

Important IOLMaster™ Clinical Information!

IOLMaster™ Measurements in Eyes with IOL implants.

Dear IOLMaster™ Customer,

The measurement of pseudophakic patients with ultrasonic biometers is problematic, if not impossible in some cases. Optical Coherence Biometry with the IOLMaster™ has simplified this measurement significantly. Nevertheless, we would like you to be aware of the following important clinical information with respect to IOLMaster™ measurement of eyes with intraocular lens implants.

Axial Length Measurement

As stated in the IOLMaster™ User's Manual, the evaluation of the Axial Length Graph by the operator is required on all patients measured with the IOLMaster™. In the case of Axial Length Measurement of Eyes with intraocular lens implants, **a falsely short axial length value (that will result in an erroneous intraocular implant power calculation) may result if graph analysis by the operator does not occur.**

Please see the following pages for two axial length graphs of the same pseudophakic patient with an intraocular lens implant. On one page you will find the correct axial length graph scenario, and on the other page you will find an erroneous axial length graph scenario. Fortunately, this scenario has only been seen in a few pseudophakic patients with acrylic intraocular lens implants. The error arises when the peak originating from the anterior surface of an intraocular lens is greater than that of the retinal peak, leading to a falsely short displayed axial length. Thus far, the erroneous peak from the intraocular lens has been found to lie typically between 18 and 21 mm. Note also that sometimes the reflection from the retinal pigment epithelium may not be discernible.

For proper axial length determination, the following steps must be carried out. Please note the latest User Manual reference pages and figures in parenthesis.

- Select the appropriate eye type (pre- or post-measurement) under the AL Settings Menu (ie: Phakic, Aphakic, Pseudophakic Acryl, etc).
- Ensure proper patient fixation by having them look directly at the red light fixation light. Note: Measure every patient both without and with their spectacles if their refractive error is greater than ± 4 diopters (for all, including phakic patients). Measuring with the spectacles may improve both patient fixation and signal quality (SNR) by ensuring measurement along the visual axis.
- Take a minimum of 10 axial length measurements per eye on all pseudophakic patients.
- Constantly vary the alignment beam location within the circular cross hairs of the display from measurement to measurement (figure 14 on page 22). This will likely modify the peak presentation and amplitude, due to a change in the angle of incidence to the intraocular lens.

- If varying the alignment beam does not produce a retinal peak with a cursor above it, then manually move the cursor from the intraocular lens peak to the retinal peak. Delete all readings where the retinal peak cannot be distinguished well enough to manually move the cursor to it (pages 42 and 46).
- Analysis of patient data should support your clinical decision. Additional examination findings such as: pre-implant refractive error, pre-implant a-scan data as well as the companion eyes' biometric data should be included in the evaluation. The fellow eye axial length should be within 0.33mm, in most cases.

Anterior Chamber Depth (ACD) Measurement

As stated on page 63 of the User's Manual, the ACD of a pseudophakic eye cannot be reliably measured with the IOLMaster™. As a result, the Haigis formula, which requires a phakic ACD measurement, cannot be used to calculate intraocular lens power for a pseudophakic eye using the ACD measured by the IOLMaster™.

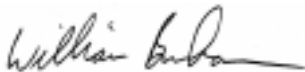
We at Zeiss Humphrey Systems feel that this new clinical information must be shared with you our customer. For additional up-to-date information pertaining to the IOLMaster™ please visit us on the Internet at:

http://www.zeiss.de/iol_master

and/or the Users Group for Laser Interference Biometry (ULIB) at:

<http://www.augenklinik.uni-wuerzburg.de/eulib>

Sincerely,



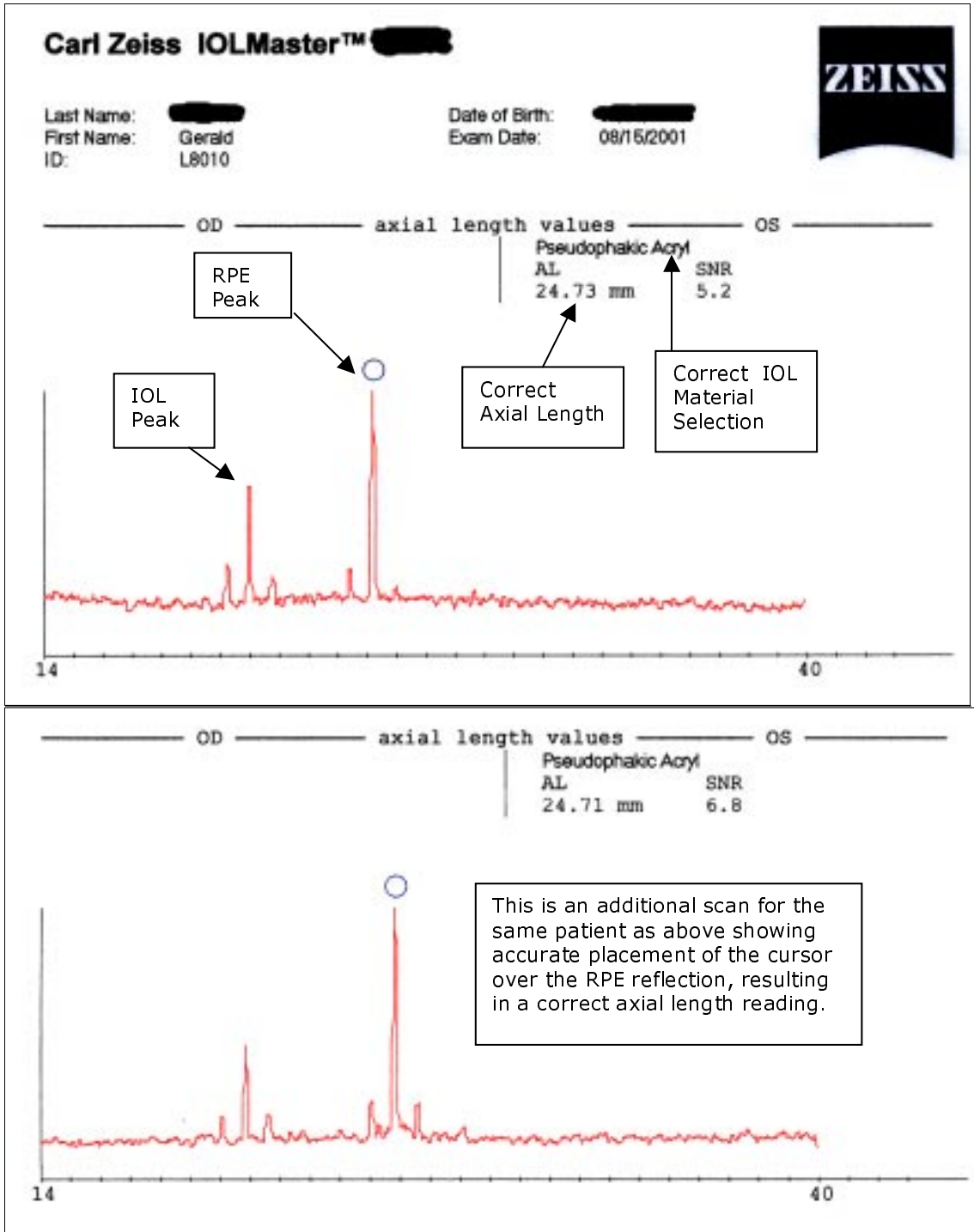
William P. Burnham, O.D.
Marketing Manager
Refractive Products

Note: The IOLMaster™ images on the following pages were kindly provided by the office of Warren E. Hill, MD in Mesa, Arizona.

Correct Axial Length Graph Scenario

Patient L8010: Correct cursor placement by the IOLMaster™ (“circle above the RPE peak”) for axial length measurement of a pseudophakic eye with an acrylic intraocular lens implant.

Cursor location is over the second peak, corresponding to the retinal pigment epithelium reflection for axial length measurements of 24.73 mm and 24.71 mm respectively. Note the rather large peak at approximately 20 mm, which corresponds to a reflection from the secondary maxima of the front surface of the acrylic intraocular lens.



Erroneous Axial Length Graph Scenario

Patient L8010: Erroneous cursor placement at the peak corresponding to a reflection from the secondary maxima of the front surface of the acrylic intraocular lens, resulting in artifactually short axial lengths of 20.14 mm and 20.17 mm. Note that the RPE peak may or may not be visible. The key concept is that this axial length does not match this patient's intraocular lens power and pseudophakic refraction, or the axial length of the fellow eye.

