Royal Cornwall Hospitals
NHS Trust

Using the Ocular Response Analyser (ORA) to measure Intraocular pressure and Corneal Hysteresis for the Monitoring and Management of Glaucoma and other related Eye Conditions
Standard Operating Procedure

V1.0

July 2024

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Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the UK Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. This Standard Operating Procedure (SOP) is applicable to all Registered Nurses (RN), Nursing Associates (NA) and Assistant Practitioners (AP) who are employed by the Royal Cornwall Hospital (RCHT) and are required to carry out Eye Pressure Testing Using a Ocular Response Analyser (ORA).

1.2. Ocular Response Analyzer (ORA) is a noncontact type of Ocular tonometer that can be used to accurately measure Intraocular pressure as well the corneal hysteresis, a possible risk factor in glaucoma.

1.3. The intended clinical application would be in the diagnosis and management of suspected glaucoma and the monitoring and treatment of established glaucoma.

1.4. The Corneal Hysteresis is an additional and significant measurement obtained with the ORA which is a possible risk factor for glaucoma and can be used as a predictor in glaucoma progression.

1.5. The ORA would be used in addition to standard care, specifically the Goldmann applanation tonometry which is the gold standard in IOP measurement for glaucoma patients (NICE,2018).

1.6. The ORA is a safe and reliable tool that can be used for patients by a competently trained person to provide repeatable intraocular pressure measurements without user variations.

2. Purpose of this Standard Operating Procedure

2.1. To provide the standards expected for the safe testing and recording of Intraocular pressures using the ORA.

2.2. To ensure that all colleagues utilising ORA are performing the test appropriately.

2.3. To describe the competency required to carry out Eye Pressure Testing Using a Ocular Response Analyser (ORA).

2.4. To ensure all colleagues know their roles and responsibilities in ensuring the patient data obtained from the ORA test is reviewed, analysed, and used correctly.

3. Ownership and Responsibilities

Ownership of this SOP will be shared between the responsible clinician, the Eye unit sister / charge nurse, the Nurse-in-charge (NIC) on the shift and the member of staff carrying out Eye Pressure Testing Using an Ocular Response Analyser (ORA).

3.1. **Role of the Responsible Ophthalmic Clinician**

The responsible Ophthalmic clinician is responsible for:

- Being aware of the standards described in this SOP and their role in following them.
- Analysing the data obtained from the ORA test and determining next steps as appropriate.
- Identifying if there is a problem with the ORA recording. If issues identified then they must inform the member of staff who carried out the test and dictate next steps required.

3.2. **Role of the Eye Unit Sister/Charge Nurse**

- To be aware of the standards described in this SOP and their role in following them.
- To ensure staff carrying out ORA tests have completed the appropriate competency and being signed off as competent.
- To assign competent colleagues to the clinics where ORA tests are required.
- Ensuring that all equipment required are checked to ensure they are functioning as required to carry out the test.
- Any changes in practice are communicated to staff immediately or as soon as possible.

3.3. **Role of the Nurse-In-Charge (NIC) on the shift**

- To be aware of the standards described in this SOP and their role in following them.
- To ensure that staff assigned on the shift to perform LogMAR tests are competent.

3.4. **Role of individual colleague carrying out the ORA test**

- To be aware of the standards described in this SOP and their role in following them.
- Staff must ensure that they are competent to undertake the ORA test and adheres to the standards required.
- To act as per the responsible clinician instruction, should an issue with the ORA recording be identified.
- Carry out visual checks of the equipment daily prior to clinic commencing.

- Staff must acknowledge their own limitation and seek support from senior colleagues or line manager if required.

4. Standards and Practice

The Registered Practitioner/HCA must demonstrate relevant knowledge and understanding of the principles and practice of infection, prevention and control as per RCH Infection prevention and control policy.

The Registered Practitioner/HCA demonstrates a working knowledge of the correct equipment and materials, preparation, set-up, and operation of equipment and materials in relation to ORA.

4.1. **Equipment required:**

- ORA Machine.
- Height Adjustable chair for the patient.

4.2. **Competency / Training:**

- Only competent colleagues can perform an ORA test.
- Training and competency requirements:
    - Colleagues will attend the in-house training and will be supervised by a registered practitioner competent on performing the procedure/skill.
    - Colleagues will be supervised until assessed as competent on performing the ORA. Once assessed as competent then they will undertake the test independently.
    - Theoretical knowledge underpinning this procedure/skill will be gained both through appropriate reading, and experientially through working alongside competent ophthalmic trained staff.
    - This SOP will be available on the RCHT intranet in the Eye unit shared folder and there will also be a hard copy available to view, within the Department, located in the Sister/Charge Nurse's Office.
    - The Eye Unit Sister/Charge Nurse will be responsible that all nurses and AHP's have been suitably trained before undertaking this task and that they have read and understood this SOP.
    - Records of Ophthalmology Staff Competency (read and understood the SOP) will be available within the Eye unit training records.

4.3. **ORA Testing Standards**

Carrying out LogMAR Test
1) **Introduces self and role to the patient.**
2) **Logs on to staff Medisoft account.**
3) **Patient Identification Check on Medisoft.** • Ask patient to confirm their name, date of birth and address. • Check that this is the same detail as detailed on Medisoft.
4) **Informed Consent.** • Explains to the patient what they will be doing to complete the ORA test. • Asks the patient if they have any questions in relation to that. • Asks the patient if they have their consent to do as described.
5) **Patient Positioning.** • The ORA machine is table-mounted and controlled by a healthcare professional through an in-built operator display. • Patient to be seated on the height adjustable seat. • The room should be well lit. • Position patient with their head in the headrest, which is adjusted to allow for measurements of the left or right eye.
6) **Testing.** • Asks patient to remove glasses (if worn). • If the patient is wearing contact lenses, please ask to remove them before the test. • Patient to be advised that the device will blow a short puff of air into their eye this puff of air momentarily slightly flattens the cornea and then it returns to its original shape). • The ORA will record 2 measurements: 1) The IOP cc, which is the corneal compensated IOP with corrections for corneal hysteresis and corneal resistant factor. 2) OP g which has been found to be closely comparable to the values obtained by Goldmann applanation Tonometer (GAT) used by all glaucoma specialists. 3) The IOPg is the measurement to be added to Medisoft (as most comparable to the Goldmann applanation tonometry reading). The difference between these 2 measurements is defined as the level of corneal hysteresis (measured in mmHg) (NICE, 2018).
7. Record outcome of the ORA Test on Medisoft.

How to record outcome of ORA test on Medisoft:

- Click on the nurse icon.
- Click on.
- Click **'save'.**

5. Dissemination and Implementation

5.1. This SOP will be signed off at specialty Business and Governance meeting.

5.2. This SOP will be available on the RCHT intranet on the Documents library, in the Ophthalmology department shared folder and there will also be a hard copy available to view, within the Eye Unit Sister/Charge Nurse Office.

5.3. The Eye Unit Sister/Charge Nurse will ensure that all nurses and AHP's have read and understood this SOP.

5.4. Competency records will be held and available in the Eye Unit Sister/Charge Nurse Office.

6. Monitoring Compliance and Effectiveness

Information Category.	**Detail of process and methodology for monitoring compliance.**
Element to be monitored.	All the SOP to be monitored.
Lead.	Eye Unit Sister.
Tool.	Audit and review tool using patient documentation.
Frequency.	Monitoring will be an ongoing practice within the Department.
Reporting arrangements.	Any concerns regarding the ongoing implementation of this SOP should be reported to the Eye Unit Sister who will investigate and report back to the team.
Acting on recommendations and Lead(s).	Any recommendations/changes to this SOP will be reported at the Departmental Business and Governance meeting/safety huddle and changes implemented.
Change in practice and lessons to be shared.	Required changes to practice will be identified and actioned immediately. A lead member of the team will be identified to take each change forward where appropriate; lessons will be shared with all the relevant stakeholders.

7. Updating and Review

This document will be reviewed every 3 years, but sooner if any amendments are required.

8. Equality and Diversity

8.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

8.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Carrying out an Eye Pressure Testing Using an Ocular Response Analyser (ORA) Standard Operating Procedure V1.0
This document replaces (exact title of previous version):	New Document.
Date Issued/Approved:	May 2024.
Date Valid From:	July 2024.
Date Valid To:	July 2027.
Directorate / Department responsible (author/owner):	Specialist Services and Surgery (SSS), Eye Unit Sister Karen Bowers and Deputy Sister Cath Miles.
Contact details:	01872 252244.
Brief Summary of Contents:	Standards for Ocular Response Analyzer (ORA) to measure corneal hysteresis, a possible risk factor for glaucoma.
Suggested Keywords:	Eye Unit, Ophthalmology, ORA, Glaucoma, IOP.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer.
Approval Route for Consultation and Ratification:	Ophthalmology Business and Governance Meetings, SSS Care Group.
General Manager confirming Approval Processes:	Roz Davies.
Name of Governance Lead confirming approval by Specialty and Care Group Management Meetings:	Maria Lane
Links to key External Standards:	https://www.nice.org.uk/advice/mib150.
Related Documents:	None required.
Training Need Identified?	Yes.

Information Category	Detailed Information
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet.
Document Library Folder/Sub Folder:	Clinical / Ophthalmology.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
July 2024.	V1.0.	Initial Issue	Karen Bowers, Sister. Cath Miles, Deputy Sister.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance, please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team. rcht.inclusion@nhs.net

Information Category.	Detailed Information.
Name of the strategy / policy / proposal / service function to be assessed:	Carrying out an Eye Pressure Testing Using an Ocular Response Analyser (ORA) Standard Operating Procedure V1.0.
Directorate and Service Area:	Ophthalmology, Eye Unit.
Is this a new or existing Policy?	New.
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Paulette Hunkin, Clinical Matron.
Contact details:	01872 252244

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed).	All staff working within the RCH Ophthalmology service where ORA is required as part of the patient requirement.
2. Policy Objectives.	To standardise and formalise the standards expected for ORA requirement in the RCH Ophthalmology service.
3. Policy Intended Outcomes.	To provide clarity and standards for ORA and the actions required by staff involved in this.
4. How will you measure each outcome?	Where standards are not met or concerns regarding standard not being achieved an incident report will be completed for investigation by the specialty governance lead.
5. Who is intended to benefit from the policy?	All staff and patients where ORA is used as part of the patient pathway.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category).	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Ophthalmology clinical lead, Governance Lead, Specialty clinicians within the Eye Unit, Ophthalmology sister and deputy, service manager. Specialty team through Business and Governance (BG) meeting discussion and sharing.
6c. What was the outcome of the consultation?	Approved by specialty.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** Audits, Complaints, Incidents.

7. The Impact.

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age.	No	All ORA testing will be performed in the same way.
Sex (male or female).	No	All ORA testing will be performed in the same way.
Gender reassignment (Transgender, non-binary, gender fluid etc.).	No	All ORA testing will be performed in the same way.
Race.	No	All ORA testing will be performed in the same way.
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.).	No	All ORA testing will be performed in the same way.

Protected Characteristic	(Yes or No)	Rationale
Religion or Belief.	No	All ORA testing will be performed in the same way.
Marriage and Civil Partnership.	No	All ORA testing will be performed in the same way.
Pregnancy and Maternity.	No	All ORA testing will be performed in the same way.
Sexual Orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	All ORA testing will be performed in the same way.

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Paulette Hunkin, Clinical Matron.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis