Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 1999

Mr. Douglas R. Morr
Chief Engineer
Bertec Corp.
6185 Huntley Road, Suite B
Worthington, Ohio 43229

Re: K991642
Trade Name: EyeTrak™: ENG System
Regulatory Class: II
Product Code: GWN
Dated: May 12, 1999
Received: May 13, 1999

Dear Mr. Morr:

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 requirement, 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.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

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) 594-4595. 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" (21 CFR 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/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

XIV. Statement of Indications for Use:

Statement of Indications for Use

510(k) Number (if known): K991642

Device Name: EyeTrak™ : ENG System

Indications for Use:

The EyeTrak™ is used to non-invasively measure the vertical and horizontal eye movements during a variety of tests performed during electronystagmography (ENG) testing. This testing includes, but is not limited to: saccadic test, smooth pursuit, optokinetic nystagmus, and kinetic vestibular tests. It provides a trained clinician with data and graphs representing a patient's ability to perform certain eye movements voluntarily, as well as the patient's involuntary eye movements due to head movement, eye movement and/or body movement as is normally performed in vestibular diagnostic testing such as in Hallpike positional tests. It is used, then, to aide in the detection and diagnosis of vestibular disorders.

The EyeTrak™ does not incorporate a camera for vertical and horizontal eye movement measurement, therefore it is not as cumbersome as other similar devices, and does not have focal length and resolution limitations based on the camera and camera lens used. The EyeTrak™ instead measures horizontal and vertical eye movement non-invasively using infra-red sensors and an IR oculography method with background light suppression. This allows for direct transmission of sensor signals to a processing unit, which in turn provides the signals to the software for processing, saving, and presentation. A camera and monitor can be used to monitor torsional eye movements, and a sensor can be added to measure head movement.

The results are used to provide documentation of a patient's performance on specific tests.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991642

PREMARKET NOTIFICATION

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

K991642/A1

BERTEC CORPORATION

1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

May 24, 1999

510(k) number: K991642

Richard Weiblinger
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

FAX: 301-827-4350

JUN 1 2 11 PM '99
RECEIVED
FDA/CDRH/ODE/DMC

Dear Mr. Weiblinger:

The comparison chart is provided per your request to further demonstrate the similarities and differences between Bertec Corporation's device submitted for pre-market approval (K991642), and substantially equivalent devices.

Of the many substantially equivalent devices, the following have been selected for comparision: K972631, K972243, and K952111.

This chart is a summary of those details used to determine substantial equivalence. It is most important to note:

- the **INTENDED USE**, for all these devices is **IDENTICAL**,
- all these devices use of some type of lightweight tight fitting eye goggles (or mask)
- all device have a non-conductive plastic/foam/or rubber substance contacting the patient, and
- the only major difference between the device in K991642 and all other substantially equivalent devices is the use of Infrared Oculography for eye motion measurement instead of Infrared video cameras.

Substantial Equivalence Comparison Chart (see next page):

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

Substantial Equivalence Comparison Chart

Item of Comparison	K991642	K972631	K972243	K925111
Infrared video camera(s) used for measurement	NO	NO	YES	YES
Infrared Oculography used for measurement	YES	NO	NO	NO
Infrared video camera(s) used for observation of movement	YES	YES	YES	YES
Non-invasive	YES	YES	YES	YES
Used to aide in detection and diagnosis of vestibular disorders (intended use)	YES	YES	YES	YES
Lightweight tight fitting eye goggles used	YES	YES	YES	YES
Non-conductive plastic/foam/or rubber contacting patient	YES	YES	YES	YES
Software provided for data collection and analysis only	YES	NO	YES	YES
Personal computer used	YES	NO	YES	YES
Computer monitor used	YES	NO	YES	YES

If any further explanation is required, please contact me.

Sincerely,

Douglas R. Morr
Chief Engineer
Bertec Corporation
614-421-2803 ext. 221
morr@bertec.com

2

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 1999

Mr. Douglas R. Morr
Chief Engineer
Bertec Corp.
6185 Huntley Road, Suite B
Worthington, Ohio 43229

Re: K991642
Trade Name: EyeTrak™: ENG System
Regulatory Class: II
Product Code: GWN
Dated: May 12, 1999
Received: May 13, 1999

Dear Mr. Morr:

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 requirement, 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.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

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) 594-4595. 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" (21 CFR 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/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

XIV. Statement of Indications for Use:

Statement of Indications for Use

510(k) Number (if known): K991642

Device Name: EyeTrak™ : ENG System

Indications for Use:

The EyeTrak™ is used to non-invasively measure the vertical and horizontal eye movements during a variety of tests performed during electronystagmography (ENG) testing. This testing includes, but is not limited to: saccadic test, smooth pursuit, optokinetic nystagmus, and kinetic vestibular tests. It provides a trained clinician with data and graphs representing a patient's ability to perform certain eye movements voluntarily, as well as the patient's involuntary eye movements due to head movement, eye movement and/or body movement as is normally performed in vestibular diagnostic testing such as in Hallpike positional tests. It is used, then, to aide in the detection and diagnosis of vestibular disorders.

The EyeTrak™ does not incorporate a camera for vertical and horizontal eye movement measurement, therefore it is not as cumbersome as other similar devices, and does not have focal length and resolution limitations based on the camera and camera lens used. The EyeTrak™ instead measures horizontal and vertical eye movement non-invasively using infra-red sensors and an IR oculography method with background light suppression. This allows for direct transmission of sensor signals to a processing unit, which in turn provides the signals to the software for processing, saving, and presentation. A camera and monitor can be used to monitor torsional eye movements, and a sensor can be added to measure head movement.

The results are used to provide documentation of a patient's performance on specific tests.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991642

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food And Drug Administration

Memorandu

From: Reviewer(s) - Name(s) RICHARD WEINGINGER

Subject: 510(k) Number K991642

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review_____.
- ☑ Is substantially equivalent to marketed devices.
- ☐ 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	☐ 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 II GWN

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

Review: Neil R. P. Ogden (Branch Chief) GSDB (Branch Code) 7/29/99 (Date)

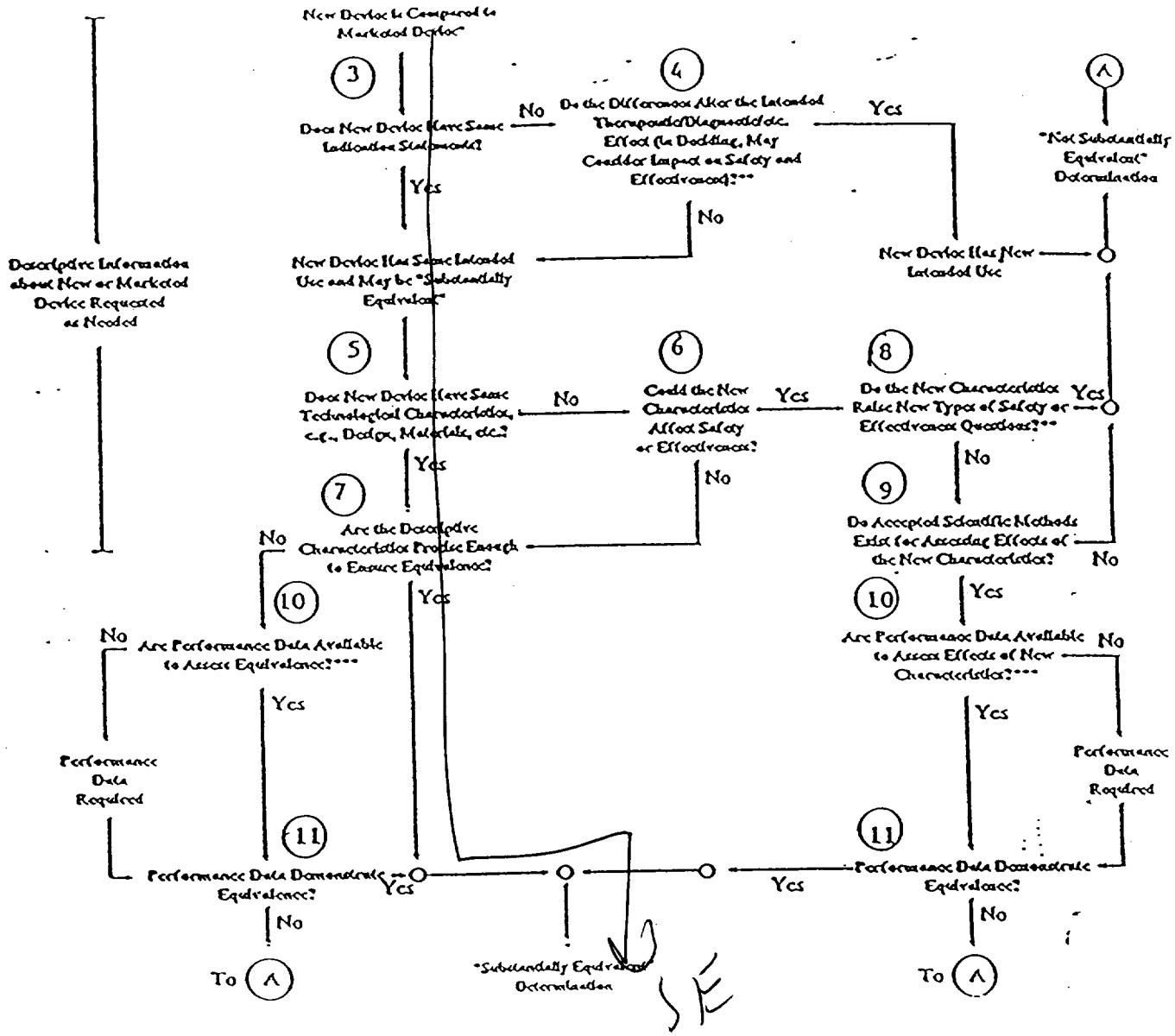
Final Review: (Division Director) 8/3/99 (Date)

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

Revised:6/2//98

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

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.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: R. Weiblinger, Biologist
ODE/DGRD/GSDB
Subject: K991642
EyeTrak™ Electronystagmograph
To: Record

Review of K991642
Original

Submission date: 5/12/99
Received date: 5/13/99
Review date: 7/28/99

Sponsor: *Bertec, Corp.*
ATTN: Doug Morr
1483 Delashmut Ave.
Columbus, OH 43212
614-421-2803 or 614-430-5421 FAX: 614-421-2811
Device: *EyeTrak™ Electronystagmograph*
Category: *Class II*
Product code: *GWN (21 CFR 882.1460 Nystagmograph)*

Introduction: The application is for the *EyeTrak™ Electronystagmograph.* The device is intended to be used as reusable product to non-invasively measure the vertical and horizontal eye movements.

Predicate Devices: The designated predicate devices are as described in the following table:

510 (k) Number	Manufacturer	Device
K972243	Sensomotoric Instruments GMBH	2D VOG Video Oculography
K925111	Eye Dynamics, Inc.	Infrared Video Electronystagmograph
K972631	ICS Medical Corp.	VEMR Video Eye Movement recorder

Proposed Indication: The subject device, *EyeTrak™ Electronystagmograph* is indicated for use to non-invasively measure the vertical and horizontal eye movements during a variety of tests performed during electronystagmography testing. The **intended use for the device is a SE intended use**.

Labeling: The firm has provided a draft copy of the subject device **labeling** which includes adequate information on the device, and instructions for use. The device is a reusable product.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Device Description: The subject device is the *EyeTrak™ Electronystagmograph*, consisting of a frames, sensors, sensors cables, lens holder, an occluder, power supply, computer, and associated data acquisition software. The firm has provided a **comparison** of characteristics demonstrating SE features and technical specifications as compared to those of the predicate device.

Device Characteristic	*EyeTrak™ Electronystagmograph* **K991642**	**K972631**	**K972243**	**K925111**
Infrared Video camera used for measurement	No	No	Yes	Yes
Infrared oculography used for measurement	Yes	No	No	No
Used to aid in detection and diagnosis of vestibular disorders	Yes	Yes	Yes	Yes
Eye goggles used	Yes	Yes	Yes	Yes
Software provided for data collection and analysis only	Yes	No	Yes	Yes

The primary **difference** between the new device and the predicate device is the use of infrared oculography for eye motion measurement instead of infrared video cameras.

Software: The firm has provided a certificate of Y2K compliance and readiness (see letter dated 7/26/99).

Safety and Effectiveness Information: The firm has provided a 510(k) "statement", and a truthful and accurate statement.

Recommended Regulatory Action: This application is now recommended to be found SE.

Richard Paul Weiblinger

I concur with SE.

7/29/99

Center for Devices and Radiological Health CDRH

cc: RWeiblinger ODE/DGRD/GSDB
Gen. Surge Div. File

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name: K991642

Submitter (Company):

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 4,5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	NA		YES		NO		✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	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:							
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*			* If no - STOP not a special	

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:							
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** **Reviewer:** _____

Date: _____ **Concurrence by Review Branch:** _____

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

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

K 991642

Reviewer: _____

Division/Branch: _____

Device Name: _____

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

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is 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 Data
11. Data Demonstrate Equivalence?			Final Decision:

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.

10

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
6185 Huntley Rd., Suite B, Worthington, OH 43229
Phone: 614-430-5421 Fax: 614-430-5425
sales@bertec.com www.bertec.com

FAX MESSAGE

TO: Richard Weiblinger
FAX NO: 301-827-4350
FROM: Douglas R. Morr (Bertec Corporation)
DATE: July 26, 1999
SUBJ.: Requested Y2K Statement

Mr. Weiblinger:

Please find one attached page per your request regarding Bertec's Y2K statement.

Please note that specific to 510k # K991642, Bertec's EyeTrak™ and SoftTrak™ products are Year 2000 compliant and ready.

Please notify me if you need any further information.

Sincerely,

Douglas R. Morr
Chief Engineer
Bertec Corporation

11

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
6185 Huntley Rd., Suite B, Worthington, OH 43229
Phone: 614-430-5421 Fax: 614-430-5425
sales@bertec.com www.bertec.com

Certificate of Y2K Compliance and Readiness

BERTEC Corporation, as a manufacturer and a supplier/distributor, CERTIFIES that all products, models, versions, and releases are Year 2000 COMPLIANT and READY. Therefore, no BERTEC products, models, versions, or releases have functionality failures which are related to General Integrity or Date Integrity issues.

The above can be validated by executing a date rollover.

The above has been certified to the United State's Food and Drug Administration (FDA). As of September 22, 1998, BERTEC certifies that all devices (hardware and software) are in compliance with the requirements of the Center for Devices and Radiological Health. This information can be found/varified on the FDA's web-site *http://www.fda.gov/scripts/cdrh/year2000/y2k_search.cfm* by searching the database for BERTEC Corporation. In full compliance with the FDA, BERTEC has a similiar certification on its website *www.bertec.com/products/products.htm*.

Problems and extra costs will occur only if the operating system, such as Microsoft Windows (refer to Micorsoft's web-site *www.microsoft.com/technet/topics/year2k* for more information), is not Y2K Compliant or Ready. Thus, BERTEC customers must upgrade their operating system(s) to the Y2K compliant/ready version.

For questions or comments, please contact BERTEC Corporation's customer support at 614-430-5421 ext. 224.

CERTIFIED this 26th *day of* July, 1999

Douglas R. Morr
Chief Engineer
Bertec Corporation

12

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2016 K991642/ A2

To: Food and Drug Administration
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

From: Bertec Corporation; 510k # K991642; Reg # 9033911

Re: NEW ADDRESS.

Date: Monday, June 28, 1999

This letter is to advise you that as of Wednesday, June 30th, 1999 all correspondances to Bertec Corp should be sent to our **new address** of:

BERTEC Corporation
Worthington Commerce Center
6185 Huntley Road
Suite B
Worthington, Ohio 43229
Phone: 614-430-5421
FAX: 614-430-5425
Website: www.bertec.com

JUL 6 3 35 PM '99
FDA/CDRH/OCE/DID

OLD ADDRESS:
1483 Dealshmut Ave
Columbus, Ohio 43212
614-421-2803
614-421-2811 Fax
www.bertec.com

Thank You,

Greg Hanweck

13

SK 65

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

May 24, 1999

510(k) number: K991642

Richard Weiblinger
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

FAX: 301-827-4350

Dear Mr. Weiblinger:

The comparison chart is provided per your request to further demonstrate the similarities and differences between Bertec Corporation's device submitted for pre-market approval (K991642), and substantially equivalent devices.

Of the many substantially equivalent devices, the following have been selected for comparision: K972631, K972243, and K952111.

This chart is a summary of those details used to determine substantial equivalence. It is most important to note:

- the **INTENDED USE**, for all these devices is **IDENTICAL**,
- all these devices use of some type of lightweight tight fitting eye goggles (or mask)
- all device have a non-conductive plastic/foam/or rubber substance contacting the patient, and
- the only major difference between the device in K991642 and all other substantially equivalent devices is the use of Infrared Oculography for eye motion measurement instead of Infrared video cameras.

Substantial Equivalence Comparison Chart (see next page):

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

Substantial Equivalence Comparison Chart

Item of Comparison	K991642	K972631	K972243	K925111
Infrared video camera(s) used for measurement	NO	NO	YES	YES
Infrared Oculography used for measurement	YES	NO	NO	NO
Infrared video camera(s) used for observation of movement	YES	YES	YES	YES
Non-invasive	YES	YES	YES	YES
Used to aide in detection and diagnosis of vestibular disorders (intended use)	YES	YES	YES	YES
Lightweight tight fitting eye goggles used	YES	YES	YES	YES
Non-conductive plastic/foam/or rubber contacting patient	YES	YES	YES	YES
Software provided for data collection and analysis only	YES	NO	YES	YES
Personal computer used	YES	NO	YES	YES
Computer monitor used	YES	NO	YES	YES

If any further explanation is required, please contact me.

Sincerely,

Douglas R. Morr
Chief Engineer
Bertec Corporation
614-421-2803 ext. 221
morr@bertec.com

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

FAX MESSAGE

TO: Richard Weiblinger
FAX NO: 301-827-4350
FROM: Douglas R. Morr (Bertec Corporation)
DATE: May 24, 1999
SUBJ.: Requested Comparison Chart

Mr. Weiblinger:

Please find two attached pages per your request.

Hard copy mailed to your attention.

Sincerely,

Douglas R. Morr
Chief Engineer
Bertec Corporation

16

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

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

May 13, 1999

BERTEC CORP.
1483 DELASHMUT AVE.
COLUMBUS, OH 43212
ATTN: DOUG MORR

510(k) Number: K991642
Received: 13-MAY-1999
Product: EYE TRAK TM, COMPUTERIZED ELECTRONYSTAGMOGRAPH (ENG), MODEL

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

17

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

CDRH SUBMISSION COVER SHEET

Date of Submission: Wednesday 12 May 1999

FDA Document Number: K991642

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modular submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☒ Original submission: ☐ Traditional ☐ Special ☒ Abbreviated ☐ Additional information: ☐ Traditional ☐ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

Section B — Applicant or Sponsor

Company / Institution name: Bertec Corporation	Establishment registration number: 9033911
Division name (if applicable):	Phone number (include area code): (614) 421-2803
Street address: 1483 Delashmut Ave	FAX number (include area code): (614) 421-2811

City	State / Province	Country
Columbus	Ohio	USA

Contact name: Doug Morr

Contact title: Chief Engineer	Contact e-mail address: morr@bertec.com

Section C — Submission correspondent (if different from above)

Company / Institution name: N/A	Establishment registration number:
Division name (if applicable):	Phone number (include area code): ( )
Street address:	FAX number (include area code): ( )

City	State / Province	Country

Contact name:

Contact title:	Contact e-mail address:

FDA/CDRH/ODE/DMC

MAY 13 9 54 AM '99

Version 2.0

FINAL DRAFT — May 8, 1998

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Section D1 — Reason for Submission — PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Process change
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Response to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other (specify below)
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):

N/A

Section D2 — Reason for Submission — IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ 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
- ☐ Other reason (specify):

N/A

Section D3 — Reason for Submission — 510(k)

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

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Section E — Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 GWN	2 GWN	3 GWN	4 GWN
5 GWN	6 GWN	7	8

Summary of, or statement concerning, safety and effectiveness data:
- ☐ 510(k) summary attached
- ☒ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K964646	1 Video Eye Trakker	1 Micro Medical Technologies, Inc.
2 982103	2 Ulmer (VNG) Video Nystagmograph	2 Synapsys Inc.
3 972243	3 2D VOG-Video-Oculography	3 Sensomotoric Instruments GMBH
4 972631	4 ICS Medical VEMR Video Eye Movement Recorder	4 ICS Medical Corp
5 926312	5 Infrared Eye Movement Monitor	5 Microguide Inc.
6 925111	6 House Infrared/video Electronystagmograph system	6 Eye Dynamics, Inc.

Section F — Product Information — Applicable to All Applications

Common or usual name or classification name:

Classification Name: Nystagmograph

Trade or proprietary or model name	Model number
1 Eye Trak TM, Computerized Electronystagmograph (ENG)	1 ETV-XXXX
2	2
3	3
4	4
5	5

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

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

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials N/A

Section G — Product Classification — Applicable to All Applications

Product code: GWN

C.F.R. Section: 882.1460

Classification panel: Neurology

Device class:
- ☐ Class I
- ☒ Class II
- ☐ Class III
- ☐ Unclassified

Indications (from labeling): The EyeTrak™ is used to non-invasively measure the vertical and horizontal eye movements during a variety of tests performed during electronystagmograph (ENG) testing.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 9033911	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: Bertec Corporation		Establishment registration number: 9033911	
Division name (if applicable):		Phone number (include area code): (614) 421-2803	
Street address: 1483 Delashmut Ave		FAX number (include area code): (614) 421-2811	
City: Columbus	State / Province: Ohio		Country: USA
Contact name: Doug Morr			
Contact title: Chief Engineer		Contact e-mail address: morr@bertec.com	

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: N/A		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:		Country:
Contact name:			
Contact title:		Contact e-mail address:	

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: N/A		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:		Country:
Contact name:			
Contact title:		Contact e-mail address:	

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION

1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

PLEASE REFER TO COVER SHEET FOR GENERAL INFORMATION

510(k) Notification:
Premarket Notification [510(k)] Submission

Date of Application:	May 12, 1999
Applicant's Name and Address:	Bertec Corporation 1483 Delashmut Ave. Columbus, OH 43212
Contact Person:	Douglas R. Morr Chief Engineer Bertec Corporation
Telephone and FAX:	614-421-2803 ext. 221 614-421-2811
Email and Web-Site:	service@bertec.com www.bertec.com
Signature of Applicant:	
Address of Manufacturing site:	Bertec Corporation 1483 Delashmut Ave. Columbus, OH 43212

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION

1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

Table of Contents:

Required Items:	**Page Number(s)**
Truthful and Accurate Statement	3
Device Name	4
Registration Number	4
Classification	4
Performance Standards	4
Declaration of Conformity to Recognized Standards	4
Labeling	5
Substantial Equivalence Comparison	5 - 6
Description of Device	6 - 11
Performance	11 - 12
Bio-compatibility	12
Software	13
Kits, Packs, or Trays	13
510(k) Statement	14
Statement of Indications for Use	15

Attachments and Appendices:

EyeTrak™ User's Manual
SoftTrak™ User's Manual
(Including warranty)

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION

1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

Premarket Notification

TRUTHFUL AND ACCURATE STATEMENT

I CERTIFY that in my capacity as Chief Engineer of BERTEC CORPORATION; 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.

Signature: _____

Typed name: Douglas R. Morr

Date: May 12, 1999

PMN#: _____

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

I. Device Name:

EyeTrak™, Computerized Electronystagmograph (ENG)

II. Registration Number:

9033911

III. Classification:

Class:	II
Regulation Number:	882.1460
Product Code:	GWN
Panel:	Neurology

IV. Performance Standards:

The FDA does not have any performance standards for nystagmographs.

See Conformity to Recognized Standards below.

V. Declaration of Conformity to Recognized Standards: for Abbreviated 510(k)

There are no Recognized Consensus Standards directly relating to nystagmographs, however the device has been designed to meet the following Generally Applicable Standards while continuing to follow the FDA's required Good Manufacturing Practices (including Design), as applicable:

IEC 60601-1
IEC 60601-1-1
IEC 60601-1-2
EN 1441
ISO 10993

There have been neither adaptations or deviations from the standards applied, nor differences between the previously approved devices and the device to be marketed.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

VI. Labeling

The following will be provided as a label on each EyeTrak™:

1) **MANUFACTURED FOR ....** *[Company Name] - when manufacturing for a distributor who is private labeling, e.g. Vestibular Technologies*

or

MANUFACTURED BY BERTEC CORPORATION
[when Bertec Corporation is manufacturing and marketting the equipment]

2) **SYSTEM NO:** *[uniquely and sequentially numbered with a common product code internal to Bertec .... **ETV-XXXX**] - where ETV is the product code and XXXX is a number starting with 5000*
3) **MODEL/SN:** *[uniquely numbered ..... **YYMMDDTTTTNN**] - where YY is two digit year, MM two digit month, DD two digit day, TTTT is four digit military time, and NN is a sequential number starting with 01*
4) **MADE IN U.S.A.**

VII. Substantial Equivalence Comparison:

As of November 13, 1998 there are 23 substantially equivalent devices according to an FDA furnished 510K REPORT. These devices span a time frame from August 21, 1981 to September 11, 1998.

The EyeTrak™ is substantially equivalent to all 23 devices with regard to the intended use, especially the devices described in following 510K's:

K964646, K982103, K972243, K972631, K926312, and K925111

The EyeTrak™ is substantially equivalent in principal and performance with regard to the technology used, equipment used, and tests performed to the following devices described in the following 510K's:

K925111, K926312, K972243, and K972631

The major difference between the EyeTrak™ and these substantially equivalent devices, besides aesthetics, is that the

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

EyeTrak™ does not require the additional use of a video camera for horizontal and vertical eye movement measurement. Instead it only uses a small video camera to monitor the torsional movement of the eye.

VIII. Description

Similar to substantially equivalent devices, the EyeTrak™ is an electronystagmographic (ENG) system used for evaluation of the vestibular system. The evaluations performed with the EyeTrak™ depend on the specific needs of the user, involve monitoring and recording eye movements, and are collectively referred to as the ENG test. ENG tests evaluate the vestibular system by testing vestibulo-ocular interactions, or the vestibulo-ocular reflex (VOR), in order to provide useful site-of-lesion information to the user. There are three main groups of ENG tests that can be performed with the EyeTrak™.

The first group of ENG tests are used to investigate the presence of abnormal eye movements and whether these change with head position: gaze test, Dix-Hallpike maneuver, and the positional test. The second group investigates the VOR: biothermal caloric test. The third group investigates visual-oculomotor function and non-vestibular eye movements: saccade test, tracking test, and optokinetic test. Currently the EyeTrak™ is used to measure eye movements only during the first and third groups of tests.

The EyeTrak™ consists of a frame, sensors, sensors cable, lens holder, an occluder, power supply, computer, and associated data acquisition software (SoftTrak™). Other items which can be used with the EyeTrak™ are a video camera, cable and monitor for viewing torsional eye movement; a visible LED for eye fixation in an occluded light environment, and a means of measuring head movement which can be accelerometers, gyroscopic sensors, or some other means. These additional items do not pose any additional risk to the user, and have been used by substantially equivalent devices for the same intended purpose. A draft copy of the EyeTrak™ and SoftTrak™ User's Manuals are included in the Appendix. Note that the EyeTrak™ User's Manual, hardware manual, has Bertec Corporation as the provider, and the SoftTrak™ User's Manual has Vestibular Technologies as the provider. When in final form, both will have Vestibular

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION

1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

Technologies as the provider since Bertec Corporation will be manufacturing both the EyeTrak™ and SoftTrak™ , while Vestibular Technologies will be marketting both.

FRAME:

The frame is head-mounted much like common eyeglasses, is lightweight and provides stable support for the sensors. This frame also allows easy adjustment of sensors, without the use of tools. The metal parts of the frame are made of anodized aluminum or stainless steel. The frame also allows for attachment of the lens holder. The frame allows for the following fitting adjustments to optimize the fit of the frame to the subject:

- nose height
- sensor sideways
- sensor and lens holder independently vertically
- distance from forehead to each ear independently

In appearance the frame resembles a binocular frame in its shape only, in that the entire mechanical frame assembly is located above the visual field. Therefore, without the sensors or lens holders inserted, the frame is invisible to the subject wearing it. There are three points of support (contact) between the frame and the subject: nose, left and right ear, with each having non-slip silicone covering.

SENSORS:

There is one sensor used per eye, or a total of two for the EyeTrak™. These sensors employ direct infrared (IR) oculography method with background light suppression, and feature very good metrological parameters including: wide aperture, high linearity, high resolution, and no drifts. Direct IR oculography uses an array of tiny IR lights reflected off the surface of each eye.

Each sensor, weighing only 25 grams, consists of two miniature PC-boards and a single sensor. The "main" board contains the IR illuminators, photodiodes and analog signal processing circuitry. The "slave" board is attached to the main board at an angle for side-light shielding, and contains output amplifiers and balancing circuitry. The side-light shielding is

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

added for comfort only, since the system is sun, fluorescent, and incandescent-light tolerant. The single sensor is mounted on a 2.54 mm (0.1") diameter rod which extends from the top.

Sensor placement is important for proper operation. Using the frame, each sensor's main board is located 25 mm (1") from the eye. Also, the sensor location is adjusted so that the center of the iris, when a patient stares at a point in the distance directly in front of her, is in the center of the aperture on the sensor. The allowable tolerance on this centering is ± 2 mm (± 0.08").

Sensor output signals are time-quantized analog outputs, due to the analog signal processing circuitry providing the output from a sample-and-hold amplifier which is updated each 100µs. Therefore, the effective frequency response is from 0 to 10 kHz (-3 dB). The Analog output can be obtained directly from the sensor from -5 to +5 volts, or digital output in any serial format can be achieved with use of a signal conditioning unit.

The sensors are not designed to eliminate cross-talk between the channels, instead they are designed to be calibrated. Therefore the analog output directly from the sensor is non-calibrated data, and the calibration coefficients (in degrees/Volt) must be determined for each patient. This allows for optimal measurement for each patient, as opposed to using an "averaged" calibration coefficient for all patients. The measuring range after any calibration is ≥± 20 degrees in the X direction, and ≥± 10 degrees in the Y direction.

The analog circuitry of the sensor has a dynamic range ≥ 110 dB, and balancing of the final amplifier stage is incorporated to optimize the output signal. In the normal situation the output signal is saturated when the EyeTrak™ frame is first put on the patient, thus requiring simple balancing adjustment. Also, minor balancing adjustment are sometimes needed after the frame has been displaced on the patient's head. The sensor has a built-in CPU that controls the measurement and provides for data serialization. A TTL signal input (or serial input, depending on the need) is used to re-balance the sensor. Re-balancing involves centering the output voltages when the subject looks straight forward, and is usually performed at least once after the sensor is in place on the frames and on the subject.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

SENSOR CABLES:

There is a cable required for each sensor, to provide power to the sensor and output from the sensor. This 2m (6.56 ft) cable is connected to the back of the sensor, or the side away from the patient. It is made of highly flexible, 10 conductor cable. The wires of the cable are spaced 2.54 mm (0.1") apart, and the connector used is a Micro-Match AMP connector.

LENS HOLDER:

The lens holder fits into the frame, and is made for standard 38 mm diameter examination lenses. The holder has two lens slots.

OCCLUDER:

A means of occlusion can be provided with the EyeTrak™ to prevent the patient from focusing on ambient light from outside the sensor-frame aperture. This can be a fabric oriented mask, a hard or soft plastic goggle, non-light transmitting lenses, or some other mechanical means of occlusion.

POWER SUPPLY:

The power supply receives Universal AC input and provides a regulated + 5 V DC supply to the sensors. The current required for one sensor is ≤ 75 mA, so low power is needed. Due to the EyeTrak™ has only one 5 VDC power supply used to power both sensors. This power supply is completed regulated and meets multiple US and International safety standards.

COMPUTER:

The computer used to receive the output signal from the sensors is a Y2K compatible desktop or laptop PC. These units are not manufactured or assembled by BERTEC, instead they are purchased, tested for Y2K compatibility and to ensure they work with the other hardware, and EyeTrak™ software is installed by Bertec. All licensees for installed software are

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

registered to the end user, and all warranties are provided to the end user by the manufacturer of the computer.

DATA ACQUISITION SOFTWARE (SoftTrak™):

(b)(4)

[redacted]

SOME POSSIBLE TESTS:

Eye movements are monitored and recorded during ENG tests using the EyeTrak™.

GAZE TEST: The gaze test is used to disclose nystagmus that occurs without vestibular stimulation by evaluating the limitation of eye movements, gaze stability, ocular flutter, spontaneous nystagmus, and latent nystagmus. The test is normally performed by recording eye movements first in the primary position and then while fixating on a target 30 to 40 degrees to the right, left, above, and below the center position.

DIX-HALLPIKE MANEUVER: The Dix-Hallpike maneuver is used to evaluate benign paroxysmal positional vertigo (BPPV) by stimulating the posterior semicircular canal one side at a time. The maneuver involves a quick movement from a seated position to a reclining position with the head hanging slightly. The patient's head is first turned 45 degrees toward the side being tested, and the patient is instructed to fall backward quickly. The examiner holds the patient's head all the while and keeps it in the turned and head-hanging position for a specific amount of time. The patient is then returned to the

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

seated position. Throughout this maneuver the EyeTrak™ is used to monitor the eyes for nystagmus.

POSITIONAL TEST: The positional test is used to determine whether various head positions cause or modify a nystagmus, called positional or static positional nystagmus. This testing is performed by monitoring the eyes for nystagmus using the EyeTrak™ while the patient's head is slowly moved into and held for a specific time in at least four positions: seated, supine, right lateral, and left lateral.

BIOTHERMAL CALORIC TEST: The EyeTrak™ system does not take measurements during this test, if performed.

SACCADE TEST: The saccade test is used to detect disorders of the saccade eye movement control system, by evaluating a patient's ability to rapidly capture visual targets in the periphery of the visual field without overshoot or undershoot. The EyeTrak™ system software provides visual targets on the computer screen for the patient to visually capture and the sensors of the EyeTrak™ system record the response. Alternatively, an LED display can be placed in the visual field of the subject while in an occluded environment to provide the visual cues.

PURSUIT TESTS: The pursuit test evaluates a patient's ability to maintain an image when the image is moving. For slow speeds of movement the smooth pursuit system is used, however at higher speeds the VOR is utilized. Therefore, there are two pursuit tests performed, usually referred to as the smooth pursuit (or tracking) test and the optokinetic (or VOR) test. The EyeTrak™ system software provides visual targets on the computer screen for the patient to visually track and the sensors of the EyeTrak™ system record the response. Alternatively, an LED display can be placed in the visual field of the subject while in an occluded environment to provide the visual cues.

IX. Performance

The EyeTrak™ illuminates the eye by pulses of IR light from 6 (six) illuminating light-emitting diodes (LED's). The pulse length is 50-60µs, and the overall IR duty cycle is 50%. Total pulse power is not more than

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

0.1 W, giving an average emitted power of 0.05 W total. The eye irradiance, when the sensor are at least 25 mm (1.0") away from the eye, does not exceed 0.03 W/cm^2 peak, and 0.010 W/cm^2 average in failure-mode (servo circuitry failure). In normal use, the irradiance levels are ≤0.010 W/cm^2 peak, and 0.006 W/cm^2 average.

The EyeTrak™ sensor output linear ranges are +/-15 degrees for X and +/- 10 degrees for Y. Although the sensors can measure outside these limits, the measurements are not linear and not required for the intended use of the sensors. The resolution is ≤ 5 arc minutes, and the accuracy is ≤ 5 arc degrees.

X. Bio-compatibility:

The EyeTrak™ system has been designed to meet ISO 10993.

The frame of the EyeTrak™ system is the only component which comes into contact with the patient. There are three points of support (contact) between the frame and the patient: nose, left and right ear, with each having non-slip silicone covering. This non-slip silicone covering is over top of metal parts of the frame are made of anodized aluminum or stainless steel.

The sensors and their associated circuitry are covered by insulating rubber to avoid electrical contact with the user. Also, a plastic shield is placed over the circuitry and aperture to further increase the electrical isolation.

The materials in contact with the patient, due to the material, nature, degree, frequency and duration of exposure to the body, **DO NOT**, either directly or through the release of their material constituents produce: (I) adverse local or systemic effects, (ii) carcinogenic, or (iii) adverse reproductive and developmental effects.

The materials used in the EyeTrak™ system which are in contact with the patient are substantially equivalent in manufacturing processes, chemical composition and body contact to those used in many of the substantially equivalent devices used previously. Therefore, following G95-1, the bio-compatibility requirements are met.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

XI. Software:

The software used with the EyeTrak™ system (SoftTrak™) is a PC based data collection, storage and presentation of the results of the tests performed. This software **DOES NOT** do any of the following: control a life supporting or sustaining device, control delivery of harmful energy, control treatment delivery, provide diagnostic information as a basis for treatment or therapy, or perform vital signs monitoring. Therefore, based on the FDA's published *Software Guidance* this software is a **"Minor level of concern"**. Also, this software **DOES NOT** control any hardware used in the testing, does not provide diagnostic information, and does not pose any health or safety risk to the user or patient.

This software **DOES** provide trained clinicians with easy to understand, documented, results of specific vestibular tests. The intended use of the software is to have the trained clinician use the results to draw their own opinions and conclusions about diagnosis and treatment using quantitative results.

The software is completely described in the User's Manual, provided in the appendix, and each version of the software is identified with a unique sequential identification.

With this discussion in mind, this software is significantly equivalent to the software used in substantially equivalent devices mentioned previously which use software in their systems **NOT** to control hardware.

XII. Kits, Packs, or Trays:

Not Applicable

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

XIII. 510(k) Statement:

510(k) Statement

I CERTIFY that in my capacity as Chief Engineer , of Bertec Corporation, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification is determined to be substantially equivalent.

The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, trade secrets, and confidential commercial information as defined in 21 CFR 20.61.

Signature of Certifier: _____

Typed Name of Certifier: Douglas R. Morr

Date: May 12, 1999

PMN#: _____

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

BERTEC CORPORATION
1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.
Phone: 614-421-2803 Fax: 614-421-2811
sales@bertec.com www.bertec.com

XIV. Statement of Indications for Use:

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: EyeTrak™ : ENG System

Indications for Use:

The EyeTrak™ is used to non-invasively measure the vertical and horizontal eye movements during a variety of tests performed during electronystagmography (ENG) testing. This testing includes, but is not limited to: saccadic test, smooth pursuit, optokinetic nystagmus, and kinetic vestibular tests. It provides a trained clinician with data and graphs representing a patient's ability to perform certain eye movements voluntarily, as well as the patient's involuntary eye movements due to head movement, eye movement and/or body movement as is normally performed in vestibular diagnostic testing such as in Hallpike positional tests. It is used, then, to aide in the detection and diagnosis of vestibular disorders.

The EyeTrak™ does not incorporate a camera for vertical and horizontal eye movement measurement, therefore it is not as cumbersome as other similar devices, and does not have focal length and resolution limitations based on the camera and camera lens used. The EyeTrak™ instead measures horizontal and vertical eye movement non-invasively using infra-red sensors and an IR oculography method with background light suppression. This allows for direct transmission of sensor signals to a processing unit, which in turn provides the signals to the software for processing, saving, and presentation. A camera and monitor can be used to monitor torsional eye movements, and a sensor can be added to measure head movement.

The results are used to provide documentation of a patient's performance on specific tests.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

USER'S MANUAL

for

EyeTrak™

Version 1.0 (DRAFT)

BERTEC CORPORATION

1483 Delashmut Avenue, Columbus, OH 43212, U.S.A.

Phone: (614) 421-2803 Fax: (614) 421-2811 e-mail: sales@bertec.com

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Warranty and Special Provisions for the United States of America and Any Other Country

Limited Warranty

LIMITED WARRANTY. Except with respect to any Bertec Corporation (Bertec) products sold by any entity other than Bertec or its authorized distributors, which are provided "as is," without warranty of any kind, Bertec warrants that (a) the Bertec hardware product is free of all defects in workmanship and material for a period of seven (7) years from receipt by the end-user or date of installation if performed by a representative of Bertec; (b) the media that Bertec software is delivered upon are free from defects in workmanship and material and will perform substantially in accordance with the accompanying written materials for a period of seven (7) years; and, (c) Bertec support engineers will make commercially reasonable efforts to solve any problem issues as they arise. Some states and jurisdictions do not allow limitations on duration of an implied warranty, so the above limitation may not apply to you. To the extent allowed by applicable law, implied warranties on both the Bertec hardware product and the Bertec software product are limited to seven years.

CUSTOMERS REMEDIES. Bertec 's and its distributors' entire liability and the customer's exclusive remedy shall be, at Bertec's option, to either repair or replace all Bertec hardware and/or software products that do not meet Bertec's Limited Warranty and are returned to Bertec. Cost of delivery of the Bertec product under warranty, to and from Bertec, will be the responsibility of Bertec for the first year of the warranty period. Thereafter, all costs associated with transport of the Bertec product under warranty shall be the responsibility of the customer. This Limited Warranty is void if failure of the Bertec hardware and/or software product has resulted from improper installation by the customer (in contravention of proper installation instructions as detailed in the user manual included with the Bertec product), unauthorized modifications, misuse of the Bertec product by the customer, and/or failure by the customer to properly maintain the Bertec product. Any replacement Bertec product will be warranted for the remainder of the original warranty period or thirty (30) days, whichever is longer.

NO OTHER WARRANTIES. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, BERTEC AND ITS DISTRIBUTORS DISCLAIM ALL OTHER WARRANTIES AND CONDITIONS, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, TITLE AND NON-INFRINGEMENT, WITH REGARD TO THE BERTEC PRODUCT OR THE PROVISION OR FAILURE TO PROVIDE SUPPORT SERVICES. THIS LIMITED WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS. YOU MAY HAVE OTHER LEGAL RIGHTS NOT MENTIONED IN THIS WARRANTY, WHICH VARY FROM STATE/JURISDICTION.

LIMITATION OF LIABILITY. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL BERTEC OR ITS DISTRIBUTORS BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES WHATSOEVER (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOST BUSINESS PROFIT, BUSINESS INTERRUPTION, LOSS OF BUSINESS INFORMATION, OR ANY OTHER PECUNIARY LOSS) ARISING OUT OF THE USE OF OR INABILITY TO USE THE BERTEC PRODUCT OR THE PROVISION OR FAILURE TO PROVIDE SUPPORT SERVICES, EVEN IF BERTEC HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN ANY CASE, THE MAXIMUM AMOUNT OF DAMAGES SHALL BE LIMITED TO THE AMOUNT ACTUALLY PAID BY THE CUSTOMER FOR THE BERTEC PRODUCT. BECAUSE SOME STATES AND JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF LIABILITY, THE ABOVE LIMITATION MAY NOT APPLY TO YOU.

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

Mechanical specs

The sensor itself consists of two PC-boards. The main board contains:

1. Optoelectronic components: IR illuminators, photodiodes;
2. Illumination servos, analog signal processing circuitry, supply decoupling capacitors;
3. Supervisor CPU.

The slave board, which is angled and serves side-light protection, contains:

1. Output amplifiers,
2. Balancing system.

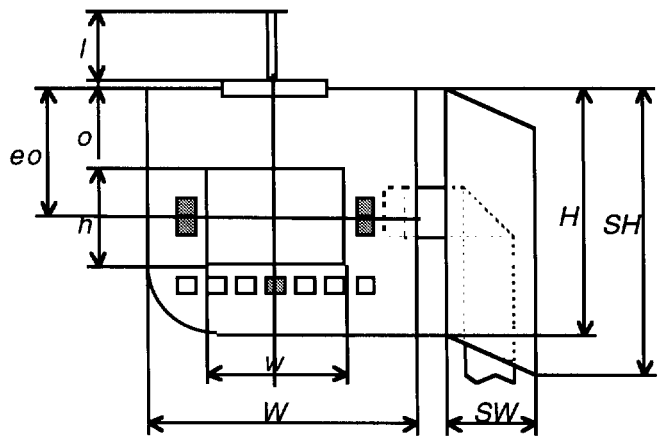


Fig. 1. Right-eye sensor dimensions (as seen from the subject' side, balancing board detached).

White rectangles – illuminators, black rectangles – photodiodes. Output cable is also shown extending from the connector. The cable and connectors are located on the front of the sensor (away from the patient).

The slave board is angled and projects in the rear (backhead) direction so as to protect the right eye from light coming from the right side of the head, and left eye accordingly to light coming from the left side. This "shade" is for added comfort only (the system is sun-, fluorescent- and incandescent-light tolerant), but also provides board space for balancing circuitry. The sensor is mounted on the frame with a 2.54mm (0,1") diameter rod which extends from the top. Sensor weight is about 25 grams.

Slave board is fixed to the mainboard.

Dimensions

aperture: *w*=1.10" (28.0mm), *h*=0.90" (22.9mm),
distance of aperture center from top of main board: *eo*=1.36" (34.5mm),
main board: *W*=2.25" (57.3mm), *H*=2,31" (58.7 mm),
side board: *SH*=2.43" (61.7mm), *SW*=1,17" (29.8mm),
mounting rod: base height *o*=0.05" (1.2mm), length *l*=0.76" (19.0mm),
diameter *fi*=0.1" (2.54mm).

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Using the sensor

Sensor placement

Sensor placement is important for proper operational parameters (linearity and crosstalk). Using our mounting frame, the sensor's main board plane is located 25mm from the eye globe. It has to be adjusted so that the iris' center, when subject looks at infinity (far point), with head upright, is in the center of the aperture (+/– 2mm).

Using the sensor and frame

Note: the frame has a total of 7 adjustable elements. Five (5) of them are red coloured. The remaining two (2) are the counter-fix screws, which have natural aluminum color.

The sensor, mounted in the frame provided, is stable enough to be used in conditions where subject is seated. No additional measures are needed to stabilize the sensor when there is no excessive head or body movement. The procedure for donning the frame is as follows:

1. Loosen the ear holder adjustment screws;
2. Don the frame on the subject. Adjust ear holders so that they won't be deformed excessively. This should provide enough stability. Tighten the ear holder adjustment screws;
3. Loosen the horizontal sensor adjustment counter-fix screws;
4. Ask the subject to look over your shoulder at some far point;
5. Adjust horizontal position of sensors so that the iris is centered horizontally in each sensor;
6. Loosen the sensor-holding screw (one at a time) and adjust each sensor vertically, so that the iris is centered vertically in each sensor;
7. Reverify the iris centering. Should vertical sensor adjustment range be insufficitent, adjust the vertical frame position with adjustment screw above the nose; repeat from step 4;
8. Tighten the horizontal sensor adjustment counter-fix screws.

Using the sensor and frame under dynamic conditions (with head and body movement)

To obtain usable signal under dynamic conditions, eg. when head is turned or body is moving, the sensors have to be additionally fastened to the head using the black rubber band provided. The band has to be fastened to the slave board. There is a small hole on the backhead side of the slave board, the rubber band fits this hole. Use the procedure mentioned in preceding section, then proceed as follows:

1. Fix the rubber band to the sensors (slave boards);
2. Fix the frame with the sensors securely on subject's head. Don't use the rubber band at this point;

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

3. After the frame has been donned, put the rubber band on top of it;
4. Adjust the band so that it won't be too tight, while providing enough stability.

The rubber band should be removed for improved subject comfort under static conditions. Alternatively other means of securing the sensors and frame to the head of the subject will be provided.

Cable connection

1m long cable is included. The cable is a high-flexibility, black 10-conductor tape cable. Wires are spaced 0.1" (2.54mm) apart. Conductor #1 is red, other conductors are black. Cable is fitted with a Micro-Match AMP connector mating the socket on sensor main board, the other end is fitted with a 10 pin IDC connector (100" pitch, 2 rows of 5 connectors). The cable conveys both power supplies and signals.

Con d #	Signal	Con d #	Signal
1	#BAL	6	GND
2	GND	7	OPT1
3	YB	8	OPT2
4	XB	9	+5V
5	GND	10	–5V

#BAL – TTL level balancing signal, active low. Pulse length minimum 10ms, no maximum.

+5V, –5V – power supplies,

GND – ground,

XB, YB – X/Y voltage output,

OPT1, OPT2 – these are left for expansion; in the prototype they are used for test purposes *and should be left unconnected*

Note: The IDC connector has pins numbered in a zig-zag fashion. First pin is indicated by a triangle on the connector's side. The odd-numbered pins are on the same side as pin #1, the even-numbered pins are on the opposite side.

Output signal

Levels, format

Output signals are inherently time-quantized (step-like) analog outputs. Internal analog signal processing circuitry provides its output from a sample-and-hold amplifier which is updated (re-sampled) each 100ms. The effective sampling rate of the system is 10kHz.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Outputs are driven by INA118 (Burr-Brown) instrumentation amplifiers and have near rail-to-rail output capability. Thus, the output signal has 10Vpp maximum amplitude.

Crosstalk, linearity

The sensor was designed for measuring primarily the X axis. The Y axis signal is never as good as that of X axis in direct-IR methods. Direct-IR sensor design cannot eliminate crosstalk between channels.

The Y axis output has not more than 20% of X axis signal present in it. The X axis is better in this respect, with crosstalk from Y axis less than 10%.

The X axis is the „better one". The X axis linearity is much better than those of Y axis and on average subject the total nonlinearity in whole measuring range (aperture) is at about 8.5%. The Y axis is worse, and the full range nonlinearity error is at about 15%.

Calibration, range

The sensor provides uncalibrated data. The calibration coefficient (degrees/Volt) varies from subject to subject. The measuring range is not less than +/–20 degrees horizontal, +/– 10 degrees vertical.

The calibration on patient is needed as long as your application needs data in angular format. Arbitrary units are OK in many applications, but simple linear calibration performed on the patient is sufficient when you need angular data. Due to the head movement, the data anyway cannot be translated to the point of gaze, unless you put a set of gyros on the mounting frame.

Balancing

The analog circuitry's dynamic range is in excess of 110dB and balancing (zeroing) of the final amplifier stage is needed to obtain useable signal. The output signal will be saturated after the system's mounting frame is first put on the patient. The zeroing is usually also needed after the mounting frame (and the sensor) have been displaced on patient's head.

Balancing is performed by lowering the #BAL line for at least 10ms.

The output signal will usually not balance to the exact 0V level. Allowable offset is +/– 1V.

Power supply

A universal AC-DC transformer is included in the system to provide +5 and -5 VDC to the sensors. This transformer meets or exceeds all safety and performance standards required and is placed near an outlet.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

HELPING PEOPLE REGAIN THEIR BALANCE ... FOR LIFE.™

User's Manual

SoftTrak

DRAFT

VESTIBULAR technologies™

VT

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

DRAFT

Limited warranty

LIMITED WARRANTY. Except with respect to any Vestibular Technologies, Inc (VTI) products sold by or manufactured by any entity other than VTI, its authorized distributors, or suppliers, which are provided "as is", without warranty of any kind, VTI warrants that (a) the VTI hardware product is free of all defects in workmanship and material for a period of one (1) year from receipt by the end-user or date of installation if such installation is performed by a representative of VTI; (b) the media that VTI software is delivered upon are free from defects in workmanship and material and will perform substantially in accordance with the accompanying written materials for a period of one (1) year; and (c) VTI support engineers will make commercially reasonable efforts to solve any problem issues as they arise, toll-free for ninety (90) days and at a commercially reasonable cost to the end-user thereafter. Some states and jurisdictions do not allow limitations on duration of an implied warranty, so the above limitation may not apply to you. To the extent allowed by applicable law, implied warranties on both the VTI hardware product and the VTI software product are limited to one (1) year.

CUSTOMERS REMEDIES. VTI's and its distributors' entire liability and the customer's exclusive remedy shall be, at VTI's option, to either repair or replace all VTI hardware and/or software products that do not meet VTI's Limited Warranty and are returned to VTI. Cost of delivery of the VTI product under warranty, to and from VTI, will be the responsibility of VTI for the first year of the warranty period. Thereafter, all costs associated with transport of the VTI product shall be the responsibility of the customer. This Limited Warranty is void if failure of the VTI hardware and/or software products has resulted from improper installation by the customer (in contravention of proper installation instructions as detailed in the user's manual included with the VTI product), unauthorized modifications, misuse or abuse of the VTI product by the customer, and/or failure by the customer to properly maintain the VTI product. Any replacement VTI product will be warranted for the remainder of the original warranty period.

NO OTHER WARRANTIES. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, VTI AND ITS DISTRIBUTORS DISCLAIM ALL OTHER WARRANTIES AND CONDITIONS, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, TITLE AND NON-INFRINGEMENT, WITH REGARD TO THE VTI PRODUCT OR THE PROVISION OR FAILURE TO PROVIDE SUPPORT SERVICES. THIS LIMITED WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS. YOU MAY HAVE OTHER LEGAL RIGHTS NOT MENTIONED IN THIS WARRANTY. THESE RIGHTS MAY VARY IN EACH STATE OR JURISDICTION.

LIMITATION OF LIABILITY. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL VTI (INCLUDING ANY OF VTI'S SUBSIDIARIES OR PARENT COMPANIES, SUPPLIERS, DISTRIBUTORS, RETAILERS, OR MANUFACTURERS) BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES WHATSOEVER (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOST BUSINESS PROFIT, BUSINESS INTERRUPTION, LOSS OF BUSINESS INFORMATION, OR ANY OTHER PECUNIARY LOSS) ARISING OUT OF THE USE OF OR INABILITY TO USE THE VTI PRODUCT OR THE PROVISION OR FAILURE TO PROVIDE SUPPORT SERVICES, EVEN IF VTI OR ITS AFFILIATES HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THE TOTAL LIABILITY OF VTI AND/OR ITS AFFILIATES FOR ANY LOSS, DAMAGE OR CLAIM, WHETHER IN CONTRACT, TORT (INCLUDING ACTIVE OR PASSIVE NEGLIGENCE OR STRICT LIABILITY) OR OTHERWISE, ARISING OUT OF, CONNECTED WITH, OR RESULTING FROM THE PERFORMANCE OR BREACH OF ANY PURCHASE ORDER OR CONTRACT OF SALE ACCEPTED OR EXECUTED BY VTI AND/OR ITS AFFILIATES, OR FROM THE DESIGN, MANUFACTURE, SALE, DELIVERY, RESALE, INSPECTION, ASSEMBLY, TESTING, REPAIR, REPLACEMENT, OPERATION, MAINTENANCE OR USE OF ANY VTI PRODUCT OR ACCESSORY OR FROM THE PERFORMANCE OF ANY SERVICE SHALL NOT, IN ANY EVENT, EXCEED THE PRICE ALLOCABLE TO THE PRODUCT OR SERVICE WHICH GIVES RISE TO THE CLAIM, LOSS OR DAMAGE. PROVIDED FURTHER, THAT THE END-USER ASSUMES ALL RISK ASSOCIATED WITH THE USE OR MISUSE OF THE VTI PRODUCT, ACCESSORY OR SERVICE IN CONTRAVENTION OF ANY DIRECTIONS OR WARNINGS PROVIDED IN VTI INSTRUCTIONAL LITERATURE OR GIVEN VERBALLY BY AN AUTHORIZED VTI REPRESENTATIVE, OR THAT SHOULD BE REASONABLE BY COMMERCIALLY ACCEPTABLE STANDARDS. THE PARTIES (VTI, VTI'S AFFILIATES, AND THE CUSTOMER OR END-USER) EXPRESSLY AGREE THAT THE LIMITATIONS ON INCIDENTAL, CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES SET FORTH HEREIN ARE AGREED ALLOCATIONS OF RISK CONSTITUTING IN PART THE CONSIDERATION FOR THE SALE OF ANY VTI PRODUCT, ACCESSORY, OR SERVICE, AND THAT SUCH LIMITATIONS SHALL SURVIVE THE DETERMINATION OF ANY COURT OF COMPETENT JURISDICTION THAT ANY REMEDY PROVIDED HEREIN OR AVAILABLE AT LAW FAILS OF ITS ESSENTIAL PURPOSE. BECAUSE SOME STATES AND JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF LIABILITY, THE ABOVE LIMITATION MAY NOT APPLY TO YOU.

HIGH RISK ACTIVITIES. THE SOFTWARE AND/OR HARDWARE SUPPLIED BY VTI IS NOT FAULT-TOLERANT AND IS NOT DESIGNED, MANUFACTURED OR INTENDED FOR USE OR RESALE AS ON-LINE CONTROL OR EQUIPMENT IN HAZARDOUS ENVIRONMENTS REQUIRING FAIL-SAFE PERFORMANCE IN WHICH THE FAILURE OF SOFTWARE AND/OR HARDWARE COULD LEAD DIRECTLY TO DEATH, PERSONAL INJURY, OR SEVERE PHYSICAL OR ENVIRONMENTAL DAMAGE ("HIGH RISK ACTIVITY"). VTI AND ITS SUPPLIERS SPECIFICALLY DISCLAIM ANY EXPRESS OR IMPLIED WARRANTIES OF FITNESS FOR HIGH RISK ACTIVITIES.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Copyright © 1999 Vestibular Technologies, Inc. & BERTEC Corporation. All rights reserved. Information in this document is subject to change without notice. Companies, names, and data used in examples herein are fictitious unless otherwise noted. No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without express written permission of Vestibular Technologies Inc. & BERTEC Corporation or their licensees.

BalanceTrak, SofTrak, SoftTrak, "Helping People Regain Their Balance ... For Life", Vestibular Technologies, and their logos are trademarks of Vestibular Technologies, Inc.

Microsoft Windows 98 is a trademark of Microsoft Corporation.

Other trademarks are the property of their respective owners.

Document No. V03UMV001

Printed in the United States of America.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Typographical Conventions

Before using this manual, it is helpful to be aware of the following formatting conventions used throughout the document:

Formatting Convention	Type of information
	Note or Caution messages. They state the most **important** things to keep in mind while using the *SoftTrak* system.
	Important messages. They state the **fundamental** things to keep in mind while using the *SoftTrak* system, including safety notices.
	Step-by-step procedures. The procedure is identified by its title written in bold italic near this symbol.
	Background of a step-by-step procedure.
	Single step of a step-by-step procedure.
	Tip messages. They state some useful information about the versatility of the *SoftTrak* system.
Bold font type	**Important terms**.
Italic font type	Quick reference for **how to read the results**.
Bold Italic font type	**Reference to other sections** of the manual where the mentioned topic is described in detail.

Copyright © 1999 Vestibular Technologies, Inc

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

VTI-Trak Contacts

For system sales:

Mel Shadowens, Ph.D.
Bob Henderson
5223 East Wagoner Road
Scottsdale AZ 85254
Phone: **1-800-752-6178**
Fax: **1-602-485-7732**
e-mail: **mel@vestibtech.com**
bob@vestibtech.com
9:00 A.M. to 5:00 P.M. PT
Monday through Friday
excluding holidays

For customer support:

Phone: **1-877-VTI-TRAK ext. 223**
(1-877-884-8725-223)
e-mail: **support@vestibtech.com**
9:00 A.M. to 5:00 P.M. ET
Monday through Friday
excluding holidays

Suggestions or comments on any Vestibular Technologies products are welcomed and encouraged.

For more information:

www.vestibtech.com

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Table of Contents

1. Introduction 1
   1.1. Overview 1
      SoftTrak Features 1
   1.2. Identifying components 2
      SoftTrak Software 2
      SoftTrak Computer System 2
   1.3. SoftTrak Notes 3
      Software notes 3
      Hardware Safety Issues 4
   1.4. SoftTrak Tips 5
      Test Protocol Tips 5
      Software Tips 5
   1.5. SoftTrak Contacts 6
2. Computer Installation and Setup 7
   2.1. Introduction 7
   2.2. SoftTrak Computer System 7
      Computer 7
      Color Printer 8
3. Getting Started 11
   3.1. Getting Ready for the Test Protocol 11
      Turning on the *SoftTrak* System 11
      Starting the *SoftTrak* Software 11
      Starting a New Patient Record 12
      Starting a New Session 13
   3.2. Test Protocol 13
      Test Selection 14
      Test Procedure 15

Copyright © 1999 Vestibular Technologies, Inc.

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

48

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

System Calibration 15
Test 15

3.3. Printing and Interpreting the Results 15
Patient's Report 16
Full Report 16

3.4. Turning off the *SoftTrak* System 17

4. Software Manual 19

4.1. Starting the *SoftTrak* software 19
First Time the Software is Used 20
Setting up User's Profiles 21
Customizing the Reports Header 21
Login Window 22
Buttons 22

4.2. Main window 22
Sessions List 23
Sorting Sessions List 24
Buttons 24

4.3. Printing the Sessions List 25
Buttons 25

4.4. Options 26
Buttons 26
Current User's Preferences 26
Buttons 27
Users Administration 27
Sorting User's Profile List 28
Buttons 28
User's Profile 28
Buttons 30

4.5. Patient's Information 30
Buttons 33

4.6. Test Protocol 33
Test Selection 34
Tests Selection 34
Buttons 35
Calibration 36
Buttons 37
Test 37
Buttons 38

4.7. Reports 38
Buttons 39
Printing the Reports 39
Buttons 40
Patient's Report 40
Full Report 40

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Page 1 41
Other Pages 41

4.8. On-line Help 41

5. Appendix 43

5.1. Customer Support 43

90 Days Toll-Free Customer Support 43

Customer Support Procedures 43

Product Return Procedure 44

5.2. Troubleshooting 44

The light on the power strip is not on 44
The computer does not start 44
The printer does not start 45
The printer is on, but does not print 45
The light on the platform cable transformer is not on 45
The light on the platform cable transformer is flashing 45
No data acquisition device is specified (software message) 46
No instrument is specified (software message) 46
No data acquisition device configured as device 1 (software message) 46
Data acquisition not supported (software message) 46
The calibration did not complete successfully (software message) 46

Copyright © 1990 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

1. Introduction

1.1. Overview

SoftTrak Features

An easy to use software provides the interface for the *SoftTrak* system. The *SoftTrak* software takes the information from the goggles analyzes it, stores it, and shows the analysis results.

No one has access to the patient's data without using the *SoftTrak* software.

The software guides the user through the tests with detailed instructions.

All completed test protocols are listed as sessions, and the results for any session can be viewed or printed. These results are used to create two types of reports. The **Patient's Report** contains basic graphs and descriptions of the patient's ability to maintain balance, and can be given to the patient since it does not include information that could compromise patient-physician confidentiality. The second report type is the **Full Report**. This report contains all the results and advanced graphs, and is designed for the clinician's records.

Additional features of the software allow for selecting which test to perform, in which order, and repeating any test. This allows the clinician to perform only certain tests, investigating specific aspects of the patient's health.

If desired, a user's name and password can be set to prevent unauthorized access to the software. Multiple users can be specified. Each user has access only to his/her patient's data. Each user may also create a customized report header and choose a system of measurement units. The software also allows for a special type of user, called the **Administrator**, who can create, edit or delete the user's profiles.

Copyright © 1998 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

1.2. Identifying components

The *SoftTrak* system contains the following components:

- *SoftTrak* Software;
- *SoftTrak* Computer System;
- *SoftTrak* User's Manual.

Different plug-in systems can be interfaced with *SoftTrak*, such as the *EyeTrak* system, part of the *VTI Trak* family of products.

For more information regarding the installation, use and technical aspects of the plug-ins, please refer to the specific hardware manual provided with them.

SoftTrak Software

It is installed by the manufacturer on the *SoftTrak* computer system and it is ready to be used.

For more information regarding the use and technical aspects of the Software, please refer to ***Software Manual***.

SoftTrak Computer System

The *SoftTrak* computer system is the interface for the *VTI Trak* family of products.

It is a laptop computer with the following characteristics:

- a Pentium 200 with MMX technology processor, with 32MB EDO memory, 3.2GB IDE hard drive, 12.1" active matrix display (or better) computer with its carrying case;
- a color printer;
- all the cables needed to connect them;
- their installation manuals;
- a PCMCIA cable, to connect the computer to the plug-ins.

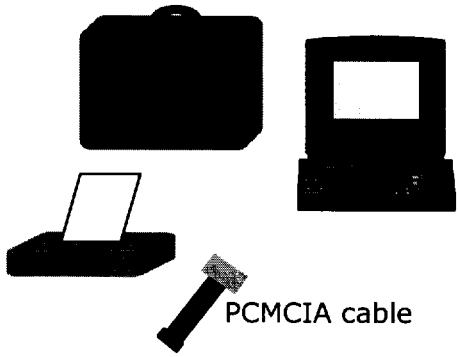


Figure 1-1. SoftTrak system: ***Computer system.***

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

For more information regarding the installation, use and technical aspects of the computer system, please refer to ***Hardware Installation and System Setup: SoftTrak Computer System***, and to the specific manuals provided with the computer and printer.

1.3. *SoftTrak* Notes

Software notes

1. To preserve Data Files integrity, it is necessary that the computer date and time are correct. If they are incorrect, change them according to the following instructions:
   1. Double click on the time on the Windows Taskbar.

Figure 1-2. Windows Taskbar.

   2. The standard Windows interface to adjust date and time will appear.

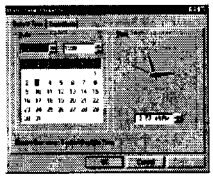


Figure 1-3. Windows Date/Time interface.

   3. Select the correct date and/or time.
   4. Click [OK] to update the system date and time and return to the *SoftTrak* software.

2. In the **Patient's Information** window, the following information MUST be entered:
   - Patient's **First** and **Last Name**, or **SSN/ID** (social security number or patient ID);
   - **Sex** (M or F);
   - **Height** (with measurements units, e.g., 1.70 m, 170 cm, 67" or 5'7");
   - **Date of Birth** (in any format Windows understands, e.g., 10-19-69, 19-10-69, 10/19/69, Oct/19/1969, 19 Oct 69);
   - **Operator's Name**.

   As a reminder, these items are underlined. The *SoftTrak*

Copyright © 1999 Vestibular Technologies, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 54

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

software will not proceed further until all the required information has been entered. A specific message will appear if something is missing or wrong.

3. The *SoftTrak* software identifies each test session by the patient name and the session number. One patient can have several entries in the list, one for each test session for that patient. Each of these entries will have a different session number.

4. The software allows only three login trials: this is a safety feature to prevent unauthorized access.

5. *SoftTrak* software supports multiple users. Only the patients tested by the user logged in will appear on the list. One user cannot access another user's patient records (unless logging in using another user's ID and password).

6. The **Options: Users Administration** section and the **Options: User's Profile** section are available only for the **Administrator.** All other users do not have access to these sections.

7. The **Current Users' Preferences** settings will only affect the user who is currently logged in. This allows different users to save their own settings.

8. To customize the **Report Header**, from the Main window select Options, then Edit. The Report footer will contain the Vestibular Technologies, Inc. logo, and, if the user is certified, the certification logo. The footer cannot be edited.

9. Only one copy of the *SoftTrak* software can be run at any time, since the software controls unique hardware devices. If a copy of the software is started while another is already running, a message will appear, and the new copy will be terminated.

10. It is strongly recommended to set the Administrator's password, to prevent unauthorized access.

Hardware Safety Issues

1. Be sure that the computer is turned off and unplugged from the power strip before doing any cabling maintenance of the *SoftTrak* system. Failure to do so can result in system damage.

2. For the user's convenience, the power strip provided with the *SoftTrak* system is also a surge protector. Any guarantee or warranty concerning this strip is made solely by the strip's manufacturer. Either the *SoftTrak* manufacturer or distributor makes no warrantee or guarantee regarding this strip and assumes no liability for any bodily injury or property damage that may result from the use of this strip. Please refer to the instructional literature provided by the power strip's manufacturer for more information regarding its specifications and intended use.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

3. If the light on the transformer is flashing, IMMEDIATELY DISCONNECT the transformer from the electric power supply, and contact *VTI Trak* Customer Support. DO NOT USE ANY *VTI TRAK* SYSTEMS. Failure to do so can result in system damage.

1.4. *SoftTrak* Tips

Test Protocol Tips

1. When printing the test results during the test protocol, it is not necessary to wait for the report to be printed out, before proceeding with the desired next test protocol.
2. While the patient is performing the test, note anything that can influence the results of the test and if necessary redo the test. When analyzing the results in the **Full Report**, it is possible to add all the test notes to the results for easy comparison between different test sessions. Also keep track of how the patient feels in general and especially while performing the test.
3. To monitor the patient's health, it is good practice to print the **Full Report** after every test session. Comparing the results from different test sessions, it is possible to evaluate the patient' s health over time.

Software Tips

1. Resting the mouse over any fields for a couple of seconds will activate the TIP connected to such field, with a quick explanation of its functionality.
2. When only one person (called **Administrator**) is using the *SoftTrak* system, there is no need to set up other user's profiles.
3. In the **Options: User's Profile**, use the **User's Name** field to uniquely identify the user. Information such as the name, address, and phone number can be entered here.
4. In the **Options: User's Profile**, the feature to change directory can be used to have different users sharing the same **Data Files Directory**: instead of letting the software creating the User's Data Files Directory automatically, create one common Data Files Directory and choose it as User's Data Files Directory for some or all the users. However, having different users sharing the same Data Files Directory will give them access to the same patients' information.

Copyright © 1999 Vestibular Technologies, Inc.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

1.5. *SoftTrak* Contacts

For system sales:

Mel Shadowens, Ph.D.
Bob Henderson
5223 East Wagoner Road
Scottsdale AZ 85254
Phone: **1-800-752-6178**
Fax: **1-602-485-7732**
e-mail: **mel@vestibtech.com**
bob@vestibtech.com
9:00 A.M. to 5:00 P.M. PT
Monday through Friday
excluding holidays

For customer support (please refer to ***Appendix A: Customer Support***):

Phone: **1-877-VTI-TRAK ext. 223**
(1-877-884-8725-223)
e-mail: **support@vestibtech.com**
9:00 A.M. to 5:00 P.M. ET
Monday through Friday
excluding holidays

Suggestions or comments on the *SoftTrak* system are welcomed and encouraged.

For more information:

www.vestibtech.com

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

2. Computer Installation and Setup

2.1. Introduction

Few steps are required to properly install the *SoftTrak* system. Following carefully the **Installation Steps** detailed here will ensure a correct installation of the *SoftTrak* system.

Read carefully all the instructions.

2.2. *SoftTrak* Computer System

To install the *SoftTrak* computer system, it is only necessary to take the components out of the boxes and connect the cables.

Computer

The computer box contains the laptop computer, the PCMCIA cable, power supply, carrying case, a power strip, printer cable, computer manual, and the *SoftTrak* User's Manual.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Installation: Computer

- Open the box containing the *SoftTrak* computer, and unpack it.
- Connect the printer cable to the parallel port LPT1 of the laptop.
- Connect the PCMCIA cable to the computer data acquisition card.
- Connect the power cord to the computer power supply and this to the laptop.
- Connect the power cord to the power strip.
- Proceed with ***Installation: Color Printer***.

To learn more about the computer, for the registration card of the operating system and more information, please refer to the computer manual provided with the computer.

All *SoftTrak* components that require electric power must be connected to the power strip to function properly.

For the user's convenience, the power strip provided with the *SoftTrak* system is also a surge protector. Any guarantee or warranty concerning this strip is made solely by the strip's manufacturer. Either the *SoftTrak* manufacturer or distributor makes no warrantee or guarantee regarding this strip and assumes no liability for any bodily injury or property damage that may result from the use of this strip. Please refer to the instructional literature provided by the power strip's manufacturer for more information regarding its specifications and intended use.

For help in connecting the computer components, please refer to the computer manual provided with the computer.

The computer manual may contain instructions for components such as speakers, microphone, etc., which are not necessary for the *SoftTrak* system. Ignore such instructions.

Color Printer

The printer comes complete with power supply and one color cartridge.

Installation: Color Printer

- Open the box containing the *SoftTrak* printer and unpack it.
- Install the paper supports (if not directly connected to the

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

printer) following the instructions in the printer manual provided with the printer.

- Connect the printer to the computer using the printer cable: plug the free end into the printer port (the other end was connected to the computer during ***Installation: Computer***).
- Connect the printer to the power strip with the power supply.
- Proceed with ***Getting Ready: STEP 1***.

For help in installing the paper supports and in connecting the printer, please refer to the printer manual provided with the printer. To learn more about the printer, for the registration card, for customer support information and to order additional cartridges, refer to the printer manual provided with the printer.

The printer software has already been installed in the *SoftTrak* computer; it is only necessary to install the new cartridge. To install it, check the printer manual. If the installation is controlled by software, the following is an example of the procedure to start the printer software and install a new cartridge:

1. **Click Start on the Windows Taskbar.**

Figure 2-1. ***Windows Taskbar.***

2. **Select Programs.**

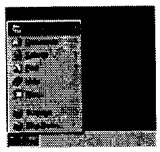


Figure 2-2. ***Windows Programs command.***

3. **Choose the printer software.**
4. **The printer software dialog box appears.**
5. **Click the Cartridge tab or button.**
6. **Select Install New Cartridge.**
7. **Follow the instructions on the screen.**

Copyright © 1999 Vestibular Technologies, Inc.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 60

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Copyright © 1999 Vestibular Technologies, Inc.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

3. Getting Started

3.1. Getting Ready for the Test Protocol

Turning on the *SoftTrak* System

Getting ready: STEP 1 Turn on the system

- Connect the power strip to a power outlet: the light on the power strip will then come on (if this is not the case, please refer to ***Appendix A: Troubleshooting*** for how to solve this problem).

Before proceeding with any testing, be sure to have the *SoftTrak* system properly installed. Failure to do so may result in damage to the *SoftTrak* system, and/or personal injuries.

Please refer to *Introduction: Safety Guidelines* for more information about the power strip.

Starting the *SoftTrak* Software

Getting ready: STEP 2 Start the software

- Turn on the *SoftTrak* printer (if not automatically turned on by turning on the computer).

Copyright © 1999 Vestibular Technologies, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 62

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

- Turn on the *SoftTrak* computer.
- Wait for the operating system and the *SoftTrak* software to load: a window will appear while the *SoftTrak* software is loading, with the indication of the current operating system installed on the computer and the software version currently in use.
- Please refer to ***Software Manual: Starting the SoftTrak Software*** if this is the first time the software is used.
- If prompted, input **User's ID** and **Password** in the login window, then click OK . If this information is not known, please contact the *SoftTrak* system **Administrator.**
- The *SoftTrak* software Main window will appear with the list of the test sessions already done using the *SoftTrak* system. Proceed with ***Getting ready: STEP 3a*** if this is the first time a patient is being tested. If the patient record is already in the list in the Main window, go to ***Getting ready: STEP 3b.***

For more information, please refer to ***Software Manual: Starting the SoftTrak Software***.

Resting the mouse over any fields for a couple of seconds will activate the TIP connected to such field, with a quick explanation of its functionality.

Starting a New Patient Record

Getting ready: STEP 3a Start a new patient record

- In the *SoftTrak* software Main window, click New Patient
  The Patient's Information window will appear.
- Fill in all the information.
- Click Next > and prepare the patient for testing.

For more information, please refer to ***Software Manual: Main Window*** and ***Software Manual: Patient's Information*** and to the specific hardware manuals of the *VTI Trak* family products to be used with the *SoftTrak* system.

The following information MUST be entered:

- Patient's **First** and **Last Name,** or **SSN/ID** (social security number or patient ID);
- **Sex** (M or F);
- **Height** (with measurements units, e.g., 1.70 m, 170 cm, 67" or 5'7");
- **Date of Birth** (in any format Windows understands,

Copyright © 1999 Vestibular Technologies, Inc.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

e.g., 10-19-69, 19-10-69, 10/19/69, Oct/19/1969, 19 Oct 69);

- **Operator's Name**.

As a reminder, these items are underlined. The *SoftTrak* software will not proceed further until all the required information has been entered. A specific message will appear if something is missing or wrong.

Starting a New Session

Getting ready: STEP 3b Start a new session

- In the *SoftTrak software* Main window, click on the patient's name (if the patient's name appears multiple times, it does not matter which one is chosen). The corresponding row will appear highlighted.
- Click [New Session]. The Patient's Information window will appear.
- Verify the Patient's Information and make corrections, if necessary.
- Add the **Clinical Contacts**.
- If desired, add **Notes**.
- Click [Next>] and prepare the patient for testing.

For more information, please refer to ***Software Manual: Main Window*** and ***Software Manual: Patient's Information*** and to the specific hardware manuals of the *VTI Trak* family products to be used with the *SoftTrak* system.

The Operator's name must be entered. As a reminder, this item is underlined. The *SoftTrak* software will not proceed further until the required information has been entered. A message will appear if the Operator's name is missing.

3.2.

Copyright © 1999 Vestibular Technologies, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 64

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

3.3. Test Protocol

Test Selection

Test Protocol: Test Selection

- The *SoftTrak* software Tests window is on the screen.
- Select the plug-in(s) connected to the *SoftTrak* computer, using the appropriate tab.
- Select the aspect of the patient's health to be tested by clicking the corresponding System Calibration's [Acquire]. Follow the instruction in the ***Test Protocol: System Calibration***.
  When done, the status of the system calibration changes from TO BE PERFORMED to PERFORMED.
- Select any one of the available tests. Follow the instruction in the specific ***Test Protocol: Test***.
  When done, the status of the test changes from TO BE PERFORMED to PERFORMED.
  If desired (and available), view the result of this test by clicking [View Results] (please refer to ***Print and Interpret the Results***).
- Repeat the above step for all the desired tests.
- Repeat the above three steps for all the desired aspects of the patient's health to be tested.
- Repeat the procedure for all the plug-ins connected to the *SoftTrak* computer.
- When done with the test protocol, click [Finish] to return to the Main window.

The tests can be performed in any order. However, it is suggested to perform all tests designed to assess a specific health aspect, before proceeding with the next aspect.
When a different System Calibration is performed, the status of the already performed calibrations is changed from PERFORMED to TO BE PERFORMED to indicate that it needs to be retaken if any test has to be retaken later.
THIS DOES NOT AFFECT THE PERFORMED TESTS.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

For more information, please refer to ***SoftTrak: Software Manual: Test Protocol*** as well as ***Software Manual: Test Protocol*** for each *VTI Trak* products that can be interfaced with the *SoftTrak* system.

Test Procedure

System Calibration

Test Protocol: System Calibration:

- The *SoftTrak* software Acquisition window is on the screen for the system calibration.
- Click [Start] to start the system calibration.
- When the message "**Calibration Completed Successfully**" appears in the Status, click [Close] to return to the ***Test Protocol: Test Selection.***

For more information, please refer to ***Software Manual: Test Protocol: Calibration***.

Test

Test Protocol: Test

- The *SoftTrak* software Acquisition window is on the screen.
- Follow the instructions on the screen to correctly administer the desired test.
- Click [Start] to start the test acquisition.
- When the message "**Test Completed Successfully**" appears in the Status, click [Close] to return to the ***Test Protocol: Test Selection***.

For more information, please refer to ***Software Manual: Test Protocol: Test***.

Copyright © 1999 Vestibular Technologies, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 66

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

3.4. Printing and Interpreting the Results

Patient's Report

Results: STEP 1 Patient's Report

- From the *SoftTrak* Main window, click [Patient's Report]. The first page of the *SoftTrak* Patient's Report is on the screen.
- To print this report, click [Print] (for more information, please refer to ***Software Manual: Reports: Printing the Reports***).
- If the previous window was the Main window, click [Next Page >] to see the next page of the Patient's Report.

  If the previous window was the Tests window, click [Close Report] to return to ***Test Protocol: Test Selection***.

For more information, please refer to ***Software Manual: Reports: Patient's Report***.

Full Report

Results: STEP 2 Full Report

- From the *SoftTrak* software Main window, click [Full Report]. The *SoftTrak* Full Report: Page 1 is on the screen, with the Patient's Information.
- If desired, add or edit the **Notes.**
- To print this report, click [Print] (for more information, please refer to ***Software Manual: Reports: Printing the Report***).
- Click [Next Page >] to see the next page of the Full Report.

For more information, please refer to ***Software Manual: Reports: Full Report***.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

3.5. Turning off the *SoftTrak* System

Turn off the system

- From the *SoftTrak* software Main window, click [Exit]. The *SoftTrak* software will end.
- Click [Start] on the Windows Taskbar.

Figure 3-1. ***Windows Taskbar.***

- Select Shut Down.

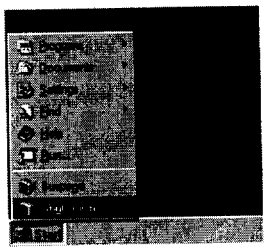


Figure 3-2. ***Windows Shut Down command.***

- The following window will appear.

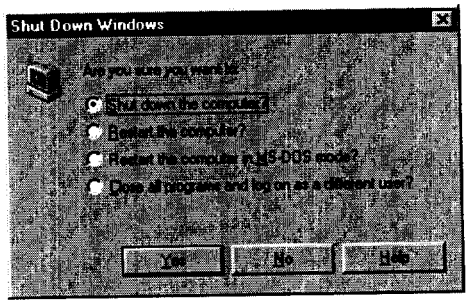


Figure 3-3. ***Windows Shut Down window.***

- Click [Yes]. The *SoftTrak* computer will automatically shut down.
- Turn off the *SoftTrak* printer (if not automatically turned off by turning off the computer).
- Disconnect the power strip from the power outlet.
- Start from ***Getting ready: STEP 1*** next time the *SoftTrak* system is used.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

4. Software Manual

4.1. Starting the *SoftTrak* software

Only one copy of the *SoftTrak* software can be running at any time, since the software controls unique hardware devices. If a copy of the software is started while another is already running, a message will appear, and the new copy will be terminated.

The *SoftTrak* software checks if the system is configured properly. If the data acquisition card identified as Device 1 is not configured, a message will appear.
Click OK to start the configuration interface. The SoftTrak software will be terminated. Contact *SoftTrak* Customer Support for assistance, if needed.

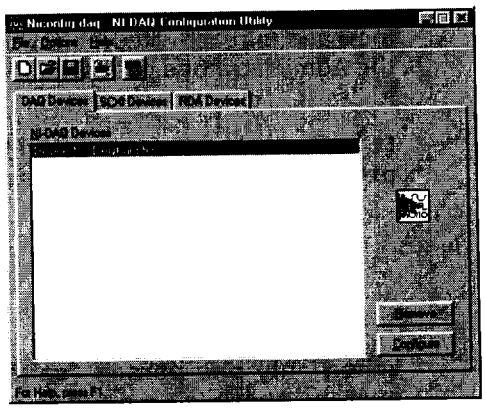


Figure 4-1. National Instruments: ***Configuration Utility.***

Copyright © 1999 Vestibular Technologies, Inc
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

The *SoftTrak* software checks if the system is configured properly. If the Device 1 is not supported by the *SoftTrak* software, a message will appear:
Click OK to start the configuration interface. The SoftTrak software will be terminated. Contact *SoftTrak* Customer Support for assistance, if needed.

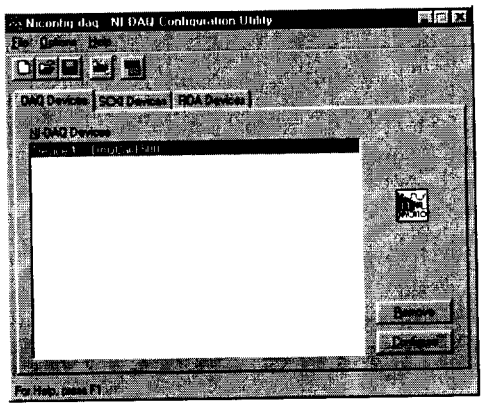


Figure 4-2. National Instruments: ***Configuration Utility.***

First Time the Software is Used

SoftTrak software supports multiple users. The first time the software is used, a message will appear on the screen, reminding the user (by default called **Administrator**) that there are no other user's profiles defined and that the Administrator's password is not set.

Click OK to open the Main window. By clicking on the check box, this message will not appear at the start up of the software, even if user's profiles are not defined or the Administrator's password is not set. This message is reactivated only when no other user's profiles are defined and the Administrator's password is deleted.

It is strongly recommended to set the Administrator's password, to prevent unauthorized access.

When only one person (called Administrator) is using the *SoftTrak* system, there is no need to set up other user's profiles.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Setting up User's Profiles

Only the **Administrator** can set up new user's profiles.

Set up a new user's profile

- Start the *SoftTrak* software and log in as **Administrator**.
- Click [Options]. The Options window will appear.
- Click the **Users Administration** tab. The Options: Users Administration section will appear.
- Click [New]. The Options: User's Profile section will appear.
- Fill in all the information for the new user.
- Click [OK] to close the Options: User's Profile section and save the new user's profile.
- Click [OK] to close the Options window.
- Click [OK] to exit the software.
- Inform the new user of the assigned User's ID and Password to be used in the login.

For more information, please refer to ***Software Manual: Options: User's Profile***.

Customizing the Reports Header

Every user can customize the reports header.

Customize the reports header

- With the *SoftTrak* software running click [Options]. The Options: Current User's Preferences section will appear.
- Click [Edit].
- The Windows' default word processor associated with .RTF files starts.
- Modify the header of the reports. If desired, add a personalized letterhead with name, address, logo, and so on.
- When done, close the word processor to return to the *SoftTrak* software.

For more information, please refer to ***Software Manual: Options: Current User's Preferences: Buttons***.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Login Window

The Login window appears only when multiple user's profiles are set, or when the single user (Administrator) has set a password.

Both the **User's ID** and **Password** must be input for the software to start: if either one is missing or incorrect a message will appear.

Select [OK] to return to the Login window.

The software allows only three login trials: this is a safety feature to prevent unauthorized access.

The software accesses the **User's Data Files Directory** specified for the user logging in. If there is any problem finding such a directory, a message will appear. Contact *SoftTrak* Customer Support for instructions.

Buttons

[OK] If the login is correct, it closes the Login window, and opens the Main window.

[Cancel] It closes the Login window, and exits the *SoftTrak* software. To start the software again, double click on the *SoftTrak* software icon on the screen.

4.2. Main window

This is the interface for the *SoftTrak* software. It allows the user to keep track of the patients tested using the *SoftTrak* system, and to perform new sessions of tests. It can be enlarged.

The Main window includes buttons to navigate through the software, a list of sessions of completed tests, and a Status bar.

The Status bar shows:

- messages from the *SoftTrak* software: the number of Sessions in the Sessions List, or what the program is doing (such as Updating Sessions List, or Printing Session # of ##);
- current date and time.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

It is necessary to preserve Data Files integrity that the computer date and time are correct. If they are incorrect, change them according to the following instructions:

- **Double click on the time on the Windows Taskbar.**

Figure 4-3. ***Windows Taskbar.***

- **The standard Windows interface to adjust date and time will appear.**

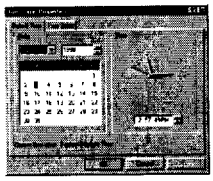


Figure 4-4. ***Windows Programs command.***

- **Select the correct date and/or time**
- **Click OK to update the system date and time and return to the *SoftTrak* software.**

***SoftTrak* software supports multiple users. Only the patients tested by the user logged in will appear on the list. One user cannot access another user's patient records (unless logging in using another user's ID and password).**

Resting the mouse over any fields for a couple of seconds will activate the TIP connected to such field, with a quick explanation of its functionality.

Sessions List

The Sessions List shows information regarding the patients already tested. Each time a patient is tested using the *SoftTrak* system, a new entry is created in the list, identified by the patient name and the progressive number of such a session.

The *SoftTrak* software identifies each test session by the patient name and the session number. One patient can have several entries in the list, one for each test session for that patient. Each of these entries will have a different session number.

Copyright © 1999 Vesnbular Technologies, Inc

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 74

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

The list shows the following information:

- **Patient's Name** (first name, middle initial, and last name);
- **SSN/ID**, social security number or patient's ID;
- **City**, of patient's address;
- **Zip/Postal Code**, of patient's address;
- **Session #**, the session number for that particular test session;
- **Started on**, the date and time when the test session was started;
- **Operator**, the clinician who used the *SoftTrak* system to test the patient;
- **Referred By**, the clinician who requested the test session;
- **Results To**, the clinician who needs to see the results of the test session;
- **Data File**, the name of the computer file associated with that particular test session.

To view all of the columns, use the scroll bar at the bottom of the list.

It is possible to adjust the width of the columns by moving the vertical line between columns. However, the next time the software runs, the default column sizes are restored.

Sorting Sessions List

To sort the sessions list, click on the title of the column to sort by. At the first click, the list will be sorted in ascending order, at the second in descending order by the selected column.

Buttons

It opens the Patient's Information window to input a new patient's information and it is always activated when the *SoftTrak* software starts.

It starts a New Session for the selected patient: the Patient's Information window will appear (the patient's information can be updated). It is available only when a patient's name is selected from the Sessions List (the corresponding information will appear highlighted).

It shows the Patient's Report for the selected test session. It is available only when a patient's name is selected from the Sessions List (the corresponding information will appear highlighted).

It shows the Full Report for the selected test session. It is available only when a patient's name is selected from the Sessions List (the

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

corresponding information will appear highlighted).

It opens the Print Sessions List window, to print the Sessions List.

It opens the Options window, to customize the *SoftTrak* software and allow the Administrator to create, edit or delete the user's profiles.

It closes the Main window, and ends the *SoftTrak* software. To restart the software, double click on the *SoftTrak* icon on the screen.

4.3. Printing the Sessions List

It allows to print the Sessions List as it appears on the screen, with the column headers.

The available options are:

- **Printer**, by default the *SoftTrak* printer. There is also the possibility to print the Session List to a file, by selecting the printer: Print to File. The list will be printed to the file Print.txt located in the directory \VTI\SoftTrak\.
- **Orientation**, the paper orientation, Portrait or Landscape. The width of the Sessions List will be scaled to fit the page. If the length of the list exceeds one page, the list is printed on multiple pages, with the column headers repeated every page.

Buttons

It executes the print command, closes the Print Sessions List window, and returns to the Main window. In the Main window, during the printing process, the following message will appear in the Status bar: **Printing Session #** (the session in printing) **of ##** (the total number of sessions found in the Sessions List).

It cancels the print command , closes the Print Sessions List window, and returns to the Main window.

Copyright © 1999 Vestibular Technologies, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 76

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

4.4. Options

The *SoftTrak* software supports multiple users allowing each user to set personal preferences. The **Administrator** is a special user who has additional capabilities, such as editing user's profiles, adding new user's profiles and deleting existing ones.

If the **Administrator** is logged in and has not set a password, a message will appear as a reminder to set a password.

Click [No] and the Options window will appear.

Click [Yes] and the **User's Profile** for the Administrator will appear so the Administrator can set a password.

Buttons

[OK] It closes the Options window, saves any changes made, and returns to the Main window.

[Cancel] It closes the Options window, discards any changes made, and returns to the Main window.

Current User's Preferences

Any user of the *SoftTrak* software can set the following preferences:

- **Measurements Units**: used by the software in the reports, and as default for the patient's height in the Patient's Information window. The options are:
  - **Customary** (or English units - this is the default);
  - **SI** (or Metric units);
  - **Centimetric**;
  - **Millimetric**.
- **Default Command after a Test**: after a step of the test protocol is completed, pressing the Enter key on the keyboard will either show the results of the test in the form of the Patient's Report, or go on to the next test protocol step, depending on which option is selected. The options are:
  - **View Results**;
  - **Next Test**.
- **Report Header**: it is possible to customize the look of the reports by creating a personalized letterhead. This can be done by clicking [Edit].

Copyright © 1992 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

These preferences will only affect the user who is currently logged in. This allows different users to save their own settings.

Buttons

It starts the Windows' default word processor associated with .RTF files, to modify the header of the reports. If desired, add a personalized letterhead with name, address, logo, and so on. When done, close the word processor to return to the *SoftTrak* software. The newly defined letterhead will be used in all the reports generated by the user who created the header. If there is not a word processor associated with .RTF files a message will appear. Contact *SoftTrak* Customer Support for instructions.

Users Administration

This section is available only for the Administrator. All other users do not have access to this section.

The list of all the user's profiles currently defined contains the following:

- **User's ID**, used in the login;
- **User's Name**, the true name of the user; it can be different from the User's ID;
- **Data Files Directory**, where the user's data files are stored.

It is possible to adjust the width of the columns by moving the vertical line between columns. However, the next time the software runs, the default column sizes are restored.

The **Administrator** can add, edit or remove user's profiles from the list.

The Administrator's profile appears in bold characters, as a reminder of the additional privileges given to such a user.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Sorting User's Profile List

To sort the User's Profiles List click on the title of the column to sort by. After the first click, the list is sorted in ascending order, after the second in descending order by the selected column.

Buttons

It opens a blank User's Profile section to add a new user.

It opens the User's Profile section to make changes to a user's profile and is available only when a user's profile is selected (highlighted) from the list.

Once a User's Profile has been defined, only the User's Name and Password can be modified. The User's ID CANNOT be changed.

It deletes the user's profile and is available only when a user's profile, different from **Administrator**, is selected (highlighted) from the list. Before deleting the selected user's profile, a message will appear, with the selected user's ID.

Click

to delete the user's profile from the list (the user's data files and header will remain and it is possible to re-access them by creating a new profile and choosing the same User's ID and data file directory as the deleted one). Click

to return to the Users Administration window without deleting the selected user profile.

The Administrator cannot be deleted.

User's Profile

The User's Profile section is accessible only by the Administrator. All other users do not have access to this section.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

The **Administrator** can create new user's profiles, edit or delete preexisting ones. A user's profile is defined by:

- **User's Name**, to identify the user;

Use the User's Name field to uniquely identify the user. Information such as the name, address, and telephone number can be entered here.

- **User's ID**, used in the login. It must be specified, otherwise a message will appear as a reminder to do so.

  Click [OK] to return to the User's Profile section, and add the User's ID.

  If the User's ID has already been assigned to another user, a message will appear, as a reminder to choose a different ID.

  Click [OK] to return to the User's Profile section, and change the User's ID.

It is possible to see the list of the currently defined users: click on the Users Administration tab to view the list (all the buttons in this section will be disabled).

- **Password**, used in the login. No password is also a valid password. However, for the Administrator it is strongly recommended to set a password to prevent access to the user's profiles from unauthorized persons.
- **Confirm Password**, retype the password to verify it was entered correctly. If the Password and Confirm Password entries are different, a message will appear.

  Click [OK] to return to the User's Profile section, and re-type the Password and Confirm Password.
- **User's Data Files Directory**, where the user's data files are stored. By default, the directory name is suggested by the program as **\VTI\SoftTrak\Users*UserID*** where the ***UserID*** is the **User's ID** currently specified. The User's Data Files Directory can be changed by clicking [...] .

The feature to change directory can be used to have different users sharing the same Data Files Directory: instead of letting the software creating the User's Data Files Directory automatically, create one common Data Files Directory and choose it as User's Data Files Directory for some or all the users. However, having different users sharing the same Data Files Directory will give them access to the same patients' information.

Copyright © 1999 Vestibular Technologies, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 80

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Buttons

It opens the standard Windows' interface to change the directory where the User's Data Files are stored. The new selected directory will appear in the User's Data Files Directory field in the Users Administration section.

It is necessary to input a dummy File Name in order to return to the User's Profile section. This dummy File Name will not be used by the *SoftTrak* software.

If the selected directory is not valid, a message will appear.

Click to return to the Change User's Data Files Directory, and select a valid directory.

It closes the User's Profile section, creates the new user's profile, and returns to the Users Administration section.

It closes the User's Profile section, without creating the new user's profile, and returns to the Users Administration section.

4.5. Patient's Information

The Patient's Information includes the following information:

- **Patient's Information**:
  - **First Name**, the patient's given name;
  - **Middle Initial**, the initial of the patient's second name;
  - **Last Name**, the patient's surname or family name;
  - **SSN/ID**, the patient's social security number or another unique patient's ID;

The combination First Name/Last Name or SSN/ID MUST be specified to uniquely identify the patient. The *SoftTrak* software will not proceed further if the patient is not uniquely identified, and a message will appear as a reminder.

Click to return to the Patient's Information, and uniquely identify the patient.

- **Sex**, **M** for male and **F** for female;

Copyright © 1999 Vestibular Technologies, L.L.C.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

The patient's Sex MUST be specified. The *SoftTrak* software will not proceed further if the patient's sex is not M or F, and a message will appear as a reminder.
Click OK to return to the Patient's Information, and specify the patient's Sex.

- **Height**, the height of the patient with measurement units (e.g., 1.70 m, 170 cm, 67" or 5'7").

If no measurement units are specified, the Current User's Preferences Measurement Units selection will be used as default (for Customary units, inches are the default).

The patient's height MUST be specified. The *SoftTrak* software will not proceed further if the patient's height is missing, and a message will appear as a reminder.
Click OK to return to the Patient's Information, and specify a valid patient's Height.

The patient's height must be between 15.75" (0.4 m) and 110.25" (2.8 m).

- **Date of Birth,** in any format Windows understands (e.g., 19-10-69, 10-19-69, 10/19/69, Oct/19/69, 19 Oct 1969).

The patient's Date of Birth MUST be specified. The *SoftTrak* software will not proceed further if the patient's Date of Birth is missing, and a message will appear as a reminder.
Click OK to return to the Patient's Information, and specify a valid patient's Date of Birth.

The *SoftTrak* software automatically capitalizes names and sex, converts the height in the Measurement Units selected in the Current User's Preferences, and the date in the format "Month Day 4-digit-year". Before proceeding with the test protocol, check if what the software interpreted is correct, and if necessary make changes.

Copyright © 1999 Vestibular Technologies, Inc.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 82

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

- **Address,** the patient's home address (Street, City, State/Prov., ZIP/Postal Code, Phone, e-mail).

The Patient's Information is unique for any patient. Any change will appear in all the test sessions for the patient.

- **Clinical Contacts**:
  - **Operator**, the clinician who is using the *SoftTrak* system to test the patient:
    - **Name;**

The Operator's Name MUST be specified. The *SoftTrak* software will not proceed further if the Operator's Name is missing, and a message will appear as a reminder.
Click **to return to the Patient's Information, and specify the Operator's Name.**

    - **Phone**;
    - **Fax**;
    - **e-mail**;
  - **Referred By**, the clinician who requested the tests. It could be the same as the Operator.
    - **Name**;
    - **UPIN**;
    - **Phone**;
    - **Fax**;
    - **e-mail**.
  - **Results To Be Sent To**, the clinician that needs to see the results of the tests. It could be the same as the **Referred By** clinician.
    - **Name**;
    - **UPIN**;
    - **Phone**;
    - **Fax**;
    - **e-mail**.

For the Clinical Contacts Name, enter a new name or select an existing one from the drop down list. If the Name has been selected from the drop down list, all the other information is automatically shown. Any changes to this information will be stored and used the next time the same Clinical Contacts Name is selected.

- **Notes**, regarding the patient.

 Copyright © 1995 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

These notes are the equivalent of a patient's medical record, and could be used to keep track of the patient's history. Information such as patient conditions, medication, or diagnosis can be recorded here. These notes can be updated every test session, adding new information. They are shown in the Full Report: Page 1, and can be printed.

There is no length limit for the Notes.

As a reminder, the information that MUST be entered is underlined.

Buttons

< Previous

It closes the Patient's Information window, and returns to the main window, without saving the patient's information. A message will appear asking for confirmation.

Click Yes to delete the test session, or No if < Previous was clicked by mistake.

Next >

It closes the Patient's Information window, and opens the Acquisition window in the *SoftTrak* software test protocol.

Copyright © 1999 Vestibular Technologies, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
84

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

4.6. Test Protocol

The tests can be performed in any order. However, it is suggested to perform all tests designed to assess a specific health aspect, before proceeding with the next aspect.

The test data are saved only when Finish is clicked. If something goes wrong during one of the tests, it is possible to redo that test.

While the patient is performing the test, note anything that can influence the results of the test and if necessary redo the test. When analyzing the results in the Full Report, it is possible to add all the test notes to the results for easy comparison between different test sessions. Also keep track of how the patient feels in general and especially while performing the test.

Test Selection

The Tests window allows the selection of which test to perform. The available tests are grouped according to the aspects of the patient's health to be tested.

Each test has a status to remind if it has been performed or not:

- **To Be Performed**, written in red, indicating that the particular test has yet to be performed;
- **Performed**, written in green, indicating that the particular test has been performed.

To select a test click Acquire on the corresponding button.

To view the results of a performed test (once the corresponding status becomes **Performed**), click the View Results button.

The results for some tests are available only when all tests of a specific type have been performed.

Tests Selection

The following tests are available for the EyeTrak plug-in:

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

- **Smooth pursuit**, when the patient is asked to follow with the eyes a target moving sinusoidally on the screen, keeping the head stationary;
- **Saccades**, when the patient is asked to follow with the eyes a target moving randomly from one position to another on the screen, keeping the head stationary;
- **Optokinetic**, when the patient is asked to count the number of stripes moving across the screen, keeping the head stationary;
- **Active head rotation**, when the patient is asked to shake the head keeping the eyes fixed on a target on the screen, following a metronome for the pace;
- **Active body rotation**, when the patient is asked to shake the body and the head keeping the eyes fixed on a target on the screen, following a metronome for the pace;
- **Gaze**, when the patient is asked stare at a target in different position on the screen, keeping the head stationary;
- **Spontaneous nystagmus**, when the patient with the eyes covered is asked stare at a fixating light as soon as it appears, keeping the head stationary;
- **Positional head**, when the patient's head with the eyes covered is moved to the left and to the right by the clinician and held in such a position for some time;
- **Positional body**, when the patient's body with the eyes covered is moved on the left and on the right side by the clinician and held in such a position for some time;
- **Hallpike-Dix**, when the patient with the eyes covered is subjected to the Hallpike-Dix position;
- **High frequency head rotation**, when the patient with the eyes covered is asked to shake the head as fast as possible and then stop;
- **Caloric**, when the patient with the eyes covered is subjected to the caloric test;

Buttons

It closes the Tests window, and returns to the Patient's Information window.

It closes the Tests window, saves the results from all the performed tests, along with the patient's information, and returns to the Main window. It becomes available after at least one of the conditions has been successfully tested.

If not all the tests have been performed, a message will appear asking for confirmation.

Click to close the test session, or if was clicked by mistake.

Copyright © 1999 Vestibular Technologies, Inc

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
86

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

Once the session is closed, it is not possible to add more tests. A New Session must be started.

It opens the Acquisition window to acquire the specific test. If in the **Current User's Preferences** the selection was **Default command after a test: Next**, the keyboard **Enter** key does the same thing as this button, allowing to acquire all tests one after another in the same order as they are listed on the screen.

It opens the Report window with the results of the specific test in the Patient's Report format. This is available after the specified test has been successfully performed. If in the **Current User's Preferences** the selection was **Default command after a test: View Results**, after an acquisition the keyboard **Enter** key does the same thing as this button.

Calibration

The calibration is the acquisition the software uses as reference for the following tests. There is one calibration for each aspect to be tested.

During the calibration, in the Calibration: Tests window the **Status** displays the messages:

- **System Ready**, when the system is waiting for the user to press to start the acquisition.

- **Test in Progress**, when the system is performing the acquisition. The Status Bar will show the progress of the acquisition.
- **Processing Data**, when the system is processing the data.
- **Calibration Completed Successfully**, when the acquisition is done, and the system is ready to go back to the Acquisition window (using) for the next test, or for repeating the same acquisition (using).

If there are any problems during any calibration, a message will appear (please refer to ***Appendix A: Troubleshooting*** for how to solve this problem).

Click to return to the Acquisition: Tests window.

Copyright © 1999 Vestibular Technologies, Inc

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

The *SoftTrak* software checks if the system is working properly. If this is not the case, the Status will show a message pertinent to the problem encountered. The following are the possible messages (please refer to *Appendix A: Troubleshooting* for how to solve these problems):

- **No Data Acquisition Device is specified;**
- **No Instrument is specified**

Buttons

It starts the data acquisition for the Calibration. Once the calibration has been successfully performed, this button is replaced with

.

It repeats the Calibration. It appears after the system has been calibrated once, replacing

.

It closes the Acquisition window, updates the system calibration status, and returns to the Tests window.

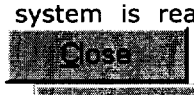
Test

The test is the acquisition the software uses.

For each test, the instructions are on the screen, and when applicable targets or real time eye movement display will appear.

During the test, in the Acquisition window, the **Status** displays the messages:

- **System Ready**, when the system is waiting for the user to press

to start the acquisition.
- **Test in Progress**, when the system is performing the acquisition. The Status Bar will show the progress of the acquisition.
- **Processing Data**, when the system is processing the data.
- **Test Completed Successfully**, when the acquisition is done, and the system is ready to go back to the Tests window (using 

), or for repeating the same acquisition (using

)

If there are any problems during any test, a message will appear (please refer to ***Appendix A: Troubleshooting*** for how to solve this problem).

Click

to return to the Acquisition: Tests window.

Copyright © 1999 Vestibular Technologies, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 88

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

The *SoftTrak* software checks if the system is working properly. If this is not the case, the Status will show a message pertinent to the problem encountered. The following are the possible messages (please refer to *Appendix A: Troubleshooting* for how to solve these problems):

- **No Data Acquisition Device is specified;**
- **No Instrument is specified.**

Buttons

It starts the data acquisition for the specific test Once the test has been successfully performed, this button is replaced with

.

It repeats the data acquisition for the specific test. It appears after the test has been performed once, replacing

.

It closes the Acquisition window, updates the specific test status, and returns to the Tests window.

4.7. Reports

The Reports show the results of the selected session: this can be the current session during the test protocol, or the session highlighted in the Main window.

There are two types of reports available:

- **Patient's Report**: a simplified version, with a description of the test results. This report is meant to be given to the patient and does not include information that could compromise patient-physician confidentiality. It is shown during the test protocol, when

is selected.
- **Full Report**: a detailed report intended to be filed with the patient chart. The patient's information as well as physician names and test notes are included, together with detailed test results.

The reports are shown on the screen as they will appear when printed on paper. They cannot be edited, except for the Header and Notes sections.

To customize the Report Header, from the Main window select

, then in the Current User's Preferences

. The Report footer will contain the Vestibular Technologies, Inc. logo, and, if the user is certified, the

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

certification logo. The footer cannot be edited.

The measurement units are determined by the selection in the Current User's Preferences section of the Options window. To select a different set of units, select Options from the Main window, then change the Measurement Units selection .

To monitor the patient's health, it is good practice to print the Full Report after every test session. Comparing the results from different test sessions, it is possible to evaluate the patient' s health over time.

Buttons

Close Report — It closes the report, and returns to the previous window (the Main window if Patient's Report or Full Report was used to show the report, or the Acquisition window if View Results was used to show the report).

Print — It opens the Print Report window, allowing to print the report (either the current page or all the pages contained in the report).

Next Page > — It shows the next page of the report. It is available only when there is a next page. It is not available when the report is shown during the acquisition using View Results . The keyboard **Page Down** key does the same thing as this button.

< Previous Page — It shows the previous page of the report. It is available only when there is a previous page. It is not available when the report is shown during the acquisition using View Results . The keyboard **Page Up** key does the same thing as this button.

Printing the Reports

It is possible to print one page or all pages of the report.

The available options are:

Copyright © 1999 Vestibular Technologies, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 90

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

- **Where to print**, select the *SoftTrak* printer.

It is not possible to print to other devices. Selecting Print to File will not produce anything readable.

- **Print Current Page**, only the page currently shown on the screen will be printed.
- **Print All Pages**, all the available pages of the current report will be printed. It is not available when the report is shown during the acquisition using View Results .

Buttons

OK — It closes the Print Report window, prints the selected page(s) of the report, and returns to the Report window.

Cancel — It closes the print Report window, cancels the printing command, and returns to the Report window.

Patient's Report

Each test has one page of results, showing the eyes movement as a strip chart. When applicable, statistical analysis is performed. When applicable, parameters such as gain and phase, target trace and head movement are displayed as well.

A brief description of the results shown on the screen is also included for the patient comprehension.

Furthermore a one page is available with a summary report comprehensive of all the performed tests.

Full Report

Page 1 of the Full Report shows the Patient's Information.

Notes can be added to all pages of the Full Report.

There is no length limit for the notes. However, only the lines that fit on the screen will be printed.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

The notes on Page 1 are the equivalent of a patient's medical record, and could be used to keep track of the patient's history. Information such as patient conditions, medication, or diagnosis can be recorded here. These notes can be updated every test session, adding new information. They are shown in the Full Report: Page 1, and can be printed.

The Notes on the other pages are specific for each test session, and should be pertinent to the specific tests, containing information regarding how the patient behaved during the test (for example, the patient had problems performing some tests). They can also be used to comment the results in comparison with results from previous test sessions or different patients.

Page 1

This page shows the Patient's Information.

This page contains the **Patient's Information** as entered in the Patient's Information window. For a description of the Patient's Information, please refer to ***Software Manual: Patient's Information***.

The Notes written in the Patient's information window can be edited here: the text box labeled **Notes** can be used as any text editor, adding information regarding the test session.

Other Pages

The other pages of the Full Report contain the results for each test performed. There is the eyes movement as a strip chart, both left and right eyes and when applicable the vertical as well as the horizontal eye movement. When applicable, statistical analysis is performed, to identify maximum, minimum and average of parameters such as gain and phase. If the test required it, target trace and/or head movement are displayed as well.

For each test there is the possibility to add Notes: the text box labeled **Notes** can be used as any text editor, adding information regarding the specific test performed.

Furthermore a one page is available with a summary report comprehensive of all the performed tests, with the possibility to include an overall description of the patient performance as well as suggestion for further testing and/or therapy.

4.8. On-line Help

The *SoftTrak* software offers an on-line Help that gives specific information about the *SoftTrak* window currently shown. It uses the standard Windows Help interface and conventions.

 Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

On-line Help

- With the *SoftTrak* software running, press the F1 key on your keyboard.
- The on-line help will start, at the page corresponding to the active *SoftTrak* window, or to the selected command.

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

5. Appendix

5.1. Customer Support

If there is any question about the *SoftTrak* system, first look in the *SoftTrak* documentation provided with the *SoftTrak* system.

If an answer cannot be found, contact *SoftTrak* Customer Support.

90 Days Toll-Free Customer Support

For the first ninety (90) days after purchase of the *SoftTrak* system, there is a toll-free *SoftTrak* Customer Support at:

phone: **1-877-VTI-TRAK - Ext. 223**
(1-877-884-8725-223)
e-mail: **support@vestibtech.com**

9:00 A.M. to 5:00 P.M. ET
Monday through Friday
excluding holidays

After the first ninety (90) days, the customer support will be for a commercially reasonable fee.

Customer Support Procedures

When contacting *SoftTrak* Customer Support, be nearby the *SoftTrak* system and have the appropriate product documentation at hand. Be prepared to give the following information:

- the ***SoftTrak* System Number**;
- a description of what happened and what you were doing when the problem occurred;
- a description of how you tried to solve the problem.

Copyright © 1999 Vestibular Technologies, Inc

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

For customer support regarding the printer of the *SoftTrak* computer system, contact the corresponding manufacturer directly.

Product Return Procedure

When returning the *SoftTrak* system for service, replacement, credit or any other reason, please follow the steps below to ensure proper handling:

Customer Support: Product return procedure

- Contact *SoftTrak* Customer Support to receive a **Return Material Authorization Number** (RMA number), a **return address**, and shipping instructions. Please ensure that this RMA number appears on all documents, packaging materials and paperwork regarding this return item.
- Include the return address, contact person and any shipping instructions including method of shipment and any applicable account numbers.
- Ensure that the returned product is properly packaged for shipment in the original packaging box. Mark the shipping box with the RMA number.

5.2. Troubleshooting

The following is a list of the most common problems that could be encountered using the *SoftTrak* system, their probable cause, and how to solve them.

The light on the power strip is not on

There are different sources of this problem:

- The power strip is not plugged in the electrical power outlet. Plug it in.
- The power strip is not on. Turn the switch on.
- The power strip does not work. Replace the power strip.
- The electric outlet where the power strip is connected does not work. Contact an electrician.

The computer does not start

There are different sources of this problem:

Copyright © 1999 Vestibular Technologies, Inc.

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

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

- The computer power cable is not plugged in the power strip. Plug it in.
- The light on the power strip is not on. See preceding comments.
- The computer power cable does not work. Replace the cable.
- The computer does not start (the on light is not on). Press the power button again. If it does not start, contact *SoftTrak* Customer Support.

The printer does not start

There are different sources of this problem:

- The printer power cable is not plugged in the power strip. Plug it in.
- The light on the power strip is not on. See preceding comments.
- The printer power cable does not work. Replace the cable.
- The printer does not start. Contact the printer manufacturer for customer support.

The printer is on, but does not print

There are different sources of this problem:

- The printer cable is not plugged correctly in the printer port of the computer, or of the printer. Plug it in.
- The printer cable does not work. Replace the cable.
- The printer does not work. Contact the printer manufacturer for customer support.

The light on the platform cable transformer is not on

There are different sources of this problem:

- The transformer power cable is not plugged in the power strip. Plug it in.
- The light on the power strip is not on. See preceding comments.
- The transformer power cable does not work. Replace the cable.
- The transformer does not work. Contact *SoftTrak* Customer Support.

The light on the platform cable transformer is flashing

IMMEDIATELY unplug the transformer power cable from the power strip and contact *SoftTrak* Customer Support.

Copyright © 1999 Vestibular Technologies, Inc
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 96

Records Processed under FOIA Request # 2015-8762; Released by CDRH on 12-08-2015

No data acquisition device is specified *(software message)*

Contact *SoftTrak* Customer Support.

No instrument is specified *(software message)*

Contact *SoftTrak* Customer Support.

No data acquisition device configured as device 1 *(software message)*

Please refer to ***Software Manual: Starting the SoftTrak software***. Contact *SoftTrak* Customer Support for assistance, if needed.

Data acquisition not supported *(software message)*

Please refer to ***Software Manual: Starting the SoftTrak software***. Contact *SoftTrak* Customer Support for assistance, if needed.

The calibration did not complete successfully *(software message)*

There are different sources of this problem:

- During the calibration something happen that invalidated the acquisition. Try to do the calibration again. If the problem persists, contact *SoftTrak* Customer Support.
- The platform cable does not work. Contact *SoftTrak* Customer Support.
- The platform does not work. Contact *SoftTrak* Customer Support.

Copyright © 1999 Vestibular Technologies, Inc.

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