ELI Edit Application Implementation Guide

REF 9515-166-55-ENG Rev D

Contents

Manufactured by Mortara Instrument, Inc., Milwaukee, Wisconsin U.S.A.

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

For patent information, please visit www.welchallyn.com/patents

Information in this document is subject to change without notice. Names and data used in the examples are fictitious unless otherwise noted. Software: v1.3.7 2019-04, Document revision: 2019-04

Trademark Information

ELI is a trademark of Mortara Instrument, Inc. All other product and company names are trademarks or registered trademarks of their respective companies.

Definition of Symbols

⚠️ - WARNING: means there is a possibility of personal injury to you or others.

⚠️ WARNINGS

- Inadequate knowledge or training could result in increased risk of harm to patients.
- User instructions for ELI™ Edit must warn that it "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."
- 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 cannot be reduced by proper procedures.
- Possible malfunction risks could be associated with installing 3rd party software. Mortara Instrument, Inc. cannot verify the compatibility of all possible hardware/software combinations.
- Operation of ELI Edit should be verified in a test environment prior to deployment for patient use.
- User instructions for ELI Edit must be provided to the target users. The user instructions must include a warning about users having adequate knowledge and training.
- The user instructions should be provided in a language that is understood by the target users.
- The organization integrating ELI Edit into their application and delivering it to their customers must offer adequate training for the proper use of ELI Edit.
- The hosting application must take care to secure all personal health information exchanged with the ELI Edit application.
- Serial comparison statements generated by algorithmic comparison of two ECGs should be confirmed by a trained physician or clinician before using in the care of the patient.
- Possible malfunction risks could be associated with improper installation of the software. Please follow the installation instructions provided herein.

Notes

- ELI Edit v1.3.7 is compatible with 12-lead ECG Waveform objects conforming to the "ELI DICOM Conformance Statement M0356-001" Revisions 8 through 11.

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 Mortara service for additional training options.

Intended Use of Application

ELI Edit is a software application that opens DICOM ECGs and allows clinical professionals to view, measure, interpret, edit, and electronically sign resting ECGs.

Intended Use of Document

This document provides instructions for software developers and their managers who will implement the integration between the ELI Edit 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.

Document Scope

The ELI Edit Application is a Windows application that can open, display, and edit DICOM 12-lead ECG Waveform files. The **Standard** version only opens ECGs made by Mortara devices. The **Professional** version also opens ECGs made by non-Mortara devices. The ELI Edit Application is intended to be launched from another application that is taking responsibility for:

- Deciding which ECG to view and/or edit.
- Deciding which ECG to use for comparison.
- Preparing the ECG(s) as .dcm files for viewing and/or editing.
- Authenticating the user and determining his privileges.
- Launching ELI Edit and telling it what to display, how to display it, and what the user is allowed to do with it.
- Storing the updated .dcm file after the ELI Edit application exists.

The rest of this document goes over installing the application on host computers and how to control the application through a combination of command line arguments and a configuration file. There is also information about the log files ELI Edit creates to aid in troubleshooting.

Installation Checklist

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

1. Verify the host computer is running Windows 7 or Windows 8.
2. Copy the ELI Edit Application files into a folder on the host computer.
3. Copy and rename the two EliEdit*Strings.xml files into the root installation folder.
4. Verify .NET Framework 4.6.1 or higher is present, and install .NET Framework 4.6.1 if necessary.
5. Verify Microsoft Visual C++ 2017 Redistributable Package (x86) is present, and install it if necessary.

Supported Operating Systems

ELI Edit 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, 64-bit

Copying Files to Host Computer

No "setup.exe" or MSI installer is provided. Installation is a matter of copying the application files into a folder on 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.

Localization

There are two XML files that specify the strings to be used in the user interface. These two XML files must be copied into the ELI Edit installation folder. If these string files don't exist, the application defaults to using English strings.

- EliEditStrings.xml
- EliEditAppStrings.xml

Versions of these files are provided for English (en), German (de), French (fr), Italian (it), and Brazilian Portuguese (pt-BR). Copy the language-specific versions of these files from the Languages folder into the application installation folder and remove the language-specific parts of the filenames. For example, rename "EliEditStrings-en.xml" to "EliEditStrings.xml".

Run-time Environment

The ELI Edit application requires the following software components to be installed on the computer hosting it:

- Microsoft .NET Framework 4.6.1
- Microsoft Visual C++ 2017 Redistributable Package (x86)

Checking for Microsoft Visual C++ 2017 Redistributable Package

The ELI Edit application needs the Microsoft Visual C++ 2017 Redistributable Package to be present on the computer hosting it. Here are a couple ways to check if this package has already been installed:

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/enus/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

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

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

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

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

Measurement Editing – By default, the global measurements cannot be edited. These include the Ventricular Rate, PR Interval, QRS Duration, QT Interval, P/R/T Axes. The `/EditGlobals` argument enables these measurements to be changed.

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

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

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

Electronic Signature – By default, the ECG 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. 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:\> EliEcgEditor.exe ecg2edit.dcm /Sign
C:\> EliEcgEditor.exe ecg2edit.dcm /Sign /Signer:"Dr. Charles
Smith"
```

Saving Edited ECG as DICOM File – If the user has permission to edit or sign the ECG, by default the original DICOM ECG 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 ECG file's filename will be used.

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

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

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

Saving Signed ECG as PDF File – If a PDF file of the ECG 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 ECG file's filename will be used, but with a .pdf filename extension.

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

Configuration File

Many aspects of the ELI Edit 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 "EliEcgEditorSettings.xml" in the application's folder will be used. If this file doesn't exist, the application will use its default settings.

```
C:\> EliEcgEditor.exe ecg2edit.dcm
/config:"\\myserver\myecgs\EliEcgEditorConfig.xml"
```

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

General Settings

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

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

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.
`<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.
`<Print/>`	When true, the user has the option to print the ECG.	**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.
`<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.

Element	Description	Values
`<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.
`<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.
`<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.
`<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.

* 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>0</EditDemographics>
      <EditGlobals>0</EditGlobals>
      <EditInterpretation>ReadOnly</EditInterpretation>
      <SaveText1>Transcribed 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.	**0*** – no demographics editing is allowed. **1** – all demographic fields can be edited. **2** – all demographic fields can be edited except the patient's name, ID, DOB, and sex.
`<EditGlobals/>`	Specifies if the global measurements can be edited.	**0*** – editing is disabled. **1** – editing is allowed.

Element	Description	Values
`<EditInterpretation/>`	Specifies if the interpretation 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 ECG. The user's name and the current date/time is appended to this label.	Default is **"Transcribed By: "** in support of the traditional transcription-save-sign workflow.
`<SignText1/>`	Specifies the text used to label who is signing the ECG. 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

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.

Element	Description	Values
`<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

ELI Edit Application 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.

Errors Triggered by software fault in displaying ECG Record

- If there was an error in displaying an ECG record, an error message: "An unexpected error has occurred. Please contact your system administrator." Will pop up and an error will be logged.

User Instructions

Theory of Operation

ELI Edit is used to view and interpret resting ECGs. The standard version may be used to open DICOM 12-lead ECG Waveform files made by Mortara resting ECG devices. The professional version may be used to open all resting ECGs in the DICOM 12-lead ECG Waveform format regardless of the device that recorded it. ELI Edit is not intended to be used by itself. It is launched by a hosting application that manages resting ECG workflow, user authentication and authorization, and persistent storage of the ECG records. Some features described below will only be available when performing certain workflow tasks and when the user has the appropriate permissions.

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

Buttons

The buttons available at the top of the application window are described below.
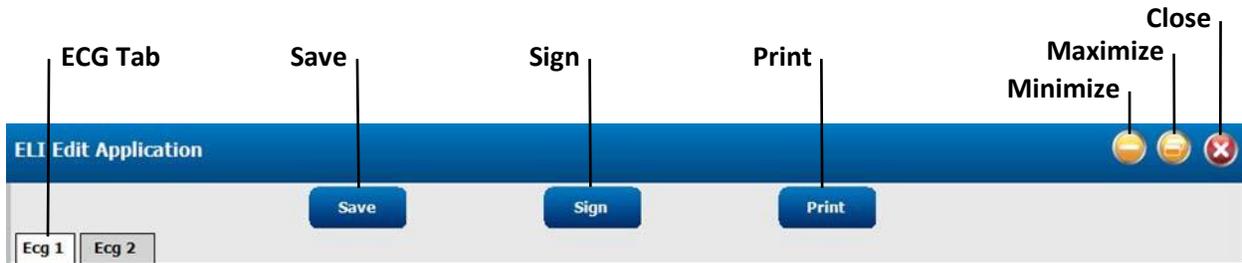
Button	When Available	Action
ECG Tab	Multiple ECGs are loaded for serial comparison.	Clicking on an ECG's tab causes it to be displayed.
Save	User has permission to make changes to demographics, measurements, and/or interpretation statements.	Saves the changes made to demographics, measurements, and/or interpretation statements and then exists the application. The ECG is marked as having been transcribed by the user.
Sign	User has permission to electronically sign the interpretation.	Saves the changes made to the demographics, measurements, and/or interpretation statements and then exists the application. The ECG is marked as having been electronically signed by the user.
Print	User has permission to print the ECG.	Displays a list of printing devices known to the computer. Prints the ECG after the user selects the printing device to use.
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 Form   Patient Summary Line   Demographics Expand / Collapse

DONALD, ROSEY; ID: 63744565; Female, 64 yr DOB: 11/11/1953 Acquired: 06/29/2018 07:32:26

Meas./Interp. Expand/Collapse

Global Measurement Form   Conclusion   Interpretation   Status   Compare Button

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 should normally be calculated from this birthdate, but the age may be entered directly when the birthdate is not known. To enter an age, uncheck the box in the DOB field. 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 because they are derived from the QT and Ventricular Rate values. The Average RR interval may not be entered because it is derived from the Ventricular Rate. The following values can also be set by measuring the intervals with time calipers drawn on the waveforms: Ventricular Rate, PR Interval, QRS Duration, and QT.

Interpretation

When the user has permission to do so, he may edit the ECG's interpretation. There are likely interpretation statements already present from the acquisition device's ECG analysis algorithms. If the user agrees with the statement, he doesn't need to change them. If he doesn't agree with them, he may delete, modify, and statements. When adding statements, ELI Edit 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 want, 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 ELI Edit 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. ELI Edit presents the statement guesses in order of popularity, the most popular 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 is usually pre-populated from the acquisition device's automatic analysis. The user may select a different conclusion if the device's conclusion isn't the best one. The Conclusion must be selected from one of the choices ELI Edit presents; the user may not enter free text into this box.

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 a user has permission to edit the interpretation but not sign it, the edited interpretation will have a status of "transcribed". This means the interpretation was most likely entered 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 user has permission to sign the interpretation, the interpretation will have a status of "electronically signed".

The status text is displayed in bold, is preceded by an icon (check or exclamation) and colored red or blue based on the following set of rules:

Edit Option set by hosting application	DICOM "Preliminary Flag" tag *(0040,A493)*	Status Text highlighting
Preliminary	N/A	Status text is displayed in bold font, red color and with an exclamation mark icon: e.g.
Final	N/A	Status text is displayed in bold font, blue color and with a check mark icon: e.g.
Undefined	PRELIMINARY	Status text is displayed in bold font, red color and with an exclamation mark icon. e.g.
Undefined	FINAL	Status text is displayed in bold font, blue color and with a check mark icon: e.g.
Undefined	Unknown	If the status text in the record is "Unconfirmed Report" (or its equivalent for ELI Edit's supported languages) , status text is displayed in bold font, red color and with an exclamation mark icon: e.g. Otherwise status text is displayed in bold font, blue color and with a check mark icon: e.g

History

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

Waveforms

The waveform area display 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.
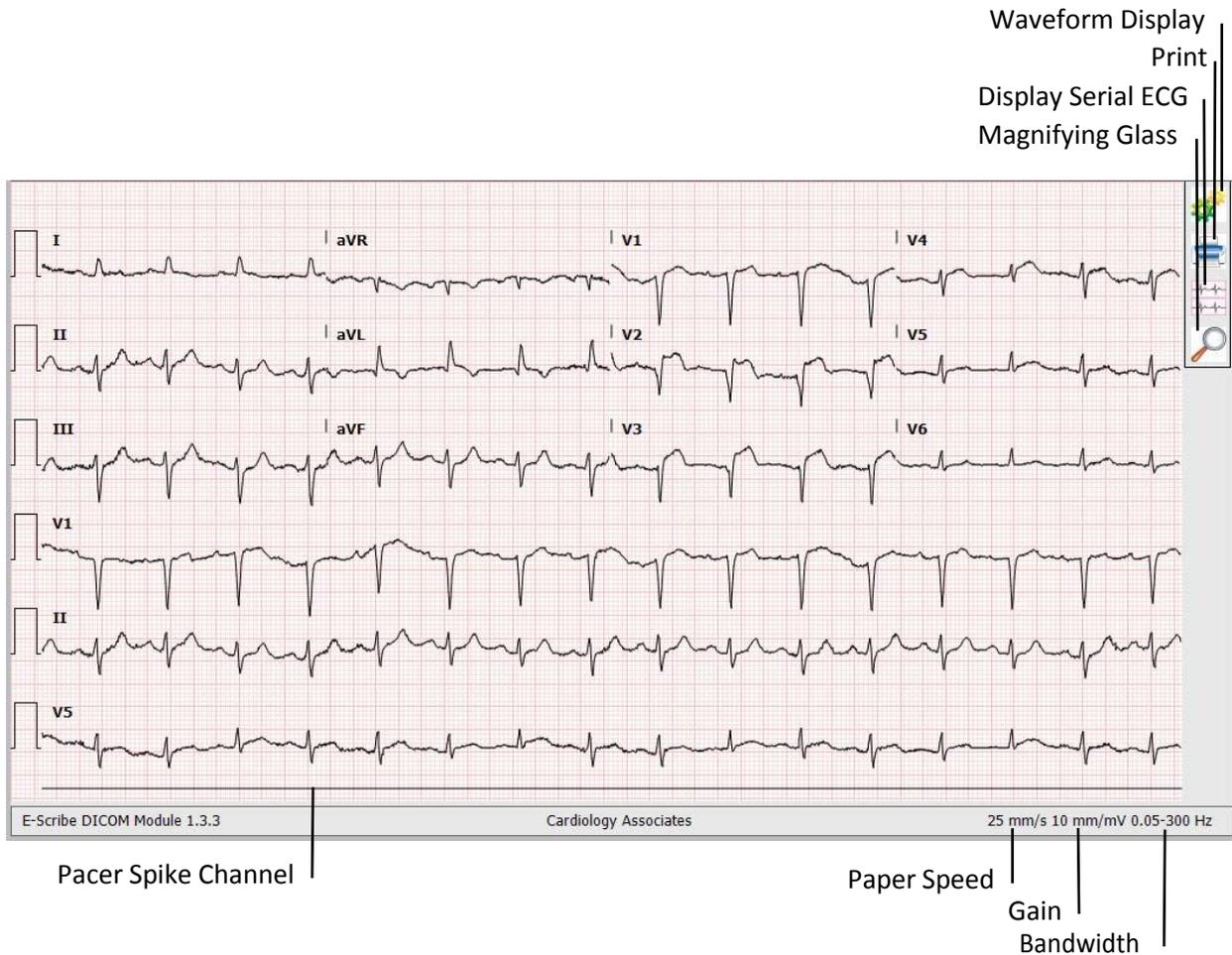
The waveform display settings are accessible with the "gear" icon on the right. The gain may be set to 5, 10, 20, or 40 mm/mV relative to the 1 mm grid in the background. The noise filter may be set to 40 or 150 Hz. Turning the noise filter off will cause the waveforms to be drawn at their native bandwidth. Mortara 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 there is some diagnostic information above this frequency.

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.
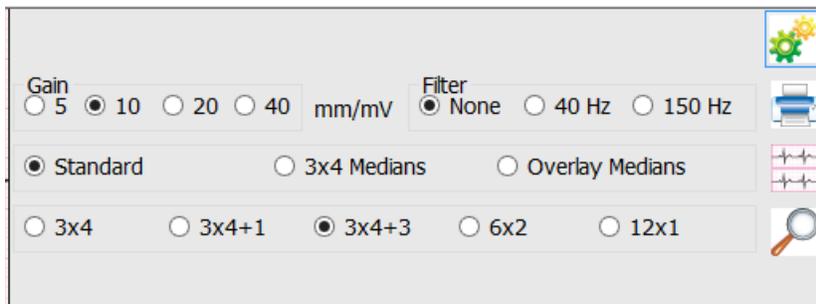
The 3x4 Medians displays the ECG's median beat, and the 12 leads are displayed in the traditional 3x4 grid. Vertical markers indicate where the electrocardiograph's automatic analysis determined the P-onset, P-offset, QRS-onset, QRS-offset, and T-offset locations to be.
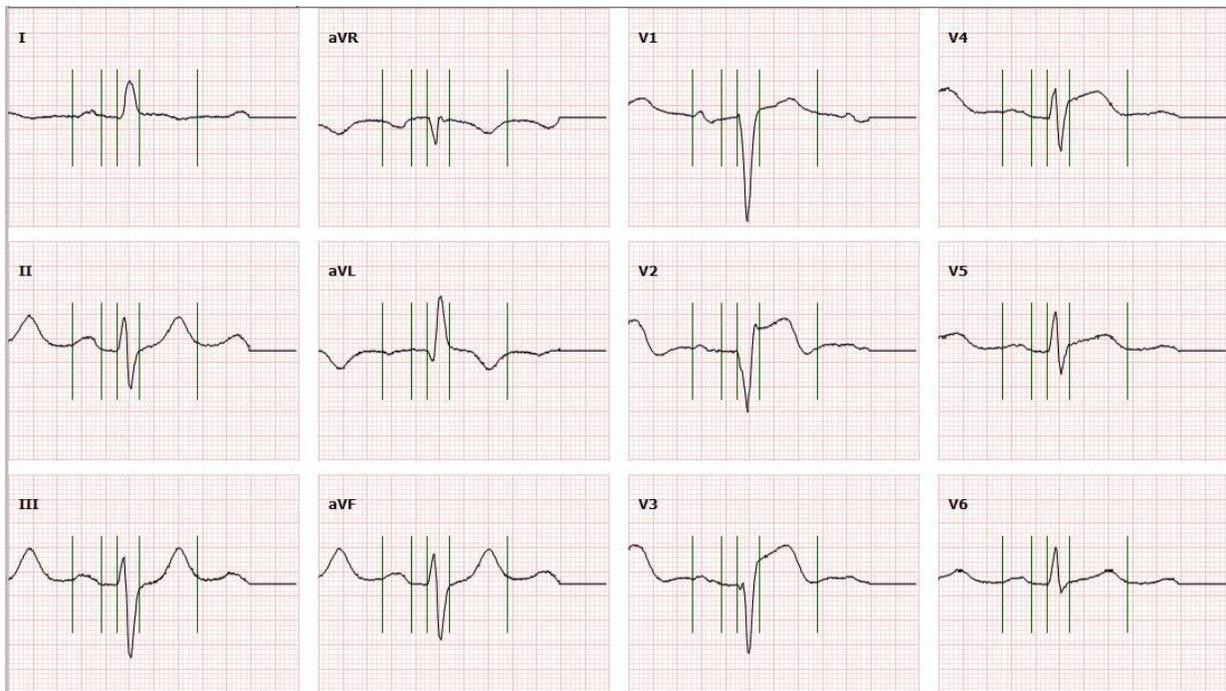
The Overlay Medians display the ECG's median beat on two grids. The left grid shows leads I, II, III, aVR, aVL, and aVF overlaid on each other. The right grid shows leads V1 – V6 overlaid on each other. Markers show where the automatic analysis determined the P-onset, P-offset, QRS-onset, QRS-offset, and T-offset locations to be.
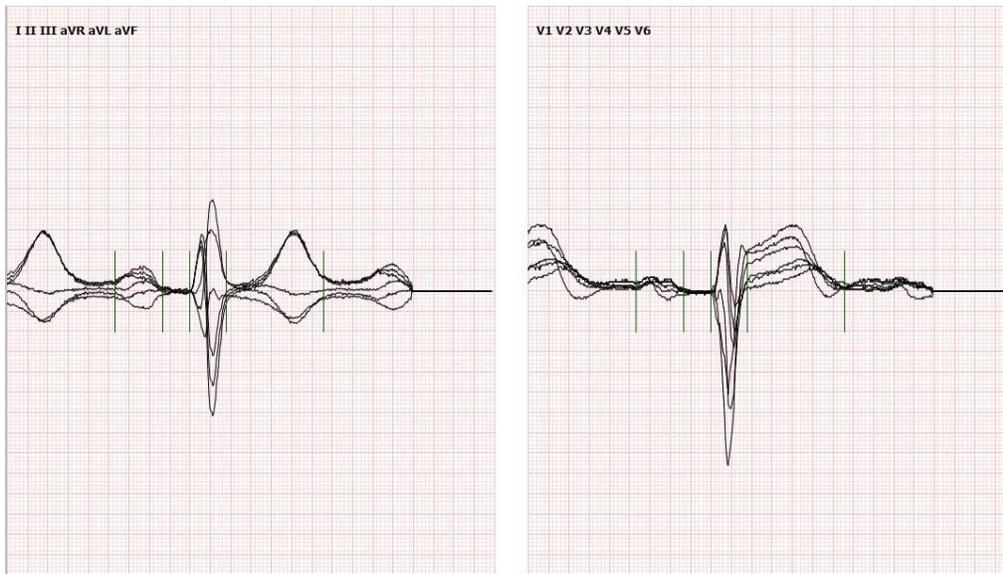
Printing

The ECG may be printed using the Print button at the top or the Print icon next to the waveforms. The button at the top simply displays a list of printing devices known to the computer, and then it prints the ECG as it is currently displayed on the screen. The print icon, on the other hand, displays a traditional Windows print dialog box. The dialog gives the user access to the printer's properties, and the user can print more than one copy. Otherwise, both print methods do the same thing. 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 Glass

When the user needs to view the details of the waveforms more closely, the magnifying glass may be used. When activated with the icon on the right, it displays an oval-shaped area where the waveforms are magnified. The magnification area follows the mouse cursor. The size and magnification power can be controlled with the mouse scroll wheel, and the scroll wheel can even be used to turn the magnifying glass on and off.

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. Voltage calipers are shown in millimeters when the gain is 10 mm/mV and microvolts when the gain is 5, 20, or 40 mm/mV. 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 duration from the caliper's time measurement.

Serial Comparison

When previous ECGs are available for the patient, ELI Edit 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", 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 Mortara devices. The automatic statements may be removed, changed, or extended in a similar manor as interpretation statements. Likewise, ELI Edit will display statement guesses as the user starts typing each statement.