Tech Corner

Automatic Implantation Detection

NOTE: PLEASE NOTE THAT THE FOLLOWING INFORMATION IS A GENERAL DESCRIPTION OF THE FUNCTION.

DETAILS AND PARTICULAR CASES ARE NOT DESCRIBED IN THE ARTICLE. FOR ADDITIONAL

EXPLANATION PLEASE CONTACT YOUR SALES REPRESENTATIVE.

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AVAILABILITY

Automaticity at Implantation is a feature present in all MicroPort CRM pacemaker models except ESPRIT. It is not available in the SR pacemaker models implanted with an atrial lead, nor CRT-P model if the ventricular pacing cavity is "left" only.

DEFINITION

Automaticity at Implantation allows the pacemaker to automatically detect if the device is implanted. It has been designed to:

- provide a secure functioning of the device during implantation without prior or post implantation interrogation
- program automatically the following pacing and sensing configurations:
 - Pacing: Unipolar (as-shipped value¹)
 - **Sensing**: Bipolar (if a bipolar lead is connected)
- automatically launch the SafeR² pacing mode (in dual chamber models)
- program the Rate Response to Learn
- automatically reset the statistics and launch AIDA diagnostics
- · automatically starts the measurement of lead impedances every 6 hours

Automaticity at Implantation is based on a ventricular "Unipolar+Bipolar" mechanism: with a bipolar lead, the ventricular pacing is guaranteed as soon as the lead is connected to the pacemaker.

Then two different types of ventricular impedance measurements are performed: in *Unipolar* to confirm the implantation and in *Bipolar* to set the lead polarities.

When available, Automaticity at Implantation is pre-set in the pacemaker and is indicated for all patients..

DESCRIPTION OF OPERATION

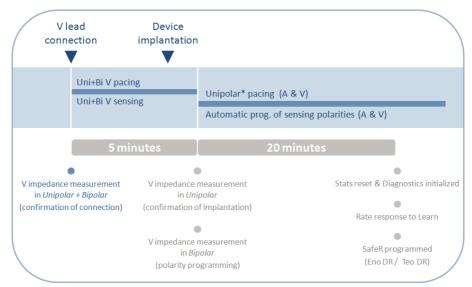
Until confirmation of implantation the device assumes a ventricular Unipolar+Bipolar pacing/sensing configuration and an atrial Unipolar pacing/sensing configuration at 1 mV.

In details, the Automaticity at Implantation performs the following steps:

² SafeR is not available in Oto DR: the pacemaker will remain in DDD mode.



¹ Except in Eno models ordered under "J" code, the pacing polarity is programmed to Bipolar, as-shipped value



^{*}Bipolar pacing in Eno models ordered under "J" code.

The atrial and ventricular sensing polarities will be automatically programmed to Bipolar if a bipolar lead is connected. If not, the sensing will be programmed to Unipolar.

Connection of the ventricular lead

- Connection of the ventricular lead: this causes an increase of current consumption or R wave detection.
- 2. The device suspects the ventricular lead connection.
- 3. The device performs a ventricular impedance measurement in **unipolar + bipolar** pacing configuration. If the measurement is normal (< 3000 Ω), the ventricular lead connection is confirmed. If the measurement is abnormal, the device restarts from step 1.

Confirmation of the pacemaker implantation

4. Five minutes after confirmation of the ventricular lead connection (step 3), the device performs a ventricular impedance measurement in **unipolar** pacing configuration. If the measurement is normal (< 3000 Ω), the device is in the pocket: **the implantation is confirmed.** If the measurement is abnormal, the device restarts from step 1.

Automatic configuration of the polarities

5. Automatic configuration of polarities can start so the device can perform a ventricular bipolar impedance measurement to check the polarity of the ventricular lead:



- if the measurement is normal (< 3000 Ω), the ventricular lead is bipolar:
 - the ventricular pacing is programmed to Unipolar (as-shipped value³). This can be reprogrammed in the box using the Implantation Auto Detection parameters.
 - the ventricular sensing is programmed to Bipolar
- if the measurement is abnormal (> 3000 Ω), the ventricular lead is unipolar:
 - the ventricular sensing and pacing will be both programmed to *Unipolar*.
- 6. Step 5 is repeated with the atrial lead for dual chamber pacemaker.

Automatic launch of algorithms

- Twenty minutes after confirmation of implantation (step 4), some algorithms and diagnostics are launched automatically.
 - For dual-chamber devices, the pacemaker switches from DDD to SafeR⁴ mode, asshipped value (or remains in DDD if SafeR Auto Launch has been reprogrammed in the box to Off using the Implantation Auto Detection parameters).
 Note: In single-chamber pacemakers, the pacing mode remains VVI; for REPLY CRT-P pacemakers the pacing mode remains DDD.
 - Rate response is programmed to "Learn"
 - Statistics are reset to zero
 - AIDA Diagnostics are initiated
 - Automatic impedance measurements are activated in each chamber. This function is not programmable, the measurement occurs every 6 hours and data are stored in AIDA diagnostics.

Note: The Sleep Apnea Monitoring feature will be automatically activated at the first interrogation⁵.

⁵ Sleep Apnea Monitoring is not available in Oto models.



³ Except in Eno models ordered under "J" code, the pacing polarity is programmed to Bipolar, as-shipped value

⁴ SafeR is not available in Oto DR; the pacemaker will remain in DDD mode.

FREQUENTLY ASKED QUESTIONS (FAQ)

"Unipolar+Bipolar" pacing and sensing in the ventricle?

How can we pace and sense in both unipolar and bipolar fashion at the same time?

At implantation, once the ventricular lead has been connected to the pacemaker, in the first five minutes until implantation is confirmed, the device paces and senses the ventricle in both **unipolar and bipolar** fashion thanks to an internal temporary connection between the lead ring and the device can.

When a bipolar ventricular lead is connected to the device at implantation and the device is not yet inserted into the pocket, **Unipolar+Bipolar** pacing will result in bipolar pacing of the ventricle, which is a safety feature for pacing-dependent patients.

Once the implantation has been confirmed (after 5 minutes), the internal temporary connection opens, and pacing/sensing polarity configuration is automatically applied.

What happens if the device is interrogated during the automatic phase at implantation?

If the device is interrogated during the first 20 minutes after confirmation of implantation, the following message will appear: "The Automatic Detection of Implantation process is currently underway. Would you like to initiate completion now?"

- If "No" is pressed: The device displays the message: "Auto-programming will occur in less than 20 minutes. If you like to program now please re-interrogate the device." (only "Nominal", "Interrogation" and "Quit" buttons are available). To continue or refresh the programmer screen at the end of the 20 min, the device must be re-interrogated or the session must be ended.
- If "OK" is pressed: Interrogation is re-launched and all automatic functions to occur 20
 minutes after implant confirmation are applied immediately. A message will appear with all
 the changes performed.

How to Reprogram "in the box" (prior to implantation)?

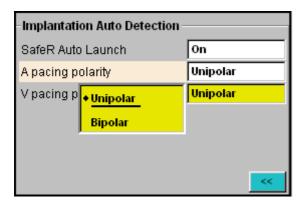
Prior to implantation, using the setting "Implantation Auto Detection" in the Advanced Parameters screen, the user can:

• switch atrial and ventricular pacing polarities to Bipolar⁶ if the automatic polarity test is successful during the automatic configuration of polarities (Steps 5 & 6)

⁶ Except in Eno models ordered under "J" code, the pacing polarity is programmed to Bipolar, as-shipped value



 switch off the automatic launch of SafeR mode for dual-chamber pacemakers (the device will then remain in DDD mode).



What happens if an AXX pacing mode is selected "in the box"?

When reprogramming the pacing mode into AXX mode (AAI for example) in the Parameter screen, the full Automaticity at Implantation function is disabled. The following message will appear: "Auto implant detection is deactivated". The user has two options to click:

- "OK": Automaticity at Implantation function is stopped and AXX mode is programmed
- "NO": Automaticity at Implantation function remains active and AXX mode is not programmed.

What happens if any other pacing mode is selected "in the box"?

When reprogramming the pacing mode into a mode other than DDD or AXX in the Parameter screen, only the automatic SafeR launch is switched off. A confirmation message will appear asking the user to confirm the mode change.

CONCLUSION

During Implantation: A safety *Unipolar+Bipolar* mechanism allows immediate ventricular pacing if necessary as soon as the lead is connected to the device.

5 minutes after implantation: Pacing polarity is programmed to *Unipolar*⁷, except if it has been reprogrammed in the box using the Implantation Auto Detection parameters (programming *Bipolar*). Sensing polarity is programmed bipolar if the automatic polarity test is successful during the automatic configuration of polarities (Steps 5 & 6).

20 minutes after implantation confirmation:

- SafeR⁸ is automatically launched (in dual chamber models). SafeR is a safe pacing mode for all types of AV conduction disorders; refer to the Tech Corner "SafeR pacing mode" for more details.
- Rate response is programmed to "Learn"
- Statistics are reset and AIDA diagnostics are initialized
- Lead impedances are automatically measured every 6 hours

At the first pacemaker interrogation:

The Sleep Apnea Monitoring feature will be automatically activated⁹.

Refer to user's manual furnished with the device for complete instructions for use (www.microportmanuals.com).

⁹ Sleep Apnea Monitoring is not available in Oto models..



⁷ Except in Eno models ordered under "J" code, the pacing polarity is programmed to Bipolar, as-shipped value

⁸ SafeR is not available in Oto DR: the pacemaker will remain in DDD mode.