Tech Corner

Automatic Implantation Detection

(ALIZEA BOREA CELEA)

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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MicroPort™ CRM

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AVAILABILITY

Automaticity at Implantation is a feature present in MicroPort CRM pacemaker models: ALIZEA, BOREA, CELEA. It is not available in the SR pacemaker models implanted with an atrial lead.

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 ventricular and atrial pacing/sensing to bipolar configuration as soon as the implantation is confirmed (*i.e.* device in the pocket) and if a bipolar lead is connected
- automatically launch the SafeR pacing mode (in dual chamber models)
- program the Rate Response to *Learn*
- 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.

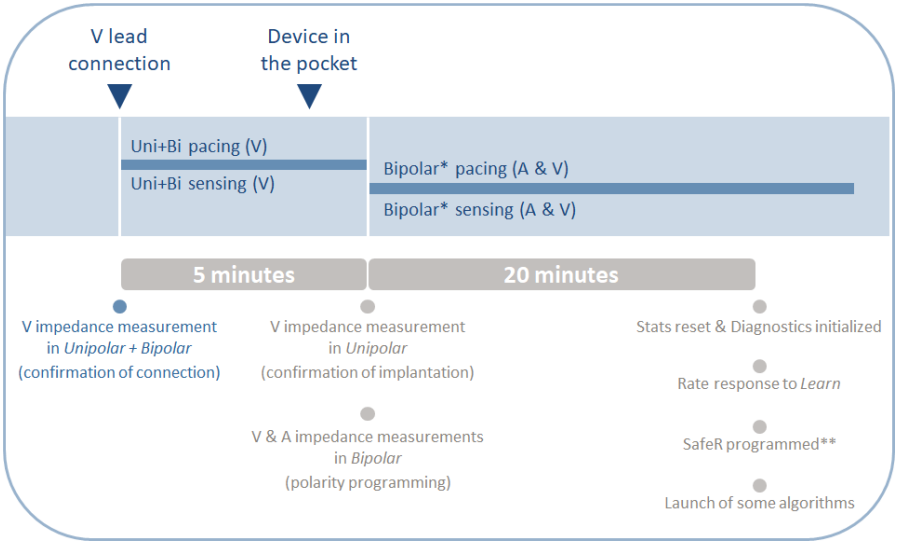
Automaticity at Implantation is pre-set in the pacemaker and is indicated for all patients. It could be deactivated if needed. See the section "Device interrogation in the box".

DESCRIPTION OF OPERATION

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

- ventricular "unipolar + bipolar" pacing/sensing configuration (3.5 V / 2.5 mV)
- atrial bipolar pacing/sensing configuration (3.5 V / 1.5 mV).

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



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

*** In dual-chamber pacemakers, except CELEA 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 the 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 with the automatic configuration of polarities: it performs a ventricular **bipolar** impedance measurement to check the polarity of the ventricular lead:

- 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).

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

- 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/0.6 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/1.5 mV).

Automatic launch of algorithms

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

- Pacing mode:
  - In dual-chamber devices, the pacemaker switches from DDD to SafeR[1] 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[2], the pacing mode remains VVI.
- Rate response is programmed to "Learn" (*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.
- Additional functions can be launched automatically at this stage, with a pre-programming "in the box" using the "Implantation Auto Detection" parameters: (see the paragraph "Pre-program the Auto Implant Detection settings")
  - Lead Polarity Switch (LPS), as-shipped = Off
  - Remote monitoring, as-shipped = Off
  - Atrial autothreshold[3], as-shipped = Monitoring
  - Ventricular autothreshold, as-shipped = Monitoring

For more details, see the section below "*Device interrogation in the box*".

Note: The Sleep Apnea Monitoring feature will be automatically activated at the first interrogation[4].

[1] SafeR is not available in CELEA DR: the pacemaker will remain in DDD mode.

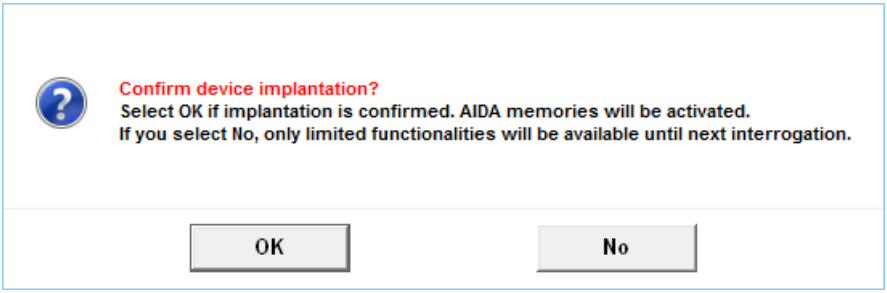
*[2] Programmed to the default **ventricular** chamber only. Auto Implant Detection is deactivated in atrial single-chamber pacemakers.*

[3] In dual chamber models only

[4] Sleep Apnea Monitoring (SAM) is not available in CELEA pacemakers.

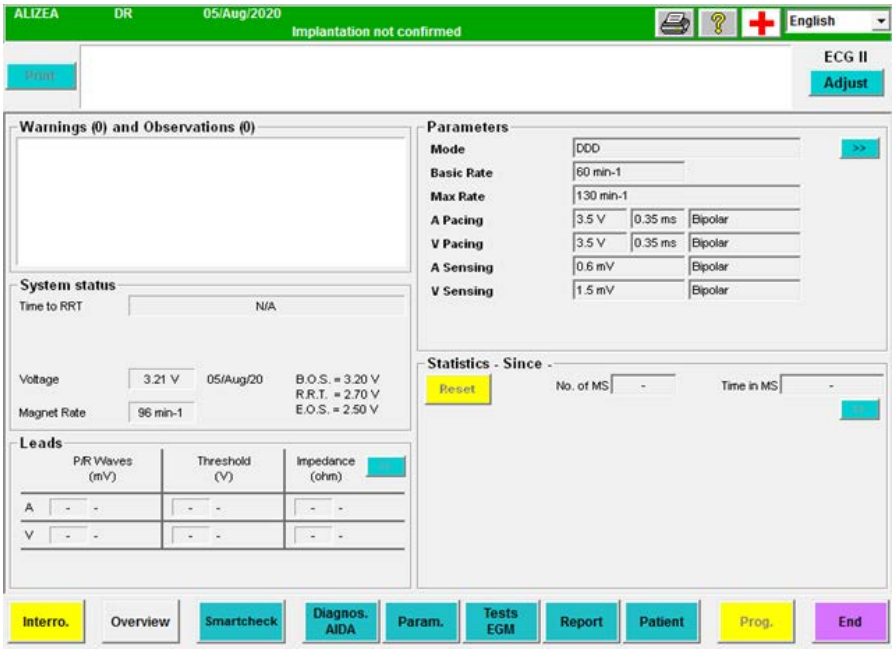
DEVICE INTERROGATION “IN THE BOX” (PRIOR TO IMPLANTATION)

Prior to implantation, if the device is interrogated in the box, the following message will display:



Click “**No**”, the Overview screen will display, with the status in the header bar: “*Implantation not confirmed*”: only some programming actions are allowed (no tests on leads, no access to AIDA memories).

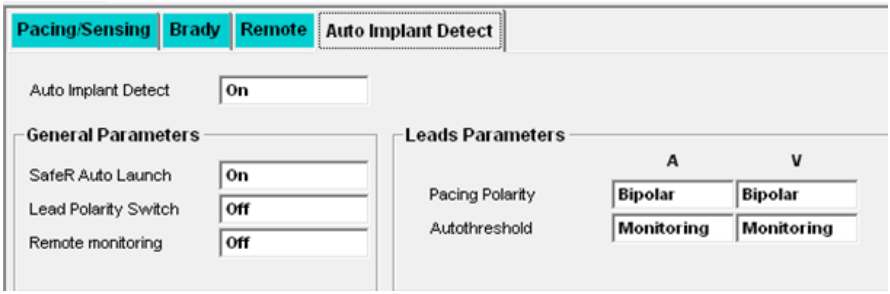
Note: If “OK” is clicked by mistake at this stage, the pacemaker will immediately work with the default parameters: atrial and ventricular bipolar pacing and sensing. It is then recommended to perform a lead polarity check, to make sure that the implanted lead(s) is(are) bipolar and work properly. The automatic launch of algorithms are deactivated, and memories are immediately initiated.



"Overview" screen: Status in header bar: "Implantation not confirmed" (above example: ALIZEA, SmartView version 3.06)

Pre-program the Auto Implant Detection settings

From the "Param." screen, using the dedicated tab "Auto Implant Detect", the user can reprogram the Auto Implant Detect parameters:



Dedicated tab for "Auto Implant Detection" with the default parameters (example: ALIZEA, SmartView version 3.06)

Auto Implant Detect

- **As-shipped: On**. The full process will apply as described above.
- **If reprogrammed to Off in the box:** The pacemaker will work with the default parameters as soon as the lead(s) is(are) connected: bipolar pacing and sensing. It is then recommended to perform a lead polarity check, to make sure that the implanted lead(s) is(are) bipolar and work properly. The algorithms described hereafter are also deactivated.

SafeR Auto Launch[5]

- **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).

Lead Polarity Switch (LPS)

- **As-shipped: Off.** The pacemaker will not activate the LPS function at the end of the 20 minute phase (Step 6)
- **If pre-programmed to On in the box:** The pacemaker will activate the LPS function at the end of the 20 minute phase (Step 6).

Remote monitoring

- **As-shipped: Off.** The pacemaker will not activate the Remote monitoring function at the end of the 20 minute phase (Step 6)
- **If pre-programmed to On in the box:** The pacemaker will activate the Remote monitoring function at the end of the 20 minute phase (Step 6).

Pacing polarities

- **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).

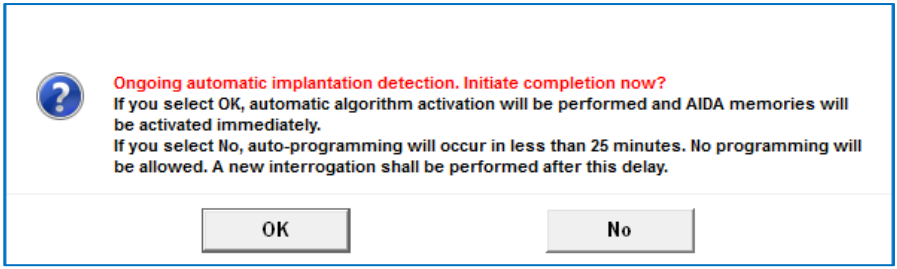
[5] *In dual-chamber pacemakers, except CELEA DR.*

Autothresholds

- **As-shipped: Monitoring.** The pacemaker will apply the programming “Monitoring” at the end of the 20 minute phase (Step 6).
- **If pre-programmed to Auto or Off in the box:** The pacemaker will apply the programming (Auto or Off) at the end of the 20 minute phase (Step 6).

DEVICE INTERROGATION IN THE 5 MIN FOLLOWING THE VENTRICULAR LEAD CONNECTION

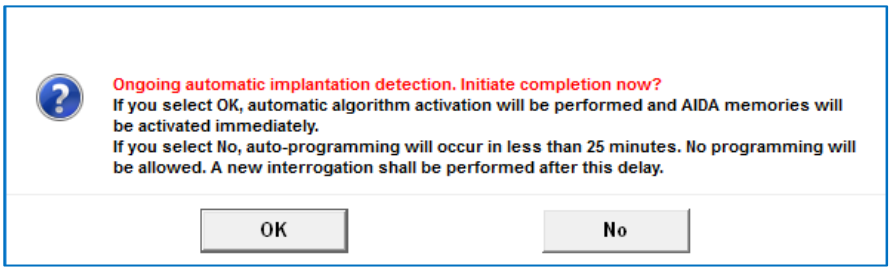
If the device is interrogated within the 5 min following the ventricular lead connection, the following message is displayed:



- If "**OK**" is pressed: The completion of the Auto Implant Detection is forced:
  - SafeR[6] is automatically launched, except if it has been reprogrammed in the box to Off
  - Lead polarities are automatically programmed to bipolar (no bipolar impedance test is performed)
  - Other features are applied immediately: Rate response is programmed to "Learn", statistics are reset and AIDA Diagnostics are initiated, automatic lead impedance measurements are activated for each chamber. Additional functions are launched automatically at this stage, as pre-programmed "in the box" on the "Implantation Auto Detection" parameter tab.
  - A message will display to confirm the applied settings.
- If "**No**" is pressed: The "Overview" screen will display, with the status in the header bar: "Ongoing auto implantation": no programming actions, no tests on leads, no access to AIDA memories are allowed.

DEVICE INTERROGATION IN THE 20 MIN FOLLOWING THE CONFIRMATION OF IMPLANTATION

If the device is interrogated within the 20 min following the confirmation of implantation (*i.e.* device inserted in the pocket), the following message is displayed:



6. In dual-chamber pacemakers, except in CELEA DR (which remains in DDD mode).

- If "**OK**" is pressed: The completion of the Auto Implant Detection is forced:
  - SafeR[7] is automatically launched, except if it has been reprogrammed in the box to Off
  - Other features are applied immediately: Rate response is programmed to "Learn" (if the lead polarity test confirmed that the lead(s) is(are) bipolar), statistics are reset and AIDA Diagnostics are initiated, automatic lead impedance measurements are activated for each chamber. Additional functions are launched automatically at this stage, as pre-programmed "in the box" on the "Implantation Auto Detection" parameter tab.
  - A message will display to confirm the applied settings.
- If "**No**" is pressed: The "Overview" screen will display, with the status in the header bar: "Ongoing auto implantation": no programming actions, no tests on leads, no access to AIDA memories are allowed.

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 the 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.** If the automatic bipolar impedance test is successful:

- **Pacing** polarities are programmed to **bipolar**, except if it has been reprogrammed in the box using the Implantation Auto Detection parameters.
- **Sensing** polarities are programmed **bipolar**.

7. In dual-chamber pacemakers, except in CELEA DR (which remains in DDD mode).

Twenty minutes after automatic polarity configuration :

- SafeR[8] 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
- Atrial[9] and ventricular autothresholds are programmed to "Monitoring", except if it has been reprogrammed in the box to Off or Auto.
- Lead Polarity Switch and Remote monitoring features are activated if they have been pre-programmed from the "Automatic Auto Implantation" screen.

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 complete instructions for use (www.microportmanuals.com).

[8] In dual-chamber pacemakers, except in CELEA DR (which remains in DDD mode).

[9] In dual chamber models only

[10] Sleep Apnea Monitoring (SAM) is not available in CELEA pacemakers.