GE Healthcare

MUSE™ v9

Cardiology Information Systems
Interval Editor Guide

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MUSE™ Cardiology Information Systems
English

Publication Information

The information in this manual applies only to the MUSE™v9 Cardiology Information Systems. It does not apply to earlier product versions. Due to continuing product innovation, specifications in this manual are subject to change without notice.

This product complies with the requirements concerning medical devices from the following regulatory bodies:

The document part number and revision are at the bottom of each page. The revision identifies the document's update level. The revision history of this document is summarized in the following table.

Revision	Date	Comments
A	14 July 2015	Internal Release.
B	28 July 2015	Customer Release.

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To access Original Equipment Manufacturer (OEM) manuals, go to the device manufacturer's Web site.

This document describes the Muse™ Cardiology Information System, also referred to as the" product", "system", or "device". This document is intended to be used by an operator of the MUSE system.

The MUSE™ Cardiology Information System is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or facility providing patient care.

This document provides information required for the proper use of the system. Familiarize yourself with this information, and read and understand all instructions before attempting to use this system. Keep this document with the equipment at all times and periodically review it.

NOTE:

All illustrations in this document are provided as examples only. Depending on system configuration, screens in the document may differ from the screens on your system.

All patient names and data are fictitious. Any similarity to actual persons is coincidental.

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This document is intended as a supplement to, not a substitute for, thorough product training. If you have not received training on the use of the system, you should request training assistance from GE Healthcare.

To see available training, go to the GE Healthcare training website (www.gehealthcare.com/training). Select *Education>Product Education-Technical> Diagnostic Cardiology*.

For more self-paced course offerings, tools, and reference guides you may find useful, please visit the GE Healthcare Education Store at www.gehealthcare.com/educationstore.

Contents

1 Introduction

Interval Editor 5

Manual Purpose 5

Intervals 5

Amplitudes 6

2 Using the Interval Editor

Interval Editor Window 7

Toolbar Icons and Description 9

Median vs. Raw Beat Editing Modes 10
Median Editing Mode 10
Raw Beat Edit Mode 10

Measuring and Editing Interval Values 12

Measuring and Editing Amplitude Values 15

Viewing and Exporting Data in Spreadsheet Format 18

Individual Beat QT Correction 19

Working in E14 Blinding Mode 20

Saving the Data 21

Keyboard Shortcuts 21

3 Set Up

Setting Up Interval Editor 23

Setting up Drug Trials 29

Creating an E14 Blinded Overreader 31

A Additional Information

Examples of Global Beat Calculations 33

Onset/Offset Global Calculation Method 34

Interval Global Calculation Method 34

1

Introduction

Interval Editor

The MUSE™ Cardiology Information System Interval Editor feature (also referred to as the Interval Editor or the tool) digitally measures and stores ten seconds worth of interval and amplitude data from up to 15 lead ECGs at either 250Hz or 500Hz.

The Interval Editor also provides automatic and semi-automatic methods to modify ECG wave onsets and offsets on lead-by-lead and beat-by-beat.

Manual Purpose

This guide contains the instructions necessary to perform interval editing on the MUSE™ v9 Cardiology Information System (also referred to as the MUSE system). This manual should be used in conjunction with the *MUSE ™ v9 Cardiology Information System Operator Manual*. For all safety and regulatory information see the *MUSE ™ v9 Cardiology Information System Regulatory and Safety Guide*. For instruction on operating the MUSE system, see the *MUSE ™ v9 Cardiology Information System Operator Manual*. Refer to the *Interval Editor Physician's Guide* for detailed information regarding the Interval Editor beyond what is provided in this manual.

Intervals

When an ECG is taken, the 12SL analysis program marks five fiducial points on the waveform. These five fiducial points are:

- P onset (beginning of the P-wave)
- P offset (end of the P-wave)
- QRS onset (beginning of the QRS complex)
- QRS offset (end of the QRS complex)
- T offset (end of T-wave)

The five fiducial points are used to calculate the following three intervals/durations:

Interval/Duration	Calculation	Formula
PR Interval	The time (in ms) between the P onset and the QRS onset	QRS onset - P onset

QT Interval	The time (in ms) between the QRS onset and the T offset	T offset - QRS onset
QRS Duration	The time (in ms) between the QRS onset and the QRS offset	QRS offset - QRS onset

The five fiducial points for each of the 12 leads can be adjusted on a patient's resting ECG. By adjusting the fiducial points, the user is able to adjust the ECG intervals .

Amplitudes

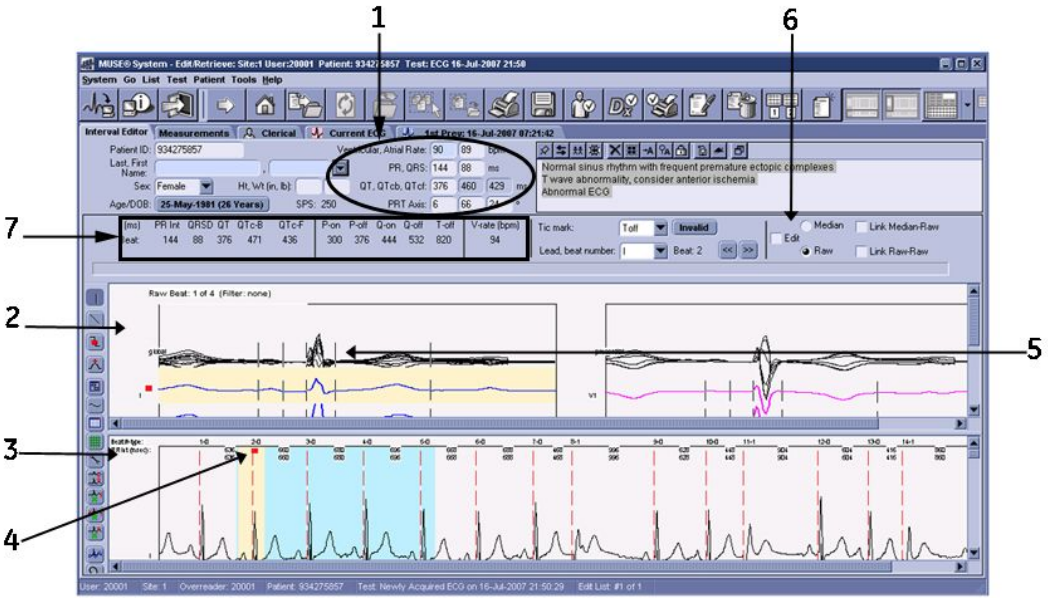
The tool allows you to review and change waveform amplitude fiducial points. To perform amplitude editing you need to define a portion of the waveform called a wavelet. These wavelets (or wave objects) are characterized by a start point of the wavelet, an end point of the wavelet, peak point, duration and area under the wavelet. Amplitude editing allows definition of up to 23 different amplitude wavelets. The amplitude review & editing function can be enabled or disabled on a site basis.

2

Using the Interval Editor

Interval Editor Window

To open the Interval Editor window, at the ***Edit/Retrieve*** window, select ***Tools > Test Editor Layout > Interval Editor Layout***.



Item	Name	Description
1	Global Measurements	The composite measurements made across all leads of the entire 10 second, 12 lead ECG. Global measurement data includes ventricular rate, PR interval, QRS Duration, QT, QTcB, QTcF, and P-R-T Axis. QTcB = QTc Bazett = QT (RR) $^{1/2}$ QTcF = QTc Fridericia = QT (RR) $^{1/3}$ where RR is the RR interval in seconds
2	***Edit*** window	Displays either the 10-second "median complex" or the currently selected beat's waveforms in two columns. The left column contains leads I, II, III, aVR, aVL, and aVF with a global lead view (all 12 leads superimposed) at the top. The right column contains the precordial leads, V1, V2, V3, V4, V5, and V6, with a superimposed precordial lead view at the top. Selected leads are blue. Data from selected leads are used in global calculations. (Done in ***Site Setup***). De-selected leads are pink. Data from de-selected leads are not used in global calculations. (Done in ***Site Setup***). To toggle a lead from blue (selected) to pink (de-selected), move the mouse pointer to the red dot and single right-click the mouse.
3	***Raw Data*** window	The 10 seconds of rhythm data for each of the 12 leads is displayed in the raw data window. Beats used for median complex are highlighted in blue. To select different beats for creating median complex, right click and drag left to right through beats you wish to select.
4	Red indicator dot	In the ***Edit*** window, this dot indicates the currently selected lead. In the ***Raw Data*** window, this dot indicates the currently selected beat.
5	Fiducial marks	Each beat displayed in the ***Edit*** window has 5 fiducial marks: P onset, P offset, QRS onset, QRS offset, and T offset. The analysis program places fiducial marks on each lead. This option allows you to move each of the fiducial marks on each of the leads.
6	Selection	Allows you to switch between edit modes (Median or Raw Beat). Also allows you to enable the Link Median-Raw and Link Raw-Raw options.
7	Beat Measurements	Displays the measurements of the currently selected beat if editing raw beats, or of the median complex if editing in median mode. Measurements include current intervals and location of current fiducial markers. Select another lead from the lead list, to display beat measurements for another lead.

Toolbar Icons and Description

Icon	Name	Description
	***Vertical measure line***	Used to measure/edit the position of the P onset, P offset, QRS onset, and QRS offset fiducial markers.
	***Slope measure line***	Used to measure/edit the slope of the T-wave.
	***Smooth filtering***	Changes the current filter. Clicking this icon toggles the filter from no filter to 40 Hz to 80 Hz.
	***Show Amplitude markers***	Turns amplitude markers on and off.
	***Measurement box***	Displays the measurement window.
	***Spline correction***	Corrects baseline wander. When this icon is enabled, spline correction is applied. When this icon is not enabled, spline correction is not applied.
	***Measurement matrix***	Displays a spreadsheet containing interval and amplitude data for all leads.
	***Toggle grid line***	Turns the pink grid lines on and off. The grid lines are at 40 ms.
	***Options***	Displays the options window. This option allows users to adjust settings for the edit mode, global calculation method, filtering, number of beats, resolution and measured leads.
	***Adjust distance between leads***	Separates different lead signals so that they can be viewed more clearly.
	***Individual QT algorithm***	Calculates lead-by-lead QT intervals of signals in the ***Edit*** window.
	***Initialize all onsets/offsets***	Recalculates all onsets/offsets with built in algorithm. All individual lead onsets/offsets are set to the recalculated global onsets/offset values.

Icon	Name	Description
	***Reinitialize all amplitude measurements***	Recalculates all amplitude values with the built in algorithm.
	***Overlay beats***	Overlays all selected raw beats for the current active lead. Those beats are aligned with QRS complex.
	***Change median resolution***	Zooms in and out of median signals.
	***Change raw resolution***	Zooms in and out of raw beat signals.
	***Print preview***	Displays a report and prompts for printing.

Median vs. Raw Beat Editing Modes

Median Editing Mode

When working in the ***Median*** editing mode, you will be adjusting the fiducial points on the median data displayed in the ***Edit*** window.

NOTE:

If the Raw Beat edit mode has been locked in ***System > Setup***, the system will allow you to switch to ***Median*** editing mode, but will not allow you to edit data in the ***Median*** edit mode.

The techniques for editing intervals in this mode are the same as those described in "Measuring and Editing Interval Values" on page 12.

Raw Beat Edit Mode

Enabling Raw Beat Editing

When editing interval or amplitude data in the ***Raw Beat*** editing mode, you may edit anywhere from 2 to 10 consecutive beats for each lead. The beats being edited are

shaded in blue in at the bottom half of the screen. The current beat being edited is indicated by the red indicator mark above the beat.

1. To enable ***Raw*** beat editing, select ***Edit*** and click on the radio button next to ***Raw***.

2. To change the beats highlighted in the ***Raw Data*** window, right-click and drag from the first beat to the last beat.

   If the number of beats has been locked in ***System > Setup***, you will be limited to selecting the number of beats that have been locked.

3. After you have selected the beats to be edited, select a lead and edit the intervals for each beat within that lead, before moving to the next lead. The techniques for editing intervals in this mode are the same as those described in "Measuring and Editing Interval Values" on page 12.

Link Median-Raw and Link Raw-Raw

The Link Median-Raw and Link Raw-Raw options facilitate editing and improve consistency.

NOTE:
If ***Edit Mode*** is locked at ***System > Setup > Sites***, this function cannot be used as it prevents you from editing in both modes.

Link Median-Raw

The ***Link Median-Raw*** option uses median markers as a reference for ***Raw*** beat editing.

1. Select ***Link Median-Raw*** check box.
2. Select the ***Median*** radio button.

   Make sure the ***Edit*** check box is selected if you are editing an ECG.
3. Select the appropriate lead.
4. Move the onset/offset marker to the appropriate position by using the mouse or keyboard.
5. Select the ***Raw*** radio button.

   Make sure the ***Edit*** check box is selected if you are editing an ECG.
6. All of the selected beat tic marks will have the same position as in the ***Median*** mode.
7. If no further editing of the ECG is required, you are finished. If further editing is required for a particular beat, uncheck the ***Link Median-Raw*** option and make the specific onset/offset adjustment beat-by-beat.

Link Raw-Raw

The ***Link Raw-Raw*** function populates tic mark position from the current ***Raw*** beat to all selected Raw beats.

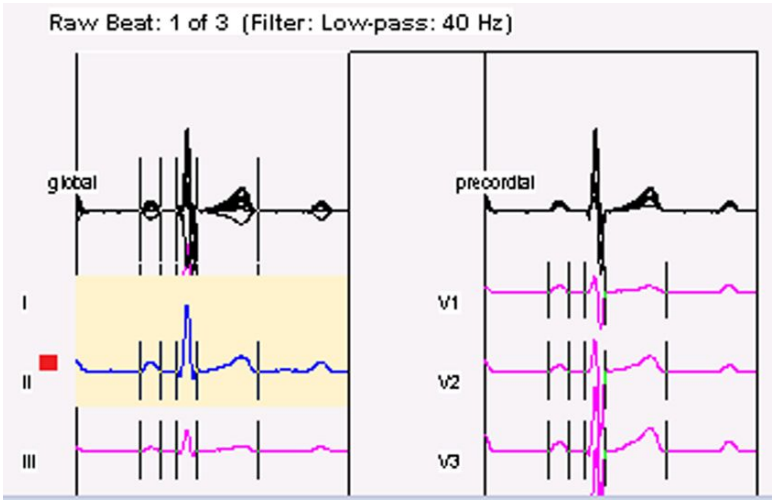
1. Place a check in the box next to ***Link Raw-Raw***.
2. Select a ***Raw*** beat to edit.
3. Select the appropriate lead.
4. Move the selected tic mark(s) to the appropriate position by using the mouse or keyboard.
5. All selected ***Raw*** beats will have the same position as the ones just edited.
6. If no further editing of the ECG is required, you are finished. If further editing is required for a particular beat, uncheck the ***Link Raw-Raw*** option and make the specific onset/offset adjustment beat by beat.

Measuring and Editing Interval Values

Measuring Interval Values

1. Clear the ***Edit*** check box to review the interval values at different fiducial marker positions without making a permanent change.
2. Adjust the filter by clicking the ***Smooth Filtering*** icon  in the toolbar. Each time the ***Smooth Filtering*** icon is clicked, the filter changes from ***None*** to ***40 Hz*** to ***80 Hz***. The current filter setting is displayed above the global lead view.

   If the filter has been locked in ***System > Setup***, this tool will be grayed and you will not be able to change the filter.



3. Click the ***Options*** icon  to adjust the global calculation methods. If the calculations method has been locked in ***System > Setup***, you will not be allowed to change it.

4. Click the ***Change median resolution*** icon  to adjust the viewing resolution. If the resolution has been locked in ***System > Setup***, you will not be allowed to change it.

5. If the medians overlap, you may increase the vertical spacing between the beats by clicking the ***Adjust distance between leads*** icon  .

   The ***Lead distance between leads*** window opens.

6. Enter a number from 150 to 450 (the default is 220) and click ***OK***.

7. To edit a median, select the ***Edit*** check box, and left-click on the appropriate median label in the top half of the window.

   The median will be highlighted in yellow.

   Median information appears in the status bar below global measurements as shown in the following figure.

8. To change the global beat calculation methods, select the ***Options*** icon  . The ***EditView Options*** window opens.

   Check the ECG waveform quality on the screen to make sure no noise is present. If noise is present, you may exclude the lead by right-clicking on the red dot of the lead label.

   Select the appropriate options to change the global beat calculation methods. See Appendix A for an explanation of the global calculation methods.

   NOTE:

   Any changes made in the ***EditView Options*** window will apply only to the current report.

Editing Interval Values

1. To edit any of the ECG intervals, select the ***Edit*** check box.

NOTE:
If the ***Edit*** check box is not selected, the value will change while you are moving the cursor, but the cursor and value will return to their previous positions after you release the mouse button.

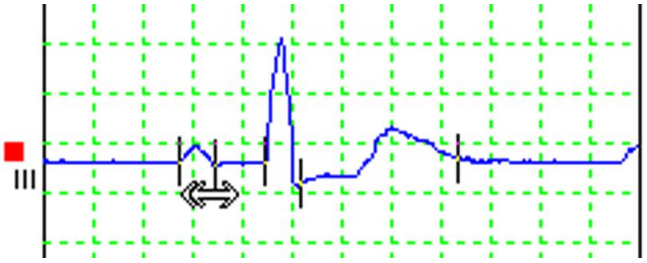
2. If possible, adjust the filter, the viewing resolution, and/or the edit viewing options.

3. Click the ***Vertical measure line*** icon  in the toolbar.

NOTE:
The ***Vertical Measure Line*** tool toggles with the ***Slope Measure Line*** tool. Only one can be active at a time. The ***Vertical Measure Line*** tool is active by default.

4. Move the cursor to the fiducial marker you want to measure.

5. Align the "active side" of the cursor with the fiducial marker you want to edit and click to activate the marker.



The active side of the cursor has double arrows.

6. Click and drag the fiducial marker. As you move the marker, the status bar displays information about the current position of the fiducial marker. The measurements displayed at the top of the window are also updated.

7. Repeat steps 4 through 6 for any other fiducial markers you want to edit.

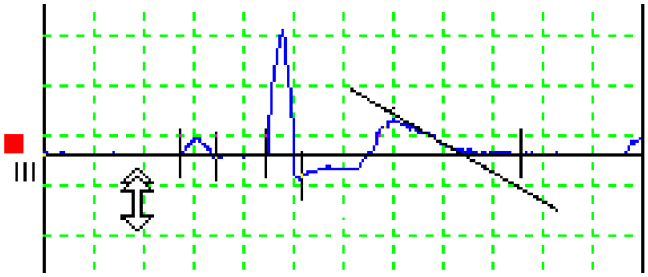
NOTE:
You can edit the T offset fiducial marker as described in steps 4 through 6.

You may click the ***Slope Measure Line*** icon  to edit the position of the T offset marker as described in the following steps 8 - 12.

8. Click the ***Slope Measure Line*** icon  in the toolbar.

9. Using the mouse, adjust the position of the slope line.

10. Move the cursor to the left side of the median (left of the P-wave). Align the "active side" of the cursor with the horizontal baseline.



The active side of the cursor has double arrows.

11. Click and drag the horizontal reference line. The arrow will appear horizontal until you click. As you move the line, the status bar displays the following information for the current location of the horizontal reference line

    a. ***Hamp (µV)*** – amplitude of current horizontal reference line in relation to the baseline

    b. ***toff*** – the point where the current horizontal reference line intersects with the T offset

    c. ***qtInt*** – the QT Interval with the above T offset location

12. After you have moved the horizontal reference to the desired position, press the **Enter** key. The T offset fiducial marker will snap to the point where the slope line crosses the horizontal reference line.

13. Repeat steps 4 through 12 above for editing other leads.

14. If there are any leads you want to include/exclude from the global calculations, right-click on the leads.

    If the lead is blue, it is included in the global calculations. If the lead is pink, it is excluded from the global calculations. If ***Measure Leads*** has been locked in ***System > Setup***, you will not be able to exclude leads that have been locked.

Measuring and Editing Amplitude Values

The ***Enable Amplitude Editing*** field must be enabled to measure or edit amplitude values.

1. Adjust the filter, the resolution, and the lead distance as described in "Measuring and Editing Interval Values" on page 12.

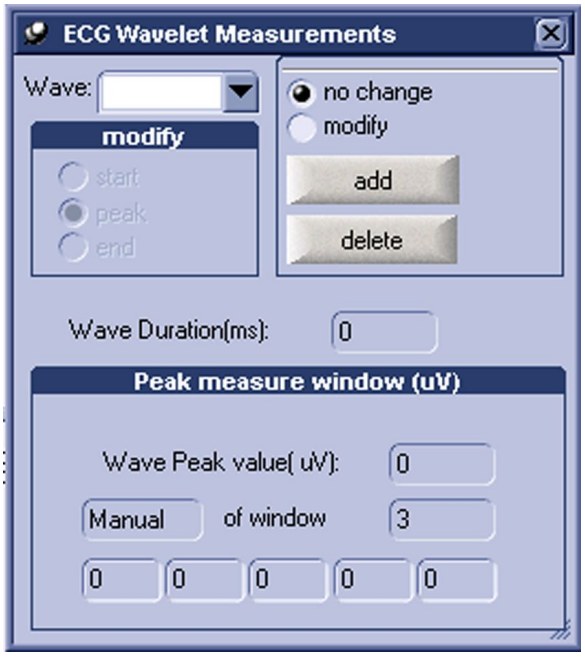
2. Left-click on the median you want to edit to select it. The selected median will be highlighted in yellow.

3. Deselect the ***Edit*** option check box.

NOTE:
Only select the ***Edit*** option check box to edit interval values.

4. Click the ***Show Amplitude markers*** icon  in the toolbar to display the red amplitude fiducial marks for the selected lead.

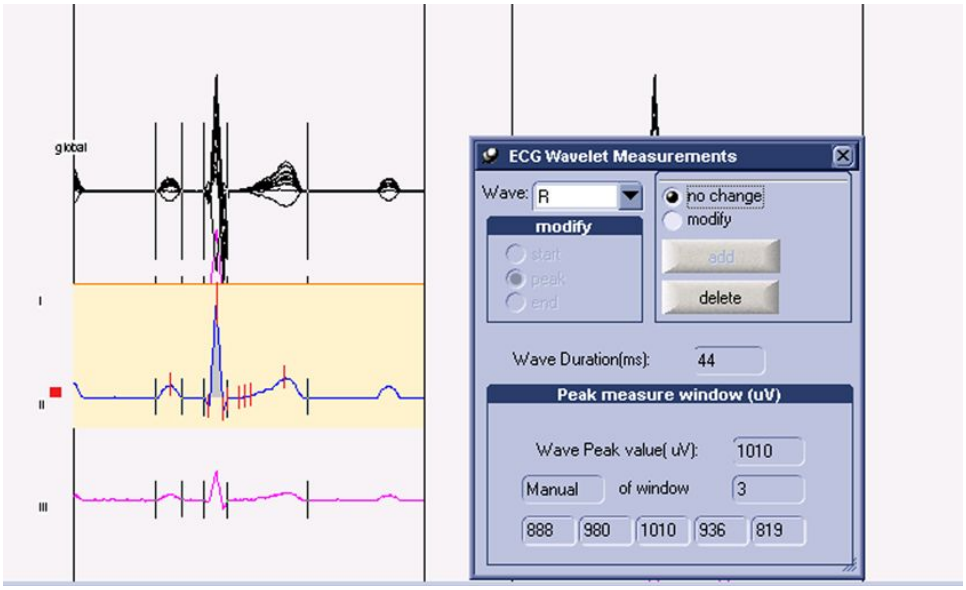
5. Click the ***Measurement box*** icon  in the toolbar to display the ***ECG Wavelet Measurements*** window.



The following table describes the ***Peak measurement window (uV)*** fields of the ***ECG Wavelet Measurements*** window.

Field Name	Description
Wave Peak value (uV)	The peak value of the wave. The peaks of Q and S-waves are reported as positive numbers.
[ ] of window [ ]	The method used to determine the peak (manual, mean, median, maximum, minimum) and the width of the measurement window in sample points. These are configured in the system setup and are read-only values in this window.
Bottom row value fields	The sample values of the peak point and the two points before and after the peak. While modifying the start or end, these are the sample values surrounding the current start or end points.

6. Left-click on the peak fiducial marker of the wavelet you want to measure. The selected wavelet appears highlighted in gray and the data for that wavelet appears in the ***ECG Wavelet Measurements*** window.



If wavelet is not defined, wave duration and peak value display 0's (zeros) and the ***add*** button is enabled. If wavelet is defined, there are values for wave duration and peak value and the ***delete*** button is enabled.

7. To edit the amplitude values for the selected lead, in the ***ECG Wavelet Measurements*** window, at the ***modify*** field, click the appropriate option button (***start***, ***peak*** or ***end***).

8. To move the peak fiducial marker, click the ***Peak*** option button in the ***ECG Wavelet Measurements*** window, and right-click at another point within the wavelet.

9. To edit the start of the wavelet, click the ***Start*** option button in the ***ECG Wavelet Measurements*** window and right-click the new start point. The gray shading updates to the new start point.

10. To edit the end of the wavelet, click the ***End*** option button in the ***ECG Wavelet Measurements*** window and right-click the new end point. The gray shading updates to the new end point.

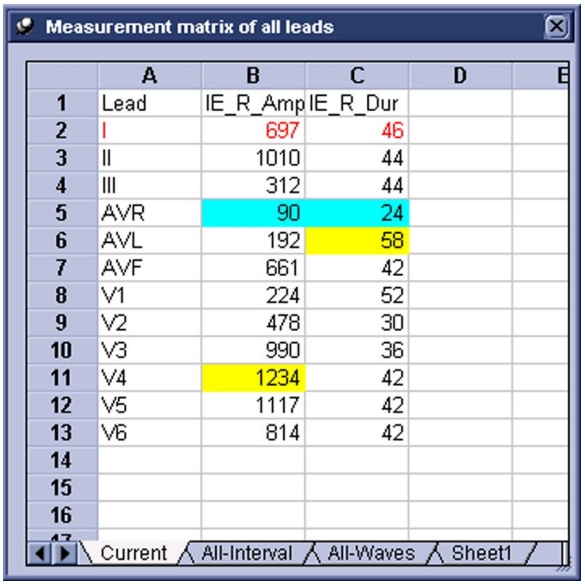
11. To delete a wave's amplitude data from the current report, click the ***Delete*** button.

    Once deleted, amplitude data can be added back to the report by clicking the ***Add*** button.

Viewing and Exporting Data in Spreadsheet Format

1. To view the measurement matrix of all leads, click the ***Measurement matrix*** icon  . This spreadsheet is view-only and is dynamically updated with values calculated from interval and amplitude measurements.

   Data for the currently selected lead appears red in the measurement matrix. The wave with the highest amplitude value is shaded in yellow. The wave with the smallest amplitude (or largest negative) value is shaded in blue.



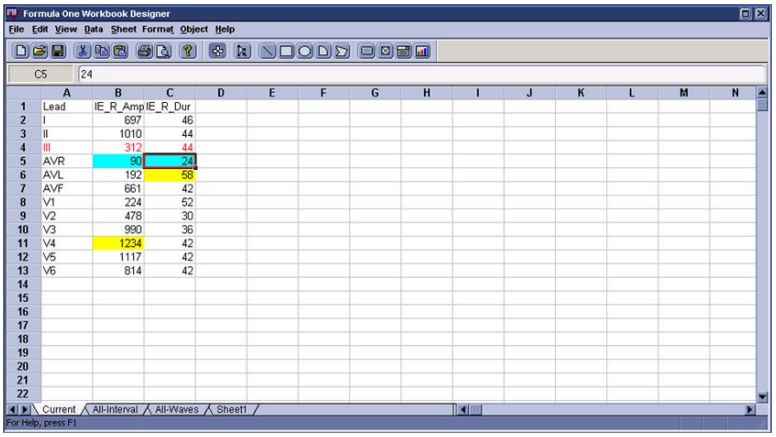
   The tabs at the bottom of the spreadsheet window contain the following data:

   - ***Current*** – displays current active interval or amplitude values for all leads. If ***Edit*** is selected, will display intervals related to the currently selected

tick mark. If ***Edit*** is not selected and amplitude editing is on, will display amplitudes and durations of the currently selected wave.

- ***All-Interval*** – displays all intervals and onset/offset values for all leads.
- ***All-Waves*** – If ***Amplitude Editing*** is enabled, this tab displays all defined wavelet values for all leads. Empty cells indicate that the wavelet is undefined.

2. Right double-click within the ***Measurement matrix*** window to open and view the data in ***Formula One Workbook Designer***.



3. To save interval and amplitude data, at the ***Formula One Workbook Designer***, select ***File > Write***.

Individual Beat QT Correction

1. At ***System > Setup > Sites > Interval Editor > General***, set the ***Edit Mode*** to ***Raw***.
2. At ***System > Setup > Sites > Interval Editor > Raw mode***, set the ***Global Calculation Method Type*** to ***Beat QT Correction***.
3. At ***System > Setup > Sites > Interval Editor > Raw Mode***, select the consecutive beats if needed at the ***Number of Beats*** field. By default, the first three raw beats are selected.
4. Follow the steps in "Measuring and Editing Interval Values" on page 12 for instructions on editing. The difference is in the Global QT and QTc calculation results. In this case, QT is corrected beat-by-beat based on the immediate previous R-R interval.
5. The individual RR interval can be changed as follows:
   a. Select beat 3 in the ***Raw beat*** window by clicking the << >> icon.
   b. Change QRS onset of beat 3 by left-clicking and moving the mouse near beat 3. Move the QRS onset to the left to shorten the R-R interval between beat 2 and beat 3.

c. After you release the mouse button, you will notice an increase of QTcB and QTcF values in the ***Beat Value*** bar below the ***Global Value*** bar.

d. If you move the QRS onset of beat 3 to the right to increase the R-R interval between beat 2 and beat 3, the QTcB and QTcF values in the ***Beat value*** bar decrease.

NOTE:

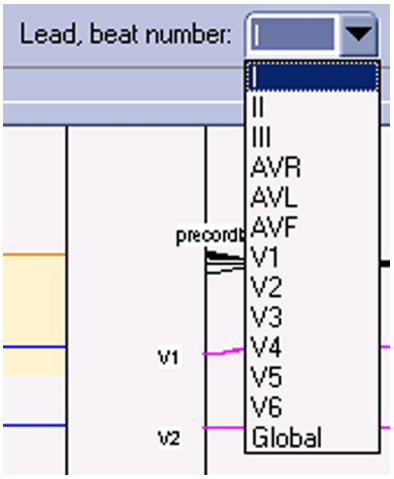
Moving the QRS onset cursor here only changes the RR interval from the previous to the current beat. It does not change the actual QRS onset as viewed in the ***Edit List*** window and, therefore, does not change the QT interval.

Working in E14 Blinding Mode.

A user logging in as an E14 blinded reader, with measurement values also blinded, will be working in ***manual editing*** mode. No tic marks are shown initially, and no global values are calculated.

1. Select the ***Edit*** option check box in the control bar of the ***Interval Editor*** window.

2. Select the lead from the lead pull down list at the control bar of the ***Interval Editor*** window.



3. Click the ***Invalid*** icon 

to toggle the selected tic mark to appear on the waveform of the ***Edit*** window. If ***Toff*** is selected, QRS onset and offset appear, making QT interval and QRS duration calculation possible.

4. Drag the tic mark to the appropriate positions.

   NOTE:
   When first appearing from an invalid state, the tic mark is in a random position.

5. To delete an invalid tic mark, select the tic mark from the pull down list at the control window and click the ***Invalid*** icon. The tic mark(s) are removed from the display and global value calculation.

Saving the Data

Before saving any report edited with the system, always ensure that the fiducial points for all leads are in the following order (from left to right): P onset, P offset, QRS onset, QRS offset, and T offset.

1. Select ***Test > Save***.
2. Select from the following options:
   - ***Diagnosis Complete***
   - ***Update to Edit List***
   - ***Store to Database Unconfirmed***
   - ***Confirm and Route***
   - ***Confirm***
   - ***Demographics Complete***
   - ***Demographics Complete and Route***

   NOTE:
   If you have edited the same report in both ***Median*** and ***Raw Beat*** modes, you will be asked to choose what data, ***Median*** or ***Raw Beat***, you want to save when confirming a report.

Keyboard Shortcuts

Keyboard Shortcuts		
Item	**Action**	**Shortcut Keys**
Red Indicator dot	Move to next selected (blue) lead.	**Ctrl + _**
Red Indicator dot	Move to previous selected (blue) lead.	**Ctrl + -**
Red Indicator dot	Move to first lead (I).	**Ctrl + Page Up**
Red Indicator dot	Move to last lead (v6).	**Ctrl + Page Down**
Red Indicator dot	Move to previous beat in raw data window.	**Page Up**
Red Indicator dot	Move to next beat in raw data window.	**Page Down**

Fiducial marker	Switch active fiducial marker to next.	**Ctrl + ®**
Fiducial marker	Switch active fiducial marker to previous.	**Ctrl + ¬**
Fiducial marker	Move current marker to the right (2 ms). Will only function when the Edit option is selected.	**®**
Fiducial marker	Move current marker to the left (2 ms).	**¬**
Fiducial marker	Move current marker to the right (10 ms). Will only function when the Edit option is selected.	**Shift + ®**
Fiducial marker	Move current marker to the left (10 ms). Will only function when the Edit option is selected.	**Shift + ¬**
The following keyboard shortcuts can be used when the ***Slope measure line*** is active:		
Slope line	Rotate clockwise.	**Shift + ®**
Slope line	Move Slope line to the right	**®**
Slope line	Move Slope line to the left	**¬**
Slope line	Rotate counter-clockwise.	**Shift + ¬**
Horizontal reference line	Move horizontal reference line up.	**-**
Horizontal reference line	Move horizontal reference line down.	**–**
T offset marker	Snap to point where slope meets horizontal reference line.	**Enter**

3

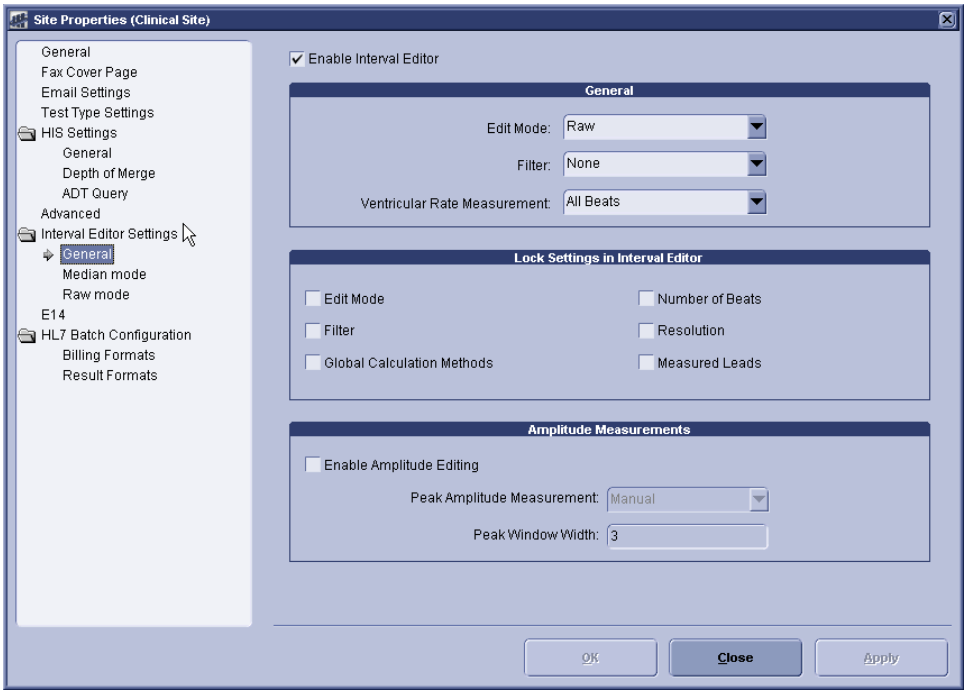
Set Up

Setting Up Interval Editor

1. Select ***System > Setup > Sites***.

   Click on a site or create a site.

2. At the ***Site Properties*** window, select ***Interval Editor Settings > General***.



3. To enable Interval Editor, select ***Enable Interval Editor***.
4. In the ***General*** box, select one of the following for the default ***Edit Mode***:
   - ***Median*** - Measure using median beats. Median beats are formed from all dominant beats in 10 seconds of raw data and are used for morphology analysis in the 12SL analysis program. (See *12SL ECG Analysis Program Physician's Guide* for an explanation of how the 12SL analysis program forms the median complex.)
   - ***Raw*** - Measure using selected consecutive beats from the 10 seconds of ECG.

5. Select ***None, 40 Hz*** , or ***80 Hz*** for the default ***Filter***.

   NOTE:
   The Interval Editor filter is applied to displayed and printed data only. The original waveform is not affected by the filters. Both 40Hz and 80Hz filters are 2nd order low-pass Butterworth filters that run forward and backward to remove the phase distortion.

6. Select one of the following for the ***Ventricular Rate Measurement***. :

   NOTE:
   The ***Ventricular Rate Measurement*** setting is only used for ***Raw Edit*** mode.

   - ***All Beats*** - All beats are used to calculate ventricular rate.
   - ***Selected Beats*** - Selected beats are used to calculate ventricular rate.

7. Set up the ***Lock Settings in Interval Editor*** as follows:

   - Select ***Edit Mode*** to lock the edit mode selected above. If this is not checked, the user will be able to make changes in either edit mode.
   - Select ***Filter*** to lock the currently selected filter. If this is checked, the Interval Editor user will not be able to switch to another filter.
   - Select ***Global Calculation Methods*** to lock all of the calculation methods for both Median and Raw Beat data.
   - Select ***Number of Beats*** to lock the number of beats entered for the evaluation of Raw Beat data.
   - Select ***Resolution*** to lock the ***Time*** and ***Amplitude*** resolutions for both Median and Raw Beat data editing. The Interval Editor will default to the resolutions set up for both editing modes. However, if you switch to another resolution, the system will prevent editing of data in another resolution.
   - Select ***Measured Leads*** to lock the leads selected in the Leads list at ***Site Properties > Interval Editor> Median mode*** or ***Site Properties > Interval Editor > Raw mode***.
     You cannot choose to include leads that have not been selected in the ***Leads*** list. However, the Interval Editor can exclude leads that have been selected in this list.

   NOTE:
   If locked settings differ from the settings used when a report was saved, a message will appear and the lock will be removed.

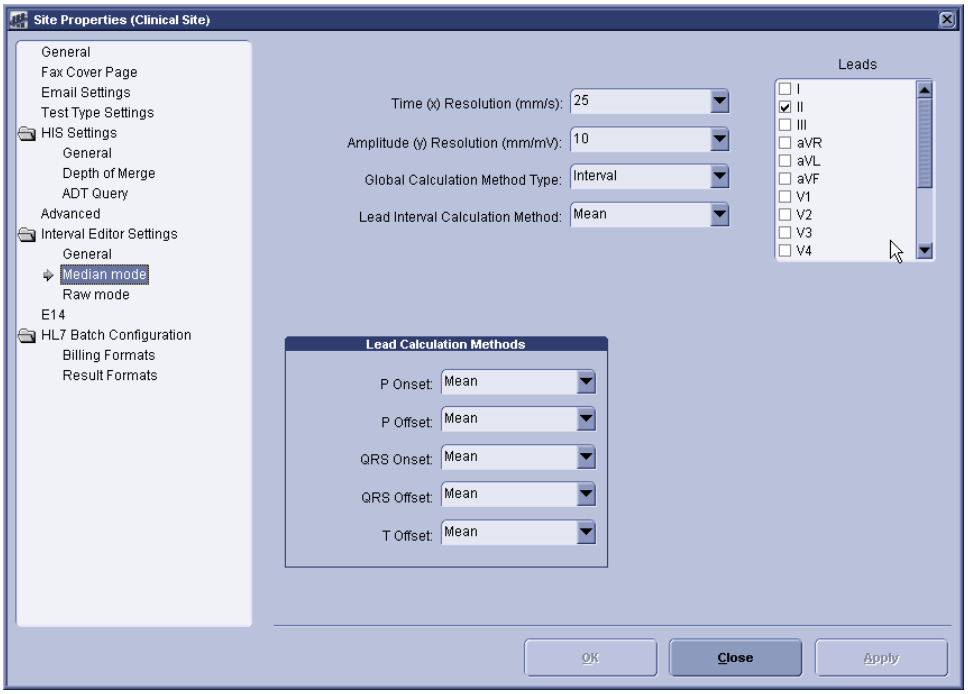
8. Set up ***Amplitude Measurements*** as follows:

   - Select ***Enable Amplitude Editing*** to allow amplitude editing at this site.
   - Select the ***Peak Amplitude Measurement method***:
     - ***Manual*** - Amplitude measured from a single peak point.
     - ***Mean*** - Amplitude measured from the mean of the defined window.
     - ***Median*** - Amplitude measured from the median of the defined window.

- ***Maximum*** - Amplitude measured from the maximum point inside the window.
- ***Minimum*** - Amplitude measured form the minimum point inside the defined window.

- At the ***Peak Window Width*** field, type the number of sample points (1-5) you want included in amplitude calculation. This field is not used if the ***Peak Amplitude Measurement method*** is manual.

9. Click ***Ok*** to close the window, or ***Apply*** to continue to another window.
10. Highlight ***Median Mode*** at the properties tree view on the left side of the window.



11. Select a ***Time (x) Resolution*** from the drop down list (***25, 50***, or ***100***).
12. Select an ***Amplitude (y) Resolution*** from the drop down list (***10, 20,*** or ***40***).

NOTE:

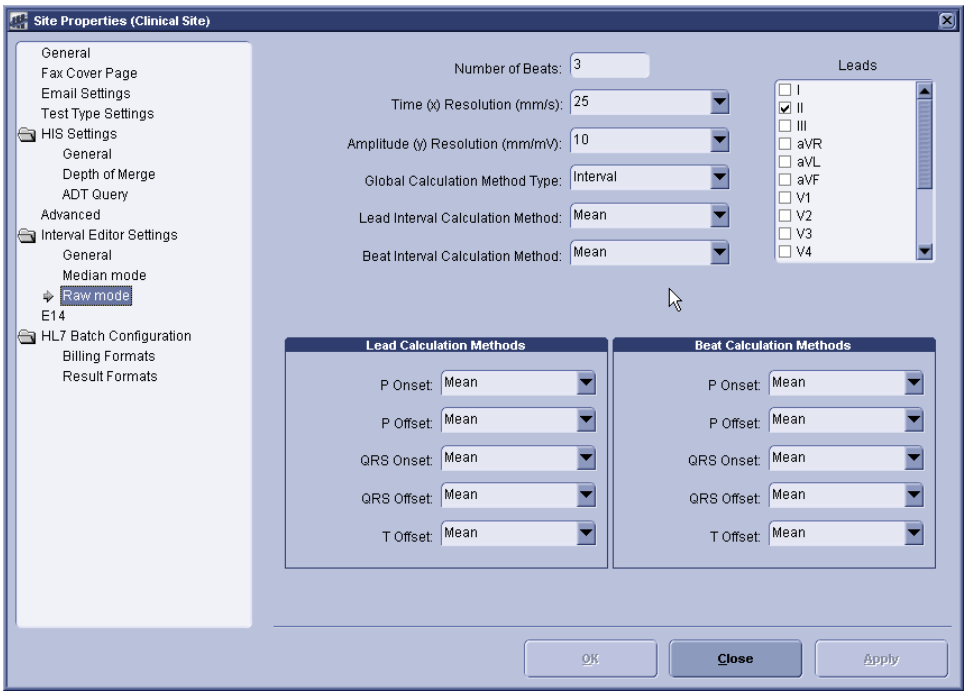
The resolutions selected in steps 11 and 12 above will be the default resolutions when viewing data in the ***Median Edit*** mode. If the resolution has been locked, the user will only be able to edit in the selected resolution.

13. Select one of the ***Global Calculation Method Type*** as follows:
    - ***Interval*** - if selected, the fiducial marks in the global waveform are determined from the intervals across all selected leads using the method selected in the ***Lead Interval Methods*** list.
    - ***Onset/Offset*** - if selected, the fiducial marks in the global waveform are determined from the onsets and offsets across all selected leads using the method selected in the ***Lead Calculation Methods*** list.

      NOTE:
      See "Examples of Global Beat Calculations" on page 33for information on how the system makes global calculations when ***Interval or Onset/Offset*** are selected.

    - ***Global***- if selected, the user can move the fiducial marks in the global waveform directly.
14. Select a ***Lead Interval Calculation Method***:
    - ***Mean*** - Global interval calculated from the mean of the individual lead intervals.
    - ***Median*** - Global interval calculated from the median of the individual lead intervals.
    - ***Minimum*** - Global interval calculated from the minimum of the individual lead intervals.
    - ***Maximum*** - Global interval calculated from the maximum of the individual lead intervals.
15. Select the ***Lead Calculation Methods*** for each of the five measurements:
    - ***Mean*** - Global fiducial point is the mean of the individual lead fiducial points.
    - ***Median*** - Global fiducial point is the median of the individual lead fiducial points.
    - ***Earliest*** - Global fiducial point is the earliest of the individual lead fiducial points.
    - ***Latest*** - Global fiducial point is the latest of the individual lead fiducial points.
16. Select the leads to be included in the global calculations. The data from the leads that are not selected will not be included in the global calculations.
17. Click ***Ok*** to close the window, or ***Apply*** to continue to another window.

18. Highlight ***Raw Mode*** at the properties tree view on the left side of the window.



19. Enter the ***Number of Beats*** you want to evaluate. The minimum is 1 and the maximum is 10.

20. Select a ***Time (x) Resolution*** from the drop-down list (***25, 50, 100***).

21. Select an ***Amplitude (y) Resolution*** from the drop-down list (***10, 20, 40***).

NOTE:

The resolutions selected above will be the default when viewing data in the ***Raw Beat*** edit mode. If the resolution has been locked, the user will only be able to edit in the selected resolution.

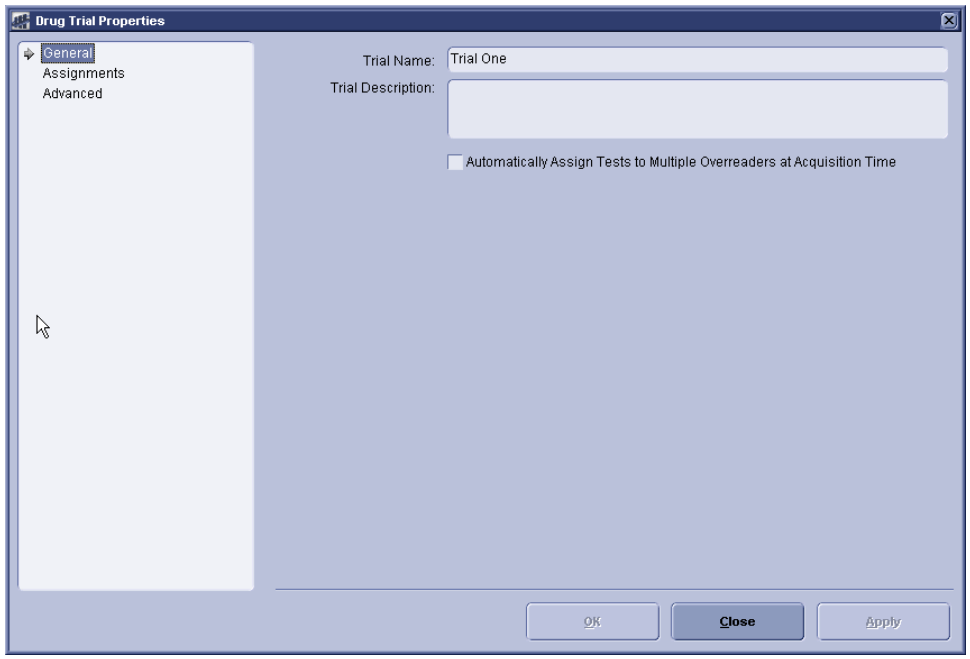
22. Select one of the ***Global Calculation Method Type***:

- ***Interval*** - if selected, the fiducial marks in the Global waveform are determined from the intervals across all selected beats and leads using the methods selected in ***Lead Interval Methods*** and ***Beat Interval Methods***. In this case, lead intervals are first calculated from the individual beats in the selected lead, then the global intervals are calculated from the selected lead intervals.
- ***Onset/Offset*** - if selected, the fiducial marks in the Global waveform are determined from the onsets and offsets across all selected beats and leads using the methods selected in ***Lead Calculation Methods*** and ***Beat Calculation Methods***. In this case, per-lead onsets and offsets are first calculated from the individual beats in the selected lead, then the global onsets and offsets are calculated from the per-lead onsets and offsets of the selected leads.
- ***Beat QT Correction*** - this is a special case of the ***Interval*** method. If selected, QT correction is calculated for each beat based on that beat's QT value and its immediate previous RR interval. The global QT correction value is calculated from all selected beat QTc values based on selected combination method.

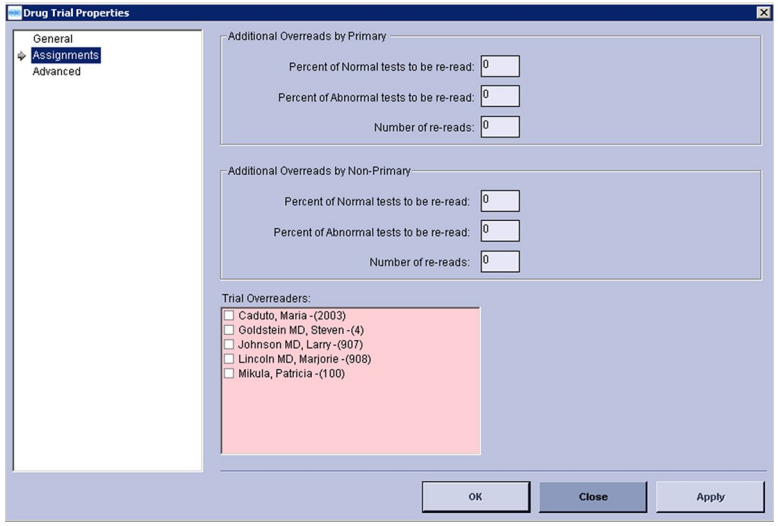
23. Select a ***Lead Interval Calculation Method***. This is used when ***Global Calculation Method Type*** is ***Interval*** or ***Beat QT Correction***.
    - ***Mean*** - Global interval calculated from the mean of the individual lead intervals.
    - ***Median*** - Global interval calculated from the median of the individual lead intervals.
    - ***Minimum*** - Global interval calculated from the minimum of the individual lead intervals.
    - ***Maximum*** - Global interval calculated from the maximum of the individual lead intervals.
24. Select a ***Beat Interval Calculation Method***. This is used when ***Global Calculation Method Type*** is ***Interval*** or ***Beat QT correction***.
    - ***Mean*** - Lead interval calculated from the mean of the individual beat intervals in selected lead.
    - ***Median*** - Lead interval calculated from the median of the individual beat intervals in selected lead.
    - ***Minimum*** - Lead interval calculated from the minimum of the individual beat intervals in selected lead.
    - ***Maximum*** - Lead interval calculated from the maximum of the individual beat intervals in selected lead.
25. Select the ***Lead Calculation Methods*** for each of the five fiducial points. This is used when ***Global Calculation Method Type*** is ***Onset/Offset***.
    - ***Mean*** - Global onset/offset calculated from the mean of the individual lead onsets/offsets.
    - ***Median*** - Global onset/offset calculated from the median of the individual lead onsets/offsets.
    - ***Earliest*** - Global onset/offset calculated from the earliest of the individual lead onsets/offsets.
    - ***Latest*** - Global onset/offset calculated from the latest of the individual lead onsets/offsets.
26. Select the ***Beat Calculation Methods*** for each of the five fiducial points for use when ***Global Calculation Method Type*** is ***Onset/Offset***.
    - ***Mean*** - Selected lead's onset/offset calculated from the mean of the individual beat onsets/offsets.
    - ***Median*** - Selected lead's onset/offset calculated from the median of the individual beat onsets/offsets.
    - ***Earliest*** - Selected lead's onset/offset calculated from the earliest of the individual beat onsets/offsets.
    - ***Latest*** - Selected lead's onset/offset calculated from the latest of the individual beat onsets/offsets.
27. Highlight the leads to be included in the global calculations. The data from the leads that are not highlighted will not be included in the global calculations.
28. Click ***Ok*** to close the window, or ***Apply*** to continue to another window.

Setting up Drug Trials

1. At ***System > Setup***, highlight ***Drug Trials*** in the menu tree at the left side of the window.
2. Double-click the appropriate drug trial. The ***Drug Trials Properties*** window opens.



3. Highlight ***General*** at the left side of the window.
4. To allow the MUSE system to automatically assign tests to an overreader as they are acquired, select ***Automatically Assign Tests to Multiple Overreaders at Acquisition Time***.
5. Highlight ***Assignments*** at the left side of the window.



6. At the ***Additional Overreads by Primary*** field, set up the following:
   a. To enable a percentage of normal tests to randomly be assigned for E14 primary overreaders, type the percentage number in the ***Percent of normal tests to be re-read*** field.
   b. To enable a percentage of abnormal tests to randomly be assigned for E14 primary overreaders, type the percentage number in the ***Percent of abnormal tests to be re-read*** field
   c. Specify the number of re-reads in the ***Number of re-reads*** field to indicate how many re-reads the primary overreader will be assigned.
7. At the ***Additional Overreads by Non-Primary*** field, set up the following:
   a. To enable a percentage of normal tests to randomly be assigned for E14 inter-reads (different reader than primary), type the percentage number in the ***Percent of normal tests to be re-read*** field.
   b. To enable a percentage of abnormal tests to randomly be assigned for E14 inter-reads (different reader than primary), type the percentage number in the ***Percent of abnormal tests to be re-read*** field.
   c. Specify the number of re-reads in the ***Number of re-reads*** field to indicate how many re-reads the non-primary overreader will be assigned.
8. At the ***Trial Overreaders*** list, select the individual(s) you want to add as overreaders for the drug trial.

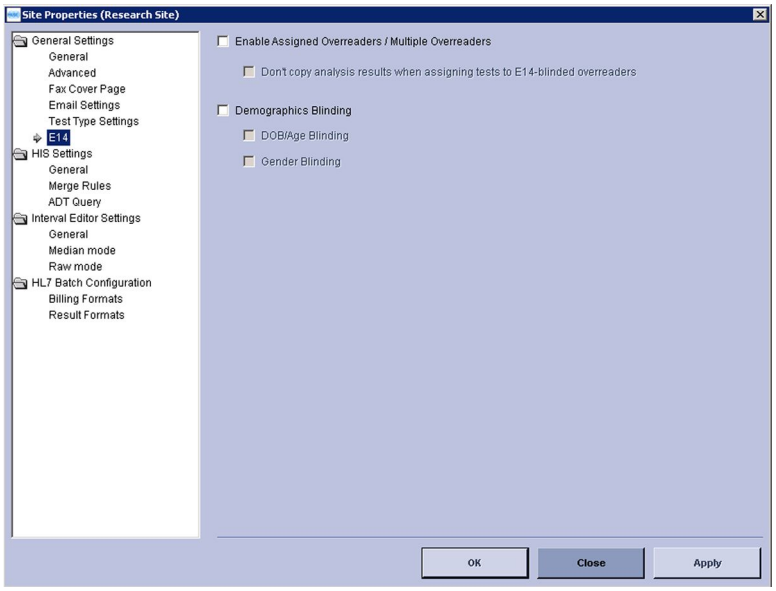
NOTE:
Assignments occur randomly at the time the test is assigned, and that is when they are used. If reviewing a study, there will be slight variances in the distribution of tests indicated here and the final percentages.

Creating an E14 Blinded Overreader

1. At ***Systems > Setup > Sites***, select the appropriate site.

   The ***Site Properties*** window opens

2. Highlight ***E14*** in the menu tree at the left side of the window.



3. To allow the MUSE system to assign a test multiple times to the same E14 blinded overreader, or a different E14 blinded overreader, select ***Enable Assigned Overreaders/Multiple Overreaders***.

   If a patient does not have any tests in the MUSE system that have been read by a primary overreader or a different overreader, then the MUSE system will automatically assign and randomly pick an overreader from the list of overreaders for that study.

   If a patient does have tests that have been read by a primary overreader or a different overreader (or assigned for overread), then the MUSE system will automatically assign the overreader to be the same overreader from the most recent test.

   The MUSE system only allows an E14 blinded user to see tests that are assigned to them (per multiple overread assignments).

   NOTE:
   Orders Interface in Site > HIS Settings and ***E14 Assigned Multiple/Overreading*** may not be enabled at the same time.

4. To remove all 12SL analysis on a multiple assigned test for an E14 blinded overreader, select ***Don't copy analysis results when assigning tests to E14 blinded overreaders***.

   NOTE:
   If a user is not E14 blinded, the 12SL measurement analysis will NOT be removed from the test.

5. To enable demographics blinding for an E14 blinded user, select ***Demographics Blinding***. The patient's demographic information will not appear on any test overread by an E14 blinded user when this field is enabled.
6. To enable date of birth and age blinding for an E14 blinded user, select ***DOB Age Blinding***. The patient's date of birth and age will not appear on any test overread by an E14 blinded user when this field is enabled.
7. To enable gender blinding for an E14 blinded user, select ***Gender Blinding***. The patient's gender will not appear on any test overread by an E14 blinded user when this field is enabled.

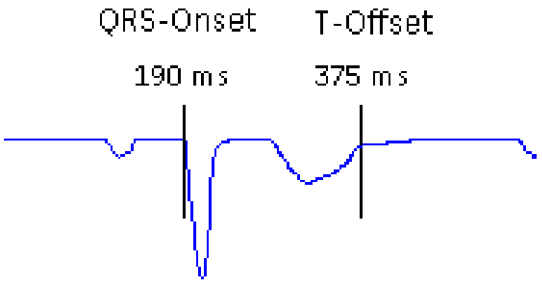
A

Additional Information

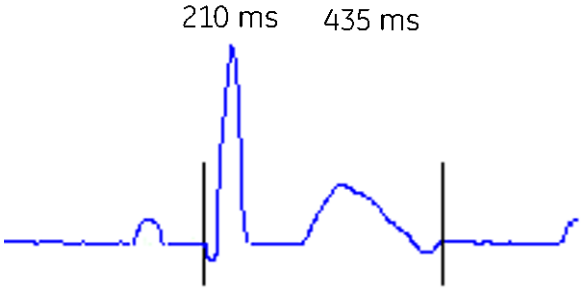
Examples of Global Beat Calculations

The following examples are provided to help you understand how the system makes global calculations when ***Onset/Offset*** is selected and when ***Interval*** is selected as a ***Median Editing*** option. The examples show how the global QT interval can vary.

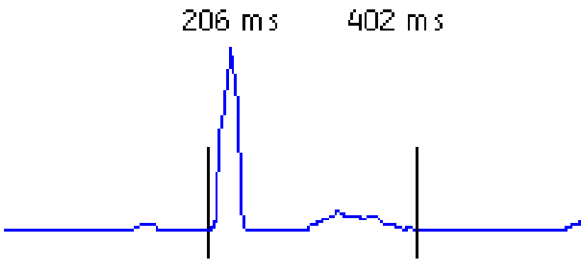
The three median complexes below represent three different leads in a resting ECG. Only the QRS-onset and the T-offset markers are shown for each lead because QT interval is used for the examples.



Three Sample Leads— Lead A



Three Sample Leads— Lead B



Three Sample Leads— Lead C

Onset/Offset Global Calculation Method

Using the data for the three medians shown in "Examples of Global Beat Calculations", the following table summarizes the QRS-onset/T-offset data for the four methods (earliest, latest, median, and mean).

	QRS-onset	T-offset
Mean	202 ms	404 ms
Median	206 ms	402 ms
Earliest	190 ms	374 ms
Latest	210 ms	435 ms

The formula for calculating the QT Interval is:

QT Interval = T-offset – QRS-onset

For example, if Earliest QRS-onset and Latest T-offset were selected for Lead Calculation Methods, the calculated QT Interval would be 245 ms for our three sample leads.

Earliest QRS-onset = 190 ms

Latest T-offset = 435 ms

QT Interval = 435 – 190 = 245 ms

The following table summarizes all possible QT Interval calculations based on QRS-onset and T-offset selections.

	Calculation of QT Interval (Onset/Offset Method)				
		QRS-Onset			
		Earliest	Latest	Mediam	Mean
T-Offset	Earliest	185 ms	165 ms	169 ms	173 ms
	Latest	245 ms	225 ms	229 ms	233 ms
	Median	212 ms	192 ms	196 ms	200 ms
	Mean	214 ms	194 ms	198 ms	202 ms

Interval Global Calculation Method

Using the data for the three medians shown in the Three Sample Leads illustration, the following table summarizes the QT Interval calculations for each of the three leads.

	QRS-Onset	T-Offset	QT Interval
Lead A	190 ms	375 ms	185 ms
Lead B	210 ms	435 ms	225 ms
Lead C	206 ms	402 ms	196 ms

Using the Interval global calculation method, the QT Interval is calculated for each lead and the global QT interval is determined by the choice selected for Lead Interval Method (Minimum, Maximum, Median, or Mean).

Lead Interval Method	Global QT Interval
Minimum	185 ms
Maximum	225 ms
Median	196 ms
Mean	202 ms

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