

Release Notes

Evidence Investigator Analyser

*Software Release Version 2.1.1
Incorporating
Software Release Version 2.1.0*

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Issued by Randox Laboratories Ltd

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Release Features

In response to operator feedback and in line with our policy of continuous improvement, the Evidence Investigator analyser software has been updated to bring additional functionality and enhancements.

Information relating to additional functionality has been incorporated into the Operator Manual where required and the manual has been updated and reissued.

Manuals and Manual Amendments

As part of our environmental commitments, Randox are moving to increased use of electronic formats and updates to Operator Manuals are now distributed electronically as PDFs. An electronic copy (PDF) of the manual is included in the software upgrade package that accompanies these Release Notes.

Within the workplace, electronic documents bring more than environmental benefits, commonly these include:

- *Fast searching of text*
- *Zoom in/out on text and images*
- *Decreased storage space requirements*
- *Copies of the manual may be installed to different PCs and used at the same time*
- *Fast updates can be made available*
- *Local prints of individual pages or the whole manual can be made if/when required.*

Future amendments may be made to the Operator Manual to increase or enhance the information provided. Amended manuals will be distributed as complete PDFs together with a list of the changes allowing end users to either, replace the old version of the file with the new version or to self-print the required pages for incorporation into any hard copies they may hold.

- *Instructions on how to complete the amendment will be included with each issue.*

Where required, the manual is designed to be printed in the following format:

- *Double sided*
- *Colour print*
- *A4 paper – this may be changed to US letter sized paper (or almost any other size) through use of the 'Fit' option shown in the settings of Print dialogue accessed from File> Print.*

NOTE:- *Despite the many advantages of electronic documents we appreciate that some end users may require manufacturer produced, printed copies to be present in the workplace. If required, printed copies of the manual and any amendments may be requested from your Randox representative.*

2.1.1 Software Update – Main Features

Feature	Update
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1	Reference and correction spot detection
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Change to code so that the thresholds that are sent to the spotfinding.dll are dynamically loaded from a new "SFTHRESHOLDS" table in the database rather than being hardcoded within the camera.

The change will be required in the InvestigatorCamera.exe code as this is the module that then passes the thresholds to the SpotFinding.dll. There are no updates required to other modules.

The change will allow for greater detection of reference and correction DTRs (Discrete Test Regions) which if not detected result in no test result for the sample. Hence requiring the operator to rerun the sample. This update may reduce instances of non-valid 6010 error codes.

Please note that the reference and correction DTRs are internal control measures spotted on each biochip which determine that the biochip has been correctly orientated within the well and is used as a reference point for calculating the analyte results within the biochip. There has been no change in the manner which the software formats or calculates the analyte results.

2.1.0 Software Update – Main Features

Feature	Update
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1 Inclusion of Cardiac Risk Prediction (CRP) Array

The Randox Cardiac Risk Prediction Array is in development and will be available soon.

2 Inclusion of the ApoE4 Array

The Evidence Investigator ApoE4 Array is a research only assay used for detection of the ApoE4 protein.

3 Update to STI Borderline Calculation

Update to STI array to display all borderline results as "Borderline".

4 Summary Report including Samples, Controls and Calibrators

It is now possible to produce an entire run summary report which includes Sample Results, QC Summary and a Calibration Summary.

5 QC summary Report

There is now the ability to view and print QC Summary QRP's as one document rather than multiple QRP's for each analyte.

A new format for QC Summary includes all analytes on one simple to understand and easy to print document for both daily and cumulative QC Reports.

6 Update of Report Title to include the Array Name

Report headings have been amended to include the Array Name.

7 Inclusion of Report Heading Containing Lab Details

It is now possible to include details such as the Lab Name in the heading of individual sample reports using text or an image.

8 Update Report Formatting for Better Clarity of Results

Presentation of reports has been improved to more clearly distinguish between positive and negative results.

For Normalised and All Quantitative arrays, positive and borderline results are highlighted for better clarity.

9 Consent Form Integrated into Troubleshooting

Consent must be given before Randox can handle an end user's sensitive test/patient data. From Software version 2.1.0. a consent form is automatically generated when a database backup is generated from the Troubleshooting screen. After completion of the consent form, it may be sent to Randox together with the database backup for troubleshooting analysis.

10 Allow Checking and Printing of the Analyte Selection

The system now allows users to check the analyte selection for each sample prior to accepting the worklist and in addition enables the analyte selection for a worklist to be exported before accepting it.

11 Auto Logout for Enhanced Security

Administrators / managers may set a period of time, after which the currently logged in user will be logged out automatically if the system is idle.

2.1.0 Software Update – Main Features

Feature	Update
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12	Change Barcode Option within Result History is Now Restricted to Managers Only
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	Following rigorous assessment, it was concluded that there is an occasional, legitimate need to assign controls where they were previously incorrectly entered as samples. However, to address concerns of possible insecurity which could allow sample names to be changed retrospectively, Software version 2.1.0 restricts this option to only users with Manager or Administrative level logons.
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13	IT Security Updates
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	Security updates to:
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- | | |
|--|--|
| | <ol style="list-style-type: none">1. Eliminate the requirement for local admin after installation.2. Eliminate the requirement for registry access after installation.3. Eliminate the requirement for user account control to be disabled after installation. |
|--|--|

14	Reference and Correction Spot Detection
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	Additional checks for the maximum permitted variation of RLU between the reference and correction DTRs (permitted ratio variation defined on an array by array basis).
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	Additional checks for the permitted distance and angle between reference and correction DTRs.
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Known Issues Within the Release of this Software

1 Change Barcode Function

Change Barcode function may be disabled after imaging carriers.

Remedial action: To enable the Change Barcode function, login with a different Manager or Administrative account or restart the software.

2 Reference Standard Report

Reference Standard Report displays incorrect page number when displaying the customer details using a large image.

The report may display "Page 1 of 2" but only 1 page may be printed.

Remedial action: To fix or prevent the above issue make sure the image height is less than 25 pixels.

Important Release Information

Before performing the Evidence Investigator Version 2.1.1 software upgrade it is important that these instructions are followed:

1. Please run a backup of your system's database using either the **Database Backup v2.1** application or **Database Tools 2.0** – If you do not have either of these applications; please contact Radox Technical Services or your Radox support provider who will be happy to provide you with a copy.
 - Make sure the backup is saved to a safe location such as an external drive or removable media.
2. Please read carefully and follow the Installation Instructions as detailed.
 - Windows™ XP & 7 operating systems Pages **8 to 15**.

After performing the upgrade:

3. Please contact Radox to confirm that the update has been done as this will help us in providing the correct support for your needs
 - If any errors are encountered during the update, please contact your Radox support provider with details of the error and screen shots if applicable.
 - Please do not run the analyser until a support representative has been contacted and any issues are resolved.

NOTES: -

1. The installer has been designed to update Investigator analysers (with software Version 1.7.1 or above) to Version 2.1.1 software (incorporating Version 2.1.0 updates).
2. If problems occur, some users may need to manually upgrade to Version 1.7.1 before re-running the Version 2.1.1 upgrade. If you do not have a copy of the previous Version 1.7.1 software, please contact your Radox support provider.
3. The software update has a base number of 2.1. The update received by end users may be higher than the base number and may, for example, have a release number of 2.1.0.5 or 2.1.0.6, etc. depending on the last validated build of software.
4. Remote sessions can be arranged, at your convenience, for a representative from Radox to perform the software update or to assess the analyser post update. Please be aware, remote sessions require an internet connection to be made available to the analyser PC.

If any of the points above require clarification or further guidance is needed, please contact your local support provider or Radox Technical Services at technical.services@radox.com

Version 2.1.1 Software Installation

The Version 2.1.1 software update uses the same setup processes as previous installations. However, users should read the following instructions to make sure they are familiar with the steps and are confident to complete the installation.

To allow Randox to provide equipment specific support, it is important that Randox are notified when software/hardware has been updated.

Please contact your Randox support provider to confirm that the update has been completed; including details of the update and of the equipment.

This may be easily achieved by viewing the **About** screen which provides details of the analyser serial number ① and the software version ②.

See Figure 1.



Figure 1

Please note: - The main UI is not updated as part of the version 2.1.1 update hence the software build version for the UI will display as 2.1.0.9

NOTES: -

1. On user's analysers, ① and ② will be different to that shown in the illustration above.
2. Users are advised to use the Randox Scheduled Backup Assistant to backup their databases to a safe location such as an external drive or removable media before installing any new software to the analyser PC.
 - The Backup Assistant is a separate application that can be provided by your local Randox Representative or by contacting Randox Technical Services.

NOTE: - Screen images shown in this document are representative of the process and may differ slightly between individual installations and operating systems.

Installation Procedure

The software can be installed in two ways. They are as follows: -

1. By obtaining a CD-ROM from Radox containing the Investigator Version Update 2.1.1
2. By connecting to the Radox FTP site, downloading and saving the Investigator Version Update 2.1.1 on to a blank USB memory device.

Note: - the customer must have internet access to complete this procedure.

CD-ROM Installation

1. Power on the PC.
2. Insert the CD-ROM containing the Version Update 2.1.1.
3. The CD should run automatically and start the update.

If the CD does not run automatically, locate the update installer application. The installer is located at the top level on the CD and not within a folder.

4. Double click on **VersionUpdate2_1_1.exe** to launch the update application. See Figure 2.
5. Proceed to Investigator Updater Application Step 1.

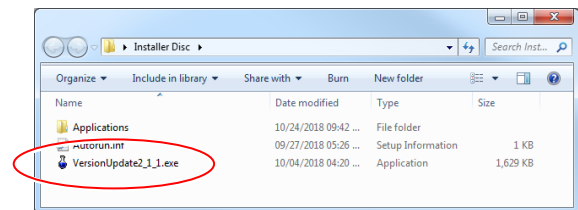


Figure 2

Using The Radox FTP Site to Download Software

Please note that you **must** have internet access to complete this procedure.

1. Open **Windows Explorer**. Windows Explorer can be found by accessing **Computer** or **My Computer** from within the **Start Menu**.
Type the following into the address bar, <ftp://ftp2.radox.com> as shown in Figure 3.

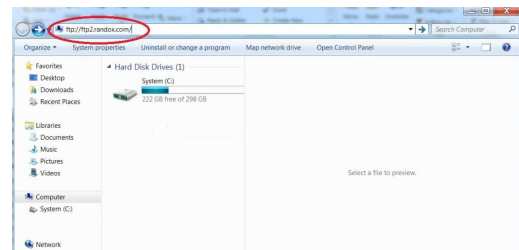


Figure 3

2. Press **Enter** and the **Log On As** window will appear as shown in Figure 4.
3. **Enter** the **unique User name** and **Password** as provided below and **click** the **Log On** button.

User name: evidenceinvestigator

Password: Investigator123

4. The FTP window with electronic version of Investigator v2.1.1 Software Release will open along with copies of the release notes and customer notification.

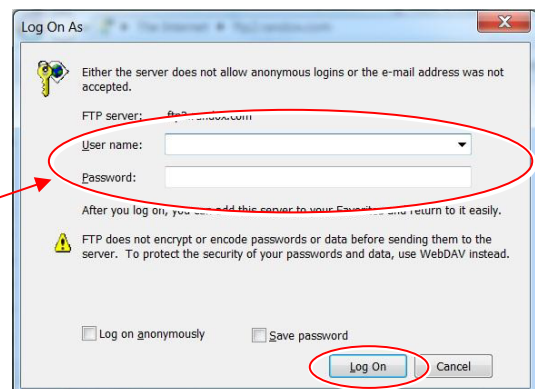


Figure 4

5. Save all files mentioned in step 4 onto a blank USB memory device to continue with the software update.
6. Remove the USB memory device containing the software update and transfer to the Evidence Investigator Analyser PC.
7. Locate the **VersionUpdate2_1_1.exe** on the USB memory device and double-click to launch the update application software.
8. Proceed to Investigator Updater Application Step 1.

Investigator Updater Application

Depending on the security settings on the analyser PC, a warning message may be displayed before any software is allowed to be installed. See Figure 5.

1. Click the **Yes** button to proceed with the software update.

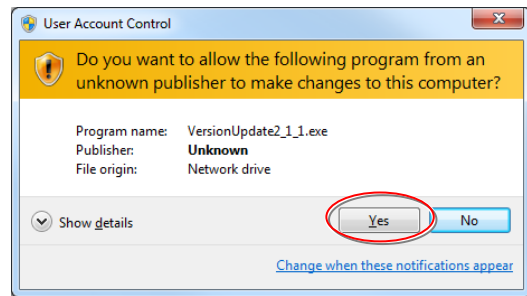


Figure 5

The Investigator Updater application screen will be displayed.

2. Click the **Run Update** button displayed at the bottom of the application window and the update will start. See Figure 6

The **software** progress window will display details of the software files as the system is updated.

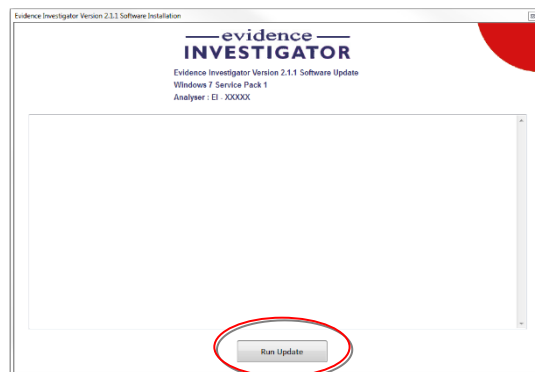


Figure 6

3. The process may pause occasionally for a few seconds but should continue soon after.
4. After loading a number of files, see Figure 7 the software update will attempt to install **Dot Net Framework 4.0**.

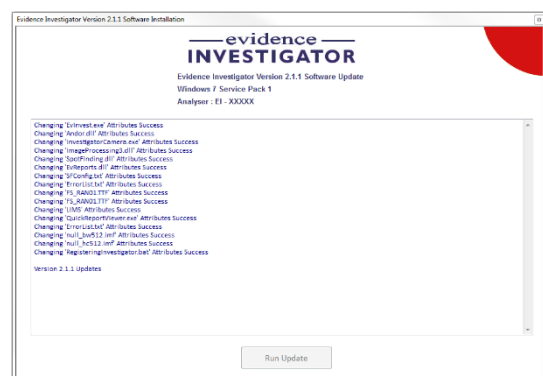


Figure 7

Dot Net Framework 4.0 Install

Before the updated analyser software is installed the installer application will attempt to install **Dot Net Framework 4.0** See Figure 8

1. Click **OK** to close the message and start the Dot Net installation.

If already installed, the installer will allow this part of the process to be bypassed.

- If already installed, click the **Close** button to move onto the next stage of the update. See Figure 9.

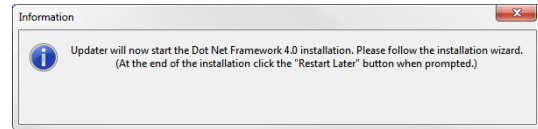


Figure 8

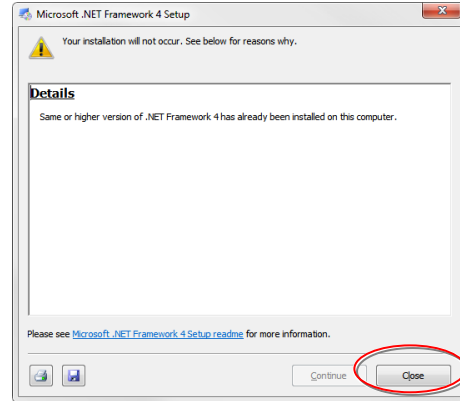


Figure 9

If not already installed (or not the correct version of Dot Net), Microsoft may require users to agree to the license terms before Dot Net Framework 4.0 installation is started. If required, the terms may be printed or saved to a file for future reference.

2. Place a **tick** in the in the check box to confirm that you agree with the terms of the license.
 3. Click on the **Install** button to start the Dot Net Framework 4.0 installation process.
- The **Dot Net Framework 4.0** installation process is shown on-screen by progress bars.

	<p>NOTE: - Do NOT restart the computer at the end of the Dot Net Framework 4.0 installation. The computer should be restarted only after the complete analyser software update has ended.</p>
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A message is displayed when the **Dot Net Framework 4.0** installation is complete.

4. Click the **Finish** button to end the Dot Net Framework 4.0 installation.
The analyser update will continue automatically after the Dot Net Framework 4.0 installation has finished.

C++ Install

Following the Dot Net installation the system will attempt to update the C++ libraries.

C++ is the programming language used to create the analyser software. Many users, particularly those running relatively new systems may find that the Version of C++ on their PC is already at a higher level than the minimum required for the analyser. See Figure 10.

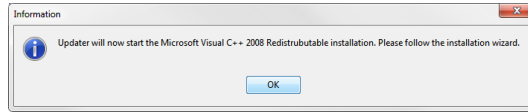


Figure 10

- If the Version of C++ on the analyser PC is lower than the required standard for Version 2.1.1. analyser software, the installer will install the new C++ libraries.
- If the Version of C++ is already the correct level or higher, the installer will inform the user with an on-screen message.
- Click the **Close** button to move to the next stage of the update. See Figure 11.

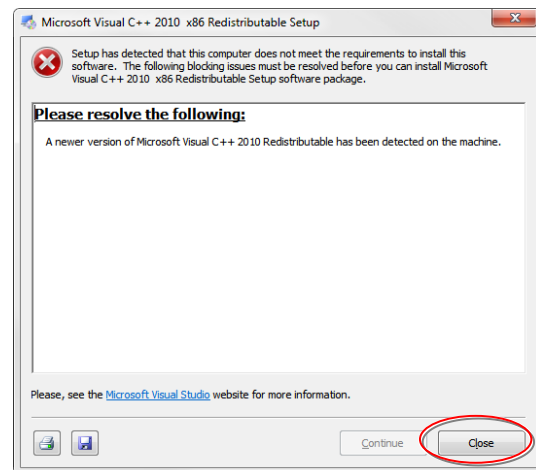


Figure 11

Analyser Update 2.1.1 Install

Version 2.1.1 and Version 2.1.0 analyser software updates will continue automatically after the C++ process has ended. Update progress is shown on-screen as each file is processed.

At the end of the process a series of messages, see Figure 12, are displayed to confirm that all required .dll files have been installed.

Click the **OK** button to acknowledge each message.

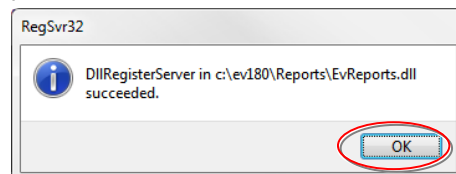


Figure 12

The update will now continue to install the analyser software files.

When all files have been installed the installation progress window will indicate that the update is complete See Figure 13. A pop-up message is also displayed to confirm that the update is complete.

1. Click the **OK** button to acknowledge the message. See Figure 14.
2. On the Installer window, click on the **Close** button to close the installation software.
3. Restart the analyser PC from the **Windows/Start** button.
4. Start the analyser software.
The Version 2.1.1 software should be displayed.

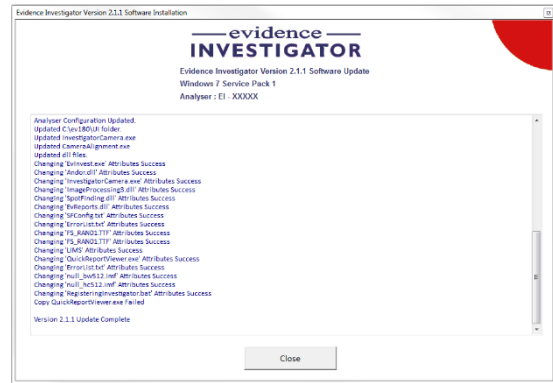


Figure 13

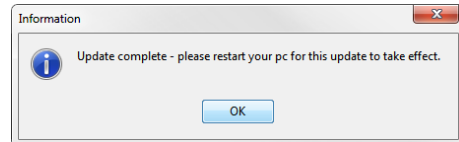


Figure 14

To check the software Version

1. Start the analyser software.
A message will be displayed with the option to start the analyser. See Figure 15.

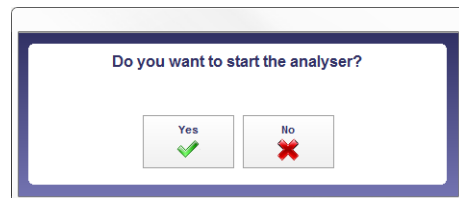


Figure 15

2. Select **Yes** to fully start the analyser and software or select **No** to start the software only.

The software version is shown near to the centre of the screen. See Figure 16.
Alternatively the version and other analyser details can be viewed at any time whilst using the analyser/software:

- Press the **F1** key on the keyboard to display the About screen.

The software Version is shown at the bottom of the window.

- Click the **Close** button to close the pop-up window and return to the main software.



Figure 16

NOTES: -

1. The address and telephone numbers can be copied and pasted if required.
2. Users with web access can click on the Radox web address to view the Radox website.

Evidence Investigator Shortcut Icon

As part of the visual upgrade to the Investigator software, the icon used to start the software has also been changed and many users will place a shortcut to the **EvInvest.exe** file on their desktop.

To place a shortcut on the desktop

1. Navigate to the **EvInvest.exe** file, found in the 'UI' folder on the C: drive (**C:\ev180\UI\ EvInvest.exe**)
2. Right click on the **EvInvest.exe** file to display a pop-up menu.
3. From the pop-up menu, select **Send to**. A range of options will be displayed on a sub-menu.
4. From the sub-menu, select **Desktop (create shortcut)**. See Figure 17

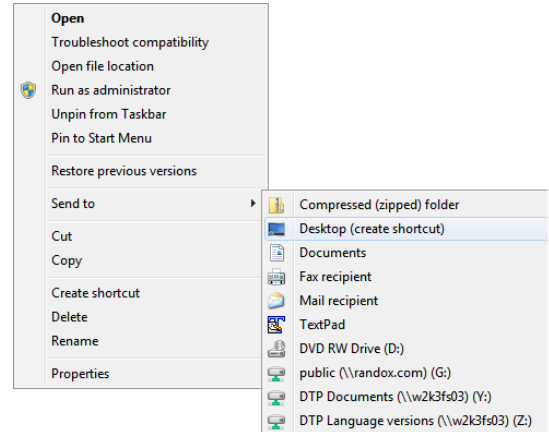


Figure 17

5. A shortcut icon to the software (denoted by the small arrow in the bottom left hand corner) will be displayed on the desktop. See Figure 19



Figure 18

For some users the screen may not display the new icon but will retain the old icon, see Figure 19 used with previous installations of the software.

- This is caused by a known issue with the Windows operating system but is not a problem and does not affect the functioning of the analyser software in any way.
- Users who wish to display the new icon should follow the steps below which should resolve the issue in the majority of cases.

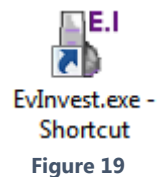


Figure 19

6. Click on the Windows Start button. See Figure 20.



Figure 20

7. Type the word **Run** into the **Search field** at the bottom of the **Start menu**. See Figure 21.
The **Run application icon** will be displayed at the top of the **Start menu**.
8. Click on the **Run** application icon. The application will be displayed.

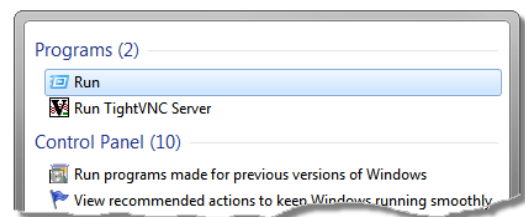


Figure 21

- In the Run application, see Figure 22, type the following text: -

Ie4unit.exe -ClearIconCache



	<p>NOTE: - There is a single space between the word ' .exe ' and the hyphen '-'.</p>
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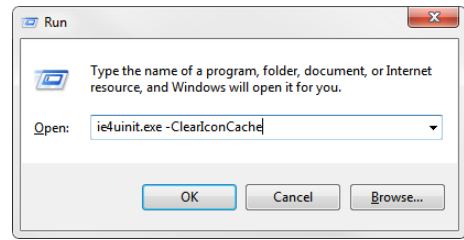


Figure 22

- Click **OK**.
- The **Run** window will close and the old analyser icon should be replaced with the new style icon.

End of procedure.