

# AMT Software Compliance with FDA Rule 21 CFR Part 11

## FDA Rule 21 CFR Part 11 includes

### Access control to the computer system

AMT complies with this requirement by allowing AMT to be used only by an authorized user on the camera control system. The user account and timestamp will be printed both physically onto every acquired image taken with AMT, and also will be encoded into the image's Secure Data Strip, which can be read and used to authenticate the user's information.

### Use of electronic signatures

AMT finds this requirement fulfilled by the solution above, automatically printing and encoding the user's account information onto all images acquired with the AMT Image Capture Engine.

### Audit trails and versioning

AMT fulfills this requirement by allowing no alterations to saved, authentic images. All images requiring modification (i.e. measurements) will be saved as new images in the Case Study with identifying tags. Any measurements made to filename\_001.tif will be saved separately as filename\_002.tif, filename\_003.tif, and will have information in their filename fields detailing how changes were made to the original image.

## Implementation

The AMT Image Capture Engine offers an "Authentication Mode" that, when activated, changes a number of things regarding total functionality.

- "Authentication Mode" is a password-protected feature that will be available only to authorized personnel.
- Users are required to start a case study and save images only to the open case. Normal saving functions are suppressed. Any images taken will be saved to the open case with an index number (image\_001.tif, image\_002.tif, etc.) .
- Alterations to images (measurement, annotation) within each case study will be saved as the next image in the Case Study with an additional comment in the filename field indicating that changes were made to the original image.

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- These images will also be saved as Read-Only, to further insure no alterations.

## Authentication Checker Interface

Along with the “Authentication Mode”, AMT provides an Authentication interface through which the user can view and open images taken, and sort them as authentic or unauthentic images.

- This interface is included in the AMT Image Capture Engine that and allows navigation through system folders and display TIFF images contained within. These images are then sorted into Authenticated and Non-Authentic images, and can be opened and displayed directly in the AMT Image Capture Engine by double clicking on the filename.
- Once open, users have the ability to work with the image with the full capability of the AMT software. As above, modifications will implement their audit trail by saving as the next image in the case study with expanded information in the file name fields (both secure data and the label).

