CARDIAC INSIGHT, INC.

Cardea SOLO™ ADX Operator's Manual

Model S400

Includes instructions for Cardea SOLO™ ADX:

- PC Software, Model D400
- Smart Cable, Model C400
- Sensor, Model M400
- Cardea Rhythm Viewer (CRV), Model A400

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

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Part Number: PN00592-02 B

Revised: February 2024

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1 Introduction

1.1 Indications for Use

The Cardea SOLO™ ADX is a multiday skin-applied ambulatory ECG recorder with analysis algorithms used to diagnose cardiac health during activities of daily living in patients with minimum anterior axillary line spacing of 15 cm (~6 inches), which can include pediatric patients.

1.2 Intended Use

The Cardea SOLO™ ADX is intended for continuous two lead ECG recording, presentation of recorded ECG data, and associated analysis information, to assist clinicians in diagnosing cardiac disease as well as cardiac health. The Sensor is not intended for use should defibrillation be required and should be removed before defibrillation.

1.3 Contraindications

Patients with known allergic reaction or hypersensitivity to adhesives or hydrogels, or family history of adhesive skin allergies.

Patients with potentially life-threatening arrhythmias, or who require inpatient monitoring or immediate analysis of their ECG.

Patients with an implantable pacemaker or with active stimulator devices (external or implanted) such as urology stimulators, TENS units, deep brain stimulators, muscle activators, spinal cord stimulators. Pacing and stimulators may interfere with the analysis of the ECG and cause misclassification of beats and rhythms or render the recorded ECG signal unanalyzable.

Do not use the Sensor on patients who are not competent to follow instructions for use for the prescribed monitoring period unless a caregiver is directly involved.

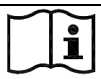
Do not use the Sensor in combination with external cardiac defibrillators or high frequency surgical equipment or near strong magnetic fields or devices such as MRI. The Sensor should be removed prior to external defibrillation or an MRI scan.

1.4 Clinician's Responsibility

Not all cardiac conditions can be detected by an ECG analysis and many potentially detectable conditions are not always present or may be transitory and not present in a specific ECG recording. The symptoms, physical exam, patient / family history and additional information are critical to the clinician's overall assessment of a patient's cardiac health.

It is the clinician's responsibility to ensure proper ECG data collection, review the raw data, interpret, and ultimately make a diagnosis of the individual's cardiac health and/or risk of cardiac events. Proper decisions of when more testing is indicated, specific treatment initiated or referral for specialty care is dependent upon good clinical judgment.

1.5 Definitions of Symbols Used

	WARNING. Indicates potentially hazardous situation, which, if not avoided, could result in the possible injury, death or other serious adverse reactions associated with use, or device failure.
	CAUTION. Indicates a potentially hazardous situation, which, if not avoided, could result in minor or moderate injury. It is also used to alert against unsafe practices.
Precaution	Information regarding any special care to be exercised by the clinician, clinical staff, and or patient/caregiver for the safe and effective use of the device.
NOTE	Informative only. No action required on the part of the user.
	Do not re-use. Indicates a medical device that is intended for one use.
	Consult instructions for use.
	Refer to instruction manual / booklet.
	Temperature limits. Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation. Indicates the range of humidity to which the medical device can be safely exposed.
	Atmospheric pressure limitation. Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Use by date. This symbol is accompanied by a date YYYY-MM-DD to indicate the device should not be used after the date shown.
	Batch or lot code. This symbol is accompanied by identifier of manufacturer lot.
	Catalog number. This symbol is accompanied by the manufacturer model number.
	Type BF Applied Part.
	Protected against the effects of splashing water and solid foreign objects.
	This product contains no natural rubber latex.
	Serial Number. This symbol is accompanied by the manufacturer serial number.
	Global Trade Identification Number.

	Manufacturer. This symbol is accompanied by the name and address of the manufacturer.
	CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a licensed physician.
	Do not use if package is damaged.
	Magnetic Resonance (MR) unsafe.
	Do not incinerate.
5V⎓200mA	Direct current (Smart Cable USB connection).

2 Getting Started – Cardea SOLO™ ADX System Components

WARNING. Read all instructions before using the system and follow all instructions while using the system.

2.1 Cardea SOLO™ ADX PC Software

The package contains:

A USB Flash drive with Cardea SOLO™ ADX PC Software

- The Flash Drive is used to setup and install the Cardea SOLO™ ADX PC Software.

NOTE: This Operator's Manual, Troubleshooting Guide, and a Quick Start Guide are available as standalone PDFs on the Flash drive. This Operator's Manual is also available from the main PC Software menu.

2.2 Cardea SOLO™ ADX Smart Cable

The package contains:

Smart Cable

- Following wear, the Electronics Module is removed from the Sensor and connected to a Windows® PC via the Smart Cable for data transfer of the ECG recording.

2.3 Cardea SOLO™ ADX Sensor

The Sensors are packaged in a carton which contains:

Sensors

- Five (5) individually packaged Sensors and instructions for use specific to the Sensor.

2.4 User-Supplied Personal Computer (PC) Requirements

WARNING. Inaccurate Diagnosis. Software viruses, worms and other forms of malware may compromise the integrity of the PC. The PC should be protected from malware using software and hardware devices as appropriate for the operating environment of the PC. Regular scans of the system to detect malware are strongly recommended.

WARNING. Inaccurate Diagnosis. The PC used for Cardea SOLO™ ADX should be properly secured for appropriate user access (password / authenticity verification / automatic logout when inactive). Malicious activities of unauthorized users could compromise diagnostic information and/or the analysis software.

2.4.1 PC Supported Operating Systems and Associated Components

Windows® 10 and higher.

Microsoft .NET Framework 4.8 and Visual C++ 2022 Runtime library. See:
https://dotnet.microsoft.com/en-us/download/dotnet-framework/net48
https://docs.microsoft.com/en-US/cpp/windows/latest-supported-vc-redist?view=msvc-170

	WARNING. PC Operating System. Cardea SOLO™ ADX has been tested for proper function with the versions of Microsoft Windows specified. Other versions of PC operating systems are not recommended as their ability to function with Cardea SOLO™ ADX is not known.
Precaution	Windows® supports user customization of display characteristics. Using Control Panel\Display to increase text size from the default 100% setting to larger sizes (e.g., Medium, or Larger) may prevent Cardea SOLO™ ADX windows from being fully or correctly displayed.

2.4.2 PC Hardware Requirements

Windows® compatible personal computer

Disk: 10 GB of user accessible free disk space or greater

NOTE: Cardea SOLO™ ADX checks the available disk space for saving patient ECGs and associated information at start-up. If the available disk space is less than 10 gigabytes, a message will be displayed. On average, a Sensor's ECG recording data and associated PDF report will require about 1.2 gigabytes.

CPU: Dual Core CPU @ 2.5 GHz or greater, 64-bit (x64) processor or equivalent

Display: 1300 x 768 or higher resolution

Memory: Minimum 4 GB of system memory

Pointing Device: Windows® compatible pointing device

Keyboard: Windows® compatible keyboard

Ports: 1 available High-Speed USB 2.0 port (minimum)

	WARNING. Operator Electrical Shock. Only use a PC certified to IEC 60950-1 or IEC 62368-1. If using a laptop PC, ensure the power supply has a UL or equivalent safety agency rating.

⚠	CAUTION. Electromagnetic Interference. The selected PC should be compliant with IEC 60601-1-2 standards for radiated emissions and immunity. Use of a PC that is not compliant may interfere with Cardea SOLO™ ADX or other medical equipment operating in the vicinity. Other operating equipment (such as MRI and other imaging devices, other medical devices, microwaves, and cell phones) may degrade or otherwise interfere with the PC function. Never disable other patient monitoring equipment without getting the approval of the attending physician.

2.5 Hardware Setup

Precaution	Unreliable AC power (surges, brown-outs, spikes, and so on) may interrupt the PC function and interrupt Physician Report creation. Surge protectors and Uninterruptible Power Supplies (UPS) should be used for PCs not powered by a charged internal battery.
Precaution	Should a power outage / PC power loss occur during ECG transfer, analysis, and entry of patient demographic information, simply restart the report creation process (refer to Section 6).
⚠	WARNING. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
⚠	WARNING. Use of accessories and cables (e.g. USB extender cables) other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Cardea SOLO™ ADX hardware setup is depicted in Figure 2.1 below.

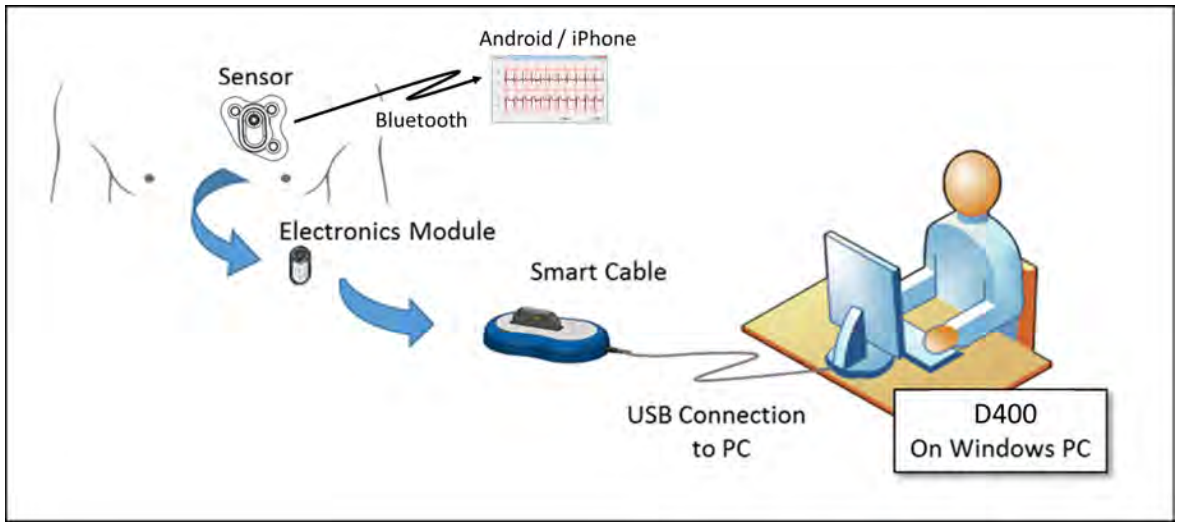


Figure 2.1. Cardea SOLO™ ADX components and data flow, from the Patient Sensor to the PC analysis software.

If the PC is directly connected to other third-party devices, such as a printer, and if the device is within the patient vicinity, then usage of medical grade power supplies (i.e., certified to IEC 60950-1 or IEC 62368-1, or a UL or equivalent safety agency rating) for the periphery equipment is recommended.

2.6 Cardea SOLO™ ADX PC Software Installation

To install the Cardea SOLO™ ADX PC Software on your PC, insert the Flash Drive that came with your System into a USB port on your PC. If the Installer doesn't automatically start, double click on the "SOLO-ADX" Windows Installer. The first screen displayed, Figure 2.2, is the Installer Set-up Wizard Welcome screen:

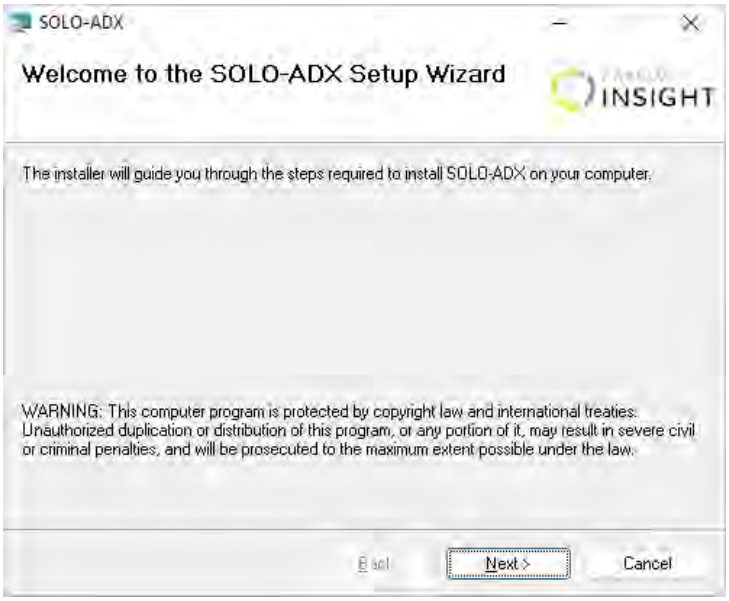


Figure 2.2. Setup Wizard Welcome Screen.

Click Next and the Wizard will present the License Agreement Screen:

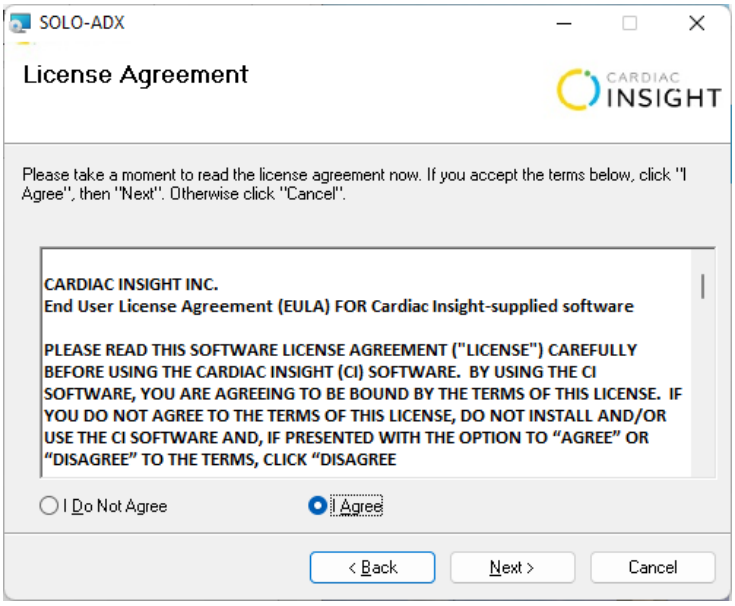


Figure 2.3. Wizard License Agreement Screen.

Click "I Agree" and then click Next.

The Wizard will next present the Installation Folder and User set-up options:

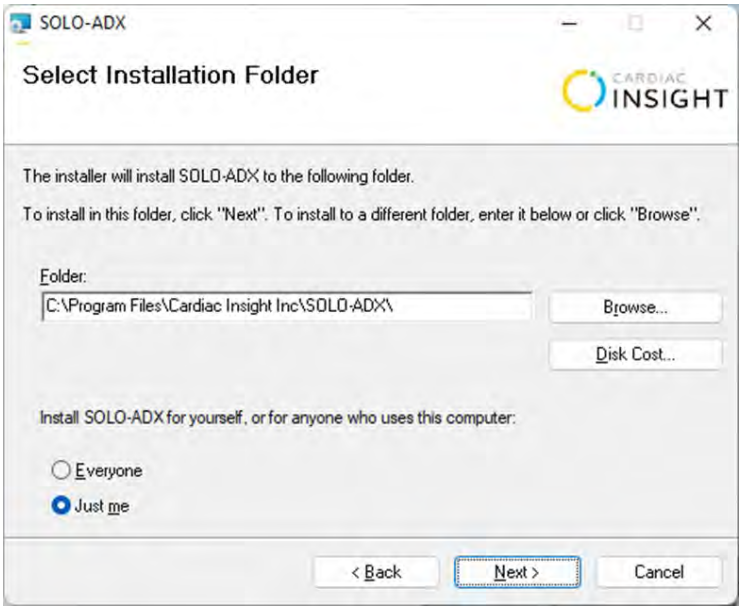


Figure 2.4. Installation Options.

Clicking Next will confirm your set-up options have been completed and installation is ready to start:

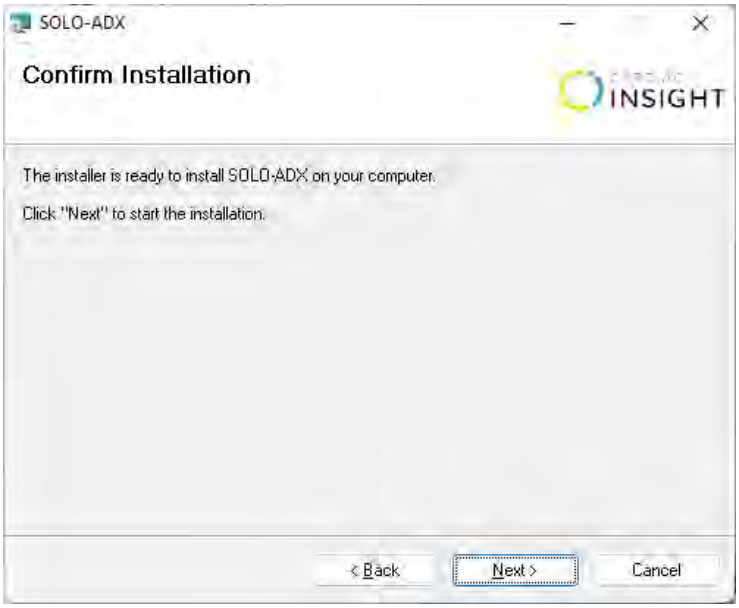


Figure 2.5. Confirm Installation and Start.

Next, the Wizard will install the System and provide a progress bar as the installation proceeds:

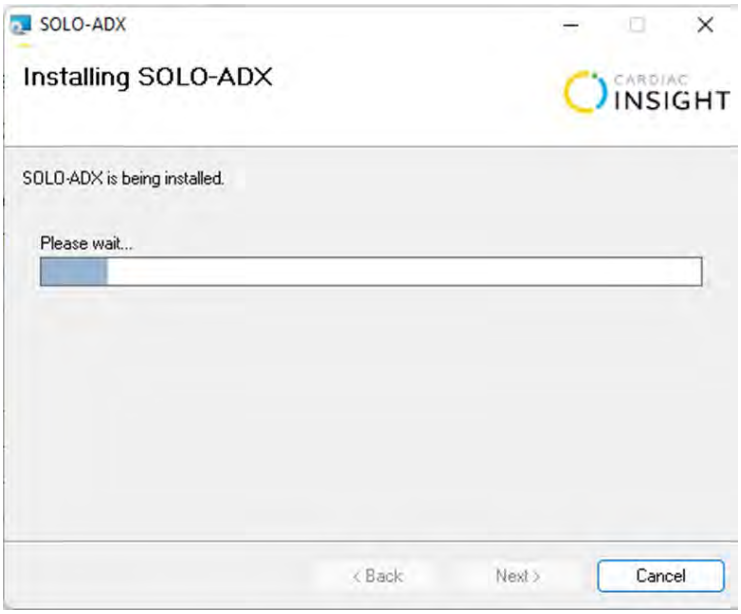


Figure 2.6. Installing System.

At the completion the Wizard will notify you the installation has been successfully done.

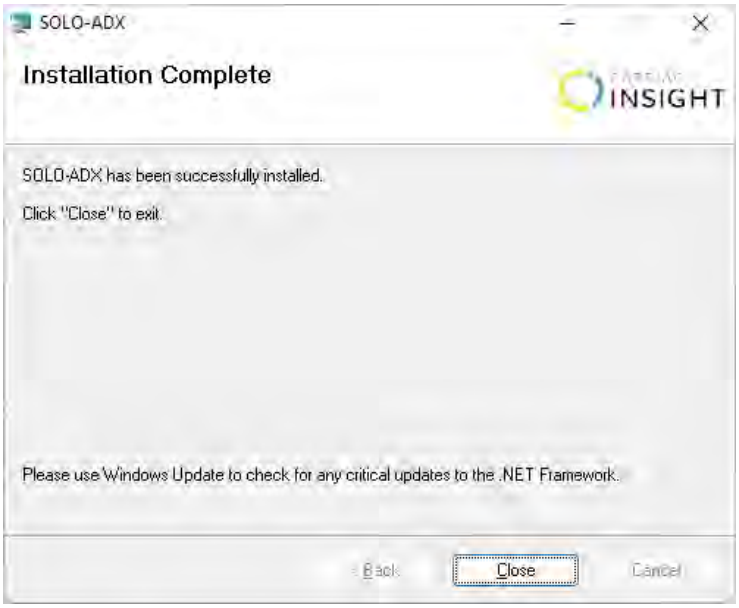


Figure 2.7. Wizard completed Install.

NOTE: If installing the PC Software on an older PC, check to confirm the .Net Framework is up-to-date. See Section 2.4.1 above.

3 Sensor Operation

NOTE: For more detailed instructions on Sensor placement and operation, refer to the Sensor Instructions for Use in the Sensor 5-pack carton.

	WARNING. Device Failure. Remove the Sensor prior to external defibrillation. The Sensor will not interfere with defibrillator energy delivery but will be permanently damaged.
	CAUTION. For Patients with sensitive skin conditions, the Sensor may cause mild discomfort, skin irritation, redness, itching, rash or contact dermatitis.
	CAUTION. Do not apply the Sensor over a bleeding wound or to irritated skin. Ignoring this caution may lead to infection.

3.1 Precautions

1. Excessive sweating may limit wear duration. Avoid situations that may cause excessive sweating.

2. The Sensor is water resistant, but not waterproof. No swimming or immersion bathing.

3. Showering while wearing the Sensor is permitted. However, instruct the patient to keep total shower time brief and to avoid a continuous, direct water spray over the Sensor.

4. Modification of the Sensor to access the Electronics Module (underneath the foam cover) and separate it from the Electrodes is allowed; this action is essential for safe operation and use of the device. No other modification is allowed as it may lead to inaccuracies in reported data or complete loss of data. There are no user serviceable parts.

5. Replace the Sensor if it peels off completely. Do not reapply. It is intended for one use only.

6. No creams, lotions, or oils should be applied in the application area immediately prior to use of the Sensor as this may interfere the adhesion to the skin. If the patient applied them prior to Sensor application clean the skin to remove all residual cream, lotion, or oil.

7. The Sensor does not replace direct communication between the patient and their health care provider. The Sensor data should be used along with all other clinical data and exams for a diagnosis.

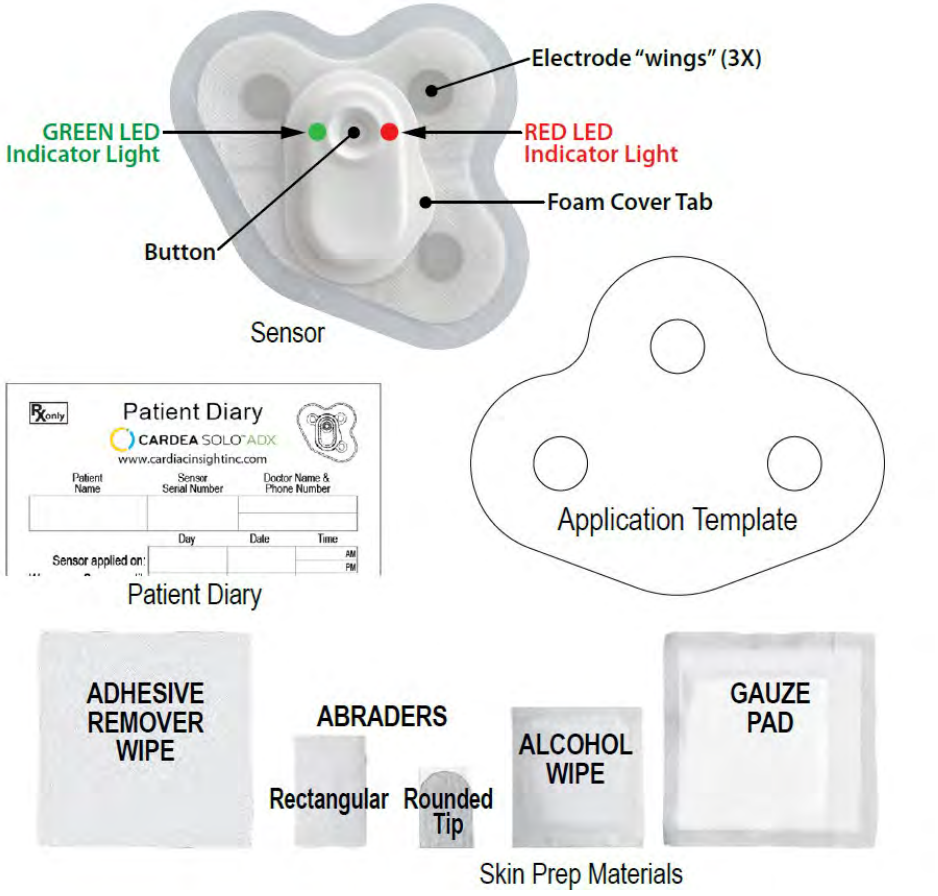
8. The Sensor will not summon emergency response in the event the patient needs help. The patient should talk to their health care provider immediately if there are any concerns or changes in condition.

9. The Sensor does not transmit ECG recording to their health care provider during wear. Inform the patient not to discard the Sensor and to return it to their health care provider in order to generate a Physician Report.

3.2 Pouch Contents

(1) Cardea SOLO™ ADX Wearable Sensor with top three protective paper elements removed.

(1) Application Template, (1**)** Patient Diary and, (1) Skin Prep Materials, (1) Adhesive Remover Wipe



3.3 Sensor – Getting Started

The Sensor is a small, lightweight, patch-style, single-use disposable, 2-lead electrocardiographic (ECG) recorder, designed for ambulatory collection of ECG data continuously for up to 10 days. The Sensor's patient contacting area has an adhesive layer with three (3) electrodes and is attached to the patient's skin in the upper chest area. Figure 3.1 illustrates the key elements of the Sensor.

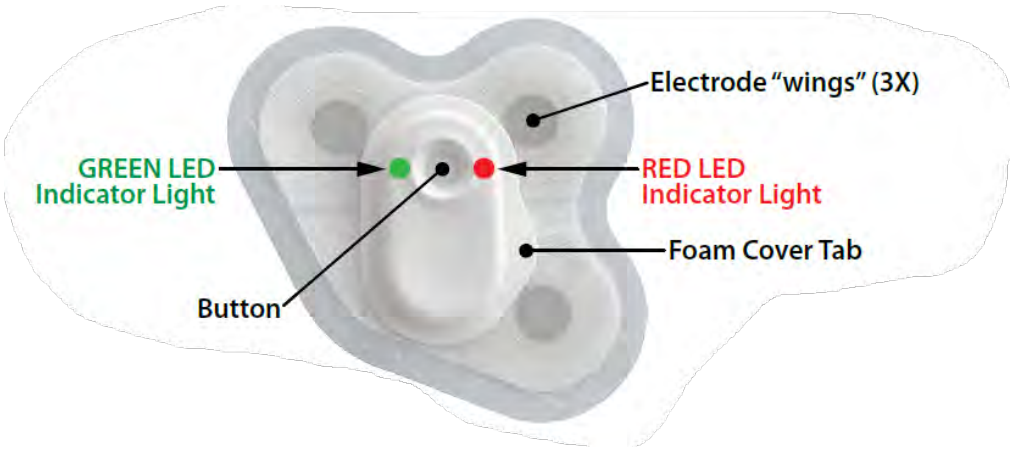


Figure 3.1. Key elements of the wearable Sensor

The button supports both device activation (i.e., start recording) and marking of patient events (e.g., palpitations, racing heart or other conditions as directed by the clinician). During initial start-up the GREEN LED blinks rapidly as the device executes a self-test to verify all components are performing as expected. If any fault condition is detected the Sensor will display the slowly blinking RED LED for 30 seconds and then shut-down. Next, the Sensor checks the quality of the electrical connection to the patient. If the Sensor cannot detect the patient (might be poor skin preparation) the GREEN LED and RED LED will alternately blink, meaning the electronics are working correctly, but there is no patient connection. Following this display the Sensor will turn off to preserve battery power. If a patient is detected, the Sensor studies the rhythm to identify the patient's QRS and then blinks the GREEN LED for about 10 seconds, synchronous with the patient's heartbeat. This signifies a successful Sensor activation.

Following successful activation, each additional button push will repeat the sequence of re-learning the QRS, followed by the GREEN LED blinking synchronously with the patient's heartbeat.

The Sensor will continue to run until the storage memory is full (10 days) and will then turn off. Button pushes following a full memory condition, or any device failure that caused a shut-down, results in the slow 30 second blinking RED LED. ANY light sequence that ends with the RED LED slowly blinking means the Sensor is NOT recording ECG data.

The Electronics Module is housed under a foam cover that provides environmental protection from the ingress of solid foreign objects and liquids. At the conclusion of the wear period, the cover is peeled-back and the Electronics Module removed for data transfer – see below.

	CAUTION. Do not remove the Sensor's foam cover until ready for data transfer. Premature removal and or damage to the cover seal may result in loss of recorded data.
Precaution	Before applying the Sensor ensure the skin is properly prepared. Improperly prepared skin (dirty or otherwise compromised) may cause poor adhesion resulting in shortened wear duration.
Precaution	The effect of loose electrodes (poor adhesion) is a poor-quality ECG recording and a shortened Physician Report. Should a Sensor electrode lift from the skin, the patient should apply firm but gentle pressure to the Sensor over the area that has lost adhesion. If the Sensor will not re-adhere, health care provider assessment is required.
Precaution	Take care to remove the Sensor from its pouch during the same session as patient application to preserve the integrity of the adhesives.
NOTE	If the Sensor is activated before being applied to a patient it will return to a sleep state to conserve battery.
	CAUTION. Although itching may initially occur, the Sensor should be removed if excessive itching or irritation persists and worsens. Contact your health care provider. Follow up with your health care provider if skin irritation or redness persists after removal.
	CAUTION. If skin irritation worsens and the Sensor is not removed, it may lead to infection.
	CAUTION. Do not "rip off" the Sensor; remove it slowly. Patients with fragile skin can experience skin damage when the Sensor is removed too quickly.

3.4 Sensor Placement

Sensor placement options are shown in the below Figure 3.2.

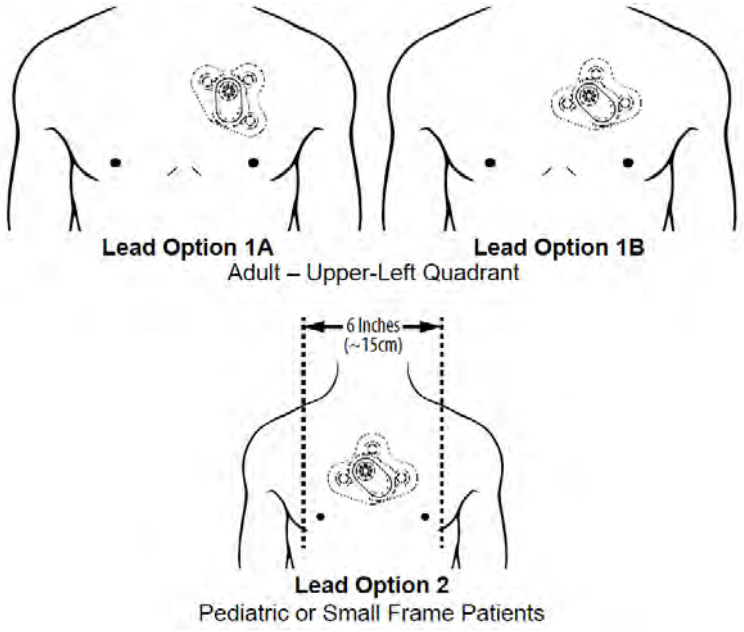


Figure 3.2. Placement options.

Lead Option 1A placement, in the upper left quadrant, is the preferred location and orientation. The leads are aligned with the orientation of Lead I and aVF in a 12-Lead recording. For some patients it may be more comfortable to position the Sensor as shown in Lead Option 1B. In Lead Option 1B and Lead Option 2 the leads are aligned with the orientation of aVL and Lead II in a 12-Lead recording.

Precaution	In large BMI individuals it may be necessary to position the Sensor higher on the chest, in the 1st or 2nd intercostal space, and closer to the sternum to avoid potential ECG single distortion from skin movement.
Precaution	In individuals with dense breast tissue and or implants, it may be necessary to modify Sensor placement by moving it toward the collar bone, slightly more medial and in a horizontal position (Lead Option 1B).

For patients with a narrow thorax, and for pediatric patients, Option 2 may be preferrable, with the Sensor centered on the sternum and positioned in a horizontal orientation.

⚠	WARNING. Use of the Sensor on individuals with an anterior axillary spacing of less than 6 inches (~15 cm) is not indicated
⚠	WARNING. Infant Use. The Sensor is not intended for infants. Safety and effectiveness of the Sensor on infants or individuals with anterior axillary spacing of less than 6 inches (~15 cm) has not been established.

WARNING. The Sensor is MR Unsafe. Remove the Sensor from the patient prior to MRI scanning.

To apply the Sensor, first remove it from the shipping Pouch. Save the Pouch for potential subsequent use by the patient. DO NOT remove the release liner on the adhesive backing. The Pouch contains an Application Template designed to assist with the skin preparation and Sensor placement. Marking the target position of the Sensor minimizes shaving to only the area that needs preparation. Marking the position of the electrodes reduces the skin area requiring abrasion. The following steps outline the application process:

1. Determine the placement location using the Application Template. Prepare an area 1 inch (2.5 cm) larger than the Sensor (see below Figure 3.3). Shave or clip hair in the application area if needed. Dry shaving may irritate the skin and induce itchiness during the wearing and should be avoided. Use an alcohol wipe (see Skin Prep Materials) to clean the skin to remove skin oil or lotions. Allow the area to dry for at least 30 seconds.

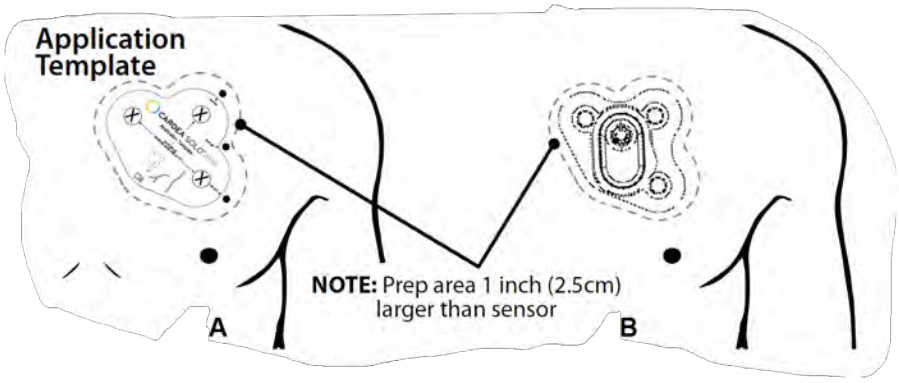


Figure 3.3. Using the Application Template to plan the positioning of the Sensor.

2. Place the Application Template against the skin in the desired placement area (refer to Figure 3.2 and Figure 3.3).

3. Use a pen to mark the skin. X's to mark electrodes (holes) and dots or a short line to mark the border of the Sensor where indicated on the template. Discard Application Template.

4. The outermost skin layer, the stratum corneum, consisting chiefly of layers of dead flattened non-nucleated cells filled with keratin, often acts as an effective electrical barrier for ECG monitoring. Good trace quality requires gentle removal of this layer before application of the Sensor. Use one of the skin abrasion items to remove the keratin layer in the areas marked as the location of the electrodes.

CAUTION. The Rounded-Rip Abrader should not be used on patients with thin skin or those on blood thinners.

NOTE: To use the Rounded-Tip Abrader, remove the adhesive backing and attach it to the tip of your finger.

5. Wipe off the placement area with the gauze pad.

6. Holding the Sensor from the foam-covered electronics module, turn it over and carefully remove the two (2) clear plastic liners covering the adhesive.

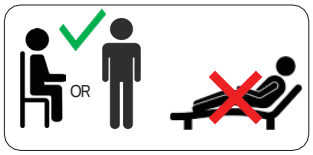
7. Position the Sensor over the patient's prepared chest placement area, aligning the edges of the Sensor with the edge marks placed on the skin, then press it down.

8. Firmly press down again and smooth out the Sensor against the skin, starting in the middle and progressing outward over all three electrodes out to the edges. Make sure the Sensor is firmly attached, lying smooth and flat across the patient's chest.

9. Remove all three (3) top paper liners from the Sensor, gently and slowly pulling each tab. Take care not to twist or pull too hard. Smooth out any edges that may have lifted.

3.5 Sensor Activation

1. It is important to maintain the patient in an upright position (sitting or standing) for the first three (3) minutes after Sensor activation. The Sensor uses these three (3) minutes to determine if the Patient is lying down (at rest) or upright (active).



2. With the patient in an upright position press the Sensor's button to activate. The GREEN LED will rapidly blink as the electronics are tested for correct functionality. Next the flashing GREEN LED will pause for 1-2 seconds as the Sensor looks for the patient QRS. Then the GREEN LED will flash in cadence with the heartbeat for 10 seconds. ECG recording has started.

3. If the electronics test is successful but the skin preparation was incomplete (i.e., the electrodes are not making good electrical contact with the skin) the Sensor will alternately blink the GREEN and RED LEDs indicating the Sensor is fine, but the connection to the patient has NOT been achieved. Following this display, the Sensor will turn off to preserve the battery. See the Troubleshooting section (Section 3.11).

4. Following the electronics test if there is any electronic abnormality, the RED LED will flash continuously for 30 seconds. Replace the Sensor.

5. The Cardea Rhythm Viewer (CRV) (refer to Section 3.6) can also be used to confirm the activation of the Sensor. When the button is pressed the Sensor will transmit and present 30 seconds of trace data via Bluetooth® as confirmation of recording. An example of the trace confirmation display is

shown in Figure 3.5 below. If both traces are not displayed, or if the correct serial number is not displayed, see Troubleshooting section (Section 3.11).

6. It is extremely important to note the date and time of activation of the Sensor since the timing of cardiac events is relative to Sensor start time. The PC Software also analyzes the patient's normal time of slumber and awakening and it is helpful to note the patient's normal time of onset of slumber and awakening. Record the date and time of activation of the Sensor on the patient's record as well as sleep and wake onset.

3.6 Cardea Rhythm Viewer (CRV)

The Cardea Rhythm Viewer (CRV) tool is a software app supported on Android and iOS (iPhone or iPad) Smart Devices. The purpose of CRV is to confirm proper application and activation of the Sensor. It is not for diagnostic use. When the Patient Event button is pressed the Sensor broadcasts 30 seconds of the ECG trace data using Bluetooth communications. CRV displays both leads of the ECG signal and supports saving the rhythm image as an image file, e.g., PNG.

3.6.1 Application Installation

A web URL is used to access, download, and install the Cardea Rhythm Viewer (CRV), Model A400.

3.6.2 Adding Demographic Information

When the user starts CRV on their Smart Device the following screen is displayed:

The user may enter the Patient's Name and Birthdate, and the Physician's Name and contact information. Additionally, CRV filters and removes AC line noise from the recording. The default filter setting is 60 Hz (US). Outside of the US, the line frequency may be 50 Hz.

The entry of the demographic and physician information is optional. The user can bypass this step and activate the Smart Device to start scanning for the Sensor's Bluetooth signal – Click Sensor Event Button & Then Continue. The CRV will pair with the Sensor and begin displaying the ECG trace data.

Figure 3.4B. CRV demographic data entry.

3.6.3 Rhythm Review

Once the Sensor and CRV are paired and the ECG data are being transmitted, the CRV screen will transition to the real-time display below.

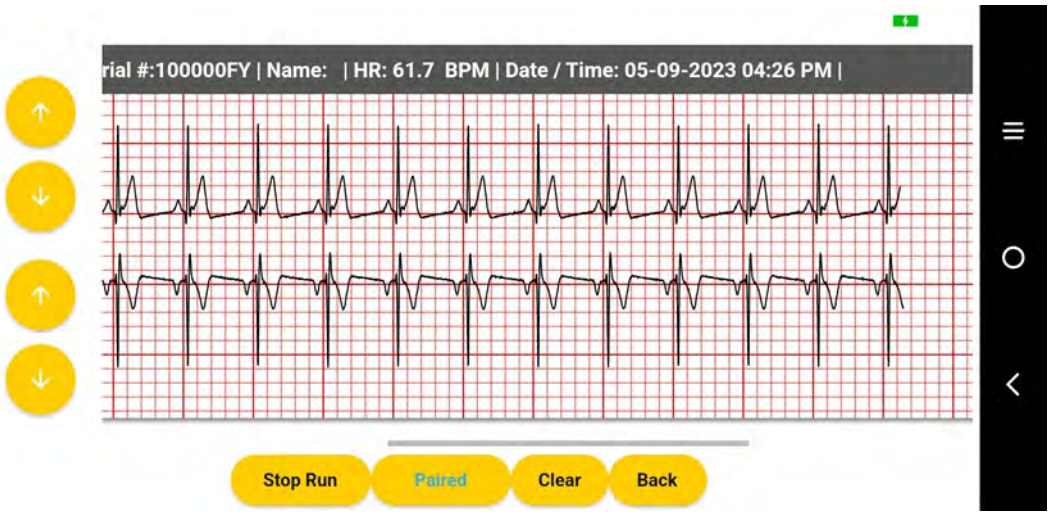


Figure 3.5. Real-time display of the ECG data.

Sensor serial number and patient name (if entered in CRV) are displayed at the top left of the screen. Verify the serial number matches the serial number of the Sensor. The arrows on the left of the screen adjust the trace amplitude, up or down. The "Back" button terminates CRV without saving the image. The "Stop Run" button terminates the Bluetooth communications but preserves the ECG data. At the end of 30 seconds the Sensor terminates broadcasting the ECG data. CRV next computes the heart rate and transitions to the below.

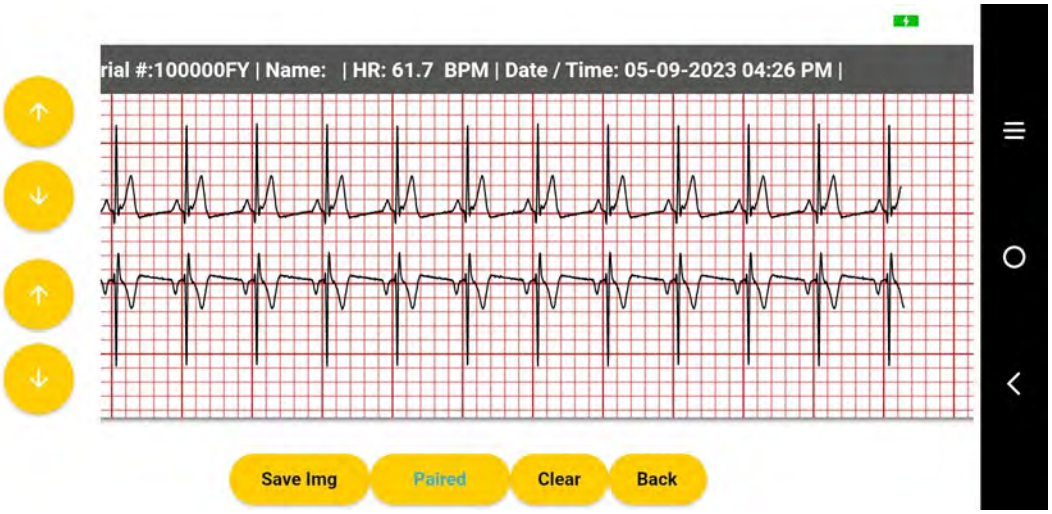


Figure 3.6. Save Image.

Finally, the ECG image, including the demographic, heart rate and date/time labeling, can be saved as a PDF image ("Save Img") on the Smart Device. The "Back" button will close CRV without saving the image. The "Clear" button will clear this display and begin listening for another waveform. The second button showing "Paired" is a status indicator.

3.7 Wearing Instructions

1. The Sensor is intended to always be worn during the monitoring period, including while showering. The use of standard soaps and cleansers is allowed. Do not use lotions in the placement area.

2. The patient should not remove the Sensor unless skin irritation or an allergic reaction (e.g., hives) develops.

3. The patient should press the button if experiencing one of the symptoms for which the Sensor is prescribed (see below Figure 3.7). This action is referred to as a patient trigger. Cardiac Insight recommends the patient relax for 30-60 seconds following the onset of the symptom and then activate the button, thus ensuring a clean, noise free ECG recording of the symptom. The PC Software searches backwards from the trigger to find abnormal events.

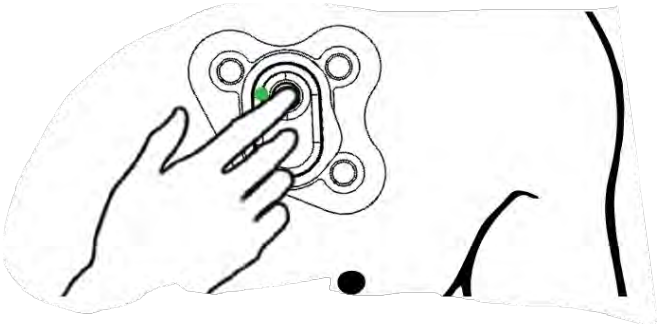


Figure 3.7. Activating the patient trigger.

a. This records a notation in the data indicating the patient felt a symptom, such as palpitations, dizziness, anxiety, light-headedness, fatigue, chest pain, shortness of breath.

b. The Sensor will flash the GREEN LED in cadence with the heartbeat for a short duration after the button press.

4. The patient should use the Patient Diary to document activities and symptoms that accompanied their decision to press the button.

3.8 Recommendations for Patient Use

1. The patient is expected to wear the Sensor continuously for up to 10 days or until the end of the prescribed monitoring period.

2. The patient should not remove the Sensor for showering or sleeping or any other activities of daily living.

3. The patient should not immerse the Sensor in water (i.e., swimming or bathing in a tub) as this may affect the adhesive longevity.

4. The patient should keep their total shower time brief and avoid a continuous, direct water spray over the Sensor.

5. If the Sensor should start to peel off before the end of the monitoring period, the patient should allow it to dry, if wet, and then press it back on to the skin, smoothing down any wrinkles. If the Sensor is still not adhering to the skin, the patient should contact their health care provider.

6. If the patient starts to significantly itch, experience significant allergic symptoms (e.g., hives), or be otherwise uncomfortable, the patient should remove the Sensor and contact their health care provider.

7. The patient should be provided with the Pouch and Patient Diary. Explain to the patient should it become necessary to remove the Sensor they should place the removed Sensor into the pouch and contact their health care provider.

8. The Sensor does not replace direct communication between the patient and their health care provider. The Sensor data should be used along with all other clinical data and exams for diagnosis.

9. The Sensor will not summon emergency response in the event the patient needs help. The patient should talk to their health care provider immediately if there are any concerns or changes in condition.

3.9 Completion of Monitoring and Removal

Precaution	Use appropriate handling procedures detailed by your facility (e.g., gloved hands) when handling a Sensor that has been worn by a patient.

1. When the monitoring period is complete, remove the Sensor from the patient.

a. For easier removal, apply petroleum jelly, baby oil, or the adhesive remover wipe between the skin and the Sensor throughout the removal process.

b. Gently hold the skin down adjacent to the Sensor. Start by lifting one edge of the bottom adhesive layer of the Sensor and slowly peel it off.

c. After removing the Sensor fold the electrode "wings" together under the middle.

d. Pull upwards on the Foam Cover Tab to remove it (see Figure 3.1).

e. Remove the Electronics Module from the adhesive attaching it to the bottom layer of the Sensor.

Discard everything except the Electronics Module, according to local regulations, e.g., regulations for e-waste may apply. The Electronics Module contains the patient's ECG recording and will be used in a subsequent step.

2. Remove any residual adhesive from the patient's skin. Rub petroleum jelly or baby oil over the residual adhesive and let sit for a minute. Use a tissue to wipe off the jelly or oil along with the remaining adhesive. Repeat as necessary.

3. There may be some residual redness and a slight odor around the area from which the Sensor is removed. This is normal and should disappear within a few days. If there is persistent redness accompanied by increased itching, the patient should contact their health care provider.

3.10 ECG Retrieval

WARNING. Moisture Exposure. Do not expose the Electronics Module to moisture prior to or during the transfer of the ECG recording.

1. On the top surface of the Electronics Module is the Sensor ID label (see Figure 3.8 below). Use this information to associate or to confirm the association of the Electronics Module with the patient chart. Copy the Sensor ID serial number (if not already there) onto the Patient Diary if a diary has been filled out by the patient.
2. To access the ECG recording, remove the Electronics Module from the Sensor. First remove the foam cover by pulling upwards on the tab (see Figure 3.8).

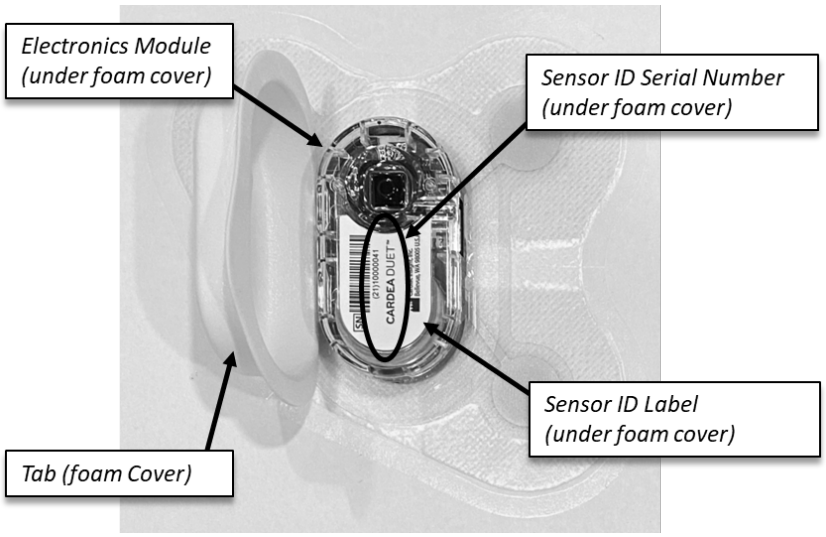


Figure 3.8. The exposed Electronics Module following removal of the foam cover. The barcode uses the GS1 standard format.

2. Separate the Electronics Module from the electrodes. Grasp one side of the Electronics Module and lift. Rock the Module in the opposite direction and peel it from the Electrodes.

3. Use the Smart Cable and Cardea SOLO™ ADX PC Software to retrieve patient ECG information for the monitoring period, as discussed in the following sections.

3. After retrieval of the patient's ECG and completion of the final report, the Electronics Module may be discarded. Discard according to local regulations, e.g., regulations for e-waste may apply.

Precaution	All portions of the Sensor are single use, disposable. The Sensor contains a Lithium battery. Do not incinerate. Recycle or dispose of this device according to your local regulations.
Precaution	Initial findings once changed may require the Electronics Module to "undo" the changes. Consider carefully before discarding the Electronics Module.

3.11 Troubleshooting

Problem: The Sensor light sequence does not occur as expected at start of monitoring period.

1. The Sensor must detect a valid ECG signal for recording to start.

2. Make sure the Sensor is properly positioned and adhered to the patient.

3. Press the Sensor's button. It is possible the ECG recording did start, but the confirmatory flashing GREEN LED was not observed. If recording is in progress, the GREEN LED will flash in cadence with the patient's heartbeat for a short duration and then extinguish.

4. Ensure electrodes are firmly attached to the patient by pressing down and smoothing over the electrodes. Allow electrodes to warm-up to body temperature for 3-5 minutes and try again to activate the Sensor.

5. If the expected light sequence does not occur after trying to activate the Sensor twice, remove the Sensor and use a replacement.

Problem: The Sensor starts to come off the skin before the end of the monitoring period.

1. The patient should apply firm but gentle pressure to the Sensor over the area that has lost adhesion.

2. If the Sensor will not re-adhere, health care provider assessment is required.

Problem: Light does not flash upon button press during monitoring period.

1. Check to see whether the flashing GREEN LED is visible after a button press in a dimly lit or dark room.

2. If no light is observed after a button press, remove the Sensor, and use a replacement or contact your health care provider.

Problem: The Sensor is difficult to remove.

1. Lift one edge of the Sensor and put an alcohol wipe in the space between.

2. Slowly peel the Sensor, using alcohol swab or wipe on the skin.

3. If there is still difficulty removing the Sensor, use petroleum jelly or baby oil. An adhesive remover wipe may also be used.

4 Cardea SOLO™ ADX PC Software – Administrative Setup

Cardea SOLO™ ADX PC Software includes administrative tools to customize the system for several clinic specific default settings and for creating individual User accounts. Setting up the system is discussed in the following sections.

4.1 Initial Start-up

The first time you start Cardea SOLO™ ADX PC Software following installation (See Section 2.6) the Administrative Log-in screen will be presented. See Figure 4.1.

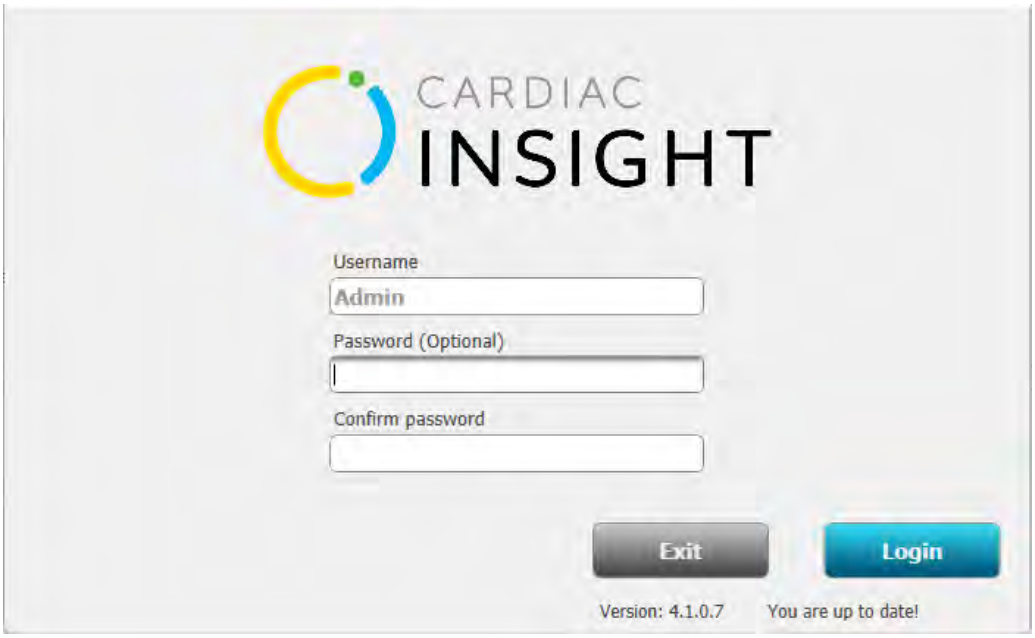


Figure 4.1. Administrative Log-in screen.

The Administrative Username is "Admin". Authentication of the Administrator is strongly recommended, via the login protocol to the PC and /or setting the Cardea SOLO™ ADX PC Software Admin password. On subsequent start-ups of the System, the Username will be blank. For Administrative access, enter "Admin" and if set, the associated Password.

During startup, Cardea SOLO™ ADX PC Software attempts to check a Cardiac Insight website to determine if a newer release is available. The results of this check are shown at the lower right in figure 4.1 ("You are up to date!").

Next, select the "Login" button to begin administrative customization. The following screen will be presented.

Figure 4.2. System Administration.

The "Save Patient Data Directory" is the location where all of the ECG trace data, patient demographic information and final PDF report are stored. A folder is created for each patient, for each Sensor worn. The data directory may be located on the PC being used (default is on the C drive) or on any fully qualified network location. For HIPAA compliance, users should consider designation of a HIPAA secure server for data storage. For data storage on a network server, the ECG data will be downloaded and processed on the PC and the completed patient folder will be moved to the specified network directory at the completion of processing.

NOTE: Low Network Bandwidth. For data storage on a network device, low network bandwidth may degrade the speed of file transfers and delay the completion of the ECG analysis.

Precaution	Path Length. Microsoft Windows places a 260-character limit on pathnames. The Data Directory path length should not exceed 100 characters, allowing extended lengths for patient folder names and associated files.

If the "Save PDF Directory (Optional)" is defined, the final PDF report will also be copied to this location. Most Electronic Medical Record (EMR) systems provide tools for uploading and associating office documents, such as PDF reports, with patient records (for example, Media Manager for Epic). Using this option simplifies the task of collecting all of the PDF reports that need to be uploaded into the EMR. The name of the PDF report is in the format "LastName_FirstName_Birthdate_TestDate.PDF". The radio button options control when the PDF is transmitted to the folder, either when over read and confirmed, or when created or updated.

Date and Time formats of choice are available and may be selected. If you change the date format after initial setup past records will not be modified to the new format.

The Line Frequency selection supports the AC line filter used during processing. For North America this should be set to 60 Hz, and to 50 Hz for Europe and other countries as appropriate.

While entering the patient demographic information, the Administrator should require the Sensor Serial Number be entered before data processing can proceed.

The minimum duration of an atrial fibrillation episode is not universally standardized. Use the checkbox if duration must exceed 30 sec.

You may also add the institution's logo to the reports. Click Browse and select a JPG or PNG formatted image. The image will be added to the screen in Figure 4.2, above the associated Browse button.

Finally, add the name of the clinic or institution.

4.2 User Setup (Manage Users)

The next step to set up the System is the creation of User profiles. It may be desirable to have different characteristics for different users, perhaps reflecting the preferences of the associated doctor, or the clinic. At least one user must be created. Select the "Manage Users" button shown in Figure 4.2. The following screen will be displayed.

Figure 4.3. Add / Edit User Profile screen.

To add a new user, complete the fields shown and discussed below:

New login profile name. This will be the Username entered for login, see Figure 4.1. Passwords are not required but are supported. User authentication, during login to the PC and/or Cardea SOLO™ ADX PC Software is strongly recommended. If desired, add and confirm the Password.

The User may provide clinical support for a prescribing physician. When the User processes Sensor data and creates a final PDF report, the prescribing physician's name will be included. The check-boxes to the right of the name grant the User access for over reading, editing, and confirming the Cardea SOLO™ ADX report ("Over-reading Physician" checkbox). The Physician's

name will be included in the report as the confirming physician. Patients may also be pre-registered into the Cardea SOLO™ ADX PC Software at the time of Sensor placement and checking the "Enable Patient Pre-Registration" enables this functionality for this User.

User access to Studies. The user can be restricted to reviewing only patients associated with the Physician.

Managing Location. The clinic may be a part of a larger organization. For example, the Organization (Company Name, Figure 4.2) might be "Overlake Health System," and the clinic might be "Eastlake Clinic."

Following entry of the required fields for a User, click the "Add" button. Continue adding Users as needed. To edit a User, use the drop-down menu option ("Select Existing Profile (Edit)") at the top of the screen. Remember to click "Update" following any edit. When the list of Users is complete, click "Done". The System will return to the System Administration screen. If you're done, click the "Done" button.

Report Options

Following entry of User information, as discussed in Section 4.2 above, clicking the Report Options button shown in Figure 4.3 above will display the following window:

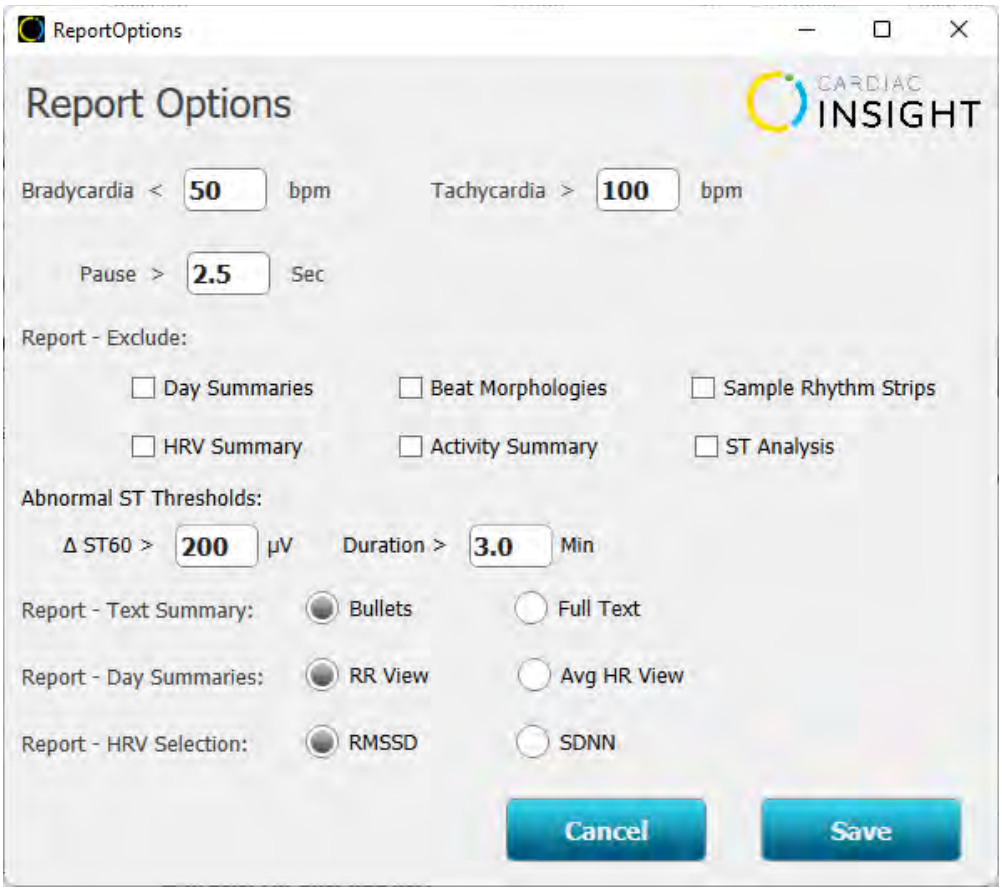


Figure 4.4. Report Options.

The first three options are User selectable parameters to define Bradycardia [allowed limit range: 30 – 75 BPM], Tachycardia [allowed limit range: 75 – 200 BPM] and Pause Duration [allowed limit range: 2 – 5 Seconds] when the User is processing the Sensor data. Default values are shown in Figure 4.4. The next options allow Users to customize data presented in the report.

"Report – Exclude." option: Users may wish to include or exclude some sections of the report – clicking the checkboxes will exclude the section. See below for more details on each section of the report.

"Abnormal ST Thresholds." Users may select minimum ST amplitudes and durations as clinically appropriate. The amplitude setting is used for identifying both ST Elevation and Depression.

"Report - Text Summary:" option: The first page of the report presents key findings. Selecting "Full Text" presents findings as a text paragraph. Selecting "Bullets" replaces the text summary with concise bulleted statements of key findings.

"Report - Day Summary:" option: The Day Summaries (the section of the report following the first page) can display the heart rate trending data as either

"Avg HR View" (20-minute average values with range bars), or as an RR plot (each RR interval is plotted as heart rate (i.e., 60/RR in seconds). "RR View" is the recommended display selection; this view is intended to facilitate quick identification of complex rhythms that may be masked by the gross averaging of the "Avg HR View" display.

"Report – HRV Selection." The user can select either Root Mean Square of Successive Differences (RMSSD) or the Standard Deviation of Normal to Normal intervals (SDNN).

4.3 Manage Physicians

Cardea SOLO™ ADX PC Software supports the creation of a Physician List, which is accessible while entering patient demographic information. The demographic entry screen includes the entry of the prescribing physician, which displays the list entered here. The Physician Profile list window is shown below.

Figure 4.5. Physician List.

4.4 Import / Export

The Export button (see Figure 4.2) will export all the System Administration settings to a file. This file can be used to quickly set-up additional Cardea SOLO™ ADX systems, without having to re-enter all of the configuration elements. The exported file is a zipped / compressed folder.

The Import button presents a file browser window – navigate to the previously exported compressed folder and select.

NOTE: Import of user settings intended to apply to multiple workstations will override existing settings and configurations and replace them with the imported setup.

Following the import, the system will exit the System Administration screen, returning to the Login screen.

NOTE: The imported administrator password is REQUIRED for the subsequent login.

4.5 Archive / Delete

The Archive / Delete button will display all the patients currently stored in the Patient Data Directory, as shown below.

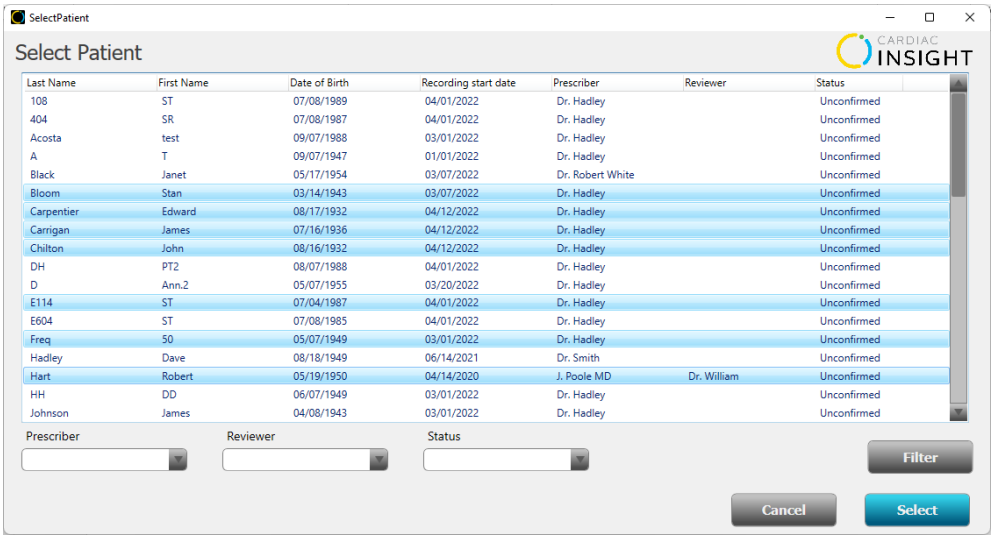


Figure 4.7. Selecting patients for archival or deletion.

The standard Windows commands are available for selecting patients for action: CTRL-Click adds the selected patient to the growing selection; Shift-Click selects all the patients from the last click to the current click. The filter buttons can be used to narrow the list to patients with specific characteristics (see Section 9.1 below). Following selection of the patient folders, click Accept – the System will display an options window:

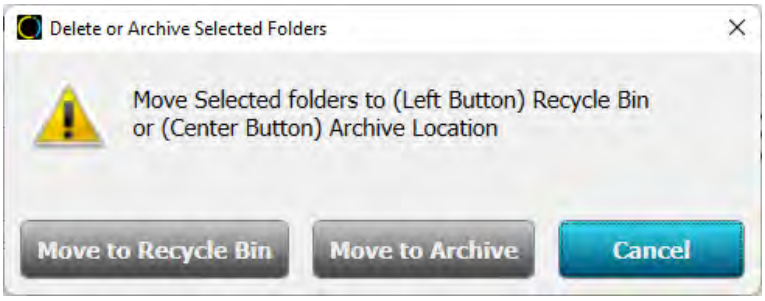


Figure 4.8. Archive/Delete Options.

If the Patient Data Directory is on the local PC, the administrator may move the records to the Trash.

NOTE: Trash is not emptied – wrongly deleted folders can be returned to the Directory using Windows drag and drop functionality.

Delete functionality is not available if the storage Directory is on a remote network drive.

The Move to Archive button will display a folder browser to select a move-to directory.

5 Patient Registration (Optional)

Cardea SOLO™ ADX PC Software supports the management of patients that are currently wearing Sensors, or have not yet returned their Sensor for processing, interpretation, and billing. Your User preference settings must be set to allow access to the Pre-registration functionality, See Section 4.2 User Setup.

Patient Registration is not required to use the Cardea SOLO™ ADX system.

5.1 Registration

Click the Patient Registration button, Figure 6.2 below, to access this functionality. The Additional Information / Patient Demographic screen will appear, Figure 6.5 below. This information should be entered at the time the Sensor is placed on the patient. Note the Patient Diary section is omitted, as the patient is actively recording data.

Upon return of the Sensor and processing of the recorded ECG data (see Section 6.2), entering the first 3 characters of the patient's last name will trigger a display of the matching registered patients. With each added character the list will dynamically shorten. Double clicking on the appropriate patient will populate the screen with the demographic information entered during registration.

Figure 5.1. Selecting a Registered patient during downloading.

The Sensor Serial Number can also be entered during patient Pre-Registration. The demographic information will populate the screen when the full Serial Number is entered.

Figure 5.2. Accessing a Pre-Registered patient via the Sensor Serial #.

All demographic fields can be edited or updated, and diary information added.

At the conclusion of data processing, the patient's registration information is deleted from the Pre-registration list.

5.2 Registration Report

Clicking the Registration Report button, Figure 6.2 below, retrieves the active list of Registered Patients and creates an Excel summary.

NOTE: Excel must be installed on the PC for this functionality to be used.

6 Cardea SOLO™ ADX PC Software – Creating the Report

This section will lead you through the full report creation process, from logging in as a User, connecting the Sensor to the Smart Cable and PC, entering patient demographic and diary information, and creating the draft PDF report.

NOTE: In this manual, the ECG analysis report, referred to in various industry Standards as "Physician Report", is referred to as "PDF report" or simply "report".

Section 7, Cardea SOLO™ ADX PC Software – Clinical Review, will lead you through the tools to review the ECG trace data, add or remove various rhythm episodes from the findings (e.g. Atrial Fibrillation, Ventricular Tachycardia), add or remove rhythm strips, update or correct demographic or diary data entry errors, remove false positive findings of atrial fibrillation or ventricular tachycardia, edit the proposed diagnostic summary and finalize the report.

Precaution	If the PC Software does not appear to be responding or if you hear the standard Windows® chime sound, check to see if an associated window or dialog box in the background (not seen) requires attention.

6.1 User Login

On start-up the Cardea SOLO™ ADX PC Software User Login screen will be displayed.

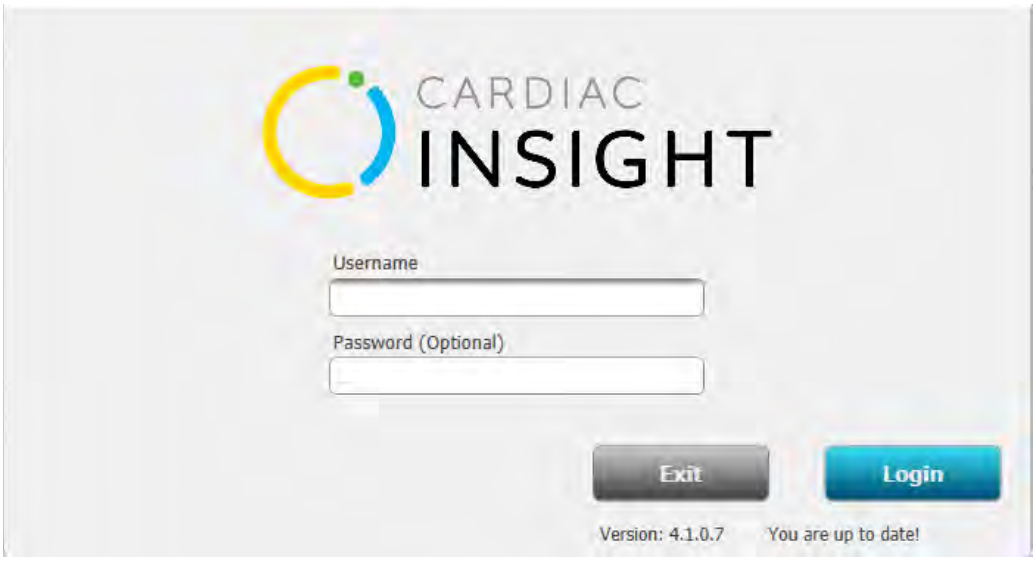


Figure 6.1. User Login screen.

Enter your User name and Password (if the Adminstrator included a Password when your account was setup). Clicking "Login" or Enter will present the main User Menu Options screen, Figure 6.2.

Figure 6.2. User Menu Options screen.

NOTE: The Patient Registration and Registration Report options (discussed in section 5) will be excluded if the User's profile is not set for access to these functions, see Section 4.2 above.

To begin the process of transferring the ECG data from the Sensor to the PDF report, click the highlighted "Download ECG" button.

6.2 Data Transfer, Demographics, and the Draft Report

6.2.1 Connecting the Electronics Module

The Smart Cable (C400) is used to transfer the ECG data from the Electronics Module to the PC and Cardea SOLO™ ADX PC Software for analysis. Plug the Smart Cable USB connector into a USB port on the PC. The LED adjacent to the PC icon on the Smart Cable will light green when the electronic connection is made. Insert the Electronics Module into the cradle portion of the Smart Cable, as shown below in Figure 6.3. The LED adjacent to the small image of the Electronics Module will light green when the electronic connection is made.

Figure 6.3. Electronics Module connected to the Smart Cable.

During data transfer operations both LEDs will blink simultaneously.

6.2.2 Starting Data Transfer

Following clicking the "Download ECG" button, the System will present the "Transfer Sensor ECG Data" screen, Figure 6.4.

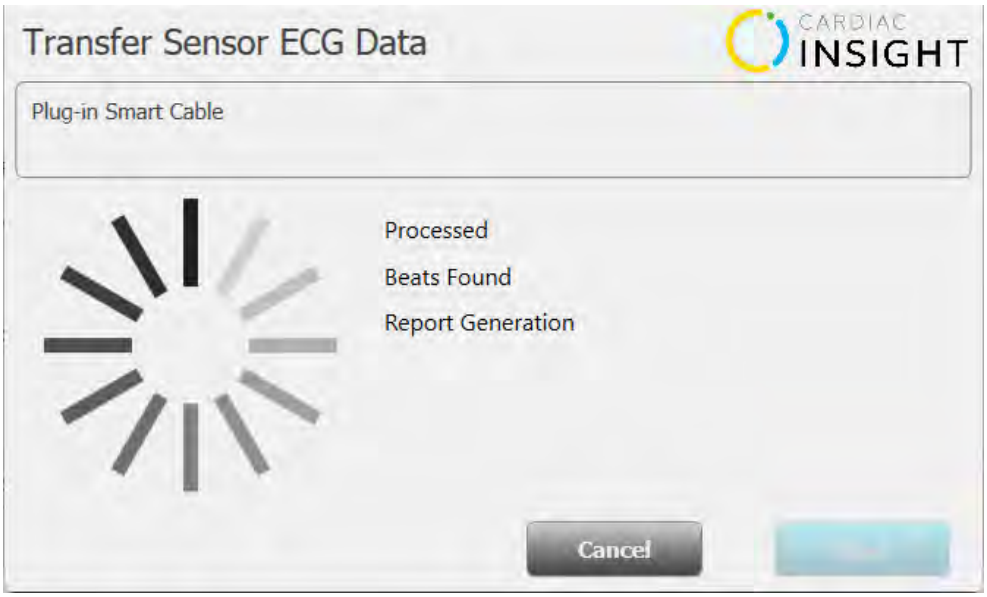
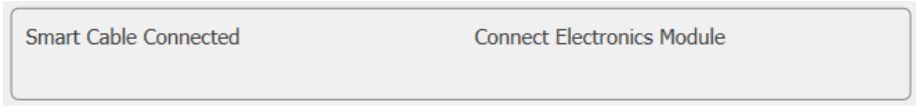
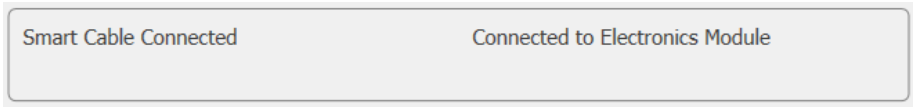


Figure 6.4. Transfer Sensor ECG Data screen.

If the Smart Cable has not been plugged into the USB port on the PC, the screen instructs you to connect the Smart Cable. Following connection of the Smart Cable, the screen will automatically transition to a notice showing the cable is connected, and invite you to insert an Electronics Module from the Sensor into the Smart Cable:



Once connection to the Electronics Module is verified, the System will provide an update similar to the following:



Once the System is connected to the Electronics Module, the "Start" button will be enabled; Clicking Start will begin the data transfer. The spinner display will rotate as data is transferred and progress updates are provided showing the number of hours processed, the total number of heartbeats detected, and the stage in the processing flow.

Clicking Start will also present the Additional Information data entry screen, discussed in the next section.

6.2.3 Demographic and Diary Data Entry

Following the start of data transfer, the Additional Information data entry screen is presented.

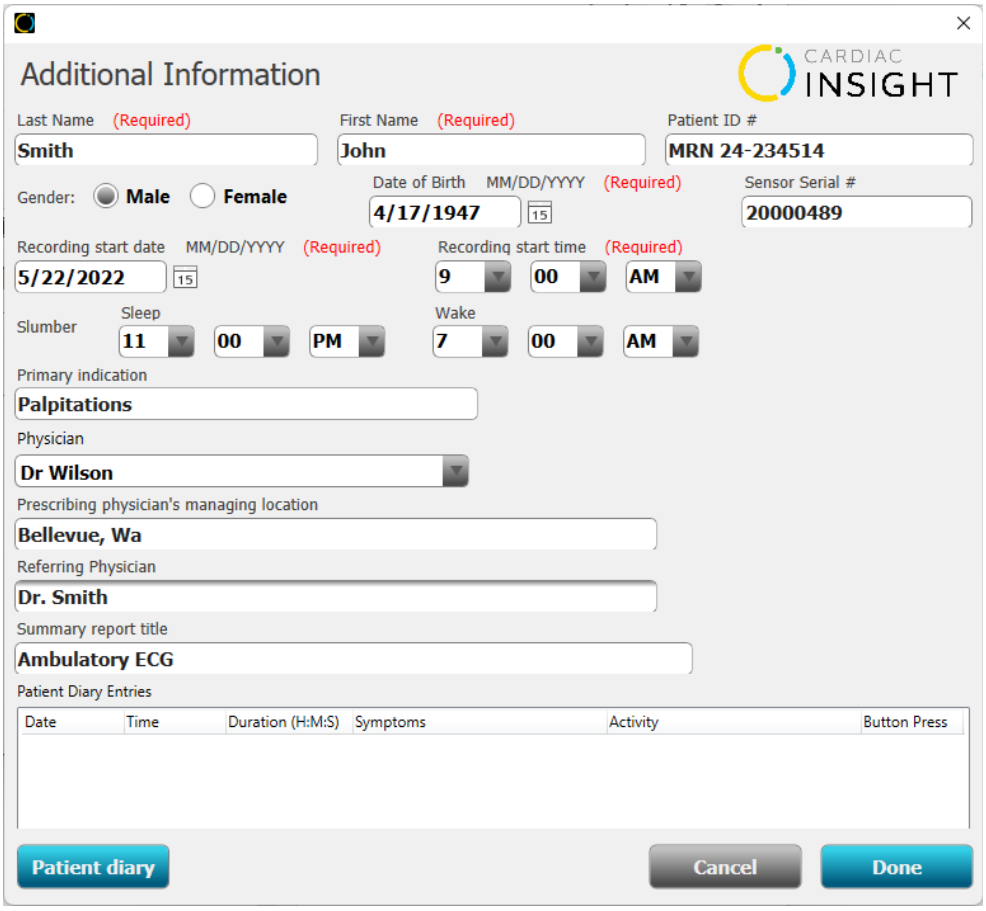


Figure 6.5. Additional Information screen.

Enter the patient information indicated as required.

NOTE: The (Required) patient information fields must be entered before the draft report can be generated. The Done button will not activate until all required fields have been entered.

The Patient ID # may be used for any free-text field desired, such as a medical record number or other identifier. Cardea SOLO™ ADX PC Software examines heart rates and arrhythmias during wake and sleep cycles. Recording and entering the Recording Start date and Recording Start time, along with the approximate time the patient nominally goes to sleep and awakens, will improve the review of heart rate findings relative to the patient's wake/sleep cycles. Setting both Sleep and Wake times to 12:00 AM will remove the sleep/wake analysis – see Section 6.2.4 below.

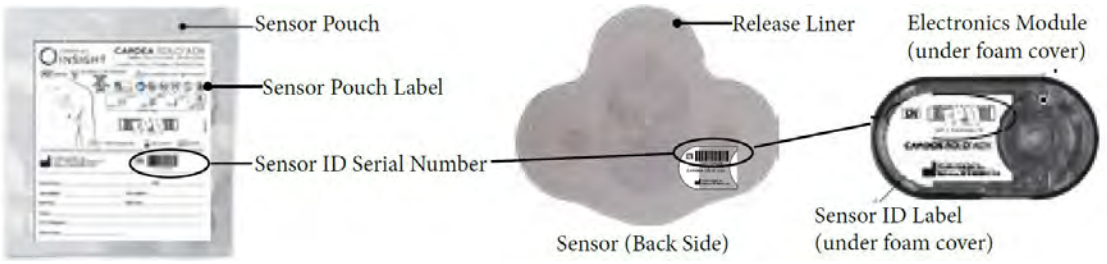


Figure 6.6. Sensor ID Serial Number locations.

The Sensor ID number is optional, and can be found on the Sensor pouch label, Sensor release liner, and Electronics Module, as shown in Figure 6.6. The barcode uses the GS1 standard format.

The Primary Indications for prescribing the wearing of the Sensor should be entered into the Primary indications field. This information may be important for reimbursement for your organization. This information will be included in the PDF report.

The Prescribing clinician, Location, and Summary report title are inherited from your User Profile, as set-up by the System Administrator, and can be edited here as necessary.

Once you have entered a start date and time, the System will enable the "Patient diary" button, located in the lower left of the screen. Clicking on this button will present a screen for entering information from the patient's diary if one was used.

NOTE: Symptoms and Activity fields are limited to 50 characters.

The drop-down menus are selectable, and the user may type in any other text required. Patient Diary entries are not required.

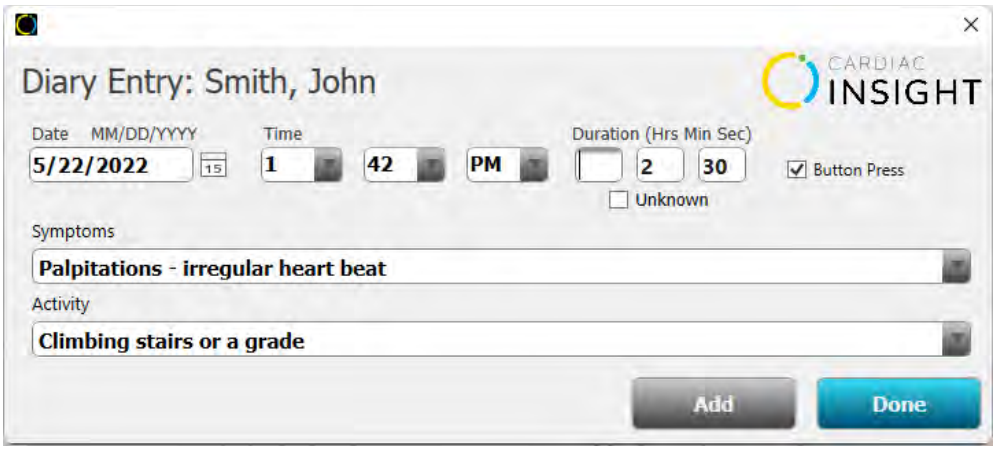


Figure 6.7. Patient Diary Entry screen.

Enter the data as indicated and click the "Add" button.

NOTE: The "Add" button is enabled when all fields, except "Button Press", are completed. Clicking the "Done" button when these fields have been completed will add this Diary Entry and close the window. If these fields are not completed, clicking "Done" will close the window and NOT save the incomplete Diary Entry.

The screen will refresh, and you may continue entering additional Diary entries. Once you have completed data entry, click "Done".

Cardea SOLO™ ADX PC Software will examine the ECG data ±5 minutes around the entered date and time for any abnormal conditions and include a 30 second rhythm strip in the report, highlighting the abnormality if found.

The updated Additional Information screen will refresh, Figure 6.8 below.

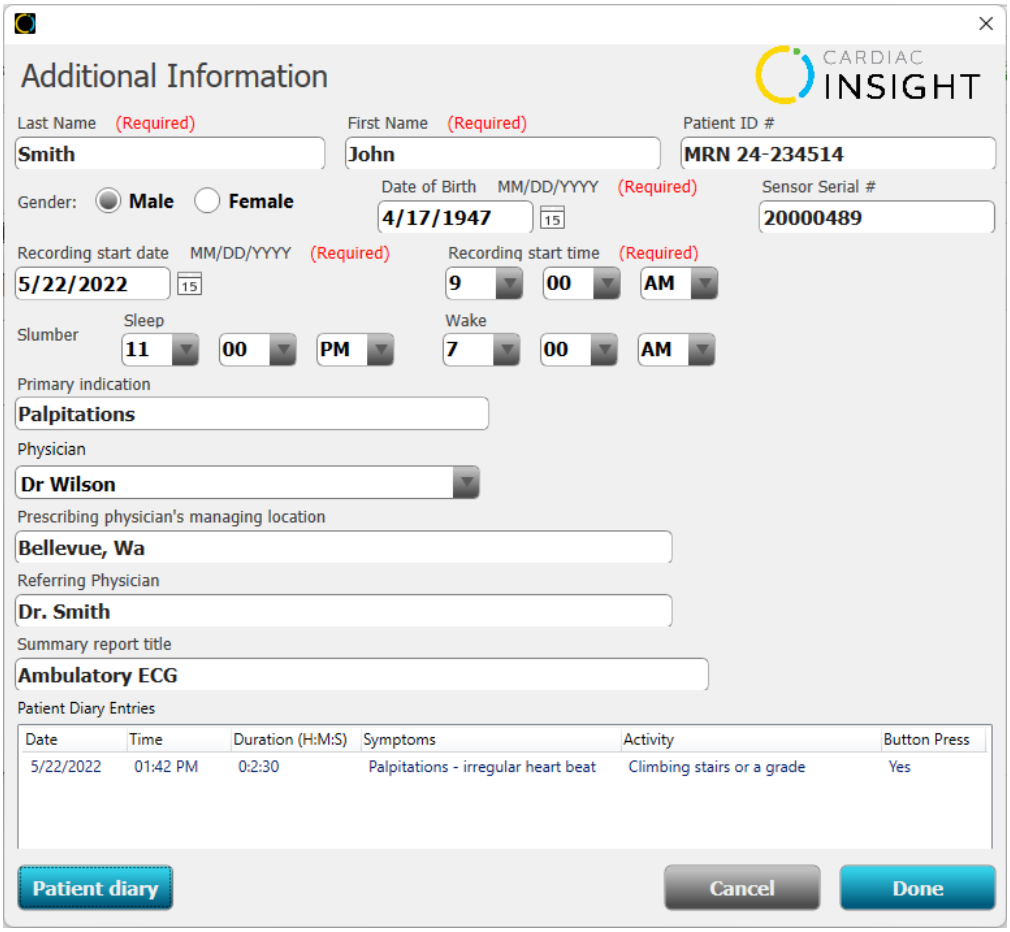


Figure 6.8. Updated Additional Information screen.

Hovering the mouse over any of the Diary entries will invite you to right-click the entry to edit or delete the data associated with that entry.

When all the relevant information has been entered and reviewed, click the "Done" button. Cardea SOLO™ ADX PC Software has been busy working in the background processing the ECG data and will likely be ready to incorporate the patient information into the draft PDF report.

6.2.4 Draft PDF Report

Following entry of the patient information, the system will finalize data transfer from the Sensor and build and present a draft PDF report. A typical first page is shown below in Figure 6.9.

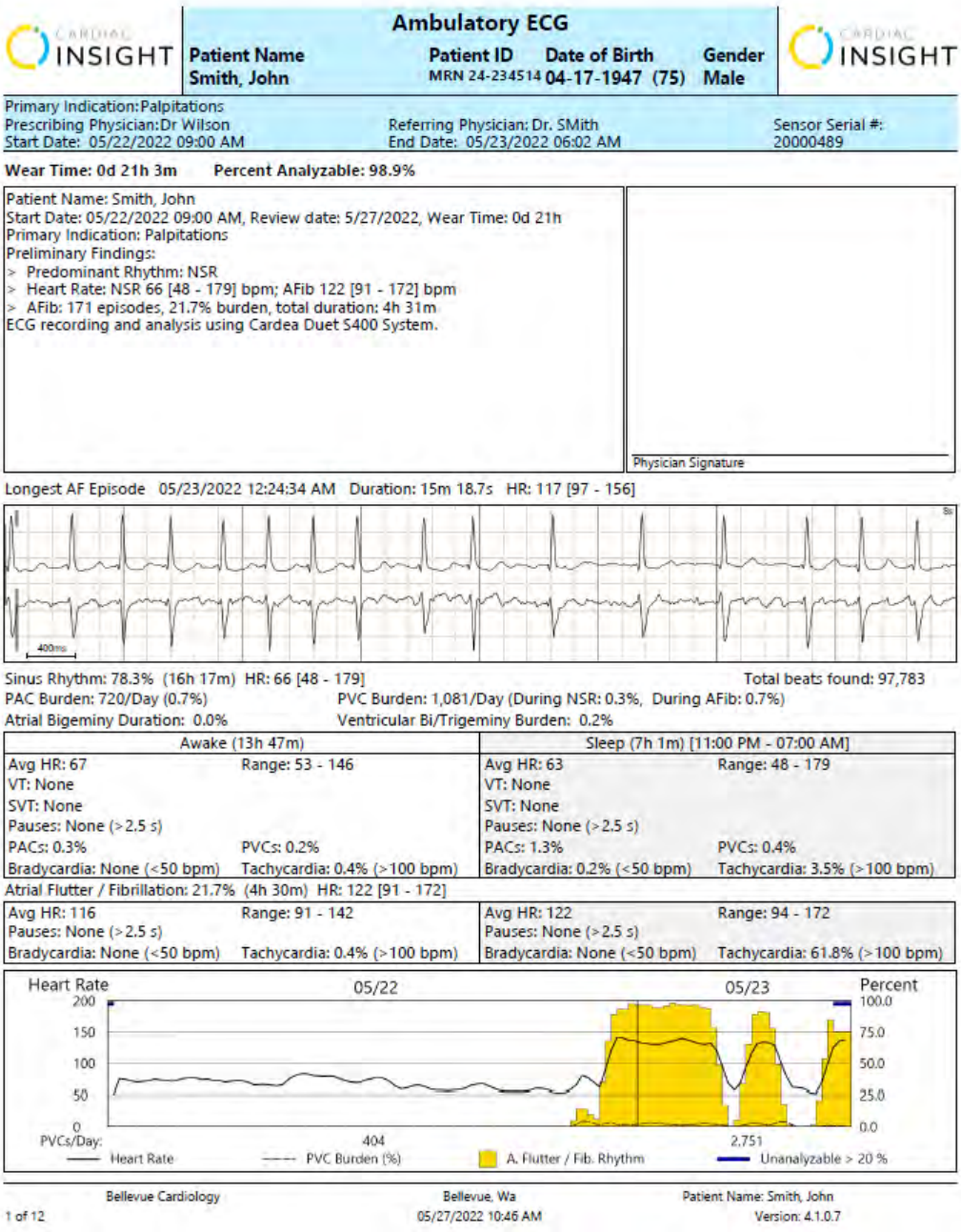


Figure 6.9. Example first page of a draft PDF report.

The Initial Findings (left box at the top) and the over reading physician's diagnosis (right box at top) may be edited – see Edit Dx in Section 7.3 below. If a logo has been selected in Admin, Section 4.1, it will be displayed at the top left of the report.

The report is structured as follows:

Header. Patient demographic information, Primary Indication for ordering the test, the prescribing clinician, office location and recording period, along with the wear time (start, end, total), percent analyzable ECG are summarized at the top of the report.

Initial Findings. Below the Header on the left is the summary of key Initial Findings. The information is presented as a bulleted list or full text depending on the User preferences. Included in these findings are the number of patient-triggered events and their associated findings (if any). (See Section 6.2.3 above).

Clinical Findings / Overreading. The space to the right of the Initial Findings is reserved for comments by the over reading physician. See Section 7.3, Edit Dx below.

Example Waveform. An example waveform is next added to the report to illustrate a key finding. The waveform is selected based upon the following priority of conditions: Atrial Fibrillation / Flutter (AFib); Ventricular Tachycardia (VT); Pause; Complete Heart Block; 2nd Deg AV Block (Mobitz II), Supraventricular Tachycardia (SVT); ST Abnormality, Ventricular Bigeminy; Ventricular Trigeminy; 2nd Deg AV Block (Mobitz I / Wenckebach), Premature Ventricular Contractions (PVCs), Atrial Bigeminy, Bradycardia; Tachycardia; Normal Rhythm. Rhythm strips are added to later pages of the report for conditions detected.

The relative amplitude of the ECG traces is indicated by the vertical bars on the left side of the ECG trace. The shorter bar indicates the smaller amplitude trace, and the height ratio is computed from the ratio of the trace amplitudes.

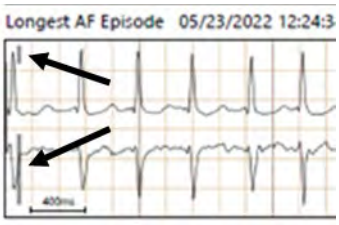


Figure 6.10. Relative trace amplitudes.

Rhythm Summaries. The summaries are partitioned into findings that occur during Sinus Rhythm and during Atrial Flutter / Fibrillation.

Sinus. The percentage of the record in Sinus rhythm.

PAC Burden. Calculated from the PACs occurring during Sinus rhythm, excluding beats in runs of SVT. Reported as both average beats/day and percent burden (PACs / Total # Beats).

PVC Burden. Calculated from the PVCs occurring over the entire record, reported as average beats/day. The percentage burden (PVCs / Total # Beats) is divided into burden occurring during Sinus rhythm and AFib. PVC counts

for each day are also included in the graph at the bottom of the page, centered below each day segment.

Atrial Bigeminy Burden. The percentage of the total record duration with Atrial Bigeminy.

Ventricular Bi/Trigeminy Burden. The percentage of the total record duration with Bi/Trigeminy.

Next, findings are presented for Awake and Sleep periods (See Section 6.2.3 Demographic and Diary Data Entry above to set the typical times the patient goes to sleep and awakens). Findings for VT and SVT runs include the number of episodes, the average heart rate and average duration, as found in the period, regardless of the bounding rhythm being Sinus or AFib. Pauses include the number of pauses and the longest pause duration observed and are categorized by occurrence during sinus rhythm and Afib. PVCs, PACs, Bradycardia and Tachycardia findings are also included as a percentage duration of the period.

Atrial Flutter / Fibrillation (AFib). The summary information follows the same format as Sinus above.

Graphical Trend Report. The last data element, at the bottom of the page, is a graphical summary to provide a quick overview of the entire record. For each point along the horizontal axis (Time) the record is reported as three components from an associated 10-minute ECG recording window: % Atrial Flutter / Fibrillation (Gold); % Normal Rhythms (White); and % Unanalyzable record (typically related to motion artifact induced noise). Time intervals where the unanalyzable percentage is greater than 20% are indicated by a thick blue bar at the top of the graph. Drawn over the graph is the smoothed average heart rate (solid line) with heart rate axis (BPM) on the left side of the graph. The smoothed PVC burden (% ventricular beats) is shown with the dashed line and axis on the right (%).

7 Cardea SOLO™ ADX PC Software – Clinical Review

Cardea SOLO™ ADX PC Software incorporates Cardiac Insight's advanced proprietary rapid automated arrhythmia processing technology, developed through years of research in collaboration with leading cardiologists and scientists worldwide. This technology accelerates and brings to the point of care sophisticated ECG waveform analysis and arrhythmia detection. Accompanied by a robust suite of viewing, editing, and reporting tools, Cardea SOLO™ ADX PC Software streamlines clinical workflow and can speed time to patient diagnosis.

This section will lead you through the tools to review the ECG trace data, update or correct demographic or diary data entry errors, edit the proposed diagnostic summary and finalize the draft PDF report. Following presentation of the draft PDF report, Cardea SOLO™ ADX PC Software will present a menu of options to support interactive review and any required edits of the summary finding, Figure 7.1.

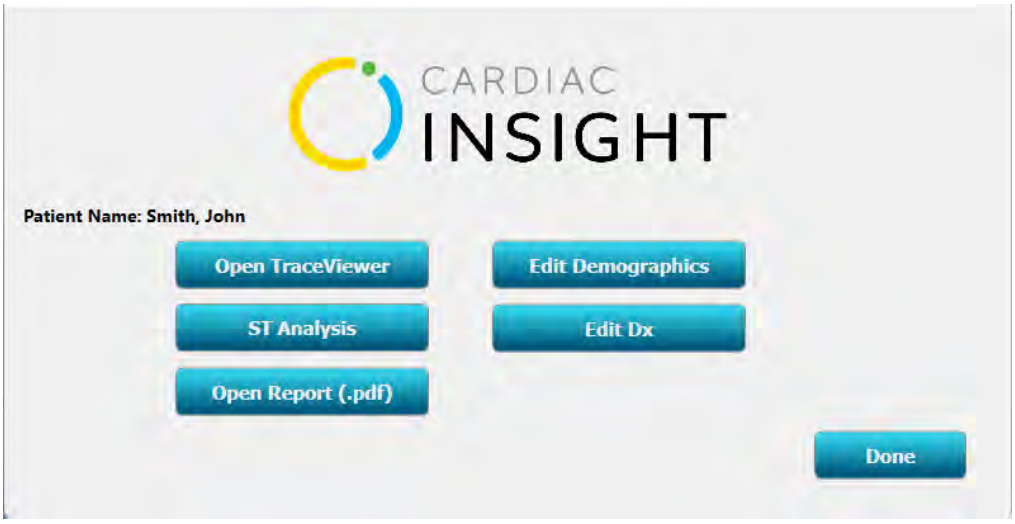


Figure 7.1. Report Review Options menu.

The following sections discuss the functionality of each menu option.

⚠	WARNING. Interpretation Hazard. A licensed physician must over read ECG interpretations. Some ECG abnormalities cannot be detected by automated ECG analysis algorithms. Computerized interpretations add value when used in conjunction with clinical findings.
⚠	WARNING. Interpretation Hazard. Pacemakers and Stimulators (patients with an implantable pacemaker or with active stimulator devices (external or implanted), such as TENS units, deep brain stimulators, muscle activators, spinal cord stimulators). Pacing and stimulators may interfere with the analysis of the ECG and cause misclassification of beats and rhythms or render the recorded ECG signal unanalyzable.

7.1 ECG Trace Review

The ECG TraceViewer has been designed to support rapid access to any 10 second strip in the entire recording. Clicking on the Open TraceViewer button, Figure 7.1, presents the TraceViewer, Figure 7.2.

RR View. RR View is the default display format. Click any Date (upper left) tab to access the RR View for that date (top left on screen). This display format provides a powerful way to visualize and identify changing rhythms. In the below example, the onset and termination of atrial fibrillation is clearly seen. Clicking on any point in the RR View displays the associated 5-minute ECG traces. Clicking the "RR View" checkbox, upper right in Figure 7.2, toggles between the RR View (heart rate plotted for every individual beat) and Avg HR View (the average 10-minute heart rate symbols), Figure 7.4 below.

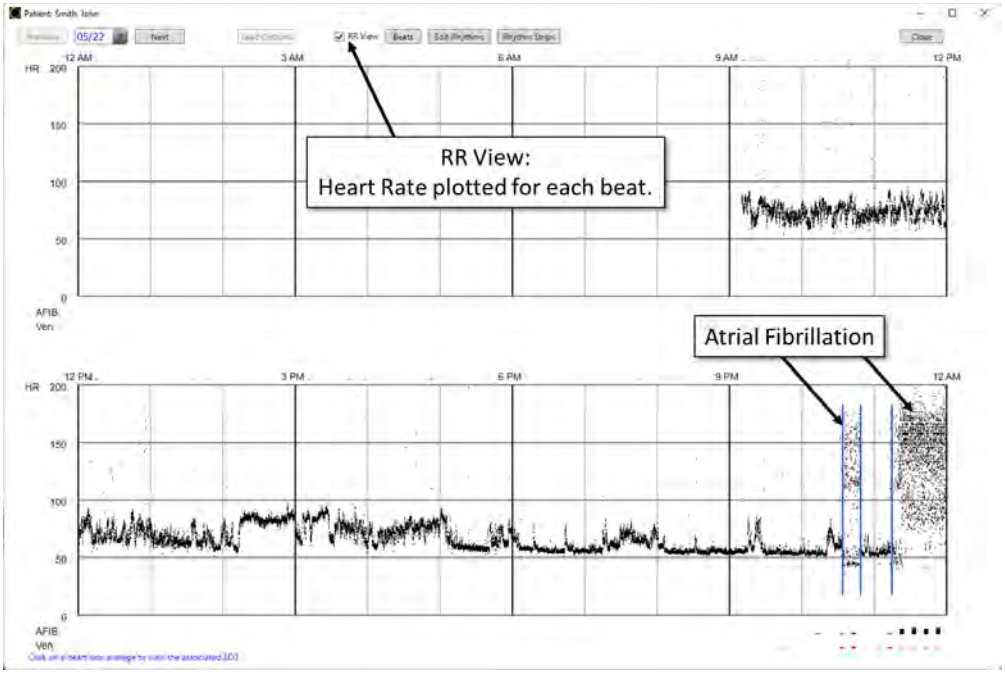


Figure 7.2. RR View showing heart rate for every RR interval.

Additional examples of ECG rhythms are shown in the following figures

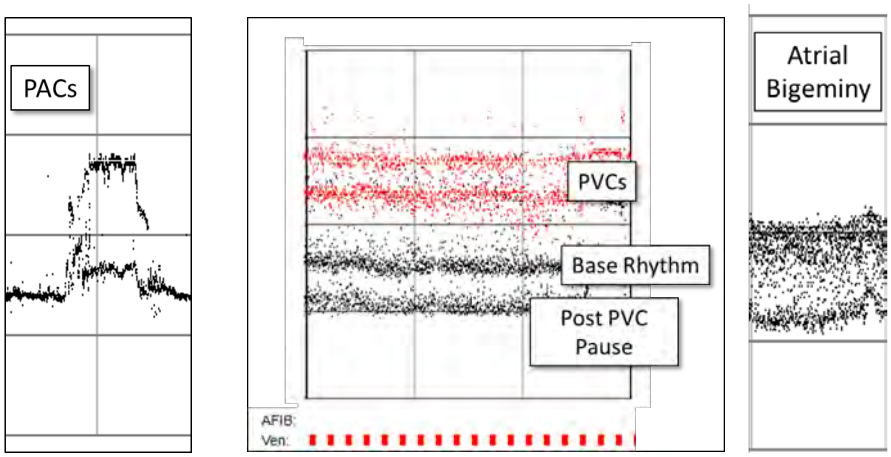


Figure 7.3 Example RR plots for premature atrial contractions (PACs), premature ventricular contractions (PVCs), and atrial bigeminy.

Avg HR View. The panels in Figure 7.4 show 10-minute heart rate averages (black dots) and ranges (vertical lines) for the selected Date tab (top left on screen). Click any date to access the averages for that date. The average dot is color coded red when the section of record contains one or more patient event button pushes, as recorded by the Sensor. Below the 12-hour panels (midnight to noon, and noon to midnight) are bars representing the relative burden of Atrial Fibrillation and Ventricular beats, providing a quick overview of where in the overall ECG record Cardea SOLO™ ADX PC Software thinks something of interest has occurred.

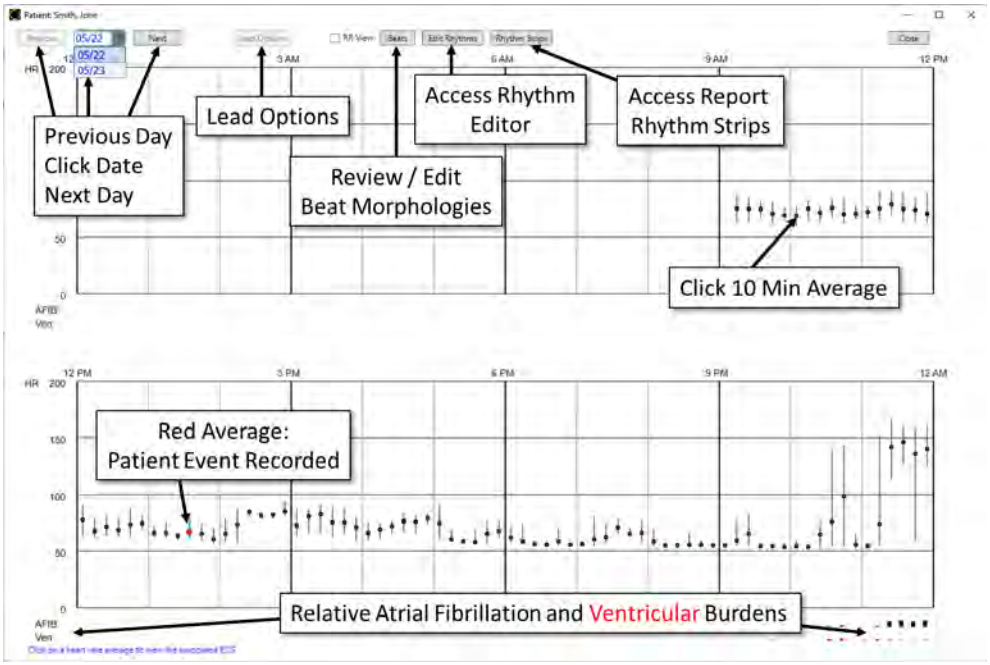


Figure 7.4. TraceViewer, Day Averages view.

Clicking the "Close" button on the top right will close the TraceViewer and return to the Report Review Options menu, Figure 7.1.

Clicking at any time point in the day view (RR or Average view) will present the 5-minute ECG record associated with the selection, Figure 7.5.

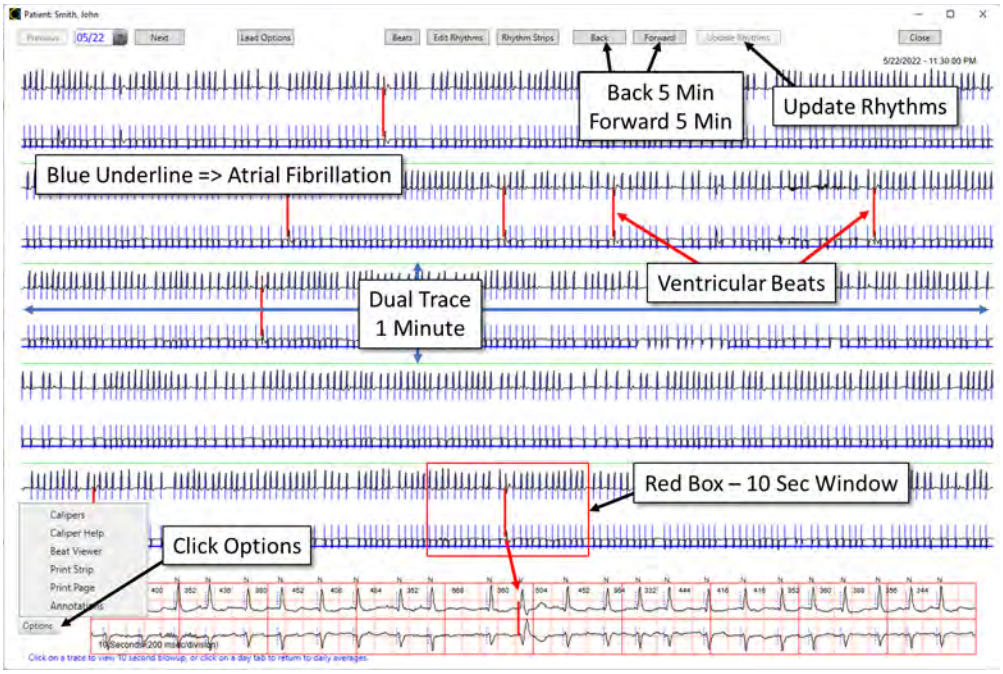


Figure 7.5. 5-minute TraceViewer.

On the top right of the screen are the "Forward", "Back" buttons. Clicking Forward or Back or clicking the < or > arrow keys on the keyboard, will advance or decrement the time view by 5-minutes.

Clicking at any point on any of the 5 one-minute traces will display a 10 second view of the trace in the window at the bottom of the screen, centered on the click point. Heart rate and time are shown at the left of the 10 second display.

The ECG trace data displayed in the 10 second window can be exported in a comma separated format for review and analysis in other applications. Using the standard Windows Copy keyboard command, Ctrl-C, copies the data to the Windows clip-board. In Excel, click on a cell location and enter the standard Paste command, Ctrl-V. Use Excel's Data/'Text to Columns' function to convert the comma separated data into columns. Associated with each sample is a flag (True/False) to indicate if the sample is valid (true) or noise (False).

If there is a patient marker within the 5-minute view, its location will be highlighted with a red asterisk (*) and when opened the 10 second window will automatically be positioned on the preceding segment.

Segments of the ECG found positive for Atrial Fibrillation will be underscored with a blue line. Ventricular beats are highlighted with a vertical red line. The light dashed vertical blue lines in the 10 second bottom window view are the isoelectric point for each beat (onset of the QRS).

Cardea SOLO™ ADX PC Software analyzes the record for muscle and motion artifacts and excludes these noise segments from analysis. Excluded segments are indicated by displaying the trace in light gray.

Clicking on the date dropdown (top left), or the Previous or Next buttons (top left) will return to the Day view.

NOTE: Beat annotations (labels) conform with ANSI/AAMI EC57:2012, e.g.

N = a normal beat or a bundle branch block beat that does not fall into the categories described below

A = a supraventricular ectopic beat (SVEB / PAC): an atrial or nodal (junctional) premature or escape beat, or an aberrant atrial premature beat

a = a PAC following the initial PAC beat (e.g., a run of SVT would be represented as Aaaaaaa)

V = a ventricular ectopic beat (VEB / PVC): a ventricular premature beat, an R-on-T ventricular premature beat, or a ventricular escape beat

Q = a beat that could not be classified

Z = a label that marks an event interpreted as noise

Beat Classes: Cardea SOLO™ ADX PC Software develops distinct beat templates used to associate beats into classes, accessed via the "Beats" button (below). The beat morphology for each class is constructed using up to 75 beats selected from the slowest heart rate sections of the record. These selected beats are time-aligned at the onset of the QRS (the isoelectric point), and a median average is used to develop the estimated morphology. For each time point, all of the beat samples are sorted from smallest to largest, and the middle half are averaged.

The behavior of the beats in the class (e.g., premature with a following pause, and with a long QRS duration) is used to classify the class as Normal or Ventricular.

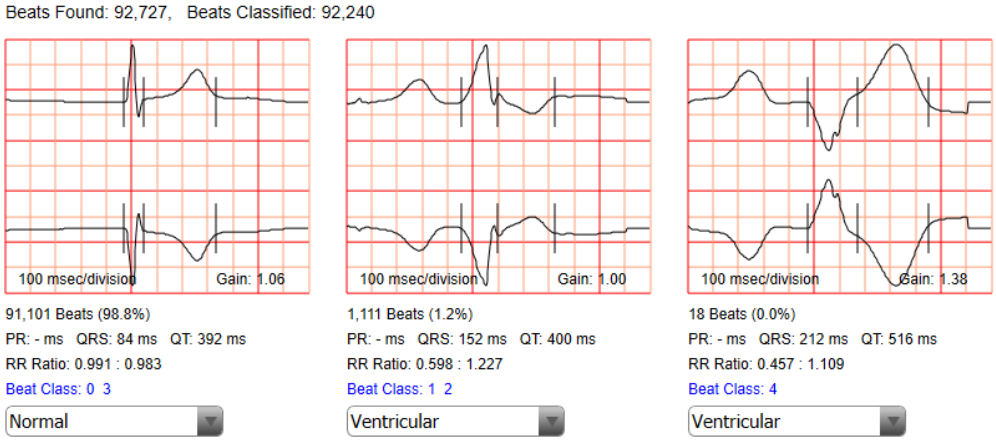


Figure 7.6. Beat morphology for each identified beat class.

The total beat count for each class is provided in the first line beneath the waveform, followed by key phase measurements. The RR ratio describes the average interval durations preceding and following the beat, divided by the running average heart rate RR. For example, a ratio of "0.658 : 0.921" indicates the class is characterized by a short RR interval preceding the beat, 66% of the expected RR, and the RR interval following the beat is close to the running heart rate. Cardea SOLO™ ADX PC Software uses the class QRS duration, the RR ratio statistics, and the beat characteristics relative to other classes to assess the likelihood the beat is Normal (Sinus in origin) or Ventricular. Should the over reading clinician disagree with the automatic classification, the drop-down box may be used to set the class to Normal, Ventricular or Noise (exclude).

NOTE: Classes set to Noise are deleted and cannot be undone.

Precaution	Setting Beats to Noise. Beats marked as Noise and automatically processed following closure of TraceViewer can only be restored by re-processing the patient's Sensor Electronics Module. Refer to Section 6.
Precaution	Changing Beat Classification. Changing beat classification (e.g., Normal to Ventricular) will, in general, have a significant impact on the rhythm analysis. This change should only be made following careful review of the trace data and associated beat class characteristics. A beat classification change can be returned to the initial designation in subsequent edits.

Clicking on the beat grid will display a pop-up menu that supports interactive editing of the waveform phases (P-onset, P-offset, etc.) or viewing the selected beats in the class in the context of the rhythm strips.

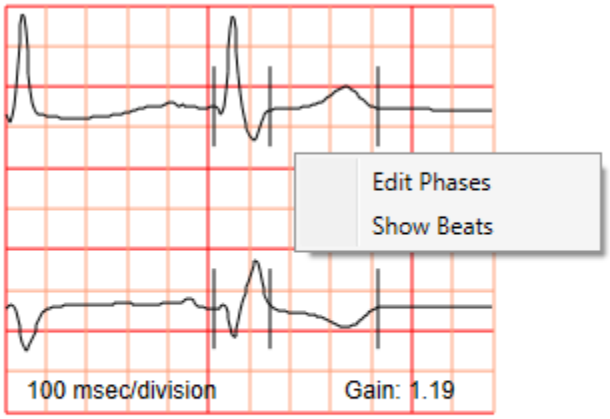


Figure 7.7. Clicking on the beat morphology displays the pop-up menu for interactively editing the beat phases or show the beat class in the context of the ECG trace.

Selecting Edit Phases will display the Phase Editor.

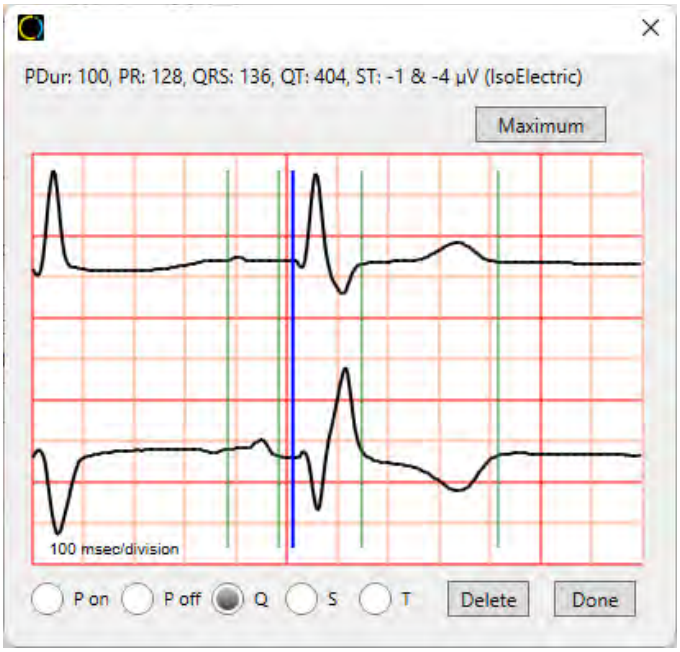


Figure 7.8. Phase Editor.

The Phase Editor supports editing the P-wave onset (Pon) and offset (Poff), the onset of the QRS (Q), end of S (S) and end of T (T). The radio buttons at the bottom can be used to select the phase to be edited; or right-clicking in the vicinity of the phase of interest will also select the phase for editing (blue highlighted vertical line). Current measurements are listed at the top of the window.

Clicking on the "Show Beats" menu item will show the first beat of the selected class in the 10 sec rhythm display, centered at the 5 second position. Next, 25 beats are selected from this class, spread uniformly across the ECG recording. Clicking the F5 key will sequentially advance to the next beat in the beat list. This allows the user to review the individual morphologies representative of beats in the class.

Not all detected beats can be classified and assigned to a beat class (Catalogued). The PC Software attempts to assign unclassified beats into either Normal, Ventricular or Noise. For noisy records there may be unassigned "beats" classified as Ventricular that should be removed.

The "delete uncatalogued V beats" function will delete all unclassified ventricular beats. Once the "Delete Uncatalogued V Beats" is clicked, TraceViewer will delete all uncatalogued ventricular beats. This button will only appear on the Beats page if there are unclassified ventricular beats in the ECG record.

When TraceViewer is closed, the PC Software will update the analysis and re-generate the PDF report. Alternatively, changes in Beat Classification will enable the "Update Rhythm" button, at the top right side of the TraceViewer window (see figure 7.5 above). Clicking this button will update the rhythm analysis but not re-create the PDF report. Updating the rhythm analysis may change the selection of rhythm strips that will be included in the report.

Lead Options: The M400 Sensor records the ECG using two orthogonal leads. In the below figure, Lead 1 (left to top electrode) and Lead 5 (top to right electrode) are the two recorded traces.

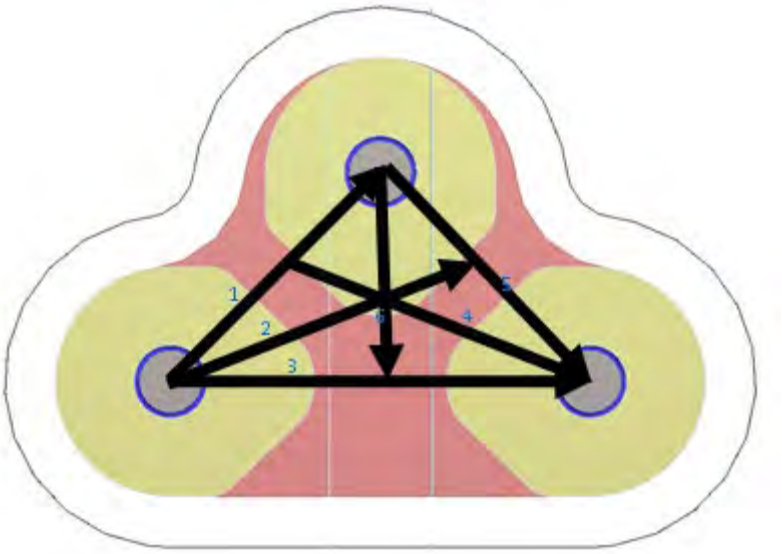


Figure 7.9. Electrode trace configurations.

Leads 1 and 5 form a lead set that can be used to create four more leads, similar to how Leads I and II are used to create the 6 limb leads for a standard 12 lead ECG. For some ectopy, these auxiliary leads may enhance the beat morphology visualization and axis determination. The Lead Options button, figure 7.4 above, displays the six possible leads, using the 10 second ECG currently displayed (bottom of figure 7.5 above).

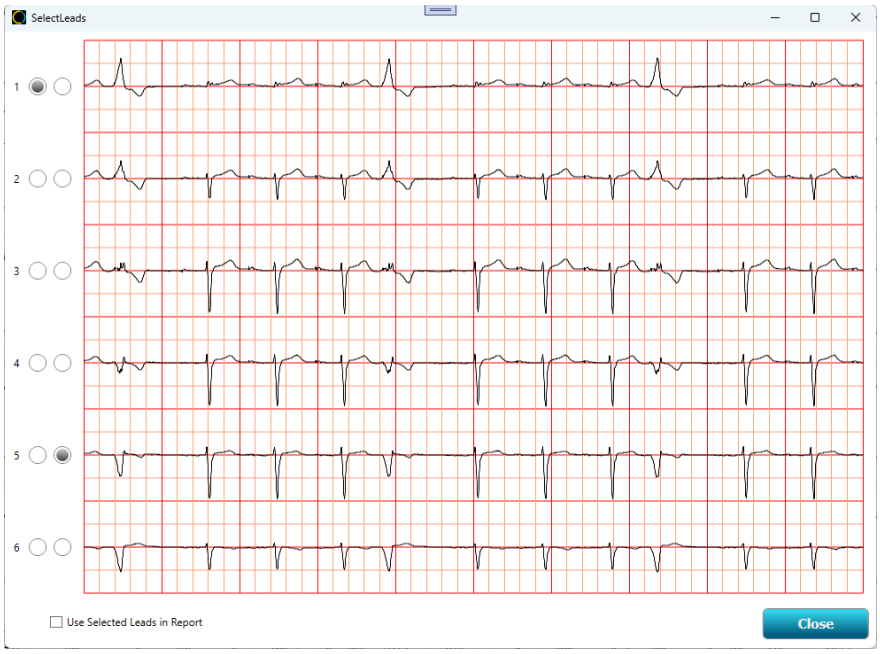


Figure 7.10. Lead selection.

The default selection is lead 2 (left radio buttons above) and lead 5 (right radio buttons above). The user may select other leads by clicking the associated radio button. TraceView will update the trace displays with the selected leads. Clicking the checkbox at the lower left will cause the system to use the selected leads for all of the rhythm strips in the associated report.

Rhythm Editor: Cardea SOLO™ ADX PC Software supports editing of episodes of Atrial Fibrillation, Ventricular Tachycardia, 3rd Degree AV Block, 2nd Degree AV Block (Mobitz II)", 2nd Degree AV Block (Mobitz I), Supraventricular Tachycardia, Pauses, ST Elevation Abnormalities, and Noise (delete section). New episodes can be inserted into the interpretation or modified or deleted. The Rhythm Editor is accessed by clicking on the Edit Rhythm button, located at the top-center of the TraceViewer window, figure 7.2 above.

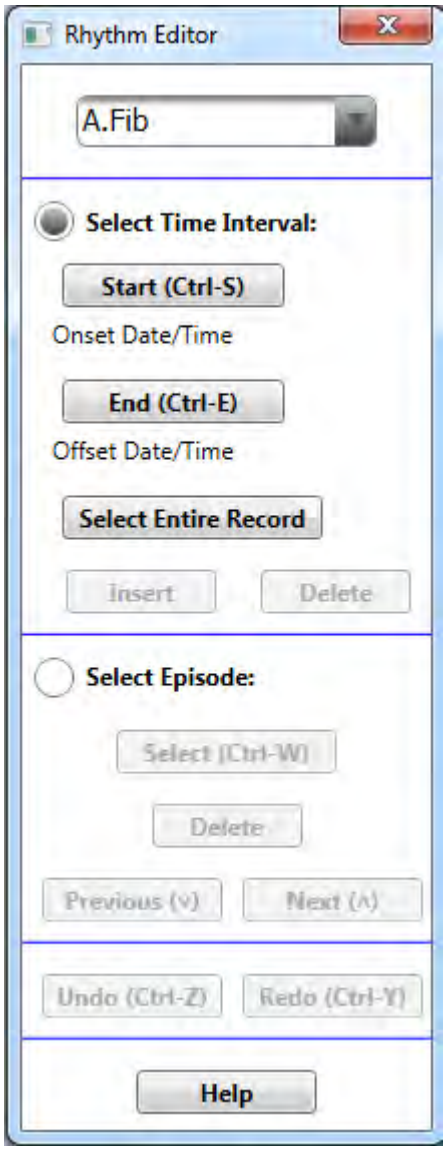


Figure 7.11 Rhythm Editor.

First, select the rhythm to be edited using the drop-down menu.

Editing of the selected rhythm can be done by specifying a time interval, defined by the Start and End times.

NOTE: Long AF episodes are divided into sequential episodes, each with a 10-minute duration.

Or the entire record can be selected. This can be very helpful in removing false positive findings for Atrial Fibrillation or Ventricular Tachycardia.

Finally, click Insert or Delete.

Alternatively, individual existing rhythm episodes can be selected and deleted.

The Previous and Next buttons will update TraceViewer to the specified Episode.

If you make an error, the Undo and Redo buttons support restoring previous rhythms.

These functions are discussed in more detail below.

Selecting a Time Interval. The Rhythm Editor works together with TraceViewer. Clicking a point in TraceViewer provides a trace sample number to the Rhythm Editor. Depending upon the action last selected (e.g. Start, End, or Select Episode), the Rhythm Editor translates the sample into a Start Time, or an End Time, or it finds the closest episode of the type selected (e.g. A.Fib).

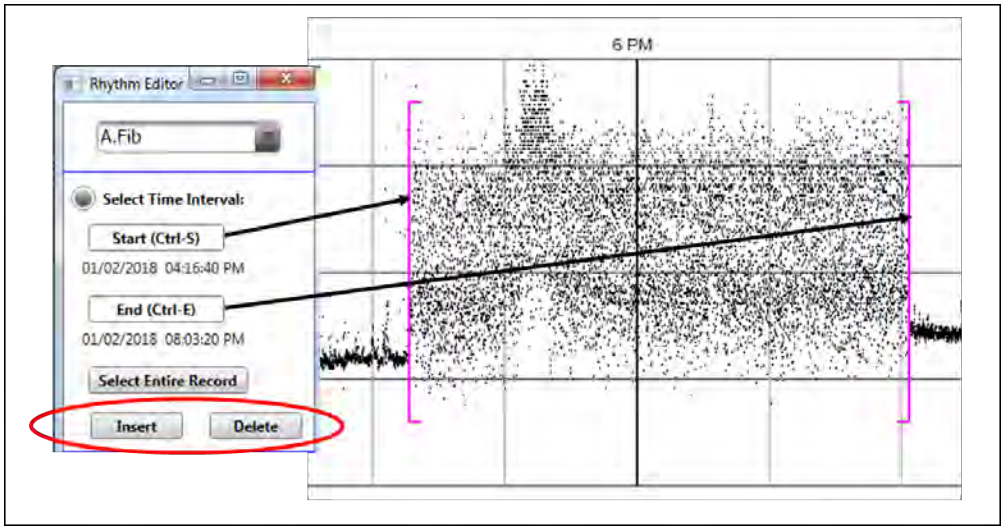


Figure 7.12. Selecting Start and End points for editing Atrial Fibrillation.

Clicking the Start button or using the keyboard accelerator (Ctrl-S), and then clicking a point in TraceViewer will cause a magenta bracket to be added to the display, signifying the start of the time interval. Repeat for the End time to complete defining the time interval.

NOTE: Selecting Start and End times can be done in either the Day view or the 5-minute trace view. Once the interval has been specified, the Insert and Delete buttons will activate.

NOTE: The keyboard keys "Insert" and "Delete" function the same as clicking the buttons in the Rhythm Editor.

For this case, clicking Insert will define the time range as 100 percent Atrial Fibrillation. Clicking Delete will remove all Atrial Fibrillation episodes in the time range. Episodes that extend beyond the bounds of the time window will be modified, either truncated or extended. The workflow is identical for inserting / deleting other rhythms.

Pause Episodes are defined by the last beat before the pause and the beat that terminates the pause.

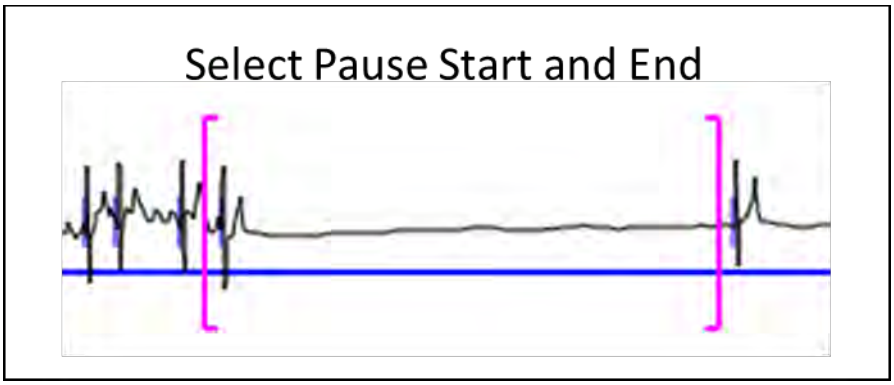


Figure 7.13. Defining a Pause.

Click Start and then click in the RR interval before the beat that defines the start of the pause. Next click End and then click just before the beat that terminates the pause. Finally click Insert to add the pause. Or, if the defined time interval encompasses false positive pauses, click Delete.

Select an Episode. TraceViewer must be in the 5-minute trace view mode to view episodes. Select the rhythm type (e.g. A.Fib). The Previous and Next buttons (or the Keyboard UP and DOWN arrows) will move the trace display to the next or previous episode, starting with the first episode. This feature provides a simple mechanism to walk through the full disclosure, examining each episode. Alternatively, clicking on the Select button, and clicking a point within an episode causes it to be selected. The episode will be underlined.

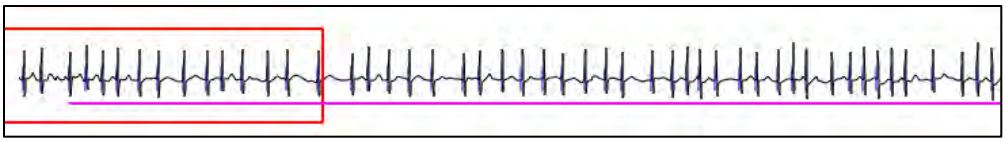


Figure 7.14. Selected Atrial Fibrillation episode. Note the magenta underline, indicating this episode is selected.

Once selected, the episode can be deleted by clicking the Delete button, or the keyboard Delete key.

Undo / Redo. The Undo and Redo buttons provide for ten levels of undo / redo. The memory storage supporting undo and redo are reset when the selected rhythm changes. For example, changes in the Atrial Fibrillation episodes can be undone, or returned to the previous status, for as long as the Rhythm Editor is focused on A.Fib. Once another rhythm is selected, the memory is cleared. Reselection of A.Fib starts fresh, there is no memory of previous changes.

Noise. Selecting the Noise option enables deleting sections of the record from analysis. Set the "Rhythm" to Noise, select the start and end times, and click Delete.

Precaution	Noise deletion cannot be undone. Only by re-processing the patient's Sensor Electronics Module can it be undone. Refer to Section 6.

Use of the Noise function will enable the "Update Rhythm" button – discussed above.

New Beat Class: Although unusual, the QRS morphology of a Normal Sinus beat can be very similar to a Ventricular beat. This is especially the case for relatively narrow LV fascicular foci PVCs. The main distinction with narrow PVCs is that the T wave vector is different from the major R or S wave vector; that is the T wave is inverted.

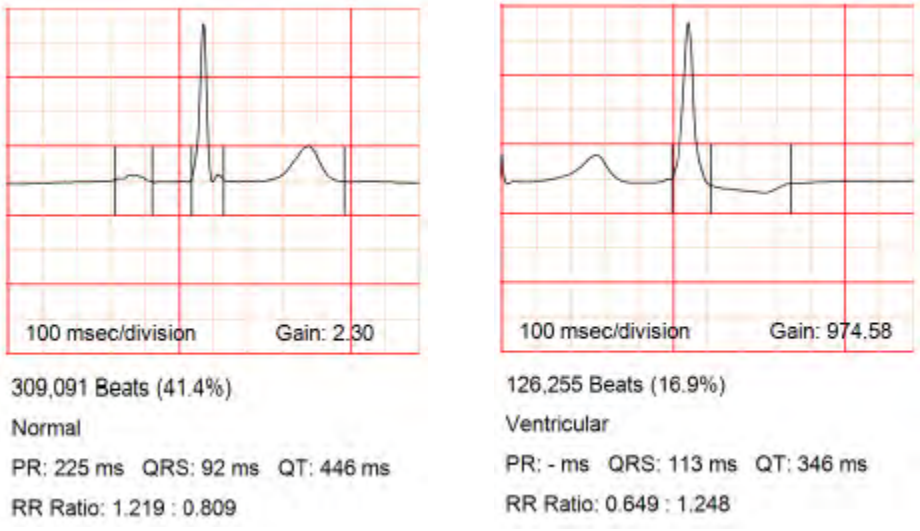


Figure 7.15. Note the very similar QRS morphology between the Normal (left) and the Ventricular (right) beats.

When this occurs the beat classification may mix the two beats into one class, resulting in either PVCs classified as PACs, or vice versa. Since premature P waves are sometimes not identified (lost in the prior T wave or low amplitude), classification of PAC's with aberrancy can occur and not be distinguished from PVCs. The New Beat Class tool is designed very specifically to identify these misclassified beats and move them into a new beat class. The following walks through an example of how to use the tool.

The initial view of the beats in TraceViewer:

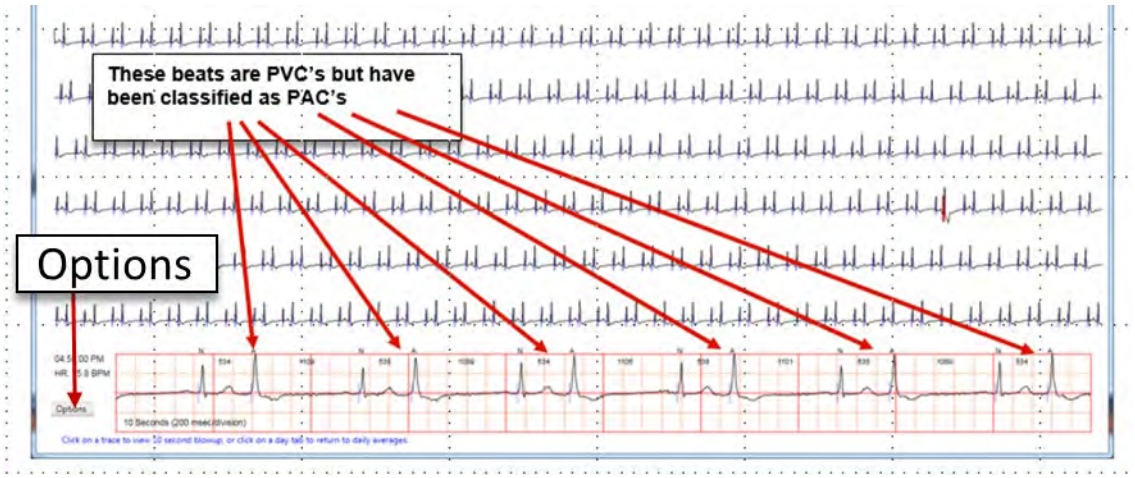


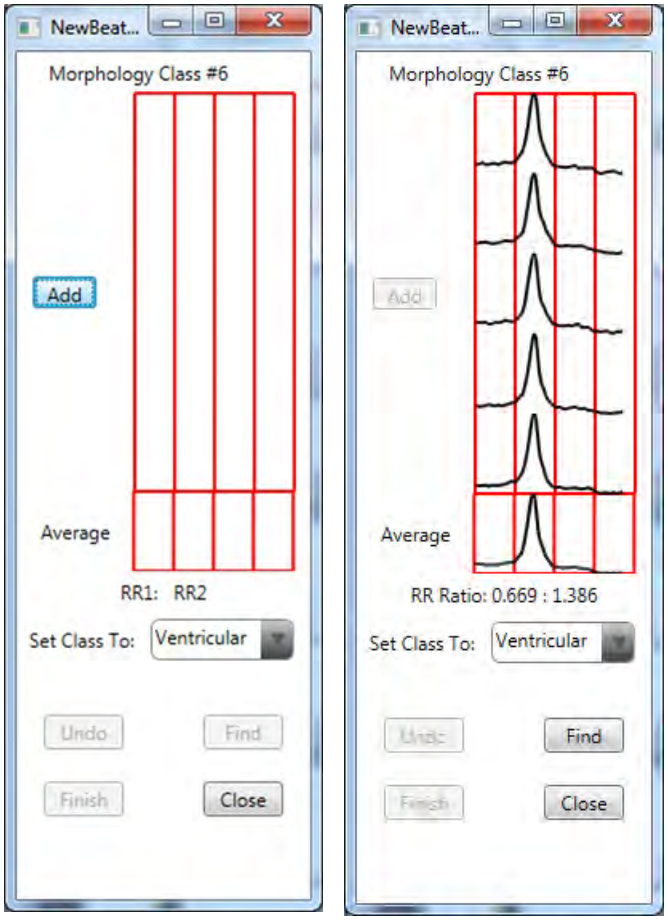
Figure 7.16. Example of PVCs classified as PACs.

The New Beat Class tool is accessed via the "Options" button at the bottom left of the TraceViewer screen.

The workflow is simple –

1. Create a representation of the QRS for the beat type that needs to be re-classified by selecting the waveform examples.
2. The PC Software will search the entire record for beats that match the selected waveforms.
3. The TraceViewer screen will update with the newly reclassified beats.
4. The UNDO button will remove the results if they are not acceptable.
5. The Finish button will add the new Beat Class to the report and close the tool.

   NOTE: For premature beats, the percent early, relative to the running heart rate, is also used in the analysis, providing a robust method for identifying premature beats with the target morphology.



When you select Options/New Beat Class the window to the left will be displayed. Click Add and then in TraceViewer select a 10 sec strip that shows one or more beats that need to be reclassified. Click on the beat in the 10 sec strip – the beat will be added to the display. Right-clicking on any added beat will remove that beat from the collection. Navigate to another example beat and select. You may add up to 5 beats to form the Average Beat, thus reducing noise.

NOTE: The PC Software cross-correlates the family of selected beats, optimally time aligns them, and then computes the average beat morphology that will be used in the search. The vertical lines are spaced at 100 msec.

Figure 7.17 New Beat Class tool.

Clicking the Find button will initiate a search and update TraceViewer with the new classifications:

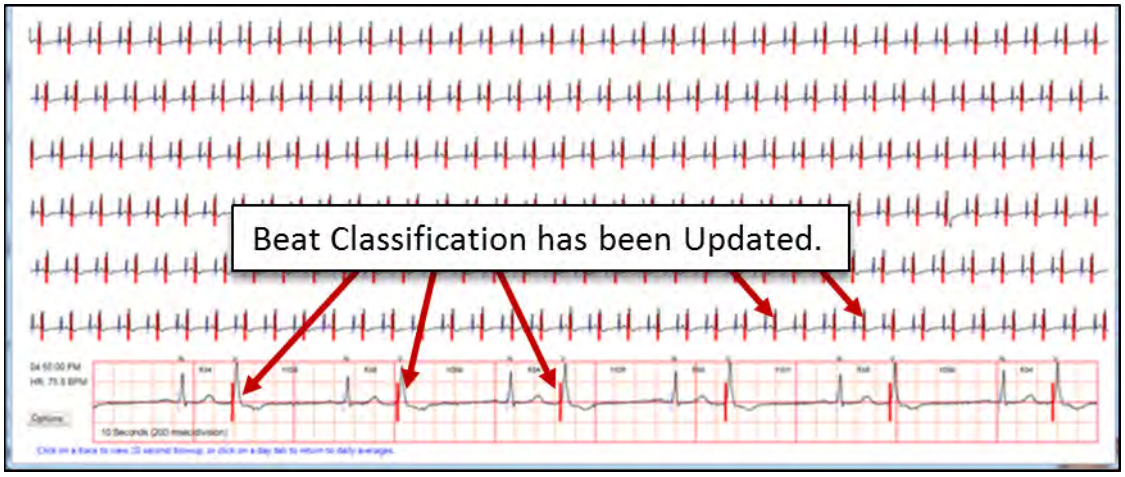


Figure 7.18. Updated beat classification.

Click Finish to finalize the update or click UNDO to discard the changes.

Individual Beat Editing. Individual beats can also be edited. In the 10 second rhythm strip at the bottom of the screen, click on any beat. A pop-up menu will appear.

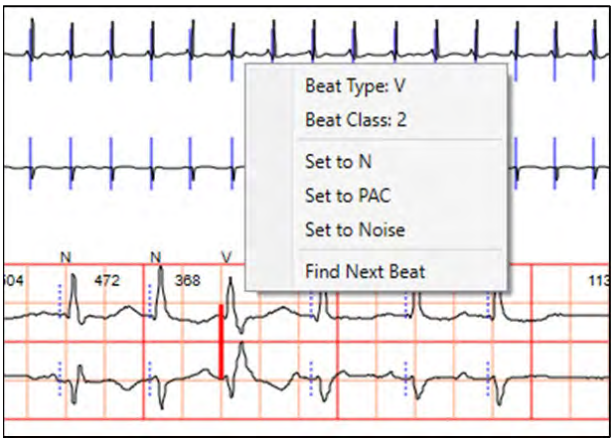


Figure 7.19. Individual Beat Editing.

The pop-up displays the beat classification (V – Ventricular) and the beat class (2 in this case). The options support reassigning the beat classification to Normal, PAC or Noise. The pop-up also supports jumping to the next beat within the same beat class.

Runs of beats can be re-assigned to Normal, Premature Atrial Contraction (PAC) or Ventricular. Click the mouse down and hold at the onset of the beat(s), drag forward in time, and release (mouse up). The section selected will be highlighted and a selection menu presented, as shown below. Clicking anywhere except on the pop-up menu clears the selection.

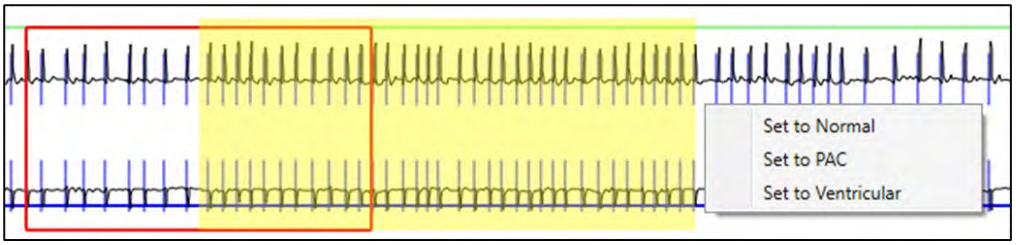


Figure 7.20. Resetting individual beats to Normal, PAC or Ventricular.

NOTE: Mouse down clicks have different meanings, depending on what the user is doing. When the Rhythm Editor is active (window is open – see below) it will capture the mouse clicks; the user cannot edit beat and run types when the Rhythm Editor is active.

Rhythm Strips: Clicking the Rhythm Strip button at the top of the screen will display the Rhythm Strip WaveCollection Tool that enables rapid Rhythm Strip navigation in TraceViewer, supporting review and editing of select ECG strips in the PDF Report:

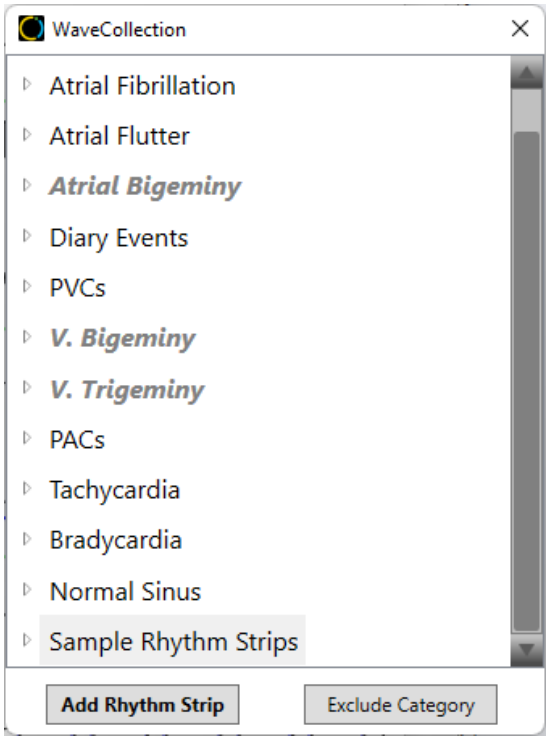


Figure 7.21. The Rhythm Strip Tool.

Clicking any of the caret (▷) symbols to the left of the category, or double-clicking the category, will display a list of all the rhythm strips included in the report. In addition, for VT, SVT and Pauses, additional rhythm strips are included for physician review.

Items ***grayed-out and in italic font*** represent nominal findings excluded from the report. For example, if the PAC findings were less than a burden of 0.5%, the report would be shortened by excluding the PAC report page.

NOTE: When found, AFib, VT, Pauses, Heart Block, and SVT are always included in the report.

Figure 7.22. Expanded strips for Atrial Fibrillation.

Clicking on any strip will update TraceViewer, showing the selected strip in the context of the 5-minute view. The selected strip can be excluded from the report by clicking on the "Exclude Strip" button. Or, if the strip has been excluded, indicated by gray italic text, it can be re-included by selecting the strip (i.e., click to select), and then selecting the "Include" button. A strip can also be toggled between Include and Exclude by right clicking on the selected strip. An entire category can be excluded by selecting the category and clicking Exclude. When any individual strip within an Excluded category is set to Include, the category will toggle back to Included.

Patient Events – Sensor Button Presses. The WaveCollection window includes a category for Patient Events. The events are numbered sequentially and can be included or excluded from the report as described above. If the patient has pressed the event button more than 30 times, the PDF report will show the total number of button presses (up to 100) in the Initial Findings section and the PC Software will select 30 strips judged to be of most interest, i.e. sinus rhythm strips will be excluded in favor of Atrial Fibrillation, Ventricular Tachycardia, etc. The report event numbering is tied to the sequence number as shown in the WaveCollection window and will contain gaps for the events that have been excluded.

Add Rhythm Strips: Select the segment of the ECG that you wish to add to the report (i.e., it is displayed in the 10 second window at the bottom of TraceViewer). Next, click the "Add Rhythm Strip" button, Figure 7.15. A window similar to the following is displayed:

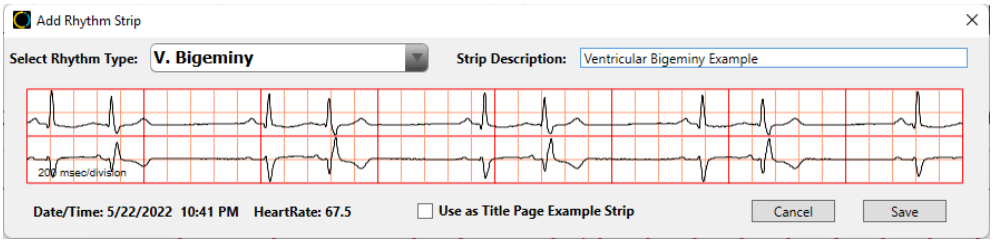


Figure 7.23. Add Rhythm Strips.

Select the category appropriate for the rhythm – the strip will be added to that section of the report; and labeled with the description you enter.

The Rhythm Type "Notable Strips" supports the user in adding particularly noteworthy rhythm strips to the report. The Notable Strips section of the report follows the Overview section, preceding the rest of the report rhythm strips.

The strip can also be designated as the example ECG on the front page of the Report. Check the "Use as Title Page" checkbox.

The first eight seconds of the currently displayed ten second rhythm strip will be saved. Rhythm strip heart rate is determined by the strip RR average. A strip description is required before clicking the Save button.

Upon closing the TraceViewer window, the PC Software will automatically update the PDF report and add or exclude the rhythm strips, as specified.

Options: The Options button (bottom left in figure 7.5 above) provides access to interactive calipers, the beat viewer and rhythm strip printing.

Calipers: Clicking Options / Calipers (lower left on Figure 7.5) will activate the calipers and display two vertical caliper lines on the 10 second rhythm strip. Clicking on the Options / Caliper Help button will display the Caliper Help:

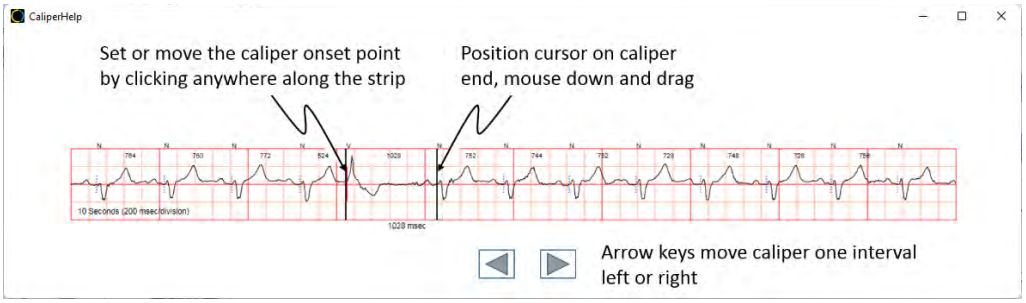


Figure 7.24. Caliper Help window.

The caliper onset point can be moved by clicking anywhere along the rhythm strip. The caliper offset point (end) can be moved by clicking down on the left mouse key when positioned over the offset line, holding down the left mouse key, and dragging left or right. The caliper time interval, in msec, is displayed at the bottom of the caliper and dynamically updates as the mouse is moved. The keyboard arrow keys will move the caliper left or right one RR interval.

Beat Viewer: Right-clicking the mouse at any location in the 5-minute ECG TraceViewer display or selecting Beat Viewer from the Options button on the lower left of Figure 7.5, will present an average beat waveform viewer. The average waveform is constructed from the suite of beats that match the beat morphology and are within ±15 beats of the beat clicked. To select the specific beat class, click at a point past the onset of the QRS of interest and within the RR interval following the beat.

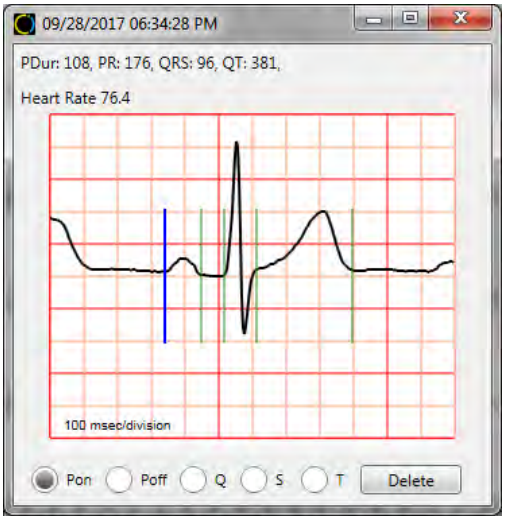


Figure 7.25. Beat Viewer.

The phases P-onset (Pon), P-offset (Poff), Q onset, end of S and end of T are automatically picked. Phases can be edited by first selecting the phase. The above blue vertical line, and the activated Pon radio button at the lower left, indicate the onset of the P-wave is enabled for editing. Clicking on the waveform anywhere before the Poff phase will move the Pon marker and update the measurements at the top of the window. Right-clicking on a phase marker, or on the appropriate radio button, will enable editing or addition of that phase (if not automatically picked).

Until the Beat Viewer window is closed (click the red X at the top right, or close the TraceViewer window), every subsequent click at any point in any 5-minute TraceViewer window will update the displayed waveform. All measurements associated heart rate, and date/time are appended to a growing Excel .csv file, stored in the associated Directory folder for this patient ("Phase Measurements.csv"). This functionality can be used to assemble QT-RR information for studies of QT dynamics for the patient.

The Beat Viewer window can be quite useful for checking for the presence of P-Waves in segments of ECG that may contain AFib. Clicking in areas of clear normal Sinus rhythm, compared to suspect segments, provides an effective way to minimize noise and assess the presence / absence of P-Waves. The Beat Viewer is also helpful for viewing PVC and ventricular tachycardia beats.

Workflow Tip: The most efficient workflow is to first examine the Beat Morphologies, review individual beats if desired, and make any changes to the class type (Normal, Ventricular or Noise) as required. If there are sections of record that should be deleted because of high noise degrading analysis, use the Rhythm Editor (Noise) function to remove. When you are satisfied with the Beat assignments and removal of severe noise segments, click the "Update Rhythm" button (See figure 7.5, top right). Continue with rhythm strip review and editing (See below).

Closing TraceViewer will trigger an update of the report, reflecting all of the edits.

Print: Clicking Options / Print Strip (lower left on Figure 7.5) will print 50 or 100 second rhythm strips, centered on the current ten second rhythm strip, to a standard Windows connected printer. Selecting Options / Print Page will print the entire 5-minute view.

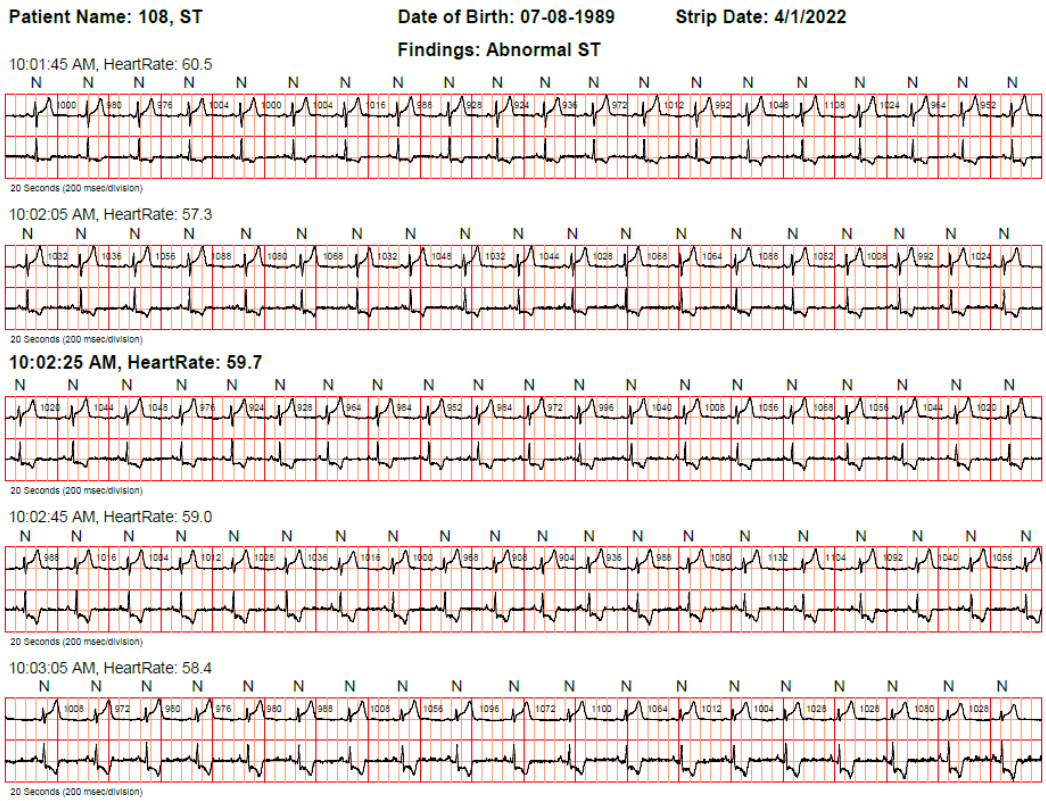


Figure 7.26. Example of a 100 second rhythm strip highlighting ST abnormalities.

7.2 Edit Demographics

The "Edit Demographics" button shown in Figure 7.1 will re-open the Additional Information screen (see Section 6.2.3, Figure 6.8) populated with all the information previously entered. The information on this screen may be edited. Editing this data does not trigger a need to re-process the ECG data stored on the Electronics Module as all needed data are saved to disk during the initial processing step. Clicking the "Done" button, Figure 6.5, will start the report generation process, concluding with the presentation of the updated PDF report.

7.3 Edit Dx

Cardea SOLO™ ADX PC Software automatically creates a summary paragraph or bullets of the Initial Findings. As you review the trace data, you may wish to review and edit the summary findings (see Report Figure 6.9 above), or add concluding remarks, diagnosis, or recommendations in the clinician's Interpretation Window. To edit these fields, click the "Edit Dx" button, Figure 7.1. Cardea SOLO™ ADX PC Software will present a text editing window, Figure 7.27 below.

NOTE: Access to the Edit Dx functionality is controlled by User settings – See Section 4.2 User Setup. Users without over-reading privileges cannot enter interpretation text or set the report status (Normal, Borderline, or Abnormal).

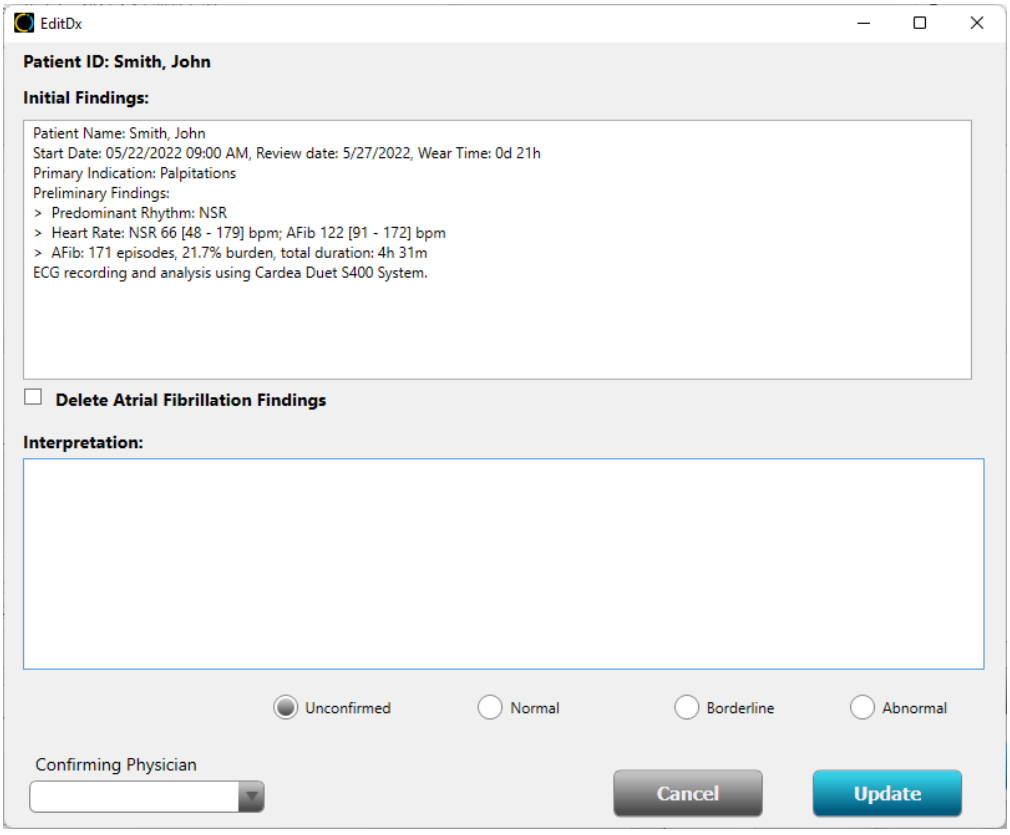


Figure 7.27. Edit Dx window.

7.3.1 Delete AFib and VT Findings

Initial Findings of Atrial Fibrillation (AFib) or Ventricular Tachycardia (VT) are very significant clinical findings. Although Cardea SOLO™ ADX PC Software has a very high Sensitivity and Positive Predictive Value for AFib and VT, the ECG data should be carefully examined.

If P waves are seen on these strips (and not Flutter P-waves), a complex atrial rhythm could be falsely diagnosed as AFib. If fibrillation is present on some of the strips and P waves seen on others the AFib burden could be less than reported. In either case, the ECG data should be carefully reviewed in TraceViewer. Complex atrial rhythms can be precursors to AFib.

Some motion artifact noise, particularly as recorded by a single lead, can appear to be VT. The TraceViewer can be very helpful in reviewing the overall rhythms and noise at the time of suspected VT.

If the Initial Findings are a false positive for AFib or VT, clicking the "Delete Atrial Fibrillation Findings" or the "Delete Ventricular Tachycardia Findings" checkbox(s) and then clicking Update will re-create the report, excluding all AFib and / or VT. Cardea SOLO™ ADX PC Software will post a confirmation window requiring you to confirm you intend to delete the findings. All of the Initial Findings text will be replaced, and Interpretation deleted, during the re-creation process – any edits made will be replaced with the updated findings.

Edits and added Interpretations should follow deletion of AFib or VT.

Following your edits, close the PDF Report if open, and click Update. The report will be updated and displayed.

NOTE: The Rhythm Editor in TraceViewer can also be used to select the entire record and delete AFib or VT.

Precaution	Delete Findings. Deleted AFib or VT findings can only be restored by re-processing the raw data from the Sensor's Electronics Module. Refer to Section 6.

7.3.2 Record Status and Confirmation

The buttons below the text box, for entering the physician's Interpretation, also support setting the status of the test (Record Status) (see Figure 7.23). The draft PDF report is initially marked as Unconfirmed. The over reading physician documents their confirmation and assessment of the report findings by selecting Normal, Borderline, or Abnormal. Next, click Save – Cardea SOLO™ ADX PC Software will regenerate the PDF report with the finalized Findings, Interpretation, Record Status, physician's name and date.

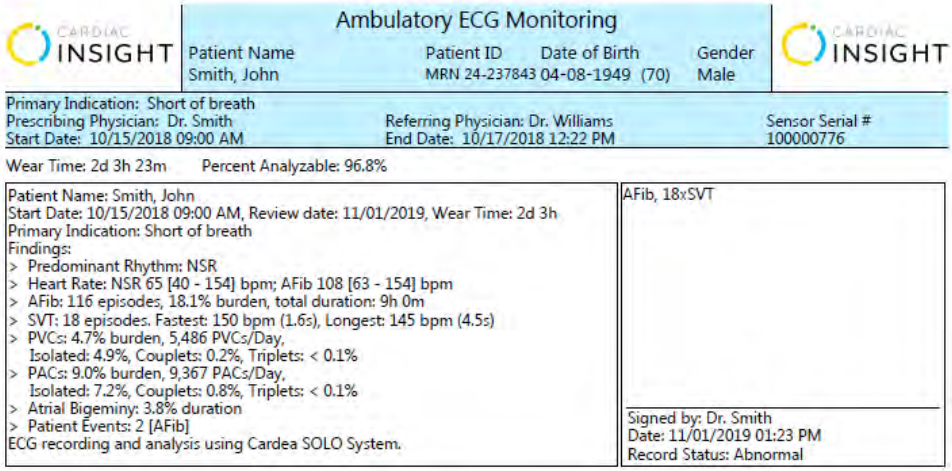


Figure 7.28. Finalization of Report.

7.4 ST Analysis

The System supports assessing the ECG traces for ST segment changes. The analysis is somewhat CPU intensive and not required on most ECG recordings. It is therefore supported as a post Download and Analysis function. ST abnormalities are defined by the minimum ST segment change, as defined by the user profile (See Report Options, figure 4.4 above). The default settings are +/- 200 µVolts (Elevation / Depression) and 3-minute duration. To be called as an ST anomaly the ECG ST changes must exceed the minimum voltage and minimum duration. The ST measurement is made at the point 60 msec beyond the end of the S-wave (j+60 msec) and is relative to the measurement at the onset of the QRS (isoelectric point).

Clicking the ST Analysis button will launch the search for abnormal ST episodes. As the search proceeds a window is displayed to shows the progress (green bar) and lists episodes found.

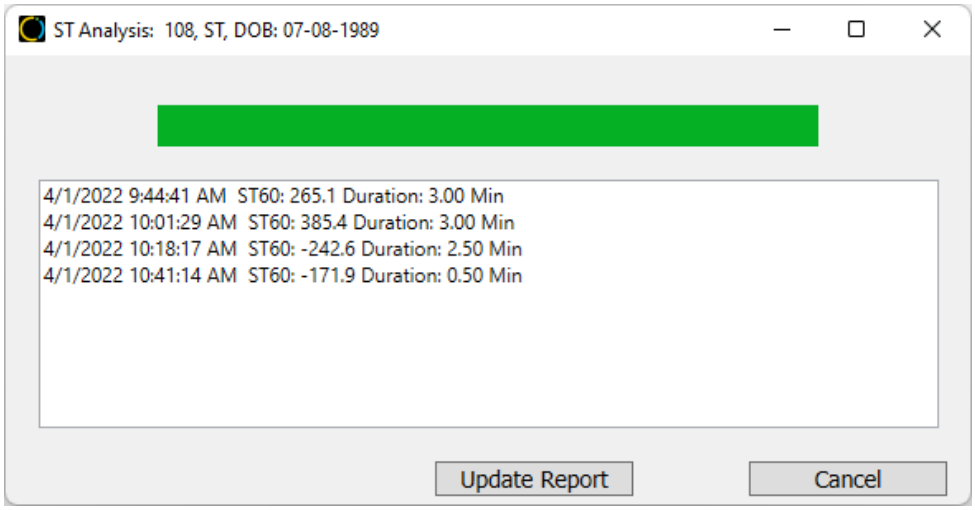


Figure 7.29. ST Status Window.

At the conclusion of the search, you can update the PDF report by clicking the "Update Report" button. The below shows an example rhythm strip identified by the ST analysis functionality.

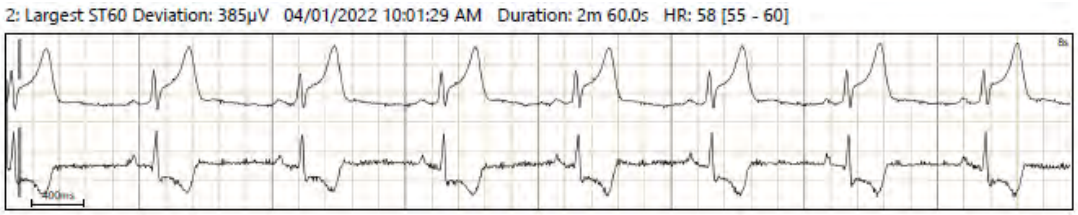


Figure 7.30 Example ST Rhythm Strip.

7.5 Heart Rate Variability (HRV)

Cardea SOLO™ ADX PC Software analysis also includes tools for HRV analysis for both Root Mean Square of the Successive Differences (RMSSD) between normal beat intervals and Standard Deviation of Normal to Normal (SDNN) beat intervals. The selection of which method will be used is set in the User Preferences (See figure 4.4 above). Non normal sinus rhythms (e.g.: Atrial Fibrillation) are excluded.

The ECG record is divided into 10-minute segments and HRV is computed for each. The following plots summarize the findings.

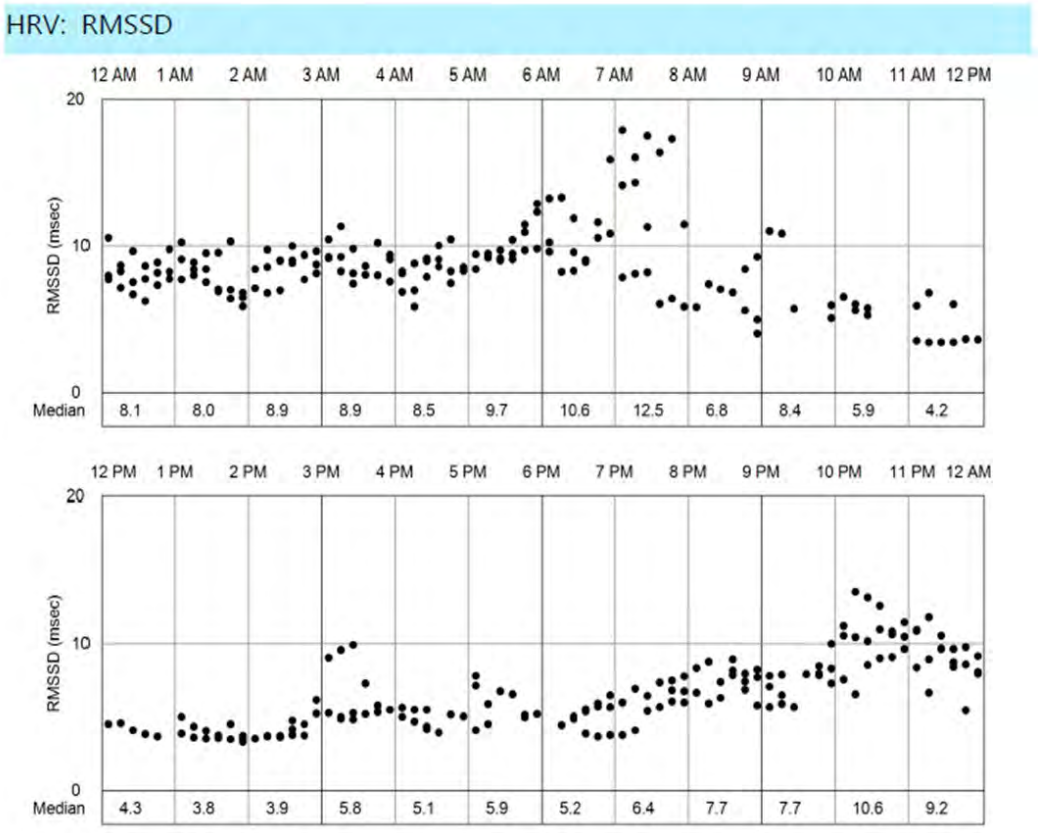


Figure 7.31 RMSSD multi-day summary. The top box represents HRV from midnight to noon, and the bottom plot is from noon to midnight. Each dot reflects a 10-minute interval. For this record, HRV is high during the sleeping period from 10 pm to 7 am, and low during the normal waking hours.

HRV is also a function of heart rate, shown in the associated figure.

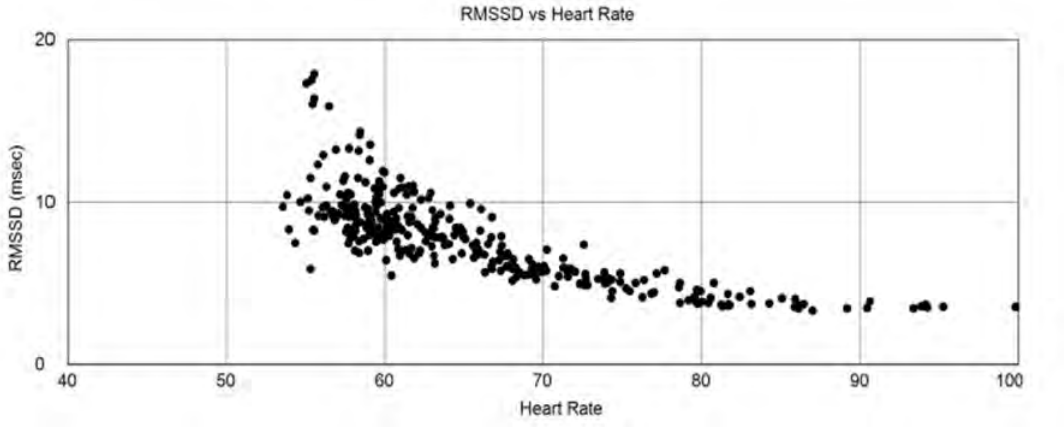
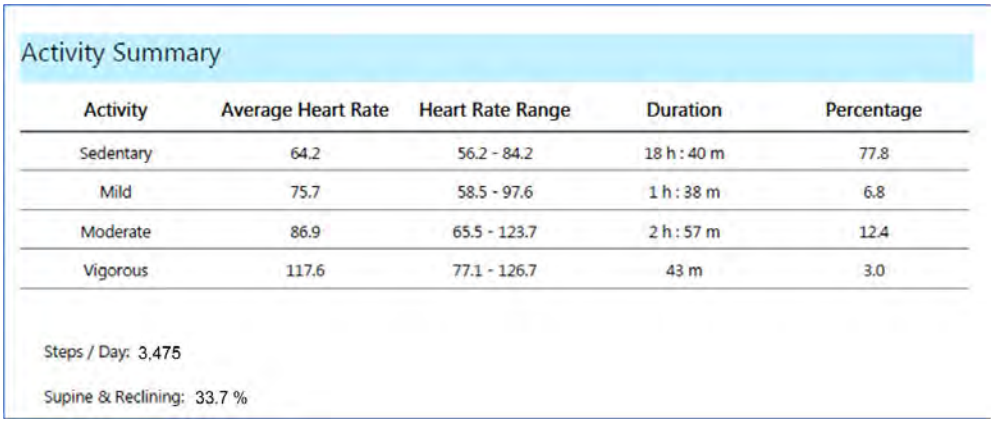


Figure 7.32. HRV versus Heart Rate.

7.6 Activity Summary

The Sensor includes a 3-axis accelerometer to continuously detect body position, movement, and step counts. As noted above, it is important for the patient to be in a relaxed upright position for the first three (3) minutes from the time of Sensor activation. This allows the Sensor to determine the orientation of the Sensor on the patient and then derive the patient's position as upright or supine for each moment of the recording. The raw acceleration data can also be converted to an Activity Index following the methods of Bai et. al.[1] The activity index has been grouped into four categories: Sedentary, Mild, Moderate and Vigorous. Heart rate ranges and duration of time spent in each category are included in the Report, along with average steps per day and percentage of time spent in a supine position.



Activity Summary

Activity	Average Heart Rate	Heart Rate Range	Duration	Percentage
Sedentary	64.2	56.2 - 84.2	18 h : 40 m	77.8
Mild	75.7	58.5 - 97.6	1 h : 38 m	6.8
Moderate	86.9	65.5 - 123.7	2 h : 57 m	12.4
Vigorous	117.6	77.1 - 126.7	43 m	3.0

Steps / Day: 3,475

Supine & Reclining: 33.7 %

Figure 7.33. Activity Summary.

The level of activity is also included on each rhythm strip.

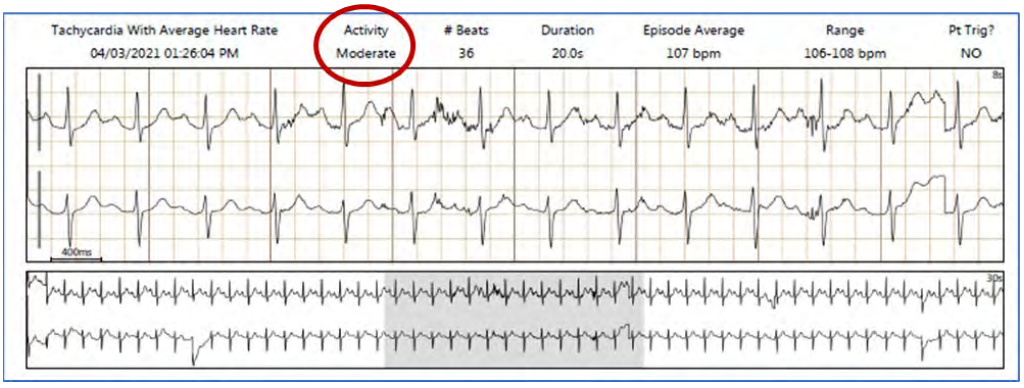


Figure 7.34. Rhythm strip showing the patient's Activity level.

1) (https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0160644).

7.7 Open Report (.pdf)

If you have closed the report PDF and need to re-open it, click on the "Open Report (.pdf)" button, shown on Figure 7.1. Cardea SOLO™ ADX PC Software will re-open the report.

7.8 Report Completion

When you have finished your review, and possibly updated the report, click "Done". Cardea SOLO™ ADX PC Software will return you to the User Option Menu screen, Figure 6.2, ready to process another patient's Sensor data.

8 Review and Editing of Previous Reports, Cohort Reporting, Help and Operator's Manual

The User Menu Options screen, Figure 6.2, supports user access and editing of previously created reports, compilation of Patient Report statistics into Excel based cohort reports, help and display of this manual. These functions are described in the following sections.

8.1 Previous Reports - PDFs

Clicking on the "Open Report (.pdf)" button will display a list of previous studies, Figure 9.1.

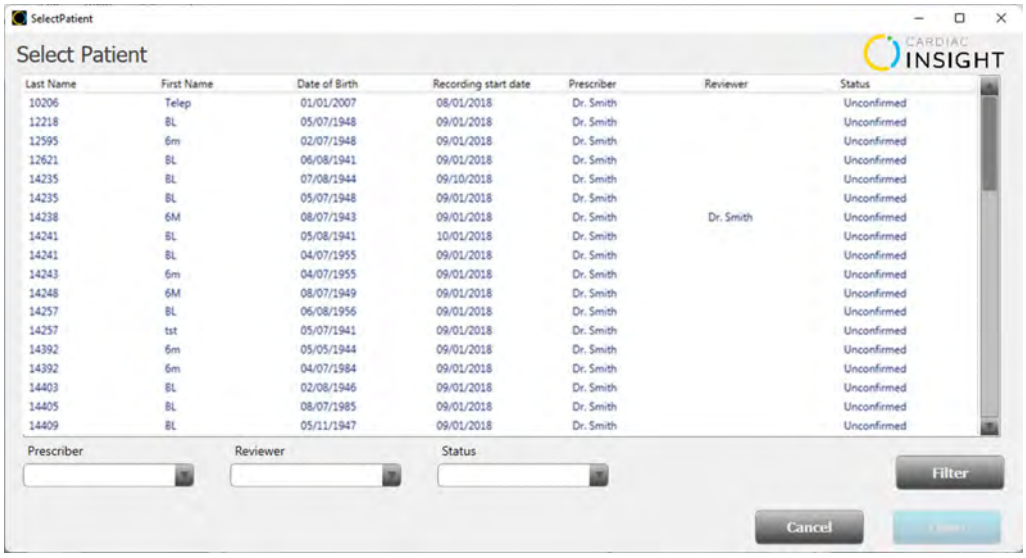


Figure 9.1. Select / Display previous final reports.

The selection window includes the prescribing physician. If the record has been over read, the over reading physician's name and record status (e.g., Abnormal) are shown. Filters are also available to support rapid access to specific patients. For example if Dr. Jones is over reading tests ordered by Dr. Smith that have not yet been over read, entering the Prescriber name and Status of Unconfirmed, and clicking Filter, will present the updated filtered list of pending tests.

NOTE: For tests completed using Cardea SOLO™ ADX PC Software versions prior to Version 3.x, the Prescribing, Reviewer and Status information is not available, and they will be blank in the display.

Double clicking on a name, or highlighting a name and clicking "Accept" will retrieve and open the associated previous PDF report. Clicking the column headers, e.g. Last Name or Date of Test, will sort the list.

8.2 Quick Patient Status Summary

The Select / Display functionality in Section 9.1 above also supports rapid compilation of summary data and creation of an Excel report. Use the filters to select the relevant tests and click on the Recording Start Date column header to organize by date.

Next, Select the tests to be compiled. You can select individual items by holding down Ctrl key and clicking each test of interest. Alternatively, select a group by first selecting a test, scrolling to the last test of interest, and hold down the Shift key and click on the last test – all tests between the first and last test are highlighted. Once the tests of interest have been highlighted, Right-click on any of the selected tests and select "Copy to Clipboard" from the pop-up menu.

Open Excel, place the cursor where you want the table to be pasted, and select Paste (or Ctrl-v).

8.3 Previous Reports – Full Disclosure ECG

Clicking the "Open TraceViewer" button will present a patient report selection window, see figure 7.1 above. Selecting a patient record will next display the full disclosure information in TraceViewer, see Section 7.1 ECG Trace Review above. Additional rhythm strips can be added to / deleted from the final report and beat classifications can be edited, following the instructions in Section 7.1 above. The PDF report will automatically be updated and displayed if changes have been made.

Precaution	Setting Beats to Noise. Beats that are marked as Noise and automatically processed following closure of TraceViewer can only be restored by re-processing the Electronics Module. Refer to Section 6.

8.4 Edit Demographics

The "Edit Demographics" button presents the patient selection window, see Figure 7.1 above. Following selection of the patient record the demographic screen is presented, filled-in with the information entered during initial processing, See Section 6.2.3. All fields and diary entries can be edited, added or removed. Clicking the "Done" button updates the ECG analysis and the associated updated final PDF report is displayed.

8.5 Over-Reading and Confirming Diagnosis

Clicking the "Edit Dx" button will present the Select Patient report window, see Figure 7.1 above. Selecting a patient record will next display the associated report PDF and the Edit Dx window, see Section 7.3 Edit Dx above. The Initial Findings and Clinical diagnosis or notes may be entered or edited. False postitive findings of atrial fibrillation or ventricular tachycardia can be deleted. And, the status of the findings (Normal, Borderline, Abnormal) can be set. See Section 7.3 above. Clicking "Update" will update the PDF with the specified changes. The

PC Software will return to the Select Patient window for confirming additional patient reports.

8.6 Operator's Manual

Clicking the "Operator's Manual" button on the User Menu Options screen will retrieve and open this manual.

8.7 Help About

Clicking the "Help About" button on the User Menu Options screen will display System information and Cardiac Insight contact information. The following screen will be displayed.

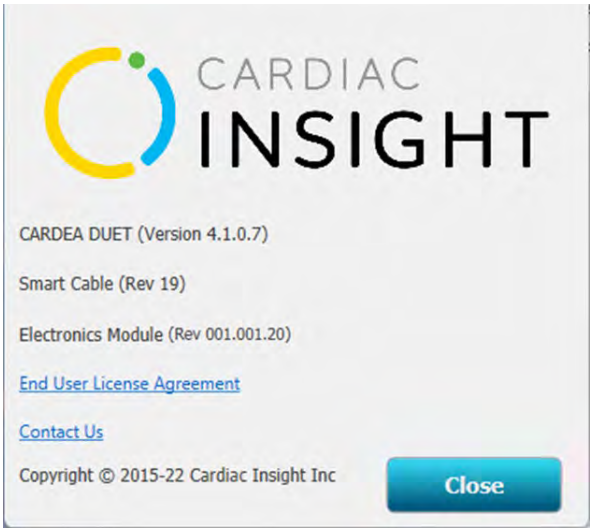


Figure 9.2. Help About screen.

The first line provides the PC Software release level for Cardea SOLO™ ADX PC Software (in the above, Version 4.1.0.7). If a Smart Cable is connected to the PC, the release level of the firmware embedded in the Smart Cable is displayed (Rev 19). Should an Electronics Module be inserted into the Smart Cable cradle, the release level of the firmware embedded in the Sensor is displayed (e.g., Rev 001.001.20). In the event of a Service or Support call, this release version information may be requested by Cardiac Insight.

Selecting the End User License Agreement link displays the agreement accepted during the installation process (see section 2.6).

Should you need help, or have any questions, click on the Contact Us hyperlink to view contact information for Cardiac Insight. The PC must be connected to the Internet.

The Cardiac Insight URL is: http://www.cardiacinsightinc.com/contact-us/

The Toll-free phone number is: 866-554-3751.

8.8 Cohort Reporting

Clicking the Excel Summary button, Figure 6.2 above, presents the Patient Selection window (See Section 9.1 above). The standard Windows commands are available for selecting patients: CTRL-Click adds the selected patient to the growing selection; Shift-Click selects all the patients from the last click to the current click. The filter buttons can be used to narrow the list to patients with specific characteristics. Following selection of the patient folders, click the "Accept" button. The System will next display the available Excel templates. Select the appropriate template. The System will extract the fields from all the selected patient records, fill-out the Excel template and prompt you with the Windows File Save tool. The available reporting data fields and descriptions are listed below.

Field Name	**Description**
LastName	Patient's Last Name
FirstName	Patient's First Name
PatientID	Patient ID / Medical Record Number
Gender	Gender
DOB	Date of Birth
Weight	Patient Weight
Height	Patient Height
DateFormat	Date Format
Units	Units of measure
SensorID	Sensor Serial #
RecordingStartDate	Recording Start Date
RecordingStartTime	Recording Start Time
RecordingEndDate	Recording End Date
RecordingEndTime	Recording End Time
Interpretation	Physician's diagnosis
SummaryFindings	Findings created by S400
EditedSummaryFindings	S400 Finding post physician review and edit
RecordStatus	Unconfirmed, Normal, Borderline or Abnormal
ConfirmationDate	Date record was confirmed
ConfirmingDr	Confirming / Over reading physician
ConfirmingDrID	Confirming physicians EMR ID

Field Name	Description
OrderNumber	EMR Order Number
SlumberSleep	Nominal time patient goes to sleep
SlumberWake	Nominal time patient wakes up
PrimaryIndication	Reason for test
PrescribingClinician	Prescribing Clinician
PrescribingClinicianID	Prescribing Clinician's EMR ID
ReferringPhysician	Referring Physician
Location	Location or Name of the clinic
ReportTitle	Report Title
WearTime	Duration of wear (days, hours, minutes)
WearTimeMin	Duration of wear in minutes
PercentAnalyzable	Percent of the record that could be analyzed
PatientTriggers	Number of patient event button presses
NSPercent	NSR Percentage of the recording
NSAvgHR	NSR Average Heart Rate
NSAvgMaxHR	Maximum HR during NSR
NSAvgMinHR	Minimum HR during NSR
NSAvgHRAwake	Average NSR HR during awake
NSMaxHRAwake	Maximum NSR HR during awake
NSMinHRAwake	Minimum NSR HR during awake
NSAwakeBradPercent	Percent of NSR record with HR < 50 during awake
NSAwakeTachPercent	Percent of NSR record with HR > 100 during awake
NSAwakePVCPercent	Percent of the total # PVC beats / # total beats, during awake NSR
NSAwakePACPercent	Percent of the total # PAC beats / # total beats, during awake NSR
NSAwakeBiTriPercent	Percent of # PVC beats in Bi/Trigeminy / # total beats, during awake NSR

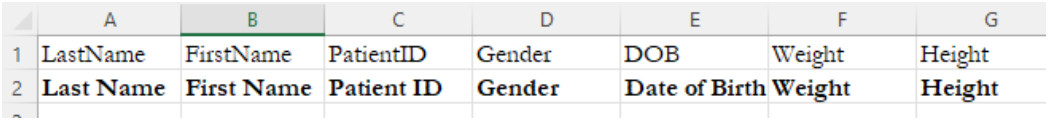
Field Name	Description
NSAwakePauseCount	Number of pause events during awake NSR
NSAwakePauseAveDur	Average pause duration during awake NSR
NSAwakePauseLongDur	Longest pause during awake NSR
NSAvgHRSleep	Average NSR HR during sleep
NSMaxHRSleep	Maximum NSR HR during sleep
NSMinHRSleep	Minimum NSR HR during sleep
NSSleepBradPercent	Percent of NSR record with HR < 50 during sleep
NSSleepTachPercent	Percent of NSR record with HR > 100 during sleep
NSSleepPVCPercent	Percent of the total # PVC beats / # total beats, during sleep NSR
NSSleepPACPercent	Percent of the total # PAC beats / # total beats, during sleep NSR
NSSleepBiTriPercent	Percent of # PVC beats in Bi/Trigeminy / # total beats, during sleep NSR
NSSleepPauseCount	Number of pause events during sleep NSR
NSSleepPauseAveDur	Average pause duration during sleep NSR
NSSleepPauseLongDur	Longest pause during sleep NSR
AFPercent	Percent of the record characterized as Atrial Fibrillation (AF)
AFAvgHR	Overall average heart rate during AF
AFAvgMaxHR	Maximum HR during AF
AFAvgMinHR	Minimum HR during AF
AFAvgHRAwake	Average HR during awake AF
AFMaxHRAwake	Maximum HR during awake AF
AFMinHRAwake	Minimum HR during awake AF
AFAwakeBradPercent	Percent of record with HR < 50 during awake AF

Field Name	Description
AFAwakeTachPercent	Percent of record with HR > 100 during awake AF
AFAwakePVCPercent	Percent of the total # PVC beats / # total beats, during awake AF
AFAwakePauseCount	Number of pause events during awake AF
AFAwakePauseAveDur	Average pause duration during awake AF
AFAwakePauseLongDur	Longest pause during awake AF
AFAvgHRSleep	Average HR during sleep AF
AFMaxHRSleep	Maximum HR during sleep AF
AFMinHRSleep	Minimum HR during sleep AF
AFSleepBradPercent	Percent of record with HR < 50 during sleep AF
AFSleepTachPercent	Percent of record with HR > 100 during sleep AF
AFSleepPVCPercent	Percent of the total # PVC beats / # total beats, during sleep AF
AFSleepPauseCount	Number of pause events during sleep AF
AFSleepPauseAveDur	Average pause duration during sleep AF
AFSleepPauseLongDur	Longest pause during sleep AF
PauseTotalCount	Total # pauses
LongestPause	Longest pause
NumberOfHeartBlocks	Number of 2nd degree Heart Block episodes (Mobitz II) detected
NumberOfCompleteHeartBlocks	Number of Complete Heart Blocks (3rd Degree) detected
NumberOfWenckebachHeartBlocks	Number of 2nd degree Heart Block episodes (Mobitz I) detected
HBLongestDurationSeconds	Longest episode duration of Mobitz II
CHBLongestDurationSeconds	Longest episode duration of Complete Heart Block 3rd Degree
WHBLongestDurationSeconds	Longest episode duration of Mobitz I

Field Name	Description
HBBurden	Mobitz II Burden
CHBBurden	Complete Heart Block Burden
WHBBurden	Mobitz I Burden
SVTAwakeCount	Number of SVT events during awake
SVTAwakeAveHR	Average SVT HR during awake
SVTAwakeAveDur	Average SVT duration during awake
SVTSleepCount	Number of SVT events during sleep
SVTSleepAveHR	Average SVT HR during sleep
SVTSleepAveDur	Average SVT duration during sleep
SVTNumEpisodes	Number of SVT episodes
VTNumEpisodes	Number of VT episodes
VTAwakeCount	Number of VT events during awake
VTAwakeAveHR	Average VT HR during awake
VTAwakeAveDur	Average VT duration during awake
VTSleepCount	Number of VT events during sleep
VTSleepAveHR	Average VT HR during sleep
VTSleepAveDur	Average VT duration during sleep
PACIsoCnt	Total number of isolated PACs in the record
PACCoupletsCnt	Total number of PAC couplets in the record
PACTripletsCnt	Total number of PAC triplets in the record
PACTotalBurden	Total PAC burden (# PACs / Total # beats)
PVCIsoCnt	Total number of isolated PVCs in the record
PVCCoupletsCnt	Total number of PVC couplets in the record
PVCTripletsCnt	Total number of PVC triplets in the record
PVCNSTotalBurden	Total PVC burden (# PVCs / Total # beats) during NSR

Field Name	Description
PVCAFTotalBurden	Total PVC burden (# PVCs / Total # beats) during AF
SVTPACBurden	Percent of SVT beats / Total # beats
VTPVCBurden	Percent of VT beats / Total # beats
PVCMaxDayCnt	Maximum number of PVCs in any 24 hour period.
PVCMaxHrCnt	Maximum number of PVCs in any 1 hour period.
VBiGemPercent	Total bigeminy PVC burden (%)
VBiGemLongest	Longest bigeminy duration
VTriGemPercent	Total trigeminy PVC burden (%)
VTriGemLongest	Longest trigeminy duration
VBiTriGemTotalPercent	Total percent of ventricular Bi & Trigeminy.
AwakeBeats	Total # of beats detected during awake
SleepBeats	Total # of beats detected during sleep
AtrialGemBurden	Atrial Geminy Burden (%)
STDeviation	Maximum ST Deviation
STDuration	Maximum ST Duration
STNumEpisodes	Number of ST episodes
NumberOfRToRIntervals	Number of valid RR intervals
RatioSVE1EventsToRRIntervals	Percent of record with isolated PACs
RatioSVE2EventsToRRIntervals	Percent of record with PAC couplets
RatioSVE3EventsToRRIntervals	Percent of record with PAC triplets
RatioVE1EventsToRRIntervals	Percent of record with isolated PVCs
RatioVE2EventsToRRIntervals	Percent of record with PVC couplets
RatioVE3EventsToRRIntervals	Percent of record with PVC triplets

Custom Excel templates can be readily constructed using the Master Template, located in the program installed folder (e.g., C:\Program Files\Cardiac Insight\CARDEA SOLO™ ADX S400\Excel Templates\Master Template.xlsx). The Master Template contains all of the above data field definitions and descriptions. The first 7 fields are shown below.



	A	B	C	D	E	F	G
1	LastName	FirstName	PatientID	Gender	DOB	Weight	Height
2	**Last Name**	**First Name**	**Patient ID**	**Gender**	**Date of Birth**	**Weight**	**Height**

Figure 9.3. Example of the Master Template first few columns.

For each column, row 1 is the field name CARDEA SOLO™ ADX PC Software uses to look-up the associated data. Row 2 is the description. You may delete any of these fields not needed for your custom report and re-arrange the columns as necessary. The first row can be hidden. Save the new template with an appropriate name in the Excel Template folder using a new name. Be careful not to overwrite the Master Template.

9 System Characteristics

The following information is provided to assist the clinician to understand the characteristics of the Cardea SOLO™ ADX system that transform electrode potentials into ECG tracings and beat and rhythm findings.

9.1 System Bandwidth and Baseline Wander Filtering

The Sensor electronics digitizes the ECG voltages at 250 samples/sec at a resolution of 3.1 μVolt. The A/D averages the signal over the duration of a sample interval, thus providing anti-aliasing filtering inherent in the hardware chip design. The A/D hardware imposes no low-frequency filtering – the raw data is flat to DC. At the completion of an ECG recording, Cardea SOLO™ ADX PC Software applies a 0.05 Hz High Pass single-pole Butterworth filter to remove long period baseline wander.

The nominal system bandwidth is 0.05 to 65 Hz.

9.2 AC Line Filtering

Cardea SOLO™ ADX PC Software uses an adaptive filter to estimate and remove any AC line signal that may be present, i.e., the amplitude and phase of a pure sine wave that best represents the observed signal. This approach provides a large dynamic range and avoids distortions and limitations associated with narrow notch filters. The filter adapts slowly, preventing any significant ringing associated with abrupt QRS signals. The AC line frequency is set in the administrative functions.

9.3 Beat and Rhythm Sensitivity and Positive Predictive Value

The performance characteristics of the ECG algorithms within Cardea SOLO™ ADX PC Software have been assessed following the guidelines provided by ANSI/AAMI EC57: 2012. All tests recommended by the guidelines have been conducted using the ECG databases available through PhysioNet (see https://www.physionet.org/). These performance statistics are provided to assist the physician in the analysis and review of the ECG trace data. However, performance will vary depending upon many factors, including trace quality and record complexity. Rhythm strips and ECG tracings (see TraceViewer) should be carefully reviewed as part of the clinical assessment.

Dual Channel:

	Sensitivity	PPV
Overall QRS Detection	99	100
Ventricular (V) Beats:		
Overall V Beats	93	99
V. Couplets	82	97
V. Short Runs	89	96
V. Long Runs	56	100
Supraventricular (SVE) Beats:		
Overall SVE Beats	48	82
SVE Couplets	83	84
SVE Short Runs	92	87
SVE Long Runs	93	83
Atrial Fibrillation / Flutter:		
Duration (Burden)	96	97
CAUTION: Afib Sensitivity declines for episodes less than 20 seconds in duration.		

PPV: Positive Predictive Value.

Single Channel

	Sensitivity	PPV
Overall QRS Detection	98	99
Ventricular (V) Beats:		
Overall V Beats	78	94
V. Couplets	81	93
V. Short Runs	89	94
V. Long Runs	59	95
Supraventricular (SVE) Beats:		
Overall SVE Beats	46	75
SVE Couplets	84	76
SVE Short Runs	93	82
SVE Long Runs	96	77
Atrial Fibrillation / Flutter:		
Duration (Burden)	94	98
CAUTION: Afib Sensitivity declines for episodes less than 20 seconds in duration.		

9.4 Slowest Heart Rate

A rhythm strip for the slowest heart rate is always added to the report. If the heart rate is below the Bradycardia rate (default = 50 bps), for at least 20 seconds, then the strip will be included in the Bradycardia section of the report. Otherwise, the first strip in the Example Rhythm Strips will highlight the lowest observed heart rate.

10 Maintenance

10.1 Cleaning the Smart Cable

To clean the Smart Cable, ensure it is unplugged from the PC. Dampen a cloth with Isopropyl alcohol or use an alcohol wipe and thoroughly wipe down the unit, being sure to remove any accumulated dust from the Smart Cable cradle. Let it dry. Plug the cable back into the PC.

	WARNING. Fluid Hazard. Do not get the Smart Cable wet. If the cradle gets wet, unplug the cable and allow it to dry. Contact Cardiac Insight for a replacement if the cable is non-functional when plugged back into the PC.
Precaution	Use only the following cleaning agents on the Smart Cable: • Isopropyl alcohol (70% solution in water) • Mild soap and water The effect of other cleaning agents is unknown.

11 EMC Declaration Tables – Sensor, Smart Cable

The Cardea SOLO™ ADX system is intended for use in the electromagnetic environment specified below:

The essential performance of the Cardea SOLO™ ADX is to acquire electrophysiological data, record data in local storage, and transfer to a pc for assessment. When exposed to large EM disturbances, the essential performance of the Cardea SOLO™ ADX may be lost or degraded in such a way that the Sensor may not acquire the electrophysiological data, store it, or transfer to the PC accurately, leading to inaccurate diagnosis or delayed patient care.

11.1 Electromagnetic Emissions

Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B

11.2 Bluetooth Transmission

Bluetooth	
Frequency Band of Transmission	2.4GHz to 2.483GHz
Effective Radiated Power	<5dBm
Modulation	BLE frequency modulation.
FCC ID	2BEOW-M400

11.3 Electromagnetic Immunity for Sensor

<table>
<tr><th>Immunity Test</th><th>Basic EMC Standard or test method</th><th>Immunity Test Levels for Home Healthcare Environment from IEC 60601-1-2:2020</th></tr>
<tr><td>Electrostatic discharge (ESD)</td><td>IEC 61000-4-2</td><td>±8 kV contact
±15 kV air</td></tr>
<tr><td>Radiated RF EM fields</td><td>IEC 61000-4-3</td><td>10 V/m
80 MHz – 2.7 GHz
80 % AM at 1 kHz</td></tr>
<tr><td>Proximity fields from RF wireless communications equipment</td><td>IEC 61000-4-3</td><td>
<table>
<tr><th>Test frequency (MHz)</th><th>Band [a] (MHz)</th><th>Service [a]</th><th>Modulation</th><th>IMMUNITY TEST LEVEL (V/m)</th></tr>
<tr><td>385</td><td>380 to 390</td><td>TETRA 400</td><td>Pulse modulation [b] 18 Hz</td><td>27</td></tr>
<tr><td>450</td><td>430 to 470</td><td>GMRS 460, FRS 460</td><td>FM [c] ± 5 kHz deviation 1 kHz sine</td><td>28</td></tr>
<tr><td>710</td><td rowspan="3">704 to 787</td><td rowspan="3">LTE Band 13, 17</td><td rowspan="3">Pulse modulation [b] 217 Hz</td><td rowspan="3">9</td></tr>
<tr><td>745</td></tr>
<tr><td>780</td></tr>
<tr><td>810</td><td rowspan="3">800 to 960</td><td rowspan="3">GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5</td><td rowspan="3">Pulse modulation [b] 18 Hz</td><td rowspan="3">28</td></tr>
<tr><td>870</td></tr>
<tr><td>930</td></tr>
<tr><td>1 720</td><td rowspan="3">1 700 to 1 990</td><td rowspan="3">GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS</td><td rowspan="3">Pulse modulation [b] 217 Hz</td><td rowspan="3">28</td></tr>
<tr><td>1 845</td></tr>
<tr><td>1 970</td></tr>
<tr><td>2 450</td><td>2 400 to 2 570</td><td>Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7</td><td>Pulse modulation [b] 217 Hz</td><td>28</td></tr>
<tr><td>5 240</td><td rowspan="3">5 100 to 5 800</td><td rowspan="3">WLAN 802.11 a/n</td><td rowspan="3">Pulse modulation [b] 217 Hz</td><td rowspan="3">9</td></tr>
<tr><td>5 500</td></tr>
<tr><td>5 785</td></tr>
</table>
[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.
</td></tr>
<tr><td>Rated power frequency magnetic fields</td><td>IEC 61000-4-8</td><td>30 A/m 50Hz and 60Hz</td></tr>
<tr><td>Proximity to magnetic fields</td><td>IEC 61000-4-39</td><td>
<table>
<tr><th>Test frequency</th><th>Modulation</th><th>IMMUNITY TEST LEVEL (A/m)</th></tr>
<tr><td>30 kHz [a]</td><td>CW</td><td>8</td></tr>
<tr><td>134,2 kHz</td><td>Pulse modulation [b] 2,1 kHz</td><td>65 [c]</td></tr>
<tr><td>13,56 MHz</td><td>Pulse modulation [b] 50 kHz</td><td>7,5 [c]</td></tr>
</table>
[a] This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] r.m.s., before modulation is applied.
</td></tr>
</table>

11.4 Electromagnetic Immunity for Smart Cable

<table>
<tr><th>Immunity Test</th><th>Basic EMC Standard or test method</th><th>Immunity Test Levels for Professional Healthcare Facility Environment from IEC 60601-1-2:2020</th></tr>
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c) r.m.s., before modulation is applied.</td></tr>
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[c] As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.
</td></tr>
</table>

11.5 Recommended Separation Distances

The following table provides the recommended separation distances between portable and mobile RF communications equipment and the Cardea SOLO™ ADX system.

The Cardea SOLO™ ADX system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cardea SOLO™ ADX system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cardea SOLO™ ADX system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power (*P*) of Transmitter W	**Separation distance according to frequency of Transmitter**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.7GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Cardea SOLO™ ADX is used exceeds the applicable RF compliance level above, then Cardea SOLO™ ADX should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Cardea SOLO™ ADX.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

c. Amplitude modulated at 80% with a modulation frequency of 1 kHz per IEC 60601-1-2.

11.6 FCC Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

CAUTION. Inspect the C400 ADX Smart Cable including the USB cable and connector for signs of damage (frayed cable, damaged connector). Damage to the Smart Cable could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

Per FCC 15.19(a)(3) and (a)(4) This device 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.

 Per FCC 15.21, Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

12 Environmental Specifications

12.1 Transport Environment - Sensor

Temperature: -25º C to 50º C (-13º F to 122º F)

Humidity: 10% to 90% (non-condensing)

Pressure: 500 hPa to 1060 hPa

12.2 Storage Environment (Recommended) - Sensor

Temperature: 5º C to 50º C (41º F to 122º F)

Humidity: 10% to 90% (non-condensing)

Pressure: 500 hPa to 1060 hPa

12.3 Operating Environment - Sensor

Temperature: 5º C to 40º C (41º F to 104º F)

Temperature (during wear): body temperature, typically 37º C (98.6º F) (Type BF Applied Part)

Humidity: 10% to 90%

Pressure: 500 hPa to 1060 hPa

Ingress of Solids and Liquids: IEC 60529:2013, IP24 (protected against intrusion from fingers and small objects, and from the effects of temporary immersion in water)

12.4 Transport Environment - Smart Cable

Temperature: -25º C to 50º C (-13º F to 122º F)

Humidity: 10% to 90% (non-condensing)

Pressure: 500 hPa to 1060 hPa

12.5 Storage Environment (Recommended) - Smart Cable

Temperature: 5º C to 50º C (41º F to 122º F)

Humidity: 10% to 90% (non-condensing)

Pressure: 500 hPa to 1060 hPa

12.6 Operating Environment - Smart Cable

Temperature: 10º C to 40º C (50º F to 104º F)

Humidity: 10% to 90% (non-condensing)

Pressure: 500 hPa to 1060 hPa