oscor®

# Instructions for Use

# PACE 203 H

**Dual-Chamber Temporary Pacemaker**

**Firmware Version 1.11**



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# Table of Contents

# 1 Preface

## 1.1 General

Read these instructions carefully before using the product described within. Should you have any questions about these instructions or the use of this product, please contact the customer service department before using the product:

**Oscor Inc. - Customer Service**

| | | | | | |
|---|---|---|---|---|---|
| USA: | Phone | 727-937-2511 | International: | Phone | +1 727-937-2511 |
| | Fax | 727-934-9835 | | Fax | +1 727-934-9835 |

This product may only be placed in service when its proper use can be assured.

The PACE 203 H is a class IIb medical product, according to Council Directive 93/42/EEC of 14 June 1993 ('Medical Device Directive'), Annex IX.

## 1.2 Checking the Delivery

Unpack the product and carefully check to see if any damage has occurred in shipment. Check to see if everything was delivered as listed on the shipping list.

Please let us know immediately if something is missing or damaged. Claims that are filed afterwards cannot be considered.

## 1.3 Optional Accessories

The BPI 202 intra-aortic balloon pump (IABP) interface is available as an optional accessory. When the BPI 202 is used, commonly available intra-aortic balloon pulsation pumps can be synchronized with the intracardiac ECG, instead of surface ECG synchronization.

## 1.4 Writing Conventions of this Manual

In this instruction manual, certain conventions are used.

Keys and displays are represented in the text as follows:

- Fixed labeled keys and dials: ON, OFF, Pause, Unlock/Lock, V-STIM
- Upper Display: **AUTO, A-TRIG.**
- Lower display and soft labeled keys: Main Menu, START

Helpful hints and notes on the usage of the device and for understanding the modes of operation will be introduced by ‘Note’.

Important facts and warnings to be observed are introduced by ‘Warning’.

# 2 Product Description

The PACE 203 H is a dual chamber external cardiac pacemaker with atrial controlled timing for routine temporary heart stimulation. All the usual modes of stimulation are available for treatment of acute brady-arrhythmia and for pre-, intra-, and post-operative stimulation of the heart. The stimulation parameters are easily adjustable by rotating dials through a wide range of values.

The PACE 203 H offers the possibility for atrial overdrive stimulation, or rapid atrial pacing, for terminating supra-ventricular tachycardia. The rate of the overdrive stimulation is adjustable within a wide range and is independent of the selected stimulation rate. The overdrive rate can be determined before and changed during overdrive therapy. If required, overdrive stimulation can be initiated with the touch of a button. The overdrive stimulation is indicated optically and acoustically.

The functional design of the PACE 203 H allows safe and easy operation with regards to all requirements of DDD stimulation.

The PACE 203 H further offers the following features:

- During battery changes, stimulation will be maintained for at least 30 s.
- A non-volatile memory keeps any desired stand-by program ready for use, even if the device is shut off.
- A standard program, which can be individualized, is available for each primary pacing mode.
- An emergency program can be “called up” by pressing an emergency key.
- A burst- and a ramp function are available for atrial overdrive-stimulation.
- An Unlock/Lock button protects against accidental change of the set parameters.
- The set parameters and (error) messages are shown on a liquid crystal display.
- The detection of the intrinsic heart activity as well as the emission of stimulation impulses are shown separately by blinking LEDs for both atrium and ventricle. Additionally, a beep-tone can be switched on whenever desired.
- System malfunctions that occur are indicated optically and acoustically.
- A lead surveillance system indicates interruptions and short circuits.
- When a battery change is required, optical and acoustic alerts are provided.
- During dual chamber pacing, an automatic mode for adapting A-V delay, maximum tracking rate (MTR), and PVARP is available.
- An automatic mode for adjusting the sensitivity in both the atrium and ventricle may be chosen.
- A Pause function is available for easy determination and measurement of the patient’s intrinsic heart activity.
- For controlling a balloon pulsation pump, or other peripheral devices, there is an optional interface available.

All further technical functions of the PACE 203 H will be described in detail in the following chapters.

# 3 Indication

The external pacemaker PACE 203 H can be used together with a stimulation lead system for temporary atrial, ventricular or A-V sequential stimulation in the clinical environment. The device can be used for therapeutic or diagnostic purposes as well as prophylactically.

Specific indications for temporary, anti-bradycardia stimulation (among others) are:

- Total or intermittent heart block;
- Symptomatic sinus-bradycardia;
- Sick sinus syndrome;
- Atrial and/or ventricular ectopic arrhythmia;
- Acute myocardial infarction with heart block;
- Temporary stimulation during asystole;
- Temporary support for hemodynamic optimization after heart surgery;
- Temporary use during the exchange of an implantable pacemaker;
- Temporary stimulation and control before implanting a pacemaker;

Indication for atrial overdrive-stimulation:

- Supra-ventricular tachycardia

# 4 Contraindication

There are no contraindications with regards to the use of the PACE 203 H for temporary cardiac stimulation for therapy and prevention of arrhythmia. The state of health of the patient, however, can restrict the choice of operational mode and stimulation parameters.

For example, a mode of operation with atrial sensing is not suitable or appropriate when atrial fibrillation occurs. This is due to excessive and chaotic frequency of detected fibrillation waves.

Overdrive-stimulation therapy must only be used in the atrium. Overdrive-stimulation in the ventricle could cause life threatening ventricular fibrillation.

# 5 Possible Complications

When using an external pacemaker such as PACE 203 H, the following complications can arise (Table 1):

| | Complication | Result |
|---|---|---|
| | Infection. | Sepsis. |
| | Thrombosis and pulmonary embolism. | Death. |
| | Perforation of the heart. | Hemopericardium. Hemothorax. Cardiac tamponade. |
| | Muscle and nerve stimulation. | Patient discomfort. |
| | Perforation of the lead.<br>Disconnection or breakage of lead.<br>Contact problems at connection sites.<br>Insufficient tightening of the collets. | System malfunction. Failure to pace.<br>Intermittent or complete failure of effective stimulation and/or sensing. |
| | Significant rise in the stimulation threshold. | Loss of effectiveness of the stimulation (exit block). |
| | Significant drop of the ECG-signal amplitude after lead dislocation or ingrown lead. | Loss of sensing (entrance-block) |
| | Abnormal pacemaker settings. | Erratic rhythm. Compromise in stroke volume / cardiac output. |
| | Inappropriately high sensitivity setting. Sensing of R or T waves in the atrium or P waves in the ventricle. Detection of interference (noise, electromagnetic interference). | Ventricular tachycardia, ventricular fibrillation, and death, if not recognized immediately. |
| | Time mismatch between intracardiac conduction and pacemaker settings. | Pacemaker mediated tachycardia.<br>(In order to prevent this, some decision overrides are implemented in the PACE 203 H. However, it is not possible to completely prevent the possibility of a pacemaker mediated tachycardia.) |
| | Overdrive stimulation in the atrium = rapid atrial pacing. | Accidental conduction into the ventricle can create ventricular arrhythmia. |
| | Battery failure or exhaustion. | Failure of impulse emission. Failure to pace. |
| | Technical defect in the PACE 203 H (failure of components). | Failure or change in the impulse emission, changed (or no) sensing, incorrect displays. Failure to pace. |
| | Undetected programming errors. | Chaotic rhythm. |
| | Erroneous lead connection. | Device does not function properly. Chaotic rhythm. Failure to pace as intended. |
| | Influence of defibrillation and RF surgery. | See chapter 7.19.8 for the effects while simultaneous use of the PACE 203 H with defibrillators or electro-surgical instruments. |

**Table 1: Complications**

# 6 Precautionary Measures and Warnings

The following list presents important precautionary measures and warnings. Further important precautionary measures and warnings will be found in the following chapters.

- In order to prevent unnecessary complications, the PACE 203 H should only be applied and used by medical personnel with extensive experience in cardiac stimulation therapy. Additionally, the person using the device should be thoroughly familiar with the contents of this instruction manual.
- All lead systems are to be connected to type CF devices only, because of the danger of current being diverted to the heart. Devices that are connected to a main supply pose increased danger for current diversions to the heart.
- Make sure that all devices in the vicinity of the patient are properly grounded.
- The stimulation leads provide a direct, low-resistance current path to the heart. Therefore, it is absolutely necessary that the connector plug is not touched with bare hands or come in contact with electrically conductive or wet surfaces. All possible static electricity sources must be kept away from the stimulation system.
- While the lead is being inserted and connected to the pacemaker, continuous ECG-monitoring is mandatory. For emergency situations, a defibrillator should always be available in a ready-to-use state.
- During atrial overdrive-stimulation an accidental conduction into the ventricle is possible and may cause ventricular tachycardia. Continuous ECG-monitoring is therefore mandatory. A defibrillator should always be available and ready-to-use.
- It is mandatory to continuously monitor the patient and to be prepared for a possible failure or malfunctioning of the pacemaker when the PACE 203 H is used in conjunction with electro-surgical instruments or defibrillators.
- To protect the patient and the pacemaker from current passing through the pacemaker/lead-circuitry caused by defibrillation discharges, the stimulation circuit should always be opened during defibrillation, if possible. Current flows caused by defibrillator discharges can endanger the patient. High current can also damage the pacemaker.
- If the PACE 203 H is to be used for a longer period of time on a patient, the stimulation threshold should be checked from time to time (the first time after a few hours, then daily), since an increase of the threshold may occur.
- An unnecessarily high sensitivity (small sensitivity value) increases the probability that proper pacemaker functioning will be affected by external interference and the device will switch to asynchronous stimulation (see also chapter 7.19.3). If there are strong electromagnetic fields caused by telecommunication devices (like mobile phones) or other sources an asynchronous mode should be set with a higher than the patient's intrinsic rate.
- During dual chamber pacing there is an inherent potential risk of cross-stimulation which is a cross-talk of an atrial stimulation or depolarization impulse into the ventricle or vice versa. The PACE 203 H is designed in such a way that this cross-talk is minimized. Furthermore, the distance between atrial and ventricular lead system should be not less than 4 cm. Due to differences in the anatomy, electro-physiological conditions and the location of the electrodes, cross-stimulation can, however, not be completely prevented. Therefore, when the device is switched on, or when the stimulation parameters are changed, the user must make sure that no cross-stimulation occurs. If this should happen, one can try to eliminate the effect by adapting the stimulation amplitudes or by exchanging the polarity of the leads. If this is not possible, the pacemaker must, in this special case, be used in a single-chamber mode without connection of the leads of the other channel.
- The PACE 203 H prevents abnormal settings (see chapter 7.19.7).
- In order to provide continuous operation of the pacemaker during battery changes, the battery must not be left in the device until it is completely drained (see also chapter 9.2).

- If the device is switched off, or to stand-by, after the request to change the battery appears, the battery must be changed before the pacemaker is turned on again.
- As a precision electronic device, the PACE 203 H needs periodic maintenance and check-ups after any malfunction or accident irrespective of usage (see chapter 9.3).
- In case that the PACE 203 H is not used for long periods of time, the battery must be removed in order to prevent damage from possible battery acid leakage. (Such damage cannot be compensated under the guarantee).
- The pacemaker must not be submerged in either water or any other cleaning solution. Do not use any scrubbing powder/liquid on the device.
- The device must not be sterilized in an autoclave or with ethylene oxide. Sterilization with plasma, ultrasound or gamma radiation is also not allowed. The PACE 203 H can be damaged by such procedures.
- Connector cables, intended for single use, cannot be re-sterilized and reinserted into a patient.
- Only the manufacturer, or facilities authorized by the manufacturer, can perform repairs or calibration of the PACE 203 H.
- All automatic settings provided by the PACE 203 H are only a guide to assist the user in finding the appropriate settings. It is the responsibility of the operator to determine if these settings are correct.

# 7 Use and Application of the PACE 203 H

## 7.1 Design

The PACE 203 H with its displays, keys, dials and terminals is shown in Figure 1.

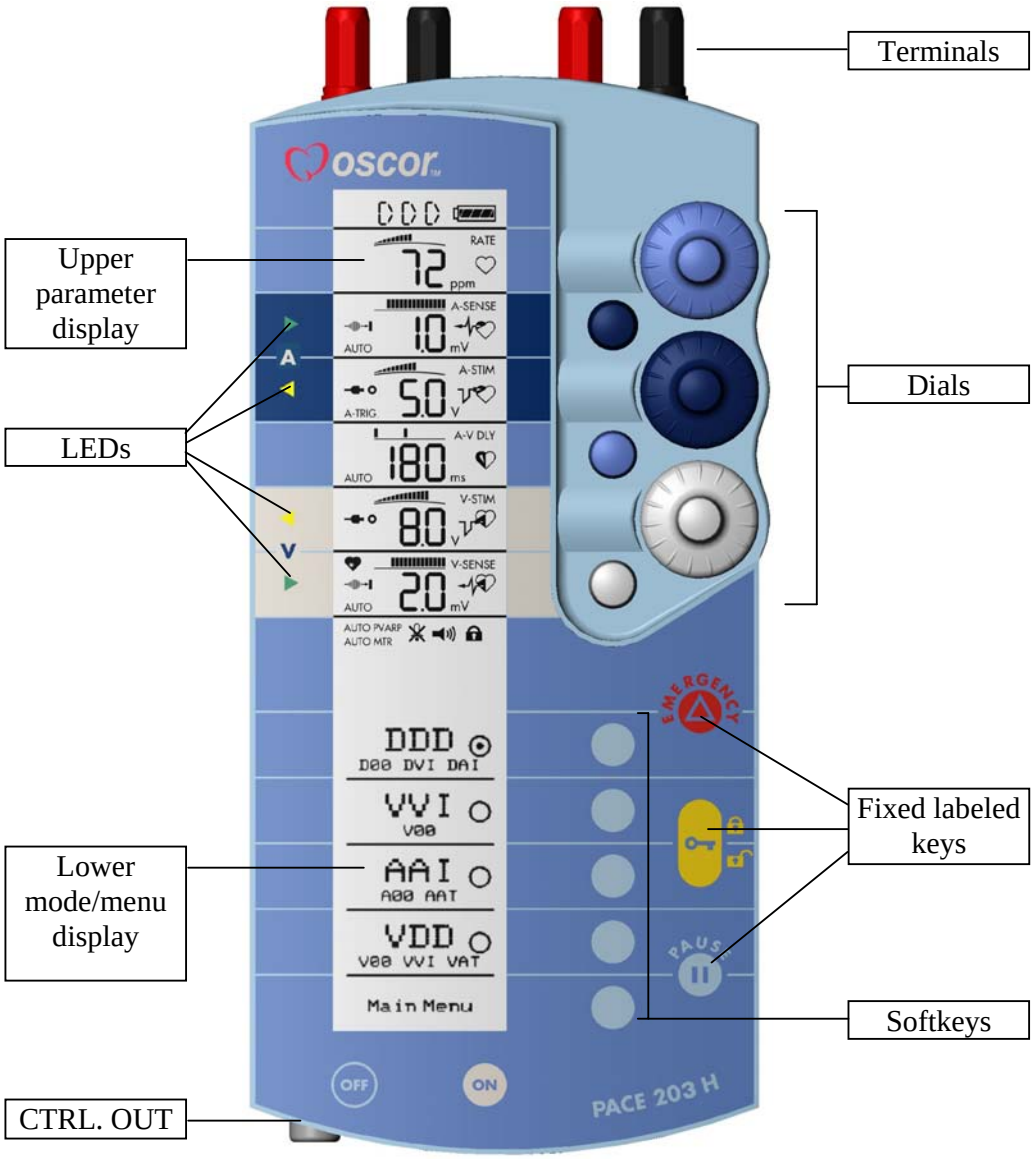



**Figure 1: PACE 203 H display face**


**Figure 2: PACE 203 H bottom view**

On the rear side of the device (see Figure 2) there is a metal hanger. This hanger deploys in three snap-in positions. Thus, it can be used as a hanger, as a stand on a table top, or it can be folded away. The easiest way to adjust the hanger is to grasp it at the sides and pull away from the pacemaker frame.

Furthermore, the rear side features a battery compartment release button. This button opens the battery compartment. The battery compartment is located at the bottom of the device. A button cover prevents the release button from being unintentionally pressed (see chapter 9.2).

## 7.2 Overview of the Display, Dials and Keys

### 7.2.1 The Upper Parameter Display

The six parameters, basic rate, atrial sensitivity, atrial pulse amplitude, A-V delay, ventricular pulse amplitude, ventricular sensitivity, as well as the pacing mode code (ISO 5841-1) and additional symbols, are continuously displayed as shown in

Figure 3. This will only occur when the pulse generator is turned on.

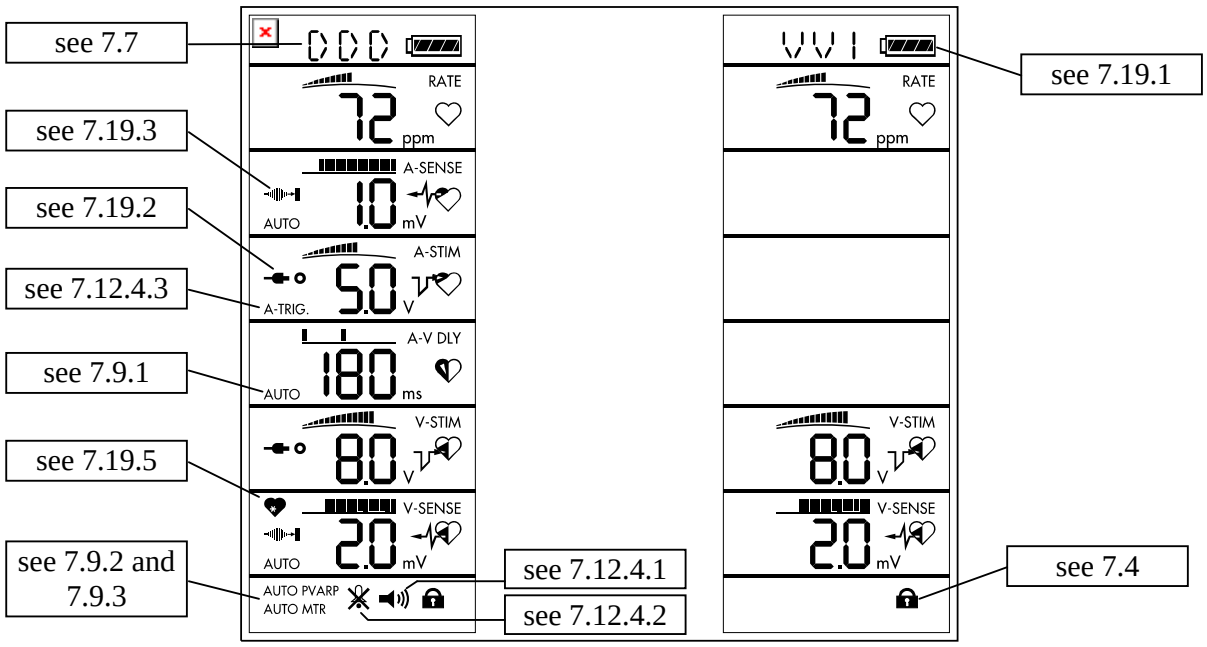



**Figure 3: Upper display**

On the left, a sample DDD mode display with numerous extra symbols as described later in this manual is shown.

If parameters have no meaning in the mode chosen, for example, atrial stimulation amplitude, atrial sensitivity and A-V delay in VVI mode, the corresponding section of the display will be empty. Such a sample display is shown on the right of Figure 3.

## 7.2.2 The Lower Mode / Menu Display

The lower display is used to show selection menus (see chapter 7.2.5) and various messages. These messages can be informative, as well as alerting the user regarding errors and conflicts.

If the lower display is off, then pressing the key

Lock/Unlock

turns the display on.

After 2½…3 min, without any user operation (turn of dials or pressing of keys), the lower display disappears for battery power saving.

## 7.2.3 The Dials

There are six dials corresponding to the parameter segments in the upper parameter display. The six parameters basic rate (& atrial overdrive rate), atrial sensitivity, atrial pulse amplitude, A-V delay, ventricular pulse amplitude and ventricular sensitivity are adjustable by rotating these dials (see Table 2).

When the dials are rotated, there is both a tactile (notched click) and acoustic response (beep).

| Dial | Function |
|---|---|
| (HI-) RATE | Adjusting the basic rate and the overdrive stimulation rate. |
| A-SENSE | Adjusting the atrial sensitivity. |
| A-STIM | Adjusting the atrial pulse amplitude. |
| A-V DLY | Adjusting the A-V delay. |
| V-STIM | Adjusting the ventricular pulse amplitude. |
| V-SENSE | Adjusting the ventricular sensitivity. |

**Table 2: Dials and their functions**

## 7.2.4 The Fixed Labeled Keys

Fixed labeled keys according to Table 3 are implemented.

| Key | Function |
|---|---|
| ON | Turning on the device. |
| OFF | Turning off the device. |
| Emergency | Setting emergency stimulation parameters. |
| Unlock/Lock | Unlocking/Locking the dials and the keys. |
| Pause | Disable stimulation (as long as pressed). |

**Table 3: Fixed labeled keys and their functions**

## 7.2.5 The Softkeys and the Menus

For setting of the pacing mode, and other parameters, and functions, five additional keys, so called softkeys, are implemented. These keys are used in conjunction with, and located next to, the lower display. Each softkey selects the option that is displayed adjacent to it in different menus shown in the lower display.

As a general rule the Mode Menu (Table 4) appears first when the lower display is turned on. The mode selection is located in the top menu level to allow a quick access.

| Mode Menu | | Key No. |
|---|---|---|
| DDD<br>D00 DVI DAI | ⦿ | 1 |
| VVI<br>V00 | ○ | 2 |
| AAI<br>A00 AAT | ○ | 3 |
| VDD<br>V00 VVI VAT | ○ | 4 |
| Main Menu | | 5 |

**Table 4: Mode Menu**

All other functions are placed in the second, third or even forth menu level. To access these features, the Main Menu must first be entered by pressing the softkey labeled

Main Menu.

If the lower display is off, then pressing the key

Lock/Unlock

turns the display on. The Main Menu appears as shown in Table 5.

| Main Menu | Key No. |
|---|---|
| High-Rate | 1 |
| Auto | 2 |
| Standard | 3 |
| Parameters<br>Options | 4 |
| ↵ | 5 |

**Table 5: Main Menu**

From here, the High-Rate (overdrive) stimulation, the automatic settings feature, the storage, and recall of standard programs, and further parameter settings and options, can be accessed.

**Note:** Pressing the softkey ↵ in any menu always returns to the Mode Menu.

### 7.2.6 Display Backlight

Both the upper and lower displays are backlit. The backlight is deployed as long as the device is unlocked.

After 30 seconds without any user operation (rotation of dials, or pressing of keys), the backlight is automatically turned off for battery power saving. This occurs in parallel upon locking the dials and keys.

If the battery voltage decreases below a specified battery depletion level, the backlight is automatically deactivated and will not turned on again, until the battery has been replaced.

### 7.2.7 LEDs for Sensing and Stimulation

To the left of the upper display there are four LEDs for indicating atrial and ventricular sensing and stimulation events. The LEDs for indicating sensing events flash green and those for indicating stimulation flash yellow.

All LEDs appear brightly shortly after turning on the PACE 203 H to verify that they are operational.

### 7.2.8 Acoustic Indications

Key pressing results in a high-frequency acoustic signal (beep).

Warnings are acoustically indicated by three successive short high frequency acoustic signals (beeps), whereas errors are indicated by one long high frequency signal (long beep).

If the Beep feature is enabled (see chapter 7.12.4.1), sensing and stimulation events are acoustically indicated (beep). Sensing and stimulation are indicated by a differential high frequency signal (beep). Specifically, sensing occurs with a lower frequency signal than stimulation.

## 7.3 Powering On the PACE 203 H

The PACE 203 H is powered on by pressing the key labeled

ON.

Subsequently, the PACE 203 H performs a self-test.

If the device was set to Stand-by (see chapter 7.5), it starts operation immediately with the last saved parameter setting.

If the device was OFF, the key

Lock/Unlock,

which is located to the right to the softkeys, must be pressed and released to indicate that it is functioning correctly. The PACE 203 H indicates this by the schematized key request shown in the lower display (Table 6 and Table 7).

| Press Unlock/Lock key request |
|---|
| Press  |
| Version n.nn<br>yyyy/mm/dd |

**Table 6: Press Lock/Unlock key request**

| Release Unlock/Lock key request |
|---|
| Release  |
| Version n.nn<br>yyyy/mm/dd |

**Table 7: Release Lock/Unlock key request**

**Note:** Version n.nn indicates the hardware and/or software version of the device, and yyyy/mm/dd the corresponding release date (year/month/day).

When the key

Lock/Unlock

has been pressed and released, the PACE 203 H begins to function with the Turn-on Program (see chapter 7.11.5). Upon shipping from the manufacturer, a DDD-mode with high sensitivity and moderate stimulation amplitudes is preset. This setting provides safe therapy for most pacing situations (see Table 34). The Turn-on program, however, may be customized according to the physician's preferences.

The language setting (see chapter 7.12.4.4) and acoustic indication of sensing and stimulation (see chapter 7.2.8) will remain unchanged during power off.

**Note:** If the indication to press and release the key

Lock/Unlock

is not followed within 30 sec, an error message stating

Startup timeout
(Press Unlock)

will appear, and the device will switch off. This prevents discharge of the battery, if the key labeled

ON

has been pressed accidentally.

**Note:** Please do not press any key during the self-testing after turning on the PACE 203. Among other tests, a key check is performed during this period. If a key is pressed, a request will be indicated as follows:

Release all keys

If the operator is not in compliance with the key request, or if a key is 'stuck', the message

Keyboard error

will appear in the lower display after 10 seconds.

## 7.4 Locking / Unlocking the PACE 203 H

In order to prevent an accidental change of pacing parameters, the device will be locked automatically, if no dial has been turned or no key has been pressed for 30 sec.

If the device is locked, pressing the key

Lock/Unlock

performs an unlock function. If the device is unlocked, pressing the key

Lock/Unlock

disables any dials and menu operation of the PACE 203 H.

Whether the device is locked or unlocked, these conditions will be continuously indicated by the lock symbol (Figure 4) in the upper display.

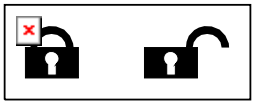


**Figure 4: Lock symbol**

If a key is pressed, or a dial is rotated, while the device is locked, a warning beep will be emitted and the lock symbol will blink for 2 seconds.

**Note:** For High-Rate Stimulation Stand-by (see chapter 7.10) the time of operating freedom is 60 seconds after last operation.

## 7.5 Powering Off the PACE 203 H

The PACE 203 H is powered off by pressing the key labeled

OFF.

In order to prevent powering off the device by mistake, a menu according to Table 8 appears in the lower display with the softkeys labeled

Off

and

Stand-by.

| Power-Off Menu | Key No. |
|---|---|
| Off (no storage) | 1 |
| | 2 |
| Stand-by (store data) | 3 |
| | 4 |
| ↵ | 5 |

**Table 8: Turn-off Menu**

Upon selecting

Off (no storage)

by pressing the corresponding softkey, the PACE 203 H switches off without storage of the actual settings, prompting the message:

Off (no storage).

Upon selecting

Stand-by (store data)

by pressing the corresponding softkey, the PACE 203 H stores the actual settings, prompting the message:

Stand-by (store data),

and then switches off. The PACE 203 H does not consume any battery power in the Stand-by mode.

When the PACE 203 H is powered on from the Stand-by mode, it will, after switching on, function with these prior settings, and not with the Turn-on program.

The PACE 203 H switches off with a short acoustic signal (beep).

## 7.6 Modes of Operation

The following terms are defined:

The **beat-to-beat interval** (a pacemaker parameter!) is the programmed interval of a complete pacing cycle, measured in milliseconds (ms). It is determined as the inverse of the basic rate. The PACE 203 H implements an atrial-based timing system, in which an atrial sensed or paced event resets the timing of the beat-to-beat interval. This implementation maintains the hemodynamically critical A-V interval, while adapting the V-A interval depending on spontaneous intrinsic heart activity.

**Wenckebach behavior** is always activated in dual chamber modes incorporating atrial sensing. In case of high spontaneous intrinsic atrial rates, the P-V delay will be prolonged in order to prevent high ventricular stimulation rates. This function limits the ventricular rate to the so-called Maximum Tracking Rate (MTR). As a consequence, Wenckebach behavior intermittently blocks the conduction of intrinsic atrial beats to the ventricular chamber.

The **A-V delay** (a pacemaker parameter!) is the programmed atrioventricular pacing interval, initiated by an atrial stimulus.

The **P-V delay** (a pacemaker parameter!) is the programmed time interval between atrial sensing (P wave) and the ventricular stimulus. The P-V delay can be interpreted as a programmable conduction delay window. It is determined by the A-V delay and by the Maximum Tracking Rate (MTR).

The **A-V interval** is the measured time interval between a sensed or paced atrial event and the subsequent ventricular sensed or paced event. In case of spontaneous ventricular depolarization, the A-V interval is shorter than the programmed A-V delay.

The **V-A delay** (a pacemaker parameter) is the programmed ventriculoatrial interval, initiated by a sensed or paced ventricular event. Known also as the Atrial Escape Interval, it is the interval from a sensed or paced ventricular event to an atrial paced event. Every cycle, the V-A delay is calculated as the difference between the set beat-to-beat interval and the A-V interval.

The **blanking period** is defined as the time during and after a sensed or paced event when the sensing channel and/or the opposite channel of a dual-chamber pacemaker are insensitive. The purpose is to avoid sensing of late potentials and sensing the event of one channel in the opposite channel (crosstalk). Thus, during the blanking period, no events are recognized.

**Refractory period** is a set time in the pacemaker, in which a signal in the respective channel will be recognized but not tracked.

**Sensing phase** is the period of time in which a signal that occurred in the respective channel will be recognized, interpreted as intrinsic, and tracked. Thus, this is the period outside blanking or refractory periods.

The **post-ventricular atrial refractory period**, or **PVARP** (a pacemaker parameter), is the period after a sensed or paced ventricular event during which the atrial sensing circuit is refractory. Thus, any atrial event occurring during PVARP will not be sensed by the atrial sensing circuit.

### 7.6.1 Ventricular Asynchronous (V00) Pacing

Ventricular asynchronous (V00) pacing is the simplest of all pacing modes because there is no sensing and no mode of response. The ventricular pacing stimuli occur at the programmed rate, regardless of any intrinsic cardiac event.

### 7.6.2 Atrial Asynchronous (A00) Pacing

Atrial asynchronous (A00) pacing behaves exactly like V00, but the pacing stimuli occur in the atrium. The atrial pacing stimuli occur at the programmed rate, regardless of any intrinsic cardiac event.

### 7.6.3 A-V Sequential Asynchronous (D00) Pacing

Dual-chamber, or A-V sequential asynchronous (D00), pacing provides atrial and subsequent ventricular stimuli with a fixed, programmed delay. The pacing stimuli occur at the programmed rate, regardless of any intrinsic atrial or ventricular events.

### 7.6.4 Ventricular Inhibited (VVI) Pacing

Ventricular inhibited (VVI) pacing incorporates sensing on the ventricular channel, and pacemaker output is inhibited by a sensed ventricular event. In VVI mode, the PACE 203 H is refractory for a period after a paced or sensed ventricular event, the ventricular refractory period. Any ventricular event occurring within the ventricular refractory period is not sensed. Any ventricular event occurring outside the ventricular refractory period is sensed and resets the timing of the pacemaker to the beginning of a new beat-to-beat interval.

### 7.6.5 Atrial Inhibited (AAI) Pacing

In the absence of intrinsic activity, ventricular or atrial stimulation impulses will be given with the set basic rate. The recognition of a P-wave in AAI mode in the pacemaker's sensing phase inhibits the delivery of the next stimulation impulse, resets the timing of the pacemaker to the beginning of the beat-to-beat interval and starts the refractory period.

### 7.6.6 Atrial Synchronous (P-Tracking) (VDD) Pacing

In atrial synchronous (P-tracking) (VDD) pacing mode, the PACE 203 H paces only in the ventricle, senses in both atrium and ventricle, and responds both by inhibition of ventricular output by intrinsic ventricular activity and by tracking of P waves.

A sensed P wave initiates the P-V delay. During the P-V delay, the atrial channel is refractory. At the end of the P-V delay, a ventricular stimulus is delivered if no intrinsic ventricular activity has been sensed, that is, P wave tracking. Ventricular activity, paced or sensed, initiates the PVARP and the V-A delay.

If no P wave activity occurs during the V-A delay, the A-V delay is initiated. During the A-V delay, the atrial channel is refractory. If no R-wave activity occurs during the A-V delay, the PACE 203 H delivers a ventricular pacing stimulus upon termination of the A-V delay.

### 7.6.7 Dual-Chamber Pacing and Sensing with Inhibition and Tracking (DDD)

This pacing mode provides dual-chamber pacing and sensing with inhibition and atrial tracking.

If intrinsic atrial and ventricular activity occur before the beat-to-beat interval terminates, both channels are inhibited and no pacing occurs.

If a P wave is sensed before the V-A interval is completed, output from the atrial channel is inhibited. The A-V delay is initiated. If no ventricular activity is sensed before the A-V delay terminates, a ventricular pacing stimulus is delivered, that is, P-synchronous ventricular pacing.

If no atrial activity is sensed before the V-A delay is completed, an atrial pacing stimulus is delivered, which initiates the A-V delay. If intrinsic ventricular activity occurs before the termination of the A-V delay, the ventricular output from the PACE 203 H is inhibited, that is, atrial pacing. If no intrinsic ventricular activity occurs before the termination of the A-V delay, a ventricular pacing stimulus is delivered, that is, A-V sequential dual-chamber pacing.

### 7.6.8 The A-V Sequential, Atrial Inhibited (DAI) Pacing

A-V sequential, atrial inhibited (DAI) pacing provides pacing in both the atrium and the ventricle but sensing only in the atrium. This mode is implicitly selected by setting first the DDD mode and, second, the ventricular sensitivity to infinite ("–.–"). Thus, sensing in the ventricular channel is disabled.

The DAI mode may be useful in situations where no ventricular sensing is possible (for instance, because of interference), or when A-V synchrony must be maintained upon a complete A-V block.

### 7.6.9 The A-V Sequential, Ventricular Inhibited (DVI) Pacing

A-V sequential, ventricular inhibited (DVI) pacing provides pacing in both the atrium and the ventricle but sensing only in the ventricle. This mode is implicitly selected by setting first the DDD mode and, second, the atrial sensitivity to infinite ("–.–"). Thus, sensing in the atrial channel is disabled.

**Note:** With the DVI mode (implicitly) set, the following exceptions are taking place:

1) The PACE 203 H - specific algorithm for determining extrasystoles is disabled. In DVI mode, the PACE 203 H cannot differentiate between high intrinsic rates and occurrences of extrasystoles, because the atrial sensing is disabled.

2) If another R-wave is detected during the V-A delay, the V-A delay will be initiated with a value equal to the difference between the beat-to-beat interval and the A-V delay.

### 7.6.10 Atrial Sensing Atrial Synchronous (P-Tracking) (VAT) Pacing

In atrial synchronous (P-tracking) (VDD) pacing mode, the PACE 203 H paces only in the ventricle but senses in the atrium only. If intrinsic atrial activity occurs, a ventricular stimulus is delivered after the P-V delay.

This mode is implicitly selected by first setting the VDD mode and, second, the ventricular sensitivity to infinite ("–.–"). Thus, sensing in the ventricular channel is disabled.

The VAT mode may be useful in situations where no ventricular sensing is possible (for instance, because of interference), or when A-V synchrony must be maintained upon a complete A-V block.

### 7.6.11 Non-Pacing 0D0 Mode (Pause)

In this mode, sensing is enabled in both channels but not pacing. The PACE 203 H is ‘listening’ to intrinsic atrial and ventricular events only.

The 0D0 mode is utilized to check the patient’s intrinsic activity (see chapter 7.14), or to get initial values for the Auto Sense feature (see chapter 7.9.1). It must be used with **great caution** on patients depending on a pacemaker.

### 7.6.12 Atrial Trigger Modes (AAT, DDD+AT, DAT)

If Atrial Trigger option (see chapter 7.12.4.3) is activated, an atrial stimulus is delivered any time an atrial activity is sensed, and with the atrial channel not being refractory.

The Atrial Trigger is enabled when either AAI (→ AAT) or DDD (→ DDD+AT) or DAI (→ DAT) modes are set.

## 7.7 Changing the Mode of Operation

If the lower display is switched on, it always displays the Mode Menu first. Each of the primary modes (DDD, VVI, AAI, VDD) can now be selected by the touch of the corresponding softkey.

If the lower display is off, it can be turned on pressing the key

Lock/Unlock.

In the event that another menu is displayed, pressing the ↵ softkey will switch to the mode menu immediately.

| Mode Menu | | Key No. |
|---|---|---|
| DDD<br>D00 DVI DAI | ⊙ | 1 |
| VVI<br>V00 | ○ | 2 |
| AAI<br>A00 AAT | ○ | 3 |
| VDD<br>V00 VVI VAT | ○ | 4 |
| Main Menu | | 5 |

**Table 9: Mode Menu**

The modes D00, V00, A00, DVI, DAI and VAT are set by selecting the "primary" mode (DDD, VVI, AAI, VDD) and setting the sensitivity in the respective channel(s) to infinite (displayed as "–.–"). Table 10 shows the resulting supplementary modes, if the sensitivity is set to infinite.

| Primary Mode | Change of Sensitivity | Resulting Mode |
|---|---|---|
| DDD | A-Sensitivity → "–.–" | DVI |
| DDD | V-Sensitivity → "–.–" | DAI |
| DDD | A- and V-Sensitivity → "–.–" | D00 |
| VVI | V- Sensitivity → "–.–" | V00 |
| AAI | A- Sensitivity → "–.–" | A00 |
| VDD | A- Sensitivity → "–.–" | VVI |
| VDD | V- Sensitivity → "–.–" | VAT |
| VDD | A- and V- Sensitivity → "–.–" | V00 |

**Table 10: Supplementary Mode Setting**

The selected mode is indicated with its NBG code[1] in the upper display.

In the new mode, the PACE 203 H continues to work with the parameters set before the mode change.

[1] Bernstein AD, Camm AJ, Fletcher RD, et al. The NASPE/BPEG generic pacemaker code for antibradyarrhythmia and adaptive-rate pacing and antitachyarrhythmia devices. Pacing Clin Electrosphysiol 1987; 10: 794-799

**Note:** In case of a change from a single to a dual chamber mode or from one chamber mode to another chamber mode (for instance VVI→AAI), the last used parameters are adopted. If the Turn-on program (see 7.11.5) has been re-defined to a single chamber mode, in case of a first change of such kind, the parameter set will be complemented from the standard program of the new mode.

The enabling of the atrial trigger function in the AAI and DDD modes is described in chapter 7.12.4.3.

A non-pacing mode (0D0) is accessible by pressing the key labeled

PAUSE

(see chapter 7.14).

**Note:** A standard program can be stored for each primary mode. These standard programs may be defined by the user (see chapter 7.11).

**Note:** If conflicts (because of abnormal settings) occur as a result of a mode change, the PACE 203 H will make use of its Automatic setting feature to solve the problem (see chapters 7.19.7 and 7.9).

## 7.8 Adjustment of Rate, Stimulation Amplitude, Sensitivity and A-V Delay Using the Dials

One dial is assigned to each of the parameters. From top to bottom:

- Rate (RATE)
- Atrial sensitivity (A-SENSE)
- Atrial stimulation amplitude (A-STIM)
- A-V delay (A-V DLY)
- Ventricular stimulation amplitude (V-STIM)
- Ventricular sensitivity (V-SENSE).

The actual values of the parameters, and the corresponding bar diagrams indicating signal intensity or magnitudes, are located in the upper display, which is always turned on. These bar diagrams indicate the set value within its range.

**General Notes:**

- In order to change a parameter, or parameters, the dials must be unlocked by pressing the key

  Lock/Unlock

  (if the PACE 203 H is not yet unlocked).
- Rotating the rate, amplitude, or A-V delay dials clockwise increases the parameter value. In contrast, counterclockwise rotation decreases the parameter value.
- Rotating a sensitivity dial clockwise increases the sensitivity value, i.e. decrease the sensitivity. In contrast, counterclockwise rotation decreases the sensitivity value, i.e. increases the sensitivity.
- If a maximum or minimum value is reached, further rotation of the dial is disregarded.
- Each parameter change is visualized on the upper display, both as a number and as a bar diagram.
- Any change of the parameters will become effective after the next sensing or stimulation event.
- Several parameters are allowed to change simultaneously.
- If a parameter has no pacing function in the mode selected, for example, A-Sense in the VVI mode, the corresponding section in the upper display is blanked. If a dial, belonging to parameter without pacing function in the mode selected, is set, the respective, previously blanked section will be switched on. A numeric value will be briefly displayed, whereupon it will disappear in approximately 2 seconds.

## 7.8.1 Adjustment of Basic Rate

Rotating the RATE dial clockwise will increase the basic rate in the range shown in Table 11. The actual rate value and the intensity bar diagram can be seen in the upper display. The intensity bar diagram enlarges from left to right with rate increase.

| Parameter | Adjustable Values | Unit |
|---|---|---|
| Rate | 30 (2) 220 | ppm |

**Table 11: Adjustable values for rate**

**Note:** The safety feature "protection against abnormal settings" (see chapter 7.19.7) prevents increasing the basic rate to a value larger then the MTR in DDD, VDD, DAI, VAT and DAT mode. Limiting the basic rate value is accompanied by a transient warning message in the lower display.

## 7.8.2 Adjustment of Stimulation Amplitude

By rotating the A-STIM dial or the V-STIM dial clockwise. the stimulation amplitude will be increased in the range shown in Table 12. The actual stimulation amplitude value and the intensity bar diagram can be seen in the upper display. The intensity bar diagram enlarges from left to right with amplitude increase.

| Parameter | Adjustable Values | Unit |
|---|---|---|
| Stimulation Amplitude | 0.1 (0.1) 2.0<br>2.0 (0.2) 6.0<br>6.0 (0.5) 12.0<br>12.0 (1.0) 18.0 | V |

**Table 12: Available values for stimulation amplitude**

### 7.8.3 Adjustment of Sensitivity

By rotating the A-SENSE dial or the V-SENSE dial clockwise, the sensitivity value (mV value) increases. This indicates that the sensitivity will decrease. The actual sensitivity value and the parameter intensity bar diagram can be seen in the upper display. The parameter intensity bar diagram diminishes from left to right, when the sensitivity value is increased (sensitivity is decreased). If the minimum sensitivity is reached, the value "infinite" is indicated by "–.–" in the display, and a mode change occurs. This is indicated by the pacing mode code, visible in the upper display (see chapter 7.7).

By rotating the A-SENSE dial or the V-SENSE dial counterclockwise, the sensitivity value (mV value) decreases. This indicates that the sensitivity value increases. The parameter intensity bar diagram expands from the right to left side.

The sensitivity is adjustable in the range and with the steps shown in Table 13.

**Warning:** Increasing the mV values indicates decreasing the sensitivity. An atrial value of 0.2 mV and a ventricular value of 1.0 mV represent the highest sensitivity in the respective channels. The value "infinite" results in an asynchronous mode for the corresponding channel. An inhibition of the stimulation pulse in this channel is not possible.

| Parameter | Adjustable Values | Unit |
|---|---|---|
| Atrial Sensitivity | 0.2 (0.1) 2.0<br>2.0 (0.2) 5.0<br>5.0 (0.5) 10.0<br>10.0 (1.0) 20.0<br>–.– (= no sensing) | mV |
| Ventricular Sensitivity | 1.0 (0.1) 2.0<br>2.0 (0.2) 5.0<br>5.0 (0.5) 10.0<br>10.0 (1.0) 20.0<br>–.– (= no sensing) | mV |

**Table 13: Available values for sensitivity**

## 7.8.4 Adjustment of A-V Delay

By rotating the A-V DLY dial clockwise, the A-V delay will become extended within the range shown in Table 14. The actual A-V delay and the parameter intensity bar diagram can be observed in the upper display. The parameter intensity bar diagram corresponds to the A-V delay. The leftmost bar represents the timely occurrence of the atrial event and is always displayed. A second bar represents the timely occurrence of the ventricular event and is "shifted" right or left, related to the increase or decrease the A-V delay, respectively.

| Parameter | Adjustable Values | Unit |
|---|---|---|
| A-V Delay | 5, 10 (10) 400 | ms |

**Table 14: Adjustable values of A-V delay**

**Note:** When atrial Auto Sense is enabled, the A-V delay and P-V delay are limited to a minimum of 30 ms. this is because Auto Sense requires a specified time to measure the intrinsic atrial activity. In case the atrial Auto Sense is enabled, and the A-V delay was set to a value smaller than 30 ms, then the A-V delay will be automatically extended to 30 ms. This action is indicated by a transient informative message in the lower display (see also 7.9.4).

**Note:** Because of its safety feature "protection against abnormal settings" (see chapter 7.19.7), the PACE 203 H prevents increasing the A-V delay to a value, which would not guarantee a minimum atrial sensing phase in dual chamber demand modes, or a minimum V-A interval in the D00 mode, respectively. The limitation of the A-V delay value will be indicated by a transient warning message in the lower display.

## 7.9 Using the Automatic Features

The PACE 203 H offers the capability for automatic setting of A-V delay, PVARP, and maximum tracking rate (MTR), with the setting of rate as well as for automatic adjustment of sensitivity.

To enable these features, the Auto Menu must first be entered by pressing the softkey labeled

Main Menu,

and then the softkey labeled

Auto.

If the lower display is off, then pressing the key

Lock/Unlock

turns it on. The Auto Menu appears as shown in Table 15.

Then, with the corresponding keys, one or more of the automatic features can be enabled or disabled individually.

| Auto Menu | | Key No. |
|---|---|---|
| Auto AVD | ☑ | 1 |
| Auto PVARP | ☑ | 2 |
| Auto MTR | ☑ | 3 |
| Auto Sense | | 4 |
| ↵ | | 5 |

**Table 15: Auto Menu**

### 7.9.1 Automatic Setting of A-V Delay with the Setting of Rate

If this feature is enabled, the PACE 203 H automatically adjusts the A-V delay with the setting of the basic rate.

To activate Auto A-V Delay, the softkey labeled

Auto AVD

in the Auto Menu has to be pressed. The corresponding check box then gets checked.

The PACE 203 H then adjusts the A-V delay depending on the basic rate according to the formula in Table 16 and rounded to the nearest manually adjustable value (see chapter 7.8.4). In the corresponding

**A-V DLY**

segment in the upper display the label

**AUTO**

indicates that the Auto A-V delay feature is activated. The calculated value for the A-V delay is also indicated numerically.

| Parameter | Automatic A-V Delay Setting Formula | Range | Unit |
|---|---|---|---|
| A-V Delay | 290 – (1.5 × Rate/ppm) | 50 ... 250 | ms |

**Table 16: Automatic setting formula for A-V delay**

Auto A-V Delay can be deactivated either via the Auto menu or simply by rotating the (unlocked) A-V DLY dial a few clicks (approximately a quarter of one revolution).

If the A-V DLY dial has been rotated to deactivate Auto A-V delay, the transient message

Auto AVD
turned off

appears in the lower display accompanied by a short beep, and

**AUTO**

disappears from the upper display.

To deactivate Auto A-V Delay in the Auto menu, the softkey labeled

Auto AVD

must be pressed again. This causes the check mark to disappear from the corresponding check box and

**AUTO**

from the upper display.

## 7.9.2 Automatic Setting of PVARP with the Setting of Rate

If this feature is enabled, the PACE 203 H automatically adjusts the post-ventricular atrial refractory period (PVARP) with the setting of the basic rate.

To activate Auto PVARP, the softkey labeled

Auto PVARP

in the Auto Menu must be pressed. The corresponding check box then gets checked.

The PACE 203 H now adjusts the PVARP depending on the basic rate according to the formula in Table 17 and rounded to the nearest manually adjustable value (see chapter 7.12.1). In the upper display the label

**AUTO PVARP**

indicates that the Auto PVARP feature is activated.

| Parameter | Automatic PVARP Setting Formula | Range | Unit |
|---|---|---|---|
| PVARP | 330 – (0.75 × Rate/ppm) | 150 ... 500 | ms |

**Table 17: Automatic setting formula for PVARP**

To deactivate Auto PVARP, the softkey labeled

Auto PVARP

in the Auto menu must be pressed again. This causes the check mark to disappear from the corresponding check box and

**AUTO PVARP**

from the upper display. The PVARP setting menu appears showing the actual value which provides the opportunity to adjust a new value manually (see chapter 7.12.1).

**Note:** The automatic setting of the PVARP can also be switched on and off in the PVARP menu (see chapter 7.12.1).

**Note:** The PVARP of the PACE 203 H is divided in two parts: an absolute part and a relative part. In the absolute part (which is 100 ms long), no atrial events are recognized. In the relative part (the remaining) atrial events are registered, but not tracked. This algorithm prevents the misinterpretation of ventricular events after premature atrial events as extrasystoles (PVCs), as described in chapter 7.19.5.

### 7.9.3 Automatic Setting of MTR with the Setting of Rate

If this feature is enabled, the PACE 203 H automatically adjusts the Maximum Tracking Rate (MTR) with the setting of the basic rate.

To activate Auto MTR, the softkey labeled

Auto MTR

in the Auto Menu must be pressed. The corresponding check box then gets checked.

The PACE 203 H then adjusts the MTR to a value 34 ppm higher than the basic rate, but with a minimum of 100 ppm and a maximum of 230 ppm, according to the formula and the range in Table 18. In the upper display the sign

**AUTO MTR**

indicates that the Auto MTR feature is activated.

| Parameter | Automatic MTR Setting Formula | Range | Unit |
|---|---|---|---|
| MTR | Rate + 34 | 100 ... 230 | ppm |

**Table 18: Automatic setting formula for MTR**

To deactivate Auto MTR, the softkey labeled

Auto MTR

in the Auto menu must be pressed again. This causes the check mark to disappear from the corresponding check box and the sign

**AUTO MTR**

from the upper display. The MTR setting menu appears showing the actual value which provides the opportunity to input a new value manually (see chapter 7.12.2).

**Note:** The automatic setting of the MTR can also be switched on and off in the MTR menu (see chapter 7.12.2).

## 7.9.4 Automatic Adjustment of Sensitivity (Auto Sense)

### 7.9.4.1 How the Auto Sense Function Works

The Auto Sense function automatically adjusts the PACE 203 H sensitivity to maintain an approximate 3:1 sensing safety margin, potentially reducing the number of under/over-sensing episodes. This feature may also reduce the need to manually determine the sensitivity threshold (see chapter 7.16).

The Auto Sense function is different from the other automatic functions in that the automatic sensing value is not calculated from another parameter. The PACE 203 H adapts the sensing value continuously to the patient's intrinsic heart activity. For this intrinsic activity, which is detected in the sensing phase of the respective channel, the amplitude is measured and the sensitivity value of the pacemaker is adapted to maintain the 3:1 sensing safety margin.

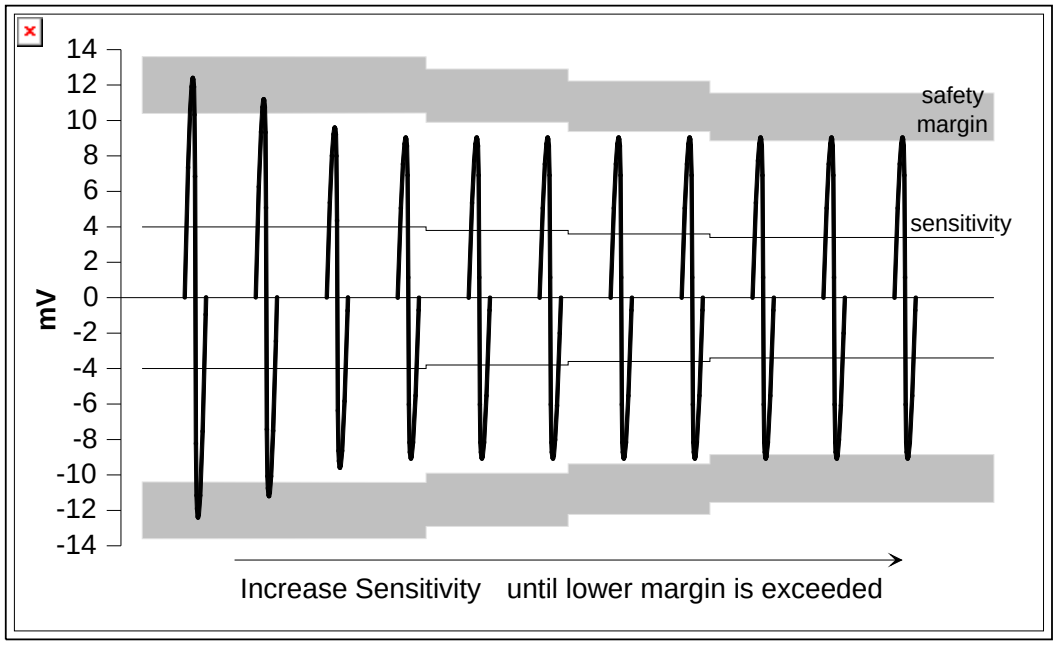



**Figure 5: The Auto Sense function increases sensitivity.**

Figure 5 shows an example in which the sensitivity is increased (i.e. sensitivity value is decreased) to maintain an appropriate safety margin when the Intracardiac ECG amplitude drops.

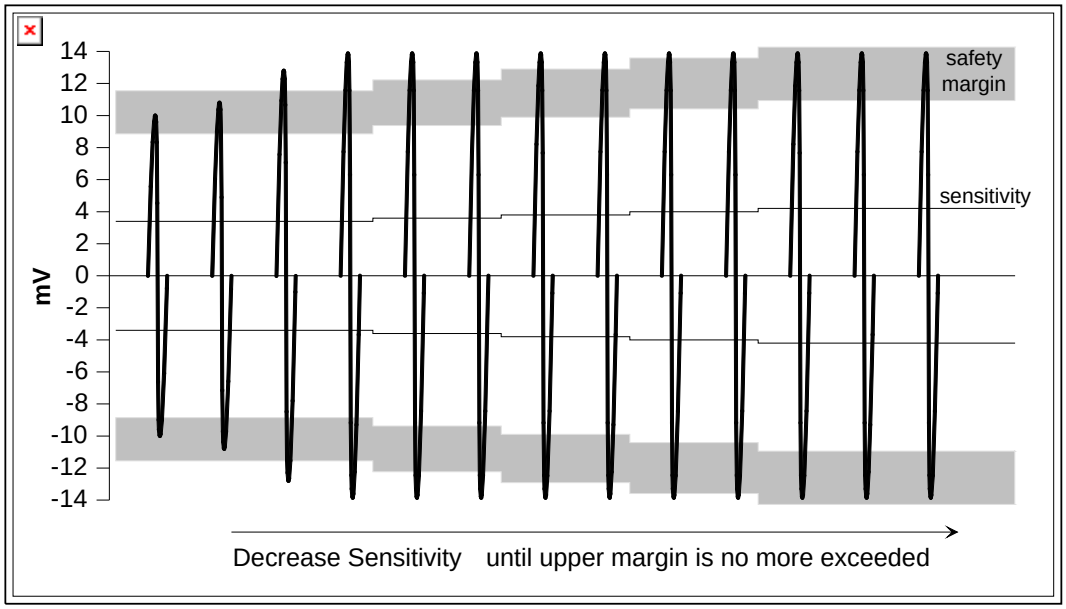



**Figure 6: The Auto Sense function decreases sensitivity.**

Figure 6 shows an example in which the sensitivity is decreased (i.e. sensitivity value is increased) when the EGM amplitude goes up. An appropriate safety margin is kept without working with unnecessarily high sensitivity, which may promote noise detection.

**Important notes for the use of the Auto Sense function:**

- Because the intrinsic activity of the patient's heart determines the sensitivity value, the Auto Sense feature can, of course, only be used in a patient who has such intrinsic activity.
- Atrial Auto Sense cannot be used together with Atrial Trigger, because the triggered stimulation prevents proper measurement of the intrinsic atrial activation (see also 7.12.4.3).
- Auto Sense requires a specific time to measure the intrinsic atrial activity. P-V delay is therefore limited to a minimum of 30 ms when atrial Auto Sense is activated. Because A-V delay cannot be shorter than P-V delay it is also limited to 30 ms. In case atrial Auto Sense is enabled, and the A-V delay was set to a value smaller than 30 ms, then the A-V delay will be automatically extended to 30 ms. This action will be indicated by a transient informative message in the lower display (see also 7.8.4).

### 7.9.4.2 Activation of Auto Sense

Because the Auto Sense algorithm requires sensed intrinsic atrial or ventricular events to become operational, an initial appropriate sensing value is required to enable the Auto Sense feature. The following procedure has been established to obtain this initial value:

To enter the Auto Sense Menu the softkey labeled

Auto Sense

in the Auto Menu must be pressed (see Table 15).

| Auto Sense Menu | | Key No. |
|---|---|---|
| | | 1 |
| Atrial Auto Sense | ☐ | 2 |
| Ventricular Auto Sense | ☐ | 3 |
| | | 4 |
| ↵ | | 5 |

**Table 19: Auto Sense Menu**

The softkey labeled

Atrial Auto Sense

and/or the softkey labeled

Ventricular Auto Sense

must be pressed in order to enable or disable the Auto Sense feature for the atrial and/or ventricular channel (Table 19).

If Auto Sense is be enabled in a channel where it was not activated before, a check mark appears in the respective checkbox. The checkbox then starts blinking, and the request to press and hold the softkey labeled

Initiate

is indicated in the lower display. Table 20 illustrates this scenario, if Auto Sense is enabled in both channels.

| Auto Sense Menu | Key No. |
|---|---|
| | 1 |
| Atrial Auto Sense  | 2 |
| Ventricular Auto Sense  | 3 |
| Initiate (Press & Hold) | 4 |
| ↵ | 5 |

**Table 20: Auto Sense Menu (channels selected, initialization request)**

When the softkey labeled

Initiate

is pressed, the PACE 203 H stops pacing as long as this key is held down. However, the PACE 203 H continues to sense and attempts to detect a regular intrinsic activation of the patient's heart. While doing this, the lower display appears as shown in Table 21. A flashing heart symbol indicates each detected event. Furthermore, the acoustic indicator will automatically be enabled temporarily, if it is not already switched on. Because the PACE 203 H goes through an initialization algorithm, individual intrinsic events may or may not be detected.

| Auto Sense Menu | Key No. |
|---|---|
| | 1 |
| Searching A-Sense  | 2 |
| Searching V-Sense  | 3 |
| Hold... | 4 |
| | 5 |

**Table 21: Auto Sense Menu (searching)**

If the PACE 203 H has found an intrinsic heart rhythm, it will display the sensed EGM amplitude as shown in Table 22.

| Auto Sense Menu | Key No. |
|---|---|
| Sensed: | 1 |
| A = 2.3 mV | 2 |
| V = 8.0 mV | 3 |
| Finished (release key) | 4 |
| | 5 |

**Table 22: Auto Sense Menu (intrinsic rhythm found)**

The softkey labeled

Initiate

can now be released. An appropriate sensitivity value will be automatically selected and set which will be visible in the upper display. Furthermore the sign

**AUTO**

will be shown in the respective section(s) of the upper display. The lower display will return to the Auto Sense Menu with the boxes checked (blinking ceases) as shown in Table 23.

| Auto Sense Menu | | Key No. |
|---|---|---|
| | | 1 |
| Atrial Auto Sense | ☑ | 2 |
| Ventricular Auto Sense | ☑ | 3 |
| | | 4 |
| ↵ | | 5 |

**Table 23: Auto Sense Menu (finished)**

**Notes for the initialization of the Auto Sense function:**

- If the user continues to press the softkey labeled

  Initiate,

  the PACE 203 H will continue to search for intrinsic activity and find the optimal value.

- If the PACE 203 H detects frequencies higher than the noise frequency (273 bpm) during the Auto Sense initialization, the corresponding interference symbol (Figure 12) is shown in the upper display. Any P or R wave value determined by the PACE 203 H during interference is cleared off the display. 2 seconds after the PACE 203 H determines interference with the Auto Sense function enabled, the sensitivity setting will be doubled in order to find a sensitivity level where the heart activity is sensed without interference.

- If no activity is sensed in a channel for 3 seconds, a previously determined P or R wave will be cleared off the display.

The pacing will be interrupted for a period of maximum 10 seconds, similar when using the Pause function. Subsequently, the PACE 203 H will resume pacing. If no intrinsic activity is detected in this period, the message

No A-Sense

or

No V-Sense

will be displayed. Table 24 shows an example were an atrial rhythm could be found, but no ventricular rhythm.

| Auto Sense Menu | Key No. |
|---|---|
| Sensed: | 1 |
| A = 2.3 mV | 2 |
| No V-Sense | 3 |
| Finished (release key) | 4 |
| | 5 |

**Table 24: Auto Sense Menu (no R wave found)**

If no intrinsic rhythm is detected in one or both channels, the respective check mark continues blinking after returning to the previous menu. The initialization request persists as shown in Table 25.

| Auto Sense Menu | | Key No. |
|---|---|---|
| | | 1 |
| Atrial Auto Sense | ☑ | 2 |
| Ventricular Auto Sense | ☑ | 3 |
| Initiate (press & hold) | | 4 |
| ↵ | | 5 |

**Table 25: Auto Sense Menu (one channel initialization request)**

The user can decide if another attempt shall be made to find an intrinsic rhythm, or if the procedure shall be terminated using the ↵ key. In the previous example, the Auto Sense feature will then be enabled only in the atrial channel.

### 7.9.4.3 Re-Initialization of Auto Sense

Once activated, the Auto Sense feature can be easily re-initialized by just pressing and holding the key

PAUSE

(see 7.14). However, this is only necessary if the amplitude of the intrinsic activity has decreased so dramatically and rapidly such that the Auto Sense algorithm could not follow this change.

**Warning:** If frequencies higher than the noise frequency (273 bpm) are detected during the re-initialization, the corresponding interference symbol (Figure 12) will be displayed in the upper display. The sensitivity setting will remain unchanged and the measured frequency will be displayed, because it may be a high-frequency tachycardia. This behavior is different from Auto Sense initialization (see above), where the sensitivity value will be increased step by step in case of noise.

### 7.9.4.4 Deactivation of Auto Sense

The Auto Sense function can be disabled either via the Auto Menu or simply by rotating the respective (unlocked) A-SENSE or V-SENSE dial a few clicks (approx. a quarter of one revolution).

If a SENSE dial has been turned to deactivate Auto Sense, the transient message

| | | |
|---|---|---|
| Atrial<br>Auto Sense<br>turned off | or | Ventricular<br>Auto Sense<br>turned off |

appears in the lower display, accompanied by a short beep. The sign

**AUTO**

disappears from the upper display.

Using the Auto menu, the Auto Sense function is disabled by pressing the corresponding softkey. As a consequence, the corresponding check box is unchecked. The sign

**AUTO**

disappears from the upper display.

**Note:** Upon a mode change (for instance VVI → AAI or DDD → VVI) that disables a channel, the Auto Sense function, enabled in this particular channel, is disabled. The Auto Sense function is not reactivated upon enabling the particular channel, because the EGM amplitudes could have changed significantly during the time the Auto Sense function was disabled.

## 7.10 High Rate Stimulation (Atrial Overdrive)

The PACE 203 H provides a function for high rate stimulation, also known as atrial overdrive stimulation, or rapid atrial pacing.

The atrial high rate stimulation function is activated by entering the main menu via the softkey labeled

Main Menu,

and, then, by selecting the high rate stand-by menu by pressing the softkey labeled

High-Rate.

**Note**: Remember to press the key

Lock/Unlock

in case the PACE 203 H keypad is locked. In case the lower display was turned off, it is then turned on.

The High-Rate Standby menu appears as shown in Table 26 and the overdrive-stimulation standby mode is entered. The acoustic indicator will automatically be switched on temporarily, if it is not already on.

**Note:** Within the High-Rate Stand-By menu, the pacemaker continues to operate in the set mode.

Any previously selected overdrive stimulation rate and the corresponding beat-to-beat interval are displayed.

**Note:** After turning on, the PACE 203 H overdrive-stimulation-rate is always set to 240 ppm.

| High-Rate Standby Menu | Key No. |
|---|---|
| START | 1 |
| 240 ppm (250 ms) | 2 |
| Dial RATE to change High-Rate! | 3 |
| | 4 |
| ↵ | 5 |

**Table 26: High-Rate Standby Menu**

The overdrive stimulation rate can be adjusted by using the RATE dial. This means that the RATE dial defaults into a HIGH-RATE dial for adjustment of the overdrive rate as long as the High-Rate Menu is shown. Warning is directed here by a blinking symbol

**HI-**

in front of the label

**RATE**

in the upper display.

The overdrive stimulation rate can be changed in 10 ppm increments between 70 ppm and 1000 ppm, as shown in Table 27.

| Parameter | Adjustable Values | Unit |
|---|---|---|
| Atrial High Rate | 70 (10) 1000 | ppm |

**Table 27: Adjustable values for atrial high rate**

The PACE 203 H delivers overdrive stimulation impulses upon pressing and holding the softkey labeled

START .

After the next sensed atrial or ventricular event, the pacemaker switches to the A00 mode and stimulates with the set overdrive-stimulation rate, showing the High-Rate Running menu (Table 28).

| High-Rate Running Menu | Key No. |
|---|---|
| running... | 1 |
| 240 ppm<br>(250 ms) | 2 |
| Dial RATE<br>to change<br>High-Rate! | 3 |
| | 4 |
| ↵ | 5 |

**Table 28: High-Rate Running Menu**

During overdrive stimulation, the PACE 203 H switches temporarily (as long as the START key is pressed) to A00 mode. To prevent confusion, the upper display is not completely changed accordingly. The display of atrial stimulation section, however, is enabled on (if not already enabled) to allow a convenient pre-setting of the atrial stimulation amplitude.

**Warning: There is a risk of causing ventricular tachycardia during atrial overdrive-stimulation. Continuous ECG-monitoring of the patient is therefore mandatory. A defibrillator should always be available and ready to use.**

## 7.10.1 High Rate Stimulation with Ramp Function

The PACE 203 H provides a function allowing the application of overdrive-stimulation with a ramp function. While in the High Rate Running Menu, turning the HIGH-RATE dial changes the overdrive stimulation rate. This feature allows the user to manually set a ramp function for atrial overdrive stimulation.

**Note**: The PACE 203 H ignores any rotation of the HIGH-RATE dial beyond the defined minimum or maximum settings.

After releasing the softkey labeled

START,

now labeled

running…,

the PACE 203 H abandons the delivery of overdrive stimulation impulses, and returns to High-Rate standby. If the overdrive rate has been changed during High-Rate running, the basic rate prior the start of the overdrive-stimulation is restored. Thus, a rate change during running overdrive stimulation is only temporary. Thus, a ramp can always be started from the same rate.

The overdrive mode is abandoned by pressing the softkey ↵, which forces the PACE 203 H to return to the Mode Menu.

**Warning: There is a risk of causing ventricular tachycardia during atrial overdrive-stimulation. Continuous ECG-monitoring of the patient is therefore mandatory. A defibrillator should always be available and ready to use.**

**Notes:**

- If no key is pressed, the pacemaker locks and returns to the Mode Menu automatically after 1 minute.
- After the start of an overdrive-stimulation, the lead surveillance in the atrial channel (see chapter 7.19.2) is enabled. If no atrial lead is connected, the error message

  Atrial lead disconnected

  will consequently appear. Nevertheless, the impulse emission with overdrive-rate will be carried out. After releasing the softkey labeled

  START,

  the previous state of the lead surveillance will be restored.
- The Pause function (see chapter 7.14) can be used to measure the frequency of atrial tachycardia up to rates of about 700 bpm). Thus, the Pause function assists in determining the optimal overdrive stimulation rate. (Please note that the atrial frequency measurement can be affected by crossblanking after ventricular senses.)
- As long as the softkey labeled

  START

  is pressed, all other keys and dials are disabled.

## 7.11 Standard Programs

The PACE 203 H provides the capability of storing and recalling a user defined standard set of parameters (a so called "standard program") for each primary mode of operation (DDD, VVI, AAI, VDD). That is, four different standard programs can be stored. Alternatively, the user can reset each primary mode to the manufacturer's default settings. In addition, the initial mode and parameter settings can be configured in the Turn-on program.

To perform one of these functions, the Standard Menu must first be entered via the softkey labeled

Main Menu,

and then via the softkey labeled

Standard.

If the lower display is off, then pressing the key

Lock/Unlock

turns the display on. The Standard Menu appears as shown in Table 29.

| Standard Menu | Key No. |
|---|---|
| Save as Turn-on | 1 |
| Save as XXX standard | 2 |
| Recall XXX standard | 3 |
| Manufacturer's default | 4 |
| ↵ | 5 |

**Table 29: Standard Menu**

### 7.11.1 Parameters Stored in a Standard Program

The parameters stored in each of the four sets are marked with "+" in Table 30. The parameters marked with "–" are not stored in the set and will remain unchanged if a stored program is recalled.

| Parameter | DDD | VVI | AAI | VDD | Unit |
|---|---|---|---|---|---|
| Basic Rate | + | + | + | + | ppm |
| Atrial Sensitivity (incl. Automatic state) | + | – | + | + | mV |
| Atrial Amplitude | + | – | + | – | V |
| Atrial Pulse Duration | + | – | + | – | ms |
| Ventricular Sensitivity (incl. Automatic state) | + | + | – | + | mV |
| Ventricular Amplitude | + | + | – | + | V |
| Ventr. Pulse Duration | + | + | – | + | ms |
| A-V delay (incl. Automatic state) | + | – | – | + | ms |
| PVARP (incl. Automatic state) | + | – | – | + | ms |
| Automatic MTR (incl. Automatic state) | + | – | – | + | ppm |
| Atrial Trigger | + | – | + | – | – |

**Table 30: Standard Program Sets**

**Note:** Because the sensitivity and the atrial trigger option are also stored, the pacing mode stored may also be one of the supplementary modes (D00, DVI, DAI, VAT, DAT, V00, A00, AAT, DDD+AT).

**Warning:** Because the automatic condition of the sensitivity adjustment is also stored, recalling a standard setting with Auto Sense = ON is followed by the request to search for initial sensitivity values as described in chapter 7.9.4.2 (Table 20ff.). Therefore, storing a standard program with Auto Sense activated, is only recommended for experienced users.

**Note:** Upon the manufacturer’s shipping of the PACE 203 H, the user standard settings are identical with the manufacturer's defaults (see chapter 7.11.4).

## 7.11.2 Store Standard Programs

By pressing the softkey labeled

Save as XXX standard

in the Standard Menu (Table 29) the actual setting will become the standard for the current primary mode (XXX stands for one of the primary modes DDD, VVI, AAI or VDD) upon answering the question

Overwrite standard XXX program?

with "YES" (Table 31).

| Standard Saving Confirmation | Key No. |
|---|---|
| Overwrite standard XXX program? | 1 |
| | 2 |
| YES | 3 |
| NO | 4 |
| ↵ | 5 |

**Table 31: Standard Saving Confirmation**

After storing the user defined Standard Program, the PACE 203 H abandons the Standard Menu and returns to the Mode Menu.

If the question

Overwrite standard XXX program?

is answered with "NO", the PACE 203 H returns to the (previous) Standard Menu.

Pressing the softkey ↵ forces the PACE 203 H to revert to the Mode Menu.

## 7.11.3 Recall Standard Programs

By pressing the softkey labeled

Recall XXX standard

in the Standard Menu (Table 29), the stored standard program for the current primary mode (XXX stands for one of the primary modes DDD, VVI, AAI or VDD) becomes the actual setting.

After pressing the softkey labeled

Recall XXX standard ,

the PACE 203 H abandons the Standard Menu and returns to the Mode Menu.

## 7.11.4 Recall Manufacturer's Defaults

By pressing the softkey

Manufacturer's default

in the Standard Menu (Table 29), the manufacturer's default for the current primary mode (as shown in Table 32) becomes the actual setting.

| Parameter | DDD | VVI | AAI | VDD | Unit |
|---|---|---|---|---|---|
| Basic Rate | 72 | 72 | 72 | 72 | ppm |
| Atrial Sensitivity | 1 | – | 1 | 0.5 | mV |
| Atrial Amplitude | 5 | – | 5 | – | V |
| Atrial Pulse Duration | 1 | – | 1 | – | ms |
| Ventricular Sensitivity | 2 | 2 | – | 2 | mV |
| Ventricular Amplitude | 8 | 8 | – | 8 | V |
| Ventricular Pulse Duration | 0.75 | 0.75 | – | 0.75 | ms |
| A-V delay | AUTO (i.e. 180) | – | – | AUTO (i.e. 180) | ms |
| PVARP | AUTO (i.e. 280) | – | – | AUTO (i.e. 280) | ms |
| MTR | AUTO (i.e. 106) | – | – | AUTO (i.e. 106) | ms |
| Automatic Sensing | OFF | OFF | OFF | OFF | – |
| Atrial Trigger | OFF | – | OFF | – | – |

**Table 32: Manufacturer’s Default Programs**

After pressing the softkey

Manufacturer's default,

the PACE 203 H abandons the Standard Menu and returns to the Mode Menu.

## 7.11.5 Change the Turn-On Program

By pressing the softkey

Save as Turn-on

key in the Standard Menu (Table 29), the actual setting will become the permanent Turn-On program when the question

Overwrite Turn-on program?

is answered with "YES" (Table 33).

| Turn-on Saving Confirmation | Key No. |
|---|---|
| Overwrite Turn-on program? | 1 |
| | 2 |
| YES | 3 |
| NO | 4 |
| ↵ | 5 |

**Table 33: Turn-on Saving Confirmation**

After storing the user defined Turn-on Program, the PACE 203 H abandons the Turn-On Menu and returns to the Mode Menu.

If the question

Overwrite Turn-on program?

is answered with "NO", the PACE203H returns to the (previous) Standard Menu.

Pressing the ↵ key forces the PACE 203 H to revert to the Mode Menu.

**Note:** Upon the manufacturer's shipping of the PACE 203 H, the Turn-On Program parameter are set according to Table 34.

| Parameter | Value | Unit |
|---|---|---|
| Mode | DDD | – |
| Basic Rate | 60 | ppm |
| Atrial Sensitivity | 0.5 | mV |
| Atrial Stimulation Amplitude | 5 | V |
| Atrial Pulse Duration | 1 | ms |
| Ventricular Sensitivity | 1 | mV |
| Ventricular Stimulation Amplitude | 8 | V |
| Ventricular Pulse Duration | 0.75 | ms |
| A-V delay | AUTO (i.e. 200) | ms |
| PVARP | AUTO (i.e. 280) | ms |
| MTR | AUTO (i.e. 100) | ppm |
| Automatic Sensing | OFF | – |
| Atrial Trigger | OFF | – |

**Table 34: Manufacturer's Turn-on Program**

**Warning:** The Manufacturer's Turn-on program is intended to provide a safe and conservative pacing therapy for the patient. A change of this program is only recommended for experienced users.

**Note:** Because the sensitivity and the atrial trigger option are also stored, the Turn-On Program mode stored may also be one of the supplementary modes (D00, DVI, DAI, VAT, DAT, V00, A00, AAT, DDD+AT).

**Note:** Because the automatic state of the sensitivity adjustment is also stored, turning on a pacemaker with a Turn-on program with Auto Sense = ON is followed by the request to search for initial sensitivity values, as described in chapter 7.9.4.2 (Table 20ff.). Because the patient should be provided with a therapeutic pacing program immediately after turning on the PACE 203 H, storing a Turn-On Program with Auto Sense enabled is **NOT** recommended.

## 7.12 Other Parameters/Options Setting

The PACE 203 H provides the capability of setting additional parameters and enabling or disabling options. To accomplish this, the Parameters/Options Menu must be entered via the softkey labeled

Main Menu

and, then, via the softkey labeled

Parameters/Options.

If the lower display is off, then pressing the key

Unlock/Lock

turns the display on. The Parameters/Options Menu appears as shown in Table 35.

At this point the corresponding softkeys for the menu setting PVARP, MTR, pulse duration, or further options can be chosen.

| Parameters/Options Menu | Key No. |
|---|---|
| PVARP | 1 |
| MTR | 2 |
| Pulse duration | 3 |
| Options | 4 |
| ↵ | 5 |

**Table 35: Parameters/Options Menu**

## 7.12.1 Adjustment of PVARP

The post ventricular atrial refractory period (PVARP) can be adjusted by pressing the softkey labeled

PVARP

in the Parameters/Options Menu. The PVARP Menu appears as shown in Table 36.

| PVARP Menu | Key No. |
|---|---|
| Auto PVARP ☐ | 1 |
| Increase ↑ | 2 |
| 280 ms | 3 |
| Decrease ↓ | 4 |
| ↵ | 5 |

**Table 36: PVARP Menu**

The PVARP can be changed with the softkey labeled

Increase ↑

or the softkey labeled

Decrease ↓

in increments / decrements of 10 ms between 150 ms and 500 ms, respectively, as shown in Table 37.

The parameter change appears immediately in the third line of the lower display and will become effective with the next intervention interval.

| Parameter | Manually Adjustable Values | Unit |
|---|---|---|
| PVARP | 150 (10) 500 | ms |

**Table 37: Manually Adjustable Values for PVARP**

**Note:** The safety feature "protection against abnormal settings" (see chapter 7.19.7) prevents increasing the PVARP to a value which would not guarantee a minimum atrial sensing phase, or Wenckebach behavior. Any limitation of the PVARP setting will be indicated by a transient warning message in the lower display.

The automatic setting of the PVARP can also be switched on and off in this menu, using the softkey labeled

Auto PVARP

(see also chapter 7.9.2).

**Note:** Changing the PVARP value manually will also switch off the automatic setting, if it was activated.

**Note:** The PVARP of the PACE 203 H is divided in two parts: an absolute part and a relative part. In the absolute part (100 ms) no atrial events are recognized. In the relative part (the remaining) atrial events are registered, but not tracked. This algorithm prevents misinterpretation of ventricular events after premature atrial events as extrasystoles (PVCs) as described in chapter 7.19.5.

## 7.12.2 Adjustment of MTR

The maximum tracking rate (MTR) can be adjusted by pressing the softkey labeled

MTR

in the Parameters/Options Menu. The MTR setting menu appears as shown in Table 38.

| MTR Menu | Key No. |
|---|---|
| Auto MTR ☐ | 1 |
| Increase ↑ | 2 |
| 106 ppm | 3 |
| Decrease ↓ | 4 |
| ↵ | 5 |

**Table 38: MTR Menu**

The MTR can be changed with the softkey labeled

Increase ↑

or the softkey labeled

Decrease ↓

in increments / decrements of 2 ppm between 80 ppm and 230 ppm, respectively, as shown in Table 39.

The parameter change appears immediately in the third line of the lower display and will become effective with the next intervention interval.

| Parameter | Manually Adjustable Values | Unit |
|---|---|---|
| MTR | 80 (2) 230 | ppm |

**Table 39: Manually Adjustable Values for MTR**

**Note:** The safety feature "protection against abnormal settings" (see chapter 7.19.7) prevents decreasing the MTR to a value smaller than the basic rate. Increasing the MTR will be limited to a value that still guarantees Wenckebach behavior. The limitation of the MTR value will be indicated by a transient warning message in the lower display.

The automatic setting of the MTR can also be switched on and off in this menu using the softkey labeled

Auto MTR

(see chapter 7.9.3).

**Note:** Changing the MTR manually will also switch off the automatic setting, if it was activated.

## 7.12.3 Adjustment of Pulse Duration

By pressing the softkey labeled

Pulse durat.

in the Parameters/Options Menu, the pulse duration setting menu appears as shown in Table 40.

| Pulse Duration Menu | | Key No. |
|---|---|---|
| A | ↑ | 1 |
| 1.00 ms | ↓ | 2 |
| V | ↑ | 3 |
| 0.75 ms | ↓ | 4 |
| ↵ | | 5 |

**Table 40: Pulse Duration Menu**

The duration of the stimulation pulse can be changed with the softkey labeled

↑

or the softkey labeled

↓

in increments / decrements of 0.05 ms between 0.05 ms and 1.50 ms, respectively, as shown in Table 41.

The parameter change appears immediately in the second line (atrial pulse duration) or in the fourth line (ventricular pulse duration) of the lower display and will become effective with the next intervention interval.

| Parameter | Manual Adjustable Values | Unit |
|---|---|---|
| Atrial pulse duration | 0.05 (0.05) 1.50 | ms |
| Ventricular pulse duration | 0.05 (0.05) 1.50 | ms |

**Table 41: Manually Adjustable Values for Pulse Duration**

## 7.12.4 Setting Options

By pressing the softkey labeled

Options

in the Parameters/Options Menu, the Option Menu for enabling and disabling acoustic signals (beep), alarms and atrial trigger appears, as shown in Table 42.

The user language can be set via the Options Menu by pressing the softkey labeled

Language.

| Options Menu | | Key No. |
|---|---|---|
| Beep | ☐ | 1 |
| Alarms | ☑ | 2 |
| Atrial Trigger | ☐ | 3 |
| Language | | 4 |
| ↵ | | 5 |

**Table 42: Options Menu**

### 7.12.4.1 Enable and Disable the Acoustic Indicator

With the softkey labeled

Beep

in the Options Menu, the acoustic indicator can be enabled or disabled. The corresponding check box then gets checked or unchecked, respectively. If the acoustic indicator is enabled, the symbol for a loudspeaker (see Figure 7) appears in the upper display.

**Figure 7: Acoustic Indicator (Symbol for a Loudspeaker)**

With the acoustic indicator enabled, the delivery of a stimulus is indicated by a high-pitched tone (beep), whereas sensing of a P or R wave will be signaled by a beep of lower frequency.

Once enabled, the acoustic indicator is disabled by pressing the softkey labeled

Beep.

The check mark disappears from the corresponding check box. The loudspeaker symbol disappears from the upper display, as well.

Upon powering off the PACE 203 H, it retains the enabled / disabled status of the acoustic indicator. Thus, the enabled / disabled status of the last usage is restored again upon powering on the PACE 203 H.

**Note:** Upon the manufacturer's shipping of the PACE 203 H, the acoustic indicator is disabled according to Table 34.

**Note:** The warning and error signals are not influenced whether or not the acoustic indicator is enabled or disabled. Warning and error signals are always accompanied by acoustic signals.

### 7.12.4.2 Enable and Disable the Alarms

With the softkey labeled

Alarms

in the Options Menu, the lead surveillance feature (see chapter 7.19.2) and the protection against abnormal settings (see chapter 7.19.7) can be enabled or disabled.

**Warning: Alarms should only be disabled in a controlled environment, specifically, where medical professionals continuously monitor the patient.**

Upon turning on the PACE 203 H, the alarms are always enabled.

With alarms enabled, pressing the softkey labeled

Alarms

causes the check mark to disappear from the corresponding check box. In the upper display, the crossed bell symbol (see Figure 8) is shown.

**Figure 8: Alarms off (crossed bell) symbol**

To reactivate the lead surveillance feature and the protection against abnormal settings the Alarms key must be pressed again. This causes the check mark to appear in the corresponding check box, and the crossed bell symbol in the upper display disappears.

**Note:** If previously disabled Alarms are enabled, the PACE 203H will solve possible conflicts caused by abnormal settings using its Automatic setting feature. The fact that a parameter has been adapted according to the current rate setting means that it will be indicated by a message to the user, apparent in the lower display (see chapters 7.19.7 and 7.9).

### 7.12.4.3 Enable and Disable the Atrial Trigger Function

When the atrial trigger function is enabled, the PACE 203 H delivers an atrial stimulus immediately after an atrial sensing within the atrial sensing phase.

With the softkey labeled

Atrial Trigger

in the Options Menu, the atrial trigger function can be enabled or disabled. In case the atrial trigger function is enabled, the corresponding check box is checked. Furthermore, the PACE 203 H indicates the label

**A-TRIG.**

in the atrial stimulation section of the upper display.

**Note**: The atrial trigger function is available in the primary modes AAI and DDD.

To turn the atrial trigger function off, the softkey labeled

Atrial Trigger

must be pressed again. The check mark disappears from the corresponding check box, and the sign

**A-TRIG.**

disappears from the upper display as well.

Atrial Trigger is also disabled when the primary mode is changed to VVI or VDD, because these modes do not provide atrial stimulation. Atrial Trigger must be activated again after changing back to the primary modes AAI or DDD.

**Note:** Atrial Trigger cannot be used together with Atrial Auto Sense, because the triggered stimulation prevents proper measurement of the intrinsic atrial activation. (see also 7.9.4)

**Note:** A sensed atrial event in the relative PVARP (see chapter 7.12.1) is never followed by a (triggered) atrial stimulation – even if atrial trigger is enabled – because it may be a ventricular echo.

### 7.12.4.4 Setting the User Language

By pressing the softkey labeled

Language

in the Options Menu, the Language Menu appears as shown in Table 43. The activated user language is marked. By pressing the corresponding key the language can be selected. The softkey labeled

more...

toggles through the different language menus.

| Language Menu | | Key No. |
|---|---|---|
| English | ⦿ | 1 |
| Deutsch | ○ | 2 |
| Français | ○ | 3 |
| more... | | 4 |
| ↵ | | 5 |

**Table 43: Language Menu**

The manufacturer's language setting default is English.

## 7.13 Starting Emergency Stimulation

In case heart stimulation becomes ineffective with the set parameters in place, the PACE 203 H provides an emergency stimulation program. This emergency program can be quickly and easily activated from all operational states by pressing the key

Emergency.

**Note**: In case the PACE 203 H is locked, it must be unlocked first by pressing the key

Lock/Unlock.

The PACE 203 H defaults immediately to the emergency stimulation program with the following parameters:

| | |
|---|---|
| Mode: | V00 (A00) |
| Basic rate: | 80 ppm |
| Amplitude: | 12 V |
| Pulse duration: | 0.75 ms (1.0 ms) |

These parameters are shown in the upper display. They are adjustable in the normally proscribed manner.

**Warning:** **If the device is operating in an atrial mode (AAI, AAT, A00), it defaults first to the V00 mode with the above mentioned values upon pressing the emergency key. However, if the lead surveillance determines that no ventricular lead is connected, the device switches to A00 mode.**

**Note:** By pressing the emergency key, the PACE 203 H irrevocably abandons the last parameter setting.

## 7.14 PAUSE Function

The PACE 203 H provides, upon the user's request, the capability of briefly abandoning any stimulation therapy to allow undisturbed monitoring of the patient's intrinsic heart activity. This PAUSE function is activated by pressing and holding the key labeled

PAUSE.

The current stimulation therapy is interrupted to check for intrinsic events.

The pause function is implemented as the pacing mode 0D0 (see also chapter 7.6.11).

In case any intrinsic heart activity is sensed, atrial and ventricular rates, and the corresponding intervals in ms are shown on the lower display. The parameter values are displayed after the second intrinsic sensed event. These events are detected up to frequencies of about 700 bpm. Furthermore, the measured P and R wave amplitudes are displayed as shown in Table 44.

If no heart activity can be sensed, or the sensitivity is set to a value much smaller or much larger than the actual P or R wave amplitude, the PACE 203 H will change the sensitivity temporarily. The PACE 203 H will attempt to find intrinsic heart activity and to measure the amplitudes optimally. When the Auto Sense function is deactivated, this change of sensitivity thresholds is only temporary. Thus, after releasing the key labeled

PAUSE,

the previous sensitivity threshold is restored. When the Auto Sense function is activated in one or in both channels, the changed sensitivity setting will be taken as new start value for the Auto Sense algorithm (see 7.9.4). Thus, the Auto Sense function is reinitialized with the determined sensitivity threshold.

The display is shown as long as the key labeled

PAUSE

is pressed, plus for approximately an additional second after releasing the key.

The acoustic indicator will automatically be enabled temporarily, if not already enabled.

| PAUSE Menu | | Key No. |
|---|---|---|
| Sensed: | | 1 |
| A | 230 bpm<br>(261 ms)<br>2.3 mV | 2<br>3 |
| V | 50 bpm<br>(1200 ms)<br>8.0 mV | 4<br>5 |

**Table 44: PAUSE Menu**

The pause function is activated for up to 10 seconds. Subsequently, the PACE 203 H resumes pacing, independent if the user continues to hold the key labeled

PAUSE

The PAUSE function is activated again after releasing and pressing the key labeled

PAUSE.

**Warning:** Because pacing is interrupted, the user must be aware that the patient receives no stimulation therapy and support by the pacemaker as long as the key labeled

PAUSE

is pressed.

**Notes:**

- The PAUSE function is always operational, except during application of atrial overdrive stimulation. It does deploy, however, during High-Rate standby and can be used to measure the frequency of the atrial tachycardia, which assists in finding the optimal overdrive stimulation rate.
- The determination of the intrinsic atrial rate can be influenced by the cross blanking after ventricular sensing. Thus, sensing of atrial activations can get "lost" due to the cross blanking, which may result in a rate determination being of too low, or unstable. Thus, if a precise measurement of the atrial frequency is desired, the ventricular lead must be disconnected
- If frequencies higher than the noise frequency (273 bpm) are detected while the key labeled

  PAUSE

  is pressed, the corresponding interference symbol (Figure 12) is displayed in the upper display. The measured frequency is displayed, nevertheless, because it may be a high-frequency tachycardia. Accordingly, for the same reason, the setting of the sensitivity threshold remains unchanged (unlike during initialization of the Auto Sense function).
- When no intrinsic activity is sensed in any channel for 3 seconds while the key labeled

  PAUSE

  is pressed, any measured values already displayed are erased.
- As long as the key labeled

  PAUSE

  is pressed, all other keys and dials are disabled.

# 7.15 Connecting the Leads to the PACE 203 H

## 7.15.1 Lead Types

For temporary stimulation of the heart with the PACE 203 H, temporary transvenous leads or permanent leads, regardless of whether they are of bipolar or unipolar configuration, can be used (Table 45). The use of myocardial leads (up to 4 electrodes) and VDD single pass leads is also permissible.

| Lead types | Description of Use |
|---|---|
| Temporary, transvenous pacing leads | These leads are advanced into the heart via a vein and are connected to the PACE 203 H either directly by means of an extension cable. |
| Heart wires (myocardial pacing leads) | Heart wires (myocardial leads) are affixed to the heart during open heart surgery, when it is expected that the patient may need stimulation for a limited period of time after surgery. The heart wires are connected to the PACE 203 H by means of an extension cable. |
| Permanent pacing leads | Prior to implantation of a permanent pacemaker, or during a pacemaker change, stimulation may be properly maintained with the assistance of the PACE 203 H. The permanent lead is connected to the PACE 203 H either directly or by means of an extension cable. |

**Table 45: Lead Types Used with the PACE 203 H**

**Warning:** All lead systems must be connected to type **CF** devices only, because of the danger of current being diverted to the heart. Devices that are connected to a mains supply pose increased danger for current diversions to the heart.

For exact specifications of leads and patient cables, please refer to our product catalog.

## 7.15.2 Lead Connection Terminals

At the top of the pacemaker are protected terminals (collets) located for plugs with a diameter of 0.9 mm to 2.0 mm. Viewing the display face of the PACE 203 H, the atrial connections are located to the left and the ventricular connections to the right (see Figure 1). Viewing the top of the PACE 203 H, as shown in Figure 9, the ventricular connections are located to the left and the atrial connections to the right.

The indifferent terminals (+) are colored red, while the different terminals (–) are colored black.

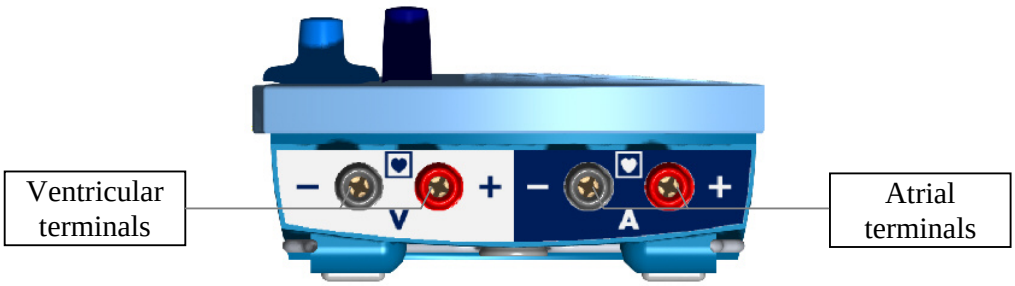



**Figure 9: Lead connection terminals**

## 7.15.3 Connection Configurations

Various connection configurations exist, depending on the leads used. One may choose between bipolar leads or unipolar leads with indifferent electrode.

| Configuration | |
|---|---|
| Bipolar | When using a bipolar, transvenous stimulation lead, the distal pole of the lead is connected to the different (–, black) terminal of the corresponding channel on the PACE 203 H. The proximal pole is then connected to the indifferent (+, red) terminal.<br><br>When using heart wires, the connection is arbitrary, since both electrodes are affixed in the myocardium. The connection may be selected to obtain the best sensing and stimulation parameters.<br><br>When a stimulus is delivered, the current flows from the negative to the positive electrode, and causes a myocardial depolarization, which then leads to a heart muscle contraction. |
| Unipolar | When using a unipolar lead, it is connected to the different (–, black) terminal of the corresponding channel on the PACE 203 H. In order to close the circuit and allow a stimulus, an indifferent electrode must be connected to the indifferent (+, red) terminal of the corresponding channel on the PACE 203 H. This electrode must have a large surface and must be attached subcutaneously.<br><br>Note: If unipolar stimulation is given in the atrium as well as in the ventricle, one indifferent electrode is sufficient. The indifferent terminals of both channels can be connected to each other. |

**Warning:** The unipolar configuration is more susceptible to external noise, as compared to the bipolar configuration.

## 7.15.4 Connecting the Leads

The PACE 203 H must be turned off while the stimulation leads are connected to it.

**Warning:** While the leads are being inserted into the patient, and the PACE 203 H is connected, continuous ECG monitoring is mandatory. For emergency situations, a defibrillator must always be in a ready-to-use state. The user must ensure that all devices in the vicinity of the patient are properly grounded.

**Before handling the pacemaker, the patient cable, or the indwelling stimulation lead, the electrostatic potential between user and patient must be equalized.**

The stimulation leads provide a direct, low-resistance current path to the heart. Therefore, it is absolutely mandatory that the connector plug is not touched with bare hands or can come in contact with electrically conductive or wet surfaces. All possible static electricity sources must be kept away from the stimulation system.

The user must follow the steps described below when connecting a stimulation lead to the PACE 203 H:

1. Turn off the PACE 203 H. Open the collets (see Figure 9).
2. If a patient cable is used, this cable must be connected first to the PACE 203 H, before the stimulation lead is connected to the patient cable. Connect the ventricular pacing leads, or the corresponding extension cable, to the ventricular output terminals of the PACE 203 H. Connect the atrial pacing leads or the corresponding extension cable, to the atrial output terminals of the PACE 203 H. Make sure the polarity is correct.
3. Secure the connections by manually turning the collets clockwise.
4. If extension cables are used, connect the leads to the extension cables.
5. Turn on the PACE 203 H and set the desired pacing mode.
6. Determine the sensitivity threshold (see chapter 7.16).
7. Determine the cardiac capture threshold (see chapter 7.17).
8. Control the proper functioning of the PACE 203 H with the assistance of an ECG monitor or recorder.

## 7.16 Determining the Sensitivity Threshold

Determining the sensitivity threshold can be accomplished by using the Auto Sense function (see chapter 7.9.1), or manually. Both methods require that the patient has intrinsic heart activity.

For manual determination of the sensitivity threshold, the patient must have heart activity with a rate that is hemodynamically tolerated over a longer period of time (a few minutes).

The manual determination of the sensitivity threshold is performed as follows:

1. Set the stimulation amplitude (in dual-chamber mode: both channels) to the smallest value so that any asynchronous stimulation, which occurs during the procedure, remains ineffective.
2. Set the basic rate 10 ppm below the patient's intrinsic rate.
3. If the PACE 203 H is operating in a dual chamber mode, the A-V delay must be set longer than the patient's intrinsic A-V interval.
4. In case the pacemaker already senses intrinsic heart activity in the atrial or ventricular channel, set the sensitivity at a low level (i.e. raise the sensitivity value), such that the PACE 203 H will not sense intrinsic events in the atrium and ventricle, respectively. Eventually, the PACE 203 H operates in asynchronous pacing mode.
5. Raise the sensitivity (i.e. lower the sensitivity value) again until stimulation is inhibited. This sensitivity set equals the sensitivity threshold. In order to create a 'safety cushion', the sensitivity must be raised further. The set value should be a 1/2 to 1/3 of the sensitivity threshold value.

   **Warning:** An unnecessarily high sensitivity (i.e. smaller sensitivity value) increases the probability that the proper pacemaker function will be affected by external interference, and the pacemaker will switch to asynchronous stimulation (see also chapter 7.19.3)
6. In case a dual chamber mode is chosen, the procedure must be repeated for the other channel.

**Note:** When setting the sensitivity threshold, it is very helpful to turn on the acoustic signal of the PACE 203 H, because it emits a different pitched tone for stimulation and for sensing (see chapter 7.12.4.1).

## 7.17 Determining the Cardiac Capture Threshold

**Warning:** If the patient has a sufficient intrinsic heart rate, the determination of the sensitivity threshold must be carried out before the cardiac capture threshold can be determined. This is done in order to make certain that no asynchronous superimposition of intrinsic rhythm and stimulation occurs.

To determine the cardiac capture threshold, the following steps should be taken:

1. Set the basic rate at least 10 ppm above the patient's own rate. If the PACE 203 H is already effectively stimulating, lower the stimulation amplitude, until the stimulus is no longer effective.
2. In case the PACE 203 H is operating in a dual chamber mode, the A-V delay must be set shorter than the patient's intrinsic A-V interval.
3. Raise the stimulation amplitude slowly until the stimulus is effective again. The amplitude set equals the cardiac capture threshold.
4. In order to create a 'safety cushion', the stimulation amplitude must be raised further. The set value should be from two to three times the cardiac capture threshold.
5. In case a dual-chamber mode is chosen, the procedure must be repeated in the other channel.

**Warning:** If the PACE 203 H is to be used for a longer period of time on a patient, the stimulation threshold should be checked from time to time (the first time after a few hours, then daily), because an increase in the capture threshold can occur.

## 7.18 Controlling an Intra-Aortic Balloon Pump (IABP)

The PACE 203 H possesses the capability of controlling the triggering of an intra-aortic balloon pump (IABP). The PACE 203 H provides an interface to the IABP, which outputs a surface ECG-type signal but derived from the intracardiac electrogram.

The PACE 203 H utilizes the intracardiac electrogram obtained from the ventricular channel. The ventricular signal is processed in such a way that its characteristics (shape, impulse amplitude, base width) are similar to a signal obtained from surface electrodes.

The PACE 203 H to connected to the IABP via an optional IABP interface device (BPI 202), which is connected to the

CTRL OUT

terminal of the PACE 203 H (see Figure 1 and Figure 2).

The IABP is connected to the optional IABP interface device via its surface ECG cables. These cables are attached directly to receptacles located on the interface device, instead being attached to the ECG surface electrodes.

The PACE 203 H accomplishes the synchronization of the IABP with the heart activity in both intrinsic and paced ventricular events by a application of a differential timing.

| Ventricular Event | PACE 203 H Control |
|---|---|
| Intrinsic event | Upon sensing of a R wave, the PACE 203 H provides a control signal, whose processed 'R wave' is delayed by approximately 5 ms, assuming that the amplitude of the R wave measured is twice the value of the sensitivity set. |
| Paced event | Upon delivery of a ventricular stimulus, the PACE 203 H provides a control signal, whose processed 'R wave' is delayed by approximately 35 ms, accounting for the latency period, that is, the time between actual delivery of the stimulus and the occurrence of ventricular depolarization. |

**Table 46: PACE 203 H differential timing for control of an IABP**

Please see the instruction manual for the IABP interface device for further information.

**Warning:** Because the ventricular intracardiac electrogram is processed to control the IABP, the output at the terminal

CTRL OUT

is only enabled if a pacing mode with sensing and / or stimulation in the ventricle is chosen. The output at the terminal

CTRL OUT

is disabled any time the PACE 203 H operates in a pacing modes using atrial sensing and / or pacing only (AAI, A00, AAT).

**Note:** The terminal

CTRL OUT

is protected by a cap which will prevent pollution. This cap should be in place, when the CTRL OUT socket is not used.

# 7.19 Internal Surveillance and Safety Features

## 7.19.1 Battery Surveillance

The PACE 203 H is powered by a standard 9 V battery.

The PACE 203 H continuously monitors the battery voltage. The battery symbol (see Figure 10), located in the upper display, continuously indicates the remaining battery voltage.

The time-to-change-battery level is reached when only one segment (the rightmost triangular one) remains and is blinking. Additionally, the warning message

Change battery!

will appear approximately every 10 min in the lower display, accompanied by an acoustic warning signal.

**Note**: The text message

Change battery!

disappears only upon the user pressing the key

Lock/Unlock.

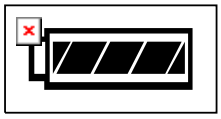


**Figure 10: Battery symbol**

If the time-to-change-battery warning is disregarded, and the voltage falls below a critical value, then the empty battery symbol blinks, requesting an immediate change of the battery (see chapter 9.2). This action is accompanied by the warning message

Hurry up! Change battery!

and the acoustic warning signals every 2 minutes.

The lifespan of the battery depends on the set stimulation parameters. In chapter 11 "Technical Data" the lifespan for 100 % stimulation in two usual modes (DDD, VVI) are given for alkaline and lithium batteries.

During a battery change, the PACE 203 H is capable of providing continuous operation for at least 30 seconds.

**Warning:** In order to provide continuous operation of the pacemaker during battery changes, it is recommended that the battery will be replaced before being completely drained (see also chapter 9.2).

If the PACE 203 H is switched off, or to the stand-by state after the first request to change the battery has appeared, the battery must be replaced before the pacemaker is turned on again. The battery can be changed without losing the stored settings.

The battery surveillance cannot be turned off with the Alarms on/off option (see chapter 7.12.4.2).

## 7.19.2 Lead Surveillance

In order to prevent system malfunctions (Exit-Block), the PACE 203 H checks, during each delivery of a stimulus, whether an interruption or a short circuit of the pacing system has occurred.

**Note:** The lead surveillance is enabled only if the pacing amplitude is set greater than or equal to 2.0 V, and if the pulse duration is set to a value greater than or equal to 0.15 ms.

### 7.19.2.1 Short Circuit in Pacing System

A short circuit in the pacing system can occur, for example, because of defective insulation. An interruption of the stimulation system can be caused by lead or cable breakage, or an incorrectly made connection.

A short circuit will be indicated by the warning messages

Atrial output short

or

Ventricular output short

(see chapter 7.19.9), located in the lower display. Each warning message will also be accompanied by an acoustic warning signal. Only pressing the key

Lock/Unlock

will discard the warning messages for a few seconds, but will reappear if the failure persists.

### 7.19.2.2 Interruption in Pacing System

In case of an interruption of the stimulation circuit – which is defined as 3 successive stimulations not properly carried out – the open lead symbol (see Figure 11) will be shown in the upper display, with respect to the corresponding atrial and/or ventricular channel.

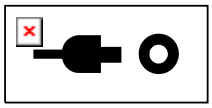


**Figure 11: Open lead symbol**

Additionally, the PACE 203 H performs lead surveillance with an intelligent lead-breakage warning function, which operates independently in the atrial and ventricular channels. The PACE 203 H enables this function in a channel automatically upon recognition that a lead is connected. According to the definition of the function, a lead is connected upon three sensed or paced events.

In case an atrial or ventricular lead, or any part of the circuit, fractures (accidentally or on purpose, identified by three failed deliveries of pacing stimuli), the open lead symbol (see Figure 11) appears in the respective section of the upper display, accompanied with an acoustic warning signal. The warning signal is repeated as long as the interruption persists. In addition, the warning messages

Atrial lead disconnected

or

Ventricular lead disconnected

appear in the lower display (only if the lower display is switched on). Once the problem for the malfunction is resolved, the warning message disappears automatically, and the acoustic warning signal ceases.

The user can confirm the error message by pressing the key

Lock/Unlock.

Confirmation causes the warning message to disappear and the acoustic signal to cease, despite the fact, for example, that the lead remains disconnected. In this case, the PACE 203 H ceases the lead-breakage warning message upon the user's confirmation, but continues to display the open lead symbol if the malfunction remains present.

If the disconnection is detected when the lower display is switched off, only the acoustic signal is enabled. A first press of the key

Lock/Unlock

switches on the lower display and the backlight, and unlocks the device. Then, the warning message is displayed. A second press on the key

Lock/Unlock.

confirms the error message.

If the disconnection is detected when the lower display is switched on, but the device is locked, a first press of the key

Lock/Unlock

switches the backlight on, and unlocks the device. The user confirms the warning message with a second press of the key

Lock/Unlock.

Once the leads are connected and functioning appropriately, the lead-breakage warning function is enabled automatically after three sensed or paced events.

**Note:** As long as the stimulation amplitude is set to less than 2.0 V, or the pulse duration is set less than 0.15 ms, the lead-breakage surveillance remains in the previously held status (enabled or disabled).

When the PACE 203 H resumes operation from the stand-by mode, the lead-breakage surveillance is always activated. The PACE 203 H assumes that the pacemaker is already connected to the pacing leads and thus, to the patient.

In any other case of beginning operation, the PACE 203 H first disables the lead-breakage surveillance. Thus, the user is able to set up the patient without being bothered by lead-breakage warnings, while the pacemaker is not connected to the pacing leads. However, upon proper connection of the PACE 203 H to the pacing leads and, thus, the patient, the PACE 203 H enables lead-breakage surveillance after three successfully sensed or paced events.

**Note:** The lead surveillance can be turned off using the Alarms on/off option (see chapter 7.12.4.2). However, it is not recommended to disable the lead surveillance function.

**Warning:** The lead surveillance function should only be disabled if a medical professional continuously monitors the patient.

### 7.19.3 Interference and Mode Switching

The PACE 203 H is designed for optimal sensing characteristics and filtering suppression of possible noise and interference of frequencies beyond the range of intrinsic and paced frequencies. However, there are types of interference whose frequencies hardly differ from those of intracardiac signals (for example, noise from mains supply and strong muscle potentials), and are of such magnitude that complete suppression cannot be achieved.

As a consequence, the PACE 203 H implements an algorithm, which decides, by means of a rate analysis of the observed signal, whether the intrinsic events or interference is sensed:

- Signals with a frequency below 273 bpm (about 4.5 Hz) will be judged as intrinsic heart signals and lead to an inhibition (or, according to the pacing mode, to a triggering) of stimulation.
- Signals with a frequency above 273 bpm (about 4.5 Hz) will be judged as interference and force the PACE 203 H to an asynchronous stimulation.

If the PACE 203 H recognizes interference in a channel, the basic rate will be increased by 10 ppm, but not above the MTR (only in the case the MTR is applicable, and the MTR set to a value less than 10 ppm above the basic rate) and not above 220 ppm. The PACE 203 H displays the symbol for interference (see Figure 12) in the upper display (atrium and/or ventricle).

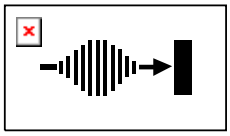


**Figure 12: Symbol for Interference**

Additionally, the pacemaker changes to the pacing mode due to interference. Table 47 shows the corresponding reaction.

| Basic mode | The pacemaker will switch to the following mode during | |
|---|---|---|
| | Interference in ventricular channel | Interference in atrial channel |
| DDD | D00 | DVI |
| D00 | (no change) | (no change) |
| VVI | V00 | (no change) |
| V00 | (no change) | (no change) |
| AAI | (no change) | A00 |
| A00 | (no change) | (no change) |
| VDD | V00 | VVI |

**Table 47: Mode Switching Due to Interference**

**Note:** Interference is not recognized (and indicated)

- If the sensitivity of the corresponding channel is set to infinite ("–.–"), or
- If the corresponding channel is refractory.

This is because sensing is turned off in all these cases.

## 7.19.4 Crosstalk and Ventricular Safety Pacing

In dual-chamber pacing modes, an atrial stimulus could be sensed on the ventricular channel, and inhibit ventricular stimulation. This is known as crosstalk, or A-V crosstalk. In a pacemaker-dependent patient, inhibition of ventricular output by crosstalk results in asystole.

For a better understanding how the PACE 203 H prevents, or operates in the presence of crosstalk, the A-V delay should be considered as an interval with three subportions: The **ventricular blanking period**, the **ventricular triggering period**, also known as the **crosstalk sensing window**, and the remaining period of the A-V delay, in which a sensed event inhibits the ventricular output. This remaining period may be not extant if the sum of ventricular blanking period and crosstalk sensing equals the A-V delay.

### 7.19.4.1 Ventricular Blanking Period

To prevent crosstalk, the PACE 203 H initiates, after an atrial stimulus, a brief ventricular blanking period. As a consequence, any possible crosstalk from the atrial pacing stimulus is masked, or blanked, with respect to the ventricular sensing circuitry.

The blanking period is of short duration because it is important for the ventricular sensing circuit to be returned to the “alert” state relatively early during the A-V delay so that intrinsic ventricular activity can inhibit the ventricular output.

### 7.19.4.2 Crosstalk Sensing Window and Ventricular Safety Pacing

The crosstalk sensing window follows the ventricular blanking period. From then on, the PACE 203 H cannot differentiate crosstalk from intrinsic ventricular activity.

To prevent ventricular systole, the PACE 203 H delivers a ventricular stimulus if either crosstalk or intrinsic ventricular activity is sensed within 40 ms after the termination of the blanking period. This interval of 40 ms is referred to as the **crosstalk sensing window**, and the ventricular response to as **ventricular safety pacing**. This ventricular pacing stimulus is delivered early, that is, 100 ms after the atrial event. This corresponds to an abbreviated A-V delay of 100 ms.

If the signal sensed is indeed crosstalk, the paced ventricular stimulus at the abbreviated A-V delay prevents ventricular asystole.

If, on the other hand, intrinsic ventricular activity occurs during this 40 ms window, the safety mechanism results in delivery of a ventricular pacing stimulus within, or immediately after, the intrinsic beat. This delivery is safe because the ventricle is refractory. Consequently, no depolarization results from the ventricular stimulus. Furthermore, the stimulus is too early to coincide with ventricular repolarization or a vulnerable period.

Crosstalk window and safety pacing are designed to supplement the ventricular blanking function to ensure that crosstalk inhibition will not occur.

The PACE 203 H indicates **ventricular safety pacing** after A-V crosstalk through a short time interval between the blinking of the LEDs corresponding to ventricular sensing and pacing, respectively.

## 7.19.5 Premature Ventricular Contraction (PVC)

The PACE 203 H assumes an extrasystole, or premature ventricular contraction (PVC), if it detects two ventricular events without an atrial event in between. The detection of a PVC is indicated in the ventricular section of the upper display by the symbol for an extrasystole (see Figure 13).

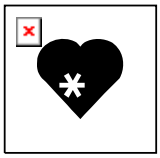


**Figure 13: Symbol for Extrasystole (Premature Ventricular Contraction, PVC)**

For patients with retrograde conduction, the sensing of a ventricular event, conducted retrogradely to the atrium, can lead to pacemaker mediated tachycardia.

**Note**: Pacemaker mediated tachycardia has been defined as a reentry arrhythmia in which the dual-chamber pacemaker acts as the antegrade limb of the tachycardia and the natural pathway acts as the retrograde limb [2] [3].

The PACE 203 H prevents pacemaker mediated tachycardia by implementation of a specific PVC algorithm. The response is different in case of isolated PVC or the initial PVC of a series, and subsequent PVCs.

### 7.19.5.1 Isolated PVC, or Initial PVC

After detection of a PVC, the PVARP is extended to 500 ms. Therefore, any sensed intrinsic atrial events are not tracked by the ventricle. After termination of the extended PVARP, the atrial channel is ‘alert’ and sensing begins again.

Despite the extended PVARP, the duration of the sensing phase, or the width of the crosstalk sensing window, is set to at least 350 ms, independent of set basic rate and A-V delay. The duration of the sensing phase may be even longer, if the difference between V-A delay and extended PVARP, i.e.

$$\text{Sensing Phase} = \frac{1}{\text{Basic Rate}} - \text{AVD} - 500\,\text{ms},$$

(where AVD means the A-V delay) reveals a value exceeding 350 ms.

A sensing phase of at least 350 ms allows atrioventricular synchronization. If the sensing phase terminates without an atrial event sensed, the PACE 203 H delivers an atrial stimulus - unless a further ventricular extrasystole has been detected.

[2] Furman S, Fisher JD. Endless loop tachycardia in an AV universal (DDD) pacemaker. Pacing Clin Electrophysiol 1982; 5: 486-489.

[3] Den Dulk K, Lindemans FW, Bar FW, Wellens HJ. Pacemaker related tachycardias. Pacing Clin Electrophysiol 1982; 5: 476-485.

#### 7.19.5.2 Subsequent PVCs

If a PVC is followed by another PVC without intermediate atrial sensed or paced event, the behavior is adapted for subsequent PVCs, ensuring appropriate pacing at higher basic rates.

After subsequent PVCs, the PVARP is extended up to 500 ms, but not exceeding

$$\text{PVARP}_{\text{MAX}} = \frac{1}{\text{Basic Rate}} - \text{AVD} - 20\,\text{ms}\,.$$

The maximum PVARP is in agreement with the rules for "abnormal settings" (see 7.19.7).

After subsequent PVCs, the V-A delay is calculated to

$$\text{VA Delay} = \frac{1}{\text{Basic Rate}} - \text{AVD}\,.$$

The sensing phase, or crosstalk sensing window, is not extended, i.e. it may be as short as 20 ms.

#### 7.19.5.3 Absolute and Relative PVARP

If the patient's heart is beating at a relatively high intrinsic rate, an extended PVARP could have the consequence that, after the recognition of a single extrasystole, subsequent extrasystoles are determined only because within the atrial channel, the PVARP takes up most of the V-A delay.

The PACE 203 H avoids this effect by dividing the PVARP in two subportions, in an absolute PVARP and a relative PVARP. Within the absolute PVARP (100 ms), no atrial events are sensed. Within the relative PVARP (equals the remaining 400 ms), atrial events are sensed, but not tracked by the ventricular channel. Thus, the PACE 203 H interprets a ventricular sensed event, following an intrinsic atrial event occurred within the relative PVARP, as a regular beat and not as an extrasystole.

As a consequence, ventricular responses caused by premature atrial contractions are not counted as extrasystoles.

### 7.19.6 Runaway Protection

The PACE 203 H can stimulate the heart with a maximum basic rate of 220 ppm or a maximum tracking rate (MTR) of 230 ppm. The output of higher stimulation rates, for example, due to a defect in the frequency generator, is limited by an independent safety function, to a maximum of 235 ppm. This safety function is referred to as runaway protection.

## 7.19.7 Protection Against Abnormal Settings

The PACE 203 H continuously monitors the setting of parameters so that abnormal settings, as shown in Table 48, can be detected and avoided. Such settings can cause danger for the patient.

| Abnormal Setting | Reason for Preventing | Mode | Action |
|---|---|---|---|
| a) Basic rate > MTR | Basic rate must not be larger than MTR | DDD<br>VDD<br>DAI<br>VAT<br>DAT | Transient warning message and prevent abnormal setting |
| b) AVD + PVARP + 20ms > LRI | To guarantee minimum atrial sensing phase | DDD<br>VDD<br>DAI<br>VAT<br>DAT | Transient warning message and prevent abnormal setting |
| c) AVD + 60ms > LRI | To guarantee minimum V-A delay | D00<br>DVI | Transient warning message and prevent abnormal setting |
| d) PVD + PVARP ≥ URI<br>(with URI = 1/MTR) | To guarantee Wenckebach behavior | DDD<br>VDD<br>DAI<br>VAT<br>DAT | Transient warning message and prevent abnormal setting |

**Table 48: Abnormal settings**

**Note:** All conflicts are avoided, when "Auto A-V Delay", "Auto PVARP" and "Auto MTR" are activated. (see 7.9)

**Note:** The protection against abnormal settings (warning and limitation) can be turned off using the "Alarms on/off" option (see chapter 7.12.4.2). If Alarms are off, it is the responsibility of the user to set appropriate parameter combinations.

### 7.19.7.1 Possible Conflicts

Conflicts can occur in the process of changing parameter settings. In the tables below, all possible cases are listed together with the transient conflict warning message, which will be displayed on the lower display. In case of a conflict, the parameter to be changed is limited to a value still permissible.

The acronyms in the tables have the following definitions:

"↗" - Value to be increased

"↘" - Value to be decreased

"A" - Parameter is set to "Automatic setting"

"M" - Parameter is set to "Manual setting"

| Basic Rate | MTR | Message |
|---|---|---|
| ↗ | M | Increase MTR to increase Rate |
| M | ↘ | Decrease Rate to decrease MTR |

**Table 49: Conflicts type a)**

| Basic Rate | AVD | PVARP | Message |
|---|---|---|---|
| ↗ | M | M | Decrease PVARP or A-V Delay to increase Rate |
| ↗ | A | M | Decrease PVARP to increase Rate |
| ↗ | M | A | Decrease A-V Delay to increase Rate |
| ↘ | A | M | Decrease PVARP to decrease Rate |
| ↘ | M | A | Decrease A-V Delay to decrease Rate |
| M | ↗ | M or A | Decrease PVARP or Rate to increase A-V Delay |
| M | M or A | ↗ | Decrease A-V Delay or Rate to increase PVARP |

**Table 50: Conflicts type b)**

| Basic Rate | AVD | Message |
|---|---|---|
| ↗ | M | Decrease A-V Delay to increase Rate |
| M | ↗ | Decrease Rate to increase A-V Delay |

**Table 51: Conflicts type c)**

| Basic Rate | AVD (PVD) | PVARP | MTR | Message |
|---|---|---|---|---|
| ↗ | M | A | A | Decrease A-V Delay to increase Rate |
| ↗ | A | M | A | Decrease PVARP to increase Rate |
| ↗ | M | M | A | Decrease PVARP or A-V Delay to increase Rate |
| ↘ | M | A | A | Decrease A-V Delay to decrease Rate |
| ↘ | A | M | A | Decrease PVARP to decrease Rate |
| ↘ | A | A | M | Decrease MTR to decrease Rate |
| ↘ | M | A | M | Decrease A-V Delay or MTR to decrease Rate |
| ↘ | A | M | M | Decrease PVARP or MTR to decrease Rate |
| M | ↗ | M or A | M or A | Decrease PVARP or MTR to increase A-V Delay |
| M | M or A | ↗ | M or A | Decrease A-V Delay or MTR to increase PVARP |
| M | M or A | M or A | ↗ | Decrease PVARP or A-V Delay to increase MTR |

**Table 52: Conflicts type d)**

### 7.19.7.2 Mode Switching

The PACE 203 H avoids conflicts as a result of mode switching by selecting appropriate parameter values, according to the rules set for the automatic modes (A-V delay, PVARP and MTR) – independent of whether these automatic modes for the respective parameters are enabled or disabled.

The basic rate is the determining parameter and will never be altered.

If a conflict type b) (Table 48) must be solved and both PVARP and A-V delay are set to ”manual”, the PACE 203 H will, first, set the PVARP to the automatic value (see chapter 7.9.2). If this does not solve the conflict, the A-V delay will be reset to the automatic value (see chapter 7.9.1).

The PACE 203 H acknowledges that a parameter has been changed appropriately, with regards to the basic rate given, by a short warning message in the lower display. Example:

AVD
adapted

In this example, the PACE 203 H changed the A-V delay.

**Note:** Because of this maneuver, the PACE 203 H does not switch to an automatic mode. The PACE 203 H simply determines and sets one or more parameters, similar to what the corresponding automatic mode would have determined.

## 7.19.8 Effects from Therapeutic and Diagnostic Energy Sources

### 7.19.8.1 Defibrillation

The PACE 203 H is designed in a manner such that it withstands defibrillation discharges according to EN 50061.

**Warning:** Any protection against defibrillation discharges is limited, due to the low resistance required by the pacemaker output circuitry. In any case, it is mandatory to monitor the patient for a period of time after defibrillation, and to be prepared for a possible failure or malfunctioning of the pacemaker.

To protect the patient and the pacemaker from current passing through the pacemaker / lead-circuit, caused by defibrillation discharges, the stimulation circuit should always be opened, if possible.

Excessively high currents can also damage the pacemaker.

### 7.19.8.2 RF-surgery

When using RF-cautery and RF-surgery instruments, very strong electrical and magnetic interference is generated which can influence, or even damage, electronic instruments like the PACE 203 H. Fibrillation currents can also be generated by crosstalk into the leads and cables.

If simultaneous use of the PACE 203 H and electro-surgical instruments is required, the PACE 203 H should be set to an asynchronous pacing mode (without any sensing).

**Warning:** In any case, it is mandatory to continuously monitor the patient, and to be prepared for a possible failure or malfunctioning of the PACE 203 H.

## 7.19.9 Summary of Text Messages

The PACE 203 H differentiates between conflicts, application related and device related errors, and warning messages.

### 7.19.9.1 Warning Messages Related to Conflicting Parameter Settings

Conflict warnings alert the user that he or she must adjust unusual, conflicting parameter settings. Such settings can result in improper pacing therapy for the patient. The PACE 203 H blocks conflicting parameter settings as long as the "Alarms" functions are not disabled (see 7.19.7 and 7.12.4.2).

When the PACE 203 H determines a conflict, it displays a warning message in the lower display, accompanied by an acoustic warning signal. The warning message alerts the user about the problem, and how to solve it. Warning messages appear after the recognition of conflicts. Depending on the warning message, it disappears automatically after a few seconds, or after confirmation by the user. The user confirms the warning message by pressing the key

Lock/Unlock.

Confirmation causes the warning message to disappear. Table 53 shows a list of these warning messages.

| | PACE 203 H Warning Message | Meaning / Cause | Measures to Eliminate the Conflict / Error | See Chapter # |
|---|---|---|---|---|
| 1 | Increase MTR to increase Rate | The user has attempted to increase the rate. This led to a conflict (type a), because MTR is set at an excessively low value. | MTR must be increased or set to "Auto MTR", before the rate can be further increased. | 7.19.7 |
| 2 | Decrease PVARP or A-V Delay to increase Rate | The user has attempted to increase the rate. This led to a conflict (type b or d), because the sum of PVARP and A-V delay is excessively high. | PVARP and/or A-V delay must be decreased or set to "Auto PVARP" and "Auto AVD", before the rate can be further increased.<br>Alternatively, in case of an implicit conflict (type d) between PVARP plus A-V delay and automatically set MTR, the manual setting of the MTR to a lower value is suggested. | 7.19.7 |
| 3 | Decrease A-V Delay to increase Rate | The user has attempted to increase the rate. This led to a conflict (type c), because A-V delay is set to an excessively high value. | A-V delay must be decreased or set to "Auto AVD", before the rate can be further increased. | 7.19.7 |
| 4 | Decrease PVARP or Rate to increase A-V Delay | The user has attempted to increase the A-V delay. This led to a conflict (type b), because there is inadequate time for a long A-V delay in the presence of a high rate and a long PVARP. | PVARP and/or rate must be decreased, before the A-V delay can be further increased. | 7.19.7 |
| 5 | Decrease Rate to increase A-V Delay | The user has attempted to increase the A-V delay. This led to a conflict (type c), because there is inadequate time for a long A-V delay in the presence of a high rate. | The rate must be decreased, before the A-V delay can be further increased. | 7.19.7 |

| | PACE 203 H Warning Message | Meaning / Cause | Measures to Eliminate the Conflict / Error | See Chapter # |
|---|---|---|---|---|
| 6 | Decrease PVARP or MTR to increase A-V Delay | The user has attempted to increase the A-V delay. This led to a conflict (type d), because there is inadequate time for a long A-V delay in the presence of a high MTR and a long PVARP. | PVARP and/or MTR must be decreased, before the A-V delay can be further increased. | 7.19.7 |
| 7 | Decrease A-V Delay or Rate to increase PVARP | The user has attempted to increase PVARP. This led to a conflict (type b), because there is inadequate time for a long PVARP in the presence of a high rate and a long A-V delay. | A-V delay and/or rate must be decreased, before the PVARP can be further increased. | 7.19.7 |
| 8 | Decrease A-V Delay or MTR to increase PVARP | The user has attempted to increase PVARP. This led to a conflict (type d), because there is inadequate time for a long PVARP in the presence of a high MTR and a long A-V delay. | A-V delay and/or MTR must be decreased, before the PVARP can be further increased. | 7.19.7 |
| 9 | Decrease PVARP or A-V Delay to increase MTR | The user has attempted to increase MTR. This led to a conflict (type d), because the sum of PVARP and A-V delay is too long. | PVARP and/or A-V delay must be decreased, before the MTR can be further increased. | 7.19.7 |
| 10 | Decrease Rate to decrease MTR | The user has attempted to decrease the MTR. This led to a conflict (type a), because rate is set to an excessively high value. | Rate must be decreased, before the MTR can be further decreased. | 7.19.7 |
| 11 | Decrease PVARP to increase Rate | The user has attempted to increase the rate. This led to a conflict (type b or d), because the sum of PVARP and A-V delay is too long with respect to basic rate or MTR. | PVARP must be decreased or set to "Auto PVARP", before the rate can be further increased.<br>Alternatively, manual setting of the A-V delay or (in case of a conflict type d) MTR to a lower value is suggested. | 7.19.7 |
| 12 | Decrease A-V Delay to increase Rate | The user has attempted to increase the rate. This led to a conflict (type b or d), because the sum of PVARP and A-V delay is too long with respect to rate or MTR. | A-V delay must be decreased or set to "Auto AVD", before the rate can be further increased.<br>Alternatively, manual setting of the PVARP or (in case of a conflict type d) the MTR to a lower value is suggested. | 7.19.7 |
| 13 | Decrease PVARP to decrease Rate | The user has attempted to decrease the rate. This led to a conflict (type b or d), because the sum of PVARP and A-V delay is too long with respect to rate or MTR. | PVARP must be decreased or set to "Auto PVARP", before the rate can be further decreased.<br>Alternatively, manual setting of the A-V delay or (in case of a conflict type d) the MTR to a lower value is suggested. | 7.19.7 |

| | PACE 203 H Warning Message | Meaning / Cause | Measures to Eliminate the Conflict / Error | See Chapter # |
|---|---|---|---|---|
| 14 | Decrease A-V Delay to decrease Rate | The user has attempted to decrease the rate. This led to a conflict (type b or d), because the sum of PVARP and A-V delay is too long with respect to rate or MTR. | A-V delay must be decreased or set to "Auto AVD", before the rate can be further decreased.<br>Alternatively, manual setting of the PVARP or (in case of a conflict type d) the MTR to a lower value is suggested. | 7.19.7 |
| 15 | Decrease MTR to decrease Rate | The user has attempted to decrease the rate. This led to a conflict (type d), because MTR is too high with respect to the sum of PVARP and A-V delay. | MTR must be decreased or set to "Auto MTR", before the rate can be further decreased.<br>Alternatively, manual setting of the PVARP or the A-V delay to a lower value is suggested. | 7.19.7 |
| 16 | Decrease A-V Delay or MTR to decrease Rate | The user has attempted to decrease the rate. This led to a conflict (type d), because the sum of PVARP and A-V delay is too long with respect to MTR. | A-V delay and/or MTR must be decreased or set to "Auto AVD" and "Auto MTR", before the rate can be further decreased.<br>Alternatively, manual setting of the PVARP to a lower value is suggested. | 7.19.7 |
| 17 | Decrease PVARP or MTR to decrease Rate | The user has tried to decrease the rate. This led to a conflict (type d), because the sum of PVARP and A-V delay is too long with respect to MTR. | PVARP and/or MTR must be decreased or set to "Auto PVARP" and "Auto MTR", before the rate can be further decreased.<br>Alternatively, manual setting of the A-V delay to a lower value might help. | 7.19.7 |

**Table 53: Warning Messages Related to Conflicting Parameters Settings**

### 7.19.9.2 Warning Messages Related to Application Errors

Generally, if the problem is identified, any application related errors can be solved by the user. Application related errors result in a warning message in the lower display accompanied by an acoustic warning signal, which will be repeated periodically. The warning message alerts the user about the problem. It appears after recognition of the error and disappears after the problem has been solved, or after confirmation by the user. The user can confirm the error message by pressing the key

Lock/Unlock.

Confirmation causes the warning message to disappear, and the acoustic signal to cease.

If an error is detected when the lower display is switched off, the acoustic signal is then the only available warning. A first press of the key

Lock/Unlock

switches the lower display and the backlight on and unlocks the PACE 203 H. The warning message is now visible. A second press of the key

Lock/Unlock

then confirms the error message.

If an error is detected when the lower display is switched on, but the device is locked, a first press of the key

Lock/Unlock

switches the backlight on and unlocks the PACE 203 H. A second press of the key

Lock/Unlock

then confirms the error message.

The message (except the "... change battery" and the "…lead disconnected" messages) will reappear a few seconds after confirmation, if the error persists. Table 54 shows these messages.

| | PACE 203 H Warning Message | Meaning / Cause | Measures to eliminate the Conflict / Error | See Chapter # |
|---|---|---|---|---|
| 1 | Change battery! | The battery change level is reached.<br>**Note:** This message will be repeated after confirmation every 10 minutes. | Insert a new battery. | 7.19.1<br>9.2 |
| 2 | Hurry up!<br>Change battery! | The critical battery change level is reached.<br>**Note:** This message will be repeated after confirmation every 2 minutes. | Insert a new battery. | 7.19.1<br>9.2 |
| 3 | Release all keys | A key is pressed while the PACE 203 H is turning on. | Release all keys during the power-on process of the device to allow a proper self-test. | 7.3 |
| 4 | Key timeout | A key is pressed for more than 120 seconds. There is a possibility that something heavy is pressing on the PACE 203 H, or it is being abutted against an edge of some sort. | In case no cause is apparent, and the error message persists, this indicates that a key is malfunctioning, and the device must be sent to the manufacturer for inspection and service. | --- |

| | PACE 203 H Warning Message | Meaning / Cause | Measures to eliminate the Conflict / Error | See Chapter # |
|---|---|---|---|---|
| 5 | Atrial lead disconnected<br>or<br>Ventricular lead disconnected | The atrial lead has been disconnected. The last stimulation could not be properly carried out.<br>**Note**: This error message will <u>not</u> be repeated after confirmation, even if the disconnection persists. The open output is only indicated by the open lead symbol (see Figure 11).<br>**Note**: Surveillance can only occur, if the stimulation amplitude is set to a value ≥ 2.0 V, and if the pulse duration is ≥ 0.15 ms. | If the lead was not disconnected intentionally, there is a possibility that lead breakage or a disconnection of the connector cable exists. Check all connections, connection cables and leads. | 7.19.2 |
| 6 | Atrial output short<br>or<br>Ventricular output short | The atrial or ventricular output, respectively, is short-circuited or low-resistance bridged. The PACE 203 H was unable to deliver the last stimulation pulse properly.<br>**Note**: Surveillance can only occur, if the stimulation amplitude is set to a value ≥ 2.0 V and if the pulse duration is ≥ 0.15 ms. | Check all connections, connection cables and leads, and attempt to find the short-circuit. | 7.19.2 |

**Table 54: Warning Messages Related to Application Errors**

### 7.19.9.3 Warning Messages Related to Device Errors

Device related errors are those which are probably caused by a malfunction of the pulse generator itself. (Some may also have external reasons.) Errors of this kind result in a warning message in the lower display, accompanied by an acoustic error signal, which will be repeated periodically. The warning message alerts the user about the problem. It appears after recognition of the error and disappears only after confirmation by the user, i.e. device related error messages *must* be confirmed. (The acoustic error signal will, however, cease when the error is no more present.) The user must confirm the error message by pressing the key

Lock/Unlock.

Confirmation causes the text message to disappear and the acoustic signal to cease.

If an error is detected when the lower display is switched off, the acoustic signal is then the only available warning. A first press of the key

Lock/Unlock

switches the lower display and the backlight on, and unlocks the PACE 203 H. The error warning message is now visible. This is despite the fact that the error no longer present. A second press of the key

Lock/Unlock

then confirms the error message.

If an error is detected when the lower display is switched on, but the device is locked, a first press of the key

Lock/Unlock

switches the backlight on and unlocks the PACE 203 H. A second press of the key

Lock/Unlock

then confirms the error message.

If the error persists, the warning message will reappear after confirmation. Table 55 lists the possible warning messages.

| | PACE 203 H Warning Message | Meaning / Cause | Measures to Eliminate the Conflict / Error | See Chapter # |
|---|---|---|---|---|
| 1 | Unexpected device error no. ###<br><br>Restart device or submit to inspection | Most of the device related errors are reported by this warning message.<br><br>The error number "###" can give the manufacturer a helpful hint as to locating the cause of the error.<br><br>**Note:** The PACE 203 H attempts to continue its operation with the current parameter set, or, if this is not possible, with the emergency mode.<br><br>If the error repeats itself, this may lead to an erratic rhythm. | Attempt to switch the PACE 203 H off and, on waiting after a few seconds, on again.<br><br>If this doesn't solve the problem, remove the battery while the device is switched on, wait for a minimum of 10 minutes and then reinsert.<br><br>**Note**: The patient must not be connected to the PACE 203 H during this maneuver.<br><br>If the error persists despite of these maneuvers, the PACE 203 H must be sent to the manufacturer for inspection and service. | --- |
| 2 | Stored data lost ! Manufacturer's defaults will be used. | The memory for the Stand-by data and the standard programs has lost its data. The manufacturer's standard turn-on program (see 7.11.5) has been set and all standard programs have been reset to their manufacturer's defaults. | In case this error repeats itself, the PACE 203 H must be sent to the manufacturer for inspection and service. | --- |
| 3 | Keyboard error | While turning on the device, a key was pressed constantly for more than 10 seconds, despite of the message "Release all keys" | Releasing all keys during the power-on process of the device is necessary to allow a proper self-check.<br><br>In case all keys were released and the error message persists, this implies that a key is malfunctioning and the PACE 203 H must be sent to the manufacturer for inspection and service. | 7.3 |

**Table 55: Warning Messages Related to Device Errors**

### 7.19.9.4 Informative Messages

The PACE 203 H displays various informative messages on the lower display, which alert the user that certain actions must be taken. These messages are accompanied by an acoustic warning signal and require no confirmation. They disappear automatically after a short period of time, or after confirmation by the user. The user can confirm an informative message by pressing the key

Lock/Unlock.

Confirmation causes the message to disappear. Table 56 shows al list of these messages.

| | PACE 203 H Message | Meaning / Cause | Measures to eliminate the problem | See Chapter # |
|---|---|---|---|---|
| 1 | Startup timeout (Press Unlock) | The key **Lock/Unlock** was not pressed within 30 sec after turning on the pacemaker. **Note**: The PACE 203 H will turn itself off after this message. | In order to turn on the pacemaker the key **Lock/Unlock** must be pressed within 30 sec after pressing the key labeled **ON**. | 7.3 |
| 2 | Auto AVD turned off | The automatic A-V delay setting has been turned off, because the **A-V DLY** dial has been turned. | If the automatic A-V delay setting is to remain enabled, activate it again via the Auto Menu and avoid turning the **A-V DLY** dial. | 7.9.1 |
| 3 | Atrial Auto Sense turned off | The automatic atrial sensing adjustment has been turned off, because the **A-SENSE** dial has been turned. | If the automatic atrial sensing adjustment is to remain enabled, activate it again via the Auto Sense Menu and avoid turning the **A-SENSE** dial. | 7.9.4 |
| 4 | Ventricular Auto Sense turned off | The automatic ventricular sensing adjustment has been turned off, because the **V-SENSE** dial has been turned. | If the automatic ventricular sensing adjustment is to remain enabled, activate it again via the Auto Sense Menu and avoid turning the **V-SENSE** dial. | 7.9.4 |
| 5 | Switch Atrial Auto Sense off to enable Atrial Trigger | Atrial Auto Sense and Atrial Trigger cannot be enabled at the same time, because the triggered stimulation prevents proper measurement of the intrinsic atrial activation. | Act according to the message. | 7.9.4 7.12.4.3 |
| 6 | Switch Atrial Trigger off to enable Atrial Auto Sense | Atrial Auto Sense and Atrial Trigger cannot be enabled at the same time, because the triggered stimulation prevents proper measurement of the intrinsic atrial activation. | Act according to the message. | 7.9.4 7.12.4.3 |

| | PACE 203 H Message | Meaning / Cause | Measures to eliminate the problem | See Chapter # |
|---|---|---|---|---|
| 7 | Switch Atrial Auto Sense off to decrease AVD | If atrial Auto Sense is activated, a minimum of 30 ms P-V delay is required to allow proper measurement of the intrinsic atrial activation.<br>Because A-V delay cannot be shorter than P-V delay, it is also limited to 30 ms. | If a shorter A-V delay is necessary, atrial Auto Sense cannot be employed and must be deactivated. | 7.8.4<br>7.9.4 |
| 8 | AVD adapted | To resolve a parameter conflict during mode switching, the A-V delay has been changed, i.e. adapted to the current rate. *)<br>OR<br>A-V delay has been increased to the minimum value of 30 ms when atrial Auto Sense has been activated. | N/A (conflict resolved by the device).<br>Please check if the altered A-V delay is appropriate for the patient. | 7.19.7<br>7.8.4<br>7.9.4 |
| 9 | PVARP adapted | To resolve a parameter conflict during mode switching, the PVARP has been changed, i.e. adapted to the current rate. *) | N/A (conflict resolved by the device).<br>Please check if the altered PVARP is appropriate for the patient. | 7.19.7 |
| 10 | MTR adapted | To resolve a parameter conflict during mode switching, the maximum tracking rate has been changed, i.e. adapted to the current rate. *) | N/A (conflict resolved by the device).<br>Please check if the altered MTR is appropriate for the patient. | 7.19.7 |

*) Sometimes only a combination of adaptations resolves the conflict completely. In this case the message reports all adapted parameters.

**Table 56: Informative Messages**

# 8 Storage

The storage temperature range of the PACE 203 H is –20…+60°C. Note that the device must be within the operational temperature range before use (+10…+45°C).

The enclosed connector cables are sterilized prior to shipment. They are packed in double Tyvek® sterile packages.

The sterilization method is ethylene oxide gas.

The sterility is guaranteed as indicated by the expiration date, if the package is not damaged and properly stored.

The sterile connection cables must be stored in a dry, cool place at temperatures between 10°C (50°F) and 25°C (77°F). Keep out of direct light.

Do not resterilze connection cables. Oscor does not guarantee sterilization by a third party.

**Warning:** Connector cables intended for single use must not be re-sterilized after use

**Warning:** In case the PACE 203 H is not to be used for longer periods of time, the battery must be removed in order to prevent damage from possible battery acid leakage. Damage because of a leaking battery is not covered by the manufacturer's guarantee.

# 9 Care and Maintenance

## 9.1 Care and Cleaning

As a precision electronic device, the PACE 203 H must be handled with corresponding care. Although the device is robustly constructed, it can be damaged by heavy mechanical stress, for example, by dropping on a hard surface.

The enclosure and the keypad of the PACE 203 H are protected against accidental liquid spills. To clean the device, use a towel or sponge moistened with water or alcohol.

For disinfection, the enclosure of the PACE 203 H can be cleaned with alhydex, cydex, or with detergicide.

**Warning:** The PACE 203 H must not be submerged in either water or in any other cleaning solution. Do not use any scrubbing powder/liquid on the device.

The device must not be sterilized in an autoclave or with ethylene oxide. Sterilization with ultrasound or gamma rays is also not permitted. The PACE 203 H can be damaged by such procedures.

Re-usable cables must be cleaned, disinfected and sterilized after each use.

Single use cables must not be re-used.

## 9.2 Changing the Battery

While the device is in use, the battery should be changed when the battery depletion symbol shows only one blinking segment and the warning message

Change battery!

appears. The amount of time remaining from this moment, until the battery is completely drained depends implicitly on the type of battery used, and therefore cannot be predicted with absolute certainty. Typically, one day of reserve energy can be expected with the recommended battery, if the PACE 203 H is set to a mode with standard parameters.

During a battery change, the PACE 203 H is capable of maintaining continuous operation for at least 30 seconds. Typically, this duration is even longer. The battery change should, therefore, be quick but does not require haste.

**Warning:** In order to provide continuous operation of the PACE 203 H during a battery change, the battery must not remain in the PACE 203 H until it is completely drained. During operation of the PACE 203 H, the user must not permit the critical depletion level to occur, indicated by battery symbol shown empty and blinking, and the warning message

Hurry up! Change battery!

and then being forced to replace the depleted battery with a new one with great haste.

If the PACE 203 H is switched off or to stand-by mode after the request to change the battery appears, the battery must be changed before the PACE 203 H is turned on again.

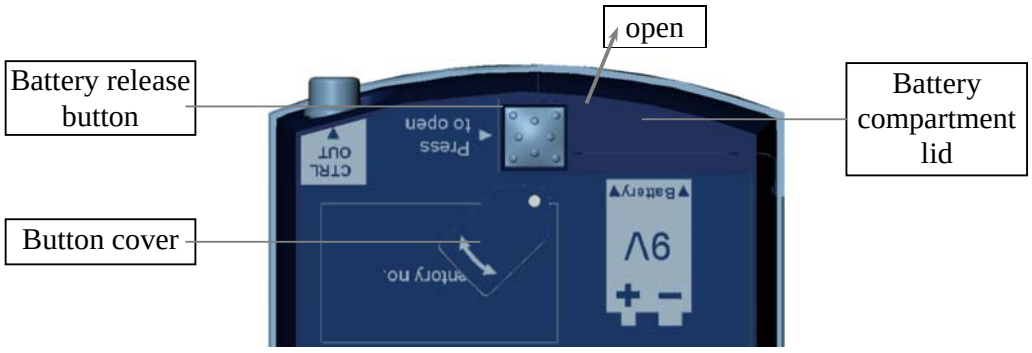



**Figure 14: Battery compartment**

For battery replacement, please adhere to the following instructions:

1. Have a new 9 V-battery (MN1604 or equivalent) ready.
2. On the bottom of the PACE 203 H, turn the protection cover of the battery compartment release button, and push the battery compartment release button. Open the battery compartment lid (see Figure 14). Make certain that the inserted battery does not drop on the floor.
3. Remove the battery from the battery compartment.
4. Place a new battery in the compartment. The orientation of the battery polarity is irrelevant.
5. Close the battery compartment lid until it is audibly latched in place. Rotate the protection cover over the battery compartment release button.
6. It is mandatory to dispose of the battery in an environmentally friendly, legal manner.

**Warning:** Avoid handling with spillage, if the battery compartment is open!

**Warning:** Only insert a 9 V-battery (MN1604 or equivalent) produced by a respected and reliable battery manufacturer!

## 9.3 Safety Check-Ups of the Pacemaker

In order to assure safe operation of the PACE 203 H, the following check-ups must be carried out on a regular basis.

*Check-ups to be made by the manufacturer or by designated authorized persons thereof:*

**Yearly checks:**

- Measuring the auxiliary currents
- Measuring the stimulation parameters (amplitude, pulse width) in the atrial and ventricular channels
- Measuring the rate.
- Measuring the sensitivity in the atrial and ventricular channels.
- Inspecting the battery surveillance and power maintenance time.
- Inspecting the lead surveillance.

We recommend having the manufacturer carry out the yearly safety check-ups and the function check.

*Check-ups to be done by the user:*

**Before each use:**

Visual inspection:

- Inspect the device and accessories for visible damage.
- Inspect the connections for visible damage.

Function test:

- Inspect all connections to see if they affix and function properly.
- Inspect all operating elements and displays for perfect function

**After each use:**

- Care and cleaning of the device and of the accessories is to be done according to chapter 9.1.

**Note: The PACE 203 H contains no parts that are repairable or can be calibrated by anyone other than those authorized in writing, by the manufacturer. Repairs or replacements made by anyone except by the manufacturer, or his authorized designees, void the guarantee of the PACE 203 H.**

## 9.4 Product Return Policy

In the event that a PACE 203 H and / or its accessories are defective and / or are beyond repair, the user (customer) must obtain a Return-to-Manufacturer-Authorization (RMA) number from the manufacturer and then return these items to the manufacturer for repair or proper disposal.

# 10 Customer Service

If you have any questions, the customer service can be reached at:

**Oscor Inc. - Customer Service**

**3816 DeSoto Boulevard**

**Palm Harbor, FL 34683**

**USA**

| | | | | | |
|---|---|---|---|---|---|
| USA: | Phone | 727-937-2511 | International: | Phone | +1 727-937-2511 |
| | Fax | 727-934-9835 | | Fax | +1 727-934-9835 |
| | e-mail | mail@oscor.com | | | |

For inspection and repair service, please contact the manufacturer:

**Osypka Medical GmbH**

**Grossbeerenstrasse 184**

**D - 12277 Berlin**

**Germany**

| | | | | | |
|---|---|---|---|---|---|
| Germany: | Phone | (030) 741 6035 | International: | Phone | +49 (30) 741 6035 |
| | Fax | (030) 7479 2507 | | Fax | +49 (30) 7479 2507 |
| | e-mail | mail@osypkamed.com | | | |

# 11 Technical Data

**PACE 203 H – Dual-Chamber External Pacemaker**

| | |
|---|---|
| Measurement conditions: | Environment temperature: 20 ± 2°C<br>Voltage supply: 9 V ± 0.5 V<br>Load resistance: 500 Ω ± 1 %<br>Test impulse: as specified in ISO 5841-1, Subclause B.1.4 (triangle 2 ms / 13 ms) |
| Pacing modes: | primary: DDD, VVI, AAI, VDD<br>supplementary: D00, V00, A00, DVI, DAI, VAT, AAT, DDD+AT, DAT |
| Basic rate: | 30 ppm…220 ppm ± 1 % |
| Maximum tracking rate (MTR): | 80 ppm…230 ppm ± 1 % |
| Atrial overdrive stimulation: | 70 ppm…1000 ppm ± 4 % ± 1ms |
| Output pulse: | cathodic, biphasic, asymmetric, capacitive coupled, passive discharge |
| Nominal pulse amplitude (500 Ω): | 0.1 V…18 V ± 10 % ± 0.01 V |
| Pulse amplitude (200 Ω … 2000 Ω): | 0.1 V…18 V ± 20 % ± 0.01 V |
| Pulse duration: | 0.05 ms…1.50 ms ± 5 % ± 0.005 ms |
| Atrial sensitivity: | 0.2 mV…20 mV ± 10 % ± 0.05 mV, ∞ |
| Ventricular sensitivity: | 1.0 mV…20 mV ± 10 % ± 0.05 mV, ∞ |
| Input impedance: | 22 kΩ ± 20 % |
| Output impedance: | < 10 Ω |
| Load impedance range: | 200 Ω…2000 Ω |
| A-V delay: | 5 ms…400 ms ± 5 % ± 2 ms<br>(minimum 30 ms when atrial Auto Sense is activated) |
| P-V delay: | Determined by A-V delay: A-V delay – 30ms ± 5 % ± 2 ms<br>(minimum 5 ms when atrial Auto Sense is not activated,<br>minimum 30 ms when atrial Auto Sense is activated);<br>may be prolonged depending on MTR |
| Escape interval: | Determined by basic rate ± 5 % |
| Atrial escape interval (V-A delay): | Determined by basic rate and A-V interval ± 6 % |
| Extended atrial escape interval:<br>(V-A delay after first PVC) | Determined by basic rate and A-V delay<br>(minimum 850 ms) ± 5 % |
| Atrial refractory period: | 250 ms ± 5 % (AAI, AAT) |
| | A-V interval plus PVARP (DDD, VDD, DAI, VAT, DAT) |
| PVARP:<br>- absolute portion:<br>- relative portion: | 150 ms ... 500 ms ± 5 %<br>100 ms ± 5 %<br>PVARP – 100 ms ± 5 % |
| Extended PVARP (after PVC): | 500 ms ± 5 % (or maximum possible period) |
| Ventricular refractory period: | 250 ms ± 5 % |

| | |
|---|---|
| Blanking period in atrial channel: | 85 ms ± 5 % +2 ms/−6 ms after atrial as well as ventricular stimulation and sensing |
| Blanking period in ventr. channel: | 85 ms ± 5 % +2 ms/−6 ms after ventricular stimulation and sensing,<br>55 ms ± 5 % +2 ms/−6 ms after atrial stimulation |
| Discharge period: | 45 ms ± 5 % ± 2 ms |
| Crosstalk detection window: | 40 ms |
| Non-physiologic A-V delay:<br>(for ventricular safety pacing) | 100 ms ± 5 % ± 2 ms |
| Emergency mode: | V00 (A00), 80 ppm, 12 V, 0.75 ms (1.0 ms) |
| Standard setting: | Standard parameter set for each primary mode, plus one turn-on parameter set |
| Acoustic Signaling: | Different for stimulation, sensing and warnings; stimulation and sensing indication can be turned on or off |
| Interference detection frequency: | > 4.5 Hz ± 5 % (> 273 bpm) |
| Interference rate: | Basic rate + 10 ppm ± 1 %<br>(but max. MTR and max. 220 ppm) |
| Defibrillation protection: | Built-in suppression diode |
| Runaway protection: | 235 ± 2 ppm |
| Lead surveillance: | Message in case of short circuit or interruption in the stimulation circuit (for a set stimulation amplitude of ≥ 2.0 V and a set pulse duration of ≥ 0.15 ms) |
| Battery: | 9 Volt (identification per IEC 86: 6LR61)<br>recommended types: Duracell Alkaline MN1604<br>Sonnenschein Lithium SLM |
| Lifespan of recommended battery: | Alkaline:<br>minimal 5 days (VVI, standard parameters)<br>minimal 4 days (DDD, standard parameters)<br>Lithium:<br>minimal 10 days (VVI, standard parameters)<br>minimal 8 days (DDD, standard parameters)<br>plus 1 day reserve after the first appearance of the battery change message |
| Battery depletion indication: | Continuous display of a battery depletion symbol, blinking of last segment and acoustic warning when the time-to-change level is reached (7.2 ± 0.2 V), blinking of the empty depletion symbol and acoustic warning when an immediate battery change is required (5.5 ± 0.5 V) |
| Power maintenance during battery change: | Minimum 30 s |
| Operating temperature: | +10…+45°C |
| Storage temperature (w/o battery): | −20…+60°C |
| Operation in explosion hazard areas: | The device may not be used in areas where flammable agents are present. |
| Housing dimensions (L×W×D): | approx. 200 mm × 96 mm × 38 mm |

| | |
|---|---|
| Overall dimensions (L×W×D): (with terminals and dials) | approx. 212 mm × 96 mm × 51 mm |
| Weight without battery: | approx. 445 g |
| Weight with battery: | approx. 490 g |
| Lead Connections: | Protected terminals (collets) for plugs with 0.9…2.0 mm diameter |
| Other Interfaces: | Intra-aortic Balloon Pump Control |

**We reserve the right to make technical changes without notice.**

# 12 Delivery Unit

| | |
|---|---|
| Specifics: | PACE 203 H incl. battery |
| | Two lead-connector cables XI.TME |
| Optional accessories: | Interface BPI 202 for controlling an intra-aortic balloon pump |
| | Adapter-box |

# 13 Conditions of Guarantee and Liability Restrictions

The medical technology products of the company Osypka Medical GmbH are produced from high quality materials and under strict adherence to controlled and proven manufacturing processes. The quality is continuously verified during production and assured before delivery.

Nevertheless, should you recognize that a product under warranty performs inefficiently, or improperly, you must return it to us within 30 days of occurrence of the malfunction. Please enclose a description of the defect or fault. The product in question will then be thoroughly examined in our factory. We will repair or replace, free of charge, all components that are found to be defective.

The guarantee expires 12 months after delivery of the product to the user (customer).

This guarantee does not include any batteries.

Product damage that occurs through improper storage or use, arbitrary alterations to the product, use other than that which the product is intended for, or by unauthorized re-use and re-sterilization, are explicitly excluded from the guarantee.

The right to this guarantee is voided, if the stipulated safety check-ups are not regularly carried out.

If inspections, interventions, alterations or changes are made by parties other than those authorized in writing by the manufacturer, the guarantee becomes void.

This guarantee only applies to the repair or replacement of the device itself. All further claims for replacement by the purchaser and from third parties are excluded. All risks that exist in connection with the medical application of our products are solely and explicitly the responsibility of the purchaser, user or patient, if applicable.

THIS WARRANTY IS GIVEN IN LIEU OF ANY OTHER WARRANTY; EXPRESSED OR IMPLIED; INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE.

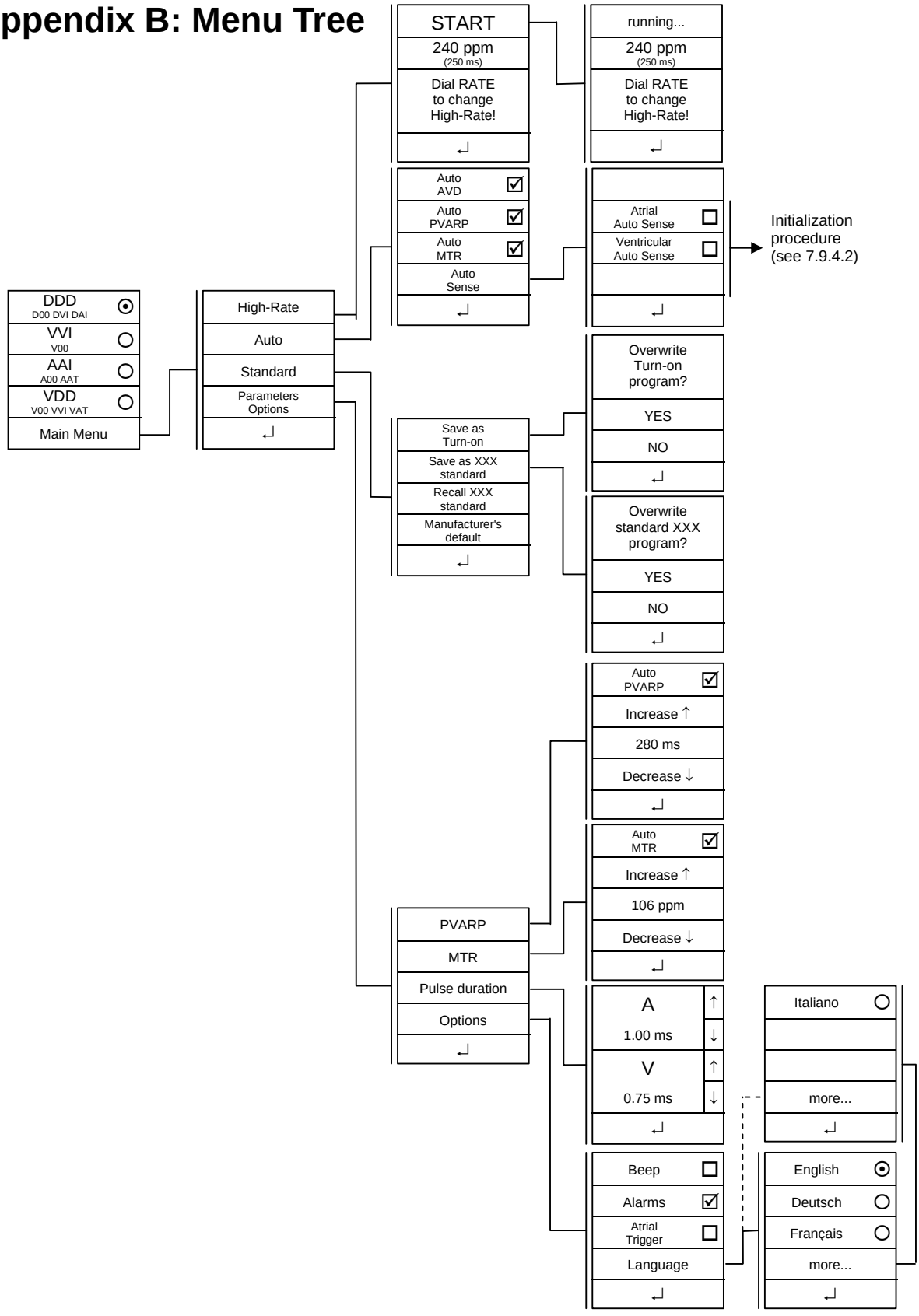
The remarks set forth herein contain the sole remedy available to any person. The manufacturer will not be liable to any person for any medical expenses, or any direct or consequential damages, resulting from the failure or malfunction of the product or accessories, whether such claim is based on warranty, contract, tort, or otherwise. No person has the authority to bind the manufacturer to any representation or warranty contrary to, or in addition to this warranty. There are no other warranties, which extend beyond the face hereof.

# Appendix A: Glossary

| | |
|---|---|
| Atrial escape interval | Time between ventricular sensed beat or a ventricular pulse and the succeeding non-triggered atrial pulse of a pulse generator, i.e. the time when the pacemaker waits for a P-wave. |
| Atrioventricular interval (AVI) | Delay between an atrial pulse or the sensing of an atrial depolarization and the subsequent ventricular pulse or the sensing of a ventricular depolarization. The actual AVI can be shorter then the adjusted A-V delay or P-V delay in case of a spontaneous ventricular depolarization. |
| A-V crosstalk | Detection of the atrial output pulse by the ventricular sensing amplifier which may result in ventricular output inhibition. |
| A-V delay (AVD) | Programmed delay between an atrial pulse and the subsequent non-triggered ventricular pulse under the condition that no sensing of a ventricular depolarization was detected by the pulse generator. |
| Basic rate (short: Rate) | Pulse rate of an pulse generator, either atrial or ventricular, unmodified by sensed cardiac or other electrical influence. |
| Basic pulse interval | Pulse interval unmodified by sensed cardiac or other electrical influence.<br>Basic pulse interval = 1 / basic rate. |
| Beat | Ordered spontaneous activity of the heart. |
| Blanking period | Period during which a sensing function of a pulse generator is disabled. |
| Cross blanking period | Period during which the sensing function of the pulse generator is disabled in one channel because of an event in the other channel. |
| Escape interval | Time between a sensed beat or a pulse and the succeeding non-triggered pulse of a pulse generator. |
| External pacemaker | Non-Implantable pulse generator and patient cables (if used). |
| Inhibition | The effect of the pulse suppression in a demand-pacemaker at sensing of a cardiac depolarization or other electrical influence in the same chamber. |
| Interference pulse rate | Pulse rate with which the pulse generator responds when it senses electrical activity other than that from the myocardium and recognizes that as interference. |
| Lower rate interval (LRI) | The longest period between consecutive (paced or sensed) events occurring in the relevant chamber. (In absence of sensed cardiac or other electrical influence: equal to basic pulse interval.) |
| Maximum tracking rate (upper rate, MTR) | Maximum ventricular pacing rate in response to sensed atrial activity. Expressed differently it is the maximum pulse rate at which the non-implantable pulse generator will respond on a 1:1 basis to a triggering signal. |
| Non-implantable pulse generator | Medical electrical equipment with an internal electrical power source which is intended for use outside the body and which produces a periodic electrical pulse intended to stimulate the heart through a lead (or combination of lead and patient cable). |
| Patient Cable | Device attached to the terminals of a non-implantable pulse generator so that the distance between it and the pacing lead can be increased. |

| | |
|---|---|
| Post-ventricular atrial refractory period (PVARP) | Period after a ventricular event (whether sensed or paced), during which synchronous ventricular pacing is disabled, regardless of any atrial event.<br><br>The PVARP of the PACE 203 H is divided in two parts: an absolute part and a relative part. In the absolute part (100 ms) no atrial events are recognized. In the relative part (the remaining) atrial events are registered, but not tracked. This algorithm prevents from misinterpretation of ventricular events after premature atrial events as PVCs (extrasystoles). |
| Premature ventricular contraction (PVC) | A sensed ventricular event not preceded by a sensed atrial event. Also named extrasystole. |
| Pulse | (Monophasic) electrical output of a pulse generator intended to stimulate the myocardium. |
| Pulse amplitude | Magnitude of the pulse expressed in volts or milliamperes. |
| Pulse duration | Duration of the pulse. |
| Pulse interval | Time interval between identical points of two consecutive pulses, expressed in milliseconds. |
| Pulse rate | Number of pulses per minute<br>1 ppm = 1/60 $s^{-1}$ |
| P-V delay (PVD) | Delay between the sensing of an atrial depolarization and the subsequent non-triggered ventricular pulse under the condition that no sensing of a ventricular depolarization was detected by the pulse generator. |
| Refractory period | Period during which a pulse generator will not respond to a beat. |
| Sensitivity | Minimum signal, expressed in millivolts, required to consistently control the function of the pulse generator. |
| Upper rate interval (URI) | The shortest period allowable between paced or sensed events, while still maintaining 1:1 atrioventricular synchrony (equal to 60 / $MTR_{ppm}$). |
| V-A delay (VAD) | Other expression for atrial escape interval. |
| Ventriculoatrial interval (VAI) | Delay between an ventricular pulse or the sensing of a ventricular depolarization and the subsequent atrial pulse or the sensing of a atrial depolarization. |

# Appendix B: Menu Tree



# Appendix C: Figures

# Appendix D: Tables