U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(anastazia.taylor)
FOLDER:	K012530 - 1236 pages
COMPANY:	NEUROVISION, INC. (NEUROVISION)
PRODUCT:	HAPLOSCOPE (HJT)
SUMMARY:	Product: AA-1 SYSTEM
DATE REQUESTED:	Sep 9, 2016
DATE PRINTED:	Sep 9, 2016
Note:	Printed

K012530

AUG 3 1 2001

510(k) Summary of Safety and Effectiveness

Submitter: Company Name: Neuro-Vision, Inc.
Address: 111 South Bedford Street Suite 100
Burlington, Massachusetts 01803
Phone: (781) 221-4680
Fax: (781) 221-7468

Registration : Pending

Manufacturer Information:

Company Name: NeuroVision, Inc.
Address: 111 South Bedford Street Suite 100
Burlington, Massachusetts 01803
Phone: (781) 221-4680

Registration Number: Pending

Official Correspondent: Richard E. Lippman, O.D., F.A.A.O.
Address: C.L. McIntosh, Inc.
12300 Twinbrook Parkway Suite 230
Rockville, Maryland 20852
Phone : 301-770-9590
Fax: 301-770-9584

DEVICE IDENTIFICATION:

Trade Name: AA-1 System for the Treatment of Amblyopia
Common Name: Amblyopia Treatment Device
Classification Name: Haploscope; Eye patch

CLASSIFICATION
Name and Reference: 21 CFR 886.1340 haploscope

REGULATORY CLASS Class I

COMMON NAME: Amblyopia Treatment Device

ESTABLISHMENT REGISTRATION: Pending

INDICATION for USE:

The AA-1 System is indicated for the treatment of amblyopia using an interactive computerized program in patients 9 years or older suffering from amblyopia.

SUBSTANTIALLY EQUIVALENT TO:

The Neurovision AA-1 System is substantially equivalent to an ophthalmic Haploscope, a Class I Exempt medical device that is an AC powered device consisting of two movable viewing tubes, each containing a slide carrier, a low intensity light source for illumination of the slides, and a high

intensity light source for creating an afterimage. The intended use of the device includes amblyopia treatment and treatment of suppression.

The Neurovision device is equivalent to the haploscope (Preamendments Device 886.1340) with respect to the intended use- treatment of amblyopia. Additionally, the subject device is further equivalent to a haploscope in its principal of action, in that the low intensity light stimulus on the haploscope slides are used to bring light stimulus to the eyes when the target slides are moved with respect to each other.

The Neurovision AA-1 System is also substantially equivalent to the Humphrey Visual Field Analyzer (K852639) in that both devices collect diagnostic information through the use of software that interprets data information and reports diagnostic information useful to the user employing the device for further diagnosis and or treatment in the given indication for use.

Lastly, the Neurovision AA-1 System is substantially equivalent to an Eye Shield (K896171) Eye Garter Company, and Eye Shield (K841599) Storz Instrument Company, that is customarily used to cover the good eye during amblyopic treatment of the amblyopic eye during treatment sessions to improve visual acuity in the affected eye.

DEVICE DESCRIPTION:

The device is a computerized interactive device that provides the user with a series of linear images oriented in vertical and horizontal planes on a video imaging screen that is designed to identify and correct visual dysfunction from reduced visual acuity by re-training the eye to utilize its optimal visual response in gaining an increased awareness of visual acuity through a series of training sessions. The device analyzes the patient's visual acuity deficiencies and sets a program for the user to increase the demand on the visual system resulting in an improvement of visual acuity. The device pre-programs a series of visual stimuli tasks and takes the patient through a series of interactive functions in identifying various objects on the video screen, and helps to provide an environment that increases visual response.

CLINICAL INVESTIGATION

A prospective randomized and controlled clinical investigation was conducted to evaluate the potential for improvement and retention of visual acuity in persons of 9 years of age or older who suffer from amblyopia (lazy eye) from any source. The investigation consisted of a series of treatment sessions in an interactive environment using a pre-programmed analysis of visual debilitation from amblyopia and a computerized software program that had analyzed the visual defect and carried the subjects through a series of sequential treatments designed to improve visual resolution capability. The investigation consisted of visual stimuli projected onto a video monitor and patient responses being recorded by the click of a computer mouse responding to the various visual stimuli. The computerized program archived the responses and analyzed the responses in preparing the subjects for the subsequent treatment session. Completion of the treatments was established when the subjects no longer improved visual acuity, and were stable to the same visual acuity readings for three consecutive visits. After a three month rest period from treatments, the subjects were measured for their ability to retain the visual improvement that was gained during the first phase of the treatments.

The investigation of the device demonstrated that the subjects who completed the study with the long term follow-up three month visit improved visual acuity performance by an average of 2.5 lines of visual acuity from their baseline visual acuity best corrected vision. Greater than 70% of the subjects showed consistency in visual improvement. The control group treated by placebo treatment showed no improvement and was detected earlier in the study

LABELING

The Neurovision AA-1 System for the Treatment of Amblyopia is provided with a User Manual for the Practitioner, and two additional brochures, one for the professional and one for the patient. The information is available from the company:

Neurovision, Inc.
111 South Bedford Street
Suite 100
Burlington, Massachusetts 01803
(781) 221- 4680

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2001

Neuro Vision, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
C.L. McIntosh, Inc.
12300 Twinbrook Parkway Suite 230
Rockville, Maryland 20852

Re: K012530
Trade Name: AA-1 System
Classification Regulation Number: CFR 886.1340
Regulatory Class: Class I
Product Code: HJT
Dated: August 3, 2001
Received: August 6, 2001

Dear Dr. Lippman:

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 (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications Statement

510(k) Number (if known) K012530

Device Name: Vision Treatment System for Amblyopia (AA-1 System)

Indications for Use:

The Vision Treatment System is indicated for the treatment of amblyopia using an interactive computerized program in patients 9 years or older suffering from amblyopia.

Additional Claims:

Attributes of the Device:

- -Improved Vision
- -Improved Stereoscopic Vision
- -Improved Contrast Sensitivity

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Presription Use ✓ OR Over -The-Counter Use _____

(Oprtional Format 1-2-96)

Dennis L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012530

ONDB – BSC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 12/28/09

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K012530/A1

To: Division Director: OP / DONED

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: [signature]

Date: 1/4/10

K012530/A1

REVITALVISION™

FDA CDRH DMC
DEC
FDA CDRH DMC
Received
DEC 23 2009
Received
1C-36

December 15, 2009

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Letter to File K012530

To Whom it May Concern:

Attached to this letter is our letter to the Office of Compliance, along with a copy of NeuroVision, Inc., letter to the Office of Compliance, stating the RevitalVision LLC has purchased the assets of NeuroVision, Inc., on November 11, 2009. As part of our purchase, RevitalVision is now the owner of the 510(K) of NeuroVision registered under number K012530.

Please update your files to reflect this change in ownership.

Please contact me if you have any questions.

Sincerely,

Mark A. Hrinya
Chief Financial Officer
mark@revitalvision.com
785-856-0417

REVITALVISION™

December 15, 2009

Office of Compliance
Registration and Listing Branch
10903 New Hampshire Ave.
Building 66 Room 2621
Silver Spring, MD 20993-0002

RE: 510(k) number K012530

To whom it may concern:

On November 11, 2009 RevitalVision LLC purchased the assets of NeuroVision, Inc., including the Premarket Approval (PMA) device registered under number K012530. The registration is currently listed as follows:

Device Classification Name:	Haploscope
510(K) Number	K012530
Device Name	AA-1 System for Treatment of Amblyopia
Applicant	NEUROVISION, Inc. 12300 Twinbrook Pkwy, Ste 230 Rockville, MD 20852
Contact	Richard E Lippman
Regulation Number	886.1340
Classification Product Code	HJT

The change in ownership will not result in a change or modification that would require a submission of a PMA supplement (§814.39) or affect the conditions of approval applicable to the PMA. RevitalVision is committed to comply with all the conditions of approval applicable to the PMA and has in its position a complete copy of the PMA including all amendments, supplements, and reports.

Please update the information to show the new ownership as follows:

Applicant	REVITALVISION, LLC. 1617 St. Andrews Drive Lawrence, KS 66047
Contact	Mark A Hrinya

Enclosed with this letter in a letter from Nir Ellenbogen, Director of NeuroVision, Inc., confirming the asset purchase by RevitalVision LLC.

Please feel free to contact me if you have any questions or need further information to transfer this registration.

Sincerely,

Mark A Hrinya
Chief Financial Officer
mark@revitalvision.com
785-856-0417

NEUROVISION
A Sharper Tomorrow

NEUROVISION, INC.
156 Cecil Street #11-01
Far Eastern Bank Building
Singapore 069544

T: 65 6536 0195
F: 65 6536 2816
www.neuro-vision.com

Date: December 08, 2009

FDA CDRH
Office of Compliance
Registration and Listing Branch
10903 New Hampshire Ave.
Building 66 Room 2621
Silver Spring, MD 20993-0002

RE: 510(k) number K012530

To whom it may concern:

I hereby confirm that on November 11, 2009 RevitalVision LLC purchased the assets of NeuroVision, Inc., including the 510(k) device registered under number K012530.

Sincerely yours,

NeuroVision, Inc.
By: Nir Ellenbogen
Title: Director

Copy: Mark A. Hrinya, RevitalVision, LLC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2001

Neuro Vision, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
C.L. McIntosh, Inc.
12300 Twinbrook Parkway Suite 230
Rockville, Maryland 20852

Re: K012530
Trade Name: AA-1 System
Classification Regulation Number: CFR 886.1340
Regulatory Class: Class I
Product Code: HJT
Dated: August 3, 2001
Received: August 6, 2001

Dear Dr. Lippman:

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 (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications Statement

510(k) Number (if known) K012530

Device Name: Vision Treatment System for Amblyopia (AA-1 System)

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Additional Claims:

Attributes of the Device:

- -Improved Vision
- -Improved Stereoscopic Vision
- -Improved Contrast Sensitivity

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Presription Use ✓ OR Over -The-Counter Use _____

(Oprtional Format 1-2-96)

Dennis L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012530

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) DENIS L. McCARTHY

Subject: 510(k) Number K 013530

To: The Record - It is my recommendation that the subject 510(k) Notification:

SE

☐ Refused to accept.

☐ Requires additional information (other than refuse to accept).

☑ Is substantially equivalent to marketed devices. First of a kind comparison to device exempt by regulation HAPLOSCOPE.

☐ NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? ☐ YES ☐ NO

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

Is this device subject to Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☒ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: CLASS I EXEMPT 21 CFR 886.1340 Haploscope

Additional Product Code(s) with panel (optional): 86 HJT

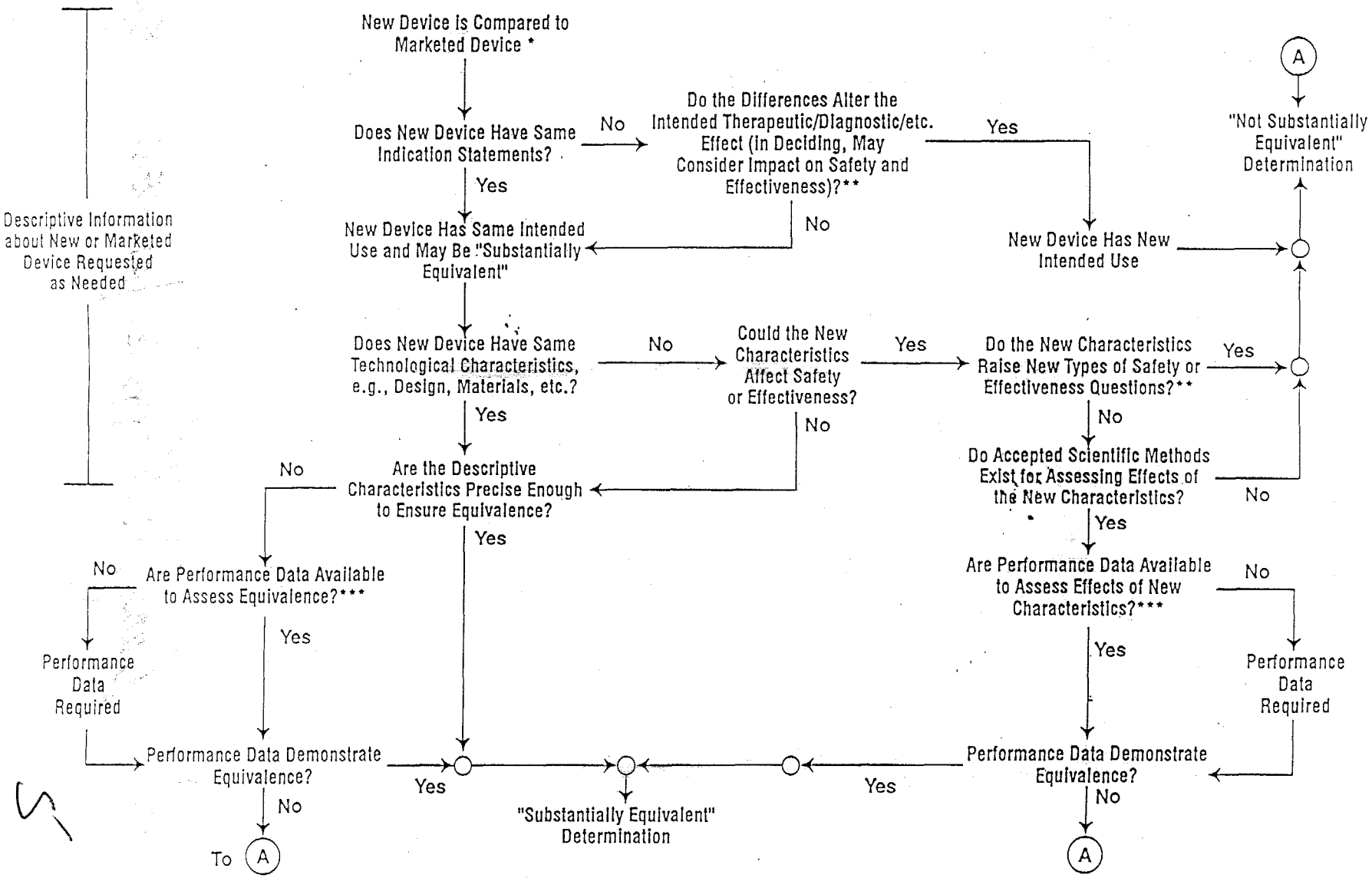
Review: [signature] (Branch Chief) DSRB (Branch Code) 8/29/01 (Date)

Final Review: [signature] for DOED (Division Director) 8/30/01 (Date)

Revised:8/17//99

4

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



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Info[illegible]ion if the Relationship Between Marketed and "Predicate" (Pre-Amendm[illegible] Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Te[illegible] Information is Sometimes Required.

*** Data May [illegible] the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

Screening Checklist
For all Premarket Notification 510(k) Submissions

3-30-01

Device Name: AA-1 System for treatment of Amblyopia | K012530

Submitter (Company): NEUROVISION INC.

Items which should be included (circle missing & needed information)	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO # 2, 5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	SPECIALS YES	SPECIALS NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i) including forms 3454 and/or 3455	NA		YES		NO		
a) trade name, classification name, establishment registration number, device class					✓		
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA				✓		
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*					✓		
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:					✓		
i) package labeling (user info)					✓		
ii) statement of intended use					✓		
iii) advertisements or promotional materials					✓		
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:						✓	N/A
i) Labeling					✓		
ii) intended use					✓		
iii) physical characteristics					✓		
iv) anatomical sites of use					✓		
v) performance (bench, animal, clinical) testing	NA				✓		
vi) safety characteristics	NA				✓		
m) If kit, kit certification							
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							
b) *STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS*			* If no - STOP not a special				

LABELING HAVE NOT CHANGED*				
c) ***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED****			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below							
iii) An identification, for each consensus standard, of							

any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed					
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device					
v) A specification of any deviations from each applicable standard that were applied					
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference					
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations					
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards					

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:						✓	N/A
i) component & material							"
ii) identify patient-contacting materials							"
iii) biocompatibility of final sterilized product							"
b) Sterilization and expiration dating information:							"
i) sterilization method							"
ii) SAL							"
iii) packaging							"
iv) specify pyrogen free							"
v) ETO residues							"
vi) radiation dose							"
c) Software validation & verification:						✓	
i) hazard analysis						✓	
ii) level of concern						✓	
iii) development documentation						✓	
iv) certification						✓	

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No**

Date: 8/13/'01

Reviewer: Denis L. McCarthy

Concurrence by Review Branch: DSDB

8

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K012530

Reviewer: Denis L. McCarthy

Division/Branch: DOED/DSDB

Device Name: AA-1 System for the treatment of amblyopia

Product To Which Compared (510(K) Number If Known): Haploscope (generic)

	YES	NO	
1. Is Product A Device	X		If **NO** = Stop
2. Is Device Subject To 510(k)?	X		If **NO** = Stop
3. Same Indication Statement?	X		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?		X	If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		X	If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?	X		If **NO** = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision: Substan. Equiv.

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

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

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: Upgraded technology (see attached device description for question #2 above.

6. Explain how new characteristics could or could not affect safety or effectiveness: Could not effect safety because hazards analysis demonstrates lack of potential for physical injury, could affect effectiveness because of the complexity of the technological upgrade.

7. Explain how descriptive characteristics are not precise enough: In addition to the descriptive characteristics explained in the submission, the performance tests described in submission attachment #9, appendices #3 and #4 were required in order to demonstrate the absence of new issues regarding device effectiveness.

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:

To: RECORD, K012530, Neurovision Inc AA-1 System for the treatment of amblyopia

From: Physicist - Optics

Subject: Device description for Substantial Equivalence Decision Making Document

The AA-1 System for the treatment of amblyopia is a computerized interactive device that provides the user (patient) with a series of images for viewing on a video imaging screen (monitor). The principle used for the treatment of amblyopia is based upon the patient identifying the images that are flashed on the screen. Correction of visual dysfunction is a result of training neurons in the visual cortex so that they may provide optimum visual response thereby acquiring increased visual acuity and improvement of other visual functions. This treatment requires a series of training sessions. Based upon patient interaction, the device analyzes each patient's neuronal deficiencies in order to design a program that will challenge the patients' visual system. This is accomplished by use of geometrically appropriate target images (i.e. Gabor patches and other figures). The visual tasks may be made easier or harder for the patient by changing the spatial frequency, contrast, placement etc. of the target imagery. The stronger eye is occluded and the amblyopic eye is used to detect some of the targets located within the flashed images. The pre-programmed series of visual tasks therefore takes the patient through a series of interactive tasks in identifying the various target objects that appear on the video screen thereby providing an environment that enhances the visual response of the patient.

The device is software driven and is set up to a central server that can be transferred over the Internet to clinics or physicians offices. The treatment set up at clinics or physicians offices requires a dedicated computer station. The device software is controlled at the manufacturing site (Neurovision Inc.). The program sorts all of the information into the various treatment sites by utilizing individual patient identification codes. The treatment programs are individually structured for each patient. All the information is stored and archived at the central location of corporate headquarters (Ramat Gam, Israel).

The system components consist of a centralized computer system hooked into a central server unit and (at the treatment sites) a computer terminal, mouse, desktop, chair and treatment room with constant background low-level illumination.

The User Manual provides clear descriptions of the system components (Section 2.1 System Description). System Accessories are described in Section 2.2 of the manual. Technical specifications for the hardware and software of the treatment, and administrative workstations are also provided in the User Manual (Appendix C: System Components and Technical Specifications).

(b)(4)Proprietary Information [redacted]

(b)(4)Proprietary Information [redacted]

A device comparison table for substantial equivalence (S/E) is provided in submission attachment #3, and a rationale for determination of substantial equivalence is provided in submission attachment #4. The table lists 3 devices (Haploscope, Eye Shield and Perimeter) as predicates. Unfortunately, the Haploscope listed (which was received through a search of the FDA 510k database) is actually a gold-based dental alloy. The FDA database for 510k's does not contain any information on Haploscopes however; the manufacturer has submitted technical, pictorial and other information on Haploscopes (see review attachment #2). This information was retrieved from the University of California (Berkeley) website. This information is adequate for the purpose of comparison to determine substantial equivalence to the generic type of device. Generically, a Haploscope consists of a patient viewing station, a notebook or other type of PC to be used for administrative purposes and for flashing, timing and sequencing of images to be displayed on the video screen of a TV monitor. The amblyopic eye is used to identify the various flashed images and the mouse is used for scoring the patient responses. The table compares the 3 predicates to the proposed device in terms of intended and indications for use; principle of operation, therapeutic effect and other factors such as programmed diagnosis, visual feedback, audio feedback, and data storage. The table summarizes the various similarities and differences among the devices. The manufacturers S/E rationale concludes that the AA-1 System is similar to the generic type of device because they both are used to treat amblyopia. The same method of occluding the stronger eye is used to strengthen the weaker eye through a series of pre-programmed sessions involving use of the amblyopic eye to recognize flashed images. The manufacturer concludes that the AA-1 system is a technological upgrade of the earlier Haploscopes merged into an advanced computerized system. In addition, the AA-1 has very similar technological features as the predicate although they are technologically more advanced. The differences between the devices do not raise new issues of safety and effectiveness. The comparison table, performance testing and a successful clinical trial of the device, has confirmed the latter.

On the basis of a review of the material submitted in the application it is recommended that the AA-1 System be ruled substantially equivalent to the generic type of device (Haploscope).

Denis L. McCarthy

Denis L. McCarthy

Review Attachment #1

HIGHLIGHTS OF THE CLINICAL RESULTS

(b)(4)Proprietary Information

[redacted]

GRAPHS OF CLINICAL RESULTS

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

15

Improvement in Contrast Sensitivity Function (CSF) Before and After Treatment

(b)(4)Proprietary Information

[redacted]

000158

(b)(4)Proprietary Information

[redacted]

DISCUSSION OF CLINICAL RESULTS

(b)(4)Proprietary Information

[redacted]

7

(b)(4)Proprietary Information

[redacted]

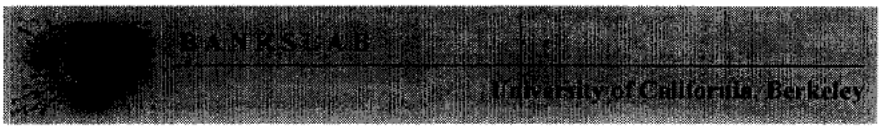
CONCLUSION

In conclusion, a normal output from the neurons in the early visual cortex is essential for normal visual functions. In amblyopia, deficiencies of some of the neurons, especially those that are sensitive for the high spatial frequencies, may prevent further visual processes from functioning normally.

Proper perceptual training, that improved neuronal sensitivity, has provided the basis for more efficient visual processing. This has enabled the restoration of visual functions that were otherwise dysfunctional.

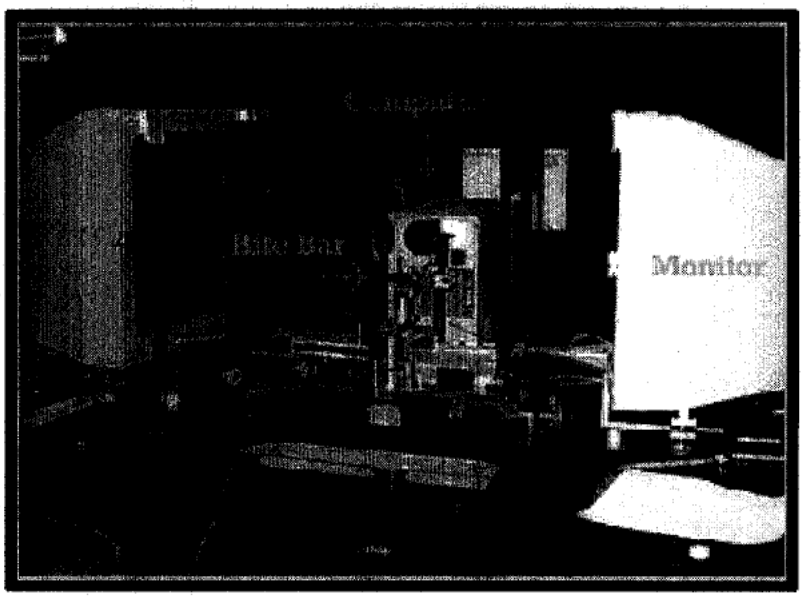
Consequently, a significant and remarkable improvement in visual acuity as well other important visual functions such as contrast sensitivity and binocular functions were found in most of our amblyopic patients, as a result of the perceptual training. This treatment has provided them with significant enhancements in the everyday functioning of their visual system with the resulting benefits in visual performance and thus improving the quality of vision.

Review Attachment #2



Picture of Haploscope

This picture shows the major parts of the haploscope. The observer's head is stabilized by use of the bite bar. The mirrors are visible just above the bite bar. The two CRT monitors are visible to the left and right. The black planes with square apertures are used to reduce stray light. The PowerPC that drives both monitors is visible in the rear.



Return to **Stereo Sequence**

[People] **[Projects]** **[Publications]** **[Software]** **[Equipment]** **[Contact]**

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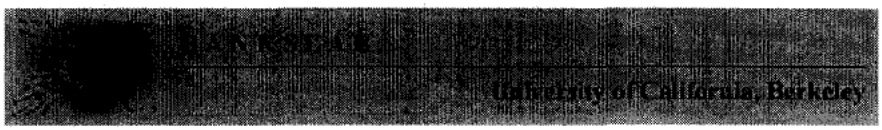
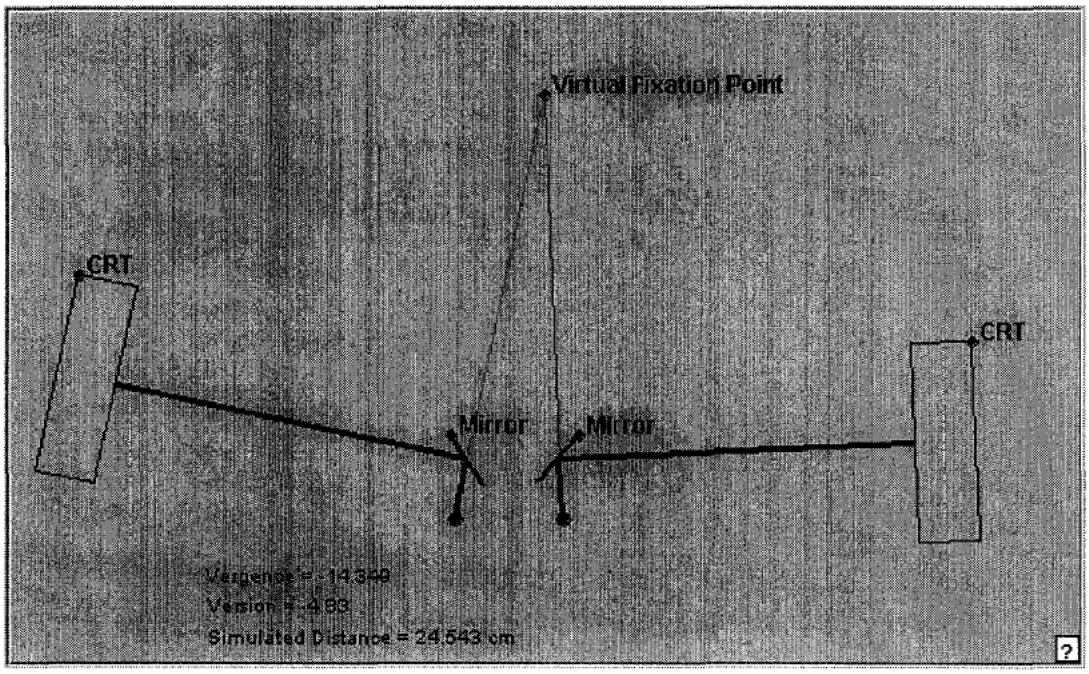


Haploscope

To examine how the visual system uses horizontal and vertical disparities and eye-position signals to estimate surface slant, we need to be able to manipulate those signals independently. We did so by using a haploscope. The sketch below is a plan view of this instrument. The observer's eyes are placed directly above the two pivot points. The CRTs and mirrors are rigidly attached to armatures that pivot about those points. Thus, the left eye views the left CRT in the left mirror and so forth. The virtual image of the Fixation Point is shown in the sketch. You can simulated conditions of the experiment by dragging the fixation point left and right or up and down. When you drag left and right, you're simulating a version eye movement; up and down simulates a vergence eye movement. Now consider given images on the left and right CRTs. Note that the retinal images created always remain the same for all positions of the two armatures. Thus, we can dissociate changes in retinal images from changes in eye position. That's key to the issues under examination and the experiments described next. If you want to learn about the resolution of the haploscope displays and the spatial calibration procedure, go to **Calibration**



NEXT PAGE

[People] **[Projects]** **[Publications]** **[Software]** **[Equipment]** **[Contact]**

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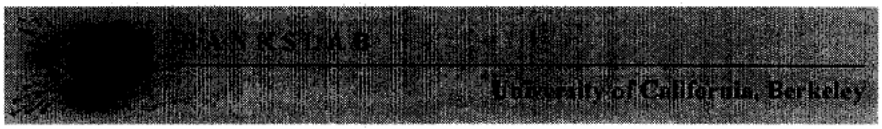
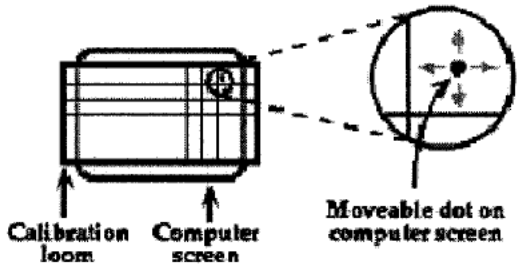


Anti-Aliasing and Calibration Procedure

Because each haploscope arm, mirror, and CRT rotates about the center of rotation of the appropriate eye, we can change the headcentric azimuth of the stimulus without altering the retinal images. Despite the short viewing distance of 42.5 cm, the visual locations of the dots in our displays are specified to within ~30 seconds of arc. This high level of spatial precision is achieved by use of two procedures: anti-aliasing and spatial calibration.

Anti-aliasing allows dot (or line) placement at arbitrary positions between integral pixel locations. Each dot is composed of four adjacent pixels whose intensities are adjusted to place the center of brightness at the desired location taking into account the adjacent-pixel nonlinearity (Klein, Hu, & Carney, 1996).

Spatial calibration is accomplished as follows. A flat loom strung with fine nylon filament is placed in front of the appropriate CRT at the image plane; the loom creates a 36-by-26-cm grid with 1-cm spacing (see figure below). The loom is mounted 1 cm in front of the CRT to be calibrated, and is viewed in the mirror from the standard viewing position. An observer positions a dot to be coincident with specified intersections in the grid. When the dot is aligned with an intersection, its coordinates are recorded. The procedure is repeated for whichever dot was most poorly aligned until the interpolated positions of all the dots are correct (about 70 explicit settings). The loom is removed during experiments. Its former location defines a virtual plane onto which stimuli were projected. The calibrated area is 47 x 35 deg on each monitor. The spatial calibration achieves unmatched precision in the positioning of dots and lines on the two CRTs and creates stereoscopic percepts that are not affected by the standard distortions on CRTs. For a photograph of the haploscope, go to **Photo**



BACK To Stereo Sequence

[People] **[Projects]** **[Publications]** **[Software]** **[Equipment]** **[Contact]**

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ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy? *	✓	
7. Is the device subject to review by CDRH?*	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

* Determined by review comparison to the generic type of device because the proposed device contains new, upgraded technology plus the ability to design individual treatment programs based on analysis of visual / neurological dysfunction of the individual patient.

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 07, 2001

NEUROVISION, INC.
C/O C.L. MCINTOSH, INC.
12300 TWINBROOK PARKWAY
SUITE 230
ROCKVILLE, MD 20852
ATTN: RICHARD E. LIPPMAN

510(k) Number: K012530
Received: 06-AUG-2001
Product: AA-1 SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

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

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

24

K 012530

CL MCINTOSH

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Suite 625
Rockville MD 20852
toll free 1 888 770 9590
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fax 301 770 9584

August 3, 2001

510(k) Document Mail Center (HFZ 401)
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, Maryland 20850

SK-65

Re: Original 510(k)
AA-1 System for the Treatment of Amblyopia
NeuroVision, Inc.

Dear Sir/Madam:

NeuroVision, Inc. hereby submits an original 510(k) application and requests review of the enclosed premarket notification for the NeuroVision AA-1 System for the Treatment of Amblyopia. This device is software driven and is intended to be applied as a series of interactive treatments for the improvement of visual acuity in people suffering from amblyopia. Amblyopia is a condition of the eye where the patient's best visual acuity is reduced from a number of different functional anomalies, but is free from pathology. Heretofore, amblyopia has been treated with limited success in children by the employment of various vision training devices. The current device is predicated upon scientific knowledge in the area of neuro-visual science and employs many of the same concepts that are known in the treatment of amblyopia in children.

The subject device is intended for the treatment of amblyopia in people from age 9 and above. The AA-1 System has several predicate devices to which it is believed that substantial equivalence may be found. This application provides the scientific background, the description of the interactive software used for the treatments, and a full statistical analysis of a prospective clinical trial with both test and control subjects to demonstrate performance of the device in support of a determination of substantial equivalence. In addition, an extensive bibliography is included in support of the scientific basis for the understanding of the neuro-visual pathways, and the concepts describing the functions and designs of the visual system in the human. The subject device applies these concepts in its design and provides the means through interactive treatments in the pursuit of improving visual acuity in people afflicted with amblyopia.

NeuroVision Inc. looks forward to a favorable review of the enclosed application. Should there be any questions to address, please contact me at the address above, and I will respond either directly or through the sponsor.

The material contained within this application is proprietary and confidential. Confidentiality of the enclosed material which contains commercial confidential information is claimed in accordance with 21 CFR Part 807.95(b)(1)(2) and all other statutes and regulations pertaining to confidentiality.

Sincerely,

Richard E. Lippman, O.D., F.A.A.O.
Senior Consultant
Official Correspondent to NeuroVision, Inc.

OP

2 S

Premarket Notification (510(k)) Checklist for Acceptance Decision

K_____ Date DMC Received_____
Device Trade Name:_____ Neurovision AA-1 System for Treatment of Amblyopia
Reason for 510 (k)_____ New Product
Division/Branch:_____ Ophthalmic devices
Administrative Reviewer Signature_____ Date _____
Supervisory Signature:_____ Date_____

		Yes	No
I.	**Critical Elements:**		
A.	Is the Product a device?	X	
B.	Is the device exempt from 510(k) by regulation or policy?		X
C.	Is device subject to review by CDRH?	X	
D. i.	Are you aware that this device has been the subject of a previous NSE decision?		X
ii.	If yes, does this new 510 (k) address the NSE issue(s) (e.g., performance data).		N/A
E. i.	Are you aware of the submitter being the subject of an integrity investigation?		No
ii.	Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991)		N/A

F. Does the submission contain the information required under Sections 510 (k), 513 (f), and 513 (i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?

- **i.** Device trade or proprietary name ..... pg. 17
- **ii.** Device common or usual name or classification name ..... pg. 17
- **iii.** Establishment registration number (only applies if establishment is registered) ..... pg. 17
- **iv.** Class into which the device is classified under (21 CFR Parts 862 to 892) ..... pg. 18
- **v.** Classification Panel ..... pg. 18
- **vi.** Action taken to comply with Section 514 of the Act ..... pg. 18
- **vii.** Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1). pg. 174, 552-617
- **viii.** Write a 510 (k) summary of safety and effectiveness or a 510 (k) statement that safety and effectiveness information will be made available to any person upon request ..... pg. 27

ix. For Class III devices only, a Class III certification and a Class III Summary ..... pg. n/a

x. Photographs of the device (Engineering Drawing) ..... pg. 236

xi. Engineering drawings for the device with dimensions and tolerances 236

xii. The marketed device(s) to which equivalence is claimed including labeling and description of the device(s) ..... pg. 20, 58

xiii. Statement of similarities and/or differences with marketed device(s) ..... pg. 20, 56

xiv. Data to show consequences and affects of a modified device ..... pg. n/a

II. Additional Information that is necessary under 21 CFR 807.87 (h):

A. Submitter's name and address ..... pg. 17

B. Contact person, telephone number and fax number ..... pg. 17

C. Representative/Consultant if applicable ..... pg. 17

D. Table of Contents with pagination ..... pg. i

E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s) ..... pg. 17

III. Additional Information that <u>may be</u> necessary under 21 CFR 807.87 (h):

A. Comparison table of the new device to the marketed device(s) ..... pg. 56

B. Action to be taken to comply with voluntary standards ..... pg. 18
See above discussion regarding 514

C. Performance data: ..... pg. 150-193
- **i.** Marketed Device: ..... n/a
  - **a.** Bench testing
  - **b.** Animal testing
  - **c.** Clinical data
- **ii.** New Device:
  - **a.** Bench testing ..... pg. 2-25, 200-530
  - **b.** Animal testing ..... n/a
  - **c.** Microbiology Testing ..... n/a
  - **d.** Chemistry Testing ..... n/a
  - **e.** Compatibility Testing ..... n/a
  - **f.** Clinical Data 25, 150-193
  - **g.** Certification of Financial Interest Statement ..... n/a

510(k) checklist for FDA with annotation of action items:
Neurovision AA-1 System for Treatment of Amblyopia

D. Sterilization information ..... n/a

E. Software information page 2-25, 200-530

F. Hardware information *Refers to software/computerized devices* page 2-25, 200-530

G. If this 510(k) is for a kit, has the kit certification statement been provided? ..... n/a

H.

i. Is this device subject to issues that have been addressed in specific guidance documents? No

ii. If yes, continue review with checklist from any appropriate guidance documents.

iii. If no, is 510 (k) sufficiently complete to allow substantive review? Yes

I. Other (specify)

Certification of Completeness (T & A Statement ..... pg. 10

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510(k) Application
Neurovision, Inc.

Section 1

Premarket Cover Sheet

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: FDA Document Number:

Section A — Type of Submission

X 510(k)
☐ 510(k) Add'l information

☐ IDE
☐ IDE Amendment
☐ IDE Supplement
☐ IDE Report

☐ PMA
☐ PMA Amendment
☐ PMA Report

☐ PMA Supplement - Regular
☐ PMA Supplement -Special
☐ PMA Supplement - 30 day
☐ PMA Supplement - Panel Track

Section B1 — Reason for Submission - 510(k)s Only

X New device ☐ Additional or expanded indications ☐ Change in technology, design, materials, or manufacturing process
☐ Other reason (specify):

Section B2 — Reason for Submission - PMAs Only

☐ New device
☐ Withdrawal
☐ Additional or expanded indications
☐ Licensing agreement

☐ Labeling change:
- ☐ Indications
- ☐ Instructions
- ☐ Performance Characteristics
- ☐ Shelf life
- ☐ Trade name
- ☐ Other (specify below)

☐ Change in ownership
☐ Change in correspondent

☐ Other reason (specify):

☐ Change in design, component, or specification:
- ☐ Software
- ☐ Color Additive
- ☐ Other (specify below)

☐ Process change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager

☐ Location change:
- ☐ Manufacturer
- ☐ Sterilizer

☐ Packager
- ☐ Distributor

☐ Report submission:
- ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect

☐ Response to FDA correspondence (specify below) ☐ Amendment
☐ Request for applicant hold
☐ Request for removal of applicant hold
☐ Request for extension
☐ Request to remove or add manufacturing site

Section B3 — Reason for Submission - IDEs Only

☐ New device
☐ Addition of institution
☐ Expansion/extension of study
☐ IRB certification
☐ Request hearing
☐ Request waiver
☐ Termination of study
☐ Withdrawal of application

☐ Emergency use:
- ☐ Notification of emergency use
- ☐ Additional information

☐ Other reason (specify):

☐ Change in:
- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer

☐ Protocol - feasibility
- ☐ Protocol - other
- ☐ Sponsor

☐ Report submission:
☐ Current investigator
☐ Annual progress
☐ Site waiver limit reached
- ☐ Final

☐ Response to FDA letter concerning:
☐ Conditional approval
- ☐ Deemed approved
- ☐ Deficient final report

☐ Deficient progress report
☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension of time to respond to FDA
- ☐ Request meeting

☐ IOL submissions only:
☐ Change in IOL style
☐ Request for protocol waiver

	FDA Document Number:

Section C Product Classification

Product code: HJT	CFR Section: 886.1340	Device class:
Classification panel: Ophthalmic		X Class I _ Class II _ Class III _ Unclassified

Section D Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data: _ 510(k) summary attached X 510(k) statement
1 HJT	2 HPT	3 HOY	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
K844395	Renaissance Haploscope	Williams Gold Refining, Inc.
K954167	Humphrey Field Analyzer	Zeiss-Humphrey
K841599	Shield Eye, Ophthalmic	Storz Instrument Company
K896171	Shield Eye, Ophthalmic	Eye Garter Company, Inc.

Section E Product Information - Applicable to All Applications

Common or usual name or classification name: Haploscope or Field Analyzer

Trade or proprietary or model name	Model number
1 AA-1 System	1
2	2
3	3
4	4

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory testing ☐ Animal trials X Human trials

Indications (from labeling): For the treatment of amblyopia using an interaactive computerized program in patients 9 years or older suffering from amblyopia.

		FDA Document Number:	
Section F Manufacturing / Packaging / Sterilization Sites			
X Original ☐ Add ☐ Delete	FDA establishment registration number:	X Manufacturer ☐ Contract sterilizer ☐ Contract manufacturer ☐ Repackager / relabeler	
Company / Institution name: NeuroVision, Inc.			
Division name (if applicable):			Phone number (include area code): (781) 221-4680
Street address: 111 South Bedford Street Suite 100			FAX number (include area code): (781) 221 7468
City: Burlington	State/County: MA	Country:	ZIP 01803
Contact Name: Dov Sella			
Contact title: President /CEO			
X Original ☐ Add ☐ Delete	FDA establishment registration number: Pending	X Manufacturer ☐ Contract sterilizer ☐ Contract manufacturer ☐ Repackager / relabeler	
Company / Institution name:			
Division name (if applicable):			Phone number (include area code):
Street address:			FAX number (include area code):
City:	State/County:	Country:	ZIP:
Contact name:			

33

	FDA Document Number:

Section G Applicant or Sponsor

Company / Institution name: NeuroVision, Inc.			FDA Establishment Registration Number: ERN # Pending
Division name (if applicable):			Phone number (include area code) (781) 221-4680
Street address: 111 South Bedford Street Suite 100			FAX number (include area code): (781) 221-7468
City: Burlington	State/Province: MA	Country:	ZIP / Postal Code: 01803
Signature:			
Name: Richard E. Lippman, O.D., F.A.A.O.			
Title: Official Representative			

Section H Submission correspondent (if different from above)

Company / Institution name: C.L. McIntosh, Inc.			
Division name (if applicable):			Phone number (include area code): (301) 770-9590
Street address: 12300 Twinbrook Parkway Suite 230			FAX number (include area code): (301) 770-9584
City: Rockville	State: MD 20852	Country: USA	Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The informaiton you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a quesiton concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597. ZIP / Postal Code: 20852
Contact name: Richard E. Lippman, O.D., F.A.A.O.			
Contact title: Senior Consultant			

510(k) Application
Neurovision, Inc.

Section 2

Checklist of Acceptance Decision

510(k) Elements List

510(k) Elements	Authority (21 CFR)	Included in Cover Sheet
Device trade or proprietary name	807.87	
Device common or usual name or classification	807.87	
Establishment registration number (if registered)	807.87	
Class in which the device has been put under section 513 of the act and, if known the appropriate panel; or if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.	807.87	
Action taken by the party required to register to comply with the requirements of the act under section 514 for special controls.	807.87	
Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. (Blue Book Memo # G91-1)	807.87	
510(k) summary or 510(k) statement.	SMDA 90	
For Class III only, a Class III certification and Class III summary.	SMDA 90	
Photographs of the device.	807.87	
Engineering drawings of the device.	807.87	
Identification of the marketed device(s) to which equivalence is claimed including labeling and description of the device. Affiliated 510(k) numbers and product codes are voluntary in cover sheet.	807.87	
Statement of similarities and/or differences with marketed devices(s)	807.87	
Data to show consequences and effects of a modified device.	807.87	
Submitter's name and address	807.87	
Contact person, telephone number and fax number	807.87	
Representative/Consultant if applicable	807.87	

510(k) Elements	Authority (21 CFR)	Included in Cover Sheet?
Table of Contents	807.87	
Name and address of manufacturing/packaging/sterilization facilities. Registration number of each facility when one exists.	807.87	
Comparison table of the new device to the marketed device.	807.87 FDA Discretion	
Action taken to comply with voluntary standards.	807.87 FDA Discretion	
Performance Data (bench, animal, clinical)	807.87 FDA Discretion	
Sterilization information (Blue Book Memo #K90-1)	807.87 FDA Discretion	
Software information (Blue Book memo #K91-1)	807.87 FDA Discretion	
Hardware information	807.87 FDA Discretion	
Information requested in specific guidance documents (if applicable for this device)	807.87 FDA Discretion	
Kit Certification Statement (for kit submission only)	807.87 FDA Discretion	

510(k) Application
Neurovision, Inc.

Section 3

Truthful and Accurate Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CR 807.87(j)]

I certify that, in my capacity as President and CEO of Neurovision, Inc. I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

D. Sella

Signature

Dov Sella, President and CEO, Neurovision, Inc.

Typed Name

July 26, 2001

Dated

N/A

Premarket Notification Number (not applicable to new submissions)

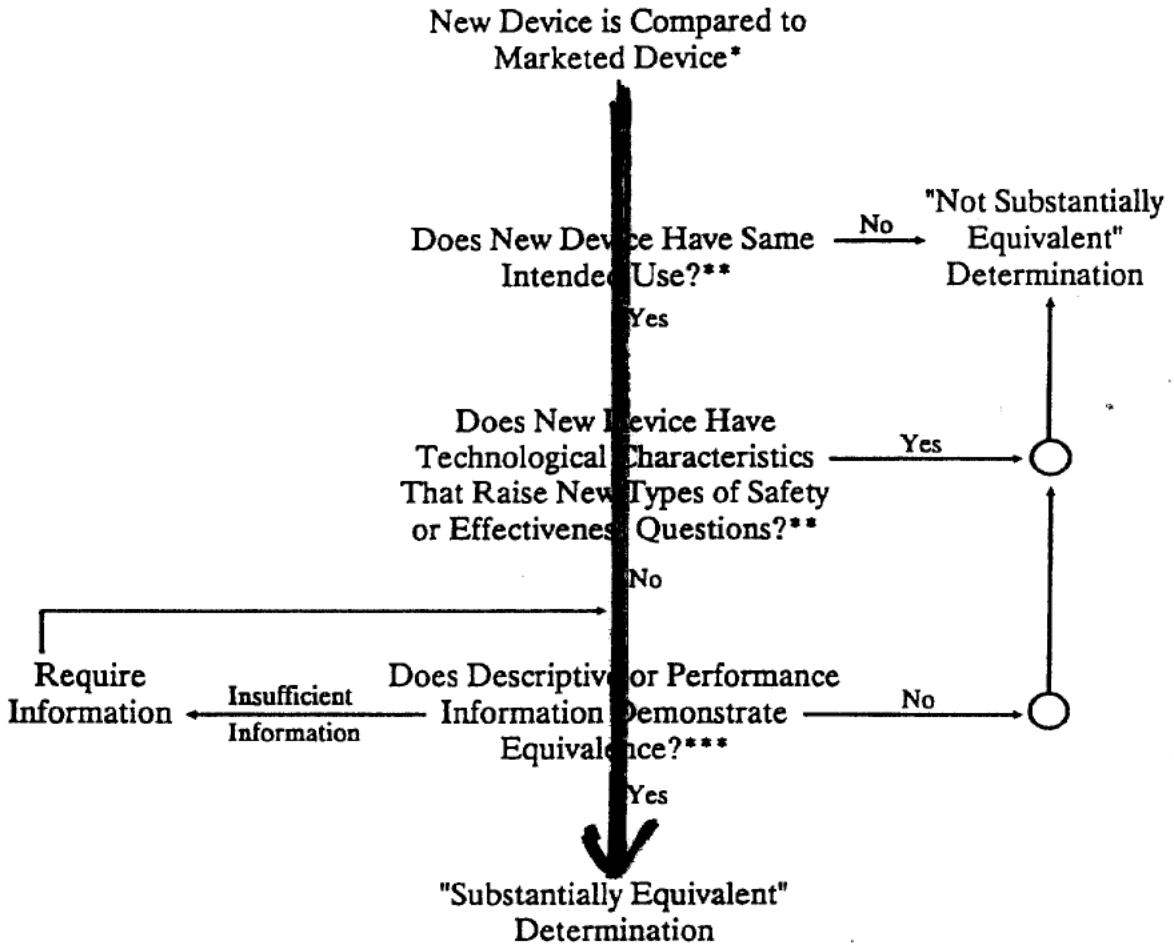
510(k) Application
Neurovision, Inc.

Section 4

510(k) Decision Tree

40

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

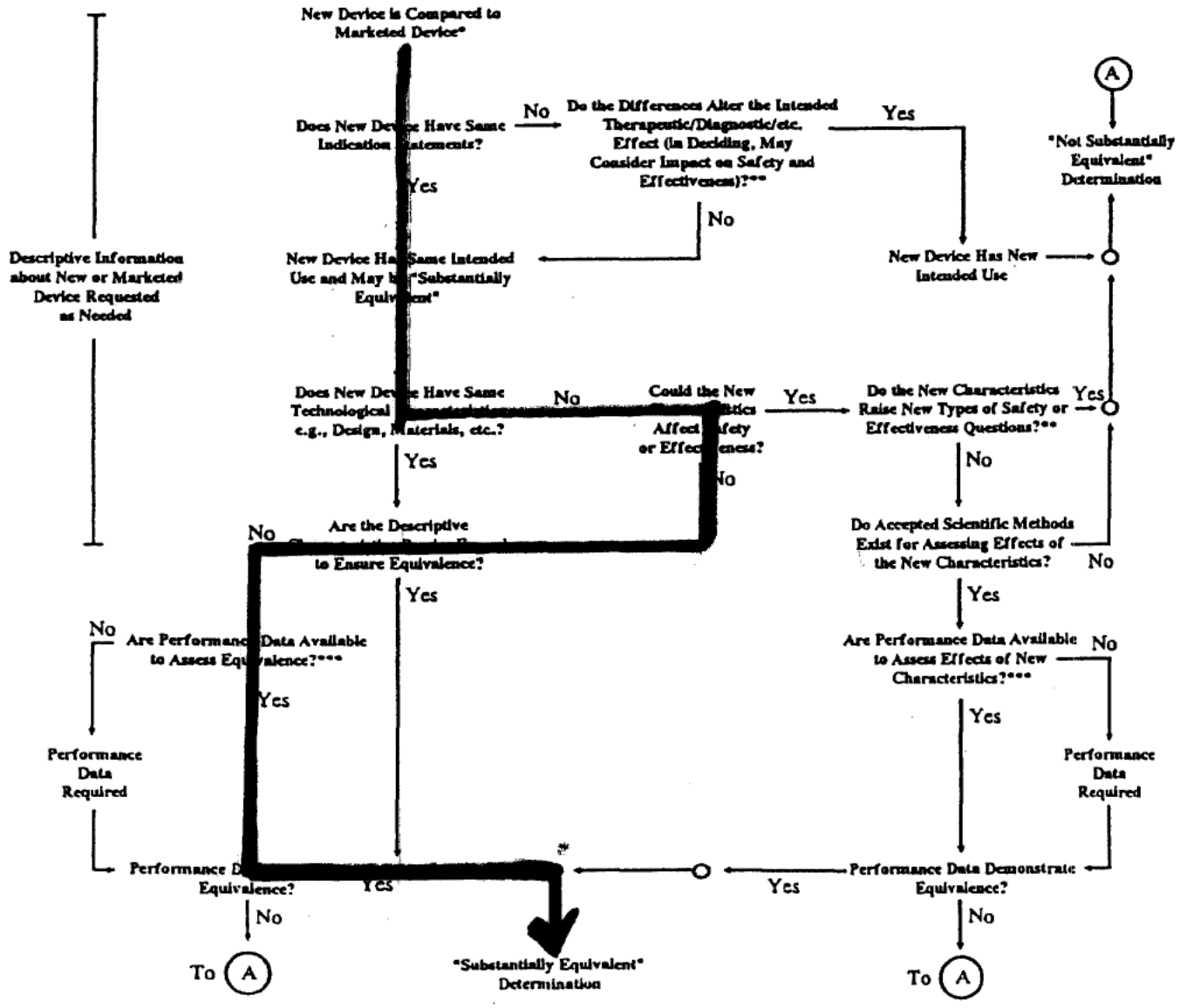


* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) device is unclear.

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

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

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



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

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

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

510(k) Application
Neurovision, Inc.

Section 5

Indication for Use

Indications Statement

510(k) Number (if known)_____

Device Name: Vision Treatment System for Amblyopia (AA-1 System)

Indications for Use:

The Vision Treatment System is indicated for the treatment of amblyopia using an interactive computerized program in patients 9 years or older suffering from amblyopia.

Additional Claims:

Attributes of the Device:

- -Improved Vision
- -Improved Stereoscopic Vision
- -Improved Contrast Sensitivity

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Presription Use ✓ OR Over -The-Counter Use _____

(Oprtional Format 1-2-96)

Dennis L. McCarthy
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012530

510(k) Application
Neurovision, Inc.

Section 6

510(k) Submittal Information

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Review: 510(k) Submittal Information

DATE: July 31, 2001

Submitter:

Company Name:	NeuroVision, Inc.
Address:	111 South Bedford Street Suite 100 Burlington, Massachusetts 01803
Phone:	(781) 221-4680
Fax:	(781) 221-7468
Registration :	Pending

Manufacturer Information:

Company Name:	NeuroVision, Inc.
Address:	111 South Bedford Street Suite 100 Burlington, Massachusetts 01803
Phone:	(781) 221 4680
Registration Number:	Pending

Official Correspondent: Richard E. Lippman, O.D., F.A.A.O.

Address:	C.L. McIntosh, Inc. 12300 Twinbrook Parkway Suite 230 Rockville, Maryland 20852
Phone :	301-770-9590
Fax:	301-770-9584

REASON for 510(k) SUBMISSION: New product

DEVICE IDENTIFICATION:

Trade Name:	NeuroVision AA-1 System for the Treatment of Amblyopia
Common Name:	Amblyopia Treatment Device
Classification Name:	Haploscope; Eye patch

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CLASSIFICATION Name and Reference:

21 CFR 886.1340 haploscope

Regulatory Class

These devices are Class I

Device Panel and Product Code

Ophthalmic: 86 HJT haploscope

STANDARDS:

US FDA has not issued performance standards for ophthalmic contact lenses.

INDICATION for USE:

The AA-1 System is indicated for the treatment of amblyopia using an interactive computerized program in patients 9 years or older suffering from amblyopia.

DEVICE DESCRIPTION:

The device is a computerized interactive device that provides the user with a series of images on a video imaging screen that is designed to identify and correct visual dysfunction by training neurons in the visual cortex to utilize their optimal visual response in gaining increased visual acuity and other visual functions through a series of training sessions. The device analyzes the patient's neuronal deficiencies and sets a program for the user to increase the demand on the visual system resulting in an improvement of visual acuity and additional visual functionalities. The device pre-programs a series of visual stimuli tasks and takes the patient through a series of interactive functions in identifying various objects on the video screen, and helps to provide an environment that increases visual response.

BACKGROUND INFORMATION RELATED TO THE DEVICE

The device is designed and predicated upon an understanding of the visual function of the human system in terms of neuroscience and its relation to the primary visual cortex. The background of the neuroscience related to the device and its application can be found in **Attachment 2**. In this paper, discussion of responses of neurons in the visual system is explained. An overview of the neural transmission from the retina to the visual cortex is described. In this discussion, contrast sensitivity function and the concept of contrast thresholds are provided. The basic premise of the function of the device is employment of the concept as presented by Gabor Patches which can modulate contrast thresholds when placed in appropriate configurations that can be enhanced or suppressed depending on the lateral placement of additional Gabor patches depending on local and global orientation and spatial frequency.

Associated along with contrast function in the neural network, is the concept of perceptual learning. This learning experience results in improvement with repetition, and occurs without any reinforcement or conscious effort. Various research has demonstrated that perceptual learning is associated with a variety of visual tasks including stereoscopic vision, grating detection ,hyper-acuity, phase discrimination, motion detection, texture discrimination, search and pattern discrimination. Some of these demonstrated specificity of learning for specific location in the visual field, particularly orientation, spatial frequency, direction of motion and eye motility. These functions demonstrated persistence in learning for up to 3 years without further repetition.

It is the combination of these two basic overall concepts that the function of the subject device is based. The background scientific paper addresses these concepts and outlines various disabilities of amblyopia and further describes the NeuroVision Technology that applies the concepts to the correction of amblyopia.

MATERIALS

The device is comprised of off-the-shelf computer, monitor, mouse, keyboard and stereo images generation hardware embedded in the computer; the patient is subject to viewing the monitor with different visual stimuli.

MARKETED SUBSTANTIALLY EQUIVALENT DEVICES:

Substantial Equivalence is established by identifying predicate devices that were designed to treat amblyopia that have traditional application in ophthalmic use. These devices are listed in 21 CFR Part 886 as well as pre-amendments devices to be found substantially equivalent. A description and determination of substantial equivalence is provided in **Attachment 4**. Additionally, a side by side comparison chart is also provided that illustrates the similarities of the devices to which substantial equivalence is established. The side-by-side comparison chart is also provided in **Attachment 3 and 4.**

SIMILARITIES and DIFFERENCES:

Please refer to the Comparison Chart as provided in **Attachment 3 and 4**.

SOFTWARE ENGINEERING PACKAGE:

1. Proposed Level of Concern:

A review of the CDRH Guidance Document titled: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" was consulted in the evaluation of the proposed Level of Concern for the software used with this device. A preliminary determination was made that the level of concern is considered 'minor' for the NeuroVision AA-1 System for the Treatment of Amblyopia.

The presentation of the logic flow and reproduction of the system flow chart is provided in **Attachment 5** in support of the proposed level of concern.

2. System Requirements Package

A series of documents that describe the software system for the NeuroVision AA-1 System for the Treatment of Amblyopia is provided in **Attachment 9 and Appendices 1-4**. The documents include the following:

1. System Requirements
2. Architecture Design Chart for the AA-1 System
3. Software Requirements Specifications (SRS) for the AA-1 System

4. AA-1 Software Test Plan

[1] *System Requirements*:

(b)(4)Proprietary Information

[redacted]

Original 510(k)
AA-1 System for Treatment of Amblyopia
NeuroVision, Inc.
July 31, 2001

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

52

Original 510(k)
AA-1 System for Treatment of Amblyopia
NeuroVision, Inc.
July 31, 2001

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

CLINICAL INFORMATION:

A prospective randomized and controlled clinical investigation was conducted to evaluate the potential for improvement and retention of visual acuity in persons of 9 years of age or older (up to 55 years of age) who suffer from amblyopia (lazy eye) due to strabismus, anisometropia, or a combination of them . The investigation consisted of a series of treatment sessions in an interactive environment using a pre-programmed analysis of visual debilitation from amblyopia and a computerized software program that had analyzed the visual defect and carried the subjects through a series of sequential treatments designed to improve neural processing and connectivity that result in improved visual abilities. The investigation consisted of visual stimuli projected onto a video monitor and patient responses being recorded by the click of a computer mouse responding to the various visual stimuli. The computerized program archived the responses and analyzed the responses in preparing the subjects for the subsequent treatment session. Completion of the treatments was established when the subjects no longer improved visual acuity (as measured using ETDRS charts) and other visual functions (measured electronically), and were stable to the same readings for three consecutive tests performed every 4 visits). After a three month rest period from treatments, the subjects were measured for their ability to retain the visual improvement that was gained during the first phase of the treatments.

The clinical investigational plan and protocol are provided in **Attachments 6 and 7,** and the Clinical Report and statistical analysis is provided in **Attachment 8**.

MANUFACTURING

A manufacturing statement is provided in **Section 8**.

PROPOSED LABELING, PACKAGING and STERILIZATION:

Please reference **Attachment 11** for the User Manual.

There is no specific packaging of the software program, as it will be provided already installed in the Treatment Stations computers that are provided to doctors offices. Updates to the software are done through the internet. There is no sterilization required for this device. The device does not come into contact with human tissue. Professional Use directions are provided in the User Manual (**Attachment 11**) and a Professional Use and Patient Use brochure are provided in **Attachment 12**.

ADDITIONAL INFORMATION:

The device has been prepared under appropriate controls as set forward in the Quality System Regulation and Device Good Manufacturing Practice Regulations for a Class I medical device. All software components have been tested, verified, and validated in accordance with the Guidance for Software Driven Devices published by the FDA CDRH. The presentation of the software system is based on the proposed determination that the level of concern is based on the minimal level for this device. A flow chart of the proposed Level of Concern determination is provided in **Attachment 5.**

LITERATURE REFERENCES

The literature references made in the Scientific Background Document **(Attachment 2)** are provided in **Attachment 13** for review.

510(k) Application
Neurovision, Inc.

Section 7

510(k) Summary

510(k) Summary of Safety and Effectiveness

Submitter:	Company Name:	Neuro-Vision, Inc.
	Address:	111 South Bedford Street Suite 100 Burlington, Massachusetts 01803
	Phone:	(781) 221-4680
	Fax:	(781) 221-7468
	Registration :	Pending

Manufacturer Information:

Company Name:	NeuroVision, Inc.
Address:	111 South Bedford Street Suite 100 Burlington, Massachusetts 01803
Phone:	(781) 221-4680
Registration Number:	Pending

Official Correspondent:	Richard E. Lippman, O.D., F.A.A.O.
Address:	C.L. McIntosh, Inc. 12300 Twinbrook Parkway Suite 230 Rockville, Maryland 20852
Phone :	301-770-9590
Fax:	301-770-9584

DEVICE IDENTIFICATION:

Trade Name:	AA-1 System for the Treatment of Amblyopia
Common Name:	Amblyopia Treatment Device
Classification Name:	Haploscope; Eye patch

CLASSIFICATION
Name and Reference: 21 CFR 886.1340 haploscope

REGULATORY CLASS Class I

COMMON NAME: Amblyopia Treatment Device

ESTABLISHMENT REGISTRATION: Pending

INDICATION for USE:

The AA-1 System is indicated for the treatment of amblyopia using an interactive computerized program in patients 9 years or older suffering from amblyopia.

SUBSTANTIALLY EQUIVALENT TO:

The Neurovision AA-1 System is substantially equivalent to an ophthalmic Haploscope, a Class I Exempt medical device that is an AC powered device consisting of two movable viewing tubes, each containing a slide carrier, a low intensity light source for illumination of the slides, and a high

intensity light source for creating an afterimage. The intended use of the device includes amblyopia treatment and treatment of suppression.

The Neurovision device is equivalent to the haploscope (Preamendments Device 886.1340) with respect to the intended use- treatment of amblyopia. Additionally, the subject device is further equivalent to a haploscope in its principal of action, in that the low intensity light stimulus on the haploscope slides are used to bring light stimulus to the eyes when the target slides are moved with respect to each other.

The Neurovision AA-1 System is also substantially equivalent to the Humphrey Visual Field Analyzer (K852639) in that both devices collect diagnostic information through the use of software that interprets data information and reports diagnostic information useful to the user employing the device for further diagnosis and or treatment in the given indication for use.

Lastly, the Neurovision AA-1 System is substantially equivalent to an Eye Shield (K896171) Eye Garter Company, and Eye Shield (K841599) Storz Instrument Company, that is customarily used to cover the good eye during amblyopic treatment of the amblyopic eye during treatment sessions to improve visual acuity in the affected eye.

DEVICE DESCRIPTION:

The device is a computerized interactive device that provides the user with a series of linear images oriented in vertical and horizontal planes on a video imaging screen that is designed to identify and correct visual dysfunction from reduced visual acuity by re-training the eye to utilize its optimal visual response in gaining an increased awareness of visual acuity through a series of training sessions. The device analyzes the patient's visual acuity deficiencies and sets a program for the user to increase the demand on the visual system resulting in an improvement of visual acuity. The device pre-programs a series of visual stimuli tasks and takes the patient through a series of interactive functions in identifying various objects on the video screen, and helps to provide an environment that increases visual response.

CLINICAL INVESTIGATION

A prospective randomized and controlled clinical investigation was conducted to evaluate the potential for improvement and retention of visual acuity in persons of 9 years of age or older who suffer from amblyopia (lazy eye) from any source. The investigation consisted of a series of treatment sessions in an interactive environment using a pre-programmed analysis of visual debilitation from amblyopia and a computerized software program that had analyzed the visual defect and carried the subjects through a series of sequential treatments designed to improve visual resolution capability. The investigation consisted of visual stimuli projected onto a video monitor and patient responses being recorded by the click of a computer mouse responding to the various visual stimuli. The computerized program archived the responses and analyzed the responses in preparing the subjects for the subsequent treatment session. Completion of the treatments was established when the subjects no longer improved visual acuity, and were stable to the same visual acuity readings for three consecutive visits. After a three month rest period from treatments, the subjects were measured for their ability to retain the visual improvement that was gained during the first phase of the treatments.

The investigation of the device demonstrated that the subjects who completed the study with the long term follow-up three month visit improved visual acuity performance by an average of 2.5 lines of visual acuity from their baseline visual acuity best corrected vision. Greater than 70% of the subjects showed consistency in visual improvement. The control group treated by placebo treatment showed no improvement and was detected earlier in the study

LABELING

The Neurovision AA-1 System for the Treatment of Amblyopia is provided with a User Manual for the Practitioner, and two additional brochures, one for the professional and one for the patient. The information is available from the company:

Neurovision, Inc.
111 South Bedford Street
Suite 100
Burlington, Massachusetts 01803
(781) 221- 4680

510(k) Application
Neurovision, Inc.

Section 8

Manufacturing Statement

Neurovision, Inc.
SFS System for the Treatment of Amblyopia
Manufacturing Statement

The device is a software driven device that is set up to a central server that can be transferred over the internet to doctors offices for set up at dedicated computer stations for the treatment programs. The device software program is controlled at the manufacturing site and sorts all of the information into the various sites by code for the particular patient. The program is structured for the specific patient, all of the input data being stored and archived at the central location at the company headquarters at Ramat Gan, Israel.

The components of the system include a central computer system hooked into a central server unit. At each site, the components needed to work this system are a computer terminal, computer mouse, desk-top, chair and a room with a constant background low level of illumination.

510(k) Application
Neurovision, Inc.

Attachment 1

Proposed Classification of Device

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Proposed Classification of Neurovision AA-1 System for the Treatment of Amblyopia

(b)(4)Proprietary Information

[redacted]

510(k) Application
Neurovision, Inc.

C000008 FDA Correspondence
April 14, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2000

Wilson, Sonsini, Goodrich & Rosati
Attn: David Hoffmeister, Esq.
650 Page Mill Road
Palo Alto, CA 94304

Re: 513(g) C000008
Product: Software Device for Lazy Eye Syndrome
Dated: February 18, 2000
Received: February 18, 2000

Dear Mr. Hoffmeister:

We are in receipt of your 513(g) request for classification of the above-referenced device for the treatment of adult amblyopia.

Based on the information you have provided, your device falls under the general heading of vision trainers, which is a diverse category of unclassified devices ranging from low to moderate risk. Devices of this type require submission of a 510(k) application, with a specific predicate device identified if possible. Since we have not been able to identify an appropriate predicate for your device, we encourage you to arrange a pre-submission meeting with us if you intend to pursue a marketing clearance for your device.

Please note, based on the description in your submission and the clarification in a telephone conference with Dr. Bruce Drum on April 6, 2000, we do not believe that your device can be classified as a biofeedback device as described in 21 CFR 882.5050. A key feature of a biofeedback device is that it must make some physiological activity consciously accessible to the subject and allow the subject to modify that activity by interacting with a related stimulus. For your device to qualify as a biofeedback device, it would have to allow the subject to control one or more critical image parameters in response to changes in the visibility of these parameters. Instead, the physician, not the patient sets the image parameters for your device, and the parameters for each session are determined by the outcome of the previous session.

Please direct general questions about the preparation and submission of a 510(k) to the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. For answers to technical questions or to arrange a pre-510(k) meeting with the Division of Ophthalmic and ENT Devices (DOED), you may contact Bruce Drum, Ph.D. at (301) 594-2018.

Sincerely yours,

Philip J. Phillips
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Koen, Frances

To: Phillip J. Phillips

Subject: Biofeedback Device Classification

Dear Phil:

(b)(4)Proprietary Information

[redacted]

Based on the above description, we believe that the device would be regulated by the FDA as a biofeedback device pursuant to 21 CFR section 882.5050, a Class II device requiring a 510(k) premarket notification submission. Please confirm our belief.

Additionally, if the company labels the device as helping to improve visual acuity for adults with lazy eye syndrome (i.e., as a treatment device and not as a training device), how will the FDA regulate this claim? Biofeedback 510(k) with clinical data needed for clearance or PMA? Again, several ophthalmologist prescribed sessions, which will be become progressively more visual intense, will be needed to complete the patient treatment.

If you need additional information to confirm our beliefs regarding the biofeedback device claims and answer our questions regarding claims of improved visual acuity, please let me know and I will provide that information. I look forward to your prompt response.

Regards
David Hoffmeister, Esq.
Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
(650) 354-4248 Direct
(650) 496-4082 Facsimile
Dhoffmeister@wsgr.com

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 23, 2000

WILSON SONSINI GOODRICH AND ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304
ATTN: DAVID HOFFMEISTER

513(g) Number: C000008
Received : 18-FEB-2000
Product : SOFTWARE DEVICE FOR LAZY EYE SYNDROME

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received your written request for the classification and/or requirements applicable to the device referenced above in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act Act. We have assigned your submission a unique 513(g) number that is cited above. Please refer prominently to this 513(g) number in any future correspondence that relates to this submission. We will notify you when the processing of your submission has been completed or if any additional information is required.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official 513(g) submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official 513(g) submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

If you have procedural or policy questions, or want information on how to check on the status of your submission (after 60 days from the receipt date), please contact the Program Operations Staff at (301) 594-1190. If you have any other questions or need guidance documents, manuals, or other materials, please contact the Division of Small Manufacturers Assistance (DSMA) at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Healt

510(k) Application
Neurovision, Inc.

Attachment 2

Scientific Background Information Document for the Device and Concept

(b)(4)

(b)(4)

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510(k) Application
Neurovision, Inc.

Attachment 3

Comparison Table of Devices for Substantial Equivalence

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Substantial Equivalence Comparison Table

	AA-1	Haploscope	Universal Eye Shield	Perimeter
K number	---	K844395	K841599	K954167
Code	---	HJT	HOY	HPT
Manufac-turer	NeuroVision, Inc.	Williams Gold Refining Co, Inc.	Storz Instrument Company (Bausch & Lomb)	Carl Zeiss, Inc.
Intended Use and indications for use	Indicated for the treatment of amblyopia using an interactive computerized program in adult patients (ages 9 and up) suffering from amblyopia.	Intended to measure strabismus (eye muscle imbalance), to assess binocular vision (use of both eyes to see), and to treat suppression and amblyopia (dimness of vision without any apparent disease of the eye).	Prevent the eye from getting image, forcing the amblyopic eye to work solely without the interference of the occluded eye.	Intended to determine the extent of the peripheral visual field of a patient.
Principle of Operation	Patient covers the healthy eye and the software presents sequences of designated images to the amblyopic eye. Practices protocol is build up in real time according to patient identified visual thresholds , and in post-session based on the overall progress and visual deficiencies of the patient – as a set of parameters for the following session	This is an AC powered device consisting of two movable viewing tubes, each containing a slide carrier, a low intensity light source for illumination of the slides, and a high intensity light source for creating an afterimage. In the haploscope, the low intensity light stimulus on the slides is used to bring light stimulus to the eyes when the target slides are moved with respect to each other.	Opaque material that prevents light signals from penetrating into the eye.	The device projects light on various points of a curved surface, and the patient indicates whether he or she sees the light
Ophthalmic Therapeutic affect	Treatment of Amblyopia in patients 9 and older.	Treat suppression and amblyopia.	Treatment of amblyopia in children by occlusion of the healthy eye and practice of the abnormal eye	No

Programmed Diagnosis	Yes	No	No	Yes
Visual feedback	Yes	No	No	No
Audio feedback	Yes	No	No	No
Data Storage	Yes	No	No	Yes

510(k) Application
Neurovision, Inc.

Attachment 4

Substantial Equivalence Determination

SUBSTANTIAL EQUIVALENCE INFORMATION

A. PREDICATE DEVICES

In terms of intended use, the AA-1 system is substantially equivalent to the market-cleared RENAISSANCE haploscope, Williams Gold Refining, Inc. (K844395)

In terms of treatment methods, the AA-1 system is substantially equivalent to a combination of the following devices:

a. The market-cleared Renaissance haploscope, Williams Gold Refining, Inc. (K844395) for the treatment of amblyopia
b. The market-cleared perimeter - Humphrey Field Analyzer (HFA II), One Zeiss Dr., (K954167) for determining the extent of visual field.
c. The market-cleared eye shield- Storz Universal Eye Shield (K841599); Storz Instrument Company (Bausch & Lomb), St. Louis, Missouri..

Attached to this section are the following documents:

1. A detailed information sheet from FDA database for the Renaissance Haploscope (Williams Gold Refining Co., Inc.)
2. A detailed information sheet from FDA database and promotional material for the Humphrey Field Analyzer (HFA II) (Carl Zeiss, Inc.)
3. A detailed information sheet from FDA database for the Storz Universal Eye Shield (Storz Instrument Company-Bausch & Lomb).

B. COMPARISON TABLE

A substantial equivalence table, which summarizes the similarities and differences between the AA-1 system and its predicate devices, is attached to this section.

C. COMPARISON DISCUSSION

Intended use and indications for use

As noted above, the AA-1 System is equivalent to the Renaissance haploscope, Williams Gold Refining, Inc. (K844395) ("Renaissance Haploscope") with respect to the intended use.

Although the intended use of haploscopes is wider and includes measuring of strabismus, assessment of binocular vision, and treatment of suppression and amblyopia, the intended use of the AA-1 system is completely contained in this of the haploscope.

Therefore, the intended use and indications for use of the AA-1 do not raise any new issues of safety or effectiveness and the AA-1 is substantially equivalent to its predicate devices.

Treatment Method and Technological Characteristics

The treatment method implemented by the AA-1 System is based on well-established methods that are utilized for years in the treatment of amblyopic patients. It is mainly based on the concept that the weaker eye must become stronger in order to see normally. The AA-1 System is designed to assist in strengthening the weak eye through a series of treatment sessions specifically designed to fit the needs of each individual.

The AA-1 System is equivalent to the Renaissance haploscope and to other haploscopes not only in indication but also in its principal of action. The haploscope is an AC powered device consisting of two movable viewing tubes, each containing a slide carrier, a low intensity light source for illumination of the slides, and a high intensity light source for creating an afterimage. In the haploscope, the low intensity light stimulus on the slides is used to bring light stimulus to the eyes when the target slides are moved with respect to each other. The low intensity light stimuli on the AA-1 System monitor serve a similar purpose in bringing visual stimulus to the eyes to which the subject is asked to respond to his/her visual perception of those targets, as they are presented. Both the Renaissance haploscope and the AA-1 System are "programmed" for subsequent treatments – manually with the haploscope and by computer with the AA-1 System.

Basically from a similar rationale, substantial equivalence is also claimed between the AA-1 system and the Humphrey Field Analyzer (HFA II), Carl Zeiss, Inc. ("Humphrey perimeter"), which is an AC-powered device that projects light on various points of a curved surface, and the patient indicates, normally by pressing a button, whether he/she sees the light.

AA-1 system like the Humphrey Perimeter provides programmed diagnosis of a vision system condition. In both cases the diagnosis is based on computed algorithm. Similar to the Humphrey Perimeter, the AA-1 is designed for a variety of tests that may be manipulated according to personal characteristics of the patient's visual ability. In addition, both systems have warning regarding patient's premature leaving. Both systems store test data in a file under patient name.

In addition, in the classic treatment of amblyopia, the patient is instructed to occlude the stronger eye when using the AA-1 System, in a similar way and for the same reason that eye patches, like the Universal Eye Shield, Storz Instrument Company provide.

In conclusion, the technological characteristics and methods of the AA-1 System and its predicate devices are basically the same. In particular, the methods of treatment, and the programmed treatment environment, are similar. Therefore, the technological features do not raise new issues of safety or effectiveness as demonstrated through comparison to predicate devices and performance testing.

Performance Test

NeuroVision, Inc. conducted comprehensive software verification and validation testing to demonstrate that the device operates in accordance with the requirements as set forth in the SRS document in **Attachment 9, Appendix 3**, and that the device does not raise new issues of safety or effectiveness. Software testing is specified in **Attachment 9, Appendix 4**. Testing results demonstrated that the AA-1 performs according to its specifications. Therefore, the AA-1 treatment does not raise any new issues of safety or effectiveness.

The AA-1 is substantially equivalent to the predicate devices listed above and in addition, has demonstrated a successful validation for conducting a treatment program for improvement of visual acuity in amblyopia.

Clinical Study

A prospective controlled clinical investigation was conducted by the sponsor to demonstrate performance of the AA-1 System Software device as it applies to the indication for the improvement of visual acuity in amblyopia. The test subjects received a treatment program with the device over a series of treatment sessions while the control subjects received a placebo treatment program on the same device until three successive visits demonstrated no improvement in visual acuity. The performance outcomes of the device demonstrated a statistical difference in visual acuity improvement in the test group and was further demonstrated that the test group outperformed the control group. The purpose of conducting the clinical investigation was to lend support to obtaining a claim for visual acuity improvement as well as retention of visual acuity improvement

with the subject device. The clinical report and statistical analysis is provided in **Attachment 8**.

Conclusion

The AA-1 system, like the predicate Renaissance haploscope, is intended for use in the treatment of amblyopia. It utilizes the classical method of occluding the strong eye by means of an eye shield occluder for the purpose of strengthening the weak eye through a series of pre-programmed sessions. Moreover, the company believes that the AA-1 system is a natural evolution of well-established methods merged into an advanced computerized system.

As explained above, the AA-1 system has very similar technological features to the predicate devices including haploscopes, perimeters and eye shield devices. Any differences in technological characteristics between the AA-1 system and the predicate devices do not raise new types of safety or effectiveness issues, as confirmed by the above comparison and further confirmed through performance testing and clinical experience. Therefore, it is concluded that the AA-1 system is substantially equivalent to the predicates.

ATTACHMENTS TO THIS DOCUMENT

1. **Substantial Equivalence Comparison Table**

2. **A detailed information sheet from FDA database for the Renaissance Haploscope (Williams Gold Refining Co., Inc.)**

3. **General information regarding Haploscopes**

4. **A detailed information sheet from FDA database for the Universal Eye Shield (Storz Instrument Company- Bausch & Lomb).**

5. **Promotional material for the for the Universal Eye Shield, Storz Instrument Company.**

6. **A detailed information sheet from FDA database Humphrey Field Analyzer (HFA II) (Carl Zeiss, Inc.)**

7. **Promotional material for the Humphrey Field Analyzer (HFA II) (Carl Zeiss, Inc.)**

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Substantial Equivalence Comparison Table

	AA-1	Haploscope	Universal Eye Shield	Perimeter
K number	---	K844395	K841599	K954167
Code	---	HJT	HOY	HPT
Manufac-turer	NeuroVision, Inc.	Williams Gold Refining Co, Inc.	Storz Instrument Company (Bausch & Lomb)	Carl Zeiss, Inc.
Intended Use and indications for use	Indicated for the treatment of amblyopia using an interactive computerized program in adult patients (ages 9 and up) suffering from amblyopia.	Intended to measure strabismus (eye muscle imbalance), to assess binocular vision (use of both eyes to see), and to treat suppression and amblyopia (dimness of vision without any apparent disease of the eye).	Prevent the eye from getting image, forcing the amblyopic eye to work solely without the interference of the occluded eye.	Intended to determine the extent of the peripheral visual field of a patient.
Principle of Operation	Patient covers the healthy eye and the software presents sequences of designated images to the amblyopic eye. Practices protocol is build up in real time according to patient identified visual thresholds , and in post-session based on the overall progress and visual deficiencies of the patient – as a set of parameters for the following session	This is an AC powered device consisting of two movable viewing tubes, each containing a slide carrier, a low intensity light source for illumination of the slides, and a high intensity light source for creating an afterimage. In the haploscope, the low intensity light stimulus on the slides is used to bring light stimulus to the eyes when the target slides are moved with respect to each other.	Opaque material that prevents light signals from penetrating into the eye.	The device projects light on various points of a curved surface, and the patient indicates whether he or she sees the light
Ophthalmic Therapeutic affect	Treatment of Amblyopia in patients 9 and older.	Treat suppression and amblyopia.	Treatment of amblyopia in children by occlusion of the healthy eye and practice of the abnormal eye	No

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Programmed Diagnosis	Yes	No	No	Yes
Visual feedback	Yes	No	No	No
Audio feedback	Yes	No	No	No
Data Storage	Yes	No	No	Yes

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[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[**CITE: 21CFR886.1340**]

[Page 436]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 886--OPHTHALMIC DEVICES--Table of Contents

Subpart B--Diagnostic Devices

Sec. 886.**1340** Haploscope.

(a) Identification. A haploscope is an AC-powered device that consists of two movable viewing tubes, each containing a slide carrier, a low-intensity light source for the illumination of the slides, and a high-intensity light source for creating afterimages. The device is intended to measure strabismus (eye muscle imbalance), to assess binocular vision (use of both eyes to see), and to treat suppression and amblyopia (dimness of vision without any apparent disease of the eye).

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[55 FR 48441, Nov. 20, 1990, as amended at 59 FR 63012, Dec. 7, 1994]

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[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[**CITE: 21CFR886.1605**]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 886--OPHTHALMIC DEVICES--Table of Contents

Subpart B--Diagnostic Devices

Sec. 886.**1605** Perimeter.

(a) Identification. A perimeter is an AC-powered or manual device intended to determine the extent of the peripheral visual field of a patient. The device projects light on various points of a curved surface, and the patient indicates whether he or she sees the light.

(b) Classification. Class I. The manual device is exempt from the premarket notification procedures in part 807, subpart E of this chapter, and it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of Sec. 820.180, with respect to general requirements concerning records, and Sec. 820.198 with respect to the complaint files.

[55 FR 48442, Nov. 20, 1990]

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[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[**CITE: 21CFR886.4750**]

[Page 448]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 886--OPHTHALMIC DEVICES--Table of Contents

Subpart E--Surgical Devices

Sec. 886.**4750** Ophthalmic eye shield.

(a) Identification. An ophthalmic eye shield is a device that consists of a plastic or aluminum eye covering intended to protect the eye or retain dressing materials in place.

(b) Classification. Class I (general controls). When made only of plastic or aluminum, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to Sec. 886.9. When made only of plastic or aluminum, the devices are exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of Sec. 820.180 of this chapter, with respect to general requirements concerning records, and Sec. 820.198 of this chapter, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 59 FR 63014, Dec. 7, 1994; 65 FR 2321, Jan. 14, 2000]

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Return to Search

Device Classification Name	HAPLOSCOPE
Regulation Number	886.1340
510(k) Number	K844395
Device Name	RENAISSANCE
Applicant	WILLIAMS GOLD REFINING CO., INC. 2978 MAIN STREET BUFFALO,NY14214
Contact	LAWRENCE A WILLIAMS
Product Code	HJT
Date Received	11/13/1984
Decision Date	01/09/1985
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	Ophthalmic
Review Advisory Committee	Dental
Type	Traditional
Reviewed by Third Party	No

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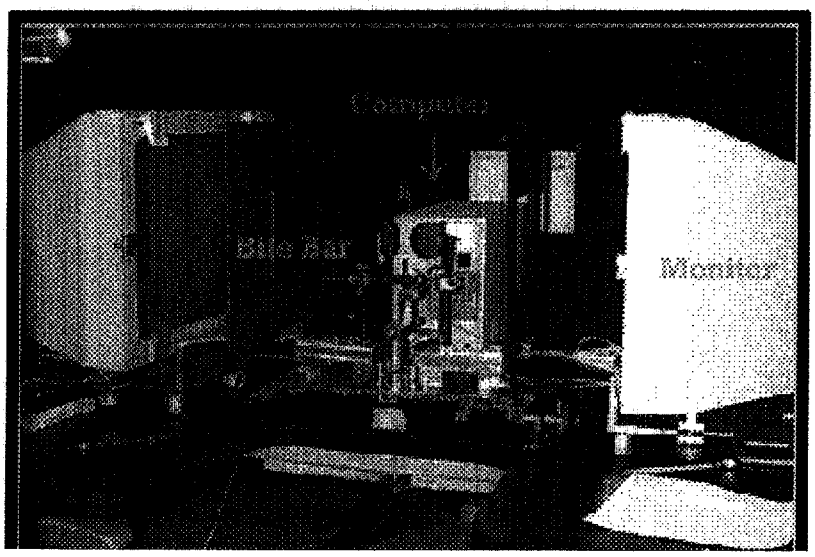
BANKSLAB
University of California, Berkeley

Picture of Haploscope

This picture shows the major parts of the haploscope. The observer's head is stabilized by use of the bite bar. The mirrors are visible just above the bite bar. The two CRT monitors are visible to the left and right. The black planes with square apertures are used to reduce stray light. The PowerPC that drives both monitors is visible in the rear.



Return to **Stereo Sequence**

[People] **[Projects]** **[Publications]** **[Software]** **[Equipment]** **[Contact]**

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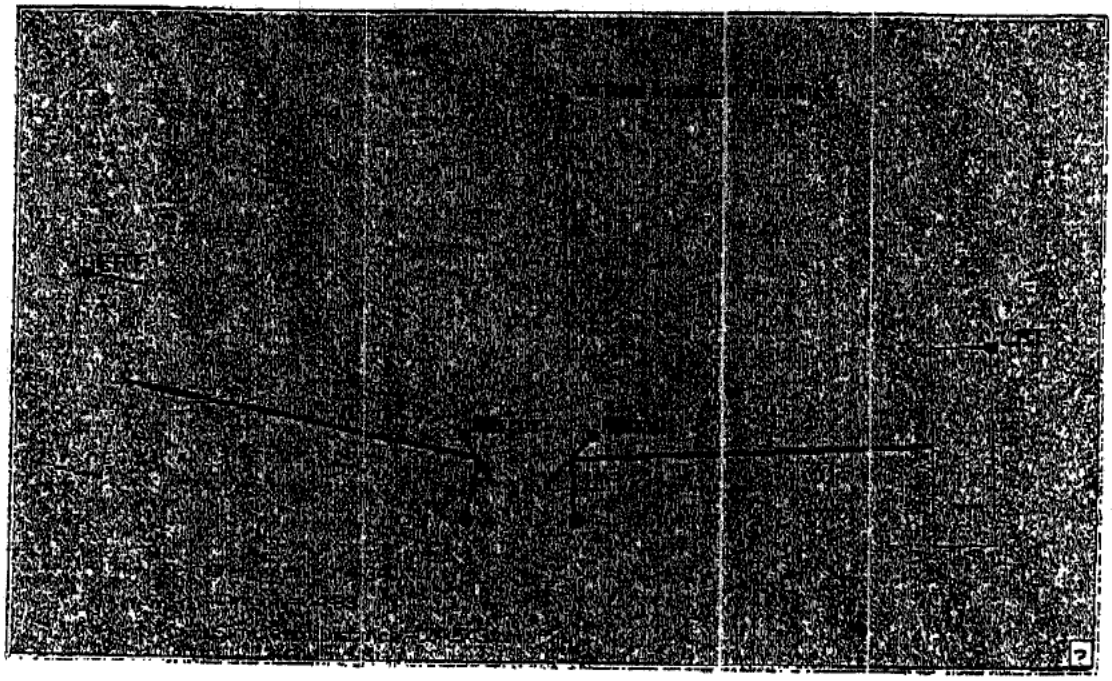
BANKSLAB
University of California, Berkeley

Haploscope

To examine how the visual system uses horizontal and vertical disparities and eye-position signals to estimate surface slant, we need to be able to manipulate those signals independently. We did so by using a haploscope. The sketch below is a plan view of this instrument. The observer's eyes are placed directly above the two pivot points. The CRTs and mirrors are rigidly attached to armatures that pivot about those points. Thus, the left eye views the left CRT in the left mirror and so forth. The virtual image of the Fixation Point is shown in the sketch. You can simulated conditions of the experiment by dragging the fixation point left and right or up and down. When you drag left and right, you're simulating a version eye movement; up and down simulates a vergence eye movement. Now consider given images on the left and right CRTs. Note that the retinal images created always remain the same for all positions of the two armatures. Thus, we can dissociate changes in retinal images from changes in eye position. That's key to the issues under examination and the experiments described next. If you want to learn about the resolution of the haploscope displays and the spatial calibration procedure, go to **Calibration**



[People] [Projects] [Publications] [Software] [Equipment] [Contact]

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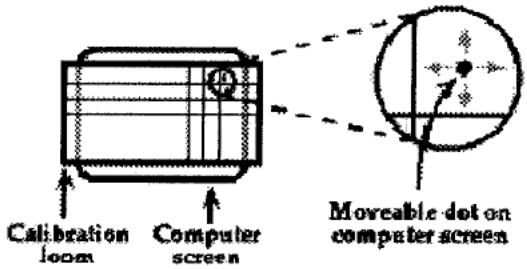
BANKS LAB
University of California, Berkeley

Anti-Aliasing and Calibration Procedure

Because each haploscope arm, mirror, and CRT rotates about the center of rotation of the appropriate eye, we can change the headcentric azimuth of the stimulus without altering the retinal images. Despite the short viewing distance of 42.5 cm, the visual locations of the dots in our displays are specified to within ~30 seconds of arc. This high level of spatial precision is achieved by use of two procedures: anti-aliasing and spatial calibration.

Anti-aliasing allows dot (or line) placement at arbitrary positions between integral pixel locations. Each dot is composed of four adjacent pixels whose intensities are adjusted to place the center of brightness at the desired location taking into account the adjacent-pixel nonlinearity (Klein, Hu, & Carney, 1996).

Spatial calibration is accomplished as follows. A flat loom strung with fine nylon filament is placed in front of the appropriate CRT at the image plane; the loom creates a 36-by-26-cm grid with 1-cm spacing (see figure below). The loom is mounted 1 cm in front of the CRT to be calibrated, and is viewed in the mirror from the standard viewing position. An observer positions a dot to be coincident with specified intersections in the grid. When the dot is aligned with an intersection, its coordinates are recorded. The procedure is repeated for whichever dot was most poorly aligned until the interpolated positions of all the dots are correct (about 70 explicit settings). The loom is removed during experiments. Its former location defines a virtual plane onto which stimuli were projected. The calibrated area is 47 x 35 deg on each monitor. The spatial calibration achieves unmatched precision in the positioning of dots and lines on the two CRTs and creates stereoscopic percepts that are not affected by the standard distortions on CRTs. For a photograph of the haploscope, go to **Photo**



BACK To Stereo Sequence

Return to Search

Classification Name:	SHIELD, EYE, OPHTHALMIC (INCLUDING SUNLAMP PROTECTIVE EYEWEAR AND POST-MYDRIATIC EYEWEAR)
Device Class:	1
Product Code:	HOY
Regulation Number:	886.4750
Medical Specialty:	Ophthalmic
Owner/Operator:	RICHMOND PRODUCTS, INC.
Owner/Operator Number:	1035253
Registered Establishment Name:	RICHMOND PRODUCTS, INC.
Establishment Registration Number:	1035253
Date of Listing:	07/14/92
Listing Status:	Active
Establishment Operations:	Manufacturer

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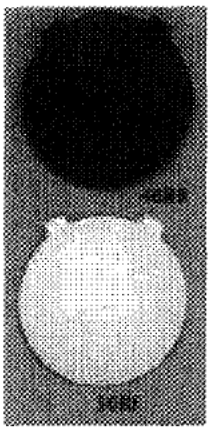
Standard Clip-On Occluders-Round Type



Sold in packages of 6.

44RBR Round-Type Clip-Ons 44mm Round Black Color $5.40

44RFR Round-Type Clip-Ons 44mm Round Flesh Color $5.40

46RBR Round-Type Clip-Ons 46mm Round Black Color $5.40

46RFR Round-Type Clip-Ons 46mm Round Flesh Color $5.40

48RBR Round-Type Clip-Ons 48mm Round Black Color $5.40

48RFR Round-Type Clip-Ons 48mm Round Flesh Color $5.40

50RBR Round-Type Clip-Ons 50mm Round Black Color $5.40

50RFR Round-Type Clip-Ons 50mm Round Flesh Color $5.40

Other Occluder / Diffuser Products

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Return to Search

Device Classification Name	PERIMETER, AUTOMATIC, AC-POWERED
Regulation Number	886.1605
510(k) Number	K954167
Device Name	HUMPHREY FIELD ANALYZER (HFA II)
Applicant	CARL ZEISS, INC. ONE ZEISS DR. THORNWOOD,NY10594
Contact	KENNETH M NICOLL
Product Code	HPT
Date Received	09/05/1995
Decision Date	11/24/1995
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	Ophthalmic
Review Advisory Committee	Ophthalmic
Statement/Summary/Purged Status	Summary only
Type	Traditional
Reviewed by Third Party	No

(Database Updated July 6, 2001)

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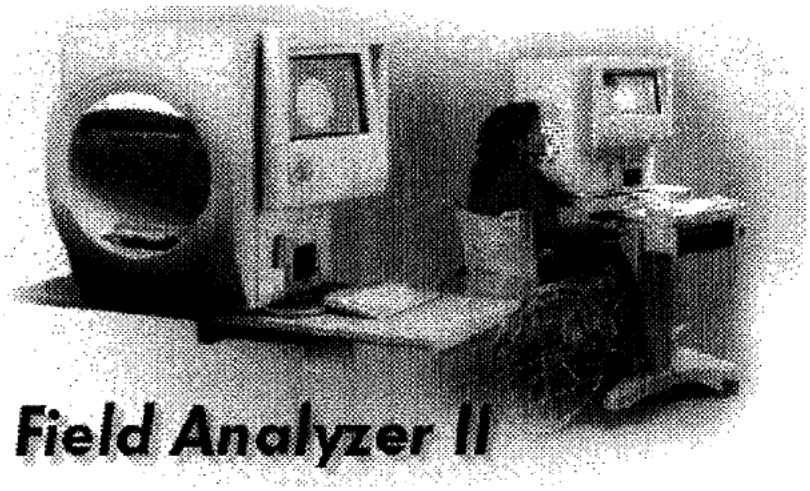

Return to Glaucoma Solutions

Humphrey® Field Analyzer II
The World Standard in Perimetry Just Got Better

SITA™
The new expert operating system for the HFA II provides unprecedented levels of accuracy, patient satisfaction, and office productivity. Individualized, self-directing, and self-correcting, the SITA system will transform visual field testing.

STATPAC™ for SITA
Improves diagnostic precision by utilizing the largest, worldwide normative database in perimetry.

STATPAC™ for Blue-Yellow
Makes interpretation of Blue-Yellow fields as easy as interpreting traditional white-on-white fields.

Automatic Pupil Measurement
Measures the diameter of the patient's pupil at the start of the test and inputs that data onto the patient record.

Blue-Yellow Testing
Short Wavelength Automated Perimetry (SWAP) provides the benefits of Blue-Yellow testing. Clinical studies suggest that Blue-Yellow allows visual field loss resulting from glaucoma to be detected much earlier than the traditional white-on-white method.

Head Tracking System
Repositions the patient's chin and head to keep the eye properly centered in the trial lens during tests.

Gaze Tracking
Displays and prints any deviation of fixation, thereby differentiating between head motion and gaze errors.

Wheelchair Accessibility
The perimeter actually comes to the patient. By upgrading to a handicap accessible system, your practice may qualify for a $5,000 tax credit

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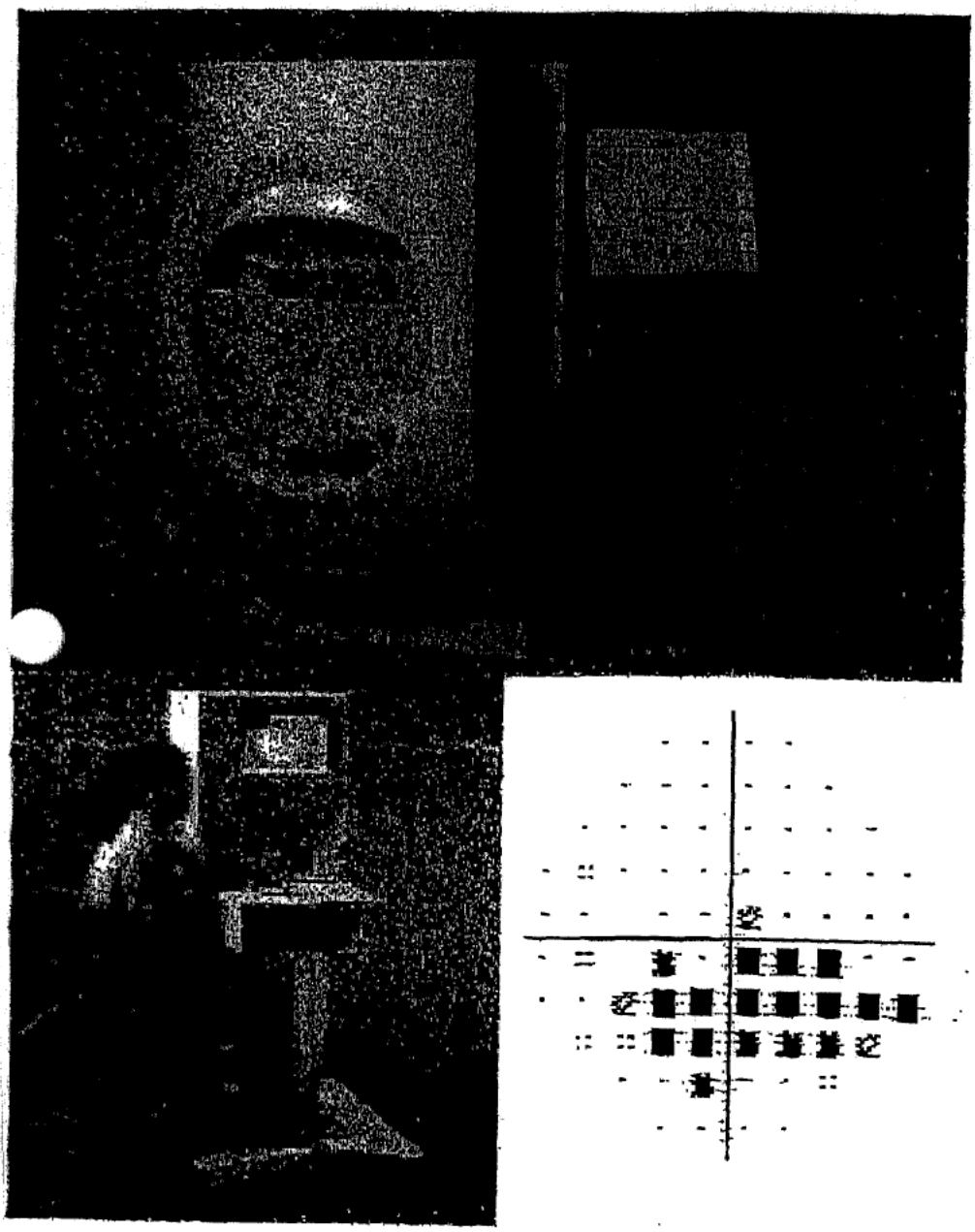
through the Americans with Disabilities Act. Consult your tax advisor for details.

Vertex Monitoring System
Alerts the operator if the patient moves away from the trial lens holder and forehead rest.

Return to Glaucoma Solutions

Humphrey® Field Analyzer II



Threshold Visual Fields in as Little as 2 Minutes

SITA™ sensitivity, reproducibility & accuracy has been shown in clinical testing

Diagnostic Precision

STATPAC™, the language of perimetry, compares results to proprietary age-normative and glaucoma databases

Early Glaucoma Detection

Blue-Yellow perimetry has been shown to provide earlier detection of glaucomatous visual field loss.

Improved Reliability

Patented fixation monitoring features automatically track and align patient head and eye position, alerting operator to patient movement away from the trial lens

Gold Standard

Over 35,000 Humphrey perimeters worldwide

Practice Friendly

4 Models to choose from to meet practice needs

Kinetic, Custom and Esterman disability testing allow the widest range of testing protocols on any perimeter

Operator Friendly

Touch screen with on-screen menus simplify and expedite instrument operations

Patient Friendly

Wheelchair accessible and award winning ergonomic design allow maximum comfort for all patient body types

ZEISS

Humphrey Systems

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Humphrey® Field Analyzer II Technical Specifications

Specifications: Models 720, 740, 745, 750

Maximum Intensity	10,000 ASB	Max. Temporal Range	90 degrees
Stimulus Duration	200 msec	Electrical Requirements	100/120/220/240 volts AC ±10% 50-60 Hz, 400 VA max.
Stimulus Wavelength	Broadband visible light	Safety Approvals	UL, CSA, IEC, CE
Bowl Testing Distance	30 cm	Dimensions	Height 23 5/8", Width 23 3/4" Depth 19", Weight 80 lbs
Bowl Illumination	31.5 ASB		Height 575mm, Width 580mm, Depth 482mm, Weight 36.4kg

Testing Features		Model 720	Model 740	Model 745	Model 750
Threshold Test Library					
Central Field Test Patterns	10-2, 24-2, 30-2, Macula	X*	X	X	X
Peripheral Field Test Patterns	60-4, Nasal Step	X*	X	X	X
Threshold Test Strategies	SITA Standard	X	X	X	X
	SITA Fast	X	X	X	X
	Full Threshold	X	X	X	X
	FastPac™	X	X	X	X
Screening Test Library					
Central Field Test Patterns	C-40, C-64, C-76, C-80, C-Armaly	X*	X	X	X
Peripheral Field Test Patterns	P-60, FF-81, FF-120, FF-135, FF-245, FF-Armaly, Nasal Step	X*	X	X	X
Screening Test Strategies	Two Zone	X	X	X	X
	Three Zone	X	X	X	X
	Quantify Defects		X	X	X
Screening Test Modes	Age Corrected, Threshold Related, Single Intensity	X	X	X	X
Specialty Test Library					
Esterman Monocular		X	X	X	X
Esterman Binocular		X	X	X	X
Superior 36		X	X	X	X
Superior 64		X	X	X	X
Kinetic Testing			Opt.†	Opt.†	X
Custom Testing			X	X	X
Stimulus/Background Color	White on White	X	X	X	X
	Red or Blue on White		X	X	X
	Blue on Yellow (Short Wavelength Automated Perimetry)			X	X
General Testing Features	Goldmann Stimulus Sizes	III	I-V	I-V	I-V
	Foval Threshold Testing		X	X	X
	Automatic Pupil Measurement				X
User Defined Test Storage		X	X	X	X
User Features					
Fixation Monitoring	Heijl / Krakau Blind Spot Monitor	X	X	X	X
	Video Eye Monitor	X	X	X	X
	Gaze Tracking		X	X	X
	Head Tracking				X
	Lens Tracking (Vertex Monitor)				X
	Remote Video Eye Monitor Capability	X	X	X	X
Operator Interface	Touch-screen on CRT	X	X	X	X
	Keyboard	X	X	X	X
	Motorized Chinrest	X	X	X	X
	Help Menus	X	X	X	X
Printer	Printrex thermal printer, table mounted	X	X	X	X
Patient Data Input	Name, DOB, I.D., Trial Lens Rx, Visual Acuity, Pupil Size	X	X	X	X
	IOP, C/D, ICD-9 Codes, CPT Codes, Comments		X	X	X
Analysis Software	STATPAC 2™ - Single Field Analysis	X	X	X	X
	STATPAC 2 - Single and Multiple Field Analysis		X	X	X
	STATPAC for Blue on Yellow	X	X	X	X
	STATPAC for SITA	X	X	X	X
Data Storage	Single 3.5" Floppy Drive	X	X	X	X
	2.2 GB Hard Disk (subject to change)		X	X	
	2.2 GB Hard Disk (subject to change) with Tape Back-up				X

* Model 720 does not include Macula, Nasal Step, C-64, FF-135 or Armaly test patterns.
† Available in a future software release.

Customer supplied peripheral options:
- Compatible with some LaserJet printers.
- Compatible with some IBM-compatible serial mouse and/or trackball. The Microsoft PS/2 mouse is not supported.

All specifications subject to change without notice.

Zeiss Humphrey Systems
5160 Hacienda Drive
Dublin, CA 94568 USA
www.humphrey.com

Toll Free: 1-877-486-7473
Tel: (925) 557-4651
Fax: (925) 557-4217
e-mail: info@humphrey.com

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510(k) Application
Neurovision, Inc.

Attachment 5

Proposed Level of Concern for Software

)(4) Levels of Concern

510(k) Application
Neurovision, Inc.

Attachment 6

Clinical Protocol/Investigational Plan

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STUDY TITLE:

EVALUATION OF A SYSTEM FOR THE TREATMENT OF AMBLYOPIA

CLINICAL STUDY PROTOCOL

PROTOCOL NUMBER:	IS02
DATE:	June 2000
PRINCIPLE INVESTIGATOR:	Dr. Tova Ma-Naim
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Attachment 9

Software System Requirements Package

Appendix 1:	**Software Requirements Traceability Matrix**
Appendix 2:	**System Requirements**
Appendix 3:	**Architecture Design Chart for AA-1 System**
Appendix 4:	**Software Requirements Specifications (SRS)**
Appendix 5:	**Software Test Plan (STP)**

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Appendix 1: Software Requirements Traceability Matrix

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Software System Requirements Package

Appendix 2: System Requirements

NeuroVision
AA1 System

System Requirements

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Appendix 3: Architecture Design Chart for AA-1 System

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Appendix 4: Software Requirements Specifications (SRS)

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Hazard Analysis (Risk Assessment)

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Attachment 11

User Manual

Appendix A:	**Visual Perceptons Tasks**
Appendix B:	**Clinic Administration Application Interface**
Appendix C:	**System Components Technical Specifications**

AA-1 System

USER'S MANUAL

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Note: US Federal Law restricts this device to sale by or on the order of a physician.

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Section 1 GENERAL INFORMATION

1.1. INTRODUCTION

Amblyopia ("Lazy Eye") is a defect in the Visual Acuity of an anatomically and functionally normal eye that persists after the refractive errors in the eye were corrected. It is caused by unequal inputs from the eyes to the visual cortex during early childhood.
Amblyopia is a Brain Related Deficiency, which is mainly reflected as an abnormal function of the neurons in the visual cortex in adults. As a result of a relative ineffectiveness of the present-day treatment of childhood amblyopia and the difficulty of diagnosing the disease when it is treatable, at least 2% of the adult population worldwide suffers from Amblyopia.

The **AA-1** system provides treatment to adults suffering from Amblyopia. It utilizes a novel method for vision improvement treatment through the use of interactive and iterative computer-based perceptual exercises. The treatment is applied in a series of sessions, about 30 minutes each, administered twice a week or more often at a doctor's clinic.

The **AA-1** system is an interactive system, continuously adaptive to the individual patient's learning and improvement.

During each treatment session, the patient at the clinic views visual stimulations displayed on a computer monitor. The patient interactively communicates with the computer. During the session data that reflects the patient's performance is recorded. At the end of the Session, this data is sent to the **AA-1** central computer located at **AA-1** Data Center via the Internet. Patient's performance and progress is analyzed, and the parameters for the next session are determined upon and transmitted to the treatment location.

1.2. INDICATIONS FOR USE

The **NeuroVision AA-1 System** - Adult Amblyopia Treatment System, is indicated for the treatment of patients above 9 years of age, suffering from Amblyopia.

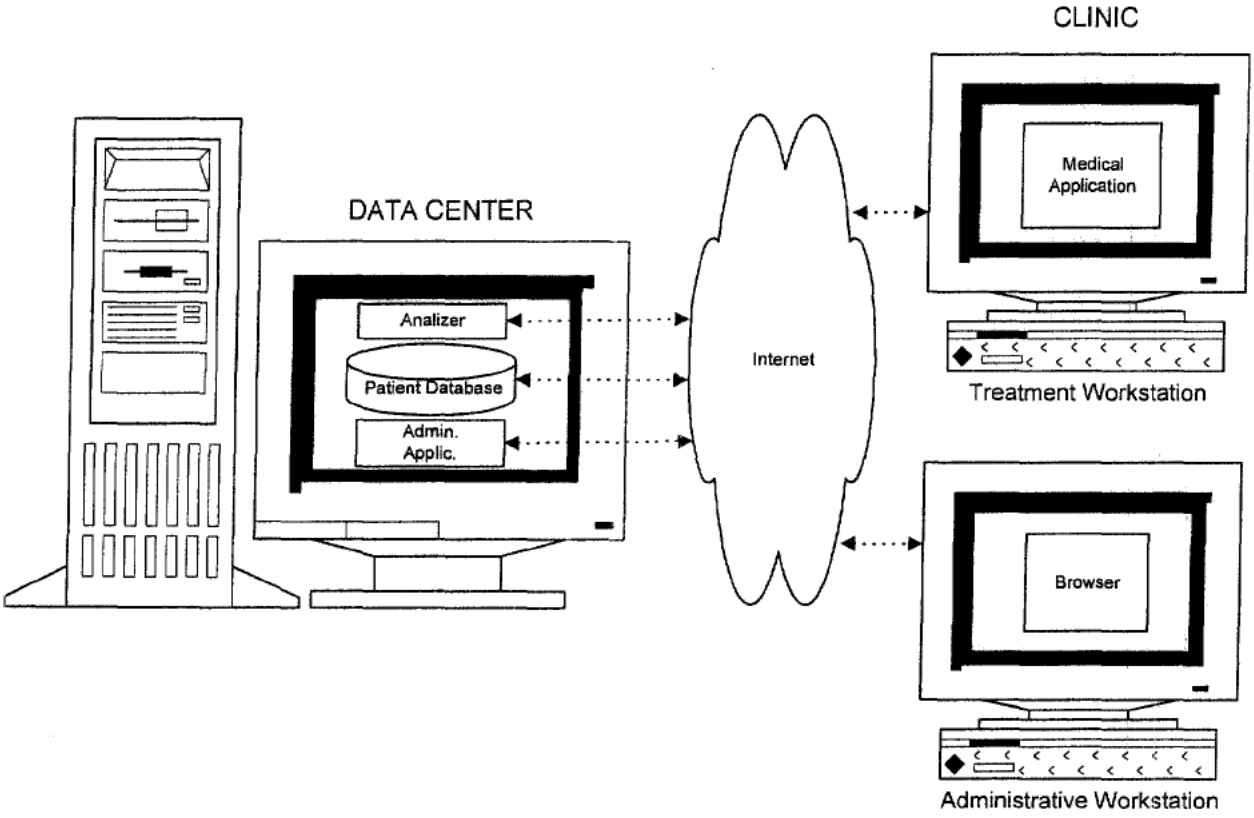
Section 2 SYSTEM DESCRIPTION

2.1 SYSTEM COMPONENTS

The **AA-1** System is designed to provide interactive treatment for the Amblyopic patient and to provide administrative support to the attending clinician, and the clinic administration staff.
The system main components are the global data center, clinic treatment workstations and clinic administration workstation. The connection between system components is accomplished through the Internet.

Figure 2-1 depicts the top-level system architecture.

Figure 2-1: AA-1 System Components



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2.1.1 Global Data Center

The **AA-1** Global Data Center is located in a secured facility. Medical and administrative data that are recorded in a clinic is sent to the Data Center over the Internet. This data is stored in a central database. The data is analyzed and processed. Based on each patient's performance and status, a new treatment session is generated specifically for each patient.

The Global Data Center implements the following functions:

1. ***Patient Database (DB)***

This database includes all patients data from all the clinics worldwide that provide **AA-1**'s amblyopia treatment. Patients data includes demographic data, medical data, and parameters which are unique to **AA-1**'s treatment.

2. ***Administrative application***

This application assists the clinic staff with the treatment management and administration. The application is Web-based and could be operated by the clinic administrator from any standard workstation, using a commercial Web browser. Once the clinic administrator has logged into the administrative application, the following operations could be performed:

- View the list of existing patients under his/her supervision.
- Edit and update an existing patient's personal and medical data.
- Add a new patient to the clinic, including allocation of a Patient ID and password.
- For each patient - view the input and output data of previously performed sessions and the setup for the next session.
- For each patient – enter his medical examinations, including his periodic Visual Acuity tests.
- For each patient – produce a personal progress report.

All patient's data that is viewed or updated by using the administrative application is stored in Patient's Database.

3. ***Session Analyzer Engine***

This application performs the automated personalization of the treatment session.
The Session Analyzer Engine sets the treatment section types for the next treatment session and defines the values of all treatment parameters based on the patient's performance in the previous treatment sessions.
When a treatment session results of a particular patient returns from a clinic, the Session Analyzer Engine is launched to analyze the incoming results, generate next session parameters, and send them back to the particular clinic.

2.1.2 Clinic

An eyecare clinic is the point of care for the **AA-1** treatment. The clinic includes one or more treatment workstations that provide the treatment, and an administrative workstation for all the required administrative tasks. The workstations can be either separately connected to the **AA-1** Global Data Center through the Internet or connected to a local network, which is connected to the Internet. The system allows the user (either administrator or patient) to log into the applicable workstations. A unique User ID and a password are required for logging in.

1. ***Administrative Workstation***

This workstation includes a Web browser to view and transfer the patients administrative data to and from the **AA-1** Data Center. The information that is transferred through the browser includes patient's demographic data, and medical data, including medical history, initial visual abilities and deficiencies, and the results of visual acuity examinations that should be performed every few sessions. These visual acuity examinations are performed independently of the **AA-1** System. The Administrator can observe the stored and analyzed patient data through this workstation.

2. ***Treatment Workstation***

Treatment sessions are administered through this workstation. The treatment workstation receives an input file through the Internet from the Data Center.
It processes the data received from the Data Center, provides the patient with the treatment tasks, and receives his/her inputs.
At the end of the treatment session, the medical workstation generates an output file, which reflects the patient's performance in the particular treatment session. This output file is transferred to **AA-1**'s Data Center. It will be saved and analyzed for the generation of the following treatment session.

2.1.3 Internet

The Internet is the means of communication between the Global Data Center and the clinic Treatment Workstation as well as between the Global Data Center and the clinic Administration Workstation.

The **AA-1 System** is designed to operate regardless of the current Internet connectivity state, meaning that it may operate properly whether there is on-line Internet connection or not. Every once in a while, the system automatically initiates Internet connection. It is required that Internet connection will be successfully achieved at least once every 24 hours. Otherwise, an alert will be generated.

When the system is on-line, all the new patients' data and all the new session parameters for the existing patients are transferred from the **AA-1** Data Center to the clinic's Treatment Workstation(s). Additionally, all the performed sessions results are transferred from the treatment workstations to the **AA-1** Data Center via the Internet.

In order to use the clinic administrative application, which is implemented as a Web-based application, an on-line Internet connection between the clinic Administrative Workstation and **AA-1** Data Center is required.

2.2 SYSTEM ACCESSORIES

Operation of the **AA-1** System requires the use of a few accessories. These accessories include prescribed eyewear, standard earphones, a computer mouse and a chair with a working surface for computer mouse operation.

2.2.1 Eye Glasses

During most of the treatment sessions, the non-amblyopic eye is blurred by a semi-translucent lens. During the advanced treatment stages, the patient wears StereoGraphics eyeglasses for dual eye performance tests.

Prior to the initiation of the **AA-1** Treatment, an eye-care professional should prescribe the patient with a pair of eyeglasses or contact lenses according to the subjective patient's refraction. The patient should wear the eyewear during all the treatment sessions. During the sessions, the patient should cover his/her non-amblyopic eye with an opaque lens. If the patient has eyeglasses the opaque lens is clipped to his eyeglasses. In case of contact lenses, standard eyeglasses with a suitable opaque lens are used.

2.2.2 Stereographic Glasses

The stereographic glasses are used to test patient's three dimentional vision abilities. The patient uses them only when a stereo-vision test is scheduled by the system. The glasses are Infrared wireless. An Infrared emitter, which is located on top of the monitor, synchronizes the stereographic glasses with the monitor. When in use, the patient wears the stereographic glasses on top of his normal eyewear.

2.2.3 Earphones

The earphones are used in order to provide the patient with treatment instructions and feedback regarding his performance. Any commercial earphones that may be connected to the Clinic Workstation is applicable for use.

2.2.4 Chair

The chair on which the patient sits during the treatment sessions should be immobile. In addition, it should have a working surface that allows placing a computer mouse, which is patient's main input device

2.2.5 Computer Mouse

A 3-button computer mouse functions as the input device that allows the patient to interact with the treatment workstation. During the treatment, the patient is exposed to different visual perception tasks. His answers to the system are generated by clicking on the several mouse buttons.

2.3 TECHNICAL SPECIFICATIONS

See Appendix C

Section 3 TREATMENT DESCRIPTION

3.1 TREATMENT PHASES

3.1.1 Treatment Process Start - Initial Comprehensive Examination

1. An Ophthalmologist and an Optometrist shall check the patient prior to the **AA-1**'s Treatment start, in order to decide whether the patient suffers from Amblyopia and whether he/she is applicable for this treatment or not.
2. A patient shall go through a comprehensive visual examination. The examination will cover Visual Functions, Ocular Examinations and Visual acuity tests.
3. An ophthalmologist shall examine the patient's medical records and his initial examinations, and decide whether the patient is qualified for the **AA-1** Treatment.
4. If the patient qualifies, the clinic administrator will open a new patient record in the database using the administrative workstation, and enter all patient's necessary details into **AA-1**'s System. For details see Appendix B.
5. Upon enrollment, **AA-1** System automatically prepares the first treatment session for the patient.

3.1.2 Digital Diagnosis Phase

1. This phase includes the first 2 treatment sessions.
2. The objective of this phase is to "digitally" map his visual deficiencies and to set up the initial parameters for his treatment.

3.1.3 Treatment Phase

1. This phase includes the a series of treatment sessions. The number of sessions depend on the individual visual abilities and performance.
2. The objective of this phase is to improve the visual acuity of his Amblyopic eye towards normal vision.
3. All treatment sessions are automatically generated by **AA-1** system.
4. The patient should undergo a periodic Visual Acuity examination after completing 4 consecutive sessions. The clinic administrator shall enter the examination results into **AA-1**'s System using the administrative workstation. For details see Appendix B.

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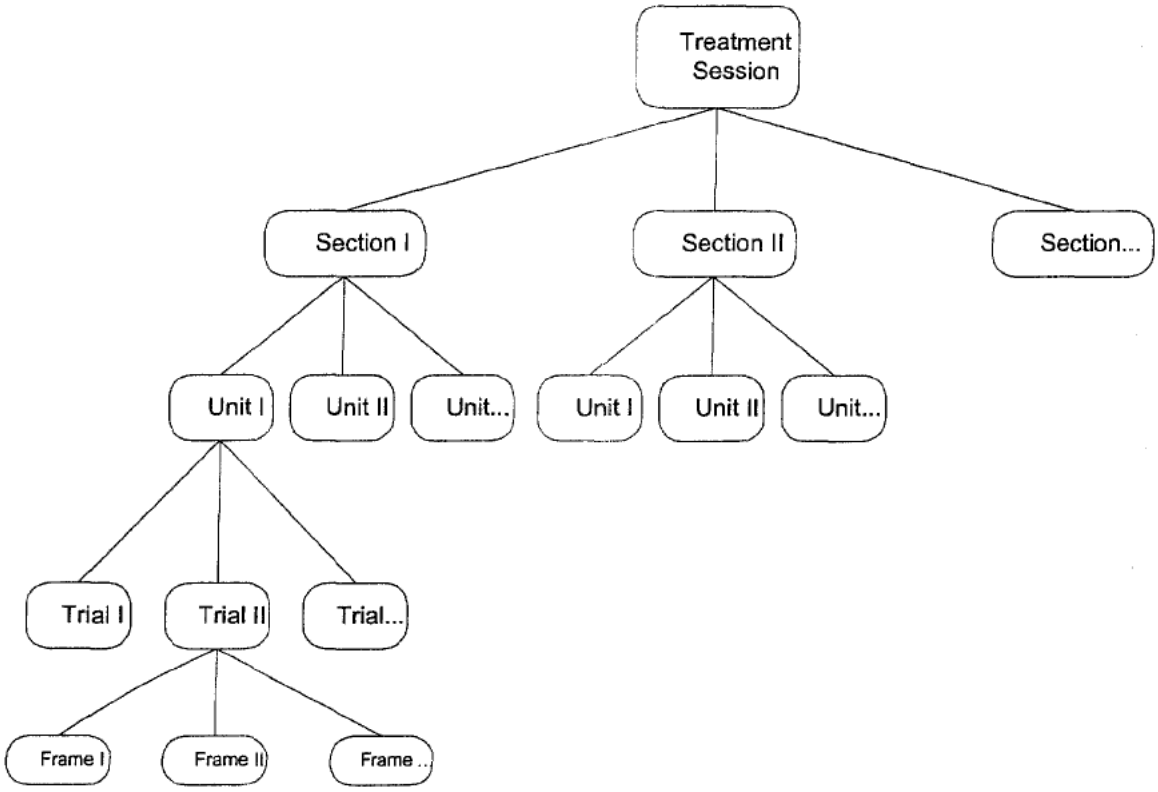
3.1.4 Treatment Process End

1. Once patient's visual improvement is exhausted, meaning that his Visual Acuity consistently doesn't improve any more, the treatment process is concluded.
2. Upon treatment conclusion, the patient shall undergo another comprehensive visual examination as done at the treatment start.
3. After treatment completion, the patient shall be scheduled every 3 months for a follow-up and updating of his visual examination records.
4. All examinations results shall be keyed into the system by the clinic administrator.

3.2 TREATMENT FUNCTIONAL DECOMPOSITION

The **AA-1** Amblyopia treatment is composed of a series of sessions appointment. During each appointment the patient will perform one treatment session. The following figure summarizes the structure of a treatment session. A detailed explanation for each component is provided below:

Figure 3-1: Treatment Session structure



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3.2.1 Section

A treatment session may be composed of one or more sections. The number and composition of sections per treatment session is pre-defined by **AA-1** Data Center for each individual patient's treatment.
A section is a sequence of interactive Visual Perception Tasks (VPT), characterized by the same type of images that the patient is exposed to, and the same type of tasks that the patient is required to perform.
The Visual Perception tasks used by **AA-1** system for the Amblyopia treatment are detailed in Appendix A.

3.2.2 Unit

A section may be composed of one or more units. The number and composition of units per section is pre-defined by the **AA-1** Data Center for each individual patient's treatment.
A unit is a treatment exercise of a specific Visual Perception Task. The units within a section may differ from each other in one or more basic parameters which characterize the setting of the exercise, such as images size or distance between images.

3.2.3 Trial

A unit is composed of a series of trials. The number and composition of trials per unit is not pre-defined. It depends on patient's performance and it is defined in real time.
A Trial is a part of the unit that contains presentation of a few display frames (currently one or two), and requires one input from the patient. The trials within a unit may differ from each other in one single parameter that may be changed from trial to trial in accordance to the patient's input.
Generally speaking, the varying parameter among the Trials will be changed in order to increase the difficulty level of patient's task if his input is correct and to decrease the difficulty level if the patient's input is incorrect.

3.2.4 Frame

A Trial may be composed of one or two Display Frames, depending on the section type.
A Display Frame is composed of one or more shapes which are displayed for a predefined fixed time duration. The time interval between the first and second display frame is fixed as well. The appearance order of the frames is randomly generated by the treatment workstation.

3.3 TREATMENT SESSION SEQUENCE

Once a patient visits the clinic for a treatment, the clinic assistant locates the patient in front of a workstation, logs-in the patient into the system using patient's unique user ID and password, and verifies that the patient can proceed with the treatment session.

Afterwards, the patient shall proceed with the following steps:

1. When the patient is requested to perform a section that includes a new Visual Perception Task that the patient hasn't experienced before, the patient will participate in an interactive Demo that demonstrates the expected images and tasks that may be performed during the new VPT.

2. The patient will always have the option to view the interactive Demo before starting a section, even if the section type is not new to him any more.

3. The patient should perform a short practice section before the initiation of a new section type. The results of the practice trials will not be sent back to the **AA-1** Data Center, but the patient will be allowed to continue to the treatment section only upon a succesful performance of the practice trials.

4. Once the Practice section is successfully accomplished, the patient starts the treatment section. The patient shall perform unit after unit, section after section, until the treatment session is completed.

5. Patient is allowed to take short breaks in between units, after completion of a unit, but not while a unit still goes on.

6. All treatment session performance parameters are stored locally, and are sent back to the **AA-1** Data Center after session end, once Internet connectivity exists.

7. When the patient completes all the session tasks, the system displays a message to show the session is completed. This message may be kept still for a few seconds while the workstation performs a synchronyzation process.

8. If a patient has aborted the session before completing 75% of it, the session data is ignored, and upon next activation, the same session setup will be applied.

3.4 PATIENT'S TASKS DURING TREATMENT

1. The patient is required to perform a series of Visual Perception tasks during his Treatment Session (such as VPT's detailed in previous subchapter). As mentioned before, each Treatment Session is composed of a few Sections that are composed of a few Units that are composed of several Trials.

2. During the treatment the patient should comply with the following requirements:
   - Sit at 5 feet distance from the monitor.
   - Do not lean forward while performing the treatment
   - Wear the personal eyewear through all the treatment
   - Wear the earphones
   - Concentrate as much as possible

3. The Trial is the basic task that the patient is required to accomplish. Before each Trial start, a circle is displayed in the display center. This circle is called the "Fixation Circle". The patient is supposed to focus his eyes and his attention on the Fixation Circle. Once focused, the patient may activate the Trial by pressing the center button on the mouse (i.e. the "continue button").

Note: Focusing the patient's eyes and attention on the "Fixation Circle", before each Trial's start, is a key element in the treatment success.

4. The Trial will start according to the particular section type and the particular unit parameters, as earlier described for each section. The Trial is completed by the patient's input generated by pressing the left or right mouse buttons.

   In each Trial, the patient may provide an answer that is either correct or incorrect . If the patient's vision ability is well above the trial's difficulty level, most of the patient's answers will be correct. But, if the patient's vision ability is well below trial's difficulty level, most of the patient's answers will be wrong. However, if the visual stimulations on the monitor correlate with the patient's vision ability, the patient should be providing incorrect and correct answers alternatively.

5. When the system identifies a certain alternating correct/incorrect answers trend, which means that the patient is working at his visual ability limitations, the system ascertains the patient's performance for the current unit and ends the unit.

6. After a unit is completed, a status bar indicating the current treatment progress is presented. The patient will start to perform the trials of the next Unit, and such until the whole Session will be completed.

3.5 CLINICIAN'S TASKS DURING TREATMENT

The clinician is required to ensure that all the conditions for a successful treatment session are fulfilled.

1. Before the treatment start, the clinician shall ensure that there is a pending treatment session for the patient by checking on the Administrative workstation.

2. The clinician will verify that the patient is feeling well and fit for the treatment session.

3. The clinician shall check whether there is a change in the type of treatment that the patient will receive on that particular day as compared with the previous treatment. (Such changes are noted on patient's summary page on the Administrative workstation). If there is such a change, the clinician shall inform the patient, explain the expected change, and encourage the patient to run a practice section before treatment start.

4. The clinician shall check if the patient requires a Visual Acuity examination during the respective visit, if positive then the clinician will ensure that the VA test is performed prior to the treatment session and not after the session.

5. When the patient is ready for treatment start, the clinician shall locate the patient in front of a treatment workstation and verify:
   - Sitting distance of 5 feet between patient and monitor.
   - The patient wears his personal eyewear.
   - The patient's good eye is occluded
   - The patient wears earphones.

6. The clinician shall double check with the patient his/her user id and password, to ensure that the correct treatment is provided to the respective patient. Then the clinician shall log-in the patient.

7. If there was a change in the type of treatment, the clinician shall verify that the patient runs a practice section first, understands the task and only afterwards starts the treatment session.

8. When the patient starts running the treatment session, the clinician shall leave the room, unless the patient is a child, then the clinician's presence is necessary to ensure compliance. Before leaving the treatment room, the clinician shall ensure that the patient runs a treatment session and not a practice session.

9. When leaving the treatment room, the clinician shall switch off the room light and close the door.

10. At the end of the session, the clinician shall record patient's feedback, verify that the patient has completed the entire session, if not, the clinician shall quit the session to allow next patient's treatment.

Section 4 NOTES FOR EFFECTIVE TREATMENT

1. In order to achieve maximal improvement, the patient should:
   I. Undergo treatment sessions at least twice a week.
   II. Wear the prescribed eyewear (eyeglasss or contact lenses) and the provided earphones during the entire treatment.
   III. Be alert and concentrate during the entire treatment session.
   III. Follow the on-line operation instructions and feedbacks that are provided by the system.
   IV. Sit comfortably at 5 feet distance from the monitor without leaning forward, even when the visual stimulations are hardly seen, unless instructed otherwise.
   V. Make efforts to achieve the best performance in all the tasks during the session.
   VI. Not undergo a treatment session if patient is not fit or suffers from any abnormal medical condition. In such a case patient should consult the clinician.
   VII. Not proceed with a treatment session if patient does not fully understand the task. In such a case patient should consult the clinician.
   VIII. Wear the prescribed eyewear for daily use (not with the blurred lens) every day as much as possible, not only during treatment.
   IX. Try to use his lazy eye in daily life, in parallel to the treatment, such as closing his good eye when watching TV, etc…

2. In order to achieve maximal improvement, **AA-1** system should be administered to patients only by a trained clinician who is familiar with all system operating procedures. The clinician should:
   I. Ensure patient's compliance with the treatment requirements before leaving the patient in the treatment room, in particular ensure that:
      - The patient is seated at a distance of 5 feet from the monitor.
      - The patient wears his personal eyewear.
      - The patient's good eye is occluded
      - The patient wears earphones.
      - The patient understands the task
      - The lights are switched off
   II. Keep noise distractions in the treatment room and around to minimum.
   III. Schedule the patient for periodic Visual Acuity examinations every 4 treatments.
   IV. Be supportive, provide the patient with all necessary information, get and record feedback from the patient.
   V. Increase patient's motivation, especially when the patient complains that the treatment is hard or if temporarily there is no progress in his Visual Acuity examinations.

Section 5 SYSTEM SETUP

5.1 CLINIC REQUIREMENTS

AA-1 System shall be installed in the clinic by a NeuroVision technician. **AA-1** System in the clinic includes one administration workstation and one or more treatment workstations.

Prior to installation, the following preparations shall be done:

1. Treatment room – A clinic may use one or more treatment workstations to provide **AA-1**'s treatment. The required space is minimum of 30 Sqft per treatment workstation (10 ft X 3 ft). The treatment room should have sealing means in order to create a darkened environment.
2. A clinic may use more then one treatment room and more then one treatment workstation per room. In case of multiple workstations in one treatment room, partitions are required to avoid interference.
3. Electricity points – There should be minimum 2 points per workstation, at close proximity to dedicated workstation location
4. Communication – All workstations (treatment and administrative) shall be connected to the Internet. If a clinic local network exists, there should be a network connection for each station. If no clinic local network is available, a separate dedicated telephone line should exist for each workstation. The communication points should be at close proximity to workstations location.
5. Internet account that supports the clinic network topology should be available. An internet account that allows the treatment workstations to be permanently connected to the Internet is preferable, however the system supports dial-up accounts as well.
6. The treatment workstation should be exclusively used for running the **AA-1** Treatment Sessions. This ensures that the station is correctly configured according to the requirements set by **AA-1** and will permanently remain that way. The administrative workstation could be used for other purposes as well.
7. Furniture - one table per treatment workstation, one chair with working surface that allows placing a computer mouse – per treatment workstation, proper furniture (table, front desk, etc…) for administration workstation.

Note: If a clinic has more than a single treatment workstation, it is not required to maintain a clinic network. Each workstation will connect to the Internet independently.

5.2 SYSTEM INSTALLATION

The treatment workstations and the administration workstation are being installed and configured by **AA-1** prior to the installation in the clinic.

The installation in the clinic is done by a NeuroVision certified technician.

5.3 SYSTEM CALIBRATION

This phase is performed in the clinic by NeuroVision certified technician after the station installation is completed.

Section 6 SYSTEM OPERATION

6.1 DAILY OPERATION PREPARATIONS

Every day, before starting the treatments, the clinic administrator shall perform the following preparations in order to ensure that the system is operable:

1. Verify appearance of **AA-1** Treatment Station log in page.
   a. If treatment workstation is off, turn it on.
   b. If the desktop is displayed, click on **AA-1** icon.

Figure 6-1: Treatment Station Log-In Page

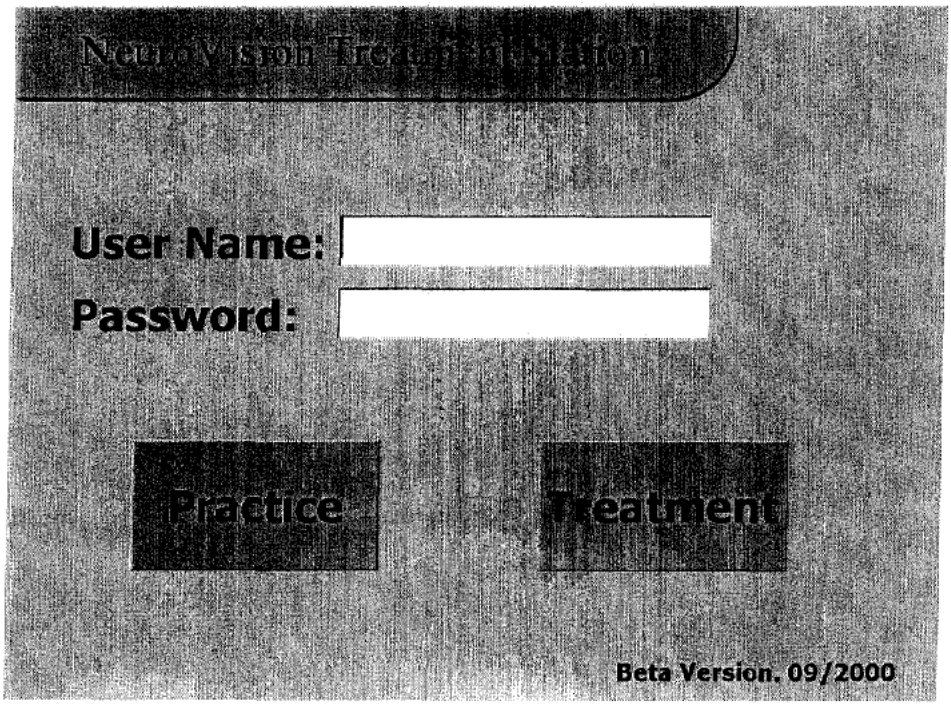

Figure 6-2: AA-1 Icon

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2. Run the treatment workstation test, verify that treatment workstation operates properly. (HOW TO RUN THIS TEST?)

3. Check which patients are scheduled for treatments during the respective day (where, in hardcopy log?).

4. Verify, using the treatment administration workstation, that all the patients that are scheduled for treatments during the respective day have a pending session. For details, see Appendix B-7.

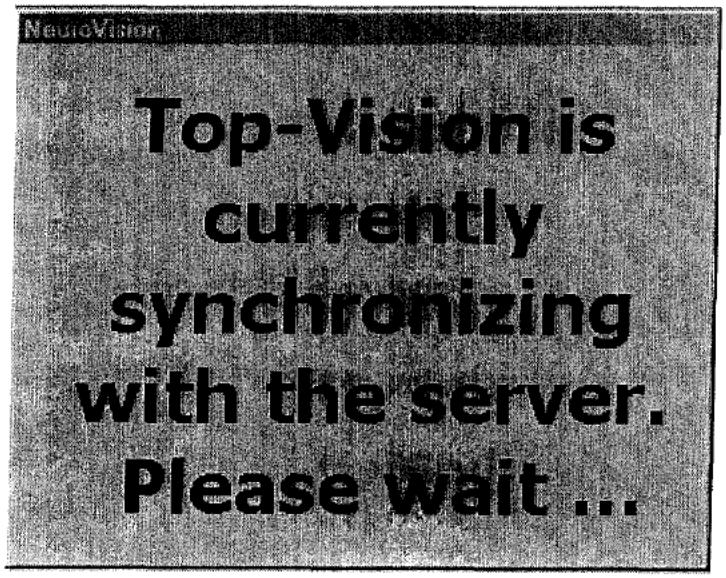
5. Verify that the treatment workstations have synchronized during the last 12 hours (how??). If station has not synchronized during the last 12 hours, synchronize manually by clicking the "agent" icon:

Figure 6-3: The Agent Icon

Agent

6. While synchronizing, the following image appears on the right bottom corner of the screen:

Figure 6-4: Synchronization in process indication



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6.2 PRACTICE BEFORE TREATMENT

The patient has the option to practice the Visual Perception Tasks before doing the real treatment.
The practice session is identical to the real treatment session, the only difference is that its results are not sent back to **AA-1** Data Center.
It is highly recommended to encourage the patient to run the practice first, in particular when there is a treatment change. Understanding of the VPT is a key success factor.

To start the Practice Session - Enter User ID and Password in the Treatment Station Log-In Page (See Figure 6-1). Press the Practice button. The system performs an identification check. If the user is identified and approved, the Session Window appears.

For the practice session patient's user interface, see the section 6-4.

6.3 INTERACTIVE DEMO

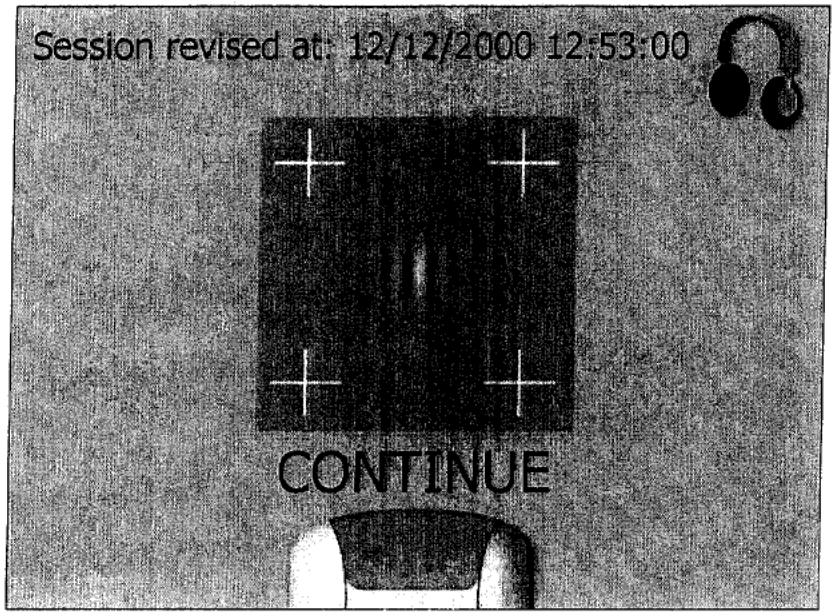
The patient has the option to view an interactive section demo at the beginning of each treatment section.
In the demo, the system demonstrates the following section's visual perception task and explains the patient how to perform it. The patient is supposed to follow the audio and visual instructions.
When the patient performs a new Section type, for his first time, the system obliges the patient to perform the Demo before starting the Treatment Session.

6.4 TREATMENT SESSION USER INTERFACE

The clinician shall initiate the treatment session after performing all the steps detailed in chapter 3.5.

To start the Treatment Session - Enter User ID and Password in the Treatment Station Log-In Page (See Figure 6-1). Press the Treatment button. The system performs an identification check. If the user is identified and approved, the Session Window appears:

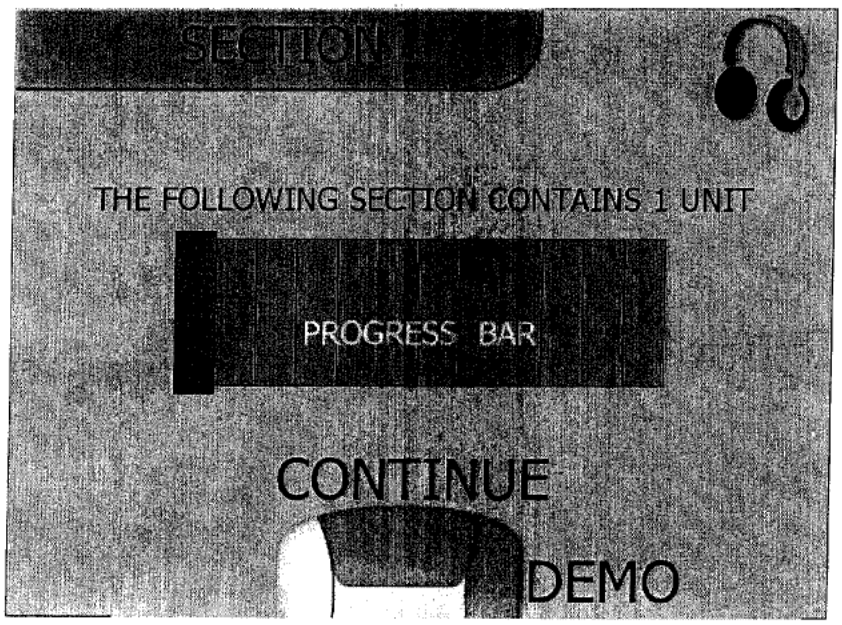
Figure 6-5: Session Window



The following steps should be done by the patient:

1. Press the center (continue) button of the mouse. The Section Window appears.
   a. The Section window is an informative display. It includes a progress bar that indicates the total number of units in the current treatment session – the small bar strips, and the number of units in the following section to go - the enlarged darker bar strips.

Figure 6-6: Section Window



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2. Press the right button of the mouse in order to view an interactive demo of the current section type.

3. Press the center (continue) button of the mouse in order to start the first unit of the actual section.

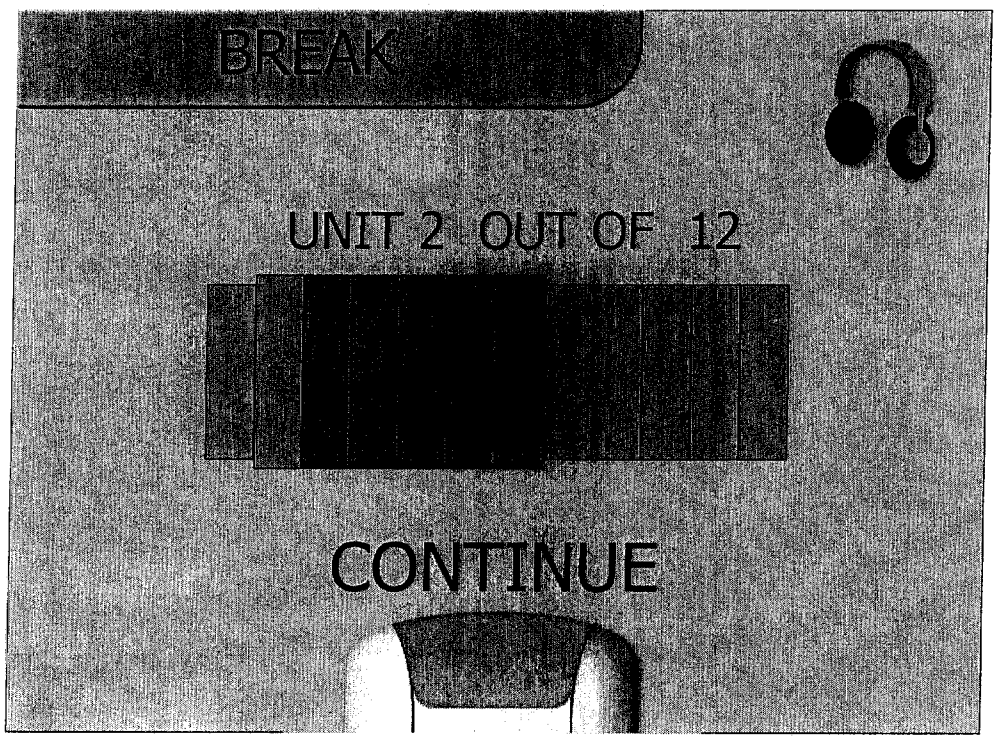
4. In a unit, the patient performs a series of trials. In a trial the system usually displays of a few image frames, and the patient is prompted to select the right answers by using the mouse buttons.

5. The system identifies correct/incorrect answers, in real time. If the user gives an incorrect answer the system plays a beep sound.

6. For detailed description of VPT types, see Appendix A.

7. A unit ends when the patient stabilizes around his visual ability threshold. At the end of a unit, the system provides an indication of the treatment session progress/remaining time:

Figure 6-7: In between Units Window



The orange bar strips indicate the units that have been performed already.
The enlarged and darkened strips indicate the units of the current section.
The small green bar strips indicate the remaining units of the following sections.

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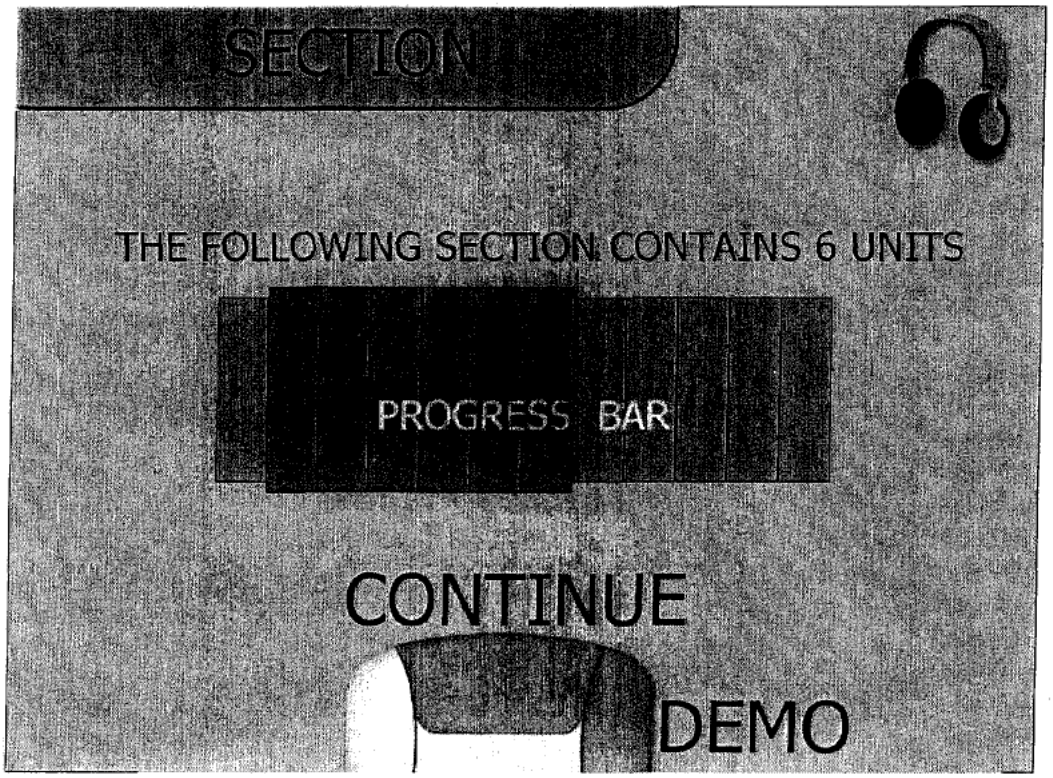
In the above example:
The whole session includes 12 units. 2 units have been performed already.
The currently performed section includes 6 units, among them 1 performed already.
After completing the current section, the following sections have 5 more units.

8. When patient is in between units, he/she is allowed to takes a short break.

9. Press the center (continue) button of the mouse in order to start the next unit of the actual section.

10. After performing all the planned section's units, the system prompts the patient to perform next Section's tasks, and the Section window appears again:

Figure 6-8: In between Sections Window



11. Press the center (continue) button of the mouse in order to start the first unit of the next section.

12. At the end of the last section of the particular treatment session, the system displays a Good Bye message and terminates the treatment. See figure 6-9.

13. If the patient can not complete the treatment session for any reason, the clinician has the option to stop the treatment session before it's completion. The clinician shall do the following:

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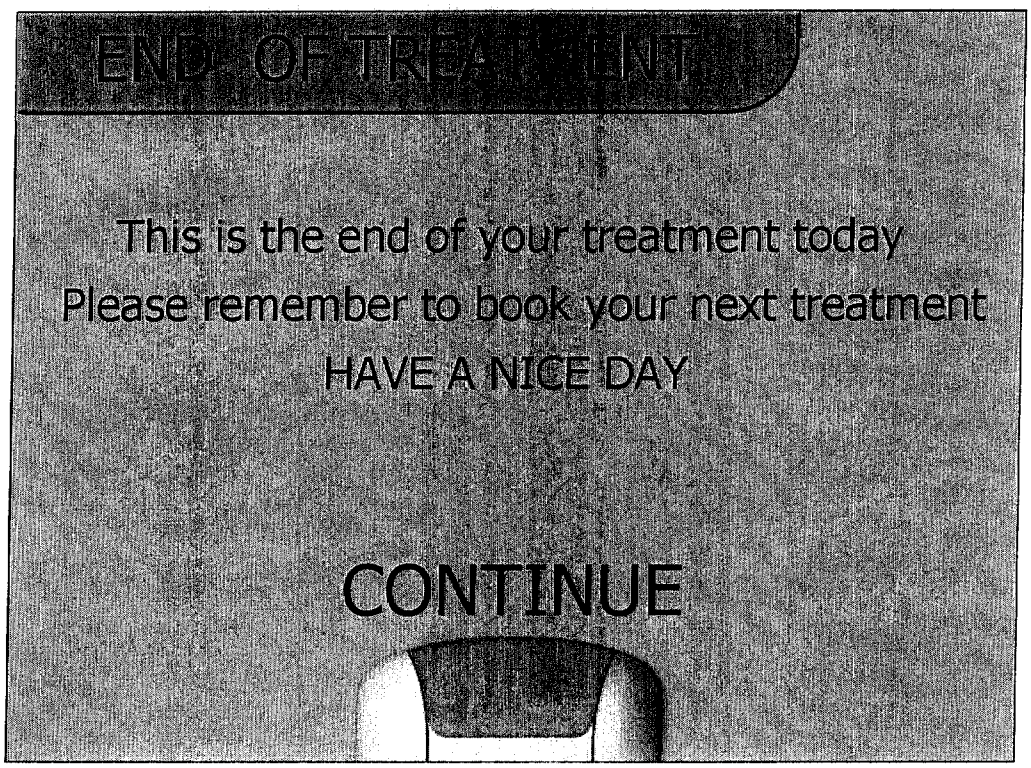
a. Type "quit" and any additional key (No feedback on screen will be displayed upon keying in the particular characters).
b. Following that, the Good Bye message will appear and the treatment session will end.

Figure 6-9: Good bye Window



Section 7 SYSTEM MAINTENANCE

7.1 CLEANING PROCEDURES

7.1.1 Mouse Cleaning

1. On monthly basis, clean the exterior of the mouse with a moist cloth wetted using water and soap.

7.1.2 Screen Cleaning

1. On weekly basis, clean the monitor screen with anti-static wet wipes. Dry the monitor with clean wipes.
2. Attention! Do not touch the setting buttons in the monitor front.

7.2 MONITOR CALIBRATION

1. The monitor calibration will be periodically performed by a NeuroVision's certified technician, every 3 months.
2. If the clinic administrator notices a change in monitor's luminance, colors, or display shape, he/she should contact **AA-1** support center for assistance.

7.3 SYSTEM RESTART

1. It is highly recommended to restart the treatment workstation and the administration workstation once in a while. The recommended restart frequency is once a month.

Section 8 TROUBLESHOOTING GUIDE

The following tables detail **AA-1** System possible operating problems, and the action that should be taken by clinic administrator in order to recover the system.

If the clinician follows the troubleshooting guidance, but system still doesn't recover, the clinician should contact **AA-1** support center.

8.1 TREATMENT WORKSTATION

Table 8-1: Troubleshooting of the Treatment Workstation

#	Problem	Resolution
1.	I typed the correct username and password but the system indicates it is wrong.	• If you have updated the patient details lately – perform a manual synchronization of the treatment station (See section 6-1). • Check that you type the username and password exactly as it appears in the clinic administration application. Pay attention to capital letters! • Verify that the patient status in the clinic administration application is active (See section B-7)
2.	I try to start a treatment but I get an error message saying that the system did not synchronize lately.	Perform a manual synchronization of the treatment station (See section 6-1).
3.	I try to start a treatment but I get an error message saying that the patient does not have a ready session.	• Verify that the patient has a "pending" session in the clinic administration application (See section B-7). • Perform a manual synchronization of the treatment station (See section 6-1).
4.	I run manual synchronization but the synchronization screen flashes for less than a second.	• Verify that the station is connected to the Internet. • If there is no Internet connection and the dial-up window does not appear – reboot the computer.
5.	At the beginning of the synchronization, the dial-up window does not disappear. There isn't any error message.	Verify that the "connect automatically" check box at the dial up box is checked, and press the connect button.

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#	Problem	Resolution
6.	At the beginning of the synchronization, the dial-up window does not disappear. An error message says that username or password is wrong.	• Verify that the username and password are correct (pay attention to capital letters!) (We should say something about keeping a name log???). • Verify that no other computer in the clinic??? uses the same username. • Verify that the "connect automatically" and "remember password" check boxes at the dial up box are checked, and press the connect button.
7.	At the beginning of the synchronization, the dial-up window does not disappear. An error message says that the line is busy.	Wait for a short while, verify that the "connect automatically" check box at the dial up box is checked, and press the connect button.
8.	At the beginning of the synchronization, the dial-up window does not disappear. An error message says that there is no dial tone.	Check that the phone line is correctly connected to the modem, verify that the "connect automatically" check box at the dial up box is checked, and press the connect button.
9.	At the beginning of the synchronization, the dial-up window does not disappear. An error message says that the port cannot be opened.	Reboot the computer.
10.	There is no feedback sound for wrong answers, or any other expected sound.	• Verify that the earphones are plugged in • Replace Earphones
11.	I have clicked the mouse but there was no reaction.	• Verify that the mouse is plugged in • Try to operate the station using other mouse
12.	Stereographic image is flickering	Verify that lights in the treatment room are off.
13.	The stereo-vision test failed	• Close the stereographic eyewear's temples, wait 5 seconds before reopening them. In case that the led flashes or did not light at all – replace batteries. • Verify that the emitter is pointing to the patient. • Verify that the emmiter red light transmission indication is on. If not, then restart the station.

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8.2 ADMINISTRATION WORKSTATION

Table 8-2: Troubleshooting of the Administration Workstation

#	Problem	Resolution
1.	I get " The page cannot be displayed" error message.	• Press the refresh button. • If the problem persists, check that the address on the browser match the application address as it appears in the manual. • Verify that the station has Internet connection
2.	I get a "an error occurred on the page, do you wish to debug" message box	• Press NO • Go to "Internet Options" (Tools menu -> Options). In the "advanced" tab, verify that disable script debugging is checked.

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Attachment 11

User Manual

Appendix A: Visual Perception Tasks

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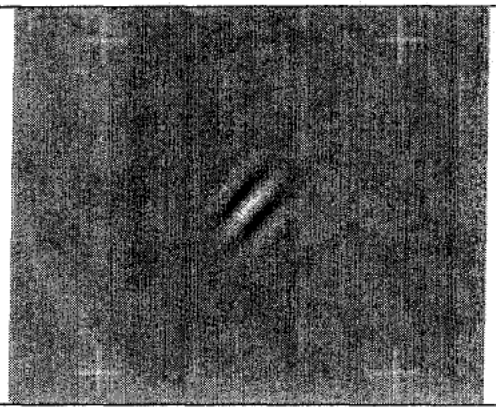
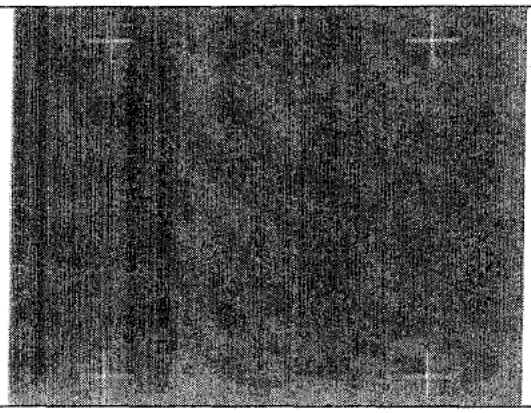
Appendix A: VISUAL PERCEPTION TASKS (VPT) TYPES

1. SINGLE IMAGE VPT

Figure A-1: Single Image Trial

Correct Frame	Incorrect Frame
	

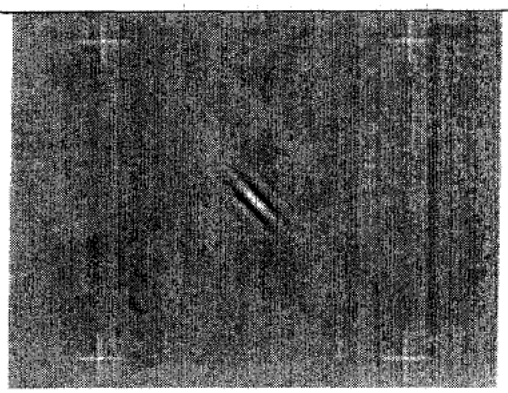
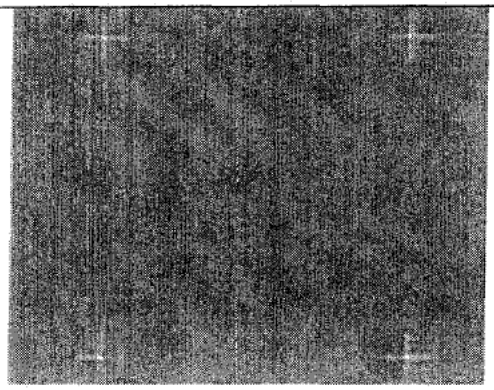
In this VPT, each trial is composed of two frames – correct and incorrect. The correct frame has one Gabor patch image at the display center and 4 crosses at the display edges, and the incorrect frame has only 4 crosses at the display edges. The patient should choose which frame is the correct one; whether the first frame or the second frame. The frame order is randomly generated by the treatment workstation.

The size, display duration, orientation, contour and initial contrast of the Gabor patch in the middle may vary among different units.

The parameter that varies from trial to trial within a unit is the contrast of the Gabor image.

2. ELYPTICAL SINGLE IMAGE VPT

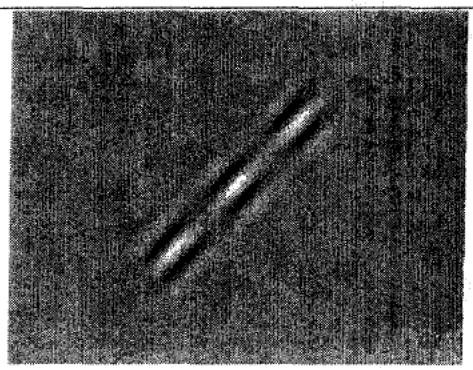
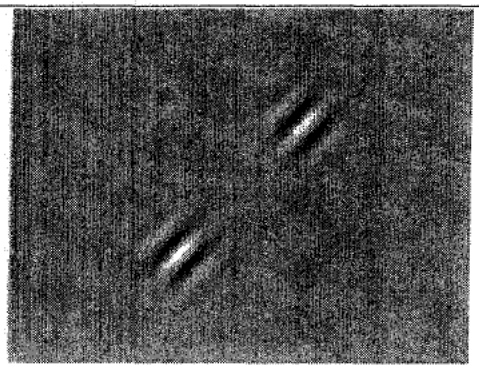
Figure A-2: Elyptical Single Image trial

Correct Frame	Incorrect Frame
	

This VPT is an extension of the Single Image VPT. The only difference is that the Gabor patch image is elongated and looks elyptical. The ratio between the elypse vertical and horizontal axis may vary among different units.

3. TRIPLE IMAGE VPT

Figure A-3: Triple Image Trial

Correct Frame	Incorrect Frame
	

In this VPT, each trial is composed of two frames – correct and incorrect. The correct frame has three aligned Gabor patch images, and the incorrect frame has only two aligned Gabor patch images, the center Gabor patch is then missing. The patient should choose which frame is the correct one; whether the first frame or the second frame. The frame order is randomly generated by the treatment workstation.

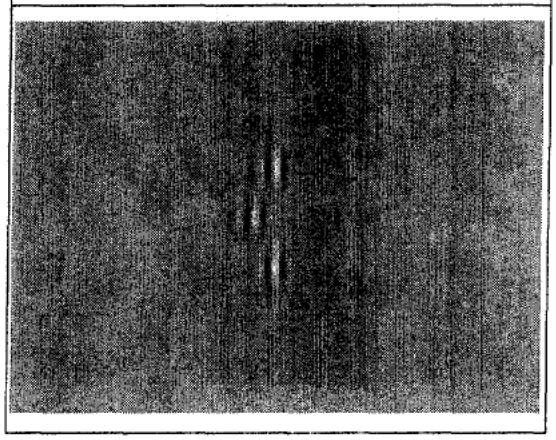
The size, display duration, distance between the shapes, orientation, contour and initial contrast of the Gabor patches may vary among different units.

The parameter that varies from Trial to Trial within a Unit is the contrast of the central Gabor Patch.

4. TRIPLE IMAGE ALIGNMENT VPT

Figure A-4: Triple Image Alignment Trial

Frame I



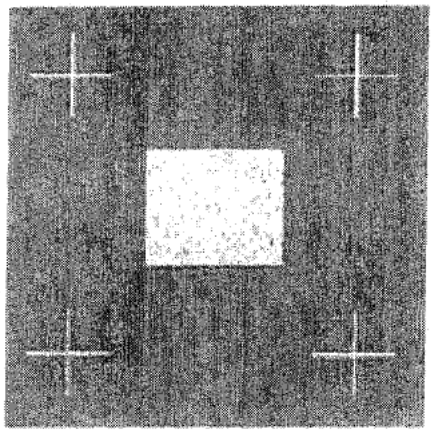
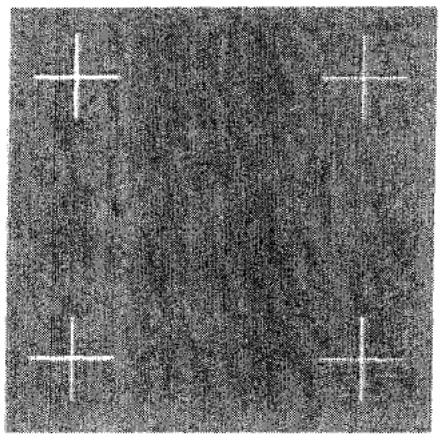
In this VPT, each Trial is composed of one Frame that includes three Gabor patches, with the center Gabor alignment to the left or to the right. The patient should choose what is the alignment direction of the central Gabor. The alignment direction is randomly generated by the treatment workstation

The size, display duration, distance between the shapes, orientation, contrast and initial alignment distance of the central Gabor of the Gabor patches may vary among different units.

The parameter that varies from Trial to Trial within a Unit is the alignment distance of the central Gabor patch.

5. NOISE DETECTION VPT

Figure A-5: Noise detection trial

Correct Frame	Incorrect Frame
	

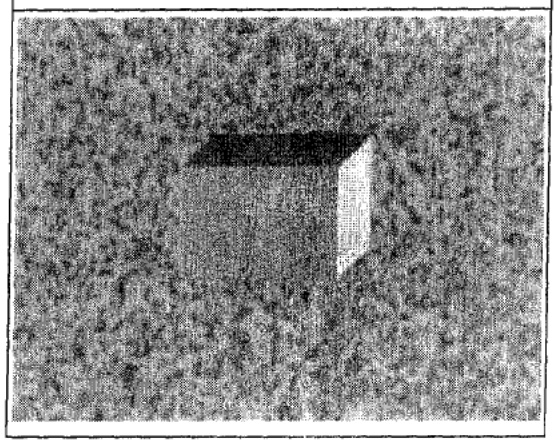
In this VPT, each trial is composed of two frames – correct and incorrect. The correct frame has a square filled with random dots (noise) at the display center and 4 crosses at the display edges, and the incorrect frame has only 4 crosses at the display edges. The patient should choose which frame is the correct one; whether the first frame or the second frame. The frame order is randomly generated by the treatment workstation.

The parameter that varies from trial to trial within a unit is the Random Dots density.

6. RANDOM DOT STEREO (RDS) VPT

Figure A-6: Random Dot Stereo trial

Frame I



In this VPT, each Trial is composed of one Frame that includes a box in the middle of the display with a random dot noise background. The box is displayed either as being shifted out of the screen or as being shifted deep into the screen.
The patient should choose what is the shift direction of the box. The shift direction (pull out of the screen or pull into the screen) is randomly generated by the treatment workstation

The background color, the box color, the random dots density and the display duration may vary among different units.

The parameter that varies from Trial to Trial within a Unit is the shift depth of the box in the middle of the display.

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Attachment 11

Appendix B: Clinic Administration Applicaton Interface

Appendix B: Clinic Administration Application Interface

The Clinic Administrator is responsible for the registration of a new patient, filling in the computerized patient's record, updating patient medical examination data. The Administrator needs only limited computer skills, such as using a medical office management application.

The Administrator's tasks include:

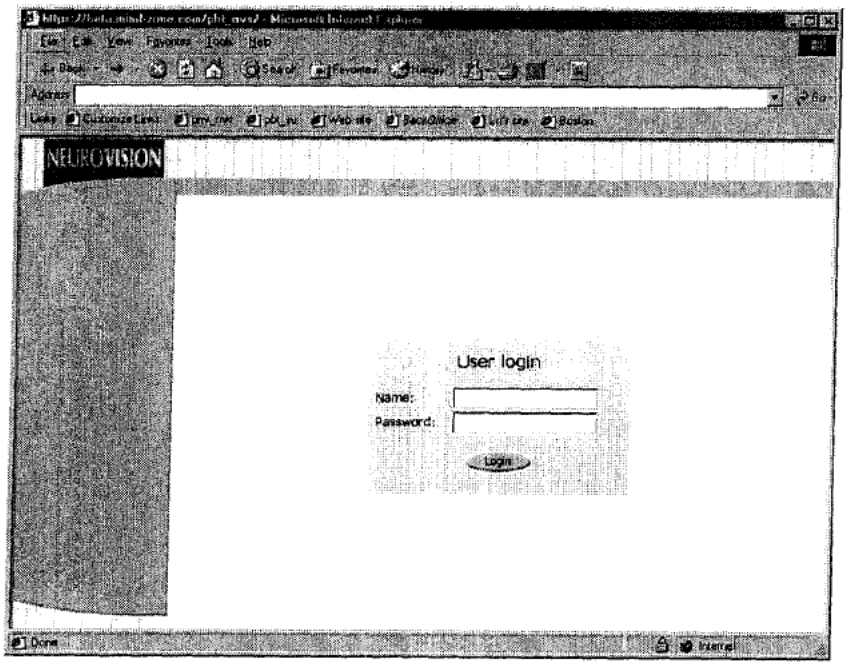
1. Log into the **AA-1** clinic administration application
2. Enrolling a new patient in the **AA-1** application
3. Searching for an existing patient
4. Viewing a summary of patient record
5. Updating the medical history for a patient
6. Recording medical examinations
7. Obtaining a visits list for a patient
8. Obtaining a printable "patients" report
9. Handling alerts

1. LOG INTO THE AA-1 CLINIC ADMINISTRATION APPLICATION

a. Establish an Internet connection.

b. Enter the http://beta.mind-zone.com/pbt_nvs site, and the User Log-in Window appears.

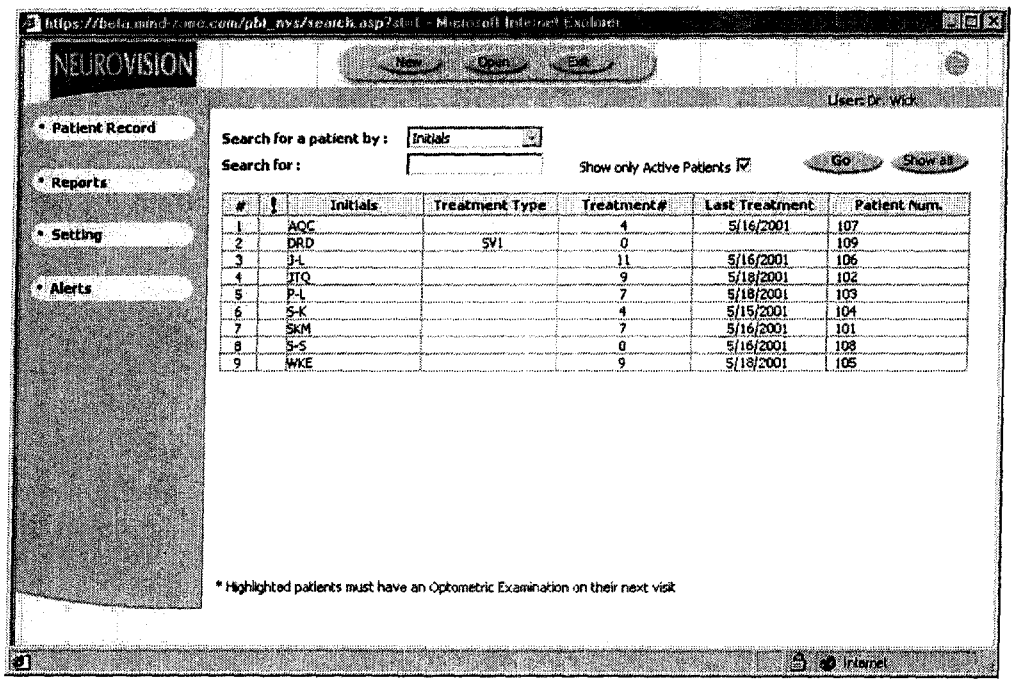
Figure B-1: User Log-in Window



c. Enter your name and password.

d. Press LOGIN. The system checks the user name and password and if they are valid, the Search Window appears (See Figure B-2). If not, the message "User not exist" is displayed and you may try again.

Figure B-2: Search Window



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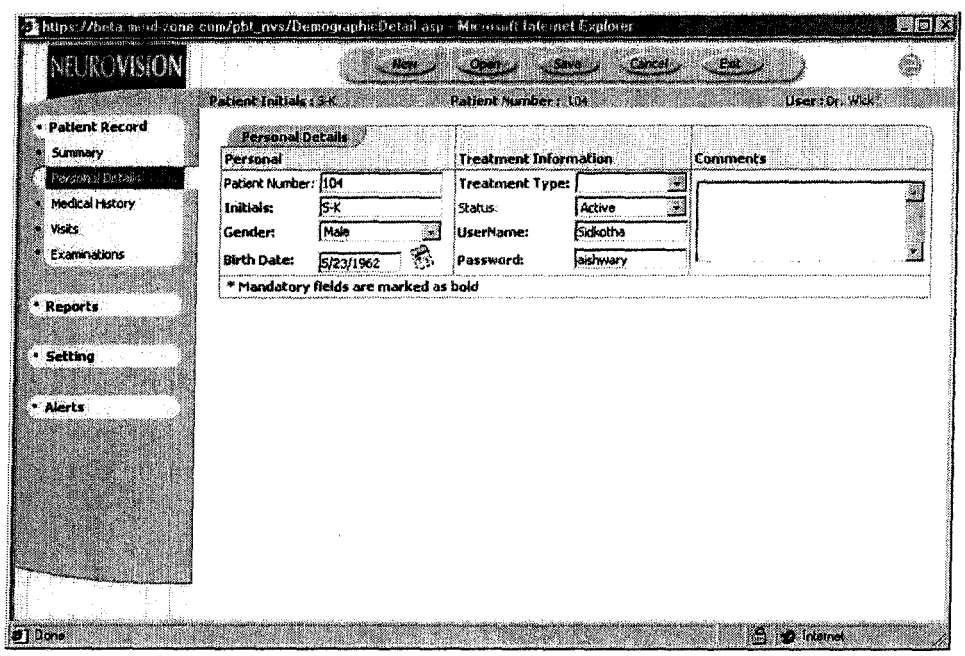
2. ENROLLING A NEW PATIENT IN THE AA-1 APPLICATION

In order to enable the use of the **AA-1** system for a particular patient, you should create a new patient record in the system.

a. Click on the **New** button in the Search Window to establish a new patient record (See Figure B-2), and an empty Personal Details Window appears (See Figure B-3). This Window includes all required personal information.

Figure B-3: Patient Personal Details Window



b. Complete all the obligatory fields that are marked with bold letters (See Figure B-3).

c. There are two types of fields: open field or preset field. In the open fields, use the keyboard to print the required parameter. Use only the valid format according to Table B-1. If a non-valid format is used, an applicable fault message will appear on the screen.
In the preset fields, use the button to move between the options and click on the applicable one.

d. Use the TAB key to move between the fields.

e. Enter the user name and password. You may choose any password. If the user name already exists in the **AA-1** system, a fault message will appear on the screen.

f. If you have any comments, fill out the Comments Area.

Table B-1: Fault messages of the Demographic Window

Fault No.	Fault Massage	Fault Description
1	Enter User name	The "User name" field is empty
2	User name exist in the system	The user name is already existing in the system. Use another name.
3	Enter password	The "Password" field is empty
4	Select gender value	The "Gender" field is not defined
5	Enter date in the right format (mm/dd/yy)	The date is in wrong format.
6	The birthday date is invalid	The birthday date is later that the actual date
7	Enter birth date	The "Birth Date" field is empty

g. Upon completion, click on the **Save** button at the top of the screen. The system will alert you if one of the obligatory fields is not completed. The alert message appears at the top of the screen, written in red color. Please correct the problems and click on the **Save** button again. If there are no alerts, the system will save the patient details and a message indicating the successful operation will appear at the bottom of the page.

h. In case of any uncertainty, you can always cancel your changes and revert to the last saved version of the patient record by clicking on the **Cancel** button.

i. You can always get back to this screen by clicking the **Personal Details** option from the left menu and update in the same manner any additional detail.

3. SEARCHING FOR AN EXISTING PATIENT

You may search the **AA-1** system for one or more existing Patients.

Looking for a specific Patient in the system is performed as follows:

a. Go to the Search for Patients screen by clicking the **Open** button on the top of any Patient details screen in the system. (You also go directly to the Search for Patients screen when you login to the **AA-1** system, as explained in Section B-1 above).

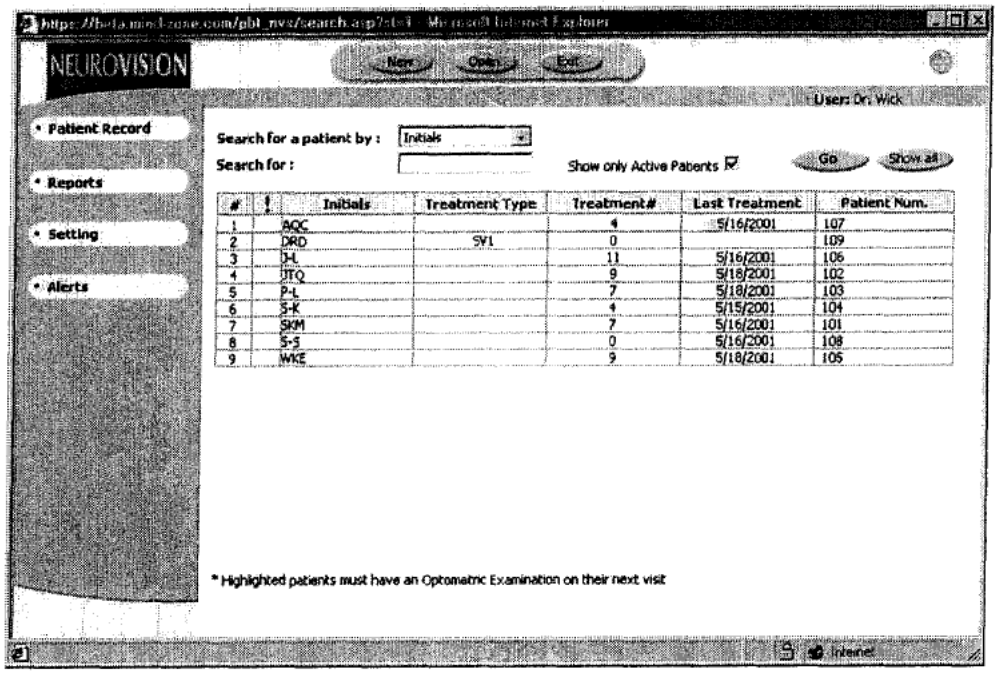
b. In the Search for Patients screen, define the search criteria in the **Search for a patient by** field. The search can be done by patient initials, patient number or treatment type.

c. Type the requested details in the **Search for** field and click **Go**. If a single patient meets your request specification, the Summary screen appears. In case several patients match the search criterion, the system presents all of them in a table, as presented below (Figure B-4). Select the required patient by clicking on patient's initials and the patient's Summary screen will appear. See Section B-4 for details on the Summary screen.

d. You can also locate a patient by scrolling the patients list up and down using the scroll bar on the right. Press **Show All** and a complete patient list appears.

e. By default, the system shows only Active patients. If you wish to search for a non-active patient, uncheck the "Show only active patients" check box. (how the system know who is active or not-active???)

Figure B-4: Search Results Table



The following information is displayed for each patient in the Search Results table:

a. The Serial Number of the patient's row in the Search Results table.
b. An indication of an open follow-up on the patient
c. The Initials of the patient. Clicking on the initials will present the Summary screen of the patient's record.
d. The Treatment Type for the Patient (Adult Amblyopia, Super Vision, etc.)
e. The Number of Treatments that the Patient has already gone through (not including calibration treatments).
f. The date of the Last Treatment that the patient had performed.
g. The internal number of the patient in the clinic.

You may reorganize patients list according to Patient Initials (from a to z) or Last Session Date (from the earliest to the latest) by clicking the desired column title in the Search Results table.

NOTE:	Patients' lines that are marked blue should undergo an Optometrist examination before the next Treatment Session.

4. VIEW A SUMMARY OF A PATIENT RECORD

To view a Summary of a patient record, you have to search for a specific patient using the Search for Patients screen as explained in section B-3 above. You may also get back to the Summary screen from any other patient details screen, by clicking on the **Summary** option on the left menu.

The Summary screen (see Figure B-5) displays the following information from a Patient Record:

a. Summary of the patient's personal information, including the patient's initials, number, gender, age and comments.

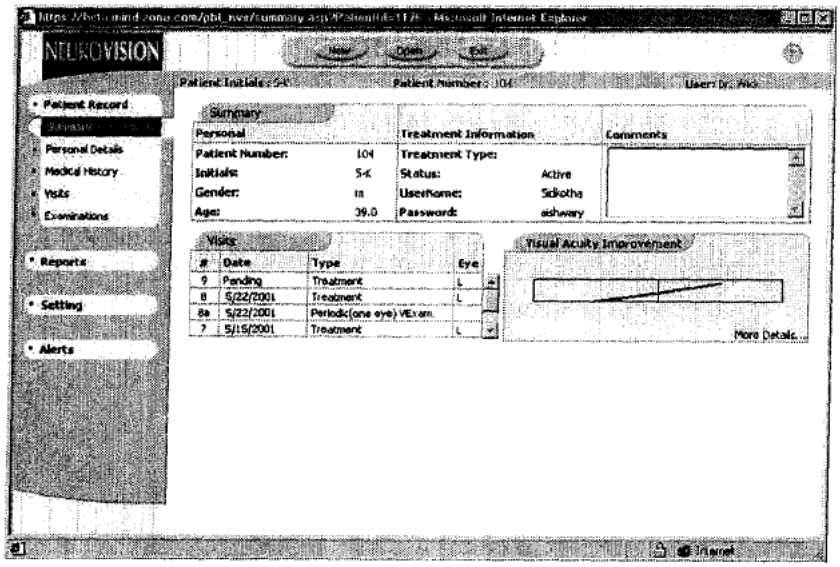
b. When the patient's next treatment is expected to have a different configuration than the previous one, a message explaining these changes will appear in the Summary screen. These changes have to be explained to the patient before starting the next treatment.

c. A list of the last five visits of the patient in the clinic appears at the bottom-left corner of the screen. You may click on a specific visit to view its details. You can also verify that there is a pending treatment ready for the patient.

d. A Quantity Graph appears at the bottom-right corner of the screen, this graph represents the improvement of the patient's visual acuity throughout the treatment process.

e. If applicable, active alerts are presented as well.

Figure B-5: Summary Screen



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5. UPDATING THE MEDICAL HISTORY FOR A PATIENT

Patient's Medical History is recorded and stored in the **AA-1** system. The Medical History file is comprised of the following sections: general history, concomitant medication, ophthalmic history and amblyopia related history.

a. To update the patient's Medical History in the system, search for the specific patient using the Search for Patient screen (described in section B-3).

b. After you have located the desired patient, click on the **Medical History** option on the left menu of the system. The Medical History screen appears (Figure B-6).

c. In this screen you should type the exact information from the Medical History paper form. When you finish, click on the **Save** button on the top of the screen.

d. The system will save the Medical History and present a successful save message. However, in case that any information is missing or incorrect, explanation alerts will be presented at the top of the screen. You should then correct the problem and click on **Save** again.

Figure B-6: Medical History Window

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New | Open | Save | Cancel | Exit

Patient Name : DKA ID : (050) User: PushMed Eran

- Patient Record
  - Summary
  - Personal Details
  - Medical History
  - Visits
  - Examinations
- Reports
- Setting
- Alerts

Medical History

Performed by: Dr. Ma-nain To Screening Date (mm/dd/yyyy): 6/28/2000

General History

Disorder / Disease: (If YES please specify)

Migraine	NO YES	If YES, exclude the patient from the study
Epilepsy	NO YES	If YES, exclude the patient from the study
Diabetes	NO YES	If YES, exclude the patient from the study
Dyslexia	NO YES	If YES, exclude the patient from the study
Cardiovascular	NO YES	
Pulmonary	NO YES	
Gastrointestinal	NO YES	
Renal	NO YES	
Endocrine	NO YES	
Hematological	NO YES	
Neurological	NO YES	
Musculoskeletal	NO YES	
Surgical History	NO YES	

Concomitant Medications
List all medications currently administered:

Medication	Dosage	Indication

Ophthalmic History

	Past	Present
Disorder/Disease		
Operations		
Medications		

Amblyopia - Related History

Subject was first diagnosed as Amblyope at: 18 years old.
(Please, write a range of ages in case of uncertainty)

Previous Treatment	Age of commencement	Duration	Results	Comments
Occlusion				
Operations				
Medications				
Glasses ☐ none				
Monovision				
Bifocal				
Exercise				
Other				

Strabismus in the past: Exo Eso Hyper Hypo Unknown None

Internet

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6. RECORDING A MEDICAL EXAMINATION

You should record the outcomes of all medical examinations performed before and during the **AA-1** Treatment period (See Section 5). Using the **AA-1** system, the recording of four types of medical examinations is available: the Ocular examinations, the Comprehensive Visual Acuity examinations, the Visual Functions examinations and the Periodic Visual Acuity examinations.

The following describes how to record any new Medical Examination in the system and how to view the details of a recorded examination.

6.1 Recording a Comprehensive Visual Acuity Examination

a. Select **Comprehensive Visual Exam.** from the examinations list.

b. Press **New** to open an empty Ocular Examination form.

c. Fill out the **Performed by** field by entering the physician name.

d. Fill out the **Examination Date** field using the mm/dd/yyyy format. You also may select a date from the Date window that is opened by pressing the calendar figure next to the **Examination Date** field (See Figure B-8). Press OK to close the date window.

e. Fill out the examination results according to the examination report provided by the physician. Note that the **LOGMAR** field is being automatically calculated.

f. Press **Save** to save the examination record. You can always click on the **Cancel** button to revert to the last saved version of the Examination.

g. In case that any information is missing or incorrect, explanation alerts will be presented at the top of the screen. You should then correct the problem and click on **Save** again.

Figure B-7: Comprehensive Visual Acuity Examinations Window

NEUROVISION

New | Open | Save | Cancel | Exit

Patient Name : Shimrit Abadi ID : 1170 User : Arava

- Patient Record
  - Summary
  - Personal Details
  - Medical History
  - Visits
  - Examinations
  - Treatments
  - Progress
- Reports
- Setting
- Alerts

Ocular Exam. | Comprehensive Visual Exam. | Visual Functions | Periodic Visual Exam.

Select a specific Examination: #1 ; 1/21/2001 Go

Performed by: Dr. Ruthy Examination Date (mm/dd/yyyy): 1/21/2001

Present RX Dis:	R:	Sph:	Cyl:	Axis:	Add:	
	L:	Sph:	Cyl:	Axis:	Add:	
Present RX Near:	R:	Sph:	Cyl:	Axis:		
	L:	Sph:	Cyl:	Axis:		

VA: s RX	R:	20/16	VA: c RX	R:	Dominant eye:	
	L:	20/50		L:	Lazy eye:	L

Subjective Refraction:

Distance:	SPH	CYL	AXIS	VA	LOGMAR(full)
R:	plano			20/16	-0.1
L:	+4.00	-1.00	75	20/40	0.3

R	VA -0.2	2	letters identified out of 10.	
R	VA -0.3	0	letters identified out of 10.	Average: -0.12
R	VA	0	letters identified out of 10.	
L	VA 0.2	8	letters identified out of 10.	
L	VA 0.1	0	letters identified out of 10.	Average: 0.22
L	VA 0	0	letters identified out of 10.	

Accommodation amplitude R 9.75 L 4.50

M System

Near:	SPH	CYL	AXIS	VA	LOGMAR(full)
R:	pl			M.5	
L:	+4.00	-1.00	75	M.5	

R	VA	0	letters identified out of 10.
R	VA	0	letters identified out of 10.
R	VA	0	letters identified out of 10.
L	VA	0	letters identified out of 10.
L	VA	0	letters identified out of 10.
L	VA	0	letters identified out of 10.

Internet

Internet

Inbox - Outlook Exp... | UM NV 2506 - Micr... | http://www.mind-zo... | http://www.min... | En 14:53

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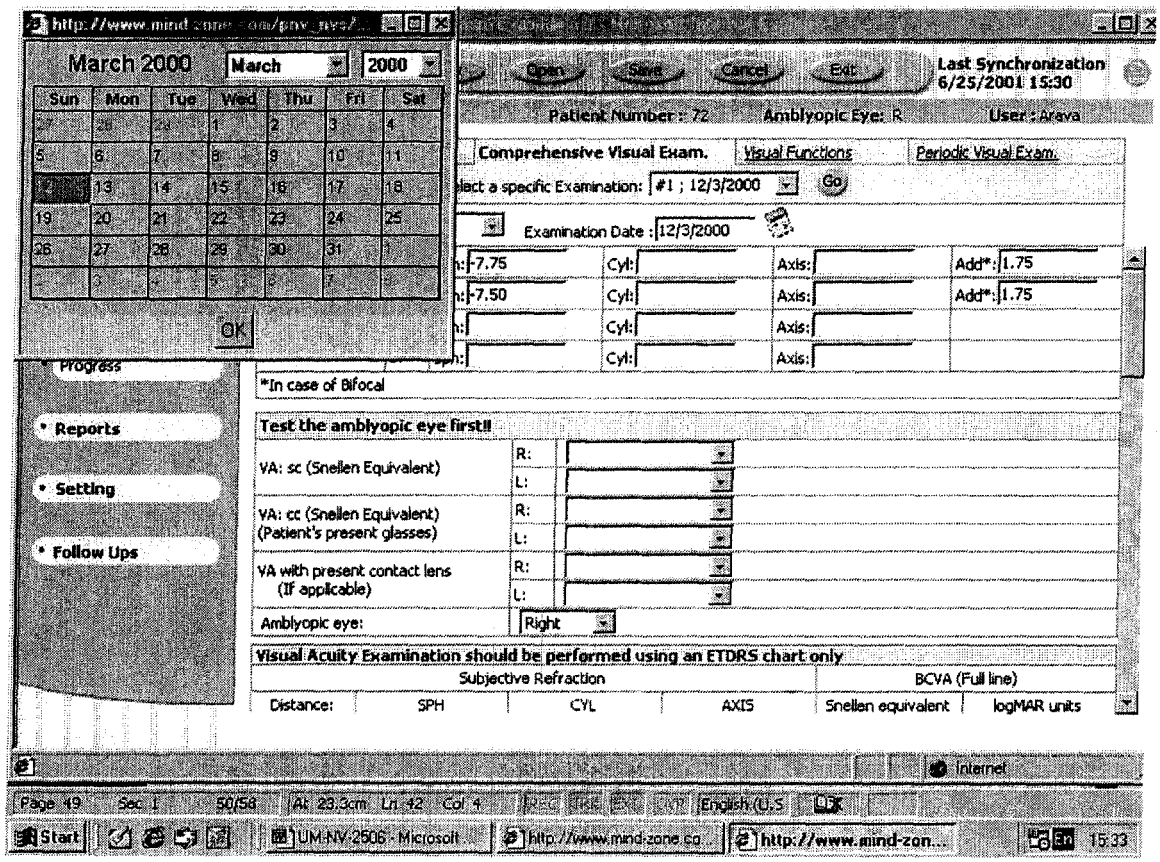
Figure B-8: Date Window



6.2 Recording an Ocular Examination

a. Select **Ocular Exam.** from the examinations list.

b. Press **New** to open an empty Ocular Examination form.

c. Fill out the **Performed by** field by entering the physician name.

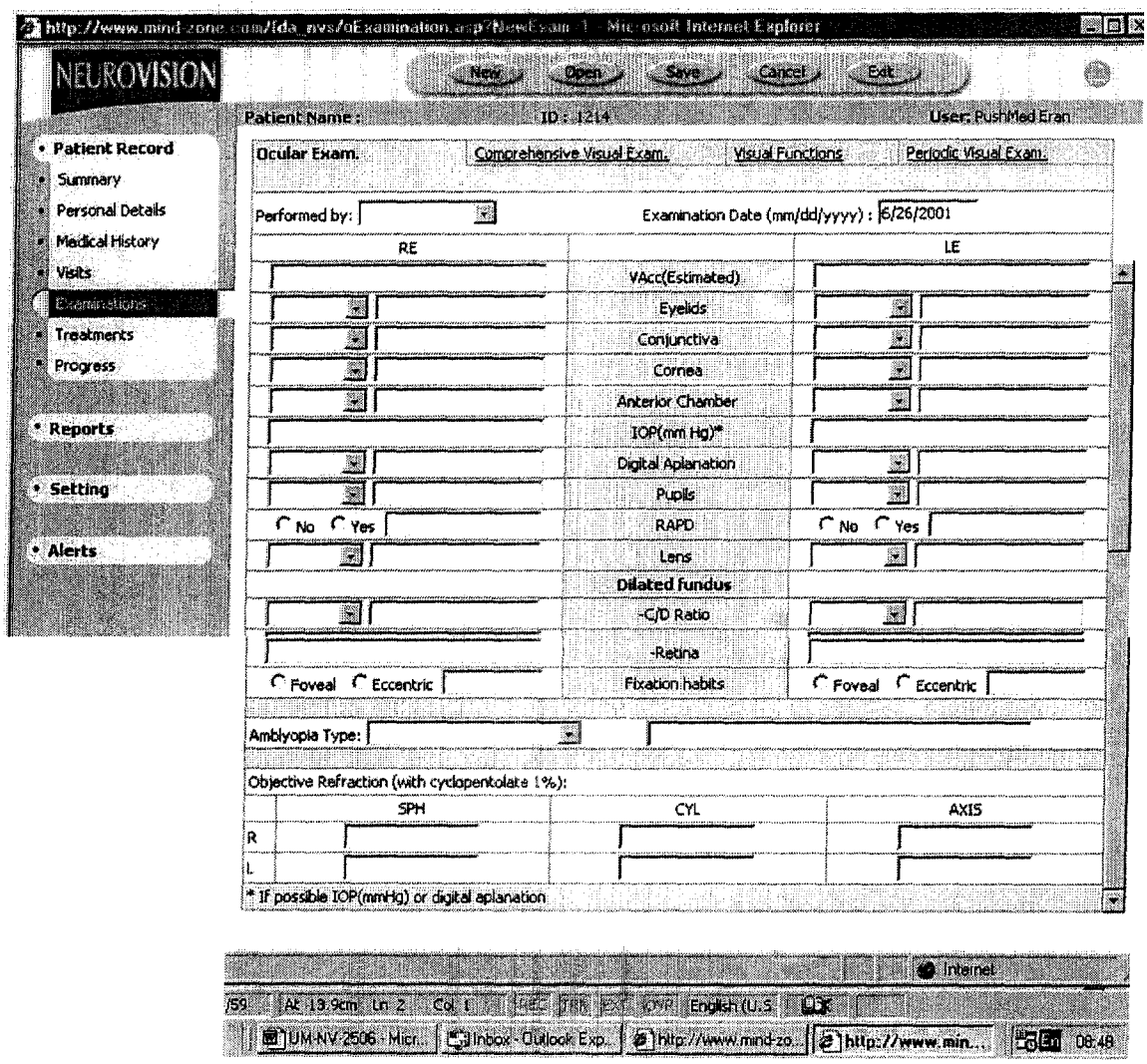
d. Fill out the **Examination Date** field using the mm/dd/yyyy format. You also may choose a data from the Date window that is opened by pressing the colander figure next to the **Examination Date** field (See Figure B-8). Press **OK** to close the date window.

e. Fill out the examination results according to the examination report provided by the physician.

f. Press **Save** to save the examination record. You can always click on the **Cancel** button to revert to the last saved version of the Examination.

g. In case that any information is missing or incorrect, explanation alerts will be presented at the top of the screen. You should then correct the problem and click on **Save** again.

Figure B-9: Ocular Examination Window



6.3 Recording a Visual Functions Examination

a. Select **Visual Functions** from the examinations list.

b. Press **New** to open an empty Visual functions form.

c. Fill out the **Performed by** field by entering the physician name.

d. Fill out the **Examination Date** field using the mm/dd/yyyy format. You also may choose a data from the Date window that is opened by pressing the colander figure next to the **Examination Date** field (See Figure B-8). Press **OK** to close the date window.

e. The Sine Wave Contrast Test (S.W.C.T) electronic form contains five columns with eight points in each one. Look at the report provided by the physician and check the number of the marked point in each column (1st, 2nd, 3rd, etc.). Select the points in the electronic form respectively.

f. Fill out the other examination results according to the examination report provided by the physician.

g. Press **Save** to save the examination record. You can always click on the **Cancel** button to revert to the last saved version of the Examination.

h. In case that any information is missing or incorrect, explanation alerts will be presented at the top of the screen. You should then correct the problem and click on **Save** again.

Figure B-10: Visual Functions Window

NEUROVISION

New | Open | Save | Cancel | Exit

Patient Name : ID : 1214 User: PushMed Eran

- Patient Record
  - Summary
  - Personal Details
  - Medical History
  - Visits
  - Examinations
  - Treatments
  - Progress
- Reports
- Setting
- Alerts

Ocular Exam. | Comprehensive Visual Exam. | Visual Functions | Periodic Visual Exam.

Performed by: Examination Date (mm/dd/yyyy) : 6/26/2001

	Right					Left				
8										
7										
6										
5										
4										
3										
2										
1										
none										
	1.5	3	6	12	18	1.5	3	6	12	18

Randot Stereotest (seconds of arc)

Titmus Stereotest (seconds of arc)

Eye movement: versions

Limitations (duction)

Overaction IO

Nystagmus (and specify)

Convergence amplitude

Distance: cover - uncover - test

Near: cover - uncover - test

Distance(Sc) :Alternate - cover - test

Distance(Cc) :Alternate - cover - test

Near(Sc) :Alternate - cover - test

Near(Cc) :Alternate - cover - test

Near(Add +3.00):Alternate - cover - test

Worth 4 Dot

4 Prism Base Out test (when applicable)

COMMENTS:

6.4 Recording a Periodic Visual Examination

a. Select **Periodic Visual Exam.** from the examinations list.

b. Press **New** to open an empty Visual functions form.

c. Fill out the **Performed by** field by entering the physician name.

d. Fill out the **Examination Date** field using the mm/dd/yyyy format. You also may choose a data from the Date window that is opened by pressing the colander figure next to the **Examination Date** field (See Figure B-8). Press **OK** to close the date window.

e. The Type field contains three options: **Periodic** for routine examination that should be performed every 4 visits; **Additional** for any extra examination, and; **Persistent** for the final follow up examination. Choose the applicable option.

f. In the **VA** fields, you should enter the number of row (-1, -2, etc.) from the row that the patient succeeded to read completely (all 10 letters). For example, if the patient read all 10 letters in the 5th row, the 7th row will be –2. In the subsequently field, enter the number of letters that were identified in this row.

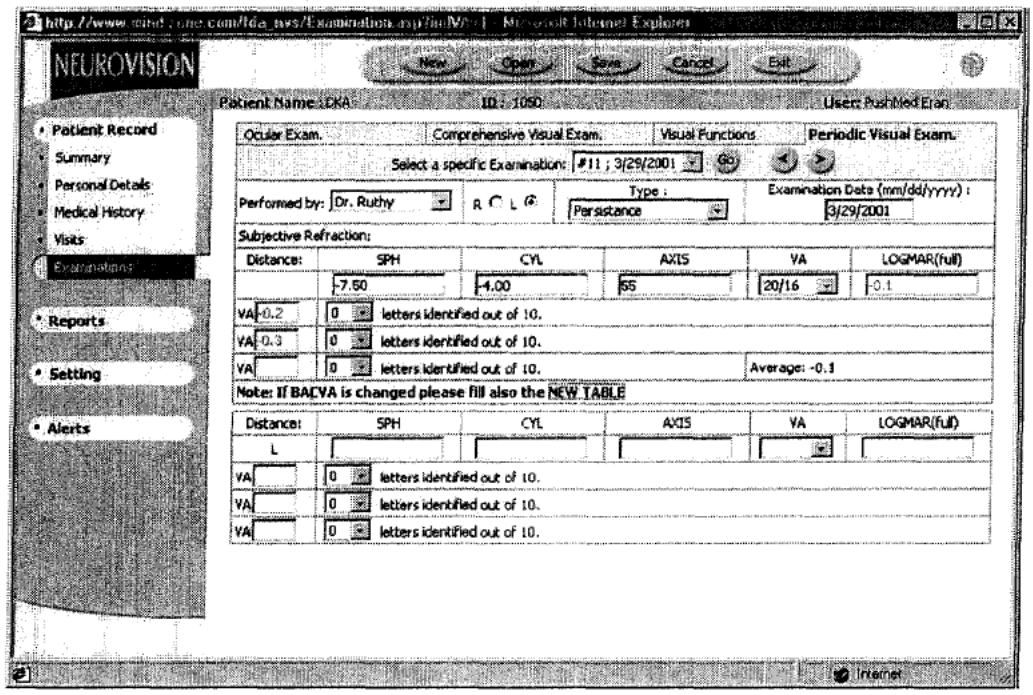
g. Fill out the other examination results according to the examination report provided by the physician.

NOTE:	When you key in Periodic Visual Acuity results in cases where the patient's BACVA has changed – you have to click on the special "New Table" link and key that table's results as well.

h. Press **Save** to save the examination record. You can always click on the **Cancel** button to revert to the last saved version of the Examination.

i. In case that any information is missing or incorrect, explanation alerts will be presented at the top of the screen. You should then correct the problem and click on **Save** again.

Figure B-11: Visual Functions Window



6.5 Viewing an existing Examination

a. From any of the patient screens, click **Examinations** in the left menu bar. The Examination screen appears.

b. Click on the **Open** button on the top of the screen to view an existing examination.

c. The examination presented is the latest one. If you whish to observe other examination, select the desired examination in the **specific examination** window and press **Go**.

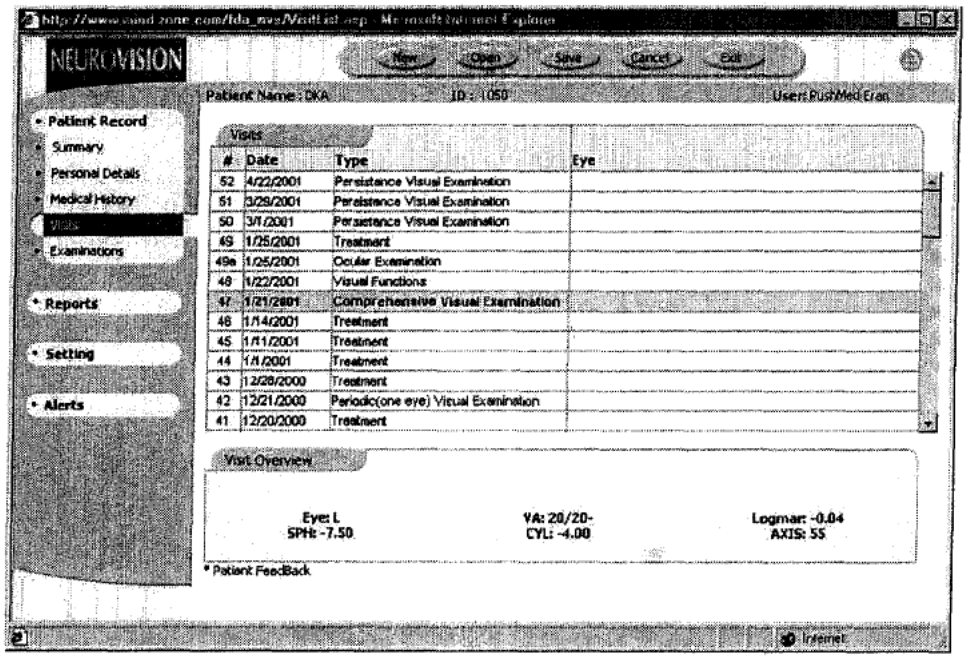
7. OBTAINING A VISITS LIST FOR A PATIENT

a. Search for an existing patient using the Search for Patient screen (see Section B-3)

b. Click the **Visits** option on the left menu. The Visits Window appears. This Window contains a list of all patient's visits organized by date. The visit serial number, date and type of the visit are provided for each visit.

c. In the case of a **Pending** treatment that has been scheduled for the patient, the treatment record will appear at the top of the visit list.

Figure B-12: Visits Window



d. You may observe a short visit overview by clicking on the visit row.

e. You can access a specific Examination directly, by clicking on the Examination date.

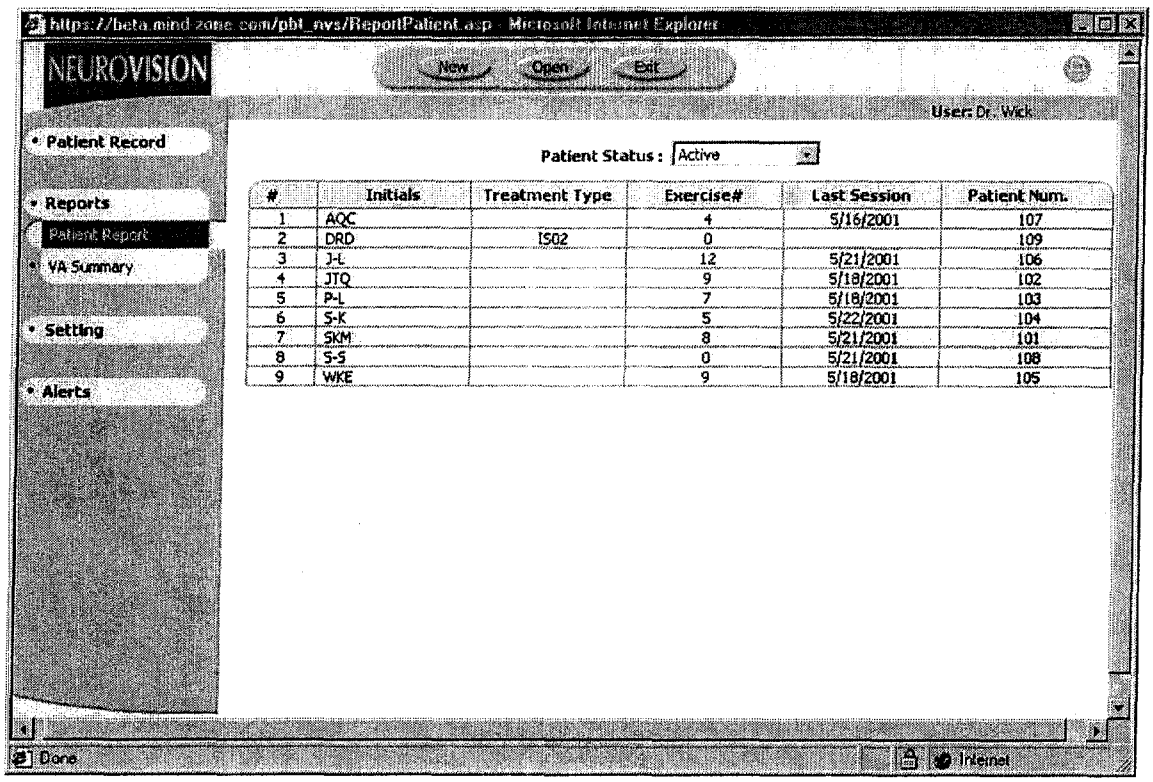
8. OBTAINING A PRINTABLE "PATIENTS" REPORT

The **AA-1** system provide the option to print out a report of all patients who have been treated with the **AA-1** Treatment at the clinic.

a. Click **Reports** in the Search Window and select **Patient Report**. The Patient Report screen appears. This screen includes a list of all patients that have been treated with the **AA-1** system in your clinic. The list obtained is similar to a complete Search table (See Figure B-13).

b. If you wish to print out this report, press on the printer icon on the upper right corner of the screen. The Print Window appears. Change the printing parameters according to your preference or press **OK**.

Figure B-13: Patients Report Window



#	Initials	Treatment Type	Exercise#	Last Session	Patient Num.
1	AQC		4	5/16/2001	107
2	DRD	IS02	0		109
3	J-L		12	5/21/2001	106
4	JTQ		9	5/18/2001	102
5	P-L		7	5/18/2001	103
6	S-K		5	5/22/2001	104
7	SKM		8	5/21/2001	101
8	S-S		0	5/21/2001	108
9	WKE		9	5/18/2001	105

9. HANDLING ALERTS

The **AA-1** system presents alerts in case that pivotal data is missing in a patient file or in case of a violation of treatment protocol. There are two ways to observe and handle an alert:

I) through the patients list
II) through the alerts menu

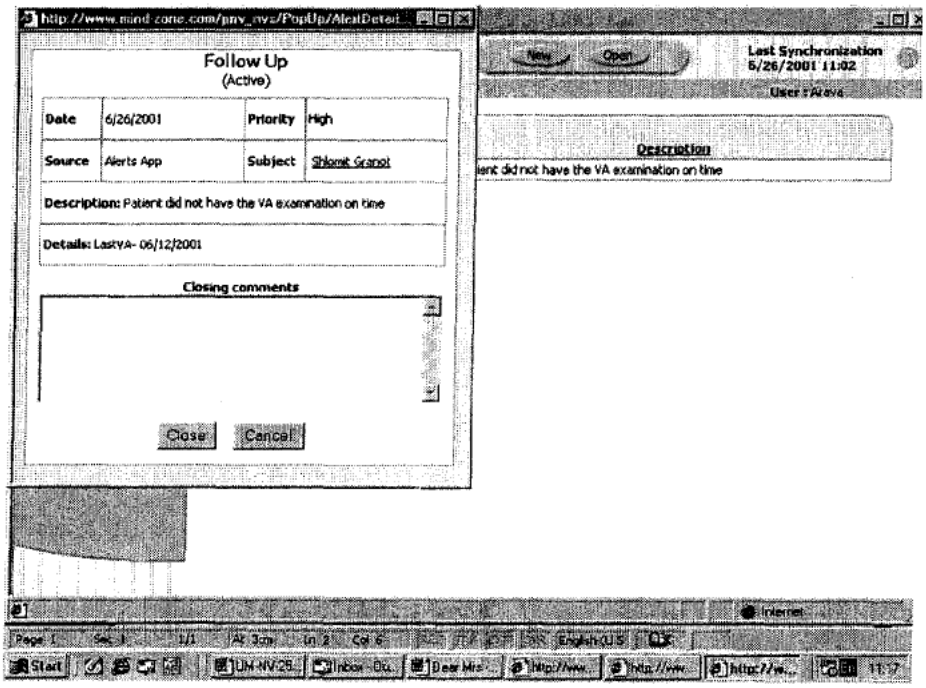
9.1 Handling Alerts Through Patients List

a. Alert is represented by "!" sign which appears on the left side of a patient name in the Search Result Table (See Figure B-4)

b. Click on patient name. The Summery Window is opened with the alert specification in the Alerts field.

c. To close an open alert, click the date near the alert specification. The Alert Window is opened. Enter Closing notes and press **OK**. The Alert Window is closed and the Alert is removed from the Summary window and from the Active Alerts list. Note that the Alert window will not be closes unless you enter closing notes.

Figure B-14: Active Alert Window



000611 82

9.2 Handling Alerts Through the Alerts Menu

To handle an Active Alert:

d. Select **Active Alert** from the **Alerts** Menu

e. The Active Alerts window is opened.

f. To close an open alert, click the date of the alert. The Alert Window is opened. Enter Closing notes and press **OK**. The Alert Window is closed and the Alert is removed from the Active Alerts list. Note that the Alert window will not be closes unless you enter closing notes.

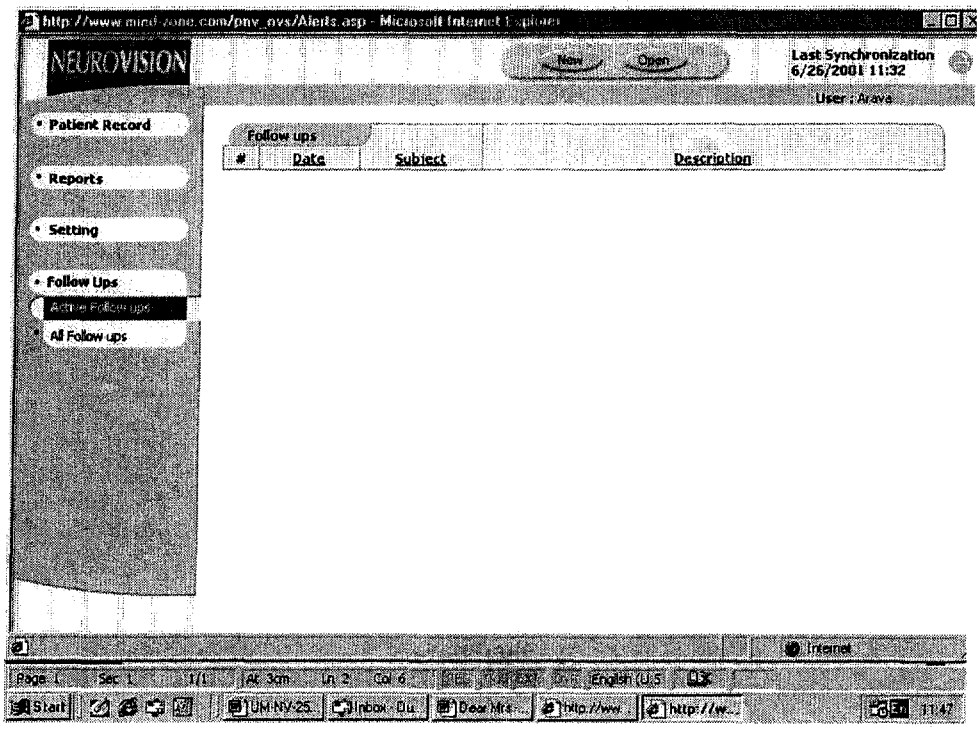
To view old (Non-Active) Alerts:

a. Select **old Alerts** from the **Alerts** Menu

b. The Old Alerts window is opened.

c. To view closing notes, click the date of the alert. The Alert Window is opened. With the closing notes. Press **OK** to close the window.

Figure B-15: Alerts List window



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Attachment 11

Appendix C: System Components Technical Specifications

Appendix C: System Components Technical Specifications

1. Treatment Workstation

a. Hardware

- PC Equivalent to Compaq DeskPro Exm Series:
  CPU - Pentium III 800 Mhz or equivalent and higher
  Memory - 128M SDRAM
  Hard Disk – 20GB
  On Board Video Card - Intel 815E or equivalent
  StereoGraphic Video Card – 3DLabs Oxigen GVX1 AGP or PCI
  Ethernet Card – 10/100 mbps
  Modem card - at least 56,000 bps
  Audio card – Creative PCI 128 or equivalent
  Keyboard – Standard PC Keyboard
  Mouse – 3 button mouse
  Earphones – Standard PC earphones
- Monitor – Philips 107P 17" monitor or equivalent
- StereoGraphic Glasses: StereoGraphics – Crystal Eye III wireless eyewear system, including glasses and emitter.

b. Software

- Windows 2000 operating system.
- NeuroVision **AA-1** system software.

2. Administrative Workstation

a. Hardware

Any PC with Internet connectivity is suitable, however the following minimum configuration is recommended:

- PC with the following specifications:
  CPU - Pentium III 400 Mhz or equivalent and higher
  Memory - 64M SDRAM
  Hard Disk – 8GB or higher
  Ethernet Card – 10/100 mbps
  Modem card - at least 56,000 bps
- Monitor – any monitor supporting 600X800 resolution and higher

b. Software

- Windows 98 or 2000 or ME operating system.
- Commercial Internet Browser

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Neurovision, Inc.

Attachment 12

Professional Use and Patient Use Brochure

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Treating Lazy Eye in Adults

Draft brochure for patients

From the latest advances in Neuroscience ...

NEUROVISION

A revolutionary new medical treatment now brings proven effectiveness for treating Lazy Eye (Amblyopia) in adults.

Adult Amblyopia – A Common Condition

An estimated 2-4% of all adults (above the age of 9) suffer from amblyopia. Although many receive treatment in childhood it is often discovered too late or does not achieve sufficient success. Persons with Amblyopia suffer from several abnormalities due to poor responses and interactions between brain cells involved in vision processing. These vision deficiencies were considered untreatable until today.

Scientifically-Based Medical Treatment

NeuroVision's treatment is based on over 20 years of research in the field of visual neuroscience. By stimulating specific areas in the brain through repetitive visual tasks, a significant improvement in the Lazy Eye's vision is achieved. This medical treatment is given under supervision at professional eye-care clinics.

Treatment Highlights

- **A non-invasive, no drugs treatment –** and with no reported adverse effects.
- **Computer-based treatment sessions –** of around 30 minutes. Taken 2-3 times weekly, typically for 3 months.
- **Individual treatment plans** - Based on a computerized analysis and adaptive to each patient's progress.
- **Administered by Professionals –** patients gain access to NeuroVision's treatment through participating clinics.

Clinical Success

As demonstrated by clinical trials in patients aged 9 to 55, having visual acuity of 20/30 to 20/100

- Average Visual Acuity improvement of the group is 2.5 lines of the visual acuity test chart.
- Among Patients with baseline VA 20/50 and worse, 70% reached 20/40 and better.
- Significantly improved binocularity and reading acuity.
- Stability monitoring after 3 months demonstrates no drop in average VA.

Improving quality of life

Until now only young children were offered the chance to treat their amblyopia. In addition to the poor level of vision, the continual presence of amblyopia can create further complications, such as the development of strabismus (a cosmetic as well as medical condition), and the constant need to protect the good eye. Treating amblyopia leads to improvement of quality of life in many day-to-day tasks, driving is safer and work activities can be more comfortable. Less vision-related limitations and visual disturbances are experienced and an overall improvement in quality of vision is achieved.

Contact Us

For more information and details on participating clinics please visit our website **www.neuro-vision.com** or contact us at:

NeuroVision, Inc.
Suite 100, 111 South Bedford St.,
Burlington, MA 01803

Tel: (781) 221-4680
Fax: (781) 221-7468

Treating Adult Amblyopia

Draft brochure for doctors

From the latest advances in Neuroscience ...

NEUROVISION

A revolutionary new medical treatment now brings proven effectiveness for treating Amblyopia in adults.

Scientifically-Based Medical Treatment

NeuroVision's treatment is based on over 20 years of research in the field of visual neuroscience. Amblyopic patients suffer from several abnormalities in visual processing due to poor neural responses and interactions. Specific stimulation, through repetitive performance of visual tasks has shown excellent efficacy. Various groundbreaking studies over the last decade have supported the notion of plasticity in the matured central nervous system. Consequently, neural plasticity has now been seen in adults with amblyopia providing for an effective treatment with long-lasting benefits. The treatment is given under supervision at professional eye-care clinics.

Treatment Highlights

- **Individual treatment plans** - Based on a computerized analysis of neural defects and adaptive to patient progress.
- **Computer-based treatment sessions** – of around 30 minutes. Taken 2-3 times weekly, typically for 3 months.
- **Easily administered** – by clinical staff as treatments are prepared and delivered via the Internet from NeuroVision.
- **A non-invasive, no drugs treatment** – and with no reported adverse effects.

Clinical Success

As demonstrated by controlled clinical trials in patients aged 9 to 55, having visual acuity of 20/30 to 20/100, with strabismic and/or anisometropic amblyopia.

- Average Visual Acuity improvement of the group is 2.5 ETDRS lines.
- Among Patients with baseline VA 20/50 and worse, 70% reached 20/40 and better.
- Significantly improved binocularity and reading acuity.
- Stability after 3 months demonstrates no drop in average VA.

A True Partnership

- Patients gain access to NeuroVision's treatment through participating clinics, receiving a local and personal service.
- Significant source of revenues with minimal set-up effort; an easily administrable treatment catering to a significant market.
- Practitioners are provided with comprehensive training and a policy of continual practice support from NeuroVision.
- Patient confidentiality is of high importance to NeuroVision, with HIPAA compliant procedures and secure, encrypted Internet data transfer.

Contact Us

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Suite 100
111 South Bedford St.,
Burlington, MA 01803

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Fax: (781)-221-7468
www.neuro-vision.com

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Attachment 13

Literature Articles

Proc. Natl. Acad. Sci. USA
Vol. 94, pp. 10426–10431, September 1997
Neurobiology

Excitatory–inhibitory network in the visual cortex: Psychophysical evidence

YAEL ADINI, DOV SAGI, AND MISHA TSODYKS

Department of Neurobiology, Brain Research, The Weizmann Institute of Science, Rehovot 76100, Israel

Communicated by Bela Julesz, Rutgers University, Piscataway, NJ, July 11, 1997 (received for review April 22, 1997)

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Proc. Natl. Acad. Sci. USA
Vol. 90, pp. 5718–5722, June 1993
Psychology

Attentional control of early perceptual learning

MERAV AHISSAR AND SHAUL HOCHSTEIN

Center for Neural Computation and Department of Neurobiology, Institute of Life Sciences, The Hebrew University, Jerusalem 91904, Israel

Communicated by Jacob Nachmias, March 1, 1993 (received for review October 26, 1992)

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Exp. Brain Res. 27, 221–232 (1977)

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Spatial Properties of Binocular Neurones in the Human Visual System

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Cresap Neuroscience Laboratory, Department of Psychology, Northwestern University, Evanston, Illinois 60201, USA

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Effects of spatial configuration on contrast detection

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Department of Neurobiology, Brain Research, The Weizmann Institute of Science, Rehovot 76100, Israel

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Contrast sensitivity in anisometropic amblyopia

A. Bradley and R. D. Freeman

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Contour Integration Deficits in Anisometropic Amblyopia

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Contour Integration Deficits in Anisometropic Amblyopia

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Learning to see: experience and attention in primary visual cortex

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The response properties of neurons in primary sensory cortices remain malleable throughout life. The existence of such plasticity, and the characteristics of a form of implicit learning known as perceptual learning, suggest that changes in primary sensory cortex may mediate learning. We explored whether modification of the functional properties of primary visual cortex (V1) accompanies perceptual learning. Basic receptive field properties, such as location, size and orientation selectivity, were unaffected by perceptual training, and visual topography (as measured by magnification factor) was indistinguishable between trained and untrained animals. On the other hand, the influence of contextual stimuli placed outside the receptive field showed a change consistent with the trained discrimination. Furthermore, this property showed task dependence, only being manifest when the animal was performing the trained discrimination.

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SPATIAL VISUAL CHANNELS IN THE FOURIER PLANE

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Harvard University, Division of Applied Sciences, Cambridge, MA 02138, U.S.A.

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SPATIAL FREQUENCY ADAPTATION CAN ENHANCE CONTRAST SENSITIVITY

KAREN K. DE VALOIS

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12

Contrast Masking Effects Change with Practice

ALAIN DORAIS,* DOV SAGI*†

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Vision Research 41 (2001) 463–471

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The effect of orientation learning on contrast sensitivity

Nestor Matthews [a], Zili Liu [b], Ning Qian [a,*]

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Vision Research 39 (1999) 3197–3221

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Mechanisms of perceptual learning

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Printed in Great Britain

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LEARNING IN GRATING WAVEFORM DISCRIMINATION: SPECIFICITY FOR ORIENTATION AND SPATIAL FREQUENCY

ADRIÁNA FIORENTINI and NICOLETTA BERARDI
Istituto di Neurofisiologia del C.N.R., Via S. Zeno, 51-56100 Pisa, Italy

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Gabor Filters as Texture Discriminator

I. Fogel[1] and D. Sagi[2]

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Perception, 1988, volume 17, number 4, pages 483-495

How contrast affects stereoacuity

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D Lynn Halpern ¶, Randolph R Blake §
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British Journal of Ophthalmology 1996; **80**: 373–377

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Physiology of suppression in strabismic amblyopia

Richard Harrad, Frank Sengpiel, Colin Blakemore

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European Journal of Physiology
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On the Nature of the Neural Abnormality in Human Amblyopia; Neural Aberrations and Neural Sensitivity Loss

R. F. Hess, F. W. Campbell, and T. Greenhalgh
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Contour Integration in Anisometropic Amblyopia

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THE THRESHOLD CONTRAST SENSITIVITY FUNCTION IN STRABISMIC AMBLYOPIA: EVIDENCE FOR A TWO TYPE CLASSIFICATION

R. F. HESS and E. R. HOWELL

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Contour Integration in Strabismic Amblyopia: the Sufficiency of an Explanation Based on Positional Uncertainty

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ROBERT F. HESS,*† WILLIAM McILHAGGA,* DAVID J. FIELD*

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Clinical Suppression and Amblyopia

Karen Holopigian,*‡ Randolph Blake,* and Mark J. Greenwald†

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Improvement in Visual Sensitivity by Changes in Local Context: Parallel Studies in Human Observers and in V1 of Alert Monkeys

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Learning perceptual skills: behavioral probes into adult cortical plasticity

Avi Karni* and Giuseppe Bertini†

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Proc. Natl. Acad. Sci. USA
Vol. 88, pp. 4966–4970, June 1991
Neurobiology

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Where practice makes perfect in texture discrimination: Evidence for primary visual cortex plasticity

(perceptual learning/preattentive vision/orientation gradient/monocularity)

AVI KARNI*† AND DOV SAGI*

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Communicated by Bela Julesz, January 28, 1991 (received for review October 16, 1990)

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The time course of learning a visual skill

Avi Karni* & **Dov Sagi†**

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Lack of Lateral Inhibitory Interactions in Visual Cortex of Monocularly Deprived Cats

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Vision Research 40 (2000) 1775–1783

Vision Research

www.elsevier.com/locate/visres

A new test of contour integration deficits in patients with a history of disrupted binocular experience during visual development

Ilona Kovács [a,*], Uri Polat [b,c], Philippa M. Pennefather [d], Arvind Chandna [d], Anthony M. Norcia [b]

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Humans Deprived of Normal Binocular Vision Have Binocular Interactions Tuned to Size and Orientation

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Proc. Natl. Acad. Sci. USA
Vol. 93, pp. 6830–6834, June 1996
Neurobiology

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Neural plasticity in adults with amblyopia

(Vernier acuity/learning/orientation/hyperacuity/practice)

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Communicated by Bela Julesz, Rutgers, The State University of New Jersey, Piscataway, NJ, March 13, 1996 (received for review December 12, 1995)

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Improvement in Vernier Acuity in Adults With Amblyopia

Practice Makes Better

Dennis M. Levi, Uri Polat,† and Ying–Sheng Hu**

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Vision Research 40 (2000) 3297–3307

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Amblyopic deficits in detecting a dotted line in noise☆

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Some results on translation invariance in the human visual system

TATJANA A. NAZIR and J. KEVIN O'REGAN

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15 May 1992, Volume 256, pp. 1018–1021

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Fast Perceptual Learning in Visual Hyperacuity

Tomaso Poggio, Manfred Fahle, and Shimon Edelman

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Fast Perceptual Learning in Visual Hyperacuity

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Functional architecture of long-range perceptual interactions

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(24)

Collinear stimuli regulate visual responses depending on cell's contrast threshold

Uri Polat*, Keiko Mizobe*, Mark W. Pettet, Takuji Kasamatsu & Anthony M. Norcia

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Neurophysiological Evidence for Contrast Dependent Long-Range Facilitation and Suppression in the Human Visual Cortex*

URI POLAT,* ANTHONY M. NORCIA†

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Lateral Interactions Between Spatial Channels: Suppression and Facilitation Revealed by Lateral Masking Experiments

URI POLAT,* DOV SAGI*

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The Architecture of Perceptual Spatial Interactions

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Proc. Natl. Acad. Sci. USA
Vol. 91, pp. 1206–1209, February 1994
Neurobiology

(48)

Spatial interactions in human vision: From near to far via experience-dependent cascades of connections

(short-range interactions/long-range interactions/lateral masking/learning/plasticity)

URI POLAT AND DOV SAGI*

Department of Neurobiology, Brain Research, The Weizmann Institute of Science, Rehovot 76100, Israel

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Abnormal Long-range Spatial Interactions in Amblyopia

URI POLAT,*‡ DOV SAGI,† ANTHONY M. NORCIA*

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Collinear effects on 3-Gabor alignment as a function of spacing, orientation and detectability

ARIELLA POPPLE [1,*], URI POLAT [2] and YORAM BONNEH [3]

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Spatial variability as a limiting factor in texture-discrimination tasks: implications for performance asymmetries

Barton S. Rubenstein and Dov Sagi

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Collinear effects on 3-Gabor alignment as a function of spacing, orientation and detectability

ARIELLA POPPLE [1,*], URI POLAT [2] and YORAM BONNEH [3]

[1] *Gatsby CNU, UCL, London WC1N 3AR, UK*
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Spatial variability as a limiting factor in texture-discrimination tasks: implications for performance asymmetries

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Received August 21, 1989; accepted February 2, 1990

Texture-discimination tasks reveal a pronounced performance asymmetry depending on which texture represents the foreground region (small area) and which represents the ground (large area). This asymmetry implies that some global processes are involved in the segmentation process. We examined this problem within the context of the texture-segmentation algorithm, assuming two filtering stages. The first stage uses spatial frequency and orientation-selective (Gabor) filters, whereas the second stage is formed by low-resolution edge-detection filters. The presence and location of texture borders are indicated by significant responses in the second stage. Spurious texture borders may occur owing to textural local variabilities (such as orientation randomization), which are enhanced by the first stage. We suggest that these spurious borders act as background noise and thus limit performance in texture-discrimination tasks. The noise level depends on which texture occupies the ground in the display. We tested this model on numerous pairs of textures and found remarkably good correlation with human performance. A prediction of the model, namely, that discrimination asymmetry will be reduced when textural elements have identical orientation, was tested psychophysically and confirmed.

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Perceptual learning: learning to see

Dov Sagi and David Tanne

The Weizmann Institute of Science, Rehovot, Israel

Perceptual learning in vision has been found to be highly specific for simple stimulus attributes, implying highly specific modifications in the nervous system. The type of specificity found (location, orientation, eye) implied plasticity at very early stages of visual processing, where processing modules were believed to be hard-wired and task independent. Recent studies show, however, that learning is task dependent. Studies examining the time course of learning indicate that at least two different learning processes are involved in perceptual learning, reflecting different levels of processing. Perceptual learning appears to be governed by associative rules and to be constrained by system architecture.

Current Opinion in Neurobiology 1994, 4:195–199

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INTEROCULAR DIFFERENCES IN CONTRAST AND SPATIAL FREQUENCY: EFFECTS ON STEREOPSIS AND FUSION

CLIFTON SCHOR and THOMAS HECKMANN*
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Vision Research 38 (1998) 2067–2080

Vision Research

Different mechanisms underlie three inhibitory phenomena in cat area 17

Frank Sengpiel *, Roland J. Baddeley, Tobe C.B. Freeman [1], Richard Harrad [2], Colin Blakemore

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Distortions in Two-Dimensional Visual Space Perception in Strabismic Observers

RUXANDRA SIRETEANU,*† WOLF-DIETRICH LAGREZE,* DAN HORIA CONSTANTINESCU*

Received 12 November 1991; in revised form 14 July 1992

Amblyopic subjects were asked to memorize circles of different radii (2, 4 and 6°), and then to reconstruct them monocularly with each eye, point by point (12 points per circle). The resulting two-dimensional maps of visual space showed considerable distortions, including expansion, shrinkage and torsion of specific regions of the visual field of the amblyopic eye, but not the normal eye. Based on the differences between the two eyes, we computed complex two-dimensional patterns (gratings, checkerboards, optotypes, written text, natural scenes) as "seen" monocularly with the amblyopic eye. These reconstructed patterns were then compared with drawings of the same patterns observed through the amblyopic eyes of the same subjects. The reconstructed patterns only partially reflected the actual perception for the amblyopic eyes. The compensation of complex, globally-extended scenes in comparison to the distortions obtained by local, punctate settings probably reflects cooperative interactions occurring at higher brain levels.

Strabismic amblyopia Spatial distortions Construction task Computer simulation Drawings

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The visual filter mediating letter identification

Joshua A. Solomon* & Denis G. Pelli†

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Visual discrimination learning requires sleep after training

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Proc. Natl. Acad. Sci. USA
Vol. 95, pp. 12729–12733, October 1998
Psychology

A perceptual memory for low-contrast visual signals

YASUTO TANAKA AND DOV SAGI*

Department of Neurobiology/Brain Research, The Weizmann Institute of Science, Rehovot 76100, Israel

Communicated by George Sperling, University of California, Irvine, CA, August 12, 1998 (received for review March 18, 1998)

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Neural Responses to Static and Moving Texture Patterns in Visual Cortex of the Macaque Monkey

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Plasticity of Low-Level Visual Networks

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Attachment 14

Substantially Equivalent Devices List

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Device Classification Name	HAPLOSCOPE
Regulation Number	886.1340
510(k) Number	K844395
Device Name	RENAISSANCE
Applicant	WILLIAMS GOLD REFINING CO., INC. 2978 MAIN STREET BUFFALO,NY14214
Contact	LAWRENCE A WILLIAMS
Product Code	HJT
Date Received	11/13/1984
Decision Date	01/09/1985
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	Ophthalmic
Review Advisory Committee	Dental
Type	Traditional
Reviewed by Third Party	No

(Database Updated July 6, 2001)

001162

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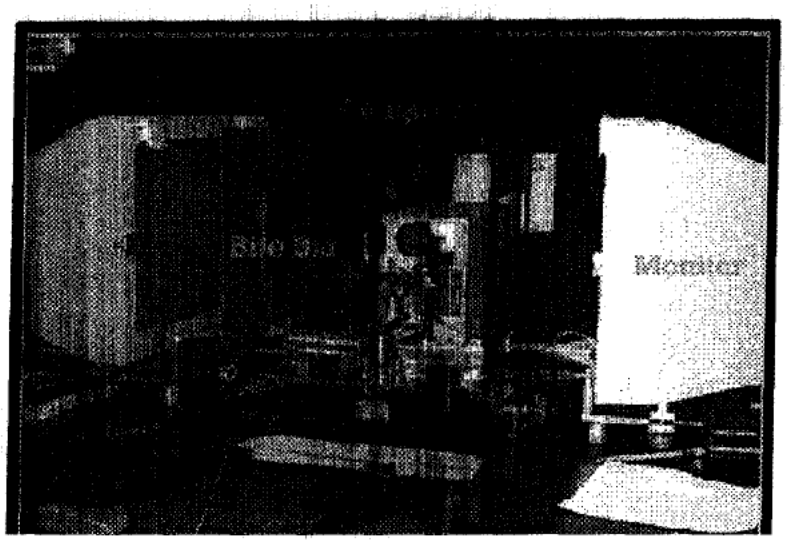
BANKSLAB University of California, Berkeley

Picture of Haploscope

This picture shows the major parts of the haploscope. The observer's head is stabilized by use of the bite bar. The mirrors are visible just above the bite bar. The two CRT monitors are visible to the left and right. The black planes with square apertures are used to reduce stray light. The PowerPC that drives both monitors is visible in the rear.



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Classification Name:	SHIELD, EYE, OPHTHALMIC (INCLUDING SUNLAMP PROTECTIVE EYEWEAR AND POST-MYDRIATIC EYEWEAR)
Device Class:	1
Product Code:	HOY
Regulation Number:	886.4750
Medical Specialty:	Ophthalmic
Owner/Operator:	RICHMOND PRODUCTS, INC.
Owner/Operator Number:	1035253
Registered Establishment Name:	RICHMOND PRODUCTS, INC.
Establishment Registration Number:	1035253
Date of Listing:	07/14/92
Listing Status:	Active
Establishment Operations:	Manufacturer

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Accessibility

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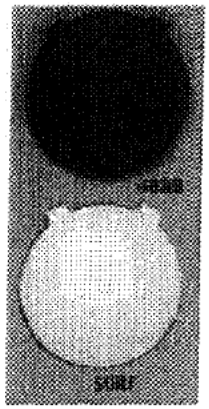
Standard Clip-On Occluders-Round Type



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48RBR Round-Type Clip-Ons 48mm Round Black Color $5.40

48RFR Round-Type Clip-Ons 48mm Round Flesh Color $5.40

50RBR Round-Type Clip-Ons 50mm Round Black Color $5.40

50RFR Round-Type Clip-Ons 50mm Round Flesh Color $5.40

Other Occluder / Diffuser Products

001165

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Return to Search

Device Classification Name	PERIMETER, AUTOMATIC, AC-POWERED
Regulation Number	886.1605
510(k) Number	K954167
Device Name	HUMPHREY FIELD ANALYZER (HFA II)
Applicant	CARL ZEISS, INC. ONE ZEISS DR. THORNWOOD,NY10594
Contact	KENNETH M NICOLL
Product Code	HPT
Date Received	09/05/1995
Decision Date	11/24/1995
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	Ophthalmic
Review Advisory Committee	Ophthalmic
Statement/Summary/Purged Status	Summary only
Type	Traditional
Reviewed by Third Party	No

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Accessibility

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