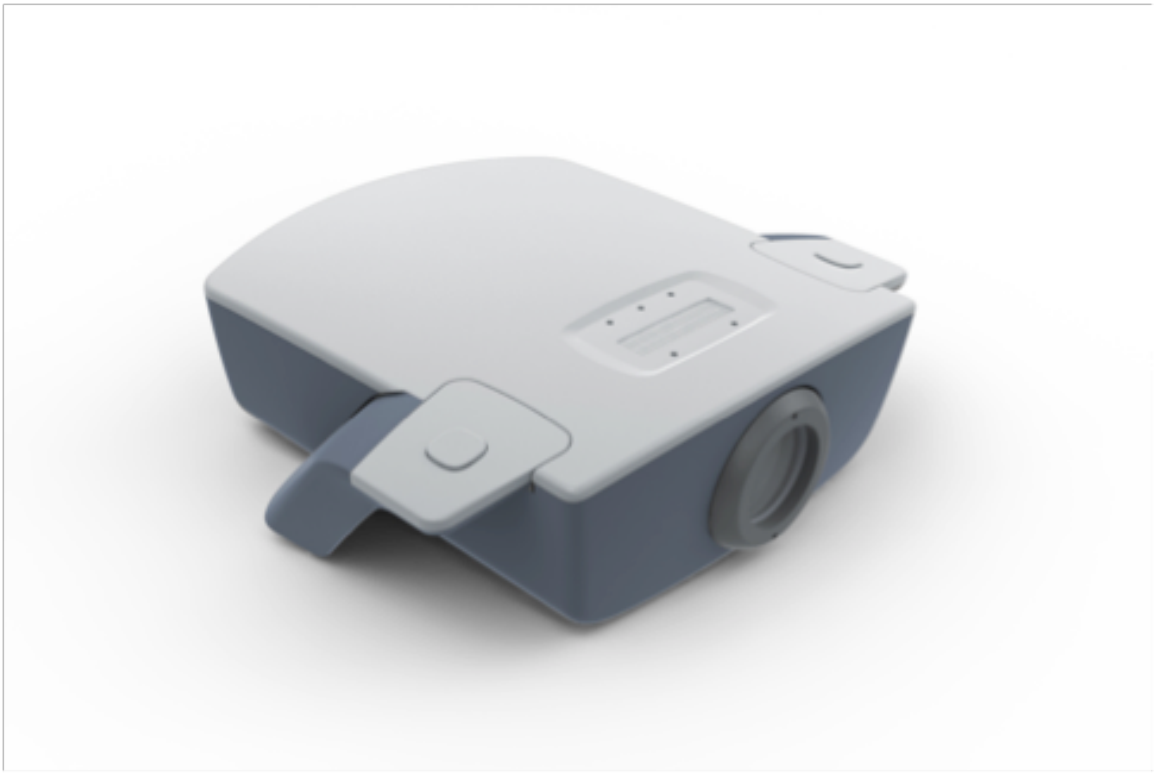
REBIScan, Inc.

Pediatric Vision Scanner



User Manual, version 1.0

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Product Information

Document Applicability

This document describes the controls and operation of the Pediatric Vision Scanner (PVS). This document applies to PVS-4, unless superseded. The device is indicated for professional use only in the office or clinical environment.

Introduction to the Pediatric Vision Scanner

The Pediatric Vision Scanner (PVS) is a hand-held vision screening device.

Indications for Use

The Pediatric Vision Scanner is intended to screen for amblyopia and/or micro-strabismus associated with amblyopia in children between the ages of 2 and 8 who are responsive to taking direction and who can pay attention for short periods of time. The device is indicated for professional use only in the office or clinical environment.

Symbol Key

The following symbols are displayed throughout the User Manual.

	**Note/Consult user manual** There are important operating and maintenance instructions found in the manual.
	**Warning** Warnings or alerts about situations that, if not avoided, could lead to personal injury or device damage.
Rx only	Federal law restricts this device to sale by or on the order of a physician.

Contraindications

The PVS is not a substitute for a comprehensive eye examination in patients with systemic disease who are at risk for ocular disease; for example, juvenile idiopathic arthritis and neurofibromatosis.

Children with obvious ocular abnormalities (such as grossly visible strabismus, corneal scarring, cataract, ptosis (drooping eyelid)) should be referred regardless of the PVS result.

Children with acute ocular problems such as eye trauma, conjunctivitis, blepharitis, chalazion, and nasolacrimal duct obstruction should be referred, or testing should delayed until the condition has resolved.

Clinical testing of the PVS excluded children exhibiting the conditions listed above. The device should not be used as a substitute for a comprehensive eye examination.

	**Note** The PVS does not attempt to identify risk factors for amblyopia or strabismus. It is designed to detect amblyopia and/or strabismus if or when these conditions are present or develop.

	**Note** Patients with **intermittent strabismus** that is well-controlled may be able to pass the PVS test because their strabismus is not manifest during normal binocular viewing, whereas patients with intermittent strabismus that is poorly controlled will not be able to pass the PVS test. If grossly visible strabismus is present, the patient should be referred to an eye care specialist.
	**Note** Some patients with **incomitant strabismus** (variable angle depending on gaze direction) may require a compensatory tilt or turn of the head in order to maintain good binocular alignment. Children who persistently exhibit an abnormal head position should be referred to an eye care specialist.

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Device Specifications

Laser Classification	Class 1 Laser product	
Scanning Laser	A laser diode, 830 nm wavelength. Class 1 Laser product at device exit.	
Rangefinder Lights	A laser diode, 650 nm wavelength. Class 1 Laser product at device exit.	
Data Acquisition Time	< 5 seconds	
Physical Dimensions	26.45 L x 31.48 W x 9.41 H (cm)	
Physical Weight	2.7 kg (6 lbs)	
Electrical Ratings	100-240 V	
	50/60 Hz	
	50 VA	
Environmental Conditions	***Transport and Storage***	***Operation***
Temperature	-40°F – 140°F (-200°C – 60°C)	50°F – 95°F (10°C – 35°C)
Relative Humidity	10% – 85%, non condensing	10% – 85%
Atmospheric Pressure	50 – 106 kPa	70 – 106 kPa
Altitude	NA	≤ 2,000 meters
Compliance	*The PVS complies with the following standards*	
Basic Safety	• IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)	
EMC Safety	• IEC 60601-1-2: 2007-03	
Optical Safety	• IEC 60825-1: 2007	
	• EN ISO 15004-2	
	• 21 CFR 1040.10	
	• 21 CFR 1040.11	

	**IMPORTANT!** Read and understand the entire User Manual before operating the device. If you have any questions concerning the use, please contact customer service.
Rx only	Federal law restricts this device to sale by or on the order of a physician.

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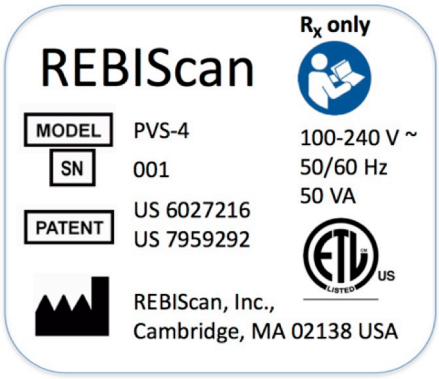
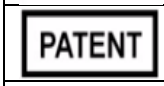
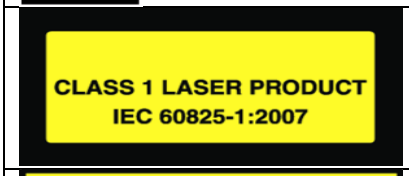
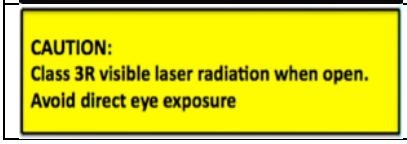
Labeling and Warnings

	Label affixed to device
	Serial number
	Model number
	Patent number(s)
	Manufacturer
	Class 1 laser product: adheres to IEC 60825 standard
	Class 3B invisible laser radiation when open; service personnel avoid exposure to the beam
	Class 3R visible laser radiation when open; service personnel avoid direct eye exposure.

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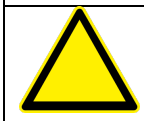
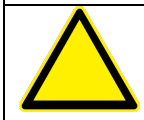
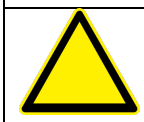
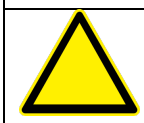
Operational Safety

	**Note** This device is not at risk of interference with other medical devices.
	**Warning** To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.
	**Warning** This instrument may cause ignition of flammable gases or vapors. Do NOT use in the presence of flammable anesthetics, or in the presence of pure oxygen.
	**Warning** No user serviceable parts.
	**Warning** Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
	**Warning** Do not open the instrument cover. There are no serviceable parts inside. Opening the instrument covers could expose you to electrical and optical hazards. Refer service to REBIScan, Inc.
	**Warning** Do not attempt to open the protective housing of the PVS for any reason. Radiation inside the protective housing could cause personal injury! No user maintenance is required. Refer service to REBIScan, Inc.
	**Warning: Phototoxicity!** Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. This device should be used with filters that eliminate UV radiation (< 400 nm) and, whenever possible, filters that eliminate short-wavelength blue light (< 420 nm). The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit. While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.
	**Note** The fundus illumination brightness of the PVS is not adjustable. It is factory set to a level that optimizes the exam efficacy and minimizes light exposure of the subject.

	**Note** The PVS uses visible and infrared light to measure properties of the retinal nerve fiber layer and uses no ultraviolet light (< 400 nm). Ultraviolet protection by the use of filters or other optical apparatus is neither required nor approved.
	**Warning** Do not insert a lens, mirror or other optically active device (other than prescription spectacles or contact lenses) between the system and the patient. Doing so may result in a higher than normal energy density in the eye that could injure the patient.
	**Warning** This instrument has no special measures to protect against harmful ingress of water or other liquids. Do not place containers of liquid on or near the instrument, nor use aerosols on or near it.
	**Warning** The PVS weighs approximately 6 pounds. To avoid injury, exercise proper lifting techniques when lifting or moving the PVS
	**Warning** In case of emergency related to the instrument, unplug the power cord from the wall outlet and call for service immediately.
	**Note** Although this instrument is designed for continuous operation, it should be turned off when not in use for an extended period.

What to Do for the PVS

- **Always** handle the PVS with care.
- **Always** operate the PVS from a power source as specified. Use of a power source other than indicated on the unit will shorten the life of the unit and may cause damage in addition to improper operation.
- **Always** operate the PVS with the power cord inserted into a standard three-prong power outlet that is correctly grounded through normal wiring.
- **Always** unplug the PVS before transporting the PVS.
- **Always** unplug the PVS before cleaning the plastic body or LCD screen. If the LCD or other body panels require more than a dusting, apply a mild household cleaner to a soft cloth to clean them.
- **Always** confirm that the aperture lens is clean before testing patients (see Maintenance)

What Not to Do to the PVS

- **Never** position the PVS in direct sunlight or near a direct source of heat.
- **Never** position the PVS in a dusty location.
- **Never** install software or utilities on the PVS without prior approval from REBIScan.
    - Any unauthorized modification to the system will void the warranty and any repair costs for damage to the PVS may be billed to the customer.
- **Never** remove any panels to access the internal components of the PVS
- **Never** clean with harsh chemicals or detergents.
- **Never** use fluids or aerosol on or near the PVS. These products can damage the PVS surface and affect the delicate optics.

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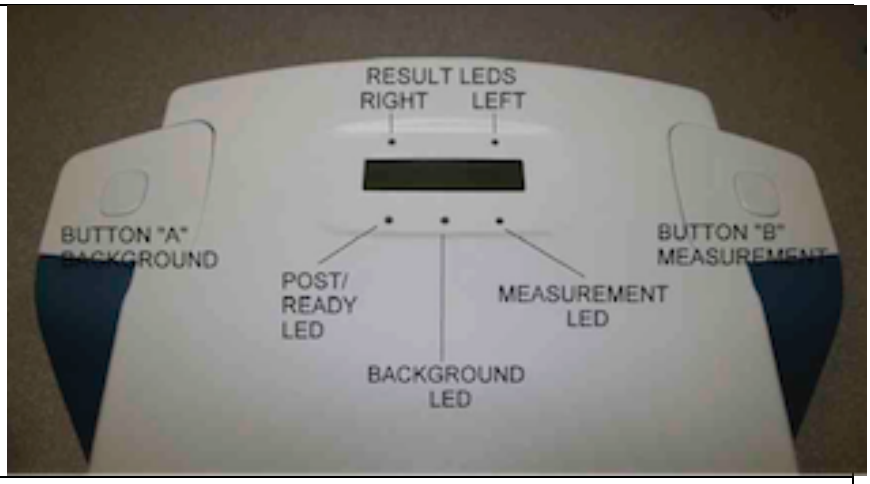
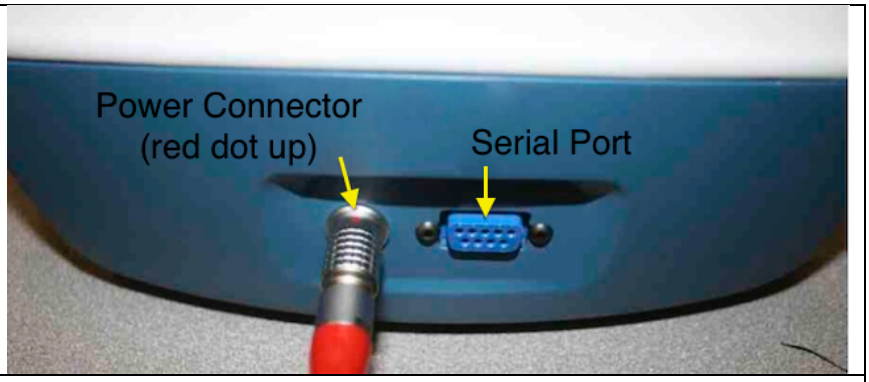
System Hardware Overview

The PVS integrates all hardware components in a unit, which includes the image acquisition optics, the system computer and visual display. The illustrations in this section label hardware elements. Directions for use are in the following sections.

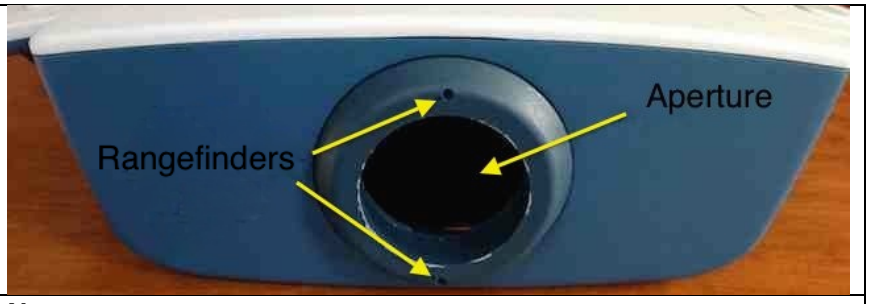
Top View

Diagram 1: Top View	
Button "A"	The button on the left-hand side of the device.
Button "B"	The button on the right-hand side of the device.
Post/Ready LED	Light to indicate power is on.
Background LED	Light to indicate stage of background measurement. • Blinking light indicates device is ready for background measurement. • Solid light indicates device has captured background measurement.
Measurement LED	Light to indicate stage of screening test. • Blinking light indicates device is ready for screening test. • Solid light indicates device has completed test.
Result LED Right	Light will illuminate upon completion of test. Right LED corresponds to the left eye of the patient • Green light indicates "pass" • Red light (solid or blinking) indicates "refer"
Result LED Left	Light will illuminate upon completion of test. Left LED corresponds to the left eye of the patient • Green light indicates "pass" • Red light (solid or blinking) indicates "refer"

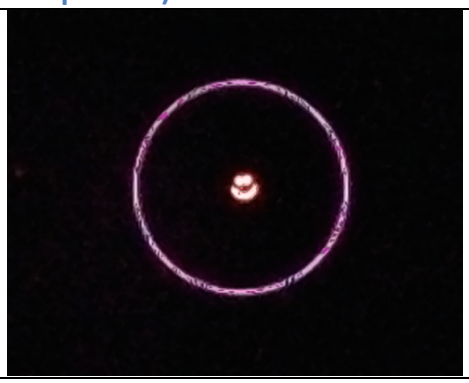
Rear/Connector View

Diagram 2: Rear/ Connector View	
Power Connector	The circular port on the left side of the rear of the device connects to the medical-grade power supply (shown later in **Diagram 7**). The power supply will only fit into the port with the red dot facing up. The unit will power on when the connector is in and the power cord is plugged into a wall. There is no power switch.
Serial Port	Serial ports on delivered devices are for service personnel only. They are not functional in the clinical setting.
	**Note** Attachments onto, and plugs into, the serial port will not alter any of the software, firmware, or safety of the device.
	**Warning** Do not insert or remove the power connector when the power supply is connected to an AC outlet. Doing so will damage the device and void the warranty.

Front View

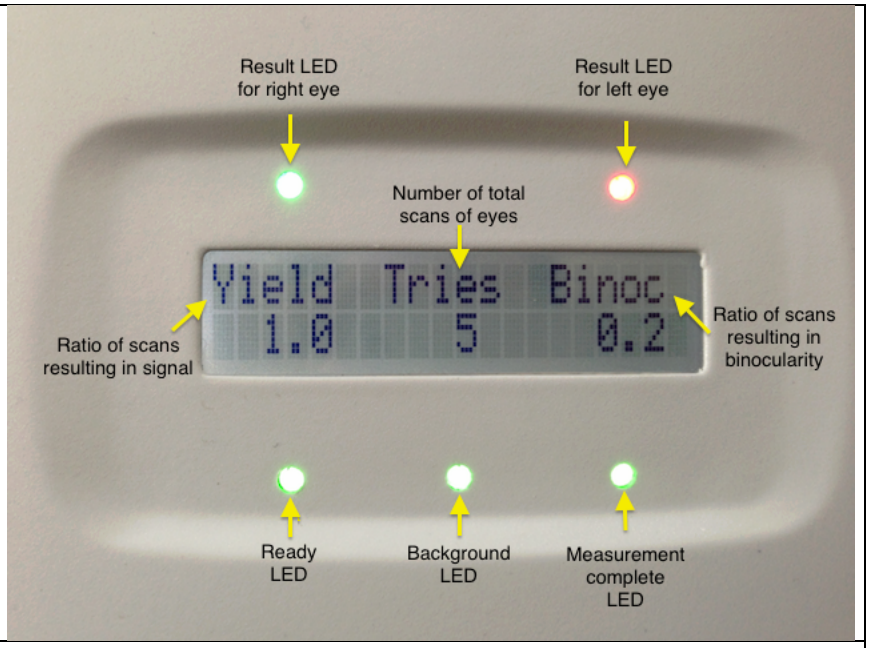
Diagram 3: Front View	
	Note **Diagram 3** is a modified view from the patient's perspective.
Rangefinder	There are two rangefinders: one above the center of the aperture, and one below the center of the aperture. The rangefinders assist the user in determining the correct distance (approximately 0.5 meters) of the PVS from the participant during the background measurement and test. The rangefinders are to converge on the bridge of the patient's nose to indicate the optimal distance. **Figure 1**, below, shows how the rangefinders appear when the device is too close (**A**), at correct distance (**B),** and too far (**C**, which appears identical to **A)**.
Figure 1: Rangefinder positioning	 **A**(too close) **B**(correct distance) **C**(too far)
	Warning Incorrect use of the rangefinder could result in an inaccurate test result.

Patient's View (View within the aperture)

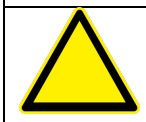
Diagram 4: Inside the Aperture	
Aperture	Inside the aperture there is a smiley face (fixation target) encircled by an illuminated, red ring (scanning laser). The ring illuminates automatically upon powering up the device. The smiley face illuminates when the Measurement LED (**Diagram 1**) is on.
	**Note** The red ring will be visible during both the background measurement and the vision test. The smiley face (fixation target) will only be visible during the vision test; it will illuminate after pressing "B" button once, and it will turn off once the test is completed.

Output View

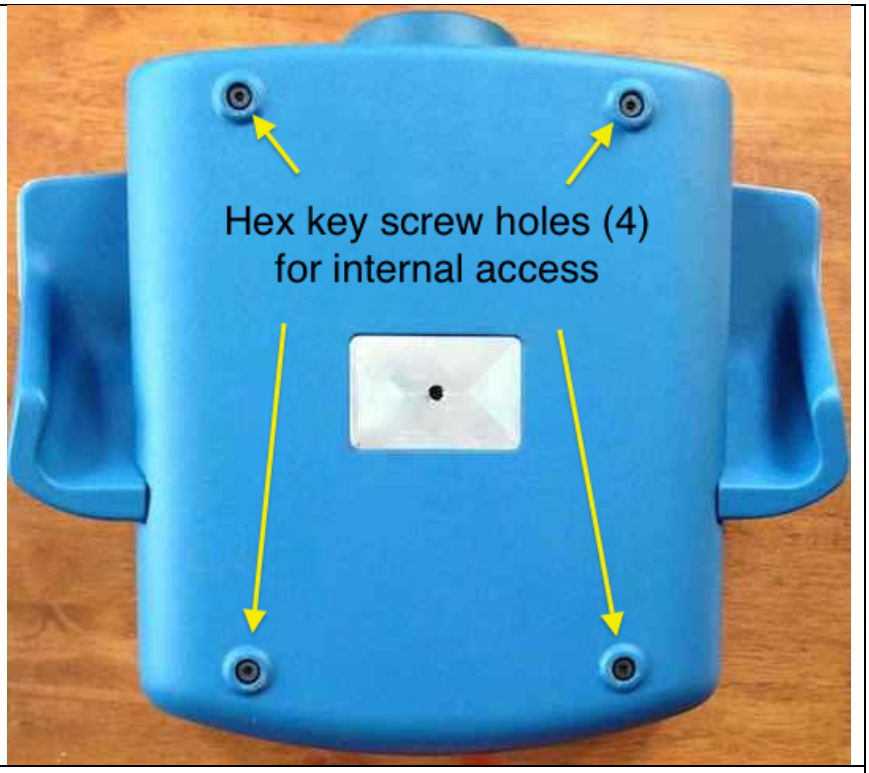
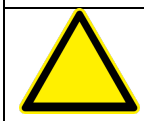
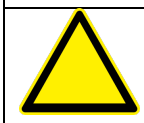
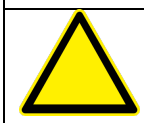
Diagram 5: Output View



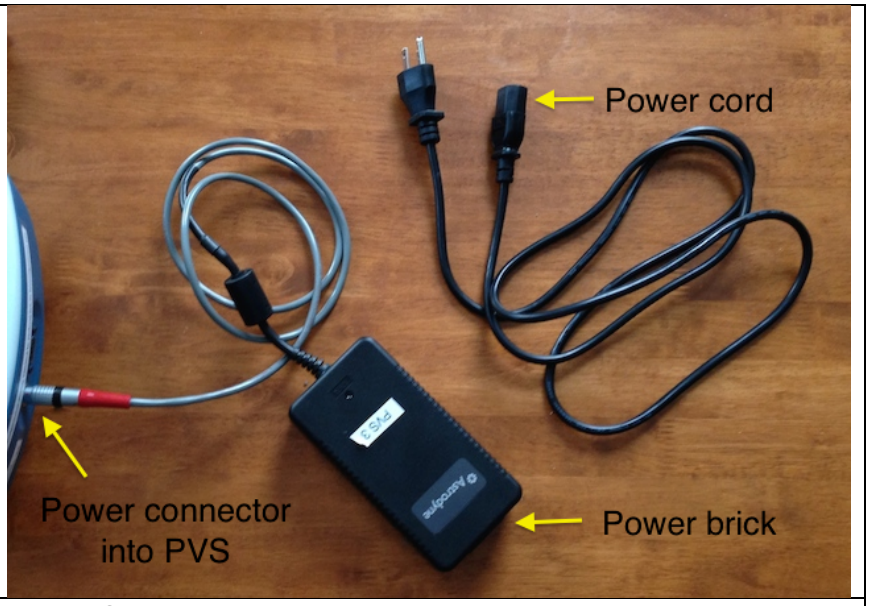
	Note This section explains the outputs on the LCD screen. Please refer to **Diagram 1** for detail on each of the LED lights.
Yield	When the user performs the test, the device captures information by scanning the retina of both eyes simultaneously for approximately 0.5 seconds. Each 0.5 sec scan of the nerve fibers is considered a single "Try". The device is programed to perform a minimum of 5 "Tries" (2.5 seconds total), but can perform as many as 10 (5 seconds total) before completing the test. At the completion of each "Try", the device determines whether a usable measurement, deemed fixation detected from at least one eye, was obtained. The Yield is then calculated at the end of the test as follows: $$\text{Yield} = \frac{(\#\text{ of Tries with at least one eye fixated})}{(\text{Tries})}$$
	Note The Yield value does not inherently determine the pass/refer output.
Tries	The number of scans performed during the test. The number will always be between 5 and 10. The exact number of tries is not under user control, it is determined by software
Binoc	Binoc is short for "Binocularity." The Binocularity score determines the final dichotomous output of "Refer" or "Pass".

	A minimum binocularity score of 0.6 (or 60%) is needed in order for a patient to receive a pass from the device, indicated by a green light. All binocularity scores below 0.6 will result in a refer recommendation, indicated by one or two red light. $$\text{Binoc} = \frac{(\#\text{ of Tries with simultaneous fixation})}{(\text{Yield} * \text{Tries})}$$
	**Warning** Final determination on whether a child should be referred to an eye specialist should be at the discretion of the prescriber depending on the specific clinical scenario. Factors to consider include the child's cooperation for the test, the overall medical status (including presence of chronic disease) and the presence of obvious structural abnormalities of the eye including gross strabismus or ocular malformations.

Underside View

Diagram 6: Underside View	
	**Warning** Do not open the instrument cover. There are no serviceable parts inside. Opening the instrument covers could expose you to electrical and optical hazards. Refer service to REBIScan, Inc.
	**Warning** *Service Personnel:* Class 3B invisible laser radiation when open; service personnel avoid exposure to the beam
	**Warning** *Service Personnel:* Class 3R visible laser radiation when open; service personnel avoid direct eye exposure.

Accessories

Diagram 7: Accessories	
Power Brick	The PVS is delivered with a medical-grade Astrodyne power brick and power connector. This is the only power supply that should be used with the PVS. The power connector is pre-attached to the power adapter, and is to be inserted into the rear of the unit, as seen previously in **Diagram 2, Rear/Connector View**. The power cord is to be attached to the power adapter, with the three-pronged end of the power cord to be plugged into a wall outlet.
Power Connector	The Power Connector comes attached to the Power Brick. The end of the Power Connector is to be inserted into the back of the PVS. The Power Connector appropriately fits into the PVS when the red dot on the Power Connector is facing upward. Please see **Diagram 2 Rear/Connector View** for reference. The Power Connector is spring loaded; to remove from the PVS device simply pull the perforated grip at the end of the Power Connector.
Power Cord	The Power Cord connects to the Power Brick. The end of the Power Cord is to then be inserted into a standard wall outlet.
	**Warning** These accessories are the only accessories that should be used with the PVS device.
	**Warning** Do not insert or remove the power connector when the power supply is connected to an AC outlet. Doing so will damage the device and void the warranty.

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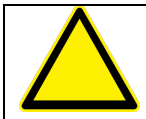
Software System

REBIScan pre-installs all software necessary to operate the PVS instrument. Software updates and installations will be managed and controlled by REBIScan.

	**Note** Instrument software does not allow for storage of data on tests beyond the most recent test result. We recommend archiving data by transcribing the results from the LCD screen and Result LEDs onto a storage medium after each test.

User Changes to Software or Hardware

The PVS is a medical device. The software and hardware have been designed in accordance with U.S., European and other international medical device standards designed to protect clinicians, users and patients from potential harm caused by mechanical, diagnostic or therapeutic failures.

	**Warning** Unauthorized modification of PVS software or hardware (including accessories) can jeopardize the safety of operators and patients, the performance of the instrument, and the integrity of patient data; it also voids the instrument warranty.

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Instrument Setup

Instrument Installation

A REBIScan service representative will deliver the PVS and perform the initial installation. The device is to be positioned onto a steady surface when installing or not in use.

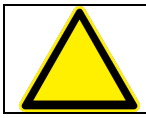
	**Note** The PVS device is intended for indoor use only.

Care in Handling

Use care when handling and transporting the PVS. The instrument contains fragile optics that have been precisely aligned at the factory.

	**Note** The PVS weighs approximately 6 pounds. To avoid injury, exercise proper lifting techniques when lifting or moving the PVS.

Installation Requirements

	**Warning** The PVS uses a medical-grade power supply, and is to be operated with a wall outlet allowing for 100-240V line voltage.

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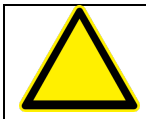
Testing Procedures

Powering on the PVS

1. Place the PVS on a sturdy surface
2. If the Power Connector (**Diagram 7**) is not yet attached to PVS, align the red-dot of the Power Connector to the red-dot on the rear-side of the device (**Diagram 2**). Push connector in until it is locked in place.
3. Connect the Power Cord (**Diagram 7**) to the Power Brick.
4. Plug the Power Cord into a three-pronged power wall or floor power outlet.
5. At this point the PVS will beep and power on automatically.

Powering off the PVS

Whenever the system will be left idle for more than 1-2 hours, it is recommended to turn off the power. To do so, unplug the cord from the wall or floor outlet.

	**Warning** You must power down the device safely. Not doing so may damage the system, or cause the PVS to fail to launch. Always power down the PVS by removing the Power Cord from the wall or floor outlet. Do not remove the Power Connector from the device while the power cord is connected to AC power.

Performing a test

With the PVS powered on the device is now ready for testing on a child. The PVS functions most accurately in dim light, which reduces stray light, removes distractions, and enhances the visibility of the target. In a dimly lit room, and the child sitting, or standing, with attention focused on the device, you may begin the testing procedures.

	**Note** Read all procedure steps to properly perform a test.
	**Warning** Improper testing procedures may result in incorrect test results.
	**Note** There is no safety risk to the patient if PVS testing is performed while the patient is wearing corrective lenses, but for efficacy of device testing, corrective lenses should be removed prior to PVS test.

Position the device

1. The child may be seated on a chair or on caregiver's lap, looking toward the operator.
2. Child should be facing the operator with no abnormal tilt or turn of the head.
3. Hold the PVS with both hands, level to the ground, aiming the aperture toward the child.

Figure 2: *Positioning the device*	

Make a background measurement

1. Position the device as noted above.
2. Press "A" Button (**Diagram 1**) once to turn on the rangefinder.
    - A single, audible beep will be heard, and the Background LED (**Diagram 1**) will begin to flash.
    - The rangefinder will illuminate.
    - The device is now in "background measurement" mode.
3. Position the PVS so that the rangefinder is on the bridge of the child's nose (**Figure 1**).
    - The child should be reasonably still during this procedure; if the child moves, reposition PVS for proper placement.
4. Adjust the distance between the PVS and the child until the two rangefinder lights are side-by-side
    - The two rangefinder lights will move up and down relative to each other, but will never overlap.
    - When they are side-by-side, the PVS is at the optimal testing distance.
5. Instruct the patient to close his or her eyes.
    - Young children may not be willing or able to close the eyes. In this case, the forehead of the child or of a parent may be used.
    - If the forehead is used for background, be sure that the rangefinder lights are positioned far enough above the eyes that the fixation target and red ring (**Diagram 4**) are not visible to the patient/parent.
6. Press the "A" Button once.
    - Keep the PVS level during the measurement.
    - The unit will beep once, pause, and then beep twice.
    - The rangefinder turns off.
    - The Background LED (**Diagram 1**) will turn solid.

	Note The eyes must remain closed throughout the entire background measurement. If the eyes open before the double beep at the end of the measurement, the background must be repeated.
	Note If the child cannot keep the eyes closed for the full duration of the background measurement, the measurement may be obtained from the caregiver (with eyes closed) or from the forehead.
	Note If the forehead is used for background, be sure that the rangefinder lights are positioned far enough above the eyes that the fixation target and red ring are not visible to the patient/parent.

7. Instruct child to open eyes.
    - Background measurement is complete.
    - Continue on to eye test procedure, or begin a new background measurement by returning to step 1, above.

	Note The background measurement minimizes signal interference from the eye test. The background measurement should be obtained immediately prior to testing, and a new background should be obtained prior to each test.
	Note Failure to perform a proper background measurement will invalidate the test.

Perform the measurement

1. Complete the “Make a background measurement” steps above.
2. Press “B” Button once.
    - The unit will beep once, and the Measurement LED (**Diagram 1**) will begin to flash.
    - The rangefinder turns on.
    - The device is now in measurement mode.
3. Position the device in front of the child with the aperture at eye-level to the child.
4. Adjust the distance between the PVS and the child until the two rangefinder lights are side-by-side (**Figure 1**)
    - The two rangefinder lights will move up and down relative to each other, but will never overlap.
    - When they are side-by-side, the PVS is at the optimal testing distance.
5. Instruct the child look directly at the smiley face fixation target (**Diagram 4**) in the center of the aperture.
    - The child should be focused exactly on the smiley face.
    - The head should not be turned or tilted to the side.
    - Strongly coax and encourage the child to discover the target to maximize the fixation and focusing ability.

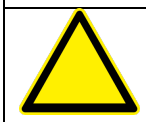
	**Note** The child should hold the head in approximately the normal straight-ahead position so that testing is performed in primary gaze without a head tilt or turn. If the child cannot do so despite encouragement, referral may be necessary.

6. Press “B” Button once.
    - The device will beep rapidly until test is complete, at which point Measurement LED will turn solid.
    - The child should sustain attention on the target throughout the measurement.
    - If the child looks away, the measurement may need to be reattempted.
7. Observe and record results from Result LEDs (**Diagram 1**)
    - The dichotomous results for each combination are shown below in this table:

Right LED	Left LED	Output
Green light	Green light	Pass
Red light	Green light	Refer
Green light	Red light	Refer
Red light	Red light	Refer bilateral

    - The LCD screen (**Diagram 5**) provides additional information.

	**Note** When both Result LEDs red, the result is a “refer bilateral.” When the PVS is used according to the user manual, this result can appear for one of two reasons: 1) the child has a medical condition that blocks the signal of light in each eye, or 2) the child was not able to cooperate sufficiently to fixate on the target during the procedure. The prescriber of the test is instructed to base the decision to refer in each case upon the totality of ocular information captured during the entire visit including, for example, the child’s attention to the target during the test procedure and the overall developmental status.
	**Note** In clinical trials, users were instructed to perform this test procedure only once on each child enrolled. In cases of “refer bilateral”, the user was asked to attempt the test a second time. The number of tests performed in practice is at the discretion of the prescriber, however, it is believed that no more than two tests per child are required. After more than two tests, younger children are likely to lose interest in the fixation target.

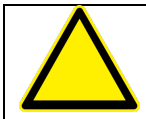
	**Note** The PVS does not export results to any medium beyond the PVS itself. The user must take care in transcribing the LED results onto the patient's medical record or chart for future reference.
	**Warning** While clinical studies have shown the PVS to be highly accurate at detecting certain eye conditions, no medical device is 100% accurate. False positive and false negative results are possible. The PVS is not a substitute for a comprehensive eye examination.

REBIScan

Maintenance

Routine Cleaning & Disinfecting

The device exterior, including the aperture lens and LCD screen, are the only parts that require routine cleaning and, potentially, disinfecting; no risks will result from multiple cleanings. The device has no serviceable parts. Cleaning throughout the life of the product will not interfere with performance of device, or create any risks on the part of the user or patient.

	**Warning** The instrument has no special measures to protect against harmful ingress of water or other liquids (classified IPX-0-0—ordinary equipment). To avoid damage to the instrument and a safety hazard, cleaning solutions, including water, must be applied sparingly, with a non-linting cloth that is dampened only—not dripping wet! You must not use aerosols on or near the instrument.

Aperture Lens

The aperture does not contact the patient's eye in normal use. Still, you should clean it regularly to remove dust and oil smudges, ensuring true results. Use an optical lens solution such as Windex™ or eyeglass cleaner with a lint-free cloth to clean the lens.

	**Note** Wipe gently and carefully to avoid scratching the lens. Rub gently in a circular motion to remove dirt or foreign matter. Do not use harsh materials or chemicals.

Instrument cover

	**Note** When dusting of the instrument is necessary, use a dry, soft, lint-free cloth. Do not use aerosols, as these can penetrate the instrument covers and damage the instrument.
	**Note** When the instrument cover requires cleaning, wipe with a lint-free cloth or cotton swab that has been moistened with water (dampened only, not dripping wet). Disinfect with an alcohol wipe (70% Isopropyl). Wipe dry with a clean, soft, lint-free cloth.

Inspection & Maintenance

The user should use care to regularly inspect the external structure of the device to assure that no potential hazards device develop. No unacceptable risk will result from prolonged lack of use.

	**Warning** Internal component inspection and maintenance should only be performed by REBIScan service personnel. REBIScan will make available to service personnel the following: diagrams, component lists, descriptions, and calibration methods.

Power Connector, Cord, and Adaptor

Inspect the cords regularly to assure that wires have not become exposed as a result of use. Also inspect the Power Brick for cracks or breaks in the casing. If wires become exposed, or cracks develop in the Power Brick, discontinue use of the device and contact REBIScan at 857-600-0982; replacement accessories will be delivered.

Calibration

The PVS is calibrated by REBIScan prior to shipping and does not require calibration in the field. If you suspect that the device is malfunctioning, you may call REBIScan at 857-600-0982. If we are unable to troubleshoot your concerns, then REBIScan will coordinate efforts to replace the unit.

Storage & Transportation Condition

Whenever the system will be left idle and stored, it is recommended to disconnect the power and place the device in a safe, dry location. There is no restricted shelf life of the device, so only routine inspection, detailed above, is necessary when removing device from storage.

Appropriate environmental conditions for storage are listed in the Specifications section of the manual.

Instrument Disposal

When it comes time to upgrade your PVS, please contact REBIScan to inquire about trade-in or upgrade values we may offer. If you wish to dispose of the device, please contact REBIScan at 857-600-0982 for disposal directions. Do not dispose of the device yourself, unless it is in accordance with local and national electrical and electronic equipment recycling requirements.

REBIScan

Troubleshooting

If you are unable to resolve a problem with your PVS please contact REBIScan customer service at 857-600-0982.

PVS Will Not Power on

First make sure the Power Connector is correctly aligned into the PVS, and that the Power Brick is connected to the Power Cord. If the Power Cord is plugged into an active outlet and still does not turn on, contact REBIScan's customer service.

I cannot see the smiley face when I look into the opening

The "smiley face" fixation target is only visible in measurement mode. It is not visible during background measurement or in any other state of operation.

The child will not stay completely still during testing

The device was designed to be a handheld unit so as to account for the variability in a child's stillness and attention. The patient's head is not required to be perfectly stationary. Most developmentally normal children are able to maintain sufficient head stability and fixation in order to complete the test. However some children may simply not be in the mood to look for the smiley face; in these situations, the prescriber must use other available clinical information to decide whether to re-test or refer.

My eye specialist tells me that I am falsely referring patients with the PVS

Certain factors can be addressed to increase your confidence in the performance of the PVS. Here are factors that you can attempt to manage to enhance device performance.

Operator Influence:

- Be sure that the aperture lens is clean and free of dust or scratches.
- Read the User Manual in its entirety to become comfortable with the testing setting and procedures
- Confirm that proper training has been provided to all users of the device. If required, REBIScan will provide additional training.
- Carefully review the background measurement procedures. The device will not produce valid results without a proper background measurement.

Patient Influence:

- Responsiveness to directions is key to performing a valid PVS test. The following external factors may interfere with a child's willingness or ability to cooperate:
    - Energy level
    - Attentiveness
    - Interest in, or fear of, being in a doctor's office

Ambient Setting Influence:

- The device should be used in a quiet setting with dim, indirect illumination.

I am unable to confirm the accuracy of the results

The quality and reliability of the device results are standardized within the software. Results on the device require only visual interpretation, however, the prescriber should utilize the PVS results in conjunction with other pieces of information collected at the time of visit to determine whether a patient should be referred to an eye specialist. This will include assessment of developmental status, patient cooperation, family history of strabismus or amblyopia, other relevant signs or symptoms of ocular disease, and the presence or absence of gross structural abnormalities of the eye or eyes.

Unfamiliar outputs appear on the LCD screen

In the highly unlikely event that the LCD screen produces an output inconsistent with the information presented in **Diagram 5**, the user may encounter one of the seven (7) messages below. None the messages indicate any risk or harm to the patient or user.

If the device presents these messages, please discontinue use and contact REBIScan's customer service.

ERROR	The system has turned off all lasers and the motor.
ERROR ADC	The right and left channel detector sampling was not completed.
ERROR MOTOR TIMEOUT	System timed out waiting for a pulse of the motor tachometer.
ERROR MOTOR SPD	The speed of the motor is out of its allowed limits.
ERROR EEPROM	The trial results and calibration data were unable to be read.
ERROR LASER FLT	The fault line of the laser driver is set.
ERROR LASER PWR	The measured power of the laser was above allowable limits, and the laser has been shut down.