INSTRUCTIONS FOR USE

Volk® Eye Check

Ophthalmic Measurement Device
Shipping Contents

<table>
<thead>
<tr>
<th>Item:</th>
<th>Part Number:</th>
<th>Description:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volk Eye Check</td>
<td>18343-US</td>
<td>Ophthalmic measurement device</td>
</tr>
<tr>
<td>USB Cord</td>
<td>18338</td>
<td>For charging and data transmission</td>
</tr>
<tr>
<td>Power Adaptors</td>
<td>18339-US</td>
<td>For charging Volk Eye Check in a wall outlet (Formats Supplied: USA)</td>
</tr>
<tr>
<td>Stylus</td>
<td>18349</td>
<td>For precise interaction with touch screen</td>
</tr>
<tr>
<td>Protective Case</td>
<td>18345</td>
<td>Case for Volk Eye Check</td>
</tr>
<tr>
<td>Protective Pouch</td>
<td>18346</td>
<td>Microfiber Pouch for Volk Eye Check</td>
</tr>
<tr>
<td>Quick Start Guide*</td>
<td>ML-1016</td>
<td>Abbreviated instructions</td>
</tr>
<tr>
<td>Registration Card</td>
<td>IM-081</td>
<td>Please fill out and return to Volk Optical</td>
</tr>
</tbody>
</table>

Optional Accessories

The Volk Precision Stickers are an accessory for Volk Eye Check which act as a positioning target aid. They also remove the need to input patient IPD at the start of a session.

After removing from the backing strip, the sticker is placed on the patient’s forehead. On completion of the session, the sticker is discarded.

<table>
<thead>
<tr>
<th>Model:</th>
<th>Part Number:</th>
<th>Description:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precision Sticker Pack</td>
<td>VLKSTKR</td>
<td>Volk Precision Stickers x72</td>
</tr>
</tbody>
</table>

Further copies of the Volk Eye Check Instructions For Use for the Volk Eye Check (This document) and for the Volk Precision Stickers can be found at:
http://volk.com/eyecheck/literature/

Preparation for First Use

1. Remove Volk Eye Check from the package and check that all parts present are undamaged.
2. Sterilization or calibration prior to first use is not required.
3. Connect Volk Eye Check to the mains using the USB cord and the appropriate power adaptor.
4. The battery will start to charge.
5. Safely place Volk Eye Check on a flat surface.
6. Charge battery for at least 3 hours before the first use.
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Intended Use

Volk Eye Check is standalone ophthalmic software, loaded on a mobile electronic platform that is intended to measure ophthalmic characteristics and to aid in the diagnosis of ophthalmic abnormalities.

Indications for Use

To be used by Ophthalmologists, Optometrists, and other trained health care professionals. Clinical support staff can also use Volk Eye Check.

Recommendations Prior to Use

It is highly recommended that all persons, eye care specialists and healthcare professionals or clinical support staff, thoroughly review this document prior to patient usage. Interpretation of the measurement data generated is advised for eye care specialists and healthcare professionals only. There are no special facilities or qualifications required relating to the device.

Contraindications for Use

Some patients may experience momentary discomfort when exposed to flash photography. Use of Volk Eye Check on patients with photosensitive epilepsy is at the discretion and professional judgment of the healthcare professional.

Warnings

There are no medicinal substances or biological materials incorporated within this device.

No personal protective equipment is required to be worn by the user or the patient when using this device.

Cautions

- Use only accessories and Li-ion batteries provided by Volk Optical with this product. Any good-quality Alkaline AAA batteries may be used in the Fixation Target.
- No modification of this equipment is allowed.
- No files may be copied to/from the device except as described later in this document.
### Important Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="CE mark" /></td>
<td>The CE mark on this product indicates it has been tested and conforms to the provisions noted within the 93/42 EEC Medical Device Directives. The CE mark with notified body identification number indicates a Class I (measuring) product.</td>
</tr>
<tr>
<td><img src="image" alt="FCC symbol" /></td>
<td>The FCC Declaration of Conformity, or the FCC label, or the FCC mark, is a certification mark employed on electronic products manufactured or sold in the United States which certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.</td>
</tr>
<tr>
<td><img src="image" alt="Trash can" /></td>
<td>Do not dispose of Volk Eye Check or Volk Eye Check’s battery (Lithium-Ion) as unsorted municipal waste.</td>
</tr>
<tr>
<td><img src="image" alt="Recycle" /></td>
<td>Recycle Volk Eye Check’s Lithium-Ion battery.</td>
</tr>
<tr>
<td><img src="image" alt="Book" /></td>
<td>Read accompanying user documentation. Indicates that important operating instructions are included in this User Manual. Failure to follow these instructions could place the patient or operator at risk.</td>
</tr>
</tbody>
</table>
**Hardware Controls and Connectors**

Things that are found on the device itself:

<table>
<thead>
<tr>
<th>Position</th>
<th>Indicator</th>
<th>Purpose</th>
</tr>
</thead>
</table>
| 1        | Back of device | INTERACTIVE TOUCH SCREEN  
Shown is the Eye Check software “Home” screen. |
| 2        | Left side of device (viewed from the back) | POWER – Physical button  
Power on the device with long press. |
| 3        | Top right of device | SHUTTER – Physical button  
Half-press - Locks the focus and exposure.  
Full-press - Takes a photo. |
| 4        | Top left of device | ATTRACT – Physical button  
To activate the fixation target (See item 10). |
| 5        | Back of device | BACK KEY – Physical button  
To go back to the previous screen. |
| 6        | Back of device | HOME KEY – Physical button  
To return to the Mode Selection Screen. |
| 7        | Bottom of device | USB CONNECTOR  
Micro USB connector used for charging and data transfer. |
| 8        | Front of device | FLASH  
Automatically illuminates the subject when taking pictures. |
| 9        | Front of device | LENS  
Camera lens. Patients should look directly at the center of the lens when the device is used in CL or OP mode. |
| 10       | Front of device | FIXATION TARGET  
Flashes when activated by the Attract Button (See item 4), the patient should look at this when using Eye Check mode. |
## Soft Controls

These controls will be found on the interactive touch screen and will change depending on mode:

<table>
<thead>
<tr>
<th>Icon</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Eye Check Icon" /></td>
<td><strong>Eye Check</strong>&lt;br&gt;Mode Icon: Displays the regulatory labels when in the EC Patient Details screen. Returns to EC Patient Details screen when in any other EC screen.</td>
</tr>
<tr>
<td><img src="image" alt="Contact Lens Icon" /></td>
<td><strong>Contact Lens</strong>&lt;br&gt;Mode Icon: Displays the regulatory labels when in the CL Patient Details screen. Returns to CL Patient Details screen when in any other CL screen.</td>
</tr>
<tr>
<td><img src="image" alt="Oculoplastics Icon" /></td>
<td><strong>Oculoplastics</strong>&lt;br&gt;Mode Icon: Displays the regulatory labels when in the OP Patient Details screen. Returns to OP Patient Details screen when in any other OP screen.</td>
</tr>
<tr>
<td><img src="image" alt="Start Icon" /></td>
<td><strong>Start</strong>&lt;br&gt;Short press: Initiates a new session and enters capture mode. Long press: Choose - normal or freestyle session or save patient details.</td>
</tr>
<tr>
<td><img src="image" alt="Attract Icon" /></td>
<td><strong>Attract</strong>&lt;br&gt;Plays a random sound when in picture capture mode. Note: Audio needs to be enabled in Application Settings for icon to be visible.</td>
</tr>
<tr>
<td><img src="image" alt="Review Icon" /></td>
<td><strong>Review</strong>&lt;br&gt;Initiates patient data review mode from the Patient Details or Capture screens.</td>
</tr>
<tr>
<td><img src="image" alt="Upload Icon" /></td>
<td><strong>Upload</strong>&lt;br&gt;Indicates the upload status of the selected session –&lt;br&gt;<strong>Red</strong> – not uploaded&lt;br&gt;<strong>Amber</strong> – upload in progress&lt;br&gt;<strong>Green</strong> – upload complete</td>
</tr>
<tr>
<td><img src="image" alt="Application Settings Icon" /></td>
<td><strong>Application Settings</strong>&lt;br&gt;Opens the Eye Check settings screen where upload, reporting and audio features can be configured.</td>
</tr>
<tr>
<td><img src="image" alt="Session Report Icon" /></td>
<td><strong>Session Report</strong>&lt;br&gt;When pressed will generate and save a report file for the current session. Note: This control is only visible if the report file does not exist.</td>
</tr>
<tr>
<td><img src="image" alt="Help Icon" /></td>
<td><strong>Help</strong>&lt;br&gt;Long press: Activates the help dialog.</td>
</tr>
<tr>
<td><img src="image" alt="Back Icon" /></td>
<td><strong>Back</strong>&lt;br&gt;Go back to the previous screen.</td>
</tr>
</tbody>
</table>
Environment and Photo-Taking Indicators

These indicators are displayed on the interactive touch screen while taking pictures:

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="https://example.com/good_photos.png" alt="Image" /></td>
<td><strong>Good photos</strong>: Indicates number of valid photos in current session.</td>
</tr>
<tr>
<td><img src="https://example.com/poor_photos.png" alt="Image" /></td>
<td><strong>Poor photos</strong>: Indicates number of poor photos in current session.</td>
</tr>
<tr>
<td><img src="https://example.com/correct_distance.png" alt="Image" /></td>
<td><strong>Correct distance</strong>: Optimal patient-practitioner distance.</td>
</tr>
<tr>
<td><img src="https://example.com/distance_too_far.png" alt="Image" /></td>
<td><strong>Distance too far</strong>: Face too small, move closer to patient.</td>
</tr>
<tr>
<td><img src="https://example.com/distance_too_close.png" alt="Image" /></td>
<td><strong>Distance too close</strong>: Too close to patient, move back.</td>
</tr>
<tr>
<td><img src="https://example.com/brightness_level.png" alt="Image" /></td>
<td><strong>Brightness level</strong>: Optimum level is between 70 and 80.</td>
</tr>
<tr>
<td><img src="https://example.com/zoom.png" alt="Image" /></td>
<td><strong>Zoom</strong>: Lens zoom setting. Preset to Z5.</td>
</tr>
<tr>
<td><img src="https://example.com/battery.png" alt="Image" /></td>
<td><strong>Battery</strong>: Indicates percentage remaining battery charge.</td>
</tr>
<tr>
<td><img src="https://example.com/gaze_indicator_ec.png" alt="Image" /></td>
<td><strong>Gaze indicator – EC</strong>: Displayed when in Eye Check mode to remind the user that the subject’s gaze should be directed to the fixation target.</td>
</tr>
<tr>
<td><img src="https://example.com/gaze_indicator_cl_op.png" alt="Image" /></td>
<td><strong>Gaze indicator – CL &amp; OP</strong>: Displayed when in Contact Lens or Oculoplastics mode to remind the user that the subject’s gaze should be directed to the center of the lens.</td>
</tr>
</tbody>
</table>
**Preparation**

Volk Eye Check can be charged by connecting the supplied USB cable to either a PC (Personal Computer) or the appropriate mains power adaptor. When not using Volk Eye Check, it is recommended that the device is completely shut down. The device will not function if the remaining battery charge falls below 15%.

**Language Selection**

Once the Eye Check device is prepared for first use, power it on with a long press on the power button. The following screen will be displayed –

![First-time run language selection screen](image)

Select the desired language by touching the appropriate button. The device will be set to default to that language and the Volk Eye Check Mode Selection Screen will be displayed.

**NOTE:**
Language selection is only possible during the very first use of the device. For information on changing the selected language please contact Volk support at service@volk.com.
Initial Settings

If not already on, power-up the device on with a long press on the power button. After completing a short self-test, the Volk Eye Check Mode Selection screen will appear.

Mode Selection Screen

Swipe left on the Mode Selection screen to display the Utility screen

Utility Screen

Swipe right on the Utility screen to return to the Mode Selection screen.
Device Settings

From the Utility Screen touch the Device Settings icon. This will display a menu of items relating to the Volk Eye Check hardware as shown below. Scroll the screen to locate the wireless and date/time settings.

Enable WiFi functionality:

1. Select wireless & networks from the device settings menu.
2. In the next screen, check the WiFi box to turn on WiFi.
3. Select WiFi Settings.
4. Scroll down to select your preferred wireless network.
5. Input the password - if required - and then choose connect.

Press the physical back button to return to the Device Settings Menu.

Set the Date, Time and Time Zone:

1. Select Date & Time from the Device Settings Menu.
2. In the following screen, ensure Automatic is un-checked.
3. Touch set date. Spin the wheels to the correct date then touch set.
4. Choose select time zone and scroll the list up or down to select your location.
5. Touch set time, spin the wheels to the correct time and touch set.
6. Set the 24-hour check box.
7. Touch select date format to select the desired date format.

Press the physical back button to return to the Device Settings Menu.

From the Device Settings Menu press the physical back button to return to the Mode Selection Screen.
Application Settings

From the *Mode Selection Screen*, touch the *Eye Check* icon to start the Eye Check application. The first screen to be displayed is *Patient Details*.

![Patient Details Screen]

Touch the gear-wheel icon on the right side of the screen to access the Application Settings.

![Application Settings Screen]
<table>
<thead>
<tr>
<th>Setting</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upload</td>
<td>Set if you wish to upload patient data automatically on completion of a patient session</td>
</tr>
<tr>
<td>Email address</td>
<td>Enter the address where the PDF report should be sent. Note: “Upload” must be set for the email PDF to be enabled.</td>
</tr>
<tr>
<td>Report</td>
<td>Set if you wish to generate a data report at the end of a patient session. If you do not check this option, no report for reference will be generated on the device at the end of each patient session.</td>
</tr>
<tr>
<td>Include picture</td>
<td>Set if you wish to include the patient photo on session reports. Note – this setting applies to both local and uploaded report content. Please be aware of HIPAA regulations within your clinical setting for this feature.</td>
</tr>
<tr>
<td>Prefix</td>
<td>A 1-3 character prefix can be added to all patient IDs.</td>
</tr>
<tr>
<td>Sound</td>
<td>Set to ON if you wish to activate the audio attract feature. This helps to attract the attention of younger patients.</td>
</tr>
<tr>
<td>K Value units</td>
<td>Allows the units in which K values are expressed to be set to either mm or Diopters. On first-run, all EU devices default to mm and US devices default to Diopters.</td>
</tr>
<tr>
<td>Show warning dialogs</td>
<td>Unset if you wish to disable the warning dialogs that may pop up during a photo taking session. It is highly recommended that this option remains set in order to direct the user during the photo taking process for maximum efficiency.</td>
</tr>
</tbody>
</table>

Generally, both Device Settings and Applications Settings only require attention once during initial setup. However, they can be changed at any time if desired.
When finished, touch the back button to return to the Patient Details screen, then again to return to the Mode Selection Screen.

**Basic Use – Start Up, Shut Down, and Capturing an Image**

An image is captured using the dual-action shutter button. At the first detent (half press) the camera will focus on the subject and lock-in its exposure settings. Pressing the shutter further, to its second detent (full press), the image is captured and analyzed. Don't wait too long between half-press and full-press because of camera-shake and subject movement.

The device may be powered off or put to sleep by choosing the power / sleep soft key from the Utilities screen (Accessed by swiping left on the Mode Selection screen). Choose either shut down or sleep. The device may also be placed into sleep mode by a short press on the power button. To wake the device from sleep mode, short-press the power button or the back button.

If a device is left in sleep/standby overnight, it will power itself down at approximately 2:30am.
Operational Modes – “Eye Check”, “Contact Lens” and “Oculoplastics”

From the Mode Selection Screen, choose Eye Check mode, Contact Lens mode or Oculoplastics mode as required. Please note: All three modes may not be available on every device.

The key features of each mode are as follows:

**Eye Check mode** provides measurements of deviation, pupil and iris size and MRD. It is typically used in eye medicine, to assist in the detection, diagnostics and treatment of eye conditions such as strabismus, anisocoria, ptosis and others. The patient should look at the fixation target when using this mode.

**Contact Lens mode** provides detailed measurements of external eye features including pupils, HVID, lid positions and corneal sag. It is typically used to assist in the fitting of soft and hard contact lenses and as a reference for oculoplastic surgery. The patient should look directly at the lens when using this mode.

**Oculoplastics mode** provides detailed measurements of external eye features including three points on the lids – one of which is MRD, pupil size, eye aperture and HVID. It is typically used to measure and document eye aperture, lid position and pupil size, particularly in the context of lid surgery. The patient should look directly at the lens when this mode is used.

Capturing a Patient Session

Follow the steps below to successfully complete a patient session.

1. Select the Eye Check, Contact Lens or Oculoplastics icon from the Mode Selection Screen.

2. In the Patient Details screen, enter the patient data as required. Patient ID, Date of Birth, Gender and IPD are mandatory – as indicated by asterisk (*). **Note:** IPD input is not required if a Precision Sticker is applied – As described below.

   In Contact Lens mode, K Values are optional.

   **IPD:**

   IPD can be input in one of two ways: as the full IPD or as right and left PD respectively, both to the nearest 0.5mm. If the IPD measurement is not available, then an optional Precision Sticker may be applied as shown below.
Positioning of an optional Precision Sticker
This can be used instead of inputting IPD

Precision Sticker:
An optional Precision Sticker may be applied to the patient’s forehead as shown below. Long-press the IPD field to confirm the use of a sticker.
Long-press the IPD field to confirm the use of a sticker

K VALUES:
Used only in Contact Lens mode, 1 or 2 \textit{K Values} per eye may be entered. If all four are input (2 per eye) then the measurements output will include the calculated sag value for each eye. Otherwise, the sag value will be estimated using only the iris measurements.

Note: Depending on the setting in the Application Settings, the \textit{K} values may be requested in \textit{mm} or Dioptres.

3. Touch the Start icon to initiate picture capture mode and begin the patient session.

The lens will extend and automatically be set to the correct zoom setting. There is a short lag as this takes place and the device prepares the new session.
4. The *attract* icon on the left hand side will only appear if the sound feature has been enabled in application settings. Press this icon to hear the sound as required.

5. The optimum light level is between **70-80** for light skinned patients and around **60** for darker skinned patients. A patient - practitioner distance of **50-60cm** is required. Check the brightness level and distance on the panel to the right side of the screen.

6. Ensure that the patient is sitting comfortably in front of a neutral background. The practitioner should be at eye level with the subject. Avoid large windows, mirrors, strong reflections and computer screens.

7. Hold the camera comfortably but firmly with two hands to avoid shaking. Use the index finger of the left hand to activate the fixation target button. This is located on the top left side of the device. The fixation LEDs will be activated all the time this button is pressed. The patient is required to look at this target throughout an *Eye Check* mode photo capture session. When using *Contact Lens* or *Oculoplastics* modes, the patient must look directly at the camera lens.

8. Frame the subject’s face, aiming for 2/3 of the face to appear on the screen from forehead to mouth. Half-press the shutter button to achieve correct focus. The white focus squares will turn green if this is the case. Fully press the shutter button to take a photo. Do not linger after focus is achieved.

   **NOTE:** All parameters – distance, brightness and focus lock - must be green to validate a picture. If the focus squares are red, completely release the shutter button and half press again. Repeat until correct focus is achieved.

   ![Picture-taking screen in Eye Check mode](image)

   *Note: Patient is looking at the fixation target as directed by the gaze indicator*
9. 2 to 4 green check photos are required to complete a session and report the measurements. The lens may automatically recalibrate after “red” 4 photos. If a picture is invalid, please adjust your position, the patient’s position or the surroundings to account for the factor that is not optimum. See “System Message” for error messages and what to do. Please do read these messages and follow their instructions.

10. Once a session analysis has been completed, the appropriate measurements report will be displayed on screen. Scroll up and down to review all data.

11. Touch the review icon to view thumbnails of the pictures for that session. Touch back to return to the results screen. The upload icon on the right side will indicate the session upload status. See WiFi Upload section.
Measurements Provided by the Volk Eye Check Device

When a session completes successfully, the results are displayed on-screen immediately. The user may scroll through the data as needed. A measurement report may be saved local for retrieval later or the same report can be emailed automatically.

Scrolling measurements display from an Eye Check (EC) mode session

Scrolling measurements display from a Contact Lens (CL) mode session
Scrolling measurements display from an Oculoplastics (OP) mode session.

Grid” image as created by an Oculoplastics session.

Each dark square represents 5mm x 5mm on the patient’s face. Each lighter square is 1mm x 1mm.
The table below lists all of the ocular measurements provided in the Volk Eye Check session analysis: Each mode will display a targeted sub-set of these measurements in the screen and printed reports.

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Abbreviation</th>
<th>Definition</th>
<th>Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pupil size (L&amp;R)</td>
<td>--------------</td>
<td>Horizontal diameter of the pupil</td>
<td>EC, CL, OP</td>
</tr>
<tr>
<td>Difference in pupil size</td>
<td>Diff. pupil size</td>
<td>Difference between right and left pupil sizes</td>
<td>EC, CL, OP</td>
</tr>
<tr>
<td>(No) Deviation</td>
<td>--------------</td>
<td>Strabismus deviation in prism dioptres if detected. Reports “no manifest deviation” if no misalignment is detected. Measured in prism dioptres (pd)</td>
<td>EC</td>
</tr>
<tr>
<td>Inter-pupillary distance</td>
<td>IPD</td>
<td>Distance between the centers of the right and left corneas in primary gaze. Distance IPD is given. If IPD was input by the user then this will be indicated on the report as “Given”. If the IPD is calculated by the device it will be shown as “Estimated”.</td>
<td>EC, CL</td>
</tr>
<tr>
<td>Horizontal Visible Iris Diameter (L&amp;R)</td>
<td>HVID</td>
<td>Maximum horizontal white-to-white measurement of the iris</td>
<td>EC, CL, OP</td>
</tr>
<tr>
<td>Horizontal Visible Iris Diameter difference</td>
<td>HVID difference</td>
<td>Difference in right and left visible iris horizontal diameters</td>
<td>EC, CL, OP</td>
</tr>
<tr>
<td>Vertical iris diameter (L&amp;R)</td>
<td>--------------</td>
<td>Calculated vertical white-to-white measurement of the iris</td>
<td>CL</td>
</tr>
<tr>
<td>Diagonal iris diameter (L&amp;R)</td>
<td>--------------</td>
<td>Calculated diagonal white-to-white measurement of the iris</td>
<td>CL</td>
</tr>
<tr>
<td>Upper margin reflex distance (R&amp;L)</td>
<td>MRD 1</td>
<td>Measurement from the purkinje image to the margin of the upper eyelid</td>
<td>EC, OP</td>
</tr>
<tr>
<td>Upper margin reflex distance difference</td>
<td>MRD 1 Difference</td>
<td>Calculation: Difference between Left MRD 1 and Right MRD 1</td>
<td>OP</td>
</tr>
<tr>
<td>Lower margin reflex distance (R&amp;L)</td>
<td>MRD 2</td>
<td>Measurement from the purkinje image to the lower eyelid margin</td>
<td>EC, OP</td>
</tr>
<tr>
<td>Lower margin reflex distance difference</td>
<td>MRD 2 Difference</td>
<td>Calculation: Difference between Left MRD 2 and Right MRD 2</td>
<td>OP</td>
</tr>
<tr>
<td>Palpebral aperture (L&amp;R)</td>
<td>--------------</td>
<td>Calculation: MRD 1 + MRD 2</td>
<td>EC, OP</td>
</tr>
<tr>
<td>Difference in palpebral aperture</td>
<td>Diff. palpebral aperture</td>
<td>Difference between the right and left palpebral apertures</td>
<td>EC, OP</td>
</tr>
<tr>
<td>Upper aperture at Limbus (L&amp;R)</td>
<td>--------------</td>
<td>Measurement from a center line through the purkinje image to the margin of the upper eyelid at points in line with the nasal and temporal limbi. Displayed in the form “temporal / nasal” for the right eye and “nasal / temporal” for the left eye.</td>
<td>OP</td>
</tr>
<tr>
<td>Lower aperture at Limbus (L&amp;R)</td>
<td>--------------</td>
<td>Measurement from a center line through the purkinje image to the margin of the lower eyelid at points in line with the nasal and temporal limbi. Displayed in the form “temporal / nasal” for the right eye and “nasal / temporal” for the left eye.</td>
<td>OP</td>
</tr>
<tr>
<td>Aperture at Limbus (L&amp;R)</td>
<td>--------------</td>
<td>Calculation: Upper aperture at Limbus + Lower aperture at Limbus.</td>
<td>OP</td>
</tr>
<tr>
<td>Pupil center to upper lid – (R&amp;L)</td>
<td>--------------</td>
<td>Measurement from the center of the pupil to the margin of the upper eyelid</td>
<td>CL</td>
</tr>
</tbody>
</table>
### Measurement Data Table

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Abbreviation</th>
<th>Definition</th>
<th>Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pupil center to lower lid – (R&amp;L)</td>
<td>--------------</td>
<td>Measurement from the center of the pupil to the lower eyelid margin</td>
<td>CL</td>
</tr>
<tr>
<td>Horizontal pupil eccentricity – (R&amp;L)</td>
<td>Horiz. pupil ecc.</td>
<td>Centre of the pupil relative to the center of the iris on the horizontal axis. Negative measurement indicates temporally located</td>
<td>EC, CL, OP</td>
</tr>
<tr>
<td>Vertical pupil eccentricity – (R&amp;L)</td>
<td>Vert. pupil ecc.</td>
<td>Centre of the pupil relative to the center of the iris on the vertical axis. Negative measurement indicates inferiorly located</td>
<td>EC, CL, OP</td>
</tr>
<tr>
<td>Corneal Sag</td>
<td>--------------</td>
<td>This is the perpendicular distance, in mm, from the apex of the cornea to a line which intersects the two ends of the curve. Calculated if all four K-Values are provided, otherwise estimated using the HVID and statistical norms.</td>
<td>CL</td>
</tr>
</tbody>
</table>

### Reviewing Patient Measurement Data

Launch the application by touching the *Eye Check*, *Contact Lens* or *Oculoplastics* icon on the *Mode Selection* Screen. Open the patient database using the *review* icon on the left side. The database is organized in numerical/alphabetical patient ID order. Scroll though the database to locate the desired patient. Select the patient, then select the required session (if there’s more than one). The measurement data for the chosen session will be displayed. Scroll through as required. To re-generate the local report file, touch the *report* icon. Note: the *report* icon will be visible only if the report for this session is not already present on the device.

If sessions from more than one mode exist for a given patient, all will be available for review, irrespective of which mode was initially chosen from the *Mode Selection* screen.

The high-resolution images taken by the device are required only for the analysis stages of each Volk Eye Check session, in order to produce the measurement data. These images are not stored on the device and will not be available to the practitioner.

---

**Four sessions (2x EC, 1x CL and 1x OP) all for the same patient**
WiFi Upload

If the settings described in the Initial Settings section have been configured correctly then, on the successful completion of each session, a PDF document containing the results will automatically be emailed to the address specified in the, WiFi connectivity permitting.

To check if the upload has been successful, Launch Volk Eye Check using any one of the mode icons on the Mode Selection Screen. Open the patient database using the review icon on the left side. The database is organized in numerical/alphabetical patient ID order. Scroll through the database until the desired patient is located. Select the patient and the session if there is more than one. The upload icon will appear green if the upload has been successful. If the upload is in progress, the icon will be amber. If an upload has failed or has not been attempted, the icon will be red. To manually initiate an upload (or to get the PDF re-sent), touch the red icon.

Please be aware that a successful session upload and subsequent receipt of the PDF email is dependent on entering the correct email address in the application settings and properly setting the WiFi connection in the device settings. If the upload fails please check all the settings and ensure the device remains within the coverage of the specified WiFi service.
Data Transfer via PC Connection

1. Connect the Volk Eye Check device to a personal computer using the supplied USB cable.
2. Once the connection is complete, return to the device and click device settings.
3. From the device settings menu, drag down from the top of the screen to open Connectivity menu.

4. Touch USB Connected – Select to copy files to/from your computer.
5. Touch Turn on USB Storage. Select OK when USB advice message appears.

6. Touch Turn on USB Storage. Select OK when USB advice message appears.

7. On your computer, locate the device in Finder (Mac) or Windows Explorer (Windows). Click on the device to open the root folder. In this folder you will find any exported data in the folders named with Patient IDs

8. Open the folder IRISSReports and begin managing the patient records. You can:
   a. Copy reports to a local drive
   b. Print via PC printer
   c. Delete reports from the device
   d. Rename files
Pre-loading Patient details

To pre-load and save patient details to the device database prior to use, follow the instructions below:

1. Enter the patient ID screen via the *Eye Check, Contact Lens or Oculoplastics* icon on the *Mode Selection Screen*.

2. Input all patient details correctly as required, including date of birth and gender.

3. **Long press** the *start* icon. An options menu will appear giving the following options:
   - Analyze
   - Freestyle
   - Save details
   - Cancel

   Select *Save Details*. These details have now been saved for later use.

4. Continue to input as many patient entries as required.

5. To access the preloaded patient details when starting a new patient session **long press** the empty *Patient Ref* field in the patient ID screen. The preloaded patient entries will appear here.

6. Scroll down and select the correct patient. Once selected the patient information will automatically populate the necessary data fields.

7. Touch the *start* icon to start a session for the selected patient in the currently active mode, following the instructions as per the *Capturing a Patient Session* section of this instruction manual.

Adding a Patient Database

To use this pre-load patient database feature, Microsoft Excel (or similar) is required to create a data list of the patient details to be saved to the device database.

1. Create a spreadsheet with the following data column headings in bold, *PatientID, DoB* (date of birth), *Gender, Name*. Input all of required information to complete the spreadsheet database.

   **Note:** The *Name* column is not mandatory and is not retained by the Eye Check database. It is useful for validation of patient identity by the practitioner. The *DoB* column must be in international ISO format `yyyy-mm-dd` (i.e., 2003-04-29). The *Gender* column should be either “M” or “F.”

2. Save this spreadsheet in a remembered file location using a designated file name and save it as a .csv format (comma separated value file).

3. Use steps 1-6 in the section *Data transfer via PC connection* to connect the device to a PC or Mac.

4. Copy the .csv file to the root folder on the device.

5. Eject the device from the physical PC connection.

6. Return to the *Mode Selection Screen*; select the *EC, CL or OP* icon to start a session.

7. **Long press** the *PatientID* field, this will display the contents of the uploaded .csv file. Scroll through the database to select the required patient. Once selected the user will be returned to the patient details screen with the other data fields now populated from the chosen record.
Selecting a patient from an uploaded file

Note: If there is more than one valid .csv file loaded onto the device, the user is required to select the correct database to be used.

Choosing a patient database file

8. Touch the start icon to initiate a session as described previously.
Starting a new session for a patient already in the database

From the Mode Selection screen, access the patient database by launching the application using the Eye Check, Contact Lens or Oculoplastics icon as required. Open the database using the review icon on the left hand-side of the screen. The database is organized in numerical/alphabetical patient ID order. Scroll though the database to locate the desired patient. Long press on the patient entry will activate a menu with the following options:

- Export
- Delete
- New session
- Cancel

Select new session. This will populate the patient details screen with the details of the chosen patient. Now touch the start icon and use as directed in the “Capturing a Patient Session” section.

Exporting patient session data

Choosing Export from the Patient Review long-press menu will gather together all thumbnail images, grid images and report files for that patient in to a folder on the Eye Check memory card. The name of the folder will be the Patient Reference.

Freestyle Mode

Follow the steps below to successfully complete a free style mode patient session.

1. Touch any of the mode selection icons on the Mode Selection Screen.

2. Enter the patient data correctly: Patient ID, date of birth and gender. Long press the start icon and select Freestyle to start a free style mode patient session.
3. The lens will extend and automatically be set to the correct zoom setting. There is a short lag as the lens extends out and the device prepares the new session.

4. Hold the camera comfortably but firmly with two hands to avoid shaking. Frame the area of interest on the subject’s face. Half-press the shutter button to achieve correct focus. The white focus squares will appear green if this is the case. Fully press the shutter button to take a photo. Do not linger after focus is achieved.

5. The photograph will be saved in the database. Continue to take as many freestyle photographs as required. Once the practitioner has completed a session, press the physical back button to return to the patient entry page.

6. Select the review icon to access the database. Scroll down to select correct patient. Select the correct session (if there is more than one) and select review icon on the left hand side to review thumbnails of the photographs taken.

Note: There will be no analysis or data measurements on the first screen when reviewing data. This will present as a black screen until the review icon is selected to view thumbnails.

Freestyle sessions are not uploaded and reports are not generated. Data and pictures may be copied from the internal memory after exporting the session.
How to update Volk Eye Check Software

To update your Volk Eye Check to the latest software (when available) follow the steps below:

1. Refer to the section titled Data Transfer via PC connection and connect the Volk Eye Check to a PC using the steps 1-6.

2. Download the new version of the software from your e-mail account to a remembered location on your PC. This may be 1, 2 or 3 files that end with ".apk"

3. Go to the saved location of the software, right click the icon/data field to select the copy option.

4. Return to locate the device in Finder (Mac) or Windows Explorer (Windows). Click on the device to open the root folder. Select the IRISSApps folder. Right click within this folder to select the paste option to paste the new software file(s) into the IRISSApps folder.

5. Safely eject the device from the computer using the device eject function in the system tray (PC) or right-clicking the device and choosing eject (Mac).

6. On the device, press the back key to return to the Mode Selection Screen. A message will display on detection of the new software: Software update found, do you want to install? Touch yes. This will automatically initiate the installation of the latest version of the Eye Check software. Follow the prompts to accept the replacement of the current version and to proceed with the installation. Touch the done control on the final screen. This may repeat if there is more than one update file.

7. Usually, when the update has completed, the Mode Select screen will be displayed. If, however, the home screens themselves have been updated, you may see a new screen with a number of icons. If that happens, press the home key. The screen shown here may be displayed. In which case, check the “use by default for this action” box and choose the “IRISS Launcher” option. You should now see the Mode Selection screen.

8. To verify that the new software update has been correctly installed, touch the Volk Eye Check icon when in the Mode Selection or Utility Screen. This will display the details of the software currently running on the device. Cross-reference these details with the details of the software update that was received.

9. At this point you can continue to use the device as directed.
## System Messages

The Volk Eye Check device will display messages for many reasons. The messages usually include an explanation and details of possible corrective actions.

List of messages displayed by the Volk Eye Check application:

<table>
<thead>
<tr>
<th>Error message:</th>
<th>What to do:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient details screen – Various messages</td>
<td>A capture session will not be possible unless all mandatory fields (indicated by an ‘*’) are completed on the Patient Details screen. In addition to the Patient ID, ensure correct date of birth, gender and IPD are input.</td>
</tr>
<tr>
<td>Future dates are not allowed</td>
<td>Check correct date of birth has been input.</td>
</tr>
<tr>
<td>Center on face Include both eyes</td>
<td>Move to a distance of 50-60cm from the patient to take photos. Frame the image so the patient’s face fills the screen. Ensure both eyes are included.</td>
</tr>
<tr>
<td>Analysis in progress – another picture required.</td>
<td>A valid picture was taken, but the device requires another to complete the analysis. Continue to take photos until the session completes.</td>
</tr>
<tr>
<td>Picture not quite in focus</td>
<td>The last picture was not in sharp focus. To help obtain properly focused pictures, hold the device firmly and operate the shutter gently. Using the first shutter detent, allow the device to focus (green focus-lock indicators) then gently press the shutter further to take the shot.</td>
</tr>
<tr>
<td>Face may be tilted</td>
<td>Adjust the patient’s head position until straight.</td>
</tr>
<tr>
<td>Picture not valid</td>
<td>Retake photo, ensuring correct distance, good lighting level and green focus lock.</td>
</tr>
<tr>
<td>Subject too bright or too far away.</td>
<td>Either reduce lighting or move closer to patient.</td>
</tr>
<tr>
<td>Too close, move away.</td>
<td>Move further away from patient and retake photo.</td>
</tr>
<tr>
<td>Too far away, move closer.</td>
<td>More closer toward patient and retake photo.</td>
</tr>
<tr>
<td>Subject not looking at target</td>
<td>Retake photo and encourage patient to focus on the fixation target (Eye Check mode) or directly on the lens (Contact Lens and Oculoplastics modes).</td>
</tr>
<tr>
<td>Zoom setting not valid</td>
<td>Incorrect zoom setting. Exit current session and restart session.</td>
</tr>
<tr>
<td>Room too bright</td>
<td>Reduce room illumination.</td>
</tr>
<tr>
<td>Light level too low</td>
<td>Increase ambient illumination to the recommended levels as outlined on page 13.</td>
</tr>
<tr>
<td>Eyes closed or unwanted reflections</td>
<td>Encourage patient to keep eyes open or relocate patient to an area free from mirrors, large windows and extra reflections.</td>
</tr>
<tr>
<td>Eyes possibly not fully open – take another picture</td>
<td>The patient’s eyes may not be open enough for the device to properly measure characteristics. Encourage the patient to open their eyes wider.</td>
</tr>
<tr>
<td>Verify IPD values or use a Precision Sticker</td>
<td>The device has determined that the entered IPD values may be incorrect. Double-check the entered data or, alternatively, apply an approved sticker to the patient’s forehead.</td>
</tr>
<tr>
<td>Battery too low</td>
<td>Return Eye Check to charger and fully charge.</td>
</tr>
<tr>
<td>The memory card is full. Clear Database.</td>
<td>Return to Eye Check settings via the settings icon on the patient ID input page. If you wish to clear database, touch clear database. This is an irreversible process. If you do not wish to delete database and require more storage space contact Volk Optical.</td>
</tr>
<tr>
<td>No WiFi or SIM connection. Please try later.</td>
<td>Check WiFi settings are correct (section 7.2) and WiFi set up within clinical environment are correct.</td>
</tr>
<tr>
<td>Sending data may breach the Personal Data Directive.</td>
<td>Check clinical setting procedures for Personal Data Directive. If this complies, touch yes. If this does not comply, touch no. The data will not be sent via WiFi upload feature.</td>
</tr>
<tr>
<td>Including a picture may breach the Personal Data Directive.</td>
<td>Check clinical setting procedures for Personal Data Directive. If this complies, touch yes. If this does not comply, touch no. The report will not contain the patient picture.</td>
</tr>
</tbody>
</table>

Messages from the Eye Check hardware:

<table>
<thead>
<tr>
<th>Error message:</th>
<th>What to do:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Check has stopped unexpectedly.</td>
<td>Choose the Force Close option. This will reset the application and return to the Mode Selection Screen.</td>
</tr>
</tbody>
</table>
Cleaning Instructions

Volk Eye Check is a precision instrument that should be handled with care. Please note the following cleaning instructions:

- Shut down the device before cleaning, except when cleaning the camera’s lens element.
- Clean the housing and display with a soft, lint-free cloth moistened with alcohol. Avoid touching electrical connectors, etc.
- The lens may be cleaned with a clean cloth or moist lens tissue such as Volk’s Precision Optical Lens Cleaner®.

CAUTION:
Do not allow Volk Eye Check to become wet. Do not irrigate with liquids.

CAUTION:
Volk Eye Check is not intended to be disinfected or sterilized.

Device Maintenance and Servicing

Volk Eye Check contains a Lithium-ion (Li-ion) battery that operates the camera. The service life of the battery is approximately 2 years, depending on usage. The battery should only be replaced by the Volk Optical or a Volk Optical certified service facility when the battery is approaching the end of its service life, or when it ceases electrical functionality.

Cease using and return for service if any of the following occur:

- The device does not power up.
- The battery does not retain its charge.
- The application no longer behaves as expected.
- The device no longer operates as expected.
- The case is cracked or broken.

Volk Eye Check contains two AAA Alkaline batteries that operate the fixation target’s LEDs. Do not recharge the alkaline batteries. Both alkaline batteries should be replaced at the same time when required. It is advised that the batteries should be removed from the device if it is to be stored for an extended period of time. See Appendix B for instructions on replacement of the AAA batteries.

All servicing and repairs, other than replacing the AAA batteries, must be carried out by Volk Optical or a Volk Optical certified service facilities and service personnel.

CAUTION:
If there is damage to the device’s display, buttons, or surfaces, or other visual defects, please contact Volk Optical or a Volk Optical certified service facility.
**Calibration**

Volk Eye Check is factory calibrated during the manufacture of the camera. This calibration process will last the lifetime of the product. No further calibration by the user is required.

**EN 62479**

Volk Eye Check has been tested to EN 62479 RF (Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields) and has been found to be safe. The manufacturer does not foresee any precautions or measures that are required to be undertaken with regard to risk of interference or external/environmental influences.
Technical Description

Volk Eye Check

| Ophthalmic measurements                        | Left and right pupil size | Pupil size difference |
|                                                | Deviation                 | Inter-pupillary distance (IPD) |
|                                                | Left and right horizontal visible iris diameter (HVID) | HVID difference |
|                                                | Left and right vertical iris diameter | Left and right diagonal iris diameter |
|                                                | Left and right Palpebral aperture | Palpebral aperture difference |
|                                                | Left and right, upper and lower, temporal and nasal aperture at limbus | Left and right, top and bottom MRD |
|                                                | Left and right distance between pupil center and upper/lower lid | Left and right, vertical and horizontal pupil eccentricity |
|                                                | Left and right, top and bottom aperture at Limbus | Corneal sag (using externally obtained k values) |

| Measurement accuracy                          | < ± 5%                     |
| Operating subject distance                    | 500mm to 650mm             |
| Average pictures per session                  | 3                          |
| Average session time                          | 30-45sec                  |
| HIPAA Compliant                               | Yes                        |
| Image Resolution                              | 16Mp – 4608x3440 pixels    |
| Touchscreen                                   | TFT-LCD, 3.2”, 400x800 pixels, 16M colors |
| Lens                                          | f/3.1 – f/5.6, Autofocus |
| Exposure                                      | Auto Exposure, Auto White Balance, Auto ISO |
| Subject Illumination                          | Xenon Flash, GN3.1m (@ 100 ISO), Auto intensity, 100µS max duration |
| Fixation target                               | 11x Visible Light LEDs flashing at approx. 6Hz |
| Storage                                       | 8GB microSD Card           |
| Connectivity                                  | USB-2 (microUSB) WiFi 802.11 b/g/n Bluetooth v2.1 +EDR |
| Dimensions                                    | Width – 162.75mm Height – 63.5mm Depth – 27.25mm (lens retracted) |
| Weight (With batteries)                       | 242g                       |
| Batteries                                     | 1x Rechargeable, Li-ion, 3.7v, 1020mAh 2x AAA Alkaline |

NOTE:
If you need a replacement Lithium-Ion battery or power adapter, please contact Volk Optical or your local retailer/distributor.
Environmental Conditions for Use, Storage and Transportation

IP Code: IPX0 (Equipment not protected against the ingress of water)

The Volk Eye Check is intended to be used in a controlled-lighting environment. There is no need for special storage of the device. No specialized handling conditions required.

Usage:
Temperature, use: +10 °C to 35 °C
Relative humidity, use: 10 % to 80 %
Atmospheric pressure: 800 hPa to 1060 hPa
Please note also EMC information given in Annex A.

Storage
Temperature, storage -10 °C to 40 °C
Relative humidity, storage: 10 % to 95 %
Atmospheric pressure: 500 hPa to 1060 hPa

Serial numbering

Volk Eye Check is a serialized product. A label indicating the serial number is attached to the base of the device.

The software version and the serial number are both displayed on the device’s display during start up and are accessible via the user interface.
Disposing of Volk Eye check

Do not dispose Volk Eye Check as unsorted municipal waste. Prepare Volk Eye Check for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply.

For more specific information, please contact IRISS Medical Technologies or your local retailer/distributor.

Contact for Product Support

If you wish to contact Volk for product support:

- Direct: 440-942-6161
- Toll free in the United States: 1-800-345-8655
- Fax: 440-942-2257
- e-mail: sales@volk.com or service@volk.com

Warranty

Volk Optical provides a 1 year warranty for the parts and labor. Warranty for the Lithium-Ion battery is 6 months.

Submitting claim:
Any claim under this warranty must be submitted in writing before the end of warranty period to Volk Optical. The claim must include a written description of any failure(s) experienced with the device.

Warranty does not cover:
Products that have been subjected to abuse, accident, alternation, modification, tampering, misuse, faulty installation, lack of reasonable care, repair or service in any way that is not contemplated in the documentation of the product, or if the model or serial number has been altered, tampered with, defaced or removed. Warranty does not cover damage caused by dropping the device or damage caused by normal wearing. Any issue related to the stickers attached to the device coming off are not covered by warranty. Repair or service done by non Volk Optical certified service facility is not covered by warranty.

For customer support, contact: service@volk.com
**Appendix A – FCC Statement**

**Electromagnetic compatibility information**

**US notice**

Wireless LAN frequency range 2412 MHz ~ 2462 MHz

**Federal Communication Commission Interference Statement**

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

**FCC Caution**

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

**Radiation Exposure Statement**

This device meets the government’s requirements for exposure to radio waves.

This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

The exposure standard for wireless device employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg. Tests for SAR are conducted using standard operating positions accepted by the FCC with the device transmitting at its highest certified power level in all tested frequency bands.

The highest SAR value for the device as reported to the FCC is 1.492 W/kg when placed next to the body.
Appendix B – Replacing the AAA Batteries

Two AAA batteries are included within the device to operate the flashing LED on the front of the camera. The user can follow the instructions below to replace the batteries. Alternatively, Volk Optical, and/or Volk Optical’s retailers will provide battery replacement service.

Replacing the Fixation Target batteries:

1. Open the battery compartment cover by removing four screws at the back. Put the screws somewhere safe so they don’t get lost.

2. Gently pry the back cover away from the front of the Eye Check device, starting at the groove on the right-hand end of the case.

3. Insert 2 fresh AAA Alkaline batteries, after first making note of the proper orientation.

   Please dispose properly of the old batteries.

4. Replace the back cover by snapping it in to position all around the edges. Finish by replacing the four screws saved from step 1.