BAROSTIM THERAPY™

System Overview

CVRx®

ABOUT THIS DOCUMENT

This document is a portion of the Instructions for Use (IFU) for the Barostim NEO2 System, Model 2104. The full IFU consists of:

System Overview	900121-001
Surgical Procedures	900121-002
Programming	900121-003
Magnetic Resonance Imaging (MRI)	900121-004
Patient Instructions	900121-005

IFU documents are available at www.cvrx.com/ifu

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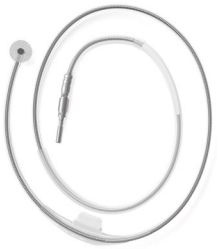
System Description

The Barostim™ System includes the following components:

- Implantable Pulse Generator, Model 2104
- Carotid Sinus Lead, Models 1036 and 1037 with:
  - Implant tool Model 5031
  - Implant Adapter Model 5033
- Programmer System, Model 9010.

The system also includes a Lead Repair Kit Model 5010.



The Barostim System is the CVRx system for improving cardiovascular function. The minimally-invasive Barostim System uses CVRx patented Barostim Therapy™ technology to trigger the body's own natural systems by electrically activating the carotid baroreceptors, the body's cardiovascular regulation sensors. In conditions such as hypertension and heart failure it is believed the baroreceptors are not functioning properly and are not sending sufficient signals to the brain. This results in the brain sending signals to other parts of the body (heart, blood vessels, kidneys) to constrict the blood vessels, retain water and salt by the kidneys and increase stress-related hormones. When the baroreceptors are activated, signals are sent through neural pathways to the brain. In response the brain works to counteract this stimulation by sending signals to these same parts of the body that relax the blood vessels and inhibit the production of stress-related hormones. These changes act to reduce afterload and enable the heart to increase blood output, while maintaining or reducing its workload.

Therapy:

Therapy is generated by the Implanted Pulse Generator (IPG) through the Carotid Sinus Lead (CSL). The therapy is an electrical pulse train of programmed frequency, pulse width, and constant current amplitude. Therapy can be programmed to deliver up to three different therapies scheduled in different daily time windows.

IMPLANTABLE PULSE GENERATOR (IPG)

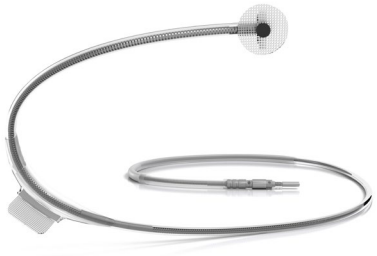
MODEL 2104

The Implantable Pulse Generator (IPG) contains a battery and circuitry in a hermetic enclosure. It provides control and delivery of BAROSTIM THERAPY™ through the Carotid Sinus Lead to the baroreceptors.

The carotid sinus lead is attached to the pulse generator through the connector module.

CAROTID SINUS LEAD (CSL)

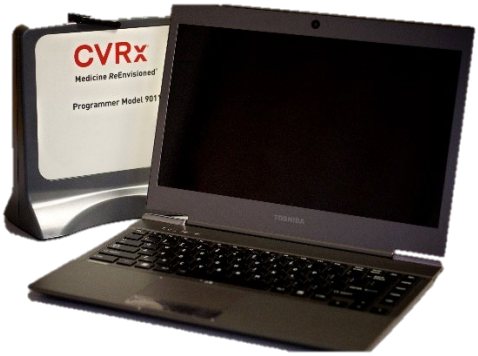
MODEL 1036 OR 1037



The Carotid Sinus Lead conducts BAROSTIM THERAPY™ from the IPG to the baroreceptors located on the carotid sinus. The leads are available in two (2) models that only differ in length; Model 1036 (40cm), and Model 1037 (50cm). Both are supplied with a 2 mm electrode and a Model 5031 Implant Tool and Model 5033 Implant Adapter. The lead models are fully interchangeable to allow for anatomical variations and to be used per the physician's discretion.

PROGRAMMER SYSTEM (PGM)

MODEL 9010



The Programmer System allows noninvasive adjustment of therapy parameters and retrieves information regarding the status of the IPG.

The Programmer System consists of the following major components:

- Programmer Software
- Programmer Interface
- Computer

PGM Programmer Software/Computer

The Programmer Software is installed on the supplied Computer. A USB memory device may be used for file transfers to and from the Computer.

PGM Programmer Interface

The Programmer Interface, powered via the USB connection, provides the telemetry interface to the IPG.

OPTIONAL ACCESSORIES FOR USE WITH THE SYSTEM

CSL Repair Kit Model 5010

The CVRx CSL Repair Kit contains tools and material to repair damage to the conductor coils of a healed in therapy lead.

2
Symbols and Definitions

	Caution, Consult Accompanying Documents
	Consult Instructions for Use
	Importer
	Do Not Reuse
	Do Not Resterilize
	Temperature Limitation
	Date of Manufacture
	Manufacturer
	Use By Date
	Peel Here
STERILE EO	Sterilized using Ethylene Oxide
	Equipment includes RF transmitter
CE	CE Mark
EC REP	Authorized Rep in the European Community
CH REP	Authorized Rep in Switzerland
LOT	Batch Code (Lot Number)
MODEL	Product Model Number
SN	Serial Number
P/N	Part Number
REF	Catalogue Number
CONTENTS	Package Contents
PATENTS	Product Protected by One or More US Patents as listed (International patents & additional patents pending)
	Keep Dry
	This Way Up
	Fragile, Handle with Care
	Do Not Use if Package is Damaged
	WEEE Directive Symbol (Special Disposal Required)
	This Device is Not Intended for the Treatment of Bradycardia or Tachycardia
	OFF; IPG Programmed Mode as Shipped
CVRx System Only	This Device is for Use with CVRx System Only
Intended Use: Barostim Therapy™ / Compatible Lead Models 103x / Lead Ports 1	This Device is for Use with CVRx IPG Model 2102 or 2104 and Unipolar Lead Models 1036 and 1037 only and not compatible with lead models 101x.
Intended Use: Neo 2102 + CSL 103x	This Device is for Use with CVRx IPG Model 2102 or 2104 and Unipolar Lead Models 1036 and 1037 only and not compatible with lead models 101x.
	Magnetic Resonance (MR) Unsafe
	Magnetic Resonance (MR) Conditional Use

3 Indications and Contra-indications

INDICATIONS:

Barostim System is indicated for patients with heart failure or resistant hypertension.

Resistant hypertension

Defined as:

- Blood pressure greater than or equal to 140 mmHg systolic and
- Resistance to maximally tolerated therapy with a diuretic and two other anti-hypertension medications.

Heart Failure

Defined as:

- New York Heart Association (NYHA) functional Class III and
- Left ventricular ejection fraction (LVEF) ≤35% despite treatment with the appropriate heart failure guideline directed therapy.

CONTRAINDICATIONS:

Patients are contraindicated if they have:

- Been assessed to have bilateral carotid bifurcations located above the level of the mandible
- Baroreflex failure or autonomic neuropathy
- Uncontrolled, symptomatic cardiac bradyarrhythmias
- Carotid atherosclerosis that is determined by ultrasound or angiographic evaluation greater than 50%
- Ulcerative plaques in the carotid artery as determined by ultrasound or angiographic evaluation.

4
Warnings and Precautions

GENERAL

The safety and effectiveness of Barostim System has been demonstrated in clinical trials.

General Warnings

- Only trained physicians may use this system.
- Prescribing physicians should be experienced in the diagnosis and treatment of hypertension and heart failure and should be familiar with the use of this system.
- Monitor blood pressure and heart rate during Carotid Sinus Lead placement and when adjusting stimulation parameters intra-operatively.
- Post-implantation, program the system to avoid the following:
  - Heart rate falls below 50 beats per minute (BPM), or
  - Systolic pressure falls below 90 mmHg, or
  - Diastolic blood pressure falls below 50 mmHg, or
  - Problematic adjacent tissue stimulation is noted, or
  - Undesirable interaction indicated by monitoring of any other implanted electrical device (see description below), or
  - Any other potentially hazardous patient responses are observed.
- The system may affect the operation of other implanted devices such as cardiac defibrillators, pacemakers, or neurological stimulation systems. For patients who currently have an implanted electrical medical device, physicians must verify compatibility with the implanted device during implantation of the system as well as whenever settings are changed in either implant interactions are more likely in devices that contain a sensing function, such as an implantable cardiac defibrillator or pacemaker. Refer to the manufacturer's documentation regarding evaluation of sensing performance in such devices. If an interaction is observed, the Barostim should be programmed to reduced therapy output settings in order to eliminate the interaction. If necessary, change settings in the other implant only if the changes are not expected to negatively impact its ability to perform its prescribed therapy. During the implant procedure, if problematic device interactions cannot be eliminated the Barostim System should not be implanted.
- Improper system implantation could result in serious injury or death.
- Do not use diathermy therapy including shortwave, microwave, or therapeutic ultrasound diathermy on patients implanted with the system.
- Patients should be counseled to stay at least 15 cm (6 inches) away from devices with strong electrical or magnetic fields such as strong magnets, loudspeaker magnets, Electronic Article Surveillance (EAS) system tag deactivators, arc welders, induction furnaces, and other similar electrical or electromechanical devices. This would include not placing items such as earphones in close proximity to the implanted pulse generator.

General Precautions

- The system should be implanted and programmed carefully to avoid stimulation of tissues near the electrode or in the area of the IPG pocket. Such extraneous stimulation could involve the following:
    - The regional nerves, causing laryngeal irritation, difficulty swallowing, or dyspnea
    - The cervical musculature, causing intermittent contraction
    - Skeletal muscles, causing intermittent contraction around the IPG pocket.
- Proper sterile technique during implantation should be practiced and aggressive pre-operative antibiotics are recommended. Infections related to any implanted device are difficult to treat and may necessitate device explantation.
- Refer to Electromagnetic Compatibility Declarations for precautions related to electromagnetic compatibility.
- Refer to the Magnetic Resonance Imaging (MRI) IFU for conditions required for safe use of MRI for patients with certain configurations of the Barostim system.

IPG

IPG Warnings

- The IPG is a single-use-only device. Do not re-sterilize or reuse. Reuse of this product may result in malfunction or adverse events such as infection or death.
- Do not implant product if the expiration "Use By" date has been reached.
- Do not implant the IPG if the storage package has been damaged, compromising the product sterility.
- Persons allergic to silicone, titanium, or polyurethane may have an allergic reaction to the IPG.
- Patients who manipulate the IPG through the skin may damage or disconnect the lead from the pulse generator.

IPG Precautions

- This system is compatible with lead models 103x only. Do not use with lead models 101x.
- Do not store the IPG outside the temperature range of -4˚ F (-20˚C) to 122 F (50˚C).
- Electrocautery may damage the IPG. Position electrocautery as far as possible from the IPG and items connected to it.
- Do not implant an IPG if the device has been dropped.
- The battery life of the IPG is limited. Patients should be counseled that replacements will be needed. Recommended Replacement Time (RRT) is indicated in the programming software and is the date calculated to be within 30 days of the expected End of Service (EOS).
- IPG operation may cause artifacts in electrocardiogram (ECG) tracings.
- Do not insert a Carotid Sinus Lead in the IPG connector without verifying that setscrews are sufficiently retracted.
- Prior to tightening the setscrews, make sure that lead is fully inserted into the IPG connector module.
- Do not ultrasonically clean the IPG.
- Do not incinerate the IPG. Extreme heat could cause the internal battery to explode. Therefore, it is recommended to remove the IPG from a deceased patient prior to cremation.
- Therapeutic radiation may damage the IPG. Damage to the IPG due to therapeutic radiation may not be immediately detectable.
- Lithotripsy procedures can damage the IPG. Position the IPG outside the ultrasound water bath.

- External defibrillation may cause damage to the IPG. During a defibrillation procedure, space electrodes as far as practical from the IPG. Verify proper IPG function after defibrillation procedures. In addition, if it is practical, it is suggested that the IPG be turned off during defibrillation.
- Sterile package seal integrity can be damaged by moisture. Do not expose to liquids.
- If any of these 3 situations is observed, a CVRx representative should be contacted immediately.
    - Low lead impedance, less than 300 Ohms, may indicate a short in the lead.
    - High lead impedance, greater than 3000 Ohms, may indicate poor lead connection to IPG or a lead fracture.
    - Drastic changes in lead impedance may indicate a problem with a lead.
- Do not place the IPG on a magnetic instrument drape. Doing so may temporarily stop therapy.
- An additional IPG should be available in the event of compromised sterility or if damage is induced during surgery.
- End of Service (EOS) is indicated when the IPG battery voltage is too low to support therapy delivery. Therapy is disabled when EOS is determined. Other IPG functions, such as lead impedance measurement and telemetry communication, will still operate after EOS is reached. However, these functions will eventually cease when the battery voltage is too low to support these functions.

CSL

CSL Warnings

- The Carotid Sinus Lead is a single-use-only device. Do not re-sterilize or reuse. Reuse of this product may result in malfunction or adverse events such as infection or death.
- Do not implant product if expiration "Use By" date has been reached.
- Do not implant the Carotid Sinus Lead if the storage package has been damaged, compromising the product sterility.
- This system carries associated risks of lead placement-related trauma to the carotid sinus and surrounding periarterial tissues, including the regional nerves and the jugular and hypoglossal veins.
- Persons allergic to silicone, platinum, iridium, or stainless steel may suffer an allergic reaction to lead placement.
- Only physicians who have appropriate experience in carotid artery surgery and device-specific training should perform implant of the Carotid Sinus Lead.
- Patients who manipulate the Carotid Sinus Lead through the skin may damage or disconnect the lead from the IPG resulting in loss of therapy.
- Lead malfunction could cause painful stimulation and/or stimulation of adjacent tissue.

CSL Precautions

- Do not store the Carotid Sinus Lead outside the temperature range of -4˚ F (-20˚C) to 122 F (50C).
- Sterile package seal integrity can be damaged by moisture. Do not expose to liquids.
- Electrocautery at a low but effective power can be used to minimize the potential of damaging the lead during dissection. Electrocautery at high power settings may damage the Carotid Sinus Lead.
- Scalpels may damage the Carotid Sinus Lead. Avoid scalpel blade contact with the lead when using scalpels.
- Do not implant the Carotid Sinus Lead if the device has been dropped.
- Exercise extreme caution in utilizing line-powered equipment in conjunction with the Carotid Sinus Lead because leakage current could injure the patient.
- Do not use any other lead beside the Carotid Sinus Lead with this system because such use may damage the IPG or injure the patient.
- An additional Carotid Sinus Lead should be available in the event of compromised sterility or if damage is induced during surgery.

PROGRAMMER

Programmer Warnings

- Do not locate any programmer system components inside the sterile operating field.

Programmer Precautions

- The components of the Programmer System should not be sterilized.
- The following are requirements to comply with IEC 60601-1 and IEC 60601-1-1:
    - The computer and power supply should be located outside the patient environment when the computer is operated on mains power.
    - The system should not be connected to other non-isolated monitoring equipment or communication networks.
    - The operator should not touch the computer and the patient simultaneously when the computer is operated on mains power.
    - The USB cable should be fully inserted into the Programmer Interface USB receptacle to avoid patient contact with the metal part of the USB connector.

      Note: The patient environment is defined as the area within 1.5m (approximately 5ft) of the patient.
- Plug the Programmer System directly into an outlet or operate using the laptop battery power. Do not plug the programmer system into a power strip or extension cord.
- Do not modify the Programmer System (i.e. connect additional equipment via USB) or install additional software. Doing so may result in reduced performance, increased emissions, decreased immunity or equivalent malfunction. Use of a USB Memory Device is acceptable.
- Do not immerse product in water or a safety hazard could arise during use. If the Programmer System requires cleaning, clean the system components with a soft cloth dampened with water. Do not allow pooling or ingress of liquid into the Programmer Interface enclosure.
- Keep the Programmer System in a controlled location to prevent loss or theft. Intentional misuse of the Programmer System could result in an IPG being programmed to settings that are not as prescribed.

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Adverse Events

It is anticipated that subjects will be exposed to operative and post-operative risks similar to related surgical procedures involving the neck and/or a pacemaker implant. These risks and potential risks of chronic device based baroreflex activation may include, but are not limited to:

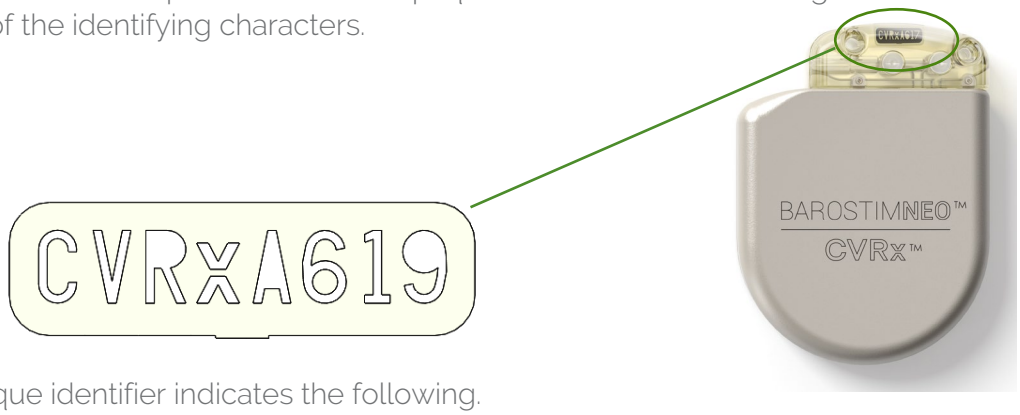
- Stroke – a neurological deficit lasting more than 24 hours or less than 24 hours with a brain imaging study showing infarction
- Transient ischemic attack (TIA) – a neurological deficit lasting less than 24 hours without evidence of permanent cerebral infarction
- Systemic embolization – downstream obstruction of a blood vessel by migration of loosened intravascular plaque or clot
- Surgical or anesthetic complications
- Infection – the need for antibiotics or possible removal of the system
- Wound Complication – including hematoma (i.e. bruising and/or swelling)
- Arterial damage – including carotid artery rupture or hemorrhage (sudden and significant blood loss at a site of blood vessel rupture that may require reoperation or transfusion)
- Pain – an unpleasant sensory experience
- Transient, Temporary, or Permanent Nerve Damage/Stimulation – including injury to or stimulation of Cranial, Marginal Mandibular, Glossopharyngeal, Recurrent Laryngeal, Vagus and Hypoglossal Nerves (numbness in head and neck, facial palsy/paralysis, altered speech, altered sense of taste, respiratory constriction, stertorous breathing, excessive salivation, dry cough, vomiting and/or regurgitation, altered sensory and motor function of tongue, altered sensory function of pharynx and oropharynx, altered sensation in external auditory canal), stimulation of extravascular tissue (muscle twitching (fasciculation), pain, tingling, oral sensations)
- Hypotension – a decrease in systolic and diastolic blood pressure below normal levels that may result in dizziness, fainting, and/or falls
- Hypertensive crisis – uncontrolled rise in blood pressure
- Respiratory – including low oxygen saturation, respiratory distress, shortness of breath
- Exacerbation of heart failure
- Cardiac arrhythmias
- Tissue erosion/IPG migration – movement of device resulting in need for reoperation
- Injury to baroreceptors – an injury that results in baroreflex failure
- Fibrosis – replacement of normal tissue by the ingrowth of fibroblasts and the deposition of connective tissue
- Allergic Reaction

- General injury to user or patient – may be due to surgical procedure, device use, or interaction with other devices
- Need for reoperation – operation to explant/replace IPG or CSLs due to tissue damage, infection, and/or device failure
- Secondary operative procedure – An increase in the complexity and risk of secondary operative procedures of the neck due to scar tissue and the presence of prosthetic material implanted for this device
- Death

6
Emergency Personnel Information

RADIOPAQUE IDENTIFIER

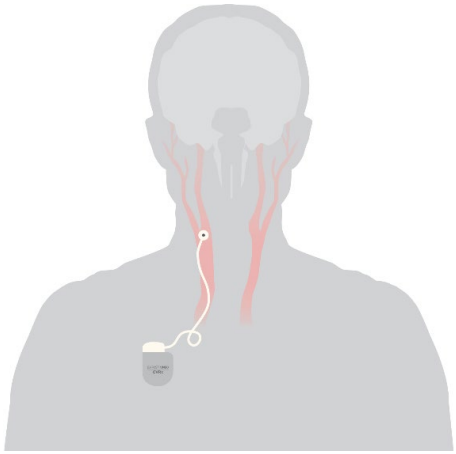
The IPG has a unique radiopaque identifier located in the connector portion of the device. This allows medical personnel to use X-ray to identify information about the implanted medical device. An example of an IPG radiopaque identifier is shown along with a description of the identifying characters.



The radiopaque identifier indicates the following.

- CVRx as the company for which the IPG was manufactured.
- The model of the IPG (example: A6 = Model 2104).
- The year in which the IPG was manufactured (example: 19=2019).

The device may be implanted on patient's right or left side. This illustration shows the device implanted on the patient's right side.



ECG ARTIFACT

Artifacts in ECG tracings may be seen when the IPG is active.

TEMPORARILY INHIBITING THE IPG OUTPUT

Standard doughnut magnets that are distributed for use with pacemakers and ICDs are readily available in both cardiology clinics and hospitals. These magnets may be used to temporarily inhibit the IPG output when the output is active. Position the center hole of the magnet over the area of the IPG connector block and leave in place to inhibit output. Remove the magnet to resume prescribed IPG therapy.

7
Warranty & Disclaimer of Warranty

IMPORTANT NOTICE – LIMITED WARRANTY

This Limited Warranty is provided by CVRx, Inc. 9201 West Broadway Avenue, Suite 650, Minneapolis, MN 55445.

This LIMITED WARRANTY assures the patient who receives Barostim NEO2 (referred to as the "Product") that, should the Product not function to specification for any reason other than battery depletion within one year after implant ("Warranty Period"), CVRx will provide a replacement at no charge. If the Product's battery is depleted during the Warranty Period, CVRx will provide a replacement at a discounted cost. The discount will be based on the ratio of the time remaining in the Warranty Period on the date of depletion to the entire Warranty Period.

All Warnings contained in the Product labeling are an integral part of this LIMITED WARRANTY.

To qualify for the LIMITED WARRANTY, these conditions must be met:

The Product must be used prior to its "Use By" date.

The Product must not have been repaired or altered outside of CVRx's control in any way which, in the judgment of CVRx, affects its stability and reliability. The Product must not have been subjected to misuse, abuse or accident.

The Product must be returned to CVRx within 30 days of discovery of the potential non-conformity leading to a claim under this LIMITED WARRANTY. All returned Product shall be the property of CVRx

CVRx is not responsible for any incidental or consequential damages, including but not limited to medical fees, based upon any use, defect, or failure of the Product, whether the claim is based on warranty, contract, tort, or otherwise.

This Limited Warranty is made only to the patient who receives the Product. As to all others, CVRx makes no warranty, express or implied, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose, whether arising from statute, common law, custom or otherwise. No such express or implied warranty to the patient shall extend beyond the period of one year. This Limited Warranty shall be the exclusive remedy available to any person.

The exclusions and limitations set out above are not intended to and should not be construed so as to contravene any mandatory provisions of applicable law. If any part or term of this LIMITED WARRANTY is held by a court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portions of this LIMITED WARRANTY shall not be affected and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

No person has any authority to bind CVRx to any representation, condition or warranty except this Limited Warranty.

8
Specifications

IMPLANTABLE PULSE GENERATOR

Specification	Value
Connectors	No sensing Unipolar Stimulation 1.5 mm lead pin bore diameter 3.48 mm lead shaft bore diameter
Mass	55 grams
Height	68 mm
Width	50 mm
Thickness	14 mm
Volume	< 36 CC
Materials	Titanium Can Polyurethane Header Silicone Seals Stainless Steel Setscrews
Leads	Use only CVRx lead Models 103x
Battery	1 carbon monofluoride and silver vanadium oxide cell 7.50 Ah Theoretical Capacity
Current Consumption and Nominal Projected Life	Current Consumption depends on parameter settings. See Section Implantable Pulse Generator for details.
Disposal of Product	Please contact CVRx representative to return product to CVRx. Product should not be disposed of in trash.
Operational Temperature Range	10˚ C to 45˚ C
Storage/Shipping Temperature Range	-20˚ C to 50˚ C
IPG Therapy Settings as Shipped	Therapy Off

Implantable Pulse Generator Parameters

Parameter	Description	Units	Programmable Values
Therapy Schedule	From/To Times for Therapy (N) or Therapy Off	HH:MM	Up to 3 entries allowed Any time during the day In 15-minute steps
Pulse Amplitude for Therapy (N)	The amplitude of each applied pulse.	milliamp	1.0 to 20.0
Pulse Width for Therapy (N)	The width of each applied pulse.	µs	15 to 500
Therapy Frequency for Therapy (N)	The frequency of applied pulses except during the Rest portion of the Burst Interval.	PPS	10 to 100
Burst	Not Checked = therapy pulses are applied throughout the burst cycle in a continuous manner Checked = pulses are applied in a cycle of active and rest periods.	N/A	Not checked / Checked
Burst Duration	The length of the active portion of the burst cycle during which the Therapy Frequency is delivered. NOTE: This parameter is not shown if Burst is not checked.	milliseconds	50 to 1950
Burst Interval	The total length of the burst cycle including the active portion and the rest portion. NOTE: This parameter is not shown if Burst is not checked.	milliseconds	100 to 2000

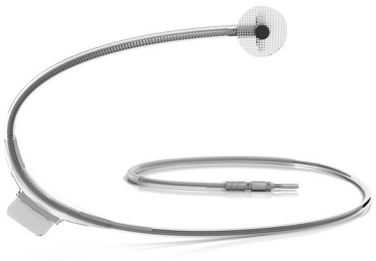
Implantable Pulse Generator Longevity

The battery lifetime of the IPG is dependent on device therapy settings. Assuming 825 Ohm lead impedance the following table indicates the resulting longevity based on different therapy settings. For these calculations, a single 24-hour therapy was assumed.

Pulse Amplitude (mA)	Pulse Width (us)	Therapy Frequency (Hz)	Device Longevity (Months)
4.2	125	40	100
5.6	125	40	74
7.2	125	40	55
*8.0	250	40	25

*Worst case conditions

LEAD (MODELS 1036 AND 1037)



Specification	Value (Nominal)
Length	Model 1036: 40 cm Model 1037: 50 cm
Compatibility	Compatible with CVRx Barostim NEO and NEO2
Connector	
Connector Type	Compatible with CVRx Barostim System
Pin	Active: Diameter = 1.41 mm, Active Length = 5.18 mm
Ring	Inactive: Diameter = 2.67 mm, Active Length = 4.06 mm
Connector (Pin to Ring) Length	14.22 mm (including active ring 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
Disposal of Product	Please contact CVRx representative to return product to CVRx. Product should not be disposed of in trash.
Storage/Shipping Temperature Range	-20˚ C to 50˚ C

CAROTID SINUS LEAD REPAIR KIT

Specification	Value (Nominal)
Length (as provided)	28 cm
Compatibility	Compatible with CVRx Rheos, Barostim, and Barostim Legacy Systems
Connector	
Connector Type	Bipolar, compatible with, Barostim NEO, NEO2, and Barostim Legacy IPG
Pin	Diameter = 1.41 mm, Active Length = 5.18 mm
Ring	Diameter = 2.67 mm, Active Length = 4.06 mm
Connector (Pin to Ring) Length	14.22 mm (including active ring 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
Disposal of Product	Please contact CVRx representative to return product to CVRx. Product should not be disposed of in trash.

PROGRAMMER SYSTEM

Specification	Value
Operating temperature	50˚ F to 95˚ F (10˚ C to 35˚ C) If equipment has been stored at temperature extremes, then the equipment should be placed at operating temperature for at least 1 hour prior to use.
Atmospheric pressure	525 mmHg to 760 mmHg (700 hPa to 1010 hPa)(10.2 psia to 14.7psia)
Vibration	0.5G, 10 to 500 Hz, 0.5 octave/min sweep rate
Storage/shipping temperature	-4° F to 140° F (-20° C to 60° C)
Storage/shipping humidity	5% to 90% relative humidity
Network Connectivity	Connection to a local network via Wi-Fi or ethernet connection is disabled. Connection to a secure network for the purposes of updating software and retrieving session information is provided through a cellular modem. There are no user features related to network connectivity.
Data Privacy	CVRx complies with data privacy regulations in the regions where the system is sold.

Programmer System Components

Component	Specification	Value
Programmer Interface	Power Supply Input	From computer
Programmer System IEC60601-1-2 System Clause	Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g., IEC 60950-1 for data processing equipment). Furthermore, all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3rd Ed. Of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above-mentioned requirements. If in doubt, consult your local representative or the technical service department.	
Programmer Interface IEC60601-1-1 System Clause	The Programmer Interface is suitable for use in the patient environment.	
System Installation and Maintenance	There are no Installation, Commissioning or Modifications required for the proper use of the Programmer System. No installation measurements are required. Regular maintenance is also not required. Inspect the Programmer Interface, computer and cables prior to each use. Notify CVRx or your CVRx representative of any items that need replacement.	

Computer

Specification	Value
Safety and EMC Requirements	EN 60950-1 UL 60950-1 EN 55022 EN 55024 FCC Part 15 Class B emissions

Programmer Miscellaneous Information

Description	Information
Type of protection against electric shock	The Programmer Interface is not mains powered equipment.
Degree of protection against electric shock	The Programmer Interface meets IEC 60601-1-1 touch current requirements.
Degree of protection against the ingress of water	Ordinary
Methods of sterilization or disinfecting	Cannot be sterilized.
Information regarding electromagnetic or other interference and advice regarding avoidance as necessary.	Do not use in the proximity of equipment that generates electromagnetic interference (EMI). EMI may cause a disruption in programmer function. Examples are cell phones, x-ray equipment, and other monitoring equipment.
Accessories or materials used with equipment that may affect safety.	Programmer Interface cable.
Cleaning and maintenance, with frequency	If the Programmer System requires cleaning, clean the system components with a soft cloth dampened with water. Do not allow pooling or ingress of liquid into the Programmer Interface enclosure. No preventative maintenance is required. Do not use programmer system if programming unit or cables appear damaged. There are no serviceable items. Please contact CVRx representative to return product for service or replacement.
Equipment Supply Disconnect	Unplug power cord to isolate equipment from supply mains.
Manufacturer Name	CVRx, Inc.
Model #(s)	Programmer System: Model 9010
Disposal of Product	Please contact CVRx representative to return product to CVRx. Product should not be disposed of in trash.

9
Regulatory Notices

The transmitters in the Programmer Interface have been certified under IC: 9464A-PGM901.

The term "IC:" before the equipment certification number only signifies that the Industry Canada technical specifications were met.

This device may not interfere with stations operating in the 400.150-406.000 MHz band in the meteorological aids, meteorological-satellite, and earth exploration-satellite services and must accept any interference received, including interference that may cause undesired operation.

Operation is subject to the following two conditions: (I) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

10
Electromagnetic Compatibility Declarations

PROGRAMMER SYSTEM EMC PRECAUTIONS

The Model 9010 Programmer System needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this guide.

Portable and mobile RF communications equipment can affect the Model 9010 Programmer System.

The use of power cords or USB cables other than those supplied with the Model 9010 Programmer System may result in increased emissions or decreased immunity.

The Model 9010 Programmer System should not be used adjacent to or stacked with other equipment. If such use is required, then the Model 9010 Programmer System should be observed to verify normal operation in this configuration.

PROGRAMMER SYSTEM RF SPECIFICATIONS

The Model 9010 Programmer System may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements. The RF telemetry operating specifications are:

MICS band 402-405 MHz. The effective radiated power is below the limits specified in:

- Europe: EN ETSI 301 839-2

2.4 GHz band 2.4-2.4835 GHz. The effective radiated power is below the limits specified in:

- Europe: EN ETSI 301 328

Table 1: Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Model 9010 Programmer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 9010 Programmer System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Model 9010 Programmer System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The Model 9010 Programmer System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 2: Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 9010 Programmer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 9010 Programmer System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T for 0,5 cycle) 40 % U_T (60 % dip in U_T for 5 cycles) 70 % U_T (30 % dip in U_T for 25 cycles) <5 % U_T (>95 % dip in U_T for 5 s)	<5 % U_T (>95 % dip in U_T for 0,5 cycle) 40 % U_T (60 % dip in U_T for 5 cycles) 70 % U_T (30 % dip in U_T for 25 cycles) <5 % U_T (>95 % dip in U_T for 5 s)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 9010 Programmer System requires continued operation during power mains interruptions, it is recommended that the Model 9010 Programmer System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the line voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 9010 Programmer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 9010 Programmer System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Model 9010 Programmer System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{3}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = \left[\frac{3,5}{3}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{3}\right]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 9010 Programmer System is used exceeds the applicable RF compliance level above, the Model 9010 Programmer System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 9010 Programmer System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 3: Separation Distance

Recommended separation distance between portable and mobile RF communications equipment and the Model 9010 Programmer System			
The Model 9010 Programmer System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 9010 Programmer System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 9010 Programmer System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{3}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{3}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{3}\right]\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,2	1,2	2,3
10	3,7	3,7	7,4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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