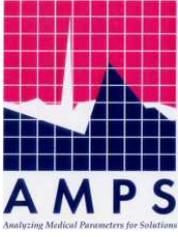


User Manual
Version 1.0

For

ViewerLight
Version 2.0.0

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Revision history

| Version | Section | Summary of change | Reason for Change | Initials | Date/Time |
|---------|---------|-------------------|-------------------|----------|-------------|
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1. Proposed and Intended Usage

The new *VIEWERLIGHT* provides the much improved graphical interface of the *FDAECG SUITE*, as it is based on the same code.

This AMPS application provides a way to *display, review* and *validate* ECG files in the format supported by the FDA (HL7 XML) and other ECG traces generated with machines from different manufacturers.

With the *VIEWERLIGHT* a single ECG can be loaded at a time.

The file display is achieved by means of a very intuitive, highly detailed and fully user-customizable graphical interface. The ECG can be visualized in various formats, including one lead at a time, superimposed leads and several others.

The graphic interface allows the user to review annotations previously obtained with annotation software (CalECG, for example); annotations, when available, are in fact visualized on the ECG tracings.

The validation tool checks that the files, which have been analyzed, are in the correct HL7 XML FDA format. Properly formatted HL7 XML FDA files increase the chances of a painless submission to the ECG FDA warehouse.

The *VIEWERLIGHT validator* component only allows validating HL7 ECG files with the first level of validation: Against Schema. The additional validation levels are available only with the *FDAECG SUITE*.

2. Using the ViewerLight tool

2.1. Getting Started

Installation is activated by double-clicking on the downloaded file "SetupViewerLight-2.0.x.exe". After installation has been completed, the user can click on the link from the 'AMPS' folder in the Start Menu to launch the software (Figure 1), or double-click on the shortcut on the desktop, if present.



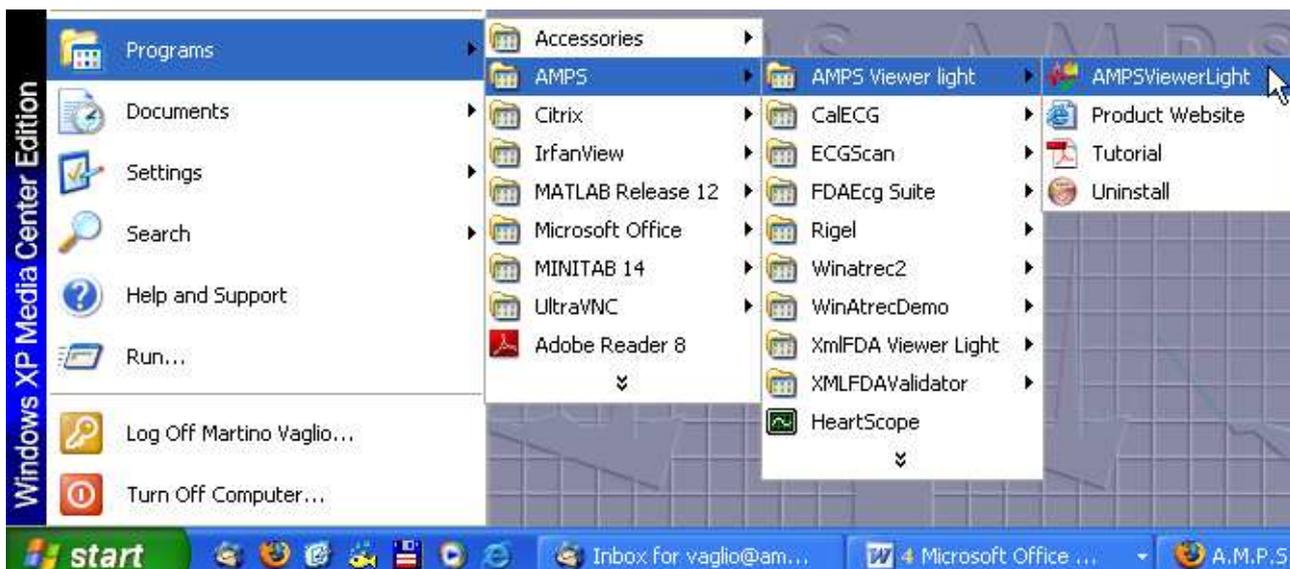


Figure 1: Launching the application from the Start menu.

When the application is launched, a blank window with a MenuBar and a Toolbar will be displayed.

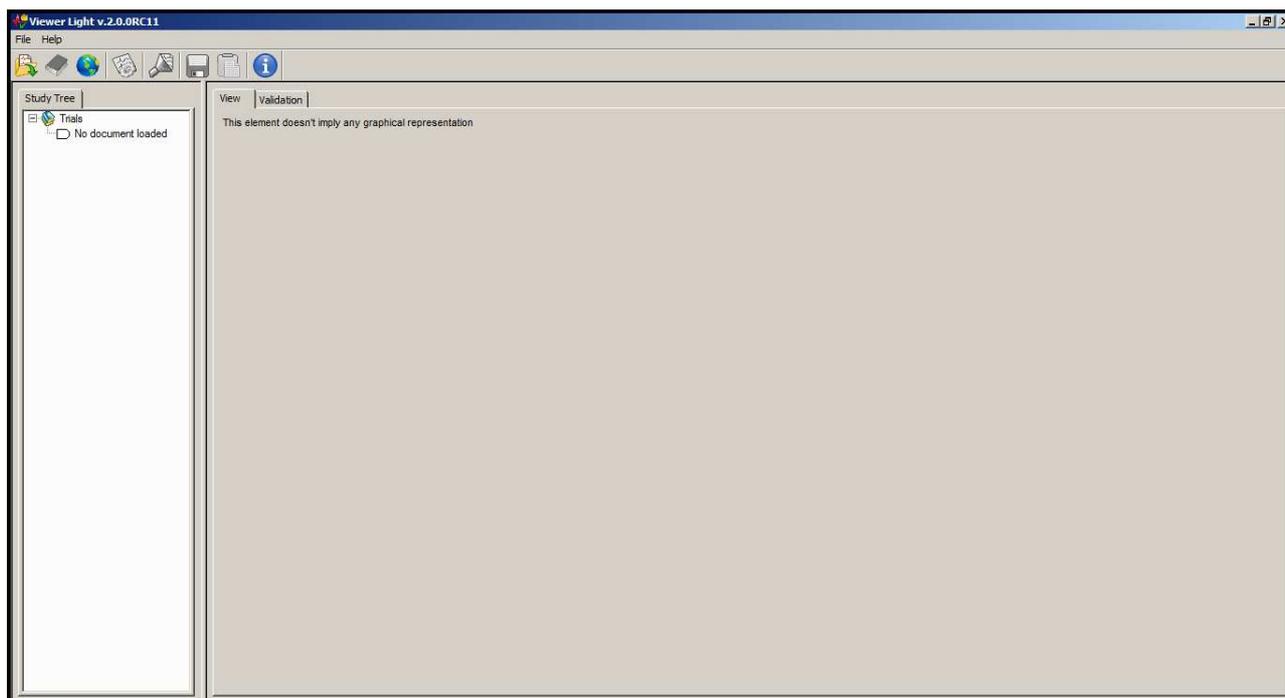
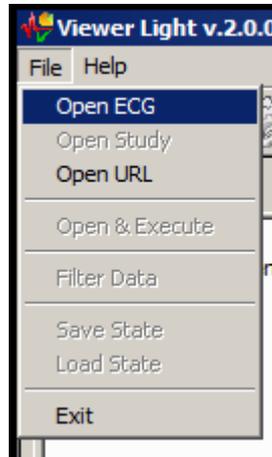


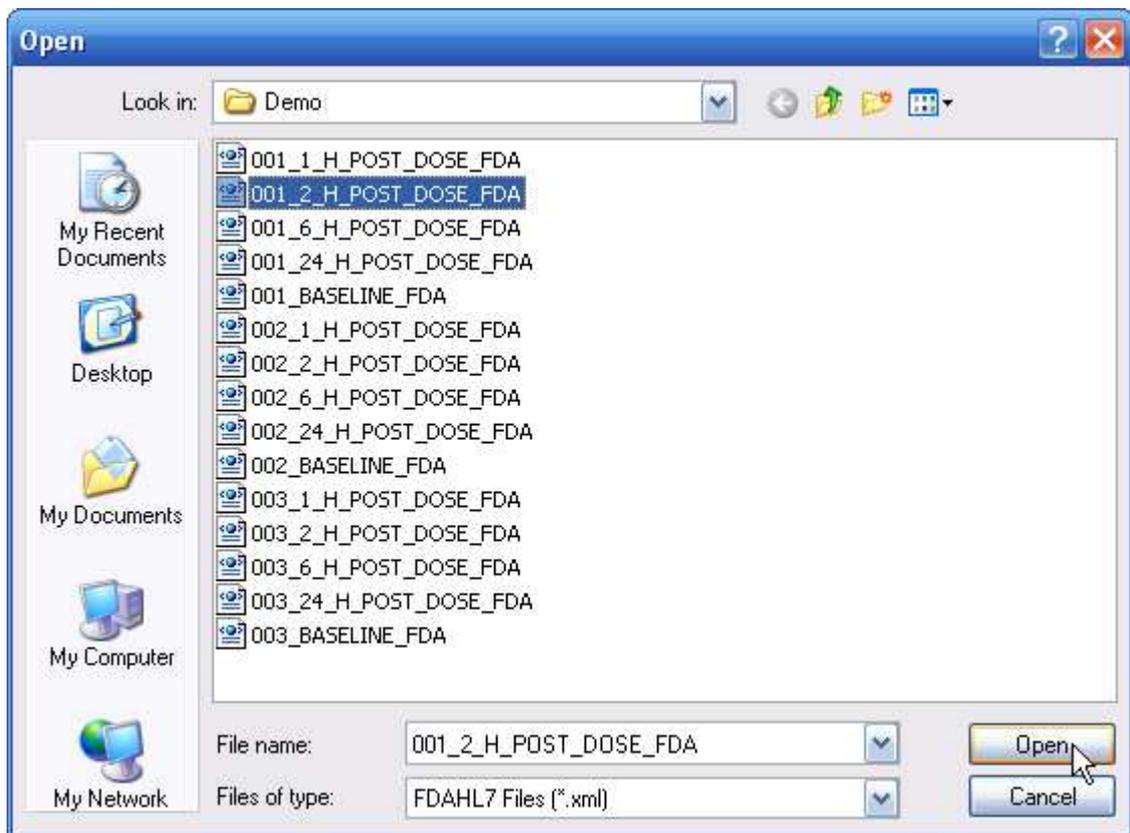
Figure 2: ViewerLight main display.

2.2. Opening a file or directory

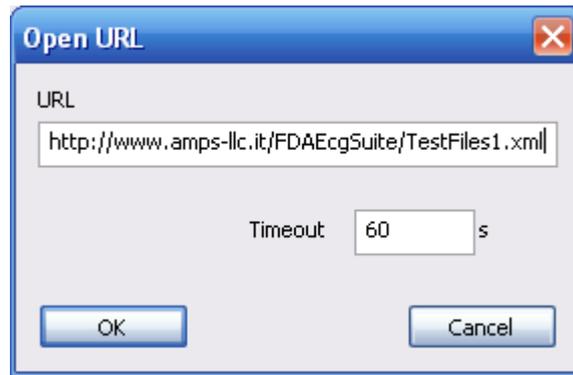
There are two separate file loading options available with the *VIEWERLIGHT* that can be accessed either from the File menu or the application toolbar:



- Open a single file or click on the toolbar icon . This option opens a new dialog where a single file can be selected.



- Open a URL or click on the toolbar icon . This loads files located in the mentioned URL address.



Both *Open Study* and *Open & Execute* options are only available in the *FDAECG SUITE*. Note again that with the *VIEWERLIGHT* a single file can be loaded at a time.

2.2.1. Supported file formats

The only supported file format that can be loaded with the *VIEWERLIGHT* in HL7 XML FDA.

2.3. View Summary

The main application window shows the contents of the folder on the left (with the details of the single loaded file), while on the right the ECG will be visualized:

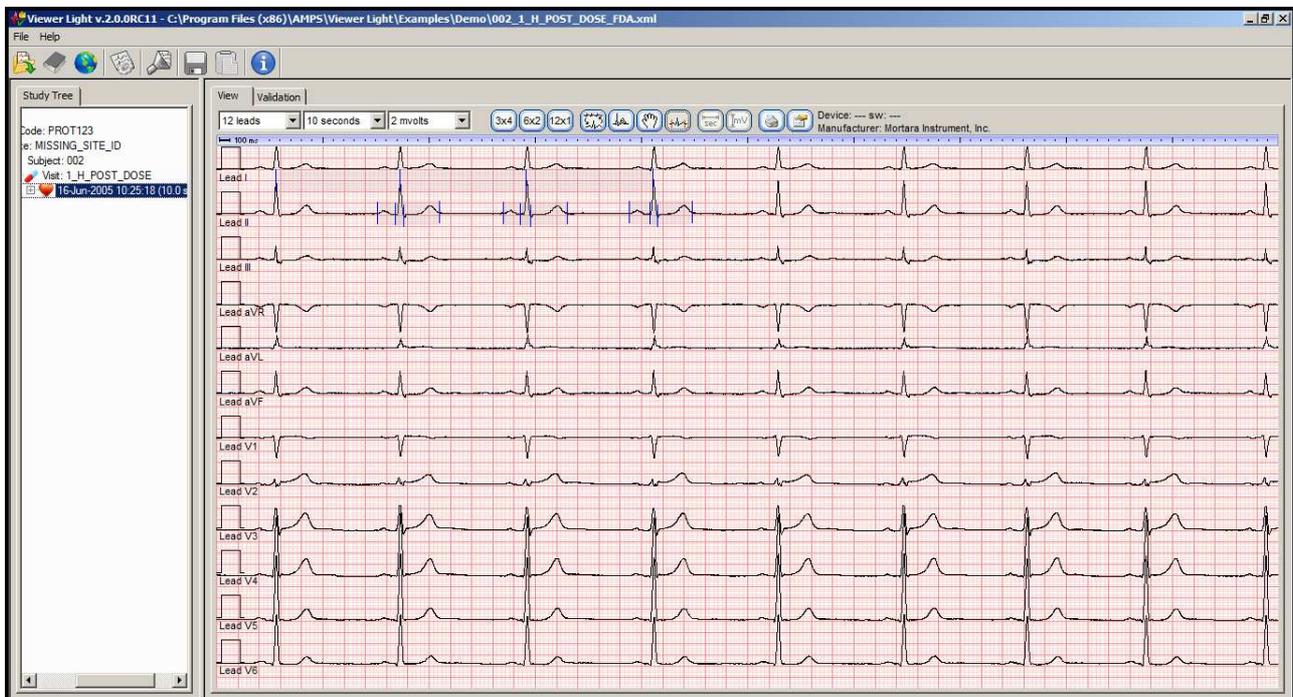


Figure 3: ECG visualization – Rhythm tracings display with ViewerLight.

2.4. Left Pane: Tree representation

On the left side, the data is structured on a tree based organization. This functionality is not of great interest as in the *VIEWERLIGHT* a single ECG can be loaded at a time.

Data is grouped based on the same *study*, so all ECGs having the same *Trial Code* will be grouped together, in the same *node of the tree* (Figure 4).

The tree structure of the left hand side is similar to that of "Windows-Explorer", with the difference that instead of representing file folders, the elements of the tree group together blocks of information from one or more HL7 XML file.

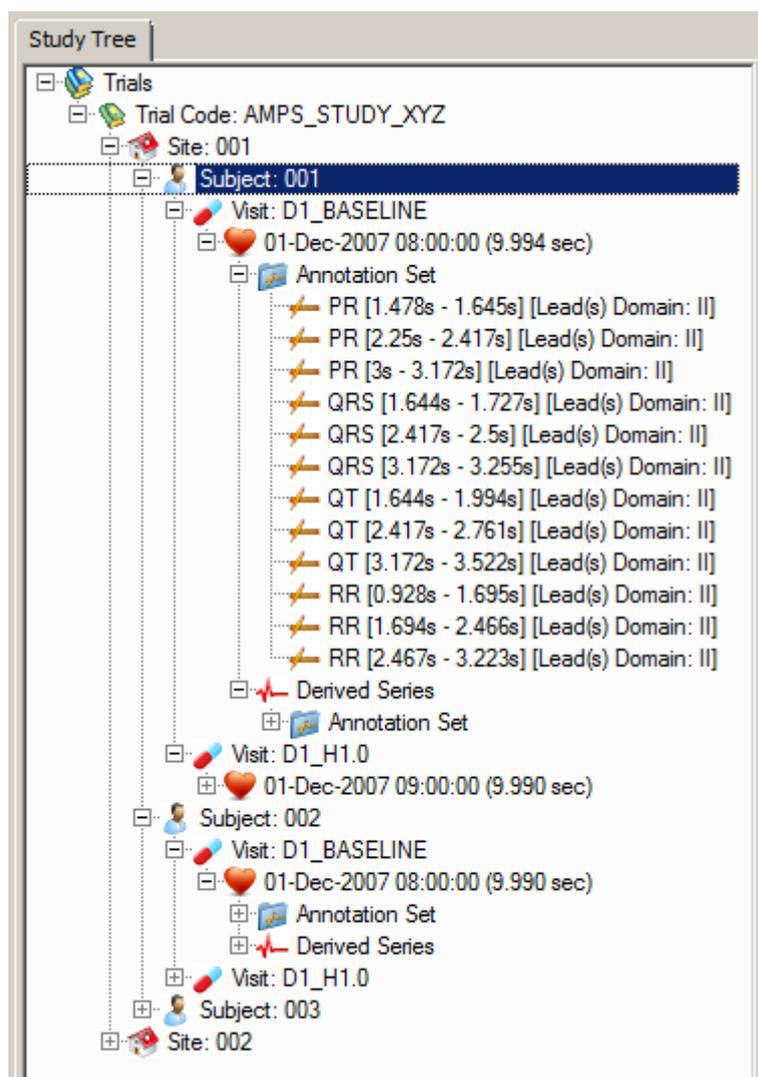


Figure 4: Example of tree-structure of the left pane.

In order to have a more intuitive interface, each node has a different icon related to its information level.

The structure of the tree contains the following information (based on its indentation level):

1. Trial Code 📁: the identifier (ID) of the study.

2. Site Code 🏠: the ID of the enrolling site.
3. Subject 👤: the subject Identification Code, included in the trial.
4. Visit 📅: examination ID, containing information on the examination: drug dosage, etc.
5. ECG Session (Time Session) ❤️: per each examination, one or more ECGs may have been recorded.
6. Annotation 📄: if annotations have been measured and saved, they are stored here.
7. Annotation Element 📏: single annotation measured (type and duration are reported).
8. Derived Series 📊: contains the Representative beats, if present.

To expand or collapse each node, click on the  or  symbol at the left of the node.

2.5. Right Pane

The right panel contains two tabs:

- View
- Validation

2.5.1. View

This tab is useful only when the selected nodes (on the left pane) are "ECG", "Annotation Set", "Annotation Element" or "Derived Series" types: when there is ECG signal to be plotted. If one of these nodes is selected, the ECG tracings with overdrawn annotations (where available) are visualized.

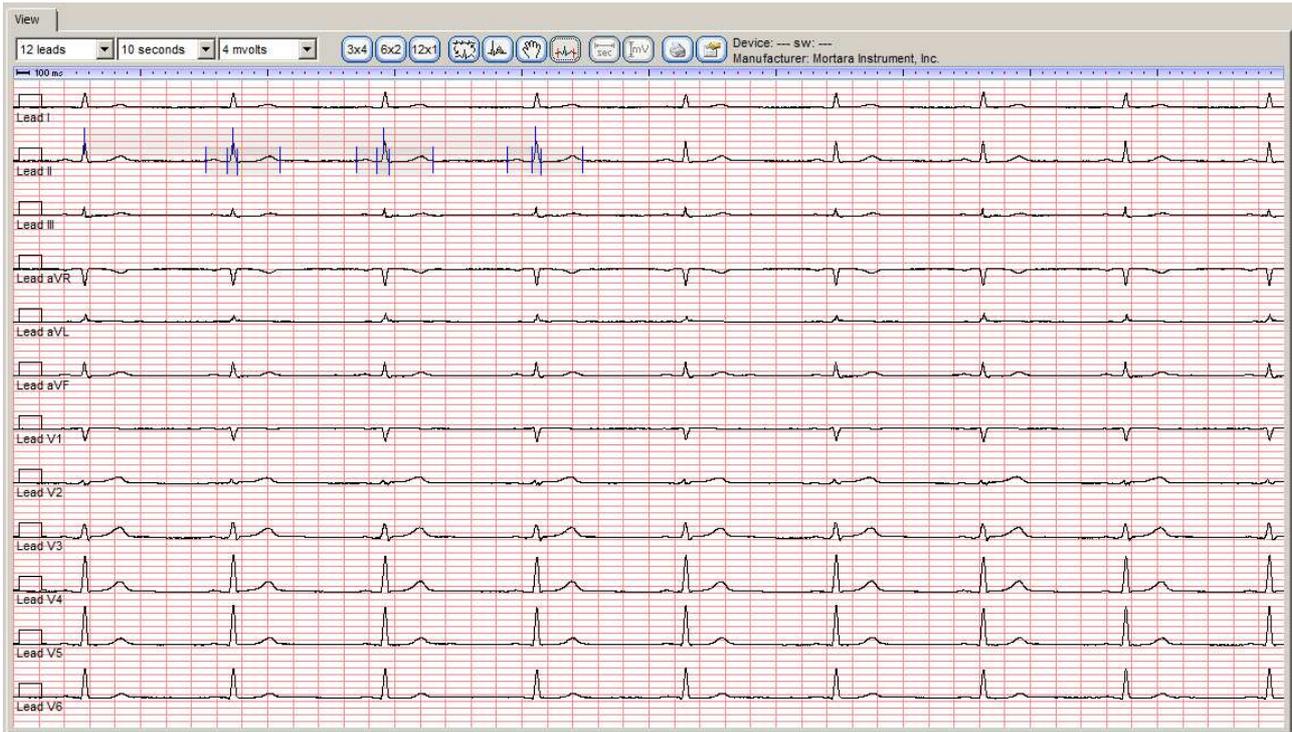


Figure 5: ECG visualization – Rhythm tracings display with ViewerLight.

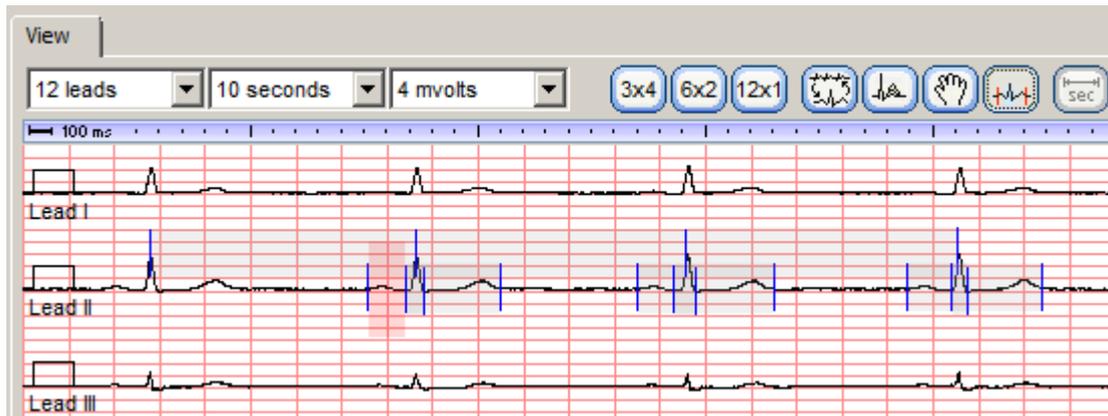


Figure 6: ECG visualization – PR interval selected in the right display and highlighted in the ECG display.

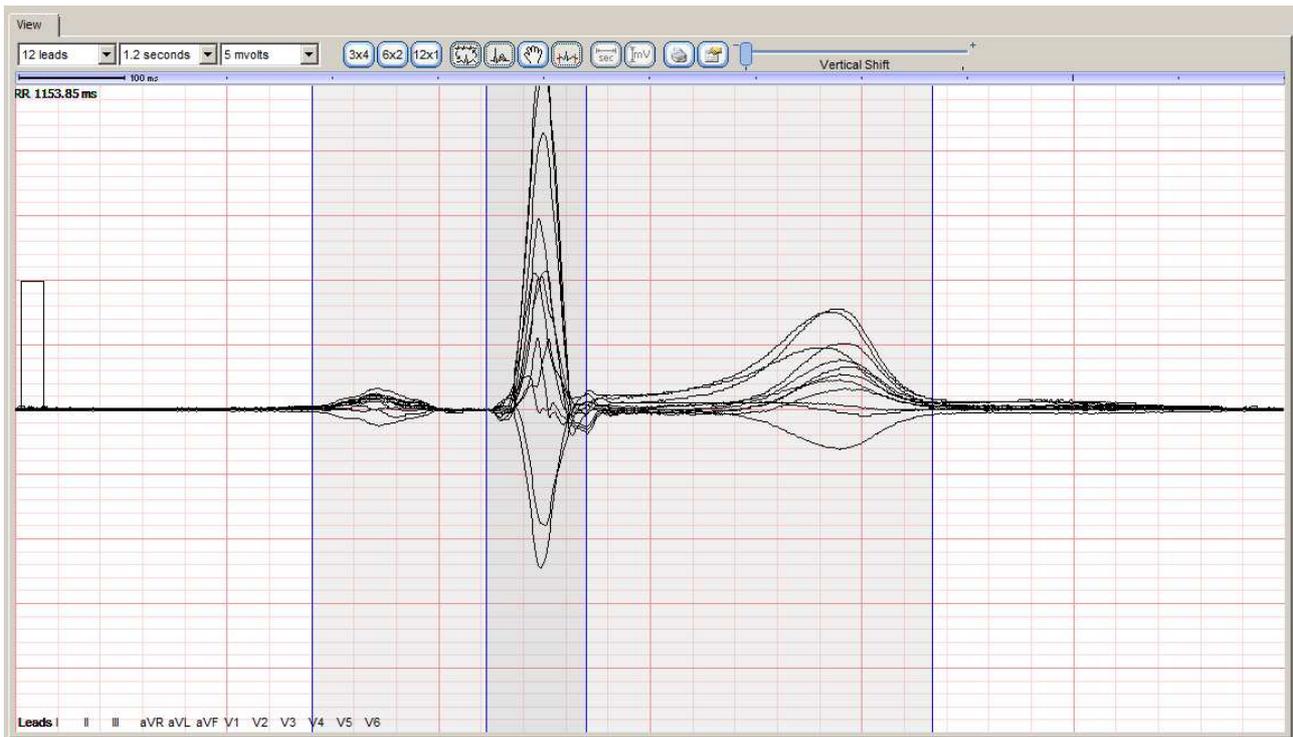
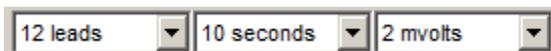


Figure 7: ECG visualization – Superimposed Representative Beats are displayed, as "Derived Series" is selected on the left display.

Display controls - Rhythm signal

Signals can be visualized in various different ways.

The control bar contains three drop-down menus indicating the number of leads, the number of seconds and the amplitude resolution to be visualized.



Allowed values are:

- Leads per page: 1 to 12
- Time per page: 0.5 to 10 s
- Amplitude per lead: 1 to 5 mV

It contains three buttons showing the ECG tracings in three standard formats:

- **3x4**, 3 X 4 format: three leads per row and four columns
- **6x2**, 6 X 2 format: six leads per row and two columns
- **12x1**, 12 X 1 format: six leads per row on a single column

When the number of leads to be shown is lower than 12, a vertical scrollbar automatically appears on the right hand side of the pane. It is also possible to scroll vertically using the mouse wheel, or pressing the toolbar icon  (for real-scroll mode activation) and then

“dragging” the signal, using the left button of the mouse; the ECG can also be scrolled horizontally.

When the time extension of the ECG is longer than the “screen paper size”, a horizontal scroll bar appears at the bottom of the pane, so the ECG can be scrolled along the x-axis.

Moreover, if 6 X 2 or 3 X 4 formats are chosen, other horizontal scroll bars are visualized to independently scroll one column of ECG tracings at a time, maintaining the others unmodified.

The same goes for vertical scroll bars. If 6 X 2 or 3 X 4 formats are chosen and the user decides to visualize less than 12 leads per page, other vertical scroll bars are visualized to scroll between leads in a single column, maintaining the other unmodified.

Display controls - Representative Beats

If the “Derived Series” is selected on the left display, the Representative Beats of the ECG are displayed in superimposed mode (SMB), as shown in Figure 7.

The toolbar icon  allows to toggle the display between Rhythm and Representative Beats ECG signals.

The toolbar icon  allows to toggle on and off the leads superimposition.

When Representative Beats are displayed in superimposed mode, the View tab on the right side will have an additional display control tool to vertically shift the visualized leads.



Measurement Controls

The toolbar icon  toggles on and off the visualization of annotations.

If in the left panel an annotation node is selected and the visualization of annotations is turned on, the selected annotation will be highlighted on the ECG, as shown in Figure 5, Figure 6 and Figure 7.

Printing

The tool gives the possibility to print a screen-shot of the displayed ECG on the default printer. The ECG screen-shot will be printed in the same way as the ECG is currently displayed within the *VIEWERLIGHT*.

Options

The Settings Dialog can be loaded, from the ECG display window, by clicking the toolbar icon , or by right clicking the mouse on the right hand side on the panel.

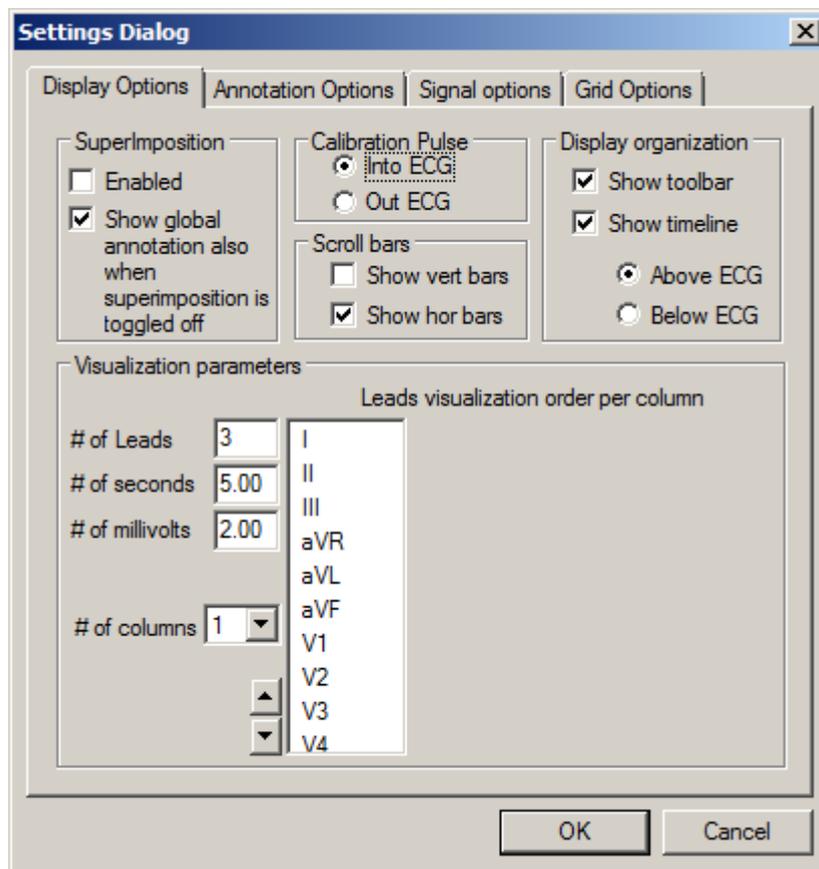
This brings up the option dialog box where the user can edit several display options, but can also modify options on the annotation format.



The option dialog is divided into four tabs, as described below:

- Display Options
- Annotation Options
- Signal Options
- Grid Options

Display Options



This tab lets the user set some useful options related to the display of the ECG signal (both rhythm and representative beats).

The calibration pulse can be drawn either on the ECG tracing or on its side by selecting in the *Calibration Pulse* subpane "Into ECG" or "Out ECG" flag, respectively.

Both vertical and horizontal scroll-bars for each column (visualized only on 3 X 4 and 6 X 2 formats) can be hidden (in *Scroll bars* subpane).

Graphical toolbar can be hidden by unselecting the flag "Show toolbar" in the *Display Organization* subpane. Once hidden, to re-visualize the Options window, right click the mouse on the ECG screen.

In this submenu it is also possible to hide the time x-axis (“Show timeline” flag) and to chose if the time axis must be displayed of top or at the bottom of the right display (“Above ECG” or “Below ECG”).

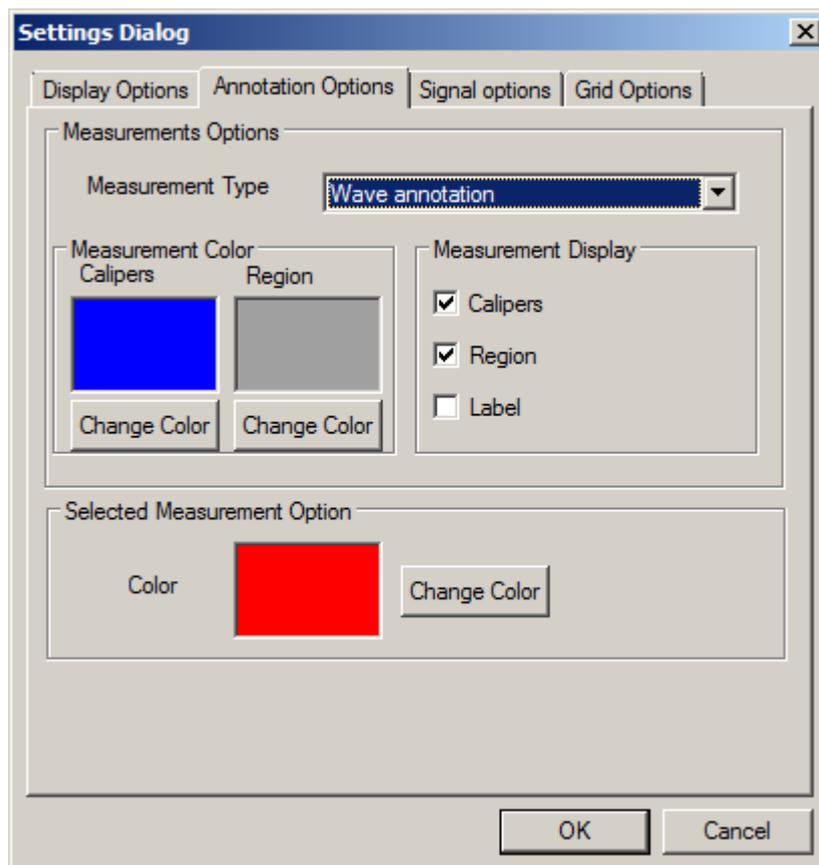
The ECG view can be set in superimposed mode, as opposed to standard “separated” leads by selecting “enabled” flag in the *SuperImposition* subpane, similarly as by selecting button . In the previous pane it is possible to display global annotation (measured on the SMB) also when the Representative Beats are not displayed in superimposed mode (“Show global annotation also when superimposition is toggled off” flag).

In addition to buttons and picks described here above, can be changed in the *Visualization Parameters* submenu.

Here, the number of leads, the tracing duration and amplitude of the ECG, can be modified.

It is also possible to change the number of column to distribute the visualized leads (1 to 4) and the leads’ order. First select the lead to be changed from the list (its label will become blue), then click on the arrows to the left of the list to move the lead in the desired position.

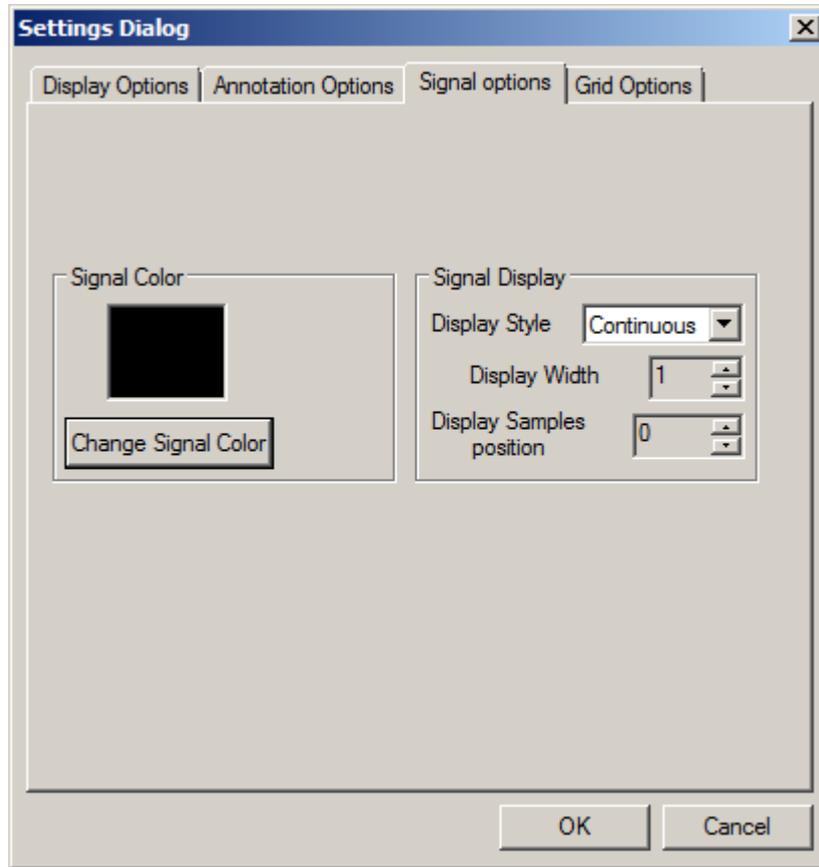
Annotation Options



Here different colors can be assigned to the callipers and regions of different annotation types. In the *Measurement Display* pane the user can decide whether to visualize callipers, region and labels for every displayed annotation.

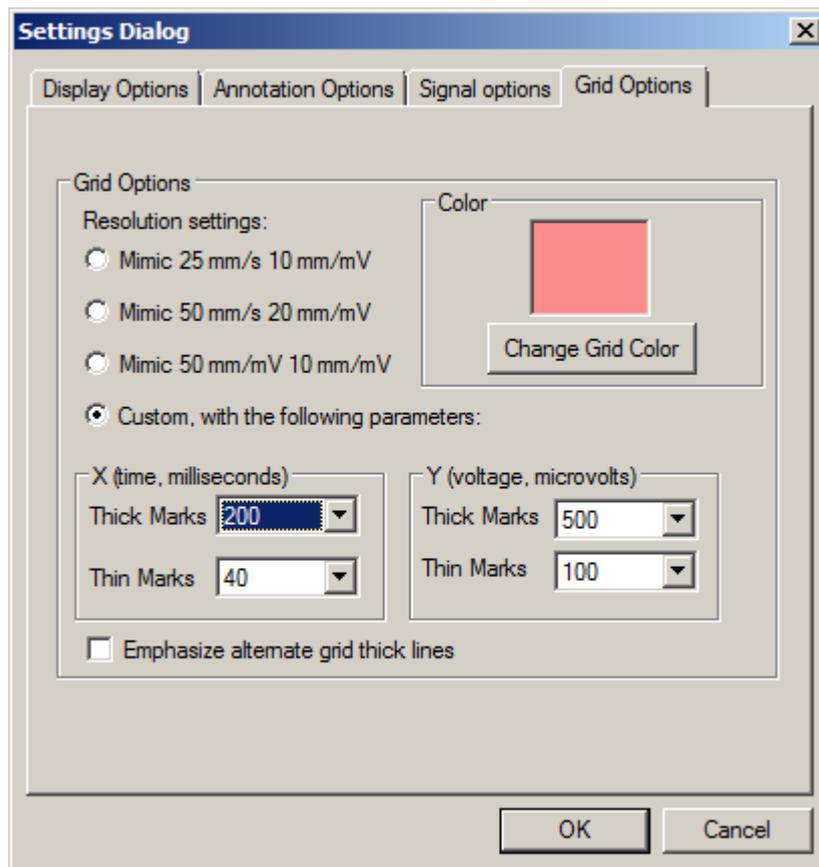
In the *Selected Measurement Option* pane the user can select the colour to be used to highlight selected annotations.

Signal Options



In this tab, the user can choose the color and thickness of the ECG tracing. The signal is typically designed continuously, but it can be drawn sample by sample. Finally, the position of the ECG samples can be labelled at selected intervals on the tracings.

Grid Options



The color of the grid can be selected in the *Grid Color* pane.

If desired the tracings can be visualized using a squared grid, instead of a rectangular grid obtained from user's customization of time and amplitude visualization setting (see above Figure).

There are three possible squared grid that mimic typical paper ECG resolution settings:

- 25 mm/s and 10 mm/mV of paper speed and paper sensitivity respectively,
- 50 mm/s and 20 mm/mV of paper speed and paper sensitivity respectively,
- 50 mm/s and 10 mm/mV of paper speed and paper sensitivity respectively.

Once this setting is selected, in the ECG display will only be possible to configure one setting at a time, between "time" and "amplitude", the other will be set automatically to guarantee the selected display setting.

Two examples of squared grid are here shown (Figure 8): the first based on mV, the second based on seconds.



Figure 8: Two examples (a, b) of squared grid.

In Figure 8a the user can only choose the number of leads and the amplitude for each lead, time menu is greyed out and automatically computed in order to keep the grid squared.

In the second example the amplitude menu is automatically computed from the user's time selection.

Finally, with the fourth option: "Custom", the user can decide the time and amplitude interval for both thick and thin grid linear marks both horizontally and vertically.

2.5.2. Validation

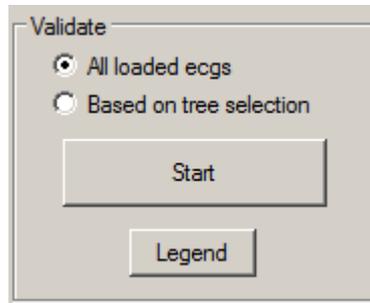
The validation tab is where the HL7 FDA XML format is checked for structure consistency. The validation process of the *VIEWERLIGHT* computes a single level checks:

- FDA Warehouse Validation

Two additional validation steps are available only with the *FDAECG SUITE*:

- Implementation Guide Validation
- XML and Schema Validation

To launch the validation of the loaded file select one of the two entries in the *Validate* pane (“All loaded ECGs” or “Based on tree’s selection”) and press the start button. With the *VIEWERLIGHT*, both options will produce the same results, as only a single ECG can be loaded at a time.



Once the validation process is completed, a popup menu will show the results (Figure 9).

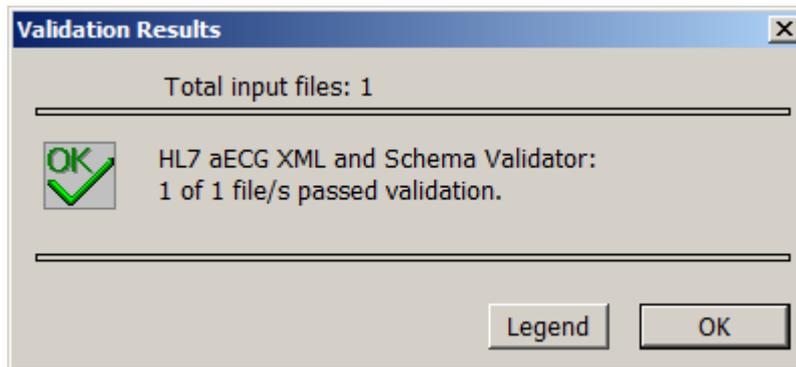


Figure 9: Validation results summary.

Once the validation is computed, the results summary can always be shown again by pressing the  button on the *Results* pane of the Validation tab. For a better understanding of this summary, a legend (Figure 10) can be visualized by pressing the  button.

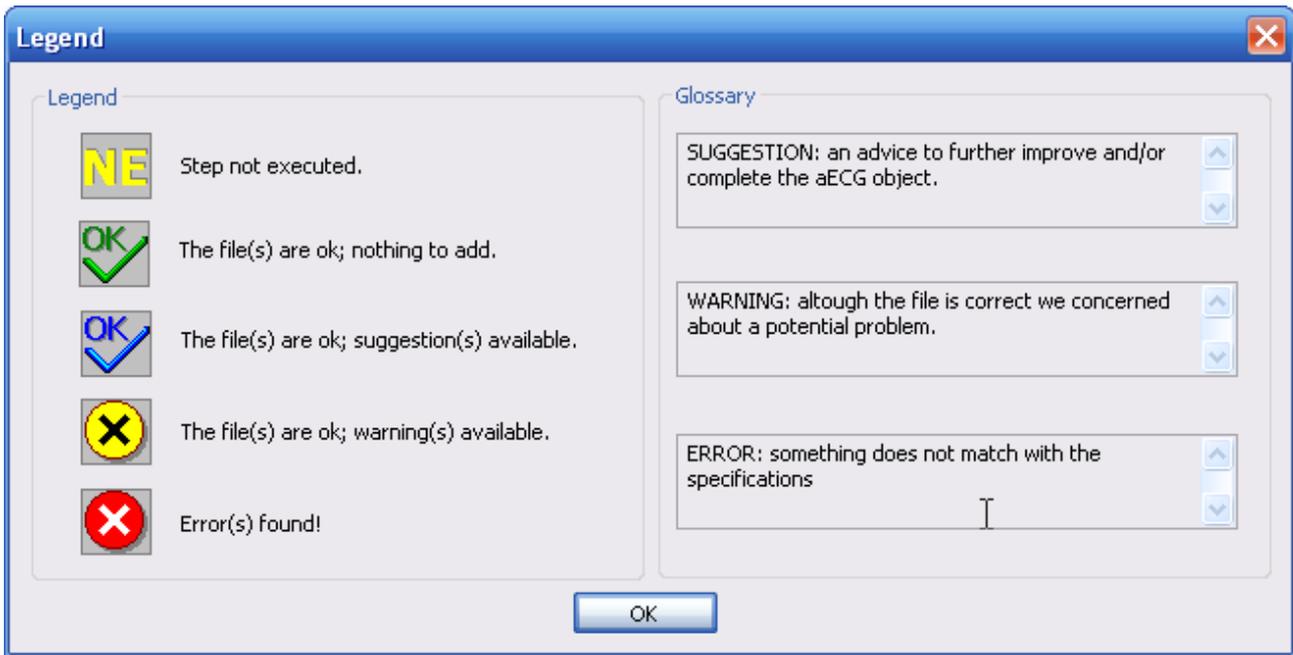


Figure 10: Legend of the Validation results summary.

Apart from the results summary (Figure 9), for all errors found there is a more detailed overview, in the Validation pane itself (Figure 11).

Warning and errors can be expanded or collapsed each by clicking on the  or  symbol at left of the text.

Moreover the display of the validation summary can be chosen between four formats:

- All reports grouped by file: warnings and errors are listed grouped by the file which generated them
- Only errors grouped by file: errors are listed grouped by file
- All reports grouped by type: warnings and errors are listed grouped by their type
- Only errors grouped by type: errors are listed grouped by their type



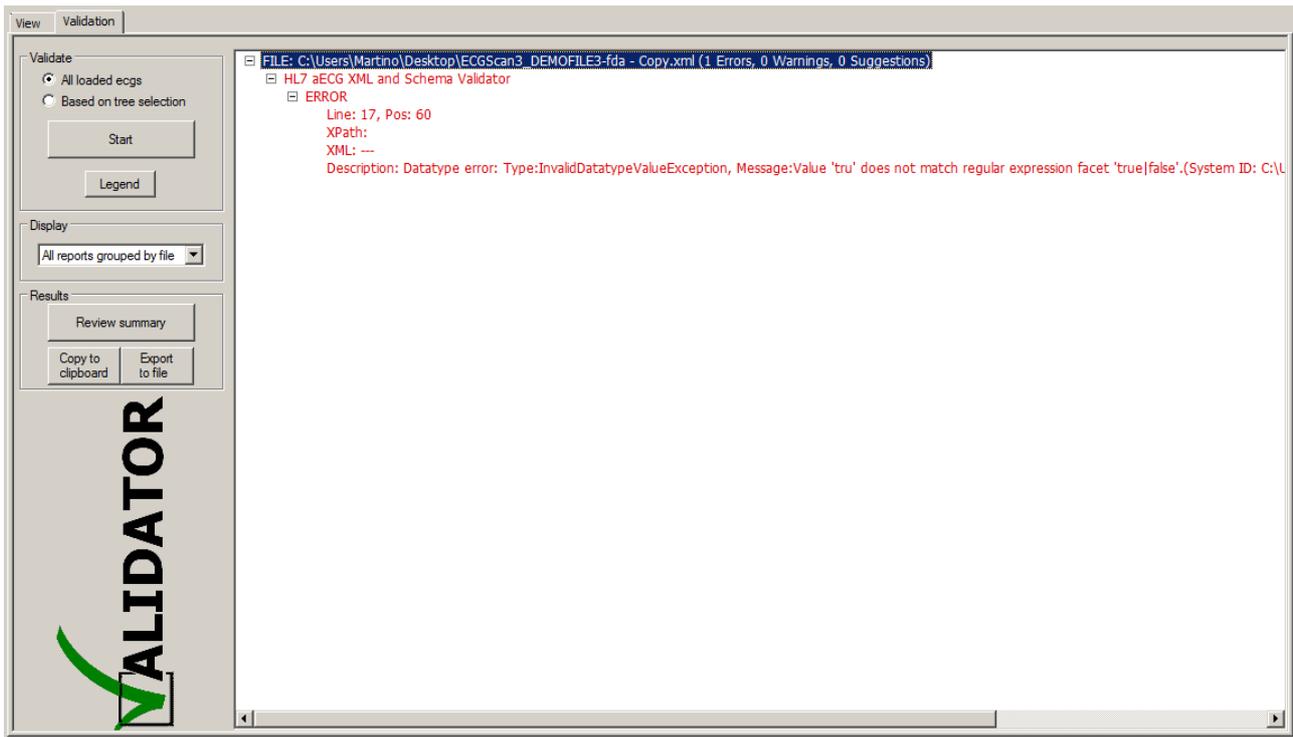


Figure 11: Validation Full Summary.

The validation report also provides information on the location inside the file that caused the particular error (line number, position and *Xpath* (path in the XML structure), together with a detailed description of the error/warning type).

The  button gives the option to export the complete results of the validation process into a log-file, while the  button copies the validation summary in the clipboard.

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