UTAS

Hardware

User's Manual

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LKC TECHNOLOGIES

CE 2797

Rx only

Part No. 96-020-EN

EN - http://www.lkc.com/IFUsPrintable instructions for use (IFU) in multiple languages are stored on the UTAS computer as PDF files in the IFU folder on the computer desktop screen, or go to www.lkc.com/IFUs

DE - Druckbare Nutzungsanweisungen (IFU) in mehreren Sprachen werden auf dem UTAS-Computer als PDF-Dateien im IFU Ordner auf Ihrem Desktop gespeichert. Alternativ können Sie www.lkc.com/IFUs besuchen.

ES - En el ordenador UTAS hay almacenadas como archivos PDF instrucciones imprimibles de uso en varios idiomas, en la carpeta IFU del escritorio del ordenador, o acceda a www.lkc.com/IFUs

FR - Des instructions d'utilisation à imprimer (IFU) dans plusieurs langues sont stockées sur l'ordinateur UTAS sous forme de fichiers PDF dans le dossier IFU présent sur le bureau. Vous pouvez également les obtenir sur www.lkc.com/IFUs

IT - Le istruzioni per l'uso stampabili (IFU) in più lingue sono archiviate sul computer UTAS come file PDF nella cartella IFU sul desktop. In alternativa, sono reperibili all'indirizzo www.lkc.com/IFUs

PL - Instrukcje obsługi (IFU) do druku w wielu językach przechowywane są na komputerze UTAS jako pliki PDF w folderze IFU na pulpicie komputera lub na stronie www.lkc.com/IFUs

European regulatory data

Basic UDI-DI (for EUDAMED database searches) – 0857901006UTAS79

Instructions for use (IFUs) in other languages may be found at www.lkc.com/IFUs

To request a printed copy of this manual please send an email to support@lkc.com and include the following information:

1) Company name
2) Your Name
3) Mailing address
4) The Serial Number of your device
5) The part number of the manual you need
   To find the correct part number, open the pdf file in the IFU in the language you want and find the part number, the part number will appear on either the front or back of the IFU. The manual part number will look something like 96-123-AB.

Your manual will be shipped to you within 7 days.

LKC Technologies, Inc.
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USA
301.840.1992

Support@LKC.com
www.LKC.com

WARRANTY

LKC Technologies, Inc. warrants this instrument to be free from defects in materials and workmanship, provided there is no evidence of abuse or attempted repairs without authorization from LKC Technologies, Inc. This Warranty is binding for one year from date of installation and is limited to: servicing and/or replacing any instrument, or part thereof, returned to the factory for that purpose with transportation charges prepaid and which are found to be defective. This Warranty is made expressly in lieu of all other liabilities and obligations on the part of LKC Technologies, Inc.

DAMAGE UPON ARRIVAL

Each instrument leaves our plant, after rigorous tests, in perfect operating condition. The instrument may receive rough handling and damage in transit. The shipment is insured against such damage. The Buyer must immediately report, in writing, any concealed or apparent damage to the last carrier as well as to us and issue an order for replacement or repair.

DEFECTS OCCURRING WITHIN WARRANTY PERIOD. Parts of the units may develop defects which no amount of initial testing would have revealed. The price of our instruments makes provision for such service, but it does not:

1. Provide for transportation charges to our factory for service,
2. Provide for services not performed or authorized by us,
3. Provide for the cost of repairing instruments that have obviously been abused or subjected to unusual environments for which they have not been designed.

We will be happy at any time to discuss by phone, letter, or e-mail suspected defects or aspects of instrument operation that may be unclear. We advise you to inform us by phone, letter, or e-mail of the nature of the defect before returning an instrument for repair. Many times, a simple suggestion will solve the problem without returning an instrument to the factory. If we are unable to suggest something that solves the problem, we will advise you as to what parts of the equipment should be returned to the factory for service.

DEFECTS OCCURRING AFTER WARRANTY PERIOD. Charges for repairs after the warranty period and within LKC product lifetime policy will be based upon actual hours spent on the repair at the prevailing rate, plus cost of parts required and transportation charges; or you may elect to purchase an extended warranty.

We will be happy to discuss by phone, letter, or e-mail any problem you may be experiencing.

LKC PRODUCT LIFETIME POLICY

The lifetime of a UTAS is 5 years from the original shipment date of the UTAS. LKC will service any UTAS that is within its lifetime.

DISPOSAL

Follow all local and national regulations regarding proper disposal.

Single use electrodes and reusable electrodes at the end of their usefulness should be disposed of in accordance with local guidelines (typically as medical waste).

The UTAS at the end of its life should be disposed of as electronic waste.

SOFTWARE LICENSE

The UTAS software is a copyrighted product of LKC Technologies, Inc. and is included with the UTAS under the following license agreement:

The software may be used in conjunction with the UTAS only. The purchaser of the UTAS may make copies of the software for convenience of use, provided the LKC copyright notice is preserved with each copy. This license specifically prohibits the use of this software in a device that does not include an LKC Technologies, Inc. UTAS Interface Unit. Additional copies of the software may be purchased to produce reports of UTAS data using a stand-alone computer system.

Contents

1 Introduction

The UTAS is an electrophysiology medical device used in the diagnosis of disorders affecting the retina and optic nerve. The principal hardware components are visual stimulators, response recording equipment, and a controlling computer with the necessary software to control the stimulator, collect and analyze the data, and display testing results. Stimulator options include full-field ganzfelds and pattern monitors. The response recording options include a UBA amplifier to measure electrical responses and a push-button to record psychophysical responses. Hardware and software options enable testing, for example, the electroretinogram (full-field, pattern, multifocal), visual evoked response (also called visual evoked potentials (VEP)) (full-field, pattern, multifocal), electro-oculogram (EOG), and dark adaptation. These tests are considered the principles of operation of the device and details for performing the tests are detailed in the applicable Software Manuals. The UTAS is a fully automated device providing features needed for both clinical and research applications. The UTAS meets all the specifications and requirements of the International Society for the Clinical Electrophysiology of Vision (ISCEV). UTAS is the trade name for this device and all associated components including software.

This manual explains how the device is connected, the specifications for the device, how to use the hardware features, and how to assist LKC in servicing the device should trouble arise. It also covers the UTAS hardware including information on configuration, set-up, calibration, electrical and environmental safety, and other important regulatory information pertaining to the use of the UTAS. Separate software manuals cover the use of the individual software including explicit instruction on testing patients. It is important to be familiar with the hardware manual and the software manual(s) before you test patients. Supporting software manuals include:

-96-034 UTAS ECLIPSE Dark Adaptometry User's Manual

-96-022 UTAS EMWin Software User's Manual

-96-014- UTAS Multifocal Software User's Manual

1.1 Intended Purpose/ and Intended Users

UTAS is an electrophysiology device used as a diagnostic and disease management aid in visual pathway dysfunctions or ophthalmic disorders.

UTAS performs electroretinogram (ERG), electro-oculogram (EOG), visual evoked potential (VEP), multi-focal ERG/VEP, and the measurement of psychophysical responses of the visual system, including dark adaptometry.

This equipment is offered for sale only to qualified Health Professionals.

The intended users of the device are intended to be physicians, optometrists, medical technicians, clinical medical assistants, nurses, and other health-care professionals.

Operator training is provided by LKC upon installation of the UTAS, training is typically 2 or 3 days depending on the configuration upon user request. This training, along with this User's Manual, should be adequate. Periodic retraining is not necessary; however, if retraining is desired, please contact LKC.

1.2 Clinical Benefit

Assist health care professionals with diagnosis and management of ophthalmic or visual pathway dysfunction/disease or to ensure drug safety.

1.3 Intended Target Groups

There are no specific intended target groups.

1.4 Indications for use

UTAS is indicated for use in the measurement of visual electrophysiological potentials, including electroretinogram (ERG) and visual evoked potential (VEP). UTAS is also indicated for use in the measurement of psychophysical responses of the visual system, including dark adaptometry. UTAS is intended as an aid in diagnosis and disease management in visual pathway dysfunctions or ophthalmic disorders (e.g., diabetic retinopathy, glaucoma).

1.5 Contraindications

- Do not use with patients diagnosed with photosensitive epilepsy.
- Avoid use when the orbit structure is damaged or surrounding soft tissue has an open lesion.

1.6 Product Performance

The UTAS's normal operation includes measuring flicker implicit time with a single-patient, single-day standard deviation that is typically less than or equal to 1.0 ms; therefore, the UTAS must operate with no unintended deviations in settings and with typical operation.

Contact your distributor or LKC if changes in performance are noted.

1.7 Essential Performance

The UTAS is neither life supporting nor life sustaining nor is it a primary diagnostic device; its function is to aid a physician in making a diagnosis in combination with other data and in light of the physician's knowledge and experience, as such the UTAS has no Essential Performance as pertains to risk.

1.8 Precautions

- The UTAS is designed for depot service; servicing of this equipment is to be performed at LKC Technologies, Inc. or at a service center approved by LKC Technologies, Inc.
- Only equipment supplied by LKC Technologies, Inc. should be plugged into the outlets at the back of the UTAS Interface component.
- The UTAS needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this User's Manual.
- Portable and mobile RF communications equipment can affect UTAS performance.
- Input overload can occur with defibrillator or electrocautery if used in the operating room.

- Do not connect the patient to a high frequency (HF) surgical equipment simultaneously with the UTAS, as it may result in burns at the site of the electrodes and may damage the UTAS
- Operation of the UTAS in close proximity to a shortwave or microwave therapy equipment may produce instability in the UTAS recordings.
- Any device connected to UTAS must be explicitly approved by LKC Technologies, Inc. and must meet the relevant requirements of IEC 60601-1.
- The use of any accessories or replacement of components other than those supplied by or approved by LKC Technologies, Inc. may compromise patient safety and result in patient harm such as bruising, burns, retinal damage, loss of hearing, cytotoxicity, sensitization, irritation, allergic reaction, and death.
- Eye infections may result from use of non-sterilized contact-lens electrodes.
- The forehead rest and multifocal forehead and chin rest should be cleaned and disinfected after each patient. None of the surfaces of the BigShot are intended for patient contact.
- This device is not protected against the ingress of water and should not be used in the presence of liquids which may enter the device.
- This device is not suitable for use in the presence of a flammable anesthetic mixture of air, or with oxygen or nitrous oxide.
- Replacement AC fuses shall only be – T 4.0A L 250V (Slow-Blow).
- To avoid the risk of electric shock, avoid accidental contact between an electrode connected to the UBA and other conductive parts (e.g., metal) before applying the electrode to the patient. For example, connect electrodes to the patient before plugging them into the UBA.
- To avoid the risk of electric shock, this equipment must only be connected to a supply-mains with protective earth. Use a three-pronged grounded outlet.
- Do not modify this equipment without authorization of the manufacturer.
- To avoid the risk of patient irritation, avoid use of sensor strip electrode and cabling on patients with skin sensitivity.
- Any modifications to equipment or instructions for connection listed in this manual pose safety risks listed in this user manual above and could result in rendering the device in inoperable, no or incorrect results, lost to access of patient data, or prolonged testing.
- Connect the UTAS Interface directly to a wall outlet. Do not connect the UTAS Interface to a wall outlet through an extension cord or a multiple socket-outlet
- To assure proper operation and safety, the operator should not touch the patient and any device attached to a mains source independent of the UTAS.
- The UTAS is an FDA Class II medical device that incorporates a personal computer. To ensure patient safety, the personal computer and all of its peripherals are powered from an isolation transformer, through the power receptacles on the back of the UTAS

Interface. All devices connected to the computer must be powered from these isolated power receptacles. Failure to observe these precautions may endanger the patient and will void the product warranty. In the event of field service LKC Technologies, Inc. will not service a UTAS whose computer is connected to external devices, nor will it give permission for others to service such a device.

- Examples of improper connections include connecting the UTAS computer to a laser printer, or to any other device that is plugged into a wall outlet or that is connected to another device that is plugged into a wall outlet (such as a printer sharing unit connected to another computer). If you have specific questions on this matter, please contact LKC Technologies, Inc. for advice.

1.9 Electromagnetic compatibility (EMC)

The UTAS device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

WARNING: Use of accessories, transducers and 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. Use of most commercial electrodes with leads 1 meter or less long should work.

Guidance and Manufacturer's Declaration – Emissions		
The UTAS device is intended for use in the electromagnetic environment specified below. The customer or user of the UTAS device should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The UTAS device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Class B
Harmonics IEC 61000-3-2	Class A	Class A
Flicker IEC 61000-3-3	Complies	Complies
		The UTAS device is suitable for use in all establishments including domestic public low-voltage power supply networks.

		To assure continued effectiveness, only use cables and accessories supplied by LKC which are specifically designed for use with the UTAS device.

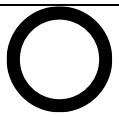
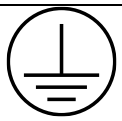
Guidance and Manufacturer's Declaration – Immunity			
The UTAS device is intended for use in the electromagnetic environment specified below. The customer or user of the UTAS device should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial, hospital, or home environment
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial, hospital, or home environment
Voltage Dips/Dropout IEC 61000-4-11	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° % UT; 1 cycle 70 % UT; 25/30 cycles for 50 Hz and 60Hz, respectively Single phase: at 0° 0 % UT; 250/300 cycle for 50 Hz and 60 Hz, respectively Single phase: at 0°	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° % UT; 1 cycle 70 % UT; 25/30 cycles for 50 Hz and 60Hz, respectively Single phase: at 0° 0 % UT; 250/300 cycle for 50 Hz and 60 Hz, respectively Single phase: at 0°	Mains power quality should be that of a typical commercial, hospital, or home environment If the user of the UTAS requires continued operation during power mains interruptions, it is recommended that the UTAS be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m, 50 Hz or 60 Hz	30 A/m, 50 Hz or 60 Hz	Power frequency magnetic fields should be that of a typical commercial, hospital, or home environment.

Guidance and Manufacturer's Declaration – Immunity			
The UTAS device is intended for use in the electromagnetic environment specified below. The customer or user of the UTAS device should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V, 0.15 MHz – 80 MHz 6 V in ISM radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz 3 V/m Professional 80 MHz – 2,7 GHz 80 % AM at 1 kHz Table 9 of IEC 60601-1-2:2014	(V1)=3Vrms (E1)=3V/m	Portable and mobile communications equipment should be separated from the UTAS device by no less than the distances calculated/listed below: $D=\frac{3.5}{V1}\sqrt{P} D=\frac{3.5}{V1}\sqrt{P}$, 150kHz to 80MHz $D=\frac{3.5}{E1}\sqrt{P} D=\frac{3.5}{E1}\sqrt{P}$, 80 to 800 MHz $D=\frac{7}{E1}\sqrt{P} D=\frac{7}{E1}\sqrt{P}$, 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
			To assure continued effectiveness, only use cables and accessories supplied by LKC which are specifically designed for use with the UTAS device.
Recommended Separations Distances for the **UTAS** device			
The UTAS device is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the UTAS device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the UTAS device as recommended below, according to the maximum output power of the communications equipment.			

Max Output Power (Watts)	Separation (m) 150 kHz to 80 MHz $D=\frac{3.5}{V1}\sqrt{P}$	Separation (m) 80 MHz to 800 MHz $D=\frac{3.5}{E1}\sqrt{P}$	Separation (m) 800 MHz to 2.5 GHz $D=\frac{7}{E1}\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3

1.10 Symbols

ISO 15223-1, Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.			
Symbol	**Reference**	**Title of Symbol**	**Description / Function**
	ISO 7000-0621	Fragile; handle with care	Indicates that the contents of the transport package are fragile and the package shall be handled with care.
	ISO 7000-0623	This way up	Indicates correct upright position of the transport package.
	ISO 7000-0626	Keep away from rain	The transport package shall be kept away from rain and in dry conditions.
	ISO 7000-0632	Temperature limit	Indicates the maximum and minimum temperature limits at which the device shall be stored, transported or used.
	ISO 7000-1641	Operator's manual; operating instructions	The operator should familiarize themself with the operating instructions before use of this device.
	ISO 7000-2493	Catalog number	Identifies the item's catalogue number.
	ISO 7000-2497 IEC 60417-6049	Date of manufacture Country Code (CC)	Indicates the date on which the product was manufactured. US country code indicates the device was manufactured in the United States.
	ISO 7000-2498	Serial Number	Identifies the device's serial number.
	ISO 7000-2620	Humidity limitation	Indicates the acceptable upper and lower limits of relative humidity for transport and storage.

	ISO 7000-2621	Atmospheric pressure limitation	Indicates the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	ISO 7000-3082	Manufacturer	Identifies LKC as the manufacturer of this device.
	ISO 7000-3650	Universal Serial Bus (USB), port/plug	indicate that the device is compatible with a USB port.
	ISO 7010-M002	Refer to instruction manual/booklet	Indicates that the Owner's Manual must be read before use.
	ISO 7010-W001	Caution	To indicate that caution is necessary when operating the device.
	ISO 7010-W027	Warning; Optical radiation	Caution – The light emitted from this instrument is potentially hazardous. 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 ICNIRP and safety guidelines after 10.7 hours (642 minutes). Use at maximum intensity and exposure durations exceeding 1.5 hours are well outside of normal usage.
EC REP	ISO 15223-1, 5.1.2-23.2(d)	Authorized representative in the European Community / European Union	Identifies the authorized representative in the European Community / European Union.
UDI	ISO 15223-1, 5.7.10-23.2(h)	Unique Device Identifier	Indicates a carrier that contains the Unique Device Identifier information.
MD	ISO 15223-1, 5.7.7-23.2(q)	Medical Device	Indicates a medical device.
	IEC 60417-5007	"OFF" (power)	indicates disconnection from the mains.
	IEC 60417-5008	"ON" (power)	indicates connection to the mains.
	IEC 60417-5019	Protective earth; protective ground	Identifies a terminal of a protective earth ground.
	IEC 60417-5032	Alternating current	Indicates that the equipment is suitable for alternating current only.
	IEC 60417-5333	Type BF applied part	Identifies a type BF applied part complying with IEC 60601-1.

	IEC 60417-6040	Ultraviolet radiation, instructional safeguard	If the BigShot Ganzfeld contains the optional UV stimulator, the Ganzfeld contains an LED source which provides UV emissions in excess of the Exempt Risk Group as defined in ISO 15004-2. The Ganzfeld risk categorization is Risk Group 2 (moderate risk). The ultraviolet radiation is centered at 365 nm. The light hazard occurs only if the UV stimulator is used as a bright background light. Brief flashes of UV light from this instrument are not hazardous. If the BigShot will be used to produce UV background light, we recommend that UV-blocking eye protection is worn while looking into the Ganzfeld. Ganzfelds equipped with UV are not intended for human use.
	IEC 60417-6414	WEEE; waste electrical and electronic equipment	Indicates that separate collection for waste electric and electronic equipment (WEEE) is required.
Symbols to be used with medical device labels, labeling, and information to be supplied — as required by the indicated regulation or body.			
Symbol	**Reference**	**Title of Symbol**	**Description / Function**
	Regulation (EC) No 765/2008	CE marking	Indicates that the device is in conformity with European Community harmonization legislation.
	Regulation (EC) No 765/2008	CE marking, including the notified body identifier	Indicates that the device is in conformity with European Community harmonization legislation; and identifies the Notified Body.
	Regulation (GB) SI 2019/696	UKCA marking	Indicates that the device is in conformity with the relevant United Kingdom legislation.
	Regulation (GB) SI 2019/696	UKCA marking, including the notified body identifier	Indicates that the device is in conformity with the relevant United Kingdom legislation; and identifies the Notified Body.
Rx ONLY	21 CFR 801.15	Prescription only	Indicates that the device is for use by prescription only. 21 CFR Part 801 Labeling, Section 801.15 Medical devices; prominence of required label statements; use of symbols in labeling FDMA 1997 SEC 126
	MU600_00_016 Version 5.0	Swiss Representative	Indicates the authorized representative in Switzerland.

1.11 Approvals

This product has been tested and complies with the requirements of

- IEC 60601-1
- ICE 60601-1-2
- IEC 60601-2-40
- ISO 15004-1
- ISO 15004-2
- ISO 10993

This product is FDA cleared and CE marked.

1.12 Environmental

1.12.1 RoHS Compliance

The UTAS is RoHS compliant in accordance with EU RoHS Directives 2011/65/EU and 2015/863 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directives). We hereby declare the restricted materials or substances are not contained therein (the material/substance is not found above the threshold level listed other than exemptions approved by RoHS). The UTAS is labeled with the CE mark indicating compliance with RoHS.

The RoHS directives allow certain exemptions from its declared limits. The UTAS complies with exemption 6(a)-I which allows Lead as an alloying element in steel for machining purposes, containing up to 0.35 % lead by weight.

1.12.2 China RoHS2 Compliance

The UTAS is RoHS compliant in accordance with the China RoHS Directive GB/T 26572-2011 on Requirements of concentration limits for certain restricted substances in electrical and electronic products (RoHS Directives). We hereby declare the restricted materials or substances are not contained therein (the material/substance is not found above the threshold level listed except as specifically indicated below).

The few steel components contained within the UTAS charging base may contain trace amounts of lead that comply with the acceptable limits of the EU RoHS exemption 6(a). Due to the possible presence of trace amounts of lead in this component the UTAS has been categorized with an Environment Friendly Use Period (EFUP) of 25 years.

1.12.3 WEEE Compliance

At the end of the product's lifetime the UTAS must be disposed of in accordance with all local and national regulations. Please contact your local authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

1.12.4 UTAS Packaging

The UTAS is a precision medical device and requires careful packaging to protect it during shipment. LKC highly recommends retaining the UTAS packaging materials, so they are available in the event it is necessary to return the UTAS to LKC for servicing or recalibration.

If retention of the shipping materials is not practical dispose of the packing materials according to local regulations. All the packing materials may be recycled as follows:

	**Exterior and interior corrugated cardboard boxes**
	**Printed material on paper**
	**Interior paperboard boxes (non-corrugated cardboard)**
	**Plastic foam packing materials** **Plastic bags** **Bubble Wrap**

1.12.5 California Proposition 65

Warning: This product can expose you to chemicals including lead, which are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/

Substance Tables:

The table below lists substances which may be contained within this product. Substances listed as Type 1 are within permissible levels; substances listed as Type 2 are used in the production of some components used in this product and may be present at trace levels but are typically destroyed during processing.

Substance	CAS #	Type	Listed as causing:
Nickel	7440-02-0	1	Cancer
Acrylonitrile	107-13-1	2	
Ethylbenzine	100-41-4	2	
Antimony Trioxide	1309-64-4	1	
Styrene	100-42-5	1	
Carbon Black	1333-86-4	1	
Lead	7439-92-1	1	Cancer Developmental Toxicity Male Reproductive Toxicity Female Reproductive Toxicity
N-Hexane	110-54-3	2	Male Reproductive Toxicity

1.13 European Representative (for medical devices only)

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Symbol

1.14 Swiss Representative (for medical devices only)

CMC Medical Devices GmbH.
Bahnhofstrasse 32,
CH-6300 Zug, Switzerland
Tel: +41 41-562-0395

Symbol

1.15 UK Responsible Person (for medical devices only)

Emergo Consulting (UK) Limited
c/o Cr 360 – UL International

Compass House, Vision Park Histon
Cambridge CB24 9BZ
United Kingdom

1.16 Reporting of serious incidents

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2 Functional Description/ Technical Specifications

In this section, the function of each equipment group is explained and a block diagram showing equipment interrelationships is discussed. The UTAS can come with either a SunBurst Ganzfeld (designed for humans and larger animals) or the BigShot Ganzfeld (fits most small animals, human, and primate faces). The BigShot Ganzfeld can be upgraded with a UV stimulator but is not approved for human use and labeled accordingly.

2.1 UTAS Specifications

2.1.1 Sunburst Ganzfeld Stimulator

Size	33.5 cm x 25.9 cm x 20 cm (13.2” x 10.2” x 7.9”)
Weight	2.7 kg (6 lbs.)
Flash Intensity	Maximum Luminance of ~2500 cd·s/m^2 (+30 dB) for Xenon Flash Typical Maximum Luminance of ~160 cd·s/m^2 (+18 dB) for white LED Flash, 18 dB for green LED Flash, 16 dB for red LED Flash, and 11 dB for blue LED Flash Dynamic Range of 105 dB (+30 dB to -75 dB) in 1 dB steps
Flash Intensity Tolerance	$\pm$ 1 dB
Background Intensity	0.005 to 5000 cd/m^2 in any color (4000 in blue) in 1 dB steps. 0.001 to 5000 cd/m^2 in white in 1 dB steps.
Background Intensity Tolerance	$\pm$ 1 dB
LED wavelength	Red (627 nm), Green (530 nm), Blue (470 nm) and Amber (597 nm)

2.1.2 Bigshot Ganzfeld Stimulator

Size	39 cm x 32 cm x 50cm (15.5” x 12.5” x 19.7”) 35.6 cm (14”) Diameter Full Field Globe
Weight	9.5 kg (21 lbs.)
Flash Intensity	Maximum Luminance of ~800 cd·s/m^2 (+25 dB) for Xenon Flash

	Typical Maximum Luminance of ~25 cd·s/m^2 (+12 dB) for white LED Flash, 10 dB for green LED Flash, 8 dB for red LED Flash, and 4 dB for blue LED Flash Dynamic Range of 100 dB (+25dB to -75dB) in 1 dB steps
Flash Intensity Tolerance	± 1 dB
Background Intensity	0.005 to 1000 cd/m^2 in any color in 1 dB steps 0.001 to 1000 cd/m^2 in white in 1 dB steps
Background Intensity Tolerance	± 1 dB
LED wavelength	Red (627 nm), Green (530nm), Blue (470 nm) and Amber (597 nm)
Optional UV LED	Wavelength 365 nm, typical Maximum Flash of 0 dB, typical Maximum background of 500 cd/m^2

2.1.3 Pattern Stimulator

Checkerboard Sizes	1 x 1 to 128 x 128 (in powers of 2)
Alternation Rate	0.25 Hz to 32.5 Hz
Screen Luminance	50 – 400 cd/m^2 ±10%

2.1.4 Amplifier Unit

Input Type	Analog differential
Input Channels	1 to 6 (user selectable)
Input Impedance	≥100 MΩ
Connector Type	1.5 mm male DIN Safety electrode connections
Noise	< 0.5 µV rms @ 1 kHz, 10 kΩ Input (gain = 8)
CMRR	> 110 dB at 50 – 60 Hz
Frequency Range	DC Coupled
DC Input Range	±4.5 V (gain = 1)
Data Resolution	0.5 µV / bit (gain = 1) to 22 nV / bit (gain = 24)
Sampling Rate	1 kHz and 2 kHz
Safety	Complies with electrical safety standards.
Size	17.5 cm x 5.4 cm x 3.7 cm (6.90” x 2.13” x 1.44”)
Weight	6.4 oz (180 g)

Computer Interface	USB (Type-A male connector)
Power Source	USB powered
Timing Accuracy	<±2.0 ms

2.1.5 Utas Interface Unit

Computer Interface	RS-232
Size	26 cm x 26 cm x 10 cm (10” x 10” x 4”)
Weight	7.3 kg (16 lb)

2.1.6 UTAS

Power Requirements	
Input Voltage	100 to 240 VAC
Input Frequency	50/60 Hz
Power Consumption	400 Watts maximum
Operating Environment	
Temperature	10 °C to 35 °C (50 °F to 95 °F)
Humidity	10% to 90% non-condensing
Atmospheric Pressure	62 kPa to 106 kPa
Storage Environment	
Temperature	-10 °C to 55 °C (14 °F to 131 °F)
Humidity	10% to 95% non-condensing
Atmospheric Pressure	62 kPa to 106 kPa
Transport Environment	
Temperature	-40 °C to 70 °C (-40 °F to 158 °F)
Humidity	10% to 95% non-condensing
Atmospheric Pressure	50 kPa to 106 kPa

Computer and Associated Devices

The UTAS has very specific configuration requirements. Only a computer purchased from LKC specifically for your UTAS should be used. Use of other computers may compromise performance and/or test results. The computer provides the control of all test and analysis operations.

2.2 UTAS Interface

The UTAS interface contains:

- 24 V Medical Grade Power Supply
- Interface printed circuit board
- A toroidal high voltage isolation transformer

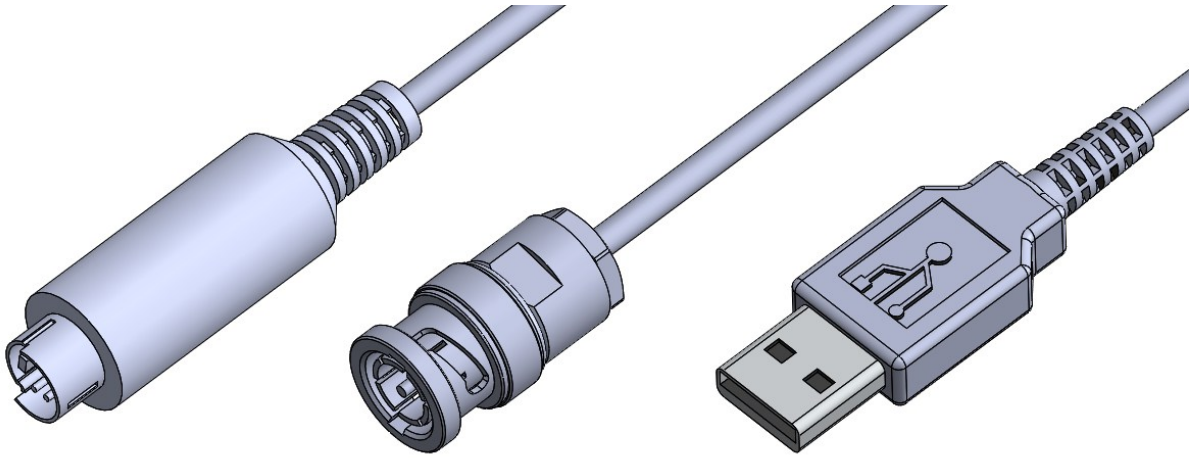
2.3 UBA Patient Amplifier

2.3.1 UBA Connections

UBA is the patient amplifier. The electrodes used on the patient plug into the amplifier. The amplifier converts data from an analog to digital signal and transfers the data to the computer via a USB connection.

The UBA has a trigger input that receives pulses that function to synchronize the patient measurements to the stimulus. The UBA cable has a BNC connector end that is attached to the Interface Unit to connect this signal.

The UBA also has a trigger input that attaches to the optional Stimulator Monitor with a mini-DIN connector to synchronize the stimulus to the patient measurements.



Left to right – Mini-DIN, BNC, and USB connectors

2.3.2 UBA Power

Powering On/Off

The UBA is powered by the USB connection to the computer; therefore, the UBA is on anytime the computer is on and the UBA is attached to the computer.

2.3.3 UBA Inputs

UBA has 1.5 mm male DIN safety connectors. The channel connections are indicated on the front label of the Amplifier adjacent to the connection points.

The UBA has 6 differential inputs, the Positive inputs have RED connectors, the Negative inputs have BLACK connectors, and the Ground input has a GREEN connector.

Connections to the amplifier should always start at the number 1 inputs with additional inputs added sequentially. Unused inputs should be deselected in EMWin or jumped to ground.

UBA Inputs

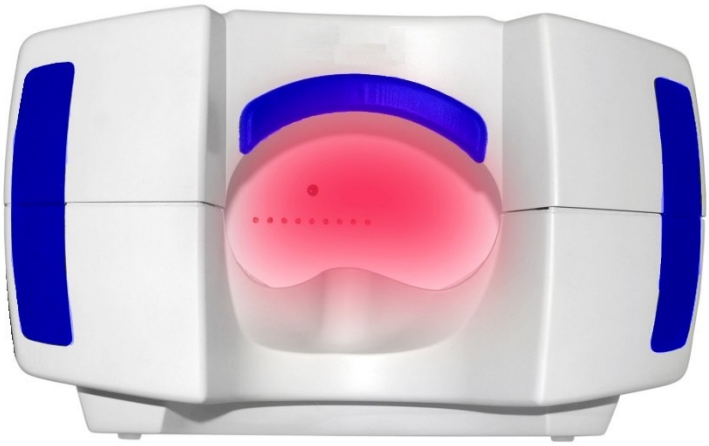
2.3.4 UBA Positioning

The UBA has three ways to position the device during testing. The UBA has anti-skid feet so if positioned on a table top it will not slide. A lanyard is supplied to allow the UBA to be hung from the patient's neck. For the shortest electrode connections to the patient the UBA is equipped with an adjustable arm strap. The arm mount is not intended for skin contact, if the patient's arm is bare, please use the supplied lanyard rather than the arm strap.

To reduce electrical noise, position the UBA at least 1 foot (1/3rd meter) from the black system interface box.

2.4 Ganzfeld

The Full-Field Ganzfeld Stimulator is connected to the interface unit and controlled by the device's computer. UTAS can come with either a SunBurst Ganzfeld or a BigShot Ganzfeld.



2.4.1 SunBurst

SunBurst has a compact size. It has an ergonomic mounting arm which provides easy adjustment to any patient and a quick disconnect feature and built-in handles for easy positioning over prone patients. The inside of the Ganzfeld can be cleaned with a damp cloth and mild detergent. SunBurst has a built-in camera to monitor the fixation of the patient.

SunBurst uses red, green, blue, amber, and white LEDs (for dim flashes) as well as a Xenon flash. All flash durations are less than 5 ms. The flicker stimuli go up to +20 dB; 1 Hz repetition rate for intensities > +20 dB.

SunBurst also has the capability to produce long duration flash (On/Off response) stimuli programmable to 6.5 seconds in 5 ms increments with adjustable intensity and chromaticity.

SunBurst also has 9 red EOG fixation LEDs in ±15° horizontal.

2.4.2 BigShot

BigShot is sized to fit larger animals such as dogs, pigs, cats, etc. The inside of the Ganzfeld is not washable. Use compressed air to blow dust particles out. Do not use water.

BigShot uses red, green, blue, amber, and white LEDs (for dim flashes) as well as a Xenon flash.

The flicker stimuli go up to +10 dB; 1 Hz repetition rate for intensities > +10 dB.

BigShot also has the capability to produce long duration flash (On/Off response) stimuli programmable to 6.5 seconds in 5 ms increments with adjustable intensity and chromaticity.

BigShot has 3 red EOG fixation LEDs in ±15° horizontal

BigShot has an optional UV stimulator that can be used for flash stimuli and background light to stimulate animal S-Cones (contact LKC if interested in upgrading to UV). **A UTAS equipped with UV is not intended for human use.**

BigShot has a built-in camera to monitor the fixation of the patient during photopic tests, for scotopic testing an IR illumination option is available.

Note: The optical coating on the interior surface of the BigShot ganzfeld is VERY delicate and should not be touched. Damage to the coating may compromise test results.

2.5 Pattern Monitor

The pattern stimulator monitor supplied with your UTAS was selected by LKC to meet the rigorous requirements of Multi-Focal ERG/Multi-Focal VEP. Commands sent by the computer to the pattern stimulator produce changes in the display on the pattern stimulator screen.

The stimuli have three pattern formats: checkerboards, square wave gratings and sinusoidal gratings. Grating pattern stimuli can be presented vertically or horizontally. Pattern alternation rate can be set at 0.25, 0.5, 1, 1.66, 2, 3.8, 5, 7.5, 15, 25 or 32.5 Hz. The exact periods will be the closest integer number of frames with the 240 Hz monitor frame rate. Pattern blank can be set to the following on:off ratios: 16:1, 8:1, 4:1, 2:1, 1:1, 1:2, 1:4, 1:8, 1:16. All three pattern formats provide red, green, blue, white and black colors. In addition, hemifield (¼, ½) patterns can be displayed, and the pattern contrast can be adjusted from 2% to 100%. Patterns can be presented in either alternating pattern or pattern blank.

Warning: the LCD pattern monitor provided by LKC is at risk for image persistence if left on the pattern display for extended periods of time without changing.

2.6 Overall Equipment Interrelations

Figure 1 below show the block diagrams of the device in the two versions (desktop and laptop), showing how the various elements of an UTAS device are interconnected.

The UTAS has three patient stimulus options: the SunBurst Ganzfeld, the BigShot Ganzfeld, and the patient monitor.

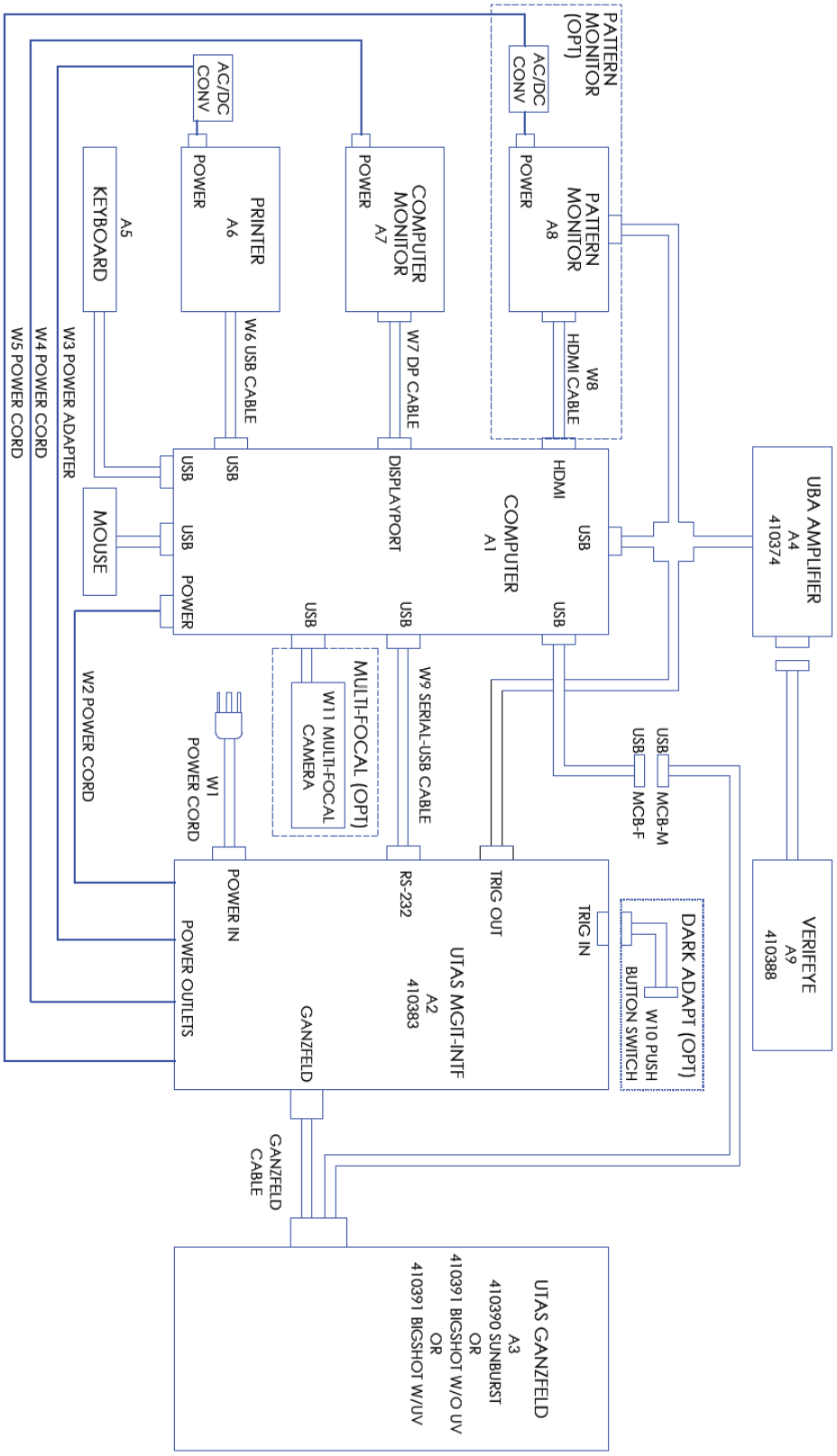
The patient's electrical response travel via electrodes to the amplifier unit (UBA) where the signals are converted from analog to digital and passed on to computer via a USB connection. Alternatively, the patient's psychophysical response can be measured with a push-button cable (UTAS Trigger-In Cable).

The computer collects signals for processing, display, analysis, and storing.

The operator utilizes the mouse and keyboard of the computer to control the device. Results can be viewed on the operator display and printed using the printer attached via a USB connection.

Electrical power from a wall outlet connects to the MGIT-Interface box via a single line cord. The MGIT-Interface box provides electrically-isolated power to the rest of the UTAS. The computer, monitors, and printer are provided with isolated AC power. The UBA and cameras are powered via USB connections (5 VDC). The ganzfeld is powered by DC voltages generated by the MGIT-Interface.

Figure 1



Ref. ID	Description	Length (m)	LKC No.
W1	AC Input Power Cord	2.4	65-010

W2, W4	Power Cord	1.5	65-034
W3	Power Cord - Adapter	0.5	65-043
W5	C3 – D14 Power Cord	1.8	65-102
W6	USB Cable	2.0	91-174
W7	DisplayPort Cable	1.0	91-230
W8	HDMI Cable	1.8	91-229
W9	RS-232 to USB Cable	2.0	91-208
W10	UTAS Trigger-In Cable	0.6 – 4.6 coil	81-367

Warning: The use of cables other than those specified in these lists may result in increased emissions or decreased immunity of the UTAS.

3 Setting Up the Device

3.1 Inventory

The UTAS device consists of an interface unit, an amplifier unit, a pattern stimulator, a Ganzfeld, and a computer with its associated peripherals. The equipment should be arranged on workstations or tables.

Make sure that the patient location is as far as possible from power mains or electromagnetic devices to minimize 60 or 50 Hz electromagnetic interference. Additionally, the patient should not be seated where he or she can be touching the Interface Unit or other electrical apparatus during testing. Therefore, the Pattern Stimulator and Ganzfeld Stimulator should be placed on the instrument table that does not contain the Interface Unit. The best arrangement for the UTAS is where interface unit and Computer Unit are placed on one workstation and the Stimulators on a separate instrument table as follows:

3.1.1 Operator's Station on workstation

- Computer
- Operator Monitor
- Keyboard
- Mouse
- Printer
- UTAS Interface Unit

3.1.2 Instrument/Patient's Station

- Video Pattern Stimulator
- Ganzfeld

Note: The amplifier unit is not listed on either station. It will typically be adjacent to the patient during testing.

3.2 Precautions

3.2.1 Power Main Interference

The principal external interfering signal is electrical noise generated by power lines or by electrical equipment connected to power lines. The typical electrical outlet provides a ready source of 100-240 Volts, which is about a million times greater than the amplitude of the ERG. Examples of equipment that generate electrical interference include fluorescent lights, motors (including motorized chairs), and power transformers. Power transformers radiate primarily third harmonic (e.g., 150 Hz or 180 Hz). These items produce powerful electromagnetic fields that can induce or couple power line interference into the recordings. The closer the patient and the equipment are to these sources; the more interference will be introduced into the recording equipment. LKC's revolutionary Universal Biomedical Amplifier (UBA) will cancel most of this interference; however, if the patient leads or amplifier are close enough to power lines or electrical equipment, power mains interference may be seen in the recordings. Therefore, care should be taken to locate the testing equipment and subject away from any major source of electrical interference.

3.2.2 High Frequency Electrical Noise

Beyond the power lines or equipment such as motors and transformers, electrical noise can be produced by equipment generating noise at radio frequencies. Although one might expect such signals to be filtered out by the amplifier filters, it is possible for this type of noise to generate low frequency artifacts by nonlinearities in the recording equipment and by mixing with other signals. Therefore, care should be exercised to keep the recording equipment and subject away from strong sources of radio frequency interference.

Noisy signals can come from nearby MRI systems. This will create noise and/or unrecordable data.

3.2.3 Shielding

If a location which is free of interfering apparatus cannot be found, it is possible to create simple shielding which can usually control the interference. A shielding material, such as copper or aluminum can be placed below the patient and covered with an anti-static mat or placed around interfering apparatus. The screen and mat, if used, should be securely connected to electrical ground.

3.3 Equipment Interconnections

The equipment is interconnected as shown in **Figure 1**. Make certain that the power is off before making any connections. All the equipment in your UTAS must be connected for the device to function properly.

The device comes with connections for two monitors. The two monitors have different video cable types and their logical connections to the computer are determined by the video cable type

Computer to Operator's Monitor. Connect the operator's monitor to the computer using an HDMI video cable.

Computer to Pattern Stimulator. Connect the pattern monitor to the computer using an DisplayPort video cable.

Computer to Printer. Plug the printer into a USB connector on the computer using the supplied USB cable.

Computer to Keyboard. Connect the keyboard to the computer using its integral USB cable.

Computer to Mouse. Connect the mouse to the computer using its integral USB cable.

Computer to UTAS Interface Unit. Connect the serial port on the Interface unit to the computer using the supplied adapter cable. This cable has a 9-Pin Serial connector on one end and a USB connector on the other end.

UBA to its various connections.

Connect the USB connector on the UBA to a USB port on the computer

Connect the BNC connector on the UBA to the BNC connector on the back of the Interface Unit

Connect the circular DIN connector on the UBA to the Pattern Monitor Sensor on the Pattern Monitor (if present).

Ganzfeld (SunBurst or BigShot) to Computer. Connects the USB cable extending from the ganzfeld to a USB port on the computer. This connection is standard on SunBurst but is optional on BigShot.

Device Interface Unit to Ganzfeld (SunBurst or BigShot). An 8-foot, fiberglass-sleeved cable connects the Interface Unit to the Ganzfeld. The 16-pin plastic connector on the cable goes to the back panel of the Interface Unit.

IMPORTANT

An isolation transformer is included within the Interface Unit to provide additional isolation from the power line ground system. The transformer will limit leakage current to inconsequential levels should there be a failure in the grounding system.

> ***NOTE:*** ***The Transformer is required to limit the leakage current to established safe levels if there is a failure in the grounding system. No part of the system, except the Isolation Transformer Unit, should be plugged into an A.C. primary (wall) outlet. Other subsystems should be connected to the power receptacles on the isolated Interface Unit.***

The Interface Unit should be plugged directly into a designated wall outlet, and not through an intermediate power strip.

WARNING: The installation of any software on the UTAS Windows based computer that is not provided directly by LKC can cause the device to stop functioning, crash unexpectedly, or disrupt the timing of the stimulus presentation and data collection.

The LKC UTAS is a precision standalone medical device. The computer provided with the device has been manufactured and configured for this specific purpose. It is absolutely essential that the timing of the stimulus presentation and data collection not be impeded by any non-LKC provided software products.

The warranty on the UTAS does not cover problems caused by installation of non-approved software on the computer. The UTAS is a medical device that uses a Windows-based computer. Installation of additional software on the UTAS computer may result in improper operation of the UTAS. It is the customer's responsibility to ensure that any additional software installed on or data connections made to the UTAS computer provided by LKC does not affect the performance or data security of their UTAS. LKC is not liable or responsible for improper operation of the UTAS caused by customer-installed software.

Therefore, LKC strongly recommends that the UTAS be used as a standalone medical device. LKC also strongly recommends that:

1. **The user does not change any user privileges or software settings.**
2. **No non-LKC approved software products be installed on the computer supplied with the UTAS**

4 UTAS Maintenance & Calibration

4.1 Computer Backup

The UTAS comes with a PC that contains a hard disk drive. The UTAS software has been installed on the hard drive, and the recordings will be stored on the hard drive as well. Unfortunately, hard disk drives sometimes fail, and when they do, there may be no way to recover the lost information. For this reason, it is recommended to occasionally backup all-important information.

4.2 Calibration

UTAS Ganzfelds are calibrated to provide known light stimuli. Some components within the ganzfeld are subject to aging or environmental contamination which can compromise test results.

- To slow environmental contamination, keep the ganzfeld covered using the supplied cover when not in use.
- If your UTAS is equipped with a SunBurst ganzfeld use the Zenith calibration checker supplied with the UTAS to check calibration at least semi-annually. If your ganzfeld fails the calibration check it will need to be recalibrated by LKC.
- ISCEV recommends the ganzfelds are recalibrated yearly. For SunBurst or BigShot ganzfelds it is possible to perform a calibration check that is adequate to determine if calibration has drifted as long as you have access to calibrated light meters. If not LKC recommends recalibration at LKC's facility.

4.3 Maintenance and Cleaning

To assure optimal performance, LKC recommends the following maintenance, inspection, and cleaning processes:

- On the ganzfeld Inspect the forehead rest, chin rest (if any) and UBA for damage, and sharp edges at least monthly. If damage or sharp edges are found contact LKC for service.
- Clean patient contact area per instructions in Section 8 between each patient.
- There are no user serviceable parts in the UTAS. If service is required contact LKC.
- Cleaning must not be performed while testing is in process.

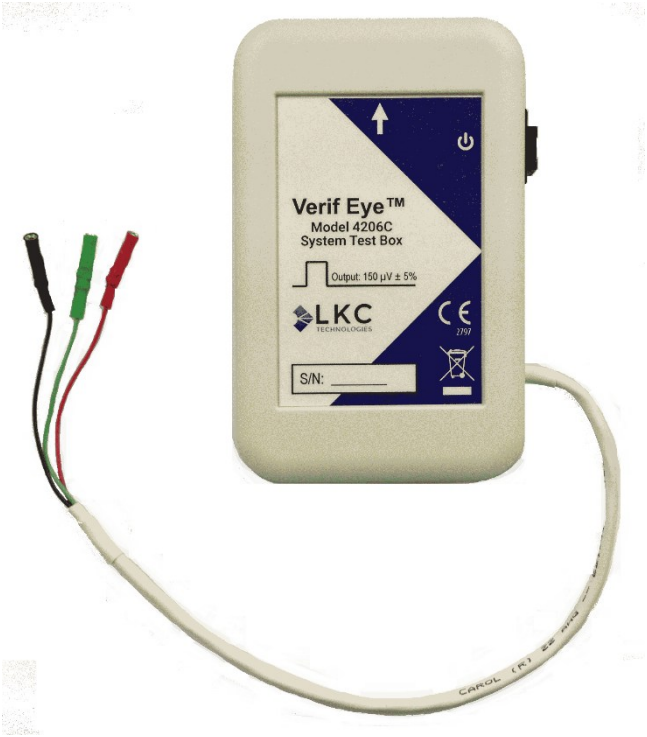
5 Checking the UTAS

5.1 Checking the UBA (Amplifier) Response

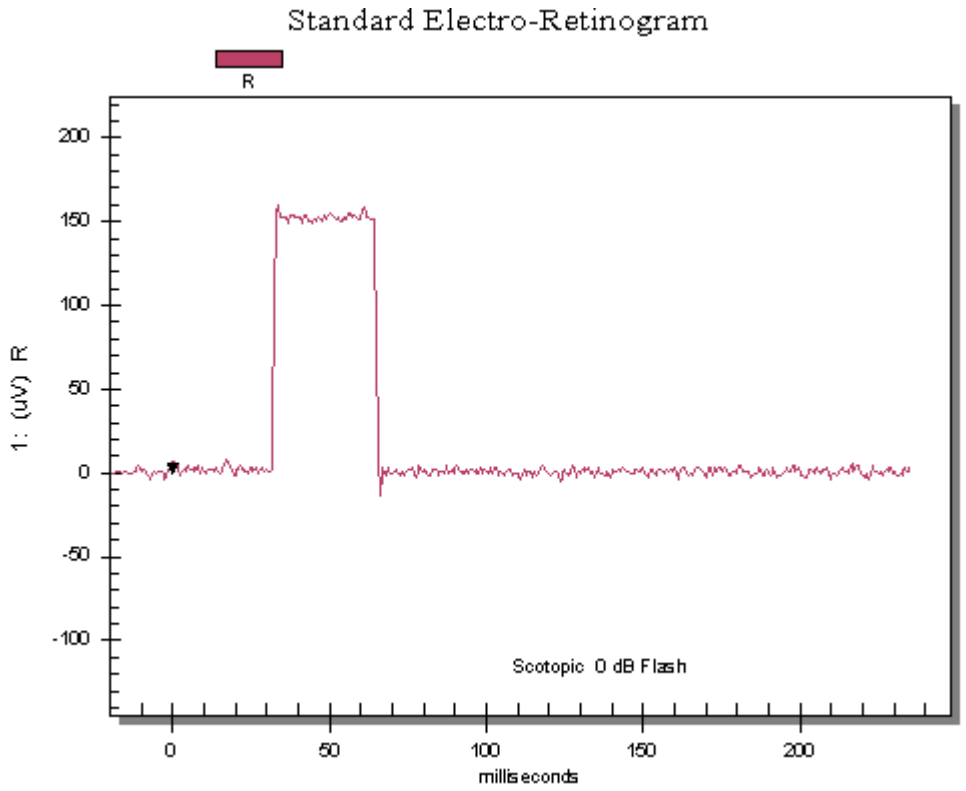
Using the VerifEye that was shipped with the UTAS, it is possible to check if the UBA is working properly.

- Plug the VerifEye's wires into the UBA, with the red wire in channel 1+, the black wire in channel 1-, and the green wire in ground
- Turn the VerifEye on (if the red light in the button doesn't turn on, replace the 9V battery)

- For BigShot, place the VerifEye on the chin rest with the sensor end (indicated by an arrow on the VerifEye Front panel) pointing into the ganzfeld.
- For SunBurst, gently place the box in the Ganzfeld to avoid scratching the paint
- On the computer, start EMWIN -> Perform Test -> ERG -> Standard ERG
- Go to a 0 dB scotopic flash step. Set the Ganzfeld Parameters to turn the IR LED off (if your ganzfeld is a BigShot it might not have IR LEDs)
- Click on Baseline and Record – Stop Baseline and then Record
- Carefully remove the VerifEye from the ganzfeld and turn it off



The Ganzfeld will deliver a 0 dB flash that will trigger the photo sensor of the VerifEye and should show as a 150 µV ± 5% pulse of 35 ms width (see picture below). The IR LEDs are automatically turned on as the UTAS is powered up. They are used in conjunction with the fixation camera to see the eyes of the patients in the dark while recording. The IR LEDs, however, saturate the photo sensor of the VerifEye; hence, they need to be turned off while checking for the pulse. In order for the response to look rectangular like the photo, you also need to turn off the high-pass filter.



5.2 Checking Ganzfeld Calibration

5.2.1 Overview

The UTAS with SunBurst comes with a calibration checking application. Original calibration values are stored in the memory of the UTAS. The calibration check software allows the user to check new calibration measurements and compare them to the original factory calibration data. Note that there is no way for the user to calibrate any of the light sources; the unit needs to be returned to the factory if such recalibration is determined to be required. Also note that this application is NOT available for BigShot.

SunBurst and BigShot have three different light sources that are used for background and/or flash purposes. Those include dim white LEDs, the red/green/blue LEDS, the amber LEDs and the Xenon Flash.

Light Source	**Used for Background Light**	**Used for Flash**
Dim White LEDs	*Yes*	*Yes*
Red, Green, Blue LEDs	*Yes*	*Yes*
Amber LEDs	*Yes*	*No*
Xenon Flash	*No*	*Yes*

IMPORTANT

Calibration check should be performed in a dark room with the Ganzfeld cover on. Also make sure that the fixation LED is turned off during calibration.

The photometric measurement of most relevance to clinical electrophysiology is the luminance. Luminance is a measure of light per unit area emitted from an extended source or reflecting surface. This measure is independent of distance. Intuitively, one can think of luminance as roughly equivalent to brightness, and as an object is approached, its brightness does not change appreciably. The Système Internationale (SI) unit of luminance is the candela per square meter (cd/m^2). For brief flashes of light, such as those used for the flash ERG and VEP, the luminance of the stimulus must be weighted by flash duration, since temporal integration of the neuronal visual pathways is longer than the duration of the flash. Thus, the appropriate unit of time-integrated luminance for brief flashes of light is cd·s/m^2.

Another measure of importance to clinical electrophysiology is retinal illuminance, an estimate of the effective stimulus at the retina. The standard measure of retinal illuminance is calculated by multiplying stimulus luminance by pupillary area. The unit of retinal illuminance is the Troland (Td).

The Troland is defined as the retinal illuminance obtained when a stimulus of 1 cd/m^2 is viewed through a pupillary area of 1 square mm (diameter of 1.128 mm). Scotopic Trolands (Td') can also be measured using V'λ to calculate stimulus luminance.

Flash intensities are often referred to in decibels (dB). The term dB is a relative one, as shown in the equation:

$$\mathrm{dB} = 10\log\left(\frac{I(x)}{I(0)}\right)$$

Where I(0) is the intensity at 0 dB and I(x) is the intensity at x dB. The intensity at 0 dB for all ganzfelds is 2.5 cd·s/m^2.

5.2.2 Checking Calibration Using Zenith Software (for SunBurst Only)

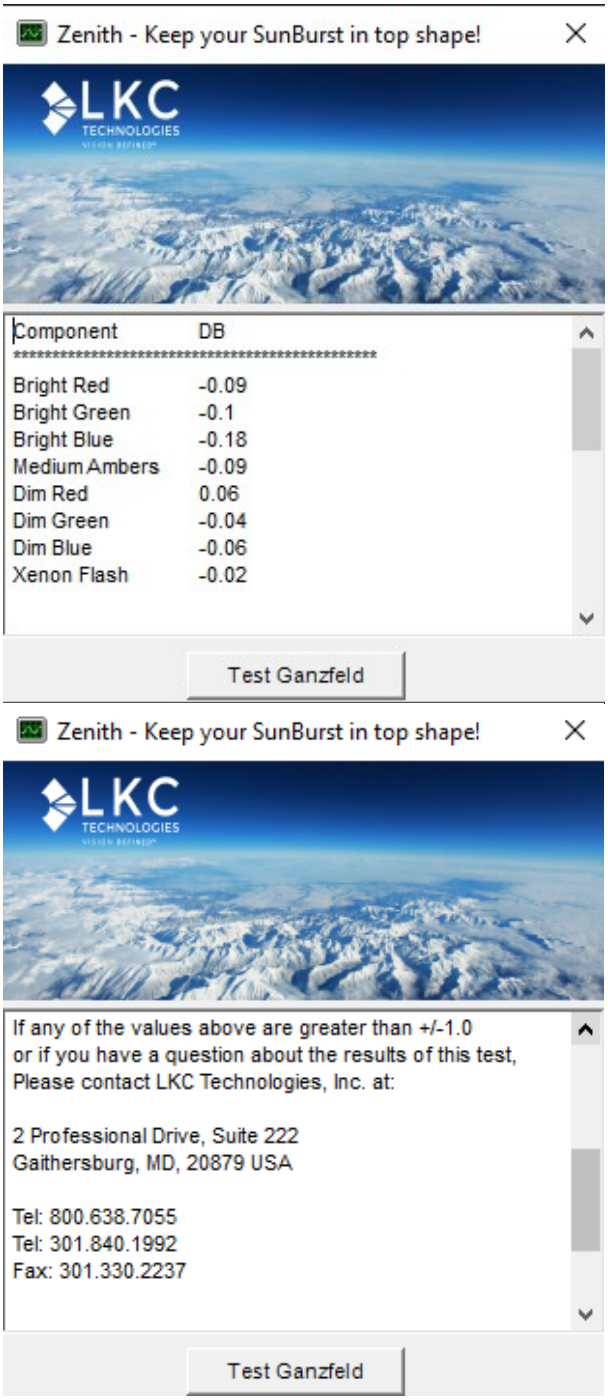
Zenith software will allow the user to run a calibration check. It will measure values of all of the SunBurst light sources 10 times and alert the user if the value varies from the initial factory calibration value. If there is more than 1 dB difference in calibration values please contact LKC Technologies.

Note: This is not available with the BigShot Ganzfeld.

Follow the instructions displayed by the Zenith prompt

Step 1: SunBurst ON with cover, Lights OFF

Step 2: Click on Test Ganzfeld



Step 3: Review Calibration Values

5.2.3 Checking Calibration on Your Own

In order to check calibration, you need to have a light meter calibrated for photopic luminance for background lights and photopic luminance energy for flashes.

6 External Triggers (Input and Output)

The rear of the LKC Interface Unit contains a BNC connector labeled Trigger Out and a phone jack labeled and Trigger In. These connectors allow for the connection of external stimulators

to the UTAS. This section will provide some information necessary to connect external stimulators to the UTAS.

Trigger In and Trigger Out are default to positive going TTL unless specified otherwise at time of purchase. Contact LKC for information on how to change trigger polarity.

6.1 Triggering External Equipment – Trigger Out

The BNC connector marked Trigger Out on the back of the Interface is normally used to trigger the UBA to synchronize the patient signals to the stimulus. This output also be used to trigger an external piece of equipment. The trigger signal is a positive going TTL compatible output of approximately 1 ms duration.

A signal appears at the Trigger Out BNC whenever SunBurst or BigShot produces a flash. In case of an ON/OFF response, the trigger will go low at the start of the stimulus and will go high again once the stimulus is over.

6.2 Receiving Triggers from External Equipment – Trigger In

The trigger in is used by the push-button switch that is provided with the dark adaptometry option (the UTAS Trigger-In Cable).

Additionally, if you have a stimulator that can provide a trigger signal to the UTAS Interface, data may be recorded using that stimulator. The phone jack connector marked *Trigger In* on the back of the interface can be used to receive triggers from an external piece of equipment.

Note that the Trigger IN signal should be a switch closure between the two pins of the Trigger In connector. The signal can be a mechanical switch or an open-collector transistor output.

Please contact LKC Technologies, Inc. before connecting any external equipment to the Trigger-In or Out connector of the Interface Unit.

Warning If the stimulators are not connected properly to the Interface Unit, damage may result to either the Interface Unit or to your stimulator. If there are any doubts, please contact LKC before proceeding.

7 Cleaning and Disinfection

WARNING: Consult the cleaning agent and germicidal cleaner agent manufacturer instructions for their proper use and germicidal efficacy prior to their use.

CAUTION: Do not submerge the device in liquid or allow liquid to enter the interior of the device as this could damage the electronics. Do not use automatic cleansing machines or sterilization.

CAUTION: Follow these instructions and only use the cleaning or germicidal cleaner agent types listed or damage may occur.

7.1 Cleaning the ganzfeld

The white interior sphere that the patient looks into (the ganzfeld), should be cleaned when necessary. The ganzfeld can be cleaned with a compressed gas air duster to remove dust. For the Sunburst ganzfeld, a damp cloth moistened with water or isopropyl alcohol may be used if compressed gas doesn't work. The BigShot ganzfeld surface should not be touched. Liquid cleaners may damage the LED lights and camera inside it.

7.2 Cleaning the exterior

Cleaning of the patient-contacting parts of the device (Sunburst forehead rest, multifocal chin/forehead rest) is recommended between patient uses.

The UTAS exterior is chemically compatible with wipes containing 70% isopropyl alcohol and with wipes containing alkyl dimethyl benzyl ammonium chloride. The use of other wipes may damage the device.

Step 1. Remove all visible soil by wiping exterior surfaces with a compatible wipe. Ensure that all visible contamination has been removed.

Step 2. Disinfect using a germicidal wipe labeled suitable for use on healthcare equipment and capable of low or intermediate level disinfection, following the procedures and contact time recommended by the germicidal wipe manufacturer.

Step 3. Inspect for any visible damage prior to use. Discontinue use if any abnormalities are found.

8 Sterilization

UTAS does require sterilization nor is intended to be sterilized.

Appendix 1: LKC Accessory Electrode and Supplies List

Electrodes & Jumper Cables	LKC Part No.
Jumper Cable	91-171
DTL Electrode Extension Cable	95-028
1 to 2 Electrode Splitter (1M-2F)	95-001
1 to 3 Electrode Splitter (1M-3F)	95-083
1 to 4 Electrode Splitter (1M-4F)	95-084
DTL Plus Electrodes	95-003
Ear Clip Electrode (1-10 mm cup with clip)	95-004
ECG Disposable Grounding Electrodes (Pack of 3)	95-098
Electrode Washers (Package of 100)	95-009
ERG-Jet Electrodes (Box of 50)	95-011
ERG-Jet Electrodes, Each	95-082
Ground Reference Lead	95-102
Needle electrodes (25)	95-016
VER Electrode (10 mm cup, gold plated), 24"	95-018
VER Electrode (10 mm cup, gold plated), 48"	95-019
EOG Electrodes (gold conductor)	95-075
RETeval Sensor Strips	95-068
RETeval Sensor Strip to DIN Adapter Cable	91-201

Gels, Creams, etc.	LKC Part No.
Electrode Cream (3.5 oz. Tube)	95-006
Electrode Gel (8.5 oz. Tube)	95-007
NuPrep (4 oz. tubes, 3 pack)	95-079

Supplies	LKC Part No.
VerifEye	92-115
Mouse/ Rat Manipulator (2 Channel)	95-048
Animal Temperature Controller	92-071

Appendix 2: Artifacts in Electrophysiological Testing

The first part of this appendix describes the most significant artifacts encountered in Visual Electrodiagnostic Testing. The second part describes various methods of limiting or minimizing artifacts, and the third part explains how certain features of the equipment may be used to yield the best possible recordings, artifacts notwithstanding.

Artifacts in electrophysiological testing include any electrical signal generated either by the subject, the recording equipment, or by the environment, which does not represent the subject's response to the stimulus. Artifacts can distort or obscure the evoked response to a degree that renders the recording of little or no diagnostic use.

Artifacts Generated by the Subject

Muscle Artifacts. Contracted muscles can generate very significant electrical activity. For example, the heart muscle generates up to 4 millivolts when measured by electrodes placed on the chest. In comparison, the ERG signal measures about 150 to 400 µV in amplitude, which is about 10 times less than those generated by the heart. Therefore, it's not surprising that significant distortion of the ERG and EOG can be produced by subjects who:

- Tense their jaw muscles
- Tense their eyelid muscles
- Blink

Muscle artifacts that interfere with the ERG and EOG produce high frequency random "noise" that appears on the baseline. The amplitude of this interference may be as high as ±50 µV, which can obscure the needed measurements. Jaw muscle noise can be particularly devastating to EOG recordings.

Eye Movement Artifacts. Eye movements can produce serious errors in the ERG as well as in the EOG when not representing controlled response movements.

There are two types of eye movement artifacts that affect the ERG; one is the subject's inability to fixate while the second is due to a reflex contraction of the orbicularis muscle in response to the strobe flash. This latter artifact is called the photomyoclonic reflex (PMR) and can potentially interfere with B wave interpretation.[1]

Eye movement artifacts resulting from improper fixation produce baseline shifts. The baseline may be shifted entirely off the screen or appear to slant up or down across the screen. The eye movement can therefore cause the recording to be off. Ideally, the baseline should appear as a horizontal line with minimal noise riding on it. If the baseline is drifting wildly, instruct the patient to carefully fixate on the red light in the Ganzfeld bowl.

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1 For a further discussion of the photomyoclonic reflex, see
Johnson, MA and Massof, RW. The photomyoclonic reflex: an artefact in the clinical electroretinogram. *Brit. J. Ophthalmol. 66, 368-372* (1981).

EEG Artifacts. For VER recordings, the principal artifact is the EEG signal. The baseline response is primarily EEG "noise", whose amplitude is about 50 µV (compared to the VER amplitude of about 10 V). In a single sweep recording, EEG noise completely obscures the VER.

Artifacts Generated by the Recording Equipment

Baseline or Amplifier Noise. All electrical circuits generate electrical noise due to molecular activity and other non-ideal aspects of signal amplification. Equipment baseline noise level can be observed by short circuiting the patient input terminals. This noise level is usually a few microvolts and is random in nature. Its amplitude depends upon the characteristics of the amplifier and on the recording bandwidth (filter settings). The amplitude of this baseline noise is small and therefore does not ordinarily interfere with the evoked potential recordings. If the baseline noise is greater than a few microvolts with shorted inputs, the equipment may be malfunctioning. On the other hand, absence of typical baseline noise is generally indicative of a "dead" or saturated amplifier. If there is a complete absence of equipment baseline noise, or excessive baseline noise, please contact the LKC Service Department.

Electrode Noise. Electrical contact between the subject and recording electrodes is never perfect. The quality of the contact is termed the *electrode impedance* - the lower this quantity, the better, however it will create some electrical noise. The higher the electrode impedance, the more noise is generated. The patient amplifier's susceptibility to electrical noise generated by the external environment increases with increasing electrode impedance. In general, the greater the electrode impedance is, the greater the noise in the recording. Electrode impedance, as measured by the UTAS, should be less than 25 kΩ for low noise recordings. However, if the baseline noise level is not excessive, it is acceptable for the electrode impedance to be higher.

Artifacts Generated by the External Environment

60 Hertz Noise. The principal external interfering signal is electrical noise generated by power lines or electrical equipment connected to power lines. The typical electrical outlet provides 110 Volt electricity, which is more than a million times greater than the amplitude of the ERG! Examples of equipment that can generate electrical interference are fluorescent lights, motors (including motorized chairs), and power transformers. These items produce powerful electromagnetic fields that can induce or couple 60 Hertz interference into the recordings. The closer the patient and the test equipment are to these sources; the more interference will be induced. LKC's balanced patient amplifiers will cancel most of this interference; however, 60 Hz interference may be seen if:

- the patient leads or amplifiers are close to power lines or electrical equipment and/or,
- the electrode impedance is high

Therefore, care should be taken to locate the testing equipment and subject away from any major source of electrical interference and to make sure electrode impedances are as low as possible.

High Frequency Electrical Noise. Besides the power lines or equipment such as motors and transformers, electrical noise can also be produced by equipment generating noise at radio frequencies. Although one might expect such signals to be filtered out by the amplifier filters, it is possible for the equipment to generate low frequency artifacts by nonlinearities in the recording equipment and by mixing with other signals. Care should be exercised to keep the recording equipment and subject away from strong sources of radio frequency signals.

Principal Artifacts and How to Limit or Minimize Them

Understanding the sources of artifacts permits appropriate action to be taken to minimize the magnitude of this interference at the source.

Artifacts Generated by the Subject. Muscle artifacts and eye movement artifacts that are due to improper fixation can be minimized by encouraging the subject to relax and to fixate on the Ganzfeld central fixation light. Press the baseline button to observe the baseline as the subject becomes calm. When it remains essentially horizontal and the random noise level appears "normal," testing may commence.

The photomyoclonic reflex (PMR) is ubiquitous, occurring, to some degree, in most ERGs. If it occurs early in the ERG, the PMR can obscure the entire waveform. If the PMR occurs somewhat later, on the rising portion of the b-wave, it can prevent ERG amplitude estimation. Sometimes, the PMR can mimic an ERG or can add apparent amplitude to ERG responses. Subtle PMRs can be recognized in ERG waveforms in several ways: 1) Changes in ERG waveform slope that are not consistent with the expected slope; 2) ERGs of unusual amplitude or shape; and 3) ERGs that do not replicate. Sometimes, the eye movement is preceded by stimulation of the orbicularis muscle, and the resultant spiking can be observed in the waveform.

If the PMR is present, it can frequently be habituated by presenting repetitive, predictable flashes of light to the subject. Stimulating approximately once per second will properly habituate the subject's response without causing too much light adaptation.

Artifacts Generated by the Environment. As mentioned above, the first step in minimizing this interference is to be sure that there is good electrode contact:

- Be sure to thoroughly clean the site of the electrode placement with skin cleaner.
- All electrode cups should be filled with an adequate amount of electrode gel or cream. If an ECG electrode is used for the reference (-) electrode, make sure that the gel is still wet.
- Good reference connections must be made.
- In ERG recordings, adding an extra drop of artificial tears to the contact lens electrode while it is in the patient's eye may reduce some electrode impedance.
- Any unused recording channels should be shorted by placing a jumper cable between the + and - inputs.
- Electrode leads should be as short as possible and kept away from any electrical equipment, power lines, or electromagnetic fields (it helps to twist the positive and

negative electrode leads in order to cancel their magnetic induction; about one twist per inch is adequate).

With these precautions, electrical noise due to primary power source equipment and radio frequency equipment will ordinarily be within acceptable limits.

How to Deal with Artifacts Using Device Features

Muscle Artifacts. If, after applying the above suggestions, the muscle artifacts are still excessive, they may be reduced by averaging. For the ERG, averaging 10 sweeps should reduce the noise level to an acceptable level. To minimize light adapting the subject from repeated flashes, set the time between sweeps to 15 seconds. Although averaging is the preferred solution in most cases, muscle artifacts may also be partially filtered by the amplifier filters. Since muscle-generated noise is generally at the high end of the spectrum, it can be reduced in the ERG by setting the low-pass (high cut) filter to 100 Hz, rather than the usual default of 500 Hz. A 70 Hz filter may be attempted, but significant distortion of the recording will result and proper latency measurements will not be possible. In the standard EOG protocol, the filter values are preset and cannot be changed.

Another way to deal with muscle noise is to smooth the waveform. Smoothing the waveform produces a filtered effect, which will not alter the latency of the waveform.

Eye Movement Artifacts. If a steady baseline cannot be obtained the baseline may be stabilized by averaging. With averaging, the effects of positive and negative eye movements are partially canceled. Averaging 10 sweeps will generally allow a satisfactory recording to be obtained. If patient light adaptation is a concern with the repeated flashes, set the time between sweeps to 15 seconds. When employing signal averaging with automated artifact rejection, the artifact reject level should be set to eliminate those waveforms that are obviously not representative of the true response. The artifact reject criterion should be selected to be about 20% greater than the largest "true" signal expected. If too many waveforms are rejected, increase the criterion.

Although averaging is the preferred solution in most cases, eye movements can be removed by analog filtering. Since eye movement noise affects the low end of the waveform frequency spectrum, it can be reduced by setting the high-pass (low cut) filter to 1 Hz (rather than the default of DC). The 5 Hz filter may be attempted for difficult cases, but there will be significant distortion on the recording.

Another option for dealing with a drifting baseline is to use the *Baseline Correct* feature in EMWin; see its User Manual for more information.

EEG Artifacts. The primary mechanism for reducing EEG artifacts in the VER is to use signal averaging. Theoretically, EEG noise and other noise uncorrelated with the stimulus will be reduced by the square root of the number of sweeps averaged. For example, if 50 sweeps were averaged, the noise would be reduced by approximately 7. This is usually adequate to obtain satisfactory VER recordings. The use of low pass (high cut) filtering can also be helpful. Whereas the VER default filter setting is at 100 Hz, the 30 Hz filter will produce a smoother waveform. *Note: the use of the 30 Hz filter will add 5 to 10 ms to the latency estimate.*

Artifacts Generated by the Equipment. Other than taking the listed precautions, there may not be much that can be done to reduce the effects of high frequency noise artifacts. It may, in fact, be difficult to recognize this form of interference since it is translated to lie within the bandwidth of the recording. As a rule, if the interference is periodic, and not 60 Hertz, then high frequency noise should be suspected. Depending on the frequency of the interference and where it originates, it may be possible to reduce it by with either the high pass or low pass filters.