

# BAROSTIM<sup>TM</sup>

## 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 NEO™ & NEO2™ Systems. The full IFU consists of:

|                      |            |
|----------------------|------------|
| System Overview      | 900133-001 |
| Surgical Procedures  | 900133-002 |
| Programming          | 900133-003 |
| Patient Instructions | 900133-005 |

IFU documents are available at [www.cvr.com/ifu](http://www.cvr.com/ifu)

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# 1

## System Description

The Barostim NEO™ & NEO2™ Systems include 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 NEO & NEO2 Systems are minimally-invasive using CVRx® patented Barostim™ technology. The Barostim systems are 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 through the Carotid Sinus Lead to the baroreceptors.

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



## CAROTID SINUS LEAD (CSL) KIT MODEL 1036 OR 1037

The Carotid Sinus Lead conducts Barostim 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

### PGM Programmer Software/Computer

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.

### PGM Programmer Interface

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

## OPTIONAL ACCESSORIES FOR USE WITH THE SYSTEM

### CSL Repair Kit Model 5010

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

# 2

## Symbols and Definitions



|                                                                              | Caution, Consult Accompanying Documents                                                                    |  |                                |                 |                                                                                                                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|--|--------------------------------|-----------------|---------------------------------------------------------------------------------------------------------------------------------------|
| <br><small>www.cvr.com/ifu</small>                                           | Consult Instructions for Use                                                                               |  |                                |                 |                                                                                                                                       |
|                                                                              | Do Not Reuse                                                                                               |  |                                |                 |                                                                                                                                       |
|                                                                              | Do Not Resterilize                                                                                         |  |                                |                 |                                                                                                                                       |
|                                                                              | Temperature Limitation                                                                                     |  |                                |                 |                                                                                                                                       |
|                                                                              | Date of Manufacture                                                                                        |  |                                |                 |                                                                                                                                       |
|                                                                              | Manufacturer                                                                                               |  |                                |                 |                                                                                                                                       |
|                                                                              | Use By Date                                                                                                |  |                                |                 |                                                                                                                                       |
|                                                                              | Peel Here                                                                                                  |  |                                |                 |                                                                                                                                       |
| <b>STERILE</b> <b>EO</b>                                                                                                                                      | Sterilized using Ethylene Oxide                                                                            |  |                                |                 |                                                                                                                                       |
|                                                                              | Equipment includes RF transmitter                                                                          |  |                                |                 |                                                                                                                                       |
| <b>LOT</b>                                                                                                                                                    | Batch Code (Lot Number)                                                                                    |  |                                |                 |                                                                                                                                       |
| <b>MODEL</b>                                                                                                                                                  | Product Model Number                                                                                       |  |                                |                 |                                                                                                                                       |
| <b>SN</b>                                                                                                                                                     | Serial Number                                                                                              |  |                                |                 |                                                                                                                                       |
| <b>P/N</b>                                                                                                                                                    | Part Number                                                                                                |  |                                |                 |                                                                                                                                       |
| <b>REF</b>                                                                                                                                                    | Catalogue Number                                                                                           |  |                                |                 |                                                                                                                                       |
| <b>CONTENTS</b>                                                                                                                                               | Package Contents                                                                                           |  |                                |                 |                                                                                                                                       |
| <b>PATENTS</b>                                                                                                                                                | Product Protected by One or More US Patents as listed (International patents & additional patents pending) |  |                                |                 |                                                                                                                                       |
|                                                                            | Keep Dry                                                                                                   |  |                                |                 |                                                                                                                                       |
|                                                                            | This Way Up                                                                                                |  |                                |                 |                                                                                                                                       |
|                                                                            | Fragile, Handle with Care                                                                                  |  |                                |                 |                                                                                                                                       |
|                                                                            | Do Not Use if Package is Damaged                                                                           |  |                                |                 |                                                                                                                                       |
|                                                                            | WEEE Directive Symbol (Special Disposal Required)                                                          |  |                                |                 |                                                                                                                                       |
|                                                                            | This Device is Not Intended for the Treatment of Bradycardia or Tachycardia                                |  |                                |                 |                                                                                                                                       |
|                                                                            | OFF; IPG Programmed Mode as Shipped                                                                        |  |                                |                 |                                                                                                                                       |
| <b>CVRx System Only</b>                                                                                                                                       | This Device is for Use with CVRx System Only                                                               |  |                                |                 |                                                                                                                                       |
| <table border="1"> <tr> <th colspan="2">Intended Use: Barostim</th></tr> <tr> <td>Compatible Lead Models<br/>103x</td><td>Lead Ports<br/>1</td></tr> </table> | Intended Use: Barostim                                                                                     |  | Compatible Lead Models<br>103x | Lead Ports<br>1 | This Device is for Use with CVRx IPG Model 2104 and Unipolar Lead Models 1036 and 1037 only and not compatible with lead models 101x. |
| Intended Use: Barostim                                                                                                                                        |                                                                                                            |  |                                |                 |                                                                                                                                       |
| Compatible Lead Models<br>103x                                                                                                                                | Lead Ports<br>1                                                                                            |  |                                |                 |                                                                                                                                       |
|                                                                            | No pacemakers                                                                                              |  |                                |                 |                                                                                                                                       |
|                                                                            | Programmer Interface Power Status                                                                          |  |                                |                 |                                                                                                                                       |
|                                                                            | Programmer Interface USB connection status                                                                 |  |                                |                 |                                                                                                                                       |

# 3

## Indications and Contra-indications

## INDICATIONS:

The Barostim NEO™ & NEO2™ Systems are 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  $\leq 35\%$ , 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.

# 4

## Warnings and Precautions

## GENERAL

The safety and effectiveness of Barostim 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.
- Do not use Magnetic Resonance Imaging (MRI) on patients implanted with the 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 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 is observed, a CVRx representative should be contacted immediately.
  - Low lead impedance, less than 300 Ohms, may indicate a short in the lead.
  - High lead impedance, greater than 3000 Ohms, may indicate poor lead connection to IPG or a lead fracture.
  - Drastic changes in lead impedance may indicate a problem with a lead.
- Do not place the IPG on a magnetic instrument drape. Doing so may temporarily stop therapy.
- An additional IPG should be available in the event of compromised sterility or if damage is induced during surgery.
- End of Service (EOS) is indicated when the IPG battery voltage is too low to support therapy delivery. Therapy is disabled when EOS is determined. Other IPG functions, such as lead impedance measurement and telemetry communication, will still operate after EOS is reached. However, these functions will eventually cease when the battery voltage is too low to support these functions.



## CSL

### CSL Warnings

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



### CSL Precautions

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



## PROGRAMMER

### Programmer Warnings

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

### Programmer Precautions

- The components of the Programmer System should not be sterilized.

- The following are requirements to comply with IEC 60601-1 and IEC 60601-1-1:



- The computer/tablet and power supply should be located outside the patient environment when the computer is operated on mains power.
- The system should not be connected to other non-isolated monitoring equipment or communication networks.
- The operator should not touch the computer/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.

Note: The patient environment is defined as the area within 1.5m (approximately 5ft) of the patient.

- Plug the Programmer System directly into an outlet or operate using 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.

## 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 (1:1), two-arm controlled trial to establish a reasonable assurance of safety and effectiveness of the Barostim NEO Systems 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  $\leq 35\%$  within 45 days prior to randomization.
- □Heart failure accompanied by BNP  $\geq 100$  or NT-proBNP  $\geq 400$  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 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  $\leq 35\%$  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   |

|                                    | BAT + Medical Management |                       |           | Medical Management |                       |           |         |
|------------------------------------|--------------------------|-----------------------|-----------|--------------------|-----------------------|-----------|---------|
| Variable                           | N                        | Mean ± SD<br>or N (%) | Range     | N                  | Mean ± SD<br>or N (%) | Range     | P-value |
| 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/m <sup>2</sup> )           | 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**

|                         | BAT + Medical Management |                       |       | Medical Management |                       |       |         |
|-------------------------|--------------------------|-----------------------|-------|--------------------|-----------------------|-------|---------|
| Variable                | N                        | Mean ± SD<br>or N (%) | Range | N                  | Mean ± SD<br>or N (%) | Range | P-value |
| 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   |

|                        | BAT + Medical Management |                    |       | Medical Management |                    |       |         |
|------------------------|--------------------------|--------------------|-------|--------------------|--------------------|-------|---------|
| Variable               | N                        | Mean ± SD or N (%) | Range | N                  | Mean ± SD or N (%) | Range | P-value |
| 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 Lifetest and 1 loop recorder).

Table 4: Heart Failure Treatments at Baseline - Intended Use

|                     | BAT + Medical Management |                    |          | Medical Management |                    |          |         |
|---------------------|--------------------------|--------------------|----------|--------------------|--------------------|----------|---------|
| Treatment           | N                        | Mean ± SD or N (%) | Range    | N                  | Mean ± SD or N (%) | Range    | P-value |
| 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   |

|                                         | BAT + Medical Management |                    |       | Medical Management |                    |       |         |
|-----------------------------------------|--------------------------|--------------------|-------|--------------------|--------------------|-------|---------|
| Treatment                               | N                        | Mean ± SD or N (%) | Range | N                  | Mean ± SD or N (%) | Range | P-value |
| 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**

|                        | Implanted Subjects (N=125) |                    |            |
|------------------------|----------------------------|--------------------|------------|
| Event                  | 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%       |

|                                           | Implanted Subjects<br>(N=125) |                          |               |
|-------------------------------------------|-------------------------------|--------------------------|---------------|
| Event                                     | Number<br>of Events           | Number<br>of<br>Subjects | Event<br>Rate |
| 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%          |
| <b>Total</b>                              | <b>4</b>                      | <b>4</b>                 | <b>3.2%</b>   |

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**

|                                                                                         | Implanted Subjects<br>(N=125) |                       |             |
|-----------------------------------------------------------------------------------------|-------------------------------|-----------------------|-------------|
| Event                                                                                   | Number of<br>Events           | Number of<br>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 Explanation   | 2                             | 2                     | 1.6%        |
| Surgical or Anesthetic Complications, Other Surgical Complication, prolonged intubation | 1                             | 1                     | 0.8%        |
| Thromboembolism, Systemic                                                               | 1                             | 1                     | 0.8%        |
| <b>Total</b>                                                                            | <b>12</b>                     | <b>9</b>              | <b>7.2%</b> |
|                                                                                         | Implanted Subjects<br>(N=125) |                       |             |
| Event                                                                                   | Number of<br>Events           | Number of<br>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%        |
| Severe Complications of Heart Failure Treatment                                         | 1                             | 1                     | 0.8%        |
| Stroke (CVA), Ischemic                                                                  | 1                             | 1                     | 0.8%        |

|                                                                                             | Implanted Subjects<br>(N=125) |                       |             |
|---------------------------------------------------------------------------------------------|-------------------------------|-----------------------|-------------|
| Event                                                                                       | Number of<br>Events           | Number of<br>Subjects | Event Rate  |
| Surgical or Anesthetic Complications,<br>Infection at Implant Site (No Explant)             | 1                             | 1                     | 0.8%        |
| Surgical or Anesthetic Complications,<br>Infection at Implant Site Requiring<br>Explanation | 1                             | 1                     | 0.8%        |
| Surgical or Anesthetic Complications, Other<br>Surgical Complication, prolonged intubation  | 1                             | 1                     | 0.8%        |
| Thromboembolism, Systemic                                                                   | 1                             | 1                     | 0.8%        |
| <b>Total</b>                                                                                | <b>12</b>                     | <b>9</b>              | <b>7.2%</b> |

During the study, there were three contralateral ICD implants that had interactions with the NEO IPG. 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 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.<sup>1</sup> 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.

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**

<sup>1</sup> 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.

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

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



|                                    | BAT<br>(N=125)                |                                          | Control<br>(N=134)            |                                          |                                           |              |
|------------------------------------|-------------------------------|------------------------------------------|-------------------------------|------------------------------------------|-------------------------------------------|--------------|
| Serious Adverse Event              | Number of Events (# subjects) | Event Rate per patient year of follow-up | Number of Events (# subjects) | Event Rate per patient year of follow-up | Relative Reduction in Event Rate (95% CI) | p-value      |
| 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        |
| <b>Total</b>                       | <b>15 (11)</b>                | <b>0.101</b>                             | <b>34 (22)</b>                | <b>0.206</b>                             | <b>0.51 (0.10, 0.73)</b>                  | <b>0.023</b> |

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.

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 8 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**

|         | BAT + Medical Management |                          | Medical Management |                           | Difference*       |         |
|---------|--------------------------|--------------------------|--------------------|---------------------------|-------------------|---------|
| Cohort  | N                        | Mean±SD (95% CI)         | N                  | Mean±SD (95% CI)          | Δ Means (95% CI)  | p-value |
| 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  |

|                                                                                         | BAT + Medical Management |                          | Medical Management |                          | Difference*       |         |
|-----------------------------------------------------------------------------------------|--------------------------|--------------------------|--------------------|--------------------------|-------------------|---------|
| Cohort                                                                                  | N                        | Mean±SD (95% CI)         | N                  | Mean±SD (95% CI)         | Δ Means (95% CI)  | p-value |
| 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 9 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**

|                                                                                         | BAT + Medical Management |                             | Medical Management |                           | Difference*         |         |
|-----------------------------------------------------------------------------------------|--------------------------|-----------------------------|--------------------|---------------------------|---------------------|---------|
| Cohort                                                                                  | N                        | Mean±SD (95% CI)            | N                  | Mean±SD (95% CI)          | Δ Means (95% CI)    | p-value |
| 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 10 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**

|                                                                                                                                                                                                                                                                                                                               | BAT + Medical Management |                              | Medical Management |                            | Difference*             |         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|------------------------------|--------------------|----------------------------|-------------------------|---------|
| Cohort                                                                                                                                                                                                                                                                                                                        | N                        | Mean±SD (95% CI)**           | N                  | Mean±SD (95% CI)**         | Δ Means (95% CI)**      | p-value |
| 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   |
| <p>*The difference is evaluated based on an ANCOVA model adjusting for the baseline value.<br/> **Results modeled parametrically on the log10 scale. Results are converted to percent change from baseline using <math>[10^{**}(\log_{10}(a) - \log_{10}(b)) - 1 = (a-b)/b]</math>. Standard deviation is on log10 scale.</p> |                          |                              |                    |                            |                         |         |

Table 11 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**

|                    | BAT + Medical Management |            | Medical Management |            |         |
|--------------------|--------------------------|------------|--------------------|------------|---------|
| Change in NYHA     | N                        | N (%)      | N                  | N (%)      | P-value |
| 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).<sup>1</sup> 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<sup>4</sup> 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

<sup>4</sup> 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. (Error! Reference source not found.)

### 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  $\leq 35\%$  and a NT-proBNP  $< 1600$  pg/ml, excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.

7

# Physician and Training Experience

## TRAINING REQUIREMENTS

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

# 8

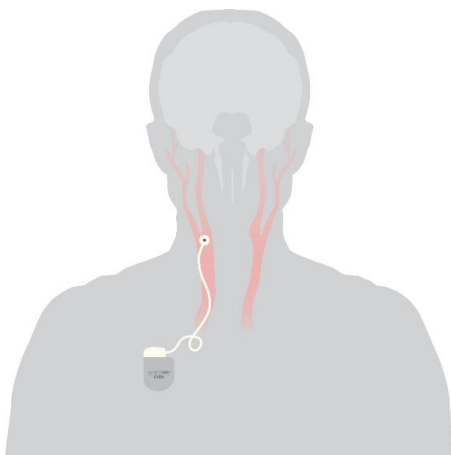
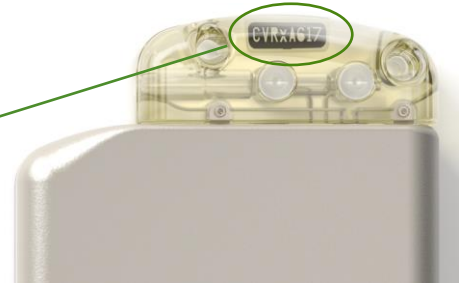
## Emergency Personnel Information



## 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.

CVRxA619



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: 19=2019).

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

## ECG ARTIFACT

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

## TEMPORARILY INHIBITING THE IPG OUTPUT

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

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<br>Unipolar Stimulation<br>1.5 mm lead pin bore diameter<br>3.48 mm lead shaft bore diameter    |                                                                                   |
| Materials                                      | Titanium Can<br>Polyurethane Header<br>Silicone Seals<br>Stainless Steel Setscrews                         |                                                                                   |
| Leads                                          | Use only CVRx® lead Models 103x                                                                            |                                                                                   |
| Materials in Port Plug                         | Port Plug not supplied nor required                                                                        | One port plug provided:<br>Comprised of a Stainless Steel shaft and silicone body |
| Battery                                        | 1 carbon monofluoride and silver vanadium oxide cell<br>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<br>Any time during the day<br>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<br>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.<br>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.<br>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<br>Model 1037: 50 cm                                                                     |
| Compatibility                      | Compatible with CVRx® Barostim NEO & NEO2™                                                                 |
| Connector                          |                                                                                                            |
| Connector Type                     | Compatible with CVRx® Barostim NEO 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, Neo, NEO2 and 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)<br>9020: 50° F to 95° F (10° C to 35° C)<br>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)<br>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<br>IEC60601-1-2 System Clause  | <p>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 3<sup>rd</sup> 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.</p> |                      |
| Programmer Interface<br>IEC60601-1 System Clause | The Programmer Interface is suitable for use in the patient environment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                      |
| System Installation and Maintenance              | <p>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.</p> <p>Inspect the Programmer Interface, computer/tablet and cables prior to each use. Notify CVRx® or your CVRx representative of any items that need replacement.</p>                                                                                                                                                                                                                                                                                                                                                                          |                      |

## Computer/Tablet

| Specification               | Value                                                                                               |
|-----------------------------|-----------------------------------------------------------------------------------------------------|
| Safety and EMC Requirements | EN 60950-1<br>EN IEC 62368-1<br>UL 60950-1<br>EN 55022<br>EN 55024<br>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                                                                 | <p>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.</p> <p>No preventative maintenance is required.</p> <p>Do not use programmer system if programming unit or cables appear damaged.</p> <p>There are no serviceable items.</p> <p>Please contact CVRx® representative to return product for service or replacement.</p> |
| Equipment Supply Disconnect                                                                              | Unplug power cord to isolate equipment from supply mains.                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Manufacturer Name                                                                                        | CVRx, Inc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Model #(s)                                                                                               | Programmer System: Model 9010<br>Programmer System Model 9020                                                                                                                                                                                                                                                                                                                                                                                                              |
| Power Supply                                                                                             | <p><b>9010:</b></p> <p>Input Voltage: 100-240V<br/>Input Current: 0.6A<br/>Input Frequency: 50/60Hz<br/>Output Voltage: 20V<br/>Output Current: 3.25A<br/>Output Power: 65W</p> <p><b>9020:</b></p> <p>Input Voltage: 100-240V<br/>Input Current: 0.6A<br/>Input Frequency: 50/60Hz<br/>Output Voltage: 15V<br/>Output Current: 1.6A<br/>Output Power: 24W</p>                                                                                                             |

| Description         | Information                                                                                                |
|---------------------|------------------------------------------------------------------------------------------------------------|
| 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: SVHBAROSTIMPG1 (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.

# 12

## Electromagnetic Compatibility Declarations

Model 9010  
Programmer System

## PROGRAMMER SYSTEM EMC PRECAUTIONS

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

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

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

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

## PROGRAMMER SYSTEM RF SPECIFICATIONS

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

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

- 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<br>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.<br><br>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. |
| RF emissions<br>CISPR 11                                                                                                                                                                                                    | Class B    |                                                                                                                                                                                                                                                                                                                                                                                                                |
| Harmonic emissions<br>IEC 61000-3-2                                                                                                                                                                                         | Class A    |                                                                                                                                                                                                                                                                                                                                                                                                                |
| Voltage fluctuations / flicker emissions<br>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)<br><br>IEC 61000-4-2                                                                                                                                                                          | ± 6 kV contact<br><br>± 8 kV air                                                                                                                                                                                | ± 6 kV contact<br><br>± 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<br><br>IEC 61000-4-4                                                                                                                                                                        | ± 2 kV for power supply lines<br><br>± 1 kV for input/output lines                                                                                                                                              | ± 2 kV for power supply lines<br><br>± 1 kV for input/output lines                                                                                                                                              | Mains power quality should be that of a typical commercial or hospital environment.                                                                                                                                                                                                                                      |
| Surge<br><br>IEC 61000-4-5                                                                                                                                                                                                  | ± 1 kV line(s) to line(s)<br><br>± 2 kV line(s) to earth                                                                                                                                                        | ± 1 kV differential mode<br><br>± 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<br><br>IEC 61000-4-11                                                                                                                  | <5 % $U_T$<br>(>95 % dip in $U_T$ for 0,5 cycle)<br><br>40 % $U_T$<br>(60 % dip in $U_T$ for 5 cycles)<br><br>70 % $U_T$<br>(30 % dip in $U_T$ for 25 cycles)<br><br><5 % $U_T$<br>(>95 % dip in $U_T$ for 5 s) | <5 % $U_T$<br>(>95 % dip in $U_T$ for 0,5 cycle)<br><br>40 % $U_T$<br>(60 % dip in $U_T$ for 5 cycles)<br><br>70 % $U_T$<br>(30 % dip in $U_T$ for 25 cycles)<br><br><5 % $U_T$<br>(>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<br><br>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<br>IEC 61000-4-6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 3 Vrms<br>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.<br><br>Recommended separation distance<br>$d = \left[ \frac{3,5}{3} \right] \sqrt{P}$                                                                                                                                                                                                                                                                                                                                                           |
| Radiated RF<br>IEC 61000-4-3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 3 V/m<br>80 MHz to 2,5 GHz  | 3 V/m            | $d = \left[ \frac{3,5}{3} \right] \sqrt{P}$ 80 MHz to 800 MHz<br><br>$d = \left[ \frac{7}{3} \right] \sqrt{P}$ 800 MHz to 2,5 GHz<br><br>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).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup><br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br> |
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <sup>a</sup> 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. |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <sup>b</sup> 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<br><br>W                                                                                                                                                                                                                                                                                                                                                                                                                                              | Separation distance according to frequency of transmitter<br>m |                                             |                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 150 kHz to 80 MHz                                              | 80 MHz to 800 MHz                           | 800 MHz to 2,5 GHz                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | $d = \left[ \frac{3,5}{3} \right] \sqrt{P}$                    | $d = \left[ \frac{3,5}{3} \right] \sqrt{P}$ | $d = \left[ \frac{7}{3} \right] \sqrt{P}$ |
| 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.                                                                                                                                                                                                                                                                                                                              |                                                                |                                             |                                           |

# 13

## Electromagnetic Compatibility Declarations

### Model 9020 Programmer System

## PROGRAMMER SYSTEM EMC PRECAUTIONS

The 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 Programmer System.

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

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

## PROGRAMMER SYSTEM RF SPECIFICATIONS

The 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 Programmer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Programmer System should ensure that it is used in such an environment. |            |                                                                                                                                                                                                                                                                                                                                                                                          |
| Emissions Test                                                                                                                                                                                        | Compliance | Electromagnetic environment - guidance                                                                                                                                                                                                                                                                                                                                                   |
| RF emissions<br>CISPR 11                                                                                                                                                                              | Group 1    | The Programmer System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.<br><br>The 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. |
| RF emissions<br>CISPR 11                                                                                                                                                                              | Class B    |                                                                                                                                                                                                                                                                                                                                                                                          |
| Harmonic emissions<br>IEC 61000-3-2                                                                                                                                                                   | Class A    |                                                                                                                                                                                                                                                                                                                                                                                          |
| Voltage fluctuations / flicker emissions<br>IEC 61000-3-3                                                                                                                                             | Complies   |                                                                                                                                                                                                                                                                                                                                                                                          |

Table 18: Electromagnetic Immunity

| Guidance and manufacturer's declaration - electromagnetic immunity                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Programmer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Programmer System should ensure that it is used in such an environment. |                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                    |
| Immunity Test                                                                                                                                                                                         | IEC 60601 test level                                                                                                                                                                                                                                                                                                                                                   | Compliance level                                                                                                                                                                                                                                                                            | Electromagnetic environment - guidance                                                                                                                                                                                                                                                             |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2                                                                                                                                                        | ±8kV contact<br><br>±2kV, ±4kV, ±8kV, ±15kV air                                                                                                                                                                                                                                                                                                                        | ±8kV contact<br><br>±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 transients / bursts<br>IEC 61000-4-4                                                                                                                                                  | ± 2 kV<br>100kHz repetition frequency                                                                                                                                                                                                                                                                                                                                  | ± 2 kV                                                                                                                                                                                                                                                                                      | Mains power quality should be that of a typical commercial or hospital environment.                                                                                                                                                                                                                |
| Surges<br>IEC 61000-4-5                                                                                                                                                                               | ± 0.5kV, ± 1 kV line-to-line<br><br>± 0.5kV, ± 1 kV, ± 2 kV line-to-ground                                                                                                                                                                                                                                                                                             | ± 0.5kV, ± 1 kV line-to-line<br><br>± 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<br>IEC 61000-4-11                                                                                                                                                      | 0% U <sub>T</sub><br>(100% dip in U <sub>T</sub> for 0,5 cycle)<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°<br><br>0% U <sub>T</sub><br>(100% dip in U <sub>T</sub> for 1 cycle)<br><br>70% U <sub>T</sub><br>(30% dip in U <sub>T</sub> for 25/30 cycles)<br>Single phase: at 0°<br><br>0% U <sub>T</sub><br>(100% dip in U <sub>T</sub> for 250/300 cycles) | 0% U <sub>T</sub><br>(100% dip in U <sub>T</sub> for 0,5 cycle)<br><br>0% U <sub>T</sub><br>(100% dip in U <sub>T</sub> for 1 cycle)<br><br>70% U <sub>T</sub><br>(30% dip in U <sub>T</sub> for 25/30 cycles)<br><br>0 % U <sub>T</sub><br>(100% dip in U <sub>T</sub> 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<br>IEC 61000-4-8                                                                                                                                                | 30 A/m<br>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 <sub>T</sub> is the line voltage prior to application of the test level.                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                    |



| Guidance and manufacturer's declaration - electromagnetic immunity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                  |                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Programmer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Programmer System should ensure that it is used in such an environment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                  |                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Immunity Test                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | IEC 60601 test level                                                                                             | Compliance level           | Electromagnetic environment - guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <p>Conducted disturbances induced by RF fields<br/>IEC 61000-4-6</p> <p>Radiated RF EM fields<br/>IEC 61000-4-3</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>3 Vrms<br/>150 kHz to 80 MHz<br/>80 % AM at 1 kHz</p> <p>3 V/m<br/>80 MHz to 2,7 GHz<br/>80 % AM at 1 kHz</p> | <p>3 Vrms</p> <p>3 V/m</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the Programmer System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[ \frac{3,5}{3} \right] \sqrt{P}$ $d = \left[ \frac{3,5}{3} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[ \frac{7}{3} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                  |                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <p><sup>a</sup> 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 Programmer System is used exceeds the applicable RF compliance level above, the 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 Programmer System.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> |                                                                                                                  |                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

Table 3: 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<br>± 5 kHz deviation<br>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 4: Separation Distance

| Recommended separation distance between portable and mobile RF communications equipment and the Programmer System                                                                                                                                                                                                                                                                                                                                              |                                                                |                                             |                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|---------------------------------------------|-------------------------------------------|
| The Programmer System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Programmer System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Programmer System as recommended below, according to the maximum output power of the communications equipment. |                                                                |                                             |                                           |
| Rated maximum output power of transmitter<br><br>W                                                                                                                                                                                                                                                                                                                                                                                                             | Separation distance according to frequency of transmitter<br>m |                                             |                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 150 kHz to 80 MHz                                              | 80 MHz to 800 MHz                           | 800 MHz to 2,5 GHz                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                | $d = \left[ \frac{3,5}{3} \right] \sqrt{P}$                    | $d = \left[ \frac{3,5}{3} \right] \sqrt{P}$ | $d = \left[ \frac{7}{3} \right] \sqrt{P}$ |
| 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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