HERU PRIME

INSTRUCTIONS FOR USE

PDPROJ-1_IFU
PDPROJ-1_DHF

Contents

INSTRUCTIONS FOR USE

1. Introduction

Heru Prime (previously Heru **re:**Vive) is a platform that provides functional and anatomical diagnostic data for the purpose of supporting the diagnosis of various eye conditions. Heru Prime is a system that works with commercially available Head Mounted Display devices (HMDs). The Heru Prime 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 Prime Application
- Browser-based Heru Portal Application (see Section 15 for browser details)
- Approved HMD hardware
- Bluetooth patient response controller
- Any approved compatible computing platform including a PC or Mac, desktop or tablet (see Section 15 for details).

Access the Heru Portal via a web browser to start, store, and review patient's clinical test results. Stable internet connection with a minimum of 10 Mbits/sec download and 5 Mbits/sec upload speed is recommended.

	Please read this instruction manual thoroughly before using Heru Prime. Please keep these instructions for future reference.

3. Intended Use

Heru Prime is a multi-modal testing system with the following tests and indications for use:

Visual Field: The Heru Prime visual field test is 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").

Pupil Test: The Heru Pupil Test is indicated to provide measurements of pupil size and reactivity to aid in the diagnosis and monitoring of various eye conditions.

Extraocular Motility: The Heru Extraocular Motility Test is indicated to provide measurements of a patient's ocular motility to aid in the diagnosis and monitoring of various eye conditions.

Cover Test: The Heru Cover Test is indicated to track eye positions and movements to aid in the diagnosis and monitoring of ocular alignment abnormalities.

Ishihara Color Vision Test: The Heru Prime Ishihara Color Vision Test is indicated to screen for and identify color vision defects by testing the patient's ability to distinguish between objects and backgrounds of differing colors.

Visual Acuity: The visual acuity (VA) test is indicated to provide measurement for the clarity or sharpness of a patient's vision, with or without correction, to aid in the diagnosis of refractive abnormalities.

Heru Prime is intended for use on adults 18 years of age or older.

Test results provided by the Heru Prime system are intended to be an aid to interpretation, not a diagnosis. Heru Prime is not intended for diagnosis. Diagnosis and patient management decisions are the responsibility of the healthcare provider.

4. Symbols and Labels

	Manufacturer
	See Instructions for Use
	This software is a medical device
	Catalog Number
	Units within Package
	Keep dry
	Temperature limit
	Waste Electronic and Electrical Equipment Directive
	Human Contact
	Fragile

	Caution
	Not MRI safe

5. General and Installation Safety Precautions

5.1. General Precautions

- Periodically change your password to the Heru Portal.
- Always log out after your session is over.
- Heru Prime is intended to be an aid to interpretation, not a diagnostic tool. Products and Services made available through Heru Prime do not make clinical, medical, or other professional decisions. Diagnosis and patient management decisions are the responsibility of the healthcare provider.
- Heru Prime 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 head mounted display (HMD) prior to use.
- Do not expose the optical lenses to direct sunlight or other strong light sources. Exposure to direct sunlight may cause permanent yellow spot damage to the screen. Screen damage caused by sunlight exposure or other strong sources of light is not covered by the warranty.
- Use an optical lens micro-fiber cloth dipped in water to clean lenses. Do not wipe the lenses with alcohol or other harsh or abrasive cleaning solutions as this may lead to damage not covered by the warranty.

5.2. Installation Safety Precautions

- A Heru representative will schedule a training appointment upon receipt of your Heru Prime equipment. During this training appointment, you and your staff will be guided through the basic operations of configuring, using, and maintaining your Heru Prime equipment. Users 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 15.
- For Technical Support or Customer Care: Please see section 16.

6. Pre-Use Requirements and Dependencies

The Heru Prime 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, or Ophthalmic Technician/Photographer.

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

7. 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.

8. Software Installation, Upgrade, and Configuration

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

A full power-down at the end of each day is recommended. Updates to the Heru Prime application will require the operator to fully power-down and restart the HMD.

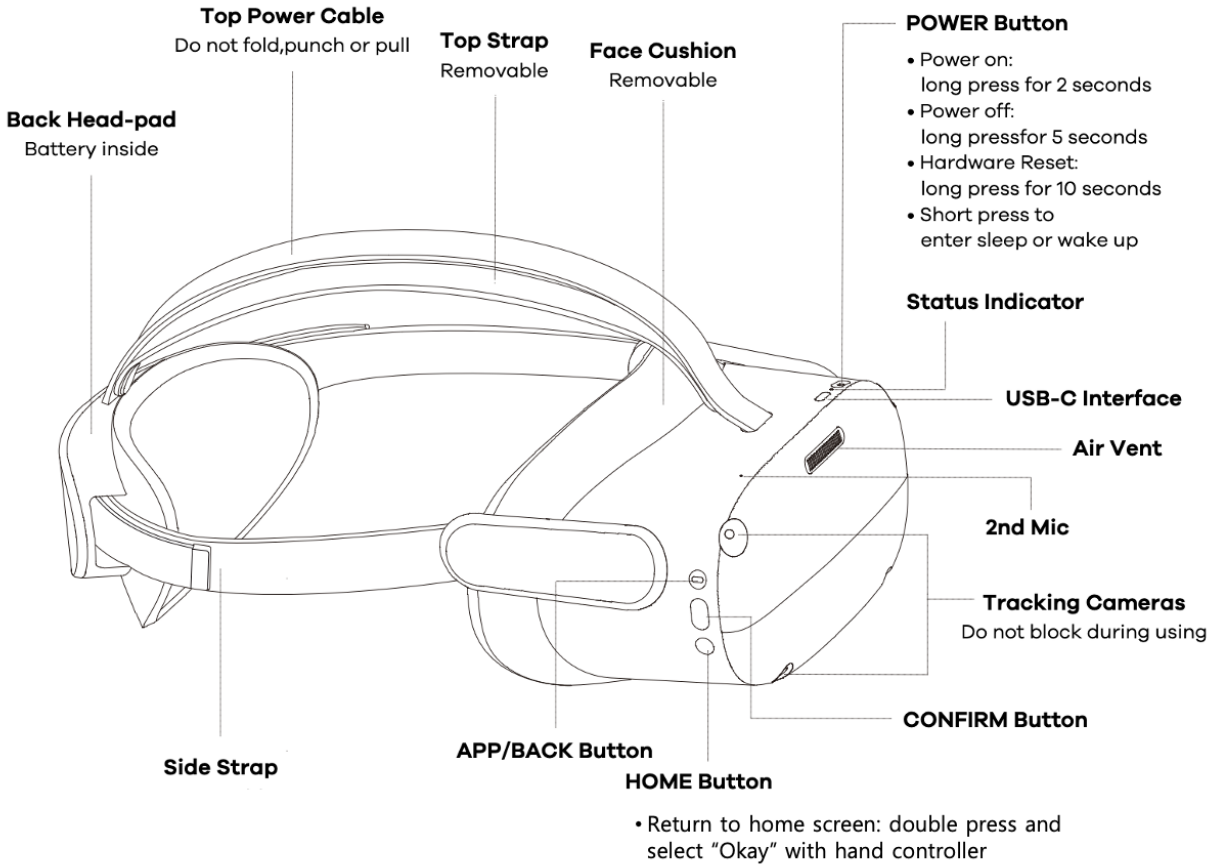
Learn how to power down the HMD in Section 13.7.

9. Cleaning the Device

To minimize cross-contamination and optimize eye-tracking performance, please clean and disinfect the device before each use, taking care to clean the areas that come in contact with the patient, including the face pad and controller.

Component	Clean with
HMD screen	Lens cloth (do not use a solvent of any kind)
HMD face pad	70% isopropyl alcohol
Controller	70% isopropyl alcohol

10. Hardware Overview



11. Overview of Tests and Reports

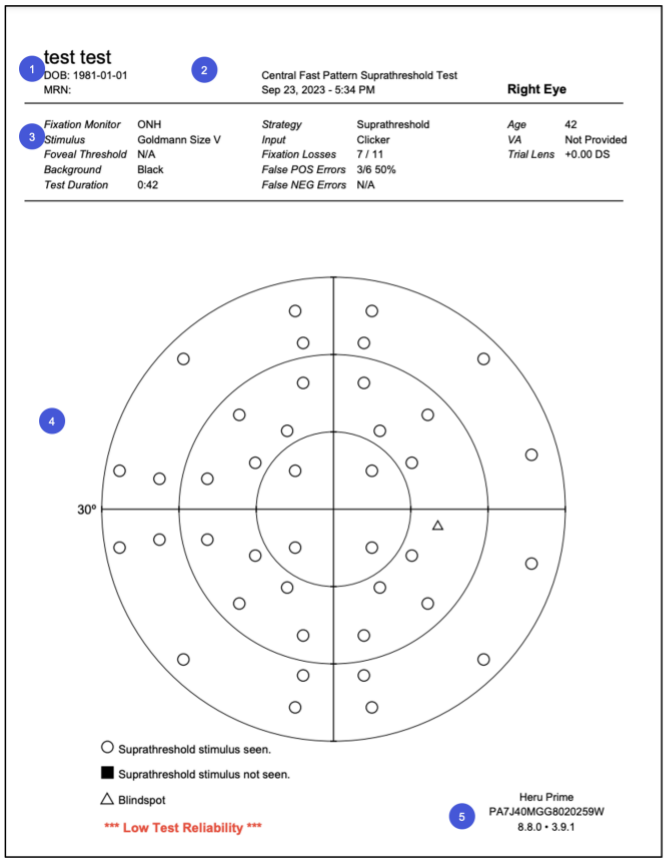
11.1. Visual Field: Suprathreshold

Heru Prime performs a static, suprathreshold visual field test to identify central visual field defects. Stimuli are presented over the patient's central 30° 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 visual field defects. Fixation monitoring is employed to ensure test reliability.

Details of the test pattern and parameters can be found below:

Test Pattern	Fast Pattern
Test Strategy	Suprathreshold, static
Extent of Visual Field Tested	30 degrees
Number of Points Tested	40 points
Stimulus Duration	200 msec
Stimulus Size	Goldmann Size V
Stimulus Color	White
Stimulus Intensity	Age corrected
Fixation Monitoring	ActiveTrack™ (gaze tracking) ONH (blind spot monitor)

The report displays patient data, test reliability indices, and test results.



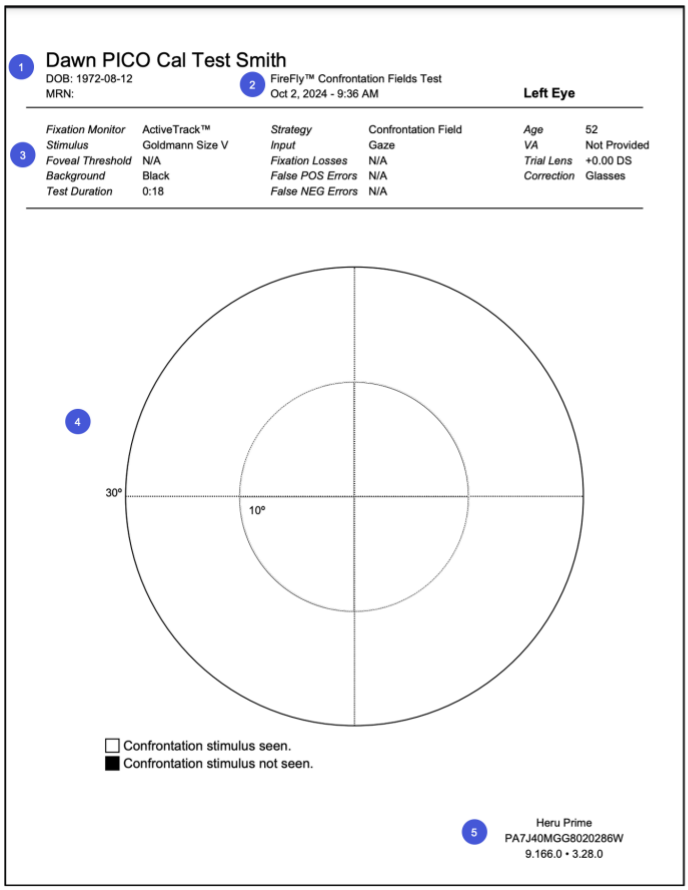
1. Patient Information
2. Test information
3. Reliability indices
   - Fixation Monitor: Heru Prime employs two types of fixation monitoring: ActiveTrackTM and ONH monitoring. If the test was conducted with ActiveTrack, there are no fixation losses since the patient's gaze is continuously monitored.
   - Fixation Losses: If ONH monitoring is used, the Heijl-Krakau method is used to estimate the patient's fixation loss (FL) rate by presenting stimuli at the patient's blind spot. FL rates that exceed 40% may indicate an unreliable test.
   - False Positives: False positives (FP) are patient responses during small gaps in the rhythm of perimetric testing (positive catch trials) in which no stimulus is presented. The False POS Error rate is calculated as the ratio of FP answers to the total number of catch trials presented. FP rates that exceed 40% may indicate an unreliable test.
4. Visual field test locations and results
5. Head mounted display (HMD) serial number and software version

11.2. Visual Field: Confrontation Visual Field (CVF) FireFly™

Heru Prime performs a static, 8-sector confrontation visual field test to identify visual field defects. Stimuli are presented over the patient's central 30° 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 visual field defects. Unique to the FireFly™ visual field test, the patient is asked to simply gaze at the peripheral stimuli, the success/failure of which will determine if the stimuli is marked as seen or unseen.

Test Pattern	30°, 4 inner-quadrants + 4 outer quadrants
Test Strategy	Suprathreshold
Extent of Visual Field Tested	30 degrees
Number of Points Tested	8 points
Stimulus Duration	200 msec
Stimulus Size	Goldmann Size V
Stimulus Color	White
Stimulus Intensity	18dB
Fixation Monitoring	ActiveTrack™ (gaze tracking), ONH (blind spot monitor)

Details of the test pattern and parameters can be found below:



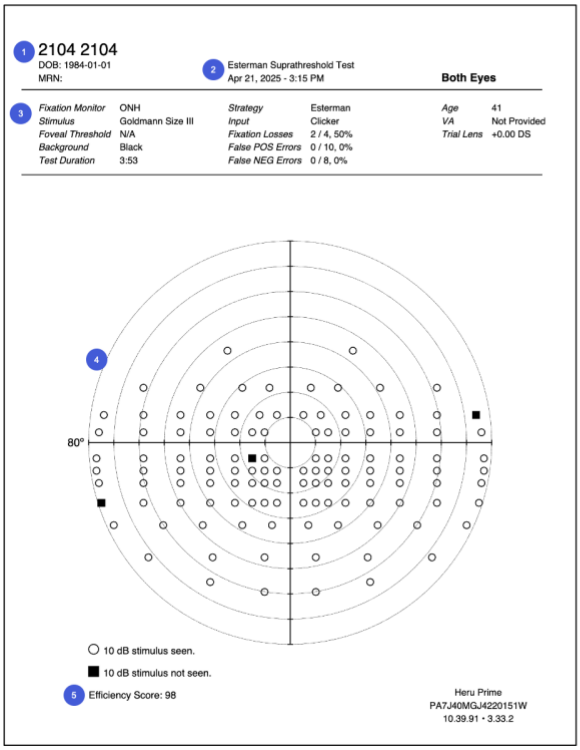
1. Patient Information
2. Test information
3. Reliability indices
   - Fixation Monitor: Heru Prime employs two types of fixation monitoring: ActiveTrackTM and ONH monitoring. If the test was conducted with ActiveTrack, there are no fixation losses since the patient's gaze is continuously monitored.
   - Fixation Losses: If ONH monitoring is used, the Heijl-Krakau method is used to estimate the patient's fixation loss (FL) rate by presenting stimuli at the patient's blind spot. FL rates that exceed 40% may indicate an unreliable test.
   - False Positives: False positives (FP) are patient responses during small gaps in the rhythm of perimetric testing (positive catch trials) in which no stimulus is presented. The False POS Error rate is calculated as the ratio of FP answers to the total number of catch trials presented. FP rates that exceed 40% may indicate an unreliable test.
4. Visual field test locations and results
5. Head mounted display (HMD) serial number and software version

11.3. Visual Field: 120-point Esterman

Heru Prime performs a static, 7-sector 120-point Esterman test to identify visual field defects. Stimuli are presented over the patient's 152° 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 visual field defects. Fixation monitoring is employed to ensure test reliability.

Test Pattern	152° Bilateral + 1 central location + 4 compass point locations + 2 upper temporal and nasal locations
Test Strategy	Suprathreshold
Extent of Visual Field Tested	Bilateral - 152 degrees horizontal, 120 degree vertical
Number of Points Tested	120 points
Stimulus Duration	500 msec
Stimulus Size	Goldmann Size III
Stimulus Color	White
Stimulus Intensity	10dB
Fixation Monitoring	ActiveTrack™ (gaze tracking), ONH (blind spot monitor)

Details of the test pattern and parameters can be found below:



1. Patient Information
2. Test information
3. Reliability indices
   - Fixation Monitor: Heru Prime employs two types of fixation monitoring: ActiveTrackTM and ONH monitoring. If the test was conducted with ActiveTrack, there are no fixation losses since the patient's gaze is continuously monitored.
   - Fixation Losses: If ONH monitoring is used, the Heijl-Krakau method is used to estimate the patient's fixation loss (FL) rate by presenting stimuli at the patient's blind spot. FL rates that exceed 40% may indicate an unreliable test.
   - False Positives: False positives (FP) are patient responses during small gaps in the rhythm of perimetric testing (positive catch trials) in which no stimulus is presented. The False POS Error rate is calculated as the ratio of FP answers to the total number of catch trials presented. FP rates that exceed 40% may indicate an unreliable test.
   - False Negatives: False negatives (FN) are captured when the system circles back and presents stimuli at a brighter intensity than previously seen (negative catch trials) and the patient does not respond. The False NEG Error rate is calculated as the ratio of FN answers to the total number of catch trials presented. FN rates that exceed 40% may indicate an unreliable test.
4. Visual field test locations and results
5. Efficiency score is calculated as [seen points] / 120
6. Head mounted display (HMD) serial number and software version

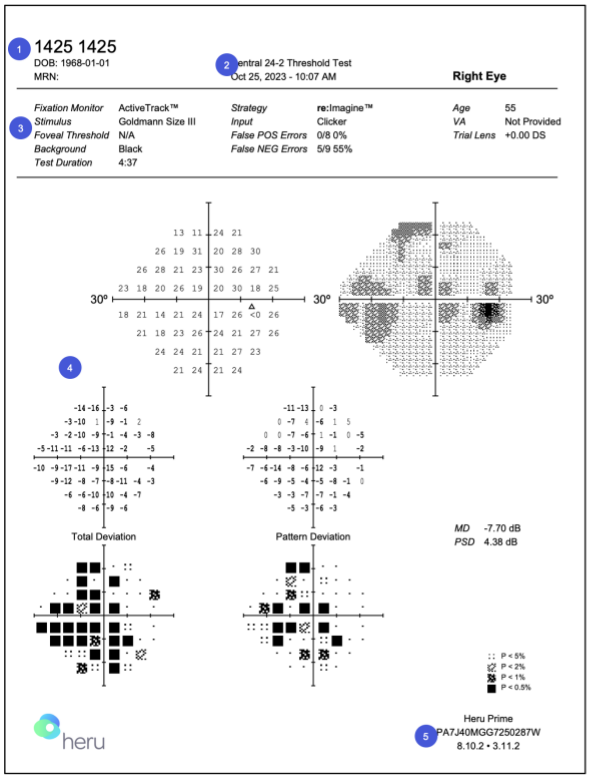
11.4. Visual Field: Full Threshold

Heru Prime performs a static, threshold visual field test to identify central visual field 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 visual field defects. Fixation monitoring is employed to ensure test reliability.

Details of the test pattern and parameters can be found below:

Test Pattern	24-2
Test Strategy	re:Imaging™
Extent of Visual Field Tested	30 degrees
Number of Points Tested	54 points
Stimulus Duration	200 msec
Stimulus Size	Goldmann Size III
Stimulus Color	White
Stimulus Intensity	Age corrected
Fixation Monitoring	ActiveTrack™ (gaze tracking) ONH (blind spot monitor)

The report displays patient data, test reliability indices, and test results.

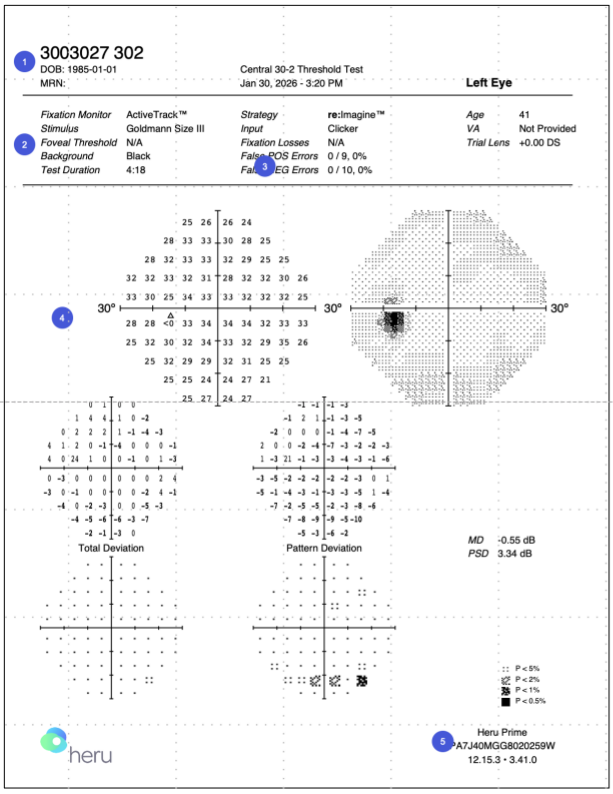


1. Patient Information
2. Test information
3. Reliability indices
   - Fixation Monitor: Heru Prime employs two types of fixation monitoring: ActiveTrackTM and ONH monitoring. If the test was conducted with ActiveTrack, there are no fixation losses since the patient's gaze is continuously monitored.
   - Fixation Losses: If ONH monitoring is used, the Heijl-Krakau method is used to estimate the patient's fixation loss (FL) rate by presenting stimuli at the patient's blind spot. FL rates that exceed 40% may indicate an unreliable test.
   - False Positives: False positives (FP) are patient responses during small gaps in the rhythm of perimetric testing (positive catch trials) in which no stimulus is presented. The False POS Error rate is calculated as the ratio of FP answers to the total number of catch trials presented. FP rates that exceed 40% may indicate an unreliable test.
   - False Negatives: False negatives (FN) are captured when the system circles back and presents stimuli at a brighter intensity than previously seen (negative catch trials) and the patient does not respond. The False NEG Error rate is calculated as the ratio of FN answers to the total number of catch trials presented. FN rates that exceed 40% may indicate an unreliable test.
4. Visual field test locations and results
5. Head mounted display (HMD) serial number and software version

The 30-2 pattern can be expanded to cover more points within the patients central 30 degree field of view.

Test Pattern	30-2
Test Strategy	re:Imaging™
Extent of Visual Field Tested	30 degrees
Number of Points Tested	76 points
Stimulus Duration	200 msec
Stimulus Size	Goldmann Size III
Stimulus Color	White
Stimulus Intensity	Age corrected
Fixation Monitoring	ActiveTrack™ (gaze tracking) ONH (blind spot monitor)

The report displays patient data, test reliability indices, and test results.



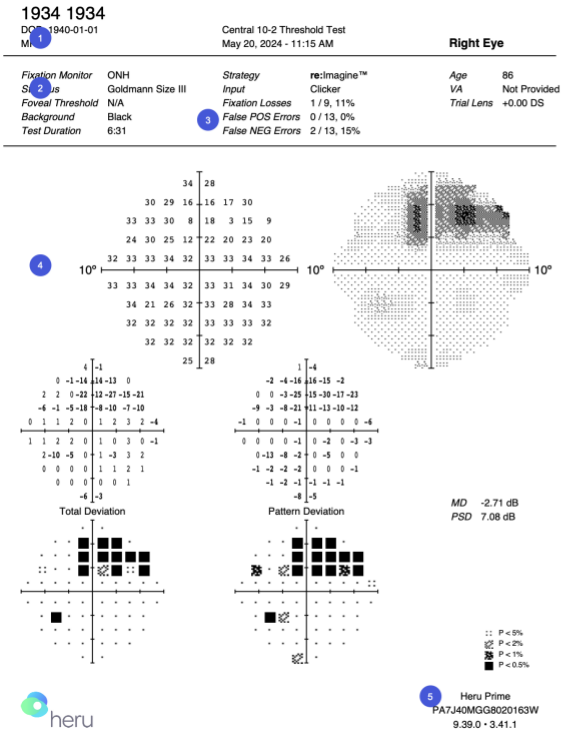
1. Patient Information
2. Test information
3. Reliability indices
   - Fixation Monitor: Heru Prime employs two types of fixation monitoring: ActiveTrackTM and ONH monitoring. If the test was conducted with ActiveTrack, there are no fixation losses since the patient's gaze is continuously monitored.
   - Fixation Losses: If ONH monitoring is used, the Heijl-Krakau method is used to estimate the patient's fixation loss (FL) rate by presenting stimuli at the patient's blind spot. FL rates that exceed 40% may indicate an unreliable test.
   - False Positives: False positives (FP) are patient responses during small gaps in the rhythm of perimetric testing (positive catch trials) in which no stimulus is presented. The False POS Error rate is calculated as the ratio of FP answers to the total number of catch trials presented. FP rates that exceed 40% may indicate an unreliable test.
   - False Negatives: False negatives (FN) are captured when the system circles back and presents stimuli at a brighter intensity than previously seen (negative catch trials) and the patient does not respond. The False NEG Error rate is calculated as the ratio of FN answers to the total number of catch trials presented. FN rates that exceed 40% may indicate an unreliable test.
4. Visual field test locations and results
5. Head mounted display (HMD) serial number and software version

A denser array of stimuli may be presented over the patient's central 10° 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 visual field defects. Fixation monitoring is employed to ensure test reliability.

Details of the test pattern and parameters can be found below:

Test Pattern	10-2
Test Strategy	re:Imaging™
Extent of Visual Field Tested	10 degrees
Number of Points Tested	68 points
Stimulus Duration	200 msec
Stimulus Size	Goldmann Size III
Stimulus Color	White
Stimulus Intensity	Age corrected
Fixation Monitoring	ActiveTrack™ (gaze tracking) ONH (blind spot monitor)

The report displays patient data, test reliability indices, and test results.



1. Patient Information
2. Test information
3. Reliability indices
   - Fixation Monitor: Heru Prime employs two types of fixation monitoring: ActiveTrackTM and ONH monitoring. If the test was conducted with ActiveTrack, there are no fixation losses since the patient's gaze is continuously monitored.
   - Fixation Losses: If ONH monitoring is used, the Heijl-Krakau method is used to estimate the patient's fixation loss (FL) rate by presenting stimuli at the patient's blind spot. FL rates that exceed 40% may indicate an unreliable test.
   - False Positives: False positives (FP) are patient responses during small gaps in the rhythm of perimetric testing (positive catch trials) in which no stimulus is presented. The False POS Error rate is calculated as the ratio of FP answers to the total number of catch trials presented. FP rates that exceed 40% may indicate an unreliable test.
   - False Negatives: False negatives (FN) are captured when the system circles back and presents stimuli at a brighter intensity than previously seen (negative catch trials) and the patient does not respond. The False NEG Error rate is calculated as the ratio of FN answers to the total number of catch trials presented. FN rates that exceed 40% may indicate an unreliable test.
4. Visual field test locations and results
5. Head mounted display (HMD) serial number and software version

11.5. Extraocular Motility (EOM)

Heru Prime performs extraocular motility (EOM) testing to assess extraocular muscle function. A fixation target is presented to the patient in 6 cardinal gaze positions 28 degrees from primary gaze. Independent eye tracking continuously monitors the patient's gaze position to detect anomalies in extraocular motility.

The report displays patient data and test results.

1. Patient Information
2. If a warning message appears, the device is unable to track the patient's gaze during testing. Please ensure that the patient's eyes are open wide during testing, especially in down gaze.
3. Extraocular motility
   - Full : The patient's extraocular motility falls within the normal range in all directions of gaze.
   - Not Full: The patient's extraocular motility is outside the normal range for 1 or more directions of gaze
   - Unknown: The HMD was unable to track the patient's gaze in 1 or more positions.
4. Gaze Information: Displays the patient's gaze information for each cardinal position.
5. RealView™ video is a playback of the patient's eyes while taking the test.
6. Head mounted display (HMD) serial number and software version

11.6. Pupil Test

Heru Prime performs pupil testing to assess direct and consensual light response, relative afferent pupillary defect (RAPD), accommodative (near) response and pupil size in dim and bright light.

A non-accommodative red target at optical infinity is presented to both eyes during light response, RAPD, and pupil size testing. Accommodative pupil testing is performed with a stereostimulus that moves from optical infinity to 40 cm. Independent eye tracking continuously monitors the patient's pupil size during testing.

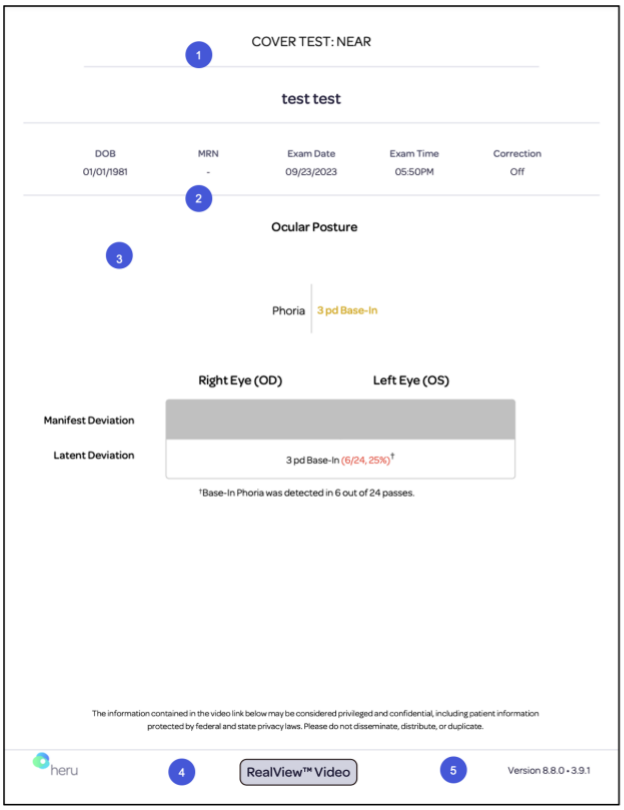
The report displays patient data and test results.

1. Patient and test information. Now includes IPD measurement in mm.
2. Pupil overview
   - PERRLA: Pupils equal, round, reactive to light and accommodation
   - PERRL: Pupils equal, round, and reactive to light
   - NO PERRLA: Indicates that one or more of the pupil metrics are outside normal limits. Metrics that fall outside normal limits are highlighted red on the report.
   - Limited eye tracking data to evaluate pupillary responses: The HMD was unable to track the patient's pupil or gaze during testing. Please ensure the patient's eyes are open wide and minimize blinking. Consult the RealView™ test video.
3. Relative afferent pupillary defect (RAPD) is derived from the direct and consensual light response from each eye.
4. Individual pupil metrics
   - Dim Light / Bright Light: Pupil diameter in dim and bright light for each eye. Pupil diameter is measured along the horizontal meridian. Difference between right and left pupil size is shown below each column. A difference greater than 0.6 mm is highlighted red.
   - Shape: Pupil shape in each eye is manually input by the operator at the time of the appointment creation, not automatically detected by the HMD during testing.
   - Reactive: Indicates the speed of pupil constriction from light reactivity.
   - Accommodation: Indicates whether an accommodative pupil response is present. A 1mm or more change in pupil size indicates a positive accommodative response
5. Light response index categorizes pupil reactivity as brisk, sluggish, or non-reactive
   - Brisk: Pupil constriction speed ≥ 0.8 mm/sec
   - Sluggish: Pupil constriction speed 0.4 to 0.8 mm/sec
   - Non-reactive: Pupil constriction speed < 0.4 mm/sec

11.7. Cover Test (Near and Distance)

Heru Prime performs near and distance cover testing to assess the presence, type, direction, and magnitude of ocular misalignment. A 20/100 fixation target is cyclically shown to both eyes and each eye independently, while tracking the patient's gaze position continuously to detect heterophoria (latent strabismus) and heterotropia (manifest strabismus).

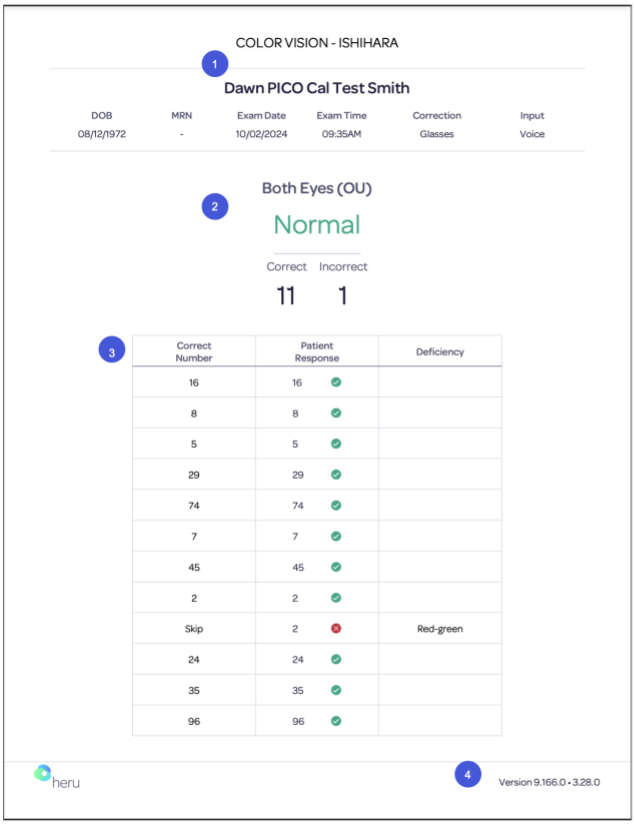
The report displays patient data and test results.



1. Patient and test information
2. Ocular posture (deviation type, direction, and magnitude)
3. Ocular posture (deviation type, direction, and magnitude
   - No tropia or phoria detected: No eye movement was detected during cover testing
   - Phoria: The report will display the direction and magnitude of the measured deviation
   - Tropia: The report twill display the laterality, direction, and magnitude of measured deviation
   - Limited eye tracking data to evaluate ocular alignment: The HMD was unable to track the patient's gaze during testing. Please ensure the patient's eyes are open wide during testing and minimize blinking.
3. Ocular posture quality metric shows the percentage of time the HMD detected a deviation. A manifest deviation that is less than 100% may indicate an intermittent tropia.
4. RealView™ video is a playback of the patient's eyes while taking the test.
5. Head mounted display (HMD) serial number and software version.

11.8. Ishihara Color Vision Testing

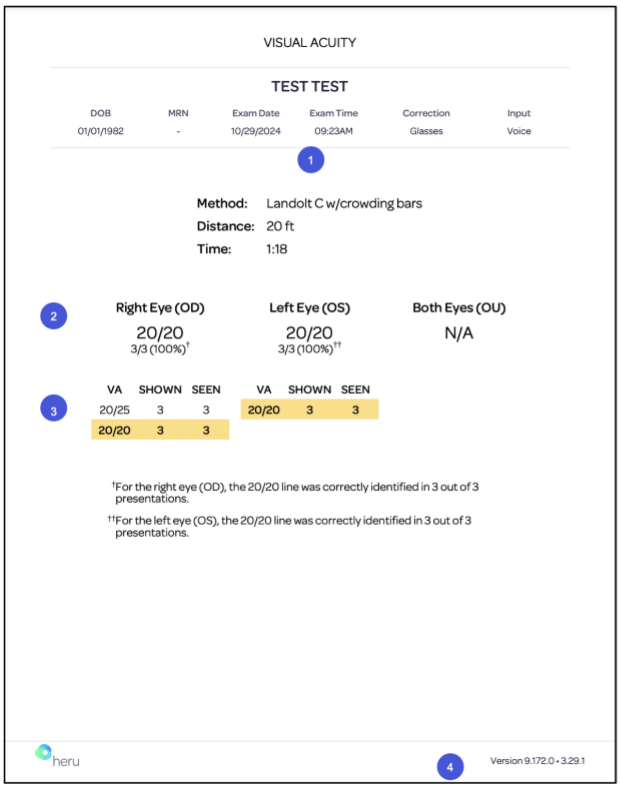
Heru Prime performs color vision testing using Ishihara Plates, including one "skip" plate, to determine the patient's color vision capability. The color vision status will be displayed as "Failed Test Plate 1, Normal, Protan or Deutan, or Red-Green, based on the recorded patient responses to the plates. The report displays patient data and test results.



1. Patient and test information
2. Color vision assessment
   - Failed Test Plate 1: The 16-plate should be visible to all patients regardless of color vision assessment.
   - Normal: The patient missed fewer than 3 plates.
   - Red-Green: The patient missed 3 or more plates.
   - Protan/Deutan: The patient missed 3 or more plates and partially identified the 35-, or 96-plates.
3. Plate-by-plate summary of the test results.
4. HMD serial number and software versions

12. Visual Acuity Testing

Heru Prime performs visual acuity testing using a Landolt C with crowding bars to determine the patient's visual acuity. The measured visual acuity will be displayed as a value between 20/20 and 20/200 based on the recorded patient responses to the different test levels.
The report displays patient data and test results.



1. Patient and test information
2. Visual acuity (VA) assessment
   - Visual acuity measurement: VA measured for OD, OS, and OU. If not tested it will display N/A.
   - +20/200: The patient's VA was measured to be greater than 20/200.
3. Summary of the test levels that determined the VA result including the VA level tested, number of times that level was shown, and how many times the patient correctly identified the optotype. The highlighted row will correspond with the measured VA.
4. HMD serial number and software versions

13. Step-By-Step Instructions

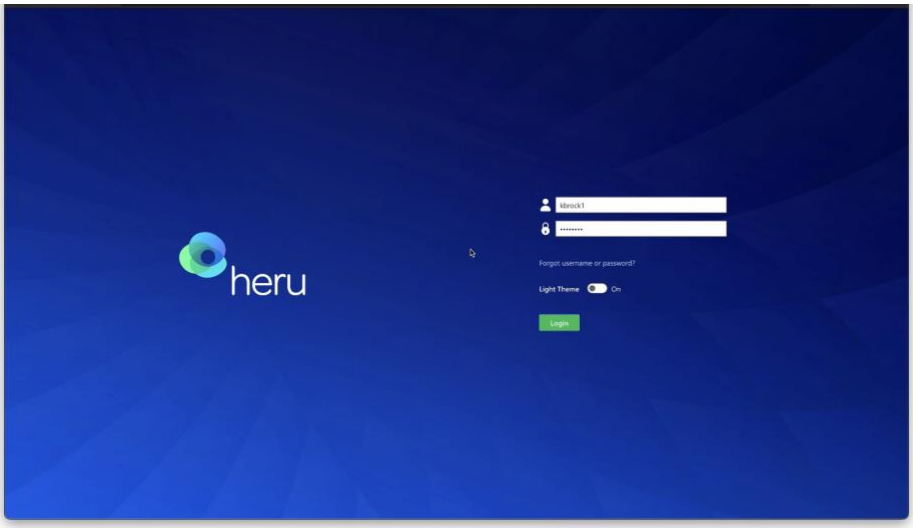
Before beginning the exam, confirm that you have successfully logged into the Heru Portal and powered on your HMD.

Note: Screenshots are for illustrative purposes.

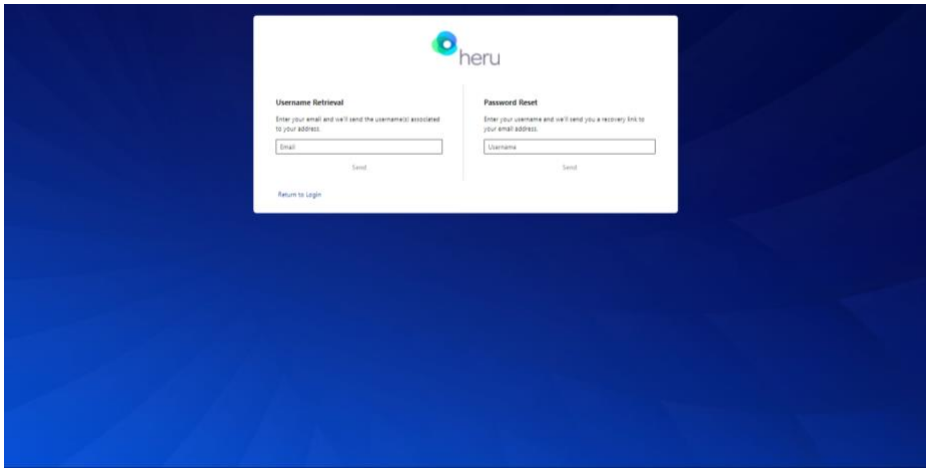
13.1. Logging into the Heru Portal

1. Using your web browser, access the Heru Portal at https://portal.seeheru.com

2. Log in with your credentials.



3. 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.



13.2. Heru Portal Overview

13.2.1. 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.

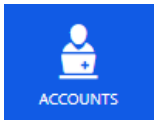
Information – Display information useful when contacting Heru, Inc. Customer Service.

The following information is displayed when you press the  button:

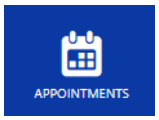
- Heru, Inc. About Us Information
- Software and Web Portal Version
- Contact Information
- Support Contact Information

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

13.2.2. Operating icons

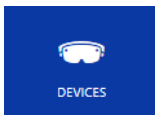


Accounts: Account management and enables multiple users to customize their preferred settings.

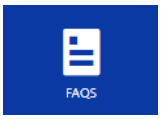


Appointments: View previous and scheduled appointments database and test data.

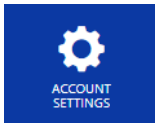
Patients: Create new patients, create new appointments for existing patients, and view or edit existing patient data.



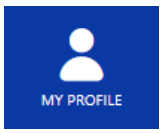
Devices: View list of devices associated with the clinic, check status of devices, and modify details such as name of devices.



FAQ: Frequently Asked Questions.



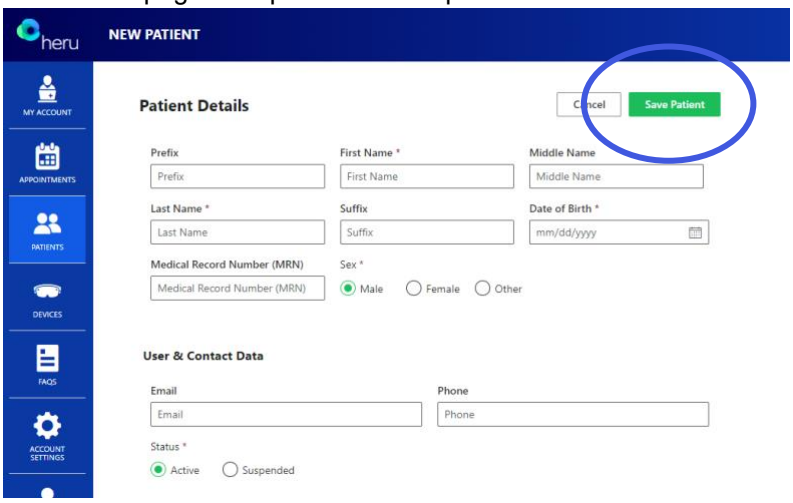
Account Settings: Available for account administrators to configure Heru portal account settings and defaults such as password strength and expiration.



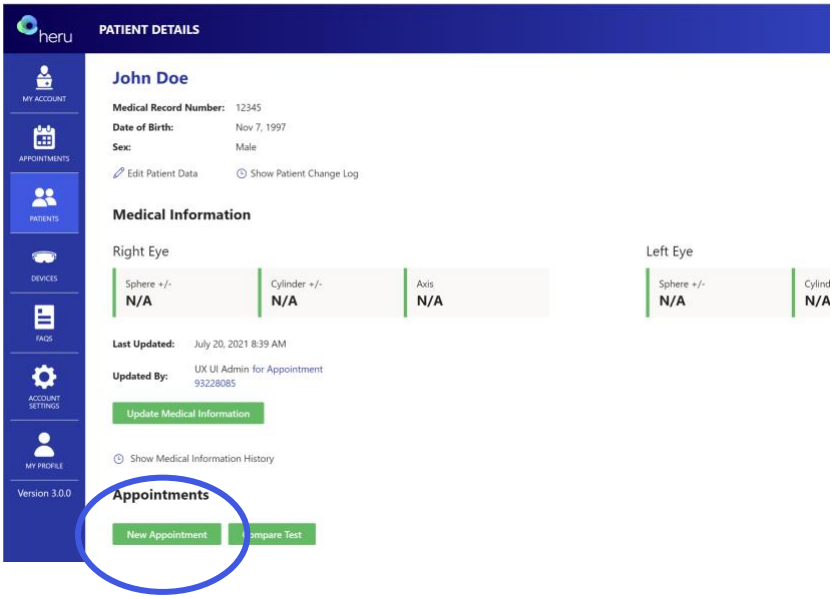
My Profile: Configure Heru portal contact details such as username or password.

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

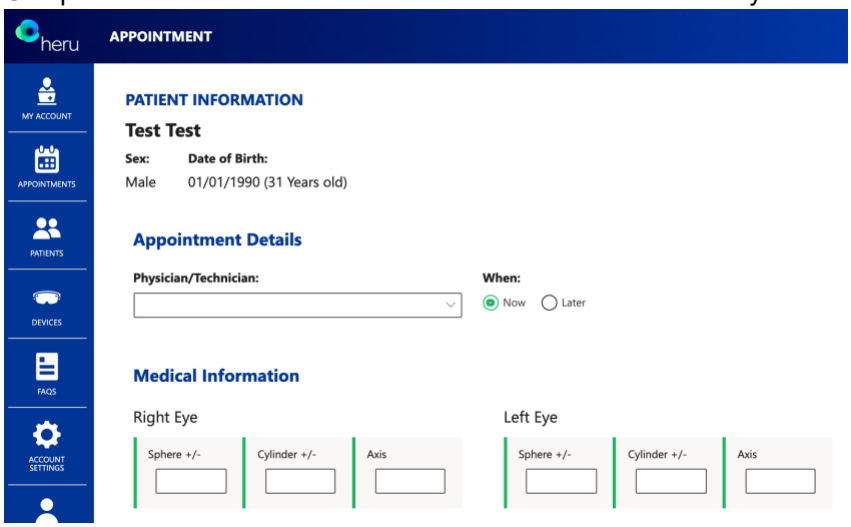
1. Click on “Patients” on the left side bar.
2. Click on “Create Patient”.
3. Patient Details page will open. Enter the patient’s details and click “Save Patient”.



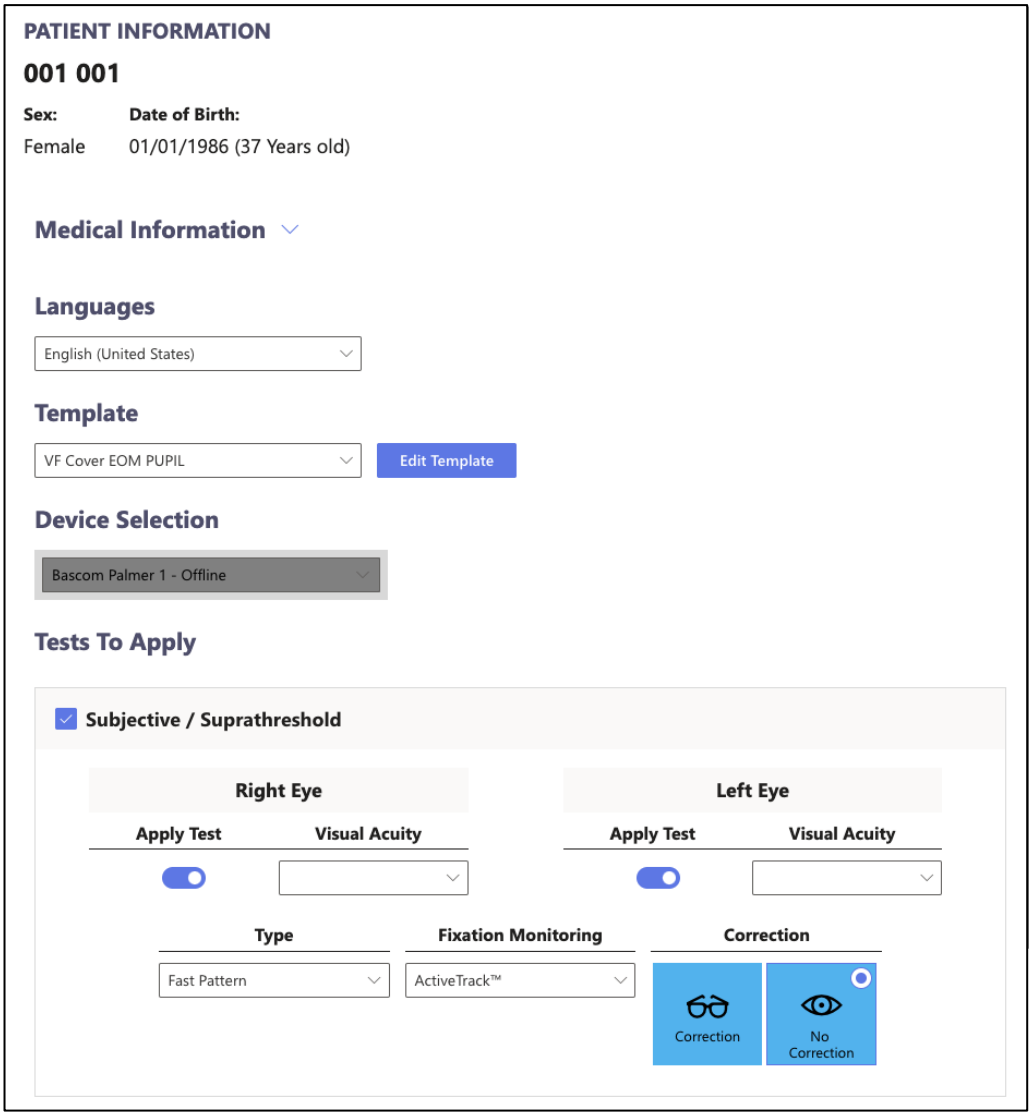
4. Select “New Appointment” to create a new appointment.



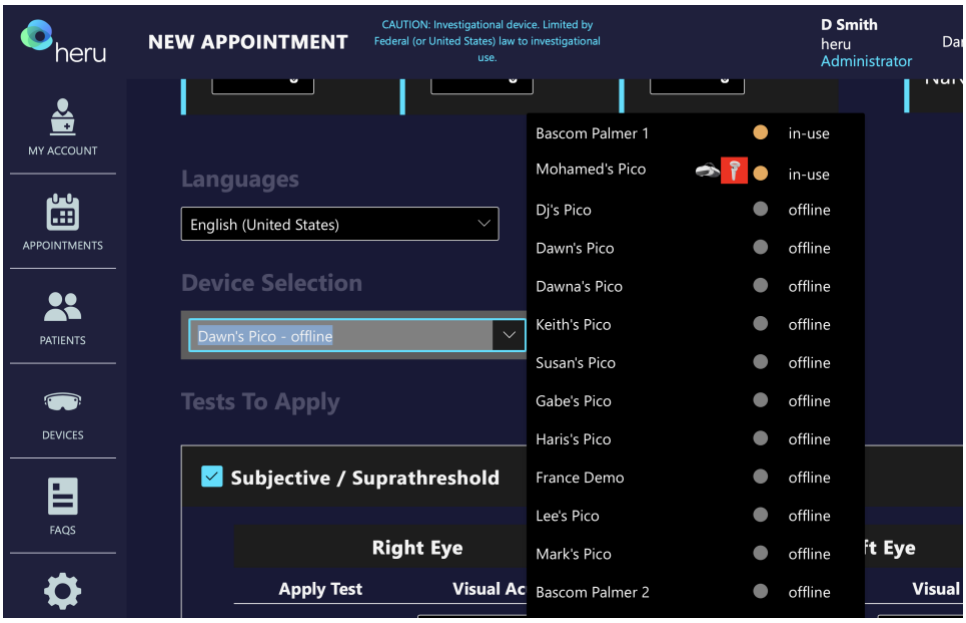
5. Complete the “Patient information” section and confirm accuracy.



6. Select the language, template (if needed), device, and tests you would like to apply. Turn ON/OFF the onboard technician (Heru Guide) for the appointment. You can begin testing directly from the New Appointments page or save the appointment for later.
7. Four customizable templates are available to streamline common appointments. Each template can be renamed and modified to suite the demands of your clinic.



8. When selecting a device from the dropdown menu, confirm the device you intend to use is online, available, and charged. If the HMD or the control icon is outlined in red, the device has dropped below 20% battery level and should be recharged before using. Click “Start” only after 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.



13.4. Taking a Test

Before beginning the exam, confirm that the HMD is turned on. The Heru Prime application should load automatically, and the HMD should show up in the Portal as “available.”

All tests can be performed without pupil dilation (non-mydriatic).

13.4.1. Fitting the HMD on the Patient

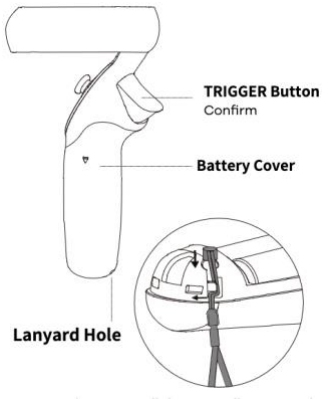
1. Ensure that the battery of the HMD and controller are sufficiently charged.
2. The Heru Prime device has no refractive error adjustment, and does not use trial lenses. The HMD allows wearing most standard glasses with a frame width of less than 160mm.

3. If the patient does not wear habitual glasses or contact lenses for distance viewing, no correction is needed for testing on Heru Prime. If the patient wears habitual correction for distance viewing, they should wear appropriate vision correction depending on the test:

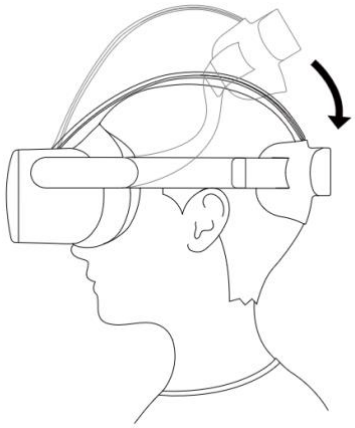
Modality	Glasses	Contact Lens	Uncorrected
Visual Field: Confrontation	*	✓	✓
Visual Field: Suprathreshold	*	✓	✓
Visual Field: Full Threshold	*	✓	✓
Visual Field: Esterman	*	✓	✓
EOM		✓	✓
Cover Test	✓	✓	✓
Pupils		✓	✓
Ishihara	✓	✓	✓
Visual Acuity	✓	✓	✓

* The Suprathreshold and Confrontation Visual Field test can be done uncorrected refractive error between +6.00 to -6.00 diopters. If the patient has a larger refractive error, glasses or contact lenses are recommended.

4. If testing with glasses on, clean the patient's glasses prior to testing.
5. Clean the face pad and hand controller with 70% isopropyl alcohol. Be careful not to get any alcohol on the HMD lenses.
6. Orient the patient to the controller, showing them the trigger that they will press during the test. This should be the only button they press throughout testing. The controller goes into the right hand of the patient.



6. Show the patient how the HMD expands. Open the headband all the way before handing to the patient. For patients wearing glasses during testing, pivot the head strap all the way up, carefully bring the headset up to the patients face over the glasses, then pivot the head strap back down into a horizontal position before tightening around the patient's head. Confirm the HMD is comfortably positioned on the patient's head.



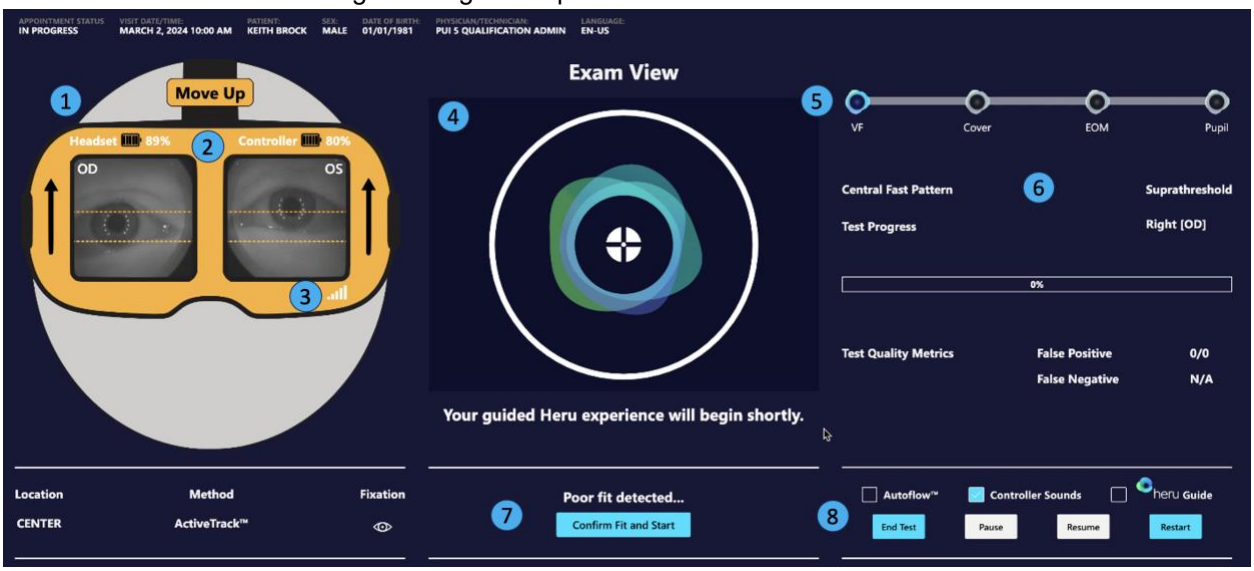
7. If using Gaze or Voice patient inputs, the hand controller is not required for testing. If using Clicker patient input, hand the controller to the patient's right hand and make sure they have their finger resting gently over the trigger and not pressing any other buttons.

NOTE: Poor positioning of the device can lead to artifacts and unreliable results. Always confirm with the patient that the circle is in full view.

9. Patient Led Alignment can be toggled on or off in the Heru Portal during appointment creation. When enabled, the patient will be shown an alignment goggle outline within the HMD that moves relative to the device's position. A target outline will also be displayed, and the patient will follow on-screen instructions (e.g., move up, move down) to align the goggle outline with the target. Once alignment is achieved, the HMD will count down from 5 and automatically confirm fit and begin testing.
10. If the fit of the HMD is determined to be good before the Patient Led Alignment process begins, alignment will automatically be skipped and testing will begin.
11. In the Heru Portal, select the patient, choose the tests to perform and set up appointment parameters.

a. If Heru Guide is turned on, the patient will be given an interactive overview of the testing process through the HMD.
b. If Heru Guide is turned off, the operator should instruct the patient how to perform testing.
c. Where gaze tracking is required, the Heru Guide will guide the patient through a gaze-tracking calibration by moving a white dot around the patient's field of view. The patient should follow the white dot with their eyes, while keeping their head stationary.

12. Click "Start" to begin testing. The operator will be shown the Exam View.



1	FitCheck – provides the operator with a view of the fitment of the device along with clear text explanation for how the fit may be improved
2	Headset and Controller battery levels
3	Headset connection signal
4	Graphical representation of what the patient is seeing during testing
5	Progress bar for the full appointment
6	Test information
7	Click Confirm fit and Start to override the FitCheck and begin testing
8	Controls for the test

13. The operator will be given a diagram to confirm or adjust the fitment of the device. If the fit is poor, clear instructions will be provided. If the fit cannot be made "good" after 15 seconds, the operator will be given a choice to continue trying to adjust the headset or confirm and start the appointment. If the fit cannot be made good after 30 seconds, the appointment will begin automatically.
14. In most cases, no further interaction with the operator is required. During certain tests (like cover testing) the operator may need to interact with Exam View to advance the test.
15. During the test, the operator can monitor the progress of the test on the Exam View.

13.4.2. Visual Field: Suprathreshold

1. The Suprathreshold Visual Field test can be done with uncorrected refractive error between +6.00 to -6.00 diopters. If the patient has a larger refractive error, glasses or contact lenses are recommended.
2. Confirm that the patient can see the full circle prior to starting visual field testing, as rim artifacts may occur if any part of their field of view is obscured.
3. Heru Prime has two fixation monitoring methods: ActiveTrack™ and Optic Nerve Head (ONH) monitoring. When using ActiveTrack™, the HMD will conduct real-time eye tracking during the exam. If a patient loses fixation during the test, stimuli will stop showing and the Heru Guide will encourage the patient to fixate while the fixation target wiggles to get their attention. Once the patient regains fixation the test will resume.
4. If the HMD continues to detect poor fixation, it will monitor the patient's fixation using ONH monitoring, which uses the Heijl-Krakau method to estimate the patient's fixation loss (FL) rate by presenting stimuli at the patient's blind spot. FL rates that exceed 30% may indicate an unreliable test.
5. Removing the headset will pause the test until the device is repositioned on the patient's head.
6. During the exam, the operator can monitor the test progress on Exam View.

13.4.3. Extraocular Motility

1. This test should be completed without glasses. Please ensure the patient has removed their glasses prior to testing. Patients may wear contact lenses during this test.
2. Confirm that the patient can see the full circle prior to starting EOM testing, as poor fit may lead to unreliable results.
3. Encourage the patient to follow the fixation target, being careful to fixate on the target in the far periphery as much as possible.
4. Removing the headset during testing will restart the EOM test.
5. During the exam, the operator can monitor the test progress on Exam View.

13.4.4. Pupil Testing

1. This test should be completed without glasses. Please ensure the patient has removed their glasses prior to testing. Patients may wear contact lenses during this test.
2. The Heru Guide will instruct the patient when to blink or keep their eyes open. For best results, encourage the patient to follow the directions of the Heru Guide.
3. Removing the headset during testing will restart the Pupil Test.
4. During the exam, the operator can monitor the test progress on Exam View.

13.4.5. Cover Test

1. This test should be completed with vision correction. Please ensure the patient has their glasses or contact lenses on prior to testing. When creating the appointment in the Portal, designate if the patient is wearing glasses.
2. If the patient wears glasses, the Exam View will remind the operator to confirm that the patient is wearing proper correction before auto-progressing into the exam.
3. Removing the headset during testing will restart the Cover Test.
4. During the exam, the operator can monitor the test progress in the Portal's Exam View.

13.4.6. Ishihara Test

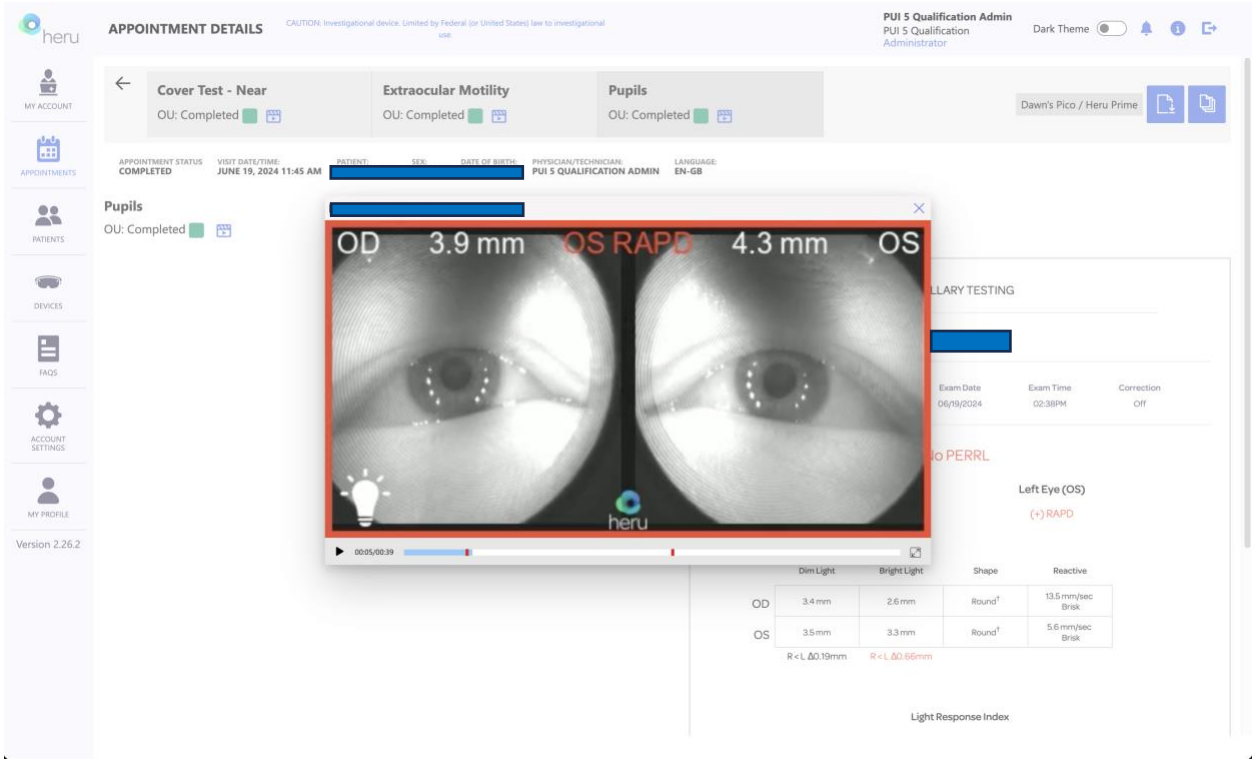
1. This test should be completed with vision correction. Please ensure the patient has their glasses or contact lenses on prior to testing. When creating the appointment in the Portal, designate if the patient is wearing glasses.
2. Removing the headset during testing will pause the Ishihara Test.
3. During the test, the operator can monitor the patient's responses in the Portal's Exam View.

13.4.7. Visual Acuity Test

1. For testing Best Corrected Visual Acuity (BCVA) testing should be completed with vision correction. Please ensure the patient has their glasses or contact lenses on prior to testing. When creating the appointment in the Portal, designate if the patient is wearing glasses.
2. Removing the headset during testing will pause the VA test.
3. During the test, the operator can monitor the patient's responses in the Portal's Exam View.

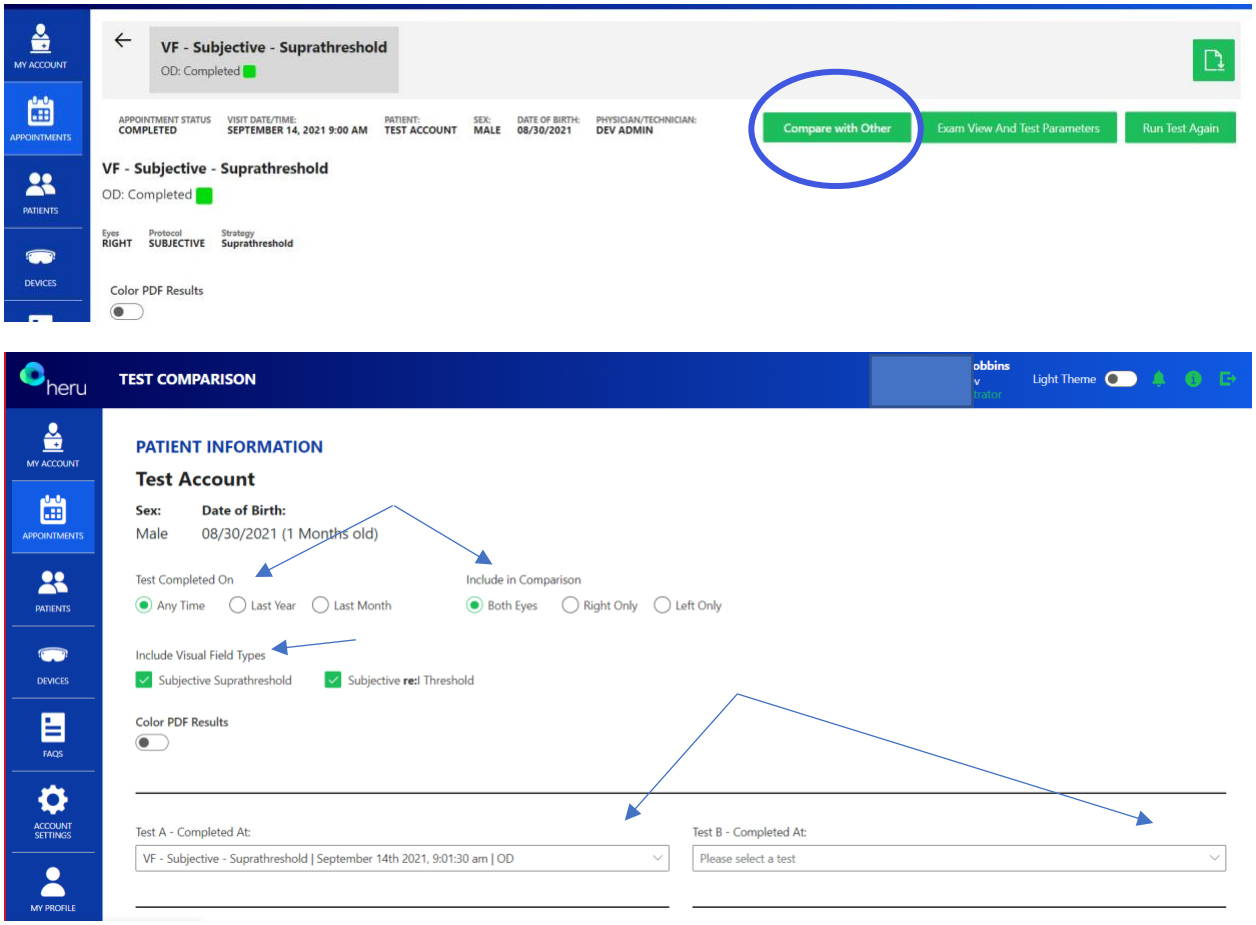
13.5. Viewing the Results

After the patient takes the test, the results will appear in the Heru Portal. For Cover Test, Extraocular Motility, and Pupil tests, the PDF report will be accompanied by a short MP4 video recording of the patient's eyes during each individual test. The MP4 video, also known as RealView ™ will provide a graphical overlay indicating the test progress as well as chapter markers indicating when an abnormal result was identified by the HMD.



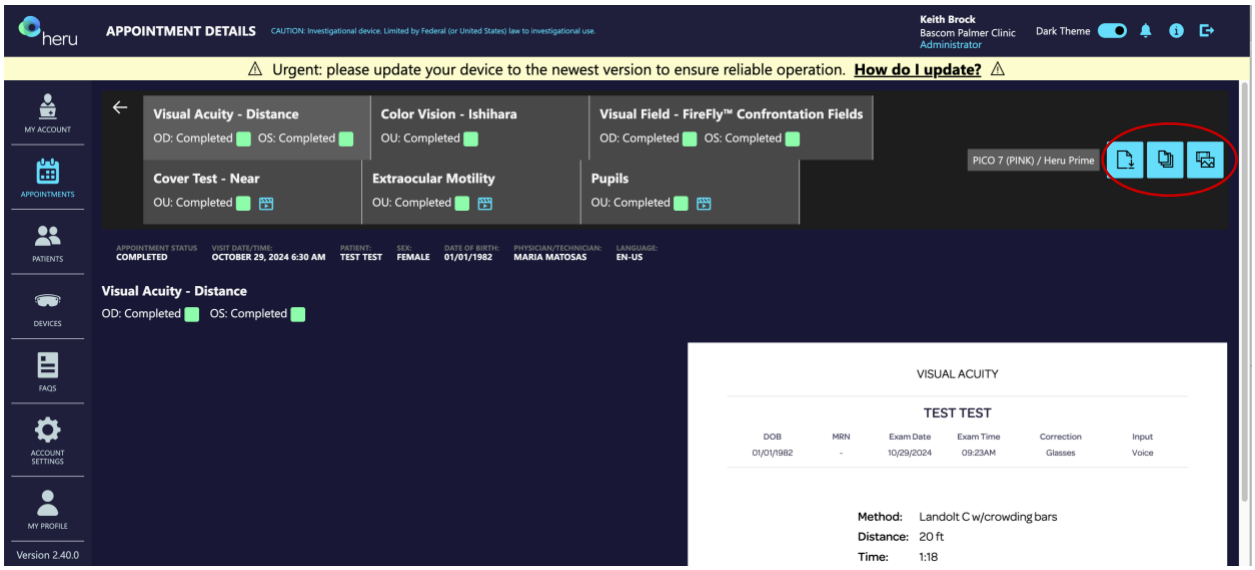
A list of all tests can be found under the Appointments tab. Clicking on the patient's name will open the test results from that appointment.

When available, the user has the option to compare tests side-by-side, by selecting Compare with Other. Select the timeframe, laterality, and visual field types to filter the list of tests, then use the dropdown to select the tests for comparison.



13.6. Printing or Saving Test Results

From the Results screen, click the download icon in the upper right-hand corner to save or print test results. The single PDF download button on the left will download the selected and displayed test results only. The multi-PDF download button in the middle will download all PDF appointment data, including every test completed during the course of that appointment. The PDF+Video button on the right will download all appointment data including any MP4 video files associated with the appointment.



13.7. Powering the HMD On and Off

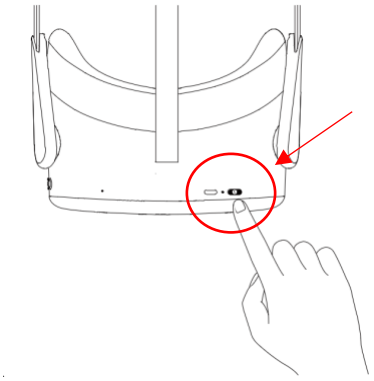
The HMD is a battery powered device and requires power management. Heru Prime should give 3 hours of continuous use between charging. Charging between patients and overnight should ensure continuous use for a full clinic workday. The HMD can also be used while charging.

The battery level can be monitored from the Portal when selecting a device or running a test. The HMD also has an indicator light:

- Blue – powered on with battery over 20%
- Blue flashing – shutting down
- Green – charging and battery is more than 98% or charge is complete
- Red – charging and battery is less than 20%
- Red flashing – battery is less than 20%
- Yellow – charging and battery is less than 98%
- Off – sleeping or powered off.

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

After 10 PM local time, the system will start a 60 minute count-down. If the device is not used for 60 consecutive minutes, the HMD will automatically power itself off. You may also long-press (5 seconds) the power button on the device.



14. Troubleshooting

Issue	Resolution
Cannot find the HMD you need when creating an appointment	• Confirm the HMD is on the “Circle” screen and you can hear birds chirping. • Confirm the HMD is charged and connected to the local WiFi network • Confirm the HMD is not “In Progress” with another appointment • Confirm the color of the HMD and hand controller match the color selected when creating an appointment
HMD screens are black, but can still hear the application audio	• Confirm the room lighting is ON • Confirm there is no one and nothing directly in front of the patient • Confirm the patient is facing a wall with some features (corner, picture/poster, etc.) • Confirm the eye tracking cameras are clean and free of obscurations • 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.
Cannot log into the Heru Portal	• Confirm you are connected to the Internet • Confirm you are using a supported web browser (see section 15) • 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.

Issue	Resolution
Cannot create an appointment	• Confirm all the required fields on “Create appointment” section are completed. • Confirm that the appointment is not created for a past date/time. • Confirm you are not logged in as a “Super Administrator”
Ambient light leaking into patient’s field of view	• Readjust the device and confirm the fit is snug. Ensure there are no sources of light directly behind the patient.
Test interrupted	• Confirm that the HMD’s battery is more than 50% charged. If not, connect the HMD to power with the charger. The test can be performed while the HMD is charging.
Patient cannot see the not full circle on the introduction screen	• Ask the patient to adjust the position of the HMD on their head until the full circle is visible, and the central target is in focus. • Use the live EyeStream™ in the Exam View to align the HMD.
Results do not appear on the Heru Portal	• Confirm the HMD and Portal are connected to the Internet. • Confirm you are using a supported web browser (see section 15)

15. Technical Specifications

Component	Attribute	Value
PICO Neo 3 Eye	Field of View	98 degrees
	Interpupillary Distance (IPD) Range	58 – 69mm (auto)
	HMD Battery Life	4 hours
	Controller Battery Life	160+ hours
Network Recommendations	Internet	Outbound, port 443 Upload speed: 5 MBits/s Download speeds: 10 MBits/s
Web Browser Requirements	Windows: Microsoft Edge (minimum version 81) Windows or macOS: Google Chrome (minimum version 80) iPad: iPadOS 15 or newer, Safari or Google Chrome (current version)	

16. Contact Us

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Miami, FL 33131

For **General Inquiries** contact us at:
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For **Service & Support** contact Heru Customer Care:

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Phone: +1 (844) SEE-HERU

17. APPROVALS

Organizational Area	Representative(s)	Signature	Date
Change Owner			
Development Management			
Program Management			
Quality/Regulatory			
Software/Quality Engineering			
Product Management			