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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

APR 10 1991

Leigh R. Abts, Ph.D.
President and CEO
Triad Investors Corporation
1629 Thames Street
3rd Floor
Baltimore, MD 21231

Re: K910124
Low Vision Enhancement System (LVES)
Regulatory Product Class: I
Product Code: 86 HPG
Dated: January 10, 1991
Received: January 11, 1991

Dear Dr. Abts:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration. As part of the labeling requirements all lenses used in eyeglasses must comply with the Code of Federal Regulations, Title 21, Part 801, Section 410 - Use of impact resistant lenses in eyeglasses and sunglasses.

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

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Richard E. Lippman

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

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

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Food and Drug Administration
Office of Device Evaluation

Memorandum

30day dev.

Date: April 1, 1991

From: Paula Wilkerson
Chemical Engineer
Surgical and Diagnostic Branch
Division of Ophthalmic Devices

Re: K910124

SUMMARY

In this submission , Triad Investors Corporation is requesting a substantial equivalence finding under 21 CFR 807.81 for it's version of a closed circuit television reading system.

INTENDED USE

This device is a head mounted video display system which displays magnified images for use by low vision patients. Although designated a Class I device, the Low Vision Enhancement System (LVES) is prescribed and fitted for patients by licensed eye care providers (ophthalmologists/optometrists). The LVES is marketed with a dispensing kit that enables the prescribing health care practitioner to make the required physical and optical adjustments to fit the device to individual patients.

DEVICE DESCRIPTION

The LVES is a portable, battery operated system that functions like a closed circuit TV (CCTV). The battery supply and video/audio electronics are mounted on a belt pack worn by the user. Standard black and white video images are displayed by miniature TV monitors mounted on each side of the patient's head. TV images are optically transmitted to the viewer's eye through a series of mirrors and lenses which collimate, magnify and provide refractive error correction for the image. The resulting image as viewed by the patient has a 50 degree horizontal field of view by a 38.5 degree vertical field of view.

The components of this device are;

1. battery pack,
2. video/audio electronics,
3. television monitors,

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4. optical chain,
5. head mounted display,
6. dispensing kit, and
7. TV camera.

ENGINEERING REVIEW

BATTERY PACK

The video/audio electronics and cathode ray tubes (CRTs) are powered by a 9.6 volt NICAD rechargeable battery that is carried in a belt pack by the user. The belt pack also contains the circuitry needed to accept standard, 1 volt peak-to-peak composite video signals. These video signals are routed to drive the CRTs via a cable connecting the belt pack to the head mounted display. High voltage is provided to each CRT by a separate transformer (one for each CRT) in the head mounted unit which converts the 9.6 volt battery voltage to 1200 to 1500 volts. CRT beam current is in the microamphere range. EACH CRT IS ELECTRICALLY INSULATED TO PREVENT A SHOCK HAZARD TO THE PATIENT. THE SPONSOR STATES THAT THE ENTIRE SYSTEM WILL BE UL LISTED BEFORE MARKETING.

The user is protected from possible implosion of the CRT by the shielding of the high impact plastic housing which also contains the associated voltage and electronics. This unit provides additional electrical insulation for the CRT and it's power supply in addition to the mechanical rigidity required to insure intregity of the optical path. The radiation level emitted from the CRTs falls below the limits in the performance standard for CFR 1020.10.

DEVICE MATERIALS

An inventory of the materials used in the device, in addition to those described in the power supply, show utilization of the following substances;

Name	Material
Lens materials	

(b)(4) Confidential and Proprietary Information

[redacted]

All of these materials are contained within the high impact

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(b)(4) Confidential and Proprietary Information

[redacted]

COMPARISON FOR SUBSTANTIAL EQUIVALENCE

The sponsor offers ~~three (3)~~ four (4) predicate devices to substantiate the claim of equivalence;

1. Optec, models VFF, II T, IV, and V.

Optec offers a series of closed CCTVs for reading, computer access, and typing.

2. Human Ware, models View Point and Clear View.

These devices are hand held, portable, closed coupled (CCD) CCTVs.

3. Telesensory, models Vantage and Voyager XL.

These are CCTVs based on CCD technology.

4. Optelec, models FDR 23 and 23s, 20/20, and 20/20+.

These devices are both remote camera operations and two camera combination for restricted sight viewing.

The LVES differs from the above CCTVs in that it is physically divided into two sections:

1. The viewing portion is contained in an impact resistant case for mounting on the patients head. The LVES uses a series of lenses and mirrors to reflect the captured image to the patients eye. Lenses and mirrors are designated as optical quality and are either made of or coated with impact resistant materials.

2. The battery pack contains 9.6 volt, 600 milliampere NICAD battery.

COMMENT

(b)(4) Confidential and Proprietary Information

[redacted]

LABELING REVIEW

The labeling for this device contains information in the following areas:

A. Information to Physicians
   1. Cautions and Warnings

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2. Instructions for use
3. Specifications for compatible accessories
4. Determination of corrective lenses
5. Adjustment for interpupillary distance
6. Adjustment of fold mirrors
7. Selection and mounting of face support
8. Guidelines for physicians instructions to the patient
9 Technical specifications.
10. Dispensing kit
11. Cleaning and maintenance
12. Service
13. Replacement parts
14. Warranty

B. Information to Patients
1. Cautions and Warnings
2. Instructions for Use
3. Specifications for compatible accessories
4. Technical Specifications
5. Cleaning and maintenance
6. Service
7. Replacement parts
8. Warranty

COMMENT

This outline of the sponsors labeling appears to be adequate for the application.

CONCLUSION

This device is substantially equivalent.

DBM
4/8/91

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) P. WILKERSON

Subject 510(k) NOTIFICATION K910124

To THE RECORD

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

✓ (A) Is substantially equivalent to marketed devices.

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

____ (C) Requires more data.

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

Additional Comments:

The submitter requests under 21 CFR §807.95:

____ No Confidentiality

✓ Confidentiality for 90 days

✓ Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

86 HPG, Class I

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

REVIEW: Denis L. McCarthy 4/8/91
(BRANCH CHIEF) (DATE)

FINAL REVIEW: Ron A. Phillips for NEL 4/10/91
(DIVISION DIRECTOR) (DATE)

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

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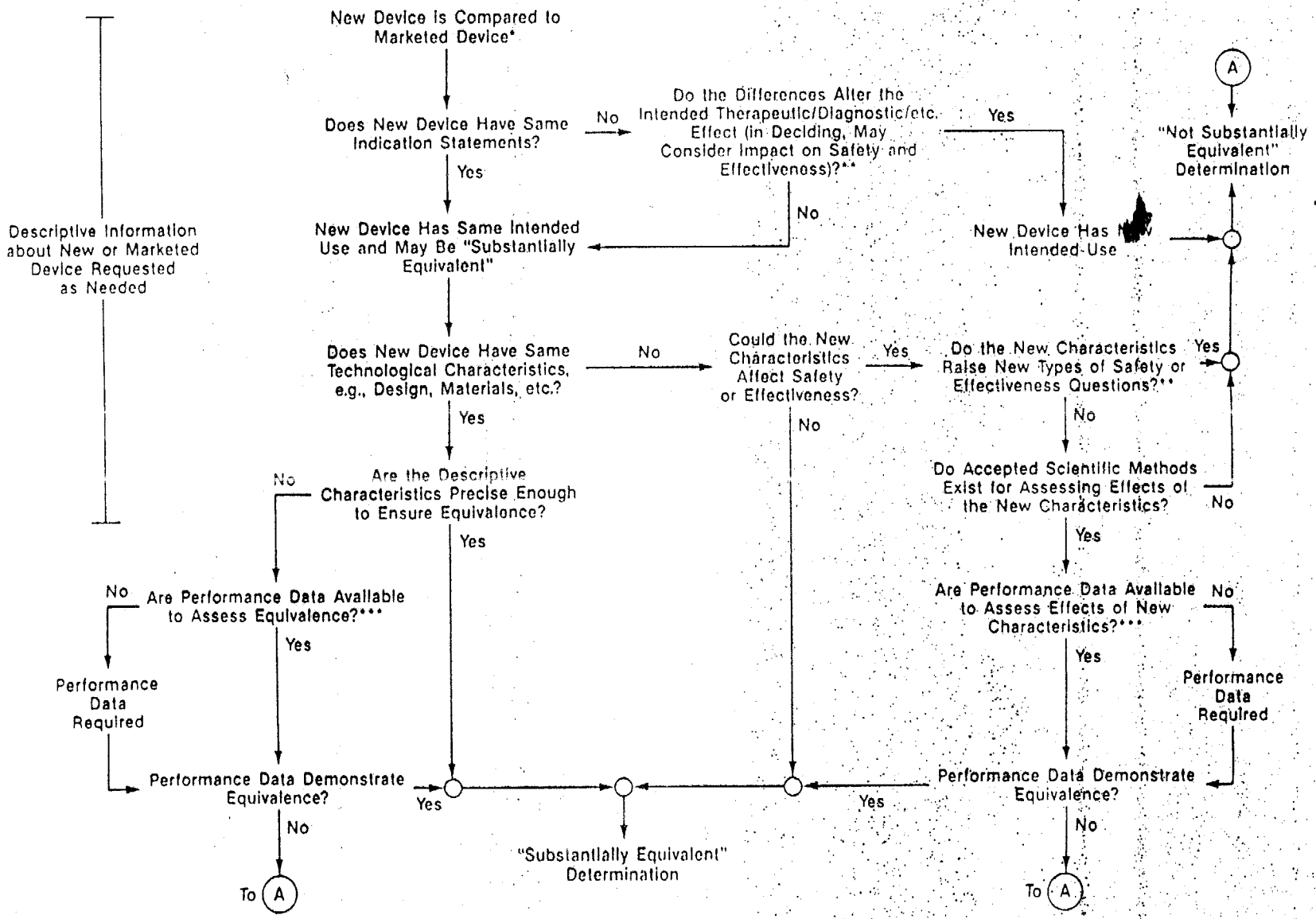
510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 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.

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K 91D124 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

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

TRADE NAME: LVES COMMON NAME: CLOSED CIRCUIT TELEVISION

PRODUCT TO WHICH COMPARED: Optiq, Human Ware, Telesensory, Optelec
(510(k) NUMBER IF KNOWN)

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

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

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

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NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: _____

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

SUMMARY: _____

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

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

1. EXPLAIN WHY NOT A DEVICE: _____

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

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

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

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS: _____

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

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7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH:

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

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

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED:

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

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

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

JANUARY 14, 1991

TRIAD INVESTORS CORP.
ATTN: LEIGH R. ABTS
1629 THAMES STREET
3RD FLOOR
BALTIMORE, MD 21231

510(k) Number: K910124
Received: 01-11-91
Product: LOW VISION ENHANCEMENT SYSTEM (LVES)

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

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

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

Please note that the Safe Medical Devices Act of 1990 may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
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Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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

Sincerely yours,

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

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

K910124

January 10, 1991

RECEIVED
11 JAN 91 11 09
FDA/CDRH/ODE/DMC

Food and Drug Administration
Center for Devices and Radiologic Health
Document Control Center, Rm. 282 (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

RE: 510(k) for LVES Closed Circuit Television System

Attention Document Control Clerk:

In accordance with Section 510(k) of the Food, Drug, and Cosmetic Act and in conformance with 21 CFR 807, three copies of this premarket notification submission are being submitted by Triad Corporation for the LVES closed circuit television system.

The following information is being submitted in accordance with 21 CFR 807.87:

1. Classification Name: Closed Circuit Television Reading System.

   Common Name: Closed Circuit Television (CCTV)

   Trade Name: LVES (Low Vision Enhancement System)

2. Establishment Registration: Establishment registration is pending.

3. Closed circuit television systems have been classified as Class I devices, 21 CFR 886.5820 under the Ophthalmology Panel.

4. No mandatory performance standards under Section 514 have been developed by the Food and Drug Administration for these devices. However, the LVES will be compliant with the requirements of 21 CFR Part 1020, Performance Standards for Ionizing Radiation Emitting Products. The requisite Initial Report requirements will be complied with.

1628 Thames Street, 3rd Floor, Baltimore, MD 21231 (301) 955-9760

Questions? Contact FDA/CDRH/OSE/Digital Media Branch at DMS@fda.hhs.gov or call 301-796-8118.

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5. No labeling has been finalized for the LVES. However, a summary of the labeling contents is provided in Appendix II.

6. The LVES is substantially equivalent to several marketed low vision magnifiers and to other CCTVs manufactured by Telesensory, Optelec, and others. The substantial equivalence information is presented in Appendix I.

The enclosed Appendixes contain the following information for your review:

Appendix I: Substantial Equivalence

Appendix II: Device Description

Appendix III: Predicate Product Information

Appendix II, Device Description, contains certain information and drawings that Triad Corporation considers to be trade secret, confidential information exempt from public disclosure. The pages and/or drawings containing this information have been so marked.

Should you have any questions or require further information, please contact our authorized regulatory consultant, Mary Jo Lyons of Bio-Reg Associates, Inc., Laurel, Maryland. Ms Lyons can be reached at (301) 206-2214.

Jim Howard

Sincerely,

Leigh Abts

Leigh R. Abts, Ph.D
President and CEO

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

1629 Thames Street, 3rd Floor Baltimore MD 21231 (301) 955-976

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Appendix I

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

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APPENDIX I

PREDICATE DEVICE

SUBSTANTIAL EQUIVALENCE COMPARISON

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

The Low Vision Enhancement System (LVES) is a battery operated head-mounted closed circuit television which shares the same intended use and technological characteristics as several other predicate, low vision medical devices. These equivalent predicate devices are comprised of two categories of low vision aids:

1. Magnification aids. This category includes low vision magnifiers (21 CFR 886.5540); magnifying spectacles (21 CFR 886.5840); low vision telescope (21 CFR 886.5870), and; optical vision aid (21 CFR 886.5915). These devices consist of magnifying lenses which are either hand held or spectacle-mounted. The optical vision aid has a battery powered light source. All of these devices are classified in Class I.

2. Closed Circuit Television System (CCTV). This category consists of a lens, video camera, and video monitor. This device was classified as Class I (21 CFR 886.5820) in the Federal Register Vol. 55, No. 224, Tuesday November 20, 1990.

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INTENDED USE

Like the above magnification aid and CCTV devices, the LVES is intended for use by patients with low vision. Typically, the low vision in this type of patient cannot be corrected through other means, i.e., spectacles, lenses, or surgery.

The objective of the magnification aid, CCTV, and LVES is to present an enlarged image to the patient. Thus, these devices enable low vision patients to conduct such activities of daily living as reading, writing, watching TV, etc.

COMMON CHARACTERISTICS

Like several of the magnification aids, especially the magnifying spectacles, the LVES is mounted on the head. There are numerous manufacturers and models of predicate, spectacle/head mounted magnifiers.

Technologically, the LVES is a CCTV with the same electronic configuration as the following manufacturers and products (Labeling and product brochures for these products are contained in Appendix III):

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	MANUFACTURER	MODEL
1.	Opteq	VFF
		II T
		IV
		V

Optec offers a series of closed CCTVs for reading, computer access, and typing.

2.	Human Ware	View Point
		Clear View

Human Ware's products are hand held, portable, closed coupled device (CCD) CCTVs.

3.	Telesensory	Vantage
		Voyager XL

Telesensory's CCTV are based on CCD technology.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
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4. Optelec FDR 23 and 23S
20/20 and 20/20+

Optelec offers remote camera operation for viewing of far objects and two camera combinations.

LVES has the following common elements as the above units:

- image enlargement and magnification
- positive or negative imaging (reverse video)
- brightness adjustment capability
- gray scale modification (contrast enhancement)
- windowing capability
- TV monitor use
- miniature electronics (videcon or CCD input)
- acceptance of composite video signals (computers, VCRs, etc.)

The LVES differs from the above CCTVs in that it is physically divided into two sections:

1. The viewing portion, or monitor, of the CCTV is contained in an impact resistant case for mounting on the patients head. This is accomplished through the use of small electronic

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components (monitors), similar to those found in recent video cassette recording cameras (VCRs). The LVES uses a series of lenses and mirrors to reflect the captured image to the patients eye. The use of corrective lenses in this segment of the LVES allows the image to be properly refracted for each patient. These lenses and mirrors are optical quality and are either made from, or coated with, impact resistant materials.

The cathode ray tubes (CRTs) which are contained in this section of the LVES, are encased in an insulated housing for electrical safety. The radiation level emitted from the CRTs is well below the limits set forth in the performance standard required in CFR 1020.10. It should be noted that the LVES will be certified according to the requirements in this standard.

2. The battery pack, or power unit, of the LVES contains 9.6 volt, 600 milliampere NICAD battery. This battery powers the LVES electronics and is contained in a light weight pack carried on the patient's belt. The power output of this unit is well below accepted safety limits.

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

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Appendix II

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

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APPENDIX II

PRODUCT DESCRIPTION

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

The Low Vision Enhancement System (LVES) is a head mounted video display system which displays magnified images for use by low vision patients (Figure I - Head Mounted Display). The LVES is prescribed and fitted for patients by appropriately licensed eye care providers, such as ophthalmologists and optometrists.

PRODUCT DESCRIPTION

I. Overview

A. Summary Description

Patients suffering from visual impairments which result in low vision can often see better when looking at magnified images. Currently, magnification is done by a variety of visual aids including optical magnifiers and closed circuit televisions (CCTV) to magnify and, in the case of CCTV's, adjust the brightness and contrast.

The LVES can display magnified video images from any video source so that people with low vision can watch television, read, write, and locate and identify faces and objects.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8113.
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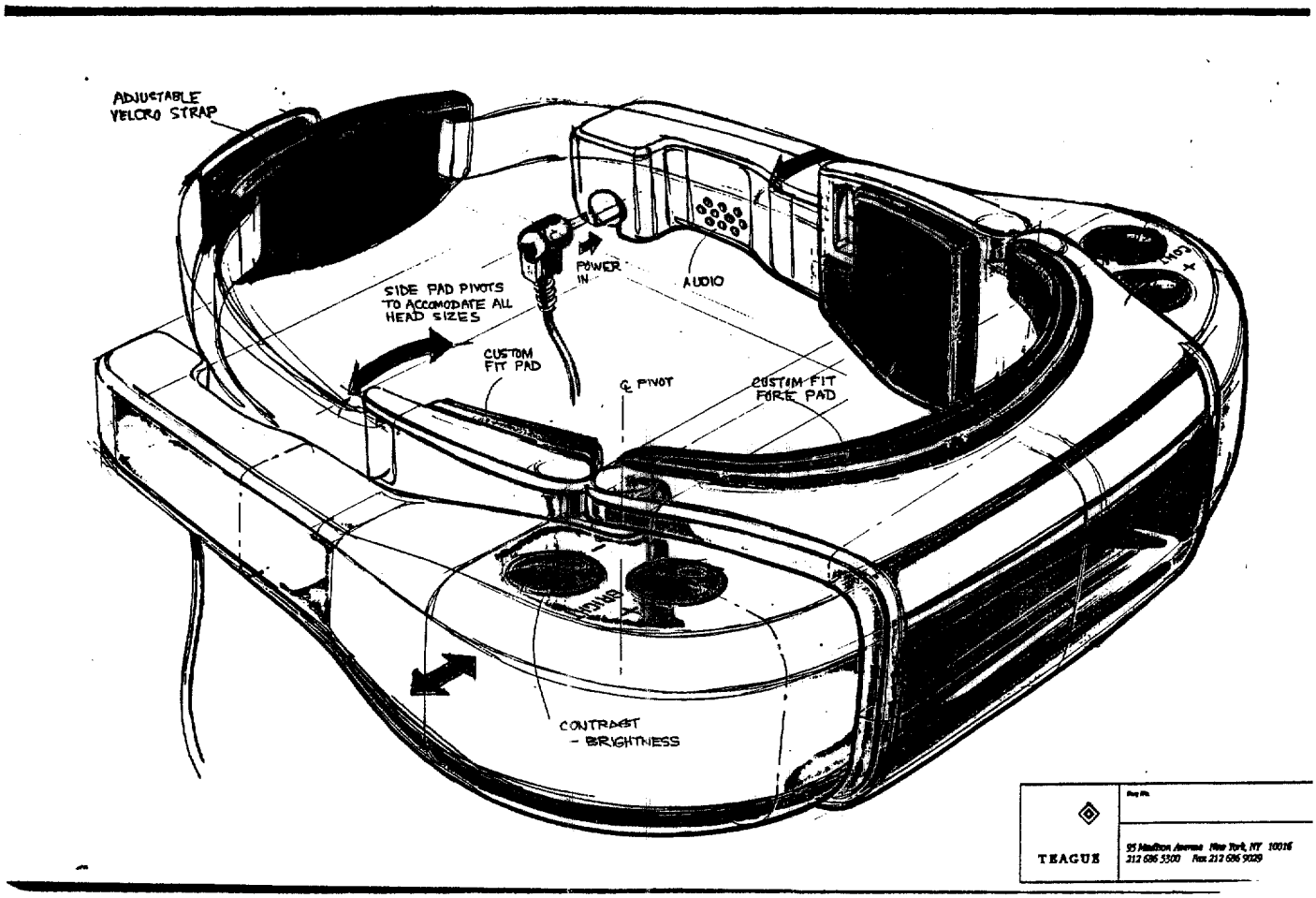
FIGURE 1

HEAD MOUNTED DISPLAY



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The Low Vision Enhancement System (LVES) has been designed as a head mounted television display (Figure 2 - LVES Layout) to enable patients to view magnified images from standard composite video sources. These sources include broadcast television, video cassette recorders (VCRs), computers, or video cameras.

The LVES is a portable, battery operated system that functions like a closed circuit TV (CCTV). The battery supply and video/audio electronics are mounted in a belt pack worn by the user. Standard black and white video images are displayed by miniature TV monitors mounted on each side of the patient's head. TV images are optically transmitted to the viewer's eye through a series of lenses and mirrors (Figure 3 - Optical Chain) which collimate, magnify and provide refractive error correction for the image. The resulting image as viewed by the patient has a 50 degree horizontal field of view by a 38.5 degree vertical field of view (i.e. equivalent to viewing a 60 inch TV from a distance of 4 feet).

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FIGURE 2

LVES LAYOUT

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FIGURE 3

OPTICAL CHAIN

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The LVES is provided with a physician's dispensing kit that enables the prescribing physician to make the required physical and optical adjustments to fit the LVES to individual patients. This kit contains an assortment of spherical and cylindrical correcting lenses and a variety of distance measuring devices.

B. Components/Subassemblies

1. Battery Pack

2. Video/Audio Electronics

3. Television Monitors

4. Optical Chain

5. Head Mounted Display

C. Accessories and Options

1. Dispensing Kit

2. TV Camera

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3. Reading Tray (TV camera over moveable tray)

4. Video Cassette Recorder (VCR)

5. Broadcast TV Tuner

II. Subassembly/Component/Accessory Descriptions

A. Battery Pack

The video/audio electronics and cathode ray tubes (CRTs) are powered by a 9.6 volt NICAD rechargeable battery that is carried in a belt pack by the user. The NICAD battery is recharged using an Underwriters Approved (UL) charger/eliminator that is plugged into an AC wall outlet. The 9.6 volt, 600 milliampere battery pack supplies power to the video and audio electronics as well as the CRTs. The number of CRTs required for each LVES depends on whether the user chooses a monocular (one eye display - one CRT) or a binocular (two eye display - two CRTs) version. When used with two CRTs, the battery pack will last for a minimum of 4 hours. When the battery voltage drops below approximately 8.8 volts, electronic circuitry activates a "low battery indicator" to alert the patient that recharging is needed. Either a visible

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indicator which can be seen in the CRT display or an audible indicator is used. If necessary, the LVES system can be operated directly from the battery eliminator.

B. Video/Audio Electronics

The belt pack also contains the circuitry needed to accept standard, 1 volt peak-to-peak composite video signals. These video signals are routed to drive the CRTs via a cable connecting the belt pack to the head mounted display. The functions of the electronics in the belt pack are described below:

1. Video Inputs

The belt pack contains two video input jacks: one for the left CRT and one for the right CRT. If two cameras or other video sources are used, they are connected to the right and left video jacks respectively, thereby allowing each eye to see the image from one of the video sources. If only one camera or other video source is used, it is connected to the right video input jack, thereby allowing the same image to be displayed on both TV monitors.

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2. Standard/Reverse Video

The user is provided with a switch on the belt pack which allows selection of standard or reverse video. In the standard mode the CRTs will display a typical grey scale image. If reverse video is selected, the circuitry inverts the video signal and the CRTs display a grey scale image in which light areas become dark and dark areas become light.

3. Video Contrast Enhancement

The belt pack electronics also provides a contrast enhancement feature in which the video signal is passed through a discriminator, the threshold of which is set either by the patient or the physician.

That portion of the video signal which exceeds the threshold of the discriminator is set to 1 volt (i.e. black for standard video). That portion of the signal which is less than the threshold is set to 0 volts (i.e. black for standard video). If standard video is selected, the image appears as black on a

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white background. If reverse video is selected, the image appears as white on a black background. The net effect is to create a video display in which contrasts above the threshold are maximized.

4. Other Video Features

The video circuitry will also display images in any format which is within the video source's capability. For example, video cameras used for text reading allow the operator to create a window to image only a selected number of text lines. Such a window would be readily displayed by the LVES.

5. Audio

If the audio option is chosen, the audio signal is routed from the belt pack to an audio amplifier and small speakers or earphones in the head mounted display unit. The display unit also contains a volume control.

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C. Television Monitors

The television monitors consist of one or two CRT's and associated high voltage supplies, video amplifiers, and sweep circuits which are mounted in the head mounted display unit as shown in Figure 4 - Right Side Assembly Drawing. For binocular versions, one CRT is mounted in each side (i.e. arm) of the head mounted display. Each CRT is 63 mm long and 19 mm in diameter and produces an 18 mm diagonal picture using video signals from the belt pack electronics. The images have a minimum resolution of 500 lines horizontal and 400 lines vertical.

High voltage is provided to each CRT by a separate transformer (one for each CRT) in the head mounted unit which converts the 9.6 volt battery voltage to 1200 to 1500 volts. CRT beam current is in the microampere range. Each CRT is electrically insulated to prevent a shock hazard to the patient. To assure electrical and mechanical safety, the entire system will be UL listed.

D. Optical Chain

The video image generated by the CRT is optically transmitted to the patient's eye through a series of lenses, mirrors, and a beam splitter (Figure 3 - Optical

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FIGURE 4

RIGHT SIDE ASSEMBLY

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Chain) which present a wide angle, virtual image to the patient.

The CRT image first passes through a triplet of aspherical lenses which form a magnified, intermediate image. After this triplet lens, a series of one to three corrective lenses provide the distance refractive error correction for the patient. The correcting lenses consist of spherical and cylindrical optical lenses prescribed for each eye.

Light emerging from the correcting lenses is reflected around the corner by a fold mirror into a beam splitter. The beam splitter reflects the light into a concave mirror that focuses the image of the CRT for the patient. The image which reflects off this mirror passes back through the beam splitter to the pupil of the patient's eye.

The video image as seen by the patient appears suspended in a black space. This image has less than 6% distortion and, because of the 8 millimeter exit pupil diameter, the viewer can look at different parts of the image without vignetting. The size of the video image in the field of view is 64 degrees diagonal, 50 degrees horizontal and 38.5 degrees vertical.

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All optical elements are rigidly fixed in the head mounted display unit. Because the optical paths for each eye are independent, physician adjustment of the head mounted display unit for inter-pupillary distance has no effect on the optics. Once the inter-pupillary distance has been set by the physician it cannot be changed by the patient.

E. Head Mounted Display

1. Design

The head mounted display is an ergonomically designed plastic housing (Figure 1 - Head Mounted Display) which can be fitted to the patient's head. Each arm of this housing contains a CRT, associated high voltage and sweep electronics, and the mirrors and lenses necessary to display the video image to one eye. This unit provides both electrical insulation for the CRT and its high voltage supply and mechanical integrity necessary to insure rigidity of the optical path.

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The images of the video screens in the LVES are focused at the far point of the eye in order to provide images which are in focus for the patient. The head mounted display is designed such that, if the patient is not in emmetrope, his distance sphero-cylindrical refractive error correction for each eye can be inserted in the optical chain prior to dispensing. In addition, the head mounted display is designed to allow mechanical adjustments as needed to assure proper fit to the patient.

2. Adjustments

a. Refractive Correction

To enable correction of the patient's refractive error, appropriate prescription lenses may be inserted into the head mounted display. The powers of these lenses are selected to provide the appropriate refractive correction in the spectacle plane. Corrections of up to $\pm$ 6 diopters [up to 12 diopters when the lenses are used in combination] can be achieved.

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b. Inter-pupillary Adjustment

The head mounted display may also be adjusted for the patient's inter-pupillary distance as measured by the physician.

c. Binocular Fusion Adjustment

If the patient has a lateral phoria or tropia that prevents fusion of monocular images, the mirrors in the binocular version of the LVES may be adjusted to induce prism translation of the images in the same way that ophthalmic prisms are used in eyeglasses.

d. Face Support Selection

The head mounted display is designed to allow use of face supports which are selected from an assortment of supports provided in the Dispensing Kit based on physician measurements of the patient's head.

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G. Dispensing Kit

The Low Vision Enhancement System is provided with an accessory dispensing kit to facilitate the fitting of the head mounted display by the prescribing physician. This kit contains the following items:

1. Inventory of spherical and cylindrical correcting lenses
2. Inventory of face support inserts
3. Tape measure
4. Six inch ruler
5. Head calipers
6. Tool for prism and inter-pupillary adjustments
7. Demonstration HMD

H. Specifications

1. TV Monitors

Monitor Type ..... Black & White

Number of TV monitors..... 1 (Monocular)
2 (Binocular)

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Anode Voltage ..... 1200 - 2000 volts

Deflection ..... Magnetic, 15 Degrees

Focusing ..... Electrostatic

Image size ..... 10.9 x 8.3 mm
640 x 480 pixels

2. Optical System

Field of view ..... 50° (horiz.) x 38.5° (vert.)

Exit pupil diameter ..... 8 mm

Eye pupil separation ..... >/= 50 mm

Effective focal length ..... 12.2 mm

f/number 1.53

Wavelength ..... Visible range

Geometric distortion ..... </= 6%

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Dioptric compensation ..... Power: +/- >10 Diopters (D.)
1/4 D resolution
Cylinder: 0 to -3 D.
1/4 D. resolution

3. Lens Material

Triplet lenses ..... Polymethylmethacrylate (PMMA) and Polycarbonate (MgF_2 anti-reflection coating)

Diopter lenses ..... PMMA, Ophthalmic crown glass, or CR-39 thermoset plastic

Fold mirror ..... Glass

Beamsplitter ..... Impact resistant glass

Concave mirror ..... Injection molded plastic (aluminized polycarbonate styrene)

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4. Audio

Output Power ..... 200 Milliwatts

Frequency Response ..... 200 Hz to 4000 Hz

5. Video Electronics

Input ..... Jack for left CRT
Jack for right CRT

Input signal ..... 1 volt peak to peak

6. Operator Controls

a. Belt Pack

On/Off

Standard/Reverse Video

Video Contrast Enhancement On/Off/Threshold

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b. Head Mounted Display

Brightness

Contrast

Volume

7. Power Supply

Battery Voltage..... 9.6 Volts DC

Battery Capacity ..... 600 - 1200 Milliamperehours

Battery Charger ..... 110 Volts AC, 60 Hz,

10 Watts

I. Labeling

Final labeling for the LVES has not been completed at this time; however, this labeling will include the following:

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I. Information to Physicians

A. Cautions and Warnings

1. Avoid access to high voltage present inside head mounted display.
   a. Do not disassemble
   b. Do not get wet

2. Do not use while walking, driving a vehicle, etc. Use only for non-ambulatory tasks such as reading or watching television.

3. Avoid physical damage to head mounted display which could break optics or damage the CRT.

4. Use only on prescription of a physician

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B. Performance claims

C. Instructions for use

1. Description of control adjustments

2. Battery charging

D. Specification of compatible accessories (eg. cameras, VCRs etc.)

E. Determination of the appropriate corrective lenses

F. Adjustment for interpupillary distance

G. Adjustment of fold mirrors to compensate for lateral phoria or tropia for binocular versions of the LVES

H. Selection and mounting of the appropriate face support insert on the head mounted display

I. Guidelines for physician instructions to the patient on operation and use of the LVES

J. Technical specifications

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K. Dispensing kit

L. Cleaning and maintenance

M. Service

N. Replacement Parts

O. Warranty

II. Information to Patients

A. Cautions and Warnings

1. Avoid access to high voltage present inside head mounted display.
   a. Do not disassemble
   b. Do not get wet

2. Do not use while walking, driving a vehicle, etc. Use only for non-ambulatory tasks such as reading or watching television.

3. Avoid physical damage to head mounted display which could break optics or damage the CRT.

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4. Use only on prescription of a physician

B. Performance claims

C. Instructions for use

1. Description of control adjustments

2. Battery charging

D. Specification of compatible accessories (eg. cameras, VCRs etc.)

E. Technical specifications

F. Cleaning and Maintenance

G. Service

H. Replacement parts

I. Warranty

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Appendix III

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APPENDIX III

PREDICATE PRODUCT INFORMATION

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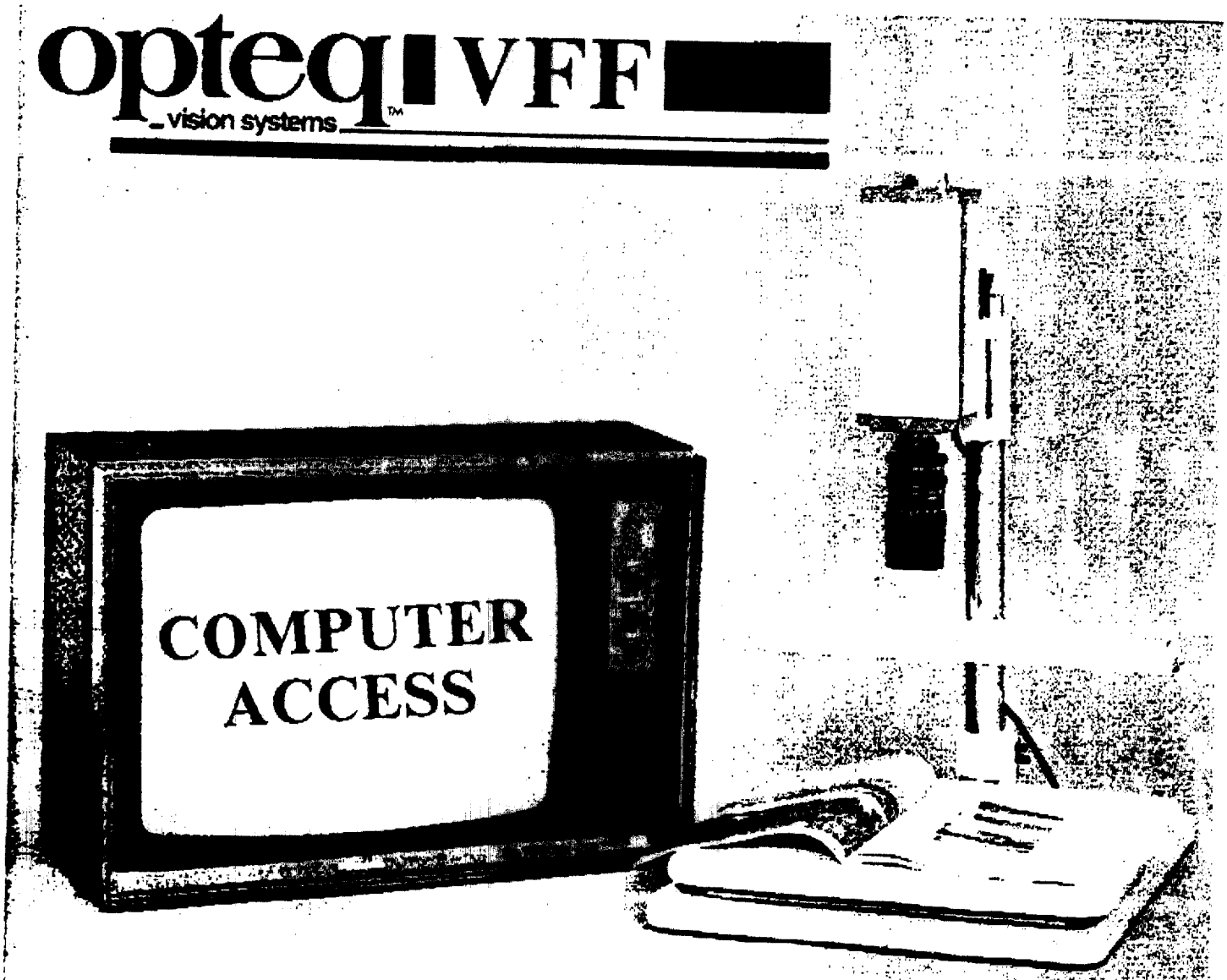
OPTEQ VFF

PC PARTNERS, INC.
6407 FREDERICK ROAD
BALTIMORE, MD 21228
(301) 744-3724

One button allows user access to full screen read and write or computer access. The OPTEQ VFF (Flip Flop Screen) with computer access to the lowest cost CCTV which interfaces with PC's, XT's, and AT's, and most clones, allowing the user to read or write, or access a computer by flipping one switch. The full 19" monitor can be used for reading or computer access. Software and firmware not included. Your local OPTEQ dealer is available to advise you on computer, software, and firmware choices.



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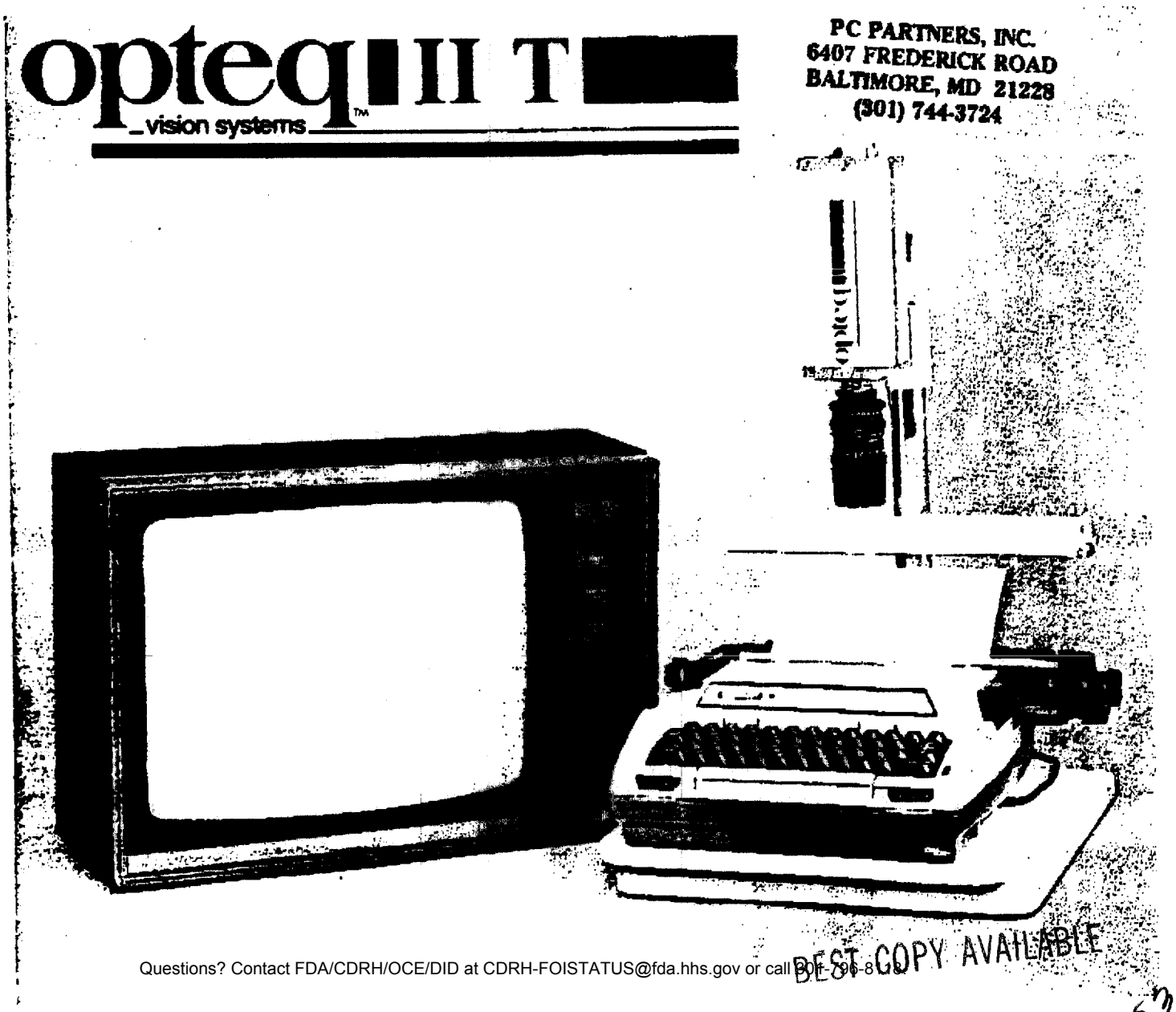
OPTEQ II T Typing System

The OPTEQ II T Typing System is a versatile CCTV which allows the user to read, write, or type. The 19″ High Resolution monitor allows print to be magnified up to 60 times in positive or negative mode. Books, mail, and any kind of reading material is easily scanned and read, utilizing an XY table. For more details contact your local OPTEQ Dealer.



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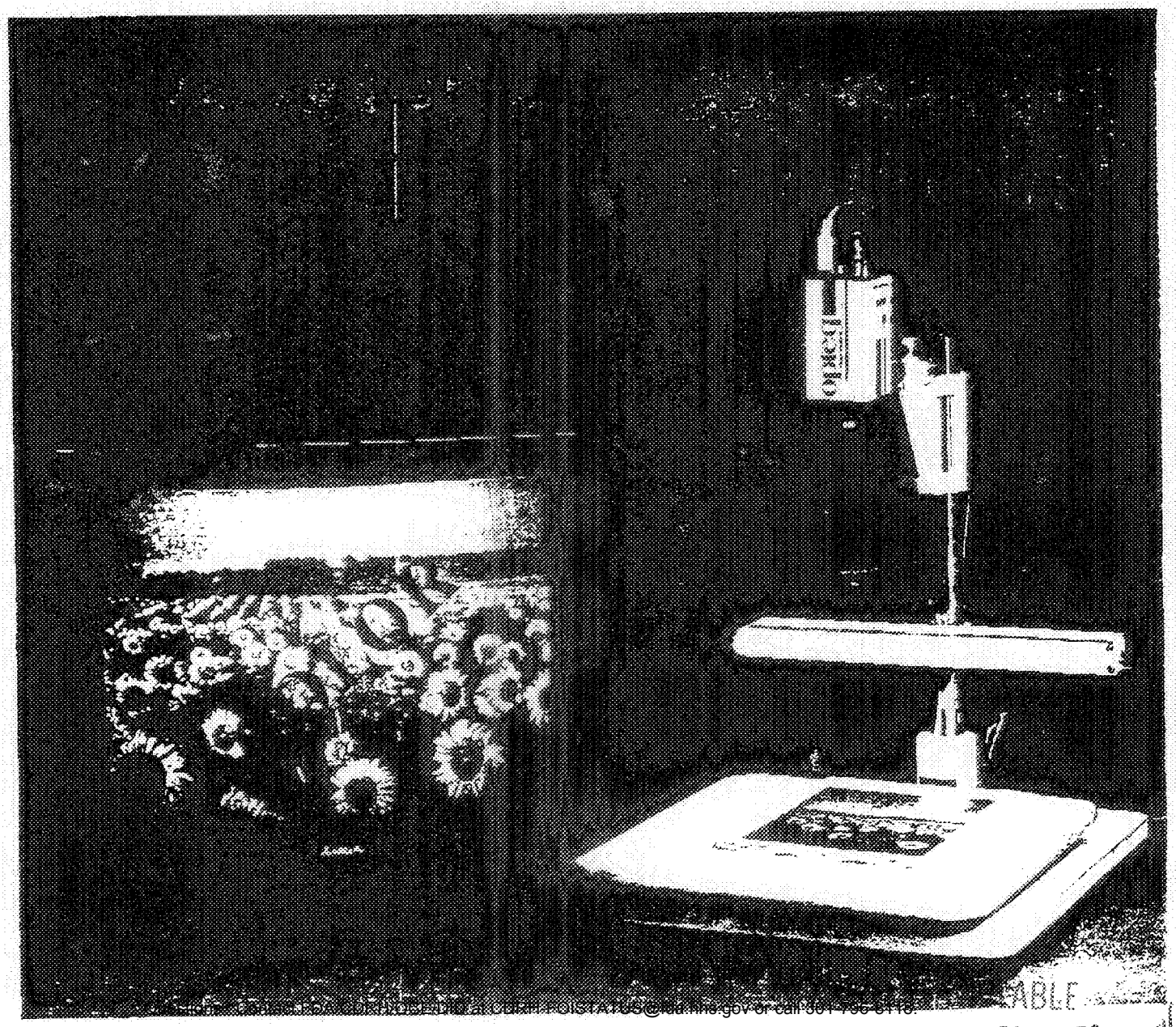
Color, Black and White, Positive/Negative!

The OPTEQ IV

PE PARTNERS, INC.
5407 FREDERICK ROAD
BALTIMORE, MD 21228
(301) 744-3724

The OPTEQ IV utilizes new technology to display crisp, clear images in full color, black and white, or positive and negative modes at a price that is under most black and white CCTV's.

For student, hobbiest or just reading, color brings a vibrancy and clarity unmatched by any existing black and white CCTV's. Versatility is achieved by the cameras unique ball joint mount which allows the camera to swivel in all directions allowing the user to view objects near and far, indoors or outdoors. For a free demonstration call **OPTEQ Vision Systems** for the name of your local dealer. The **OPTEQ IV** is available in 20" and 13" versions. See price sheet for details.



OPTEQ Vision System 17355 Merrow Lane Brookfield Wi. 53005 (414) 784-4979

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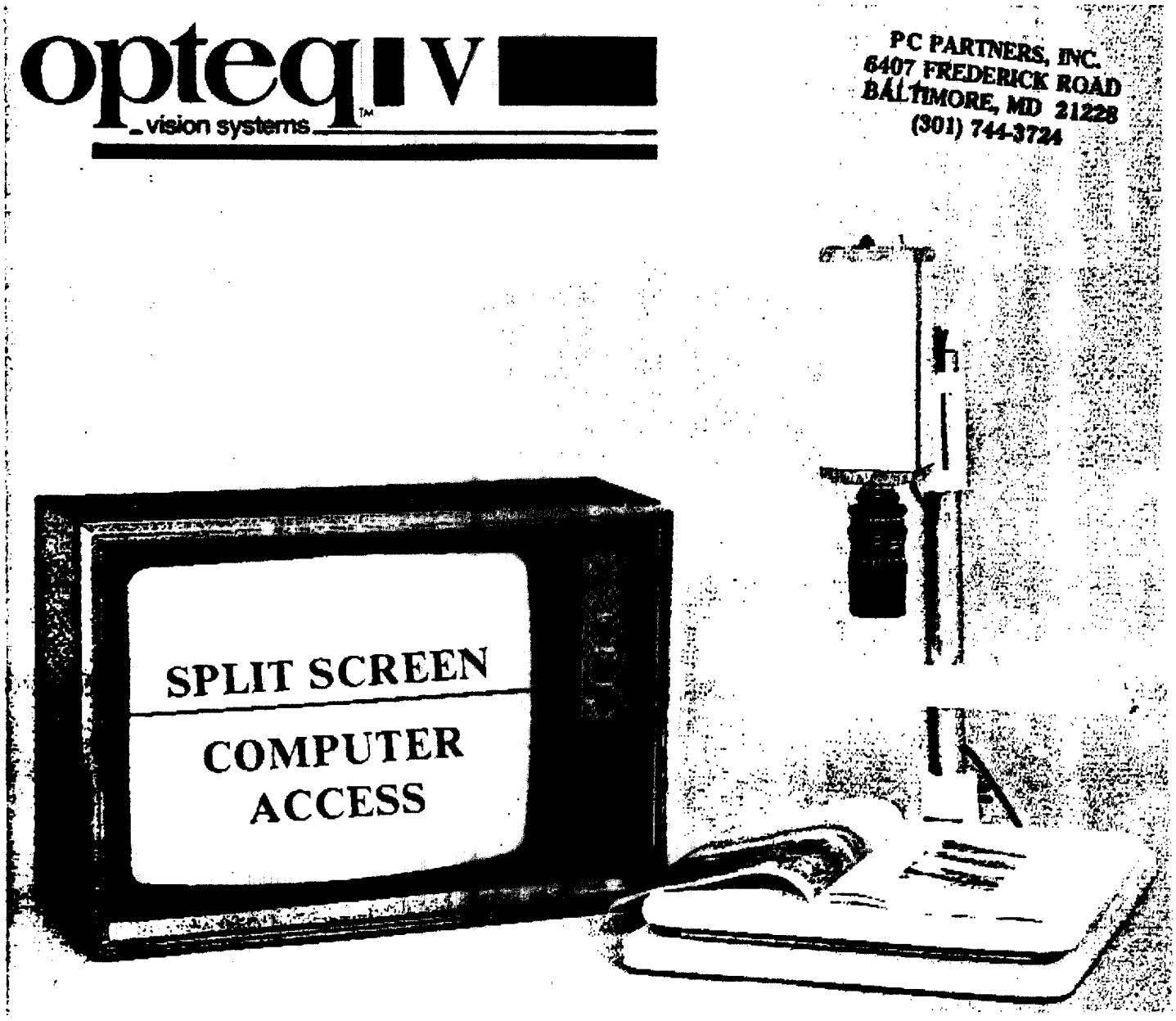
OPTEQ V
SPLIT SCREEN/COMPUTER ACCESS

The OPTEQ V split screen with computer access is a low cost CCTV which interfaces with PC's, XT's, AT,s and most clones allowing user to read, write, and input or access computer data size. The software is not included with your OPTEQ purchase, but your local OPTEQ dealer can advise users as to availability and costs. Your local OPTEQ dealer is available for application assessment, demonstration, and training as needed.



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OPTEQ Vision System 17355 Mierow Lane Brookfield Wi. 53005 (414) 784-4979

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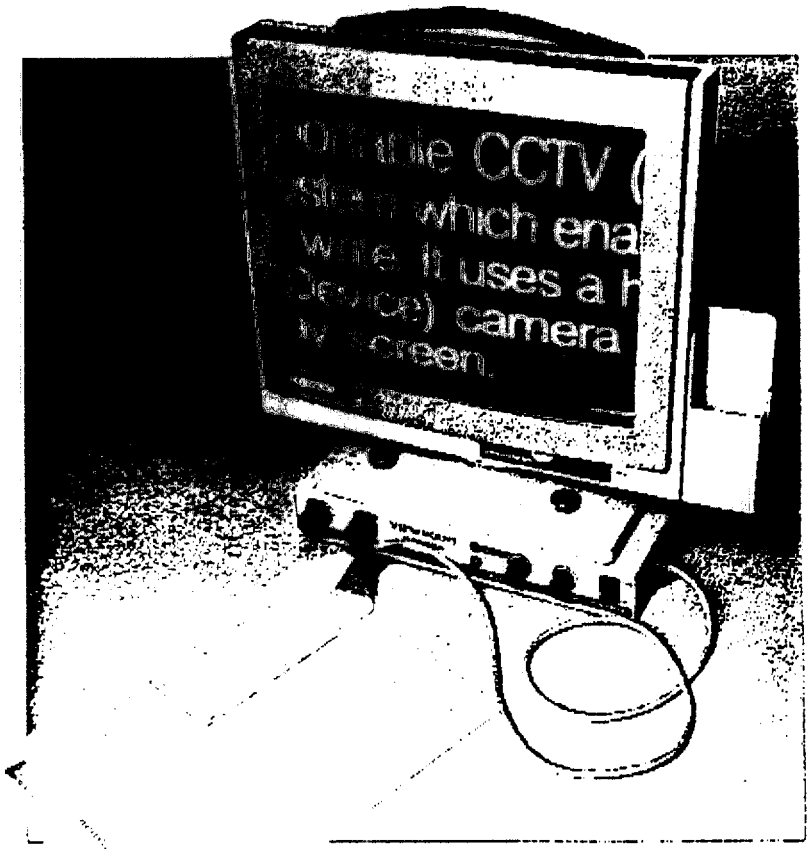
Viewpoint

Revolutionary Print Enlarging System

The *Viewpoint* delivers a large-print reading system that's completely portable. Its 14" monitor detaches easily, so you can maintain separate monitors at home, work or school and carry the camera/electronics in a small case. And the entire system weighs less than half as much as other 14"



systems. *Viewpoint's* flexible CCD camera makes reading as easy as pointing. When hand-held, the camera rests comfortably against the reading material, eliminating the need to refocus. For large print anywhere, anytime...*Viewpoint* is the answer.

HumanWare

The link between technology and people.

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Viewpoint

What is a Viewpoint?

Viewpoint is a very flexible Closed Circuit Television (CCTV) magnifying system which enables partially sighted people to read and write. It uses a hand-scanned CCD (Charged Coupled Device) camera and compact high performance display screen.

The display unit, which has a screen of 14" diagonal measurement, is similar to a computer monitor. Its pedestal contains the system electronics and operating controls. The screen may be tilted or swivelled to give the best viewing position. The screen is a high contrast, flat design with a low glare front surface.

The *Viewpoint* camera fits easily into the hand. Rollers on the underside allow the camera to be easily rolled in straight lines across a printed page. The camera incorporates its own lighting source to insure exellent contrast.

Operation of the *Viewpoint* for reading is very simple. It is just a matter of switching the system on, placing the camera on the reading material, choosing an appropriate magnification, then rolling the camera back and forth to read.

For those users who require a portable system, a second monitor can be purchased for use at home, school, or the office, and the camera and electronics can be carried in a briefcase or back pack.

Because the *Viewpoint* camera follows the contour of a page, focusing is unnecessary. Even when the magnification is changed, no adjustment to focus is required.

To maximize the readability of text, the user can select a very high contrast setting for the display. For viewing pictures and photographs, a low contrast setting, reproducing 16 levels of grey, can be chosen.

The camera automatically sets its black/white threshold to suit the reading material. For very poor quality source material, manual adjustment of the threshold is possible.

The image may be selected to be positive or negative as preferred.

Viewpoint it also a writing system. By placing the camera on the optional handwriting adapter, *Viewpoint* allows handwriting of letters, reports, or signing of documents or checks.

Optional Configurations

Additional monitors are available in white or green 14" screens.

A handwriting adapter, which comprises a compact, folding stand, and built-in lights, which illuminate the writing surface, is also available as an optional extra.

Computer access, which allows the user to access standard MS-DOS based computers, uses the *Viewpoin* screen as the output. This system allows the user to pop back and for between material being read by the *Viewpoint*'s camera and enlarged print output from the computer.

Specifications

- Camera: 1 $^5/_8$" (H) x 1 $^1/_2$" (W) x 6" (L). Weight: 1.7 lbs.
- 14" Display Unit: 13" (W) x 12" (x 15" (H). Weight: 19.3 lbs.
- Screen Colors: White, green
- Image: Variable contrast, 16 gre scales, positive or negative polarity automatic or manual threshold settings, fixed focus.
- Magnification Settings: Approx.10x 14x 20x 28x 40x

Service and Technical Support

HumanWare Inc. always stocks the service parts necessary to properly maintain all equipment that we s *HumanWare's* Toll-Free Hot-line is always available by dialing 1·800·722·3393. Our Fax number 916·652·7296.

Warranty

HumanWare products are sold wit one year warranty on parts and service. An additional service agr ment may be purchased in order t extend the warranty on *HumanW* proprietary products.

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HumanWare, Inc. 6245 King Road Loomis, CA 95650 *Phone* 916·652·7253 1·800·722·3393 *FAX* 916·652·7296

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ClearView

What is a ClearView?

ClearView is a closed curcuit television (CCTV) specifically designed for people who require large print. It is ideal for enlarging the print on newspaper, mail, personal correspondence, bills, bank statements, cans, boxes, medical containers, etc. This new CCTV has all of the advantages of a 17" monitor without taking much more room than other in-line 14" systems.

Another major advantage of the *ClearView* relates to the innovative CCD (charge coupled device) camera, which eliminates the bothersome "ghosting" and blooming found on traditional CCTV systems. It also eliminates the potential problems traditional systems have of burning the camera tube because *ClearView's* digital camera has no tube.

ClearView produces an extremely clear, crisp image with fantastic contrast. A true state of the art CCTV.

Standard Features

- Large 17" screen
- CCD camera eliminates burning, ghosting, blooming, and smearing
- Relatively small footprint
- Adjustable height between viewing object and camera
- Movable reading table with margin stops, friction brake and table-locking device
- Florescent illumination
- Magnification 5 to 47 x
- Electronic line markers and windowing for easy highlighting of text
- Positive and negative polarity choices for comfortable viewing
- All controls and adjustments easily identified and made on the front panel
- Allows for typewriter carriage display

Optional Configurations

- Monitor color: white, amber, green
- 15" Computer access screen display
- Computer access, which allows the user to access standard MS-DOS based computers, uses the *ClearView* screen as the out put. This system allows th user to pop back and forth between material being re by the *ClearView's* camera and enlarged print output from the computer.

Service and Technical Support

HumanWare Inc. always stocks the service parts nec essary to properly maintai all equipment that we sell *HumanWare's* Toll-Free Hot line is always available by dialing 1·800·722·3393. C Fax number is 916·652·72

Warranty

HumanWare products are sold with a one year warranty on parts and service An additional service agre ment may be purchased i order to extend the warra on *HumanWare* proprietar products.

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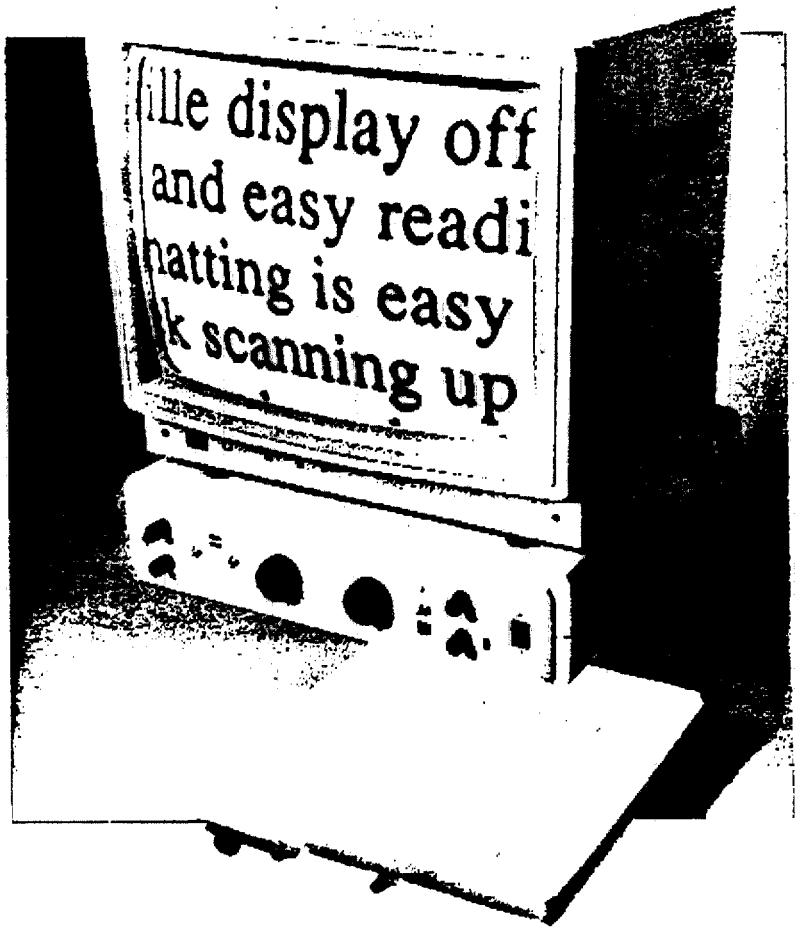
ClearView

The Big/Little CCTV

This new in-line CCTV has all of the advantages of a 17" monitor without taking any more table space than other 14" systems. While traditional systems go out of focus at the binding of thick books, the innovative CCD camera has a better depth of field than regular cameras, reducing the need to



constantly refocus the lens. Also, bothersome 'ghosting' or 'blooming' problems, inherent to traditional CCTVs, disappear with the *ClearView*. We are excited to announce that *ClearView* is setting new standards for in-line CCTVs!

HumanWare

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The link between technology and people

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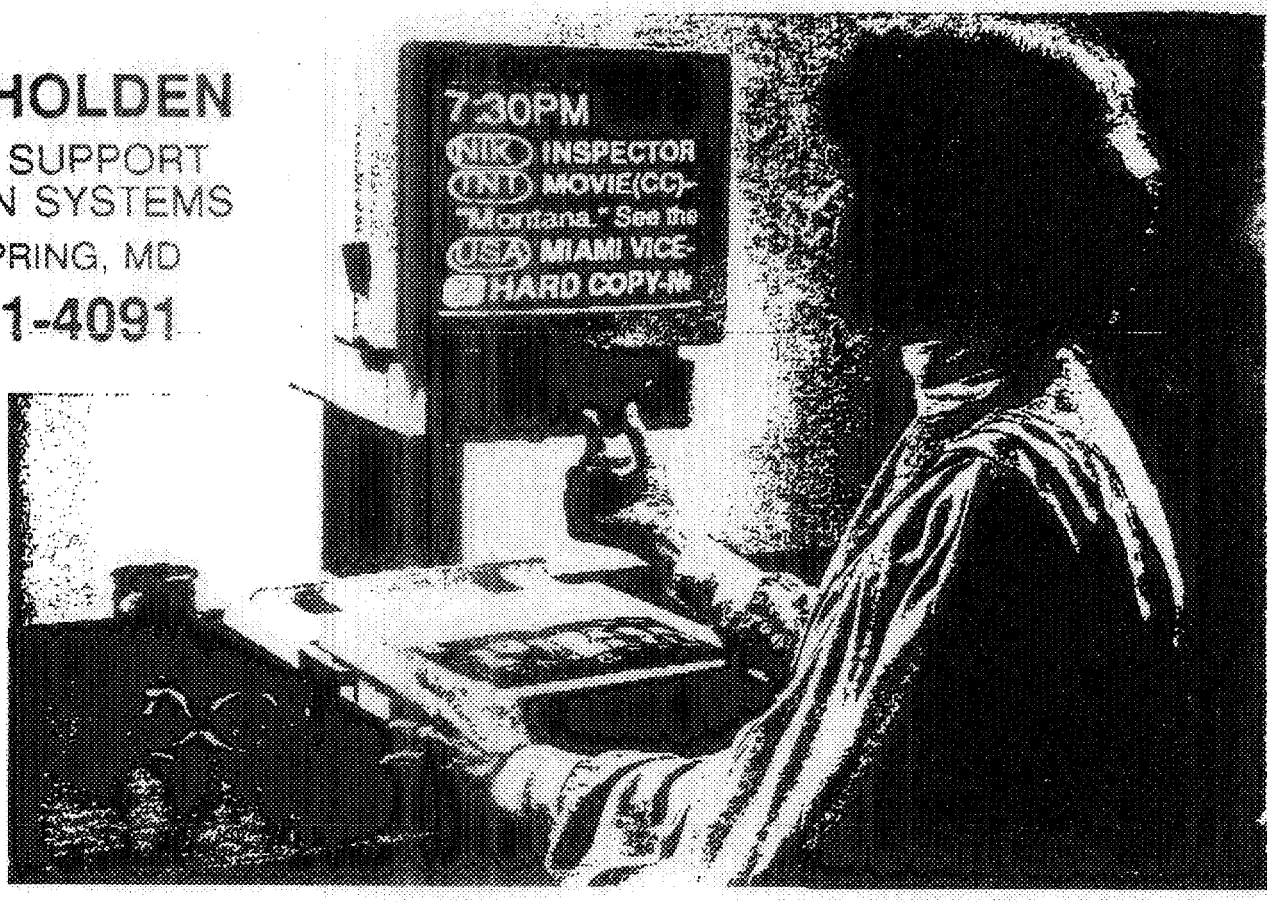
TeleSensory

CCTV Systems

SCOTT HOLDEN
SENSORY SUPPORT
LOW VISION SYSTEMS
SILVER SPRING, MD
301-681-4091



If you have macular degeneration, cataracts, diabetic retinopathy, glaucoma, detached retina or retinitis pigmentosa, you may be missing out on the world of print. Over 12 million people have some degree of visual impairment, but there is help!

TeleSensory's innovative Closed Circuit Televisions (CCTVs) magnify reading, writing, and other materials up to 60 times the original size. Nearly anyone who has some vision can benefit from TeleSensory's family of visual aids. CCTVs have helped countless people successfully undertake activities they thought were no longer possible.

TeleSensory's CCTVs were designed for professionals, students, and people at home. In the office, activities such as reading memos, writing reports, and balancing ledger accounts are accomplished with ease. In the classroom, a student can use the same textbooks, handouts, and library materials that other students use. At home, writing letters, reading newspapers, and pursuing hobbies are all possible again with a video magnifier.

Here's how it works

Place any book, magazine, or letter on the viewing table. The table glides vertically and horizontally, allowing the text to be viewed. The camera then produces the magnified image on the screen. Controls are conveniently located and easy to identify on the front panel. You control the magnification, brightness, and contrast that is most comfortable for your reading and writing needs.

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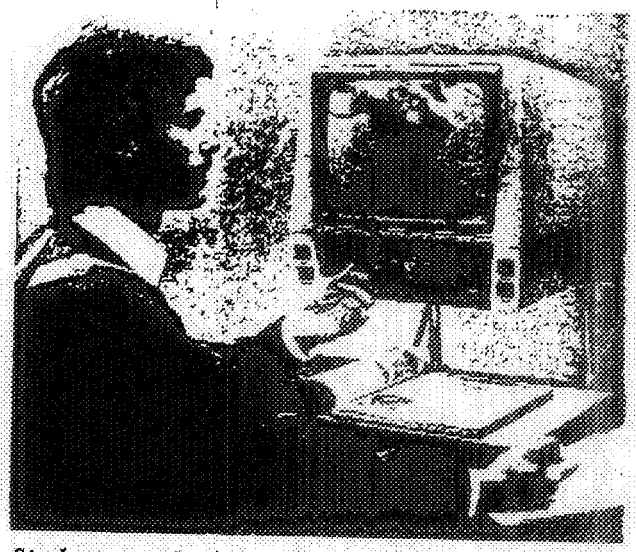
The basics

TeleSensory wants you to have the video magnifier that meets your needs. We've developed a family of CCTVs to suit individual preferences. No one in the sensory aids field can give you so many choices.



Students can look at classroom materials with the 12-inch Voyager.

Standard features in every Vantage CCD, Voyager, and Voyager XL CCD include:

Magnification
Vantage CCD's 14-inch monitor and Voyager's 12-inch monitor enlarge materials up to 45 times the original size. The Voyager XL CCD magnifies print up to 60 times on a 19-inch black and white monitor.

Brightness and contrast
For many low vision people, high contrast is as important as magnification. TeleSensory's special CCTV design includes enhanced contrast capabilities. For easy adjustments, the brightness and contrast controls are on the front panel of the Vantage CCD and Voyager and on the monitor of the Voyager XL CCD.

Image reversal
Flip a switch to select either a positive (black letters on a white background) or a negative (white letters on a black background) display. Most people prefer the negative image for reading text. The positive image is best used for viewing photographs and maps or for writing letters and checks.

Windowing
The ability to isolate lines of print by blocking out portions of the display makes some reading tasks even easier.

Tilt screen display
All TeleSensory monitors can be easily tilted for the most comfortable viewing angle with the least glare.

Reading table
Gliding vertically and horizontally, the reading table has a full range of movement and easy fingertip control.

Two camera systems
For those people who want to look at two sources of print at the same time, like a dictionary and a note pad, options allow two cameras to display their outputs simultaneously on one monitor.

Advantages of Vantage CCD

Solid State camera
Vantage CCD uses a solid state CCD camera to produce its magnified images. This is the latest in camera design.

Revolutionary lift assist
Vantage's unique design makes it easy to raise and lower the monitor. This "floating monitor" design allows easy adjustment of Vantage's viewing height for maximum comfort.

Advanced Vantage CCD
Vantage's front panel is easy to use with only six basic operating controls. All advanced features like electronic windowing, overline/underline, and split screen controls are hidden behind a snap-off panel.

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Choice of screens
With Vantage CCD, you can choose between black and white, green, or amber screens.

Maximum magnification

19-inch monitor
Voyager XL CCD also uses a solid state CCD camera, enlarging print material up to 60 times. Its 19-inch screen provides a wide field of view.

Versatility
Voyager XL CCD is the best choice for multi-user environments like schools, libraries, retirement or rehabilitation centers.

Flexibility
The Voyager XL CCD's 19-inch monitor may be positioned in-line directly over the reading material or beside the camera unit, depending upon your visual needs, space, and viewing comfort.

Unique Voyager

The 12-inch Voyager uses a minimum of desk space, yet enlarges material to a maximum of 45 times. To meet your viewing needs, Voyager is available with a variety of options including typing capability.

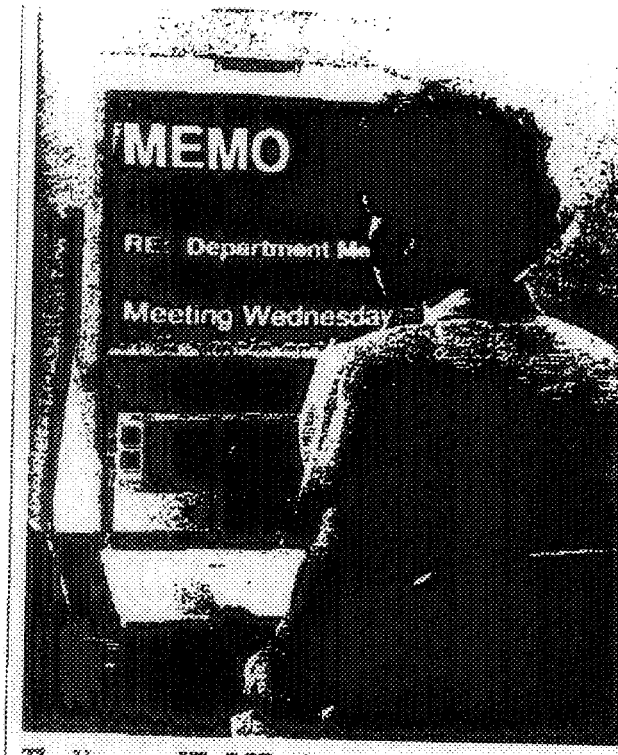
Screen choice
The Voyager 12-inch screen is offered in black and white, green, or amber.

Accessories

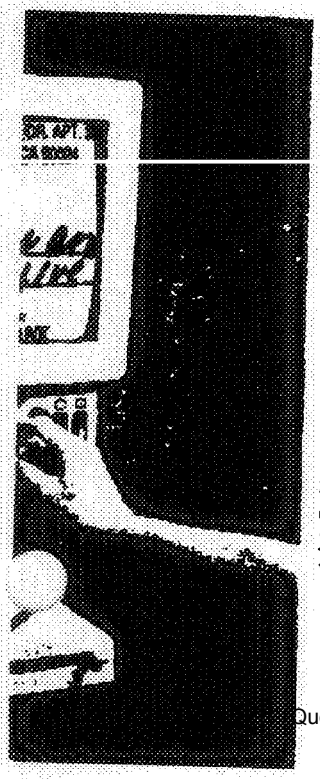
Voyager and Voyager XL CCD are available with a variety of accessories. For large source materials such as blueprints, oversized books, or computer print-outs, extended legs can be ordered.

Auto focus
At the touch of a button, Voyager and Voyager XL CCD's exclusive Auto Focus option brings viewing material into sharp, clear focus in less than three seconds. Auto Focus is particularly valuable for individuals who have difficulty using their hands because of arthritis, Parkinson's disease, cerebral palsy, or multiple sclerosis.

Automated table
This unique option for the Voyager and Voyager XL CCD allows hands-free viewing of the source material. Horizontal and vertical table movement and speed can be controlled by foot pedal or joystick, or it can be set on automatic.



The Voyager XL CCD 19-inch monitor may be positioned in-line directly over the reading material.



Seeing what you write is easy with the 14-inch Vantage CCD.

Split screen systems

Vantage CCD, Voyager, and Voyager XL CCD offer high-performance split screen viewing with TeleSensory's large print computer access products or a second camera. Business people and students find the split screen display invaluable because they can view two sources at the same time on the same monitor.

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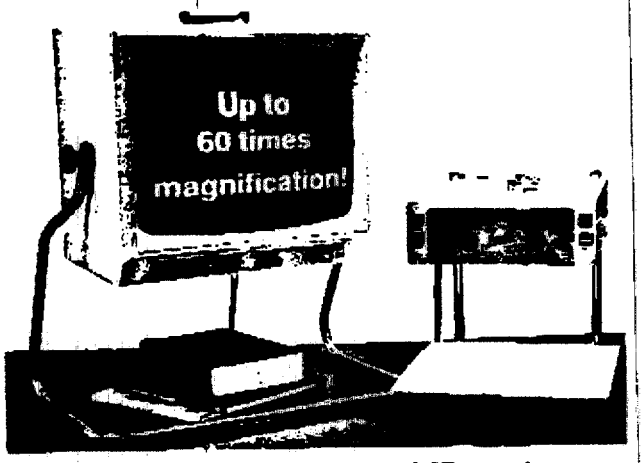
TeleSensory

You choose

We welcome the opportunity to show you how our equipment can be the solution to a variety of your visual tasks. We have a network of experienced local sales representatives who provide free, no-obligation demonstrations.

For information on the representative in your area, call TeleSensory toll free (within the U.S.) at 1-800-227-8418.



The flexible 19-inch Voyager XL CCD monitor can also be placed next to the camera unit.

Customer support

TeleSensory provides unparalleled customer support. We have local sales representatives, authorized service centers, a toll-free telephone number for customer service and a technical support hot line available to answer your questions as they happen.

When you purchase a TeleSensory product, you have the commitment of over 20 years of the company's experience, support, and reliability.

Product warranty

TeleSensory products are durable and designed to last. Video magnifiers carry a minimum one-year limited service and parts warranty. Extended warranty plans are available.

Product specifications

Separate product specification sheets are available for Vantage CCD, Voyager, Voyager XL CCD, and computer access products. For technical product specification sheets, call TeleSensory toll free (within the U.S.) at 1-800-227-8418.

About TeleSensory

TeleSensory has been in the sensory aids business over 20 years. Today, we are the leading worldwide manufacturer of these aids. Corporate headquarters and manufacturing are in Mountain View, California with additional manufacturing plants in southern California and Ireland. Our company has a long history of providing solutions that work for visually impaired individuals. TeleSensory products help thousands of people access the world of print and electronic information.

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1-800-227-8418

Your Representative:

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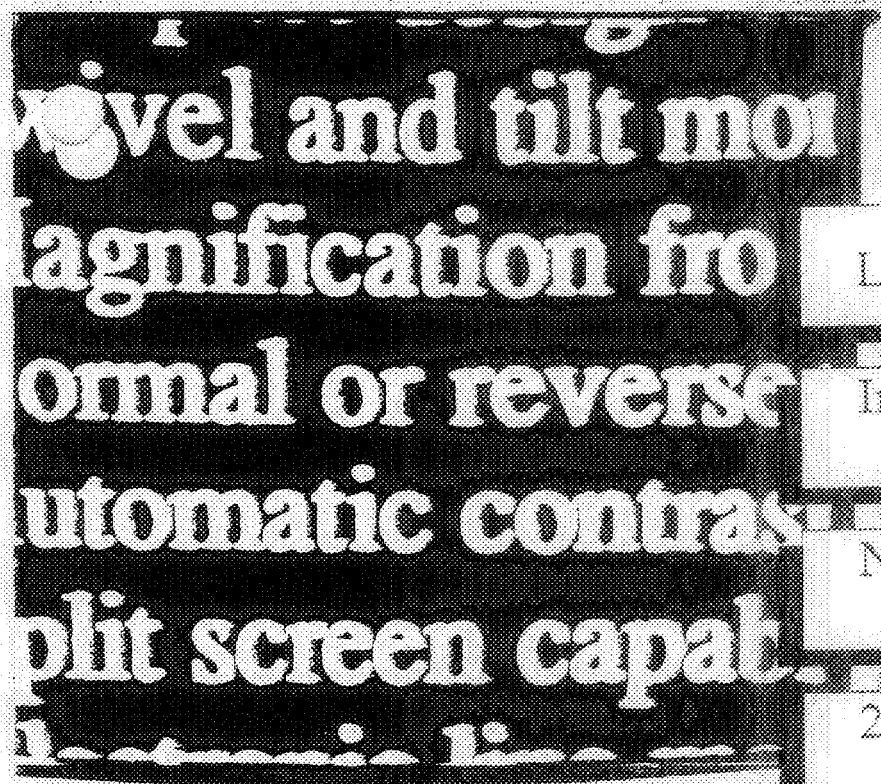
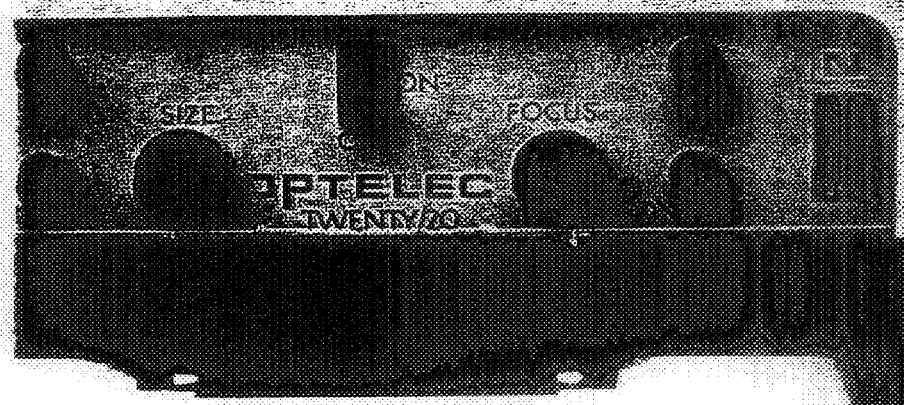


Low Vision Reading Systems.

Innovative Technology for the Visually Impaired.

National & International Support System.

2 Year Warranty with Guaranteed Response Time.



"Ask Anyone Who Owns One"

OPTELEC U.S.A., INC

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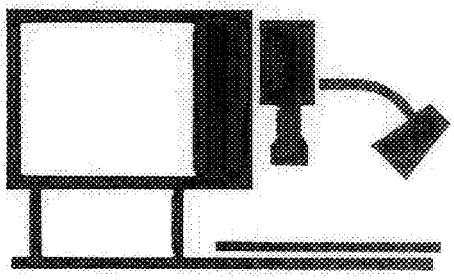
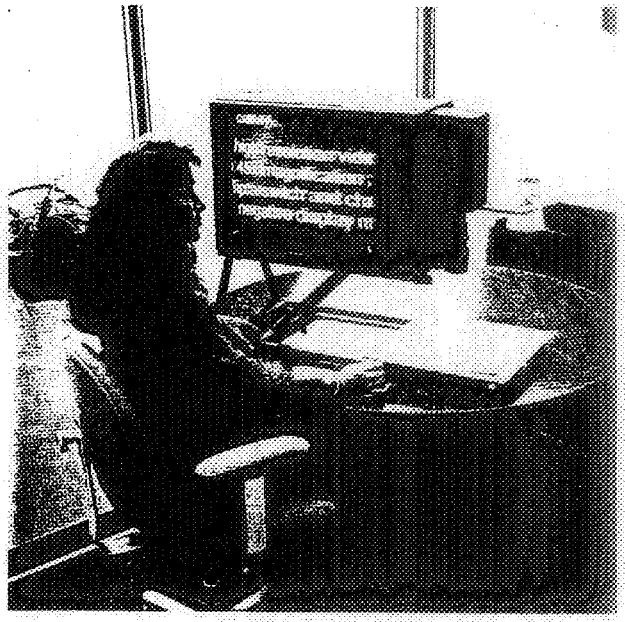
FDR23

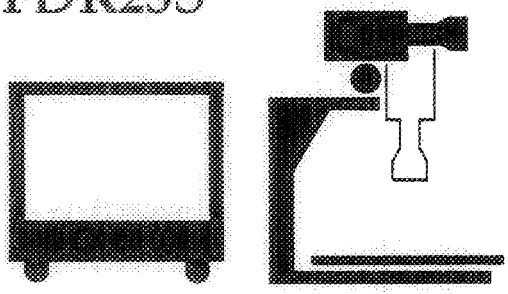
- 19" High Resolution Monitor
- Built-In Camera
- Zoom Lens - 8X to 45X



The FDR23 is our basic reading machine, incorporating a 19" high resolution monitor with a built-in-camera, integral lamp and low friction reading table. A zoom lens provides magnification from 8X to 45X and the image may be displayed in either normal (black on white) or reverse (white on black) video mode.

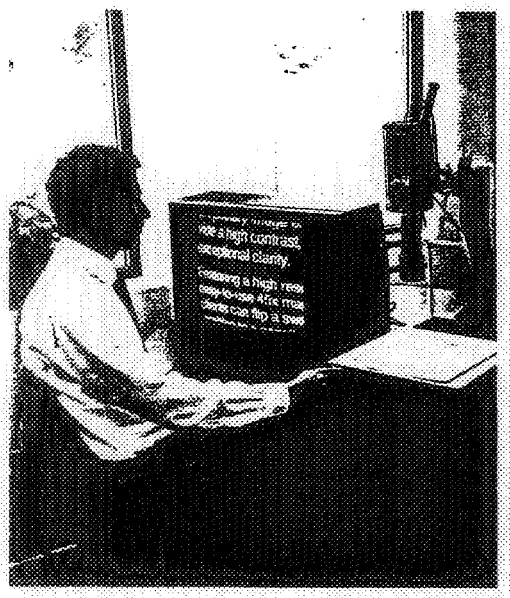


FDR23S



The FDR23S combines a 19" high resolution monitor with an independent camera and X-Y table. The swivel head camera mounting is ideally suited for classroom use. Our most versatile system, the FDR23S is used, not only for reading and writing, but for any application where it is neccessary to put large articles under the camera.

- 19" High Resolution Monitor
- Independent Swivel Camera
- Highest Quality, Lowest Price



Innovative Technology for the Visually Impaired

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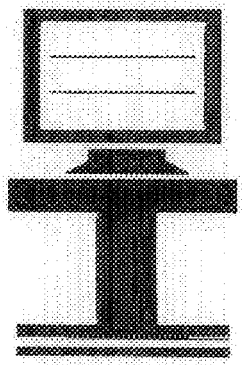
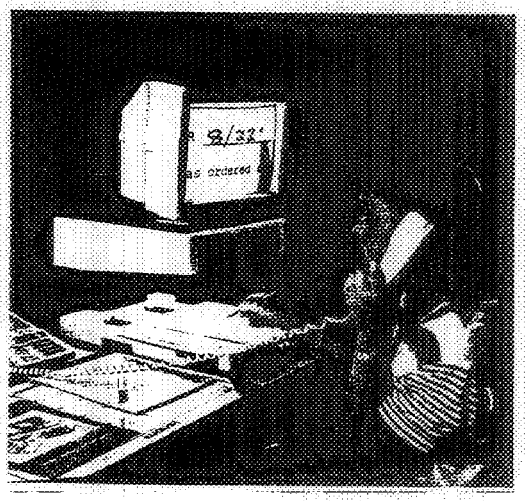
20/20

The First 14" System with CCD Technology!

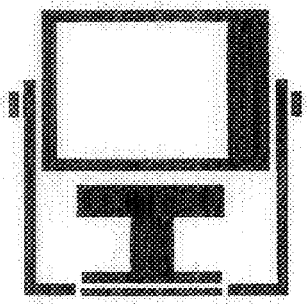


- Uses Only 14" of Desk Space
- 3X to 60X Magnification
- Ergonomically Designed
  Monitor with tilt swivel head.

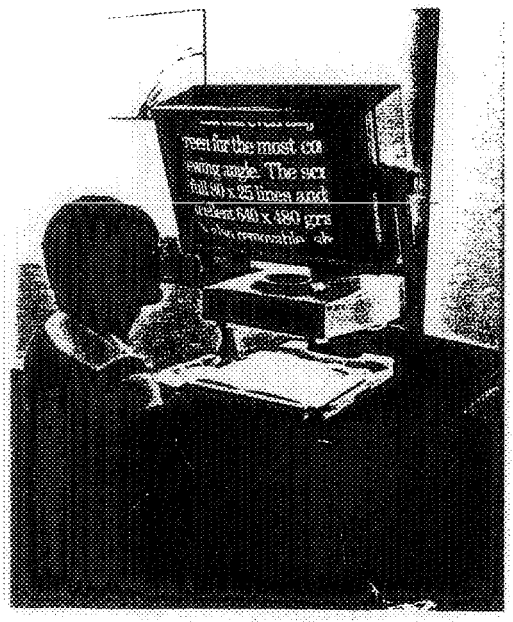
The 20/20 is ideal where space is at a premium, such as the classroom or office environment. This self contained, compact unit requires only 14 inches of table space. The 20/20 utilizes a state of the art CCD (CHIP) camera; allowing ghost free images as well as no vidicon burn...ever. The CCD camera provides a depth of field that is so superior to standard vidicon cameras that it allows the end user to read into the fold of a book without re-focusing. Standard features also include electronic line markers and split screen capability. The 20/20 is the only system available with a tilt and swivel monitor. The swivel monitor has been heralded by professionals and end users alike as a *breakthrough* in ergonomic design. With a magnification range of 3X to 60X, the 20/20 is the logical choice for the compact system user.



20/20+



The 20/20+ combines all the benefits of the CCD solid state camera with the large viewing area of a 19" monitor. The monitor may positioned above or beside the reading table, and may be tilted for ease of viewing. The 20/20+ is priced well below other 19" systems (even those utilizing older style vidicon cameras). Couple the 20/20+ with your personal computer and LPDOS software, and you have a powerful large print workstation at a fraction of the cost of comparable systems.



- 19" High Resolution Monitor
- Split Screen/In-Line Use
- Computer Access
  At a fraction of the cost of comparable systems.

OPTELEC U.S.A., INC.

Optical and Electronic Applications Specialists

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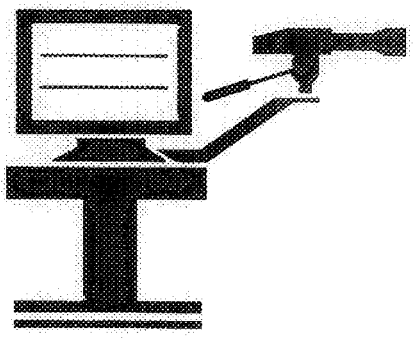
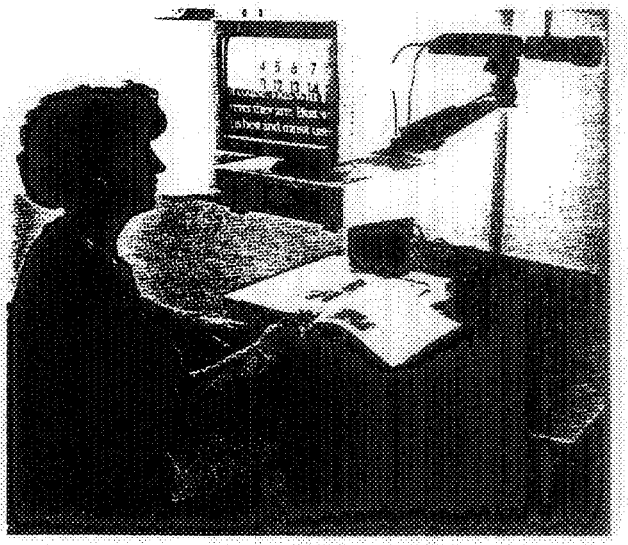
Remote Camera Option

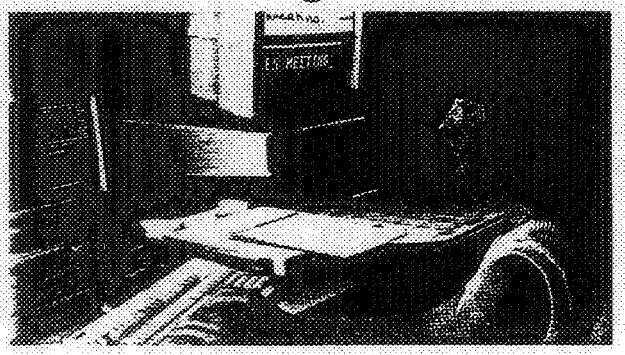
- Two Cameras / Pans and Tilts
- Blackboard Monitoring
- Educators *First* Choice !
  Recommended by school systems world wide.



Optelecs' remote camera and lens assembly, with moveable arm (pictured here on our 20/20) allows the user to view distant objects such as a blackboard, while simultaneously reading documents on the reading table. Additional uses include scanning a room or outdoor viewing. The camera and arm assembly can also be used on the 20/20+.



LPDOS Large Print



Our LPDOS is the standard of the industry. It is a full large print adaptor on one disk. LPDOS enables you to run your IBM PC/PS 2 (or compatible machine) with enlarged text and graphics. It is compatible with CGA, EGA and VGA systems and provides faithfull color reproduction. A variety of 25 different text sizes are available, providing letters up to 3" high on our 19" monitor. LPDOS' unique features enable the program to focus the users attention on the important areas of the screen. The system is highly portable and may be installed on up to three computers at one time.

Utilizing state of the art closed circuit television technology, our series of low vision reading systems have been designed to meet the many varied needs of the visually impaired, from simple reading and writing, to large print computer access and classroom applications.

The FDR series of 19" machines is ideally suited to home use where the large screen area provides clear highly magnified images of exceptional clarity.

For office or classroom use, the compact 20/20 is the obvious choice. This versatile machine will interface directly with a computer and is easily transported. Coupling CCD technology, the 20/20 is the latest advance in low vision.

In addition to our reading systems, we offer a range of accessories to meet the requirements of special users.

OPTELEC U.S.A., INC.

Optical and Electronic Applications Specialists

4 Lyberty Way, Westford, MA 01886
(508) 392-0707 • (800) 828-1056
FAX (508) 692-6073

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OPTELEC US INC.
PRICE LIST

MODEL	DESCRIPTION
20/20	COMPACT DESIGN REQUIRES ONLY 14" OF DESK SPACE. SWIVEL AND TILT MONITOR FOR EASE OF VIEWING, NORMAL OR REVERSE VIDEO DISPLAY MODE. C.C.D. CAMERA OFFERS CLEAR IMAGES, NO BURN IN, MINIMUM FOCUSING REQUIRED. SECOND CAMERA OPTION AVAILABLE FOR DISTANCE VIEWING.
20/20 +	19" CCTV READING AID PROVIDING THE MANY ADVANTAGES OF THE POPULAR 20/20 SYSTEM; C.C.D CAMERA FOR GREATER DEPTH OF FOCUS, TILT MONITOR, ADJUSTABLE STAND FOR VARIABLE HEIGHTS. THE READING TABLE MAY BE USED BOTH IN LINE, REQUIRING 25" OF TABLE SPACE, OR SIDE BY SIDE.
FDR 23	CCTV READING AID COMPRISING HIGH RESOLUTION 19" MONITOR AND CAMERA MOUNTED ON STAND. COMPLETE WITH READING TABLE AND LIGHT SOURCE. REQUIRES ONLY 32" OF TABLE SPACE.
FDR 23S	19" HIGH RESOLUTION MONITOR, REMOTE CAMERA ON SEPARATE STAND WITH READING TABLE AND LIGHT SOURCE. CAMERA IS MOUNTED ON SWIVEL HEAD TO PERMIT BLACKBOARD VIEWING OR USE WITH PORTABLE TYPEWRITER.
FDR23C	AS FDR23 WITH SPLIT SCREEN FACILITY CAMERA FOR USE WITH A COMPUTER (IN CONJUNCTION WITH LPDOS LARGE PRINT SOFTWARE) OR SECOND CAMERA. USING THIS SYSTEM, TWO IMAGES MAY BE VIEWED SIMULTANEOUSLY ON ONE SCREEN. THE SCREEN MAY BE SPLIT HORIZONTALLY OR VERTICALLY.
FDR 24	19" HIGH RESOLUTION MONITOR. TWO SEPARATE CCTV CAMERAS, READ AND WRITE COMBINATION WITH VARIABLE SCREEN SPLIT IN VERTICAL OR HORIZONTAL MODE, SWIVEL HEAD STANDARD IN SECOND CAMERA TO ALLOW MONITORING BLACKBOARD AND WRITING SIMULTANEOUSLY.

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