**Application Note**

**echoPlaque 4.3 versions**

**Methods for dealing with anomalous Infraredx DICOM files**

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January 24, 2022 rld

## Overview

In October 2021, users of Infraredx NIRS IVUS systems received a notice[1] of anomalies in DICOM files acquired using a few specific versions of the TVC-MC10 system software. Because echoPlaque measurements of distances, area, and volumes are affected by the physical spacing information provided in DICOM files, it is important to detect and correct such anomalous DICOM files before performing numerical analyses.

Work on an updated version of echoPlaque that automatically detects such anomalous files is ongoing, but not yet ready for release. In the meantime, we have developed procedures that can be used with existing echoPlaque 4.3 software.

This Application Note gives details of how to perform these necessary steps:

Detect whether a given file is one of the anomalous files described in the Infraredx notice.

If you have an anomalous case

1. determine the correct calibration to be applied.
2. apply the corrected calibration using one of two possible methods
    a. manual (mouse drawing) calibration in echoPlaque
    b. highest resolution method editing an echoPlaque proprietary file
3. save the updated file for use in later analysis
4. document the changes

Details of each step follow.

[1] October 25, 2021

**Subject:** Makoto Imaging System software anomaly notification

**Product:** Makoto Intravascular Imaging System **Model Number:** TVC-MC10

## Detect whether a given pullback file is one of the anomalous files

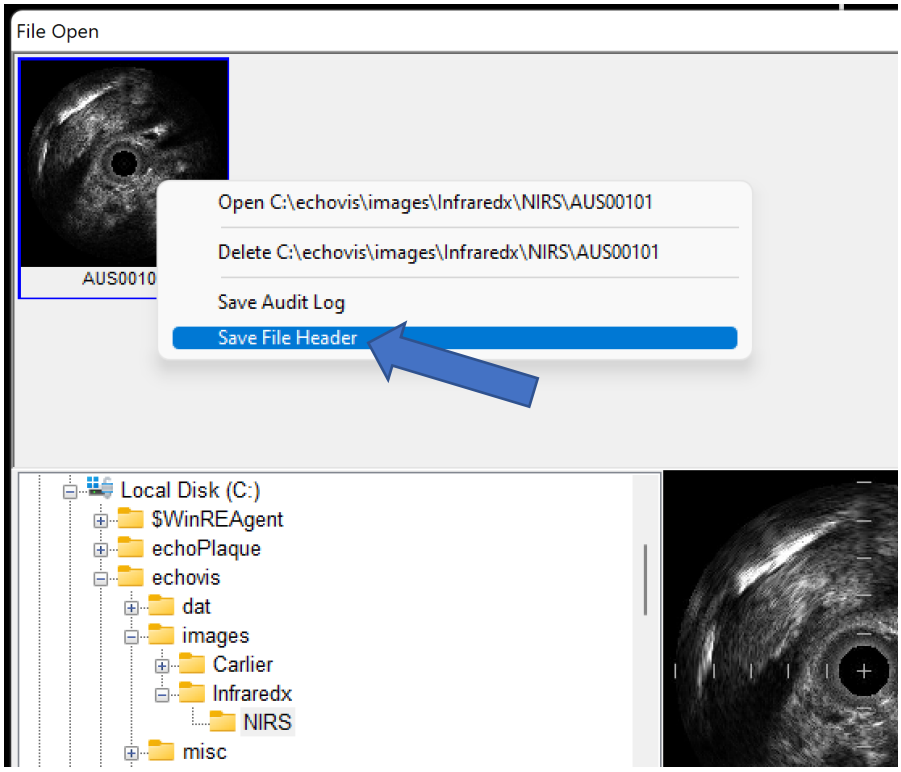
### Use echoPlaque to make an initial determination

Launch echoPlaque, click “Open”, then “Pullback”. Browse to the file of interest. If more than one file is available at this point, left click once on the file of interest to update the file preview.

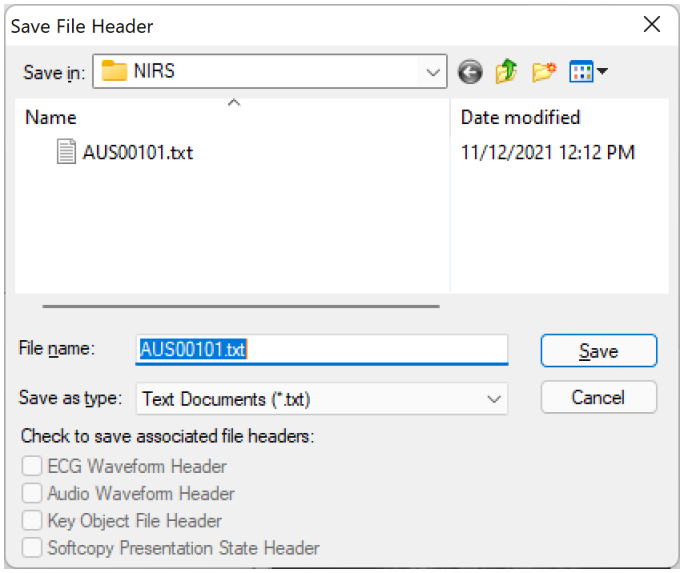

If the Equipment field includes the word “Infraredx” (in this case, it reads “InfraReDx, Inc.”) *and* the Model field shows “TVC-MC10”, then you may have an anomalous case. [Otherwise, you ***do not*** have an anomalous case, so ignore the rest of these instructions, and proceed with analysis as usual.]

## Extract and save DICOM header information from the file.

Staying in echoPlaque in the Open Pullback dialog, right click on the file of interest and select **Save File Header**, which saves a text file containing DICOM header information.




Left click on “Save File Header” to save the header. By default, a text version of the header will be saved in the same folder as the DICOM pullback you have selected.



Leaving echoPlaque open, switch to a text editor (Windows Notepad will suffice) to look at the saved DICOM header information.

Use your text editor to search for the DICOM tag (0018, 1020)

In our example, we find

(0018,1020) LO [4.7.0.37] # 8, 1 SoftwareVersions

Record the numbers in the square brackets (here 4.7.0.37)

If you see any of these values

4.6.0.91

4.7.0.35

4.7.0.37

then you ***do have*** one of the anomalous files.

Otherwise, you ***do not*** have one of the anomalous cases, so ignore the rest of these instructions, and proceed to analysis as usual.

# If you have an anomalous case

## Determine the correct calibration to apply

We provide two different ways to determine and apply the corrected calibration. Method 1 is the quickest method, using the burned-in grid marks on the image, but it requires careful and precise mouse movements.

Method 2 requires a few more operations to save, edit, and re-load a special echoPlaque file, but will give the highest accuracy in the resulting calibration.

The first step in either Method is to extract the value of a DICOM tag that we can use to determine the correct tissue ball diameter. This number will serve as a "reality check" for Method 1, and is crucial for Method 2.

### Determine the tissue ball diameter

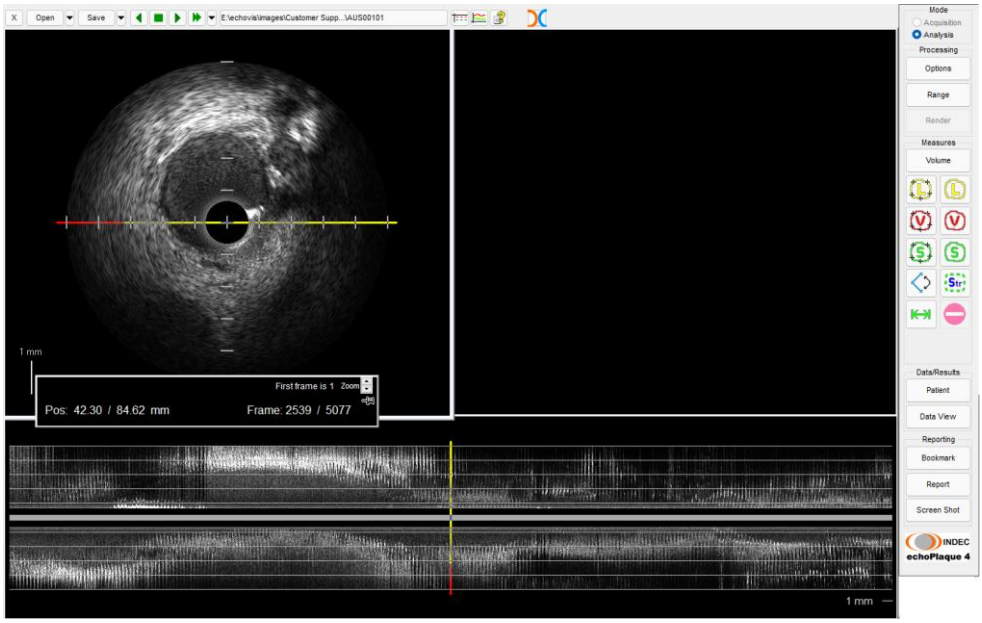
Continue using the text editor to look at the DICOM header.

Search for the tag (0018,5050), and record the value within the square brackets (here, "5")

(0018,5050) IS [5] # 2, 1 DepthOfScanField

This value is the depth of scan (IVUS radius) in mm, so in this case the diameter of the IVUS tissue ball is 5*2 or 10 mm. [Your file might have a diameter of from 6 mm through 16 mm.]

## Load the pullback file into echoPlaque



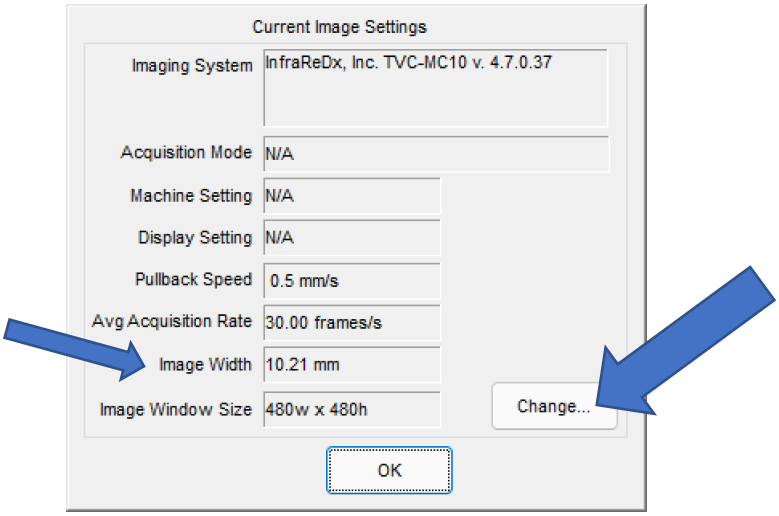

Now, choose either Method 1 or Method 2 to correct the anomalous calibration information.

## Method 1 Manual mouse clicking on grid markers

Infraredx pullback files typically have “burned-in” grid markers on the images that you can use to guide a manual update of the calibration. Calibration using this method has a small degree of potential error, because it depends on

1. Your ability to control the mouse cursor’s position very carfully
2. Your ability to draw lines that are strictly vertical or horizontal

Draw a line on the transverse image from top grid marker to bottom (or from left to right-most grid marker). Then click on the file name in the top bar to show the Current Image Settings dialog. [Notice the (anomalous) Image Width.]




Click on “Change” to show the Acquisition Settings dialog.


Enter the line length (i.e., the number of grid markers your green line covers) in the acquisition parameters field, and click ”OK”. In our case, we entered 10.00.

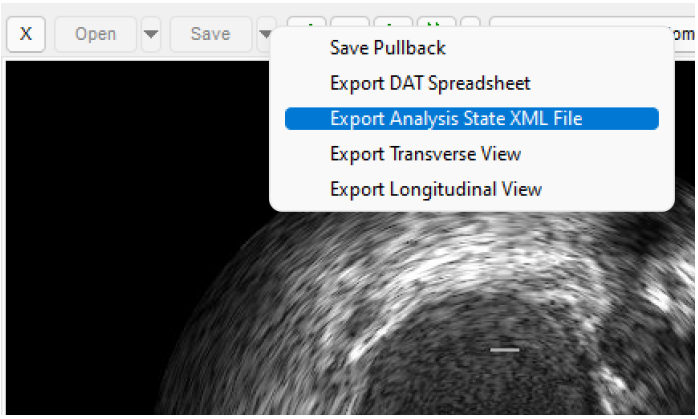
After you click “OK”, the image calibration is automatically updated accordingly. Proceed to the section “Confirm that the new values look right”.

## Method 2 Precise setting of calibration information

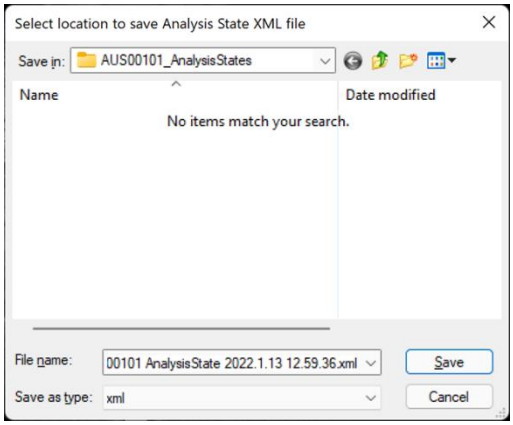
### *Save an Analysis State File*

Using echoPlaque (with the DICOM Pullback loaded), click on the downward pointing triangle just to the right of the “Save” button to show the menu items.

Click on “Export Analysis State XML File”




Take care to notice where the Analysis State File is being stored[2]

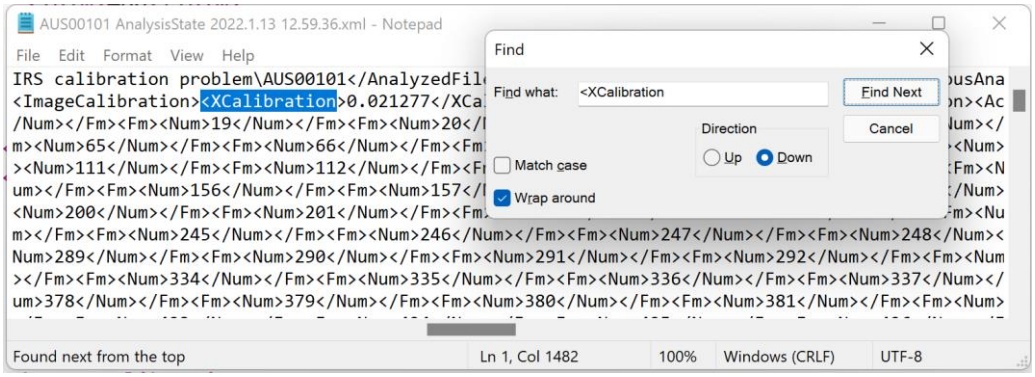



You can browse to the newly saved file and then display it in formatted form by double clicking on the file (Windows will load the file into a browser page).

[2] The default folder is a folder in the same location the pullback file was loaded from, given the name of the DICOM pullback file name followed by “_Analysis State”. The default Analysis State File name has the date and time appended to the pullback file name and “Analysis State”.


### *Edit the Analysis State File*

Although Windows will *show* the formatted contents in a browser page, it does not provide for *editing* them. Instead, you can use a text editor such as Windows Notepad, and try to ignore the crammed together view by searching for the exact field you will edit.




Use Table 1 to determine what value to use to replace the anomalous values.

| Depth of Scan Field (0018,5050) | Corrected XCalibration | Corrected YCalibration |
|---|---|---|
| 3 | 0.013333333 | 0.013333333 |
| 4 | 0.017777778 | 0.017777778 |
| 5 | 0.022222222 | 0.022222222 |
| 6 | 0.026666667 | 0.026666667 |
| 7 | 0.031111111 | 0.031111111 |
| 8 | 0.035555556 | 0.035555556 |

**Table 1 Corrected Physical Pixel Spacing values[3]**

In the example shown in this App Note, the Depth of Scan Field tag (0018,5050) has the value 5, so in the sequence

<XCalibration>0.021277</XCalibration><YCalibration>0.021277</YCalibration>

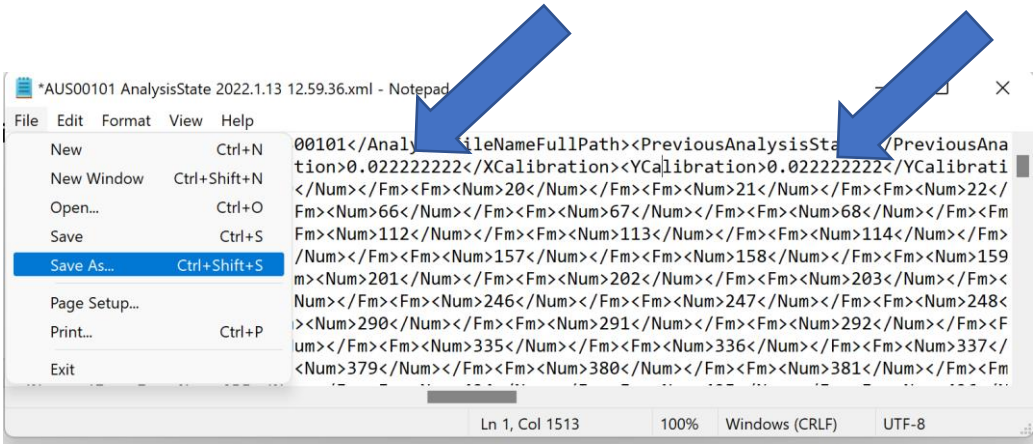
we replace the two values 0.021277 with 0.022222222

After the edit, the affected region of the Analysis State reads:

<XCalibration>0.022222222</XCalibration><YCalibration>0.022222222</YCalibration>

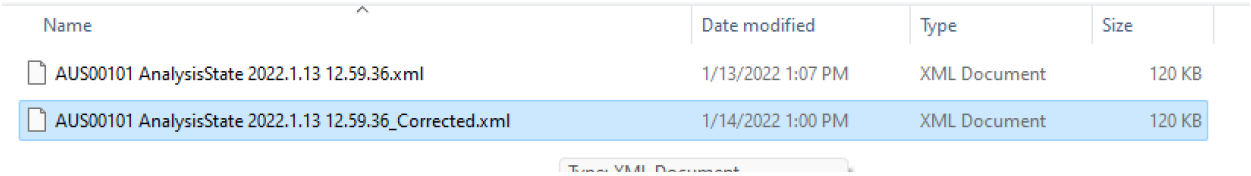
Save the edited file with a new name using the "Save As options" so you can tell which version is which. Here we used the name "AUS00101 AnalysisState 2022.1.13 12.59.36_Corrected.xml".

[3] The echoPlaque internal value XCalibration corresponds to the DICOM tag (0018,602c) PhysicalDeltaX and gives the spacing (in mm) between adjacent horizontal pixels in each (scan converted) image. YCalibration is analogous.




Return to echoPlaque which is still showing the uncorrected version of the anomalous file.

Click the down-pointing arrow to the right of the "Open" button, choose "Load Analysis State XML File" and then choose the modified Analysis State file to be loaded.




echoPlaque will automatically apply the corrected calibration information.

## Confirm that the new values look right

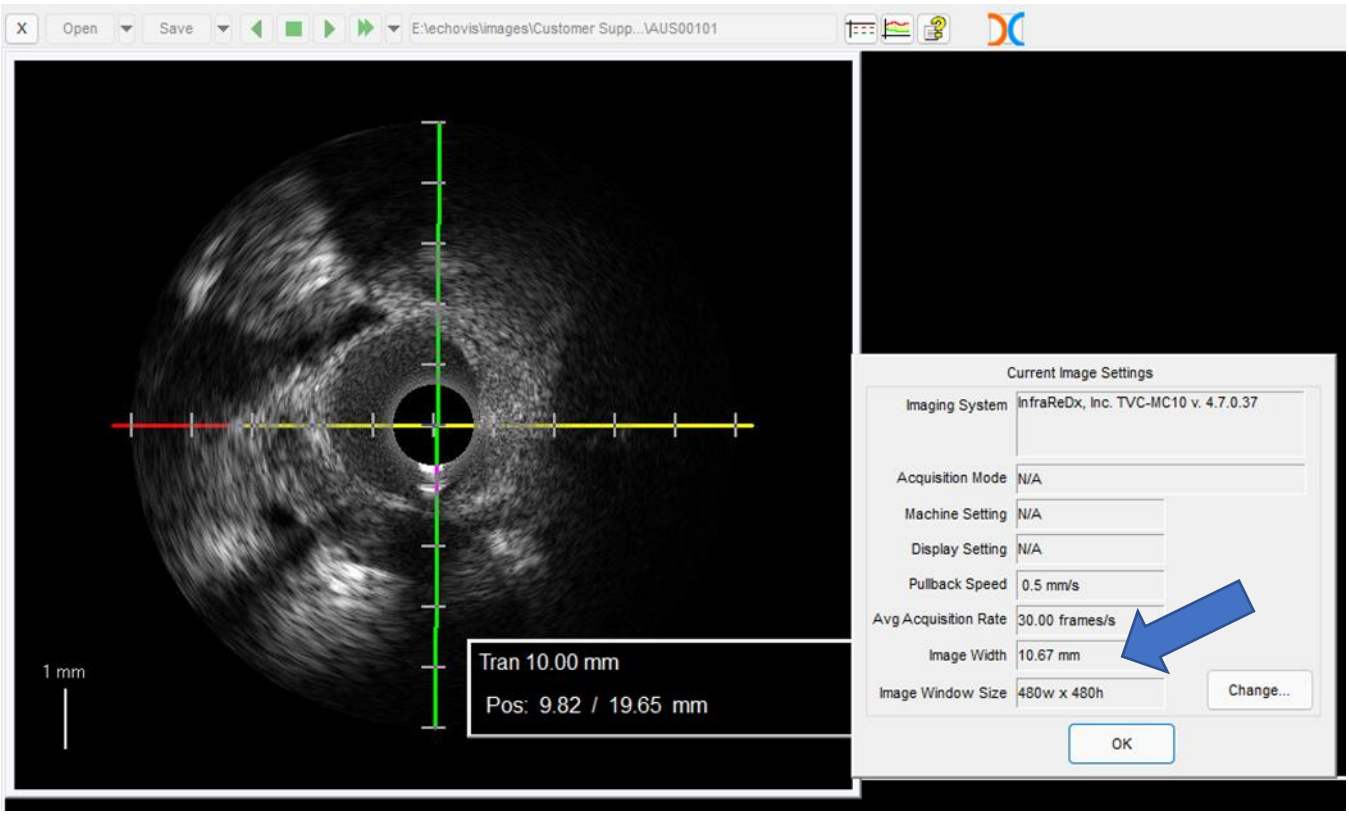
Use Table 2 to verify that the changes have taken effect and are correct.

| Depth of Scan | "Tissue ball" diameter | Corrected Image Width |
|---|---|---|
| 3 | 6 | 6.40 |
| 4 | 8 | 8.53 |
| 5 | 10 | 10.67 |
| 6 | 12 | 12.80 |
| 7 | 14 | 14.93 |
| 8 | 16 | 17.07 |

**Table 2 Corrected Image Width values[4]**

Assuming your DICOM pullback file was saved with standard 1mm markers, you can measure the "tissue ball" diameter using the echoPlaque linear measurement line. Here (again with Depth of Scan Field 5) the green line is 10 mm (twice the scan field depth) while the Image Width is 10.67 mm. [Because there was no chemogram data in this particular pullback file, the 15 pixel wide ring at the outer edge of the tissue ball is black, so difficult to see.]

[4] Infraredx DICOM pullback frames (images) are 480 pixels wide, which accounts for the Image Width after correction being (in the Depth of Scan Filed 5 example) 480*0.022222222 = 10.66666656 mm.

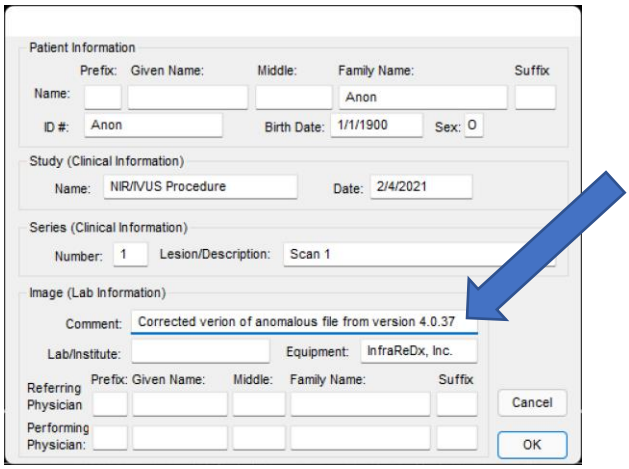



Because the Scan Depth (scan radius) is 5, the "tissue ball" diameter is 5*2 or 10 mm. The image width is 5*2 plus 30 pixels to make room for the Infraredx NIRS chemogram ring, so the width of the entire image is 10.67[5] mm.

[5] In the depth of scan 5 case, 10 + 30*0.022222222 = 10.67

## Save the updated file for use in later analysis

You can use the echoPlaque Comment field[6] to add important notes about how the corrected file was created.




You can save the corrected file as a DICOM file or as an (INDEC) *.BMG file. In both cases, echoPlaque will include the corrected calibration information so when you load the saved file for further analysis, no changes (such as the ones described in this App Note) are necessary[7].

## Document the changes in accord with your local procedures.

The documentation you generate to keep track of these changes is, of course, based on your local procedures. Values that may be relevant include

| | |
|---|---|
| Source of file | e.g., Study, Hospital, ?, demographic info, etc. |
| Location of original file | e.g., PACS, local storage info, path on local system |
| Original File Name | e.g. AUS00101 |
| DICOM header file | e.g. e:\infraredx\anomalous\AUS00101\AUS00101.txt |
| Manufacturer | e.g. Infraredx |
| Model | e.g. TVC-MC10 |
| Software Version | e.g. 4.0.37 |
| Verified as anomalous | e.g. Yes |
| Depth of Scan | e.g. 5 |

[6] Click on the "Patient" button on the toolbar at the right side of echoPlaque to access this dialog.

[7] All parameters necessary to do analysis in echoPlaque are preserved, however, the Infraredx private tags that we used to determine their model, software version and depth of scan in the original file are not saved.

| | |
|---|---|
| Original pixel spacing | e.g. 0.021277 |
| Corrected pixel spacing | e.g. 0.022222 |
| Corrected image width | e.g. 10.67 |
| Edited Analysis State File | e.g. e:\infraredx\anomalous\AUS00101\ AUS00101_AnalysisStates\ AUS00101 AnalysisState 2022.1.13 12.59.36_Corrected.xml |
| Saved corrected pullback | e.g. e:\infraredex\AUS00101\AUS0101_Corrected |
| Person making changes | e.g. Raymond Langsford |
| Date changes made | e.g. January 20, 2022 |

## Perform analyses as per your normal procedures

*Thank you for using echoPlaque!*

If you have any questions or suggestions, please contact us at techsupport@Indecsystems.com