic rhythm, that is, when continuous inhibition by the spontaneous rhythm has occurred during the previous 180 cycles, at the very least.

Scan Rate Hysteresis

The scan rate hysteresis promotes a spontaneous rhythm during longer phases of pacing.

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If scan hysteresis is activated, the pacemaker will reduce the pacing rate temporarily to the hysteresis rate after every 180 consecutive atrial paced events. The number of scan intervals can be programmed (See Figure 9).

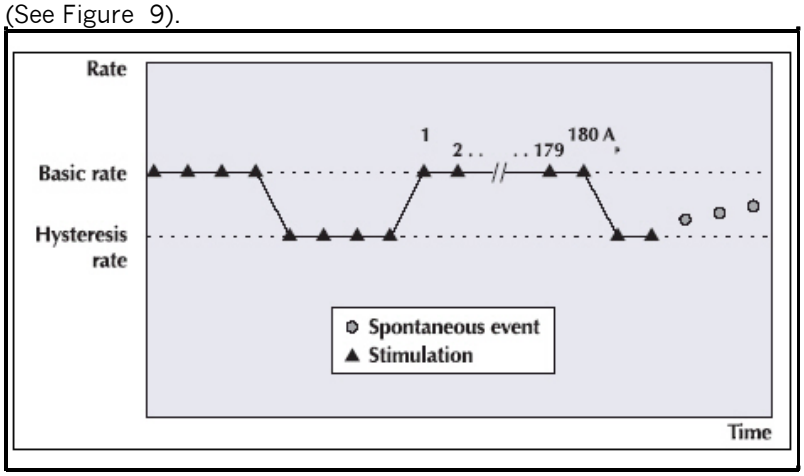

Figure 9: Scan rate hysteresis

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

Reaction to Vasovagal Syncopes and Carotid Sinus Syndrome

The scan rate hysteresis can be used in conjunction with the repetitive rate hysteresis to treat patients with vasovagal syncopes and carotid sinus syndrome of a primarily cardioinhibitory type. The following programming is recommended for this purpose.

Basic rate	Increased value, for example 90 ppm
Rate hysteresis	Such that the hysteresis rate at rest is always lower than the intrinsic rhythm (e.g., -50)
Scan rate hysteresis	Enabled, with the number of cycles set according to the patient's condition
Repetitive rate hysteresis	Enabled, with a low number of cycles

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Basic Rate:

Increased value, for example 90 ppm

Rate Hysteresis:

Such that the hysteresis rate at rest is always lower than the intrinsic rhythm (e.g., -50)

Scan Rate Hysteresis:

Enabled, with the number of cycles set according to the patient's condition

Repetitive rate hysteresis

Enabled, with a low number of cycles

This programming will inhibit the pacemaker until bradycardia episodes occur. If the rate drops due to an event, the pacemaker will pace at the hysteresis rate for the set number of repetition cycles (the confirmation period). The pacemaker will switch to the higher intervention rate to prevent possible syncope only if a spontaneous rhythm does not occur during the confirmation period, which should be set as short as possible. The pacemaker will scan for a spontaneous rhythm every 180 cycles (scan rate hysteresis) to avoid long pacing phases. If the attack has been terminated by that time, the pacemaker will be inhibited; otherwise, it will repeat the scan every 180 cycles.

Note: These patients should only be treated with a DDD(R) system to exploit the contribution of the atrium to ventricular filling and to overall hemodynamics as much as possible during such attacks.

Night Program

When the night program is activated, the pacemaker reduces its activity 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 VOO pacing may prevent the possible worsening of hemodynamics.

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The beginning and end of the night, as well as the basic night rate, can be programmed. At the beginning of the night period, the basic rate and the hysteresis rate are gradually 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 pacemaker resumes its daytime pacing values.

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

Note: The internal clock of the pacemaker is automatically adjusted to the clock of the programmer at every follow-up. Ensure that the time displayed by the programmer is correct.

Refractory Period

Sensed events that occur during the refractory period do not affect the timing. The functions related to tachycardia behavior are an exception: automatic mode conversion and mode switching. In these functions, sensed events within the refractory period are utilized for arrhythmia detection.

In DDD(R) and VDD(R) modes with automatic mode conversion, the atrial refractory period (ARP) can be triggered, i.e., a sensed event occurring in the atrial refractory period can restart it.

In the DDD mode the ARP not only starts after atrial sensing or pacing, but also with ventricular extrasystoles (VES). This is to prevent pacemaker-mediated tachycardia. For the same reason, the ARP also begins in the VDD mode upon ventricular pacing that was not triggered by an atrial event, and upon VES. In the DDI mode, the ARP starts only after an atrial sensed or paced event.

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Dynamic AV Delay

Valid for Cylos DR and Cylos DR-T

The AV delay defines the period of time between an atrial event and the subsequent ventricular stimulus. The "dynamic" AV delay lets you optimize the AV delay for five different atrial rate ranges. The AV delay selected for this rate is then effective depending on the current atrial rate (the A-A interval). The dynamic AV delay is valid after atrial detection and after sensor-driven atrial pacing. The AV delay can be individually set for the following rate ranges:

Basic rate, < 70 ppm, 70 – 90 ppm, 91 – 110 ppm, 111 – 130 ppm, > 130 ppm.

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

In addition to the option of setting the AV delay individually for these ranges, the programmer also offers three settings (low, medium and high). Refer to the table below for details. You can deactivate the optimization feature and select fixed AV delays. In non-rate-adaptive modes, the AV delay after atrial pace events is different from the AV delay after atrial sense events.

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Rate range	AV delay (in ms) for programming the dynamic AV delay to		
	Low	Medium	High
Basic rate (for non-rate-adaptive modes)	180	180	180
Less than 70 ppm	180	180	180
70 - 90 ppm	170	160	150
91 -110 ppm	160	140	120
111 - 130 ppm	150	120	100
Over 130 ppm	140	100	75

Table 3: Dynamic AV delays

The dynamic AV delay serves to prevent pacemaker-mediated tachycardias and supraventricular tachycardias. See also the "Antitachycardia Functions" section.

AV Hysteresis

An AV hysteresis can be programmed to a low, medium or high setting to promote intrinsic AV conduction. With AV hysteresis active, the AV delay is extended by a defined time period after sensing an intrinsic ventricular event. The long AV interval remains intact as long as an intrinsic ventricular activity is measured during the extended AV delay. The short AV delay interval without extension by the hysteresis value follows after ventricular pacing.

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

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AV Repetitive Hysteresis

In AV repetitive hysteresis, the AV delay is also extended by the defined hysteresis value after the sensing of an intrinsic ventricular event. In contrast to normal AV hysteresis, once the ventricular pace event occurs, the long AV delay remains intact for a programmed number of cycles. If intrinsic activity occurs during one of these repetitive cycles, the long AV delay remains intact. Only once the repetitive cycles have elapsed without any instances of spontaneous AV conduction does the pacemaker switch back to the short AV delay. The AV repetitive hysteresis hence reduces pacing when existing intrinsic activity is suppressed by occasional pace events within the extended AV delay.

AV Scan Hysteresis

In AV scan hysteresis, 180 consecutive cycles are observed and if there were only paced events and no spontaneous ventricular activity, the AV delay is extended by the additional AV hysteresis interval. The long AV delay remains intact for a pre-defined number of cycles. If spontaneous AV conduction occurs within the defined number of cycles, the AV hysteresis remains intact. The short AV delay interval resumes only when no ventricular event has been detected within the defined number of cycles and instead every one of these cycles ends with a pace. The cycle counter once again begins counting the consecutive cycles in which there was pacing. Intrinsic ventricular events (excluding VES) reset the counter to zero. AV scan hysteresis hence reduces pacing in situations in which intrinsic conduction exists but does not fall within the defined AV delay.

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Negative AV Hysteresis

Purpose

In individual cases it can be necessary to promote ventricular pacing and allow the least possible amount of conductions of the atrial sinus rhythm. This can be especially necessary for patients with hypertrophic obstructive cardiomyopathy (HOCM).

Description

With a sensed ventricular event (Vs), the function decreases the AV delay and thereby promotes ventricular pacing. With a conventional positive AV hysteresis, in contrast, the AV delay is increased to support sinus rhythms.

Negative AV hysteresis is optional. It is possible to program the negative AV hysteresis together with the negative AV repetitive hysteresis. This ensures that the pacemaker paces with the shorter AV delay for a programmable number of cycles when a sensed event occurs.

The following table shows the correlation between the standard values of the AV delay and the negative AV hysteresis:

AV Delays (Standard)	Negative AV Hysteresis
100	100
120	100
130	100
140	100
150	100
160	120
170	120
180	130
190	140
200	150
225	170
250	180
300	200

Table 4: Negative AV Hysteresis

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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 physiologic conditions. To this end, sense compensation can be used to shorten the AV delay after atrial sensing. You can program values of -15 to -120 ms for the sense compensation. In this case, the AV delay after atrial sensing is shorter than it would be following atrial pacing according to the value you have set. The AV delay after atrial pacing then corresponds to the programmed AV delay.

Blanking Period

Atrial Blanking Period

The atrial blanking period is started after a ventricular pace (see Figure 10). Atrial sensing does not occur during the atrial blanking period. This prevents atrial sensing of ventricular pacing (a phenomenon known as “crosstalk”).

Ventricular Blanking Period

The ventricular blanking period is started after an atrial pace (see Figure 10). During the ventricular blanking period, ventricular sensing does not occur. This prevents ventricular sensing of atrial pacing (a phenomenon known as “crosstalk”).

Programmable Values

The following values can be programmed for the blanking periods:

- Ventricular blanking period from 16 to 72 ms
- Atrial blanking period from 32 to 72 ms

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Note: It is recommended that the lowest possible values be selected, so that ventricular/atrial sensing is ensured for the period during which ventricular/atrial intrinsic rhythm may occur.

Note: It is also recommended that the selected values be high enough to prevent undesired sensing of pacing in the other chamber.
This is possible with high atrial/ventricular pulse energies and/or high ventricular/atrial sensitivities.

The blanking period is automatically extended by one increment in some combinations of pacing and sensing polarities in order to prevent crosstalk. The programmer will indicate the amount by which the blanking period has been extended.

Safety AV Delay

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

This prevents ventricular pulse inhibition due to ventricular sensing of atrial pacing (which would be crosstalk). (See Figure 10).

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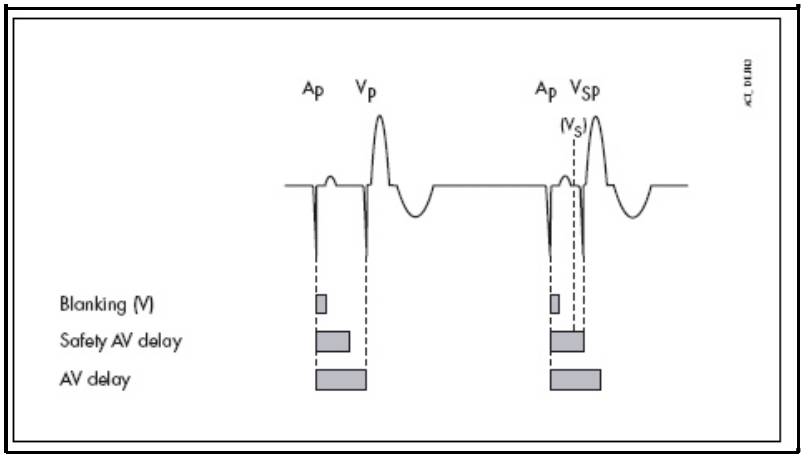

Figure 10: Ventricular blanking period and the AV safety delay

If AV sequential pacing is observed with an AV delay corresponding to the AV safety delay, this may be evidence of ventricular crosstalk (recognition of atrial pulse delivery). In order to avoid crosstalk, you can define a lower atrial pulse energy, a lower ventricular sensitivity (assigning it a higher numerical value), and/or a longer ventricular blanking period.

Pacing When Exposed to Interference

The pacemaker is equipped with interference protection to protect the patient against undesired inhibition by non-cardiac signals. An “interference interval” is started at the same time as the refractory period. The interference interval is similar to a refractory period of 125 ms that can be re-set. If an event is detected in one of the two chambers during the interference interval, the interference interval is restarted in the corresponding channel. If the detected rate exceeds 480/min (= 8 Hz), then the interference interval is continually restarted, so that the channel remains refractory throughout the entire basic interval. The pacemaker will then pace asynchronously at the programmed basic rate in that particular chamber as long as the interference persists (one example would be electrical or electromagnetic interference). For further details, see the “Cautionary Notes” section.

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Depending on whether interference is sensed in either the atrium or the ventricle, the following pacing modes will be used for the duration of the interference:

Mode	Interference During EMI in the		
	Atrium	Ventricle	Atrium and ventricle
DDD-CLS	DVI-CLS	DAD-CLS	DOO(R)
DDD(R)(+)	DVI(R)	DAD(R)(+)	DOO(R)
DDI(R)	DVI(R)	DAI(R)	DOO(R)
DVI(R)		DOO(R)	
VDD(R)	VVI(R)	VAT(R)	VOO(R)
VVI-CLS		VOO(R)	
VVI(R)		VOO(R)	
AAI(R)(+)	AOO(R)		
DDT(R)	DVT(R)	DAT(R)(+)	DOO(R)
DDT(R)/A(+)	DVD(R)	DAT(R)(+)	DOO(R)
DDT(R)/V(+)	DVT(R)	DAD(R)	DOO(R)
DDI/T(R)	DVT(R)	DAT(R)	DOO(R)
DVT(R)		DOO(R)	
VDT(R)	VVT(R)	VAT(R)	VOO(R)
VDI(R)	VVI(R)	VOO(R)	VOO(R)
VVT(R)		VOO(R)	
AAT(R)(+)	AOO(R)		

Table 5: Interference modes

Mode	Interference During EMI in the		
	Atrium	Ventricle	Atrium and ventricle
DDD(R)	DVD(R)	DAD(R)	DOO(R)
DDI(R)	DVI(R)	DAI(R)	DOO(R)
DVI(R)		DOO(R)	
VDD(R)	VVI(R)	VAT(R)	VOO(R)
VVI(R)		VOO(R)	

Table 6: Interference modes

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Mode	Interference During EMI in the		
	Atrium	Ventricle	Atrium and ventricle
AAI(R)	AOO(R)		
DDT(R)	DVT(R)	DAT(R)	DOO(R)
DDT(R)/A	DVD(R)	DAT(R)	DOO(R)
DDT(R)/V	DVT(R)	DAD(R)	DOO(R)
DDI/T(R)	DVT(R)	DAT(R)	DOO(R)
DVT(R)		DOO(R)	
VDT(R)	VVT(R)	VAT(R)	VOO(R)
VDI(R)	VVI(R)	VOO(R)	VOO(R)
VVT(R)		VOO(R)	
AAT(R)	AOO(R)		

Table 6: Interference modes

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Pacing and Sensing Functions

Pulse Amplitude and Pulse Width

In dual-chamber systems, the pulse amplitude and the pulse width are independently programmable for the atrium and the ventricle.

The BIOTRONIK PAC ("Pulse Amplitude Control") system keeps all pulse amplitudes below 8.4 V constant during the entire service time of the pacemaker.

This means that the pacing safety margin is maintained even when the battery voltage drops. The pulse widths also stay constant during the entire service time of the pacemaker.

Note: If a pulse amplitude of 7.2 V or higher is programmed and high pacing rates are attained, output amplitudes may differ from the programmed values, as in this case the amplitude control may not have enough time for an exact adjustment.

Sensitivity

The "sensitivity" parameter is used to set the pacemaker's sensing threshold for intracardiac signals. The lower you set the value to be, the higher the sensitivity.

When the sensitivity is high, there is a risk of the pacemaker being inhibited by interference signals.

If bipolar leads are used, this risk can be reduced by programming the pacemaker for bipolar sensing. In the case of high ventricular sensitivity values, particular attention should be paid to the possibility of ventricular pacing being inhibited by the atrial pulse (a phenomenon known as crosstalk). Please see the "Ventricular Blanking Period" and "AV Safety Delay" sections for more information.

Note: The sensitivity should be programmed to less than 0.5 mV only when sensing is bipolar.

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Lead Configuration

In a unipolar configuration, the negative pole (the cathode) is situated in the heart, while the positive pole (the anode) is formed by the housing of the pacemaker. In a bipolar configuration, both poles of the leads are situated in the heart.

The pacemakers allow you to program separate lead polarities for pacing and sensing.

Compared with bipolar pacing, unipolar pacing has the advantage of being clearly identifiable on the surface ECG, and its energy consumption is a bit lower. Because one pole is formed by the pacemaker housing in this case, unipolar pacing at high pulse amplitudes can occasionally result in muscle stimulation in this area.

Because of its lower susceptibility to interference signals, i.e., skeletal myopotentials, bipolar sensing offers a much better “signal-to-noise-ratio” than unipolar sensing. Therefore, you can program higher sensitivities (which are expressed as lower numerical values).

Caution! If a unipolar lead is used in one of the chambers, that lead configuration has to be programmed to “unipolar.” Otherwise entrance and/or exit block will result.

Continuous Measurement and Recording of Lead Impedance

Cylos implants are also able to continuously measure the existing lead impedance and record it as a short-term or a long-term trend.

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To this end, up to 4 stimuli of 4.8 V are triggered every 1.5 hours in order to be able to determine the impedance under defined conditions. If an amplitude higher than 4.8 V is set, the measurement is conducted with the preset amplitude. Impedances between 200-3000 Ohm are considered.

Automatic Lead Check

When this function is activated, the lead impedance is automatically measured with every pace. If the impedance values lie above or below the limits for several consecutive measurements, the system automatically switches from a bipolar to a unipolar lead configuration. The event is stored in an impedance trend. In the case of unipolar configuration and a measurement outside the limits, the automatic lead check is deactivated. In both cases, a message is generated that is displayed at the next follow-up when the pacemaker is interrogated. The automatic lead check can be activated for both the atrium and the ventricle. The selected mode must provide for pacing in the selected chamber.

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Amplitude Control (ACC)

Purpose

The amplitude control function (Active Capture Control - ACC) does the following:

- Continuously monitors for effective ventricular pacing
- Periodically determines the ventricular pacing threshold
- Verifies the stimulus response

The advantage for the patient is that pacing remains effective even when there are changes in threshold. Because the pacing amplitude is continuously being adjusted to the threshold, it is possible to optimally configure the energy reserves of the pacemaker and thus ensure reliable patient care.

The ACC function works for a ventricular rate of up to 100 bpm.

Note: Leads that generate high polarization artifacts are not suitable for ACC.

Description

The efficacy of a stimulus is monitored by a beat-to-beat algorithm, and the pacing energy is continuously adapted in the case of pacing threshold fluctuations. The ACC function features the following sub-functions:

- Signal analysis
- Automatic pacing threshold search
- Verification of the stimulus response

Signal Analysis

Purpose

This 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” or appropriate signals are evaluated. The signal analysis function works for ventricular rates of up to 100 bpm.

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Description

— The device measures with a constant, maximum pacing amplitude for a duration of 5 cycles. The AV delay is shortened to 50 ms after pace and to 15 ms after sense.
— After another 5 cycles, a second pulse is delivered with the same amplitude 100 ms after the effective pace. This pace reaches refractory tissue and thus does not evoke a stimulus response. This makes it possible to determine the sole polarization artifacts of the lead.
— 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.
— 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.
— If insufficient signal quality is measured repeatedly, then the function is deactivated and the pacemaker switches to permanent safety pacing.

Automatic Pacing Threshold Search

Purpose

The pacing threshold search function enables the pacing threshold with the resulting stimulus to be automatically determined.

Prerequisite

Only after the signal quality has been successfully checked can the pacing threshold search and amplitude adjustment functions be executed.

Description

The threshold is determined as follows:

— After successful verification of the signal quality, the pacing amplitude is incrementally decreased with every second pace. The AV delay is shortened to 50 ms after pace and to 15 ms after sense.

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— The incremental decrease of the pacing amplitude continues until loss of capture is measured (meaning the pace is ineffective). The last effective pacing amplitude that is measured is accepted and saved.
— After the first ineffective pace is detected, either the AV delay (for atrial-controlled pacing) or the basic rate (for ventricular-controlled pacing) is changed with the subsequent pace.
If again no stimulus response is measured, the ineffectiveness of the pacing is confirmed.
— A safety pulse with maximum pulse width is delivered after every ineffective ventricular pace. This produces continuously effective pacing.

Verification of the Stimulus Response

Purpose

This function allows the pacing amplitude to be continuously verified. Verification of the stimulus response is possible for a ventricular rate of up to 110 bpm.

Description

The pacing effectiveness is verified after each ventricular stimulus.
— When pacing is effective, any current settings are retained.
— When pacing is ineffective, a safety pace with a higher level of energy is delivered after 130 ms at the latest. This is done at the same amplitude but a greater pulse width.
— When a series of 3 consecutive ventricular paces – even after the AV delay has been changed – does not produce effective pacing, first the signal analysis function is started and a new threshold search is executed.
— If pacing continues to be ineffective, the pacing amplitude is increased in order to secure effective pacing. Due to this automatic amplitude control, it is possible to select a smaller safety margin, which can produce lower energy consumption with safe pacing.
— After the monitoring interval has elapsed, the threshold search function is automatically executed. The pacing amplitude is set to the threshold value plus the safety margin.

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Pacing in Single-Chamber Pacemakers

In order to ensure pacing in single-chamber pacemakers during signal analysis and threshold verification, the device paces at a rate that is 10 ppm higher than the intrinsic rate.

Programmable Parameters

Amplitude Control - ACC

ON; OFF; ATM

The "minimum ventricular amplitude" and "maximum ventricular amplitude" parameters prevent a certain value of the ventricular amplitude from being exceeded or undershot.

Minimum Ventricular Amplitude:

0.2...(0.1)...3.6...(0.1)...4.8 V

Maximum Ventricular Amplitude

2.4; 3.6; 4.8 ; 6.4 V

The search period parameter determines the times or intervals during which the signal quality is continuously verified and the automatic threshold search is executed. Intervals or times can be alternately selected.

Scan Period

Interval; Times of Day

Interval

0.1; 0.3; 1; 3; 6; 12; 24 hours

Times of Day: 1st / 2nd Time of Day

00:00 to 24:00 hours, min. time unit of 15 min

Safety pacing is carried out at the amplitude of the last-measured pacing threshold plus the set safety margin or the programmed initial amplitude. The largest value of the pacing threshold influences the safety pacing.

Safety Margin:

0.3...(0.1)..1.2 V

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Options for the ACC Function

The following options are available for the amplitude control function:

Active capture control (ACC)

ON; OFF; ATM

ON

This option activates all sub-functions: The pacing threshold is monitored and recorded, and the pacing energy is continuously adapted. This is done with the following:

— Signal analysis
— Automatic pacing threshold search
— Verification of the stimulus response

ATM (Active Threshold Monitoring) Option

The threshold is monitored and recorded at programmable time intervals. This is done with the following:

— Signal analysis
— Automatic pacing threshold search

Therefore, there is **no** continuous adaptation of the pacing amplitude.

OFF

This setting deactivates the entire amplitude control function.

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

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ACC Status

It is possible to display information via the status of the Active Capture Control (ACC) function. The following statuses are possible:
- OK
- OFF; the following is displayed: "---------"
- Deactivated
- Unconfirmed
- High pacing threshold

OK

Shows that the ACC and ATM functions are activated and operating properly.

OFF

Shows that ACC and ATM have been deactivated by the user.

Deactivated

After a maximum of 25 activation attempts per day, the function is switched off by the implant, and the "Deactivated" status is displayed.

The programmer's printout displays the reason for the deactivation:
- Insufficient signal quality
- Stimulus is frequently ineffective
- Initial test was not successful
- Implant is in ERI mode

Unconfirmed

This status is displayed after the ACC function has been activated by the user. Subsequently, the signal analysis and pacing threshold search sub-functions are started. While these functions are running, the status "Unconfirmed" is displayed.

Note: Re-interrogate the implant to confirm the status.

After the sub-functions have run successfully, "OK" is displayed. The ACC function is working properly.

High pacing threshold

If the recorded pacing threshold is higher than the maximum ACC amplitude you have set, it is not possible to conduct signal analysis or measure the pacing threshold. In this case, the user will see – on the programmer display – a message indicating the need to increase the maximum ACC amplitude.

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Lead Detection and Auto-Initialization

Lead Detection

Purpose

The lead detection function allows the implant to recognize the connected leads as early as during implantation. This is also the basis for being able to activate the auto-initialization function.

When the connected leads have been successfully detected, the pacing and sensing polarities are automatically set. This depends on the type of leads connected (be they unipolar or bipolar). The pacemaker uses the lead impedance as a basis for the automatic polarity setting.

The pacemaker goes through the following phases:
— An initial lead detection
— Lead polarity is recognized
— Confirmation

The Initial Lead Detection

To detect a lead, the implant (depending on the type) provides unipolar pacing both in the atrial and ventricular channel and measures the impedance of each stimulus. If intrinsic events are detected, they trigger a pulse in the same chamber in which the event was detected. This mimics the pacing response of an implant in the DDT mode. If the measured impedances lie within 200-3000 Ohm, the lead is considered detected.

Recognizing Lead Polarity

After successful detection of the lead, the implant switches to bipolar pacing. The impedance is also measured during pacing. If it lies between 200-3000 Ohm, a bipolar lead is considered confirmed.

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If the impedance lies outside of this range, the implant switches to unipolar pacing. A unipolar lead is then confirmed.

Any sense event occurring during the phase for recognizing lead polarity triggers a stimulus in the same chamber. This allows the impedance to be measured.

The Confirmation Phase

After successful lead detection and detection of the lead polarity, an implantation confirmation time of 30 minutes is started. Upon each stimulus, the prior detected status must be confirmed. If this occurs, lead recognition is successfully concluded.

The pacing pulse is as a rule inhibited when there are intrinsic cardiac events. If intrinsic cardiac events are detected during the confirmation phase, a stimulus is triggered every 10 minutes in the atrium and ventricle to determine the lead impedance.

If there is no confirmation of the prior detected status, the initial lead detection is restarted.

Auto-Initialization

Purpose

A few implant functions are automatically activated by the auto-initialization function. A prerequisite is the successful detection and confirmation of the connected leads (in both chambers in the case of dual-chamber implants).

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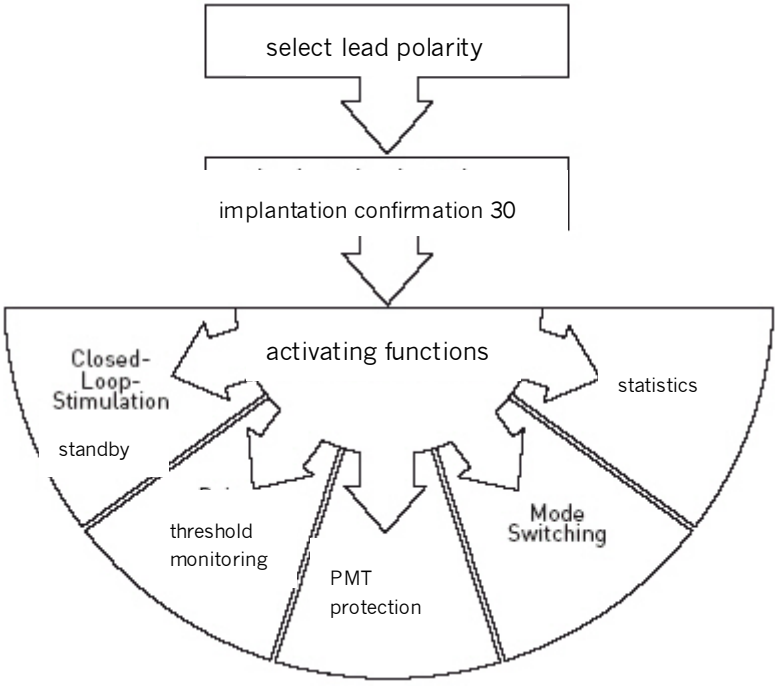

Figure 11: Implant functions that are activated by auto-initialization

During auto-initialization, the implant activates the following functions:

— Statistics
— ATM (the threshold recording feature of the ACC function)
— Mode switching
— PMT management
— Closed Loop Stimulation standby mode, meaning that the function has been completely initialized and deactivated

Note: If the implant parameters have been changed in the factory program prior to implantation, the auto-initialization function can no longer be executed. In this case, only the lead detection function can be run. Exception: Patient data can always be configured regardless of the auto-initialization function.

Note: The lead detection and auto-initialization functions can be run in the ventricle only with single-chamber pacemakers.

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CLS Standby Mode

CLS Standby Mode is where, after auto-initialization, Closed Loop Stimulation is fully installed but deactivated. When the implant is interrogated for the first time, Closed Loop Stimulation can be activated. The CLS Standby Mode entails the following:

— Closed Loop Stimulation has been installed, but is deactivated.
— Until CLS is activated, the implant will pace at the basic rate.
— During the first implant interrogation, the user can activate Closed Loop Stimulation.

CLS is activated

Activating CLS after the first interrogation means the following parameters have been set:

— DDD-CLS mode for dual-chamber implants or VVI-CLS mode for single-chamber implants.
— AV delays and AV hystereses are automatically optimized for CLS.

CLS is not activated

When Closed Loop Stimulation has not been activated after the first follow-up, the following parameters are automatically set:

— DDD mode for dual-chamber implants or VVI mode for single-chamber implants.
— The AV delays from the factory program are activated. AV hystereses are turned off.

Programmable Parameters

In addition to activating and deactivating the entire function, the sub-functions of lead detection can be activated individually.

Note: Patient data can always be configured regardless of the auto-initialization function.

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Note: The auto-initialization function can only be accessed before implantation. After the pacemaker has been implanted and the auto-initialization function has been run, this parameter is no longer displayed on the Parameters screen.

Note: If the implant is interrogated while auto-initialization is still running, the programmer will show a message indicating this.

Auto-Initialization

ON; OFF; Lead Detection

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Antitachycardia Functions

Overview of antitachycardia functions:

- Upper tracking rate
- Tachycardia mode
- Tachycardia response
  - mode conversion and
  - mode switching
- PMT management
- Preventive overdrive pacing
- VES Lock-in Protection

Upper Tracking Rate

In atrial-controlled dual-chamber modes, the upper tracking rate, along with the atrial refractory period, determines the maximum P-wave-triggered ventricular rate.

In all the triggered modes, the upper tracking rate limits the pacing rate triggered by sense events.

Caution! The upper tracking rate must be selected so that it can be tolerated by the patient for an extended period of time. The upper tracking rate determines the minimum interval between a sense or pace event and the subsequent atrial or ventricular pace event. A decrease of the pacing interval to that of the interval corresponding to the upper rate may be initiated - also at rest - for example, by detection of atrial extrasystoles, muscle potentials, or other interferences. Therefore, programming a low upper tracking rate may be indicated for patients with increased vulnerability.

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Tachycardia Mode

The resulting tachycardia mode (either 2:1 or Wenckebach) is automatically displayed, depending on the combination of selected parameters.

A response similar to Wenckebach block (the WRL mode) results if the selected upper tracking rate is lower than the rate corresponding to the atrial refractory period. If the upper tracking rate is exceeded in the WRL mode, the AV delay is continually prolonged so that the ventricular pacing rate does not exceed the programmed upper tracking rate.

Extension of the AV delay is interrupted as soon as a P wave occurs before the end of the extended AV delay initiated by the preceding P wave. In this case, the corresponding ventricular pulse is inhibited. If the atrial rate is only slightly above the upper rate, then a 6:5 block, for example, is the result.

Higher atrial rates produce higher degree blocks. If the length of the atrial cycle eventually becomes shorter than the programmed atrial refractory period, then a 2:1, 3:1, etc. block results.

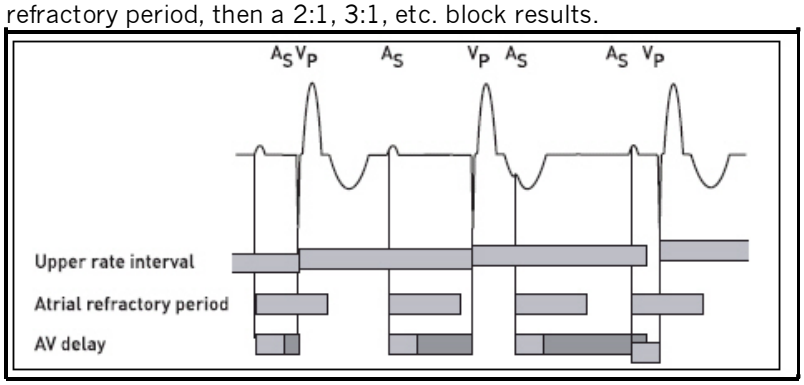

Figure 12: Wenckebach-typical pacing behavior

If the selected upper tracking rate exceeds the rate corresponding to the atrial refractory period, the maximum P-wave-triggered ventricular rate results exclusively from the atrial refractory period, not from the programmed upper tracking rate. If the length of the atrial cycle is shorter than the programmed atrial refractory period, a 2:1 block, then a 3:1 block, etc., will result before the upper tracking rate is reached in the ventricle (DDD mode, 2:1 mode).

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The extended AV delay in the WRL mode and the associated desynchronization of the atrium and ventricle increase the likelihood of detecting retrograde P waves. This should especially be considered if the dynamic AV delay is to be used for preventing or terminating (pacemaker-mediated) reentry tachycardia, since the WRL mode deactivates the dynamic AV delay when the upper rate is exceeded. (See also PMT Management.)

If the spontaneous atrial cycle is shorter than the upper rate interval in a rate-adaptive mode, the resulting pacing rate will depend on whether the 2:1 rate has been exceeded or not. If this is the case, the pacemaker will use the sensor rate as the pacing rate.

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

Minimum PVARP

This parameter enables the programming of a minimal value for the PVARP and can be activated by the physician as an additional option. When the parameter is activated, the respective PVARP value is displayed on the programmer, approximately corresponding to the ARP minus the highest possible value of the set dynamic AV delay.

In Wenckebach mode, the parameter can provide additional protection against PMTs.

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Tachycardia Behavior

Cylos offers a choice of two algorithms that effectively suppress atrial tachycardia from being conducted to the ventricle. At the start of a tachycardic episode, the pacemaker automatically switches from an atrial-controlled to a ventricular-controlled mode.

The following functions are available:

- Automatic Mode Conversion
- X/Z-out-of-8 Mode Switching

Automatic Mode Conversion

This option is available in the atrial modes DDD(R) and VDD(R) as well as in DDT(R)/A and DDT(R)/V modes. In the case of atrial tachycardias -- when the P-P interval is shorter than the ARP (the atrial refractory period) – there is an automatic conversion to a mode without atrial control. If the pacemaker is in DDD(R), DDT(R)/A, or DDT(R)/V mode, it converts to DVI(R); if it is operating in VDD(R) mode, it converts to VVI(R). This procedure prevents P-wave-triggered ventricular pacing during tachycardia.

When mode conversion is disabled, an atrial sensed event within the refractory period does not trigger an interval. In activated mode conversion, however, an atrial sensed event within the refractory period triggers a restart of the refractory period. The basic interval and the AV delay are not restarted. If the coupling interval between the consecutive P waves becomes shorter than the atrial refractory period, the atrial refractory period will be continuously restarted. This means that the pacemaker remains refractory in the atrium during the entire basic interval (see Figure 13).

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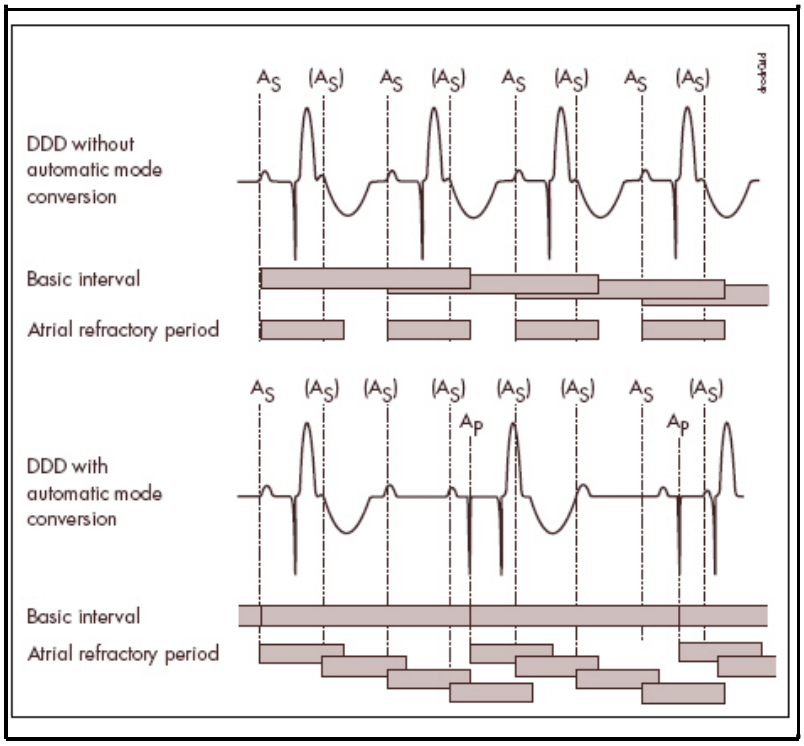

Figure 13: In DDD mode without mode conversion (shown in upper graphic), every second P wave triggers a ventricular pace during an atrial tachycardia. In the DDD mode with mode conversion (shown in the lower graphic), an atrial sensed event occurring in the atrial refractory period restarts the atrial refractory period without the basic interval being restarted. This results in DVI response for the duration of the atrial tachycardia.

This leads to non-P-wave-triggered AV-sequential pacing at the basic rate for the duration of the atrial tachycardia. In DDD, DDT/A and DDT/V modes, the pacemaker paces in the atrium and ventricle; in VDD mode it paces only in the ventricle.

In rate-adaptive modes, the pacemaker paces at the sensor rate during atrial tachycardia.

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Mode Switching with X/Z-out-of-8 Algorithm

This X/Z-out-of-8 algorithm can be used to program activation and deactivation criteria. This prevents, for example, unnecessary mode oscillations in the case of atrial extrasystoles or unstable atrial signals. In addition, this algorithm can be employed to determine the speed at which a de- and resynchronization of ventricular depolarization takes place. This intervention rate can be programmed within a range from 100... (10)... 250 ppm.

The postventricular atrial blanking (PVAB) period after a ventricular event can be programmed in a range from 50 – 200 ms. This prevents any ventricular events from being registered in the atrial channel.

When an atrial tachycardia is detected, the pacemaker automatically switches to a non-atrial-controlled mode: from DDD(R) to DDI(R), from DDD(R)$^+$ to DDI(R), or from VDD(R) to VDI(R) as well as from DDT(R)/A and DDT(R)/V to DDI(R).

The mode switch can be programmed so that you can switch from a non-rate-adaptive mode to a rate-adaptive mode, and vice versa. This serves to prevent an undesirable rate drop to the basic rate in case of physical stress.

An atrial tachycardia is considered sensed when the so-called X-out-of-8 conversion criterion has been fulfilled. The X value can be programmed in the value range (X = 3... (1)...8).

Detection is based on the continual evaluation of the last 8 atrial intervals. When X out of 8 intervals reveal an atrial rate that lies above the programmed intervention rate, then the conversion criterion is fulfilled and mode switching automatically follows.

The pacemaker works in the programmed non-atrial mode until the switch-off criterion (Z out of 8) has been fulfilled. The Z value can be programmed in the value range (Z = 3... (1)...8). Likewise, the last 8 consecutive atrial intervals are continuously evaluated. 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 to the originally programmed atrial-controlled mode.

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

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Basic Rate during Mode Switching

It is possible to set a higher basic rate during mode switching, in order to lessen undesirable hemodynamic conditions during mode switching. This basic rate can be programmed to a higher value than the standard basic rate, which leads to a slight increase of the cardiac output.

Programmable parameters:

Basic Rate during Mode Switching

+5...(5)...+30 ppm

Note: In the CLS modes, the Closed Loop rate is slowly reduced to the sensor rate during mode switching. If no rate-adaptive mode has been set for mode switching, the CLS rate is slowly reduced to the basic rate for during mode switching.

2:1 Lock-in Management

Description

When high atrial rates occur (such as during atrial flutter) in conjunction with a relatively large AV delay, every other P wave may regularly fall in the atrial far-field blanking (FFB) period. In this case, the implant only detects half of the preceding atrial rate.

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The implant behavior thus resembles a 2:1 block. The implant paces in the ventricle at a rate that corresponds to one-half of the atrial rate. At very high atrial rates, this can produce high ventricular rates that are physiologically unsuitable.

Example: If atrial flutter at a rate of 280 bpm takes place, then the pacemaker paces with a ventricular rate of 140 ppm.

This phenomenon is called 2:1 lock-in and can cause the patient severe problems in cases of long atrial flutter episodes.

Effects on Mode Switching

In such a 2:1 situation, the Mode Switching function may not start at all or only start at a very high rate, even though the function is necessary. Therefore, the purpose of this function is to ensure the effective use of mode switching.

To terminate 2:1 lock-in behavior, the AV delay is extended by a value equal to the far-field blanking period, and the device may switch to a ventricular-controlled pacing mode. The algorithms for the 2:1 lock-in behavior have been designed as follows:

— A phase where the behavior is suspected
— Confirmation of such
— Termination

When 2:1 Lock-In Behavior is Suspected

The following criteria must be fulfilled in order for there to be a 2:1 situation:

— Eight (8) consecutive V_pA_s intervals must occur
— The actual ventricular rate must be higher than 100 ppm
— The average deviation of the 8 V_pA_s intervals must lie within the tolerance limit of the 2:1 lock-in stability criterion

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

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Confirmation of 2:1 Lock-In

Detection of a 2:1 situation is determined as follows:

— The AV delay is lengthened for one cycle by a maximum of 300 ms, in order to confirm the 2:1 lock-in situation. In this manner, events that previously fell within the blanking period are detected by the implant as atrial refractory events. At the same time, the minimum PVARP function is activated for the time of the AV delay extension.

Termination

Termination is initiated as follows:

— If the As-Ars interval attains the mode switch rate, the implant immediately switches to the previously selected ventricular mode (without first waiting for the criteria for X/Z-out-of-8 mode switching).

— If the rate that corresponds to the As-Ars interval is greater than the mode switching rate, then the AV delay is reduced to the current value in increments of 50 ms.

Programmable Parameters

The following parameter is displayed on Mode Switching screen, where you can make the necessary settings.

2:1 Lock-in Protection

ON; OFF

PMT Management

The following features are provided for the prevention, detection, and termination of pacemaker-mediated tachycardias (PMT):

PMT is prevented by

— Restarting the basic interval and the atrial refractory period

— Extending the atrial refractory period

PMT protection is offered by

— PMT detection

— PMT termination

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PMT Prevention

Pacemaker-mediated tachycardia is generally triggered by ventricle depolarization that is out of synchrony with atrial depolarization, e.g., as would be the case in ventricular extrasystoles (VES). The tachycardia is maintained retrogradely by VA conduction coming from the ventricle depolarization due to pacing and antegradely by P-wave-triggered ventricular pacing.

In order to prevent PMT in cases where there is ventricular sensing without a preceding atrial event, the pacemakers restart the basic interval and the atrial refractory period (ARP). If an atrial refractory period extension has been programmed, this is additionally prolonged even further after a VES. A retrograde P wave with a VA conduction time shorter than the ARP cannot trigger a ventricular pulse and hence cannot trigger a PMT (see Figure 14).

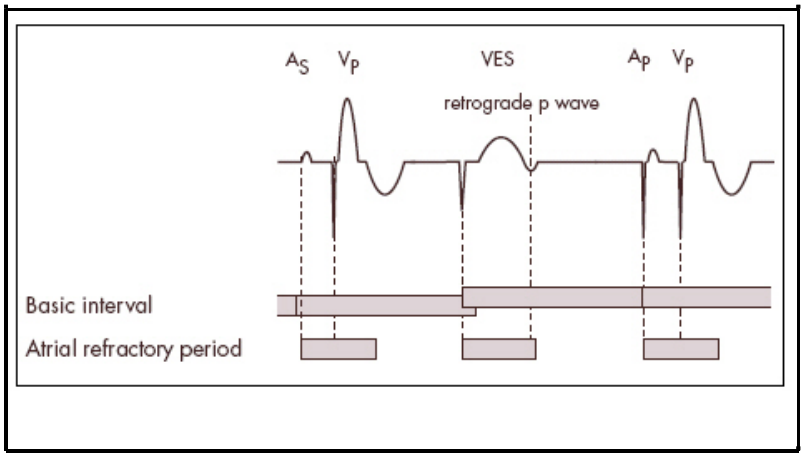

Figure 14: VES starts the ARP to prevent pacemaker-mediated tachycardia

Atrial Refractory Period Extension

In the case of a programmed atrial refractory period extension, the atrial refractory period is extended by the programmed value after a ventricular event, if the event

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

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

PMT Protection

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

PMT Detection

The period between a ventricular event and the sensing of a retrograde P wave is designated as the VA delay or retrograde conduction: V_p-A_s interval (V_p = ventricular pace, A_s = a sensed atrial event). The VA delay is a programmable parameter (VA criterion) and can be set between 250 and 500 ms.

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

- Eight consecutive V_p-A_s intervals must be shorter than the programmed VA delay.
- The average standard deviation of the eight V_p-A_s intervals must lie within the tolerance limits of the PMT stability criterion.

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If these two conditions are met, the pacemaker automatically extends or shortens the AV delay by a defined value. If the resulting V_p-A_s interval remains constant, the PMT is considered confirmed. The algorithm for terminating the PMT is automatically started.

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

PMT Termination

The PMT is terminated by extending the total atrial refractory period (TARP) for a pacing cycle. This interrupts the retrograde conduction loop and hence the PMT. Consequently, the PVARP must be longer than the retrograde conduction period after ventricular pacing or sensing. The duration of the PVARP depends on the duration of the TARP used in the systems and on the AV delay (PVARP = TARP minus the AV delay).

Note: A safety interval of 300 ms protects against competitive pacing and prevents the atrial pulse from reaching refractory and/or vulnerable tissue.

This safety interval cannot be programmed and is only active when the PMT function is active.

Preventive Overdrive Pacing

Atrial overdrive pacing is a preventive measure to reduce the incidence of atrial tachycardias. Numerous clinical studies and publications indicate a decreased risk of developing atrial tachycardias. The overdrive algorithm effects atrial overdrive pacing and ensures pacing at a rate that is slightly above the intrinsic sinus rate. Atrial overdrive pacing thereby minimizes the number of detected atrial events. The overdrive mode is available in the modes DDD(R)$^+$, DDT/A(R)$^+$, DDT/V(R)$^+$, AAI(R)$^+$ and AAT(R)$^+$.

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Incremental Rate Increase and Decrease

Each time an atrial event is sensed, the pacing rate is increased by a programmable increment (see Figure 15). This overdrive increment can be set to either low (approx. 4 ppm), medium (approx. 8 ppm), or high (approx. 12 ppm). If the intrinsic rate does not continue to rise after a programmable number of cycles (the overdrive pacing plateau), the overdrive pacing rate is reduced in increments of 1 ppm. The drop in rate occurs each time after the programmed number of cycles has been completed (see Figure 16). Values between 1 and 32 cycles can be assigned to the overdrive pacing plateau.

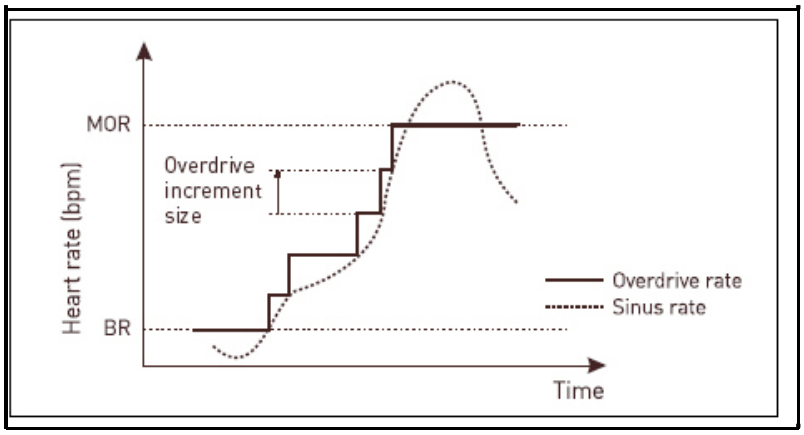

Figure 15: Incremental rate increase in preventive overdrive pacing

The pacing rate is reduced until the next atrial event is sensed. Subsequently, the overdrive cycle begins again with the rate increase.

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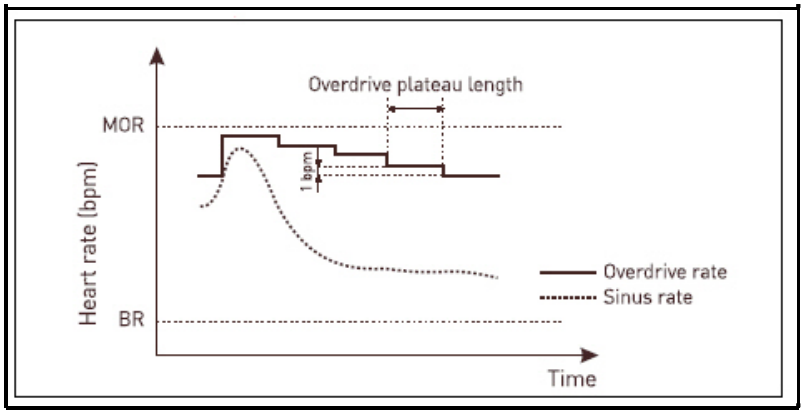

Figure 16: Incremental rate reduction with preventive overdrive pacing

Safety Function of the Algorithm

Preventive overdrive pacing provides various safety functions which are, for example, effective for high atrial rates:

- When the programmed maximum overdrive rate (MOR) is exceeded, such as in the case of atrial tachycardias, then the algorithm is automatically deactivated. Should the rate fall below the MOR, the overdrive algorithm is reactivated.
- The function is likewise deactivated when the average atrial rate of the last 64,000 cycles exceeds the average safety rate (ASR). In this case, the pacing rate is incrementally decreased to the basic rate. The ASR is dependent on the programmed basic rate and the MOR. When the average atrial heart rate falls below the ASR, preventive overdrive pacing is reactivated.

The overdrive remains permanently switched off after the fourth deactivation due to the ASR being exceeded. The overdrive mode can be reactivated only after the next interrogation of the pacemaker.

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Caution! When programming the DDD(R)+ overdrive mode, you should check whether a pacemaker-mediated tachycardia could be triggered on the basis of the selected pacemaker program, and whether atrial overdrive pacing might then develop.
If this is the case, we recommend programming the maximum overdrive rate (MOR) for the atrial overdrive to a value which is lower than the expected rate of the pacemaker-mediated tachycardia.

VES Lock-in Protection

Purpose

Terminating VES lock-in behavior by an atrial stimulus after detecting a P wave during the refractory period. This function is particularly suitable for patients with first-degree AV block.

Description

When ventricular extrasystoles (VES) occur, the following implant behavior can occur:

— When VES occur, the basic interval and atrial refractory period are restarted. This enables the P waves to fall within the atrial refractory period.
— As a result, no ventricular pacing pulses are triggered by the P waves. This implant behavior is termed VES lock-in.
— To terminate this VES behavior, an atrial stimulus is emitted during the refractory period after the atrial sense event to resynchronize the implant with the cardiac activity.

The VES lock-in protection function can be optionally activated, and you have the option to set the number of detection cycles.

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Rate Adaptation

Cylos uses two completely separate principles for rate adaptation:

- Rate adaptation by an accelerometer
- Physiologic rate adaptation using Closed Loop Stimulation

The programmable rate-adaptive modes fall into the following categories:

Rate Adaptation		
Closed Loop Stimulation	Accelerometer-based	
physiological rate adaptation	activity modes	atrial overdrive pacing
DDD-CLS VVI-CLS	DDDR DDIR DDITR DDTR DDTRA DDTRV DVIR DVTR VDDR VDTR VDIR VVIR VVTR V00R AAIR AATR A00R D00R	DDDR+ DDTR+ DDTRA+ DDTRV+ AAIR+ AATR+

Table 7: Overview of rate adaptation

Accelerometer-Based Rate Adaptation

Sensor-controlled rate adaptation allows an adjustment of the pacing rate to changing metabolic needs at rest and during exertion. The pacing rate increases at the onset of exercise to the sensor-determined rate. It slowly returns to the basic rate when exercise is no longer detected.

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The pacemakers are equipped with an accelerometer that is integrated into the hybrid circuit. This sensor produces an electric signal that is constantly processed by analog and digital signal facilities. If a rate-adaptive mode is programmed, then this effects an adjusted increase of the basic rate, depending on the exertion level of the patient. With the sensor being integrated in the hybrid circuit, it is not sensitive to static pressure on the pacemaker housing.

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

Convenient diagnostics features allow you to quickly set individual and optimal rate adaptation for the patient (see the section on “Follow-up Options” for more details).

Physiologic Rate Adaptation (The CLS Feature)

How Closed Loop Stimulation Works

The contraction dynamics of the myocardium vary depending on the patient's exertion. These changes are characteristic, allowing Closed Loop Stimulation to determine a pacing rate that is patient-specific and physiologically appropriate. This also applies to times when the patient is emotionally stressed.

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The pacemaker evaluates the dynamics of the myocardial contraction quickly after ventricular contraction. Impedance is measured via a ventricular lead and is largely dependent on the specific conductivity of a small volume of tissue surrounding the electrode tip.

Changes in impedance are characteristic of ventricular contraction and are directly proportional to heart stress. The pacemaker calculates the necessary pacing rate by measuring the current impedance and comparing it with impedance data that was measured at rest. CLS is able to immediately respond to exertion by using contractility as input for rate adaptation. There is therefore no need to combine CLS with accelerometer-based rate adaptation.

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 continually occurs throughout the entire service time of the pacemaker.[1]

It may be necessary to adjust the CLS in individual cases, as when a patient is extremely active or inactive.

[1] Among other things, the baseline impedance curves used for comparison are regularly updated by pacing cycles with extended or reduced AV delays.

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Individually Adjusting CLS Parameters

The following parameters can be individually adjusted with the “extended CLS settings”:

- The required V_P
- The CLS dynamics
- Dynamic runaway protection

The Required V_P

In the DDD CLS mode, the default setting includes AV hysteresis to support existing adequate intrinsic conduction. For patients with inadequate or non-existing intrinsic conduction, it may be necessary to turn off AV hysteresis. To do this, turn on the parameter [**required V_P**].

CLS Dynamics

The factory settings for Closed Loop Stimulation provide most patients with optimum rate dynamics. Typically, there is no need to make adjustments.

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 [**CLS Dynamics**] parameter influences the pacemaker-internal target rate, which is dependent on two other pre-set parameters: the basic rate and the maximum closed loop rate. The pacemaker internally controls rate adaptation so that 20% of the pace events are always above the internal target rate. If CLS dynamics are reprogrammed to a higher value, then the rate distribution includes higher rates, and vice versa: lower programmed values yield rate distribution with lower rates.

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Dynamic Runaway Protection

This parameter sets the pacing rate attainable during rest to a programmable value,[1] for example 20 ppm, above the preset basic rate. This suppresses any non-specific rate fluctuations at rest without limiting the rate adaptation under mental stress. In cases where runaway protection is not clinically appropriate, this feature can be turned off.

The CLS Safety Feature

The pacemaker regularly checks internally that everything needed for correct Closed Loop Stimulation is available. If one of these requirements is not met, then Closed Loop Stimulation is interrupted, and the pacing rate is lowered to the sensor rate. As soon as all requirements are met, Closed Loop Stimulation automatically restarts. The following events interrupt Closed Loop Stimulation:

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

Automatic Initialization of Closed Loop Stimulation

CLS Standby Mode

Closed Loop Stimulation has been pre-installed and deactivated in the implant, meaning CLS is in standby. Following auto-initialization, the user is prompted to activate Closed Loop Stimulation or not (see the section on “Auto-initialization” for more information).

[1]The exact value depends on the ratio of the basic rate to the maximum Closed Loop rate, see the “Technical Data” section on page 147.

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Sensor Gain

The sensor gain designates the factor by which the electric signal of the sensor is amplified before subsequent signal processing occurs. The programmable sensor gain permits adaptation of the desired rate adaptation to the individually variable signal strengths. The optimum setting is achieved when the desired maximum pacing rate is attained during exertion (see Figure 17).

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

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

Note: Apart from the manual adjustment of the sensor gain, an automatic sensor gain function is available (see the "Automatic Sensor Gain" section).

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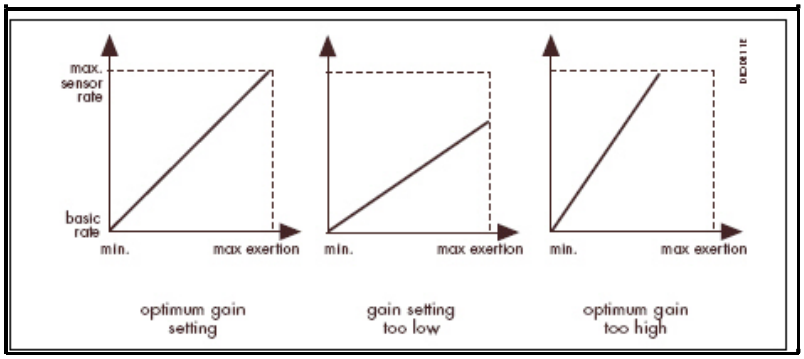

Figure 17: Impact of sensor gain on rate adaptation

Automatic Sensor Gain

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

The "automatic sensor gain" function checks daily whether 90% of the set "maximum sensor rate" (MSR) has been reached for a total of 90 seconds. When this occurs, it reduces the sensor gain by one increment.

If the "maximum activity rate" is not achieved, the current setting will initially remain unchanged. If the MSR is not reached within a period of seven days, sensor gain will be increased by one step (see Figure 17).

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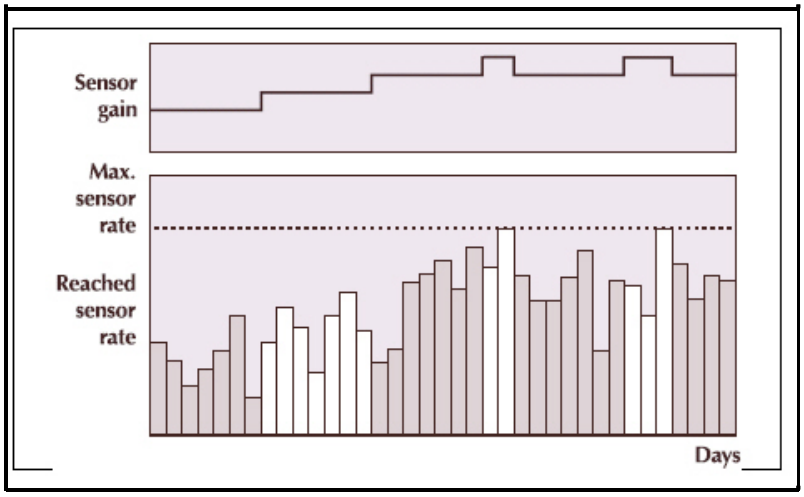

Figure 18: Automatic adjustment of sensor gain with a 7:1 algorithm

Sensor Threshold

The minimum strength of the signals used for rate adaptation is determined with the programmable sensor threshold. Sensor signals below this threshold do not affect rate adaptation (see Figure 19). Through the programmable sensor threshold, a stable rate at rest of the patient can be achieved 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.

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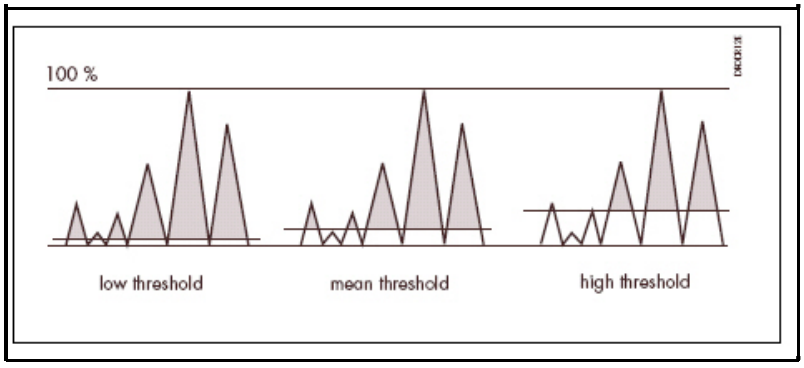

Figure 19: Only signals above the programmed threshold influence the rate adaptation

Rate Increase

The rate increase parameter determines the maximum speed by which the pacing rate rises if the sensor signal indicates increasing exertion (see Figure 20).

When the rate of increase is set to 2 ppm per cycle, the rate increases from 60 ppm to 150 ppm in 45 cycles, for example.

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

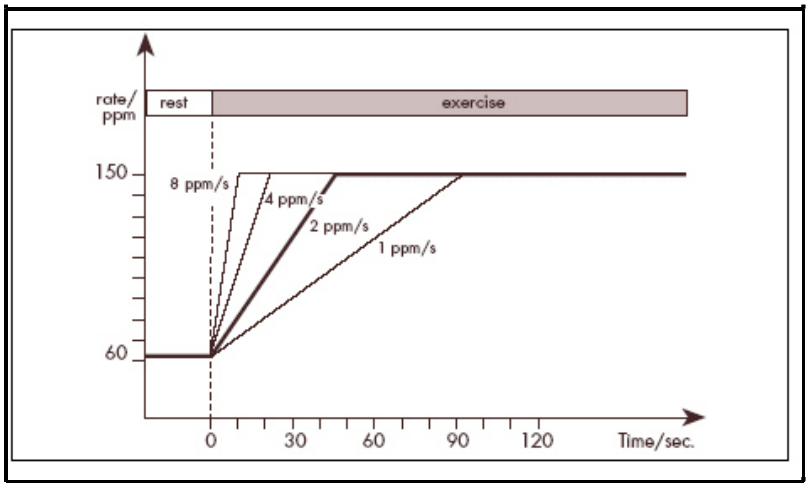

Figure 20: Rate increase during exertion

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Maximum Activity Rate

Regardless of the sensed amplitude of the sensor signal, the pacing rate will not exceed the programmed maximum activity rate (see Figure 21).

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

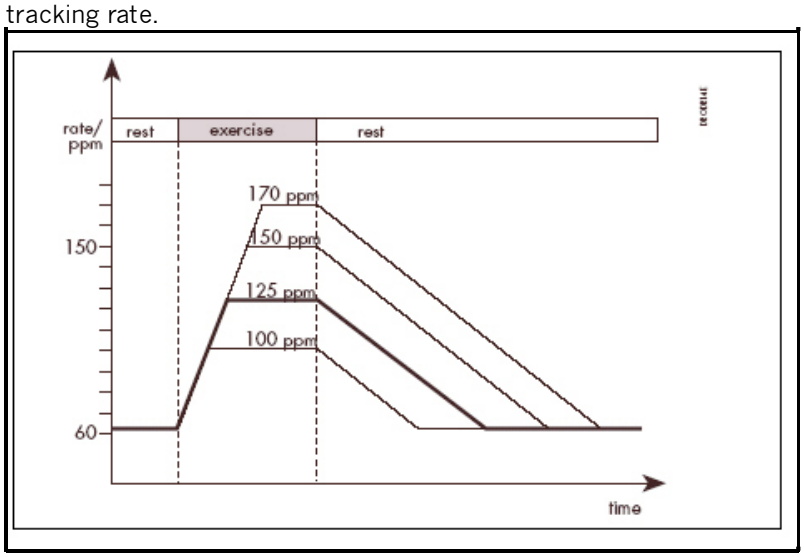

Figure 21: Maximum activity rate

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

Rate Decrease

The value programmed for the rate decrease determines the maximum speed by which the pacing rate is reduced when there is a fading sensor signal (see Figure 22).

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Setting the decrease speed to 0.5 ppm per cycle means that the rate decreases from 150 ppm to 60 ppm in 180 cycles, for example.

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

The programmed rate decrease setting applies only to the decrease in pacing rate during sensor-driven operation and does not affect the pacing rate during atrial-controlled ventricular pacing.

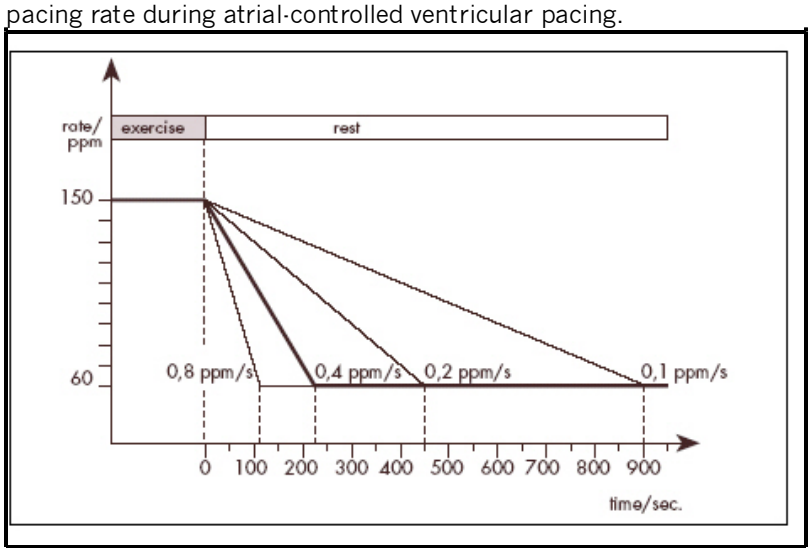

Figure 22: Rate decrease following exertion

Sensor Simulation

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

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

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Thus, sensor information is available prior to the activation of the rate adaptation, which can be used to evaluate the sensor response (see also the "Sensor Histogram" and "Activity Chart" sections under "Diagnostic Memory Functions").

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

Rate Fading – Rate Smoothing

In all atrial-controlled modes, controlled rate fading during a sudden incident of bradycardia leads to a more favorable adjustment of the pacemaker's pacing rate to the patient's intrinsic rate.

When controlled rate fading is enabled, the pacemaker calculates a "backup rate" that is always active in the background. As soon as the rate decreases, the pacemaker paces at the backup rate. The backup rate follows with a certain delay of the intrinsic rate corresponding to the programmable rate increase (1; 2; 4; 8 ppm/cycle) and the programmable rate decrease (0.1; 0.2; 0.5; 1.0 ppm/cycle). These settings determine the sensitivity of the rate fading.

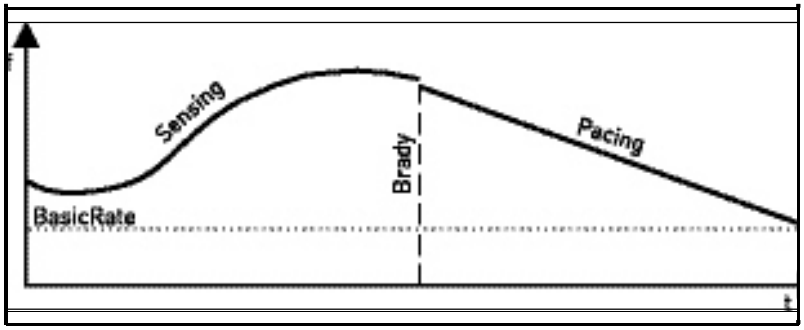

Figure 23: Rate fading after a physiological rate increase

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After four consecutive A_S, the target rate for the backup rate is calculated from the current atrial sensing rate minus 10 ppm. AES and A_P set the target rate to the value of the basic/sensor rate.

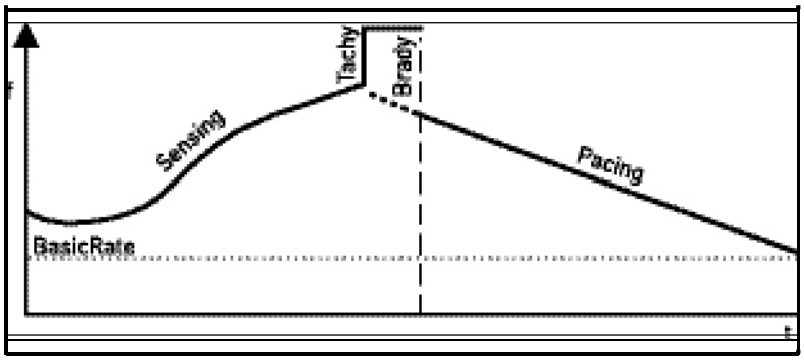

Figure 24: Controlled rate fading after a sudden incident of tachycardia

If atrial tachycardia occur suddenly triggering a mode switch, the target rate is set to either the sensor or basic rate. The current pacing rate in the ventricle is determined from the current value of the backup rate prior to the mode switching event.

If the pacing rate reaches the intrinsic rate during the rate drop, at least four consecutive intrinsic cycles above the pacing rate are required before the pacing rate is once again adapted to the last intrinsic event.

Controlled rate smoothing is thereby continued during intermittent sense events.

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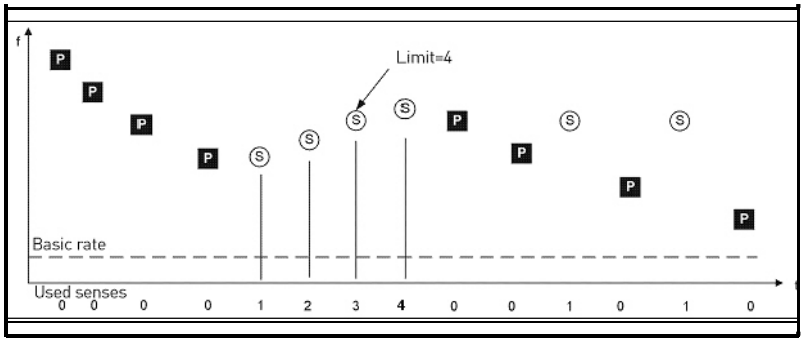

Figure 25: Updating the backup rate (rate fading), P=pacing, S=sinus rhythm

Four consecutive intrinsic sense events are necessary to activate rate fading. Individual sense events do not affect rate fading.

Backup Rate	Rate that the pacemaker uses to pace when there is a sudden rate decrease. This can be a maximum of 10 ppm less than the intrinsic rate and follows the target rate with an increase of 1,2,4, or 8 ppm per cycle, or 0.1...1 ppm per cycle if the target rate is less than the current backup rate.
Target Rate	The target rate is either the current detection rate minus 10 ppm, or the sensor/basic rate. The backup rate follows the target rate with the programmed rate increase or decrease.

Table 8: Backup rate and target rate

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IEGM Recordings

Purpose

This function makes it possible to automatically record the progression of intracardiac events. These recordings are made between follow-ups and provide diagnostic information about the origin of the tachycardia, especially the time just prior to a tachycardia episode.

Description

When the preset criteria are satisfied, the IEGM recordings are automatically started and data are recorded for up to 10 seconds. The recordings can be shorter if the rates and amplitudes are high.

A maximum of 20 IEGM recordings is possible, and each recording type can be assigned a specific number according to the memory management priorities.

Optimized Memory Management

The IEGM recordings are saved in the order that they occur until all memories are full. With this principle, these IEGM recordings are not overwritten, and thus not deleted:

- The last 3 patient IEGMs that were activated by magnet application
- 4 IEGMs for the atrial rate or mode switching:
  - —The oldest, longest, most recent recording for the atrial rate and highest ventricular value recorded
- 3 IEGMs for high ventricular rates:
  - —The longest, highest, and most recent recording

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When all 20 IEGM memories are full, the device searches for disk space that is not protected and will record the following:

- The oldest recording for the ventricular rate
- The oldest recording, triggered by magnet application
- The oldest recordings for mode switching, a high atrial rate and PMT termination

When the maximum number of entries is exceeded, then the oldest recordings are overwritten (meaning there is a loop memory principle in place for each recording type). The first recording and the recordings with the longest duration for each event type are archived and are available for viewing.
During the follow-up treatment, IEGM recordings can be interrogated and displayed.

Types of IEGM Recordings

Overview

The different types of IEGM recordings are initiated by the following events, and you can program their criteria:

1

IEGM recording at a high atrial rate (HAR)

2

IEGM recording during mode switching (MSW)

3

IEGM recording during high ventricular rate (HVR)

4

IEGM recording during PMT termination (PMT)

5

IEGM recording by patient (PAT)

Cylos VR

In VVI(R) mode, only the HVR type of IEGM recording is available. In AAI(R) mode, only the HAR type of IEGM recording is available.

IEGM Recording during High Ventricular Rates

This type is initiated by high atrial rates and atrial tachycardias. Recordings at high atrial rates are determined by the following parameters:

— The atrial detection rate defines how high a rate must be before atrial tachycardia is considered definite and the recording is started.

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IEGM Recording during Mode Switching

This type is initiated by mode switching. The parameters can only be set in the Mode Switching function.

Note: Do not activate IEGM recording for high atrial rates and for mode switching at the same time.

IEGM Recording during High Ventricular Rates

This type is initiated by high ventricular rates and ventricular tachycardias. The following parameter triggers recording during high ventricular rates:

— The ventricular detection rate determines how high a rate must be before ventricular tachycardia is considered definite and the recording is started.

IEGM Recording Triggered by the Patient

The patient can start the recording by placing a magnet (M50) over the implant.

Note: Program the magnet effect to [synchronous] when IEGM recording should be possible by the patient.

Caution! Due to the compression and reconstruction processes that the signals undergo, the IEGM recordings are not suitable for direct morphologic analyses. If you have activated the "patient-triggered IEGM recording" function, please tell the patient how to use the magnet to trigger an IEGM recording.
Have the patient review the information included with the pacemaker, including the section entitled **"Storing Intracardiac Data Through Magnet Application."**

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IEGM Recording during PMT Termination (PMT)

This type starts a recording at the end of a PMT. The PMT protection function must be activated beforehand, however.

Displaying IEGM Recordings

After the list of IEGM recordings has been selected, the desired IEGM recording is selected and interrogated. The data are read from the implant and displayed in the associated window as a graph.

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Diagnostic Memory Functions (Statistics)

Overview

The diagnostic memory functions are divided into the following five groups of statistics that in turn contain various subgroups. These are the following:

- Timing statistics
  - Timing events
  - Special events
  - Atrial rate histogram
  - Ventricular rate histogram
  - A/V rate trend
  - Far-field histogram
  - Histogram showing intrinsic AV conduction
- Arrhythmia statistics
  - Tachy episode trend
  - AT histogram
  - AES trend
  - AES versus atrial rate
  - AES coupling interval
  - VES classification
  - VES versus ventricular rate
  - VES coupling interval
- Sensor statistics
  - Rate / sensor trend
  - Sensor gain trend
  - Sensor histogram
  - Activity chart
- Sensing statistics
  - P-wave trend (short- and long-term trend)
  - R-wave trend (short- and long-term trend)
- Pacing statistics
  - A/V impedance trend (short- and long-term trend)
  - Ventricular (pacing) amplitude trend
  - Ventricular threshold trend
  - Ventricular (pacing) amplitude histogram
  - ACC status

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Description of Displays

The contents of the diagnostic memory are displayed as a combined text/graphical image, with the following display options:

— Event counters
— Histograms
— Trends

Event counters are displayed as bar charts showing the event totals expressed as a percentage.

Histograms count the frequency of events in different time or rate intervals (e. g., how many events have occurred in the 160-169 ppm range).

Trends represent a certain number of events at a fixed point in time (e.g., rates). The trends are plotted as points that are joined together by a curve. For instance, if two curves are displayed in a diagram for dual-chamber pacemakers, the thicker line always represents the ventricular trend, and the thinner line is always the atrial trend.

Note: Applying a magnet interrupts diagnostic data recording, regardless of the programmed magnet effect.

Interrogating and/or Starting Statistics

The recorded diagnostic data (the saved data contents of the pacemaker) are always read out (meaning they are transmitted during interrogation) at the beginning of a follow-up treatment, and saved in the programmer. This allows you to call up the relevant data via the programmer at any time. After which, when recording of the same statistical data is started up once again, any pre-existing statistics are deleted from the pacemaker memory. Therefore, the user is prompted for confirmation before a new statistics function can be started. This safeguard prevents you from inadvertently overwriting statistics data if you are starting the same statistics function again and again. For more detailed information on saving statistics data and the transmission of pacemaker data to the Cardiac Data Manager 3000, please consult the technical manual of the software.

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Timing Statistics

Timing Events

The display of the event counter varies depending on the kind of pacing. In addition to the graphic display, absolute values of the event counter are displayed. The event counters are categorized into three groups:

- All transitions
- Atrial sensing (A sense) and atrial pacing (A pace)
- V sense and V pace

The event counter can register the following events and event sequences over a time period of several decades:

- Atrial sensing A_S (outside the ARP)
- Atrial pacing A_P
- Ventricular sensing V_S (outside the VRP)
- Ventricular pacing V_P
- Event sequences:
  - A_S followed by V_S
  - A_S followed by V_P
  - A_P followed by V_S
  - A_P followed by V_P
- V followed by V[1] (ventricular extrasystole = VES)
- A_{RS} refractory sense events in the atrium
- V_{RS} refractory sense events in the ventricle

The event sequence V—V means two consecutive ventricular events (sensing or pacing) without a previous atrial event.

[1] In this context, V - V means that all possible ventricular events can follow, such as V_S, V_P and/or VES.

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Ventricular extrasystoles are counted both as VES as well as ventricular sense events.

Special Events

The following events can be recorded:
— Successful AV scan hysteresis
— Overdrive safety switch-off
— Mode switching counter
— PMT termination
— VES lock-in protection

Note: All event counter data are transmitted to the programmer and evaluated there, but not all events are displayed in detail on the programmer.

Atrial and Ventricular Rate Histogram

Dual-chamber pacemakers are equipped with a separate atrial and ventricular histogram. A bar chart displays the heart rate percentages as well as the absolute values. The number of times a heart rate occurs within certain rate ranges is recorded separately according to sensing and pacing. The rate range is divided into 16 equidistant rate classes between ≤ 40 and 180 ppm. The distribution of occurring heart rates can be displayed in a chart during follow-up.

Valid for Cylos DR and Cylos DR-T

A/V Rate Trend

The A/V rate trend is displayed as a line chart and consists of the heart rate trend and the pacing rate trend. Both atrial as well as ventricular events are recorded at a fixed point in time. There are two available kinds of recording, a short-term trend ([12 min/fixed]) and a long-term trend ([auto/rolling]). The long-term trend begins with a resolution of 2 seconds with 120 time intervals, the time intervals are continually compressed and in the last compression level the recording takes place with a resolution of 512 seconds and 180 time intervals. Subsequently, the long-term trend is recorded in repetitive cycles. The general rule is that the shorter the recording interval, the higher the resolution. The short-term trend thus serves to create a very exact recording of short-term rate changes, for instance during an exercise test.

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In the A/V rate trend, the heart rate in ppm is recorded in the upper chart, and the percentage distribution of the pacing rate is recorded in the lower chart. The ventricular curve for the heart rate as well as for the pacing rate is indicated by a thicker line than the atrial curve.

Far-Field Histogram

The frequency of events that fall within the far-field interval is recorded. The rate range between < 50 and > 190 ppm is divided into 16 equidistant rate classes. The graphical display shows the percentages of the individual classes in the form of a bar chart and the total number of events.

The far-field histogram can only be selected for the following pacing types:

— DDD(R), DDI(R), VDD(R), DDIT(R), VDT(R), VDI(R), DDT(R), DDT/A(R), DDT/V(R)

— $DDD(R)^+$, $DDT/A(R)^+$, $DDT/V(R)^+$

Valid for Cylos DR

Intrinsic AV Conduction

Statistics from intrinsic AV conduction help optimize the programmed AV delay and AV hysteresis. Within a single rate class, the cases of intrinsic conduction are displayed in relationship to the programmed AV delays and AV hystereses as a histogram for atrial pace and sense events. On the left side of a rate class (< 70; 70-90; 90-110; 110-130; > 130 bpm), instances of intrinsic conduction following atrial pace events are shown. On the right, we see instances of intrinsic conduction following atrial sense events. Totals for A_SV_S and A_PV_S within a specific rate class are shown on the printout, as are overall totals.

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Arrhythmia Statistics

The pacemaker monitors the cardiac rhythm and characterizes it according to the following classification criteria:
- SR (sinus rhythm)
- ST-AT range (sinus tachycardia/atrial tachycardia)
- Afl/AF range (atrial flutter/atrial fibrillation)

Arrhythmia detection does not occur at any individual interval, but rather within arrhythmia ranges with suitable criteria. These criteria are described below.

Mode Switching

The tachy event trend can only be selected for the following modes:
- DDD(R) and DDD(R)+
- VDD(R)
- DDT(R)/A and DDT/A(R)+
- DDT(R)/V and DDT/V(R)+

If this is not taken into account, a corresponding error message appears on the screen of the programming device. The tachy event trend can only be selected when mode switching has been set. The tachy event trend registers atrial tachycardias (PAT) that are recognized by the pacemaker and lead to mode switching. The last atrial tachycardias (up to 64) are recorded. Several consecutive mode switching events within 45 sec triggers recording of a tachy event.

The tachy event trend displays the atrial tachycardia events graphically as a function of time. The respective date and time at the beginning and end of the tachycardia events are also printed out. This documents both the frequency and length of the tachycardia periods, which can be evaluated at follow-up.

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The tachy event trend is automatically started by activating the mode switching function. The memory contents are deleted and the memory function is restarted with every permanent programming and every restart of the mode switching function. It is not possible to manually switch off the tachy event trends while the mode switching function is activated.

The beginning and end times of the tachycardias are saved with a resolution of 2 seconds. The counter evaluates tachy episodes within the entire follow-up time period.

Note: When the elective replacement indication (ERI) has been attained, the content of the tachy event trends as well as all other memory contents are "frozen," and recording is stopped.

When Are Atrial Sense Events Classified as AES?

AES Classification

The basis for evaluating whether an atrial extrasystole (AES) has occurred is provided by the atrial extrasystole value window (AESW). The objective of the absolute atrial refractory period (AARP) is to simulate the natural refractory period in the atrium. Atrial events occurring during AARP are not classified as AES. The AARP is shortened dynamically as the rate increases. The AESW is limited by an AARP and an atrial prematurity.

The window of time for an AES cannot exceed a maximum interval length of 800 ms. An atrial sense event that is detected 800 ms or more after the last atrial event is no longer classified as an AES.

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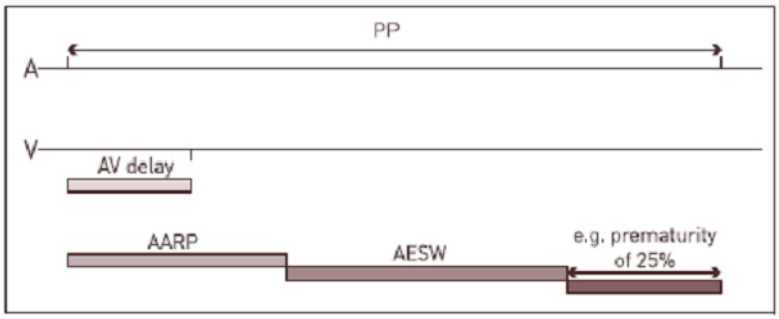

Figure 26: AES/AT classification

Atrial sense events that occur within the AESW are classified as AES. The AESW timing is triggered under the following conditions:

- The AESW starts at the end of the AARP until the requirement for atrial prematurity is met.
- The requirement for atrial prematurity can be programmed within the range of 5...(5)...50%.
- The atrial prematurity is the percentage of the last four PP intervals.

An atrial prematurity of 25% means that an atrial sensed event qualifies as an AES when the PP interval is at least 25% shorter than the average of the last 4 PP intervals.

Determining Arrhythmia Ranges

The diagnostically relevant arrhythmia ranges are limited by rate limits.

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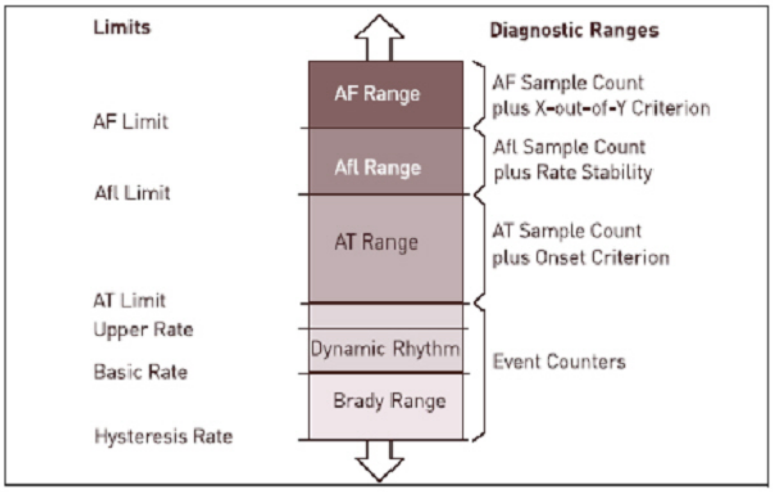

Figure 27: Arrhythmia detection

The diagnostically relevant arrhythmia ranges can be set as follows:
— ST/AT range between 80...(10)...200 ppm
— Afl/AF range between 100...(10)...400 ppm

In addition to the arrhythmia ranges, other criteria must be fulfilled:
— Activation criteria
— Atrial rate stability
— Sudden rate increase

Note: All classifications are exclusively for diagnostic purposes, i.e., in case of arrhythmia this fact is documented, but the cardiac pacemaker does not automatically respond with therapy.

AT Histogram

In the AT histogram, the events are displayed in 9 arrhythmia ranges, whereby the number and type of the ATs are indicated. The transitions from a tachycardic phase to other phases as well as the number of episodes are counted.

The programmed areas of the various ATs are also displayed.

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AES Trend

In the AES trend, the sequence of atrial extrasystoles per minute is displayed in the form of a line chart. The AES trend is a rolling long-term trend with a recording time of 180 days and a resolution of 24 hours. 0-100 AES/min. are displayed.

In addition, individual AES, couplets, triplets, the shortest Ax-AES interval, and the maximum number of AES per hour are displayed.

AES Versus Atrial Rate

The display of the AES vs. atrial rate histogram takes place in 16 equidistant rate classes of < 31 to > 179 ppm. The graphical display shows the percentages of the individual classes in the form of a bar chart and the total number of events.

AES Coupling Interval

The AES coupling interval shows in which millisecond range the prematurity has taken place. The intervals of the AES—AES sequences are displayed from ≤ 126 to > 1499 ms in 16 histogram classes. The graphical display shows the percentages of the individual classes in the form of a bar chart and the total number of events.

VES classification

This function permits long-term recording (over several years) and classification of ventricular extrasystoles (VES). Events that occur in one of the two following situations are classified as VES:

- When a ventricular event without a preceding sensed or paced event takes place,
  - — then the Vx-Vs interval must be shorter than 500 ms in order for the ventricular (Vs) event is classified as VES.
- When a preceding atrial event is sensed during the refractory period,
  - — then the Ars-Vs interval must be longer than 300 ms in order for the ventricular sense event to be classified as VES.

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Hence it is recommended that you ensure that stable atrial sensing exists prior to the activation of the VES analysis. If the atrial lead is bipolar, bipolar sensing should be considered.

The event counters of the VES classification are subdivided into three percentage classes:

— 0 - 25%
— 25 - 50%
— > 50%

In addition, individual VES, couplets, triplets, runs, tachycardias and the maximum number of VES per hour are displayed.

VES Versus Ventricular Rate

The VES vs. ventricular rate is likewise displayed in a histogram with 16 equidistant classes of < 40 to >179 ppm. The graphical display shows the percentages of the individual classes in the form of a bar chart and the total number of events.

VES Coupling Interval

The VES coupling interval documents the time difference between a regular ventricular event and subsequent VES of 0 to 500 ms duration. This display corresponds to the three event counters of prematurity at 0-25%, 25-50% and > 50%. The graphical display shows the percentage value of the individual classes in the form of a bar chart and the total number of events.

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Sensor Statistics

The sensor statistics contain the recording of the rate trend and sensor trend. A setting of [12 min/fixed] integrates the sensor optimization.

Rate / Sensor Trend

The rate / sensor trend is displayed in the form of a line graph containing the length of the time intervals and the trend data. The permanent sensor parameters can be edited at the setting [12 min/fixed]. The edited sensor parameters are simulated and displayed as a trend.
The thicker line corresponds to the recorded trend, and the thinner line to the simulated trend.

Sensor Gain Trend

The sensor gain can be recorded up to 180 days (rolling). The sensor gain is displayed on a semi-logarithmic scale from 1 to 40 with a time resolution of 2 s to 24 h, depending on the recording duration.

Sensor Histogram

The frequency with which the sensor rate occurs in certain rate ranges is recorded. The rate range is divided between < 40 to > 179 ppm into 16 equidistant rate classes. The graphical display shows the percentages of the individual classes in the form of a bar chart and the total number of events.

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.

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Activity Chart

The activity chart on the programmer is divided into three ranges: "MAR" (maximum activity rate), "Activity", and "No Activity." The activity range indicates the time in which the sensor was active, but not with the maximum sensor rate. All values are expressed as percentages.

Sensing Statistics

P-Wave Trend

This is where the course of sensitivity in the atrium is displayed. The P-wave trend is displayed in the form of a line chart. The P-wave trend is a rolling trend and records values in the range of 0.0 to 7.5 mV. The P-wave trend can be:

— A long-term trend with a recording duration of 180 days
— A short-term trend with a recording duration of 33 hours

The long-term trend can be displayed only after recording has been running for 3 days.

R-Wave Trend

This is where the sensitivity course in the ventricle is displayed. The R-wave trend is displayed in the form of a line chart. The R-wave trend is a rolling trend and records values in the range of 0.0 to 15 mV.

The R-wave trend can be:

— A long-term trend with a recording duration of 180 days
— A short-term trend with a recording duration of 33 hours

The long-term trend can be displayed only after recording has been running for 3 days.

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Pacing Statistics

Ventricular (Pacing) Amplitude Trend

The ventricular (pacing) amplitude trend is a long-term trend that records values in the range of 0.0 to 10 V with a recording duration of 180 days.

Ventricular Threshold Trend

The ventricular threshold trend is a long-term trend that records values in the range of 0.0 to 8 V with a recording duration of 180 days.

Ventricular (Pacing) Amplitude Histogram

The frequency with which ventricular pacing occurs in certain ranges – in the context of the amplitude control (ACC) function – is recorded. The range between < 0.3 V and > 4.8 V is divided into 16 equidistant classes. The graphical display shows the percentages of the individual classes in the form of a bar chart and the total number of events.

ACC Status

The ACC statistics shows the following for the active capture control (ACC) function:

— The last measured threshold
— Status of the active capture control function
— Indication of the "deactivated" and “high pacing threshold” status

A/V Impedance Trend

In the pacemaker, the atrial and ventricular impedances are measured every 1.5 hours, and both values are displayed in the A/V impedance trend in the form of a line chart. The AV impedance trend is a rolling trend. The values of the A/V impedance trend lie between 0 and 3000 Ohm. The AV impedance trend is possible as the following:

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— Long-term trend with a recording time of 180 days and a resolution of 24 hours
— Short-term trend with a recording time of 33 hours and a resolution of 1.5 hours

The thicker line represents the ventricular impedance curve, the thinner line the atrial impedance curve.

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Follow-up Options

The pacemaker is equipped with an extensive array of automatic functions that greatly simplify the adjustment and monitoring of the pacing system and reduce the time required for follow-up examinations. These functions include, for instance, automatic interrogation of all programmed and memory data at the beginning of the follow-up examination; the status window displays pacemaker response at BOS (beginning of service) and ERI (elective replacement indication, see the section on replacement indications for more details) with and without a magnet applied, the date of the last follow-up examination, and other information about the condition of the pacemaker.

Note: Programming and additional information about the individual functions are described in the technical manual of the corresponding software module.

Realtime IEGM Transmission with Markers

The pacemaker offers the option of realtime transmission of the filtered or unfiltered intracardiac electrogram (IEGM) to the programmer. The filtered signal is used for the pacemaker timing. The programmable settings relate to the filtered signal. Therefore only the filtered IEGM is suitable for selecting a proper sensitivity setting. A simpler alternative is to use the P/R-wave test to determine the amplitudes of the intracardiac signal. In dual-chamber systems it is possible to transmit and display the atrial and ventricular IEGM simultaneously. During dual-chamber operation, the IEGM can be derived from the atrium and ventricle simultaneously with a sampling rate of 5 to 60 Hz. If the IEGM is derived either from the atrium or the ventricle, a sampling rate of 5 to 80 Hz is used.

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The IEGM is transmitted together with the atrial and ventricular markers for sensing, pacing, and sensing within the refractory period. The IEGM, markers, and surface ECG can be displayed directly on the programmer screen, printed by the programmer printer, or output to an external ECG recorder.

IEGM Recordings

Purpose

The recording of intracardiac information over a short period of time before a tachycardia phase provides valuable details about the arrhythmogenesis of tachycardia. An IEGM recording can be triggered by the following events:

- IEGM recording during high ventricular rates
- IEGM recording during mode switching
- IEGM recording during high ventricular rates
- IEGM recording during PMT termination
- IEGM recording triggered by the patient

Description

Every instantaneous recording provides information from the recording period about the following:

- Type of triggering event
- The time and date of the recording
- Sensed and paced events in the atrium and ventricle including refractory events
- Duration and filtered amplitude of the sensed events
- Number of measured maximum values within every sensed event

The recordings are stored according to a specific system. The aim is to take optimal advantage of memory storage space as well as to record a uniform number of images of every type of event if possible, while simultaneously taking into consideration the above-mentioned priority ranking of triggering events. During the next follow-up, the programmer will automatically indicate that instantaneous recordings of arrhythmia have been recorded. An appropriate command displays the recording on the screen.

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Note: Program the magnet effect to [**synchronous**] when you want the patient to do IEGM recording.

Caution! Due to the compression and reconstruction processes that the signals undergo, the IEGM recordings are not suitable for direct morphologic analyses. If you have activated the "patient-triggered IEGM recording" function, please tell the patient how to use the magnet to trigger an IEGM recording.
Have the patient review the information included with the pacemaker, including the section entitled "Storing Intracardiac Data Through Magnet Application."

Analog Telemetry of Battery, Pulse and Lead Data

The following pulse, battery, and lead data can be measured non-invasively by means of analog telemetry:

Parameters	Unit of Measurement
Battery Voltage	V
Battery Impedance	kΩ
Battery Current	µA
Pulse Voltage	V
Pulse Current	mA
Pulse Energy	µJ
Pulse Charge	µC
Lead Impedance	Ω

Table 9: Measurable parameters of analog telemetry

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Rate and Sensor Trend

The rate trend is a real-time trend, whereas the sensor trend is a simulated trend.

Sensor Trend with Rate Forecasting

Valid for Cylos

The pacemaker can record the sensor rate curve over a period of 12 minutes to optimize sensor rate settings. The resolution is four seconds. Recording stops automatically after 12 minutes.

After the sensor trend has been recorded, the rate forecast function can simulate various settings for every parameter that influences the rate (for example sensor gain, sensor threshold, maximum activity rate, basic rate, etc.).

This makes it easier to optimize rate-adaptive parameters, since repeated exercise tests are no longer necessary.

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

High-Resolution Threshold Test

For facilitating follow-up, the pacemaker features a high-definition threshold test with a resolution of 0.1 V in the range of 0.1 to 4.8 V. The test is activated as a temporary program. Lifting the programming head or pressing the key terminates the threshold test and makes the pacemaker immediately revert to the permanent program.

During the threshold test, the pacing rate should be higher than the spontaneous rate to avoid competitive pacing.

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Automatic Threshold Test in the Ventricle

The prerequisites for an automatic threshold test in the ventricle are as follows:

- Ventricular rate < 100 bpm
- Adequate signal quality
- The implant is not set to mode switching

P/R-Wave Test

A P/R-wave test is available for measuring the amplitude of spontaneous events during follow-up examinations. This test measures the minimum, mean, and maximum amplitude values over several cycles. This provides a simple and reliable method for adjusting the sensitivity of the pacemaker's sensing features. An optional realtime printout contains an amplitude annotation of the measured value in each individual cycle.

Retrograde Conduction Test

Valid for Cylos

To measure the retrograde conduction time, an appropriate test function is available at follow-up. During the test, the patient is paced at an increased ventricular rate over several cycles while the VA interval is measured. (This is the time between ventricular pacing and the subsequent atrial sensing). The result is displayed as a minimum, mean, and maximum value. An optional realtime printout contains an amplitude annotation of the measured value in each individual cycle.

External Pulse Control (NIPS)

The pacemaker offers a high-speed digital communication mode that enables the transmission of pacemaker pulses to be controlled with the programmer.

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Through its external pulse control function, the pacemaker can be used as an "implanted electrophysiologic laboratory" for non-invasive programmed stimulation (NIPS) and for terminating tachycardia. The maximum pacing rate is 800 ppm for single-chamber operation (corresponding to a minimum coupling interval of 75 ms).

Two operating modes are available:

- Burst stimulation with realtime control of the burst rate
- Programmed stimulation adjustable over a broad range with up to four extrastimuli.

Caution! External pulse control must be carried out bearing the usual safety precautions in mind, because, depending on the stimulation protocol and the patient's condition, dangerous arrhythmia including ventricular fibrillation and flutter may be induced during any electrophysiological study. If defibrillation becomes necessary, care should be taken to place the leads so as to minimize the risk of damage to the implanted pacemaker. Anterior and posterior placement as far as possible from the pacemaker is best.

Caution! With high triggered rates, high pulse amplitude, and large pulse width, a temporary decrease of the pulse amplitude may occur. Therefore, the effectiveness of the pacing pulses must be secured by continuous ECG monitoring. After the replacement indication has been reached, external pulse control is blocked.

Temporary Program Activation

The pacemakers feature two program memories, one for the permanent program and the other for a temporary program. This makes it possible to temporarily activate complete programs during follow-up. Temporary programs remain active only as long as the programming head is positioned over the pacemaker and no other program is being transmitted. As soon as the programming head is removed, the temporary program is replaced by the permanent program within one cycle. Programs containing a parameter conflict cannot be transmitted as permanent programs, but can (with some exceptions) be transmitted as temporary programs.

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Temporary program activation facilitates a quicker and safer follow-up. All test programs that could be hazardous to the patient should only be activated temporarily. If a dangerous situation arises, the permanent program can be reactivated immediately by removing the programming wand. Temporary programming is also terminated by the following:

- Interrogating the implant
- Transmitting the magnet effect and patient data
- Saving the follow-up data in the implant
- Interrogating and beginning statistics
- Transmitting settings for statistics (AF/AFL range) and IEGM recordings

If you want to have sensing intact during temporary programming, do not program the magnet effect to "asynchronous."

When the pacemaker is interrogated, the permanent program is always displayed, even while a temporary program is active. During magnet application, i.e., during temporary program activation, the rate adaptation and the event counters are always inactive.

Note: If you are terminating a temporary program by removing the programming head, make sure that the distance between the programming wand and the pacemaker is large enough (at least 10 cm or 4 inches). This is to ensure that the reed switch in the magnet really opens.

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Patient Data Memory

Individual patient data can be stored in the pacemaker. This data includes the patient's name, patient code, symptoms, etiology, ECG indication, implantation date, and lead polarity. The extent and type of the stored data depends on the programmer software module being used.

Storing Follow-up Data

Purpose

This function allows you to store up to 4 follow-ups in the implant. This enables you to quickly detect the significant changes that occur between the individual follow-ups.

Description

After interrogation of the implant, the stored follow-up data are transmitted and can be displayed on the programmer. It is possible to store data from the following follow-up tests:

— Date of the individual follow-ups
— Lead impedance in the atrium and ventricle
— Lead polarity for all follow-up tests
— The amplitudes of the P and R waves
— Atrial and ventricular thresholds
— Retrograde conduction time
— Battery status

Position Indicator for the Programming Wand

The programmer indicates via a visual and audible signal when the programmer head is in telemetry contact with the pulse generator. This eases positioning of the programming wand.

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Handling and Implantation

Sterilization and Storage

The pacemaker and its accessories have been sterilized with ethylene oxide gas. To guarantee sterility, the container should be checked for damage before opening. If resterilization becomes necessary, contact your local BIOTRONIK representative.

The pacemaker is shipped in a cardboard box equipped with a quality control seal and an information label. The label contains the model specifications, technical data, the serial number, expiration date, and sterilization and storage information of the pacemaker. The box contains the plastic container with the pacemaker and documentation material.

Caution! The pacemaker should only be stored at temperatures between 5°C and 55°C (41°F to 131°F). Exposure to temperatures outside this range may result in pacemaker malfunction.

Automatic Transportation Mode

The implant is shipped in transportation mode; ERI detection is deactivated in this mode. ERI detection is automatically activated when one of the following conditions occurs:

- Auto-initialization was successfully executed
- The programmer measures a lead impedance smaller than 3200 Ohm
- The pacemaker is stored for longer than 24 months
- The safe program was successfully transmitted

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Opening the Sterile Container

Caution! Use only the BIOTRONIK screwdriver to connect and loosen the screw in the connector block. If you need to exchange a lead, order another sterile screwdriver from BIOTRONIK.

For protection against mechanical jolting during transportation and to preserve sterility, the pacemaker is packaged in two plastic containers, one within the other. Each one is separately sealed and then sterilized with ethylene oxide. This double packaging ensures the sterility of the outer surface of the inner container which can, therefore, be directly removed by the implanting physician.

Peel off the sealing paper of the non-sterile outer container in the direction indicated by the arrow.

Remove the sterile inner container using the recessed grip and open it by peeling the sealing paper in the direction indicated by the arrow.

Connecting the Leads

The pacemaker has been designed for and is recommended for use with unipolar or bipolar leads with an IS-1 connector. Appropriate adapters should be fitted when using electrodes with another connection.

Caution! When connecting unipolar leads to the pacemaker, you must set the pacing and/or sensing function of the respective channel to unipolar configuration.

In cases where you are replacing the pacemaker, make sure that the leads and lead connectors are not damaged.

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If you cannot insert the lead connector completely, it may be that the setscrew is projecting into the hole for insertion on the screw block.

Turn the setscrew counterclockwise with a screwdriver far enough to allow you to insert the lead connector completely.

Caution! To prevent cross threading, do not back the setscrew all the way out of the threaded hole. Leave the screwdriver in the slot of the setscrew as you insert the lead.

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Connecting Cylos DR/DR-T with an IS-1 Connector

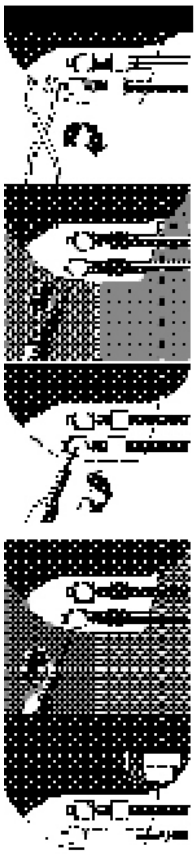
Insert the lead connector into the connector receptacle without bending the lead until the connector pin becomes visible behind the set screw block.

A: Using the screwdriver included, pierce the slot of the silicone plug vertically and insert the blade of the screwdriver into the setscrew.

B: Tighten setscrew with the enclosed screwdriver clockwise until the torque becomes limited (you will hear a crackling sound). Carefully withdraw the screwdriver without turning back the setscrew.

When you withdraw the screwdriver, the silicone plug automatically seals the lead connector block safely. The proximal pole of the bipolar lead is automatically connected. Now attach the second lead connector as described above.

Insert the non-absorbable fixation suture through the opening in the lead connector block and fixate the pacemaker in the prepared pocket.



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Connecting Cylos VR with an IS-1 Connector

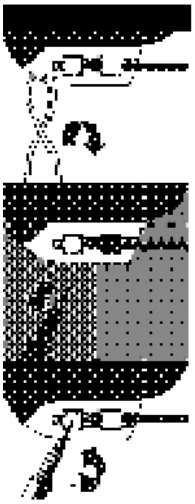
Insert the lead connector into the connector receptacle without bending the lead until the connector pin becomes visible behind the setscrew block.

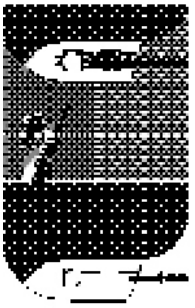
A: Using the screwdriver included, pierce the slot of the silicone plug vertically and insert the blade of the screwdriver into the setscrew.

B: Tighten setscrew with the enclosed screwdriver clockwise until the torque becomes limited (you will hear a crackling sound). Carefully withdraw the screwdriver without turning back the setscrew.

When you withdraw the screwdriver, the silicone plug automatically seals the lead connector block safely. The proximal pole of the bipolar lead is automatically connected.

Insert the non-absorbable fixation suture through the opening in the lead connector receptacle and fixate the pacemaker in the prepared pocket.





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Follow-up Basics

Follow-up lets you check the pacing system and optimize settings.

The likelihood of an electronic defect or a premature battery depletion is extremely low. Pacing system malfunctions attributed to other causes such as threshold increase are considerably more probable. In most instances, they can be corrected by reprogramming the pacemaker. The follow-up intervals are, therefore, primarily determined by medical considerations, taking into account the patient's dependency on the pacemaker.

The following notes are meant to stress certain product features of the pacemaker that are of importance for the follow-up. For detailed recommendations on the performance of follow-up tests and medical considerations, please refer to the pertinent medical literature.

See the respective software module manual for a detailed description of the procedure and for more information on the individual functions.

Note: Only ECG devices that do not delay the display of the ECG curve should be used for pacemaker follow-up. Devices with such a delay (e.g., devices with automatic base line adjustment) are fundamentally unsuitable for pacemaker follow-up.

Battery Status

The replacement indication is reached when the pacing rate without magnet application is 4.5 – 11% lower than the programmed basic rate (depending on the selected mode).

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If the pacing rate only decreases when a magnet is applied, then the replacement indication has not yet been reached but may be expected shortly.

The replacement indication will also be displayed by the programmer when interrogating the pacemaker and will appear in a data printout. For a detailed description of the replacement indication and the expected service times, please refer to the section entitled "Replacement Indication."

The battery condition can also be tested by using analog data telemetry. Nevertheless, the point of reference for replacement indication is always the basic rate.

Activation of ERI Detection

ERI detection is automatically activated when one of the following conditions occurs:

- Auto-initialization was successfully executed
- The programmer measures a lead impedance smaller than 3200 Ohm
- The pacemaker is stored for longer than 24 months
- The safe program was successfully transmitted

Testing the Pacing Threshold

To facilitate follow-up, the pacemakers feature a high-resolution threshold test with a resolution of 0.1V in the range of 0.1V to 4.8V.

The ventricular threshold test can be performed manually or automatically. The prerequisites for an automatic threshold test in the ventricle are as follows:

— A ventricular rate of < 100 bpm
— Adequate signal quality
— The implant is not set to mode switching

The pulse amplitude for the permanent program is selected based on the measured threshold and under consideration of the safety margin.

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Sensing Functions

A measuring function for the P- and R-wave amplitudes is available for testing the sensing function. This test measures the minimum, mean, and maximum amplitude values over several cycles. An optional realtime printout contains an amplitude annotation of the measured value in each individual cycle.

Additionally, the pacemaker provides an intracardiac electrogram with marker signals. The triggered pacing mode may also be selected, at which the pacemaker triggers pacing pulses simultaneously with the sensing events. This enables easy identification of sensed events in the ECG.

Particularly with unipolar sensing, the sensing function should be checked for susceptibility to interference from skeletal muscle potentials. If “oversensing” occurs, reducing sensitivity (setting a higher value) and/or programming the pacemaker to bipolar sensing (if a bipolar lead is in place) should be considered.

Retrograde Conduction

Ventricular events that are not synchronized with the atrium (such as VES) can be conducted to the atrium through retrograde conduction. The sensing function in the atrium may result in a pacemaker-mediated tachycardia (PMT).

To prevent PMT, the pacemaker's atrial refractory period must be longer than the sum of the AV delay and the retrograde conduction period.

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A measuring test is available for verifying the retrograde conduction time. See also the "Follow-up Options" section.

If retrograde conduction is present, the measured times should be nearly identical. If the measured conduction times vary significantly, this may be due to unstable atrial sensing or the absence of conduction.

Rate Adaptation

With rate adaptation enabled, the programmed values should be checked during each follow-up visit to ensure their therapeutic suitability for the individual patient. Any change in the patient's general well-being and cardiac performance since the follow-up should be taken into consideration. As during the initial programming of rate-adaptive pacing, it is recommended that the sensor-mediated rate at rest as well as during and following exertion be checked at follow-up. The control parameters may require adjustment if significant changes are detected. Ensure that the settings for maximum sensor rate, rate increase, and rate decrease are always well tolerated by the patient.

The pacemaker's diagnostic memory functions may be used to monitor the rate response of the sensor under conditions of normal daily activities. Recording the sensor trend during an exercise test is recommended during follow-up. This facilitates the simulation of different sensor settings on the programmer’s screen. In this manner, a repetition of the exercise test can be avoided.

The pacemaker's standard program includes sensor settings that are appropriate for many patients. A non-rate-adaptive mode may be programmed when you are in doubt as to whether certain settings are appropriate for a specific patient. In this mode, the sensor rate is recorded (sensor rate histogram and activity report) without being activated.

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Sensor Gain

The sensor gain controls the change in pacing rate for a certain change in workload detected by the sensor. An exercise test (such as walking) is recommended in order to achieve a rate response proportional to workload by optimizing the sensor gain. If the pacing rate is too high for the specific amount of workload, the sensor gain should be reduced. If the pacing rate is too low, a higher gain setting should be selected. The sensor trend with rate forecast can be used to record the pacing rate during exercise.

Additionally to the fixed sensor setting, an automatic sensor gain is available.

Sensor Threshold

The sensor threshold controls the signal amplitude that has to be exceeded to cause a rate increase. This parameter is meant to assure a stable pacing rate at rest and to prevent rate increases at signal levels not consistent with physical exertion.

The sensor threshold should be optimized after adjusting the sensor gain.

If the patient does not have a stable pacing rate at rest, the sensor threshold should be increased. If, however, the pacemaker tends to respond only at higher workloads, a reduction of the sensor threshold should be considered. The sensor trend with rate forecast can be used to record the pacing rate during provocation tests.

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Note: Values can only be selected for the sensor threshold that are greater than those used in the permanent program.

Battery, Pulse and Lead Data

Battery, pulse and lead data can be obtained non-invasively by means of analog telemetry. These data contain important information about the status of the pacing system. Therefore, they should be documented at each follow-up examination.

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Replacement Indication

The length of the period from beginning of service (BOS) until replacement indication (ERI) is reached depends on several factors. These include battery capacity, lead impedance, pacing program, pacing to inhibition ratio, and the properties of the pacemaker circuit.

Expected Time Until ERI

In the course of the follow-up, the pacemaker displays the expected value up until ERI, based on the permanent program. This value is derived from the measured energy consumption of the battery. If program parameters are modified, the remaining time until ERI for the edited program is also displayed on the program screen. If the remaining time until ERI falls under six months, an appropriate message is displayed.

BOS	"Beginning of Service"	Battery is in good condition; normal follow-up.
ERI	"Elective Replacement Indication"	The replacement time has been reached. The pacemaker must be replaced.
EOS	"End of Service"	End of service time with regular pacemaking activity.

Table 10: Operating status indications of the pacemaker

Elective Replacement Indicator (ERI)

The pacemaker indicates the elective replacement indication with a defined drop in both the programmed basic rate and the magnet rate (see Table 11).

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Magnet Effect	cycles 1-10 after magnet application	after 10th cycle
automatic	asynchronous with 80 ppm	synchronous with basic rate reduced by 4.5 - 11% [a]
asynchronous	asynchronous with 80 ppm	asynchronous with 80 ppm
synchronous	synchronous with basic rate reduced by 4.5 – 11% [a]	synchronous with basic rate reduced by 4.5 – 11% [a]

Table 11: Magnet response after reaching ERI

a) The pacing rate decreases by 11% in the pacing modes DDD(R), DDT(R), DDT(R)/A, DDT(R)/V, DOO(R), VDD(R), VDI(R), VDT(R), VVI(R), VVT(R), AAI(R), AAT(R), and AOO(R). In the pacing modes DDI(R), DDI/T(R), DVI(R), and DVT(R) only the VA delay is extended by 11%. This reduces the pacing rate by 4.5-11%, depending on the selected AV delay.

In dual-chamber modes, the pacemaker switches to single-chamber pacing when it reaches replacement indication. This replacement mode varies according to the programmed pacing mode and is shown on the programmer.

The replacement indication is also indicated by the programmer when interrogating the pacemaker; it can then be printed out with the data. The battery status can also be tested using analog telemetry. Nevertheless, the reference for the replacement indication is always the basic rate.

Deactivating Functions at ERI

The following functions are deactivated when ERI has been reached:

- Night program
- Rate adaptation
- Atrial overdrive pacing
- Rate hysteresis
- Rate fading
- Lead check
- Active capture control (ACC)
- AV hysteresis
- PMT protection
- Statistics are not continued

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Remaining Service Time after ERI

The following tables show the mean[1] and minimum[2] values for the remaining service time between reaching the ERI (elective replacement indication) and magnet rate after reaching replacement indication EOS (end of service) for the standard program[3] and a program with a higher pulse energy.[4]

The data are based on a lead impedance of 500 Ohms, 100% pacing and the data supplied by the battery manufacturer. These times are at most 30% shorter at a lead impedance of 300 Ohms instead of 500 Ohms.

Cylos DR/DR-T		Expected times in DDDR mode (in months)	
		Standard Program	Program with Higher Pulse Energy
Beginning of ERI to EOS	Mean Value	9	8
	Minimum Value	7	6

Table 12: Expected service times for Cylos DR

Cylos VR		Expected times in VDDR mode (in months)	
		Standard Program	Program with Higher Pulse Energy
Beginning of ERI to EOS	Mean Value	8	8
	Minimum Value	6	6

Table 13: Expected service times for Cylos VR

Note: The expected service times could differ from those given here if program settings are different from those listed in the above tables.

[1] 50% of the pacemakers reach or exceed these values
[2] 99.9% of the pacemakers reach or exceed these values
[3] Pulse amp. A/V 3.6 V, pulse width A/V 0.4 ms, rate 60 ppm
[4] Pulse amp. A/V 4.8 V, pulse width A/V 1.0 ms, rate 90 ppm

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Cautionary Notes

The pacemaker, the lead(s), and, if used, the lead extensions and adapters, become part of the artificial pacing system upon implantation. The functioning of the artificial pacing system depends on all these components, as well as the physiologic condition of the patient.

The following notes are intended to emphasize some aspects that have been deemed especially important in the medical literature for evaluating and avoiding risks. This information could be useful in evaluating and avoiding risks, but it is not a substitute for the study of medical literature.

Medical Complications

Possible medical complications of cardiac pacemaker therapy include the following: necrotic tissue formation, thrombosis, embolisms, elevated pacing thresholds, foreign body rejection phenomena, cardiac tamponade, muscle/nerve stimulation, infection, and pacemaker-induced arrhythmias (some of which could be life-threatening, such as ventricular fibrillation).

Technical Malfunctioning

Events that could compromise functioning are, for example: a defect in one of the pacemaker components, battery depletion, lead dislocation, lead fracture, or an insulation defect.

Muscle Potentials

The filter properties of BIOTRONIK pacemakers have been adjusted to the rate spectrum of cardiac actions, so the risk of sensing skeletal muscle potentials is low. However, this risk cannot be completely ruled out, especially not in unipolar systems and at a high pacemaker detection sensitivity. If the pacemaker senses skeletal myopotentials as intrinsic cardiac activity, then inhibition or asynchronous and/or triggered pacing may result, depending on the pacing mode and the interference pattern. You can test the whether the pacing system functioning is safe from skeletal myopotentials, for example, by monitoring the Holter or pacemaker performance while the patient does movements involving chest muscles.

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To avoid skeletal myopotentials interfering with pacemaker functioning, a lower sensitivity (a higher value), bipolar sensing, or a different pacing mode can be programmed, depending on the availability of these features.

Electromagnetic Interference (EMI)

Every implanted pacemaker can be affected by interference with signals that the pacemaker sees as intrinsic cardiac activity and/or that compromise measurements the pacemaker uses for rate adaptation. Depending on the pacing mode and the type of interference, these sources of interference may lead to pacemaker pulse inhibition or triggering, an increase in the sensor-dependent pacing rate, or a fixed-rate pulse delivery. Under unfavorable conditions, for example during diagnostic or therapeutic procedures, the interference sources may induce such a high level of energy into the artificial pacing system that the pacemaker and/or cardiac tissue around the lead tip is damaged.

BIOTRONIK pacemakers have been designed so that their susceptibility to EMI is minimized. However, due to the variety and intensity of EMI, absolute safety is not possible.

It is generally assumed that EMI produces only minor symptoms, if any, in pacemaker patients.

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If interference is expected to have clinically relevant consequences, the patient must be protected from the interference or its effects, e.g., through appropriate warnings or pacemaker reprogramming.

Household Appliances

Electrical household appliances (e.g., ranges, microwave ovens, radios, televisions, VCRs, electric shavers and toothbrushes) do not normally affect pacemaker operation if the appliances are in good condition and properly grounded and insulated. Simple electrical tools, such as drills and battery-operated screwdrivers, are to be kept at a distance of at least 12 inches (30 cm) from the pacemaker.

Cellular Phones

The possible influence of cellular phones on cardiac pacemakers cannot be ruled out. Therefore, the patient should always hold the cellular phone to the ear that is located on the opposite side of the body from where the pacemaker was implanted. Some cellular phones emit signals even when they are not turned on and are only on standby. For this reason, cellular phones should not be carried at chest level. As a rule, possible interference is only temporary, and the pacemaker will again function properly once the cell phone is out of the immediate vicinity of the implant. We recommend a minimum distance of 6 inches (15 cm) to the implant.

Note: When pacemaker sensitivities between 0.1 and 0.3 mV have been programmed, a distance of 8 inches (20 cm) is recommended.

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Interference Due to Strong Electromagnetic Fields

To assess the potential for interference, medical advice must be sought, especially in case of strong electromagnetic fields such as those stemming from the following: electric arc welders; electric melting furnaces; radio, radar, and television transmitters; power plants; exposed ignition systems (e.g., internal combustion engines); electrical tools; high-voltage power lines; and defective electrical equipment that is not properly grounded or sufficiently insulated.

Anti-Theft Installations

Anti-theft installations used in department stores, libraries, or other places can in rare cases interfere with pacemaker functioning. The general recommendation is to pass quickly through such anti-theft installations.

Risky Therapeutic and Diagnostic Procedures

Before using any of the following procedures, the benefits should be thoroughly weighed against the risks. After performing any of these procedures, the pacemaker function and pacing threshold must be thoroughly checked.

Caution! Some of the following procedures may cause latent damage to the pacemaker. This damage may not be detected when testing the pacemaker after the procedure. However, these may lead to pacemaker malfunctions at a later time, and in extreme cases to pacemaker failure.

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Caution! Diathermy, transcutaneous nerve stimulation, magnetic resonance imaging, and electrocautery have been reported to interfere with electromyographic monitoring. Cardiac activity during any of these procedures should therefore be monitored by additionally taking the patient's peripheral pulse or blood pressure.

Defibrillation

The circuitry of BIOTRONIK pacemakers is protected against the energy normally induced by defibrillation. Nevertheless, complete protection is not possible. Any implanted pacemaker can be damaged by defibrillation. Circumstances permitting, the following precautions should be taken:

— The paddles should be in an anterior-posterior position or perpendicular to the axis formed by the pacemaker and the heart.
— The energy setting should not be higher than necessary for defibrillation.
— The distance between the defibrillator paddles and the pacemaker and the implanted lead should be at least 10 cm (4 inches).

After defibrillation, the pacemaker function and pacing threshold must be checked and monitored for a sufficient time period.

Interaction with an Implantable Cardioverter- Defibrillator(ICD)

When implanting both an ICD and a pacemaker with bipolar pacing, the tip electrodes should be positioned as far apart as possible. Appropriate testing must ensure that the functioning of the one device cannot interfere with the other. Such testing will include, among other things:

— Test the arrhythmia detection function of the ICD while the pacemaker is pacing. To do so, set the most unfavorable combination, depending on the parameters set, with relation to the pacing mode, the rate, and pulse energy.
— Test the pacemaker's functions after delivery of a maximum energy shock from the ICD.

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Ultrasound Therapy and Diathermy

As a rule, ultrasound therapy and diathermy are fundamentally contraindicated for pacemaker patients due to possible heat build-up in the implant. If a therapy must be performed, it should not be applied in the immediate vicinity of the pacemaker or the lead. The peripheral pulse of the patient should be continuously monitored during treatment. The pacemaker function and pacing threshold must be checked after the therapy.

Radiation Therapy

The electronic circuit elements of the pacemaker can be damaged by radiation therapy. The pacemaker should be shielded during such treatment. Following the radiation treatment, the pacemaker function must be checked and monitored for a sufficient period of time.

Transcutaneous Electrical Nerve Stimulation(TENS)

This therapy is contraindicated for pacemaker patients. If the therapy must be used, the following precautions are recommended:

— The TENS electrodes should be placed as close as possible to each other to reduce the spread of electricity.
— The TENS electrodes should be placed as far away as possible from the pacemaker and the lead.
— Cardiac activity and the peripheral pulse should be monitored during the nerve stimulation.

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After stimulation, the pacemaker function and pacing threshold must be checked. For home use, the electrode positioning and current strength settings must be such that the nerve stimulation does not interfere with pacemaker functioning.

Magnetic Resonance Imaging (MRI)

This diagnostic procedure is contraindicated for pacemaker patients, because a variety of complications may result, e.g., repositioning; pulse inhibition; asynchronous and/or triggered pacing—depending on the pacing mode and the interference pattern of the implanted pacemaker—; damage to the circuitry; tissue damage in the vicinity of the pacemaker and/or tip electrode; and lead dislocation.

If this procedure cannot be avoided, the patient and his/her peripheral pulse must be constantly monitored. After an MRI, the pacemaker function and pacing threshold must be checked and monitored for a sufficient period of time.

Lithotripsy

This treatment is contraindicated for pacemaker patients because electrical and/or mechanical interference with the pacemaker is possible. If it must be used, the selected site for electrical and mechanical stress should be as far away as possible from the pacemaker. The patient's peripheral pulse should be continuously monitored throughout the treatment. After the procedure, the pacemaker function must be checked and monitored for a sufficient period of time.

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Electrocautery

Electrocautery should never be performed within 15 cm (6 inches) of an implanted pacemaker or lead because of the danger of inducing ventricular fibrillation and/or damaging the pacemaker. For transurethral electroresection of the prostate, placing the neutral electrode under the buttocks or around the upper thigh, but not in the thoracic area, is recommended. The pacemaker should be programmed to an asynchronous mode to avoid inhibition by interference signals. The patient's peripheral pulse should be continuously monitored throughout the treatment. The pacemaker function must be checked after the treatment.

Hyperbaric Oxygen Therapy

In-vitro tests conducted to date have not yielded any results of compromised pacemaker and lead functioning if the hyperbaric pressure does not exceed 1.5 bar (2.5 bar absolute). At higher pressures, deformation of the pacemaker housing was observed. However, until these test results can be clinically confirmed with statistically significant case data, hyperbaric oxygen therapy is contraindicated regardless of the pressure applied, because the environmental conditions entailed in this therapy are out of the defined range of use.

If this procedure cannot be avoided, the hyperbaric pressure must absolutely not exceed 1.5 bar (2.5 bar absolute), and the patient must be continually monitored. After the procedure, the pacemaker and the artificial pacing system must be checked and observed for a sufficient period of time.

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Explantation

Explanted pacemakers can be sent to the local BIOTRONIK representative for proper, environmentally friendly disposal. Before returning it, the explanted pacemaker should be cleaned with a sodium hypochlorite solution containing at least 1% chlorine and then thoroughly washed with water, if possible. The pacemaker should be explanted before a deceased pacemaker patient is cremated.

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Technical Data

Pacing Modes

Cylos DR	DDD-CLS, VVI-CLS, DDDR, DDTR/A, DDTR/V, DDTR, DDIR, DDIR/T, DVIR, DVTR, D00R, VDDR, VDTR, VDIR, VVIR, VVTR, V00R, AAIR, AATR, A00R DDD, DDT/A, DDT/V, DDT, DDI, DDI/T, DVI, DVT, D00, VDD, VDT, VDI, VVI, VVT, V00, AAI, AAT, A00, OFF DDD(R)$^+$, DDT/A(R)$^+$, DDT/V(R)$^+$, AAI(R)$^+$, AAT(R)$^+$
Cylos VR	VVI-CLS, VVIR, VVTR, V00R, VVI, VVT, V00, OFF
Valid for Cylos DR-T	Home Monitoring is possible for the following modes: DDD(R) , DDT(R)/A, DDT(R)/V, DDT(R), DDI(R), DDI(R)/T, VDD(R), VDT(R), VVI(R),VDI(R), DDD(R)+, DDT(R)/A+, DDT(R)/V+; DDD-CLS; VVI-CLS

Home Monitoring — Programmable Parameters

Valid for Cylos DR-T	
Home Monitoring	Off, On
Monitoring Interval	1 day
Time of Trend Message	Between 0:00 (12:00 a.m.) ...(10)... and 23:50 (11:50 p.m.)
Patient Message	Off, On
Event Message	Off, On

Home Monitoring – Non-Programmable Parameters/Value Ranges

Valid for Cylos DR-T

For Home Monitoring, stored data and events are displayed under the following topics:

— Stored Messages
— Atrial Rhythms
— Ventricular Rhythms
— System Status

Stored Messages

The following are displayed:

— Type and time of last message
— Elapsed time in days
— Number of trend messages
— Number of patient messages

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Atrial Rhythms

Mean Value AES	0; 1...(10); **>** 10; **>** 100
Number of Atrial Tachycardias (AT)	0; 1...(10); **>** 10; **>** 20
Number of Atrial Fibrillation (AF)	0; 1...(10); **>**10; **>** 20
Number of Atrial Flutter (AFl)	0; 1...(10); **>** 10; **>** 20
AV Synchrony (Ax Vx/Vx)	0; 3...(3)...100%
Number of Tachycardia Episodes	0 ... (1)...10...(2)...60; **>** 60
Duration of Tachycardia Episodes	0; 3...(3) ...100%

Ventricular Rhythms

Mean Ven. Heart Rate	**<** 50; 52; ...(2)...174; **>** 174 bpm
Max. Ven. Heart Rate[a)]	**<** 85; 85;)...248; **>** 248 bpm
Duration of Max. Ven. Heart Rate[a)]	**<** 0.5; 0.5 ...1.0; 1.0 ...2.0; 2.0 ...2.5; ≥ 5 min
Max. Ven. Heart Rate during Tachycardia Episodes[b)]	**<** 120; ≥ 120; ≥ 140; ≥ 160; ≥ 180; ≥ 200; ≥ 220 bpm
Number of Max. VES/h	0;1...10; 11...30; **>** 30
Number of Ven. Runs	0; 1; 2; (1)...10; **>** 10
Number of Ven. Episodes (VT)	0; 1; 2; **>** 2

a) Captured by IEGM recording during high ventricular rates
b) Captured by IEGM recording of Mode Switching

System Status

Atrial/Ven. Lead Check	OK; not OK [a)] , (if not OK, then switch from bipolar to unipolar)
Mean P/R-Wave Amplitude	No measurement [b)]; **<** 50%[a)] ; 50 - **<** 100%; ≥ 100% safety margin
(Battery) Status ERI	OK; ERI active [a)]

a) Parameter value triggers event report
b) Or the measurement is below the programmed sensitivity

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Active Capture Control (ACC)

Status Amplitude Control (ACC)	On; Off; Deactivated
Ventricular Thresholds	< 0.3; ≥ 0.3; ≥ 0.5;... (0.2) ... ≥ 4.7; ≥ 4.8

Pulse and Timing Parameters[1]

Cylos DR/DR-T	
Basic Rate [a), b)]	30 ... (1) ... 88 ... (2) ... 122 ... (3) ... 140 ... (5) ... 180 ppm
Night Program	off; on
Rate Hysteresis [a)]	off; -5 ... (5) ... -50 bpm
Repetitive rate hysteresis	off; 1 ... (1) ... 10
Scan rate hysteresis	off; 1 ... (1) ... 10
Upper Tracking Rate (UTR) [a)]	100; 110; 120; 130; 140; 160; 185 ppm
Tachycardia Mode	2:1; WRL (automatic adjustment)
Runaway protection [a), c)]	195 ... 220 ppm
Dynamic AV Delay	Off, low; medium; high; individual; fixed
AV Delay Values	15; 50; 75; 100; 120 ... (10) ... 200; 225; 250; 300 ms (programmable in 5 ranges)
AV hysteresis	Off; low; medium; high; negative
AV Repetitive Hysteresis	Off; 1...(1)...6
AV Scan Hysteresis	Off; 1...(1)...6
Repetitive Negative AV Hysteresis	1...(1)...10...(3)...100...(10)...180
Sense Compensation	Off, -15 ... (-15) ... -120 ms
AV Safety Delay	100 ms
Atrial Blanking Period	32; 40; 48; 56; 72 ms
Far- Field Blanking	56...(25)...200 ms
Ventricular blanking period [d)]	16; 24; 32; 40; 48; 56; 72 ms
Magnet Effect	auto; asynchronous; synchronous

[1] 37°C, 500 Ω

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Cylos DR/DR-T	
Pulse amplitude A Pulse amplitude V	0.1 ...(0.1) ... 4.8 ... (0.6) ... 8.4 V 0.1 ... (0.1) ... 4.8 ... (0.2) ... 8.4 V
Pulse width A Pulse width V	0.1; 0.2; 0.3; 0.4; 0.5; 0.75; 1.0; 1.5 ms 0.1; 0.2; 0.3; 0.4; 0.5; 0.75; 1.0; 1.5 ms
Sensitivity A Sensitivity V	0.1 ... (0.1) ... 1.5 ... (0.5) ... 7.5 mV 0.5 ... (0.5) ... 7.5 mV
Refractory period A Refractory period V	200 ... (25) ... 775 ms 170; 195; 220; 250; 300; 350; 400 ms
Atrial refractory period extension	0 ... (50) ... 350 ms
Tachycardia behavior	Off, Mode Conversion, Mode Switching
Mode conversion	Off; On (in modes DDD(R), DDT(R)/A, DDT(R)/V, and VDD(R))
Mode switching	Off; On (in modes DDD(R), DDT(R)/A, DDT(R)/V, DDD(R)$^+$, DDT/A(R)$^+$, DDT/V(R)$^+$ and VDD(R))
Intervention rate	110...(10)...250 ppm
X-out-of-8 criterion	3...(1)...8
Z-out-of-8 criterion	3...(1)...8
Basic Rate during Mode Switching	+5...(5)...+30 ppm
2:1 Lock-in Protection	On; Off
PMT Management	Off; On
VA Criterion	250...(10)...500 ms
Overdrive Mode	Off; On
Max. Overdrive Rate	100...(10)...160 ppm
Levels of Overdrive Pacing (for Rate Increase)	low; medium; high
Overdrive pacing plateau (the rate decrease thereafter)	1...(1)...32 cycles
Min. PVARP	Off; On
Lead configuration for A/V pacing A/V sensing	 unipolar; bipolar / unipolar; bipolar unipolar; bipolar / unipolar; bipolar
Autom. lead monitoring	Off; On
Active capture control (ACC)	On; Off; ATM
Minimum Ventricular Amplitude	0.2...(0.1)...3.6...(0.1)...4.8 V
Maximum Ventricular Amplitude	2.4; 3.6; 4.8; 6.4 V

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Cylos DR/DR-T	
Scan Period	Intervals; Times of Day
Intervals	every 0.1; 0.3; 1; 3; 6; 12; 24 hours
Times of Day, the 1st/2nd Time of Day	0:00 to 24:00 hours
Safety Margin	0.3...(0.1)...(0.5) ...(0.1)...1.2 V
Auto-Initialization	Off; Lead Detection; On
VES Lock-in Protection	On; Off
Termination after	4; 6; 12 cycles

a) The corresponding intervals (t) correlate with the rates (r) according to the formula t = 60,000 / r (where t is in ms, r in ppm)
b) The values 30, 31, 32, 33, and 34 are for temporary settings only.
c) In the event of an electronic defect
d) The values depend on the atrial blanking period set

Cylos VR	
Basic rate a), b)	30 ... (1) ... 88 ... (2) ... 122 ... (3) ... 140 ... (5) ... 180 ppm
Night Program	Off; On
Rate Hysteresis a)	off; -5 ... (5) ... -80 bpm
Repetitive rate hysteresis	off; 1 ... (1) ... 10
Scan rate hysteresis	off; 1 ... (1) ... 10
Upper Tracking Rate (UTR) a)	100; 110; 120; 130; 140; 160; 185 ppm
Tachycardia Mode	2:1; WRL (automatic adjustment)
Runaway protection a), c)	195 ... 220 ppm
Dynamic AV Delay	low; medium; high; individual; fixed
AV Delay Values	15; 50; 75; 100; 120 ... (10) ... 200; 225; 250; 300 ms (programmable in 5 ranges)
AV hysteresis	Off; low; medium; high; negative
AV Repetitive Hysteresis	Off; 1...(1)...6
AV Scan Hysteresis	Off; 1...(1)...6
Negative AV Hysteresis	1...(1)...10...(3)...100...(10)...180
Magnet Effect	auto; asynchronous; synchronous
Atrial Blanking Period	32; 40; 48; 56; 72 ms
Far- Field Blanking	56...(25)...200 ms
Pulse Amplitude V	0.1 ... (0.1) ... 4.8 ... (0.2) ... 8.4 V
Pulse Width V	0.1; 0.2; 0.3; 0.4; 0.5; 0.75; 1.0; 1.5 ms

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Sensitivity A Sensitivity V	0.1 ... (0.1) ... 1.5 ... (0.5) ... 7.5 mV 0.5...(0.5)...7.5 mV

Cylos VR	
Refractory period A Refractory period V	200 ... (25) ... 775 ms 170; 195; 220; 250; 300; 350; 400 ms
Atrial Refractory Period Extension	0 ... (50) ... 350 ms
Tachycardia Behavior	Off, Mode Conversion, Mode Switching
Mode conversion	Off; On (in mode VDD(R))
Mode Switching	Off; On (in mode VDD(R))
Intervention Rate	180...(10)...250 ppm
X-out-of-8 Criterion	3...(1)...8
Z-out-of-8 Criterion	3...(1)...8
Basic Rate during Mode Switching	+5...(5)...+30 ppm
2:1 Lock-in Protection	On; Off
PMT Management	Off; On
VA Criterion	250...(10)...500 ms
Min. PVARP	Off; On
Lead configuration for V pacing A sensing V sensing	 unipolar; bipolar bipolar unipolar; bipolar
Automatic Lead Monitoring	Off; On
Active capture control (ACC)	On; Off; ATM
Minimum Ventricular Amplitude	0.2...(0.1)...3.6...(0.1)...4.8 V
Maximum Ventricular Amplitude	2.4; 3.6; 4.8; 6.4 V
Scan Period	Intervals; Times of Day
Intervals	every 0.1; 0.3; 1; 3; 6; 12; 24 hours
Times of Day, the 1st/2nd Time of Day	0:00 to 24:00 hours
Safety Margin	0.3...(0.1)...(0.5) ...(0.1)...1.2 V
Auto-Initialization	Off; Lead Detection; On
VES Lock-in Protection	On; Off
Termination after	4; 6; 12 cycles

a) The corresponding intervals (t) correlate with the rates (r) according to the formula t = 60,000 / r (where t is in ms, r in ppm)

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b) The values 30, 31, 32, 33, and 34 are for temporary settings only.
c) In the event of an electronic defect

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Rate Adaptation

Cylos DR/DR-T/VR	
Max. (sensor or) activity rate [a]	80...(5)...180 ppm
Sensor Gain	auto; 1 ... 40 (in 32 steps)
Automatic Sensor Gain	Off; On
Sensor Threshold	Very Low; Low; Medium; High; Very High
Rate Increase	1; 2; 4; 8 ppm/cycle
Rate Decrease	0.1; 0.2; 0.5; 1.0 ppm/cycle
Rate fading	On; Off
R Rate Increase	1; 2: 4; 8 ppm/cycle
R Rate Decrease	0.1; 0.2; 0.5; 1.0; 1.2 ppm/cycle

a) In DDIR and DVIR modes for Cylos DR (partially due to the AV delay selected) and VVIR and VOOR modes in Cylos in general, there are lower maximum sensor rates than stated here. The programmer will show the respective values.

CLS Parameters	Cylos DR, Cylos DR-T, Cylos VR
Maximum CLS rate	80 ... (5) ... 160 ppm
Additional parameters	CLS dynamics (very low; low; medium; high; very high) Dynamic runaway protection (on; off) [a] V_P is required (yes; no)

a) The pacing rate attained at rest is calculated from the following formula: basic rate + 20 ppm + 1/8 (basic rate – Closed Loop rate).

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Parameters at Replacement Indication

Basic Rate	Programmed value minus 11% (minus 4.5 · 11% in modes DVI(R), DDI(R), DVT(R), and DDI/T(R), depending on the programmed AV delay)
Magnet Rate	80 ppm for 10 cycles directly after magnet application (not so in synchronous magnet mode)
Pulse Width	Programmed values
Pulse amplitudes	– programmed values with ACC deactivated (Off) – last measured threshold + 1.2 V with ACC activated (On) before ERI was reached
Sensitivity	Programmed values

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Additional Functions

Cylos DR/VR

- Automatic Amplitude Control (ACC)
- Automatic Initialization
- Automatic Lead and Polarity Detection
- IEGM Recordings
- Preventive Atrial Overdrive Pacing[1]
- Tachycardia Behavior
  - Automatic Mode Conversion
  - X/Z-out-of-8 Mode Switching with 2:1-Lock-In Protection
- PMT Management
- VES Lock-in Protection
- Rate Fading
- Dual-channel IEGM with Event Markers
- AV Hysteresis
  - AV Scan and AV Repetitive Hysteresis
  - Negative AV Hysteresis
- Storage of Follow-up Data in the Implant

Cylos DR-T

Same range of functions as Cylos DR, and additionally:

- Home Monitoring

Cylos VR

- Automatic Amplitude Control (ACC)
- Automatic Initialization
- Automatic Lead and Polarity Detection
- IEGM Recordings
- Automatic Lead Check
- Rate Fading
- Storage of Follow-up Data in the Implant

[1] Valid for Cylos DR-T and Cylos DR only.

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Default Programs

Cylos DR/DR-T

Parameter/Function	Factory Settings	Standard Program	Safe Program
Mode	DDD	DDD	VVI
Basic rate	60 ppm	60 ppm	70 ppm
Night program	Off	Off	Off
Rate hysteresis	Off	Off	Off
Repetitive rate hysteresis	—	—	—
Scan rate hysteresis	—	—	—
Upper tracking rate	130 ppm	130 ppm	—
Dynamic AV delay	Low	Low	—
AV hysteresis	off	off	—
Repetitive AV Hysteresis	—	—	—
AV Scan Hysteresis	—	—	—
Sense compensation	-45 ms	-45 ms	—
AV safety delay	100 ms	100 ms	—
Atrial blanking period	56 ms	56 ms	—
Ventr. blanking period	32 ms	32 ms	—
Magnet effect	Asynchronous	Auto	Auto
Pulse amplitude A Pulse amplitude V	3.6 V 3.6 V	3.6 V 3.6 V	— 4.8 V
Pulse width A Pulse width V	0.4 ms 0.4 ms	0.4 ms 0.4 ms	— 1.0 ms
Sensitivity A Sensitivity V	1.0 mV 2.5 mV	1.0 mV 2.5 mV	— 2.5 mV
Refractory period A Refractory period V	425 ms 250 ms	425 ms 250 ms	— 300 ms
Atr. refractory per. ext.	0 ms	0 ms	—
Mode conversion	off	off	—
Mode Switching	off	on	—
X-out-of-8 Criterion	—	5-out-of 8	—
Z-out-of-8 Criterion	—	5-out-of 8	—

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Parameter/Function	Factory Settings	Standard Program	Safe Program
Intervention Rate	—	160	—
Far-Field Blanking	56 ms	56 ms	—
Switch to	—	DDIR	—
Basic Rate during Mode Switching	—	+ 10	—
2:1 Lock-in Protection	off	off	—
VES lock-in protection	off	off	—
Min. PVARP	235 ms	235 ms	—
Sensor Threshold	—	—	—
Sensor Gain	—	—	—
Autom. sensor gain	—	—	—
Rate Increase	—	—	—
Max. Activity Rate	—	—	—
Rate Decrease	—	—	—
Rate Fading	off	off	off
RF Rate Increase	—	—	—
RF Rate Decrease	—	—	—
Lead Configuration			
Pace A/V	unipolar	unipolar	unipolar
Sense A/V	unipolar	unipolar	unipolar
PMT Management	off	on	—
VA Criterion	—	380 ms	—
Autom. Lead Monitoring A/V	off	off	off
Auto-Initialization	on	—	—
ACC	off	ATM	off
Max. Amplitude	—	3.6 V	—
Scan Time	—	at intervals	—
Interval	—	12 hours	—

Cylos VR

Parameter/Function	Factory Settings	Standard Program	Safe Program
Mode	VDD	VDD	VVI
Basic Rate	60 ppm	60 ppm	70 ppm
Night Program	off	off	off

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Rate hysteresis	off	-10 ppm	off
Parameter/Function	Factory Settings	Standard Program	Safe Program
Repetitive rate hysteresis	—	off	—
Scan rate hysteresis	—	off	—
Upper tracking rate	130 ppm	130 ppm	—
Dynamic AV Delay	Low	Low	—
AV hysteresis	off	off	—
AV Repetitive Hysteresis	—	—	—
AV Scan Hysteresis	—	—	—
Sense compensation	—	—	—
AV safety delay	—	—	—
Atrial blanking period	56 ms	56 ms	—
Magnet effect	Auto	Auto	Auto
Pulse amplitude V	3.6 V	3.6 V	4.8 V
Pulse width V	0.4 ms	0.4 ms	1.0 ms
Sensitivity A Sensitivity V	0.2 mV 2.5 mV	0.2 mV 2.5 mV	— 2.5 mV
Refractory Period A Refractory Period V	425 ms 250 ms	425 ms 250 ms	— 300 ms
Atrial Refractory Period Extension	0 ms	0 ms	—
Tachycardia Behavior			
Mode conversion	off	off	—
Mode Switching	off	on	—
X-out-of-8 Criterion	—	5-out-of 8	—
Z-out-of-8 Criterion	—	5-out-of 8	—
Intervention Rate	—	160	—
Far-Field Blanking	56 ms	56 ms	—
Switch to	—	VDIR	—
Basic Rate during Mode Switching	—	+ 10	—
2:1 Lock-in Protection	off	off	—
VES lock-in protection	off	off	—
Min. PVARP	235 ms	235 ms	—
Sensor Threshold	—	Medium	—

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Sensor Gain	—	4	—
Autom. Sensor Gain	—	on	—

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Parameter/Function	Factory Settings	Standard Program	Safe Program
Rate Increase	—	2 ppm/s	—
Max. Activity Rate	—	120 ppm	—
Rate Decrease	—	0.5 ppm/s	—
Rate Fading	off	off	off
RF Rate Increase	—	—	—
RF Rate Decrease	—	—	—
Lead Configuration			
Pacing V	unipolar	unipolar	unipolar
Sensing A/V	bipolar/ unipolar	bipolar/ unipolar	—/ unipolar
PMT Management	off	on	—
VA Criterion	—	380 ms	—
Autom. Lead Monitoring A/V	off	off	off
Auto-Initialization	on	—	—
ACC	off	ATM	off
Max. Amplitude	—	3.6 V	—
Scan Period	—	at intervals	—
Interval	—	12 hours	—

Materials in Contact with Human Tissue

Housing	titanium
Seals	silicone
Connector block	epoxy resin
Coating (if used)	silicone

Programmer

ICS 3000, PMS 1000plus, PMS 1000 C, PRT 1000,
TMS 1000plus, TMS 1000

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Electrical Data[1]

Cylos DR-T/DR/VR			
Circuit	hybrid electronics with VLSI-CMOS chip		
Input impedance A Input impedance V	> 10 kOhm > 10 kOhm		
Waveform	biphasic, asymmetric		
Polarity	cathodic		
Power consumption	DR/DR-T	D	SLR
BOS, inhibited	13 µA	13 µA	13 µA
BOS, 100% pacing	21 µA	21 µA	21 µA
Surface area of housing that is electrically conductive	uncoated: coated:	32.8 cm^2 7.23 cm^2	
Shape of housing that is electrically conductive	uncoated: coated:	flattened ellipsoid elliptical	

Battery

Type	Li/I	
Manufacturer	Wilson Greatbatch or	Litronik
Model	WG 8431 or	LIS 3150
No-load voltage	2.8 V	
Nominal capacity [a)]	1.3 Ah	

a) Information from the battery manufacturers

Service Times

Service Times (in years) [a)]	DR/DR-T	VR
Nominal service time [b)] for pulse amplitudes of 3.6 V	tbd	tbd
Expected service time [c)] for pulse amplitudes of 3.6 V	tbd	tbd
Remaining capacity at ERI (in Ah)	tbd	tbd

a) Other parameters such as the standard program, 100% pacing, are calculated using data from the battery manufacturers.
b) Calculated using the formula: T = 2740 x Cbat / (IBOS + IEOS)

[1] 37°C, 500 Ω

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c) Anticipated service times taking all available data into consideration

Mechanical Data

	Cylos DR	Cylos DR-T	Cylos VR
Lead connection	IS-1 (accepts unipolar and bipolar)		
Weight	26 g	27 g	24 g
Volume	10 cm^3	12 cm^3	9 cm^3
Dimensions	6 x 42 x 51 mm	6 x 44 x 51 mm	6 x 39 x 51 mm

Storage Conditions

Relative Humidity	max. 70%
Temperature	5 ... 55 °C
Pressure	0.7 ... 1.5 bar

X-ray Identification

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Projected Tolerances of Factory Settings[1]

Data according to EN 455002-2-1

Cylos DR/DR-T		
Basic rate Interference rate	60 ± 1.5 min^{-1}	
Basic Interval	1000 ± 20 ms	
Escape Interval	1000 ± 20 ms	
Magnet Rate	90 ± 3 min^{-1} (for 10 cycles)	
Magnet Interval	664 ± 20 ms (for 10 cycles)	
AV Delay Basic rate <70 ppm 70-90 ppm 91-110 ppm 111-130 ppm >130 ppm	 180 +15/-5 ms 180 +15/-5 ms 160 +15/-5 ms 140 +15/-5 ms 120 +15/-5 ms 100 +15/-5 ms	
	Atrium	Ventricle
Pulse Amplitude maximum value EN 455002-2-1 mean value	3.6 +0.1/-0.7 3.3 +0.1/-0.7	3.6 +0.1/-0.7 3.3 +0.1/-0.7
Pulse width	0.42 ± 0.02 ms	0.42 ± 0.02 ms
Sensitivity 15 ms sin^2 40 ms sin^2	1.0 ± 0.5 mV	 2.5 ± 0.5 mV
EN 455002-2-1 delta pulse	1.8 ± 0.5 mV	2.5 ± 0.5 mV
Refractory period	425 +10/-20 ms	250 +10/-20 ms
Runaway protection	200 +20/-5 min^{-1}	200 +20/-5 min^{-1}

Cylos VR	
Basic rate Interference rate	60 ± 1.5 min^{-1}
Basic Interval	1000 ± 20 ms
Escape Interval	1000 ± 20 ms
Magnet Rate	90 ± 3 min^{-1} (for 10 cycles)
Magnet Interval	664 ± 20 ms (for 10 cycles)

[1] 37°C, 500 Ω

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Cylos VR		
AV Delay Basic rate <70 ppm 70-90 ppm 91-110 ppm 111-130 ppm >130 ppm	 180 +15/-5 ms 180 +15/-5 ms 160 +15/-5 ms 140 +15/-5 ms 120 +15/-5 ms 100 +15/-5 ms	
	Atrium	Ventricle
Pulse Amplitude maximum value EN 455002-2-1 mean value		 3.6 +0.1/-0.7 3.3 +0.1/-0.7
Pulse width		0.42 ± 0.02 ms
Sensitivity 15 ms sin^2 40 ms sin^2	 0.2 + 0.05/-0.1 mV	 2.5 ± 0.5 mV
EN 455002-2-1 delta pulse	0.24 + 0.05/-0.1 mV	2.5 ± 0.5 mV
Refractory period	425 +10/-20 ms	250 +10/-20 ms
Runaway protection		200 +20/-5 min^{-1}

Product Line

Model	Lead Connection	Catalog Number
Cylos DR uncoated coated	 IS-1 IS-1	 349799 349804
Cylos DR-T uncoated coated	 IS-1 IS-1	 349806 349810
Cylos VR uncoated coated	 IS-1 IS-1	 341824 341815

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Block Diagram for Cylos DR

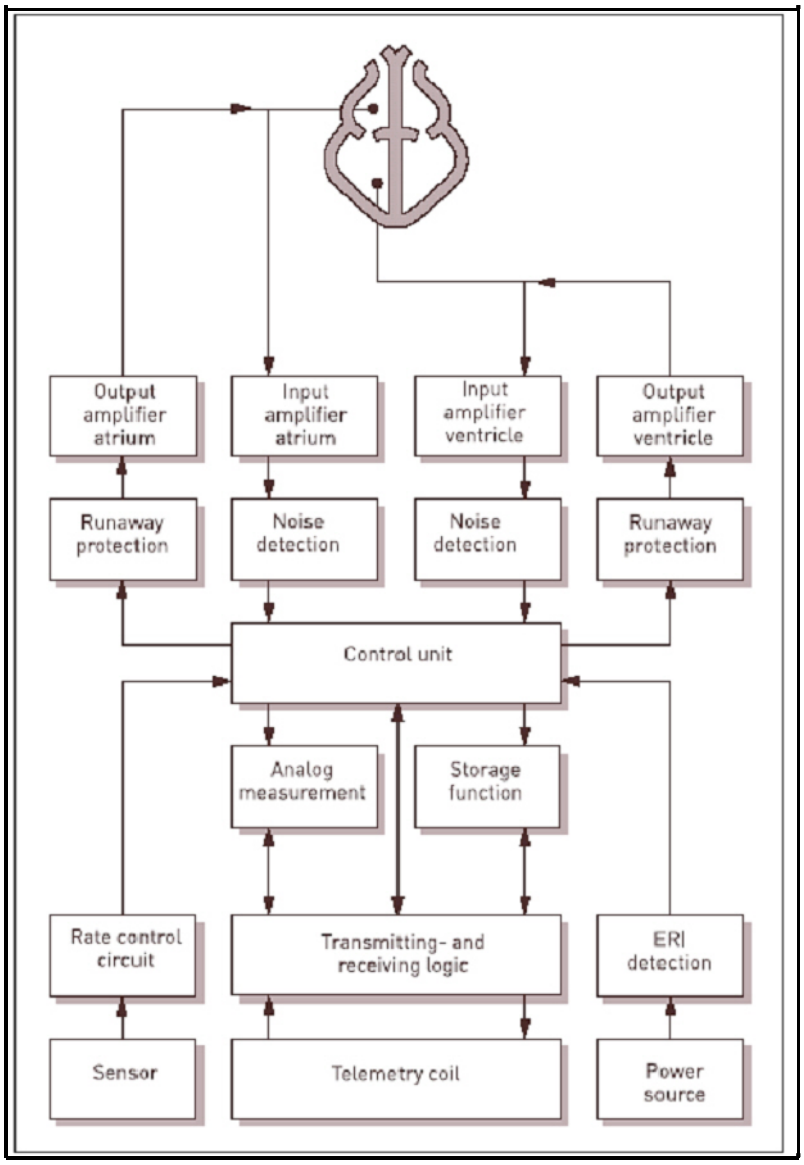

Figure 28: Block Diagram for Cylos DR

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Block Diagram for Cylos DR-T

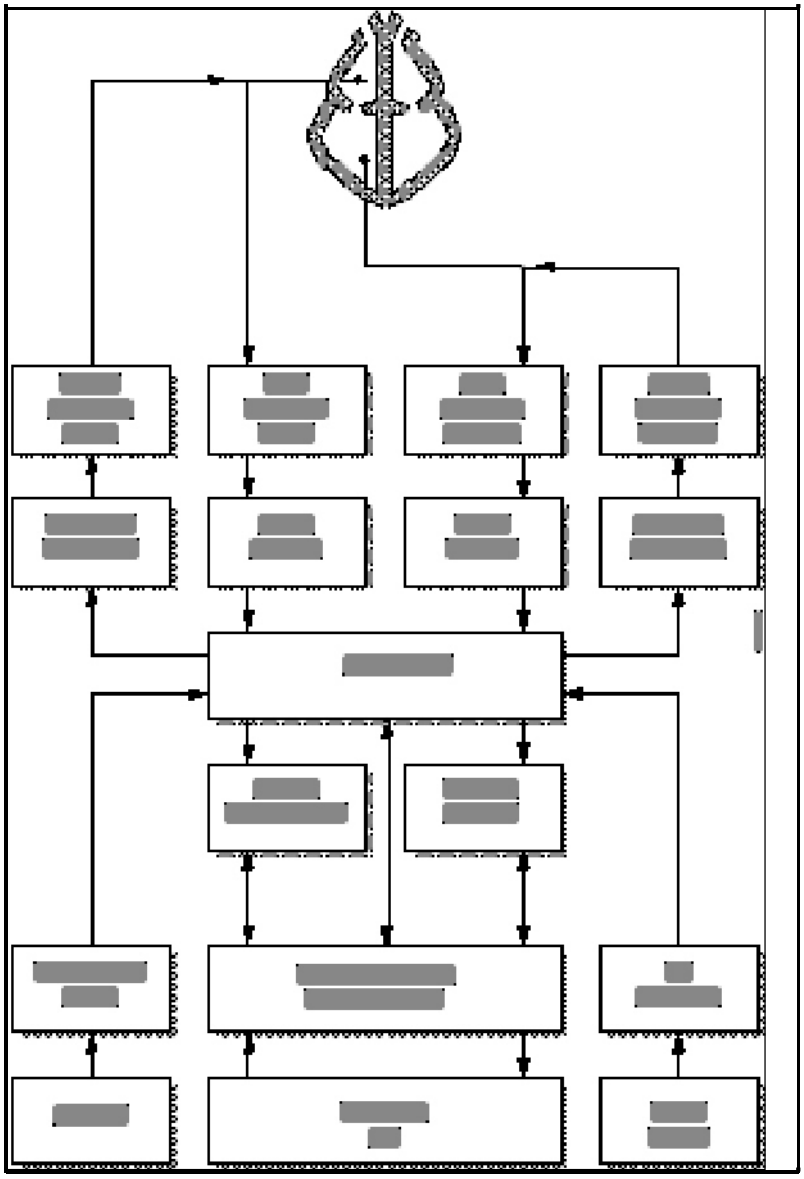

Figure 29: Block diagram for Cylos DR-T

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Block Diagram for Cylos VR

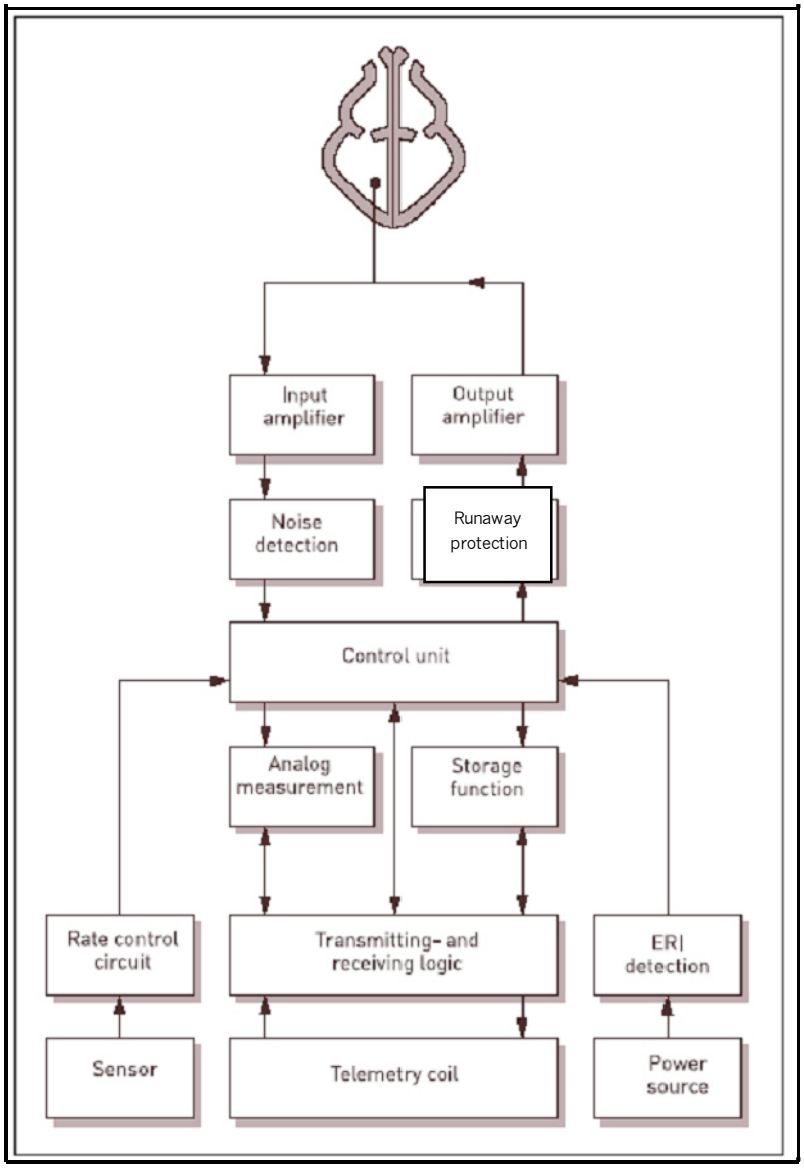

Figure 30: Block Diagram for Cylos VR

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Federal Communications Commission Disclosure

The CYLOS DR-T pacemaker is equipped with an RF transmitter for wireless communications. This transmitter is authorized by rule under the Medical Implant Communications Service (47 CFR Part 95) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

The FCC ID number for this device is: PG6CYLOS.

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Terms and Abbreviations

AA
Interatrial conduction time

AESW
Atrial extrasystole interval (atrial extrasystole window)

ARP
Atrial refractory period

AUI
Atrial upper interval

AUR
Atrial upper rate

Autoshort
Capacitor discharge time after pace

AV
Interval between an atrial action and the following ventricular action

B
Blanking

BiA , BiV
Biatrial, biventricular

BI
Basic interval

BOS
Beginning of service (for the implant)

Cross-Triggering
After atrial sensing events, pacing occurs in the other atrium

Cut-off voltage
Minimum operational voltage of the implant

Detection
Evaluation of a sensed signal by the implant

DSS
Reduction interval (decrement step size)

Double-Triggering
In response to each atrial action, triggering follows in both atria

EMI
Interference that causes the pacemaker to switch to a safety mode (electromagnetic interference)

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EOS

End of pacemaker functioning (end of service)

ERI

Replacement indication (elective replacement indication)

FFP

Far-field protection

Home Monitoring

The implant data are made available to the treating physician via the cellular phone network and the Internet

IAC

Interatrial conduction time

LA

Left atrium

LAESW

Left atrial extrasystole safety window

LV

Left ventricle

MAR

Maximum activity rate (= sensor rate)

MOR

Maximum overdrive rate

Mode

Mode, pacing mode

MSW

Mode Switching

Multisite

Pacing via the pacemaker's third channel

NIPS

Non-Invasive Programmed Stimulation. No additional devices are needed for external pulse control, use only implants, programmers, and software that are intended solely for this function.

OAR

Overdrive average rate

Overdrive

Overdrive pacing

pace

Paced event

PMT

PMT protection (pacemaker-mediated tachycardia)

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RA

Right atrium

RAESW

Right atrial extrasystole safety window

Rate fading

Rate smoothing. If the rate suddenly drops, e.g., upon the onset of bradycardia after a higher intrinsic rate.

RV

Right ventricle

Sense

Sensed event

SMS

Short messages via cellular phone (short message service)

SW

Safety interval (safety window)

Triggering

Forwarding and triggering of an action

ULAS

Left atrial sensing not used for timing the pacemaker (u = unused)

UTI/UTR

Upper rate limit (upper tracking rate/interval)

VES

Ventricular extrasystole (synonym: PVC = premature ventricular contraction)

VES lock-in

By definition, an atrial event that occurs during the atrial refractory period will not start a new basic interval.

VV

Interventricular conduction time

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