510(K) ROUTE SLIP

510(k) NUMBER K925111 PANEL NE DIVISION DCRND BRANCH

TRADE NAME HOUSE INFRARED/VIDEO ELECTRONYSTAGMOGRAPH SYSTEM

COMMON NAME

PRODUCT CODE ___

NEDB GWN ST FA

APPLICANT EYE DYNAMICS, INC.
SHORT NAME EYEDYNA
CONTACT RONALD A WALDORF
DIVISION
ADDRESS 2291 205TH STREET, SUITE 203
TORRANCE, CA 90501
PHONE NO. (310) 328-0477 FAX NO. (310) 328-0697

MANUFACTURER EYE DYNAMICS, INC. REGISTRATION NO. 2028047

DATE ON SUBMISSION 08-OCT-92 DATE DUE TO 510(K) STAFF 23-DEC-92

DATE RECEIVED IN ODE 09-OCT-92 DATE DECISION DUE 07-JAN-93

DECISION __ DECISION DATE MAR 2 3 199

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	11-NOV-93	12-NOV-93	26-JAN-94	10-FEB-94	07-JAN-94
S002	17-JAN-94	18-JAN-94	03-APR-94	18-APR-94	

CORRESPONDENCE	SENT	DUE BACK	
C001	28-SEP-93	30-NOV-93	HOLD LETTER
C002	07-JAN-94	06-FEB-94	HOLD LETTER

SE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

MAR 23 1994

Mr. Ronald A. Waldorf
Chairman
Eye Dynamics, Inc.
2291 205th St., Suite 203
Torrance, California 90501

Re: K925111
House Infrared/Video
Electronystagmograph System
Regulatory Class: II
Dated: January 17, 1994
Received: January 18, 1994

Dear Mr. Waldorf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(K) ROUTE SLIP

510(k) NUMBER K925111 PANEL NE DIVISION DCRND BRANCH

TRADE NAME HOUSE INFRARED/VIDEO ELECTRONYSTAGMOGRAPH SYSTEM

COMMON NAME

PRODUCT CODE

APPLICANT EYE DYNAMICS, INC.
SHORT NAME EYEDYNA
CONTACT RONALD A WALDORF
DIVISION
ADDRESS 2291 205TH STREET, SUITE 203
TORRANCE, CA 90501, CA 90501
PHONE NO. (310) 328-0477 FAX NO. (310) 328-0697

MANUFACTURER EYE DYNAMICS, INC. REGISTRATION NO. 202804

Dmc 1/7/94 hold

DATE ON SUBMISSION 08-OCT-92 DATE DUE TO 510(K) STAFF 23-DEC-9

DATE RECEIVED IN ODE 09-OCT-92 DATE DECISION DUE 07-JAN-9

DECISION DECISION DATE

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	11-NOV-93	12-NOV-93	26-JAN-94	10-FEB-94	

CORRESPONDENCE	SENT	DUE BACK	
C001	28-SEP-93	30-NOV-93	HOLD LETTER

Telephone Hold

JAN 10 1994

Changed Name of MF 9-11-10-93

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-92-5111

10/20/92

Eye Dynamics, Inc.

FROM:
~~OCULOKINETICS, INC.~~
ATTN: RONALD A. WALDORF
2291 205TH STREET
SUITE 203
TORRANCE, CA 90501

LETTER DATE	LOGIN DATE	DUE DATE
10/08/92	10/09/92	01/07/93

TYPE OF DOCUMENT: 510 (k)

CONTROL # K925111

PHONE NO: 310-328-0477

SHORT NAME: OCULOKINETICS ESTABLISHMENT NO: 2028047

TO: ODE/DMC

CONT. CONF.: ?
STATUS : R ~~RA~~ OT NE
REV PANEL : ~~RA~~
PAN/PROD CODE(S): ~~RA~~/~~OT NE~~/ /

SUBJECT:
HOUSE INFRARED/VIDEO ELECTRONYSTAGMOGRAPH SYSTEM

DECISION:
DECISION DATE: / /

RQST INFO DATE:	INFO DUE DATE:
DATE: / /	DATE: / /
DATE: / /	DATE: / /
DATE: / /	DATE: / /
DATE: / /	DATE: / /
DATE: / /	DATE: / /

10.29.92 - MR - Try Opthalmics

DMC — OP 10-~~30~~-92 DMC 9-28-93 RA-Hold

4/16/93 transferred to DCRND

SEP 28 1993

Hold

3

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date: MARCH 15, 1994

From: REVIEWER(S) - NAME(S) JANINE MORRIS

Subject: 510(k) NOTIFICATION K 925111/S2

To: THE RECORD

It is my recommendation that the subject 510(k) Notification:

- ✓ (A) Is substantially equivalent to marketed devices.
- _____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- _____ (C) Requires more data.
- _____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments: 882.1460 Nystagmograph (CLASS II)

Is this device subject to Postmarket Surveillance? Yes ☐ No ☑

This 510(k) contains: (check appropriate box(es))

- ☐ A 510(k) summary of safety and effectiveness, or
- ☑ A 510(k) statement that safety and effectiveness information will be made available
- ☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

- _____ No Confidentiality
- _____ Confidentiality for 90 days
- _____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class: 84 GWN Class II

Additional Product Code(s) w/Panel (optional): 77 ETO ; 86 HLG

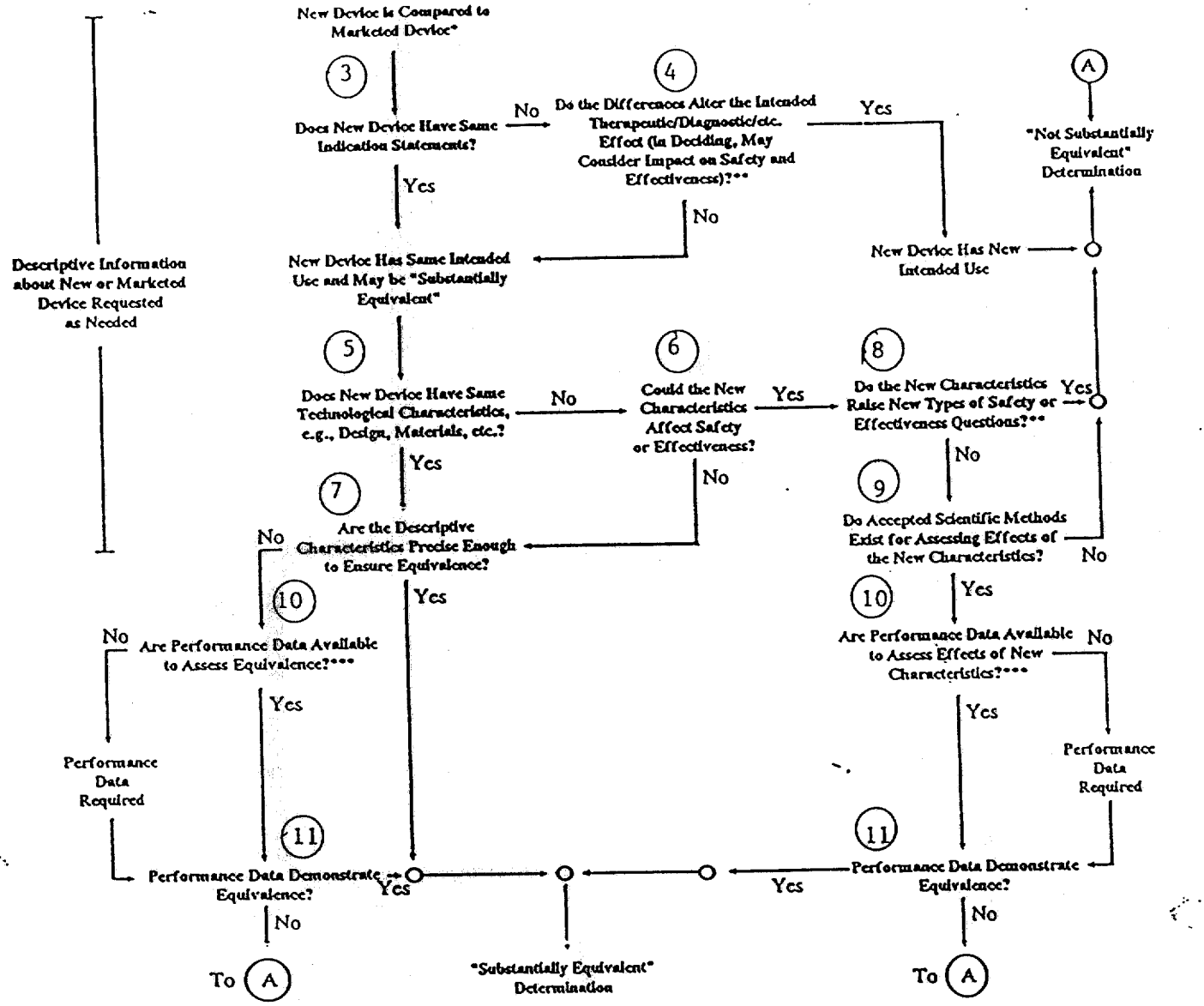
REVIEW: _____ (BRANCH CHIEF) NEDB (BRANCH CODE) 3/22/94 (DATE)

FINAL REVIEW: Lynne Reamer (DIVISION DIRECTOR) MAR 22 1994 (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



- 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

K 925111 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: JANINE MORRIS INFRARED/HDDO DIVISION/BRANCH: DCRND/NEDB

TRADE NAME: ELECTRONYSTAGMOGRAPH SYSTEM COMMON NAME: Nystagmograph

PRODUCT TO WHICH COMPARED: NICOLET NYSTAR PLUS SYSTEM K884294
(510(k) NUMBER IF KNOWN)

		YES	NO	
1.	IS PRODUCT A DEVICE?	✓		- IF NO STOP
2.	DEVICE SUBJECT TO 510(k)?	✓		- IF NO STOP
3.	SAME INDICATION STATEMENT?	✓		- IF YES GO TO 5
(4.)	DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP - NE
5.	SAME TECHNOLOGICAL CHARACTERISTICS?	✓		- IF YES GO TO 7
(6.)	COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			- IF YES GO TO 8
7.	DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	✓		- IF NO GO TO 10 - IF YES STOP - SE
(8.)	NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP - NE
9.	ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP - NE
10.	PERFORMANCE DATA AVAILABLE?			- IF NO REQUEST DAT
(11.)	DATA DEMONSTRATE EQUIVALENCE?			

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

K 925111

Company: EYE DYNAMICS, INC.

Device Proprietary Name: INFRARED/VIDEO ELECTRONYSTAGMOGRAPH SYSTEM

1. Is this device life-supporting or life-sustaining? NO

2. Is this an implanted device (short-term or long-term)? NO

3. If device incorporates a microprocessor, does the firm certify that testing has shown that shows all system requirements are fulfilled and that software changes will require retesting before release? Estimated level of concern is: (Major, Moderate, Minor).

Reviewed by Jim Cheng. (see memo dated 12/27/93)

4. Subject device can be compared to (prior devices): NICOLET NYSTAR PLUS SYSTEM (device name, manufacturer)
BIOLOGIC SYSTEM CORP. K884294
K850180 ENG DEVICE

5. Submission provides: comparative specifications? Yes

bench test or in vitro data? Yes animal test data? NO

clinical data? Yes ref. to industry stds? Yes*

6. SUMMARY (device characteristics; differences between device and preenactment (predicate) devices; new intended use; new technology and new kinds of safety issues):

*ANSI Z-136.1-1993: Standard for devices which emit radiation

7. RECOMMENDATION:

I believe that this device is equivalent to: 84 GWN (panel & product codes)

Classification should be based on: 882.1460 ELECTRO- (CFR Section # and device name)

Nystagmograph presently class: II

other product codes:
77 ETO 86 HLL
86 HLG 86 HMC
86 HLH

Janice Morris 3/15/94 (signed, date)

7

510k REVIEW
SUPPLEMENTAL SUMMARY SHEET

510K NUMBER: K925111B
MANUFACTURER: Eye Dynamics, Inc. (formerly OculoKinetics, Inc.)
DEVICE NAME: House InfraRed/Video Electronystagmographic (ENG) System

SUMMARY:

Device Description and Intended Use

This 510k Notification represents an electronystagmographic (ENG) system intended for recording and analyzing eye movements as part of the ENG examination for vestibular and ocular motor function. This device consists of two modules: House Ocular Motor Module (OMM) and the House IR/Video ENG goggle. The OMM portion of the device consists of a fiberglass viewport containing two black and white video cameras in which the subject's eyes are viewed on standard video monitors. The subject places their face against the viewport and follows a visible target light which moves either horizontally or vertically. Ocular function is typically evaluated by moving light stimuli for smooth pursuit, gaze, and/or saccadic eye movement tasks.

The House IR/Video ENG goggles are light weight plastic goggles which are attached to two black and white video cameras for each eye and are intended for the ENG test portion which includes positional, caloric, or rotational eye movement.

Device Comparison with Predicate Device

The current nystagmographs on the market utilize electrodes to record eye movement. The use of video cameras and infrared light is a new application of well known technology. Data is obtained optically rather than electrically thru electrodes. Although the method to obtain eye movement data is quite different the firm reports there are still a number of similarities:

- Both types of devices record eye movement induced by stimuli including caloric, positional, rotational, ocular motor functions, etc.
- Both systems record classic "saw-tooth" waveforms depicting nystagmus.
- Physicians can directly use data from both systems to analyze nystagmus.
- Both systems have the capability to print standard ENG reports.

The firm reports the advantages in the use of video include:

- There is no electrical contact to the patient
- There is no variation in data due to skin resistance changes, electrode placement, etc.
- Electrode calibration not required
- Eliminates false data that may be introduced with electrodes from tightly closed eyes.
- Permanent video record of exam.
- Record can be analyzed at a later date

8

The principles of operation of this device utilizing video technology and digital processing are described in the firm's letter dated January 17, 1994 on page 4, item 6. Essentially device obtains a record of the eye thru video by physically taking a picture of the eye which does not involve a signal at all. His device takes pictures of the eye at a rate of 60 pictures per second. Through software and hardware his device can identify the pupil as the only dark object. Once the pupil is identified the area of the pupil can be computed and the center located. Once these coordinates are determined for each picture it is a simple calculation to determine the rate of eye movement and track the eye.

Sterilization and Labeling - sterilization not applicable

Material Specification and Biocompatibility Testing - not applicable

Measurement Characteristics
The firm reports the following features as compared with the typical electronystagmograph:

FEATURE	ELECTRICAL	VIDEO
range of horizontal eye movement	± 40°	unlimited
range of vertical eye movement	± 30°	unlimited
accuracy	1-2°	1°
ability to record with closed eyes	yes	no
ability to record with head movement	yes	yes
susceptibility to eye-blink artifact	yes	yes
sensitivity to electrical interference	yes	no
sensitivity to room light	yes	no
sensitivity to EMG interference	yes	no

Since the principles of operation for this device is not based on electrical signal processing it is not possible to directly compare the accuracy of the device with respect to the predicate devices. The firm was requested to provide data to demonstrate that the use of video was still as sensitive to eye movement responses as the predicate devices. The firm provided eye movement data from a patient obtained simultaneously from their device and a predicate device utilizing the typical electrodes which replicates the electrode data on both channels of the IR/Video system (Letter dated November 11, 1993, page 19-22, figures 2 and 3). In addition the firm reports that their device essentially has a sampling frequency of 60 Hz which is comparable to electrode systems subject to a bandwidth of 30 Hz (see page 5 of the January 17, 1994 letter).

9

Software Description, Development, Verification and Testing

(b) (5) [redacted]

Safety Characteristics and Hazard Analysis

(b) (5) [redacted]

Substantial Equivalence

The House InfraRed/Video Electronystagmographic (ENG) System is being compared with predicate nystagmograph devices, e.g., Nicolet Nystar Plus System and Bio-Logic ENG Device (K884294 and K850180) and predicate pupilometer devices, e.g., Pupilscan (K854169).

Based on the information provided the House InfraRed/Video Electronystagmographic (ENG) System has the same intended use as the predicate devices. There seems to be no new technology or safety issues to consider in this design.

It is my recommendation that the House InfraRed/Video Electronystagmographic (ENG) System be found substantially equivalent to predicate devices under **84 GWN Electronystagmograph** and they be classified under **21 CFR 882.1460 class II.**

Other product codes associated with this device include:

77 ETO	Nystagmograph
86 HLG	Pupilometer, powered
86 HLH	Pupilometer, manual
86 HLL	Eye Movement Monitor
86 HMC	Eye Movement Monitor, Diagnostic

Janine M. Morris 3/18/94

Janine M. Morris, Mechanical Engineer
Neurological Devices Branch
Division of Cardiovascular, Respiratory,
and Neurological Devices

February 18, 1994

To: Janine M. Morris,

Subject: Consultant review of K925111/S2 House Infrared/Video Electronystagmograph System

From : Robert J. Landry

I have reviewed the supplementary optical radiation safety information provided for the subject 510k as requested. The results of this review are summarized in the following paragraphs.

(b) (5)

(b) (5)

[redacted]

Please call me at 3-2965 if you wish to discuss this review further.

Robert J. Landry

Robert J. Landry

1.

Hazard Evaluation for IR LED Eye illumination

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFE-401)
1390 Piccard Drive
Rockville, Maryland 20850

January 21, 1994

EYE DYNAMICS, INC.
2291 205TH STREET, SUITE 203
TORRANCE, CA 90501
ATTN: RONALD A. WALDORF

510(k) Number: K925111
Product: HOUSE INFRARED/VIDEO ELECTRONYSTAGMOG RAPH SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K925111 1/2

EYE DYNAMICS, INC.
2291 205th St., Suite 203, Torrance, CA 90501
Telephone (310) 328-0477 Fax (310) 328-0697

January 17, 1994

Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20850

RE: K925111, The House InfraRed/Video Electronystagmographic System
Dated, October 8, 1992
Received, October 9, 1992
Response to request for additional information and clarification

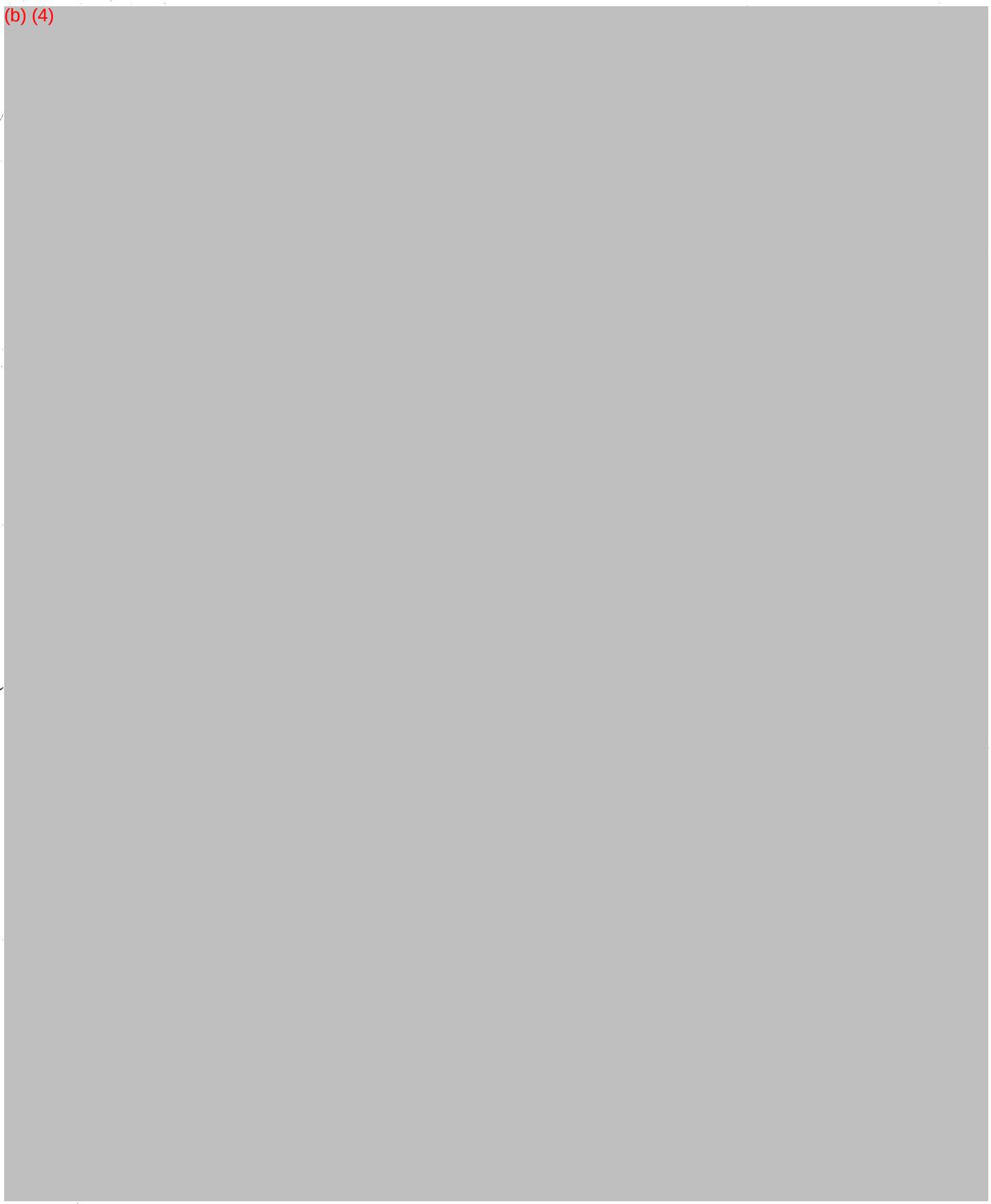
Ladies and Gentleman:

The following is provided as a response to your reviewers request for additional information regarding the pre-market application for The House InfraRed/Video Electronystagmographic System, K925111.

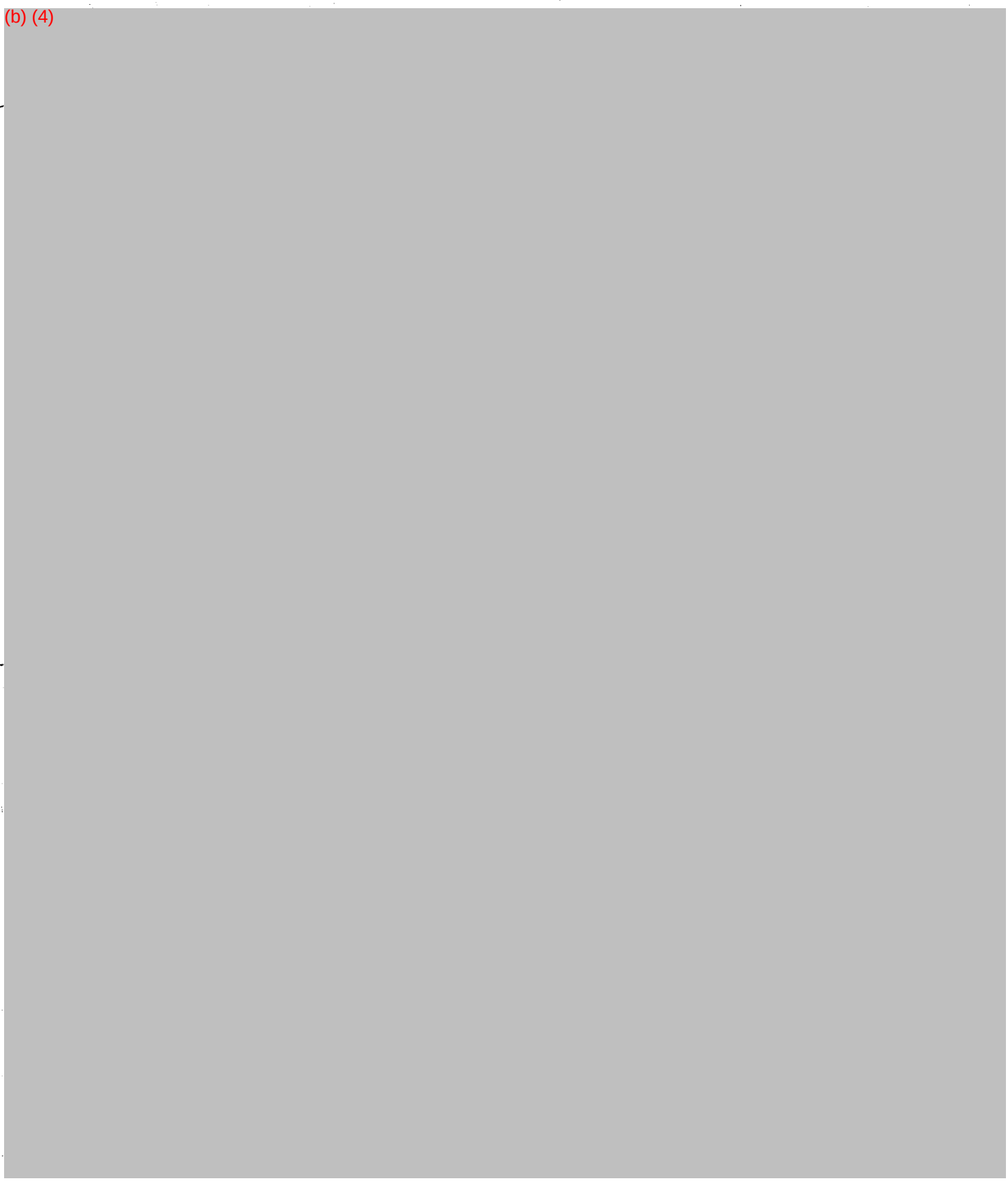
Item 1: Additional information on I/R LED's - Lambertian Radiation Pattern

(b) (4)

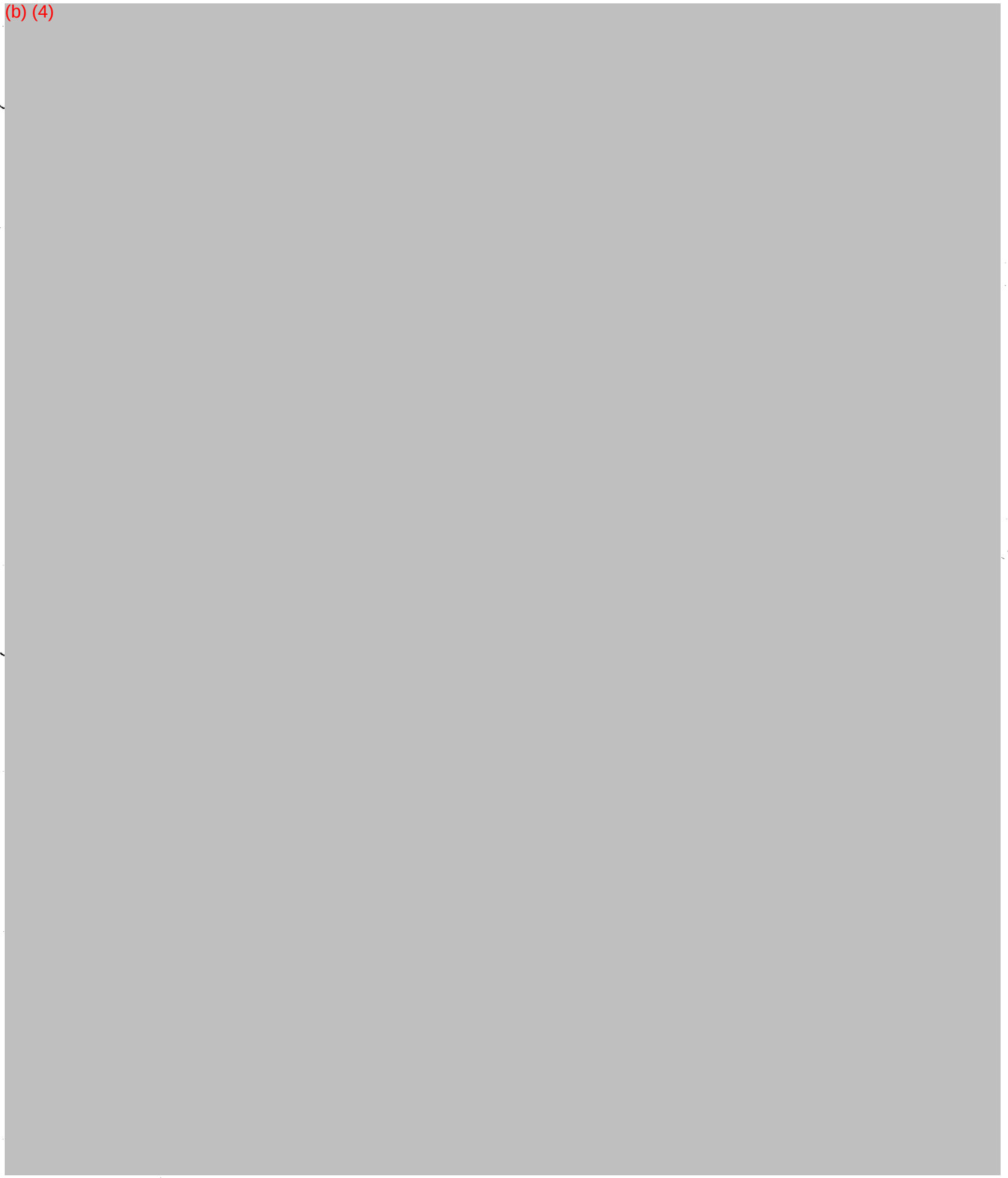
(b) (4)



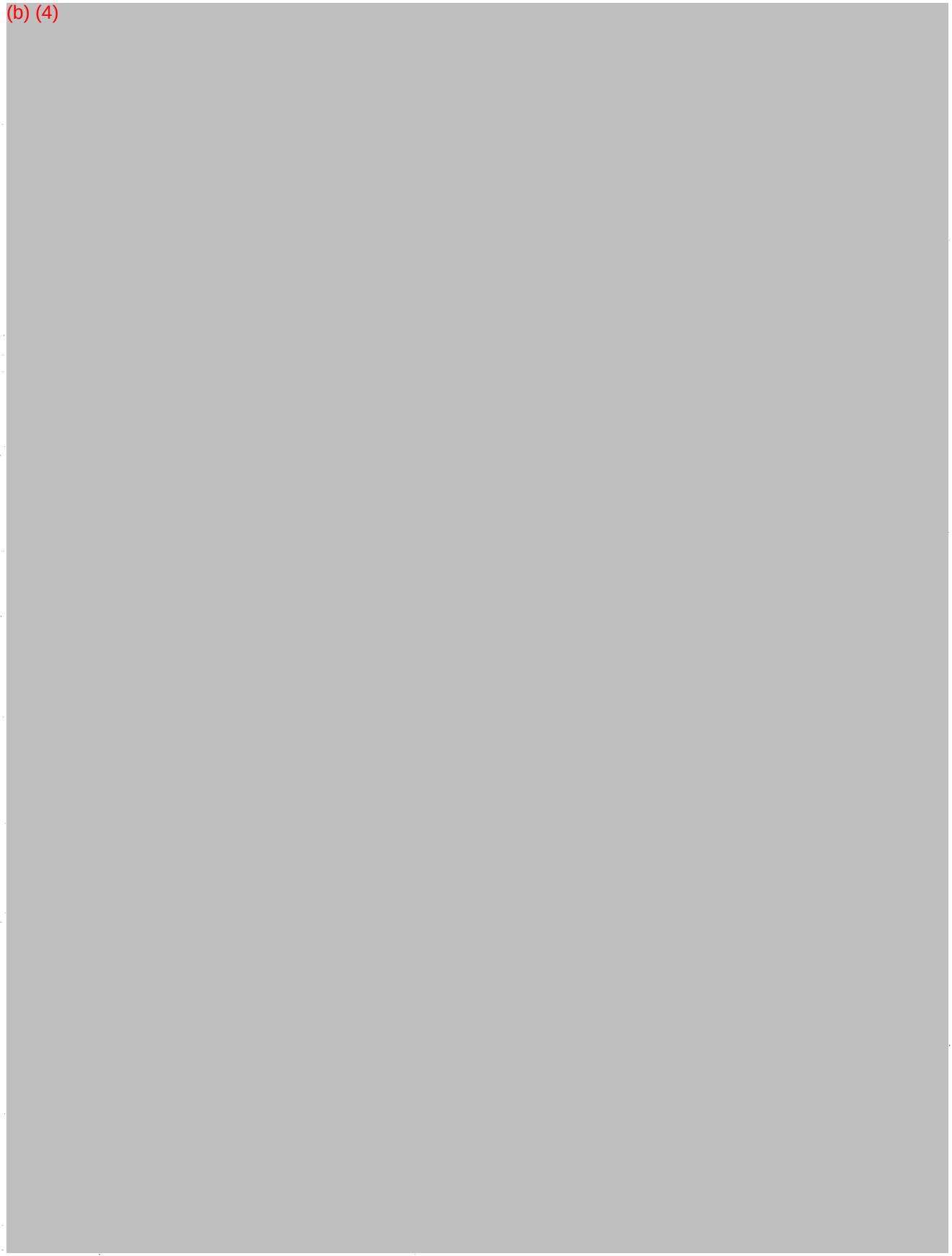
(b) (4)



(b) (4)



(b) (4)



(b) (4)

The above answers all of the requested items. Thank you for your prompt attention and review of these materials.

Sincerely,

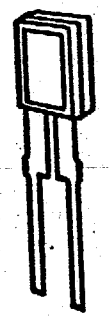
Eye Dynamics, Inc.

Ronald A. Waldorf
Chairman

Infrared Optoisolators

Digi-Key Part No.	Dia-gram	Pulse Forward Current	Optical Power Output	Peak Emission Wavelength	Beam Angle	Pricing 1	10	100	500
PANASONIC INFRARED LIGHT EMITTING DIODE									
LN54PA-ND	L	1 A	4.6mW	950nm	17 deg.	.96	9.10	78.75	332.50
LN64PA-ND	M	1.5 A	7mW	950nm	45 deg.	.87	8.22	71.10	300.20
LN66-ND	O	1.5 A	3-8mW	950nm	25 deg.	.68	6.47	56.03	236.55
* LN175PA-ND	N	2 A	12mW	900nm	115 deg.	2.08	19.68	170.33	719.15

N



DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

January 11, 1994

EYE DYNAMICS, INC.
2291 205TH STREET, SUITE 203
TORRANCE, CA 90501
ATTN: RONALD A. WALDORF

510(k) Number: K925111
Product: HOUSE INFRARED/VIDEO ELECTRONYSTAGMOG RAPH SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

37

510(K) ROUTE SLIP

10(k) NUMBER K925111 PANEL NE DIVISION DCRND BRANCH

TRADE NAME HOUSE INFRARED/VIDEO ELECTRONYSTAGMOGRAPH SYSTEM

COMMON NAME

PRODUCT CODE ___

APPLICANT EYE DYNAMICS, INC.
SHORT NAME EYEDYNA
CONTACT RONALD A WALDORF
DIVISION
ADDRESS 2291 205TH STREET, SUITE 203
TORRANCE, CA 90501
PHONE NO. (310) 328-0477 FAX NO. (310) 328-0697

MANUFACTURER EYE DYNAMICS, INC. REGISTRATION NO. 2028047

DATE ON SUBMISSION 08-OCT-92 DATE DUE TO 510(K) STAFF 23-DEC-92

ATE RECEIVED IN ODE 09-OCT-92 DATE DECISION DUE 07-JAN-93

DECISION __ DECISION DATE

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	11-NOV-93	12-NOV-93	26-JAN-94	10-FEB-94	07-JAN-94

CORRESPONDENCE	SENT	DUE BACK	
C001	28-SEP-93	30-NOV-93	HOLD LETTER
C002	07-JAN-94	06-FEB-94	HOLD LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date 1/7/94

From REVIEWER(S) - NAME(S) JMMorris

Subject 510(k) NOTIFICATION k925111/S1

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices. 1/10/94

✓ (C) Requires more data. per telecom 1/6/94 for clarification

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☑

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☑ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

_____ Confidentiality for 90 days

✓ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

—

Additional Product Code(s) w/Panel (optional):

—

REVIEW: RFan (BRANCH CHIEF) NEDB (BRANCH CODE) 1/7/94 (DATE)

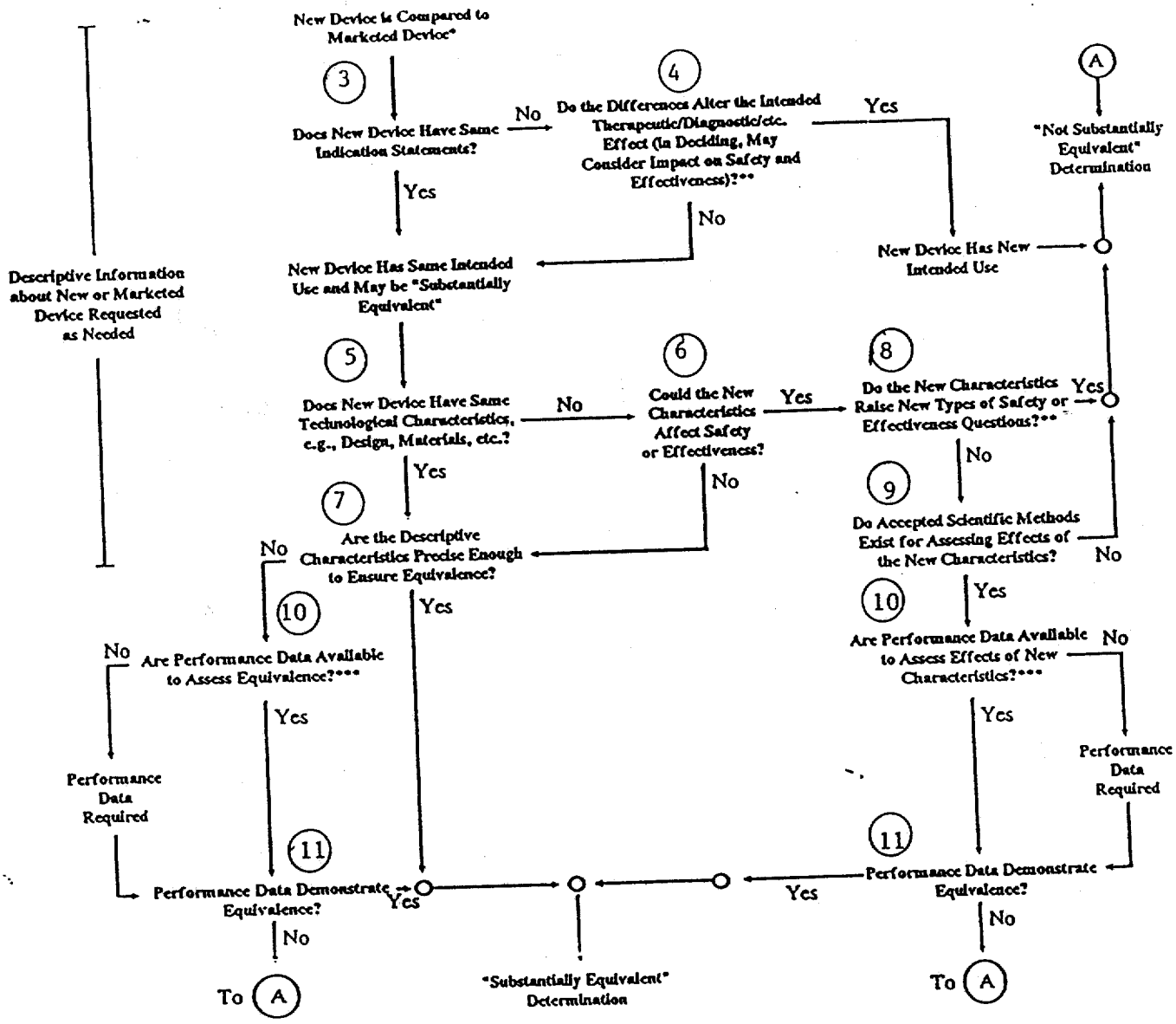
FINAL REVIEW: _____ (DIVISION DIRECTOR) (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

8

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

November 19, 1993

EYE DYNAMICS, INC.
2291 205TH STREET, SUITE 203
TORRANCE, CA 90501, CA 90501
ATTN: RONALD A. WALDORF

510(k) Number: K925111
Product: HOUSE INFRARED/VIDEO ELECTRONYSTAGMOG RAPH SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

I N T E R O F F I C E M E M O R A N D U M

Date: 06-Jan-1994 11:02am EST
From: Robert J. Landry
RJL
Dept: OST-DPS
Tel No: 443-2965

TO: Janine M. Morris (JZM)

Subject: Telecon-Eye Dynamics, Inc.

MEMO TO THE RECORD

FROM: Robert J. Landry, EOB, DPS/OST

SUBJECT: Summary of telephone conversation with representatives of Eye Dynamics Inc. re: additional information submitted for K925111 on potential optical radiation hazards.

At about 1:30 PM on January 5, 1994, I entered into a detailed discussion with Ron Waldorf (Chairman), Barbra(?) Mauch (engineer), and Charles Phillips (President) of Eye Dynamics Inc., re: (b) (4), (b) (5)

(b) (4), (b) (5)

[redacted]

MEMO RECORD

From: James Cheng JC 12/27/93
To: Janine Morris
Subject: K925111 Eye Dynamics, Inc.
House Infrared/Video Electronystagmograph System: Software Consult

Date: 12/27/93
Office: ODE
Division: DCRND

SUMMARY

Janine,

(b) (5)

Jim

December 9, 1993

HFZ-450
DCRND/NEDB

Review Record

K925111
House InfraRed/Video Electronystagmographic (ENG) System
Eye Dynamics, Inc. (formerly OculoKinetics, Inc.)

MEMORANDUM OF TELEPHONE CONVERSATION

Between: JANINE M. MORRIS
DCRND/NEDB, HFZ-450

And: Ronald Waldorf
(310) 328-0477

(b) (4), (b) (5)

[redacted]

Janine M. Morris 12/9/93

Janine M. Morris, Mechanical Engineer
Division of Cardiovascular, Respiratory,
and Neurological Devices

K925111/S1

EYE DYNAMICS, INC.
2291 205th St., Suite 203, Torrance, CA 90501
Telephone (310) 328-0477 Fax (310) 328-0697

November 11, 1993

Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20850

RE: K925111
House InfraRed/Video Electronystagmograph System
Dated: October 8, 1992
Received: October 9, 1992

Response to FDA Letter of September 28, 1993

Ladies and Gentlemen:

The enclosed information is provided as a response to the Food and Drug Administration's letter of September 28, 1993 regarding the 510(k) application for The House InfraRed/Video ENG System.

(b) (4)

THE HOUSE INFRARED/VIDEO ENG SYSTEM

The House InfraRed/Video Electronystagmographic System is used for the recording of multi-channel eye data related to the vestibular and other associated neurological systems.

* First complete, non-electrode eye movement recording system.

* Records multi-channel ENG data related to vestibular and ocular motor examinations.

* Patients' eyes are open in total darkness, eliminating optic fixation.

* Multi-channel recording capability

House IR/Video ENG Goggle

* Comfortable, lightweight goggle equipped with miniature video cameras.

* Safe, invisible, infrared illumination allows the patients to keep their eyes open without fixation.

House Ocular Motor Module

* Can be used for various vestibular examinations:
  - A. Positionals
  - B. Dix-Hallpike
  - C. Calorics
  - D. Torsion Chair
  - E. Rotational Studies

* Simultaneous monocular eye movements are easily observed and can be documented on any conventional video tape recorder.

* Simple operation, binocular horizontal and vertical tracking, gaze and saccadic testing capability.

* Both systems can be interfaced to a computer for automated analysis.

Distributed exclusively by:

JEDMED INSTRUMENT COMPANY
6096 Lemay Ferry Road • St. Louis, MO 63129-2217 • Phone (314) 845-3770 • Fax [314] 845-3771

The House InfraRed/Video ENG System was developed by OculoKinetics, Inc. in conjunction with the House Ear Clinic and Institute, Los Angeles, California.

The InfraRed/Video technology was developed to enhance the science of clinical eye movement testing by elimination of technical artifacts and limitation of electrode-based ENG systems.

The advantages of InfraRed/Video ENG technology as compared to electrode-based ENG techniques are presented in the table below.

The House IR/Video System is equivalent to a pure direct-coupled, 4 channel, ENG system in that bilateral, monocular, horizontal and vertical eye positions and movements can be recorded.

The benefit of The House IR/Video ENG System is that testing can be conducted with the patients' eyes open and without any of the artifacts associated with electrode-based eye movement recordings. No calibrations are required.

In addition, torsional eye movements, i.e., those about the visual axis, can be viewed and documented with The House IR/ Video ENG System.

A printout of the multi-channel ENG data is available.

FEATURE	ELECTRO-OCULOGRAPHY	VIDEO*
Recording device	Paste-on electrodes	Video camera
Principle	Corneoretinal potential	Digital processing of video image
Range of horizontal eye movement, degree	±40	Unlimited
Range of vertical eye movement, degree	±30	Unlimited
Range of torsional eye movement	. . .	Unlimited
Approximate accuracy, degree	1-2	1
Will record when patient's eyes close	Yes	No
Able to record normal vision	Yes	Yes
Able to record during head movement	Yes	Yes
Susceptible to eye blink artifacts	Yes	Yes
Sensitive to changes in room lighting	Yes	No
Sensitive to electrical interference	Yes	No
Sensitive to electromyographic interference	Yes	No
*Computer analyed video recordings		

Source: Baloh and Furman, Modern Vestibular Testing, *Western Journal of Medicine*, 150 (1): 59-67, 1989.

The House IR/Video ENG Goggle: US Patent No. 4,815,239 and Foreign Patents Granted.
House Ocular Motor Module: US Patent No. 5,137,345 and Foreign Patents Pending.
The House name is used with permission from The House Ear Institute, Los Angeles, California.

JEDMED INSTRUMENT COMPANY
6096 Lemay Ferry Road • St. Louis, MO 63129-2217 • Phone (314) 845-3770 • Fax [314] 845-3771

POPH011.193

THE HOUSE INFRARED/VIDEO ELECTRONYSTAGMOGRAPHIC SYSTEM

Version: 2.00

OPERATING MANUAL

The House InfraRed/Video Electronystagmographic System is used for the recording of multi-channel eye data related to the vestibular and other associated neurological systems.

The information contained in this Manual is for the operational use of Eye Dynamics' House InfraRed/Video Electronystagmographic (ENG) System which is comprised of the IR/Video ENG Goggle and the Ocular Motor Module.

These are the video-based components of the House IR/Video ENG System which allow for the observation of a patient's eye movements while their eyes are open in a totally dark, non-fixating, environment during vestibular or ocular motor testing.

The House IR/Video ENG Goggle, through the use of miniature video cameras, magnifies the image of each eye onto the respective video monitors. This allows the ENG operator to view the patient's horizontal, vertical, and torsional (rotary) vestibulo-ocular responses.

The House Ocular Motor Module (OMM) is also an infrared/video based system. This Module contains an operator controlled moving visual target light which provides the stimuli for horizontal or vertical - right or left eye - tracking, saccadic, or gaze testing. There is also a pupil function test capability with the OMM.

For both the House IR/Video ENG Goggle and Ocular Motor Module, the patient's name, folio or chart/ID number, time and date, as well as the description of the stimulus are annotated on the computer data display screen. The eye movements from either the right or left can be recorded on any conventional video tape recorder. Computer analysis of the eye movements is available, along with a hard copy printout of the resulting data.

It is suggested that the operator read this Manual in its entirety prior to installing and operating the House InfraRed/ Video ENG System. This will make it easier to learn the procedures necessary for its clinical application.

B. The Nicolet Nystar Plus - Based on the enclosed Technical Specifications, under the heading of **EOG AMPLIFIER**, this system is a multi-channel (2) electrode ENG system.

C. Biologic ENG System - On page 49 of the 510(k) application, under the heading of **Acquisition Parameters**, the Bio-Logic system is stated to be a multi-channel (2) electrode ENG System. Furthermore, under the heading of **Expansion Capabilities**, the recording channels can be expanded up to 32 channels.

The House InfraRed/Video ENG System is a multi-channel recording system, allowing for up to 4 channels of eye movement recording. Our revised product labeling (Attachment B of the 510(k) application) clarifies this capability by changing the following statement ... "Disconjugate eye movements are easily determined"... to ..."Multi-channel recording capability".

Torsional eye movements are observable on the video monitors as a result of incorporating predicate infrared/video technology as the basis for achieving the intended use of the House InfraRed/Video ENG System. No data is recorded by the House System from the torsional movements and therefore they cannot be used in the House System's multi-channel recording or analysis. The draft product brochure (Attachment B of the 510(k) application) has been revised with the original statement ..."Observes and documents horizontal, vertical and rotary eye movements related to vestibular and ocular motor examinations." ... changed to ..."Records multi-channel ENG data related to vestibular and ocular motor examinations."

Item 3. The statement on the product brochure (Attachment B of the 510(k) application)..."For the first time, the physician can have a truly complete eye movement report for enhanced diagnostic purposes." ... has been changed to ..."A printout of the multi-channel ENG data is available."

Item 4. The statement on page 5 of the 510(k) cover letter regarding differences between the House System and predicate devices, ..."increased reliability/patient safety" ... should be deleted.

NICOLET NYSTAR® PLUS
TECHNICAL SPECIFICATIONS

The Nicolet Nystar® Plus ENG System is an automated, computerized ENG system designed to provide all standard ENG procedures plus advanced ENG testing with on-line analysis of all test results. The system includes a 13" monitor with touch screen operation, an HP printer, an EOG amplifier and a curved, digitally controlled lightbar.

ENG SOFTWARE

Nystagmus analysis of Optokinetic, Caloric, Gaze, Positional, and Positioning testing. Advanced test analysis of vertical EOG, Random Saccade, Rotary Chair, and Smooth Pursuit. Identifies and eliminates contaminating artifacts. Menu-driven with touch screen operation.

Criteria for minimum nystagmus automatic beat analysis:
approximately 2.8 degrees/sec,
2 beats in a 5 second period,
1 to 2 degrees amplitude.
Amplitude resolution: 0.06 degrees.

COMPUTER

Three-microprocessor-based system:
80286 control microprocessor,
8031 microprocessor for offset and gain control,
8751 microprocessor for I/O control.
1 megabyte RAM.

MONITOR

13" amber, high-resolution monochrome (720 horizontal x 348 vertical pixels).

Weight: 45 lbs. (20.5 kg)
Size: 13" x 13" x 17"
(33.0 x 33.0 x 43.2 cm)

CURVED LIGHTBAR OPTICAL STIMULATOR

Curved shape provides a uniform viewing distance at 91 cm. LED is 0.1" x 0.25" each with uniform brightness. 80° x 10° field for optokinetic tests. Computer-controlled target stimulus for all ENG tests. Mar-resistant, glare-reducing red filter. Wall mount bracket with rotation for vertical tests.

Curve size: 56" x 9" x 3.5"
(14.2 x 22.9 x 8.9 cm)

Weight: 28 lbs. (12.7 kg)

DATA STORAGE

The internal disk drive accommodates 3.5" 720 kilobyte disks and provides fast data storage and retrieval. For more speed, an optional 40 Mbyte hard drive can be added.

EOG AMPLIFIER

Two-channel EOG amplifier. True DC coupling with programmable gains and offsets. Optically isolated for patient safety. Two-pole 40-Hz filter with 50/60-Hz notch filter. Automatic gain and offset for each channel under software control.

IMPEDANCE SYSTEM

Internal offset automatically determines unacceptable impedance tolerances. Provides screen display messages for required impedance adjustments.

PRINTER

Hewlett Packard LaserJet III printer—300 dots per inch, horizontal and vertical resolution.

Hewlett Packard DeskJet Plus printer—300 dots per inch, horizontal and vertical resolution.

Hewlett Packard ThinkJet printer—150 cps, 192 dots per inch horizontal, 96 dots per inch vertical.

KEYBOARD

Keyboard facilitates the entry of patient information, date/time, etc.

ACCESSORIES

Patient cable, footswitch, accessory kit (electrodes and skin preparation paste), user manual.

ENVIRONMENTAL SPECIFICATIONS

Storage temperature:	-10 to 130 degrees Fahrenheit (-23 to 55 degrees Centigrade)
Operating temperature:	45 to 90 degrees Fahrenheit (7 to 32 degrees Centigrade)
Relative humidity:	25 to 85% non-condensing
Voltage:	100 to 130 VAC and and 220 to 250 VAC
Frequency:	50 to 60 Hz

Specifications subject to change without notice.
Revised October 1, 1990.

Nicolet Biomedical Instruments

5225 Verona Road, Madison, WI, USA 53711-4495, 608/271-3333, FAX 608/273-5067.
Sales and Service Offices Worldwide, Subsidiary Offices: Belgium, Canada, France, Germany, United Kingdom and Japan.

Nicolet
INSTRUMENTS OF DISCOVERY

Advantages of House IR/Video ENG System

1. No Electrodes
   a. No electrical contact to patient.
   b. No variations in data due to skin resistance changes, electrode placement, CRP fluctuations, etc.
   c. Special training to place electrodes no longer required.
   d. More comfortable to subjects.
   e. The time necessary for electrode calibration is eliminated, allowing for more subjects to be tested per unit time, i.e. a more efficient use of operators time.

2. Observe Eyes In Total Darkness
   a. More natural (subject comfort)
   b. Eliminates false data introduced by tightly closing eyes.

3. Video Tape Actual Eye Movements
   a. Permanent video record.
   b. Record may be analyzed at a later date or other location or by those not present at the actual test.
   ~~c. Can record torsional eye movements.~~

4. Building Block System
   a. Optional ENG Goggle or Ocular Motor Module
   b. Optional computer (data manipulation)

Disadvantages of House IR/Video ENG System

Slightly more expensive then comparable electrode-based computerized ENG systems because of the video cameras, which are more costly then electrodes.

Similarities

* Both types of ENG recording devices [House System or electrodes] record eye movements induced by various stimuli (i.e. caloric, positional, rotational, ocular motor functions, etc.).
* Both systems record classic 'saw-tooth' waveforms depicting nystagmus.
* Doctors can directly use the data from both systems to analyze nystagmus.
* Both types of ENG recording devices print reports in standard ENG format.

Differences:

* Data obtained optically [House System] rather than electrically [electrodes].
* Video record of torsional nystagmus [House System].
* ~~Increased reliability / patient safety [House System].~~

Advantages of House IR/Video ENG System

1. No Electrodes
   a. No electrical contact to patient.
   b. No variations in data due to skin resistance changes, electrode placement, CRP fluctuations, etc.
   c. Special training to place electrodes no longer required.
   d. More comfortable to subjects.
   e. The time necessary for electrode calibration is eliminated, allowing for more subjects to be tested per unit time, i.e. a more efficient use of operators time.

2. Observe Eyes In Total Darkness
   a. More natural (subject comfort)
   b. Eliminates false data introduced by tightly closing eyes.

3. Video Tape Actual Eye Movements
   a. Permanent video record.
   b. Record may be analyzed at a later date or other location or by those not present at the actual test.
   c. Can record torsional eye movements.

4. Building Block System
   a. Optional ENG Goggle or Ocular Motor Module
   b. Optional computer (data manipulation)

Disadvantages of House IR/Video ENG System

Slightly more expensive then comparable electrode-based computerized ENG systems because of the video cameras, which are more costly then electrodes.

Similarities

* Both types of ENG recording devices [House System or electrodes] record eye movements induced by various stimuli (i.e. caloric, positional, rotational, ocular motor functions, etc.).
* Both systems record classic 'saw-tooth' waveforms depicting nystagmus.
* Doctors can directly use the data from both systems to analyze nystagmus.
* Both types of ENG recording devices print reports in standard ENG format.

Differences:

* Data obtained optically [House System] rather than electrically [electrodes].
* Video record of torsional nystagmus [House System].

Item 5. INFRARED HAZARD ANALYSIS

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

ITEM 6. SOFTWARE VERIFICATION, VALIDATION & TESTING

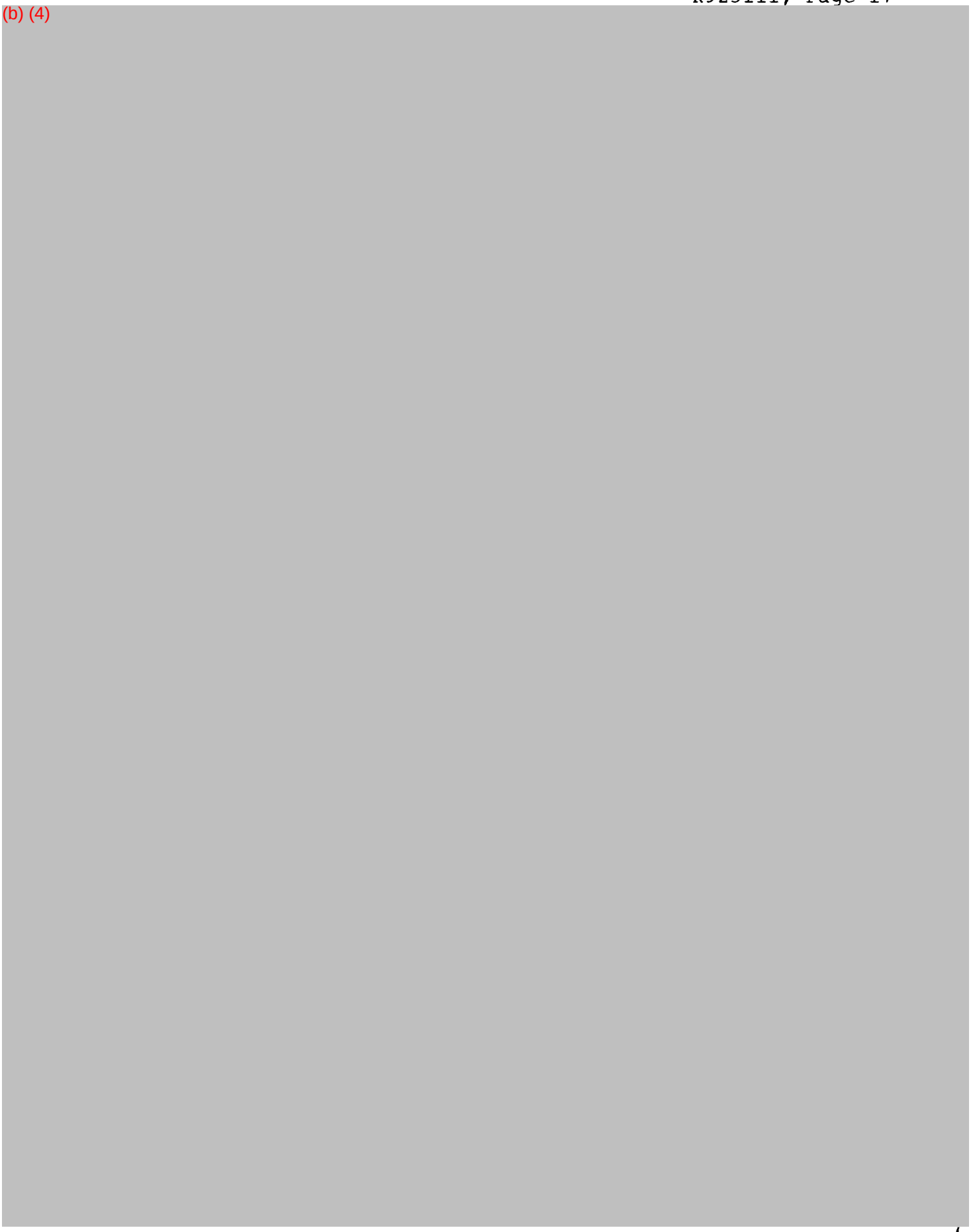
(b) (4)

(b) (4)

FAILURE TYPE

Figure 1. Fault Tree Analysis

(b) (4)



Testing/Verification/Validation:

(b) (4)

(b) (4)

[redacted]

III. Testing/Verification/Validation of the Entire System:

As the above history indicates, the individual software

(b) (4)

[redacted]

(b) (4)

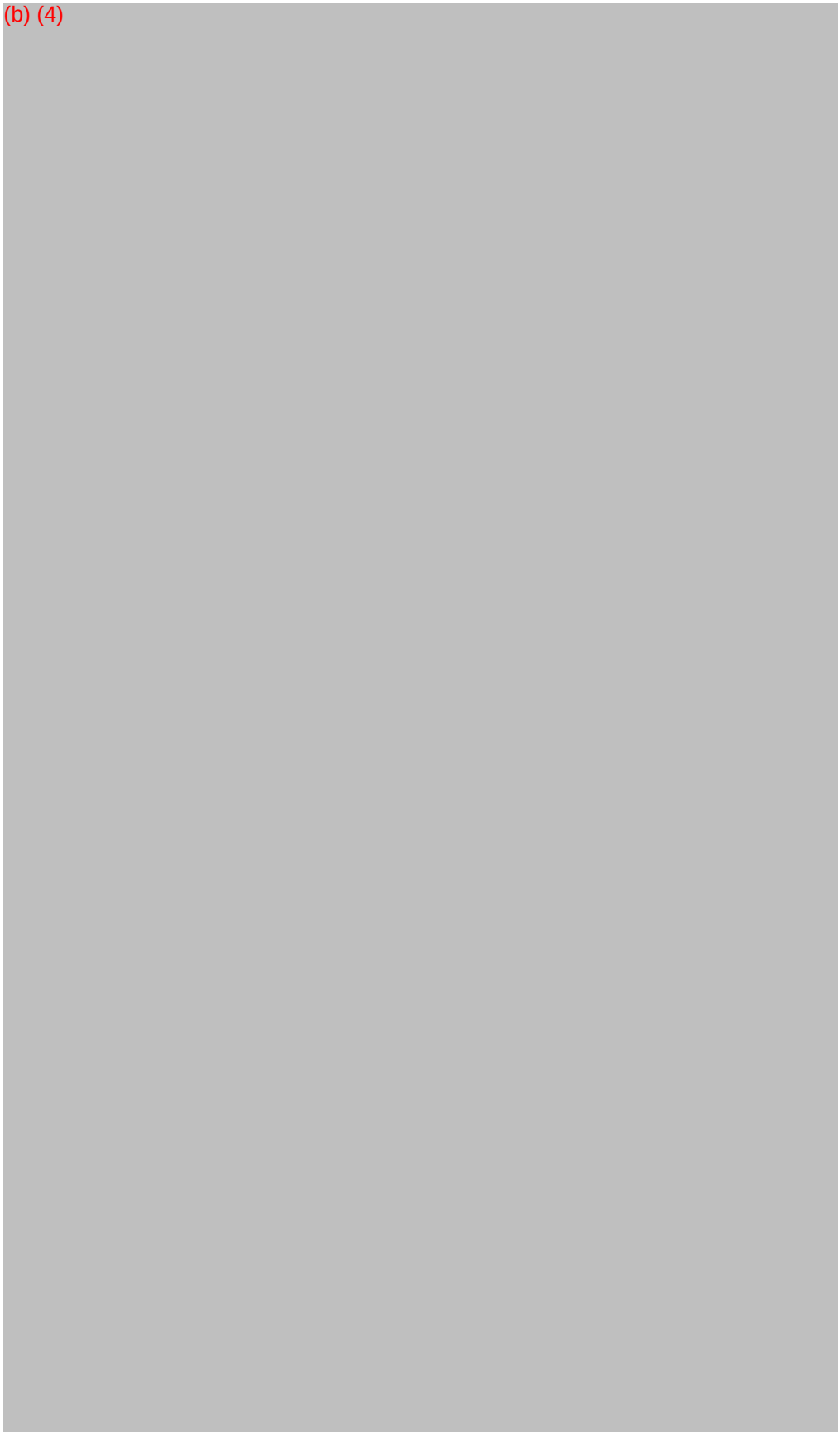
(b) (4)

(b) (4)

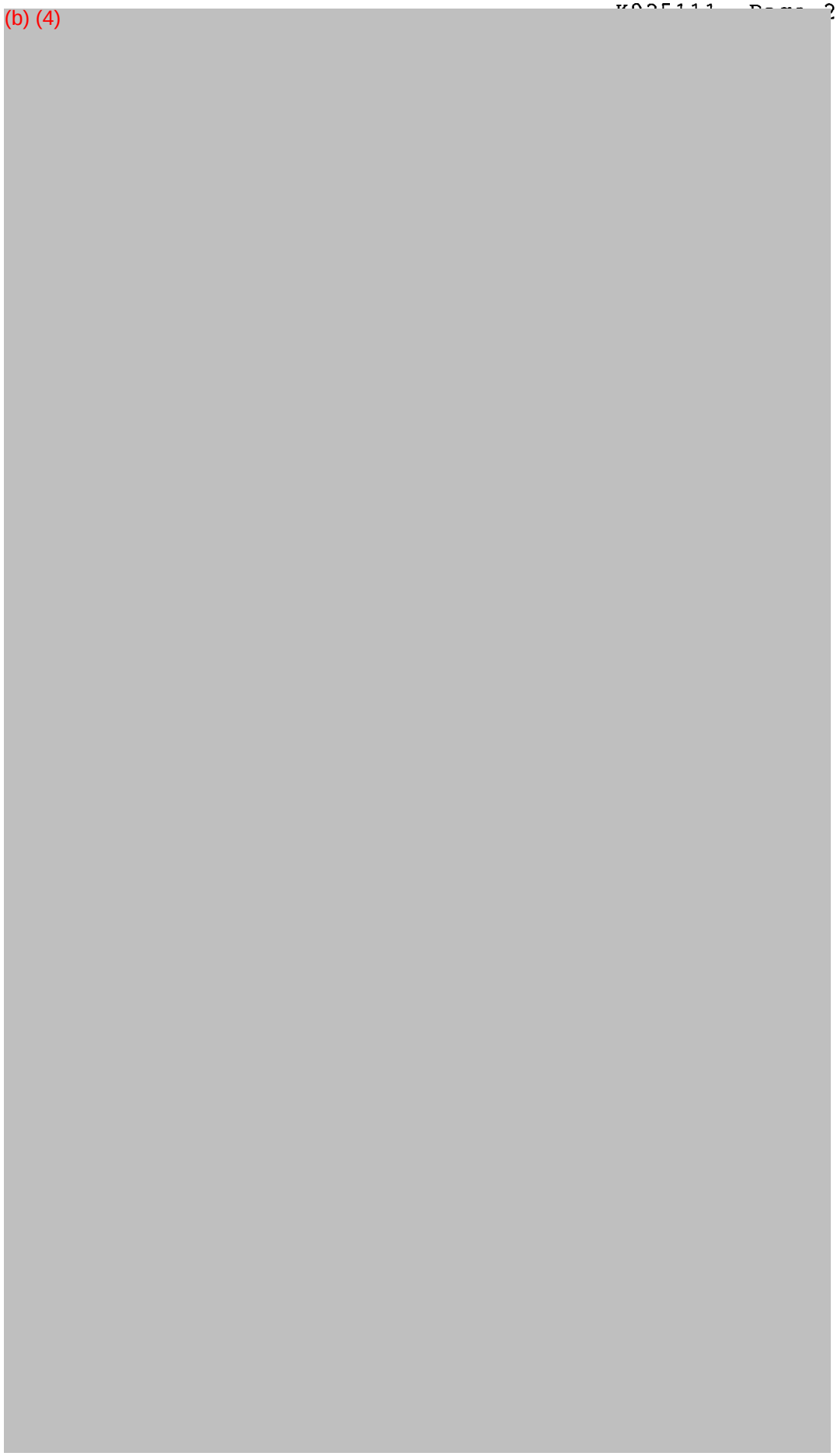
IV. Maintenance

(b) (4)

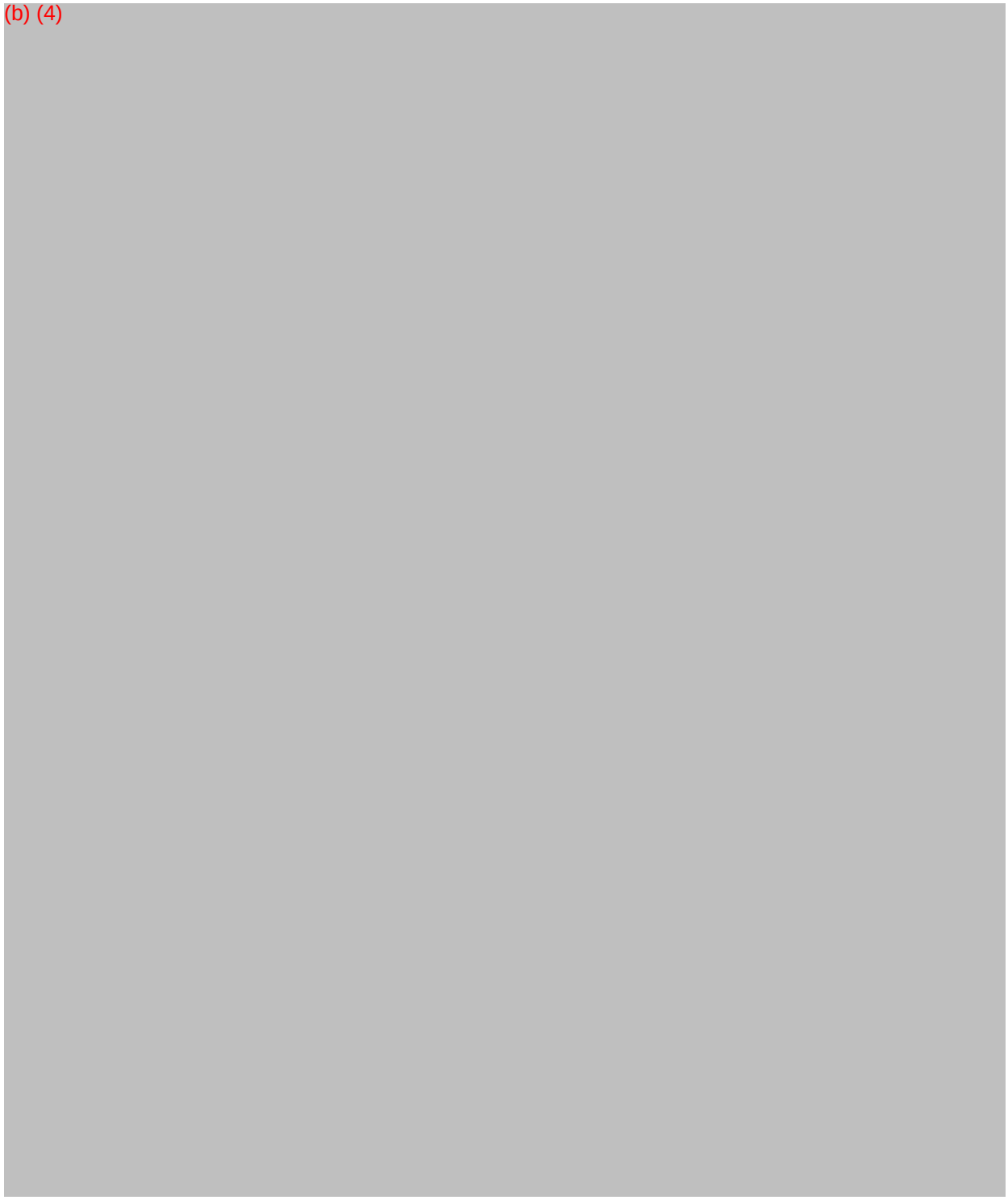
(b) (4)



(b) (4)



(b) (4)



V. Certification

I hereby certify that the stated software development process was followed, that Good Quality Assurance Procedures were adhered to and that test results demonstrate that the system specification and functional requirements were met.

Eye Dynamics, Inc.

Ronald A. Waldorf **Date** Nov. 11, 1993

Chairman

We have answered all the items and submitted herewith supporting documents and data as requested in your letter of September 28, 1993. Thank you for your prompt attention and review of the submitted materials.

Sincerely,

Eye Dynamics, Inc.

Ronald A. Waldorf
Chairman

Enc.

70

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

CORRECTION

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

November 10, 1993

EYE DYNAMICS, INC.
2291 205TH STREET, SUITE 203
TORRANCE, CA 90501, CA 90501
ATTN: RONALD A. WALDORF

510(k) Number: K925111
Product: HOUSE
INFRARED/VIDEO
ELECTRONYSTAGMOG
RAPH SYSTEM

Extended Until: 30-NOV-93

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

71

510(K) ROUTE SLIP

510(k) NUMBER K925111 PANEL NE DIVISION DCRND BRANCH

TRADE NAME HOUSE INFRARED/VIDEO ELECTRONYSTAGMOGRAPH SYSTEM

COMMON NAME

PRODUCT CODE

APPLICANT EYE DYNAMICS, INC.
SHORT NAME EYEDYNA
CONTACT RONALD A WALDORF
DIVISION
ADDRESS 2291 205TH STREET, SUITE 203
TORRANCE, CA 90501, CA 90501
PHONE NO. (310) 328-0477 FAX NO. (310) 328-0697

MANUFACTURER EYE DYNAMICS, INC. REGISTRATION NO. 2028047

DATE ON SUBMISSION 08-OCT-92 DATE DUE TO 510(K) STAFF 23-DEC-92

DATE RECEIVED IN ODE 09-OCT-92 DATE DECISION DUE 07-JAN-93

DECISION DECISION DATE

CORRESPONDENCE	SENT	DUE BACK	
C001	28-SEP-93	30-NOV-93	HOLD LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

November 09, 1993

OCULOKINETICS, INC.
2291 205TH STREET
SUITE 203
TORRANCE, CA 90501
ATTN: RONALD A. WALDORF

510(k) Number: K925111
Product: HOUSE INFRARED/VIDEO ELECTRONYSTAGMOGRAPH SYSTEM

Extended Until: 30-NOV-93

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until' date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-119[illegible].

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

EYE DYNAMICS, INC.
2291 205th St., Suite 203, Torrance, CA 90501
Telephone (310) 328-0477 Fax (310) 328-0697

October 17, 1993

Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20850

RE: K925111
House InfraRed/Video Electronystagmograph System
Dated: October 8, 1992
Received: October 8, 1992

Request For Extension To Respond To FDA Letter Of 9/28/93

Ladies and Gentlemen:

Because of a illness in the family of one of the key individuals involved in developing the response to the questions contained in your letter of September 28, 1993, a 30-day extension for submittal of the information desired is requested.

In addition, since the time of the submittal of this 510(k) application, OculoKinetics, Inc. has changed its name to Eye Dynamics, Inc. Please make this change to your records as required.

Should you require any additional information, please contact me at (310) 328-0477. Thank you for your cooperation.

Sincerely,

Eye Dynamics, Inc.

Ronald A. Waldorf
Chairman

RW/bg

24

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

November 05, 1993

OCULOKINETICS, INC.
2291 205TH STREET
SUITE 203
TORRANCE, CA 90501
ATTN: RONALD A. WALDORF

510(k) Number: K925111
Product: HOUSE INFRARED/VIDEO ELECTRONYSTAGMOGRAPH SYSTEM

Extended Until: 29-NOV-93

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

EDI EYE DYNAMICS, INC.
2291 205th St., Suite 203, Torrance, CA 90501
Telephone (310) 328-0477 Fax (310) 328-0697

October 17, 1993

Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20850

RE: K925111
House InfraRed/Video Electronystagmograph System
Dated: October 8, 1992
Received: October 8, 1992

Request For Extension To Respond To FDA Letter Of 9/28/93

Ladies and Gentlemen:

Because of a illness in the family of one of the key individuals involved in developing the response to the questions contained in your letter of September 28, 1993, a 30-day extension for submittal of the information desired is requested.

In addition, since the time of the submittal of this 510(k) application, OculoKinetics, Inc. has changed its name to Eye Dynamics, Inc. Please make this change to your records as required.

Should you require any additional information, please contact me at (310) 328-0477. Thank you for your cooperation.

Sincerely,

Eye Dynamics, Inc.

Ronald A. Waldorf
Chairman

RW/bg

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

SEP 28 1993

Mr. Ronald A. Waldorf
Chairman
OculoKinetics, Inc.
2291 205th Street, Suite 203
Torrance, California 90501

Re: K925111
House InfraRed/Video Electronystagmograph System
Dated: October 8, 1992
Received: October 9, 1992

Dear Mr. Waldorf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete our review, we require the following:

(b) (4)

(b) (4)

[redacted]

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.

---

[1] Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, 1992-1993, American Conference of Governmental Industrial Hygienists, ISBN: 0-936712-99-6, Cincinnati, Ohio, 1992.

[2] American National Institute Standard for the Safe Use of Lasers, 1993, ANSI Standard Z-136.1, 1430 Broadway, New York, N.Y.

If you have questions concerning the contents of this letter, please contact Janine M. Morris at (301) 594-1744.

Sincerely yours,

Lynne Reamer

for Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) ROUTE SLIP

510(k) NUMBER K925111 PANEL NE DIVISION DCRND BRANCH

TRADE NAME HOUSE INFRARED/VIDEO ELECTRONYSTAGMOGRAPH SYSTEM

COMMON NAME

PRODUCT CODE ___

APPLICANT OCULOKINETICS, INC.
SHORT NAME OCULOKINETICS
CONTACT RONALD A WALDORF
DIVISION
ADDRESS 2291 205TH STREET
SUITE 203
TORRANCE, CA 90501
PHONE NO. (___) ___-____ FAX NO. (___) ___-____

MANUFACTURER OCULOKINETICS, INC. REGISTRATION NO. 2028047

DATE ON SUBMISSION 08-OCT-92 DATE DUE TO 510(K) STAFF

DATE RECEIVED IN ODE 09-OCT-92 DATE DECISION DUE 07-JAN-93

DECISION __ DECISION DATE

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
____					

OUT GOING CORRESPONDENCE

SUPP001		28-SEP-93		28-OCT-93	

SEP 28 1993

Mr. Ronald A. Waldorf
Chairman
OculoKinetics, Inc.
2291 205th Street, Suite 203
Torrance, California 90501

Re: K925111
House InfraRed/Video Electronystagmograph System
Dated: October 8, 1992
Received: October 9, 1992

Dear Mr. Waldorf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete our review, we require the following:

(b) (4)

(b) (4)

[redacted]

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.

---

[1] Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, 1992-1993, American Conference of Governmental Industrial Hygienists, ISBN: 0-936712-99-6, Cincinnati, Ohio, 1992.

[2] American National Institute Standard for the Safe Use of Lasers, 1993, ANSI Standard Z-136.1, 1430 Broadway, New York, N.Y.

If you have questions concerning the contents of this letter, please contact Janine M. Morris at (301) 594-1744.

Sincerely yours,

Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Draft:JMMORRIS:jmm:9/21/93
final type:jau:9/27/93
Spellchk:jmm:9/21/93
Proofread:

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
2450	Morris	9/27						
HFZ450	Murray	9/28/93						
450	Reimer	9/29/93						

☆ U.S. GOVERNMENT PRINTING OFFICE 1991-511-771

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

ate 9/21/93

rom REVIEWER(S) - NAME(S) JM Morris

ubject 510(k) NOTIFICATION K925111

o THE RECORD

It is my recommendation that the subject 510(k) Notification:

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

✓ (C) Requires more data. per letter. 9/28/93 HOLD

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☒

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☒ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

_____ Confidentiality for 90 days

✓ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class: [redacted]

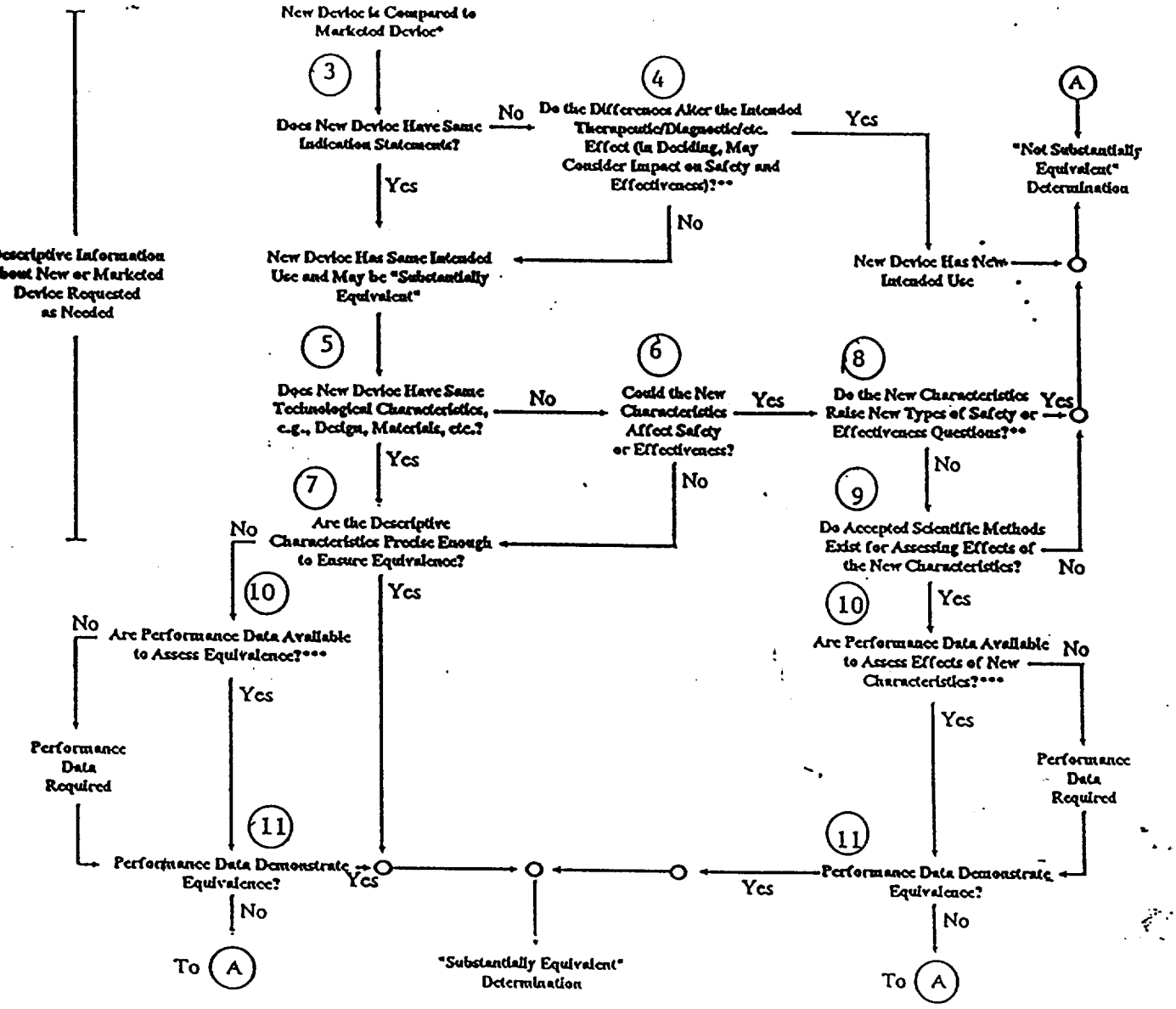
Additional Product Code(s) w/Panel (optional): _____

REVIEW: _____ (BRANCH CHIEF) NEDB (BRANCH CODE) 9/28/93 (DATE)

FINAL REVIEW: _____ (DIVISION DIRECTOR) (DATE)

84

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

510k REVIEW
SUPPLEMENTAL SUMMARY SHEET

510K NUMBER: K925111
MANUFACTURER: OculoKinetics, Inc.
DEVICE NAME: House InfraRed/Video Electronystagmographic (ENG) System

SUMMARY:

This 510k was logged into the Neurological Devices Branch from Opthalmics Branch on 4/19/93, three months after the 90th day due date. In accordance with Program Integrity, Document Reviewing Processing, #I91-1 (2/4/92), this file was placed in queue along with my other documents. In June 1993 I received a large PMA for expedite review which required me to suspend all my current 510k documents. Finally in August 1993 we were provide with OST resources which allowed us to transfer this document to Bob Landry to review. It was agreed that Bob Landry conduct the majority of the review and I would conduct the administrative work and draft the appropriate letter to the firm.

Attached is Bob Landry's review and comments regarding this device and it was concluded that additional information was required before a substantial equivalence determination could be made. In addition to Bob's request for additional information the firm must also provide additional information regarding verification, validation, and testing of the software incorporated into their device.

Janine M. Morris 9/21/93

Janine M. Morris, Mechanical Engineer
Neurological Devices Branch
Division of Cardiovascular, Respiratory,
and Neurological Devices

To: Janine M. Morris,

Subject: Consultant review of K925111 House Infrared/Video Electronystagmograph System

From : Robert J. Landry

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

For your convenience I have attached a list of requests for additional information/clarification that you may wish to use as you deem appropriate for this 510k. Please call me at 3-2965 if you wish to discuss this review further.

Robert J. Landry

REQUESTS FOR ADDITIONAL INFORMATION/CLARIFICATION

(b) (4)

(b) (4)

K_____ "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER:_____ DIVISION/BRANCH:_____

TRADE NAME:_____ COMMON NAME:_____

PRODUCT TO WHICH COMPARED: Biologix ENT (K850150); Nicolet (K851190); Micromed (K863424)
(510(k) NUMBER IF KNOWN)

	YES	(NO)	
1. IS PRODUCT A DEVICE?			- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?			- IF NO STOP
3. SAME INDICATION STATEMENT?			- IF YES GO TO 5
(4.) DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP - NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?			- IF YES GO TO 7
(6.) COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?			- IF NO GO TO 10 - IF YES STOP - SE
(8.) NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP - NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP - NE
10. PERFORMANCE DATA AVAILABLE?			- IF NO REQUEST DAT
(11.) DATA DEMONSTRATE EQUIVALENCE?			

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: _____

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

SUMMARY: _____

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. EXPLAIN WHY NOT A DEVICE:_____

2. EXPLAIN WHY NOT SUBJECT TO 510(k):_____

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION:_____

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE:_

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS:_____

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS:_____

7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH:

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW:

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED:

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED:

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT:

ATTACH ADDITIONAL SUPPORTING INFORMATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

OCTOBER 20, 1992

OCULOKINETICS, INC.
ATTN: RONALD A. WALDORF
2291 205TH STREET
SUITE 203
TORRANCE, CA 90501

510(k) Number: K925111
Received: 10-09-92
Product: HOUSE
INFRARED/VIDEO
ELECTRONYSTAGMOGRAPH

We have received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date, you may want to check with FDA to determine the status of your submission.

In addition, the SMDA requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages manufacturers to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. **Since the law**

requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that a device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 227-8639.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

OculoKinetics, Inc. k925111

Submitted: October 8, 1992

Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20850

RE: 510(K) Notification
House InfraRed/Video Electronystagmographic (ENG) System

Ladies and Gentlemen:

In accordance with section 510(K) of the Federal Food, Drug, and Cosmetic Act, and in conformance with 21 CFR 807, this premarket notification is being submitted prior to the date when OculoKinetics, Inc. proposes to introduce into interstate commerce for commercial distribution an eye movement device to be known as the House InfraRed/Video Electronystagmographic (ENG) System.

The following information is being submitted in conformance with 21 CFR 807.87 to notify you that OculoKinetics, Inc. intends to market the following device:

1.	Classification Name:	Nystagmograph
	Trade/Proprietary Name:	House InfraRed/Video Electronystagmograph System
	Common/Usual Name:	House IR/Video ENG System
2.	Establishment Registration Number:	2028047 (OculoKinetics, Inc.)
3.	Device Classification:	Class II 882.1460 Nystagmograph
4.	Performance Standards:	Not Applicable
5.	Label/Promotional Material:	Draft labeling, promotional literature and Instructions for Use are included in Attachment A, B & C, respectively.

2291 205th Street, Suite 203 • Torrance, California 90501 • (310) 328-0477 FAX (310) 328-0697

6. Substantial Equivalence:

Substantially equivalent devices are commercially available in the U.S. which generate the same type of data as the House InfraRed/ Video ENG System. These devices are described below along with an overview of the ENG examination.

Modern vestibular (balance system) and/or neurological function testing has focused on objective measurements of vestibular reflex activity, including vestibulo-ocular reflexes. Electro-nystagmography (ENG) is the simplest and most readily available method for recording eye movements related to the evaluation of vestibular or ocular motor function (Baloh & Furman, 1989. Copy provided in Attachment D). An overview of the ENG examination is described in Electronystagmography 1990 (copy is provided in Attachment D). A bibliography of other literature references is also enclosed in Attachment D.

The House InfraRed/Video Electronystagmographic (ENG) System provides for the video observation and/or the recording and analysis of eye movements as part of the ENG examination. The House InfraRed/Video ENG System is comprised of the following modules: the House Ocular Motor Module and the House IR/Video ENG Goggle (See Photo's 1 & 2, page 9 of this Cover Letter). System specifications are provided in Attachment C, pages 29 and 30.

The House Ocular Motor Module (OMM) is a fiberglass viewport which contains two black and white video cameras (one per eye). The operator, usually an ENG technician or medical practitioner, easily views the subject's eyes on standard video monitors. The House OMM allows for the observation and/or recording of eye movements related to those portions of the ENG examination which test for ocular motor function, commonly evaluated by moving light stimuli conventionally known as smooth pursuit, gaze, and/or saccadic eye movement tasks. During these tests, the subject places his or her face against the foam rubber lined House OMM viewport and follows a visible target light which moves, under operator/computer control, either horizontally (left and right) or vertically (up and down).

The House InfraRed/Video ENG Goggle is a light-weight, plastic goggle to which is attached two black and white video cameras, one for the observation of each eye. The House IR/Video ENG Goggle is worn by the subject during those portions of the ENG examination which test for positional, caloric, or rotational eye movement responses.

As with the other substantially equivalent marketed devices described below, the medical practitioner can request an entire ENG examination be performed, or some subset or partial ENG Examination. For example, some subjects may require an ENG exam which only evaluates ocular motor eye movement responses whereas other subjects may have only caloric procedures. Therefore, it is possible to have

applications where only the House Ocular Motor Module or the House IR/Video ENG Goggle would be required. A complete examination would, of course, necessitate the use of both modules comprising the total House InfraRed/Video ENG System. The medical practitioner interprets the subjects' eye movement responses. These responses are evaluated from the observation of the subject's eye movement responses and/or from the recordings generated either from electrode recorded signals or, as in the case of the House InfraRed/Video ENG System, from the video signal.

Literature for substantially equivalent marketed electrode ENG devices and their comparison with the House InfraRed/Video ENG System is provided in Attachments E and F, respectively.

The House InfraRed/Video Electronystagmographic (ENG) System is substantially equivalent to the following products which are commercially available in the U.S.:

1. Nystar Plus ENG System — K Number: K851190, K851190A, K884294
   Nicolet Biomedical Instruments
   5225-4 Verona Road
   Madison, WI 53711
   (800) 345-6880
   (608) 271-3333
   Attachment E, Pages 1-11

2. Computerized ENG System — K Number: K850180, K850180A
   Bio-Logic Systems Corp.
   One Bio-Logic Plaza
   Mundelein, Il 60060
   (312) 949-5200
   (800) 323-8326
   Attachment E, Pages 12-13

3. Model 1500B Computerized ENG — K Number: K863424, K863424A
   Micromedical Technologies
   110 W. Walnut
   Chatham, IL 62629
   (800) 334-4154
   Attachment E, Pages 14-19

These substantially equivalent ENG systems utilize electrodes, attached to the subjects skin around the eyes for the recording of eye movements, and computer analysis of the resulting data. The House IR/Video ENG System does not use electrodes or any other electrical connections to the subject. It simply uses video cameras which are aimed to look at a subject's eyes with the resulting video signals available for the observation of these eye responses by the operator/medical practitioner on the respective video monitors (see pictures 1 and 2) and/or for the recording and analysis by the dedicated computer system and/or any conventional video tape recorder (VCR). The digitized House IR/Video ENG data also includes information regarding pupil size, if this option is desired by the medical practitioner.

Illumination of the eye is provided by diffuse, non-coherent (non-laser), low-level near infrared light-emitting diodes (LED's) with peak wavelengths of 940 nanometers. This common place infrared illumination is invisible to the subject. The video cameras are selected because of their sensitivity to this infrared illumination.

When the subject places his or her face against the foam rubber seal on the OMM or the IR/Video Goggle, all of the visible outside, or ambient light, is eliminated from the internal chambers of the modules. The internal infrared illumination allows the subject to keep their eyes open without having the ability to see anything inside the Goggle or Ocular Motor Module. This is an advantage over electrode-based ENG systems which require the subject to keep their eyes closed which may cause changes in the way the eye moves behind the closed eye lid, or changes in the CRP, or even from certain mechanical artifacts in the recorded eye movement data from eye lid tremor.

In addition, electrode-based ENG systems, because of inherent technical limitations of electrode placement and CRP physiology, can not establish the presence of torsional eye movements, i.e. those eye movements about the eye's visual axis. With The House IR/Video ENG System this limitation is eliminated since torsional eye movements can be easily observed by the operator/medical practitioner on the video monitors.

This infrared method for the illumination of the eye is substantially equivalent to the following product which is commercially available in the U.S.:

4. PUPILSCAN K Number: K854169
Fairville Medical Optics, Inc.
P.O. Box 832
Mendenhall, PA 19357
(215) 388-0383 Attachment E, Pages 25-26

Literature for the PUPILSCAN and its comparison with the House InfraRed/Video ENG System is provided in Attachments E and F, respectively.

Examples of data recorded from the House IR/Video ENG System are provided in the Instruction for Use Manual (Attachment C, pages 21 - 23). An example of data from an electrode-based ENG system is also provided (Attachment E, pages 20-24).

In summary, the House InfraRed/Video Electronystagmographic System compares to conventional ENG systems as follows:

Advantages of House IR/Video ENG System

1. No Electrodes
   a. No electrical contact to patient.
   b. No variations in data due to skin resistance changes, electrode placement, CRP fluctuations, etc.
   c. Special training to place electrodes no longer required.
   d. More comfortable to subjects.
   e. The time necessary for electrode calibration is eliminated, allowing for more subjects to be tested per unit time, i.e. a more efficient use of operators time.

2. Observe Eyes In Total Darkness
   a. More natural (subject comfort)
   b. Eliminates false data introduced by tightly closing eyes.

3. Video Tape Actual Eye Movements
   a. Permanent video record.
   b. Record may be analyzed at a later date or other location or by those not present at the actual test.
   c. Can record torsional eye movements.

4. Building Block System
   a. Optional ENG Goggle or Ocular Motor Module
   b. Optional computer (data manipulation)

Disadvantages of House IR/Video ENG System

Slightly more expensive then comparable electrode-based computerized ENG systems because of the video cameras, which are more costly then electrodes.

Similarities

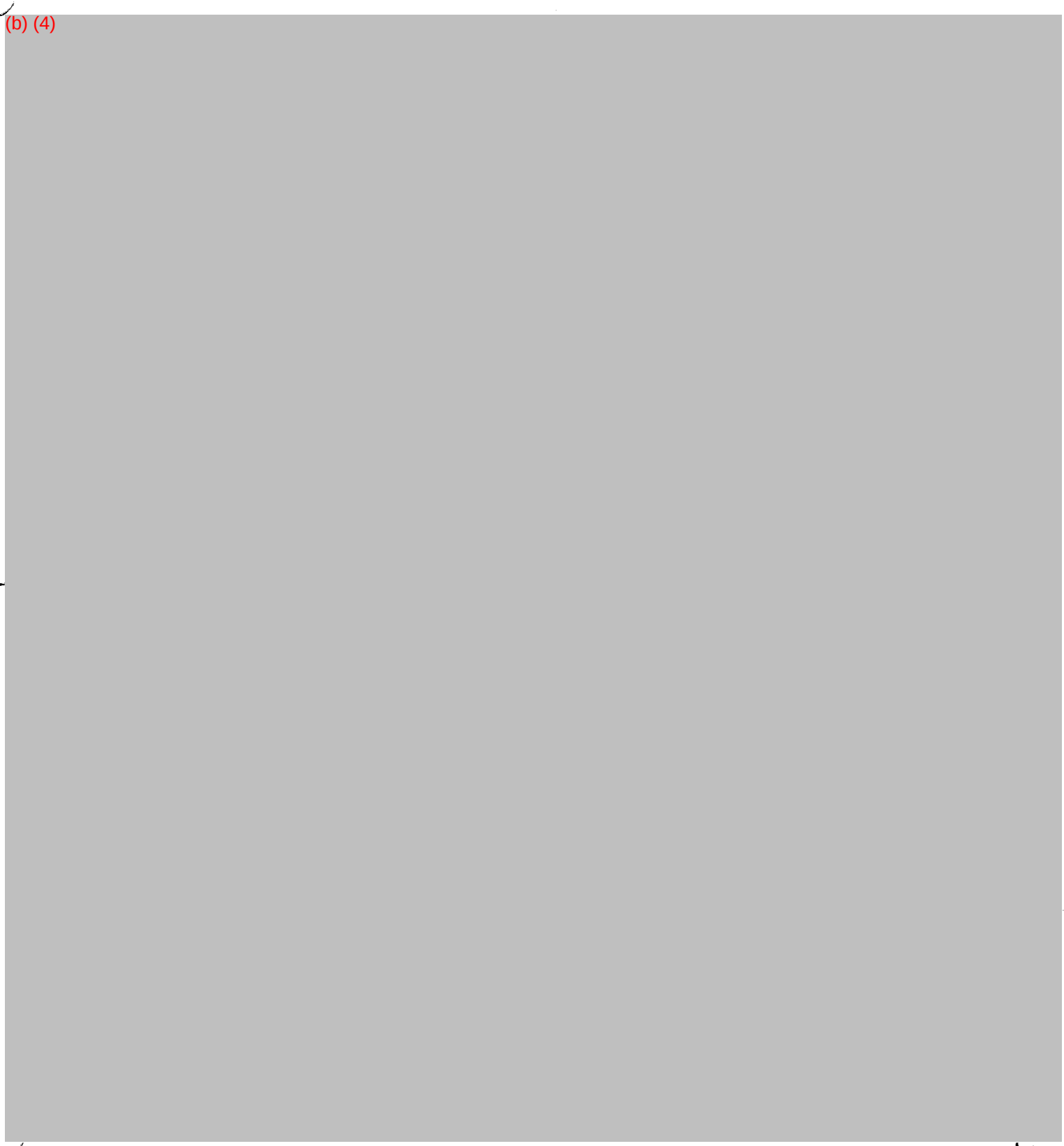
* Both types of ENG recording devices [House System or electrodes] record eye movements induced by various stimuli (i.e. caloric, positional, rotational, ocular motor functions, etc.).
* Both systems record classic 'saw-tooth' waveforms depicting nystagmus.
* Doctors can directly use the data from both systems to analyze nystagmus.
* Both types of ENG recording devices print reports in standard ENG format.

Differences:

* Data obtained optically [House System] rather than electrically [electrodes].
* Video record of torsional nystagmus [House System].
* Increased reliability / patient safety [House System].

7. Software Documentation

(b) (4)



Software Development:

(b) (4)

Test Results and Analysis:

(b) (4)

Certification:

The software development was followed, good quality assurance procedures were adhered to, and the test results demonstrate that the system specifications and the functional requirements were met.

8. Safety and Effectiveness:

Certification:

OculoKinetics agrees to provide a summary of information concerning the safety and effectiveness of this device to any person who requests it.

We believe that the House InfraRed/Video ENG System is substantially equivalent to nystagmographs currently in commercial distribution in the U.S. and should therefore be accepted and granted an approval of this 510(K) Notification.

Should you require any additional information, please contact me at (310) 328-0477.

Sincerely,

OculoKinetics, Inc.

Ronald A. Waldorf
Chairman

OculoKinetics, Inc.

October 8, 1992

Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20850

RE: 510(K) Notification
House InfraRed/Video Electronystagmographic (ENG) System

Ladies and Gentlemen:

I certify that OculoKinetics, Inc. will make available all information in this Premarket Notification on safety and effectiveness that supports a finding of substantial equivalency within thirty days of request by any person.

The information I agree to make available does not include confidential patient identifiers.

Sincerely,

Ronald A. Waldorf
Chairman

2291 205th Street, Suite 203 • Torrance, California 90501 • (310) 328-0477 FAX (310) 328-0697

OculoKinetics, Inc.

October 8, 1992

Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20850

RE: 510(K) Notification
House InfraRed/Video Electronystagmographic (ENG) System

Ladies and Gentlemen:

I certify that OculoKinetics, Inc. will make available all information in this Premarket Notification on safety and effectiveness that supports a finding of substantial equivalency within thirty days of request by any person.

The information I agree to make available does not include confidential patient identifiers.

Sincerely,

Ronald A. Waldorf
Chairman

2291 205th Street, Suite 203 • Torrance, California 90501 • (310) 328-0477 FAX (310) 328-0697

OculoKinetics, Inc.

October 8, 1992

Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20850

RE: 510(K) Notification
House InfraRed/Video Electronystagmographic (ENG) System

Ladies and Gentlemen:

I certify that OculoKinetics, Inc. will make available all information in this Premarket Notification on safety and effectiveness that supports a finding of substantial equivalency within thirty days of request by any person.

The information I agree to make available does not include confidential patient identifiers.

Sincerely,

Ronald A. Waldorf
Chairman

2291 205th Street, Suite 203 • Torrance, California 90501 • (310) 328-0477 FAX (310) 328-0697

OculoKinetics, Inc.

Submitted: October 8, 1992

Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20850

RE: 510(K) Notification
House InfraRed/Video Electronystagmographic (ENG) System

Ladies and Gentlemen:

In accordance with section 510(K) of the Federal Food, Drug, and Cosmetic Act, and in conformance with 21 CFR 807, this premarket notification is being submitted prior to the date when OculoKinetics, Inc. proposes to introduce into interstate commerce for commercial distribution an eye movement device to be known as the House InfraRed/Video Electronystagmographic (ENG) System.

The following information is being submitted in conformance with 21 CFR 807.87 to notify you that OculoKinetics, Inc. intends to market the following device:

1.	**Classification Name:**	Nystagmograph
	Trade/Proprietary Name:	House InfraRed/Video Electronystagmograph System
	Common/Usual Name:	House IR/Video ENG System
2.	**Establishment Registration Number:**	2028047 (OculoKinetics, Inc.)
3.	**Device Classification:**	Class II 882.1460 Nystagmograph
4.	**Performance Standards:**	Not Applicable
5.	**Label/Promotional Material:**	Draft labeling, promotional literature and Instructions for Use are included in Attachment A, B & C, respectively.

2291 205th Street, Suite 203 • Torrance, California 90501 • (310) 328-0477 FAX (310) 328-0697

6. Substantial Equivalence:

Substantially equivalent devices are commercially available in the U.S. which generate the same type of data as the House InfraRed/ Video ENG System. These devices are described below along with an overview of the ENG examination.

Modern vestibular (balance system) and/or neurological function testing has focused on objective measurements of vestibular reflex activity, including vestibulo-ocular reflexes. Electro-nystagmography (ENG) is the simplest and most readily available method for recording eye movements related to the evaluation of vestibular or ocular motor function (Baloh & Furman, 1989. Copy provided in Attachment D). An overview of the ENG examination is described in Electronystagmography 1990 (copy is provided in Attachment D). A bibliography of other literature references is also enclosed in Attachment D.

The House InfraRed/Video Electronystagmographic (ENG) System provides for the video observation and/or the recording and analysis of eye movements as part of the ENG examination. The House InfraRed/Video ENG System is comprised of the following modules: the House Ocular Motor Module and the House IR/Video ENG Goggle (See Photo's 1 & 2, page 9 of this Cover Letter). System specifications are provided in Attachment C, pages 29 and 30.

The House Ocular Motor Module (OMM) is a fiberglass viewport which contains two black and white video cameras (one per eye). The operator, usually an ENG technician or medical practitioner, easily views the subject's eyes on standard video monitors. The House OMM allows for the observation and/or recording of eye movements related to those portions of the ENG examination which test for ocular motor function, commonly evaluated by moving light stimuli conventionally known as smooth pursuit, gaze, and/or saccadic eye movement tasks. During these tests, the subject places his or her face against the foam rubber lined House OMM viewport and follows a visible target light which moves, under operator/computer control, either horizontally (left and right) or vertically (up and down).

The House InfraRed/Video ENG Goggle is a light-weight, plastic goggle to which is attached two black and white video cameras, one for the observation of each eye. The House IR/Video ENG Goggle is worn by the subject during those portions of the ENG examination which test for positional, caloric, or rotational eye movement responses.

As with the other substantially equivalent marketed devices described below, the medical practitioner can request an entire ENG examination be performed, or some subset or partial ENG Examination. For example, some subjects may require an ENG exam which only evaluates ocular motor eye movement responses whereas other subjects may have only caloric procedures. Therefore, it is possible to have

applications where only the House Ocular Motor Module or the House IR/Video ENG Goggle would be required. A complete examination would, of course, necessitate the use of both modules comprising the total House InfraRed/Video ENG System. The medical practitioner interprets the subjects' eye movement responses. These responses are evaluated from the observation of the subject's eye movement responses and/or from the recordings generated either from electrode recorded signals or, as in the case of the House InfraRed/Video ENG System, from the video signal.

Literature for substantially equivalent marketed electrode ENG devices and their comparison with the House InfraRed/Video ENG System is provided in Attachments E and F, respectively.

The House InfraRed/Video Electronystagmographic (ENG) System is substantially equivalent to the following products which are commercially available in the U.S.:

1. Nystar Plus ENG System — K Number: K851190, K851190A, K884294
   Nicolet Biomedical Instruments
   5225-4 Verona Road
   Madison, WI 53711
   (800) 345-6880
   (608) 271-3333
   Attachment E, Pages 1-11

2. Computerized ENG System — K Number: K850180, K850180A
   Bio-Logic Systems Corp.
   One Bio-Logic Plaza
   Mundelein, Il 60060
   (312) 949-5200
   (800) 323-8326
   Attachment E, Pages 12-13

3. Model 1500B Computerized ENG — K Number: K863424, K863424A
   Micromedical Technologies
   110 W. Walnut
   Chatham, IL 62629
   (800) 334-4154
   Attachment E, Pages 14-19

These substantially equivalent ENG systems utilize electrodes, attached to the subjects skin around the eyes for the recording of eye movements, and computer analysis of the resulting data. The House IR/Video ENG System does not use electrodes or any other electrical connections to the subject. It simply uses video cameras which are aimed to look at a subject's eyes with the resulting video signals available for the observation of these eye responses by the operator/medical practitioner on the respective video monitors (see pictures 1 and 2) and/or for the recording and analysis by the dedicated computer system and/or any conventional video tape recorder (VCR). The digitized House IR/Video ENG data also includes information regarding pupil size, if this option is desired by the medical practitioner.

Illumination of the eye is provided by diffuse, non-coherent (non-laser), low-level near infrared light-emitting diodes (LED's) with peak wavelengths of 940 nanometers. This common place infrared illumination is invisible to the subject. The video cameras are selected because of their sensitivity to this infrared illumination.

When the subject places his or her face against the foam rubber seal on the OMM or the IR/Video Goggle, all of the visible outside, or ambient light, is eliminated from the internal chambers of the modules. The internal infrared illumination allows the subject to keep their eyes open without having the ability to see anything inside the Goggle or Ocular Motor Module. This is an advantage over electrode-based ENG systems which require the subject to keep their eyes closed which may cause changes in the way the eye moves behind the closed eye lid, or changes in the CRP, or even from certain mechanical artifacts in the recorded eye movement data from eye lid tremor.

In addition, electrode-based ENG systems, because of inherent technical limitations of electrode placement and CRP physiology, can not establish the presence of torsional eye movements, i.e. those eye movements about the eye's visual axis. With The House IR/Video ENG System this limitation is eliminated since torsional eye movements can be easily observed by the operator/medical practitioner on the video monitors.

This infrared method for the illumination of the eye is substantially equivalent to the following product which is commercially available in the U.S.:

4. PUPILSCAN K Number: K854169
   Fairville Medical Optics, Inc.
   P.O. Box 832
   Mendenhall, PA 19357
   (215) 388-0383 Attachment E, Pages 25-26

Literature for the PUPILSCAN and its comparison with the House InfraRed/Video ENG System is provided in Attachments E and F, respectively.

Examples of data recorded from the House IR/Video ENG System are provided in the Instruction for Use Manual (Attachment C, pages 21 - 23). An example of data from an electrode-based ENG system is also provided (Attachment E, pages 20-24).

In summary, the House InfraRed/Video Electronystagmographic System compares to conventional ENG systems as follows:

Advantages of House IR/Video ENG System

1. No Electrodes
   a. No electrical contact to patient.
   b. No variations in data due to skin resistance changes, electrode placement, CRP fluctuations, etc.
   c. Special training to place electrodes no longer required.
   d. More comfortable to subjects.
   e. The time necessary for electrode calibration is eliminated, allowing for more subjects to be tested per unit time, i.e. a more efficient use of operators time.

2. Observe Eyes In Total Darkness
   a. More natural (subject comfort)
   b. Eliminates false data introduced by tightly closing eyes.

3. Video Tape Actual Eye Movements
   a. Permanent video record.
   b. Record may be analyzed at a later date or other location or by those not present at the actual test.
   c. Can record torsional eye movements.

4. Building Block System
   a. Optional ENG Goggle or Ocular Motor Module
   b. Optional computer (data manipulation)

Disadvantages of House IR/Video ENG System

Slightly more expensive then comparable electrode-based computerized ENG systems because of the video cameras, which are more costly then electrodes.

Similarities

* Both types of ENG recording devices [House System or electrodes] record eye movements induced by various stimuli (i.e. caloric, positional, rotational, ocular motor functions, etc.).
* Both systems record classic 'saw-tooth' waveforms depicting nystagmus.
* Doctors can directly use the data from both systems to analyze nystagmus.
* Both types of ENG recording devices print reports in standard ENG format.

Differences:

* Data obtained optically [House System] rather than electrically [electrodes].
* Video record of torsional nystagmus [House System].
* Increased reliability / patient safety [House System].

7. Software Documentation

(b) (4)

Software Development:

(b) (4)

Test Results and Analysis:

(b) (4)

[redacted]

Certification:

The software development was followed, good quality assurance procedures were adhered to, and the test results demonstrate that the system specifications and the functional requirements were met.

8. Safety and Effectiveness:

Certification:

OculoKinetics agrees to provide a summary of information concerning the safety and effectiveness of this device to any person who requests it.

We believe that the House InfraRed/Video ENG System is substantially equivalent to nystagmographs currently in commercial distribution in the U.S. and should therefore be accepted and granted an approval of this 510(K) Notification.

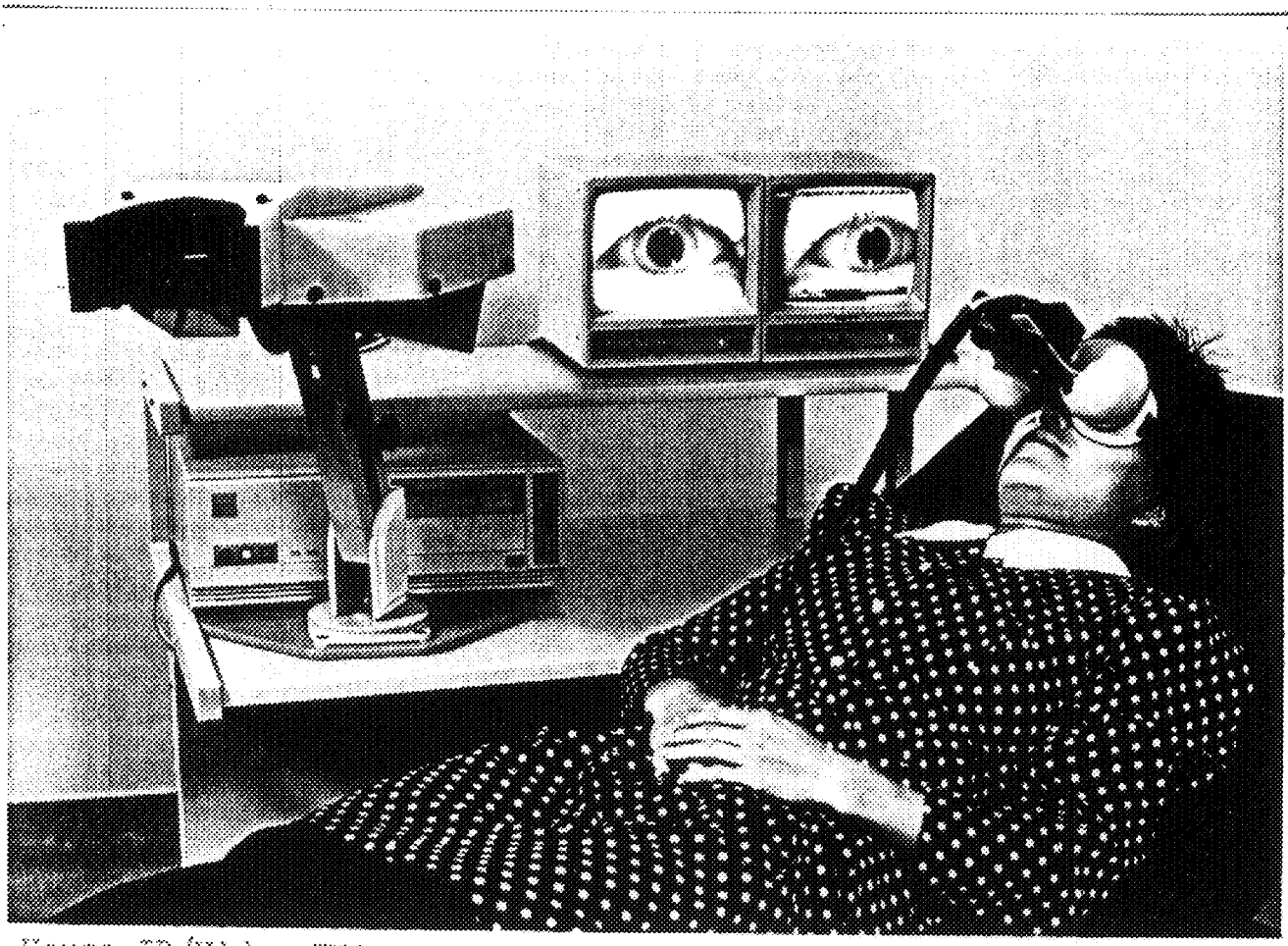
Should you require any additional information, please contact me at (310) 328-0477.

Sincerely,

OculoKinetics, Inc.

Ronald A. Waldorf
Chairman

House Ocular Motor Module Picture 1



House IR/Video ENG Goggle Picture 2

HOUSE IR/VIDEO ENG SYSTEM

___ Ocular Motor Module

___ VGA/Data Display Monitor

___ Video Monitor

___ IR/Video ENG Goggle Assembly

___ Central Computer/
Video Annotator Unit

___ Printer

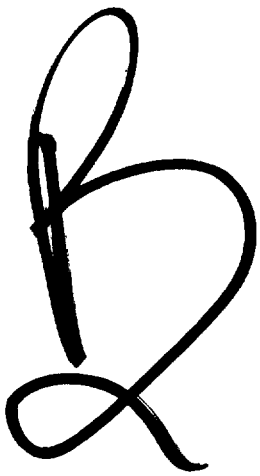
___ Cart

Serial No._____

OculoKinetics, Inc.
2291 W. 205th St., #203 - Torrance, CA 90501

120

HOUSE IR/VIDEO ENG SYSTEM
ITEM:_____
SERIAL NO:_____
OCULOKINETICS, INC.
Torrance, CA 90501



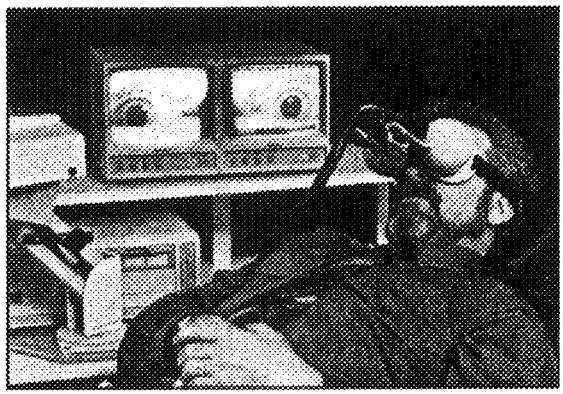
The House InfraRed/Video ENG System

Oculoptics, Inc.

- FIRST COMPLETE, NON-ELECTRODE EYE MOVEMENT RECORDING SYSTEM.
- OBSERVES AND DOCUMENTS HORIZONTAL, VERTICAL *AND* ROTARY EYE MOVEMENTS RELATED TO VESTIBULAR AND OCULAR MOTOR EXAMINATIONS.
- PATIENTS' EYES ARE OPEN IN TOTAL DARKNESS, ELIMINATING OPTIC FIXATION.
- DISCONJUGATE EYE MOVEMENTS ARE EASILY DETERMINED.

House Ocular Motor Module

- SIMPLE OPERATION, BINOCULAR HORIZONTAL AND VERTICAL TRACKING, GAZE AND SACCADIC TESTING CAPABILITY.
- BOTH SYSTEMS CAN BE INTERFACED TO THE HOUSE COMPUTER FOR AUTOMATED ANALYSIS.



House IR/Video ENG Goggle

- COMFORTABLE, LIGHTWEIGHT GOGGLE EQUIPPED WITH MINIATURE VIDEO CAMERAS.
- SAFE, INVISIBLE, INFRARED ILLUMINATION ALLOWS THE PATIENTS TO KEEP THEIR EYES OPEN WITHOUT FIXATION.
- CAN BE USED FOR VARIOUS VESTIBULAR EXAMINATIONS:
  - A. POSITIONALS
  - B. DIX-HALLPIKE
  - C. CALORICS
  - D. TORSION CHAIR
  - E. ROTATIONAL STUDIES
- SIMULTANEOUS MONOCULAR EYE MOVEMENTS ARE EASILY OBSERVED AND CAN BE DOCUMENTED ON ANY CONVENTIONAL VIDEO TAPE RECORDER.

Oculokinetics' InfraRed/Video technology was developed to enhance the science of clinical eye movement testing by elimination of technical artifacts and limitation of electrode-based ENG systems.

The advantages of InfraRed/Video ENG technology as compared to electrode-based ENG techniques are presented in the table below.

The House IR/Video System is equivalent to a pure direct-coupled, 4 channel, ENG system in that bilateral, monocular, horizontal and vertical eye positions and movements can be recorded.

The benefit of The House IR/Video ENG System is that testing can be conducted with the patients' eyes open and without any of the artifacts associated with electrode-based eye movement recordings.

In addition, torsional eye movements, i.e., those about the visual axis, can be viewed *and* documented with The House IR/Video ENG System.

For the first time, the physician can have a truly complete eye movement report for enhanced diagnostic purposes.

FEATURE	ELECTRO-OCULOGRAPHY	VIDEO*
Recording device	Paste-on electrodes	Video camera
Principle	Corneoretinal potential	Digital processing of video image
Range of horizontal eye movement, degree	±40	Unlimited
Range of vertical eye movement, degree	±30	Unlimited
Range of torsional eye movement	...	Unlimited
Approximate accuracy, degree	1-2	1
Will record when patient's eyes closed	Yes	No
Able to record normal vision	Yes	Yes
Able to record during head movement	Yes	Yes
Susceptible to eye-blink artifacts	Yes	Yes
Sensitive to changes in room lighting	Yes	No
Sensitive to electrical interference	Yes	No
Sensitive to electromyographic interference	Yes	No

*Computer analyzed video recordings.

Source: Baloh and Furman, Modern Vestibular Testing, *Western Journal of Medicine*, 150 (1): 59-67, 1989.

House IR/Video ENG Goggle: U.S. Patent No. 4,815,239 and Foreign Patents Granted.
House Ocular Motor Module: Patent Granted.
The House name is used with permission from The House Ear Institute, Los Angeles, California

For additional information contact:
Oculokinetics, Inc. • 2291 W. 205th Street • Torrance, CA 90035 • (310) 328-0477 • FAX (310) 328-0697

[redacted]

C

THE HOUSE INFRARED/VIDEO ELECTRONYSTAGMOGRAPHIC SYSTEM

OPERATING INSTRUCTIONS

The information contained in this Manual is for the operational use of OculoKinetics' House InfraRed/Video Electronystagmographic (ENG) System which is comprised by the IR/Video ENG Goggle and the Ocular Motor Module.

These are video-based modules of the House IR/Video ENG System which allow for the observation of a subject's eye movements while their eyes are open in a totally dark, non-fixating environment, during vestibular or ocular motor testing.

The House IR/Video ENG Goggle, through the use of miniature video cameras, magnifies the image of each eye onto the respective video monitors. This allows the ENG operator to view subject's horizontal, vertical, and torsional (rotary) vestibulo-ocular responses.

The House Ocular Motor Module is also an infrared/video based system. This Module contains an operator controlled moving visual target light which provides the stimuli for horizontal or vertical - right or left eye - tracking, saccadic, or gaze testing.

For both the House IR/Video ENG Goggle and Ocular Motor Module, the subject's name, chart or ID number, time and date, as well as the description of the stimulus are annotated on the video image of the eye. The eye movements and annotated video information can be recorded on any conventional video tape recorder. This allows for the documentation and, if desired, the re-evaluation of the subject's eye movement responses. Computer analysis of the eye movements are is available, along with a hard copy printout of the resulting data.

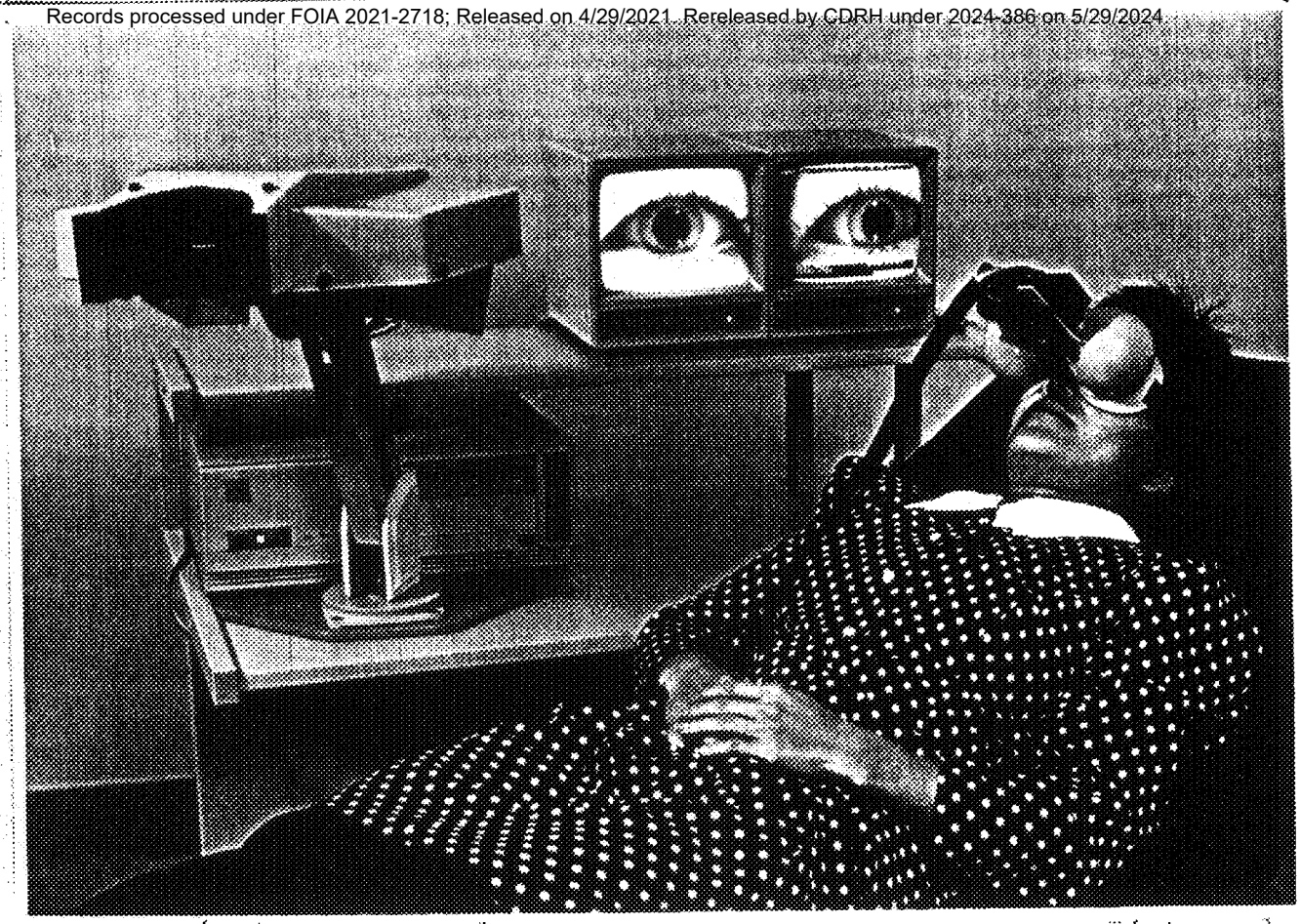
TABLE OF CONTENTS

I. OPERATIONAL CONSIDERATIONS

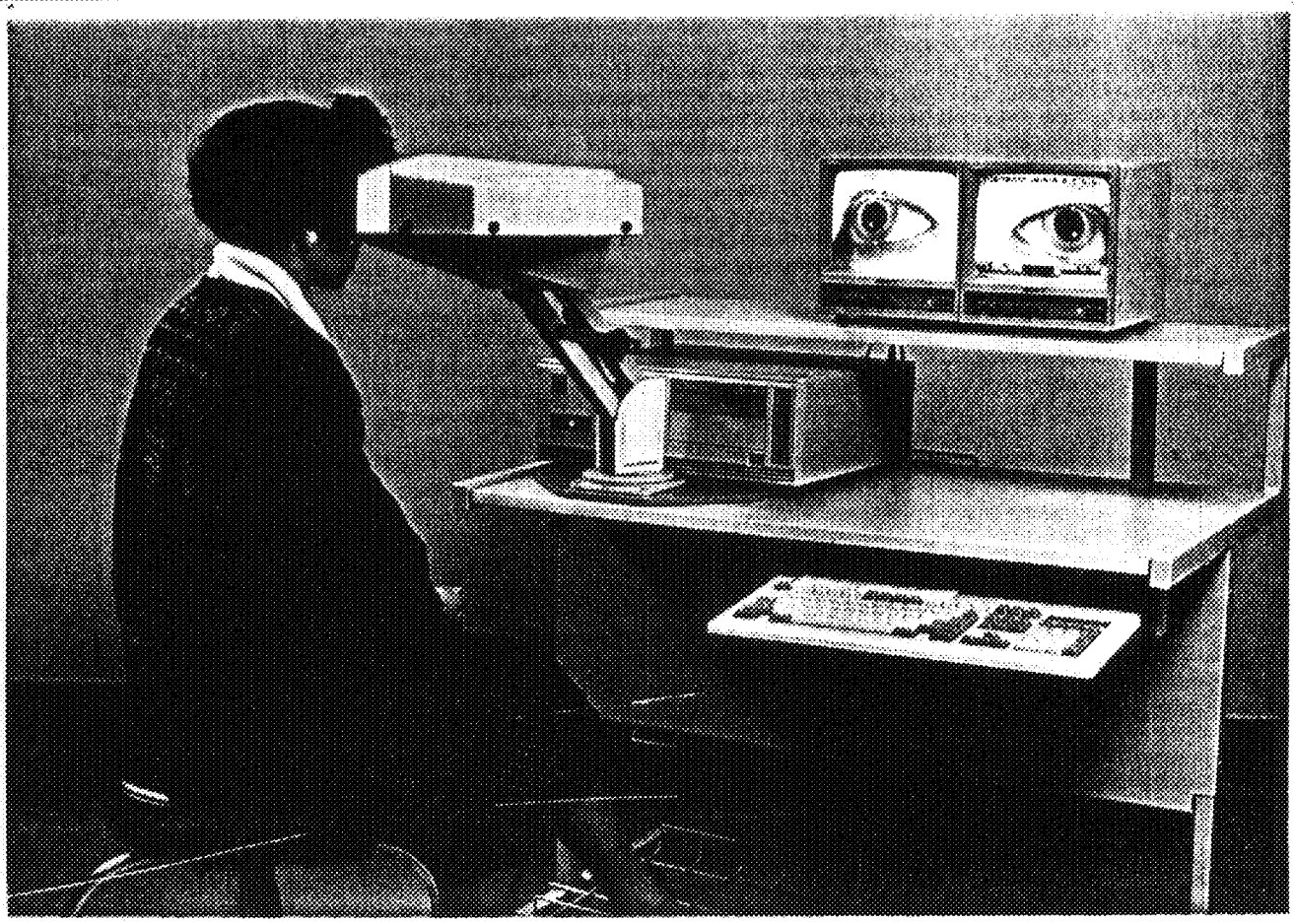
The House InfraRed/Video ENG System Consists of: The House InfraRed/Video ENG Goggle and the House Ocular Motor Module.

The House IR/Video ENG Goggle (Picture 1) is used for observation and recording of eye movements related to all modes of vestibular stimulations: positionals, Dix-Hallpike, calorics, torsion swing and, rotational examinations. The eye movements are easily visualized on video monitors. Subject information and stimulation procedure description are overlayed on the video picture and on the VGA/Data Display Monitor. The video image of either eye, and the annotated information, can be recorded on any conventional video tape recorder, allowing for the documentation and re-evaluation of the ocular responses.

The House IR/Video Ocular Motor Module (Picture 2) is also an infrared/video based system which allows for the testing of the subject's ocular motor system. The Ocular Motor Module has a moving visual target light which is used to provide stimuli for smooth pursuit tracking, saccadic, and gaze responses. Both eyes are observed by the operator in a procedure which is similar to the House IR/Video ENG Goggle. Target stimulation is presented in a monocular fashion, either horizontally or vertically. Responses from the Ocular Motor Module can also be recorded on any standard video tape recorder.



House IR/Video ENG Goggle Picture 1



House Ocular Motor Module Picture 2

II. FUNCTIONAL DESCRIPTION

The House IR/Video ENG Goggle - A comfortable, lightweight, plastic goggle which is worn by the subject. The foam rubber seal eliminates all outside or ambient light from the internal chambers of the Goggle. Two infrared sensitive, miniature, video cameras are attached to the Goggle and provide video images of each eye for the video monitors. Invisible, infrared, illumination illuminates the internal aspect of the Goggle allowing the subject to keep their eyes open without the interference of fixation. If fixation is desired, a single visible target light can be illuminated by the operator.

The House Ocular Motor Module - The viewport of the Ocular Motor Module (OMM) is a molded plastic housing with a foam-lined opening for the subject's face. As with the House IR/Video ENG Goggle, the OMM is a light-sealed environment which eliminates all ambient light from the internal aspect of the housing once subject's place their faces against the foam rubber lined opening. Inside the housing two infrared sensitive video cameras are positioned to focus on the subject's eyes which are illuminated with invisible, infrared, light. The subject observes a visible target light of pinpoint size which moves to the left and right, or up or down, under the ENG operator's control. This is the stimuli for ocular motor testing which includes monocular - horizontal or vertical - saccadic, tracking, or gaze examinations.

VIDEO MONITORS - The subject's eyes, magnified and open in total darkness, plus the annotated video information are viewed on two monochrome video monitors. At the user's option, the video image of either eye can also be video taped on any standard VCR.

CENTRAL COMPUTER/VIDEO ANNOTATION UNIT (CC/VAU) and KEYBOARD - The CC/VAU controls the functions available in the House IR/Video ENG Goggle and/or the House Ocular Motor Module. The CC/VAU provides the power to the video cameras, infrared illuminators, fixation, and visual target stimulation lights. It also provides the capability for annotation of the video images along with subject name, ID, time/date, and test information. In the IR/Video Goggle, the fixation lights can be turned on by the ENG operator. For the Ocular Motor Module, the CC/VAU controls the target stimuli for the tracking, saccadic, and gaze examinations. The CC/VAU can also automatically track the subject's eye movements and make this computer data available to the operator for analysis and printout.

III. INSTALLATION INSTRUCTIONS

SYSTEM CART: Assemble per the accompanying instructions.

CONNECTION STEPS: Connect the modules per Diagram A, Page 7.

1. Central Computer/Video Annotation Unit (CC/VAU). This is the House IR/Video host computer and associated electronic which are required for the operation of the House IR/Video ENG System.

2. Keyboard. Plug Keyboard into rear panel of CC/VAU. Top of connector is marked with a depression in the metal so it only fits in one way.

3. Video Monitors (Right and Left). For each monitor, using supplied cables, connect 'RCA pin plug' end to 'Video Out' receptacle on CC/VAU rear panel. Connect 'BNC' plug on other end of cable to 'IN' receptacle on rear panel of each Video Monitor. 'BNC' connector locks in position with 1/4 turn to right. Set impedance switch on rear of monitors to 75 ohms (low impedance).

4. VGA/Data Display Monitor. The computer text information as well as the digitized eye movement data is displayed on the VGA/Data Display Monitor. Connect the multi-pin cable which is attached to the monitor to the indicated connector on the rear panel of the CC/VAU. Attached the supplied power cord to the connector on the rear of the VGA/Data Display Monitor and connect to the AC multiplug strip.

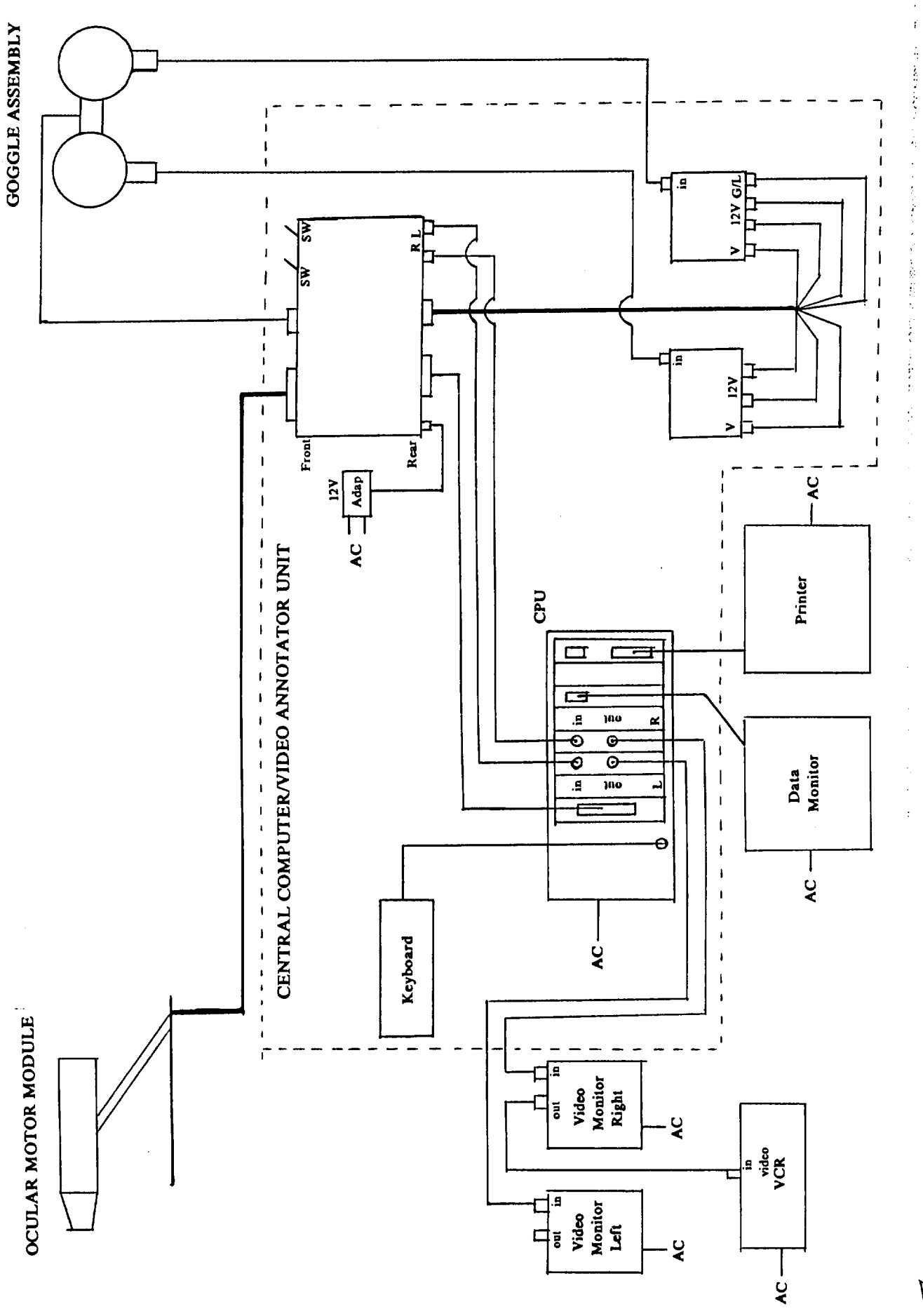
5. House IR/Video ENG Goggle. The two video camera assemblies are labeled right and left eye. Connect the video cables to the video cameras on each of the respective sides of the Goggle. These cables connect to the corresponding CC/VAU camera electronic connectors. The six-pin push connector should be attached at the corresponding center connector located on the Goggle. The six-pin connector at the opposite end of the cable attaches to the corresponding connector on the CC/VAU. This cable provides for the control of the infrared LED's and fixation lights.

6. House Ocular Motor Module (OMM). The large multipin connector plugs into the I/O receptacle on the front panel of CC/VAU.

7. AC Multiplug Power Center. Is supplied to provide central 120 Volt AC power for the CC/VAU, Video and Data Display monitors, and Printer. This power center has surge suppression capability and must be used in order to protect the House InfraRed/Video System from voltage surges and spikes in the 120 volt AC power supply line.

Be certain that all connections are secure and correct prior to turning on the AC switch on the multiplug power center for the multiplug, CC/VAU, Video Monitors and VCR. Location of power switches for the Video Monitors are on their front panels. The power switch for the CC/VAU is located either at rear of the right side or in front on the right side.

There is no power switch on the House IR/Video ENG Goggle or Ocular Motor Module. For these modules, direct coupled (D.C.) operating power is supplied from the CC/VAU via the multipin connectors and cables.



IV. OPERATING INSTRUCTIONS

A. THE HOUSE INFRARED/VIDEO ENG GOGGLE.

1. Make sure the House IR/Video ENG Goggle is connected to the CC/VAU as described in the above section.
2. Turn on AC Power via the multiplug power strip and the power switches on the CC/VAU, video monitors, printer, and video tape recorder if this option is being used.
3. Computer should be in 'Turbo' mode. If Turbo indicator light on front panel of computer is not lit, depress 'Turbo' switch.
4. OculoKinetics' House IR/Video ENG System TITLE SCREEN will appear on the screen.
5. Press 'ENTER' Key.
6. Type in Operators Name in the space indicated. Press 'ENTER' Key.
7. Type in Subjects' Folio Number, i.e. Chart Number, Social Security Number, etc. Press 'ENTER" Key.
8. If Folio Number is not already existing in the computer, follow instructions on the VGA/Data Display Monitor.
9. Type in Subjects' Name. Press 'ENTER" Key.
10. Type in Subject Description, i.e. subject's medical problem, current medication, or other relevant comment information. Press 'ENTER" Key.

11. If Subject Folio Number, Name, and Description is correct press 'ENTER" Key. If not, press 'ESC' Key and begin steps 7-11 again.

12. Main Menu now appears on the VGA/Data Display Monitor. Using the 'Up or Down Arrow' Keys, the desired function will be highlighted. Choose either: Test Subject; Edit Data; Print Report; Erase Test; or Delete Subject. Selection is accomplished by pressing the 'ENTER' Key.

I. Test Subject

A. Choose ENG Goggle Module by highlighting this choice with the 'Up or Down Arrow' Keys. Press 'Enter' Key.

B. The operator may type in any comments desired at this time. Press 'ENTER' Key.

C. Place the House IR/Video Goggle on the subject, adjusting the position of the Goggle to insure that the subject's left and right eyes are center on the respective video monitors. The eyes will be clearly visible.

D. Adjust the velcroix head band to secure the Goggle to the subject. If adjustment for centering of the eye(s) is(are) required, loosen the camera adjustment knob(s) on the Goggle and center the eye(s). If focusing is necessary, turn the respective camera lens adjustment while viewing the appropriate video monitor.

E. As Indicated on the VGA/Data Display Monitor, start the video tape recorder if that option is being used.

F. Press the 'ENTER' Key. The CC/VAU will automatically establish an electronic 'lock-on' to the subject's eyes. This will be indicated by each individual pupil being 'whited' with a black cross-hair being position at the center of the pupil, as viewed on the respective left eye and right eye video monitors.

G. If the Goggle is readjusted, automatic 'lock-on' should be re-established simply by pressing the 'A' Key.

H. The VGA/Data Display Monitor is configured to display the real-time Horizontal and Vertical Eye Movement components. The Right Eye will be displayed in Red, the Left Eye will be displayed in Green. The Subjects Folio Number and Name, the Examiners Name, the Time and Date, as well as the selected Test Stimuli are displayed below the Horizontal and Vertical Graphs.

I. The operator, based on the ENG test procedure desired, should annotate the IR/Video Eye Movement Data <u>prior</u> to commencing each test procedure. Simply Press the indicated Keyboard Keys, which are arranged by either Positional Tests or Caloric and Special Tests.

For ease of operator use, a keyboard template is provided which details the various Function Key commands.

Function Keys: Positional Tests

F1 = Spontaneous (usually used for Supine-30 degree position)

F2 = Supine

F3 = Lateral (body supine, head turned)

F4 = Postural (whole body turned)

F5 = H.H. (Head Hanging)

F6 = H.H. Inverted

F7 = Head Erect

F8 = Head Back

F9 = Head Forward

NOTE: The 'R' (Right) and 'L' (Left) Keys can be used to indicate which position is being used for Postural, Body, and Head Hanging examinations. Whenever the operator/medical practitioner desires to test for fixation responses, the 'F' (Fixation) Key can be pressed. This will turn on the fixation light inside the Goggle. Pressing the 'F' Key again will cause the internal fixation light to turn off.

Shift - Function Keys: Caloric Procedures

Shift F1 = Warm

Shift F2 = Cool

Shift F3 = Ice

Shift F4 = Minimum

Shift F5 = Inverted

Shift F6 = Fixation

Shift F7 = Fistula

Shift F8 = Torsion Chair

Shift F9 = Rotation

NOTE: The 'R' (Right) and 'L' (Left) Keys can be used to indicate which ear is being irrigated for any of the caloric tests or which ear is having a Fistula Test. The Screen can also be annotated with 'H' (Horizontal Semi-Circular Canal), 'S' (Superior Semi-Circular Canal, or 'P' (Posterior Semi-Circular Canal). The 'F' (Fixation) Key can be activated anytime the fixation light is turned on inside the Goggle. For the Fistula Test, the 'I' (Increasing) or 'D' (Decreasing) Keys can be used to indicate the type of pressure stimuli.

J. With the Subject looking straight ahead, Press the 'C' Key to center the data on the graphs displayed on the VGA/Data Display Monitor. This operation is functional at any time within a test procedure.

K. The 'SPACE BAR' Key is used to start or pause the collection of eye movement data. When in the Pause mode, the VGA/Data Display Monitor will indicate PAUSE in the lower right hand portion of the monitor's screen.

L. Eye movement data is saved to the CC/VAU's hard disk if any of the following events occur or are selected by the operator:

1. Anytime during a test procedure that the operator pauses eye movement data collection.
2. Anytime that the operator ends a test procedure.
3. The computers real-time memory allocation (approximately 5 minutes of data collection) is filled, the CC/VAU will automatically save the data to the hard disk before continuing.

M. Press 'ESC' Key to return to Main Menu.

B. House Ocular Motor Module

This component should be placed on the system cart as indicated in Diagram A (not included in the Draft Version). The Ocular Motor Module's supporting arm, by loosening the retention knob on its side, can be adjusted for different subject heights.

1. Make sure the House Ocular Motor Module is connected to the CC/VAU as described in the above section.
2. Turn on AC Power via the multiplug power strip and the power switches on the CC/VAU, video monitors, printer, and video tape recorder if this option is being used.
3. Computer should be in 'Turbo' mode. If Turbo indicator light on front panel of computer is not lit, depress 'Turbo' switch.

4. OculoKinetics' House IR/Video ENG System TITLE SCREEN will appear on the screen.
5. Press 'ENTER' Key.
6. Type in Operators Name in the space indicated. Press 'ENTER' Key.
7. Type in Subjects' Folio Number, i.e. Chart Number, Social Security Number, etc. Press 'ENTER' Key.
8. If Folio Number is not already existing in the computer, follow instructions on the VGA/Data Display Monitor.
9. Type in Subjects' Name. Press 'ENTER' Key.
10. Type in Subject Description, i.e. subject's medical problem, current medication, or other relevant comment information. Press 'ENTER' Key.
11. If Subject Folio Number, Name, and Description is correct press 'ENTER' Key. If not, press 'ESC' Key and begin steps 7-11 again.
12. Main Menu now appears on the VGA/Data Display Monitor. Using the 'Up or Down Arrow' Keys, the desired function will be highlighted. Choose either: Test Subject; Edit Data; Print Report; Erase Test; or Delete Subject. Selection is accomplished by pressing the 'ENTER' Key.

I. Test Subject

A. Choose Ocular Motor Module by highlighting this choice with the 'Up or Down Arrow' Keys. Press 'Enter' Key.

B. The operator may type in any comments desired at this time. Press 'ENTER' Key.

C. Have the subject place their face against the foam rubber seal on the OMM Viewport. The height of the Viewport can be adjusted using by loosing the adjustment knob on the side of the Viewport arm. When the desired height is attained, tighten this adjustment knob.

D. Adjust the subject's head/viewport position to insure the subject's left and right eyes are center on the respective video monitors.

E. As indicated on the VGA/Data Display Monitor, start the video tape recorder if that option is being used.

F. Press the 'ENTER' Key. The CC/VAU will automatically establish an electronic 'lock-on' to the subject's eyes. This will be indicated by each individual pupil being 'whited' with a black cross-hair being position at the center of the pupil, as viewed on the respective left eye and right eye video monitors.

G. If the Ocular Motor Module is readjusted or if the subject changes their head position, automatic 'lock-on' should be re-established simply by pressing the 'A' Key.

H. The VGA/Data Display Monitor is configured to display the real-time Horizontal and Vertical Eye Movement components. The Right Eye will be displayed in Red, the Left Eye will be displayed in Green. The Subject's Folio Number and Name, the Examiners Name, the Time and Date, as well as the selected Test Stimuli are displayed below the Horizontal and Vertical Graphs.

I. The operator, based on the ENG test procedure desired, should annotate the IR/Video Eye Movement Data prior to commencing each test procedure. Simply Press the indicated Keyboard Keys, which are arranged by the various ocular motor tests:

Simply Press the indicated Keyboard Keys:

F1 = Track (Smooth Pursuit) - Horizontal

F2 = Track (Smooth Pursuit) - Vertical

F3 = Gaze - Horizontal

F4 = Gaze - Vertical

F5 = Saccade - Horizontal

F6 = Saccade - Vertical

NOTE: The 'R' (Right) and 'L' (Left) Keys should be used to indicate which eye is being stimulated. The F5 (horizontal) or F6 (vertical) Keys must be pressed each time the operator desires to sequence the change of the saccade light position. The instantaneous angle of gaze for all of the Ocular Motor Module tests is provided below the stimulus annotation on the VGA/Data Display Monitor.

J. The 'SPACE BAR' Key is used to start or pause the collection of eye movement data. When in the Pause mode, the VGA/Data Display Monitor will indicate PAUSE in the lower right hand portion of the monitor's screen.

K. With the Subject looking straight ahead, Press the 'C' Key to center the data on the graphs displayed on the VGA/Data Display Monitor. This operation is functional at any time within a test procedure.

L. Eye movement data is saved to the CC/VAU's hard disk if any of the following events occur or are selected by the operator:

1. Anytime during a test procedure that the operator pauses eye movement data collection.
2. Anytime that the operator ends a test procedure.
3. The computers real-time memory allocation (approximately 5 minutes of data collection) is filled, the CC/VAU will automatically save the data to the hard disk before continuing.

M. Press 'ESC' Key to return to Main Menu.

C. EDIT DATA

EDIT DATA is a software program wherein the operator can graphically view and analyze desired aspects of the subject's eye movement responses.

A. From the Main Menu appearing on the VGA/Data Display Monitor, use the 'Up or Down Arrow' Keys to highlight Edit Data. Selection is accomplished by pressing the 'ENTER' Key.

B. Type desired Folio Number and press the 'ENTER' Key.

C. Select desired test procedure for analysis by using the 'Up or Down Arrow' Keys to highlight selection. Press 'ENTER' Key.

D. The initial VGA/Data Display Monitor graphs consists of the Horizontal and Vertical Eye Position plotted against Time. The Right Eye is indicated by the data displayed in Red. The Left Eye is indicated by the data displayed in Green.

E. The following commands control the EDIT DATA Program:

Base Line: The data baselines can be moved Up or Down by using the corresponding 'ARROW' KEYS.

Time Base: The time domain of the displayed data can be increased or decreased by pressing the 'X' Key followed by a number Key from 1-5.

Signal Gain: The gain or amplitude of the displayed data can be increased or decreased by pressing the 'Y' Key followed by a number Key from 1-5.

Cursor: The cursor can be moved by the corresponding right or left 'ARROW' Keys. Holding the 'SHIFT' Key while pressing the selected 'ARROW' Key will move the cursor 25 spaces at a time. Pressing the 'HOME' Key and then 'ARROW' Key will move the cursor to the extreme left of the screen. Pressing the 'SHIFT' and then 'HOME' Key will bring the cursor to the beginning of the protocol. Pressing the 'PAGE UP' or 'PAGE DOWN' Keys moves the data 1/2 screen to the left or right respectively.

F. To compute the average slow component velocity (degrees/second) of any nystagmic eye movements in a portion of data, position the cursor to the beginning of the data desired for analysis and press the 'M' Key for Marker #1. Using the corresponding right or left 'ARROW' Keys, move the cursor to the end of the data desired for analysis. Press the 'M' Key for Marker #2.

G. The CC/VAU Computer will automatically compute the average speed of the slow component of any nystagmic eye movements occurring between Markers #1 and #2.

The following examples from EDIT DATA show the capability and functionality of this computer analysis portion of the House IR/Video ENG System.

Figure 1. An example of a subjects left ear warm water caloric nystagmic response as recorded from the House IR/Video ENG Goggle. The data from the right eye is plotted. Conventional medical nomenclature for the display of eye movements is used wherein eye movements to the right being displayed vertically-up and eye movements to the left being displayed vertically-down. Thus, because nystagmus direction is defined as the direction of the quick-component of the beat, this is a example of a spontaneous left beating caloric nystagmus. The data information provided at the lower left of the plot indicate that Mark 1 and 2 were set at 138/60 seconds a part (Delta T) and that the speed of the slow component of the nystagmus beat indicated at the moving cursor (indicated by the arrow) is 5 degrees/sec (R_Slope).

Figure 2. An example of smooth pursuit tracking as recorded from the House Ocular Motor Module. Data from the right eye is plotted along with the moving target stimulus (which was programed to move during this presented portion of the data at 15 degrees/second to the right. The time interval between Mark 1 and Mark 2 is 75/60 second. The target light at Mark 1 was at 8 degrees (LED=8) and at Mark 2 was at 27 degrees (LED=27) for a change of gaze angle of 19 degrees (Delta LED=19). The slope of the resulting eye movement at the cursor (indicated by the arrow) is 14 degrees/second.

Figure 3. An example of horizontal and vertical eye movement during a vertical smooth pursuit and gaze task as recorded from the House Ocular Motor Module. Data is from the right eye plotted along with the moving target stimulus (which was programed to move during this presented portion of the data at 15 degrees/second upward to a vertical gaze position of 27 degrees upward. During the interval between Mark 1 and Mark 2, the right eye horizontal data is basically 'flat' indicating no change in the horizontal placement of the eye while the vertical data indicates an upward movement. The time between Mark 1 and Mark 2 is 62/60 second.

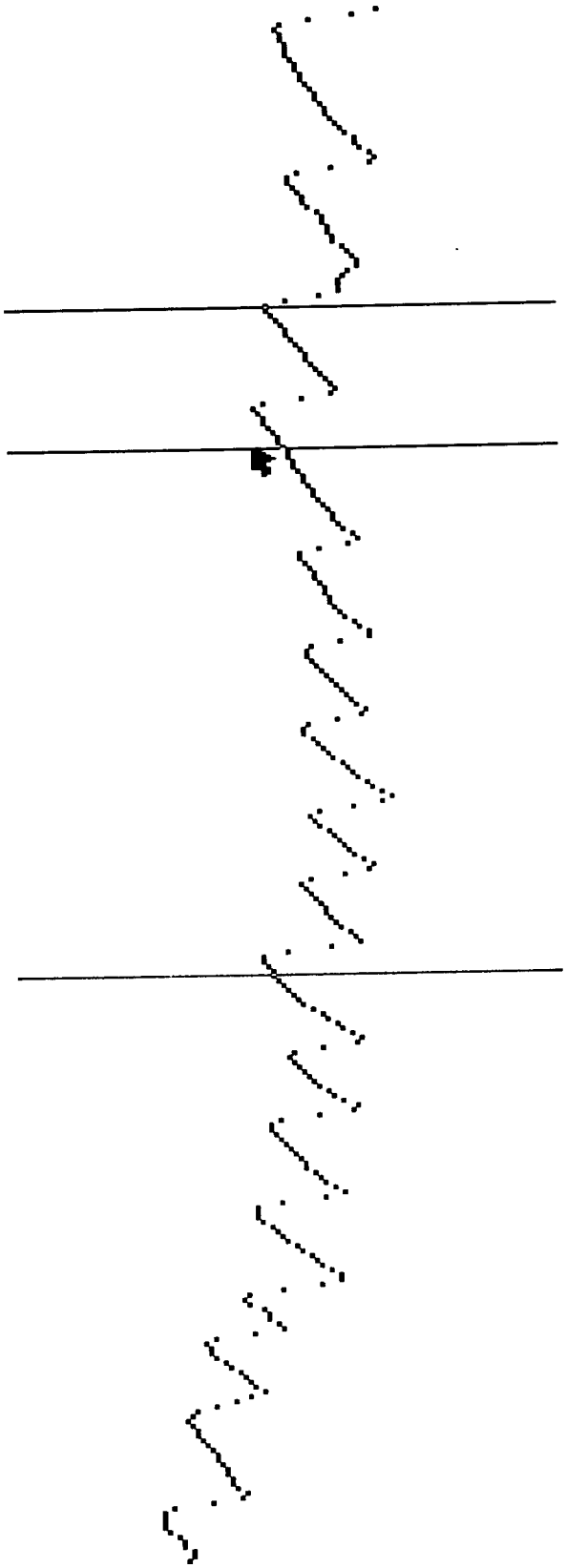


Figure 1

See page 20 for Legend

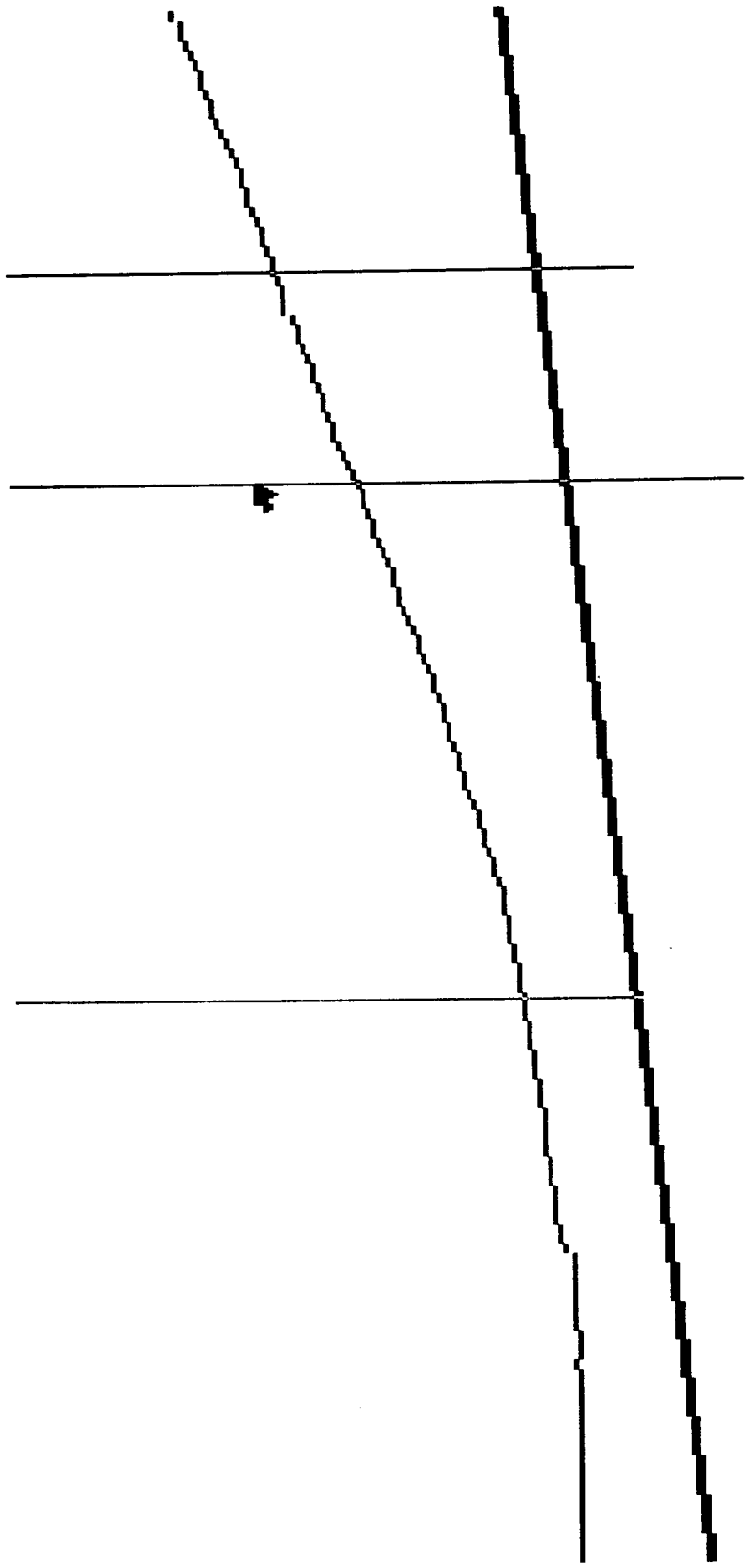


Figure 2

See page 20 for Legend

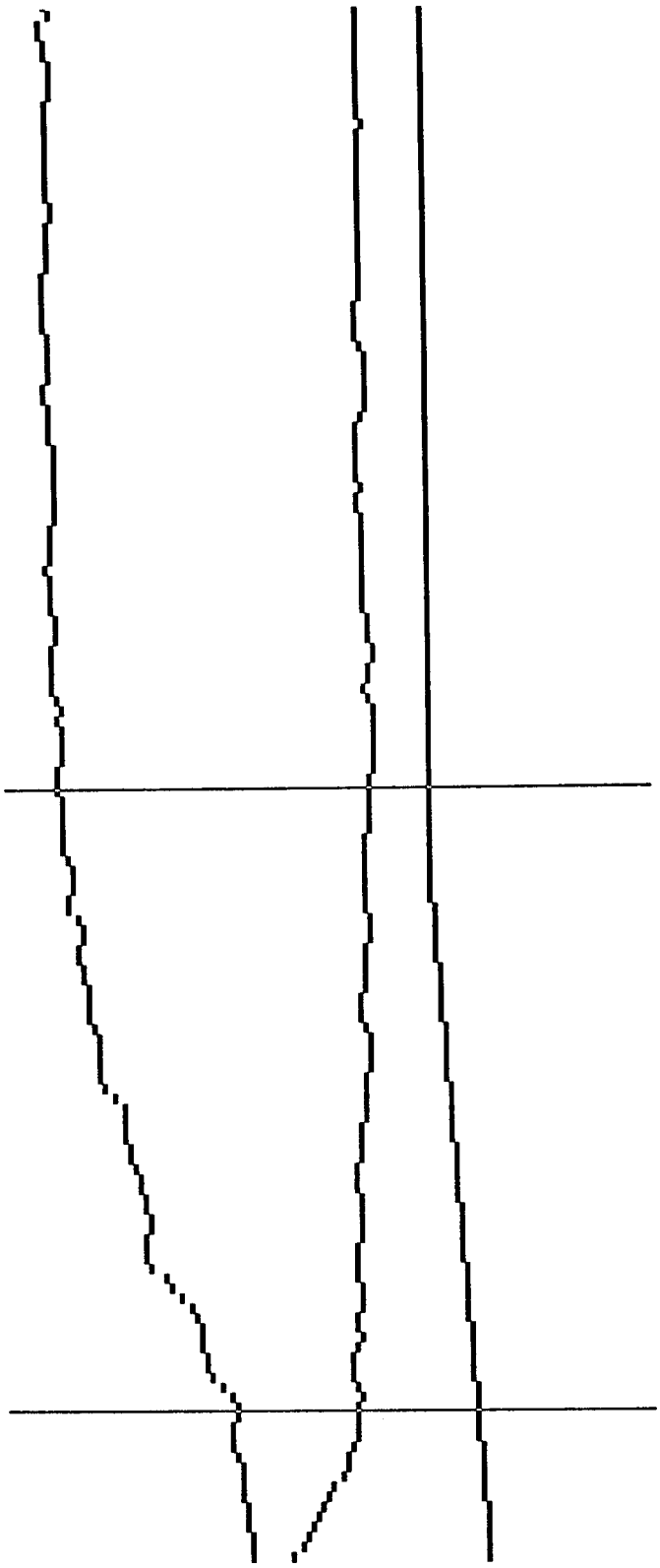


Figure 3

See page 20 for Legend

H. Press 'Q' Key for quit when data analysis is complete. The Main Menu will now appear on the Data Display Monitor Screen.

D. PRINT REPORT

A. From the Main Menu appearing on the VGA/Data Display Monitor, use the 'Up or Down Arrow' Keys to highlight Edit Data. Selection is accomplished by pressing the 'ENTER' Key.

B. Type desired Folio Number and press the 'ENTER' Key.

C. Follow instructions on VGA/Data Display Screen to print the results of the data analysis performed under the EDIT DATA function describer in Section II above.

D. Once the CC/VAU has completed the Printout of the desired subject eye movement data, the Main Menu screen will re-appear on the VGA/Data Display Screen.

An example of the House IR/Video ENG System Printout is provided on pages 25 and 26 of this Manual. It presents the horizontal and vertical eye movement data based on ocular motor, positional, and caloric test results. The caloric data is further depicted in graphic and numerical form for Reduced Vestibular Response (RVR) and Directional Preponderance (DP) calculations.

E. ERASE TEST

A. From the Main Menu appearing on the VGA/Data Display Monitor, use the 'Up or Down Arrow' Keys to highlight Edit Data. Selection is accomplished by pressing the 'ENTER' Key.

B. Type desired Folio Number and press the 'ENTER' Key.

The House InfraRed/Video ENG System

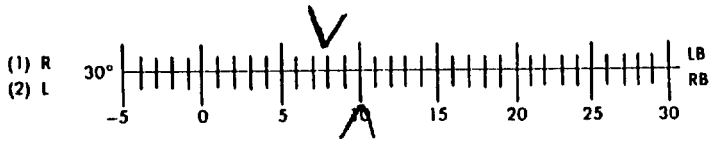
NAME John E. Doe

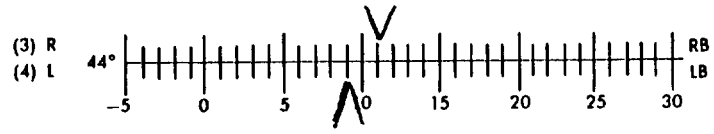
DATE 1/1/92 TESTER AO

MEDICATION Antivert, non 48 hrs.

Spontaneous Nystagmus 30° Angle None

Canal Checked ✓ Calibration Overshoot No





	Supine			Postural		Head Hanging	
	S 0	R 0	L 7L	R 0	L 12L	R 0	L 0
Rotatory			Yes		Yes		
Vertical			—		—		
Latent							
Fatigable							
Vertigo							

HALLPIKE POSITION R NP L NP

FAILURE FIXATION SUPPRESSION No

ICE WATER R NP L NP

INVERTED POSITION Not performed

SIMILARITY TO SYMPTOMS Yes

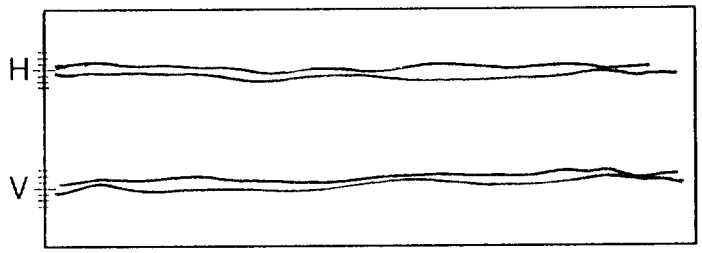
POSITIVE FINDINGS:

$\frac{(1+3)-(2+4)}{1+2+3+4}$ x 100= 0 %

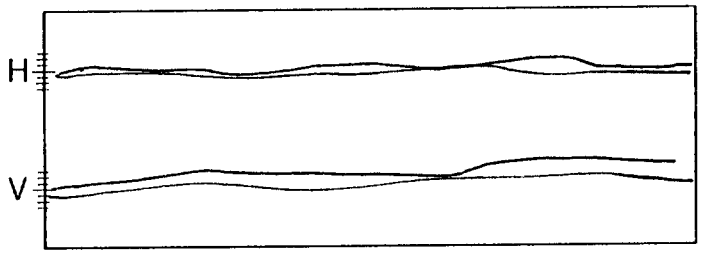
RVR + = Left —=Right

$\frac{(2+3)-(1+4)}{1+2+3+4}$ x 100= 11 %

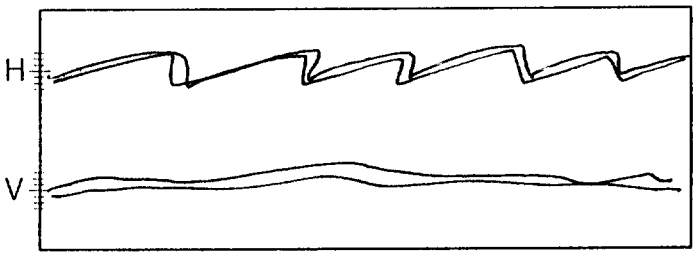
Preponderance (+=Right) —=Left



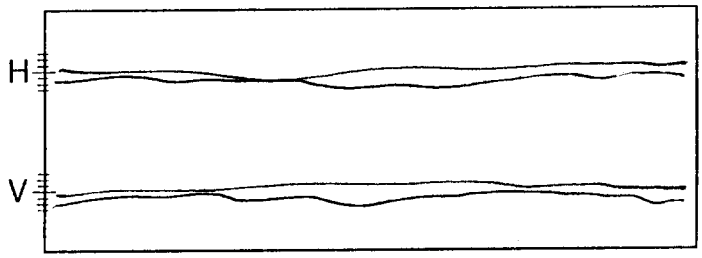
SUPINE - 30 DEGREE



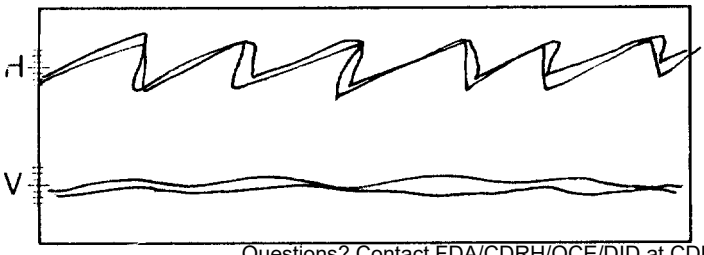
SUPINE



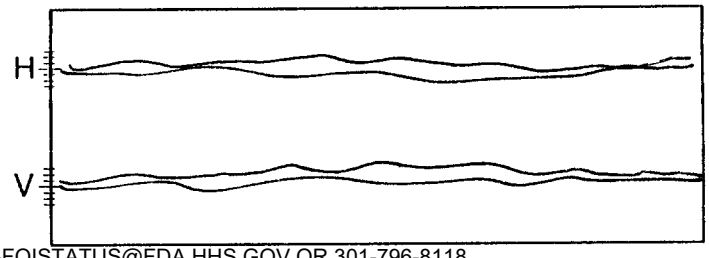
LATERAL - LEFT Left, 7°/sec.



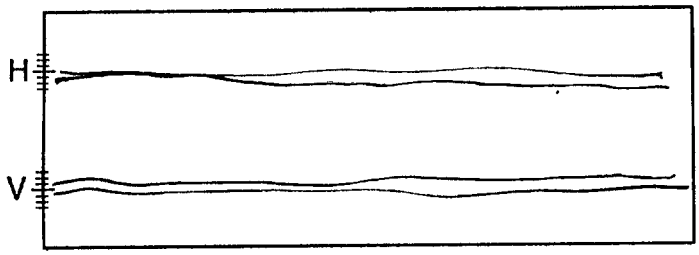
LATERAL - RIGHT



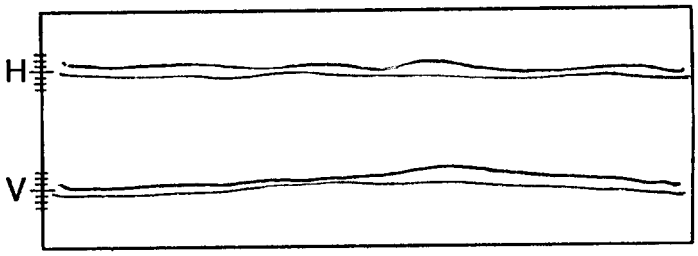
POSTURAL - LEFT ~~Left, 12°/sec.~~ 25



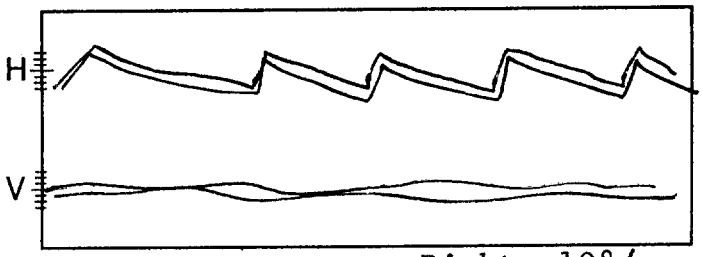
POSTURAL - RIGHT



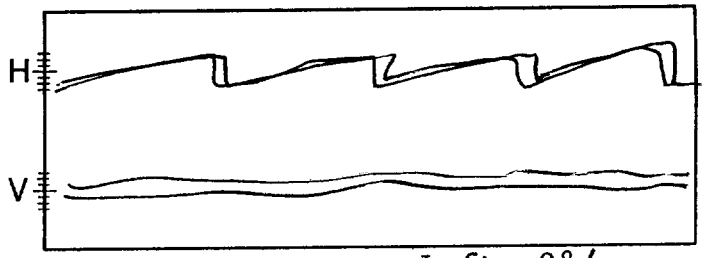
H. H. LEFT _____



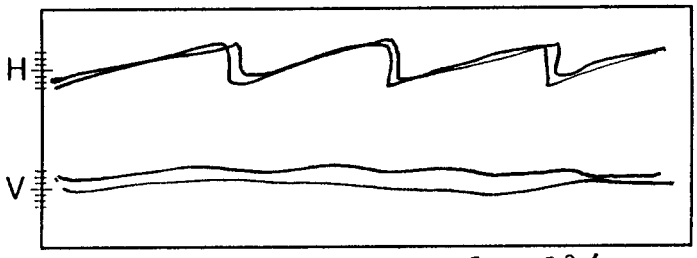
H. H. RIGHT _____



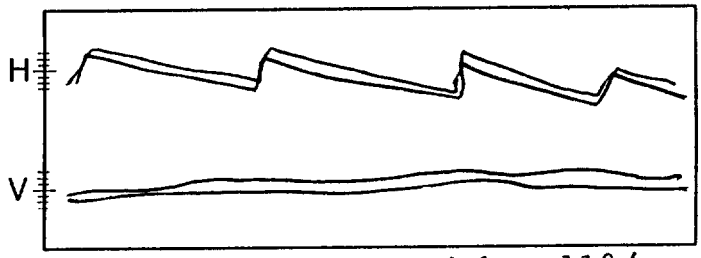
LEFT - 30 DEGREE Right, 10°/sec.



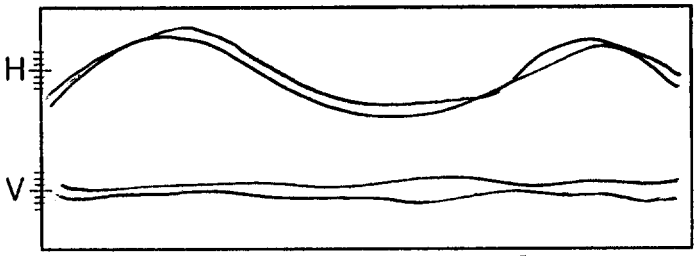
RIGHT - 30 DEGREE Left, 8°/sec.



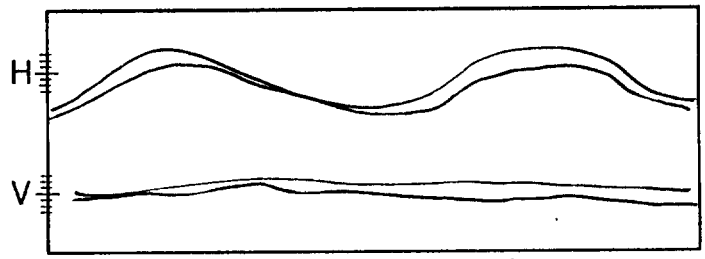
LEFT - 44 DEGREE Left, 9°/sec.



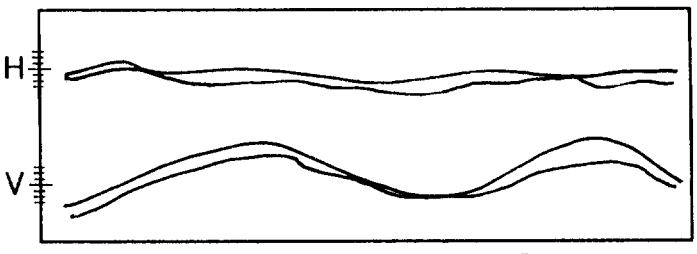
RIGHT- 44 DEGREE Right, 11°/sec.



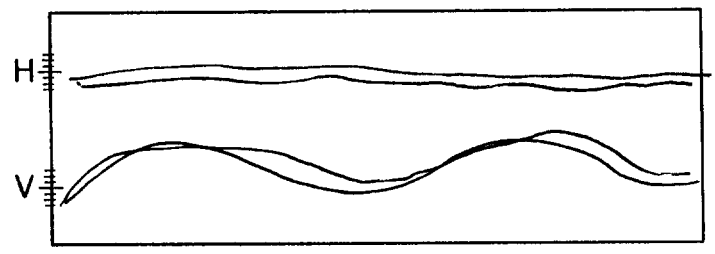
HORIZONTAL TRACKING - L Regular



HORIZONTAL TRACKING - R Regular



VERTICAL TRACKING - L Regular



VERTICAL TRACKING - R Regular

150

C. The instructions on the VGA/DATA Display Screen will request confirmation of the subject and date of test to be erased.

D. Press 'Y' Key if subject/date is confirmed and then press 'ENTER' Key.

E. Press 'N' Key if subject/date is not correct. The VGA Data Display Screen will again request Folio Number, Section B above.

F. DELETE SUBJECT

A. From the Main Menu appearing on the VGA/Data Display Monitor, use the 'Up or Down Arrow' Keys to highlight Edit Data. Selection is accomplished by pressing the 'ENTER' Key.

B. Type desired Folio Number and press the 'ENTER' Key.

C. The instructions on the VGA/DATA Display Screen will request confirmation of the subject (and all associated test data) to be erased.

D. Press 'Y' Key if subject is confirmed and then press 'ENTER' Key.

E. Press 'N' Key if subject is not correct. The VGA/Data Display Screen will again request Folio Number, Section B above.

V. VIDEOTAPE INSTRUCTIONS (Optional Feature)

Often it is desirable to videotape the eyes of a subject during either the IR/Video ENG Goggle or Ocular Motor Module examinations.

1. See Diagram A, Page 7 for connection instructions.
2. Turn on the VCR at the beginning of an examination when instructed by the CC/VAU.
3. Stop or pause the video tape recorder at the end of each portion of the examination.

VI(A): HOUSE INFRARED/VIDEO ENG GOGGLE: SPECIFICATION

(b) (4)

VI(B): HOUSE OCULAR MOTOR MODULE: SPECIFICATION

CONFIGURATION:

(b) (4)

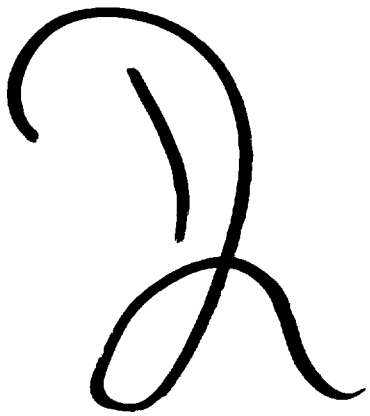
VII. WARRANTY

OculoKinetics warrants all products for a period of 1 year from the date of delivery.

OculoKinetics, Inc.
2291 W. 205th Street, Suite 203
Torrance, California 90501
(310) 328-0477, FAX (310) 328-0697

The House InfraRed/Video ENG System

House InfraRed/Video ENG Goggle:	U.S. Patent (4,815,839) and Foreign Patents Granted
House Ocular Motor Module:	U.S. Patent (5,137,345) and Foreign Patents Pending



REPRESENTATIVE BIBLIOGRAPHY

1. Aschan, G., Bergstedt, M., and Stahle, J.: Nystagmography: Recording of Nystagmus in Clinical Neuro-Otological Examinations. Acta Otolaryngol. [Suppl.] (Stockh.) 129:5-103, 1956.

2.* Baloh, R.W., and Furman, J.M.R.: Modern Vestibular Function Testing. Western Journal of Medicine. 150:59-67, 1989.

3. Barber, H.O., and Wright, G.: Manual of Electronystagmography. 2nd. ed. St. Louis, Mo., Mosby. 1980.

4.* Brookler, K.: Electronystagmography 1990. Neurologic Clinics. 8(2) 235-259, 1990.

5. Jongkees, L.B.W., and Philipszoon, A.J.: Electronystagmography. Acta Otolaryngol., (Suppl.) 189: 1964.

6. Kasai, T., and Zee, D.S.: Electronystagmography. Acta Otolaryngol. (Stockholm) Suppl. 189, 1964.

7. Kileny, P., and Kemink, J.L.: Artificats and Errors in the Electronystagmographic (ENG) Evaluation of the Vestibular System. Ear and Hearing. 7(3):151-6, 1986.

8. Mehra, Y.G.: Electronystagmography: A Study of Caloric Tests in Normal Subjects. Journal of Laryngology and Otology. 78:520, 1964.

9. National Research Council. Commission on Behavioral and Social Sciences and Education. Committee on Hearing, Bioacoustics, and Biomechanics. Evaluation of Tests for Vestibular Function. Pages 1-81. 1991.

10. Rubin, W.: Nystagmography: Terminology, Technique and Instrumentation. Arch. Otolaryngol. 87:266-271, 1968.

* - Copy Enclosed in Attachment H.

2291 205th Street, Suite 203 • Torrance, California 90501 • (310) 328-0477 FAX (310) 328-0697

The Western Journal of Medicine

Medical Progress

Modern Vestibular Function Testing

ROBERT W. BALOH, MD, *Los Angeles, and* JOSEPH M. R. FURMAN, MD, PhD, *Pittsburgh*

Current tests of vestibular function concentrate on the horizontal semicircular canal-ocular reflex because it is the easiest reflex to stimulate (calorically and rotationally) and record (using electro-oculography). Tests of the other vestibulo-ocular reflexes (vertical semicircular canal and otolith) and of the vestibulospinal reflexes have yet to be shown useful in the clinical setting. Digital video recording of eye movements and vestibular-evoked responses are promising new technologies that may affect clinical testing in the near future.

(Baloh RW, Furman JMR: Modern vestibular function testing. West J Med 1989 Jan; 150:59-67)

As with other sensory systems, there are two general categories of tests of vestibular function: those relying on the subjective response of a patient and those relying on objective measurements of reflex activity. Unlike tests of the auditory and visual systems, however, quantifying the sensation of movement derived from excitation of the vestibular receptors has been a difficult task for clinicians.[1] It is often impossible for a patient to differentiate those sensations that are strictly vestibular from visual and proprioceptive sensations. Equally important, the subjective awareness of vestibular stimulation depends on a patient's general state of alertness and degree of cooperation. For these reasons, modern vestibular function testing has focused on objective measurements of vestibular reflex activity. The horizontal semicircular canal-ocular reflex has received the most attention to date because there are several relatively simple techniques for stimulating and recording it. In the future, the clinical assessment of vestibular function must include tests of the other suborgans of the vestibular apparatus, namely, the vertical semicircular canals and otolith organs.

Electronystagmography

Methods of Recording Eye Movements

Electro-oculography (EOG) is the simplest and most readily available method for recording eye movements.[2] With this technique, a voltage surrounding the orbit is measured whose magnitude is proportional to the amplitude of the eye movement. When used for evaluating vestibular function, the technique has been termed electronystagmography (ENG), and often the terms EOG and ENG are used interchangeably.[3-5] With EOG the velocity, frequency, and amplitude of spontaneous or induced nystagmus and the changes in these measurements brought about by a loss of fixation—either with the eyes closed or with the eyes open in darkness—can be quantified. Also, visually guided eye movements (saccadic and pursuit) can be quantitatively assessed.

The principle of electro-oculography is shown in Figure 1.[6] The pigmented layer of the retina maintains a negative potential with regard to the surrounding tissue by means of active ion transport. The potential difference between the cornea and the retina, known as the corneoretinal potential, acts as an electric dipole oriented in the direction of the long axis of the eye. In relation to a remote electrode, an electrode placed in the vicinity of the eye becomes more positive when the eye rotates towards it and less positive when it rotates in the opposite direction. With EOG, the measured voltage is proportional to the sine of the angle of motion.

The advantages of EOG are that it is relatively inexpensive, easily administered, noninvasive, does not interfere with vision, and does not require head restraint. It is reasonably accurate, even for the large horizontal eye movements that are encountered during routine vestibular and ocular motor testing. The disadvantages of EOG include the inability to accurately measure vertical eye movements, interference of eye-blink artifacts,[7] poor signal to noise ratio, susceptibility to changes in skin resistance caused by perspiration, and a dependence on lighting conditions in the test room.[8,9]

Table 1 compares the characteristics of EOG with those of three other eye movement recording techniques that are currently used, primarily in research.[10-14] These other techniques are more sensitive than EOG but at present are not practical for routine ENG testing. The direct video recording of eye movements is the newest and most promising of these techniques. A video camera is used that interfaces with a digital computer. At regular intervals images are stored by the computer for subsequent data analysis.[13] Specialized algorithms for digital signal processing are then used to determine horizontal and vertical eye positions. With the rapid advances occurring in this area, it is reasonable to expect that the sensitivity will improve and the costs will decrease in the near future.

Electronystagmography can be used to evaluate many types of eye movement disorders by adapting the testing procedure for specific abnormalities. It is useful, however, to have a standard test battery that screens all important areas. A typical test battery includes tests for pathologic nystagmus, vestibulo-ocular reflex function (usually the bithermal caloric test), and visual ocular control (saccades and smooth pursuit).

From the Department of Neurology, University of California, Los Angeles, School of Medicine (Dr Baloh), and the Department of Otolaryngology, University of Pittsburgh School of Medicine, and the Eye and Ear Hospital, Pittsburgh (Dr Furman).

Supported by National Institutes of Health grant No. NS-09823.

Reprint requests to Robert W. Baloh, MD, Department of Neurology, UCLA School of Medicine, Los Angeles, CA 90024-1769.

160

ABBREVIATIONS USED IN TEXT

ENG = electronystagmography
EOG = electro-oculography
VOR = vestibulo-ocular reflex
VOR-Fix = VOR with fixation-suppression
VVOR = visual vestibulo-ocular reflex

Recording for Pathologic Nystagmus

Pathologic nystagmus may be spontaneous (present in the primary position with the patient seated), positional (induced by a change in head position), or gaze-evoked (induced by a change in eye position).[6]

Spontaneous nystagmus of peripheral vestibular origin is strongly suppressed with fixation and usually is not evident on routine examination unless a patient is seen within a week of the acute incident (Table 2). By contrast, peripheral vestibular nystagmus can be recorded with patients' eyes closed or with their eyes open in darkness and for as long as five to ten years after an acute peripheral vestibular lesion. About 10% to 20% of normal subjects will have a low-velocity spontaneous nystagmus with eyes closed or with eyes open in darkness—less than 3 degrees per second.[5,15] As a general rule, spontaneous nystagmus present with fixation—that is, seen on routine examination—that persists for more than a week is a central sign. Congenital spontaneous nystagmus is usually easily differentiated from acquired central vestibular nystagmus because the former has a high frequency and variable waveform and has been present since infancy.

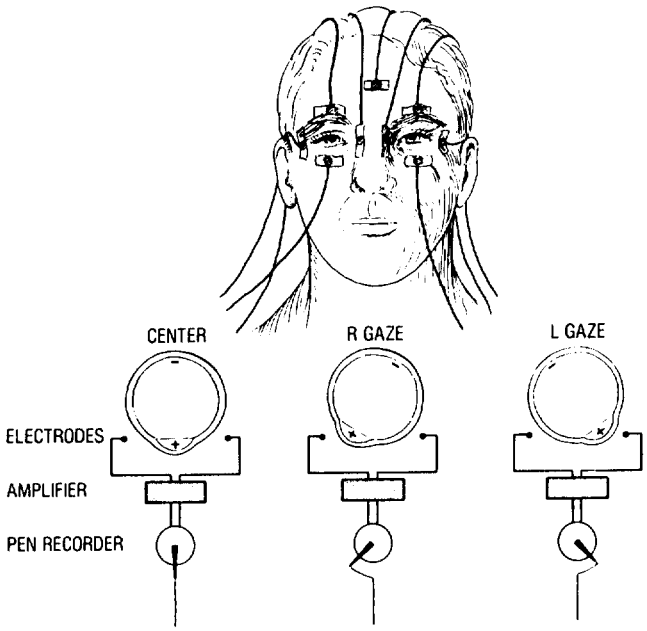


Figure 1.—The technique of electro-oculography is shown (from Baloh[6]).

Positional nystagmus can be static or paroxysmal (Table 3). Static positional nystagmus is induced by slowly placing the patient in the supine, right lateral, and left lateral positions. This type of positional nystagmus persists as long as the position is held. Paroxysmal positional nystagmus, on the other hand, is induced by a rapid change from the erect sitting to the supine head-hanging left, center, or right positions. It is initially high in frequency but rapidly dissipates within 30 seconds to 1 minute.

The most common variety of paroxysmal positional nystagmus—so-called benign positional nystagmus—usually has a 3- to 10-second latency before it begins and rarely lasts longer than 15 seconds. The nystagmus has linear and torsional components with the fast component directed upward—that is, towards the forehead.[16] A key feature is that patients experience severe vertigo with initial positioning but with repeated positioning, vertigo and nystagmus rapidly disappear. By contrast, paroxysmal positional nystagmus of central origin typically does not decrease in amplitude or duration with repeated positioning, does not have a clear latency, and usually lasts longer than 30 seconds.[17] The direction is unpredictable and may be different in different positions. It is often truly vertical with the fast component directed downward—that is, towards the cheeks.

Static positional nystagmus is a common finding both in normal subjects and patients when eye movements are recorded with their eyes open in darkness or with their eyes closed. As in the case of spontaneous nystagmus, however, the average slow-phase velocity of static positional nys-

TABLE 1.—*Important Features of Different Eye Movement Recording Techniques*

Feature	Eye Movement Recording Techniques			
	Electro-oculography	*Infrared Reflection*	*Scleral Search Coil*	*Video**
Recording device	Paste-on electrodes	Photovoltaic diodes on glasses	Coil inside contact lens	Video camera
Principle	Corneoretinal potential	Differential reflection of iris and sclera	Electric current induced in coil	Digital processing of video image
Range of horizontal eye movement, degree	±40	±10-15	Unlimited	Unlimited
Range of vertical eye movement, degree	±30	±5-10	Unlimited	Unlimited
Range of torsional eye movement	...	...	Unlimited	Unlimited
Approximate accuracy, degree	1-2	0.5	0.01	1
Approximate cost, $†	2,000	8,000	20,000	100,000
Will record when patient's eyes closed	Yes	No	Yes	No
Able to record normal vision	Yes	Yes	Yes	Yes
Able to record during head movement	Yes	No	Yes	Yes
Susceptible to eye-blink artifacts	Yes	Yes	Yes	Yes
Sensitive to changes in room lighting	Yes	No	No	No
Sensitive to electrical interference	Yes	Yes	Yes	No
Sensitive to electromyographic interference	Yes	No	No	No

*Computer analyzed video recordings.
†Including electronic amplifiers, if needed.

tagmus in normal subjects does not exceed 3 degrees per second.[15,18,19] The nystagmus may be unidirectional in all positions or direction-changing in different positions. Both direction-changing and direction-fixed types of static positional nystagmus occur most commonly with peripheral vestibular disorders, but both also occur with central lesions.[19] Their presence only indicates a dysfunction in the vestibular system without a localizing value. As with spontaneous nystagmus, however, a lack of suppression with fixation and signs of associated brain-stem dysfunction suggest a central lesion.

Gaze-evoked nystagmus is induced by having a patient fixate on a target 30 degrees to the right, left, above, and below the center position. Eye position should be held for at least 30 seconds. A gaze deviation beyond 40 degrees should be avoided because it may result in nystagmus even in normal subjects ("end-point nystagmus"). Normal subjects can have gaze-evoked nystagmus in the dark or with eyes closed, but gaze-evoked nystagmus recorded with fixation is always an abnormal sign.

Symmetric gaze-evoked nystagmus is most commonly produced by the ingestion of drugs such as phenobarbital, phenytoin, alcohol, and diazepam. It can also occur in patients with such varied conditions as myasthenia gravis, multiple sclerosis, and cerebellar atrophy.[1] Asymmetric horizontal gaze-evoked nystagmus always indicates a structural brain-stem or cerebellar lesion, with the lesion usually on the side of the larger amplitude nystagmus ("Bruns's nystagmus").[20] Rebound nystagmus is a type of gaze-evoked nystagmus that either disappears or reverses direction as an eccentric gaze position is held. When the eyes are returned to the primary position, nystagmus occurs in the direction of the return saccade. Rebound nystagmus is the only variety of nystagmus thought to be specific for cerebellar involvement.[21,22]

Bithermal Caloric Testing

The caloric test uses a nonphysiologic stimulus to induce endolymphatic flow in the horizontal semicircular canal and thus horizontal nystagmus by creating a temperature gradient from one side of the canal to the other. Unfortunately, because of their position in the temporal bone, the vertical semicircular canals cannot be reliably activated by a caloric stimulus.

With bithermal caloric testing each ear is irrigated with a constant flow rate of water that is 7°C below body temperature (30°C [86°F]) and 7°C above body temperature (44°C [111°F]). The patient lies in the supine position with the head tilted 30 degrees forward so that the horizontal semicircular canals are in the vertical plane. Recordings are made with the patient's eyes open behind Frenzel glasses or in total darkness. Recording with patients' eyes closed is not recommended since eye closure can suppress vestibular nystagmus in some subjects; in others, lid artifacts are prominent.[23] From the ENG recordings, the maximum slow-phase velocity is calculated for a five- to ten-second interval at the peak of response. Slow-phase velocity is a much more sensitive indicator of vestibular function than either the duration or frequency of the caloric response.[24]

The four responses of a bithermal caloric test are routinely compared with two standard formulas. The vestibular paresis formula,

$$\frac{(L\,30°C + L\,44°C) - (R\,30°C + R\,44°C)}{L\,30°C + L\,44°C + R\,30°C + R\,44°C} \times 100,$$

compares the right-sided responses with the left-sided responses, and the directional preponderance formula,

$$\frac{(L\,30°C + R\,44°C) - (L\,44°C + R\,30°C)}{L\,30°C + R\,44°C + L\,44°C + R\,30°C} \times 100,$$

compares nystagmus to the right with nystagmus to the left in the same person. In both of these formulas, the difference in response is reported as a percentage of the total response. This is important because the absolute magnitude of caloric response is dependent on several factors, including age. Dividing by the total response normalizes the measurements to remove the large variability in absolute magnitude of normal caloric responses. In our laboratories, the upper normal value for vestibular paresis is 22%, while that for directional preponderance is 28% (using the maximum slow-phase velocity in the above equations).[15]

A caloric fixation-suppression index can be obtained by having a patient fixate on a target during the middle of the response. Because the slow-phase velocity of caloric-induced nystagmus is constantly changing, it is important that the fixation period occur near the time of maximum

TABLE 2.—*Types of Spontaneous Nystagmus*

Nystagmus Type	*Description*	*Location of Lesion*
Peripheral vestibular	Combined horizontal-torsional, inhibited with fixation except in acute stage (<1 week)	Labyrinth or vestibular nerve
Central vestibular	Pure horizontal, vertical, or torsional not well inhibited with fixation	Central vestibular pathways—brain stem and cerebellum
Congenital	High-frequency variable waveform present since infancy	Unknown, no structural correlate

TABLE 3.—*Types of Positional Nystagmus*

Nystagmus Type	*Description*	*Locating Lesion*
Paroxysmal Positional		
Peripheral	Torsional up-beat, brief (<30 sec), fatigability, usually prominent in only one position	Labyrinth, probably posterior semicircular canal
Central	Pure horizontal or vertical, persists (>30 sec), no fatigue, prominent in multiple positions	Fourth ventricular region
Static Positional		
Peripheral	Combined horizontal-torsional, inhibited with fixation except in acute stage	Labyrinth or vestibular nerve
Central	Pure horizontal, vertical, or torsional, not inhibited with fixation	Central vestibular pathways—brain stem and cerebellum

response to obtain the best estimate of fixation-suppression. The fixation-suppression index is defined as the average slow-phase velocity with fixation divided by the average slow-phase velocity without fixation × 100. In normal subjects, the average visual-suppression index is 48% ± 10%.[25]

Abnormal findings on the bithermal caloric test are summarized in Table 4. As a general rule, a substantial vestibular paresis indicates a peripheral vestibular lesion (including the nerve root entry zone), while a substantial directional preponderance is nonlocalizing—that is, it can occur with peripheral and central lesions. The caloric test is relatively insensitive for identifying bilateral vestibular lesions, such as those caused by ototoxic drugs. Because of the wide range of normal values for a maximal slow-phase velocity—5 to 100 degrees per second in our laboratory—a patient's value may decrease severalfold before falling below the normal range.[24] Lesions of the cerebellum occasionally can lead to bilateral increased caloric responses, but again because of the wide range of normal values, it is rare to find caloric responses that exceed the upper normal range. Impaired fixation-suppression of caloric-induced nystagmus indicates a central nervous system lesion, most commonly a lesion involving the midline cerebellum.

Saccades and Smooth Pursuit

Along with the vestibulo-ocular reflexes, two visually controlled ocular stabilizing systems produce conjugate eye movements—the saccadic and smooth pursuit.[26] The saccadic system responds to a retinal position error to bring a peripheral target to the fovea in the shortest possible time. The smooth pursuit system maintains gaze on a moving target by generating a continuous match of eye and target velocity. Optokinetic nystagmus is a form of smooth pursuit in which eye tracking motion in one direction is periodically interrupted by corrective saccades in the opposite direction to relocate the gaze onto new targets coming into the visual field. Saccadic and pursuit eye movements are typically induced by having a patient follow a target moving in a stepwise and a sinusoidal pattern, respectively. For optokinetic testing, a striped pattern is moved across the patient's visual field in a clockwise and counterclockwise direction. With ENG, features of these visually controlled eye movements can be accurately measured and the results compared with normative data. Typically measured are the peak velocity, accuracy, and reaction time of saccadic eye movements.[27] For pursuit and optokinetic nystagmus, the tracking eye velocity is compared with the target or optokinetic drum velocity.[27]

Abnormalities of visual ocular control are helpful for localizing lesions of the central nervous system (Table 5).[28] With one exception, peripheral vestibular lesions do not impair visual ocular control. After an acute unilateral labyrinthine or vestibular nerve lesion, smooth pursuit and optokinetic nystagmus slow-phase velocity will be transiently decreased to the contralateral side—that is, in the direction of the spontaneous nystagmus. The asymmetry of smooth pursuit and optokinetic nystagmus disappears in a few weeks despite the persistence of the vestibular nystagmus in the dark.

Rotational Testing of the Horizontal Semicircular Canals

Rotational testing of the horizontal vestibulo-ocular reflex is becoming more widely used because modern motor-driven platforms can be precisely controlled and multiple graded stimuli can be delivered in a relatively short time. In addition, rotatory testing is often less bothersome to patients than caloric testing. Unlike caloric testing, rotatory testing depends only on the inner ear and is unrelated to the physical features of the external ear or temporal bone. Thus, rotational testing is a more reliable vestibular stimulus. A major disadvantage of rotational testing is that both ears are stimulated simultaneously so that it is less useful than caloric testing for identifying unilateral peripheral vestibular lesions.

TABLE 4.—*Interpreting the Results of a Bithermal Caloric Test*

Result	*Description*	*Location of Lesion*
Vestibular paresis	>22%* asymmetry between right- and left-sided responses	Unilateral labyrinth, vestibular nerve, including root entry zone
Directional preponderance	>28%* asymmetry between left-beating and right-beating nystagmus	Nonlocalizing (anywhere in peripheral and central vestibular pathways)
Bilateral hypoactive	Slow-component velocity <5 degrees/sec bilaterally	Bilateral labyrinth, vestibular nerves, including root entry zones
Impaired fixation-suppression	Fixation does not produce at least 50% decrease in maximum slow-component velocity	Central—brain stem and midline cerebellar

*Normal values for UCLA; each laboratory should establish normative data.

TABLE 5.—*Summary of Visual Ocular Control Abnormalities Produced by Focal Neurologic Lesions*

Location of Lesion	*Saccades*	*Smooth Pursuit and Optokinetic Nystagmus Slow Phase*
Cerebellopontine angle	Ipsilateral dysmetria*	Progressive ipsilateral impairment
Diffuse cerebellar	Bilateral dysmetria	Bilateral impairment
Intrinsic brain stem	Decreased maximum velocity, increased delay time	Ipsilateral or contralateral impairment
Basal ganglia	Hypometria,† increased delay time (bilateral)	Bilateral impairment
Frontoparietal cortex	Contralateral hypometria	Normal
Parieto-occipital cortex	Normal	Ipsilateral impairment

*Undershoots and overshoots.
†Undershoots only.

For rotational testing in our laboratories, a patient is seated in a chair mounted on a motorized rotating table placed inside a light-tight electrically shielded room.[29] For EOG calibration, an array of three light-emitting diodes spaced at the center and 15 degrees to the right and left is attached to a chair directly in front of the patient. Frequent calibrations are interspersed throughout the testing procedure to correct for any fluctuations in the corneoretinal potential. The rotatory chair, a surrounding optokinetic drum, and calibration lights are all controlled by the same microprocessor that analyzes the nystagmus response.

The vestibular system is tested by rotating the chair sinusoidally—in the dark (vestibulo-ocular reflex, or VOR), in the light with the optokinetic drum stationary (visual vestibulo-ocular reflex, or VVOR), and in the dark with the center light-emitting diode lit (VOR with fixation-suppression, or VOR-Fix). In the first instance, the vestibular system is tested without visual influence, whereas in the second, the vestibular and optokinetic systems are stimulated in a synergistic fashion; in the third, the pursuit system is used to suppress vestibular-induced nystagmus. The computer generates stimulus signals at frequencies ranging from 0.0125 to 1.6 Hz and peak velocities of 15 to 100 degrees per second. For screening purposes, we routinely use 0.05 Hz and a peak velocity of 60 degrees per second.

Typical responses of a normal subject to optokinetic and the three standard rotational tests are shown in Figure 2, left panel. In each case, the peak stimulus velocity is 60 degrees per second. All responses are symmetric. The mean gain (defined as peak slow-phase velocity divided by peak stimulus velocity) ± 1 standard deviation for similar testing in 20 normal subjects is as follows: optokinetic nystagmus, 0.83 ± 0.13; VOR, 0.50 ± 0.15; VVOR, 0.99 ± 0.05; VOR-Fix, 0.03 ± 0.02.

Patients with unilateral lesions of the labyrinth or eighth nerve have two characteristic abnormalities on VOR testing; they show an asymmetric gain—that is, a decreased slow-phase velocity with rotation towards the side of the lesion—and an increased phase lead (abnormal timing) of eye velocity relative to stimulus velocity at low frequencies of rotation, 0.05 Hz and lower (Figure 2, center panel).[30] The asymmetry of response is most pronounced with acute lesions and often disappears as recovery occurs, whereas the abnormal timing at low frequencies remains indefinitely.[31] With bilateral peripheral vestibular lesions, the VOR responses are symmetrically decreased or absent at low frequencies (Figure 2, right panel), although VOR responses may be preserved at higher frequencies. As a general rule, optokinetic nystagmus and visual-vestibular interaction tests are normal in patients with peripheral vestibular lesions although a transient asymmetry can occur if there is a strong spontaneous nystagmus.

As opposed to patients with peripheral vestibular lesions, patients with central nervous system lesions usually have abnormalities of visual vestibular interaction. Three characteristic abnormal patterns on the standard rotational test battery are shown in Figure 3. Lesions of the lateral medulla involving the vestibular nuclei characteristically affect both visual and vestibulo-ocular responses.[32] Often the optokinetic nystagmus gain is greater towards the side of the lesion, whereas the VOR gain is greater away from the side of the lesion. Fixation-suppression of the VOR is uniformly impaired, particularly slow phases towards the side of the lesion. Patients with lesions involving the vestibulocerebellum have severely impaired optokinetic responses.[33] The gains of their VOR, VVOR, and VOR-Fix responses are approximately the same—that is, these patients are unable to modulate their vestibulo-ocular reflex with vision. Finally, lesions of the visual motor pathways from the parietal-occipital cortex to the horizontal gaze center in the pons impair ipsilateral visual following responses—smooth pursuit and optokinetic nystagmus slow phases—without affecting VOR responses.[34] Fixation-suppression of contralateral VOR slow phases is impaired because pursuit in one direction is used to inhibit VOR slow phases in the opposite direction.

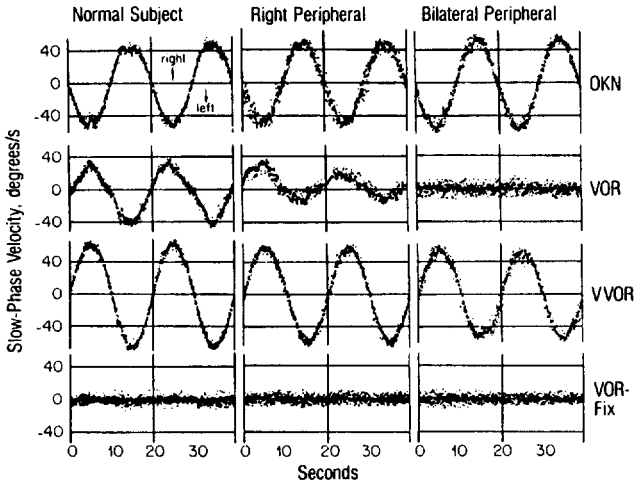


Figure 2.—The plots show slow-phase velocity versus time for optokinetic nystagmus (OKN) and sinusoidal rotational tests (0.05 Hz, peak velocity 60 degrees per second) in a normal subject **(left)**, a patient who underwent right labyrinthectomy **(center)**, and a patient with bilateral vestibulopathy due to using ototoxic drugs **(right)** (from Baloh et al[29]). VOR = vestibulo-ocular reflex, VVOR = visual VOR, VOR-Fix = VOR with fixation-suppression

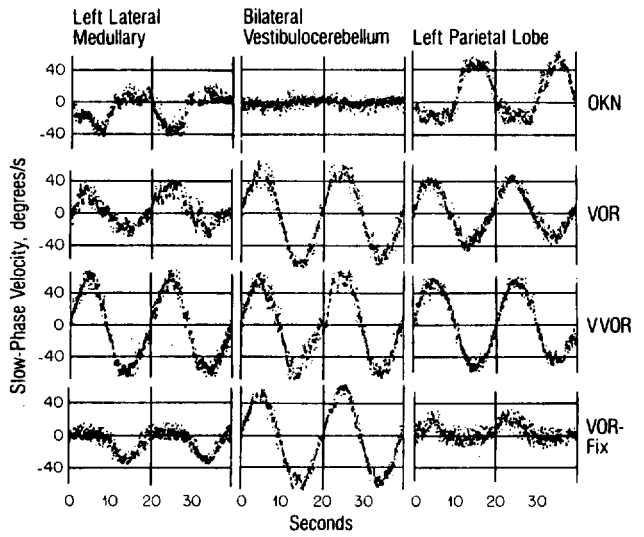


Figure 3.—The plots show slow-phase velocity versus time for optokinetic nystagmus (OKN) and the four standard sinusoidal rotational tests (0.05 Hz, peak velocity 60 degrees per second) in a patient with infarction of the left lateral medullary region **(left)**, a patient with caudal midline cerebellar atrophy **(center)**, and a patient with glioma in the deep parietal lobe on the left side **(right)**. VOR = vestibulo-ocular reflex, VVOR = visual VOR, VOR-Fix = VOR with fixation-suppression

TABLE 6.—*Vestibular Tests and the Suborgans They Stimulate**

Test	Semicircular Canals		Otoliths
	Horizontal	Vertical	
Conventional rotatory chair	×	...	...
Pitch rotation			
Upright	...	×	×
On-side	...	×	...
Ocular counterrolling			
Static	...	...	×
Dynamic	...	×	×
Eccentric rotation	×	...	×
Off-vertical rotation	×	...	×
Linear track	...	...	×
Parallel swing	...	...	×

*× denotes stimulation.

Tests of the Vertical Semicircular Canals and Otoliths

As noted, vestibular tests that are in current use evaluate only the horizontal semicircular canals. Future tests, designed to evaluate other vestibular suborgans—the vertical semicircular canals and otolith organs—will require movements that stimulate these receptors singly or in combination.[35] The determination of which vestibular suborgans are stimulated by a particular movement is often complex and requires a knowledge of three factors: whether the stimulus is an angular or a linear acceleration, the orientation of the skull (and thus the labyrinth) with respect to the movement, and the orientation of the movement with respect to gravity. Table 6 lists the tests we will describe and indicates which suborgans the various tests are designed to evaluate.

Pitch Rotation

Rotating the head in the sagittal plane—like nodding the head "yes"—stimulates all four vertical semicircular canals. If the pitch stimulus is delivered with the subject seated in the upright position (upright pitch), the head changes its orientation with respect to gravity as it tips forward and backward. This change in orientation with respect to gravity stimulates the otolith organs in addition to the vertical semicircular canals. If, however, a subject is seated in a conventional rotatory chair with the head tilted towards the shoulder so that one ear is down, the orientation of the subject with respect to gravity will not change during rotation and the otoliths will not be stimulated. This stimulus, called "on-side" pitch, is thus comparable to conventional rotation described above, except that for on-side pitch rotation, the vertical rather than the horizontal semicircular canals are stimulated.

There are major limitations to the use of pitch rotation clinically because of problems with delivering the stimulus and measuring the response. Although on-side pitch can be delivered with only minor modifications of a conventional rotatory chair, upright pitch requires cumbersome and costly equipment. Moreover, the vertical eye movements that are induced by pitch rotation cannot be measured accurately with EOG; rather, either the magnetic scleral search coil or a video recording system is used. Preliminary studies in normal animals and humans indicate that there is a difference in the vestibulo-ocular responses to pitch between the upright and the on-side positions.[36-38] The gain was decreased and asymmetries were present in the latter compared with the former.

Ocular Counterrolling

The otolith-ocular reflex produces torsional eye movements during static head tilts. Rotating the head towards the right shoulder causes the eyes to counterrotate to the left, and rotating the head towards the left shoulder causes the eyes to counterrotate to the right. Such rotation of the head in the coronal plane is called roll and the counterrotation of the eyes is called ocular counterrolling.[39-41] To complicate matters, dynamic roll movements also stimulate the vertical semicircular canals because of the angular acceleration of the movement. Thus, when using roll stimulation, a distinction should be made between static and dynamic ocular counterrolling.

As with pitch rotation, the use of ocular counterrolling clinically is hampered by difficulties both in delivering the stimulus and in measuring the response. For patients to be rotated in their coronal plane, they must be securely fastened to a cumbersome and costly device. In addition, the amount of torsional eye movement produced by a static tilt in the coronal plane is relatively small. For example, if the head is tilted 45 degrees, the eyes counterroll only about 7 degrees. Electro-oculography and infrared reflection techniques are insensitive to this type of movement so that photographic or video recording or the magnetic scleral search coil must be used.

To date, several studies have indicated that unilateral peripheral vestibular lesions produce asymmetries in static ocular counterrolling.[42-44] Further research is needed, however, to determine the reliability of this technique in clinical vestibular laboratories.

Eccentric Rotation

Eccentric (off-center) rotation is delivered by seating a subject upright in a conventional rotatory chair so that the head is away from the axis of rotation, as if the head were placed at the end of the arm of a centrifuge. During angular acceleration with the head eccentric, the labyrinth is exposed to both a rotational and a linear acceleration and thus both the otolith organs and the horizontal semicircular canals are stimulated. Once a constant angular velocity is achieved, only the otoliths are stimulated. A complexity in fully describing this vestibular stimulus arises from the fact that the net linear acceleration delivered to a subject is the vector summation of the linear acceleration produced by the movement itself and the linear acceleration produced by gravity. The advantages of eccentric rotation are that conventional rotatory chairs (with minor modifications) and EOG methods can be used for this test.

With sinusoidal angular acceleration, the eye movements induced with the head at the center of rotation are compared with those induced during eccentric rotation, the difference being caused by the otolith organs.[45] Preliminary studies suggest that this might be a useful clinical test of the otolith-ocular reflex.[46] An even simpler test of otolith function is to have the patient estimate the subjective vertical—using a vertical light bar—during constant-velocity eccentric rotation.[47] Unlike other tests of subjective vestibular sensation, the sensation of tilt experienced during eccentric rotation appears to be highly reproducible. Patients with unilateral peripheral

vestibular lesions experience less of a sensation of tilt when the damaged ear is outermost.[47]

Linear Acceleration on Sleds

Another technique that has been used to study otolithic function in research laboratories is to deliver a pure linear acceleration on a linear track.[48,49] The device typically consists of a roller-coasterlike sled that runs along a track. As with eccentric rotation, the otolith organs sense the net linear acceleration—that is, the vector summation of the linear acceleration induced by the sled itself and that induced by gravity. For a relatively simple case in which the subject is placed on the sled facing the side as if looking out of the side window of an automobile moving forward, a consistent horizontal eye movement (including nystagmus) can be recorded with EOG. For other head orientations, vertical or torsional eye movements are induced, requiring other eye movement recording techniques such as the magnetic scleral search coil or a video system. The use of linear sleds clinically would be severely limited by the expense and size of the equipment.

Parallel Swing

The parallel swing is a simple technique for inducing linear acceleration that may be practical in a clinical laboratory.[50,51] It consists of a platform suspended from the ceiling by supporting cables at each of its four corners. For small-amplitude displacements, almost pure horizontal linear acceleration is experienced by a subject seated on the platform. As with a linear sled, the eye movement response on a parallel swing depends on the orientation of the subject's head relative to the linear acceleration of the swing and gravity. Thus, various combinations of horizontal, vertical, and torsional eye movements may be induced. Preliminary studies indicate that horizontal eye movements are reliably induced when normal human subjects are seated in the dark facing the side so that the linear acceleration occurs along the interaural axis.[50,51] Patients with bilateral peripheral vestibular lesions have diminished or absent responses.[51]

Off-Vertical Rotation

The off-vertical rotation test is done by seating the subject in a conventional rotatory chair and then tilting the entire apparatus, including the chair and subject.[52,53] In this way, as the subject rotates, the head is continually changing its orientation with respect to gravity. In the extreme case, in which the chair is tipped completely on its side (earth horizontal axis or "barbecue rotation"), the subject is rotated from supine to lateral to prone to lateral, and so on. Once a constant velocity is achieved, only the otolith organs are stimulated as the canals respond only to angular acceleration.

A major advantage of this type of otolith test is that a conventional rotatory chair can be used if the angle of the inclination is kept small. Subjects can be placed in or removed from the apparatus easily, and conventional EOG can record the eye movements because they are largely horizontal. A disadvantage is that the stimulus often produces nausea.

Off-vertical rotation testing using a constant velocity in normal subjects induces two horizontal eye movement components, a bias and a modulation component. In patients with unilateral peripheral vestibular lesions, the bias component is diminished when a patient rotates towards the involved ear, while the modulation component remains unchanged.[54,55]

Summary of Vertical Semicircular Canal and Otolith Tests

The tests of the vertical semicircular canal and otolith function briefly described are all based on the knowledge that the vertical semicircular canals sense angular acceleration in the coronal and sagittal planes and the otoliths sense linear acceleration in all directions. Each test induces a combination of horizontal, vertical, and torsional eye movements depending on the characteristics of the movement, the orientation of the subject with respect to the movement, and the orientation of the movement with respect to gravity. Further research is needed to determine the potential clinical usefulness of these investigational techniques.

Vestibulospinal Testing

The neural pathways that underlie the vestibular contribution to the control of head, body, and limb positions are collectively called the vestibulospinal system.[56] As noted, current vestibular laboratory tests concentrate on the vestibulo-ocular system; the vestibulospinal system has been relatively neglected. A major reason for this neglect is that it is difficult to accurately assess the role of the vestibulospinal system in isolation from other sensory systems, namely, vision and somatosensation.

Static Force Plates

The simplest method of recording human postural sway uses a so-called force plate. There are several devices of this type, each designed with the basic idea of recording the position of a subject's center of mass when upright. In fact, these devices measure the position of the center of force, which is a good estimate of the position of the center of mass if a body is moving slowly. The major limitation of such devices relates to the following: the nervous system uses a combination of sensory modalities during the maintenance of an upright stance, and static force plates do not yield controlled stimulus-response measures of vestibulospinal function and thus must rely on spontaneous movements of the body. This latter consideration is analogous to assessing the vestibulo-ocular system by simply monitoring eye position in the absence of vestibular stimulation. Measuring postural sway might be useful as a screening test for imbalance, but the information it provides is nonspecific and probably not helpful for identifying vestibular lesions.[57,58]

Moving Platform Posturography

Moving force platforms have been designed to overcome the limitations of static force platforms discussed above both by controlling the relative contributions of the visual, somatosensory, and vestibular inputs that are normally used to maintain an upright posture and by incorporating stimulus-response measures. With such a device, the platform on which a subject stands can be moved simultaneously with the visual surround. By coupling the platform to the sway of the subject, it is possible to maintain a constant angle between the foot and lower leg, thereby reducing a major source of somatosensory input to the postural control system.[59] If the subject closes his or her eyes or if the movement of the visual enclosure is coupled to body sway, the subject is also deprived of visual information about postural sway. In this way, the influence of the labyrinth on the upright posture through the vestibulospinal system can be studied in a more or less isolated manner.[60] A disadvantage of this technique is that during postural sway, many of the suborgans of the vestibular

labyrinth are stimulated simultaneously, including the vertical semicircular canals and the otolith organs. For this reason, moving platform studies are incapable of providing an assessment of the individual suborgans of the vestibular labyrinth. To date, moving force platform studies have indicated that a bilateral reduction in peripheral vestibular function results in abnormal postural sway when the device is operated to isolate the vestibulospinal system.[61] More research is required, however, to determine the usefulness of moving force platforms for routinely assessing the vestibulospinal system.

Vestibular Evoked Potentials

The ability to record a human vestibular evoked potential has obvious merits as it would provide an objective measure of peripheral vestibular function that would be independent of either the ocular motor or postural control systems. Despite the fact that sensory evoked potentials using auditory, visual, and somatosensory inputs have been developed and are in routine clinical use, short-latency vestibular evoked potentials have been recorded successfully only in small laboratory animals.[62,63] This lack of development is related to the difficulty in delivering a vestibular stimulus that is capable of triggering a coordinated volley of neural activity, a requirement for eliciting a measurable evoked potential. The vestibular equivalent of an auditory click, visual flash, or somatosensory prick is a brief, abrupt, high-intensity rotation equivalent to the rotation encountered during a blow to the face—an angular acceleration in the range of 7,000 degrees per second squared.

Prior research regarding human vestibular evoked potentials has focused on recording long-latency cortical potentials rather than brain-stem evoked potentials.[64-67] The results of these studies are conflicting; it is still unclear whether the recorded potentials are specific for the vestibular stimulus. Considering their possible clinical usefulness, research on vestibular evoked potentials will undoubtedly continue.

REFERENCES

1. Baloh RW, Honrubia V: Clinical Neurophysiology of the Vestibular System. Philadelphia, FA Davis, 1979
2. Young LR, Sheena D: Eye movement measurement techniques. Am Psychol 1975; 30:315-330
3. Kris C: Electro-oculography, *In* Glasser O (Ed): Medical Physiology, Vol 3. Chicago, Year Book Medical, 1960, pp 692-700
4. Jongkees LBW, Philipszoon AJ: Electronystagmography. Acta Otolaryngol (Stockh) 1964; 189(suppl): 1+
5. Barber HO, Stockwell CW: Manual of Electronystagmography. St Louis, CV Mosby, 1980
6. Baloh RW: Dizziness, Hearing Loss, and Tinnitus—The Essentials of Neurotology. Philadelphia, FA Davis, 1983
7. Barry W, Melvill Jones G: Influence of eyelid movement upon electro-oculographic recording of vertical eye movements. Aerospace Med 1965; 36:855-858
8. Gonshor A, Malcolm R: Effect of changes in illumination level on electro-oculography (EOG). Aerospace Med 1971; 42:138-140
9. Proctor L, Hansen D, Rentea R: Corneoretinal potential variations. Arch Otolaryngol 1980; 106:262-265
10. Collewijn H, Van der Mark F, Jansen TC: Precise recording of human eye movements. Vision Res 1974; 15:447-450
11. Optican LM, Frank DE, Smith BM, et al: An amplitude and phase regulating magnetic field generator for an eye movement monitor. IEEE Trans Biomed Eng 1982; 29:206-209
12. Truong DM, Feldon SE: Sources of artifact in infrared recording of eye movement. Invest Ophthalmol Vis Sci 1987; 28:1018-1022
13. Hall RW: Image processing algorithms for eye movement monitoring. Comput Biomed Res 1983; 16:563-579
14. Parker JA, Kenyon RV, Young LR: Measurement of torsion from multitemporal images of the eye using digital signal processing techniques. IEEE Trans Biomed Eng 1985; 22:28-36
15. Sills AW, Baloh RW, Honrubia V: Caloric testing—II. Results in normal subjects. Ann Otol Rhinol Laryngol 1977; 86 (suppl 43):7-23
16. Baloh RW, Honrubia V, Jacobson K: Benign positional vertigo: Clinical and oculographic features in 240 cases. Neurology 1987; 37:371-378
17. Gregorius FK, Crandall PH, Baloh RW: Positional vertigo with cerebellar astrocytoma. Surg Neurol 1976; 6:283-286
18. Barber HO, Wright G: Positional nystagmus in normals. Adv Otol Rhinol Laryngol 1973; 19:276-281
19. Lin J, Elidan J, Baloh RW, et al: Direction-changing positional nystagmus: Incidence and meaning. Am J Otolaryngol 1986; 7:306-310
20. Baloh RW, Konrad HR, Dirks D, et al: Cerebellar-pontine angle tumors—Results of quantitative vestibulo-ocular testing. Arch Neurol 1976; 33:507-512
21. Hood JD, Kayan A, Leech J: Rebound nystagmus. Brain 1973; 96:507-526
22. Hood JD: Further observations on the phenomenon of rebound nystagmus. Ann NY Acad Sci 1981; 374:532-539
23. Baloh RW, Solingen L, Sills AW, et al: Caloric testing: I. Effect of different conditions of ocular fixation. Ann Otol Rhinol Laryngol 1977; 86 (suppl 43):1-6
24. Baloh RW, Sills AW, Honrubia V: Caloric testing—III. Patients with peripheral and central vestibular lesions. Ann Otol Rhinol Laryngol 1977; 86(suppl 43): 24-30
25. Takemori S: Visual suppression test. Ann Otol Rhinol Laryngol 1977; 86:80-84
26. Leigh J, Zee D: The Neurology of Eye Movements. Philadelphia, FA Davis, 1983
27. Baloh RW, Langhofer L, Honrubia V, et al: On-line analysis of eye movements using a digital computer. Aviat Space Environ Med 1980; 51:563-567
28. Baloh RW, Sills AW, Honrubia V: Eye tracking and optokinetic nystagmus—Results of quantitative testing in patients with well defined nervous system lesions. Ann Otol Rhinol Laryngol 1977; 86:108-114
29. Baloh RW, Sakala SM, Yee RD, et al: Quantitative vestibular testing. Otolaryngol Head Neck Surg 1984; 92:145-150
30. Baloh RW, Honrubia V, Yee RD, et al: Changes in the human vestibulo-ocular reflex after loss of peripheral sensitivity. Ann Neurol 1984; 16:222-228
31. Wolfe JW, Engelken EJ, Olson JE: Low-frequency harmonic acceleration in the evaluation of patients with peripheral labyrinthine disorders, *In* Honrubia V, Brazier AB (Eds): Nystagmus and Vertigo. New York, Academic Press, 1982
32. Baloh RW, Yee RD, Honrubia V: Eye movements in patients with Wallenberg's syndrome. Ann NY Acad Sci 1981; 374:600-613
33. Baloh RW, Yee RD, Honrubia V: Optokinetic nystagmus and parietal lobe lesions. Ann Neurol 1980; 7:269-276
34. Baloh RW, Yee RD, Honrubia V: Late cortical cerebellar atrophy: Clinical and oculographic features. Brain 1986; 109:159-180
35. Gresty M, Barratt H, Bronstein A, et al: Clinical aspects of otolithoculomotor relationships, *In* Keller EL, Zee DS (Eds): Adaptive Processes in Visual and Oculomotor Systems. Oxford, England, Pergamon Press, 1986
36. Baloh RW, Richman L, Yee RD, et al: The dynamics of vertical eye movements in normal human subjects. Aviat Space Environ Med 1983; 54:32-38
37. Baloh RW, Honrubia V, Yee RD, et al: Vertical visual-vestibular interaction in normal subjects. Exp Brain Res 1986; 64:400-406
38. Tomko DL, Wall C, Robinson FR, et al: Gain and phase of cat vertical eye movements generated by sinusoidal pitch rotations with and without head tilt. Aviat Space Environ Med 1987; 58:186-188
39. Uemura T, Suzuki J, Hozawa J, et al: Neuro-otologic Examination. Baltimore, University Park Press, 1977
40. Diamond SG, Markham CH, Simpson NE, et al: Binocular counterrolling in humans during dynamic rotation. Acta Otolaryngol 1979; 87:490-498
41. Kirienko NM, Money KE, Landolt JP, et al: Clinical testing of the otoliths: A critical assessment of ocular counterrolling. J Otolaryngol 1984; 13:281-288
42. Nelson JR, House WF: Ocular countertorsion as an indicator of otolith function: Effects of unilateral vestibular lesions. Trans Am Acad Ophthalmol Otolaryngol 1971; 75:1313-1321
43. Diamond SG, Markham CH: Binocular counterrolling in humans with unilateral labyrinthectomy and in normal controls. Ann NY Acad Sci 1981; 374:69-79
44. Diamond SG, Markham CH, Furuya N: Binocular counterrolling during sustained body tilt in normal humans and in a patient with unilateral vestibular nerve section. Ann Otol Rhinol Laryngol 1982; 91:(2 pt 1):225-229
45. Gresty MA, Bronstein AM: Otolith stimulation evokes compensatory reflex eye movements of high velocity when linear motion of the head is combined with concurrent angular motion. Neurosci Lett 1986; 65:149-154
46. Gresty MA, Bronstein AM, Barratt H: Eye movement responses to combined linear and angular head movement. Exp Brain Res 1987; 65:377-384
47. Dai MJ, Curthoys IS, Halmagyi M: Effects of unilateral vestibular neurectomy on perception of tilt in roll, *In* Huang JC, Daunton NG, Wilson VJ (Eds): Basic and Applied Aspects of Vestibular Function. Hong Kong, Hong Kong University Press, 1988, p 234
48. Niven JI, Hixon WC, Correia MJ: Elicitation of horizontal nystagmus by periodic linear acceleration. Acta Otolaryngol 1966; 62:429-441
49. Buizza A, Schmid R, Droulez J: Influence of linear acceleration on oculomotor control, *In* Fuchs AF, Becker W (Eds): Progress in Oculomotor Research. New York, Elsevier/North-Holland, 1981, pp 517-524
50. Jongkees LBW, Philipszoon AJ: Nystagmus provoked by linear acceleration. Acta Physiol Pharmacol Neerl 1962; 10:239-247
51. Baloh RW, Beykirch K, Honrubia V, et al: Eye movements induced by linear acceleration on a parallel swing, *In* Huang JC, Daunton NG, Wilson VJ (Eds): Basic and Applied Aspects of Vestibular Function. Hong Kong, Hong Kong University Press, 1988, pp 165-174
52. Benson AJ: Modification of the response to angular accelerations by linear accelerations, *In* Kornhuber HH (Ed): Handbook of Sensory Physiology—Vestibular System. Berlin, Springer-Verlag, 1974, pp 281-320
53. Stockwell CW, Turnipseed GT, Guedry FE: Nystagmus Responses During

Rotation About a Tilted Axis. Pensacola, Fla, Naval Aerospace Medical Research Laboratory - 1129, 1971

54. Denise P: Rotation d'axe incline par rapport a la gravite—Effets des petits angles et interet clinique, Thesis. Paris, Universite Pierre et Marie Curie, 1986

55. Kamerer DB, Wall C III, Furman JMR: Earth Horizontal Axis Rotational Responses in Patients With Unilateral Peripheral Vestibular Deficits (Abstr). Barany Society Meeting, Bologna, Italy, 1987

56. Wilson VJ, Jones GM: Mammalian Vestibular Physiology. New York, Plenum Press, 1979

57. Wall C III, Black FO: Postural stability and rotational tests: Their effectiveness for screening dizzy patients. Acta Otolaryngol 1983; 95:235-246

58. Bles W, de Jong JMBV: Uni- and bilateral loss of vestibular function, *In* Bles W, Brandt TH (Eds): Disorders of Posture and Gait. Amsterdam, Elsevier, 1986, pp 127-139

59. Nashner LM: A model describing vestibular detection of body sway motion. Acta Otolaryngol 1971; 72:429-436

60. Nashner LM, Black FO, Wall C III: Adaptation to altered support and visual conditions during stance: Patients with vestibular deficits. J Neurosci 1982; 2:536-544

61. Black FO, Wall C III, Nashner LM: Effects of visual and support surface orientation references upon postural control in vestibular deficit subjects. Acta Otolaryngol (Stockh) 1983; 95:199-201

62. Elidan J, Sohmer H, Nizan M: Recording of short latency vestibular evoked potentials to acceleration in rats by means of skin electrodes. Electroencephalogr Clin Neurophysiol 1982; 53:501-505

63. Elidan J, Langhofer L, Honrubia V: Recording of short-latency vestibular evoked potentials induced by acceleration impulses in experimental animals: Current status of the method and its application. Electroencephalogr Clin Neurophysiol 1987; 68:58-69

64. Salamy J, Potvin A, Jones K, et al: Cortical evoked responses to labyrinthine stimulation in man. Psychophysiology 1975; 12:55-61

65. Hofferberth B: Evoked potentials to rotatory stimulation. Acta Otolaryngol 1984; 406 (suppl): 134-136

66. Hood JD, Kayan A: Observations upon the evoked responses to natural vestibular stimulation. Electroencephalogr Clin Neurophysiol 1985; 62:266-276

67. Pirodda E, Ghedini S, Zanetti MA: Investigations into vestibular evoked responses. Acta Otolaryngol (Stockh) 1987; 104:77-84

ire practically cor ·ted and clinically evaluated that will give the knowl-
·dgeable physicia gnificant information. This can best be accomplished
vhen testing is done in physical proximity to the responsible physician and
vhen the tests used are knowledgeably ordered and evaluated. Under such
·ircumstances, vestibular function testing is always cost-effective and ther-
ıpeutically useful.

REFERENCES

1. Black FO: Vestibular function assessment in patients with Ménière's disease: The vestibulospinal system. Laryngoscope 92:1419–1436, 1982
2. Black FO: Vestibulospinal function assessment of moving platform posturography. Am J Otol (suppl):39–46, 1985
3. Black FO, Nashner LM: Postural control in four classes of vestibular abnormalities. *In* Igarashi M, Black FO (eds): Vestibular and Visual Control on Posture and Locomotor Equilibrium. Basel, Karger, 1985, pp 271–281
4. Brookler K, Berko D, Felder T: Contemporary office audiology. Am J Otol 5(6):438–440, 1984
5. Duffy FH: Topographic display of evoked potentials: Clinical application of brain electrical activity mapping (BEAM). Ann NY Acad Sci 388:188–196, 1982
6. Nashner L, Peters JF: Dynamic posturography in the diagnosis and management of dizziness and balance disorders. A balance platform study. Submitted for publication
7. Rubin W: Harmonic acceleration tests as a measure of vestibular compensation. Ann Otol Rhinol Laryngol 91(5):489, 1982
8. Rubin W: Biochemical evaluation of the patient with dizziness. Semin Hearing 10(2):151–160, 1989
9. Wolfe JW, Engelken EJ, Kos CM: Low-frequency harmonic acceleration as a test of labyrinthine function: Basic methods and illustrative cases. Trans Am Acad Ophthalmol Otol 86:130–142, 1978
0. Wurtzman RJ, Fernstrom JO: Nutrition and the brain. Sci Am 230:84–91, 1974

ıdress reprint requests to

Vallace Rubin, MD, PC
-430 Houma Boulevard
Metairie, LA 70006-4226

Electronystagmography 1990

*Kenneth H. Brookler, MD, MS, FRCSC, FACS**

Contemporary electronystagmography (ENG) remains the modality by which the vestibulo-ocular reflex (VOR) is measured. This provides a permanent and objective record of the eye movements. Testing routines evaluating the patient with vestibular complaints have evolved utilizing ENG. Since the majority of patients have peripheral rather than central vestibular disorders, the ability to test the vestibular system with the eyes closed with ENG remains a great advantage. With the advent of ENG, many stimuli were incorporated into the test battery and later found to have very limited clinical value.

At this time any patient with a vestibular complaint or in whom the vestibular portion of the eighth cranial nerve needs to be evaluated should undergo a vestibular evaluation with ENG. The test routine should reveal whether the vestibular system is functioning normally; if abnormal, whether central or peripheral; and if peripheral, whether right or left. The test time should be brief enough to reduce or eliminate patient fatigue and contain the most amount of information to assist in the management of the patient.

This vestibular information is then factored into the entire clinical picture with the results of the audiology, imaging, and laboratory studies.

EQUIPMENT

The most important piece of equipment is the individual performing the test. This should be an efficient, conscientious, and sympathetic person. Much care should be taken in the selection of this individual.

ENG testing should be undertaken in a room dedicated to the test.[2] The equipment should be arranged to allow for ease of use by the technical personnel performing the test. The room temperature should be comfortable for the patient and staff. If the patient is too warm, perspiration could interfere with electrode conductivity or add to an ill-at-ease feeling associated with some of the test battery.

*Clinical Professor of Otolaryngology, New York Medical College; Attending Otolaryngologist, Lenox Hill Hospital; Associate Assistant Surgeon (Otolaryngology), Manhattan Eye, Ear, and Throat Hospital, New York, New York

The patient will recline upon a table for the test. The table should be comfortable and capable of elevating the head and shoulders to 30 degrees, preferably by a motor drive. The base of the table should be fixed in some way to maintain the same relationship to the calibrating lights.

A method of calibration should be available, preferably with calibration lights or a light bar. This allows for a target for the patient to follow, making the calibration procedure more accurate, rather than asking the patient to look at dots permanently fixed on the wall or ceiling. Some of the currently available computerized ENG have the controls for the calibration lights in the software.

An otoscope should be part of the ENG room because an otoscopic examination is undertaken to look for any cerumen that may obstruct the irrigating device or for a perforation that may preclude open irrigation caloric testing in some patients.

A method for measuring the nystagmus is the next piece of equipment essential to the test procedure. In the past this consisted of a preamplifier specially wired to a stripchart recorder. At this time there is a new generation of computerized ENG machines that perform these tasks and reproduce the tracings on the available computer printers. The recorders may have one or two channels, preferably the latter. The electrodes may be AC or DC coupled. If AC coupled, there should be a long time constant in order to avoid an artifact that could be interpreted as nystagmus.

Electrodes to couple the skin to the recorder system are also necessary. These electrodes should be small enough to apply around the eyes, easy to affix, and with enough adhesive to adhere during the procedure. There are now available disposable electrodes that are small and have the adhesive applied. Alcohol wipes are used to remove any makeup or skin grease, to allow the electrodes to adhere properly and couple electrically with the recorder.

A caloric irrigator is also necessary to perform caloric stimulation of the ears. The more reliable caloric stimulus appears to be water rather than air. Current machines are of an open or closed design. The closed design or the closed loop is the most popular, having the advantages of the open water and air stimuli without their respective disadvantages.[3] The closed system simply involves balloons that inflate in the ear canal and recirculate as the water flows. The open system has an irrigating tip that is inserted into the external auditory canal and that flushes the ear canal with the water but requires a system to collect the water as it comes out the ear. Both systems have timers for the duration of the stimulus, flow controls for the the volume flow, and thermostats to control the temperatures in the two water baths. The temperatures, by convention, should produce a stimulus of 30 and 44° centigrade.[5] With the closed loop system this requires a water bath temperature at 28° centigrade to equal the open bath at 30° centigrade.

To estimate the presence of perilymphatic fistulas, an acoustic impedance bridge capable of manipulating the middle ear pressures is desirable.

In instances in which the cool caloric response is below a desirable level, the use of an ice water caloric may be considered. For the ice water, a refrigerator with an ice maker and a 30-dl syringe with a soft irrigation tip attached are used.

METHOD OF TESTING

This methodology addresses the tests necessary to arrive at a clinic diagnosis without resorting to all of the tests available with ENG.

The patient is ushered into the room. Questions are asked about pri medication and alcohol ingestion. The patient should not have taken a drugs that could interfere with the test. These include the vestibu suppressant medications such as meclizine, cyclizine, and cyproheptadi which should have been discontinued 24 hours prior to testing. Other dr such as diazepam and tranquilizers will require a variable length abstinence prior to testing. In those patients habituated to these medi tions, it may be necessary to wean them. Drugs used for the treatmen epilepsy may be continued if necessary and the results interpreted acco ingly. Abstinence from alcohol should be for 48 hours. All medications patient has taken and the time of the last alcoholic beverage taken sho be noted on the report form.

The patient sits on the ENG table, and the external auditory ca are inspected for cerumen that could obstruct the caloric irrigator or the presence of a tympanic membrane perforation (Fig. 1). Once the e are inspected, the patient lies down on the table with the head elevate

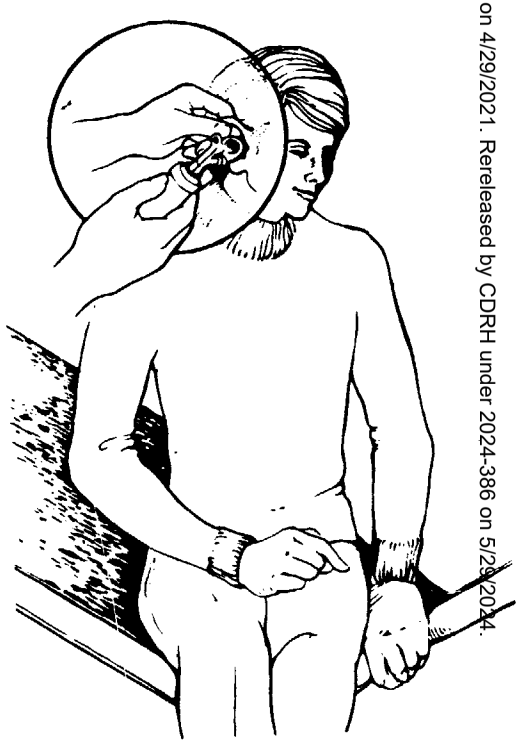


Figure 1. The patient is ushered into the room and sits on the ENG table. The ears are inspected for obstructing cerumen, tympanic membrane perforations, and the shape of the ear canal. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

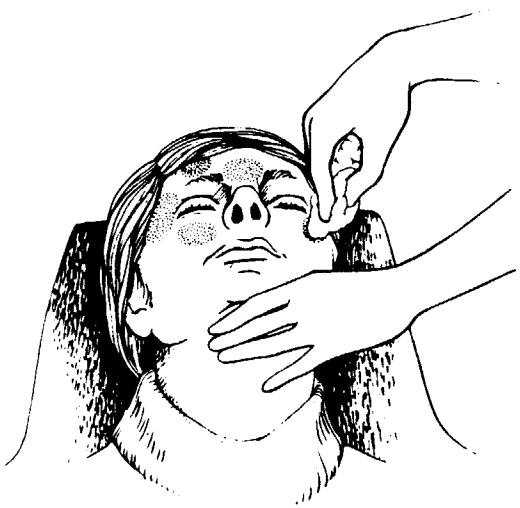


Figure 2. The skin around the eyes where the electrodes will be placed are cleansed of make-up or skin grease. This allows for better coupling of the electrodes to the skin. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ. Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

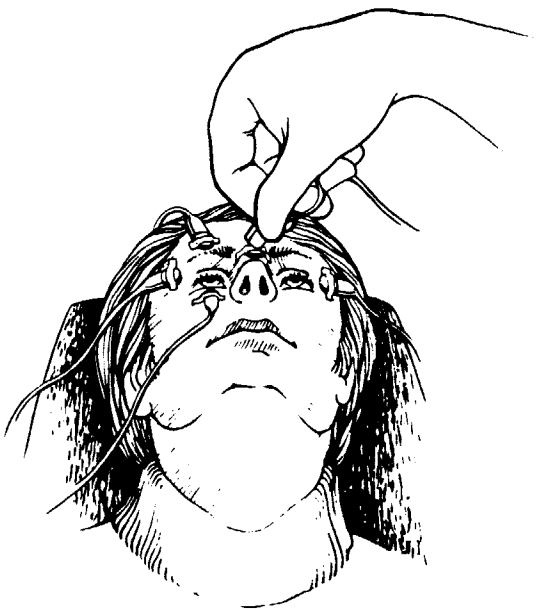


Figure 3. The electrodes are placed with the ground at the root of the nose, the horizontal channel at the outer canthus of each eye, and the vertical channel electrodes above and below an eye. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

the 30-degree position. The skin around the eyes where the electrod be placed is cleansed of make-up and/or skin grease (Fig. 2). The ele are applied with a ground electrode at the root of the nose and one outer canthus of each eye (Fig. 3). For simultaneous vertical traci the second channel, an electrode is placed above and below an ey corneoretinal electrical potential is an electrical potential betwe cornea and retina that allows the surface electrodes to record movement (Fig. 4). The calibration is undertaken to produce a stand eye movement in response to a known distance between the cal lights (Fig. 5). By convention, this standard is 1 degree of eye d equal to 1 mm deflection on the stripchart or to some ratio progra into the computer. The same convention has the paper or recordin from the right to the left. An upward movement on the horizontal indicates eye movement to the right (Fig. 6). Similarly, eye move the left on the horizontal channel is represented by a downward de (Fig. 7). On the vertical channel, upward movement of the ey upward deflection (Fig. 8), and downward is a down (Fig. 9). The con also describes the nystagmus by its quick component.

Once the channels are calibrated, the first test is to look for nys

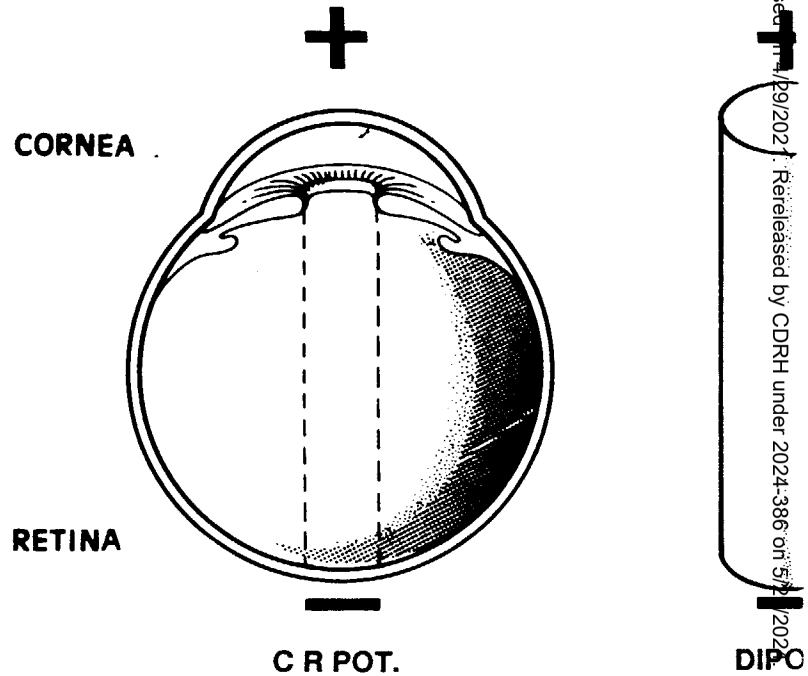


Figure 4. The corneoretinal electrical potential is a dipole whose movement detected within a field set up by the electrodes. (*From* Brookler KH: The clinical and p aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with p sion.)

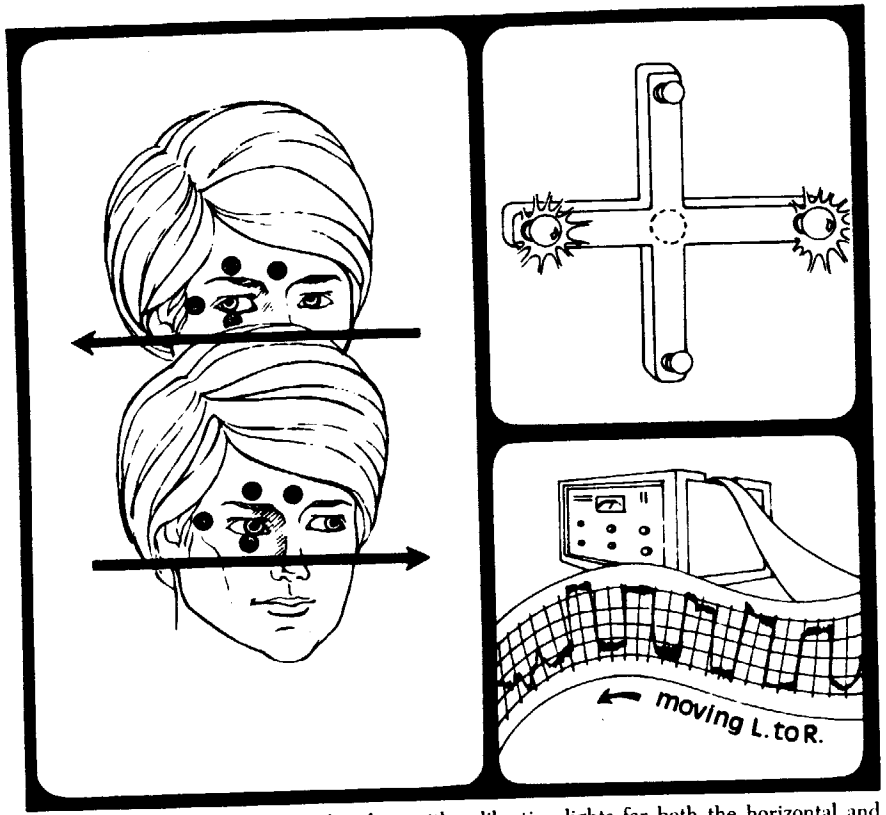


Figure 5. Calibration is undertaken with calibration lights for both the horizontal and vertical eye movements. By convention the paper or recording moves from right to left. The distance between the lights is fixed and the deflection of the tracing is usually 1 mm for each degree of eye movement. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

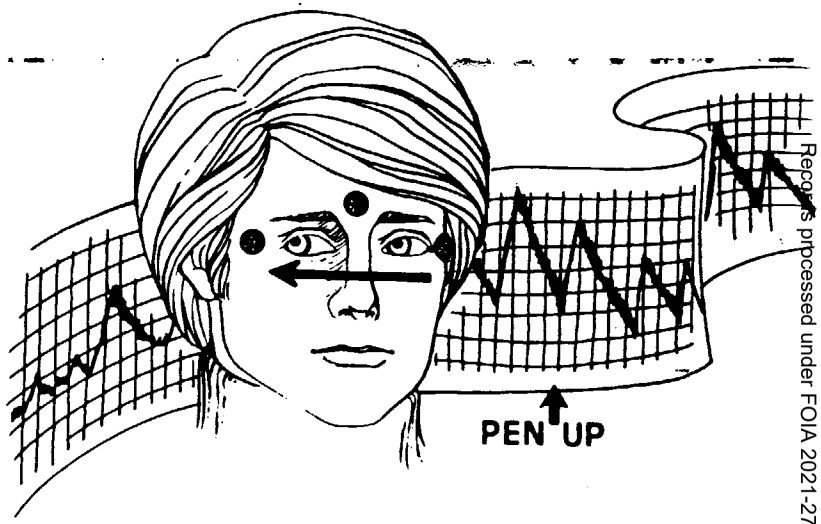


Figure 6. On the horizontal channel when the tracing moves up the eyes have mo the right. The nystagmus direction is indicated by the direction of the quick componen is a right beating nystagmus. (*From* Brookler KH: The clinical and practical aspe electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Proce in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

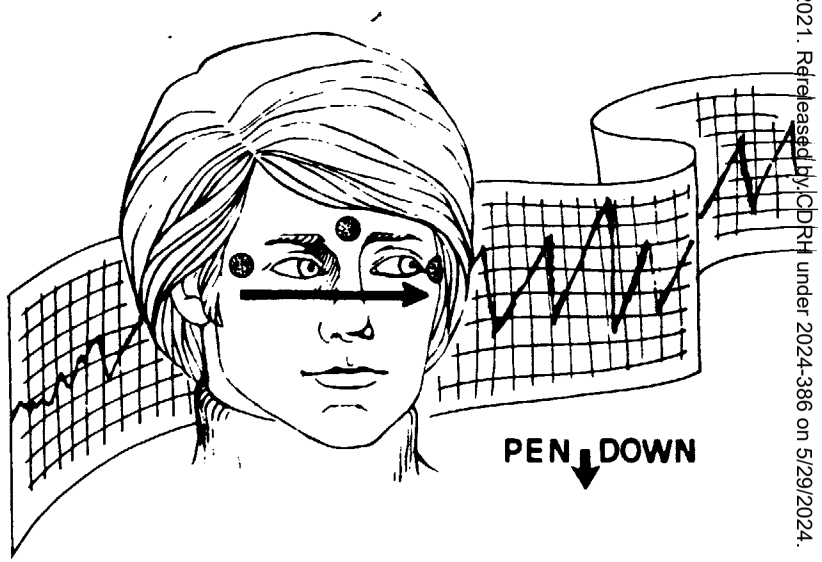


Figure 7. On the horizontal channel when the tracing moves down the eyes have m to the left. This is a left beating nystagmus. (*From* Brookler KH: The clinical and pra aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with pe sion.)

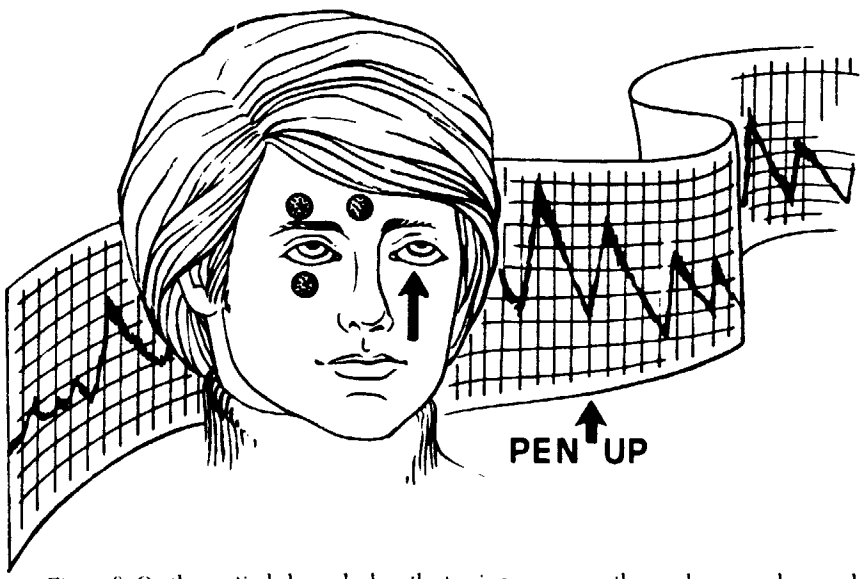


Figure 8. On the vertical channel when the tracing moves up, the eye has moved upward. This would indicate an up beating nystagmus. There are other electrical events that are recorded between the vertical electrodes, making vertical eye movements more difficult to analyze than the horizontal. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

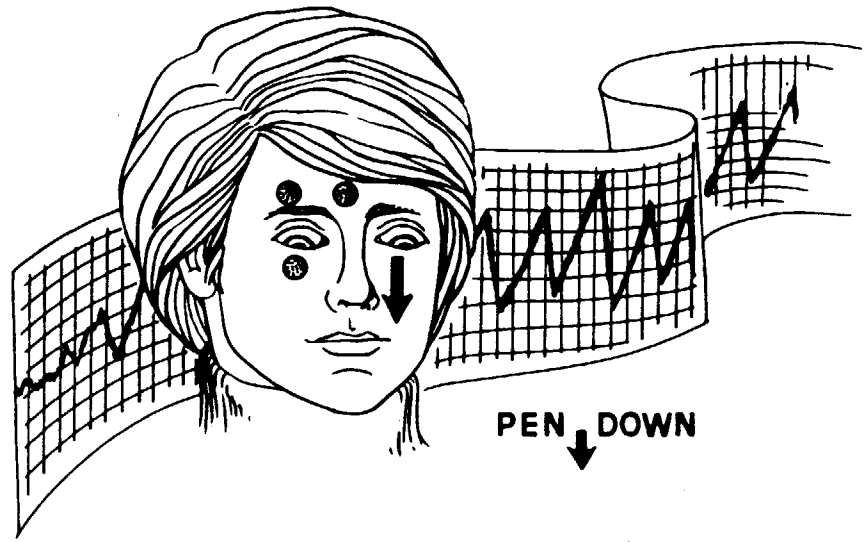


Figure 9. On the vertical channel when the tracing moves down, the eye has moved down. This reveals a down beating nystagmus. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

in the 30-degree supine position (Fig. 10). The positional tests are perforn with simultaneous recording from the horizontal and vertical chann Thirty seconds of recording are undertaken with the eyes closed follow by opening the eyes to search for the eyes-open effect. The head of table is then lowered to the 0-degree position and a search for nystagn both with the eyes closed and open is undertaken (Fig. 11). Next, the h is turned to the right, with a search for nystagmus in the neck tor position, with the eyes first closed, then open (Fig. 12). This is followed turning the whole body to the right, with the neck straight on the b and a search for nystagmus, with eyes closed, then open. Next, the h is rolled into the supine position and the neck turned to the left. The sea for nystagmus in the left neck torsion and later the left lateral position undertaken as on the right side (Fig. 13). After these positions, the ca portion of the test follows.

The head of the table is brought up into the 30-degree supine posi This brings the lateral semicircular to a vertical orientation, allowin maximal stimulation (Fig. 14). The eye movement recording is from t horizontal channel for caloric testing. The irrigating unit first stimula with the cool water in either the right or left ear (Fig. 15). The duratio the stimulus is usually 30 seconds, followed by recording of nystagmus 60 seconds. The maximum eye movement occurs in this 60 seconds. O the maximum nystagmus with the eyes closed has been recorded, t patient is asked to open the eyes to search for ocular fixation suppres In rare instances, no nystagmus will be recorded until the eyes are ope or a very weak nystagmus may be enhanced by opening the eyes. A minute rest is undertaken between stimuli, and the other ear is stimulat

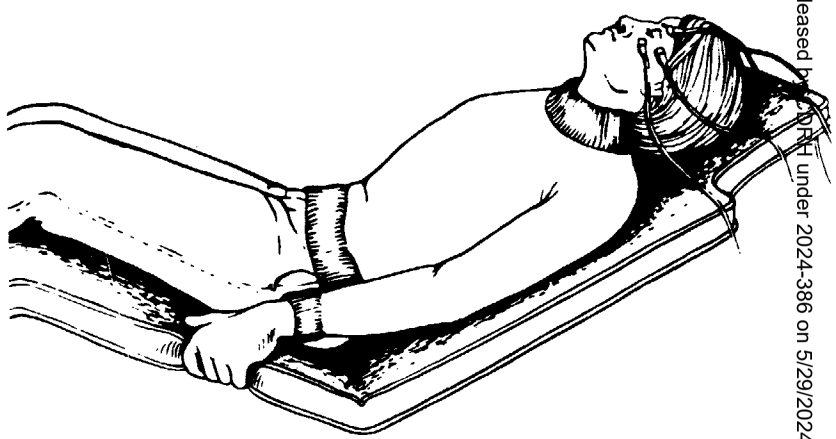


Figure 10. A search is made for nystagmus in the 30-degree supine position. This is t caloric position. It is important to know if any nystagmus is present in this position. If so, th pre-existing nystagmus needs to be counted in the induced responses from the calo stimulations. (*From* Brookler KH: The clinical and practical aspects of electronystagmograph *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and N Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

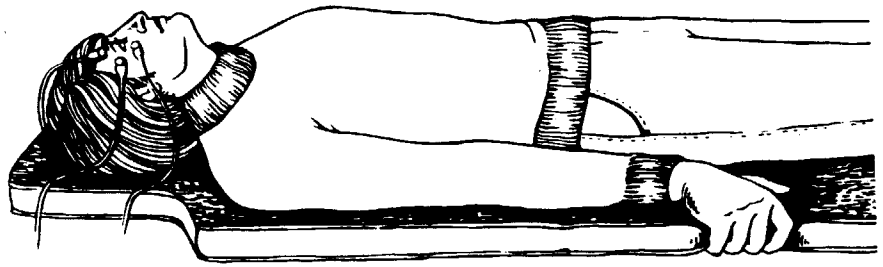


Figure 11. Nystagmus is searched in the 0-degree supine position. The search is undertaken with the eyes opened and closed. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

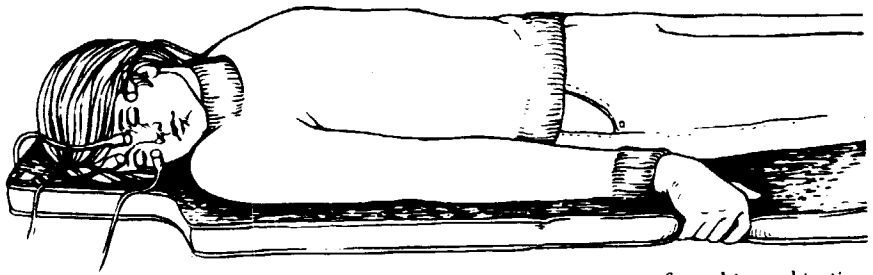


Figure 12. The neck is turned on the body to search for nystagmus from this combination. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

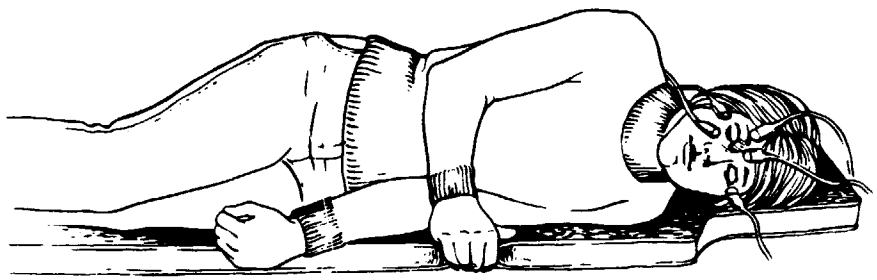


Figure 13. A search is made for nystagmus with the body turned as well to exclude the neck influence and look only at the effect of the ears turned on that side. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

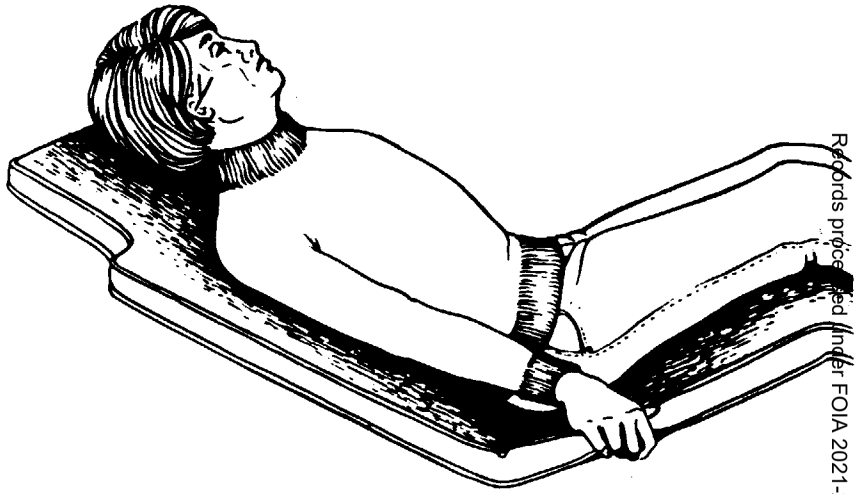


Figure 14. With the body in the 30-degree supine position the lateral semicircular canals are placed vertical. In this position they will respond maximally to caloric and pressure stimuli. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

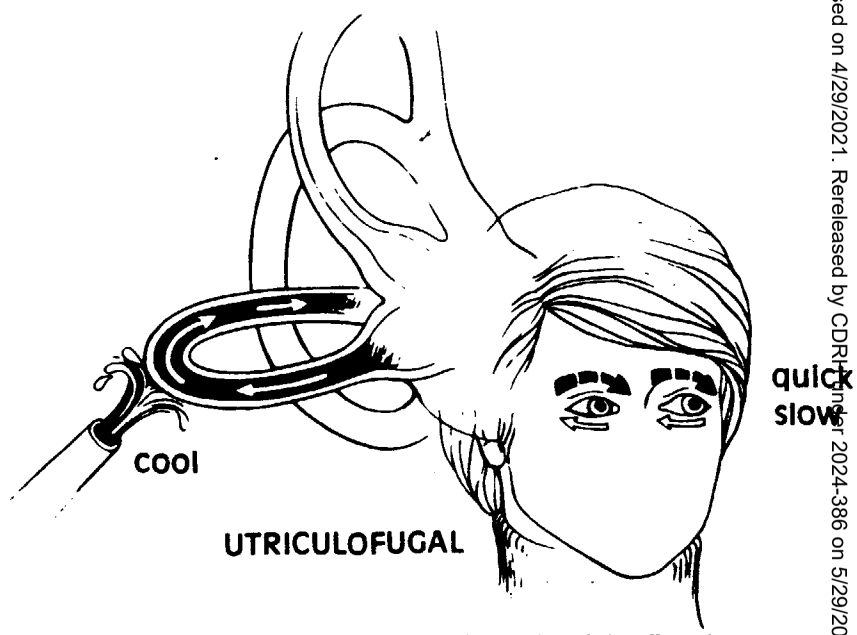


Figure 15. This is a cartoon of the semicircular canals and the effect of cool stimulation on the lateral semicircular canal and the resulting flow of endolymph. This produces a slow deviation of the eyes in the horizontal plane toward the ear, with the quick component away from the irrigated ear. By convention nystagmus is designated by the quick component. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

with the cool stimulus. During these 5 minutes, if a stripchart recorder is used, the results of the positional testing can be cut and mounted and the nystagmus calculated. The method for calculating the nystagmus involves not assessing the one or two most rapid nystagmus beats but to average the velocities of the best nystagmus occurring over a period of 10 seconds.[2] This technique recognizes that the stimulus is not at threshold but at a superthreshold level, and the response should be measured and interpreted in this light.

In the other 5-minute rest period between the stimuli, the nystagmus can be assessed for each of the stimuli. After the monaural cool calorics, the simultaneous binaural cool calorics are performed.[1] If there is a closed loop system with two channels, then each tip is inserted into each ear and the system activated for 30 seconds. If this is an open irrigating system, then it may be of two possible types. The first is one that recirculates to the irrigating tip. This type requires a Y-connector to divert the water flow into two channels, each to one ear (Fig. 16). From the Y-connector intravenous tubing is attached to allow for the insertion into the external auditory canals. This tubing can be taped to the face and held in each ear.

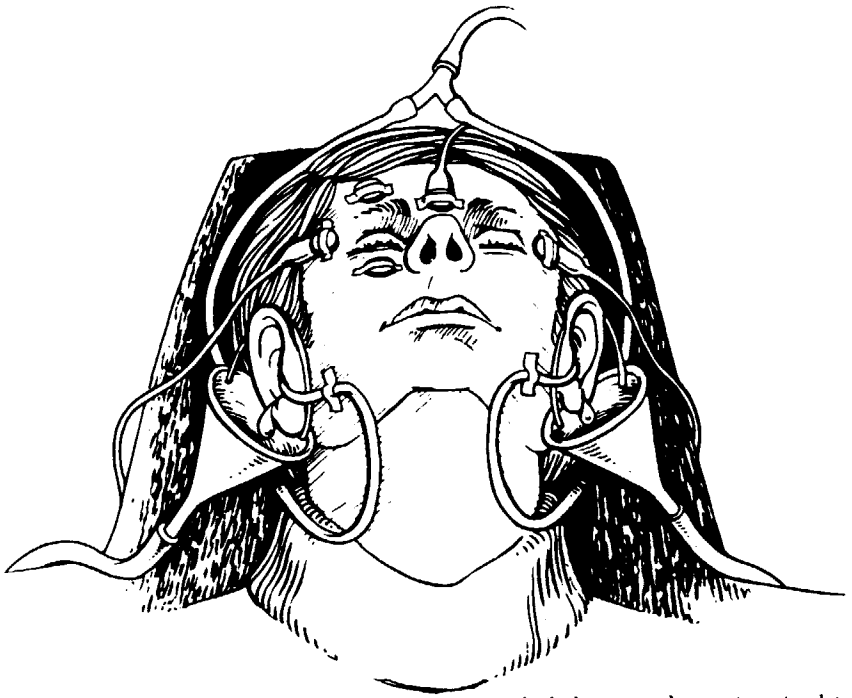


Figure 16. The use of an open irrigation system in which the warmed water is recirculated to the irrigation tip. With a Y-connector the flow of water is split equally to each ear. The tubing is taped to the face and kept in place during the irrigations. Funnels connected to the tubing drain away the water. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

In order to collect the water, funnels can be fixed under the earlobes kidney basin can be placed below each ear.

The other type of open irrigator does not recirculate to the tip. In instance, it is necessary to purge the line before the irrigation to inappropriate stimulation. In this instance, an additional T-connect two Y-connectors are used. This allows for the diversion of the wat of the system before it reaches the second Y-connector, thus allowi purging prior to the actual stimulation. The second Y-connector will the water equally to each ear.

There is a 7-minute break after the simultaneous stimulus. The stimulation routine is undertaken with the warm water stimulus (Fig. The reason for remaining with one temperature throughout is to pr mixing of the temperatures within the tubing, which can lead to var in the temperature and could modify the stimulus and the res nystagmus.

If the nystagmus in response to the cool stimulus to each ear sepa

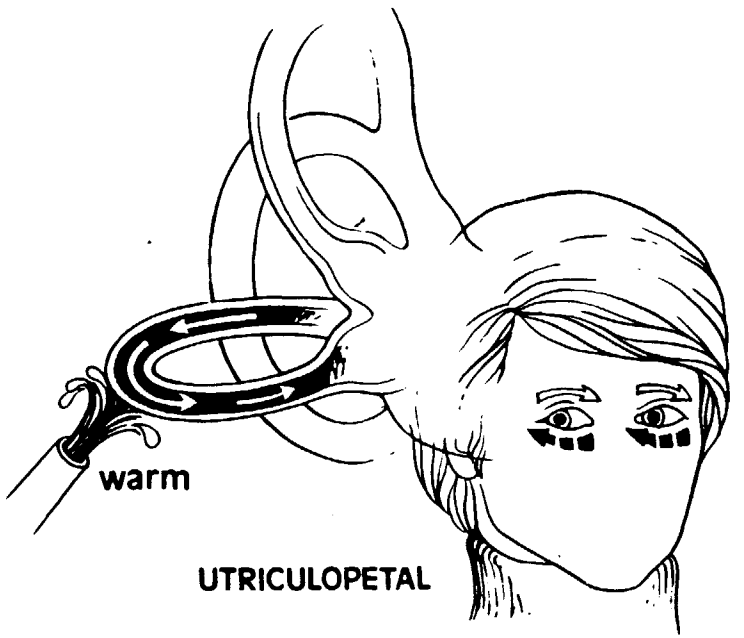


Figure 17. This is a cartoon of the semicircular canals and the effect of warm stim on the lateral semicircular canal and the direction of flow of the endolymph. This pro slow horizontal deviation of the eyes away from the ear and the quick component to a irrigated ear. Therefore, stimulating the same ear with water above and belo temperature produces a nystagmus in different directions depending upon the temper Since the velocities of the nystagmus can be different, then the sides can be compared and the direction of beating of nystagmus can be compared (DP). (*From* Brookler KH clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambu Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & St 1986; with permission.)

is less than 5 degrees per second, then a 30-dl ice water stimulus to that ear is performed and the resultant nystagmus calculated. In this instance, the recorder is usually on for the entire stimulation.

The fistula sign can be elicited using ENG. The patient is placed in the 30-degree supine position and with the impedance bridge a seal of the ear canal is obtained. The pressure in the external auditory canal is manipulated in both a positive and a negative direction while the nystagmus in the horizontal plane is recorded. A search is made for nystagmus with each of these manipulations. If nystagmus is elicited, a perilymph fistula can be suspected. If nystagmus is not elicited, a fistula can still be present but not evident with the fistula sign.

INTERPRETATION

Positional Tests

Nystagmus of any velocity or direction in any position is abnormal (Fig. 18). This indicates abnormal function that may relate to the patient's symptom. When present in one position, the nystagmus may indicate that

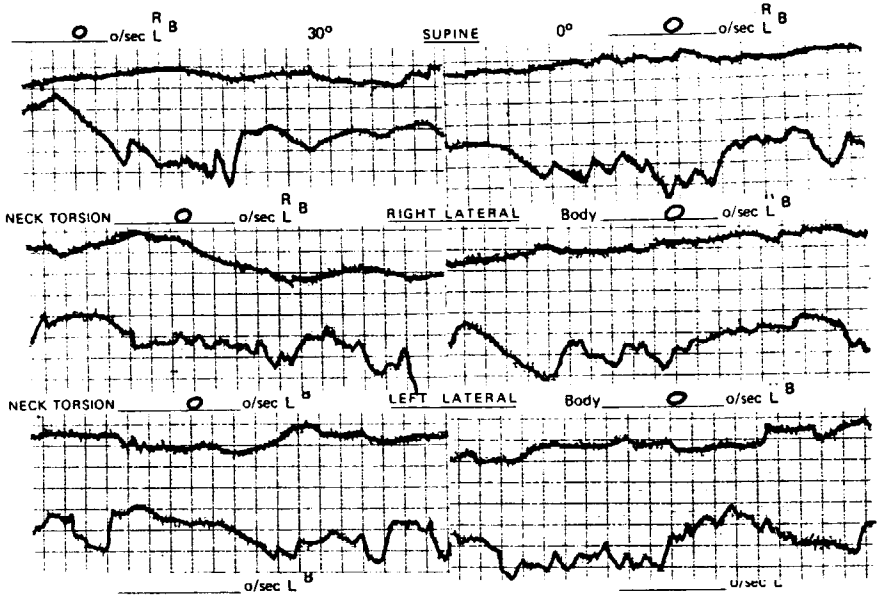


Figure 18. This is a tracing of normal positional testing. In each strip the upper is the horizontal channel. No nystagmus is seen in the supine positions both 0 and 30 degrees. There is no nystagmus when the body and neck are turned on the right or left sides. There is some random electrical activity in the vertical channels, which is insufficient to consider as vertical nystagmus. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

position to produce an input to the nervous system enough to elicit th movement. When the nystagmus is present in several positions and the same direction of beating, this is considered a direction-fixed posit nystagmus (Fig. 19). This type of nystagmus indicates a vestibular sy abnormality but has no localizing value as to central or peripheral and or left. When the nystagmus is present in all of the positions and is same direction of beating and of approximately the same velocity, designated spontaneous nystagmus (Fig. 20). Spontaneous nystagm indicative of a vestibular system abnormality and has no localizing v When the nystagmus is present in more than one position but has a d direction of beating in one position compared with another, this is re as direction-changing positional nystagmus (Fig. 21). This is also ab and has no localizing value. The literature would have one believe t direction-fixed positional nystagmus is always seen with a peripheral

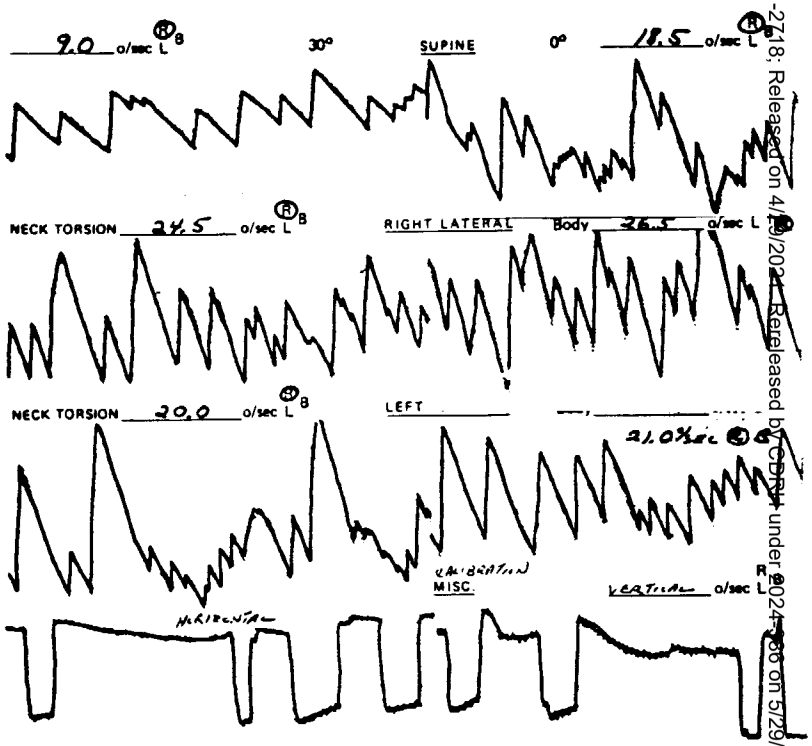


Figure 19. This is the tracing of positional nystagmus with only the horizont movement. In all of the tracings the nystagmus is right beating. The intensity of the nyst varies greatly depending on the position. This is a direction fixed positional nystagmus bottom tracings are of the calibration of the horizontal and vertical channels. (*From* Br KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, & Stratton, 1986; with permission.)

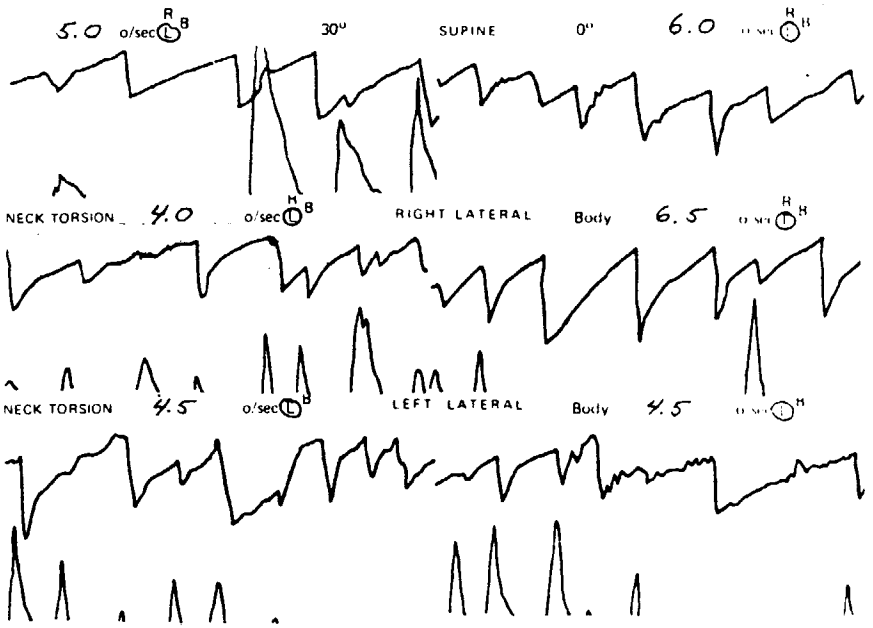


Figure 20. Another positional tracing of mainly horizontal eye movements. There is some vertical channel contamination of the tracing. These positions all reveal a left beating nystagmus. In this instance the intensity or velocity does not change significantly from one position to the other. This is spontaneous nystagmus. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

ular disorder, and a direction-changing with central vestibular disorders. This is often not the case; thus, such rules cannot be relied upon.

If nystagmus appears with neck torsion, this indicates a stimulation of the vestibular system as a result of that movement (Fig. 22). This does not reveal cervical vertigo or nystagmus but is a reflection of an input into the vestibular system sufficient to elicit nystagmu . This is not frequently seen and when present is again evidence of an abnormally functioning vestibular system.

The importance of identifying a vestibular system abnormality is to confirm a malfunction with which the associated clinical symptoms could occur. One could argue that these findings are sometimes seen in patients without symptoms, and this is true. That abnormalities within the vestibular system can be compensated is quite well known and is the basis upon which several treatments rely for their success. For the same reason, a clear-cut abnormality can be identified in an asymptomatic individual. The importance of this testing is to find evidence on the testing to link the symptoms to abnormal function in a battery of vestibular tests.

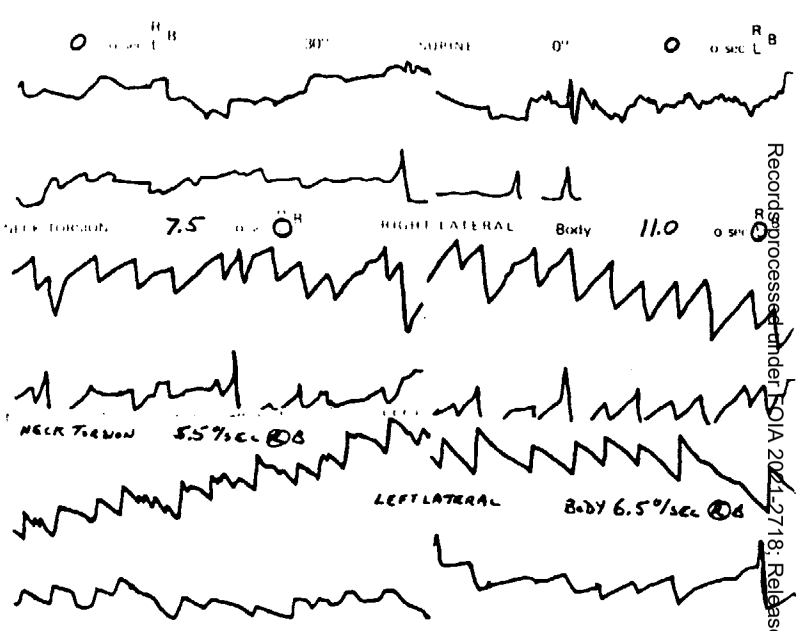


Figure 21. In this positional testing the nystagmus is not seen in the supine po There is a left beating nystagmus with the right ear down and a right beating nystagm the left ear down. This is a direction-changing positional nystagmus. This may also ac positional alcohol nystagmus in the 24- to 48-hour period after ingestion. Note the c of the intensity of the nystagmus with the neck turned compared with the body on th side. (*From* Brookler KH: The clinical and practical aspects of electronystagmography KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck S Philadelphia, Grune & Stratton, 1986; with permission.)

Caloric Tests

The caloric tests can be looked upon in the same manner. Th morphology of the nystagmus should be carefully examined for th metry as the test is conducted. Alerting dysrhythmia may be fou patients for whom the alerting task is too easy. This dysrhythm characterized by bursts of clear nystagmus interrupted by interva nystagmus. This is in contradistinction to central dysrhythmia, wh characterized by successive nystagmus beats that bear no resemblan the preceding or succeeding nystagmus beats (Fig. 23). The intensity nystagmus response is also examined. Once the nystagmus is calcul the velocity should be at least 5 degrees per second. When the velo below 5 degrees per second from the cool stimuli, then an ice stimulus is performed on that ear. An individual response is con hyperactive when the velocity exceeds 25 degrees per second.

When the patient is normal or has a peripheral vestibular diso then opening the eyes or ocular fixation will suppress the nystagmus.

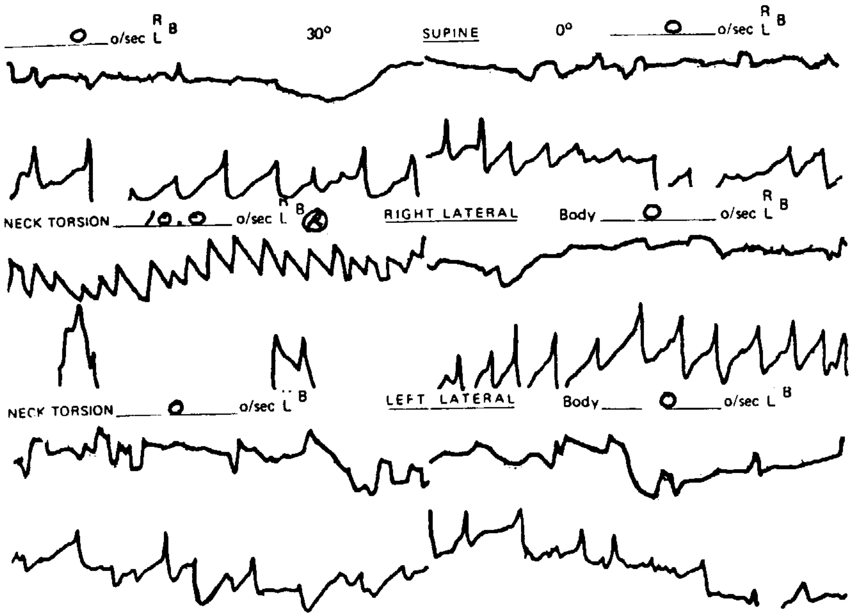


Figure 22. Positional testing. Neck torsion nystagmus with the head turned to the right is revealed. The vertical channel on the right side reveals some electrical activity judged insufficient to be considered nystagmus. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

from the positional tests or the caloric tests. When there is either a central nervous system abnormality or oculomotor pathology, then opening the eyes will fail to suppress any nystagmus or may enhance nystagmus. Since the caloric nystagmus is the most brisk from which to assess fixation suppression, it should be performed for each caloric.

The nystagmus velocity is calculated by reviewing the entire response and selecting the best 10 seconds of tracing. The velocities of each of the beats in that 10 seconds are calculated and averaged over the 10 seconds instead of selecting the maximum velocity of one or more beats or averaging the velocities alone. Since this is a response to a superthreshold stimulus, it should be averaged in this manner. Many of these evaluations have been scored as normal by examining only a few beats, when by just eyeballing the tracing it is clearly abnormal. If this calculation is performed manually on a stripchart tracing, then the total distance the eyes have traveled in the 10 seconds can be measured by adding the lengths of the fast phases in centimeters, which will give the velocity in degrees per second if the calibration was 1 degree per millimeter of eye deflection.

The nystagmus is calculated for each of the four alternate bithermal stimuli (ABB). The numbers are placed in Jongkees' formula, and two

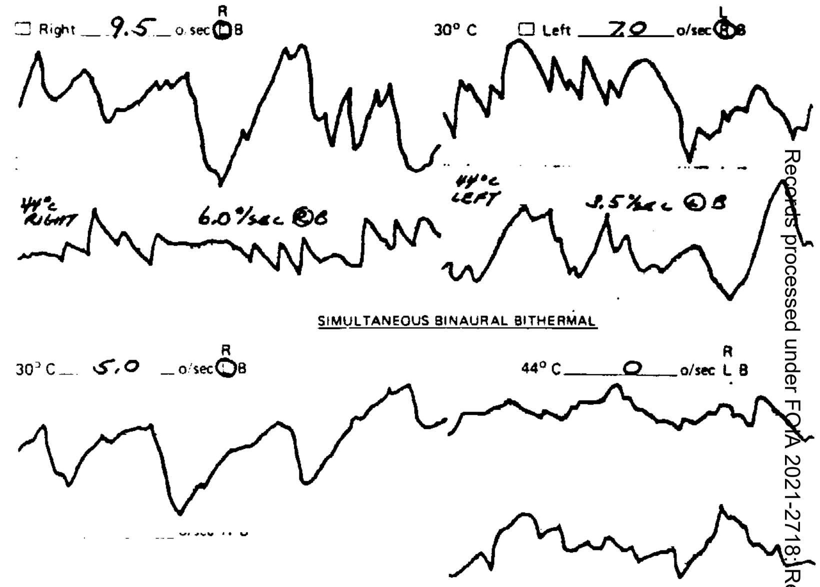


Figure 23. This is a caloric tracing of central dysrhythmia. Note that no two succ beats bear any morphologic relationship to each other. (*From* Brookler KH: The clini practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory S and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 198 permission.)

parameters are developed. The first looks for a reduced vestibular resp (RVR). This compares the intensity of the response from one ear t other, looking for a difference significant enough to be considered abno The criteria developed in a retrospective computer analysis revealed 3 cent or greater to be significant for an RVR (Fig. 24).[4] This indicates the less active side is pathologic and likely emanating from the inne or vestibular nerve (Fig. 25). This assumes that there is no middl problem. At times, the responses may be hyperactive on one side when used in the formula could mislead one into assuming that the active side is the abnormal one. Therefore it is necessary to famili oneself with these variables and take them into consideration when i preting the results.

The second looks for a directional preponderance (DP) of ca nystagmus. This compares the intensity of nystagmus in one direction the nystagmus in the other direction. In the same retrospective stud difference of 30 percent or greater was considered to be abnormal 24). A pathologic directional preponderance indicates a vestibular sy abnormality but has no localizing value. Again, when present, it i abnormal finding and will likely relate to the symptoms of the patient.

To interpret the findings in response to the simultaneous bin bithermal stimulus (SBB), only two decisions need to be made.[1] The is to decide whether nystagmus was produced in response to the stim

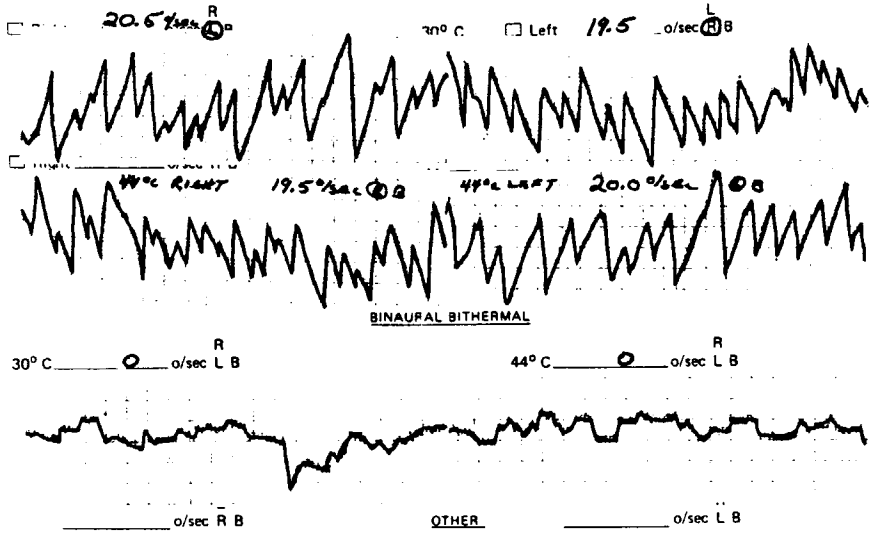


Figure 24. These are tracings from caloric responses. The top traces are in response to the cool alternate stimuli with the right ear on the left and the left ear on the right. The second line of traces are in response to the warm alternate stimuli with the ears in the same position. The bottom traces are in response to the simultaneous binaural bithermal with the 30° C on the left side and the 44° C on the right side. These are normal tracings. The velocities of each of the alternate stimuli fall between 5 and 25 degrees per second. There is a 1 per cent difference between the right and left sides and a 2 per cent difference between the right and left beating nystagmus. The SBB response is type I, revealing no nystagmus from equally normally functioning inner ears and their associated connections. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

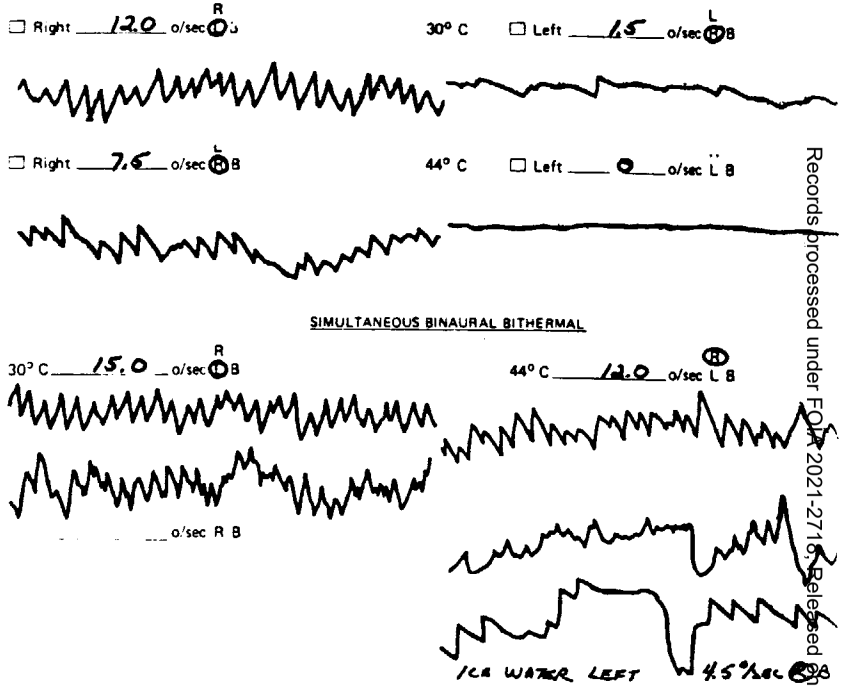


Figure 25. These tracings reveal the caloric responses of a patient with an RVR of 8[illegible] cent. There is very little response from the left ear. The SBB confirms an RVR left (typ[illegible] with a left beating nystagmus in response to the cool stimulus and a right beating respon[illegible] the warm. The vertical tracing with the cool SBB is up beating, which is frequently seen [illegible] cool stimuli. This nystagmus represents a contamination response from the vertically orie[illegible] semicircular canals and is normal. Thirty dl of ice water was placed in the left ear, whic[illegible] produce a response suggesting a form of recruitment possibly indicative of an end-[illegible] origin. (*From* Brookler KH: The clinical and practical aspects of electronystagmograph[illegible] Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and [illegible] Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

The second is to decide on the direction of the nystagmus. Once ha[illegible] made these decisions, the response can classified into four main categor[illegible]

The first category is type I. This category is characterized by [illegible] absence of nystagmus in response to either the warm or cool stimulus. Th[illegible] is indicative of equal vestibular function. It is necessary to look at [illegible] results of the response to the alternate stimulus to decide. If the respons[illegible] on the ABB are in the normal range, then this category is normal (Fig. 5). If there are low to no responses, then type I is based upon equally ab[illegible] or low functioning inner ears. If the response on the ABB is hyperact[illegible] then type I represents equally hyperactive ears.

Type II response is characterized by nystagmus in opposing direction[illegible] For example, the response to the cool stimulus in both ears is right-beati[illegible] nystagmus, and the response to the warm stimulus in both ears is le[illegible] beating nystagmus. This is nystagmus in opposing directions. Take th[illegible]

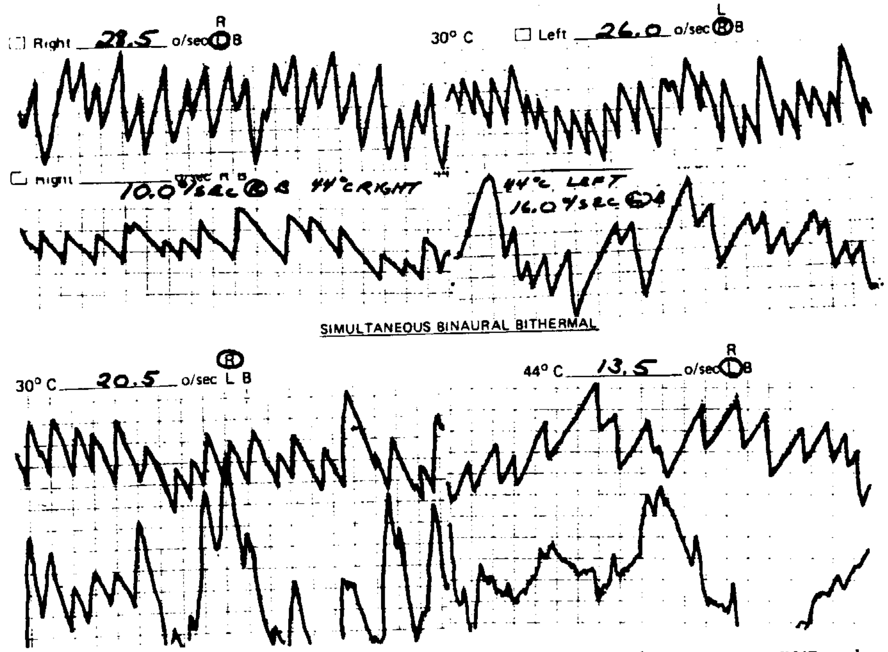


Figure 26. These are normal caloric responses to the ABB with a 4 per cent RVR and a 10 per cent DP. The SBB clearly demonstrates a type II response of an RVR right. Note the normal up beating nystagmus with the cool SBB. Many patients may have a "normal" caloric with the ABB. The SBB is more sensitive in finding vestibular abnormalities. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

example a little further and examine the possible explanation for this response. In order to produce a right beating nystagmus with a cool stimulus, there is greater function in the left ear, because both ears are stimulated simultaneously. In order to produce a left beating nystagmus with a warm stimulus, there is greater function in the left ear, because both ears are stimulated simultaneously. In this instance, there is either a hyperactive left ear or a hypoactive right ear. By convention, the hypoactive side is considered pathologic. Before deciding, the results of the ABB stimulation should be examined (Fig. 26). To decide on a hyperactive response or a sign of vestibular recruitment, the clinical history and other findings may be necessary, especially if the ABB responses are in the normal range. This type, indicating the hypoactive side, is the most frequently found and is usually in keeping with other facets of the history. Many times the ABB may be normal in this instance (Fig. 27).

Type III is characterized by nystagmus whose direction is the same no matter what temperature the stimulus. For example, a right beating nystagmus is produced in response to stimulating both ears with the cool

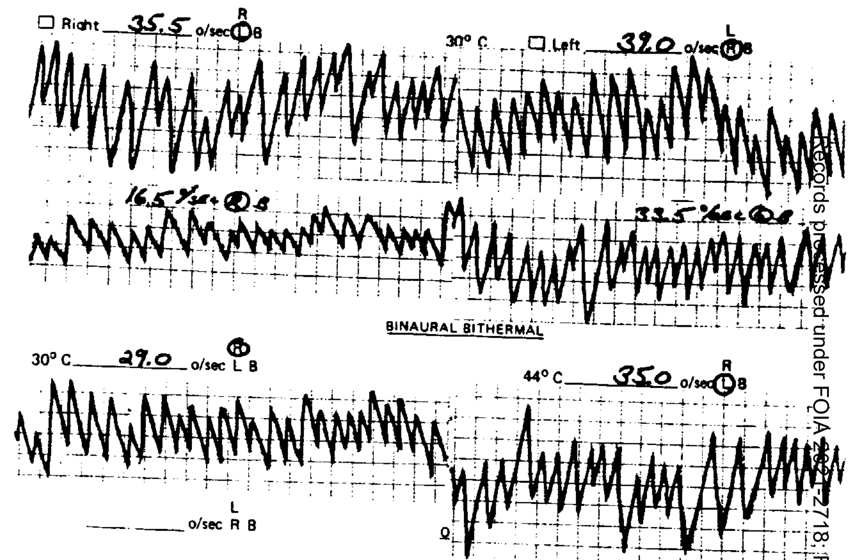


Figure 27. The caloric responses to this ABB are hyperactive except for the warm ri… When a search is made for an RVR (16 per cent) or a DP (11 per cent) there are… abnormalities found. The SBB clearly reveals a type II RVR right. (*From* Brookler KH: … clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambula… Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Strat… 1986; with permission.)

stimulus (Fig. 28). Also, there is a right beating nystagmus when both e… are stimulated by warm water. This response is considered abnormal l… not localizing as to central or peripheral. This response defines the conc… of directional preponderance. In some instances, the response on the A… also shows a DP.

Type IV is the last category and is characterized by the absenc… nystagmus from only one of the stimuli. For example, the cool stimulus… both ears fails to produce a nystagmus response, while the simultane… warm response is left beating. This category is a wastebasket of t… remaining responses. When present it is abnormal but has little localiz… value. In following the evolution of this response and in follow-up test… the response may shift to a type I if the patient is better, or may go on… a type II or type III response.

The SBB has shown a 55 per cent greater incidence of detecting… vestibular system abnormality than the ABB. As a result, many patie… thought to have psychogenic vestibular symptoms based upon "norma… test results without the SBB might be considered to have an organic ba… for their symptoms.

RESULTS

The results of a vestibular evaluation utilizing electronystagmograph… can give insight into the manifestations of the vestibular symptoms. Th…

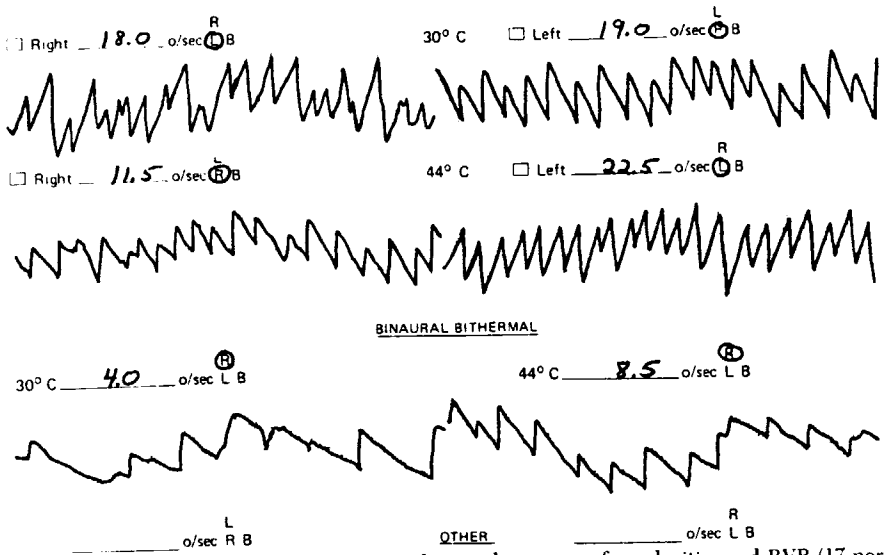


Figure 28. These caloric tracings reveal normal responses for velocities and RVR (17 per cent) and DP (14 per cent). The SBB is abnormal and classifies as a type III. No matter which temperature of water is applied simultaneously the resultant nystagmus is right beating. This signifies an abnormally functioning vestibular system, but has no localizing value. (*From* Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surgery. Philadelphia, Grune & Stratton, 1986; with permission.)

positional testing may reveal a direction-fixed nystagmus that could lead to a peripheral vestibular diagnosis. A nystagmus whose direction is fixed no matter what position and whose velocity is not different in each of the positions is a spontaneous nystagmus and could well denote a peripheral vestibular disorder. A direction-changing positional nystagmus makes one think of a central lesion unless the clinical history is consistent with Ménière's disease, which can mimic any vestibular lesion. Although these positional signs suggest a central or peripheral origin, they are not exclusively so. By turning the neck to the position, another stimulus is added to sharpen the effect. Nystagmus with neck torsion just indicates another vestibular system abnormality to verify objectively the vestibular complaints.

Caloric testing allows for a more defined although artificial stimulus. By stimulating each ear separately and with water warmer and cooler than body temperature (ABB), knowledge as to how these responses compare to the ideal can be derived and factored into the decisions in the clinical management of the patient. The caloric responses can be further sharpened by applying the bithermal stimulus simultaneously in both ears (SBB). Stimulating both ears at the same time can reduce the neurologic facilitatory and inhibitory influences that affect the response when a single ear is stimulated. As a result, the SBB is more sensitive in finding vestibular system abnormalities than the ABB. In addition, there appears to be some specificity with regard to the side of a peripheral lesion with the SBB.

This permanent record is available for perusal as the patient undergoes treatment and the response to treatment. If the anticipated progress is not made in response to treatment, then the evaluation can be repeated to search for changing aspects of function.

In 1990, ENG remains the basis for objectively measuring the function of the vestibulo-ocular reflex with a battery of tests designed to extract the most important information in the least amount of time.

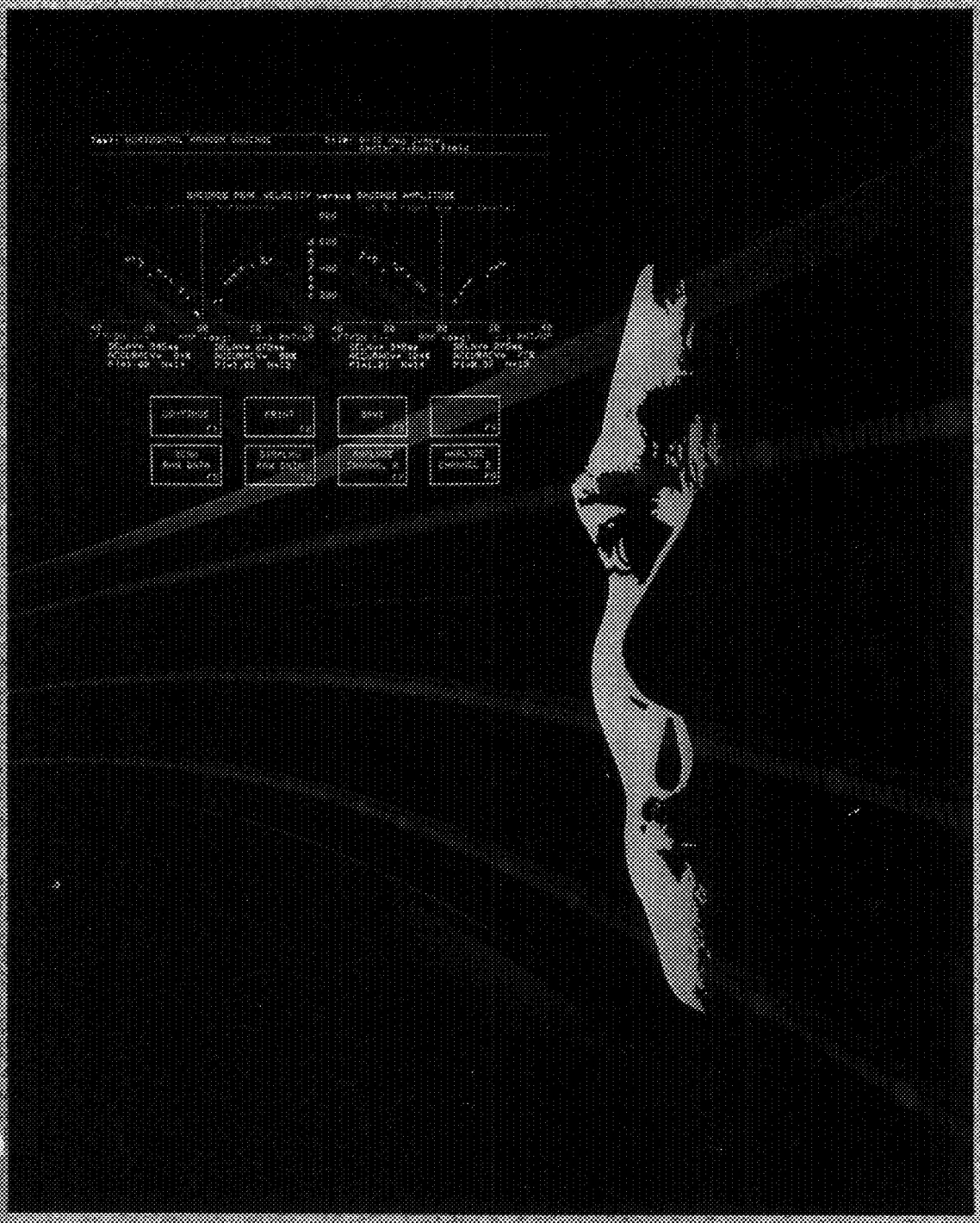
REFERENCES

1. Brookler KH: The simultaneous binaural bithermal: A caloric test utilizing electronystagmography. Laryngoscope 86:1241–1250, 1976
2. Brookler KH: The clinical and practical aspects of electronystagmography. *In* Lee KJ, Stewart C (eds): Ambulatory Surgery and Office Procedures in Head and Neck Surg. Philadelphia, Grune and Stratton, 1986
3. Brookler KH, Baker AH, Grams G: Closed loop water irrigator system. Otolaryngol Head Neck Surg 87:364–365, 1979
4. Brookler KH, Pulec JL: Computer analysis of electronystagmography records. Trans Am Acad Ophthalmol Otolaryngol (May-June) 563–575, 1970
5. Stahle J: Electronystagmography in caloric and rotary tests: A clinical study. Acta Otolaryngol (Suppl) 137:1–83, 1968

Address reprint requests to

Kenneth H. Brookler, MD, MS
Neurotologic Associates, P.C.
111 East 77th Street
New York, NY 10021

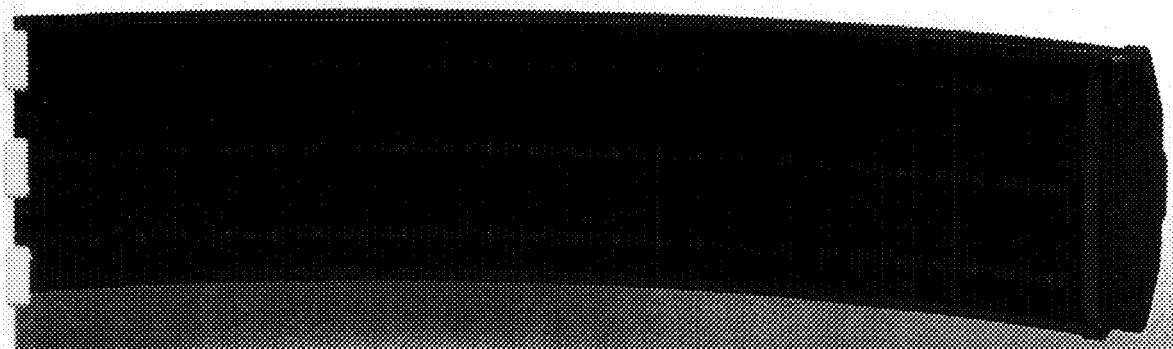
The Nicolet Nystar™ Plus.



Power and convenience that keeps you ahead in ENG.

Nicolet

Nystar™ Plus ENG capabilities on Spirit.

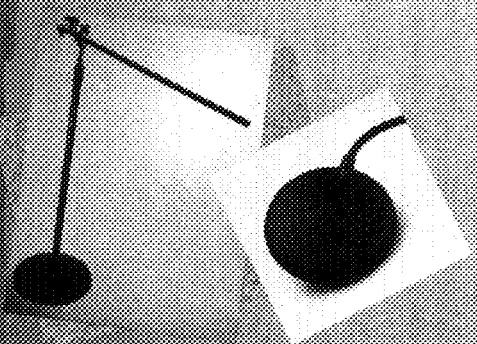


The addition of Nystar™ Plus software and necessary hardware gives the Nicolet Spirit full capability to perform ENG tests including Caloric, Smooth Pursuit, Optokinetic, Positional, Saccade, Fistula, Positioning, Gaze and Spontaneous.

Patient data is automatically compared to an age-specific database for accurate diagnoses. Analysis features provide reliable data even for difficult-to-test patients. And customized hardcopy reports allow you to decide what data to include in high quality printouts.

Hardware featured in the ENG package includes:

- Full-color, high-resolution monitor
- Uniquely curved lightbar
- Auxiliary lightbar
- Remote-operating footswitch
- Data-clarifying amplifier



Stay on the leading edge of ENG with Nystar® Plus.

For years, health care professionals worldwide have liked what they've seen in the Nystar Plus. Clear, concise, detailed information. Ease of operation. Fast, reliable performance. Professional reports.

Today, the many exciting enhancements built into this advanced analytical ENG instrument have made it better than ever:

- Full-color monitor
- Simple system operation – three ways
- Age-specific reference data
- Custom-designed, professional reports
- Uniquely curved lightbar

See data clearly. Manage it conveniently.

A quick glance at our bright, easy-to-follow, full-color display monitor allows you to make fast and accurate analyses.

The Nystar Plus maximizes efficiency in data acquisition and analysis. It offers you three convenient ways to operate the system:

- Simple touch-screen monitor
- Familiar mouse
- Traditional keyboard

Choose the method you're most comfortable with. You'll minimize the time spent learning and using the system, and almost immediately improve your productivity.

Remote operation of the Nystar Plus is performed by using the convenient footswitch. It frees your hands so you can maintain patient contact during testing.

Handle a full range of ENG tests.

With the Nicolet Nystar Plus, you can conduct a battery of comprehensive standard and advanced tests. It's also easy to customize so you can design tests to meet your specific requirements.

Standard ENG tests include:

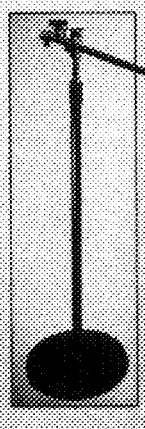
- Caloric
- Fistula
- Smooth Pursuit
- Positioning
- Optokinetic
- Spontaneous
- Positional
- Gaze
- Saccade
- Rotation

You can even conduct this wide variety of ENG tests on the Nicolet Spirit™ evoked potential system. Simply order the Nystar Plus computerized ENG package with the Nicolet Spirit to give you a combination of capabilities – evoked potential *and* ENG testing.

Capture high quality data every time.

The Nicolet Nystar Plus obtains diagnostic information through proven algorithms. Traditional strip chart recording methods can't analyze data this thoroughly. And because eye blink artifact is automatically detected and rejected, your data is as accurate as possible.

The uniquely curved lightbar of the Nystar Plus also enhances data quality. It allows you to accurately record a patient response to the lightbar's clear, easy-to-follow targets.



An optional auxiliary lightbar facilitates testing of patients in a supine position, saving time and maximizing patient comfort.

Nystar Plus maximizes your potential with:

- *Displayed reference data*
- *Detailed analysis features*
- *Full-color display*
- *Touch-screen, mouse or keyboard operation*

Fast. Easy. Complete.

Do more, analyze more, report more with additional Nystar Plus features:

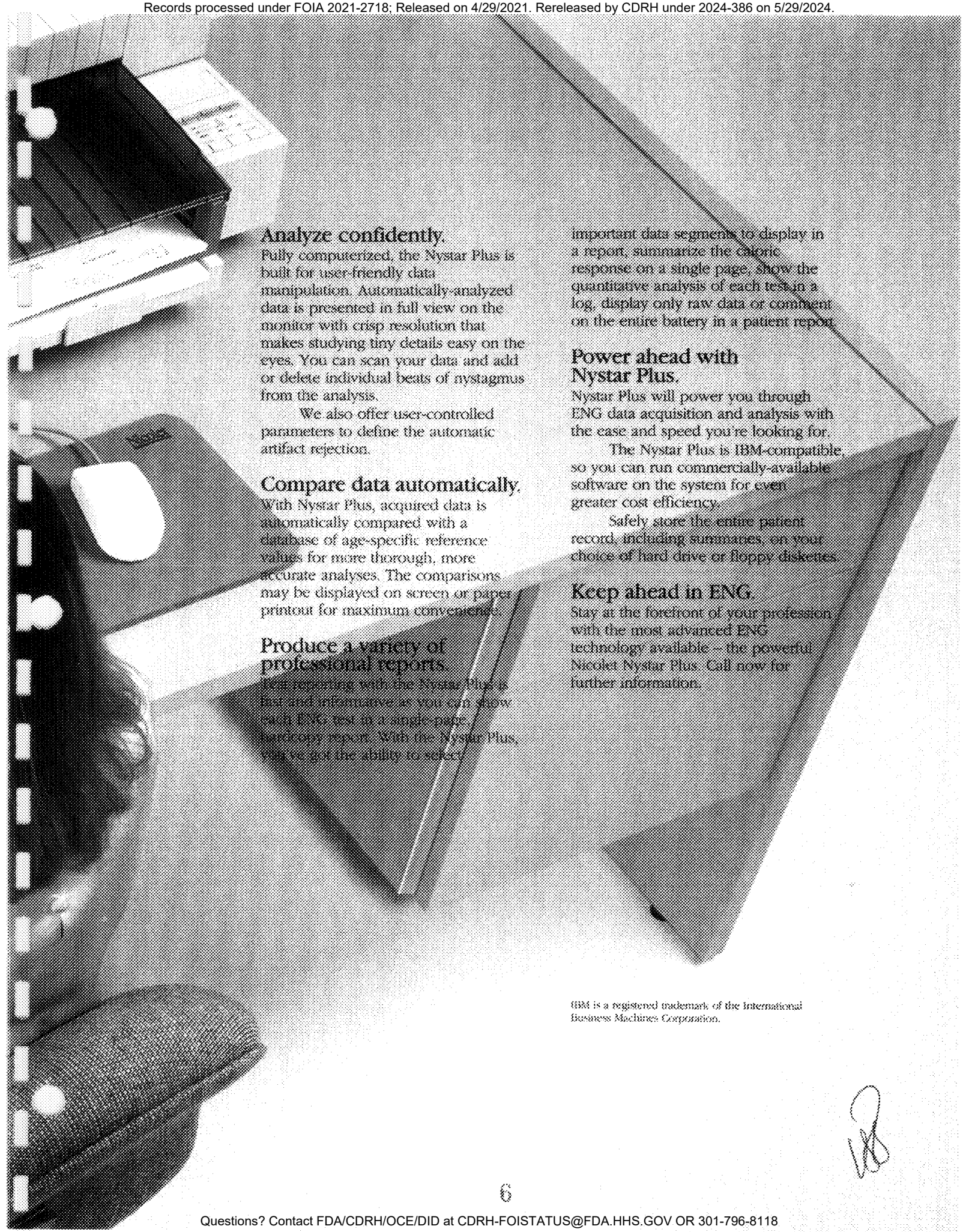
Age-specific reference values
Provides fast and accurate comparison of patient data to an age-specific database.

High-resolution, full-color display
Maximizes data clarity so it's easy to read, lets you quickly identify significant patient responses.

Customized hardcopy reports
Allows you to decide what data you wish to include in high quality reports.

Touch screen, keyboard or mouse operation
Saves time and optimizes productivity as you choose the method you're most comfortable with.

Enhanced oculomotor data analysis
Gives you even more information when you analyze saccade, pursuit and optokinetic eye movements.



Analyze confidently.

Fully computerized, the Nystar Plus is built for user-friendly data manipulation. Automatically-analyzed data is presented in full view on the monitor with crisp resolution that makes studying tiny details easy on the eyes. You can scan your data and add or delete individual beats of nystagmus from the analysis.

We also offer user-controlled parameters to define the automatic artifact rejection.

Compare data automatically.

With Nystar Plus, acquired data is automatically compared with a database of age-specific reference values for more thorough, more accurate analyses. The comparisons may be displayed on screen or paper printout for maximum convenience.

Produce a variety of professional reports.

Data recording with the Nystar Plus is fast and interactive so you can show each ENG test in a single-page hardcopy report. With the Nystar Plus, you've got the ability to select important data segments to display in a report, summarize the caloric response on a single page, show the quantitative analysis of each test in a log, display only raw data or comment on the entire battery in a patient report.

Power ahead with Nystar Plus.

Nystar Plus will power you through ENG data acquisition and analysis with the ease and speed you're looking for.

The Nystar Plus is IBM-compatible, so you can run commercially-available software on the system for even greater cost efficiency.

Safely store the entire patient record, including summaries, on your choice of hard drive or floppy diskettes.

Keep ahead in ENG.

Stay at the forefront of your profession with the most advanced ENG technology available – the powerful Nicolet Nystar Plus. Call now for further information.

IBM is a registered trademark of the International Business Machines Corporation.

Service that keeps you up and running

Nicolet is more than reliable instruments. It's reliable people, too.

That's why we emphasize service so much. Before, during and after the sale.

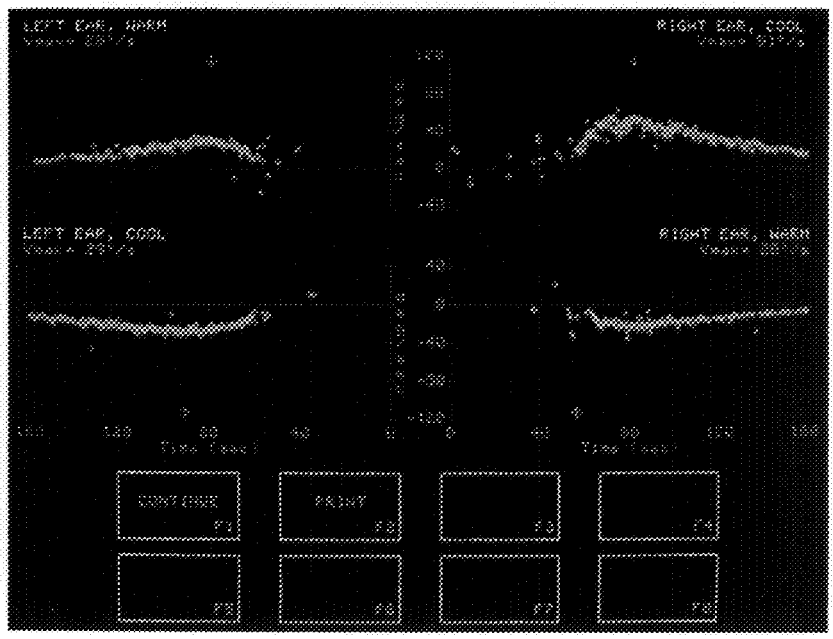
The knowledgeable people in our ever-growing Nicolet service network are committed to keeping you – and your instruments – at peak productivity and efficiency every step of the way.

From trouble-shooting shortcuts to helping you resolve simple or complex application concerns, help is always but a phone call away.

Nicolet's worldwide network of sales and service offices stands ready to serve you. For further information or a demonstration on how the Nystar Plus can advance your EMG testing capabilities, call Nicolet now at 1-800-356-8086.

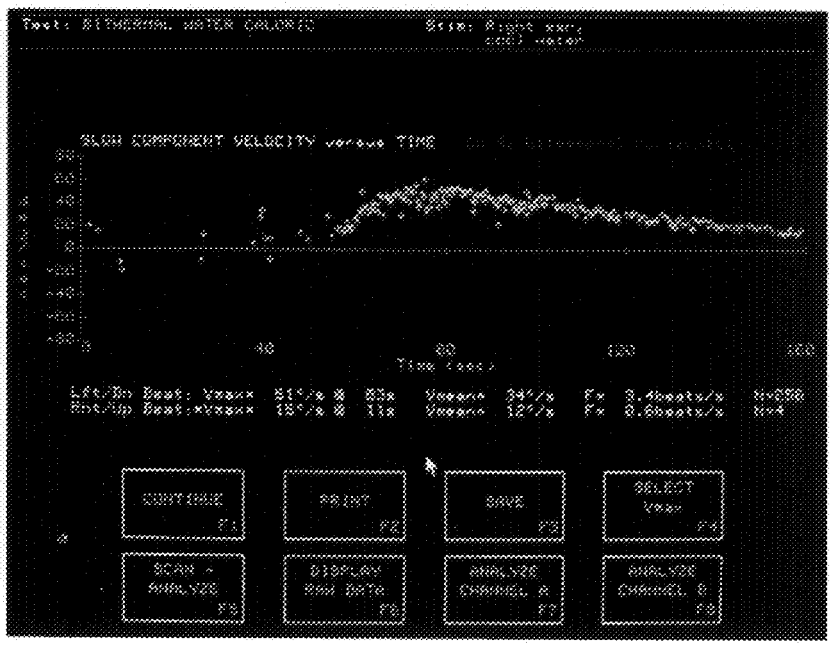
Nicolet Biomedical Instruments
5225 Verona Road, Madison, Wisconsin USA 53711-4495, Tel. (608) 273-5000, Toll Free 1-800-356-8086, FAX (608) 273-5061
Sales and Service Offices Worldwide. Subsidiary Offices: Belgium, Canada, France, Germany, Japan and United Kingdom.

Nicolet
brand name of Viasys



Caloric Data Summary

When creating customized reports, data can be shown in a variety of formats: summarize calorics on a single page with data samples and automatic calculation of unilateral weakness and directional preponderance; generate a printout for each caloric to show the entire raw data with automatic analysis or only raw data; display automatic analysis in a test log; or note your impressions on the comment page.



Caloric Test

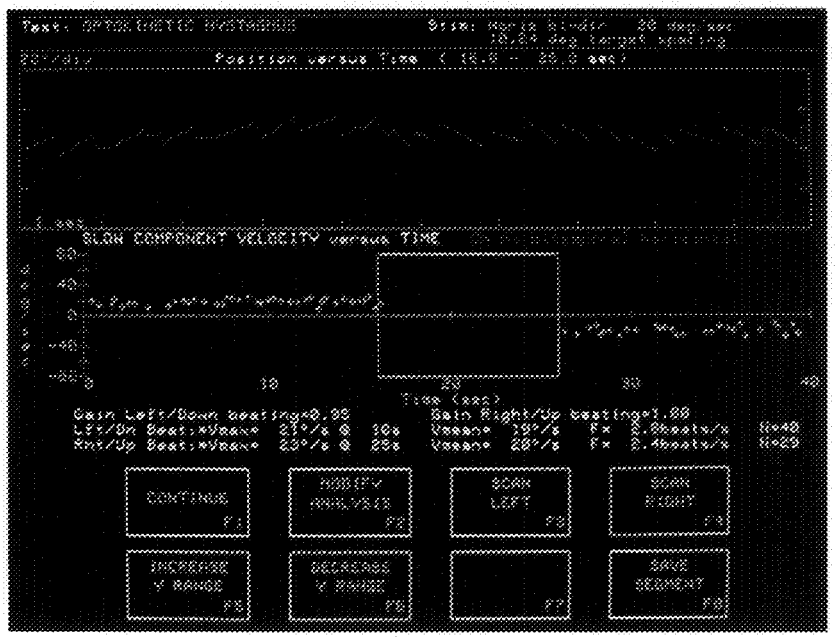
Analyze data confidently as clear, full-color displays show test type, stimulus used and electrode configuration.

Nicolet Biomedical Instruments

5225 Verona Road, Madison, Wisconsin USA 53711-4495, Tel. 608/273-3000, Toll free 1-800-356-8088, FAX 608/273-5067.
Sales and Service Offices Worldwide. Subsidiary Offices, Belgium, Canada, Germany, Japan and United Kingdom.

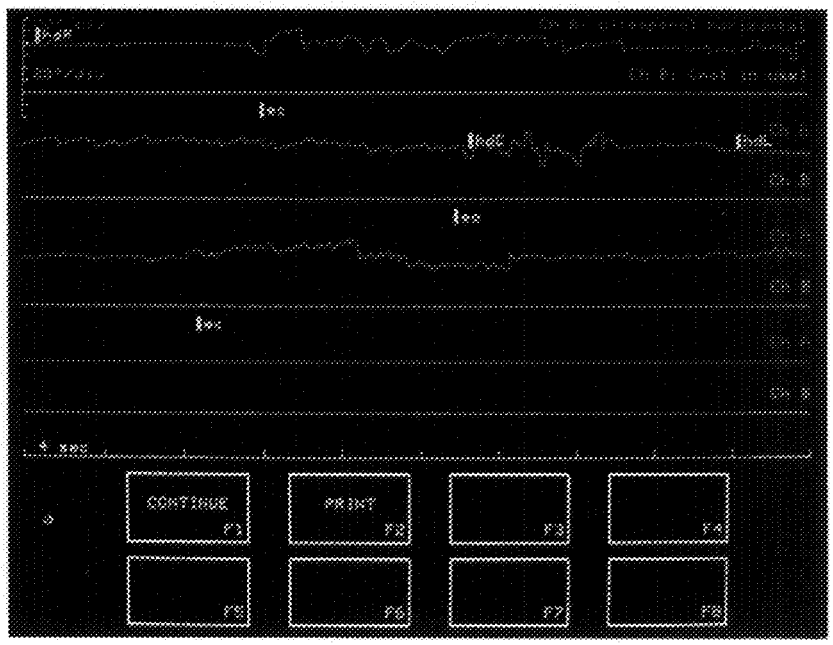
Nicolet

INSTRUMENTS OF DISCOVERY



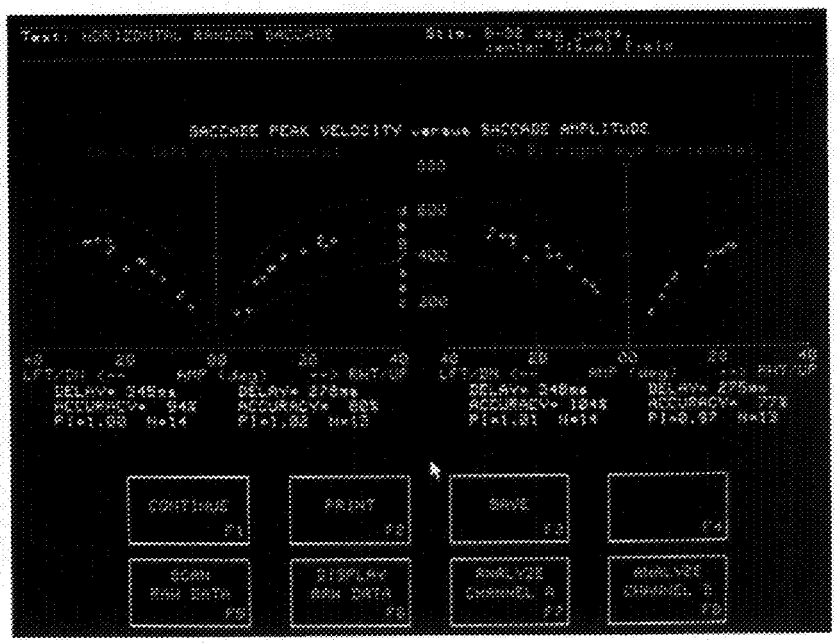
Nystagmus Data Scan

Thoroughly analyze your patient's response by scanning raw data, zooming in on fine details, adding and/or deleting nystagmus beats to the analysis and adjusting automatic analysis parameters. Feel confident in the reliability of your test results, even when it involves the most difficult-to-test patient.



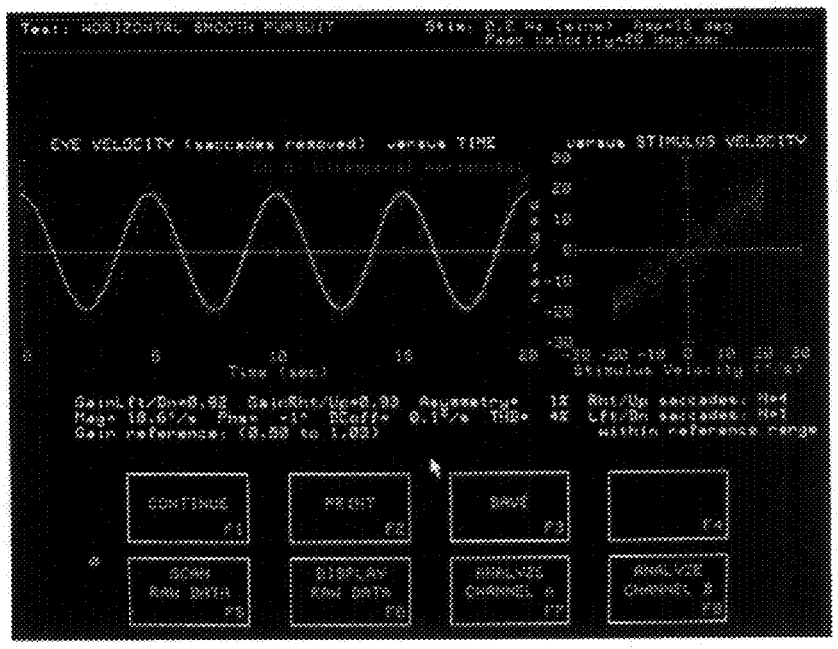
Positional Test

Data is easy to view with an entire raw tracing of the patient response clearly displayed in high-resolution color. Changes in patient activity are noted with easy-to-read markings.



Voluntary Saccade

Enhance your diagnostic information with automatic, complete and accurate quantitative measures of patient data. Saving, printing and analyzing data is easy with simple screen prompts. System operation is simple using either the mouse or keyboard.



Smooth Pursuit

Oculomotor test results are automatically compared to an age-specific database for fast, easy analysis. Patient test results that fall outside of the database are flagged both on the screen display and hardcopy printouts.

NICOLET NYSTAR® PLUS
TECHNICAL SPECIFICATIONS

The Nicolet Nystar® Plus ENG System is an automated, computerized ENG system designed to provide all standard ENG procedures plus advanced ENG testing with on-line analysis of all test results. The system includes a 13" monitor with touch screen operation, an HP printer, an EOG amplifier and a curved, digitally controlled lightbar.

ENG SOFTWARE

Nystagmus analysis of Optokinetic, Caloric, Gaze, Positional, and Positioning testing. Advanced test analysis of vertical EOG, Random Saccade, Rotary Chair, and Smooth Pursuit. Identifies and eliminates contaminating artifacts. Menu-driven with touch screen operation.

Criteria for minimum nystagmus automatic beat analysis:
approximately 2.8 degrees/sec,
2 beats in a 5 second period,
1 to 2 degrees amplitude.
Amplitude resolution: 0.06 degrees.

COMPUTER

Three-microprocessor-based system:
80286 control microprocessor,
8031 microprocessor for offset and gain control,
8751 microprocessor for I/O control.
1 Megabyte RAM.

MONITOR

13" amber, high-resolution monochrome (720 horizontal x 348 vertical pixels).

Weight: 45 lbs. (20.5 kg)
Size: 13" x 13" x 17"
(33.0 x 33.0 x 43.2 cm)

CURVED LIGHTBAR OPTICAL STIMULATOR

Curved shape provides a uniform viewing distance at 91 cm. LED is 0.1" x 0.25" each with uniform brightness. 80° x 10° field for optokinetic tests. Computer-controlled target stimulus for all ENG tests. Mar-resistant, glare-reducing red filter. Wall mount bracket with rotation for vertical tests.

Curve size: 56" x 9" x 3.5"
(14.2 x 22.9 x 8.9 cm)

Weight: 28 lbs. (12.7 kg)

DATA STORAGE

The internal disk drive accommodates 3.5" 720 kilobyte disks and provides fast data storage and retrieval. For more speed, an optional 40 Mbyte hard drive can be added.

EOG AMPLIFIER

Two-channel EOG amplifier. True DC coupling with programmable gains and offsets. Optically isolated for patient safety. Two-pole 40-Hz filter with 50/60-Hz notch filter. Automatic gain and offset for each channel under software control.

IMPEDANCE SYSTEM

Internal offset automatically determines unacceptable impedance tolerances. Provides screen display messages for required impedance adjustments.

PRINTER

Hewlett Packard LaserJet III printer—300 dots per inch, horizontal and vertical resolution.

Hewlett Packard DeskJet Plus printer—300 dots per inch, horizontal and vertical resolution.

Hewlett Packard ThinkJet printer—150 cps, 192 dots per inch horizontal, 96 dots per inch vertical.

KEYBOARD

Keyboard facilitates the entry of patient information, date/time, etc.

ACCESSORIES

Patient cable, footswitch, accessory kit (electrodes and skin preparation paste), user manual.

ENVIRONMENTAL SPECIFICATIONS

Storage temperature:	-10 to 130 degrees Fahrenheit (-23 to 55 degrees Centigrade)
Operating temperature:	45 to 90 degrees Fahrenheit (7 to 32 degrees Centigrade)
Relative humidity:	25 to 85% non-condensing
Voltage:	100 to 130 VAC and and 220 to 250 VAC
Frequency:	50 to 60 Hz

Specifications subject to change without notice.
sed October 1, 1990.

Nicolet Biomedical Instruments

5225 Verona Road, Madison, WI, USA 53711-4495, 608/271-3333, FAX 608/273-5067.
Sales and Service Offices Worldwide, Subsidiary Offices: Belgium, Canada, France, Germany, United Kingdom and Japan.

Nicolet
INSTRUMENTS OF DISCOVERY

169-403000

Bio-logic's Computerized ENG System frees you from the drudgery of conventional ENG testing.

Never again will performing an ENG test require hours of recording, reading through reams of eye movement tracings, measuring slopes, correlating the slope with eye movements, and compiling reports. Bio-logic's ENG system does it all for you.

- Bio-logic replaces reams of pen and ink tracings with video screen tracings as you collect data. But when you do plot data, it is in ENG recorder format. (10 mm/second; ten degrees/cm).
- Bio-logic's diskette storage allows you to plot your choice of waveforms (color-coded by channel) or print a comprehensive report immediately or at a later time. Now you can easily retrieve data from storage for analysis at your convenience.
- Bio-logic enables you to measure and average slopes automatically.
- Bio-logic provides both DC- and AC-coupled amplifiers. DC amplifiers provide more accurate readings, free from the distortion of AC coupling. But, you retain the option of using AC amplifiers if indicated.
- Bio-logic provides a keyboard-controlled impedance test eliminating the need for an additional impedance meter.

Why Bio-logic ENG?

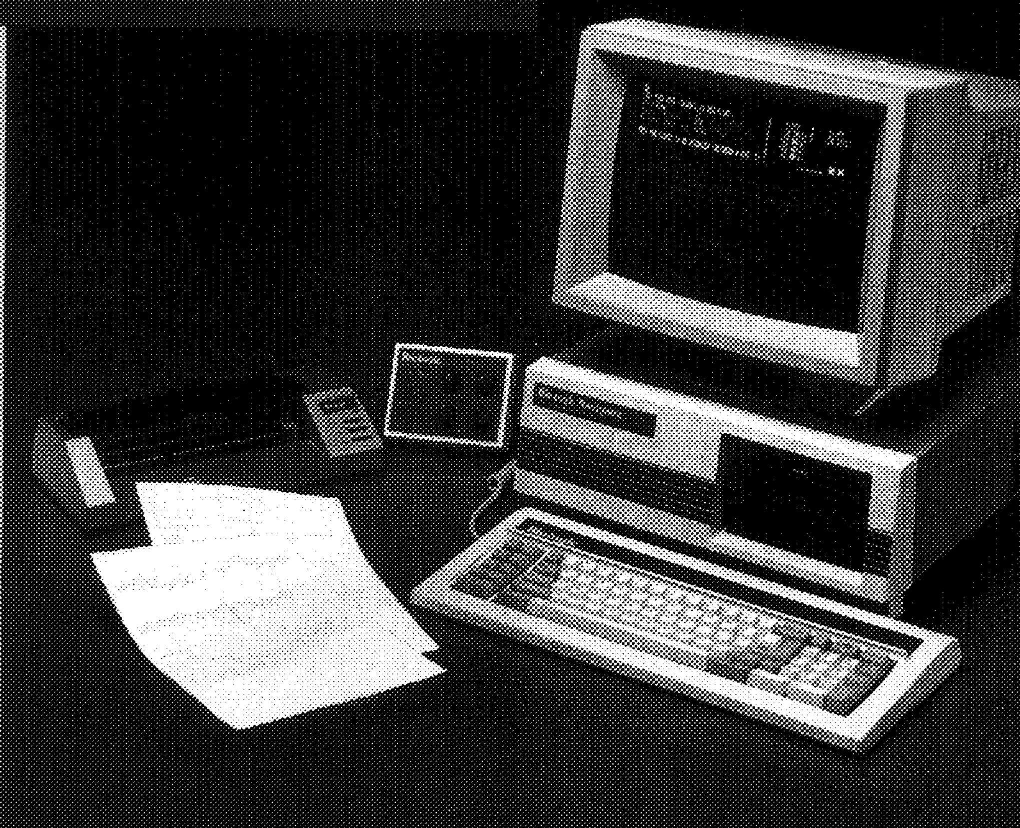
Bio-logic has a proven record of providing high quality, reliable and cost effective electrodiagnostic systems.

- ENG is fully compatible with all other Bio-logic systems: AEP, SEP, VEP, ENN, NCV, EOG, ERG, Bone Conduction, ECoG, 40 Hz ERP, CSA, and Topographic Brain Mapping.
- ENG is available as a stand-alone system which can be expanded to include all other Bio-logic systems. Or, ENG can be an addition to the portable Traveler, the desk-top Navigator, or the Brain Atlas.
- All Bio-logic systems are IBM PC compatible allowing you to use more than 10,000 commercially available programs such as word processing or statistical analysis.
- Bio-logic is well-known for its affordable prices made possible by combining proven computer capability with custom designed electrodiagnostic hardware and software.
- At Bio-logic, the customer comes first—we prove it by providing professional seminars, continuous consultations, and service and support supplemented by a world wide audiological distributor network and hundreds of computer service centers.

Why Call?

To request a demonstration and ask about our prices. You'll like what you see and what we have to say.

Now in Color



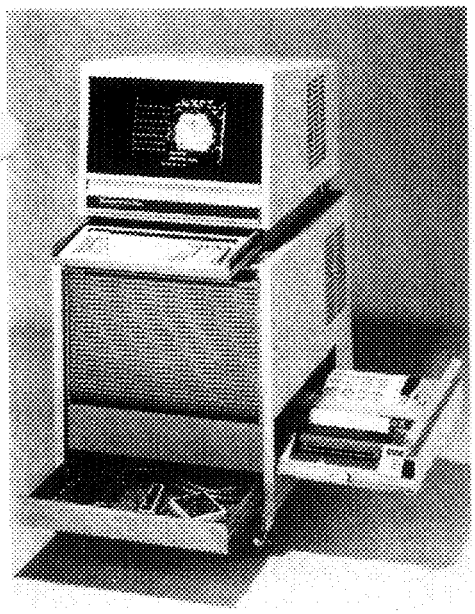
Bio-logic
Systems Corp.

Corporate Headquarters
One Bio-logic Plaza
Mundelein, IL 60060

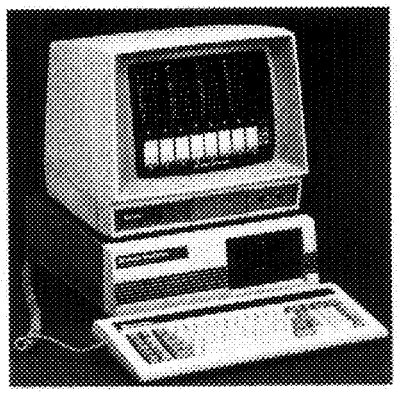
Call toll free at 800-323-8326
(Illinois call collect 312-949-5200)
Telex: 650-1733095 MCI
FAX: (312) 949-8615

Europe/Middle East
Dickenson House, Albion Street,
Chipping Norton, Oxfordshire,
OX7 5BJ

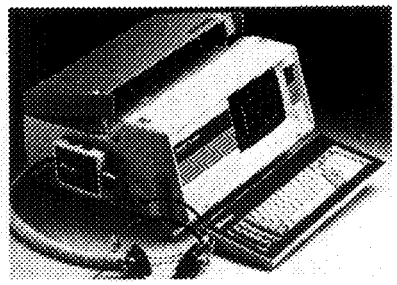
Telephone 44 608 41961
Telex: Ref. EFG001,
265871 MONREF G
FAX: 44 608 41687



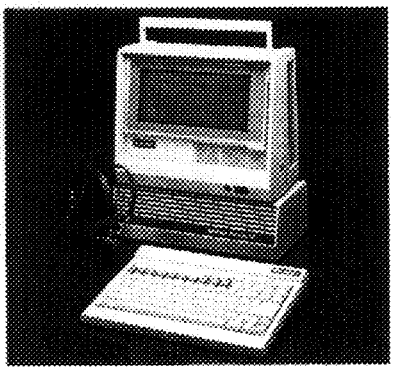
Brain Atlas® III



Navigator®



Traveler®



Traveler® LT

Specifications
Bio-logic® Electronystagmography (ENG)

IBM PC/AT Compatible

Acquisition Parameters

- Traveler, Navigator, or Brain Atlas: 2 channels
- AC and DC amplifiers
- Built-in impedance test

Display and Printout Parameters

- Control box can be used to adjust gain or offset
- Keyboard control of gain and offset
- Demographic data is retained for all tests
- Internal clock controls the maximum time of each test (up to 2½ minutes)
- Keyboard or control box test interruption
- User-definable test names
- User-defined test sequence
- Control box or keyboard calibration
- Five speeds for waveform display
- Slopes calculated automatically
- Built-in calculation of averages of slopes and standard deviations under user control
- Keyboard control of cursor speed
- Color-coded plotting of waveforms
- Full summary reporting
- Table of calculation results available
- Reports are printed in standard ENG format

Expansion Capabilities

- Traveler and Navigator can be expanded to do topographic brain mapping and recording up to 32 channels
- Can be expanded to do AEP, VEP, SEP, ENG, ENN, NCV, EOG, ERG, bone conduction, ECoG, 40 Hz ERP, CSA, and topographic brain mapping

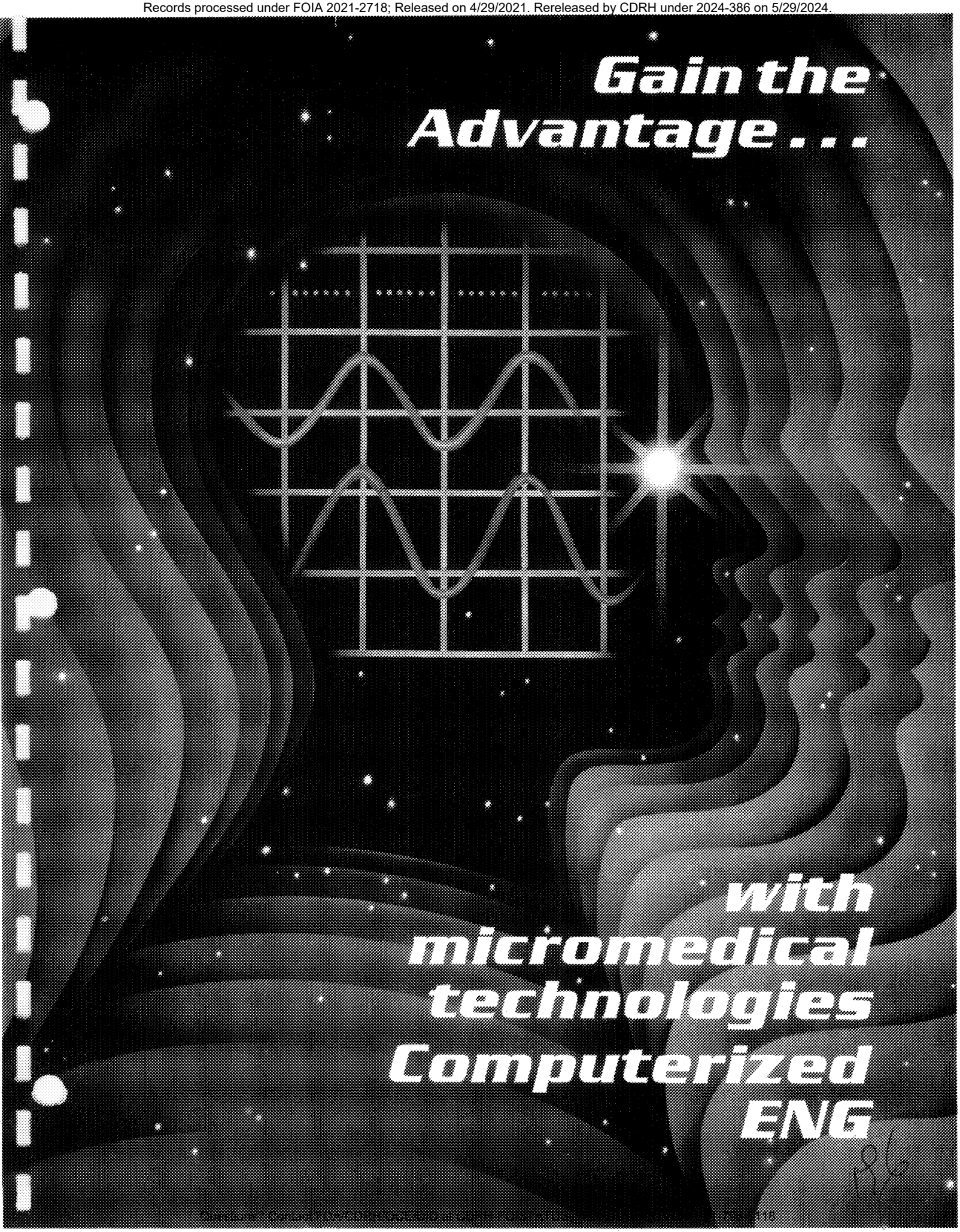
Bio-logic ENG is available as a stand-alone system or as an option on any Bio-logic electrodiagnostic system. Complete information on prices is available by calling 800-323-8326 (Illinois call collect 312-949-5200).

Bio-logic® Systems Corp.

Corporate Headquarters
One Bio-logic Plaza
Mundelein, IL 60060

Europe/Middle East
Dickenson House, Albion Street,
Chipping Norton, Oxfordshire,
UK OX7 5BJ

Telephone 44 608 41 981
Telex: Ref. EEG001,
265871 MONREF G
FAX: 44 608 41887



micromedical technologies inc.

Portable

Desktop

Computerized ENG

micromedical technologies inc.

Micromedical Technologies computerized ENG is:
Easy to learn
Fast, one button operation
Computer accurate

Key features

* Full ENG test battery: caloric, gaze, Hallpike, positionals, OKN, saccade, and pendular tracking
* Flexible test schedule for each patient
* Automatic waveform measurements with manual override
* Computer calculation of caloric equations, including spontaneous nystagmus
* Printed report can be a short summary or complete with all observed waveforms
* Plus, our famous 24 months of free software updates and a 12 month hardware warranty

Specifications

Microcomputer:
* IBM—AT compatible computer
* 20 Meg hard disk
* 1.2 Meg floppy disk
* EGA graphics display
* dot matrix printer
* digital light bar
* caloric calibration bar

EOG Amplifier:
* three channel
* isolated inputs
* DC—30 Hz frequency response
* automatic waveform centering
* signal quality check
* automatic amplitude adjustment
* start-up kit

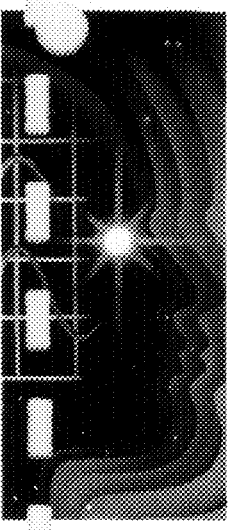
Upgradeable

Both the desktop and the portable can be upgraded with Micromedical Technologies VORTEQ, our inexpensive auto-rotational sensor or Micromedical Technologies rotational chair, laser and optokinetic projector.

Call 1-800/334-4154 today for more information or a demonstration

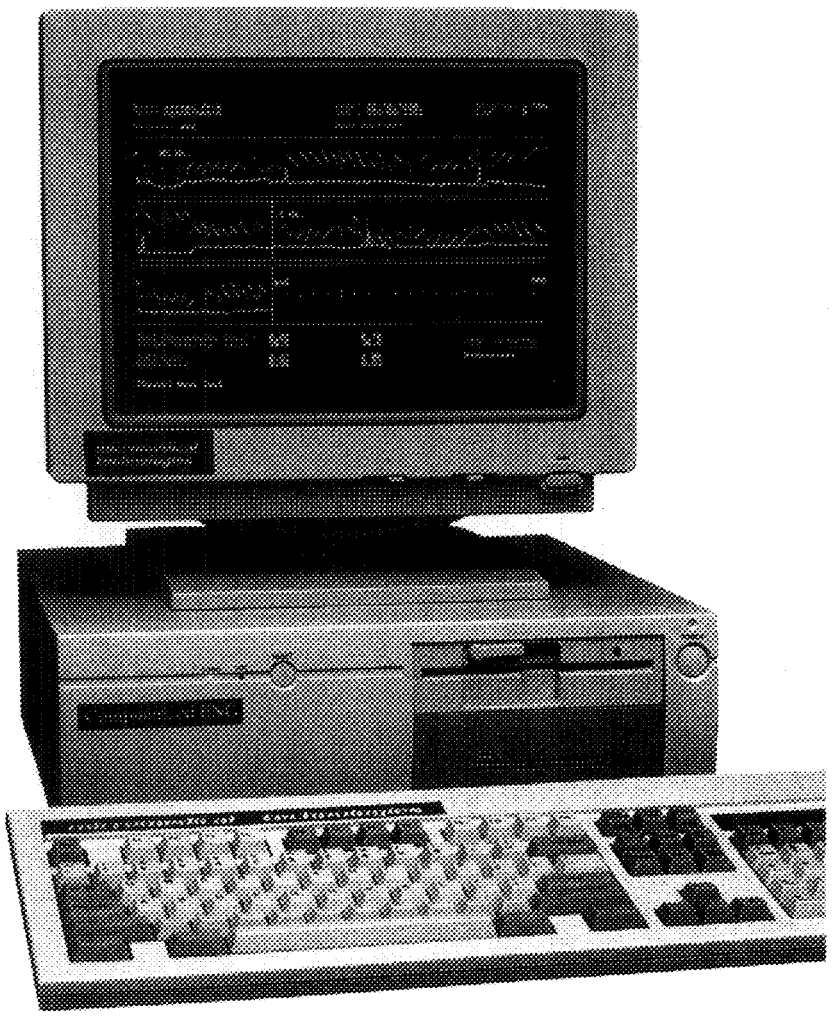
Micromedical Technologies, Inc. • 110 West Walnut • Chatham, IL 62629

Telephone: 217/483-2122 • 1-800/334-4154 • FAX: 217/483-4533

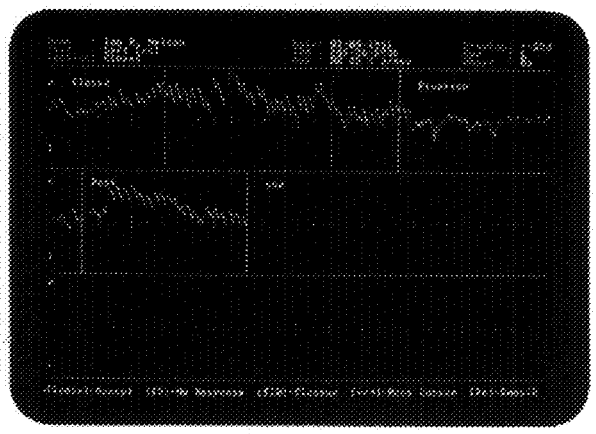


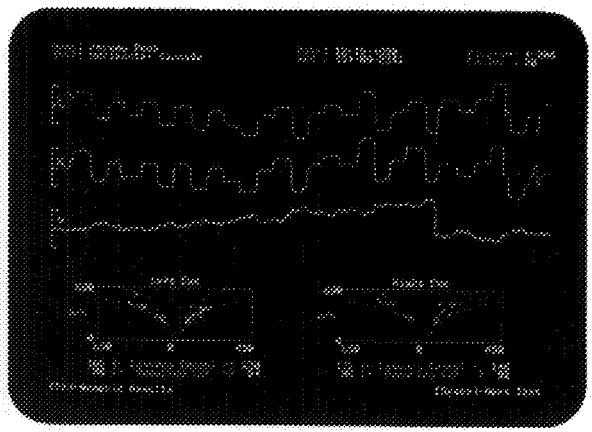
GAIN THE ADVANTAGE

Give your patients the best that technology can provide at an affordable price with Micromedical Technologies Model 1500B Computerized ENG.



FROM TEST



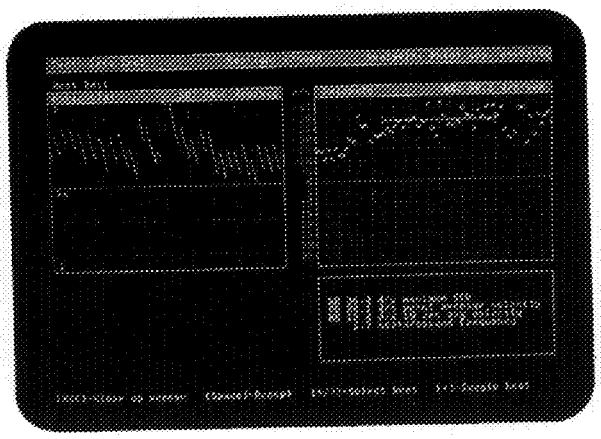


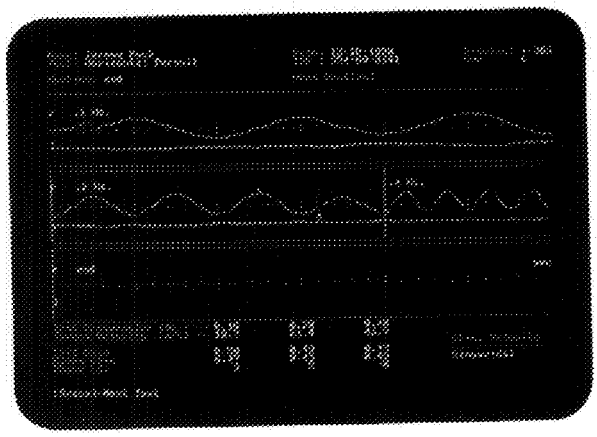
MICROMEDICAL TECHNOLOGIES 1500B COMPUTERIZED ENG utilizes advanced hardware design to achieve a new level of reliability in ENG testing.

- Includes an IBM 386/SX compatible computer with VGA color monitor.
- The footswitch can control the entire nystagmus test sequence.
- A digital light bar or laser produces the stimulus for oculomotor and gaze testing.
- For caloric, Hallpike, and positional testing, a ceiling mounted lightbar is provided.

We provide simplicity: A 3 channel EOG amplifier inside the computer automatically adjusts gain and removes offset.

To Analysis

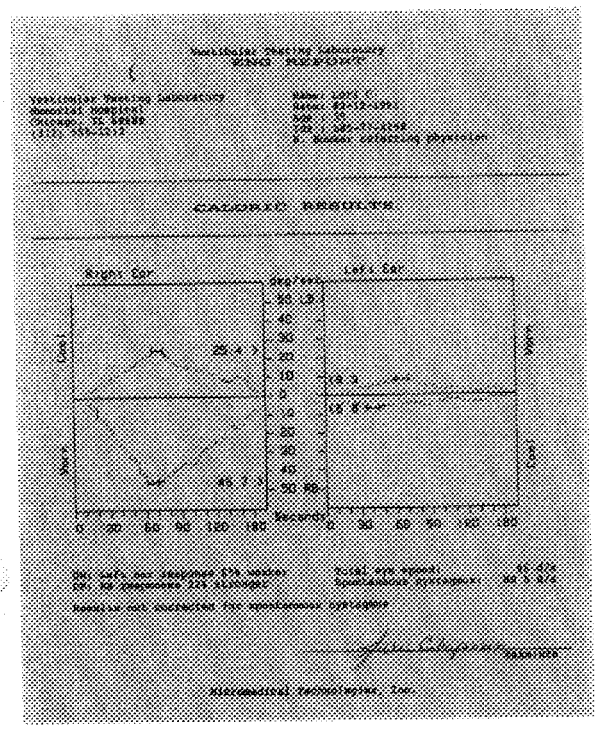




Micromedical Technologies 1500B Computerized ENG utilizes intelligent software to achieve a new level of accuracy in ENG analysis.

- Nystagmus measurement is automatic. Slow phases are shown in white while fast phases and artifacts are red.
- Manual override options include: (1) ability to delete and insert nystagmus beats and (2) ability to adjust the average caloric velocity.
- The computer identifies the 10 second section with the highest average velocity.
- On screen "cut and paste" eliminates paper waste.
- Waveforms can be stored on the hard disk or on diskette permitting convenient reanalysis.

We provide performance: Waveforms are analyzed in only 2 to 4 seconds depending on the duration of the test.



To Report

Micromedical Technologies 1500B Computerized ENG utilizes a comprehensive format to achieve a new level of flexibility in ENG reporting.

- The ENG report can be customized for each referral source and modified for each patient.
- Nystagmus report options include: (a) 10 second measured sections (b) 1/2 page whole test and (c) full scale stripchart.
- Spontaneous nystagmus can be removed from the caloric test results with the touch of a key.

We provide convenience: For ease in interpretation, all test results outside of clinical thresholds are summarized on the face page. A second page shows graphic and numeric results of all four caloric tests.

Other products from micromedical technologies, inc.

[illegible]

Designed especially for laboratories that perform caloric and other nystagmus tests. Systems can be upgraded for oculomotor testing.

[illegible]

Users of Contraves/Neurokinetics and Templin rotational chairs may upgrade their systems with Micromedical Technologies current rotational software and hardware.

[illegible]

VOR can be measured at frequencies from 0.01 to 1.28 Hz at velocities up to 300 degrees/second. Gain, phase, and gain asymmetry are calculated and analyzed automatically.

[illegible]

Natural, active head movements are measured by a head band mounted angular velocity sensor. When VORTEQ is combined with our System 2000 Rotational Chair, the VOR can be studied over a range of test frequencies from 0.01 Hz to 8 HZ.

[illegible]

[illegible] A stand mounted laser system designed specifically to project a pinpoint stimulus for oculomotor testing in the 1500B computerized ENG system.

[illegible] This laser system mounts on the rotational vestibular chair to provide an accurate stimulus during oculomotor and VOR testing.

[illegible] Mounted to the VORTEQ headband, this laser system produces a stimulus that is synchronous to head movement during active VOR testing.

[illegible] is committed to advancing the field of computerized vestibular instrumentation. We are continually upgrading and enhancing our systems to help you [illegible]

micromedical technologies, inc.

110 West Walnut • Chatham, IL 62629

217-483-2122 Outside U.S.
800-334-4154 U.S. and Canada
217-483-4533 FAX

201

(b) (4)

(b) (4)

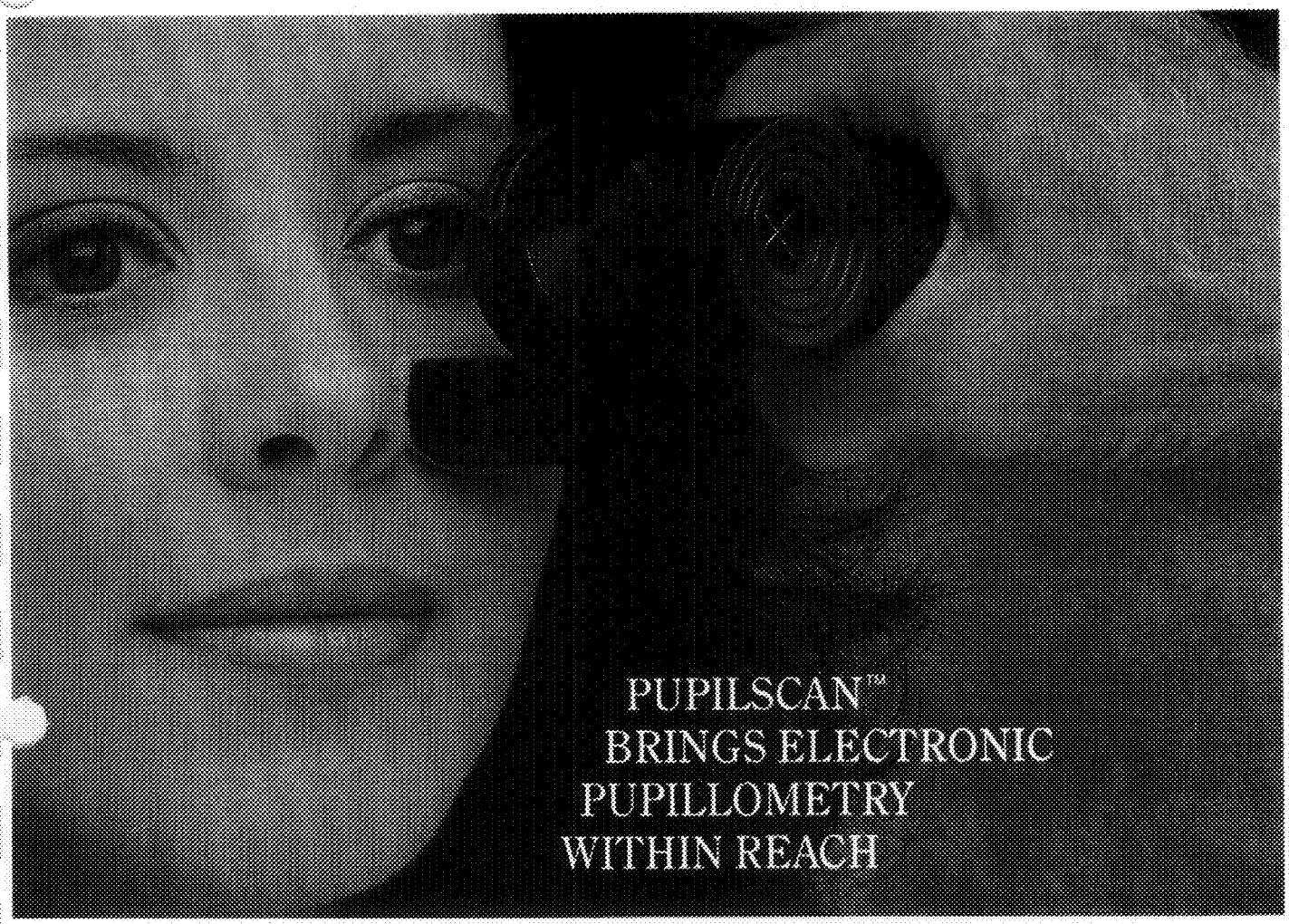
(b) (4)

(b) (4)

(b) (4)

FAIRVILLE MEDICAL OPTICS, INC.

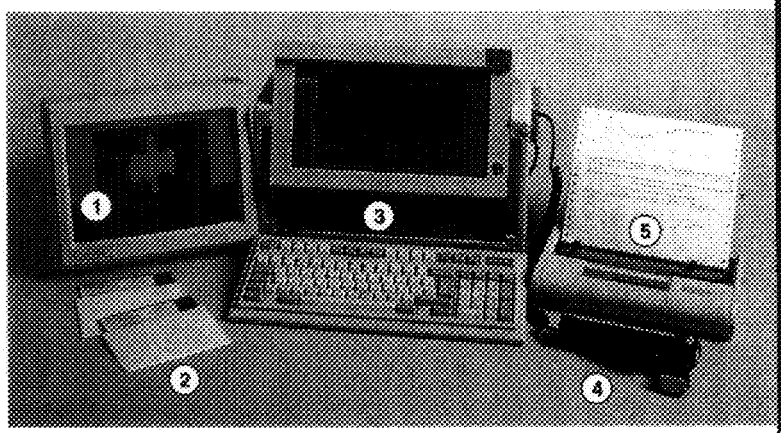
PUPILSCAN™



Accident and emergency staff, anaesthesiologists, clinical pharmacology researchers, diabetologists, general practitioners, neurologists, opthalmologists, psychologists, recovery room personnel, traumatologists and substance abuse testers.

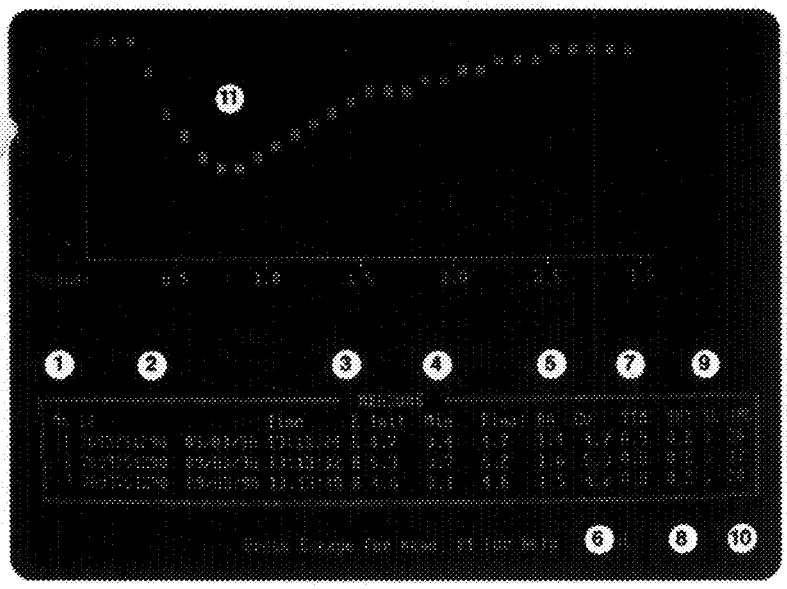
- PUPILSCAN is the breakthrough in practical pupillometry many sectors of the medical, research and forensic communities have long wanted.
- It offers accurate, quantitative and dynamic measurement of pupil size and reflex by infra-red scanning, with data capture, analysis, recording, display and printout in flexible formats. Capabilities previously available only with laboratory sized video based equipment.
- But at a fraction of the cost. And with convenience and ease of use that have never been known before.
- PUPILSCAN is a compact, lightweight, hand-held automatic instrument that plugs into a circuit board installed in any IBM compatible personal computer. Operating programs provide instant, reliable and sophisticated results.
- This means pupillometry ceases to be expensive and complicated or a crude estimation technique.
- It becomes a practical and precise diagnostic method that can be used at accident sites, in pre-op and post-op contexts, in hospital wards and consulting rooms, on housecalls and in any place where screening for fatigue, stress or substance abuse is necessary.
- Or it can be used in clinical or research settings, where pupil data can be integrated with other physiological measurement and patient data.

COMPLETE SYSTEM



1. Optional auxiliary monitor
2. Program floppy disks (5¼" or 3½")
3. IBM PC or compatible computer

25

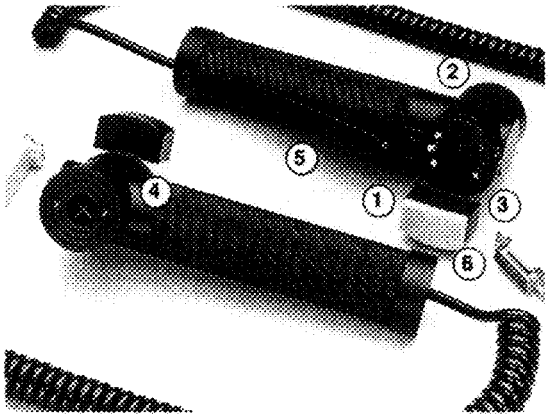


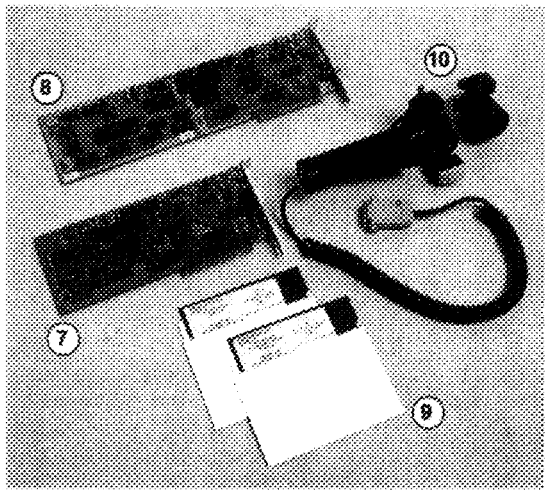
MEASURE SCREEN

1. **Measurement sequential serial number**
2. **Subject identification**
3. **Eye measured**
4. **Diameters (mm)**
5. **Reflex amplitude (mm)**
6. **Maximum constriction velocity (mm/sec)**
7. **Time to minimum diameter (sec)**
8. **Stimulus pulse duration (sec)**
9. **Stimulus intensity**
10. **Infra-red illumination level**
11. **Pupil response plot**

SPECIFICATIONS — Type 6 Optical Unit

Dimensions		L: 190 mm (7½") W: 50 mm (2") H: 32 mm (1¼")
Weight		265 gm./10 oz.
Image Sensor		65K rectangular pixel array.
Eye Illumination	(1)	Yellow diode (1) 583 nm peak wavelength. Typical intensity 1 foot-candle.
Image Sensor Illumination	(2)	Infra-red emitting diodes (4) 880 nm peak wavelength. Intensity adjusted automatically by software in range 1.5 mw/cm² to 6.5 mw/cm².
Stimulus Pulse	(3)	High intensity green diodes (2) 565 nm peak wavelength. Intensity selectable in 3 steps in range 3 to 13 foot-candles. Pulse duration programmable in 0.1 second steps from 0 (no pulse) to 10 seconds. Reprogrammable in MEASURE mode.
Alignment Aid	(4)	Red diodes (2) on handle centerline indicate direction to move to center instrument on pupil.
Pupil Image Display		On computer monitor, software selectable, and on auxiliary monitor with Type 6EV circuit board.
Scan Rate		10/second or 20/second, software selectable.
Actuating Switch	(5)	Push button, depress to turn on illumination, release to start automatic measurement/stimulus cycle. Can also start measurement cycle from computer keyboard.
Material	(6)	Hand-size handle, viewing tube, cross hair ring and rotating cheekrest in black Delrin™.
Driver Circuit Board		PUPILSCAN Type 6 circuit board (⅔ industry standard length) or Type 6EV (full length industry standard card); installs in expansion slot in IBM PC or compatible personal computer. (½ length industry standard card available early 1991).
Software		Operating programs are menu-driven PC-DOS or MS-DOS executable files with help screen supplied on either 5¼" or 3½" floppy disks. Configurable from menu to allow selections to match computer hardware and to set default measurement parameters. Measurement data and response plot of each record can be reviewed; data and plots are printed from menu and stored to disk. Data analysis via popular spreadsheet/graphics/database programs or unique PUPILEX program (available early 1991).
	(7)	**Type 6 Circuit Board**
	(8)	**Type 6EV Circuit Board**
	(9)	**Program floppy disks (5¼" or 3½")**
	(10)	**Type 6 CS (Consensual Stimulus) Optical Unit**





or more information, to arrange a demonstration or to order, please write or telephone.

PUPILSCAN™

PORTABLE ELECTRONIC PUPILLOMETER

[redacted]

Cardinal®

OcuLoKinetics, Inc.

HOUSE IR/VIDEO - ELECTRODE ENG COMPARISON CHART

	Nicolet Nystar+	Biologic ENG	Micromed. 1500B	House IR/Video
Operation				
Electrode				
Video				
Number of Channels				
AC Equivalent				
DC Equivalent				
Power Source 120V/60Hz				
Bandwidth or Sampling Freq.(Hz)				
Computer Control				
Output				
VGA Display				
Printer				
Optical Stimuli				
Fixation				
Ocular Motor				
Horizontal Testing				
Vertical Testing				
Gaze				
Smooth Pursuit				
Saccadic				
Software Controlled				

(b) (4)

* Nicolet Nystar Plus - Curved Lightbar Optical Stimulator accessory
\# Bio-logic - does not market a lightbar accessory
\+ Micromedical - digital light and calibration bar accessory

2291 205th Street, Suite 203 • Torrance, California 90501 • (310) 328-0477 FAX (310) 328-0697

OculoKinetics, Inc.

HOUSE IR/VIDEO - PUPILSCAN COMPARISON CHART

	House IR/Video	Pupilscan
Image Sensor		
CCD array		
Size (pixels)		
Illumination		
Infrared LED's		
Peak Wavelength		
Number/Eye		
Intensity		
Image Display		
monitor		
Scan Rate		

(b) (4)

2291 205th Street, Suite 203 • Torrance, California 90501 • (310) 328-0477 FAX (310) 328-0697