RESEARCH
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DIAGNOSTICS

ClearView Shell
Risk Analysis Documentation Form

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 General

1.1 Device or Accessory Name: <u>ClearView Shell</u>

1.2 Complete Description of the Device or Accessory: <u>The ClearView Shell is intended to be used to replace the Microsoft Windows shell for computer systems that contain the ClearView client user interface software. This shell severely limits the functions the user can perform in a windows environment (browsing, adding software, adding printers, etc.). By limiting or restricting access to these windows functions, the shell will limit the areas of the system the user could access and thereby create configuration issues. The patient will never come in contact with the shell program, nor does the shell program have any connection with the ClearView client user interface software other than to launch the application.</u>

2.0 Identification of Qualitative and Quantitative Characteristics

2.1 Intended Use: <u>The ClearView Shell is intended to be used to launch the ClearView client user interface software and to prevent a user of the ClearView system from gaining access to operating system configuration options.</u>

    2.1.1 Indication for Use: <u>A replacement for the Windows shell.</u>

    2.1.2 Intended User: <u>Qualified, trained ClearView operators only.</u>

    2.1.3 Required Skill and Training of the User: <u>ClearView trained operators.</u>

    2.1.4 Environment of Use: <u>In doctor's offices, hospitals, and/or other locations that provide health care to the public.</u>

    2.1.5 Potential Influence(s) of Patient on Device Use: <u>Patient cannot influence the shell as they do not have direct access to it.</u>

2.2 Intended Contact

    2.2.1 User Contact (doctor, nurse, etc.): <u>The health care professional will utilize the ClearView Shell to launch the ClearView software.</u>

    2.2.2 Patient Contact (non-invasive, invasive, etc.): <u>N/A, the patient has no contact or access to the ClearView Shell.</u>

    2.2.3 Anatomical Surface(s) contact (blood, tissue, skin, etc.): <u>N/A.</u>

    2.2.4 Duration of Patient Contact (transient, short-term, long-term): <u>N/A.</u>

    2.2.5 Frequency of Patient Contact: <u>N/A.</u>

2.3 Materials and/or Components:

N/A, the Shell is simply a small software product that controls the launching of the ClearView client user interface software.
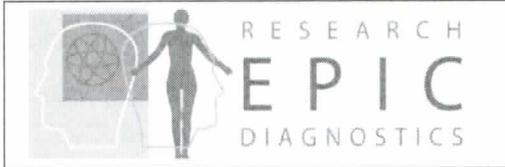
2.4   Energy Delivered or Extracted: <u>None.</u>

2.5   Substances Delivered or Extracted: <u>None.</u>

2.6   Biological Materials Processed for Subsequent Reuse: <u>None.</u>

2.7   Sterility Considerations: <u>N/A.</u>

2.8   Patient Environment Modification: <u>N/A.</u>

2.9   Measurements Made: <u>None.</u>

2.10   Interpretations Made: <u>None.</u>

2.11   Control of or Interactions with Other Devices: <u>The ClearView Shell is the program that launches the ClearView client user interface application and starts the operating system shutdown process when requested by the user.</u>

2.12   Unwanted Outputs of Energy or Substances: <u>None, there is no energy or substances produced by the ClearView Shell.</u>

2.13   Environmental Influences:

    2.13.1 Operation: <u>None</u>

    2.13.2 Transport and Storage: <u>N/A.</u>

2.14   Essential Consumables or Accessories: None.

2.15   Routine Maintenance and/or Calibration: <u>None.</u>

2.16   Software: <u>The ClearView Shell is a standalone product that requires no other software other than the host operating system.</u>

    2.16.1 <u>Device Functions Controlled by Software N/A, the shell does not control any aspect of the ClearView device.</u>

    2.16.2 <u>Software Feature Functions</u>

- <u>Launches the ClearView application</u>
- <u>Initiates the windows shutdown sequence when requested by the user.</u>
- <u>Prevents user access to other Windows configuration functionality.</u>

<u>The ClearView Shell presents an icon on the desktop that can be used to launch the ClearView application. This icon is the only way the ClearView application can be launched.</u>

<u>The windows shutdown sequence can be started using the ClearView Shell, the functionality and accessibility points mimic the standard Windows shutdown initiation process.</u>

The ClearView Shell hides access to all other Windows programs and configuration settings, preventing the user from inadvertently misconfiguring the system.

2.17   Shelf-life Restrictions: From a software perspective, the application has no predefined shelf-life, as it will be updated on a yet to be defined frequency basis with new and/or modified code.

2.18   Delayed and/or Long-term Use Effects: N/A.

2.19   Mechanical Forces: N/A, No mechanical forces are being delivered or received.

2.20   Lifetime of the Device: The software that drives the system will be updated on a yet to be determined frequency, thereby extending its lifetime indefinitely.

2.21   Single Use or Reuse: ClearView Shell is intended for reuse.

3.0   Identification of Possible Hazards:

Normal Conditions	Fault Conditions
	Shell will not start.
	Shell runs, but fails to start the ClearView user interface.
	Shell shuts down Windows unprompted by the user.
	Unable to exit out of the shell
	Date time not displayed in the shell
	Date time inaccurate in the shell