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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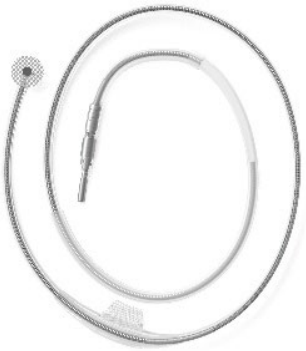
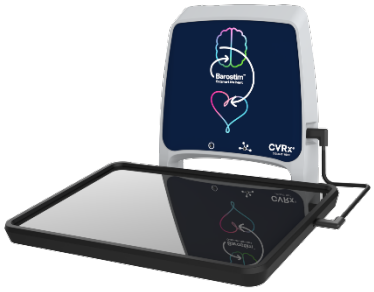
System Description

The Barostim System includes the following components:

Description	Model Number
Implantable Pulse Generator	2102
Implantable Pulse Generator	2104
Carotid Sinus Lead	1036
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 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

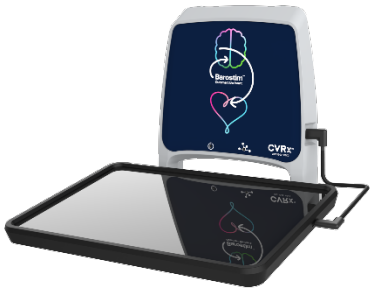
The Carotid Sinus Lead conducts Barostim Baroreflex Activation Therapy from the IPG to the baroreceptors located on the carotid sinus. The model 1036 lead is 40cm long with a 2 mm electrode and is supplied with an implant tool and an implant adapter.

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 Model 1036 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])

3
Indications and Contra-indications

INDICATIONS:

Barostim is indicated for patients who are NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed medical therapies (medications and devices), have a left ventricular ejection fraction of ≤ 35%, and a NT-proBNP <1600 pg/ml.

Barostim delivers Baroreflex Activation Therapy to improve patients' heart failure functional status, six-minute hall walk, and quality of life.

CONTRAINDICATIONS:

Patients are contraindicated if they have:

- Bilateral carotid bifurcations located above the level of the mandible.
- Baroreflex failure or autonomic neuropathy
- Uncontrolled, symptomatic cardiac bradyarrhythmias
- Carotid artery stenosis greater than 50% caused by atherosclerosis, as determined by ultrasound or angiographic evaluation
- 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 randomized clinical trials.

General Warnings

- Only trained physicians may use this system.
- Prescribing physicians should be experienced in the diagnosis and treatment of heart failure and should be familiar with the use of this system.
- Blood pressure and heart rate should be monitored during Carotid Sinus Lead placement and when adjusting stimulation parameters intra-operatively.
- System programming post-implantation should 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 and 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.
- Magnetic Resonance Imaging (MRI) IFU should be followed 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.

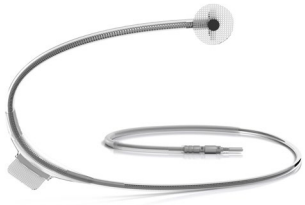
IPG Precautions

- 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. Artifacts may appear as higher frequency signals. See Section 9 for instructions to temporarily inhibit the IPG output to collect an ECG free from therapy artifact.
- 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

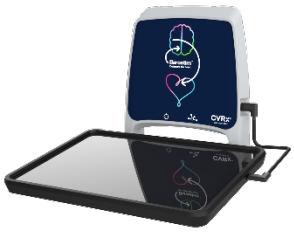
- Do not store the Carotid Sinus Lead outside the temperature range of -4° F (-20°C) to 122° F (50C).
- Sterile package seal integrity can be damaged by moisture. Do not expose to liquids.
- Electrocautery at a low but effective power can be used to minimize the potential of damaging the lead during 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.

5
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, two-arm controlled trial to establish a reasonable assurance of safety and effectiveness of the Barostim System for the treatment of heart failure and reduction of the symptoms for patients. Subjects were randomized in a 1:1 ratio to receive 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). 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
- NT-proBNP < 1600 pg/ml
- On optimal, stable, Guideline Directed Medical Therapy (GDMT)

Excluding:

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

The trial randomized 467 subjects at 73 sites, 72 in the United States (US) and 1 in the United Kingdom (UK).

BeAT-HF was designed as a two-phase trial. The first phase, the Pre-Market Phase, supported a PMA under the FDA Breakthrough Devices Program. The second phase, the Post-Market Phase, collected post-market long-term information, including morbidity and mortality (M&M) data. The updated information from both phases is included in this summary.

The following endpoints were pre-specified prior to data unblinding

Primary Endpoints

- Safety – Related Major Adverse Neurological & Cardiac Events (MANCE) free rate over all follow-up
- Effectiveness –
- Pre-Market: Six Month Improvement – 6 Minute Hall Walk (6MHW), Minnesota Living with Heart Failure (QoL), NT-proBNP
- Post-Market: Rate of cardiovascular mortality and heart failure morbidity

Additional Analyses

- Symptomatic Improvement at 12 months in 6 Minute Hall Walk (6MHW), and at 12 and 24-months in Minnesota Living with Heart Failure (QoL) and New York Heart (NYHA) Class
- Hierarchical Win Ratio analysis of cardiovascular mortality, heart failure morbidity and Minnesota Living with Heart Failure (QoL)
- Freedom from death, LVAD and heart transplant

In summary,

- Pre-Market data included the safety and symptomatic endpoints described above for the first 6 months of the study. These data resulted in FDA PMA approval of Barostim for symptomatic improvement on August 16, 2019.
- The Post-Market phase included the updated 6- month data and 12 and 24-month symptomatic data, presented along with the mortality and morbidity, Win Ratio, and freedom from LVAD and heart transplant.

Baseline demographics are in Table 1 below. The majority of the subjects are white males. The average age is 63 years, average BMI is 31, and average LVEF is 27%. Mean core lab NT-proBNP is approximately 725 pg/ml. Just under half of the subjects had a prior heart failure hospitalization in the past 12 months (45%). The baseline demographics were well balanced between BAT and the Medical Management arms with no statistical differences.

Table 1: Demographics at Baseline

	BAT + MM			MM			
Variable	**N**	**Mean ± SD or N (%)**	**Range**	**N**	**Mean ± SD or N (%)**	**Range**	**P-value**
Race							
Asian	163	3 (1.8%)	N/A	160	2 (1.3%)	N/A	1.000
Black or African American	163	29 (17.8%)	N/A	160	24 (15.0%)	N/A	0.549
White	163	120 (73.6%)	N/A	160	116 (72.5%)	N/A	0.900
Other/Unknown	163	11 (6.7%)	N/A	160	18 (11.3%)	N/A	0.177
Female	163	28 (17.2%)	N/A	160	35 (21.9%)	N/A	0.326
Age at Screening (years)	163	63 ± 11	27 - 92	160	63 ± 10	35 - 86	0.674
BMI (kg/m2)	163	31 ± 5	17 - 40	160	31 ± 5	18 - 43	0.718
SBP (mmHg)	163	120 ± 16	80 - 183	160	121 ± 16	90 - 179	0.596
DBP (mmHg)	163	74 ± 10	48 - 107	160	73 ± 10	50 - 101	0.392

	BAT + MM			MM			
Variable	N	Mean ± SD or N (%)	Range	N	Mean ± SD or N (%)	Range	P-value
HR (bpm)	163	75 ± 10	56 - 103	160	75 ± 11	40 - 100	0.977
LVEF (%)	163	27 ± 6	10 - 35	160	28 ± 6	10 - 35	0.161
Core Lab NT-proBNP (pg/mL)*	163	736 (474, 1057)	64 - 1582	160	704 (442, 1044)	54 - 1587	0.847
NYHA: Class III	163	155 (95.1%)	N/A	160	151 (94.4%)	N/A	0.808
6 Minute Walk (m)	163	314 ± 66	156 - 475	160	300 ± 71	60 - 442	0.065
QOL	163	53 ± 24	3 - 100	160	51 ± 24	6 - 105	0.456
eGFR	163	62.5 ± 16.3	28 - 113	160	61.1 ± 18.9	25 - 144	0.468
QRS Interval	163	109.9 ± 17.8	49 - 168	160	111.6 ± 25.7	23 - 241	0.483
LBBB	163	4 (2.5%)	N/A	160	2 (1.3%)	N/A	0.685
At Least One HF Hospitalization	163	66 (40.5%)	N/A	160	79 (49.4%)	N/A	0.118
Number of HF Hospitalizations in Past 12 Months	163	0.6 ± 0.9	0 - 6	160	0.7 ± 0.8	0 - 4	0.531
Origin of Subject: Advertising	163	20 (12.3%)	N/A	160	21 (13.1%)	N/A	0.868
*Results reported as median (IQR).							

As shown in Table 2, most of the subjects had coronary artery disease (65%) and/or a prior MI (58%). Approximately 37% had a history of atrial fibrillation, 27% chronic kidney disease and 48% Type II diabetes. The baseline comorbidities were balanced between BAT and the Medical Management arms with no statistical differences.

Table 2: Medical History Reported Comorbidities

	BAT + MM			MM			
Variable	N	Mean ± SD or N (%)	Range	N	Mean ± SD or N (%)	Range	P-value
Coronary Heart Disease							
Coronary Artery Disease	163	104 (63.8%)	N/A	160	107 (66.9%)	N/A	0.640
Myocardial Infarction	163	89 (54.6%)	N/A	160	97 (60.6%)	N/A	0.311
CABG	163	35 (21.5%)	N/A	160	44 (27.5%)	N/A	0.244
PCI	163	72 (44.2%)	N/A	160	72 (45.0%)	N/A	0.911
Cardiac Arrhythmia							
Bradycardia	163	19 (11.7%)	N/A	160	18 (11.3%)	N/A	1.000
Tachycardia	163	54 (33.1%)	N/A	160	56 (35.0%)	N/A	0.726
Atrial Fibrillation	163	53 (32.5%)	N/A	160	66 (41.3%)	N/A	0.108
Stroke or TIA	163	29 (17.8%)	N/A	160	37 (23.1%)	N/A	0.270
Chronic Kidney Disease	163	45 (27.6%)	N/A	160	43 (26.9%)	N/A	0.901
Diabetes							
Type I	163	0 (0.0%)	N/A	160	2 (1.3%)	N/A	0.245
Type II	163	74 (45.4%)	N/A	160	80 (50.0%)	N/A	0.436

Baseline heart failure treatments are shown in Table 3 below. In general, subjects were well treated with guideline directed therapies as defined at the time of enrollment. Most of the subjects (85%) were on an ACE-I/ARB or ARNI, 93% on a beta blocker and 86% on a diuretic. Approximately 78% had an ICD and <10% had another cardiac device [5 pacemakers, 10 CRT (1 misclassified as other cardiac device), 7 CardioMEMS, 3 Lifevests, and 1 loop recorder]. The baseline heart failure treatments were balanced between BAT and the Medical Management arms with no statistical differences.

Table 3: Heart Failure Treatments at Baseline

	BAT + MM			MM			
Treatment	N	Mean ± SD or N (%)	Range	N	Mean ± SD or N (%)	Range	P-value
Number of Meds	163	4.0 ± 1.3	1 - 8	160	4.1 ± 1.5	1 - 9	0.995
ACE-I/ARB							
Use	163	88 (54.0%)	N/A	160	87 (54.4%)	N/A	1.000
% recommended dose	84	31.5 ± 26.8	6 - 100	87	29.5 ± 26.0	6 - 100	0.609
Beta-Blocker							
Use	163	152 (93.3%)	N/A	160	147 (91.9%)	N/A	0.676
% recommended dose	152	29.2 ± 27.1	6 - 150	146	28.8 ± 27.7	3 - 150	0.900
Diuretic							
Use	163	138 (84.7%)	N/A	160	139 (86.9%)	N/A	0.634
Ivabradine							
Use	163	4 (2.5%)	N/A	160	9 (5.6%)	N/A	0.167
MRA							
Use	163	74 (45.4%)	N/A	160	64 (40.0%)	N/A	0.368
% recommended dose	74	56.4 ± 34.9	25 - 300	62	59.3 ± 51.3	25 - 400	0.701
ARNI							
Use	163	57 (35.0%)	N/A	160	43 (26.9%)	N/A	0.120
% recommended dose	57	40.6 ± 20.6	13 - 100	43	41.4 ± 28.5	6 - 100	0.862
ICD	163	125 (76.7%)	N/A	160	127 (79.4%)	N/A	0.593
Pacemaker (non-ICD)	163	3 (1.8%)	N/A	160	2 (1.3%)	N/A	1.000
CRT	163	4 (2.5%)	N/A	160	5 (3.1%)	N/A	0.749
Other cardiac device (e.g., CardioMEMS)	163	8 (4.9%)	N/A	160	4 (2.5%)	N/A	0.379

Safety Results

The system or procedure related Major Adverse Neurological and Cardiovascular Events (MANCE) endpoint includes all events that occurred across the duration of follow-up. The analysis includes subjects in BAT+MM arm who had an implant attempted (n=159), representing 6664 total months of implant follow-up. All implant attempts were successful.

As shown in Table 4 below, the MANCE-free rate is 96.9% (154/159) with a lower bound one-sided 95% confidence level of 93.5% (p value <0.001 compared to a performance goal of 85%).

Table 4: System or Procedure Related MANCE-Free Rate Across All Follow up in BAT + MM

	Total Number of Subjects	Number of Subjects MANCE-Free	MANCE-Free Rate	One-Sided 95% Lower Bound	P-value
MANCE Event-Free	159	154	96.9%	93.5%	<.001

The five related MANCE events were two infections that required explant, right neck pain that required lead repositioning, a stroke, and a decompensation of heart failure that required hospitalization. All resolved with no residual effect except the stroke, where no follow-up was deemed necessary.

The MANCE components are shown in Table 5 below.

Table 5: System or Procedure Related MANCE Events in BAT + Medical Management

	Implanted Subjects (N=159)		
Event	Number of Events	Number of Subjects	Event Rate
CV Death	0	0	0.0%
Stroke	1	1	0.6%
Cardiac Arrest	0	0	0.0%
Acute MI	0	0	0.0%
Acute Decompensated HF	1	1	0.6%
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	1.3%
Cranial Nerve Damage	0	0	0.0%
Non-Elective Major Restorative Procedures	1	1	0.6%
Total	5	5	3.1%

Out of the 159 subjects implanted, 10 subjects experienced 14 system- or procedure-related complications within six months of implant. The complication-free rate is 93.7%. A listing of the system or procedure related complications is shown in Table 6 below.

Table 6: Six Month System or Procedure Related Complications in BAT + MM

Event	Implanted Subjects (N=159)		
	Number of Events	Number of Subjects	Event Rate
Fibrosis	1	1	0.6%
Heart Failure, Acute Decompensated Heart Failure	1	1	0.6%
Nerve Damage/Stimulation, Cranial Nerve Damage, Temporary	1	1	0.6%
Nerve Damage/Stimulation, Cranial Nerve Stimulation	1	1	0.6%
Other Nerve, Hoarseness	1	1	0.6%
Respiratory, Pneumonia	1	1	0.6%
Severe Complications of Heart Failure Treatment	1	1	0.6%
Stroke (CVA), Ischemic	1	1	0.6%
Surgical or Anesthetic Complications, Infection at Implant Site (No Explant)	1	1	0.6%
Surgical or Anesthetic Complications, Infection at Implant Site Requiring Explantation	2	2	1.3%
Surgical or Anesthetic Complications, Other Surgical Complication, Anesthetic Complication	1	1	0.6%
Surgical or Anesthetic Complications, Other Surgical Complication, prolonged intubation	1	1	0.6%
Thromboembolism, Systemic	1	1	0.6%
Total	14	10	6.3%

There were no unanticipated adverse events reported in the study.

Effectiveness Results

The Pre-Market Phase of the study previously demonstrated significant improvement in six minute hall walk (6MHW), Minnesota Living with Heart failure (MLWHF QoL), and NT-proBNP. The difference between the arms in 6MHW was +60 meters ($p<0.001$), in MLWHF QOL -14 points ($p<0.001$) and -25% for NT-proBNP ($p=0.004$). These Pre-Market Phase effectiveness endpoints were met.

The Post-Market Phase primary endpoint was to demonstrate that treatment with the Barostim System, relative to medical management, reduces the rate of cardiovascular mortality or worsening heart failure that led to hospitalization or emergency room visit, cardiac assist device or heart transplant.

The results of the negative binomial analysis of CV mortality and HF morbidity: RR=0.94 (95% CI 0.57, 1.57), p-value = 0.82. The Post-Market Phase primary effectiveness endpoint was not met.

The primary endpoint components are shown in Table 7 below. Note that a subject can have more than one heart failure hospitalization or emergency room visit.

Table 7: CV Mortality and HF Morbidity Components

	BAT + Medical Management (N=159)			Medical Management (N=160)			Total (N=319)		
Event	N Events	N (%) Patients	Rate Events / PY FUP	N Events	N (%) Patients	Rate Events / PY FUP	N Events	N (%) Patients	Rate Events / PY FUP
Endpoint Event	177	63 (39%)	0.325	155	68 (43%)	0.315	332	131 (41%)	0.320
CV Death	27	27 (17%)	0.050	29	29 (18%)	0.059	56	56 (18%)	0.054
HF Event	145	54 (34%)	0.266	116	52 (33%)	0.236	261	106 (33%)	0.252
HF Hospitalization	122	49 (31%)	0.224	107	48 (30%)	0.218	229	97 (30%)	0.221
HF Emergency Room Visit	23	16 (10%)	0.042	9	7 (4%)	0.018	32	23 (7%)	0.031
LVAD Implant	2	2 (1%)	0.004	7	7 (4%)	0.014	9	9 (3%)	0.009
Heart Transplant	3	3 (2%)	0.006	3	3 (2%)	0.006	6	6 (2%)	0.006

Observations of primary effectiveness endpoint components included:

- The rate of CV death was 0.50 event per patient year follow-up in BAT + MM subjects and 0.59 in MM control subjects.
- The rate of LVAD implants was 0.004 event per patient year follow-up in BAT + MM subjects and 0.014 in MM control subjects.
- The rate of heart transplant was 0.006 event per patient year follow-up in each group.
- The rate of HF events was 0.266 event per patient year follow-up in BAT + MM subjects and 0.236 in MM control subjects.

Additional Analyses

The following additional analyses were pre-specified prior to data unblinding in the Post-Market Phase.

Six-minute hall walk (6MHW) performed according to a standard protocol, Minnesota Living With Heart Failure Quality of Life (MLWHF QOL) questionnaire data, New York Heart Association (NYHA) Class, and NT-proBNP changes were collected at the baseline, 6-, 12- and 24-month visits (or as required by protocol). The results for each are reported below.

As shown in Table 8 below, the six-minute hall walk for the BAT + MM arm shows an improvement at both six and twelve months compared to the MM arm. The difference between the arms at 6 months is 56 meters and at 12 months the difference is sustained with 44 meters. These improvements between the arms are not only statistically significant, but they are approximately twice the clinically significant value of 25 meters.[1]

Table 8: Six Minute Hall Walk by Visit

Visit	BAT + MM* N=163 Mean ± SD (95% CI)	MM* N=160 Mean ± SD (95% CI)	Difference (95% CI)**
Baseline	313.7 ± 66.3	299.5 ± 71.3	
6-Month Change	46.8 (35.8, 57.8)	-8.7 (-22.5, 5.2)	55.5 (37.7, 73.3)
12-Month Change	40.6 (26.4, 54.7)	-3.0 (-13.5, 7.6)	43.5 (25.7, 61.4)

*Statistics are estimated mean improvement and 95% confidence interval from repeated measures model
**From generalized estimating equation repeated measures model with covariate for baseline value

The Minnesota Living With Heart Failure Quality of Life results are shown below in Table 9. The BAT + MM arm shows a decrease (improvement) in QOL points ranging from 17 to 20 points from baseline across the follow-up visits. The differences between the arms at 6, 12 and 24 months are -14, -8 and -10, respectively, which is not only statistically significant, but is greater than a clinically meaningful difference of 5 points.[2]

[1] Gremeaux V, Troisgros O, Benaïm S, Hannequin A, Laurent Y, Casillas J, Benaïm C. Determining the Minimal Clinically Important Difference for the Six-Minute Walk Test and the 200-Meter Fast-Walk Test During Cardiac Rehabilitation Program in Coronary Artery Disease Patients After Acute Coronary Syndrome. *Arch Phys Med Rehabi*l 2011 Apr;92(4):611-9. doi: 0.1016/j.apmr.2010.11.023.
[2] Rector TS, Tschumperlin LK, Kubo SH, Bank AJ, Francis GS, McDonald KM, Keeler CA, Silver MA. Use of the Living with Heart Failure Questionnaire to Ascertain Patients' Perspectives on Improvement in Quality of Life Versus Risk of Drug-induced Death. *J Cardiac Failure* 1995;1:201-206.

Table 9: Minnesota Living with Heart Failure by Visit

Visit	BAT + MM* N=163 Mean ± SD (95% CI)	MM* N=160 Mean ± SD (95% CI)	Difference (95% CI)**
Baseline	52.7 ± 23.7	50.8 ± 24.0	
6-Month Change	-19.8 (-23.1, -16.5)	-6.3 (-9.5, -3.1)	-13.5 (-18.1, -8.9)
12-Month Change	-17.0 (-20.4, -13.6)	-8.6 (-11.8, -5.4)	-8.4 (-13.1, -3.7)
24-Month Change	-18.0 (-21.7, -14.2)	-8.0 (-12.0, -4.0)	-10.0 (-15.5, -4.5)
*Statistics are estimated mean improvement and 95% confidence interval from repeated measures model **From generalized estimating equation repeated measures model with covariate for baseline value			

New York Heart Association (NYHA) Class was measured at the baseline, 6-, 12-, and 24-month visits. The frequency and percentage of subjects who improved in NYHA Class from baseline at each follow-up time point by treatment arm is presented. NYHA Class results are shown below in Table 10. Approximately 2/3 of the BAT + MM subjects improved at least one NYHA class across the follow-up visits. The percent (%) of subjects improving between the arms at 6, 12 and 24 months were higher in the BAT + MM arm compared to the MM arm.

Table 10: NYHA Class by Visit

Visit	BAT + MM*	MM *	Difference (95% CI)**
Baseline			
Class I	0.0% (0/163)	0.0% (0/160)	
Class II	4.9% (8/163)	5.6% (9/160)	
Class III	95.1% (155/163)	94.4% (151/160)	
Class IV	0.0% (0/163)	0.0% (0/160)	
6-Month	66.6 (59.2, 74.0)	36.8 (29.1, 44.6)	29.8 (19.1, 40.5)
12-Month	72.7 (65.6, 79.7)	40.8 (32.9, 48.7)	31.9 (21.2, 42.5)
24-Month	68.0 (60.0, 76.0)	41.1 (31.5, 50.6)	26.9 (14.4, 39.4)
*Statistics are estimated mean improvement and 95% confidence interval from repeated measures model **From generalized estimating equation repeated measures model with covariate for baseline value			

NT-proBNP was measured at the baseline, 6-, and 12-month visits. As shown in Table 11 below, at six months the BAT + MM arm showed a 17% relative reduction compared to +1% in the MM arm for a difference of -17%. At 12 months the BAT + MM arm showed a 9% relative reduction compared to an 11% in the MM arm for a difference of 3%.

Table 11: NT-proBNP by Visit

Visit	BAT + MM* N=163 Mean ± SD (95% CI)	MM* N=160 Mean ± SD (95% CI)	Difference (95% CI)**
Baseline	643.2 ± 0.3	634.3 ± 0.3	
6-Month	-16.7% (-26.4%, -5.7%)	0.9% (-9.9%, 13.1%)	-17.4% (-30.2%, -2.3%)
12-Month	-8.5% (-19.7%, 4.2%)	-11.0% (-23.1%, 2.8%)	2.9% (-15.4%, 25.0%)
*Statistics are estimated mean improvement and 95% confidence interval from repeated measures model **From generalized estimating equation repeated measures model with covariate for baseline value			

The hierarchical composite analysis using the Win Ratio was evaluated using the components of the cardiovascular morbidity and heart failure mortality endpoints and the Minnesota Living with Heart Failure Quality of Life. The following hierarchy was used, following the standard methodology for cardiovascular trials:

1. Cardiovascular Death
2. Heart transplant or LVAD
3. Number of hospitalizations or emergency department visits for heart failure using the expanded definition of heart failure
4. Number of unscheduled clinic visits w/IV diuretic using the expanded definition for heart failure
5. Change from baseline in Minnesota Living with Heart Failure Quality of Life at 12 months (5 points is minimal clinically relevant difference).

Table 12 demonstrates that the components of the Win Ratio, based on the primary endpoint as well as Minnesota Living with Heart Failure Quality of Life, resulted in a Win Ratio of 1.26 (95% CI 1.02, 1.58) reflecting beneficial trend in the heart transplant/LVAD over the course of the study and Minnesota Living with Heart Failure Quality of Life at 12 months.

Table 12: Win Ratio Analysis of Focused CV Mortality, HF morbidity and 12M MLWHF QoL

Endpoint Component	BAT+MM Win	MM Win
CV Death	3085 (50.2%)	3060 (49.8%)
Heart transplant or LVAD	1420 (73.0%)	526 (27.0%)
HF Event (Expanded definition)	3091 (47.2%)	3453 (52.8%)
Unscheduled clinic visits w/IV diuretic (Expanded definition)	51 (17.3%)	243 (82.7%)
Change in MLWHF at 12 months with imputation for missing data	5701 (63.5%)	3284 (36.5%)
Win Ratio with the hierarchy of: 1) CV Death, 2) Heart transplant or LVAD, 3) Number of hospitalizations for Heart Failure using the expanded definition of HF, 4) Number of unscheduled clinic visits w/IV diuretic using the expanded definition for HF, 5) Change in MLWHF QoL at 12 months with imputation for missing data. Percent of Total BAT+MM vs MM comparisons that did not end in a tie is 95.2%		

Freedom from all-cause mortality (all-cause death, LVAD and heart transplant) was also evaluated. In the BAT + MM arm, the crude event rate was 7.0 per 100 years with 38 events during 544 patient-years at risk. In the MM arm, the crude event rate was 10.4 per 100 years with 51 events during 492 patient-years at risk. As shown in Figure 1 below, the hazard ratio for all-cause mortality = 0.662 (95% CI 0.435, 1.007), representing a relative risk reduction of 34% in the BAT + MM arm compared with the MM arm. The hazard ratio for all-cause mortality using a per protocol analysis = 0.589 (95% CI 0.380, 0.923), representing a relative risk reduction of 41% in the BAT + MM arm compared with the MM arm.

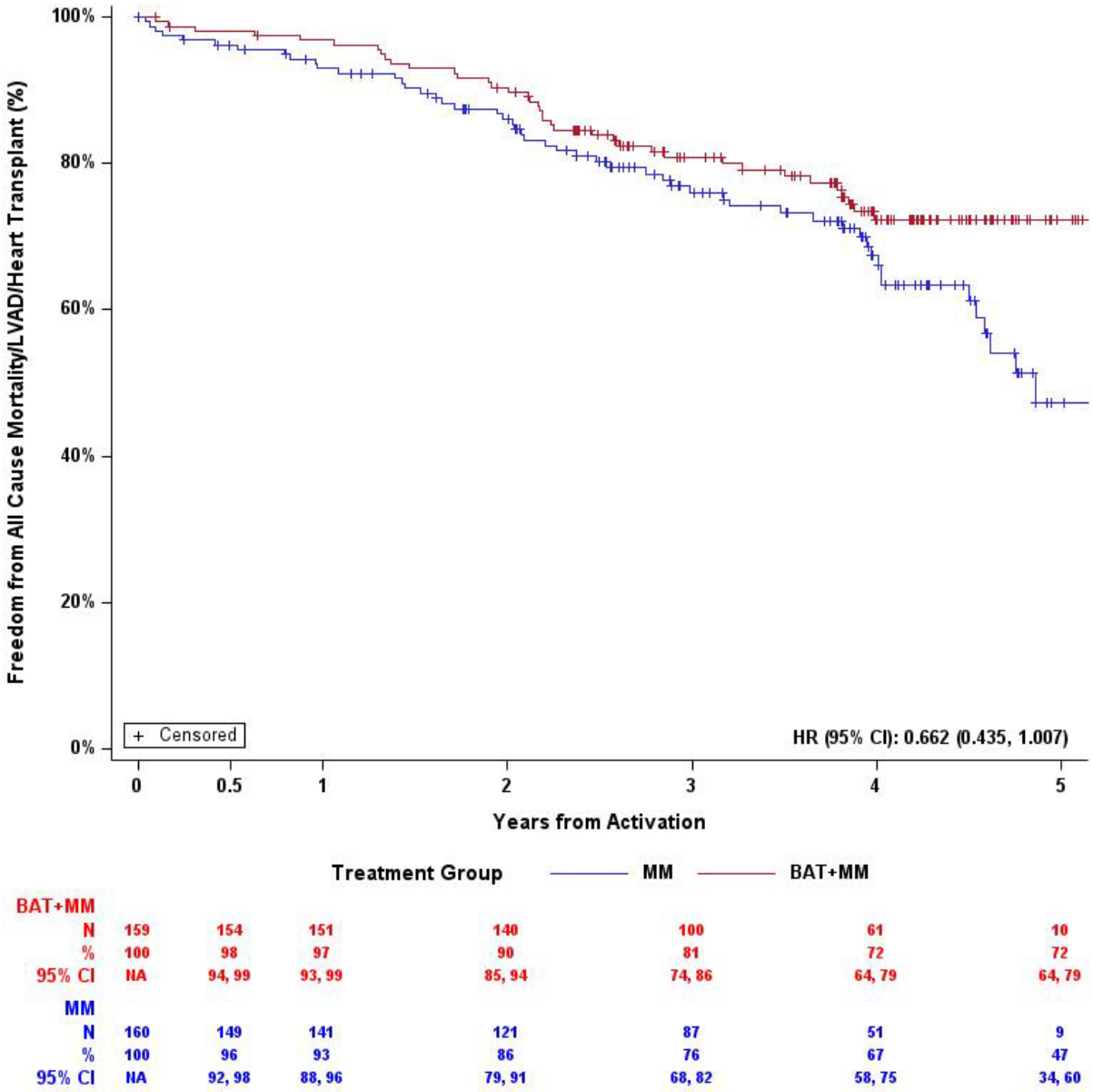


Figure 1: Kaplan-Meier Analysis of Freedom from All-Cause Mortality, LVAD and Heart Transplant

Study Limitations

The COVID-19 pandemic caused changes in care patterns and accessibility to healthcare and has been shown to have impacted multiple clinical studies. Analysis of the BeAT-HF data has demonstrated that there was a statistically significant interaction in the rate of HF morbidity in the MM arm during 2020, which was not evident in the BAT + MM arm. Further study is required to fully address this impact. The analyses shown in the primary effectiveness endpoint have not been adjusted for COVID.

Caution is required when interpreting the results of NT-proBNP as shown in Table 11 due to the large number of subjects that began ARNI during follow-up, particularly in the Control arm at 12 months, as well as the differential number of subjects censored in the control arm at 12 months.

Caution is required when interpreting the individual levels of the Win Ratio shown in Table 12 other than the first level of a hierarchical composite analysis using win ratio. In the table above, less than 60% of the HF events and Unscheduled clinic visits were evaluated for the third and fourth components, requiring careful interpretation.

Discussion and Conclusion

In the BeAT-HF Trial, safety was demonstrated in 159 subjects implanted over 6664 months of follow up with a system- or procedure-related MANCE-free rate of 96.9%. There were five MANCE events related to the system and/or the procedure of which all recovered, four 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. The primary safety endpoint was met and successful.

BAT + MM showed a directional reduction in the rate of cardiovascular (CV) mortality and heart failure (HF) morbidity between the arms [rate ratio (RR) = 0.94 (95% CI 0.57, 1.57, p-value = 0.82)], although not reaching statistical significance. Neither cardiovascular mortality (cardiovascular death, LVAD, heart transplant) nor HF morbidity (heart failure hospitalization and emergency room visit) reached statistical significance. The primary effectiveness endpoint was not met.

The pre-specified additional analysis of long-term measures of symptomatic improvement favored the BAT + MM arm. This includes improvements at 6 and 12 months in six-minute hall walk (6MHW) and at 6, 12 and 24 months in Minnesota Living With Heart Failure quality of life (MLWHF QOL) and New York Heart Association (NYHA) Class. For 6MHW in the BAT + MM arm, subjects improved 47 meters at 6 months and 41 meters at 12 months, while the MM arm decreased 9 and 3 meters at 6 and 12 months, respectively, for a clinically meaningful difference between the arms of 56 meters at 6 months and 44 meters at 12 months. The BAT + MM arm improved in MLWHF QOL almost 20 points at 6, 12 and 24 months resulting in a clinically meaningful difference of -14, -8 and -10 points at 6, 12 and 24 months, respectively, between the arms. Similarly, at least 67% of BAT + MM subjects improved at least one NYHA Class at 6, 12 and 24 months, also resulting in differences between the arms. Over 12% of the BAT + MM arm improved to a NYHA Class I at 6, 12 or 24 months.

The pre-specified additional analysis of the hierarchical Win Ratio of the components of the CV mortality and HF morbidity and the MLWHF QOL resulted in a WR=1.26 (95% CI 1.02, 1.58) reflecting a beneficial trend in the BAT + MM arm for heart transplant / LVAD over the course of the study and the Minnesota Living with Heart Failure Quality of Life at 12 months.

The prespecified additional analysis of freedom from all-cause mortality (all-cause death, LVAD and heart transplant) demonstrated a 34% reduction between the arms [(HR = 0.66 (95% CI 0.435, 1.007)]. A per protocol sensitivity analysis of the same endpoint showed a reduction of 41% [HR = 0.59 (95% CI 0.380, 0.912)].

In summary, the primary safety endpoint in the Pre-Market Phase was previously met and confirmed in the Post-Market Phase. In the Pre-Market Phase, all effectiveness endpoints were previously met, demonstrating 6-months improvements in 6MHW, quality of life, NYHA Class and NT-proBNP. The Post-Market Phase effectiveness primary endpoint of CV death and HF hospitalization was not met. Additional Post-Market Phase effectiveness analyses (Win Ratio, freedom from all-cause mortality) suggested a favorable effect of Barostim therapy. The totality of the 6, 12 and 24-month data demonstrated symptomatic improvements for heart failure patients who are NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed therapies and have a left ventricular ejection fraction≤35% and a NT-proBNP<1600 pg/ml.

7
Patient Preference Information

Patient Preference Information

When assessing therapies to treat heart failure patients, an additional consideration may be the factors that patients' value when treating their disease and involved in shared decision making with the patient. Patient preference information (PPI) to assess what patients' value most when treating their diseases may be obtained by designing and performing scientifically based PPI studies is a recent development for medical devices. Several tools, publications and FDA guidance have been published to educate, guide and inform the medical device industry, academia, regulators and clinicians using patient engagement materials like PPI studies since 2012. Some of these tools have been created in concert with the Medical Device Innovation Consortium (MDIC)[3],[4] an organization founded by FDA/CDRH, industry and academia to advance the regulatory science for the medical device industry in a safe collaborative environment.

To quantify heart failure patients' perspectives of the benefit-risk tradeoffs associated with heart failure medical devices MDIC executed a heart failure PPI study.[5] The MDIC PPI study was a unique collaborative project that included MDIC staff, FDA/CDRH heart failure review and patient engagement staff, six industry companies including CVRx, Inc., Duke Clinical Research Institute (DCRI) and patients with heart failure. 613 evaluable patients (mean age, 65; 49% female) with heart failure recruited from a national web panel or academic medical center completed a web based discrete-choice experiment survey in which they were randomized to one of a set of experimentally controlled choice questions comprised of two catheter-based device scenarios and a no-device scenario. Each scenario provided patients with opportunities to choose their preferences among a variety of risks and benefits associated with heart failure treatment options, including the following attributes and combinations of these attributes:

Benefits

- 1-year extension of life with functioning equivalent to New York Heart Association (NYHA) class II
- 1-year extension of life with functioning equivalent to New York Heart Association (NYHA) class III
- Associated extended survival times
- A remote adjustment device feature

Risks

- 30-day mortality risks ranging from 0% to 15%
- In-hospital complication risks ranging from 0% to 40%

[3] Ho M, Saha A, McCleary KK, et al. A Framework for Incorporating Patient Preferences Regarding Benefits and Risks into Regulatory Assessment of Medical Technologies. *Value Health J Int Soc Pharmacoeconomics Outcomes Res*. 2016;19(6):746-750. doi:10.1016/j.jval.2016.02.019

[4] Rincon-Gonzalez L, Selig WKD, Hauber B, et al. Leveraging Patient Preference Information in Medical Device Clinical Trial Design. *Ther Innov Regul Sci*. 2023;57(1):152-159. doi:10.1007/s43441-022-00450-9

[5] Reed SD, Yang JC, Rickert T, et al. Quantifying Benefit-Risk Preferences for Heart Failure Devices: A Stated-Preference Study. *Circ Heart Fail*. 2022;15(1):e008797. doi:10.1161/CIRCHEARTFAILURE.121.008797

Baroreflex activation therapy (BAT) performance may be compared (with some limitations) to the patient preference results based on these BeAT-HF study outcomes:

- The cardiovascular mortality component of the primary composite endpoint
  - Limitation: the patient preference study limited the definition to 30-day mortality; the BeAT-HF study measured the cumulative rate over four years.
- The major adverse neurological or cardiovascular events (MANCE) the primary safety endpoint or procedure/device-related event rate as one of the secondary trial endpoints
  - Limitation: the patient preference study limited the definition of an adverse event to an in-hospital complication resulting in a 2-day hospital stay; the BeAT-HF study measured the cumulative MANCE rate

The major limitation of the application of the PPI study is that the definitions of the preference study's attributes do not correlate exactly to the endpoints identified in the clinical trial. That said, the similarity of the preference study attributes and clinical trial endpoints, combined with the significant performance of BAT compared to patient expectations for success (see Table 13 below), indicate that BAT meets or exceeds the patient population's expectations for benefit/risk.

Table 13: Comparison of PPI Benefits/Risk with BAT Performance

	Patient Tolerance for Risk		BAT Performance	
	Maximum Risk of 30-Day Mortality	AE with 2-day hospital stay	30-Day Mortality	AE with 2-day hospital stay
One-year life extension in NYHA Class II	6%	27%	0%	3%*
One-year NYHA Class III life	5%	21%		

*The BeAT-HF Study Barostim MANCE event free rate was 97% over the course of the study. Regardless, this is well within the tolerance levels of heart failure patients, given BAT's benefits, namely improved NYHA functional status.

Patient Preference Summary and Conclusion

This patient preference study indicated that people suffering heart failure symptoms were inclined to prefer treatments that met the following criteria:

- Increased lifespan with improved physical functioning (measured using the NYHA Class system)
- Less than a 5% risk of death within 30 days
- Less than a 21% risk of a complication resulting in a 2-day hospital stay

The Barostim device performed better than these patient expectations in its clinical study, indicating that the Barostim device meets or exceeds the benefit/risk requirements of most people with heart failure.

8
Physician and Training Experience

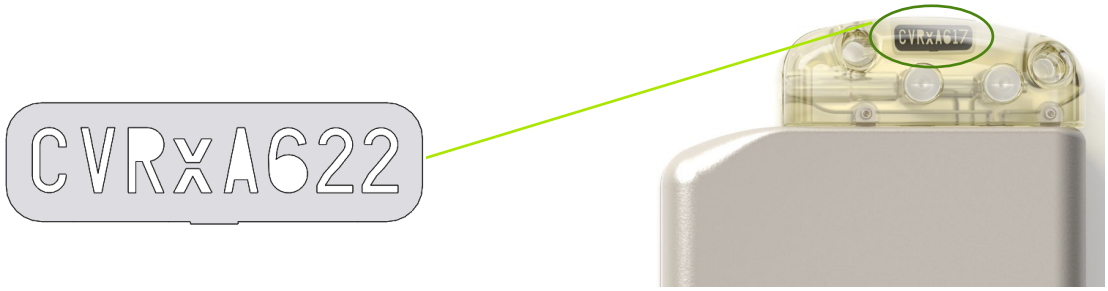
TRAINING REQUIREMENTS

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

9
Emergency Personnel Information

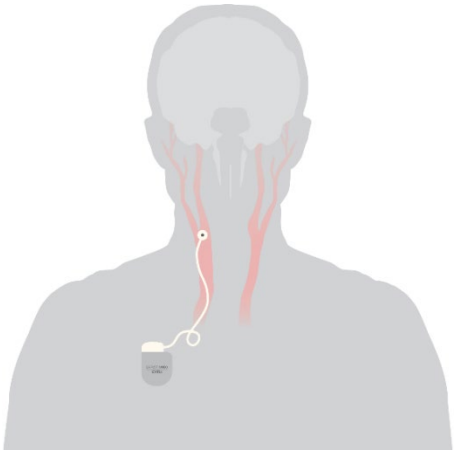
RADIOPAQUE IDENTIFIER

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. Artifacts may appear as higher frequency signals.

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 necessary to perform other medical diagnostics (ECG), procedures or surgeries. 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. The specific duration of inhibiting therapy is at the discretion of the medical staff.

10
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 and 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.

11
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 (MODEL 1036)

Specification	Value (Nominal)
Length	Model 1036: 40 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 and 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.

12 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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