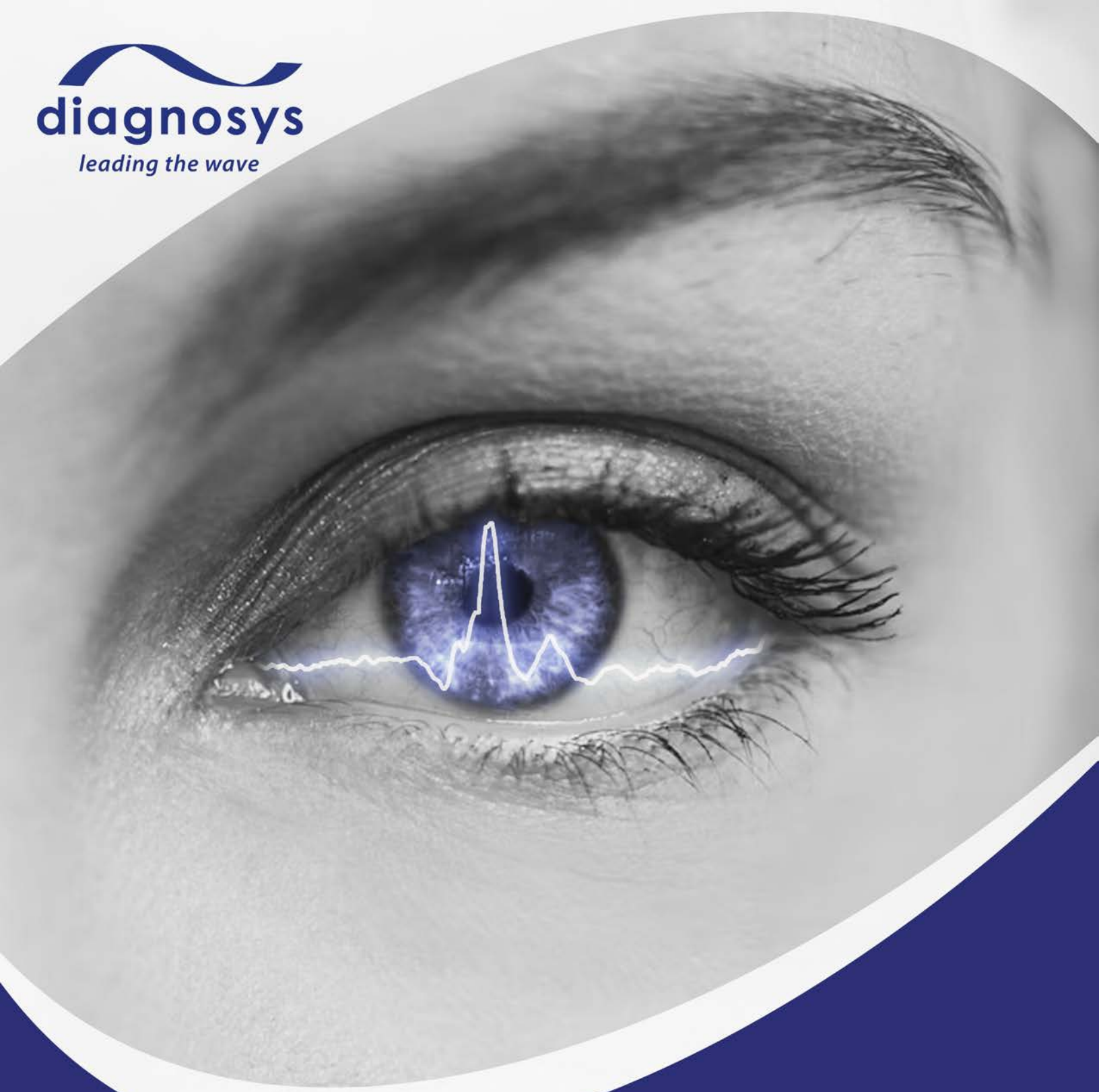
diagnosys

leading the wave



Clinical Systems

Objective Visual Function Testing

A Complete Suite of Visual Function Testing

Electroretinography (ERG)

Electroretinograms (ERGs) are recorded using corneal or skin electrodes to characterize dysfunction based on the size, shape, and speed of the retina's response

Full Field Electroretinogram (ffERG)

Evaluate rod and cone pathways

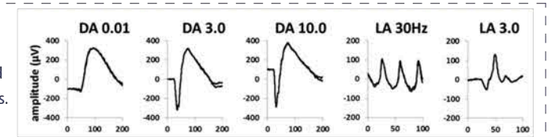
Inherited Retinal Diseases, Diabetic retinopathy

Pattern Electroretinogram (pERG)

Focal stimulation of macular cones and RGCs

Early Glaucoma detection, Macular Dystrophy

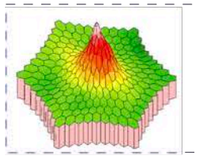
Normal full-field ERG
Dark and light adapted ERG steps illustrate rod and cone responses to flash stimuli of varying intensities.



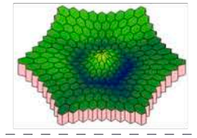
Multifocal Electroretinogram (mfERG)

Topographical map of macular function

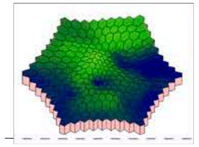
Macular Degeneration, Plaquenil Toxicity, Diabetic Retinopathy



Normal mfERG
Strong central peak with gradually sloping parafoveal response



Plaquenil Toxicity
Central peak preserved with significant loss of parafoveal function



Macular Degeneration
Severe central peak loss with residual parafoveal function

Visually Evoked Potentials (VEP)

VEPs are performed with electrodes on the scalp above the visual cortex. Results can reveal delays or misrouting of the visual

Visually Evoked Potentials (VEP)

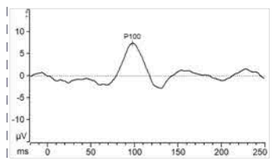
Detect disturbances in the visual pathway

Optic Neuropathy, Albinism, CVI

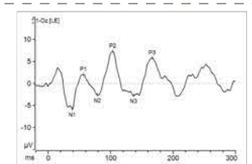
Sweep VEP (sVEP) Visual Acuity Assessment

Estimate visual acuity (VA) using pattern VEP methods

Functional Vision Loss, Unexplained Vision Loss, CVI



Normal pattern VEP
A robust positive peak at ~100 milliseconds (P100)



Normal flash VEP
A series of negative and positive waves useful in testing patients unable to perform a patten VEP.

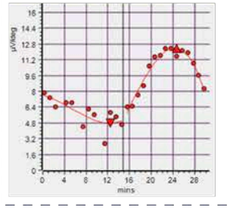
Electro-oculogram (EOG)

EOGs measure the standing potential between the cornea and RPE.

Electro-oculogram (EOG)

Retinal pigmented epithelium (RPE)

Bestophinopathy, AZOOR, AVMD



Normal EOG
A ratio of 2.0 between the RPE potential in the light as compared to in the dark

Psychophysical Tests

Psychophysical tests require patients to respond to visual stimuli with button boxes to assess light sensitivity.

Full-field Sensitivity Threshold (FST)

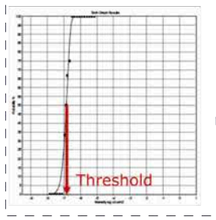
Quantify visual changes in low vision patients

Low Vision, IRD, Clinical Trials

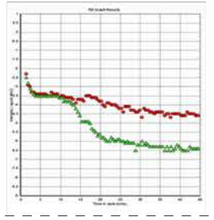
Dark Adaptometry (DA)

Measure the time it takes to dark adapt

Macular Degeneration



High Quality FST
A light sensitivity threshold is deteremined when the patient reliably responds to a light stimulus



Dark Adaptometry Curve
Measures the time it takes to adapt from bright light to darkness

Diagnosys Systems

Diagnosys systems offer globally trusted, versatile diagnostic solutions with five plug-and-play stimulators and optional add-on modules.

Tabletop **E3 Console**

The **E3 Console** is a tabletop system that is the most widely used worldwide.

This system requires a table that is not included

Why Choose E3?

- Compact design for small spaces
- Portability option with travel case
- Cost-effective, globally trusted

Cart-based **Profile**

The **Profile** system cart can roll into any operating room, or be locked in place.

Why Choose Profile?

- Suitable for operating room testing
- Self-contained entirely on a cart
- Spatially flexible, movable on wheels

Diagnosys systems come in tabletop and cart-based variations.

Both systems can interface with any stimulator or add-on module.

An example of a desktop system with 4 stimulators: the ColorDome, ColorFlash, Envoy, and LCD Monitor provide a complete testing suite

Two cart system examples, one LCD Monitor and one ColorDome on an operating room (OR) cart for testing supine or seated patients

Flash Stimulators

ColorDome

Mounted, binocular ganzfeld

- Infrared camera for patient monitoring in dark room
- Trillion-to-one luminance range that spans the entire range of human light perception

ColorFlash

Handheld, binocular, designed for pediatrics

- Testing can be done from a distance
- Attention-getting light and sound effects for children

ColorBurst

Handheld, monocular ganzfeld

- Well-suited for infants held in arms
- Ideal for Flash VEP

	ColorDome	ColorFlash	ColorBurst
Full-field ERG	●	●	●
PhNR	●	●	●
Flash VEP	●	●	●
Extended ISCEV	●	●	●
EOG	●	-	-
FST	● *	●	-
DA	● *	-	-
Pupillometry	● *	-	-

** Add-on module, not included with stimulator purchase*

Pattern Stimulators

LCD Monitor

Binocular LCD Monitor

- Flash artifact free with LI upgrade
- Fixation camera to monitor patient gaze

Envoy

Monocular, handheld OLED Monitor

- Artifact-free testing for easy PERG
- Can be used for bedside pattern testing

	LCD Monitor	Envoy
Multifocal ERG	●	-
Pattern ERG	● †	●
Pattern VEP	●	●
Sweep VEP (Visual Acuity)	● *,†	-

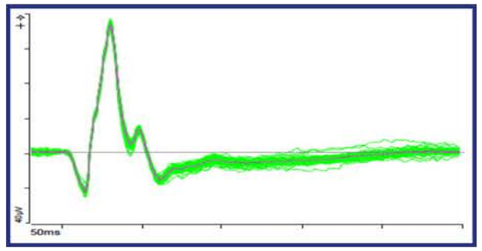
*† Requires LI-upgrade * Add-on module, not included with stimulator purchase*

Reliable, Precise, and Accurate

Our amplifiers detect the tiniest signals where other systems fail, enabling us to record ERGs on patients who would otherwise be presumed to have extinguished signals.

Ultra-Sensitive Amplifier

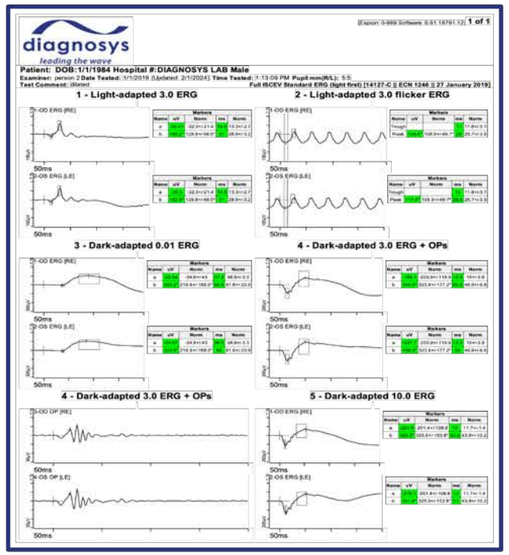
A fully differential, high-resolution 1 nanoVolt (nV), 32-bit amplifier with a 5 volt range and common mode rejection



Unmatched repeatability

Here are 44 overlaid PhNR responses recorded from the same person, across multiple Diagnosys systems in 8 different test sessions

Easily Interpretable Reports



Tests & Reference Data

- Systems include ISCEV standard protocols
- Normative reference data is available
- Easily edit and create custom protocols

Output Test Results

- Concise reports to simplify interpretation
- Customizable report layouts
- DICOM compatible outputs

Our ultra-sensitive amplifiers offer unmatched test repeatability

Our preferred corneal electrode is the **DTL Plus Electrode**; however, our systems work with any non-propiretary electrodes.

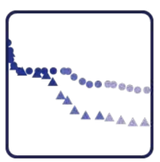
Fine conductive threads

- Well-tolerated
- Direct corneal contact
- Minimal risk of abrasion or infection

Customizable Espion Software

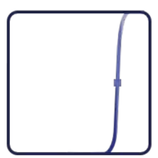
- ISCEV standard protocols are included; custom protocols can be created easily
- Software is pre-loaded with all systems; software updates are always free
- All systems are sold with all-in-one computers
- Encryption and audit trails ensure data security

Add-on Modules for expanded testing capabilities



Dark Adaptometry

An early biomarker of AMD, and an ideal replacement for the Goldmann Weekers Dark Aadptometer

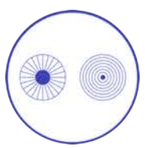


Diagnosys*FST*

Quantify light perception in patients with very low vision once the ERG goes flat and as a clinical trial endpoint for interventional therapies

iMask

Restrict visual field size by creating a partial-field stimulus for any ColorDome test



Pupillometry

Measure the pupillary light reflex by recording changes in pupil diameter and area

Objective Visual Acuity (VA)

Quantify the estimated VA with established Sweep VEP methods for fixating and non-fixating patients and children

LI-LCD Monitor

Upgrade the LCD monitor to have isoluminant pattern reversal stimulation required for PERG and VA testing

The industry leader.
Decades of experience, thousands of installations.

- *Most experienced customer support team in the industry*
- *Hundreds of peer–reviewed papers published using our systems*
- *Extensive world–wide network of leading experts operating Diagnosys systems*

Pediatric Testing

Diagnosys Exclusive
Abridged Pediatric Protocol

- No formal dark adaptation
- No anesthesia
- Skin electrodes

Clinical Trials

Consultation Services

- Pre-study consultation
- Site setup and training
- Data Services

diagnosys

www.diagnosysllc.com

Ordering information

D310: Profile Cart-based System

D315: E3 Tabletop System

All systems are configured with selected stimulators and modules.

Please contact us if you would like more information on Diagnosys products.

US: Diagnosys LLC; 55 Technology Drive, Suite 100, Lowell, MA 01851; 978-458-1600; sales@diagnosysllc.com
EU: Diagnosys Vision Ltd; Office 117, DOC Building, Balheary Road, Swords, Dublin, K67 E5A0, Ireland; +44 (0) 1223 520699; mail@diagnosysvision.com
UK: Diagnosys UK Ltd; 5 Trust Court, Chivers Way, Vision Park Histon, Cambridge, CB24 9PW, UK; +44 (0) 1223 520699; mail@diagnosysuk.co.uk

Doc #: 16980 **Rev**: A **ECN #**: 2120 **Date**: 17 Jan 2024

CE 0413