

CONNECTICUT LIONS EYE RESEARCH FOUNDATION

LIONS EYE HEALTH PROGRAM

PEDIATRIC EYE SCREENING PROGRAM



PROTOCOL MANUAL

BASED ON
PEDIAVISION ASSESSMENT SOLUTION
SPOT VS100 VISION SCREENER

Summary

This is only a summary of the full protocol manual. There have been some developments and lessons learned since the manual was created. The screening can be done in less than 2 minutes when more efficiency is attained. Here are a few tips.

1. The manual calls for 3 volunteers. I recommend that you have the screener-computer operator, printer handler, and liaison to the facility, who also operates lights and hands out the reward sticker. A 4th person on the team can make the screening more efficient.
2. Use a fully darkened room for the eye screening. Successful screenings occur much faster in darkened rooms. We added small utility lights for the printer operator and computer operator, so they can see what they need to see and be efficient. These lights should illuminate the keyboard and paper to remain effective. The 3rd person can also operate the overhead lights at the instructions of the screener.
3. Two to four children can be brought to an outer room to wait their turn. If the waiting area is inside the "screening room", just an open door can bring in enough light to make transitions into the screening area. The screening area should place the child that is being screened so they are not facing the door or other light source, and that the Vision Screener is not pointed toward the door.
4. We added the use of the "**I am a Lion SightSaver**" sticker to the program, so these children are rewarded for their participation. A roll of stickers has been added to the Pediatric Eye Screening kit for this purpose. It is recommended that you speak with the daycare provider to have the more confident children do the screening first.
5. When a Lions Club decides to run a screening in their town, they should not seek just one facility for this important work. The goal should be to screen "every child" between the age of 6 months and 5 years of age. That means seeking additional facilities in town, so every child can be screened. Of course, children that already have eyeglasses, or are already receiving treatment do not need to be screened. While some clubs would like to run this screening on an annual basis, they are competing for the single Pediatric Eye Screening kit; which is used throughout the district. Plan to make your screening as complete as possible.
6. Setup at a facility can be done in just 10 minutes when the site has been checked out ahead of time. If a facility has only 20 children, it can be performed with 10 minutes of setup time, 40 minutes to screen all children and 10 minutes to pack up and leave the facility. It is conceivable to visit 3 different facilities on the same day. Because some elementary schools have a morning and afternoon session, you can plan to visit a secondary facility between these two sessions.
7. Make plans at least 6 weeks in advance, but do not be surprised that your date is not available. September and October are very popular months to hold this screening; when it can be run at any time throughout the school year.

INDEX

Preface

Selection Criteria for Screener Trainees Volunteer Application

Instructions for Contacting Local Head Start or Nursery School Programs Sample letter of Introduction to Local

Head Start or Nursery Director Memorandum of Understanding

Consent form

Managing Screening Paperwork "Refer" Letter

"Pass" Letter

List of Local Eye Care Specialists Accounting Sheet

Setting Up a Screening Area

Hooking Up and Turning On Equipment

Screening Procedures

PREFACE

The Connecticut Lions Eye Research Foundation through its Lions Eye Health Program (LEHP) is expanding its program of eye screening to include children in the 6 months to 5 year age group.

Through this program LEHP intends to take eye screenings to pre-school children throughout Connecticut. The initial program is aimed at children enrolled in Head Start programs, private nursery schools and other public, pre-school programs that do not have access to pediatric eye screening programs.

The program is based on the use of the PediaVision SPOT VS100 Screening Equipment. Initially, LEHP initially purchased an older model of these machines to establish a pilot-screening program that can then be expanded to cover the entire State. LEHP trained small groups of Lions from a few clubs in the State and conducted pilot screenings in those areas. This pilot program and the small group of initial trainees will serve as the nucleus for expand the program statewide.

The PediaVision equipment will allow screening for such eye abnormalities as:

- Astigmatism: irregularly shaped corneas or lenses
- Myopia: nearsightedness
- Hyperopia: farsightedness
- Strabismus: Misalignment of the eyes
- Anisometropia: unequal refractive power
- Anisocoria: pupil size anomalies

The program was conceived in the Summer of 2009. Funding was put in place by CLERF in February of 2010. The first group of screeners was trained in March 2010 and the first actual screening took place in April 2010 in Thompson, Connecticut. A second pilot screening took place in Naugatuck. In 2011-12, over 1200 children were screened in Windsor Locks, Avon, Terryville, Wolcott, Watertown, East Hampton, East Haddam, Salem, and New Fairfield.

SELECTION CRITERIA FOR SCREENER TRAINEES

The LEHP Pediatric Eye Screening Program will require a number of trained Lion screeners who can take this program to the pre-school public. Individual Clubs will be asked to provide LEHP with the names of members willing to receive the required training and serve as screeners for their geographic area.

The program is based on the use of the PediaVision SPOT VS100 Screener. While the training for, and operation of this equipment is quite simple, there are some factors in the selection of screener trainees that clubs should be aware of:

1. The PediaVision equipment operates like a camera, with a built-in keypad and display for entering the child's information. It comes with a wireless printer for printing results. Proposed trainees should be competent with using a cell phone or other device with light typing capability and have a steady hand, with the ability to take clear photographs.
2. The program is aimed at Head Start programs and other nursery and pre-school programs that operate during weekday business hours. There will be virtually no screenings done in the initial development of this program on weekends or evenings. Therefore, clubs should select screener trainees that have daytime, weekday hours available. It is conceivable that screening of an average Head Start group could take one or two mornings, based on 20 children per hour.
3. Although the PediaVision screening process is done entirely from a distance of about 3 feet from the patient, it is important to remember that screeners will be in communication with pre-school children throughout the course of a screening. Screener trainees must have the patience, attitude, personality and experience that will enable them to work well with little children for many hours at a time.
4. Since we will be working with children in a public setting it will be necessary for all screeners to be subjected to a background check, the results of which will be kept on file by LEHP. Screener trainees will be required to bring a copy of their driver's license to the training and will be asked to fill out a simple background check form.

Clubs should carefully consider these criteria before naming screener trainees. The success and expansion of this program will depend to a great extent on how efficiently and professionally we can administer these screenings.



**CONNECTICUT LIONS EYE RESEARCH FOUNDATION
LIONS EYE HEALTH PROGRAM**

PEDIATRIC EYE SCREENING PROGRAM VOLUNTEER APPLICATION

A COPY OF A VALID GOVERNMENT ISSUED PHOTO IDENTIFICATION MUST BE ATTACHED TO COMPLETE THIS APPLICATION.

Name _____ Date _____

Address _____

City _____ State _____ Zip _____

Home Phone _____ Business Phone _____

Cell Phone _____ E-Mail _____

Date of Birth _____ Occupation _____

Social Security # (Optional, mandatory if requested) _____

Employer _____

Address _____

Lions Club affiliation _____ District _____

Special certification (CPR, Medical, Etc.) _____

Have you ever been convicted or plead guilty to any crime(s)? Yes _____ No _____

If yes, describe each in full _____

Have you ever been refused participation in any other youth related program? Yes____ No____

If yes, explain: _____

Please list 3 references, at least one of which is not a member of your Lions Club:

Name_____ Phone_____

Name_____ Phone_____

Name_____ Phone_____

As a condition of volunteering for the LEHP Pediatric Eye Screening Program, I give permission for LEHP to conduct a background check on me, which may include a review of sex offender registries, child abuse and criminal history records. I understand that my participation in this program is conditional upon LEHP receiving no inappropriate information on my background. I hereby release and hold harmless from liability CLERF, LEHP, its officers, volunteers, employees, or any other person or organization that may provide such information.

Applicant Signature_____ Date_____

INSTRUCTIONS FOR CONTACTING LOCAL HEAD START OR NURSERY SCHOOL PROGRAMS

Under the LEHP Pediatric Eye Screening Program, it is the responsibility of each local Lions Club to seek out and contact Head Start programs, public or private nursery schools and day care centers to determine if they are willing to host a pediatric eye screening for children under their care.

A sample letter is included in this manual. This letter should be copied onto club stationary and sent to the childcare facility by the club. Whenever possible, personal contact by telephone should be made by a club member, an appointment made, and the letter hand delivered. Head Start programs are mandated to screen all first year children within 45 days after the opening day of the program (usually in late August). Clubs should plan the screening at least six weeks in advance, since the facilities need to distribute the Parental Consent forms.

If there is interest on the part of the childcare facility to host a screening, the club should establish a tentative date, contact the District LEHP Chairman and secure the equipment and consent forms. A memorandum of understanding should then be executed with the facility. The consent forms can then be given to the child care facility for distribution to each child's parent or guardian. Signed consent forms must be returned to the child care facility prior to the date of the screening. NO CHILD CAN BE SCREENED UNLESS A SIGNED CONSENT FORM FOR THAT CHILD IS ON HAND PRIOR TO THE SCREENING. In some cases, the child care facility may have its own consent form it wishes to use. In that case, both the facility's form and the Lion's form must be signed.

Remember that this program is currently aimed at children between the ages of 2 and 5 who are enrolled in childcare facilities. The program is not yet prepared to do public or mass screenings and is not yet prepared to be taken into the public schools for children in kindergarten or above.

A note about "Prevent Blindness":

Prevent Blindness Tri-State (formerly Prevent Blindness Connecticut) has been and currently is performing pediatric eye screenings for some Head Start facilities in Connecticut. It is not our intent to replace them at these facilities. If you contact a Head Start facility and they tell you they are already having this screening done by Prevent Blindness, urge them to continue with that provider and let the facility know that you may be able to assist in the future if any problem develops.

SAMPLE LETTER OF INTRODUCTION TO LOCAL HEAD START OR NURSERY SCHOOL DIRECTOR

Dear Head Start/Nursery School Director,

The _____ Lions Club wishes to inform you that it now has the capability of performing pediatric eye screenings of pre-school children, ages six-months old through 5 years.

Members of our Lions Club have been trained in the use of the PediaVision Spot Vision Screener and are available to perform screenings at your location at any time. We can screen toddlers and infants from 6months.

The vision screener we use is capable of screening for Astigmatism, Myopia, Hyperopia, Anisometropia, Strabismus, Amblyopia, and Anisocoria. The individual screening takes just a few seconds and is performed from a distance of about three feet. There is no physical contact with the child and no eye drops are administered. Our equipment provides a print-out of the results for each individual which is given to you for forwarding to the parent. We provide parent consent forms and cover letters for you to send to the parents prior to the screening date.

It is important to understand that this is only a screening and does not constitute an examination or diagnosis of vision problems.

This service is offered free of charge by the local Lions Club under the Lions Eye Health Program administered by the Connecticut Lions Eye Research Foundation. If the children at your facility do not currently receive regular eye screenings, please contact me to discuss how and when we can provide this vital service.

I can be reached at _____

Sincerely yours,

MEMORANDUM OF UNDERSTANDING:

Between the (Lions Club) _____ operating under
The Connecticut Lions Eye Research Foundation, Lions Eye Health Program, and the
(Child Care Facility) _____
to perform an Eye Screening for children registered at the facility on or about
(Date) _____

The Lions Club will perform the screening using the PediaVision S08 Vision Screener and will provide printed documentation of the results of each individual screening to the facility. The Lions Club will also provide blank consent forms and referral letters.

The Child Care Facility will distribute consent forms to all parents and insure that signed forms are on hand prior to the screening. The Child Care Facility will distribute all individual screening results and referral information to the parents and will be responsible for all follow-up of referrals.

The Child Care Facility also will insure that a member of their staff will be present in the screening room whenever children are being screened.

Signed:

(For the Lions Club)

(Date) _____

(For the facility)

(Date) _____

MANAGING SCREENING PAPERWORK

When conducting a screening, you will be handling six items of paperwork. They are listed below, along with the proper disposition of each:

1. Consent forms

Enough blank consent forms will be provided to you by LEHP for your screening. These should be given to the childcare facility director prior to the date of the screening so that he or she can send them out to each parent and get them returned prior to the screening. After the screening, these signed forms should remain with the facility director.

2. Individual screening printouts

These are produced by the printer that is part of the screening equipment. They should be given, along with the appropriate "Pass" or "Refer" letter, to the facility director to be sent home to the child's parent or guardian.

Note: Copies of individual screening printouts should not be taken from the facility by the Lions. The laptop computer that runs the screening equipment stores the individual results for access at a later time by authorized personnel.

3. "Refer" letter

An adequate number of these will be provided to you by LEHP. If an individual printout reveals that a child should be "referred", a copy of this letter should be stapled to the printout before it is given to the facility director. Provide a list of local Eye Care Providers with the Referral letter with each referral. If your screening can estimate the number of children to be screened, consider making 2 copies for every 10 children.

4. "Pass" letter

An adequate number of these will be provided to you by LEHP. If an individual printout reveals that a child has "passed", a copy of this letter should be stapled to the printout before it is given to the facility director.

5. List of pediatric eye care specialists

An adequate number of these will be provided to you by LEHP. If an individual printout reveals that a child should be "referred", a copy of this list should be stapled to the printout and the "refer" letter before they are given to the facility director.

6. Accounting sheet

This sheet will be provided to you by LEHP. It should be filled out at the end of the screening and returned to the LEHP administrator.



CONNECTICUT LIONS EYE RESEARCH FOUNDATION

LIONS EYE HEALTH PROGRAM

VISION SCREENING CONSENT FORM

On _____ the local Lions Club in your community will conduct a free vision screening for all children in your child's pre-school/day care facility. The screening equipment being used may determine the presence of eye disorders including far and near sightedness, astigmatism, anisometropia, strabismus and anisocoria. The screening is done by a photographic process from a distance of three feet. No physical contact is made with the child and no eye drops are administered.

I, the undersigned, hereby give permission for my child, _____, to participate in the screening. I understand the following regarding this program:

- 1. The information obtained from this vision screening is preliminary only, and does not constitute a complete exam or diagnosis of vision problems.**
- 2. There is no charge to participate in the vision screening process.**
- 3. The results of my child's individual screening will be provided to me by the pre-school/day care facility. Results will also be kept on file by the Lions Eye Health Program.**
- 4. Should the screening indicate any abnormality, a complete eye examination and any follow-up care is my responsibility.**
- 5. If referred, I authorize my child's eye care professional to release the results of my child's eye exam to the pre-school/day care facility and to the Lions Eye Health Program.**
- 6. I will not hold the Lions Club organizations, the Connecticut Lions Eye Research Foundation, The Lions Eye Health Program or the pre-school/day care facility accountable for any errors of commission, omission, or any other misdiagnosis.**

Signature of parent or guardian

Date

PLEASE PRINT

Child's Last Name _____ First Name _____

Age _____ Male _____ Female _____

Please Circle 'Date of Birth'

Year	2012	2011	2010	2009	2008	2007																									
Month	01 January	02 February	03 March	04 April	05 May	06 June	07 July	08 August	09 September	10 October	11 November	12 December																			
Day:	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Parent or Guardian's Name _____ Phone # _____

Address _____
(Street) (City) (Zip Code)



LEONES DE CONNECTICUT FUNDACIÓN DE INVESTIGACION DE OJOS
PROGRAMA DE LOS LEONES DE SALUD DE LOS OJOS
FORMA de CONSENTIMIENTO de INVESTIGACION de VISION

En _____ el Club de Leones local en su comunidad llevará a cabo un examen de gratis de la vista para todos los niños en las pre-escolar/ instalación de guardería. El equipo de detección que siendo utilizado puede determinar la presencia de desórdenes de ojo inclusive distante y cerca de visión de futuro, el astigmatismo, anisotropía, el estrabismo y anisocoria. El equipo de detección es hecho por un proceso fotográfico a una distancia de tres pies. No hay contacto físico con el niño y no se administran gotas para los ojos.

Yo, El abajo firmante, Doy permiso para que mi niño, _____, para tomar parte en la investigación de detección. Yo entiendo lo siguiente acerca de este programa:

1. La información obtenida en este examen de la vista es preliminar, y no constituyen un examen completo o el diagnóstico de problemas de visión.
2. No hay ningún cargo para participar en el proceso de examen de la vista.
3. Los resultados de la evaluación individual de mi niño será siempre para mí por el centro de atención pre-pre-escolar/ instalación. Los resultados también se mantendrá en archivo por el Programa de los Leones de Salud de los ojos.
4. Si el examen indica alguna anormalidad, un examen completo de los ojos y la atención de seguimiento es mi responsabilidad
5. Si referido, yo autorizo a la atención de mi niño profesional de la visión para liberar a los resultados de examen de los ojos de mi hijo a la pre-escolar/ instalación de guardería y el Programa de los Leones de Salud de los ojos.
6. No voy a responsabilizar a las organizaciones Club de Leones, los Leones de Connecticut Fundación De Investigación De Ojos, el Programa de los Leones de Salud de los ojos o el centro de atención las pre-escolar/ instalación de guardería responsables de los errores de comisión, omisión o cualquier otro mal diagnóstico.

Firma del padre o tutor

Fecha

POR FAVOR IMPRIMA

Apellido del niño _____ Nombre _____

Edad _____ Masculino _____ Femenino _____

Por favor, Círculo la 'Fecha de nacimiento'

Año

2012	2011	2010	2009	2008	2007
------	------	------	------	------	------

Mes

01 enero	02 febrero	03 marzo	04 abril	05 mayo	06 junio
07 julio	08 agosto	09 septiembre	10 octubre	11 noviembre	12 diciembre

Día

01	02	03	04	05	06	07	08	09	10	
11	12	13	14	15	16	17	18	19	20	
21	22	23	24	25	26	27	28	29	30	31

Nombre del Padre o Tutor _____ Número de Teléfono: _____

Dirección _____
(Calle) (Ciudad) (Código Postal)



**CONNECTICUT LIONS EYE RESEARCH FOUNDATION
LIONS EYE HEALTH PROGRAM
VISION SCREENING RESULTS**

Name of child_____

Location of screening_____

Date of Screening_____

Dear Parent or Guardian,

Thank you for allowing your child to take part in the Lions Eye Health Program Pre-School Eye Screening.

The attached result form indicates that your child has passed the screening criteria.

Please understand that this is a screening, not a complete eye exam. The Lions Eye Health Program recommends that all children have a complete eye exam performed by an Optometrist or Ophthalmologist at least once between the ages of 3 and 5.



**CONNECTICUT LIONS EYE RESEARCH FOUNDATION
LIONS EYE HEALTH PROGRAM
VISION SCREENING RESULTS**

Name of child _____

Location of screening _____

Date of Screening _____

Dear Parent or Guardian,

Thank you for allowing your child to take part in the Lions Eye Health Program Pre-School Eye Screening.

The attached result forms indicate that your child did not pass the screening criteria.

Although this is only a screening, not a full eye exam, it is recommended that you have your child's eyes examined by an eye care professional as soon as possible, and that you take the attached forms with you to the exam.

If you do not have a family eye care professional, a list of local Optometrists and Ophthalmologists in your area is attached.



**CONNECTICUT LIONS EYE RESEARCH FOUNDATION
LIONS EYE HEALTH PROGRAM**

PEDIATRIC EYE SCREENING PROGRAM

ACCOUNTING SHEET

Name of facility _____

Address of facility _____

Date of screening _____

Club conducting screening _____

Number of children screened _____

Number "passed" _____

Number referred _____

Number "aborted" _____

Lion Screener contact name _____

Phone # _____

SETTING UP A SCREENING AREA

General Space Requirements:

Screenings should be conducted on an individual basis in a room as free from distractions as possible and in which lighting can be controlled. There should be enough space for two 6' tables, a screening team of three people, the patient, and at least one adult school staff person. The patient should be positioned in such a way that he/she cannot see the laptop screen.

Screening Distance:

The distance from the front of the camera to the patient's eyes is one meter, or 3.3 feet. A measuring tape (or stick) is provided with the equipment to help set up the initial space allocations.

Light in the Room:

It is important that the screening area does not have direct sunlight or lighting from halogen or other heat producing bulbs. Avoid lighting, mirrors or other reflective surfaces in front or behind the patient. The screening device or child should not be looking into a light source or reflection. Draw blinds or shades and keep the light level in the room as low as practical. The lower the light level, the better the screening device will work.

A volunteer may be used to turn off the overhead lights when the screening begins, and turn them back on when the screening is complete.

Fluorescent lighting is OK, but try to reduce the number of lights or bulbs lit if possible. If the laptop tells you "pupils too small" or "pupils not found", try dimming the lights to help dilate the pupils to an adequate size.

HOOKING UP AND TURNING ON EQUIPMENT

The screening equipment comes in three cases. The larger case (carry bag) contains the paper, pass and refer forms and other supplies. The medium case contains the wireless printer. The smaller case holds the delicate hand held screening device and recharging cable.

Remove and identify all items. When the hand held screening device is charged, only the printer needs to be plugged in. See the following pages for identifying the items and for graphic descriptions of the connections.

VERY IMPORTANT-READ CAREFULLY

Press the buttons lightly on the printer and hand held screening device.

When the touch screen gets dirty, use only a pre-moistened cleaning cloth (such as eyeglass cleaning pads) to clean it. Use the soft cloth to clean the lens if it gets dirty. Never use a cleaning solution or water alone to clean any of the electronics.

The electronic equipment should never be stored in a cold or hot place. A garage or automobile is not a good environment for temporary storage.

SCREENING PROCEDURES

Screening can be done most efficiently using a three person screening team. One person should handle the screening camera and all data entry. The second person should handle the printouts and collate them with the appropriate pass or refer forms (See "Managing Screening Paperwork"). The third person should be assigned to control the lights and give out the Reward Stickers. This person might also help by passing along Parental Consent forms, and coordinating with the staff. Management of the children should be left as much as possible to the nursery school staff.

At least 15 minutes should be allowed for setting up the equipment. Get the equipment turned on as soon as possible so that the camera has a couple of minutes to adjust to lighting conditions in the room. On average, allow about 3 to 5 minutes to screen each child. As you become more proficient with the equipment, this time will shorten, but there will always be the occasional uncooperative child or false reading that will require more than the minimum average time. Just before the screening begins, you might ask the school coordinator to send in the more confident children first. When they return to class with their "Reward Sticker", this helps the more timid children to gain confidence.

Children wearing eyeglasses need not be screened. This child is already under the care of a professional and the results of our screening add little to what is already known about that child. If you do screen a child who wears glasses, the screening should be done with the glasses on.

The best position for the screener is seated, with the camera held tightly at stomach level, with the screening device held at chest level with both hands, seems to work best. There should be room to push the screening device forward, so the distance of one meter is established. The child should be seated in a chair or, in the case of a very young child, seated in the lap of a parent or nursery school staffer. Pre-position the chairs using the one-meter (from face of camera to eye of child) measuring tape (stick) provided prior to bringing in the first child. Holding that position as closely as possible will make the screenings go faster. Keep the screening device as level as possible with the child's eyes. You can mark the floor with removable painter's tape at the positions where the screener and child's chair is to be located.

When a child's eyelashes interfere with their pupil, ask the child to "Open Wide" or "Hold your chin up slightly". When lighting is not ideal, consider holding the screening device at knee level, so the child looks downward slightly.

Basic Operation

This section explains preparatory steps before you start screening with Spot and basic operation.

Terminology

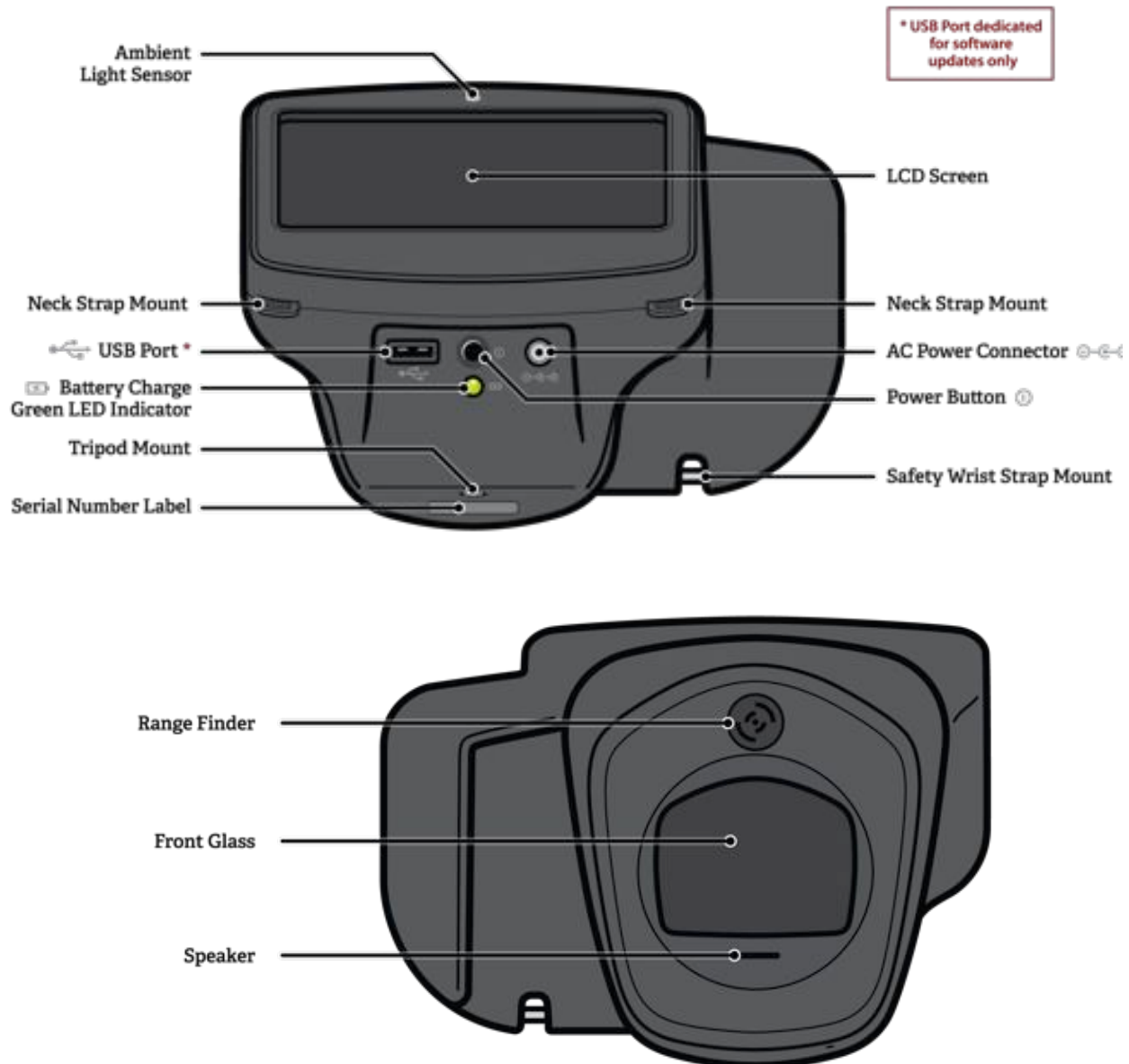


Figure 2

NOTE: The USB port shall only be used for software installations and import/export of data via a USB flash drive. It shall not be cable connected to any other device.

Basic Camera Care

1. Spot is a precision instrument. DO NOT drop it or subject it to physical shock.
2. Spot is NOT waterproof. If you accidentally drop it into liquid or liquid is spilled on it, please promptly contact PediaVision Customer Service. If minor water droplets are found on Spot, please wipe them off with a soft dry cloth.
3. DO NOT leave Spot in excessive heat such as in a car or in direct sunlight. High temperatures can cause Spot to malfunction.
4. Spot contains precision electronic circuitry. Never attempt to disassemble Spot yourself. This will void any warranty.
5. DO NOT use cleaners that contain organic solvents to clean Spot's body or front glass. For stubborn dirt, use the provided cleaning cloth with a small amount of water or a non-abrasive cleaner. If you have any questions about proper cleaning procedures, please contact PediaVision Customer Service.
6. When plugging the AC power connector into Spot, be sure NOT to force the power connector into the Spot device as this may cause damage not covered under warranty.
7. The safety wrist strap on Spot is intended to assist in the event the device slips or is dropped. It is not to be used to carry or support the weight of Spot.

Display Care

Spot has an all-in-one 5" LCD Display and touchscreen. To ensure long lasting functionality and performance, please be aware of the following:

1. DO NOT push or scratch display surface with anything stiff or rigid.
2. DO NOT spill liquids on the display. Please wipe off drops of liquid like saliva and water on LCD panel surface immediately.

Front Glass Care

Spot uses a piece of optical glass with a special coating. If dirt or fingerprints are visible, use a soft cloth to wipe clean. For stubborn dirt, try using the provided cleaning cloth with a small amount of water or a non-abrasive cleaner.

Warnings

1. Changes or modifications not expressly approved by PediaVision could void the user's authority to operate the equipment.
2. The supplied cord set is to be used. Replacement or substitution may only be done with a CSA or UL approved hospital grade power supply/charger cord set.
3. The supplied power supply/charger may not be substituted and shall only be replaced by an approved unit supplied by PediaVision.
4. Interconnection of this medical device with other medical devices, medical used systems or non-medical devices shall be evaluated to the requirements of CSA/IEC 60601-1-1 in the end use application.
5. This equipment is ESD sensitive; do not touch connector pins during use.
6. If the power cord or external power supply becomes damaged or its integrity is suspect, or the building power receptacle outlet is ungrounded, then the Spot shall only be used with the internal battery power until replacement parts become available.
7. The operator shall not touch accessible conductive parts (ac/dc adaptor output connector, camera power input connector and USB port) and the subject simultaneously.

Screening Environment

For the best screening results, be sure to screen in a proper, subdued lighting environment. **Take care to eliminate sunlight and/or incandescent light.** Florescent light is acceptable but note that the subject's pupil size will be affected by light in the room and will decrease your chances of a successful screening. Subject's pupils should be greater than 5mm for best results.

NOTE: A minimum pupil size of 4mm is required for screening to occur and may be difficult to achieve in a room with any light source. Subject's pupils should be greater than 5mm in size for best results.


Best screening environment (minimal fluorescent light):



Figure 3

Getting Started

Charging Spot

Spot contains a rechargeable battery for mobile use. To charge the battery, first connect the provided AC power cord to the provided power supply/charger. Tilt Spot forward and find the power connector port , then gently insert the AC power connector as seen below. DO NOT force the AC power connector into the AC power port on Spot. It should easily insert. Forceful insertion can cause damage to Spot and potentially void the limited warranty. Finally, plug the power cable into an available AC outlet. When the battery charge indicator (green LED) is steady, no further charging is required (*Figure 4*). Spot will also run directly off the AC power source.

Powering Spot On and Off

To power on Spot, press and release the power button. The system will take approximately 30 seconds to complete its start-up process. When complete you will be on the Main Menu with the blue Spot logo.

To power off Spot, hold the power button for about 2 seconds. A confirmation screen will appear to confirm shutdown of the device.

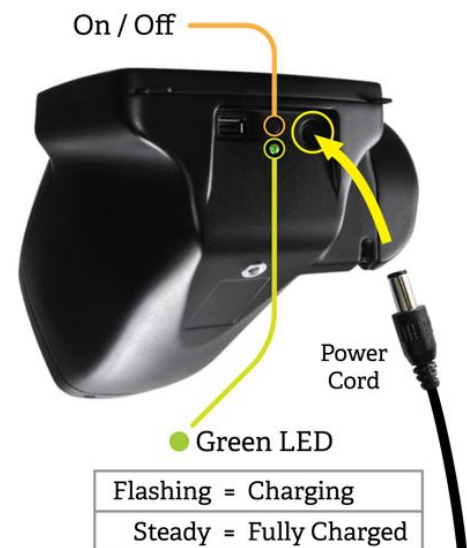


Figure 4

Wrist Strap

Use the included wrist strap as extra precaution to help prevent damage to Spot if it slips from your hands. Attach the wrist strap to the pin located under the handle.

DO NOT carry Spot by the wrist strap. The wrist strap is an extra precaution but does not guarantee damage will be prevented if dropped.

Optional Neck Strap

PediaVision offers an optional neck strap to assist during extended usage. The neck strap connects to the two tabs located below the display on Spot. Please contact PediaVision Customer Service to order a neck strap.

Helpful Hints




- When there is no activity on Spot, the device will automatically dim the screen and then turn the screen black. Simply touch the screen to bring the application back.
- To delete ALL records from Spot, go to the Records screen and touch the trash can icon. This will bring up the Delete All Records screen.
- Be sure you have correctly exported any desired data to a USB drive, then select Delete All Records.
- You can also turn the capture sound on and off by pressing the  icon in the bottom left corner of the capture screen.
- Spot has several keyboard layouts to provide all characters you may need while screening. Simply select the shift key or the special character keys to switch back and forth.
- The best way to know if your Spot is connected to a wireless network, is to go to the Main Menu and see if you see your network name and IP address are in the lower left corner.
- Spot requires a minimum pupil size of 4mm for screening to occur and this may be difficult to achieve in a room with any light source. Subject's pupils should be greater than 5mm in size for best results.
- To power off Spot, press the power button for about 2 seconds. A confirmation screen will appear to confirm shutdown of the device.
- Do not power off Spot during a screening. Instead, exit the screening by selecting the , then power down the device normally.
- Holding down the  button on any input screen will delete all data from the field.



Figure 5

User Operation

Main Menu

When Spot is powered on, the main menu screen (*Figure 5*) will appear with the following information and features. If Spot is connected to a network, the network name and IP address will be visible in the lower left corner as seen in *Figure 5* above.

Start:

To begin the screening process, select the Start function (the blue Spot logo). This will allow you to enter subject information, find queued subjects, begin the capture process, and review and print screening results.

Records:

The records section will allow you to view already screened subjects (complete records) and select individual records to review results, select queued subjects from a list to begin the screening capture process and delete all records from Spot.

Tools:

The tools section allows you to customize Spot to meet your specific needs. From Tools, you will be able to set things such as the date & time, set up a printer & print a test page, connect to a wireless network, enable a security pin, review screening criteria, set the measurement formats, recalibrate your touchscreen, import/export data and view the software version currently running on your Spot device.

Subject Data Entry

To begin screening, select the Start function (blue Spot logo) from the main menu. Using the onscreen keyboard (*Figure 6*), enter subject information as outlined below:



Figure 6







1. **Subject ID (Optional)** – If you use an ID number for the subject you are screening, enter it here. If not, you may leave this field blank and proceed to the next entry by selecting “ok” or the **continue icon** . You may also use the ID field to search for records you previously imported onto Spot. Simply type the queued subjects ID number (case sensitive) and touch the continue icon. You will skip the rest of the input screens and go straight to the Subject Confirmation screen. If you don’t see the character you need, select the  icon for additional keyboards.
2. **First Name (Optional)** – The next screen will ask you for the subject’s First Name. After entry, select “ok” or the **continue icon** .
3. **Last Name (Optional)** – The next screen will ask you for the subject’s Last Name. After entry, select “ok” or the **continue icon** .
4. **Gender (Optional)** – The next screen will ask you to select the subject’s Gender (*Figure 7*). After you make your selection, you will be moved to the DOB screen or select the **continue icon** .



Figure 7

5. **Date of Birth/Age** (*Required*) – On the final entry screen, you will be asked to enter the subject's date of birth (DOB) or age in months and/or years (*Figure 8*). For the DOB, use the format MM/DD/YY. If entering an age, simply enter the number of months, years, or a combination of both. Example, 3 Years and 4 months would be 3y4m. After entry, select "ok" or the **continue icon** .

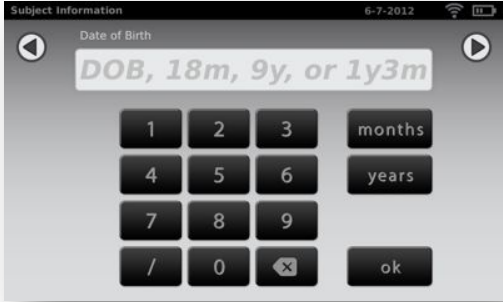



Figure 8

6. **Subject Screen** – On the subject screen (*Figure 9*), confirm all data is correct. To change or add information, simply select the desired field. If the DOB/age is missing or incomplete, the date of birth box will be highlighted red. Simply touch the red box to add/edit the age data. You can also select whether or not the subject has a vision prescription for glasses or contacts. After all information is confirmed, select the **continue icon**  to begin the capture process.

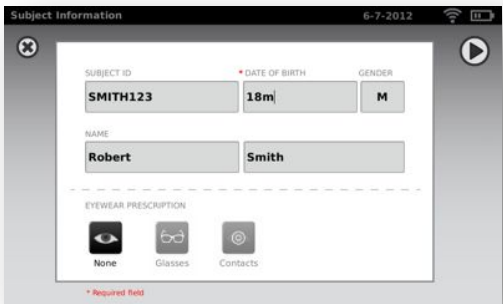


Figure 9

7. **Eyewear Confirmation Screen** – If you selected that a subject has a vision prescription on the subject screen, you will be asked if the subject is currently wearing their prescription. Simply select Yes or No. The screening will then begin.

Screening a Subject

When all information is entered position yourself about 1 meter from the subject, as shown below (*Figure 10*).



Figure 10


Check the lighting in your environment per the instructions on page 6 and then position yourself appropriately. Have the subject sit, cradle Spot in your left hand and hold the right handle. Prior to screening, hold the nose of Spot pointing down. Begin the screening by slowly rotating Spot upward to meet both of the subject's eyes. Adjust your distance to the subject until both eyes are clear on the screen. A blue screen indicates you are too close or too far from the subject.


NOTE: Keeping Spot even (on axis) with the subject's eyes will promote quicker results and help ensure you are not capturing other objects.



Position yourself with one foot in front of the other and slowly lean forward and back until the spinning icon appears, indicating you are in range (*Figure 11*). Hold the device steady until the screening process is complete.



Figure 11

You can also turn the capture sound on and off by pressing the  icon in the bottom left corner of the capture screen.

NOTE: Do not power off Spot during a screening. Instead, exit the screening by selecting the , then power down the device normally.

If you are unable to capture the subject or select the exit icon  from the screening process, you will be presented with a Screening Options menu (Figure 12). From here you can try to Re-Screen subject again, switch to Monocular screening mode, Flag the subject as unscreened, or return to the Main Menu. Selecting the exit icon  will return you to the subject information screen.

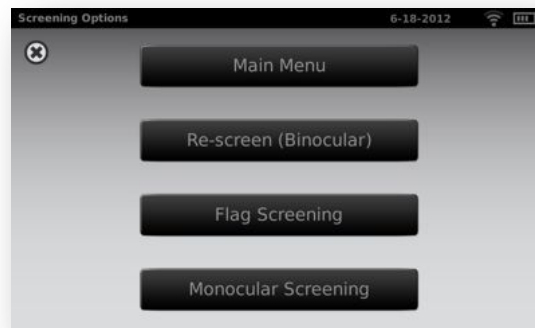


Figure 12

Monocular Screening

In monocular mode, you will be given the option (Figure 13) to choose which eye to screen. Simply touch the side of the screen that corresponds with the eye you would like to screen. When complete, you can repeat the process with the other eye by choosing Monocular from the Results Menu.

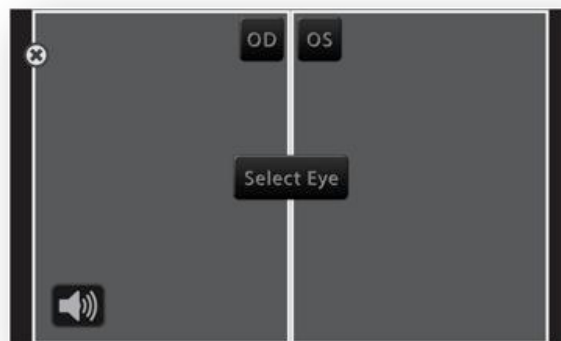




Figure 13

Viewing the Results

The results screen will appear at the end of the screening process (*Figure 14*).

Results that are out-of-range are indicated in red. The screener/user will make the final recommendation regarding a follow up exam with an eye care professional.

On the Results screen, you can toggle the results data between raw and formatted results by touching the values in the box under the eyes. You can also toggle between positive and negative cylinder conventions by selecting the **CYL** label found between the boxes. At any time you can select  to close this screen and return to the main menu or select the **continue icon**  for additional options.

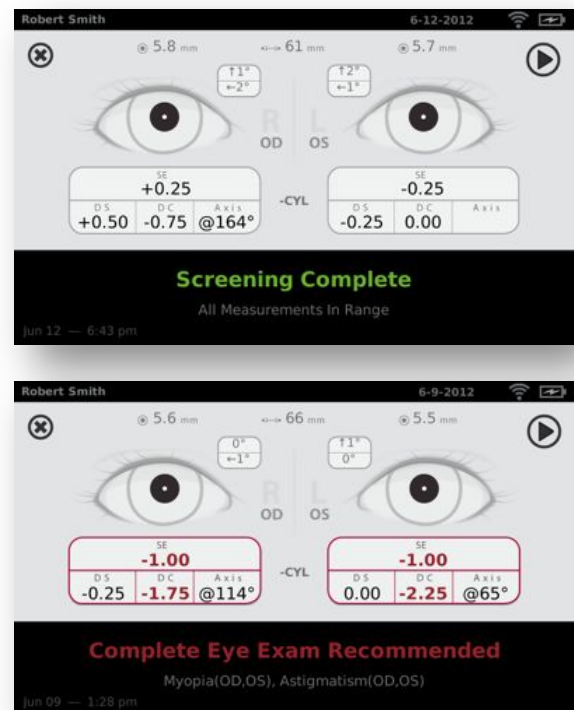


Figure 14

From the Results Menu screen (*Figure 15*), you can print the screening results certificate, re-screen the current subject, switch to monocular mode or return to the Main Menu.

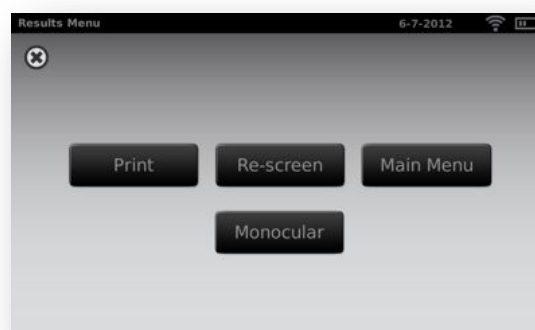


Figure 15