System Overview

Caution: Federal law restricts this device to sale by or on the order of a physician.

ABOUT THIS DOCUMENT

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

System Overview	900133-001
Surgical Procedures	900133-002
Programming	900133-003
Magnetic Resonance Imaging (MRI)	900133-004
Patient Instructions	900133-005

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

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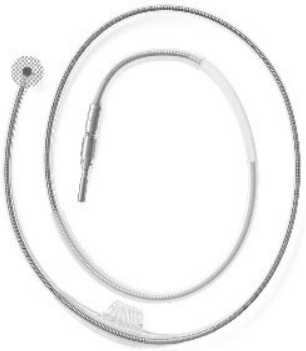
System Description

The Barostim System includes the following components:

Description	Model Number
Implantable Pulse Generator	2102
Implantable Pulse Generator	2104
Carotid Sinus Lead	1036
Carotid Sinus Lead	1037
Programmer System	9010
Programmer System	9020
Carotid Sinus Lead Repair Kit	5010



The Barostim System is minimally-invasive using CVRx patented Barostim™ technology. The Barostim System is designed to electrically activate the carotid baroreceptors, the body's natural cardiovascular regulation sensors. When the baroreceptors are activated, signals are sent through neural pathways to the brain and interpreted as a rise in blood pressure. The brain works to counteract this perceived rise in blood pressure by sending signals to other parts of the body (heart, blood vessels, and kidneys) that relax the blood vessels and inhibit the production of stress-related hormones.

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.

Intended Users:

The system implantation, programming and operation is managed by the patient's care team. This may be individually or any combination of Cardiologists, Hypertension Specialists, Nephrologists, Heart Failure Specialists, Electrophysiologists, or Vascular Surgeons.

IMPLANTABLE PULSE GENERATOR (IPG)
MODEL 2102 OR 2104

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

The carotid sinus lead is attached to the pulse generator through the connector module. Barostim NEO™ Model 2102 has two lead connections; Barostim NEO2™ Model 2104 has one lead connection.

CAROTID SINUS LEAD (CSL)
MODEL 1036 OR 1037

The Carotid Sinus Lead conducts Barostim Baroreflex Activation 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 CVRx's implant tool and 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)

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

The Programmer System is available in two different models, the Model 9010 and the Model 9020. Both models include the following major components:

- Programmer Software
- Programmer Interface
- Computer/Tablet
- USB/USB-C cable

PGM Programmer Software/Computer/Tablet

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

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.

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Symbols and Definitions

	Caution, Consult Accompanying Documents		Keep Dry
www.cvrx.com/ifu	Consult Instructions for Use		This Way Up
	Do Not Reuse		Fragile, Handle with Care
	Do Not Resterilize		Do Not Use if Package is Damaged
	Temperature Limitation		WEEE Directive Symbol (Special Disposal Required)
	Atmospheric Pressure Limits		Humidity Limits
	Date of Manufacture	BRADY TACHY	This Device is Not Intended for the Treatment of Bradycardia or Tachycardia
	Manufacturer	OFF	OFF; IPG Programmed Mode as Shipped
	Use By Date	CVRx System Only	This Device is for Use with CVRx System Only
	Peel Here	Intended Use: Barostim	This device is a component of the implantable Barostim System.
STERILE EO	Sterilized using Ethylene Oxide	Compatible Lead Models 103x	This Device is for Use with CVRx Unipolar Lead Models 1036 and 1037 only and not compatible with lead models 101x.
	Equipment includes RF transmitter	Compatible IPG Models 2102 and 2104	This Device is for Use with CVRx IPG Models 2102 and 2104 and not compatible with IPG Model 2100 (Barostim Legacy).
LOT	Batch Code (Lot Number)	Lead Ports 1	This IPG has only one lead connection (Model 2104).
MODEL	Product Model Number	Lead Ports 2	This IPG has two lead connections (Model 2102).
SN	Serial Number	MR	Magnetic Resonance (MR) Unsafe
P/N	Part Number	MR	Magnetic Resonance (MR) Conditional Use
REF	Catalogue Number		No pacemakers
CONTENTS	Package Contents		Programmer Interrface Power Status
PATENTS	Product Protected by One or More US Patents as listed (International patents & additional patents pending)		Programmer Interface USB connection status
UDI-DI:	Unique Device Identification=Device Identifier in HRI format (human readable interpretation)	UDI	Unique Device Identification as Automatic Identification and Data Capture format [e.g. linear or 2D-Barcodes])

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Indications and Contra-indications

INDICATIONS:

The Barostim System is indicated for the improvement of symptoms of heart failure—quality of life, six-minute hall walk and functional status—for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are NYHA Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤ 35%, a NT-proBNP < 1600 pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.

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.
- Known allergy to silicone or titanium.

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Warnings and Precautions

GENERAL

The safety and effectiveness of the 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 NEO & NEO2 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.
- 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.
- 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.

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.

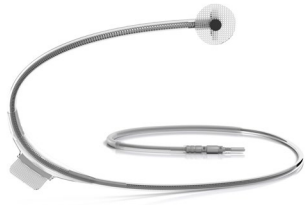
IPG Precautions

- 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 are 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.
- Only hospitals/healthcare facilities (may include ambulatory surgery centers, or one day surgery centers) where vascular surgery is performed should perform placement of Carotid Sinus Leads.
- 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

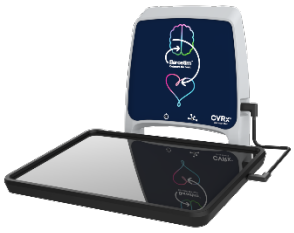
- Do not store the Carotid Sinus Lead outside the temperature range of -4° F (-20°C) to 122° F (50C).
- Sterile package seal integrity can be damaged by moisture. Do not expose to liquids.
- Electrocautery at a low but effective power can be used to minimize the potential of damaging the lead during 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:
  - The Programmer System is intended for use in the professional healthcare facility environment only.
  - The computer/tablet and power supply should be located outside the patient environment when the computer/tablet is operated on mains power.
    Note: The patient environment is defined as the area within 1.5m (approximately 5ft) of the patient.
  - The system should not be connected to other non-isolated monitoring equipment or communication networks.
  - The operator should not touch the computer/tablet and the patient simultaneously when the computer/tablet 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.
- Plug the Programmer System directly into an outlet or operate using 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.
- Avoid having the computer/tablet always plugged in and charging, this can reduce the life of the rechargeable battery. Periodic recharges of the computer/tablet above 50% but less than 100% every 6 months are recommended. Prolonged periods between charging the tablet may diminish the battery performance.

IMPLANT ADAPTER, IMPLANT TOOL

Warnings

- FOR SINGLE USE ONLY. Do not re-sterilize or reuse. Reuse of this product may result in malfunction or adverse events such as infection or death.
- Do not use product if “Use Before” date has been reached.

Precautions

- Store between -4° F (-20° C) and 122° F (50° C).
- Do not use if the storage package has been damaged, compromising the product sterility.
- Sterile package seal integrity can be damaged by moisture. Do not expose to liquids.

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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 Barostim 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 – A condition where the heart beats too fast, too slow, or irregularly
- 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
Clinical Summary

CLINICAL SUMMARY

The Baroreflex Activation Therapy for Heart Failure (BeAT-HF) trial was a prospective, randomized (1:1), two-arm controlled trial to establish a reasonable assurance of safety and effectiveness of the Barostim System for the reduction of the symptoms of heart failure in patients. The trial generated data from subjects who met the following key criteria:

- Currently NYHA Class II or III heart failure. For NYHA Class II, must have been NYHA Class III at any point in time within 3 calendar months prior to enrollment or at time of screening.
- Left ventricular ejection fraction ≤ 35% within 45 days prior to randomization.
- Heart failure accompanied by BNP≥100 or NT-proBNP ≥ 400 within 45 days prior to randomization, or a heart failure hospitalization in the past 12 months.
- On optimal, stable, Guideline Directed Medical Therapy (GDMT) per country specific guidelines for the treatment of heart-failure throughout screening/baseline evaluation and for at least 4 weeks prior to obtaining any post-consent screening parameters.

Excluding Subjects who:

- Received cardiac resynchronization therapy (CRT) within six months of randomization or is actively receiving CRT.
- Currently have a Class I indication for a cardiac resynchronization therapy (CRT) device according to AHA/ACC/ESC guidelines for the treatment of congestive heart failure.

The trial enrolled 408 randomized subjects at 92 sites, 91 in the United States (US) and 1 in the United Kingdom (UK).

It was designed as a two-phase trial. The first phase, the Expedited Phase, supports a PMA under the FDA Breakthrough Devices Program, which is the information included in this summary. The second phase, the Extended Phase, is ongoing and is intended to collect post-market long-term information, including morbidity and mortality (M&M) data.

The following endpoints were evaluated at 6 months:

- Safety - Major Adverse Neurological & Cardiac Events, event free rate
- Effectiveness – 6 Minute Hall Walk (6MHW), Minnesota Living with Heart Failure (QoL) and NT-proBNP.

Subjects were randomized in a 1:1 ratio to receive Barostim, Baroreflex Activation Therapy (BAT) with an implanted Barostim System in addition to medical management (BAT + MM) or to receive medical management (MM) alone (no device implant). After evaluating the pre-planned Expedited Phase initial data review in early October 2018, a large, important and clinically relevant population was identified. This subgroup population is characterized by having NYHA Class III or II (recent history of Class III) heart failure, left ventricular ejection fraction ≤ 35% and baseline NT-proBNP < 1600 pg/ml at the time of baseline. **This subgroup, referred to as the Intended Use Population, is the focus of the PMA.**

The Intended Use Population for the Expedited Phase analysis of the 6-month efficacy endpoints includes all subjects randomized with a baseline NT-proBNP<1600 that have complete baseline and six-month data for MLWHF QOL, 6MHW and/or NT-proBNP. The evaluation of the MANCE free rate includes all subjects in the BAT + MM arm in the Intended Use Population that have an attempted implant.

Within the Intended Use Population supporting the Expedited Phase, there are two cohorts of data. Data that was previously analyzed in the original PMA dated December 14, 2018, called the Initial Cohort data, and data that had not been previously unblinded and analyzed and also is included here, called the Second Cohort data that was collected through April 22, 2019. See Table 1 below for a breakdown of the intended use populations that were used for the safety and effectiveness analyses.

Table 1: Analysis Populations for the Expedited Phase - Intended Use

Description	BAT + Medical Management	Medical Management	Total
Expedited Phase Population - Intended Use	130	134	264
Expedited Phase Six Month Efficacy Analysis Population - Intended Use	120	125	245
Not in Expedited Phase Six Month Efficacy Analysis Population - Intended Use	10	9	19
No Implant Attempt	5	N/A	5
Died / LVAD / Heart Transplant prior to 6 month visit	1	5	6
Withdrew / LTFU prior to 6 month visit	2	0	2
Missed 6 month visit	2	4	6
Expedited Phase Safety Analysis Population - Intended Use	125	N/A	125
Not in Expedited Phase Safety Analysis Population - Intended Use	5	N/A	5
No Implant Attempt	5	N/A	5
Total Randomized - Intended Use	130	134	264

The demographics of the study Intended Use Population are typical for a reduced ejection fraction heart failure study performed in the US and UK. Baseline demographics for Expedited Phase Intended Use Population subjects are in Table 2 below. Demographics between the two randomized arms were balanced. Approximately 35% had a history of atrial fibrillation, 24% chronic kidney disease and 47% Type II diabetes. Almost all subjects (93 to 95%) are NYHA Class III at baseline with an average LVEF of 27% for BAT +MM and 28% for MM.

Table 2: Demographics at Baseline - Intended Use

Variable	BAT + Medical Management			Medical Management			P-value
	N	Mean ± SD or N (%)	Range	N	Mean ± SD or N (%)	Range	
Race							
Asian	130	3 (2.3%)	N/A	134	2 (1.5%)	N/A	0.680
Black or African American	130	24 (18.5%)	N/A	134	20 (14.9%)	N/A	0.510
White	130	97 (74.6%)	N/A	134	96 (71.6%)	N/A	0.677
Other/Unknown	130	6 (4.6%)	N/A	134	16 (11.9%)	N/A	0.044
Female	130	24 (18.5%)	N/A	134	29 (21.6%)	N/A	0.542
Age at Screening (years)	130	62 ± 11	27 - 92	134	63 ± 10	35 - 83	0.614
BMI (kg/m2)	130	31 ± 5	17 - 40	134	31 ± 5	20 - 43	0.699
SBP (mmHg)	130	120 ± 17	80 - 183	134	121 ± 16	90 - 179	0.385
DBP (mmHg)	130	73 ± 10	48 - 107	134	73 ± 10	50 - 101	0.618
HR (bpm)	130	75 ± 10	56 - 99	134	75 ± 11	40 - 100	0.864
LVEF (%)	130	27 ± 7	10 - 35	134	28 ± 6	12 - 35	0.192
Core Lab NT-proBNP (pg/mL)*	130	731 (475, 1021)	72 - 1582	134	765 (479, 1052)	54 - 1587	0.786
NYHA: Class III	130	121 (93.1%)	N/A	134	127 (94.8%)	N/A	0.614
6 Minute Walk (m)	130	316 ± 68	156 - 475	134	294 ± 73	60 - 442	0.015
QOL	130	53 ± 24	3 - 100	134	52 ± 24	6 - 105	0.800
eGFR	130	63.6 ± 16.8	32 - 113	134	61.9 ± 19.5	25 - 144	0.430
QRS Interval	130	108.9 ± 17.6	49 - 168	134	110.5 ± 25.6	23 - 241	0.545
LBBB	130	3 (2.3%)	N/A	134	1 (0.7%)	N/A	0.365
At Least One HF Hospitalization	130	54 (41.5%)	N/A	134	68 (50.7%)	N/A	0.140
Number of HF Hospitalizations	130	0.6 ± 1.0	0 - 6	134	0.7 ± 0.8	0 - 4	0.815
Enrolled under Rev. D of Protocol	130	110 (84.6%)	N/A	134	107 (79.9%)	N/A	0.338
Origin of Subject: Advertising	130	18 (13.8%)	N/A	134	21 (15.7%)	N/A	0.730

*Results reported as median (IQR).

As shown in Table 3, most of the subjects had coronary artery disease (65%) and/or a prior MI (59%). Approximately 35% had a history of atrial fibrillation, 24% chronic kidney disease and 47% Type II diabetes.

Table 3: Medical History Reported Comorbidities - Intended Use

Variable	BAT + Medical Management			Medical Management			P-value
	N	Mean ± SD or N (%)	Range	N	Mean ± SD or N (%)	Range	
Coronary Heart Disease							
Coronary Artery Disease	130	80 (61.5%)	N/A	134	92 (68.7%)	N/A	0.246
Myocardial Infarction	130	68 (52.3%)	N/A	134	86 (64.2%)	N/A	0.061
CABG	130	23 (17.7%)	N/A	134	39 (29.1%)	N/A	0.030
PCI	130	53 (40.8%)	N/A	134	62 (46.3%)	N/A	0.387
Cardiac Arrhythmia							
Bradycardia	130	13 (10.0%)	N/A	134	14 (10.4%)	N/A	1.000
Tachycardia	130	43 (33.1%)	N/A	134	46 (34.3%)	N/A	0.897
Atrial Fibrillation	130	38 (29.2%)	N/A	134	57 (42.5%)	N/A	0.029
Stroke or TIA	130	24 (18.5%)	N/A	134	30 (22.4%)	N/A	0.449
Chronic Kidney Disease	130	31 (23.8%)	N/A	134	33 (24.6%)	N/A	0.887
Diabetes							
Type I	130	0 (0.0%)	N/A	134	2 (1.5%)	N/A	0.498
Type II	130	58 (44.6%)	N/A	134	68 (50.7%)	N/A	0.327

Baseline heart failure treatments are shown in Table 4 below. Most of the subjects (87%) were on an ACE-I/ARB or ARNI, 95% on a beta blocker and 92% on a diuretic. Approximately 78% had an ICD and <5% had another cardiac device (6 CardioMems, 3 Lifevest and 1 loop recorder).

Table 4: Heart Failure Treatments at Baseline - Intended Use

Treatment	BAT + Medical Management			Medical Management			P-value
	N	Mean ± SD or N (%)	Range	N	Mean ± SD or N (%)	Range	
Number of Meds	130	3.9 ± 1.2	1 - 8	134	4.1 ± 1.4	1 - 8	0.228
ACE-I/ARB							
Use	130	75 (57.7%)	N/A	134	79 (59.0%)	N/A	0.901
% recommended dose	73	29.3 ± 25.5	3 - 100	79	27.6 ± 24.3	6 - 100	0.672
Beta-Blocker							
Use	130	124 (95.4%)	N/A	134	127 (94.8%)	N/A	1.000
% recommended dose	124	29.8 ± 26.4	6 - 125	126	28.1 ± 27.7	3 - 150	0.614
Diuretic							
Use	130	110 (84.6%)	N/A	134	117 (87.3%)	N/A	0.596
Ivabradine							
Use	130	3 (2.3%)	N/A	134	6 (4.5%)	N/A	0.501
MRA							
Use	130	63 (48.5%)	N/A	134	56 (41.8%)	N/A	0.322
% recommended dose	63	55.6 ± 36.0	25 - 300	54	59.3 ± 54.1	25 - 400	0.660
ARNI							
Use	130	41 (31.5%)	N/A	134	35 (26.1%)	N/A	0.344
% recommended dose	41	41.5 ± 20.6	25 - 100	35	42.9 ± 28.6	13 - 100	0.806
ACE/ARB or ARNI Use	130	115 (88.5%)	N/A	134	113 (84.3%)	N/A	0.372
ICD	130	101 (77.7%)	N/A	134	106 (79.1%)	N/A	0.881
Pacemaker (non-ICD)	130	2 (1.5%)	N/A	134	1 (0.7%)	N/A	0.618
CRT	130	3 (2.3%)	N/A	134	4 (3.0%)	N/A	1.000
Other cardiac device (e.g., CardioMEMS)	130	6 (4.6%)	N/A	134	4 (3.0%)	N/A	0.536

Safety Results

The system or procedure related Major Adverse Neurological and Cardiovascular Events (MANCE) endpoint includes all events that occur within 6-months post implant. The analysis includes the BAT + MM in the Intended Use Population who had an implant attempted (n=125).

As shown in Table 5 below, the MANCE-free rate for the Intended Use Population is 96.8% (121/125) with a lower bound one-sided 95% confidence level of 92.8% (p value <0.001). As the lower bound is greater than 85%, the safety endpoint has been met in the Intended Use Population.

Table 5: System or Procedure Related MANCE-Free Rate in BAT + Medical Management - Intended Use

	Total Number of Subjects	Number of Subjects MANCE-Free	MANCE-Free Rate	One-Sided 95% Lower Bound	P-value
MANCE Event-Free	125	121	96.8%	92.8%	<.001

The four MANCE components are shown in Table 6 below. There were 2 infections requirement explant, 1 acute decompensated heart failure event and 1 stroke.

Table 6: System or Procedure Related MANCE Events in BAT + Medical Management - Intended Use

Event	Implanted Subjects (N=125)		
	Number of Events	Number of Subjects	Event Rate
CV Death	0	0	0.0%
Stroke	1	1	0.8%
Cardiac Arrest	0	0	0.0%
Acute MI	0	0	0.0%
Acute Decompensated HF	1	1	0.8%
Hypertensive Crisis	0	0	0.0%
Severe Complication of HF Treatment	0	0	0.0%
Systemic and Pulmonary Thromboembolism	0	0	0.0%
Infection Requiring Explant	2	2	1.6%
Cranial Nerve Damage	0	0	0.0%
Non-Elective Major Restorative Procedures	0	0	0.0%
Total	**4**	**4**	**3.2%**

Out of the 125 subjects implanted in the Intended Use Population, 9 subjects experienced 12 system- or procedure-related complications within six months of implant. The complication-free rate in the Intended Use Population is 92.8%. A listing of the system or procedure related complications is shown in Table 7 below.

Table 7: Six Month System or Procedure Related Complications in BAT + Medical Management - Intended Use

Event	Implanted Subjects (N=125)		
	Number of Events	Number of Subjects	Event Rate
Heart Failure, Acute Decompensated Heart Failure	1	1	0.8%
Muscle and Bone	1	1	0.8%
Nerve Damage/Stimulation, Cranial Nerve Stimulation	1	1	0.8%
Other Nerve, Hoarseness	1	1	0.8%
Respiratory, Other Respiratory, Acute hypercarbic respiratory failure	1	1	0.8%
Respiratory, Pneumonia	1	1	0.8%
Stroke (CVA), Ischemic	1	1	0.8%
Surgical or Anesthetic Complications, Infection at Implant Site (No Explant)	1	1	0.8%
Surgical or Anesthetic Complications, Infection at Implant Site Requiring Explantation	2	2	1.6%
Surgical or Anesthetic Complications, Other Surgical Complication, prolonged intubation	1	1	0.8%
Thromboembolism, Systemic	1	1	0.8%
Total	12	9	7.2%

During the study, there were three contralateral ICD implants that had interactions with the Barostim System. All were noted to have been addressed by reducing the programmed therapy settings for the NEO IPG.

Additional Safety Information

Additional safety information using the data cutoff from the April 30, 2019, Executive Summary (PMA) Report includes the analysis shown in Table 8 below. This table was reported in the supplementary material of the peer reviewed Zile et al, JACC 2020 article, Appendix Table 13:

Cardiovascular Serious Events.[1] In the report the average follow-up time in the Intended Use Population for these cardiovascular events was 14.5 months, with over 313 total years of follow-up.

Table 8 demonstrates that BAT appears to reduce the rate of cardiovascular serious events compared to control in the Intended Use Population [2, 3]

Table 8: Cardiovascular Serious Events in Intended Use Subjects

Serious Adverse Event	BAT (N=125)		Control (N=134)		Relative Reduction in Event Rate (95% CI)	p-value
	Number of Events (# subjects)	Event Rate per patient year of follow-up	Number of Events (# subjects)	Event Rate per patient year of follow-up		
Cardiac Arrhythmias/Cardiac Arrest	8 (6)	0.054	18 (12)	0.109	0.50 (-0.14, 0.78)	0.100
Hypotension/Syncope	2 (2)	0.014	6 (4)	0.036	0.63 (-0.85, 0.92)	0.226
MI/Angina	5 (4)	0.034	10 (10)	0.060	0.44 (-0.63, 0.81)	0.288
Total	15 (11)	0.101	34 (22)	0.206	0.51 (0.10, 0.73)	0.023

There were no unanticipated adverse events reported in the study.

Effectiveness Results

Six-minute hall walk (6MHW) performed according to a standard protocol, Minnesota Living With Heart Failure Quality of Life (MLWHF QOL) Questionnaire data, and a blinded core lab evaluated NT-proBNP were collected at the baseline visit and during follow-up at 6-months. The 6-month results are reported below in the Expedited Phase Efficacy Analysis for the Intended Use Population subjects.

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[1] Zile et al, *Appendix Table 13: Cardiovascular Serious Events*, Supplemental Information to "Baroreflex Activation Therapy in Patients With Heart Failure With Reduced Ejection Fraction." *J Am Coll Cardiol* 76(1): 1-13, 2020.

[2] Zile et al. Baroreflex Activation Therapy in Patients With Heart Failure With Reduced Ejection Fraction. *J Am Coll Cardiol*, 2020, 76(1): 1-13.

[3] Supplemental Information to "Baroreflex Activation Therapy in Patients With Heart Failure With Reduced Ejection Fraction." *J Am Coll Cardiol* 2020, 76(1): 1-13.

Within the population supporting the Expedited Phase, there are two cohorts of data. Data that was previously analyzed in the original PMA Clinical Report, dated December 14, 2018, called the initial data, and data that has not been previously unblinded and analyzed and is included here, called the second data, that was collected through April 22, 2019. Unless otherwise specified, the data presented is the Initial Cohort and Second Cohort.

Table 9 below shows the six-minute walk differences between the arms in the Second and Initial Cohorts for the Intended Use Population. The results showed a consistent and clinically meaningful and statistically significant improvement between the arms for the Initial, the Second and Combined Cohorts.

Table 9: Change in Six-Minute Walk Distance at 6 Months – Intended Use Second, Initial and Combined Cohorts

Cohort	BAT + Medical Management		Medical Management		Difference*	p-value
	N	Mean±SD (95% CI)	N	Mean±SD (95% CI)	Δ Means (95% CI)	
Initial	69	49.0 ± 71.6 (31.8, 66.2)	80	-11.9 ± 92.8 (-32.5, 8.8)	65.4 (38.5, 92.3)	<0.001
Second	49	48.1 ± 58.7 (31.2, 64.9)	40	0.1 ± 79.2 (-25.3, 25.4)	49.8 (21.8, 77.9)	<0.001
Combined	118	48.6 ± 66.3 (36.5, 60.7)	120	-7.9 ± 88.4 (-23.9, 8.1)	60.1 (40.3, 79.9)	<0.001

*The difference is evaluated based on an ANCOVA model adjusting for the baseline value.

Table 10 below shows the quality-of-life differences between the arms in the Second and Initial Cohorts for the Intended Use Population. The results showed a consistent and clinically meaningful and statistically significant improvement between the arms for the Initial, the Second and Combined Cohorts.

Table 10: Change in Quality of Life at 6 Months - Intended Use Second, Initial and Combined Cohorts

Cohort	BAT + Medical Management		Medical Management		Difference*	p-value
	N	Mean±SD (95% CI)	N	Mean±SD (95% CI)	Δ Means (95% CI)	
Initial	70	-21.3 ± 25.2 (-27.3, -15.2)	83	-9.0 ± 19.6 (-13.3, -4.7)	-12.1 (-18.7, -5.6)	<0.001
Second	50	-19.9 ± 25.9 (-27.2, -12.5)	42	-0.8 ± 20.0 (-7.0, 5.5)	-17.8 (-26.1, -9.4)	<0.001
Combined	120	-20.7 ± 25.4 (-25.3, -16.1)	125	-6.2 ± 20.1 (-9.8, -2.7)	-14.1 (-19.2, -8.9)	<0.001

*The difference is evaluated based on an ANCOVA model adjusting for the baseline value.

Table 11 below shows the Log10 NT-proBNP differences between the arms in the Initial, Second and Combined data Cohorts for the Intended Use Population. The results showed and clinically meaningful and statistically significant improvement between the arms for the Second Cohort, validating the strong signal seen in the Initial Cohort.

Table 11: Change in Log10 NT-proBNP at 6 Months – Intended Use Second, Initial and Combined Cohorts

Cohort	BAT + Medical Management		Medical Management		Difference*	p-value
	N	Mean±SD (95% CI)**	N	Mean±SD (95% CI)**	Δ Means (95% CI)**	
Initial	67	-16.7% ± 0.3 (-30.2%, -0.5%)	82	1.9% ± 0.3 (-12.4%, 18.5%)	-17.9% (-34.3%, 2.7%)	0.08
Second	53	-26.4% ± 0.4 (-43.7%, -3.9%)	41	6.4% ± 0.3 (-15.9%, 34.5%)	-36.5% (-55.2%, -10.1%)	0.01
Combined	120	-21.1% ± 0.4 (-32.3%, -8.2%)	123	3.3% ± 0.3 (-8.9%, 17.2%)	-24.6% (-37.6%, -8.7%)	0.004

*The difference is evaluated based on an ANCOVA model adjusting for the baseline value.
Results modeled parametrically on the log10 scale. Results are converted to percent change from baseline using [10(log10(a) - log10(b)) - 1 = (a-b)/b]. Standard deviation is on log10 scale.

Table 12 below shows the New York Heart Association (NYHA) Class functional status differences between the arms in the Combined (Initial and Second Cohorts) of the Intended Use Population.

Table 12: Change in NYHA Class at 6 Months– Intended Use, Combined Cohort

Change in NYHA	BAT + Medical Management		Medical Management		P-value
	N	N (%)	N	N (%)	
Improved 2 Classes	120	16 (13.3%)	125	3 (2.4%)	<.001
Improved 1 Class		62 (51.7%)		36 (28.8%)	
No Change		42 (35.0%)		84 (67.2%)	
Deteriorated		0 (0.0%)		2 (1.6%)	

Adding New Class of Heart Failure Drugs

Table 13 shows the data reported in Appendix Table 12, Subjects Adding New Class of Heart Failure Drugs by Six Months in Cohort D Control (n=125). in the JACC 2020 article supplementary material.

During the 6-month follow-up there was a significant difference in medical management between the 2 arms, with a higher number of medications added in the control group (Supplemental Table 12, Zile et al).1 Patients in the control group were more likely to have a new class of drugs added compared to BAT, with BAT still providing benefit and meeting the endpoints for 6MHW, QoL, and NT-proBNP.

Table 13: Addition of New Class of Heart Failure Drugs[4] in Intended Use Subjects

	Control (N=125)	BAT (N=120)	Difference (95% CI)	P-value *
Any Medication Class	36 (28.8%)	21 (17.5%)	11.3% (0.8, 21.8)	0.049
ACE / ARB	5 (4.0%)	4 (3.3%)	0.7% (-4.0, 5.4)	1.000
ARNI (Sacubitril/Valsartan)	20 (16.0%)	5 (4.2%)	11.8% (4.5, 19.2)	0.003
Beta Blocker	4 (3.2%)	3 (2.5%)	0.7% (-3.5, 4.9)	1.000
Digitalis	3 (2.4%)	0 (0.0%)	2.4% (-0.3, 5.1)	0.247
Diuretic	3 (2.4%)	5 (4.2%)	-1.8% (-6.2, 2.7)	0.493
Ivabradine	1 (0.8%)	3 (2.5%)	-1.7% (-4.9, 1.5)	0.362
MRA	4 (3.2%)	3 (2.5%)	0.7% (-3.5, 4.9)	1.000
Other HF Meds	9 (7.2%)	2 (1.7%)	5.5% (0.5, 10.6)	0.060

* p-value from 2-sided Fisher's exact test

Discussion and Conclusion

In the Intended Use Population, safety was demonstrated in the BeAT-HF trial in the 125 implanted subjects with a system- or procedure-related MANCE-free rate of 96.8%. There were four MANCE events related to the system and/or the procedure of which all recovered, three with no residual effect. There were no deaths in the BAT + MM associated with either system or the procedure. There were no unanticipated adverse events.

For the three effectiveness endpoints in the Intended Use Population, the BAT + MM arm consistently showed significant improvement from baseline to six months, while the Medical Management arm showed virtually no change. In the Second cohort, the difference between the device was +50 meters ($p<0.001$) in 6MHW, -18 points in MLWHF QOL ($p<0.001$) and -37% for NT-proBNP ($p=0.01$). These improvements were clinically significant within the BAT + MM arm, as well as between the arms. These effectiveness results were consistent across the Initial and the Second cohorts.

In the Expedited Phase Intended Use Population analysis for the PMA, the MANCE safety endpoint and the two symptomatic endpoints (6MHW and QOL) were statistically and clinically significant. Additionally, as reported, the blinded core lab evaluated NT-proBNP provided objective evidence of device effect as validated by the Second Cohort's statistically significant results. The results of the BeAT-HF trial demonstrate compelling evidence that the Barostim NEO is both safe and effective and is ready for commercial use for the improvement of the symptoms of heart failure in patients who remain symptomatic despite treatment with guideline-directed therapy, have a left ventricular ejection fraction ≤ 35% and a NT-proBNP <1600 pg/ml, excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.

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[4] Zile et al, *Appendix Table 12: Subjects Adding New Class of Heart Failure Drugs by Six Months in Cohort D Control (N=125)*, Supplemental Information to "Baroreflex Activation Therapy in Patients With Heart Failure With Reduced Ejection Fraction." *J Am Coll Cardiol* 76(1): 1-13, 2020.)

7
Physician and Training Experience

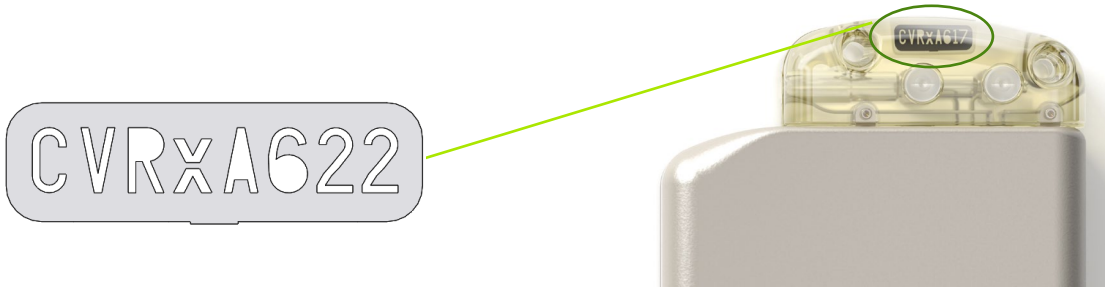
TRAINING REQUIREMENTS

CVRx requires training for physicians who wish to use this system.

8
Emergency Personnel Information

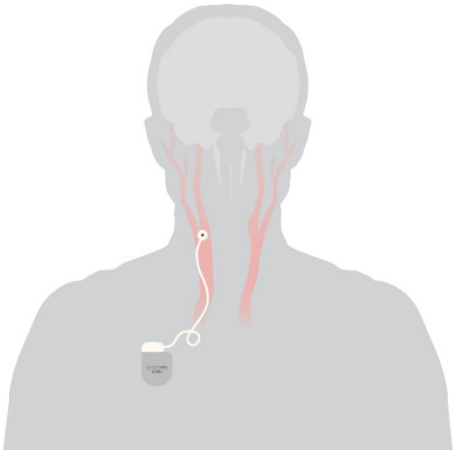
RADIOPAQUE IDENTIFIER

The IPGs have 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: A5 = Model 2102, A6 = Model 2104)
- The year in which the IPG was manufactured (example: 22=2022)



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.

9
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 NEO & NEO2 (referred to as the "Product") that, should the Product not function to specification for any reason within one year after implant ("Warranty Period"), CVRx will provide a replacement at no charge.

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.

10
Specifications

IMPLANTABLE PULSE GENERATOR

Specification	2104	2102
Mass	55 grams	60 grams
Height	68 mm	72 mm
Width	50 mm	50 mm
Thickness	14 mm	14 mm
Volume	< 36 CC	< 40 CC
Connectors	No sensing Unipolar Stimulation 1.5 mm lead pin bore diameter 3.48 mm lead shaft bore diameter	
Materials	Titanium Can Polyurethane Header Silicone Seals Stainless Steel Setscrews	
Materials in Port Plug	Port Plug not supplied nor required	One port plug provided: Comprised of a Stainless Steel shaft and silicone body
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

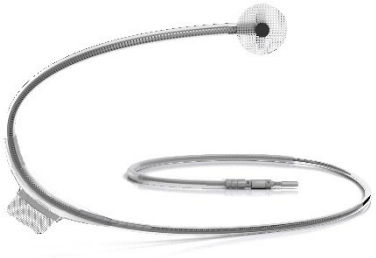
Implantable Pulse Generator Longevity

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)	2104 Device Longevity (Months)	2102 Device Longevity (Months)
4.2	125	40	100	79
5.6	125	40	74	60
7.2	125	40	55	44
*8.0	250	40	25	28

*Worst case conditions

LEAD (MODELS 1036 AND 1037)



Specification	Value (Nominal)
Length	Model 1036: 40 cm Model 1037: 50 cm
Compatibility	Compatible with Barostim NEO & NEO2 IPG
Connector	
Connector Type	Compatible with Barostim NEO & NEO2 IPG
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 NEO & NEO2, and Barostim™ Legacy Systems
Connector	
Connector Type	Bipolar, compatible with, Barostim NEO, Barostim 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	9010: 50° F to 95° F (10° C to 35° C) 9020: 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	9010: -4° F to 140° F (-20° C to 60° C) 9020: 32° F to 95° F (0° C to 35° 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/tablet
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 62368-1 for information technology equipment). Furthermore, all configurations shall comply with the requirements for medical electrical systems (see clause 16 of the 3rd Ed. Of IEC 60601-1). 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, Clause 16 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/tablet and cables prior to each use. Notify CVRx or your CVRx representative of any items that need replacement.	

Computer/Tablet

Specification	Value
Safety and EMC Requirements	EN 60950-1 EN IEC 62368-1 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 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.	USB cable to connect computer/tablet to Programmer Interface.
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 Programmer System: Model 9020

Description	Information
Power Supply	9010: Input Voltage: 100-240V Input Current: 0.6A Input Frequency: 50/60Hz Output Voltage: 20V Output Current: 3.25A Output Power: 65W 9020: Input Voltage: 100-240V Input Current: 0.6A Input Frequency: 50/60Hz Output Voltage: 15V Output Current: 1.6A Output Power: 24W
Disposal of Product	Please contact CVRx representative to return product to CVRx. Product should not be disposed of in trash.

11 Regulatory Notices

REGULATORY LABELING REQUIREMENTS

This system is equipped with an RF transmitter for wireless communications.
Each component has an RF identification number registered with the following regulating agency:

Federal Communications Commission: FCC ID: SVHBAROSTIMIPG1 (All IPGs)
Federal Communications Commission: FCC ID: SVHBAROSTIMPGM1 (Model 9010 Programmer System)
Federal Communications Commission: FCC ID: SVHBAROSTIMPGM2 (Model 9020 Programmer System)

STATEMENT OF FEDERAL COMMUNICATIONS COMMISSION (FCC) COMPLIANCE

This device complies with Title 47, Part 15 of the FCC rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

This transmitter is authorized by rule under the Medical Device Radio communication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radio Communication Service.

Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

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Electromagnetic Compatibility Declarations

Model 9010 Programmer System

PROGRAMMER SYSTEM EMC PRECAUTIONS

The Model 9010 Programmer System requires special precautions regarding Electromagnetic Compatibility (EMC) and is 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:

- USA: 47 CFR 95 Subpart I
- Canada: RSS-243

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

- USA: 47 CFR 15.249
- Canada: RSS-210

Table 14: 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 15: 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 16: 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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Electromagnetic Compatibility Declarations

Model 9020 Programmer System

PROGRAMMER SYSTEM EMC PRECAUTIONS

The Model 9020 Programmer System requires special precautions regarding Electromagnetic Compatibility (EMC) and is to be installed and put into service according to the EMC information provided in this guide.

Portable and mobile RF communications equipment should be used no closer than 30cm to any part of the 9020 Programmer System. Otherwise, degradation of the performance of this equipment could result.

The use of accessories, power cords or cables other than those supplied with the Model 9020 Programmer System may result in increased emissions or decreased immunity and may result in improper operation.

The Model 9020 Programmer System should not be used adjacent to or stacked with other equipment since this could result in improper operation. If such use is required, then the Model 9020 Programmer System and other equipment should be observed to verify normal operation in this configuration.

PROGRAMMER SYSTEM ESSENTIAL PERFORMANCE

Essential performance of the 9020 Programmer System is maintained except when any of the following occurs:

1. Permanent, irreversible loss of telemetry when positioned 2 meters away from an IPG implanted at a depth of 6cm where the failure impacts two programmer systems. Also, this functionality is only essential performance in an operating room since loss of telemetry could increase the probability of infection due to extending the time of a surgical procedure.

2. Permanent, irreversible loss of a programmer system user interface function (i.e., black screen, touch-screen non-functional, etc.) where the failure impacts two programmer systems. Also, this functionality is only essential performance in an operating room since loss of a programmer system user interface function could increase the probability of infection due to extending the time of a surgical procedure.

3. Incorrect display of information on the user interface related to patient safety, including incorrect display of lead impedance, compliance, and therapy output parameters.

Electro-magnetic disturbances can cause loss of telemetry as specified in item 1 for as long as the electro-magnetic disturbance exists.

PROGRAMMER SYSTEM RF SPECIFICATIONS

The Model 9020 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:

- USA: 47 CFR 95 Subpart I
- Canada: RSS-243

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

- USA: 47 CFR 15.249
- Canada: RSS-210

Table 17: Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Model 9020 Programmer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 9020 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 9020 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 9020 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 18: Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 9020 Programmer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 9020 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	± 8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air	± 8 kV contact ±2kV, ±4kV, ±8kV, ±15kV 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 100kHz repetition frequency	± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 0.5kV, ± 1 kV line-to-line ± 0.5kV, ± 1 kV, ± 2 kV line-to-ground	± 0.5kV, ± 1 kV line-to-line ± 0.5kV, ± 1 kV, ± 2 kV line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions IEC 61000-4-11	0% UT (100% dip in UT for 0,5 cycle) At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT (100% dip in UT for 1 cycle) 70% UT (30% dip in UT for 25/30 cycles) Single phase: at 0° 0% UT (100% dip in UT for 250/300 cycles)	0% UT (100% dip in UT for 0,5 cycle) 0% UT (100% dip in UT for 1 cycle) 70% UT (30% dip in UT for 25/30 cycles) 0 % UT (100% dip in UT for 250/300 cycles)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Programmer System requires continued operation during power mains interruptions, it is recommended that the Programmer System be powered from an uninterruptible power supply or a battery.
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 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 9020 Programmer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 9020 Programmer System should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 80 % AM at 1 kHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Model 9020 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 EM fields IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	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 9020 Programmer System is used exceeds the applicable RF compliance level above, the Model 9020 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 9020 Programmer System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 19: Immunity to Proximity Fields from RF Wireless Communications Equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Max power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1,8	0,3	27	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1kHz sine	2	0,3	28	28
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9	9
745							
780							
810	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0,3	28	28
870							
930							
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28	28
1845							
1970							
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9	9
5500							
5785							

Table 20: Separation Distance

Recommended separation distance between portable and mobile RF communications equipment and the Model 9020 Programmer System			
The Model 9020 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 9020 Programmer System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 9020 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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REF 900133-001 Rev. B IFU System Overview
2022-04