



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 23 1990

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Mr. Stan Finkelstein, M.D.
Permobil, Inc.
30 Ray Avenue
Burlington, MA 01803

RE: K902954
OBER2 Monitor, Eye
Movement (Ophthalmic)
Class II
Dated: June 27, 1990
Received: July 5, 1990

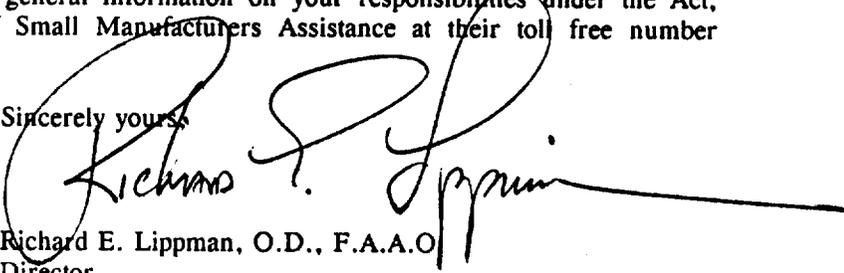
Dear Dr. Finkelstein:

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 practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) 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 pre-amendments 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 anyway 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, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. 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,



Richard E. Lippman, O.D., F.A.A.O.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

BEST COPY AVAILABLE

To: Record
From: Paula Wilkerson, Chemical Engineer
Surgical and Diagnostic Devices
Division of Ophthalmic Devices

Re: K912954
ober2
Permobil, Inc., Permibile Meditech
30 Ray Avenue
Burlington, MA 01803

Infra-red Eye-movement System (Diagnostic)

The ober 2 is an eye movement registration system composed of three principle parts:

1. a pair of goggles which house an infra-red emission and detection system,
2. a controller card, and
3. software which controls the measurement and data collection procedures and provides targets for eye movement measurement.

The eye movement measurements are made using (b) (4) sets of transmitters and detectors mounted inside the goggles and arranged in a square around each eye. Low level Infra-Red (IR) radiation is bounced off the white of the eye as well as the darker portions (iris and pupil) and successive measurements of the relative location of the darker portion is monitored. An IBM PC, XT or AT compatible computer with two disk drives is used by a controller card to control IR emissions and to sample and collect data. The software for the device provides data saving and printing facilities, along with visual stimuli which can be used to register different types of eye movements. Data collection is performed at a rate of (b) (4) Hz for movement of (b) (4) eyes in two perpendicular axis. The (b) (4) is adaptable to (b) (4) by using D.C. light sources around the experimental set up.

The sponsor submitted the names and addresses of 11 companies which he/she claims presently market eye view monitors similar in principle and performance to the ober2. No applicable information or 510k numbers could be found in FDA records by this reviewer on any of the listed companies. The sponsor also submitted descriptive literature on four devices, also currently marketed, which perform similar functions. One of these submissions has been selected by this reviewer to serve as a comparison.

The comparative device is the ISCAN Evil Eye, Eye Slaved Target Acquisition System. This product resembles the ober2 in the following critical points:

1. both devices employ non-invasive Infra-Red eye imaging sensors used to monitor the position of the subject's eye.
2. both systems use a computation unit that calculates the subject's point of gaze with respect to a scene being viewed.
3. the components of both systems are mounted on the body, eliminating the need to immobilize the subject.

The application(s) of the Evil Eye is given in the promotional material as:

1. Rapid Weapons Pointing
2. Surveillance Camera Guidance
3. Aircraft Cockpit Control
4. Automatic Tracking Initialization, and
5. Human Factors Evaluation.

This warlike application does appear a bit removed from a diagnostic tool for reading difficulties, but the actual jobs performed by the two devices are mechanically quite similar.

Technical specifications of importance in this comparison are:

	ober2	Evil Eye
Irradiance at eye:	(b) (4)	1.2mW/sq.cm.
wavelength	(b) (4)	880nm.
Visual angle Range	(b) (4)	Y +/- 15 X +/- 20
Sample rate	(b) (4)	60Hz
recording channels	left and right eye horiz. & vert.	one eye only horiz. & vert.
frequency	50 Hz	60Hz

BEST COPY AVAILABLE

3

Additional information specific to the functioning of the computer portion of the Evil Eye is not available in the promotional material. (b) (4)

(b) (4)

CONCLUSION

This device is found to be significantly equivalent.

substantially

DFM 8/23/90

Paula J. Wilkerson

Sponsor called on 8/20/90, and completed information on performance data.

Also talked to inventor/developer Dr. Sal Aisenberg, PhD, same date.

PW

BEST COPY AVAILABLE

Memorandum

From REVIEWER(S) - NAME(S) PAULA WILKERSON

Subject 510(k) NOTIFICATION K902954

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:

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:

HMC/886.1570/CLASS II

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

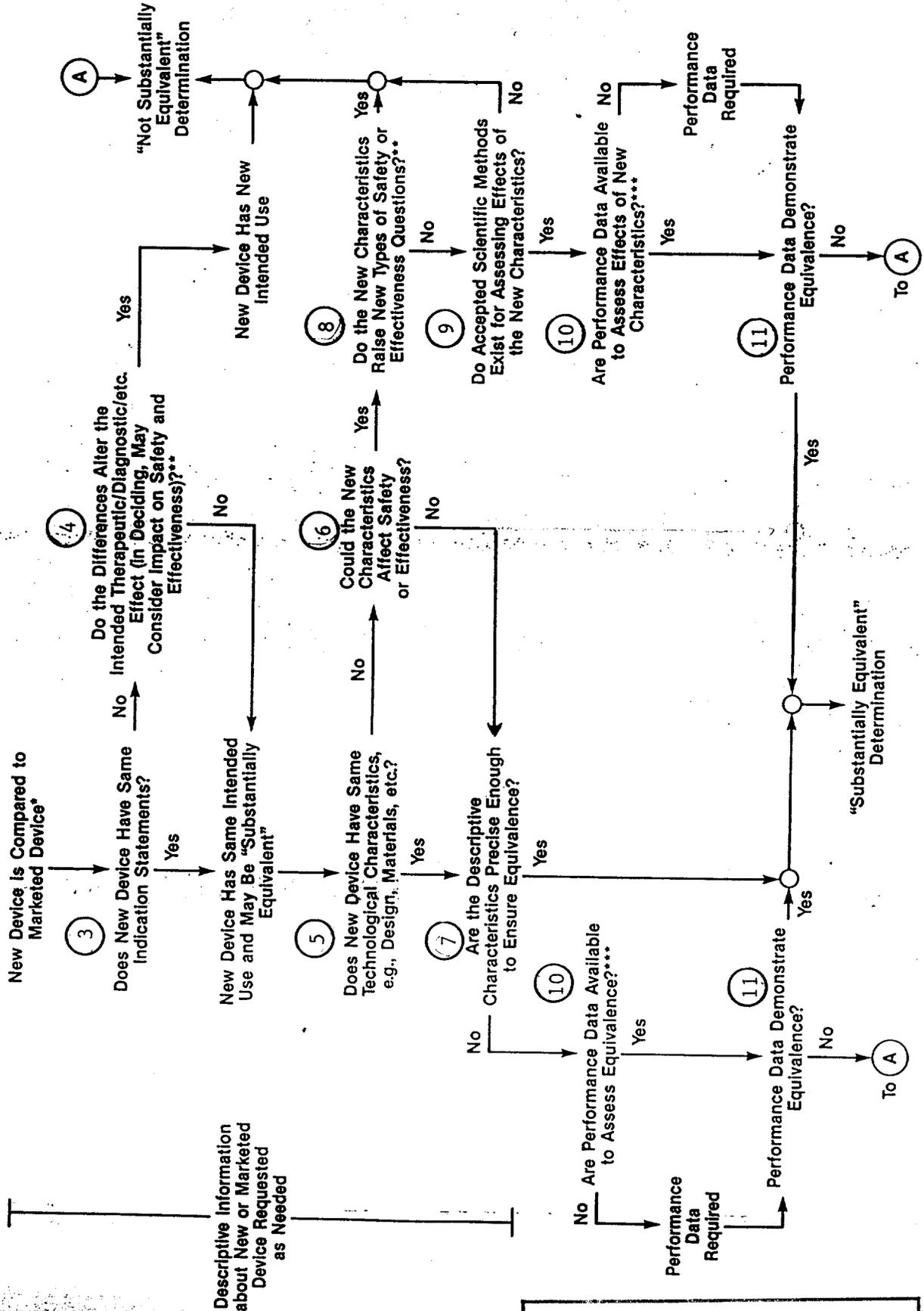
REVIEW: _____ (BRANCH CHIEF) _____ (DATE)

FINAL REVIEW: R. Phillips / REL 8/23/90
(DIVISION DIRECTOR) (DATE)

BEST COPY AVAILABLE

X
5

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



BEST COPY AVAILABLE

510(k) decisions compare new devices to marketed devices. FDA requests information if the relationship between marketed and "predicate" devices or reclassified post-amendments devices is unclear.
 ** This information is normally based on descriptive information alone, but sometimes requires additional information from the manufacturer.
 ... Data are in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

6

K 90-2954 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: P. WILKERSON DIVISION/BRANCH: DOD/SDOB

TRADE NAME: ober 2 COMMON NAME: EYEMOVEMENT MONITOR

PRODUCT TO WHICH COMPARED: _____
(510(k) NUMBER IF KNOWN)

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

BY PHONE

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

BEST COPY AVAILABLE 7

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: _____

BEST COPY AVAILABLE

9

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

BEST COPY AVAILABLE

10

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

JULY 7, 1990

PERMOBIL, INC.
ATTN: STAN FINKELSTEIN, MD
30 RAY AVENUE
BURLINGTON, MA 01803

D.C. Number : K902954
Received : 07-05-90
90th Day : 10-03-90
Product : OBER2 MONITOR, EYE
MOVEMENT
(OPHTHALMIC)

-- The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug, and Cosmetic Act for the above referenced device has been received and assigned an unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, 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
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

BEST COPY AVAILABLE

Permobil, Inc.
Permobil Meditech

K902954

RECEIVED

30 Ray Avenue
Burlington, MA 01803

5 JUL 90 08 43

Tel: (617) 229-9784
Fax: (617) 229-9841

6/27/90

FDA/CDRH/OCE/DMC

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
5600 Fishers Lane
Rockville, MD 20857

RE: 510(k) Notification

Attention: Document Mail Clerk

In accordance with the requirements of section 510(k) of the Food, Drug, and Cosmetic Act, this to notify you of the intention to import and distribute the device described in the enclosed notification document.

As instructed we are providing two (2) bound copies of the Premarket Notification Submission, including supporting information. Also included are two (2) copies of this cover letter.

Trade or Proprietary Name: ober2

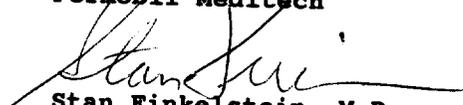
Classification Name: Monitor, Eye Movement (Ophthalmic)

Establishment Registration Number: 1221084

Information about the labeling and the substantial equivalence is given in the bound Premarket Notification Submission.

If you have any questions, please do not hesitate to contact me at (617) 229-9784.

Sincerely,
Permobil Meditech


Stan Finkelstein, M.D.

SA:pc

Enclosures

900627
pr-ober-35-3
5101006p.wp0

BEST COPY AVAILABLE

12

510(k) PREMARKET NOTIFICATION

FOR

ober2

Infra-red Eye-movement System

Submitted to:

**Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
5600 Fishers Lane
Rockville, MD 20857**

Prepared by:

**Permobil, Inc.
Permobil Meditech
30 Ray Avenue
Burlington, MA 01803**

**Tel: (617) 229-9784
Fax: (617) 229-9841
1-800-736-0925**

Submission Date:

Copy Number:

**890627
perm-35-3
510k006g.wp0**

BEST COPY AVAILABLE

TABLE OF CONTENTS

Section	Description	Page No.
	TITLE PAGE	
	TABLE OF CONTENTS	i
1.0	DEVICE NAME	1
2.0	ESTABLISHMENT REGISTRATION NUMBER	1
3.0	DEVICE CLASS	1
4.0	ACTIONS TAKEN	1
5.0	PROPOSED LABELING	1
	5.1 Photographs	1
	5.2 Labels	1
	5.3 Labeling Literature	2
	(Circular/Brochure)	
	5.4 Advertising	3
	5.5 Drawings	3
6.0	SIMILARITY TO OTHER PRODUCTS IN COMMERCIAL DISTRIBUTION	3
	6.1 Identification of Similar Products	4
	6.2 Identification of Materials	10
	6.3 Identification of Design and Design Considerations	10
	6.3.1 Features	10
	6.3.2 Typical Specifications	11
	6.4 Energy expected to be Used or Delivered by Device	12
	6.5 Description of Operational Principles of Device	12
	6.6 Warranty	13

1.0 DEVICE NAME

- a. Trade or Proprietary Name: ober2
- b. Usual or Classification Name: Monitor, Eye Movement (Ophthalmic)

2.0 ESTABLISHMENT REGISTRATION NUMBER: 1221084

The device is manufactured in Sweden by Permobil Meditech ab and will be imported and distributed in the United States by Permobil, Inc.

3.0 DEVICE CLASS

We feel that this device belongs in ~~Class I~~, and is substantially equivalent in safety and efficacy to devices that are already in class I.

CLASS II

4.0 PERFORMANCE STANDARDS:

There are no known performance standards for this device.

5.0 PROPOSED LABELING

5.1 PHOTOGRAPHS

See section 5.3 (circulars/brochures).

5.2 LABELS

The following label will be placed on each suitable component such as the printed circuit board, and the adaptor box. It also will be placed on the goggles, provided there is room for the label on the goggles. It will permit the users to contact us for help and information.

Permobil Meditech
30 Ray Avenue
Burlington, MA 01803

5.3 LABELING LITERATURE (Circular/Brochure)

The literature is attached in the following un-numbered pages.

BEST COPY AVAILABLE

16

ober 2

EYE MOVEMENT REGISTRATION SYSTEM

PRE-RELEASED INFORMATION, May 1988

Easy to use
Competitively priced
Suitable for use in any environment

BEST COPY AVAILABLE

17

The eye movement registration system developed by Dr Jan Ober (Institute of Biocybernetics and Biomedical Engineering, Polish Academy of Science) and Dr Per Uddén (Permobil AB, Timrå, Sweden), with the assistance of Dr Jozef Ober (The Technical University, Gliwice, Poland). It is designed to allow non-invasive measurement of most types of eye movements. Its possible applications are therefore very varied. The user-friendly operating system ensures that even the most computer shy person will find the system easy to operate. However, the system is also designed for sophisticated uses.



Description of the Components

The eye movement registration system has three components: a pair of goggles, a controller card and software which controls the measurement and data collection procedures and provides targets for eye movement measurement. The price level is within the \$3,000—\$5,000 range.

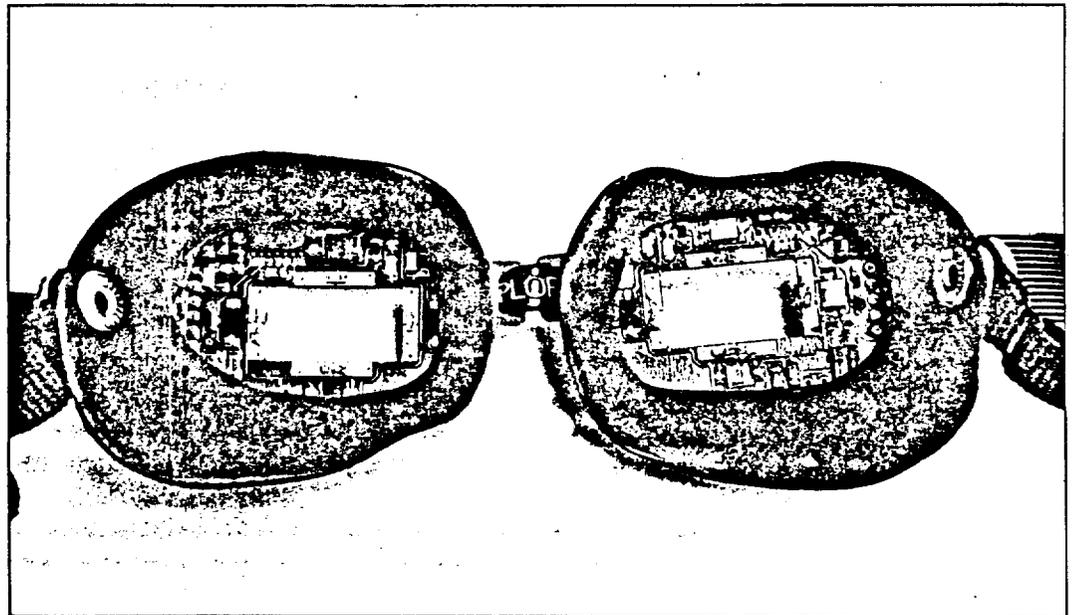
The goggles (figure 1) house the infra-red emission and detection components. An elastic strap, which goes round the head to keep the goggles firmly in position, can be adjusted for individual comfort. The distance between the eye pieces is variable, allowing a comfortable fit to many sizes of face. However, the exact positioning of the eye movement detection system is not crucial to accurate eye movement recordings. The rubber outer whirling fits snugly around the orbit of the eye. This both prevents movement of the transmitters during measurement and cuts down on the amount of stray light which can enter.

The eye movement measurements for each eye are made using four sets of transmitters and detectors arranged in a square around each eye. These allow precise registration (with a resolution of 5 minutes of arc) of eye movements along the horizontal axes. The vertical eye movement is less precise. This system is suitable for use with a large range of inter-

pupillary distances. Measurements can be made on children of 3 years of age and adults using the same equipment. A system suitable for measuring eye movements in babies and monkeys will be designed.

This system is unique among non-invasive systems in allowing the eye movements to be recorded when the subject is not looking directly ahead. No alteration to the geometry of the eye movement detectors is needed. The eye movements made during normal reading are performed with the eyes pointing downwards. Hence, reading involves more than just the eye muscles which perform horizontal eye movements. If reading difficulties involve fatigue of the eye muscles, it is important to measure reading eye movements with the eyes in the normal reading position so that all the eye muscles normally activated are involved. This system allows this type of measurement to be performed easily.

Figure 1



BEST COPY AVAILABLE

18

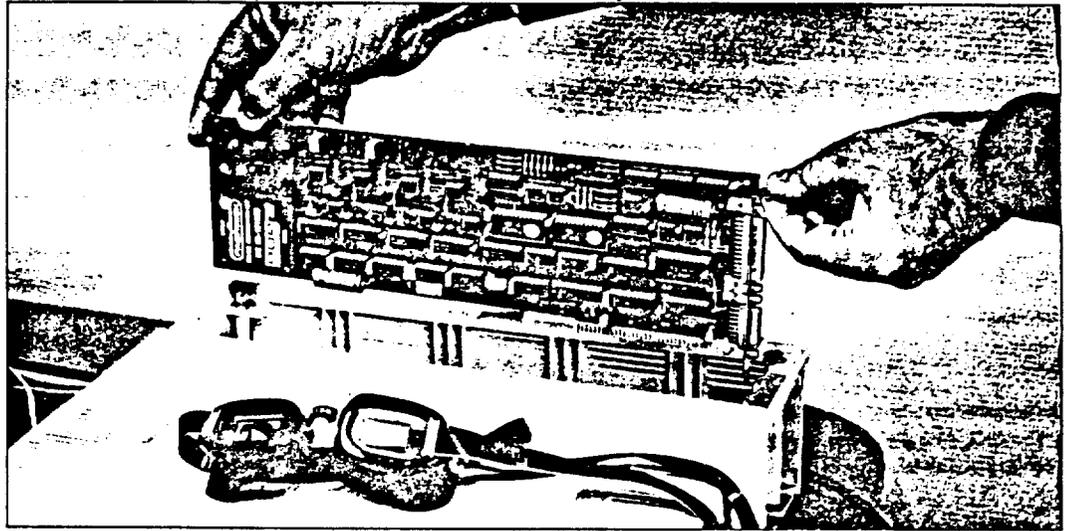


Figure 2

The controller card (figure 2) fits into a long slot in an IBM PC XT or AT compatible computer running at from 4 to 12 MHz. At least one floppy disc drive is required in order to run the program. Data storage requires a second disc drive, and a hard disc is recommended. The board uses the computer's processing facilities to control IR emission and to sample and collect data. The data is stored in a compact binary format. An EGA card and a high resolution color monitor are also required in order to operate this system. An IBM graphics compatible printer can be used to print out data records.

The software which accompanies this package provides data saving and printing facilities, along with a number of visual stimuli which can be used to register different types of eye movements. The software allows the operator to save, load, print and view data collected during several different types of eye movements (figure 3). Fixation movements, saccades, smooth pursuit and reading eye movements can all be recorded using stimuli produced on screen. It is also possible to record other types of eye movements in response to external stimuli by using the on-line data collection facility.

It is possible to print data using the screen dump facility, however, this procedure is slow. The software, therefore includes fast routines to print data on IBM Graphics-compatible dot matrix printers. Routines will also be available to interface the program with HP-compatible plotters. Data collection is performed at a rate of 100 Hz in Europe or 120 Hz in the USA for movements of both eyes in two perpendicular axes. It is possible to arrange for the data to be sampled more frequently (500 Hz), however this requires the use of only D.C. light sources around the experimental set up.

For ease of use, the system is designed so that all adjustments are performed via the software. There are no unwieldy knobs to twiddle or buttons to press.

The software can display the difference signal between the two eyes. The data display mode also allows measurement of the amplitude and duration

of portions of the eye movement record. A cursor line is displayed on screen (figure 4), and this can be positioned by the operator. The initial position of the cursor is used to set the starting point of the measurement. The position of the start of the eye movement is displayed at this point. The cursor can then be moved to the end point of the eye movement to be measured. The duration of that eye movement, and the position of the dot on the screen are displayed.

The eye movement registration system is also adapted to operate in conjunction with a video recorder or camera. It is possible to record eye movements while the subject watches a video, and then to superimpose the eye movements back onto the video signal to determine the point of attention of the subject. This facility would be useful in cognitive psychology, especially for attentional studies.

Figure 3 Menu for the eye movement registration software

Rodin Remediation Foundation ober2 - Permobil Meditech, Sweden	
F1 - Single Fixation Point (14 secs) F2 - Saccadic Tracking (X and Y) F3 - Continuous Tracking (X and Y) F4 - Splitting Target (X and Y) F5 - Online Data Collection (X and Y) F6 - Text Reading 14 sec F7 - Save Data F8 - Load Data F9 - Print all Data ESC - Return to Operating System	Press any key to view data

BEST COPY AVAILABLE

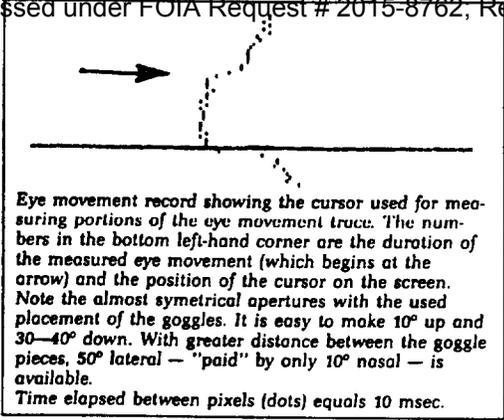
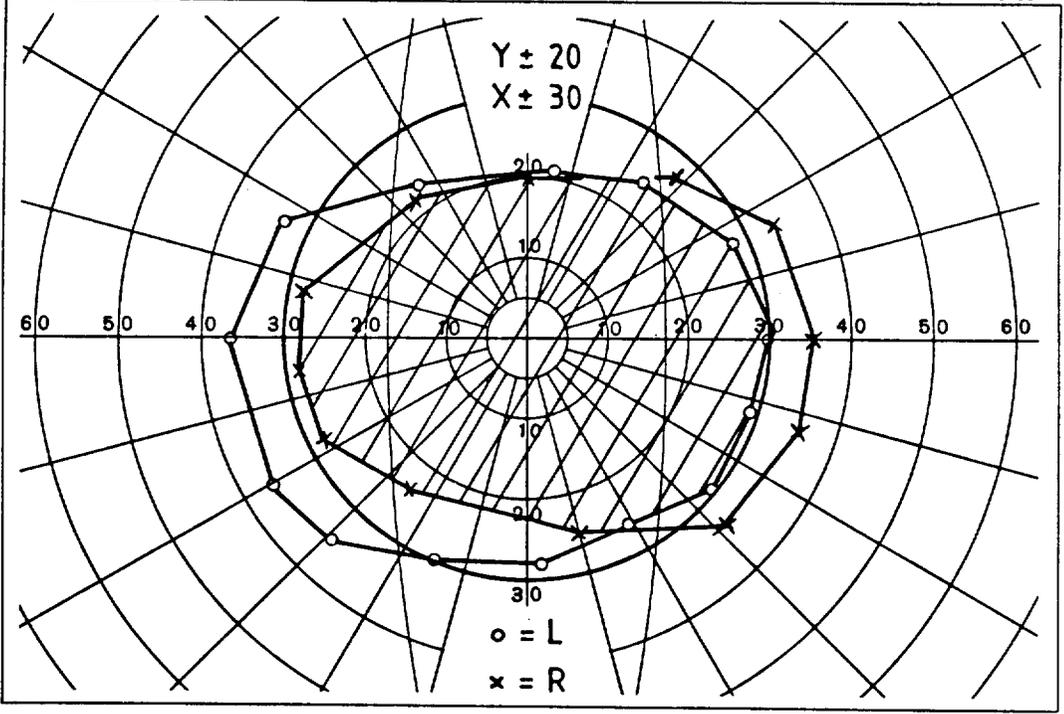


Figure 4

Technical Specifications

The visual fields are restricted by the aperture in the goggles. Figure 5 shows the fields plotted on a perimetric chart. The size of the available field is dependent on the distance between the aperture and the eye. This distance can be decreased, thus increasing the size of the field by mounting the emission and detection system on a pair of spectacles rather than within the goggles. This system has to be protected from direct light in order to operate correctly. This means of mounting the measuring system has the additional, important and unique benefit of being applicable to subjects who wear prescription lenses. Hence, eye movement records can be made while the subject is wearing his/her own glasses.

Figure 5: Perimetric chart for left and right eye showing the size of the visual field seen through the aperture in the goggles



BEST COPY AVAILABLE

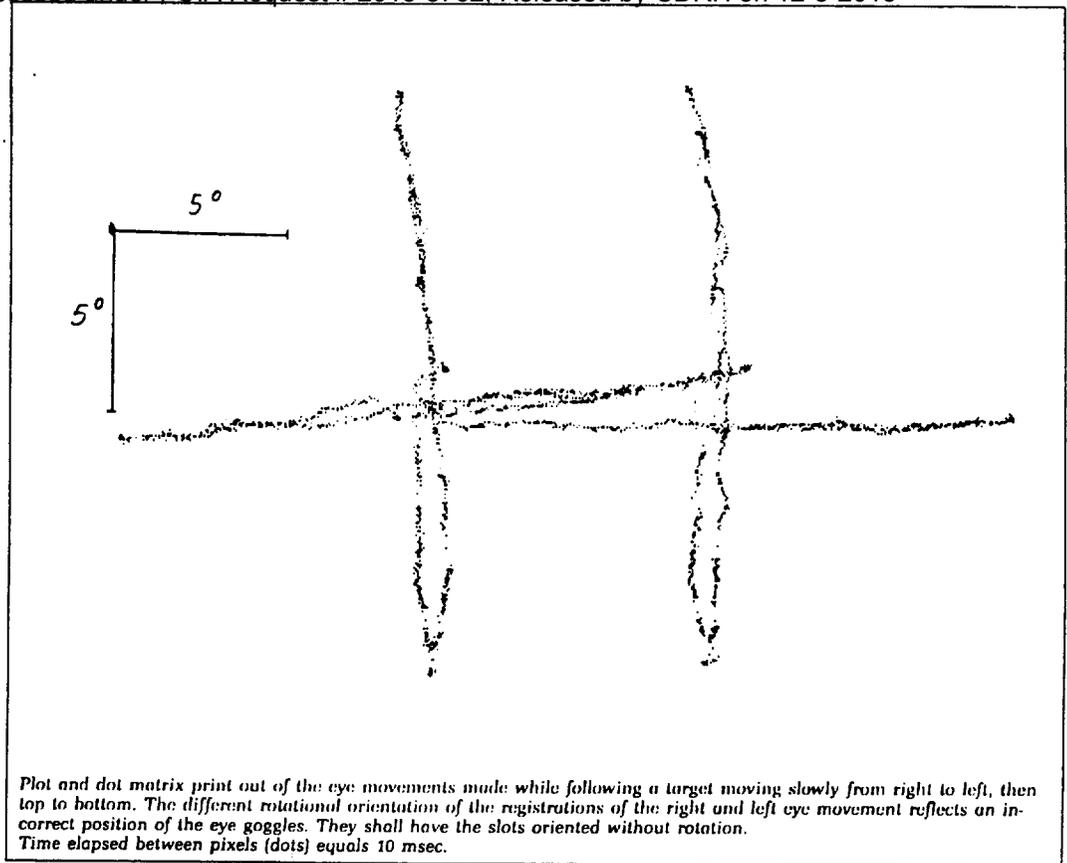


Figure 6

A system for monitoring head movements is also planned. Whenever the head moves, a vestibulo-ocular eye movement is made to allow the eyes to remain on target. By monitoring head movements it should be possible to subtract compensatory eye movements occurring in response to head movements from the eye movement trace, leaving only voluntary eye movements.

Possible Applications.

Anyone with an interest in eye movement registration could use this system. Unlike most other systems, it is completely non-invasive, requiring only that the subject wears a pair of light goggles in which is mounted the infra-red monitoring components total weight: 80g. The menu-driven control also makes it easy to use.

Clinical ophthalmologists might find it useful in measuring nystagmus, assessing limitations of gaze, or in investigating the smooth pursuit (figure 6), the saccadic or the vergence eye movements. A unilateral ptosis can also be detected via the vertical registration system. This would show up as a large difference between the eyes in the y-axis. The system can print records of the eye movements produced — useful in reviewing cases or in making comparisons between subjects. Data storage on disc also allows further off-line analysis of eye movement records.

The prohibitive cost of eye movement measuring systems up until recently has meant few clinical departments or laboratories could afford the luxury of investing in such a system. As a result, there is little information available especially on pathological eye movement control and on eye movement control outside the laboratory environment. Research is beginning into the effects of various disease states on eye movements - both for neurological conditions like Parkinson's disease and myasthenia gravis, and psychiatric disorders like schizophrenia. Changes in eye movement control might be found to be useful in the early diagnosis of such diseases.

Eye movement control is also being investigated in an educational framework (figure 7). Recent research has suggested that children with poor control of their vergence eye movements have greater difficulty than their peers when learning to read. Other research points to differences in scanning patterns between normal and poor readers. Failure to diagnose these difficulties, and to intervene educationally (if not clinically) might result in severe reading failure — dyslexia.

Basic research into the normal properties of eye movements and the development of eye movement control is also in its infancy. This eye movement registration system might prove useful in furthering our knowledge in this field. The eye movement

BEST COPY AVAILABLE

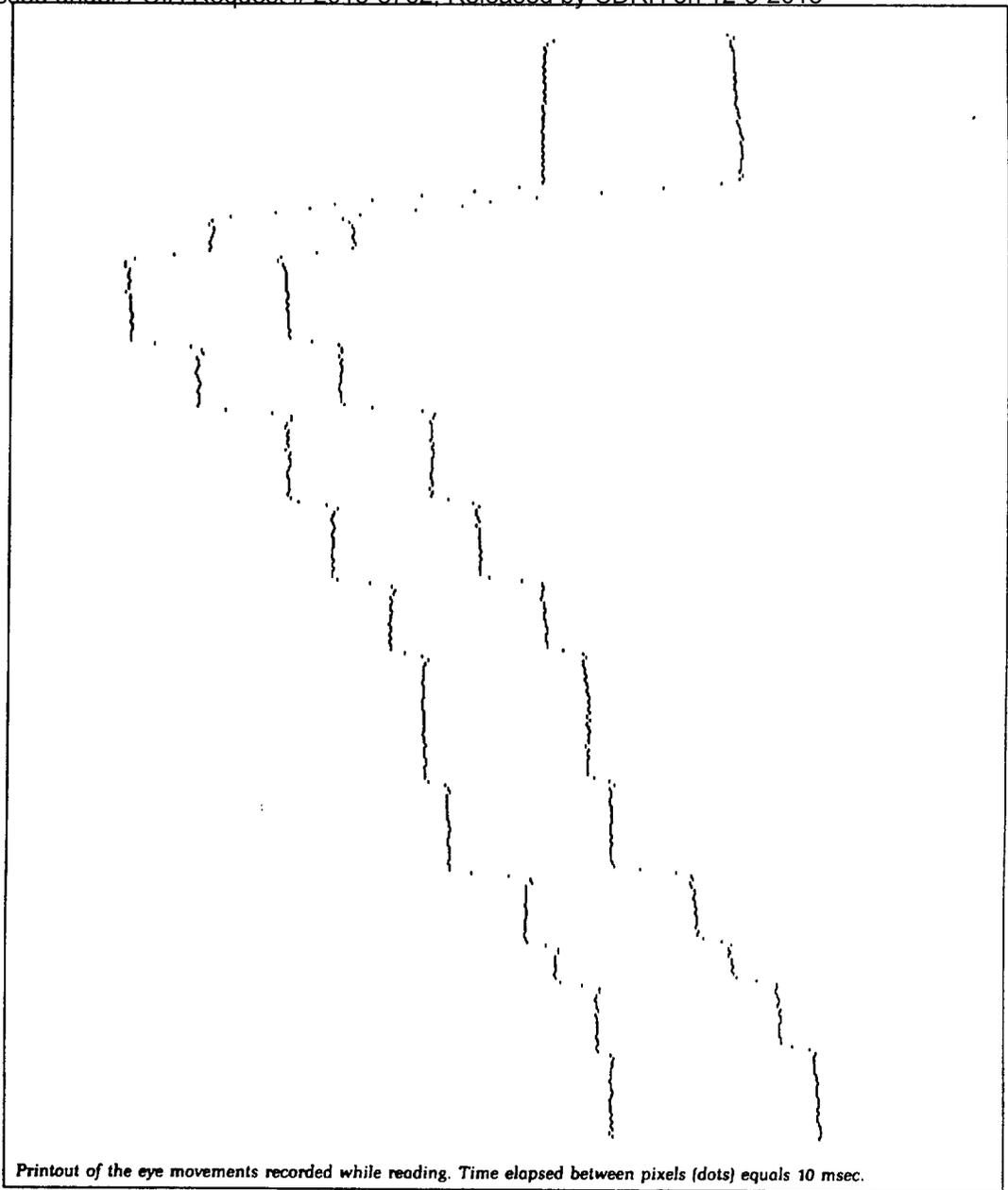


Figure 7

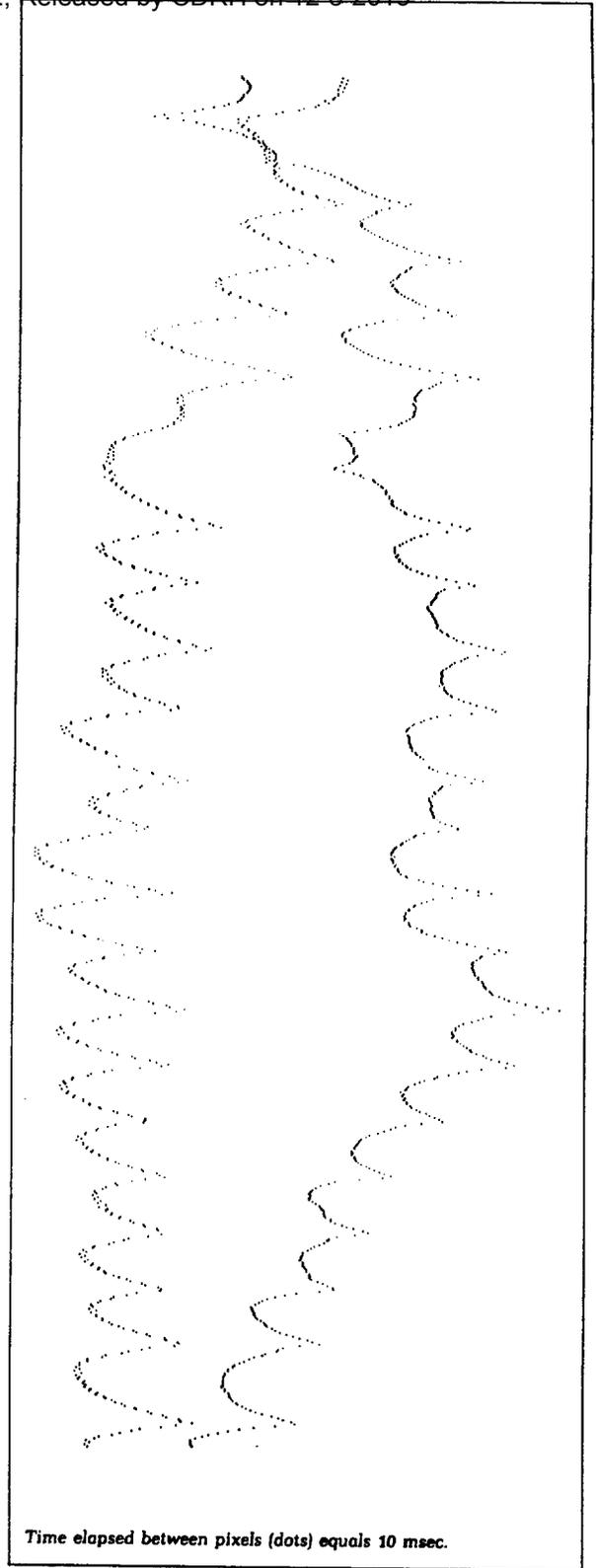
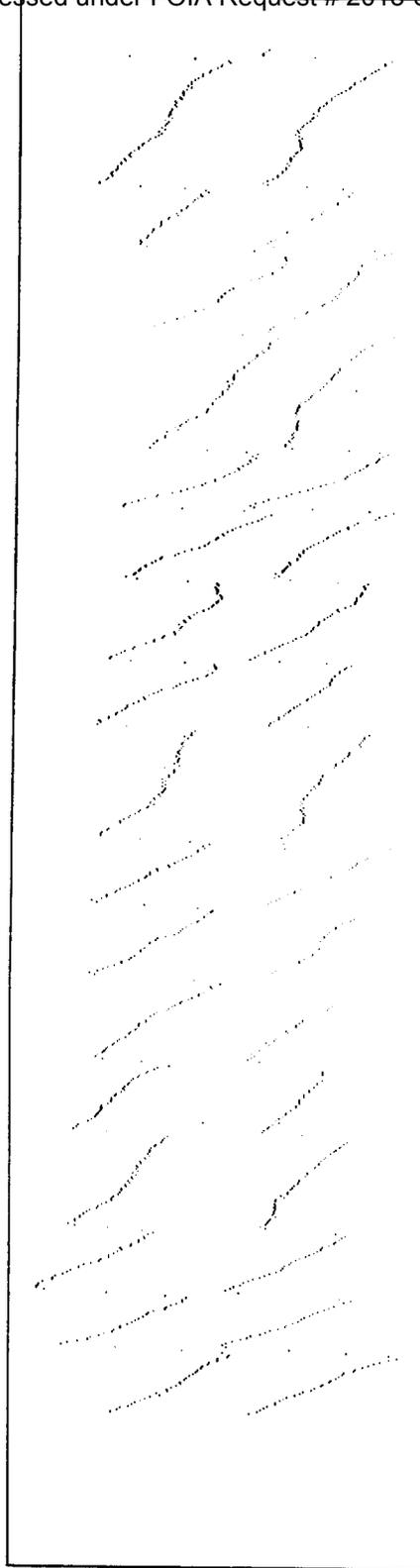
control system is known to be very sensitive to pharmacological changes after drug administration. Thus eye movement recording might be one possible way of assessing the presence of drugs, either in the laboratory, or in the clinic. Since some psychiatric drugs are known to adversely affect the basal ganglia, and therefore eye movement control, eye movement measurement could be used to assess the correct dose of these drugs for an individual patient.

The system has industrial applications too. It might be possible to measure eye movement control in

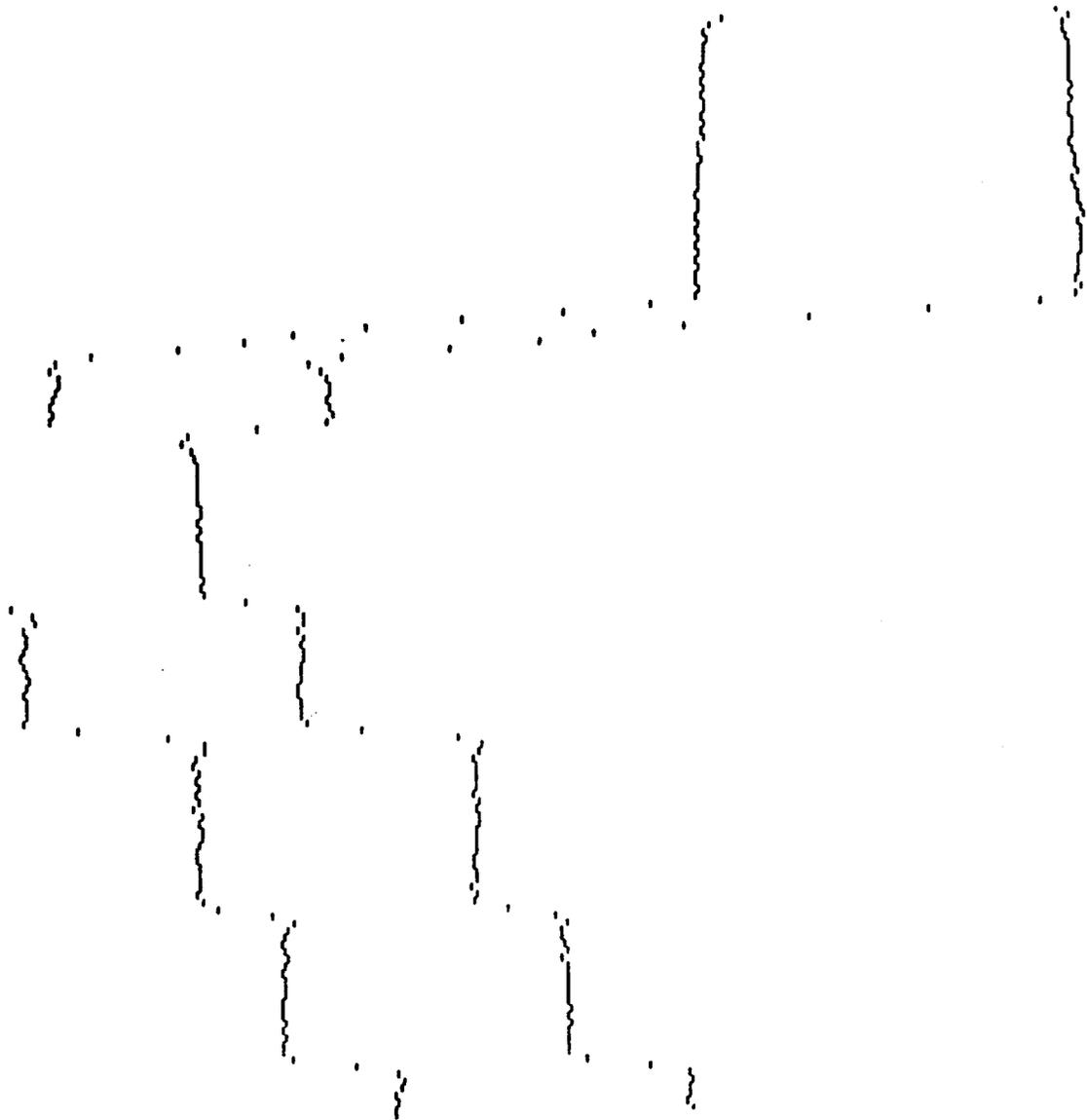
individuals who work with dangerous equipment on a regular basis. This would allow assessment of changes in attention with fatigue or as a result of drug administration. This type of eye movement registration might therefore help to reduce the incidence of industrial accidents.

These are only a few of the possible applications of this eye movement registration system. By providing a system which is non-invasive, easy to use and competitively priced, we hope that users will be inspired to find many more uses for this equipment.

BEST COPY AVAILABLE



BEST COPY AVAILABLE



permobil
meditech ab
box 120 s-861 00 timrå sweden
tel 060-57 27 70 fax 060-57 52 50

BEST COPY AVAILABLE

24

5.4 ADVERTISING

None prepared at present.

5.5 DRAWINGS

See section 5.3 (circulares/brochures).

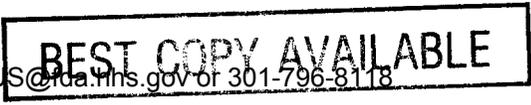
6.0 SIMILARITY TO OTHER PRODUCTS IN COMMERCIAL DISTRIBUTION

The present device, the ober2, is similar in principal and performance to a number of eye view monitors already available in the market. It uses low level Infra-Red (IR) illumination of the eye and measures the different IR reflection from the white of the eye and the darker portions of the eye (iris and pupil). Successive measurement of the location of the darker portion of the eye permits monitoring of the motion of the eye.

According to Volume 1 of the 1987 Medical Device Register, (Medical Device Register, Inc., Stamford CT, 1987), p. III-488, the following companies have devices that are already in use and that are listed under the category "Monitor, Eye Movement (Ophthalmic) 86QVH":

- 1. Applied Sciences Labs.
335 Bear Hill Road, Waltham, MA 02154
- 2. Gould Inc., Recording Systems Div.
3631 Perkins Ave., Cleveland, OH 44114
- 3. Life-Tech, Inc.
P.O. Box 36221, Houston, TX 77236
- 4. Neuronics Inc.
830 N. State St, Chicago, Il 60610
- 5. Siemens Corporation, Medical Systems
186 Wood Avenue South, Iselin, NJ 08830
- 6. Storz Instrument Company
3365 Tree Court Industrial Blvd., St. Louis, MO 63122
- 7. WCO Ophthalmic Instrument Div.
4597 15th St., E. Bradenton, FL 34203

86-2014 New device
 A-111111
 CLASS II
 CLASSIFICATION
 876.1570
 (GENERIC)



In addition to the ones listed above, there are a number of other companies that provide eye movement systems that have been used and are offered for sale.

8. ISCAN Inc.
125 Cambridgepark Drive, Cambridge, MA 02238
9. LC Technologies, Inc.
4415 Glenn Rose Street, Fairfax, VA 22032
10. Micro Measurements, Inc.
1921 Hopkins Street, Berkeley, Ca 94707
11. SRI International
333 Ravenswood Avenue, Menlo Park, CA 94025

6.1 Identification of Similar Products

Copies of descriptive literature for eye movement monitoring systems sold by the following companies are attached for information purposes because they demonstrate the existence and the offered sale of devices similar to the ober2. The principles of operation and performance are similar to that of the ober2.

Samples of descriptive literature for these devices are provided in the following pages.

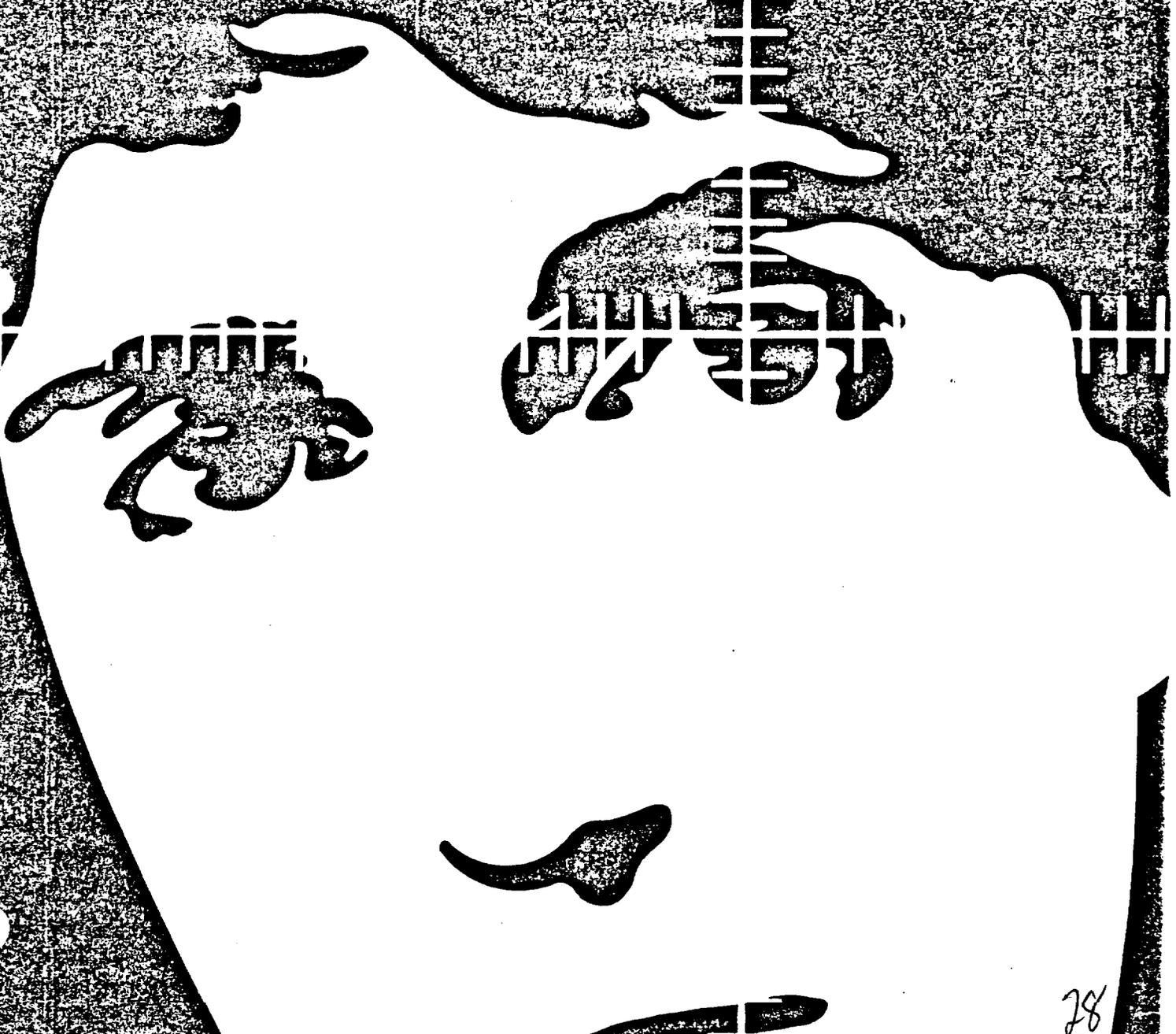
**Applied Sciences Labs.
335 Bear Hill Road, Waltham, MA 02154**

The literature is attached in the following un-numbered pages.

GW Applied Science
Laboratories
MEMBER OF WESTERN RESEARCH AND DEVELOPMENT GROUP

Field Proven Systems for
Quantitative Analysis of
Eye Movement, Pupillometry,
and Visual Function

eye-trac



Contact FDA/CDRH/OCE/DIV. OF FOIA at FOIA@fda.hhs.gov or 301-796-8118

BEST COPY AVAILABLE

28

Selection Guide

MODEL	EYE MOVEMENT	POINT OF GAZE OR FIXATION	PUPIL DIAMETER	DEGREE OF HEAD FREEDOM	OUTPUTS	RESPONSE OF SAMPLE RATE
Model 106 Eye-Trac [®] Photoelectric Limbus Tracker	YES (Horizontal only)	NO	NO	Chinrest	<ul style="list-style-type: none"> • Chart record • Analog signals 	Electrical output signals Recorder: 40 Hz or 30 ms
Model 200 Eye-Trac [®] Spectacle Mounted Limbus Tracker	YES	Yes with fixed head	NO	Free head with spectacle mount for eye movement with respect to head; chinrest or bite board required for point of gaze	<ul style="list-style-type: none"> • Analog • Digital¹ • TV fixation point display² • Panel Meter 	Time constant: 4 ms, 26 ms with built-in filter
Series 1000 TV Pupillometer	NO	NO	YES	Chinrest	<ul style="list-style-type: none"> • TV display • Analog • Digital • Panel meter 	Television sampling 60 (50) second (Internal filter is present)
Model 1992 Laboratory Eye View Monitor System	YES	YES	YES	Chinrest	<ul style="list-style-type: none"> • TV display of crosshairs or spot superimposed over scene being viewed • Analog • Digital • Panel meter for pupil diameter 	Television sampling 60 (50) second (running average of two TV fields is output each may be eliminated)
Model 1994 Remote Eye View Monitor System	YES	YES	YES	Chinrest or headrest	Same as above	Same as above
Model 1996 Computer based Eye View Monitor System	YES	YES	YES	Headrest [16cm ³ (1 in ³) of head motion allowed]	In addition to Model 1992/1994: Optional computer output of raw or processed data along with other experimental variables	Television sampling 60 (50) second (running average of four TV fields is output each may be eliminated)
Model 1998 Computer Based Eye View Monitor with Head Tracking Mirror	YES	YES	YES	¹ From 230 cm ² (36 in ²) to 03 m ² (1 ft ²)	Same as above	Same as above

EYE MOVEMENT MEASUREMENT RESOLUTION	NOMINAL POINT OF GAZE ACCURACY	OPTIONS	FEATURES	APPLICATIONS	PAGE
zontal: 0.5°	N/A	<ul style="list-style-type: none"> • Reading analysis package • Variable rate fixation stimulator 	<ul style="list-style-type: none"> • Economical • Binocular measurement • Built in chart recorder 	<ul style="list-style-type: none"> • Reading analysis • Nystagmus studies • Vergence studies • Color perception • Applications in which eye movements (as opposed to point-of-gaze) are sufficient 	4
Vertical: 1° Horizontal: 0.25° (Higher resolution is possible with rigid head restraint)	Vertical: 2° Horizontal: 1° (along major axes)	<ul style="list-style-type: none"> • Digital outputs • Video fixation point display unit 	<ul style="list-style-type: none"> • Economical • Binocular measurement; one axis for each eye • Eyelid used for vertical measurement • Head mounted walk-around system • High response speed • High resolution 	<ul style="list-style-type: none"> • Eye movement measurement studies in which an economical, high resolution, medium accuracy, high speed head mounted device is suitable 	6
N/A	N/A	<ul style="list-style-type: none"> • Binocular measurement • Programmable photostimulator • Chart recorders • Computer data recording package • Pupillary area measurement for high resolution • Remote eye camera 	<ul style="list-style-type: none"> • Simplicity of operation • High degree of subject comfort • Unique pupil pattern recognition circuitry • Patented status indicators to the operator 	<ul style="list-style-type: none"> • Psychological research • Arousal • Fatigue • Workload • Drug studies • Ophthalmology • Neuroscience • Schizophrenia research • Binocular imbalance 	10
<0.5°	11° in central field, 2° in peripheral corners	<ul style="list-style-type: none"> • Computer Based Data Acquisition & Recording System (DARS) • EYENAL off-line data analysis system 	<ul style="list-style-type: none"> • Simple setup • Rapid calibration • Acceptance of wide subject population • Upgradable system • Automatic pattern recognition • Head motion compensation • Patented status indicators to the operator 	<ul style="list-style-type: none"> • Reading studies • Visual search • Scanning • Psychomotor studies • Perception • Human factors research • Simulation • Advertising 	13
<0.5°	Same as above	Same as above	<p>In addition to features of Model 1992:</p> <ul style="list-style-type: none"> • Bright pupil system • The optical system is remote and therefore less obtrusive to the subject • Greater tolerance of eyeglasses, eyelids and other artifacts 	<p>Same as above, where increased subject freedom is desired</p>	13
<0.5°	1°	<ul style="list-style-type: none"> • EYEDAT real time Eye position data recording system... also records external data • EYENAL off-line data analysis system • Integral computer generated text or graphic display • Stimulus generation 	<ul style="list-style-type: none"> • EYEPOS Real time software package for calibration, control and output of computed eye position • Rapid computerized automatic calibration & linearization • High subject-camera distance up to 200 cm (90 inches) • Highly unobtrusive measurement • Increased head motion • High tolerance of eyeglasses, eyelids, and other artifacts • Flexible system placement • Future program updates may be easily incorporated • Integral powerful general purpose minicomputer with operating system, FORTRAN, BASIC, utilities, etc. 	<p>Same as above, where increased head motion, rapid calibration, and data handling are desired</p>	16
<0.5°	1°	<p>Same as above plus:</p> <ul style="list-style-type: none"> • Automatic remote focusing capability • Extended head tracking • Magnetic head tracking • Simulator configuration 	<p>Same as above plus:</p> <ul style="list-style-type: none"> • Aircraft simulation • Locomotive, automobile and other operational simulators • Real aircraft and other vehicles • Highly realistic and free head requirement applications 	16	

*Optional
†See detailed specifications

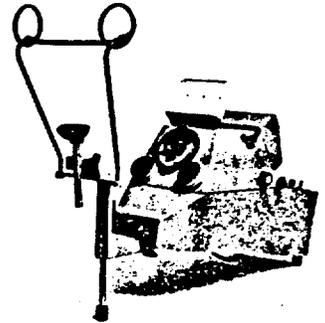
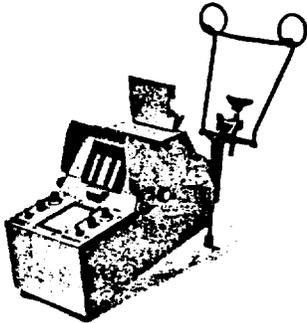
NOTE
 1. These measurement systems are not medical devices and are sold under the condition that they will not be used as medical devices
 2. If a medical device version is required, please write for special price and delivery.

Questions? Contact FDA/CDRH/OCE/DID at CDRH.DIST@fda.hhs.gov or 301-706-8115

30
3

BEST COPY AVAILABLE

Eye-Trac Model 106 Eye Movement Monitoring System



This simple, economical photoelectric device means:

- No film to develop
- No electrodes to paste on the subject
- Use on subjects with or without glasses

In a matter of minutes you can obtain an objective, quantitative and permanent recording of the key elements of binocular visual function and performance. Aides or paramedical technicians can run the tests for subsequent examination and diagnosis.

The Eye-Trac Model 106 is used most widely in reading diagnosis and evaluation of visual perceptual development.

- How well does Johnny read?
- At what reading speed — with what comprehension?
- At what grade level — how efficiently?
- Does he have dynamic binocular coordination?
- What type of remediation is needed?

All this in a three to five minute test. And the permanent recordings provide objective data for evaluation of remedial progress.

A number of sophisticated measurements can be made with the Model 106 using appropriate visual targets:

- Saccadic fixations
- Pursuit movements
- Vergence
- Binocular fixation ability
- Near-far fixations
- Color perception

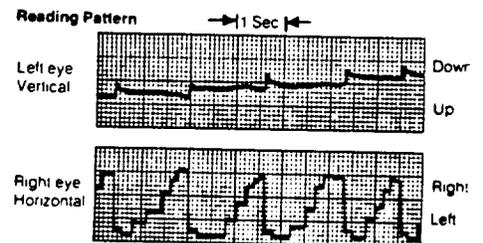
The effects of surgery, corrective lenses, medication, drugs, alcohol, fatigue, etc. . . . on these functions may also be studied.

The Model 106 measures horizontal eye position for both eyes, with external outputs provided for computerized data acquisition systems.

In normal operation, no regular maintenance is required except for replenishment of recording paper.

The Eye-Trac will resolve horizontal eye movements to better than one-half of a degree.

The Eye-Trac 106 uses a filtered, incandescent light source and non-contacting photodiode receptors for tracking eye movements, the results of which are instantaneously recorded on a built-in, two-channel head writing recorder.

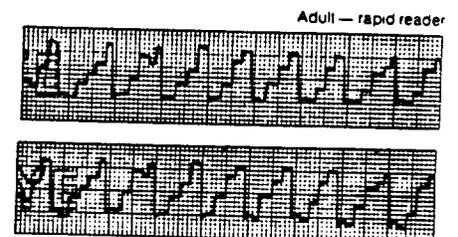
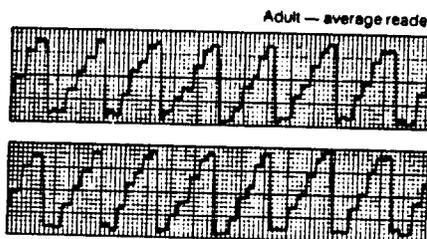
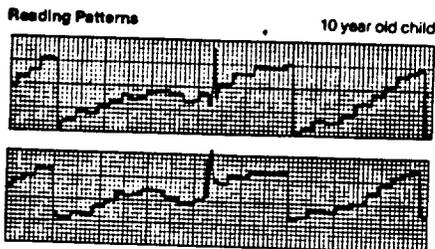


READING PATTERNS

An illuminated easel, designed to hold reading cards or similar test material, is

supplied as part of the basic Eye-Trac. From a reading pattern recording, one can determine reading rate, number and duration of fixations and regressions, and many other aspects of

oculomotor performance. A set of 64 reading selections (grade 1 through college), along with a complete reading analysis package is available.



READING ANALYSIS PACKAGE

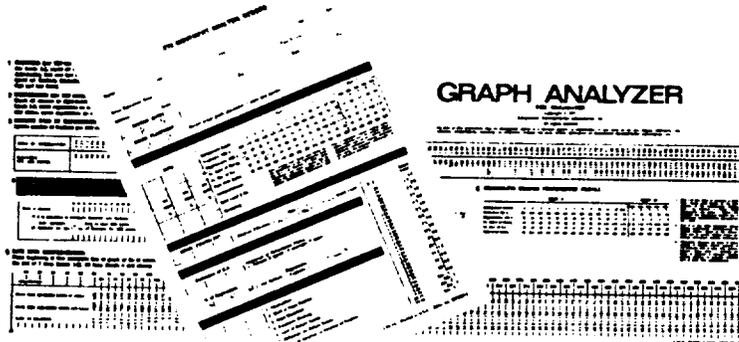
A reader's eye movement characteristics provide objective evidence of his reading performance or the way he habitually employs his eyes in reading. Eye-movement patterns are a reflection of a reader's visual-functional, perceptual, and interpretive competence. Eye movement recording provides direct information about the reader's efficiency (the time and effort expended and the visual approach employed). It also provides indirect information about his effectiveness (his ability to accomplish expected comprehension goals).

Through an analysis of eye movement recording, the reading diagnostician is able to evaluate reading performance in terms of reading behavior. This analysis of eye movements can be completed quickly,

efficiently, and thoroughly using the materials provided in the Reading Analysis Package. A collection of materials including charts and graphs (see ordering information) is provided along with reading selections for standard testing of reading performance.

Resulting analysis provides the following data:

- Fixations
- Regressions
- Average span of recognition
- Average duration of fixations
- Rate with comprehension



SPECIFICATIONS

Power	105-125 VAC @ 60 Hz, 1 Amp (210-250 VAC, 50 Hz available)	
Weight	11.4 kg (25 lbs)	
Maximum Dimensions	79 x 58 x 28 cm (31 x 23 x 11 inches) L x H x W	
Headrest	Fully adjustable with both gross and fine elevation adjustment, chin cup tilt adjustment, and built-in lateral head supports.	
Eye Illumination	IR-filtered incandescent lamps 15 cp; GE 941F or equivalent.	
Photo Sensors	Silicon photocells	
Electronics	Solid-state, plug-in printed circuit boards	
Recorder	Response — 40 Hz Paper speed — 10mm/sec Medium — Heat-sensitive paper 50mm (2.5 inches) wide, 100 foot roll	
Output signal	Typical range — ± 3.0 V Typical scale — 300 V/degree Output impedance — 100 ohms	
Resolution	$\frac{1}{2}$ degree	
Range from Center	linear	± 10 degrees
	usable	± 20 degrees
Response	40 Hz band width or 40 ms time constant for recorder; 1 kHz band width or 2 ms time constant for electrical output signal	
Artifacts	Blinks, head movements, ambient light variation	

Specifications subject to change without notice

ORDERING INFORMATION

719-1060 Model 106 Eye-Trac (110V, 60 Hz; or 220V, 50 Hz)

719-1082 Reading Analysis Package consisting of:

1. Test Selections: Set of 64 reading selections, for grade level 1 through adult, prepared by Educational Development Laboratories. Printed on 3.5 x 5 inch cards to fit in easel. (Part No. 719-0002)
2. Examiner's Copy, Test Selections. (Part No. 719-0009)
3. Manual, Eye Movement Analysis With Reading Eye II. (Part No. 719-0010)
4. Eye Movement Analysis Record Sheets (50). (Part No. 719-0007)

719-0003 Heat sensitive chart recorder paper (2 rolls per box)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTA US@fda.hhs.gov or 301-796-8118

32

5

BEST COPY AVAILABLE

eye-trac Model 200 Research Eye Movement Monitor

- Measures Horizontal or Vertical Eye Movements—simultaneously monitors both eyes.
- High Sensitivity, Accuracy, Resolution— minutes of arc possible — millisecond response.
- Analog and Digital Outputs Available— compatible with most display and recording devices and computerized data systems.
- Non-Contacting Photoelectric Technique— does not require electrodes or attachment to the eye.

APPLICATIONS

The Eye-Trac Model 200 finds application whenever an economical or head-mounted eye movement measurement device is required. Uses include studies involving:

Scan patterns
Drug effects
Psycholinguistics
Fatigue
Human factors engineering

Perception
High frequency eye movements
Dominance
Advertising, consumer reaction
Vigilance testing

Anxiety
Fixation & gaze avoidance
Tracking
Small eye movements

DESCRIPTION

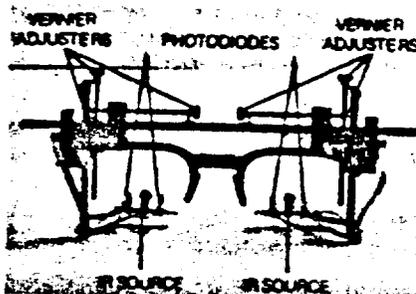
The Eye-Trac Model 200 Research Eye Movement Monitor measures both horizontal and vertical eye movements by employing a non-contacting photoelectric technique. The outputs produced are simultaneous analog voltages (digital optional) which are direct functions of the position and movement of each eye.

The instrument consists of a sensing assembly and an associated electronics control package connected by an eight foot flexible cable.

The monitor does not require attachments to the eye or skin, nor does it significantly interfere with the subject's head movements or vision. Low level, invisible, modulated, infrared eye illumination and synchronous detection of the reflected signal minimize both subject distraction and ambient illumination artifacts.

The Model 200 measures direction of gaze horizontally by utilizing the differential reflectivity of the iris and the sclera. It measures horizontal position of the eyes over a range of approximately $\pm 20^\circ$, with a resolution of better than one quarter of a degree. The resolution can be improved to a few minutes of arc with a rigid head mounting fixture (bite board or good head and chin rest). Vertical eye movement recording is accomplished by monitoring either upper or lower eyelid movement. In this case, the difference in reflectivity between the lid and sclera is employed to make the measurement. Vertical range is $+10^\circ$ (up) and -20° (down), with a resolution of approximately 1° .

Crosstalk between horizontal and vertical



measurements can normally be kept under 10% by careful alignment and set-up of photo sensors. Additional electronic crosstalk reduction is provided for and is adjustable by front panel controls. The time constant of the instrument is approximately four milliseconds. Front panel "filter" switches allow the response time to be increased to 26 milliseconds in order to minimize 60 or 120 Hz interference.

A front panel selector switch allows the output signal from either channel to be presented on the monitoring meter. The analog signals from both channels are simultaneously available at rear panel binding posts and front panel jacks. These signals are suitable for direct interfacing to most recorders, oscilloscopes, magnetic tapes, and other common recording /display devices. The optional digital outputs (both channels available simultaneously) appear on a rear mounted connector. The analog and digital signals produced by the Model 200 are compatible with almost all recording and data acquisition systems.

All Model 200 sensor assemblies are supplied in the "Clip-on" configuration, and may be used by subjects with or without corrective spectacles. In addition, three-way vernier adjustment of each sensor assembly facilitates alignment and calibration procedures.

The Model 200 requires only modest set-up and calibration. Preparation consists of placing the spectacle assembly on the subject, adjusting the position of the photoelectric sensors, and setting the front panel operating controls

SCAN PATTERN ON X-Y PLOTTER

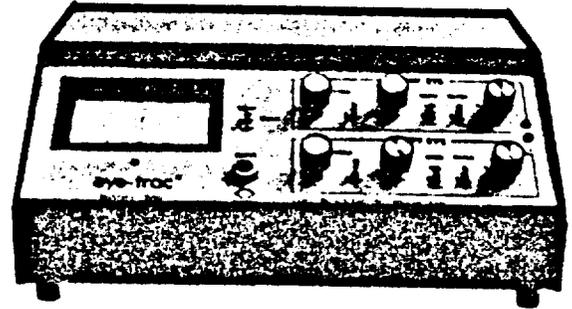
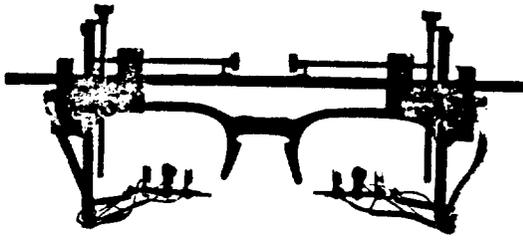
The Model 200 can be utilized to superimpose a subject's eye movement pattern directly on the viewed material. This is accomplished by placing a copy of the material in the bed of an X-Y recorder and connecting the Model 200 horizontal and vertical output signals to the

respective horizontal and vertical inputs of the plotter. The result of this procedure is an immediately available hard copy of the subject's scan pattern superimposed on the viewed scene.



BEST COPY AVAILABLE

33



OUTLINE TRACING

A subject's eye movements may be recorded as he visually traces the outline of geometric figures (after Yarbus). This record-

ing was made by the Model 200 Eye Movement Monitor and an X-Y Plotter set-up as described above.



MINIATURE EYE MOVEMENTS

The Model 200 is capable of reliably measuring changes in horizontal eye position as small as a few minutes of arc. Such measurements do require effective restraint of the subject's head to prevent movement artifacts. The recording shown of a 1° eye movement was made with the subject's head

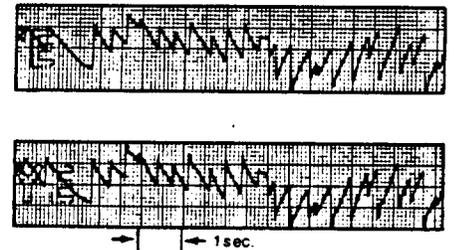
restrained in a Model 115 Head Rest. This particular device utilizes a chin cup. A bite plate is optional for high precision requirements.



NYSTAGMUS

oscillatory eye movements of both spontaneous and induced types are readily and accurately recorded with the Model 200 Eye Movement Monitor. Nystagmus recordings

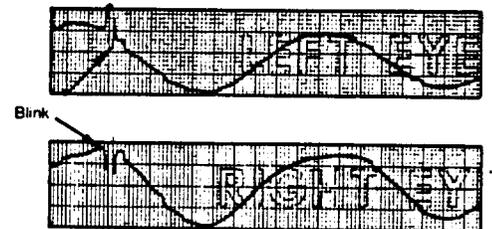
are most useful in diagnosis of neurological problems (tumors, lesions, etc.), vestibular studies, motion and position effects, inner ear malfunctions (Meniere's Syndrome, etc.), and drug and fatigue studies



PURSUIT MOVEMENTS

A subject's ability to track a moving target is of significant interest to neurologists, psychologists, ophthalmologists, and human factors engineers. The Model 200 provides for

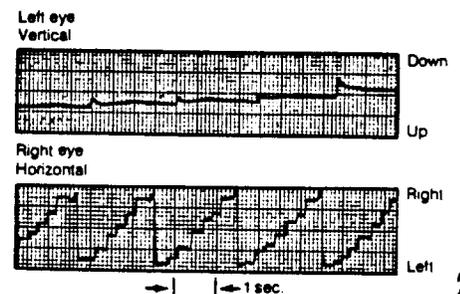
a simple, straightforward and noise-free recording of tracking performance. Pursuit movements, like nystagmus, are most useful in neurological, oculomotor, vestibular, drug and fatigue studies.



READING PATTERNS

Eye movement patterns produced by reading activity have long been of interest to educators and psychologists. Such patterns are most useful for analysis and research on reading difficulties, learning disabilities, dominance, comprehension, perception and other

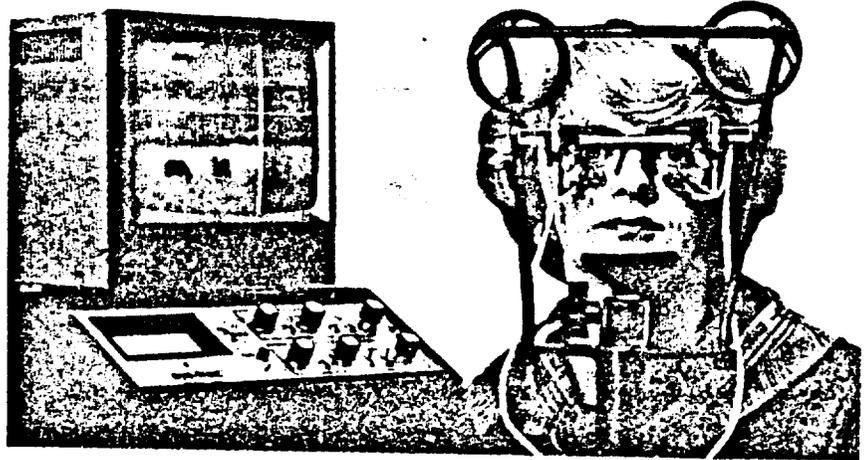
aspects of psycholinguistics. The Model 200 produces reading eye movement recordings of truly superior quality. The figure illustrates one such recording in which the left eye is being monitored for vertical movement and the right for horizontal movement.



VIDEO FIXATION POINT DISPLAY UNIT (Optional)

This device presents the subject's eye position in a very convenient, visual display format. It provides a cursor in the form of crosshairs or a spot superimposed over a television monitor image of the scene being viewed by the subject. The meter on the Model 200 control panel indicates the position of one eye at a time in a form not directly related to the scene. When the Video Fixation Point (VFP) unit is added, a dramatic "Point-of-Gaze" display is also produced. This feature can be used to determine the accuracy of the Model 200 system at various points in the scene and greatly simplifies calibration of the device. In addition, the VFP display allows video recording of eye movement data as well as the standard analog and digital recording formats. Also provided is a linearizing circuit which may be used to make the gains symmetrical about the vertical and horizontal centers. This is in addition to the cross-talk correction on the front panel of the control unit.

The VFP system consists of a TV camera for viewing the scene, a 9 inch TV monitor and a modified Model 200 Control Unit.



DATA ACQUISITION AND RECORDING SYSTEM (DARS)

The Data Acquisition and Recording System (DARS) is a hardware/software configuration designed to operate with any of the Applied Science Laboratories (ASL) Eye Movement Monitoring (EVM) devices. Some of the sophisticated and powerful recording capability which is part of the sophisticated computer based Models 1996/1998 Eye View Monitors is made available.

This system is equally applicable to many other data recording situations which require a rapid real-time controllable recording of experimental data onto a mass storage device under computer control with the capability of later off-line processing.

The DARS configuration, shown in the figure, is built around a Computer Automation LSI/2 computer. The standard version can support an operating system and assemblers. A version with an additional 8K of memory (totaling 24K) will support FORTRAN for much more convenient analysis programming.

A software package is loaded into the computer and performs the following functions:

- 1) The program cycles once per sampling interval. For the TV based Eye View Monitors, this sampling interval is 1/60th (1/50th) of a second, i.e. 1 TV field.
- 2) In each sampling interval, the DARS software inputs the latest sample of a) vertical eye position, b) horizontal eye position, c) pupil diameter (where applicable). These are normally the digital outputs on the Eye View Monitor System as originally provided.
- 3) DARS also inputs external experimental data from 1 or more 16 bit General Purpose Intelligent Cable (GPIC) channels available to the user for entering any digital data, e.g., slide number, etc.
- 4) Up to 10 event markers, entered by actuating the terminal keyboard, are also recorded.
- 5) A real-time clock is recorded along with the data.

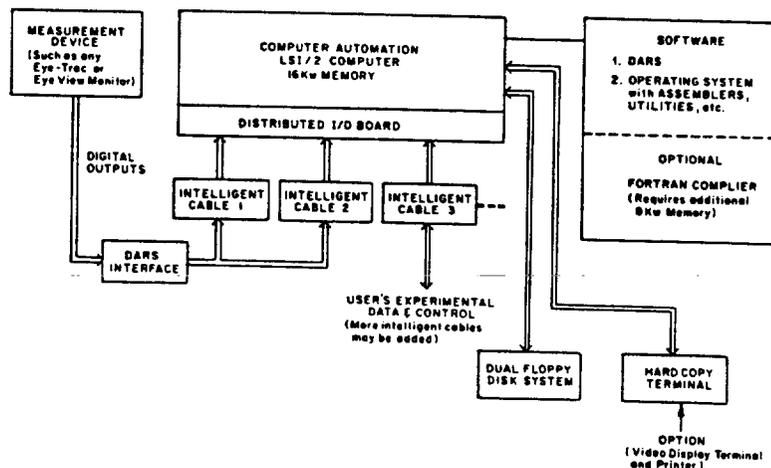
Off-line, the DARS package contains utilities which allow the user to access the data and to generate analysis programs in either Assembly language or FORTRAN.

The amount of data recorded on any one disk can extend to approximately 20 minutes. Future versions of DARS will allow continuing alternate disks for an unlimited length of time.

With a command to the keyboard, the user may:

- a) open a floppy disk file
- b) record real-time data
- c) suspend recording — the record or suspend sequence may be repeated over as many segments as desired
- d) close a disk file
- e) reopen a disk file for additional recording whenever desired
- f) print out on the terminal any selected portions of the recorded data

Data analysis programs may be custom provided by ASL or they may be written by the user. The standard DARS allows the user to write Assembly language analysis programs. As seen in the figure, FORTRAN capability requires an additional 8K of memory.



35

TYPICAL SPECIFICATIONS

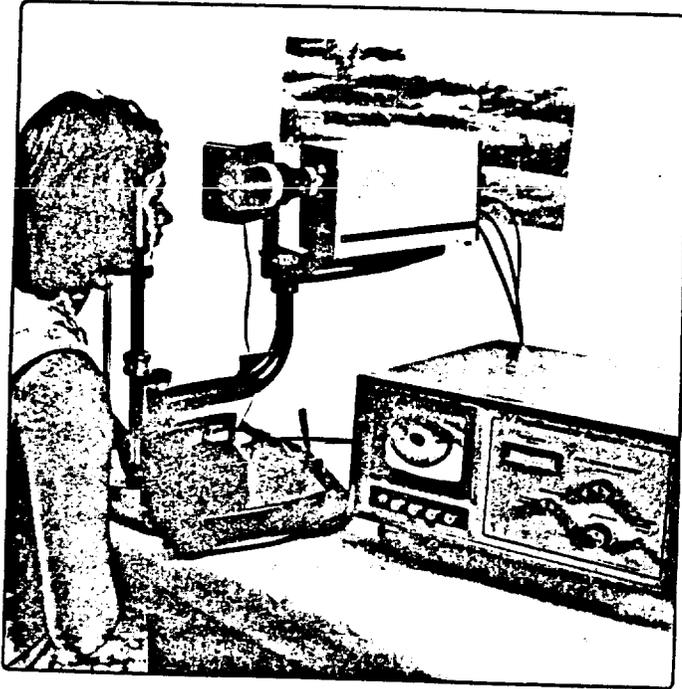
	HORIZONTAL	VERTICAL (EYELID)	REMARKS
Range (From Center)	± 20°	+ 10° (up) - 20° (down)	
Precision (See page 30)	0.25°	1°	A few minutes of arc possible with rigid head restraint
Accuracy (See page 30)	1°	2°	
Response Time Unfiltered — 4 milliseconds Filtered — 26 milliseconds			
Output Signals (Both channels simultaneously available) Analog Digital (Optional)	300 mV/degree nominal 8 bit binary — TTL Compatible		Both outputs updated once each millisecond; busy-bit signal during updating
Instrument Drift	10 mV/hr.		
Calibration Controls	Electronic position, gain, linearity, and crosstalk controls are provided		Crosstalk is adjustable to less than 10%
Power Requirements	105-125V AC, 50-60 Hz (210-250V AC, 50 Hz available)		230-250V AC 50 Hz optional
Weight	3.6 kg. (8 lbs.)		
Dimensions	30.8 x 25.4 x 11.4 cm (12 x 10 x 4.5 inches) WxLxH		
Accessories & Options	Digital outputs; Head restraint system (bite board and chin rests); Video Fixation Point Display unit; Data Acquisition & Recording System (DARS)		

Specifications subject to change without notice

ORDERING INFORMATION

PART NO.	DESCRIPTION
719-2001	Eye-Trac MODEL 200-1 Research model, 120 Volts, 60 Hz. Measures horizontal and/or vertical eye movements, simultaneously monitors both eyes. Analog Outputs only.
719-2002	Eye-Trac MODEL 200-2 Same as above with Analog and Digital Outputs.
719-3000	OPTIONAL VIDEO FIXATION POINT DISPLAY UNIT Consisting of: (1) Modification to Model 200 with linearized output in each major axis (2) TV camera for viewing the scene (3) 9 Inch TV monitor
719-1150	TABLE MOUNT HEAD RESTRAINT MODEL 115
719-1130	BITE BOARD ACCESSORY FOR MODEL 115
719-2000	Eye-Trac MODEL 200 SPECTRA-SENSORS™ Must be calibrated with control unit for best results.
719-DARS	DARS Computer Based Data Acquisition and Recording System for use with Model 200.

Series 1000 TV Pupillometer System



- Simplicity of Operation
- Adaptable for Lab Animals
- High Degree of Subject Comfort
- Pupil Delimiters and Other Indicators to the Operator
- Unique Pupil Recognition Circuitry

APPLICATIONS

Measurement of changes in pupil diameter has become an extremely powerful tool for studying human response to various conditions and stimuli. It has been widely used in clinical research, psychological experiments, drug studies, ophthalmology, physiology, and neuro-sciences.

Pupil diameter is an indicator of at least three stimuli: retine light intensity, accommodation and psychological state. It has been used in studies relating to all three, but it offers a unique psychological indicator which is completely unaffected by conscious or subjective considerations. It is more reliable and practical than traditional techniques such as measurement of galvanic skin response or heart rate. Specific applications have been in drug treatment of hyperactive children, measurement of drug efficacy, various aspects of learning, determination of vigilance, and work load studies under stress and fatigue.

DESCRIPTION

The TV PUPILLOMETER is a reliable, simple-to-use instrument for accurate, real-time measurement and display of the absolute diameter of the pupil. The pupil is continuously monitored, and pupil diameter is shown directly on a panel meter and also provided in digital and analog forms. Measurement is independent of eye movement and other variations over a large field of view.

The TV PUPILLOMETER utilizes a closed circuit, low light level, silicon matrix tube television system to observe the eye and a special Pupil Recognition Circuit to automatically acquire the pupil from the iris, the eyelids and other noise with minimum operator adjustment. A TV monitor displays the image of the eye with superimposed Pupil Delimiters to clearly indicate the accuracy of the measurement. The automatic circuitry will maintain proper measurement for a large range of settings and conditions.

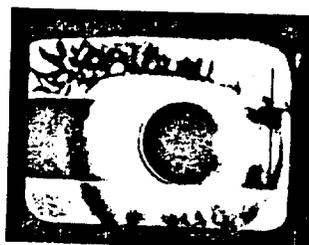
A bibliography of Pupillometry Research is available from ASL.

SYSTEM OUTPUTS

On all models, pupil diameter is presented as a direct readout on the analog panel meter with a scale of 0 to 10 mm. The model 1071 and 1081 chart recorder versions also record pupil diameter on single and dual pen stripchart recorders. The chart recorder models can be adjusted by the operator to display either the full 0 to 10 mm range or an expanded sub-interval of the measurement range. An external pupil diameter output signal, scaled at 1V/mm diameter, and a digital output signal are furnished on all models.



WITHOUT NOISE



WITH NOISE

OPERATION

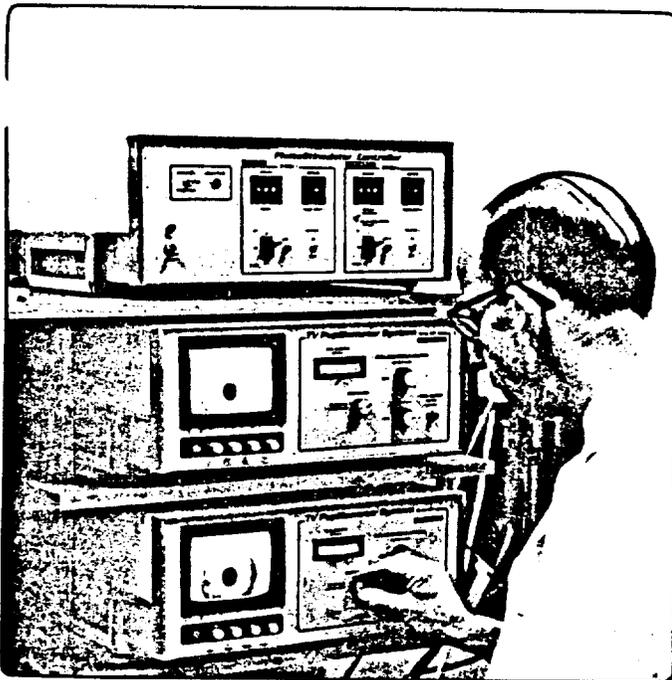
The subject places his head in a chin rest or in a dentist type headrest, and has an unobstructed view of the scene being presented.

The operator obtains a picture of the subject's eye. After setting the TV monitor for a clear image, the operator adjusts the wide-range Discriminator control until a crescent appears at the left edge of the pupil and Delimiters appear in the monitor on top of and below the pupil. As long as the Delimiters are properly positioned, in spite of other noise and artifacts, the measurement is correct. Pupil diameter in millimeters is displayed on a panel meter. The system also provides an analog and digital output signal.

PUPIL RECOGNITION CIRCUIT ACQUIRES PUPIL IN PRESENCE OF ARTIFACTS AND NOISE

BEST COPY AVAILABLE

37



BINOCULAR TV PUPILLOMETER

The Binocular TV Pupillometer is composed of two mechanically, electronically and optically integrated pupillometers which are capable of functioning together or independently. The Binocular System can be used to simultaneously monitor pupil diameter of both eyes. Binocular studies are particularly useful in detecting drug or neurological effects that show an imbalance in pupillary response of the two eyes. When the Pupillometer system is coupled with a Binocular Photostimulator, this type of imbalance may be "quantified."

MONOCULAR AND BINOCULAR PHOTOSTIMULATOR AND CONTROLLER

The Series 1100 Photostimulator and Controller, is a powerful laboratory and research device for experiments involving the placement of controlled and programmed pulses of stimulus light into one or both eyes of a subject. The beams of light are controllable in exposure frequency, pulse width, focus, beam diameter and intensity.

One or both eyes may be stimulated, and the controls for the two channels may be synchronized in any desired phase and temporal relationship in order to test binocular responses.

There is an integrated aiming capability for placement of the beam into the pupil of the subject. Focusing produces a parallel beam or allows beam focus on some other plane in or out of the eye, e.g. a Maxwellian view.

A general purpose filter holder is provided for the insertion of any desired filter. This holder may be conveniently swung out of the way. A neutral density wedge may also be used for continuous intensity control.

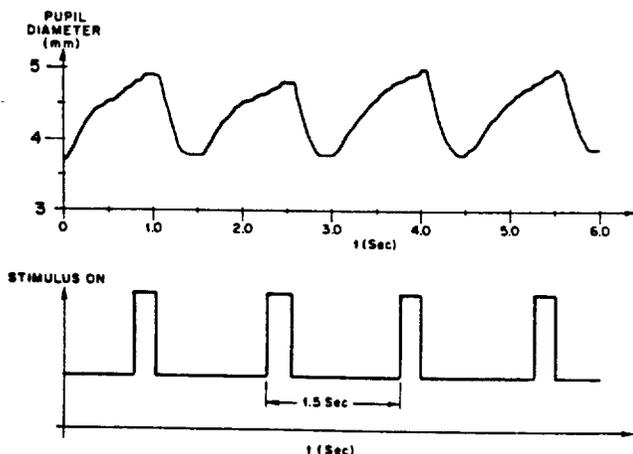
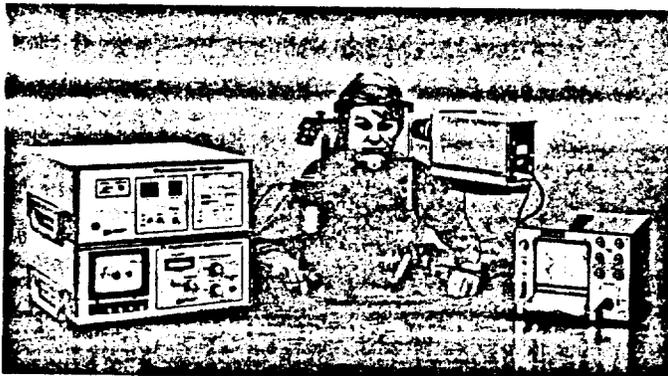
A virtual point source tungsten concentrated arc lamp is used with appropriate optics to provide the collimated beam of light.

The Controller provides a very convenient way of programming the shutter exposure times for one or two channels. The pulse width and the period may be controlled for each channel, and the phase relationship between the two systems can also be determined. This provides virtually any pulse profile that may be desired. Continuous cyclic operation or single pulse actuation is possible. The two channels may be locked phase or randomly related.

The Photostimulator is suitable for studies of pupil diameter response to light stimuli under various subject conditions such as during drug administration.

For pupillometry, the Photostimulator is integrated with the Series 1000 TV Pupillometer.

Consult ASL for further specifications.



Pupil Diameter Variations Resulting From Photostimulator Pulsations

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTAT@fda.hhs.gov or 301-796-8118

BEST COPY AVAILABLE

38
1

SPECIFICATIONS — Series 1000 TV Pupillometer

Allowable Eye Movement	Pupil Diameter Measurement Range	Measurement Resolution	Precision	Noise	Linearity	Sampling Rate
Horizontal 30°, 40° or higher with reduced accuracy. Eye lids may limit this range with some subjects	2.0 to 10 mm or higher (normal pupil diameter 2.9 mm to 6.5 mm) Smaller pupil diameter is also measurable. Vertical pupil diameter is measured (horizontal diameter measurement is also possible)	1 TV Scan line 500 (600) full scale	Better than 0.5 mm or 1/2%	0.01 volt or 0.01 mm with model pupil	Analog and Digital Outputs Better than 0.01 mm or 1% Meter Better than 0.2 mm or 2%	60 (50) per second Output is averaged every two fields, i.e. each 1/30th (1/25th) of a second. Nonaveraged output is also available

Analog Pupil Diameter Output	Digital Pupil Diameter Output	Timing Outputs	TV Camera	Illumination	Operator Setting Indicators
External analog signal output: 0-10 volts DC. Scaling: 1.0 Volt/mm of pupil diameter. Frequency response smoothing filter, flat from 0 to 6 Hz; may be switched out. Output impedance: 75 ohms	9 bits TTL compatible representing pupil diameter in straight binary Logical "1" > 2.5 volts Logical "0" < 0.5 volts	Positive strobe and busy signal are output every 1/60th (1/50th) of a second for transferring data. Data is constant during strobe pulse and changing during busy signal. Strobe pulse is 1-2 microseconds, busy pulse is 0.5-0.8 milliseconds. Output drives up to 4 TTL loads	Output impedance: 75 ohms. Silicon matrix vidicon tube with 2:1 interface.	Invisible near infrared filtered incandescent lamp illumination centered at 8500 Angstroms.	Discriminator crescent appears on monitor, at edge of pupil, along with delimiters above and below as determined by a Pupil Recognition Circuit. The proper position of the delimiters indicates to the operator that no adjustments have to be made and that the measurement is being performed correctly

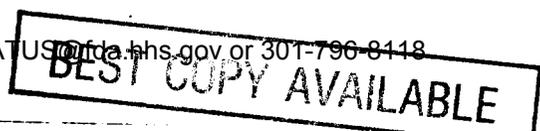
Mechanical: Control Unit Weight: 66 kg (130 lbs)
Dimensions: 43 x 19 x 43 cm (17 x 7.5 x 17 inches) (WHD)

Power Source: 105-125 volts AC, 60 Hz (2A total)
220 volts AC, 50 Hz available

Specifications subject to change without notice

ORDERING INFORMATION

- 1050 TV Pupillometer System (110V, 60 Hz or 220V, 50 Hz)
- 1050B Binocular TV Pupillometer
- 1000R Remote Pupil Camera Option
- 1071G TV Pupillometer with single channel thermal writing chart recorder
- 1071P TV Pupillometer with single pen potentiometric chart recorder
- 1081G TV Pupillometer with dual channel thermal writing chart recorder
- 1081BP Binocular TV Pupillometer with dual pen potentiometric chart recorder
- 1081BG Binocular TV Pupillometer with dual channel thermal writing chart recorder
- 1000Area Pupillary area measurement option
- 1000-EM Single channel event marker
- 1000-EM2 Dual channel event marker
- 1100-1 Monocular Photostimulator and Controller
- 1100-2 Binocular Photostimulator and Controller
- 1000-DARS Computer-based Data Acquisition and Recording System (DARS)
- 1000-RM Rack mount adapters for control unit
- 1000-ATV Auxiliary, external, 9 inch monitor for viewing the subject's eye



Models 1992 and 1994 Eye Movement Monitoring System

- Accurate point-of-gaze measurement independent of small head motions
- Pupil diameter measurement
- Modular and upgradable system
- Rapid subject setup and calibration
- Visual, video, analog, and digital outputs



TV Based Eye View Monitors

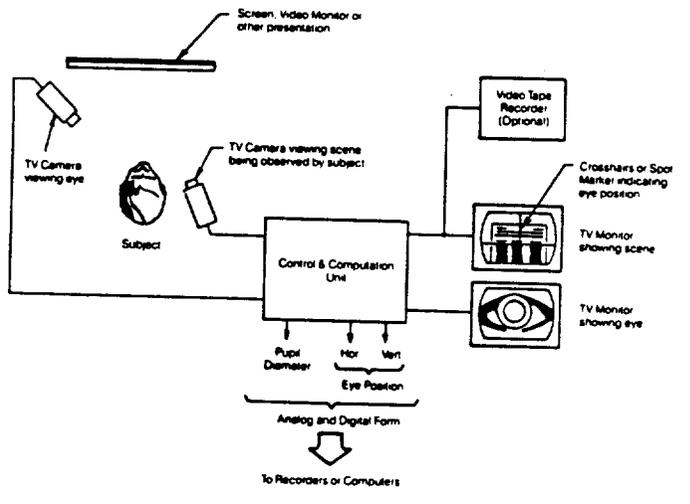
The Model 1992 and 1994 Eye View Monitors are television based systems which accurately measure eye point-of-gaze and pupil diameter independently of small head motions. The instrument does not contact the subject, nor does it obscure the subject's field of view.

Eye position, pupil diameter, and various other status indicators are provided in analog, digital, and visual forms. Point-of-gaze is displayed visually as a cursor superimposed on a video image of the scene being viewed by the subject, and this presentation can be recorded on video tape. Pupil diameter is displayed by a meter on the control unit front panel. Analog signals representing point-of-gaze coordinates and pupil diameter may be conveniently recorded on strip chart recorders, X-Y recorders, FM tape recorders, or storage oscilloscopes. Digital output containing the same information may be read by an external computer, a digital tape recorder, or any other digital device.

SYSTEM CONFIGURATION

As shown by the adjacent schematic, a television camera views one eye of the subject which is illuminated by a near infrared invisible illuminator. The resulting picture of the eye is displayed on a 5" TV monitor. A second camera views the scene being observed by the subject.

The system uses a sensitive silicon matrix tube television camera, which functions at very low illumination, to view the eye. The illuminator does not annoy or distract the subject. In the Remote System (Model 1994), the illumination is coaxial with the camera and produces an image of a backlighted bright rather than dark pupil.



PRINCIPLE OF OPERATION

The Eye View Monitor processes video information from the pupil camera to identify and determine the centers of the pupil and the corneal reflection (reflection of the illuminator from the surface of the cornea). Assuming that the subject's eye is a relatively long distance from both the illuminator and the visual illuminator, the separation between the pupil and the corneal reflection (CR) varies with eye rotation (change in point-of-gaze), but does not vary with eye translation (head motion). A change in pupil-CR separation is proportional to the change in point-of-gaze to the first order.

By measuring the vertical and horizontal distance between the centers of these features and correcting for some second order effects, the Eye View Monitor calculates look-point independently of head motion. Note that if only pupil position were measured, there would be no way to distinguish between a 0.1 mm head translation and an approximately 1 degree change in line-of-gaze. Measurement of only CR position would result in a similar ambiguity.

The point-of-gaze information is presented to the operator as a cursor superimposed on a nine inch television monitor image of the scene being viewed by the subject.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

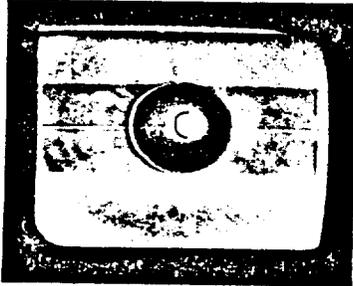
BEST COPY AVAILABLE

ND
13

SPECIAL RECOGNITION CIRCUITRY

Special Recognition Circuitry (software) detects the pupil and the corneal reflection from the video signal. The horizontal scan lines which intersect them are selected to the exclusion of scan lines which intersect the eyelids, eyelashes, or other noise. The Recognition Circuitry allows operation for a broad range of

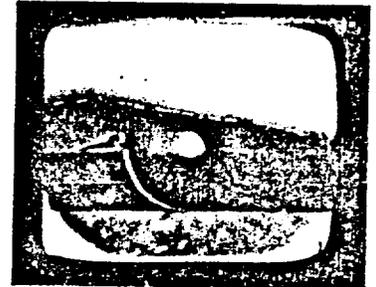
subjects and under varying conditions with minimum operator adjustments. It superimposes Delimiters and other indicators on the eye TV image to clearly show the operator that the system is functioning properly.



ACCEPTABLE



ACCEPTABLE



UNACCEPTABLE

Operator indicators superimposed on TV image of eye as a function of threshold setting showing status of measurement. Measurement is good when pupil is properly delimited.

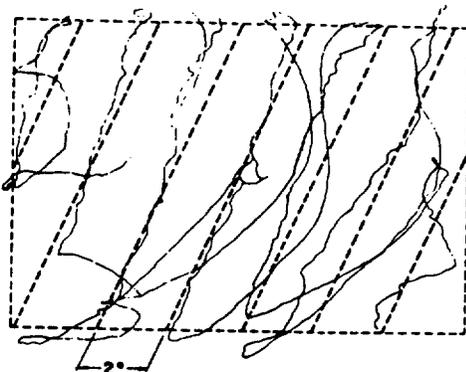
OUTPUTS

The output is available in digital, analog, and visual forms for recording on stripchart recorders, X-Y recorders, storage oscilloscopes, digital tape or directly into a digital computer. This data can be processed at the time of the experiment or recorded for later analysis by computer.

The point-of-gaze cursor, superimposed on a video image of the scene, may be displayed either as a set of crosshairs or

as a spot. The cursor is available to the operator for calibrating the instrument, monitoring an experiment, and if videotaped, for reviewing or studying data.

A scan pattern may be obtained by superimposing an X-Y recording of the point-of-gaze coordinates over a picture of the scene being viewed.

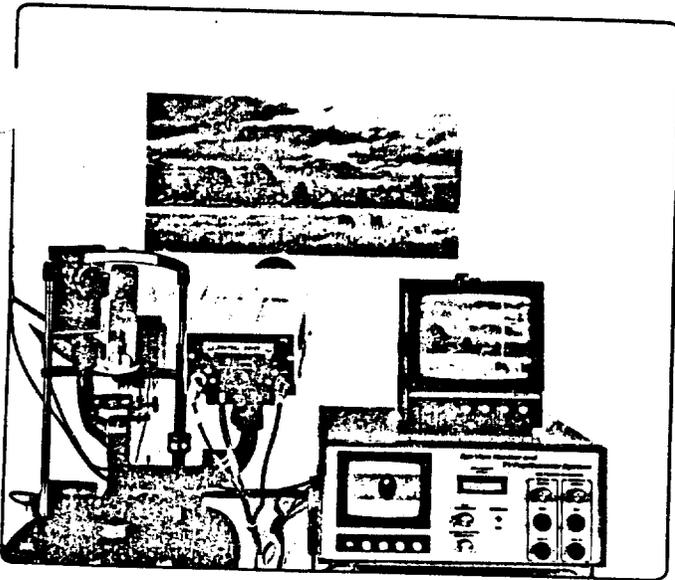


X-Y Recording of Eye Fixation as Subject Scans a Number of Diagonal Lines

FIXED HEAD MEASUREMENT

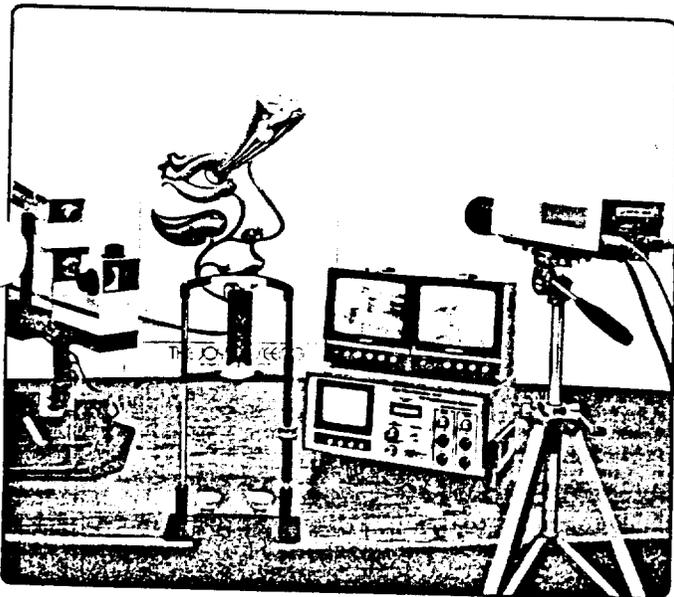
Additional precision and accuracy (see page 30) can be obtained by using the Series 1900 Eye View Monitors in the fixed head mode. If head motion freedom is not required, and a suitable restraining device such as a bite plate is used, performance improves dramatically. Noise is reduced, and precision and accuracy increase substantially.

41



Model 1992 Basic Eye View Monitor

The subject steadies his head with a chinrest and views the scene presented him. A special low light level television camera with silicon matrix pickup tube views one eye as it is illuminated by an invisible, near-infrared illuminator. Special circuitry extracts the centers of the pupil and corneal reflection, then computes and displays eye position.



Model 1994 Remote Eye View Monitor System

The subject sits with his head in a headrest or chinrest. The optical system is removed two feet from the subject's head and is out of his field of view. He is physically and psychologically less encumbered, and is less aware of the fact that his eye motion is being monitored. This allows the subject to talk, makes for a more natural experimental situation, and results in more useful data.

A coaxial illuminator is used to obtain a bright, as opposed to dark pupil. This allows use with a greater subject population, and will generally work with most eyeglasses, and some contact lenses. The system allows somewhat more head motion and provides greater tolerance of eyelids and other artifacts than the Model 1992.

SPECIFICATIONS

See performance specifications on pages 28 and 29.

OPTIONS

- 1900-DARS Computer Based Data Acquisition and Recording System (DARS).
- 1900-Z 18-90mm focal length zoom lens for scene camera.
- 1900-ATV Auxiliary external 9 inch TV monitor for viewing the eye.
- 1900-RM Rack mounting.
- 1900-DCU Digital output calibration and display unit.
- 1900-VTR Video tape recorder.
- 1992-CAS Travel cases for 1992.
- 1994-CAS Travel cases for 1994.

ORDERING INFORMATION

DESCRIPTION

- Model 1992 Eye View Monitor System
- Model 1994 Remote Eye View Monitor System
- Both of the above models include:
 - Silicon matrix tube TV camera for viewing the eye.
 - Control and Computation Unit with TV monitor for eye image.
 - TV Camera for viewing scene being presented.
 - 9 inch monitor showing scene with crosshairs indicating point of fixation.
 - Adjustable camera base.
 - Outputs — Digital and Analog
 - (a) Vertical Eye Position
 - (b) Horizontal Eye Position
 - (c) Pupil Diameter (in millimeters).
 - 1994 only (Wide angle locating camera).
 - 1994 only (Wide angle locating monitor).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-795-8118

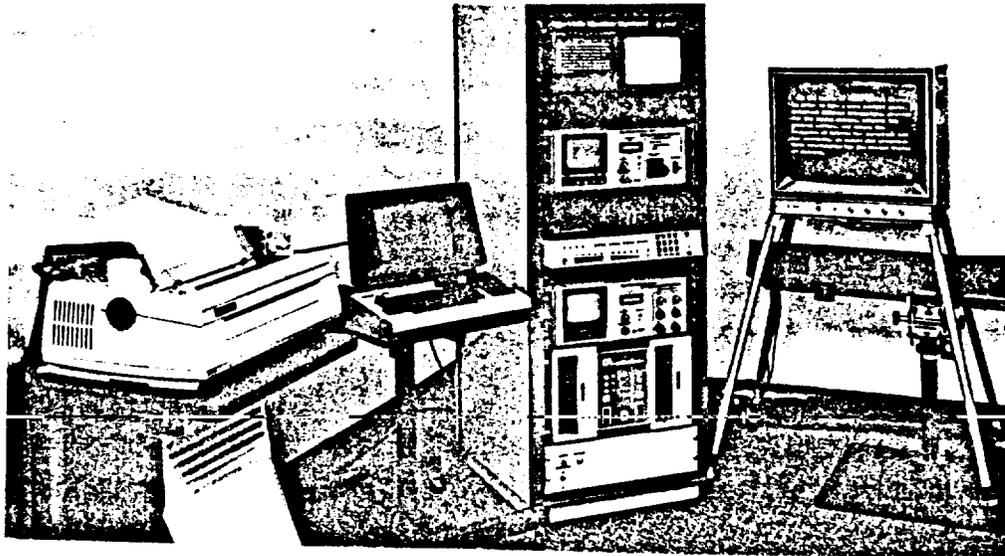
BEST COPY AVAILABLE

models 1996 and 1998 *Eye Movement Monitoring System*

MODELS 1996 AND 1998 COMPUTER BASED EYE VIEW MONITOR SYSTEMS WITH PUPIL DIAMETER MEASUREMENT

The computer based systems offer a number of features that make them superior to the hardware systems in increased flexibility, optimum performance, and more efficient use! ... Including:

- Automatic calibration and linearization
- Up to one cubic foot of allowable head motion
- Video stimulus display for text and graphics
- High degree of unobtrusiveness
- Can control or monitor other laboratory equipment
- Automatic & remote focus
- Acceptance of eyeglasses drooping eyelids, or other artifacts
- Data recording and processing software
- Simulator configuration
- Helmet mounted version



NEW DIMENSIONS IN EYE MOVEMENT MONITORING

The Models 1996 and 1998 computer based Eye View Monitor Systems (EVM) provide a virtually complete eye movement laboratory with powerful capabilities ranging from point-of-gaze measurement to data analysis.

These advanced systems unobtrusively measure a subject's point-of-gaze and pupil diameter. The model 1998 also employs a servo controlled mirror to track the eye during head motions. Since the optics can be flexibly positioned and may be up to ninety inches from the eye, subjects are allowed a great deal of physical and psychological freedom with minimum awareness of the testing apparatus. Indicators enable the EVM operator to know the precise status of the measurement at all times, and the actual point-of-gaze is clearly indicated by a visible cursor superimposed over a TV image of the scene.

The extensive data processing capability of the computer based systems makes them far more flexible and powerful than their non-computer based (hardware) counterparts. Calibration is automatic and generally requires less than thirty seconds per subject. Complex eye geometries, nonlinearities, eyelid truncation of the pupil, interference from eyelashes, and other artifacts can now be handled. All eye colorations, most eyeglasses, and some contact lenses are acceptable.

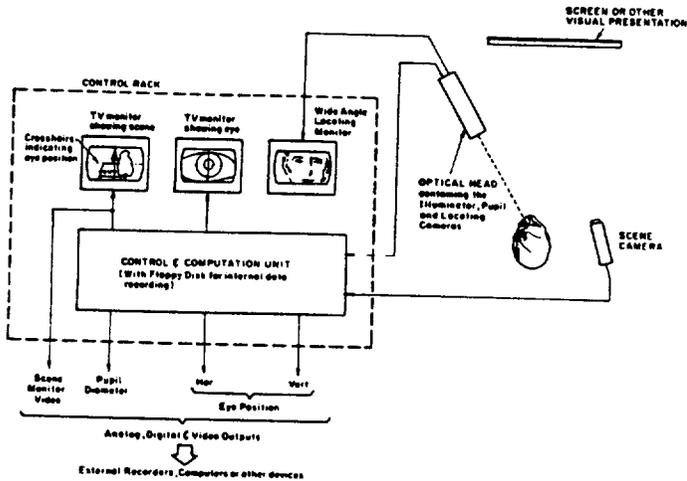
A computer based EVM may be installed in an aircraft simulator as well as in other special locations. For applications requiring completely free subject motion, a helmet mounted version of the EVM can be supplied on a custom basis.

The EVM's integral computer and floppy disk system may be used to record and analyze eye position data using specially developed software packages. In addition, video, analog, and digital outputs can be recorded on various external media or input to a host computer system. The EVM computer also can be used to present stimulus material on a video monitor, and when the EVM is not in use the computer may be used to perform other laboratory monitoring and control functions.

BEST COPY AVAILABLE

CB

BASIC EYE VIEW MONITOR CONFIGURATION



camera, locating camera, and light source are all enclosed in a single housing referred to as the "optical head".

A third TV camera (scene camera) provides a view of the scene being presented to the subject. The EVM superimposes a cursor on this scene to indicate the subject's point-of-gaze.

All of the TV monitors as well as the computer and EVM control unit are housed in a single 19 inch rack referred to as the "control rack." The basic EVM configuration thus includes three physically separate units: the optical head, the control rack, and the scene camera.

Note that the subject can move his head laterally or vertically only until his eye moves beyond the pupil camera field of view (about one inch square). A high back chair usually provides sufficient head restraint for a cooperative subject.

Model 1998

The basic model 1998 configuration is the same as that for the model 1996 except that the optical head also contains a servo controlled head tracking mirror. The mirror automatically tracks the eye during lateral or vertical head motions of as much as one foot, thus allowing the subject much greater freedom. (See page 19 for a detailed description of head tracking.)

Model 1996

A TV camera with a telephoto lens (pupil camera) is directed at one of the subject's eyes. The eye is illuminated by a collimated, near infrared light source that is beamed coaxially with the pupil camera. A second TV camera (locating camera) provides a wide angle view of the head to simplify locating the eye. The illuminator (usually barely visible to the subject as a dim red light) retro-reflects from the retina producing an image of a backlighted bright rather than dark pupil. The pupil

Principle of Operation

The Eye View Monitor processes video information from the pupil camera to identify and determine the centers of the pupil and the corneal reflection (reflection of the illuminator from the surface of the cornea). Assuming that the subject's eye is a relatively long distance from both the illuminator and the visual stimulus, the separation between the pupil and the corneal reflection (CR) varies with eye rotation (change in point-of-gaze), but does not vary with eye translation (head motion). A change in pupil-CR separation is proportional to the change in point-of-gaze to the first order.

By measuring the vertical and horizontal distance between the centers of these features and correcting

for some second order effects, the Eye View Monitor calculates look-point independently of head motion. Note that if only pupil position were measured, there would be no way to distinguish between a 0.1 mm head translation and an approximately 1 degree change in line-of-gaze. Measurement of only CR position would result in a similar ambiguity.

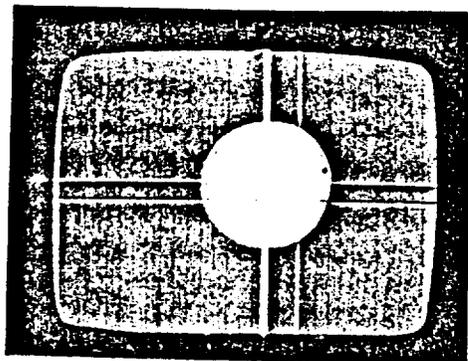
The point-of-gaze information is presented to the operator as a cursor superimposed on a nine inch television monitor image of the scene being viewed by the subject.

Operator Indicators

ASL has given major consideration to designing a research tool which is easy to operate. An awareness of human factors affecting both the subject and the system operator has led to an abundance of high information content indicators that allow the operator to continuously monitor the status of the measurement.

The system places markers on the pupil monitor image of the eye to indicate features detected by the EVM circuitry. Crosshairs indicate the centers of those features identified by the computer as the pupil and corneal reflection. A scene monitor cursor indicates computed point-of-gaze on the stimulus scene.

The operator knows at a glance whether the system is performing properly, the quality of the measurement, and the precise nature of any problem.



PUPIL MONITOR IMAGE SHOWING A BRIGHT PUPIL AND CORNEAL REFLECTION WITH CROSSHAIRS AND CENTROID CROSSHAIRS

BEST COPY AVAILABLE

CALIBRATION

Automatic calibration on the computer based EVM system allows quick, easy, and precise calibration of even difficult subjects. The subject is required merely to fixate nine points, one at a time. At each fixation the operator presses a button on the terminal or computer console. After the completion of this step, which takes only seconds, the computer automatically determines the calibration coefficients and the experiment can begin.

Selective recalibration of any missed points (useful with children and uncooperative subjects) is possible, precluding the need for repeating a full calibration.

BUILT IN STIMULUS GENERATION CAPABILITY

The integral computer can be used to store several "pages" of text or graphics which can be called up and displayed on a video screen at the push of a button. If desired the EVM may be synchronized with other displays or television systems for complete laboratory integration. See lower left photograph on page 20.

OUTPUT

The EVM system provides a number of convenient output formats as shown in the table. Included are video, analog, and digital output for eye position and pupil diameter, as well as various other status indications. The video scene monitor output, which may be recorded on video tape, includes a cursor to indicate point-of-gaze. The analog outputs are easily recorded on strip chart recorders, X-Y recorders or storage oscilloscopes, and the digital outputs may be fed to other computers.

The EVM computer also may be used to record data on an integral floppy disk system for later off-line data processing (see EYEDAT and EYENAL software descriptions on page 23 and 24).

EVM OUTPUT	RECORDING DEVICE	OUTPUT	REMARKS
VISUAL		Meter reading Cross hair position	Useful for operator setup, calibration, & observation
VIDEO	Video tape recorder Photographic camera	Video tape Prints	
ANALOG	Strip chart recorder X-Y recorder FM recorder Storage Oscilloscope	Chart record Chart record Chart record	May be correlated with stimuli May be overlaid over picture of scene May be input to a digital computer with A/D Converter May be photographed
DIGITAL	Computer	Computer analysis Digital magnetic tape or disk	May be controlled by integral computer with EYEDAT Program

EYE VIEW MONITOR OUTPUT INTERFACE GUIDE

PROGRAM DUMP AND RELOAD

At any time the contents of memory, containing a particular program version, target setup, and subject calibration coefficients, may be written to disk for permanent storage. This disk may be conveniently autoloading at a later time, and will provide valid calibration for that same subject if other variables have not changed.

HEAD TRACKING

AUTOMATIC AND REMOTE FOCUS OPTION (AF)

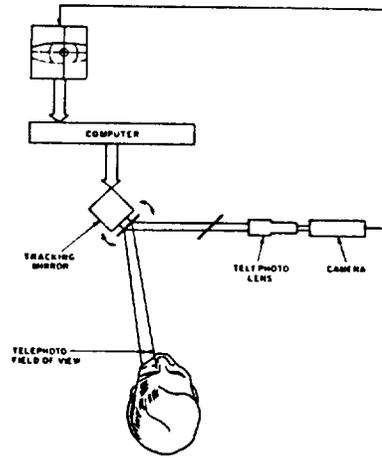
The AF option, available with either the Model 1996 or 1998 EVM, provides automatic and manual remote focusing to correct for Z axis (fore-aft) subject head motion. Focus information is extracted from the pupil camera video signal and is used to automatically drive a servo motor controlled lens toward best focus. Manual adjustments can be made with a joystick on the EVM control unit. The lens can focus over a range of approximately one foot with some variation depending on the nominal subject to camera distance for which the lens was selected.

BEST COPY AVAILABLE

45

TRACKING MIRROR (Standard Model 1998)

The Eye View Monitor is designed to recognize the video image of a "bright" pupil as seen through a telephoto lens. (See figure at right.) In order for the Eye View Monitor (EVM) to calculate eye point-of-gaze, the pupil must be within the telephoto field of view. The Model 1998 attempts to keep the pupil image centered in the telephoto field by sending appropriate commands to a tracking mirror which directs the image to the camera. For example, if the image is left of center, the computer detects this and commands the mirror to move so as to recenter the image. If the subject moves his head so quickly that the mirror cannot keep up, the image is lost from the camera field of view by turning the mirror in the direction the pupil was moving when last detected. If this search fails, the operator must intervene to reacquire the pupil with the manual joystick. The mirror can track lateral and vertical head motions up to about ± 6 inches with some variation depending on mirror to subject distance.



STANDARD MIRROR TRACKING SYSTEM

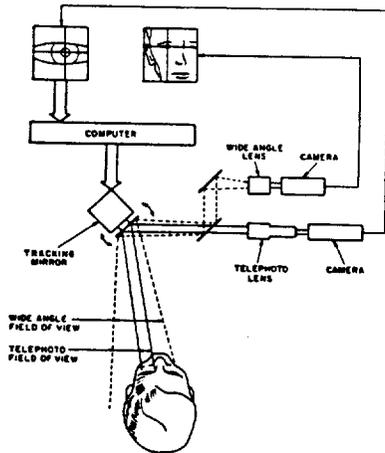
EXTENDED HEAD TRACKING OPTION (EHT)

The EHT option greatly expands the capabilities of the Model 1998 Eye View Monitor by providing an additional tracking loop that can handle more rapid head motion.

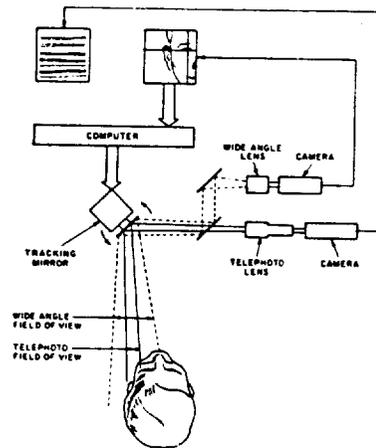
As shown in the figure at lower left, the extended system uses not only a telephoto image of the pupil, but also a wide angle image that includes a much broader field of view. (A separate hardware control unit contains circuitry for the wide angle pupil recognition.) As long as the pupil remains in the small telephoto field, the computer attempts to center the telephoto image just as before. If the image is lost from the telephoto field

(due to a motion too rapid for the mirror to follow), the computer uses information from the wide angle view to automatically reacquire the pupil (as shown in the figure at lower right). Note that the pupil must still be in the telephoto field in order for the EVM to calculate eye point-of-gaze.

With the extended head tracking option (EHT) the subject can move much more rapidly or suddenly without causing the machine to lose track of the eye. Operator intervention is therefore needed less frequently.



EHT SYSTEM WHEN EYE IS WITHIN TELEPHOTO FIELD



EHT SYSTEM WHEN EYE HAS ESCAPED FROM TELEPHOTO FIELD

MAGNETIC HEAD TRACKING OPTION (MHT)

The MHT option, which is available on Model 1998 AF systems, is an external head position sensing device that makes the EVM virtually operator independent once the subject has been calibrated, and so long as his head remains in a nominal 0.03 m³ (1 ft³) volume of space. A small (2 cm³ 0.13 in³), lightweight, magnetic sensor is attached to a headband worn by the subject. A slightly larger magnetic source is fixed to the laboratory or simulator cockpit so that it is about 20 inches from the subject's head is centered in the

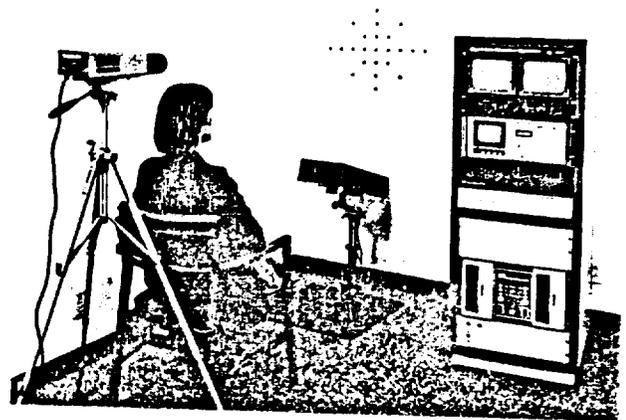
allowable cubic foot of space.

The MHT system control unit, which fits in the 19 inch control rack along with other EVM components, computes the orientation and position of the magnetic sensor (and hence the eye) with respect to the fixed source in six degrees of freedom. The information is used to drive the servo mirror and focus motor to automatically reacquire the subject's eye whenever it is lost from the pupil camera field of view.

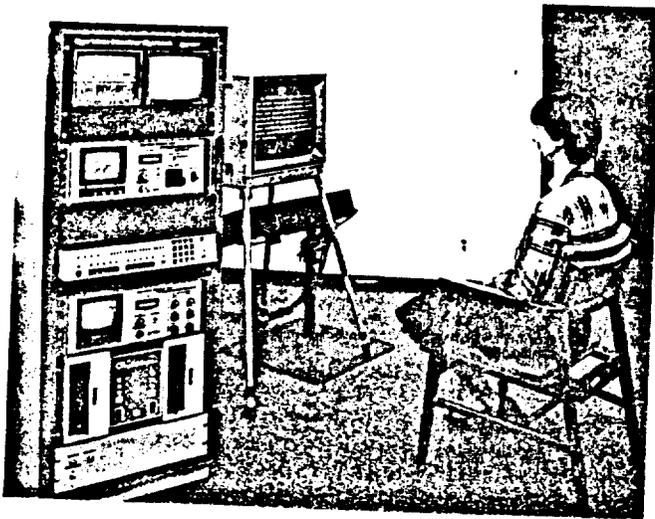
OPTICAL CONFIGURATIONS

BASIC OPTICAL CONFIGURATION

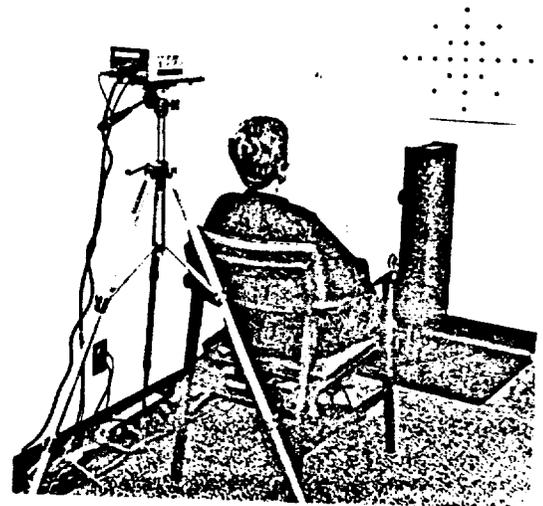
In the basic Model 1996 and 1998 optical configurations the optical head is located approximately in front of the subject and below eye level at a distance ranging from 12 to 90 inches from the subject's eye. The scene or stimulus material is just above the optical head and a scene camera may be directed at the same scene from behind the subject. If the system is a model 1998, the optical head may be oriented in either the "shelf" or "post" configuration shown by the photo (lower left and lower right). The most common variations of this basic optical configuration are described on the next page; many others are possible (consult the factory).



EVM MODEL 1996



EVM MODEL 1998 EHT WITH THE OPTICAL HEAD IN A HORIZONTAL, OR "SHELF," CONFIGURATION. THE SUBJECT IS LOOKING AT A VIDEO TEXT DISPLAY GENERATED BY THE EVM COMPUTER AS DISCUSSED ON PAGE 18.



EVM MODEL 1998 SHOWING THE OPTICAL HEAD IN A VERTICAL, OR "POST," CONFIGURATION. A SCENE CAMERA IS AIMED AT THE TARGET BEING VIEWED BY THE SUBJECT

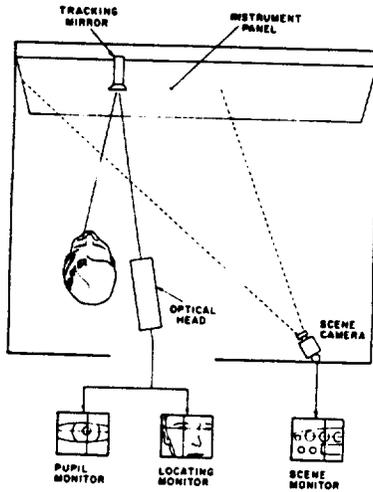
BEST COPY AVAILABLE

47

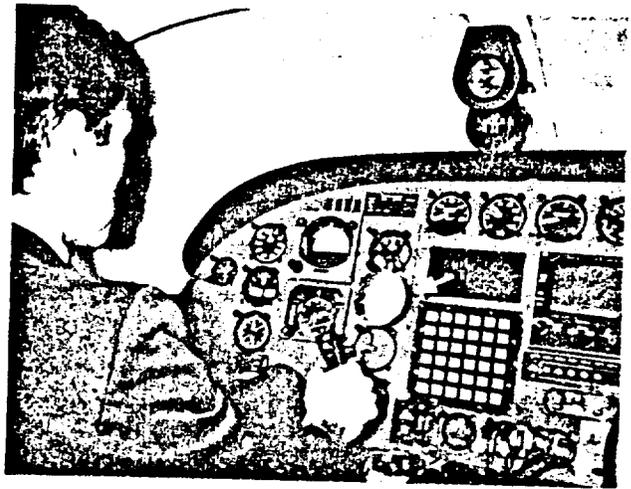
SIMULATOR CONFIGURATION (SC)

The Model 1998 EVM may be configured for installation in aircraft simulator cockpits (or similar environments) by using a tracking mirror specially designed to fit in place of a standard, three inch panel instrument. The EVM optical head, containing the infrared light source, telephoto eye camera, and wide angle locating camera, views the pilot's eye through the tracking mirror. A scene camera captures the field of view to be monitored, and the EVM system superimposes crosshairs (or a spot) over the pilot's look point within this field. Typical locations for the optical head and scene camera are shown by the diagram at left, but other arrangements are possible as well (consult factory).

The Federal Aviation Administration's GAT-2B simulator, shown in the photo, is equipped with an ASL Eye View Monitor System and is currently being used as part of the FAA's effort to study human factor aspects of aviation. Pilot scanning behavior during a simulated flight is being monitored by the EVM system using the tracking mirror (indicated by arrow) in the instrument panel. The optical head (containing the eye camera) is aimed over the pilot's shoulder as shown in the schematic diagram, and is not visible in the photograph.



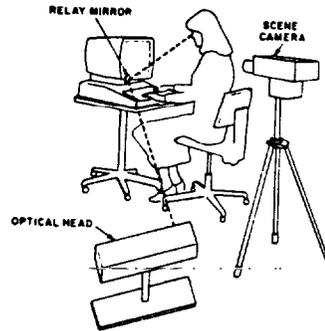
SIMULATOR CONFIGURATION SCHEMATIC



EVM TRACKING MIRROR IN A GAT-2b SIMULATOR

VIDEO DISPLAY TERMINAL CONFIGURATION (VC)

All 1996 or 1998 EVMs can be configured to monitor point-of-gaze as a subject works at a video display terminal (VDT). The schematic diagram shows such a setup using a Model 1998 EVM. The pupil camera is directed at the eye through both the tracking mirror contained in the optical head, and a stationary relay mirror that is fixed to the VDT. The relay mirror is actually the only non standard EVM component. The EVM scene monitor may display either a video signal taken directly from the VDT or from a scene camera that is directed at the work station.



VDT CONFIGURATION SCHEMATIC

HELMET MOUNTED OPTICS (HMO)

Some applications require the subject to have almost unlimited head motion freedom (e.g. the subject must walk about), or require line of gaze measurement over a very wide field of view. On a custom basis, an EVM system can be provided with helmet mounted optics.

An illuminator, solid state sensor, relay lens, and visor mounted on a lightweight helmet. The visor is coated transparent in the visible spectrum but reflective to the near infrared, and reflects the eye image through the relay lens to the camera. A small scene camera and/or magnetic head position sensor can also be mounted on the helmet. (Consult factory for details.)

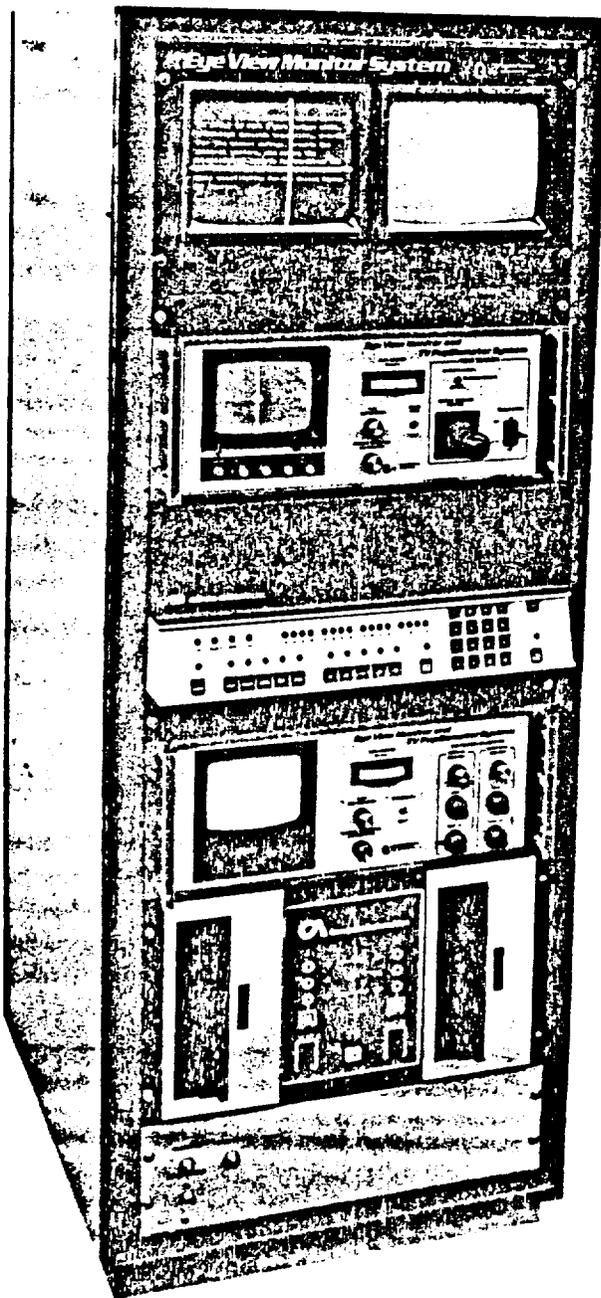
COMPUTER SYSTEM DESCRIPTION

The Computer Automation Model LSI 2/20 used in the EVM was selected for its high operating speed and powerful input/output (I/O) capabilities needed to handle the rigorous real time computation and interface requirements. This 16 bit minicomputer is also a flexible general purpose system suitable for recording and processing data generated by the EVM as well as for other laboratory functions.

The computer may be configured in a number of possible arrangements with a wide choice of peripheral devices. It supports up to 32K words of CORE memory or RAM. The CPU has a built-in current loop and RS232 interface port, and the EVM system includes at least one

direct memory access (DMA) I/O board with four input and output channels. Two of the four channels are used by the EVM, but additional channels may be added.

The Computer Automation LSI 2/20 will support IBM compatible floppy disks, hard disks, and magnetic tape systems. Eye position data may be recorded on one of these devices for later off-line analysis. The system can also generate subject displays and can easily communicate with other laboratory computers.



CAPABILITY AS A GENERAL PURPOSE LABORATORY COMPUTER

When the Eye View Monitor is not in use, the I/O capabilities of the LSI 2/20 make it ideal for monitoring and controlling other laboratory equipment. The computer can be interfaced to parallel, RS232, or analog devices, by simply connecting the appropriate Computer Automatic firmware cable to any port on the computer distributed I/O board.

EYE VIEW MONITOR SOFTWARE GENERAL DESCRIPTION

Six software packages are available with the Eye View Monitor:

- 1) EYEPOS (standard) is the program which operates the computer-based Eye View Monitor and provides various utilities.
- 2) A Disk Operating System (standard) supports software generation, file handling, and other executive functions.
- 3) EYEDAT (optional) allows the user to record eye position, pupil diameter and other data on the integral floppy disk in real time. A set of library subroutines enables the user to write his own assembly language or Fortran program to access the recorded data.
- 4) EYENAL (optional) is a set of "off-line" analysis programs which display and process data that has been recorded with EYEDAT. EYENAL programs perform some common analysis tasks and can be employed by many users in lieu of writing their own assembly language or Fortran analysis programs.
- 5) FORTRAN Compiler
- 6) BASIC Interpreter

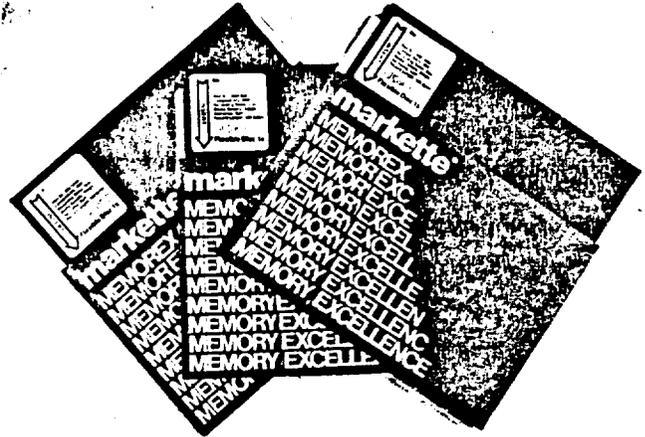
49

EYEPOS

The EYEPOS software operates the model 1996 and 1998 computer based Eye View Monitor. It examines preprocessed video data to eliminate artifacts, identify the pupil and corneal reflection, and calculate point-of-gaze. This program handles subject calibration, and in the case of the model 1998 drives the servo controlled tracking mirror.

EYEPOS provides various test and service utilities. The most useful of these is a dump program which can store the EYEPOS program at any point in time saving all target, calibration and compensation data.

EYEPOS is very easily bootstrapped using the built-in computer autoload ROM. Any dumped version may also be autoloaded in this way.



OPERATING SYSTEM

The file-based floppy disk operating system includes the following utilities:

1. Assemblers (standard and MACRO)
2. Editors
3. File handling utilities
4. Debugging utility
5. Miscellaneous service programs

EYEDAT

EYEDAT is the data recording software for the computer-based Eye View Monitor, and resides in memory along with the EYEPOS program. With a single key stroke on the keyboard terminal the user can:

- Open a new data file on a floppy disk
- Reopen an old data file
- Begin recording eye position data on the disk
- Record up to ten different event marks
- Suspend recording data
- Close the data file
- Enter a routine to list out the data just recorded

The following measurements are sampled and recorded 60 times per second and constitute a field of data:

- Vertical eye point of gaze coordinate (VPOS)
- Horizontal eye point of gaze coordinate (HPOS)
- Pupil diameter
- Sixteen bits of external user-generated data (XDAT)
- Time

In addition, one of ten separate event marks (0 through 9) may be recorded at any instant of time with a single key stroke. Losses due to blinks or other artifacts are indicated on the recordings by zero pupil diameter values.

EYEDAT packs data on each disk in a specially designed format to allow maximum storage. Up to 20 minutes of data can be recorded on a single 8 inch floppy disk, and, by using multiple disks, an unlimited amount can be recorded without interruption.

A set of library subroutines is provided to facilitate data access by user written computer programs. Using these subroutines, users can write off-line assembly language or Fortran analysis programs that access data previously recorded by EYEDAT.

EYENAL

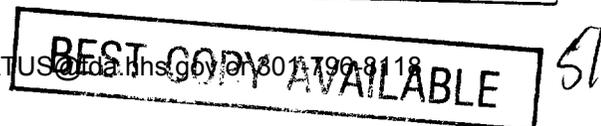
EYENAL is a set of offline programs which display and analyze data that has been recorded with EYEDAT. The programs run on the same computer that is an integral part of the Eye View Monitor system. The term "off-line" refers to the fact that these programs are not used while the Eye View Monitor is in operation, but rather are used to process pre-recorded data.

These programs, which run under the Computer Automation operating system, provide directories of data disks, tables and time plots of eye position and pupil

diameter data, fixation point determination from raw eye position data, and separation of fixation points into user specified areas-of-interest for dwell time or fixation sequence analysis. Programs may also be custom written for a user's particular needs.

The following table contains a brief description of each individual program currently in the EYENAL package. Consult Applied Science Laboratories for a complete list and detailed descriptions.

PROGRAM	PURPOSE	APPLICATION	FEATURE
EYENAL DUMP (EN:DMP)	Print the contents of any disk sector in its raw hexadecimal form.	This program was written for use by ASL in writing and debugging EYEDAT software. Although rarely needed by system users, it is nonetheless available.	
EYENAL MAP (EN:MAP)	Print the directory of a data diskette (recorded by EYEDAT) including the number of segments on the diskette, location and length of each segment, and location of any recording errors. The term "segment" refers to continuous data recorded between EYEDAT "record" and "stop" commands.	Check data diskettes for errors and keep a record of their contents.	
EYENAL TABLE (EN:TBL)	List eye position and pupil diameter data in tabular form.	Inspect or scan data.	<ul style="list-style-type: none"> The program lists values of time, horizontal eye position, vertical eye position, pupil diameter, XDAT (external user generated data), and any event marks. The user can select any desired sample frequency. For example, the user can elect to list one sample at every 1/60 second interval, or at every 2/60 second interval, etc. Each data item can be assigned a scaling factor and offset value. A low pass filter can be selected to reduce aliasing errors associated with sampled data. Eye recognition losses that occurred during recording (due to blinks or other artifacts) are indicated. All options selected are printed at the beginning of the table.
EYENAL PLOT (EN:PLT)	Use a printer to plot eye position coordinates, pupil diameter, and XDAT (external user generated data) versus time. The plots are in strip chart form with one axis representing one or more of the dependent variables, (vertical eye position, horizontal eye position, pupil diameter, and XDAT) and the other axis representing time.	Examine time profiles of any or all recorded data items.	<ul style="list-style-type: none"> The user can elect to include a single data item or any combination of data items on the same plot. For example, EN:PLT may be used to obtain a plot showing just horizontal eye position versus time. It may also be used to obtain a single time plot with two curves, one representing horizontal eye position and one representing vertical eye position or it can be used to plot four curves (all four data items) on the same time plot, etc. The sample frequency is selectable. The user can elect to plot one sample point every 1/60 second interval, every 2/60 second interval, etc. Eye recognition losses (due to blinks or other artifacts) are detected and indicated. Each dependent variable can be assigned a scale factor and offset value. A smoothing filter can be selected to reduce aliasing errors associated with sampled data. The dependent variable axis is automatically scaled and labeled so that maximum plot range is used on each time plot. All selected options are printed at the beginning of the plot.
EYENAL FIXATE (EN:FIX)	Reduce eye position data by extracting fixation points (periods of lovetion on stationary targets as opposed to saccadic motions, etc.). Print and record each fixation coordinate (horizontal and vertical position on the scene) and the length of each fixation.	Reduce eye position data to a list of points that the subject actually looked at. This is a prerequisite to dwell time or fixation sequence analysis.	<p>The term "fixation" refers to a person's point of regard as he looks at a stationary target in a visual field. Fixations are distinguished, primarily, from saccades (rapid voluntary eye movements used to move from one fixation to another) and very small involuntary eye movements of several types which occur during fixation. Other types of ocular behavior such as smooth pursuit and nystagmus, are not frequently encountered during presentation of static scenes.</p> <p>There is currently no precise, universally accepted definition of a fixation, but there are known parameters of ocular physiology which allow reasonable criteria to be used. Specifically, there is research documenting the minimum latency of saccades in response to visual stimuli (thus suggesting a minimum fixation duration) and data defining the maximum amplitude of involuntary eye movements during the fixation (thus establishing maximum fixation boundaries).</p> <p>A fixation is defined, by EN:FIX, to be the mean x and y eye position coordinates measured over a minimum period of 100 msec during which the eye does not move more than one degree. More simply stated, point-of-gaze must continuously remain within a one degree radius for at least 100 ms. Blinks are not considered discontinuities. The detailed algorithm and documentation of supporting data are included in the program user's manual.</p>
EYENAL AREAS-OF-INTEREST (EN:AOI)	Define areas-of-interest on the visual scene and store for later dwell time or sequence analysis.	Store scene coordinates of important scene elements for subsequent correlation with subject fixation points. EN:AOI is used primarily to create a file for subsequent use by EN:FDS.	<ul style="list-style-type: none"> Areas of interest can be defined as either squares, rectangles, or circles of any dimension. Each area is assigned a sequential number and is also assigned a label of the user's choice.
EYENAL FIXATION DWELL AND SEQUENCE (EN:FDS)	Match fixation points with areas of interest. Calculate total dwell time spent fixating each area of interest and sequence of fixations on areas of interest. Output to the printer as well as to a disk file if desired.	Study the amount of time subjects spend viewing various scene elements and the sequence in which they were viewed.	



CHOOSING A COMPUTER-BASED EYE VIEW MONITOR (Ordering Information)

A wide range of configurations and options is available computer-based Eye View Monitors so that users may select a system that is cost effective and is tailored to their specific application. The various options have been divided into five categories and are listed below. Allowable and recommended combinations are illustrated on pages 26 and 27.

I. HEAD TRACKING OPTIONS

- Model 1996 Standard . . . no head tracking
- Model 1998 Standard . . . automatic mirror tracking; see page 19
- AF . . . Automatic and remote focus; available with either Model 1996 or 1998; see page 18
- EHT . . . Extended Head Tracking; available with Model 1998; see page 19
- MHT . . . Magnetic Head Tracking; available with Model 1998; must also have AF system; see page 19

II. OPTICAL CONFIGURATIONS

- Standard . . . Basic Model 1996 or 1998 configurations; see page 20
- SC . . . Simulator Configuration; available with Model 1998; see page 21
- VC . . . video display terminal configuration; available with either Model 1996 or 1998; see page 21
- HMO . . . Helmet Mounted Optics; see page 21; consult factory

III. COMPUTER HARDWARE CONFIGURATION . . . all options are available with either Model 1996 or 1998

- Standard . . . dual floppy disk drive; hard copy terminal; 16K words memory with Model 1996; 24K words memory with Model 1998
- Add on memory . . . (RAM or CORE) up to a system total of 32K words
- Magnetic tape system for increased data storage
- Paper tape system in lieu of floppy disk subsystem
- Video display terminal in lieu of hard copy terminal
- High Speed Printer

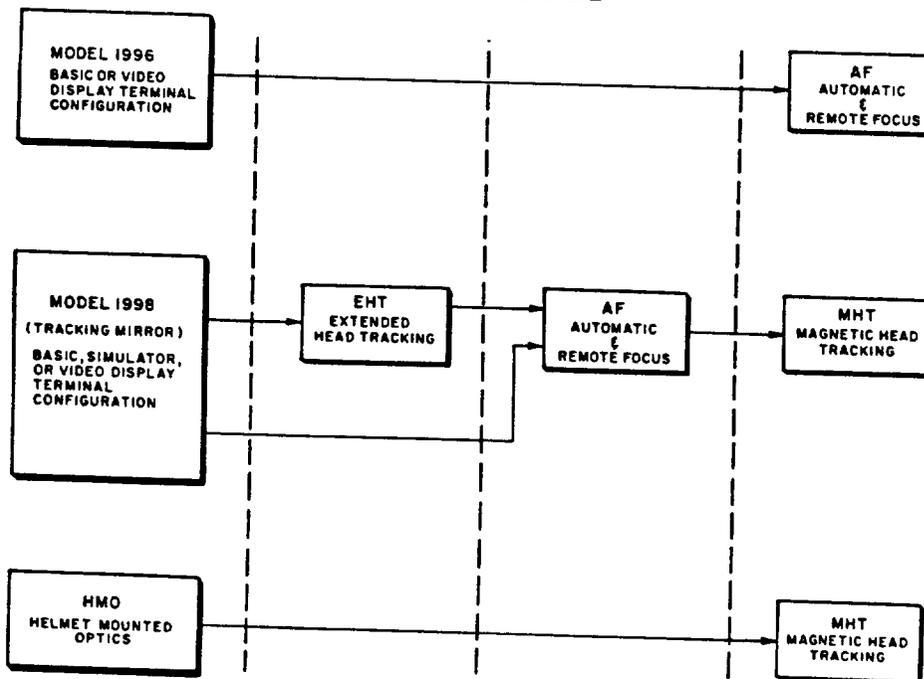
IV. SOFTWARE . . . all software is available with either Model 1996 or 1998

- Standard . . . EYEPOS program; floppy disk operating system; see page 23
- EYEDAT . . . EVM data recording package; requires dual floppy disk system; see page 23
- EYENAL . . . EVM offline data analysis package; must also have EYEDAT; see page 24
- FORTRAN compiler . . . requires dual floppy disk system, keyboard terminal, and at least 24K words memory
- BASIC interpreter . . . requires keyboard terminal and dual floppy disk system

V. MISCELLANEOUS OPTIONS

- Built in stimulus generation . . . includes character generator, 19 inch video monitor with adjustable height stand, and necessary software (see description on page 18 and photo on page 20).

EVM HEAD TRACKING AND OPTICAL CONFIGURATION GUIDE



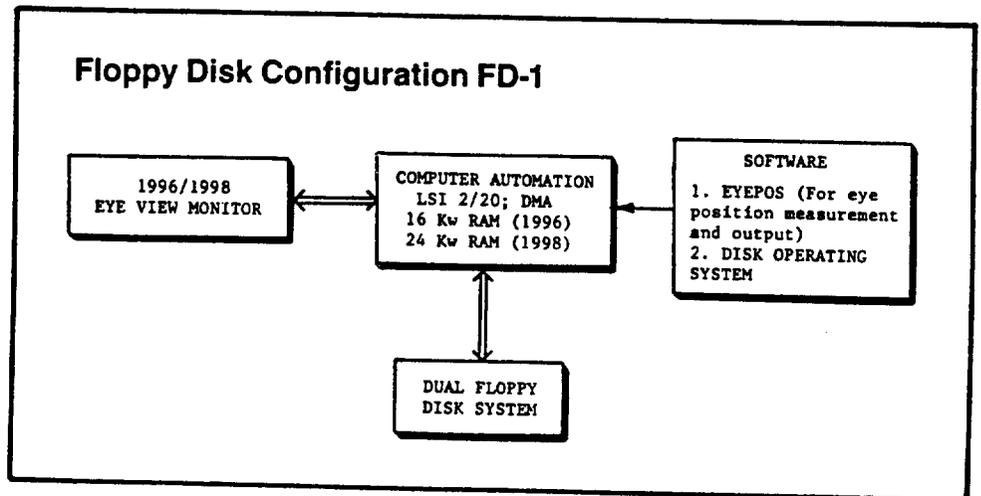
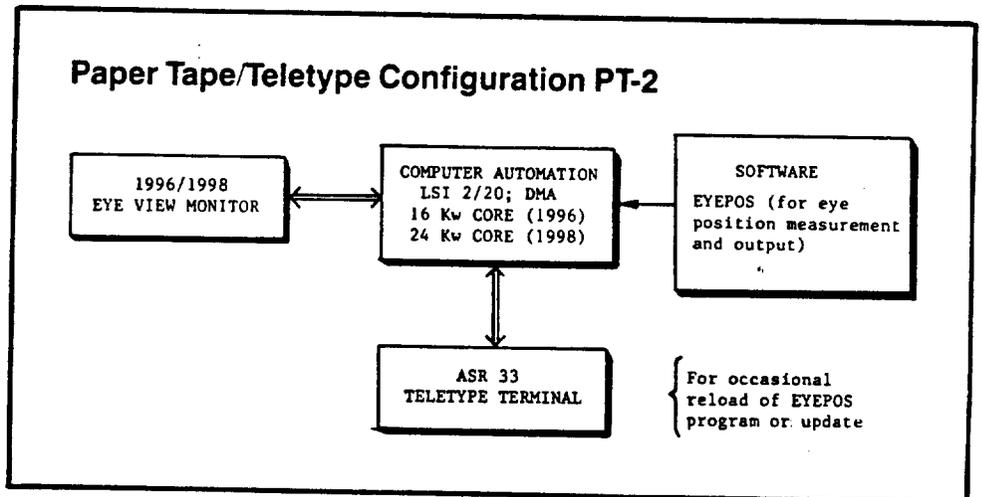
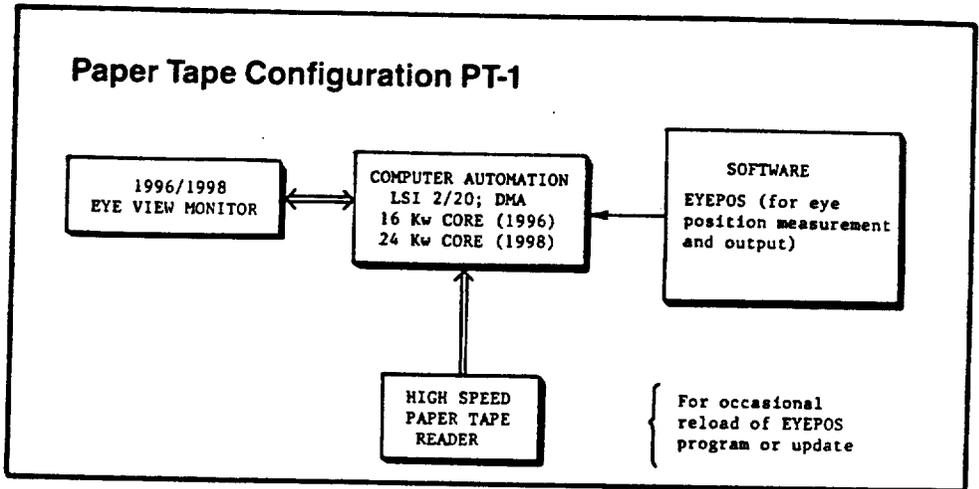
ALLOWABLE OPTION COMBINATIONS MAY BE CHOSEN BY MOVING ALONG ANY ARROW/LINE AND STOPPING AT ANY OF THE VERTICAL DASHED LINES

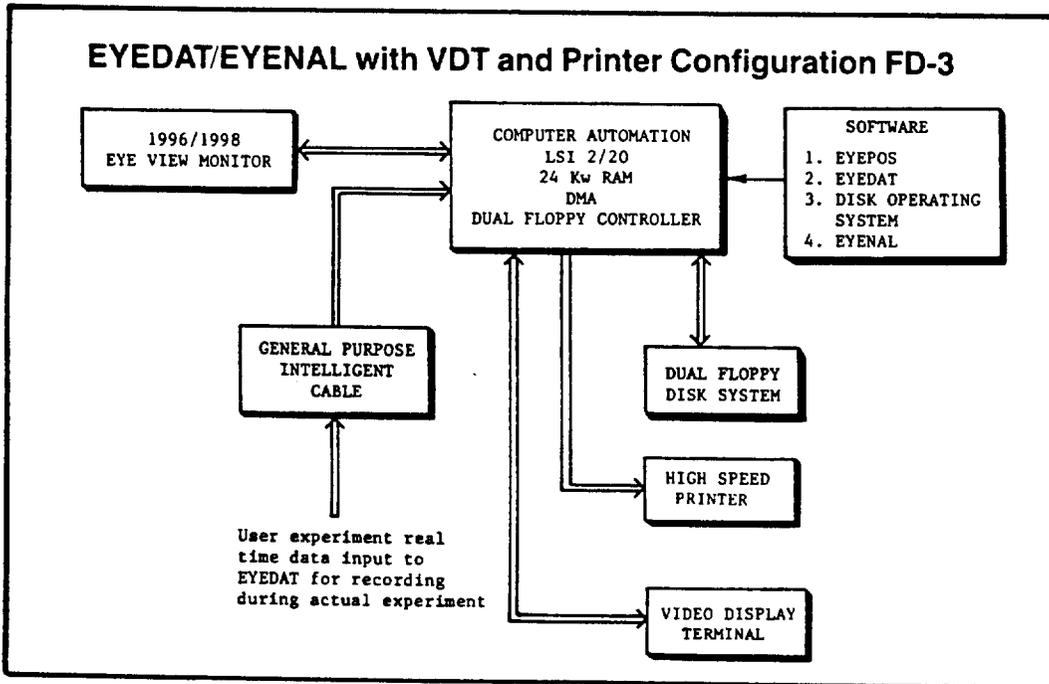
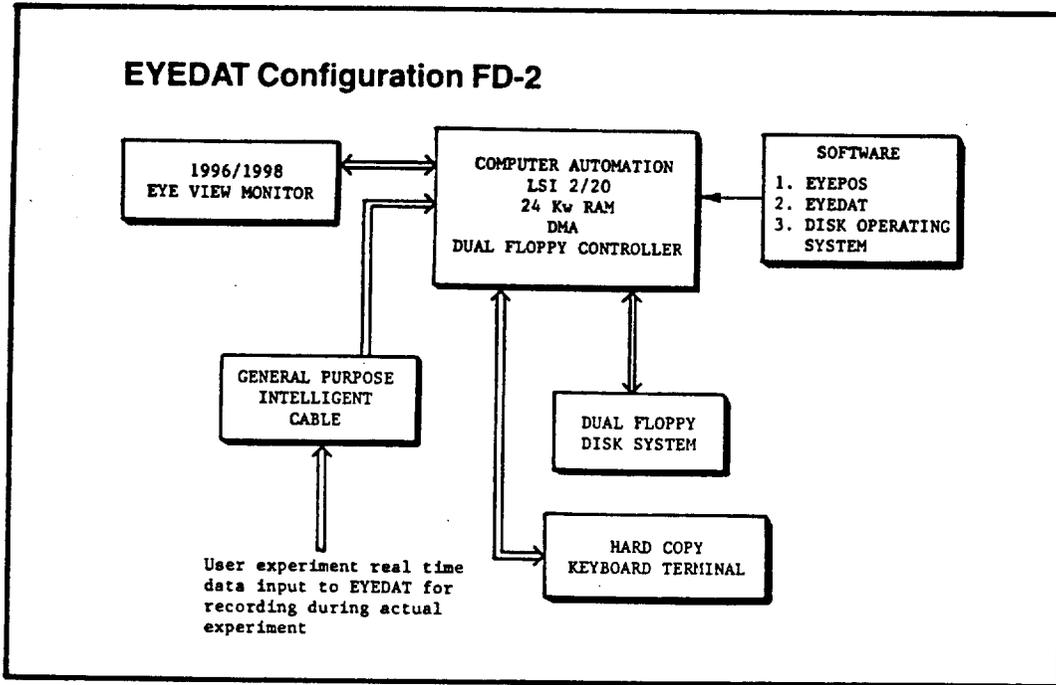
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIS@fda.hhs.gov or 301-796-8118

BEST COPY AVAILABLE

58
25

EYE VIEW MONITOR MODELS 1996 and 1998 Recommended Computer Hardware and Software Configurations





GENERAL SYSTEM DESCRIPTION AND CONFIGURATION

	1982	1984	1986	1988
TYPE OF SYSTEM	Basic chinrest system	Remote chinrest or headrest system	Computer processor based free head system with: <ul style="list-style-type: none"> Greater head motion Greater eye motion Greater eyelid tolerance Greater camera-subject distance Automatic calibration Automatic and remote focus pupil camera lens (optional) 	<ul style="list-style-type: none"> Automatic Servocontrolled head tracking mirror added to focal 1986 capabilities Extended head tracking (optional) Magnetic head position sensing (optional)
ILLUMINATION OPTICS	Indirect dark pupil	Cosmel, bright, retroreflected pupil	*	*
TV CAMERA	High quality instrumentation grade; silicon matrix pick-up tube, line locked 2:1 interface, 525 lines (625 ~ 50Hz); Output Impedance: 75 ohms	*	*	*
CALIBRATION	Manual 5 point calibration	*	Automatic 8 point, calibration; requires less than 30 seconds; corrective selective recalibration possible	*
SYSTEM COMPONENT CONFIGURATION	<ul style="list-style-type: none"> Pupil camera Pupil monitor Scene camera Scene Monitor 	<ul style="list-style-type: none"> * * * * Wide angle eye location camera Wide angle eye location monitor	See diagrams of system configurations (pgs. 26 & 27)	See diagrams of system configurations (pgs. 26 & 27)
INTEGRAL EYE POSITION MEASUREMENT SOFTWARE	None	*	EYEPOS Disk Operating System EYEDAT (optional) EYENAL (optional)	*

* Same as item to the left

PERFORMANCE SPECIFICATIONS

	1982	1984	1986	1988												
ALLOWABLE EYE MOVEMENT	Generally depends on magnification used and camera placement. Along the horizontal axis: 30°, 40° or higher with reduced accuracy. Along the vertical axis: 25°, 30° or higher with reduced accuracy. Range in the left direction may be increased if subject is permitted to look all around and beyond the pupil camera. Eyes may limit this range with some subjects. The measurable visual field will generally be oval in shape.	*	Along the horizontal axis: 40° or more. Along the vertical axis: 30° or more depending on pupil camera placement and eyelets. The measurable visual field will generally be oval in shape.	*												
ALLOWABLE EYE SPACE (Head Movement)	Head in chinrest	Head in chinrest or headrest	Headrest or 16 cm ² (1 in ²)	<table border="1"> <thead> <tr> <th></th> <th>X-Y Plane</th> <th>Z Axis</th> </tr> </thead> <tbody> <tr> <td>†Standard Model 1988 or 1988-EHT</td> <td>230 cm² (36 in²)</td> <td>3 cm (1 in)</td> </tr> <tr> <td>With Option APF</td> <td>230 cm² (36 in²)</td> <td>30 cm (12 in)</td> </tr> <tr> <td>With Option APF and MHT</td> <td>800 cm² (144 in²)</td> <td>30 cm (12 in)</td> </tr> </tbody> </table>		X-Y Plane	Z Axis	†Standard Model 1988 or 1988-EHT	230 cm ² (36 in ²)	3 cm (1 in)	With Option APF	230 cm ² (36 in ²)	30 cm (12 in)	With Option APF and MHT	800 cm ² (144 in ²)	30 cm (12 in)
	X-Y Plane	Z Axis														
†Standard Model 1988 or 1988-EHT	230 cm ² (36 in ²)	3 cm (1 in)														
With Option APF	230 cm ² (36 in ²)	30 cm (12 in)														
With Option APF and MHT	800 cm ² (144 in ²)	30 cm (12 in)														
PRECISION OR REPRODUCIBILITY	Better than 1/4"	*	*	*												
LINEARITY OR ACCURACY	Nominal spatial error between true eye position and computed measurement is <1". Error may increase to <2" in the periphery of the visual field.	*	Spatial error between true eye position and computed measurement is <1". Errors may increase to <2" in the periphery of the visual field.	Mirror motion may add one additional degree to eye position measurement error over the entire volume of space.												
CAMERA TO SUBJECT DISTANCE	12-15 cm (5-6 inches)	30-80 cm (1-3 feet)	30-225 cm (12-90 inches); 50-100 cm (20-40 inches) is the normal operating range.	*												
CAMERA PLACEMENT	Eye level, left of subject (right possible)	*	Variable; usually below eye level and in front of or slightly to one side of subject.	*												
EYEGLASSES ACCEPTED	Some	Most	*	*												
CONTACT LENS ACCEPTED	Some	*	*	*												
AMBIENT ILLUMINATION REQUIREMENTS	None	Complete darkness to moderate illumination resulting in pupil diameters greater than 3 mm; diameters below 3 mm may result in marginal performance.	*	*												

* Same as item to the left

†These are nominal values; accuracy may be reduced at the peripheral portions of the field of view. This volume will greatly vary depending on subject, geometric conditions, and other factors.

55

SYSTEM OUTPUTS

			1992	1994	1996	1998
SYSTEM OUTPUTS	EYE POSITION	ANALOG	2 outputs for vertical & horizontal eye position; \pm 5 volts linearly related to calibrated eye position, gain & zero adjustable. Analog outputs are generated from digital outputs through an internal digital to analog converter.		*	
		DIGITAL	2 outputs for vertical & horizontal, 8 bits, TTL compatible, linearly related to calibrated eye position in offset binary.		2 outputs for vertical and horizontal, 10 bits, TTL compatible, linearly related to calibrated eye position in offset binary. Fewer bits may be used or outputs may be transformed by the computer to 8 bits if desired.	
	PUPIL DIAMETER	PUPIL DIAMETER MEASUREMENT AXIS	Vertical diameter (pupillary area is optional)		Horizontal diameter	
		ANALOG	Pupil measurement and display range: 2.0 to 10mm (normal pupil diameter: 2.8 mm to 6.5 mm) Analog output signal accuracy: better than 1%. Front panel meter accuracy: 2% of full scale. Analog output is generated from the digital output through an internal digital to analog converter. Frequency response: smoothing filter, flat from 0 to 6 Hz, may be switched out. Scaling: 1.0 volt/mm of pupil diameter (0.1V/mm optional)		*	
	DIGITAL	8 bits TTL compatible representing pupil diameter in straight binary. (8 bits are sufficient for most applications.)		*		
DATA OUTPUT RATE			Measurements of eye position and pupil diameter are made 60 (50) times/sec. They are averaged over the latest 2 fields (1 frame) (33 (40) msec) (unaveraged output is available) and the running average is updated and output each field (17 (20) msec), i.e. 60(50) times per second.		Measurements of eye position and pupil diameter are made 60 (50) times/sec. They are averaged over the latest 2 frames (67 (80) msec) (unaveraged output is available) and the running average is updated and output each field (17 (20) msec), 60 (50) times per second.	
TIMING OUTPUTS			Positive strobe and busy signal are output every 1/60th (1/50th) of a second for transferring of data. Data is stable during strobe pulse and changing during busy signal.		Positive strobe is output every 1/60th of a second for transferring of data. Data is stable during strobe pulse.	
OPERATOR SETTING INDICATORS			Discriminator crosshairs appear on pupil monitor at edge of the pupil and the corneal reflection along with a white centerline through the vertical center of the pupil and a black centerline through the vertical center of the corneal reflection as determined by the Recognition Circuit. The proper position of those lines indicates to the operator that no adjustments are necessary and that the measurement is being performed correctly. Delimiters are placed on the top and bottom of the pupil to indicate the precise vertical discrimination boundaries.		Recognition outlines appear on pupil monitor around the pupil and the corneal reflection, with white recognition crosshairs through the center of the pupil and black recognition crosshairs through the center of the corneal reflection as determined by the recognition hardware and software. The proper position of those lines indicates to the operator that no adjustments are necessary and that the measurement is being performed correctly.	

* Same as item to the left

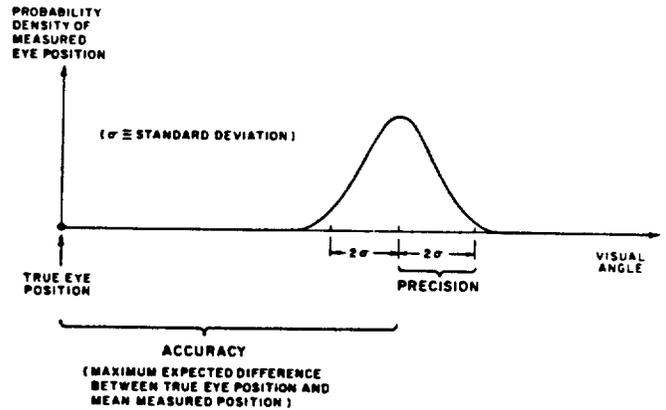
Specifications subject to change without notice

PRECISION AND ACCURACY

The precision and accuracy of the eye position measurement is affected by many variables such as eye to camera distance, subject variation, head position change within the allowable space, section of the scene being fixated, pupil diameter, eyelid position, tear film, or other physiological variables. Values listed in the specification table (previous page) are considered representative of common EVM usage.

Precision, or repeatability, can be thought of as the amount of instrument noise in the eye position measurement when the eye is perfectly stationary. However, there is always some involuntary eye movement; so, as an operational definition, EVM precision is at least twice the standard deviation of measured eye position values when a cooperative, head restrained subject fixates a central point for about one second.

Accuracy may be considered the largest expected difference, or error, between true eye position and mean computed eye position when the eye is stationary.



SINGLE AXIS REPRESENTATION OF PRECISION AND ACCURACY DURING A FIXATION

USER APPLICATIONS

Model 106 Eye-Trac

- Evaluation of reading and perceptual skills
- Determination of visual efficiency
- Study of binocular smooth tracking and saccadic fixation
- Measurement of nystagmus, vergence and other oculomotor functions

Model 200 Eye-Trac

- Cognitive and learning behavior studies
- Neurological effect of certain drugs on the vestibular system
- Non-verbal communication research
- Fatigue and stress studies
- Human factors engineering
- High frequency eye position measurement

Series 1000 TV Pupillometer

- Pharmaceutical research
- Mental work load experiments
- Schizophrenia research
- Binocular studies of neurological imbalance
- Pupillary latency measurements

Series 1900 Eye View Monitor

- Visual search and scanning studies
- Human factors research for various displays, terminals, and control panels
- Analysis of advertising material
- Research concerning the entertainment and educational quality of children's television
- Infant development studies
- Pilot training
- Fatigue and workload analysis
- Pilot or driver simulator experiments

Eye View Monitor with Helmet Mounted Optics

- Control "area-of-interest" type visual scene displays
- Automobile (or other vehicle) driving studies
- Human factors research for industrial control rooms and other environments where subjects must walk about or scan wide areas

REFERENCES

- ten, M.J., Vision and Highway Safety, New York, Chilton Book Company, 1970, page 34.
- Angel, R.W. and Garland, H., Transfer of Information From Manual to Oculomotor Control System, *Journal of Experimental Psychology*, 1972, 96 (1), pages 92-96.
- Brickner, C.A., "The Analysis of Eye-Movement Recordings From Samples of Under-Achieving Secondary and Primary Students," *AV Communication Review*, 1970, 18(4): pages 414-424.
- Elmstrong, G., "What's New: Eye-Trac®," *J. of Am. Optom. Assn.*, 1970, 41(6): page 562.
- Fleming, M., "Eye Movement Indices of Cognitive Behavior," *AV Communication Review*, (1969), 17(4): pages 383-398.
- Gibbon, S.Y., et. al., "Report of the Conference on Visual Information Processing Research and Technology," U.S. Dept. of HEW, Nat. Inst. of Education, Report CS-001770, 1975.
- Metz, H.S., Scott, A.B., O'Meara, D., and Stewart, H.L., "Ocular Saccades in Lateral Rectus Palsy," *Arch. Ophthalmol.*, October, 1970, 84: pages 453-460.
- Monty, Richard A. (ed.), Eye Movement and Psychological Processes, Erbaum Assoc., 1976.
- Newman, J.S., "Eye-Movement Measurements," *Medical Electronics and Data*, May-June 1970, 1(3): pages 82-84.
- Nodine, C.F. and Lang, N.J., Development of Visual Scanning Strategies for Differentiating Words," *Development Psychology*, 1971, 5(2), pages 221-232.
- Noton, D. and Stark, L., "Eye Movements and Visual Perception," *Scientific American*, 1971, 224(6), pages 34-43.
- Reinecke, Robert D., Carroll, John, Beyer, Charles K., and Montross, Richard, An Innovation in Eye Care, *The Sight-Saving Review*.
- Schmidt, Stephanie, A Study of Eye Movement Patterns in Children With a Specific Learning Disability, *Journal of Optometric Vision Therapy*, March 1973.
- Senders, J.W., Fisher, D.F., Monty, R.A. (eds.) Eye Movement in the Higher Psychological Function, Erbaum Assoc., Hillsdale, N.J., 1979.
- Spache, George D., Evaluation of Eye-Movement Photography in Reading Diagnosis and Reading Training, Research and Evaluation in College Reading, The Ninth Yearbook of the National Reading Conference for College and Adults, Fort Worth: Texas Christian University Press, Reprint No. 5, 1960.
- Taylor, Daniel M., Is Congenital Esotropia Functionally Curable, *Tr. Amer. Ophthal. Soc.*, 1972, Vol. LXX.
- Taylor, Earl A., Ed.D., The Spans: Perception, Apprehension and Recognition as Related to Reading and Speed Reading, *American Journal of Ophthalmology*, October 1957, Vol. 44, No. 4, Part 1.
- Troost, B.T., Weber, R.B. and Daroff, R.B., Hemispheric Control of Eye Movements, *Archives of Neurology*, 1972, 27, pages 441-452.
- Waldstreicher, Joel S., Educational Rehabilitation and Visual Education — an Integrated Approach, *The Optical Journal and Review of Optometry*, May 1, 1962.
- Winter, J.D., "Clinical Use of Direct Recording Oculographic Instruments," paper presented at the American Academy of Optometry, Miami Beach, Fla., Dec. 12-15, 1970.
- Young, L.R. and Sheena, D., "Survey of Eye Movement Recording Methods," *Behavior Research Methods and Instrumentation*, 1975.

For more information, call or write:

A. _____
Marketing and Sales Manager



**Applied Science
Laboratories**

GULF + WESTERN RESEARCH AND DEVELOPMENT GROUP

335 Bear Hill Road
Waltham, Massachusetts 02154
(617) 890-5100

58

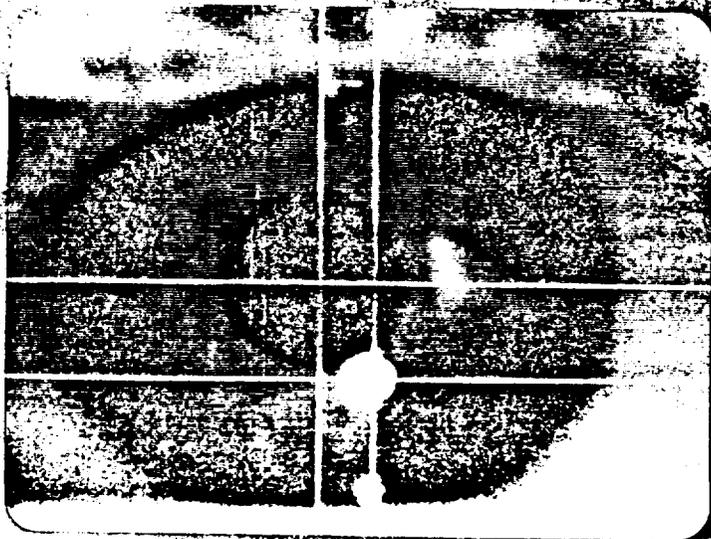
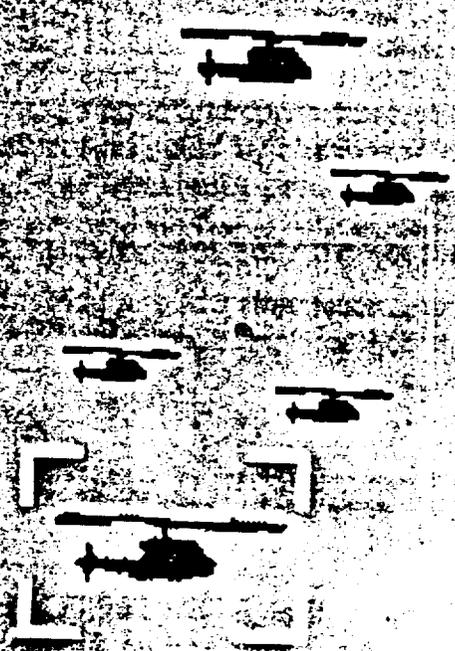
ISCAN Inc.
125 Cambridgepark Drive, Cambridge, MA 02238

The literature is attached in the following un-numbered pages.

BEST COPY AVAILABLE ⁵⁹

ISCAN[®]

EVIL EYE[™]



EYE SLAVED TARGET ACQUISITION SYSTEM

60

ISCAN® EVIL EYE™

EYE SLAVED TARGET ACQUISITION SYSTEM

The ISCAN EVIL EYE™ Eye Slaved Target Acquisition System is an advanced man/machine interface that allows an operator to rapidly, accurately and naturally designate areas of interest or targets within the field of view. Just by looking at the target of interest, the operator may designate or control various machine functions. The EVIL EYE™ is the first eye movement based control system which works reliably in "real world" environments and with virtually any human operator. Applications of the EVIL EYE™ include:

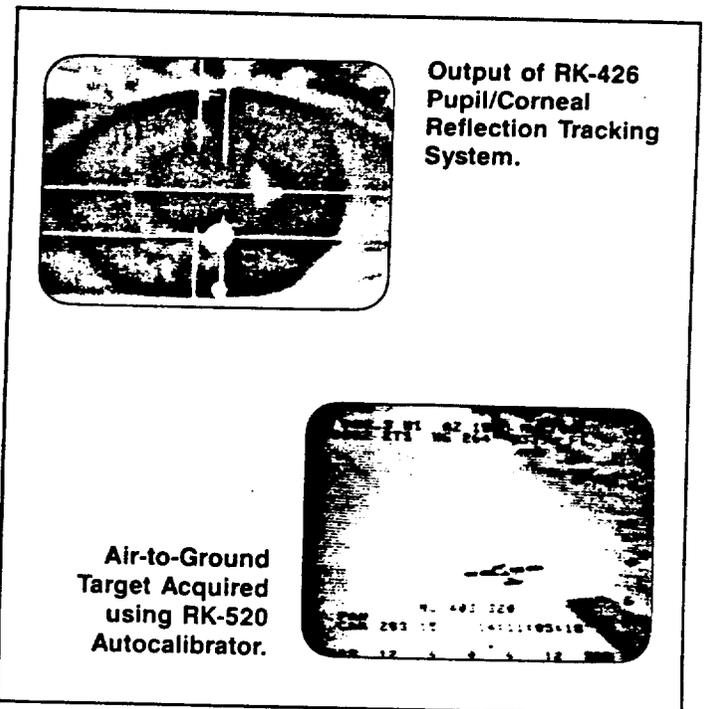
- Rapid Weapons Pointing
- Surveillance Camera Guidance
- Aircraft Cockpit Control
- Automatic Tracking Initialization
- Human Factors Evaluation

General Information

The human eye is an ideal input device for advanced man/machine interface applications due to the inherent ability of the human oculomotor system to rapidly and precisely shift the vector of attention in response to visual stimuli.

The ISCAN EVIL EYE™ system employs a non-invasive, video based eye tracking technique to monitor the position of the subject's eye with respect to an imaging sensor. The lightweight eye imaging sensor and associated optics may be completely mounted beneath a flight helmet visor or embedded into a fixed sighting system. The system operates at a sample rate of 60 Hz and the subject's visual point of regard may be determined with an accuracy of better than 1 degree over a ± 15 to ± 20 degree visual angle range.

Data corresponding to the subject's point of regard may be used to control various system functions or designate targets of interest on a helmet-mounted



or external display. The EVIL EYE™ automatically compensates for slippage between the subject's head and the eye imaging assembly, allowing for normal head movements while in operation. Eye-glasses or contact lenses do not affect system performance.

SYSTEM COMPONENTS

The components of the EVIL EYE™ are the Eye Imaging System, the RK-426 Pupil/Corneal Reflection Tracking System and an Autocalibration System.

ISCAN Eye Imaging System

The Eye Imaging System consists of the lightweight imaging and illumination components required to obtain high quality eye images. These components may be helmet mounted or embedded into a fixed sighting station. The system includes a miniature two dimensional image sensor with optics, a solid state infrared illuminator, a dichroic mirror and mechanical assembly. The dichroic mirror is transparent to the operator. ISCAN can custom mount an eye imaging assembly to a variety of flight, communication and combat helmets.

66

ISCAN RK-426 Pupil/Corneal Reflection Tracking System

The RK-426 is a real time, digital image processor that simultaneously tracks the center of a subject's pupil and a reflection off of the subject's cornea from the infrared illuminator. By tracking both the pupil and corneal reflection, data corresponding to eye movements can be separated from data generated by movements of the subject's head within the camera's field of view. The RK-426 is a dark pupil tracking system that operates in high illumination environments with virtually any subject using simple optical components. The RK-426 offers ISCAN's unsurpassed eye tracking performance and minimal operator adjustments because it is able to automatically discriminate the pupil and corneal reflection from shadows or highlights which are invariably present in eye images. Computation of the pupil and corneal reflection center positions is not affected by changes in pupil size or if the corneal reflection moves to the edges of the pupil area.

ISCAN Autocalibration System

The standard RK-520 Autocalibration System is a computational unit that accurately calculates the subject's point of gaze with respect to a scene being viewed using the raw eye position data generated by the RK-426. Point of gaze data may be output as a cursor on the operator's display as well as in parallel digital format for computer interface. The RK-520 features a flexible five point calibration procedure which is simple to operate and can be completed in a few seconds. After the calibration procedure, the RK-520 automatically translates the raw eye data from the RK-426 to point of regard coordinates.

The system also includes a manual joystick and on-screen numerical data display for delimiting fixed scene elements within the field of view, such as control panel buttons or switches, which can then be selected by sight. ISCAN can custom design appropriate calibration hardware and software for particular system requirements.



EVIL EYE™

TECHNICAL SPECIFICATIONS

EYE IMAGING SYSTEM

Monocular Imaging Assembly:

Weight: 4 ounces
Construction: 1/16th Anodized Aluminum

Imaging Sensor Head:

Size: 17.5mm D x 52.9mm L
Spatial Resolution: 511H x 256V pixels
Temporal Resolution: 60 Hz

Dichroic Mirror:

Size: 2" x 2" Square w/rounded edge
Transmission: 70%, 400-700nm
Reflection: 750-1200nm

Illuminator:

Solid State Infrared LED
(No cooling required)
Size: 1.25" x 0.5" D Cylinder
Wavelength: 880nm
Irradiance at Eye: 1.2mW/sq.cm., typical

EYE TRACKING ELECTRONICS

RK-426 Pupil/Corneal Reflection Tracker:

Power: 115/230 VAC, 60/50 Hz, 20W
Eye Video Input: EIA Standard RS-170
or PAL
Eye Video Output: Same as above.
Data Outputs (Digital TTL):
Pupil Horizontal Position (9 Bits)
Pupil Vertical Position (8 Bits)
Corneal Refl. Horizontal Position (9 Bits)
Corneal Refl. Vertical Position (8 Bits)

RK-520 Autocalibration System:

Power: 115/230 VAC, 60/50 Hz, 15W
Scene Video Input: EIA Standard RS-170
or PAL
Scene Video Output: Same as above.
Data Outputs (Digital TTL):
Point of Regard Horizontal Position (9 Bits)
Point of Regard Vertical Position (8 Bits)
Data Strobe

For further information about ISCAN Eye Movement Monitoring Systems, ISCAN Automatic Video Tracking Systems or the ISCAN Optimouse™ Remote Cursor Control System, please contact:

SCAN®

125 Cambridgepark Drive
P.O. Box 2076
Cambridge, MA 02238
USA

ISCAN® is a registered trademark of ISCAN, Incorporated.
EVIL EYE™ is a trademark of ISCAN, Incorporated.

Copyright © 1989, ISCAN, Incorporated.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIST/ATUS@fda.hhs.gov or 301-796-8118

Telephone: 617-868-5353 Fax: 617-868-9231

BEST COPY AVAILABLE

63

LC Technologies, Inc.
4415 Glenn Rose Street, Fairfax, VA 22032

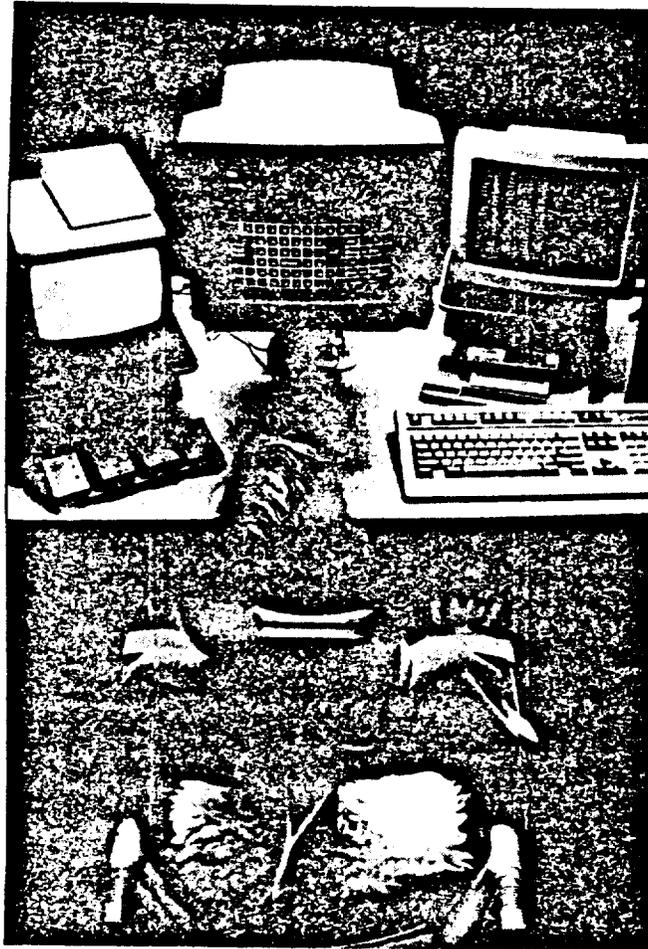
The literature is attached in the following un-numbered pages.

64



THE EYEGAZE SYSTEM™

FOR THE PHYSICALLY DISABLED



LC Technologies, Inc.
4415 Glenn Rose Street
Fairfax, VA 22032

1-800-733-5284
(703) 425-7509
FAX: (703) 323-4782

BEST COPY AVAILABLE

605

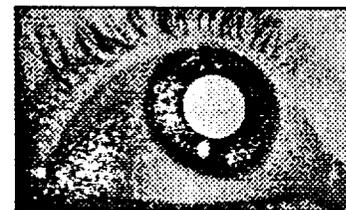
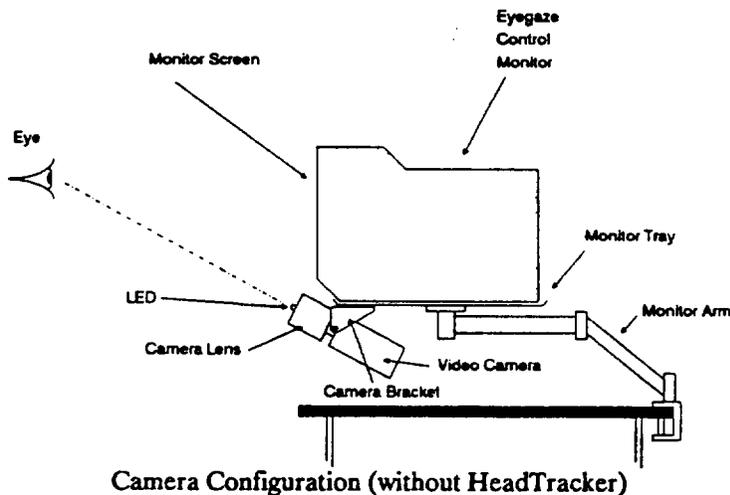
THE PURPOSE OF THE EYEGAZE SYSTEM™

The purpose of the Eyegaze System is to enable severely disabled people to do many things with their eyes that they would otherwise do with their hands. Simply by looking at control keys displayed on a computer monitor screen, the user can perform a broad variety of functions including speech synthesis, environmental control (controlling lights, appliances, televisions, etc.), playing games, typing, operating a telephone, and running most DOS-compatible software.

The Eyegaze System enhances the quality of life of a disabled person, his family and his community by broadening his communication, entertainment, learning and productive capacities. Additionally, the Eyegaze System has been demonstrated to be an invaluable diagnostic tool in the administration of intelligence and psychological testing of individuals who are both physically impaired and nonverbal.

PRINCIPLE OF OPERATION

The Eyegaze System, including its monitors, camera, computer, and control devices, is designed for table-top mounting. To operate the system, the user sits in front of the Eyegaze Control Monitor. A video camera located below the Control Monitor observes one of the user's eyes. Nothing is attached to the user's head or body. A low-power infrared light emitting diode (LED) mounted in the center of the camera lens illuminates the eye and provides a bright image of the pupil and a bright spot reflecting off the cornea. The image of the eye is displayed on a second monitor called the Eye Monitor.



Eye Image with Bright Pupil and Corneal Reflection

Based on the images of the eye's pupil and the corneal reflection, sophisticated image-processing software continually computes where on the Control Monitor screen the user is looking. Typically the system predicts the gaze point with an accuracy of better than a quarter of an inch, enabling the user to activate keys as small as 5/8ths of an inch square. As a form of feedback to the user, the Eyegaze System can display a cursor on the screen at the user's predicted gaze point.

The user operates the Eyegaze System by looking at rectangular keys or buttons that are displayed on the Eyegaze Control Monitor. For example, looking at the "on" key for a light turns it on. To "press" a key visually, the user looks at the key for a specified time called the "gaze duration". If the user keeps his eye focused within the key for the full gaze duration, the key flashes to give him feedback that he has pressed it. The computer then takes the action associated with the key.

The user or the caregiver can adjust the gaze duration time required to press a key. Typical gaze duration values range between 2/3rds and 1/4 of a second. As the user improves his ability to run the Eyegaze System, he may increase his operating speed by reducing the gaze duration.

REQUIREMENTS FOR USE

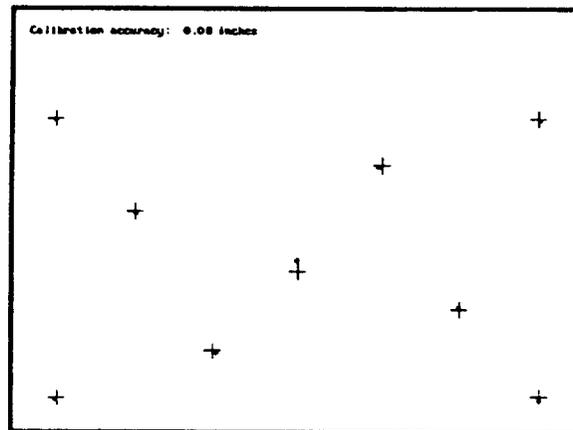
To use the Eyegaze System most easily and effectively, a person should have good control of at least one eye. He should be able to move his gaze freely over the full range of the computer monitor screen. To select and activate the various keys, he should be able to fix his focus at any desired position on the screen for a period of about 2/3rds of a second.

In most cases, eyetracking works with glasses and contact lenses. The lens boundary in bifocal glasses, however, often splits the camera's image of the eye and invalidates the image measurements. Soft contact lenses that cover all or most of the cornea generally work well with the Eyegaze System. Small hard contacts can cause problems if the lenses move around considerably on the cornea.

Generally, the Eyegaze System must be operated in a room lit with fluorescent lights. Too much infrared light from the sun or incandescent lamps can interfere with the light from the LED on the camera and corrupt the camera's clear image of the eye.

CALIBRATION PROCEDURE

To calculate a person's gaze point accurately, the Eyegaze System must first learn some of the physiological properties of the eye including the radius of curvature of the cornea and the angular offset between the eye's optic and focal axes. The system learns these parameters by performing a calibration procedure. The user fixes his gaze on a sequence of dots that the computer displays at specific locations on the screen. After looking at the individual dots, the Calibration program graphically displays the user's overall calibration accuracy, with small circles representing the original calibration points and crosses showing the corresponding gaze point predictions. The calibration procedure usually takes about 15 seconds, and the results can be saved for future sessions.

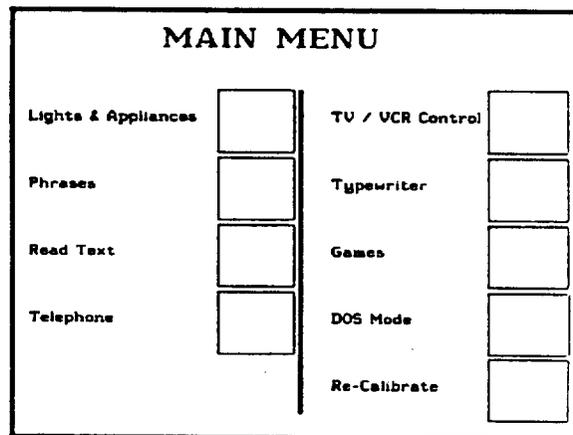


Calibration Performance Results

MAIN MENU

Upon completing the calibration procedure, the Eyegaze System displays its Main Menu. The Main Menu is the navigational center of the Eyegaze System. It presents a list of the various Eyegaze programs and gives the user a way to access the functions he wants. The user calls up the program of his choice by visually pressing the key next to the desired program name. When the user is finished with a program, pressing the "exit" or "quit" key for that program restores the Main Menu.

The following paragraphs summarize the operation of several of the different Eyegaze programs.

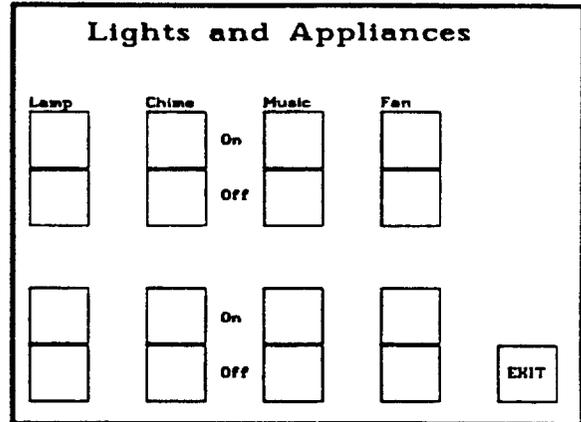


Eyegaze System Main Menu

LIGHTS AND APPLIANCES

The Lights and Appliances program allows a person to control household lights and appliances anywhere within the house. The program displays a set of switches for the various devices that can be controlled by the computer. The user looks at the "on" or "off" key of the desired switch to control a device.

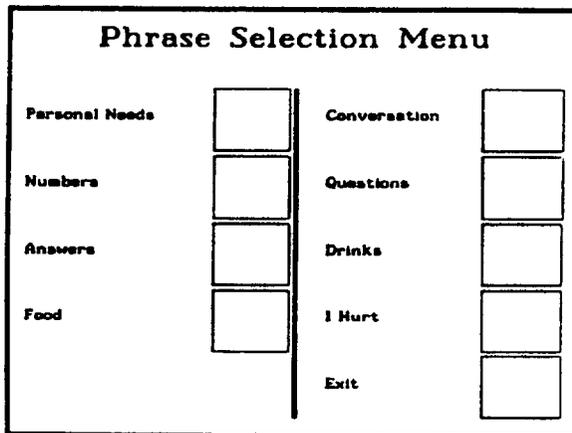
The Eyegaze System uses the X-10 Powerhouse^{*} Home Controller to make the electrical connection between the computer and the appliance switches. The X-10 Powerhouse sends signals over the existing house wiring to control small modules that plug in between the electric outlets and the appliance plugs. (The lights and appliances may also be controlled manually by non-disabled people by physically pushing switches on the control panel of the X-10 device.)



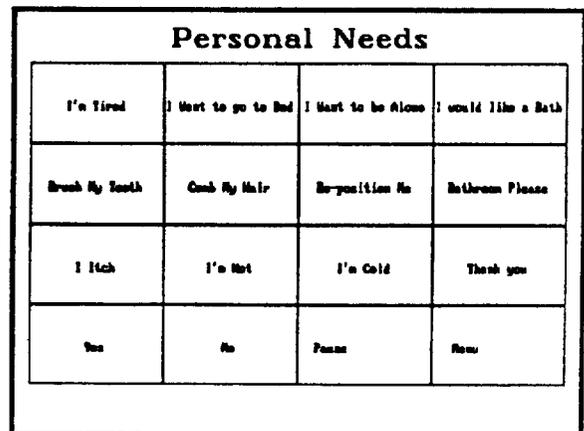
Lights and Appliances Control Screen

PHRASES

With the use of a speech synthesizer, the Phrases program allows a nonverbal person to verbalize regularly-used phrases with a single glance of the eye. It eliminates the need for the user to type in the whole phrase each time he wishes to speak it. The Phrases Menu allows the user to select different categories of phrases. The individual Phrases screens use a simple large-key format for people with limited eye control. The "pause" button on the screen allows the user to deactivate Phrases keys temporarily so he can look at the screen without verbalizing phrases. Hitting the "pause" button again re-activates the Phrases keys. LC Technologies provides a library of eight sets of phrases as a starting point for the user. As discussed later, the phrases are easily edited to meet individual needs.



Phrases Menu



Example Phrases Screen

* X-10 Powerhouse is a trademark of X-10 (USA) Inc

68

TELEPHONE

The Telephone program allows a person to place and receive telephone calls. The phone system consists of a speakerphone, an automatic dialer, and a telephone control screen for eyegaze control. Nonverbal people use the speech synthesizer to speak into the speakerphone.

The number to be dialed is selected by visually pushing the appropriate digits on the keypad display. Alternatively, the user may press the "Book" key which displays a list of up to 15 stored numbers, and a single eye stroke then selects the full phone number. When the user presses the "dial" button, the Eyegaze System dials the number. When the phone is answered, nonverbal users introduce themselves by activating the "announce" button which verbalizes a stored message. To continue the conversation, the nonverbal user exits the Telephone program and uses the Phrases and/or Typewriter programs to speak. When the conversation is over, he re-enters the Telephone program and activates the "hang-up" button.

Incoming phone calls are answered by entering the Telephone program and pressing the "answer" button. The "announce" key may be activated to introduce the nonverbal user.

Telephone							
1	ABC	DEF	Dial	<-Erase	Annce.		
4	GHI	JKL	Pause	Dial	Answer		
7	MNO	PQR		HangUp	Pause		
*	STU	VWX		Clear	Book		
	YZ0	#					Exit

Telephone Program

READ TEXT

The Read Text program enables the user to access any text that is in a computer-readable format. Upon entering the Read Text program, the computer presents a menu of the texts available on the computer disk. At this point, the user may select a text, page forward through the list of available texts, or exit back to the Main Menu. If the user selects a text, the Eyegaze System displays the first page of the text for the user to read. Once the text is displayed and the user has read what he wants, he may page forward through the text, page back, or return to the text selection menu.

Select File	
11/3/88: Disabled Can Operate New Computer System With Their Eyes	<input type="checkbox"/>
11/7/88: Eyes Control Computer Keyboards	<input type="checkbox"/>
Eyegaze Computer System User's Manual (Draft)	<input type="checkbox"/>
10/17/88: Seeing is Believing...	<input type="checkbox"/>
Total Files: 14	
Files Listed: 5 to 8	
Next Page	<input type="checkbox"/>
Exit	<input type="checkbox"/>

Read Text Selection Menu

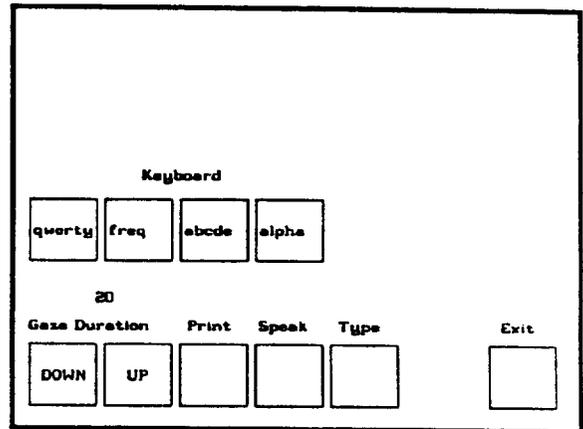
Eyegaze Computer System: Let Your Eyes Do the Typing (And More)		
from "In the Mainstream," Nov.-Dec. 1988 by Nancy Cleveland		
"W-a-i-t-y-a" Marilyn Hoggatt, President of the Oklahoma Chapter of the National Spinal Cord Injury Association, had an opportunity in August to type her name with her eyes using a new vision-controlled computer at the NSCIA Conference in Denver. A quadriplegic, she uses a sip and puff switch to run her wheelchair, but finds it too slow for typing. "I just love this thing! I've got to have one of these. Using this computer, I could return to my old job doing data entry."		
Designed for use by people with severe disabilities, the Eyegaze Computer System has been developed by LC Technologies to bring a broad variety of functions together under control of a person's eyes. The System's capabilities include typing, word processing, speech (via voice synthesizer), controlling		
Page Down	<input type="checkbox"/>	Page Up
	<input type="checkbox"/>	Menu
	<input type="checkbox"/>	<input type="checkbox"/>

Text Reading Screen

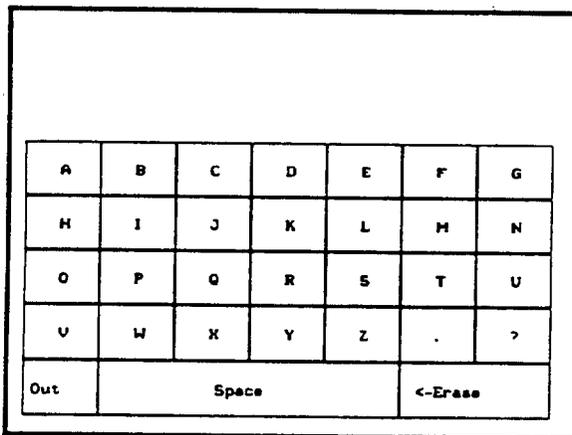
TYPEWRITER

The Typewriter program allows a person to type simply by looking at the keys on a keyboard display. As the user types, the typed characters appear on the screen above the keyboard. Four different keyboards are available. The Alpha keyboard is a simplified, large-key layout for use by children or people with limited gaze fixation accuracy. The key dimensions are 1" by 1 1/4". The Qwerty, Alphabetic computer, and Frequency computer keyboards all have 5/8" square keys. The Qwerty keyboard is a standard typewriter layout. The two computer keyboards contain all the keys on a full computer keyboard and are designed to enable the user to operate the Eyegaze System as a standard computer. (See the discussion of the Eyegaze DOS Mode.)

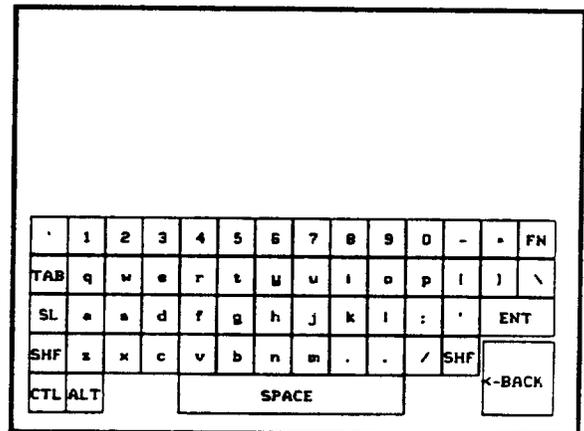
The Keyboard Control Menu allows the user to select the keyboard he prefers, change the gaze duration (to increase or decrease typing speed), print what he has typed, verbalize it via the speech synthesizer, return to the typewriter keyboard, or return to the Main Menu.



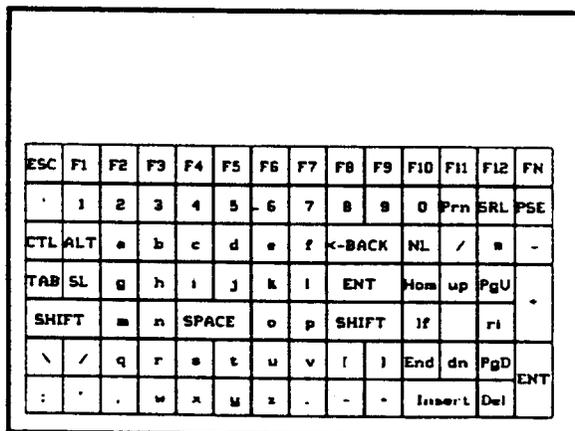
The Keyboard Control Menu



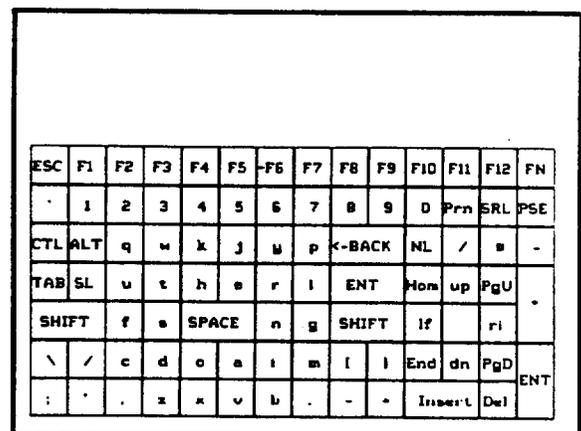
The Alpha Keyboard



Qwerty Keyboard



Alphabetic Computer Keyboard



Frequency of use Computer Keyboard

TV/VCR CONTROL

The TV/VCR Control program provides a disabled person control of any remote controlled television and video cassette recorder. The TV and VCR control functions are displayed on the Eyegaze Control Monitor, and the user activates the controls by looking at the desired keys. A universal infrared remote controller connected to the computer takes commands from the Eyegaze System and transmits them to the TV and VCR.

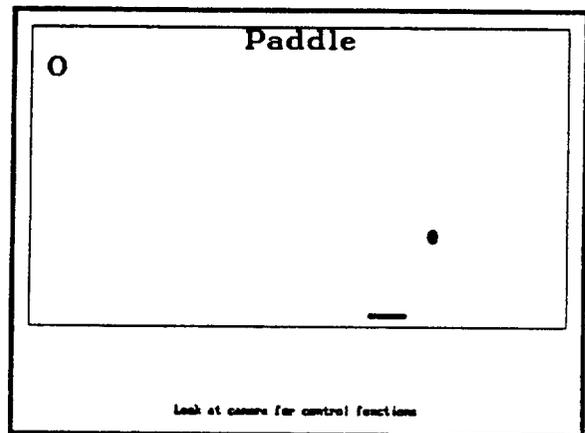
TV		Channel			VCR	
Mute	Power	4	5	7	Power	TV/VCR
Ch Up	Ch Dn	9	20	22	Stop	Play
Vol up	Vol dn	26	32	45	Rewind	Fast F
VOL UP	VOL DN	Pause	Next Page	Pause	Exit	

TV / VCR Control Menu

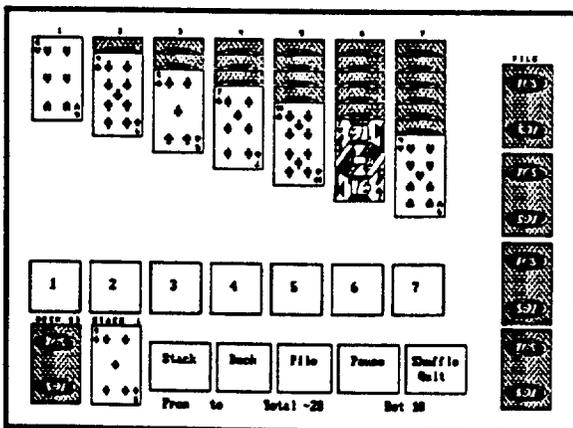
GAMES

There are several eye-operated games that a person can play on the Eyegaze System. In the Paddle game, a ball bounces around the screen and the user maneuvers the paddle with his eyes to bounce the ball back up in the air so it doesn't hit the ground. The user moves the paddle side to side with his horizontal eye motion. The Paddle game puts a disabled person into a dynamic action environment, gives him good eye motor control exercise, and provides practice in controlling things with his eyes.

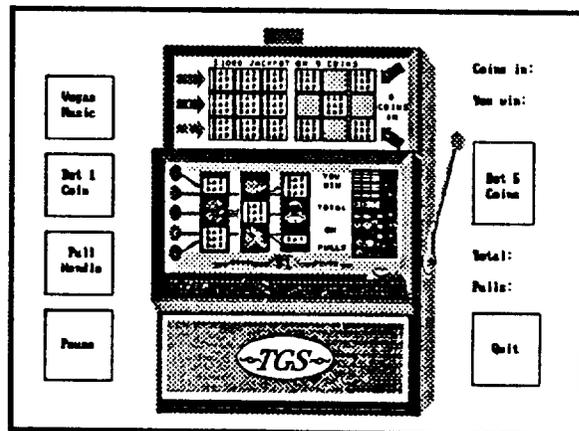
Other games include Klondike Solitaire and a slot machine from Ted Gruber Software.



Paddle Ball Game



Klondike Solitaire Game



Microbucks II Slot Machine Game

EYEGAZE DOS MODE

In the Eyegaze DOS Mode, the user has access to the Personal Computer's Disk Operating System, and he runs the Eyegaze System as a standard computer. He can run off-the-shelf DOS software programs that use keyboard input, such as word processors, data base systems, computer programming tools, CAD software, spread sheets, graphics programs and entertainment packages.

In the Eyegaze DOS Mode, the Eyegaze Computer keyboard screen appears on the Control Monitor, replacing the manual keyboard. Displays generated by the DOS software programs appear on a third monitor called the Applications Monitor. As the user types in DOS commands and runs programs, the characters he types appear at the top of the keyboard screen. The computer responses to his inputs occur on the Applications Monitor.

CAREGIVER AIDS

The Eyegaze System has several features to aid caregivers in teaching disabled people to learn to use the Eyegaze System. The Eyegaze Teaching program, which the caregiver brings up manually outside the framework of the Main Menu, presents a simplified calibration procedure with fewer calibration points and lower requirements for the user to keep his gaze fixed on the calibration points. After the user calibrates, the caregiver selects among five different very-large-key screens to help the user practice various aspects of his gaze control and gain experience pressing keys visually. The Teaching program responds to the user's visual key presses by flashing the keys and verbalizing responses.

Within the Main Menu framework, the caregiver can activate many of the system selections by physically pressing keys on the manual keyboard that correspond to visual keys on the screen. Thus, for example, the caregiver can move to programs of his choice or help the user out of difficult situations, without the user having to do it with his eyes.

CUSTOMIZING THE EYEGAZE SYSTEM

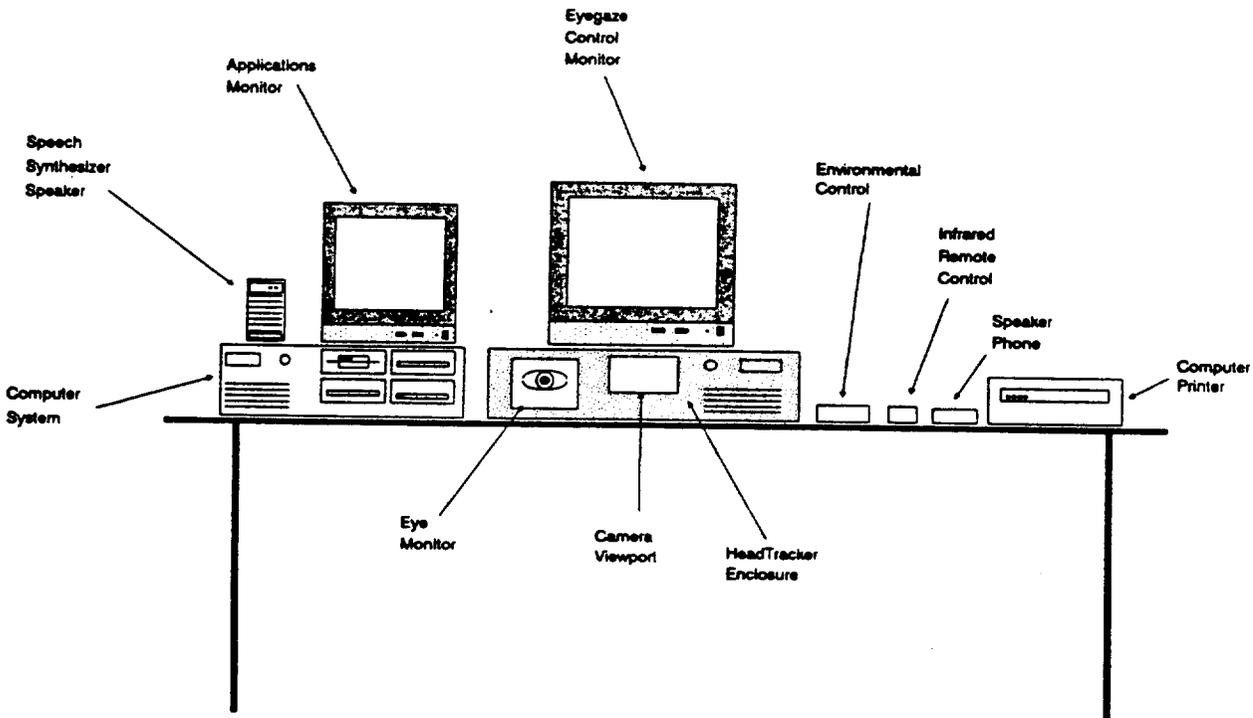
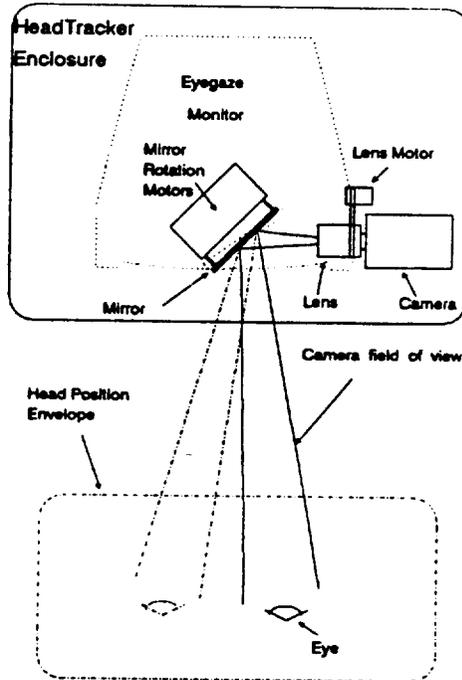
Many of the Eyegaze programs have user selectable parameters, data and information. The gaze duration, phrases, appliance names, and paddle width, for example, can all be easily changed. The user or the caregiver may edit the Eyegaze text or change the Eyegaze data values by running a program called CONFIG. The disabled user can access the CONFIG program through the Eyegaze DOS Mode.

HEADTRACKER™

Designed to compensate for poor head control or spasticity, the HeadTracker is a device that allows the Eyegaze camera to follow the user's eye as he moves his head throughout a large volume of space. The HeadTracker system uses a rotating mirror to track vertical and lateral head motion and an automatic focus to keep a clear camera image of the eye as the user moves his head back and forth. The HeadTracker can compensate for head motions over a range of 18 inches side to side, 10 inches up and down, and 10 inches forward and back.

The HeadTracker is enclosed in a 7-inch high cabinet which replaces the monitor support arm. No attachments to the head are required.

HeadTracker (top view)



Eyegaze System with HeadTracker

**EYEGAZE SYSTEM FOR THE DISABLED
COMPONENTS & PRICES**

BASIC SYSTEM:

Eyegaze Software/Hardware (without computer system)	\$16,600
Main Menu Program	
Phrases Program (speech available as an option)	
Eyegaze Keyboard Emulator Program	
Games Programs	
Read Text Program	
Teaching Program	
Monitor Support Arm with Camera Bracket	
High-Speed Infrared Sensitive Camera and 75mm TV lens	
Infrared LED, Power Source and Filter	
Video Frame Grabber Board	
Eye-image Video Monitor (Monochrome)	
Power Surge Protector	
Telephone Modem for Transfer of Software Updates	
All Necessary Cables and Connectors	
Installation, Training & 1 Year Warranty	
 Computer System (80286 based computer w/ math co-processor)	 3,000
Applications Monitor (VGA Color Screen)	
Manual Keyboard (as alternate input device)	
1.2 Megabyte Floppy Disk Drive	
40 Megabyte Hard Disk Drive	
Disk Operating System Software	

BASIC SYSTEM: 19,600

STANDARD OPTIONS:

Telephone Program, Speaker Phone	350	
TV/VCR Control Program, Programmable Infrared Remote Controller	350	
Lights and Appliances Control Program	350	
X-10 Powerhouse™ Appliance Controller		
Eight Lamp and Appliance Modules		
Panasonic Dot Matrix Printer	250	
Prosc 4000 Speech Synthesizer	1,750	
Serial Interface Board (required for full option set)	495	
Total Standard Options:		3,545

STANDARD SYSTEM: 23,145

ADDITIONAL OPTIONS:

Computer Upgrade (80386 based computer w/ math co-processor, required for DOS capability or HeadTracker™)	1,000	
DOS Keyboard Emulation Capability	1,500	
Keyboard Emulation Monitor		
HeadTracker Assembly (delivery Spring 1990)	14,000	
Head Motion Tracking Assembly with Automatic Focus		
Total Additional Options:		16,500

FULL SYSTEM: 39,645

Virginia residents add 4.5% sales tax. The above prices do not include shipping or travel expenses.
Bank financing, short-term leasing, or lease-purchase options are also available.
The prices and specifications are subject to change without notice.

November 1989

LC TECHNOLOGIES, Inc. 4415 Glenn Rose Street, Fairfax, VA 22032 * Phone 1-800-733-5284 * (703) 425-7509 * FAX: (703) 323-4782

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118

BEST COPY AVAILABLE

9 74

Micro Measurements, Inc.
1921 Hopkins Street, Berkeley, Ca 94707

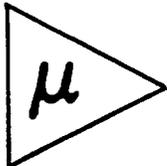
The literature is attached in the following un-numbered pages.

COMPUTER BASED INSTRUMENTS FOR:

- **PERFORMANCE**

- **SIMPLICITY**

- **FLEXIBILITY**



**MICRO
MEASUREMENTS
INC.**

**1921 HOPKINS STREET
BERKELEY, CA 94707**

(415) 841-1186

MICROMEASUREMENTS CATALOG OF PRODUCTS AND SERVICES

MARCH 1982

PRODUCTS

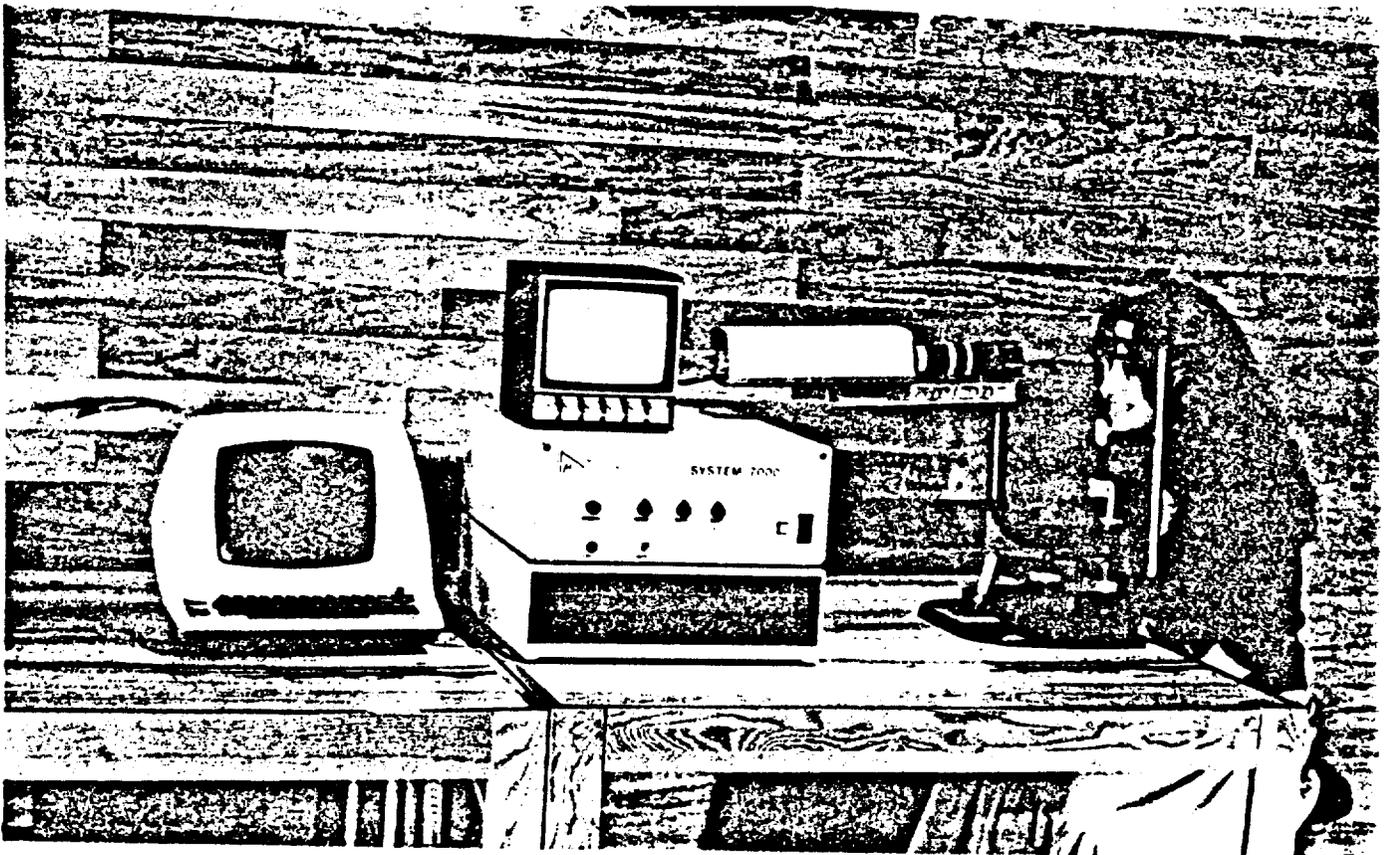
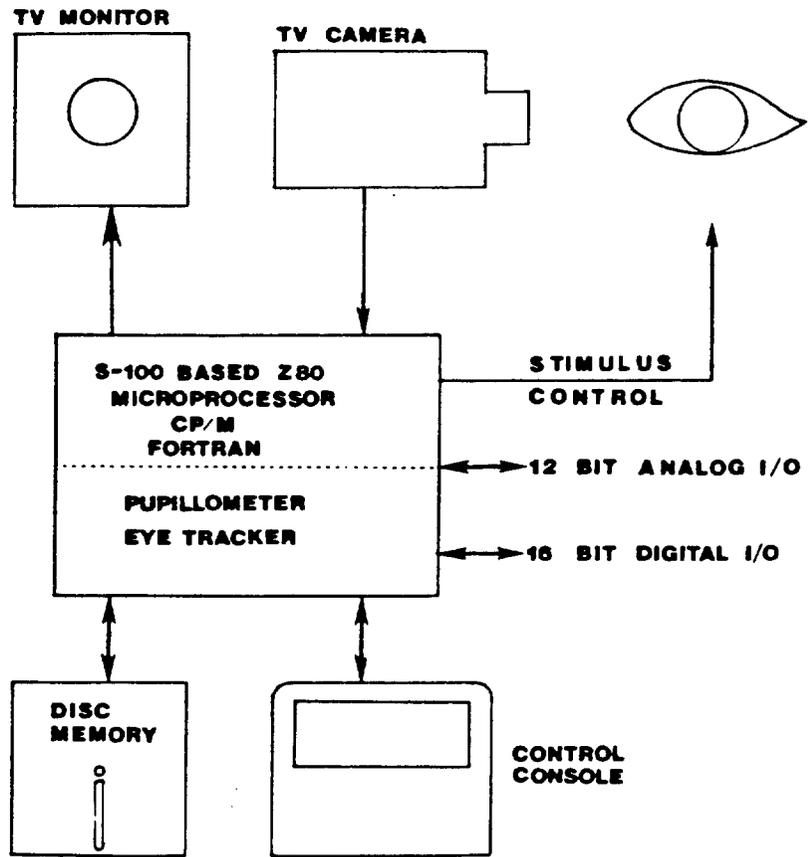
SYSTEM 7000 EYE MONITOR WITH COMPUTER
SYSTEM 1000 EYE MONITOR
LABORATORY COMPUTER SYSTEMS
DATA ACQUISITION AND ANALYSIS SOFTWARE

SERVICES

SYSTEM ENGINEERING
TURNKEY INSTALLATION
ON SITE TRAINING
SPECIAL PURPOSE SOFTWARE
CONSULTING

TABLE OF CONTENTS

PAGE	SECTION
3	EYE MONITOR SYSTEM DESCRIPTION
4	SYSTEM PERFORMANCE
5	SYSTEM CONFIGURATION
6	DATA ACQUISITION AND ANALYSIS SOFTWARE
7	THE AREA MEASUREMENT TECHNIQUE
8	EYE MONITOR SYSTEM OPTIONS
9	EXAMPLES OF DATA
10	COMPUTER SYSTEMS
11	APPENDIX



MMI EYE MONITOR SYSTEMS

PERFORMANCE

The MMI Eye Monitor Systems measure horizontal and vertical eye position and pupil size in realtime. These systems employ the area measurement method to find pupil size and to track the center of the pupil. Therefore, the signal to noise and resolution advantages which apply to pupil size measurement (see page 7) obtain for eye position as well. Every eye position and pupil measurement method is subject to errors of various types. The computer allows most of these errors to be corrected in realtime (see page 6). The system tolerates blinks, eyeglasses and contacts, ptosis, and irregular pupils, and some head movement. Use of an IR camera means that cross talk between horizontal and vertical eye movement is minimized, as is the influence of ambient fluorescent light.

SIMPLICITY

A computer should make an instrument system easier to use, not harder. The computer controls the experiment as specified by the user. It automatically generates calibration patterns and experimental stimuli, controls recording equipment, and provides a tracking window which assures a high quality image. Relieved of these tasks, the user may concentrate on the experiment rather than the apparatus.

FLEXIBILITY

The inherent flexibility of software, coupled with a proven computer system, means that the MMI Eye Monitor System will grow and adapt as your needs evolve. The system is built around an S-100 based 280 microcomputer, operating under CP/M*. This configuration is recommended by Thompson and Webster in their new book Microprocessor Based Medical Instrumentation Systems¹. The S-100 is the only computer bus with an IEEE standard configuration, ensuring compatibility among manufacturers. It is easily expandable, and many I/O and specialized hardware devices are available. A wealth of software, including fortran, basic, word processing, and scientific computation software are presently available. Thompson and Webster summed up the importance of CP/M: "CP/M is to software compatibility what the S-100 bus is to hardware compatibility".

* Registered Trademark of Digital Research Corporation

1

Prentice Hall, 1981.

PERFORMANCE-SYSTEM 1000 and SYSTEM 7000 EYE MONITORS

PUPILLOMETERY

Resolution:	12 bits
Precision:	.001mm diameter (Typical)
Signal to Noise Ratio:	60 dB
Range:	0-10mm diameter
Linearity:	Within 1/2%
Sampling Rate:	60 Hz
Errors due to Eye Position:	Corrected (See Page 6)
Allowed Eye Movement:	40 degrees horizontal 30 degrees vertical
Controls:	Mode (Manual-Auto) Pupil Threshold Circular window size and position AutoCalibration

EYE POSITION MONITOR

Eye Position Output: (Analog or Digital)	8 bits horizontal, 8 bits vertical
Resolution:	1/2 LSB (Typically $\pm .1^\circ$)
Range:	Depends on Lens (Typically $\pm 20^\circ$)
Interchannel Isolation:	30 dB
Sampling Rate:	60 Hz
Errors Due to Small Head Movements:	Corrected (See page 6)
Controls:	Same as Pupillometer

Specifications subject to change without notice.
Performance parameters depend upon lens and camera placement

BEST COPY AVAILABLE

80

CONFIGURATION-SYSTEM 7000 EYE MONITOR

The System 7000 Eye Monitor System comprises a computer system, a video system, and a headrest/camera mount. These components are fully described in the data sheets in the appendix. The System 7000 may be used as a general purpose computer, e.g. for data collection, data analysis, simulation, and graphics.

SUMMARY OF SYSTEM PARAMETERS

Computer System:

CPU: 280 6 MHz with 24 bit address capability allows access to 16 MBytes of memory. Compliant w/IEEE 696/S-100 Specification.

Memory: 64K Static RAM-compatible with 10 MHz CPU
8K EPROM (Up to 32K optional)
600K Dual Floppy Disk Drives-with DMA.
10M Byte Winchester Hard Disk (optional)

I/O: 2 independent, programmable, serial I/O ports, with RS-232 drivers. Hardware UARTs.

A/D: 32 s/e, 16 d/e channels of 12 bit A/D.

D/A: 4 channels of 12 bit D/A.

Chassis: 20 card slots, fully terminated motherboard with Faraday shielding. HD power supply.

Terminal: Televideo 912C (ADM-3A Optional)

Video System:

Camera: RCA TC1005/U01
1" Infrared sensitive Ultracon tube
Resolution: 700 TVL lines.
Bandwidth: 10MHz
Lens: 150 mm 1:3.3

Monitor: RCA TC1009-9" B/W (Desk top or rack mount)

IR Source: 7800-14000 Angstroms. Filtered to eliminate visible light.

SYSTEM 1000

The System 1000 is identical to the 7000, except that a dedicated hardware computation unit is substituted for the computer. Thus the system 1000 cannot function as a general purpose computer. The System 1000 may be upgraded to a 7000.

MMI-81: DATA ACQUISITION AND ANALYSIS SOFTWARE PACKAGE

The MMI-81 data acquisition and analysis package comprises five major programs. More capabilities are being developed and will be announced as they become available.

EM-The Eye Monitor program collects and stores eye position, pupil size, and up to 16 additional channels of 12-bit data at a 60 Hz sampling rate. It automatically adjusts the circular windows, and outputs analog or digital signals representing eye position (horizontal and vertical) and pupil size (area or diameter). It provides for automatic calibration of eye movement and pupillometer measurements and collects narrative data in a header.

The Eye Monitor program performs realtime error correction of eye position and pupil area measurements. Errors in pupil size due to changes in gaze angle are corrected according to an empirical relation developed by Haines (Amer.J.Opth. 68 (4),1969). Errors in pupil size due to nonlinearities in the detector are corrected by a simple lookup table. Errors in eye position due to small (less than about 2 cm) head movements are corrected by comparing the movement of the first Purkinje image with that of the center of the pupil. The difference represents an improved measure of true eye movement. The Eye Monitor program recognizes blinks by noting that the apparent pupil area has fallen below the physiological range. It implements a search algorithm which recovers eye position in less than 30 msec.

AD/DA-The analog to digital/digital to analog conversion program is a general purpose data collection/data output routine, similar to the EM program. This program allows the user to collect or read out data at up to 20 KHz (total all channels), preprogram stimuli, provide for rest periods, and control other experimental apparatus.

ANALYSIS-The data analysis package includes the following:

- AVG-average a series of records.
- DERIV-Take the time derivative of a record.
- SMOOTH-smooth a record to remove artifacts, e.g. blinks.
- FILT-Linear or nonlinear filter.
- FFT-Fast Fourier Transform.

STIM-The stimulus program allows the user to create a file of arbitrary stimulus values. This file is interpreted by the EM program or by the AD/DA program, which then output analog signals to control the stimulus. When used with the AD program, it is updated at a rate specified by the user for data collection.

CONVERT-This program converts binary data, as generated by the EM or AD programs, to ASCII format. This is useful for transferring data between different computer systems.

SRI International
333 Ravenswood Avenue, Menlo Park, CA 94025

The literature is attached in the following un-numbered pages.

BEST COPY AVAILABLE

83

BINOCULAR VISUAL PROCESSES AND INSTRUMENTATION

Development of the DPI Eyetracker

Final Report

August 1982

By: Hewitt D. Crane, Director
Visual Sciences Program
Bioengineering Research Center

Prepared for:

U.S. Public Health Service
National Eye Institute
9000 Rockville Pike
Bethesda, Maryland 20205

Grant EY 01031

SRI Project 3336

SRI International
333 Ravenswood Avenue
Menlo Park, California 94025
(415) 859-6200
TWX: 910-373-2046
Telex: 334 486



84

I INTRODUCTION

This report summarizes the development of the dual-Purkinje-image (DPI) eyetracker, and associated equipment, over the eight-year course of NEI Grant EY 01031 (from March 1974 to April 1982). The development can be traced through several generations, with instruments having been made for various laboratories at each stage of development. With the termination of this grant, we have reached the fifth and, at least for the moment, final design of the instrument.

The basic instrument is now much smaller in size and much easier to use than earlier models and, most importantly, is much more accurate. This continuous process of improvement would not have been possible without the steady support of this grant and of an earlier National Institutes of Health (NIH) grant from the National Institute of Neurological Diseases and Blindness in the late 1960s (see Section II). Other elements of support came from the many institutions that purchased instruments, and from two periods of National Aeronautics and Space Administration (NASA) support---from 1965 to 1971 and again from 1978 to 1982.

The eyetracker is now being used in a number of different vision research laboratories. As of this writing, one of its first clinical applications is awaiting initial clinical testing at the Eye Research Institute (ERI) of the Retina Foundation, Boston, in the form of a stabilized laser photocoagulator. Some other current applications are summarized in Section IV.

6.2 Identification of Materials

The materials used in the ober2 include the following:

1. A printed circuit controller board for use in an IBM compatible microcomputer. It interfaces the measuring system with the IBM (or compatible) microcomputer. The board is powered by +/- 15 Volts dc.
2. A goggles adapter card which connects the eye movement goggles with the controller board. It has a DB-25 connector which connects to the main board, and two male connectors which connect to the cables from the goggles. It also has a 4mm socket for use with a wrist band which is used to cut down static charge.
3. A synchronizing unit which controls the sampling rate. This has a DB-15 male connector which connects to the controller board.
4. A low voltage dc supply which powers the synchronizing unit.
5. The eye movement measuring goggles with flat ribbon cables which connects to the goggles adaptor card.
6. A wrist band with cable to cut down potentially interfering static signal. A one megohm limiting resistor in the cable) which connects to the 4mm socket in the goggles adaptor card is used to limit the static current level.
7. A 5.25" floppy diskette containing the ober2 software, and start up instruction file. This software operates under DOS 3.3 or later versions.
8. A manual containing installation and operating instructions.

6.3 Identification of Design and Design Considerations

6.3.1 Features

The ober2 infra-red eye movement monitoring system can be used with any IBM personal computer PC/XT/AT or other compatible system. The system requires DOS version 3.3 or later, plus an EGA graphics card, and a high resolution EGA monitor.

6.4 Energy expected to be Used or Delivered by Device

The eyes are illuminated by low level infra red (IR) light emitting diodes, and the diodes are operated with low duty cycles to further reduce the average energy.

The goggles are made of insulating rubber so that there is no electrical contact with the user. A plastic shield is placed over the goggle electronics to further increase the electrical isolation.

The IR energy for each eye is 0.76 mW/sq cm and is much less than the 10 mW/sq cm that is specified by the American Conference of Governmental Industrial Hygienists in their document "TLVs, Threshold Limit Values and Biological Exposure Indices for 1985-86", with a publication identification number of ISBN: 0-936712-61-9. This document has a section covering "Biological Exposure Indices", and their information for infrared radiation is given on p. 97. The relevant information is quoted here for convenience.

"Infrared radiation: To avoid possible delayed effects upon the lens of the eye (cataractogenesis), the infrared radiation (wavelength=770 nm) should be limited to 10 mW/sq cm."

6.5 Description of Operational Principles of Device

Infra-red reflection can be used to measure eye movements because of the different reflective properties of the various parts of the eye. The white of the eye will reflect back more of the IR light than the colored portion (iris and pupil) of the eye. By using this difference, a calculation of the position of the eye in relation to each of the IR detectors can be made. Less IR light will be reflected back to the sensors which are nearer the colored part of the eye. An array of four such detectors can be arranged around the eye in order to measure both horizontal and vertical positions and movements.

The system measures the difference in position that results from movement of the eye. The absolute position is determined by using the data recorded when the eye looks at a number of horizontal and vertical calibration targets. This gives the absolute zero position as well as the scale factors.

The ober2 does not monitor the position of the eyes continuously, but uses short pulses of IR light at frequencies of 50Hz and above to measure the eye position intermittently.

6.6 Warranty

The unit comes with a full one year limited warranty on parts and labor. A copy of the warranty is included on the following page.

permobil of America, Inc.

30 Ray Avenue Burlington, Massachusetts 01803
Phone: (800) 736-0925 • FAX: (617) 229-9841

LIMITED WARRANTY ONE FULL YEAR PARTS AND LABOR

Permobil of America, Inc. (PAI) agrees that the Permobil will be free of defects in material and workmanship for a period of one (1) year under normal use and service; and PAI's obligation as set forth herein is limited solely to repair or replacement, at PAI's option, at a PAI service center designated by PAI, of any part or parts thereof which (i) our examination shall disclose to our satisfaction to have been defective, and (ii) which shall, within one (1) year from date of original installation or eighteen (18) months from the date of shipment from factory to the Purchaser, whichever date may first occur, be returned to PAI at its designated service center with transportation charges to PAI, and from PAI to Purchaser, prepaid.

THIS AGREEMENT TO REPAIR OR REPLACE DEFECTIVE PARTS IS MADE EXPRESSLY IN LIEU OF AND IS HEREBY IN DISCLAIMER OF ALL OTHER EXPRESS WARRANTIES, AND IS IN LIEU OF AND IN DISCLAIMER AND EXCLUSION OF ANY IMPLIED WARRANTIES OR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AS WELL AS ALL OTHER IMPLIED WARRANTIES, IN LAW OR EQUITY, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON OUR PART, AND IN NO EVENT WILL PAI BE LIABLE FOR SPECIFIC, INDIRECT OR CONSEQUENTIAL DAMAGES ARISING OUT OF THE DELIVERY, USE OR PERFORMANCE OF PRODUCTS SOLD HEREUNDER. THERE ARE NO WARRANTIES WHICH EXTEND BEYOND THE DESCRIPTION HEREOF. PAI neither assumes nor authorizes any person to assume on behalf of PAI any liability or obligation in connection with the sale of Permobil, except the repair or replacement of the defective parts as set forth above. PAI's liability does not include any labor charges for replacement of parts, adjustments, repairs, or any other work done by parties other than PAI, and PAI's liability does not include any consequential or resulting damage to person, property, equipment, goods, merchandise, profits, goodwill or reputation arising out of any defect in or failure of the Permobil. PAI's obligation to repair or replace shall not apply to any Permobil which shall have been repaired or altered in any way by parties other than PAI, or such other repair facilities as are designated by PAI, or which has been subject to negligence or to misuse. ON PARTS NOT OF PAI'S MANUFACTURE, PAI EXTENDS ONLY THE SAME WARRANTIES AS GIVEN TO PAI. PAI'S AGREEMENT HEREUNDER RUNS ONLY TO THE IMMEDIATE PURCHASER AND DOES NOT EXTEND, EXPRESSLY OR BY IMPLICATION, TO ANY OTHER PERSON. Nothing in the above warranty provisions, however, shall impose any liability or obligation of any type, nature or description upon PAI if PAI has not received payment in full for the Permobil.

BEST COPY AVAILABLE 90

END

**890627
perm-35-3
510k006g.wp0**

BEST COPY AVAILABLE

91