



Medtronic

CHRONICLE® 9520B

Implantable Hemodynamic Monitor

DRAFT

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Reference Manual

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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Introduction

About This Manual

The *Chronicle Implantable Hemodynamic Monitor 9520B Reference Manual* describes the operation and intended use of the Chronicle Implantable Hemodynamic Monitor 9520B system. The system provides hemodynamic monitoring.

Information provided in this manual is organized into the following chapters and appendices:

- 1 Quick overview
- 2 System overview
- 3 Implanting the device
- 4 Setting up collected data
- 5 Conducting a patient follow-up session
- 6 Using the programmer
- 7 Solving system problems
- Appendices:
 - A Warnings and precautions
 - B Parameters
 - C Clinical investigation
 - D Patient Management Strategies

Before you implant the device, it is strongly recommended that you read this manual and the additional literature provided with the device.

Programmer hardware

The information provided in this manual about using the programmer assumes that the Medtronic programmer is used.

Manual conventions

- Throughout this manual, the word “device” refers in general to Chronicle IHM device.
- On-screen buttons are shown with the name of the button within brackets: [Button Name].

New nomenclature for product battery life terms

This manual uses a new nomenclature for certain terms related to product battery life. This new nomenclature is defined in CENELEC pacemaker standard EN 45502-2-1:2003, which applies to Automatic Implantable Medical Devices (AIMD) intended to treat bradyarrhythmias. This standard was approved and published in December 2003.

Medtronic has adopted the new nomenclature to utilize consistent terminology with the CENELEC standard and in anticipation of the nomenclature becoming an international standard.

The new nomenclature, and the terms replaced by the new nomenclature, are presented in the following table:

New nomenclature		Old nomenclature	
BOS	Beginning of Service	BOL	Beginning of Life
EOS	End of Service	EOL	End of Life
RRT	Recommended Replacement Time	ERI	Elective Replacement Indicator
PSP	Prolonged service period	Post-ERI conditions	
Projected service life		Longevity	

Using this manual

Before you implant the Chronicle IHM device, it is strongly recommended that you follow these instructions:

- Refer to the product literature packaged with the Chronicle IHM device for information about prescribing the Chronicle IHM device.
- Thoroughly read this manual and the technical manuals for the leads used with the device.
- Discuss the procedure and the Chronicle IHM system with the patient and any other interested parties, and provide them with any patient information packaged with the Chronicle IHM device.

Technical support

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products.

In addition, Medtronic maintains a professional staff of consultants to provide technical consultation to product users. For medical consultation, Medtronic can often refer product users to outside medical consultants with appropriate expertise.

For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate address or telephone number listed on the back cover.

Customer education

Medtronic invites physicians to attend an educational seminar on the complete Chronicle IHM system. The course provides an overview of Chronicle IHM system functions and covers indications for use, implant procedures, and patient management information.

Notice

This software is provided as an informational tool for the end user. The user is responsible for accurate input of patient information into the software. Medtronic makes no representation as to the accuracy or completeness of the data input into the software. Medtronic SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES TO ANY THIRD PARTY WHICH RESULTS FROM THE USE OF THE INFORMATION PROVIDED IN THE SOFTWARE.

Abbreviations and acronyms

bpm	beats per minute
dP/dt	derivative pressure/derivative time
EGM	electrogram
ePAD	estimated pulmonary arterial diastolic pressure
EPR	external pressure reference
HF	heart failure
IHM	implantable hemodynamic monitor
mmHg	millimeters of mercury
MPAP	Mean Pulmonary Arterial Pressure
ms	milliseconds
PC	personal computer
PEI	pre-ejection interval
PSA	pacing system analyzer
PSL	pressure sensing lead
RV	right ventricle
RVOT	right ventricular outflow tract
STI	systolic time interval
V	volts

Quick reference **1**

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Primary capabilities

Data collection

- Accurate monitoring of cardiac filling pressures, dynamic pressure gradients, and cardiac sub-cycle times
- Compilation of each hemodynamic measurement into long-term clinical trends
- Automatic collection of high resolution event data during high or low heart rate episodes
- Patient-triggered collection of high resolution event data during symptomatic episodes

Note: Heart rates less than 30 bpm are recorded as 30 bpm. If an episode of asystole occurs during a low heart rate episode of less than 30 bpm, the asystolic episode appears as consecutive beats and is not detected.

Data retrieval

- Home-based transtelephonic retrieval of trend data
- Internet-based data access for clinicians through the Medtronic CareLink Network

Other features

- Medtronic icon-based user interface
- Full-size report printing
- Real-time telemetry of pressure, ventricular electrogram, and Marker Channel waveforms
- Save-to-Disk and Read-from-Disk patient data features

Physical characteristics

Physical specifications (nominal)

Table 1-1. 9520B device physical characteristics^a

Volume	14 cm ³
Mass	23 g
H x W x D ^b	43 mm x 59 mm x 8 mm
Surface area of device can	41 cm ²
Radiopaque ID ^c	PLM
Materials in contact with human tissue ^d	Titanium/polyurethane/silicone rubber
Battery	Lithium silver vanadium oxide or lithium hybrid ^e

^a Measurements are nominal values based on CAD (computer aided design) model measurements and are rounded to the nearest unit.

^b Grommets may protrude slightly beyond the can surface.

^c Engineering series number follows the radiopaque code.

^d These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue.

^e "Hybrid" denotes a mixture of carbon monofluoride (CFx) and silver vanadium oxide (SVO).

Lead compatibility

The device is to be implanted only with a Chronicle PSL (Pressure Sensing Lead).

Projected service life

The projected service life of 3.7 years on average for the Implantable Hemodynamic Monitor is based on the following assumptions:

- the typical 4 month shelf storage duration
- the suggested nominal program selection (all sensor parameters programmed to On) and an average heart rate of 70 bpm

The device measures and telemeters its battery voltage upon interrogation.

- When the telemetered voltage reaches 2.78 V, a highlighted area on the interrogate screen warns the user that the battery is approaching the end of its useful life. At 2.78 V, there is a minimum of 3 months of useful life remaining.
- When the telemetered voltage reaches 2.62 V, a highlighted area on the interrogate screen warns the user that the battery is below a usable level. In addition, a dialog box appears for each interrogation with the same message. At or below 2.62 V, pressure and temperature data are neither displayed nor printed.

Replacement indicators

Battery voltage and messages about replacement status appear on the programmer display and on printed reports. Battery voltage can be evaluated by interrogating the device. Table 1-2 lists the Recommended Replacement Time (RRT) and the End of Service (EOS) conditions.

Table 1-2. Replacement indicators

Recommended Replacement Time (RRT) voltage	≤ 2.78 V
End of Service (EOS) voltage	3 months after RRT

RRT date – The programmer displays the date when the battery reached RRT.

EOS indication – If the programmer indicates that the device is at EOS, replace the device immediately.

Prolonged service period after RRT – The prolonged service period is the time between the Recommended Replacement Time (RRT) and End of Service (EOS). The prolonged service period is defined as 3 months, assuming 70 bpm and with the pressure sensing lead enabled.

Magnet application

The device creates and stores a high resolution event record when a magnet is applied, such as in the Chronicle Tracker EPR Model 2955HF.

⚠ Warning: Do not place or carry the EPR over any other active implanted medical device. The EPR contains a strong magnet that could unintentionally change the operation of the other implanted device and prevent therapy.

⚠ Caution: Do not carry or wear the EPR over an implanted Chronicle IHM device. This could erase stored data and could result in premature depletion of the Chronicle IHM device battery.

Measurement, telemetry and diagnostic capabilities

Clinical trend reporting – Right and estimated left side filling pressures, dynamic pressure gradients, and cardiac sub-cycle times.

Automatic event collection – High resolution data during high or low heart rate episodes.

Patient triggered event collection – High resolution event data during symptomatic episodes.

Electrical reset settings

For a list of values in effect after an electrical reset, refer to the POR column of the Functional parameters tables. The tables are located in Appendix B Parameters on page 95.

Factory shipped settings

For a list of which features are enabled at shipping, refer to the Shipping column of the Functional Parameters tables in Appendix B Parameters on page 95.

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System overview

The Chronicle IHM system is an implantable hemodynamic monitoring system that collects hemodynamic data for the chronic management of patients with heart failure.

The Chronicle Model 9520B, along with the Chronicle PSL Pressure Sensing Lead, constitutes the implantable portion of the Chronicle system. The lead is implanted using standard transvenous placement techniques.

The Chronicle system includes the following external constituents:

- Chronicle Tracker External Pressure Reference (EPR) Model 2955HF
- Medtronic CareLink Monitor for Chronicle Systems Model 2490F
- Chronicle Tracker EPR base cable
- Medtronic CareLink Network
- Medtronic programmer and Chronicle software application

Programmers from other manufacturers are not compatible.

Use of components

The Chronicle IHM, combined with the pressure sensing lead, measures and stores hemodynamic data, heart rate, patient activity, and temperature for the ambulatory patient. The patient also carries an external pressure reference (EPR), which corrects the intracardiac pressure data for any changes in the barometric pressure.

The Chronicle IHM and EPR data can be obtained through the programmer (for in-office visits) or viewed on the web-based Medtronic CareLink Network. The patient uses the Medtronic CareLink Monitor for Chronicle Systems to send Chronicle IHM and EPR data via a phone line in their home to the Medtronic CareLink Network. The data are then stored on the secure Medtronic CareLink Network for clinician viewing. Use of the data allows clinicians to assess a patient's hemodynamic status and to make clinical decisions to better manage a patient's heart failure.

Detailed instructions on using the individual components of the Chronicle system can be found in the technical and patient manuals for the respective components.

Indications and usage

The Medtronic Chronicle Implantable Hemodynamic Monitoring (IHM) system is indicated for the chronic management of patients with moderate to advanced heart failure who are in NYHA Class III or IV to reduce hospitalizations for worsening heart failure in these patients.

Contraindications

There are no known contraindications for the Medtronic Chronicle IHM system.

Refer to the pressure sensing lead technical manual for any contraindications specific to the lead.

⚠ Warning: Only the Medtronic Chronicle PSL is appropriate for use with the Chronicle IHM Model 9520B.

⚠ Warning: Do not implant the Model 9520B implantable hemodynamic monitor concomitantly with implanted cardiac devices from manufacturers other than Medtronic. Testing has not been performed on cardiac devices from other manufacturers to determine compatibility with the Model 9520B.

Implanting the device

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Implant overview

The device implant chapter includes the following topics:

1. Setting up programmer equipment
2. Initializing the device
3. Performing pre-implant calibration
4. Calibrating the lead and the device to the patient's EPR
5. Positioning the PSL
6. Testing lead operation
7. Connecting the lead to the device
8. Testing system performance at implant
9. Positioning and securing the device
10. Placing a concomitant device at implant
11. Replacing a Chronicle device
12. Replacing the Chronicle PSL

These topics are described in the sections that follow.

Preparing for an implant

▲ Warnings: Do not permit the patient to contact grounded equipment, which could produce hazardous leakage current during implantation. Resulting arrhythmia induction could result in the patient's death.

△ Caution: The device and lead must be used in an area where measures have been taken to reduce static electricity. These measures include, but are not limited to, grounding of personnel, equipment, and work surfaces. Preferably, the area in which the lead is implanted should have conductive flooring.

Equipment for an implant

The following equipment is needed for an implant:

Sterile supplies for an implant

The sterile supplies that are needed for an implant are as follows:

- an implantable Chronicle IHM device and a Chronicle PSL
- programming head sleeve or programming head
- lead introducers appropriate for the Chronicle PSL
- extra stylets of appropriate length and shape
- torque wrench

Non-sterile supplies for an implant

The non-sterile supplies that are needed for an implant are as follows:

- Medtronic programmer with programming head
- Chronicle software application
- Chronicle Tracker External Pressure Reference (EPR) Model 2955HF
- Chronicle Tracker EPR base cable
- pressure sensing lead calibration coefficient disk (within the pressure sensing lead package)
- 3 V disc battery (within the EPR package)
- printer (optional)

Setting up programmer equipment

This topic describes the basic steps for setting up equipment for the implant: setting up the programmer, connecting the EPR, and starting the application.

1. Set up the programmer as described in the instructions provided with the programmer. If you want to connect the programmer to a full-size printer, connect the printer cable to the parallel port.
2. Before placing the battery in the EPR, check the expiration date of the battery. Place the battery in the EPR.

3. Before turning on the programmer, place the patient's EPR in the base cable cradle. Connect the EPR base cable to the appropriate port located at the back of the programmer. For information about connecting the EPR, refer to the EPR technical manual.
4. Turn on the programmer. Install the software application on the programmer if it is not already installed.
5. Place the programming head over the device and start the application.

Note: To prevent EPR battery depletion, remove the EPR from the base cable cradle before ending a patient session on the programmer. If the EPR has been left in the base cable cradle for 7 hours or longer, the EPR battery should be replaced.

Initializing the device

△ **Caution:** Allow the device to reach room temperature before programming or implanting, because rapid temperature changes could affect initial device function and the accuracy of pre-implant calibration.

Certain Chronicle system information and patient-specific information is stored in the Chronicle IHM device. Use the programmer to initialize the Chronicle IHM device just prior to performing the pre-implant calibration.

Before opening the sterile package, prepare the device for implant as follows:

1. Check the "Use by" date printed on the package. Do not implant the device after the "Use by" date because the battery's longevity could be reduced.
2. Interrogate the device and print a full summary report for a baseline.

Note: Do not implant the device if the programmer reports that an electrical reset occurred. Notify your Medtronic representative.

3. Confirm that the battery voltage is at least 3.0 V at room temperature.

If the device has been exposed to lower temperatures, the battery voltage will be temporarily lower.

4. Set up the data collection parameters:

- a. Insert the lead coefficient disk into the programmer. Select the lead serial number and follow the directions on the programmer. Refer to the lead technical manual for information on lead calibration. Confirm the lead serial number.
 - b. Use the programmer to enter patient ID information.
 - c. Enter the patient's expected maximum systolic pressure.
 - d. Enter the expected altitude ranges for the patient's geographic location. If desired, save the selections in the programmer as the nominal values for altitude.
5. Set the internal device clock. See "Device clock" on page 55.

Performing pre-implant calibration

Pre-implant calibration is required before the Chronicle IHM device and the pressure sensing lead are implanted. Pre-implant calibration, performed to calibrate the device and lead to the EPR's barometric pressure, results in a pressure offset. The programmer uses the offset to adjust for differences between the barometric pressure measured by the EPR and the RV pressure measured by the pressure sensing lead and the device.

- △ **Caution:** Always sheath the programming head and cable in a sterile bag before bringing the head within the sterile field.
- △ **Caution:** During calibration, use only standard room lighting to illuminate the device and the pressure sensor. The high intensity lighting used during the implant procedure may radiate enough heat to cause calibration errors.
- △ **Caution:** During calibration, be sure that the diaphragm of the pressure sensor is not in contact with another object. Depression of the diaphragm may cause calibration errors.

Preparing for calibration

Before beginning calibration, follow these steps:

- **Connect the pressure sensing lead to the device within the sterile field.**
- Make sure that the programmed settings for Maximum Altitude and Minimum Altitude are appropriate for the patient. Nominal values are available if the values have been previously saved in the programmer.

Calibrating the device and lead to the patient's EPR

To calibrate the device and the pressure sensing lead to the patient's EPR using the programmer, follow these steps:

1. Program Data Collection to Off if this parameter is programmed to On.

Note: The Pre-Implant Calibration button is available only if Data Collection is programmed to Off.

2. Press [Pre-Implant Calibration] to initiate the pre-implant calibration sequence.
3. Follow the instructions on the "Lead and Device outside the body?" message window that appears. When you press [Calibrate], the "Test in Progress" message appears to let you know that sample collection is in progress.
4. Wait for the programmer to complete sample collection. This should take about 30 s.

Check the device and lead temperature value on the Live Rhythm Monitor. You should see a numerical value for the device and lead temperature on the Live Rhythm Monitor. If the device or lead has not equilibrated to the implant room temperature, follow these instructions:

- a. Gently place the device with the connected pressure sensing lead for 10 min in sterile water that is at the implant room temperature.

△ **Caution:** Do not immerse the unconnected device or unconnected lead in saline. Immersion in saline could cause localized corrosion to internal metal parts of the connector port and the lead. Normally, the connector port and surfaces are protected from corrosion because the lead is inserted into the connector port.

- b. Do not wipe the sensor. Use the free end of a gauze to wick all water from the entire pressure sensing lead. Carefully wipe the device dry.

If the pressure offset is within ± 10 mmHg, the pre-implant calibration is successful, and the "Calibration Successful" message window is displayed. This window shows the pressure offset, lead/device reading, and EPR reading.

5. Select [OK] or [Recalibrate] from the Calibration Successful message window.

After a successful calibration, verify the value of the Pre-Implant Cal Number shown.

6. Press [PROGRAM] to set the pending calibration value in the device.
7. If the message “Calibration Unsuccessful” is displayed, follow the steps below:
 - a. If the pressure offset is greater than ± 10 mmHg, carefully recheck the lead connections to the device connector and press [Recalibrate].
 - b. If a large pressure offset persists, follow the instructions displayed on the screen.

Disconnecting the pressure sensing lead and device

1. Before disconnecting the lead, be sure that the setscrew is fully disengaged to prevent damage to the lead sealing rings.
2. Carefully remove the lead from the connector block and proceed with the lead implant.

Positioning the Chronicle PSL

The pressure sensing lead is a transvenous lead. Implant transvenous leads according to the supplied instructions. Use standard transvenous implant techniques to position the pressure sensing lead tip in the right ventricular outflow tract. Refer to the pressure sensing lead technical manual for the recommended implant procedure, and related warnings and precautions.

Testing lead operation

It is important to perform the following tests to ensure the pressure sensing lead is placed in the correct position and is in contact with the tissue in the heart chamber:

- R-wave amplitude
- pacing threshold
- pacing lead impedance
- pressure waveform

Medtronic recommends that you use the Analyzer lead analysis device Model 8190, 5311, 5311B, or 2290 to perform pacing measurements. If you use a Pacing System Analyzer (PSA), perform the ventricular measurements through the ventricular channel of the PSA. Refer to the lead technical manual for the recommended implant procedure, method for testing the lead position, and instructions for obtaining R-wave amplitude and pacing measurements.

Note: The pressure sensing lead has a unipolar sensing and pacing configuration only; therefore, a unipolar setup configuration to the ring electrode is necessary to test sensing and pacing thresholds on the pressure sensing lead.

Measured sensing and pacing values on the pressure sensing lead must meet the requirements shown in Table 3-1.

Table 3-1. Sensing and pacing values on PSL at implant

Measurement	Pressure sensing lead
R-wave amplitude	≥ 5.0 mV
Pacing threshold	< 1.0 V ^a
Pacing impedance	300-800 Ω

^a At 0.5 ms pulse width

Testing system performance at implant

EGM sensing – The Chronicle IHM device should be programmed to reliably sense R-waves without T-wave oversensing. If the EGM waveform or sense markers are aberrant, refer to “R-wave sensing problems” on page 82.

Pressure waveform assessment – The pressure waveform should have a smooth morphology throughout the cardiac cycle. Non-physiologic peaks or overshoot may indicate recording artifact resulting from intracardiac anatomical structures mechanically interfering with the pressure sensing lead, while high-frequency noise may indicate an intermittent connection between the lead and IHM.

Proper functioning of the Chronicle device requires that it reliably collect pressure waveforms from the pressure sensing lead. Therefore, it is necessary to assess the pressure waveform to verify that the lead position is acceptable.

To verify lead position with a waveform assessment:

1. Connect the lead to the device and place the device into the pocket. See “Connecting the lead to the device” on page 31.
2. Place the programmer head on the device.
3. Assess the waveform to be sure that it has the following properties:

- a. The waveform is smooth, without spiky artifacts.
 - b. All beats have a consistent shape.
 - c. Physiological values are being measured.
4. Reposition the lead as necessary to obtain the desired result.
 5. Adjust the slack on the lead, giving the lead a moderate J-shape.

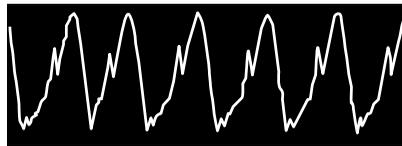
Note: It may be possible to give the lead extra stability by setting it on the floor of the atrium or against the lateral wall of the atrium.

Figure 3-1 and Figure 3-2 respectively show acceptable and unacceptable waveforms.

Figure 3-1. Acceptable waveforms



Figure 3-2. Unacceptable waveforms



In some patients, respirophasic baseline variation may be present. This is often due to the state of sedation of the patient. As long as the waveforms are smooth and consistent, this is acceptable in terms of lead placement. Figure 3-3 shows a waveform indicating acceptable respirophasic baseline variation.

Figure 3-3. Acceptable respirophasic baseline variation

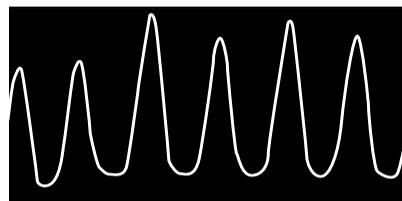
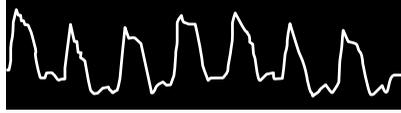


Figure 3-4 shows a waveform indicating unacceptable respirophasic baseline variation.

Figure 3-4. Unacceptable respirophasic baseline variation

Clipping of the pressure waveform occurs when the measured pressure is outside the preset range (see Figure 3-5). Clipping can be eliminated by selecting the appropriate maximum pressure and altitude via the Pressure Settings screen on the programmer.

Figure 3-5. Clipping

Diastolic pressure – The RV diastolic pressure should be reasonable for the patient’s known severity of heart failure and from filling pressure historical trends.

For information on normal pressure ranges, refer to Appendix C Clinical investigation on page 99. For information pertinent to pressure sensing problems, see “Pressure sensing problems” on page 83.

Temperature – The Chronicle system measures the patient’s temperature for the purposes of calibrating pressure and system diagnostics, and displays the temperature on the programmer. The implanted lead should measure the patient’s temperature between 35 °C and 39 °C, which is the range set for the device operation. If not, refer to “Temperature sensing problems” on page 84.

Note: Pressure and temperature values recorded during the immediate post-implant period (approximately 10 min) may be offset by a few mmHg if the device circuitry has not warmed to body temperature.

Connecting the lead to the device

For more detailed information about lead and connector compatibility, see the implant manual accompanying the pressure sensing lead, or contact a Medtronic representative.

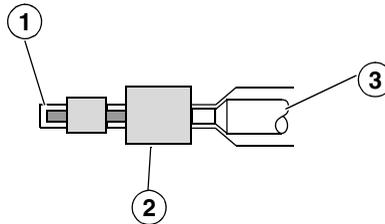
△ **Cautions:** Loose lead connections may result in inappropriate sensing and improper data acquisition.

△ **Cautions:** Use only the torque wrench supplied with the device. It is designed to prevent damage to the device from overtightening a setscrew.

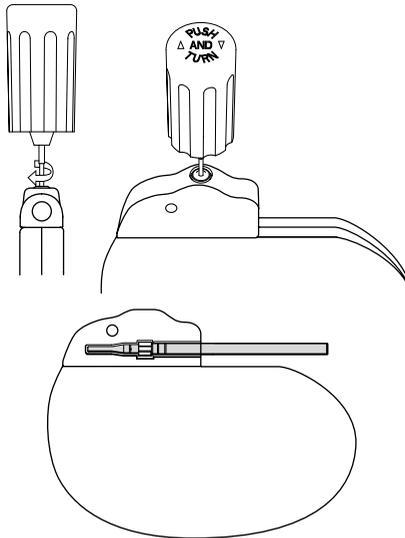
1. Insert the torque wrench into the appropriate setscrew.
 - a. If the port is obstructed, retract the setscrew to clear it. Take care not to disengage the setscrew from the connector block.
 - b. Leave the torque wrench in the setscrew until the lead is secure. This allows a pathway for venting trapped air when the lead is inserted.
2. Push the lead into the connector port until the lead connector pin is clearly visible in the pin viewing area. No sealant is required, but sterile water may be used as a lubricant.

△ **Caution:** Do not immerse the unconnected device or unconnected lead in saline. Immersion in saline could cause localized corrosion to internal metal parts of the connector port and the lead. Normally, the connector port and surfaces are protected from corrosion because the lead is inserted into the connector port.

3. Tighten the setscrew by turning it clockwise until the torque wrench clicks.
4. Tug gently on the lead to confirm a secure fit. Do not pull on the lead until the setscrew has been tightened.

Figure 3-6. Ensure the lead tip is visible beyond the MBC block.

- 1 Tip electrode extends past multi-beam contact (MBC) block
- 2 Ring electrode seats fully beneath the setscrew block
- 3 Lead

Figure 3-7. Connecting the lead to the device

Surgical incisions

A single-incision submuscular or subcutaneous approach is recommended when the device is implanted in the pectoral region. Make the implant pocket about 1.5 times the size of the device.

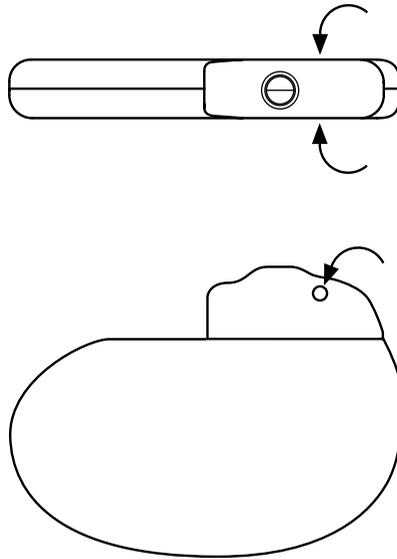
Submuscular implant – An incision extending over the deltoid-pectoral groove typically provides access to the cephalic and subclavian veins as well as the implant pocket. Place the device sufficiently medial to the humeral head to avoid interference with shoulder motion.

Subcutaneous implant – A transverse incision typically permits isolation of the cephalic vein. Place the device far medially to keep the lead away from the axilla. Make sure that the upper edge of the device remains inferior to the incision.

Positioning and securing the device

1. Ensure that the lead connector pin is fully inserted into the connector block and that the setscrew is tight.
2. Coil any excess lead length beneath the device. Avoid kinks in the lead conductors.
3. Implant the device within 5 cm (2 in) of the skin. This position optimizes the ambulatory monitoring operations. Place the device in the subcutaneous pocket with the graphics facing outward.
4. Suture the device securely within the pocket to minimize post-implant rotation and migration of the device. Use a normal surgical needle to penetrate the suture holes.
5. Close the pocket in layers as in a pacemaker-like closure.

Figure 3-8 shows the location of the suture hole for the Chronicle device.

Figure 3-8. Location of the suture hole

Concomitant device

- ⚠ Warning:** Do not implant the Model 9520B implantable hemodynamic monitor concomitantly with implanted devices from manufacturers other than Medtronic. Testing has not been performed on devices from other manufacturers to determine compatibility with the Model 9520B.
- ⚠ Warning:** Do not place or carry the EPR over any other active implanted medical device. The EPR contains a strong magnet that could unintentionally change the operation of the other implanted device and prevent therapy.
- ⚠ Warning:** Output pulses, especially from unipolar devices, may adversely affect device sensing capabilities. If a patient requires a separate stimulation device, either permanent or temporary, allow enough space between the leads of the separate systems to avoid interference in the sensing capabilities of the devices.

This section describes the general steps and precautions when implanting a Chronicle IHM device in a patient who already has a Medtronic device, such as a defibrillator or pacemaker:

- Implant the Chronicle IHM device on the opposite pectoral region of the other implanted Medtronic cardiac devices (for example, pacemakers or defibrillators).
- Before implant, perform a pre-implant calibration of the Chronicle PSL. See “Performing pre-implant calibration” on page 25.
- Place the pressure sensing lead in the RVOT. For more information, refer to “Positioning the Chronicle PSL” on page 27 in this manual, and the appropriate section in the lead manual.
- Test the implanted Chronicle system. For further information, see “Testing lead operation” on page 27.

Replacing an implanted Chronicle IHM device

When replacing the Chronicle IHM device while retaining a previously implanted Chronicle PSL, perform the following evaluations to ensure appropriate pressure sensing:

- Check the integrity of the pressure sensing lead.
- Ensure proper fit of the lead connector in the Chronicle connector block.

Note: To meet the pressure sensing lead implant requirements, it may be necessary to reposition or replace the pressure sensing lead. Refer to the pressure sensing lead technical manual for the recommended implant procedure.

Note: The EPR must also be replaced when replacing a Chronicle IHM device in order to maximize system performance.

Explanting and replacing a Chronicle IHM device

Notes: If you are replacing the Chronicle IHM device but not the lead, you must transfer the calibration information from the lead calibration coefficient diskette to the programmer for transfer to the new device. When the lead is already implanted, you cannot perform the calibration step. For more information, contact your Medtronic representative.

Check the “Use by” date printed on the package. Do not implant the device after the “Use by” date, because the battery’s longevity could be reduced.

1. Interrogate the currently implanted device. Perform a Save To Disk operation and turn Data Collection to Off. Print a summary report.
2. Set the device internal clock. See “Device clock” on page 55.
3. Program the new device to the same parameter values as in the summary report, or as appropriate for the patient.
4. Insert the lead calibration coefficient disk (provided with the previously implanted pressure sensing lead, or use the disk saved to in step 1) into the programmer to load data into the new device.
5. Select the lead serial number in the programmer screen and follow the instructions displayed on the screen. Confirm the lead serial number. Verify proper R-wave sensing with the implanted lead. For information about pressure sensing lead calibration, see “Performing pre-implant calibration” on page 25.
6. Use a torque wrench to retract the setscrew. Carefully disconnect the old device from the implanted lead.
7. Connect the lead to the device and implant the new device. See “Connecting the lead to the device” on page 31 and “Positioning and securing the device” on page 33.
8. Program Data Collection to On. The programmer displays a real-time pressure waveform when Data Collection is programmed to On.
9. A shift in pressure may be seen since a pre-implant calibration cannot be performed with the lead implanted. If necessary, program the pre-implant calibration number to adjust for any offset. See “Performing pre-implant calibration” on page 25.

Replacing a Chronicle Pressure Sensing Lead

To properly perform a pre-implant calibration, the device and lead must be equilibrated outside of the pocket. Therefore, when replacing only the pressure sensing lead, the Chronicle IHM device must be removed from the pocket to perform pre-implant calibration. For more information on pre-implant calibration, refer to “Performing pre-implant calibration” on page 25.

Refer to the lead technical manual for the recommended implant procedure and method for testing the lead position.

Completing the implant procedure

After implanting the device, x-ray the patient to verify device and lead placement. To complete programming the device, select parameters that are appropriate for the patient.

Completing device programming

1. Ensure the patient's EPR is connected to the programmer with the appropriate cable.

Note: To prevent EPR battery depletion, remove the EPR from the base cable cradle before ending a patient session on the programmer. If the EPR has been left in the base cable cradle for 7 hours or longer, the EPR battery should be replaced.

2. Program Data Collection to On if it is not already. Confirm the proper pressure and altitude settings.

Note: Pressure values recorded during the immediate post-implant period (approximately 10 min) may be offset by a few millimeters of mercury (mmHg) if the device circuitry has not warmed to body temperature.

3. Monitor the patient after the implant, and x-ray the patient as soon as possible to document and assess the location of the lead.
4. Program patient information.
5. Confirm data collection parameters that were set up at pre-implant calibration.
6. Recheck pressure sensing values and adjust if necessary.

Preparing for patient discharge

Before a patient is discharged from the hospital after the implant, the device should be tested and programmed. This section describes the following tasks:

- Confirming data collection
- Checking pressure data within range
- Instructing the patient

Confirming data collection – Use the following procedure to begin data acquisition before sending the patient home:

1. Place the EPR assigned to the patient in the EPR base cable attached to the programmer.
2. Interrogate the device.
3. If data collection is disabled, program Data Collection to On.

Checking pressure data within range – After temperature sensing has stabilized, verify that the temperature on the Live Rhythm Monitor window is at or near the patient's body temperature. Also, verify the settings for the expected pressure range. If necessary, adjust the settings to be within the expected pressure range. For more information about the expected pressure range, see "Pressure" on page 45.

Instructing the patient – The Chronicle IHM system includes the following patient-operated medical equipment:

- Chronicle Tracker External Pressure Reference (EPR), Model 2955HF
- Medtronic CareLink Monitor for Chronicle Systems, Model 2490F

Be sure that the patient understands what this equipment is used for, and how and when to operate it.

Chronicle Tracker External Pressure Reference (EPR), Model 2955HF – Review the labeling and patient literature packaged with the EPR. Instruct the patient as follows:

- Always carry the EPR when away from home.
- Never remove the battery from the EPR.
- Bring the EPR to every follow-up appointment.

- Demonstrate to the patient how to place the EPR magnet over the device to trigger an event record.

Note: To prevent EPR battery depletion, remove the EPR from the base cable cradle before ending a patient session on the programmer. If the EPR has been left in the base cable cradle for 7 hours or longer, the EPR battery should be replaced.

⚠ Warning: Do not place or carry the EPR over any other active implanted medical device. The EPR contains a strong magnet that could unintentionally change the operation of the other implant and prevent therapy.

⚠ Caution: Do not carry or wear the EPR over an implanted Chronicle IHM device. This could erase stored data and could result in premature depletion of the Chronicle IHM device battery.

Medtronic CareLink Monitor for Chronicle Systems, Model 2490F – Review the labeling and patient literature packaged with the product. Demonstrate to the patient how to interrogate the Chronicle IHM device using the Medtronic CareLink Monitor.

Patient literature – Patient information concerning the EPR and Medtronic CareLink Monitor is provided in the patient literature packaged with those instruments. The Chronicle 9520B IHM patient manual contains information about the basic functioning of the device and provides guidelines for patients. The Patient Manual is packaged with the Chronicle IHM device.

Patient literature should be given when each patient receives the device or patient-operated equipment. Offer the literature to the patient on each return visit or as deemed appropriate.

To obtain copies of patient literature, contact a Medtronic representative.

Setting up collected data

4

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Overview

The Chronicle IHM system takes data measurements during each cardiac cycle and compiles the results into reports. The physician retrieves the results, available by both online display and printed reports, from the Medtronic CareLink Network.

The full set of data measurements includes:

- RV systolic and RV diastolic pressure
- RV pulse pressure
- heart rate
- patient activity
- ePAD (estimated pulmonary arterial diastolic pressure)
- RV dP/dt max and RV dP/dt min
- RV Pre-Ejection Interval
- RV systolic time interval
- core body temperature
- barometric pressure

The physician can select how frequently the measurements are collected. The selected length of recording time determines the sampling frequency, according to the fixed data storage capacity of the system.

Data acquisition

Electrical

Summary: sensing and measurements

The device uses an implanted transvenous pressure sensing lead to sense cardiac electrical activity. Cardiac sensing is unipolar between the lead tip and Chronicle IHM device. The physician can adjust the electrical sensitivity to accommodate changes in the condition of the patient or the implanted system.

At each sensed event, the device measures the time elapsed since the previous event and calculates the cardiac rate in beats per minute.

Filling interval and diastolic duration are also calculated from each sensed electrogram. This enables the Chronicle system to identify the functional phases of the heartbeat using time markers.

Parameters

* Medtronic nominal setting

Sensitivity (mV)	0.5; 1; 1.5; 2* ... 8
------------------	-----------------------

Considerations

Program the device to prevent oversensing and undersensing.

To program heart rate sensing

1. Select Sensitivity.
2. Select a threshold value.
3. Select **[PROGRAM]**.

Details about heart rate sensing

When the implanted electrode senses an electrical signal that exceeds the programmed sensitivity, the device records a ventricular event.

The device then measures the time between ventricular events and compiles these times into a daily measurement of the patient's heart rate.

Heart rate data will trigger event recordings if the rate is due to either bradycardia or tachyarrhythmia. Asystole does not trigger event recordings.

Post-sense blanking period – A digital blanking period of 200 to 400 ms is enforced after each sensed event to prevent double counting of depolarization signals.

Motion

Summary

The device continuously measures the patient's physical activity using an accelerometer to measure the physical motion. This record of activity assists the clinician in interpreting the collected heart rate data.

Parameters

* Medtronic nominal setting

Activity Level	Low; Medium Low*; Medium High; High
----------------	-------------------------------------

To program activity level sensing

1. Select **Additional Settings...**
2. Select a value for Activity Level.
3. Select **[OK]**.
4. Select **[PROGRAM]**.

Details about activity sensing

A band pass accelerometer within the device transduces physical motion into an electrical signal when the patient is physically active.

When the patient's measured motion exceeds the programmed activity threshold and then returns to 0, an activity count increments by 1. Each activity counter provides one measure of the patient's motion, varying according to the activity threshold applied.

Every 2 s, the device reviews the activity counters at several different thresholds and compiles these measures into an estimated force of patient motion.

When the device is interrogated, the programmer summarizes the force estimates into a running graph of patient activity during the entire period of hemodynamic monitoring.

Pressure

Sensing and measurements

The Chronicle system measures intracardiac pressure. From these raw pressure measurements, the Chronicle system calculates the cardiac pressures and pressure variabilities, and estimates the pulmonary artery pressure.

Pressure measurements are affected by individual lead, device, and patient behavior; thus, the system must calibrate and normalize its raw data to obtain the most accurate information.

△ **Caution:** If the patient travels outside of his or her programmed altitude range, a temporary adjustment of altitude parameters is necessary to avoid any loss of data.

Parameters

Maximum Altitude (feet)	-100; 1000; 2000 ... 10000
Minimum Altitude (feet)	-100; 1000; 2000 ... 10000
Maximum Systolic Pressure (mmHg)	40; 45 ... 100; 110 ...150; 170
Minimum Diastolic Pressure (mmHg)	-10 (fixed)

Programming pressure sensing

1. Select **Pressure Settings...**
2. Select values for Maximum Altitude and Minimum Altitude.

Note: If you select a new value for altitude or a value different from the current nominal value, you can save the new value in the programmer as the nominal.

3. Select a value for Maximum Systolic Pressure.
4. Select **[OK]**.
5. Select **[PROGRAM]**. If any values are selected, the "Attention-Data will be cleared" message window is displayed. Select **[Clear]** or **[Cancel]**.

Details about pressure sensing

The implanted lead includes a pressure transducer that generates a continuous electrical signal representing the measured pressure. Within each heartbeat, the measured filling time, systolic duration, and so on enable the device to synchronize its measurements to the parts of the cardiac cycle.

The pressure measurements are:

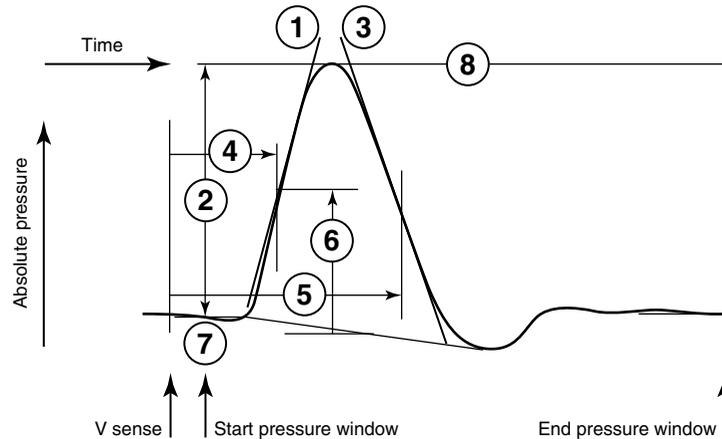
- RV Systolic pressure
- RV Diastolic pressure
- RV Pulse pressure
- RV dP/dt max
- RV dP/dt min
- ePAD (estimated pulmonary arterial diastolic pressure)

The implanted pressure sensing lead and device are calibrated together at implant to ensure that the device accurately registers data reported by the pressure transducer.

The implanted lead measures the RV temperature along with each pressure measurement to correct for any sensor signal variations due to fluctuating internal temperature.

The patient carries a small ambulatory barometer (EPR) so that the Chronicle IHM system can eliminate variations in local atmospheric pressure from the device measurements.

Figure 4-1. Pressure parameter measurements



- 1 RV dP/dt max
- 2 RV pulse pressure
- 3 RV dP/dt min
- 4 RV Pre-ejection interval
- 5 RV STI
- 6 ePAD
- 7 RV diastolic pressure
- 8 RV systolic pressure

RV dP/dt max – The maximum rate (mmHg/s) of the rise of RV pressure during pressure development.

RV pulse pressure – The difference between the systolic and diastolic pressures, measured in millimeters of mercury (mmHg).

RV dP/dt min – The maximum rate (mmHg/s) of the fall of RV pressure during ventricular relaxation.

RV Pre-Ejection Interval (PEI) – The time in milliseconds from detected R-wave to +RV dP/dt max.

RV Systolic Time Interval (STI) – The time in milliseconds from detected R-wave to -RV dP/dt min.

estimated Pulmonary Arterial Diastolic Pressure (ePAD) – The value in millimeters of mercury (mmHg) of the RV pressure waveform at +RV dP/dt max.

RV diastolic pressure – Measured as the RV pressure at the time of a ventricular event. This definition is for a consistently measured estimator of diastolic pressure measured in mmHg.

RV systolic pressure – The peak pressure in the cardiac cycle, measured in millimeters of mercury (mmHg).

Mean Pulmonary Arterial Pressure (MPAP) – The estimated mean pressure in the pulmonary artery.

Activity – The device determines the activity counts from the activity sensor in the device. Counts are a relative measure from 0 to some positive level, typically 10 to 12 counts at a peak activity.

Heart Rate – Heart rate (bpm) is derived from the interval between 2 ventricular events from the unipolar intracardiac electrogram. You can view the real time electrogram on the programmer screen, along with a marker channel indicating proper synchronization with heart rhythm. Heart rates less than 30 bpm are recorded as 30 bpm; asystole is not detected.

Temperature

Sensing and measurements

The Chronicle system captures body temperature measurements using temperature sensing in the implanted lead. The system is able to provide temperature trend information.

Parameters

None

Considerations

The Chronicle system provides approximate measurements of the patient's body temperature. The derivation techniques supply good dynamic precision in characterizing relative scale and trends of body temperature changes, such as during a fever. However, the individual numerical values do not necessarily represent clinically accurate body temperature measurements.

Details about temperature sensing

The implanted pressure sensing lead captures the right ventricle temperature at each sensed event. The Chronicle system requires a temperature value to correct its absolute pressure reading when internal pressure changes are caused by local temperature fluctuations.

Using lead calibration data gathered at implant, this temperature parameter is also used to calculate an estimate of body temperature. The estimated body temperature is reported upon interrogation.

Data storage

Trend buffer storage

Summary

The Chronicle system compiles its measurements into long term trend reports to represent the cardiac behavior over time. The physician selects the duration of the data storage.

Parameters

* Medtronic nominal setting

Trend A	3 hours (2 s); 1 day (32 s); 1 week (256 s); 2 weeks (512 s)*; 1 month (1024 s); 2 months (2048 s); 3 months (3072 s)
Trend B	3 hours (2 s); 1 day (32 s); 1 week (256 s); 2 weeks (512 s); 1 month (1024 s); 2 months (2048 s); 3 months (3072 s)*

Considerations

The storage interval derives from the selected trend duration, because the total data capacity is fixed. For example, the system can store 1 week of measurements taken every 4 min, or 1 month of data measured every 17 min.

Table 4-1. Sampling frequency derived from the programmed duration

Trend duration	Sampling frequency
3 months	3072 s
2 months	2048 s
1 month	1024 s
2 weeks	512 s
1 week	256 s
1 day	32 s
3 hours	2 s

Note: The programmer does not print all stored data points due to report resolution restrictions.

The programmed trend duration value represents a minimum duration at the corresponding sampling rate. Some padding is included to accommodate interruptions of data collection, for example, due to device interrogation or measurements that are not retained.

Ensure that the next data transmission or follow-up visit is actually completed within the selected trend duration. Overwritten data is lost and cannot be retrieved. If the follow-up interval is programmed for 2 weeks and the patient is actually seen in 3 weeks, the memory contains only the most recent 2 weeks of data. To avoid loss of data, carefully consider scheduling data transmissions and follow-up visits.

Setting the trend duration

The trend duration you select determines the resolution of the stored trend data. Trend resolution is not programmed independently. Data triggers are fixed.

To program follow-up trend intervals

1. Select **Trend Intervals A**.
2. Select a value.
3. Select **Trend Intervals B**.
4. Select a value.
5. Select **[PROGRAM]**. If any values are selected, the “Attention-Data will be cleared” message window is displayed. Select **[Clear]** or **[Cancel]**.

△ **Caution:** If the patient does not transmit within the specified trend interval, data will be overwritten in the device.

Details about activity data storage

At each ventricular event, the current mean value for patient activity and temperature are recalculated and reported upon interrogation.

Details about pressure and heart rate data storage

Each of the pressure and heart rate measurements is initially stored in temporary histograms as they occur for extraction of summary values (mean, median, and certain percentile values). Temporary histograms cannot be retrieved by the physician.

If any pressure measurement is outside its recordable range, all pressure measurements for that beat are not included in the histograms. This is intended to reduce any corruption of the data by timing or artifact disruptions, such as coughing or cardiac oversensing.

Upon interrogation, the physician may select one or both trends from the Custom Report window for reporting.

The device retrieves the summary values from each temporary histogram and compiles them into the long term trend reports, which are also presented in histogram format.

Heart rates less than 30 bpm are recorded as 30 bpm; asystole is not visible in trend data.

Trigger storage

Summary

The device stores detailed waveforms during episodes of slow heart rate, fast heart rate, or patient triggered recording during symptoms. The triggered event records provide more detail to direct clinical investigation of the patient's cardiac condition and progress.

Each event record includes approximately 10 s of EGM and pressure waveforms and Marker Channel telemetry.

Parameters

* Medtronic nominal setting

Patient Trigger	On; Off
Brady Trigger Rate Less Than (bpm)	Off; 30; 35 ... 50* ...65; 71; 75; 80; 86; 91
Tachy Trigger Rate Greater Than (bpm)	Off; 100; 109; 120; 130; 140; 150; 162; 171; 182*; 188; 200
Tachy V. Beats to Detect	6 of 16; 12 of 16*
Tachy Activity Counts	Off; 1; 2 ...15

Considerations

If you program any setup parameters for the brady or tachy triggers, all triggered data stored in the device is cleared.

Heart rates less than 30 bpm are recorded as 30 bpm; asystole does not trigger event recordings and is not visible in trigger data.

Patient-triggered event recording requires the patient to apply a magnet over the implanted device. Be sure the patient understands the instructions for using the EPR.

To program triggered episode storage

1. Select **Triggers....**
2. Select **Patient Trigger** to enable or disable the patient trigger.
3. Select a heart rate value for the brady trigger if desired.
4. Select heart rate, activity, and beats to detect for the tachy trigger if desired.
5. Select **[OK]**.
6. Select **[PROGRAM]**. If any values are selected, the "Attention-Data will be cleared" message window is displayed. Select **[Clear]** or **[Cancel]**.

Brady and tachy triggers – The physician selects a heart rate threshold for the brady and tachy heart rate trigger. The tachy trigger can incorporate a threshold level of patient activity so that an activity-induced excursion does not trigger episode recording.

Patient trigger – When the patient feels a symptomatic episode, he or she applies a magnet over the implanted device to trigger an event record. A small magnet is integrated into the EPR for convenient use by the patient.

Details about triggered episodes

Up to 3 episodes of each trigger type can be saved. If more than 3 episodes of either type occur, older records are overwritten to provide the most recent 3 episodes of each type. The 3 episodes for each trigger type are stored with high-resolution data.

Each trigger type is enabled and disabled independently. Up to 16 patient triggered timestamps can be recorded. If more than 16 events are recorded, the oldest ones are overwritten. The 16 additional timestamps are not associated with high-resolution hemodynamic data.

Patient triggered episodes (non-programmable)

The operating parameters for patient triggered episode records are fully automatic and require no programming.

RV pressure waveforms

Summary

The device captures and stores RV pressure waveforms to provide a surveillance mode to detect transients or shifts in signal that may interfere with the hemodynamic measurements.

Waveform collection occurs daily at 3:00 a.m. and requires the patient to be at rest. The collection also requires the criteria be met for the RV Pressure Waveform Rate Less Than parameter.

The device captures waveform snapshots for up to 4 consecutive ventricular events. Waveform collection for a ventricular event stops when the device senses the onset of the next ventricular event. The device stores snapshots for a maximum of 16 four-waveform sets. The stored waveform snapshots can be viewed only on the Medtronic CareLink Network.

Parameters

* Medtronic nominal setting

RV Pressure Waveform Rate Less Than (bpm)	70; 75; 80; 85; 90*; 95; 100; 105;109; 115;120
-------------------------------------------	------------------------------------------------

To program RV pressure waveforms

1. Select **Additional Settings....**
2. Select **RV Pressure Waveform Rate Less Than (bpm)**.
3. Select a pressure waveform rate value.
4. Select **[OK]**.
5. Select **[PROGRAM]**.

Setting up sensing

At implant and each follow-up visit, the physician can adjust the device to the best value for acceptable electrical sensing. Remember that the quality of the EGM can vary over time and vary with patient activities.

Perform the sensing tests with the patient lying on his or her back. If inappropriate cardiac sensing is suspected, also test with the patient in upright positions, such as sitting and standing.

To program sensitivity:

1. Increase the sensitivity setting until undersensing occurs (QRS complexes observed on the ECG trace without a matching marker annotation for each one).
2. Record the largest sensitivity setting that does not result in undersensing. This is the undersensing threshold.
3. Decrease the sensitivity setting (make it more sensitive) until oversensing occurs (marker annotations observed without a matching QRS complex).
4. Record the smallest sensitivity setting that does not result in oversensing. This is the oversensing threshold.
5. Set the device sensitivity to a value midway between the undersensing threshold and oversensing threshold.

Note: If there is no undersensing or oversensing, then program the sensitivity to the nominal value of 2.0 mV.

6. To print the screen, press a print speed button you prefer on the programmer case.

Device clock

The device uses an internal clock, separate from the programmer clock, to mark the date and time of significant events throughout the life of the device. It stores these date and time stamps in memory along with other event data.

The device clock should be set during the implant procedure and under other circumstances such as if the patient changes time zones for a length of time.

Note: You can change the device clock only if Data Collection is turned to Off.

To set the device clock

1. Select **Additional Settings....**
2. Select **Device Date/Time.**
3. Use the up and down arrow buttons to select hour, minute, and date settings. Use 24-hour notation: midnight is 00:00; noon is 12:00.
4. Select **[OK]**.
5. Select **[PROGRAM]**.

Holter Telemetry

The Holter Telemetry feature transmits EGM, RV pressure, and Marker Channel data continuously for a selectable number of hours, regardless of whether the programming head is positioned over the device. The EGM, RV pressure, and Marker Channel data transmitted using Holter Telemetry is not stored in device memory. Additional equipment is required to record the data. Please contact a Medtronic representative for more information about the use of Holter Telemetry.

Conducting a patient follow-up session

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Patient follow-up guidelines

Before interrogating the EPR, turn the programmer off and connect the EPR to the programmer. Perform these steps at each in-office follow-up. Always retrieve the stored data before any other programming.

- Interrogate the device and EPR.
- Perform a save-to-disk and print out any desired reports.
- Review the programmed parameters and device status and adjust the programmed parameters, if appropriate.

The retrieved data can then be saved at the office of the physician.

Interrogating the Chronicle IHM system

After the programmer is started and recognizes telemetry with the implanted device, it attempts to interrogate the device automatically.

If the automatic interrogation is not successful, you must interrogate the device manually.

To interrogate the Chronicle device:

1. Press **[Interrogate...]**.
2. Select **[Since Last Session]** or **[ALL]** on the screen.

Note: When you select **[ALL]**, the programmer retrieves all of the data stored in the EPR. The interrogation can take up to 10 min to complete.

3. Select the **[Start]** or **[Cancel]** button.

After the initial interrogation, the programmer prompts you to save files to disk.

Replacement indicators

Battery voltage and messages about replacement status appear on the programmer display and on printed reports. Battery voltage can be evaluated by interrogating the device. Table 5-1 lists the Recommended Replacement Time (RRT) and the End of Service (EOS) conditions.

Table 5-1. Replacement indicators

Recommended Replacement Time (RRT) voltage	$\leq 2.78 \text{ V}$
End of Service (EOS) voltage	3 months after RRT

RRT date – The programmer displays the date when the battery reached RRT.

EOS indication – If the programmer indicates that the device is at EOS, replace the device immediately.

Prolonged service period after RRT – The prolonged service period is the time between the Recommended Replacement Time (RRT) and End of Service (EOS). The prolonged service period is defined as 3 months, assuming 70 bpm and with the pressure sensing lead enabled.

Electrical reset

An electrical reset is a device-activated safety feature that can reset device parameters to values that provide basic device functionality. These basic parameters are considered safe for the vast majority of patients.

An electrical reset may occur when the device is exposed to extreme conditions, such as cold temperatures (before implant); intense, direct x-ray exposure; electrocautery; or external defibrillation.

Device status indicator warnings

During every interrogation, the user is informed if an electrical reset has occurred. The Device Status Indicators are important. Please inform your Medtronic representative if any indicators are displayed after interrogating a device. The Device Status Indicators are described below:

Warning - Electrical Reset – Indicates that an electrical reset has occurred. Programmed parameters may have been set to electrical reset values. Read the message accompanying the indicator, and follow the screen instructions carefully. If the error message does not indicate that parameters have been reprogrammed, then the reset did not affect any programmed parameters.

Note: If the message **SERIOUS DEVICE ERROR** is displayed, an error has occurred from which the device cannot recover. *Immediate* replacement is recommended.

Clearing device status indicators

To clear the device status indicator, select **[Clear]** from the window that displays the Device Status Indicator message.

Sensing tests

Perform the sensing tests with the patient lying on his or her back. If inappropriate cardiac sensing is suspected, also test with the patient in upright positions, such as sitting and standing. For more information, refer to “Setting up sensing” on page 55.

Assessing and adjusting programmed parameters

Review triggered episodes and trends. Verify that the altitude settings and maximum systolic pressure settings cover the range of the patient's expected systolic pressures, environment, and lifestyle between follow-up visits.

If a patient travels outside of the range, loss of trend data may occur during that time.

Heart rates less than 30 bpm are recorded as 30 bpm; asystole does not trigger event recordings and is not visible in trend or trigger data.

Transmitting to the Medtronic CareLink Network

The Medtronic CareLink Network provides users with Internet access to information about patients and their implanted devices. After data is transferred to the Medtronic CareLink Network from the Medtronic CareLink monitor, physicians can retrieve chronic care reports, such as patient triggered event records and long-term trend data. The Internet address for the Medtronic CareLink Network is <http://www.medtronic.com/carelink>.

Using the programmer

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Setting up and using the programmer

Patient sessions for the Chronicle IHM are managed with a Medtronic CareLink Model 2090 programmer. The programmer reference guide provides instructions on setting up the programmer for a patient session, using printers, and use of the between-sessions screens.

Connecting the EPR to the programmer

Before turning on the programmer, connect the patient's EPR to the programmer with the EPR base cable. For details about connecting the EPR, see the technical manual for the EPR base cable.

Programmer functions before and after patient sessions

Before starting a patient session, you can set or change the following programmer preferences:

- programmer time and date
- audio preferences
- language preference for the software display

Using the programming head

When the programming head is placed over the device and telemetry is established, the amber light on the programming head turns off, and one or more of the green indicator lights turn on. You can find the optimum position for the programming head by moving it around the implanted device until the greatest number of green lights turn on. To ensure proper telemetry, make sure to position the programming head so at least two of the green lights are on.

If the programming head slides off the patient, the session is not terminated. Place the programming head back over the device to resume programming or interrogating the device.

Note: Any successful interrogation or programming verifies proper communication between the device and the programmer.

Marker transmissions

The device continuously transmits Marker Channel and Marker Supplement data via telemetry while the programming head is positioned over the device. The device stops these transmissions when you lift the programming head unless the Holter Telemetry feature is programmed on. If Holter Telemetry is programmed on, the device transmits telemetry regardless of the programming head position.

Alternative program and interrogate buttons

The programming head provides buttons that you can use to program [P] or interrogate [I] the device. These buttons are active only when [PROGRAM] and [Interrogate] are displayed as active buttons on the display screen.

Starting and ending a patient session

Since the programmer collects data on a session-by-session basis, you must start a new session for each patient. At the start of a session, the programmer interrogates the patient's device. Before you start a session with another patient, you must end the previous session.

Note: If the Chronicle software application has not been installed, the programmer displays a message. You must install the software application to proceed. See the programmer reference guide for more information.

If the programmer detects a device serial number that is different from the one it sensed during the initial interrogation, it forces you to end the current session.

Note: Connect the programmer skin electrodes to the patient if you would like to display surface ECG signals on the programmer. See "Recording live waveform strips" on page 71 or the programmer user manual for more information.

Initial interrogation – After turning on the programmer, you can start a patient session using any of the following methods:

- Place the programming head over the device and select [Auto-Identify]. The programmer determines the device model, starts the correct software application, and interrogates the device.
- Place the programming head over the device. Select the device model from a list on the Select Model screen and select [Start]. The programmer starts the software application and interrogates the device.

Note: During initial interrogation, programmer functions are not available.

Starting a patient session using [Auto-Identify]

1. Display the Select Model screen. If the programmer is on, but the Select Model icon is not displayed, you must end the current session before starting a new one. See “Ending a patient session” on page 67.
2. Position the programming head over the patient’s device and hold it steady.
3. Select the [Auto-Identify] button at the bottom of the screen, or press the [I] programming head button. The programmer loads the appropriate software application and immediately begins to interrogate the device.

Starting a patient session using [Start]

1. Display the Select Model screen. If the programmer is on, but the Select Model icon is not displayed, you must end the current session before starting a new one. See “Ending a patient session” on page 67.
2. Choose to view Other devices.
3. Select Chronicle® 9520B from the list of devices.
4. Position the programming head over the patient’s device, and hold it steady.
5. Select the [Start] button. The programmer loads the Chronicle® software application and immediately begins to interrogate the device.

Ending a patient session

1. Select [End Session...].
2. To save session data to a disk, select [Save To Disk...].
3. To end the session and return to the Select Model screen, select the [End Now] button.

Viewing live waveform traces

The Live Rhythm Monitor window displays live waveform traces for RV pressure, ECG, and EGM. The window normally appears above the task area, but you can select an icon in the upper right corner of the window to expand it to cover the task area. You can use the waveform adjustment button bar to change the appearance of the waveforms in view. With the Adjust window, you can make additional changes to the waveform display.

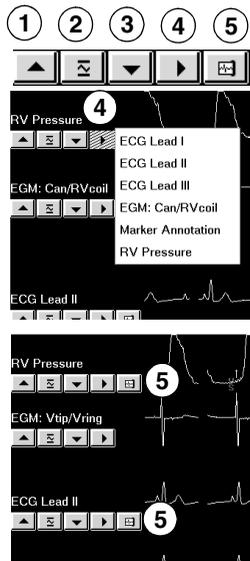
Parameters

Table 6-1 describes the parameters available for live waveform traces in the Live Rhythm Monitor window.

Table 6-1. Parameters for live waveform traces

Parameter	Description	Capability
Clipping	Truncates the tops and bottoms of waveform traces at a 22 mm boundary.	enable; disable
Sweep Speed	Sets sweep speed.	12.5; 25; 50; 100 mm/s
ECG Filter	Changes the bandwidth of waveforms to improve the clarity of the displayed ECG in the presence of interference.	disable (0.05 to 100 Hz) enable (0.5 to 40 Hz)
Show Artifacts	Displays pacing artifacts superimposed over waveform traces	enable; disable
Normalize	Equalizes the spacing between the waveform traces and resizes each trace to its default setting.	—
Calibrate	Adds a reference signal to the waveform.	—

How to use the waveform adjustment button bar



1. Select the up arrow to increase the size of the waveform trace.
2. Select the Normalize button to restore the waveform trace to its default size.
3. Select the down arrow to decrease the size of the waveform trace.
4. Select the waveform Source button to select the source of the displayed waveform trace.
5. Select the waveform Print Selection button to enable or disable the trace for printing. Up to 2 traces can be selected.

How to use the Adjust window

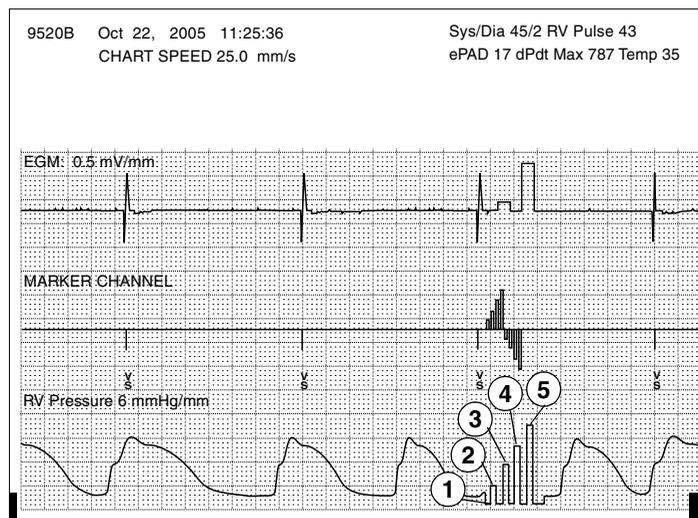
1. Select [Adjust...] to display the full screen Live Rhythm Monitor and the Adjust window.
2. Adjust the size, source, and print selection options for each waveform trace using the waveform adjustment bar.
3. Select the color field in the waveform trace area to change the color of a waveform.
4. Select [Clipping], [ECG Filter], and [Show Artifacts] to enable or disable these options as desired.
5. Select the Sweep Speed if desired.
6. Select [Normalize] to equalize the trace spacing and, if clipping normally, adjust the size of each trace to the default setting.
7. Select [Calibrate] to add a reference signal to the waveform.
8. When you finish making adjustments, select [OK].

Calibrating an external recording

The [Calibrate] button in the Adjust window enables you to add an amplitude reference signal to the waveforms on an externally connected monitor or recorder and on a programmer strip chart. When you press [Calibrate], a reference signal is added to the Marker Channel, RV pressure, EGM, and ECG waveforms. The reference signals are displayed on the Live Rhythm Monitor, on an external monitor or recorder, and on a strip chart printed from the programmer. In addition to calibration signals, the real time pressure discrete values are printed on the strip chart when the print option is selected for the RV Pressure Waveform. Pressure discrete values also display on the device status line.

The calibration signal on the RV pressure waveform is illustrated in Figure 6-1.

Figure 6-1. Calibration signal on the RV pressure waveform



- 1 EPR
- 2 EPR + 20 mmHg
- 3 EPR + 40 mmHg
- 4 EPR + 60 mmHg
- 5 EPR + 80 mmHg

For information about analog output of Marker Channel, ECG, and EGM calibration signals, see the programmer reference guide.

Details about the Live Rhythm Monitor

The Live Rhythm Monitor can display up to 5 different waveforms during a patient session:

- **RV pressure waveform** – Displayed when the EPR is connected to the programmer and Data Collection is enabled.
- **ECG leads I, II, and III** – Available when you attach ECG leads to the patient's skin and connect them to the programmer.
- **Marker annotations** – Shows device operations are telemetered from the device to the programmer when the programming head is over the device.
- **EGM signal** – The EGM signal is telemetered from the device. The programmer cannot display or record an EGM trace until the current EGM Range setting has been interrogated from the device.

Table 6-2. Waveform trace information

Trace	Description
RV pressure waveform	The RV pressure waveform is a continuous electrical signal generated by the implanted pressure sensing lead. The waveform represents the measured pressure for the cardiac cycle.
ECG Lead I, II, III	ECG signals are detected using skin electrodes attached to the patient. The ECG cable attached to these electrodes must be connected to the programmer.
Marker annotations	Marker annotations indicates sensing events.
EGM	The EGM signal is telemetered from the device.

Marker Channel telemetry annotations

Marker Channel telemetry annotations appear as 2 characters below the Marker Channel trace of the waveform display. These annotations indicate sensing events. Marker Channel symbols appear only on real-time waveform recordings, not on screens or in episode recordings. These symbols sometimes appear compressed, depending on the printout speed of the programmer strip chart recorder.

Note: Since the displayed waveforms depend on telemetry with the device, marker annotations are not displayed unless the programming head is positioned over the device. Therefore, any interruption in telemetry may result in missing markers on the trace display.

Recording live waveform strips

At any time during a patient session, you can start a continuous, live recording of the patient's pressure, ECG and EGM¹ from the programmer strip chart recorder; however, you can only view 2 waveforms at any given time.

Note: Because the printed recording provides a higher resolution, it may show artifacts and events that do not appear on the programmer display.

A printout of the live waveform includes the following information:

- RV pressure waveform, ECG, and EGM traces
- an indication of an executed command when confirmation of the command is received
- transmission markers that show active transmissions between the device and the programmer
- any change in RV pressure waveform, ECG, or EGM range setting; which is marked with a vertical dotted line and the new gain setting

Printing a report while recording a live waveform strip

If you select an option from the Print menu while recording a live strip, the report goes to the print queue. Alternatively, if you start recording a live strip while the programmer is printing a report, the report stops printing and is sent to the print queue.

This applies only to reports printed on the programmer strip chart recorder. Printing to a full-size printer is not affected.

¹ The programmer cannot record an EGM or pressure trace until the device has been interrogated.

Automatic programming attempts

If telemetry between the programmer and device is not established, the programmer automatically makes up to 2 attempts to transmit data. This may result in multiple sets of programming and confirmation indicators being recorded.

EGM and Marker Channel telemetry

The programmer cannot display or record an EGM trace until the current EGM Range setting has been interrogated from the device.

If you change the EGM Range setting during a recording, the programmer marks the change with a vertical dotted line on the paper recording and annotates it with the new gain setting.

EGM and Marker Channel telemetry can be momentarily interrupted during an interrogation or programming.

Saving and retrieving device data

The programmer allows you to save interrogated data to a disk. Later, when a patient session is not in progress, you can use the Read From Disk Application on the programmer to retrieve and view data saved on the disk.

Saving device data to disk

Review the following information before saving data to a disk:

Interrogate first – Make sure to interrogate the device before saving data to a disk because the programmer saves only the data it has interrogated. If you want to save all of the information from the device, select the All option from the interrogation window.

Ejecting disk – Do not eject the disk from the drive while a save is in progress. This can cause a disk error to occur.

Disk requirements

The disk you use for saving data from the programmer must satisfy these requirements:

- It must be a formatted, IBM-compatible, 3.5 inch disk.
- Its capacity must be 720 KB (DS, DD) or 1.44 MB (DS, HD).

If you save data to a disk that is corrupt or not IBM-formatted, the programmer may become unresponsive. If this occurs, remove the disk, and turn the programmer off and then turn it on again. Normal operation should resume. Please inform your Medtronic representative of this occurrence.

Data file names

Saved files are automatically named with a file name representing the date and time the file was saved. When you save a data file to a disk, the file name takes the format DDHHMMSS.PDD or DDHHMMSS.EPR, as in the following description:

- **DD** represents the day of the month (01 to 31).
- **HH** represents hours (24-hour clock).
- **MM** represents minutes.
- **SS** represents seconds.
- **PDD** is the extension for the programmer data file.
- **EPR** is the extension for the EPR data file.

The programmer prompts you to save to disk after every interrogation.

To save device data to a disk

1. Interrogate the device.
2. From the main screen, select [**Session**].
3. Select [**Save to Disk...**]. The “Save to Disk-Insert Diskette” window is displayed.
4. Insert a diskette into the programmer disk drive and select the [**Save**] button. The file is saved with a default filename corresponding to the current date and time.

Note: You also have the option to Save to Disk when you select [End Session...].

Reading device data from a disk

After the programmer has read data that was saved during a patient session, it presents the information in a read-only view similar to the way it present “live” information during a patient session. In this read-only mode, the programmer allows you to view the saved data, print reports, and display all programmed parameter values. You cannot program the device or perform tests on the device when reading data from a disk.

△ **Caution:** The Read From Disk Application is designed only for viewing saved data while no patient session is in progress. You cannot program a device from the Read From Disk Application.

To read device data from a disk

1. Insert a diskette that contains information saved during a patient session.
2. From the Select Model screen, select Other from Devices.
3. Select Chronicle 9520B-Read From Disk.
4. Select [Start].
5. Select [OK] from the warning message.
6. Select [Open File...].
7. Select the data record that displays the desired patient, device serial number, date, and time.
8. Select [Open File]. The read-from-disk screen displays information from the saved session.

Printing reports

This section describes the types of available reports, printing reports, and information about the Print Queue.

Types of reports

Information collected by the device is available in several report options. You can print either a Full Summary report or a Custom report. You can print reports at any time during a patient session.

Note: A report can be printed only if its data has been collected. If there is missing data, the name of the report appears inactive.

Full Summary Report

Select [Full Summary...] from the Reports icon to print a report that includes all the following information:

- Observation Report
- Episode List Report
- Parameters Summary Report
- Trend A Report

Full Summary Report

If you would like to choose which information categories to include in the printed report, select [Custom ...] from the Reports icon.

Printing a report from the main screen

Information collected by the device is available in several report options. From the Reports icon, you can choose either a Full Summary report or a Custom report.

1. To print a report, select [**Print...**] on the programmer screen. A print options window is displayed.
2. Select the Number of Copies.
3. Select the Printer. The default printer is the programmer.
 - a. To print to the strip printer, select Programmer.
 - b. To print to a connected full-size printer, select Full Size and select a print driver.
4. Select [**Print Now**] for immediate printing, or select [**Print Later**] to add the print request to the print queue.
 - a. To print from the print queue, select Print Queue from the Report icon and then select [**Print**].
 - b. To delete a print request from the print queue, select Print Queue from the Report icon and then select [**Delete**]. You cannot delete a report if its status is "Printing" or "Waiting."

Print Queue

When you select [Print Later], your print job is held in the Print Queue. To display the Print Queue window, select the Reports icon. In the Print Queue window, you can check the status of a print job and either print or delete a print job from the queue. The print queue Status column displays the print status for each report currently in the queue:

- **Printing:** Indicates a report is currently printing.
- **Deleting:** Indicates a report is currently being deleted.
- **Waiting:** Indicates a report is waiting for another report to finish printing.
- **Hold-Later:** Indicates a report is on hold until you print it. A Hold-Later status could also indicate a report was interrupted by the start of a recording or the printer is not operational (if it is out of paper, for example).
- **Done:** Indicates the completed status of a print job.

Solving system problems

7

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Typical troubleshooting scenarios

This topic describes the symptoms and illustrates possible issues that require correction. For information on correcting an issue, see “Solving system problems” on page 81.

Oversensing

Oversensing includes the following indicators:

- elevated heart rate
- PEI/STI values changes
- multiple tachy triggers
- pressure values could be incorrect
- change in RV waveform

Figure 7-1. Oversensing example



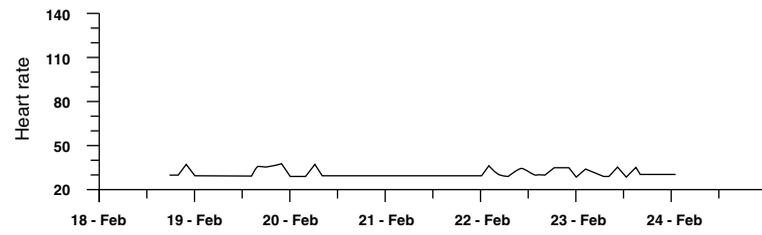
Figure 7-1 displays an RV pressure waveform as seen during oversensing of an atrial pacing pulse from a concomitant device.

Undersensing

Undersensing includes the following indicators:

- multiple Brady triggers
- depressed heart rate
- heart rate ≤ 29 bpm

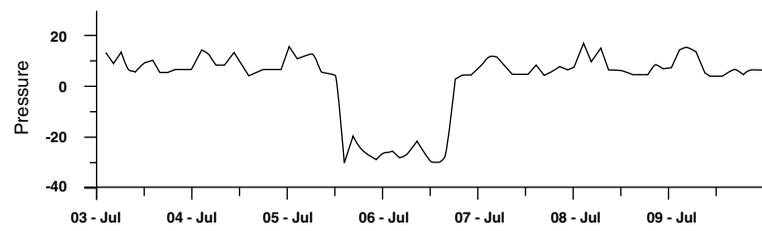
Figure 7-2. Undersensing showing low heart rate



Patient traveling without the EPR

If a patient travels without his or her EPR, there will be a sudden change in pressure until the patient returns to his or her original geographic location. Check the barometric pressure to see if it has remained stable. If so, the patient likely traveled without the EPR.

Figure 7-3. Patient traveling without the EPR



Patient traveling outside of programmed altitude range

If a patient travels outside of his or her programmed altitude range, there will be a loss of data. To prevent data loss, reprogram the altitude range temporarily.

- △ **Caution:** If the patient travels outside of his or her programmed altitude range, a temporary adjustment of altitude parameters is necessary to avoid any loss of data.

Figure 7-4. Clipping

Figure 7-4 displays an RV waveform of a patient traveling outside the altitude range programmed for the patient.

Lead dislodgement with continued sensing

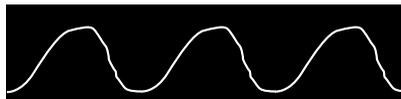
- Changes in the RV pressure waveform
- Overlapping PEI and STI trends
- Variable heart rate

Interpreting waveform morphology

This topic shows examples of acceptable and unacceptable pressure waveforms.

Acceptable waveforms

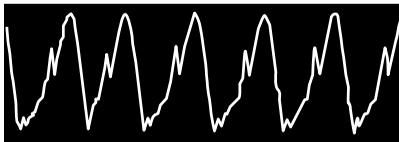
Acceptable RV pressure waveforms can differ in morphology. One similarity consistent among all acceptable waveforms is the absence of spikes.

Figure 7-5. Acceptable (normal) waveform

Unacceptable waveform

Unacceptable RV pressure waveforms demonstrate spikes. If spikes are observed, the lead must be repositioned.

Figure 7-6. Unacceptable waveform



Solving system problems

This section describes problems that can occur with the system and suggests some corrective actions. These problems are classified into the following categories:

- R-wave sensing
- Pressure sensing
- Temperature sensing

To solve a system problem, you must follow these steps:

1. Define the problem.
2. Identify the cause of the problem.
3. Perform a corrective action.

The system provides a set of diagnostic tools to help you accomplish these tasks.

Note: The following information is not intended to be an all-inclusive list of system problems. Rather, it is presented as an aid to use in an overall problem-solving strategy.

R-wave sensing problems

Sensing is a vital component of nearly all device operations. Problems with pressure measurements and triggers can often be traced to a problem with sensing. Table 7-1 lists some potential problems with sensing, their probable causes, and some corrective actions that may solve those problems.

Table 7-1. R-wave sensing problems

Observed problem	Possible cause	Suggested corrective action
No, or too few, normal sense markers displayed in the Live Rhythm Monitor; or EGM flatline	Lead disconnected from the device connector port	Verify all connections, especially the setscrew contact.
	Lead dislodgement or no EGM signal	Reposition the lead.
	Lead fracture or insulation defect	Replace the lead.
	Undersensing	<ul style="list-style-type: none"> ▪ Decrease sensitivity threshold. ▪ Decrease Post V. Sense Blanking
	Telemetry link between the device and programmer lost	<ul style="list-style-type: none"> ▪ Reposition the programming head. ▪ Remove any sources of EMI.
	Current leakage in the device connector port	Verify that all connections are dry.
Double-sensing of ventricular events	T-wave sensing after intrinsic events	<ul style="list-style-type: none"> ▪ Increase sensitivity threshold. ▪ Increase Post V. Sense Blanking. ▪ Reposition the lead.
Extra ventricular sensed events, especially when the patient moves or the device/lead is manipulated.	Poor connection to the device connector port	Verify all connections, especially the setscrew contact.
	Lead fracture or insulation defect	Replace the lead.
Triggers show extra ventricular sensed events, but the Live Rhythm Monitor shows normal sensing	<ul style="list-style-type: none"> ▪ Temporary exposure to an EMI source ▪ Poor connection to the device connector port ▪ Lead fracture or insulation defect 	<ul style="list-style-type: none"> ▪ Counsel the patient to keep away from sources of EMI. ▪ Verify all connections, especially the setscrew contact. ▪ Replace the lead.

Pressure sensing problems

Table 7-2. Pressure sensing problems

Observed problem	Possible cause	Suggested corrective action
Pressure trace pinned to bottom or top window edge	Programmer display gain is too high	Lower the programmer display gain.
	Pressure is below -10 mmHg or above the programmed pressure range	<ul style="list-style-type: none"> ▪ Change the pressure range. ▪ Verify the lead serial number.
	System is not yet temperature equilibrated	Wait 10 min for the IHM to equilibrate to the patient's body temperature, then re-interrogate.
	EPR is not connected	Verify that the EPR is properly connected.
	Lead not fully inserted into the connector port	Verify that the lead's connector pin is fully seated in the lead connector port and that the setscrew is tight.
	Data collection is off	Turn data collection on.
	Patient without EPR	Remind patient to keep EPR on their person.
	Patient traveled outside of programmed altitude range	Reprogram range before and after patient travels outside the usual geographic location.
Pressure waveform has aberrant peaks or contains high-frequency noise.	Lead dislodgement/artifact	Reposition the lead.
	Lead fracture or insulation defect	Replace the lead.
	Telemetry link interference	<ul style="list-style-type: none"> ▪ Reposition the programming head. ▪ Remove any sources of EMI.

Temperature sensing problems

Table 7-3. Temperature sensing problems

Observed problem	Possible cause	Suggested corrective action
Temperature error	Displayed temperature is not within patient's known body temperature.	<ul style="list-style-type: none"> ▪ Verify lead serial number is correct. ▪ Verify that the device is inserted into the pocket. ▪ Verify that EGM sensing is intact.
	The IHM is not equilibrated to the patient's body temperature.	Wait 10 min for the IHM to equilibrate to the patient's body temperature, then re-interrogate.

Warnings and precautions

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Device handling

Checking and opening the package – Before opening the sterile package tray, visually check for any signs of damage that might invalidate the sterility of the package contents. Refer to the sterile package opening instructions inside the product box.

If the package is damaged – The device packaging consists of an outer tray and inner tray. Do not use the device or accessories if the outer packaging tray is wet, punctured, opened, or damaged. Return the device to Medtronic because the integrity of the sterile packaging or the device functionality may be compromised. This device is not intended to be resterilized.

Reducing static electricity – The device and lead must be used in an area where measures have been taken to reduce static electricity. These measures include, but are not limited to, grounding of personnel, equipment, and work surface areas.

Handling the pressure sensing lead – Handle the lead with care at all times.

- Do not implant the lead if it is damaged. Return the lead to a Medtronic representative.
- Protect the lead from materials that shed small particles such as lint and dust. Lead insulators attract these particles.
- Do not handle the lead by the sensor capsule or connector pin.
- Handle the lead with sterile surgical gloves that have been rinsed in sterile water or a comparable substance.
- Do not severely bend, kink, or stretch the lead.
- Do not implant the lead if it has been dropped.
- Do not immerse the lead in mineral oil, silicone oil, or any other liquid except blood or sterile water at the time of implant.
- Do not use surgical instruments to grasp the lead.
- Do not force the lead if resistance is encountered during lead passage.

Handling the lead sealing rings – The sealing rings on the connector end of the implantable lead must be protected from damage during insertion and removal from the connector block.

- Before inserting the lead into the device, look into the connector port opening. If the dark colored setscrew is visible, retract the setscrew one turn beyond the point where it disappears from view.
- After pre-implant calibration, loosen the setscrew three turns before removing the lead, to prevent damage to the lead sealing rings.

Dropped pressure sensing lead – Do not implant the pressure sensing lead if it has been dropped after removal from packaging.

Dropped device – Do not implant the device if it has been dropped on a hard surface from a height of 30 cm (12 in) or more after removal from packaging.

For single use only – Do not resterilize and reimplant an explanted device that has been contaminated by contact with body fluids.

Sterilization – Medtronic has sterilized the package contents with ethylene oxide prior to shipment. This device is for single use only and is not intended to be resterilized.

Device storage

Avoid magnets – To avoid battery depletion, store the device in a clean area away from magnets or kits containing magnets.

Temperature limits – Store and transport the package between -18 °C (0 °F) and +55 °C (131 °F).

Equilibration – Allow the device to reach room temperature before programming or implanting, because rapid temperature changes could affect initial device function and the accuracy of pre-implant calibration.

“Use by” Date – Do not implant the device after the “Use by” date because the battery longevity could be reduced.

Device implant

Accessories – Use this device only with accessories, parts subject to wear, and disposable items that have been tested to technical standards and found safe by an approved testing agency.

Programmer and software – Use the appropriate Medtronic programmer and software to program this device. Programmers from other manufacturers are not compatible with Medtronic devices but will not damage Medtronic devices.

Lead compatibility – Do not use another manufacturer’s leads without demonstrated compatibility with Medtronic devices.

Reducing static electricity – The device and pressure sensing lead must be implanted in an environment where measures have been taken to reduce static electricity. The measures include, but are not limited to, grounding of personnel, equipment, and work surface areas. Preferably, the area in which the lead is implanted should have conductive flooring.

Removing the shorting bar – The shorting bar must be removed from the lead connector prior to implant, in an area where measures have been taken to reduce static electricity. Do not handle the lead connector pin after the shorting bar has been removed. Handle the polyurethane lead body only.

Pre-implant calibration – Perform pre-implant calibration of the pressure sensing lead and device on the sterile surgical table. Move sharp or heavy instruments away from the calibration area to prevent damage to the pressure sensing lead capsule, lead body, or device.

Previously implanted leads – Exercise caution in the placement of the pressure sensing lead in patients with previously implanted ventricular leads. Mechanical contact with a pre-existing lead may cause errors in the cardiac pressure measurements.

Lead evaluation and lead connection

- Do not use ventricular transvenous leads in patients with tricuspid valve disease or a mechanical prosthetic tricuspid valve. Use with caution in patients with a bioprosthetic valve.
- Do not use excessive force or surgical instruments to insert a stylet into a lead.
- Use care when positioning the pressure sensing lead. Avoid known infarcted or thin ventricular wall areas to minimize the occurrence of perforation and dissection.
- Use the correct anchoring sleeve for the lead to immobilize the lead and protect it against damage from ligatures. Use the lead anchoring sleeve to secure the lead lateral to the venous entry site.
- Do not suture directly over the lead body, tie a ligature directly over the lead body, or otherwise create excessive strain at the insertion site. These actions may damage the lead.

Refer to the lead technical manuals for additional instructions and precautions about lead handling.

Device operation

Battery depletion – Carefully monitor battery longevity. Battery depletion will eventually cause the device to stop functioning.

End of Service (EOS) – Replace the device when the programmer displays an EOS message and a battery voltage of 2.62 V or less.

Programmers – Use only Medtronic programmers, application software, and accessories to communicate with the Chronicle IHM device.

Multiple active implanted devices – Do not place or carry the EPR over any other active implanted medical device. The EPR contains a strong magnet that could unintentionally change the operation of the other implant and prevent therapy.

Implanted Chronicle IHM device – Do not carry or wear the EPR over an implanted Chronicle IHM device. This could erase stored data and could result in premature depletion of the Chronicle IHM device battery.

Explant and disposal

Explant and disposal – Explant devices postmortem. In some countries, explanting battery operated implantable devices is mandatory because of environmental concerns; please check your local regulations. In addition, if subjected to incineration or cremation temperatures, the device could explode. Medtronic implantable devices are intended for single use only. Do not resterilize or re-implant explanted devices. Return explanted devices to Medtronic for analysis and disposal. See the back cover for mailing addresses.

Medical therapy hazards

Diathermy – People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and implantable hemodynamic monitors (IHMs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, and/or the need to reprogram or replace the device.

Electrosurgical cautery – Electrosurgical cautery may induce ventricular arrhythmias and fibrillation or may cause device malfunction or damage. If electrosurgical cautery cannot be avoided, observe the following precautions to minimize complications:

- Interrogate the device before the procedure, and turn off data collection until the procedure is completed.
- Keep temporary pacing and defibrillation equipment available.

- Use a bipolar electrocautery system if possible. If unipolar cautery is used, position the ground plate so the current pathway does not pass through or near the device and lead system. The current pathway should be a minimum of 15 cm (6 in) away from the device and lead system.
- Avoid direct contact of the cautery equipment with the implanted device or leads.
- Use short, intermittent, and irregular bursts at the lowest clinically appropriate energy levels.
- Verify proper device operation after electrocautery has been used.

External defibrillation – External defibrillation may damage the implanted device. External defibrillation may also temporarily or permanently damage the myocardium at the electrode tissue interface. Current flow through the device and lead may be minimized by following these precautions:

- Use the lowest clinically appropriate defibrillation energy.
- Position the defibrillation patches or paddles a minimum of 15 cm (6 in) away from the device.
- Position the defibrillation patches or paddles perpendicular to the device-lead system.

If an external defibrillation is delivered within 15 cm (6 in) of the device, contact a Medtronic representative.

Hyperbaric oxygen therapy (HBOT) – Exposing the device and lead system to pressure levels above 25 psi-absolute could permanently damage the pressure sensor.

Lithotripsy – Lithotripsy may permanently damage the implanted device if it is at the focal point of the lithotripter beam.

Magnetic resonance imaging (MRI) – Do not use magnetic resonance imaging (MRI) on patients who have an implanted device. MRI can induce currents on implanted leads, potentially causing tissue damage and the induction of tachyarrhythmias. MRI may also cause damage to the device.

Radio frequency (RF) ablation – An RF ablation procedure may cause device malfunction or damage. Radio frequency ablation risks may be minimized by observing the following precautions:

- Keep temporary pacing and defibrillation equipment available.
- Position the ground plate so the current pathway does not pass through or near the device and lead system. The current pathway should be a minimum of 15 cm (6 in) away from the device and lead system.
- Avoid direct contact between the ablation catheter and the implanted system.
- Verify implanted device operation after the procedure. Abandon any diagnostic data collected during the procedure.

Therapeutic ultrasound – Exposure of the device to therapeutic ultrasound is not recommended as it may permanently damage the device.

Radiation hazards

Note: Consider the accumulated dose of radiation to the implanted system, from both previous and current exposures, for patients undergoing multiple procedures, such as fluoroscopy or radiation therapy.

Contact your Medtronic representative if you have any questions about the information provided in this section.

Diagnostic radiation and short duration fluoroscopy – The accumulated dose from diagnostic radiation, including chest x-rays, mammograms, computerized axial tomography (CT or CAT) scans, and short duration fluoroscopy, is normally not sufficient to affect the performance of the implanted system.

Device and pressure sensing lead damage from high-dose radiotherapy or long duration fluoroscopy – Do not expose the device or the pressure sensor on the pressure sensing lead to high doses of direct or scattered radiation. An accumulated dose of radiation above 0.5 Gy may affect the performance of the device and pressure sensor; however, the affect may not be immediately apparent. The affect on the performance of the system may be indicated in various ways, including a shift in sensing performance or a clinically noticeable offset in reported pressure and temperature. If an offset occurs, it does not recover over time and should be considered when interpreting the data.

If a patient requires radiation therapy, from any source, do not expose the device or pressure sensor to radiation exceeding an accumulated dose of 0.5 Gy. In cases where a patient requires a long duration fluoroscopic procedure, exposure durations beyond 30 min should be recorded in the patient's medical records for assessment of accumulated exposure. Use appropriate shielding or other measures to limit the radiation exposure to the implanted system. Consider the accumulated dose of radiation to the implanted system from both previous and current exposures for patients undergoing multiple diagnostic procedures, such as fluoroscopy or radiation therapy.

Operational errors associated with photon beam

radiotherapy – Exposing the device to direct or scattered neutrons may cause reset of the device, errors in diagnostic data, or loss of diagnostic data. To help prevent device reset due to neutron exposure, deliver radiotherapy treatment using photon beam energies less than or equal to 10 MV. The use of conventional x-ray shielding during radiotherapy does not protect the device from the effects of the neutrons. If photon beam energies exceed 10 MV, Medtronic recommends interrogating the device immediately after radiotherapy treatment. A device reset requires reprogramming of device parameters. Electron beam treatments do not produce this effect.

Home and occupational environments

Barometric pressure in water – Exposing the device-lead system to high pressures such as water at depths beyond 3.05 m (10 ft) can cause a clinically noticeable offset in the reported pressure. This offset may not recover over time and should be considered in interpreting subsequent data. Re-establish the patient's optivolemic state over the next follow-up period by following the same procedures used at the initial implant of the device.

Cellular phones – This device has been tested using the ANSI/AAMI PC-69 standard to ensure compatibility with cellular phones and other hand-held transmitters with similar power. These transmission technologies represent the majority of cellular telephones used worldwide. The circuitry of this device, when operating under nominal conditions, has been designed to minimize the effects from cellular telephones.

To further minimize the possibility of interaction, observe these cautions:

- Maintain a minimum separation of 15 cm (6 in) between the device and the cellular phone, even if the cellular phone is not on.
- Maintain a minimum separation of 30 cm (12 in) between the device and any antenna transmitting above 3 W.
- Hold the cellular phone to the ear farthest from the device.

Electromagnetic interference (EMI) – Instruct patients to avoid devices that generate strong EMI. Electromagnetic interference may cause device malfunction or damage. The patient should move away from the EMI source or turn off the source because this usually allows the device to return to its normal mode of operation. EMI may be emitted from sources such as:

- high-voltage power lines
- communication equipment such as microwave transmitters, linear power amplifiers, or high-powered amateur transmitters
- commercial electrical equipment such as arc welders, induction furnaces, or resistance welders

Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with device operation. There are reports of temporary disturbances caused by electric hand tools or electric razors used directly over the implant site.

Electronic Article Surveillance (EAS) – Electronic Article Surveillance equipment such as retail theft prevention systems may interact with the implanted device. Advise patients to walk directly through an EAS system, and not remain near an EAS system longer than is necessary.

Static magnetic fields – Patients should avoid equipment or situations where they would be exposed to static magnetic fields greater than 10 gauss or 1 millitesla since it could improperly trigger the device to capture data. Sources of static magnetic fields include, but are not limited to: stereo speakers, bingo wands, extractor wands, magnetic badges, or magnetic therapy products.

Parameters

B

Functional parameters 96

Functional parameters

Programmable parameters are determined by the software used in the programmer.

Table B-1 General operating parameters

Parameter	Capability	Shipped	Nominal	POR
Data Collection	Off; On	Off	Off	Off
Lead	(enter serial number)	??a	—	Unchanged
Sensitivity (mV)	0.5; 1 ... 8	2.5	2	2.5

^a Value is unknown at shipping and must be programmed at time of implant.

Table B-2 Pressure setting parameters

Parameter	Capability	Shipped	Nominal	POR
Maximum Altitude (feet)	–100; 1000; 2000 ... 10000	??a	— ^b	??a
Minimum Altitude (feet)	–100; 1000; 2000 ... 10000	??a	— ^b	??a
Maximum Systolic Pressure (mmHg)	40; 45 ... 100; 110 ... 150; 170	??a	—	??a
Minimum Diastolic Pressure (mmHg)	–10 (fixed)	–10	–10	–10
RV Pressure Waveform Rate Less Than (bpm)	70; 75; 80; 85; 90; 95; 100; 105; 109; 115; 120	90	90	90

^a Value is unknown at shipping and must be programmed at time of implant.

^b Value can be saved in the programmer as a nominal.

Table B-3 Trend data storage parameters

Parameter	Capability	Shipped	Nominal	POR
Trend A	3 hours (2 s); 1 day (32 s); 1 week (256 s); 2 weeks (512 s); 1 month (1024 s); 2 months (2048 s); 3 months (3072 s)	1 day	2 weeks	1 week
Trend B	3 hours (2 s); 1 day (32 s); 1 week (256 s); 2 weeks (512 s); 1 month (1024 s); 2 months (2048 s); 3 months (3072 s)	2 weeks	3 months	??? ^a

^a Value is unknown at shipping and must be programmed at time of implant.

Table B-4 Trigger data storage parameters

Parameter	Capability	Shipped	Nominal	POR
Patient Trigger	On; Off	Off	—	Off
Brady Trigger Rate Less Than (bpm)	Off; 30; 35 ... 65; 71; 75; 80; 86; 91	Off	50	Off
Tachy Trigger Rate Greater Than (bpm)	Off; 100; 109; 120; 130; 140; 150; 162; 171; 182; 188; 200	Off	182	Off
Tachy V. Beats to Detect	6 of 16; 12 of 16	12 of 16	12 of 16	12 of 16
Tachy Activity Counts	Off; 1; 2 ... 15	Off	—	Off

Table B-5 Additional settings parameters

Parameter	Capability	Shipped	Nominal	POR
EGM Range (mV)	±2; ±4; ±8; ±16	±8	±8	±8
Activity Level	Low; Medium Low; Medium High; High	Medium Low	Medium Low	Medium Low
Holter Telemetry (hours)	Off; 0.5; 1; 2; 4; 8; 16; 24; 36; 46	Off	Off	Off
Pre-Implant Cal Number (mmHg)	-10; -9 ...10	0	0	Unchanged
V. Blank Post VS (ms)	200; 210 ... 400	200	200	200
Device Date/Time	(enter date & time)	—	—	Jan 1, 1994 00:00
Patient Information	(type name or ID #)	???	—	Unchanged

^a Value is unknown at shipping and must be programmed at time of implant.

Clinical investigation

C

For information about the clinical investigation, please refer to the panel package. A description of the clinical investigation will be added to this appendix at final labeling.

Patient Management Strategies

D

Optivolemic treatment recommendation 102

Hypervolemic treatment recommendation 103

Hypovolemic treatment recommendation 104

Optivolemic treatment recommendation

The optivolemic definition is shown in Table D-1

Table D-1 Optivolemic Definition

Patient Symptoms	Minimal Congestive Symptoms AND Minimal Evidence of Poor Perfusion
Invasive Hemodynamic Monitoring^a	Systemic Vascular Resistance (SVR) = 900–1100 dsc ⁻⁵ Pulmonary arterial systolic pressure = 24–36 mmHg Pulmonary arterial end diastolic pressure = 8–18 mmHg Right atrial pressure = 6–10 mmHg
Chronicle Parameters^a	RV systolic pressure (RVsys): 25–40 mmHg RV diastolic pressure (RVdias): 4–10 mmHg ePAD: 8–18 mmHg
Daily Minimum Trends (Nocturnal - midnight to 4:00 a.m. - mean measurements with no activity)	Within Pre-determined Optivolemic range
Week, Month, Year Trends (continuous 24 hour data)	Stable Trend Data

^a **Physician Panel Note:** Although optimum parameters must be established individually, these values are based on the clinical expertise of a subset of Chronicle investigators. These values were determined without signs and symptoms of poor perfusion and/or worsening ischemia.

Treatment intervention at investigator discretion:

1. No medication changes based on volume data
2. Baseline chronic aggressive medical therapy
 - a. Angiotensin Converting Enzyme (ACE) Inhibitor (angiotensin receptor blocker (ARB) or other vasodilator if ACE not tolerated) to target doses as tolerated
 - b. Digoxin, diuretic, electrolyte replacement, advised
 - c. Consider spironolactone as indicated in patients with stable renal function and potassium handling
 - d. Dose vasodilators to reasonably appropriate doses as tolerated
 - e. Begin beta-blockade in appropriate patients when not hypervolemic, titrate dose to reasonably appropriate doses as tolerated
 - f. Consider nitrates if evidence or suggestion of myocardial ischemia

3. If patient has signs and symptoms of poor perfusion (cold), consider other interventions including:
 - a. Admission for monitoring and further adjustment of medical regimen
 - b. Intravenous therapeutic agents
 - c. Increase intravascular volume if still without evidence of congestion at rest
 - d. Consider invasive hemodynamic monitoring for determination of cardiac output if indicated
 - e. There may be no further chronic conventional therapy available for the “cold and dry” patient

Hypervolemic treatment recommendation

The hypervolemic definition is shown in Table D-2.

Table D-2 Hypervolemic definition

Patient Symptoms	Congestion Symptoms (Wet)
Chronicle Parameters^a	Above the Pre-determined
QuickLook (Nocturnal - midnight to 4:00 a.m. - mean measurements with no activity)	Optivolemic Range
Daily Minimum Trends (Nocturnal - midnight to 4:00 a.m.- mean measurements with no activity)	Elevation in Trend Data outside pre-determined Optivolemic Range
Week, Month, Year Trends (continuous 24 hour data)	Elevation in Trend Data

^a **Physician Panel Note:** If signs and symptoms of congestion are present and Chronicle Real-time pressures are not elevated, further evaluation is warranted prior to intervention.

Treatment Intervention at Investigator Discretion:

1. Add/increase diuretic (and appropriate electrolyte replacement)
 - a. Increase or add loop diuretic
 - b. Change to another loop diuretic (i.e. change from furosemide to torsemide)
 - c. Add thiazide diuretic (with caution due to tendency toward hypokalemia)
 - d. Give intravenous dose of loop diuretic

- e. Re-assessment in 1 to 7 days with Chronicle interrogation and serum electrolyte determination with any change in baseline medications¹
2. Add/increase nitrates (especially if evidence or suggestion of ischemia)
3. Start or re-educate in salt and/or fluid restriction
4. If patient has signs and symptoms of poor perfusion (cold) in addition to being Hypervolemic:
 - a. Consider admission if clinical evidence suggests need for intravenous diuretics, telemetry monitoring, or the use of intravenous therapeutic agents
 - b. Consider invasive hemodynamic monitoring for determination of cardiac output if indicated

Hypovolemic treatment recommendation

The hypovolemic definition is shown in Table D-3.

Table D-3 Hypovolemic definition

Patient Symptoms^a	Poor Perfusion in absence of signs and symptoms of congestion
Chronicle Parameters^b	Below the Pre-determined Optivolemic Range
QuickLook (Nocturnal - midnight to 4:00 a.m. - mean measurements with no activity)	
Daily Minimum Trends (Nocturnal - midnight to 4:00 a.m. - mean measurements with no activity)	Decrease in Trend Data outside the Pre-determined Optivolemic Range
Week, Month, Year Trends (continuous 24 hour data)	Decrease in Trend Data

^a **Physician Panel Note:** Optimal renal function parameters are variable and should be individualized taking into consideration measured hemodynamic parameters.

^b **Physician Panel Note:** If signs and symptoms of poor perfusion are present and Chronicle Real-time pressures are not decreased or low, further evaluation is warranted prior to intervention.

Treatment Intervention at Investigator Discretion:

1. Lower/discontinue diuretic:
 - a. If on thiazide diuretic with loop diuretic, lower or discontinue dose of thiazide (and adjust electrolyte replacement)

¹ Renal dysfunction may preclude lowering filling pressures in some patients.

- b. If on only loop diuretic, lower dose or discontinue
 - c. Consider liberalization of oral fluid restriction and/or salt restriction
2. If postural hypotension, hold or lower vasodilators and/or oral nitrates, especially if hypotensive when sitting or supine (unless evidence of myocardial ischemia)
 3. If worsening renal function, especially if hypotensive, hold or lower ACE/ARB dose
 4. If patient has signs and symptoms of poor perfusion (cold) in addition to being Hypovolemic:
 - a. Consider admission if clinical evidence suggests need for intravenous fluid repletion, telemetry monitoring, or the use of intravenous therapeutic agent(s)
 - b. Consider invasive hemodynamic monitoring for determination of cardiac output if indicated

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