Sensor Optimization of CRT Response (SOCR) System

User Guide

Caution: Investigational device. Limited by federal law (USA) to investigational use.

Exclusively for clinical investigations.

Investigational Device / Instrument de recherche.
To Be Used by Qualified Investigators Only / Réservé uniquement à l'usage de chercheurs compétents.

SYMBOLS DEFINITIONS:

	Attention, consult accompanying documents.
	Device is type CF, direct cardiac applied parts.
	Caution or Warning notice.
	Do not reuse, single patient use only.
	Conformité Européenne (European Conformity). This symbol means that the device fully complies with R&TTE Directive 1999/5/EC.
	***Do not dispose of this product in the unsorted municipal waste stream. Dispose of the product according to local regulations.***

TERMINOLOGY DEFINITIONS:

Term	**Definition**
Subject	Patient under study.
Impedance	Ratio of voltage measured divided by current injected.
Vector	Pacing lead electrode configuration for impedance measurement.

Medtronic

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1. PHYSICAL CHARACTERISTICS

1.1 SYSTEM COMPONENTS

Components included as part of the SOCR research system are shown in Table 1.

Table 1. System Components

Component	Description
Investigational Model 19061 AHM Module	Impedance measurement and pacing component
Investigational Model 19062 Heart Sound Sensor Device	Heart sounds component
Biopac MP150 and UIM100C	Data acquisition system
Model 2090 Programmer with Viva/Brava Software with 2090 A/B and cable	Programmer for Heart Sound Sensor Device
Model 2090 Programmer with SOCR Investigational Software with 2090 A/B and cable	Programmer for AHM Module
Laptop Computer with AcqKnowledge Software package	Used for data acquisition software
Investigational Model 15420 Patient Cable	Used for connection of AHM Module to subject pacing leads
RA/RV leads	Connections to subject right heart
LV lead or LV catheter/patient cable	Connections to subject left heart
Millar pressure catheter	LV pressure component
Millar PCU-2000 and patient cable	LV pressure measurement component

1.2 POWER SOURCE

The AHM Module is powered by six 3.6V AA lithium batteries. A set of batteries will provide at least 4-hours of procedure time before requiring replacement. These batteries will be provided by Medtronic to centers for use in the study. The Heart Sound Sensor Device has a self-contained battery. All other system components requiring power (i.e. the laptop, Biopac MP150, and the 2090 Programmers) will use AC line power.

⚠ **Caution:** It is recommended that the AHM Module be fitted with a fresh set of 3.6V AA lithium batteries provided by Medtronic prior to each clinical case.

Caution: It is recommended that the SOCR System be disconnected from the subject during battery replacement.

Caution: The 2090 Programmer is powered with AC line power.

Caution: The Biopac MP150 Data Acquisition System is powered with AC line power.

Caution: The laptop computer is powered with AC line power.

1.3 INTENDED USE ENVIRONMENT

The SOCR System is designed to operate in an Electrophysiology (EP) Lab or hospital environment under the direct supervision of medical personnel. The system was not tested to handle exposure to autoclave (except for the Model 15420 Patient Cable sterilization procedure), hyperbaric chambers, cold temperatures, high temperatures, high humidity, steam, special gases (anesthetic etc.), fluids, or other severe conditions.

Caution: The Model 19061 AHM complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications of any kind not expressly approved by Medtronic could void the user's authority to operate the equipment.

AHM FCC ID: LF519061

2. SYSTEM OVERVIEW

2.1 SYSTEM DESCRIPTION

The SOCR System (Figure 1) contains electronics that control the continuous stimulation and sensing required to collect real-time intracardiac impedance and heart sounds signals. The impedance signals are collected from selected electrode vector configurations using the subject's implanted pacing leads/LV catheter and an investigational impedance pacing unit, the Model 19061 Acute Human Monitor (AHM) Module. A Model 2090 programmer with the SOCR Investigational Software along with a switch on the front panel of the AHM Module allow the user to select specific electrode vector configurations for current stimulation and voltage sense measurement. The heart sounds signals are collected from an investigational Model 19062 Heart Sound Sensor Device placed on the subject.

Real-time impedance and auxiliary signals from analog output terminals of the AHM Module, real-time heart sounds and EGM/marker signals from the two programmers through a 2090A/B Analog Output Module, and real-time LV pressure signals from the Millar PCU-2000 are transmitted to the applicable Biopac Data Acquisition System's analog input terminals. The Biopac Data Acquisition System transmits the acquired analog input signals to the computer's data acquisition software [AcqKnowledge®] which subsequently saves the data to the computer's hard disk and displays real time waveform data on the computer's display.

The AHM Module also contains circuitry for standard pacing interventions with the implanted right atrial (RA) lead, right ventricular (RV) pacing lead, and left ventricular (LV) pacing lead or catheter. The leads are connected to an investigational Model 15420 Patient Cable in order to interface with the AHM Module. The LV catheter is directly connected.

The Biopac MP150 Data Acquisition System also collects physiologic signals from standard EP laboratory equipment used for subject monitoring during device implant. These physiologic signals may include ECG, blood pressure, or other physiologic signals. Available physiologic signals can be recorded simultaneously with the above signals but are not required by Medtronic to obtain the study objectives.

The SOCR system is shown pictorially in Figure 1.

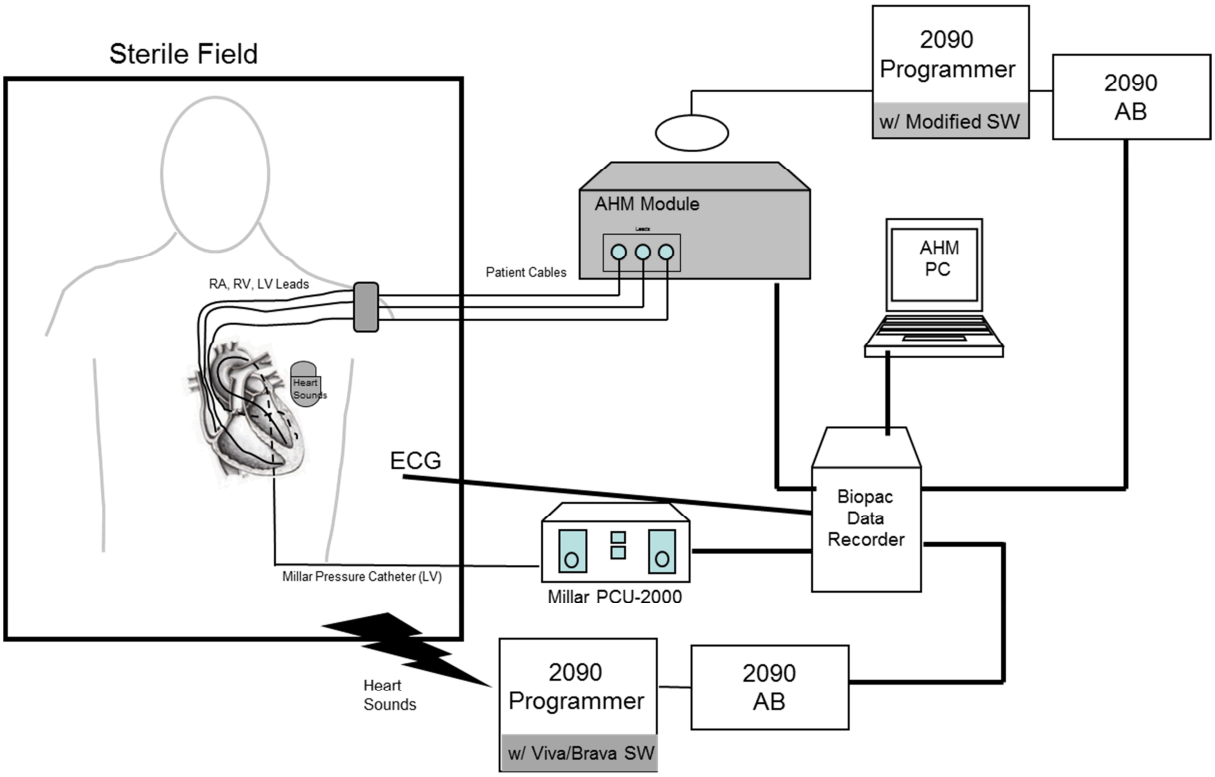


Figure 1. SOCR System Components.

⚠ **Warning:** The SOCR System is intended for investigational use only and should be used only by trained Medtronic personnel, clinical study investigators and designated clinical staff trained in performing the acute clinical study protocol.

2.2 INTENDED USE

The SOCR System (Figure 1) is intended to be used in the Electrophysiology (EP) Lab for the clinical investigation of continuous intracardiac impedance and heart sounds signals during the defined acute human study protocol.

2.2.1 INTENDED USE OF THE MODEL 19061 AHM MODULE

The AHM Module contains electronics that control the continuous stimulation and sensing required to collect real-time intracardiac impedance signals from a selected electrode vector configuration using conventional implanted pacing leads/LV catheter. A Model 2090 programmer operating the SOCR investigational software along with the HVB/LVR3 switch on the front panel of the AHM Module allow the user to select specific electrode vector configurations for current stimulation and voltage sense measurement. The AHM Module also contains electronics to provide the standard pacing interventions using the conventional implanted pacing leads/LV catheter needed during the course of the study. The real-time impedance signal and EGM/markers generated by the AHM Module are recorded by the data acquisition system.

2.2.2 INTENDED USE OF THE MODEL 19062 HEART SOUND SENSOR DEVICE

The Heart Sound Sensor device is used to collect a real-time heart sounds signal. Although the Heart Sound Sensor device has a header and shield graphics indicating that leads can be connected to it, no leads are connected to the device for the purposes of this study. The device has no therapy functions. The heart sounds signal is transmitted through telemetry, using the Viva/Brava software operating on a Model 2090 programmer, and recorded by the data acquisition system.

The Heart Sound Sensor device is provided sterile. It can be temporarily placed in the subject's device pocket during an implant procedure, and, for this purpose, it is single use.

The Heart Sound Sensor device can be cutaneously attached to the subject post implant, and, for this purpose it can be re-used. See Section 2.3 for cleaning instructions.

Do Not Reuse: The Medtronic Model 19062 Heart Sound Sensor device is for single patient use only when placed in the subject's device pocket.

2.2.3 INTENDED USE OF THE MODEL 15420 PATIENT CABLE

The Model 15420 patient cable is used for connection between the implanted subject's pacing leads to the AHM Module. The cable will be supplied non-sterile. It should be cleaned and steam sterilized prior to use. All surfaces may be cleaned with water, mild detergent or 70% isopropyl alcohol. Care should be taken to ensure complete removal of all cleaning agents. A soft bristle brush may be used to facilitate the cleaning of small surfaces. During cleaning, the connector block should be opened and the adaptor area cleaned. The cable may be wiped clean. This cable will enter the sterile field and therefore must be sterilized prior to use, including first use. Autoclave the cable under the following conditions: 121 °C (250 °F), vacuum cycle for 50 minutes.

2.3 CLEANING AND MAINTENANCE

After completion of the study, the AHM Module should be cleaned using damp cloth or towel with either water or alcohol based solvent. The module should not be immersed or exposed to excessive moisture. Patient cables can be wiped down and must be returned to the clinical staff for sterilization prior to their next use. After cutaneous use, a Heart Sound Sensor device can be cleaned using damp cloth or towel with either water or alcohol based solvent. No special maintenance is required between uses of the SOCR System.

2.4 WARNINGS AND PRECAUTIONS

⚠ **Warning:** The AHM Module supplied by Medtronic is to only be used for pacing interventions and impedance signal generation. The Heart Sound Sensor device is to only be used for heart sounds signal generation. Neither can be used for rescue attempts in the event that defibrillation, cardioversion or resuscitation is required. Emergency backup equipment must be available prior to the start of the study.

⚠ **Warning:** External defibrillator pads should be placed no closer than 2.5 cm to any other study electrodes.

⚠ **Caution:** If an LV catheter is placed, ensure that none of the unused catheter cable pins present a direct unintended conductive path to

the heart. Capping the unused pins is an acceptable method of preventing this.

⚠ **Caution:** The AHM Module is not designed to be sterilized or intended to be used within a sterile field. The module should be used in conjunction with sterilized patient cables to provide sterile connection to the subject.

2.5 POTENTIAL ADVERSE EVENTS

Potential adverse events related to the use of SOCR system include, but are not limited to:

- LV catheter placement risks such as stroke, bleeding, and pro-arrhythmia
- Standard CRT system implantation risks
- Bleeding and bruising due to use of blood thinners

For a full list of potential adverse events, see the Clinical Investigational Plan.

2.6 CONTRAINDICATIONS

The following contraindications exist for this system:

- Patient requires dual chamber cardiac pacing or single chamber (ventricular) pacing at rest for rate support
- Recent echocardiogram (within the last 6 months) has revealed the presence of an LV thrombus

For further details and a complete list of inclusion/exclusion criteria, see the Clinical Investigational Plan.

3. SYSTEM SETUP

3.1 BIOPAC SYSTEM OVERVIEW

All analog output signals from the AHM Module, 2090A/B Analog Output Modules, and Millar PCU-2000 will be independently connected via a supplied connection cables to separate analog input channels on the Biopac MP150 Data Acquisition System with the Biopac UIM100C module (Figure 2). Additional physiologic input signals such as ECG, blood pressure, blood pressure plethysmography or any other physiologic signals, per implanting physician's discretion, may also be connected to an unassigned input channel on the Biopac UIM100C (Figure 3) to monitor the subject's vital signs. Available physiologic signals can be recorded simultaneously with the above signals but are not required by Medtronic to obtain the study objectives.

Data will be acquired through the AcqKnowledge® (Ver 4.0 or later) data acquisition software via the Biopac MP150 / UIM100C and supplied laptop computer.

Figure 2. Biopac MP150 Data Acquisition System with Biopac UIM100C Module.

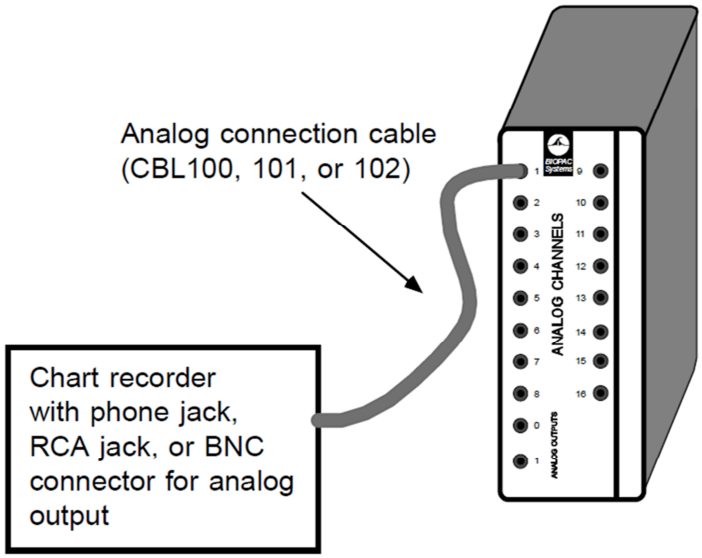


Figure 3. Depicts an example of an external physiologic signal connection to the UIM100C Analog Input Channel Array via provided custom cables.

3.2 CONNECTIONS TO THE BIOPAC SYSTEM

Table 2 depicts assigned connections to the Biopac MP150 and UIM100C analog input channels:

Table 2. Connections to the Biopac System

Channel Input	Description	Connection Method
1	ECG	Cable from an ECG source available in the lab
2	EGM1	Cable from Output B of 2090A/B Analog Output Module connected to AHM Module programmer
3	EGM2	Cable from Output C of 2090A/B Analog Output Module connected to AHM Module programmer
4	Markers	Cable from Output D of 2090A/B Analog Output Module connected to AHM Module programmer
5	Impedance vector toggle	Cable from HVB/LVR3 output of AHM Module
6	Pace blanking	Cable from IBLANK output of AHM Module
7	Impedance	Cable from AOUT output of AHM Module
8	Impedance gain	Cable from Gain output of AHM Module
9	Heart sounds	Cable from Output B of 2090A/B Analog Output Module connected to Heart Sound Sensor programmer
10	LV Pressure	Cable from PCU-2000

All connections to the Biopac MP150 interface are made using cables provided by Medtronic.

3.3 CONNECTIONS TO AND USE OF THE AHM MODULE

Table 3 depicts channel connections to the AHM Module's rear (Figure 4), and front panels (Figure 5). The LV TIP, and LV RING 1-3 connections only apply when an LV catheter is placed. When an LV catheter is placed, select the distal electrode on the LV catheter as electrode AA. Select electrodes BB, CC, and DD such that the edge-to-edge distance between BB and AA is closest to 21mm, between CC and BB is closest to 1.3mm, and between DD and AA is closest to 46mm.

Table 3. Connections to the AHM Module

Connection	Connection Method
HVB/LVR3	Cable to Biopac UIM100C Analog Input Channel 5
I BLANK	Cable to Biopac UIM100C Analog Input Channel 6
AOUT	Cable to Biopac UIM100C Analog Input Channel 7
GAIN	Cable to Biopac UIM100C Analog Input Channel 8
PATIENT CABLE	Model 15420 Patient Cable to sterile field for connection to subject pacing leads
LV TIP	Cable to LV catheter electrode AA (if LV catheter is placed)
LV RING 1	Cable to LV catheter electrode BB (if LV catheter is placed)
LV RING 2	Cable to LV catheter electrode CC (if LV catheter is placed)
LV RING 3	Cable to LV catheter electrode DD (if LV catheter is placed)
Model 2067 or 2067L Programming Head	Programmer Head for Model 2090 Programmer

Except for the LV catheter, all connections to the AHM Module are made using cables provided by Medtronic. LV catheter cables are provided by the LV catheter manufacturer.

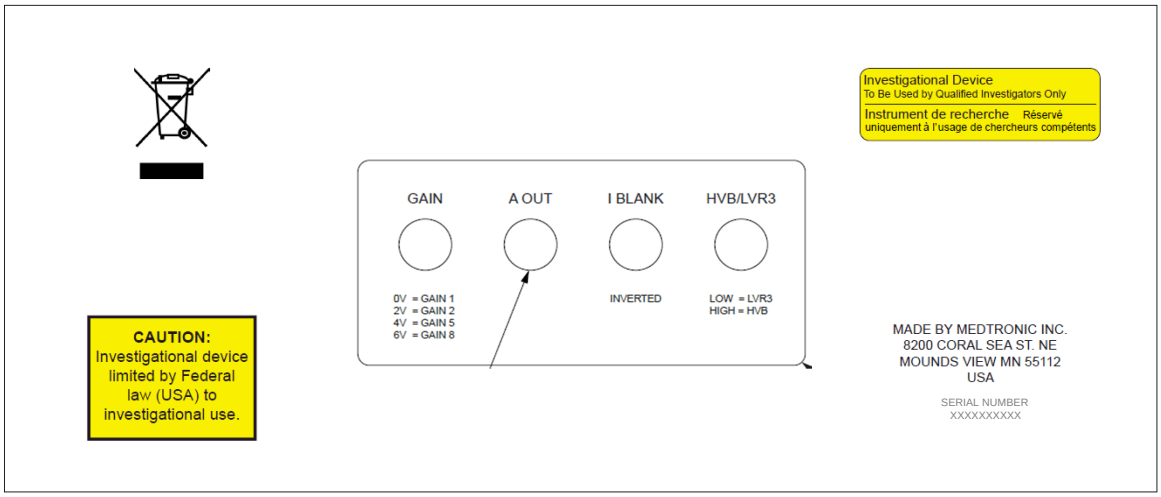


Figure 4. Rear panel of the AHM Module

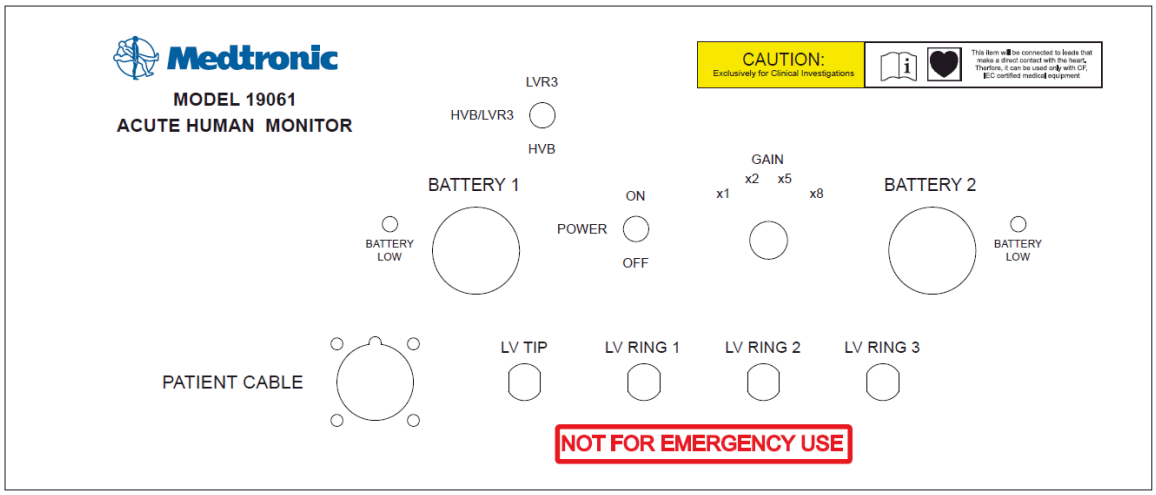


Figure 5. Front panel of the AHM Module.

Leave the GAIN switch on the front panel in the “x8” position for the study.

Place the programming head in the designated area on top of the AHM Module.

The unit is powered by 6 AA lithium batteries. The unit takes 3.6V batteries, supplied by Medtronic. Replace the batteries prior to each subject use.

Warning: Do not dispose of the lithium batteries in the unsorted municipal waste stream. Dispose of the batteries according to local regulations.

Power to the unit is turned on and off by use of the power switch labeled "POWER" with the conventional on/off switch positions. The power must be applied to the AHM Module during use.

3.4 CONNECTIONS TO THE SUBJECT

Table 4 and Figure 6 show the patient cable connections in the sterile field for device connection to the subject. Run an impedance test using the SOCR software to verify that all leads are properly connected.

Table 4. Connections to the Subject

Cable / Label		Subject Connection
Medtronic Model 15420	RV-DF4	Connection to subject's RV-DF4 lead (if applicable)
	LV-IS4	Connection to subject's LV-IS4 lead (if applicable)
	RA-IS1	Connection to subject's RA-IS1 lead
	LV-IS1	Connection to subject's LV-IS1 lead (if applicable)
	HVB-DF1	Connection to subject's HVB-DF1 leg of RV IS1/DF1 lead (if applicable)
	RV-IS1	Connection to subject's RV-IS1 leg of RV IS1/DF1 lead (if applicable)
	SVC-DF1	Connection to subject's SVC-DF1 leg of RV IS1/DF1 lead (if applicable)

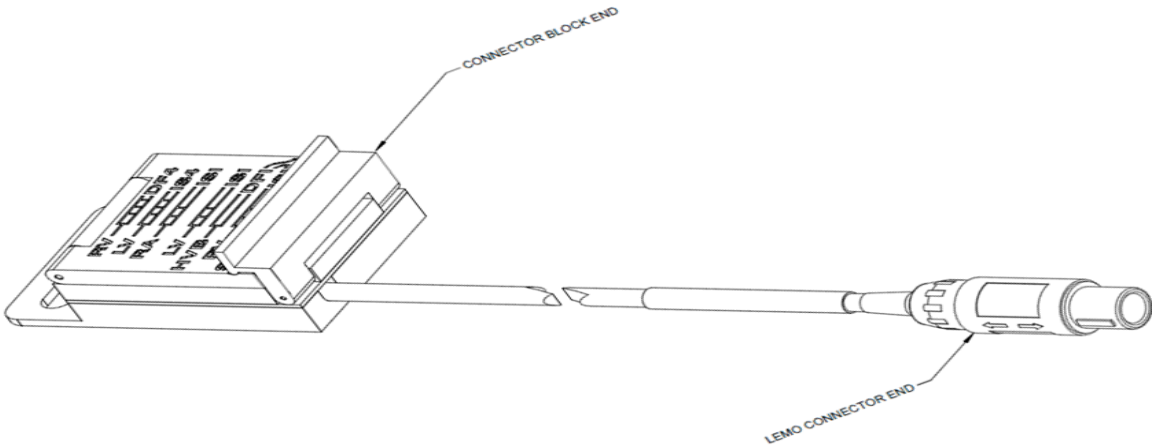


Figure 6. Medtronic Model 15420 Patient Cable for AHM Module connection to subject's pacing leads

3.5 INSTALLING AND UNINSTALLING THE SOCR INVESTIGATIONAL SOFTWARE

Refer to Appendix A for instructions on how to install the SOCR Investigational Software onto a Model 2090 Programmer. The installation only needs to be done once per programmer.

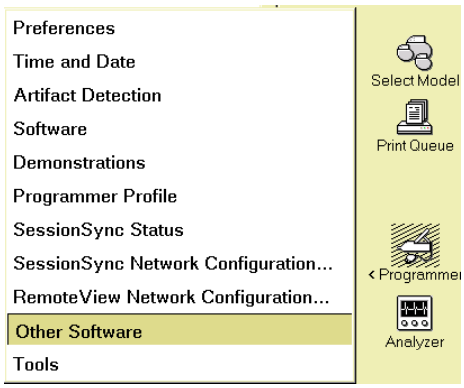
When the clinical study is complete, the software must be uninstalled from all Medtronic Model 2090 CareLink Programmers on which it was installed. Refer to Appendix B for instructions on how to uninstall the SOCR Investigational Software.

3.6 STARTING THE SOCR INVESTIGATIONAL SOFTWARE

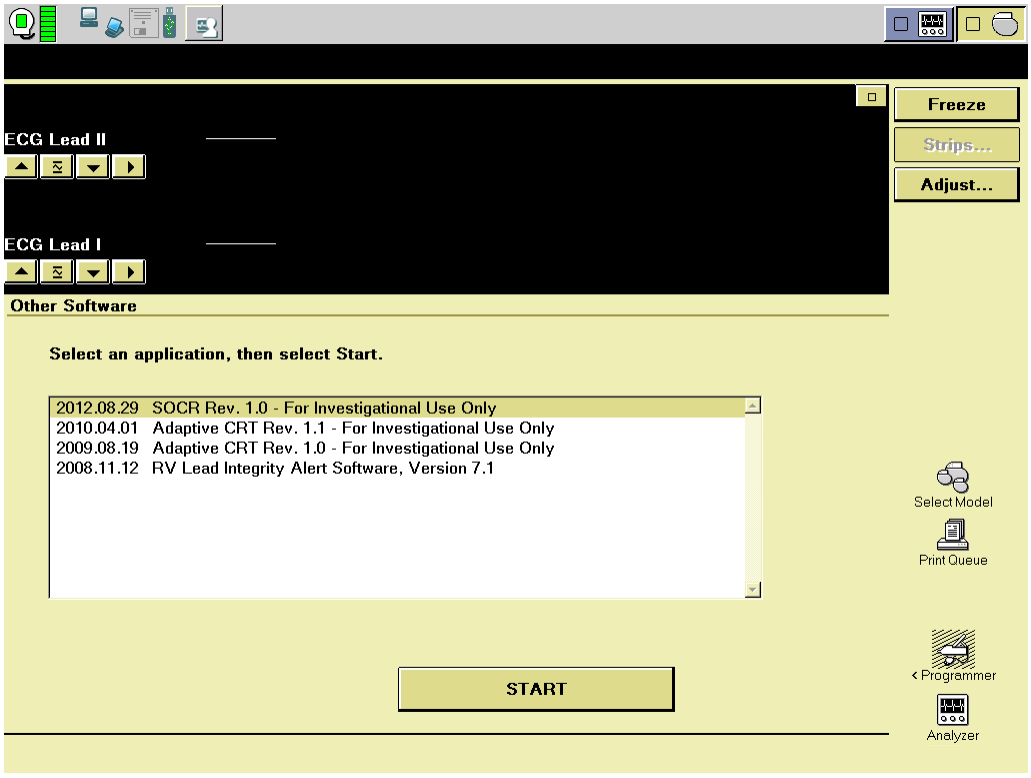
After installing the SOCR Investigational Software application on the programmer, do the following to access it:

1) Turn the Medtronic Model 2090 CareLink Programmer's power On.
2) If the Find Patient window is displayed, select Cancel.
3) Select "Programmer" from the icons on the right side. 

4) Select "Other Software" from the options displayed.



5) Select "SOCR Rev. 1.0 – For Investigational Use Only" from the list displayed.



6) Select Start.
7) After about 5 seconds, the SOCR Investigational Software will be activated and the system is ready for use.

After using the software, select the End Session button to go back to the Other Software screen.

3.7 SOFTWARE SETUP FOR THE AHM MODULE

The programmer used with the AHM Module must have the SOCR Investigational Software installed (see section 3.5).

Follow the steps below for proper use of the programmer with the AHM Module:

1) Ensure that the AHM Module's power is on and that neither battery low indicator is set.
2) Follow the steps in section 3.6 to start the software.
3) Press **Interrogate…** and then **Start**.
4) **Clear** the electrical reset and press **Continue**.
5) **Disable** ALL therapies and ALL detection parameters. (Params>Pacing)
6) Place the device in **DDD** mode. (Params>Pacing)

7) Set V. Pacing is set to **LV->RV.** (Params>Pacing>CRT)
8) Ensure that LV Pace Polarity is set to **LV1 to RVcoil.** (Params>Pacing)
9) **Disable** the following features: (Params>Pacing)
    a. Capture Management (Amplitude/Pulse Width)
    b. Rate Adaptive AV (AV Intervals)
    c. V. Sense Response (Arrhythmia/Post Shock)
10) Program the following:
    a. LV amplitude to a minimum of **3V**.
    b. LV pulse width to a minimum of **0.4 ms**.
    c. RV amplitude to a minimum of **3V**.
    d. RV pulse width to a minimum of **0.4 ms**.
    e. A amplitude to a minimum of **3V.**
    f. A pulse width to a minimum of **0.4 ms**.
11) Program the following:
    a. EGM1 Source to **RVtip to RVring**.
    b. EGM3 Source to **LV1 to RVcoil**.
    c. Impedance Vector to **RV to LV Distal**.
12) Enter the live waveform screen. Position EGM1 above EGM3. Select EGM1 and EGM3 for printing.
13) Set Lower Rate and Paced AV to achieve AV sequential pacing. (Params>Pacing)
14) Observe that atrial and biventricular pace markers are occurring.
15) Set the pacing mode to **ODO.**

AHM Module software setup is complete.

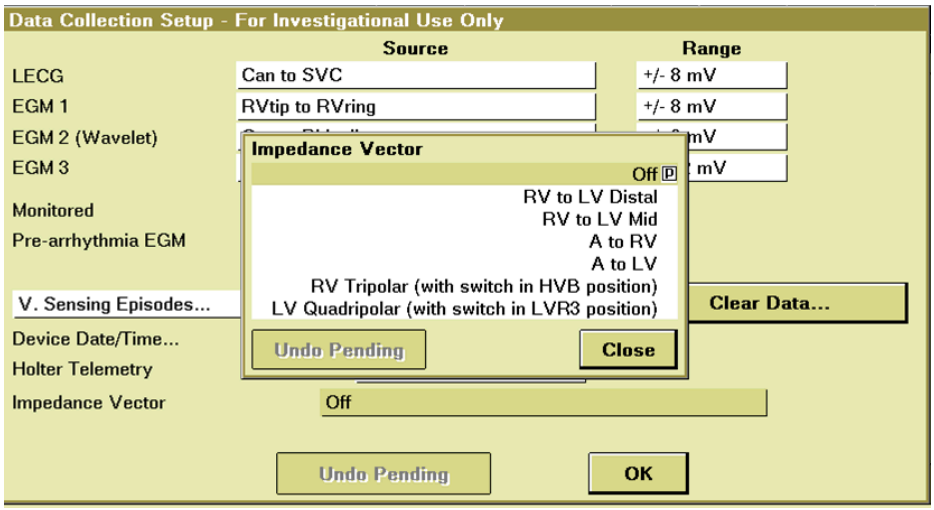
Be sure to power down the AHM Module prior to the completion of the study.

Sensing performance and pacing thresholds should already be assessed as a part of the lead implant prior to the start of this study. Refer to the investigational Viva/Viva Quad, Brava/Brava Quad CRT-D Reference Manual for any additional instructions on interfacing with the Model 2090 Programmer.

Capture thresholds will be monitored and adjusted as needed to maintain consistent capture; adequate safety margins will be used. EGM signals will be monitored and sensing thresholds will be adjusted as needed to maintain proper sensing.

3.7.1 PROGRAMMING IMPEDANCE VECTORS

The SOCR Investigational Software provides the capability of programming the Impedance Vector to any of six possible values from the Params->Data Collection Setup screen. Note that the HVB/LVR3 switch on the front panel of the AHM Module must be set to the proper position when programming the last two selections.



3.8 SOFTWARE SETUP FOR THE HEART SOUND SENSOR DEVICE

The programmer used with the Heart Sound Sensor device must have the Viva/Brava software installed. Contact the Medtronic Clinical Study Team if the software is not installed on your programmer.

Power up the programmer.

Follow the steps below for proper use of the Model 2090 Programmer with the Heart Sound Sensor device:

1) When the Find Patient screen is displayed, ensure that the “Use Wireless” checkbox is selected.
2) Place programming head over the Heart Sound Sensor device until the programmer recognizes the device, then return the programming head to the programmer tray.
3) Wait for the interrogation to complete. If a pop-up message specifying electrical reset is displayed during this process, do not proceed with this Heart Sound Sensor device (repeat setup for a backup device if available).
4) Navigate to the Parameters screen and ensure that EGM3 is set to LV3 to LV4 with +/-4mV range and that Pacing Mode is ODO.
5) Enter the live waveform screen. Position EGM3 above all other waveforms and select for printing.
6) Ensure that EGM3 (heart sounds signal) amplitude is at least above half of the dynamic range but without signal clipping. Adjust EGM3 Range to +/-2mV or +/-8mV, even +/-16mV as needed.

The heart sounds signal is now being transmitted, and Heart Sound Sensor device software setup is complete.

4. SETUP TEST PROCEDURE

The following setup procedure must be completed prior to protocol initiation. These steps are not in any particular order, except for the last step, which must be executed last.

✓	**Setup Procedure**
☐	Confirm that each 2090A/B Analog Output Module is connected to its respective Medtronic programmer.
☐	Confirm Output B of the 2090A/B Analog Output Module connected to the Heart Sound Sensor programmer is connected to the Biopac MP150 as outlined in section 3.2, Table 2.
☐	Confirm Output B, Output C, and Output D of the 2090A/B Analog Output Module connected to the AHM Module programmer are connected to the Biopac MP150 as outlined in section 3.2, Table 2.
☐	Confirm the output cables on the rear panel of the AHM Module are connected to the applicable Biopac MP150 analog input channels as outlined in section 3.2, Table 2.
☐	Confirm ECG is connected to the Biopac MP150 as outlined in section 3.2, Table 2.
☐	Confirm the Millar PCU-2000 output is connected to the Biopac MP150 as outlined in section 3.2, Table 2.
☐	Confirm the Ethernet cable is connected from the Biopac MP150 to the laptop computer.
☐	Confirm 6 new 3.6V AA lithium batteries have been placed in the AHM Module as shown on the front panel, Section 3.3, Figure 5, and that neither battery low indicator is set. Also confirm that the GAIN switch is in the “x8” position. Turn power on.
☐	Confirm the Medtronic patient cable is connected to the PATIENT CABLE input on the front panel of the AHM Module.
☐	Confirm the Medtronic programmer head of the AHM Module programmer is positioned on the top of the AHM Module as outlined in section 3.3, Table 3.
☐	Confirm that the AHM Module programmer setup as outlined in section 3.7 has been completed, and the atrial and ventricular pace markers occurred as expected.
☐	Confirm that the Heart Sound Sensor programmer setup as outlined in section 3.8 has been completed.
☐	If an LV catheter has been placed, confirm the LV catheter cables are connected to the front panel of the AHM Module as outlined in section 3.3, Table 3 and Figure 5. If an LV catheter has not been placed, confirm that there are no connections to those inputs.
☐	Confirm that the pacing leads have been connected to the Model 15420 patient cable and that the impedance test shows proper connections.
☐	Confirm the Millar pressure catheter is connected to the Millar PCU-2000.
☐	**Perform Last:** Confirm that the laptop computer is displaying physiological-looking signals for ECG, EGM, impedance, heart sounds, and LV pressure, and that the markers, IBLANK, GAIN, and HVB/LVR3 signals are appropriate.

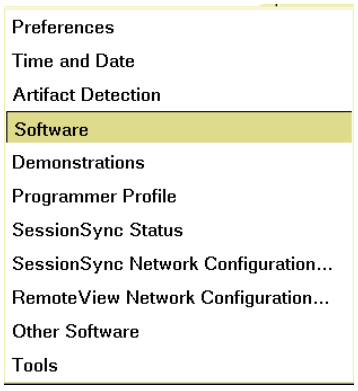
APPENDIX A – INSTALLING THE SOCR INVESTIGATIONAL SOFTWARE

To use the SOCR Investigational Software with a Medtronic Model 2090 CareLink Programmer, the software must first be installed on a programmer running Vision Release 2.5 or later. To determine the Vision Release on a 2090 programmer, select the Programmer icon from the main screen. Select Software from the dropdown list. Verify the 2090 programmer lists Vision Release 2.5 or higher. If the programmer release is not current or correct, ask your Medtronic representative about updating the programmer software. The installation of the SOCR Investigational Software only needs to be done once per programmer.

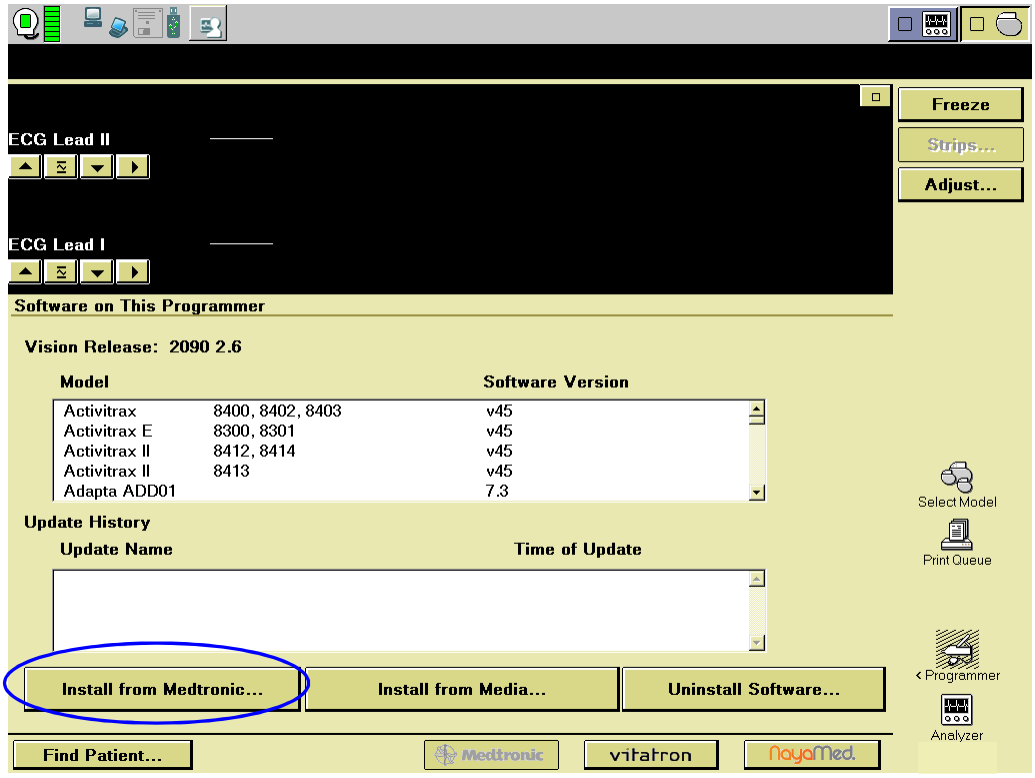
Installation requires use of a network connection to access the Medtronic Software Distribution Network (SDN). The SDN uses a world-wide private network to connect to servers. If you have not yet used SDN, you will be prompted to enter in a Programmer Profile during the install. Follow the Programmer Reference Guide provided with the Medtronic Model 2090 CareLink Programmer to fill in this information. To install the Investigational Software application on your programmer using SDN:

1) Contact the Medtronic Clinical Study Team to add your programmer serial number to the approved SOCR Investigational Software list.
2) Turn the programmer's power On. Connect the programmer to a network, either wired, wireless, or dial-up.
3) Select the Programmer icon. 

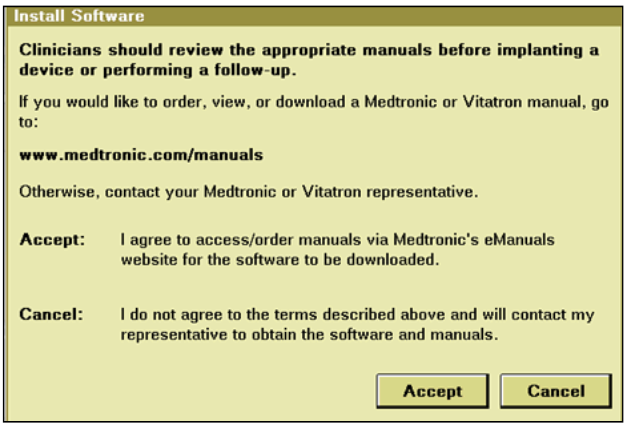
4) Select Software from the menu.



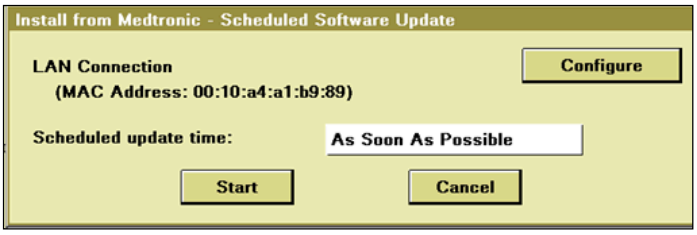
5) Select Install from Medtronic…



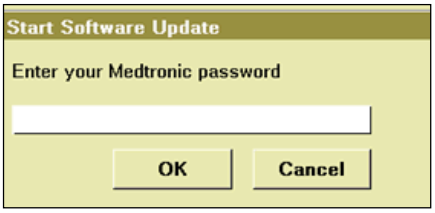
6) US Only: Press Accept to agree to the terms of the installation agreement. The download will begin. Note that the manuals available on the Medtronic website are for market released products only, including the device and 2090 programmer being used during this study.



7) If the programmer has a combo card installed, the Install from Medtronic - Schedule Software Update window appears showing the LAN connection by default. You may configure this connection by selecting Configure. If the programmer has a modem card installed, you can ignore this step.



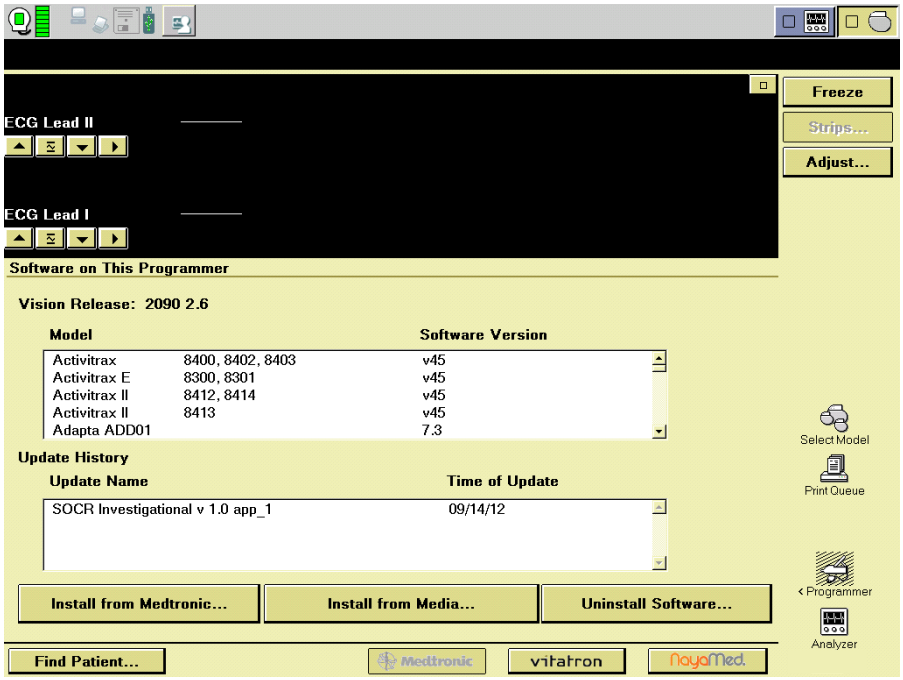
8) Type in your Medtronic password on the Start Software Update window.



9) The Update Software window will appear to start the installation. Review this window to verify the current settings.

10) Press Start to begin the software download. The screen will temporarily go blank and reboot while connecting to the SDN and installing the software.

11) When the installation is complete, the Software on This Programmer screen shows the SOCR Investigational Software application and the Time of Update.



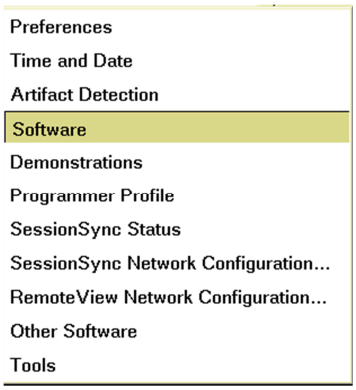
12) For further instructions on accessing the SDN installation, see the Medtronic CareLink Programmer for Model 2090 Programmer Reference Guide, available on the Medtronic Manuals website.

APPENDIX B – UNINSTALLING THE SOCR INVESTIGATIONAL SOFTWARE

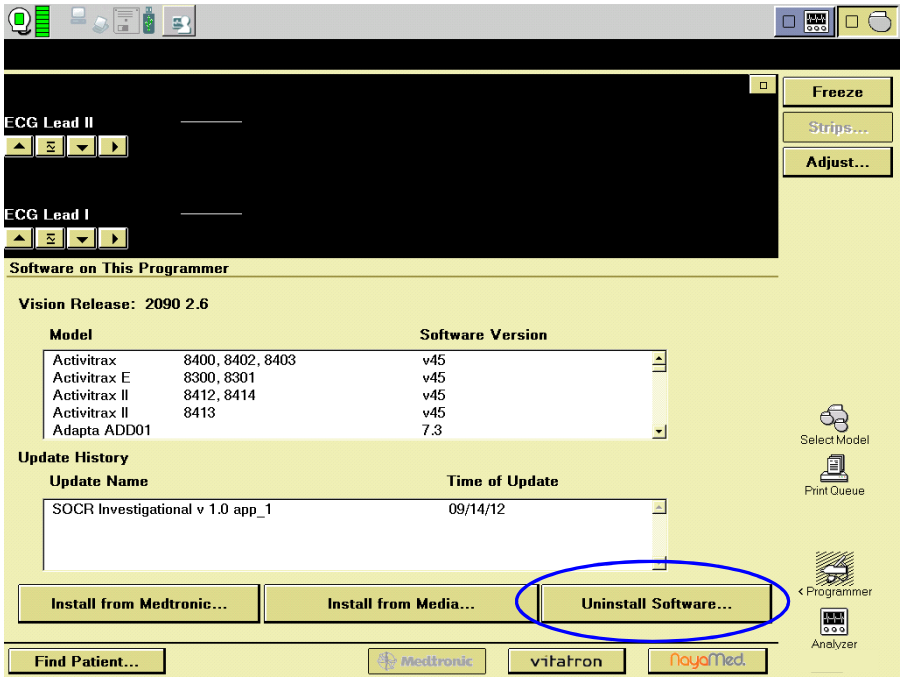
When the clinical study is complete, the software must be uninstalled from all Medtronic Model 2090 CareLink Programmers on which it was installed. If the software needs to be re-installed onto the same programmer after it has been uninstalled, contact Medtronic for assistance.

1) Turn the programmer's power On.
2) Select the Programmer icon. 

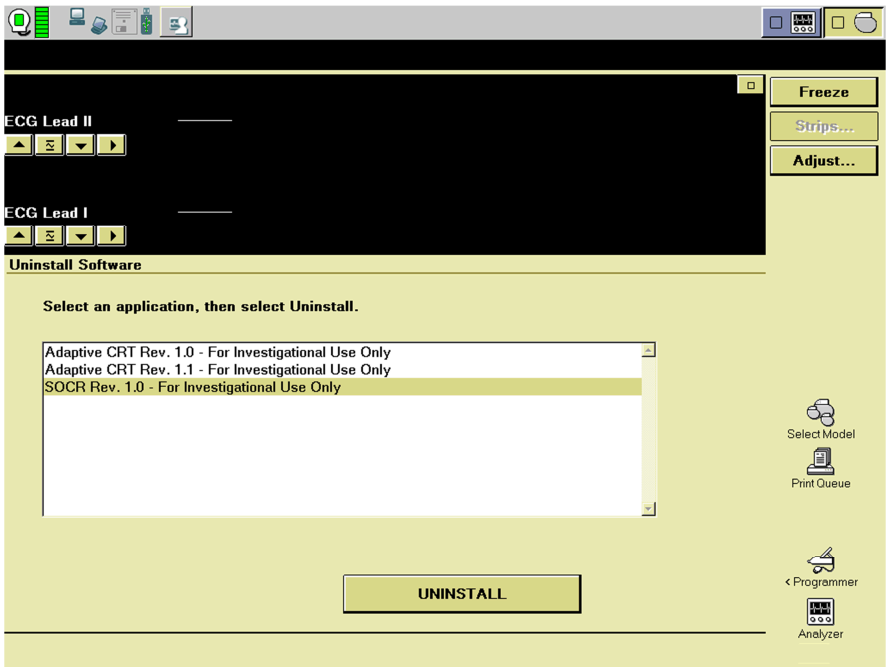
3) Select Software from the menu.



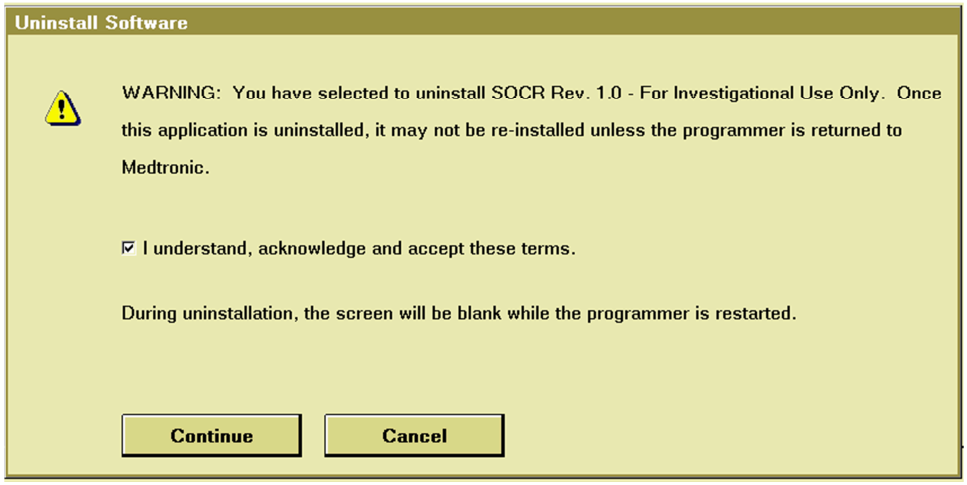
4) Select Uninstall Software...



5) On the Uninstall Software screen, select the SOCR Investigational Software application. Press Uninstall.



6) An Uninstall Software warning window will appear to confirm the uninstall of SOCR. Verify that the software to be removed is SOCR, accept the term of this uninstall, and press Continue.



7) The Software on This Programmer screen is updated to display the SOCR Investigational Software Uninstall update.

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