



TAGecg™ and TAGconnect™ Operator's Manual

TAGecg System

Includes instructions for:

- *TAGconnect Software*
- *TAGecg Smart Cable*
- *TAGecg Sensor*



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

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Table of Contents

1	Introduction	1
1.1	Indications for Use	1
1.2	Intended Use	1
1.3	Contraindications	1
1.4	Clinician's Responsibility	1
1.5	Definitions of Symbols Used	2
2	Getting Started	4
2.1	TAGconnect Software Blister Pack	4
2.2	TAGecg Smart Cable Shipping Carton	4
2.3	Device User-Supplied Personal Computer (PC) Requirements	4
2.3.1	Supported Operating Systems and Associated Components	4
2.3.2	Hardware Requirements	5
2.4	Hardware Setup	7
2.5	TAGconnect Software Installation	8
3	Sensor Operation	10
3.1	Precautions	10
3.2	Pouch Contents	11
3.3	Sensor – Getting Started	12
3.4	Sensor Placement	13
3.5	Wearing Instructions	15
3.6	Recommendations For Patient Use	15
3.7	Completion of Monitoring and Removal	16
3.8	ECG Retrieval	17
3.9	Troubleshooting	17
4	TAGconnect Software – Administrative Setup	19
4.1	Initial Start-up	19
4.2	User Setup	21
5	TAGconnect Software – Creating the Report	22
5.1	User Login	22
5.2	Data Transfer, Demographics and the Draft Report	23
5.2.1	Connecting the Electronics Module	23
5.2.2	Starting Data Transfer	24
5.2.3	Demographic and Diary Data Entry	25
5.2.4	Draft Final Report	28
6	TAGconnect – Clinical Review	31
6.1	ECG Trace Review	32
6.2	Edit Demographics	37
6.3	Edit Dx	37
6.3.1	Delete AFib Findings	37
6.4	Open Report (.pdf)	38
6.5	Report Completion	38
7	Previous Reports, Cohort Reporting, Help and Operator's Manual	39
7.1	Previous Reports - PDFs	39
7.2	Previous Reports – Full Disclosure ECG	39
7.3	Previous Reports – Edit Dx	39
7.4	Operator's Manual	40
7.5	Help About	40
7.6	Cohort Reporting	41
8	System Characteristics	45
8.1	System Bandwidth and Baseline Wander Filtering	45
8.2	AC Line Filtering	45
8.3	Beat and Rhythm Sensitivity and Positive Predictive Value	46
9	Maintenance	47
9.1	Cleaning the Smart Cable	47
9.2	Returning products	47
10	EMC Declaration Tables – Smart Cable, Sensor	49
10.1	Electromagnetic Emissions	49
10.2	Electromagnetic Immunity for Sensor	49
10.3	Electromagnetic Immunity for Smart Cable	50
10.4	Recommended Separation Distances	50

10.5	FCC Notice.....	51
10.6	Operational Environment - Sensor.....	52
10.7	Storage Environment - Sensor.....	52

1 Introduction

1.1 Indications for Use

The TAGecg System 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

The TAGecg System 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 in use. Paced beats may interfere with the analysis of the ECG and cause misclassification of beats and rhythms.

Do not use the Sensor in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI.


















Do not use the Sensor on patients who do not have the competency to wear the Sensor for the prescribed monitoring period.

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
	A copy of the (Directions for Use) DFU is available on this website. A printed copy of the DFU can be ordered from Welch Allyn for delivery within 7 calendar days.
	Temperature limits. Indicates the temperature limits to which the device can be safely exposed. ISO 15223-1:2012 Symbol 5.3.7
	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
	Humidity limitation. Indicates the range of humidity to which the device can be safely exposed. ISO 15223-1:2012 Symbol 5.3.8
	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.



Reorder number ISO 7000, Symbol 6050

2 Getting Started



Caution

Read all directions for use, including safety procedures, before using the TAGecg System and follow all instructions while using the TAGecg System.

2.1 TAGconnect Software Blister Pack

The package contains:

A USB Flash drive with TAGconnect Software

- The Flash Drive is used to setup and install the TAGconnect software.

Note: This Operator's Manual is available as a standalone PDF on the Flash drive, as well as on the main software menu.

2.2 TAGecg Smart Cable Shipping Carton

The shipping carton contains:

Smart Cable

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

Note: A Quick Start Guide (containing an overview of the TAGecg System and abbreviated guidance on how to set up your system) and a Troubleshooting Guide (with guidance information for addressing problems should they arise) are available on the Welch Allyn website:

www.welchallyn.com/TAGecgSetup

2.3 Device 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 TAGecg System 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.

2.3.1 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. TAGconnect 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 TAGconnect windows from being fully or correctly displayed.

2.3.2 Hardware Requirements

Windows® compatible personal computer, IEC/EN 60950-1 or 62368-1 certified

Disk: 2 GB of free disk space or greater

NOTE: TAGconnect 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)



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 TAGconnect 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.

2.4 Hardware Setup



Warning

Operation of the PC within the patient vicinity (6 feet / 1.83 m surrounding the perimeter of the bed, gurney, examining table, table or chair and 7.5 feet / 2.29 m above the floor) while connected to the AC mains requires use of either a medical grade power supply or medical grade isolation transformer. Only use properly grounded medical grade AC outlets.



Caution

Data Loss. 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.

The TAGecg System hardware setup is depicted in Figure 2.1 below.

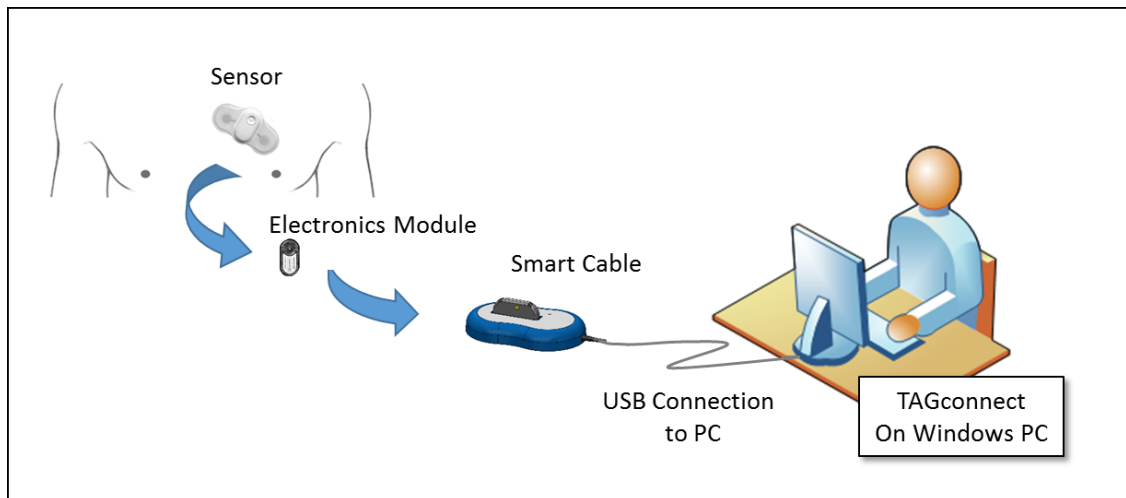


Figure 2.1. TAGecg System components and data flow, from the Patient Sensor to the TAGconnect software.

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 is recommended.

2.5 TAGconnect Software Installation

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

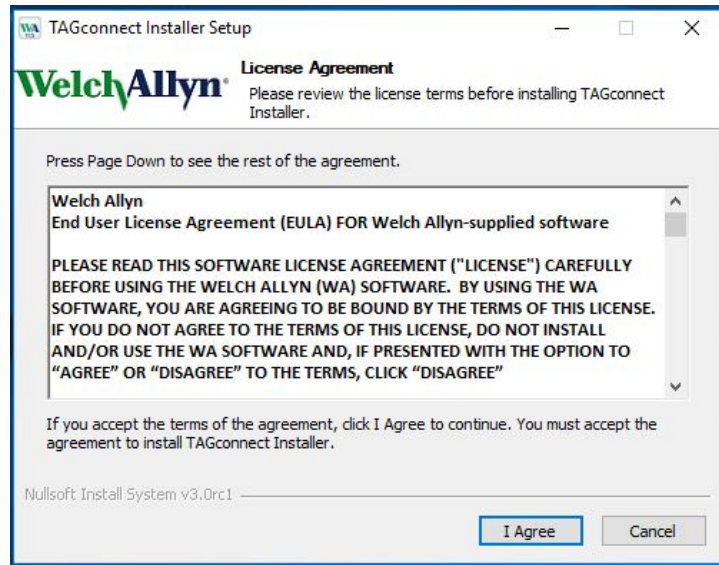


Figure 2.2. License Agreement.

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.

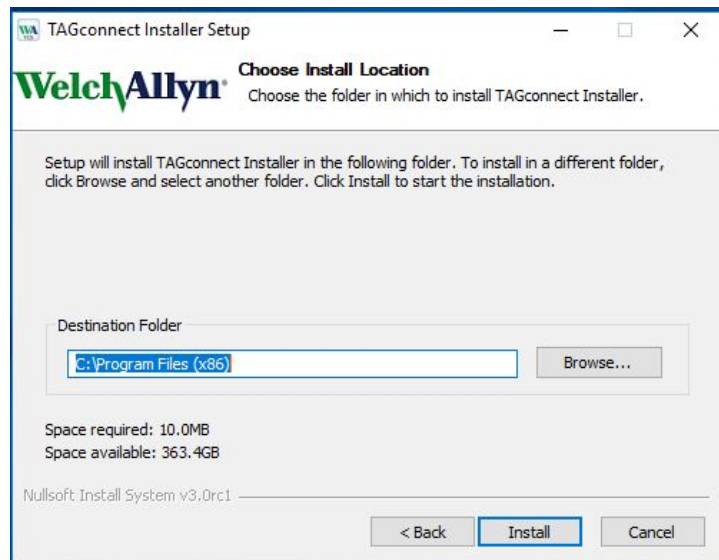


Figure 2.3. Install Location.

Click "Install" to install TAGconnect.

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.

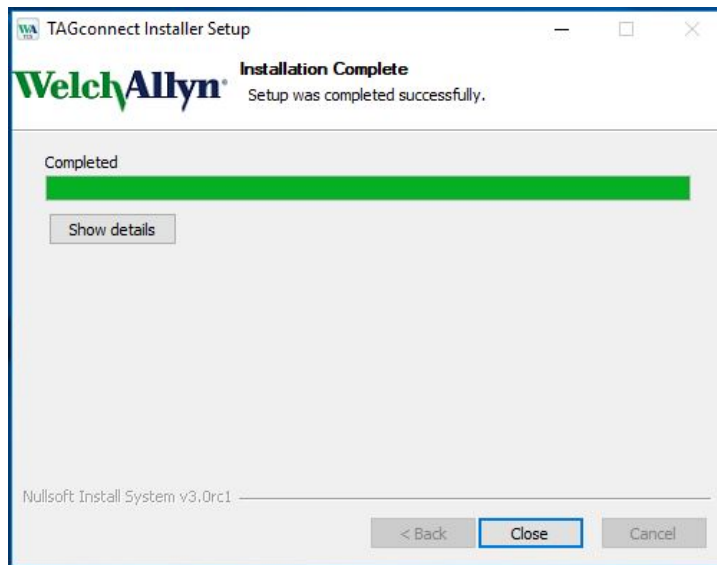


Figure 2.4. Installation Complete.

Click “Close” to complete the installation.

Welch Allyn recommends retaining the installation media. If discarded, dispose according to applicable local regulations.

3 Sensor Operation



Warning

Shock Hazard. DO NOT touch the Sensor or patient during defibrillation. Death or serious injury may occur from the electrical defibrillator discharge.



Warning

Burn Hazard. NEVER position defibrillator pads or paddles close to or in contact with the Sensor. Remove the Sensor to allow for correct positioning of the defibrillator pads or paddles. Severe burns may result from incorrect placement of defibrillator pads or paddles. Consult the operating instructions for the defibrillator.

NOTE: For more detailed instructions on Sensor placement and operation, refer to the Sensor DFU 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.

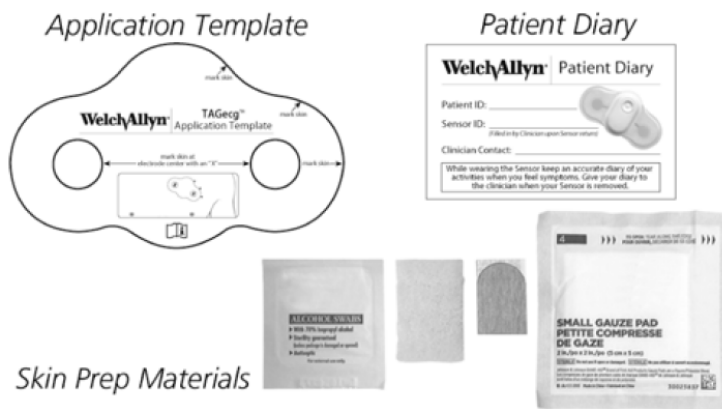
The Sensor does not replace direct communication between the patient and their health care provider. The Sensor data should be used along with all other clinical data and exams for a diagnosis. The Sensor will not summon emergency response in the event the patient needs help. The patient should talk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

3.2 Pouch Contents

- (1) TAGecg 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.

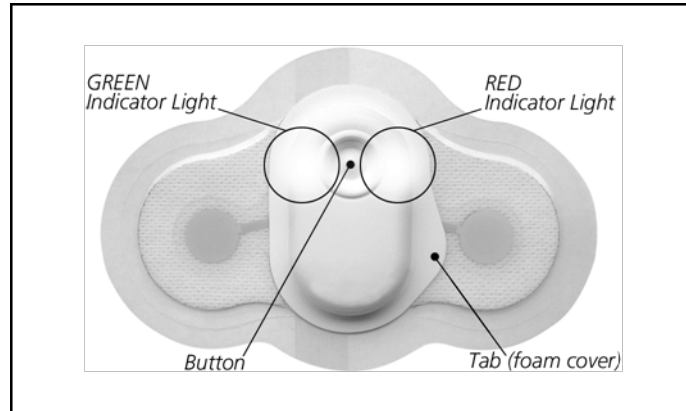


Figure 3.1. Key elements of the wearable Sensor

The button supports both device activation (i.e. start recording) and logging 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.

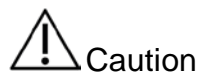
If the Sensor is not applied to a patient, or the patient preparation has been inadequate to enable an electrical connection with the patient’s skin, the Red and Green lights will alternately blink and the Sensor will return to a shut-down shipping mode.

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

Improperly prepared skin (dirty or otherwise compromised) may cause poor or incorrect readings. Before applying the Sensor ensure the skin is properly prepared.



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.



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.

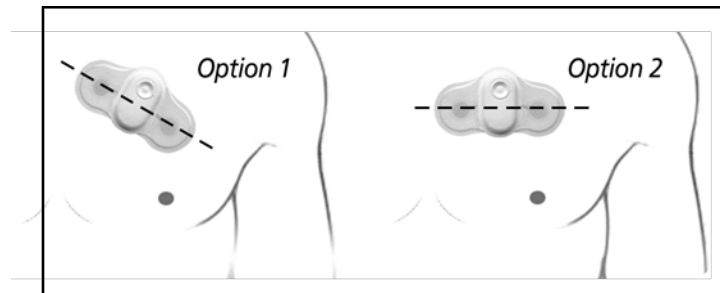


Figure 3.2. Placement options.

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.

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.

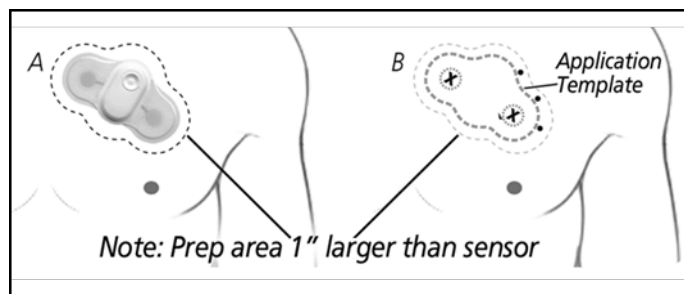


Figure 3.3. Using the Application Template to position the Sensor.

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. TAGconnect 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, the Sensor is either defective or is not able to make a good electrode contact through the patient's outer most skin (See 3 above). Remove and apply another. 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.

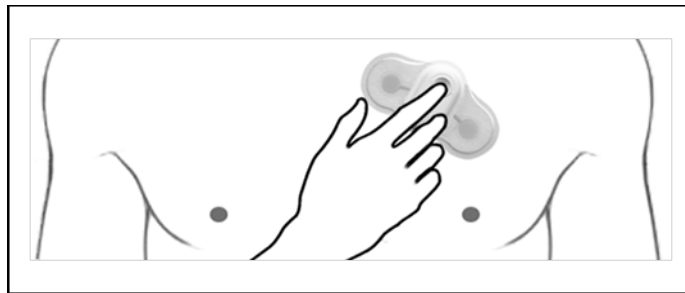


Figure 3.4. Activating the patient trigger.

- 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



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 number (if not already there) onto the Patient Diary if a diary has been filled out by the patient.

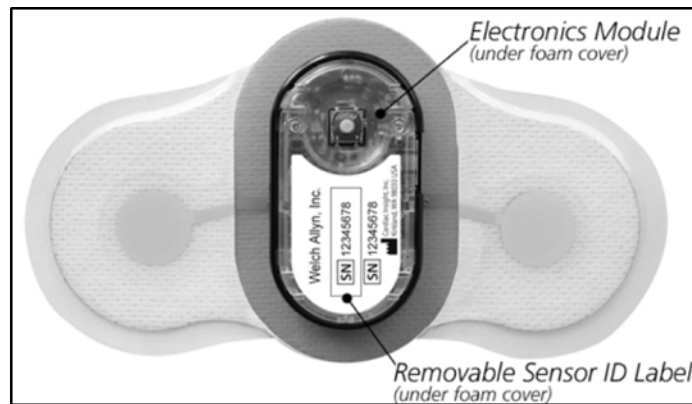


Figure 3.5. The exposed Electronics Module following removal of the foam cover.

2. Use the Smart Cable and TAGconnect Software to retrieve patient ECG information for the monitoring period, as discussed in the following sections.
3. After retrieval of the patients 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 TAGconnect Software – Administrative Setup

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

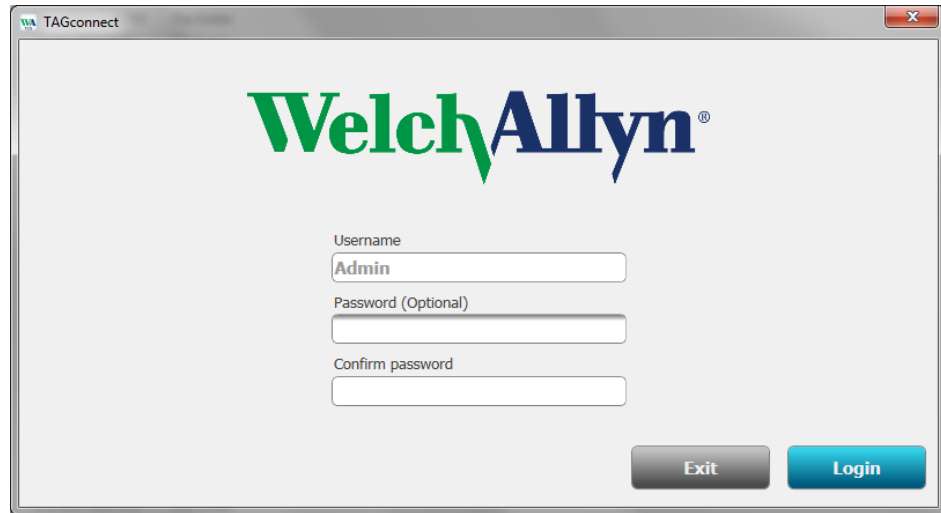


Figure 4.1. Administrative Log-in screen.

The Administrative Username is “Admin”. Authentication of the Administrator is strongly recommended, via the login protocol to the PC and /or setting the TAGconnect 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.

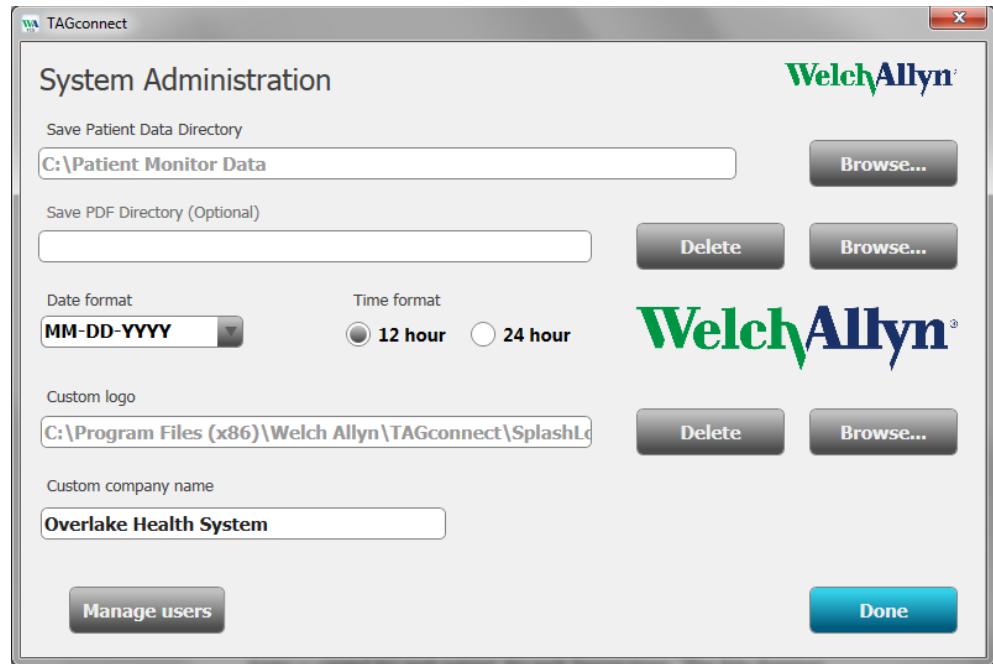


Figure 4.2. System Administration.

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.

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 PDFs, with patient records (for example, MediaManager for Epic). Using this option simplifies the task of collecting all of the PDFs that need to be uploaded into the EMR. The name of the PDF is in the format “LastName_FirstName_Birthdate_TestDate.PDF”.

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.

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.

Click the “Done” button.

4.2 User Setup

Following clicking “Done” above, 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. Log in as “Admin”. Select the “Manage users” button shown in Figure 4.2. The following screen will be displayed.

The screenshot shows a web application window titled "TAGconnect" with the WelchAllyn logo in the top right corner. The main heading is "Add / Edit User Profile". Below the heading is a dropdown menu labeled "Select Existing Profile (Edit)". There are five text input fields: "New login profile name", "Prescribing clinician", "Report Title (default)", "Managing Location (default)", and "Password (Optional)". Below the password field is a "Confirm password" field. At the bottom are four buttons: "Delete", "Update", "Add", and "Done".

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 TAGconnect, is strongly recommended. If desired, add and confirm the Password.

The User may provide clinical support for a prescribing clinician. When the User processes Sensor data and creates a final PDF report, the prescribing clinician’s name will be included.

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.

5 TAGconnect 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 final report.

Section 6, TAGconnect – 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.

5.1 User Login

On start-up the TAGconnect User Login screen will be displayed.

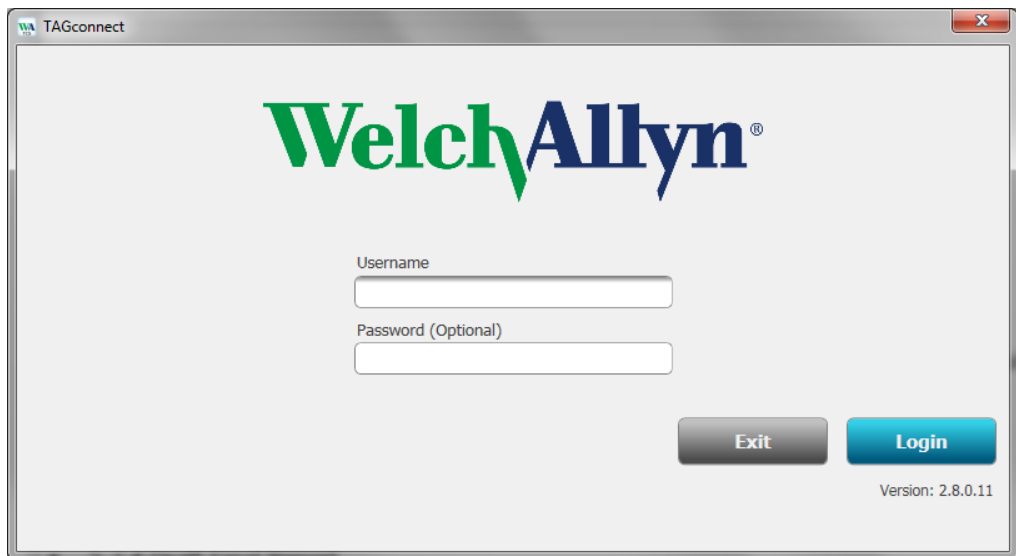


Figure 5.1. User Login screen.

Enter your User name and Password (if the Administrator included a Password when your account was setup). Clicking “Login” or Enter will present the main User Menu Options screen, Figure 5.2.

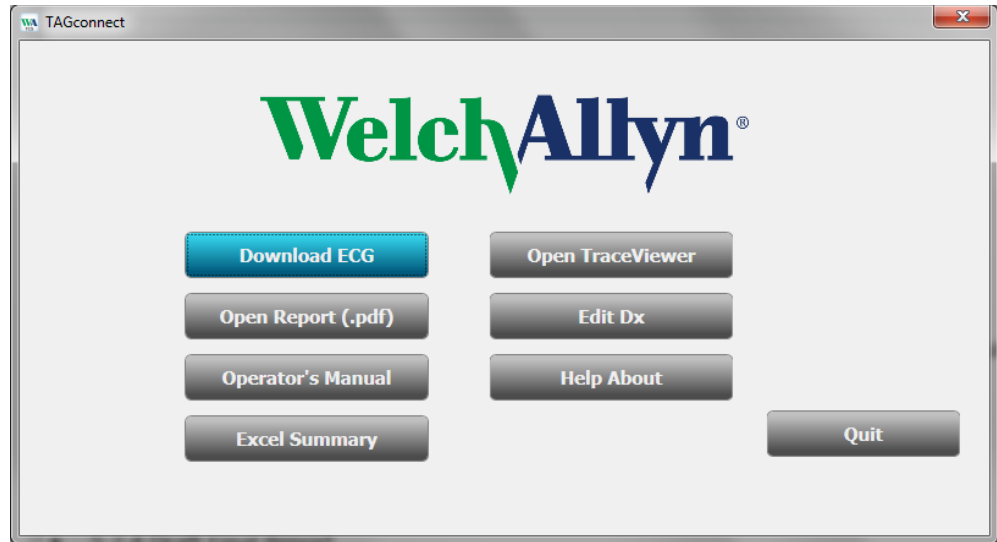


Figure 5.2. User Menu Options screen.

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

5.2 Data Transfer, Demographics and the Draft Report

5.2.1 Connecting the Electronics Module

The Smart Cable is used to transfer the ECG data from the Electronics Module to the PC and TAGconnect 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 5.3. The LED adjacent to the small image of the Electronics Module will light green when the electronic connection is made.



Figure 5.3. Electronics Module connected to the Smart Cable. During data transfer operations both LEDs will blink simultaneously.

5.2.2 Starting Data Transfer

Following clicking the “Download ECG” button, the System will present the “Transfer Sensor ECG Data” screen, Figure 5.4.

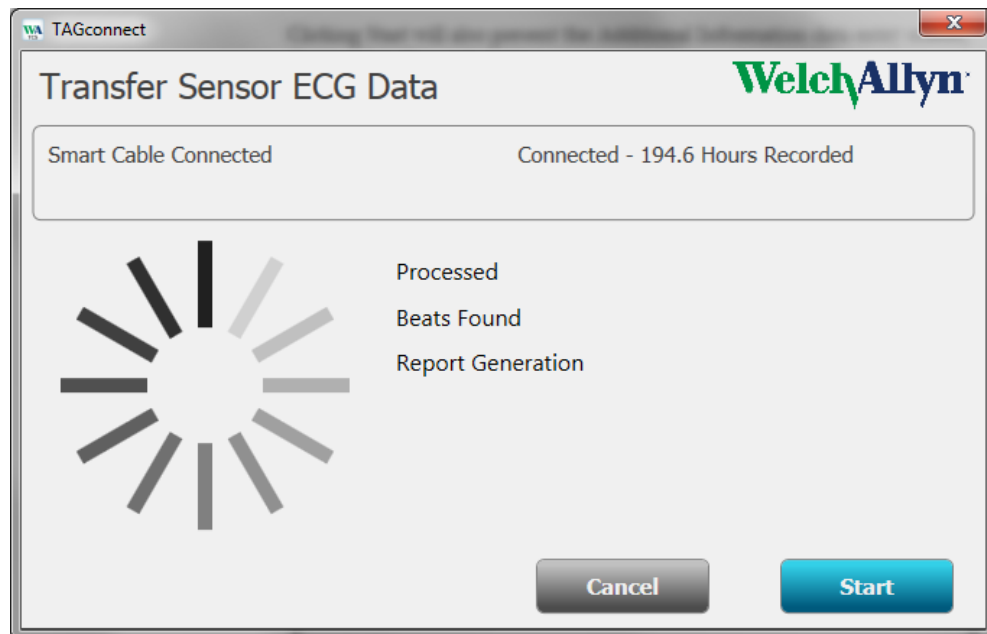
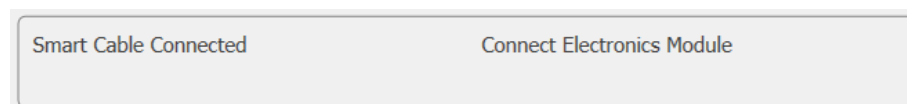
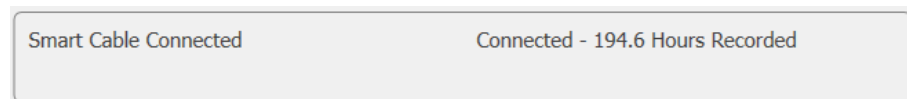


Figure 5.4. Transfer Sensor ECG Data screen.

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.

5.2.3 Demographic and Diary Data Entry

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

The screenshot shows the 'Additional Information' screen with the following data entered:

- Last Name (Required): Johnson
- First Name (Required): James
- Patient ID #: (Empty)
- Gender: Male Female
- Date of birth (Required): 04/08/1947
- Recording start date (Required): 06/11/2018
- Recording start time (Required): 9:15 AM
- Sleep: 11:00 PM
- Wake: 7:00 AM
- Primary indication: Shortness of breath
- Prescribing clinician: Dr. Smith
- Prescribing clinician's managing location: Eastlake Clinic
- Summary report title: Ambulatory ECG Cardiac Monitoring

At the bottom, there is a 'Patient diary' button, a 'Cancel' button, and a 'Done' button. A table for 'Patient Diary Entries' is also visible but empty.

Figure 5.5. 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. TAGconnect examines heart rates 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 Sleep and Wake times to 12:00 AM will remove the sleep/wake analysis – see Section 5.2.4 below.

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.

The screenshot shows a software window titled "Diary Entry: Johnson, James" with the WelchAllyn logo in the top right. The window contains several input fields: "Date" (MM/DD/YYYY) with the value "06/12/2018", "Time" with a dropdown menu showing "7:45 AM", and "Duration (min)" with the value "5". There is also a checkbox labeled "Button Press" which is checked. Below these fields are two text input areas: "Symptoms" containing the text "Palpitations" and "Activity" containing the text "Walking upstairs". At the bottom right of the window are two buttons: "Add" and "Done".

Figure 5.6. 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”.

TAGconnect 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 5.7 below.

Additional Information WelchAllyn

Last Name (Required) First Name (Required) Patient ID #

Gender: Male Female Date of birth MM/DD/YYYY (Required)

Recording start date MM/DD/YYYY (Required) Recording start time (Required)

Slumber Sleep Wake

Primary indication

Prescribing clinician

Prescribing clinician's managing location

Summary report title

Patient Diary Entries

Date	Time	Duration	Symptoms	Activity	Button Press
06/12/2018	07:45 AM	5	Palpitations	Walking upstairs	Yes

Figure 5.7. 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. TAGconnect has been busy working in the background processing the ECG data and will likely be ready to incorporate the patient information into the draft final report.

5.2.4 Draft Final 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 5.8.

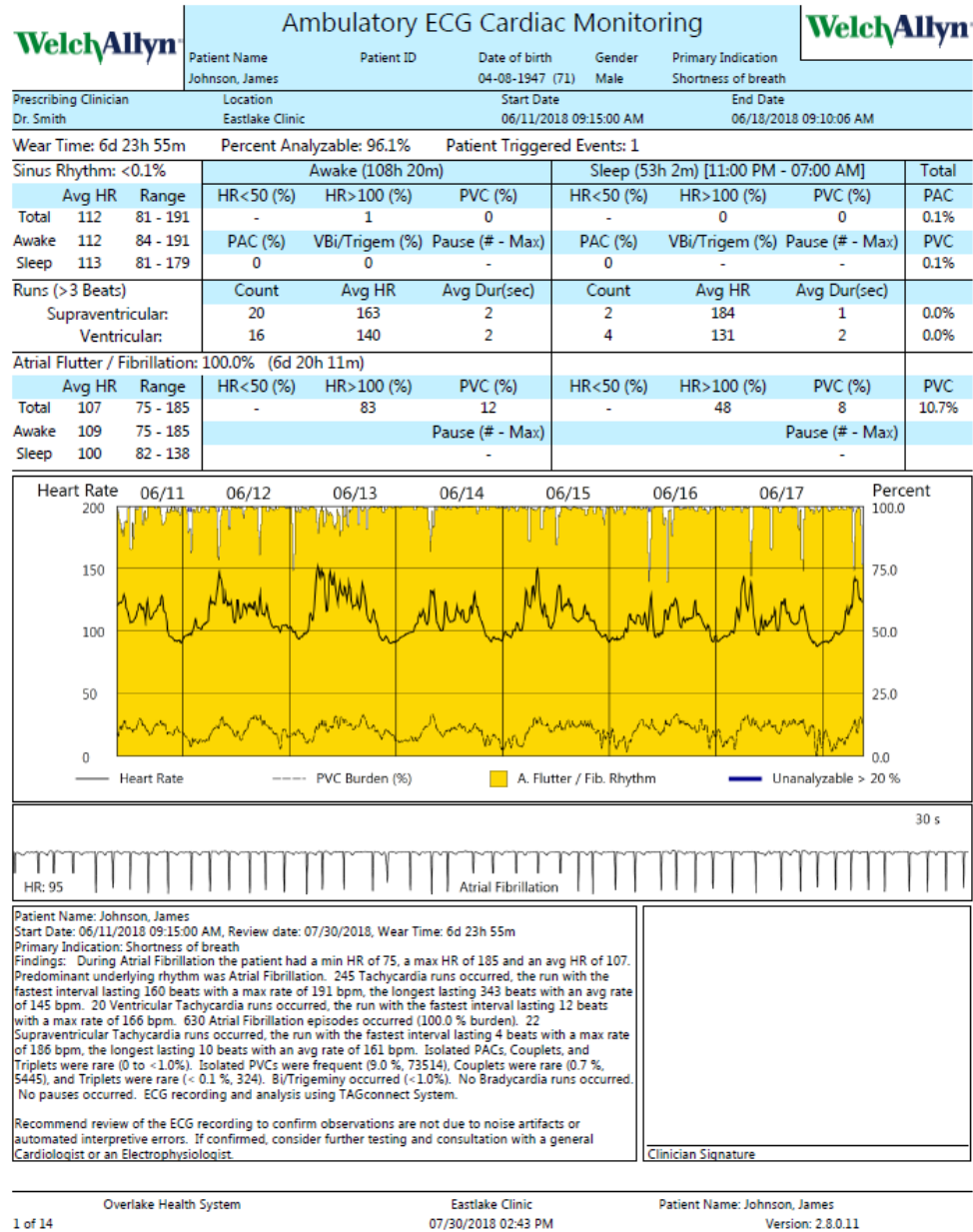


Figure 5.8. Example first page of a draft PDF report. The Initial Findings (left box at the bottom) and the clinician’s diagnosis (right box at bottom) may be edited – see Edit Dx in Section 6.3 below).

The report is structured as follows:

Header. Patient demographic information, Primary Indications for the reason the test was ordered, the prescribing physician and recording period, along

with the total wear time, percent analyzable ECG and number of patient triggered events are summarized at the top of the report.

Rhythm Summaries. The rhythm summaries are divided into several components:

- Sinus Rhythms
- Ventricular and Supraventricular runs.
- Atrial Flutter / Fibrillation
- Awake versus Sleep

For each summary the following additional information is provided:

- Heart rate average and range (beats per minute), total for the summary and for Awake (A) and Sleep (S) periods.
- HR < 50 BPM – Bradycardia. The percentage is based upon the duration of bradycardia relative to the period, e.g. 1 hour of bradycardia during 16 hours of awake time would be reported as 6%.
- HR > 100 – Tachycardia. Percentage based upon duration.
- PVC (%). Ventricular burden as a percentage of beats (# ventricular beats / total # of beats), excluding VT runs.
- PAC (%). Percentage of beats that are premature atrial contractions, excluding SVT runs.
- Bi/Trigem (%). Percentage duration of the time the patient was in either bigeminy or trigeminy. Note: The ventricular beats in these rhythms are also included in the reported PVC (%).
- Pauses (# - Max). The number of pauses observed and the maximum duration. Note: Pauses are counted when the pause is greater than 2.5 sec.

Graphical Trend Report. The graphical summary provides 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 ECG record window of 10 minutes: % Atrial Flutter / Fibrillation, % Normal Rhythms, and % Unanalyzable record (typically related to motion artifact induced noise). Time intervals where the unanalyzable percentage is greater than 20% is indicated by a blue bar at the top of the graph. Drawn over the graph is the smoothed average heart rate (solid line) with heart rate axis 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.

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; Ventricular Tachycardia; Bigeminy; Trigeminy; Supraventricular Tachycardia; Bradycardia; Tachycardia;

Normal Rhythm. Rhythm strips are added to later pages of the report for all conditions detected.

Initial Findings. A paragraph is added to the report that summarizes all of the key initial findings.

Recommendation. Initial Findings may trigger the addition of a recommendation:

“Recommend review of the ECG recording to confirm observations are not due to noise artifacts. If confirmed, consider further testing and consultation with a general Cardiologist or an Electrophysiologist.”

This recommendation is added when any of the following conditions are detected with a frequency of half or more of the recording days (e.g. in a 6 day recording, if any of the following were detected on 3 or more days):

1. Two or more Atrial fibrillation episodes lasting 30 sec or longer.
2. PVCs greater than 5%
3. PACs greater than 10%
4. Two or more VT episodes longer than 5 beats
5. Two or more SVT episodes longer than 20 beats
6. Two or more pauses longer than 3.5 sec.
7. HR > 110 BPM for four or more hours during Wake
8. HR < 40 BPM for four or more hours during Wake.
9. HR > 90 BPM for two or more hours during Sleep.
10. HR < 30 BPM for two or more hours during Sleep.

Note: If the user sets Wake and Sleep times to 12:00 AM, conditions 7 – 10 are omitted.

6 TAGconnect – 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 report. Following presentation of the draft PDF report, TAGconnect will present a menu of options to support interactive review and any required edits of the summary finding, Figure 6.1.

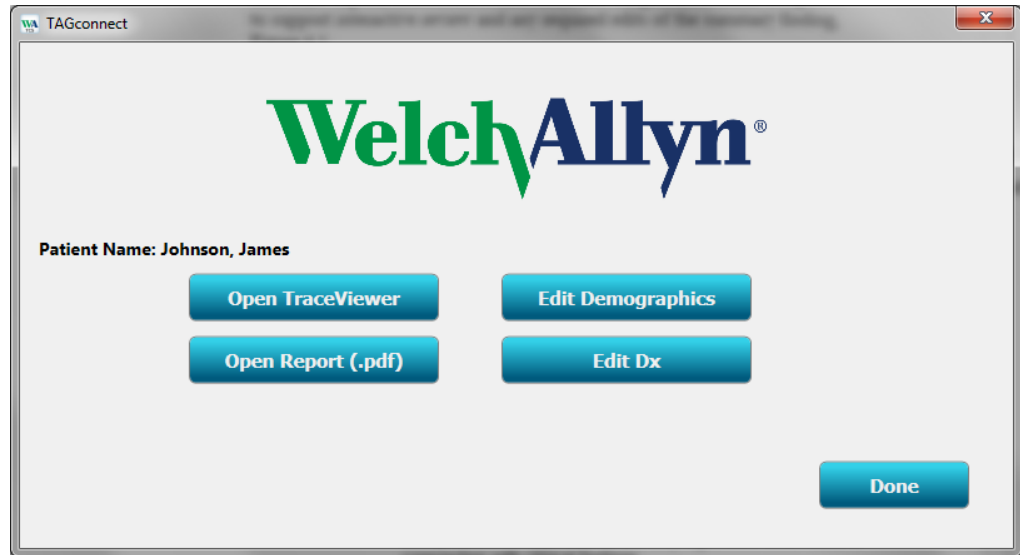


Figure 6.1. Report Review Options menu.

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

Pacemaker. Automatic interpretations derived from paced ECGs are NOT valid.

6.1 ECG Trace Review

The ECG Trace Viewer has been designed to support rapid access (3 mouse clicks) to any 10 second strip in the entire recording. Clicking on the ECG Trace Review button, Figure 6.1, presents the Trace Viewer, Figure 6.2.

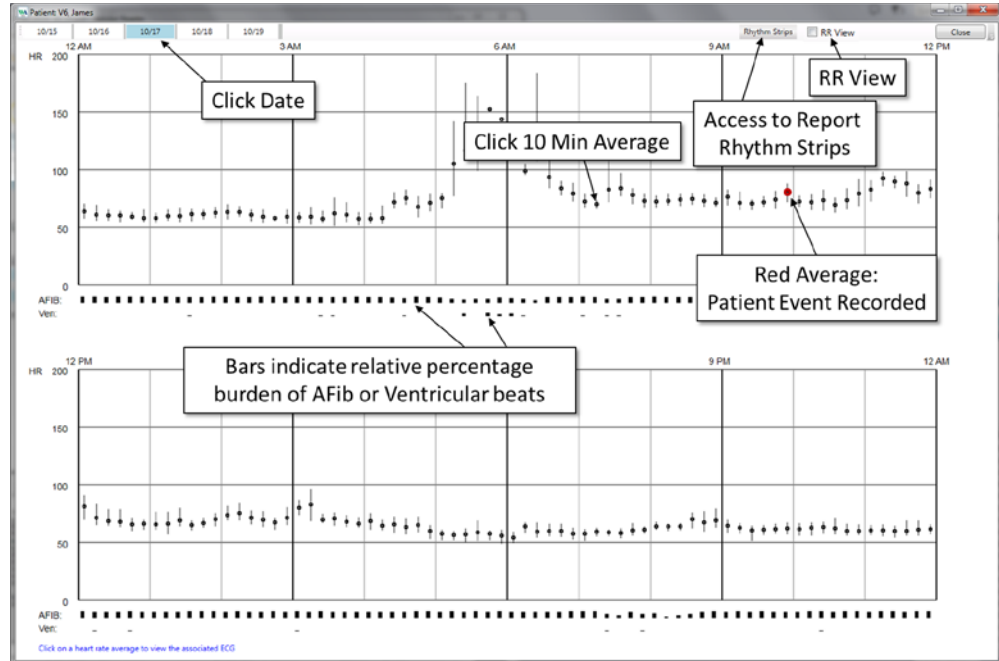


Figure 6.2. Trace Viewer, day averages view.

The panels in Figure 6.2 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 TAGconnect thinks something of interest is occurring. The Rhythm Strips button, top right, provides direct access to the point in the ECG full disclosure where each Report Rhythm Strip is located, supporting rapid review of the data included in the Report.

Clicking the “Close” button on the top right will close the Trace Viewer and return to the Report Review Options menu, Figure 6.1.

RR View. Clicking the “RR View” checkbox, upper right in Figure 6.2, replaces the average 10 minute heart rate symbols with the heart rate plotted for every individual beat, Figure 6.3 below. 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. As above, clicking on any point in the display triggers the display of the associated 10 minute ECG traces.

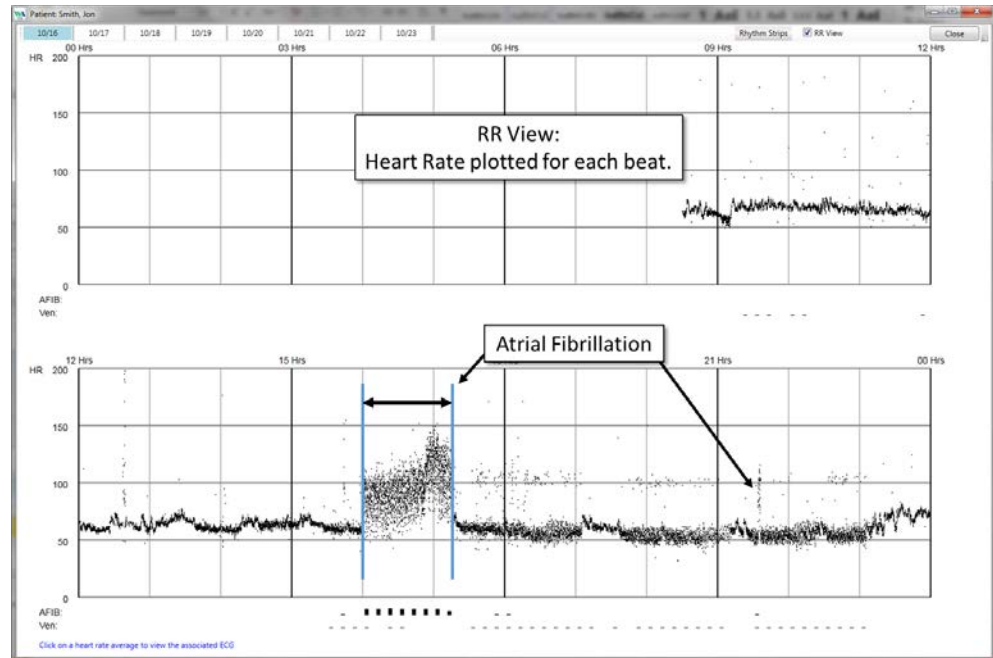


Figure 6.3 RR View showing heart rate for every RR interval.

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

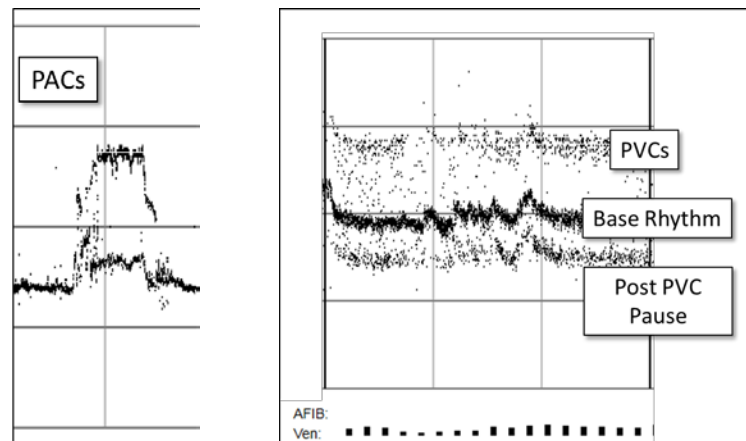


Figure 6.4 Example RR plots for premature atrial contractions (PACs) and premature ventricular contractions.

Clicking on either the 10 minute averages (Figure 6.2) or RR View data (Figure 6.3) presents the 10 minute ECG record for the average, Figure 6.5.

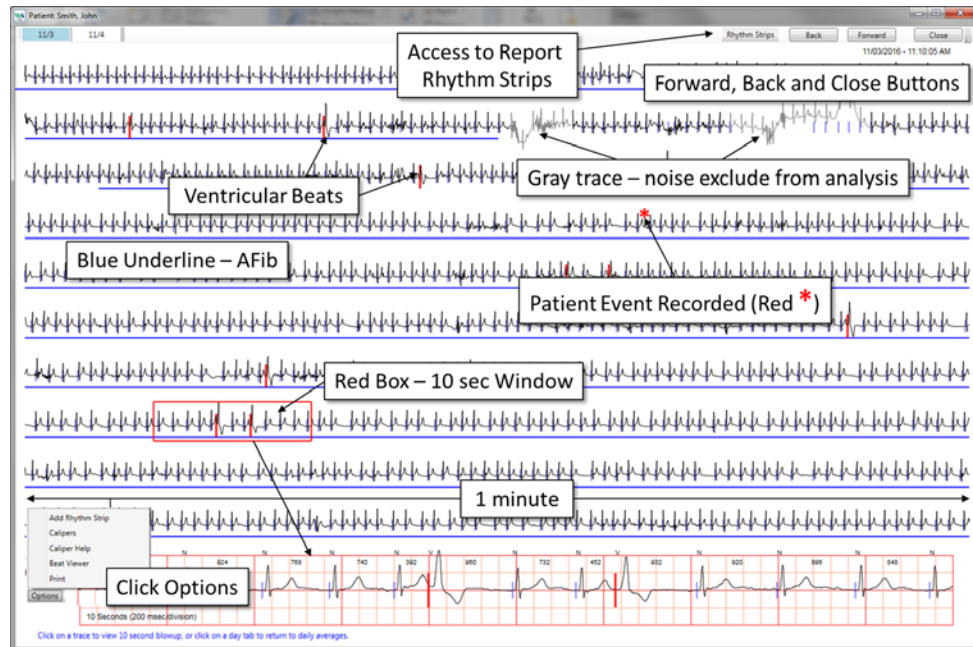


Figure 6.5. 10 Minute Trace Viewer.

On the top right of the screen are the “Forward”, “Back” buttons. Clicking Forward or Back will advance or decrement the time view by 10 minutes.

To the left of the Forward and Back buttons is the Rhythm Strip button. Clicking on the button will display a menu of rhythm types (Atrial Fibrillation, Pauses, Ventricular Tachycardia, etc.). Selecting a rhythm will next display the associated rhythm strips that are included in the report (e.g. AF_Highest_Max for the atrial fibrillation rhythm strip associated with the highest heart rate). The F5 key will automatically advance through the list and the F6 key will return to the previous strip displayed for the selected rhythm.

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.

TAGconnect 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.

Add Rhythm Strips: Clicking Options / Add Rhythm Strips (lower left on Figure 6.5) displays the tool for adding rhythm strips to the final PDF report.

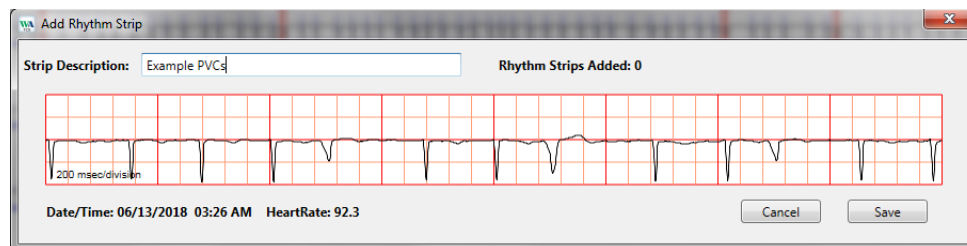


Figure 6.6. Add Rhythm Strips.

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 Trace Viewer window, TAGconnect will automatically update the PDF report and add all of the selected rhythm strips in chronological order.

Calipers: Clicking Options / Calipers (lower left on Figure 6.5) 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:

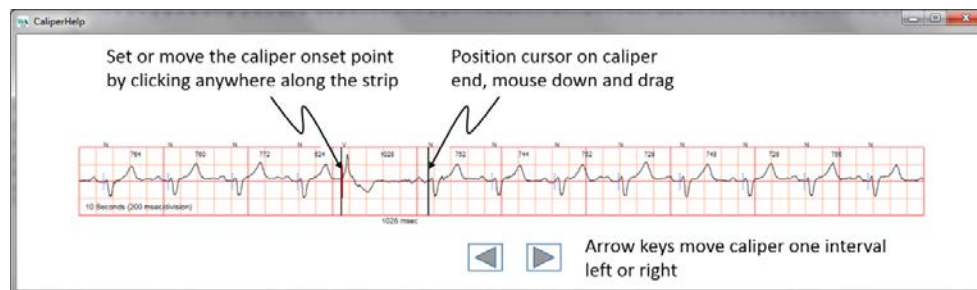


Figure 6.7. Caliper Help window.

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.

Beat Viewer: Right-clicking the mouse at any location in the 10 minute ECG Trace View display, or selecting Beat Viewer from the Options button on the lower left of Figure 6.5, will present an average beat waveform viewer, constructed from the dominant beats in the vicinity of the mouse click:

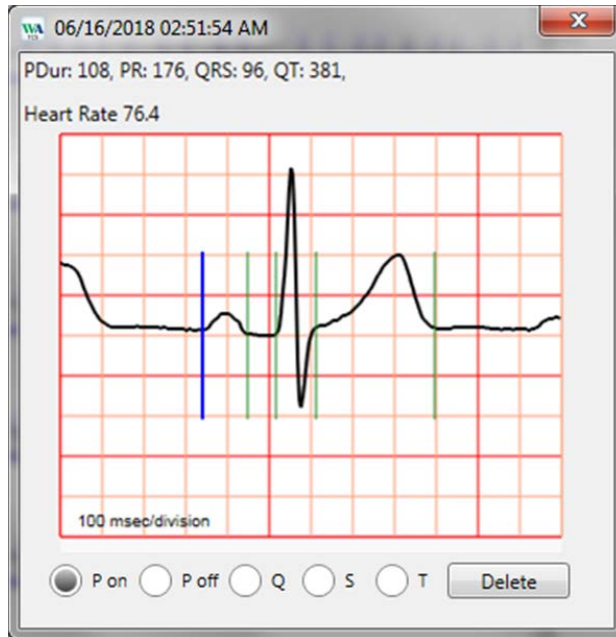


Figure 6.8. Beat Viewer.

The phases P-onset, P-offset, 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 Trace View window), every subsequent click at any point in any 10 minute Trace View 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").

Print: Clicking Options / Print (lower left on Figure 6.5) will print the current ten second rhythm strip to a standard Windows connected printer.

6.2 Edit Demographics

The “Edit Demographics” button shown in Figure 6.1 will re-open the Additional Information screen – see Section 5.2.2 – restoring 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. Clicking the “Done” button, Figure 5.7, will start the report generation process, concluding with the presentation of the updated PDF report.

6.3 Edit Dx

TAGconnect automatically creates a summary paragraph of the Initial Findings. As you review the trace data, you may wish to review and edit the summary findings (see Report Figure 5.8 above), or add concluding remarks, diagnosis or recommendations in the clinician’s interpretation window. To edit these fields, click the “Edit Dx” button, Figure 6.1. TAGconnect will present a text editing window, Figure 6.9.

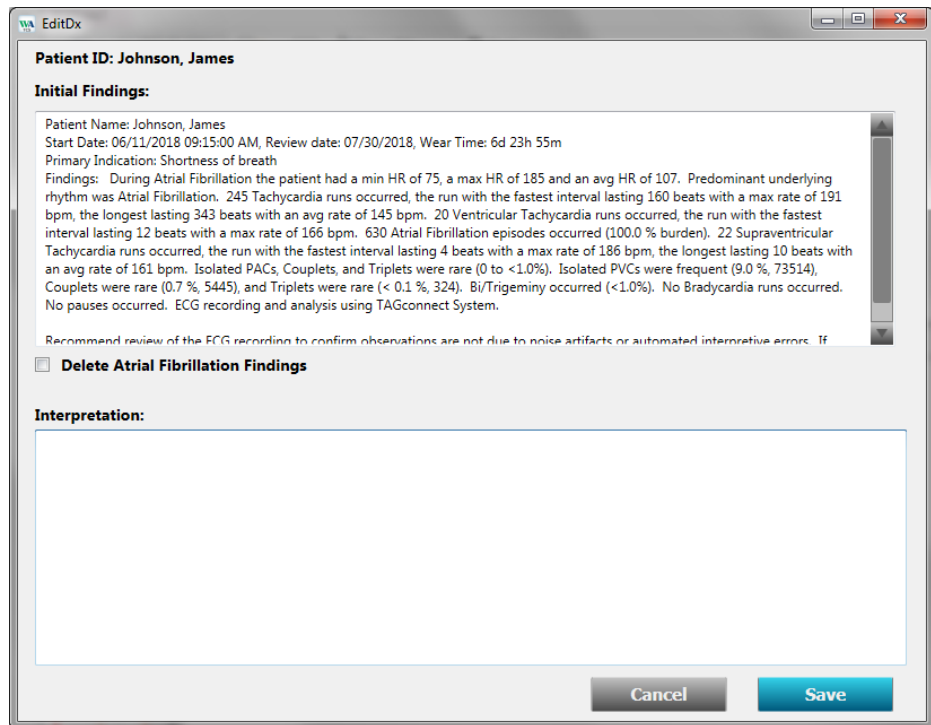


Figure 6.9. Edit Dx window.

6.3.1 Delete AFib Findings

An Initial Finding of Atrial Fibrillation (AFib) is a very significant clinical finding. Although TAGconnect has a very high Sensitivity and Positive Predictive Value for AFib, 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 Trace Viewer. Complex atrial rhythms can be precursors to AFib.

If the Initial Findings are a false positive for AFib, clicking the “Delete Atrial Fibrillation Findings” checkbox and then clicking Save will re-create the report, excluding AFib. TAGconnect will post a confirmation window to confirm you intend to delete ALL AFib findings. Deleted AFib findings can only be restored by re-processing the raw data from the Sensor’s Electronics Module. Refer to Section 5.

NOTE: All of the Initial Findings text will be replaced, and Interpretation deleted, following re-creation – any edits made will be replaced with the updated findings. Edits and added Interpretations should follow deletion of AFib.

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

6.4 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 6.1. TAGconnect will re-open the report.

6.5 Report Completion

When you have finished your review, and possibly updated the final report, click “Done”. TAGconnect will return you to the User Option Menu screen, Figure 5.2, ready to process another patient’s Sensor data.

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

The User Menu Options screen, Figure 5.2, supports user access to previously created final 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.

7.1 Previous Reports - PDFs

Clicking on the “Open Report (.pdf)” button will display a list of previous reports, Figure 7.1.

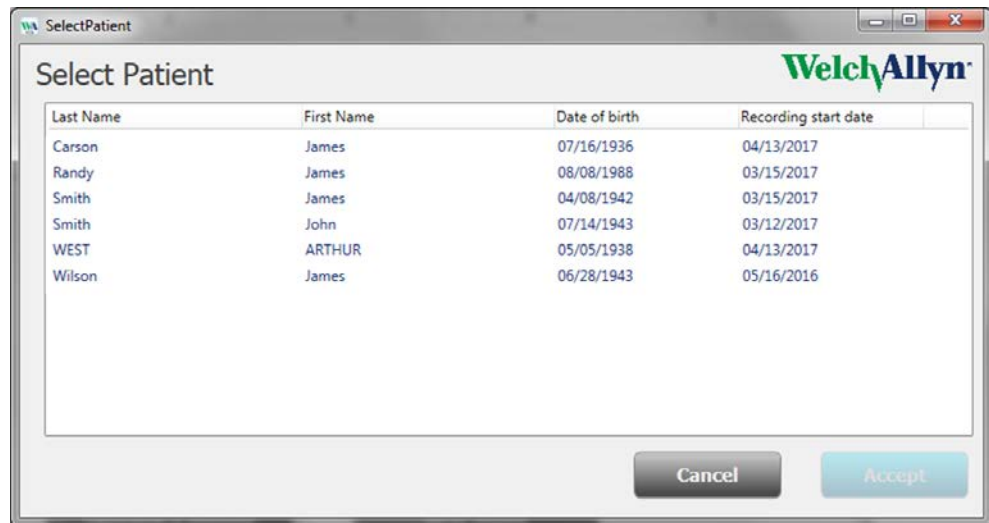


Figure 7.1. Select / Display previous final reports.

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.

7.2 Previous Reports – Full Disclosure ECG

Clicking the “Open TraceViewer” button will present a patient report selection window, see figure 7.1 above. Selecting a patient will next display the full disclosure information in TraceViewer, see Section 6.1 ECG Trace Review above. Additional rhythm strips can be added to the final report, following the instructions in Section 6.1 above.

7.3 Previous Reports – Edit Dx

Clicking the “Edit Dx” button will present a patient report selection window, see figure 7.1 above. Selecting a patient will next display the Edit Dx window, see Section 6.3 Edit Dx above. The Initial Findings and Clinical diagnosis or notes may be entered.

NOTE: Deleted AFib 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 5.

7.4 Operator's Manual

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

7.5 Help About

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

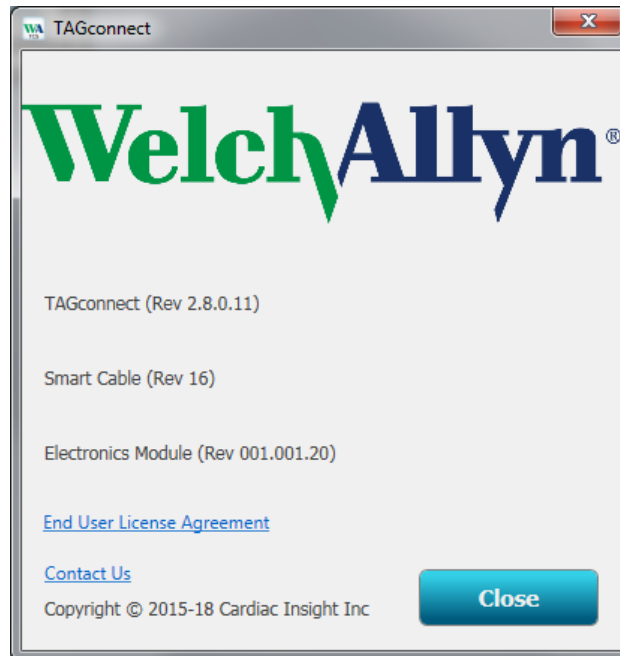


Figure 7.2. Help About screen.

The first line provides the software release level for TAGconnect (in the above, Rev 2.8.0.11). 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 Welch Allyn.

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 Welch Allyn. The PC must be connected to the Internet.

The Welch Allyn URL is: www.welchallyn.com

7.6 Cohort Reporting

Clicking the Excel Summary button 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). TAGconnect 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)
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

Field	Description
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
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

Field	Description
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
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

Field	Description
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
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

8 System Characteristics

The following information is provided to assist the clinician to more fully understand the characteristics of the TAGecg System that transform electrode potentials into ECG tracings and beat and rhythm findings.

8.1 System Bandwidth and Baseline Wander Filtering

The Sensor electronics digitizes the ECG voltages at 250 samples/sec at a resolution of 0.77 μ Volt. 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, TAGconnect 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.

8.2 AC Line Filtering

TAGconnect 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.

8.3 Beat and Rhythm Sensitivity and Positive Predictive Value

The performance characteristics of the ECG algorithms within TAGconnect 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.

9 Maintenance

9.1 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 Welch Allyn 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.

9.2 Returning products

When returning a product to Welch Allyn for service, ensure that you have the following information:

- Product name, lot number, and serial number. This information may be found on the product packaging.
- A complete return shipping address.
- A contact name and phone number.
- Any special shipping instructions.
- A purchase-order number or credit-card number if the product is not covered by a warranty.
- A full description of the problem or service request.

Contact Welch Allyn and request a Return Material Authorization (RMA) number.

NOTE: Welch Allyn does not accept returned products without an RMA.

WARNING Safety risk. Do not ship any battery that has been physically damaged or shows signs of leakage unless you receive specific instructions which meet the requirements for the shipment of Lithium batteries. Dispose of damaged or leaking batteries in an environmentally safe manner consistent with local regulations.

NOTE: In the United States, the applicable regulations can be found in the Code of Federal Regulations (CFR). Refer to 49 CFR 173.185 for shipping lithium batteries by air or ground. Use 49 CFR 172.102 sections 29, 188, 189, A54, A55, A100, A101, A103, and A104 to find the special provisions for shipping lithium batteries.

NOTE: To ensure safe receipt of your device by the service center and to expedite processing and return of the device to you, **thoroughly clean all residues from the device before you ship it to Welch Allyn.** United States federal regulations prohibit the processing of any device contaminated with blood-borne pathogens. Welch Allyn thoroughly cleans all returned devices on receipt, but any device that cannot be adequately cleaned cannot be repaired. Put the device, enclosed in a plastic bag **with a packing list**, into the original shipping carton with the original packing materials or into another appropriate shipping carton. Write the Welch Allyn RMA number with the Welch Allyn address on the outside of the shipping carton.

10 EMC Declaration Tables – Smart Cable, Sensor

The TAGecg System is intended for use in the electromagnetic environment specified below:

10.1 Electromagnetic Emissions

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

10.2 Electromagnetic Immunity for Sensor

Immunity Test	Basic EMC Standard or test method	Immunity Test Levels for Home Healthcare Environment from IEC 60601-1-2:2014																																																																
Electrostatic discharge (ESD)	IEC 61000-4-2	±8 kV contact ±15 kV air																																																																
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz																																																																
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	<table border="1"> <thead> <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> </thead> <tbody> <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> </tbody> </table>	Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1,8	0,3	27	450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0,3	28	710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9	745	780	810	800 – 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0,3	28	870	930	1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0,3	28	1 845	1 970	2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0,3	28	5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9	5 500	5 785
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Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50Hz and 60Hz																																																																

10.3 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 TAGconnect is used exceeds the applicable RF compliance level above, then TAGconnect should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating TAGconnect.

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.

10.4 Recommended Separation Distances

The following table provides the recommended separation distances between portable and mobile RF communications equipment and the TAGecg System.

The TAGecg System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TAGecg System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment

(transmitters) and the TAGecg 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.

10.5 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 generates, uses and 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

10.6 Operational Environment - Sensor

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

Humidity: 10% to 95%

Ingress of Solids and Liquids: EN 60529:1991, Level IPX7 (protected against the effects of temporary immersion in water)

10.7 Storage Environment - Sensor

Temperature: 0° C to 50° C (32° F to 122° F)

Humidity: 10% to 95% RH