

User Manual: Software for Assessing Texture Reproduction of Camera-phone-based Medical Devices

Tool Reference

RST Reference Number: RST24ES01.01

Date of Publication: 08/08/2023

Recommended Citation: U.S. Food and Drug Administration. (2023). *Method for Assessing Texture Reproduction of Camera-phone-based Medical Devices* (RST24ES01.01). <https://cdrh-rst.fda.gov/method-assessing-texture-reproduction-camera-phone-based-medical-devices>

For more information

[Catalog of Regulatory Science Tools to Help Assess New Medical Devices](#)

Disclaimer

About the Catalog of Regulatory Science Tools

The enclosed tool is part of the Catalog of Regulatory Science Tools, which provides a peer-reviewed resource for stakeholders to use where standards and qualified Medical Device Development Tools (MDDTs) do not yet exist. These tools do not replace FDA-recognized standards or MDDTs. This catalog collates a variety of regulatory science tools that the FDA's Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Labs (OSEL) developed. These tools use the most innovative science to support medical device development and patient access to safe and effective medical devices. If you are considering using a tool from this catalog in your marketing submissions, note that these tools have not been qualified as [Medical Device Development Tools](#) and the FDA has not evaluated the suitability of these tools within any specific context of use. You may [request feedback or meetings for medical device submissions](#) as part of the Q-Submission Program.

For more information about the Catalog of Regulatory Science Tools, email RST_CDRH@fda.hhs.gov.

Software for Assessing Texture Reproduction of Camera-phone-based Medical Devices

Software running environment:


- The software needs to be run with [MatLab](#).
- The following Matlab toolboxes are required to run the software.
 - MATLAB
 - Image Processing Toolbox
 - Wavelet Toolbox (for two-step denoising, not needed if set 'wav_opt' as '0' for one-step denoising)

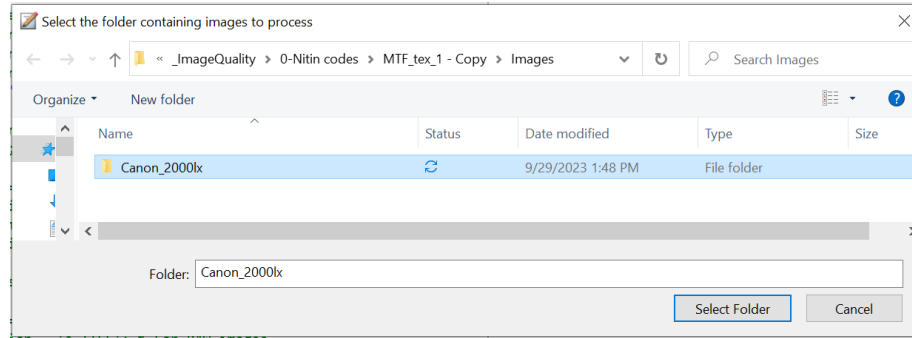
Note: Running “[fList,pList] = matlab.codetools.requiredFilesAndProducts('texMTF_v6_mse_clean.m')” to return a list of the MATLAB® program files (fList) and a list of the MathWorks® products (pList) possibly required to run 'texMTF_v6_mse_clean.m'.

The software consists of the following components:

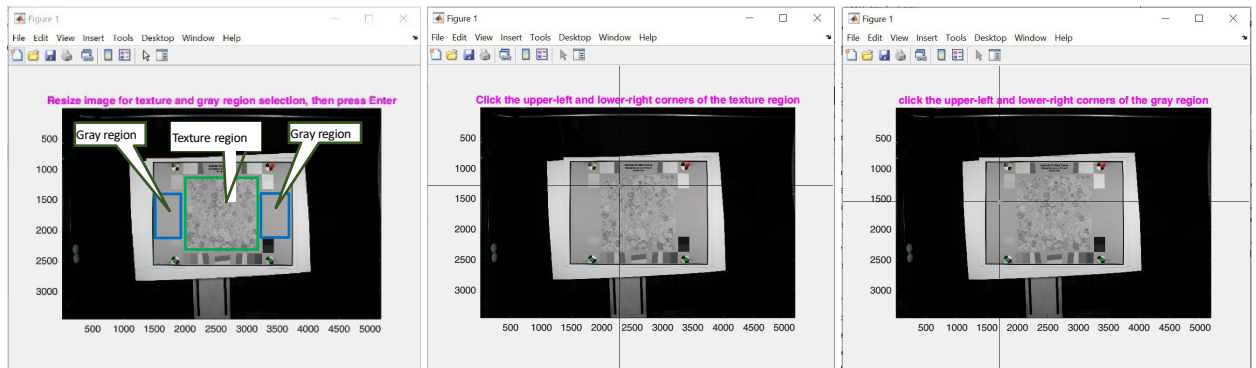
- A main program named “texMTF_v6_mse_clean.m”.
- A folder named “private” containing various subroutines. The main program will call these subroutines during operation. On Mac computers, this folder might not be recognized. If this occurs, you can move the subroutines to the same folder as the main program.
- A folder named “Images”.
 - This folder can contain different sub-folders.
 - Each sub-folder contains continuously captured images of the same target under identical settings. When running the main program, you will be prompted to select a sub-folder for image analysis.
 - We have included a sub-folder named “Canon_2000lx” with three example images for test run of the software.
 - The images in each sub-folder should be in the same format. This software can analyze images in jpg, tif, and png formats.
 - You can create a sub-folder and place your own target images for analysis.
- A folder named “outputs”. MTF results after the image analysis will be saved in this folder in the formats of image (a file named “*.fig”) and matrix (a file named “*.mat”).
- For technical details and mathematical principles, please refer to our paper (<https://doi.org/10.1364/OSAC.2.001863> [1]. For further information, please email RST_CDRH@fda.hhs.gov.

You can follow the following steps to run the software:

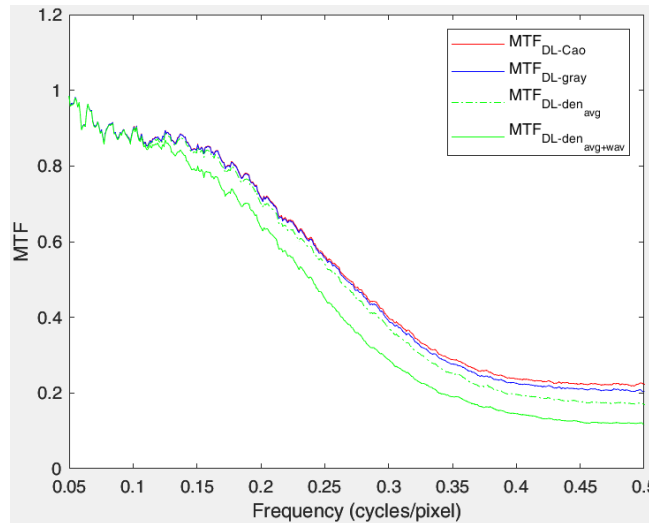
1. Follow the guidelines outlined in our paper [1] to capture target images and place them in a sub-folder within the “Images” directory.
2. Ensure Matlab is installed on your computer.
3. Download the zip file labeled “MTF_tex_1_share.zip” from GitHub and extract its contents.
4. Double click the main program named “texMTF_v6_mse_share.m” to open it in Matlab.
5. Click the “Run”  button within Matlab to initiate the software.
6. A window will appear, displaying the contents of the “Images” folder. Select relevant sub-folder containing the images you wish to analyze, then click the “Select Folder” button.



7. A figure window will open. Follow the prompts within the window to perform the following actions:
 - Resize the image to your preference, then press the Enter key.
 - Click the upper-left and lower-right corners of the texture region.
 - Click the upper-left and lower-right corners of the gray region. If there are multiple gray regions that can be circumscribed with a rectangle, select a relatively large one.



8. The final MTF curves will be presented in a figure as outlined below. The four curves in the figure are generated using different methods as detailed in our paper (<https://doi.org/10.1364/OSAC.2.001863>). Specifically, MTF_{DL-Cao} and $MTF_{DL-gray}$ are derived from the same method as elucidated in Fig. 10 of the paper. On the other hand, $MTF_{DL-den_{avg}}$ and $MTF_{DL-den_{avg+wav}}$ are derived based on the one-step denoised image (I_{avg}) and two-step denoised image ($I_{avg+wav}$), illustrated in Fig.2 of the paper.



Note: If 'wav_opt' was set as '0' for one-step denoising, the $MTF_{DL-den_{avg}+wav}$ will not show up.

9. After each run, the results will be stored in the "outputs" folder in two different formats: an image and a data matrix.
10. Both the image and the data matrix share similar names, differing only in their file extensions (.fig for figure and .mat for data matrix). Both names commence with the identifier of the analyzed images, succeeded by the timestamp indicating when the files were generated, formatted as DD-MM- YYYY_HH-MM-SS.
 - The image file is the preserved MTF image, as demonstrated in Step 8.
 - The data matrix file encompassed the data utilized in generating the MTF image. The matrix comprises four sets of data, with two columns allocated for each set, corresponding to the four MTF curves (MTF_{DL-Cao} , $MTF_{DL-gray}$, $MTF_{DL-den_{avg}}$ and $MTF_{DL-den_{avg}+wav}$) in the MTF figure. Within each set, the first column represents frequency data, while the second column contains MTF data.
 - To modify the figure output, simply double-click the figure file to open it in Matlab.
 - For inspecting the values of the eight columns of data in the data matrix, double-click the data matrix file to open it in Matlab.

Note: If 'wav_opt' was set as '0' for one-step denoising, the fourth set of data for $MTF_{DL-den_{avg}+wav}$ will be absent.

Reference:

- [1] N. Suresh, T. J. Pfefer, J. Su, Y. Chen, and Q. Wang, "Improved texture reproduction assessment of camera-phone-based medical devices with a dead leaves target," *OSA Continuum*, vol. 2, no. 6, pp. 1863-1879, 2019, doi: <https://doi.org/10.1364/OSAC.2.001863>.