# Tech Corner

## Automatic Implantation Detection

## (ENO TEO OTO and previous generations)

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.

MicroPort™ CRM

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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.

This article describes the functioning of the Automatic Implant Detection on all MicroPort CRM pacemakers, except ALIZEA BOREA CELEA (a separate article is available for these models).

Depending on countries, some models may not be available in your geography. Please refer to your MicroPort CRM Representative for more information or to the manual website: www.microportmanuals.com.

## DEFINITION

Automaticity at Implantation allows the pacemaker to detect automatically 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 ventricular and atrial pacing/sensing configurations as soon as the implantation is confirmed (*i.e.* device in the pocket):
  - in ENO with "J" code[1]
    - **Pacing**: Bipolar (if a bipolar lead is connected)
    - **Sensing**: Bipolar (if a bipolar lead is connected)
  - in ENO with "C" code, TEO, OTO and previous generations
    - **Pacing**: Unipolar
    - **Sensing**: Bipolar (if a bipolar lead is connected)
  - in REPLY USA
    - **Pacing**: Bipolar
    - **Sensing**: Bipolar
- automatically launch the SafeR[2] pacing mode (in dual chamber models)
- program the Rate Response to *Learn*

*[1] ENO with "J code" is available in Japan and Europe*

*[2] SafeR is not available in OTO DR: the pacemaker will remain in DDD mode.*

- automatically reset the statistics, launch AIDA diagnostics and some algorithms
- automatically starts the measurement of lead impedances every 6 hours

Automaticity at Implantation is based on a ventricular "unipolar + bipolar" mechanism as long as the implantation is not confirmed (*i.e.* the device is not in the pocket):

- with a bipolar ventricular lead, the ventricular pacing is guaranteed as soon as the lead is connected to the pacemaker
- with a unipolar ventricular lead, the ventricular pacing is guaranteed as soon as the lead is connected to the pacemaker and the pacemaker is in its pocket (in contact with body tissues).

Then two different types of ventricular impedance measurements are performed:

- in unipolar to confirm that the device is inserted in the pocket (in contact with tissues) and
- in bipolar to set the lead polarities.

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

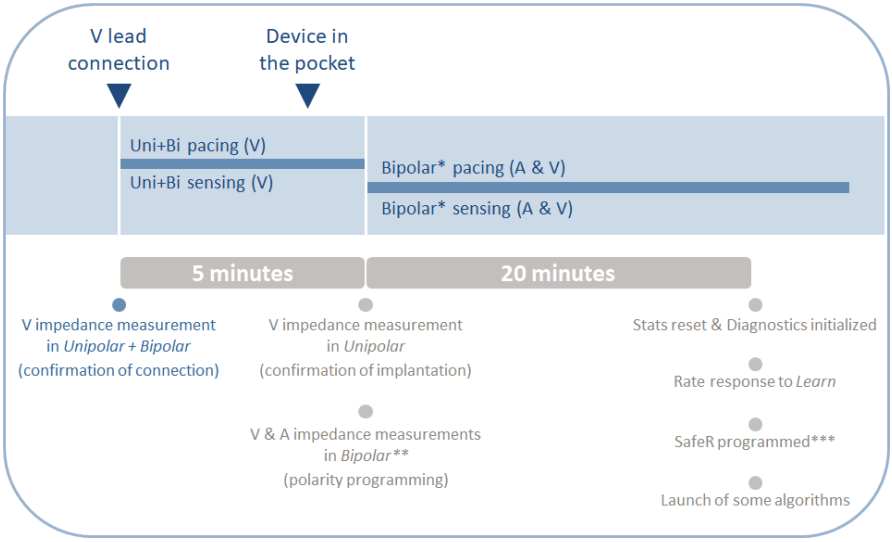
## DESCRIPTION OF OPERATION

Until confirmation of the implantation (*i.e.* the device is in the pocket), the device assumes a:

- in ENO with "J" code
  - **ventricular "unipolar + bipolar"** pacing/sensing configuration (3.5 V / 2.5 mV)
  - **atrial unipolar** pacing/sensing configuration (3.5 V / 1 mV)
- in ENO with "C" code, TEO, OTO and previous generations:
  - **ventricular "unipolar + bipolar"** pacing/sensing configuration (3.5 V / 2.5 mV)
  - **atrial unipolar** pacing/sensing configuration (3.5 V / 1 mV).
- in REPLY USA:
  - **ventricular "unipolar + bipolar"** pacing/sensing configuration (3.5 V / 1.5 mV)
  - **atrial bipolar** pacing/sensing configuration (3.5 V / 1 mV)

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

## ENO with “J” code and REPLY USA

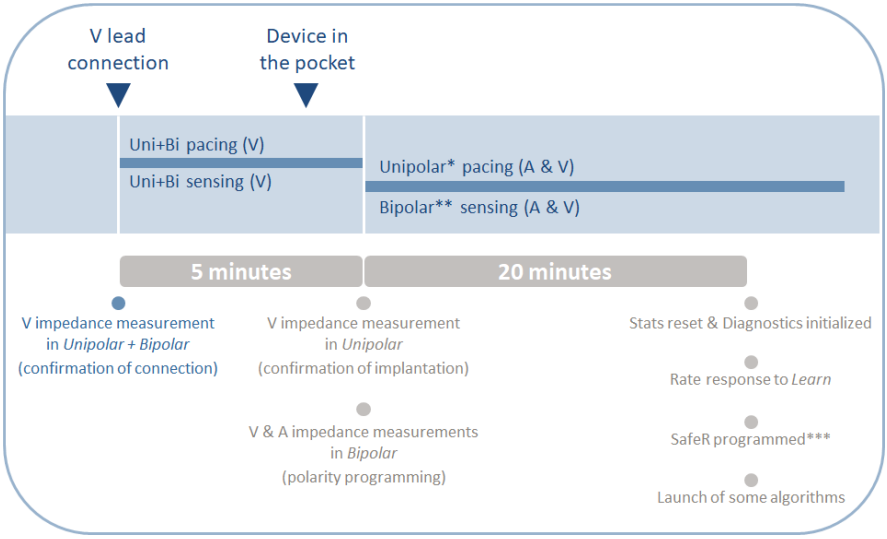



** Bipolar is automatically programmed if the automatic bipolar impedance test is successful, if not: unipolar. In REPLY USA no automatic polarity test is performed (bipolar is always programmed).*

*** Except in REPLY USA: no V & A impedance measurements in bipolar*

**** In dual-chamber pacemakers*

## ENO with “C” code, TEO, OTO and previous generations




** Unipolar pacing is automatically programmed (pre-programming can be changed in the box before implantation).*

***Bipolar sensing is automatically programmed if the automatic bipolar impedance test is successful, if not: unipolar.*

**** In dual-chamber pacemakers, except OTO DR.*

## Connection of the ventricular lead

①. Connection of the ventricular lead: this causes an increase of current consumption or R wave detection: the device suspects the ventricular lead connection.

②. 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 (> 3000 Ω), the process restarts from step 1.

## Confirmation of the pacemaker implantation (*i.e.* in the pocket)

③. Five minutes after confirmation of the ventricular lead connection (step 2), the device performs a ventricular impedance measurement in **unipolar** configuration.

- If the measurement is normal (< 3000 Ω), the presence of connected device in the pocket is **confirmed**.
- If the measurement is abnormal (> 3000 Ω), the process restarts from step 1.

## Automatic configuration of the polarities

④. Then, the device proceeds to the automatic configuration of polarities: it performs a ventricular **bipolar** impedance measurement to check the polarity of the ventricular lead[3]:

- ENO with "J" code:
  - If the ventricular bipolar measurement is normal (< 3000 Ω), the ventricular lead is bipolar: **Pacing and Sensing** are automatically programmed to **bipolar** (3.5 V/2.5 mV).
    Note: The ventricular pacing polarity applied at this step can be pre-programmed to unipolar "in the box" using the "Implantation Auto Detection" parameters.
  - If the ventricular bipolar measurement is abnormal (> 3000 Ω), the ventricular lead is unipolar: Pacing and Sensing are automatically programmed to **unipolar** (3.5 V/2.5 mV).

- In ENO with "C" code, TEO, OTO and previous generations:
  - If the ventricular bipolar measurement is normal (< 3000 Ω), the lead is bipolar: **Pacing** is automatically programmed to **unipolar** and **Sensing** is programmed to **bipolar** (3.5 V/2.5 mV).
    Note: The ventricular pacing polarity applied at this step can be pre-programmed to bipolar "in the box" using the "Implantation Auto Detection" parameters.
  - If the ventricular bipolar measurement is abnormal (> 3000 Ω), the lead is unipolar: Pacing and Sensing are automatically programmed to **unipolar** (3.5 V/2.5 mV).

[3] *Except in REPLY USA: The ventricular pacing and sensing are automatically programmed to bipolar.*

- In REPLY USA: There is no automatic check of lead polarity:
  - Ventricular **pacing and sensing** are programmed to **bipolar** (3.5 V/1.5 mV),

⑤. Step 4 is repeated with the atrial lead for dual chamber pacemaker[4]:

- ENO with "J" code:
  - If the atrial bipolar measurement is normal (< 3000 Ω), the atrial lead is bipolar: **Pacing and Sensing** are automatically programmed to **bipolar** (3.5 V/1 mV).
    Note: The atrial pacing polarity applied at this step can be pre-programmed to unipolar "in the box" using the "Implantation Auto Detection" parameters.
  - If the atrial bipolar measurement is abnormal (> 3000 Ω), the atrial lead is unipolar: **Pacing and Sensing** are automatically programmed to **unipolar** (3.5 V/1 mV).

- In ENO with "C" code, TEO, OTO and previous generations:
  - If the atrial bipolar measurement is normal (< 3000 Ω), the atrial lead is bipolar: **Pacing** is automatically programmed to **unipolar** and **Sensing** is programmed to **bipolar** (3.5 V/1 mV).
    Note: The atrial pacing polarity applied at this step can be pre-programmed to bipolar "in the box" using the "Implantation Auto Detection" parameters.
  - If the atrial bipolar measurement is abnormal (> 3000 Ω), the atrial lead is unipolar: **Pacing and Sensing** are automatically programmed to **unipolar** (3.5 V/1 mV).

- In REPLY USA: There is no automatic check of lead polarity:
  - Atrial **pacing and sensing** are programmed to **bipolar** (3.5 V/1 mV).

[4] *Except in REPLY USA: The atrial pacing and sensing are automatically programmed to bipolar.*

## Automatic launch of algorithms

⑥. Twenty minutes after the automatic polarity configuration (step 5), some algorithms and diagnostics are activated automatically.

- Pacing mode:
  - In dual-chamber devices, the pacemaker switches from DDD to SafeR[5] mode.
    Note: The automatic launch of SafeR can be deactivated with a pre-programming "in the box" using the "Implantation Auto Detection" parameters; in this case the device remains in DDD mode.
  - In single-chamber pacemakers[6], the pacing mode remains VVI.
  - In REPLY CRT-P pacemakers, the pacing mode remains DDD.
  - In REPLY VDR pacemakers, the pacing mode remains VDD
- Rate response is programmed to "Learn"[7] (*i.e.* sensor calibration is activated and no rate response is applied).
- Statistics are reset.
- AIDA Diagnostics are initiated.
- Automatic lead impedance measurements are activated for each chamber: the measurement occurs every 6 hours and data are stored in AIDA diagnostics. This function is not programmable.

Note: The Sleep Apnea Monitoring feature will be automatically activated at the first interrogation[8].

[5] *SafeR is not available in OTO DR: the pacemaker will remain in DDD mode.*

[6] *Programmed to the default ventricular chamber only. Auto Implant Detection is deactivated in atrial single chamber pacemakers.*

[7] *Except in REPLY D*

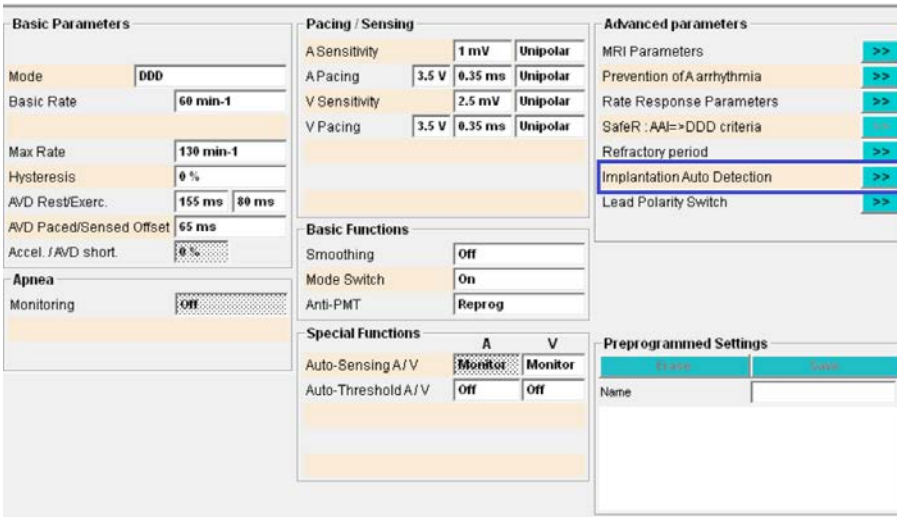
[8] *Sleep Apnea Monitoring (SAM) is not available in REPLY nor OTO models.*

## DEVICE INTERROGATION "IN THE BOX" (PRIOR TO IMPLANTATION)

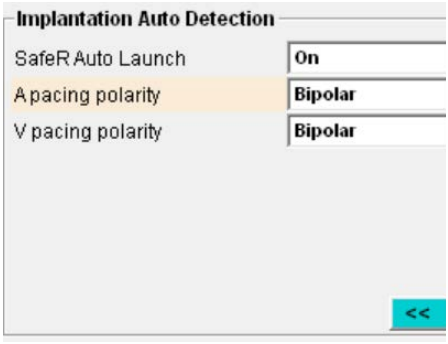
Prior to implantation, if the device is interrogated in the box, following actions can be performed using the settings in "Implantation Auto Detection" under "Advanced Parameters" (in "Param." screen):

## Pre-program the Auto Implant Detection settings

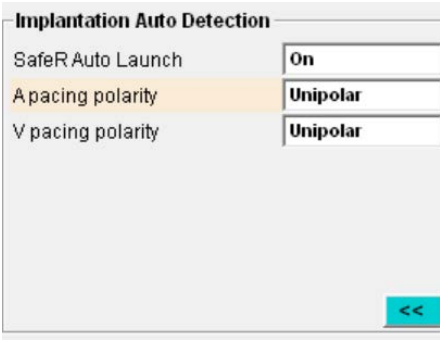
**Parameter screen** *(SmartView version 3.06)*




**Settings in Implantation Auto Detection** *(SmartView version 3.06)*




*Pre-programmed A & V pacing polarities:* ***Bipolar*** *for* ***ENO with "J" code***




*Pre-programmed A & V pacing polarities:* ***Unipolar*** *for* ***ENO with "C" code, TEO, OTO*** *and previous generations*

**SafeR Auto Launch**

- **As-shipped: On.** The pacemaker will switch from DDD into SafeR mode 20 minutes after the confirmation of implantation, *i.e.* 20 minutes after the device has been inserted into the pocket (Step 6).
- **If pre-programmed to Off in the box:** The pacemaker will remain in DDD mode at the end of the 20 minutes following the confirmation of implantation, *i.e.* 20 minutes after the device has been inserted into the pocket (Step 6).

**Pacing polarities**

- in ENO with "J" code:
  - **As-shipped: Bipolar.** The pacing polarities will be programmed to bipolar 5 minutes after the ventricular lead connection, if the leads are confirmed as "bipolar leads" (Steps 4 & 5).
  - **If pre-programmed to unipolar in the box:** The pacing polarities will be programmed to unipolar 5 minutes after the ventricular lead connection (Steps 4 & 5).
- in ENO with "C" code, TEO, OTO and previous generations:
  - **As-shipped: Unipolar.** The pacing polarities will be programmed to unipolar 5 minutes after the ventricular lead connection (Steps 4 & 5).
  - **If pre-programmed to bipolar in the box:** The pacing polarities will be programmed to bipolar 5 minutes after the ventricular lead connection, if the leads are confirmed as "bipolar leads" (Steps 4 & 5).
- in REPLY USA:
  - **As-shipped: Bipolar.** The pacing polarities will be programmed to bipolar 5 minutes after the ventricular lead connection (Steps 4 & 5). No pre-programmed polarity settings in the box.

## Reprogram to AXX pacing mode “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 display: “*Auto implant detection is deactivated*”. The user has two options:

- If “**OK**” is presseed: Automatic Implant Detection function is stopped and the AXX mode is programmed
- If “**NO**” is pressed: Automatic Implant Detection function remains active and AXX mode is not programmed.

## Reprogram to a pacing mode other than AXX “in the box”

When reprogramming the pacing mode into a mode other than 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.

# DEVICE INTERROGATION IN THE 5 MIN FOLLOWING THE VENTRICULAR LEAD CONNECTION

If the device is interrogated within the 5 minutes following the ventricular lead connection, there is no message displayed.

A ventricular impedance measurement is launched by the programmer:

- in unipolar configuration (ENO with “J” code, ENO with “C code”, TEO, OTO and previous generations)
- in bipolar configuration (REPLY USA).

**If the measurement is normal (< 3000 Ω):** statistics are reset, AIDA Diagnostics are initiated and the following polarities are applied:

- unipolar pacing and sensing (ENO with “J” code, ENO with “C code”, TEO, OTO and previous generations)
- bipolar pacing and sensing (REPLY USA)

Note: There is no automatic launch of SafeR, nor programming of the rate response sensor to Learn.

**If the measurement is abnormal** (> 3000 Ω): the programmer interrogation goes on, as well as the automatic implant detection. Refer to the section DEVICE INTERROGATION "IN THE BOX" (PRIOR TO IMPLANTATION) to see the actions which can be performed at this stage.

## DEVICE INTERROGATION IN THE 20 MIN AFTER CONFIRMATION OF IMPLANTATION

If the device is interrogated within the 20 minutes following the confirmation of implantation (*i.e.* device inserted in the pocket), the following message will display: "*The Automatic Detection of Implantation process is currently underway. Would you like to initiate completion now?*"

- 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.
- If "**No**" is pressed: The device displays the message: "Auto-programming will occur in less than 20 minutes." (only "Nominal", "Interrogation" and "Quit" buttons are available). To continue or refresh the programmer screen at the end of the 20 minutes, the device must be re-interrogated or the session must be ended.

## SUMMARY

**As soon as the ventricular lead is connected** to the device, a safety "unipolar + bipolar" mechanism allows immediate ventricular pacing if necessary (providing that the ventricular lead is bipolar).

Note: If a unipolar lead is connected (mainly in case of device replacement), the "unipolar + bipolar" mechanism allows ventricular pacing as soon as the pacemaker is inserted in the pocket.

**Five minutes after ventricular lead connection:** The device confirms that it is inserted in the pocket thanks to a unipolar impedance test.

Once confirmed, the device proceeds with the **automatic configuration of polarities**:

- ENO with "**J**" code: if the automatic bipolar impedance test is successful:
  - **Pacing** polarities are programmed to **bipolar**, except if it has been pre-programmed in the box using the Implantation Auto Detection parameters.
  - **Sensing** polarities are programmed **bipolar**.

- ENO with "**C**" code, TEO, OTO and previous generations: if the automatic bipolar impedance test is successful:
  - **Pacing** polarities are programmed to **unipolar**, except if it has been pre-programmed in the box using the Implantation Auto Detection parameters.
  - **Sensing** polarities are programmed to **bipolar**.
- REPLY USA: no automatic polarity test is performed.
  - Pacing and sensing polarities are programmed to **bipolar**, immediately after the confirmation of implantation (*i.e.* the can inserted in the pocket).

**Twenty minutes after confirmation of implantation** (*i.e.* device inserted in the pocket):

- SafeR[9] is automatically launched, except if it has been reprogrammed in the box to Off. Refer to the Tech Corner "SafeR pacing mode" for more details on the SafeR feature.
- Rate response is programmed to "Learn" (*i.e.* sensor calibration is activated and no rate response is applied)
- 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 (SAM) feature will be automatically activated[10].

Refer to user's manual furnished with the device for intended use and relevant warnings, precautions, side effects, and contraindications.

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

*[9] In dual-chamber pacemakers, except in OTO DR (which will remain in DDD mode).*

*[10] Sleep Apnea Monitoring is not available in REPLY nor OTO models.*