National Institute of Standards and Technology
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Standard Reference Material® 2196
Axial Resolution Standard for Optical Medical Imaging

SAMPLE

CERTIFICATE

Purpose: The certified values delivered by this Standard Reference Material (SRM) are intended primarily for the verification of the calibration of 3D optical medical imaging devices to ensure their uniformity and reliability of test results. The phantom SRM is created to replicate structural characteristics of tissue or material for which the imaging device is used. The SRMs are readily deployed to the sites where devices are being used. Therefore, numerous user site devices do not need to be physically relocated for calibration or performance testing.

Description: A unit of SRM 2196 consists of three polydimethylsiloxane (PDMS) layers on a gridded glass slide: a thin clear layer sandwiched between two thicker scattering layers. A white coated fiduciary slide with 5 mm clearance holes is provided along with the SRM to help align the target grids under an imaging device.

Certified Values: The thicknesses of the layers in the SRM are certified values. The thickness of each layer of the SRM was measured by a calibrated spectral domain optical coherence tomography (OCT) device in the NIST Applied Physics Division and corrected by the refractive index of PDMS at the OCT measurement wavelength. The uncertainties of the thickness values were evaluated to assure the accuracy of the measurements, establish certified values, and characterize 9 areas of interest for each SRM specimen. A NIST certified value is a value for which NIST has the highest confidence in its accuracy, in that all known sources of instrumental and measurement uncertainties have been investigated or considered. The measurands are thicknesses of the layers as measured by the NIST's calibrated OCT imager. Traceability is to the International System of Units (SI): the micrometer (layer thickness) and the wavelength of the light used to measure the refractive index of the layered sample [1]. The certified values determined for the SRM 2196 series are given in the Table 1 below.

Period of Validity: The certified values delivered by **SRM 2196** are valid within the measurement uncertainty specified until **01 February 2028**. The certified values are nullified if the material is stored or used improperly, damaged, contaminated, or otherwise modified.

Maintenance of Certified Values: NIST will monitor this SRM over the period of its validity. If substantive technical changes occur that affect the certification, NIST will issue an amended certificate through the NIST SRM website (https://www.nist.gov/srm) and notify registered users. SRM users can register online from a link available on the NIST SRM website or fill out the user registration form that is supplied with the SRM. Registration will facilitate notification. Before making use of any of the values delivered by this material, users should verify they have the most recent version of this documentation, available through the NIST SRM website (https://www.nist.gov/srm).

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Certified Values: Certified values of the layer thickness of the SRM 2196. Listed are the mean values obtained for each layer thickness in Table 1 for each of the 9 Regions of Interest (ROIs) (i.e., the ROI numbers (1, 2, 3, 4, 5, 6, 7, 8, 9) corresponding to each square region (3C, 3D, 3E, 4C, 4D, 4E, 5C, 5D, 5E) in Figure 1 below, respectively). The data analysis method is described in the 'Data Analysis" section of the reference 2. The uncertainty of each thickness value was calculated by the formula described in the "Uncertainty Analysis" section of reference 2.

Table 1. Certified values of the layer thickness of the SRM 2196 SAMPLE.

Sample ROI		Mean thickness(μ) calculated by the code and the final thickness uncertainty (ε)	
		μ (μm)	ε (μm)
1 (3C)	Top	SAMPLE	SAMPLE
	Middle	SAMPLE	SAMPLE
	Bottom	SAMPLE	SAMPLE
2 (3D)	Top	SAMPLE	SAMPLE
	Middle	SAMPLE	SAMPLE
	Bottom	SAMPLE	SAMPLE
3 (3E)	Top	SAMPLE	SAMPLE
	Middle	SAMPLE	SAMPLE
	Bottom	SAMPLE	SAMPLE
4 (4C)	Top	SAMPLE	SAMPLE
	Middle	SAMPLE	SAMPLE
	Bottom	SAMPLE	SAMPLE
5 (4D)	Top	SAMPLE	SAMPLE
	Middle	SAMPLE	SAMPLE
	Bottom	SAMPLE	SAMPLE
6 (4E)	Top	SAMPLE	SAMPLE
	Middle	SAMPLE	SAMPLE
	Bottom	SAMPLE	SAMPLE
7 (5C)	Top	SAMPLE	SAMPLE
	Middle	SAMPLE	SAMPLE
	Bottom	SAMPLE	SAMPLE
8 (5D)	Top	SAMPLE	SAMPLE
	Middle	SAMPLE	SAMPLE
	Bottom	SAMPLE	SAMPLE
9 (5E)	Top	SAMPLE	SAMPLE
	Middle	SAMPLE	SAMPLE
	Bottom	SAMPLE	SAMPLE

Storage: For the best stability, SRM should be stored at 25 °C or below and precautions should be taken to prevent moisture from contacting this material to avoid swelling of the layers. For long-term storage, a container filled with dry air or dry nitrogen is recommended.

Use: To use the SRM, align the white and ground glass sides of both the sample and fiduciary slides with the SRM sample on top of the fiduciary slide. The number 3 hole in the fiduciary slide aligns with the target grids but slightly off center of the regions of interest. After alignment, the fiduciary slide may be removed if desired.

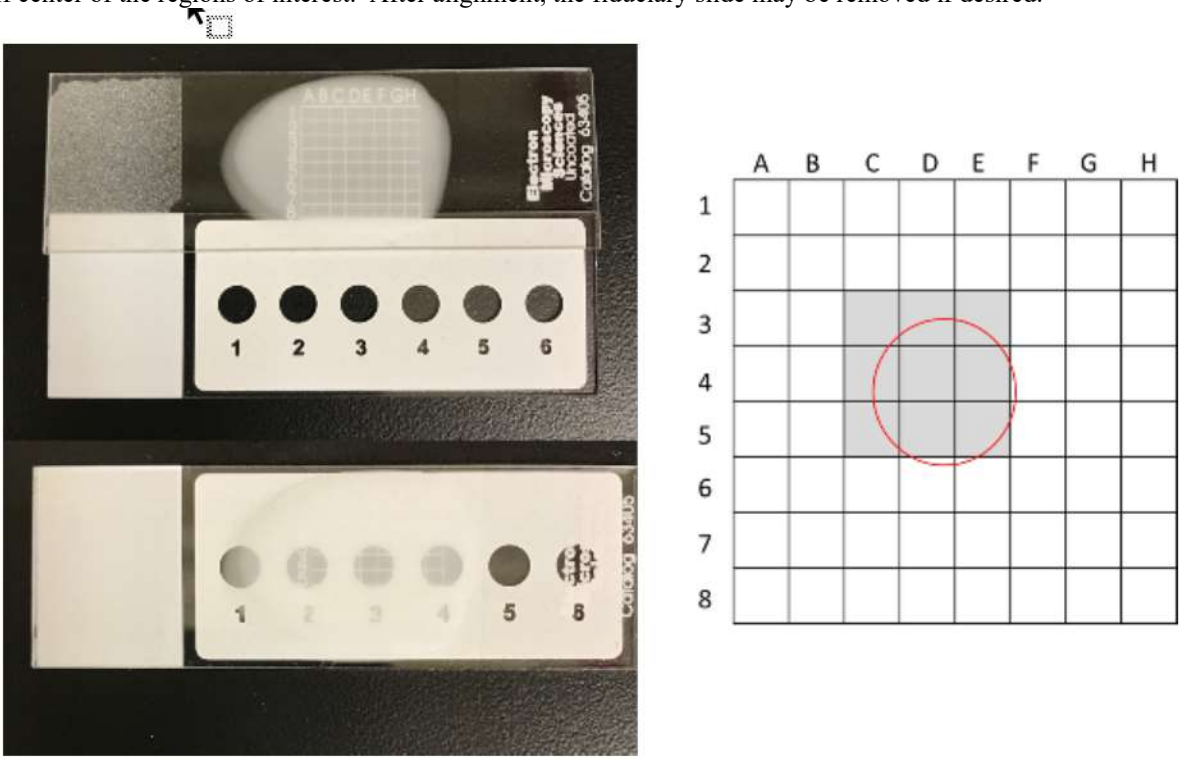

Figure 1. How to use the fiduciary slide to find the ROIs of the target.

The certified thickness value from one or more of the ROIs can be used to check and correct the calibration of the end user's imaging device. Depending on the device, the discrepancy needs to be corrected in the image acquisition and/or data analysis software. For example, in OCT, the data acquisition needs to be set for the correct refractive index value of the PDMS material at the wavelength of the light source. Then the dimension of each axial pixel can be calibrated according to the certified values. In most microscopes, the sample refractive index value is not adjustable during the acquisition, therefore post processing calibration can be implemented, following the procedure described in reference 2. For best practice in calibration, it is strongly encouraged to use the NIST-developed image analysis algorithm provided in reference 2 on the image data obtained from the user's imaging device to mitigate any algorithm-dependent uncertainty variations.

REFERENCES

[1] Beauchamp, C.R.; Camara, J.E.; Carney, J.; Choquette, S.J.; Cole, K.D.; DeRose, P.C.; Duewer, D.L.; Epstein, M.S.; Kline, M.C.; Lippa, K.A.; Lucon, E.; Molloy, J.; Nelson, M.A.; Phinney, K.W.; Polakoski, M.; Possolo, A.; Sander, L.C.; Schiel, J.E.; Sharpless, K.E.; Toman, B.; Winchester, M.R.; Windover, D.; *Metrological Tools for the Reference Materials and Reference Instruments of the NIST Material Measurement Laboratory*; NIST Special Publication (NIST SP) 260-136, 2021 edition; U.S. Government Printing Office: Washington, DC (2021); available at https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.260-136-2021.pdf (accessed Feb 2023).

[2] Hwang, J.; Briggman, Rentz, N.; Kim, H-J.; Allen, D., Richter, L.; Yoon, S.; Lu, J.; *Certification of Standard Reference Materials® 2196 Axial Resolution Standard for Optical Medical Imaging*; NIST Special Publication (NIST SP) 260-228, U.S. Government Printing Office: Washington, DC (2022); available at https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.260-228.pdf (accessed Feb 2023).

If you use this SRM in published work, please reference:

Hwang J, Briggman K, Rentz N, Kim H-J, Allen D, Richter L, Yoon S, Lu, J (2022) Certification of Standard Reference Materials® 2196 Axial Resolution Standard for Optical Medical Imaging. (National Institute of Standards and Technology, Gaithersburg, MD), NIST Special Publication (SP) 260-228. https://doi.org/10.6028/NIST.SP.260-228

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