Hillrom™

Welch Allyn® CardioConfirm

User Manual and Application Implementation Guide

Manufactured by Welch Allyn, Inc. Skaneateles Falls, NY U.S.A

CE 0459

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

Software V2.2.X
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NOTICES

Copyright and Trademark Notices

Notice to EU Users and/or Patients:

Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Equipment Identification

The SN and UDI numbers can be located on the packaging label.

The serial number format is as follows:

YYYWWSSSSSSS

YYY = First Y is always 1 followed by two-digit Year of manufacture

WW = Week of manufacture

SSSSSSS = Sequence number of manufacturer

USER SAFETY INFORMATION

 **WARNING:** Means there is the possibility of personal injury to you or others.

 **CAUTION:** Means there is the possibility of damage to the device.

NOTE: Provides information to further assist in the use of the device.

Warnings to CardioConfirm Integrators

Target Users

1. Warnings in the section "Warnings to CardioConfirm Target Users" must be provided to the target users.
2. User instructions for CardioConfirm must be provided to the target users.
3. The user instructions and warnings should be provided in a language that is understood by the target users.
4. Adequate training should be provided to the target users.

Host Application

5. The host application is responsible for securing all personal health information (PHI) and clinical data exchanged with CardioConfirm.
6. The host application is responsible for authenticating and authorizing users before they are allowed to use CardioConfirm to view, edit, and electronically sign the ECGs and reports.

Integration

7. Proper functionality of CardioConfirm as it is integrated with the host application must be verified before it is used for patient care. Verification must be repeated each time the host application or CardioConfirm is modified.

Installation

8. Possible malfunction risks could be associated with improper installation of the software. Please follow the installation instructions provided herein.
9. Possible malfunction risks could be associated with malware in the CardioConfirm environment. The host application vendor or computer administrator should employ antimalware/antivirus solutions to prevent and detect unauthorized modifications to the host environment or CardioConfirm application files.
10. After installation, proper functionality of CardioConfirm as it is integrated with the host application must be verified before it is used for patient care.

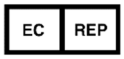
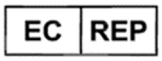
Warnings to CardioConfirm Target Users

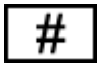
1. Inadequate knowledge or training could result in increased risk of patient misdiagnosis.
2. CardioConfirm presents data reflecting a patient's physiological condition that when reviewed by a trained physician or clinician can be useful in determining a diagnosis; however, the data should not be used as a sole means for determining a patient's diagnosis
3. When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met. The 40 Hz filter significantly reduces high-frequency components of the ECG and pacemaker spike amplitudes, and is recommended only if high-frequency noise obscures clinical information present in the waveforms. The applied filter is shown as the upper cutoff frequency on the waveforms, e.g. "0.05 – 40 Hz".
4. After modifying the host computer, such as operating system patches and installation of other software, verify CardioConfirm functionality by viewing and editing a test record before resuming use with patient records.
5. Serial comparison statements generated by algorithmic comparison of two resting ECGs should be confirmed by a trained clinician before using in the care of the patient.
6. If CardioConfirm does not allow changing inaccurate or misleading information, it is recommended that it be noted in the conclusions section before finalizing the report.

Notes

- CardioConfirm is compatible with data conforming to the "CardioConfirm DICOM Conformance Statement M0356-004".
- The device and IT Network the device is connected to should be securely configured and maintained per the IEC 80001 standard, or an equivalent network security standard or practice.

EQUIPMENT SYMBOLS AND MARKINGS

	CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.
	WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. In addition, when used on a patient applied part, this symbol indicates defibrillation protection is in the cables.
	Do not dispose as unsorted municipal waste. Requires separate handling for waste disposal according to local requirements
	Follow instructions/directions for use (DFU) -- mandatory action. A copy of the DFU is available on this website. A printed copy of the DFU can be ordered from Hillrom for delivery within 7 calendar days.
	Prescription device only
	Manufacturer
	Authorized Representative in the European Community
	Indicates compliance to applicable European Union directives
	Serial number
	Reorder number
	Authorized representative in the European Community

	Product identifier
	Global Trade Item Number
	Medical device symbol
	Lot number

INTRODUCTION

Target Application Users

Users are expected to be licensed clinical professionals knowledgeable about medical procedures and patient care, and adequately trained in the use of this device. Before attempting to use this device for clinical applications, the operator must read and understand the contents of the user manual and other accompanying documents. Inadequate knowledge or training could result in increased risk of harm to users, patients and bystanders, or damage to the device. Contact Welch Allyn service for additional training options.

Product Description

CardioConfirm is a software component that is embedded into a host application (e.g. EMR) as a Dynamic Link Library (DLL) or launched as an executable application. CardioConfirm allows the user to display, edit and finalize diagnostic cardiology ECG, Stress, and Holter reports. A Clinician can open a diagnostic cardiology test from a workstation application and pass it to CardioConfirm as a DICOM object for viewing or editing. CardioConfirm is able to open and edit diagnostic cardiology ECG, Stress, and Holter reports from Welch Allyn Cardiology devices and offers an optional version which can edit diagnostic cardiology ECG, Stress, and Holter reports from multiple diagnostic cardiology equipment vendors.

CardioConfirm allows the clinician the ability to view, measure, and compare previously acquired resting ECGs as well as perform serial comparison of acquired adult ECGs. The clinician can edit the patient demographics, previous measurements and interpretations, and sign final ECG reports. The clinician can also view and edit stress and Holter reports that includes editing patient demographics, summary statistics and physician conclusions. The clinician can electronically sign both stress and Holter final reports in CardioConfirm and print final reports or generate PDF copies to store in the host application. If a physician wants to amend a previously finalized report with additional information, CardioConfirm has an option to perform amendments to final reports and store the updated test in the host application.

Intended Use of Application

CardioConfirm is intended to be used by qualified clinicians to finalize preliminary cardiology reports for adult and pediatric patients. To aid the clinician's interpretation of ECG waveforms, CardioConfirm supports the display and onscreen measurement of ECG waveforms as well as algorithmic comparison of serial adult ECGs. Report tools allow the user to edit and electronically sign the preliminary conclusions generated by the acquiring device and its operator.

Intended Use of Document

This document provides instructions for software developers and their managers who will implement the integration between the CardioConfirm Application and a host application. The Warnings in this document must be included in the final product's labeling provided to the end users. The user instructions included in this document may be used as a basis for the final product's user instructions.

INSTALLATION CHECKLIST

Below is a checklist summarizing the steps necessary to install the CardioConfirm Application. Details about each step follow.

1. Verify the host computer is running Windows 7 or Windows 10.
2. Copy the CardioConfirm Application files and folders into a folder on the host computer. Copy the *DefaultConfig.xml* file into the root application folder.
3. Select the CardioConfirmStrings-*lang*.xml file according to the language. Remove the "*-lang*" portion of the filename (renamed to *CardioConfirmStrings.xml*) and put the file into the application's root folder.

Language Code	Language
de	German
en	English
fr	French
it	Italian
pt-BR	Brazilian Portuguese

4. Verify at least .NET Framework 4.6.1 is present, and install it if necessary. Verify Microsoft Visual C++ 2017 Redistributable Package is present, and install it if necessary.

Note: *The device and IT Network the device is connected to should be securely configured and maintained per the IEC 80001 standard, or an equivalent network security standard or practice.*

1. Supported Operating Systems

CardioConfirm is a Windows application. Although it likely runs on more versions of Windows, it has only been tested on:

- Windows 7 Pro, 32-bit
- Windows 7 Pro, 64-bit
- Windows 10 Pro, 64-bit

2. Copy Files to Host Computers

No “setup.exe” or MSI installer is provided. Installation is a matter of copying the application files into a CardioConfirm application folder local to each computer that will run it. Do not run the application from a shared folder over a network because it is not designed to handle multiple computers running it simultaneously from a shared location.

Below is the list of included files and folders to copy to the designated CardioConfirm application folder on the computer:

1. ApplicationToolbox.dll
2. CardioConfirm.exe
3. CommandLineArguments.dll
4. DebenuPDFLibrary64DLL1411.dll
5. DebenuPDFLibraryDLL1411.dll
6. EliEditMod.dll
7. EliEditUIControlLibrary.dll
8. HolterViewLib.dll
9. OpenDicom.dll
10. RenderInformation.dll
11. StressViewLib.dll
12. StringManagerFx2.dll
13. UiControlLib.dll
14. UiControlsFx2.dll
15. DisplayMessageInterface.dll
16. EZEditLibrary.dll
17. VersionControl.dll
18. Entire *Languages* folder

3. Localization

There are many XML files in the *Languages* folder that contain language-specific strings. Copy the entire Languages folder tree, as it, to CardioConfirm's application folder.

To specify the language CardioConfirm will use, copy the appropriate **CardioConfirmStrings-*lang*.xml** file from the Languages folder and place it into the CardioConfirm application folder (one level up from the Languages folder). Then remove the "*-lang*" portion of the filename so the file is named **CardioConfirmStrings.xml**.

> ***Note:*** *do not rename any files in the Languages folder tree; only rename the CardioConfirmStrings.xml file copied into the CardioConfirm application folder.*

The table below lists the language codes used in the XML file names. Boxes with an "X" indicate that translations are provided by Welch Allyn.

> ***Note****: Although there is a complete set of XML sting files for the languages listed below, not all files include a complete translation from Welch Allyn. If an XML file of the selected language is missing a string, CardioConfirm will use the English equivalent built into the application.*
>
> ***Caution****: If modifications are made to the XML string files, CardioConfirm should be tested prior to clinical use to verify the updated strings appear appropriately and do not cause the application to malfunction.*

Language Code	Language	Rest UI	Rest Interp.	Rest Serial	Rest Concl.	Holter UI	Holter Templ.	Stress UI	Stress Templ.
cs	Czech		X		X				
de	German	X	X	X	X	X	X	X	X
en	English	X	X	X	X	X	X	X	X
es	Spanish		X	X	X				
fi	Finnish			X					
fr	French	X	X	X	X	X	X	X	X
hr	Croatian		X		X				
hu	Hungarian		X	X	X				
it	Italian	X	X	X	X	X	X	X	X
ja	Japanese		X		X				
lv	Latvian		X		X				
nl	Dutch	X	X	X	X	X	X	X	X
no	Norwegian		X		X				
pl	Polish		X	X	X				
pt-BR	Brazilian Portuguese	X	X	X	X	X	X	X	X
pt-PT	European Portuguese		X		X				
ro	Romanian		X		X				
ru	Russian		X		X				
sw	Swedish		X	X	X				
tr	Turkish		X		X				
zh-Hans	Chinese		X		X				

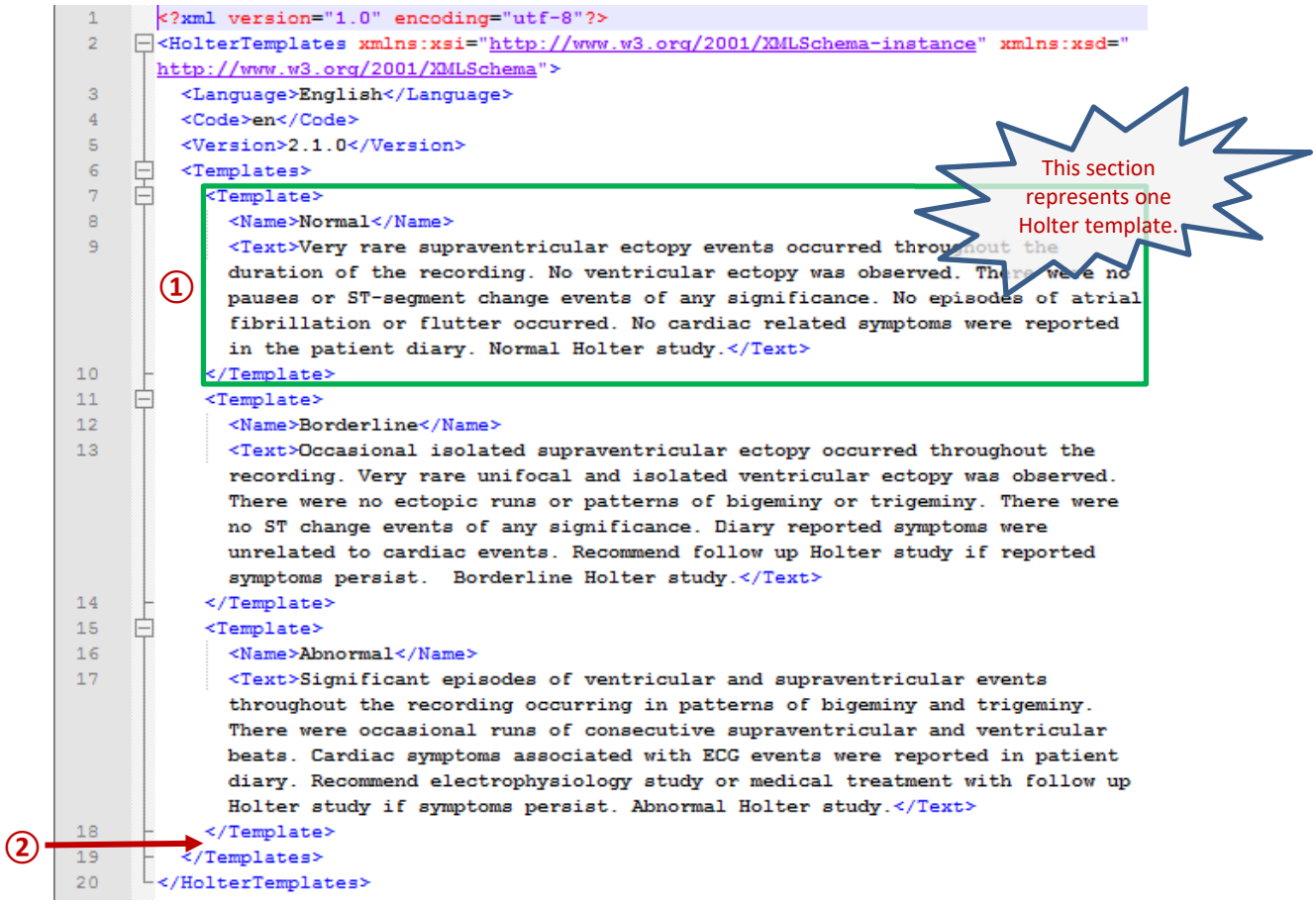
Stress and Holter Conclusion Templates

Welch Allyn provides stress and Holter conclusion templates in the **Languages\Templates\Stress** and **Languages\Templates\Holter** folders. To add or edit the templates, open the appropriate XML file(s) for editing, i.e. the language-specific file for the chosen language for example, "*CardioConfirmHolterTemplates-en.xml*." An XML-aware editor is best, but NotePad can work when care is taken to format the XML correctly.

Each <Template/> is a child of <Templates/>. Copy and paste one of the existing <Template/> structures to add another template. Each <Template/> has a <Name/> and <Text/>. The Name is displayed to the user in the dropdown menu, and the Text is what is copied into the Conclusions box. When editing the Text, keep in mind that XML requires these reserved characters be escaped:

Character	XML Escape Sequence
quote (")	`&quot;`
apostrophe (')	`&apos;`
ampersand (&)	`&`
less than (<)	`<`
greater than (>)	`>`

Example Holter Template Edit:




```
<?xml version="1.0" encoding="utf-8"?>
<HolterTemplates xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:xsd="
http://www.w3.org/2001/XMLSchema">
  <Language>English</Language>
  <Code>en</Code>
  <Version>2.1.0</Version>
  <Templates>
    <Template>
      <Name>Normal</Name>
      <Text>Very rare supraventricular ectopy events occurred throughout the
      duration of the recording. No ventricular ectopy was observed. There were no
      pauses or ST-segment change events of any significance. No episodes of atrial
      fibrillation or flutter occurred. No cardiac related symptoms were reported
      in the patient diary. Normal Holter study.</Text>
    </Template>
    <Template>
      <Name>Borderline</Name>
      <Text>Occasional isolated supraventricular ectopy occurred throughout the
      recording. Very rare unifocal and isolated ventricular ectopy was observed.
      There were no ectopic runs or patterns of bigeminy or trigeminy. There were
      no ST change events of any significance. Diary reported symptoms were
      unrelated to cardiac events. Recommend follow up Holter study if reported
      symptoms persist.  Borderline Holter study.</Text>
    </Template>
    <Template>
      <Name>Abnormal</Name>
      <Text>Significant episodes of ventricular and supraventricular events
      throughout the recording occurring in patterns of bigeminy and trigeminy.
      There were occasional runs of consecutive supraventricular and ventricular
      beats. Cardiac symptoms associated with ECG events were reported in patient
      diary. Recommend electrophysiology study or medical treatment with follow up
      Holter study if symptoms persist. Abnormal Holter study.</Text>
    </Template>
  </Templates>
</HolterTemplates>
```

To add a template:

1. Open the desired XML template file. For example, *"CardioConfirmHolterTemplates-en.xml"*
2. Copy an existing template section ① from the XML (bounded by the green box)
3. Paste a copy of the template between the **<Templates>** and **</Templates>** XML tags ②. Make sure pasting the new template doesn't alter the other existing templates in the file.
4. Edit the black text to change the Name of the template and the Text in the template. Note: *Template variables* can be used to insert data into the text section as described below.
5. Save the XML file to commit the changes.

To delete a template:

1. Open the desired XML template file.
2. Simply delete the desired template section ① (bounded by the green box)
3. Save the XML file to commit the changes.

Using Template Variables

CardioConfirm substitutes values from the report for supported variables. To include a variable in the <Text/> of the template, enter the variable name surrounded by <angle brackets>. Note that the less-than and greater-than characters must be escaped in the XML. For example, here's how the patient's name and ID can be included in the template text:

```
<Text>This report is for the patient &lt;PatientName&gt; with ID &lt;PatientId&gt;.</Text>
```

For the patient John Smith with ID 12345, CardioConfirm would translate this into:

```
This report is for the patient John Smith with ID 12345.
```

Stress Template Variables:

Variable	Description
PatientName	Patient's full name, e.g. First Middle Last
PatientId	Patient ID
PatientBirthDate	Patient's birthdate, formatted according to computer's regional settings for Short Dates
PatientAge	Patient's age in years
PatientSex	Patient's sex
PatientRace	Patient's race
Location	Patient's location
Operator	Name of the technician who performed the test
ReferredBy	Name of referring physician
RequestedBy	Name of requesting physician
Comment	Comments
Reason	Reason for test
ExerTime	The amount of time spent in the exercise phase, formatted as h:mm:ss.
MaxSpeed	Maximum treadmill speed, including units of MPH or km/h. Only applies to treadmill tests.
MaxGrade	Maximum treadmill grade expressed as a percentage. Only applies to treadmill tests.
LeadsOver100	List of leads with at least 100 uV of ST elevation or depression.
DukeScore	Duke treadmill score when the Bruce exercise protocol is used. Ranges from approximately -57 to 21.
ExamAngina	Angina Index used in the Duke Score, as "None", "Non-limiting", or "Exercise Limiting".
FaiPercLow	Functional Aerobic Impairment score, expressed as a percentage. This is the value for a person with a sedentary lifestyle.
FaiPercHigh	Functional Aerobic Impairment score, expressed as a percentage. This is the value for a person with an active lifestyle.
MaxHr	Maximum heart rate achieved, expressed in units of BPM.
MaxHrTime	Time at which the maximum heartrate was achieved, expressed as h:mm:ss from beginning of the exercise phase.
MaxMets	Maximum METs (estimated metabolic equivalents) achieved.
MaxMetsTime	Time as which the maximum METs was achieved, expressed as h:mm:ss from beginning of the exercise phase.
HrTimesBp	Maximum double product (systolic BP * HR) achieved.
HrTimesBpTime	Time at which the maximum double product was achieved, expressed as h:mm:ss from beginning of the exercise phase.
MaxSbpSystolic	The systolic value of the BP measurement having the maximum systolic value.
MaxSbpDiastolic	The diastolic value of the BP measurement having the maximum systolic value.
MaxSbpTime	Time at which the BP measurement having the maximum systolic value was taken,

Variable	Description
	expressed as h:mm:ss from beginning of the exercise phase.
MaxDbpSystolic	The systolic value of the BP measurement having the maximum diastolic value.
MaxDbpDiastolic	The diastolic value of the BP measurement having the maximum diastolic value.
MaxDbpTime	Time at which the BP measurement having the maximum diastolic value was taken, expressed as h:mm:ss from beginning of the exercise phase.
StEleValue	Maximum ST elevation value, expressed as uV or mm.
StEleTime	Time when maximum ST elevation occurred, expressed as h:mm:ss from beginning of the test.
StEleLead	Lead in which the maximum ST elevation occurred.
StDepValue	Maximum ST depression value, expressed as uV or mm.
StDepTime	Time when maximum ST depression occurred, expressed as h:mm:ss from beginning of the test.
StDepLead	Lead in which the maximum ST depression occurred.
StEleChangeValue	Maximum positive ST change from beginning of test, expressed as uV or mm.
StEleChangeTime	Time when maximum positive ST change occurred, expressed as h:mm:ss from beginning of the test.
StEleChangeLead	Lead in which the maximum positive ST change occurred.
StDepChangeValue	Maximum negative ST change from beginning of test, expressed as uV or mm.
StDepChangeTime	Time when maximum negative ST change occurred, expressed as h:mm:ss from beginning of the test.
StDepChangeLead	Lead in which the maximum negative ST change occurred.
StHrIndexValue	Maximum ST/HR index measured during the test.
StHrIndexTime	Time when maximum ST/HR index was measured, expressed as h:mm:ss from beginning of the test.
StHrIndexLead	Lead in which the maximum ST/HR index was measured.
ProtocolName	Name of the stress protocol used for the test.
LastStage	Number of the last exercise stage before moving into recovery. Stage numbers start at 1.
JPoint	Milliseconds from J-point where ST level was measured.
ApmHr	Patient's predicted maximum heart rate, e.g. 220 – age.
MaxHrPredictedPerc	Maximum amount of predicted maximum heart rate achieved during the test, expressed as a percentage.
MaxWorkload	Maximum workload expressed as Watts. Only applies to ergometer tests.
ApmWorkload	Patient's predicted maximum workload expressed as Watts.
ApmWorkloadPerc	Maximum amount of predicted maximum workload achieved during the test, expressed as a percentage.

Holter Template Variables

Variable	Description
PatientName	Patient's full name, e.g. First Middle Last
PatientId	Patient ID
PatientBirthDate	Patient's birthdate, formatted according to computer's regional settings for Short Dates
PatientAge	Patient's age in years
PatientSex	Patient's sex
PatientRace	Patient's race
Location	Patient's location
Operator	Name of the technician who performed the test
ReferredBy	Name of referring physician
RequestedBy	Name of requesting physician
Comment	Comments

Variable	Description
Reason	Reason for test
TotalQrs	Total number of detected QRS complexes, regardless of classification.
NormalBeats	Total number of detected QRS complexes classified as normal beats.
UnknownBeats	Total number of detected QRS complexes that could not be classified.
BbbBeats	Total number of detected QRS complexes classified as bundle branch block beats.
FusionBeats	Total number of detected QRS complexes classified as fusion beats.
SupraBeats	Total number of detected QRS complexes classified as supraventricular beats.
RecordingDuration	Recording duration, expressed as *HH* hr *mm* min.
AnalyzedDuration	Total duration analyzed for the report, expressed as *HH* hr *mm* min.
ArtifactDuration	Total duration of artifact (unanalyzed), expressed as h:mm:ss.
MinMaxHr	Indicates which beats were used for minimum and maximum heart rate statistics: “All Beats” or “Normal Only”.
PauseExcluded	Indicates if pauses were excluded from the minimum heart rate statistics: “Yes” if pauses were excluded, otherwise “No”.
MinHr	Minimum heart rate, expressed in BPM.
MinHrTime	Time when minimum heart rate occurred, expressed in real time hh:mm:ss tt.
MaxHr	Maximum heart rate, expressed in BPM.
MaxHrTime	Time when maximum heart rate occurred, expressed in real time hh:mm:ss tt.
AverageHr	Average heart rate, expressed in BPM.
Tachycardia	Tachycardia heart rate threshold, expressed as > *rate* BPM, e.g. “> 120 BPM”
Bradycardia	Bradycardia heart rate threshold, expressed as < *rate* BPM, e.g. “< 50 BPM”
TachyBradyDuration	Duration of sustained heart rate to be considered an episode of tachycardia or bradycardia, expressed as > H:mm:ss, e.g. “> 0:01:00” for one minute.

4. Run-time Environment

The CardioConfirm application requires the following software component(s) to be installed on the computer hosting it:

- Microsoft Visual C++ 2017 Redistributable Package

Checking for Microsoft Visual C++ 2017 Redistributable Package

The CardioConfirm application needs the Microsoft Visual C++ 2017 Redistributable Package to be present on the computer hosting it. Here is one of the methods to check if this package has already been installed:

1. Look for **Microsoft Visual C++ 2017 Redistributable***in **Programs and Features** under the **Control Panel**. Please note that depending on the OS, the redistributable name shall appear with “x86” for 32 Bit OS and “x64” for 64 Bit OS.

Installing the Microsoft Visual C++ 2017 Redistributable Package

If the package is not present, download it from the Microsoft website. Because the location of specific downloads on the Microsoft website may change, it is best to search for the current download location. At the time this manual was created, the URL was: https://support.microsoft.com/en-us/help/2977003/the-latest-supported-visual-c-downloads . Select the installer matching the OS (32 bit – x86 or 64 Bit – x64). After installing the Visual C++ 2017 Redistributable Package, perform a **Windows Update** to ensure the computer receives the latest service packs and security patches.

COMMAND LINE ARGUMENTS

File to Open – The first argument must be the full path to the file to open. The file must be in the *DICOM 12-lead or General ECG Waveform* or *DICOM Encapsulated PDF* format. UNC paths are supported.

```
C:\> CardioConfirm.exe "\\myserver\myecgs\ecg2edit.dcm"
```

Resting ECG File to Compare – If the user wants to compare a resting ECG to another resting ECG, use the `/file2:` argument to specify the full path of the comparison ECG file. The file must be in the DICOM 12-lead or General ECG Waveform format. The comparison ECG will not be editable.

```
C:\> CardioConfirm.exe ecg2edit.dcm /file2:"\\myserver\my
ecgs\ecg2compare.dcm"
```

Demographics Editing – By default, demographics editing is not allowed. Partial or full editing can be enabled with a flag. Partial editing allows all fields to be changed except the patient's primary identifying fields: name, ID, date of birth, and sex. Full editing allows all fields to be changed, including the patient's primary identifying fields.

```
C:\> CardioConfirm.exe ecg2edit.dcm /EditDemoPartial
C:\> CardioConfirm.exe ecg2edit.dcm /EditDemoFull
```

Measurement and Statistics Editing – By default, the global measurements or summary statistics cannot be edited. Resting ECG measurements include the Ventricular Rate, PR Interval, QRS Duration, QT Interval, and P/R/T Axes. The editable summary statistics vary by test, e.g. stress or Holter. The `/EditGlobals` argument enables these measurements and statistics to be changed.

```
C:\> CardioConfirm.exe ecg2edit.dcm /EditGlobals
```

Interpretation and Conclusions Editing – By default, the interpretation or conclusions cannot be edited. Use the `/EditInterp` argument to enable editing of the existing interpretation or conclusions, and use `/AppendInterp` to only allow new statements to be added to the existing interpretation or conclusions.

```
C:\> CardioConfirm.exe ecg2edit.dcm /EditInterp
C:\> CardioConfirm.exe ecg2edit.dcm /AppendInterp
```

Electronic Signature – By default, the ECG or stress/Holter report cannot be electronically signed by the user. Use the `/Sign` argument to enable signing, and use `/Signer:` to specify how the signer's name should appear on the ECG or report. Surround the signer's name in double quotations when it includes spaces. If the signer's name is not specified by `/Signer:`, the Windows username will be used.

```
C:\> CardioConfirm.exe ecg2edit.dcm /Sign
C:\> CardioConfirm.exe ecg2edit.dcm /Sign /Signer:"Dr. Charles
Smith"
```

Saving Edited ECG or report as DICOM File – If the user has permission to edit or sign the ECG or report, by default the original DICOM file is replaced with the updated version. If the original DICOM file should be backed up before it is replaced, use the `/dcmObsoletePath:` argument to specify where to put the original file before it is replaced. If a path is specified without a filename, the original file's filename will be used.

```
C:\> CardioConfirm.exe ecg2edit.dcm
/dcmObsoletePath:"\\myserver\myOriginalEcgs\ecg2editBackup.dcm"
C:\> CardioConfirm.exe ecg2edit.dcm
/dcmObsoletePath:"\\myserver\myOriginalEcgs"
```

If the original file should not be replaced or moved, use the `/dcmoutPath:` argument to specify the path and filename of the new file. If a path is specified without a filename, the original file's filename will be used.

```
C:\> CardioConfirm.exe ecg2edit.dcm
/dcmoutPath:"\\myserver\mySignedEcgs\signedEcg.dcm"
C:\> CardioConfirm.exe ecg2edit.dcm
/dcmoutPath:"\\myserver\mySignedEcgs"
```

Saving Signed ECG or report as PDF File – If a standard PDF file of the ECG or report should be saved when it is signed, use the `/pdfPath:` argument to specify the path and filename of the file. Surround the path and filename in double quotes if it contains spaces. If a path is specified without a filename, the original file's filename will be used, but with a .pdf filename extension.

```
C:\> CardioConfirm.exe ecg2edit.dcm /Sign
/pdfPath:"\\myserver\myecgs\signedEcg.pdf"
C:\> CardioConfirm.exe ecg2edit.dcm /Sign
/pdfPath:"\\myserver\myecgs"
```

CONFIGURATION FILE

Many aspects of the CardioConfirm application behavior can be specified in an XML configuration file. The location and name of the configuration file can be specified with the `/config:` command line argument. If the name and location of the configuration file is not specified, the file "DefaultConfig.xml" in the application's folder will be used. If this file doesn't exist, the application will use its default settings.

```
C:\> CardioConfirm.exe ecg2edit.dcm
/config:"\\myserver\myecgs\CardioConfirmSettings.xml"
```

The root element of the configuration file is `<CardioConfirmSettings/>`, and the groups of settings described below are children.

General Settings

The application's general settings are specified within the `<ComponentParameters/>` element. Below are the factory default settings followed by an explanation. Some of the settings only apply to resting ECGs.

```
<ComponentParameters>
      <DisplayLocation>false</DisplayLocation>
      <DisplayOperator>false</DisplayOperator>
      <DisplayRefPhy>false</DisplayRefPhy>
      <DisplayReqPhy>false</DisplayReqPhy>
      <DisplayComment>false</DisplayComment>
      <ReasonForProcedure>false</ReasonForProcedure>
      <ConvertInterpToUppercase>true</ConvertInterpToUppercase>
      <Print>true</Print>
      <DisplayType>true</DisplayType>
      <LeadLayout>true</LeadLayout>
      <Gain>true</Gain>
      <FilterMode>true</FilterMode>
      <DisplayQTcB>false</DisplayQTcB>
      <DisplayQTcF>false</DisplayQTcF>
      <DisplayAverageRR>false</DisplayAverageRR>
      <HideOriginalInterpretation>false</HideOriginalInterpretation>
      <DisplayPaceSpikes>true</DisplayPaceSpikes>
      <DisableMortaraAutoComplete>false</DisableMortaraAutoComplete>
</ComponentParameters>
```

Element	Description	Values
<DisplayLocation/>	When true, the **Location** field is displayed with the rest of the demographics. This is DICOM tag (0038,0300).	**false*** – hide the field. **true** – display the field.
<DisplayOperator/>	When true, the **Operator** field is displayed with the rest of the demographics. This is DICOM tag (0008,1070).	**false*** – hide the field. **true** – display the field.
<DisplayRefPhy/>	When true, the **Referring Physician** field is displayed with the rest of the demographics. This is DICOM tag (0008,0090).	**false*** – hide the field. **true** – display the field.
<DisplayReqPhy/>	When true, the **Requesting Physician** field is displayed with the rest of the demographics. This is DICOM tag (0032,1032).	**false*** – hide the field. **true** – display the field.
<DisplayComment/>	When true, the **Visit Comments** field is displayed with the rest of the demographics. This is DICOM tag (0038,4000).	**false*** – hide the field. **true** – display the field.
<ReasonForProcedure/>	When true, the **Reason for Procedure** field is displayed with the rest of the demographics. This is DICOM tag (0040,1002).	**false*** – hide the field. **true** – display the field.
<ConvertInterpToUppercase/>	When true, forces interpretation edits to be entered in all capital letters.	**false** – allows mixed case interpretation editing. **true*** – forces edited interpretation to be entered in all capital letters.
<Print/>	When true, the user has the option to print the ECG.	**false** – hide the option. **true*** – offer the option.
Resting ECG Only		
<DisplayType/>	When true, the user has the option to change the display type between Standard ECG, 3x4 Medians, and Median Overlay.	**false** – hide the option. **true*** – offer the option.
<LeadLayout/>	When true, the user has the option to change the lead layout when using the Standard ECG display. The lead layout options include 3x4, 3x4+1, 3x4+3, 6x2, and 12x1.	**false** – hide the option. **true*** – offer the option.
<Gain/>	When true, the user has the option to change the gain of the waveforms as drawn on the 1mm grid. The gain options include 5, 10, 20, and 40 mm/mV.	**false** – hide the option. **true*** – offer the option.
<FilterMode/>	When true, the user has the option to change the low pass filter applied to the waveforms drawn on the display. The filter options include None, 40 Hz, and 150 Hz.	**false** – hide the option. **true*** – offer the option.
<DisplayQTcB/>	When true, the **QTcB** (QTc Bazett) field is displayed with the rest of the global measurements.	**false*** – hide the measurement. **true** – display the measurement.

Element	Description	Values
<DisplayQTcF/>	When true, the **QTcF** (QTc Fridericia) field is displayed with the rest of the global measurements.	**false*** – hide the measurement. **true** – display the measurement.
<DisplayAverageRR/>	When true, the **Average RR Interval** field is displayed with the rest of the global measurements.	**false*** – hide the measurement. **true** – display the measurement.
<HideOriginalInterpretation/>	When true, the automatic interpretation from the electrocardiograph will be hidden.	**false*** – hide the interpretation. **true** – display the interpretation.
<DisplayPaceSpikes/>	When true, an additional channel is displayed at the bottom of the Standard ECG display. Tick marks are shown on this channel to indicate where pacer spikes were detected by the electrocardiograph.	**false** – hide the pacer spike channel. **true*** – display the pacer spike channel.
<DisableMortaraAutoComplete/>	When true, CardioConfirm suppresses its statement completion feature.	**false*** – enable statement completion feature. **true** – disable the statement completion feature.

* default value

Edit Settings

The application's edit settings are specified within the <EditOptions/> element. Below are the factory default settings followed by an explanation.

```
<EditOptions>
      <EditDemographics>None</EditDemographics>
      <EditGlobals>None</EditGlobals>
      <EditInterpretation>ReadOnly</EditInterpretation>
      <SaveText1>Edited By:</SaveText1>
      <SignText1>Electronic Signature:</SignText1>
      <DateFormat>MM/dd/yyyy</DateFormat>
      <TimeFormat>HH:mm:ss</TimeFormat>
</EditOptions>
```

Element	Description	Values
<EditDemographics/>	Specifies if the demographics can be edited.	**None*** – no demographics editing is allowed. **Full** – all demographic fields can be edited. **Partial** – all demographic fields can be edited except the patient's name, ID, DOB, and sex.
<EditGlobals/>	Specifies if the global measurements or summary statistics can be edited.	**None*** – editing is disabled. **Full** – editing is allowed. **CalipersOnly** – resting ECG globals can only be changed with the calipers.

Element	Description	Values
<EditInterpretation/>	Specifies if the interpretation or conclusions can be edited.	**ReadOnly*** – editing is disabled. **SaveAndSign** – existing interpretation can be edited and signed. **AppendSaveAndSign** – new interpretation statements can be appended to the existing interpretation and signed.
<SaveText1/>	Specifies the text used to label who is saving the edited file. The user's name and the current date/time is appended to this label.	Default is **"Edited By: "** in support of the traditional transcription-save-sign workflow.
<SignText1/>	Specifies the text used to label who is signing the file. The user's name and the current date/time is appended to this label.	Default is **"Electronic Signature: "**.
<DateFormat/>	Specifies the format for the current date that is appended after the save and sign user names.	Default is **"MM/dd/yyyy"**. The recognized notations include: **M** – 1 or 2-digit month **MM** – 2-digit numeric month **MMM** – 3-letter month abbreviation **MMMM** – full name of the month **d** – 1 or 2-digit day-of-the-month **dd** – 2-digit day-of-the-month **ddd** – 3-letter day-of-the-week abbreviation **dddd** – full name of the day-of-the-week **y** – last digit of the year **yy** – last 2 digits of the year **yyyy** – 4-digit year
<TimeFormat/>	Specifies the format for the current time that is appended after the save and sign user names.	Default is **"HH:mm:ss"**. The recognized notations include: **h** – 1 or 2-digit hour, 12-hour format **hh** – 2-digit hour, 12-hour format **t** – A or P **tt** – A.M. or P.M. **H** – 1 or 2-digit hour, 24-hour format **HH** – 2-digit hour, 24-hour format **m** – 1 or 2-digit minute **mm** – 2-digit minute **s** – 1 or 2-digit second **ss** – 2-digit second

* default value

Display Options

CardioConfirm's resting ECG display settings are specified within the <DisplayOptions/> element. Below are the factory default settings followed by an explanation.

```
<DisplayOptions>
      <DisplayType>Standard</DisplayType>
      <LeadLayout>ThreeByFourPlusThree</LeadLayout>
      <Gain1>Standard</Gain1>
      <Gain2>Double</Gain2>
```

```
        <Gain3>Quad</Gain3>
        <FilterMode>None</FilterMode>
        <GridType>OneAndFiveMm</GridType>
        <GridColor>Red</GridColor>
</DisplayOptions>
```

Element	Description	Values
<DisplayType/>	Specifies how to display the resting ECG.	**Standard*** – displays a standard ECG layout. **OverlayMedians** – displays the median beat in the overlay format. **ThreeByFourMedians** – displays the median beat in the 3x4 grid.
<LeadLayout/>	Specifies the resting ECG lead layout for a Standard display mode.	**ThreeByFourPlusThree*** – 3x4+3. **ThreeByFourPlusOne** – 3x4+1. **ThreeByFour** – 3x4 **SixByTwo** – 6x2 **TwelveByOne** – 12x1
<Gain1/>	The default gain to use for the Standard display type.	**Standard*** – 10 mm/mV **Half** – 5 mm/mV **Double** – 20 mm/mV **Quad** – 40 mm/mV
<Gain2/>	The default gain to use for the 3x4 Median display type.	**Standard** – 10 mm/mV **Half** – 5 mm/mV **Double*** – 20 mm/mV **Quad** – 40 mm/mV
<Gain3/>	The default gain to use for the Median Overlay display type.	**Standard*** – 10 mm/mV **Half** – 5 mm/mV **Double** – 20 mm/mV **Quad*** – 40 mm/mV
<FilterMode/>	The default filter setting for the Standard display type.	**None*** – Native bandwidth stored in the file **FortyHz** – 40 Hz **OneHundredFiftyHz** – 150 Hz
<GridType/>	Specifies the type of grid to use.	**OneAndFiveMm*** - 1mm grid with 5 mm major line. **FivMm –** 5mm grid **None** – no grid
<GridColor/>	Specifies the color of the grid.	**Red*** **Green** **Black** **Blue**

* default value

Frame Settings

The application's frame settings are specified within the `<FrameOptions/>` element. Below are the factory default settings followed by an explanation.

```
<FrameOptions>
      <PercentageWidth>80</PercentageWidth>
      <PercentageHeight>80</PercentageHeight>
      <PercentageTopSpace>10</PercentageTopSpace>
      <PercentageLeftSpace>10</PercentageLeftSpace>
</FrameOptions>
```

Element	Description	Values
`<PercentageWidth/>`	Specifies the width of the application frame as a percentage of the total screen width.	**80*** - 80% of the screen's width.
`<PercentageHeight/>`	Specifies the height of the application frame as a percentage of the total screen height.	**80*** - 80% of the screen's height
`<PercentageTopSpace/>`	Specifies how much space to leave between the top of the screen and the top of the application frame. 0% would put the application on the top edge of the screen.	**10*** - Leave 10% of the screen's height between the top of the screen and the top of the application's frame.
`<PercentageLeftSpace/>`	Specifies how much space to leave between the left of the screen and the left of the application frame. 0% would put the application on the left edge of the screen.	**10*** - Leave 10% of the screen's width between the left of the screen and the left of the application's frame.

* default value

Path Settings

The application's path settings are specified within the `<PathOptions/>` element. Below are the factory default settings followed by an explanation.

```
<PathOptions>
      <DcmOutPath></DcmOutPath>
      <PdfPath></PdfPath>
      <DcmObsoletePath></DcmObsoletePath>
</PathOptions>
```

Element	Description	Values
`<DcmOutPath/>`	Specifies the full path to a folder where the DICOM ECG files should be saved.	Should be a full UNC path, without a trailing backslash. By default, the DICOM ECG file opened for viewing is updated with the changes.
`<PdfPath/>`	Specifies the full path to a folder where PDF files of signed ECGs should be saved.	Should be a full UNC path, without a trailing backslash. By default, PDF files are not saved.
`<DcmObsoletePath/>`	Specifies the full path to a folder where the original DICOM ECG file should be copied into before it is updated.	Should be a full UNC path, without a trailing backslash. By default, a copy of the original DICOM ECG file is not saved.

ERROR HANDLING AND LOGGING

Log Directory

CardioConfirm creates a log directory named "Log" in the application folder. All the logs files are saved in this directory.

Log File Names

Log files are numbered starting at one i.e. log1.txt. When the file size exceeds 1 MB, the log file number is incremented by 1 and goes up to 99. Possible log file names are log1.txt, log2.txt, ... log99.txt.

Log File Retention

Log files older than 3 months are automatically deleted.

Errors Triggered by Bad Launch Parameters

- If the configuration file contains an XML syntax error, an “XML parsing error” message will pop up and an error will be logged.
- If the application is launched without any arguments, an “input file missing” message will pop up and an error will be logged.
- If the specified ECG file cannot be found, an “error opening file” message will pop up and an error will be logged.
- If a directory path cannot be found, a “directory does not exist” message will pop up and an error will be logged.

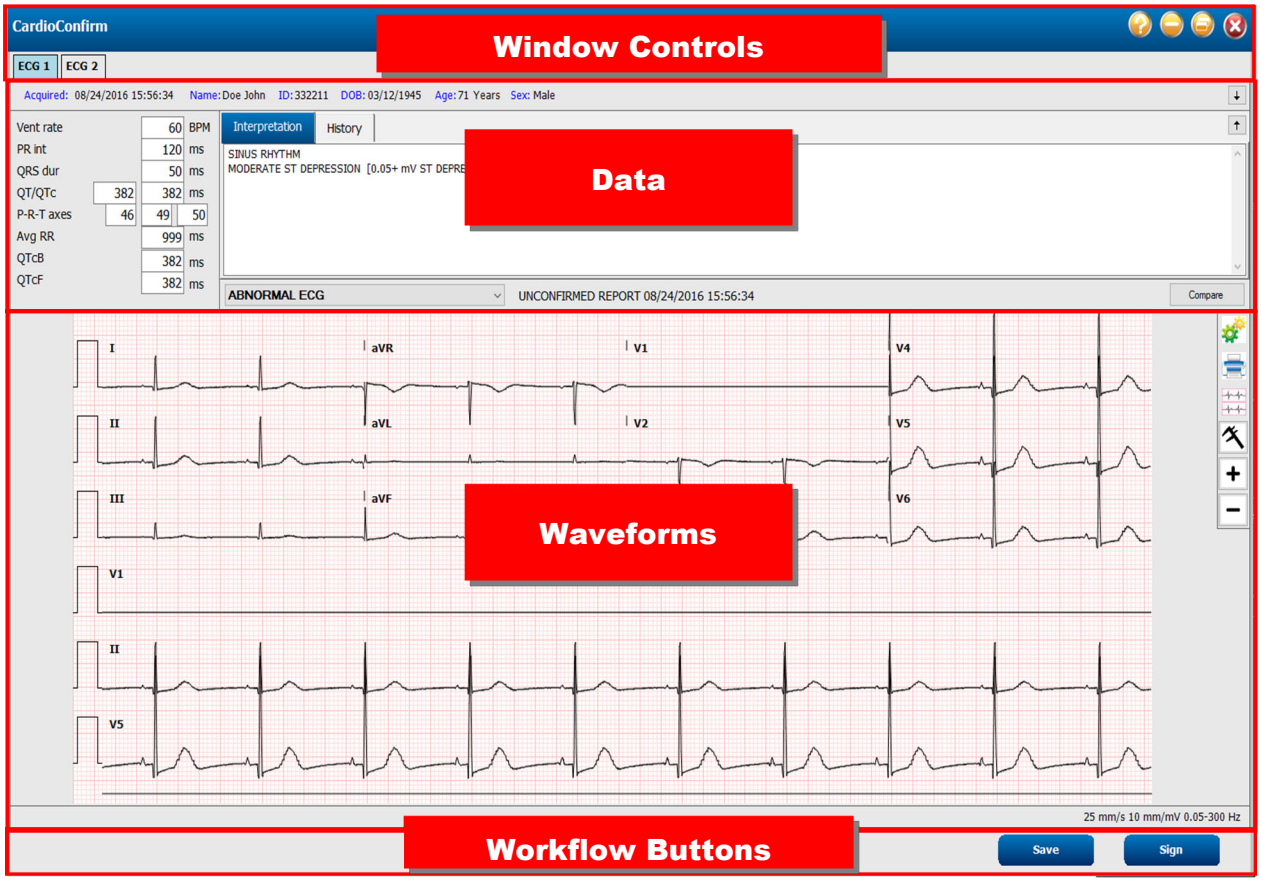
USER INSTRUCTIONS

Theory of Operation

CardioConfirm is used to view and confirm preliminary resting ECGs, stress reports, and Holter reports. The standard version may be used to open DICOM 12-lead and General ECG Waveform files made by Welch Allyn resting ECG devices as well as DICOM Encapsulated PDF files made by Welch Allyn stress and Holter systems. The professional version may be used to open resting ECGs in the DICOM 12-lead or General ECG Waveform format regardless of the device that recorded it. CardioConfirm is not intended to be used by itself. It is launched by a hosting application that manages the diagnostic ECG reporting workflow, user authentication and authorization, and persistent storage of the ECG records and reports. Some features described below will only be available when performing certain workflow tasks and when the user has the appropriate permissions.

Resting ECG Module

The main areas of the user interface are the Window Controls, Data, Waveforms, and Workflow Buttons as illustrated below.



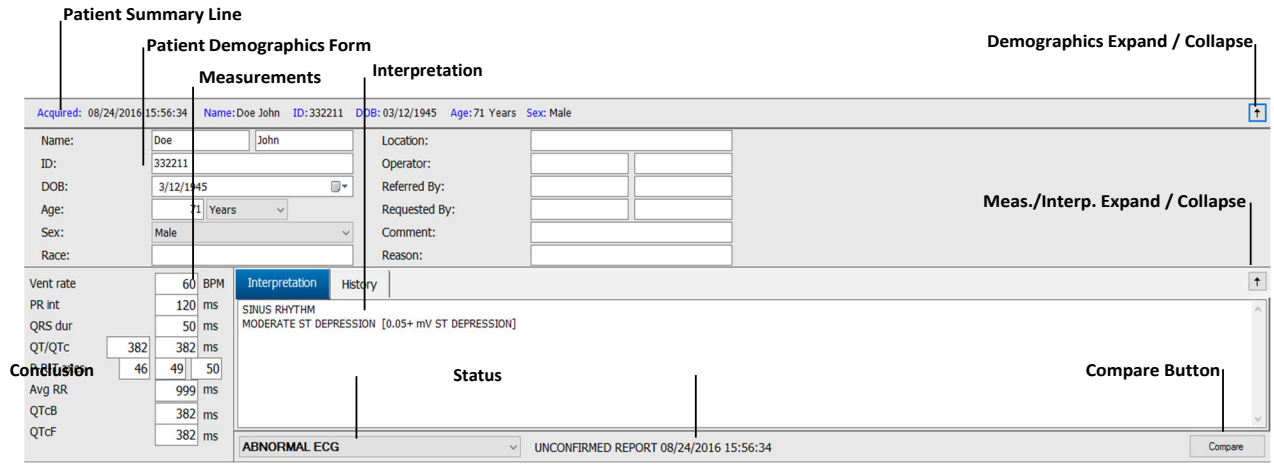
Window Controls

The buttons available at the top of the application window are described below.

Button	When Available	Action
ECG Tab	Multiple ECGs are loaded for serial comparison.	Clicking on an ECG's tab causes it to be displayed.
About	Always	Displays a dialog box that gives information about the application, including its UDI.
Minimize	Always	Minimizes the application window.
Maximize	Always	Maximizes the application window. Clicking again restores the application's previous size and position.
Close	Always	Closes the application without saving changes.

Data

The Data area of the application consists of patient demographics, global measurements, and the interpretation.



Patient Demographics

The demographics form can be expanded and collapsed with the arrow icon on the right-hand end of the patient demographics summary line. When expanded, all available demographics are displayed. The user may edit the demographic values if he has permission to do so. The patient's age is calculated from his birthdate, but the age may be entered directly when the birthdate is not known. Names of people (patient, device operator, referring physician, and requesting physician) have two text boxes.
The person's first name goes into the box on the left, and the person's last name goes into the box on the right.

Measurements

The measurements and interpretation form can be expanded and collapsed with the arrow icon in the upper right-hand corner of the form. When the user has permission to do so, the global measurements may be changed directly in the measurements form. The corrected QT values may not be entered directly because they are derived from the QT and Ventricular Rate values. The Average RR interval may not be entered directly because it is derived from the Ventricular Rate. The following values can be set by measuring the intervals with time calipers drawn on the waveforms: Ventricular Rate, PR Interval, QRS Duration, and QT Interval.

Interpretation

When the host application allows it, the user may edit the ECG's interpretation. Preliminary interpretation statements may already present. If the user agrees with the statements, he doesn't need to change them. If he doesn't agree with them, he may delete, modify, and add statements. When adding statements, CardioConfirm will do its best to predict the full statement after the user enters a few characters. It guesses by matching on the first word in its statement library, and by matching the first characters of multiple words in the statement. When the user sees the statement he wants, he may use the arrow keys and Enter to select it, or he may use the left mouse button to select it. For example, entering "AF" will cause CardioConfirm to guess "ATRIAL FIBRILLATION" because the first letters of multiple words were entered. It will also guess this same statement when the user enters "AT", the first part of the first word. CardioConfirm presents the statement guesses in order of use frequency, the most frequently used statements first.

The following keyboard shortcuts are available when editing interpretation statements:

Keyboard Action	Description
Down arrow	Moves focus to the statement pick list.
Enter (in statement pick list)	Adds highlighted statement to the interpretation.
Ctrl – L	Deletes the statement text, leaving a blank line.
Ctrl – L Ctrl – L	Deletes the statement without leaving a blank line.
Esc	Closes the statement pick list.

Conclusion

The Conclusion may be pre-populated in the preliminary ECG. The user may select a different conclusion from one of the choices CardioConfirm presents, but a free text conclusion is not supported.

Status

The status shows the ECG's current status. ECGs generally start with automatic interpretations that have yet to be confirmed by a qualified clinician. These will have a status of "Unconfirmed" along with the time of the automatic interpretation.

When the host application allows a user to edit the interpretation but not sign it, the edited interpretation will have a status of "Edited" along with the name of the person who edited the interpretation and the time it was edited. This means the interpretation was most likely edited by a medical assistant from a physician's dictation or handwritten notes. It is expected that the transcribed interpretation will later by checked and signed by a physician.

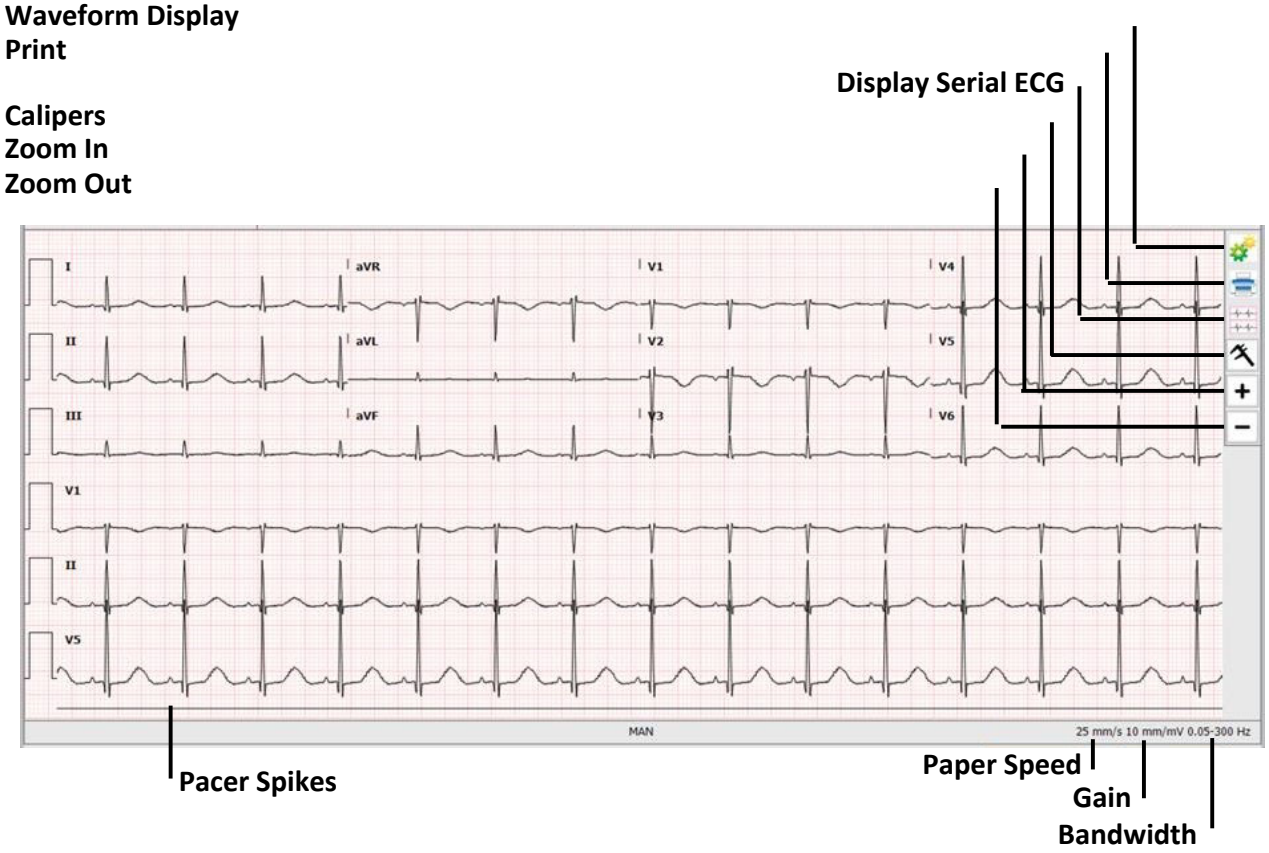
When the host application allows the user to sign the interpretation, the interpretation will have a status of “Electronically Signed” along with the name of the person who signed the interpretation and the time it was signed.

History

As the ECG is edited and signed, the history is saved in the ECG record. The history can be viewed by clicking on the History tab.

Waveforms

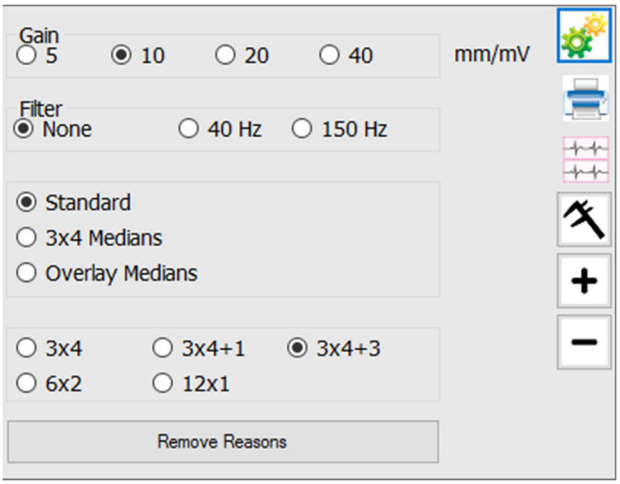
The waveform area displays the ECG waveforms. The 10-second ECG is drawn in its entirety, no matter how much or little space is available on the screen. This allows the user to get an overall view of the entire recording. The waveforms are drawn over a traditional 1 mm grid with 5 mm major lines. The paper speed is always 25 mm/s, and the gain defaults to 10 mm/mV. Each waveform channel starts with a traditional “calibration pulse” that is 1 mV tall and 200 ms wide. All leads are labeled at their beginning a few mm above their baseline.



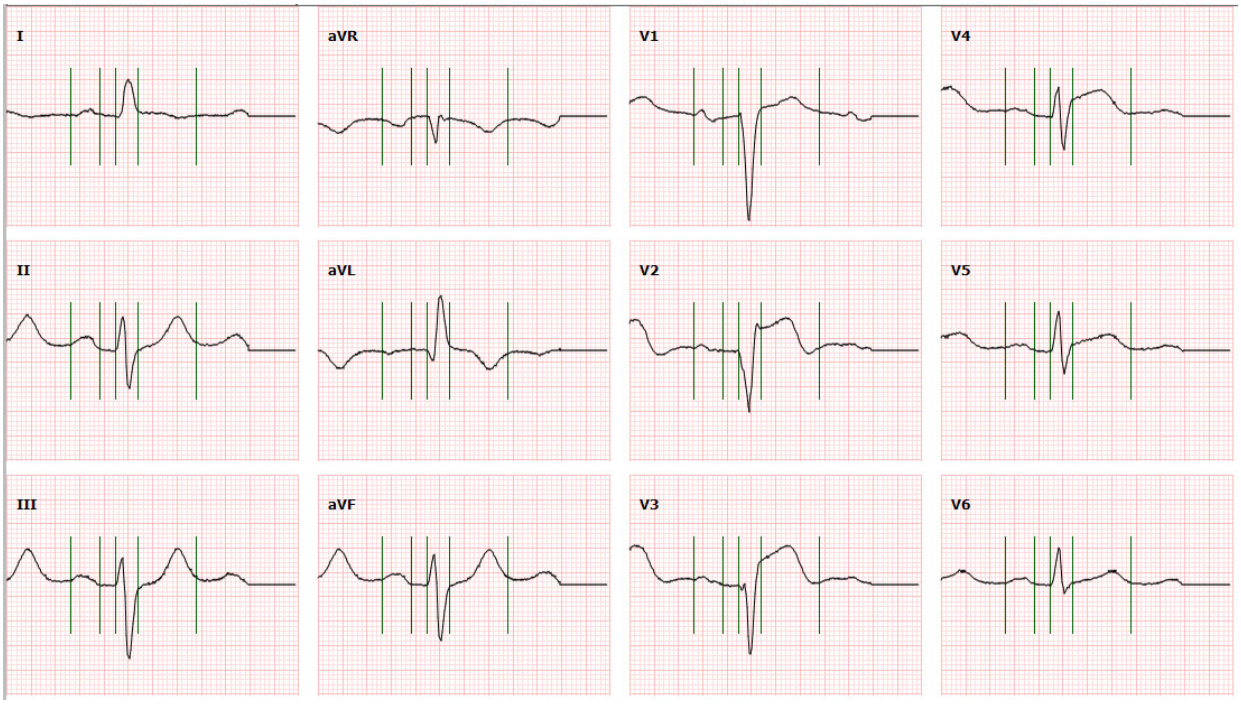
The waveform display settings are accessible with the “gear” icon on the right. The gain may be set to 5,10, 20, or 40 mm/mV relative to the 1 mm grid in the background. The noise filter may be set to 40 or 150 Hz. Turning the noise filter off will cause the waveforms to be drawn at their native bandwidth

Welch Allyn ECGs have a native bandwidth of 0.05 to 300 Hz. Note, the 40 Hz filter should only be used when the high frequency noise obscures the underlying signal too much. The 40 Hz filter attenuates frequencies above 40 Hz, and some diagnostic information may be attenuated along with the noise.

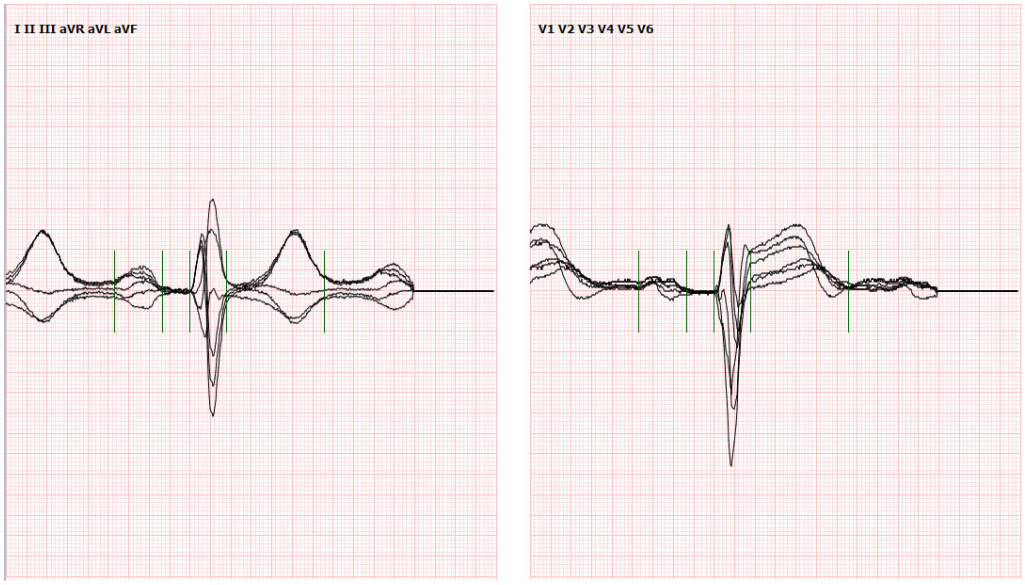
The display mode can be switched between Standard, 3x4 Medians, and Overlay Medians. The Standard display shows the traditional waveform layout printed by most electrocardiographs. The Standard layout can further be configured for 3x4, 3x4+1, 3x4+3, 6x2, and 12x1 formats.



The 3x4 Medians displays the ECG’s median beat, and the 12 leads are displayed in the traditional 3x4 grid. Vertical markers indicate where the electrocardiograph’s automatic analysis determined the P-onset, P-offset, QRS-onset, QRS-offset, and T-offset locations to be.



The Overlay Medians display the ECG's median beat on two grids. The left grid shows leads I, II, III, aVR, aVL, and aVF overlaid on each other. The right grid shows leads V1 – V6 overlaid on each other.
Markers show where the automatic analysis determined the P-onset, P-offset, QRS-onset, QRS-offset, and T-offset locations to be.



Printing

The ECG may be printed using the Print icon next to the waveforms. The print dialog gives the user access

to the printer's properties, and the user can print more than one copy. Note, printing is intended to be performed with a black and white printer, so the grid is not printed in color even if the printer is capable of printing colors.

Magnifying Loupe

When the user needs to view the details of the waveforms more closely, the magnifying loupe may be used. It is activated and sized with the mouse scroll wheel. It displays an oval-shaped area where the waveforms are magnified, and it follows the mouse cursor.

Calipers

In any of the display modes, calipers can be drawn on the waveforms to measure voltage or time. Time calipers are shown in milliseconds. When multiple voltage calipers are drawn, the sum of all the amplitudes is displayed in parenthesis.

To draw a caliper, the user simply drags the mouse over the waveforms while depressing the left mouse button. Dragging in the vertical direction measures voltage, and dragging in the horizontal direction measures time. Once a caliper is placed on the waveforms, it can be moved and resized. It can be moved by dragging the dashed line with the left mouse button, and it can be resized by dragging one of the caliper lines with the left mouse button.

The following keyboard shortcuts apply to the most recently manipulated caliper:

Keyboard Shortcut	Description
Delete	Removes the caliper.
+ **-**	Use the Plus and Minus keys to make fine adjustments to the caliper's length.
Left arrow **Right arrow** **Up arrow** **Down arrow**	Use the arrow keys to make fine adjustments to the caliper's position.
Shift + **Shift -**	Hold the Shift key while using the Plus and Minus keys to make medium adjustments to the caliper's length.
Shift – Left arrow **Shift – Right arrow** **Shift – Up arrow** **Shift – Down arrow**	Hold the Shift key while using the arrow keys to make medium adjustments to the caliper's position.

Shift – Ctrl + **Shift – Ctrl -**	Hold the Shift key while using the Plus and Minus keys to make coarse adjustments to the caliper's length.
Shift – Ctrl – Left arrow **Shift – Ctrl – Right arrow** **Shift – Ctrl – Up arrow** **Shift – Ctrl – Down arrow**	Hold the Shift and Ctrl keys while using the arrow keys to make coarse adjustments to the caliper's position.

A context menu with more options is available when clicking the right mouse button while the cursor is over the caliper's dashed line. The caliper can be removed from the display, or all calipers can be removed. Time calipers can be "marched out" which causes additional calipers lines to be shown at the same interval. This is useful for measuring the periodicity. When the user has permission to edit the global measurements, addition options are given for setting the ventricular rate, PR interval, QRS duration, and QT interval from the caliper's time measurement.

Serial Comparison

CardioConfirm supports the algorithmic comparison of serial adult ECGs and allows the user to edit the automatic comparison statements. When previous ECGs are available for the patient, CardioConfirm can display them so changes can be noted when interpreting the current ECG. Clicking the Serial ECG icon on the right toggles the display of the previous ECG under the current ECG. The previous ECG is drawn with blue waveforms to make it distinguishable. The previous ECG's interpretation is also displayed. If it obscures an important part of the waveforms, it can be moved by dragging it with the left mouse button, or the arrow to the right of the ECG's acquisition time can be used to hide it.

The waveforms of the previous ECG can be superimposed on the waveforms of the current ECG for a more direct comparison of the waveform rhythm and morphology. The following mouse and keyboard actions are available for manipulating the waveform superimposition:

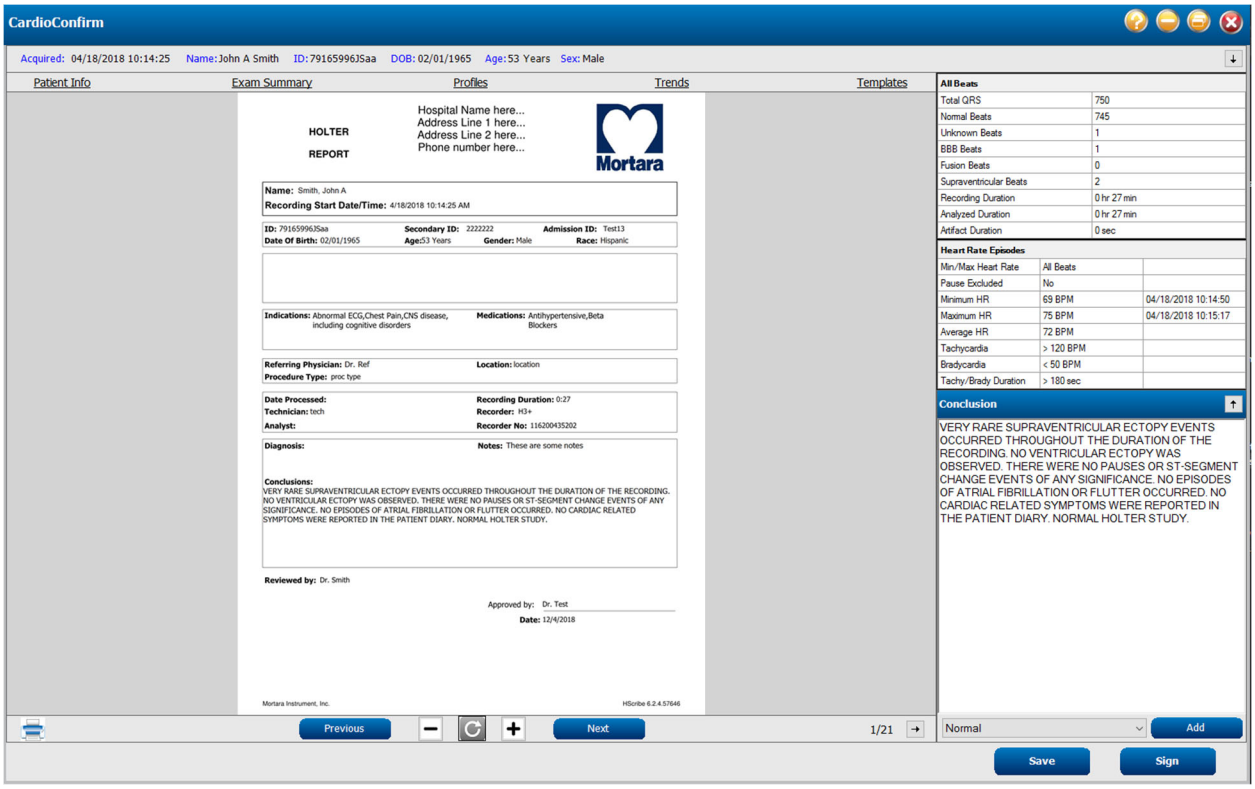
Mouse or Keyboard Action	Description
Shift – Left Mouse Button	Use the left mouse button while holding the Shift key to drag the serial waveforms on top of the current ECG's waveforms.
Left arrow **Right arrow** **Up arrow** **Down arrow**	Use the arrow keys to make fine adjustments to align the serial waveforms with the current ECG's waveforms.
Shift – Left arrow **Shift – Right arrow** **Shift – Up arrow** **Shift – Down arrow**	Hold the Shift key while using the arrow keys to make medium adjustments to align the serial waveforms with the current ECG's waveforms.
Shift – Ctrl – Left arrow **Shift – Ctrl – Right arrow** **Shift – Ctrl – Up arrow** **Shift – Ctrl – Down arrow**	Hold the Shift and Ctrl keys while using the arrow keys to make coarse adjustments to align the serial waveforms with the current ECG's waveforms.

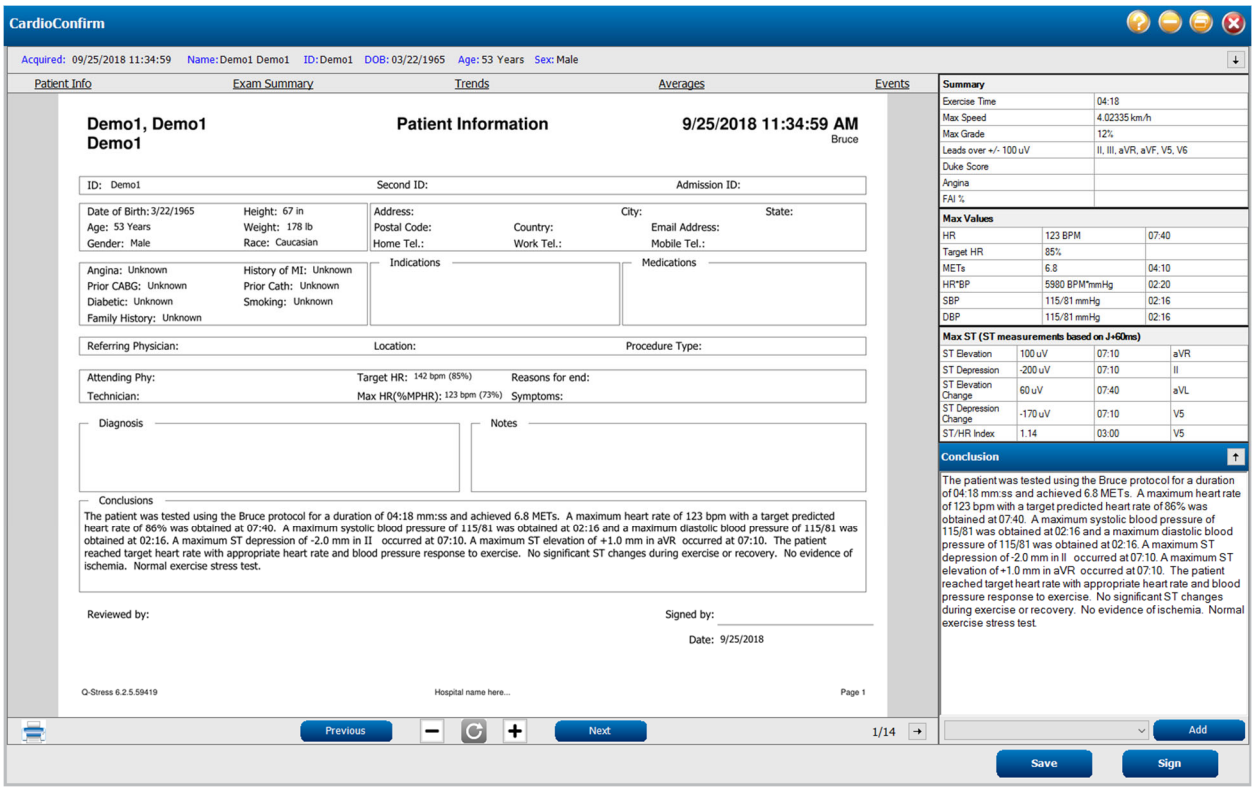
The other ECGs can be viewed by themselves by clicking the tabs at the top. The tab labeled "ECG 1" is the ECG being interpreted. The other ECGs available for comparison are labeled "ECG 2", "ECG 3", etc.

Serial comparison statements are kept separate from the traditional interpretation statements by entering them into the text box to the right of the interpretation box. If the serial comparison box is not visible, click the "Compare" button. The Compare button will also add automatic comparison statements if both ECGs were produced by Welch Allyn devices. The automatic statements may be removed, changed, or extended in a similar manor as interpretation statements. Likewise, CardioConfirm will display statement guesses as the user starts typing each statement.

HOLTER AND STRESS REPORT MODULES

Holter and stress reports can be viewed and signed in CardioConfirm. The report pages are displayed in the main part of the window. Patient demographics are displayed at the top like they are for resting ECGs (see Resting ECG section). Some of the summary statics can be viewed in the table in the upper- right-hand corner. The physician's conclusions can be entered in the lower-right-hand corner using the Add button to select from predefined dropdown options.





Report Navigation

Click the Next button to go to the next page, and click the Previous button to go to the previous page. When the report has focus, the Up, Down, Left, and Right arrow keys can also be used. The current page number and total number of pages are displayed in the lower right-hand corner of the display area. If the report has major sections, clicking the section hyperlink above the display area will go directly to that section. For Holter reports, the report sections are grouped together as Patient Info, Exam Summary, Profiles, Trends and Templates. For Stress reports, the report sections are grouped together as Patient Info, Exam Summary, Trends, Averages and Events.

Magnification and Zoom

When zoomed all the way out so a full page fits in the display read, a magnifying loupe can be activated with the mouse scroll wheel. The loupe can be moved around the page with the mouse. The loupe can be hidden by moving the scroll wheel in the opposite direction.

A page zoom feature is also available by using the “+” and “-“ buttons. When zoomed, the page can be dragged on the screen with the left mouse button.

Statistics

Summary statistics are visible in the upper right-hand corner of CardioConfirm. If the user has edit privileges, these values can be edited and saved, and CardioConfirm will change the values on the report.

Conclusions

When the host application allows Edit privileges, the user may enter free-text conclusions into the Conclusions box. If conclusion templates are available, a template can be loaded into the Conclusions box by selecting the template and clicking the Add button. CardioConfirm will update the appropriate report page with the entered conclusions.

Save and Sign

When the host application allows Save privileges, a Save button is available at the bottom of the CardioConfirm window. Clicking Save will save the changes to the report without electronically signing it.

When the host application allows Signing privileges, a Sign button is available at the bottom of the CardioConfirm windows. Clicking Sign will save the changes and electronically sign the report.

Print

A print icon is available at the bottom of the report display area. Clicking this icon will cause the standard Windows printer dialog to be displayed so an appropriate printer can be selected for printing the report.