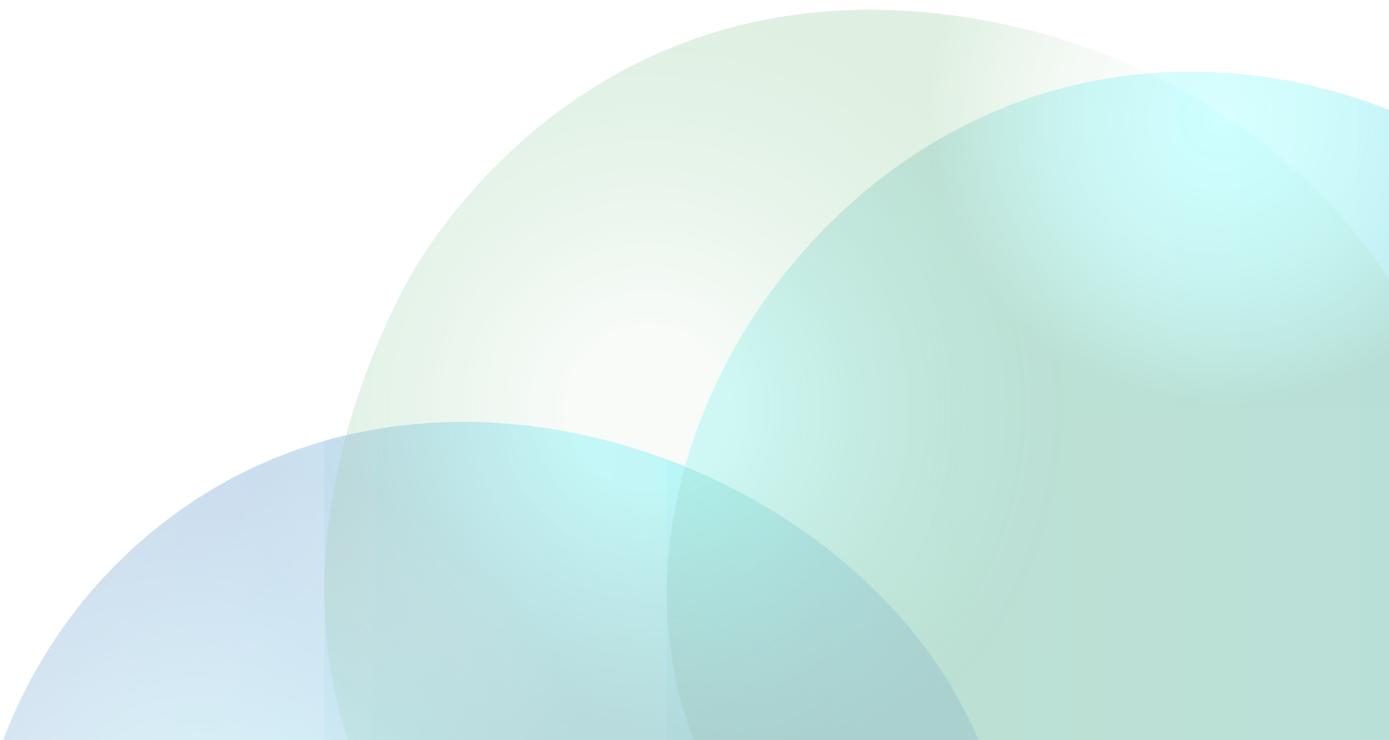


# Heru Platform

---

## Instructions For Use



# Contents

|  |           |
|--|-----------|
| <b>1. INTRODUCTION</b>   | <b>2</b>  |
| <b>2. DEVICE DESCRIPTION</b>   | <b>2</b>  |
| <b>3. INTENDED USE</b>   | <b>2</b>  |
| <b>4. GENERAL AND INSTALLATION SAFETY PRECAUTIONS</b>                    | <b>3</b>  |
| 4.1. General Precautions   | 3         |
| 4.2. Installation Safety Precautions                                     | 3         |
| <b>5. PRE-USE REQUIREMENTS AND DEPENDENCIES</b>                          | <b>4</b>  |
| <b>6. HERU PORTAL REGISTRATION</b>                                       | <b>4</b>  |
| <b>7. SOFTWARE INSTALLATION, UPGRADE, AND CONFIGURATION</b>              | <b>4</b>  |
| <b>8. CLEANING THE DEVICE</b>  | <b>4</b>  |
| <b>9. LIGHT SHIELD AND LENS HOLDER INSTALLATION</b>                      | <b>5</b>  |
| <b>10. STEP-BY-STEP INSTRUCTIONS</b>                                     | <b>6</b>  |
| 10.1. Logging into the Heru Portal                                       | 6         |
| 10.2. Heru Portal Overview   | 6         |
| 10.3. Adding a new patient and creating an appointment (testing session) | 7         |
| 10.4. Taking a Test  | 8         |
| 10.5. Reviewing the Results  | 12        |
| 10.6. Printing or Saving Test Results                                    | 13        |
| 10.7. Powering Off Your HMD  | 13        |
| 10.8. Dark Adaptation  | 14        |
| <b>11. TROUBLESHOOTING</b>   | <b>16</b> |
| <b>12. TECHNICAL SPECIFICATIONS</b>                                      | <b>18</b> |
| <b>13. SYMBOLS AND LABELS</b>  | <b>19</b> |
| <b>14. CONTACT US</b>  | <b>20</b> |

## 1. INTRODUCTION

Heru is a platform that provides functional and anatomical diagnostic data for the purpose of supporting the diagnosis of various eye conditions. Heru is a system that works with commercially available Head Mounted Display devices (HMDs) such as the Magic Leap 1 (Magic Leap) and HoloLens 2 (Microsoft). The Heru system provides speed, flexibility, and precision not available with legacy non-wearable devices.

## 2. DEVICE DESCRIPTION

The complete system is comprised of the following items:

- Heru HMD Application
- Browser-based Heru Portal Application (see Section 12. Technical Specifications for browser details)
- Approved HMD hardware
- Bluetooth patient response controller
- Light shield and integrated Dark Adaptation Accessory hardware
- Lens holder and Neutral Density Filter (NDF) Attachment
- Any approved compatible computing platform including a PC, Mac, Desktop or tablet (see Section 12. Technical Specifications for manufacturers recommended platforms)

You will need to access the Heru Portal via a web browser to start, store, and review patient's clinical test results. Stable internet connection of 10 Mb download and 5 Mb upload speed is required.

The Heru application performs static visual field testing to identify and quantify central vision defects. Stimuli are presented over the patient's field of view, and according to the response of the patient, a map of the visual field is created to indicate the presence and

locations of field defects. One stimulus will be displayed at a time. Eye tracking is employed to ensure that the patient is gazing at the fixation target.

The Heru application performs contrast sensitivity testing to identify and quantify macula function. The system will present a 20/267 tumbling "E" to the patient at various contrast levels ranging from 0.00 to 2.55 log units.

The Heru application performs Ishihara color vision testing to screen for and identify color vision defects and D-15 to categorize color vision defects.

The Heru application performs Dark Adaptation testing to determine the dark adaptation ability of the patient's eyes to aid in diagnosis of macular disease.

The Heru application works with no pupil dilation (non-mydriatic).

## 3. INTENDED USE

Heru is a multi-modal testing platform intended for use on patients that are eighteen or over. The following tests and indications for use are available:

**Visual Field:** The Heru visual field perimetry test intended to measure the field of view of the eye for the purpose of mapping the visual field utilizing commercially available head mounted display devices ("HMDs").

**Contrast Sensitivity:** The Heru contrast sensitivity test is intended to measure visual function by testing the patient's ability to distinguish between an object and the background behind it.

**Color Vision:** The Heru Ishihara Color Vision Screening is intended to measure visual function by testing the patient's ability to distinguish between objects and backgrounds of differing colors. The Heru Farnsworth D15 Extended Color Vision exam is intended to measure visual function by testing the patient's ability to distinguish colors well enough to order a set of colored shapes in sequence by similarity. This exam aids the clinician in classifying color vision defects.

**Dark Adaptation:** The Heru Dark Adaptation test is intended to determine the dark adaptation ability of the patient's eyes to aid the doctor in diagnosis and management of macular disease.

**Note:** Test results provided by the Heru system are intended to be an aid to interpretation, not a diagnosis. Physician should confirm interpretation of results through independent methods.

### 4. GENERAL AND INSTALLATION SAFETY PRECAUTIONS

#### 4.1. General Precautions

- Periodically change your password to the Heru Portal.
- Always log out after your session is over.
- Heru does not provide a diagnosis of an eye pathology. Products and Services made available through Heru do not make clinical, medical, or other professional decisions.
- Heru is not intended for use on patients under 18 years of age.
- DO NOT administer a test to a patient who is not in a stable sitting position. The clinician is solely responsible for obtaining necessary consents for use and disclosure of patient information.
- Please read the general safety precautions and the manufacturer's instructions for use for the HMD prior to use.

#### 4.2. Installation Safety Precautions

- A Heru representative will schedule a training appointment upon receipt of your Heru equipment. During this training appointment, you and your staff will be guided through the basic operations of configuring, using, and maintaining your Heru equipment. User should obtain training before clinical use.
- Use only those parts provided by Heru to achieve optimum performance and safety.
- Make sure that your computer meets the technical specifications in section 12.
- For Technical Support or Customer Care: Please see section 14.

## 5. PRE-USE REQUIREMENTS AND DEPENDENCIES

The Heru application is intended for use in healthcare provider offices and other clinical environments.

The operators are healthcare providers with professional training or experience in the use of ophthalmic equipment.

The operator should be a licensed practitioner, trained in at least one of the following professions:

- Ophthalmologist
- Optometrist
- Nurse
- Medical Technician
- Ophthalmic Technician/Photographer

The operator must have training and the ability to carry out the system operation.

## 6. HERU PORTAL REGISTRATION

An authorized Heru administrator will create your account and assign a username during initial setup. At this time, the email address associated with the account will be sent a link to set a password.

## 7. SOFTWARE INSTALLATION, UPGRADE, AND CONFIGURATION

An authorized Heru representative will install and configure the Heru Test prior to shipment. To ensure optimal customer experience, Heru will remotely push software updates to both the HMD and the Heru Portal.

Updates to the Heru application will require the operator to fully power-down and restart the HMD. Heru recommends a full power-down at the end of the day.

Learn how to power off your HMD in Section 10.7. Powering Off Your HMD.

## 8. CLEANING THE DEVICE

To minimize cross-contamination and optimize eye-tracking performance, clean the device before each use, taking care to clean the areas that come in contact with the patient, such as the HMD, light shield, lens holder, and controller.

| COMPONENT                         | CLEAN WITH            |
|-----------------------------------|-----------------------|
| HMD screen                        | Lens cloth            |
| Trial lenses                      | Lens cloth            |
| Neutral Density Filter Attachment | Lens cloth            |
| HMD                               | 70% isopropyl alcohol |
| Controller                        | 70% isopropyl alcohol |
| Light shield                      | 70% isopropyl alcohol |
| Lens holder                       | 70% isopropyl alcohol |

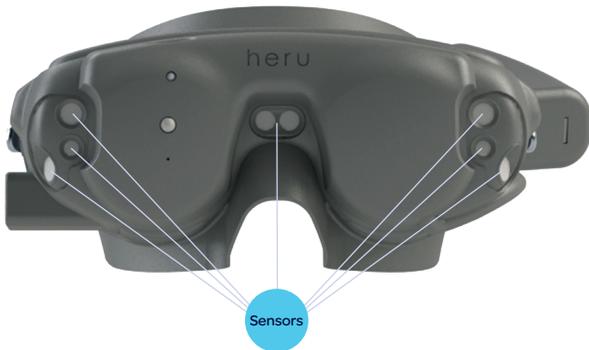
## 9. LIGHT SHIELD AND LENS HOLDER INSTALLATION

The purpose of the HMD light shield is to obscure the patient's view and to prevent light leakage during the operation of the test.



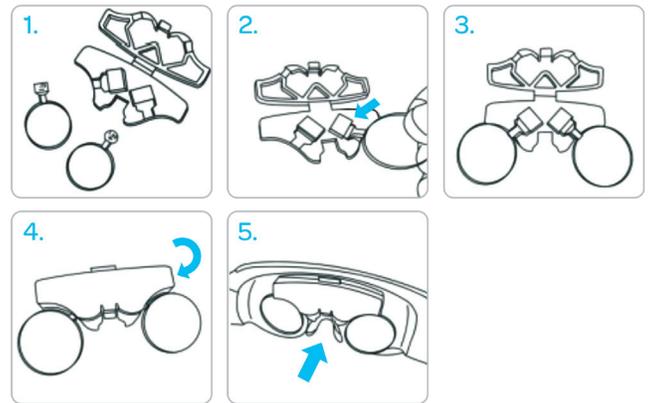
Start by unpacking your HMD, light shield, and lens holder and follow the steps below:

1. Slide the light shield over the front of the HMD and carefully align the nosepiece, sides, and forehead. Ensure the sensors on the front of the HMD are not occluded.



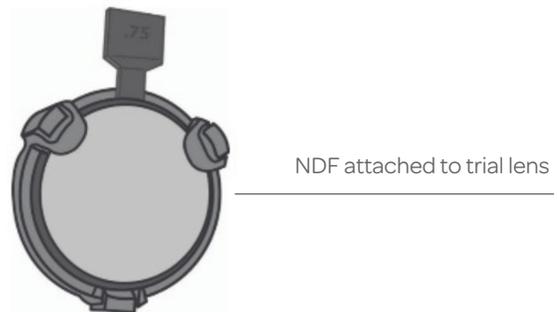
**Note:** It is critical that you ensure the light shield is not folded over inside the HMD, blocking the patient's field of view. Always confirm with the patient that they can see all four corners of the fit confirmation screen.

The purpose of the lens holder is to position off-the-shelf trial lenses to correct the patient's distance vision as necessary for the tests. The lens holder replaces the forehead pad in the HMD device. To install the lens holder, remove the standard insert that comes with the HMD and the forehead pad by pulling them straight out. Install the lens holder by inserting the back poles to the device. To insert the trial lenses, open the lens holder and slide the lenses in by their handle as shown below:



**Note:** It is recommended to minimize reflections by carefully cleaning each lens with a lens cloth before placement and by placing the flattest portion of the lens towards the HMD screens.

For Dark Adaptation Testing, always apply the NDF Attachment to the trial lens of the eye being tested before inserting it into the lens holder.



## 10. STEP-BY-STEP INSTRUCTIONS

Before beginning the exam, confirm that you have successfully logged into the Heru Portal and executed the HMD shield/lens holder installation (if refractive correction is required).

**Note:** Screenshots are for illustrative purposes.

### 10.1. Logging into the Heru Portal

- Using your web browser, access the Heru Portal at <https://portal.seeheru.com>
- Log in with your credentials.



- If you forget your username or password, select “Forgot username or password” and use a registered email address to retrieve or reset your login credentials.

### 10.2. Heru Portal Overview

#### 10.2.1. Title bar icons



**Light Theme toggle** – Change theme from light to dark for comfortable viewing in a dark room.

**Alert** – Notifications such as, but not limited to, pending errors or warnings from ongoing tests.

**Information** – Display information useful when contacting Heru, Inc. Customer Service.

The following information is displayed when you press the  button:

- Heru, Inc. About Us Information
- Software and Web Portal Version
- Contact Information
- Support Contact Information

**Logout** – Log out or sign in under a different user.

#### 10.2.2. Operating icons

|  |  |
|--|--|
| <br>ACCOUNTS           | <b>Accounts:</b> Account management and enables multiple users to customize their preferred settings.  |
| <br>APPOINTMENTS      | <b>Appointments:</b> View previous and scheduled appointments database and test data.  |
| <br>PATIENTS         | <b>Patients:</b> Create new patients, create new appointments for existing patients, and view or edit existing patient data.                                   |
| <br>DEVICES          | <b>Devices:</b> Confirm list of devices associated with the clinic, check status of devices, and modify details such as name of devices.                       |
| <br>FAQS             | <b>FAQ:</b> Frequently Asked Questions.  |
| <br>ACCOUNT SETTINGS | <b>Account Settings:</b> Available for account administrators to configure Heru portal account settings and defaults such as password strength and expiration. |
| <br>MY PROFILE       | <b>My Profile:</b> Configure Heru portal contact details such as modifying username or password.   |

### 10.3. Adding a New Patient and creating an appointment (testing session)

1. Click on “Patients” on the left side bar.
2. Click on “Create Patient”.
3. Patient Details page will open. Enter your patients details and click “Save Patient”.

**NEW PATIENT** CAUTION: Investigational device. Limited by Federal (or United States) law to Investigational use.

**Patient Details**

Prefix:  First Name \*:  Middle Name:

Last Name \*:  Suffix:  Date of Birth \*:

Medical Record Number (MRN):  Sex \*:  Male  Female  Other

**User & Contact Data**

Email:  Phone:

Status \*:  Active  Suspended

Buttons: Cancel, Save Patient

4. Select to create an appointment by clicking on “New Appointment”.

**New Appointment**

**PATIENT DETAILS** CAUTION: Investigational device. Limited by Federal (or United States) law to Investigational use.

**Test Test**

Date of Birth: Jan 1, 1980  
Sex: Female

**Medical Information**

**Appointments**

Buttons: Update Medical Information, New Appointment

5. Complete the “Patient information” section and confirm accuracy.

**NEW APPOINTMENT** CAUTION: Investigational device. Limited by Federal (or United States) law to Investigational use.

**PATIENT INFORMATION**

**Test Test**

Sex: Female Date of Birth: 01/01/1980 (42 Years old)

**Medical Information**

Right Eye: Sphere +/-, Cylinder +/-, Axis

Left Eye: Sphere +/-, Cylinder +/-, Axis

6. Select the language you would like the directions to be given to the patient, then select the test you would like to apply to the appointment.

**NEW APPOINTMENT** CAUTION: Investigational device. Limited by Federal (or United States) law to Investigational use.

**Languages**

English (United States)

**Tests To Apply**

Subjective / Suprathreshold

Subjective / red Threshold

Color Vision - Ishihara

Color Vision - D-15

Contrast Sensitivity

Dark Adaptation - Rapid

Dark Adaptation - Extended

Buttons: Cancel, Save For Later, Start

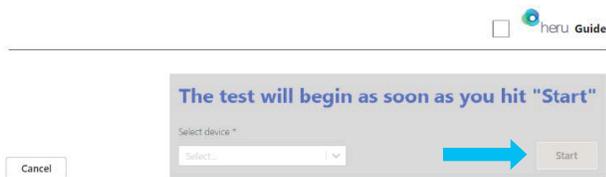
7. AutoWorkflow

By selecting AutoWorkflow, the test will seamlessly proceed directly from a screening to a diagnostic exam when an abnormal screening result is observed. The table below defines the modalities that can automatically progress using AutoWorkflow and the criteria defined as an abnormal screening result.

| Screening Modality       | Abnormal Result          | Diagnostic Modality    |
|--------------------------|--------------------------|------------------------|
| SupraThreshold VF        | 3 or more unseen stimuli | Full Threshold 24-2 VF |
| Ishihara Color Screening | 3 or more missed plates  | D-15 Color Vision Test |

Tests To Apply

8. Select available device from dropdown menu or type device label code into search field on the right upper side of the screen. Click “Start” only once the device has been properly fitted to the patient and you are ready to begin the appointment. Pressing “Start” will initiate testing on the HMD.



**Note:** The HMD will begin testing as soon as you select the device in the Heru Portal and click Start.

10.4. Taking a Test

Before beginning the exam, confirm that you have successfully completed the HMD light shield / lens holder installation (see section 9). You do not need to occlude either eye for the Heru Visual Field Test. Turn on the HMD as well as the controller at the beginning of the day.

10.4.1. Magic Leap 1 HMD

**Note:** If you are using a HoloLens 2 HMD, refer to section 10.4.2.

1. Ensure that the battery of the HMD is charged to at least 50%. Refer to HMD manual for charging instructions.
2. You will need to use the trial lens holder if the patient has a distance prescription. Select the appropriate trial lens by calculating the spherical equivalent or use the look-up table below for each eye being tested.

**Spherical Equivalent = (Cylinder/2) + Sphere**

Install the trial lenses in the HMD following the instructions in section 9.

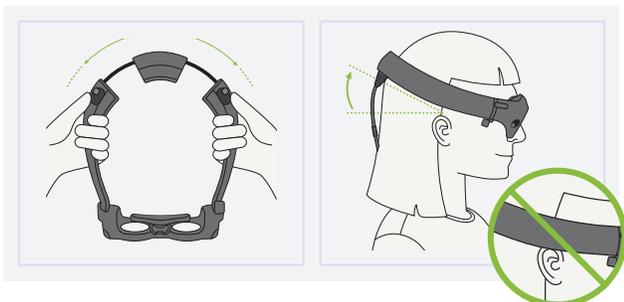
3. Orient the patient to the controller, showing them the bumper that they will press during the test. This should be the only button they press to throughout testing during the Heru application.

### PATIENT CONTROLLER



4. Show the patient how the HMD expands to fit most heads and instruct them to keep the back padding high on the back of their head. Instruct the patient to hold the light shield out of the way while fitting on their heads to minimize obscuration of their field of view. Make sure the HMD is comfortably positioned with the back of the HMD resting high on the back of the patient's head.

**Note:** Keeping the back of the HMD high on the patient's head will minimize slipping down the patient's nose and will optimize the patient's field of view.



5. Hand the patient the controller and make sure they have their finger resting gently over the bumper and not pressing any other buttons.

### 6. Alignment step:

- First, the patient will be shown a screen reminding them how to fit the HMD on their head and will ask the patient to confirm they can see all four corners of the screen. This will ensure that the patient's view is unobstructed during testing.
- If the patient cannot see the four corners, have them adjust the device on the head until all four corner markers are visible.

7. Once the patient is comfortable, set up the appointment parameters (which tests, which eyes, parameters for each test) in the Portal. The Heru Guide will walk them through the test initialization and the operator can follow along from the Exam View in the Heru Portal.

- Where gaze tracking is required, the Heru Guide will walk the patient through a quick gaze-tracking calibration by moving a white dot around the patient's field of view.

### 8. Heru Guide:

- If the Heru Guide is turned on, the patient will be given an interactive overview of the testing process.
- If the Heru Guide is turned off, the patient will need to be instructed by the technician on the operation of the test.

9. The technician must click "**Start**" in the Portal on the Appointments page to begin testing.

10. The test will progress automatically. In most cases, no further interaction with operator is required. During certain tests, like Dark Adaptation testing, the operator will have to interact with the exam view in order to move the test along.

11. During the test, the operator will be able to see the progress of the test on the Exam View. There is also a progress bar in the Exam View.

12. When using ActiveTrack™ real-time eye tracking during the exam, if a patient loses track of the fixation point in any area of the screen stimuli will stop showing and the Heru Guide will return to encourage the patient to fixate while the fixation target wiggles to get their attention. Once the patient looks back at the target the test will resume after a few seconds.
13. If the HMD continues to detect poor fixation, it will track the patient's fixation using Optic Nerve Head (ONH) Fixation Monitoring, keeping track of fixation losses as they are detected.
14. If the patient's two eyes are being tested: after the first eye is done, the device will go to a resting step and ask the patient to start by pressing the bumper when they are ready (see step 10).
15. Once testing is complete, the Heru Guide will congratulate the patient and instruct them to return the HMD and controller to the operator.
4. Place the device on the patient's head. Make sure it is comfortably positioned. Ensure device is secured onto the patient's head, to prevent it from sliding down.
5. Explain to the patient that during the exam that he/she needs to keep their head straight without moving it.
6. A voice prompt will say: "Welcome to Heru" and the same message will appear on the screen of the HMD.
7. Ask the patient to look in the direction of the monitor. The operator will use the access code to start the test. Press the upper button and read the code.  
  
The HMD will read the code again and ask for confirmation.  
  
If the code is correct, press the middle button of the clicker for HoloLens 2. Alternatively, press the upper button and say "Yes" then press the upper button again.  
  
If code is incorrect, press the lower button of the clicker. Alternatively, press the upper button and say "No" then press the upper button again. In that case the device will go back to step 4.

### 10.4.2. HoloLens 2 HMD

**Note:** If you are using a Magic Leap 1 HMD, refer to section 10.4.1 for instructions.

Before beginning the exam, confirm that you have successfully completed the Heru portal registration and HMD light shield / lens / liner installation (see sections 6 and 9).

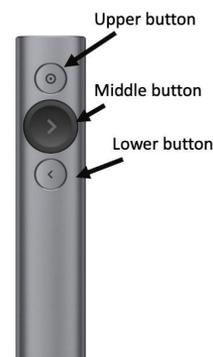
1. Ensure that the battery of the HMDs is charged to at least 50%. Refer to HMD instructions for use for charging instructions.
2. Select the trial lens to go onto the trial frame, using spherical equivalent for each eye.
3. Turn on the device as well as the patient clicker.

8. **Calibration steps:** This calibration step only happens if the patient has not used the device before. If the patient has used the device before with successful calibration, the HMD will skip this process and go directly to step 7.

- The patient will see a gray with white corners screen on the HMD.
- Ask the patient if her/she can see all four corners.
- If the patient can see the four corners, then the device is positioned correctly. The patient needs to press on the middle button on the clicker.
- If the patient cannot see the four corners, have them adjust the device on the head until all four corners are visible, then the patient can click on the middle button on the clicker.
- A voice prompt will say “Hold your head still and follow the gems with your eyes”. Ask the patient to follow the gems that appears on the HMD with their eyes.
- If the calibration is successful: A voice prompt will say “Your HoloLens 2 is calibrated. You can always make changes in settings if something doesn’t look right”.
- If the calibration is not successful, a voice prompt will say “It is not working, let’s keep going and you can adjust this later in settings”.
- The operator or the patient needs to say “Done”. Alternatively, the patient can reach out with their finger to press the button saying “Done”.

9. The HMD will present a screen to the patient with the name and date of birth of the patient and ask for confirmation:

- If the name and date of birth of the patient is correct, press the middle button of the clicker of the HoloLens 2. Alternatively, press the upper button and say “Yes” then press the upper button again.
- If the name or date of birth of the patient is incorrect, press the lower button of the clicker. Alternatively, press the upper button and say “No” then press the upper button again.



10. A voice prompt will say: “Starting the test in 3 - 2 - 1” and the same message will appear on the screen of the HMD.
11. A white rectangle will appear on the screen. Ask the patient if they can see all four corners of this rectangle.
- If the patient can see the four corners of the white rectangle, then the device is positioned correctly. Remind patient to keep their head position straight.
  - If the patient cannot see the four corners of the white rectangle, have them adjust the device on the head until all four corners of the white screen are visible.

12. While the patient is on the screen with the white rectangle, give them the following instructions:

Fixate your eyes on the bright white dot that will appear in the center and follow this white fixation target wherever it moves.

There will be flashes of light in your peripheral vision. Do not move your eyes to look at the flashes.

Click the middle button whenever you see a flash. The brightness of the flashes will vary during the test.

13. To start the actual visual field test:

The patient needs to hit the middle button.

**Note:** if the calibration was not successful in step 8, the patient will need to press once to get to a black screen. Press another time to go to step 14.

14. A bright white dot will appear in the middle of the screen and the test will progress.

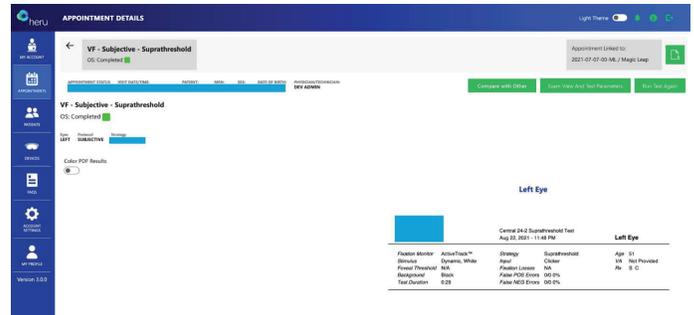
15. During the test, you will be able to see the progress of the test on a progress bar on the web portal screen. If an error occurs during the test, an error message will appear.

16. When the test is completed, a voice prompt saying “test completed” will be heard and the same message will appear on the screen of the HMD.

17. If the patients’ two eyes are being tested: after the first eye is done, the device will pause and resume testing.

### 10.5. Reviewing the Results

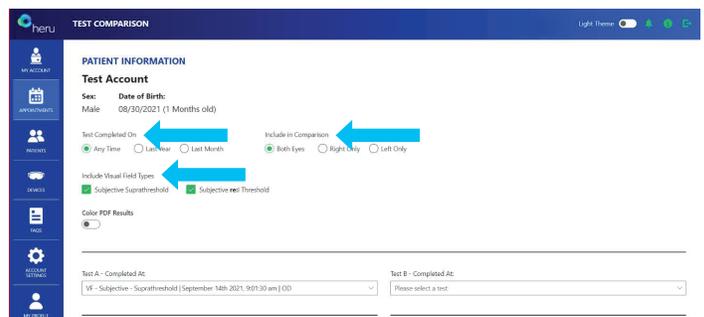
After the patient takes the test, the results will appear in the Heru Portal under the Appointments tab.



The eye care provider has option to compare tests side-by-side, by selecting Compare with Other.

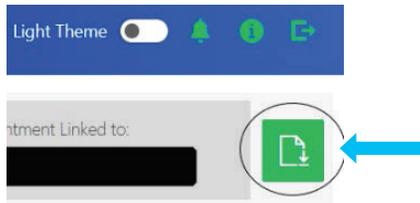


- Select Test Completed On (options: Any Time, Last Year or Last Month)
- Include in Comparison (options: Both Eyes, Right EYE Only or Left Eye Only)
- Visual Field Types (options: Subjective Suprathreshold or Subjective re:I Threshold)
- On dropdown select the dates you are wanting to view



## 10.6. Printing or Saving Test Results

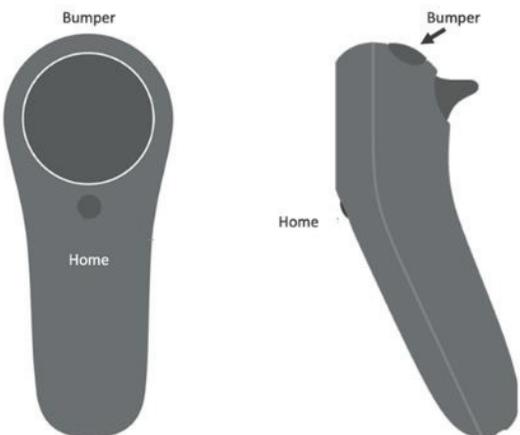
From the Results display screen, the download icon can be found in the upper right-hand corner to save or print your results.



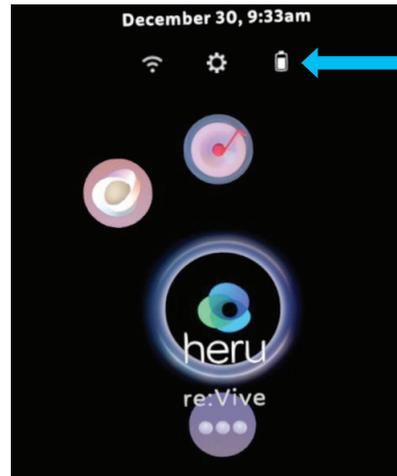
## 10.7. Powering Off Your HMD

The HMDs should be powered off every night to ensure proper charging and stability of the instrument software. Also, new software is pushed through Over-the-Air (OTA) updates regularly but can only be applied by rebooting the HMD.

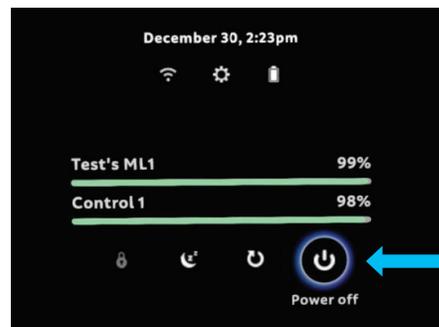
### PATIENT CONTROLLER



To power off your Magic Leap 1, exit the Heru application by pressing the Home button on the hand controller.



On the main menu, select the battery icon at the top of the screen using the trigger on the hand controller. This will be located directly below the date and time.



Select the fourth icon labeled "Power Off" at the bottom of the screen below the battery status levels.

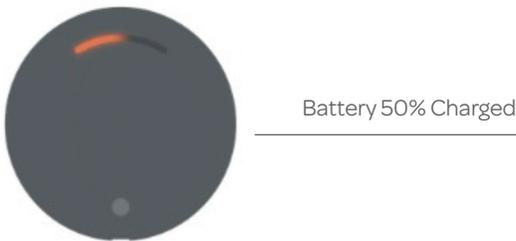
Complete the circle on the touchpad of the hand controller. The Magic Leap 1 will shut down. The Heru platform is safe to leave plugged into its charger overnight when the device is fully powered down.

If you received an email notification from Heru regarding a new software update becoming available, please reboot your device and wait 15-minutes before opening the app.

10.8. Dark Adaptation

**Note:** Dark Adaptation is only available when using Magic Leap 1.

1. Make sure the headset is charged.
  - a. **Extended DA:** Make sure there is at least 50% battery on the headset and the controller before running the test. The Dark Adaptation Accessory is not designed to run the test while it is actively charging.

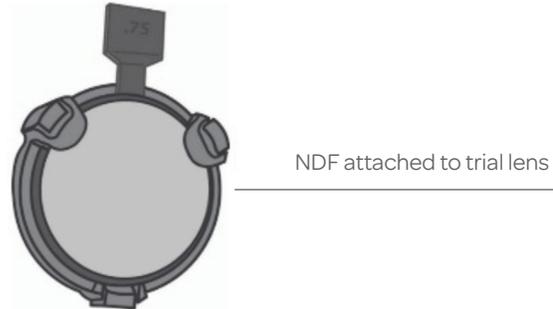


2. Ensure Bluetooth is turned on through the Magic Leap 1 settings.
3. Please conduct the test in a room where the lights may be dimmed or turned off. The operator will be asked to turn off or dim the lights once the test begins.
4. Ensure the Dark Adaptation Accessory is properly attached by ensuring the light shield is not blocking any of the sensory.
5. Insert the distance spherical equivalent trial lenses in both eyes – not just the eye being tested.

**Spherical Equivalent = (Cylinder/2) + Sphere**

6. Attach the neutral density filter (NDF) attachment to the trial lens of only the eye that will be tested. When inserting the trial lens and NDF attachment in the headset, the NDF should be oriented so that it is on the side closest to the screen (not the patient's eye).
  - a. If no prescription is needed on the tested eye, you may attach it to a plano or a -0.25 DS trial lens.

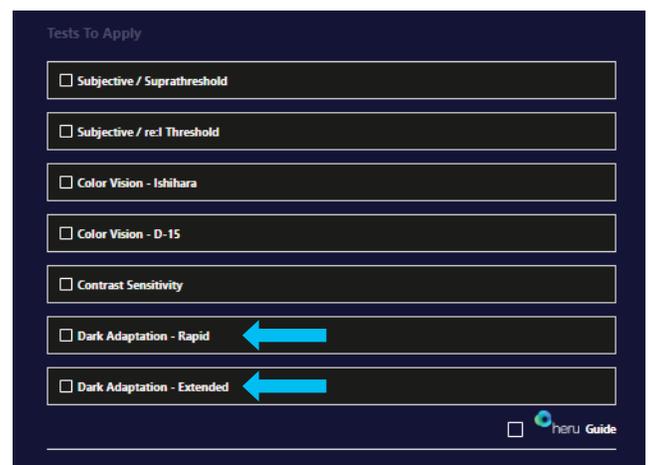
- b. The NDF attachment should not be used in other tests.



7. Select the Dark Adaptation test in the portal. Select the test type, test eye, and the device and click "Start".

**Note:** Dark Adaptation tests cannot be stacked with other tests. You will notice the other tests will gray out and you will not be able to select those tests to be run before or after Dark Adaptation. You may only run one eye at a time for Dark Adaptation tests.

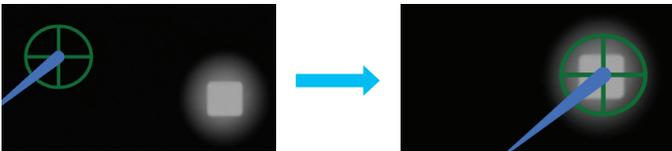
To run Dark Adaptation testing, you will need a device with a Dark Adaptation accessory. Devices with the Dark Adaptation accessories will show up with a small icon with the letters DA.



## HERU PLATFORM INSTRUCTIONS FOR USE

---

8. At the start of the test, make sure the room lights are on. If the lights are off or too dim, the patient will have a hard time seeing the laser pointer.
9. Follow the instructions on the Exam View within the portal.
10. The headset will automatically connect to the accessory. This may take up to 15 seconds.
11. Once the connection is made, the system will perform eye tracking calibration.
12. After the demo, the patient will go through the LED calibration. A dim stationary light will appear, and the patient will be instructed to use the controller to move the green crosshairs over this light and select "Click Here to Continue" at the bottom of the screen. Alternatively, the operator may click the "Patient Done Calibrating" button on the portal to advance to the next step if the patient reports they have centered the green crosshair over the light.



What the patient will see at the beginning of the LED calibration step. Then the goal of the end of the LED calibration step.

13. Once the calibration is complete, dim the room lights. After confirming the patient is looking at the fixation target, click "Ready to Flash".
  - a. Move quickly in this step to maximize the accuracy of the flash/bleach.
  - b. In order to conduct a reliable test, it is recommended to restart the test if there are any concerns about improper alignment for any reason.
14. The test will begin after the flash/bleach has been administered.
15. During the test, the patient should focus on the fixation target and click the bumper each time they see a faint light appear below.
  - a. It is normal for the patient to not see anything for the first 30 seconds because their eyes are still adjusting. If you do not see them clicking after one minute, review the instructions again to make sure the patient understood the directions.
  - b. Patients with disease may take even longer to notice these dim lights.
16. The test will give breaks and encouragements to the patient to keep them rested and engaged for more reliable data collection.
17. The Rapid test shall end in 4.5 minutes and the Extended test will take 20 minutes. If the test needs to be cancelled at any point, the operator may click "End Test" on the Exam View. A report will be generated depending on how much data was collected prior to test being cancelled. If the operator clicks "Restart", then the data collected will be discarded and the test will start over.
18. Once the test ends, turn on the lights and remove the headset.

11. TROUBLESHOOTING

| ISSUE  | RESOLUTION  |
|--|---|
| Cannot find the HMD you need when creating an appointment                | <ul style="list-style-type: none"> <li>• Confirm the HMD is on the four corner screen.</li> <li>• Confirm the HMD is charged and connected to the local WiFi network.</li> <li>• Confirm the HMD is not “In Progress” with another appointment. Always confirm the color of the HMD and handcontroller match the color selected when creating an appointment.</li> <li>• The device must have a DA label in the drop down in order to select it.</li> </ul>   |
| HMD screens are black, but can still hear the application                | <ul style="list-style-type: none"> <li>• Confirm the room lighting is ON.</li> <li>• Confirm there is no one and nothing directly in front of the patient.</li> <li>• Confirm the patient is facing an open space such as a hallway.</li> <li>• Confirm the Eye Tracking cameras are clean and free of obscurations.</li> <li>• Exit the application using the Home button on the hand controller. Hit the Home button again and Close the Heru Application. Hit the Home button again to reach the Applications page, and restart the Heru Application.</li> </ul> |
| Difficulty logging into the Heru Portal                                  | <ul style="list-style-type: none"> <li>• Make sure you are connected to the Internet.</li> <li>• Make sure you are using an approved web browser (see section 12).</li> <li>• Reset your password. Select “Forgot username or password” from the login screen and use a registered email address to retrieve or reset your login credentials.</li> </ul>  |
| Not able to create the appointment for the patient                       | <ul style="list-style-type: none"> <li>• Make sure that all the required fields on “Create appointment” section are completed.</li> <li>• Make sure that the appointment is not created for a past date/time.</li> </ul>  |
| Ambient light leaking into patient field of view                         | <ul style="list-style-type: none"> <li>• Readjust the light shield. Ensure there are no sources of light directly behind the patient.</li> </ul>  |
| Test interrupted   | <ul style="list-style-type: none"> <li>• Make sure that the HMD’s battery is more than 50% charged. If not, then connect the HMD to power with the charger that is provided with it. The test can be performed while the HMD is connected to power.</li> </ul>  |
| The patient is complaining that the HMD is sliding down their face/nose. | <ul style="list-style-type: none"> <li>• Make sure the HMD is positioned at an angle with the back of the device sitting high on the patient’s head.</li> </ul>   |

| ISSUE   | RESOLUTION  |
|---|---|
| <p>The patient is not seeing the four corner markers during alignment displayed on the HMD screen.</p>  | <ul style="list-style-type: none"> <li>• Ask the patient to adjust the position of the wearable device until he/she sees the four corners.</li> <li>• Confirm the light shield is not folded into the patient’s field of view.</li> <li>• Confirm the back of the HMD is sitting high on the patient’s head.</li> <li>• It is normal if half of the screen is dimmer, making it harder to see the corners of the side with the NDF. If the NDF makes it too difficult for the patient to see all four corners, ensure the headset is aligned such that they can still appreciate the two corners in the eye without the NDF.</li> </ul> |
| <p>Results are not appearing in the results section of the web portal.</p>  | <ul style="list-style-type: none"> <li>• Make sure the HMD and Portal are connected to the Internet.</li> <li>• Make sure that you are using a supported browser. See section 12 for a list of supported browsers.</li> </ul>   |
| <p>The patient cannot see the laser pointer from their controller during the LED Calibration step in Dark Adaptation testing.</p>   | <ul style="list-style-type: none"> <li>• Ensure the room lights are on.</li> <li>• Make sure the controller is pointed straight ahead.</li> <li>• Make sure the patient is holding the controller in front of them, and not on their side.</li> </ul>   |
| <p>A “No dark adaptation accessory detected” error will be displayed if the device is out of battery during Dark Adaptation testing.</p>  | <ul style="list-style-type: none"> <li>• Please charge the Dark Adaptation Accessory. Note: The flash will not be administered if the accessory is charging.</li> </ul>   |
| <p>A “Flash Error” is detected when the patient’s sensitivity is above the expected level in the beginning of the Dark Adaption test. This may happen due to incorrect fixation during the flash/bleach step.</p> | <ul style="list-style-type: none"> <li>• Restart the test.</li> <li>• Consider ending the test once the error is detected. We advise re-running the same eye in roughly 20 minutes or wait until any after image patient may be seeing is completely resolved. Alternatively, consider testing the other eye instead.</li> </ul>  |
| <p>The fixation loss number will turn red if it is above 30% during the dark adaptation test.</p>   | <ul style="list-style-type: none"> <li>• Even though the Heru Guide will remind them, please remind the patient to look at the fixation target.</li> </ul>  |

**12. TECHNICAL SPECIFICATIONS**

| COMPONENT                         | ATTRIBUTE   | VALUE  |
|-----------------------------------|---|--|
| Light Shield for HoloLens 2 HMD   | Weight  | 114g (0.25g)   |
|                                   | Dimensions  | 11.7cm x 9.7cm x 19cm  |
| Light Shield for Magic Leap 1 HMD | Weight  | 45g  |
|                                   | Dimensions  | 13.78" x 19.69" x 13.78"   |
| Dark Adaptation Accessory         | Weight  | 6.1 ounces (about 172.93 g)  |
|                                   | Dimensions  | 5.2 inches x 2.6 inches  |
| Heru Modalities                   | Visual Field Test Patterns                          | 24-2<br>10-2   |
|                                   | Visual Field Testing Strategy                       | re:Imagine™<br>Suprathreshold  |
|                                   | Stimulus Duration                                   | 200 msec   |
|                                   | Wavelength  | Broadband visual light   |
|                                   | Maximum Visual Field Range Tested                   | 24 degrees temporally<br>30 degrees nasally                            |
|                                   | Number of Stimuli tested                            | 54 points (24-2)<br>68 points (10-2)                                   |
|                                   | Spacing Between Stimuli                             | 6 angular degrees (24-2)<br>1 angular degree (10-2)                    |
|                                   | Fixation Monitor                                    | ActiveTrack™ (Gaze) or<br>Blind spot (Fixation Losses)                 |
|                                   | Contrast Sensitivity Optotype Size                  | 20/672   |
|                                   | Contrast Sensitivity Testing Range (log units)      | 0.00 to 2.55   |
| Network recommendations           | Chrome Web Browser (recommend using latest version) | Outbound, port 443<br>Upload speed: 5 MB/s<br>Download speeds: 10 MB/s |

13. SYMBOLS AND LABELS

| SYMBOL  | SYMBOL TITLE                 | EXPLANATORY TEXT  | STANDARD TITLE  | STANDARD REFERENCE                                  |
|---|------------------------------|---|---|---|
|    | Manufacturer                 | Indicates the medical device manufacturer   | Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements | ISO 15223-1 Reference #5.1.1 FDA Recognition #5-117 |
|    | Consult Instructions for Use | Indicates the need for the user to consult the instructions for use   | Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements | ISO 15223-1 Reference #5.4.3 FDA Recognition #5-117 |
|    | Medical Device               | Indicates the item is a medical device  | Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements | ISO 15223-1 Reference #5.7.7 FDA Recognition #5-117 |
|    | Catalog #                    | Indicates the manufacturer's catalog # so that the medical device can be identified   | Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements | ISO 15223-1 Reference #5.18 FDA Recognition #5-117  |
|  | Keep Dry                     | Indicates a medical device that needs to be protected from moisture   | Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements | ISO 15223-1 Reference #5.3.4 FDA Recognition #5-117 |
|  | WEEE                         | Signifies waste from electrical and electronic equipment that should be collected separately from municipal waste   | Waste Electrical and Electronic Equipment Directive   | WEEE Directive 2012/19/EU                           |
|  | Type BF applied part         | Identifies a Type B applied part complying with IEC 60601-1<br>Note: B = Body F = Floating  | Graphical symbols for electrical equipment in medical practice  | IEC 60417 Reference #5333 FDA Recognition #5-102    |
|  | Fragile, handle with care    | Indicates a medical device that can be broken or damaged if not handled carefully   | Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements | ISO 15223-1 Reference #5.3.1 FDA Recognition #5-117 |
|  | Caution                      | Indicates that caution is necessary when operating the device close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences | Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements | ISO 15223-1 Reference #5.4.4 FDA Recognition #5-117 |

## **14. CONTACT US**

### **Headquarters**

Heru, Inc.  
201 S. Biscayne Blvd  
Suite 1310  
Miami, FL 33131

For **General Inquiries** contact us at:

[info@seeheru.com](mailto:info@seeheru.com)

For **Service & Support** contact us at:

[support@seeheru.com](mailto:support@seeheru.com)

### **Heru Hours Of Operation**

Monday - Friday  
8:00 a.m. - 6:00 p.m. EST  
+1 (844) SEE-HERU (733-4378)