



ORIGINATOR:

Name	Job Title	Signature	Date
Brian Cullinan	Software Developer		5/18/12

APPROVALS:

Name	Job Title	Signature	Date
Scott Pletzer	Director of Quality & Program Management		18MAY12
Andrew Mason	Chief Technology Officer		5/18/12

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	18May12	Initial Release	S. Pletzer



1.0 Purpose

This document is intended to provide a protocol for use in verifying and validating the Shell version 1.0. This protocol is intended to provide a method for conducting the testing as well as to be used as a formal record of the validation activities.

2.0 Scope

This protocol is intended to be used to test the Shell version 1.0.

3.0 Definitions

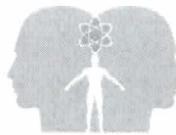
N/A

4.0 Responsibilities

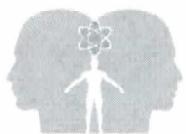
User	<ul style="list-style-type: none">• Complies with the policy and procedure.• Ensures the most current version of this document is used when referenced.
Departmental Management	<ul style="list-style-type: none">• Ensures departmental personnel are properly trained before using this policy or procedure.• Provides oversight to the validation process and ensures that all quality system requirements are met.
Quality Assurance	<ul style="list-style-type: none">• Monitors the implementation and effectiveness of this document.• Audits to ensure compliance with the referenced procedures

5.0 Policy

- 5.1 This protocol is intended to be updated for any changes made to the Shell such that the instructions provide a comprehensive test to demonstrate whether the Shell meets the intended use.
- 5.2 Follow the instructions provided within this protocol as written. Any deviations from the written protocol will be recorded on Attachment A, Deviations from Protocol.



- 5.2.1 An individual will be assigned responsibility from the Validation Team to oversee the execution of the protocol. This validation designee will review each deviation as documented prior to moving forward in the validation process.
 - 5.2.2 The validation designee will be required to determine whether the deviation requires formal documentation through EPIC's Deviation procedure or if the deviation is minor enough to warrant documentation only.
 - 5.2.3 Upon completion of the protocol, the Validation Team has the responsibility to review all deviations recorded to determine whether or not they significantly impact the protocol/validation process. Any deviation deemed significant will be handled through EPIC's Deviations procedure.
 - 5.2.4 The individual performing the validation protocol will complete each column of Attachment A for all deviations from the written protocol prior to moving forward. The validation designee will review each deviation prior to moving forward in the validation process. This review is indicated by documenting a signature and date in the Review column of the Deviations from Protocol worksheet located in Attachment A.
 - 5.2.5 The validation designee should be aware during the execution of this validation protocol that the intention is to validate all functionality of the ClearView Shell. If at any time a portion of the ClearView Shell is identified as not being challenged, notify the validation team immediately and document the omission on the non-conformances worksheet.
-
- 5.3 The written protocol is intended to capture the steps needed to properly challenge each ClearView Shell function. However, given the evolving nature of ClearView Shell development, the instructions may not be 100% accurate. Therefore, any minor deviation from the written instructions will be corrected in writing during the execution of the validation protocol. These corrections will be reviewed by QA as a part of the validation analysis. The review will determine appropriate corrective and preventive action for any deviations notes.
 - 5.4 Record the results of each validation step by initialing and dating in the space provided. If the characteristic cannot be verified, record a reference number on the protocol and the Non-Conformances Worksheet (Attachment B) and describe the failure in a specific and complete manner by completing all columns on the Non-Conformance Worksheet. Some validation steps ask the validation



designee to record the results side-by-side. In these cases, record initials and date on each side of the slash mark after validating each step as instructed.

5.5 All verification and/or validation documentation created will be labeled with the version number, the Sample # (indicated in the protocol) and the initials and date of the individual performing the verification/validation step.

5.6 **Execute Section 6 of this protocol on Windows XP. Execute Section 7 of this protocol on Windows 7.**

6.0 Procedure (Windows XP)

6.1 User Functions

6.1.1 Log on to Windows under EpicUser and confirm the shell starts rather than explorer.exe.

JG 5/18/12 Verified _____ Not Verified _____ Non-Conform Ref # _____

6.1.2 Click the Start button and verify that the options ClearView, Log-off, and Shutdown appear.

JG 5/18/12 Verified _____ Not Verified _____ Non-Conform Ref # _____

6.1.3 Click ClearView and verify that ClearView starts as normal.

JG 5/18/12 Verified _____ Not Verified _____ Non-Conform Ref # _____

6.1.4 Click log-off and verify that both ClearView and the shell closed and the user is logged off.

JG 5/18/12 Verified _____ Not Verified _____ Non-Conform Ref # _____

6.1.5 Log in as EPICAdministrator and verify the shell does not start.

JG 5/18/12 Verified _____ Not Verified _____ Non-Conform Ref # _____

6.1.6 Open the ClearView shell by navigating to C:\Windows\Shell.exe, and verify the shell starts with the Settings option.

JG 5/18/12 Verified _____ Not Verified _____ Non-Conform Ref # _____

6.1.7 Click Settings and verify the settings dialog opens.



gt 5/18/12 Verified _____ Not Verified _____ Non-Conform Ref # _____

6.1.8 Select log-off from the shell and verify the user is completely logged off.

gt 5/18/12 Verified _____ Not Verified _____ Non-Conform Ref # _____

6.1.9 Log in as EPICUser and verify the shell starts. Press CTRL+ALT+~~DELETE~~ and ~~cancel~~ ^{END gt 5/18/12} Verify the Settings button appears, a message may be displayed and Ok or Cancel should be selected. ^{out of screen gt 5/18/12}

gt 5/18/12 Verified _____ Not Verified _____ Non-Conform Ref # _____

^{A dialog box appears, click OK. gt 5/18/12} 6.1.10 Click settings and Verify the settings dialog appears and is grayed out.

gt 5/18/12 Verified _____ Not Verified _____ Non-Conform Ref # _____

6.1.11 Click Edit and verify the settings are un-grayed and the settings can be edited.
You may be prompted to log in as an administrator.

6.2 The following steps should be executed in the order relative to the default settings, e.g. some steps should be reversed if the checkbox is already checked. These settings only apply to the EPICUser account tab in the settings dialog.

Verified _____ Not Verified _____ Non-Conform Ref # _____

^{Open settings. click edit. gt 5/18/12}

6.2.1 Check the Capture keys option and verify that ALT+Tab and ALT+F4 do not switch windows or close the settings dialog.

Verified _____ gt 5/18/12 Not Verified _____ Non-Conform Ref # _____

6.2.2 Uncheck the Capture keys option and verify that ALT+F4 closes the settings dialog.

gt 5/18/12 Verified _____ Not Verified _____ Non-Conform Ref # _____

6.2.3 Reopen the settings dialog. Check the Disable task manager and verify that when CTRL+ALT+Delete is pressed Task Manager is not available. ^{END gt 5/18/12} ^{click cancel. gt 5/18/12}

gt 5/18/12 Verified _____ Not Verified _____ Non-Conform Ref # _____

6.2.4 Uncheck Disable task manager and verify that task manager can be accessed by pressing CTRL+ALT+Delete. ^{END gt 5/18/12} ^{click cancel. gt 5/18/12}

gt 5/18/12 Verified _____ Not Verified _____ Non-Conform Ref # _____



6.2.5 Check Always on top and verify the taskbar stays in-front of all other windows no matter which window has focus.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

6.2.6 Uncheck Always on top and verify that when another window has focus the taskbar can fall behind the window.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

6.2.7 Check Disable CD auto-run and verify a CD with an auto-run program does not launch when inserted in to the CD drive.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

6.2.8 Uncheck Disable CD auto-run and verify that the CD runs a program.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

6.2.9 Check Replace shell with this App and verify the shell appears when the EPICUser is logged in.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

6.2.10 Uncheck Replace shell with this App and verify that the normal explorer.exe is shown when EPICUser logs in.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

6.2.11 Verify that Maximize ClearView is unchecked.

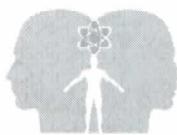
_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

6.2.12 Verify when Set desktop background is checked the ClearView logo appears on the desktop.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

6.2.13 Verify when Auto-hide is checked the taskbar is hidden when the mouse is outside the taskbar and focus is on another window.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____



6.2.14 Verify when the ClearView option is clicked on the Start menu, the program specified in the Clearview: textbox is launched.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

6.2.15 Verify when Close is clicked the settings dialog disappears.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

6.2.16 Verify Clearview can be closed by right clicking the icon in the taskbar and selecting Close.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.0 Procedure (Windows 7)

7.1 User Functions

7.1.1 Log on to Windows under EpicUser and confirm the shell starts rather than explorer.exe.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.1.2 Click the Start button and verify that the options ClearView, Log-off, and Shutdown appear.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.1.3 Click ClearView and verify that ClearView starts as normal.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.1.4 Click log-off and verify that both ClearView and the shell closed and the user is logged off.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.1.5 Log in as EPICAdministrator and verify the shell does not start.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.1.6 Open the ClearView shell by navigating to C:\Windows\Shell.exe, and verify the shell starts with the Settings option.

_____ **Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____



7.1.7 Click Settings and verify the settings dialog opens.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.1.8 Select log-off from the shell and verify the user is completely logged off.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.1.9 Log in as EPICUser and verify the shell starts. Press CTRL+ALT+DELETE and verify the Settings button appears, a message may be displayed and Ok or Cancel should be selected.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.1.10 Click settings and verify the settings dialog appears and is grayed out.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.1.11 Click Edit and verify the settings are un-grayed and the settings can be edited.
You may be prompted to log in as an administrator.

7.2 The following steps should be executed in the order relative to the default settings, e.g. some steps should be reversed if the checkbox is already checked. These settings only apply to the EPICUser account tab in the settings dialog.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.2.1 Check the Capture keys option and verify that ALT+Tab and ALT+F4 do not switch windows or close the settings dialog.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.2.2 Uncheck the Capture keys option and verify that ALT+F4 closes the settings dialog.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.2.3 Reopen the settings dialog. Check the Disable task manager and verify that when CTRL+ALT+Delete is pressed Task Manager is not available.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.2.4 Uncheck Disable task manager and verify that task manager can be accessed by pressing CTRL+ALT+Delete.



_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.2.5 Check Always on top and verify the taskbar stays in-front of all other windows no matter which window has focus.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.2.6 Uncheck Always on top and verify that when another window has focus the taskbar can fall behind the window.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.2.7 Check Disable CD auto-run and verify a CD with an auto-run program does not launch when inserted in to the CD drive.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.2.8 Uncheck Disable CD auto-run and verify that the CD runs a program.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.2.9 Check Replace shell with this App and verify the shell appears when the EPICUser is logged in.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.2.10 Uncheck Replace shell with this App and verify that the normal explorer.exe is shown when EPICUser logs in.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.2.11 Verify that Maximize ClearView is unchecked.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.2.12 Verify when Set desktop background is checked the ClearView logo appears on the desktop.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____

7.2.13 Verify when Auto-hide is checked the taskbar is hidden when the mouse is outside the taskbar and focus is on another window.

_____**Verified** _____ **Not Verified** _____ **Non-Conform Ref #** _____



7.2.14 Verify when the ClearView option is clicked on the Start menu, the program specified in the Clearview: textbox is launched.

 Verified **Not Verified** **Non-Conform Ref #**

7.2.15 Verify when Close is clicked the settings dialog disappears.

 Verified **Not Verified** **Non-Conform Ref #**

7.2.16 Verify Clearview can be closed by right clicking the icon in the taskbar and selecting Close.

 Verified **Not Verified** **Non-Conform Ref #**

1.0 Reference

EG-011, Software Validation

QA-004, Deviations

CS-003, Customer Feedback

2.0 Attachments

Attachment A, Deviations from Protocol

Attachment B, Non-conformances Worksheet



EPIC™
RESEARCH
DIAGNOSTICS

**ClearView Shell
Verification and Validation Protocol
Version 1.0**

Attachment A

Deviations from Protocol

NOTE: This form is used for minor deviations from the protocol as written. Fill out all sections of this form prior to moving forward in the validation process.

No.	Date	Name	Description of Deviation (include reference to the protocol section)	Resolution/Action Taken	Reviewed
1	5/8/12	B, Cullinan	Missing steps due to remote desktop.	Protocol will be revised and executed on a physical ClearView system.	



ClearView Shell
Verification and Validation Protocol
Version 1.0

ClearView Shell

**Verification and Validation Protocol
Version 1.0**

Attachment B

Non-conformances Worksheet

NOTE: This form is used for all protocol steps which did not perform as expected. Fill out all sections of this form prior to moving forward in the validation process.