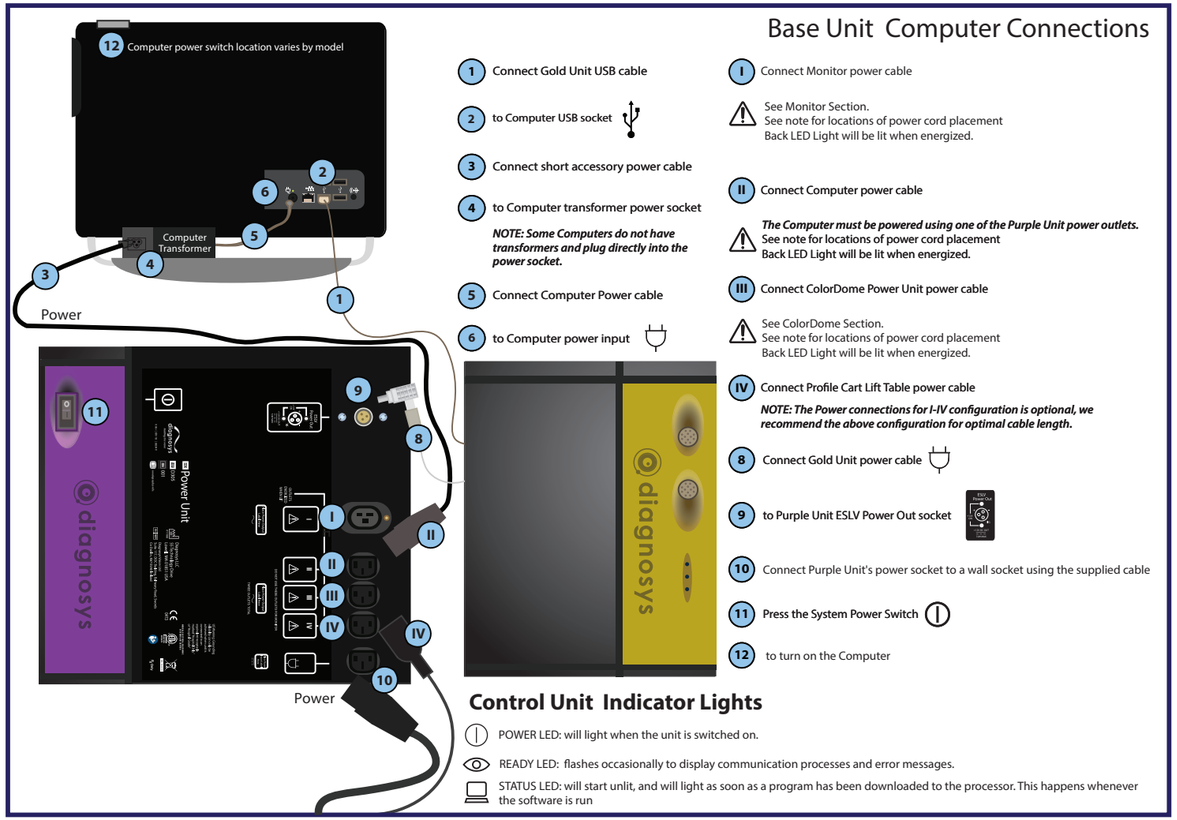
Base Unit Computer Connections



1. Connect Gold Unit USB cable
2. to Computer USB socket
3. Connect short accessory power cable
4. to Computer transformer power socket

NOTE: Some Computers do not have transformers and plug directly into the power socket.

5. Connect Computer Power cable
6. to Computer power input

I. Connect Monitor power cable

⚠ See Monitor Section.
See note for locations of power cord placement
Back LED Light will be lit when energized.

II. Connect Computer power cable

⚠ ***The Computer must be powered using one of the Purple Unit power outlets.***
See note for locations of power cord placement
Back LED Light will be lit when energized.

III. Connect ColorDome Power Unit power cable

⚠ See ColorDome Section.
See note for locations of power cord placement
Back LED Light will be lit when energized.

IV. Connect Profile Cart Lift Table power cable

NOTE: The Power connections for I-IV configuration is optional, we recommend the above configuration for optimal cable length.

8. Connect Gold Unit power cable
9. to Purple Unit ESLV Power Out socket
10. Connect Purple Unit's power socket to a wall socket using the supplied cable
11. Press the System Power Switch
12. to turn on the Computer

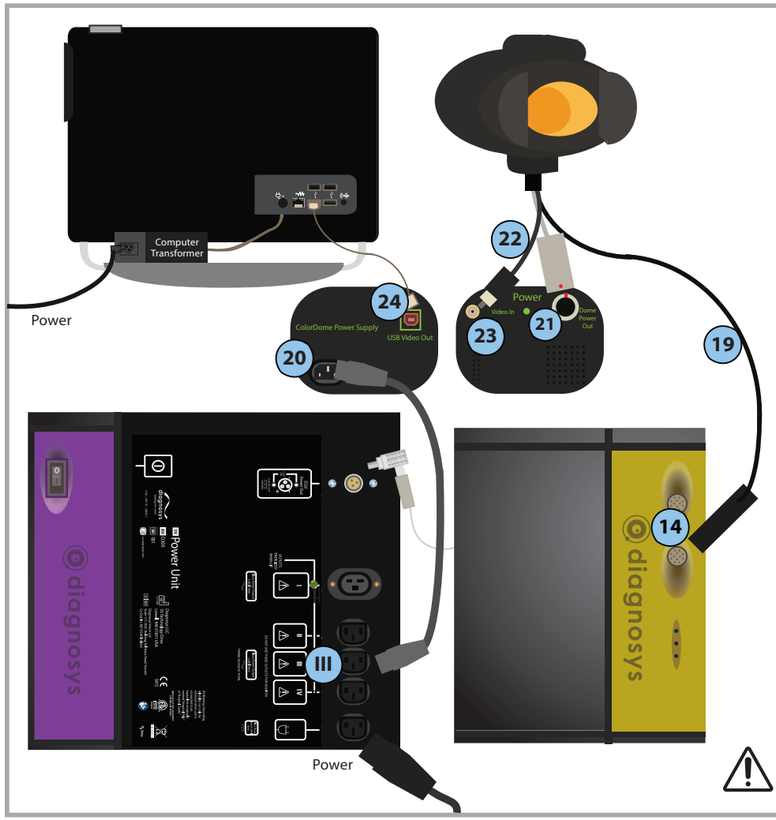
Control Unit Indicator Lights

POWER LED: will light when the unit is switched on.

READY LED: flashes occasionally to display communication processes and error messages.

STATUS LED: will start unlit, and will light as soon as a program has been downloaded to the processor. This happens whenever the software is run

ColorDome



19. Insert the ColorDome stimulator connector
14. into the stimulator Connector on the Gold Unit.
20. Connect ColorDome power supply
III. to Base Unit Power socket using the supplied accessory cables
21. Connect ColorDome silver colored Power connector to the ColorDome Power Supply Power Out socket
22. Connect ColorDome Video cable (using the male to male connector)
23. to the ColorDome Power Supply Video in socket (Unless the system is supplied with a separate video converter. In that case, the ColorDome video cable is connected to the yellow socket on the video converter is connected to the Computer using the USB cable.)
24. Connect ColorDome Power Supply Video Out socket to a Computer USB socket using USB cable (Unless the system is supplied with a separate video converter. In that case, leave this port unused.)

⚠ **Caution: Before placing the ColorDome head on its stand or after removing it from the stand, please ensure that the mount plate is sufficiently tight by turning the mount screw clockwise and using the locking screw.**

Gold Unit to Amplifier

13. Connect the amplifier into the Patient socket

Type BF applied part complying with IEC 60601-1.

ColorBurst

14. Insert the stimulator Connector on the Gold Unit.
Allow several seconds for the software to detect the connected stimulator.

You may plug and unplug the stimulator with the power-on as required.

Allow several seconds for the software to detect the connected stimulator.

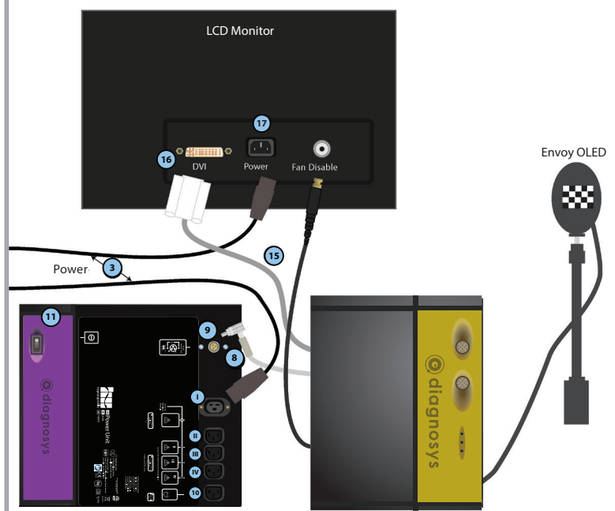
ColorFlash

14. Insert the stimulator Connector on the Gold Unit.
Allow several seconds for the software to detect the connected stimulator.

You may plug and unplug the stimulator with the power-on as required.

Allow several seconds for the software to detect the connected stimulator.

LCD Monitor



15. Insert the pattern stimulator Monitor Connector
16. into the DVI socket at the base of the monitor
3. Connect Monitor Power supply
17. to the Monitor Power port
I. and Purple Unit Power socket using the supplied accessory power cable

Envoy OLED Monitor

Insert the stimulator connector into the DVI port of the Base Unit (See above).

D310 Profile Instructions For Use

REF D310

MD Profile

www.diagnosysllc.com/IFU

diagnosys
leading the wave

MD ColorDome
REF D125

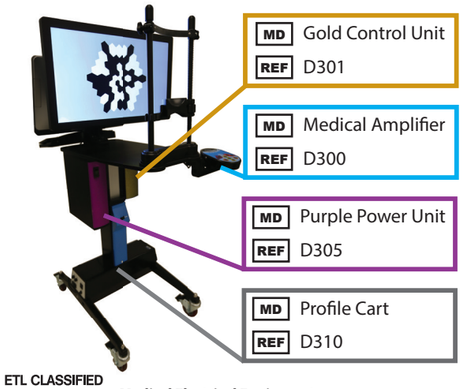
MD LCD Monitor
REF D358

MD ColorFlash
REF D382

MD ColorBurst
REF D213

MD Envoy
REF D352

MD Computer
REF D336



MD Gold Control Unit
REF D301

MD Medical Amplifier
REF D300

MD Purple Power Unit
REF D305

MD Profile Cart
REF D310

ETL CLASSIFIED

Medical Electrical Equipment
Conforms to AAMI ES60601-1
Certified to CSA STD C22.2#60601-1
Conforms to IEC 60601-1-6
Conforms to IEC 60601-2-26
Conforms to IEC 60601-2-40

Intertek 5002629

CE marking indicates product conformance with the applicable European Union Directives.

0413

WEE/EE marking indicates product conformance to the Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

WEE/ EE 1597TW Proof of Registration reference #: WEE/EE1597TW

Equipment Classifications:

The Profile is classified under the European Commission Medical Device Directive as a Class IIa Medical Device.

The Profile System amplifiers are classified as type BF applied parts, as defined by the IEC standards listed below.

Standards Applied:

The Profile meets the following standards:

- ISO 60601-1
- ISO 60601-1-1
- ISO 60601-1-2
- ANSI Z80.36
- ISO 60601-2-40
- ISO 60601-2-26
- ISO 62366-1
- ISO 62304
- ISO 14971
- ISO 10993-1
- ISO 15004-2
- ISO 15223-1
- ISO 20417

Directives and Regulations Applied:

The Profile meets the following European directives and regulations:

- (EU) Council Directive 93/42/EEC
- (EU) 2017/745 of the European Parliament and of the Council of Medical Devices
- Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)

Intended Use:

The Profile system is an electro-diagnostic device used to generate photic signals and to display the images of waveforms from the electrical signals generated by the retina and the visual nervous system. It displays digitized images of waveforms for electroretinogram (ERG), visual evoked potential (VEP), and sensory electro-oculogram (EOG) signals, as well as sweep visual evoked potentials, electrically evoked response (EER), pupillometry testing in response to photic flashes, and psychophysical tests such as scotopic threshold sensitivity testing (FST) and dark adaptometry testing.

Intended Medical Indications:

Quantification of the electrophysiological response of the retina and visual nervous system.

Intended User Profile:

Rx Only Federal law in the USA and Canada restricts this device to sale by or on the order of a licensed medical practitioner.

Data Analyst: Ophthalmologists, Optometrists (or equivalent), or other medical doctor.

Operator: Ophthalmologists, Optometrists (or equivalent), other medical doctor, nurse, certified medical technician, non-certified assistant.

Light Hazard - For ColorDome Use Only:

Required CAUTION for EU: The light emitted from this instrument is potenitally hazrdous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 34 miutes.

Intended Patient Population:

Patients with ophthalmic conditions.

Age: The patient population includes ranges from pediatric to elderly.

Weight: Any weight patient may be tested.

General Health: Test subjects are usually in good general health, because the test involves diseases that progress slowly and do not threaten life.

Condition: Test subjects are conscious, ambulatory, and alert, and usually tested in a sitting position; with the exception of patients who may be sedated or anesthetized.

Intended Type of Tissue Interacted With:

Only the intact skin of the patient's head is contacted. During some testing the patient is intended to rest their chin and forehead on chin and forehead rest.

Intended Use Environment:

The system is designed to be operated in a professional healthcare environment (emergency rooms, patient rooms, intensive care, surgery rooms except near HF SURGICAL EQUIPMENT, outside the RF shielded room of an ME SYSTEM for magnetic resonance imaging).

Operating Site Requirements:

We recommend the system to be positioned on a flat surface, in a location where the technician running the test can easily read the computer display and reach both the computer and the patient.

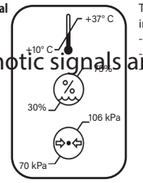
Location near other equipment may affect EMC performance. Equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

You will also need all other facilities normally required for visual electro-physiological testing, such as access to running water, and the ability to control room lighting.

Intended Conditions of Use:

Physical Environment: Many kinds of ophthalmic electrophysiology tests must be done in total darkness or controlled-light conditions. The standard full suite of ISCEV standard full-field testing requires about an hour, during which the patient must be comfortably seated. AC power must be available for the system. These three conditions require an indoor, climate-controlled professional office or hospital setting.

Environmental Conditions



The permissible environmental conditions for which a hazard is not induced include:
- Ambient temperature range of +10° C to +37° C
- Relative humidity range of 30% to 75%
- Atmospheric pressure range of 70 kPa to 106kPa

Exclusions:

The Profile is a sensitive recording device, and strong electromagnetic fields such as those produced by RF equipment, or dimmer switches may cause interference in the recorded results; location near other equipment may affect device performance.

Not suitable in rooms containing HF SURGICAL EQUIPMENT, such as the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high. Not suitable for use in the presence of a flammable anesthetic mixture with air or nitrous oxide. Not to be used in conjunction with defibrillators or any other electrical medical device.

Frequency of Use Testing is infrequent; a particular patient may be tested only once in their life. Some patients may be tested annually or bi-annually.

Clinical Benefit:

For a comprehensive listing of all clinical benefits, see www.iscev.org

Residual Risks:

Corneal Abrasions: The risk of corneal abrasions are very low.

Induction of seizures: The risk of seizures is very low; patients with severe photophobia or seizure disorders (such as epilepsy) may be susceptible.

Benefit Risk Assessment:

Evaluation and quantification of the benefits of Diagnosys LLC's products and equipment to patients are compared to the potential harm caused to those patients, which are analyzed and assessed to determine the benefit/risk ratio. Determination of the benefit/risk ratio considers the duration of effects, an evaluation of the clinical risks of devices, the severity, number, and rates of harmful events, the probability of a harmful event, the duration of harmful event, the risks posed from false-positive or false-negative results and the evaluation of acceptability of the benefit/risk profile.

The clinical benefits of Diagnosys LLC's products and equipment include the positive impact of the devices on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcomes, including outcomes related to diagnosis, or a positive impact on patient management or public health.

These outcomes are measured in terms of weight of benefit and probability of occurrence, using a scale of High, Medium, and Low.

Benefit Risk Assessment (cont.):

Clinical Benefit	Individual	Patient Management	Public Health	Weight
Detection and Assessment of Eye Conditions and Diseases	Yes	No	No	Medium
Detection of the Disease or Carrier States	Yes	No	No	Medium
Perioperative Monitoring	Yes	Yes	No	Medium
Quantitative Assessment	Yes	Yes	No	Medium
Determining Efficacy and/or Toxicity of a Drug or Elemental Compound	Yes	Yes	Yes	High
Used to Diagnose Certain Inflammatory Ocular Diseases	Yes	No	No	Low
Used to Protect Patient Health	Yes	No	No	Low
Used to Investigate Function of Visual Pathways	Yes	Yes	No	Medium

Clinical Risk means the negative impact of Diagnosys LLC's devices on the health of an individual, patient management, or public health.

These outcomes are measured in terms of weight of benefit and probability of occurrence, using a scale of High, Medium, and Low.

Clinical Risk	Individual	Patient Management	Public Health	Weight
Corneal Abrasion	Yes	No	No	Low
Induction of Seizures	Yes	No	No	Low

Based on the above Benefit/Risk ratio, the final determination is that the benefits of Diagnosys LLC's products and equipment significantly outweigh the rare and minimal potential risks.

When to Contact Diagnosys:

For any questions regarding user or patient safety, failure of any controls, or damaged equipment contact your local dealer or Diagnosys LLC immediately.

Contraindications to Ophthalmic Electrophysiology:

1. Contraindications for pupil dilation-Narrow anterior chamber angles or known or suspected predisposition to angle closure glaucoma
2. Active corneal or conjunctival disease (e.g. pink eye or conjunctivitis) or infections
3. Ruptured globe
4. Immediately following cataract surgery or post LASIK refractive surgery or trabeculectomy or any surgical/laser intervention
5. Suspected penetrating ocular injury
6. Ocular prosthesis
7. Allergies to topical anesthetic or dilating drops
8. Patients under miotic therapy for angle closure glaucoma
9. When pupil reactions need to be preserved such as when same day referral is required in neurological examination
10. Patients with severe photophobia or seizure disorders (such as epilepsy)

Side Effects:

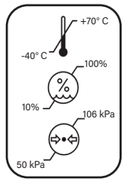
No known side effects to ophthalmic electrophysiology.

Damaged Packaging:

If your order arrives damaged, or exposed to environmental conditions outside of those specified, contact your local dealer or Diagnosys for instructions.

Keep Dry Fragile Keep Out Of Sunlight

Transportation & Storage Requirements:



The permissible environmental conditions for transport and storage of equipment should fall within an ambient temperature range of -40° C to + 70° C, a relative humidity range of 10% to 100%, including condensation, and an atmospheric pressure range of 50 kPa to 106 kPa.

Safe Disposal:

WEE/ EE 1597TW

The expected service life of this product is 10 years. After which, or before if it is decided that the device is no longer needed, please contact your local dealer or Diagnosys.

If you wish to dispose of the device manually, please follow the requirements within the country that the equipment resides.

Lifting Instructions & Equipment Setup:

When the system arrives, do not attempt to assemble the equipment. A Diagnosys technician or representative will be present, either on-site or remotely, for setup.

Warning: Parts of this unit weigh as much as 25lbs (12kg). Think before lifting/ handling equipment. Adopt a stable posture to maintain balance evenly distributed between both legs. Get a good hold on the parcel and keep it close to the body when carrying. Maintain straight posture and refrain from twisting and bending while carrying the load.

Warning: Do not connect any electrical equipment to the Profile that was not supplied with the system.

Maintenance:

Warning - electrical shock hazard: No user maintenance is possible. Inspect all system equipment each time you use it for any external sign of wear or damage (e.g. frayed cables). Maintenance may only be carried out by personnel authorized to do so by the manufacturer, if it is required.

External Connections:

See the table below for a list of all cables and maximum lengths of cables that may affect emissions and/or immunity.

Use of cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Cables

Part Number:	Description:	Length:
10598	Medical Line Cord	10 ft
10115	Power Cable	8 ft
13849	USB Cable	6 ft
13922	Computer Power Cable	3 ft
14071	Desktop Power Supply Cable	3 ft
15131	Laptop Power Cable	6 ft
13677	DVI/VGA Cable	6 ft
12631	Amplifier Cable	6 ft
13217	DVI to VGA Cable	6 ft

Service:

For servicing, contact your local dealer or Diagnosys.

Alterations and repairs may only be carried out by personnel authorized to do so by the manufacturer. A return authorization number is issued if the system must be returned for repair. Pack the System in its original packaging. If the original packaging is no longer available, contact Diagnosys or a representative.

Calibration:

All stimulators of the system should be calibrated with a frequency of once per year. An automatic 'stimulator calibration warning' when due may be enabled on the system. For more information about calibrating your equipment, contact Diagnosys.

Cleaning:

Warning - electrical shock hazard: Always disconnect the power from the Profile and any powered equipment before cleaning it. The exterior of the system, screen, patient Amplifier, and stimulators should be cleaned occasionally using a slightly damp soft cloth. You will need to clean off the fingermarks left by touching the screen after every few tests. Chin and forehead rests should be cleaned with alcohol wipes in between each patient use.

NOTE: The system is not designed to be sterilized. For components not manufactured by Diagnosys, please refer to the instruction book supplied by the original manufacturer.

Training:

Diagnosys provides Customer Support Representatives to deliver remote or on-site hands-on training to the intended operators to ensure proficient operation of the equipment; contact your local dealer or Diagnosys.

Technical Support:

For technical support, contact your local dealer or Diagnosys.

Software Support & Updates:

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

Software License:

The Profile software is licensed, not sold.
You may install and use one copy of the Profile software on a single Profile . You may not install it on any additional Profiles or computers. You may make one copy of the Profile software solely for backup purposes.
If the Profile software is an upgrade from a previous version, the previous license is terminated. Software licenses for use on additional computers or networks may be obtained from Diagnosys LLC.

Disclaimer:

This product will perform reliably only when operated and maintained in accordance with the instructions contained in this IFU, accompanying documents and labels, which must be read very carefully before using the equipment for the first time.

Information in this IFU is subject to change without notice and does not represent a commitment on the part of Diagnosys LLC nor can it be held responsible for any errors or omissions herein.

Diagnosys LLC specifically disclaims any warranties expressed or implied about the fitness of this system for any particular purpose and in no event shall be liable for any loss of profit or other commercial damage including, but not limited to special, incidental, consequential or other damages.

Health care providers have responsibility for the protection of patient health information (PHI), both hard copy and electronic. To protect patient confidentiality of your exported electronic data, the use of encryption is recommended and is the responsibility of the user.

Warranty:

See separate warranty document for the Profile.
Diagnosys supplies certain non Diagnosys products on an "as is" basis. Non Diagnosys manufacturers or suppliers may provide their own warranty.

Trademarks:

All trademarks acknowledged. See separate warranty document. Diagnosys supplies certain non Diagnosys products on an "as is" basis. Non Diagnosys manufacturers or distributors may provide their own warranty.

Copyright:

sed to generate photic signals and to display the images of waveforms from the electrical signals generated by the retina and the visual nervous system. It displays digitized images of wa

Warnings:

Flammable Anesthetic:

The Profile is not suitable for use in the presence of a flammable anesthetic mixture with air or nitrous oxide.

Ingress of Water:

The Profile is classified as ordinary equipment with respect to the degree of protection against harmful ingress of water, as defined by the IEC standards listed.

Operating Temperature:

Room temperature should not exceed 37 degrees centigrade.

Mode of Operation:

The Profile is designed for continuous operation, as defined by the IEC standards listed.

Restrictions on Sale:

Federal law in the USA and Canada restricts this device to sale by or on the order of a licensed medical practitioner.

Fuses:

The Profile contains internal fuses which are not accessible to the user.

Leakage Currents:

The Profile meets the requirements for leakage currents defined in the IEC standards listed above, provided that it is connected according to the instructions contained in this manual.

In order to avoid a hazard due to summation of leakage currents, the Profile must not be used in conjunction with any other equipment.

Operator must not touch any grounded or low voltage connector or device while touching the patient at the same time.

Defibrillators:

The Profile must not be used in conjunction with defibrillators or any other electrical medical device

RF Communications:

Portable RF communications equipment (including peripherals such as antenna cables and external antennae) should be used no closer than 30 cm (12 inches) to any part of the Profile, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Compatibility:

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The Profile is a sensitive recording device that has been tested for radiated RF immunity only at selected frequencies. Use nearby of emitters at other frequencies could result in improper operation
Portable and mobile RF communications equipment can affect medical electrical equipment.

Detailed EMC information may be found in the Guidance and Manufacturer's Declaration, regarding Electromagnetic Emissions and Immunity, and is available to download at: www.diagnosysllc.com/IFU

Supply Mains/Protected Earth:

To ensure patient safety and avoid the risk of electric shock, the equipment must only be connected to a supply main with protected earth.

Connecting Outside Devices:

The end user is instructed to NOT connect any outside devices to ANY of the available USB ports and other SIP\SOP style connectors around the product.

Equipment Positioning

Be sure to position the equipment to ensure the power supply (disconnecting device) is not obstructed in any way. For such parts, the voltage to earth or to other accessible parts shall not exceed 43 V peak AC or 60 V DC in normal condition or in single fault condition. The DC limit of 60 V applies to DC with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 43 V peak limit applies. The energy shall not exceed 240 VA for longer than 60 s or the stored energy available shall not exceed 20 J at a potential up to 2 V.

Location near other equipment may affect EMC performance. Equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

End User Involvement:

Do not modify this equipment without the authorization of the manufacturer.

Light Hazard - For ColorDome Use Only:

Required CAUTION for United States:
The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater is the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the recommended maximum exposure (RME) of 2.2 J/cm2, unless additional action is taken by the user to minimize exposure, after 47.1 minutes. The risk of retinal injury at an exposure of 2.2 J/cm2 is not high, but because some patients may be more susceptible than others, caution is advised if this radiant exposure value is exceeded. However, because of a significant risk of injury at exposures exceeding 10 J/cm2, the user should avoid exposures longer than 214 minutes.

Required warning for US and Denmark:

Proper grounding can only be guaranteed using hospital grade line plug (NEMA 5-15 HG).
The end user is instructed NOT to connect any outside devices to ANY of the available USB ports and other SIP/SOP style connectors around the product.

Connecting the System:

Use only the instruments and cables supplied by the manufacturer. Connect only according to the instructions contained in this IFU.

Cables, Transducers and Accessories:

Warning - electrical shock hazard: Some of the external signal connections have built in electrical isolation. Interfaces that do not have built in isolation must either be isolated independently, powered wholly from the console or not be in the vicinity of the patient. The patient must NOT be able to touch any non-isolated equipment that is physically connected to the Profile.

See the table on page 2 for a list of all cables and maximum lengths of cables, transducers and other accessories that may affect emissions and/or immunity.

Emergency Shut Down:

For emergency shutdown, pull the power cable from the wall.

Trapping Zone Compliance:

The trapping zone complies with ISO 13852:1996. The distance is 1 inch or 25.4 mm. Please refer to ISO 60601-1 IEC 2005, section 9.2.2.2. This section states: "A trapping zone is considered not to present a mechanical hazard if the gaps of the trapping zone comply with the dimensions specified in Table 20". Please also see section 9.2.2.5, "a" and "b". Due to these circumstances, we are not required to put a warning or Emergency Stop button on the stand.

Overtravel:

The risk of overtravel has been mitigated, or reduced to an acceptable level, due to the absence of a trapping zone as well as compliance with the following sections in ISO 60601-1 IEC 2020; 9.2.2.4.4, 9.2.2.5, 9.2.2.6, 9.2.3.2, 9.2.3.1, and 9.2.3.2. As a result, no emergency stops are required for our equipment

Operations and/or Instructions for Use:

If the supply mains to the equipment is interrupted, no change of the operator settings shall occur, including the mode of operation, or all stored patient data shall remain.

Extent of Mobility:

Because of the requirement that some testing be performed in a completely dark room, the equipment is generally located in a fixed location.

Essential Performance:

For the purposes of safety risk analysis, ophthalmic electrophysiology equipment has no Essential Performance. That is, no type of malfunction would produce a diagnostic indication whose presence or absence would result in physical harm, including harm resulting from inappropriate treatment, or lack of treatment. Since there are no surgical or treatment decisions made solely on data obtained by the instrument, it was determined that the instrument has no "essential performance" as defined in IEC 60601-1 standard.

False Negative:

If some response were expected of the patient, a "no response" finding would not be believable, and the instrument would be troubleshot and the test repeated. If "no response" was an expected result, a false confirmation would do no harm, since there are no surgical or treatment decisions made solely on data obtained by the instrument.

False Positive:

A false positive failure would be that the instrument synthesizes a random waveform that looks like an ERG response. This risk is unlikely since all test results are automatically repeated, and the synthesis of an artificially normal looking ERG wave is so improbable it could not reasonably be expected to occur twice. A false positive response would not cause physical harm to a patient, because there are no surgical or treatment decisions made solely on data obtained by the instrument.

Essential Function in Particular Standards That Might Apply:

ISO 60601-2-40, "Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment" does not specify any Essential Functions.

ISO 60601-2-26 "Particular requirements for the Basic Safety and Essential Performance of Electroencephalographs" includes Essential Functions relating to amplifier performance.

Amplifier performance is an Essential Function in an electroencephalograph. Though electrically the two instruments are similar, the Profile amplifier has a very different and much less critical diagnostic function. Despite this, the instrument has been tested to and has passed all criteria for 60601-2-26.

Essential Function not Related to Safety:

Though an ophthalmic electrophysiology device has no Essential Function that bears on patient safety, it does have expected performance characteristics including:

Photic Stimulators – Flash:

- Full-field stimulators will stimulate the entire visual field with uniform (±15%) illumination
- Background illumination will be displayed in photopic and scotopic cd/m2 and will be within ±15% of the stated value.
- Flash illumination will be displayed in photopic and scotopic c*sec/m2 and will be within ±15% of the stated value.
- Flicker rate will be in displayed in Hz and will be within ±1% of the stated value.
- LED flash triggers will occur at the middle of the flash

ColorDome Stimulator (D125):
The ColorDome is a flash stimulator component compatible with D310 & D315 that enables the ERG, VEP, EOG, FST, DA, Pupillometry tests.

ColorBurst Stimulator (D213):
The ColorBurst is a flash stimulator component compatible with D310 & D315 that enables the ERG and VEP tests.

ColorFlash Stimulator (D382):
The ColorFlash is a flash stimulator component compatible with D310 & D315 that enables the ERG, VEP, FST, DA tests.

Photic Stimulators – Pattern:

- Pattern stimulators will stimulate at least 30 degrees of the visual field.
- Pattern illumination will be displayed in photopic and scotopic cd/m2 and will be within ±15% of the stated value.
- Flicker rate will be in displayed in Hz, or in reversals per second, and will be within ±1% of the stated value.
- Angular subtense of the stimulus will be corrected for distance from the patient, and will be accurate to within ±20 minutes of the stated value.
- Alternating patterns presented on an LCD screen will produce a luminance artefact less than 10% the magnitude of the average luminance.
- Alternating patterns presented on a CRT screen will produce no luminance artefact (inherent in design of CRT).
- Alternating patterns presented on an OLED screen will produce no luminance artefact (inherent in design of OLED).

LCD Stimulator (D359):
The LCD Monitor is a pattern stimulator component compatible with D310 & D315 that enables the ERG and VEP tests.

Envoy Stimulator (D352):
The Envoy Monitor is a pattern stimulator component compatible with D310 & D315 that enables the ERG and VEP tests.

Electrical Stimulators:

- Produces current no greater than 2.5A
- Wide range of current; output adjustable in increments of 5 µA between 0 and 2,500 mA
- Pulses available in monopolar positive or negative pulses, bipolar pulses, or tripolar pulses (bipolar pulses with 0 current intervals interpolated between positive and negative components)
- Duration of positive, negative, or 0-current components of each pulse separately configurable in increments of 250 microseconds

EER Stimulator and Amplifier (D366):
The EER is an electrical stimulator component compatible with D310 & D315 that enables the EER tests.

Medical Amplifiers:

Accuracy of signal reproduction:
Input signals in the range of ±0.5 mV, varying at a rate to 12 mV/s, shall be reproduced on the output with an error of ≤ ±20 % of the nominal value of the output or ±10 µV, whichever is greater.

Input dynamic range and differential offset voltage:
With a DC offset voltage in the range of ±300 mV and differential input signal voltages of ±0.5 mV that vary at rates up to 12 mV/s, when applied to any LEAD WIRE, the time-varying output signal amplitude shall not change by more than ±10 % over the specified range of D.C. offset.

Input noise:
The signal noise caused by the amplifier and PATIENT CABLE shall not exceed 6 µV peak-to-valley referred to the input.

Frequency response:
The amplifiers shall meet the requirement for a frequency response (bandwidth) of at least 0.5 Hz to 50 Hz when tested with sinusoidal input signals. The output at 0.5 Hz and 50 Hz shall be within 71 % to 110 % of the output obtained with a 5 Hz sine wave input signal.

Common mode rejection:
A 1 V RMS signal at mains frequency (50 Hz/60 Hz) with 200 pF source capacitance, connected between earth and all LEAD WIRES connected together shall not produce an output signal greater than 1mV over a 60 second period. In series with each ELECTRODE shall be a 51 kΩ resistor in parallel with a 47 nF capacitor.

Accompanying Documentation:

The Symbols Glossary (15905) contains detailed explanation of all symbols used in labeling and documentation provided by the manufacturer, per the appropriate ISO Standards.

IFUs for additional products can be downloaded at: www.diagnosysllc.com/IFU

User, Software and Troubleshooting guides are stored electronically and can be located at: www.diagnosysllc.com/IFU.

IFU translations are stored electronically and can be located at: www.diagnosysllc.com/IFU.

Brochures and additional marketing materials are available at: www.diagnosysllc.com

Required information from ISO 60601-1-2, Guidance and Manufacturer's Declaration, regarding Electromagnetic Emissions and Immunity (Doc 16566), is available to download at: www.diagnosysllc.com/IFU

Please note that electronic versions of the above documents come preloaded on your computer for easy reference.

Specifications:

Weight and Dimensions

Electric Stand Specification		Description
8.1.1	Size	530mm x 360mm (20.87" x 14.17")
8.1.2	Vertical Moving Range	640-860mm (25.20"- 33.86")
8.1.3	Maximum Loading Capacity	50kg (110.23 lbs.)
8.1.4	Voltages	250V or 125V
8.1.5	Amps	3A or 5A
8.1.6	Weight	23.8 kg (52.5 lbs.)
Tabletop Stand Specification		**Description**
8.2.1	Size	584.2 mm x 355.6 mm x 25.4 mm (23" x 14" x 1")
8.2.2	Weight	13.83kg (30.5 lbs.)
Amplifier Stand Specification		**Description**
8.4.1	Vertical Moving Range	889 mm – 1600.2 mm (35"-63")
8.4.2	Maximum Load Capacity	11.3 kg (25 lbs.)
8.4.3	Weight	4.5 kg (10 lbs.)
Articulating OR Arm Specification		**Description**
8.5.1	Extension limits	736.6 mm – 850.9mm (29" - 33.5")
8.5.2	Lift height	329.9 mm (12.99")
8.5.3	Loading capacity	2.3 kg -11.3 kg (5.1 lbs. – 24.9 lbs.)
8.5.4	Weight	2.3 kg (5 lbs.)
8.5.5	Tilt angle	75 degrees
8.5.6	Rotation Angle	360 degrees
Standing Chin Rest Specification		**Description**
8.6.1.1	Vertical Moving Range	203.2 mm – 317.5 mm (8"-12.5")
8.6.1.2	Maximum Load capacity	18.1 kg (40 lbs.)
8.6.1.3	Weight	2.7 kg (6 lbs.)
Sliding Chin Rest Specification		**Description**
8.6.2.1	Horizontal Moving Range	203.2 mm – 317.5 mm (8"-12.5")
8.6.2.2	Horizontal Moving Range	44.5 mm- 146.1 mm (1.75" – 5.75")
8.6.2.3	Maximum Load capacity	15.9 kg (35 lbs.)
8.6.2.4	Weight	4.5 kg (10 lbs.)

Base Unit Specification

Mechanical		Description
4.1.1	Dimensions	42*30*8 cm, 16.5*12*3 inches
4.1.2	Weight	12.2kg
4.1.3	Coating	Hardcoat Modified
4.1.4	LEDs	3 * green LEDs for status (can be turned off in software)
Output Connections		**Description**
4.2.1	Stimulator	1 * 13 way for ColorDome and ColorBurst
4.2.2	Headbox	1 * 18 way for 5 channel montage
4.2.3	Pattern generator	9-way male D-type for PSG stimulator only
4.2.4	Trigger out	Optically isolated BNC 0-5V (TTL) or 0-12V software selectable, Pulse mark, space periods software configurable. Should drive a Grass strobe directly
4.2.5	Trigger In	Optically isolated BNC TTL input, software selectable positive or negative edge trigger
4.2.6	USB	USB V2.0 full speed (12mb/s) connection to PC
4.2.7	Auxiliary power	5V, 0.5A fused output (Option)
Power Connections		**Description**
4.3.1	Input power	IEC either 110V-60Hz or 220/240V-50Hz input with integrated dual line on/off switch. Note input voltage is fixed at time of manufacture
4.3.2	Output power	4 * isolated 10A fused IEC power outputs for ColorDome, Printer, Monitor and PC. Max total output 1.3A (240V) 2.6A (110V)

Computer

PC Specification		Description
5.1.1	Processor	Pentium 4 or above
5.1.2	Hard Disc	250GB or bigger
5.1.3	RAM	4GB
5.1.4	Screen	1024*768 15" TFT with touch screen
5.1.5	Network	1 * 100mb/s RJ45 connections
5.1.6	USB	2+ * USB V2.0 high speed ports
5.1.12	Operating System	Windows 7, Windows 10, Windows 11, Windows Professional Edition

Specifications:

Acquisition

Acquisition System Specification		Description
6.1.1.1	Control	DSP CPU real-time
6.1.1.2	Channels	5 differential or single ended
6.1.1.3	Sample rate	4kHz internal, decimated down to 100, 1000, 1202, 1303, 2000, 3606, and 4000 Hz
6.1.1.4	Impedance Check	Integrated individual electrode check with nominal current of 100nA at 50/60Hz
6.1.1.5	Calibration	Internal automatic
6.1.1.6	Resolution	32-bit ADC with no DC offset required
6.1.1.7	Max record time	Maximum recording time should be no less than 30 seconds
Amplifiers Specification		**Description**
6.2.1.1	Anti-alias filter	Built in
6.2.1.2	Gain	PGA built in
6.2.1.3	CMRR	Greater than 110dB at 50/60Hz (1k source imbalance)
6.2.1.4	Noise	Less than 1uV RMS
6.2.1.5	Input Impedance	Greater than 106 ohms
6.2.1.6	Filtering	Digital, in software. High-pass: 0-1999 Low-pass: 0-1999. A 50/60Hz subtract option is also available
6.2.1.7	Input range	+/- 2.5V
6.2.1.8	Input balance	Better than 1%
6.2.1.9	Isolation	Greater than 4000V
6.2.1.10	Input Type	DC (not AC therefore no saturating)

LCD

VEP Patterns Specification		Description
7.2.2.1	Luminance	Of the order 800cd/m2 (standard 800cd/m2)
7.2.2.2	Frame rate	75Hz
7.2.2.3	Sample rate	16 samples / frame. Locked to the frame
7.2.2.4	Viewing distance	Settable
7.2.2.5	Resolution	1000*600, or 800*600, or 1366*768
7.2.2.6	Color	White, red, blue, green

Envoy

VEP Patterns Specification		Description
7.2.4.1.1	Spatial resolution	Minimum 800*600 (depends on hardware)
7.2.4.1.2	Frame rate	Minimum 60Hz, (depends on hardware)
7.2.4.1.3	Luminance resolution	6-bit DACs minimum (depends on hardware) Min 100cd/m2
7.2.4.1.4	Contrast	0-100% Either 0.5% steps, or 0.003%

ColorDome

ERG Flash Specification		Description
7.1.1.3.1.1	Number of stimulators	Supports 1 ColorDome
7.1.1.3.1.2	Output mode	Single/double/multiple flash, On/Off, sine/ramp/exponential waveform, user definable
7.1.1.3.1.3	Flash frequency	0.001Hz to 500Hz (depends on hardware) 0.001Hz resolution
7.1.1.3.1.4	Flash time	LED 1ms-9999ms
7.1.1.3.1.5	Flash intensity	LED 0-60cd.s/m2 photopic
7.1.1.3.1.6	Flash color	White, red, blue, green
7.1.1.3.1.7	Background	0-500cd/m2
EOG Flash Specification		**Description**
7.1.1.3.1.1	Angle	+/-30 or +/-60 deg
7.1.1.3.1.2	Number of LEDs	9 red LEDs with variable intensity covering the full angle

ColorBurst

ERG Flash specification		Description
7.1.2.2.1.1	Number of stimulators	Supports 1 ColorBurst
7.1.2.2.1.2	Output mode	Single/double/multiple flash, On/Off, sine/ramp/exponential waveform, user definable
7.1.2.2.1.3	Flash frequency	0.001Hz to 500Hz (depends on hardware) 0.001Hz resolution
7.1.2.2.1.4	Flash time	LED 1ms-9999ms (calibrated at 4ms)
7.1.2.2.1.5	Flash intensity	LED 0-30cd.s/m2 Photopic. Selectable photopic or scotopic input. Resolution depends on hardware and intensity but typically 6 orders of magnitude available
7.1.2.2.1.6	Flash color	White, red, blue, green, or any mixture of RGB LEDs. Colors definable in CIE coordinates
7.1.2.2.1.7	Background	Similar to flash color. 0-500cd/m2 (depends on color)

ColorFlash

ERG Flash specification		Description
7.1.2.2.1.1	Number of stimulators	Supports 1 ColorFlash with identical output, or one flash one background (User programmable for total independence)
7.1.2.2.1.2	Output mode	Single/double/multiple flash, On/Off, sine/ramp/exponential waveform, user definable
7.1.2.2.1.3	Flash frequency	0.001Hz to 500Hz (depends on hardware) 0.001Hz resolution
7.1.2.2.1.4	Flash time	LED 1ms-9999ms (calibrated at 4ms)
7.1.2.2.1.5	Flash intensity	LED 0-1000 cd.s/m2 Photopic. Selectable photopic or scotopic input. Resolution depends on hardware and intensity but typically 6 orders of magnitude available
7.1.2.2.1.6	Flash color	White, red, blue, green or any mixture of RGB LEDs. Colors definable in CIE coordinates
7.1.2.2.1.7	Background	Similar to flash color. 0-500cd/m2 (depends on color)
7.1.2.2.1.8	Attention LED	17 attention LEDs, with 4 attention behaviors intensity

Database

Database specifications		Description
14.6.1.1	Type	SQL Client\server using Firebird
14.6.1.2	Database size	All records stored in one file, size limited by hard disc, although larger files are slower to access
14.6.1.6	Security	Database is username and password controlled
14.6.1.7	21 CFR part 11 compliance	Database has audit trail which records all database changes
14.6.1.13	Create database	Create new a new database
14.6.1.14	Transfer	Transfer In records to a database
14.6.1.15	Update	Update the current database to new format of the database
14.6.1.16	Backup database	Backup the database to a set destination with the selected frequency
Other		**Description**
14.6.2.1	Patient records	Create, modify, and archive a patient
14.6.2.2	Patient sorting	By last name, first name, DOB, and hospital number
14.6.2.3	Patient filtering	Last name, date of test, diagnosis, Normal, user category, SQL statement
14.6.2.4	Patient fields	User definable, can be enabled, disabled, printed, ignored.
14.6.2.5	Patient record Transfer	Ability to transfer patient records for current patient or all patients with or without tests included. Records can be transferred with anonymity
14.6.2.6	Diagnoses records	Create, modify, and archive a patient diagnosis
14.6.2.7	Save a test	Save the test after end of test
14.6.2.8	Load old tests	Single or multiple tests loaded simultaneously
14.6.2.9	Reporting	Integrated with Microsoft Word (not supplied). Reports can be based on user template, data drag and dropped into the document, and saved into database
14.6.2.10	Configuration	Most parameters can be configured globally
14.6.2.11	Transfer	Records can be transferred from one database to another and across networks
14.6.2.12	Finish and shutdown	Return to windows or shutdown system from application