



APPROVALS:

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Camera Functions Requirements

1.0 Purpose

The purpose of this document is to describe the requirements for the ClearView system calibration process. This process is accessed through the Camera button on the top ribbon of the ClearView Software Solution.

2.0 Scope

The scope consists of the Calibration Process Requirements as a whole, no other systems requirements are defined in this document. The initial release of this document addresses only the requirements for the core system; this will be augmented as new requirements are introduced.

3.0 Definitions

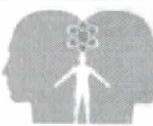
Calibration	A process to verify that the scanner is performing to a specified level.
Intensity	The measurement of the brightness of a given pixel in the captured image, it is reported as a value between 0 and 255.
Calibration Image	A graphic captured in Bitmap format that shows the image produced by the scanner when a calibration probe is in the machine. The image is captured at a resolution of 320 pixels wide by 240 pixels tall.
Tolerance	The quantity of pixels that are allowed to fail before the calibration is considered bad.

4.0 System Requirements

- 4.1 The calibration process must energize the scanner 5 times before capturing the 10 images to use in the actual calibration calculation process.
- 4.2 The calibration must be calculated using 10 sample images captured sequentially.
- 4.3 There should be a brief delay between image captures.

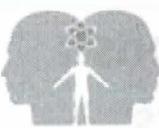


- 4.4 The calibration process will be accessible to all users.
- 4.5 The button to access the calibration process must appear on the main menu.
- 4.6 Calibration is required before a scan can be performed under the following circumstances:
 - 4.6.1 If 24 hours have elapsed since the last calibration process has been performed.
 - 4.6.2 If more than 4 hours have elapsed since the device was last accessed (aka. a scan was performed).
 - 4.6.3 If the calibration settings have been changed in any way.
- 4.7 The date and time of a successful calibration as well as the images associated with the calibration must be stored in the database. No record of an unsuccessful calibration needs to be maintained.
- 4.8 The calibration process should be controlled by a single button available to all users labeled 'Auto Calibration'. Clicking this button should do the following without user input:
 - 4.8.1 Perform 5 warm-up energize events.
 - 4.8.2 Collect and assess 10 images to use in the calibration process.
 - 4.8.3 Persist data if successful.
- 4.9 Present the user with a progress indicator of some sort so they are aware of where they are in the process.
- 4.10 The process must prevent the user from exiting the process once it has begun until a final result has been reached.
- 4.11 The administrator and techadministrator users only, should be able to manually load calibration images, bypassing the auto calibration process. Once the user

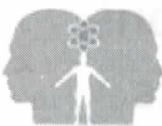


has added the images, a button to perform the calibration calculations should be available.

- 4.12 The calibration process should not be accessible unless a scanner is attached to the system. If no scanner is found, a message should be displayed indicating such.
- 4.13 The calibration dialog should allow the 10 captured images to be seen during the calibration process.
- 4.14 Calibration can be re-run at any time and for as many times as the user desires. Only the last successful calibration will be used for analysis purposes.
- 4.15 If a calibration process fails, a message should be displayed to the user. In addition the criteria that caused the failure should be placed in the alerts section of the application so they can be reviewed if necessary.
- 4.16 The calibration calculation is defined as follows:
 - 4.16.1 The calibration image will be broken down into four distinct regions of interest (the outer noise region, the inner noise region, the corona region and the high plateau region).
 - 4.16.2 Each of the areas is then compared to the threshold values for the respected area.
 - 4.16.3 If the total count of pixels that fail are equal to or greater than the limit specified for the given area, the image fails.
 - 4.16.4 The same process will be performed on all 10 images that have been collected.
 - 4.16.5 If none of the 10 images fail, the calibration is considered a success.
- 4.17 The calibration images and the calibration data should be able to be exported from the ClearView database. The export process will label the images with finger and hand references as part of the filename (e.g., 1R).



- 4.18 When a successful calibration is obtained, the images and a reference to the calibration are stored in the database. All scans performed after the calibration will reference the calibration. An audit trail will be kept for each image set stored in the database consisting of the following tracking points:
- ID of the user that performed the calibration.
 - Date and time of the calibration down to the minute.
- 4.19 Upon a successful calibration, the images should be passed back to the Matlab engine to generate the values necessary for the NS calculation. The NS calculation is specifically described in the Analysis Requirements document.
- 4.20 Each calibration image captured should be checked immediately for pass/fail status before grabbing the next image. If the image fails, the process should be immediately stopped.
- 4.21 The user should be able to select from the preconfigured calibration setting(s) that were defined.
- 4.22 Up to 4 preconfigured calibration settings should be available for use. The only users that can configure these settings are the administrator or techadministrator. The adjustable settings should be:
- 4.22.1 Brightness
 - 4.22.2 Gain
 - 4.22.3 Exposure Delay
 - 4.22.4 Boost Voltage
 - 4.22.5 The Default flag
- 4.23 The user performing a calibration should be able to select from the preconfigured settings before starting the calibration process.
- 4.24 The user should be able to re-run the calibration process in the case where it fails without having to exit and reload the calibration dialog page.



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5.0 Reference Documents

SR-203, Analysis Functions- Requirements



Document Revision History

Version Number:	Description of Change:	Date:	Updated by:
000	Introduction	5/24/11	A. Mason
001	Update requirements to match new calibration pass/fail requirements as identified in ENG-007.	7/8/11	A. Mason
002	Update system requirements to specify the delay between calibration image capture to equal 2 seconds and to clarify the verbiage regarding the reported pixels for failed images.	8/31/11	A. Mason
003	Define requirement to allow export of the calibration images and calibration data.	10/20/11	A. Mason
004	Add requirements for electronic records audit trail and number the requirements.	3/5/12	A. Mason
005	Removed specifics pertaining to the delay times in the calibration routine. Added a requirement to force a calibration to be run when settings are modified in any way.	7/18/12	A. Mason
006	Removed/Changed requirements to accommodate new calibration routine. Added in requirement to have up to four preconfigured calibration settings.	10/24/12	A. Mason