vitatron

C-series

C70 DR	C70A4
C60 DR	C60A4
C50 D	C50A4
C20 SR	C20A4
C10 S	C10A4

C-series VSF15 (Vitatron CareLink)

Reference Manual

Contents

1 Introduction

1.1 About this manual

This Reference Manual contains an extensive description of the Vitatron C-series of pacemakers (Vitatron C70 DR, Vitatron C60 DR, Vitatron C50 D, Vitatron C20 SR and Vitatron C10 S). It describes how to program these pacemakers using the Vitatron CareLink programmer.

General information is given about the Vitatron pacing system, beginning with an introduction to the manual (see Chapter 1), and a description of each pacemaker (see Chapter 2). This is followed by a description of each available pacing mode, together with the relevant indications and contraindications (see Chapter 3). How to carry out common programming procedures and program the programmer preferences are described in Chapter 4.

Basic follow-up procedures are described in Chapter 5. This is followed by a more detailed description of how to optimize pacing and sensing characteristics (see Chapter 6). Advice on how to make optimal use of the diagnostic features included in the pacemakers is given in Chapter 7. The Selected Episodes diagnostic feature is explained in Chapter 8.

The basic pacing therapies, including timing characteristics are described in Chapter 9. This is followed by advice on maintaining rate stability (see Chapter 10), the importance of maintaining and restoring AV synchrony (see Chapter 11), rate response (see Chapter 12) and AF prevention therapies (see Chapter 13).

The appendices provide technical information. Safety features are described in Appendix A and precautions are listed in Appendix B. In Appendix C and Appendix D the programmable parameters of each individual pacemaker and their most important specifications are listed.

1.2 Programming instructions

The gray block at the beginning of some sections contains instructions for programming the parameter. For example:

Parameters
⇒ Therapies
⇒ Lower Rate…
⇒ Night Lower Rate

Range: 40 - (5) - 130 min^{-1}

Availability: All modes, except OOO

The first line contains the name of the icon in the control panel (see Section 4.3). You can press the tab or value boxes named on the following lines to program the parameter.

The “Range” usually shows the lowest and highest values that you can program. The number in brackets shows the programming steps within this range. In some cases you can choose an option, for example “On” or “Off”.

The “Availability” line lists any restrictions on the use of the parameter, for example, in which modes it is available.

2 The pacemaker

2.1 Introduction

The Vitatron C-series are multiprogrammable pacemakers, consisting of dual chamber pacemaker models (Vitatron C70 DR, Vitatron C60 DR and Vitatron C50 D) and single chamber pacemaker models (Vitatron C20 SR and Vitatron C10 S).

These pacemakers provide therapies for the treatment of bradycardia and the prevention of atrial fibrillation or flutter (AF). The AF prevention therapies and Ventricular Rate Stabilization are specially designed to reduce the incidence and symptoms of AF.

Diagnostic tools quickly provide accurate information about the effectiveness of pacemaker therapy and simplify follow-up sessions. Detailed information and intracardiac electrograms (EGMs), recorded during selected episodes of high rates, are stored for interrogation at the next follow-up session. Storage of EGMs has a negligible effect on the pacemaker longevity.

Therapy Advisor automatically scans pacemaker data at the start of a follow-up session (battery status, diagnostic data and programmed parameters). It immediately reports any important events, including AF, and gives suggestions for programming the pacemaker.

2.2 Vitatron C70 DR (Model C70A4)

The Vitatron C70 DR is a dual chamber rate responsive pacemaker (activity sensing using an accelerometer) for permanent atrial and ventricular pacing. It has the following features:

- Ventricular Rate Stabilization (VRS), to regulate the ventricular rate during episodes of conducted atrial tachyarrhythmia
- Refined Atrial Pacing (RAP) and Refined Ventricular Pacing (RVP), to promote intrinsic rhythm and intrinsic AV conduction
- Therapy Advisor, which provides clear and concise programming advice on pacemaker settings and therapies, including the AF prevention therapies
- Selected Episodes with multiple triggers, which provides detailed information about episodes of high rates
- AF prevention therapies, designed to reduce the incidence of atrial fibrillation or flutter
- Beat-to-Beat mode switching enables the pacemaker to detect atrial arrhythmias and respond immediately to them

2.3 Vitatron C60 DR (Model C60A4)

The Vitatron C60 DR is a dual chamber rate responsive pacemaker (activity sensing using an accelerometer) for permanent atrial and ventricular pacing. It has the following features:

- Ventricular Rate Stabilization (VRS), to regulate the ventricular rate during episodes of conducted atrial tachyarrhythmia
- Refined Atrial Pacing (RAP) and Refined Ventricular Pacing (RVP), to promote intrinsic rhythm and intrinsic AV conduction
- Beat-to-Beat mode switching enables the pacemaker to detect atrial arrhythmias and respond immediately to them
- Therapy Advisor, which provides clear and concise advice on pacemaker settings and therapies
- Selected Episodes with multiple triggers, which provides detailed information about episodes of high rates

2.4 Vitatron C50 D (Model C50A4)

The Vitatron C50 D is a dual chamber pacemaker for permanent atrial and ventricular pacing. Rate responsive pacing (activity sensing using an accelerometer) is available in single chamber pacing modes (AAIR or VVIR). It has the following features:

- Ventricular Rate Stabilization (VRS), to regulate the ventricular rate during episodes of conducted atrial tachyarrhythmia
- Refined Atrial Pacing (RAP) and Refined Ventricular Pacing (RVP), to promote intrinsic rhythm and intrinsic AV conduction
- Beat-to-Beat mode switching enables the pacemaker to detect atrial arrhythmias and respond immediately to them
- Therapy Advisor, which provides clear and concise advice on pacemaker settings and therapies
- Selected Episodes with multiple triggers, which provides detailed information about episodes of high rates

2.5 Vitatron C20 SR (Model C20A4)

The Vitatron C20 SR is a single chamber rate responsive pacemaker (activity sensing using an accelerometer) for permanent atrial or ventricular pacing. It has the following features:

- Ventricular Rate Stabilization (VRS), to stabilize the ventricular rate during episodes of irregularity which are probably due to conducted atrial tachyarrhythmia (VVI(R) mode only)
- Therapy Advisor, which provides clear and concise advice on pacemaker settings and therapies
- Selected Episodes with multiple triggers, which provides detailed information about episodes of high rates

2.6 Vitatron C10 S (Model C10A4)

The Vitatron C10 S is a single chamber pacemaker for permanent atrial or ventricular pacing. It has the following features:

- Therapy Advisor, which provides clear and concise advice on pacemaker settings and therapies
- Selected Episodes with multiple triggers, which provides detailed information about episodes of high rates

2.7 Connector configuration

Vitatron digital pacemakers all have IS-1 connectors. Access to the connector screws is from above for single chamber pacemakers and from the engraved side for dual chamber pacemakers (see Figure 1).

Figure 1. Connector configuration

1 Dual chamber connection
2 Single chamber connection

3 The patient

3.1 Introduction

Cardiac pacing is an accepted method of controlling heart rate in patients with symptomatic bradyarrhythmias. Vitatron pacemakers are therefore intended for use in patients for whom permanent cardiac pacing is indicated for the treatment of disorders in impulse formation or conduction.

This chapter describes specific indications and contraindications, together with a description of each of the available pacing modes.

3.2 Indications

Dual chamber pacing is indicated if AV synchrony needs to be restored to optimize cardiac output (for example, in patients with symptomatic second or third degree AV block).

Dual chamber rate responsive pacing modes are of specific benefit to patients with chronotropic incompetence of the sinus node.

AF prevention therapies and Ventricular Rate Stabilization are indicated for patients who can benefit from the reduction of the incidence and symptoms of atrial fibrillation or flutter.

Rate responsive modes can help patients who have a requirement for an increase in pacing rate, in response to physical activity.

Single chamber ventricular pacing can help patients with permanent atrial tachyarrhythmias, including atrial fibrillation and flutter.

Single chamber atrial pacing can help patients with symptomatic bradyarrhythmias and normal AV conduction.

3.3 Contraindications

There are no known contraindications to the use of pacemakers as a means to control the heart rate. The patient's individual medical condition dictates which particular pacing system and mode of operation is chosen by the physician.

AF prevention therapies are contraindicated for patients with permanent atrial tachyarrhythmias, including atrial fibrillation and flutter. Rate responsive modes, AF prevention therapies and Ventricular Rate Stabilization may be contraindicated if they are expected to aggravate clinical symptoms (angina pectoris for example) or congestive heart failure caused by fast heart rates.

Pacemakers are contraindicated in the following situations:

- dual chamber
  - permanent supraventricular tachyarrhythmias, including atrial fibrillation and flutter
  - expected aggravation of clinical symptoms (for example, angina pectoris) or congestive heart failure caused by fast heart rates
  - inadequate intracavitary atrial complexes
- single chamber AAI(R)
  - AV conduction disturbances
  - inadequate intracavitary atrial complexes
- single chamber VVI(R)
  - known pacemaker syndrome
  - a need for AV synchrony
  - expected aggravation of clinical symptoms (for example angina pectoris) or congestive heart failure caused by fast heart rates

3.4 Potential adverse events

Adverse events associated with pacemaker systems include: cardiac perforation, cardiac tamponade, death, erosion through the skin, hematoma/seroma, infection, improper operation caused by theft-prevention systems, myopotential sensing, nerve stimulation, muscle stimulation, pacemaker syndrome, rejection phenomena (local tissue reaction, fibrotic tissue formation, pacemaker migration), threshold elevation, and transvenous lead-related thrombosis.

3.5 Pacing code

Pacemaker modes are described using the NBG code. The five-letter NBG[1] code, named after The North American Society of Pacing and Electrophysiology (NASPE) and the British Pacing and Electrophysiology Group (BPEG), describes the operation of implantable pulse generators. The NBG code, which supersedes the ICHD Code, is described in Table 1.

[1] Bernstein A.D, et al., The Revised NASPE/BPEG Pulse Generator Code, Pace, 25, No 2, Feb 2002.

Table 1. The Revised NASPE/BPEG Generic Code for Antibradycardia Pacing

Position:	I	II	III	IV	V
Category:	Chamber(s) Paced	Chamber(s) Sensed	Response to Sensing	Rate Modulation	Multisite Pacing
	O = None A = Atrium V = Ventricle D = Dual (A + V)	O = None A = Atrium V = Ventricle D = Dual (A + V)	O = None T = Triggered I = Inhibited D = Dual (T + I)	O = None R = Rate modulation	O = None A = Atrium V = Ventricle D = Dual (A + V)
Manufacturers' designation only:	S = Single (A or V)	S = Single (A or V)			

Note: The programmer displays A or V (not S) for chambers paced and sensed.

3.6 Mode descriptions, indications and contraindications by mode

3.6.1 DDDR mode

The pacemaker senses and paces in both the atrium and the ventricle. Sensed atrial events inhibit the atrial channel and start an AV delay. Sensed atrial events conducted to the ventricles before the end of the AV delay inhibit the ventricular channel. Sensed atrial events not conducted before the end of the AV delay trigger the release of a ventricular stimulus (tracking of the atrial rate).

Paced atrial events also start an AV delay. Paced atrial events conducted to the ventricles before the end of the AV delay inhibit the ventricular channel. Paced atrial events not conducted before the end of the AV delay trigger the release of a ventricular stimulus.

In the absence of sinus rhythm and spontaneous AV conduction, both chambers are paced at the sensor rate, the Flywheel rate, or the lower rate (whichever is highest).

In the presence of atrial tachyarrhythmias, Beat-to-Beat mode switching is initiated (the ventricular rate is stabilized by rate responsive ventricular pacing). The atrial rate is monitored on a beat to beat basis and AV synchronous pacing is restored as soon as possible.

Indications:

- chronotropic incompetence due to atrial bradyarrhythmia or AV block
- sick sinus syndrome, including brady-tachy syndrome
- paroxysmal atrial arrhythmias in patients who require restoration of AV synchrony

Contraindications:

- permanent atrial tachyarrhythmias, including atrial fibrillation and flutter
- expected aggravation of clinical symptoms (for example angina pectoris) or congestive heart failure caused by fast heart rates

3.6.2 DDD mode

The pacemaker senses and paces in both the atrium and the ventricle. Sensed atrial events inhibit the atrial channel and start an AV delay. Sensed atrial events conducted to the ventricles before the end of the AV delay inhibit the ventricular channel. Sensed atrial events not conducted before the end of the AV delay trigger the release of a ventricular stimulus (tracking of the atrial rate).

Paced atrial events also start an AV delay. Paced atrial events conducted to the ventricles before the end of the AV delay inhibit the ventricular channel. Paced atrial events not conducted before the end of the AV delay trigger the release of a ventricular stimulus.

In the absence of sinus rhythm and spontaneous AV conduction both chambers are paced either at the Flywheel rate or the lower rate (whichever is highest).

In the presence of atrial tachyarrhythmias, Beat-to-Beat mode switching is initiated. The atrial rate is monitored on a beat to beat basis and AV synchronous pacing is restored as soon as possible.

Indications:

- intermittent or complete AV block with normal sinus rhythm
- sick sinus syndrome, including brady-tachy syndrome
- paroxysmal atrial arrhythmias in patients who require restoration of AV synchrony

Contraindications:

- permanent atrial arrhythmias, including atrial fibrillation and flutter
- expected aggravation of clinical symptoms (for example angina pectoris) or congestive heart failure caused by fast heart rates

3.6.3 DDIR mode

The pacemaker senses and paces in both the atrium and the ventricle. Atrial inhibition does not trigger an AV delay. In the absence of spontaneous conduction to the ventricle the pacemaker actively resynchronizes the atrium with the ventricle using an atrial synchronization pace (ASP). The pacing rate is dictated by the sensor rate.

Indications:

- atrial bradyarrhythmia in patients with paroxysmal atrial tachyarrhythmias, with or without normal AV conduction
- brady-tachy syndrome

Contraindications

- complete AV block with normal sinus rhythm (allows retrograde P-wave sensing or continuous atrial synchronization pacing)

3.6.4 DDI mode

The pacemaker senses and paces in both the atrium and the ventricle. Atrial inhibition does not trigger an AV delay. In the absence of spontaneous conduction to the ventricle the pacemaker actively resynchronizes the atrium with the ventricle using an atrial synchronization pace (ASP). The pacing rate is dictated by the programmed lower rate.

Indications:

- atrial bradyarrhythmia in patients with paroxysmal atrial tachyarrhythmias, with or without normal AV conduction
- brady-tachy syndrome

Contraindications

- complete AV block with normal sinus rhythm (allows retrograde P-wave sensing or continuous atrial synchronization pacing)

3.6.5 DOO mode

The pacemaker provides asynchronous, AV sequential pacing at the programmed lower rate.

Indications:

- intended primarily as a temporary mode to reduce the likelihood of triggering or inhibition during electrosurgery or electromagnetic interference

Contraindications:

- intrinsic cardiac activity at a rate sufficient to cause competitive pacing

3.6.6 VDDR mode

The pacemaker senses in both the atrium and the ventricle but can only pace the ventricle. It tracks spontaneous sinus rhythm and is inhibited by ventricular sensing. In the absence of sinus rhythm, or in the presence of atrial tachyarrhythmias, rate responsive ventricular pacing is initiated.

Indications:

- intermittent or complete AV block with normal sinus rhythm, with or without paroxysmal atrial tachyarrhythmia

Contraindications:

- likelihood of loss of AV synchrony (atrial bradyarrhythmia) and associated complications (retrograde conduction, anticipated or known pacemaker syndrome)
- permanent atrial tachyarrhythmias, including atrial fibrillation and flutter
- expected aggravation of clinical symptoms (for example angina pectoris) or congestive heart failure caused by fast heart rates
- inadequate intracavitary atrial complexes

3.6.7 VDD mode

The pacemaker senses in both the atrium and the ventricle but can only pace the ventricle. It tracks spontaneous sinus rhythm and is inhibited by ventricular sensing. In the absence of sinus rhythm, or in the presence of atrial tachyarrhythmias, ventricular (VVI) pacing at the programmed lower rate is initiated.

Indications:

- intermittent or complete AV block with normal sinus rhythm, with or without paroxysmal atrial tachyarrhythmia

Contraindications:

- likelihood of loss of AV synchrony (atrial bradyarrhythmia) and associated complications (retrograde conduction, anticipated or known pacemaker syndrome)
- permanent atrial tachyarrhythmias, including atrial fibrillation and flutter
- inadequate intracavitary atrial complexes

3.6.8 VVIR mode

The pacemaker senses and paces in the ventricle and is inhibited by sensed ventricular events. In the absence of spontaneous ventricular rhythm, rate responsive ventricular pacing is initiated.

Indications:

- permanent atrial fibrillation and flutter with symptomatic ventricular bradyarrhythmia

Contraindications:

- expected aggravation of clinical symptoms (for example angina pectoris) or congestive heart failure caused by fast heart rates
- anticipated or known pacemaker syndrome
- a need for the restoration of AV synchrony

3.6.9 VVI mode

The pacemaker senses and paces in the ventricle and is inhibited by sensed ventricular events. In the absence of spontaneous ventricular rhythm, ventricular pacing at the programmed lower pacing rate is initiated.

Indications:

- permanent atrial fibrillation and flutter with symptomatic ventricular bradyarrhythmia

Contraindications:

- anticipated or known pacemaker syndrome
- a need for the restoration of AV synchrony

3.6.10 VVT mode

The pacemaker paces and senses in the ventricle. Operation is identical to the VVI mode except that events sensed during the ventricular escape interval trigger an immediate pacing pulse.

Indications:

- intended as a temporary diagnostic mode, used to verify sensing and evaluate arrhythmias. This mode may also be useful in preventing inappropriate inhibition in the presence of electromagnetic interference.

Contraindications:

- anticipated or known pacemaker syndrome
- a need for the restoration of AV synchrony

3.6.11 VOO mode

The pacemaker paces in the ventricle at the programmed lower rate (asynchronous ventricular pacing). It is not inhibited by sensed ventricular events.

Indications:

- intended primarily as a temporary mode to reduce the likelihood of triggering or inhibition during electrosurgery or electromagnetic interference

Contraindications:

- intrinsic cardiac activity at a rate sufficient to cause competitive pacing

3.6.12 AAIR mode

The pacemaker senses and paces in the atrium and is inhibited by sensed atrial events. In the absence of spontaneous rhythm, rate responsive atrial pacing is initiated.

Indications:

- atrial bradyarrhythmia with normal AV conduction

Contraindications:

- AV conduction disturbances
- atrial fibrillation and flutter
- expected aggravation of clinical symptoms (for example angina pectoris) or congestive heart failure caused by fast heart rates
- inadequate intracavitary atrial complexes

3.6.13 AAI mode

The pacemaker senses and paces in the atrium and is inhibited by sensed atrial events. In the absence of spontaneous atrial rhythm, atrial pacing at the programmed rate is initiated.

Indications:

- atrial bradyarrhythmia with normal AV conduction

Contraindications:

- AV conduction disturbances
- atrial fibrillation and flutter
- inadequate intracavitary atrial complexes

3.6.14 AAT mode

The pacemaker paces and senses in the atrium. Operation is identical to the AAI mode except that events sensed during the atrial escape interval trigger an immediate pacing pulse.

Indications:

- intended as a temporary diagnostic mode, used to verify sensing and evaluate arrhythmias. This mode may also be useful in preventing inappropriate inhibition in the presence of electromagnetic interference.

Contraindications:

- inadequate intracavitary atrial complexes

3.6.15 AOO mode

The pacemaker paces in the atrium at the programmed lower rate (asynchronous atrial pacing). It is not inhibited by sensed atrial events.

Indications:

- intended primarily as a temporary mode to reduce the likelihood of triggering or inhibition during electrosurgery or electromagnetic interference

Contraindications:

- intrinsic cardiac activity at a rate sufficient to cause competitive pacing
- AV conduction disturbances

3.6.16 OOO mode

In the OOO mode pacing is switched off.

Indications:

- used for diagnostic purposes, such as the analysis of underlying rhythm

Contraindications:

- patients with no underlying rhythm

4 The programmer

4.1 Introduction

Vitatron C-series pacemakers can be programmed with a Vitatron CareLink programmer with Vitatron C-series software. This manual only describes the software for the Vitatron C-series. For specific programmer information, please refer to the programmer manual which is provided with the programmer.

This chapter describes how to carry out a follow-up session using the programmer.

- how to start a programmer session (see Section 4.2)
- how to use the cardiac dashboard (see Section 4.3)
- how to view diagnostics (see Section 4.4)
- how to program parameters (see Section 4.5)
- how to start tests (see Section 4.6)
- how to enter patient information (see Section 4.7)
- how to save and reload data (see Section 4.8)
- how to print and set print options (see Section 4.9)

Two sections describe how to change the programmer settings and display.

- how to adjust the programmer (see Section 4.10)
- how to adjust the ECG display (see Section 4.11)

The last section explains how to perform emergency programming (see Section 4.12).

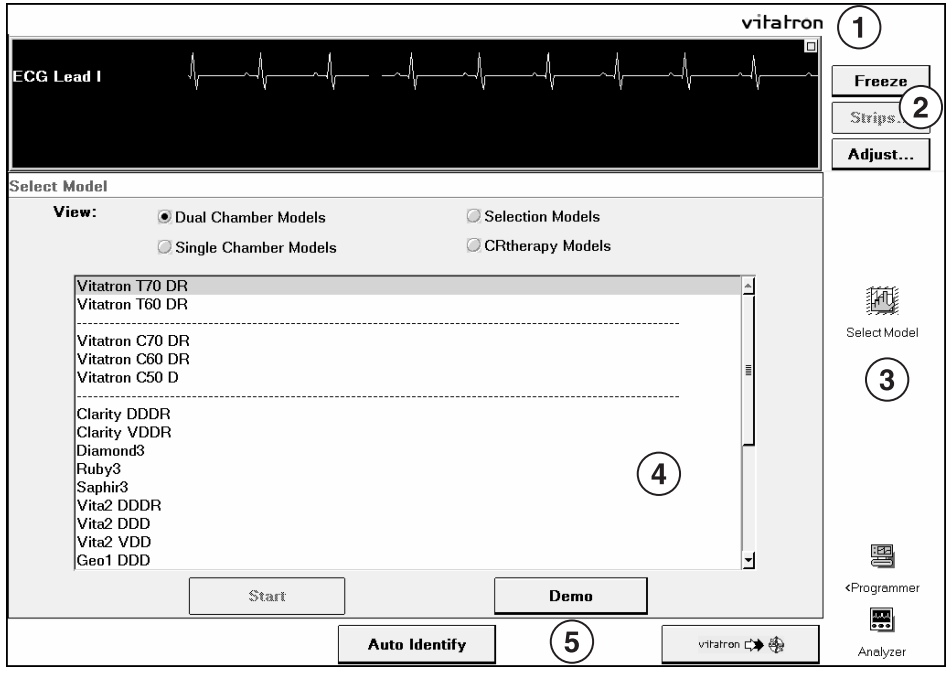
Notes:

- Programmers other than the Vitatron CareLink are not compatible.
- When using a second programmer during the same follow-up session, the first session must be ended before the second begins.
- The screens in this chapter show examples based on dual chamber pacemakers, and are subject to minor changes. The screens for single chamber pacemakers have a simpler layout because many features are not applicable to all models.

4.2 How to start a programmer session

After switching the programmer on the Vitatron desktop appears.

Figure 2. The Vitatron desktop



The main parts of the desktop are described briefly in this section. The task bar, which appears above the top line, is described in the programmer manual.

1 Top line – The desktop always shows the Vitatron logo on the top line. During a follow-up session, the patient's name, the pacemaker model name and number are also shown. The top line is not usually included in the illustrations used in this manual.

2 ECG window and controls – While the desktop is active, the ECG window displays the default surface electrocardiogram (ECG lead I, II or III). During a follow-up session, the filtered atrial and ventricular intracardiac electrograms (AEGM and VEGM), marker annotations and marker intervals are also available. For a description of this window, see Section 4.3.1.

The ECG controls on the right allow you to freeze the ECG, adjust the ECG settings and ECG markers or recall previously stored ECGs. For a detailed explanation see Section 4.11.

For instructions on connecting the ECG cable and leads, refer to the programmer manual.

3 Control panel – Pressing one of the control panel icons opens the relevant window in the main window.

4 Main window – At startup the main window always contains the Select Model window. During a follow-up session, the main window contains the cardiac dashboard or one of the detailed windows.

5 Button line – When the desktop is active, the bottom line contains the [Auto Identify] button and a Vitatron to Medtronic switch, which is used to go from Vitatron to Medtronic applications and vice versa. During a follow-up or demonstration session, the bottom line contains buttons that are available in all windows. On some buttons, three dots indicate that pressing the button opens another window in which you can program related parameters.

4.2.1 Starting a demo session

Select a model from the Select Model window and press [Demo] to start a simulated programming session.

4.2.2 Starting a follow-up session

To start automatic pacemaker recognition position the programming head and press [Auto Identify]. This starts initial interrogation of the pacemaker. The cardiac dashboard appears in the main window (see Section 4.3). Press [Stop] to return to the Select Model window.

The [Start] button can only be used to launch applications that are not started with auto identify.

Notes:

- If the programmer is unable to identify the pacemaker the following message is displayed: “Position programming head”.
- In the unlikely event that more than one pacemaker is in close proximity to the programming head, the programmer will warn you that more than one pacemaker has been detected. The pacemakers are then listed and you are asked to select the one to be interrogated.

4.2.3 Starting a reloaded data session

Select the “Programmer” icon and choose the reload session data option to reload session data stored on diskette. For more information, see Section 4.8.3.

4.2.4 Starting the Analyzer program

If the Medtronic lead analysis software and hardware are installed on the programmer, the Vitatron desktop will contain the “Analyzer” icon. Clicking the icon starts the analyzer program. After ending the analyzer program the programmer restarts the Vitatron software. For more information about the analyzer please refer to the documentation provided with it.

4.2.5 Adjusting programmer settings

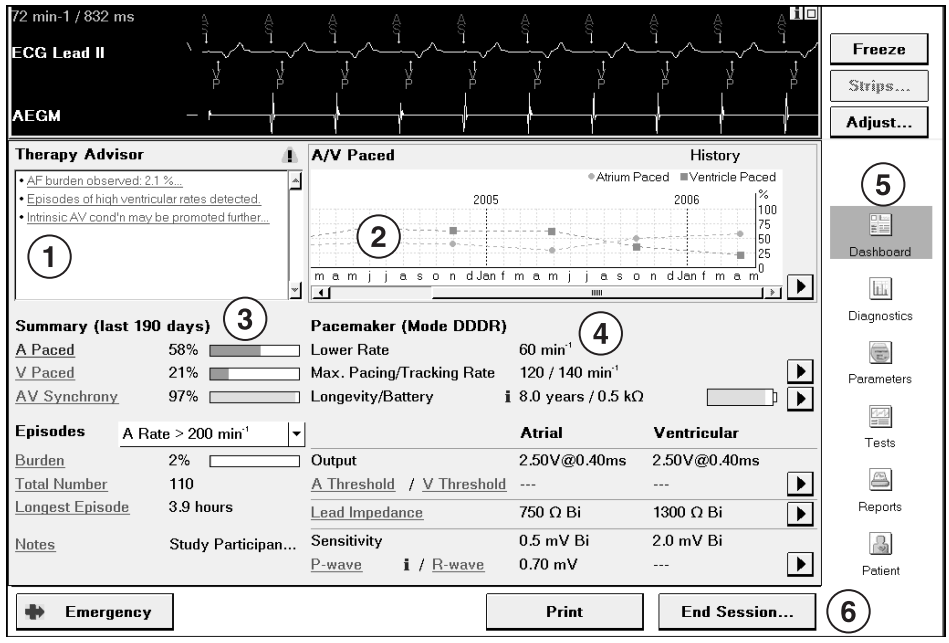
Select the “Programmer” icon to change the programmer time and date, language, audio or printer options, turn the Therapy Advisor on or off, manage memory contents files or check the software version. See Section 4.10 for more information.

4.3 How to use the cardiac dashboard

When the pacemaker has been identified with [Auto Identify], the programmer starts initial interrogation of the pacemaker. When pacemaker interrogation is complete (indicated by a progress bar), the cardiac dashboard appears. The cardiac dashboard gives an overview of how the pacemaker has performed during the last follow-up period. Therapy Advisor messages and the most important patient and pacemaker information indicate whether the pacemaker may need reprogramming to optimize pacing therapy. If you change pacemaker settings or measurements during the follow-up session, the cardiac dashboard is updated.

You can select the “Dashboard” icon at any time to return to the cardiac dashboard.

Figure 3. Cardiac dashboard window



1 Therapy Advisor window – The main Therapy Advisor messages are shown here, if the Therapy Advisor is switched on. For a description of the Therapy Advisor, see Section 7.2.

2 Dynamic window – Press one of the underlined hyperlinks on the cardiac dashboard to display more detailed information in the dynamic window. If you press a Therapy Advisor hyperlink, details and programming advice appear in this window. If you press a parameter or diagnostic hyperlink, the dynamic window contains a graph showing its history over the previous follow-up periods. The anticoagulation information in the Burden graph comes from details entered in the Patient window.

The graphs are based on the History data in the pacemaker (see Section 6.8 and Section 7.4.2). If any relevant parameter settings were changed between history periods, no trend line will be shown on the graph.

3 Patient summary – This gives a summary of the most important pacing and sensing data during the follow-up period, including notes from the Patient window. The Episodes information applies to data collected during the follow-up period, and does not reflect any episode trigger changes in the current follow-up session.

4 Pacemaker information – This contains technical information on parameter settings, battery and lead status, threshold and testing results. If no information is available, "---" is displayed. If "***" is displayed, this means that no senses were detected during a test.

If you change any settings during the follow-up session, the cardiac dashboard will show the new value. At initial interrogation, the P-wave amplitude is derived from the P-wave amplitude histogram. If a P-wave amplitude test is carried out during the follow-up session, the test result replaces the initial value. R-wave information is only available after an R-wave amplitude test has been performed during the follow-up session.

5 Control panel – The control panel icons are used to access stored information and to perform programming and test functions during a follow-up session.

6 Button line – During a follow-up session, the bottom line normally contains three buttons:

- The [Emergency] button is always active during a follow-up session. When pressed it programs the pacemaker to emergency settings (see Section 4.12).
- The [Print] button prints the data displayed in the current window (see Section 4.9.1).
- The [End Session] button allows you to close the follow-up session (see Section 4.3.2). There is also an option to save pacemaker data to diskette or the network before closing the session.

Note: You cannot program parameters in this window. Select the "Parameters" icon to change parameter values.

A number of symbols may appear on the cardiac dashboard or in diagnostics and parameter programming windows (see Table 2).

Table 2. Programmer symbols

Symbol	Description
Hyperlink	When pressed, shows more detailed information or the history of a parameter in the dynamic window. The last hyperlink pressed changes from green to blue.
	When pressed, leaves the cardiac dashboard and jumps directly to the relevant diagnostic, test or therapy programming window.
	When pressed, leaves the cardiac dashboard and jumps directly to the stored EGM window of the first episode in the Selected Episodes diary.
	Indicates the nominal (delivery) value of the parameter concerned.

Table 2. Programmer symbols (continued)

Symbol	Description
	Indicates the currently programmed value of the parameter concerned.
	Indicates that more information is available. This information will appear if the icon is pressed.
	Indicates either a warning about possible undesirable interaction with other parameters, or a caution about using an option. If the icon is pressed, it displays an explanation of the warning or caution.
	Warns that certain parameters are not programmable, or that certain values are not allowed because of a conflict with other parameters.

4.3.1 The ECG window

During a follow-up session, the programmer can display recordings from up to seven sources. The ECG leads I, II and III are always available and are detected via skin electrodes, if the programmer is connected to these electrodes with the ECG cable. Filtered atrial and ventricular EGMs (AEGM and VEGM) can be switched on and off as desired. The Marker Annotation and Marker Intervals can be superimposed on an ECG to facilitate interpretation.

For information on arranging the recordings and adjusting the ECG window display, see Section 4.11.

The top left-hand corner of the ECG window shows the current heart rate (paced or sensed) and the corresponding interval in milliseconds; this information is derived from the ECG markers.

During tests, multiple recordings are displayed. The signals are the previously displayed surface ECG combined with marker annotations and the intracardiac electrogram (EGM) of the chamber being tested.

Marker intervals – The programmer automatically measures the intervals between pace and sense markers and displays them (in milliseconds) as a separate recording. For dual chamber modes the AV intervals and the VV intervals are displayed. For single chamber modes the AA or VV intervals are displayed, depending on the chamber being paced.

Marker annotation – Marker annotations depict pacemaker operation by showing events as they occur. These annotations are intended to simplify ECG interpretation. Typically, the Marker Annotation channel is superimposed on an ECG recording. Atrial events are shown above the baseline and ventricular events below it.

Press [i] in the top right-hand corner of the window for an explanation of marker annotations.

The following marker annotations are used:

- Atrial events
  - **AP** Atrial pace
  - **AS** Atrial sense
  - **BS** Atrial sense in blanking period
  - **PC** Premature atrial contraction
  - **RC** Retrograde atrial sense
  - **RS** Atrial sense in refractory period
  - **SP** Atrial synchronization pace
  - **TS** Atrial tachy sense
  - **+P** Triggered atrial pace
- Ventricular events
  - **RS** Ventricular sense in refractory period
  - **VE** Premature ventricular contraction
  - **VP** Ventricular pace
  - **VS** Ventricular sense
  - **XP** Ventricular safety pace
  - **+P** Triggered ventricular pace

Note: Parameter programming or pacemaker interrogation may momentarily interrupt the transmission of the EGM or marker annotations. This can result in missing markers on the recording.

4.3.2 Ending a follow-up session

To end a programming session press [End Session…].

If applicable a warning is given that programming has not been completed or that a print job is still in process. A [Save Session…] option allows you to save pacemaker information to a diskette (see Section 4.8.1). This makes it possible to do an “off-line” analysis of the data by reloading the data at a later stage (see Section 4.8.3).

Confirm that you wish to end the session by pressing [End Now]. To continue with the current programming session press [Cancel].

Applying the programming head to another pacemaker without switching the programmer off or without pressing [End Session…] automatically opens the End Session window. If the session is then ended you return to the Vitatron desktop, and all information stored in the programmer memory is cleared.

Check the “Keep diagnostic data until next session” check box if you want to retain data collected since the last follow-up session (which is otherwise automatically cleared one hour after the programming session ends; see Section 7.3.1).

If the “Automatic SessionSync” check box is checked, the session data will be saved on the network when you press [End Now]. For information on saving session data to the network, see Section 4.8.2.

4.4 How to view pacemaker diagnostics

Select the “Diagnostics” icon to see the following tab options.

Rhythm Overview – This window contains an overview of pacemaker diagnostics and gives access to histogram and Holter graphs containing more detailed information (see Chapter 7).

Selected Episodes – This shows a summary of the main selected episode information recorded during the collection period and gives access to more detailed information and a stored EGM (see Chapter 8).

Sensor – This window shows how the accelerometer sensor has performed in the period since the last follow-up session (see Section 7.8.2).

Battery – This option provides a remaining longevity estimate and measured battery data (see Section 5.8.1).

History – This option shows the most important pacing data and Selected Episodes from the current follow-up period and up to five previous periods (see Section 7.4.2).

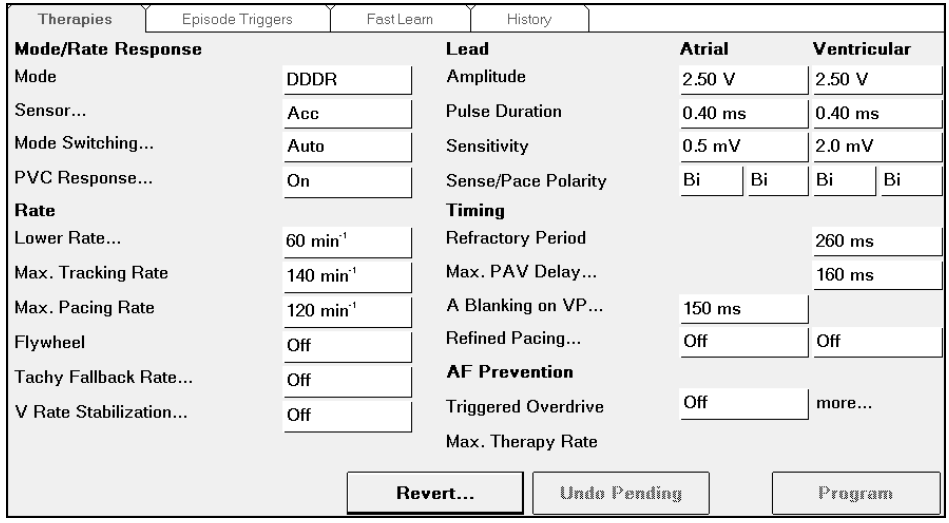
4.5 How to program parameters

The “Parameters” icon allows you to program pacing therapy parameters, program rate response with Fast Learn, and choose settings for recording of Selected Episodes.

4.5.1 Programming therapy parameters

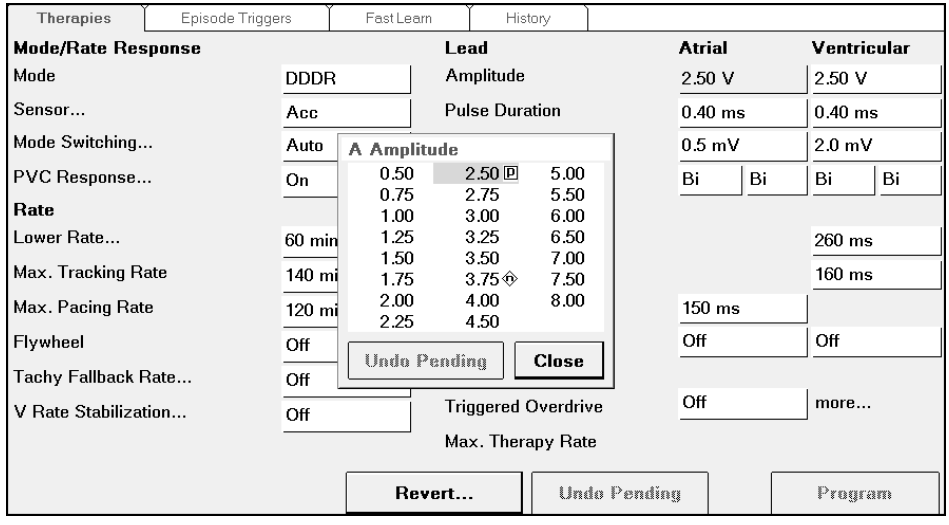
Parameters
⇒ Therapies

Figure 4. Therapies window



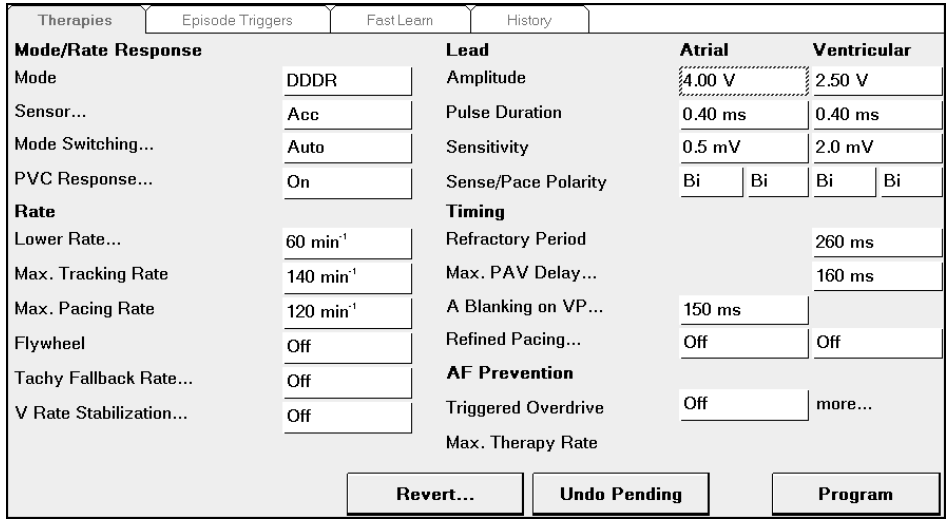
To program a parameter, for example, atrial amplitude, press the parameter value box on the right of the parameter name. A value selection window appears. The currently programmed value, for example, 2.50 V, is highlighted and followed by a boxed [P] (see Figure 5).

Figure 5. Selecting amplitude programming



Select a new value, for example, 4.00 V. The value selection window closes. The new value is boxed to indicate that it is pending and has not yet been programmed (see Figure 6).

Figure 6. The chosen value is pending



To program the new value, press [Program]. The box around the pending value disappears.

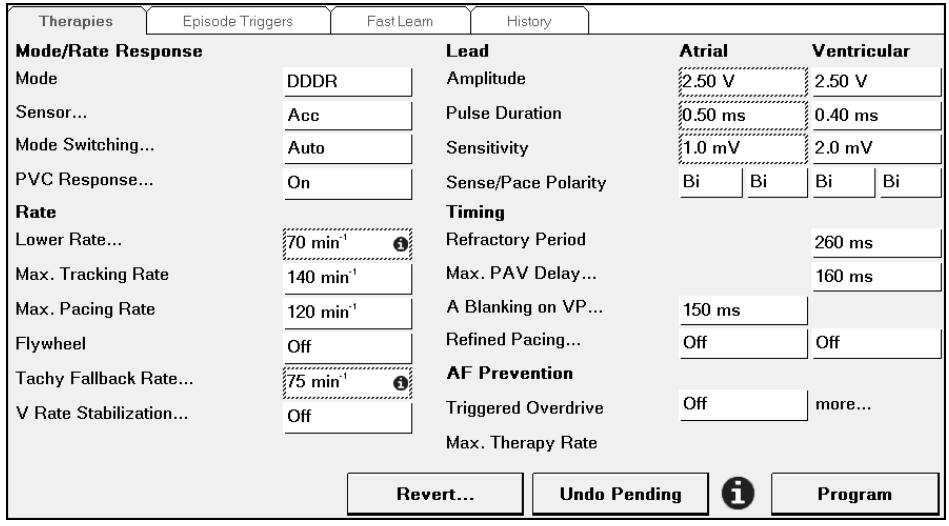
Press [Undo Pending] to cancel the pending parameters.

If you open a value selection window and then decide not to select a new value, you can close the window either by pressing [Close] or by pressing outside the window.

Some parameter names (for example, Mode Switching…) are followed by three dots. This indicates that another window opens, in which you can program related parameters.

Batch programming – It is also possible to program several parameters in one batch. To do this select a new value for each parameter you wish to program. All pending parameter values are then boxed. Individual parameters can subsequently be changed before final programming.

Figure 7. Batch programming



Now press [Program]. The values are unboxed, indicating that the corresponding parameters have been reprogrammed. Press [Undo Pending] to cancel all pending parameters.

Note: If power to the programmer is unexpectedly lost, remove the programming head from the pacemaker to cancel any temporary features and restore the pacemaker to its permanently programmed state. Loss of power during permanent programming of a parameter cancels the programming action. After the programmer is switched back on and the appropriate application is started, the programming action must be repeated.

If power is lost before permanent programming of batched parameters can be completed, all reprogramming is cancelled. All parameters then keep the values they had before the batch programming was started. After the programmer is restarted, the batch programming must be repeated.

If power is lost during a follow-up session, the start of session values in the programmer memory are lost. When the programmer is restarted, the pacemaker is reinterrogated, giving new start of session values.

Parameter pertinency – Only the parameter values applicable to a selected feature or mode, for example, atrial amplitude in the AAI mode, are shown. This is called parameter pertinency.

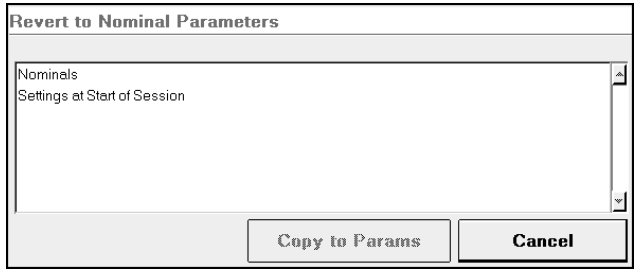
For example, if the pacemaker is in the DDD mode and the atrial amplitude is prepared for reprogramming from 3.75 V to 2.50 V, the new value is boxed to indicate that it is pending. If the mode is then changed to VVI, the boxed atrial value of 2.50 V disappears. However, pressing [Program] results in permanent programming of both the VVI mode and the atrial amplitude. Following any subsequent reprogramming to an atrial or dual chamber mode the atrial amplitude will be 2.50 V.

Caution: If you select a pending value for any parameter and then select a new mode, to which the parameter concerned is not pertinent, the pending value disappears. However, it is still pending and will be permanently programmed if you press [Program]. To prevent this, press [Undo Pending].

Nominal programming – Nominal programming is used to change all parameters to nominal (delivery) values (refer to the product specifications in the appendices) or the settings at the start of the follow-up session.

For nominal programming, press [Revert…] on the bottom left of the Therapies window.

Figure 8. Revert to Nominal Parameters window



Now choose between “Nominals” and “Settings at Start of Session” and press [Copy to Params]. The programmer returns to the Therapies window and all relevant parameters are boxed showing their new values.

Press [Program] to change all relevant parameters to nominal settings or to the settings at the start of the session. Press [Undo Pending] to cancel all pending parameters. To cancel individual pending parameters select the relevant value box and press [Undo Pending]. In both cases the pending values are then unboxed.

4.5.2 Programming Selected Episodes

Parameters
⇒ Episode Triggers

See Section 8.3 for details of how to choose the episode type and how to set up episode recording.

4.5.3 Programming Fast Learn

Parameters
⇒ Fast Learn

Fast Learning adjusts the activity slope to optimize rate responsive pacing (see Section 12.5).

4.5.4 Viewing parameter history

Parameters
⇒ History

Parameter history shows the settings of therapy parameters at the start of the current follow-up session and up to five previous sessions.

Note: Pressing [Clear History] clears all the diagnostics, parameters and tests history data in the pacemaker. Only the data from the current follow-up session remains in the pacemaker.

4.6 How to start tests

Select the “Tests” icon to see the following tab options.

Threshold – This option allows you to carry out pulse amplitude and pulse duration threshold tests, which can be used to optimize pacing conditions (see Section 6.2.3).

Sensing – This tab gives access to P-wave and R-wave amplitude tests, which can be used to optimize sensing conditions (see Section 6.3).

Lead – This option allows you to measure lead impedance, to check the stability of leads (see Section 6.4).

VA Interval – This option allows you to start a manual or automatic VA interval measurement, to help in detecting retrograde conduction and far-field R-wave (FFRW) sensing (see Section 6.5).

Temporary – This option allows you to set pacemaker programmers temporarily, to test the effects of new settings on pacing (see Section 6.6).

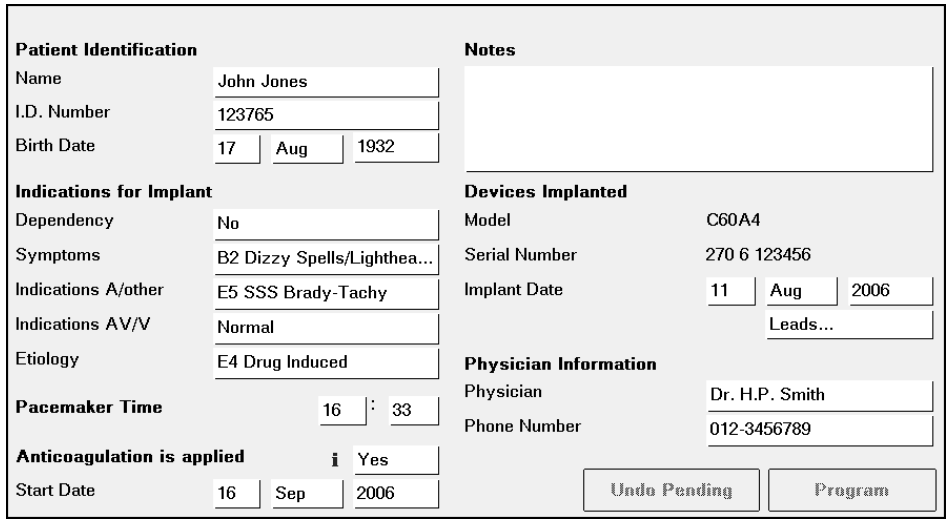
Atrial Burst Pacing – This option allows you to attempt to end an atrial tachyarrhythmia or determine the Wenckebach point (see Section 6.7).

History – This tab shows the results of lead impedance measurements and the results of threshold and sensing tests that have been carried out during the current follow-up period and up to five previous periods (see Section 6.8).

4.7 How to enter patient information

To enter patient data and pacing system information into the pacemaker, select the “Patient” icon.

Figure 9. Patient window



Patient identification – To enter the patient’s name and ID number, press the corresponding value box. You can now enter the patient’s name and ID number (both will accept a maximum of 20 characters) using the on-screen keyboard.

When using the on-screen keyboard press the appropriate characters to select them. Use the backspace key [<-] to delete the last entered character (you can also delete characters by selecting them with a sliding movement of the touch pen and then pressing the backspace key).

Confirm the patient’s name or code by pressing [Enter] or press [Cancel] to leave the window without programming a name or code. A confirmed name or code is boxed in the value box, indicating that it is pending.

To enter the patient's date of birth, press the appropriate value boxes for day, month and year and then select the correct dates.

Indications for implant – A number of boxes are provided to enter the following information:

- (pacemaker) dependency (yes or no)
- symptoms
- indications (atrial or other)
- indications (AV or ventricular)
- etiology

In the value boxes select the indication appropriate for the patient or select "Unspecified".

Pacemaker time – Here you can alter the pacemaker time (24-hour clock) by pressing the appropriate value boxes (hours and minutes) and selecting the correct values.

Be aware that changing the pacemaker time clears all diagnostic data stored in the pacemaker memory. Diagnostic data collected before the change can still be displayed during the current follow-up session.

Notes – This space is provided so that any additional notes may be added (with a maximum of 80 characters).

Anticoagulation is applied – Here you can specify whether the patient is receiving anticoagulation medication. If you select "Yes", you can enter the date when anticoagulation treatment started.

Devices implanted – The programmer automatically displays the pacemaker model number, serial number and implant date. The implant date can be changed by the user.

Leads – Press this value box to open a secondary window where you can enter the lead manufacturer, model name, serial number and implant date for each lead.

Physician information – The physician's name and phone number can be entered here.

Saving patient information – Press [Program] to enter data into the pacemaker. Press [Undo Pending] to cancel entering patient or pacing system data.

4.8 How to save and reload data

Session data files contain all data that has been interrogated during the follow-up session. This includes device data at initial interrogation and all valid parameter data at the moment the session data file was saved.

With a session data file, it is possible to do an “off-line” analysis of the data by reloading the data from diskette at a later stage (see Section 4.8.3). The saved file can also be used to organize and analyze patient and programmer information in the Medtronic Paceart data management system.

The session data file also includes the contents of the pacemaker memory as read at initial interrogation. This information can be useful for Vitatron specialists, in situations where analysis of the pacemaker function is required.

Caution: Do not modify the session data file in other applications because the file will become unreadable to Vitatron applications. Vitatron is not responsible for the inappropriate use of data saved to diskette.

4.8.1 Saving pacemaker (session) data to disk

There are two ways to save session data to diskette. First insert a diskette into the programmer disk drive.

End Session
- ⇒ Save Session...
  - ⇒ Save

Reports
- ⇒ Save Session...
  - ⇒ Save

The programmer automatically generates a file name using the current date and time (see Figure 10).

Figure 10. Save Session Data to Diskette window

Cautions:

- Make sure only virus-free diskettes are used!
- Remove the diskette from the disk drive before you turn the programmer off. Do not switch the programmer on if a diskette is in the disk drive.
- Keep the programming head and any other (electro)magnetic devices away from diskettes; this may erase data stored on the diskettes.

4.8.2 Saving pacemaker (session) data to the network

You can send the saved session data through the SessionSync network connection. The saved file can be used to organize and analyze patient and programmer information in the Medtronic Paceart data management system.

To save session data to the network, press [End Session…]. If the “Automatic SessionSync” check box is checked, the session data will be saved on the network when you press [End Now]. The programmer automatically generates a file name using the current date and time.

This option is only available if the programmer is configured with a SessionSync network connection, and the SessionSync option is enabled in Programmer Preferences on the Medtronic desktop. The network icon in the task bar indicates whether the SessionSync option is available.

4.8.3 Reloading session data

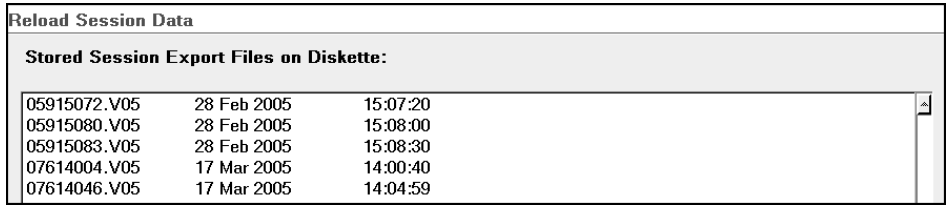
Programmer (Vitatron desktop)
⇒ Reload Session Data
⇒ Reload Data

You can reload session data that has previously been saved to diskette. This enables you to perform the following actions:

- Analyze (and compare) data from previous follow-ups.
- Run demo follow-up sessions using different patient profiles.

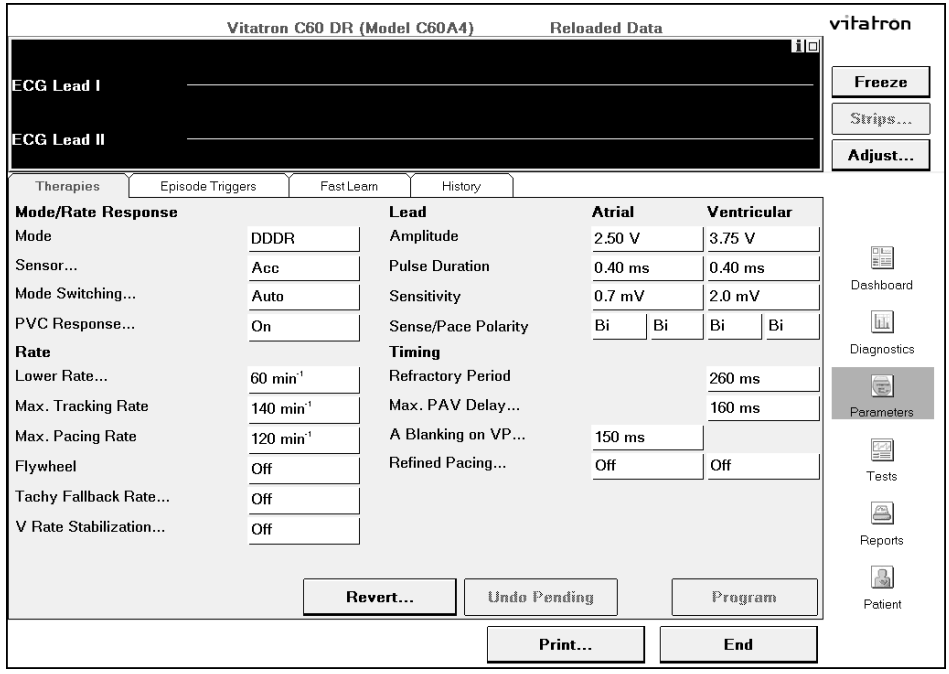
Start the reload session data option from the Vitatron desktop. If necessary, press [End Session] to return to the desktop. When you choose the “Reload Session Data” option, you are asked to insert the relevant diskette into the programmer disk drive. The programmer displays a list of all session export files stored on the diskette.

Figure 11. Reload Session Data window



Select the desired file and then press [Reload Data]. This loads the session data and allows you to analyze the follow-up data or conduct a demo follow-up session.

Figure 12. Example of a Reloaded Data Therapies window



Reloaded sessions can be identified by the text “Reloaded Data” in the top line and by the fact that during a reloaded session ECG recordings are shown as a flat line. The reloaded sessions only contain the data that was read out during initial interrogation of the pacemaker. The results of any subsequent programming actions or measurements carried out during the follow-up session are not displayed, although they are stored on the diskette and can be accessed using commercially available software.

During a reloaded session you can simulate a follow-up session and analyze the data. You can also “reprogram” pacing parameters; any changes may be reflected in the information presented on the programmer or in reports during the reloaded session. When you press [End] and return to the Vitatron desktop, all changes will be discarded. You cannot change the contents of the file on the diskette.

4.8.4 Using memory contents files

In the case of programming difficulties, if the pacemaker behavior cannot be interpreted, or if a pacemaker malfunction is suspected, the programmer often generates a memory contents file on the programmer hard disk. The contents of this file enable Vitatron specialists to evaluate the pacemaker status and assist during follow-up. For information on managing memory contents files, see Section 4.10.6.

4.9 How to print

You can print the current window, a report or the ECG recording on the built-in, thermal strip printer, or on a full-size, external printer.

You can also choose a printer and adjust printing options (see Section 4.9.4).

Note: After printing data on the (thermal) strip printer Vitatron recommends that you make photocopies of printed data (the quality of printing on thermal paper diminishes with time).

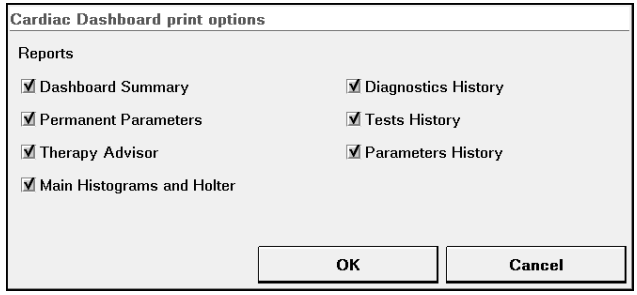
4.9.1 Using the Print button

In most windows, you can press the [Print] button to print the data currently displayed in the window (the current page).

If the Print - Options window appears after you press [Print], you can choose whether to print the current page or the full report for the current window (see Section 4.9.4).

Printing from the cardiac dashboard – If you press [Print] on the cardiac dashboard, you can choose one or more reports from a list of cardiac dashboard reports.

Figure 13. Cardiac Dashboard print options window

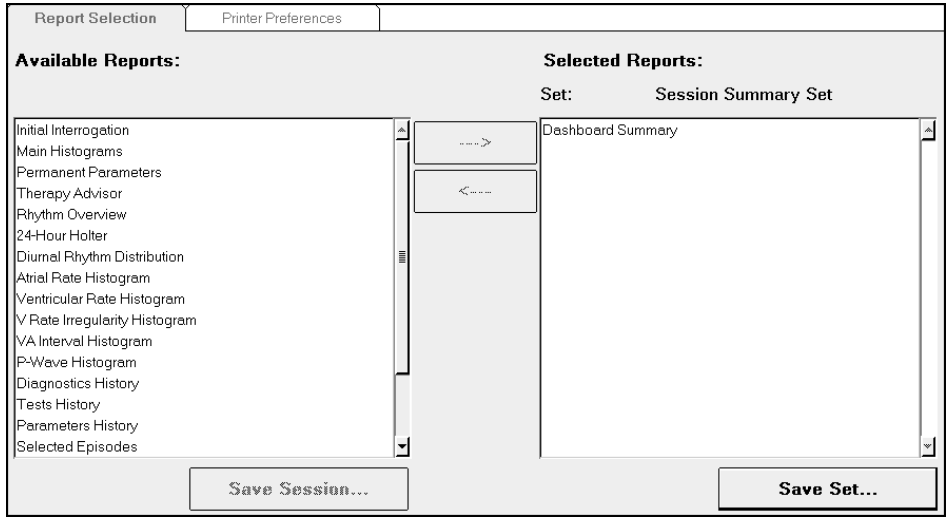


4.9.2 Printing reports

Reports
⇒ Report Selection

In the Report Selection window you can select reports to print, or define your own standard set of reports to print at each session.

Figure 14. Report Selection window



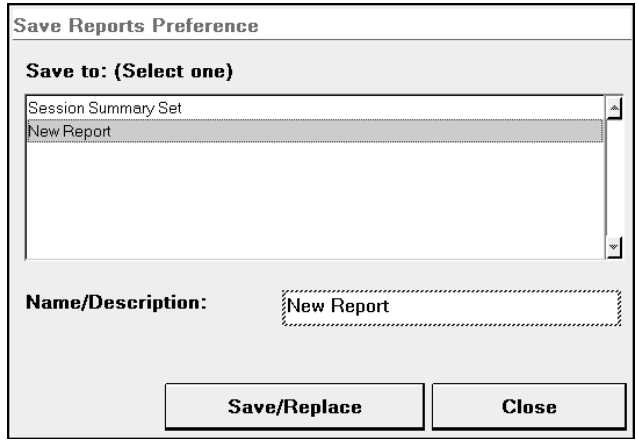
The Report Selection window provides a list of all available reports (left) and selected reports (right). The available reports include all the reports that have been generated during the current session. For example, if you have performed a threshold test during the current follow-up session, the Threshold Test report is available.

To add one or more reports to the list of selected reports, select the name in the available reports list and press [--->]. To remove a report from the selected reports list, select its name and press [<---].

Press [Print] to print the selected reports on the built-in or external printer.

You can save the set of selected reports for use in future follow-up sessions by pressing [Save Set…]. In the Save Reports Preference window, select “New Report” (see Figure 15). Give the new report set a name in the Name/Description value box, and press [Save/Replace].

Figure 15. Save Reports Preference window



4.9.3 Printing the ECG

To print the ECG using the built-in printer, press one of the print speed control buttons on the left of the programmer keyboard. All three ECG lead recordings are then printed at 12.5, 25 or 50 mm/s.

The print speed, which is shown when printing starts, can be changed with immediate effect. This is shown on the printout by a dashed vertical line, followed by the new print speed.

ECG marker annotations are included if they are switched on.

To stop printing, press the same print speed control button.

4.9.4 Choosing the printer and print preferences

Programmer (Vitatron desktop)

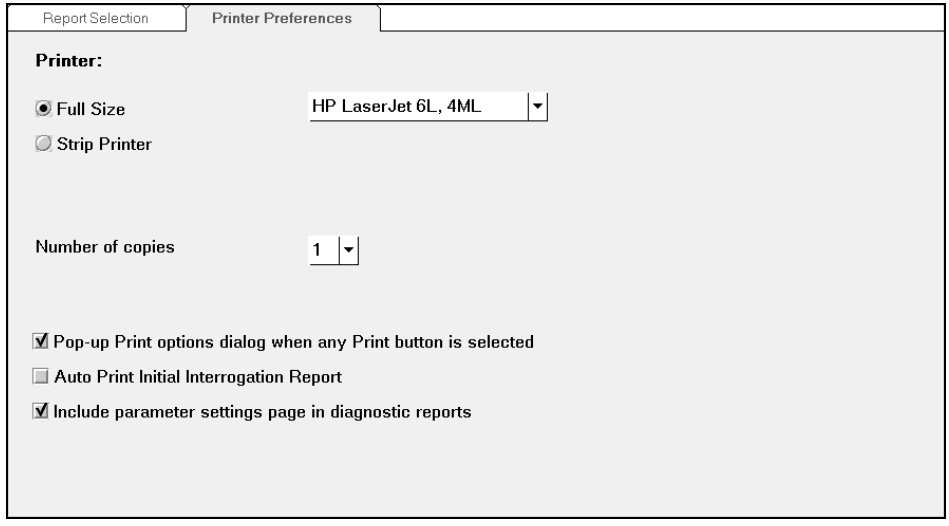
⇒ Programmer Preferences

Reports

⇒ Printer Preferences

There are two ways to change the printer and print options: from the Vitatron desktop or during a follow-up session. Both methods change the default settings for subsequent programming sessions.

Figure 16. Printer Preferences window



You can adjust the following options:

Printer – Select the printer, which is either the built-in, thermal strip printer (the default setting) or a full-size external printer. If you select the full-size printer you can choose the printer from a drop-down list of all supported printer types.

Number of copies – Set the default number of copies to be printed.

Pop-up print options dialog – If you check this box, every time you press a [Print] button, the Print - Options window will open. In this window you can overrule the preference settings for a particular print job, and choose whether to print the current page or a full report.

Auto print initial interrogation report – If this option is switched on (the default setting) a full initial interrogation report is printed as soon as initial pacemaker interrogation is complete.

Include parameter settings page – Check this box to add a list of relevant therapy settings and the Selected Episodes settings to every full diagnostic report. This option is not available from the Vitatron desktop,

4.10 How to adjust the programmer

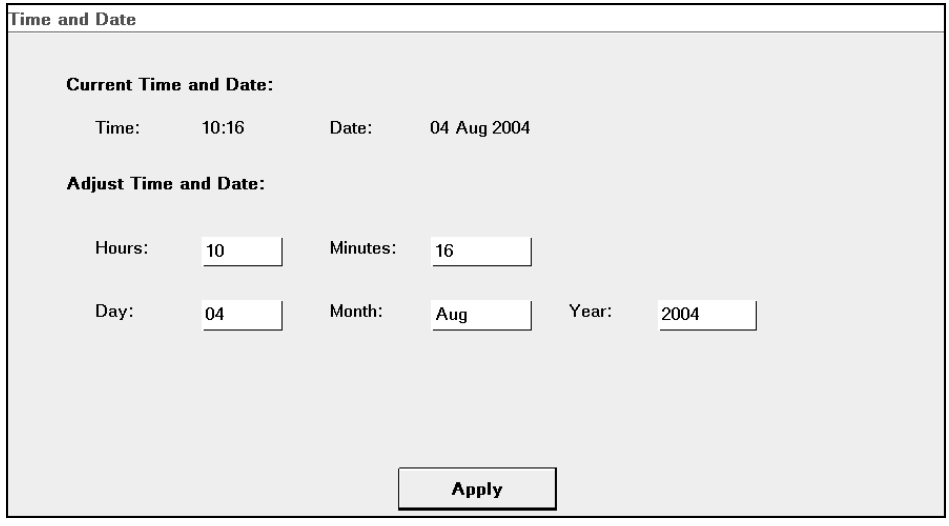
You can adjust programmer settings from the Vitatron desktop before you start a follow-up session.

4.10.1 Changing the programmer time and date

Programmer (Vitatron desktop)
⇒ Time and date

The window displays the current time and date in the programmer (in the 24-hour clock format).

Figure 17. Time and Date window



To change the programmer time or date, press the relevant value box and select the time or date. Press [Apply] to apply the changes. Press another icon to leave the window without making any changes.

Caution: The programmer clock is battery-powered so if the battery is depleted the date and time will be incorrect and should not be used to set the pacemaker time. A warning to this effect will be given by the programmer.

4.10.2 Changing the programmer language

Programmer (Vitatron desktop)
⇒ Programmer Preferences

To change the language, press the “Language” value box and select the desired language from the list. The change takes immediate effect.

4.10.3 Changing the programmer sounds

Programmer (Vitatron desktop)
⇒ Programmer Preferences

To mark certain events (for example, programming confirmed, start/end emergency, end test, error) audible signals are used. The audio option allows you to switch the sound on or off. To do this press the “Audio” value box and select the desired option (Off, Low, Medium or High).

If the sound is switched off, only emergency beeps will still be audible. The last three options are equivalent to “On” and do not provide different volume levels.

4.10.4 Changing the Therapy Advisor setting

Programmer (Vitatron desktop)
⇒ Programmer Preferences

Press the Therapy Advisor check box to switch the Therapy Advisor on or off.

4.10.5 Checking software release numbers

Programmer (Vitatron desktop)
⇒ Software

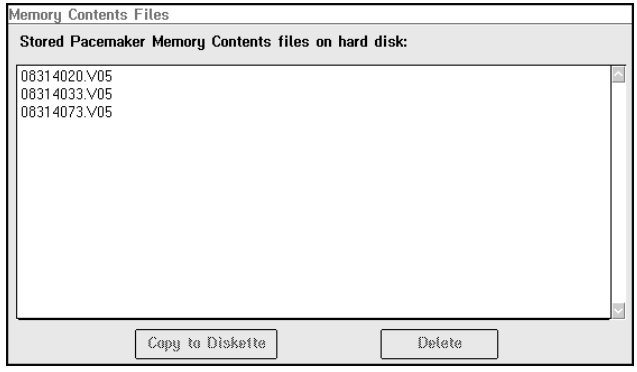
The Software window shows the version numbers and service release numbers of the currently installed Vitatron software.

4.10.6 Managing memory contents files

Programmer (Vitatron desktop)
⇒ Memory Contents Files

The Memory Contents Files window lets you copy pacemaker memory files (memory dumps) from the programmer hard disk to diskette.

Figure 18. Memory Contents Files window



All stored pacemaker memory contents files are listed. Each file name starts with an eight-digit number followed by a year code; if more than one file is listed the one with the highest number is the newest for that particular year.

To copy a selected file from the programmer to a diskette, press [Copy to Diskette].

Use [Delete] to remove a selected file from the programmer.

Cautions:

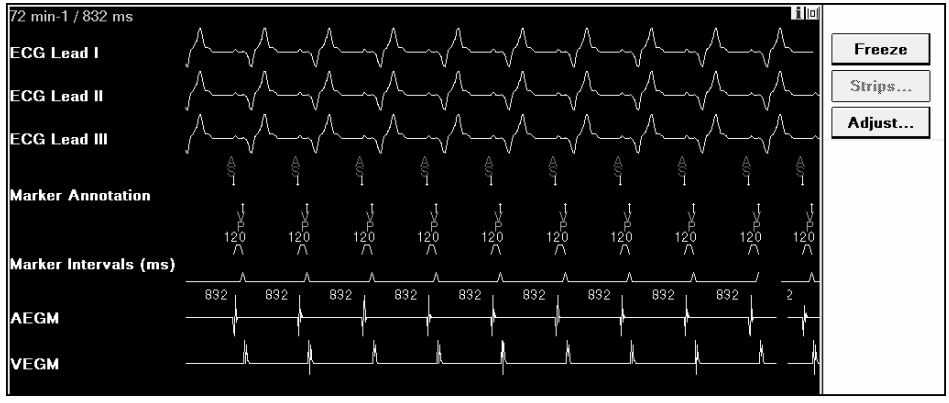
- Make sure only virus-free diskettes are used!
- Remove the diskette from the disk drive before you turn the programmer off. Do not switch the programmer on if a diskette is in the disk drive.

4.11 How to adjust the ECG window

4.11.1 Expanding the ECG window to full size

The ECG window automatically opens in the minimized format when the programmer is switched on. To view all the available signals, you can expand the ECG window to its full size using the square button in the upper-right corner of the ECG window. To return to the partial-view window, press the square button again.

Figure 19. Displayed recordings



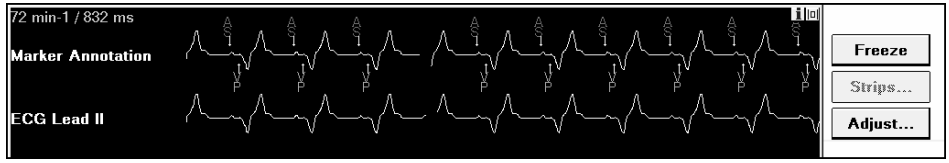
4.11.2 Arranging the ECGs

You can arrange the ECG recordings in any order, and you can superimpose the marker annotation and marker intervals on an ECG to facilitate interpretation.

Use the touch pen to “drag” an ECG recording to the desired position. The example below shows how to move the Marker Annotation recording from its position over Lead I to a position over Lead II.

First decide which recording you want to reposition. If its name (in this case, Marker Annotation) is not displayed, tap the name of the superimposed recording to display the hidden name.

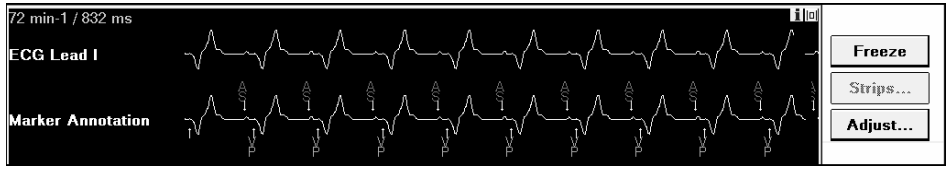
Figure 20. Select the ECG to be moved



Press and hold the touch pen against the name of the ECG you want to move.

Without lifting the touch pen, drag the box now appearing around the recording name to the desired location.

Figure 21. Move the ECG to its new location

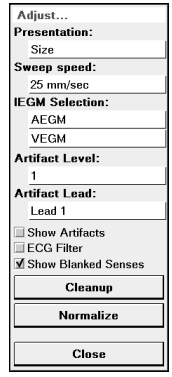


When you have the box positioned where you want the ECG to appear, lift the touch pen. If you are positioning one ECG over another, it will snap into position. To equalize the spacing between the recordings in the new arrangement, press [Cleanup] in the Adjust window.

4.11.3 Adjusting and configuring the display

To change the ECG settings press [Adjust…] in the ECG control panel.

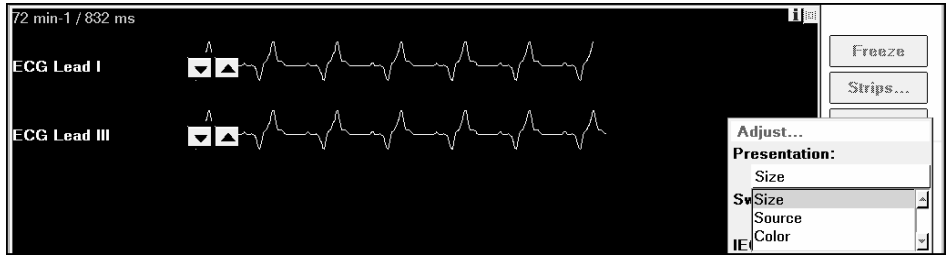
Figure 22. The Adjust window



The Adjust window contains controls that allow you to tailor the ECG display to your specific needs.

Presentation: signal size – To adjust the size (or amplitude) of a signal select “Size” in the Adjust window and alternately press and release the increase or decrease button to change the size of the signal you want to adjust.

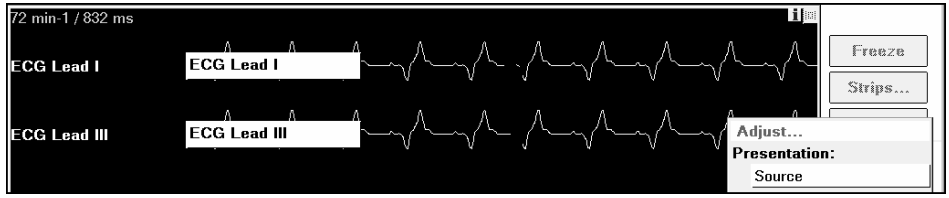
Figure 23. Adjusting signal size



To return to the default setting, press [Normalize]. This resets the size of all recordings to the default setting and equalizes the spacing between the recordings.

Presentation: ECG source – To change the order in which the recordings appear in the window, select “Source” in the Presentation list. The source of the ECG is then superimposed on the signal on a white background (see Figure 24).

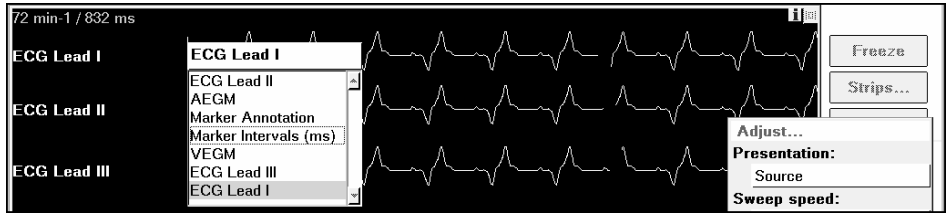
Figure 24. Adjusting the source



Note that ECGs may be superimposed on one another (for example, when using marker intervals or marker annotation). If this is the case the name of the source that is on top appears. To display an underlying source and move it to the top, select the source name on the left of the screen. The name changes to show the recording beneath it.

If you want to change the position of a superimposed signal, it must first be put on top so that its name appears on the left of the screen (see Figure 25).

Figure 25. Changing the source

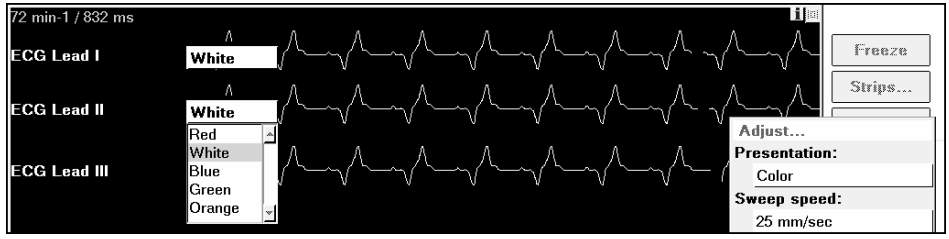


Now select the source for the ECG you want to change. A list appears displaying source options. From this list select the desired source. Selecting a new source causes the source of the recording presently displayed to change positions with the source you selected.

Presentation: color coding – This changes the color of one or more of the recorded signals. To change the color first select “Color” in the Adjust window.

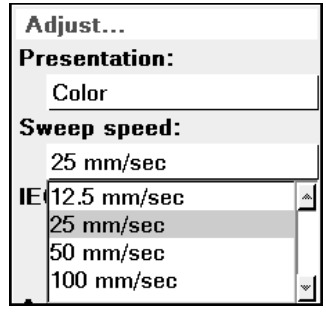
Select the color field for the recording you want to change and from the list of options, select the desired color.

Figure 26. Selecting the desired color



Sweep speed – By selecting “Sweep speed” from the Adjust window, you can set the ECG sweep speed to 12.5, 25, 50, or 100 mm/s. The initial default setting is 25 mm/s, but any change is saved and used as the default at the next follow-up session.

Figure 27. Selecting sweep speed



EGM selection – This feature lets you activate the atrial and ventricular EGMs, which are displayed in the ECG window. The following options are available:

- Off – no recording is displayed
- AEGM - the filtered atrial EGM detected by the atrial lead
- VEGM - the filtered ventricular EGM detected by the ventricular lead

Since the EGMs depend on information received from the pacemaker, they are not displayed unless the programming head is positioned over the pacemaker. This feature is not available if the pacemaker is recommended for replacement.

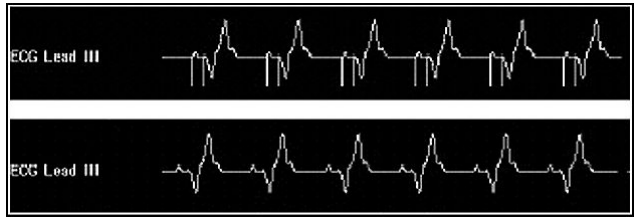
Artifact level – If “Show artifacts” is switched on, pacing spikes are shown in the ECG window. The sensitivity to sensed pacing pulses can then be adjusted by changing the artifact level. To prevent interference signals being interpreted as pacing pulses or to prevent certain pacing pulses from being sensed you should select the appropriate artifact level. The artifact level can range from 1 (very sensitive) to 5 (very insensitive).

The required artifact level may vary due to the amount of electromagnetic interference (EMI) present at the follow-up site.

Artifact lead – This option determines which ECG lead is used to detect pacing pulses. During programming and interrogation of the pacemaker, communication signals may appear as artifacts on the ECG.

Show artifacts – Press the “Show Artifacts” check box to enable or disable pacing artifact enhancement. A check mark indicates that it is enabled. The two ECGs in Figure 28 show how an ECG appears with and without this feature enabled.

Figure 28. Artifact enhancement enabled (upper panel) and disabled (lower panel)



ECG filter – Press the “ECG Filter” check box to switch the ECG filter on or off. A check mark indicates that the filter is switched on. In the presence of interference the filter may improve the quality of both the displayed and printed ECG. The filter affects the ECG detection bandwidth as follows:

- Filter Off: bandwidth = 0.05 to 100 Hz
- Filter On: bandwidth = 0.5 to 40 Hz

Show blanked senses – If this option is switched off (the check box is not checked) blanked sensed atrial events are suppressed in the ECG recording. This allows you to avoid an overload of markers in the ECG recording during periods of high (sensed) atrial rates. The option is switched on at the start of each new follow-up session.

Cleanup – Press this button to equalize the spacing between the recordings.

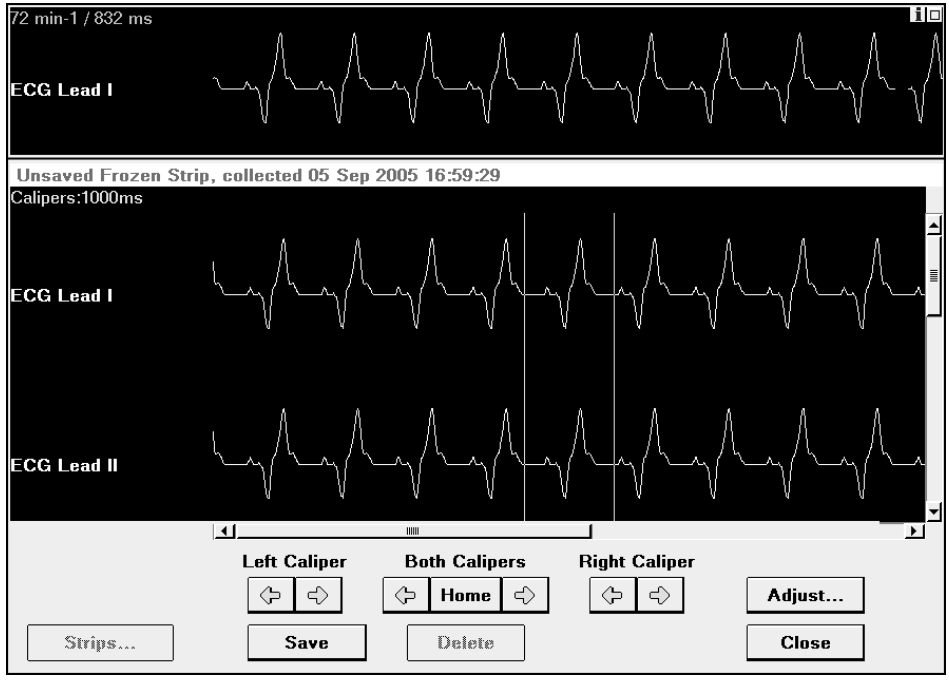
Normalize – Press this button to equalize the spacing between the recordings and to adjust the size of each to the default setting.

Close – Press [Close] to leave the Adjust window.

4.11.4 Freezing and analyzing an ECG

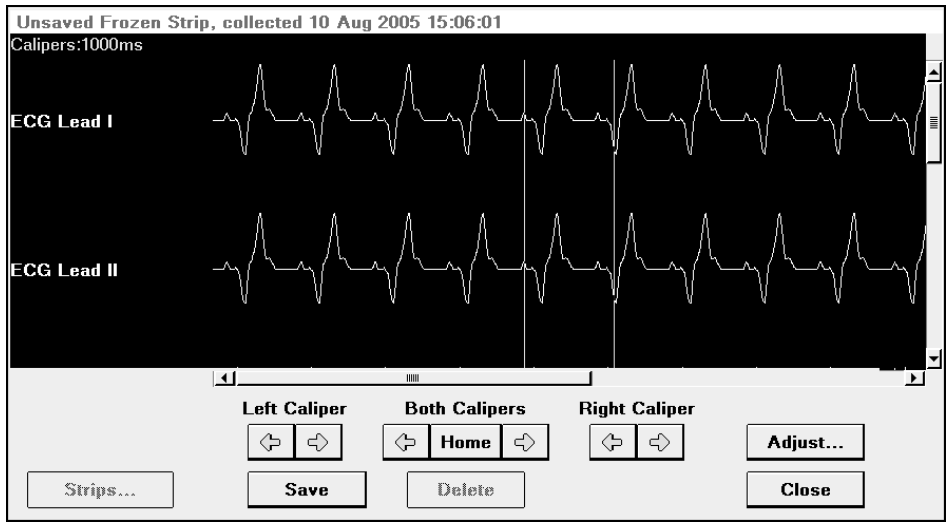
This option lets you freeze the last 15 seconds of all ECGs displayed in the expanded window. Press [Freeze] in the ECG control panel to open the frozen ECG viewing window.

Figure 29. Freezing an ECG



Using the on-screen calipers – The control buttons control the frozen ECG viewing window by letting you move each of the two vertical cursors appearing in the window to any desired position. The cursors thus act as calipers allowing you to measure the time interval between events. The caliper measurement is displayed in milliseconds in the upper-left corner of the frozen ECG window.

Figure 30. Using the calipers



Alternately press and release the appropriate button to effect small movements, or press and hold the button to effect larger movements.

Viewing other portions of the frozen ECG – Use the vertical scroll bar to scroll the display up or down to view other ECGs. Touch and drag the box to scroll the strip up or down. Tap the scroll up arrow or scroll down arrow to scroll the ECGs in small increments.

Use the horizontal scroll bar, which operates like the vertical scroll bar, to move the display to the right or left to see other portions of the 15-second strip.

Saving a frozen ECG recording – You can save the frozen ECG by pressing [Save]. You may then recall the saved recording for later viewing or printing.

Printing the frozen strip – Press [Print] to print the frozen ECG recording you are viewing (at 12.5, 25, 50, 100 or 200 mm/s).

Closing the frozen viewing window – Press [Close]. If you have not saved the recording, a pop-up window will remind you to save or delete it.

4.11.5 Recalling a saved ECG

Before ending a follow-up session, you can recall and view any ECG collected and saved during the session. Such recordings may be those saved during a test (for example, the threshold test) or an ECG saved following use of the Freeze option.

To view a previously collected ECG, press the [Strips…] button in the ECG control panel or the [Strips…] button in the frozen ECG window. From the Other Strips window now displayed, select the “Collected by programmer” option.

From the list of recordings in the selection field, select the one you want to view. It may be necessary to use the scroll bar on the right of the field if there are more than five recordings available.

To delete a saved recording, press [Delete]. This button is only active if you are viewing a saved recording.

Press [Open].

4.11.6 Connecting an external ECG device

You can send analog output from the programmer to an external ECG device (such as an ECG monitor, recorder or strip printer) through a cable box (which can be ordered separately). For information on connecting the device, refer to the programmer manual.

During a follow-up session, the output is sent through four channels:

- channel A sends the top ECG recording from the ECG window
- channel B sends the top EGM recording from the ECG window (if EGM is selected in the Adjust window)
- channel C sends the lower EGM recording from the ECG window (if EGM is selected in the Adjust window)
- channel D sends the marker annotations

Calibrating the ECG – Press the calibration button on the cable box to generate calibration signals for the ECG and the ECG markers. These signals are transferred to the ECG window and, if applicable, to the built-in strip printer.

The calibration signals for the ECG consist of two pulses with an amplitude of 1 mV and 5 mV respectively. Those for the ECG Markers consist of 8 pulses corresponding to amplitude levels of -4 mV to +4 mV. These signals appear in the ECG window and the marker channel. You can use the signals to analyze the ECG and ECG marker amplitudes by comparing them to the amplitude of the applicable calibration signal.

4.12 Emergency programming

If an error occurs, or if you make a mistake during programming, first try to correct it using normal programming procedures. If this fails press [Emergency] on the programmer to force the pacemaker to function with the emergency settings listed in Table 3. All other pacing therapy parameters will be programmed to nominal (delivery) settings (refer to the product specifications in the appendices). The programmer will stop all current activities and restart the follow-up session by interrogating the pacemaker again. Diagnostic data collection stops; diagnostic information is not lost, but remains in the programmer memory.

As soon as the emergency settings have been programmed, the cardiac dashboard appears and all functions are available. You should then reprogram the pacemaker to settings appropriate for the patient.

Note: When programming emergency settings could cause battery depletion, the programmer first programs the emergency settings, then gives a warning that higher power consumption may reduce the time remaining before pacemaker replacement is required. Vitatron recommends that you then decrease the output settings. If you do not decrease output settings, see Section 5.8 for an explanation of the possible consequences.

Table 3. Emergency settings

Mode[a]	**VVI**	**AAI**
Lower rate	60 min^{-1}	60 min^{-1}
Pulse duration	1.0 ms	1.0 ms
Pulse amplitude	7.5 V	5.0[b] V
Sensitivity	2.0 mV	0.7 mV
Refractory period	400 ms	400 ms
Polarity (pacing and sensing)	unipolar	unipolar

[a] Mode is VVI, except for single chamber pacemakers programmed to AXX mode.
[b] Keeps value if greater than 5 V.

Warning: For patients with a co-implanted implantable cardiac defibrillator (ICD), emergency programming can lead to undesirable interaction with the ICD due to unipolar pacing.

Cautions:

- Emergency programming initiated from Vitatron C-series software only works with Vitatron C-series pacemakers.
- Other Vitatron software applications cannot be used for emergency programming of Vitatron C-series pacemakers.

5 Follow-up

5.1 Introduction

The intention of this chapter is to offer post-implant and follow-up advice to the medical personnel working with Vitatron pacemakers.

Follow-ups at regular intervals are required to check on the medical condition of the patient and to confirm that the programmed parameter values are still appropriate. Additionally, both the operation of the pacemaker and the condition of the battery require regular monitoring.

The sections in this chapter are arranged as follows:

- post-implant configuration (see Section 5.2)
- record an ECG (see Section 5.3)
- program patient information (see Section 5.4)
- checks and programming (see Section 5.5)
- optimizing the pacemaker (see Section 5.6)
- the ECG/EGM (ElectroCardioGram/Intracardiac ElectroGraM) (see Section 5.7)
- follow-up frequency and longevity (see Section 5.8)

5.2 Post-implant configuration

During implant, the pacemaker configuration procedure starts automatically once the pacemaker detects that a lead is connected. Note that even if the pacemaker is a dual chamber device, the procedure begins as soon as the first lead is connected. A minimum period of two hours is then required for the pacemaker to complete configuration.

If in the first two hours after implant, lead replacement or repositioning is necessary, then the two-hour configuration period starts again. Vitatron advises you not to program the pacemaker before implant as this could delay configuration. The pacemaker gives the required pacing therapy at the delivery settings during the configuration period.

Once configuration is completed, the pacemaker program determines that implant is complete and automatically programs the implant date. Programming the implant date activates the diagnostic features and the pacemaker starts to collect diagnostic data. If the implant date is set manually, the collection of diagnostic data starts one hour later. Refer to Chapter 7 for a full description of the diagnostic features.

The first time a programming head is placed over the pacemaker after implant, the programmer synchronizes the implant date in the pacemaker with the programmer date. The pacemaker then starts recording selected episodes and stored EGM (see Chapter 8).

Note: Vitatron recommends that you check the pacemaker has set the implant date and thus has switched on the collection of diagnostic data. If required, you have the option to manually adjust the implant date (see Section 4.7). A time difference may appear in diagnostic data collected before and after the date change.

5.3 Record an ECG

First, connect the patient to an ECG, either the built-in ECG or an external ECG monitor. Then record and print out a copy of the ECG. During any programming session, either post-implant or scheduled follow-up session, keep the ECG active to allow all cardiac events to be continuously monitored.

As the post-implant ECG provides an important baseline record of the patient, Vitatron recommends that you place a printout of the ECG in the patient's file. This ensures that a record is available for reference during the service life of the pacemaker. For the same reason Vitatron recommends keeping a printout of the ECG recordings made at each scheduled follow-up session.

5.4 Program patient information

Select the "Patient" icon and then enter the patient and pacing system data in the Patient window. For specific information on programming the data in this window, refer to Section 4.7. This information, stored in the pacemaker, will throughout the service life of the pacemaker allow you to perform the following tasks:

- identify both the patient and the pacemaker system
- retrieve information about diagnostic and implant information
- retrieve information on the physician, implant center and the implant that is essential for gathering further information
- write comments, remarks and observations on a "notepad" and thus record additional patient information or reminder notes for the next follow-up session. This can prove especially useful when the patient files are not available.

5.5 Checks and programming

Vitatron suggests the following checks and programming after implant to ensure that the pacemaker program meets the patient's requirements.

During routine follow-up sessions, use this section to ensure that any patient changes are recognized and met. If any help is required with programming, or for specific programming instructions, refer to Chapter 4.

5.5.1 Interrogate the pacemaker

With the programmer head positioned over the pacemaker, use the cardiac dashboard to assess the pacemaker status. Print out a copy of the cardiac dashboard summary report (see Section 4.9.1). If applicable, print out the diagnostics, including the Holter and the histogram data. Place all the printouts in the patient's file so that a record is available for analysis if required.

If the "Auto print initial interrogation report" option is checked in the Printer Preferences window, the results of the initial pacemaker interrogation are printed automatically (see Section 4.9.4).

Note: As soon as the programmer head is correctly positioned the pacemaker switches to its magnet pacing rate. This rate continues until either the interrogate button on the programmer head or the [Auto Identify] button is pressed, and communication is established. Then the magnet rate is switched off. In patients who experience discomfort while the magnet rate is active, it is advisable to press the interrogate button before positioning the programmer head. This limits the length of time during which the magnet rate is active.

5.5.2 Confirm lead function

Check the lead impedance displayed on the cardiac dashboard. Compare the values displayed on the screen with the values obtained at the last follow-up session.

5.5.3 Pulse amplitude and pulse duration threshold tests

Use the pulse amplitude and pulse duration threshold tests to determine the minimum pulse amplitude and pulse duration, at which it is possible to obtain effective capture. If required, see Section 6.2 for more detailed information on performing these tests. Adapt the output values if necessary.

5.5.4 Rate response

The delivery setting is the non rate responsive mode.

If the patient requires rate responsive pacing, program the mode setting to the appropriate rate responsive mode.

5.5.5 Mode switching

The delivery setting is “Fixed”.

There are two options available, “Fixed” and “Auto” (automatic). Unless the patient’s medical condition dictates differently, Vitatron advises you to use the following settings.

- In DDDR mode, ageing patients: program mode switching to “Auto” with mode switching sensitivity set to “Standard”.
- In DDDR mode, young patients: program mode switching to “Auto” with mode switching sensitivity set to “Moderate”.
- In VDDR mode, all patients: program mode switching to “Fixed” or “Auto”, with mode switching sensitivity set to “Moderate”.

See Section 10.5 for further information on mode switching and mode switching sensitivity.

5.5.6 Lower rate

The delivery setting is 60 min^{-1} .

Use the patient’s medical condition to determine whether to keep the delivery setting, or to use a more appropriate setting.

See Section 9.4 for further information on the lower rate parameter.

5.5.7 Maximum tracking rate

The delivery setting is 140 min^{-1}.

Use the patient’s age and medical condition to determine whether to keep the delivery setting, or to use a more appropriate setting. For further information, see Section 9.5.

5.6 Optimizing the pacemaker

Vitatron recommends that you perform the following pacemaker optimizing procedures, both during the post-implant stage and at the subsequent follow-up sessions. These procedures help to deliver the optimal pacemaker therapy to the patient and ensure a long pacemaker lifetime.

5.6.1 Optimizing pacing

Having determined the thresholds, check that the pulse amplitude and pulse duration are appropriate for the patient. When programming the pulse amplitude, as a generally accepted standard Vitatron recommends that you program a safety margin of twice the pulse amplitude threshold. When programming the pulse duration, Vitatron recommends that you program a safety margin of three times the pulse duration threshold. Check that the pacing polarity settings are appropriate. See Section 6.2 for detailed programming instructions on optimizing pacing.

5.6.2 Optimizing sensing

First, check that the sensitivity is still at an appropriate setting for the patient. Then check that the sensing polarity setting is correct. Following on from these checks, carry out the P-wave and R-wave amplitude tests.

See Section 6.3 for detailed programming instructions on optimizing sensing.

5.6.3 Diagnostics

If there are any significant changes, or if the patient has reported any problems, the pacemaker diagnostic procedures can help to quickly locate the cause of the problem. Refer to Chapter 7 and Chapter 8 for detailed information on using the pacemaker diagnostics.

5.6.4 Atrial burst pacing

If the patient is suffering from atrial tachyarrhythmia during the follow-up session, atrial burst pacing can be used to try to end the tachyarrhythmia. Atrial burst pacing can also be used to determine the Wenckebach point. See Section 6.7 for detailed information on atrial burst pacing.

5.6.5 Updating the patient's file

When the required optimizing and diagnostic procedures are completed, Vitatron suggests printing out all the data and saving it in the patient's file. In addition, save the information to disk (see Section 4.8.1) and place the disk in the patient's file.

5.7 The ECG/EGM

At the beginning of each follow-up session, Vitatron recommends that you connect the patient to either the built-in ECG, or an external ECG monitor. If you use the built-in ECG it is possible to integrate the ECG information with other information from the pacemaker. See Chapter 4 for a more detailed description.

EGM – This feature lets you obtain, display and view graphs of intracardiac signals on the programmer screen. From the EGM information, you can determine the properties of intracardiac signals such as amplitudes, intervals and rhythms. It is also possible to use the information to determine if electromagnetic interference (EMI), far-field and retrograde signals are affecting the intracardiac signals.

Note: The EGM display is only available when the programming head is in position over the pacemaker.

5.8 Follow-up frequency and longevity

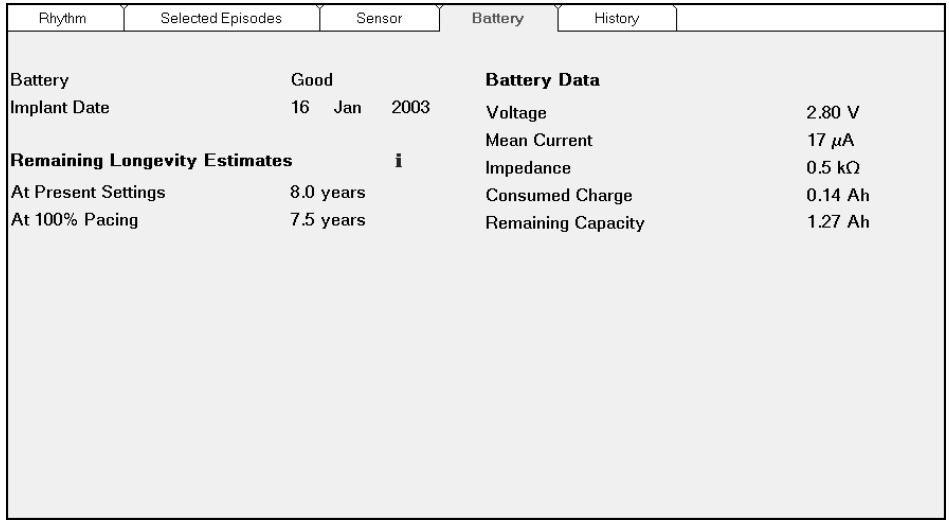
The follow-up frequency depends on the patient's condition and the age of the pacemaker. Use the following pacemaker information to determine the optimal follow-up frequency.

5.8.1 Pacemaker battery lifetime indicators

Diagnostics
⇒ Battery

The programmer calculates and displays pacemaker lifetime estimates on screen. Use the Battery window to assess the remaining battery lifetime (see Figure 31). There is also additional information on the battery, as well as other pacemaker information that can affect the service life of the pacemaker under various conditions. From this information it is possible to make an estimate of the time to the next follow-up session.

Figure 31. Battery window



The programmer calculates the estimated time until the recommended replacement time (RRT) of the pacemaker. This estimation is based on the programmed settings and the pacemaker recorded data. Although a small percentage of pacemakers may reach RRT sooner than the remaining longevity estimate, the main purpose of the feature is as an aid in estimating the appropriate follow-up session interval.

Battery status and remaining longevity are dependent on the present settings of the pacemaker. If any of the following remaining longevity critical parameters are pertinent and if any or all of them are altered, the battery status can change:

- mode
- lower rate
- pacing polarity (atrial or ventricular)
- pulse amplitude (atrial or ventricular)
- pulse duration (atrial or ventricular)
- Ventricular Rate Stabilization
- tachy fallback rate
- AF prevention therapies
- Selected Episodes trigger
- EGM recording

Notes:

- Current consumption and remaining longevity are strongly influenced by changes in mode, pacing rate, sensing (especially AF sensing), and therapies. Remaining longevity is therefore not always accurately predictable, as it is highly dependent on the patient/therapy interaction.
- At high output settings it is possible that remaining longevity and remaining capacity cannot be estimated accurately. In this case dashes (---) appear in the relevant fields.
- When the pacemaker battery is maturing, changing a pacemaker setting to a value that uses more current could result in the battery status changing, for example, from 'Good' to 'Ageing' . Before accepting the change, note that there is then the possibility of the pacemaker reaching 'Replace PM' in less then six months at this stage in the battery's lifetime.

As a further aid to estimating the pacemaker lifetime, the calculated lifetime figures for each model are shown.

Table 4. Calculated lifetime

Model	Pacing mode	Calculated lifetime (years)				
		100% pacing		50% pacing		100% inhibited[c]
		70[a] min^{-1}	60[b] min^{-1}	70[a] min^{-1}	60[b] min^{-1}	70[a] min^{-1}
Vitatron C70 DR	DDDR	8.9	10.2	10.4	11.5	12.4
Vitatron C60 DR	DDDR	8.9	10.2	10.4	11.5	12..4
Vitatron C50 D	DDD	9.2	10.6	10.8	12.0	13.0
Vitatron C20 SR	VVIR	12.4	13.8	13.7	14.9	15.4
Vitatron C10 S	VVI	13.0	14.4	14.5	15.7	16.3

[a] Conditions: 2.5 V, 0.5 ms, 500 Ω.
[b] Conditions: 2.5 V, 0.4 ms, 500 Ω.
[c] During periods in which the pacemaker senses high frequency atrial rhythms, especially AF, there will be an increase in power consumption. This will result in a reduction in battery lifetime. As an example, battery life could be reduced by 15% if the pacemaker were to sense an AF rhythm of 300 min^{-1} through 25% of the pacemaker lifetime.

5.8.2 Follow-up intervals

Vitatron recommends that you schedule a follow-up session at least once a year, even though the pacemaker memory can store more than a year's diagnostics.

You can determine the recommended follow-up interval using information provided by the programmer, or using a magnet, to monitor the battery.

Using the programmer – The follow-up intervals suggested in Table 5 are based on the battery status and estimated longevity. The medical condition of the patient dictates when to schedule the next follow-up session within the suggested follow-up interval.

Table 5. Follow-up intervals - using programmer

Battery status	Remaining longevity[a]	Suggested follow-up interval
"Good"	more than one year	Dependent on the patient's condition, up to one year.
"Good"	more than six months	Dependent on the patient's condition, up to six months.
"Ageing"	less than six months	Dependent on the patient's condition, up to three months.
"Replace PM"	none[b]	Schedule replacement of the pacemaker.

[a] At high output settings remaining longevity cannot be estimated accurately and is shown as "---". In this case, the follow-up interval should be less than 3 months.
[b] The pacemaker has sufficient battery capacity to operate at reduced output settings for at least 90 days after the battery status changes to "Replace PM" (see Section 5.8.3).

Using a magnet – Placing a magnet over the pacemaker switches the pacemaker to fixed rate pacing magnet mode. Removing the magnet causes the pacemaker to revert to the programmed settings. From the fixed pacing rates shown in Table 6 it is possible to determine battery status without using the programmer.

Warning: In magnet mode the pacemaker operates in an asynchronous pacing mode. If the intrinsic rate is higher than the magnet rate, this may induce ventricular tachycardia or ventricular fibrillation.

Table 6. Follow-up intervals - using magnet

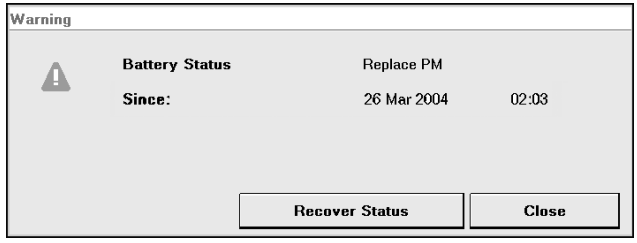
Magnet pacing rate	Battery status and pacemaker restore	Suggested follow-up interval[a]
100 min^{-1} (600 ms)	"Good"	Dependent on the patient's condition, up to six months.
95 min^{-1} (630 ms)	"Ageing"	Dependent on the patient's condition, up to three months.
86 min^{-1} (700 ms)	"Replace PM"[b]	Schedule replacement of the pacemaker.
90 min^{-1} (670 ms)	"Partial restore"	Refer to Appendix A for information on how to proceed once a "partial restore" has occurred.

[a] At high output settings the follow-up interval should be less than three months.
[b] The pacemaker has sufficient battery capacity to operate at reduced output settings for at least 90 days after the battery status changes to "Replace PM" (see Section 5.8.3).

5.8.3 Pacemaker replacement

During the initial interrogation, if the pacemaker determines that the battery status appears to be “Ageing” or “Replace PM”, then a warning opens over the cardiac dashboard. If available, the time when the status changed from good or ageing is also indicated (see Figure 32).

Figure 32. Battery warning



When the battery status indicates “Replace PM”, and the programmer determines that recovery is possible, then the [Recover Status] button is displayed. Pressing [Recover Status] resets the “Replace PM” indication to either “Ageing” or “Good”, dependent on the current pacemaker settings.

Check the time when the status changed. The longer the time since the battery status changed to “Replace PM”, the more urgent it is to replace the pacemaker. The pacemaker settings and the battery impedance determine the battery status “Replace PM”. At that moment when the pacemaker determines that the battery status reached “Replace PM”, 99.9% of the pacemakers have sufficient battery capacity to operate at “Replace PM” settings for at least 90 days before the pacemaker no longer functions within specifications.

Note: The period can be less than 90 days if either the settings or the output load of the pacemaker are greater than normal assumptions.

Pacemaker replacement characteristics – When the pacemaker determines that the battery status has changed to “Replace PM”, several changes take place automatically to prolong the battery life (see Table 7). Also note that the escape interval lengthens by 100 ms.

Table 7. Pacemaker replacement characteristics

Parameter name	before “Replace PM”	“Replace PM” (RRT)
Mode	DDD(R) VDD(R) VVI(R) DDI(R) AAI(R) DOO	VVI VVI VVI VVI AAI VOO
Flywheel mode	As programmed	Off
EGM range	As programmed	Off
PVC synchronous Astim	As programmed	Off
Post-PVC response	As programmed	Off
Rate response	As programmed	Off
Tachy fallback rate	As programmed	Off
AF prevention therapies	As programmed	Off
Ventricular Rate Stabilization	As programmed	Off
Diagnostic data collection	Available	Suspended
Selected Episodes setup	Available	Not available
Therapy Advisor	Available	Not available
EGM	Available	Not available

6 Optimizing pacing and sensing

6.1 Introduction

This chapter describes how to program pulse amplitude, pulse duration, sensitivity and pacing/sensing polarity. It also describes the following procedures, which are useful in optimizing pacing and sensing:

- Pulse amplitude and pulse duration threshold tests, which can be used to optimize pacing conditions. Instructions on how to program the (atrial and ventricular) pulse amplitude, pulse duration and pacing polarity are given (see Section 6.2).
- P-wave and R-wave amplitude tests, which can be used to optimize the sensing conditions. Instructions on how to program the (atrial and ventricular) sensitivity and sensing polarity are given (see Section 6.3).
- Lead measurement, which is used to check the stability of the atrial and ventricular leads (see Section 6.4).
- VA interval measurement, manual and automatic, which is helpful in diagnosing retrograde conduction and far-field R-wave (FFRW) sensing (see Section 6.5).
- Temporary test, which is helpful for temporarily reprogramming pacemaker parameters, for diagnostic purposes and for investigation of FFRW sensing (see Section 6.6).
- Atrial burst pacing, which is used to try to end an atrial tachyarrhythmia, for example atrial flutter, or to determine the Wenckebach point (see Section 6.7).
- Tests history, which provides historical information about the results of threshold tests, sensing tests and lead impedance measurements (see Section 6.8).

Notes:

- During the tests and measurements (except the lead measurement) post-PVC response, tachy fallback rate and Flywheel are temporarily disabled.
- When measuring pacing and sensing parameters with pacing system analyzers it should be realized that considerable differences may be observed when the results are compared with the results of the tests described in this chapter, because the measuring methods employed by such systems may differ.

6.2 Optimizing pacing

The stimulation threshold is the minimum amount of energy needed to consistently capture the heart outside the refractory period. Capture occurs when a pacing pulse is intense enough (pulse amplitude) or long enough (pulse duration) to trigger a depolarization wave in the myocardium. The stimulation threshold varies from patient to patient.

Measuring the stimulation threshold provides an effective method of assessing the safety margin between the measured threshold and the programmed pulse amplitude or pulse duration. An optimally programmed pulse amplitude and pulse duration results in safe pacing conditions and contributes to the prolongation of the service life of the pacemaker.

6.2.1 Pulse amplitude

Parameters
⇒ Therapies
⇒ Amplitude Atrial

Range: 0.5 - (0.25) - 4.0 - (0.5) - 8.0 V

Availability: DDD(R), DDI(R), DOO, AAI(R), AAT and AOO modes

Parameters
⇒ Therapies
⇒ Amplitude Ventricular

Range: 0.5 - (0.25) - 4.0 - (0.5) - 8.0 V

Availability: DDD(R), DDI(R), DOO, VDD(R), VVI(R), VVT and VOO modes

The pulse amplitude is the intensity or strength of a pacing pulse. Vitatron recommends programming a safety margin of twice the pulse amplitude threshold (see Section 6.2.3).

6.2.2 Pulse duration

Parameters
⇒ Therapies
⇒ Pulse Duration Atrial

Range: 0.1 - (0.05) - 1.0 ms

Availability: DDD(R), DDI(R), DOO, AAI(R), AAT and AOO modes

Parameters
⇒ Therapies
⇒ Pulse Duration Ventricular

Range: 0.1 - (0.05) - 1.0 ms

Availability: DDD(R), DDI(R), DOO, VDD(R), VVI(R), VVT and VOO modes

Pulse duration is the duration (width) of a pacing pulse. Vitatron recommends programming a safety margin of three times the pulse duration threshold (see Section 6.2.3).

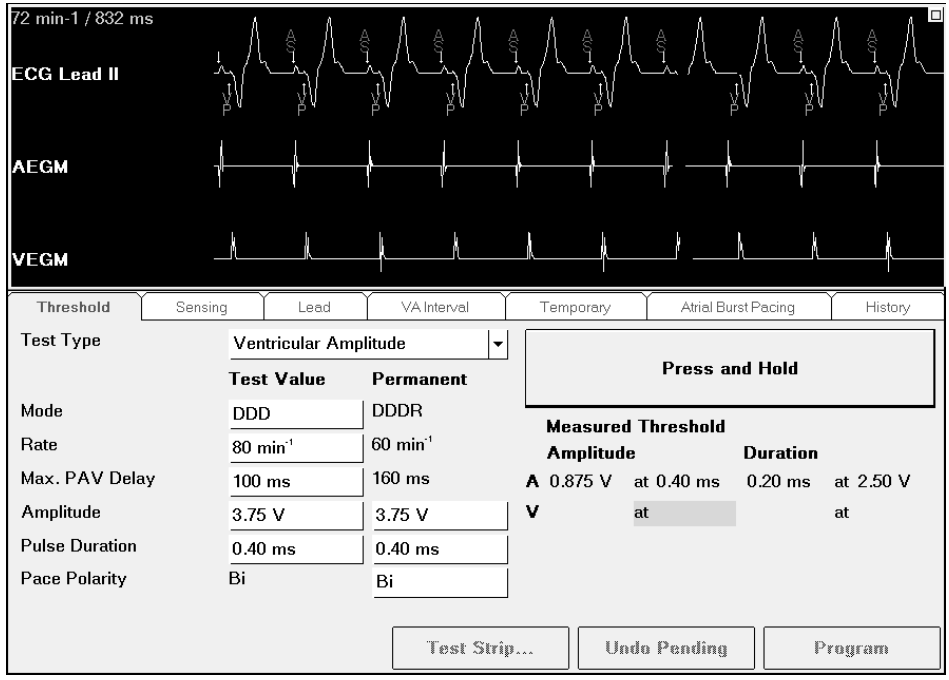
6.2.3 Pulse amplitude and pulse duration threshold tests

Tests
⇒ Threshold

Availability: All modes, except OOO

Measurement of stimulation thresholds makes it possible to determine the minimum pulse amplitude and duration at which effective capture is obtained. The measurement can be performed in both the atrium and the ventricle, depending on the programmed mode.

Figure 33. Threshold window with ECG



Setting up the threshold test – To prepare for the test take the following steps:

1. Position the programming head on the pacemaker.
2. Use the “Test Type” drop-down list to select the appropriate threshold test (Atrial/Ventricular Amplitude or Atrial/Ventricular Pulse Duration).
3. Adjust the test values of pulse amplitude and pulse duration in the “Test Value” column. The selected test value is used as the start value for the threshold test.
4. Adjust the mode and rate in the “Test Value” column. The test modes available depend on the permanently programmed mode. The test rate can be temporarily programmed between 80 min^{-1} and 120 min^{-1} . The higher rates are useful in patients with high spontaneous rates, while the lower rates may be more comfortable for patients with, for example, angina pectoris.

5. Adjust the maximum paced or sensed AV delay in the “Test Value” column. The standard setting is 200 ms if the test chamber is the atrium and 100 ms if the test chamber is the ventricle.
6. If required, reprogram the permanent pacing polarity prior to starting or repeating the measurement.

Performing the threshold test – The following steps describe the general procedure:

1. Press the touch pen on [Press and Hold] and keep it pressed there to perform the measurement. The pacemaker paces at a decreasing pulse amplitude or pulse duration until the step-down cycle ends automatically (below 0.25 V or 0.1 ms) or is stopped manually.
2. Watch the EGM or the ECG carefully. The marker annotations (on the programmer screen) are useful to identify the atrial or ventricular paced events. As soon as the EGM or ECG shows loss of capture, release [Press and Hold] or remove the programming head to stop the measurement.
3. If the measurement is stopped manually, the threshold value is one step-down value higher than the last active test value. The threshold value is displayed on the right-hand side of the screen.
4. If the measurement is not stopped manually and the programmer has reached the end of the step-down cycle, the message “Test ended automatically” is displayed. The threshold value is 0.1 ms (pulse duration) or 0.25 V (pulse amplitude).
5. Measured threshold values can be corrected manually by pressing on the displayed threshold value with the touch pen. You can then select a higher value from the displayed list. Be aware that if you manually correct the measured threshold value it is also automatically updated in the pacemaker, so this can only be done if the patient is still present.
6. If more than six senses occur during 10 consecutive cycles, the measurement is stopped automatically and a message is displayed. Press [Close] to return to the Threshold Test window. Increase the test rate or shorten the AV delay in the “Test Value” column to decrease the number of senses.
7. Press [Print] to print the threshold test report.
8. Press [Test Strip…] to view the ECG strip collected during the last successful threshold test of the specified type and in the specified chamber.

Notes:

- The observation of atrial capture can be improved by optimizing the quality of the ECG (see Section 4.11.3).
- If the “Permanent” column contains boxed parameters, measuring pacing thresholds is not possible. Press [Program] or [Undo Pending] first, then start the measurement.
- During the test, the programming head must be continuously applied to the pacemaker. The measurement is stopped if the programming head is removed.
- If the measurement is stopped or completed, the pacemaker returns to its permanently programmed settings.
- Measured pulse amplitude and pulse duration thresholds are stored in the programmer memory. They can be printed later by selecting the “Threshold Test” report in the Reports window.

Reprogramming pulse amplitude and pulse duration – In the “Permanent” column of the Threshold window, the pacemaker can be programmed to a new (atrial or ventricular) pulse amplitude or duration based on the outcome of the threshold test. The displayed test result is the minimum pulse amplitude or pulse duration that can be programmed. As a generally accepted standard Vitatron recommends programming a safety margin of three times the pulse duration threshold or twice the pulse amplitude threshold.

6.2.4 Pacing polarity

Parameters
⇒ Therapies
⇒ Sense/Pace Polarity Atrial

Range: Uni, Bi

Availability: DDD(R), DDI(R), DOO, AAI(R), AAT and AOO modes

Parameters
⇒ Therapies
⇒ Sense/Pace Polarity Ventricular

Range: Uni, Bi

Availability: DDD(R), DDI(R), DOO, VDD(R), VVI(R), VVT and VOO modes

If the atrial or ventricular pace polarity is programmed from unipolar to bipolar, the programmer initiates an automatic polarity check to confirm that a bipolar lead is connected. If the bipolar lead impedance exceeds 2000 Ω or is less than 200 Ω, the programmer screen displays a warning that no bipolar lead is detected. Press [OK] to confirm or [Cancel] to cancel the programming step. If the programming step is confirmed, press [Program] to program the pending polarity setting.

Vitatron recommends programming the pacing polarity to bipolar if bipolar leads are implanted and muscle or nerve stimulation is observed during unipolar pacing.

Warning: Pacemakers co-implanted with an ICD device must be set to bipolar pacing.

6.3 Optimizing sensing

The objective is to reliably sense all relevant cardiac signals (P-waves and R-waves) while rejecting those that originate outside the chamber in which the lead is positioned, such as myopotentials or far-field R-waves. Programming the appropriate sensitivity or sensing polarity increases the reliability of sensing.

6.3.1 Sensitivity

Parameters
⇒ Therapies
⇒ Sensitivity Atrial

Range: 0.25 (Bi), 0.3 (Bi), 0.4 (Bi), 0.5 - (0.1) - 1.0 - (0.5) - 7.5 mV

Availability: DDD(R), DDI(R), VDD(R), AAI(R) and AAT modes

Parameters
⇒ Therapies
⇒ Sensitivity Ventricular

Range: 1.0 - (0.5) - 10.0 mV

Availability: DDD(R), DDI(R), VDD(R), VVI(R) and VVT modes

Sensitivity is the programmable threshold of the pacemaker to sense a signal registered in the atrial or ventricular channel. Programming the sensitivity to a higher setting decreases the number of sensed P- and R-waves with lower amplitudes.

Vitatron recommends using a sensing safety margin of at least 100%. This means, for example, programming the atrial sensitivity to a setting less than 0.5 mV if the measured P-wave amplitude is 1.0 mV (see Section 6.3.3) or programming the ventricular sensitivity to a setting less than 3.0 mV if the measured R-wave amplitude is 6.0 mV (see Section 6.3.4).

6.3.2 Sensing polarity

Parameters
- ⇒ Therapies
  - ⇒ Sense/Pace Polarity Atrial

Range: Uni, Bi

Availability: DDD(R), DDI(R), VDD(R), AAI(R) and AAT modes

Parameters
- ⇒ Therapies
  - ⇒ Sense/Pace Polarity Ventricular

Range: Uni, Bi

Availability: DDD(R), DDI(R), VDD(R), VVI(R) and VVT modes

If the atrial or ventricular sense polarity is programmed from unipolar to bipolar, the programmer initiates an automatic polarity check to confirm that a bipolar lead is connected. If the bipolar lead impedance exceeds 2000 Ω or is less than 200 Ω, the programmer screen displays a warning that no bipolar lead is detected. Press [OK] to confirm or [Cancel] to cancel the programming step. If the programming step is confirmed, press [Program] to program the pending polarity setting.

Vitatron recommends programming sensing polarity to bipolar if bipolar leads are implanted and oversensing is observed during unipolar sensing.

6.3.3 P-wave sensing

Tests
- ⇒ Sensing
  - ⇒ P-Wave Amplitude

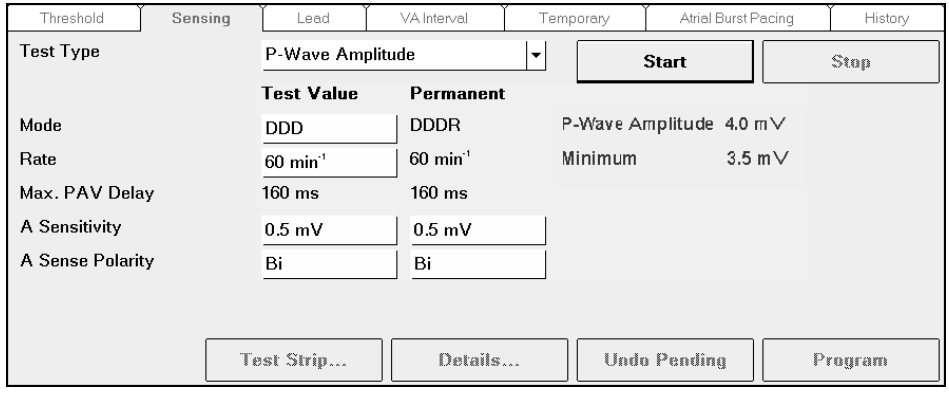
Availability: All modes (except single chamber (V) pacemaker)

The P-wave histogram and the P-wave amplitude measurement provide help when assessing the P-wave sensing safety margin and when programming atrial sensitivity.

First examine the P-wave histogram and look for signs of atrial undersensing, as described in Section 7.9.1. If atrial undersensing is suspected, measure the P-wave amplitude.

The P-wave amplitude can be measured even if the permanently programmed pacing mode does not support atrial sensing.

Figure 34. Sensing window: P-wave Amplitude



Setting up the P-wave amplitude test – To prepare for the test take the following steps:

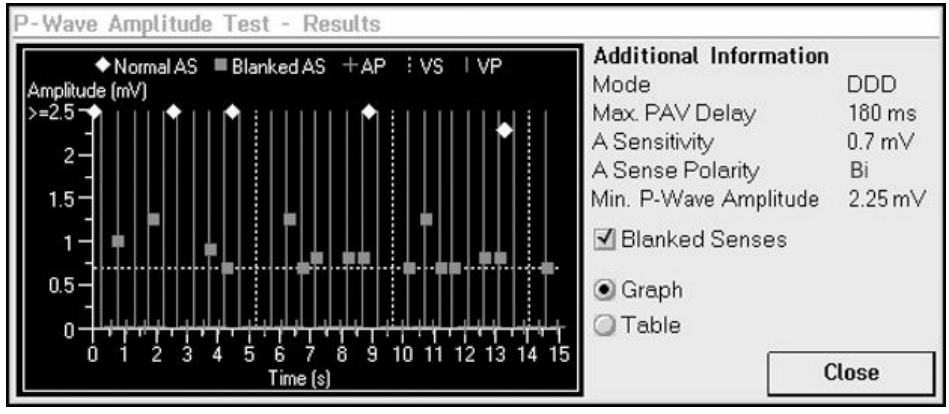
1. Position the programming head on the pacemaker.
2. Use the “Test Type” drop-down list to select the P-wave amplitude test.
3. Adjust the test value of atrial sensitivity in the “Test Value” column.
4. Adjust the mode or atrial sense polarity in the “Test Value” column. The test modes available depend on the permanently programmed mode.
5. Select a test rate between 30 min^{-1} and 120 min^{-1} in the “Test Value” column.

Performing the P-wave amplitude test – The following steps describe the general procedure:

1. Press [Start] to start the measurement. The programmer monitors atrial events and displays the measured amplitude. When the user stops the measurement the programmer processes the results collected during the last 15 seconds of the measurement. The test rate is the only parameter that can be changed during the test.
2. Watch the EGM or the ECG carefully. The marker annotations (on the programmer screen) are used to identify sensed atrial events. If no spontaneous atrial events are sensed, try to decrease the test rate or stop the test and increase the atrial sensitivity.

3. Press [Stop] or remove the programming head to stop the measurement.
4. Press [Test Strip…] to view the ECG recorded during the last measurement.
5. If the measurement was successful, the last measured P-wave amplitude and the minimum P-wave amplitude are displayed on the right-hand side of the Sensing window.
6. Press [Details…] to view the detailed results of the test. They are presented either in a graph (see Figure 35) or in a table. Select the preferred representation by pressing the “Graph” or “Table” radio button. Press the “Blanked Senses” check box to mark the atrial senses that would normally be blanked (see Section 9.7 for advice on adjusting the atrial blanking periods).
7. Press [Print] to print the sensing test report.
8. Press [Close] to leave the Results window.

Figure 35. P-wave Amplitude Test - Results (graph)



Notes:

- If the “Permanent” column contains boxed parameters, measuring the P-wave amplitude is not possible. Press [Program] or [Undo Pending] first, then start the measurement.
- During the test the programming head must be continuously applied to the pacemaker. The measurement is interrupted if the programming head is removed.
- If the measurement is stopped or interrupted, the pacemaker returns to its permanently programmed settings.
- During the P-wave amplitude measurement the magnet mode, Flywheel and rate response are temporarily disabled.

Reprogramming atrial sensitivity – In the “Permanent” column, you can reprogram the atrial sensitivity based on the outcome of the test. Before reprogramming the atrial sensitivity, check the outcome of the test against the P-wave amplitude distribution in the P-wave histogram (see Section 7.9.1).

Vitatron recommends using a sensing safety margin of at least 100%, which means programming the atrial sensitivity to a setting less than 50% of the measured P-wave amplitude. This means, for example, programming the atrial sensitivity to a setting less than 0.5 mV if the measured P-wave amplitude is 1.0 mV.

If a high atrial sensitivity is required, the sensing polarity should be programmed to bipolar. Unipolar sensing in combination with high atrial sensitivities may result in myopotential or FFRW sensing and cause inappropriate mode switching. Myopotential sensing can be investigated while exercising the pectoral muscles. Check the marker channel for sensed atrial events not due to sensed P-waves. The latter could apply to far-field R-wave senses as well. FFRW sensing can be avoided by programming an appropriate atrial blanking or by reducing the atrial sensitivity. However, reducing the atrial sensitivity requires the amplitudes of the far-field R-waves to be much smaller than those of true atrial signals to avoid atrial undersensing. The P-wave histogram reveals the amplitude distribution of sensed and blanked atrial events. FFRW sensing can be confirmed by the VA interval histogram, VA interval measurement or temporary test.

In case of spontaneous AV conduction, check for reliable atrial sensing by reducing the lower rate and programming a short AV delay.

6.3.4 R-wave sensing

Tests

⇒ Sensing

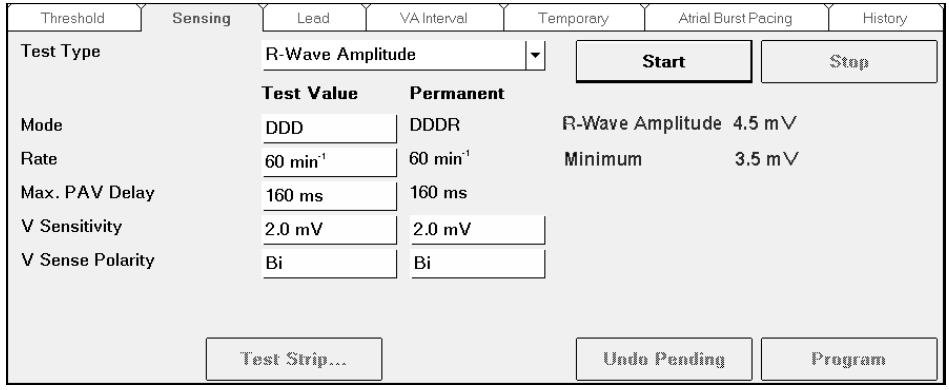
⇒ R-wave Amplitude

Availability: All modes (except single chamber (A) pacemaker)

This measurement provides help when assessing the R-wave sensing safety margin and when programming ventricular sensitivity.

The R-wave amplitude can be measured even if the permanently programmed pacing mode does not support ventricular sensing.

Figure 36. Sensing window: R-wave Amplitude



Setting up the R-wave amplitude test – To prepare for the test take the following steps:

1. Position the programming head on the pacemaker.
2. Use the “Test Type” drop-down list to select the R-wave amplitude test.
3. Adjust the test value of ventricular sensitivity in the “Test Value” column.
4. Adjust the mode and ventricular sense polarity in the “Test Value” column. The test modes available depend on the permanently programmed mode. Temporarily programming the pacemaker to the VVI mode may be useful for patients with a high degree AV block.
5. In the “Test Value” column, adjust both the (lower) rate and the maximum paced AV delay to an appropriate value to prevent ventricular pacing. The test rate is programmable from 30 min^{-1} to 120 min^{-1}.

Performing the R-wave amplitude test – The following steps describe the general procedure:

1. Press [Start] to start the measurement. The programmer monitors ventricular events until the user stops the measurement. The programmer then processes the results of the 10 last measured R-wave amplitudes. The test rate and the maximum paced AV delay are the only parameters that can be changed during the test.
2. Watch the EGM or the ECG carefully. The marker annotations (on the programmer screen) are used to identify sensed ventricular events. If no ventricular events are sensed, try to lengthen the maximum paced AV delay or to decrease the test rate. Alternatively, stop the test and increase the ventricular sensitivity.
3. Press [Stop] or remove the programming head to stop the measurement.
4. If no ventricular events are sensed during the measurement, the programmer screen displays a message.
5. If the measurement was successful, the last measured R-wave amplitude and the minimum R-wave amplitude are displayed on the right-hand side of the Sensing window.
6. Press [Test Strip…] to view the ECG recorded during the last measurement.
7. Press [Print] to print the sensing test report.

Notes:

- If the “Permanent” column contains boxed parameters, measuring the R-wave amplitude is not possible. Press [Program] or [Undo Pending] first, then start the measurement.
- During the test the programming head must be continuously applied to the pacemaker. The measurement is interrupted if the programming head is removed.
- If the measurement is stopped or interrupted, the pacemaker returns to its permanently programmed settings.
- During the R-wave amplitude measurement the magnet mode, Flywheel and rate response are temporarily disabled.

Reprogramming ventricular sensitivity – In the “Permanent” column, you can reprogram the ventricular sensitivity based on the outcome of the test. Vitatron recommends using a sensing safety margin of at least 100%, which means programming the ventricular sensitivity to a setting less than 50% of the measured R-wave amplitude. This means, for example, programming the ventricular sensitivity to a setting less than 3.0 mV if the measured R-wave amplitude is 6.0 mV.

Diagnostic information in the Rhythm Overview window can be helpful when assessing ventricular sensing. Ventricular undersensing could be suspected if the percentage ventricle paced counter is higher than expected.

Ventricular oversensing should be suspected if the VSPs counter is high (crosstalk) or if the PVCs counter is higher than expected (myopotential sensing). Programming the ventricular sensing polarity to bipolar or selecting a less sensitive ventricular sensitivity setting (which means programming a higher ventricular sensitivity value) is then recommended. Use the ECG to check that the PVCs counter is not increased by atrial undersensing (see Section 7.9.1).

6.4 Lead measurement

Tests

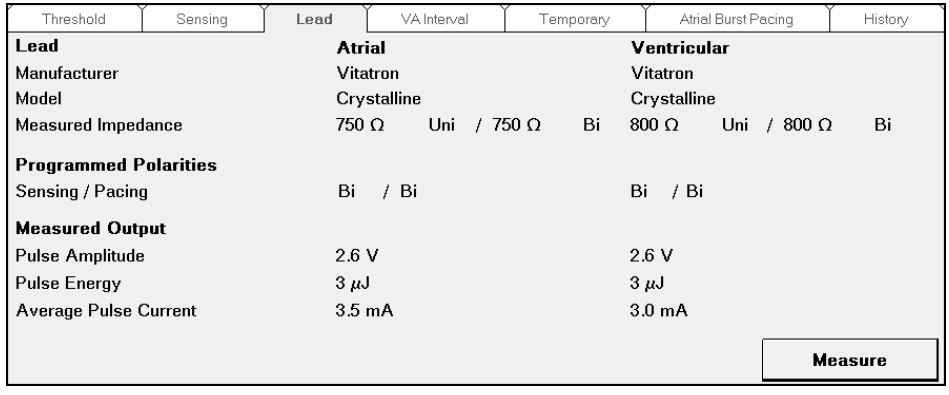
⇒ Lead

Availability: All modes, except OOO

The lead measurement is used to measure the exact output voltage, mean output current, pulse energy and lead impedance for the atrial or ventricular lead, as shown in Figure 37. In a single chamber mode, only the active chamber is displayed.

The lead measurement is performed automatically every 10 minutes and the most recent information is read out during initial interrogation of the pacemaker. The results are stored for later review or printing. If required, the lead measurement can be repeated in the Lead window.

Figure 37. Lead window (dual chamber pacemaker)



Performing the lead measurement – The following steps describe the general procedure:

1. Position the programming head on the pacemaker.
2. Press [Measure] to start the measurement. The measurement ends automatically.
3. If the measurement was successful, the programmer displays the measured lead impedance, pulse amplitude, pulse energy and average pulse current for the atrial or ventricular lead. Press [Print] to print the battery status/lead measurement report.
4. If the measurement was not successful, the programmer displays a message indicating why the lead measurement failed.

Notes:

- During the test the programming head must be continuously applied to the pacemaker. The measurement is ended if the programming head is removed.
- If the pacing or sensing polarity is bipolar, both the unipolar and bipolar lead impedance are measured.
- Lead impedance measurement results may be disturbed by electrocardiogram monitoring equipment.

6.5 VA interval measurement

Tests
⇒ VA Interval

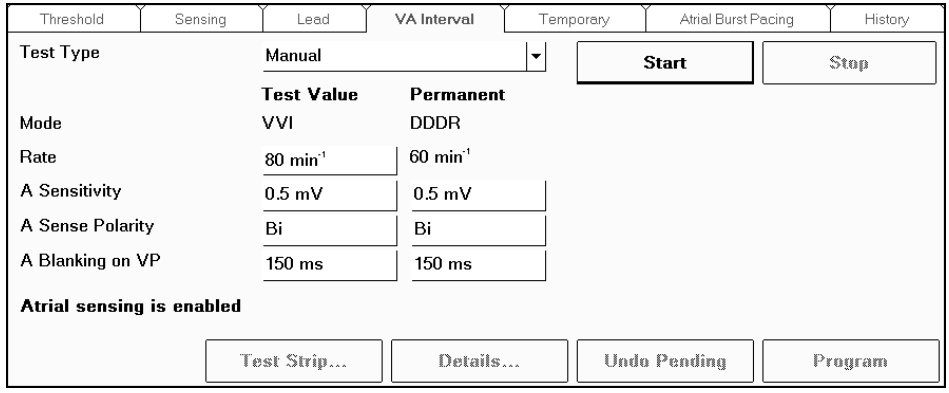
Availability: DDD(R), DDI(R), VDD(R) modes

Dual chamber pacemakers feature a VA interval measurement, manual and automatic, which is helpful in diagnosing retrograde conduction and FFRW sensing. During this test the interval between the paced ventricular event and the sensed atrial event is measured at one (manual test) or three (automatic test) ventricular pacing rates. The manual test should be repeated at different rates to avoid a false positive diagnosis of retrograde conduction if the sinus rhythm is the same as the ventricular pacing rate.

Warning: During the VA interval measurement the mode is changed to a ventricular pacing mode. Consequently, there is no response to atrial arrhythmias.

6.5.1 Manual VA interval measurement

Figure 38. VA Interval window (manual test)



Setting up the manual VA interval measurement – To prepare for the measurement take the following steps:

1. Position the programming head on the pacemaker.
2. Use the “Test Type” drop-down list to select the manual test.
3. Select the test rate in the “Test Value” column. The test rate can be any value from 40 min^{-1} to 130 min^{-1}.
4. Adjust the atrial sensitivity, atrial sense polarity and atrial blanking in the “Test Value” column.

Performing the manual VA interval measurement – The following steps describe the general procedure:

1. Press [Start] to start the measurement. The programmer measures the VA interval until the measurement is stopped.
2. Watch the EGM or ECG carefully on the programmer display. The marker annotations are useful to identify the atrial and ventricular events. The measured VA intervals are shown as marker intervals in the ECG window. If the pacemaker is inhibited by spontaneous ventricular activity, stop the measurement and increase the test rate. The test rate can be changed during the measurement if the VA interval has already been measured at the new rate.
3. Press [Stop] or remove the programming head to stop the measurement.
4. Press [Test Strip…] to view the ECG recorded during the last measurement.

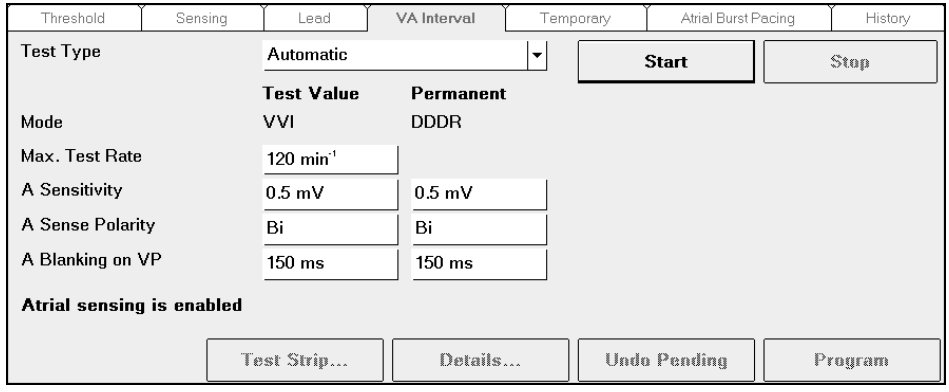
5. Press [Details…] to view the results of the measurement. They are presented either in a graph (see Figure 40) or in a table. Select the preferred representation by pressing the “Graph” or “Table” radio button. For the manual test, the last six measurement rates are displayed.
6. Press [Print] to print the VA interval measurement report.
7. Press [Close] to leave the Results window.

Notes:

- If the “Permanent” column contains boxed parameters, measuring the VA intervals is not possible. Press [Program] or [Undo Pending] first, then start the measurement.
- During the test the programming head must be continuously applied to the pacemaker. The measurement is interrupted if the programming head is removed.
- When the measurement is stopped or interrupted, the pacemaker returns to its permanently programmed settings.
- The VA interval is measured in the VVI mode. During the measurement Flywheel and rate response are temporarily disabled.
- Measured VA intervals are stored in the programmer memory. They can be printed later by selecting the “VA Interval Measurement” report in the Reports window.

6.5.2 Automatic VA interval measurement

Figure 39. VA Interval window (automatic test)



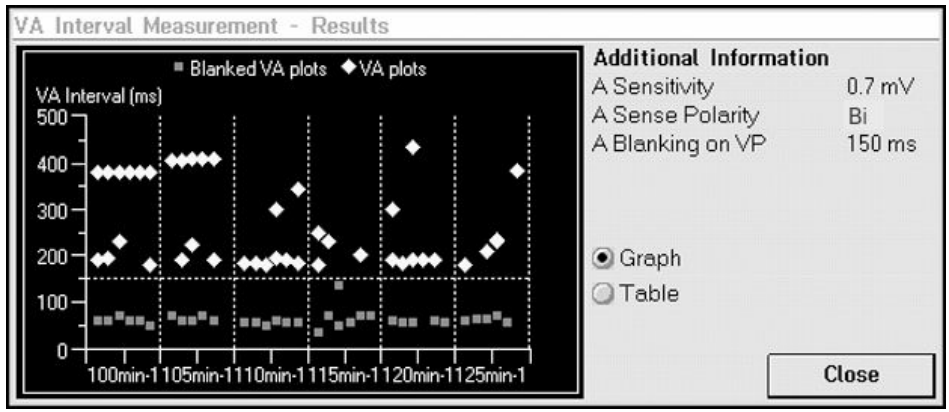
Setting up the automatic VA interval measurement – To prepare for the measurement take the following steps:

1. Position the programming head on the pacemaker.
2. Use the “Test Type” drop-down list to select the automatic test.
3. Select the maximum test rate in the “Test Value” column. The maximum test rate can be any value from 40 min^{-1} above the programmed lower rate up to 130 min^{-1}.
4. Adjust the atrial sensitivity, atrial sense polarity and atrial blanking in the “Test Value” column.

Performing the automatic VA interval measurement – The following steps describe the general procedure:

1. Press [Start] to start the measurement. The programmer automatically starts to measure the VA interval at a rate 20 min^{-1} above the programmed lower rate. The start rate is increased by 10 min^{-1} if there are more than three sensed ventricular events in the first ten pacing cycles. The check for sensed ventricular events and the increase of the start rate is repeated until fewer than four sensed ventricular events occur in the first ten pacing cycles. The current rate is then used as the start rate. If the start rate exceeds the selected maximum test rate, the test is stopped and a warning is displayed on the programmer screen.
2. The pacemaker automatically repeats the test at a rate 10 min^{-1} above the start rate and at a rate 20 min^{-1} above the start rate.
3. If the test rate of the third measurement exceeds the selected maximum test rate, the measurement is stopped and a message is displayed on the programmer screen.
4. The measurement ends automatically after the third measurement. The pacemaker returns to its permanently programmed settings.
5. Press [Test Strip…] to view the ECG recorded during the last measurement.
6. Press [Details…] to view the results of the measurement. They are presented either in a graph (see Figure 40) or in a table. Select the preferred representation by pressing the “Graph” or “Table” radio button.
7. Press [Print] to print the VA interval measurement report.
8. Press [Close] to leave the Results window.

Figure 40. VA Interval Measurement - Results (graph)



Notes:

- If the “Permanent” column contains boxed parameters, measuring the VA intervals is not possible. Press [Program] or [Undo Pending] first, then start the measurement.
- During the test the programming head must be continuously applied to the pacemaker. The measurement is interrupted if the programming head is removed.
- When the measurement is completed or interrupted, the pacemaker returns to its permanently programmed settings.
- The VA interval is measured in the VVI mode. During the measurement Flywheel and rate response are temporarily disabled.
- Measured VA intervals are stored in the programmer memory. They can be printed later by selecting the “VA Interval Measurement” report in the Reports window.

6.5.3 Programming advice to prevent FFRW sensing and retrograde conduction

Programming advice to prevent FFRW sensing – When the measured VA interval is shorter than 200 ms FFRW sensing should be suspected. Check the EGM or ECG for retrograde conduction between 150 and 200 ms. Try to eliminate FFRW sensing by changing the sensing polarity to bipolar, changing the atrial sensitivity to a less sensitive (higher) setting or lengthening the atrial blanking period.

Programming advice to prevent retrograde conduction – If the VA interval is stable between 150 and 450 ms, at different ventricular pacing rates, retrograde conduction should be suspected. To prevent retrograde conduction and avoid inducing pacemaker mediated

tachycardias (PMTs), Vitatron recommends programming mode switching to “Auto”, PVC synchronous atrial stimulation to “On” or programming a short atrial synchronization pace (ASP) interval.

Note: Although the VA interval measurement may reveal retrograde conduction in the test mode (VVI), a permanently programmed AV synchronous mode might prevent the occurrence of retrograde conduction (see Section 11.6).

6.6 Temporary test

Tests

⇒ Temporary

Availability: All modes

Temporary test offers the possibility to temporarily reprogram a number of basic pacing parameters for diagnostic purposes or for testing the effects of reprogramming on pacing. The permanently programmed settings are restored automatically when the temporary test ends or when the programming head is removed.

Figure 41. Temporary window (dual chamber pacemaker)

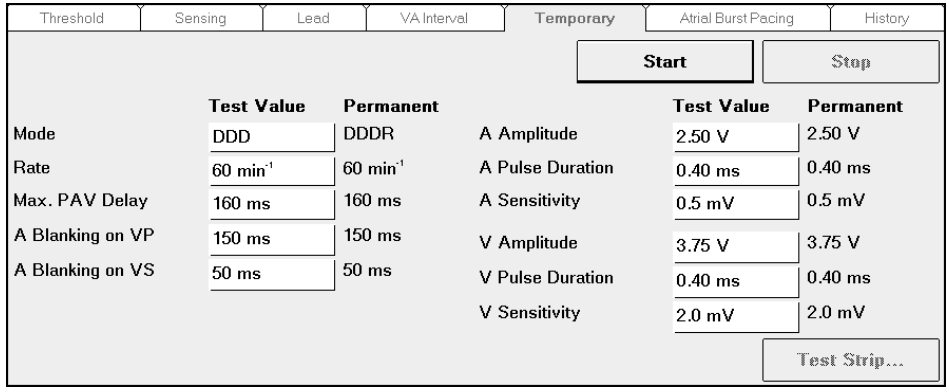
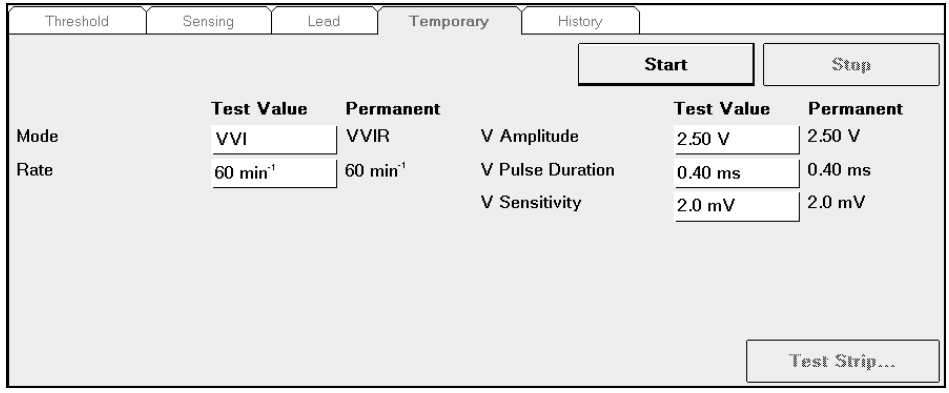


Figure 42. Temporary window (single chamber pacemaker)



Setting up the temporary test – To prepare for the test take the following steps:

1. Position the programming head on the pacemaker.
2. Adjust the test values for mode, rate, maximum paced AV delay, atrial blanking (on VP and VS), amplitude (atrial and ventricular), pulse duration (atrial and ventricular) and sensitivity (atrial and ventricular) in the Temporary Test window.
3. Select the appropriate test mode using the following guidelines:
   - Use the OOO mode to check the patient's intrinsic rhythm.
   - Use the AAI mode to check AV conduction at various rates.
   - Use the VVI mode to test for pacemaker syndrome (retrograde conduction).
   - Use the triggered modes (AAT and VVT) to check sensing characteristics.
4. Increase or decrease the test rate to respectively suppress or search for intrinsic rhythm
5. Adjust pulse amplitude or pulse duration to investigate crosstalk at high output settings (in combination with a low sensitivity setting in the other channel).
6. Adjust the temporary sensitivity values to check for myopotentials (in combination, for example, with a triggered mode) or for crosstalk (in combination with high output settings in the other channel).
7. In dual chamber pacemakers, temporarily change the atrial blanking period to check for the occurrence of far-field R-waves (in combination with low atrial sensitivity settings).

8. In dual chamber pacemakers, temporarily change the maximum paced or sensed AV delay to search for intrinsic AV conduction, to optimize AV delay or to prevent fusion.

Performing the temporary test – The following steps describe the general procedure:

1. Press [Start] to start the test.
2. Watch the ECG carefully on the programmer display. During the test all parameters, except mode, can be changed.
3. Press [Stop] or remove the programming head to stop the test. The pacemaker returns to its permanently programmed settings.
4. Press [Test Strip…] to view the ECG recorded during the last temporary test.

Note: During the test the programming head must be continuously applied to the pacemaker. The measurement is interrupted if the programming head is removed.

6.7 Atrial burst pacing

Tests
⇒ Atrial Burst Pacing
⇒ A Burst Rate

Range: 100 - (10) - 320 - (15) - 425 min^{-1}

Availability: All modes, except OOO

Tests
⇒ Atrial Burst Pacing
⇒ VOO Backup

Range: On, Off

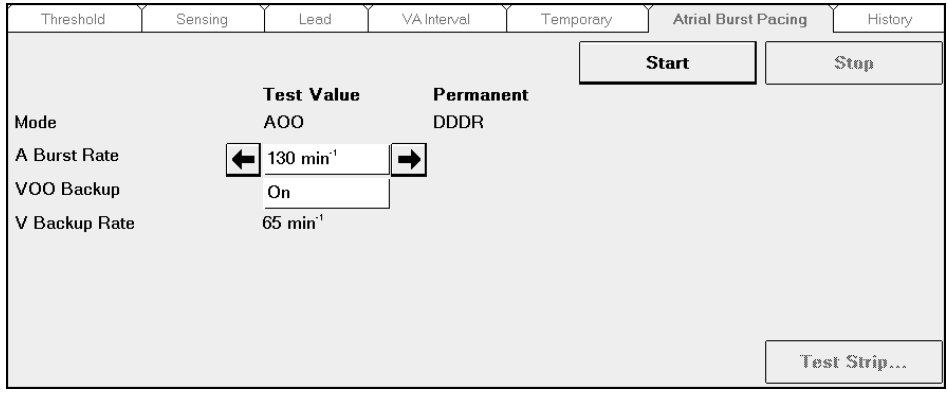
Availability: All modes, except OOO

Atrial burst pacing can be used in an attempt to end an atrial tachyarrhythmia (for example atrial flutter). By programming the atrial burst rate above the spontaneous atrial rate, it may be possible to end the atrial tachyarrhythmia.

During this procedure VOO backup pacing can be enabled. VOO backup pacing is useful for patients with a high degree AV block, because their intrinsic ventricular rate might be too low. When VOO backup pacing is programmed on, the ventricle is paced at the ventricular backup rate. The ventricular backup rate is not programmable; it depends on the selected atrial burst rate and varies between 60 min^{-1} and 110 min^{-1}.

Atrial burst pacing can also be used to determine the Wenckebach point of the heart in patients with intact AV conduction. The Wenckebach point is determined by increasing the atrial burst rate and observing the spontaneous AV conduction to the ventricles.

Figure 43. Atrial Burst Pacing window



Setting up the atrial burst pacing test – To prepare for the test take the following steps:

1. Position the programming head on the pacemaker.
2. Program the atrial burst rate by pressing on the parameter value box or by pressing the increase or decrease buttons. The atrial burst rate displayed is either the last programmed value or the delivery setting. (The delivery setting is displayed at the first test or after a partial restore.)
3. If required, program VOO backup pacing to “On”. When VOO backup pacing is programmed on, the ventricular backup rate is displayed.

Performing the atrial burst pacing test – The following steps describe the general procedure:

1. Press [Start] to start the test.
2. Watch the EGM or the ECG carefully. The marker annotations (on the programmer screen) are useful to identify the atrial or ventricular events. During the test the atrial burst rate can be changed, provided VOO backup pacing is off. VOO backup pacing cannot be programmed on once the test is started.
3. Press [Stop] or remove the programming head to stop the test.
4. Press [Test Strip…] to view the ECG recorded during the last test.

Notes:

- During the test the programming head must be continuously applied to the pacemaker. The test is interrupted if the programming head is removed.
- When the test is completed or interrupted, the pacemaker returns to its permanently programmed settings. The last programmed atrial burst rate is stored in the pacemaker and is used as the starting rate if atrial burst pacing is selected again.
- During atrial burst pacing the atrial pulse amplitude, the atrial pulse duration and the atrial pace polarity are the permanently programmed values.
- Atrial burst pacing is not possible if the atrial or ventricular pulse amplitudes are programmed above 3.75 V or if the battery status is “Ageing” or “Replace PM”.

6.8 Tests history

Tests
⇒ History

Tests history shows the results of automatic lead impedance measurements, threshold tests and sensing from the current follow-up session and up to five previous collection periods.

On the cardiac dashboard, you can press a hyperlink to see a graphical presentation of the history of that measurement over the previous follow-up periods (see Section 4.3).

Threshold – Threshold measurements that are obtained during the follow-up session are stored in history. Changes in threshold measurement over time may indicate an unstable lead position, ischemia, or the effects of (changes in) drug therapy.

Lead impedance – The lead impedance is the last value measured at initial interrogation. Results of manually initiated lead impedance measurements are not stored in History.

P-wave amplitude – The P-wave amplitude is an average value derived from the P-wave amplitude histogram at initial interrogation. P-wave amplitude measurements that are obtained during the follow-up session are not stored in history.

R-wave amplitude – R-wave amplitude measurements that are obtained during the follow-up session are stored in history.

Note: Pressing [Clear History] clears all the diagnostics, parameters and tests history data in the pacemaker. Only the data from the current follow-up session remains in the pacemaker.

7 Diagnostics

7.1 Introduction

The diagnostic information available in the pacemaker helps the physician to monitor the patient and to check how the pacemaker is responding. Diagnostics can also reveal whether pacemaker parameters need adjusting in order to offer the patient optimum pacing therapy.

This chapter explains how the diagnostics help the user to recognize unexpected patterns or events. The Therapy Advisor (see Section 7.2) highlights information on important events and displays suggestions for programming the pacemaker. Rhythm Overview (see Section 7.4.1) gives an overview of atrial and ventricular rhythm. More detailed diagnostic information on the distribution of events in graphs, Holters and histograms can be used to evaluate the effectiveness of pacemaker or drug therapy.

The first part of the chapter provides general information about the following features:

- Therapy Advisor (see Section 7.2)
- data collection and storage (see Section 7.3)
- how to display the data (see Section 7.4)

The second part of the chapter guides you through the diagnostic options available for assessing the following events:

- atrial rhythm and AF (see Section 7.5)
- ventricular rhythm (see Section 7.6)
- AV synchrony (see Section 7.7)
- rate response (see Section 7.8)
- the pacemaker's sensing, including P-wave sensing, FFRW sensing and retrograde conduction (see Section 7.9)

Refer to Chapter 8 for a description of Selected Episodes.

7.2 Therapy Advisor

The Therapy Advisor analyzes technical, diagnostic and programming data taken from the pacemaker memory (battery status, histograms, Holters, counters and programmed parameters) and alerts you to important events or areas of concern. It also gives suggestions for programming the pacemaker to offer optimal therapy and offers advice for managing AF.

Therapy advice is available in DDD(R), VDD(R), VVI(R) and AAI(R) modes, when data has been collected for at least one week.

Therapy Advisor messages appear on the cardiac dashboard immediately after initial interrogation of the pacemaker. The information is based on the contents of pacemaker memory at initial pacemaker interrogation, and is not updated during the follow-up session. The Therapy Advisor can be switched on or off in the Programmer Preferences window (see Section 4.10.4).

Press one of the Therapy Advisor messages to see more diagnostic information and programming advice for optimizing therapy in the dynamic window. Consider whether these suggestions provide the optimal therapy for the patient or whether specific circumstances apply which justify a different therapy or setting.

A message stating that there is nothing significant to report means that the pacemaker has not detected anything unusual in the pacemaker diagnostics.

The Therapy Advisor first checks lead and sensing conditions. If it detects a problem with lead impedance, P-wave sensing or FFRW sensing, no therapy advice is given. Therapy advice is not available if the pacemaker has been reset and full restore was not possible, after emergency programming or when the pacemaker is indicated for replacement.

Notes:

- The Therapy Advisor has no knowledge of either the initial indication for pacing or the patient's medical condition. These are therefore not taken into account when formulating advice.
- In Therapy Advisor messages, the term "AF Burden" refers to episodes of high atrial rates recorded by Selected Episodes. The burden shows the combined duration of all the recorded episodes, as a percentage of the total collection period. The programmed episode trigger, onset and end duration determine when an episode is detected (see Section 8.3). These settings therefore influence the AF burden reported in the Therapy Advisor. If any parameters that affect sensing or selected episode detection are changed, the Therapy Advisor cannot provide information about an increase or decrease in AF burden.

Warning: "Therapy Advisor" should not replace the physician's expert judgement.

7.3 Data collection and storage periods

The pacemaker records each occurrence of specific cardiac events, such as atrial senses (AS), ventricular paces (VP), or premature ventricular contractions (PVCs). It also collects data on episodes of certain cardiac behavior, such as a period of atrial tachyarrhythmia.

The pacemaker collects most diagnostic data between follow-up sessions. These session-to-session diagnostics are intended for assessing the status of the patient since the last follow-up session. One hour after the end of a session, diagnostic data from the previous period, including Selected Episodes and Therapy Advisor information, is cleared from the pacemaker memory and data collection starts again. There is an option to keep diagnostic data from the previous follow-up period (see Section 7.3.1).

The pacemaker records the incidence of certain cardiac events and episodes in counters. The data collected in the main counters is presented in the Rhythm Overview window (see Section 7.4.1). Some counters display the incidence of events as a percentage of the collection period. Other counters show how often an event or episode occurred, for example the number of PVCs per day. This represents the average occurrence over a certain period. The chosen period (minute, hour, day, week, month or year) is the shortest unit of time during which at least one relevant event or episode occurred. The atrial and ventricular event counters are listed in Section 7.5.1 and Section 7.6.1.

Holters accumulate data in the pacemaker over a limited collection period. The 24-hour Holter (see Section 7.4.4) collects data continuously over a 24-hour period. When you call up this Holter during a follow-up session the programmer displays the data recorded in the last 24 hours. Data collection continues during the follow-up session. Data older than 24 hours is cleared automatically. The 30-minute Holter (see Section 7.4.5) is intended for testing during the follow-up session. You may start collection during a follow-up session, for example, to show the rate pattern during an exercise stress test.

Notes:

- Session-to-session and 24-hour diagnostic data is cleared from the pacemaker if the user reprograms a pacing therapy parameter, changes the Selected Episodes setup, or resets the pacemaker time. Diagnostic data collected before the change can still be displayed during the current follow-up session.
- Collection of diagnostic data stops after a partial restore, emergency programming, or when the battery status is “Replace PM”. Any data collected up to that time remains in the pacemaker’s memory and can still be displayed on the programmer.
- After a full restore (see Appendix A), all collected data is cleared and data collection restarts.

7.3.1 Keeping diagnostic data

The pacemaker normally deletes the session-to-session diagnostics one hour after the end of a follow-up session. If you want to save this data, you can check the box “Keep diagnostic data until next session” when you end the follow-up session (see Section 4.3.2). The pacemaker continues to add diagnostic data to the saved data until the start of the next follow-up session. Session-to-session diagnostics, including Selected Episodes and the Therapy Advisor, are based on all the saved data.

This option is not available if you have permanently reprogrammed a pacing therapy parameter, changed the Selected Episodes setup, or reset the pacemaker time during the current follow-up session.

7.4 Displaying diagnostic data

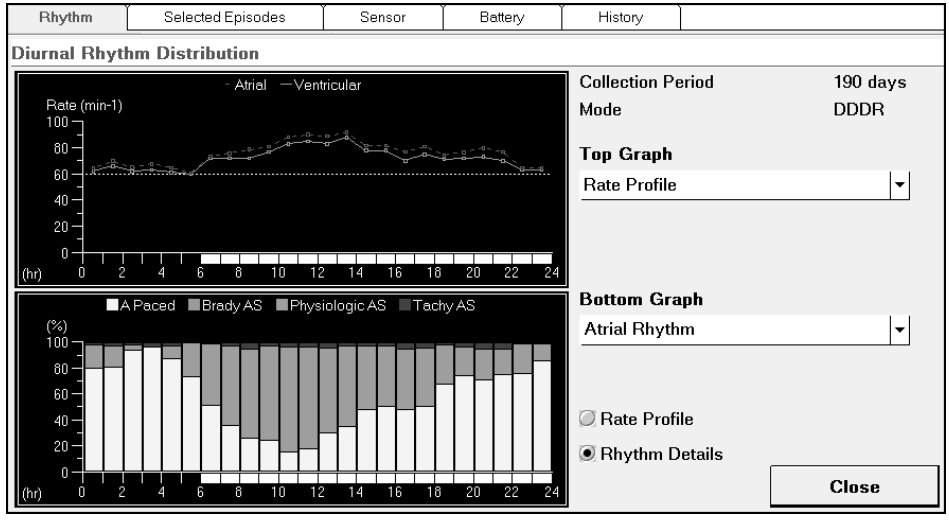
Therapy advice appears in the cardiac dashboard after initial pacemaker interrogation.

Press the “Diagnostics” icon and select the “Rhythm” tab to access more detailed diagnostics in the Rhythm Overview window (see Section 7.4.1).

Select the “Collection Settings” tab to review all the pacemaker settings that were in effect during the data collection period.

For an example of a more detailed diagnostic window see Figure 44.

Figure 44. Diagnostics graph window example



When viewing diagnostics graphs, press [Close] to close any diagnostic graph window and return to the Rhythm Overview window. Press [Print] for a printed copy of any diagnostic window.

In the diagnostic graph windows, there is additional information on the right side of the screen that lists the pacemaker mode and the settings of relevant pacemaker parameters during the data collection period.

In diagnostic graphs, the color green represents physiological rhythm. Yellow indicates pacing. Red and orange alert you to unexpected or pathological patterns and events.

In histogram windows, data can be presented in graphical format, or with the exact values in table format.

Two formats are available for presenting Diurnal Rhythm Distribution and Holter data: rate profile and rhythm details. Choose the desired type of graph by pressing the appropriate radio button.

Rate profile – A rate profile diagram shows the atrial and ventricular rates in each time period, averaged over the collection period. The atrial and ventricular rates will be identical during AV synchronous operation.

The information is presented in the form of a line diagram, with the rates given in beats per minute (min^{-1}). Horizontal lines represent the lower rates (day and night), maximum pacing rate and maximum tracking rate. The maximum tracking rate is only shown when it falls within the range of recorded rates. A white bar along the x-axis indicates the daytime hours programmed in the pacemaker.

Rhythm details – Rhythm details graphs present the contents of counters for each time interval, averaged over the collection period. A split window allows comparison of two graphs. A white bar along the x-axis indicates the daytime hours programmed in the pacemaker.

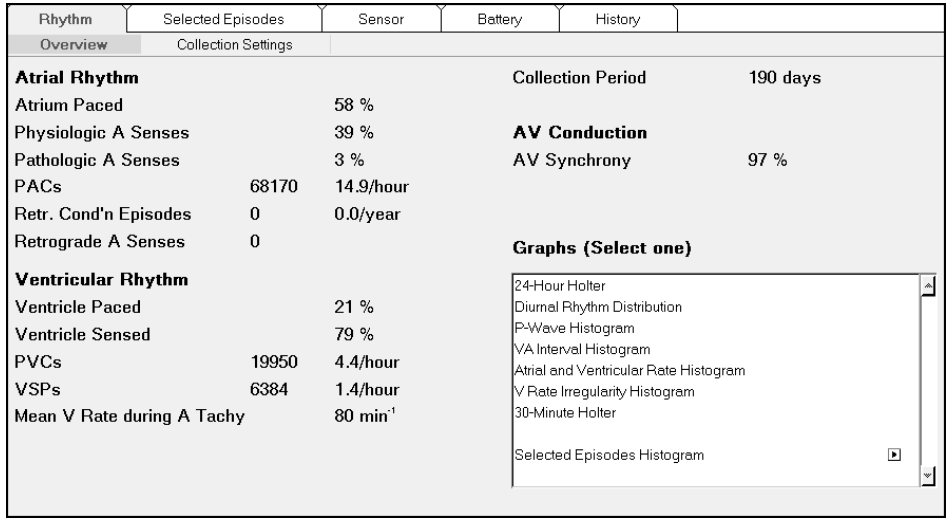
Use the drop-down lists to choose any two rhythm details graphs to display in the top and bottom graph. Comparison of the two graphs is helpful when analyzing the causes of cardiac events or pacemaker behavior at certain times. See Section 7.5.2 and Section 7.6.2 for a list of the available graphs.

7.4.1 Rhythm Overview

Diagnostics
⇒ Rhythm
⇒ Overview

The rhythm overview gives a quick impression of the patient's cardiac rhythm in the period since the previous follow-up session (see Figure 45). Various counters inform the user about atrial and ventricular events and episodes, as well as selected episodes recorded during the collection period. Unexpectedly high or low values in these counters may indicate that you should look into more detailed diagnostic data to find the cause.

Figure 45. The Rhythm Overview window



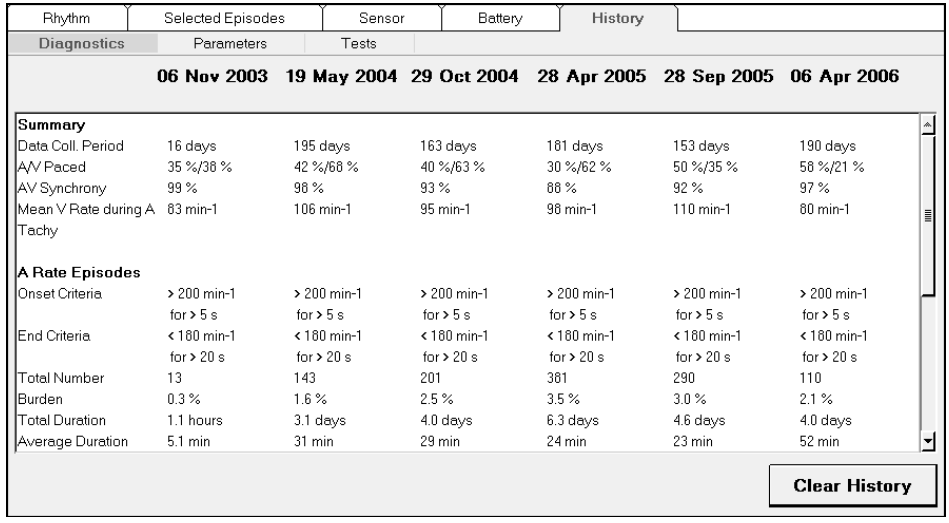
Select one of the graphs to display the distribution of cardiac events in Holters and histograms. Histograms show the distribution of cardiac events and episodes in the period since the last follow-up session. Holters are used to reveal trends in rate and rhythm over a limited period.

7.4.2 Diagnostics history

Diagnostics
⇒ History

Diagnostics history shows information recorded during the last follow-up period and up to five previous collection periods. It can give an impression of how the pacemaker has paced and how the burden of arrhythmias has changed over time. Differences may be caused by the progress of disease or by therapy adjustment. History is also useful for assessing the efficacy of changed therapies.

Figure 46. The Diagnostics History window



	06 Nov 2003	19 May 2004	29 Oct 2004	28 Apr 2005	28 Sep 2005	06 Apr 2006
Summary						
Data Coll. Period	16 days	195 days	163 days	181 days	153 days	190 days
A/V Paced	35 %/38 %	42 %/68 %	40 %/63 %	30 %/62 %	50 %/35 %	58 %/21 %
AV Synchrony	99 %	98 %	93 %	88 %	92 %	97 %
Mean V Rate during A Tachy	83 min-1	106 min-1	95 min-1	98 min-1	110 min-1	80 min-1
A Rate Episodes						
Onset Criteria	> 200 min-1 for > 5 s	> 200 min-1 for > 5 s	> 200 min-1 for > 5 s	> 200 min-1 for > 5 s	> 200 min-1 for > 5 s	> 200 min-1 for > 5 s
End Criteria	< 180 min-1 for > 20 s	< 180 min-1 for > 20 s	< 180 min-1 for > 20 s	< 180 min-1 for > 20 s	< 180 min-1 for > 20 s	< 180 min-1 for > 20 s
Total Number	13	143	201	381	290	110
Burden	0.3 %	1.6 %	2.5 %	3.5 %	3.0 %	2.1 %
Total Duration	1.1 hours	3.1 days	4.0 days	6.3 days	4.6 days	4.0 days
Average Duration	5.1 min	31 min	29 min	24 min	23 min	52 min

In the Diagnostics History window, you can choose between seeing the history of diagnostics, parameters, or tests, during the previous follow-ups, by selecting the appropriate sub tab.

On the cardiac dashboard, you can press a diagnostic hyperlink to see a graphical presentation of the history of that diagnostic over the previous follow-up periods (see Section 4.3).

Notes:

- Pressing [Clear History] clears all the diagnostics, parameters and tests history data in the pacemaker. Only the data from the current follow-up session remains in the pacemaker.
- A collection period may contain data from more than one follow-up interval, if the user chose the “Keep diagnostic data until next session” option at the end of a follow-up session (see Section 7.3.1).

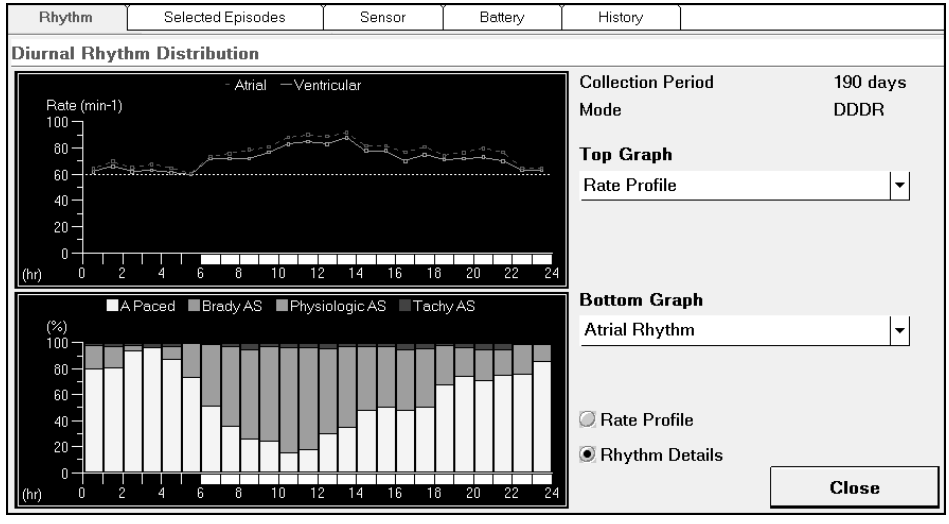
7.4.3 Diurnal Rhythm Distribution

Diagnostics
⇒ Rhythm
⇒ Overview
⇒ Diurnal Rhythm Distribution

The diurnal rhythm distribution diagnostics show the distribution of certain events over the day. For each hour of the day, the pacemaker keeps a count of the relevant events during the whole collection period.

Diurnal rhythm distribution data can help you to correlate cardiac events with patient activities or the patient's reaction to drug intake at certain times of the day. This information is helpful when optimizing the pacemaker settings or drug therapy. You may also use this information to relieve a patient of symptoms that occur at a particular time of day. The diurnal rhythm distribution graphs provide baseline information on average rates and patterns over the collection period. This can be useful, in combination with the 24-hour Holter (see Section 7.4.4), to identify recent changes in rate and rhythm when a patient presents with new symptoms.

Figure 47. Diurnal Rhythm Distribution window: Rhythm Details example



The available rhythm details graphs are listed in Section 7.5.2 and Section 7.6.2.

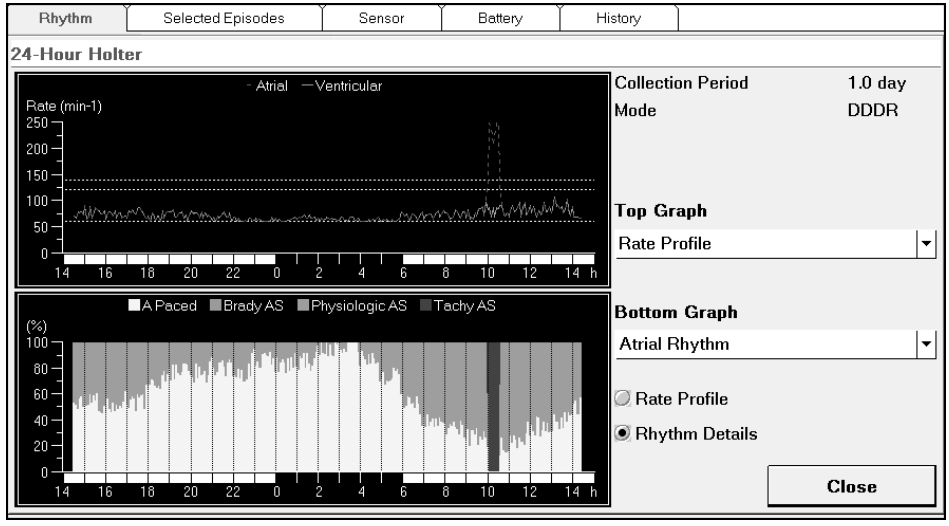
Note: Diurnal rhythm distribution diagnostics are only available if data has been collected in the pacemaker for at least 24 hours.

7.4.4 24-hour Holter

Diagnostics
⇒ Rhythm
⇒ Overview
⇒ 24-hour Holter

The 24-hour Holter shows information about the rate and rhythm over the day and night immediately preceding the follow-up session. This may help you to identify unexpected patterns at the time when the patient reported symptoms (see Figure 48).

Figure 48. The 24-hour Holter window: Rhythm Details example



The 24-hour Holter presents the data collected in counters for each five minutes over the previous 24 hours. Two graphical formats are available: rate profile and rhythm details.

The rate profile diagram shows the atrial and ventricular rates, averaged over each five-minute period during the previous 24 hours. The rhythm details graphs present the contents of counters for each five-minute period over the previous 24 hours. The rhythm details graphs available for the 24-hour Holter are listed in Section 7.5.2 and Section 7.6.2.

7.4.5 30-minute Holter

Diagnostics
⇒ Rhythm
⇒ Overview
⇒ 30-minute Holter

The 30-minute Holter collects data during a follow-up session. It is useful, for example, to record the rate pattern and the results of the activity sensor during an exercise stress test.

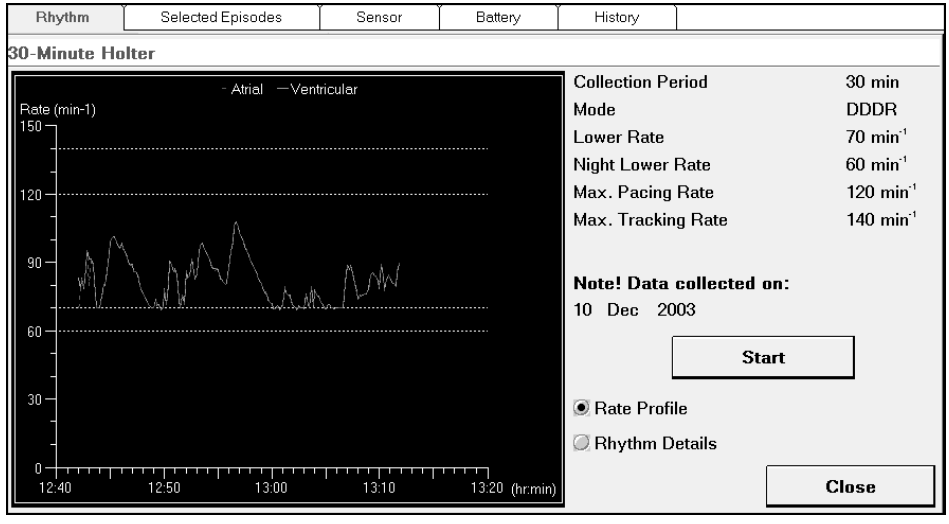
When you select the 30-minute Holter, any data remaining from a previous recording is displayed. A note states the date on which the data was collected.

To start recording a 30-minute Holter, press [Start] in the Rate Profile window. Any previously recorded 30-minute Holter data is cleared. Recording stops automatically after 30 minutes. It is not possible to stop the recording manually. At any time during the 30-minute data collection period, you can see a snapshot of the data collected so far by closing and reopening the window.

You can restart the 30-minute Holter while it is running by pressing [Start] again.

Two graphical formats are available: rate profile and rhythm details. The rate profile diagram shows the patient's atrial and ventricular rates averaged for each 10-second period over the 30 minutes (see Figure 49). Rhythm details graphs present the contents of counters for each 10-second period over the 30 minutes. The rhythm details graphs available for the 30-minute Holter are listed in Section 7.5.2 and Section 7.6.2.

Figure 49. The 30-minute Holter window: Rate Profile example



Note: The parameter settings are those that were applicable when you started the 30-minute Holter. Changes made to these parameters during recording will not be shown.

7.5 Assessing atrial rhythm and AF

The following diagnostics can be helpful for evaluating sinus node function, arrhythmias and rate response.

- The Rhythm Overview window summarizes atrial rhythm information (see Section 7.5.1) and the Collection Settings window gives an overview of the Selected Episodes detection criteria.
- You can investigate atrial rhythm details by looking at Diurnal Rhythm Distribution graphs and Holters (see Section 7.5.2).
- The atrial rate histogram shows the distribution of atrial events during the collection period. The distribution of tachy and sinus rhythm can be helpful when assessing AF (see Section 7.5.3).
- Diagnostics history can give an impression of how pacing and the burden of AF have changed over time (see Section 7.4.2).
- Selected Episodes windows provide information about the incidence and onset of AF if the episode trigger is “Atrial Rate” (see Chapter 8). Four levels of information are available.
  - The Rhythm Overview window gives a quick impression of the number of arrhythmia episodes and the AF burden during the collection period. Histograms can be used to investigate events that occur in the period preceding the onset of episodes of fast atrial rhythm.
  - The diary helps you to assess the progress of a selected episode type over time. It also helps to identify patterns in the distribution of episodes, for example a cluster of episodes in a short period.
  - Detailed onset reports help you to identify patterns of events that may lead to onset of arrhythmia episodes.
  - A stored EGM is useful for confirming that the pacemaker has correctly identified episodes of arrhythmia.

Note: The length of the episodes recorded in Selected Episodes diagnostics is based on beat-to-beat classification, and may not correspond exactly to data collected in the atrial rate histogram, which is based on the interval durations of individual events. For example, a single, fast atrial beat contributes to the “Atrial Tachy Episodes” accumulated in the atrial rate histogram. However, it is not included in the length of selected episodes because an isolated, fast beat does not meet the detection criteria.

7.5.1 Atrial rhythm overview

The first three atrial counters in the Rhythm Overview window record all atrial events in the collection period, and thus add up to 100%. The other counters give information about the incidence of atrial events and episodes.

Atrium Paced – The percentage of time that the atrium was paced during the collection period. Information about the incidence of atrial pacing is helpful when programming the lower rate and night lower rate. A high percentage of atrial pacing at low rates may indicate a need for rate responsive pacing.

Physiologic A Senses – The percentage of atrial sensed events that the pacemaker classified as physiological.

Pathologic A Senses – The percentage of atrial sensed events that the pacemaker classified as bradyarrhythmia or atrial tachyarrhythmia. To investigate the underlying causes of a high percentage of pathologic atrial senses, look at the atrial rate histogram.

PACs – The total number of premature atrial contractions (PACs) recorded by the pacemaker in the collection period, and the average number of PACs per unit of time. For more information, refer to the diurnal rhythm distribution graphs or the 24-hour Holter.

Retrograde Conduction Episodes – The total number of episodes of retrograde conduction detected by the pacemaker in the collection period, and the average number of episodes per unit of time.

Retrograde A Senses – The total number of retrograde atrial sensed (RAS) events recorded by the pacemaker in the collection period.

7.5.2 Atrial rhythm details graphs

You can select the following atrial rhythm details graphs in the “Rhythm Details” drop-down lists of Diurnal Rhythm Distribution or Holters.

Rate Profile – The average atrial and ventricular rates during the collection period. The rates are given in beats per minute (min^{-1}), in the form of a line diagram.

Atrial Rhythm – The percentage of time that the pacemaker sensed and paced in the atrium during the collection period. Atrial sensed events are divided into physiological, bradyarrhythmia and tachyarrhythmia senses.

Atrial Tachy Episodes – The percentage of time or number of episodes during which the pacemaker detected an atrial tachyarrhythmia during the collection period.

PACs – The percentage of time or number of times that the pacemaker sensed a premature atrial contraction (PAC) during the collection period.

Note: For Atrial Tachy Episodes and PACs, the diurnal rhythm distribution graphs show the percentage of time when a certain event or episode occurred; Holter graphs show the number of events or episodes per unit of time.

7.5.3 Atrial rate histogram

Diagnostics
⇒ Rhythm
⇒ Overview
⇒ Atrial and Ventricular Rate Histogram

Availability: DDD(R), DDI(R), DOO, VDD(R), AAI(R), AAT, AOO modes

The atrial rate histogram shows the rate distribution of all atrial events recorded since the previous follow-up session. It also shows the proportion of various types of rhythm as a function of the atrial rate. This can be helpful when assessing the patient's sinus node function, arrhythmias and pacemaker-driven rates.

The atrial rate histogram can help you to identify whether the sinus node is functioning normally. It also provides information about tachyarrhythmias and bradyarrhythmias, and whether the pacemaker is providing an adequate substitute for normal sinus node function. Information about bradyarrhythmias is especially important for patients with the pacemaker programmed in the VDD mode.

This information can be useful when making adjustments in the pacemaker settings for lower rates, maximum rates and sensors. The histogram can show four types of data.

Brady – The percentage of time that the pacemaker classified atrial senses as atrial bradyarrhythmia.

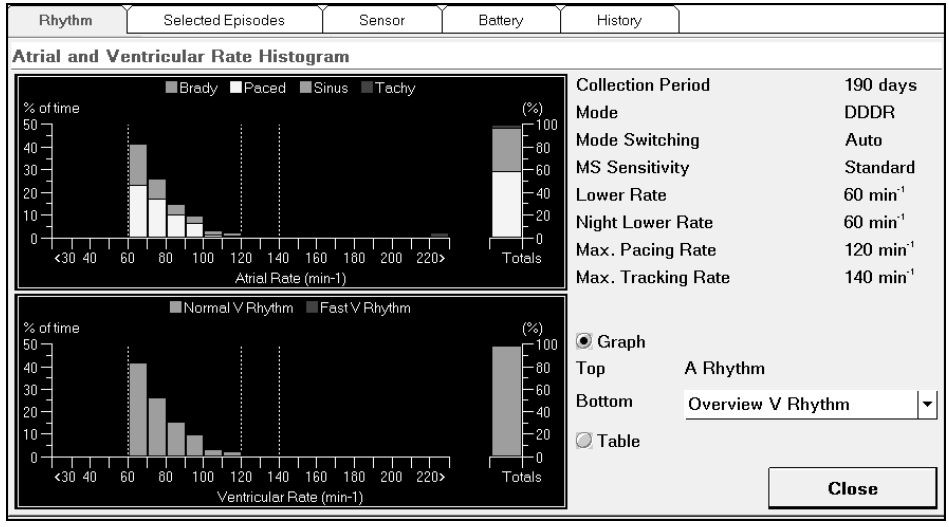
Paced – The percentage of time that the pacemaker paced the atrium.

Sinus – The percentage of time that the pacemaker classified atrial senses as physiological atrial senses.

Tachy – The percentage of time that the pacemaker classified atrial senses as tachyarrhythmia.

The histogram presents data in 21 rate classes, each representing a rate of 10 min^{-1}. In graph format, the atrial rate histogram shows the occurrence of different rate types for each rate class (see Figure 50). In table format, the atrial rate histogram shows the rate class and recorded percentages of each rate type.

Figure 50. Atrial and Ventricular Rate Histogram window: Graph example



7.6 Assessing ventricular rhythm

The following diagnostics can be helpful for evaluating the patient's AV node function, mode switching, and rate response in VVIR mode.

- The Rhythm Overview window summarizes ventricular rhythm information (see Section 7.6.1) and the Collection Settings gives an overview of the Selected Episodes detection criteria.
- You can investigate ventricular rhythm details by looking at Diurnal Rhythm Distribution graphs and Holters (see Section 7.6.2).
- The ventricular rate histogram shows the distribution of ventricular events during the collection period (see Section 7.6.3).

- The ventricular rate irregularity histogram shows the beat-to-beat variation in ventricular rhythm during the collection period (see Section 7.6.4).
- Diagnostics history can give an impression of how pacing and the burden of arrhythmias have changed over time (see Section 7.4.2).
- The Selected Episodes windows provide information about episodes of high ventricular rates if the episode trigger is “Ventricular Rate” (see Chapter 8).
  - Selected Episodes histograms can be used to investigate events that occur in the period preceding the onset of episodes of fast ventricular rhythm (see Section 8.5).

7.6.1 Ventricular rhythm overview

The first two ventricular counters in the Rhythm Overview window represent all ventricular events during the collection period, and thus add up to 100%. The other counters give information about the incidence of ventricular events and episodes.

Ventricle Paced – The percentage of time that the pacemaker paced in the ventricle during the collection period. This includes AV synchronous pacing and pacing during mode switching, as well as ventricular safety paces (VSPs).

In dual chamber modes, the ventricle paced counter allows evaluation of the patient’s AV node function. Ventricular pacing may occur either at the end of the AV delay, or during bradyarrhythmia or atrial tachyarrhythmia. Frequent ventricular pacing may also occur as a result of detection of artifact signals in the VSP window (see Section 9.8). It is helpful to look at the ventricle paced counter when programming the maximum AV delay, adaptive AV delay and AV delay hysteresis. If the percentage ventricle paced rises over successive follow-ups, this may indicate that the patient has a progressive AV block.

Ventricle Sensed – The percentage of ventricular events that were sensed during the collection period. This includes AV synchronous and AV asynchronous senses, as well as premature ventricular contractions (PVCs).

PVCs – The total number of premature ventricular contractions (PVCs) recorded during the collection period and the average number of PVCs per unit of time.

VSPs – This counter shows how often the pacemaker delivered a ventricular safety pace (VSP) during the collection period, and the average number of VSPs per unit of time.

Mean V Rate during A Tachy – The average ventricular rate during periods of atrial tachyarrhythmia.

AV Synchrony – The percentage of time during which a sensed or paced atrial event was followed by a synchronous sensed or paced ventricular event. Low AV synchrony associated with a high percentage of ventricular sensing may indicate atrial undersensing.

7.6.2 Ventricular rhythm details graphs

You can select the following ventricular rhythm details graphs in the “Rhythm Details” drop-down lists of Diurnal Rhythm Distribution or Holters.

Rate Profile – The average atrial and ventricular rates during the collection period. The rates are given in beats per minute (min^{-1}), in the form of a line diagram.

Ventricular Rhythm – In dual chamber modes, the percentage of time during which the pacemaker classified the ventricular rhythm as normal or fast.

Ventricular Rhythm – In ventricular modes, the percentage of time that the pacemaker sensed or paced in the ventricle during the collection period.

AV Conduction – The percentage of time in the collection period during which the pacemaker sensed or paced AV synchronous or AV asynchronous events in the ventricle (dual chamber modes only).

PVCs – The number of premature ventricular contractions (PVCs) the pacemaker detected during the collection period.

7.6.3 Ventricular rate histogram

Diagnostics
⇒ Rhythm
⇒ Overview
⇒ Atrial and Ventricular Rate Histogram

Availability: DDD(R), DDI(R), DOO, VDD(R), VVI(R), VVT and VOO modes

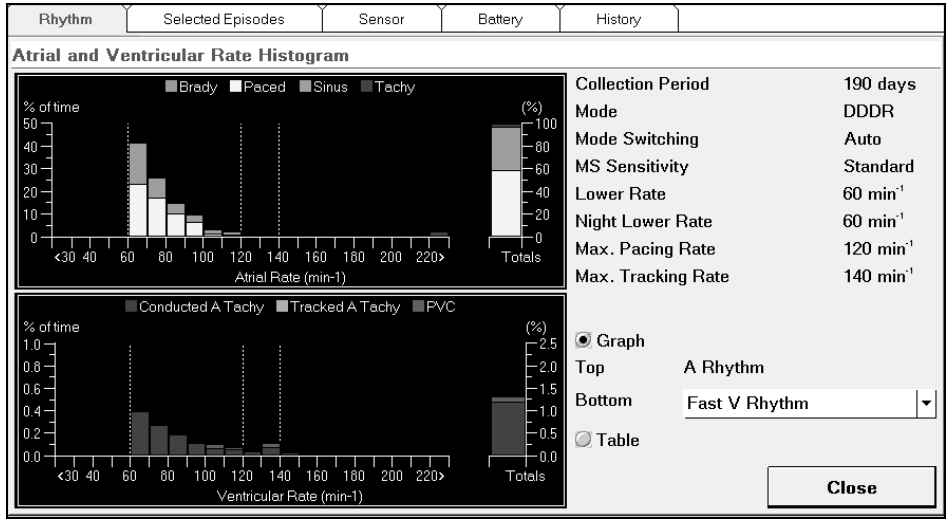
The ventricular rate histogram shows the distribution of all ventricular rates recorded since the previous follow-up session. It also shows the proportions of different rhythm types as a percentage of all ventricular rates.

The ventricular rate histogram can be helpful when explaining patient complaints and when assessing the need to change pacemaker therapy or medication. The histogram helps to explain the following patient and pacemaker characteristics:

- Unexpected incidence of high rates that any of the following may have caused :
  - frequent PVCs (possibly due to atrial undersensing)
  - conducted atrial tachyarrhythmias
  - tracked atrial tachyarrhythmias (with mode switching “Fixed”)
  - a too fast sensor rate during AV synchronous pacing or mode switching

- Unexpected lack of high rates that any of the following may have caused :
  - chronotropic incompetence (inadequate sinus rate increases during exercise)
  - a too slow sensor rate (during AV synchronous pacing or mode switching)
  - no sensor activated (non rate responsive mode)
- In VDD mode, unexpected incidence of paced or spontaneous ventricular escape rates that any of the following may have caused:
  - a too high lower rate
  - severe atrial bradyarrhythmia
  - atrial undersensing

Figure 51. Atrial and Ventricular Rate Histogram: Fast V Rhythm example



The histogram presents data in 21 rate classes, each representing a rate of 10 min^{-1}. The information can be presented in graph or table format.

The type of data shown by the histogram for each rate class depends on the programmed mode.

Dual chamber modes – There are three types of data presentation to choose from:

- Overview: showing normal and fast ventricular rhythm.
- Normal V Rhythm: the percentage of time that the pacemaker classified ventricular rates as normal, divided into the following:
  - V Sense: normal sensed ventricular events
  - Sync V Pace: AV synchronous paced ventricular events
  - Async V Pace: asynchronous paced ventricular events (resulting from mode switching)
- Fast V Rhythm: the percentage of time that the pacemaker classified ventricular rates as fast, divided into the following:
  - Conducted A Tachy: when atrial tachyarrhythmia sensed events are spontaneously conducted to the ventricle
  - Tracked A Tachy: when atrial tachyarrhythmia sensed events or PACs are tracked and paced in the ventricle (atrial tachy sensed events that fall within the tracking window when mode switching is “Fixed”)
  - PVCs: premature ventricular contractions

Single chamber ventricular modes – There are two rhythm types:

- Paced: the percentage of ventricular rates that were pacemaker driven
- Sensed: the percentage of spontaneous ventricular rates that were sensed by the pacemaker

7.6.4 Ventricular rate irregularity histogram

Diagnostics
⇒ Rhythm
⇒ Overview
⇒ V Rate Irregularity Histogram

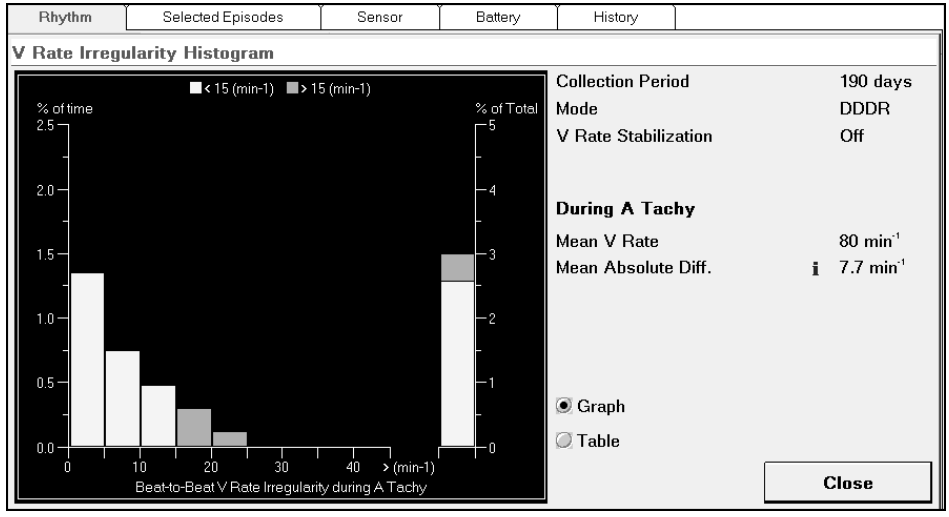
Availability: DDD(R), DDI(R), VDD(R), VVI(R) and VVT modes

The ventricular rate irregularity histogram shows the amount of variation in the ventricular rhythm recorded since the previous follow-up session.

The ventricular rate irregularity histogram can be helpful for explaining a patient's symptoms. In dual chamber modes, it can show whether ventricular irregularity is associated with atrial tachyarrhythmias. (Ventricular irregularity may also be the result of frequent PVCs, irregular sinus rhythm or intermittent atrial undersensing.) This histogram is also useful for assessing the effect of Ventricular Rate Stabilization therapy during atrial tachyarrhythmias.

The information presented depends on the programmed mode. In dual chamber modes, the graph shows the variation in ventricular rhythm during periods of atrial tachyarrhythmia (see Figure 52). In single chamber, ventricular modes, the graph shows the ventricular variation over the collection period.

Figure 52. Ventricular Rate Irregularity Histogram: dual chamber example



At each ventricular event, the pacemaker calculates the difference in rate between the last two VV intervals. Physiological ventricular rhythm normally shows rate changes between 0 min^{-1} and 15 min^{-1}. Rate changes between 15 min^{-1} and 30 min^{-1} may be considered to be large. Rate changes higher than 30 min^{-1} may be considered to be extreme.

If the ventricular rate irregularity histogram shows large or extreme rate variation, Vitatron recommends programming Ventricular Rate Stabilization on (see Section 10.6).

The column on the right of the screen shows additional information on the mean ventricular rate recorded during the collection period. The mean absolute difference is the mean of all the beat-to-beat ventricular rate changes that were recorded during the collection period. In dual chamber modes, this information applies to ventricular rates during episodes of atrial tachyarrhythmia.

The ventricular rate irregularity histogram presents data over nine classes of 5 min^{-1}. The height of each column of the histogram represents the percentage of time during the collection period when variation was recorded within that rate variation class. The information can be presented in graph or table format.

7.7 Assessing AV synchrony

The AV synchrony counter in the Rhythm Overview window shows the percentage of time during which a sensed or paced atrial event was followed by a synchronous sensed or paced ventricular event. Information on the percentage of AV synchrony facilitates the evaluation of proper sinus node and AV node function or pacemaker behavior. When the percentage of AV synchrony is lower than 100%, you can investigate possible causes by looking at the percentage of pathological atrial senses, the number of PVCs, atrial tachyarrhythmia episodes or the number of retrograde conduction episodes counters.

The AV Conduction graph in the Holter or diurnal rhythm distribution details shows the incidence of sensed or paced AV synchronous or AV asynchronous events in the ventricle.

The ventricular rate histogram (see Section 7.6.3) provides more information on asynchronous pacing as a result of mode switching.

The rate profile diagrams of the diurnal rhythm distribution and the 24-hour Holter may show whether lack of AV synchrony related to mode switching occurs at certain times of day. In VDD modes, these rate profile diagrams may show atrial rates below the lower rate associated with mode switching.

7.8 Assessing rate response

In the Rhythm Overview window, a high percentage of atrial pacing may indicate the need to activate rate responsive pacing or may be the result of a too fast sensor setting. Use the atrial rate histogram to confirm chronotropic incompetence and to assess whether the pacemaker is providing an adequate substitute for normal sinus node response to exercise.

High average paced rates in the atrial rate histogram (or, in VVIR mode, the ventricular rate histogram) may indicate a too rapid rate response to activity. Low average paced rates in the 24-hour Holter or the atrial rate histogram (or, in VVIR mode, the ventricular rate histogram) may indicate that the sensor is reacting too slowly to patient activity.

Refer to Chapter 12 for instructions on testing and adjusting rate response settings by performing a fast learn procedure or resetting the activity threshold.

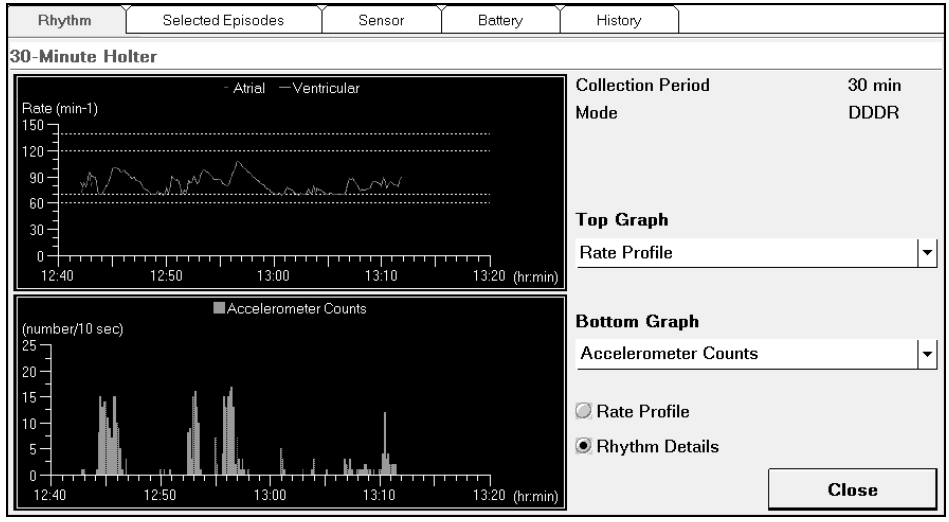
7.8.1 Accelerometer counts

Diagnostics
⇒ Rhythm
⇒ Overview
⇒ 30-Minute Holter (Rhythm Details (Accelerometer Counts))

You can use the 30-minute Holter (see Section 7.4.5) to record the response of the pacemaker to activity during an exercise stress test.

The Accelerometer Counts graph (rate responsive modes only) presents the number of accelerometer counts recorded by the accelerometer for each period of 10 seconds during the 30-minute collection period. This is useful when optimizing activity threshold programming (see Section 12.2).

Figure 53. The 30-minute Holter window: Accelerometer counts graph, Rhythm Details example



7.8.2 Sensor data

Diagnostics
⇒ Sensor

Availability: DDDR, DDIR, VDDR, VVIR and AAIR modes

The Sensor window (see Figure 54) shows how the accelerometer sensor has performed in the period since the last follow-up session. This information is useful when adjusting the sensitivity of the accelerometer with the activity threshold (see Section 12.2.2).

Figure 54. Sensor window example

Rest – Rest counts show the lowest number of accelerometer counts (per 10 seconds) recorded during the collection period. This represents the accelerometer response when the patient is at rest. A relatively high value may indicate that the sensor is reacting too sensitively to low levels of patient activity. If the average number of counts at rest is higher than one per 10 seconds, consider programming the activity threshold to a higher (less sensitive) setting.

Exercise – Exercise counts show the highest number of accelerometer counts (per 10 seconds) recorded during the collection period. This represents the highest level of patient activity. A low value may indicate either that the patient is not very active, or that the sensor is reacting too slowly to patient activity. If the maximum number of counts at exercise is lower than ten per 10 seconds, consider programming the activity threshold to a lower (more sensitive) setting.

Average Sensor Rate – This shows the average sensor-driven pacing rate during the collection period. Compare this with the maximum pacing rate and the lower rate. An average sensor rate close to the lower rate may indicate that the sensor is reacting too slowly to patient activity. Consider programming the activity threshold to a lower (more sensitive) setting.

7.9 Assessing sensing

Diagnostic data helps you to evaluate the pacemaker's atrial sensing behavior during the collection period and provides guidance for programming the atrial sensitivity. For example, a large number of PVCs shown in the rhythm overview and the PVCs rhythm details graph may indicate atrial undersensing.

Use the P-wave histogram (see Section 7.9.1) to investigate possible atrial undersensing, including undersensing of atrial tachyarrhythmias. This histogram also provides information about blanked atrial sensed events.

Use the VA interval histogram (see Section 7.9.2) to detect the presence of FFRW sensing or retrograde conduction. This histogram also provides information about the effectiveness of atrial blanking in avoiding FFRW sensing and the optimal sensing of atrial tachyarrhythmias.

For additional information on undersensing and oversensing, use ECG event markers and the EGM (see Chapter 4) to show, for example, FFRW sensing, myopotentials and atrial pacing artifacts during the AV-delay.

7.9.1 P-wave histogram

Diagnostics
- ⇒ Rhythm
  - ⇒ Overview
    - ⇒ P-wave Histogram

Availability: DDD(R), DDI(R), VDD(R) and AAI(R) modes

The P-wave histogram provides information about the amplitude distribution of sensed atrial events in the period since the last follow-up session. This can be helpful when programming the atrial sensitivity, and may reveal potential sensing problems. Atrial sensitivity must be high enough to sense the small amplitude differences of atrial fibrillation, but must avoid being too sensitive to noise.

The P-wave histogram can be used to identify the amplitude of atrial tachyarrhythmia signals and to verify the programming of the atrial sensitivity. In patients with sinus rhythm, the histogram usually has one peak. In patients with atrial arrhythmia, the histogram often has two peaks or a wide distribution, because atrial arrhythmias usually have lower amplitudes.

When all atrial events are sensed properly, the peak in the histogram is within the sensing range. When the lower amplitude side looks "chopped off", this indicates that the lowest P-wave amplitudes may not be sensed and the P-wave sensitivity needs to be adapted.

A low percentage of sensed P-waves can be caused by pacing during bradyarrhythmias, atrial undersensing or a large number of PVCs.

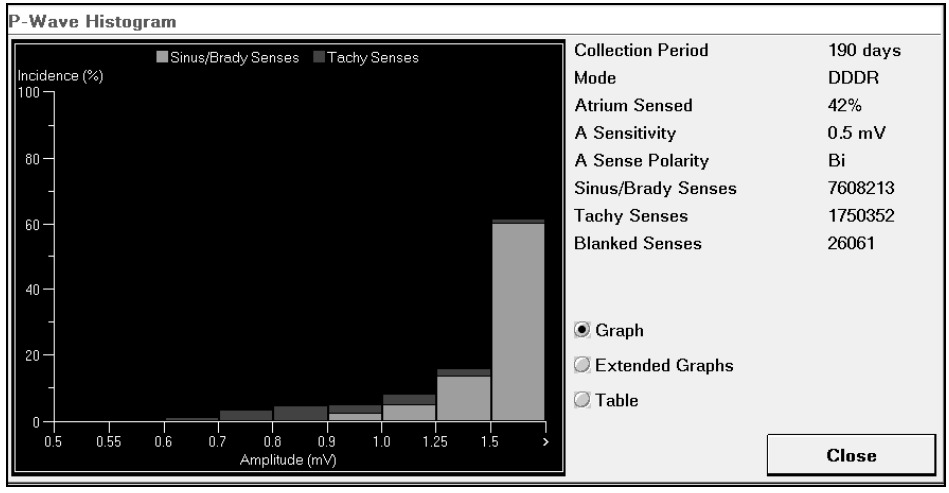
Sensed P-waves are divided into amplitude classes. The lowest class is the current atrial sensitivity setting. The other classes represent the programmable atrial sensitivity settings, up to a maximum of nine classes above the current setting.

P-wave amplitude data can be presented in graphic or table format. In dual chamber modes, an extended graph is also available.

The extended graphs format also shows the distribution of blanked atrial sensed events. Together with the VA interval histogram, this information can be used to optimize atrial blanking in the pacemaker.

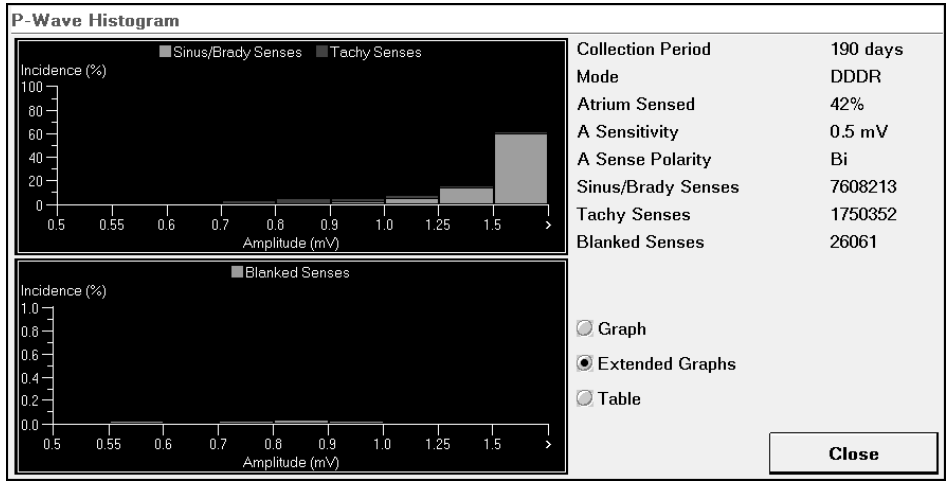
Graph – The standard P-wave amplitude graph shows the P-waves that were recorded in each of the amplitude classes, as a percentage of all atrial senses. The pacemaker classifies these P-waves as “Sinus/Brady Senses” or “Tachy Senses”.

Figure 55. The P-wave Histogram: Graph format



Extended Graphs – The extended graph presents two histograms in a split window (see Figure 56). This enables you to compare the P-wave amplitude distribution from the standard graph with the distribution of blanked atrial sensed events after a ventricular event. In dual chamber modes, the blanked atrial sensed events in each amplitude class are shown as a percentage of the total number of ventricular cycles.

Figure 56. The P-wave Histogram: Extended Graphs format



7.9.2 FFRW sensing

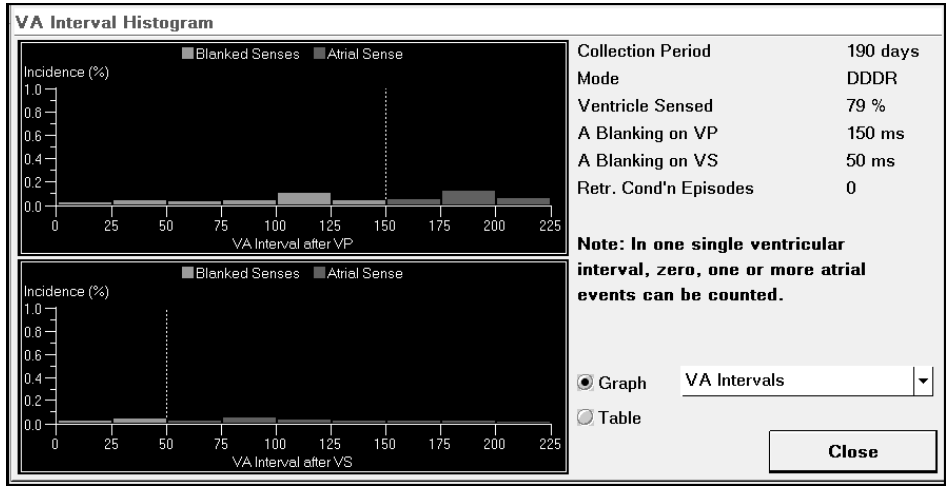
Diagnostics
⇒ Rhythm
⇒ Overview
⇒ VA Interval Histogram (VA Intervals)

The VA interval histogram helps you to assess the presence of far-field R-waves and the effectiveness of atrial blanking in avoiding FFRW sensing in the period since the previous follow-up.

This assessment relies on the distinctive sensed VA intervals associated with far-field R-waves. The presence of FFRW sensing is indicated by a relatively high number of VA intervals in the range 0 ms to 200 ms. When atrial blanking is effective, these intervals are stored by the pacemaker but they are not tracked. The VA intervals are also relatively stable. You can use the EGM to confirm the presence of FFRW sensing.

This graph shows the VA interval histogram in a split window (see Figure 57). The distribution of sensed VA intervals occurring after a paced ventricular event shown in the upper window can be compared with the distribution of sensed VA intervals occurring after a sensed ventricular event in the lower window.

Figure 57. VA Interval Histogram: VA Intervals graphs



The VA interval histogram records relevant VA intervals in nine interval classes of 25 ms, from 0 to 225 ms.

When the graph shows a significant peak in one or two adjacent interval classes, FFRW sensing should be suspected. If these interval classes are outside the atrial blanking period, try to eliminate FFRW sensing by programming longer blanking periods, changing the atrial sensing polarity to bipolar or changing the atrial sensitivity to a less sensitive (higher) setting. For more information on using atrial blanking to avoid FFRW sensing, see Section 9.7.

7.9.3 Retrograde conduction

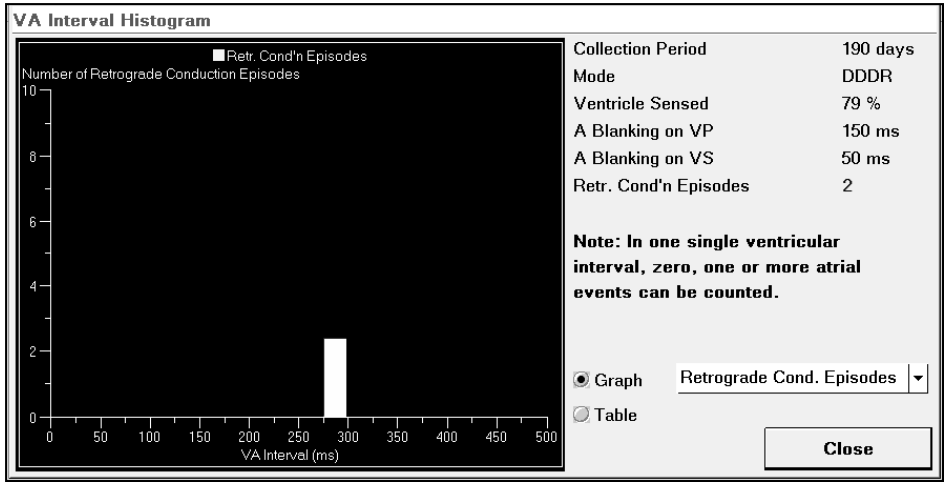
Diagnostics
- ⇒ Rhythm
  - ⇒ Overview
    - ⇒ VA Interval Histogram (Retrograde Cond. Episodes)

The VA interval histogram helps you to assess the presence of retrograde conduction and the optimal sensing of atrial tachyarrhythmias.

This assessment relies on the distinctive sensed VA intervals associated with retrograde conduction. The presence of retrograde conduction is indicated by a relatively high number of VA intervals in the range 150 ms to 450 ms. The VA intervals for retrograde conduction are also relatively stable.

This graph shows the number of retrograde conduction episodes that occurred for each VA interval class (see Figure 58).

Figure 58. VA Interval Histogram: Retrograde Conduction Episodes graph



The VA intervals are divided into 20 classes of 25 ms, from 0 to 500 ms.

When the graph indicates a high incidence of retrograde conduction, consider programming pacemaker settings to avoid retrograde conduction. For more information on retrograde conduction management, see Section 11.6.

8 Selected Episodes

8.1 Introduction

Selected Episodes diagnostics provide information about episodes of fast cardiac rhythm that occurred in the period since the last follow-up session.

Episode information helps the physician to explain patients' symptoms, investigate pacemaker behavior under certain conditions and assess the effect of pacing therapies or antiarrhythmic drug therapy. It may also reveal asymptomatic, but possibly serious, cardiac events.

The first part of the chapter explains how Selected Episodes works and how to set it up to record episodes of interest:

- Introduction to how Selected Episodes collects and stores data (see Section 8.2).
- Instructions for setting up the feature to record selected episodes (see Section 8.3).

The following sections describe how to present episode information:

- Selected Episodes Overview gives a summary of the selected episodes recorded since the last follow-up session (see Section 8.4).
- Selected Episodes Histograms help you to analyze the distribution of episodes (see Section 8.5).
- Selected Episodes Diary provides the most detailed episode information showing the events that occurred around the time of onset of individual episodes (see Section 8.6).
- Selected Episodes Stored EGM shows the morphology of events that occurred around the time of onset (see Section 8.7).

8.2 Data collection

Selected Episodes can simultaneously collect information about the following episode types:

- high atrial rates
- high ventricular rates

Selected Episodes records information at four levels of detail.

- An overview that gives a summary of the total number of episodes detected during the collection period and the total duration of the episodes.

- A diary that contains information on up to a maximum of 25 episodes with onset reports. This information includes the date and time when the episode started and how long it lasted. Diary information is useful for identifying patterns in the distribution of episodes.
- Onset reports containing detailed information about the onset of up to 25 episodes. These reports contain stored EGM recording of the events that occurred around the onset of an episode can help you to verify the details of an episode onset. Episode details help you to identify patterns of events that may lead to onset of arrhythmia episodes.

8.2.1 Episode detection

An episode starts when the pacemaker detects an appropriate trigger.

The pacemaker starts recording an episode when the rate exceeds the onset rate for a number of seconds. When the rate drops below the end rate, and stays there for a number of seconds, the pacemaker records the end of the episode.

To avoid recording many, short episodes, the pacemaker waits a few seconds before confirming the onset or end of an episode. This waiting time is known as “onset duration” and “end duration”. The end rate is automatically set below the onset rate.

For example, you can set up Selected Episodes to record all episodes of high atrial rates, when the atrial rate is higher than 200 min^{-1} for longer than 10 seconds. The episode ends when the atrial rate drops below 180 min^{-1} for longer than 10 seconds.

One hour after the end of the follow-up session, the pacemaker starts to collect information each time the trigger for the selected episode occurs.

For an explanation of how to set up the trigger and detection criteria see Section 8.3.

8.2.2 Technical details of episode detection

Arrhythmias often start in an irregular way. To ensure that episodes are detected reliably, the pacemaker goes through a number of stages before confirming that a real episode is present, or has ended. The exact confirmation criteria depend on the episode trigger.

To detect an episode, the pacemaker goes through the following stages:

1. Onset suspected. The heart rate exceeds the onset rate trigger.
2. Onset confirmed. The onset rate is exceeded for a number of seconds (onset duration). To allow for occasional blanking and undersensing, it is not necessary that every beat should meet the detection criterion. Once the episode onset is confirmed, the pacemaker stores the average heart rate over the minute before the “onset suspected” stage began.

3. End suspected. After the first beat at a rate below the end rate, the pacemaker waits a number of seconds (end duration). If, during this time, a single beat does not meet the criterion, the pacemaker returns to the “onset confirmed” stage.
4. End confirmed. When the end detection criterion has been met for a number of seconds, the pacemaker records the end of the episode.

The pacemaker records the start of an episode as the first beat in the “onset suspected” stage. It records the end of the episode as the first beat in the “end suspected” stage. The period between is the “episode duration”.

Note: Selected episode recording stops as soon as a new follow-up session begins on the programmer. If an episode is being recorded at that moment, the pacemaker detects this as the end of the episode. If an episode is occurring when data collection resumes after the follow-up session, the pacemaker records this as the start of the episode.

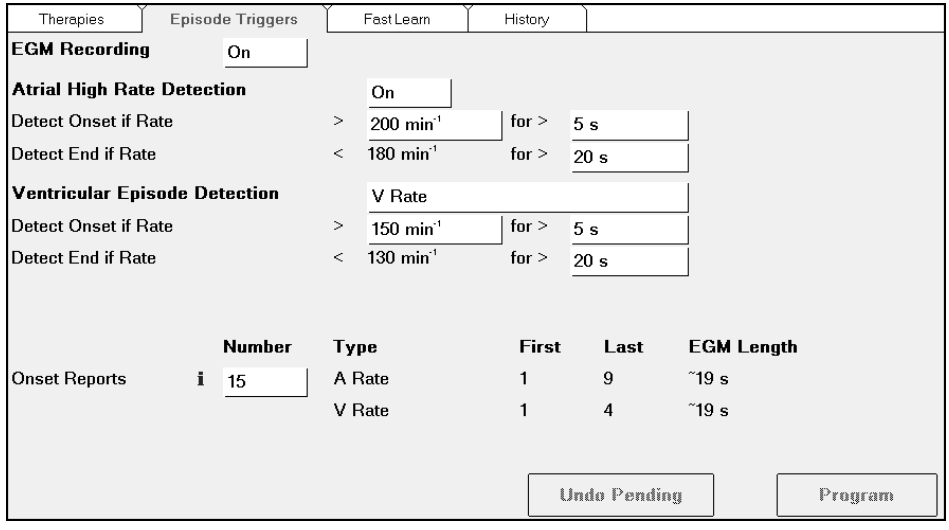
8.3 Setting up episode selection

Parameters

⇒ Episode Triggers

You can set up Selected Episodes recording by selecting an episode trigger and detection criteria in the Episode Triggers window.

Figure 59. The Episode Triggers window



You can switch off Selected Episodes recording by programming the Trigger to “Off”.

When you have finished setting up episode selection, press [Program] to program the settings or [Undo Pending] to cancel the settings.

You can record episodes of interest by selecting from the following triggers.

- Atrial High Rate Detection
- Ventricular Episode Detection

Which triggers are available depends on the programmed mode.

If you change the episode trigger, the detection criteria are automatically set to the default values of the new trigger.

Note: At the first programmer session after implant, if the pacemaker is a dual chamber model programmed to dual chamber sensing, the atrial high rate detection and the ventricular episode detection (V rate) triggers switch on. Selected Episodes will then start to record automatically. If the pacemaker is a dual chamber, or a single chamber model, programmed to ventricular sensing, only the ventricular episode detection (V rate) trigger switches on. If the pacemaker is a dual chamber, or a single chamber model, programmed to atrial sensing, Selected Episodes recording stays off.

To ensure reliable detection, the available range for detecting episode onset may be limited by the programmed lower rate and the length of the refractory period. Press [i] for details of possible limitations.

8.3.1 Atrial High Rate Detection trigger

Parameters
⇒ Episode Triggers
⇒ Atrial High Rate Detection

Availability: DDD(R), DDI(R), VDD(R), AAI(R), AAT

Range: Detect Onset if Rate > 140 - (10) - 240 min^{-1} for > 5, 8, 10, 15, 20, 30 seconds

With the Atrial High Rate Detection trigger, the pacemaker records episodes of fast atrial rhythm. Detection is based on sensed atrial rates. You can use this trigger to look for events that may lead to the onset of AF. It is also useful for assessing the benefits of antiarrhythmic therapy, and tracking the progress of AF over time.

First program the onset rate, above which the pacemaker will detect an episode of high atrial rates. Then program the onset duration and end duration. The pacemaker automatically sets the end rate of an episode 20 min^{-1} lower than the onset rate.

Note: Therapy Advisor reports “false early recurrences of AF” when a number of high atrial rate episodes are separated by short pauses of a minute or less. If this occurs, consider programming a longer end duration to ensure that such episodes are combined in a single, longer episode.

8.3.2 Ventricular Episode Detection trigger (V rate)

Parameters

⇒ Episode Triggers

⇒ Ventricular Episode Detection (V Rate)

Availability: DDD(R), DDI(R), VDD(R), VVI(R), VVT

Range: Detect Onset if Rate > 90 - (10) - 190 min^{-1} for > 2, 5, 8, 10, 15, 20, 30 seconds

With the Ventricular Episode Detection trigger (V rate), the pacemaker records episodes of fast ventricular rhythm. Detection is based on sensed and paced ventricular rates. You can use this trigger to investigate why a patient is experiencing a fast heart rate. The reason could be periods of ventricular tachyarrhythmia, or conduction or tracking of atrial tachyarrhythmia events to the ventricle.

First program the onset rate, above which the pacemaker will detect an episode of high ventricular rates. Then program the onset duration and end duration. The pacemaker automatically sets the end rate 20 min^{-1} lower than the onset rate.

8.3.3 Setting up episode details

Parameters

⇒ Episode Triggers

⇒ Number

Range: 5, 8, 10, 15, 20, 25

You can store information that is more detailed on up to 25 episodes in the form of onset reports. In the Episode Triggers window you can program the number of onset reports you want to store.

Note that as more onset reports are stored, the length of each individual report reduces.

The list of onset reports always includes the “First” episodes that occurred at the beginning of the collection period, and the “Last” episodes that occurred just before the current follow-up session.

The estimated length of the onset reports is based on a typical arrhythmia episode onset. “EGM length” shows the approximate length of one EGM recording stored around the onset, if “EGM Recording” is set to “On”.

8.3.4 Setting up EGM recording

Parameters
- ⇒ Episode Triggers
  - ⇒ EGM Recording

Range: On, Off

An EGM recording around the onset of an episode helps you to verify the information presented in the onset reports. It can show the morphology of intracardial signals around the onset of an arrhythmia or other episode.

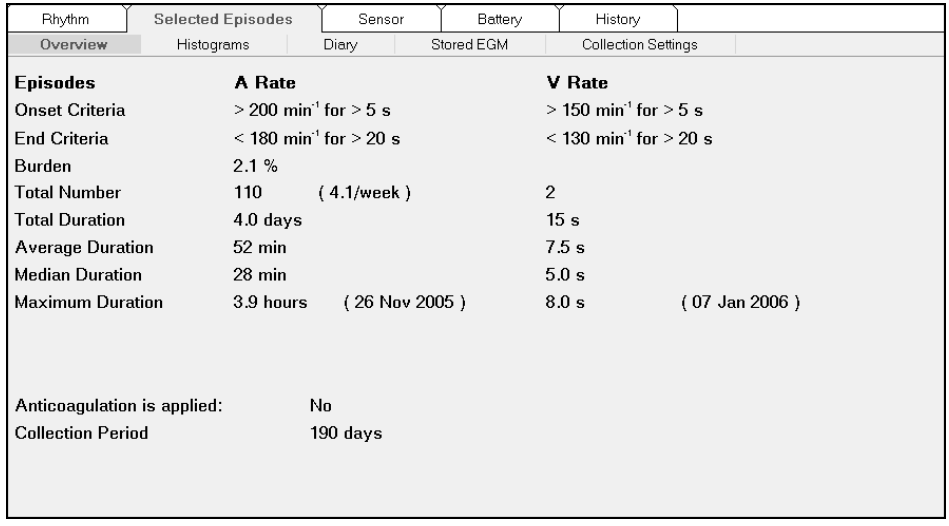
Storing EGM recordings has a minimal effect on the pacemaker’s energy consumption. If EGM recording is continuously programmed on throughout the lifetime of the pacemaker, it may reduce the lifetime of the pacemaker by about a month. You can check the remaining lifetime in the Battery window (see Section 5.8.1).

8.4 Selected Episodes overview

Diagnostics
- ⇒ Selected Episodes
  - ⇒ Overview

The Selected Episodes Overview window shows episode pacemaker settings and summaries of the main selected episode information (see Figure 60).

Figure 60. Selected Episodes Overview window



This includes the selected episode data recorded for both the atrial rate and the ventricular rate triggers, during the collection period. It shows the number of episodes recorded, and gives a quick impression of the duration of these episodes.

“Burden” shows the combined duration of all recorded atrial rate episodes as a percentage of the collection period.

The “Median Duration” is based on data in the Episode Duration histogram (see Section 8.5.1).

Note: “Total duration” is based on the length of episodes recorded in Selected Episodes. This may not correspond exactly to data collected in the atrial and ventricular rate histograms, which are based on the interval durations of individual events. For example, a single, fast atrial beat contributes to the “Atrial Tachy Episodes” accumulated in the atrial rate histogram. However, it is not included in the duration of selected episodes, because an isolated fast beat does not meet the detection criteria.

Note: Burden indications for ventricular rate episodes are not shown. This is because the relatively low number of accumulated detected ventricular episodes over a data collection period means they are not a useful diagnostic indicator

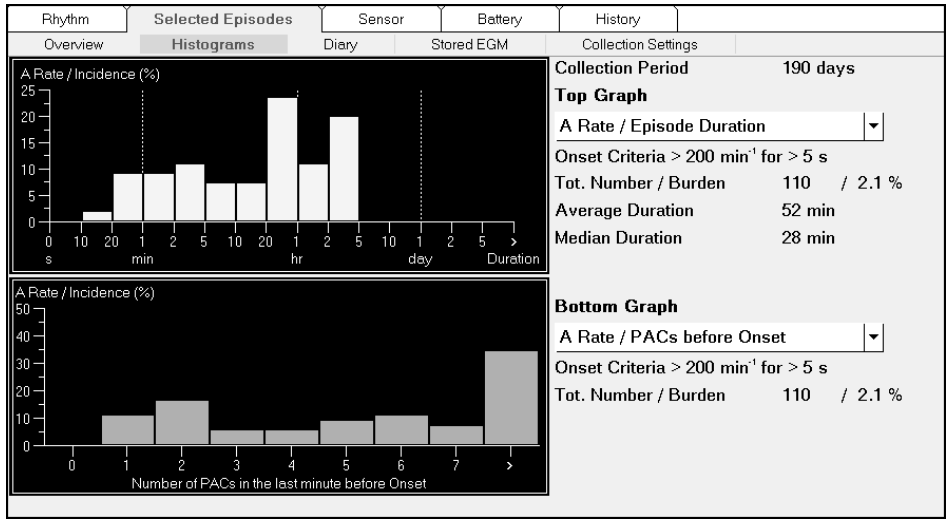
8.5 Selected Episodes histograms

Diagnostics
⇒ Selected Episodes
⇒ Histograms

The Selected Episodes histograms can be used to identify correlations between the onset of selected episodes and conditions in the period preceding the onset. This can be helpful when choosing or assessing drug and pacing therapies.

Select the required histograms from the drop-down list. (see Figure 61).

Figure 61. Selected Episodes Duration Histogram



There are two histograms:

- Episode Duration
- PACs/PVCs before Onset

Each Selected Episodes histogram can collect data for at least one year.

8.5.1 Episode duration histogram

The “Duration” histogram shows the pattern of episode length over the collection period. It can be used to show whether the patient suffers mainly from short or long arrhythmia episodes.

This information can be helpful when choosing antiarrhythmic drugs and may indicate a need for anticoagulation therapy.

The histogram presents the percentage of episodes recorded in one of 15 rate classes, ranging from an episode duration of < 10 seconds to > 5 days.

8.5.2 PACs or PVCs before onset histograms

The “PACs” and “PVCs” histograms show the incidence of premature beats in the last minute before the onset of the episode is suspected. They can be used to investigate possible correlations between episode onsets and premature beats.

This information can help you when choosing antiarrhythmic drugs or AF prevention therapies. For example, if there is a high correlation between PACs and atrial high rate episodes, consider programming PAC Suppression or Post-PAC Response on.

The “PACs” histogram is available for atrial high rate episodes. The “PVCs” histogram is available for ventricular high rate episodes.

The histogram presents the percentage of episodes recorded in each of nine rate classes, ranging from 0 premature beats to > 8 premature beats in the last minute before onset.

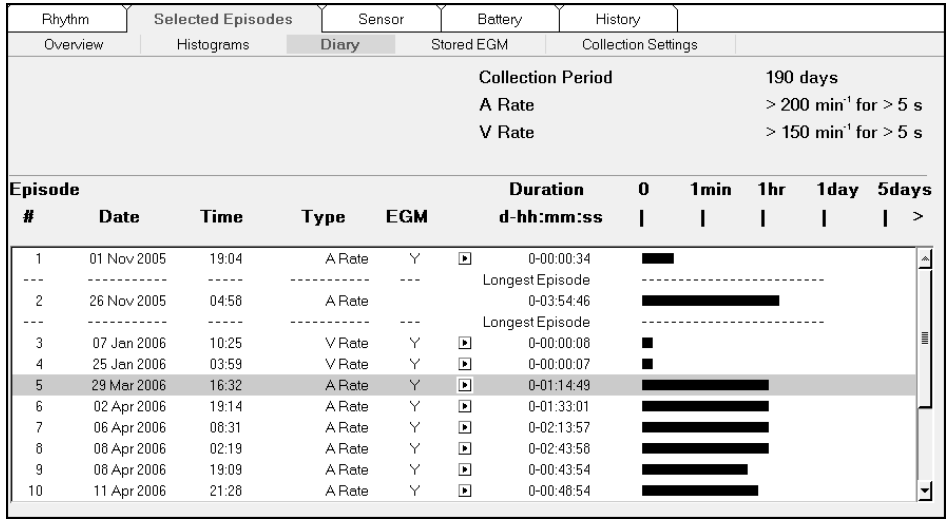
8.6 Selected Episodes diary

Diagnostics
- ⇒ Selected Episodes
  - ⇒ Diary

The Selected Episodes diary lists the episodes in the order in which they occurred and shows details of a subset of episodes. The diary helps you to assess the progress of a selected episode type over time. It also helps to identify patterns in the distribution of episodes, for example a cluster of episodes in a short period.

The window always shows the longest episode recorded during the collection period. The list of onset reports includes the ’First’ episodes recorded at the beginning of the collection period and the ’Last’ episodes that occurred just before the end of the collection period (see Figure 62).

Figure 62. Selected Episodes Diary



A “Y” in the EGM recording column indicates that the pacemaker has stored further details of that episode. You can press on an episode to see the episode details, with an EGM recording if available.

A “>” symbol before the duration indicates that the episode end was forced by the start of a follow-up session. Not to be confused with the similar looking on-screen programmer symbol (see Table 2).

8.7 Selected Episodes stored EGM

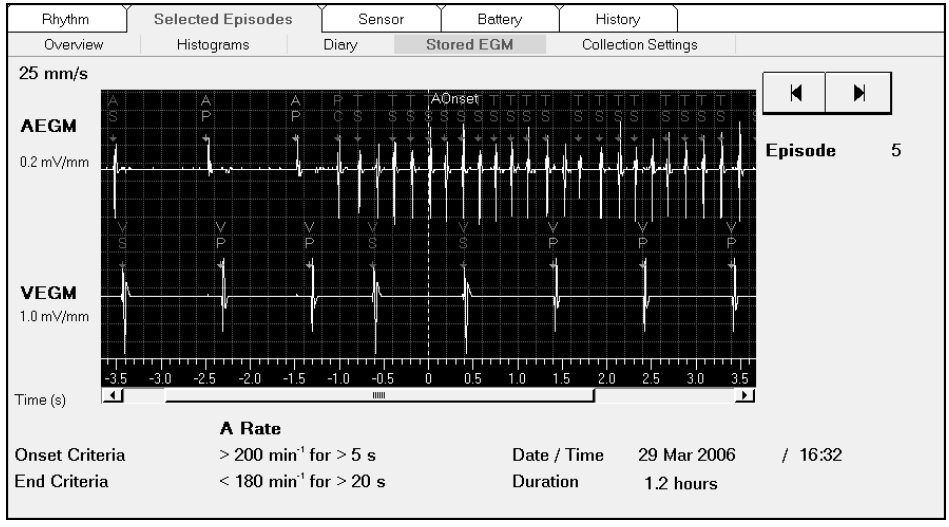
Diagnostics
- ⇒ Selected Episodes
  - ⇒ Stored EGM

Stored EGMs show intracardial signals which occurred around the onset of an arrhythmia or other episode. The stored EGM is useful for confirming that the pacemaker has correctly identified episodes of arrhythmia.

Select the Stored EGM sub tab to go straight to the first available EGM recording stored in the diary. Two EGM sources can be recorded simultaneously: AEGM and VEGM. The EGM strips are annotated with ECG markers. For an explanation of ECG marker annotations, see Section 4.3.1.

To look at the previous or next episode, press the “back” or “forward” button.

Figure 63. Episode Details window: stored EGM example



The “Onset” or “End”, shown as a vertical line, is the moment when episode onset or end was suspected (see Section 8.2). The x-axis shows the time, in seconds, before and after the onset moment. A horizontal, white bar under the x-axis indicates the EGM recording period, if available.

9 An introduction to Vitatron pacing therapies

9.1 Introduction

An extensive description of the Vitatron pacing therapies is provided in Chapter 9, Chapter 10, Chapter 11, Chapter 12, and Chapter 13.

The basis of optimal pacing therapy is a pacemaker programmed to suit the individual patient while avoiding any interference with normal functioning. The basic pacing therapies, including timing characteristics, are described in Chapter 9.

A regular heart rhythm is essential for optimal pacing therapy, to avoid symptoms associated with high ventricular rates or sudden drops in rate. How to achieve regular pacemaker behavior by managing atrial arrhythmias and stabilizing the heart rate is described in Chapter 10, Rate stability. This chapter also describes pacemaker behavior during atrial bradyarrhythmias, and explains how the pacemaker avoids high conducted ventricular rates during atrial arrhythmias by immediate mode switching and Ventricular Rate Stabilization.

Maintaining AV synchrony when possible is important in optimizing cardiac output through atrial contribution, especially at lower heart rates. Immediate AV resynchronization after a loss of AV synchrony avoids complications such as retrograde conduction, which may be associated with pacemaker syndrome and pacemaker mediated tachycardias. The available techniques for maintaining or restoring AV synchrony and for managing retrograde conduction are described in Chapter 11, AV synchrony.

Sensor-driven pacing can compensate for chronotropic incompetence of the sinus node, and for mode switching as a response to atrial tachyarrhythmias. Rate responsive pacing can restore the natural situation of a stable and chronotropically competent heart rate. This is described in Chapter 12, Rate response.

Preventing the onset of atrial fibrillation or flutter (AF) is important for the management of atrial arrhythmias. The use of triggered overdrive pacing therapies to prevent the onset of episodes of atrial tachyarrhythmia is described in Chapter 13, AF prevention therapies.

9.2 Basic pacing therapies

This chapter describes the basic pacing therapies as well as pacemaker timing and interference. Pacemaker timing is a fundamental component of the pacing therapies and interference can affect the timing. The contents of the chapter are as follows:

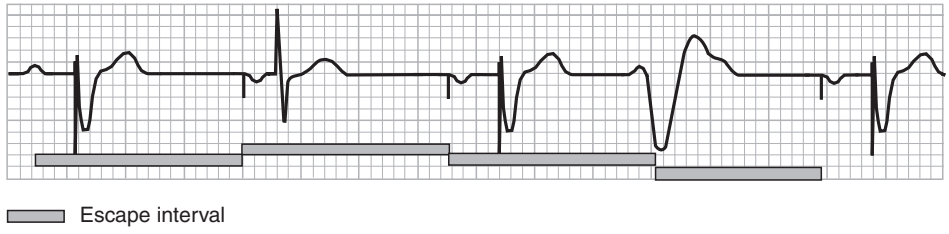
- Pacemaker timing explains how the pacemaker determines when to pace (see Section 9.3).
- Lower rate pacing explains why there are two lower pacing rates, lower rate and night lower rate, and gives instructions on how to change the pacemaker time and when to change it (see Section 9.4).
- Maximum rates explains the purpose of the maximum rate, followed by a description of the two rates, maximum tracking rate and maximum pacing rate (see Section 9.5).
- Refractory period explains the purpose of the refractory period as well as describing atrial refractory period and ventricular refractory period (see Section 9.6).
- Blanking explains the purpose of blanking as well as describing the atrial blanking on ventricular pace, the atrial blanking on ventricular sense and the ventricular blanking on atrial pace (see Section 9.7).
- Ventricular safety pacing (VSP) explains why it is required and describes what VSP does (see Section 9.8).
- Atrial hysteresis, including Refined Atrial Pacing and conditional hysteresis, explains how to promote sinus rhythm (see Section 9.9).
- Interference management describes how the pacemaker operates when there is interference present (see Section 9.10).

9.3 Pacemaker timing

In dual chamber pacemakers, the timing is atrial-based during AV synchronous operation. In case of loss of AV synchrony, for example during a premature ventricular contraction (PVC), Wenckebach behavior, or mode switching, the system uses ventricular timing.

The pacemaker uses atrial timing in atrial modes and ventricular timing in ventricular modes. Refer to Chapter 3 for a more extensive description of the various pacing modes. Atrial-based timing, including timing behavior after a PVC, is shown in Figure 64.

Figure 64. Pacemaker timing



The pacemaker starts an escape interval after either a sensed or a paced event. If by the end of an escape interval there is no sensed event the pacemaker paces the appropriate chamber.

An atrial event, either sensed or paced, starts an AV delay. The AV delay maintains synchrony between the atrial and the ventricular contractions. If no ventricular event is sensed by the end of AV delay, the pacemaker generates a ventricular pace. Refer to Chapter 11 for a more extensive description of how the pacemaker uses the AV delay to maintain synchrony.

9.4 Lower rate pacing

The purpose of lower rate pacing is to protect the patient against bradyarrhythmias. The pacemaker uses two programmable rates for lower rate pacing: during the day, the lower rate, and during the programmed night hours, the night lower rate.

Note: During the application of hysteresis, pacing can occur at a rate lower than the programmed lower rate or night lower rate. The pacemaker however, fixes the lowest possible pacing rate at 30 min^{-1}.

9.4.1 Lower rate

Parameters
⇒ Therapies
⇒ Lower Rate...
⇒ Lower Rate

Range: 40 - (5) - 130 min^{-1}

Availability: All modes, except OOO

Careful adjustment of the lower rate helps prevent the heart rate from dropping below a rate appropriate for the patient. This is because the optimum value of the lower rate is patient dependent.

9.4.2 Night lower rate

Parameters
⇒ Therapies
⇒ Lower Rate...
⇒ Night Lower Rate

Range: 40 - (5) - 130 min^{-1}

Availability: All modes, except OOO

Parameters
⇒ Therapies
⇒ Lower Rate…
⇒ Start of Night

Range: 18:00 - (5 min) - 02:55 hh:mm

Availability: All modes, except OOO

Parameters
⇒ Therapies
⇒ Lower Rate…
⇒ End of Night

Range: 04:00 - (5 min) - 11:55 hh:mm

Availability: All modes, except OOO

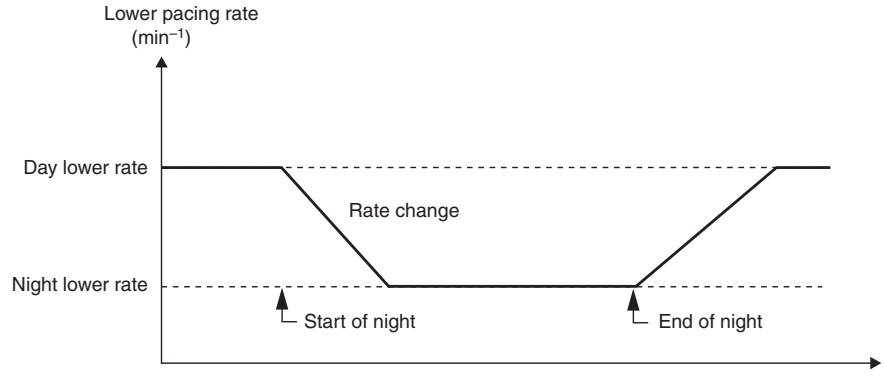
A patient's heart rate normally slows down to its lowest rate during the night. Mimicking this behavior, the night lower rate allows the pacemaker to further decrease the lower rate during the programmed night hours.

At the programmed start of night, the rate gradually decreases towards the night lower rate. As a general indication of the speed of change, a decrease in rate from 60 min^{-1} to 50 min^{-1} takes approximately ten minutes. At the programmed end of night, the rate gradually increases back to the day settings in a comparable time (see Figure 65).

Lowering the pacing rate during the night can increase patient comfort, while the reduction in pacemaker power consumption helps to extend pacemaker longevity.

Note: Inform patients that if they intend to travel through time zones, then the start of night and end of night parameters will need reprogramming before departure and on return.

Figure 65. Lower pacing rate during day and night



9.4.3 Pacemaker time

Parameters
⇒ Therapies
⇒ Lower Rate…
⇒ Pacemaker Time

Range: 00:00 - (1 min) - 23:59 hh:mm

Availability: All modes

Pacemaker time allows you to change the time to the patient's local time and to make any adjustments required by changes in either daylight saving or time zones.

At the start of a programming session, the programmer checks for any significant difference between the pacemaker time and the programmer time. If the programmer determines that the difference is significant, it displays an appropriate warning. You then have the option to synchronize the pacemaker time with the programmer time.

Note: Be aware that changing the pacemaker time clears all diagnostic data stored in the pacemaker memory.

9.5 Maximum rates

The purpose of the maximum rates is to prevent the pacemaker from pacing at a rate higher than is safe, or comfortable for the patient. The pacemaker uses two programmable rates to control the maximum rate, the maximum tracking rate and the maximum pacing rate.

9.5.1 Maximum tracking rate

Parameters
- ⇒ Therapies
  - ⇒ Max. Tracking Rate

Range: 90 - (5) - 190 min^{-1}

Availability: DDDR, DDD, VDDR and VDD modes

The maximum tracking rate is the maximum rate at which the pacemaker paces the ventricle in response to tracked atrial events.

A guideline to programming the maximum tracking rate is: (220 – age) min^{-1} based on the maximum expected heart rate during strenuous exercise. If the patient has angina, then a lower setting might be preferred.

9.5.2 Maximum pacing rate

Parameters
- ⇒ Therapies
  - ⇒ Max. Pacing Rate

Range: 90 - (5) - 170 min^{-1}

Availability: DDD(R), DDI(R), VDD(R), VVI(R), VVT, AAI(R) and AAT modes

The maximum pacing rate is the highest sensor-driven, or Flywheel-driven rate, that the pacemaker paces in the above modes. When using non rate responsive modes, it is only possible to program the maximum pacing rate with the Flywheel programmed to “On”.

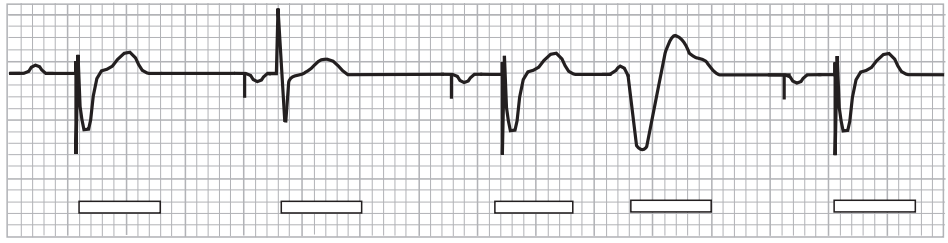
When Refined Atrial Pacing is programmed on, the programmable maximum pacing rate range may be limited by the atrial hysteresis if the programmed atrial hysteresis results in an escape rate more than 30 min^{-1} below the maximum pacing rate. Try decreasing the length of the atrial hysteresis interval (see Section 9.9.1) or the maximum pacing rate.

9.6 Refractory period

The purpose of the refractory period is to ensure that the pacemaker functions are not influenced by detected signals. Following a sensed, or a paced event in a chamber, the pacemaker ignores for a programmed period, any input from that chamber.

Note: Events detected during the refractory period are stored for diagnostic purposes and presented as blanked senses on the ECG.

Figure 66. Refractory period in dual chamber modes



In dual chamber modes both sensed and paced ventricular events start the programmed ventricular refractory period (see Section 9.6.2). An example of the refractory period in the DDD mode is shown in Figure 66 .

Note: The pacemaker does not use the atrial refractory period in dual chamber modes. Therefore, to prevent oversensing the pacemaker uses blanking (see Section 9.7).

9.6.1 Atrial refractory period

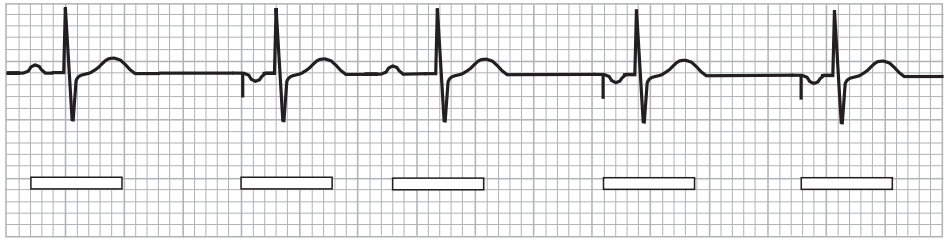
Parameters
⇒ Therapies
⇒ Refractory Period Atrial

Range: 250 - (10) - 500 ms

Availability: AAI(R) and AAT modes

In atrial modes, both sensed and paced atrial events start the programmed atrial refractory period (see Figure 67).

Figure 67. Atrial refractory period in the AAI mode



The length of the atrial refractory period is determined by the programmed value of the atrial refractory parameter.

9.6.2 Ventricular refractory period

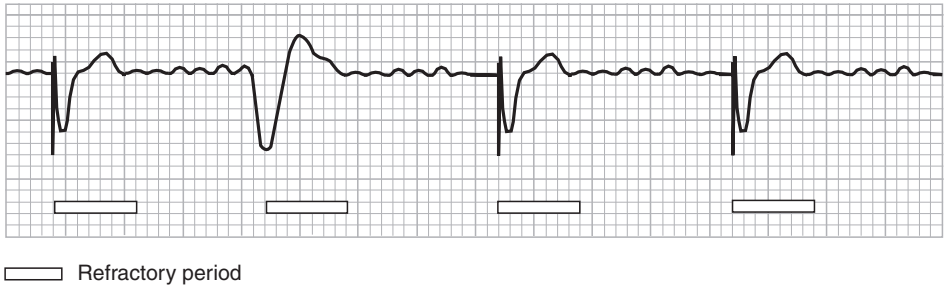
Parameters
⇒ Therapies
⇒ Refractory Period Ventricular

Range: 250 - (10) - 500 ms

Availability: DDD(R), DDI(R), VDD(R), VVI(R) and VVT modes

In ventricular modes both sensed and paced ventricular events start the programmed ventricular refractory period (see Figure 68).

Figure 68. Ventricular refractory period in the VVI mode

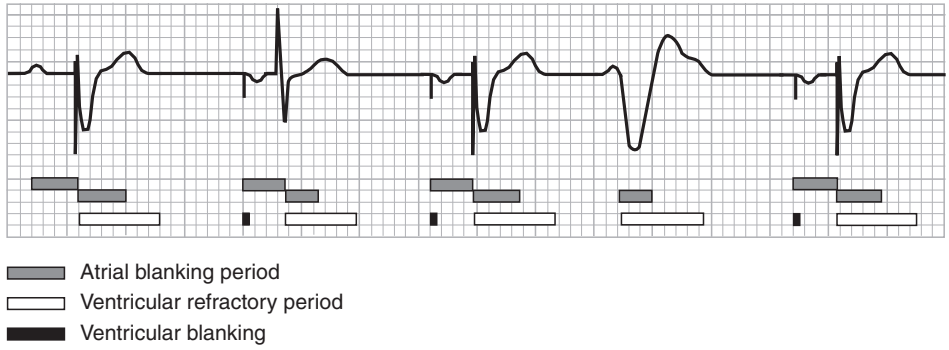


The length of the ventricular refractory period is determined by the programmed value of the ventricular refractory parameter.

9.7 Blanking

The blanking period is that period during which the pacemaker ignores events present in the blanked channel. Blanking prevents the pacemaker sensing and incorrectly interpreting intracardiac signals and pacing artifacts. Far-field R-waves (FFRW) and crosstalk are examples of the types of signals. Both sensed and paced events start a blanking period. The different blanking periods used are shown in Figure 69.

Figure 69. Blanking periods



In dual chamber modes the total atrial blanking consists of the blanked AV delay and blanking following the ventricular event, atrial blanking on VP (see Section 9.7.1) and atrial blanking on VS (see Section 9.7.2). Ventricular blanking is applied at the atrial pace (see Section 9.7.3).

Note: Events detected during atrial blanking are stored for diagnostic purposes only (not for rate classification) and presented as blanked senses on the ECG.

9.7.1 Atrial blanking on VP

Parameters
⇒ Therapies
⇒ A Blanking on VP…
⇒ Atrial Blanking on VP

Range: 50 - (25) - 300 ms

Availability: DDD(R), DDI(R) and VDD(R) modes

A ventricular paced event starts an atrial blanking period. The length of the atrial blanking period is determined by the parameter “Atrial Blanking on VP”. The aim is to adjust the length of the blanking period so as to avoid FFRW sensing in the atrium, while retaining the capability to sense a spontaneous atrial event. The VA interval measurement can be used to check for FFRW sensing (see Section 6.5.3).

If the programmable range is limited in the Atrial Blanking window, try decreasing the maximum pacing rate (see Section 9.5.2).

9.7.2 Atrial blanking on VS

Parameters
⇒ Therapies
⇒ A Blanking on VP…
⇒ Atrial Blanking on VS

Range: 25 - (25) - 150 ms

Availability: DDD(R), DDI(R) and VDD(R) modes

A sensed ventricular event starts an atrial blanking period. The length of the atrial blanking period is determined by the parameter “Atrial Blanking on VS”. The aim is to adjust the length of the blanking period so as to avoid FFRW sensing in the atrium, while retaining the capability to sense a spontaneous atrial event. The VA interval measurement can be used to check for FFRW sensing (see Section 6.5.3).

If the programmable range is limited in the Atrial Blanking window, try decreasing the maximum pacing rate (see Section 9.5.2).

9.7.3 Ventricular blanking on AP

Parameters
⇒ Therapies
⇒ Max. PAV Delay…
⇒ V Blanking on AP

Range: 20 - (5) - 50 ms

Availability: DDD(R) and DDI(R) modes

Ventricular blanking avoids inhibition of the ventricular channel and resulting asystole due to AV crosstalk.

Warning: If the ventricular blanking period is too short, then crosstalk might occur that could inhibit the ventricular channel. If VSP is programmed on, this results in a ventricular safety pace delivered at a safe moment. However, if the ventricular blanking period is too long, the pacemaker might not sense an early ventricular contraction, for example, a PVC. This could result in ventricular paces during the spontaneous ventricular contraction.

9.8 Ventricular safety pacing (VSP)

Parameters
⇒ Therapies
⇒ Max. PAV Delay…
⇒ Ventricular Safety Pacing

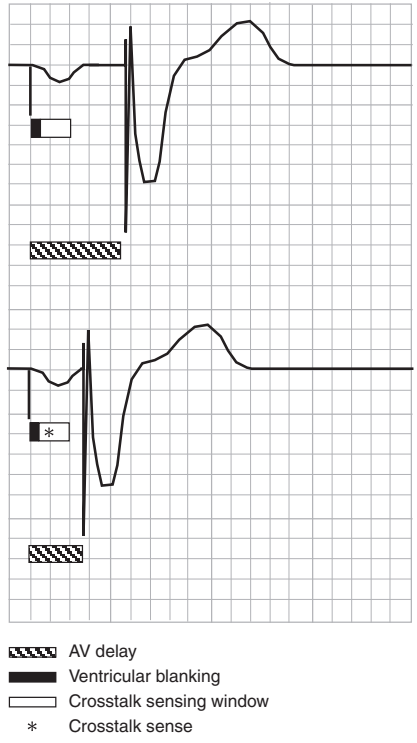
Range: On, Off

Availability: DDD(R) and DDI(R) modes

AV crosstalk during atrial pacing can cause ventricular inhibition. This can result in ventricular asystole if spontaneous ventricular activity is absent. Ventricular Safety Pacing (VSP) is a selectable option, active in the delivery setting, that secures ventricular pacing if there is crosstalk.

Delivery of the VSP is normally at a shortened AV delay of 110 ms, or at an AV delay that is dependent on the AV delay setting and the paced rate (see Chapter 11). The absolute minimum value of the paced AV delay is 80 ms. The intention of the short AV delay during VSP is to avoid pacing in the T-wave of a spontaneous ventricular event occurring in the crosstalk-sensing window.

Figure 70. VSP after crosstalk detection



The upper panel of Figure 70 shows a normal situation where the AV delay programming defines the length of the AV delay. The assumed resting situation is with a paced AV delay of, for example, 180 ms.

The lower panel shows an asterisk to indicate sensing of an AV crosstalk artifact. The paced AV delay is now 110 ms, since in the resting situation this is the shorter interval.

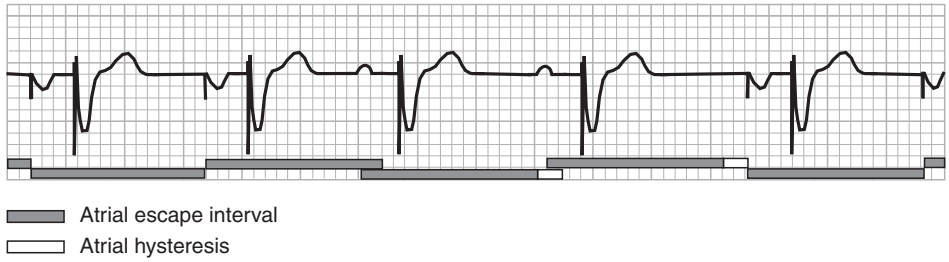
In the Vitatron system, AV delay settings, VSP, or mode switching and consequent resynchronization pacing (see Chapter 10), can cause short AV intervals of this kind

Warning: Pacemaker-dependent patients must have the VSP programmed to “On”.

9.9 Atrial hysteresis

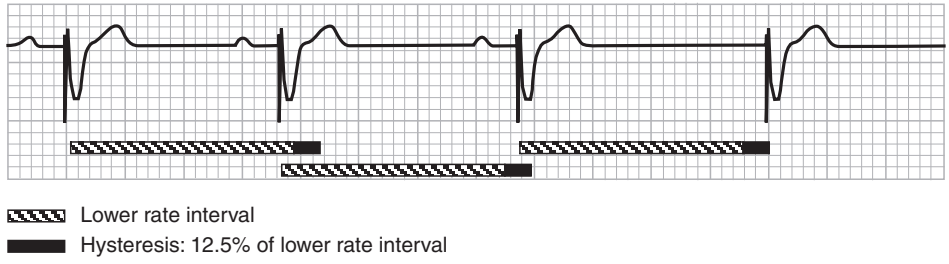
Atrial hysteresis is an extension of the escape interval to promote the occurrence of spontaneous events. It is always active in the DDD(R), VDD(R) and AAIR modes. The escape interval is extended after a trackable sensed atrial event (see Section 10.3) in the DDD(R) and VDD(R) modes, or after any sensed atrial event in the AAIR mode. The pacemaker continues to operate with the extended escape interval until the next paced atrial event, as shown in Figure 71.

Figure 71. Atrial hysteresis in the DDD(R) mode



The pacemaker extends the atrial escape interval by 40 ms in the DDD(R) and AAIR modes and the ventricular escape interval by 12.5% of the lower rate interval in the VDD(R) mode. Atrial hysteresis is especially important in the VDD(R) mode, because a preference for spontaneous atrial events makes it possible to maintain AV synchrony even if the spontaneous rate is slightly below the lower rate, the Flywheel rate or the sensor rate (see Figure 72).

Figure 72. Atrial hysteresis in the VDD(R) mode at the lower rate and at the sensor rate



9.9.1 Refined Atrial Pacing (RAP)

Parameters
⇒ Therapies
⇒ Refined Pacing… Atrial
⇒ Refined Atrial Pacing

Range: On, Off

Availability: DDD(R), AAIR

Parameters
⇒ Therapies
⇒ Refined Pacing… Atrial
⇒ Atrial Hysteresis

Range: 100 - (25) - 200 ms

Availability: DDD(R), AAIR

When Refined Atrial Pacing (RAP) is programmed on, the length of the atrial hysteresis interval is programmable. The pacemaker extends the atrial escape interval with the programmed atrial hysteresis after a trackable sensed atrial event (see Section 10.3) in the DDD(R) mode, or after any sensed atrial event in the AAIR mode. The pacemaker continues to operate with the extended escape interval until the next paced atrial event.

The programmable atrial hysteresis range may be limited by the maximum pacing rate if the atrial hysteresis results in an escape rate more than 30 min^{-1} below the programmed maximum pacing rate. Try decreasing the length of the atrial hysteresis interval or the maximum pacing rate (see Section 9.5.2).

In the VDD(R) mode or when RAP is programmed off, the pacemaker operates as described in Section 9.9.

Note: Vitatron advises you not to program a long atrial hysteresis interval in patients who are susceptible to AF.

9.9.2 Conditional hysteresis

Parameters
⇒ Therapies
⇒ Hysteresis

Range: 0 - (5) - 30 min^{-1}

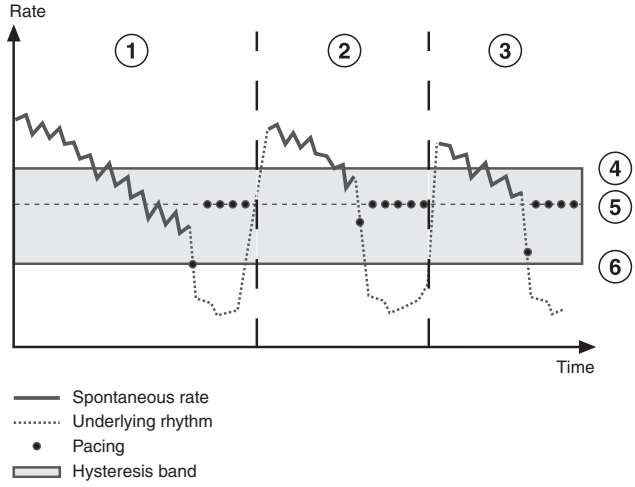
Availability: VVI, VVT, AAI and AAT modes

Conditional hysteresis is standard in the single chamber pacemakers but is not available in dual chamber pacemakers, even when programmed to single chamber modes.

The purpose of applying conditional hysteresis in an area around the active lower pacing rate is to promote the spontaneous rate and to protect patients from dramatic rate drops due to hysteresis.

The programmable hysteresis value is from 0 to 30 min^{-1} below the lower rate. The pacemaker limits the minimum hysteresis rate to 40 min^{-1} (see Figure 73).

Figure 73. Example of conditional hysteresis



1 **Left** - pacing starts at the lower rate minus hysteresis upon a sudden drop in rate.
2 **Middle** - pacing starts at a rate close to the lower rate upon a sudden drop in rate.
3 **Right** - pacing starts at a rate close to the lower rate minus hysteresis upon a sudden drop in rate.
4 LR+15
5 LR
6 LR–hysteresis

Conditional hysteresis is active in a band from 15 min^{-1} above the lower rate to the lower rate minus the programmed hysteresis value.

When programming conditional hysteresis you may observe the following conditions:

If the patient's spontaneous rate is at, or just below the lower rate and suddenly drops, then the pacemaker delivers a first pace at the programmed hysteresis rate, before returning to pacing at the lower rate (see Figure 73 - left).

If the patient's spontaneous rate is between the lower rate +15 min^{-1} and the lower rate, then drops suddenly, the pacemaker starts pacing at an escape rate between the lower rate and lower rate minus the hysteresis.

The escape rate depends on the patient's average rate before pacing occurs.

- If the spontaneous rate is in the top part of the hysteresis band, just below the lower rate +15 min^{-1}, then the escape rate is slightly below the lower rate (see Figure 73 - middle).
- If the spontaneous rate is just above the lower rate, then the escape rate is just above the lower rate minus hysteresis (see Figure 73 - right).

There is a direct linear relationship between the escape rate and the average rate for all rates between the lower rate and the lower rate +15 min^{-1}.

Note: Observing the programmed conditional hysteresis is only possible when the spontaneous rate is between the lower rate and the lower rate minus the hysteresis.

9.10 Interference management

The pacemaker is unable to sense spontaneous events in a chamber if it continuously senses electromagnetic interference (EMI). During periods of interference, the pacemaker paces in the affected chambers.

The pacing rate is dependent on the lower rate, sensor rate and Flywheel settings as well as the programmed settings. Interference behavior may result in pacing the affected chamber until the interference ends. The pacemaker then automatically reverts to its programmed mode of operation.

10 Rate stability

10.1 Introduction

This chapter explains how to use pacing therapies to maintain a stable heart rate, through the management of the consequences of atrial arrhythmias.

In Vitatron dual chamber pacemakers, the management of atrial arrhythmias is based on the classification of the heart rate as physiological (sinus rhythm), or pathological (atrial bradyarrhythmia or atrial tachyarrhythmia). The classification of atrial rhythm is explained in Section 10.2.

The rest of this chapter explains how the pacemaker responds to atrial rhythm. It also describes the therapies aimed at maintaining a stable heart rate.

- During normal sinus rhythm, the pacemaker tracks the atrial rate and paces in the ventricle if necessary (see Section 10.3).
- If the pacemaker detects bradyarrhythmia, it responds by pacing (see Section 10.4).
- If the pacemaker detects an atrial tachyarrhythmia, it avoids tracking the atrial beats in the ventricle by switching to a non-tracking mode (see Section 10.5).
- During episodes of conducted atrial tachyarrhythmia, the pacemaker aims to stabilize the ventricular rate (see Section 10.6).

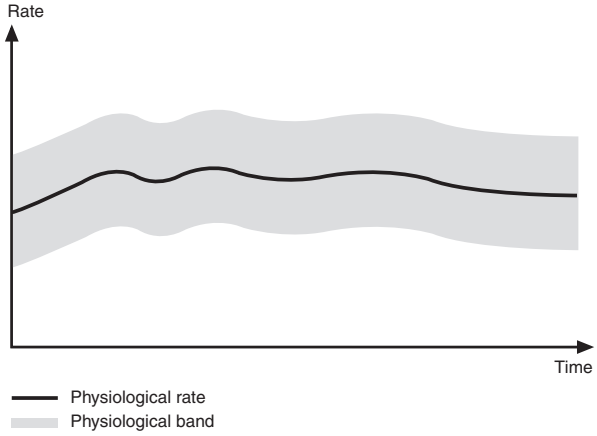
Warning: It is important to prevent far-field R-wave (FFRW) sensing insofar as possible (see Section 6.5.3). An FFRW sense may be falsely interpreted as an atrial event and therefore result in an inappropriate response of the therapies described in this chapter. Vitatron advises you to optimize the atrial blanking periods to ensure the correct detection of atrial tachyarrhythmias, but to prevent the detection of FFRW senses.

10.2 Atrial rhythm classification

The classification of atrial rhythm forms the basis for the classification of diagnostic data in the pacemaker.

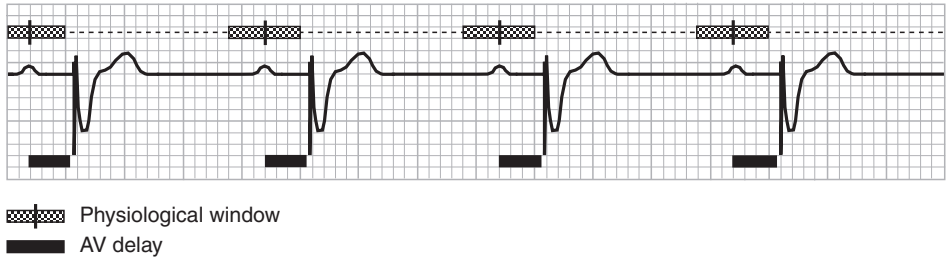
The physiological rate is a moving average of the heart rate during sinus rhythm. To allow for natural variation in heart rate, there is a physiological band that surrounds the physiological rate (see Figure 74). The physiological band extends from 15 min^{-1} above the physiological rate to 15 min^{-1} below the physiological rate.

Figure 74. The physiological band surrounds the physiological rate



In the rest of this chapter, electrocardiogram (ECG) drawings are used to illustrate cardiac rhythm. The physiological band is represented by a physiological window on the ECG (see Figure 75). Atrial events are classified according to whether they fall inside or outside the physiological window.

Figure 75. The physiological window



Atrial senses that fall inside the physiological window are classified as physiological (sinus rhythm). Atrial senses that occur later than the physiological window are classified as atrial bradyarrhythmia. Atrial senses that occur earlier than the physiological window are classified as atrial tachyarrhythmia. Atrial tachyarrhythmias are generally characterized by an abrupt increase in rate.

The physiological rate is not a fixed rate. To stay as close as possible to the sinus rhythm, the pacemaker updates the physiological rate continuously, according to monitored atrial events. The physiological rate moves up or down in steps of 2 min^{-1} per beat. For example, from a rate of 80 min^{-1} the physiological rate may decrease by 10 min^{-1} in about four seconds.

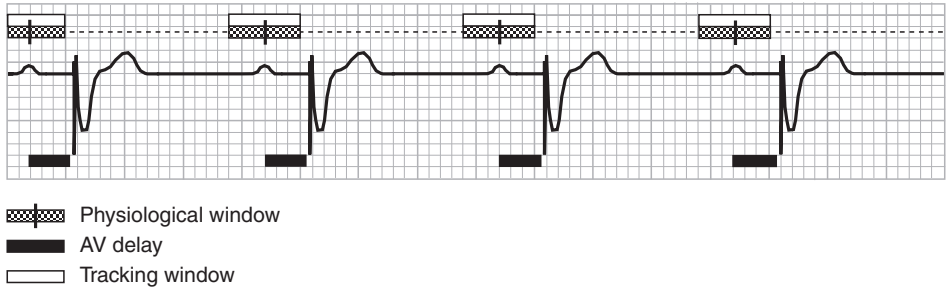
Not all atrial events (sensed and paced) will update the physiological rate. Only physiological atrial events update the physiological rate. Otherwise, the physiological rate decreases gradually towards the pacing rate determined by the active therapy.

10.3 Atrial tracking behavior

The pacemaker responds to sinus rhythm with atrial tracking behavior. After a physiological atrial sense, the pacemaker starts an AV delay. If no ventricular event is sensed before the end of the AV delay, the pacemaker delivers a ventricular stimulus (see Figure 76). For more information about programming the AV delay, refer to Chapter 11.

Classification of atrial rhythm is based on the physiological window, but tracking behavior depends on a tracking window. Tracking occurs when the atrial sense falls within the tracking window. In certain circumstances the tracking window can be longer than the physiological window, as explained in Section 10.4 and Section 10.5.

Figure 76. Atrial tracking in response to sinus rhythm



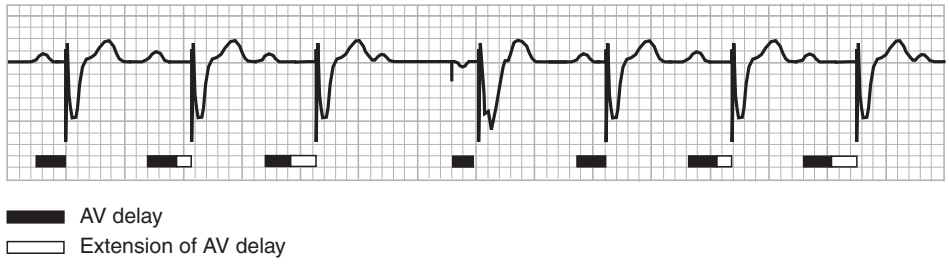
10.3.1 Wenckebach response

If the physiological rate exceeds the maximum tracking rate, the pacemaker responds with Wenckebach behavior to maintain AV synchrony during high atrial rates.

During Wenckebach behavior, the pacemaker extends the AV delay after each atrial sense to allow tracking. The AV delay may be extended, by up to 20% of the maximum tracking rate interval, to maintain tracking. Beyond this limit, atrial events are not tracked. The ventricle is then paced at the lower rate, the sensor-indicated rate or the Flywheel rate (see Section 10.4.1), whichever is the highest (see Figure 77). The next physiological P-wave is then tracked, or atrial pacing occurs at the escape rate.

Wenckebach behavior continues until the atrial rate reaches 1.25 times the maximum tracking rate. At this point, mode switching occurs (see Section 10.5.1).

Figure 77. Wenckebach response to high physiological atrial rates



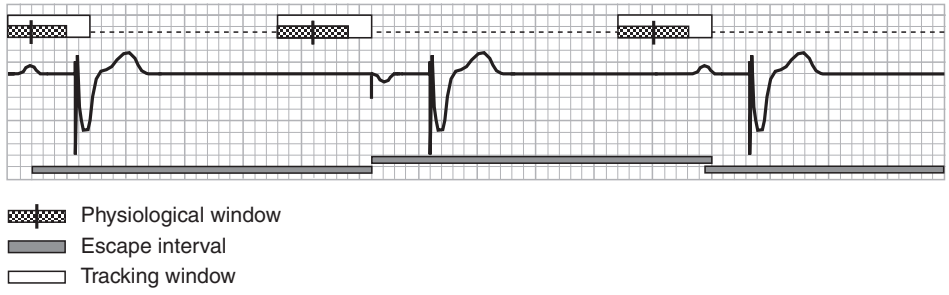
10.4 Bradyarrhythmia

The pacemaker classifies the rhythm as bradyarrhythmia when no atrial event is sensed before the close of the physiological window.

If no atrial event is sensed, the pacemaker starts pacing at the end of the escape interval (see Figure 78, second beat). The length of the escape interval is determined by the lower rate, the sensor-indicated rate or the Flywheel rate, whichever is the highest.

A bradyarrhythmic atrial event sensed later than the physiological window, but within the tracking window, will be tracked (see Figure 78, third beat).

Figure 78. Pacing after the escape interval when Flywheel is off



The Flywheel rate described in Section 10.4.1 is intended to smooth the transition between different rates. For information about programming the lower rate, see Section 9.4. The sensor controls the sensor-indicated rate in rate responsive modes (refer to Chapter 12).

10.4.1 Flywheel

Parameters

⇒ Therapies

⇒ Flywheel

Range: On, Off

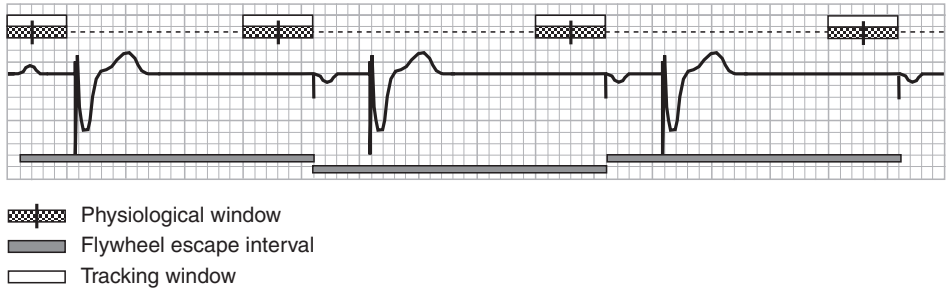
Availability: DDD(R), DDI(R), VDD(R), VVI(R), AAI(R), AAT and VVT modes

The Flywheel mode is intended to avoid sudden drops in heart rate during, for example, episodes of atrial bradycardia.

The escape rate controlled by Flywheel is intended to prevent sudden drops in heart rate. If no atrial event is sensed within the tracking window, Flywheel paces at the close of the tracking window (see Figure 79). It then reduces the pacing rate gradually until it either reaches the spontaneous heart rate, or one of the other escape rates, which then determines the pacing rate.

The speed of decrease depends on the mode. For example, in VDD(R) mode, Flywheel decreases the rate from 100 min^{-1} to 60 min^{-1} in 16 seconds. In all other modes, Flywheel decreases the rate from 100 min^{-1} to 60 min^{-1} in about one minute.

Figure 79. When Flywheel is on it prevents a sudden drop in heart rate



The maximum Flywheel rate is the same as the programmed maximum pacing rate (see Section 9.5.2).

Vitatron recommends programming Flywheel on in the DDD(R) mode for optimal operation of mode switching, and in the case of a pause. In VDD mode, Vitatron recommends programming Flywheel off to avoid loss of AV synchrony.

10.5 Atrial tachyarrhythmia

The dual chamber pacemaker classifies the rate as atrial tachyarrhythmia when it senses atrial events before the start of the physiological window. The pacemaker responds by switching to a non-tracking mode (mode switching). It then attempts to restore AV synchrony as soon as the atrial tachyarrhythmia is over (see Section 10.5.3).

10.5.1 Beat-to-Beat mode switching

Parameters
⇒ Therapies
⇒ Mode Switching…
⇒ Mode Switching

Range: Auto, Fixed

Availability: DDD(R) and VDD(R) modes

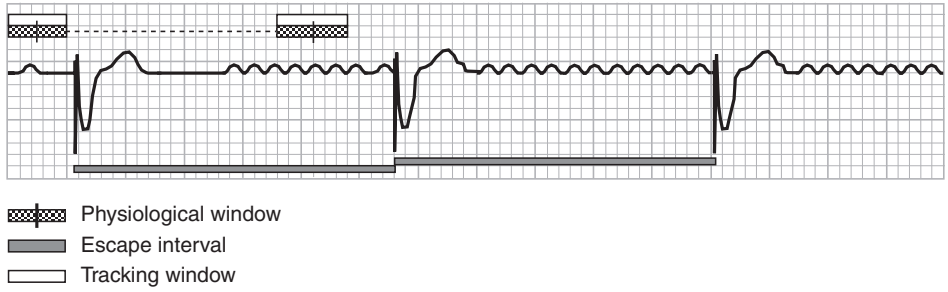
When the pacemaker detects an atrial tachyarrhythmia, it switches to a non-tracking mode immediately. This is called mode switching. The pacemaker then paces the ventricle while monitoring the atrium to detect the return to sinus rhythm. In DDD(R) mode the pacemaker switches to DDI(R) and in VDD(R) mode it switches to VDI(R).

While the atrial tachyarrhythmia lasts, the ventricle is temporarily paced at an escape rate. The escape rate may be the lower rate, the sensor-indicated rate, the Flywheel rate, the tachy fallback rate or the PAC Suppression rate, whichever is the highest.

The response to atrial tachyarrhythmias depends on the programmed settings of mode switching and mode switching sensitivity.

When mode switching is “Auto”, the tracking window opens at the same time as the physiological window (see Figure 80). The pacemaker only tracks atrial events within the tracking window.

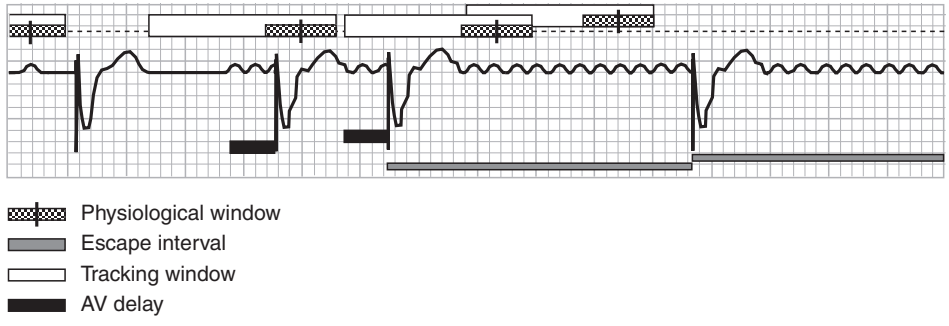
Figure 80. Response to atrial tachyarrhythmias if mode switching is “Auto”



When mode switching is “Fixed”, the tracking window opens earlier than the physiological window. This means that the pacemaker continues tracking atrial rates up to the maximum tracking rate. It stops tracking only after a sudden increase in the atrial rate above the maximum tracking rate.

The response to variations in the atrial rate and a sudden increase in rate if mode switching is “Fixed”, is shown in Figure 81. (Note that atrial events sensed within the AV delay are blanked (see Section 9.7)).

Figure 81. Response to atrial tachyarrhythmias if mode switching is “Fixed”



10.5.2 Mode switching sensitivity

Parameters
⇒ Therapies
⇒ Mode Switching…
⇒ Mode Switching Sensitivity

Range: Standard, Moderate

Availability: DDD(R) and VDD(R) modes

You can adjust the size of the tracking window to suit patients with a high rate variability by programming the mode switching sensitivity. When mode switching is programmed to “Auto” and mode switching sensitivity is programmed to “Moderate”, the pacemaker allows greater variations in the atrial rate before switching mode.

When the mode switching sensitivity is “Standard”, the tracking window opens 15 min^{-1} earlier than the physiological rate (see Figure 82). When the mode switching sensitivity is “Moderate”, the tracking window opens 30 min^{-1} earlier than the physiological rate (see Figure 83). The close of the tracking window is not affected by the mode switching sensitivity setting.

Mode switching does not occur if the tracking window opens earlier than 85 min^{-1} with mode switching sensitivity “Standard”, or 95 min^{-1} with mode switching sensitivity “Moderate”.

An example of how the pacemaker mode switches in response to an atrial tachyarrhythmia with mode switching sensitivity “Standard” and mode switching “Auto”, is shown in Figure 82. In the same situation, with mode switching sensitivity “Moderate” and mode switching “Auto”, the pacemaker does not mode switch (see Figure 83).

Figure 82. Response to atrial tachyarrhythmia if mode switching sensitivity is “Standard”.

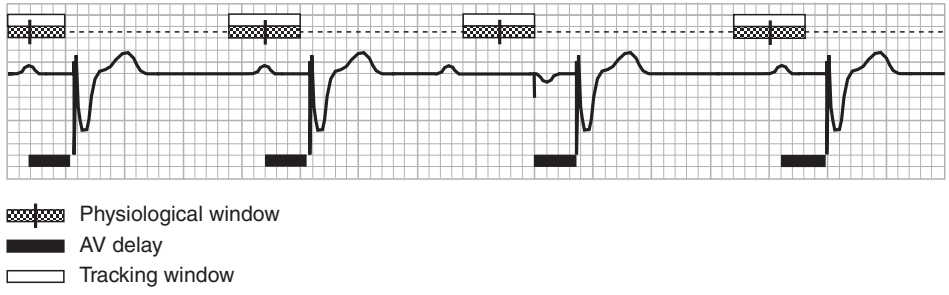
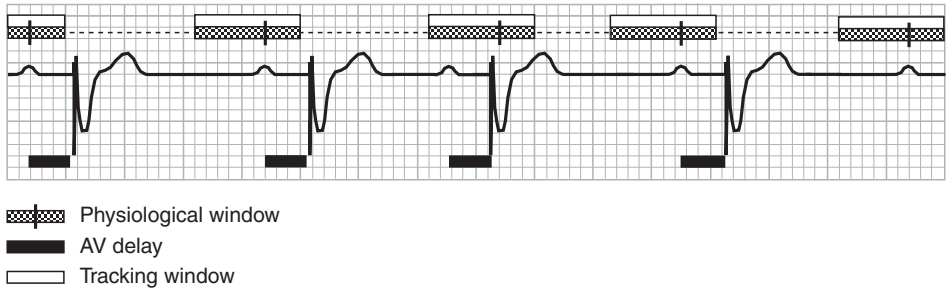


Figure 83. Response to atrial tachyarrhythmia if mode switching sensitivity is “Moderate”.



10.5.3 Restoring AV synchrony

Passive resynchronization – After a mode switch, the pacemaker continues to monitor the atrial rate. When the atrial rate falls within the tracking window again, the pacemaker switches back to atrial tracking (DDD(R) or VDD(R) mode).

Active resynchronization – If loss of AV synchrony occurs, for example due to mode switching, the pacemaker attempts to restore AV synchrony actively by delivering an atrial synchronization pace (ASP) just before the ventricular pace (see Figure 82). See Section 11.5 for a description of how to program the ASP interval.

10.5.4 Tachy fallback rate

Parameters
- ⇒ Therapies
  - ⇒ Tachy Fallback Rate…
    - ⇒ Tachy Fallback Rate

Range: Off, 45 - (5) - 100 min^{-1}

Availability: DDD(R) and VDD(R) modes

During an episode of atrial tachyarrhythmia, the pacemaker’s lower rate may be too slow for the patient to maintain normal daily activities. The tachy fallback rate limits the rate decrease by pacing at a rate that is higher than the lower rate.

When the pacemaker detects the end of the atrial tachyarrhythmia, in VDD(R) mode the tachy fallback rate immediately switches back to the pacing rate of the active therapy, in order to avoid loss of AV synchrony. In DDD(R) mode the tachy fallback rate gradually decreases towards the lower rate. For example, from an initial tachy fallback rate of 85 min^{-1} the rate decreases to 60 min^{-1} in about one minute.

Vitatron advises you to program the tachy fallback rate to a rate adapted to the daily activities of the patient. The tachy fallback rate is not necessary in rate responsive modes.

10.5.5 Night tachy fallback rate

Parameters
⇒ Therapies
⇒ Tachy Fallback Rate…
⇒ Night Tachy Fallback Rate

Range: 40 - (5) - 100 min^{-1}

Availability: DDD(R) and VDD(R) modes

Vitatron advises you to program the night tachy fallback rate, to avoid unsuitably high ventricular pacing rates during atrial tachyarrhythmias at night.

At the programmed start of night time the tachy fallback rate decreases gradually towards the night tachy fallback rate. At the programmed end of night time, the night tachy fallback rate increases gradually towards the tachy fallback rate.

See Section 9.4 for a description of how to program the start and end of night time and how to reprogram the pacemaker time for daylight saving time or if the patient moves to a different time zone.

Note: Night tachy fallback rate and night lower rate use the same start and end of night times. Therefore, changing the start or end of night time for one of these parameters automatically changes the settings for the other parameter.

10.6 Ventricular Rate Stabilization

Parameters
⇒ Therapies
⇒ V Rate Stabilization…
⇒ V Rate Stabilization

Range: On, Off

Availability: DDD(R) and VVI(R) modes

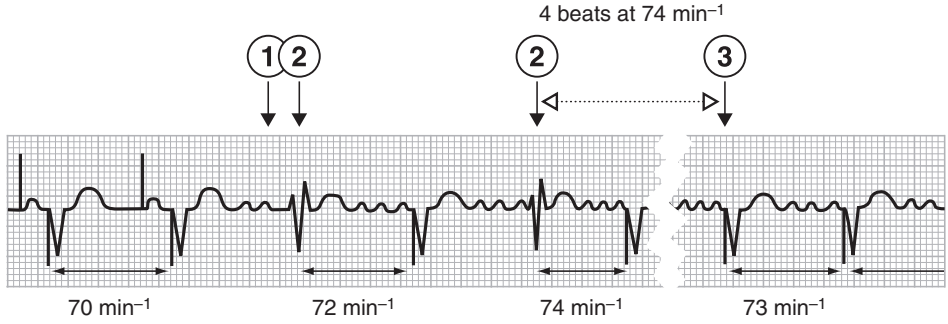
Ventricular Rate Stabilization (VRS) aims to reduce the symptoms of conducted atrial fibrillation and flutter by regulating the ventricular rate during episodes of atrial tachyarrhythmia. By setting the pacing rate around the underlying mean ventricular rate, it eliminates very long VV intervals and significantly reduces the occurrence of very short VV intervals.

This therapy is appropriate for two groups of patients. In dual chamber mode (DDD(R)) it is suitable for patients with paroxysmal atrial fibrillation. In single chamber mode (VVI(R)) it is suitable for patients with permanent atrial fibrillation.

Dual chamber mode – In dual chamber mode, VRS is activated when the pacemaker detects the start of an atrial tachyarrhythmia episode (see Section 10.5). The pacemaker stabilizes the ventricular rate by first setting the pacing rate slightly below the underlying average ventricular rate (see Figure 84). The pacing rate subsequently increases after every sensed ventricular event, but does not increase above the maximum therapy rate (see Section 10.6.1). When no ventricular event is sensed, the pacemaker decreases the pacing rate until it senses another ventricular event or it reaches the lower rate limit.

When the pacemaker detects the end of the atrial tachyarrhythmia episode (after 6 beats without atrial tachycardia senses), it inactivates VRS. The pacing rate then continues to decrease at a fixed rate (for example, a rate decrease from 120 min^{-1} to 100 min^{-1} takes approximately 45 seconds).

Figure 84. VRS response to an atrial tachyarrhythmia in DDD(R) mode



1 An atrial tachyarrhythmia is detected.
2 The pacing rate is increased after each spontaneous ventricular event.
3 When no ventricular event is sensed, the pacing rate decreases.

Notes:

- VRS cannot be programmed to “On” when mode switching is “Fixed” (see Section 10.5.1).
- When VRS is active, adaptive AV delay and AV delay extension are disabled in order to limit rate variations.
- When atrial tracking or pacing occurs while VRS is active, the AV delay is set to 45 ms (sensed atrial event) or 80 ms (paced atrial event).
- As VRS increases the ventricular rate and physiological window, sensed atrial events may be blanked or sensed atrial events below the maximum tracking rate may appear in the physiological window. This may cause the pacemaker to falsely interpret the atrial rate as physiological and may inactivate VRS too early.

Single chamber mode – In single chamber mode (VVI(R)), VRS is continuously active when it is programmed on. Because the VVI(R) mode does not include sensing in the atrium, continuous atrial tachyarrhythmia is assumed. The pacemaker stabilizes the ventricular rate by increasing the pacing rate after two consecutive sensed ventricular events. The pacing rate subsequently increases after every sensed ventricular event, but does not increase above the maximum therapy rate (see Section 10.6.1). After a ventricular paced event, the pacemaker decreases the pacing rate until it senses another ventricular event or it reaches the lower rate limit.

Note: VRS cannot be programmed to “On” when conditional hysteresis (see Section 9.9.2) is programmed to a value greater than 0 min^{-1}.

10.6.1 Maximum therapy rate

Parameters
⇒ Therapies
⇒ V Rate Stabilization…
⇒ Max. Therapy Rate

Range: 70 - (10) - 120 min^{-1}

Availability: DDD(R) and VVI(R) modes

The maximum therapy rate is the maximum rate to which VRS and the AF prevention therapies (see Chapter 13) can increase the pacing rate.

11 AV synchrony

11.1 Introduction

AV synchrony refers to the precise timing of atrial and ventricular contractions, to allow for optimum ventricular filling. In patients with AV conduction disorders, dual chamber pacing is an effective way to maintain or restore AV synchrony. The pacemaker is designed to mimic as closely as possible the physiological behavior of the heart. Each atrial event within the tracking window (see Section 10.3) starts an AV delay. The AV delay is the time between an atrial event and the subsequent ventricular stimulus. During the AV delay the atrial channel is blanked.

The Vitatron dual chamber pacemakers feature the following options for maintaining or restoring AV synchrony:

- Sensed and paced AV delays are separately programmable, to compensate for the time interval between the spontaneous atrial contraction and sensing by the pacemaker (see Section 11.2).
- Rate adaptive AV delay shortens the AV delay when the rate increases. The pacemaker reproduces the physiological behavior of the healthy heart, which shortens the PR interval as the sinus rate increases (see Section 11.3).
- Refined Ventricular Pacing (RVP) promotes spontaneous AV conduction by extension of the AV delay after one sensed, or a series of paced, ventricular events (see Section 11.4).
- Atrial synchronization pacing is intended to restore AV synchrony as soon as possible. Loss of AV synchrony may occur due to various causes such as: atrial tachyarrhythmias, premature atrial contractions (PACs) or retrograde conduction (see Section 11.5).
- Retrograde conduction management is intended to prevent retrograde conduction and persistent pacemaker mediated tachycardias (PMTs) (see Section 11.6).

11.2 Paced and sensed AV delay

11.2.1 Paced AV (PAV) delay

Parameters
⇒ Therapies
⇒ Max. PAV Delay…
⇒ Max. Paced AV Delay

Range: 80 - (5) - 300 ms

Availability: DDD(R), DDI(R) and DOO modes

The maximum paced AV delay is the AV delay after an atrial stimulus while pacing at the lower rate.

11.2.2 Sensed AV (SAV) delay

Parameters
⇒ Therapies
⇒ Max. SAV Delay…
⇒ Max. Sensed AV Delay

Range: 45 - (5) - 260 ms

Availability: VDD(R) mode

The maximum sensed AV delay is the AV delay after an atrial sense, while sensing close to the lower rate. In VDD(R) mode, the sensed AV delay is programmable because the atrium is not paced in this mode. In DDD(R) mode, the sensed AV delay is derived from the paced AV delay by subtracting the programmed sensed/paced AV offset from the programmed paced AV delay.

11.2.3 Sensed/paced AV offset

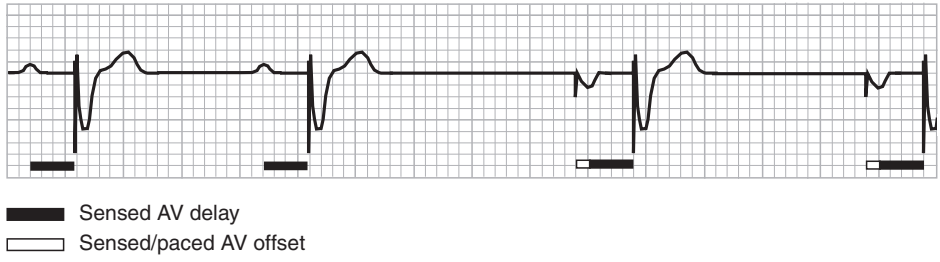
Parameters
- ⇒ Therapies
  - ⇒ Max. PAV Delay…
    - ⇒ Sensed/Paced AV Offset

Range: 20 - (5) - 50 ms

Availability: DDD(R) mode

The sensed/paced AV offset is the programmable difference between the sensed and paced AV delay, as shown in Figure 85. When the pacemaker senses a spontaneous atrial event it starts the AV delay after the atrial depolarization has already started. When the pacemaker delivers an atrial stimulus it starts the AV delay before the atrial contraction has started. To compensate for this difference, the paced AV delay must be programmed longer than the sensed AV delay.

Figure 85. Sensed/paced AV offset



11.3 Adaptive AV delay

Parameters
- ⇒ Therapies
  - ⇒ Max. PAV Delay…
    - ⇒ Adaptive AV Delay

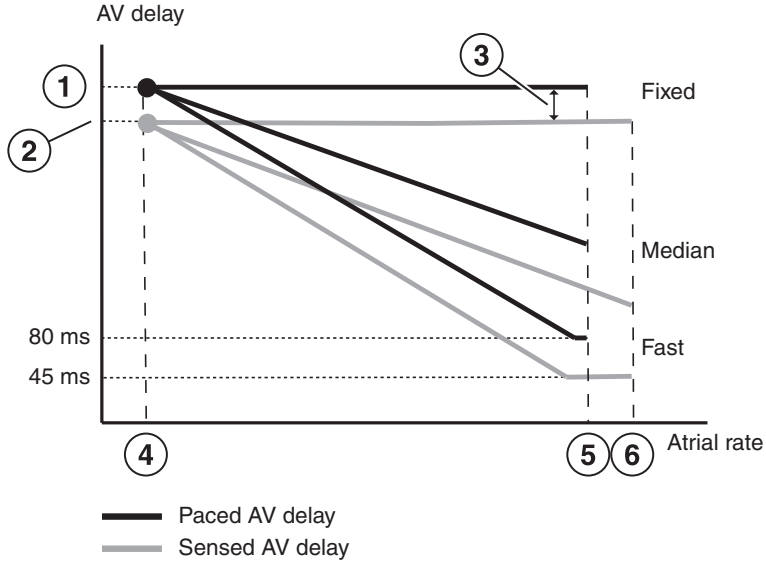
Range: Off, Median, Fast

Availability: DDD(R), DDI(R) and VDD(R) modes

The programmed setting determines by how much the (rate) adaptive AV delay shortens as a result of an increasing atrial rate (see Figure 86). If adaptive AV delay is programmed off, the sensed and paced AV delay are fixed at the programmed values. If adaptive AV delay is programmed to “Median”, the sensed and paced AV delay shorten by 5 ms per 10 min^{-1} rate increase. If adaptive AV delay is programmed to “Fast”, the sensed and paced AV delay shorten by 10 ms per 10 min^{-1} rate increase.

The sensed AV delay will never be shorter than 45 ms and the paced AV delay will never be shorter than 80 ms. The programmed sensed/paced AV offset is maintained for all atrial rates.

Figure 86. Relationship between atrial rate and AV delay



1 Maximum paced AV delay
2 Maximum sensed AV delay
3 Sensed/paced AV offset
4 Lower rate
5 Maximum pacing rate
6 Maximum tracking rate

Notes:

- The minimum sensed AV delay can slightly increase during a programmer session and the initial interrogation of the pacemaker.
- The adaptive AV delay may not be effective after an atrial synchronization pace (see Section 11.5), since the AV delay may have been shortened to fit in the atrial synchronization pace.
- Independent of the programming of adaptive AV delay, the AV delay may start shortening at higher pacing rates to assure the delivery of ventricular safety paces (see Section 9.8) at high rates.
- The atrial blanking period for atrial tracking is determined by the AV delay and the programmed atrial blanking period on VS or VP (see Section 9.7). If this period exceeds the maximum tracking rate interval, atrial events with higher rates may be blanked. Vitatron suggests balancing the AV delay (possibly with AV delay shortening) and the atrial blanking period on VS or VP against the choice of the maximum tracking rate.

11.4 Refined Ventricular Pacing (RVP)

Parameters
⇒ Therapies
⇒ Refined Pacing... Ventricular
⇒ Refined Ventricular Pacing

Range: On, Off

Availability: DDD(R), DDI(R), VDD(R)

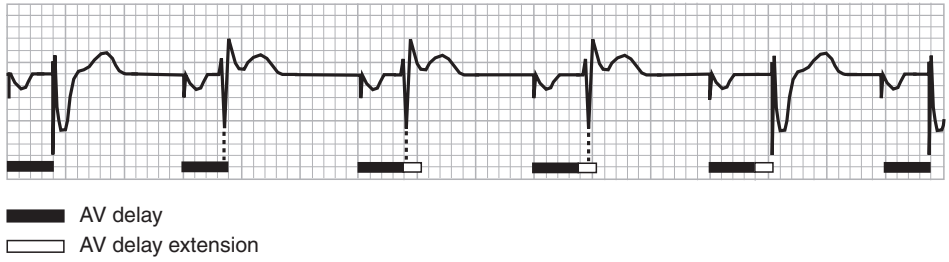
Parameters
⇒ Therapies
⇒ Refined Pacing... Ventricular
⇒ AV Delay Extension

Range: 60 - (20) - 120 ms

Availability: DDD(R), DDI(R), VDD(R)

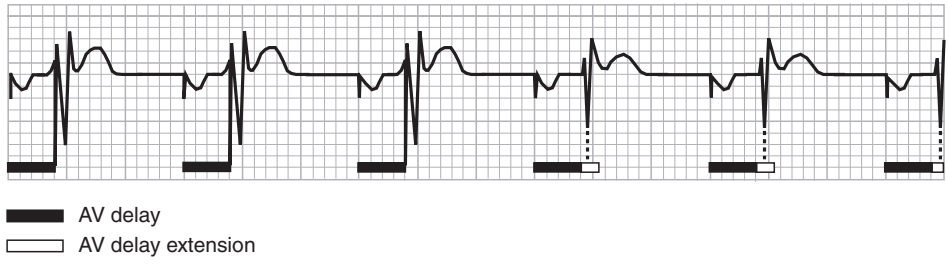
When RVP is programmed on, the pacemaker extends the AV delay with the programmed AV delay extension if the previous beat revealed spontaneous AV conduction (see Figure 87). If the pacemaker does not sense a ventricular event during the extended AV delay, it returns to the normal AV delay. The normal AV delay is the AV delay based on the atrial rate (when adaptive AV delay is set to “Median” or “Fast”) or the programmed sensed/paced AV delay (when adaptive AV delay is set to “Off”).

Figure 87. AV delay extension is based on the previous ventricular event



RVP (if programmed on) also includes a scanning algorithm, which scans for spontaneous AV conduction. After a series of paced ventricular beats, the pacemaker automatically extends the AV delay with the programmed AV delay extension for a single beat (see Figure 88). If no ventricular event is sensed during the extended AV delay, the pacemaker returns to the normal AV delay. If a spontaneous contraction is sensed during the extended AV delay, the pacemaker continues to operate with the extended AV delay until the next paced ventricular beat.

Figure 88. AV delay extension after a series of paced ventricular events



The scanning algorithm counts the number of paced ventricular beats that must occur before the AV delay extension is applied. This number depends on the programmed AV delay extension setting, as shown in Table 8.

Table 8. AV delay extension

Extension setting (ms)	AV scan (number of paced ventricular events)
60	30
80	30
100	60
120	120

11.5 Atrial synchronization pace (ASP) interval

Parameters
⇒ Therapies
⇒ Mode Switching…
⇒ ASP Interval

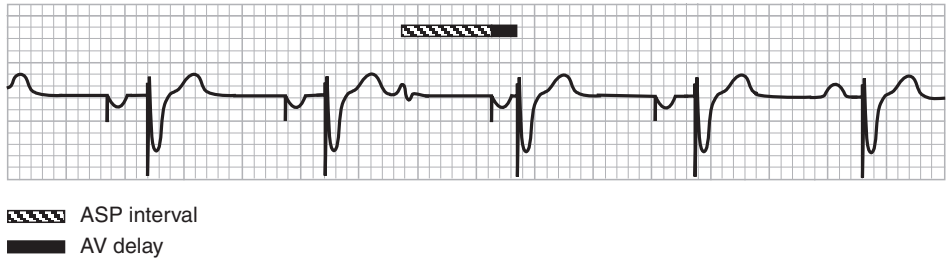
Range: 250 - (5) - 400 ms

Availability: DDD(R) and DDI(R) modes

Atrial synchronization pacing actively restores AV synchrony. An ASP is delivered when the pacemaker anticipates continuation of AV synchrony after the ASP. If AV synchrony is lost (due to, for example, a PAC, a retrograde P-wave or Wenckebach behavior (see Section 10.3.1), a ventricular pace is scheduled at the end of the ventricular escape interval. The ASP is delivered one AV delay before the scheduled ventricular pace, respecting the programmed ASP interval. To enable the delivery of an ASP, the pacemaker can shorten the AV delay to a minimum of 80 ms and extend the ventricular escape interval by a maximum of 65 ms. In the case of retrograde conduction, the ventricular escape interval can be extended by a maximum of 250 ms.

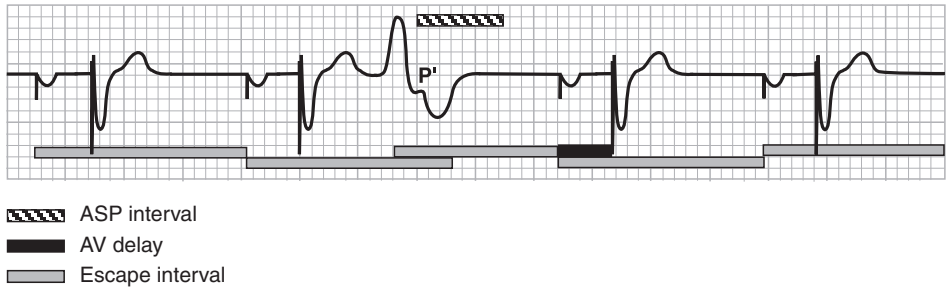
The reaction of the pacemaker to a PAC and the immediate restoration of AV synchrony by delivery of an ASP, are shown in Figure 89.

Figure 89. Pacemaker reaction to a PAC



The reaction of the pacemaker to a premature ventricular contraction (PVC) is shown in Figure 90. When programmed to DDD(R) or DDI(R) mode the pacemaker extends the ventricular escape interval by the AV delay after a PVC in an attempt to track the next atrial event. When the PVC is followed by a (retrograde) P-wave, AV synchrony is lost (mode switching) and the pacemaker delivers an ASP to restore the AV synchrony immediately.

Figure 90. Pacemaker reaction to a PVC with retrograde P-wave



11.6 Retrograde conduction and PVC management

Retrograde conduction may occur when AV synchrony is lost. For example, a PVC may be conducted to the atrium as a retrograde P-wave. Tracking this retrograde P-wave may cause the pacemaker to deliver a ventricular stimulus after the AV delay. Retrograde conduction of this ventricular depolarization can lead again to a retrograde P-wave and a pacemaker mediated tachycardia (PMT) may be induced. A PMT results in ventricular pacing up to the maximum tracking rate.

Vitatron dual chamber pacemakers have several algorithms to manage or prevent retrograde conduction and persistent PMTs and to restore AV synchrony as soon as possible:

- Post-PVC response extends the escape interval once after a PVC to mimic a compensatory pause, which is especially important in VDD(R) mode (see Section 11.6.1).
- PVC synchronous atrial stimulation paces the atrium immediately after a PVC to accelerate resynchronization and to prevent retrograde conduction by making the atrium refractory (see Section 11.6.2).

- Automatic detection identifies retrograde conduction if it occurs (see Section 11.6.3).
- Mode switching avoids tracking of retrograde P-waves (see Section 11.6.4), thereby preventing PMTs (see Section 11.6.5).

11.6.1 Post-PVC response

Parameters
⇒ Therapies
⇒ PVC Response…
⇒ Post-PVC Response

Range: On, Off

Availability: DDD(R), DDI(R) and VDD(R) modes

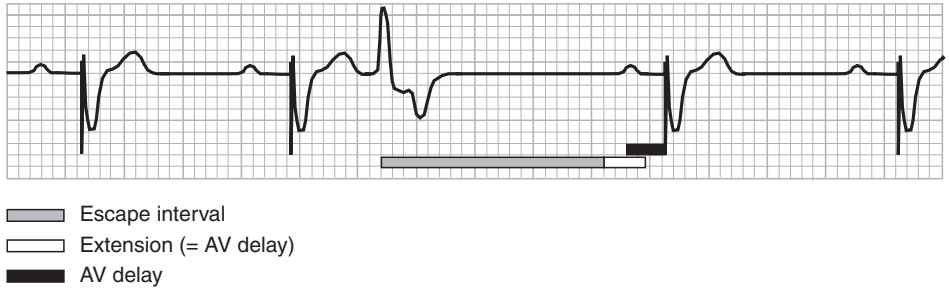
A PVC is defined as a sensed ventricular event without a preceding atrial event. When post-PVC response is programmed on, the pacemaker automatically extends the escape interval after a PVC, to facilitate the detection of spontaneous atrial contractions and a passive return to AV synchrony (VDD(R) mode). This extension is equal to the paced AV delay (DDD(R) and DDI(R) mode) or the sensed AV delay (VDD(R) mode). The extension is only applied to the first PVC in a series.

During the post-PVC extension the following situations may occur, in the DDD(R) and DDI(R) modes:

- The PVC is followed by a retrograde P-wave and AV synchrony must be restored actively by delivering an ASP (see Section 11.5).
- A sinus event is sensed in the tracking window and is therefore tracked (not in DDI(R) mode).
- An atrial event is sensed before the tracking window and is therefore blocked, depending on the mode switching setting (see Section 10.5). An ASP is delivered before the ventricular pace.
- No atrial event is sensed and therefore an atrial stimulus is given at the end of the escape interval.

In the VDD(R) mode, the extended ventricular escape interval is intended to allow sensing of the next atrial event, as shown in Figure 91. If an atrial event is sensed before the scheduled ventricular stimulus it is tracked with the appropriate AV delay, thereby restoring AV synchrony.

Figure 91. Extended escape interval after a PVC allows sensing of the next spontaneous P-wave



11.6.2 PVC synchronous atrial stimulation

Parameters
⇒ Therapies
⇒ PVC Response…
⇒ PVC Synchronous Astim

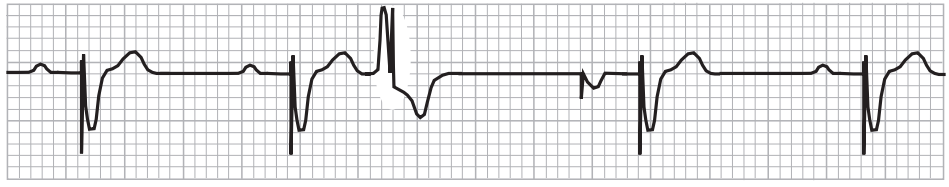
Range: On, Off

Availability: DDD(R) and DDI(R) modes

PVC synchronous atrial stimulation can prevent retrograde conduction after a PVC. If PVC synchronous astim is programmed on, the detection of a PVC triggers an atrial stimulus (see Figure 92). The atrial stimulus starts an atrial contraction and makes the atrium refractory, which blocks retrograde conduction.

The PVC synchronous atrial stimulus is only given at the first PVC in a series and only if the resulting atrial interval exceeds the programmed ASP interval (see Section 11.5).

Figure 92. PVC synchronous atrial stimulation blocks retrograde conduction



11.6.3 Automatic detection of retrograde conduction

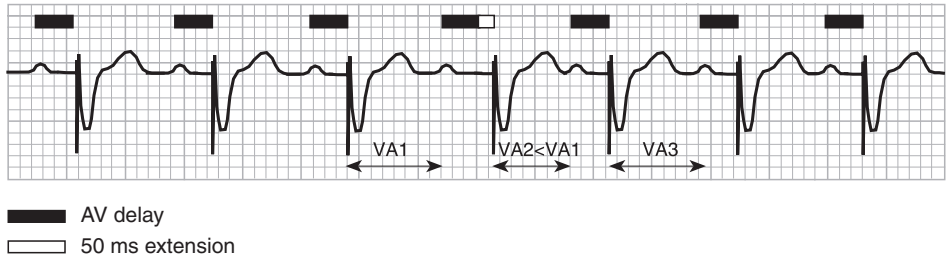
In DDD(R), DDI(R) and VDD(R) mode, during continuous atrial sensing and ventricular pacing (atrial tracking), the pacemaker periodically carries out an automatic retrograde conduction test. This enables the pacemaker to discriminate between atrial rhythm and retrograde conducted P-waves. The test is carried out if the measured VA interval is less than 450 ms.

During the test the pacemaker analyzes the VA interval, to check if the ventricular contraction is conducted to the atrium as a retrograde P-wave. The stability of the VA interval is tested by temporarily lengthening the AV interval. If the VA interval does not change when the AV interval is extended, retrograde conduction is suspected.

The retrograde conduction test is carried out three times and retrograde conduction is confirmed if the VA interval does not change in each of the three tests.

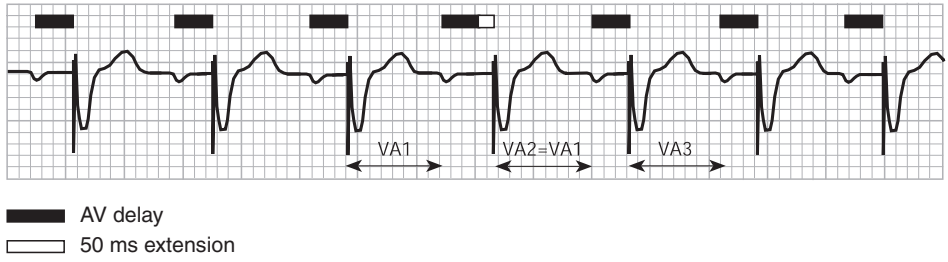
An example of an automatic retrograde conduction test during sinus rhythm is shown in Figure 93.

Figure 93. Automatic retrograde conduction test during sinus rhythm



An example of an automatic retrograde conduction test during a PMT caused by retrograde conduction is shown in Figure 94.

Figure 94. Automatic retrograde conduction test during PMT



11.6.4 Terminating retrograde conduction

When tracking of retrograde P-waves is confirmed by the retrograde conduction test, the pacemaker automatically changes to a non atrial tracking mode and tries to restore AV synchrony as soon as possible through ASP (see Section 11.5).

After the mode switch, the pacemaker continues to monitor the VA interval and returns to the atrial tracking mode if retrograde conduction is no longer present.

The following situations indicate that retrograde conduction has ended:

- The VA interval is longer than 450 ms.
- An ASP is delivered.
- Multiple atrial events are sensed in one ventricular interval, but potential far-field senses (VA interval is shorter than 150 ms) are excluded.
- Three consecutive ventricular events are sensed.
- No atrial events are sensed for three successive ventricular cycles (VDD(R) mode only).

11.6.5 Preventing retrograde conduction and PMTs

In AV synchronous mode, retrograde conduction may occur in the situations listed below. Follow the instructions to prevent retrograde conduction.

- Atrial undersensing: investigate the P-wave histogram or measure the P-wave amplitude and increase the atrial sensitivity, if necessary.
- Atrial oversensing:
  - myopotential sensing on the atrial lead: change the sensing polarity from unipolar to bipolar or decrease the atrial sensitivity, if possible
  - far-field R-wave (FFRW) sensing: make sure that the atrial blanking period is not too short. Far-field R-waves are interpreted as premature atrial events.
- Atrial non-capture: perform a threshold test and increase the pulse amplitude or duration, if necessary.
- A long AV interval: decrease the programmed maximum sensed or paced AV interval.

Prevent retrograde conduction by programming PVC synchronous atrial stimulation to “On”. Programming a short ASP interval increases the possibility that AV synchrony is restored.

Programming mode switching to “Auto” (see Section 10.5.1) reduces the risk of PMT initiation. In this case, a retrograde P-wave is classified as a premature atrial event because it is sensed before the tracking window. This causes the pacemaker to switch to a non atrial tracking mode, which effectively prevents PMTs.

12 Rate response

12.1 Introduction

Many pacemaker patients suffer from some form of chronotropic incompetence, mainly caused by cardiac disorders. Rate responsive pacing is designed to restore the heart's natural response to physical activity. The activity sensor of the rate responsive pacemaker detects and measures body movements. An increased activity signal results in increased pacing rates. Rate response becomes active by programming the pacemaker to a rate responsive mode (XXXR).

This chapter describes the following rate response related items:

- The activity sensor of the rate responsive pacemakers and the programmable activity threshold (see Section 12.2).
- The slope (change in pacing rate) of the activity signal and an explanation of how it is calculated (see Section 12.3).
- Daily Learning, the automatic adjustment of the activity slope (see Section 12.4).
- Fast Learning, the immediate adjustment of the activity slope (see Section 12.5).
- Acceleration and deceleration, the programmable increase and decrease of the pacing rate (see Section 12.6).

12.2 Activity sensor

The activity sensor responds to physical activity. An accelerometer is a specific type of activity sensor that responds to body movements ("accelerations") along the anterior-posterior axis (back and forth motion). The activity sensor converts physical motion into an electrical signal proportional to the level of movement. Each time the activity sensor signal exceeds a programmable limit (activity threshold) an accelerometer count is generated.

12.2.1 Activity threshold

Parameters
⇒ Therapies
⇒ Sensor…
⇒ Activity Threshold

Range: Low, Low/Medium, Medium, Medium/High, High

Availability: DDDR, DDIR, VDDR, VVIR and AAIR modes

The sensitivity of the activity sensor is programmable by the activity threshold parameter. Programming the activity threshold from “High” to “Low” increases the sensitivity of the activity sensor to body movements.

12.2.2 Optimizing the activity threshold

The default activity threshold setting “Medium” is designed to result in effective activity sensing for most patients. Program the activity threshold to a higher setting if the number of accelerometer counts at rest is too high. Program the activity threshold to a lower setting if the number of accelerometer counts at low exercise levels is too low, as this results in an insufficient rate increase.

The accelerometer counts graph of the 30-minute Holter (see Section 7.8.1) and the number of “Rest” and “Exercise” counts in the Sensor window (see Section 7.8.2) are helpful in optimizing the activity threshold. Check the average number of accelerometer counts at rest, at a low exercise level (slow walking for example) and a high exercise level (fast walking). Optimize the activity threshold if the average number of accelerometer counts at rest is higher than two (per 10 seconds) or does not increase considerably at increasing exercise levels. Repeat the test if the activity threshold is reprogrammed.

The average sensor rate shown in the Sensor window also gives an indication of whether the activity sensor is reacting properly to patient activity.

12.3 Slope

Parameters
⇒ Therapies
⇒ Sensor…
⇒ Sensor Slope

Range: Auto, Fixed

Availability: DDDR, DDIR, VDDR, VVIR and AAIR modes

The activity slope is defined as the change in pacing interval caused by a change in accelerometer counts. The relationship between the number of accelerometer counts and pacing interval is linear. The number of accelerometer counts is at its lowest, usually zero, at rest. The pacing rate should then be at the programmed lower rate. At maximum exercise the number of accelerometer counts is at its highest and the pacemaker should be pacing at the programmed maximum pacing rate. The current slope is stored in the pacemaker, providing a reference value for the number of accelerometer counts at each pacing interval.

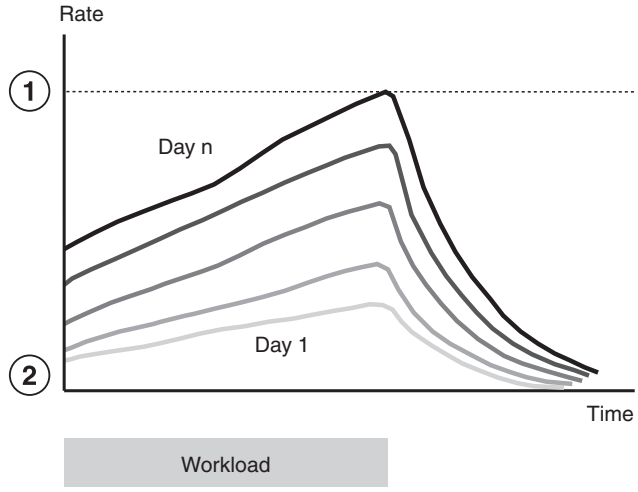
When the slope is programmed to “Auto”, the pacemaker automatically adjusts the activity slope, based on the daily activities of the patient. This is called daily learning (see Section 12.4). After a few weeks this results in slope settings such that the pacemaker paces at the lower rate if the patient is at rest and at the maximum pacing rate during the patient’s maximum exercise. Vitatron advises you to program the slope to “Auto”, since the pacemaker then continuously adapts the rate response to the patient. Changing patient conditions will then be reflected in the rate response. As the slope setting “Auto” is designed for the pacemaker to pace at the programmed maximum pacing rate when the number of accelerometer counts is at highest, it is important to select this rate carefully. A setting which is too high could result in symptoms such as palpitations or angina complaints. When selecting the maximum pacing rate, consider the patient’s activity level and medical condition, including age and symptoms of angina and heart failure.

When the slope is programmed to “Fixed”, the pacemaker fixes the activity slope at its current value. It does not adapt further to the patient’s daily activities. In this case, it is recommended to use the fast learning procedure (see Section 12.5).

12.4 Daily learning

When the slope is programmed to “Auto” the activity slope is automatically adjusted by a daily learning process. The automatic slope adaptation algorithm measures and adjusts the slope at the maximum pacing rate. The objective is to pace at the maximum pacing rate whenever the patient reaches the maximum daily exercise level. This is achieved by correlating the daily maximum number of accelerometer counts to pacing at the maximum pacing rate. The effects of daily learning on the rate response are shown in Figure 95. Normally it takes some weeks for the slope to reach its optimal values. After this only minor variations occur.

Figure 95. The effects of Daily Learning (automatic slope adaptation) on the rate response



1 Maximum pacing rate
2 Lower rate

Daily learning is especially beneficial for patients who have just received their first pacemaker or have been upgraded from a non rate responsive pacemaker. Upon delivery, the slope is such that the rate gradually increases until a moderate value is reached. This allows the patients to gradually become accustomed to their newly restored chronotropic competence (see Figure 95).

Notes:

- When the maximum pacing rate is reprogrammed, the slope may not immediately achieve optimal values. Daily learning continues to adjust the slope.
- When the mode is reprogrammed from a rate responsive mode to a non rate responsive mode, the activity slope remains stored. When a rate responsive mode is programmed again, the pacemaker uses the stored activity slope.
- Vitatron advises you to perform the fast learning procedure if the patient's condition has changed considerably since the previous follow-up session.

12.5 Fast learning

Parameters
⇒ Fast Learn

Availability: DDDR, DDIR, VDDR, VVIR and AAIR modes

While daily learning only allows small adaptations of the slope on a day-to-day basis, the fast learning procedure sets the slope for the accelerometer immediately. At delivery, the slope of the accelerometer is such that the pacing rate increases only gradually until it reaches a moderate value. The fast learning procedure can be used to obtain an adequate rate response immediately. Use the fast learning procedure if the patient is already used to a rate responsive pacemaker.

The slope should preferably be programmed to "Auto", since the pacemaker then continuously adapts the slope to the patient's daily activities. If special circumstances require the slope to be programmed to "Fixed", the fast learning procedure is recommended since in this case the slope does not adapt to the patient's daily activities.

The fast learning procedure involves an exercise measurement. This procedure is carried out using the programmer.

Notes:

- The exercise measurement is stopped if the programming head is repositioned over the pacemaker at any time during the procedure.
- If the programming head is not positioned over the pacemaker within one hour of the start of the exercise test, the pacemaker stops the fast learning procedure and reverts to its original slope settings. However, if the Fast Learn window has not been left, the measurement results of the exercise test are still available and can be read out and processed by positioning the programming head over the pacemaker.
- The exercise test must be completed or stopped before the programmer is used to perform a follow-up session with another patient.

12.5.1 Exercise measurement

The Fast Learn window shows an area labelled “Test Status”. All the sequential events executed during the procedure are shown here. A series of dots indicates that a particular phase is being executed; the appearance of the word “Done” indicates that it has been completed.

Setting up the exercise test – To start the setup procedure, make sure the programming head is correctly positioned, and press [Start]. During the exercise test setup the pacemaker makes all necessary preparations, for example setting a higher slope to reach the maximum pacing rate more easily. The programmer screen indicates when the setup procedure is finished.

Performing the exercise test – Remove the programming head to continue with the exercise measurement. The patient must now perform an exercise stress test that reflects the patient’s **maximum** exercise during normal daily activities. This exercise test can be for example, a hall walk test, a six-minute walking test or a treadmill test. The exercise test should **not** be stopped when the pacing rate reaches the maximum pacing rate, but must be continued until the patient has finished the exercise test. In this way, the pacemaker can measure any additional increase in the number of accelerometer counts while pacing at the maximum pacing rate. The exercise test must be completed within one hour.

Note: The exercise test must be stopped if the patient is in distress, in which case the test can be repeated at a lower exercise level.

Ending the exercise test – To complete the exercise stress test, position the programming head over the pacemaker. The programmer reads out the measurement results and, if necessary, adapts the slope.

If the measurement is successful, the message “Fast Learn completed” appears on the programmer screen. Press [Close] to terminate the fast learning procedure.

If the measurement is not successful, the programmer displays a message indicating why the exercise measurement failed. The measurement results are not accepted and the slope remains unchanged. Press [Close] to terminate the fast learning procedure.

12.6 Activity acceleration and deceleration

Two additional parameters are available to adjust the rate response to meet the specific requirements of individual patients. It is possible to influence the speed of rate change from the lower rate to the maximum pacing rate (activity acceleration) and vice versa (activity deceleration).

12.6.1 Activity acceleration

Parameters
- ⇒ Therapies
  - ⇒ Sensor…
    - ⇒ Activity Acceleration

Range: Fast, Standard, Gradual

Availability: DDDR, DDIR, VDDR, VVIR and AAIR modes

The programmed option determines how fast the pacing rate increases. The rate increase, for example, from a lower rate of 60 min^{-1} to a maximum pacing rate of 120 min^{-1} takes approximately 40 seconds (Fast), 80 seconds (Standard) or 160 seconds (Gradual).

12.6.2 Activity deceleration

Parameters
- ⇒ Therapies
  - ⇒ Sensor…
    - ⇒ Activity Deceleration

Range: Fast, Standard, Gradual

Availability: DDDR, DDIR, VDDR, VVIR and AAIR modes

The programmed option determines how fast the pacing rate decreases. The rate decrease, for example, from a maximum pacing rate of 120 min^{-1} to a lower rate of 60 min^{-1} takes approximately three minutes (Fast), five minutes (Standard) or ten minutes (Gradual).

13 AF prevention therapies

13.1 Introduction

This chapter explains how to use the AF prevention therapies to prevent the onset of episodes of atrial tachyarrhythmia. The AF prevention therapies deliver triggered overdrive pacing aimed to stabilize the heart rhythm, which helps to prevent atrial tachyarrhythmias.

Triggered overdrive pacing is triggered by one of the events that may mark the onset of atrial tachyarrhythmias. Two triggered overdrive pacing therapies are available:

- PAC Suppression is designed to reduce the incidence of premature atrial contractions (PACs) by increasing the heart rate when appropriate (see Section 13.2.1)
- Post-PAC Response is designed to eliminate post-PAC pauses and provide a smooth transition from the PAC rate to the underlying rate (see Section 13.2.2)

The maximum pacing rate of PAC Suppression is set by the programmable maximum therapy rate (Section 13.2.3).

Warning: It is important to prevent far-field R-wave (FFRW) sensing insofar as possible (see Section 6.5.3). An FFRW sense may be falsely interpreted as an atrial event and therefore result in an inappropriate response of the therapies described in this chapter. Vitatron advises you to optimize the atrial blanking periods to ensure the correct detection of atrial tachyarrhythmias, but to prevent the detection of FFRW senses.

Note: Atrial fibrillation (AF) detection requires optimal sensitivity to sense all atrial events. To meet this requirement, Vitatron recommends using bipolar atrial leads.

13.2 Triggered overdrive pacing

Parameters
⇒ Therapies
⇒ Triggered Overdrive

Range: On, Off

Availability: DDD(R) mode

When the Parameters Therapy window is opened, the programmer sets triggered overdrive to “On” if one of the triggered overdrive pacing therapies (see Section 13.2.1 and Section 13.2.2) is programmed on. Triggered overdrive is set to “Off” if both triggered overdrive pacing therapies are programmed off.

You can program triggered overdrive to “On” in the Parameters Therapy window, in which case both triggered overdrive pacing therapies are programmed on. Each triggered overdrive pacing therapy can be individually programmed off in the Triggered Overdrive window by pressing [more…].

When you program triggered overdrive to “Off” in the Parameters Therapy window, both triggered overdrive pacing therapies are programmed off.

13.2.1 PAC Suppression

Parameters
⇒ Therapies
⇒ Triggered Overdrive (more…)
⇒ PAC Suppression

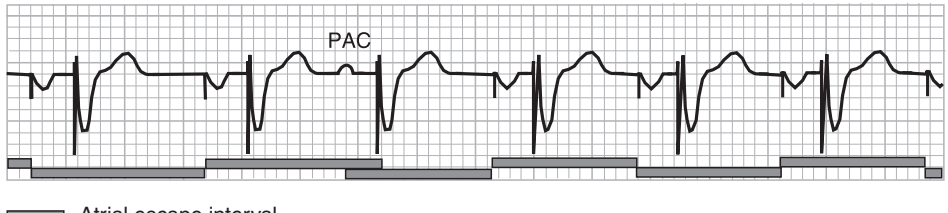
Range: On, Off

Availability: DDD(R) mode

PAC Suppression aims to reduce the incidence of PACs by increasing the heart rate upon detection of a PAC. Because PACs may occur in clusters, the increased rate is kept stable for a certain period of time following a PAC.

When the pacemaker detects a PAC, it increases the pacing rate to 15 min^{-1} above the physiological rate (see Figure 96). In the period following this increase the rate is kept stable for 600 beats. Any PACs occurring in the stable period do not induce additional rate increases. At the end of the stable period the pacing rate slowly decreases until the lower rate is reached, or normal sinus rhythm is detected. The stable period ends prematurely when an atrial tachyarrhythmia is sensed for five seconds or normal sinus rhythm is detected.

Figure 96. PAC Suppression responds to a PAC (mode switching is “Auto”)



To prevent excessively high pacing rates after the stable period, the pacemaker only increases the pacing rate after a PAC during sinus rhythm or while pacing at a rate less than 15 min^{-1} above the lower rate. In the latter case a limited pacing rate increase up to 15 min^{-1} above the lower rate is allowed. The pacing rate does not increase above the maximum therapy rate (see Section 13.2.3).

Notes:

- PAC Suppression cannot be active when mode switching is “Fixed”.
- If both PAC Suppression and Post-PAC Response are programmed on, Post-PAC Response controls the pacing rate in the first interval after a blocked PAC and the highest rate of Post-PAC Response or PAC Suppression controls the first interval after a tracked PAC. PAC Suppression controls the pacing intervals following the first beat after a (blocked or tracked) PAC.
- The rhythm is interpreted as normal sinus rhythm after five consecutive physiological atrial senses which can be tracked.

13.2.2 Post-PAC Response

Parameters
⇒ Therapies
⇒ Triggered Overdrive (more…)
⇒ Post-PAC Response

Range: On, Off

Availability: DDD(R) mode

Post-PAC Response aims to prevent post-PAC pauses by controlling the atrial rate in the two beats after a PAC. Upon detection of a PAC, providing a smooth transition from the PAC coupling interval to the preceding heart rate reduces the atrial rate instability.

The atrial escape rate of the first beat after a PAC equals the average of the PAC rate and the physiological rate. In the second beat after a PAC, the atrial escape rate equals the physiological rate. Subsequently, the atrial escape rate returns to that of before the PAC.

A PAC does not induce a Post-PAC Response when it occurs within six beats of an atrial tachyarrhythmia or within two or three atrial beats of a previous PAC, which started the Post-PAC Response therapy.

Notes:

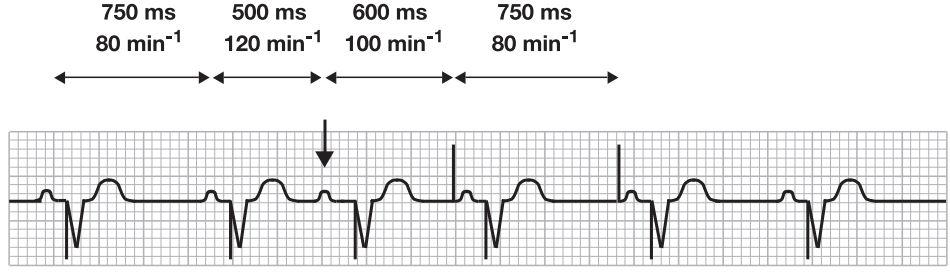
- Post-PAC Response cannot be active when mode switching is “Fixed”.
- If both PAC Suppression and Post-PAC Response are programmed on, Post-PAC Response controls the pacing rate in the first interval after a blocked PAC and the highest rate of Post-PAC Response or PAC Suppression controls the first interval after a tracked PAC. PAC Suppression controls the pacing intervals following the first beat after a (blocked or tracked) PAC.
- The atrial synchronization pace (ASP) interval used by Post-PAC Response may be shorter than the programmed ASP interval.

The following situations might occur upon the detection of a PAC.

Long PAC coupling interval – PACs with a relatively long PAC coupling interval (late PACs) can be tracked in the ventricle. Tracking is allowed only if the resulting ventricular rate does not increase more than 30 to 40 min^{-1} above the underlying mean ventricular rate and the ventricular rate remains below the maximum tracking rate. Normal tracking behavior is explained in Section 10.5.2.

The AV delay of a tracked PAC is equal to the (rate) adaptive sensed AV delay at 100 min^{-1}. The AV delay may be lengthened up to a maximum of 20% of the maximum tracking rate interval (see Section 10.3.1) to enable tracking of a PAC, as shown in Figure 97.

Figure 97. The Post-PAC Response to late PACs



Short PAC coupling interval – PACs with a relatively short PAC coupling interval (early PACs) cannot be tracked in the ventricle and an ASP is scheduled to restore AV synchrony (see Figure 98). This may result in a single prolonged ventricular escape interval, possibly slightly below the lower rate (see Figure 99, the lower rate has been programmed to 70 min^{-1}).

Figure 98. The Post-PAC Response to early PACs

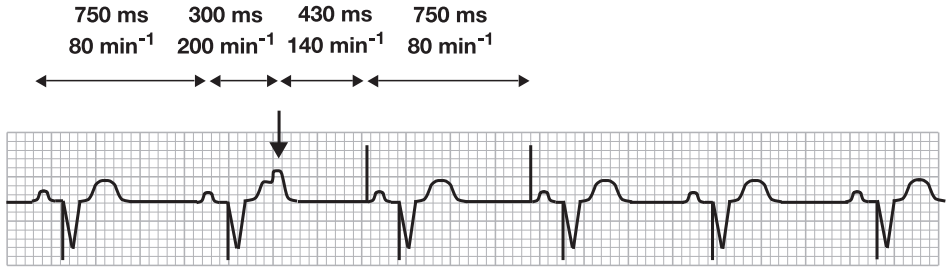
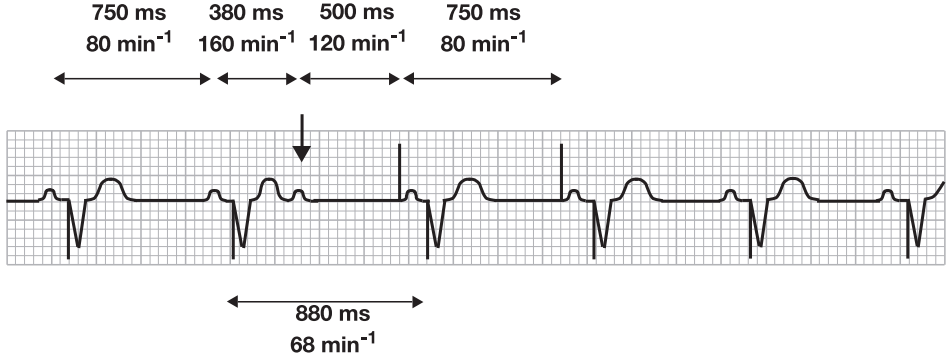
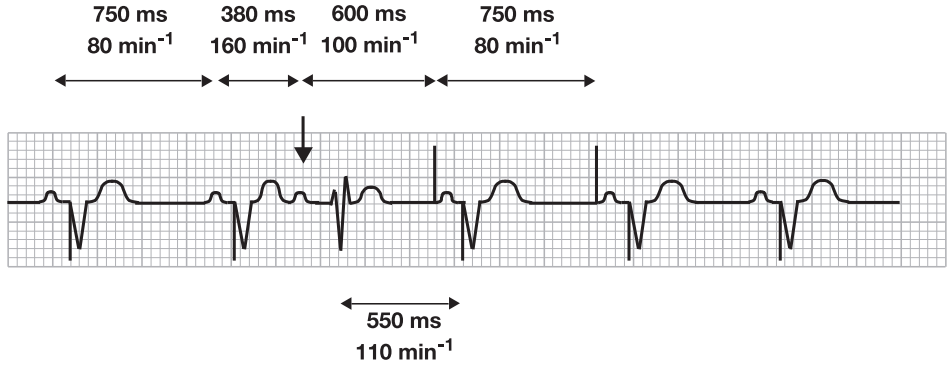


Figure 99. The Post-PAC Response to early PACs, with a prolonged ventricular escape interval



Spontaneously conducted PAC – If an early PAC is conducted spontaneously to the ventricle, the atrial escape interval may be lengthened so that the resulting ventricular rate does not increase more than 30 min^{-1} above the underlying mean ventricular rate (see Figure 100).

Figure 100. The Post-PAC Response to early PACs, with a prolonged atrial escape interval



13.2.3 Maximum therapy rate

Parameters
- ⇒ Therapies
  - ⇒ Triggered Overdrive (more…)
    - ⇒ Max. Therapy Rate

Range: 70 - (10) - 120 min^{-1}

Availability: DDD(R) and VVI(R) modes

The maximum therapy rate is the maximum rate to which the AF prevention therapies and VRS (see Section 10.6) can increase the pacing rate. If the patient has angina or congestive heart failure, then a lower setting of the maximum therapy rate might be preferred.

A Safety features

A.1 Introduction

Vitatron pacemakers and the programming system provide a range of safety features that should, in the unlikely event of a technical problem, ensure patient safety at all times. Until corrective action is possible, the pacemaker continues to function as normally as possible.

If a mistake occurs during programming, pressing the emergency button on the programmer forces the pacemaker to function with emergency settings (see Section 4.12). You can then reprogram the pacemaker.

If a technical problem occurs the pacemaker attempts to recover from it automatically. There are three stages of recovery, depending on how much of the pacemaker's settings can be restored.

Once a problem is recognized backup pacing is initiated, delivering a basic VVI therapy to ensure patient safety. The pacemaker then attempts to restore the previously programmed settings. First, a partial restore is initiated, to set functions to safe values that are valid for all pacemakers. Subsequently, the pacemaker attempts a full restore, to return to the settings programmed in the pacemaker before the problem occurred.

If more than five restore attempts are made between follow-up sessions, the pacemaker diagnoses a recurrent malfunction and automatically switches to, and stays in, the backup pacing mode.

Note: A pacemaker that is operating in backup mode can be recognized by the distinctive backup settings (see Table 9). In a pacemaker where a restore has occurred, settings may vary depending on the degree of restoration. The occurrence of a full or partial restore is reported at the start of the next follow-up session.

Warning: The pacing polarity is unipolar during backup and partial restore pacing. This can cause an undesirable interaction with a co-implanted ICD (Implantable Cardioverter Defibrillator).

A.1.1 Backup pacing

If the pacemaker function cannot be restored, it remains in the backup mode until the next follow-up session. As soon as a programming head (or a magnet) is then placed over the pacemaker, an automatic pacemaker restore is attempted (see Section A.2). If the restore is not successful, the backup pacemaker continues to determine the pacing parameters and it is impossible to establish further communication with the pacemaker. At this point, contact the local Vitatron representative.

The backup pacemaker settings, which are listed in Table 9, have been chosen to ensure that single chamber (SSI) pacing is at least maintained.

Table 9. Backup pacing parameter settings

Parameter	Backup setting
Mode[a]	VVI/AAI
Lower rate, day & night	65 min^{-1}
Pulse duration	0.8 ms
Pulse amplitude	7.5 V ±20%
Sensitivity	2.0 mV ±80%
Refractory period	330 ms
Polarity (pacing and sensing)	unipolar

[a] VVI, except for a single chamber pacemaker programmed to atrium (mode = AXX).

A.2 Pacemaker restore

A.2.1 Full restore

If a technical problem occurs, the pacemaker tries to restore its programmed settings from memory. If a full restore is successful, the pacemaker is restored to the programmed parameters that were in effect at the end of the last follow-up session and all diagnostic features are reset. If a restore occurs within one hour of a follow-up session, the restored parameters are those in effect at the start of the last follow-up session.

At the start of the next follow-up session, the programmer warns that a restore has occurred. Save the pacemaker status list and memory contents to disk (this helps Vitatron to identify the cause of the error) then contact the local Vitatron representative. For an explanation of how to copy the memory contents file to a disk see Section 4.10.6.

After a full restore, the pacemaker can be programmed as normal.

A.2.2 Partial restore

If a full restore is not possible, the programmed parameters are partially restored. The exact settings depend on how much information could be restored from pacemaker memory. The minimum partial restore settings are listed in Table 10.

Table 10. Minimum partial restore settings

Parameter	Partial restore setting
Mode[a]	VVI/AAI
Lower rate, day & night	60 min^{-1}

Table 10. Minimum partial restore settings (continued)

Parameter	Partial restore setting
Magnet rate	90 min^{-1}
Pulse duration	1.0 ms
Pulse amplitude	7.5 V ±20%
Sensitivity	2.0 mV ±80%
Refractory period	350 ms
Polarity (pacing and sensing)	unipolar

[a] VVI, except for single chamber pacemaker programmed to atrium (mode = AXX).

The pacemaker functions with the partial restore settings until the next follow-up session. At this follow-up session, the programmer warns that a partial restore has occurred.

Press [Save] to save the pacemaker status list and memory contents to the programmer hard disk, then contact the local Vitatron representative. This helps Vitatron to identify the cause of the error. For an explanation of how to copy the memory contents file to a disk see Section 4.10.6.

After saving the pacemaker restore information, press [Restore] to attempt a full restore. If the full restore is successful, normal programming can be resumed after pressing [Close]. Otherwise, press [End Session] to end the follow-up session.

B Precautions

B.1 Effects of extreme conditions

The pacemaker may be affected by abnormal impacts, such as those that can occur in contact sports, and high ambient pressures, such as those that can occur when scuba diving.

Note: The maximum absolute pressure that the pacemaker can withstand is 300 kPa.

B.2 Area restrictions

Patients should consult a physician before entering an area where there are signs placed prohibiting patients with an implanted pacemaker.

B.3 Environmental and medical therapy hazards

Pacemakers use spontaneous cardiac signals to inhibit or trigger pacemaker output. There are some signals existing in the environment, and during some forms of medical treatment, that have similar characteristics. Certain types of electromagnetic interference (EMI) can damage the pacemaker and could interfere with its operation, possibly leaving the patient without pacing therapy. In some circumstances, these signals can interfere with the pacemaker function. Contact Vitatron if there is concern about any particular patient.

B.3.1 Home and occupational environment

High voltage power transmission lines can generate enough EMI to interfere with pacemaker operation if approached too closely.

Communication equipment such as microwave transmitters, linear power amplifiers, or high-power amateur transmitters can generate enough EMI to interfere with pacemaker operation if approached too closely.

Commercial electrical equipment such as arc welders, induction furnaces, or resistance welders can generate enough EMI to interfere with pacemaker operation if approached too closely.

Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with pacemaker operation. There are reports of pacemaker disturbances caused by electric hand tools or electric razors used directly over the pacemaker implant site.

Electronic Article Surveillance (EAS) – Some types of EAS equipment, such as those found at store entrances and exits, can temporarily inhibit the pacemaker or cause the pacemaker to partially restore. Vitatron pacemaker wearers should walk through theft prevention systems, preferably through the middle, and not linger close to the theft prevention system. If a pacemaker wearer feels weak or dizzy, move away from the system.

Cellular phone – Keep the cellular phone 15 cm away from the pacemaker.

Cordless phones – Short range phones intended for domestic use are safe to use. For cordless phones that can transmit up to 8 km, keep the phone 30 cm from the pacemaker.

Portable and cellular phones transmitting above 3 W – Keep the antenna 30 cm from the pacemaker by doing the following actions:

- Hold the phone to the ear opposite the side of the pacemaker.
- Carry the phone in a pocket away from the pacemaker. (In standby or listen mode the phone is still capable of transmitting.)

Note: Patients experiencing dizziness or palpitations while using a cellular or cordless phone, should move the phone antenna further from the pacemaker. Similar symptoms may occur in close proximity to radio or radar transmitters, and in the presence of strong magnetic fields. Moving away from the source will restore normal pacemaker function.

B.3.2 Hospital and medical therapy hazards

The influence of medical equipment on pacemaker performance varies considerably according to the type of unit and the energy levels employed. It is advisable in all cases to monitor the pacemaker function during the procedure and to check the pacemaker after the procedure. The following medical devices are likely to be a source of interference.

Defibrillation (external) – Do not defibrillate with the paddles placed on the skin above the pacemaker. Place the paddles at least 15 cm away from the pacemaker and afterwards check that it is functioning properly.

Defibrillation currents may cause changes in myocardial tissue with a subsequent loss of capture (increased stimulation threshold) and possibly, a loss of sensing (decreased amplitude of the intracardiac signal). Such changes are usually only temporary.

Following defibrillation, perform a normal patient follow-up.

Diathermy – People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and the diathermy can cause tissue damage, fibrillation, or damage to device components, which could result in serious injury, loss of therapy, and the need to reprogram or replace the device.

Electrosurgical cautery – If possible, do not use an electrocautery unit when replacing a pacemaker. Currents generated from such units can cause a permanent loss of output. Spontaneous changes in the programmable parameter values may be observed following cauterization.

Electrosurgical cautery could induce ventricular arrhythmias or fibrillation, and may cause asynchronous or inhibited pacemaker operation. If use of electrocautery is necessary, keep both the current path and ground plate as far from the pacemaker and leads as possible.

In addition, program the pacemaker to an asynchronous mode (DOO/VOO/AOO).

High radiation source – Large doses of therapeutic and diagnostic radiation can adversely influence pacemaker function. Therefore shield the pacemaker during exposure, and carefully monitor pacemaker function after exposure to large radiation doses. Continue to monitor the pacemaker function for several weeks, since changes induced by radiation may not be immediately apparent.

Lithotripsy – Lithotripsy can permanently damage the pacemaker if the pacemaker is at the focal point of the lithotripsy beam.

If lithotripsy is required, follow these procedures:

- Program the pacemaker to single chamber, non-rate responsive mode VVI/AAI or VOO/AOO before treatment.
- Keep the focal point of the lithotripsy beam at least 5 cm away from the pacemaker.

Computed tomographic x-ray (CT scan) – If the patient undergoes a CT scan procedure and the device is not directly in the CT scan x-ray beam, the device is not affected. If the device is directly in the CT scan x-ray beam, oversensing may occur for the duration of the time in the beam.

If the duration of the time in the beam is longer than 4 s, take appropriate measures for the patient, such as enabling an asynchronous mode for pacemaker-dependent patients or enabling a non-pacing mode for non-pacemaker-dependent patients. These measures prevent false inhibition and false tracking. After completing the CT scan, restore the desired parameters.

Magnetic Resonance Imaging Systems (MRIS) – Magnetic resonance imaging of pacemaker patients has resulted in significant adverse effects. The use of MRI in pacemaker patients is therefore contraindicated. If MRI is required, closely monitor pacemaker patients

subjected to MRI and verify programmed parameters after the MRI. Limited studies of the effects of MRI on pacemakers have shown the following traits.

- Magnetic and radio frequency (RF) fields produced by MRI may adversely affect the operation of the pacemaker and may inhibit the pacing output.
- Magnetic fields may activate magnet mode operation and cause asynchronous pacing.
- Reported[2] effects of MRI on pacing include increased ventricular pacing beyond the rate limit.

Radiofrequency ablation – The radiofrequency ablation procedure in a pacemaker patient may cause any of the following events:

- The pacemaker will pace asynchronously above or below the programmed rate.
- The pacemaker will revert to asynchronous operation.
- The pacemaker will reset.
- The pacemaker will prematurely trigger “Replace PM” indicators.

Reduce the risks with the following procedures:

- Program the pacemaker to a non-rate responsive, asynchronous pacing mode prior to RF ablation.
- Avoid direct contact between the ablation catheter and the implanted lead or pacemaker (the advised minimum distance is 1.3 cm between catheter and lead tip).
- Position the ground plate so that the current pathway does not pass through or near the pacing system (place the ground plate under the patient’s buttocks or legs).

Manage the risks with the following precautions:

- Have a Vitatron programmer available for emergency programming.
- Have defibrillation equipment available.

Transcutaneous Electrical Nerve Stimulators (TENS) – The effects of TENS used in close proximity to the pacing system are dependent on the type of pulse train employed. The most probable effect is a temporary switch, by the pacemaker, to its interference mode (fixed rate pacing at the programmed rate). Temporary inhibition of the pacemaker is, however, also possible. Vitatron recommends closely monitoring the pacemaker function during nerve stimulation.

Note: Because of the possible effects on pacemaker function, pacemaker patients should not be allowed to use TENS at home without adequate medical supervision.

[2] Holmes, Hayes, Gray et al. The effects of magnetic resonance imaging on implantable pulse generators. Pace. 1986; 9 (3) 360-370.

C Product specifications Vitatron C70 DR, Vitatron C60 DR, Vitatron C50 D

C.1 Programming parameters

Table 11. Pacing and sensing parameters

Parameter name	Range	Delivery settings per model		
		Vitatron C70 DR C70A4	**Vitatron C60 DR C60A4**	**Vitatron C50 D C50A4**
Mode	DDDR, DDIR, DDD, DDI, DOO, VDDR, VDD, VVIR, VVI, VVT, VOO, AAIR, AAI, AAT, AOO, OOO	DDD	DDD	DDD
Lower rate	40-(5)-130 min^{-1}	60 min^{-1}	60 min^{-1}	60 min^{-1}
Maximum pacing rate	90-(5)-170 min^{-1}	120 min^{-1}	120 min^{-1}	120 min^{-1}
Maximum tracking rate	90-(5)-190 min^{-1}	140 min^{-1}	140 min^{-1}	140 min^{-1}
Pulse amplitude[a]	0.5-(0.25)-4.0-(0.5)-8.0 V	3.75 V	3.75 V	3.75 V
Pulse duration[a]	0.1-(0.05)-1.0 ms	0.4 ms	0.4 ms	0.4 ms
Atrial sensitivity	Uni: 0.5-(0.1)-1.0-(0.5)-7.5 mV Bi: 0.25, 0.3-(0.1)-1.0-(0.5)-7.5 mV	0.7 mV	0.7 mV	0.7 mV
Ventricular sensitivity	1.0-(0.5)-10.0 mV	2.0 mV	2.0 mV	2.0 mV
Sensing/pacing polarity[a]	Unipolar, Bipolar	Unipolar	Unipolar	Unipolar
Atrial blanking on VP	50-(25)-300 ms	150 ms	150 ms	150 ms
Atrial blanking on VS	25-(25)-150 ms	50 ms	50 ms	50 ms
Ventricular blanking on AP	20-(5)-50 ms	30 ms	30 ms	30 ms
Ventricular safety pacing	On, Off	On	On	On
Atrial refractory period	250-(10)-500 ms	330 ms	330 ms	330 ms
Ventricular refractory period	250-(10)-500 ms	260 ms	260 ms	260 ms

Table 11. Pacing and sensing parameters (continued)

Parameter name	Range	Delivery settings per model		
		Vitatron C70 DR C70A4	**Vitatron C60 DR C60A4**	**Vitatron C50 D C50A4**
Maximum sensed AV delay	45-(5)-260 ms	150 ms	150 ms	150 ms
Maximum paced AV delay	80-(5)-300 ms	190 ms	190 ms	190 ms
Sensed/Paced AV offset	20-(5)-50 ms	40 ms	40 ms	40 ms
Adaptive AV delay	Off, Median[b], Fast[c]	Median	Median	Median
Refined Ventricular Pacing	On, Off	Off	Off	Off
AV delay extension	60-(20)-120 ms	60 ms	60 ms	60 ms
Refined Atrial Pacing	On, Off	Off	Off	Off
Atrial hysteresis	100-(25)-200 ms	100 ms	100 ms	100 ms

[a] Independently programmable in atrium and ventricle.
[b] Median = 5 ms per atrial rate change of 10 min^{-1}.
[c] Fast = 10 ms per atrial rate change of 10 min^{-1}.

Table 12. Other programmable parameters

Parameter name	Range	Delivery settings per model		
		Vitatron C70 DR C70A4	**Vitatron C60 DR C60A4**	**Vitatron C50 D C50A4**
Flywheel	On, Off	Off	Off	Off
Tachy fallback rate	Off, 45-(5)-100 min^{-1}	Off	Off	Off
Night tachy fallback rate	40-(5)-100 min^{-1}	60	60	60
Night lower rate	40-(5)-130 min^{-1}	60	60	60
Start of night	18:00-(5 min)-02:55 hh:mm	00:00	00:00	00:00
End of night	04:00-(5 min)-11:55 hh:mm	06:00	06:00	06:00
Pacemaker time	00:00-(1 min)-23:59 hh:mm	00:00	00:00	00:00
Post-PVC response	On, Off	On	On	On
PVC synchronous Astim	On, Off	Off	Off	Off
Sensor slope	Auto, Fixed	Auto	Auto	Auto

Table 12. Other programmable parameters (continued)

Parameter name	Range	Delivery settings per model		
		Vitatron C70 DR C70A4	**Vitatron C60 DR C60A4**	**Vitatron C50 D C50A4**
Activity threshold	Low, Low/Med, Medium, Med/High, High	Medium	Medium	Medium
Activity acceleration	Fast, Standard, Gradual	Standard	Standard	Standard
Activity deceleration	Fast, Standard, Gradual	Standard	Standard	Standard
Mode switching	Auto, Fixed	Fixed	Fixed	Fixed
Mode switching sensitivity	Standard, Moderate	Standard	Standard	Standard
ASP interval	250-(5)-400 ms	300	300	300
A burst rate[a]	100-(10)-320-(15)-425 min^{-1}	130	130	130
VOO backup[a]	On, Off	Off	Off	Off
Ventricular Rate Stabilization	On, Off	Off	Off	Off
Triggered overdrive pacing[b]	On, Off	Off	—	—
PAC Suppression	On, Off	Off	—	—
Post-PAC Response	On, Off	Off	—	—
Maximum therapy rate	70-(10)-120 min^{-1}	100	100	100

[a] Only temporarily programmable.
[b] When triggered overdrive is programmed to “On”, both triggered overdrive pacing therapies (PAC Suppression and Post-PAC Response) are programmed on.

Table 13. Diagnostic programmable parameters

Parameter name	Range	Delivery settings per model		
		Vitatron C70 DR C70A4	**Vitatron C60 DR C60A4**	**Vitatron C50 D C50A4**
EGM recording	On, Off	Off	Off	Off
Atrial high rate detection[a]	On, Off	Off	Off	Off
Atrial high rate onset rate	140-(10)-240 min^{-1}	200 min^{-1}	200 min^{-1}	200 min^{-1}
Atrial high rate onset duration	5, 8, 10, 15, 20, 30 s	15 s	15 s	15 s

Table 13. Diagnostic programmable parameters (continued)

Parameter name	Range	Delivery settings per model		
		Vitatron C70 DR C70A4	**Vitatron C60 DR C60A4**	**Vitatron C50 D C50A4**
Atrial high rate end rate	120-(10)-220 min^{-1}	180 min^{-1}	180 min^{-1}	180 min^{-1}
Atrial high rate end duration	5, 8, 10, 15, 20, 30, 60, 180 s	8 s	8 s	8 s
Ventricular episode detection[a]	Off, Ventricular Rate	Off	Off	Off
Ventricular episode onset rate	15, 20, 30, 40, 90-(10)-190 min^{-1}	140 min^{-1}	140 min^{-1}	140 min^{-1}
Ventricular episode onset duration	2, 5, 8, 10, 15, 20, 30 s	2 s	2 s	2 s
Ventricular episode end rate	10, 15, 20, 30, 70-(10)-170 min^{-1}	120 min^{-1}	120 min^{-1}	120 min^{-1}
Ventricular episode end duration	5, 8, 10, 15, 20, 30, 60, 180 s	5 s	5 s	5 s
Number of onset reports	5, 8, 10, 15, 20, 25	15	15	15

[a] At the first programmer session after implant, if the pacemaker is programmed to dual chamber sensing, the atrial high rate detection and the ventricular episode detection (V rate) triggers switch on. Selected Episodes will then start to record automatically. If the pacemaker is programmed to ventricular sensing, only the ventricular episode detection (V rate) trigger switches on. If the pacemaker is programmed to atrial sensing, Selected Episodes recording stays off.

Table 14. Tolerances (valid between 22 °C and 45 °C throughout the pacemaker lifetime)

Parameter	Tolerance
Lower rate (min^{-1})	Programmed value ±15 ms
Maximum pacing rate (min^{-1})	Programmed value ±15 ms
Maximum tracking rate (min^{-1})	Programmed value ±15 ms
Pulse amplitude (V)	Programmed value ≤ 1.0: +40%/-10% Programmed value > 1.0 ≤ 4.0: +20%/-10% Programmed value > 4.0 ≤ 7.0: +10%/-10% Programmed value > 7.0: +10%/- 20%
Pulse duration (ms)	Programmed value - 0.02/+0.04
Atrial sensitivity (mV)	Programmed value ±(10% +0.16) at 37 °C[a]
Ventricular sensitivity (mV)	Programmed value ±(20% +0.16) at 37 °C[a]
Blanking period (ms)	Programmed value ±15
Refractory period (ms)	Programmed value ±15
Sensed/paced AV delay (ms)	Programmed value ±15

Table 14. Tolerances (valid between 22 °C and 45 °C throughout the pacemaker lifetime) (continued)

Parameter	Tolerance
Sensed/paced AV offset (ms)	Programmed value ±15
Atrial hysteresis (ms)	Programmed value ±15
Lead impedance (Ω)	Measured value ±(20% +20)
Battery voltage (V)	Measured value ±0.03
EGM amplitude (atrial)	±(10% +0.16 mV) +1% of full scale (at 37 °C)[a]
EGM amplitude (ventricular)	±(20% +0.16 mV) +1% of full scale (at 37 °C)[a]
ECG marker timing	±10 ms

[a] Add ±10% over temperature range 22 °C to 45 °C.

Table 15. Telemetered patient and pacemaker data

Data item
Patient's name and identification code
Patient's date of birth
Pacemaker type, model number and serial number
Pacemaker implant date
Lead manufacturer, model number and serial number (atrial and ventricular)
Lead implant date (atrial and ventricular)
Pacemaker dependent (yes/no)
Symptoms
Indications for pacing
Etiology
Pacemaker time
Anticoagulation is applied (yes/no)
Anticoagulation start date
Notes
Physician's name and phone number

Table 16. Measurements

Measurement
Remaining pacemaker longevity
Lead polarity (atrial and ventricular)
Lead impedance (atrial and ventricular)
Pulse amplitude (atrial and ventricular)
Battery status
Remaining battery capacity

Table 16. Measurements (continued)

Measurement
Battery impedance
Battery voltage
Mean battery current
Consumed battery charge
Average pulse current
Pulse energy
P-wave amplitude
R-wave amplitude
Stimulation threshold
VA interval
Fast Learning

Table 17. Diagnostic capabilities

Category	**Feature**
ECG and therapy analysis	Intracardiac EGM
	ECG event marker intervals
	ECG marker annotation
	Therapy Advisor
Holters	24-hour Holter
	30-minute Holter
Histograms/tables	Diurnal rhythm distribution
	P-wave amplitude
	Atrial rate
	Ventricular rate
	Ventricular rate irregularity
	VA interval
History	Diagnostics
	Tests
	Parameters

Table 17. Diagnostic capabilities (continued)

Category	Feature
Counters	Percentage of atrium paced
	Percentage of physiologic atrial senses
	Percentage of pathologic atrial senses
	Percentage of ventricle paced
	Percentage of ventricle sensed
	Percentage of AV synchrony
	Mean V rate during A tachy
	Number of retrograde atrial senses
	Number of episodes of retrograde conduction
	Number of PACs
	Number of PVCs
	Number of VSPs
	Number of accelerometer counts
Selected Episodes	Atrial Rate
	Ventricular Rate

C.2 Technical parameters

Table 18. Magnet mode

Parameter	Rate
Magnet pacing mode	Fixed rate pacing in programmed mode.
Magnet rate, battery status “Good”	100 min^{-1} (600 ms)
Magnet rate, battery status “Ageing”	95 min^{-1} (630 ms)
Magnet rate, battery status “Replace PM”	86 min^{-1} (700 ms)

Warning: In magnet mode the pacemaker operates in an asynchronous pacing mode. If the intrinsic rate is higher than the magnet rate, this may induce ventricular tachycardia or ventricular fibrillation.

Table 19. Exposed materials

Item	Material
Can	Titanium
Connector	Polyether-Urethane (PUR) and silicone rubber

Table 20. Physical characteristics

Characteristic	Value
Dimensions[a]	50.9 x 45.9 x 7.25 mm
Mass	28.6 ± 0.5 g
Volume	12.7 ± 0.5 cm^3
Surface area	33.1 cm^2
X-ray identification	VF
Connector	IS-1 dual chamber

[a] Connector thickness may vary.

Table 21. Electrical specifications

Characteristic	Value			
Output capacitor	3.4 µF			
Input impedance: atrium	≥ 100 kΩ			
Input impedance: ventricle	≥ 100 kΩ			
Current/Energy consumption	**DDDR**	**DDD**	**VVIR**	**VVI**
Pacing[a]	21.4 µA	20.9 µA	13.8 µA	13.3 µA
Inhibited	10.6 µA	10.1 µA	8.4 µA	7.8 µA

[a] 100% pacing at 60 min^{-1}, 3.75 V, 0.4 ms, 500 Ω.

Table 22. Power source

Characteristic	Value
Cell type	Pi 223 lithium iodine
Voltage	2.8 V (RRT[a] 2.6 V)
Capacity	1.4 Ah (RRT[a] 0.1 Ah)
Battery manufacturer	MECC

[a] RRT = Recommended Replacement Time.

Table 23. Interference and high rate protection

Parameter	Value
Interference detection frequency	15.4 ±0.5 Hz (923 ±29 min^{-1})
Pacing mode during interference	DOO(R) if programmed to a dual chamber mode. VOO(R) if programmed to a ventricular mode. AOO(R) if programmed to an atrial mode. OOO if programmed to the OOO mode.
Pacing rate during interference	Pacemaker behaves as if no spontaneous cardiac activity is present. If interference continues, the eventual pacing rate is either the sensor-indicated rate or the lower rate, whichever is the higher.
Ventricular high rate protection	205 ±10 min^{-1}

D Product specifications Vitatron C20 SR and Vitatron C10 S

D.1 Programming parameters

Table 24. Pacing and sensing parameters

Parameter name	Range	Delivery settings per model	
		Vitatron C20 SR C20A4	**Vitatron C10 S C10A4**
Mode	VVIR, VVI, VVT, VOO, AAIR, AAI, AAT, AOO, OOO	VVI	VVI
Lower rate	40-(5)-130 min^{-1}	60 min^{-1}	60 min^{-1}
Maximum pacing rate	90-(5)-170 min^{-1}	120 min^{-1}	120 min^{-1}
Pulse amplitude	0.5-(0.25)-4.0-(0.5)-8.0 V	3.75 V	3.75 V
Pulse duration	0.1-(0.05)-1.0 ms	0.4 ms	0.4 ms
Atrial sensitivity	Uni: 0.5-(0.1)-1.0-(0.5)-7.5 mV Bi: 0.25, 0.3-(0.1)-1.0-(0.5)-7.5 mV	0.7 mV	0.7 mV
Ventricular sensitivity	1.0-(0.5)-10.0 mV	2.0 mV	2.0 mV
Sensing/pacing polarity	Unipolar, Bipolar	Unipolar	Unipolar
Refractory period	250-(10)-500 ms	330 ms	330 ms
Conditional hysteresis[a]	0-(5)-30 min^{-1}	0 min^{-1}	0 min^{-1}

[a] Conditional hysteresis is only applicable in VVI, VVT, AAI and AAT modes.

Table 25. Other programmable parameters

Parameter name	Range	Delivery settings per model	
		Vitatron C20 SR C20A4	**Vitatron C10 S C10A4**
Flywheel	On, Off	Off	Off
Night lower rate	40-(5)-130 min^{-1}	60 min^{-1}	60 min^{-1}
Start of night	18:00-(5 min)-02:55 hh:mm	00:00	00:00
End of night	04:00-(5 min)-11:55 hh:mm	06:00	06:00
Pacemaker time	00:00-(1 min)-23:59 hh:mm	00:00	00:00
Sensor slope	Auto, Fixed	Auto	—
Activity threshold	Low, Low/Med, Medium, Med/High, High	Medium	—
Activity acceleration	Fast, Standard, Gradual	Standard	—

Table 25. Other programmable parameters (continued)

Parameter name	Range	Delivery settings per model	
		Vitatron C20 SR C20A4	Vitatron C10 S C10A4
Activity deceleration	Fast, Standard, Gradual	Standard	—
Ventricular Rate Stabilization	On, Off	Off	—
Maximum therapy rate	70-(10)-120 min^{-1}	100 min^{-1}	—

Table 26. Diagnostic programmable parameters

Parameter name	Range	Delivery settings per model	Delivery settings per model
		Vitatron C20 SR C20A4	Vitatron C10 S C10A4
EGM recording	On, Off	Off	Off
Atrial high rate detection[a]	On, Off	Off	Off
Atrial high rate onset rate	140-(10)-240 min^{-1}	200 min^{-1}	200 min^{-1}
Atrial high rate onset duration	5, 8, 10, 15, 20, 30 s	15 s	15 s
Atrial high rate end rate	120-(10)-220 min^{-1}	180 min^{-1}	180 min^{-1}
Atrial high rate end duration	5, 8, 10, 15, 20, 30, 60, 180 s	8 s	8 s
Ventricular episode detection[a]	Off, Ventricular Rate	Off	Off
Ventricular episode onset rate	15, 20, 30, 40, 90-(10)-190 min^{-1}	140 min^{-1}	140 min^{-1}
Ventricular episode onset duration	2, 5, 8, 10, 15, 20, 30 s	2 s	2 s
Ventricular episode end rate	10, 15, 20, 30, 70-(10)-170 min^{-1}	120 min^{-1}	120 min^{-1}
Ventricular episode end duration	5, 8, 10, 15, 20, 30, 60, 180 s	5 s	5 s
Number of onset reports	5, 8, 10, 15, 20, 25	15	15

[a] At the first programmer session after implant, if the pacemaker is programmed to ventricular sensing, the ventricular episode detection (V rate) trigger switches on. Selected Episodes will then start to record automatically. If the pacemaker is programmed to atrial sensing, Selected Episodes recording stays off.

Table 27. Tolerances (valid between 22 °C and 45 °C throughout the pacemaker lifetime)

Parameter	Tolerance
Lower rate (min^{-1})	Programmed value ±15 ms
Maximum pacing rate (min^{-1})	Programmed value ±15 ms
Pulse amplitude (V)	Programmed value ≤ 1.0: +40%/-10% Programmed value > 1.0 ≤ 4.0: +20%/-10% Programmed value > 4.0 ≤ 7.0: +10%/-10% Programmed value > 7.0: +10%/-20%
Pulse duration (ms)	Programmed value - 0.02/+0.04
Atrial sensitivity (mV)	Programmed value ±(10% +0.16) at 37 °C[a]
Ventricular sensitivity (mV)	Programmed value ±(20% +0.16) at 37 °C[a]
Refractory period (ms)	Programmed value ±15
Hysteresis (conditional) (min^{-1})	Programmed value ±15
Lead impedance	Measured value ±(20% +20 Ω)
Battery voltage	Measured value ±0.03 V
EGM amplitude (atrial)	±(10% +0.16 mV) +1% of full scale (at 37 °C[a]
EGM amplitude (ventricular)	±(20% +0.16 mV) +1% of full scale (at 37 °C[a]
ECG marker timing	±10 ms

[a] Add ±10% over temperature range 22 °C to 45 °C.

Table 28. Telemetered patient and pacemaker data

Data item
Patient's name and identification code
Patient's date of birth
Pacemaker type, model number and serial number
Pacemaker implantation date
Lead manufacturer, model number and serial number
Lead implantation date
Pacemaker dependent (yes/no)
Symptoms
Indications for pacing
Etiology
Pacemaker time
Anticoagulation is applied (yes/no)
Anticoagulation start date
Notes
Physician's name and phone number

Table 29. Measurements

Measurement
Remaining pacemaker longevity
Lead polarity
Lead impedance
Pulse amplitude
Battery status
Remaining battery capacity
Battery impedance
Battery voltage
Mean battery current
Consumed battery charge
Pulse energy
Average pulse current
P/R wave amplitude
Stimulation threshold
Fast learning (C20A4 only)

Table 30. Diagnostic capabilities

Category	**Feature**
ECG and therapy analysis	Intracardiac EGM
	ECG event marker intervals
	ECG marker annotation
	Therapy Advisor
Holters	24-hour Holter
	30-minute Holter
Histograms/tables	Diurnal rhythm distribution
	P-wave amplitude (AAI and AAIR modes)
	Ventricular rate (VXX modes)
	Ventricular rate irregularity (VXX modes, C20A4 only)
	Atrial rate (AAI, AAIR and AAT modes)
History	Diagnostics
	Tests
	Parameters

Table 30. Diagnostic capabilities (continued)

Category	Feature
Counters	Percentage of atrium or ventricle paced
	Percentage of ventricle sensed (VXX modes)
	Percentage of physiologic atrial senses (AAI, AAIR and AAT modes)
	Percentage of pathologic atrial senses (AAI, AAIR and AAT modes)
	Number of PACs (AAI, AAIR and AAT modes)
	Number of accelerometer counts (AAIR and VVIR modes)
Selected Episodes	Atrial Rate
	Ventricular Rate

D.2 Technical parameters

Table 31. Magnet mode

Parameter	Rate
Magnet pacing mode	AOO or VOO
Magnet rate, battery status “Good”	100 min^{-1} (600 ms)
Magnet rate, battery status “Ageing”	95 min^{-1} (630 ms)
Magnet rate, battery status “Replace PM”	86 min^{-1} (700 ms)

Warning: In magnet mode the pacemaker operates in an asynchronous pacing mode. If the intrinsic rate is higher than the magnet rate, this may induce ventricular tachycardia or ventricular fibrillation.

Table 32. Exposed materials

Item	Material
Can	Titanium
Connector	Polyether-Urethane (PUR) and silicone rubber

Table 33. Physical characteristics

Characteristic	Value
Dimensions[a]	46.8 x 45.9 x 7.25 mm
Mass	27.3 ± 0.5 g
Volume	11.9 ± 0.5 cm^3
Surface area	33.1 cm^2

Table 33. Physical characteristics (continued)

Characteristic	Value
X-ray identification	VF
Connector	IS-1 single chamber

[a] Connector thickness may vary.

Table 34. Electrical specifications

Characteristic	Value	
Output capacitor	3.4 µF	
Input impedance	≥ 100 kΩ	
Current/Energy consumption	**VVIR**	**VVI**
Pacing[a]	13.8 µA	13.3 µA
Inhibited	8.4 µA	7.8 µA

[a] 100% pacing at 60 min^{-1}, 3.75 V, 0.4 ms, 500 Ω.

Table 35. Power source

Characteristic	Value
Cell type	Pi 223 lithium iodine
Voltage	2.8 V (RRT[a] 2.6 V)
Capacity	1.4 Ah (RRT[a] 0.1 Ah)
Battery manufacturer	MECC

[a] RRT = Recommended Replacement Time.

Table 36. Interference and high rate protection

Parameter	Value
Interference detection frequency	15.4 ± 0.5 Hz (923 ± 29 min^{-1})
Pacing mode during interference	VOO(R) if programmed to a ventricular mode. AOO(R) if programmed to an atrial mode. OOO if programmed to the OOO mode.
Pacing rate during interference	Pacemaker behaves as if no spontaneous cardiac activity is present. If interference continues, the eventual pacing rate is either the sensor-indicated rate or the lower rate, whichever is the higher.
High rate protection[a]	205 ± 10 min^{-1}

[a] Atrial high rate protection for pacemakers programmed to AXX modes; ventricular high rate protection for pacemakers programmed to VXX modes.

Glossary

AEGM – Atrial EGM

AF – Atrial fibrillation

AP – Atrial pace

AS – Atrial sense

ASP – Atrial synchronization pace

ECG – Electrocardiogram

EGM – Intracardiac electrogram

EMI – Electromagnetic interference

FFRW – Far-field R-wave

ICD – Implantable cardioverter defibrillator

MRIS – Magnetic resonance imaging system

PAC – Premature atrial contraction

PAV – Paced AV delay

PMT – Pacemaker mediated tachycardia

PVC – Premature ventricular contraction

RAP – Refined atrial pacing

RAS – Retrograde atrial sense

RRT – Recommended replacement time

RVP – Refined ventricular pacing

SAV – Sensed AV delay

TENS – Transcutaneous electrical nerve stimulator

TS – Atrial tachy sense

VEGM – Ventricular EGM

VP – Ventricular pace

VRS – Ventricular Rate Stabilization

VS – Ventricular sense

VSP – Ventricular safety pace

Index

D

E

F

G

H

I

K

L

M

N

O

P

R

S

T

V

W

Manufacturer
Vitatron Holding B.V.
Endepolsdomein 5
6229 GW Maastricht
The Netherlands
Tel. +31-43-356-6551

M938936A001A
2009-12-01

CE
0344

M938936A001