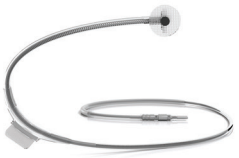
# The BAROSTIM NEO System™ Product Specifications

## System Components

The BAROSTIM NEO System includes the following components:

### CAROTID SINUS LEAD

One thin lead wire implanted on the carotid artery and connected to the device. Conducts activation energy from the IPG to the baroreceptors, on the carotid artery.



### IMPLANTABLE PULSE GENERATOR (IPG)

Implanted under the skin below the collar bone. Provides control and delivery of activation energy from the IPG to the baroreceptors, on the carotid artery.


### PROGRAMMER SYSTEM

An external system used to adjust and customize therapy settings via wireless communication.


## Longevity

| | Example 1 | Example 2 | Example 3 |
|---|---|---|---|
| **PROGRAMMING SETTINGS** Amplitude (mA) - Width (µs) - Frequency (pps) | 6 – 65 – 40 | 6 – 125 – 40 | 8 – 250 – 20 |
| **LONGEVITY** (months) | 84 months | 58 months | 42 months |
| **LONGEVITY** (years) | ~7 years | ~5 years | ~3.5 years |

## Radiopaque ID

A unique IPG identifier that is visible during X-ray, in order to determine IPG placement. An example is featured below.


BAROSTIM THERAPY™

BAROSTIMNEO™

# General Specifications

## IPG (MODEL 2102)

| SPECIFICATION | VALUE |
|---|---|
| **Connectors** | No sensing<br>Unipolar stimulation<br>1.5 mm lead pin bore diameter<br>3.48 mm lead shaft bore diameter |
| **Mass** | 60 grams |
| **Height** | 72 mm |
| **Width** | 50 mm |
| **Thickness** | 14 mm |
| **Volume** | < 40 CC |
| **Materials** | Titanium can<br>Tecothane header<br>Silicone seals<br>Stainless steel setscrews |
| **Leads** | Use only CVRx lead models 103x |
| **Materials in Accessory Kit** | Port plug is comprised of a stainless steel shaft and silicone body |
| **Battery** | 1 carbon monofluoride and silver vanadium oxide cell<br>7.50 Ah theoretical capacity |

## LEAD (MODELS 1036 AND 1037)

| SPECIFICATION | VALUE (NOMINAL) |
|---|---|
| **Length** | Model 1036: 40 cm<br>Model 1037: 50 cm |
| **Compatibility** | Compatible with BAROSTIM NEO™ |
| **Connector:** | |
| **Connector Type** | Compatible with BAROSTIM NEO IPG |
| **Pin** | Active diameter = 1.41 mm<br>Active length = 5.18 mm |
| **Ring** | Inactive diameter = 2.67 mm<br>Active length = 4.06 mm |
| **Connector (Pin to Ring)** | 14.22 mm<br>(including inactive ring length) |
| **Length:** | |
| **Pin/Ring Material** | Stainless steel |
| **Seal/Insulating Material** | Silicone rubber |
| **Lead Body:** | |
| **Conductor Material** | Cobalt-nickel-chromium-molybdenum alloy with silver core |
| **Lead Body Insulation Material** | Silicone rubber |
| **Electrodes:** | |
| **Electrode Material** | Platinum iridium with iridium oxide coating |
| **Electrode Backer Material** | Silicone rubber |

## IPG PARAMETERS

| PARAMETER | UNITS | PROGRAMMABLE VALUES |
|---|---|---|
| **Therapy Schedule From/To Times for therapy (N) or Therapy Off** | HH:MM | Up to 3 entries allowed<br>Any time during the day in 15 minute steps |
| **Output Pathway for Therapy (N)** | NA | LEFT and RIGHT are independently selected |
| **LEFT Pulse Amplitude for Therapy (N)** | milliamp | 0.8 to 20.0 |
| **RIGHT Pulse Amplitude for Therapy (N)** | milliamp | 0.8 to 20.0 |
| **LEFT Pulse Width for Therapy (N)** | µs | 15 to 500 |
| **RIGHT Pulse Width for Therapy (N)** | µs | 15 to 500 |
| **Therapy Frequency for Therapy** | PPS | 10 to 100 |

## MAGNET MODE OPERATION

- BAROSTIM THERAPY will be switched off while a standard magnet is present over the IPG.

## RECOMMENDED REPLACEMENT TIME (RRT)

- Expected RRT date, and time remaining until RRT date, display on the programmer.
- Yellow RRT alert displays on the programmer when RRT date has passed.

## END OF SERVICE (EOS)

- Battery voltage remains below 2.3V for one day.
- Red EOS alert displays on the programmer when EOS has occurred.

CE

The BAROSTIM NEO™ system is CE Marked and approved for sale for heart failure patients in Europe. It is also CE Marked and approved for sale for hypertension patients in Europe. Exclusively for clinical investigations for the treatment of hypertension and heart failure in Canada. Caution: BAROSTIM NEO™ is an investigational device and is limited by United States law to investigational use. U.S. federal law restricts this device to sale by or on the order of a physician. For more information, please visit www.barostimtherapy.com. For a complete listing of all risks and benefits, please visit www.cvrx.com/benefit-risk/. CVRx, BAROSTIM NEO, Baroreflex Activation Therapy and BAROSTIM THERAPY are all trademarks of CVRx, Inc. All other trademarks are property of their respective owners.



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