1978FedTradeCommLetterFromDonWhitneyPg1.jpg

COMPANY CONFIDENTIAL

August 28, 1978

Ms. Faith Dornbrand
Legal Assistant
Federal Trade Commission
Bureau of Consumer Protection
Washington, D. C. 20580

Dear Ms. Dornbrand:

This is in response to your letter of August 7 requesting information on the accuracy to which our Lensometers are manufactured, and the precision to which "skilled" and "average" operators can duplicate readings.

American Optical Corporation currently manufactures and markets two models of its Lensometer. The first (Model 12603) has the conventional scale power readout, whereas the second (Model 12620) has a digital readout for power, and automatically calculates the cylinder from power readings taken in the two principal meridians. Since the optical system and calibration procedures are identical, the accuracy of these instruments is the same as manufactured. The digital power readout does, however, improve operator repeatability since it eliminates the need for the operator to interpolate a power scale.

First let's discuss the accuracy of the instruments as manufactured. In considering this question I thought it might be helpful to show, not only the extreme tolerance limits (3 sigma values), but also the two sigma values which should represent 95% of instruments shipped. This value is arrived at statistically, and is legitimate because calibration errors can be expected to follow a normal distribution pattern, and to be random.

Lensometer Accuracy as Manufactured

Attribute	3 Sigma Limit (99.7% Certainty)	2 Sigma Limit (95% Certainty)
Sphere Power	$\pm$ .05 diopters	$\pm$ .03 diopters
Cylinder Power	$\pm$ .07 diopters	$\pm$ .04 diopters
Cylinder Axis	$\pm \frac{1}{2}$ degree	$\pm$ 1/3 degree
Prism Power	$\pm$ .03 prism diopters (△)	$\pm$ .02 prism diopters (△)
Prism Axis	$\pm$ 1°	$\pm$ 2/3°

As discussed on the phone, the Lensometer doesn't measure cylinder power directly. Rather, it is necessary for the operator to make two separate power readings - one in the sphere meridian and the other in the cylinder meridian. Cylinder power is then arrived at by algebraic subtraction. Though the subtraction is done automatically on our digital readout instrument (Model 12620), the accuracy remains the same as with the instrument having conventional scale readout.

Now let's direct our attention to operator precision - the ability of an operator to duplicate readings. As you requested, I am including information for a skilled laboratory technician as well as for a somewhat less skilled "average" operator. Also, since a digital readout improves operator repeatability on sphere and cylinder meridian power readings, the two instruments are listed separately.

Operator Repeatability

	Conventional Readout (Model 12603)		Digital Readout (Model 12620)	
	Skilled Technician	"Average" Operator	Skilled Technician	"Average" Operator
Sphere Power	.03 diop.	.06 diop.	.03 diop.	.05 diop.
Cylinder Power	.04 "	.08 "	.04 "	.07 "
Cylinder Axis:				
< 1.00 cylinder	2^o	3^o	2^o	3^o
≥ 1.00 cylinder	1^o	2^o	1^o	2^o
Prism Power *	.06 $\triangle$	.12 $\triangle$	.06 $\triangle$	.12 $\triangle$
Prism Axis *	1^o	2^o	1^o	2^o

* The precision of prism power and prism axis readings is affected by the magnitude and relative orientation of cylinder (cylinder power and cylinder axis). When prism is present in a prescription also incorporating large cylinder power at an axis oblique to that of the prism, the precision to which prism power and axis can be duplicated may be somewhat less than indicated by the above table.

In looking at the above data, I should point out that the highly skilled technician has, at his disposal, techniques for significantly improving his precision. For example, by averaging a series of 10 readings, the sphere power repeatability can be improved from .03 diopters to .01 diopter. Such a technique is used when extreme precision is desired, but it would not be practical in a more normal application.

The figures on Lensometer Accuracy are taken or derived from formal specification sheets. The information on operator precision is based on limited in-house studies, combined with the application of known fundamental optical principles, and more than 30 years of personal experience. Recognizing your desire for reference material on this subject, I have asked a member of my staff to conduct a literature search. This is currently underway, and should be complete within the next two or three weeks.

1978FedTradeCommLetterFromDonWhitneyPg3.jpg

In your letter of August 7, you ask for any additional information which I feel might be of help to your study. Along these lines, I think it is important to recognize what is common practice among the professions in writing a prescription. First, it is significant that the smallest commonly employed interval for sphere and cylinder powers is 0.25 diopters. Only rarely do we encounter a prescription where the interval is 0.12 diopters. As for cylinder axis, the tendency appears to be to round to the closest 5°, and it is interesting to note that a great many prescriptions (about 40%) call for either 90° or 180°.

The majority of prescriptions does not call for prism, and our information on the commonly encountered interval is somewhat more sketchy. In terms of prism power, it is certainly no less than 0.25 prism diopters. As for prism axis, this is usually prescribed as either 90° or 180° (base in, base up, base down, or base out). Except in cases where compound prism is resolved mathematically, the interval would be no smaller than 5°.

Finally, I would like to repeat what I told you during our last telephone call relative to prescription duplication. When a patient goes to a dispenser and asks for a new pair of eyeglasses like the ones he is wearing, the optician will perform all the necessary measurements on a focimeter. After the prescription has been fabricated, and before dispensing it to the patient, the optician will check the new eyeglasses on a focimeter to assure conformance to prescription. In the vast majority of cases the same focimeter will be used; thus, any calibration errors inherent in that specific focimeter will automatically cancel out. What is really at issue, then, is operator precision which I have discussed in terms of the ability of an operator to duplicate readings. Lensometer calibration, per se, is almost irrelevant in this application.

I must point out that we consider the material contained in the two tables (Lensometer Accuracy as Manufactured, and Operator Repeatability) to be confidential within the meaning of Section 4.10 of the Federal Trade Commission's Rules of Practices. This material is submitted pursuant to the protection afforded by these Rules. Nevertheless, I hope the above information is helpful to you. I will be forwarding along the results of our literature survey as soon as it becomes available. Please let me know if I can be of further assistance.

Sincerely,

Donald B. Whitney
Director, Product Support Services
Research and Development

DBW/ys

bcc - W Huber - RR Dion - OG Everbach - HL Burnett - JT Gardner - B. Grolman - RE Bannon - HA Downing - N. DePratti - FN Winters, Jr. - GT Croft - JG Kringel - JT Winthrop - AP Seprinski - R. Tackaberry, SID

DA LAMARRE 11/1/78

1978FedTradeCommLetterFromDonWhitneyPg6.jpg

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

BUREAU OF
CONSUMER PROTECTION

August 7, 1978

Mr. Don B. Whitney
Director, Product Support Services
Research and Development
American Optical Corp.
Southbridge, Mass. 01550

Dear Mr. Whitney:

As I explained to you last week, the FTC is exploring issues involved in the duplication of eyeglass lenses. We are trying to determine how accurately ophthalmic practitioners can duplicate lenses without a prescription. One factor affecting the accuracy of duplication is the degree of precision which can be achieved with a focimeter. Pursuant to our phone conversations last week, would you please send me the following information about each of the focimeters manufactured by American Optical Corporation.

First, please indicate the overall margin of error for each machine. Please break this figure down to indicate the tolerance in the component measurements: axis, prism magnitude, sphere power, prism direction, and cylinder power.

Second, please indicate if American Optical has data from studies conducted to test the accuracy of its focimeters. Have tests been run to show the machines' tolerance level when operated by average operators as well as precision operators? Please indicate the form of this data. Are all these reports public information?

Third, as we discussed, please include any additional information which you think will help us assess the accuracy of your focimeter.

Thank you for your assistance. Please call if you have any questions.

Yours truly,

Faith Dornbrand

Faith Dornbrand
Legal Assistant