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VISION SCREENING INSTRUMENT SUBMISSION DOCUMENT

Submission Date: _____

Your Name: _____

Your Title: _____

Company: _____

Company Website: _____

Phone #: _____

Email: _____

Instructions: Answer the following questions regarding the instrument you are submitting for review by Prevent Blindness. An "instrument" may include a vision screening machine and software. Note- Prevent Blindness is only able to consider instruments that are currently commercially available and have received FDA designation (if appropriate.) Please address all questions that are relevant to the instrument being submitted (for those that are not relevant, please indicate with "N/A").

Upon completion, email this completed application, the validation studies form, and a full copy of supporting peer-reviewed publications and any supplemental information to Kira Baldonado – kbaldonado@preventblindness.org.

Instrument Information

1. State the formal name of the instrument, and specify the software version being reviewed.

2. If applicable, state any informal name used for marketing purposes.

3. Describe the customer/user support services for the instrument, including how services are accessed and any fees the customer must pay to use these services.

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4. What training is needed to conduct the screening?
    a. Is a standard training guide/video/information/program available for screener training? (Provide a copy or internet link with this submission.)
    b. Is there a training certification process for screeners?
    c. Are there fees charged for training services?

5. Are there other specific aspects of the screening environment that need to be controlled or modified (such as lighting, distance, etc.) to operate the instrument successfully?

6. How does the experience level of the screener and adherence to screening protocol impact the reliability of the screening result?

7. Specify instrument type by selecting the most appropriate choice from the following options:
    - ○ Instrument measures subjective visual acuity directly
    - ○ Photoscreening and/or autorefracting instrument
    - ○ Other type of instrument (please describe) _____
      _____

8. What criteria are used to determine pass/refer for each parameter evaluated?

9. Are age-specific referral criteria used?

10. Does the instrument permit the user to modify the pass/refer criteria?

11. How is the pass/refer criterion **derived** in the instrument?

12. How is the pass/refer criterion **adjusted** in the instrument?

13. Does the vision screening instrument require the use of pharmaceutical agents such as anesthetic or dilating drops?

14. Describe, in layman's terms, the technology upon which the instrument is based in one single-spaced page or less.

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Instrument Data Collection, Export, and Manipulation Capabilities

1. Does the instrument interface with electronic health record systems or other medical registries? If yes, please describe.

2. Does the instrument permit preloading child data prior to a mass screening?

    a. If yes, how are data preloaded?

3. Will the instrument export demographics on children screened?
    a. If yes, by what process?
    b. Is the user required to manually adjust settings to export data?

4. Does the instrument provide the capability to download data for specific screening locations or a specific date range?

5. Is there other information about the instrument design, accessories, or operation that the committee should know?

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Validation Studies

Provide evidence supporting the validity of the vision screening instrument by completing the information requested in the table below for each study that you are using as support. It is required that you provide a minimum of two **peer-reviewed** articles with the submission. Additional supplemental data (that is unpublished) may be provided in addition to the peer-reviewed data. Studies submitted should include sensitivity and specificity. Studies that demonstrate testability only should not be submitted.

Answer all pertinent questions on the characteristics for EACH study you are submitting as validation for your screening instrument.

Disclosure of Commercial Relationships

Please disclose any commercial relationships you or your company may have in the peer-reviewed studies being included with this submission. Declaration of a commercial relationship will not degrade the review of the instrument; however it will better inform the experts involved in the instrument review. Follow the guidelines established by ARVO as you identify and describe commercial relationships in relation to each of the supporting studies you will be including with this submission.

ARVO Commercial Relationships Policy:
http://www.arvo.org/About_ARVO/Policies/ARVO_Commercial_Relationships_Policy/

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Study Characteristics	Study #1	Study #2	Study #3	Study #4
Article Citation				
Is this one of the two required, peer-reviewed studies or supplemental information?	Indicate one-required or supplemental			
Is this information confidential	Yes/No			
Define the parameters evaluated by the instrument in each study (i.e.; visual acuity, refractive error, media opacity, eyelid position, eye alignment, etc.)				
What version of the instrument and software was used to collect the data in this study?	Version/software number provided			
Is the version of the instrument and software used in this study the same as the one currently commercially available? If different, please describe the differences.	Yes/No If no, please describe differences			
Were all data in this study collected using the same version of the instrument and software?	Yes/No			
How were the children selected for the study? Describe the inclusion and exclusion criteria for the children.				
Were any children with disabilities included? How were children with disabilities defined?	Yes/No and define			
Where did the study take place? - Medical clinic - School - Day care - Research laboratory - Other (please describe)	Select location			
Who conducted the	List screener			

screening with the instrument on the children? - Lay screeners - Medical technicians - Students - Nurse/medical assistant - Primary care provider - Other (describe)	type from options provided			
How were the screeners selected for the study?				
Did all of the screeners in the study have the same or similar qualifications?				
How were the screeners trained in the study screening approach?				
How many children in each of the age ranges below were included in the study? - age 0 to <36 months - age 36 to <48 months - age 48 to <72 months - age 72 months to <12 years - age 12 years+ -Total of all ages included				
How many children in each of the age ranges below were successfully screened in the study? - age 0 to <36 months - age 36 to <48 months - age 48 to <72 months - age 72 months to <12 years - age 12 years+				
How many children in each of the age ranges below received a comprehensive eye exam with cycloplegia in the study? - age 0 to <36 months - age 36 to <48 months - age 48 to <72 months - age 72 months to <12 years - age 12 years+ -Total of all ages included				
How long (in minutes/seconds) does it take to screen the child in each of the following age				

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groups? (Include time taken to initiate data collection) - age 0 to <36 months - age 36 to <48 months - age 48 to <72 months - age 72 months to <12 years - age 12 years+	☐ ☐ ☐ ☐ ☐			
What are the differences in outcome (i.e., sensitivity and specificity) between the younger and older children within the 36-<72-month age range? - age 0 to <36 months - age 36 to <48 months - age 48 to <72 months	Describe according to age groups provided.			
Do children need to have an eye patched for screening?	Yes/No			
Were the data for the untestable children included in the data analysis? If yes, please explain.	Yes/No, and describe if yes.			
Were the screening results compared against a comprehensive eye exam with cycloplegia?	Yes/No			
How are the screening results compared to results from a comprehensive eye exam with cycloplegia? Describe in detail.				
Were the examiners masked to the results of the screening?	Yes/No			

Thank you for your submission. Upon receipt, your submission will be reviewed for completeness and then provided to a committee of three experts for consideration. The experts will have 90 days to complete their review of the instrument and provide a report to Prevent Blindness. This report language will be utilized to further educate consumers of vision screening instruments and improve screening practices based on scientifically-validated approaches.