



**Glaucoma Automated
Tests Evaluation**

STANDARD OPERATING PROCEDURES (SOP)

Image acquisition and storage

GATE: Glaucoma Automated Test Evaluation

Comparative study of new imaging technologies
for the diagnosis of glaucoma (HTA Reference Number: 09/22/111)

Sites:

1. Aberdeen Royal Infirmary
2. Hinchingsbrooke Hospital
3. Moorfields Eye Hospital
4. St. Paul's Eye Unit, Liverpool
5. Bedford Hospital Trust

Instruments: HRT-III, GDx-PRO, Spectralis-OCT

Contact lens wear

There is currently no consensus as to whether a patient should be imaged with or without contact lenses. If a patient presents wearing contact lenses please follow local best practice.

Imaging Test order

Imaging should be performed in the random order allocated for each participant in the study. This can be found on the clinic log entry for that patient study ID on the GATE website.

Pupil dilation for imaging

Images should routinely be performed **without dilation** prior to clinician assessment and prior to visual field measurements. If pupil dilation is required to obtain an adequate quality HRT or OCT image then the GDx scan should be attempted prior to dilation (if not already performed). If an adequate quality GDx image is still not obtained prior to dilation the GDx scan should be repeated after pupil dilation. Whenever possible the random allocated test order should be used.

General indications for pupil dilation are media opacities and/or small pupils. However, the scan should always be attempted first to determine whether images are acceptable or if dilation is necessary.

Criteria for dilating the pupil are as follows:

- Unable to 'lock-on' to the pupil and save a scan
- Acceptability of best saved image is below requirements stated in SOP for that imaging technique

Acceptability criteria for each imaging technique are clearly detailed in the text for each technique below. Once an acceptable image has been obtained no further images should be acquired.

Acceptable quality criteria for imaging (summary)

HRT	Mean standard deviation ≤ 30 , Image quality score: Good, Very Good, or Excellent
GDx	$Q \geq 8$
OCT	$Q > 15$

Heidelberg Retina Tomograph (HRT-III)

Acquiring the image

Before imaging a subject on the HRT you should record their refraction (focimetry or auto-refraction). The focimetry/autorefractometry is useful to guide the setting of the scan focus before image acquisition, but is not required to be input in the software.

Patients should not be imaged with their contact lenses in.

1. Ensure that IOP measurements (and other contact exams like gonioscopy) are done **after** HRT imaging.
2. Explain examination (method, time and requirements) to the patient.
3. Disinfect chin- and forehead supporting-stand.
4. Check optics for dirt or smudges, clean if required, with lint/oil-free lens paper moistened with a drop or two of photography quality lens cleaner.
5. Enter new patient details:
 - a) Click on the new patient icon on the HEYEX tool bar to enter the subject's details and the operator initials. Enter the corneal curvature as an average of the two axes (i.e. $7.6 \times 7.8 = 7.7$) and enter the refractive error.

The patient details need to be recorded as follows:

- **Last Name:** 'GATE'
 - **First Name:** <site> e.g. 'Aberdeen'
 - **Title:** leave blank
 - **Date of birth:** enter patient date of birth
 - **Sex:** enter patient gender
 - **Patient ID:** enter < Participant study number>
 - **Ancestry:** enter the patient's ethnicity
6. Ensure that the table and the headrest are at the correct height for the subject. Adjust the chinrest height so that the patient's eyes are at the same level as the red canthus marks on the headrest posts. When the subject's details are entered the laser will activate and image acquisition can begin. As a starting point the focussing dial at the front of the HRT should be set to the subject's refraction.

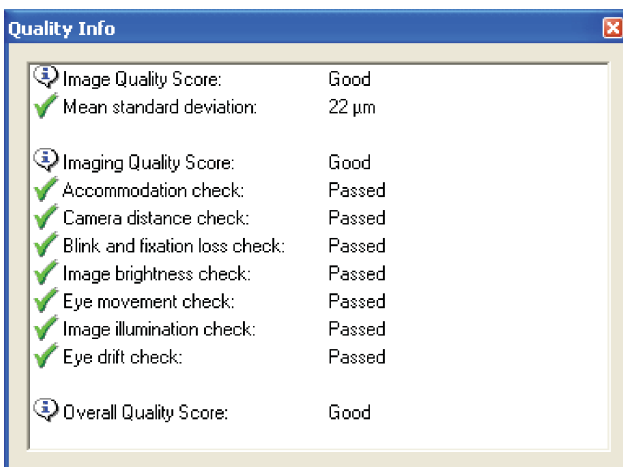
7. Check that the subject is comfortable, and the scanning head is correctly aligned using the black adjustment handles on the HRT. The imaging distance between the HRT objective lens and the cornea is 1.5 cm; this can be judged by focussing the scanning beam on the iris (moving the scanning head towards or away from the eye). When the laser beam is focussed (sharp outline) on the iris, move the scanner sideways so the beam enters the pupil. All of the red light emitted from the HRT should be going straight into the pupil with little or none visible on the iris.
8. If cylinder correction exceeds ± 0.75 diopter, place supplemental cylinder lens in front of the objective (image acquisition) lens. Note that the HRT will display a flashing alert on the refractive error correction dialog box if cylinder correction is recommended:
 - a. click on the check box to display the recommended cylinder lens strength to be used. The lens should be oriented according to the axis provided by the autorefractometer.
 - b. orientation of the cylinder may be adjusted manually during imaging in order to achieve the highest image quality on the screen (see point 9)
9. The HRT has an internal fixation point, a yellowy/green light which, when fixated by subject, should bring the optic disk into view on the screen. Once the scan is activated, the fixation point will appear on the subject's left for the right eye and on their right for the left eye (i.e. always towards the nose). Explain the fixation target (green light outside the red "carpet"). Once the subject is fixating, check the alignment of the laser in the pupil and make small adjustments to the focusing to optimise the image quality. The operator may also manually adjust the cylinder lens axis, if present, to achieve the best image quality.
 - a. Images that are dark, have vignetting of the image corners or are grainy can be improved by dilation. If a good quality image cannot be obtained and dilation is required, delay the image acquisition until after clinical assessment as described in the flow chart in the GATE study procedures manual.
 - b. In some cases where the internal fixation light cannot be seen by the patient, the external fixation device must be used. To use this, the opposite eye fixates on the green light which is manually positioned by the operator to display the optic nerve head in the centre of the screen.
10. Instruct the subject to blink as much as possible before you attempt to acquire a scan to avoid imaging a "dry eye" (drying of the corneal surface). The scan

duration is approx 6-8 seconds, during which time the subject should not blink and must maintain fixation. When ready, an image is acquired by pressing either the foot pedal or the grey button on the rear of the scan head.

11. Optimise image quality if necessary (artificial tears, elevate upper eyelids, re-adjust camera).
 - a. Detector sensitivity should be as low as possible (<80)
 - b. The image quality bar should be green for a good quality image and above 70%**
12. The screen will display the progress of the scan; the HRT will take at least three scans of the optic nerve in one session.
 - a. Monitor the progress of the scan to ensure that the subject's position and fixation is constant.
 - b. The image series may be reviewed as a movie immediately after acquisition. HRT software can compensate for some movement but any scans containing large eye movements or blinks will have to be discarded and repeated.
 - c. If you are satisfied with the scan select "save". Repeat to acquire another scan if image quality is not adequate.
 - d. Move the machine over to image the fellow eye, the HRT software will recognise which eye you are scanning.

Checking image quality

Images acquired using the HRT III software allow the user to check the quality of the image by clicking on the **QC** icon in the right hand corner of the image:



- a. Ensure that all elements are ticked. The overall quality score is given as one of Very Poor, Poor, Acceptable, **Good, Very Good, Excellent**. Ensure the overall quality score is Good or higher.
- b. Check the **standard deviation** value displayed at the top of the topography. A value of **30 or below** is considered good image quality.
- c. Repeat the image acquisition if required to obtain a good image quality.
- d. If an acceptable image cannot be obtained after repeated attempts then the image acquisition should be attempted again after pupil dilation (please refer to study procedures document flow chart to ensure the order of clinical/imaging tests and visual field testing is correct)

Computing the topography

1. Once both eyes have been imaged, the topographies need to be computed.
 - a. Exit from of the acquisition mode by clicking the “X” in the right hand corner of the acquisition window and you will be prompted to process the scans that have just been taken. When the scans are processed double click on the image to bring up the resulting topographical data in the examination results window

Drawing a contour line

1. Using the left mouse button select at least 3 points on the optic nerve rim to create a contour line and reposition to ensure the optic nerve rim is accurately located. Use the 3D viewer button to review your selection if required.
2. When you have located the optic nerve rim select ‘Contour’ then ‘Accept Contour’
3. The contour and segment lines will appear.

HRT Report Printout:

Three printouts are required for the HRT scan,

1. Moorfields Regression Analysis (MRA) of right eye,
2. MRA of left eye and
3. GPS report

A hardcopy of each report should be filed in the study file for each participant.

An electronic copy of each report in **JPEG** format should also be saved to a memory stick and uploaded to the GATE study website.

The naming convention for filenames of any saved reports should be followed:

- MRA Right eye report: 'GATE<studyID>MRARight.jpg'
- MRA Left eye report: 'GATE<studyID>MRAleft.jpg'
- GPS report: 'GATE<studyID>GPS.jpg'

Printing a Moorfields Regression Analysis(MRA) Report

- Click the Moorfields classification tab
- Select 'Print'
- Select 'Examination report'
- Ensure the 'Moorfields report' is selected in the reports window
- Select 'preview'
- The Moorfields report for that eye will appear
- Select 'Save as'
- Enter the filename as 'GATE<studyID>MRARight.jpg' for right eye (or GATE<studyID>MRAleft.jpg for left eye)
- Select 'Save' to save the jpeg of the report
- Select 'print' to print a hardcopy report for the file
- Select other eye from Heidelberg Eye explorer window
- Repeat from start to print/save report from the other eye.

Printing a GPS report

- To print report select 'GPS classification' tab
- Select 'Print'
- Select 'Examination report'

To save as a jpeg file to upload to the GATE website

- Ensure GPS report is highlighted in the report window
- If more than one image is stored for the other eye, select the corresponding eye image for the GPS report
- Select Preview
- The GPS report will appear on the print preview screen
- Select 'Save as'
- Enter the filename as 'GATE<studyID>GPS.jpg'
- Select save to save the jpeg of the report

To print a hardcopy report

- Select 'Print'

HRT Data Export:

HRT imaging data should be exported on the same day every week. Export all the images since the last export.

- 1) From the main database screen select the patient you wish to export.
- 2) When the patient details appear on the right hand side of the screen double click the patient name.
- 3) Right click on the exam you wish to export and select the export option.
- 4) Select yes to export the 3D image series. Selecting this option could result in a prompt to retrieve the raw image data for that exam.
- 5) Select a folder to export using the browse option.
- 6) The file will export and appear as an *.E2E file in the selected export folder.
- 7) Save with filename 'GATE<studyID>rawHRTOS.e2e' for left eye, and 'GATE<studyID>rawHRTOD.e2e' for right eye

GDx ECC/GDx Pro

Acquiring the image

1. Patients should not be imaged wearing their contact lenses. Ensure that IOP measurements and other contact exams like gonioscopy are performed after GDx imaging
2. With the GDx VCC and peripherals properly connected, the Access card inserted and the optics unlocked turn the machine on using the power switch on the side.
3. Disinfect face rest.
4. When the warm-up test is complete, the logo screen will be displayed. Select “new patient”.
5. The patient details need to be recorded as follows:
 - **Patient ID** - Use <GATE Participant study number>
 - **Last name** – ‘GATE’
 - **First name** – <site>e.g. Aberdeen
 - **Middle name** – leave blank
 - **DOB** – enter patient date of birth
 - **Doctor** –use any identifier usually used or leave blank

Press √ button to continue.

6. Input ancestry and gender information as prompted. Press √ button to continue.
7. Check patient information for accuracy. If changes are needed press edit.
8. Select “full exam”.
9. Refraction input is needed for focusing purposes. Select Refraction. Press the **auto-refraction** button.

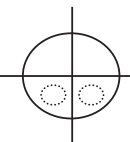
10. Position the subject in front of the GDx with the face placed comfortably against the face rest. For optimal positioning, ask the patient to place their brow bones on top of the upper rest “like wearing a mask”. Ask the subject to gaze at the blinking fixation target in the red field– located to the left hand side for the right eye and vice versa. The exam begins with the right eye as the default position.

11.

- Move the joystick , by pulling forwards and backwards, to vertically align the white focus dot on the horizontal red line



- Centre the pupil in the target by moving the joystick up/down/ left/right and ensure that the 2 white dots are located in the bottom 2 quadrants of the target



- Once aligned, ask the patient not to blink and press the **image acquisition button** on top of the joystick to scan the eye

- Once the refraction data is displayed on the top lhs select **image acquisition button** again to acquire refraction data from the other eye

- Click **image acquisition button** a 3rd time to display the ‘modify ellipse – measuring cornea’ screen

12. Following a cornea measurement, the “Modify Ellipse – Measuring Cornea” screen appears. The macular ellipse should be centred directly over the macula “bowtie”-pattern.

13. To change the macular ellipse position, use the arrow buttons. Do not change the size of the macular ellipse.

14. If the macula “bowtie” is not well defined, press the “Irregular Pattern” button to use an alternative cornea calculation based on the macula area within the dotted square which does not require macular ellipse placement (press the “Macular Ellipse” button to re-enable the macular ellipse placement options).

15. Press √ button to go to the “Modify Ellipse – Measuring Cornea” screen for the next eye. Optimise the placement of the cornea measurement ellipse in the same manner as for the first eye. Press √ button again when complete.

16. When ellipse modification is completed, the system displays the “Image Check-Measuring cornea” screen. The scan **quality score should be 8 and above**. If the scan quality is less than 8 then retake the image for that eye.
17. If image quality is acceptable then select “Accept”. The acquisition screen will now appear. If after repeating the GDx scan the image quality is still not acceptable then the image acquisition should be attempted again after pupil dilation (please refer to GATE study procedures flow chart to ensure the order of clinical/imaging tests is correct)
18. Move the joystick to vertically align the white focus dot on the horizontal red line and centre the pupil in the reticule. Once aligned, press the image acquisition button on top of the joystick to scan the eye. After the first image is captured the system will automatically move to the other eye.
19. Repeat step 18 for the left eye.
20. At the “Image Check” screen verify that the ellipses for both eyes are the correct size, shape and centred on the Optic Nerve Head (ONH). You can both change the ellipse diameter and shape using the arrow keys. (Note: While it is helpful to align the ellipse with the ONH margin, accurate centration is more important than perfect ellipse size).
21. When ellipse modification is completed, verify that the scans quality scores are 8 or above. If quality is less than 8, re-scan the patient. Proper ONH placement can influence image quality scores. Verify that placement is correct before deciding to retake an image.
22. If image quality is acceptable then select “Accept”.
If not acceptable then the image acquisition should be attempted again after the clinician has dilated pupils for their routine clinical assessment (please refer to GATE study procedures flow chart to ensure the order of clinical/imaging tests is correct)
23. Press “print” or “save only” button.

GDx Printout

A printout of the GDx ECC report is required for the study file. Ensure that ECC is reported in the middle text box (white).

A hardcopy of each report should be filed in the study file for each participant.

A scanned electronic copy of each report in **JPEG** format should be uploaded to the GATE study website.

The naming convention for filenames of any saved reports should be followed:

- GDx ECC report: 'GATE<studyID>GDX.jpg'

After printing out the report you should select 'Save' to save the file for this patient

GDx Data Export

Data export is done on a floppy disk.

1. Select "existing patient".
2. Enter the patient ID number in the "Patient ID".
3. Press the "review" button
4. Use "Previous" and "Next" buttons to move through the list
5. Then using the "Select/Deselect" button highlight the chosen exam
6. Repeat 2 and 3 to select more than one exam
7. Press "review" button and then "export" button
8. Choose 'Export raw data'
9. You will be presented with a folder: My Computer. Press the tab key to get into the folder.
10. Using the arrow keys highlight the Floppy A Folder. Then press enter.
11. Name the folder (although the software will automatically save the data with Patient name and ID).
12. Press " $\sqrt{\quad}$ " button or the "enter" key.
13. You will be presented with the message: "Exporting Data" and when finished with the message "Export complete".

Optical Coherence Tomography Using: Heidelberg Spectralis OCT

Patients should not wear contact lenses

Acquiring the image

1. Explain examination (method and requirements) to the patient
2. Ensure that IOP measurements (and other contact exams like gonioscopy) are done **after** OCT imaging
3. Disinfect chin-and forehead-supporting stand
4. Check optics for dirt or smudges, clean if required/with lint/oil free lens paper moistened with a drop or two of photography quality lens cleaner
 5. Ensure that the table and headrest are the correct height for the subject. Adjust the chinrest height so that the patient's eyes are at the same level as the red canthus marks on the headrest posts.
5. Create a new patient record by clicking on the **New Patient** button.

In the **Patient File** window you should enter the following patient details

- **Patient ID** - Use < Participant study number>
- **Patient Name** (Surname= 'GATE', Forename=<site> e.g. 'Aberdeen')
- **DOB** – enter patient date of birth
- Enter **Gender** and **Ethnicity** information

Examination Data Window

The **Examination Data** dialog opens before each exam, but can also be opened at any later stage using the **Examination** button in the patient file.

The respective **Device Type** for the examination must be selected from the dropdown menu; all other data is optional.

1. Select Spectralis OCT
2. Enter operator initials
3. Enter Study name as GATE

Eye Data Window

This window enables the entry of the eye parameters for both eyes. **Please Note:** Do NOT enter any data into this window.

1. Wait for the Laser On/Off button on the Control Panel to turn from Red to Yellow.
2. Press the Yellow On/Off button on the Control Panel to activate the Laser/OCT. Make sure that the OCT button is selected. (Note - On the Control Panel, Inactive/unselected buttons are Red; Active/Selected buttons are Blue).
3. Select the IR + OCT button.
4. Make sure that the Volume button is selected.
6. Field button should be at 30 degrees.
7. IR Intensity button will default to 100% but should be adjusted for patient media, typically 50% - 75%.
8. Always activate the ART Mean function when performing an OCT-Scan
9. Select **RNFL** preset on the monitor screen
10. Ensure HR for high resolution imaging is selected (not HS – high speed)
11. The OCT has a blue internal fixation point which when fixated by the subject should bring the optic disc into view on the screen
 - a) slowly bring the camera towards the patient's eye,
 - b) encourage the patient to blink just before a scan, since maintaining a good tear film is important for OCT image quality. In cases where the patient suffers from dry eye, or when the cornea cannot be kept moist enough by blinking alone, artificial tears may be used.
 - c) Using the joystick (up, down, right or left) move the camera to the center of the pupil and adjust the distance between the objective and the examined eye to approx. 14 mm between the front edge of the objective and the cornea.
 - d) Use the OCT Acquisition Window on the monitor to align the camera with the Optic disc Image on the left side of the window.
 - e) Fine tune brightness and sharpness of the image using the focus knob. The optimum camera position is reached when no dark corners and overexposed areas are visible.
11. The bar above the OCT image will appear red if the OCT image touches the upper border. Move the camera further away from the patient if the OCT image is shown inverted. If the OCT image is tilted in a horizontal direction, move the camera slightly left/right (if capturing a horizontal scan) or up/down (if capturing a vertical scan). (Note in patients with moderate myopia, the scan can be tilted).
12. The blue **Quality bar** in the lower part of the image indicates the signal strength. The quality score range is **0 (no image) to 40 (excellent quality)**. **Acceptable quality is**

>15. If the score is 15 or less, the quality bar turns red. If an acceptable quality image cannot be obtained, imaging should be repeated after pupil dilation (see flowchart in study procedures manual to determine test order)

13. To achieve optimum image quality, position the OCT image in the upper half of the **Acquisition** window. Using the joystick, move the camera slightly up/down and sideways until the optic disc and OCT image appear brightest and most evenly illuminated.
14. To acquire images, press the foot switch, the **Acquire** button on the control panel or the central button on the joystick. After acquiring images, save them using the **Save images** option in the top left corner of the **Acquisition** window. To end the acquisition session, exit the **Acquisition** window. The camera will automatically turn off.

OCT RNFL Basic Report OU Printout

- A hardcopy RNFL Basic Report OU should be filed in the study file for each participant.
- Add an image from each eye to the lightbox
- Select both images in the lightbox then select Print from the context menu
- The 'print spectralis report' window will appear
- Select the RNFL Basic Report option
- Select Preview
- Select Save to save a JPEG format then select Print to printout a hardcopy
- An electronic copy of each report in **JPEG** format should also be saved to a memory stick and uploaded to the GATE study website. The naming convention for filenames of any saved reports should be followed: OCT report: 'GATE<studyID>OCT.jpg'

OCT Data Export

OCT imaging data should be exported on the same day every week. Export all the images since the last export.

- 1) From the main database screen select the patient you wish to export
- 2) To export images and other data in an examination as an E2E file, select the desired thumbnail image(s) from the **Patient File** window, and select the item **Export ► asE2E** from the **Context Menu** in the **Patient File**.

- 3) Save with filename 'GATE<studyID>rawHRTOS.e2e' for left eye, and 'GATE<studyID>rawHRTOD.e2e' for right eye
- 4) The *Batch* ► *Export E2E* feature in the *Database* window enables export of multiple patient records at once.