Electro Diagnostics Unit

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Title	**:**	**Equipment, Maintenance and Calibration**
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Training Requirements	**A** ✓	**B**	**C**	**D**

A = New procedure requiring documented assessment of competence

B = Modified procedure requiring documented reassessment of competence

C = Familiarity with new procedure required (no assessment of competence necessary)

D = Familiarity with changes required (no assessment of competence necessary)

	Signature	**Name (print)**	**Date**
Prepared by			
Reviewed and approved by			

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1. INTRODUCTION

The purpose of this statement of procedure (SOP) is to describe the main equipment that is used by the Visual Electrodiagnostic Testing Service (VETS) and how this equipment is maintained and calibrated.

The equipment described is used to provide a clinical testing service for ophthalmologists across the Yorkshire region. Patients are referred by consultant ophthalmologists to the VETS and subsequent testing comprises a range of key diagnostic tests: *electro-retinography*, *electro-oculography* and *visual evoked potential recording,* which form part of the clinical ophthalmological assessment of patients who may be suffering from a variety of hereditary or acquired eye diseases.

All of the equipment described is located in the Electrodiagnostics Unit (EDU) which operates the VETS and is located in room F10 (Xxxxx Building) in the Xxxxx School of Optometry & Vision Science (BSOVS), University of Xxxxx.

In general the maintenance and calibration of specific instruments will be carried out in accordance with the manufacturers' recommendations and as detailed in the appropriate instrument manual.

Records of instrument maintenance and calibration will be maintained.

2. SCOPE

This SOP describes the main hardware and software used in the electrodiagnostic testing and covers the procedures involved in the calibration and maintenance of this equipment that is required for its optimal operation.

3. RESPONSIBILITIES

Director of VETS Dr Xxxxx Xxxxx
(BSOVS, University of Xxxxx).

The VETS Director has overall responsibility for ensuring that all of the equipment used in the EDU is appropriate and safe for its intended use.

In addition the VETS Director will be responsible for:

- Identifying and organising equipment maintenance regimes.

- Identifying calibration regimes and organising their implementation.
- Preparation of instrument log books.
- Holding service records.
- Records of calibration performed other than at routine maintenance are logged in the appropriate equipment maintenance and calibration log book.

4. RELATED DOCUMENTS

- Electrode Application and Removal Procedure (*ED FAC05*)
- Espion User Guide (V3.0)
- Portable Appliance Testing Policy (*UoB 014*)
- Facilities Cleaning (*ED FAC01*)
- Patient Data Management and Storage (*ED FAC08*)
- Patient Management and Referral Procedure (*ED FAC04*)

5. SPECFIC EQUIPMENT

5.1. Espion Sytem.

The Espion E2 Electrophysiology System (Diagnosys LLC, MA, USA) housed in the EDU consists of the E2 console, a Pattern Stimulus Generator and a ColorDome Ganzfeld Stimulator which are attached to the main unit.

The Espion E2 System has been designed for clinical visual electro-physiology applications. It enables visual evoked potential (VEP), electroretinogram (ERG) and electrooculogram (EOG) to be performed. Where applicable, tests are designed to meet the standards prescribed by the International Society for Clinical Electrophysiology of Vision (ISCEV).See www.iscev.org.

Pattern Stimulus Generator

The Pattern Stimulator Generator (PSG) provides computer controlled generation of visual stimuli (checkerboards, gratings) and allows precise manipulation of their luminance, contrast, spatial and temporal properties. The stimuli themselves are present on a standard CRT Monitor (Elonex V999) and are used for VEP and pattern-ERG recording.

ColorDome

The ColorDome full-field Desktop Ganzfeld stimulator designed for ERG testing. It is capable of producing standardized and user-definable protocols for full-field ERG testing. Predefined

protocols are also available for EOG, 30Hz flicker, Flash VEP, Single Flash Cone ERG, Single Flash Rod Response.

An accompanying document: *Electrode Application and Removal Procedure (ED FAC05)* describes the use and maintenance of electrodes used in the electrodiagnostic testing procedures.

5.1.1 Servicing and Technical support

This is provided by the local Diagnosys dealer:
Diagnosys UK Ltd.,
54 Impington Lane,
Impington,
Cambridge, CB4 9NJ UK,
Phone: 01223520699. Fax: 01223 520699. E-mail: mail@diagnosysuk.co.uk

5.1.2 Software support and updates

For software support contact diagnosys.
Software updates are available from http://www.diagnosysllc.com

5.1.3 Safety standards

The Espion E2 System complies with the following standards:

IEC60601-1	Medical Electrical Equipment. General Requirements for Safety.
IEC60601-2-40	Medical Electrical Equipment - Part 2-40: Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment
IEC60601-1-1	Medical Electrical Equipment. Safety Requirements for Medical Electrical Systems.
IEC60601-1-2	Medical Electrical Equipment. Electromagnetic Compatibility.

Equipment classifications – see Espion User Guide (v3.0) for further Information

6. PROCEDURE

6.1. Assessment of calibration and maintenance requirements.

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Maintenance and calibration requirements are assessed by the VETS Director.

The maintenance and calibration requirements are based on manufacturer's recommendations (see: *Espion User Guide V3.0*).

These requirements are recorded below can be found also the equipment maintenance and calibration log book.

6.2. Equipment maintenance and calibration log books.

An historical record of each appropriate instrument in the laboratory will be maintained in an Equipment Maintenance and Calibration logbook. All entries will be dated and initialled.

Equipment logbooks are divided into relevant sections for each piece of equipment and the following information is recorded:-

- Name of instrument
- Manufacturer
- Date of initiation of logbook or section
- Name of person responsible for the equipment
- Is instrument covered under a service/maintenance agreement? If yes, record details of service agreement
- Details of routine maintenance required
- Details of periodic calibrations required.
- A record of maintenance and calibrations completed.

All routine maintenance should be recorded in the instrument logbook, see form ED LAB F02

6.2 Specific Routine Cleaning and Maintenance

On a weekly basis:

All the Espion E2 System equipment will be inspected for any external sign of wear or damage, (e.g. frayed cables) and also prior to use.

Routine cleaning of Espion equipment will be carried out by the VETS director. This will include cleaning the:

exterior of the Espion E2 System console, screen, patient montage, and stimulators should be cleaned on a weekly basis using a slightly damp soft cloth.

ColorDome interior using a slightly damp cloth or some rubbing alcohol to remove finger-marks left by touching the screen after tests.

Pattern Stimulator CRT screen using a slightly damp soft cloth to ensure that it is free from dirt and finger-marks.

After each patient appointment chin rests, headrests and the external surface of the ColorDome will be wiped down.

NOTE: None of the Espion E2 System is designed to be disinfected or sterilized.
NOTE: Always disconnect the power from the Espion E2 System console and any powered equipment before cleaning it.

6.3 Calibration

Following ISCEV guidelines, all equipment that can be calibrated should be calibrated with a frequency of no less than once per year.

The Espion E2 System has built in calibration systems which help to keep values stable over time to reduce this requirement to a minimum.

ColorDome

The colour will be checked with a calibrated photometer every 6 months. The stimulator also has a built in calibration unit which tests the LED outputs every time a protocol is run, compensating for time and temperature drifts.

The ColorDome has an additional light source - a xenon tube which is inherently more unstable than the LED degrades with use (light output reduces over time). However, the automatic calibration feedback circuit measures the actual light produced by every flash and will compensate for a decaying xenon tube up until the time the tube fails at which point the program will produce an error message.

Pattern Stimulus Generator

The Pattern Generator CRT requires regular calibration as CRT screens decay in brightness over time.

The CRT will be checked every 2 months check them to monitor their luminance drop off using a photometer.

NOTE: Do not adjust the controls of the monitor (e.g. the brightness, contrast and size controls) after it has been calibrated as any alterations will invalidate the calibration.

6.4 Portable Appliance Testing

All equipment in the EDU will be PAT tested on a yearly basis and marked with a sticker indicating the date it was tested and passed (see: *Portable Appliance Testing, UoB 014*).

Equipment that has passed this testing will be marked with a sticker indicating the date passed and the date of retesting.

Any PAT testing failure will be noted in the equipment log book.

6.5 Equipment failure, including out of calibration.

Each time an item of equipment included in the laboratory maintenance and calibration scheme fails or is outside its calibration criteria the information must be recorded in the instrument logbook, together with details of repairs and time out of commission.

Any operator who identifies a piece of equipment to be outside acceptable calibration range, or otherwise unfit for use, should immediately notify the VETS Director

The VETS Director must decide what action is to be taken, e.g. request maintenance/repair visit, and document the action taken in the equipment log. No equipment should continue in use without rectification of identified problems with calibration or otherwise.

If the equipment is found to be outside acceptable calibration limits, the VETS Director will assess the effect of this on the validity of the work performed since the equipment was last calibrated. This assessment and the conclusion reached will be documented by the VETS Director and held with the equipment records.

Where appropriate, service users may be requested to return to the EDU for confirmatory evaluations.