

Instruction Manual: Dual-Confocal Laser Caliper Method for Refractive Index and Thickness Measurements of Intraocular Lens Implants and Thin Films

Tool Reference

RST Reference Number: RST26OM06.01

Date of Publication: 08/24/2026

Recommended Citation: U.S. Food and Drug Administration. (2026). *Dual-Confocal Laser Caliper Method for Refractive Index and Thickness Measurements of Intraocular Lens Implants and Thin Films*. (RST26OM06.01). <https://cdrh-rst.fda.gov/dual-confocal-laser-caliper-method-refractive-index-and-thickness-measurements-intraocular-lens>

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.

Instruction Manual

The principle DCLC setup (Fig. 1) is based on a dual-confocal laser measurement platform including two independent confocal channels consisting of two identical apertureless fiber-optic confocal microscope designs constructed by use of a single-mode fiber coupler [1-3]. The key single-mode fiber component provides several critical DCLC operational functions including the delivery of the input laser emission into two confocal channels; serving simultaneously as a spatially high-sensitive point source for collimating and confocal sensing; and the delivery of the confocal optical signals to the detecting system. These advanced DCLC features provide a novel regulatory science tool for noncontact, noninvasive, high-precision, and self-calibrating sensing and measuring refractive-index and thickness of transparent (IOL) and non-transparent (thin-films, tissue) samples and materials [4].

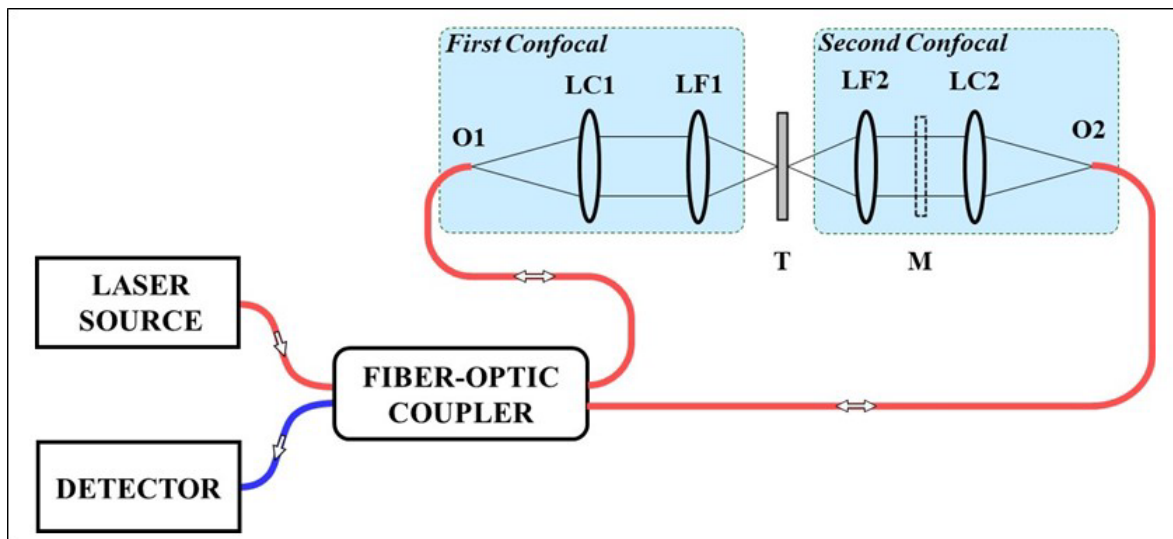


Fig. 1: Principle dual-confocal laser caliper (DCLC) method design: O, fiber-optic confocal output; LC, collimated lens; LF, focusing lens; T, target sample; M, total reflectance mirror [1-3].

The DCLC RST test procedure for noncontact high-precision sensing and measuring refractive-index and thickness of IOL implants and thin films includes the following key steps, which are illustrated in Fig. 2:

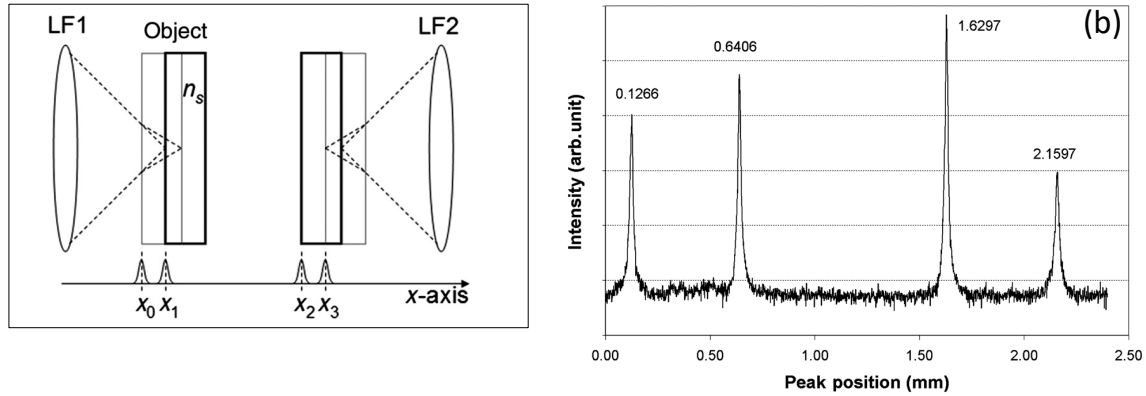


Fig. 2: (a) The dual-confocal laser caliper sensing principle; and (b) typical confocal reflection intensities for thickness and refractive-index measurements of IOL implants [1-3].

- Employ the DCLC test methodology and principal DCLC RST schematic presented in Fig. 1 and described in Ref. [1-3] including specifications of the key RST components to assemble the DCLC tool design.
- Perform precise axial alignment of both first and second confocal microscopes (Fig. 1) [3].
- Using the DCLC sensing principle to measure the axial peak position (x_0 , x_1 , x_2 , and x_3) of the confocal reflection intensities produced by the first and second confocal microscopes from the front and back surfaces of the test sample at the axial sample scanning (Fig. 2). The axial peak positions x_1 and x_2 (2nd and 3rd peaks in Fig. 2b) are related to the reflections from the front surfaces (including from nontransparent samples) and the axial peak positions x_0 and x_3 (1st and 4th peaks in Fig. 2b) are related to the reflections from the back sample surfaces.
- Measure the axial peak positions x_{10} and x_{20} by axial translation of a nontransparent object with a known etalon thickness (e.g., $t_0 = 1 \text{ mm} \pm 0.001 \text{ mm}$) between the two fixed confocal arms.
- Calculate the measured self-calibrating distance D between the two focal points related to the first and second confocal microscopes: $D = t_0 + (x_{20} - x_{10})$
- Measure the axial peak positions, x_1 and x_2 , of an object (transparent or nontransparent) with unknown thickness t_s and calculate the measured distance d between the peak points: $d = (x_2 - x_1)$
- Calculate the unknown sample thickness t_s using the simple expression:

$$t_s = D - d \quad (1)$$

- In case of transparent objects (e.g., IOL samples), measure the axial peak positions x_0 and x_1 , related to the reflections from the back sample surfaces (Fig. 2), and calculate the object refractive index n_s employing the measured axial peak positions, the sample thickness t_s , and the focusing objective NA , using the following expression:

$$n_s = [NA^2 + (1 - NA^2) (t_s/(x_1 - x_0))^2]^{1/2} \quad (2)$$

- In case of testing thickness and refractive index of thin film objects, such as samples of fragile silk fibroin material intended for use in regenerative corneal treatment [4], follow the DCLC measurement procedure described above, which will provide a direct, noninvasive, high-precision and *in-situ* tool for thickness and refractive index testing of these thin film samples.

Publications:

- [1] I. Ilev, D. Kim, R. James, and D. Calogero, "Systems and methods for conducting contact-free thickness and refractive-index measurements of intraocular lenses using a self-calibrating dual confocal microscopy system", **U.S. Patent No. 11,454,794** (September 27, 2022).
<https://image-ppubs.uspto.gov/dirsearch-public/print/downloadPdf/11454794>
- [2] I. Ilev, D. Kim, R. James, and D. Calogero, "Systems and methods for conducting contact-free thickness and refractive-index measurements of intraocular lenses using a self-calibrating dual confocal microscopy system", **U.S. Patent No. 10,712,545** (July 14, 2020).
<https://image-ppubs.uspto.gov/dirsearch-public/print/downloadPdf/10712545>
- [3] D. Kim, R. James, D. Calogero, and I. Ilev, "Noncontact method for sensing thickness and refractive index of intraocular lens implants using a self-calibrating dual-confocal laser caliper", **Journal of Biomedical Optics**, v. 23, pp. 067004, 2018.
<https://doi.org/10.1117/1.JBO.23.6.067004>
- [4] X. Tan, D. Hammer, and I. Ilev, "A novel fiber-optic confocal laser caliper approach for non-contact optical characterization of silk fibroin thin films created by riboflavin photo-crosslinking", **International Conference on Lasers and Electro-Optics (CLEO-2021)**, Paper AF2Q.3, May 9-14, 2021, San Jose, CA.
https://www.nihms.nih.gov/pmc_docs/1956292/