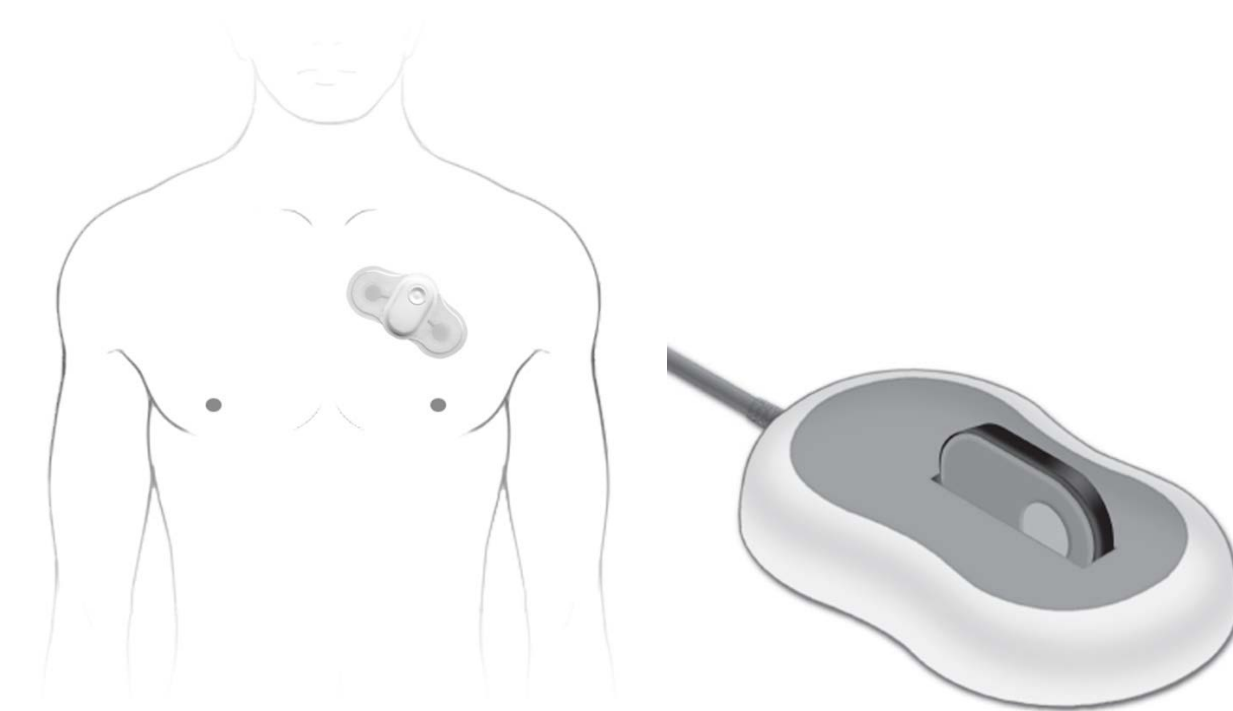




TAGconnect™ Software Quick Start Guide



Ambulatory ECG System with Analysis Software



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

Refer to Operator's Manual and other product documentation for additional information and specifications. Welch Allyn reserves the right to make changes in specifications and features shown herein at any time and without notice or obligation.

Overview

Welcome to TAGconnect™ Software

Thank you for your recent purchase.

Welch Allyn is dedicated to helping save lives through cardiovascular research and product innovation. With a mission to provide affordable, high quality ECG systems, Welch Allyn developed the TAGecg System and the TAGconnect PC Software to help clinicians characterize heart rates and rhythms over a 7 day recording period using a comfortable and light-weight wearable Sensor. The TAGconnect provides computer-assisted interpretation of the ECG recording and simple-to-use tools for rapid review of the ECG trace data and editing of the initial findings.

Delivery

- | | |
|---|--|
| TAGconnect Software Blister Pack | – TAGconnect Setup and Installation software (Flash Drive) |
| TAGecg Smart Cable Shipping Carton | – Following wear, the Electronics Module is removed from the Sensor and connected to a Windows PC using the Smart Cable. |

Available at www.welchallyn.com/TAGecgSetup

- | | |
|------------------------------|--|
| Quick Start Guide | – (this document) Overview of TAGconnect Software, simplified use instructions |
| Troubleshooting Guide | – Guidance information for addressing problems should they arise |

The purpose of the Quick Start Guide is to provide an overview of the TAGconnect Software. It includes instructions on how to transfer and analyze data from the TAGecg Wearable Sensor.



CAUTION

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

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.

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.

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 interfere with the analysis of the ECG and may 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

System Setup

PC Requirements

- Windows® 7 or higher compatible PC
- 2 GB of free disk space or greater
- Dual Core CPU @ 2.5 GHz or greater, 32-bit (x86) or 64-bit (x64) processor or equivalent
- 1300 x 768 or higher resolution Display
- Minimum 4 GB of system memory
- Windows® compatible pointing device (mouse)
- Windows® compatible keyboard
- 1 available High Speed USB 2.0 port

Software Installation

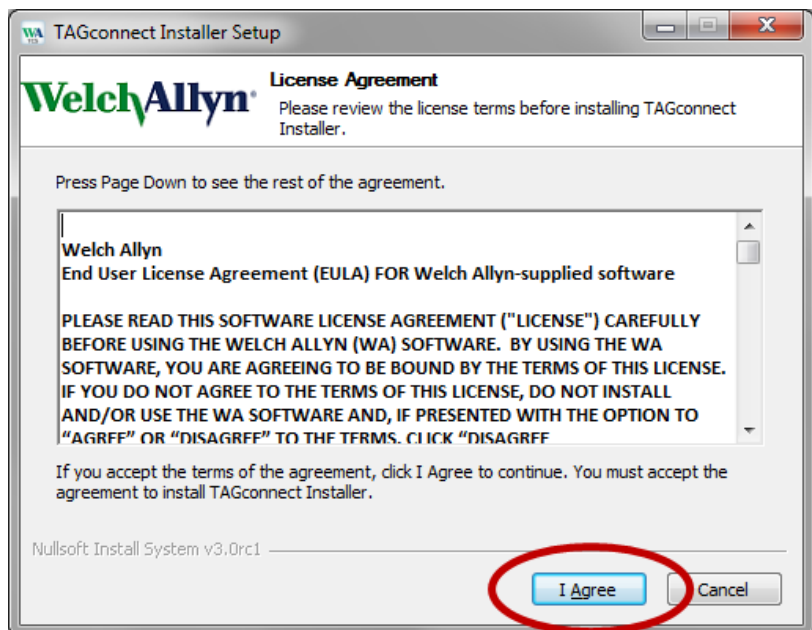
Note: Software installation on a Windows PC generally requires Administrator privileges – see your IT staff. The Operator's Manual, available as a PDF on the software Flash Drive, provides additional information for System setup and configuration.

Step 1 Insert the **TAGconnect Software** Flash Drive into the USB port on the PC.

Step 2 Double click “TAGconnect Setup”.

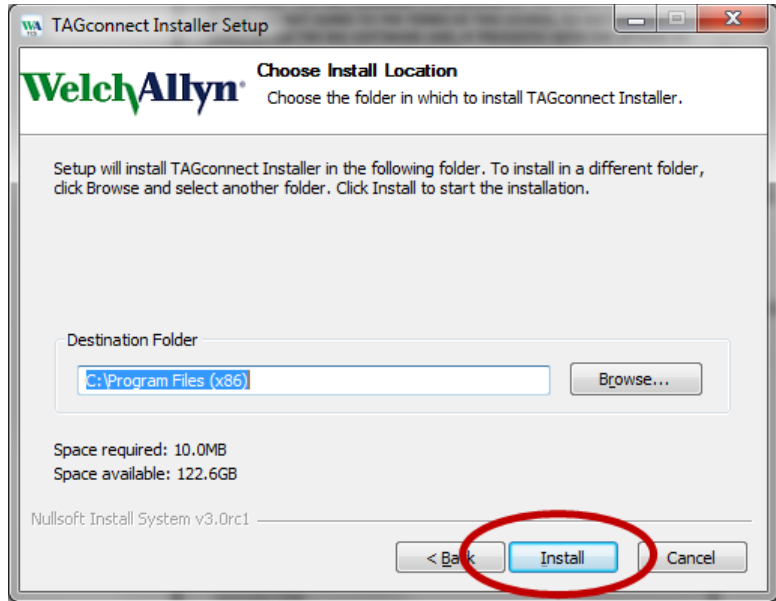
Review the License Agreement.

Select “**I Agree**” to continue the installation.



Step 3 Choose the install location and click **Install**.

Setup will install the software and confirm installation is complete.



Administrative Setup

Step 1 On the PC desktop double-click the **TAGconnect** icon:



Enter and confirm an Admin Password and click **Login**.



- Step 2** Setup System Administration items, including institution (company) name and logo.

Custom logo will appear in the upper right corner on the 1st page of the Summary Report & the custom company name will appear in the footer.

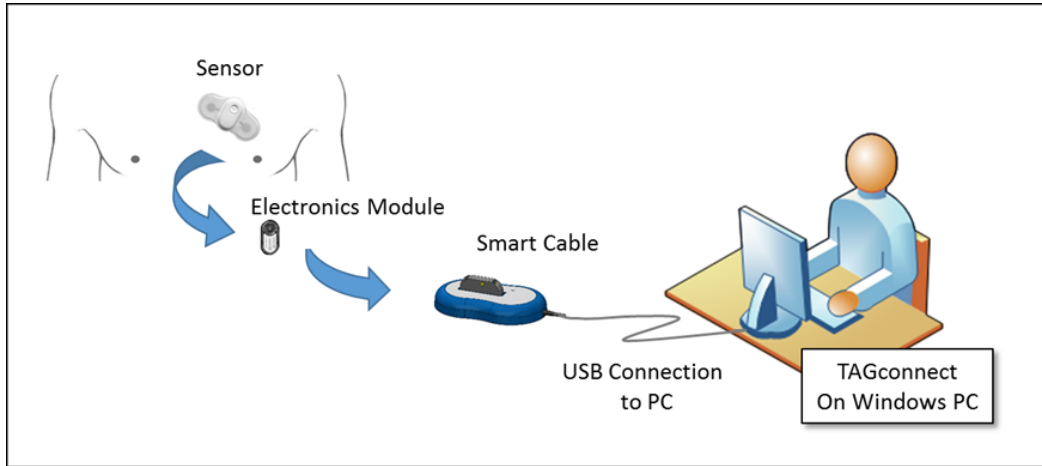
Refer to Operator's Manual, Section 4.1.

- Step 3** Setup individual User Profiles.

Prescribing clinician, Report Title, & Managing Location will appear as defaults on the "Additional Information" screen when creating a Summary Report.

Refer to Operator's Manual, Section 4.2.

Using the System



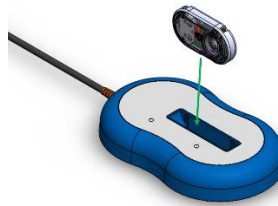
Components & Data Processing

Step 1 Connect the Smart Cable to the PC.

The LED next to the computer icon  on the Smart Cable will illuminate green.

Step 2 Insert Electronics Module into Smart Cable cradle.

The LED next to the Electronics Module icon  will illuminate green.

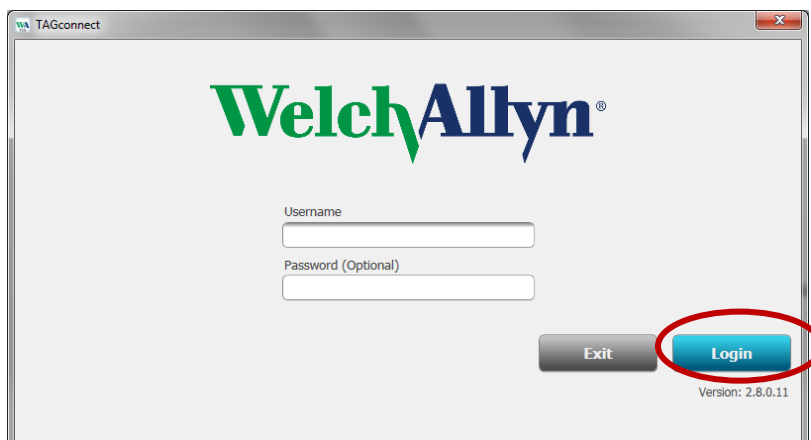


Step 3 On the PC desktop double-click the **TAGconnect** icon:

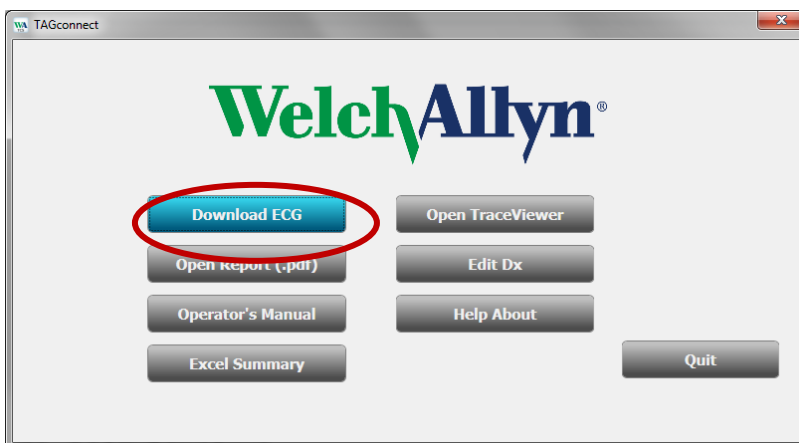


Enter Username
(refer to
Administrator
Setup).

Click **Login**.



Step 4 Click **Download ECG**.



Step 5 Enter “Additional Information”.

Enter the patient information.

Enter specific sleep & wake times if ECG analysis is desired for periods of Slumber other than the shown defaults.

Note the required information fields.

Additional Information

WelchAlllyn

Last Name (Required): Johnson First Name (Required): James Patient ID #

Gender: ☒ Male ☐ Female Date of birth MM/DD/YYYY (Required): 04/08/1947

Recording start date MM/DD/YYYY (Required): 06/11/2018 Recording start time (Required): 9:15 AM

Slumber 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

Patient Diary Entries

Date	Time	Duration	Symptoms	Activity	Button Press

Buttons: Patient diary, Cancel, Done

Step 6 Enter “Patient Diary” information.

Click **Add** after each entry and to continue with Diary entries. Click **Done** when all entries are complete.

Diary Entry: Johnson, James

WelchAlllyn

Date MM/DD/YYYY: 06/12/2018 Time: 7:45 AM Duration (min): 5 ☒ Button Press

Symptoms: Palpitations

Activity: Walking upstairs

Buttons: Add, Done

Step 7 Click **Done**.

Additional Information

WelchAlllyn

Last Name (Required): **Johnson** First Name (Required): **James** Patient ID #

Gender: ☒ Male ☐ Female Date of birth MM/DD/YYYY (Required): **04/08/1947**

Recording start date MM/DD/YYYY (Required): **06/11/2018** Recording start time (Required): **9:15 AM**

Slumber: 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**

Patient Diary Entries

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

Buttons: Patient diary, Cancel, Done

Step 8 No User action required.

TAGconnect Software finalizes data transfer, rhythm analysis and presents the draft PDF report.

Refer to "Example of 1st Page of Draft Report", page 11.

Transfer Sensor ECG Data

WelchAlllyn

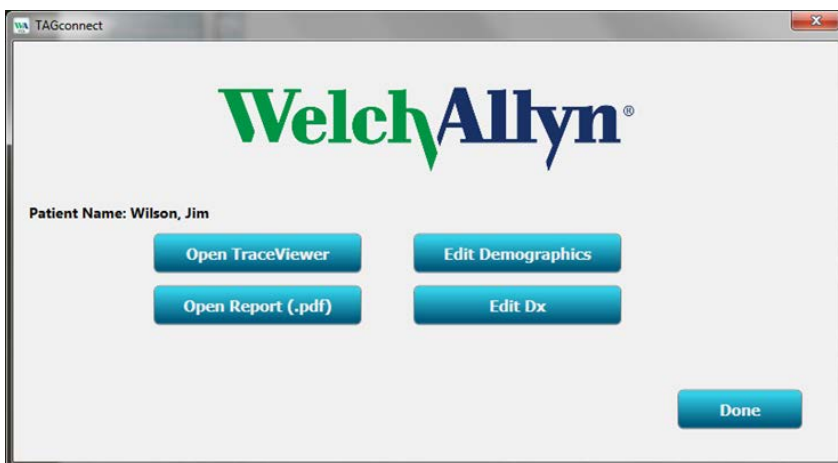
Smart Cable Connected Connected - 194.6 Hours Recorded

Hours Processed: 96
Beats Found: 306088
Report Generation - Adding:

Buttons: Cancel, Start

Step 9 Review Draft Report using available menu options.

The term “Draft Report” is used until the reported results are reviewed and confirmed by a clinician.

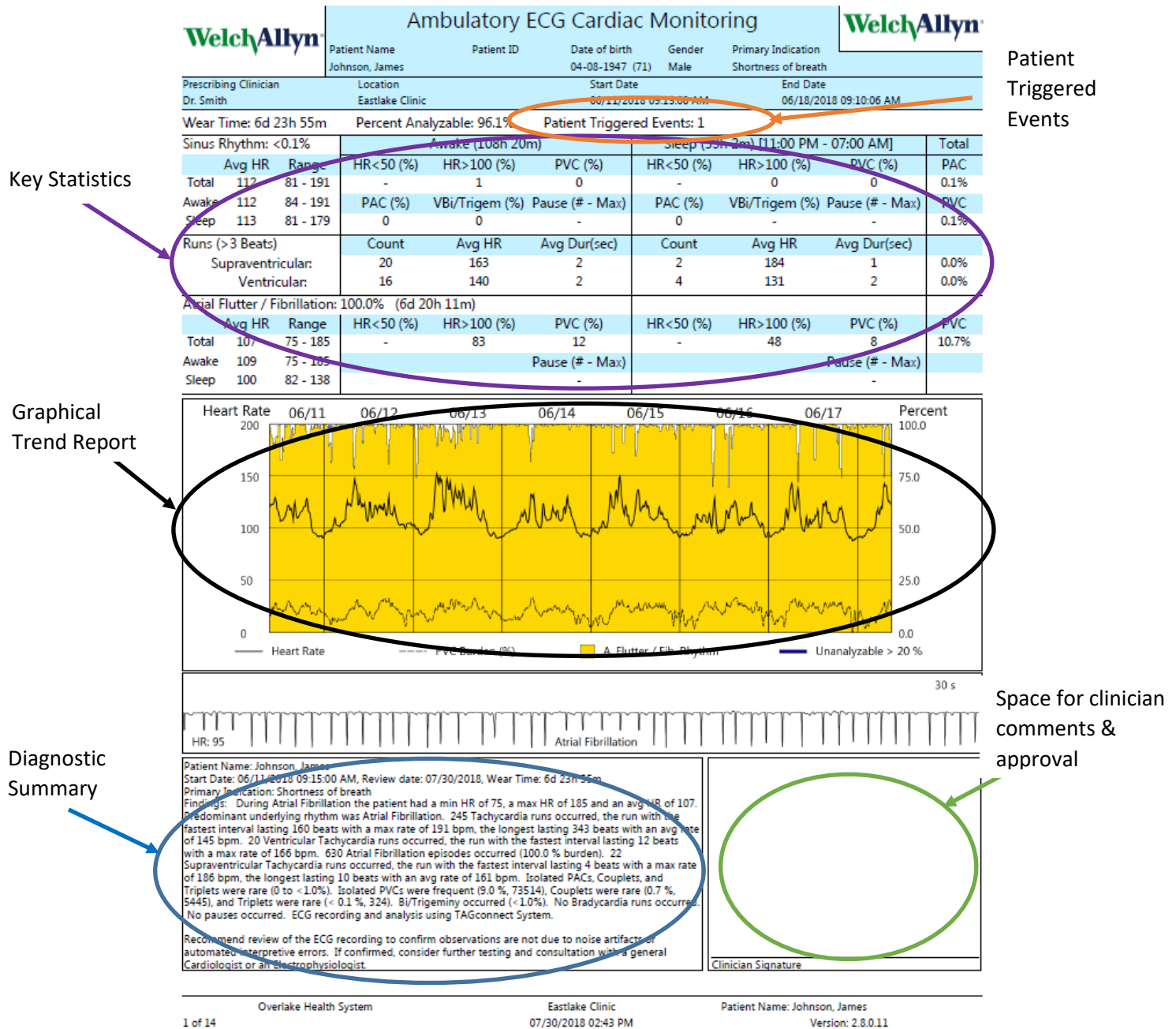


TAGconnect Software presents a menu to support trace review and editing of the **Diagnostic Summary** section findings.

Refer to the Operator's Manual for more information on these features.

The Operator's Manual is accessible from **TAGconnect Software** main menu **Help About** – shown in “Using the System” Step 4, page 7.

Example of 1st Page of Draft Report



CUSTOMER SUPPORT

Distributed by:

Welch Allyn, Inc.

4341 State Street Road

Skaneateles Falls, New York 13153 USA

WEBSITE: WWW.WELCHALLYN.COM

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CARDIAC INSIGHT, INC.

KIRKLAND, WASHINGTON 98033

USA

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