	Title:	Vision – Retinal Camera		
	Version Date:	2017-FEB-16	Document Number:	SOP_DCS_0027
	Effective Date:	2017-MAY-15		
Data Collection Site (DCS)	Version:	3.1	Number of Pages:	6

1.0 Purpose:

The purpose of this document is to describe the standardized procedure for vision assessment with the TOPCON TRC-nw8 Retinal Camera.

2.0 Scope:

This document is to be used by the DCS staff while conducting the vision assessment with the TOPCON TRC-nw8 Retinal Camera with a study participant.

3.0 Responsibilities:

It is the responsibility of the DCS staff to perform the procedures as described in the current and approved version of the standard operating procedure.

4.0 Related Documents:

- SOP_DCS_0046 - **Vision – Topcon Retinal Camera SOP – Maintenance**

5.0 Definitions:

Not applicable

6.0 Equipment:

- TOPCON TRC-nw8 Retinal Camera.

7.0 Supplies:

Not applicable

8.0 Procedure Steps:

Contraindications:

- Detached retina or eye surgery within last 3 months (Contraindications Questionnaire); or
- An eye infection in both eyes (Contraindications Questionnaire).

The on-site technician can only comment on the quality of the picture and cannot make a diagnosis of “normal, marginal or abnormal”.

The room needs to be as dark as possible.

For difficult participants, turn off the computer monitor in the room. Other things that will help facilitate the vision assessment include rapid blinking before starting the test, dropping the brightness level of the test room (usually set at 3), leave in darkness for 5 minutes.

Ask participant with droopy eyelids to lift their eye brows during the test.

*****Be sure the participant removes their glasses or contact lenses (in a sterile solution) for this test. Onyx will tell you if the participant is wearing contacts or glasses.*****

The retinal images will be taken in two separate stages, starting with the right eye. Between the two images, the General Health Stage questionnaire will be run.

Right Eye Measurement

Step 1: At the *Interview Tab* in Onyx, look for the “Retinal Camera – Right Eye” measurement in the list of stages. Then select **Start** in that row.

Step 2: The “Retinal Camera: Start” window will pop up.

Step 3: **Scan** the Interview ID barcode and click on **Continue**.

Step 4: To start the Retinal Camera software click the **Start** button in Onyx.

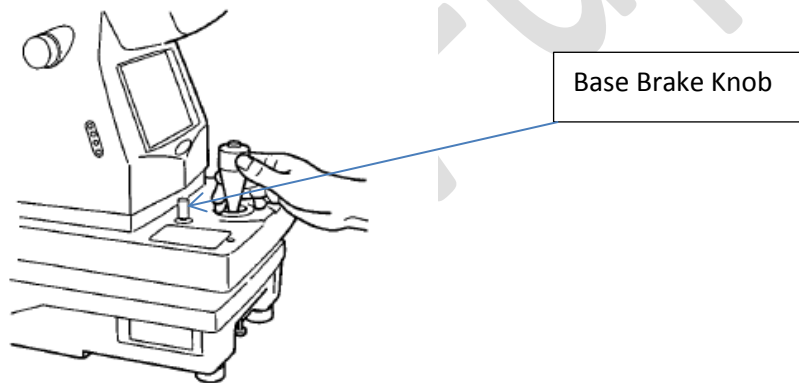
Step 5: At the Log on pop up window to the IMAGEnet_R4, choose **OK**.

Step 6: Enter the **Participant ID** into the ID Code on the IMAGEnet R4 software and click **Open**.

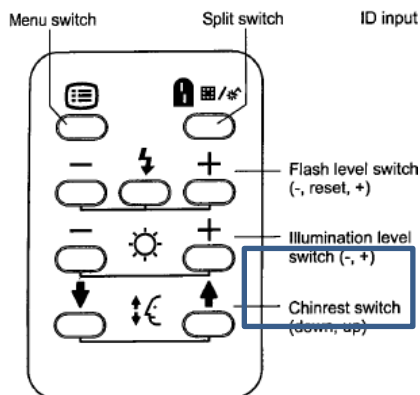
Step 7: The participant’s name will show up and then on the far right side of the software

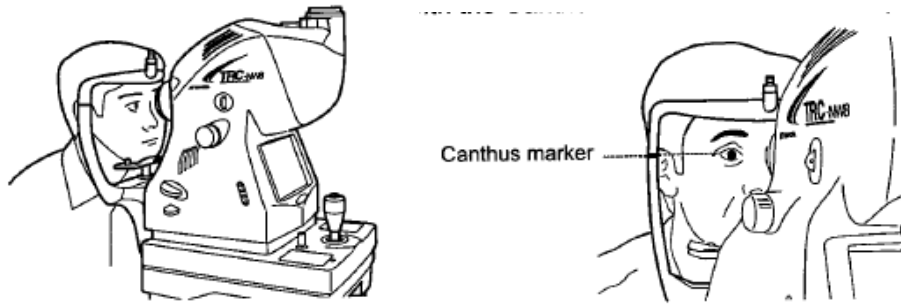
click on the **NW8 icon**  .

Step 8: **Remove** the lens cap and **unlock the table** by turning the grey knob to the left of the control stick.



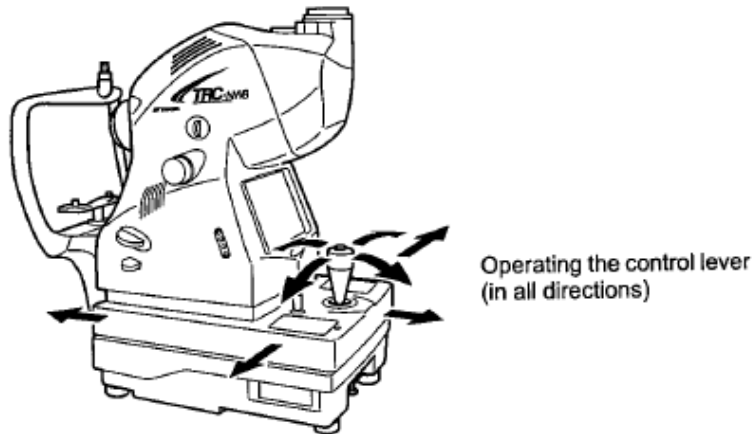
Step 9: Ask the participant to support his/her chin on the chin rest. Adjust the height of the chin rest by moving it up and down with the chinrest switch until the marked line (Canthus marker) on the chin rest post lines up with the participant’s eyes.



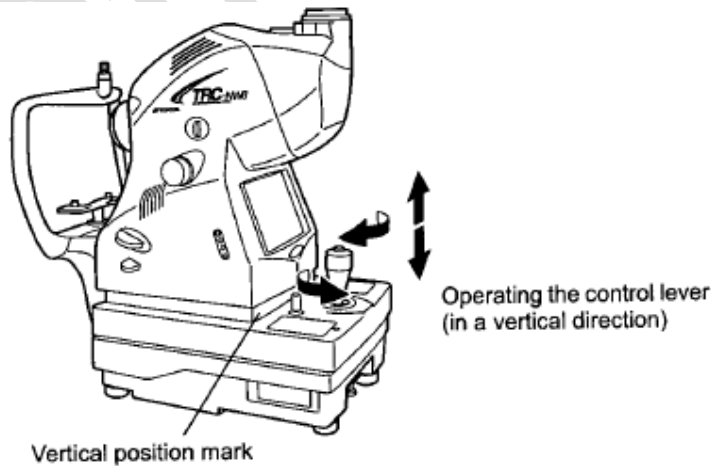


Step 10: Ask the participant to focus on the green light. Inform the participant that nothing will touch their eyes and they will see a flash of light while taking the picture.

Fine movements of the base, back and forth and right and left, are done by tilting the control lever. Before performing this operation, free the base by turning the base brake knob to the left.

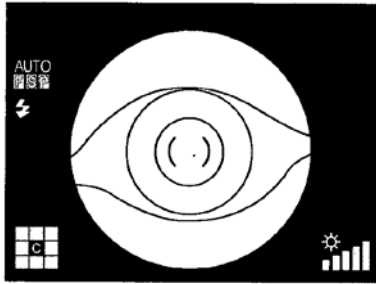


To move the instrument body up/down, turn the control lever right for upward movement, and left for downward movement.



Step 11: To position the table, hold the control lever and pull the instrument backward toward the operator. As the internal fixation target flickers, instruct the participant to look at the green light. Observe the anterior image on the LCD monitor. Move the instrument body using the control lever until the participant's eye is centered in the

LCD monitor. Hold the control lever perpendicularly, which facilitates centering on the eye.

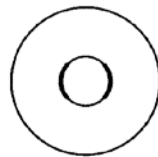


Step 12: On the LCD monitor, bring the (.) scale toward the participant's pupil, and make sure that the pupil is larger than the (.) scale. If the participant has small pupils, dim the lights in the room. Suggestion: ask the participant to cover the other eye using the lens cap without closing the eye.

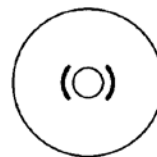
The following pictures are provided as a reference.



Well dilated.

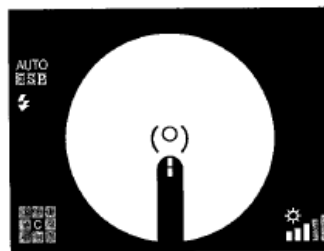
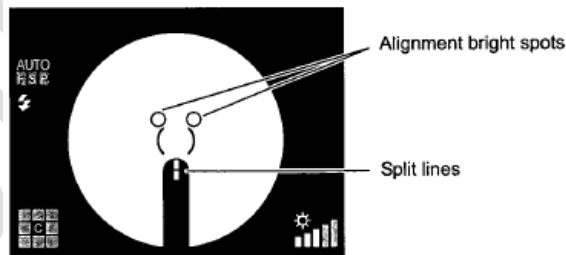


Narrowly dilated for photography.



Pupil diameter is too small: darken the room and further dilate the pupil. If the pupil diameter is still smaller than the (.) scale, use the small pupil mode (P.51).

Step 13: Once the pupil is centered in the camera's objective, slowly bring the instrument closer to the participant; the retina image will appear on the monitor. **Instruct the participant to look at the green light.** Bring the instrument even closer to the participant; and two bright spots become visible.



- You need to use the control stick to overlap the light dots into the same position and move the table to move the lighted dot into the camera objective. Turn the control stick slightly to make minor adjustments.

- The camera will auto focus and auto shoot. If the participant blinks more than usual or if the camera does not auto focus and shoot, use the button control stick to take the picture.
- If a participant refuses to do both eyes, go to **Step 15** and save the collected image.

Ideal Image: No white edges, clear bright image not cloudy.

- Participants that have fair complexions, as well as, younger participants will have brighter red images.
- Participants with darker complexion will have darker images, as will participants as they age.
- Black spots indicate dust on the inside of the machine. White spots indicate dust on the outside of the machine.

Step 14: When finished capturing the image click on the **Save Images** icon (disk) at the top left corner of the software.

Step 15: If the software doesn't automatically exit for you, click the **X** at the top right.

Step 16: In Onyx, click on **Refresh** to view the image information collected. If you had to skip the measurement, click on **Skip remaining measurements** and provide a reason in the comment field (e.g., flash too uncomfortable).

Step 17: Click **Next**. The conclusion screen will appear and indicate that you have completed the measurement.

Step 18: Click **Finish**. The "Retinal Camera" window will pop up.

Step 19: Indicate in the Onyx **comment** field if anything affected or influenced the measurement. Ensure that comments do not contain any personally identifying information.

Step 20: Click **Continue** to return to the status page.

You will then complete the General Health Question Stage.

Left Eye Measurement

Step 1: At the *Interview Tab* in Onyx, look for the "Retinal Camera – Left Eye" measurement in the list of stages. Then select **Start** in that row.

Step 2: Repeat Steps 2-20 for the left eye.

9.0 Documentation and Forms:

Not applicable

10.0 References:

- <http://webvision.med.utah.edu/book/part-viii-gabac-receptors/visual-acuity/>

F1 Revision History:

New Version #	Revision Date	Revision Author	Content Approval
3.1	2017-FEB-16	Lorraine Moss	Mark Oremus
Summary of Revisions			
Updated formatting			
New Version #	Revision Date	Revision Author	Content Approval
3.0	2015-JUN-15	Lorraine Moss	Mark Oremus
Summary of Revisions			
Note added: The retinal images will be taken in two separate stages, starting with the right eye. Between the two images, the General Health Stage questionnaire will be run.			
SOP steps were adjusted to reflect the change in process.			

FOLLOW-UP