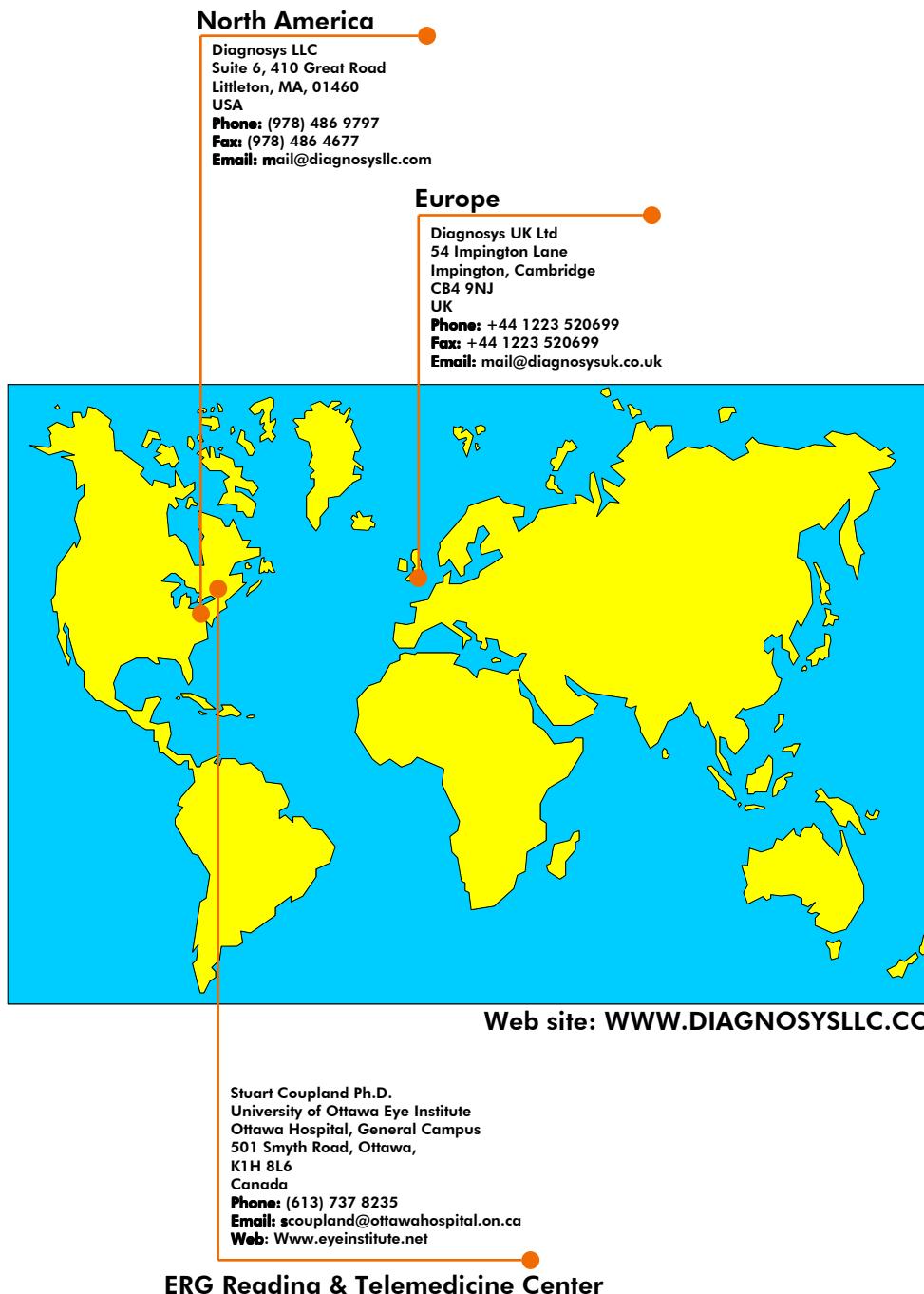
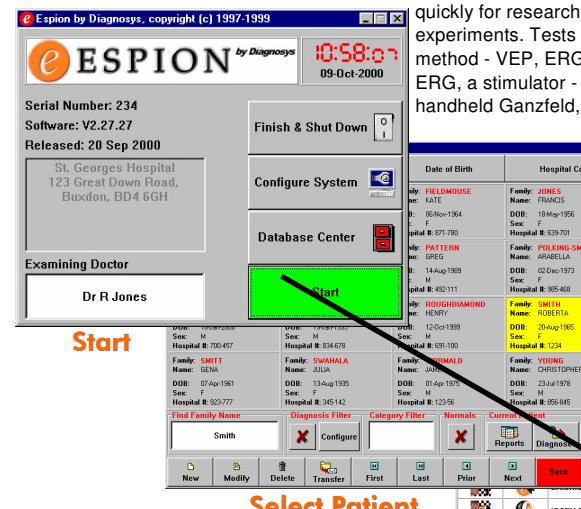


Diagnosys Sales & Support Offices



The Espion system has been designed to interrogate the visual system layer by layer to provide objective assessment of macular, pan-retinal and optic nerve function. It not only performs all the standard ISCEV clinical vision tests but is also capable of performing new tests as they are developed. Based around a fast PC running Windows and written in conjunction with leading experts in the field, it incorporates into its design many aspects that are very desirable for electrophysiology including a proper client/server SQL database, advanced normal selection, fully programmable protocols, digital filtering, automatic report generation and proper diagnosis facilities. The hardware supports multiple external stimulators with options for expansion as technology changes.

Follow green buttons to select and run a test



Design Philosophy

Housed in a stylish designed case, the system has been designed to cover the following points:

- A product designed especially for the electrophysiology market, not an add-on to another machine
- Easy to use. A hi-tech no knobs technology which doesn't require the user to be a computer wizard or PC expert to understand
- Self contained. (all the major electronics in one box)
- The system is portable can be carried direct to the patient
- Designed to be not only to be the

most accurate, but also the most reproducible system on the market

- Data can be exported/imported easily not only between the system and other software but also between machines world wide for group projects
- Minimum footprint size
- The design is modular, both in hardware and software so further modules can be easily added including customer specific stimuli
- External cables are kept to a minimum and the system does not require a mouse or keyboard
- The system exceeds both American and European clinical safety standards to be one of the safest clinical electrophysiological systems in the world

The software has been designed to allow new hardware and software to be incorporated with minimum change. This means that custom stimuli, hardware stimulators or even new types of tests can be added quickly for research or clinical experiments. Tests consist of a method - VEP, ERG, EOG, FOCAL ERG, a stimulator - Pattern, handheld Ganzfeld, full field

Most parameters and options can be changed by simply selecting from a drop down list of values speeding up configuration. If required, an external mouse and keyboard may be added and these run in conjunction with the touch screen. Each parameter is supplied with a default list of values which are normally selected from a much larger range. Almost all of these parameters can be configured by the customer and the current list may be changed at any time to cover the values of interest.

User Controls

The Espion console is supplied with an infra-red touch-screen which incorporates a touch keyboard eliminating all need for an external keyboard and mouse.

Most parameters and options can be changed by simply selecting from a drop down list of values speeding up configuration. If required, an external mouse and keyboard may be added and these run in conjunction with the touch screen. Each parameter is supplied with a default list of values which are normally selected from a much larger range. Almost all of these parameters can be configured by the customer and the current list may be changed at any time to cover the values of interest.

Features

◆ Performs ISCEV Tests

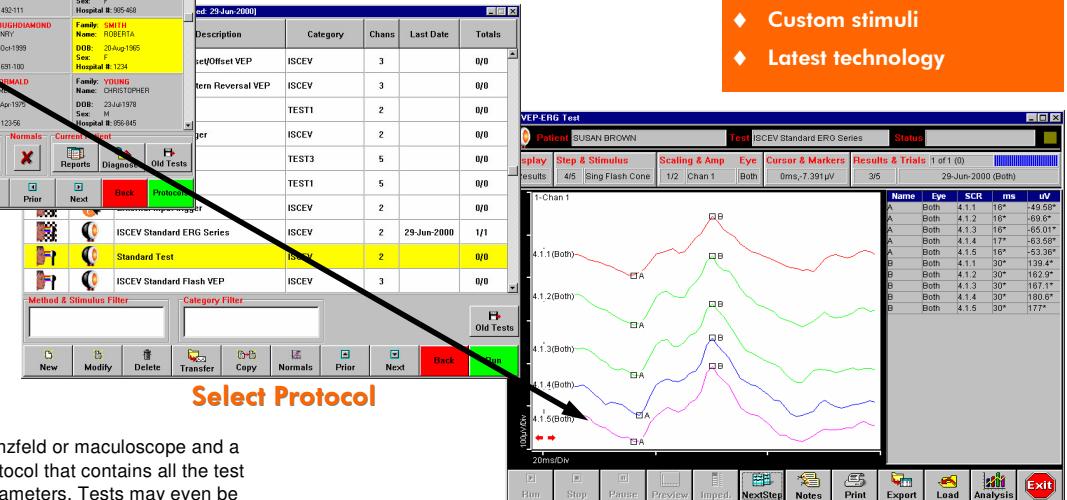
- Pattern VEP
- Flash VEP
- Pattern ERG
- Flash ERG
- Focal ERG
- EOG
- User Defined

◆ Fully Configurable

- ◆ Run tests automatically
- ◆ SQL Database
- ◆ Touch Screen support
- ◆ Windows operating system
- ◆ Integrated Networking
- ◆ Import/Export records
- ◆ Multiple operator modes
- ◆ Support for external stimulators
- ◆ External triggering
- ◆ Custom stimuli
- ◆ Latest technology

Operator modes

The software can be run on several different levels, from supervisor mode where all the options and operations are available to user mode where only predefined protocols are available and there is no possibility of deleting or modifying inappropriate parts of the system. The user is led through the selection of a patient and protocol and then on to perform the test in very few



button pushes making it very straightforward for even a novice to be able to use it. Changing operator modes is password protected to stop unauthorized changes being made to the system configuration.

Run Test

Software Updates

Diagnosys has a policy of continuous improvement and make available new features on a regular basis. Bug fixes and minor upgrades are normally available free of charge.

Electrophysiology System
Reinventing Vision Testing

Database



- ◆ Industry standard SQL
- ◆ Client/Server
- ◆ No record limit
- ◆ User defined fields
- ◆ Automatic sorting
- ◆ Group selection
- ◆ SQL Query
- ◆ Multiple databases
- ◆ Sophisticated patient diagnosis
- ◆ Password Security
- ◆ Automatic backup
- ◆ Open data policy

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Databasing

Based around an industry standard SQL database, all patient, tests, protocols and diagnoses are stored in tables as records not flat files which can be accessed by many other 3rd party programs if required. The software supports multiple databases, although only one database can be connected at any one time. New databases may be created anytime.

Client/Server

The standard database is supplied as a local client/server installation (all software resides on the Espion) but with the purchase of the necessary licenses it can be configured as a fully fledged remote client/server system with more than one client connected to the database over the network at the same time. Applications include a clinic with more than one ESPION installed or a customer who wishes to connect the ESPION to their own network and access the data from a PC running another Espion software installation.

Patient Details

Patient details are displayed in a simple grid showing important parameters for easy selection. Records may be sorted by first name, last name, Date of birth and hospital number in both ascending and descending order and found by string lookup on any one of these fields. These records can also be filtered by diagnosis, normal, or category to reduce the available subset and produce sets of similar patients for group analysis etc.

Patient Fields

Patient fields include not only name, address, DOB, gender, hospital no. etc but also ethnic origin, eye acuity, eye color, a user defined category and three user definable fields. All fields can be set such that they must be filled in, left blank or even disabled before a new patient is entered into the system.

Patient Selection

Family Name	First Name	Date of Birth	Hospital Code
Family: BLACKSMITH Name: JEAN	Family: FIELDHOUSE Name: HARRIET	Family: FIELDHOUSE Name: KATE	Family: JONES Name: FRANCIS
DOB: 09-Aug-1982	DOB: 02-Apr-1999	DOB: 06-Nov-1964	DOB: 18-May-1956
Sex: M	Sex: F	Sex: F	Sex: F
Hospital #: 601-564	Hospital #: 834-45	Hospital #: 871-780	Hospital #: 539-701
Family: KARN Name: SHALEM	Family: PATEL Name: SEMA	Family: PATTERN Name: GREG	Family: POLKING-SMYTHE Name: ARABELLA
DOB: 11-Nov-1984	DOB: 04-Jul-1998	DOB: 14-Aug-1989	DOB: 02-Dec-1973
Sex: M	Sex: F	Sex: M	Sex: F
Hospital #: 582-943	Hospital #: 045-786	Hospital #: 492-111	Hospital #: 385-468
Family: RICHARDS Name: JOHN	Family: ROBSON Name: JOSS	Family: ROUGHDIAMOND Name: HENRY	Family: SMITH Name: ROBERTA
DOB: 18-Jan-2000	DOB: 19-Jan-1995	DOB: 12-Oct-1999	DOB: 20-Aug-1965
Sex: M	Sex: M	Sex: M	Sex: F
Hospital #: 700-457	Hospital #: 834-678	Hospital #: 691-100	Hospital #: 123-4
Family: SMITI Name: GENA	Family: SWAHALA Name: JULIA	Family: WORMALD Name: JAMES	Family: YOUNG Name: CHRISTOPHER
DOB: 07-Apr-1961	DOB: 13-Aug-1935	DOB: 01-Apr-1975	DOB: 23-Jul-1978
Sex: F	Sex: F	Sex: M	Sex: M
Hospital #: 923-777	Hospital #: 345-142	Hospital #: 123-56	Hospital #: 896-845

Exporting Records

To allow all types of records to be transferred between different databases on the same computer or different computers in different locations, the software supports both single and multiple record extraction. The selected records are stored in a designated file which can be emailed to another system as an attachment and then imported into the current database. In this way groups of users can be sent new protocols to run, results can be stored or interpreted centrally and patient normals collected together making it ideal for group trials or shared research.

Patient Fields

SUSAN P BROWN	Total tests: 1, last recorded: 29-Jun-2000	
OD Acuity	20/40	
OS Acuity	20/20	
OS Refraction (SE)	+1.72 Dpters	
OD Refraction (SE)	+2.3 Dpters	
Gender	F	
Hospital Number	123-567	
Patient	Details	Address
Patient		
Details		
Address		

Contact your local sales office for a quote

Equipment

Console

The console is the heart of the Espion system and is designed to be a hi-tech no knobs self-contained unit that is not only elegant but also extremely easy to use. It is designed to be as small as possible for portability but retain the power of a desktop computer to maximize the available features for stimulus generation, acquisition, printing and analysis. Containing the computer, display and isolated amplifiers, it has connectors for all the external stimulators, the patient headbox and also the pattern generator hardware (if supplied). The console is fully isolated and does not require the PowerBloc for proper operation. This allows the console and one or more handheld stimulators to be carried around in the back of a car or even on normal flights as standard luggage (flight case required).

PowerBloc (Isolation unit)

The PowerBloc houses the isolation transformers required to isolate the pattern stimulator monitor, an inkjet printer and the full-field Ganzfeld if they are located in the patient environment. The software has been written to make full use of the color and high resolution output to produce single sheet quality reports. A laser or other printer may be configured provided it is connected via the network and outside the patient environment. For customers who require a portable solution, the console can be fitted with an infra-red option which removes the need for the PowerBloc entirely.

- Custom design
- Small footprint
- Fast Pentium computer
- Windows operating system
- 128MB RAM
- 40GB hard disc or greater
- 250MB ZIP drive for data backup
- SVGA (800x600) TFT display with 16 million colors
- Infra-red touch panel for fast control and reliability
- Keyboard and mouse supplied
- USB, isolated RS232, Parallel printer, 10baseT network connection (via PowerBloc)
- 5 differential amplifier channels
- Optional Infra-red printer connection
- Integral On/Off switch and power on indicator
- Dimensions 12.75" x 18.25" x 3" (324mm x 465mm x 76mm)
- Weight 20.5lb (9.3kg)

NOTE: The PowerBloc is not required to isolate the console but actually draw its power from the console.

Trigger Out

The Espion is capable of triggering external equipment with a standard TTL pulse. Output pulses can be configured for both mark and space times as well as being fully isolated for safety.

- TTL Compatible BNC
- Isolated voltage for safety
- On/Off pulse time programmable in ms steps
- Single pulse or pulse train

Trigger In

The Espion system can be triggered by external equipment with a digital negative going TTL pulse or self triggered by monitoring anyone of the analog inputs. Analogue input triggers start the system when either a rising or falling edge is detected on any input. The slope of the edge to be detected can be programmed.

- 5 differential channels
- Fully isolated
- 22 bit resolution producing 100nV, no gain required
- 16 bit ADCs coupled with 12 bit DC offset

Digital Trigger In

- TTL Compatible BNC
- Isolated voltage for safety
- Edge triggered (negative)
- No minimum pulse width (<100ns)

Analog Trigger In

- Trigger from any channel
- Negative or Positive slope
- Slope slew rate programmable

Printer

The Espion system is designed to couple directly to a color inkjet printer using parallel or USB connections and provide isolated power from the PowerBloc. This is required if the printer is positioned in the patient environment. The software has been written to make full use of the color and high resolution output to produce single sheet quality reports. A laser or other printer may be configured provided it is connected via the network and outside the patient environment. For customers who require a portable solution, the console can be fitted with an infra-red option which removes the need for the PowerBloc entirely.

- Fast color Inkjet printer
- Single sheet output
- Isolated power
- Parallel or USB connection as standard
- Support for more than one printer

NOTE: Printer is not supplied as standard



Photometer (Calibration)

Diagnosys can provide a high quality photometer to calibrate the entire range of stimulators. It has an RS232 interface for automated calibration and can be purchased or rented as required.

- Calibrated to U.S national institute of standards
- DC and integration measurements
- 5V bias for flash measurement
- Scotopic and Photopic filters
- RS232 interface for automatic operation

NOTE: Photometer is not supplied as standard

Hardware



Safety

- ◆ Fully complies with American and European safety standards
- ◆ CE₀₄₁₃
- ◆ EN60601-1:1990,A2:1996
- ◆ EN60601-1-1
- ◆ EN60601-1-2
- ◆ EN60601-2-26:1994
- ◆ UL2601 2nd edition; 1997
- ◆ CAN/CSA C22.2 no. 601.1-M90,S1:1995

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Visit WWW.DIAGNOSYSLLC.COM for more information



Pattern Stimulator



ColorBurst Handheld Ganzfeld

The ColorBurst is a ultra compact handheld monocular Ganzfeld based on LED technology. It incorporates three rings of ultra bright red, green and blue LEDs which combined together give the whole visible spectrum of colors. High resolution pulse width modulation allows very fine control of the actual luminance and keeps the value constant over time and temperature. Flashes can be created with short or very long time duration for on/off responses unlike standard Xenon flash technology, and superimposed on any color background. It produces all the standard ISCEV flash intensities.

ColorDome Full field Ganzfeld



The pattern stimulator has been designed to produce standard ISCEV patterns on a monitor for VEP and ERG tests.

- Configurable monitor timing
- Default: 800*600 @ 100Hz
- 8-15 bit luminance control for accurate contrasts (depending on option).
- Factory calibrated gamma correction built-in
- Supports all standard monitors
- 21" high quality color monitor included
- Luminance > 100cd/m² (depending on monitor)

NOTE: The monitor is subject to availability and specification may change.

Maculoscope

The maculoscope is the ophthalmoscope stimulator of the Espion system. It produces the flickering circular stimulus which is the standard for focal ERG. The stimulus is projected directly onto the retina where it can be positioned by the examiner. Its unique sensitivity allows it to identify maculopathy even in patients with mild visual loss.

- 4° spot of light flickering at 42Hz
- 100% contrast with a square temporal waveform
- Peak retinal illuminance of 4.8 log-Trolands.
- Stimulus is centered with 12 deg annular surround of 5.5 log-Trolands retinal luminance
- Critical ratio of surround to stimulus illuminance of 0.7 log units is maintained throughout range
- Flicker frequency up to 100Hz
- Incorporates accommodating lenses from -2.5 to 4.0 diopters



- Flash duration shorter than 4ms using 250ns PWM control
- Flashes current controlled not voltage controlled for ultra stable luminance and color output.
- Maximum flash duration >1s
- Any color flash
- Any color background
- Dim and Bright LED rings for 6 orders of luminance range
- Max white flash >30cd.s/m², 10x ISCEV standard flash
- Luminance linearity <2% deviation over entire range
- Calibrated luminance output in both cd/m² and cd.s/m²
- Very stable output, fully adjusted for temperature
- 3 Red fixation LEDs with adjustable intensity
- On/Off flashes and arbitrary flash waveforms e.g. ramp, sine and exponential possible
- Calibrated in both Scotopic and Photopic luminance ranges
- Sphere diameter is 3.5" and eye viewport diameter is 2.15"
- Colors selectable using standard CIE coordinates
- Color wavelengths typically Red 640nm, Green 530nm, blue 470nm

Calibration

Diagnosys recommends that the ColorBurst is calibrated at least once a year either by returning it to the manufacturer or one of its representatives.

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Stimulators

Designing Protocols

Result Markers

Each step may define a series of markers which mark specific points on the result e.g. P100, N135, N75 for VEP and A, B for ERG.

These markers can be made automatic such as they are positioned by the software in the appropriate places after the result has been recorded speeding up diagnosis. Each marker may be set to show absolute periods and amplitudes or relative to other marker values, Marker values are displayed in a table on the

Protocols are special records which consist of a series of parameters that control how individual tests are performed, displayed, and printed. Any number of

SUSAN BROWN [Total tests: 1, last recorded: 29-Jun-2000]					
Method	Stimulus	Protocol Description	Category	Chans	Last Date
ISCEV	ISCEV Standard OnsetOffset VEP	ISCEV		3	0/0
ISCEV	ISCEV Standard Pattern Reversal VEP	ISCEV		3	0/0
TEST1	Saccade test	TEST1		2	0/0
ISCEV	External output trigger	ISCEV		2	0/0
TEST3	mfg test	TEST3		5	0/0
TEST1	Amplifier Test	TEST1		5	0/0
ISCEV	External input trigger	ISCEV		2	0/0
ISCEV	ISCEV Standard ERG Series	ISCEV		2	29-Jun-2000 1/1
ISCEV	Standard Test	ISCEV		2	0/0
ISCEV	ISCEV Standard Flash VEP	ISCEV		3	0/0

Selecting Protocols

protocols may be setup and categorized for ease of selection such as ISCEV, Prototype etc. Selecting a protocol from the current list is simply a case of touching it and pressing the green button to run the test.

Creating Protocols

Protocols can be created, deleted, copied and modified at will provided the current user has the correct operator status and no data has been saved using that protocol. A protocol encapsulates a test method (VEP,ERG, EOG) a test stimulator (Ganzfeld, Pattern generator, external trigger) and a number of channels to record. Once these are set, then the individual parameters can be modified. Once a protocol has been defined, it may never need to be changed again. Of course new protocols may be based on existing protocols to make configuration even quicker. Most protocol parameters can even be changed when running the test for further refinement on a patient by patient basis.

Defining Steps

Each protocol contains a series of parameters that include acquisition, amplifier, stimulus, timing, and markers which are grouped together into steps. A protocol might consist of one or more steps each of which contains identical parameters except one which varies between steps. An example would be checkerboard spatial size for VEPs or a flash intensity series for ERGs. Conversely the protocol might instead consist of a series of quite different steps. An example might be producing 30Hz flicker, bright and dark adapted flashes for ERGs.

Step Parameters

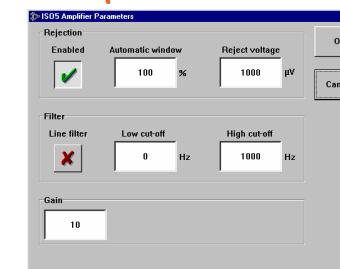
including the positive direction and initial graph scaling. The system also supports the concept of virtual channels; these are channels whose inputs are actually taken from another channel's. This allows the program to record the same inputs but apply different settings like filtering or produce a channel which is the difference of two other channels.

Filtering

All channels have built in digital filters which cover all the standard ISCEV filter requirements.

- 75,100 to 300Hz
- 0,0.03,0.15,0.6,2.5 to 30Hz
- 0,0.03,0.15,0.6,2.5 to 100Hz
- 0,0.03,0.15,0.6,2.5 to 300Hz
- No filtering
- Line filter 50/60Hz

Amplifier Parameters



Group by category, stimulator, test type, description

Easy creation

All parameters are configurable

Record 5 channels simultaneously

Auto-rejection of trials

36 Steps per Protocol

16 Markers per step

No limit on number of average per step

No limit on number of trials in average

Support for virtual channels

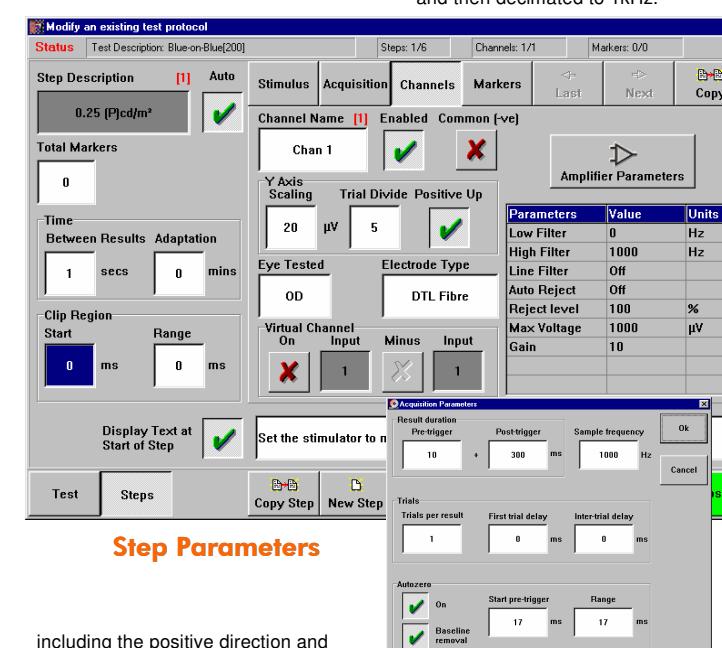
Acquisition >32secs

Records all trials for later analysis

Digital filtering

Data Acquisition

Data is sampled internally at 10kHz and then decimated to 1kHz.



Acquisition Parameters

Acquisition parameters include pre/post trigger periods, auto-zero ranges and various timing delays. Total acquisition periods can stretch from 100ms to greater than 32secs.

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Generating Stimuli



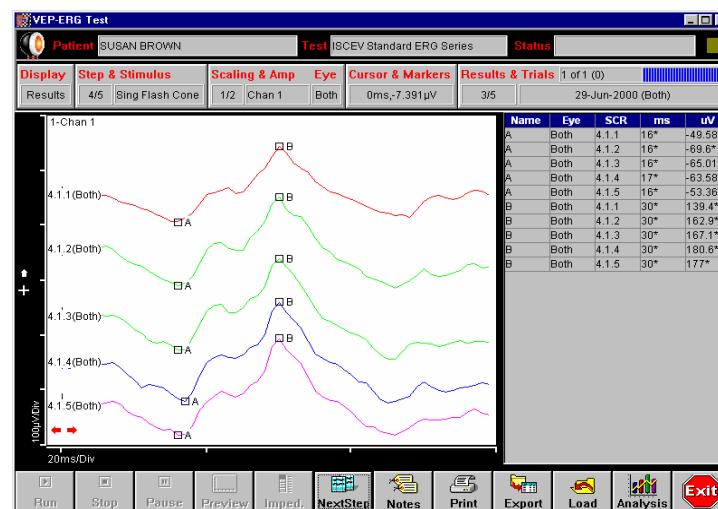
- ◆ Fully programmable
- ◆ External stimulators triggered
- ◆ Monochrome and colored stimuli
- ◆ Single/multiple flashes
- ◆ Pulse, sine, exponential and ramp waveforms
- ◆ LED flash technology
- ◆ Luminance and color calibrated using international standards
- ◆ Luminance entered in standard Units not dB
- ◆ Scotopic/Photopic units for luminance selection
- ◆ Checkerboards, bars and gratings standard
- ◆ Iso-luminance displays
- ◆ Custom stimuli
- ◆ Dual stimulator control simultaneously

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Running a Test



Main VEP/ERG Display

reduce time and paper wastage.

Exporting Data

Once the data has been collected it can be saved into the database for later retrieval or exported to other applications for further analysis e.g. Microsoft Excel or SigmaPlot. This can be achieved by saving the data to a file in ASCII form or using the Windows graphical metafile format via the clipboard for cutting and pasting. Full control is provided in selecting which bits of the data are actually exported including results, trials, marker values and other useful information.

Measurement of Peaks/Troughs

Each protocol can incorporate a complete set of markers which are positioned on each new result automatically. These markers once positioned can easily be moved for more precise alignment as determined by the practitioner and new ones can be created, modified or deleted as required. For quick measurements, a cursor may be positioned on any result indicating period and amplitude either relative to the zero point or to another arbitrary defined position.

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Once a patient and protocol have been selected, the next stage is to run the test. The actual screen layout, colors used, printing options are dependent on the type of test being performed. During a test, parameters in individual steps parameters may be changed and even new steps created to extend stimulus sequences etc. The VEP/ERG display is made up of two sets of buttons; those at the top effect display and normally produce a separate window with additional functionality and those at the bottom control the running of the test. The program not only records the averages or results of each individual stimulus, but also records all the individual trials that make up the average. This facility means trials can be further manually rejected as desired. If more than one result is obtained for any stimulus, an average of averages can be generated to further enhance the record.

amplifier requires both its inputs not only have a low but also equal impedances. This last point is very important as the common mode rejection (CMRR) of the amplifier is reduced significantly when not in balance. A low CMRR means the amplifier is adversely effected by large voltages superimposed on both inputs such as mains pickup. Unlike many other systems, the Espion as well as measuring each electrode's impedance directly, also measures

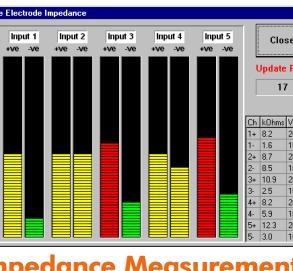
Displaying Data

Before a result is collected, it is advisable to check the current inputs to make sure they look acceptable. The software not only allows the inputs to be previewed before running, it also allows the test to be paused at anytime whilst still displaying incoming data for real-time feedback. During the test, the current recorded data is superimposed on the building average and the average may be in its turn superimposed on any previous averages already recorded. This gives instant feedback on the quality of the new result before it has finished.

Comparing Results

The software has very powerful overlay and separate facilities. It is possible to overlay one or more results for a particular step to check on reproducibility, to overlay results from different steps to examine trends and also to overlay results from different channels to compare left-right eye results for example. Not only overlaying of results but also automatic separation are built in to spatially separate them for better cross analysis and display. Individual results can be dragged around the screen just by pointing and dragging.

To make things even clearer, individual result colors can be changed and traces turned on and off.



Impedance Measurement

and displays all current electrode impedances simultaneously. This not only pinpoints the electrodes with bad skin contact, it also graphically displays the impedance balance between amplifier inputs allowing the impedance matching to be improved increasing the amplifier's CMRR. All this is achieved with an impedance current of less than 300nA.

Printing Data

The program can print the results of any step or all steps, and the user can select various options to control the actual printed output. These options include:

- Graphs
- The marker values in table form
- Step parameters
- Notes

The graphical output is based on the current display (WYSIWYG) and like most serious programs, a print preview feature is included to

Measuring Impedance

To produce the biggest signals with the least unwanted noise any