

MOBITRAK v3.00

VIDEO ENG SYSTEM FOR WINDOWS

OPERATING MANUAL

	TABLE OF CONTENTS		
	NEW FEATURES QUICK START INSTRUCTIONS	PAGE 3 4	
OPE	ERATING INSTRUCTIONS	10	
Ι.	OPERATIONAL CONSIDERATIONS	12	
II.	FUNCTIONAL DESCRIPTION	13	
III.	INSTALLATION INSTRUCTIONS	14	
IV.	OPERATING INSTRUCTIONS and MENU OPERATIONS	16	
	SETUP OPTIONS	16	
	SUMMARY PAGE HEADINGS	17	
	OPERATOR SETUP	17	
	CUSTOMIZE TEST PROTOCOL	18	
	FOLIO MANAGEMENT & OTHER OPTIONS	18	
	TEXT OVERLAY & VIDEO CONTROLS	19	
	ADVANCED TRACKING CONTROLS	19	
		20	
		22	
		23	
		23	
	EDIT & MARKING DATA	20 20	
		30	
	Graph Scale		
	Centering Data		
	Scrolling the Data		
	Test Information		
	PRINT FUNCTIONS	33	
		35	
	MARK OBSERVATIONS	36	
	RENAME TEST	36	
	DELETE TEST	37	
	REPEAT A TEST	37	
V.	INFRARED/VIDEO GOGGI E SPECIFICATIONS	38	
VI.	LIMITED WARRANTY	39	
VII.	COMPANY INFORMATION - Where to contact	40	
ADD	DENDUM	41	

- I. NORMAL VALUES & LITERATURE CITATIONS
- II. EXAMPLES OF MOBITRAK VIDEO ENG DATA & SUMMARY REPORT
- III. INSTALLATION DIAGRAM

NEW FEATURES IN MOBITRAK v3.00

Release of **Version 2.12** of TRAK Series software includes the following upgraded features:

- 1. **QUAD DIRECTIONAL GAZE TESTS**. New Gaze tests have been added that track the eye from the center of the screen to all four sides. These test the eye's ability to hold a target at an angle.
- 2. **EXPORT DATA**. The software can now export data from marked tests. This feature is under "File" on the Menu tab.

New from v 2.00:

- 3. <u>ACTIVE HEAD ROTATION.</u> Revised to included Gain, Asymmetry and Phase calculations and to plot these on a chart for both Horizontal and Vertical tests. A full new page is added to the Summary Report for this feature.
- 4. <u>FOLIO MANAGEMENT.</u> Changed to a more simplified format with all functions actuated by an array of buttons to be pushed by the mouse. Also, technique for moving or archiving folios allows for multiple folios to be selected and archived all at once. Archive folder is established at time of software installation on the main 'C:\' hard drive. Folios may be either copied or moved to the Archive folder.
- 5. <u>THREE POSITION FOOTSWITCH.</u> Footswitch has been revised to have a third switch for selecting 'NEXT TEST'. This additional switch is actuated by depressing the center portion of the main body of the Footswitch. FIXATION & PAUSE functions are unchanged.
- 6. <u>LARGE ON SCREEN TIMER.</u> During all tests, except Ocular Motor Tests, a large timer is shown on the Vertical tracing section of the VGA screen. This timer indicates the duration of the test and is calibrated in seconds and 60ths of seconds for the fractions.

QUICK START INSTRUCTIONS MOBITRAK v3.00

Turn on power to the IR/Video ENG System with the main power switch on the multiple outlet strip. Turn the computer on with the push button power switch on the front panel. It will boot to the WINDOWS DESKTOP. Double click on the MOBITRAK icon to start the program. Click OK or wait a few seconds to reach the '**Choose Operator**' screen.

Click on the desired Operator Protocol, then on OK to make the selection. This moves you to the Folio management window where you may select a previously entered patient or enter a new patient. To select an existing patient, click on the desired patient record then on Open. You may also locate an existing patient by entering the patient's ID number (all or partial) or the patient's name (all or part). 'To enter a new patient, click on New; this moves you to the Folio Information window.

To change or add an Operator Protocol, see page 9, #12 in the Operating Manual.

Enter your patient ID number. The folio Name is entered automatically by the computer. Enter the patient's Name and Age. Click to select Male or Female. The selected Operator Protocol is entered automatically. Enter any Subject Description information that you desire. For a new patient, the Set No. is automatically 001 for the first test session to be conducted on this patient. You may add the physician's name, or other reviewer, in the Reviewed By area and a Description of Set, if desired.

If this is a second test on this patient, change the Set No. to 002 and enter any desired Description of Set such as 'pre-op', 'post-op' or other comment. Click OK to continue.

NOTE: It is recommended that Marking and Analysis of Data collected be done <u>only after</u> the complete testing protocol is completed.

SET GOGGLE AND PATIENT

MOVE PATIENT TO POSITION & ADJUST GOGGLE - Seat the patient in front of the computer screen, adjust the goggle so the eye image is centered vertically and the goggle is snug but not uncomfortable to the patient.

CENTER CAMERA (Left & Right) - Now, with the goggle properly on the patient, center the camera (left & right) on the patient's eye by loosening the set screw on top of the camera mount. Turn the camera so the eye image is centered left & right. Now, **Gently But Snugly** tighten the set screw to hold the camera in position while the patient can shake their head left and right.

DO NOT OVERTIGHTEN SET SCREW, YOU WILL STRIP IT!!

FOCUS THE CAMERA - Use the lever that moves around the shaft of the camera to focus on the Iris (colored area around the pupil) of the patient's eye.

SET PROPER TRACKING LEVEL (Whitespace in pupil *only*) - Double click on the first test on the Protocol list at the Top Right of the monitor screen. Choosing a test activates the tracking level to appear in the pupil of the eye image. The usual protocol is the "TRACKING .4 Hz" test to do the horizontal tracking at 0.4 Hz. Remove the eye cover over the left eye. The target is presented to

the left eye looking through the goggle (when the camera is on the right eye). Press the 'A' key or click on the Auto Capture button at the top right of the screen to assist the computer lock-on of the patient's pupils. You should see a clean white circle with cross hairs covering the patient's pupils.

THE CROSSHAIRS CENTER THEMSELVES ON THE WHITESPACE OF THE IMAGE. IF THERE IS WHITESPACE OUTSIDE THE PUPIL, THE CROSSHAIRS WILL JUMP, CAUSING BAD DATA COLLECTION.

The 'A' key sets the whitespace to a default level. You can adjust this level by clicking the "Done" button until the folio is closed. Go to "Options->Video Setup" on the menu. Adjust the "Tracking Level" slider to a new position and click OK. Now, whenever you click "Autocapture" or hit the 'A' key, the new tracking level that you set will appear in the pupil.

You can micro-adjust the whitespace also. On the laptop computer, hit the "Num Lk" button to activate the keypad feature on the laptop. The keypad starts at the letter 'U' on the keyboard. If you look closely at the front edge of the keys, you will see numbers. Use the "-" key at the top of the keyboard to reduce the whitespace. Use the ";" key under the right pinky (there is a small "+" sign on the front edge of that key that is active) to increase the whitespace in the pupil. Use this as often as you need to.

Adjust until ONLY the pupil is completely white AND THE CROSSHAIRS ARE STABLE IN THE CENTER OF THE PUPIL. THIS IS THE MOST IMPORTANT STEP TO ACCURATE DATA COLLECTION. CHECK THIS BEFORE EVERY TEST.

OCULAR MOTOR TESTS

PROPER DISTANCE FROM SCREEN STIMULUS - Make sure the patient is the proper distance from the laptop computer screen stimulus and that the black stimulus area is centered in the see through area of the goggle. This should be about 20.75 inches from the patient's eyeball to the computer screen. A quick way to check the proper distance is if a healthy person tracks the stimulus perfectly, the height of the red wave tracking the eye, from the very top to the very bottom, will be the same as the yellow stimulus wave. If the person is too close, the red wave will be too tall. If the person is too far away, the red wave will be too flat.

To start the test, press the **Space Bar**, or press the Left side of the Foot Switch or click on the **Pause** button at the top center of the screen. Record 15 to 20 seconds of horizontal tracking data to insure that you have 10 seconds of clean, representative data for analysis.

NOTE: Either of these controls may be used to stop the test at the end of the desired data collection or they may be used to stop the test to further instruct the patient and then to restart the data collection. You may, however, step from test to test without stopping each test, except the CALORIC tests. You must click the "DONE" button at the end of each Caloric Test in order to prevent the possibility of losing the data collected.

Click on **Next** at the top left of the screen to select SACCADES. If data collection has been stopped, click on the **Pause** button to start data collection. Record data for 15 to 20 seconds as above.

NOTE: The data is automatically saved if you have recorded at least 10 seconds of data. If any test is 10 seconds or less, it will not be saved. Once the test is complete and you have stopped the data collection and gone on to the next test, the completed test will be moved from the Protocol to the

Completed Test list at the lower portion of the screen. Clicking the "DONE" button before choosing the next test will also save the just completed test and move it to the lower portion of the screen entitled 'Completed Tests'.

To repeat a Test or to do a test that is not on the selected Protocol list, click on **Tests** at the top left of the screen. Click on **Run Any Test**, click on the desired test to repeat or to run and click on OK. Now, run the desired test as before.

Click on Next to select OPK RIGHTWARD. Record for 15 to 20 seconds.

NOTE: Display Gain and Centering: At any time during data collection or data analysis, you may change the display gain - the size of the graphical data - by clicking on the 5, 10, 20 or 40 degree buttons at the top of the horizontal eye position graph. Note, that the scale at the left changes as you change the display gain.

The data screen displays 10 seconds of data. When the tracing reaches the right side of the display, the data is automatically centered vertically. If you need to center the data during the 10 second sweep, click on the **Center** button. Also, you may move all the data, the Right or Left eye data or the Stimulus (yellow tracing) vertically with the up and down buttons to the right of the horizontal vertical tracings or with the moving button between the up and down buttons. Use the **All, Left, Right or Stimulus** buttons to select which tracings to center or to move up and down.

Click on Next to select OPK LEFTWARD. Record for 15 to 20 seconds.

Click the **DONE** button to save all data.

ACTIVE HEAD ROTATION TESTS

For Active Head Rotation tests, the patient will look at the AHR receiver instead of the computer stimulus.

Patient should be sitting up straight with head level. The receiver can be placed anywhere as long as it is the same height as the patient's eyes and the patient is the proper distance away as in the Oculo Motor test. These tests are horizontal and vertical. For the horizontal test, when the test is started, a beep will come from the interface controller. It will begin slowly and increase in speed. The patient should move their head left and right to the speed of the beep. ALWAYS LOOKING AT THE AHR RECEIVER. The speed of the beep will become too much for most patients to follow at the end. MAKE THEM DO THEIR BEST.

YOU MUST COLLECT AT LEAST 30 SECONDS OF DATA FOR THESE 2 TESTS. THESE 2 TESTS USE ALL THE DATA COLLECTED, NOT JUST A 10 SECOND WINDOW. IF YOU STOP THE TEST EARLY, THERE WILL BE NO DATA AT 4 AND 5 HZ. TO ANALYZE.

Click the **DONE** button to save all data.

The Vertical test is run the same way with the patient moving their head up and down. Click the **DONE** button to save all data.

POSITIONALS and HALLPIKES

PLACE THE EYE COVER BACK ON THE GOGGLE. ALL REMAINING TESTS REQUIRE COMPLETE DARKNESS FOR THE PATIENT.

Double click on SPONTAEOUS to switch to the IR/Video Goggles and to select the first positional test. Move the patient to the ENG examination table. Place the Goggle Assembly on the patient

and adjust (see previous section SET GOGGLE AND PATIENT). Put the patient in the supine position with head elevated 30 degrees. This is the same position as the calorics tests will use.

Instruct the patient to stay still and keep their eyes wide open. Press the Left foot switch to start the data collection. Record data for 15 or 20 seconds. Press the Left foot switch again to stop data collection.

Click on **Next** to select GAZE w/FIX. Instruct patient to gaze at fixation light and keep eyes wide open. Press the Left foot switch to start the data collection. Record data for 15 or 20 seconds. Press the Left foot switch again to stop data collection.

Click the **DONE** button to save all data.

Double click on TORSION in the green protocol area. Sit patient in a rotating chair. Place goggle on patient (see previous section SET GOGGLE AND PATIENT). Tilt the patient's head forward 30 degrees to make the horizontal canals parallel with the plane of rotation. Instruct the patient you will turn the chair left and right and that they need to keep their head straight with their shoulders as you do this, not to let it move left or right as you turn the chair. Start the test. Turn the patient between 100 and 150 degrees in a smooth, medium-speed motion. Record data for 15 or 20 seconds.

Click on **Next** to select TORSION FIX. Run test as above but instruct patient to gaze at fixation light.

Click the **DONE** button to save all data.

Double click on HALLPIKE RIGHT in the green protocol area. Place patient on ENG table. Move patient so their head is hanging off edge of table 30 degrees down. Sit them up gently. Place goggle on patient (see previous section SET GOGGLE AND PATIENT). Start test with footswitch then turn the patient's head as far to the right as they can manage. Bring patient down quickly but gently into position with head off edge of table, down 30 degrees and turned to the right. Click the "Done" button to save all data. Sit patient up gently and KEEP PATIENT IN SAME POSITION FOR HALLPIKE LEFT.

Double click on HALLPIKE LEFT in the green protocol area. Run test as above but turn patient's head to the left.

Click the **DONE** button to save all data.

Double click on SUP HEAD CTR in the green protocol area. Lay patient on their back on the ENG table with head flat(no pillow). Set goggle. Instruct patient to look straight ahead in the dark with eyes open. Start test. Record data for 15 or 20 seconds.

Click on Next to select SUP HEAD RIGHT. Turn patient's head to right. Take data as above.

Click on **Next** to select SUP HEAD LEFT. Turn patient's head to left. Take data as above.

Click on **Next** to select BODY RIGHT. Roll patient on right side. Take data as above.

Click on **Next** to select BODY LEFT. Roll patient on left side. Take data as above.

Click the **DONE** button to save all data.

CALORIC IRRIGATION TESTS

Place patient in the Caloric test position. Laying on back with head up 30 degrees. Make sure patients ears are clean of wax.

Switch the irrigator to the Warm temperature position (AIR - 48 Degrees)

Double click on CAL WARM RIGHT in green protocol area. This is the first caloric test. When ready, start the RIGHT EAR IRRIGATION. Irrigate for 60 seconds. Make sure hose tip is not bent in patient's ear. This will restrict air flow causing an "F7" overheat error on the irrigator. Listen to the sound of the irrigator. If the motor sound is lower it means the air is being restricted (the pump is working harder). Ask patient if air is blowing on their ear drum or on the side of their ear canal. When irrigation is finished, press the Left foot switch to start data collection. Record for 45 seconds. Turn on fixation light for 15 seconds. Turn fixation light off and record for 15 more seconds.

CLICK THE **DONE** BUTTON TO SAVE DATA. YOU MUST CLICK THE **DONE** BUTTON AFTER EVERY CALORIC TEST TO SAVE DATA !

Wait approximately five (5) minutes between irrigations for inner ear temperatures to stabilize.

Double click on CAL WARM LEFT caloric test. Run test as above with LEFT EAR IRRIGATION.

CLICK THE **DONE** BUTTON TO SAVE DATA. YOU MUST CLICK THE **DONE** BUTTON AFTER EVERY CALORIC TEST TO SAVE DATA !

Wait approximately five (5) minutes between irrigations for inner ear temperatures to stabilize.

Switch the irrigator to the Cool temperature position (AIR - 26 Degrees)

Double click on CAL COOL RIGHT caloric test. Run test as above with RIGHT EAR IRRIGATION.

CLICK THE **DONE** BUTTON TO SAVE DATA. YOU MUST CLICK THE **DONE** BUTTON AFTER EVERY CALORIC TEST TO SAVE DATA !

Wait approximately five (5) minutes between irrigations for inner ear temperatures to stabilize.

Double click on CAL COOL LEFT caloric test. Run test as above with LEFT EAR IRRIGATION. CLICK THE **DONE** BUTTON TO SAVE DATA. YOU MUST CLICK THE **DONE** BUTTON AFTER EVERY CALORIC TEST TO SAVE DATA !

DATA ANALYSIS

Note: The data should be analyzed and marked preferably at the end of the testing procedure.

Double click on the **'Completed Test'** to be analyzed. Use the left and right arrow buttons at the bottom of the Horizontal Eye Position graphs (or the movable button between te left and right arrow buttons) to move or scroll through the data. Not the times displayed above the right side of the graphs. The total length of the data recording is displayed in seconds. The beginning of the

segment that you are viewing is displayed in seconds from the beginning of the recorded data. Once you have 'Marked' the data, the beginning of the 10 second data that you have selected is displayed.

Select the 10 second segment of the test data that is representative of the patient's response, or the maximum Slow Component Velocity (SCV) of the positional and caloric irrigation tests. Click on the **Mark** button at the top left of the screen. The data is now 'marked'.

AHR tests can be marked at the beginning. The graphical analysis uses all of the data gathered. Not just a 10 second window like the other tests use.

Step through all the **Completed Tests** and **Mark** each test that you wish to be reported. An extra marking for each Caloric test is required in order to calculate the percent of fixation suppression. DO NOT MARK A NYSTAGMUS VALUE OF 'ZERO' FOR THE MAIN OR EXTRA MARKING. THIS WILL CAUSE A PROGRAM PROBLEM BECAUSE IN THE PERCENT CALCULATION OF SUPPRESSION IT IS NOT POSSIBLE TO DIVIDE BY 'ZERO'. MARK ANY VALUE GREATER THAN ZERO ABOUT 10 SECONDS INTO THE FIXATION LIGHT SUPPRESSION DATA.

REPORT PREPARATION

Click on **Print** at the top of the screen. Select **Graphs and Summary** to print the complete report. Click on **To Printer** to print a copy of the report. Or, click on **To Screen** to view the report on the computer screen.

OPERATING INSTRUCTIONS

The information contained in this Manual is for the operational use of the INTELLINETX TRAK Series Video ENG System.

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

The ENG Goggle, through the use of a miniature video camera, magnifies the image of the eye onto the video monitor. This allows the ENG operator to view the patient's horizontal, vertical, and torsional (rotary) vestibulo-ocular responses.

The Ocular motor tests have the stimulus displayed on the VGA Monitor screen. An operator controlled moving visual target light provides the stimuli for horizontal tracking, OPK, saccade, or gaze testing.

The patient's name, folio or chart/ID number, time and date, as well as the descriptions of the test visit and stimulus are annotated on the computer data display screen. The eye movements can be recorded on any conventional video tape recorder. Computer analysis of the eye movements is provided, along with a hard copy printout of the resulting data.

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

Regarding clinical applications, the Video ENG System may be used for all conventional test procedures during ENG testing. Ocular motor tests are usually performed first as it is important to know if the eyes move in a normal fashion, prior to any examination of the vestibular-ocular reflex. It is important to instruct the patient <u>constantly</u> to follow the moving target in a back/forth (or up/down) manner, as their attention to the task dramatically effects their ability to follow the stimulus.

The saccade test is a constant 20 degree back and forth movement and again instruction to the patient is very important. OPK and Gaze testing can also be performed, if desired. There are 2 speeds of Tracking tests, .4hz and .2hz, which is one-half the speed of .4hz. The .2hz test is done if the patient is unable to reasonably perform the .4hz test. Sometimes both tests are administered and both results will be shown on the Summary Report.

Spontaneous nystagmus testing is typically performed when the patient is positioned for the bithermal caloric tests. The importance of this test is the

determination if there is any existing nystagmus which would have an effect on the interpretation of the caloric results.

Other position or positioning tests can be performed as desired by the user. There are various positions which seem to hold clinical importance, i.e. head turned to the right/left vs. whole body turned to the right/left for positional vs. cervical influences; head hanging positions, and the Dix-Hallpike tests. The user can configure the Video ENG System for any positions they deem important.

The analysis of caloric responses is straight forward in terms of average slow component velocities. Use of the bithermal results to calculate Unilateral Weakness (Reduced Vestibular Response) and Directional Preponderance is automatically presented, and also may be compensated to allow for the existence of any spontaneous nystagmus.

NOTE: Certain of the TRAK Series software applications may not contain tests for Bithermal Caloric Testing.

Any questions regarding the operation of the Video ENG System or for technical support, please contact:

INTELLINETX 2301 W. 205th St., #102 Torrance, CA 90501 (800) 293-1858 or (310) 328-0477 and Fax (310) 328-0697

I. OPERATIONAL CONSIDERATIONS

The **IR/VIDEO ENG GOGGLE** is used for the observation and recording of eye movements related to all modes of vestibular stimulations: i.e. Positionals, Dix-Hallpike,

Repositioning Maneuvers, Calorics, Fistula, Torsion Swing and, Rotational examinations. The eye movements, including torsional components, are easily visualized on the video monitor. The Goggle has fixation-suppression capability. Patient information and stimulation procedure descriptions are presented on the Data Display Monitor. The video image of the eye can be recorded on a standard video tape recorder. This provides video documentation of ocular responses.

As with any ENG procedure, it is preferable to have the patient refrain from antivertiginous medications, sleeping pills, tranquilizers, alcohol and other CNS depressants for several days prior to the examination. **The patient should consult with their physician before stopping any medications.** In addition, with the Video ENG System it is recommended that patients not wear eye makeup, i.e. eye liner, mascara, artificial lashes, etc, as this makes the computer tracking of the eye more difficult. In terms of contact lenses, it is preferable that they be removed prior to the Video ENG examination, especially hard lenses, as they can slide about the pupil during lid blinks and eye movements.

II. FUNCTIONAL DESCRIPTION

- THE IR/VIDEO ENG GOGGLE A comfortable, lightweight, plastic Goggle which is worn by the patient. The headstrap secures the Goggle to the patient. The foam seal eliminates all outside ambient light from the internal chambers of the Goggle. An infrared sensitive, miniature, video camera is attached to the Goggle and provides video images of the eye for the video monitor. Invisible, infrared light illuminates the internal aspect of the Goggle allowing the patient to keep their eyes open without the interference of fixation. If fixation is desired, a visible target light can be illuminated by the operator.
- PATIENT'S EYE ON LAPTOP COMPUTER DISPLAY The patient's eye is displayed on the computer monitor in a small window at the top center. This window can be maximized and minimized by clicking in the video image.
- LAPTOP COMPUTER and INTERFACE CONTROLLER the Computer controls the functions in the Video ENG Goggle. The Interface Controller provides the power to the video cameras, infrared illuminators, fixation and visual target stimulation lights. The Computer automatically tracks the patient's eye movements and displays this data for analysis and printout. A footswitch allows the operator to control pause and fixation light functions from a position close to the patient.
- <u>PRINTER</u> The Video ENG System interfaces to most Hewlett Packard Deskjet or Laserjet Printers (any laser printer to be used should have sufficient memory, 2MB, to print full page graphics).

III. INSTALLATION INSTRUCTIONS

VIDEO ENG SYSTEM CONNECTION STEPS:

Connect the modules per the diagram included in the Addendum.

1. <u>COMPUTER and INTERFACE CONTROLLER.</u> This is the Computer and Controller which are required for the operation of the IR/Video ENG System. The Interface Controller connects to the computer COM (Serial) port with a supplied cable.

EYE VIEW ON THE LAPTOP COMUTER. Connect the output labeled "RIGHT" on the Interface Controller to the supplied Video Capture Cable. (There is a male-male adapter on the end of this cable that plugs in here) The other end of the video capture cable connects to the right side USB port on the computer.

- 5. <u>FOOTSWITCH.</u> Connect the footswitch per the Diagram in the Addendum. This item allows Pause, Fixation and Next Test features to be operated remotely from the computer.
- 6. <u>IR/VIDEO ENG GOGGLE.</u> Connect the video cable modular connector to the center receptacle on the goggle. The modular connector at the opposite end of the cable attaches to the back of the Interface Controller. This cable provides power to the video camera, video signal and control of the infrared and fixation lights. Velcro straps insert in the slits on the side of the Goggle. The headstrap inserts on the top slit of the Goggle, with the side straps adjustable by the side Velcro straps. The cable sweeps back over the patient's head and is secured to the headstrap by a Velcro cable stabilizer. Focus of the lens is by a lever on the underside of camera.
- 7. **PRINTER.** The printer connects to the parallel or USB printer port on the rear panel of the Computer.
- **9.** <u>AC MULTIPLUG POWER CENTER.</u> This is supplied to provide central 120 Volt AC power for the Computer, Interface Controller, Video and Data Display monitors, and Printer. This Power Center has surge suppression capability and must be used in order to protect the InfraRed/Video System from voltage surges and spikes in the 120 volt AC power supply line.
- **10.** <u>VIDEOTAPE RECORDING.</u> If the operator desires to video tape record the video images of the eye, use a standard VCR. Follow instruction manual for the VCR unit to set tuner to the 'LINE' or 'AUX' input position in order to record the eye movements.
- 11. <u>SWITCHING VIDEO CAMERA FROM RIGHT EYE TO LEFT EYE.</u> If desired, the video camera can be switched from the right eye to the left eye by removing the camera adjustment knob/screw and rotating latch and carefully pulling the camera, light occluding boot and cover rearward until it is free from its mounting position. Remove the cover from the left side camera mount location and install the camera and boot in the left side, inserting the camera carefully into the camera mount tube, making

sure the boot covers the outer surface of the camera mount tube. Replace the camera adjustment knob/screw and tighten to hold the camera in place. Secure the cover by flipping up the rotating latch. Place cover from left side on right side camera mount space and secure with rotating latch.

- Be certain that all connections are correct and secure prior to turning '**ON**' the AC switch on the multiplug power center. Location of the power switch for the Computer is on the front of its cabinet. The power switch for the video monitor is on its front panel. The power switch for the Data Display Monitor is on the front of its cabinet. There is no power switch for the Interface Controller nor the Video ENG Goggle. D.C. operating power is supplied from the Interface Controller via the multipin connectors and cables.
 - NOTE: All modules should be left in the '**ON**' position, with total system power '**ON/OFF**' coming from the AC Multiplug Power Center.

IV. OPERATING INSTRUCTIONS and MENU OPERATIONS

- 1. Make sure the IR/Video ENG System components are connected as described in Section III.
- Turn on AC Power via the AC Multiplug Power Strip. [The power switches on the computer, monitors, and printer should be left in their 'ON' positions.
- From the WINDOWS Desktop, select the VIDEO ENG icon and double click on it.
 The VIDEO Screen will appear with the Task Bar at the top and the Tool Bar just below.
- 4. The System Setup has factory default settings. If it is desired to alter the Factory Setup, you must first choose an Operator. Click on File on task bar and then Operator on drop down menu. Select an operator or make a new operator by clicking on or typing the appropriate items in the dialog box. After choosing/establishing an operator, click on 'Cancel' button to close Operator dialog box. Then choose Options on the task bar and click with left mouse button. Now choose Setup and click on it.
- Setup Options Use mouse/Windows standard conventions to point and click for choices.
 - Data Path This defines where data and folio information files are stored.
 - Archive Path This defines where other folio storage such as separate directory on the main hard drive, ZIP drive or any other file storage location that exists for archiving purposes.
 - **Default Graph Scale** You may choose different graph scales for the Data Acquisition Screen.

Analysis Options

Offset Calorics: When chosen subtracts any Spontaneous

Nystagmus measurement from Caloric Nystagmus measurements in the calculation of Unilateral Weakness and Directional Preponderance.

Legacy S.C.V.: When chosen provides nystagmus measurements on same calculation basis as all prior InfraRed/Video ENG software versions.

System Type: Defines whether system is 2 channel or not and COM Port location used for Interface Controller connection.

- 6. Summary Page Headings Select 'Options' with mouse and then 'Report Text' to personalize the VIDEO ENG System Summary Report header. Move the mouse pointer to the line of text that is to be edited and click on it. Using the standard 'Home', 'End', 'Delete' and Space bar word processing functions, the text can be centered, capital letters, etc., all at the discretion of the user. When finished, press the OK button.
- With the mouse point to File on the task bar and single click with left mouse button. List of selections appears in pull down menu.
- 8. The operator may choose several menu functions:
 - Operator Open Folio Close Folio Export Print Exit

With mouse pointer choose 'Operator' and single click with left mouse button.

9. Choose Operator dialog box appears. With mouse pointer, select operator and

single click with left mouse button. Now depress 'OK' button.

- 10. To set up **New Operator**, use mouse pointer to depress 'New' button. Now the 'Edit Operator and Protocol' box appears. Type in Operator's name and depress 'OK' button.
- **11.** Each operator may also customize the standard test protocol for themselves. Otherwise the standard protocol will be listed when testing begins.
- 12. To customize the protocol, all available tests are listed in the standard protocol order. Use the mouse pointer and a single click to highlight a test. Then you may highlight the position in the Protocol you wish the test to be placed. Now, put the pointer on 'Insert' button and click on it. The test will then be listed on the left column as the custom protocol for that particular operator. It is important to highlight and insert the tests in the order you want them performed if you do not want to specifically place it in the Protocol.

If a mistake is made and a chosen test is not wanted, highlight it on the protocol column and depress the 'Remove' button with the mouse pointer. Use the scroll bar on the right side of the columns to review all tests available and/or chosen.

- **13. To access an existing Folio or start a new Folio,** with mouse pointer, click on 'Open Folio' in the File drop down menu on the task bar.
- **14.** Folio Management dialog box contains a list of Patient Folios and provision to create a Folio for a new patient.
- **15. Existing Folio.** To open an existing Folio, with the mouse pointer highlight the Folio and then depress the Open button.
- **16. New Folio.** To create a new folio, depress the 'New' button. The Folio Information dialog box appears. Fill in all the requested information. Either the mouse pointer or the tab key can be used to advance from one item to the next. When it is complete, depress 'OK' button.
- **17. Operations.** There are various other functions that can be accomplished with the Folio Management facility. Copying or Moving folios to or from the Archive

Directory as well as creating new patient folios. There are buttons that can be pushed for these functions. There is a box in the upper left section that indicates where the list of folios you are viewing is from the Active Folios list or the Archived Folios list.

18. Text Overlay- The text feature is new. The adjustable video controls formerly were installed inside the Interface Controller, which required a trained technician to access and make adjustments. These controls are in the software and the operator can make those adjustments, as required for patients that have eyes that are difficult to capture for eye tracking.

a. TEXT:

Text provided is the patient's name, ID information, date and name of test that is being run. The video of the eye is overlaid on the text screen and both are displayed on the video monitor. Use the 'TEXT' connector on the rear of the Interface Controller to be able to have text and the video image together.

The choice of video overlay and the adjustable video tracking level control are accessed by clicking on 'Options' on the top line of the software main screen, then choose 'Video Controls' from the drop down menu. Check 'Video Overlay' if that option is desired.

b. ADJUSTABLE VIDEO CONTROLS:

The control is set on a factory default level, but are adjustable by dragging the control up or down as required with the mouse. The adjustments include, level of white out on the pupil, density of black cross hairs on pupil and overall tracking level to assure proper pupil capture for eye tracking purposes.

There is an additional check box at the top. This is for choosing video overlay. By checking this box, the video of the eye will be overlaid with the text.

'TEXT' connector jack on the Interface Controller should be used for the display output to the video monitor.

19. Advanced Tracking Controls. This is accessed by clicking on the 'Adv. Tracking' selection on the top line of the MedTrak software main screen.

Displayed in a dialog box is:

a. TRACKING LEVEL ADJUSTMENT:

This is similar to tracking level control under 'Video Controls' under 'Options', and is adjusted in same manner by using mouse to drag the control either up or down to increase or decrease the tracking level. TRACKING LEVEL CAN ALSO BE ADJUSTED BY PUSHING THE "A" KEY ON THE COMPUTER KEYBOARD OR CLICKING "AUTOCAPTURE" WITH THE MOUSE IN WINDOWS, THEN USING THE "KEYPAD" FEATURE ON THE LAPTOP.

THIS FEATURE IS ACCESSED BY PUSHING THE "NUM LOCK" BUTTON ON THE KEYBOARD. BEGINNING WITH THE NUMBER "7" ACROSS THE TOP, SOME KEYS HAVE SMALL NUMBERS ON THE FRONT EDGE.

THE "+" KEY IS ON THE FRONT OF THE SEMICOLON KEY. THE "-" KEY IS ON THE FRONT OF THE MINUS KEY AT TOP.

HOLD OR TAP THE SEMICOLON KEY WITH THE "+" ON THE FRONT TO INCREASE WHITESPACE. HOLD OR TAP THE MINUS KEY WITH THE "-" ON THE FRONT TO DECREASE WHITESPACE.

b. CAPTURE MASK:

This reduces the area of the video screen for eye tracking capture. This is used only in the event the patient may have an eye that is difficult to capture for eye tracking. This difficulty may be caused by eye shadow, heavy mascara, permanent eye liner (tattooed on), deep set eyes, etc.

To reduce the troublesome area of the eye, use the four controls to pull down and up as well as to pull in from each side, only as needed, the eye tracking area limits. The limit lines are displayed on the video monitor.

Drag the controls with the mouse and the reduced area is shown in the dialog box and the actual lines shown on the video monitor.

- 20. Full screen stimulus for Oculomotor tests. Full screen stimulus is provided for Tracking, OPK and Saccade tests. If this option is chosen, when the test starts running the stimulus portion of the screen increases in size to a full screen. There is an added selection at the top of the main screen 'Controls' that when accessed gives two options to choose from large or normal screen stimulus.
- 21. Eye View on VGA Monitor. If this option is provided, the patient's eye will appear in the upper center of the data screen once a test is chosen. For all Ocular Motor and Active Head Rotation tests, the Eye View will automatically disappear after five seconds. For all other tests, the Eye View remains on the screen throughout the test. To hide the Eye View during a test, push the "Eye View" button on the task bar, using the mouse. To bring back the Eye View, push the Eye View

button again.

The eye can be shown full screen by placing the mouse pointer anywhere on the Eye View screen and clicking the mouse one time. To change the Eye View back to its normal size, just click the mouse button again making sure that the mouse pointer is in the image.

When a different or the next test is selected, the eye will automatically appear on the screen.

A. TESTING A NEW PATIENT

- **1.** Turn on AC Power via the AC Multiplug Power Strip.
- From the WINDOWS Desktop, using the mouse, select the VIDEO ENG icon and double click on it.
- With mouse, click on 'File' and on menu select 'Operator' and then select 'Folio' or 'Create a Folio' for a new patient. After filling out Folio Information box, click on 'OK'.
- 4. Select test to be conducted from Protocol column on right side of screen. Place mouse pointer on the test and a single click will highlight it. When the test is completed it will be shown in the lower Completed Test portion of the column.
- 5. With mouse pointer click on 'Run' button on left side of tool bar. To start data acquisition, click on 'Pause' button on tool bar.
- Data screen Graph Scale can be adjusted by clicking on the selected scale degree button at the top of the data screen.
- Across centerline of data screen are one second timing marks and indicate screen width of 10 seconds..
- 8. When test is completed, press 'Pause'. Operator may press 'Next' and the next test in the protocol will be chosen.

Press 'Pause' again to start the new test. To change to the next test it is not mandatory to pause. You may depress Next and the next test will be selected and data collection continues on a non-stop basis. Be assured that each time a current test is completed and a new test is selected, the current test is and all those tests that preceded it are held in a buffer memory and are later saved in the Patient's Folio when the 'Done' button is pushed at the end of the test session.

- You may continue all tests through the protocol, pausing and stopping as you may select.
- 10. When finished with all tests, you must press 'Done' for the test data to be saved and the folio can be closed.

B INFRARED/VIDEO ENG GOGGLE PLACEMENT

- Place the Goggle on the patient, adjusting the position of the Goggle to ensure that the patient's eye is fully visible on the video monitor, preferably centered, if possible.
- 2. Adjust the Velcro closure on the headstrap to tightly secure the Goggle to the patient. If adjustment for centering of the eye is required, loosen the camera adjustment knob on the Goggle and center the eye on the video screen. If the iris markings are not clearly in focus, turn the camera lens adjustment lever while viewing the eye on the video monitor until focus is achieved..

C. OCULAR MOTOR TESTS

- Patient should be seated in exam chair facing front of VGA Data Monitor. Remove cover plate over left eye on goggle so patient's left eye can see the ocular motor stimulus which will be displayed on the VGA Data Monitor.
- 2. Patient's eye should be about 20 inches from the computer screen for a 15" monitor. The wave heights of the stimulus and the eye will be equal when patient is the correct distance from the screen. If the patient is too close, the red eye wave will be taller than the yellow stimulus wave. If

the patient is too far, the red eye wave will be shorter than the yellow stimulus wave.

- The stimulus for Tracking, Saccade and Optokinetic tests will be displayed on the VGA Data Monitor.
- 4. Press the 'Auto Capture' button on the tool bar or 'A' on the keyboard and the computer will automatically establish an electronic 'lock-on' to the patient's eye. This will be indicated by the pupil being 'white' with a black cross-hair positioned at the center of the pupil.
 - NOTE: The 'white' pupil area and its black cross-hair <u>only</u> indicates the location on the eye the VIDEO computer is tracking. The '+' and '-' keys on the numeric keypad allows fine adjustment of the eye tracking threshold feature.
- 5. If the patient changes their head position, or closes their eyes, the 'lock-on' should be reestablished by pressing the 'Auto Capture' button on the tool bar.
- 6. The Data Display Monitor displays the real-time horizontal and vertical eye movement components. The Right Eye is displayed in <u>RED</u>, and a stimulus is <u>YELLOW</u>. The patient's Folio Number and Name, Subject Description, Test Set Number, Operator's Name, the Time and Date and test length time are also displayed.
- **7.** The operator selects the test desired from the Protocol column on the right side of the data acquisition screen.
- 9. The 'Pause button or 'PAUSE' (left) Footswitch are used to start or pause the collection of eye movement

data. When in the Pause mode, the Data Display Monitor will indicate PAUSED in a window on the

toolbar.

9. Eye movement data is saved to the computer's hard disk after conclusion of each test; and when the testing process is concluded it is mandatory to save the last

test by pressing the DONE button on the Task bar.

10. The FIXATION LIGHT can be activated to show the patient the direction of

straight ahead within the dark Goggle. The fixation light will illuminate within the side of the Goggle by depressing the Left or Right button on the tool bar. Pressing the button a second time turns off the fixation light. On the keyboard, letters keys 'D' operates Left fixation and 'F' operates Right fixation lights.

- 11. The PAUSE button or the PAUSE on the footswitch is used to start or pause the collection of eye movement data. When in the pause mode, the Data Display Monitor will indicate 'PAUSED' in a window on the tool bar. The pause mode can be used at the end of each test in order to setup for the next test.
 - NOTE: **Footswitch:** There are three switches on the Footswitch base and provide for foot operated **PAUSE**, **FIXATION** and **NEXT TEST** functions. **PAUSE** is done using the mouse to press the Pause button on the tool bar. This starts and stops any test that is taking place. The footswitch is labeled - left switch for **PAUSE** and right for **FIXATION**. The center main body of the Footswitch can also be depressed to choose the **NEXT TEST**.
- **12.** Press the Center button on the data screen to center the data on the graphs displayed once data acquisition begins. This centering operation is functional at any time within a test procedure.

Centering

does not effect the baseline position of the data, only its displayed position because of the limited

size of the Data Display Window. NOTE: The data will automatically be centered each

time the

data scrolls to the left side of the Data Display Window, i.e. every 10 seconds of data acquisition.

This will have no effect on any subsequent analysis, it is only for display purposes.

D. RECOMMENDED ORDER OF TESTS and PLACEMENT OF PATIENT.

- **Tracking and Saccade Tests:** Observe patient's eye on video monitor for later marking of observations in Mark Test Data mode. There are 2 speeds of Tracking tests available, .4hz, which is standard and .2hz, which is one-half the speed of .4hz and should be used when the patient is reasonably unable to perform the test at .4hz. If both tests are administered, the result of both tests will be shown and printed on the Summary Report. Computer will analyze for Gain and Phase of Tracking and for Peak Velocity and Latency of Saccade test.
- **Optokinetic Test:** Computer will analyze and report slow component velocity (SCV) of nystagmus. Best method for good data from OPK test is to advise patient to stare intently at full screen of stimulus bars and try to follow a bar across the screen. The two OPK tests are done with stimulus moving leftward and then rightward.
- GAZE SERIES TESTS-Gaze Left, Gaze Right, Gaze Up, Gaze Down: Four Gaze tests are run in a continuing series. DO NOT STOP BETWEEN THEM. Patient should be set up the proper distance away from the screen with the black stimulus area centered in their field of view. The stimulus will start at the center of the screen and move out in the direction of the test. Patient should keep their head straight forward and attempt to hold the gaze of the stimulus at an angle to their eye. After 25 seconds, the next Gaze test will start automatically.
- Active Head Rotation (AHR) Horizontal and Vertical. Remove cover from goggle to open up one eye so patient can see a point of fixation on the VGA Data Monitor. Position patient directly in front Data Monitor and <u>adjust tilt of the AHR Receiver on top of the Data Monitor so it faces directly at the AHR Transmitter on the goggle. This aiming adjustment is important and if not done correctly will adversely affect the quality of data obtained during these tests.</u>
- **AHR Horizontal.** Advise patient to fixate on place on data monitor. Instruct patient to move <u>head</u> left and right in time to metronomic beeps from the computer while keeping their eyes on the fixated place

on the data monitor. On Data Monitor, yellow line is head position; red data line is the position of the eye. First 10 seconds of the test is for setup of the data and data for analysis is gathered after the first 10 seconds of the test. As the test progresses, the speed of the beeps increases through 1 Hz up to a maximum of 5 Hz. It is important that the patient try to keep moving the head back and forth at the speed of the beeps. Collect data for thirty (30) seconds to get full analysis.

AHR Vertical. This test is conducted as the Horizontal test above except that the head motion is up and down for vertical movement rather than left and right for horizontal movement.

Data derived from Horizontal and Vertical tests is plotted on charts with center point of the charts being the

most normal. Normal deviations from this center point range from:

	HORIZONTAL	VERTICAL
Velocity Gain	80-120%	70-130%
Asymmetry	+10 to -10%	+10 to-10%
Velocity Phase	160-210 deg.	160-210 deg.

Data is plotted and reported on Page 2 of the Summary Report and includes:

1. Velocity Gain Percent - is difference between the eye movement and the head movement.

A low gain percent implies that the Vestibulo-Ocular Reflex mechanism under compensates during head motion. For example, a symptom presented due to this could be a complaint of veering to the side when walking.

2. Gain Asymmetry Percent - is comparison of left vs. right, or up vs. down movement and calculation of difference, or asymmetric movement.

A" plus" percent indicates that the rightward direction of movement is slower than the leftward movement of the eye.

A "minus" percent indicates that the leftward direction of movement is slower than the rightward movement of the eye.

The slower direction of eye movement)rightward or leftward) often indicates the probability of a lesion or weakness on that side. According to literature, the eyes tend to deviate toward the side of a peripheral lesion during horizontal AHR (VOR) testing.

3. Velocity Phase - is whether the eye movement is leading or lagging behind the head

movement and is reported in degrees. Perfect phase is 180 degrees, i.e. the eye and head are moving in exactly opposite directions.

Next Four Tests: Spontaneous, Gaze w/ Fixation, Torsion Swing and Torsion Swing w/ Fixation.

- Turn patient away from Data Monitor. Place cover on open side of ENG Goggle so patient is in darkness. With patient sitting erect in exam chair, conduct::
- **Spontaneous Test.** Data may be recorded for an extended time, but must be in excess of ten seconds in order to be saved as a completed test.
- **Gaze w/Fixation.** Patient in same position. Turn on Fixation light with 'F' key or Fixation Button on Task bar and commence test. Advise patient to look at Fixation light. At end of test turn off fixation light by pressing 'F' key or Fixation Button on Task bar.
- **Torsion Swing Test.** Patient in same position. Make sure fixation light is off. Turn exam chair back and forth at least 15 degrees to the left and 15 degrees to the right for a total movement of 30 degrees of arc. The speed of rotation should be between 1 and 2 Hz. Observe eye of patient on video monitor for later marking of observations in Mark Test Data mode.
- **Torsion Swing Test w/ Fixation.** Patient in same position. Turn on fixation light and again, rotate chair in same manner as prior test moving back and forth through an arc of at least 30 degrees at a speed of 1 to 2 Hz. Observe eye on video monitor for later marking of observations in Mark Test Data mode.
- Positional Tests Supine, Head Center, Left & Right; Body turned left & right; Dix-Hallpike Head Left & Head Right. This series of tests is done with patient on exam table with head elevated to 30 degree level. When the Dix-Hallpike tests begin, lower head to flat position with body positioned so head hangs over end of table in order to achieve the head inverted position.
- Slow component velocity (SCV) of nystagmus will be the result of analysis of eye movements for all of these various positional tests. During Mark Data Mode, the SCV can be viewed in the lower right corner of the data screen. The result will be printed out on the Summary Test Results page.
- **Bithermal Caloric Tests with either air or water irrigation.** These tests should be administered with the patient in a supine position with the patient's head elevated 30 degrees to bring the horizontal

vestibular canal perpendicular to the ground plane. Prior to the start of the procedure, the patient's ears should be inspected with an otoscope for cerumen and/or tympanic membrane perforations.

- Turn the patient's head to the side and gently start the irrigation for typically 45 seconds, catching excess water that flows out of the ear canal with a pan. If using an AIR irrigator, the irrigation time is longer, up to 60 seconds because air is not as efficient a conductor of heat as is water. At the end of the irrigation, turn the head further to empty the water out of the ear canal and return the patient's head to center and begin recording ongoing nystagmus for one or two minutes.
- The water temperatures to be used are 30 degrees Celsius for the 'Cool' irrigations and 44 degrees for the 'Warm' irrigations. In the case of Air irrigations, the recommend temperatures is 48 degrees for the Warm irrigations and 26 degrees for the Cool irrigations. It is recommended that the four irrigations be spaced five minutes apart to allow the patient to return to a normal state in between tests.
- Note: Consult the Handbook of Balance Function Testing by Jacobson, Newman and Kartush for a comprehensive review of caloric testing procedures and protocols.
- Slow component velocity (SCV) of nystagmus will be the result of analysis of eye movements for all of these various positional and caloric tests. During Mark Data Mode, the SCV can be viewed in the lower right corner of the data screen. The result will be printed out on the Summary Test Results page. The caloric tests will also compute the difference from one ear to the other and so indicate on the Summary Page report.

29

E. EDIT AND MARKING DATA

- 1. From File menu choose 'Open Folio'. Folio dialog box appears. Highlight with mouse pointer the Folio to be marked and depress 'Open' button. Verify Folio information and depress 'OK' button.
- In lower right is column of completed tests. With mouse pointer, highlight the test to be marked. Double click on the chosen test and it will be opened and displayed on the data screen.
- 3. Edit/Marking Screen Features
 - a. Tracings: Red is right eye

Yellow is fixation light on, or stimulus for Ocular Motor Tests

b. Upper portion is Horizontal eye position

Lower portion is Vertical eye position

- c. Graph Scale: 5 deg = Each division of scale is 5 degrees
 - 10 deg = Each division of scale is 10 degrees
 - 20 deg = Each division of scale is 20 degrees

40 deg = Each division of scale is 40 degrees

A single click with mouse pointer on chosen scale is selection method.

d. Centering data on graph. Eye, Stimulus or All may be chosen for centering.
Point to your choice and single click with mouse. Then point to CENTER
and single click on mouse and whatever was chosen will be centered.
Centering point is from the first data point on the left edge of the Data
Screen.

e. Scrolling through test. At bottom of the Horizontal graph screen is a

conventional WINDOWS scroll bar. This will move the data to left and right. Use conventional WINDOWS method with mouse pointer to move the scroll bar.

On the right side of both Horizontal and Vertical graph screens is a scroll bar for moving data up and down.

f. Information Section provides:

Subject name

Tested by, time and date of testing

Name of test being displayed

Length of test in seconds

Marking choice

Current 'View' position in seconds from beginning of test

Mark position in seconds from beginning of test

4. The average nystagmic slow component velocity (S.C.V. in degrees/second) for all nystagmic eye movements in the displayed 10 second portion of data is shown in the S.C.V. 'Viewed' windows (horizontal and vertical channels) on the lower right corner of the Data Screen. This window includes the S.C.V. for the data that is in view; The S.C.V. where it has been marked and also a common Normal threshold value. The vertical placement of the data should be accomplished as described above for the baseline function. Press the 'MARK' button to mark the displayed 10 second section of data for analysis. The task bar 'Markings' can be selected to show type of marking choices. Default will mark both vertical and horizontal movements. If different markings is desired,

select and click on the desired marking method. If the operator scrolls forward or backward to view another section of data within the same test sequence, the S.C.V. for the section and the time of the Viewed Segment as well as the time and S.C.V. for the Marked Segment (if any) are displayed in the lower right corner of the graph display.

- 5. If the operator wishes to unmark a test, choose 'Markings' on the task bar and click on 'Unmark' on the drop down menu.
- 6. If the operator desires to make notations regarding the presence of rotary nystagmus, latency of response, fatigability of the response, and if the patient experienced subjective sensations of vertigo (dizziness or lightheadedness), depress the 'SUMMARY' button on the tool bar. Text can be written to any length desired and will be printed with the Summary Report. Click on any part of the screen that is outside the comment area to return to the eye movement data.
- 7. Depress the 'NEXT' button on the tool bar to bring up the next test for marking.
- When finished marking all tests, depress the 'DONE' button to exit the EDIT mode and the Folio.

F. PRINT FUNCTIONS

- 1. With the selected patient Folio open, depress the 'PRINT' button on the tool bar.
- 2. The Print dialog box appears. With the mouse pointer, click on one of the choices of 'What to Print'.

The following instructions describe the manner in which the marked data will be

displayed or printed, depending on the 'print' or 'preview' function chosen by the

operator.

- NOTE: Graphs are printed with the bold or red line representing the eye; and the thin or light line being the 'STIMULUS'; Fixation is a bold line on the horizontal 'time line'. The vertical line is divided into 5 degree segments. Each tic mark on the vertical line is 5 degrees.
- a. The Summary Pages will be previewed/printed in sections. If in the PRINT mode, the Summary Pages will be printed, and the conventional WINDOWS indicator will show the status of printing. If in the PREVIEW (screen) mode, to view the bottom of a page or the top of the page, use the 'UP' and 'DOWN ARROW' Keys or the scroll bar on the right side of the page.
- b. The '**Graphs & Summary**' choice will preview/print the marked data tracing graphs and the Summary Page.
- c. '**Print One Graph**' will preview/print any selected graph which has been marked, and will print the 10 seconds that is marked and always print it as a complete 4-channel analysis.
- d. **'Full Test Graph**' allows for the preview/printing of an entire test (not just a 10 second segment). After choosing this function, select which test file

is desired and which eye graph to print - left or right. Horizontal and vertical eye data (2-channel) will be printed in alternating horizontal and vertical 40 second segments.

3. To the right of the dialog box are two additional choices:

To Printer: Items chosen will be printed

To Screen: Items chosen will be displayed on VGA monitor screen With mouse pointer, click on button of your choice. If in Screen or Preview mode, click on 'Page' on the task bar in upper left corner. A drop down menu allows selection of 'Next' page, 'Previous' page or 'Exit' preview mode.

- 4. Examples of the VIDEO ENG System Printout(s) are provided in the Addendum to this manual. They present the horizontal and/or vertical eye movement data graphs based on the ocular motor, positional, and caloric test results which were marked by the operator during the 'EDIT and Mark DATA' operation.
- 5. The operator can make their Observational comments as to the presence of rotary eye movements, latency, fatigable nystagmus, and patient sensations of dizziness and vertigo where appropriate, by clicking on the particular observation during the analysis of various Goggle tests. A dialog box for these observations appears when appropriate during the Edit and Marking process. It is located on the upper left portion of the Data Screen. Tests which were not performed or marked for analysis, are indicated by three periods [...] or N.A.. on the printout. For both the ' Summary Report' and the 'Data Tracings', a zero (0) result means no or less than one degree of nystagmus was detected.

34

6. Unilateral Weakness (Reduced Vestibular Response-RVR) and Directional Preponderance (DP) percentages are calculated, per the following formulas, for each selected eye, with the calculations being corrected for any spontaneous nystagmus if the 'Caloric Offset' option was selected during system setup. If compensation results in the reversal of the caloric direction a value of 'zero' will be

assigned and used in the following formulas:

UW or RVR % =	(Rt. Cool + Rt. Warm) - (Lt. Cool + Lt. Warm) X 100	
	Rt. Cool + Lt. Cool + Rt. Warm + Lt. Warm	
DP % =	(Lt. Cool + Rt. Warm) - (Rt. Cool + Lt. Warm) X 100	
	Rt. Cool + Lt. Cool + Rt. Warm + Lt. Warm	

NOTE: If the patient has the unusual situation of <u>no caloric responses - bilaterally</u>, the RVR and DP computations will be shown as: **NR=AU**, meaning **NO RESPONSE, BILATERALLY**.

G. DATA EXPORT

1. With the selected patient Folio open, Mark all the tests that you want to export. Only marked data will be exported. Go to "**File**" at the upper left of the Menu bar at top and choose "**Export**". A dialog box will appear to confirm system information and the data path for the export.

Make sure data path ends with a '\'

Example: "C:\Export Folder\"

H. MARK OBSERVATIONS

1. There are times when user evaluation of items such as; presence/absence of torsional (rotary) nystagmus,

latency of response, fatigability, and subjective sensations.

2. This function is done in the 'EDIT AND MARK DATA' function. Look for the dialog box in the upper left portion of the Data Screen.

H. RENAME TEST

- NOTE: This function is to be used only if a test performed using the Goggle module was incorrectly labeled at the time of data acquisition, i.e., a warm left caloric was performed but was mistakenly labeled as a cold right caloric. Because this inaccurate labeling will have an effect on the resulting analysis, the 'Rename Test' function allows the operator to correct this mistake. <u>Ocular Motor tests cannot be renamed since the stimulus is</u> <u>computer controlled and provides only the stimulus selected.</u>
- 1. With mouse pointer, highlight the test that you want to Rename.
- 2. On task bar choose 'TESTS' to access drop down menu. With mouse pointer, click on 'Rename Test' in the drop down menu.
- 3. List of test names appears. With pointer click on the test name that will replace

the name of the selected test. Press 'OK', the name automatically replaces the

name of the test to be renamed in your completed test section.

I. DELETE TEST

NOTE: Use of this feature is not recommended unless the Operator is very experienced.

- Highlight the test to be deleted. On the task bar choose 'TESTS' to access drop down menu.
- 2. Next click on drop down menu item 'Delete Test'. CAUTION: DOING THIS WILL DELETE THE TEST FROM THE FOLIO AND IT CANNOT BE RECOVERED.
- 3. Confirmation box will ask Yes or No to confirm deletion of the selected test.

J. REPEAT A TEST

- Highlight any test in the upper Protocol section. On the tasks bar choose 'TESTS->'Run Any Test' on drop down menu and from the displayed list, click on the test you want to repeat.
- 2. The chosen test will be placed in the Protocol and is ready for doing a repeat of the test.
- 3. Operator must make sure that the proper test is chosen to mark when editing.

V. INFRARED/VIDEO ENG GOGGLE SPECIFICATION

CONFIGURATION:

Infrared/Video ENG Goggle	
ter	
1 set (cables, etc.)	
15" SVGA	
CD Video Camera NTSC 60 Hz	
On Video Screen Standard VCR	
3 ft. Candles LED Peak Wavelength 660 nm	
Indirect, Diffuse Illumination Infrared LED Peak Wavelength 940 nm	
9" High Resolution Video Monitor Or Video Capture of Eye on VGA Screen	
100/117VAC +/- 10% 50/60 Hz Approx. 200VA	
+10 to +40 Degrees C operating +10 to + 50 Degrees C storage 10% to 80% operating, non-condensation 5% to 85% storage non-condensation	

VI LIMITED WARRANTY

INTELLINETX warrants the InfraRed/Video Electronystagmographic System and all of its component modules to be free from defects in material and workmanship under normal use and conditions for a period of one year from date of original purchase by end user. Should service be necessary under this warranty for any reason due to manufacturing defect or malfunction during this period, INTELLINETX will provide repair service through an authorized dealer.

THIS WARRANTY MAY BE VOID IF THE PRODUCT IS:

- 1. Damaged through negligence, misuses, abuse, or accident.
- 2. Modified or repaired by anyone other than an authorized dealer.
- 3. Damaged because it is improperly connected to the equipment of other manufacturers.
- 4. Inoperable because additional hardware/software is added to the computer without permission from INTELLINETX or its authorized dealer.

THIS WARRANTY DOES NOT COVER:

- 1. Damage to the equipment of other manufacturers not properly connected to the product.
- 2. Costs incurred in the shipping of the product to the factory or to an authorized dealer.
- 3. Damage or improper operation of unit caused by customer abuse, misuses, negligence, or failure to follow operating instructions provided with the product.
- 4. Ordinary adjustments to the product which can be performed by customer as outlined in the Operator Manual.
- 5. Software included with the computer equipment, which is covered by the software manufacturer's warranty.

This warranty is non-transferable and applies only to the original purchaser and does not extend to subsequent owners of the product. Any applicable implied warranties are limited in duration to a period of the express warranty as provided herein beginning with the date of original purchase by end user and no warranties, whether expressed or implied shall apply to this product thereafter. Under no circumstances shall INTELLINETX be liable for any loss, direct, indirect, incidental, special, or consequential damage arising out of or in connection with the use of the product or software, provided with same. (Some states do not allow limitation on implied warranties or exclusion of consequential damage, therefore these restrictions may not apply to you.) This warranty gives the purchaser specific legal rights, however, you may have other rights which may vary from state to state.

THE VIDEO ENG SYSTEM IS MANUFACTURED BY

INTELLINETX 2301 WEST 205TH STREET, SUITE 102 TORRANCE, CALIFORNIA 90501 PHONE: (800) 293-1858 or (310) 328-0477 FAX: (310) 328-0697

VIDEO ENG Goggle and Ocular Motor Module: U.S. and Foreign Patents Granted. The "House" name is used with permission from the House Ear Clinic and Institute, Los Angeles, California.

ADDENDUM

MOBITRAK v3.00

I. NORMAL VALUES AND LITERATURE CITATIONS

II. EXAMPLES OF MOBITRAK IR/VIDEO ENG DATA

- A) SUMMARY PAGE
- B) GRAPHS
- C) PRINT ONE GRAPH
- D) FULL TEST GRAPH
- III. INSTALLATION DIAGRAM

I. NORMAL VALUES AND LITERATURE CITATIONS

The following discussion, other tables and literature citations provide a review of important ocular motor and bithermal caloric normative data. This data may be used as a basis for the user to decide if test results are within or outside of normal limits (age and sex related, where appropriate). The concept of what is normal for ENG results is best addressed by citing various published articles which discuss the more common ENG tests used during typical clinical protocols. *IT IS SUGGESTED THAT EACH ENG FACILITY ESTABLISH THEIR OWN NORMATIVE VALUES BASED ON THEIR SPECIFIC TESTING PROTOCOL.*

The following discussion of 'normal' values is presented in the following format:

A. OCULAR MOTOR TESTS

- 1. SMOOTH PURSUIT (TRACKING)
- 2. SACCADE
- 3. OPTOKINETIC TESTS
- 2. SPONTANEOUS OR POSITIONAL TESTS
- 3. ACTIVE HEAD ROTATION TESTS
 - D. CALORIC TESTS
 - 1. UNILATERAL WEAKNESS / REDUCED VESTIBULAR RESPONSE
 - 2. DIRECTIONAL PREPONDERANCE
 - 3. BILATERAL WEAKNESS (HYPOACTIVE RESPONSE)
 - 4. HYPERACTIVE RESPONSE
 - 5. FIXATION SUPPRESSION

As will be seen, these are some general guidelines which can be used, but it must be stressed that there are exceptions (both for what is normal and what is abnormal) and therefore ENG test results should be used as an adjunct to the other diagnostic elements at the disposal of the clinician, i.e history, physical exam, other vestibular/auditory tests, etc.

A. OCULAR MOTOR TESTS

- 1. **PURSUIT** According to Hain (7) gains of 0.8+ (80+%) are normal; gains of 0.2 -0.8 (20-80%) are moderately impaired; and, gains of 0.2 (20%) or less are the most important patients to be identified as they have practically no pursuit capability at all.
- 2. SACCADES The values presented below for peak saccadic velocities and latencies are based on <u>electrode</u> recorded data. Since the sampling rate of video differs from electrode systems, the IR/Video values for velocity and latency may be less. The symmetry between left and right eye responses will still be maintained for significant comparison data. Other published data suggests a wide variance in normal saccadic peak velocity. For example, for a 30° horizontal saccade there exists a mean peak velocity 400 deg/sec with a standard deviation of $\pm 200^{\circ}$.
 - a) Average Peak Saccadic Velocities for 40° horizontal saccades by age (8):

Age Group	Peak Velocities (deg./second)
7-14 years	460 <u>+</u> 50
20-50 years	490 <u>+</u> 90
76-up years	425 <u>+</u> 75

b) Average Latencies for 40° horizontal saccades by age (8):

Age Group	Average Latency (milliseconds.)
7-14 years	220 <u>+</u> 50
20-50 years	190 <u>+</u> 50
76-up years	225 <u>+</u> 45

These authors found no differences in left to right or right to left saccades (8). Saccadic velocity, for a given amplitude, should be equal between eyes (7). Velocity should also be equal whether the eye is abducting or adducting (7).

The above information suggests that a peak velocity of 250 deg/sec. Or higher is a normal level. As age increases, the peak velocity for normals tends to be reduced.

Mean latencies of 200ms or less are usual in normal subjects (1). For Abel et al (6), their values for latencies were 229.8 \pm 62.5ms for young subjects and 275.2 \pm 74.7ms for elderly.

c) Inaccuracies - There are two types of saccade inaccuracies: <u>Hypometria</u> - must be reproducible and extreme to be abnormal, as normal subjects usually produce slightly hypometric saccades. As stated by Hain (7), undershoot dysmetria is abnormal when the first saccade is < 50% of target displacement.

<u>Hypermetria</u> - or calibration overshoot, must be reproducible to be significant. however, even a small amount is abnormal. As stated by Hain (7) overshoot dysmetria is abnormal when it is frequent (at least 50% of the time), of significant size (greater than 2⁰), and when it occurs in saccades larger than 20⁰. He does not feel numerical criteria for overshoot is necessary as the diagnosis is usually obvious from inspection.

2. OPTOKINETIC TESTS - Literature generally discusses two aspects of OPK test results that may be significant. Gain and Asymmetry are most often noted.

a) Gain is the ratio between speed of the stimulus and the slow component velocity (SCV) of the nystagmus that is elicited by the OPK stimulus.

Howard (9) states that optokinetic nystagmus gain has been found to be near 1.0 for stimulus velocities between 20 and 50 deg/sec. And, Yee(10) states that a normal range is \pm 1 standard deviation for several OPK stimuli; .88 \pm .05 at constant 30 deg/sec velocity.

From this information, it appears that an SCV of .8 or greater of the stimulus velocity is in the normal range. Calculation is SCV/Stimulus Velocity = Gain. However, many subjects find the test difficult to perform and a result of .5 may be considered suitable.

The INTELLINETX 'TRAK' series InfraRed/Video ENG System provides an OPK stimulus velocity of 20 deg/sec, therefore an SCV of 16 or greater can be considered to be in the normal range if the subject can perform the test properly.

b) Asymmetry is the comparison of SCV results from leftward moving stimuli and rightward moving stimuli. A similar SCV result from both directions should be expected. If the variance exceeds 20%, a result other than normal may be indicated and should be noted in the report.

2. SPONTANEOUS OR POSITIONAL NYSTAGMUS - True spontaneous or

positional nystagmus is persistent and remains present for as long as the patient's head remains within each position [at least 30 seconds or more for each position] (2). Some clinics choose not to report spontaneous or positional nystagmus with slow phase velocities of less than 6-7°/sec. Although low-velocity nystagmus might be clinically insignificant in some patients, nystagmus should not be present if the patient's vestibular systems are truly normal (2). The presence of low-velocity spontaneous or positional nystagmus provides objective evidence that an asymmetry or other organic vestibular system abnormality is present (2).

3. **ACTIVE HEAD ROTATION TESTS.** This test is performed in both horizontal and vertical mode. Data derived is plotted on a chart with center point of the charts being the most normal. Normal deviations from this center point range from:

	HORIZONTAL	VERTICAL
Velocity Gain	80-120%	70-130%
Asymmetry	+10 to -10%	+10 to -10%
Velocity Phase	160-210 deg.	160-210 deg.

Data is plotted and reported on Page 2 of the Summary Report & includes:

4. <u>Velocity Gain Percent</u> - This is eye velocity divided by head velocity and expressed as a percent. If the subject looks straight ahead at a spot or target, and moves their head to the right, the eyes will move to the left at the same amount of distance and at the same speed. This measurement calculates the difference between the eye movement velocity and the head movement velocity.

A low gain percent implies that he Vestibulo-Ocular Reflex mechanism undercompensates during head motion. For example, a symptom presented due to this could be a complaint of veering to the side when walking.

5. <u>Gain Asymmetry Percent</u> - Eye velocity is measured when moving leftward and rightward and the difference is calculated and expressed in percent of difference.

A "plus" percent indicates that the rightward direction of movement is slower than the leftward movement of the eye. A "minus" percent indicates that the leftward direction of movement is

A "minus" percent indicates that the leftward direction of movement is slower than the rightward movement of the eye.

The slower direction of eye movement (rightward or leftward) often indicates the probability of a lesion or weakness on that side. According to literature, the eyes tend to deviate toward the side of a peripheral lesion during horizontal AHR (VOR) testing. <u>Velocity Phase</u> - is whether the Eye movement is leading or lagging behind the head movement and is reported in degrees. Perfect phase is 180 degrees, ie. the eye and head are moving in exactly opposite directions.

Both gain and phase are indicators of the degree of oscillopsia that may be present.

D. CALORIC TESTS

- 1. UNILATERAL WEAKNESS or REDUCED VESTIBULAR RESPONSE - A clinically significant unilateral weakness is defined as an interaural (for example, ear versus ear) difference in mean maximum slow phase velocity (SPV) of 20% or greater (1)(2).
- 2. DIRECTIONAL PREPONDERANCE A clinically significant directional preponderance is defined as a 27% (1) to 30% (2) or greater difference in intensity of the maximum SPV between two right-beating responses [right warm and left cool] and the two left-beating responses [left warm and right cool].
- 3. BILATERAL WEAKNESS (Hypoactive Responses) Bilateral weakness is operationally defined as total caloric slow phase velocities that are less than 22° per second (1). Barber and Stockwell use a limit of < 30°/sec. They have suggested that a patient will have a bilateral weakness if the total response from both sides is less than 11°/sec. for warm caloric irrigations and 6°/sec. for cool caloric irrigations.</p>
- 4. HYPERACTIVE CALORIC RESPONSES Barber and Stockwell (3) consider hyperactive responses as SPV's which exceed 50°/sec. for cool irrigations and 80°/sec. for warm irrigations. Jackobson et al (1) state that hyperactivity is operationally defined as total cool and total warm responses exceeding 99°/sec and 146°/sec, respectively, and a total SPV exceeding 221°/sec.
- FIXATION SUPPRESSION Upper limits suggest that physiologically normal individuals should be able to suppress caloric nystagmus 60% or more with visual fixation (1). Baloh and Honrubia (4) reported that nystagmus should be attenuated by at least 50% to be considered normal. Odkvist (5) has reported a normal

attenuation factor of at least 70% with fixation. Cyr (2) uses at least 40%. Most clinicians use the 50% factor.

LITERATURE CITED

- Handbook of Balance Function Testing. Eds.: Gary P. Jacobson, Craig W. Newman, and Jack M. Kartush. Singular Publishing Group, San Diego, CA, 1997. Chapter 9. Interpretation and Usefulness of Caloric Testing.
- 2) David G. Cyr and Lee A. Harker: Otolaryngology Head and Neck Surgery, Second Edition, Chapter 146, Vestibular Function Tests
- Barber HO, Stockwell CW: Manual of Electronystagmography. St. Louis, CV Mosby, 1976.
- 4) Baloh and Honrubia (Baloh RW, Honrubia V: Clinical Neurophysiology of the Vestibular System, ed 2. Philadelphia, FA Davis, 1990.
- Odkvist LM: Value of vestibular function tests in the differential diagnosis of vertigo. Acta Otolaryngol 1988; 122-127.
- 6) Abel L, Troost, and T. Dell'Osso: The effects of age on normal saccadic characteristics and their variability. 1983; Vis Res 23:33-37.
- Handbook of Balance Function Testing. Eds.: Gary P. Jacobson, Craig W. Newman, and Jack M. Kartush. Singular Publishing Group, San Diego, CA., 1997. Chapter 6, Interpretation and Usefulness of Ocular Motility Testing by Timothy C. Hain
- The Vestibular System, Neurophysiologic and Clinical Research. Eds. Malcolm D. Graham, John L. Kemink. Raven Press, NY, 1987. Ocular Motor Tests in Different Age Groups. Ulf Rosenhall, Gote Bjorkman, Kai Pedersen, and Per Hanner. Pages 401-409.
- The Vestibulo-Ocular Reflex and Vertigo. Eds. James A. Sharpe, Hugh O. Barber. Raven Press, NY, 1993. The Optokinetic System. Ian P. Howard. Pages 163-184.
- 10) Yee RD: Optokinetic Nystagmus in Clinical Tests. ICS Medical ENG Report, July 1984; 21-24.

II. EXAMPLES OF MOBITRAK ENG DATA (On the following pages)

In general, there are two types of prints, **Summary Pages** and **Graph Pages**. The **Summary Pages** present the marked data in a format which makes it easy to view the results of the ocular motor, positional, positioning, caloric and any other tests performed. The **Graph Pages** present the eye movement data for each 10 second segment which was marked for analysis.

The **Summary Page(s)** contain the user site name, subject name, folio number, set #, date, and 'marked by' name on the top of each page.

The **Graph Page(s)** contain the user site name at the top with the folio number, test set # and Graph Page number at the bottom of each page. The number of Graph Pages will depend on the number of tests that was marked for analysis.

A. SUMMARY PAGE

The top section presents the **GAIN** and **PHASE** data from one or more of the tracking stimulations. **GAIN** is the amplitude relationship between the stimulus and the eye tracking response, and is presented in % amplitude of the eye/stimulus. **PHASE** is the relationship between the position of the stimulus and the eye, and is presented as the phase lag of the eye to the stimulus in degrees ('+' indicates a lag in time; '-' indicates the eye is moving faster then the stimulus).

Next are the results from the saccadic test procedure. These results are the **PEAK VELOCITY** that the eye response has to stimulus provided during the test, presented in degrees/second of velocity. And, the **LATENCY**, which is the length of time the eye takes to begin moving after stimulus presentation, given in terms of time (seconds). Next are results of the optokinetic tests based on the presence of nystagmus computed as an average of the slow components of nystagmus for the marked 10 second test segment.

The next line provides the results of the gaze nystagmus tests based on the presence of nystagmus computed as an average of the slow components for the marked 10 second segment.

Torsion Swing, without and with fixation are also included. These test results are observational by the operator for normal or abnormal results.

Next section pertains to the position(ing) and other Goggle tests performed. The bithermal caloric data (Horizontal and Vertical responses - respectively) is shown. Both horizontal and vertical eye movement analysis is listed.

With these bithermal caloric results is the calculated **Unilateral Weakness** (Reduced Vestibular Response) and **Directional Preponderance** results. If there are no bithermal caloric responses, bilaterally, the value presented will be '**NR** = **AU**' (meaning <u>No</u> <u>R</u>esponses, Bilaterally). Ice water calorics results, if performed, are presented in the same numerical and graphic fashion that was used for the bithermal tests results.

If the caloric offset option is activated in the Options menu, then any spontaneous nystagmus (recorded from the Goggle) will be added to or subtracted from the bithermal caloric results. If the compensation results in no response or in a perverted response, the magnitude of that result will be expressed as '0' degrees/sec. and '0' will be used in the unilateral weakness and directional preponderance calculations.

At the bottom of the Summary Page, the operator can provide their comments, i.e as to test results, patient feelings, medication information and other observations. The writings can be extensive and automatically wraps over to an additional page when printed.

Page 2 of the Summary Report includes the charts for the Active Head Rotation tests, which are self-explanatory.

NOTE: The print order of the graphs is such that the ocular motor tests are printed first (if performed), the Active Head Rotations tests are next followed by the positionals and bithermal calorics. Other tests, like fixation, fistula, torsion chair, etc. will be the last graphs printed.

B. GRAPHS

The print format for the graphs is for the Horizontal and Vertical data to be side by side. The data channel, stimulus, and resulting analysis are all provided along the top of each 10 second box. Vertical gain markings are in 5° intervals.

Tests are printed in the order that they were performed, separated from each previous or subsequent test(s) by a heavy horizontal line.

C. PRINT ONE GRAPH

This function allows the user to print any one of the marked tests. In the case of the **PRINT ONE GRAPH** option, data will <u>always</u> be printed with the identification of test, stimulus, and analysis presented along the top of each 10 second data box.

D. FULL TEST GRAPH

This capability allows the user to print responses for any of the recorded and marked tests. Each selection will print up to two minutes of data, in alternating horizontal and vertical channels. Each two segment (horizontal and vertical data) displays 40 seconds of data. Three (3) segments will be printed on a single page. User site notation is provided at the top of the page, and the folio number, set#, and a graph page number is at the bottom of the page. There is no presented analysis of the data. It is displayed at the gain settings, and baseline alignment, indicated during 'EDIT and MARK DATA'.