

Procedures for ETDRS 4M Refraction and Vision Testing

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Specializing in
ophthalmic clinical
research training

C 1

E R 2

T I F 3

E Y E D 4

A S S O C 5

I A T E S, L L C 6

K A T H E R I N E 7

B U R K E, B. S., C O, C O M T 8

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- Hello and thank you for joining this important meeting
- Consistency across all sites in all countries is of the utmost importance
- Standardization of procedures will be discussed

VAE Examiners

- Experienced and **certified** personnel, ONLY, may perform refractions and visual acuity testing for these clinical trials
- There should be at least two VAEs per site who consistently perform the testing
- Four maximum (there may be some exceptions)

VAE Survey

- All VAEs must have a survey on file
- One survey for EACH VAE
- VAE FULL name, Investigator name, site name, **site number**, city, state OR country
- Please leave the right side blank
- Done as a WORD DOCUMENT
- E mail to CertifEYED
- Print, sign, initials
- Keep signed copy at the site
- *No hand written, scanned or faxed forms will be accepted*

**Please type in the gray boxes, attach this form as a word document and e mail to:
Then print it, sign, and keep the copy at your site
Hand written forms will not be accepted. Please use one form for each VAE**

<p>Investigator:</p> <p>Site Name: Site #:</p> <p>City: State/Country:</p> <p>VAE Name:</p> <p>Degrees and Certifications:</p> <p>How many years experience in ophthalmology:</p> <p>Signature: _____ Initials: _____ (signed copy to be kept at the site)</p>	<p>For</p> <p>Survey received:</p> <p> / Blank / 2007</p> <p>Received by:</p> <p>Blank</p>
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Previous Ophthalmic Clinical Trial Participation, if any (list all and VAE certification number if available)

The survey will be customized for your study

Site Visits

- Sites will be visited as determined by the sponsor
- VAE survey helps us determine the need
- “Team” of VAE certifiers available
- Sites may request a visit for training and/or certification
- **Call your *monitor, sponsor or CertifEYED* with questions or issues concerning VAEs**

VAE number

- Site specific
- e.g.: 025-V1
- **The first person certified at site 25**
- Each VA worksheet must be signed at the bottom and the VAE # noted
- No number is re-issued
- The VA worksheet is a source document

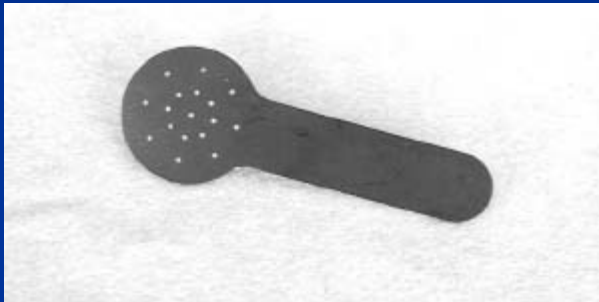
MASKING

- *When possible, VAEs* should be masked
- Only previous refraction should be supplied
- You may **NOT** have access to patient chart before refraction begins

Equipment

- Retro-illuminated Box ETDRS
- Charts, 1, 2, and “R” (3)
- Trial lens set with cylinders
- Trial frame
- Pinhole occluder
- Tissues/eye pads and paper tape
- **1 meter rigid** measuring stick
- Lensometer

Proper Equipment for Refraction and Vision Testing



Pinhole Occluder

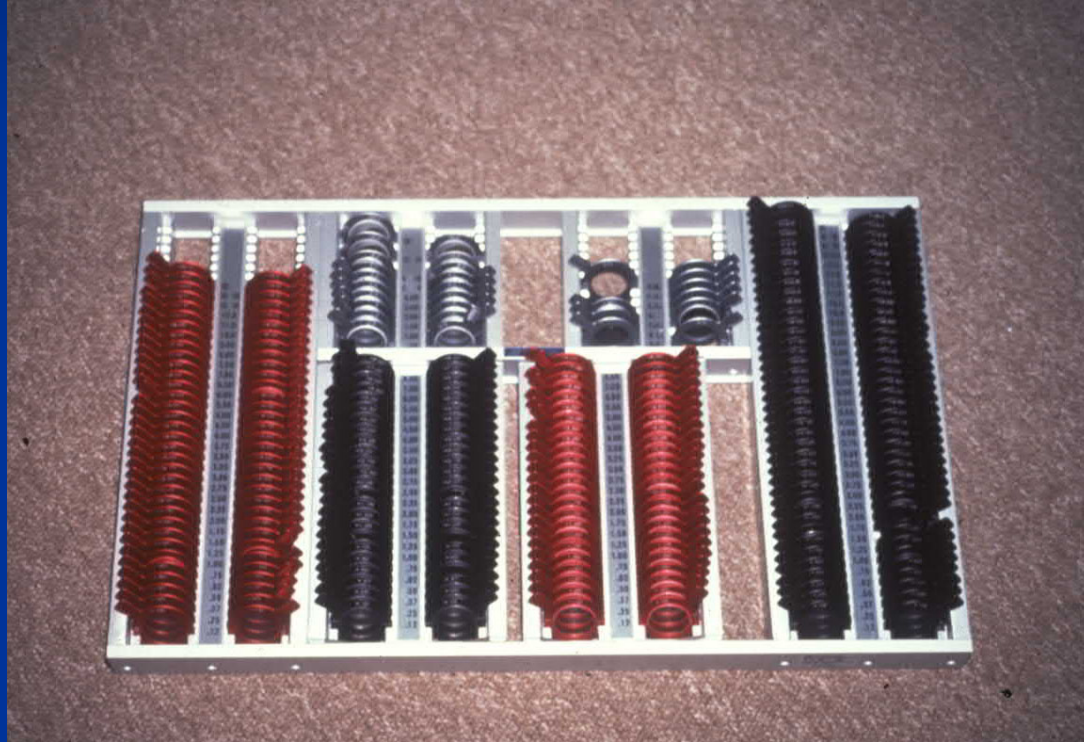
Many varieties, one or multiple pin holes, are OK

Proper Equipment for Refraction and Vision Testing

Lensometer, to measure current glasses, automatic or manual



Trial Lens Set



Plastic, metal or wire rim OK, should be complete, in good order, not scratched

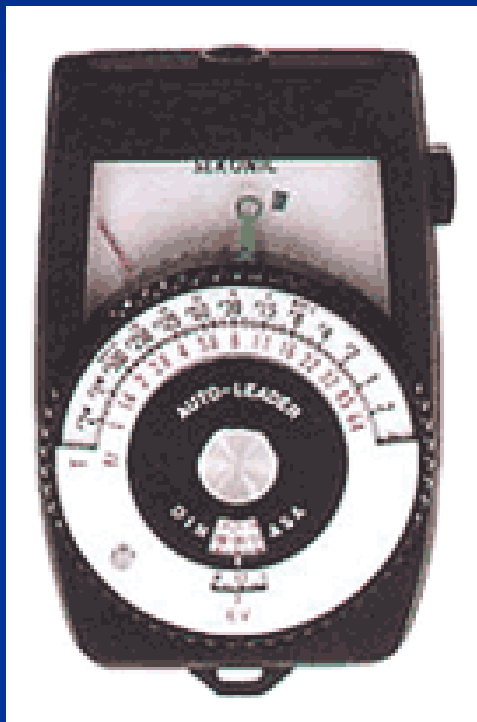
Proper Equipment for Refraction and Vision Testing



Trial Frames

Be sure they are in good condition, not broken, loose or with screws missing

Proper Equipment for Refraction and Vision Testing



Lighting conditions

Must be a dimly lit room, ≤ 15 foot candles (161.4 Lux) can fall on the chart when the box is **OFF**.

Small reading lamp OK

No light should shine on the patient's face or the light box

You do not need to purchase a light meter, sponsor will check

VA Exam Room

- Must be dimly lit (<15 ft. candles)
- Must be a 4M unobstructed lane
- Quiet dedicated room
- There should not be other exams going on simultaneously

Box and Bulbs

- Bulbs must be changed yearly
- Must be burned in for 96 hours before use
- Must have spare burned in bulbs on hand
- A sticker should be placed on the back of the box with date bulbs were installed

Concentration
to Center
of Gaze

U.S. GOVERNMENT PRINTING OFFICE: 1963 O - 350-000

OD
Right
Eye

40 30

N C K Z O

30 18

R H S D K

20 12

D O V H R

15 9

C Z R H S

10 6

O N H R C

8 4

==== D K S N V ====

6 3

Z S O K N

4 2

C K D N R

3 1.5

S R Z K D

2 1

H Z O V C

15 100

K R O O K

H A O V O

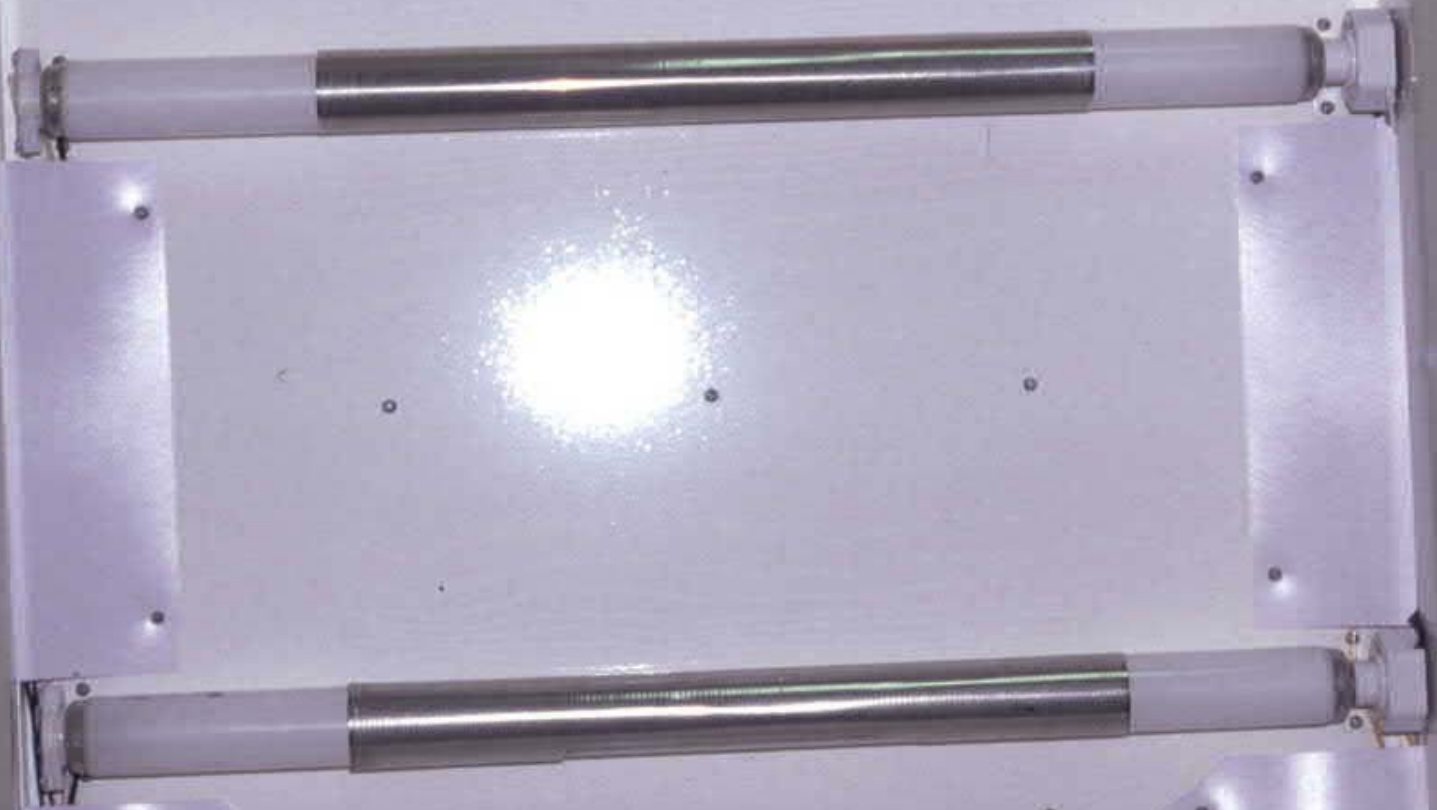
S L A O D

Concentration to Center of Gaze
Instructions: Read the letters in the lines from top to bottom. The letters in each line are arranged in a pattern that is difficult to read. The letters are arranged in a pattern that is difficult to read. The letters are arranged in a pattern that is difficult to read.



U.S. GOVERNMENT PRINTING OFFICE: 1963 O - 350-000

MUST have baffles (sleeves) in place



The baffles provide even illumination over the testing chamber

Equipment Check List

- Will be filled in by your monitor or when visited for “on site” certification
- All equipment must be in place and in good order

Equipment Check List (1)

review

- 1. ETDRS charts 1, 2 and R (or 3): Present and in **good condition**. Cracked and dirty charts should be replaced.
- 2. Retro illuminated **box**: wall mounted or stand
- 3. Light box correct **height** (the third row of letters should be between 47 and 51 inches from the floor)
- 4. VA lane should be sufficiently long and **unobstructed** with a **closing door** for 4 M testing
- 5. Exam room **dimly lit**, no windows without shades, etc

Equipment Check List (2)

review

- 6. Light bulb “baffles” placed on fluorescent tubes, date bulbs changed, documented with sticker on box
- 7. **Spare** set of “burned in” bulbs (location of spares noted)
- 8. **Trial frame**, available and in good condition, complete set of **loose lenses** including plus or minus cylinders, **hand held cross cylinders** in .25, .50, and 1.00

Equipment Check List (3)

review

- 9. 1M rigid measuring stick, clear permanent floor markings for 4M testing
- 10. Tissue or eye pads and Tape for **occluding** the eye not being tested
- 11. Pin hole occluder
- 12. Lensometer

Beginning Approximate Refraction

(refer to VA protocol summary card)

- $VA \geq 20/100$, no glasses, begin with plano
- $VA \geq 20/100$, glasses, measure, start there
- $VA \leq 20/100$ cc or sc, retinoscopy or autorefractometer
- Contact lens wearers:
 - Refract over CL, or
 - Remove (preferred), wait 30 minutes and proceed

Subjective Refraction

- Using **Chart R** measure VA
- Patient will be refracted at 1 or 4 M depending on level of VA
- Clear and permanent floor markings @ **4M**
- For **1M** refraction or testing, measure with a **rigid measuring stick** for each eye from the outer canthus to the 2nd letter (OS) or the 4th letter (OD) of the third line, for **EACH EYE**

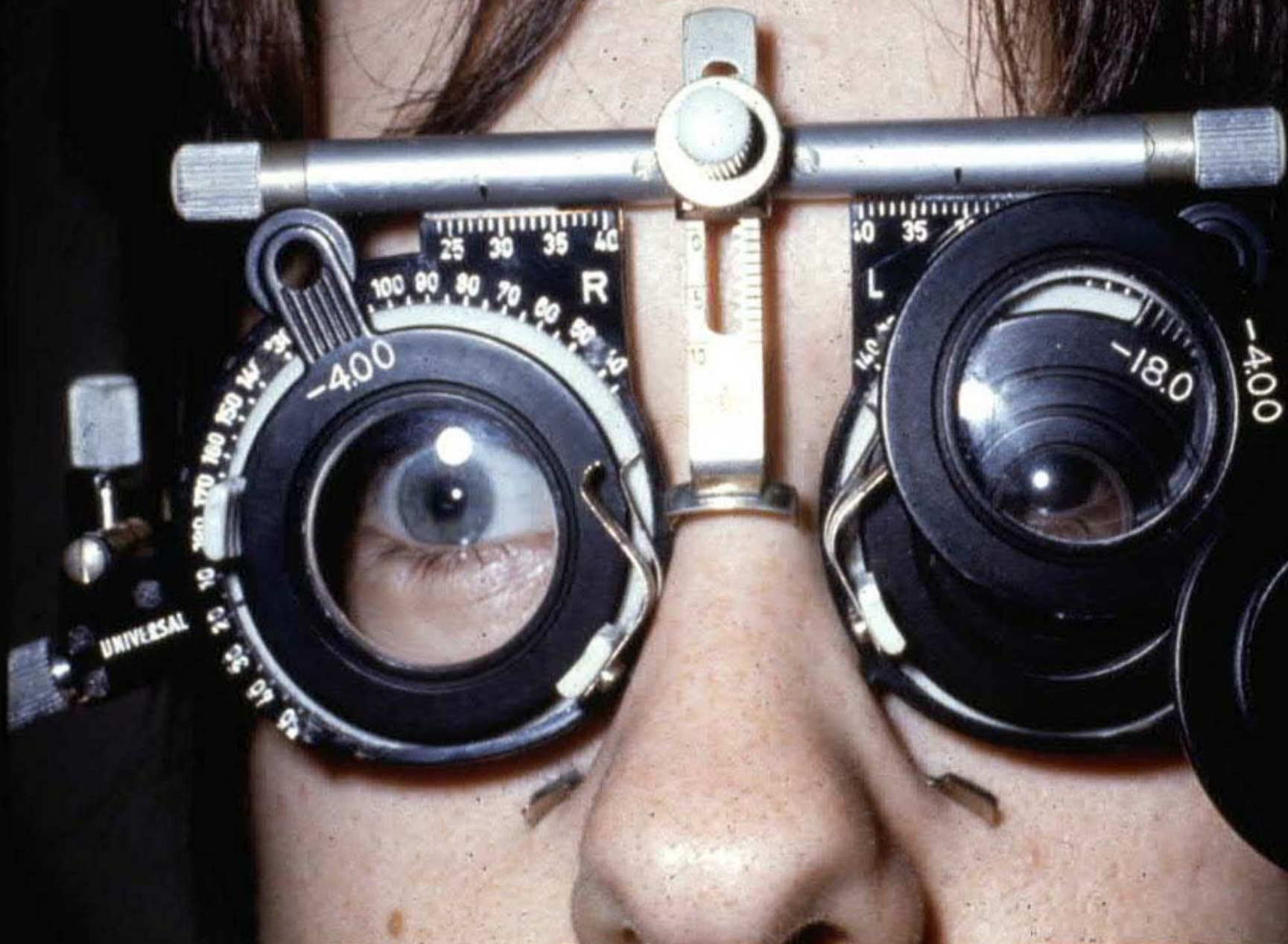
Measuring for left eye (1M)



Subjective Refraction

- Adjust trial frame so patient is comfortable
- Place spheres in the back cell
- Place cylinders in front, adjust axis
- Occlude fellow eye with pad and tape
- *Be sure the trial frame is comfortable*

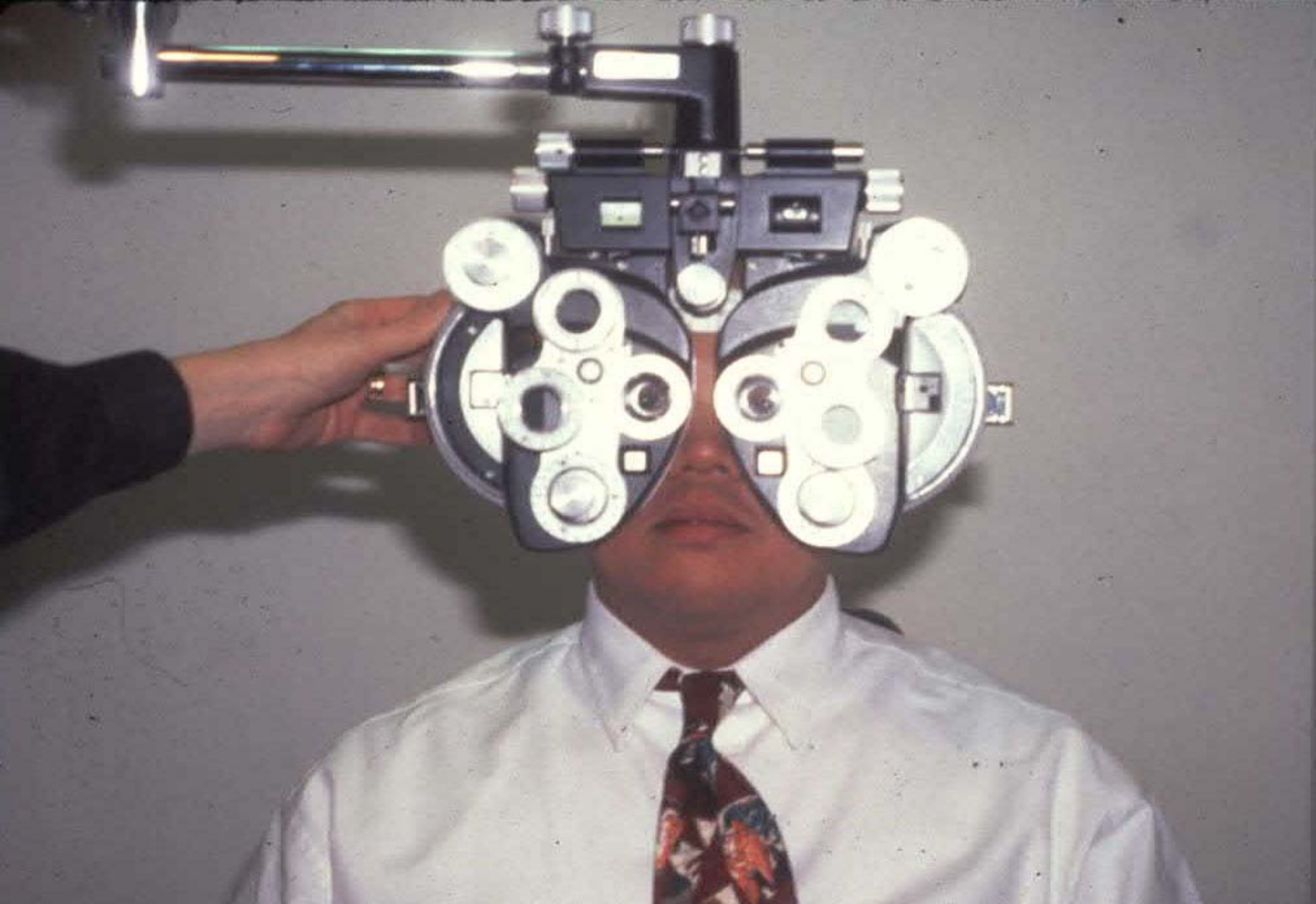
Pupil centered in lens



Encourage head turning for eccentric fixation

Eye patched lightly with tape, no peeking





Phoropter may NOT be used

Please Refer to Refraction Protocol Summary

(laminated card)

Refraction Protocol Summary

Refraction Distance	Check Sphere First Check Cx. Axis then Cx. Power					Sphere “Refinement”	
If VA on “R” chart is between:	Power (a)	Increment	Axis (b)	Power (c)	Increment	Power (d)	Increment
20/10 - 20/80 (4 meters)	+.50 -.50	+.50 -.50	.25 JCC	.25 JCC	+.25 -.25	+.25 -.25	+.25 -.25
20/100 - 20/160 (4 meters)	+1.00 -1.00	+1.00 -1.00	.50 JCC	.50 JCC	+.50 -.50	+.50 -.50	+.50 -.50
20/200 - 20/400 (1 meter)	+2.00 -2.00	+2.00 -2.00	1.00 JCC	1.00 JCC	+1.00 -1.00	+1.00 -1.00	+1.00 -1.00
<20/400 (1.0 meters)	+2.00 -2.00	+2.00 -2.00	No cylinder test required			No refinement required	

Refraction, VA 20/10-20/80

Refract at 4M

- Spherical “challenge lens”:
 - Power: $+0.50/-0.50$
 - Increment: $+0.50/-0.50$
- Cylinder: $.25$
- Spherical “refinement lens”:
 - Power: $+0.25/-0.25$
 - Increment: $+0.25/-0.25$

Refraction, VA 20/100-20/160

Refract at 4M

- Spherical “challenge lens”:
 - Power: +1.00/-1.00
 - Increment: +1.00/-1.00
- Cylinder: .50
- Spherical “refinement lens”:
 - Power: +.50/-.50
 - Increment: +.50/-.50

Refraction, VA 20/200-20/400

Refract at 1M

- Spherical “challenge lens”:

- Power: +2.00/-2.00
- Increment: +2.00/-2.00

- Cylinder: 1.00

- Spherical “refinement lens”:

- Power: +1.00/-1.00
- Increment: +1.00/-1.00

Refraction, VA <20/400

Refract at 1M

- **Spherical “challenge lens”:**
 - Power: +2.00/-2.00
 - Increment: +2.00/-2.00
- **Cylinder:** No cylinder test required
- **Spherical “refinement lens”:** No refinement required
 - Move patient to 4M if VA improves during refraction

Refraction, plus lens

- Start with $+0.50$ ($+1.00$, $+2.00$) sphere
- “Better, worse, or no change”
- If better or no change, **ADD PLUS**
- Continue to add plus, until worse

Refraction, minus lens

- $-.50$ (-1.00 , -2.00), “better, worse, or no change”
- If worse, go back to plus, confirm worse
- If better, must read at least one more letter to add minus
- Continue with minus until no improvement
- End by checking plus again

Cylinder Axis

- Refine cylinder axis
- Look at a round letter 2 lines *larger* than lowest line read
- Explain that the CC makes it “blurry”
- Which is better, #1 or #2

If there is no cx in beginning approximate refraction

(do the following)

- Place a +0.50 cylinder at 90, 180, 45, 135
- Compare better with, or without
- If they like it at any of these positions, place the cx in the trial frame and proceed with axis and power refinement with the proper JCC for the vision level (.25, or .50)
- *See “option 1 and option 2” in the protocol*

Suggested Axis Steps for CX Refinement

- $<1.00D$ 15 degrees
- $1.00-<2.00D$ 10
- $2.00-<3.00D$ 5
- $3.00-<5.00D$ 3
- $5.00-<8.00D$ 2

Cylinder Power Refinement

- Look at *smallest* line patient can see
- Which position is better, “one”, or “two”
- Always check axis first
- If cx power changes, check axis again

Spherical Power Refinement

- Always end by **refining** sphere
- +/-0.25 (increment +/-0.25) VA 20/10-20/80
- +/-0.50 VA 20/100-20/160
- +/-1.00 VA 20/200-20/400
- +/-2.00 VA <20/400
- Plus, minus, plus

Record the 4M Refraction Result on VA Worksheet

- Record the 4M result
- If refracted at 1M record what the 4M result would be, i.e., subtract “+0.75”
- **Example #1:** 1M result is $-1.00+1.00X90$
- Record on worksheet $-1.75+1.00X90$
- **Example #2:** 1M result is $+3.25$
- Record on worksheet $+2.50$

Best Corrected Visual Acuity Testing

- *ALLWAYS TEST AT 4M FIRST EVEN IF REFRACTION WAS AT 1M*
- *When you move to 1M add .75 (do not stack lenses) and MEASURE the distance with the 1M stick*

Best Corrected Visual Acuity Testing

- Chart 1 OD, Chart 2 OS
- Hide chart before testing
- Always start with OD
- Fellow eye occluded with eye patch and lightly *TAPED*
- Lenses in place
- Patient instructed properly each time

Visual Acuity Testing

- Always start at top left
- Instruct patient
- Read **SLOWLY**
- No numbers, only letters
- One chance per letter
- Can change mind before going to next letter
- Can point briefly if loses place

Scoring

- Circle correct letters
- X incorrect letters
- Leave blank missed letters
- Encourage patient, turn head, try hard
- If they read <20 letters, must check at 1M
- ≥ 20 letters read, gets the “bonus”
- Add +0.75 to refraction for 1M testing
- *Do not stack lenses*

Example #1

≥ 20 letters read at 4M
Does not need to read at 1M,
Gets 30 letter “bonus”
Total Score is 54,
Snellen Equivalent is 20/80

Patient Name: #1 Date: / /
 Visit: Week #

RECORD PREVIOUS VISIT REFRACTION or CURRENT Rx if FIRST VISIT
 + _____ + _____ × _____
 - Sphere - Cylinder - Axis

RIGHT EYE CHART 1 VERSION 1 4M
 RECORD TODAY'S 4 METER REFRACTION RESULT
 + _____ + _____ × _____
 - Sphere - Cylinder - Axis

Circle each letter the patient correctly identifies at 4M and record the total number of letters read correctly in the column to the right. If the patient reads less than 20 letters, then move the patient to 1.0M, add +0.75D of sphere, and record the number of letters read correctly. If the patient is unable to read letters correctly at both 4.0M and 1.0M, then the Visual Acuity Score is recorded as 0 and patient must be tested for CF, HM, LP and NLP

Row	Acuity Equivalent	Chart 1 Letters	Number correct at 4.0 meters	Row	Acuity Equivalent	Chart 1 Letters	Number correct at 1.0 meter
1	20/200	O O O O O	5	1	20/800	N C K Z O	
2	20/160	P O S O O	5	2	20/640	R H S D K	
3	20/125	Q O U O O	5	3	20/500	D O V H R	
4	20/100	R O T O O	5	4	20/400	C Z R H S	
5	20/80	S O P O C	4	5	20/320	O N H R C	
6	20/63	D K S N V		6	20/250	D K S N V	
7	20/50	Z S O K N		Total # of letters correct at 1.0 meter			
8	20/40	C K D N R		Visual Acuity Score - Right Eye			
9	20/32	S R Z K D		A. Total number of letters correct at 4.0M: <u>24</u>			
10	20/25	H Z O V C		B. If ≥20 letters correct at 4.0M, add 30: <u>30</u>			
11	20/20	N V D O K		C. Total number of letters correct at 1.0M: <u>0</u>			
12	20/16	V H C N O		Visual Acuity Score (sum of A, B, C) <u>54</u>			
13	20/13	S V H C Z		APPROXIMATE SNELEN EQUIVALENT			
14	20/10	O Z D V K		(Smallest line with 1 or no error) 20 / <u>80</u>			
Total # of letters correct at 4.0M: <u>24</u>							
IF SCORE IS <20 letters TEST AT 1.0 METER							
If no letters can be read at 4.0M or 1.0M, indicate patient's ability to: <input type="checkbox"/> Count Fingers <input type="checkbox"/> Light perception <input type="checkbox"/> Hand motion <input type="checkbox"/> No light perception							

VAE signature _____ VAE# _____
 VA worksheet, 07FEB2007, RIGHT EYE

Example #2
<20 letters read at 4M
Must read at 1M,
Does not get 30 letter "bonus"
Total Score is 46
Snellen equivalent is 20/100

Patient Name: #2 Date: / /
 Visit: Week #

RECORD PREVIOUS VISIT REFRACTION or CURRENT Rx if FIRST VISIT
 + . + . ×
 — Sphere — Cylinder — Axis

RIGHT EYE CHART 1 VERSION 1 4M

RECORD TODAY'S 4 METER REFRACTION RESULT
 + . + . ×
 — Sphere — Cylinder — Axis

Circle each letter the patient correctly identifies at 4M and record the total number of letters read correctly in the column to the right. If the patient reads less than 20 letters, then move the patient to 1.0M, add +0.75D of sphere, and record the number of letters read correctly. If the patient is unable to read letters correctly at both 4.0M and 1.0M, then the Visual Acuity Score is recorded as 0 and patient must be tested for CF, HM, LP and NLP.

Row	Acuity Equivalent	Chart 1 Letters	Number correct at 4.0 meters	Row	Acuity Equivalent	Chart 1 Letters	Number correct at 1.0 meter
1	20/200	O O O O O	5	1	20/800	O O O O O	5
2	20/160	O O O O X	4	2	20/640	O O O O O	5
3	20/125	O O O X X	3	3	20/500	O O O O O	5
4	20/100	O O O X	4	4	20/400	O O O O O	5
5	20/80	O N H R C		5	20/320	O O O O O	5
6	20/63	D K S N V		6	20/250	O O O O O	5
7	20/50	Z S O K N		Total # of letters correct at 1.0 meter			30
8	20/40	C K D N R					
9	20/32	S R Z K D					
10	20/25	H Z O V C					
11	20/20	N V D O K					
12	20/16	V H C N O					
13	20/13	S V H C Z					
14	20/10	O Z D V K					
Total # of letters correct at 4.0M:			16				

IF SCORE IS <20 letters TEST AT 1.0 METER

Visual Acuity Score - Right Eye	
A. Total number of letters correct at 4.0M:	16
B. If ≥20 letters correct at 4.0M, add 30:	0
C. Total number of letters correct at 1.0M:	30
Visual Acuity Score (sum of A, B, C)	46
APPROXIMATE SNELLEN EQUIVALENT (Smallest line with 1 or no error) 20 /	100

If no letters can be read at 4.0M or 1.0M, indicate patient's ability to: Count Fingers Light perception Hand motion No light perception

VAE signature _____ VAE# _____

Example #3
<20 letters read at 4M
Must read at 1M
Does not get 30 letter "bonus"
Total Score is 29
Snellen equivalent is 20/125

Patient Name: A3 Date: ___/___/___

Visit: Week # ___

RECORD PREVIOUS VISIT REFRACTION or CURRENT Rx if FIRST VISIT

+ _____ - _____ + _____ - _____ × _____
 _____ Sphere _____ Cylinder _____ Axis

RIGHT EYE CHART 1 VERSION 1 4M

RECORD TODAY'S 4 METER REFRACTION RESULT

+ _____ - _____ + _____ - _____ × _____
 _____ Sphere _____ Cylinder _____ Axis

Circle each letter the patient correctly identifies at 4M and record the total number of letters read correctly in the column to the right. If the patient reads less than 20 letters, then move the patient to 1.0M, add +0.75D of sphere, and record the number of letters read correctly. If the patient is unable to read letters correctly at both 4.0M and 1.0M, then the Visual Acuity Score is recorded as 0 and patient must be tested for CF, HM, LP and NLP.

Row	Acuity Equivalent	Chart 1 Letters	Number correct at 4.0 meters	Row	Acuity Equivalent	Chart 1 Letters	Number correct at 1.0 meter
1	20/200	0 X 0	3	1	20/800	0 0 0 0	5
2	20/160	X H 0 0	2	2	20/640	0 0 0 0	5
3	20/125	0 0 X 0 0	4	3	20/500	0 0 X 0 0	3
4	20/100	C Z R H S	___	4	20/400	0 0 X X X	2
5	20/80	O N H R C	___	5	20/320	0 0 X X 0	3
6	20/63	D K S N V	___	6	20/250	0 0 X X X	2
7	20/50	Z S O K N	___	Total # of letters correct at 1.0 meter			20
8	20/40	C K D N R	___				
9	20/32	S R Z K D	___	Visual Acuity Score - Right Eye			
10	20/25	H Z O V C	___	A. Total number of letters correct at 4.0M: <u>9</u>			
11	20/20	N V D O K	___	B. If ≥20 letters correct at 4.0M, add 30: <u>0</u>			
12	20/16	V H C N O	___	C. Total number of letters correct at 1.0M: <u>20</u>			
13	20/13	S V H C Z	___	Visual Acuity Score (sum of A, B, C) <u>29</u>			
14	20/10	O Z D V K	___	APPROXIMATE SNELLEN EQUIVALENT			
Total # of letters correct at 4.0M: <u>9</u>			(Smallest line with 1 or no error) 20 / <u>125</u>				

IF SCORE IS <20 letters
TEST AT 1.0 METER

If no letters can be read at 4.0M or 1.0M, indicate patient's ability to: Count Fingers Light perception Hand motion No light perception

VAE signature _____ VAE# _____

VA worksheet, 07FEB2007, RIGHT EYE

Scoring

If they read ≥ 20 letters:

- They do not have to read at 1M
- They get a 30 letter “credit” or “bonus”
- Total score is 4M and 1M score combined
- **DO NOT FORGET** to test at 1M if the 4M score is < 20
- Snellen equivalent = Lowest line with one or no errors
- **EVERY LETTER IS COUNTED**

Testing Count Fingers

- If they cannot read any letters at 1M
- Test for CF by holding 1,2, or 5 fingers 2 ft. in front of patient
- Light shining on the hand from behind pt.
- Present randomly 5 times
- Must identify 3 out of 5 presentations

Testing Hand Motion

- If cannot Count Fingers
- Test for HM 2 feet in front of patient
- Move hand up and down, left and right
- Repeat 5 times
- Must identify 3 out of 5 times

Testing for Light Perception, No Light Perception

- Use an indirect at 1 M, maximum voltage in a darkened room
- Move the beam in and out at least 4 times
- Must be convinced patient sees LP
- If not NLP

Remote VAE Certification Test

- For new certification, until site visit is possible and/or if site visit is waived
- Urgent circumstances
- For re-certification

Remote VAE Certification Test

- Certification
- Must be taken via e mail
- We cannot accept faxed or scanned tests
- Remember to type your site number
- Corrected test will be e-mailed back within 5 business days (usually sooner)
- **VAE number** will be generated
- Certification e mail letter will be sent to your site, keep in regulatory binder

Remote VAE Certification Test

- *How do I get the test?*
- Go to: www.certifeyed.com
- User name: “xxxxxxx”
- Password: “xxxxx”
- **ALL VAE RELATED MATERIAL MAY BE FOUND HERE**

On Site Certification Visits

- Sites will be visited as determined by the sponsor
- “Team” of VAE certifiers
- Sites may request an on site visit for training and/or certification
- *We are here to help you*
- *Call or e mail anytime*

Thank You

?? Questions ??

Call or e mail your monitor, the sponsor or CertifYEYED anytime

Specializing in
ophthalmic clinical
research training

C 1
E R 2
T I F 3
E Y E D 4
A S S O C 5
I A T E S, L L C 6
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