

Reference and Instruction Manual

Functional Vision Analyzer



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P/N 56184

Introduction

Congratulations! You have just received the most sophisticated and state of the art vision testing system on the market today!

The Functional Vision Analyzer is a precision vision testing device that can be used as a clinical testing device or used for vision testing for research and clinical trials. The Functional Vision Analyzer's precision illumination is continually controlled by a microprocessor for accuracy and repeatability of the tests. The exclusive LED (light emitting diode) system allows complete homogenous illumination that eliminates hot spots on testing slides, which can create inaccuracies of test results.

The instrument is designed to do quick, accurate, reliable and confidential testing. Please take a few moments to familiarize yourself with the Functional Vision Analyzer.

Safety Aspects

Symbol Definitions:



- Attention, consult the accompanying documents.



- Caution



Type B applied part.

Use this device properly and safely.



BEFORE USE OR MAINTENANCE, READ THIS MANUAL.

This operator's manual contains information necessary for the operation of the OPTEC FVA Vision Tester. This manual includes operating procedures, safety precautions, and specifications. IEC standards are applied in this manual.

Safety Precautions

In this manual, a signal word is used to designate the degree or level of safety alerting. The definitions are as follows.



CAUTION indicates a potentially hazardous situation which, if not avoided, may result in injury or property damage.

Even situations indicated by “CAUTION” may result in serious injury under certain conditions. Safety precautions must be strictly followed at all times.

Handling Precautions

Before use of instrument **CAUTION**

-Do not use the device for other than its intended purpose.

-This device is not intended to be used in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

STEREO OPTICAL will assume no responsibility for accident or malfunction caused by improper use

-Never modify or touch the internal structure of the device. Electric shock or malfunction may result. There are no user-serviceable parts inside the device.

-Verify that the following specified environmental conditions for installation are met. In addition, verify that usage area meets the following conditions.

Make certain that the instrument is operated in the following environment conditions:

- Humidity 30% to 75%
- No large amount of dust is contained in the air.
- Subdued ambient light.
- Locate instrument in a place free from vibration or impact
Locate instrument on a stable surface.

Place instrument in a place free from vibration or impact
Place instrument on a stable surface

Be sure that a power outlet meets the power requirements.

If the supplied voltage is too high or low, the device may not deliver full performance and malfunction, or fire may result.

Be sure to use the power supply that came with device. Using any adapter other than the supplied one may result in malfunction, or may void the warranty.

Do not use an extension cord when supplying the device with power.

Be sure to connect using a grounded outlet. Electrical shock or fire may result in event of malfunction or electrical leakage.

Never crush or pinch the power cord with heavy objects. Damage may result in electrical shock or fire.

Before connecting the electronic control panel cable to the instrument, turn the instrument OFF and disconnect the power supply from the power outlet.

Usage Precautions



CAUTION

The device has been tested and found to comply with the limits for the medical devices to the IEC 60601-1-2 and EN55011. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This device generates uses and can radiate radio frequency energy. If not installed and used in accordance with instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that the interference to other devices, which can be determined by turning the device off and on, is caused by this instrument. The user is encouraged to try to correct the interference by one or more of the following methods:

Reorient or relocate the receiving device.

Increase the separation between the device

Connect the device into an outlet on a circuit different from that which was previously used.

Consult STEREO OPTICAL for help

Connect the cable to the interface connector securely, maintaining the correct orientation of the connector of the cable.

If power to the device is interrupted by moving the cord, or the plug or cord becomes extremely hot, this indicates that the cord is damaged. Immediately replace the power cord by contacting your authorized distributor for replacement.

In case of malfunction, immediately unplug the power cord from the power outlet and contact your authorized distributor for replacement; otherwise, electric shock or fire may result.

In the even that a strange odor or smoke is coming from the device, turn it off and unplug the power cord immediately. After confirming the odor or smoke in no longer being produced by the device, contact your authorized distributor. Continued use may result in electric shock or fire.

Maintenance



CAUTION

-Only service technicians trained properly by STEREO OPTICAL may service the device. STEREO OPTICAL assumes no responsibility for accidents resulting from improper servicing.

There are no user-serviceable parts inside the device.

All returns must have a Return Material Authorization Number.

Disposal

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components. It is recommended to commission the disposal to a designated industrial waste disposal contractor.

-When disposing of packing materials sort them by material and follow local governing ordinances and recycling plans.

Power Supply:

Input Voltage: 100 – 240VAC, 50 – 60Hz, 1.5A



CAUTION

Be sure to use the power supply that came with the device. Using an adapter other than the supplied one may result in malfunction, and will void the warranty.

Be sure to connect the power supply using a grounded outlet. Electrical shock or fire may result in event of malfunction or electrical leakage.



CAUTION

The power supply plug must remain easily accessible in the case of an emergency.

In the case of an emergency the device can be de-energized by disconnecting the power from the AC outlet.

Labels and indications on the device

Warning labels and indications are affixed on the device. If the device's labels are removed, contact STEREO OPTICAL or your authorized distributor.





Attention, consult the accompanying Documents.

Any applied parts on this device are classified as Type B

Environmental Conditions

The environmental conditions (Humidity, Temperature and Pressure/Altitude are as follows:

- Operating Temperature: 10°C - 40°C
- Operating Humidity: 30% - 75%
- Operating Atmospheric Pressure: 700 – 106 kPa
- Handling Requirements:

Temp: 18°C to 49°C,

Humidity: 10% - 91%

Pressure: 93 – 106 kPa

Maintenance Troubleshooting

In the event that the device does not work correctly, correct the problem according to the following table before contacting your authorized distributor

Suggested action:

If the device will not work at all

Make sure that the power cord is connected properly

Make sure that the cord of the power supply is connected properly. Make sure that the voltage applied to the power outlet is within the specified range.

Contact STEREO OPTICAL or your authorized distributor if the above suggestions do not eliminate the corresponding problem.

Cleaning

When the cover or panels of the device becomes soiled, wipe with a soft cloth. For stubborn soiling, immerse the cloth in a neutral detergent diluted with water, and wipe. Finally wipe with a dry, soft cloth.



CAUTION

Never use an organic solvent such as paint thinner. The surface of the device may be damaged.

Never use a sponge or cloth containing excessive moisture to wipe the device. The water may leak into the inside of the device and cause device malfunction.

- If the fixation lamps are smeared, proper measurements cannot be performed.

Specifications and Classifications

Classifications

This equipment has been evaluated to: ANSI/AAMI ES60601-1 (2005),

CAN/CSA-C22.2 No. 60601-1 (2008)

[Type of protection against electric shock]

The Optec FVA Vision Tester is classified as Class 1

A Class 1 is a device in which the protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in such a way that means are provided for the connection of the device to the protective (ground) conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure in the basic insulation.

[Degree of protection against electrical shock] Type B Applied Part

The Optec FVA Vision Tester is classified as a device with a Type B Applied Part.

A Type B Applied Part provides a particular degree of protection against electrical shock. Particularly regarding the following:

Allowable leakage currents

Reliability of the protective earth connection (if applicable)

The Optec FVA Vision Tester is classified as an ordinary device without protection against liquid intrusion.
Avoid exposing water or other liquid to the device

External Features

Forehead Activator: Controls illumination inside the vision analyzer. It will only activate the lights when the subject maintains pressure against the activator, insuring the subject to be at a proper distance for testing. When forehead pressure is applied to the bar, the green "Ready" indicator will be illuminated on the control panel and the subject will be ready to be tested.

Headrest Tissue: The tissue cushions the subject's forehead while allowing maximum hygienic conditions.

Lens System: The upper lenses are for FAR Point testing (simulated distance of 20 ft.) The subject looks straight ahead. The lower lenses are for NEAR Point testing (simulated distance of 16 in.) with the subject looking down while holding his/her head straight. The lenses are easily accessible for cleaning and the faceplate is wide enough to accommodate wide, contemporary eyeglass frames.

Instrument Base: It gives a stable foundation for the vision analyzer in all positions.

Elevation Adjustment: Simply depress the button in the base and adjust the instrument to the desired height for each subject. Release button and the instrument is locked in place.

Observation Doors: Located on both sides of the instrument, allow the tester easy access to both FAR and NEAR test slides. A pointer can be used by the tester to assist the subject in identifying the targets. The pointer is held in place by clips inside the door. The doors are held closed with magnets.

FAR and NEAR Indicators: Located on both sides of the instrument, these lights indicate how the instrument is set, to test accordingly.

Test Dial and Knob: Located on both sides of the instrument, is used to change slides in the viewing area. The numbers on the dial correspond to the numbers on the record form for identifying the test slide. The number under the lit indicator is the number of the test in the viewing area. On the (motor-driven) vision analyzer, this small knob should not be used. All slides should be advanced from buttons on the remote control panel.

Digital Control Panel: Operates the functions of the vision analyzer, power switch, right and left eye switches, Near and Far switches, Day and Night switches, glare switch, and the peripheral test controls.

Instrument Body: The Instrument Body is lightweight and is made of flame retardant ABS plastic.

Carrying Handle: Built-in for maximum convenience. The rigid handle and lightweight body aid in ease of portability. Ancillary Lens Holder



- 1. Forehead Activator
- 2. Headrest Tissue Holder
- 3. Lens System
- 4. Instrument Base
- 5. Elevation Adjustment
- 6. Observation Door

- 7. Far and Near Indicators
- 8. Test Dial & Knob
- 9. Receptacle for power cord and control panel
- 10. Instrument Body
- 11. Carrying Handle
- 12. Ancillary Lens Holder
- 13. On/Off Button



Internal Features

- An advanced Day and Night lighting system renders a white homogeneous light, resulting in high contrast images and truer color reproduction.
- The microprocessor controlled homogeneous illumination system assures accurate and repeatable testing results.
- Front surface mirror offers a ghost-free image for more accurate testing of distance vision. The instrument also includes glare system for use in both day and night testing conditions.
- Up to 12 test slides are mounted on a rotary drum. The slides can easily be removed or replaced in seconds.
- Stereo Optical's slides are manufactured from a high-resolution photographic film mounted between 2 layers of glass. The high resolution of (500/line pairs/mm) affords a much finer acuity level for more accurate testing.
- Stereo Optical's slides are trans-illuminated to eliminate glare and reflection. The result is a more accurate image, resulting in a more accurate test.

Advanced Design Control Panel

The control panel is designed for convenience in both operation and maintenance. The figure on next page shows the control panel for the Functional Vision Analyzer.

Right Eye:  The diagram shows a small circle on the left and a larger circle on the right containing an eye icon with an 'R' above it, representing the right eye selector.

When the forehead activator is depressed, the right eye will see the test target. When the switch is turned OFF, the right eye will see nothing. To turn switch ON, depress; to turn switch OFF, press again.

Left Eye:  The diagram shows a larger circle on the left containing an eye icon with an 'L' above it, and a small circle on the right, representing the left eye selector.

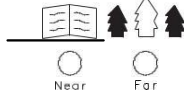
When the forehead activator is depressed, the left eye will see the test target. When the switch is turned OFF, the left eye will see nothing. To turn switch ON, depress; to turn OFF, press again.

Binocular:

When both the left eye and right eye are activated, a binocular test is being performed. Day or Night can be used for either monocular or binocular tests. Glare can be used for binocular or monocular testing and Day or Night conditions.

Day/Night Switch:  The diagram shows a sun icon above a circle labeled 'Day' and a moon icon above a circle labeled 'Night', representing the Day/Night switch.

When the FVA is initially turned on, the instrument defaults to daytime testing (85cd/m^2) Depressing the switch one time changes the testing conditions to Night (3cd/m^2)

Far/Near Switch:  The diagram shows an open book icon above a circle labeled 'Near' and a house icon above a circle labeled 'Far', representing the Far/Near switch.

When the power switch is on, the unit is set for FAR point testing. The testing distance simulated in the instrument is 20 feet. Cycle the test appropriately to achieve the test you desire according to the Near and Far indicators.

Power Switch:

Master On/Off power, (located on the back of the instrument) depress ON, press again for OFF.

Ready Light:

Green light indicates that the subject is pressing against headrest activator and is at proper testing distance.

Perimeter Switches:

Functional Vision Analyzer with perimeter. The perimeter function is to test the lateral (horizontal) visual field. Four switches pertain to peripheral vision testing. All are momentary switches (they stay on only if pressure is applied.)

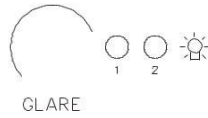
45° nasal 70° temporal
55° temporal 85° temporal

The same switches are used for testing both eyes, right & left. Depress the eye selector for the eye that is to be tested.

Forward and Reverse Switches:

This switch determines direction of the slide advancement. Pressing this switch once advances test slides one at a time. Holding this switch down allows for continual advancement of the test slides, until the desired slide is in the correct position.

Glare:



This switch determines the glare levels that will be used during testing. Pressing the Glare Switch once will put the FVA in the Glare Level 1 mode. Pressing the Glare Switch twice will put the FVA in the Glare Level 2 mode.

Glare Level	Day	Night
1	10 Lux	1 Lux
2	135 Lux	28 Lux

Functional Vision Analyzer Control Panel



Vision Testing--The Right Way

- Look into the instrument and note what happens when the eye switches are ON and OFF.
- Experiment with viewing FAR point slides at NEAR point and vice versa, by dialing through all 12 slides. First, view all slides in the FAR point mode, and then repeat in the NEAR mode. Note: *FAR test slides viewed at NEAR position are upside-down, as are the NEAR test slides viewed at FAR position*
It is important to recognize whatever the subject may be describing and be able to answer any questions.
- Concentrate on acquiring a smooth delivery of instruction and description of the test target, as well as confidence in handling the instrument. The tester's administrative expertise can help relax the subject, achieve cooperation, and a more accurate response.
- When speaking to the subject, never act surprised or provoked by their response or lack of response. Give the subject every opportunity to demonstrate his/her best vision. If the subject normally wears glasses or contact lenses, he/she should wear them during the testing to determine whether or not his/her prescription is still adequate.
- Select a table or counter of convenient height with sufficient surface space for the instrument and the recording of the results. Normal room lighting is acceptable, but care should be taken to avoid light shining on the lenses or on the subject's face.

IMPORTANT CHECKPOINTS:

- Be certain the instrument is plugged into a 110/120VAC outlet.
- Adjust instrument to proper height for subject's comfort by depressing button on base and moving the housing.
- Push power switch on back of instrument to activate the instrument.
- Tear off headrest tissue, so a clean tissue is ready for the subject.
- Be certain the subject presses their forehead against the headrest activator so the illumination in the unit is activated and the GREEN "READY" indicator on the control panel is lit.
- Be certain the subject is comfortable.
- Be certain to have a clean record form and a scoring marker.

You Are Now Ready To Test

Functional Vision Analyzer Peripheral Test

Test Description: This is a test of peripheral vision on the horizontal plane. The lights flash at 85, 70, and 55 degrees temporally and approximately 45 degrees nasally, so a possible total of 130 degrees arc for each eye can be attained. (Highest temporal reading plus nasal reading). Caution should be taken because the temples of eyeglass frames could interfere with this test. The test should be performed with eyeglasses on. If the test subject fails the peripheral test they should be tested again without the glasses to determine if the spectacle frame is interfering with peripheral vision.

To Administer The Test:

FAR Switch ON
RIGHT Eye switch ON
LEFT Eye switch OFF
Dial #1 at Far Indicator

Subject should look straight ahead, through the FAR lens system, with his/her forehead against the headrest activator. Ask the subject to look at slide #1. Then ask the test subject to point a finger in the direction of the flashing light. The test administrator will then press one of the four switches labeled: Nasal, 55°, 70° or 85° on the right side of the control panel. The switches can be pressed in any order and should be held down for two or three seconds.

Repeat the test for the left eye:

RIGHT Eye switch OFF
LEFT Eye switch OFF
RIGHT occluder OFF and the LEFT occluder ON.

NOTE: This test can be administered to a one-eyed person. In this case, the nasal test becomes very important because it will determine if there is peripheral vision on the blind side.

Maintenance of your Functional Vision Analyzer

Stereo Optical's Functional Vision Analyzer is designed to minimize maintenance. All bearings and internal mechanisms have been sealed at the factory. It has been engineered and built for a lifetime of use. The only annual maintenance required is simple and does not necessitate a service call. The only components requiring occasional maintenance are:

Eyepiece Lenses: The external side of these lenses needs to be cleaned occasionally. Care should be taken not to use any abrasive material on these lenses. Use the cleaner supplied with the vision analyzer, or plain soap and water can be substituted. It is important to dry the lenses with a soft, lint-free cloth.

Cleaning of Slides: Open the rear door. Use a damp, soft, lint free cloth with lens cleaner and wipe the slide. Turn the dial and go on to the next slide repeating the same procedure. Note: Always unplug the tester before opening the back door and accessing the slides.

Replacement of the Slides: The slide drum assembly holds up to 12 slides and can be easily reached through the door located above the control panel. To replace a slide, rotate the dial until the number of the slide to be removed is under the YELLOW indicator. Open rear door, remove slide on top of drum by rotating clips toward each other until they clear the slide. Remove unwanted slide.

Insert new slide with label showing and arrow pointing away from you; return spring clips to their former positions to secure slide. Close the instrument door and you are again ready for operation.

Control Panel Removal: The panel is designed with reliable solid state components. The modular design allows quick segmentation from the rest of the instrument.

Exterior: The plastic, of which the instrument body and base are made, is similar to your telephone and can be cleaned in the same manner. Use damp, clean cloth and a mild detergent. A dust cover is provided for dust protection and to discourage tampering when instrument is not in use. An eight foot power cord can be disconnected to discourage tampering as well.

Inside Mirror: Behind the rear door you will find a front-surface mirror. Handle the mirror with care and avoid placing fingers on its surface. We recommend using the cleaner supplied with the instrument along with a damp, soft, lint-free cloth. DO NOT TAMPER WITH THE THREE SCREWS SURROUNDING THE MIRROR. The mirror has been carefully aligned to achieve precise light reflections and any tampering will require factory adjustment.

Accessories and Supplies Available:

Test Slides: Black and White

Color Special

Reference & Training Manual: F.A.C.T.® *
(Contrast Test Slides) Custom

Record Forms: F.A.C.T. 50 sheets per pad 10 pads per package Custom 50 sheets per pad 10 pads per package

Headrest Tissue: 50 sheets per pad 100 pads per package

Dust Cover

Pointer: 6 per package

Power Cord & Power Supply

Lens Cleaner - 2 oz. bottle

Plus Lenses: plus 1.75D plus 2.25D

Intermediate Lenses: Set of 5

Lens #1	39.25 in.	100 centimeters
Lens #2	31.48 in.	80 centimeters
Lens #3	26.23 in.	66.7 centimeters
Lens #4	22.49 in.	57.1 centimeters
Lens #5	19.68 in.	50 centimeters

EyeView® ** Software: Requires PC Platform (Macintosh not currently supported), with 486 DX/66MHz or higher processor. Windows 95 or higher. VGA color monitor. CD-ROM or DVD- ROM drive.

Carrying Case: Hard or soft sided

* F.A.C.T. is a registered trademark of Stereo Optical Co., Inc.

** EyeView is a registered trademark of Vision Sciences Research Corp.

A c c e s s o r y Kit *(supplied with the instrument)*
Reference and Instruction Manual 1
(including slide descriptions)

Scoring Pad.....	1 pad of 50 sheets
Headrest Tissue.....	10 pads of 50 sheets
Dust Cover.....	1
Pointer.....	1
Lens Cleaner.....	1 bottle (2 oz.)
Power Cord.....	1
Power Supply.....	1

Glossary

Accommodation:

The ability of the eye to refocus from one distance to another.

Acuity:

Quantity of vision.

Amblyopia:

Also referred to as lazy eye, loss of sight in one eye.

Astigmatism:

A misshaping of the eye that prevents light rays from coming to a single focus on the back of the eye.

Binocular:

Ability to use two eyes simultaneously to focus on the same object and to fuse two images into a single image.

Candela:

The standard unit of luminous intensity. Illumination of target slide represented in cd/m^2

Cataract:

Opacity of the crystalline lens.

Color Deficiency:

Diminished ability to perceive differences in certain colors.

Contact Lens:

The thin shell of plastic which rests directly on the tear film of the cornea and corrects refractive error.

Convergence:

Turning the two eyes inward to see a nearby object.

Cornea:

The clear transparent covering on the front of the eye.

Dark Adaptation:

The process by which an eye adjusts to decreased illumination and becomes more sensitive to light.

Depth Perception:

The ability to judge distance of objects from each other or from the observer.

Diopter: A measurement of optical power of lenses.

Diplopia: Double vision.

Divergence:

The process of directing two eyes from a near point to a far point.

Esophoria:

The tendency of the eye to pull inward on the horizontal plane.

Exophoria:

The tendency of the eye to pull outward on the horizontal plane.

Far Point:

Twenty feet to infinity.

Fixation:

Directing the eye so the image centers on the fovea.

Focus:

The point at which light rays will come together after passing through a lens.

Fusion:

Power of coordination by which images received by two eyes become a single image.

Hyperopia:

Farsightedness, the images focus behind the retina.

Hyperphoria:

When either eye has a tendency to pull up on the vertical plane.

Intermediate Vision:

Vision which focuses at some point beyond 18 inches or 45 centimeters (Near Point) and less than 20 feet or 6 meters (Far Point).

LUX: The unit for measuring of glare.

Malingering:

A person who pretends to have a vision problem.

Mesopic:

Pertaining to illumination between the photopic and scotopic ranges.

Monocular:

Seeing with only one eye.

Muscle Balance:

The coordination of muscles allowing two eyes to work together on the vertical and lateral planes

Myopia:

Nearsightedness; has problem seeing at a distance; images focus in front of the retina.

Near Point:

14 to 16 inches or 35 to 40 centimeters.

Occlusion:

Obscuring the vision of an eye.

Orthophoria:

Expected or normal teamwork of the eyes.

Peripheral Vision:

Ability to perceive the presence, motion, or color of objects outside the direct line of vision.

Phoria:

Root word denoting a latent deviation in which the eyes have a constant tendency to turn from the normal position for binocular vision.

Photopic:

Vision under bright lighting levels.

Potential Acuity:

A quick assessment of macular function in cataract patients and documents that surgery is expected to improve visual performance.

Presbyopia:

Loss of accommodation so it is difficult to focus on near objects.

Refraction:

The bending of the rays of light. Sometimes used to refer to an examination for glasses or contact lenses.

Scotopic:

Vision at low light levels.

Stereopsis:

The ability to perceive depth.

Strabismus:

A muscle imbalance. Eyes turn inward or outward.

Suppression:

The non-use of vision in one eye.

Vision:

The ability to see and to interpret what is seen.

Visual Acuity:

Vision of an eye or eyes.



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