

Case History 27

Imaging System Re-Engineering

Market

Cytology

Client Type

Major Medical Device OEM (confidential)

Unmet Need

Viable supply chain for key imaging components

Approach

The client's directive was to find a purely hardware solution to their component obsolescence problems. Due to the facts that the operating software was an old legacy program lacking modularity and tribal knowledge, and RA/QA had onerous validation concerns, no software changes were to be permitted. We would be allowed to change the optics, mechanics, camera, and camera interface hardware. We identified the critical camera specifications and conducted a global search for a replacement that would have long term support. If an equivalent was not found, the nearest equivalent would be used and the optics & mechanics would be modified as needed.

Results

We were successful at finding a camera that was *almost* equivalent to the existing camera. We conducted a tolerance analysis to determine whether it would be equivalent enough. Results were positive, so systems were retrofit and tested for linearity with illumination and for MTF using test targets (variable Ronchi rulings) and a MTF analysis program. As seen in the graphs above, the new camera met requirements, so no changes were required to the optics. We also enabled field replacement of cameras, thus eliminating expensive depot refurbishments. We concluded the project by documenting the product changes and test results and transferring the file to the client's Manufacturing Department.

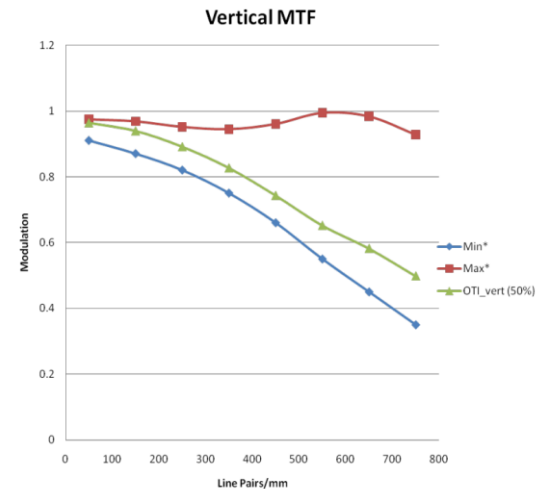
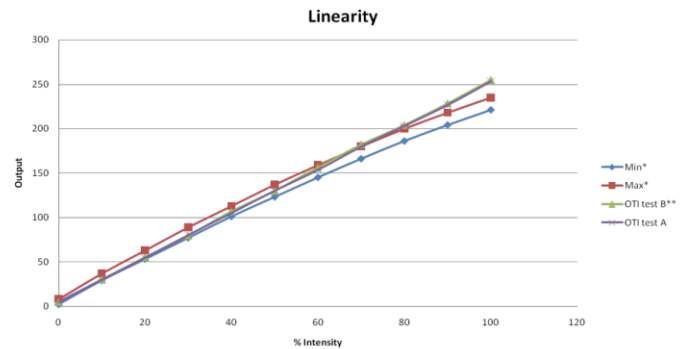
Services Provided by OTI

- Optical analysis
- Supply chain search
- Design verification testing and reporting
- Design documentation and transfer

Client Comment

"We were not optimistic about finding a simple solution to our obsolescence issue, but OTI came through for us. They found a way for us to make a product update with minimal validation and that required only a letter to our regulatory file. This made R&D, Manufacturing, and Regulatory very happy."

- (confidential), Director of R&D



114 PLEASANT ST.
SOUTHBRIDGE, MA 01550
T 508 765 8100
F 508 765 8101
E INFO@OPTIMUM-TECH.COM

WWW.OPTIMUM-TECH.COM

