SVOne Enterprise
User Manual

The self-guided vision exam device from Smart Vision Labs
Welcome! Smart Vision Labs (SVL) is thrilled that you have received your SVOne Enterprise.

This instruction manual is intended for operators of the SVOne Enterprise (“Device”), and includes instructions on how to maintain the unit, safe handling procedures, proper implementation, and technical specifications.

Please be sure to read this manual fully and carefully prior to operating the SVOne Enterprise to ensure proper use. Maintain this manual in an area accessible to operators of the Device for reference.

Complete review of these materials is key to a positive user experience. If there are any additional questions, comments, or concerns, please e-mail our team at support@smartvisionlabs.com or call (212) 796-6124.

NOTE: The information in this manual is subject to change without prior notice at the discretion of Smart Vision Labs, Inc. The latest version of this manual can be found here: http://www.smartvisionlabs.com/enterprise-manual

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Table of Contents

1. Safety Labeling
2. About the SVOOne Enterprise
3. Intended Use
4. Enterprise System Components
5. Technical Specifications
6. Basic Care
   a. Transport
   b. Cleaning
   c. Precautions
7. Getting Started
   a. Assembly
   b. Setting Up Your Space
      i. What you will need
      ii. The Screening Environment
   c. Powering On
   d. Connecting your Device
   e. Activating the SVL app
   f. Logging In
8. Operation
9. Reviewing Results
10. Enterprise Web Platform
11. Charging the Device
12. Updates to the App
13. Warranty and Repairs
14. Return Policy
15. Contact
## Safety Labeling

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
</table>
| ![CLASS 1 LASER PRODUCT](image) | Laser Safety label for a Class 1 Laser Device.  
Definition: *Device laser output is safe for use under all circumstances.* |
| ![Direct Current (DC) Power Supply](image) | Direct Current (DC) Power Supply |
| ![Non-removable Lithium Ion Battery](image) | Product contains a **non-removable** Lithium Ion battery.  
Definition: *Do not dispose battery in standard trash containers. Proper disposal of Device and its components is required. Consult your nearest recycling center for proper disposal instructions.* |
| ![CE Marking Certification](image) | CE Marking Certification.  
Definition: *Certifies this product has met European Union consumer safety, health and environmental requirements.* |
| ![Manufacturer Address](image) | Manufacturer address. |
| ![Temperature Limitation Range](image) | Temperature limitation range for proper Device operation. |
| ![Humidity Limitation Range](image) | Humidity limitation range for proper Device operation |
| ![Caution](image) | Caution: *See instructions for use due to specific instructions or warnings.* |
| ![European Authorized Representative](image) | European Authorized Representative |
| ![Consult Instructions for Use / User Manual](image) | Consult Instructions for Use / User Manual |
| ![Catalog/Model Number](image) | Catalog/Model Number |
| ![Serial Number](image) | Serial Number |
About the SVOne Enterprise

The SVOne Enterprise device is a smart autorefractor that is precise and powerful. The device is a Shack-Hartmann wavefront aberrometer that works in collaboration with the camera on the iPhone 5s and the Smart Vision Labs app to capture the objective refractive error of a human eye by measuring sphere, cylinder, and axis. It is designed to provide a cost-effective, self-guided vision exam for patients, as well as offer lead generation and remote patient monitoring for eye care professionals and providers of corrective lenses.

By using the SVOne Enterprise, you agree to our Terms of Use and acknowledge that you have read and understand all the Device handling instructions. To review our Terms of Use and our Privacy Policy, please visit https://www.smartvisionlabs.com/terms/.

Please contact SVOne to review a copy of your Purchase Agreement.

The SVOne is a FDA-registered Class 1 510(k) Exempt Device, and has been certified to meet CE Marking standards for European Union sales and distribution. For detailed regulatory information, please visit https://www.smartvisionlabs.com/regulatory/.

Intended Use

US FEDERAL LAW RESTRICTS THE SALE AND OPERATION OF THIS DEVICE IN THE UNITED STATES EXCLUSIVELY TO A PHYSICIAN, LICENSED PRACTITIONER OR LICENSED ENTITY ENGAGED IN THE BUSINESS OF PROVIDING MEDICAL SERVICES. CONSULTATION IN YOUR LOCAL HEALTH LAWS IS REQUIRED TO DETERMINE IF THESE RESTRICTIONS APPLY WHEN IN USE OUTSIDE OF THE UNITED STATES.

The SVOne Enterprise is strictly a diagnostic tool to identify refractive error, and is only meant to be used by a qualified professional on human patients. This Device does not provide a complete eye health exam, is not intended to replace a eye health exam, and should only be used as described in the following instructions. **A licensed physician or entity is required to provide a legal prescription for corrective lenses.**

Enterprise System Components

- SVOne Enterprise device, with integrated iPhone 5s
- Black Charging/holding cradle with USB extension cable
- Two (2) charging cables
  - White Apple Lightning cable for charging the smartphone
  - Black 5mm Mini-USB cable for charging the Device's red light source battery supply
- USB wall adaptor for charging cables
- Silver Hex Tool (Ball-end, 0.050” diameter)
- Blue padded carrying case
- Black adjustable stand with integrated 6’ usb extension cable and base

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S2LB07 RevA Date: 28-JUN-2016
Technical Specifications

Technology: Shack-Hartmann wavefront sensor
Weight: 1 lb
Data Acquisition: Auto-captures 3 readings (pictures) per eye
Working Distance: ≤5 mm from the pupil
Fixation Target: Open view, any target >12 ft. distance
Indication for Use: Adults age 18+ (inclusive)
Device Dimensions: 8.6 cm x 13.2 cm x 18.8 cm (3.38 in x 5.19 in x 7.43 in)
Sphere Range: -14 to +14 diopters
Cylinder Range: -7 to +7 diopters
Diopter Display: 0.25 diopter increment
Axis Display: 1 degree increment
Laser Safety: IEC 60825-1 Class 1 Laser Device
Regulation: US FDA Registered and Class 1 510(k) Exempt, CE Mark
Operating ambient temperature: 32° to 95° F (0° to 35° C)
Storage/Transport temperature: -4° to 113° F (-20° to 45° C)
Relative humidity: 5% to 95% non-condensing
Operating altitude: tested up to 10,000 feet (3000 m)
Interfaces: Compatible with any Airprint-enabled wireless printer on the same network
Materials: This product, including rubber eye-cup, is latex-free
Battery Specifications: 3.7v 1020mAh Li-Ion; Rechargeable +200 hours per charge
SVOne is a portable autorefractor that uses wavefront aberrometry to provide refraction readings.

A Eye cup  
B Mini-USB charging port  
C Charge level & on/off LEDs  
D On/off switch  
E Pupil viewfinder  
F Screen power button  
G Screen charging port

Patents: US Patent 09066683  

(To review the approved patents on the SVOOne Device, visit http://patentimages.storage.googleapis.com/pdfs/US20140300868.pdf)
Basic Care

Treat the SVOne Enterprise Device as you would a camera or smartphone. While the Device has no moving parts, it is still composed of delicate materials and should be protected accordingly. Smart Vision Labs recommends always utilizing the cradle when the Device is not in use, and the padded case provided for storage and transport. Keep charging cables in their separate pouch in the padded blue bag to avoid scratching the casing.

Smart Vision Labs strongly recommends using the specialized stand to support the optimal setup of the Enterprise device. It is not recommended to use any other stand unless approved by SVL as there may be an increased risk of damage to the unit.

The SVOne Enterprise is not designed to bear weight. It should not be placed beneath heavy objects or under significant pressure.

Smart Vision Labs does not recommend placing the SVOne Enterprise in checked luggage.

Do not store the Device in direct sunlight, or extreme heat or cold.

Do not store the Device near equipment that gives off heat.

Cleaning

The eyecup should be sanitized to avoid transmission of potentially harmful bacteria. We recommend wiping down the rubber eyepiece after each use with alcohol pads or antimicrobial towelettes.

A deionized water based lens cleaner and lens cloth may be used to wipe the face of the screen clean. Do not use silicone, alcohol, ammonia-based cleaners, or abrasive materials such as paper to clean the screen.

The SVOne Enterprise should not be used in or submersed in water. The Device contains optical and electrical hardware which needs to stay dry to function.

Precautions

The Device should not be charged with any other cable other than those provided to avoid damaging the electrical components. When traveling in other countries, always use the appropriate conversion adapter for device charging to avoid power surges that may damage the Device.

The SVOne Enterprise, and therefore all electrical components of the Device, are in compliance with CE Marking Certification.
If multiple operators will be managing the Device, the account owner may want to apply additional security to the Device (i.e setting a PIN code, parental restrictions, etc.) so that apps cannot be downloaded or deleted.

Patients interacting with the Device during an exam should not use the device outside of the specified workflow dictated within the SVL app.

**Getting Started**

**Assembly**

1. Unpack the stand components (base and post).
2. Screw the post onto the base. Be careful with the integrated USB cable as you assemble the stand.

3. Unpack the SVOne device and cradle from the shipping box.
4. Screw on the cradle to the top of the post.
5. Attach the top post USB cable end to the cradle.

6. Place the SVOne device into the cradle, confirming it is seated snugly into the receptacle.
7. Finish assembly by tightening the thumb screw beneath the cradle post, which will secure the SVOne device to the cradle.
8. You may plug the USB cable into the USB charging plug at the bottom of the stand.
9. Plug the charging plug into a power extension cord.
10. Adjust the height of the stand by turning the adjustment handle counter-clockwise, then raising/lowering the stand to the desired height.
11. To lock the height, tighten the adjustment handle clock-wise.
Setting Up the Exam Space

What you will need:

1. Enterprise device mounted on the provided cradle, 6’ extension, and stand (provided)
2. WiFi connection
3. Computer with access to the SVL platform
4. Access to power plug
5. 6 - 12 feet of space
6. Focal target (i.e. eye chart, mirror, etc.)
7. Alcohol wipes or antimicrobial towelettes
8. Acuity measurement (Snellen) chart
9. Pupilometer or PD ruler
10. Lensometer or patient’s current Rx, if applicable

**Exam Environment**

**Lighting**
Whenever possible, it is recommended to *perform refractions in low lighting*. Ideally, the patient should not be looking out a window or at other sources of bright light that may constrict the pupil.

**Sound**
The SVOne Enterprise uses a combination of short instructional videos and voice prompts to walk the patient through the workflow. If the space is especially noisy, it may impede patients from hearing the proper instructions. SVL recommends setting up your space in a quiet area.

**Space**
The patient must focus on a distant target a minimum of ≥12 feet to achieve an accurate measurement. If the patient is looking in at the red light or at any target within 12 feet, there is risk of accommodation error. If you do not have 12 feet of space, using a mirror set up 6 feet away and having the patient focus on the reflection of the Device or their self in the mirror will suffice. *It will be critical to set up a specific target that is large enough to be seen by both of the patient’s eyes in turn.*

Ensure that there are no obstructions between the distant target during the exam. This may include staff or other customers walking in between the patient and the target.

Please see the diagram below of the optimal exam space set-up:
Powering On

Smartphone
Your Enterprise System comes with the Device already turned on and charged. The smartphone component should remain on at all times, and is kept charged when mounted in the cradle. To wake the screen, press the round Home button (located in the bottom center of the device) and swipe the screen from left to right.

If the screen does not power on, try charging the device in the cradle or with appropriate cables. If that does not work, manually turn it on using the small tool provided, inserted as shown below:
Insert the tool and push inward until a click is felt. Hold the tool in this position until the screen powers on. If the screen does not power on, it may need to be recharged using the supplied charging cables or cradle.

**IT IS NOT RECOMMENDED TO USE ANY OTHER TOOL OTHER THAN THE TOOL PROVIDED TO POWER THE DEVICE ON OR OFF AS YOU MAY POTENTIALLY DAMAGE THE DEVICE.**

**LASER**

With the screen facing towards you, turn on the red light source in the aberrometer by sliding the switch on the top of the casing to the left. A green light will indicate that it has been powered on. You can also check that it is on by peering into the eyepiece and looking for a bright red light.

If the red light does not come on, it may require charge. Please see the “Charging” section below for detailed instructions.

**Connecting Your Device**

The device must be always connected to WiFi or have network service to perform refractions and send data into the online portal for review by an eyecare professional.
If not connected, an error message will appear prompting you to connect to WiFi.

Trouble connecting the smartphone to a WiFi signal? Please see page 16 of Apple’s guide here for additional instructions.

We ask that users leave the smartphone on airplane mode to maximize battery life and limit background processes that may impact down the Device’s performance. Airplane mode and WiFi can be activated simultaneously, as long as airplane mode is turned on first.

**Account Creation and Activating the SVL App**

**Activating your account**

Our Customer Experience team will create your user account using the e-mail address you provided upon purchase. You will receive an email titled “You’re Invited” from our noreply address that will direct you to a webpage, where you will be prompted to create a password and activate the account. Passwords must be a minimum of 8 characters and include at least 1 number or symbol.

Once you have successfully created your password, you can log into the SVOne app on the Device using these credentials.
Remember to connect your SVOne Enterprise to WiFi. Open the blue SVOne app.

**Home Screen**

**Login Screen**

Passwords are case-sensitive. Five (5) failed attempts with an incorrect password on either the Device or website will result in the account being locked, in which case the
account owner/administrator must reset the password by selecting “Forgot?” on the login screen and accessing a reset link through the account's original email address. Enter the email address associated with the account in the popup, and tap “Submit” to receive a password reset link to that email. After resetting the password, you may log in again using the new password. You may also contact Customer Experience for additional assistance.

The account will remain logged in even if the smartphone is powered completely off, as long as the operator does not go into the Menu within the app and manually logout.

Forgot your password? You can reset the account password by selecting “Forgot” on the login screen as detailed above.

Preparing your Patient for the Exam

Patient Qualification

The Enterprise system is designed to be used only for those patients who meet specific age and health qualifications, and will exclude any patients showing symptoms of known eye health issues or with medical history that requires further attention from a doctor for an accurate prescription.

The first interaction your patient will have with the device will be to fill out a basic health questionnaire. If the patient indicates that they have any one of the listed concerns, they will be unable to complete the process.

In order to produce an accurate prescription for your patient, our doctors will need several additional data points along with the refraction information provided by the SVOne Enterprise. You will need to also collect:

1. Visual Acuity (including determination if corrected or uncorrected)
2. Pupillary Distance
3. Current Rx (if applicable)

Patients who are wearing contacts should remove them at least 3 minutes prior to using the Enterprise system.

Operation
STEP 1

The technician may begin by collecting the patient's Visual Acuity, Pupillary Distance, and Current Rx (if applicable). This step may also be done after the exam has completed. The operator/technician/assistant will enter this data into the patient's profile on the platform after the exam has completed since the patient profile will not have been created until then. Details on this process are described further below.

STEP 2

Clean the eyecup on the device using an alcohol wipe or antimicrobial towelette to ensure the eyepiece is sanitary.
STEP 3
Have the patient step up to the screen-side of the device, and select the “Tap to Begin” button. They will follow the on-screen prompts to enter necessary information.

Once the patient has filled out the eye health survey questions, they will review the instructional GIFs for how to proceed through the measurement.

STEP 4
Once the patient has finished entering in the required information, the voice prompts will have them step around to the other side of the device to begin.

NOTE: If no activity on the SVL App occurs during the exam within 10 minutes, the App will discard the exam-in-progress and revert to the “Welcome” screen.

At this point, the patient should remove their glasses and focus on the specified distant target.

Again, the patient must be fixating on a distant target a minimum of 12 feet away to prevent accommodation error. Ideally this is a specific target, at eye level or slightly above, large enough to be seen on either side of the device with each eye in turn.
Be sure there is nothing to block the patient’s field of vision, including other people walking in between the device and the target.

It may be helpful to inform the patient that, while they will see a bright red light in the center foreground of their field of vision, they should continue to focus only on the distant target, exemplified in the image below.

**STEP 5**

The patient will be guided through the vision exam process. This process may change slightly due to software revisions, but is outlined as a basic example of workflow.

Voice prompts:

1. “OK, let’s begin. Move to the other side of the device.” - Patient steps around from screen side of the device to the eyecup

2. “If you are wearing glasses, please take them off.”

3. “Place your right eye against the eyecup.” - The device begins with the patient’s right eye (OD). The patient’s face (generally the brow) should make contact with the eyecup. There should not be space between the face and the eyecup, or the accuracy of the results may be adversely affected.

4. “Center the bright red light but focus on the target.”

The patient’s view of the red light in the foreground with focus on the distant target
5. “Keep both eyes open.” - This will be critical to preventing accommodation. The patient may be tempted to close one eye while looking for the red light. Ensure that both eyes are open and fixated on the distant target for the measurement.

6. “Now place your left eye against the eyecup.” - Once the right eye is measured, the patient will switch to place their left eye up to the eyepiece in the same manner. The following voice prompts may or may not be triggered for one or both eyes depending on the patient’s success in positioning correctly relative to the red light so that a measurement is obtainable:

7. “Please adjust your position slightly. Make sure the bright red light is completely centered.” - If this voice prompt is triggered, it means that the patient is not quite positioned as needed to capture a measurement. The technician may need to guide them to adjust the position of their head relative to the eyecup in order to center the pupil so that the red light is in the direct middle of the eye.
8. “Is the red light centered? You’re almost there.” - The 2nd of 3rd prompts to help the patient adjust if they are still not positioned so that the red light is directly centered in the pupil and a grid is visible on the Device screen.

9. “Try adjusting your position one more time.” - The 3rd and final prompt to push the patient to continue adjusting their head to get the red light centered.

10. “OK, let’s get some help.” - If this prompt is heard, then the patient has simply been unable to position the red light as needed to acquire a measurement, and the technician or operator will need to step in.

If successful, the following prompts will be heard.

11. “Ok, you can relax. One moment while we process your results.” - Once both eyes are measured, the patient can step back while the Device averages the refraction results.

**Manual Operation:**

If necessary, at the point when the patient has made three unsuccessful attempts at the self-guided measurement or during the patient’s exam, you may be required to step in and assist by operating the Enterprise system manually. Tap the “Manual Mode” button on the upper left hand corner to enter manual mode.
If one or both eyes failed, there will be an option to go through automatic mode again or manual mode.

In Manual mode, you have the option to do one or both eyes again.
Once aligned, a full, circular grid of evenly-dispersed red dots will be visible in the central region of the screen, and the circle on the screen will light up green. The Device will automatically trigger an image capture, signified by the sound of a shutter click. The Device requires 3 measurements to produce results, so be sure to have maintain position until you have heard all 3 shutter clicks confirming the capture is complete.

If necessary, you can override the auto-capture and manually trigger the image capture by tapping the “Capture [OD/OS]” button. The Device will then capture three images in succession, with a short pause between each one.

![Manual option to capture](image)

You may occasionally see bright glare in the grid, as exemplified below. This is called corneal reflection, and it can negatively affect the refraction results. While the SVL software is programmed to account for corneal reflection in most cases, it is advisable to avoid this glare whenever possible.
To eliminate corneal reflection from the grid, have the patient make very tiny, slight adjustments to the position of their head against the Device until a clean grid is evident once more.

Once you are finished using the Device, it is recommended to turn off the interior red light by sliding the top-mounted switch to its off position (away from the five LEDs) so that the green light turns off. You can verify that the red light is powered down by peering into the eyecup and ensuring no red light is visible.

Always store the SVOne Enterprise on the charging cradle or in the padded carrying case when not in use.

**Refraction Results**

Once the patient has completed their test using the device, their results will be available on the SVL Platform along with complete exam details for review by the technician or doctor. The results will then be verified and the patient will receive an email on how to retrieve their prescription.
Enterprise Web Platform

To access the Enterprise Web Platform, please visit http://platform.smartvisionlabs.com

A unique account and password will be provided by Smart Vision Labs.
Once logged in, the patient's exam can be located and opened for additional information entry and review.

The patient's visual acuity, pupillary distance, and other information will be entered into the exam information page.
After data has been entered, click “SAVE”. Once you have completed data entry and are ready to submit results to a telemedicine doctor, click “Send for Review”.

**Charging the Device**

There are two separate components to the Device that require charging - the smartphone and the lithium battery that charges the interior red light. Please note that the charging cradle only maintains charge on the smartphone, and the red light battery will need to be charged separately.

To charge the interior red light, use the black 5mm USB charging cable and insert into the port on the top left side of the casing. The USB end can be plugged into the stand...
extension cable near the cradle, or the wall adaptor may be used to plug into a wall socket. Allow Device to charge for at least 2-4 hours. When fully charged, the battery life of the red light is 200+ hours. It is generally recommended to turn off the red light at the end of each day of use, and to fully recharge on a weekly basis (depending on frequency of use).

The top of the Device contains five mini lights (LEDs) to indicate charging status and whether the Device's red light is on or off, with the first green light indicating on/off, and the four yellow lights indicating the remaining battery level. The green-colored LED closest to the switch will illuminate when the switch is in the ON position, indicating the internal red light is on.

When the Device is plugged into its USB charging cable, four yellow charging status LEDs will light up indicating red light battery charge status (note: other end of USB cable must also be plugged into the wall adapter / wall outlet).

Exterior illumination description

Each yellow LED corresponds to 25% charge capacity. When all four yellow LEDs are lit, the red light source battery is fully charged. The charge status LEDs will briefly illuminate anytime the red light is turned on or off. To conserve battery power, those LEDs turn off after two seconds.

The Device can be stored in the charging cradle between uses to maintain the smartphone's battery during days of use, but should be left off the cradle and allowed to run down during long periods of inactivity (i.e if the Device will not be used for >5 days,
simply allow the battery to die and then recharge prior to another day of use. This gives
the battery an overall longer lifespan.) If the levels in the battery icon at the top right of
the screen appear red, or if a “low battery” alert dialogue box appears, the smartphone
portion will need to be charged.

If needed, you may occasionally power the smartphone completely off to help lengthen
the overall life of the Device battery. To power completely down, insert the tool until you
hear the click and are given the “Slide to Power Off” option.

In addition to the charging cradle, there is a white Lightning charging cable and a wall
adaptor provided as an alternate means to charge the smartphone. To charge the
smartphone while not on the cradle, insert the provided Lightning cable into the port on
the bottom of the Device and insert the other end into a USB charging port or the
provided wall adapter.

**Updates to the App**

Smart Vision Labs may regularly issue software updates to the SVOne app. When
updates are ready, they will be issued automatically through WiFi as long as the device is
connected to the internet. There is no interaction on your part to initiate updates as they
are seamless and done during off hours.

Note: **DO NOT REMOVE OR DELETE THE SVL SOFTWARE/ICON AT ANY TIME.** The updates
will automatically replace the existing version of software, requiring no additional effort
by the operator.
Warranty and Repairs

All SVOne Devices come with a warranty, known as “Smart Vision Care,” good for 1 year from the date of training. Smart Vision Labs offers dedicated and personalized service to purchasers of the SVOne, and may offer repairs on certain manufacturing defect or software issue that may arise, provided the user agrees to the Terms of Use and follows the guidelines provided in Basic Care.

SMART VISION LABS DOES NOT WARRANT THAT THE DEVICE, THE THIRD PARTY HARDWARE AND/OR THE APP WILL OPERATE WITHOUT INTERRUPTION OR WILL BE ERROR-FREE, OR THAT ALL ERRORS MAY BE CORRECTED.

The warranty does not cover physical damage incurred by the Device due to dropping, hitting, crushing, submerging, or otherwise negligent or abusive treatment of the Device by the user. Nor does it cover software issues that may be incurred by the user’s decision to download additional applications, programs, or software, or manipulation of the smartphone for anything other than the stated, intended use.

To review the complete terms of the warranty, please read the Purchase Agreement.

Should a manufacturing default or software issue be identified as present and caused by no fault or harm of the user, the owner may request an RMA for repair of the hardware and/or software by Smart Vision Labs, by contacting a Customer Experience representative at (212) 796-6124 or support@smartvisionlabs.com

For additional terms, please visit https://smartvisionlabs.com/terms.
Contacting Smart Vision Labs

Need assistance? We are here for you!
Visit the FAQs on our webpage: https://www.smartvisionlabs.com/autorefractors/details/
Email us: support@smartvisionlabs.com
Give us a call (Monday through Friday from 9 am to 6 pm EST): 212 796-6124

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