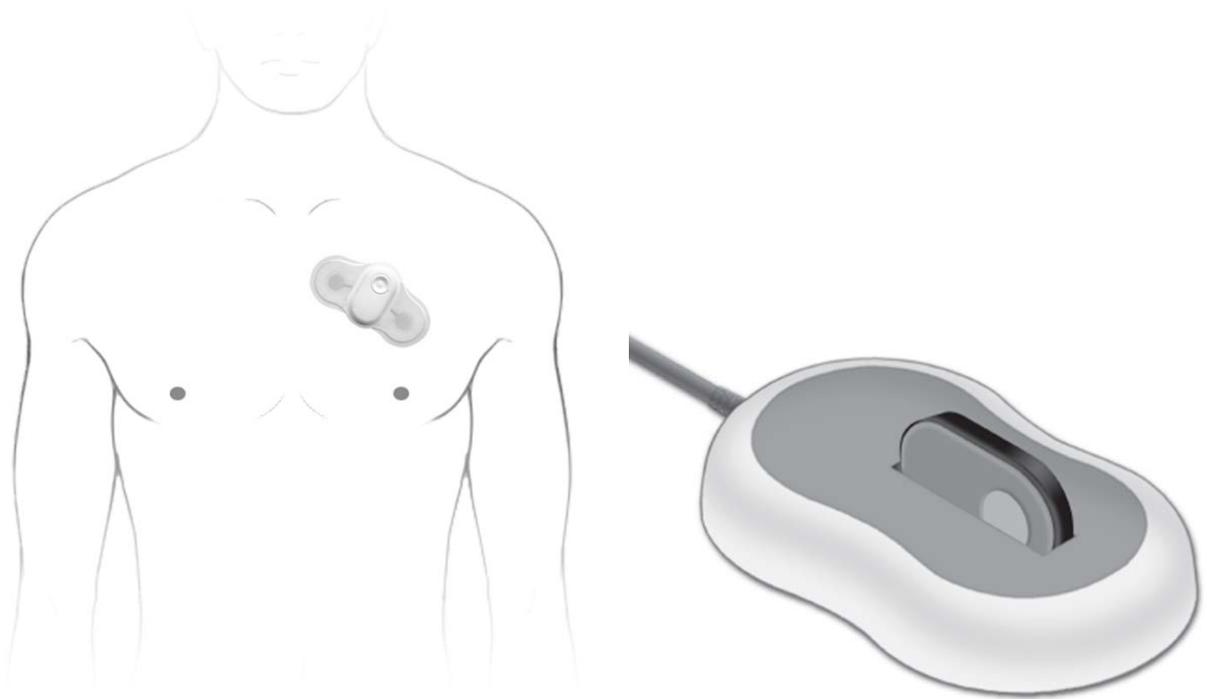# WelchAllyn®

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
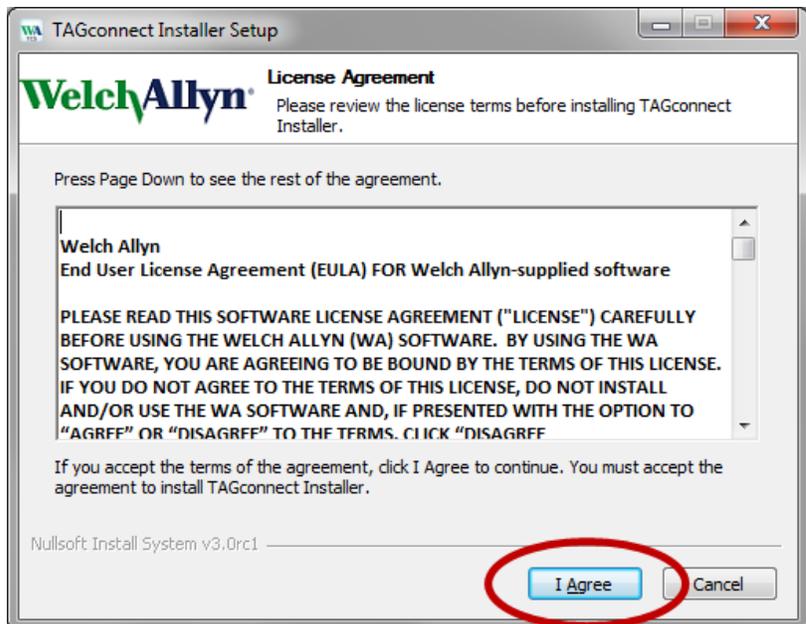
Software Installation

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.

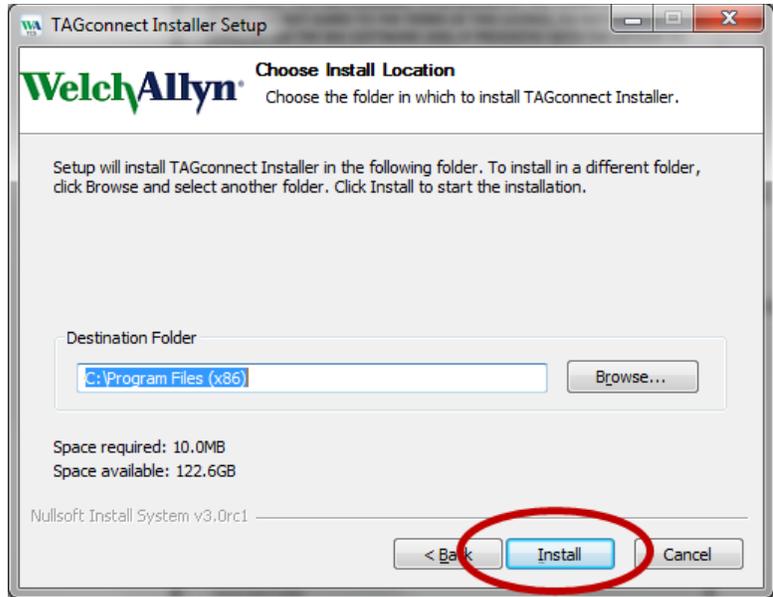**Step 2** Double click "**TAGconnect Setup**".

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-
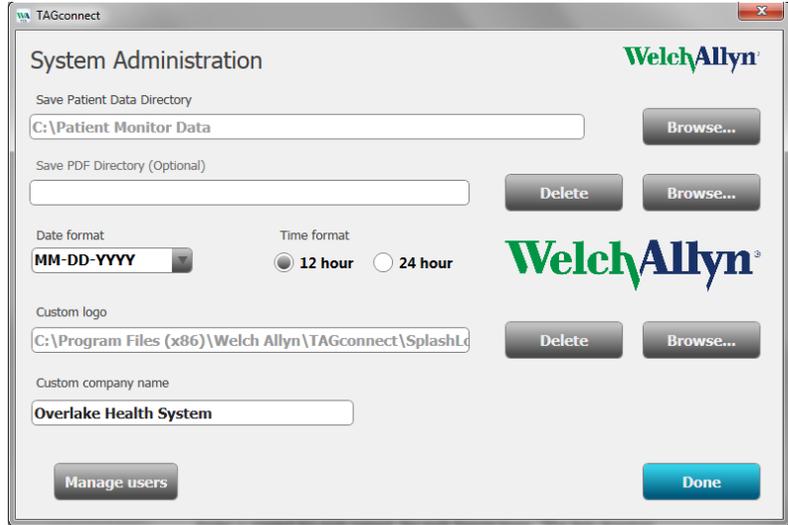click the **TAGconnect** icon:

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.
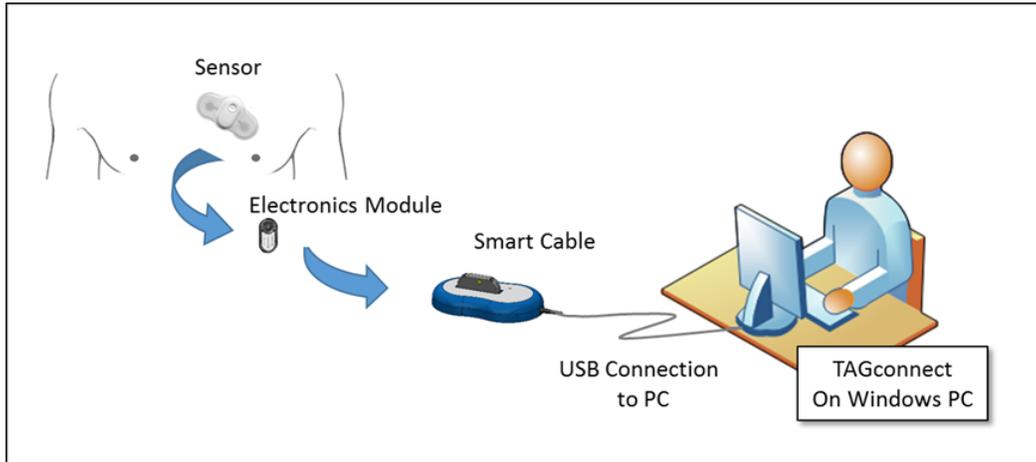
Refer to Operator's Manual, Section 4.1.

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

Sensor

Electronics Module

Smart Cable

USB Connection
to PC

TAGconnect
On Windows PC

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.

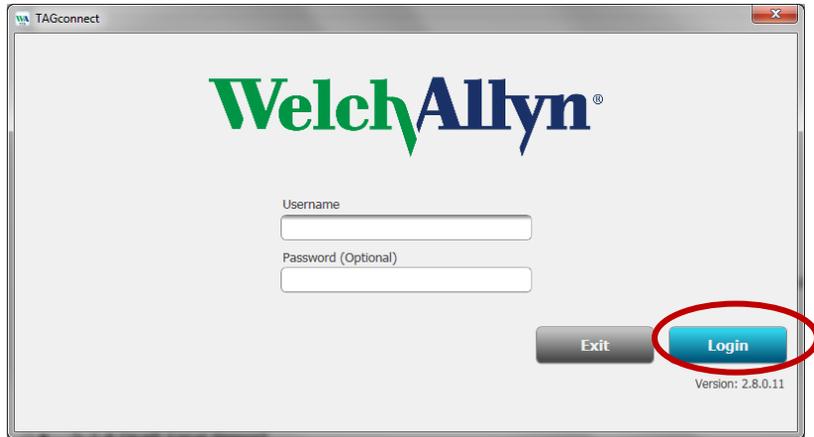The LED next to the Electronics Module icon will illuminate green.

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.

Step 6 Enter "Patient Diary" information.

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

Step 7 Click **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.

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

Patient Triggered Events

Key Statistics

Graphical Trend Report

Space for clinician comments & approval

Diagnostic Summary

Ambulatory ECG Cardiac Monitoring

Patient Name	Patient ID	Date of birth	Gender	Primary Indication
Johnson, James		04-08-1947 (71)	Male	Shortness of breath

Prescribing Clinician	Location	Start Date	End Date
Dr. Smith	Eastlake Clinic	06/11/2018 09:15:00 AM	06/18/2018 09:10:06 AM

Wear Time: 6d 23h 55m   Percent Analyzable: 96.1%   Patient Triggered Events: 1

Sinus Rhythm: <0.1%

	Avg HR	Range	HR<50 (%)	HR>100 (%)	PVC (%)	HR<50 (%)	HR>100 (%)	PVC (%)	PAC
Total	112	81 - 191	-	1	0	-	0	0	0.1%
Awake	112	84 - 191	PAC (%)	VBi/Trigem (%)	Pause (# - Max)	PAC (%)	VBi/Trigem (%)	Pause (# - Max)	PVC
Sleep	113	81 - 179	0	0	-	0	-	-	0.1%

Runs (>3 Beats)	Count	Avg HR	Avg Dur(sec)	Count	Avg HR	Avg Dur(sec)	
Supraventricular:	20	163	2	2	184	1	0.0%
Ventricular:	16	140	2	4	131	2	0.0%

Atrial Flutter / Fibrillation: 100.0%   (6d 20h 11m)

	Avg HR	Range	HR<50 (%)	HR>100 (%)	PVC (%)	HR<50 (%)	HR>100 (%)	PVC (%)	PVC
Total	107	75 - 185	-	83	12	-	48	8	10.7%
Awake	109	75 - 165		Pause (# - Max)			Pause (# - Max)		
Sleep	100	82 - 138		-			-		

Heart Rate   06/11   06/12   06/13   06/14   06/15   06/16   06/17   Percent

— Heart Rate   PVC Burden (%)   A. Flutter / Fib. Rhythm   — Unanalyzable > 20 %

30 s

HR: 95   Atrial Fibrillation

Patient Name: Johnson, James
Start Date: 06/11/2018 09:15:00 AM, Review date: 07/30/2018, Wear Time: 6d 23h 55m
Primary Indication: Shortness of breath
Findings: During Atrial Fibrillation the patient had a min HR of 75, a max HR of 185 and an avg HR of 107. Predominant underlying rhythm was Atrial Fibrillation. 245 Tachycardia runs occurred, the run with the fastest interval lasting 160 beats with a max rate of 191 bpm, the longest lasting 343 beats with an avg rate of 145 bpm. 20 Ventricular Tachycardia runs occurred, the run with the fastest interval lasting 12 beats with a max rate of 166 bpm. 630 Atrial Fibrillation episodes occurred (100.0 % burden). 22 Supraventricular Tachycardia runs occurred, the run with the fastest interval lasting 4 beats with a max rate of 186 bpm, the longest lasting 10 beats with an avg rate of 161 bpm. Isolated PACs, Couplets, and Triplets were rare (0 to <1.0%). Isolated PVCs were frequent (9.0 %, 73514), Couplets were rare (0.7 %, 5445), and Triplets were rare (< 0.1 %, 324). Bi/Trigeminy occurred (<1.0%). No Bradycardia runs occurred. No pauses occurred. ECG recording and analysis using TAGconnect System.

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

Clinician Signature

Overlake Health System	Eastlake Clinic	Patient Name: Johnson, James
1 of 14	07/30/2018 02:43 PM	Version: 2.8.0.11

CUSTOMER SUPPORT

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