CARDIAC INSIGHT, INC.

Cardea SOLO™ Operator's Manual

Model S300

Includes instructions for **Cardea SOLO:**

- *Software, D300*
- *Smart Cable, C300*
- *Sensor, M300*

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

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Part Number: PN00328-04

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1 Introduction

1.1 Indications for Use

Cardea SOLO™ is indicated for use on adult patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, dizziness, anxiety, fatigue, syncope, pre-syncope, light-headedness, shortness of breath or who are at risk of developing atrial fibrillation and where a software-assisted analysis of an ambulatory ECG could identify potential cardiac causes of these symptoms. It includes a prescription only, single use, continuous ECG recorder that can be worn up to 7 days during activities of daily living.

1.2 Intended Use

Cardea SOLO is intended for continuous single lead ECG recording and presentation of ECG trace data and associated analysis information to assist clinicians in diagnosing cardiac arrhythmias. The Sensor is not intended for use should defibrillation be required; the Sensor 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 do not have the competency to wear the Sensor for the prescribed monitoring period.

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.

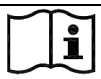
1.4 Clinician's Responsibility

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 for a clinician's overall assessment of a patient's cardiac health.

It is the clinician's responsibility to ensure proper ECG data collection, review and interpretation 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 or referral for specialty care is dependent upon good clinical judgment.

1.5 Definitions of Symbols Used

 Warning	Indicates a potentially hazardous situation, which, if not avoided, could result in death or serious injury.
 Caution	Indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices. ISO 15223-1:2012 Symbol 5.4.4
	Do not re-use. Indicates a medical device that is intended for one use. ISO 15223-1:2012 Symbol 5.4.2
	Consult instructions for use. ISO 15223-1:2012 Symbol 5.4.3
	Follow instructions for use. IEC 60601-1 Table D.2, Symbol 10
	Temperature limits. Indicates the temperature limits to which the medical device can be safely exposed. ISO 15223-1:2012 Symbol 5.3.7
	Humidity limitation. Indicates the range of humidity to which the medical device can be safely exposed. ISO 15223-1:2012 Symbol 5.3.8
	Atmospheric pressure limitation. Indicates the range of atmospheric pressure to which the medical device can be safely exposed. ISO 15223-1:2012 Symbol 5.3.9
	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. ISO 15223-1:2012 Symbol 5.1.4
	Batch or lot code. This symbol is accompanied by identifier of manufacturing lot. ISO 15223-1:2012 Symbol 5.1.5
	Catalog number. ISO 15223-1:2012 Symbol 5.1.6
	Type BF Applied Part.
	Protected against the effects of temporary immersion in water.
	This product contains no natural rubber latex.
	Serial Number. ISO 15223-1:2012 Symbol 5.1.7
	Global Trade Identification Number.
	Manufacturer. ISO 15223-1:2012 Symbol 5.1.1

	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. ISO 15223-1:2012 Symbol 5.2.8
	MR Unsafe. ASTM F2503-13
	Do not incinerate.
5V⎓200mA	Direct current (Smart Cable USB connection). IEC 60601-1 Table D.1, Symbol 4

2 Getting Started – Cardea SOLO System Components

⚠ Caution	Read all instructions for use, including safety procedures, before using the Cardea SOLO system and follow all instructions while using the Cardea SOLO system.

2.1 Cardea SOLO Software Blister Pack

The package contains:

A USB Flash drive with Cardea SOLO Software

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

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

2.2 Cardea SOLO Smart Cable Shipping Carton

The package contains:

Smart Cable

- Following wear, the Electronics Module is removed from the Sensor and connected to a Windows® PC using the Smart Cable.

2.3 Cardea SOLO Sensor Shipping Carton

The package contains:

Sensors

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

2.4 User-Supplied Personal Computer (PC) Requirements

⚠ **Warning**	Misdiagnosis. Software viruses, worms and other forms of malware may compromise the integrity of the PC. The PC should be protected from malware through the use of 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**	Misdiagnosis. The PC used for Cardea SOLO 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® 7 (SP1) and higher.

Microsoft .NET Framework 4.5 and Visual C++ 2013 Runtime library. See:
https://www.microsoft.com/en-us/download/details.aspx?id=30653 and
http://www.microsoft.com/download/en/details.aspx?id=5555

Warning

PC Operating System. Cardea SOLO has been tested for proper function with the versions of Microsoft Windows specified above. Other versions of the PC operating system should not be used.

NOTE: Windows® supports user customization of the 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 windows from being fully or correctly displayed.

2.4.2 PC Hardware Requirements

Windows® compatible personal computer

Disk: 2 GB of free disk space or greater

NOTE: Cardea SOLO checks the available disk space for saving patient ECGs and associated information at start-up. If the available disk space is less than 1 gigabyte (GB) a message will be displayed. On average, a Sensor's ECG recording and associated PDF report will require about 450 megabytes (MB).

CPU: Dual Core CPU @ 2.5 GHz or greater, 32-bit (x86) or 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 / EN 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 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

⚠ Caution	Interruption of Physician Report creation. Unreliable AC power (surges, brown-outs, spikes, and so on) may interrupt the PC function. Surge protectors and Uninterruptible Power Supplies (UPS) should be used for PCs that are not powered by a charged internal battery. 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 5).

Cardea SOLO hardware setup is depicted in Figure 2.1 below.

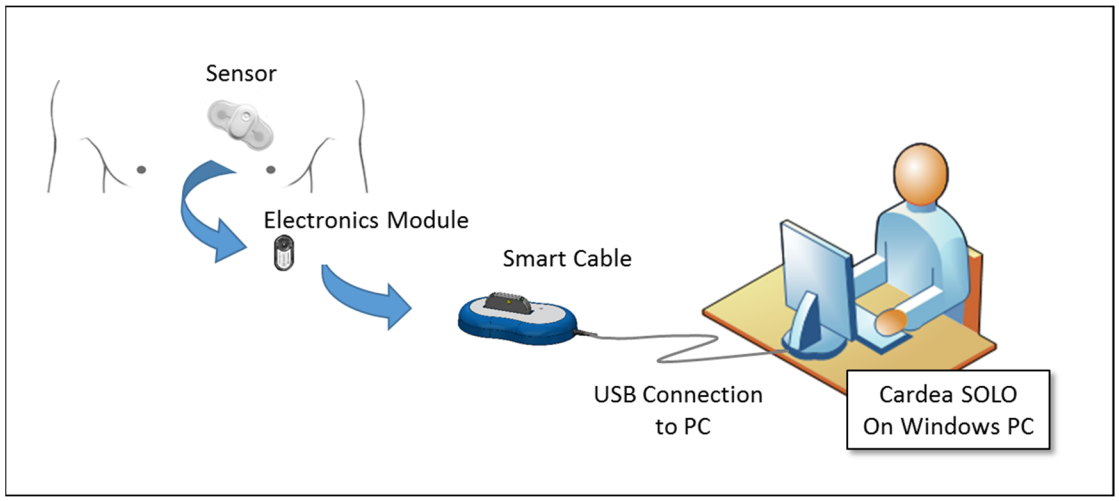


Figure 2.1. Cardea SOLO components and data flow, from the Patient Sensor to the PC analysis software.

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 / EN 60950-1 or IEC 62368-1, or a UL or equivalent safety agency rating) for the periphery equipment is recommended.

2.6 Cardea SOLO Software Installation

To install the Cardea SOLO 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 "Cardea SOLO Setup" executable. The first screen displayed, Figure 2.2, presents the End User License Agreement.

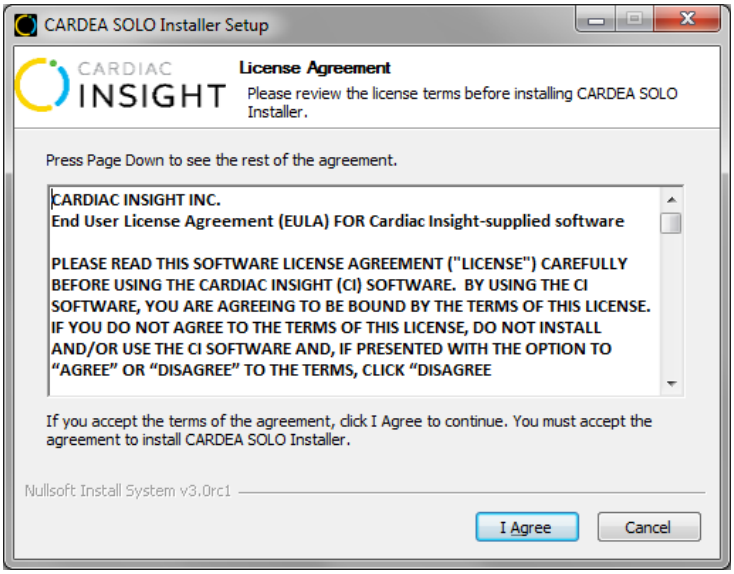


Figure 2.2. License Agreement.

Click "I Agree" if you agree to the terms of the Agreement.

Next, the Installer will prompt for an install directory, with the standard default location of c:\Program Files (x86), Figure 2.3 below.

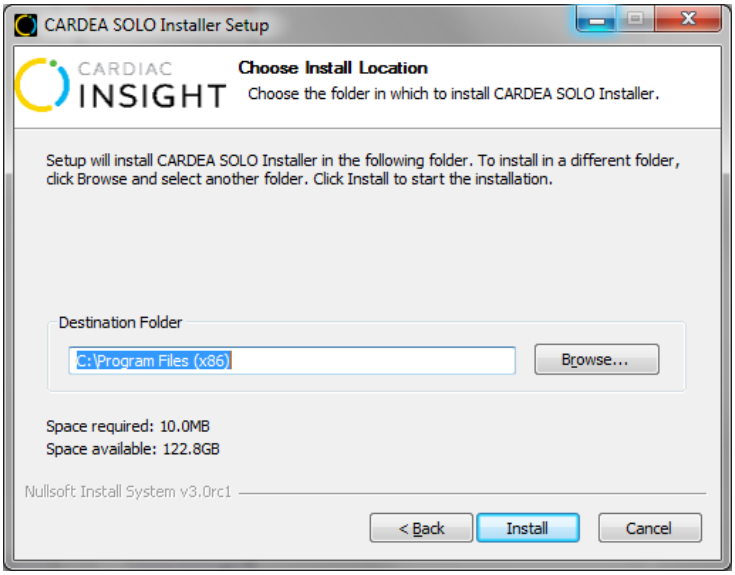


Figure 2.3. Install Location.

Click "Install" to install Cardea SOLO.

When the installation is complete the Installer will present a screen verifying correct installation, or listing any problems encountered during the installation. See Figure 2.4 below.

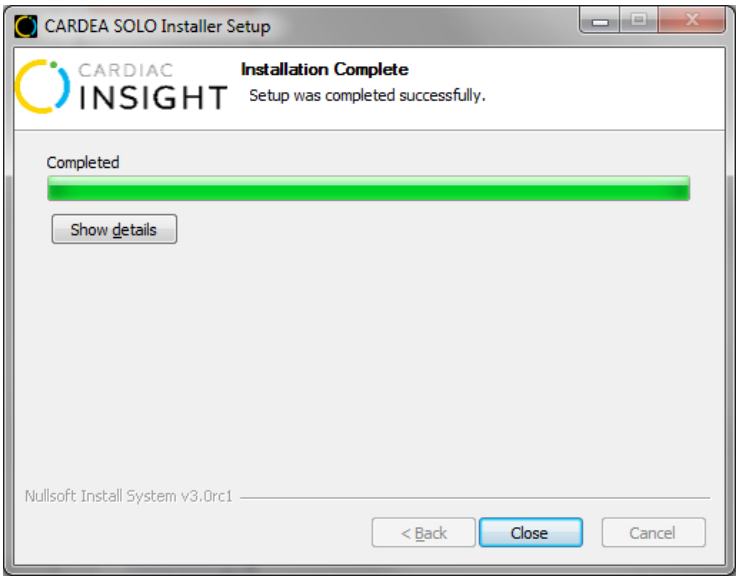


Figure 2.4. Installation Complete.

Click "Close" to complete the installation.

Cardiac Insight recommends retaining the installation media. If discarded, dispose according to applicable local regulations.

3 Sensor Operation

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

3.1 Precautions

1. The Sensor should be removed prior to external defibrillation or an MRI scan.

2. Patients with sensitive skin conditions should use the Sensor with caution. The Sensor may cause mild discomfort, skin irritation, redness, itching, rash or contact dermatitis in some individuals. The device should be removed if any pain or discomfort occurs. This may be facilitated through the use of an adhesive removal agent such as the wipe included with the Patient Diary. If skin irritation or redness persists after the device has been removed the patient should consult their health care provider.

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

4. The Sensor electrodes should not contact other conductive equipment or electric ground prior to wear.

5. The Sensor is intended for single patient use.

6. The Sensor should not be applied to an open wound or to broken, damaged or irritated skin.

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

8. 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.

9. No modification of the Sensor beyond access to the Electronics Module is allowed. Modification may lead to inaccuracies in reported data or complete loss of data.

10. Replace the Sensor if it peels off completely; do not reapply (it is meant for one-time use).

11. Do not use the Sensor if it or its immediate packaging appears damaged or if it is not activated within 15 minutes of application.

12. No creams or lotions should be applied in the application area immediately prior to use of the Sensor.

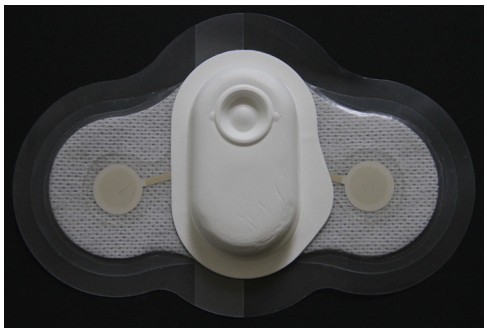
13. Store the Sensor at controlled room temperature.

14. The Sensor is not intended for use on infants or pediatric patients. Safety and effectiveness of the Sensor on pediatric patients has not been established.

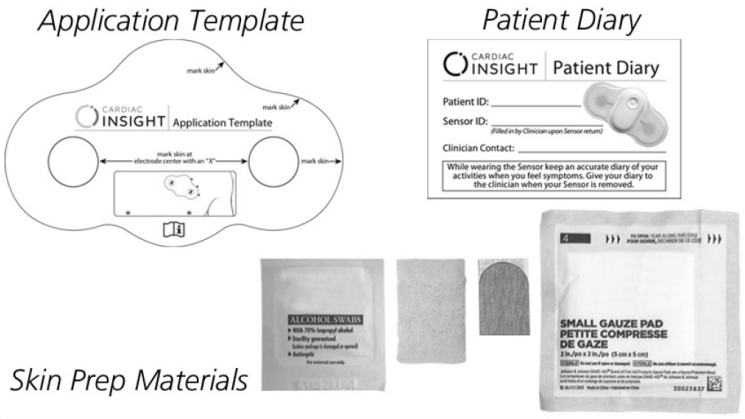
The Sensor does not replace direct communication between the patient and their health care provider. The Sensor data should be used along with all other clinical data and exams for a diagnosis. The Sensor will not summon emergency response in the event the patient needs help. The patient should talk to their health care provider immediately if there are any concerns or changes in condition.

3.2 Pouch Contents

(1) Cardea SOLO Wearable Sensor



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



3.3 Sensor – Getting Started

The Sensor is a small, lightweight, patch-style, single-use cardiac recorder, designed for ambulatory collection of electrocardiographic (ECG) data continuously for up to 7 days. Figure 3.1 illustrates the key elements of the Sensor.

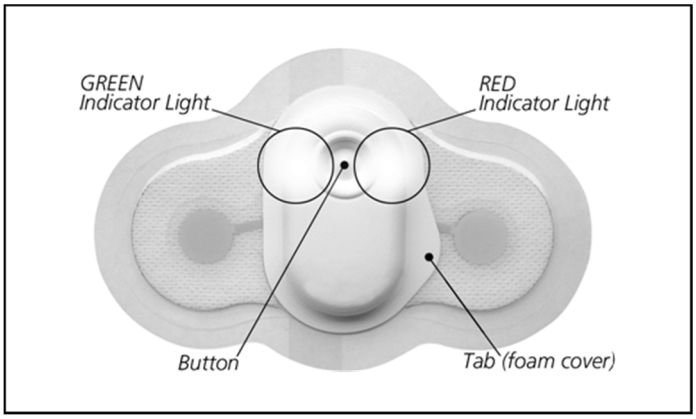


Figure 3.1. Key elements of the wearable Sensor

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). The Green light blinks rapidly during start-up and will blink synchronously with the patient's heartbeat following start-up and subsequent button pushes during monitoring. If any electronics malfunction is detected during self-test startup the Red light will turn on.

If the Sensor is not applied to a patient, or the patient preparation has been inadequate to enable an electrical connection with the patient's skin, the Red and Green lights will alternately blink and the Sensor will return to a shut-down shipping mode.

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

⚠ Caution	Do not remove the foam cover until the patient has completed the monitoring period. Premature removal and damage to the environmental protection may result in loss of data.
⚠ Caution	Improperly prepared skin (dirty or otherwise compromised) may cause poor adhesion resulting in shortened wear duration. Before applying the Sensor ensure the skin is properly prepared.

⚠ Caution	The effect of loose electrodes (poor adhesion) is a poor quality ECG recording and subsequent reduced diagnostic information available in the Physician Report. Should the 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.
⚠ Caution	Infection. Sensor placement on broken or otherwise compromised skin may lead to infection. Before applying the Sensor ensure the skin is clean, unbroken and properly prepared.
⚠ Caution	If the Sensor is removed from its pouch, the useful life of the ECG electrode hydrogel becomes limited (use within 15 min). Take care to remove the Sensor from its pouch during the same session as patient attachment. The effect of degraded electrodes is a poor quality ECG recording and subsequent reduced diagnostic information available in the Physician Report.
⚠ Caution	If the Sensor is activated and it does not detect an ECG signal (e.g., activated when not attached to a patient), it will return to its as-shipped state to conserve battery.
⚠ Caution	To avoid contacting the Sensor electrodes with unintended conductive surfaces, leave the release liner in place until placement on the patient's skin.
Precaution	Patient Skin Irritation. Some patients may experience skin irritation. Monitor the Sensor site and, if irritation occurs, consider removal. Patients with fragile skin can experience skin damage when the Sensor is removed too quickly. Do not "rip off" the Sensor; remove it slowly.

3.4 Sensor Placement

Sensor placement options are shown in the below Figure 3.2.

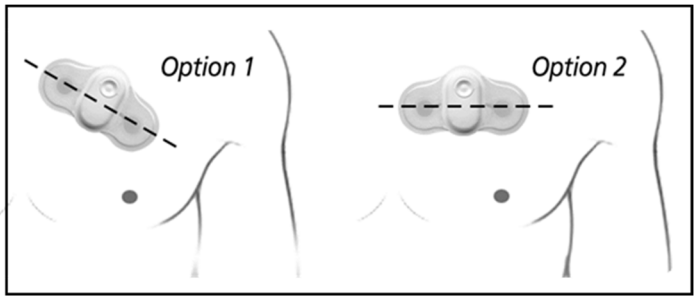


Figure 3.2. Placement options.

Option 1 approximates the lead orientation of Lead II of a standard 12 lead ECG, whereas Option 2 is aligned with Lead I. Orientation may be selected

based upon patient comfort and garment constraints (e.g. an orientation that causes chafing under clothing should be avoided).

For Option 1, the right electrode should be placed at about the 2nd intercostal space and the left electrode at the 3rd or 4th intercostal space.

For Option 2 the Sensor is placed horizontally, approximately in the 3rd or 4th intercostal space.

NOTE: In large BMI individuals, to avoid folding and distortion of the Sensor as the skin folds, it may be necessary to position the Sensor in the 1st or 2nd intercostal space.

NOTE: In individuals with dense breast tissue and or implants, it may be necessary to slightly modify Sensor placement by moving it toward the collar bone, slightly more medial and in a horizontal position (Option 2).

In both options, the right electrode should be placed proximal to the sternum.

To apply the Sensor, first remove it from the shipping Pouch – 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. For men, marking the target position of the Sensor could result in shaving only the area that needs preparation. Marking the position of the electrodes reduces the skin area requiring electrical preparation. The following steps outline the application process:

1. Determine the placement location using the Application Template. Prepare an area 1 inch larger than the Sensor (see below Figure 3.3). This allows for slight movement of the Sensor over the monitoring period. 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. Open the Skin Prep Materials from the pouch and prepare the skin with alcohol to remove skin oil or lotions. Allow the area to dry for at least 30 seconds.

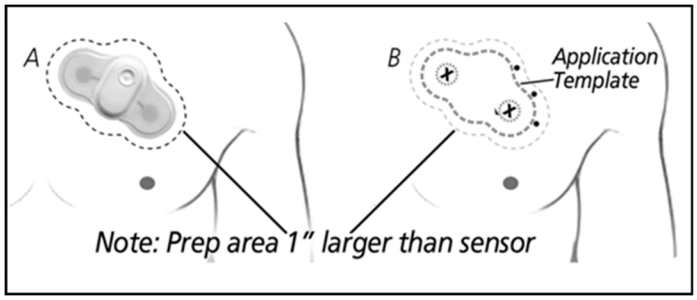


Figure 3.3. Using the Application Template to position the Sensor.

2. Place the Application Template against the skin in the desired placement area as illustrated in Figure 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.

3. The outer most 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. Utilize one of the skin abrasion items to remove dead skin in the areas marked as the location of the electrodes.

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

5. Remove one side of the release liner and place the Sensor (button towards the patient's head) on the area marked by the template, taking care not to wrinkle the outer adhesive border.

6. With one side attached, remove the other side of the release liner and apply the second half of the Sensor to the skin. Press the Sensor firmly onto the skin and smooth out the clear adhesive border against the skin.

7. Press the Sensor's button. The indicator will blink green, pause and then flash green in cadence with the heartbeat for 10 seconds. The ECG acquisition sequence has started.

8. It is extremely important to note the date and time of activation of the Sensor since the timing of events is computed from this information. Cardea SOLO Software also analyzes sleeping versus wake intervals 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.

NOTE: If you do not see the light sequence described above, see the Troubleshooting section (Section 3.9).

3.5 Wearing Instructions

1. The Sensor is intended to be worn at all times 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 3.4). This action is referred to as a patient trigger.

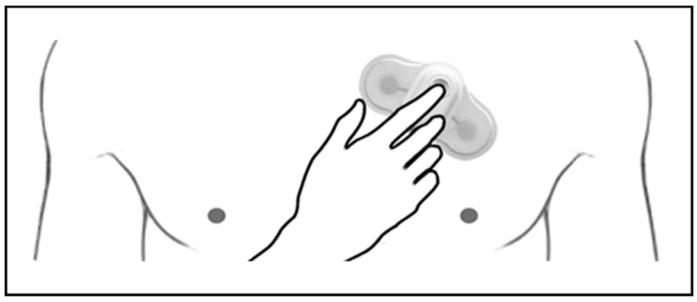


Figure 3.4. Activating the patient trigger.

a. This records a notation in the data indicating the patient felt a symptom.

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

c. Try to remain motionless for about 30-60 seconds following the button press.

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

3.6 Recommendations for Patient Use

1. The patient is expected to wear the Sensor continuously for up to 7 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 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 the zippered pouch and Patient Diary. Instruct the patient should it become necessary to remove the Sensor they should place the removed Sensor adhesive side down onto any appropriately sized piece of paper, insert the Sensor into the pouch, and contact their health care provider.

3.7 Completion of Monitoring and Removal

⚠ Caution	When handling a Sensor that has been worn by a patient use appropriate handling procedures (e.g. gloved hands).

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

a. 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. Petroleum jelly or baby oil applied between the skin and the Sensor

adhesive may be used to ease removal. An adhesive remover wipe may also be used.

b. Place the Sensor, adhesive side down, onto any appropriately sized piece of paper.

c. Pull upwards on the tab of the foam cover to remove it (see Figure 3.1).

d. 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. 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 with the adhesive. Repeat as necessary.

3. There may be some residual redness and a slight odor in 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.

3.8 ECG Retrieval

⚠ Caution	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 3.5 below). Use this information to associate or to confirm 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.

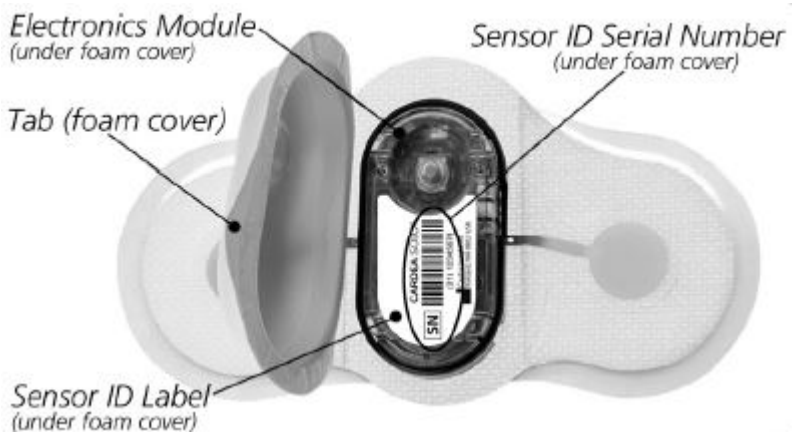


Figure 3.5. The exposed Electronics Module following removal of the foam cover.

2. Use the Smart Cable and Cardea SOLO 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.

NOTE: All portions of the Sensor are single use, disposable. Device contains a Lithium battery. Do not incinerate. Recycle or dispose of this device according to your local regulations.

3.9 Troubleshooting

Problem: 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 that ECG recording did start, but that the confirmatory flashing green light was not observed. If recording is in progress, the light will flash green in cadence with heartbeat for a short duration and then extinguish.

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

5. If after trying to activate the Sensor twice, the expected light sequence does not occur, 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 light is visible after a button press in a dark room.

2. If no light is observed after a button press, remove the Sensor and 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 Software – Administrative Setup

Cardea SOLO 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 Software following installation (See Section 2.4) the Administrative Log-in screen will be presented. See Figure 4.1.

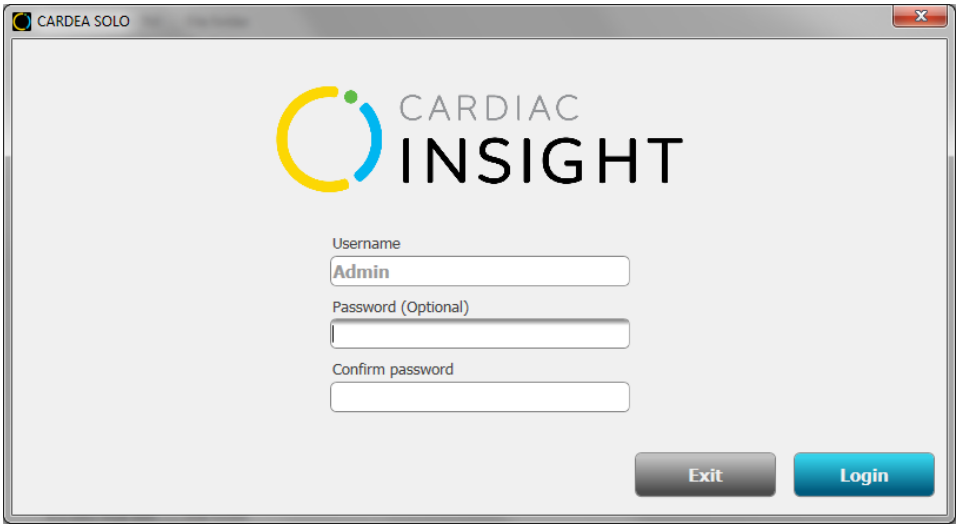


Figure 4.1. Administrative Log-in screen.

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 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.

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

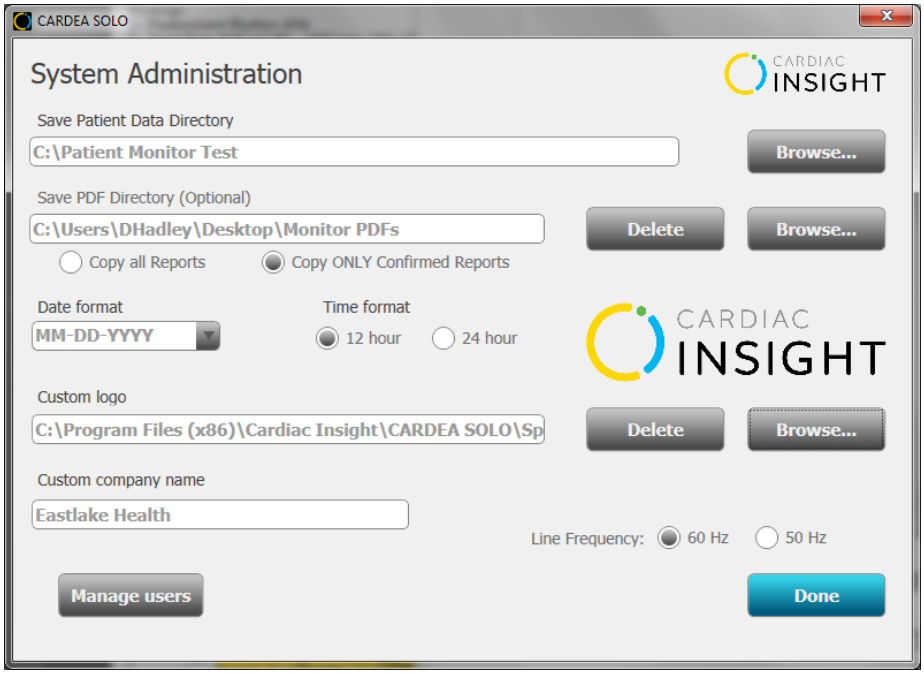


Figure 4.2. System Administration.

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, low network bandwidth will degrade ECG processing performance.

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, MediaManager 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 and 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.

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

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 User name 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, 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 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 system at the time of sensor placement, and checking the "Enable Patient Pre-Registration" enables this functionality for this User.

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.

4.3 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:

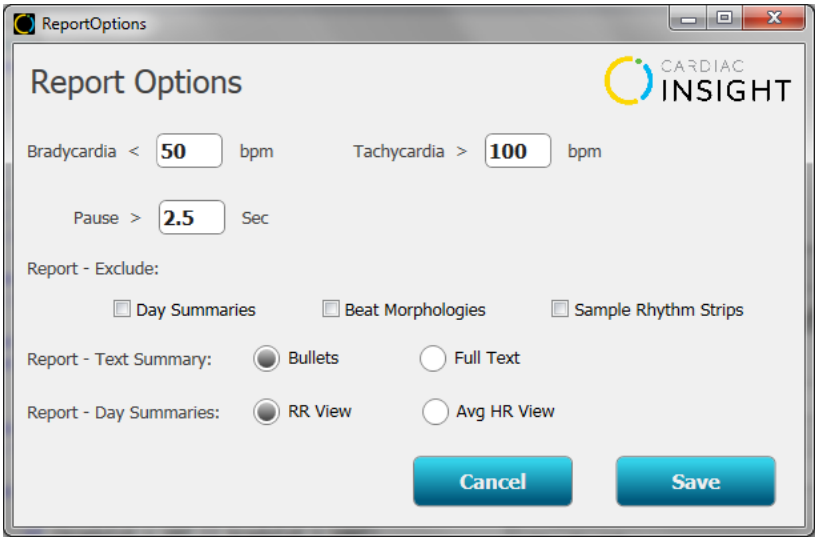


Figure 4.4. Report Options.

The first three options are User selectable parameters to define Bradycardia, Tachycardia and Pause Duration 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.

"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 by selecting, or as an RR plot, where each RR interval is plotted as heart rate (i.e. 60/RR in seconds) by selecting "RR View". "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".

5 Patient Registration (Optional)

Cardea SOLO Software supports the tracking 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 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 that 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.

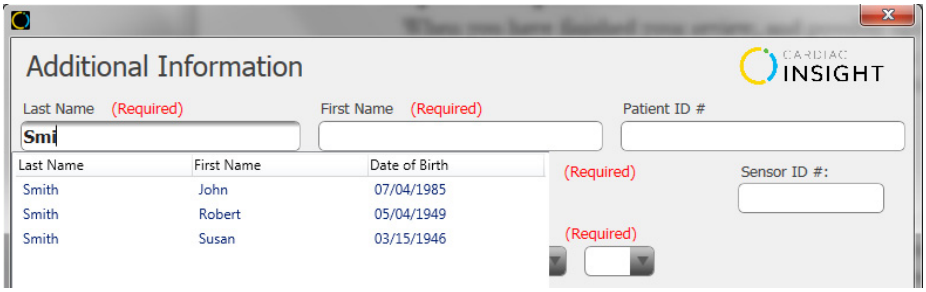


Figure 5.1. Selecting a Registered patient during downloading.

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 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 Software – Clinical Review, will lead you through the tools to review the ECG trace data, add rhythm strips to the report, update or correct demographic or diary data entry errors, edit the proposed diagnostic summary and finalize the report.

6.1 User Login

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

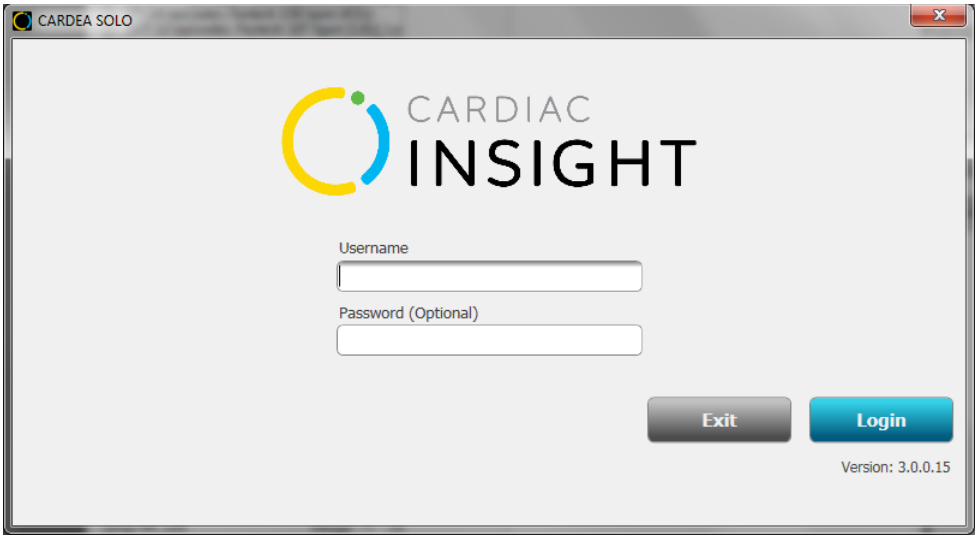


Figure 6.1. User Login screen.

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 "Download ECG" button.

6.2 Data Transfer, Demographics and the Draft Report

6.2.1 Connecting the Electronics Module

The Smart Cable is used to transfer the ECG data from the Electronics Module to the PC and Cardea SOLO Software for analysis. Plug the Smart Cable USB connector into a USB Rev 2.0 high speed 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.

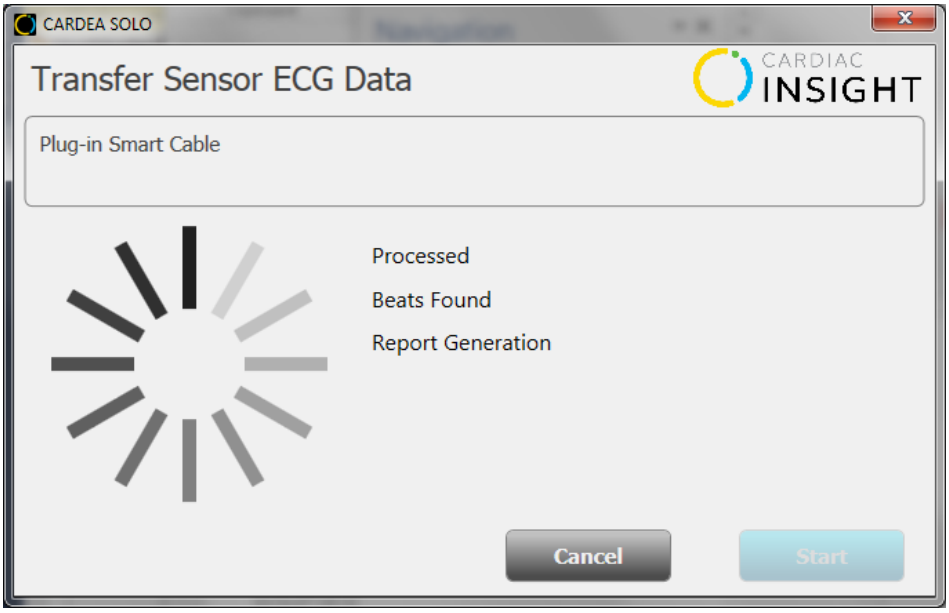
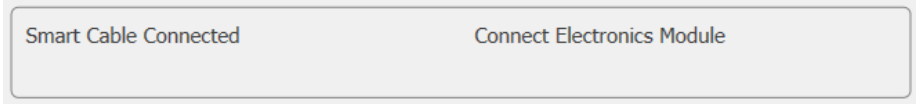
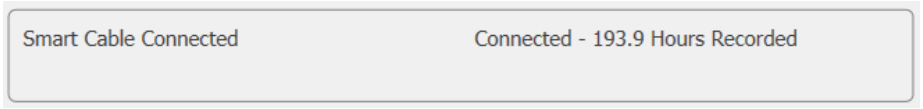


Figure 6.4. Transfer Sensor ECG Data screen.

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 connected to the Electronics Module, the System will read the duration of the recorded record and provide an update similar to the following:



If the data is processed shortly after removal of the Sensor from the patient, the "Hours Recorded" will reflect the recording duration. If the Sensor was processed at some later date, the hours recorded will reflect a longer interval, up to the maximum capacity of the Sensor's memory – data processing will automatically stop when the System detects the end of patient data.

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 heart beats 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.

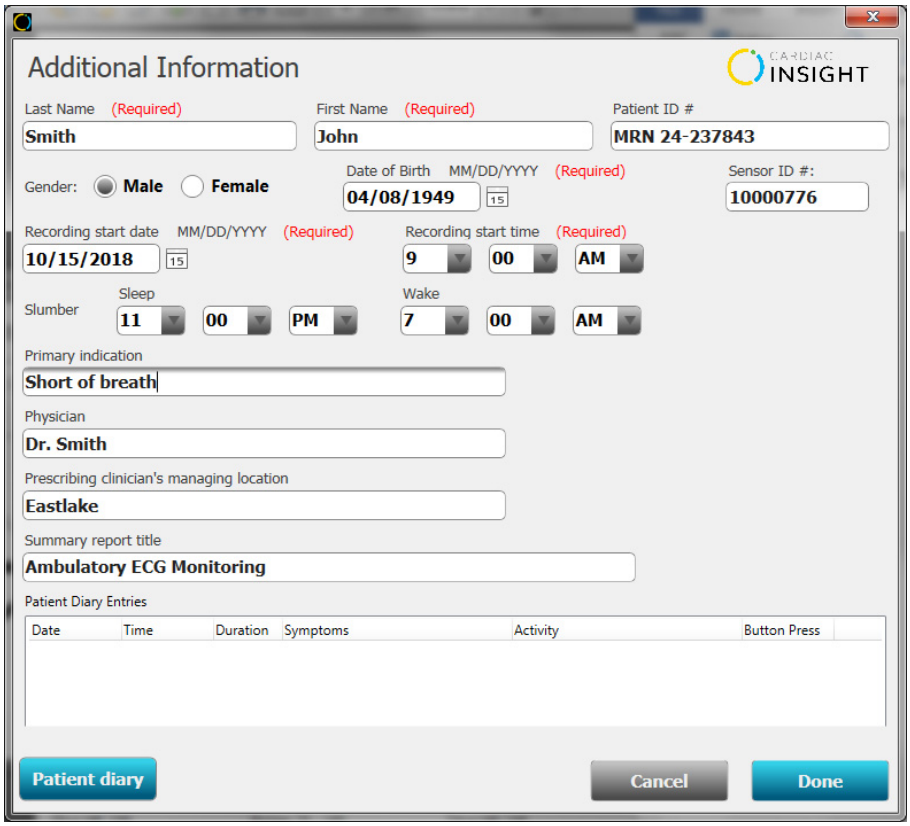


Figure 6.5. Additional Information screen.

Enter the patient information indicated as required.

NOTE: The (Required) patient information fields must be entered before the draft report can be generated.

The Patient ID # may be used for any free-text field desired, such as a medical record number or other identifier. Cardea SOLO 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.

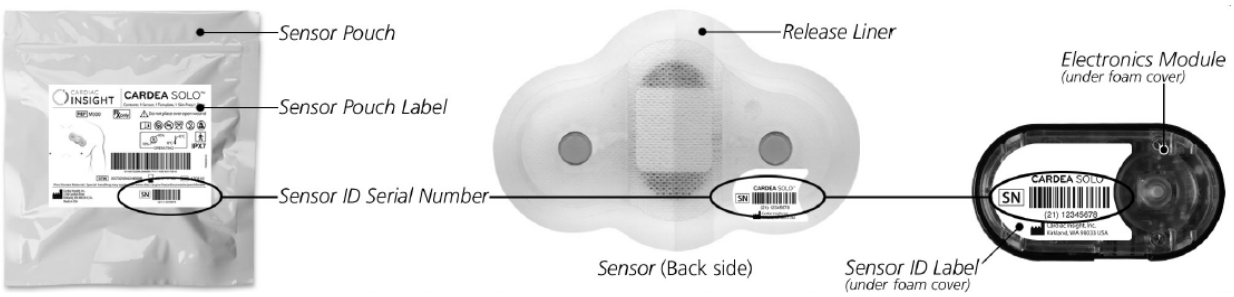


Figure 6.6. Sensor ID Serial Number locations.

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 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. The Patient Diary is not required.

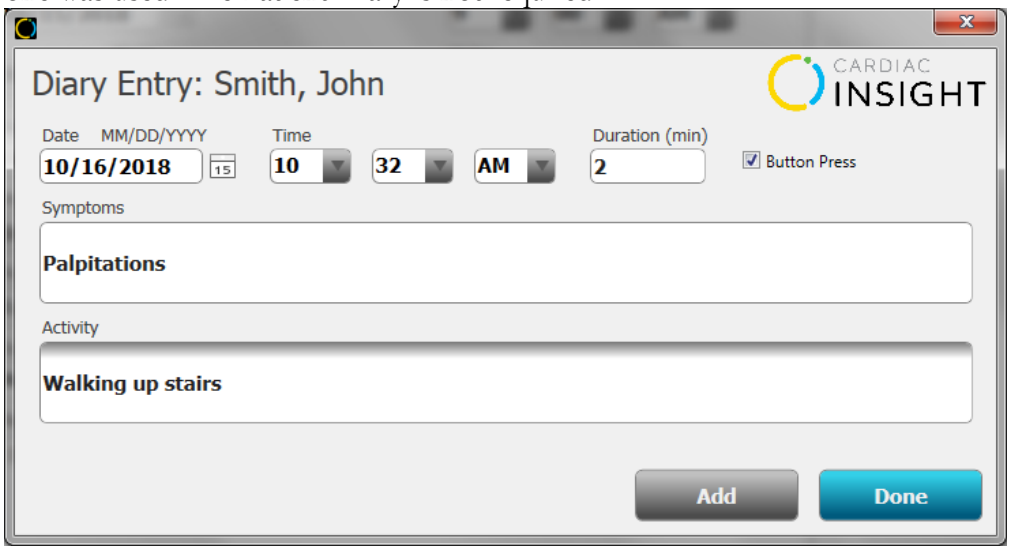


Figure 6.7. Patient Diary Entry screen.

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 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.

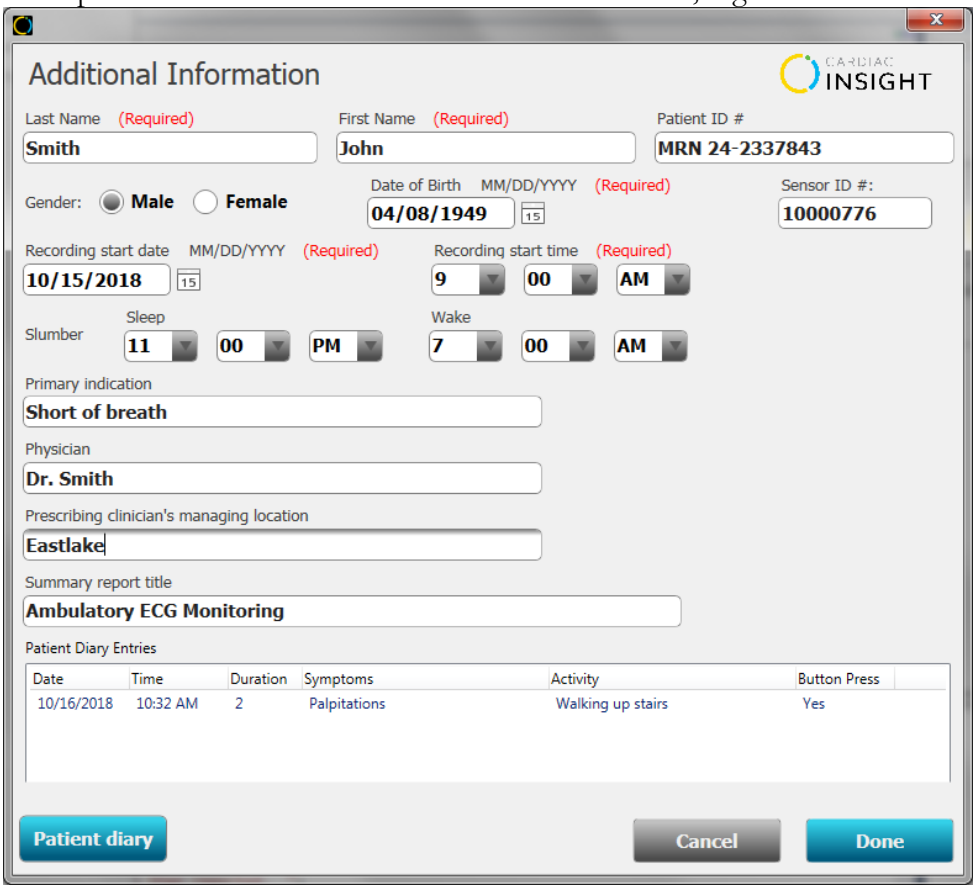


Figure 6.8. Updated Additional Information screen.

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 of the relevant information has been entered and reviewed, click the "Done" button. Cardea SOLO 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.

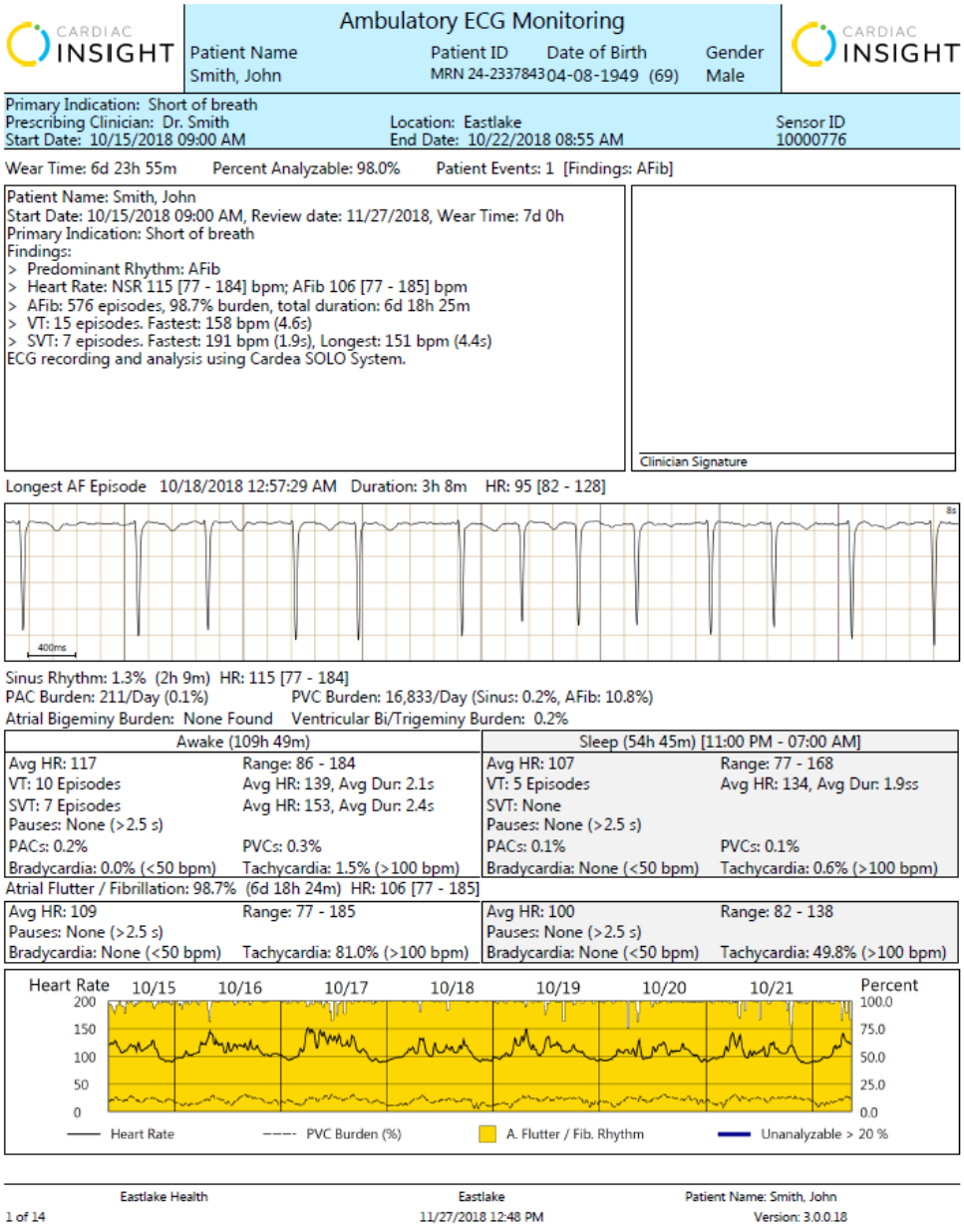


Figure 6.9. Example first page of a draft PDF report.

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 and number of patient triggered events and their associated findings (if any) 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 (See Section 4.3 above).

Clinical Findings / Over reading. 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 Flutter/Fibrillation (AFib); Ventricular Tachycardia (VT); Pause; Supraventricular Tachycardia (SVT); Ventricular Bigeminy; Ventricular Trigeminy; Atrial Bigeminy, Bradycardia; Tachycardia; Normal Rhythm. Rhythm strips are added to later pages of the report for conditions detected.

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

Sinus. The percent of the record that is 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 percent burden (PVCs / Total # Beats) is divided into burden occurring during Sinus rhythm and AFib.

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. 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 (%).

NOTE: If the maximum PVC burden is lower than 10% the scale is multiplied by 10 to increase visual resolution.

7 Cardea SOLO Software – Clinical Review

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 Software will present a menu of options to support interactive review and any required edits of the summary finding, Figure 7.1.

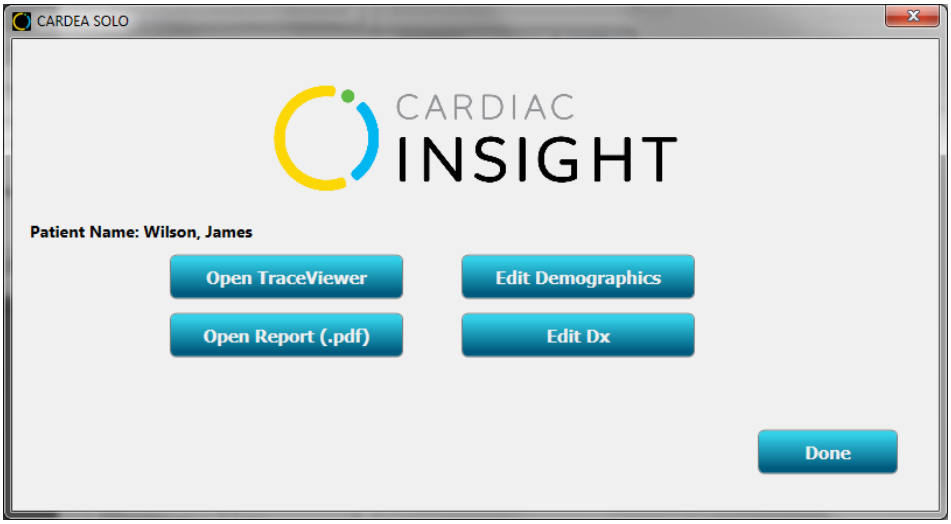


Figure 7.1. Report Review Options menu.

The following sections discuss the functionality of each menu option.

⚠ Caution	Interpretation Hazard. A licensed physician must over read ECG interpretations. Some ECG abnormalities cannot be detected by automated ECG analysis algorithms. Computerized interpretations are only significant when used in conjunction with clinical findings.
⚠ **Warning**	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 10 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.

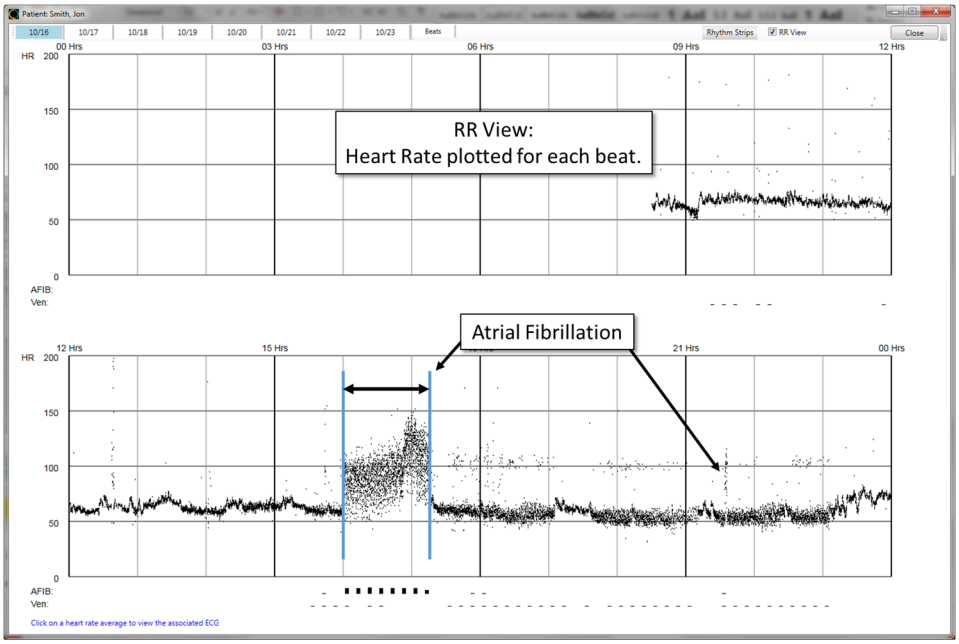


Figure 7.2. RR View showing heart rate for every RR interval.

Additional examples of ECG rhythms are shown in the following figures.

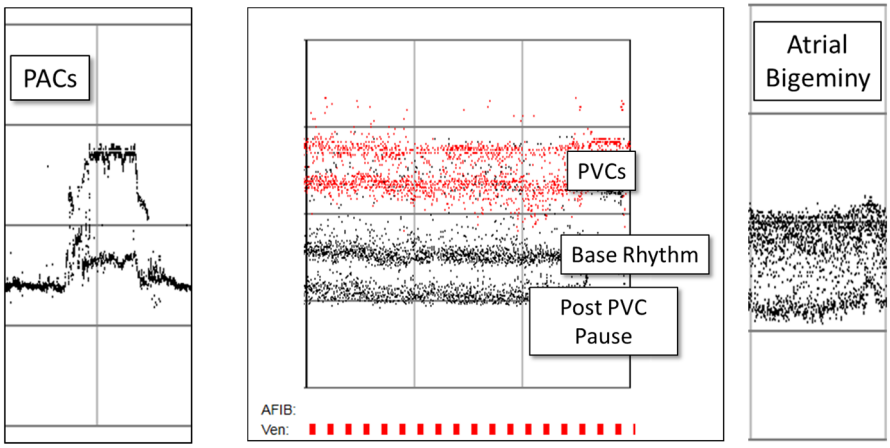


Figure 7.3 Example RR plots for premature atrial contractions (PACs), premature ventricular contractions (PVCs), and atrial bigeminy.

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 10 minute 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 Software thinks something of interest has occurred.

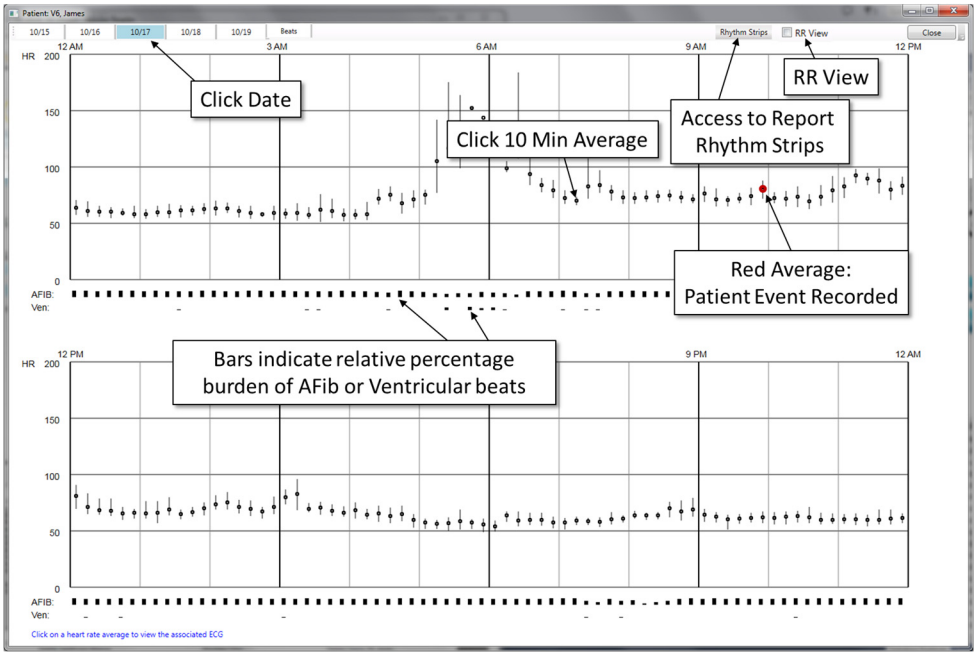


Figure 7.4. TraceViewer, day averages view.

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 will present the 10 minute ECG record associated with the selection, Figure 7.5.

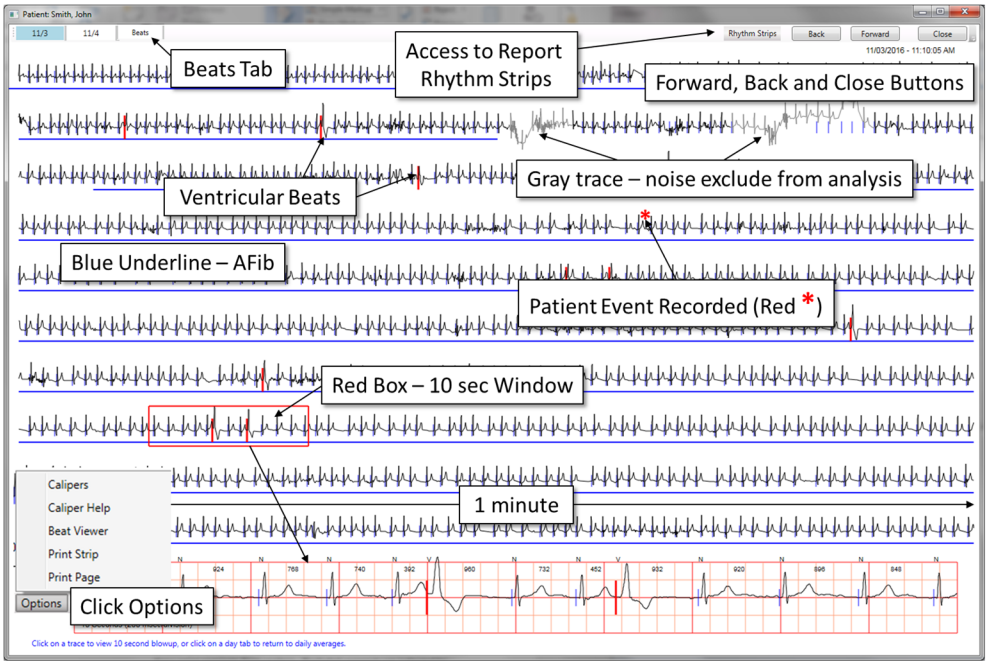


Figure 7.5. 10 Minute TraceViewer.

On the top right of the screen are the "Forward", "Back" buttons. Clicking Forward or Back, or clicking the < or > arrow keys, will advance or decrement the time view by 10 minutes.

Clicking at any point on any of the 10 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.

If there is a patient marker within the 10 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.

Cardea SOLO 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 any Day tab at the top left will return to the Day average view.

Print: Clicking Options / Print Strip (lower left on Figure 7.5) will print the current ten second rhythm strip to a standard Windows connected printer. Selecting Options / Print Page will print the entire 10 minute view.

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:

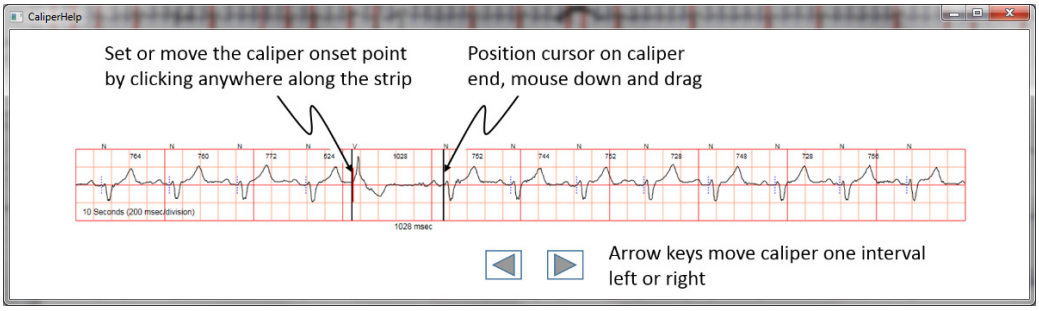


Figure 7.6. Caliper Help window.

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 interval.

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 that is interpreted as noise

Rhythm Strips: Clicking the Rhythm Strip button at the top right of the screen will display the Rhythm Strip WaveCollection Tool:

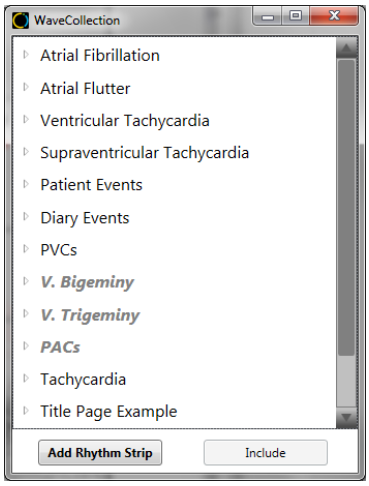


Figure 7.7. The Rhythm Strip Tool.

Items that are grayed-out and in italic font represent nominal findings that were 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. AFib, VT, SVT and Pauses are always included in the report.

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

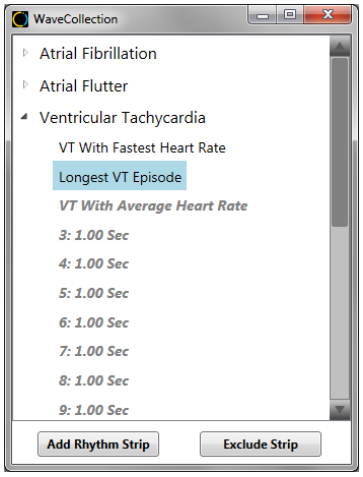


Figure 7.8. Expanded strips for VT.

Clicking on any strip will update TraceViewer, showing the selected strip in the context of the 10 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.

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 7.7. A window similar to the following is displayed:

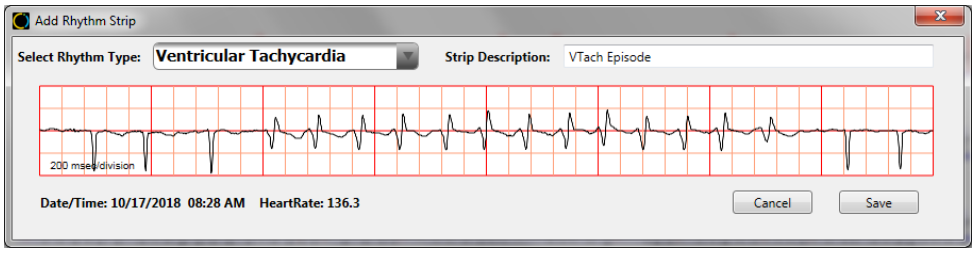


Figure 7.9. Add Rhythm Strips.

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 first eight seconds of the currently displayed ten second rhythm strip will be saved. A strip description is required before clicking the Save button.

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

Beat Templates: Cardea SOLO develops distinct beat templates used to associate beats into classes. 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. The beat classes are displayed by clicking the "Beats" tab in TraceViewer, see Figure 7.5 above.

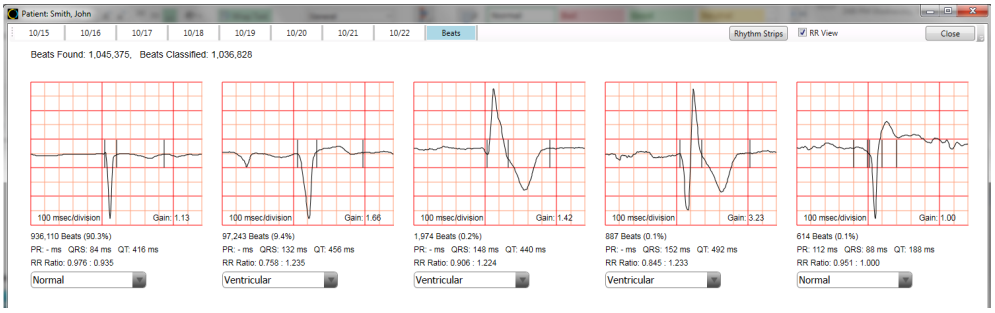


Figure 7.10. Beat Tab showing the beat morphology for each identified beat class.

Details for each beat are shown in the following expanded view of a single beat.

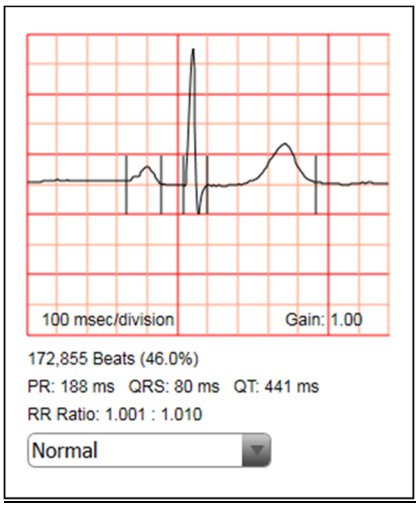


Figure 7.11. Beat Class information.

The total beat count for this class is provided in the first line beneath the waveform, followed by key phase measurements. The RR ratio describes the average intervals preceding and following the beat, divided by the running average heart rate RR. For example, a ratio of "0.68 : 1.34" indicates that the class is characterized by a short RR interval preceding the beat, 68% of the expected RR, and the RR interval following the beat is 34% longer than expected – the characteristics of a PVC beat. Cardea SOLO uses the class QRS duration, the RR ratio statistics and the beat characteristics relative to other classes to assess the likelihood that 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). When TraceViewer is closed, the software will automatically re-process the record and re-generate the PDF report.

NOTE: Beats that are marked as Noise can only be restored by re-processing the patient's Sensor Electronics Module. Refer to Section 6.

Beat Viewer: Right-clicking the mouse at any location in the 10 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, constructed from the dominant beats in the vicinity of the mouse click:

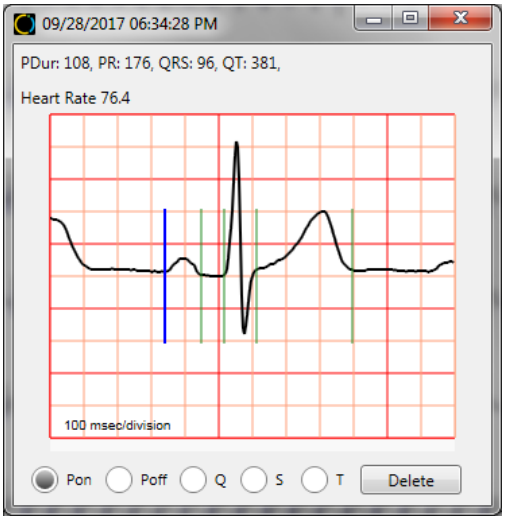


Figure 7.12. Beat Viewer.

The phases P-onset (Pon), P-offset (Poff), Q, S and 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 that 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 (if not automatically picked) of that phase.

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 10 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.

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 6.5) with all of the information previously entered. All of 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 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 Software will present a text editing window, Figure 7.13 below.

NOTE: Access to the Edit Dx functionality is controlled by User settings – See Section 4.2 User Setup.

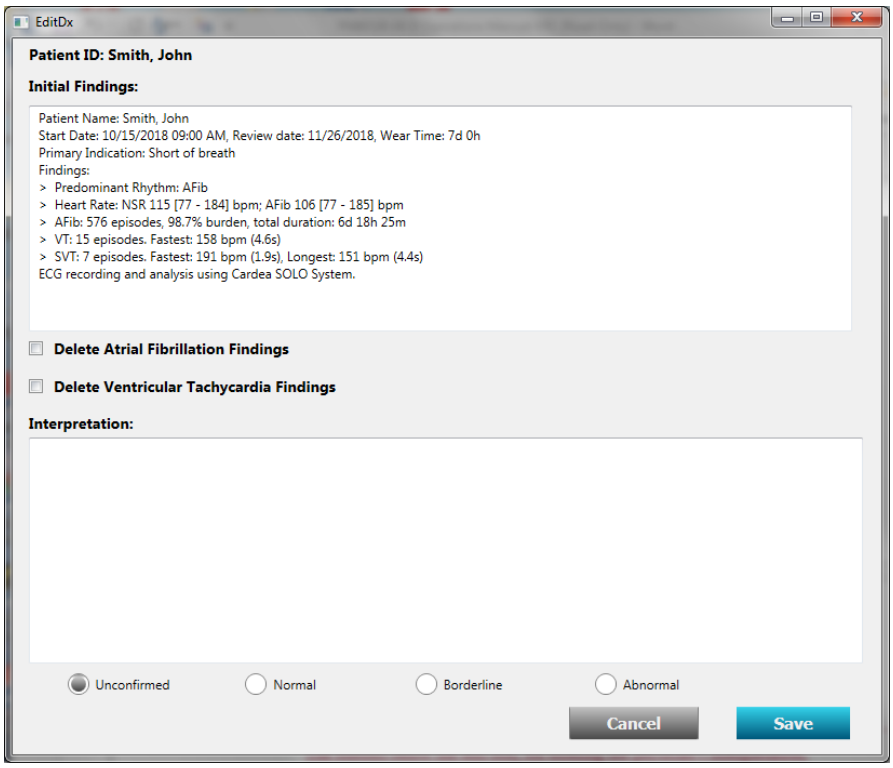


Figure 7.13. Edit Dx window.

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 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 Save will re-create the report, excluding AFib and / or VT. Cardea SOLO 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 Save. The report will be updated and displayed.

NOTE: 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 7.13). 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 will regenerate the PDF report with the finalized Findings, Interpretation, Record Status, physician's name and date.

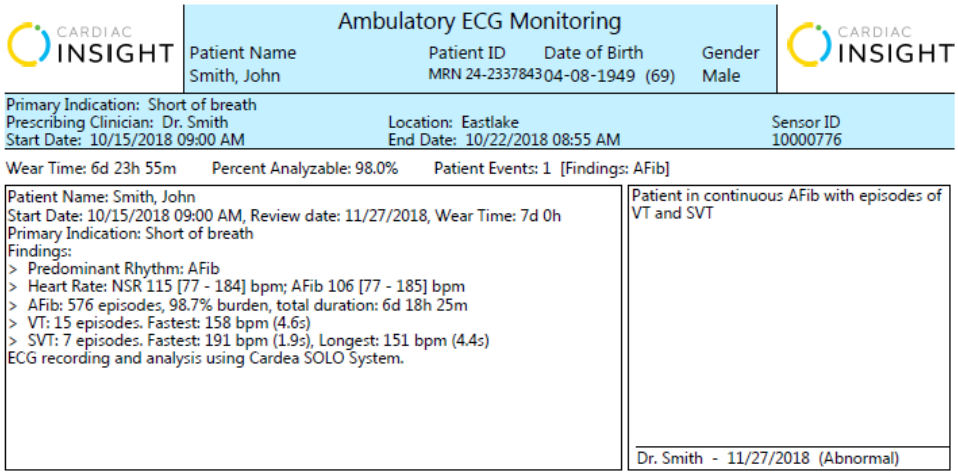


Figure 7.14. Finalization of Report.

7.4 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 Software will re-open the report.

7.5 Report Completion

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

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

The User Menu Options screen, Figure 6.2, supports user access to previously created PDF 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 8.1.

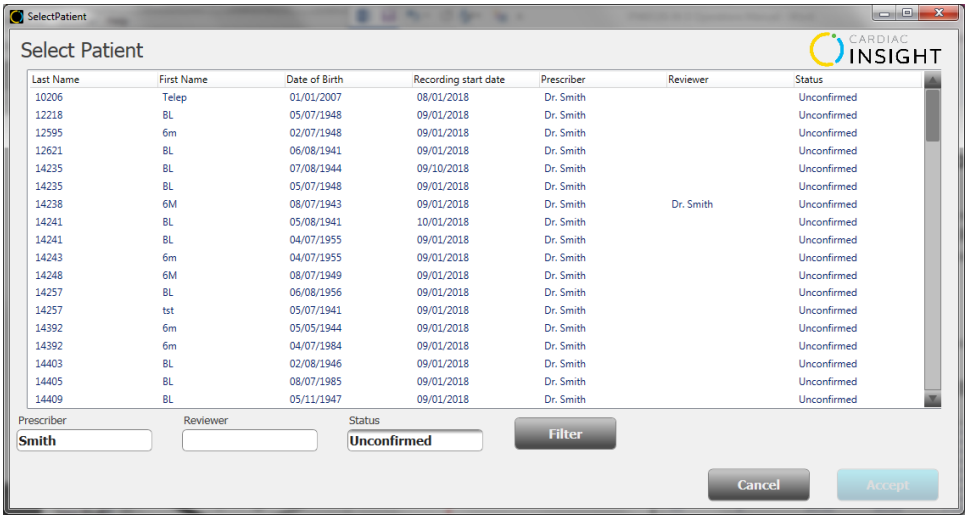


Figure 8.1. Select / Display previous final reports.

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 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, will sort the list.

8.2 Previous Reports – Full Disclosure ECG

Clicking the "Open TraceViewer" button will present a patient report selection window, see figure 8.1 above. Selecting a patient will next display the full disclosure information in TraceViewer, see Section 7.1 ECG Trace Review above. Additional rhythm strips can be added / deleted to the final report and

beat classifications can be edited, following the instructions in Section 7.1 above.

NOTE: Beats that are marked as Noise can only be restored by re-processing the patient's Sensor Electronics Module. Refer to Section 6.

8.3 Previous Reports – Edit Dx

Clicking the "Edit Dx" button will present a patient report selection window, see Figure 8.1 above. Selecting a patient will next display the Edit Dx window, see Section 7.3 Edit Dx above. The Initial Findings and Clinical diagnosis or notes may be entered.

NOTE: Deleted AFib and / or VT findings can only be restored by re-processing the raw data from the Sensor's Electronics Module in order to re-create the tables necessary for full report recreation. Refer to section 6.

8.4 Operator's Manual

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

8.5 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 8.2. Help About screen.

The first line provides the software release level for Cardea SOLO (in the above, Version 3.0.0.18). If a Smart Cable is connected to the PC, the

firmware release level is displayed (Rev 16). Should an Electronics Module be inserted into the Smart Cable cradle, the firmware release level of the electronics 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 2.4).

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.

8.6 Cohort Reporting

Clicking the Excel Summary button, Figure 6.2 above, presents the standard Windows folder browser. Excel reports can be created from a single patient, or for a cohort. For a single patient, navigate the folder browser to the patient folder of interest. For the cohort, navigate to the "Save Patient Data Directory" (See Section 4.1). Cardea SOLO will next create and present an Excel spreadsheet for all of the data logged during data analysis for each patient. The data field definitions follow:

Field	Description
LastName	Patient Last Name
FirstName	Patient First Name
PatientID	Patient ID / Medical Record Number
Gender	Gender
DateOfBirth	Date of Birth
StartDate	Recording start date
StartTime	Recording start time
SlumberSleep	Nominal time patient goes to sleep
SlumberWake	Nominal time patient wakes up
PrimIndications	Primary indications for the test
Clinician	Physician
Location	Clinic location
ReportTitle	Customized report title
SummaryFindings	Text summary findings (raw)

Field	Description
EditedSummaryFindings	Edited summary findings
Interpretation	Added physician interpretation comments
WearTime	Duration of wear, format xd yyh zzm (days, hours, minutes)
%Analyzable	Percent of the record that was analyzable
PTriggers	Number of patient event markers detected
NS:%	Percentage of normal Sinus rhythm
NSAvgHR	Overall average heart rate (HR) during Normal Sinus Rhythm (NSR)
NSMaxHR	Maximum HR during NSR
NSMinHR	Minimum HR during NSR
NSAwakeAvgHR	Average HR during awake NSR
NSAwakeMaxHR	Maximum HR during awake NSR
NSAwakeMinHR	Minimum HR during awake NSR
NSAwakeBrad%	Percent of record with HR < 50 during awake NSR
NSAwakeTach%	Percent of record with HR > 100 during awake NSR
NSAwakePVC%	Percent of the total # PVC beats / # total beats, during awake NSR
NSAwakePAC%	Percent of the total # PAC beats / # total beats, during awake NSR
NSAwakeBiTri%	Percent of # PVC beats in Bi/Trigeminy / # total beats, during awake NSR
NSAwakePauseCt	Number of pause events during awake NSR
NSAwakePauseAveD	Average pause duration during awake NSR
NSAwakePauseLD	Longest pause during awake NSR
NSSleepAvgHR	Average HR during sleep NSR
NSSleepMaxHR	Maximum HR during sleep NSR
NSSleepMinHR	Minimum HR during sleep NSR
NSSleepBrad%	Percent of record with HR < 50 during sleep NSR
NSSleepTach%	Percent of record with HR < 100 during sleep NSR

Field	Description
NSSleepPVC%	Percent of the total # PVC beats / # total beats, during sleep NSR
NSSleepPAC%	Percent of the total # PAC beats / # total beats, during sleep NSR
NSSleepBiTri%	Percent of # PVC beats in Bi/Trigeminy / # total beats, during sleep NSR
NSSleepPauseCt	Number of pause events during sleep NSR
NSSleepPauseAveD	Average pause duration during sleep NSR
NSSleepPauseLD	Longest pause during sleep NSR
AF:%	Percent of the record characterized as Atrial Fibrillation (AF)
AFAvgHR	Overall average heart rate (HR) during AF
AFMaxHR	Maximum HR during AF
AFMinHR	Minimum HR during AF
AFAwakeAvgHR	Average HR during awake AF
AFAwakeMaxHR	Maximum HR during awake AF
AFAwakeMinHR	Minimum HR during awake AF
AFAwakeBrad%	Percent of record with HR < 50 during awake AF
AFAwakeTach%	Percent of record with HR > 100 during awake AF
AFAwakePVC%	Percent of the total # PVC beats / # total beats, during awake AF
AFAwakePauseCt	Number of pause events during awake AF
AFAwakePauseAveD	Average pause duration during awake AF
AFAwakePauseLD	Longest pause during awake AF
AFSleepAvgHR	Average HR during sleep AF
AFSleepMaxHR	Maximum HR during sleep AF
AFSleepMinHR	Minimum HR during sleep AF
AFSleepBrad%	Percent of record with HR < 50 during sleep AF
AFSleepTach%	Percent of record with HR < 100 during sleep AF

Field	Description
AFSleepPVC%	Percent of the total # PVC beats / # total beats, during sleep AF
AFSleepPauseCt	Number of pause events during sleep AF
AFSleepPauseAveD	Average pause duration during sleep AF
AFSleepPauseLD	Longest pause during sleep AF
PauseTotalCount	Total # pauses
LongestPause	Longest pause
SVTAwakeCount	Number of SVT events during awake
SVTAwakeAvgHR	Average SVT HR during awake
SVTAwakeAvgDur	Average SVT duration during awake
SVTSleepCount	Number of SVT events during sleep
SVTSleepAvgHR	Average SVT HR during sleep
SVTSleepAvgDur	Average SVT duration during sleep
VTAwakeCount	Number of VT events during awake
VTAwakeAvgHR	Average VT HR during awake
VTAwakeAvgDur	Average VT duration during awake
VTSleepCount	Number of VT events during sleep
VTSleepAvgHR	Average VT HR during sleep
VTSleepAvgDur	Average VT duration during sleep
PACIsoCnt	Total number of isolated PACs in the record
PACCoupCnt	Total number of PAC couplets in the record
PACTripCnt	Total number of PAC triplets in the record
PACTotalBurden	Total PAC burden (# PACs / Total # beats)
PVCIsoCnt	Total number of isolated PVCs in the record
PVCCoupCnt	Total number of PVC couplets in the record
PVCTripCnt	Total number of PVC triplets in the record
PVCNSTotalBurden	Total PVC burden (# PVCs / Total # beats) during NSR
PVCAFTotalBurden	Total PVC burden (# PVCs / Total # beats) during AF
SVTPACBurden	Percent of SVT beats / Total # beats
VTPVCBurden	Percent of VT beats / Total # beats

Field	Description
VBiGem%	Total bigeminy PVC burden (%)
VBiGemLong	Longest bigeminy duration
VTriGem%	Total trigeminy PVC burden (%)
VTriGemLong	Longest trigeminy duration
AwakeBeats	Total # of beats detected during awake
SleepBeats	Total # of beats detected during sleep

9 System Characteristics

The following information is provided to assist the clinician to more fully understand the characteristics of the Cardea SOLO 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 0.77 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 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 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.

9.3 Beat and Rhythm Sensitivity and Positive Predictive Value

The performance characteristics of the ECG algorithms within Cardea SOLO 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.

	Sensitivity	PPV
Overall QRS Detection	98.5	99.9
Ventricular (V) Beats:		
Overall V Beats	88.8	97.1
V. Couplets	87.5	96.8
V. Short Runs	89.8	93.8
V. Long Runs	62.3	76.8
Bigeminy (Duration)	70.0	80.0
Trigeminy (Duration)	85.0	49.0
Supraventricular (SVE) Beats:		
Overall SVE Beats	71.6	69.4
SVE Couplets	78.0	76.0
SVE Short Runs	93.0	92.0
SVE Long Runs	89.0	97.0
Atrial Fibrillation / Flutter:		
Duration (Burden)	96.7	98.7
CAUTION: Afib Sensitivity declines for episodes less than 20 seconds in duration.		

PPV: Positive Predictive Value.

10 Maintenance

10.1 Cleaning the Smart Cable

To clean the Smart Cable, 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 Electronics Module connection well. Dry with a clean, soft, and dry cloth.

NOTE: Do not wipe the exposed connector.

⚠ Caution	Fluid Hazard. Do not immerse. Fluids must not be allowed to enter the Smart Cable. If fluids have penetrated the device it should be replaced or inspected by a Cardiac Insight qualified technician before use.
⚠ Caution	Equipment Damage. Do not use ether, strong bleach, acetone, benzene, or similar solvents to clean the Smart Cable. Use only the following cleaning agents: • Isopropyl alcohol (70% solution in water) • Mild soap and water
⚠ Caution	Equipment Damage. Do not hot sterilize the Smart Cable.

11 EMC Declaration Tables – Smart Cable, Sensor

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

11.1 Electromagnetic Emissions

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

11.2 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 60601-1-2:2014</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 [b]</th><th>Maximum power (W)</th><th>Distance (m)</th><th>IMMUNITY TEST LEVEL (V/m)</th></tr>
<tr><td>385</td><td>380 –390</td><td>TETRA 400</td><td>Pulse modulation [b]
18 Hz</td><td>1,8</td><td>0,3</td><td>27</td></tr>
<tr><td>450</td><td>430 – 470</td><td>GMRS 460, FRS 460</td><td>FM [c]
± 5 kHz deviation
1 kHz sine</td><td>2</td><td>0,3</td><td>28</td></tr>
<tr><td>710</td><td rowspan="3">704 – 787</td><td rowspan="3">LTE Band 13, 17</td><td rowspan="3">Pulse modulation [b]
217 Hz</td><td rowspan="3">0,2</td><td rowspan="3">0,3</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 – 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">2</td><td rowspan="3">0,3</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 – 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">2</td><td rowspan="3">0,3</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 – 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>2</td><td>0,3</td><td>28</td></tr>
<tr><td>5 240</td><td rowspan="3">5 100 – 5 800</td><td rowspan="3">WLAN 802.11 a/n</td><td rowspan="3">Pulse modulation [b]
217 Hz</td><td rowspan="3">0,2</td><td rowspan="3">0,3</td><td rowspan="3">9</td></tr>
<tr><td>5 500</td></tr>
<tr><td>5 785</td></tr>
</table>
</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>
</table>

11.3 Electromagnetic Immunity for Smart Cable

Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms[c]
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m[c]
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.		
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Cardea SOLO is used exceeds the applicable RF compliance level above, then Cardea SOLO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Cardea SOLO. 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 EN 60601-1-2.		

11.4 Recommended Separation Distances

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

The Cardea SOLO 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 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cardea SOLO 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 2.5 GHz $d = 2.3 \sqrt{P}$
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.

11.5 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 that 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

12 Environmental Specifications

12.1 Transport Environment - Sensor

Temperature: -10º C to 50º C (14º F to 122º F)

Humidity: 10% to 95% (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 95% (non-condensing)

Pressure: 500 hPa to 1060 hPa

12.3 Operating Environment - Sensor

Temperature: 5º C to 45º C (41º F to 113º F)

Humidity: 10% to 95%

Pressure: 500 hPa to 1060 hPa

Ingress of Solids and Liquids: IEC 60529 Ed. 2.1:2001, IP27 (protected against intrusion from fingers and small objects, and from the effects of temporary immersion in water)

12.4 Transport Environment - Smart Cable

Temperature: -10º C to 50º C (14º F to 122º F)

Humidity: 10% to 95% (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 95% (non-condensing)

Pressure: 500 hPa to 1060 hPa

12.6 Operating Environment - Smart Cable

Temperature: 10º C to 45º C (50º F to 113º F)

Humidity: 10% to 95% (non-condensing)

Pressure: 500 hPa to 1060 hPa