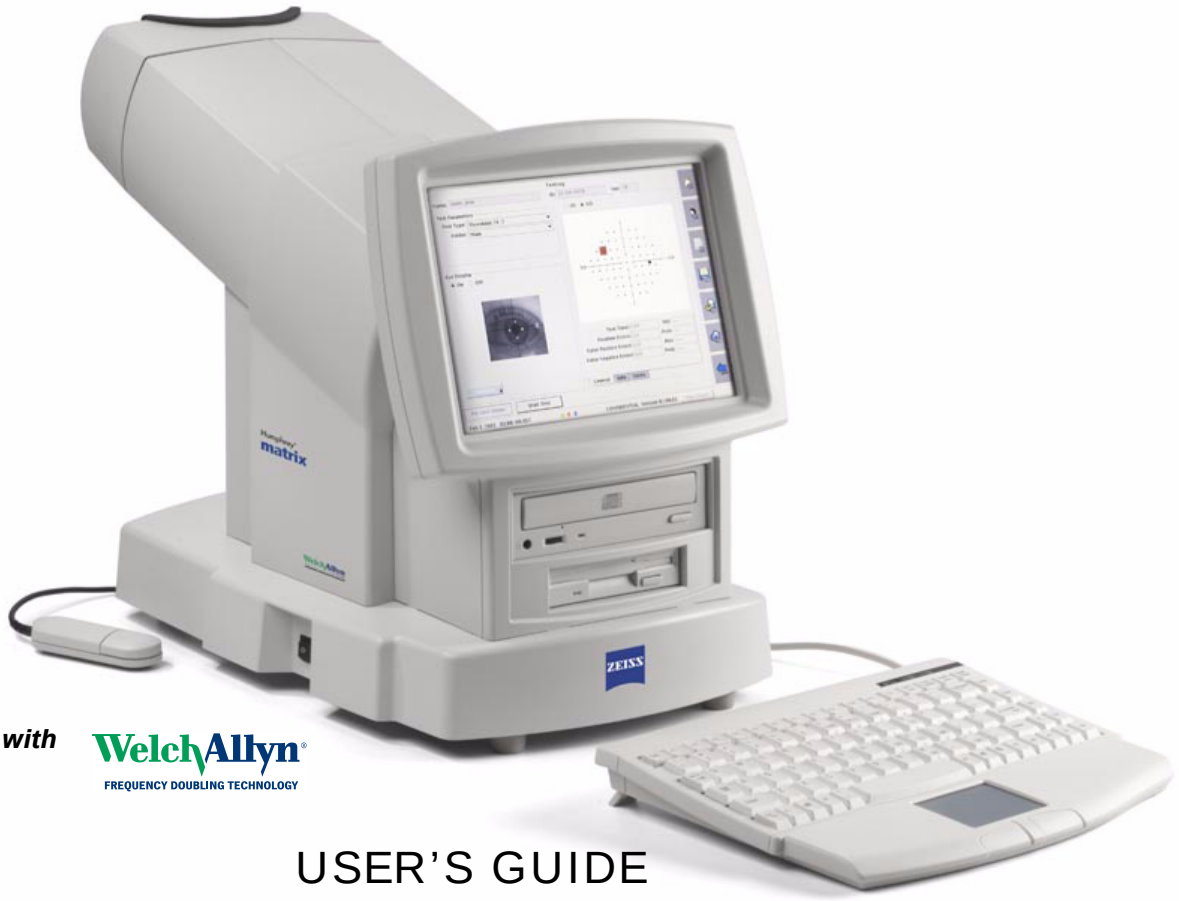
Humphrey® matrix™

Visual Field Instrument



with WelchAllyn FREQUENCY DOUBLING TECHNOLOGY

USER'S GUIDE

ZEISS

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Patents

Protected by one or more of the following patents:

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AUS. Pat. 611,585; 701,075

Others Pending

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The information in this User's Guide is based on Humphrey Matrix SBC Software V04.04.XX.

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IMPORTANT SAFETY INFORMATION - PLEASE READ FIRST

All operating personnel should be familiarized with the general safety information in this summary. Additional safety information may also be found throughout this manual.

ATTENTION - refer to the operating instructions. This symbol is intended to alert the operating personnel to the presence of important operating or maintenance instructions in the documents accompanying the instrument.

SERVICE or REPAIR to be performed by QUALIFIED, AUTHORIZED PERSONNEL ONLY. There are **NO USER SERVICEABLE PARTS INSIDE** the Humphrey Matrix instrument. Disassembly of the instrument presents a possible **ELECTRICAL SHOCK** hazard and will **VOID** the warranty.

REPLACEMENT PARTS and ACCESSORIES- Use only approved replacement parts and accessories specified in this manual. Refer to the maintenance section of this or Printer User's Guide for more information.

MAINS DISCONNECT- Disconnect from the mains via the appliance inlet.

POWER CORD- Use an approved hospital-grade power inlet cord only.

DO NOT STERILIZE the instrument or any of its components.

DO NOT USE the instrument near other equipment that produces strong magnetic fields (such as MRI). The video monitor performance may be adversely affected.

Patients with a history of epileptic seizures or photosensitivity may be at increased risk of having a seizure during or immediately after this test.

PRINTER- Use only the printer and printer cables provided (or approved alternate) with this device to meet medical safety requirements. The Matrix instrument must provide the printer power or patient isolation may be compromised

UNIVERSAL SERIAL BUS (USB) CONNECTOR- Do not connect another printer or computer to the USB connector as patient isolation may be compromised.

TYPE BF – Indicates this equipment contains Type BF applied parts; the Patient Forehead Rest and Patient Response Button.

SHIPPING and STORAGE TEMPERATURE range - Limit the temperatures the instrument is exposed to between **-20° C (-4° F) and +60° C (+°140 F)** to avoid possible damage to the instrument. Refer to the environmental specifications section of the manual for more information.

PATIENT RESPONSE BUTTON CONNECTOR - Connect ONLY the Patient Response Button supplied with the instrument or an approved replacement to the connector on the bottom of the instrument. Connection of any other device to the patient response button connector may damage the instrument or create an unsafe condition and will void the warranty.

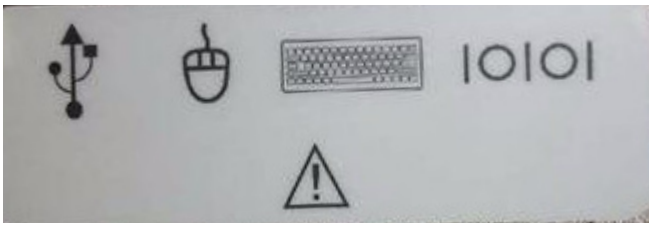
UNIVERSAL SERIAL BUS (USB) CONNECTOR – Connect ONLY the printer supplied with the instrument or an approved replacement to the USB connector on the bottom of the instrument using the USB cable supplied with the instrument or an approved replacement.

TRACK PAD – Connect ONLY the track pad supplied with the instrument or an approved replacement to the connector on the bottom of the instrument. The track pad cable has a green connector with a mouse symbol on it that is similar to the symbol on the bottom of the instrument.

KEYBOARD - Connect ONLY the keyboard supplied with the instrument or an approved replacement to the keyboard connector on the bottom of the instrument. The keyboard cable has a purple connector with a keyboard symbol on it that is similar to the symbol on the bottom of the instrument.

COMPUTER INTERFACE CONNECTOR - Connect ONLY **RS-232 serial compatible** computer ports to the computer interface connector on the bottom of the instrument. Connection of any other computer port or device to the computer interface connector may damage the instrument. This computer interface is reserved for future use

.



1 INTRODUCTION

Thank you for purchasing the Humphrey Matrix Visual Field Instrument, featuring Welch Allyn's Frequency Doubling Technology. This revolutionary new instrument represents the latest breakthrough in visual field testing, providing early detection of glaucoma and management of visual field loss.

ABOUT THE USER'S GUIDE

The User's Guide is designed to help you understand the capabilities and operation of the Humphrey Matrix Visual Field Instrument with Welch Allyn's Frequency Doubling Technology. This instrument is designed for use by anyone familiar with the operation as described in this User's Guide; no special training or qualifications are required. To achieve satisfactory results, read the User's Guide thoroughly before using the instrument. Only appropriately trained eye care professionals should perform interpretation of the results. A Set-up & Training video on CD, Quick Reference Guide, and Clinical Examples Reference Guide are also provided to maximize your success using the Humphrey Matrix Visual Field Instrument.

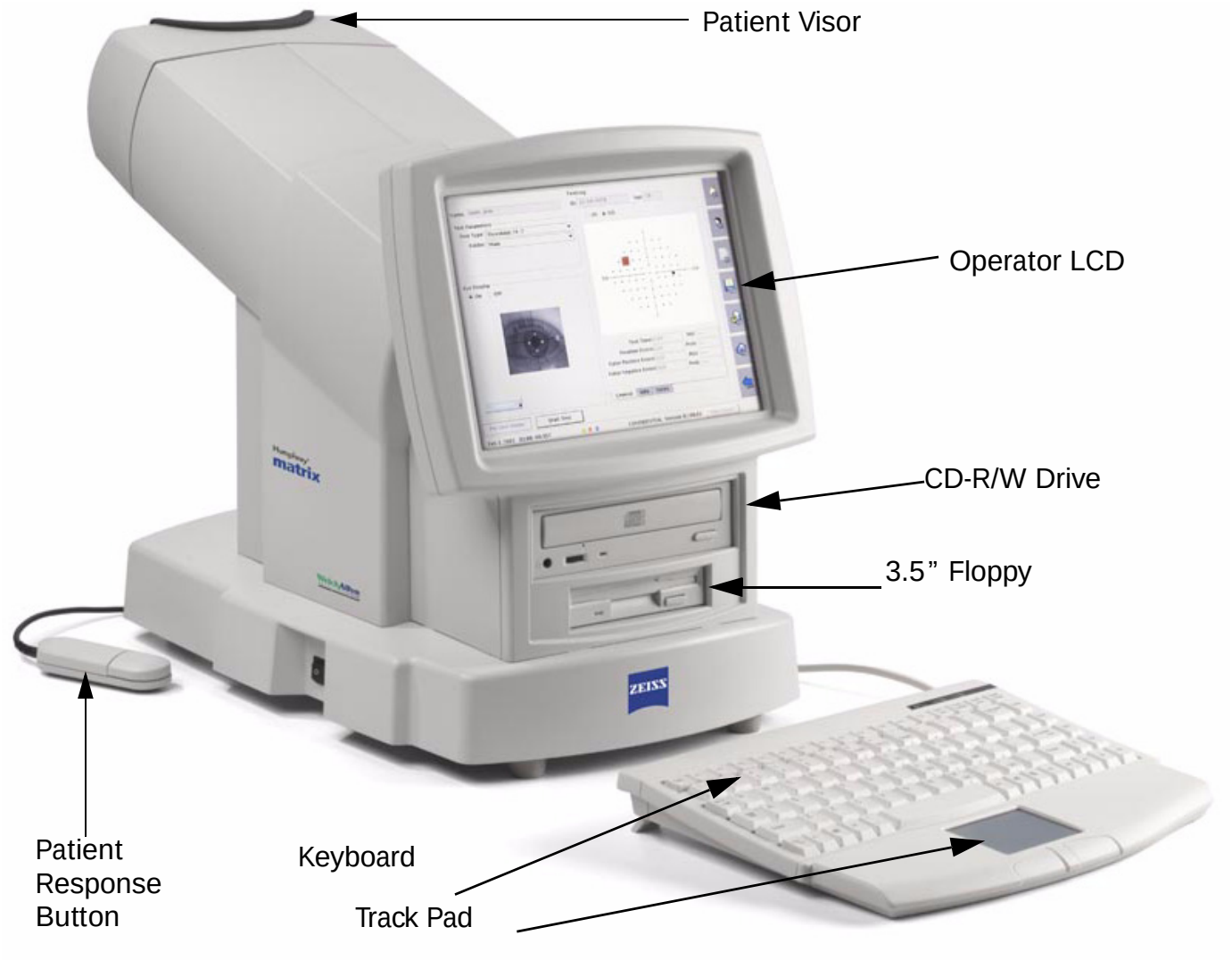
INSTRUMENT OVERVIEW

The Humphrey Matrix Visual Field Instrument is an innovative, efficient, compact, and affordable automated visual field testing instrument. Years of research and clinical trials of Welch Allyn's patented Frequency Doubling Technology have resulted in an instrument that provides rapid, clinically validated and user-friendly visual field testing.

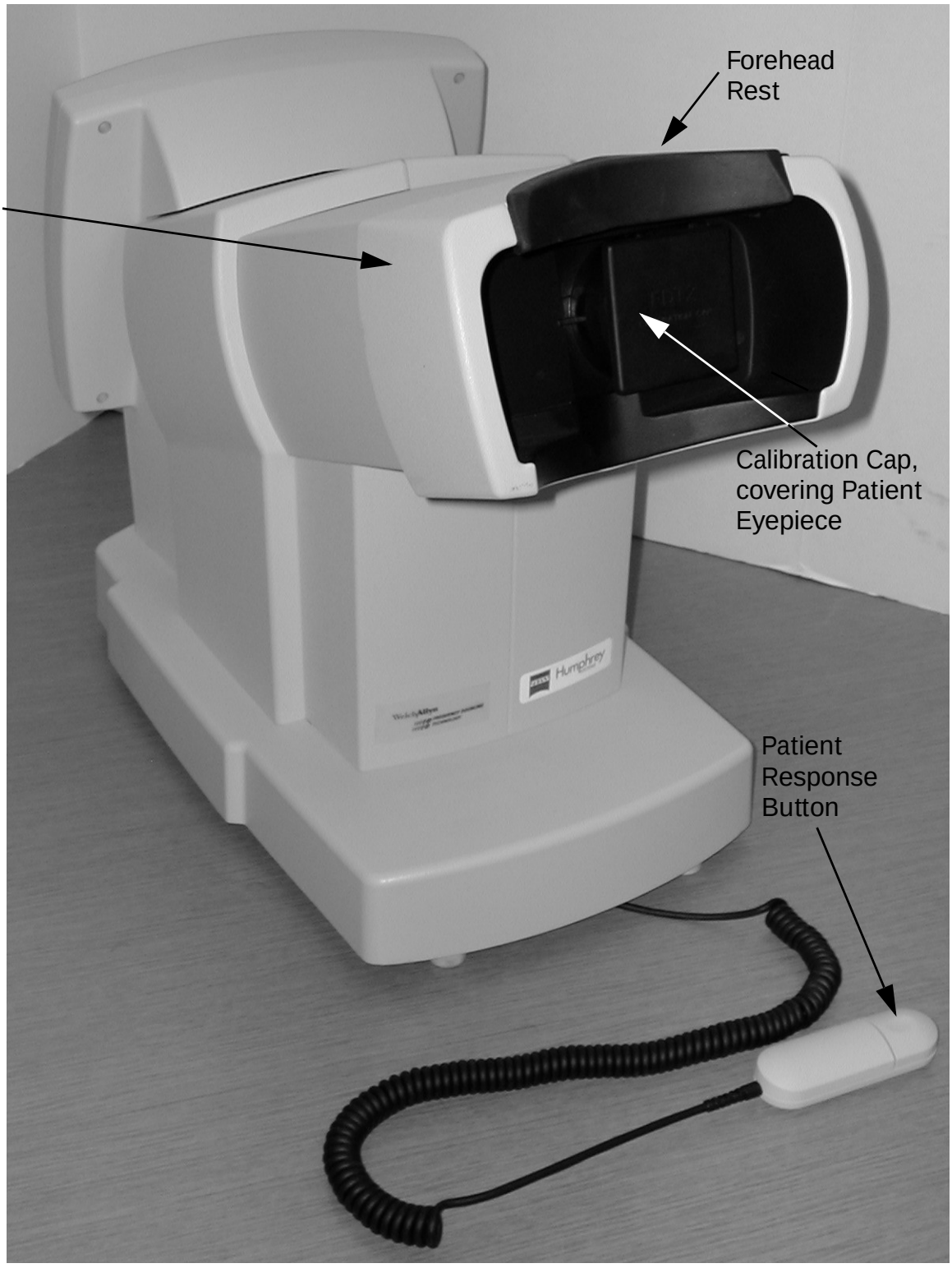
Key features of the Humphrey Matrix Visual Field Instrument include:

- World-class clinical validation by leading researchers in the field
- Statistically significant correlation to the Humphrey Field Analyzer
- Extensive age-normative reference database to ensure accurate, reliable tests
- Accurate & reliable supra-threshold screening tests in less than 1 minute per eye
- Full-threshold test results in five minutes per eye
- 24-2, 30-2, 10-2, N-30 and Macula FDT full-threshold tests
- Humphrey FDT N-30 threshold and screening tests
- Video eye monitoring for patient alignment and fixation monitoring
- Easy to use; no special operator training or certification is needed
- No corrective (trial) lens needed up to +/- 3 diopters; patients can usually wear their own correction or none at all (refer to Patient Correction section of User's Guide)
- No eye patch is needed for the untested eye - it is automatically occluded
- Not affected by normal ambient lighting, so using normal room lighting is possible
- 8 ½" x 11" color inkjet printer for results
- Floppy and CD-R/W drives for data storage and transfer
- Storage for more than 1 million patient tests and associated data
- Software upgrade capability for future enhancements

INSTRUMENT COMPONENTS



The instrument has a sliding Patient Visor that aids in isolating the eye for testing and automatically occludes the opposite (untested) eye. A ¾ size keyboard with an integrated track pad controls the operation of the instrument. A plain paper 8.5” x 11” USB inkjet printer and a USB printer cable are included with the instrument. Detachable Patient Response Button with holder, two Power Cords (one for the instrument and one for the printer), Calibration Cap and dust cover are also provided.



FREQUENCY DOUBLING TECHNOLOGY (FDT) OVERVIEW

FDT isolates a subset of low redundancy, retinal ganglion cell mechanisms in the magnocellular (M-cell) pathway. These M-cells have large diameter fibers and comprise only 3% to 5% of all retinal ganglion cells. The damage to these cells in the disease process is detected effectively and efficiently by FDT. Refer to the Clinical Examples Reference Guide for more information.

2 INSTRUMENT SET UP

Because of its light weight and small size, you can set up your Humphrey Matrix virtually anywhere in your office.

Please refer to the information provided in the printer box for printer set-up, use, maintenance and service information. Refer also to the Training video on CD for instrument set-up instructions.

UNPACKING

Open the shipping box by carefully cutting the packing tape securing the top flaps of the box. Lift out the top foam insert. Lift the instrument out of the remaining foam insert by grasping the instrument at the two cutouts provided and set the instrument on a flat, stable surface. Remove the plastic bag from the Humphrey Matrix Visual Field Instrument.

After you have unpacked the instrument and its components, confirm that in addition to this User's Guide, you have received the following items in good condition:

- Humphrey Matrix Visual Field Instrument
- Calibration Cap (covering the Patient's Eyepiece inside the Patient Visor)
- Patient Response Button & Response Button Holder
- Instrument Power Cord (appropriate for local operating voltage)
- Keyboard
- Dust Cover
- Keyboard shelf
- Training video on CD ***(CD will NOT operate in the Matrix CD-R/W drive)***
- Quick Reference Guide
- Clinical Examples Reference Guide
- Inkjet printer in its own box including:
    - USB cable for the printer
    - Power cord for the printer
    - Printer Set-Up, Use, Maintenance, and Service Information

Aligning the instrument with your patient is important for good test results. A height-adjustable table and a height-adjustable patient chair are recommended when performing testing. A height-adjustable table is available as an optional Humphrey Matrix accessory.

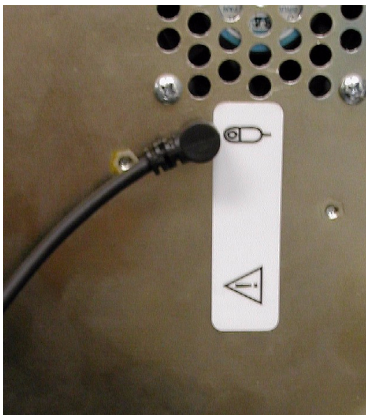
RETAIN THE SHIPPING MATERIALS (BOX AND PACKAGING) IN THE EVENT OF SHIPPING DAMAGE OR FOR RETURN, IF NECESSARY, TO AN AUTHORIZED SERVICE OR DISTRIBUTION LOCATION AT ANY TIME IN THE FUTURE.

PREPARATION FOR USE

Once you've chosen a location, carefully lay the instrument on its side to prepare the instrument for use by connecting all of the components.

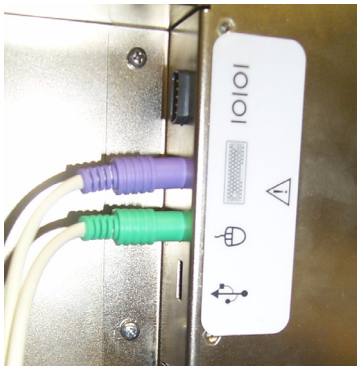
PATIENT RESPONSE BUTTON CONNECTION

Plug the **Patient Response Button** connector into the small round connector jack towards the patient end, underneath the base of the unit (at the center) and near the patient response button symbol.



KEYBOARD/TOUCH PAD CONNECTIONS

While the unit is still on its side, plug the keyboard and touch pad connectors into their jacks. Their jacks are located underneath the base of the unit near the keyboard and mouse symbols, towards the operator's side. Match the symbols on the connectors with the labels on the jacks. Plug the purple connector into the keyboard jack, the green connector to the mouse jack.

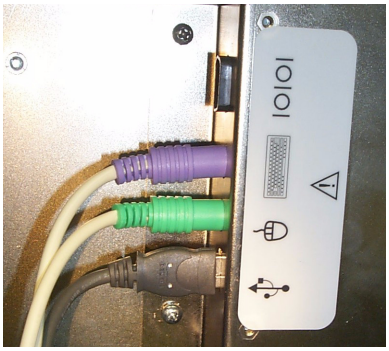


Open the Printer shipping box by carefully cutting the packing tape securing the top flaps of the box. Remove the printer, USB cable, power cord, Printer information, and Printer software CD (for reference only) from the printer box. To protect the printer during shipping some components were secured with tape and packing material. Make sure all tape and packing material is removed before operating the printer.

To achieve satisfactory results, read the Printer information thoroughly before using the printer. Refer to the Printer information to install the print cartridges to complete the printer set-up. Once the printer set-up is completed, connect the Printer USB cable to the USB port on the printer, and then connect the Printer Power cord to the printer.

PRINTER (USB) CONNECTION

Plug the Universal Serial Bus (USB) printer cable supplied with the printer into the USB jack located underneath the base, adjacent to the keyboard and mouse connections.



Printer Power Connection

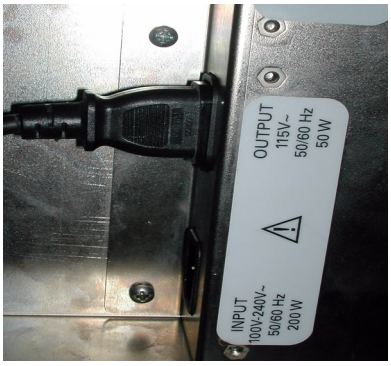


Figure (A)

Power Connections

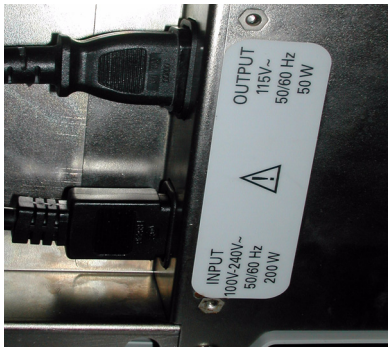


Figure (B)

Underneath the base of the unit there are two Power Cord receptacles, one for the printer and the other to power the instrument. Plug the printer power cord supplied with the printer into the accessory power OUTPUT receptacle on the unit (Figure A). Plug the approved hospital grade Power Cord provided with the instrument into the appropriate Power Cord INPUT receptacle (Figure B).

PRINTER- Use only the printer and printer cables provided (or approved alternate) with this device to meet medical safety requirements. The Humphrey Matrix instrument must provide the printer power or there is a risk of comprised patient isolation.

Verify ALL connections are fully seated. Once all the cables are connected, turn the Humphrey Matrix Visual Field Instrument upright. Verify that the instrument feet are not on top of any cables.

Affix the Patient Response Button Holder to the right patient side of the instrument by peeling the tape off the holder and firmly pressing the holder in the desired position.

3 GENERAL OPERATION

TO TURN THE INSTRUMENT ON

Before plugging the instrument into an appropriate power outlet, make sure that the Power Switch (0/I) is in the OFF (0) position. The Power Switch is located on the left side of the instrument when facing the operator side. To turn the instrument ON, connect the instrument's power cord to an appropriate power outlet, then switch the Power Switch (O/I) to the ON (I) position. The system will begin to load the operating software. A status bar will indicate progress of the instrument initialization. After approximately 2 minutes the **MAIN MENU (F1)** will appear on the Operator LCD Display.

Once the Power Switch on the Matrix is turned ON, press the Printer Power Button to turn the Printer ON. Note that the Printer will only operate when the Humphrey Matrix power is ON.

TO TURN THE INSTRUMENT OFF

First, press the Printer Power Button to turn the Printer OFF. Refer to the Printer User's Guide for more information. Then, ***select*** **Shut Down** (lower right corner of the LCD) to turn OFF the instrument from any screen. Wait until the message "Power down" appears (~ 1 minute) before turning OFF the main power switch. **Turning the main power switch OFF without Selecting Shut Down will make it take longer to power up next time and could potentially corrupt the Humphrey Matrix software and require service to restore normal operation.**

KEYBOARD AND TOUCH PAD OPERATIONS

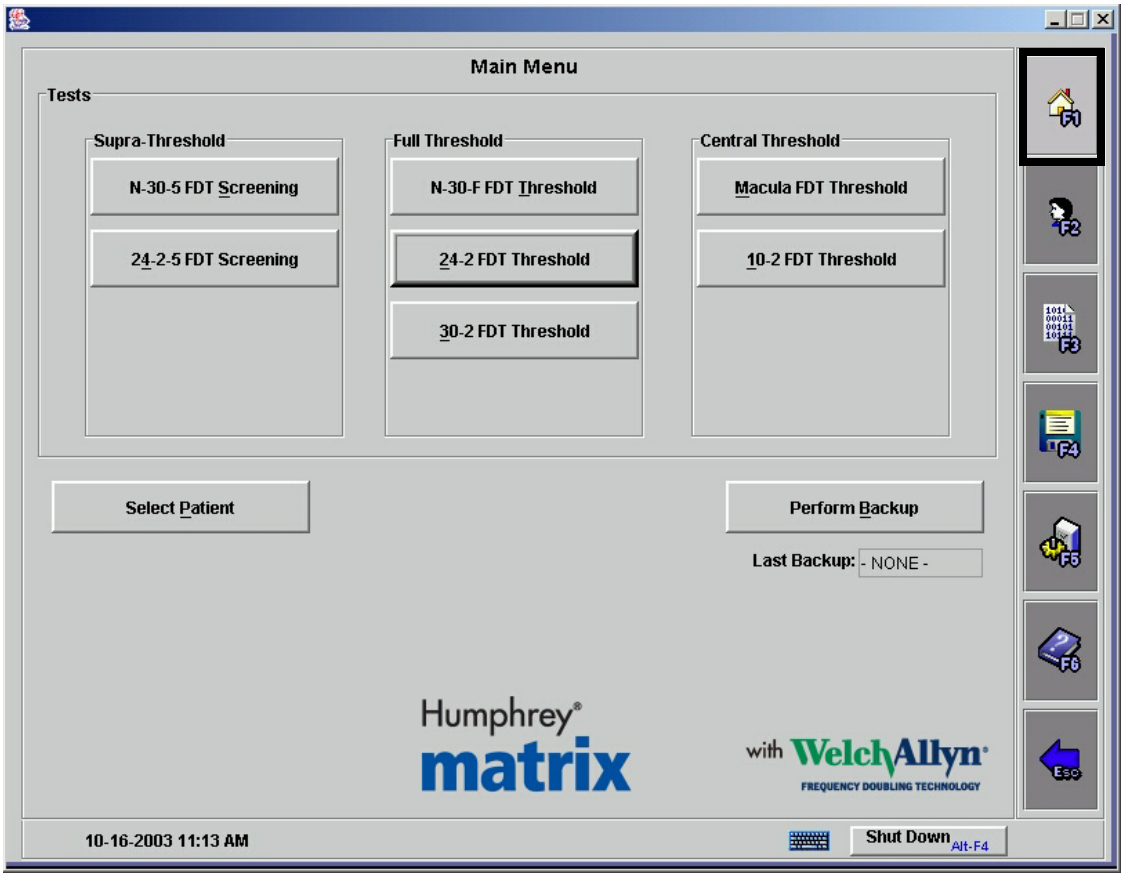
The keyboard functions similarly to normal computer keyboards. Pressing ALT and the underlined letter or number on the button selects the button (English language only). The Touch Pad controls the cursor like a mouse. The left button is used to select items or buttons. Double tapping the touch pad is the same as clicking the left button. The right button is not active for the Humphrey Matrix software.

SCREENS OVERVIEW

The functions of the Humphrey Matrix instrument are organized into various screens. The screen name is displayed at the top of every screen. The bottom of the screen contains the date and time. The Shut Down Button is also located at the bottom of the screen. Only shut down the instrument using the Shut Down Button and follow the instructions on the screen.

The Main Toolbar is located vertically along the right side of the display and is always visible. This toolbar is used to navigate the available functionality of the instrument. Select the Toolbar Buttons using the mouse or with the hot keys shown in the button icons (F1-F6 & Esc). Pressing the Esc Key returns the user to the previous screen. Selecting the Enter Key selects the default button on a screen.

F1: MAIN MENU



Main Menu

View Patients

Recall Tests

File Functions

System Settings

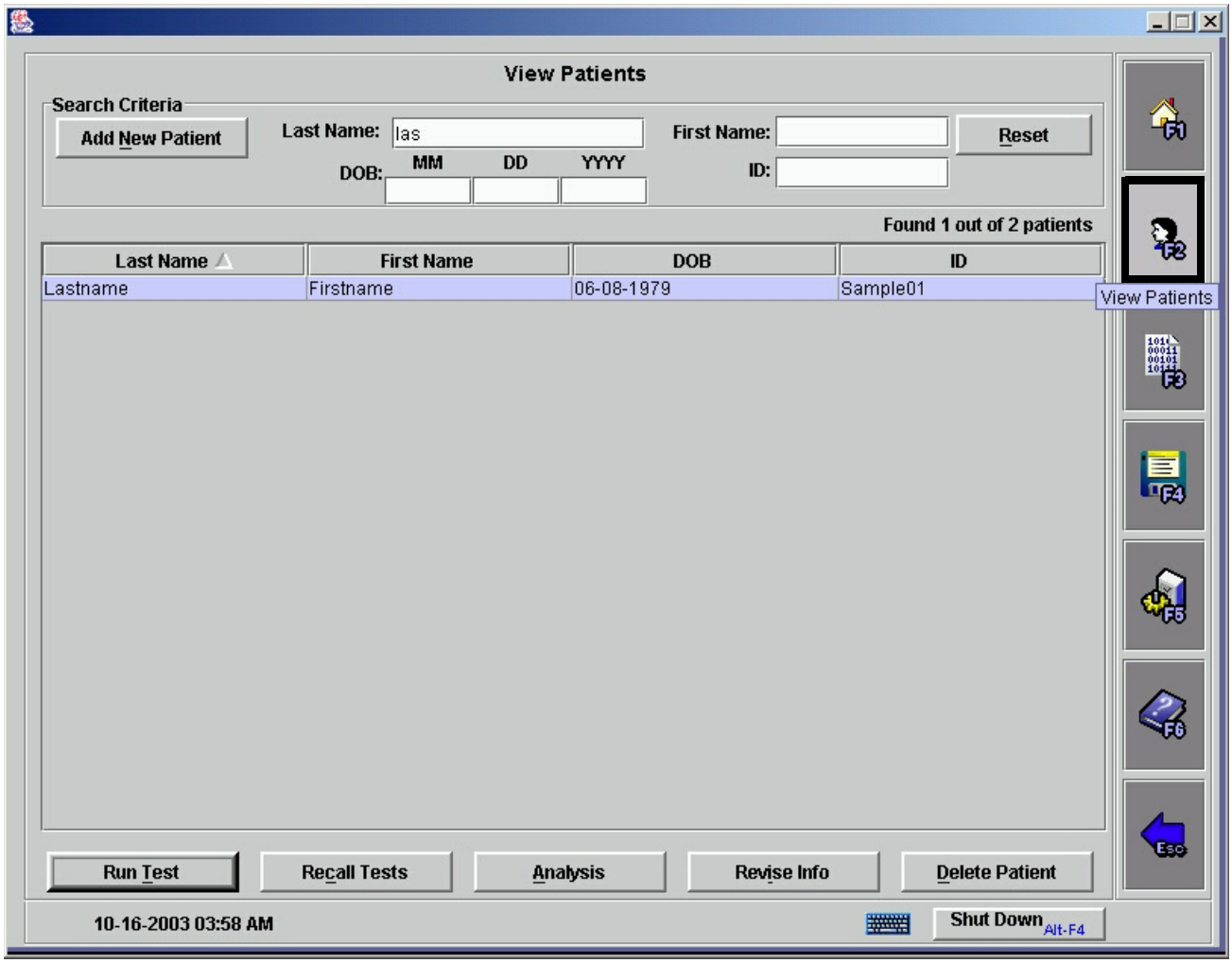
Help

The Main Menu screen appears automatically after instrument initialization is completed when the instrument is initially powered on. The Main Menu provides buttons for selecting all the visual field tests available on the instrument. You may also initiate testing by selecting the Select Patient Button, which also selects the most recent test/settings for patients already in the instrument database.

Because backing up patient test data is important, the MAIN MENU also has a Perform Backup Button, along with an indicator telling you the date of your last backup. You should back up your database regularly. Select a backup schedule that fits your practice. Many practices perform weekly backups to protect their patient visual field data. The default backup reminder is 1 week, or you can also change the default in the F5 System Settings Screen.

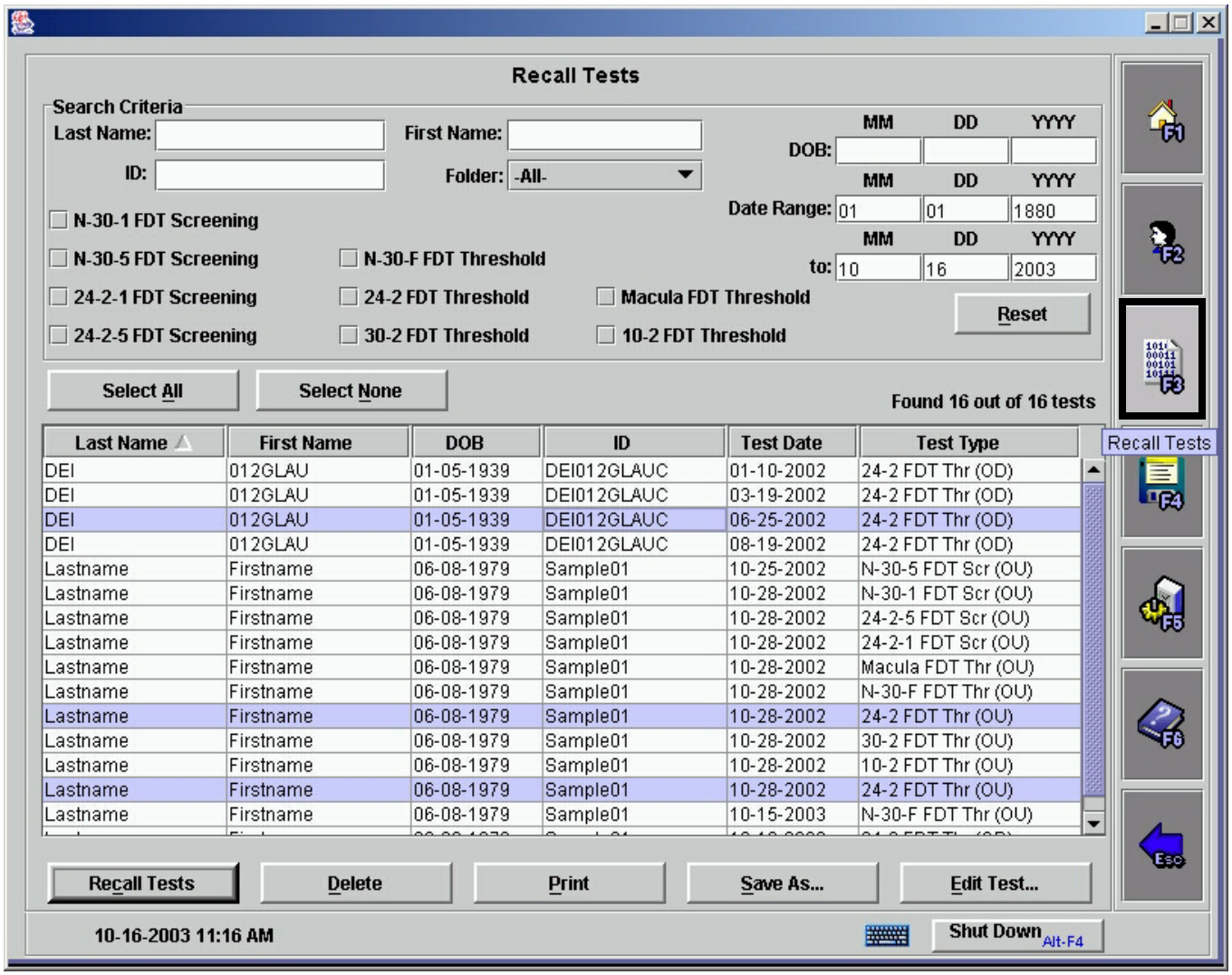
All Humphrey Matrix data stored on the hard disk, CD, and/or floppy discs are your records, and it is your responsibility to preserve the integrity of these data / files. Welch Allyn and Carl Zeiss Meditec are not responsible for the loss of patient data / files stored on the hard disk, CD and/or floppy disks. Data stored on the Humphrey Matrix, which identifies patients or contains demographics capable of identifying patients, will be handled confidentially in a manner conforming to the confidentially regulations promulgated under the Health Insurance Portability Act of 1996 (HIPPA).

F2: VIEW PATIENTS



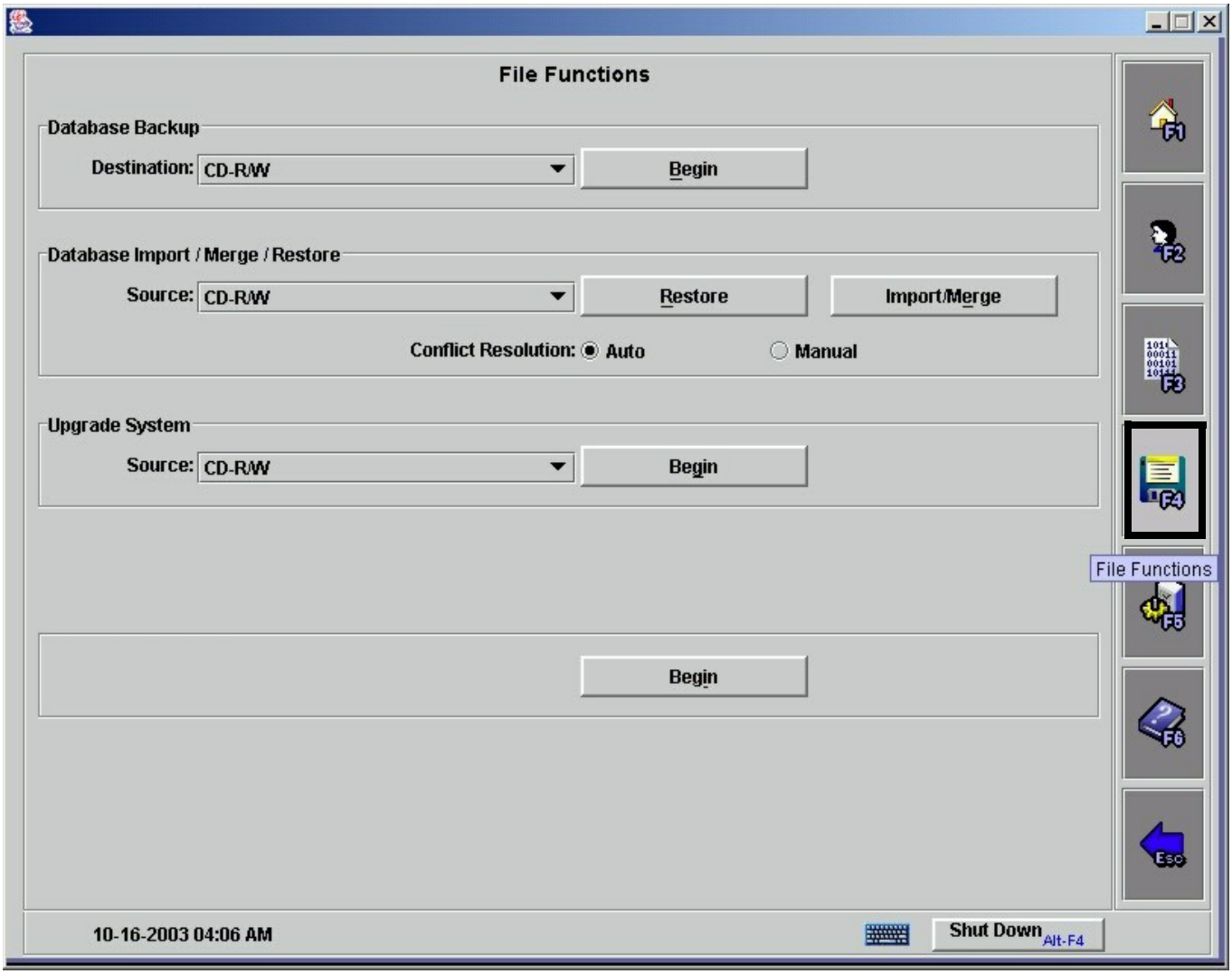
The View Patients Screen is where new patients are added or existing patient entries in the database are searched, recalled, and revised. The View Patients Screen is also accessed from the Main Menu by selecting any of the Screening, Threshold, or Central Test Buttons. Once a patient is selected, you may run a test, recall previous test(s), analyze test results, revise patient information, or delete the patient from the database. To delete a patient, it is necessary to delete all of his or her field tests in the Recall Tests (F3) Screen first.

F3: RECALL TESTS



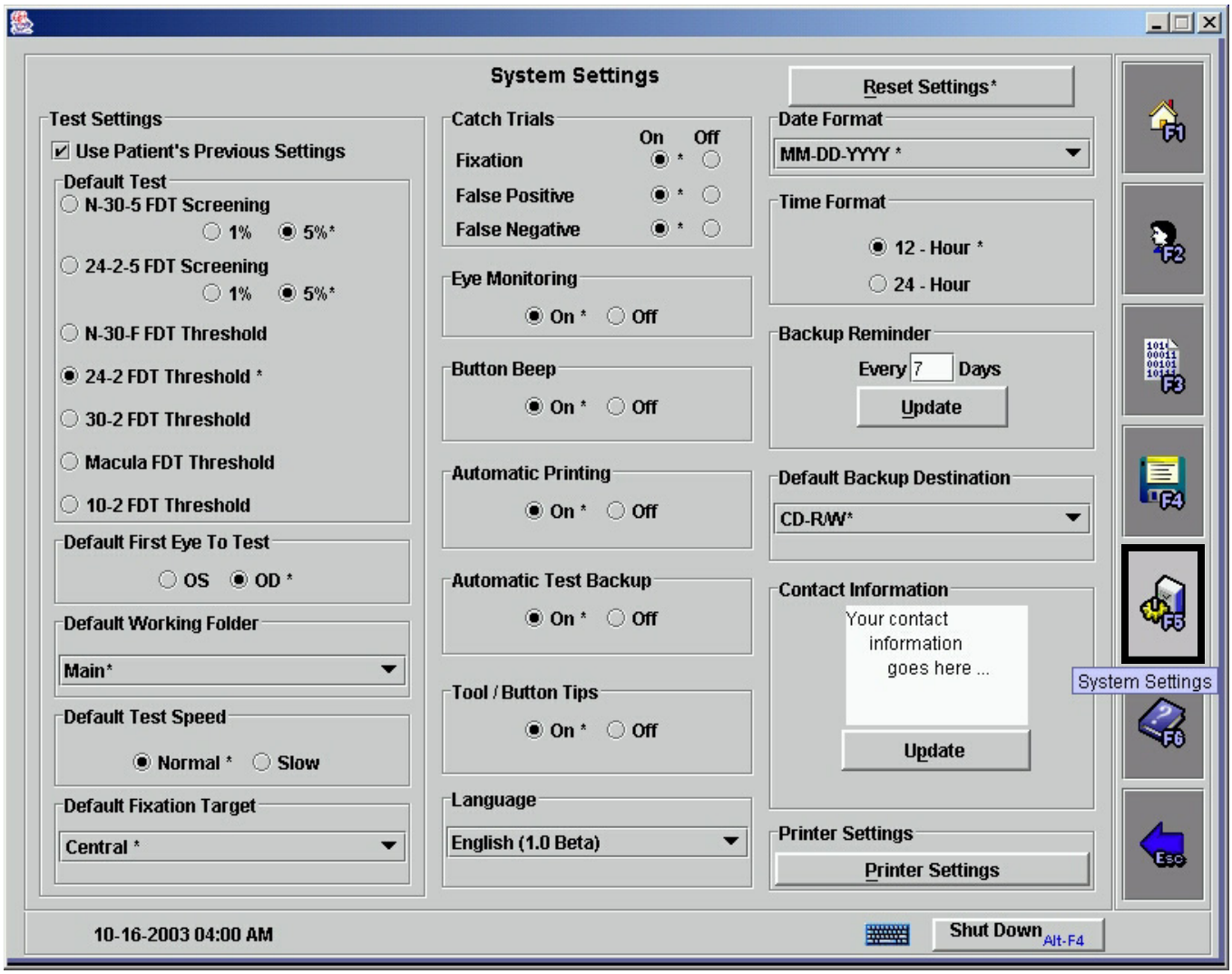
The Recall Tests Screen is where individual tests in the database are searched by patient or test information. Once the desired individual tests are selected, you can then recall, delete, print, or save to floppy or CD-R (as JPEG image, Humphrey Matrix database backup, or CSV text format) the test results. In addition, operator entered test information is available for editing. **Note that deleting a test from the database is permanent.** The deleted test is only recovered if it is available on a previous database backup.

F4: FILE FUNCTIONS



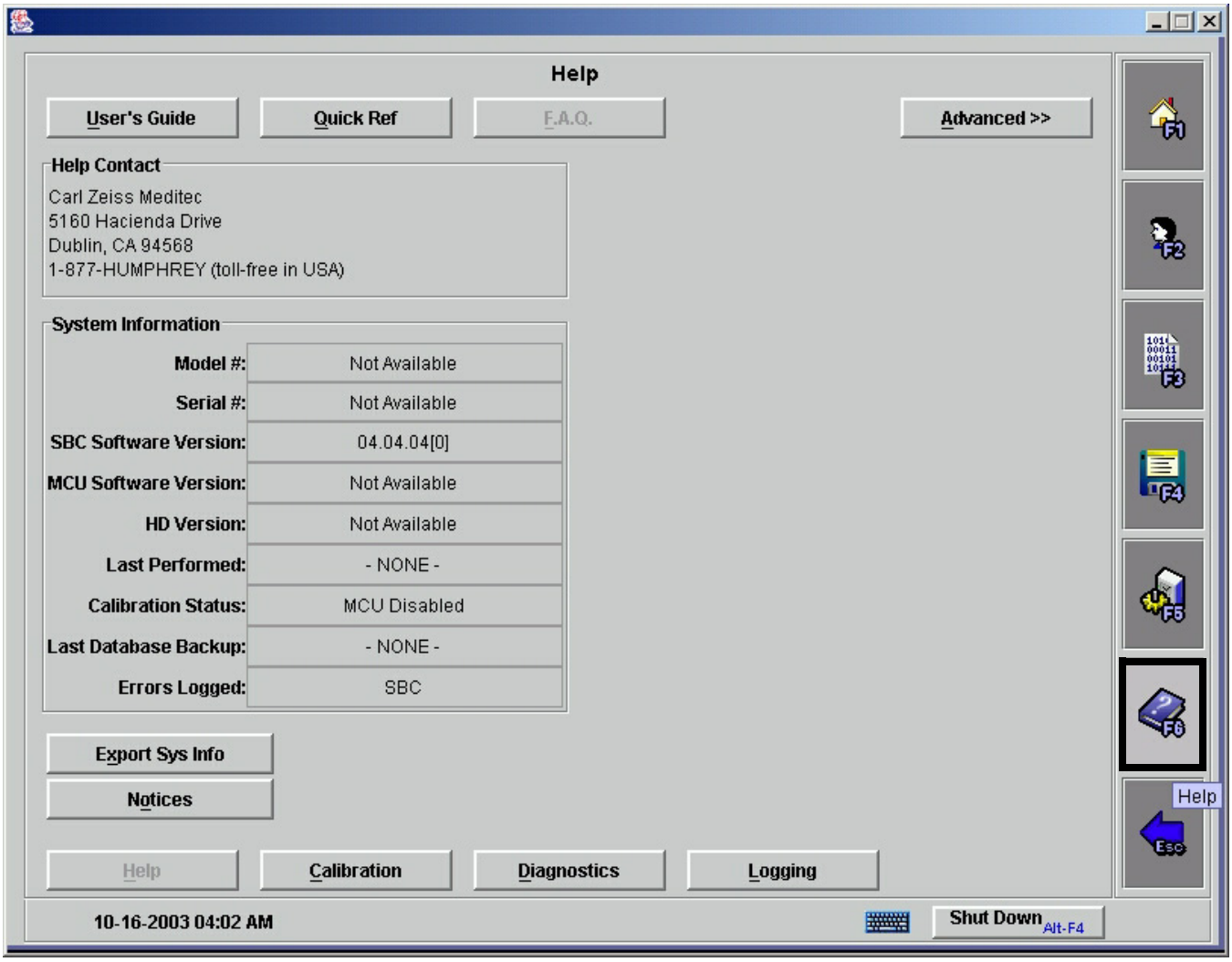
The File Functions Screen is where the patient test database is backed up or imported / merged / restored. The File Functions Screen is also where available software upgrades of the Humphrey Matrix system software are performed.

F5: SYSTEM SETTINGS



The System Settings Screen provides the operator with the ability to customize the configuration of the Humphrey Matrix Visual Field Instrument by changing default system settings.

F6: HELP



The Help Screen is where the user may view the instrument's system information and the User's Guide. When needed, the Calibration, Diagnostics, and Logging Functions are also accessed from the Help Screen.

4 TEST RESULTS AND RELIABILITY MEASURES

VISUAL FIELD TESTS SUMMARY

The table below summarizes the various FDT visual field tests available on the Humphrey Matrix Visual Field Instrument. Sample printouts for all the tests listed are included at the end of this User's Guide for your reference.

The screening tests provide qualitative results regarding the patient's visual function. Screening tests are typically used for patients where no eye disease has been detected as part of a routine eye examination. Threshold testing is used to obtain quantitative visual field results to confirm the presence of eye disease and monitor visual function over time.

FDT Test	Visual Field Locations	Probability Level Classifications	Fixation Catch Trials	False Positive Trials	False Negative Trials	Test Strategy
N-30-5, N-30-1 Screening	19	4	3	3	0	Supra-Threshold
24-2-5, 24-2-1 Screening	55	2	10	10	0	Supra-Threshold
N-30-F Threshold	19	4	6	6	3	MOBS
24-2 Threshold	55	4	10	10	6	ZEST
30-2 Threshold	69	4	10	10	6	ZEST
10-2 Threshold	44	4	10	10	6	ZEST
Macula Threshold	16	4	6	3	0	ZEST

SCREENING TESTS

All of the Humphrey Matrix visual field FDT **screening** tests are **supra-threshold** tests meaning that they test at specific age-corrected contrast values determined by the normative database probability levels. Select the probability levels to use for screening for general clinical use to maximize **sensitivity** (-5 uses the 5% probability level) or for population based screening to maximize **specificity** (-1 uses the 1% probability level). The screening test results consist of probability plots of the tested locations for each eye and overall reliability measures along with patient and test information. The test locations indicate the different probability levels with different patterns, increasing in darkness with decreasing probability level. Refer to the sample printouts included at the end of this User's Guide.

The **N-30-5 (or N-30-1) FDT screening test** is essentially the same 19-point rapid screening test performed on the Humphrey FDT Visual Field Instrument, except that moving the fixation target is not required with the Humphrey Matrix. The same normative database is used for the N-30

tests in the Humphrey FDT and Humphrey Matrix Visual Field Instruments so the tests are comparable between the two instruments. Each test location is assigned one of four probability levels, depending on the test selected. Each visual field location is tested until the patient responds, or until all three probability levels are tested. The initial probability level is tested twice if needed, followed by once at each of the other levels to complete the N-30 screening. As a result, the screening test time will increase for patients with eye disease.

The **24-2-5 (or 24-2-1) FDT screening test** is a screening version of the 24-2 full threshold test. Each test location is assigned one of two probability levels, depending on the test selected. Each visual field location is tested at a single probability level (pass/fail). Each visual field location is tested until the patient responds or the location is tested twice at the initial probability level to complete the 24-2 screening.

THRESHOLD TESTS

All the Humphrey Matrix visual field **threshold** tests are **full threshold** tests meaning that they provide quantitative measures of the visual function at each location tested. The threshold test results consist of a raw threshold plot (dB values), a gray scale plot (pattern shading), total and pattern deviation plots (dB values), total and pattern deviation probability plots (pattern shading), MD and PSD global indices (numeric with probability values), overall reliability measures, along with patient and test information for each eye tested. The probability plots indicate one of five possible probability levels with different patterns, increasing in darkness with decreasing probability level. Refer to the sample printouts included at the end of this User's Guide.

The **N-30-F FDT full threshold test** is essentially the same 19-point full threshold test performed on the Humphrey FDT Visual Field Instrument, except that moving the fixation target is not required and the threshold algorithm has been optimized to reduce test time with the Humphrey Matrix. The same normative database is used for the N-30 tests in the Humphrey FDT and Humphrey Matrix Visual Field Instruments so the tests are comparable between the two instruments.

For the **N-30-F FDT full threshold test**, the instrument utilizes a staircase threshold strategy known as a **Modified Binary Search (MOBS)**. The Humphrey Matrix utilizes a four-reversals rule (N-30-F) for determining the threshold level. The range of possible threshold level values for the raw data (patient threshold scores) is between 0 dB Maximum Contrast (lowest patient sensitivity) and 56 dB Minimum Contrast (highest patient sensitivity). The formula used to calculate the dB values is $\log_{10} \times \left(\frac{2048}{c}\right) \times 10 \times H$ where c ranges from 1 (minimum contrast) to 2048 (maximum contrast) and H is approximately 2. Note that XX dB is displayed if the threshold is not determined due to inconsistent patient responses which do not meet the MOBS threshold criteria. The magnitude of the threshold level values is directly correlated to the Humphrey Field Analyzer values.

The **24-2, 30-2, 10-2 and Macula FDT full threshold tests** are modeled after the Humphrey Field Analyzer tests to provide visual field test results that are familiar to you. **The FDT test results for the threshold tests correlate with the HFA results, but they are not directly comparable.** The FDT tests use a large (~270 subjects for each eye) age normative FDT database. The FDT full threshold tests use a maximum likelihood threshold strategy known as a ZEST (Zippy Estimate of Sequential Testing) to provide accurate threshold results as quickly as

possible. ZEST is similar to SITA used on the Humphrey Field Analyzers, but differs in the specific algorithm details.

The **24-2** (55-point) and **30-2** (69-point) **FDT full threshold tests** are central 30 degree visual field tests for use in general visual field testing and glaucoma management. These tests also provide a Glaucoma Hemifield Test that provides a plain language interpretation of the visual field results based on an asymmetry analysis between test locations in the upper vs. lower hemifield to detect glaucoma.

Glaucoma Hemifield Test (GHT) messages

Outside normal limits

Borderline

Borderline - General reduction of sensitivity

General reduction of sensitivity

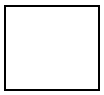
Abnormally high sensitivity

Within normal limits

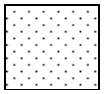
The **10-2** (44-point) **FDT full threshold test** is a central 10 degree visual field test for use with retinal disease (AMD, Diabetic Retinopathy) and end-stage glaucoma. The **Macula** (16-point) **FDT full threshold test** is a central 5 degree visual field test subset of the 10-2 test.

Mean Deviation and Pattern Standard Deviation (**MD & PSD)** are global statistical indices calculated from points over the entire visual field for the threshold tests. These indices reduce the individual threshold scores to a single number to provide overall information about the entire visual field. The magnitude of the **MD & PSD** values are directly correlated to the Humphrey Field Analyzer indices.

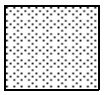
PROBABILITY LEVEL CLASSIFICATIONS



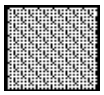
The patient achieved a threshold level in the range that **95% (P>=5%)** of normal subjects of the same age achieved for the test locations with this shading.



The probability is less than **5% (P<5%)** that a normal subject of the same age would perform at the threshold level that this patient achieved for the test locations with this shading.



The probability is less than **2% (P<2%)** that a normal subject of the same age would perform at the threshold level that this patient achieved for the test locations with this shading.



The probability is less than **1% (P<1%)** that a normal subject of the same age would perform at the threshold level that this patient achieved for the test locations with this shading.

The probability is less than **0.5% (P<0.5%)** that a normal subject of the same age would perform at the threshold level that this patient achieved for the test locations with this shading. This shading will also occur if the patient **failed to respond** at the **maximum contrast level** of the instrument (**0 dB** is indicated).

RELIABILITY MEASURES

When reviewing the results of the visual field test, give careful consideration to the **reliability indicators** (catch trials). They are an important measure of patient reliability in taking the test (and of the reliability of the results). They are indicated as a ratio of the number responded to the number presented (as well as a percentage of the total). For example, 1/10 (10%) indicates that the patient responded to 1 of the 10 catch trials presented.

FIXATION ERRORS - The ratio of the number of times the patient responded to a target placed in the blind spot versus the total number of times fixation was tested (i.e., total number of targets placed in the blind spot). Fixation errors indicate the patient is not maintaining good fixation during the test, is misaligned, or does not understand the test.

FALSE POSITIVE ERRORS - The ratio of the number of times the patient responded to a "pause" in the testing sequence (i.e., no target presented) versus the total number of "pauses" in the testing sequence. False positive errors indicate the patient is pressing the button even if the patient does not see any patterns (a "happy clicker") or does not understand the test.

FALSE NEGATIVE ERRORS - The ratio of the number of times the patient did not respond to a test pattern at the maximum possible contrast level of the instrument versus the total number of times that maximum possible contrast level patterns were tested. When possible, false negative catch trials are only presented at locations where the patient has previously responded. False negative catch trials are not used with screening tests. False negative errors indicate the patient is likely not paying attention, does not understand the test, or has a severe loss at the location of the false negative catch trial(s).

5 PATIENT TESTING

To prepare to perform a visual field test, just follow the simple procedure outlined below. A Quick Reference Guide is at the end of this User's Guide for your use.

TEST SET-UP

1. When you are ready to conduct the first test of the day, ***remove*** the **CALIBRATION CAP** from the Patient Eyepiece. Replace the calibration cap on the Patient Eyepiece when the instrument is not in use to minimize the accumulation of dust and debris on the Patient Eyepiece.
2. Check that the **Patient Visor** is in the correct position to test the corresponding eye. For testing the RIGHT eye (factory default setting), position the Patient Visor so that it extends past the housings on your RIGHT side when viewing from the Operator LCD side of the instrument. This positions the Patient Eyepiece on the RIGHT side facing the Patient Visor. If the Patient Visor is not correctly positioned, a popup message will appear on the screen when the Start Test Button is pressed.
3. Make sure the **Patient Response Button** is properly connected. The patient test will not begin if the Patient Response Button is not connected.

PATIENT SELECTION

1. From the Main Menu Screen (F1), ***select*** the button for the test that you want to perform or the **Select Patient** Button. Pressing the Select Patient Button will use the most recent test/ settings for patients already in the instrument database. Either selection proceeds to the **View Patients** Screen. Alternately, you may select the **View Patients (F2)** function directly from the Task bar.
2. For an **existing patient** already in the testing database, start typing the patient's last name, first name, DOB (date of birth), or ID to initiate a hot search of the testing database. The patient list is automatically refined until you can see and select the desired patient. Once the desired patient is selected, ***select*** the **Run Test** Button to open the **Testing** Screen (see Figure C).
3. For a **new patient**, ***select*** the **Add New Patient** Button. Complete as much data as desired about the patient. Note however, the minimum data requirement is DOB, first and last name, or DOB and patient ID.

   Required fields (**DOB** in addition to **First** and **Last Name** or **ID**) are marked with an asterisk (*).

   Enter the Date of Birth (DOB) in the format specified in System Settings (F5). MM-DD-YYYY is the system default (i.e. 12 25 1919 for December 25, 1919).

   Once the required patient information is entered, ***select*** the **Add Patient** Button to open the **Testing** Screen (see Figure D).

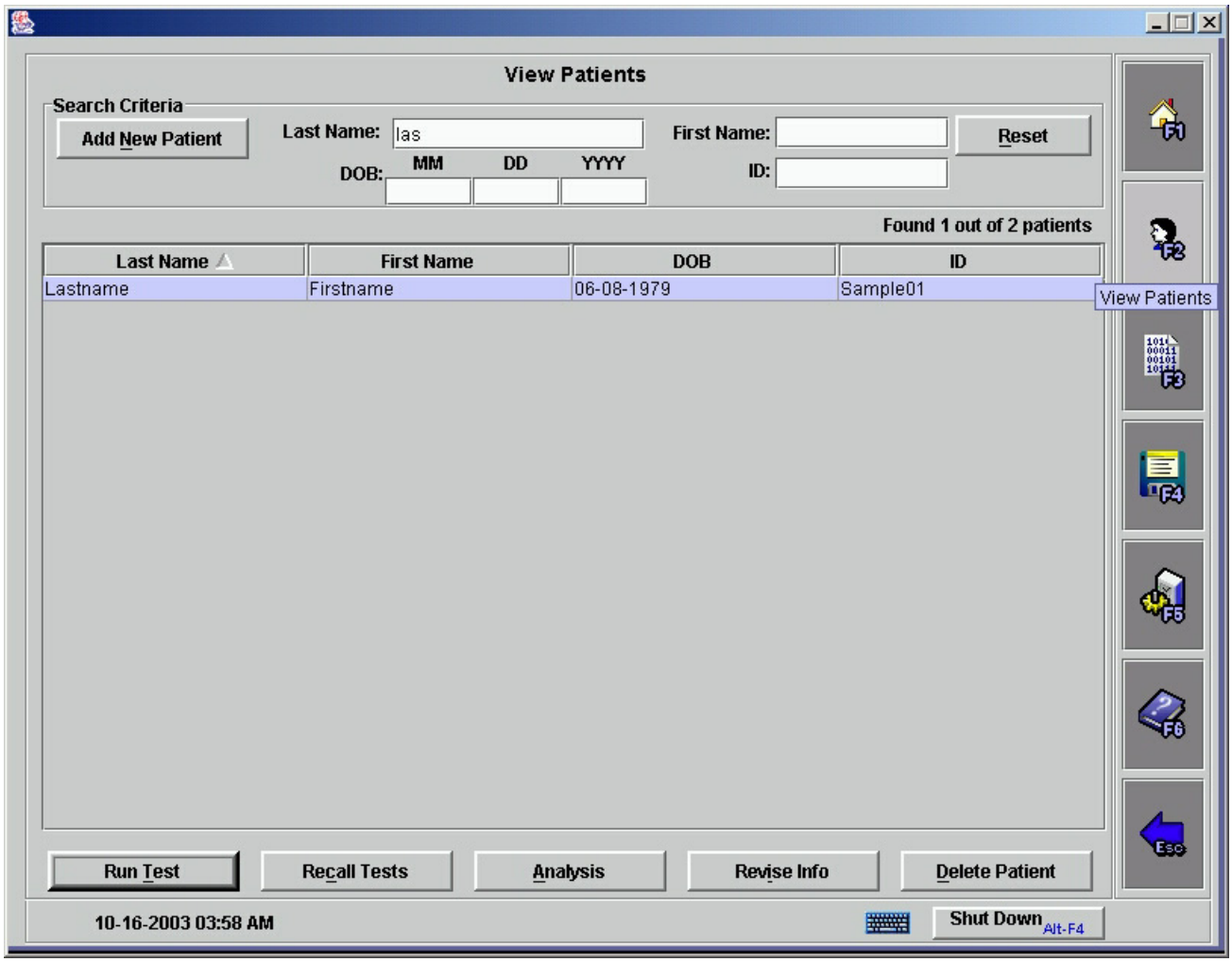

View Patients
Search Criteria
Add New Patient
Last Name: las
First Name:
Reset
DOB: MM DD YYYY
ID:
Found 1 out of 2 patients
Last Name
First Name
DOB
ID
Lastname
Firstname
06-08-1979
Sample01
View Patients
F1
F2
F3
F4
F5
F6
Esc
Run Test
Recall Tests
Analysis
Revise Info
Delete Patient
10-16-2003 03:58 AM
Shut Down Alt-F4

Figure (C)

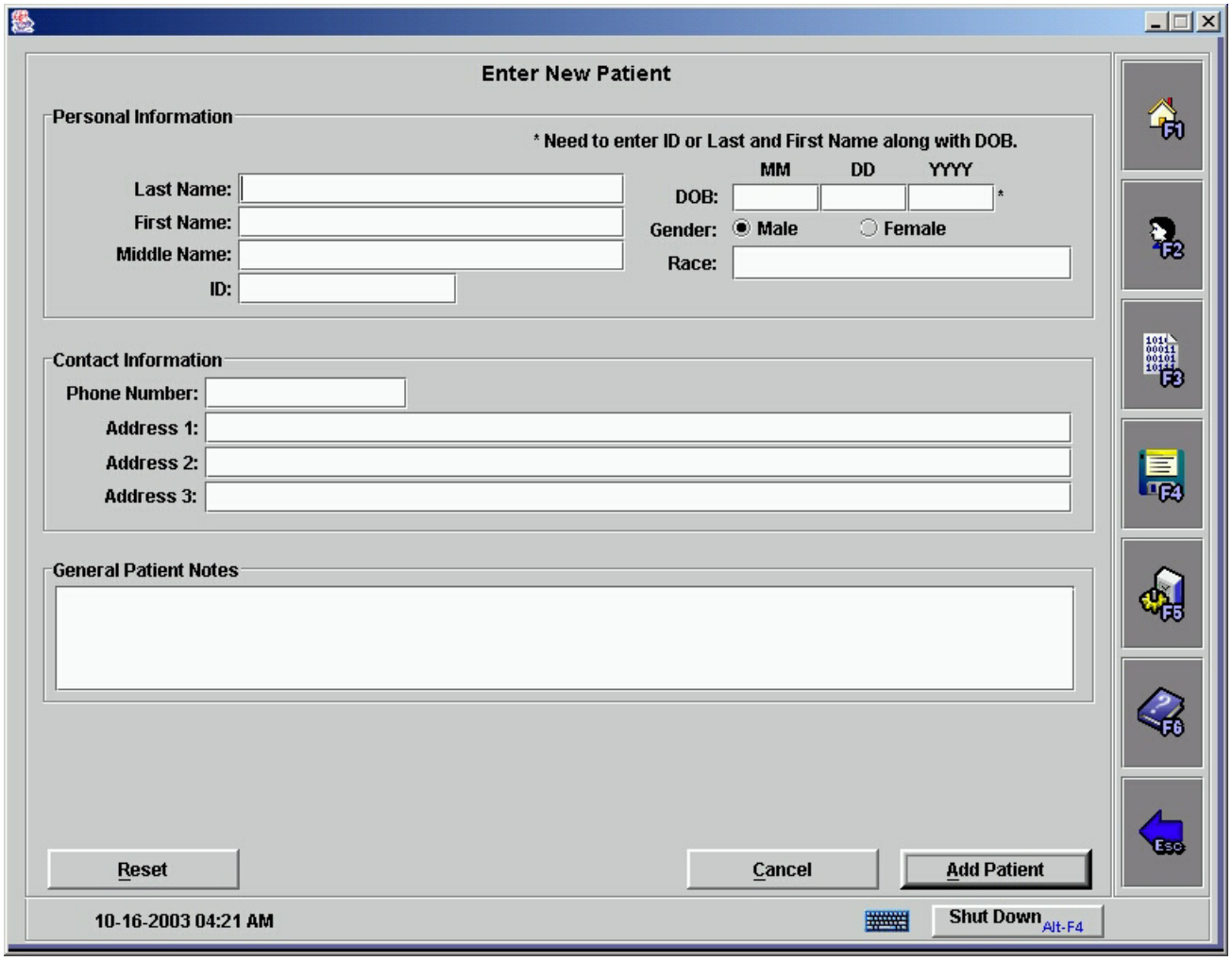


Figure (D)

ADMINISTERING THE TEST

The Testing Screen (Figure E) allows you to prepare the patient for the test and to confirm or modify the testing configuration selections, if needed, prior to performing the visual field test.

The status box under the chart on the right side of the screen shows that the **Pre-test Demo** is running. Until the test is started, stimulus presentations for the selected test are automatically displayed to demonstrate the test to the patient.

Confirm that the patient's name, ID and date of birth are correct. Return to View Patients (F2) if changes are needed.

Confirm the desired **Test Type** is selected in the upper right of the screen. Also, confirm proper selection of the **Folder**, **Test Speed**, and **Fixation Target**. Refer to the System Settings section of this User's Guide for more information. You can change each of these by using the pull down menu (click on the arrow to change if necessary).

You can alter the first eye tested in this screen by selecting the OD (RIGHT) or OS (LEFT) buttons above the chart.

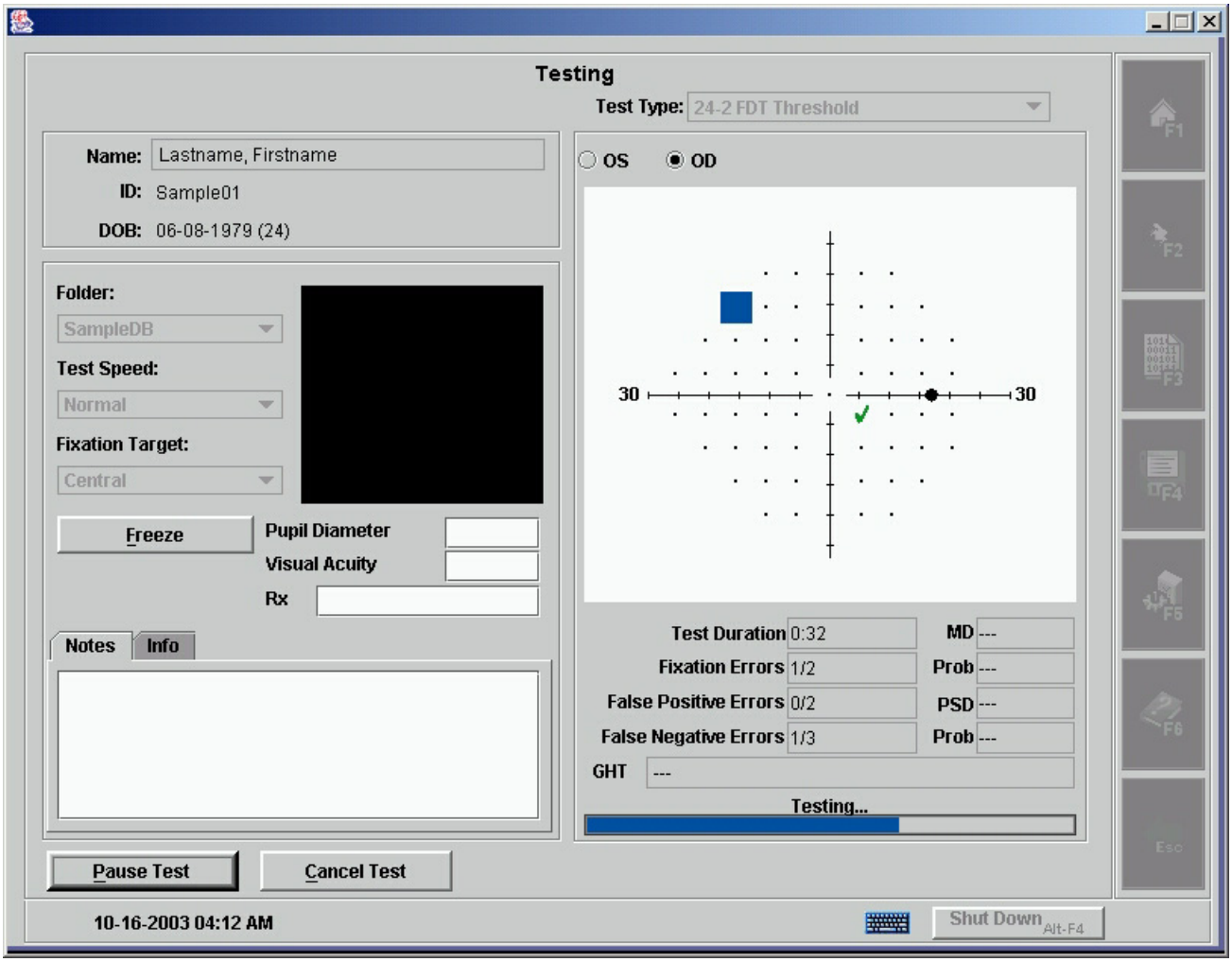


Figure (E)

In the Testing Screen, the video eye monitoring will display a live image of the patient's eye to aid in proper alignment of the patient and to ensure fixation during testing. Selecting the **Freeze** Button will freeze the live image of the eye. This provides the capability to measure the pupil size using the increments on the cross hair in the frozen video image. The markings on the cross hair are in 1mm increments. Press the **Unfreeze** Button to return to live video.

PATIENT CORRECTION

For accurate visual field test results, correct the patient to within the refractive error cited in the table below. Use the patient's habitual correction or a trial frame if needed. It is OK to use bi-focal or progressive lenses.

Tests	Patient Corrected within:
N-30-5 (-1) FDT Screening N-30-F FDT Threshold	+/- 6 Diopters
24-2-5 (-1) FDT Screening 24-2 FDT Threshold 30-2 FDT Threshold	+/- 3 Diopters
Macula FDT Threshold 10-2 FDT Threshold	+/- 2 Diopters

Use a trial frame instead of the patient's habitual correction if:

- Corrective lenses are tinted or photo-chromatic
- Small or thick eye glass frames obscure part of the testing field

Verify that the patient's eyes are undilated during the visual field test, unless his or her pupil is less than 3 mm.

PATIENT SEATING AND POSITION

- Confirm the **Patient Visor** is in the correct position so that the Patient Eyepiece is aligned with the tested eye.
- Check that the patient is relaxed and holding the Response Button properly.
- **Adjust the position of the patient or the instrument to obtain proper, comfortable patient alignment**. Proper alignment requires the patient to see all four self-alignment points at the same time while fixating on the black square target in the center. It is OK if the fixation target appears fuzzy to the patient.

  Align the patient's head against the forehead rest by adjusting the table or seat height for proper, comfortable head position relative to the instrument. Slide the instrument towards the patient if needed.
- When **Eye Monitoring** is turned on, an image of the patient's eye is displayed on the Testing screen. **Keep the patient's pupil inside the circle** on the video image throughout the test. Keeping the pupil perfectly centered for proper alignment is not necessary, but it should stay within the circle.

  A very important factor affecting test reliability is the steadiness of the patient fixation. Unless the tested eye accurately fixates on the target while responding to stimuli, there is a possibility of unreliable results.

  A comfortable patient position with good fixation is more important than obtaining or keeping exactly centered alignment.

TESTING

Once the test preparations are complete and the patient is ready to begin,

- ***Select*** the **Start Test** Button located on the lower left of the Testing Screen to begin the test.
- If the **Patient Visor** is not in the correct position for the test selected, the **Patient Response Button** is not connected properly, there is too much ambient light, or calibration is needed, then an error message will appear when the Start Test Button is selected.

Once the test starts there is a test progress bar indicating "Testing…" below the chart display on the right side of the screen. The tested visual field location is indicated on the chart display throughout the test. There are also two buttons on the lower left of the screen to control the test:

Pause: Selecting this button pauses the test. When paused the progress bar will say, "Paused…" and the Pause Button changes to Resume Test. Pressing the Resume Test Button will resume the test.

Cancel: Selecting this button will bring up a prompt asking "Are you sure you want to cancel the test?" Clicking on the **No** button will resume the test, while clicking on the **Yes** button will delete the data collected during that test and bring up four options:

Re-Test Right (Left): Select this button to repeat the test on the same eye.

Test Left (Right) Eye: Select this button to test the opposite eye.

New Test: Select this button to bring up the original Testing Screen for the same patient for additional testing.

Done Testing: Selecting this button returns to the Main Menu.

At any time during the test the patient may press and hold the Response Button to pause the test. The test will resume automatically when the Response Button is released.

Once the test for the first eye is complete the instrument will beep momentarily. Choose one of the three options relative to testing the second eye:

Start Left (Right) Eye: Select this button to perform the same test type on the other eye.

New Test: Select this button to bring up the original Testing Screen for the same patient for additional testing.

Done Testing: Selecting this button returns to the Main Menu.

You may enter "**Notes**" or Patient "**Info**rmation" at any time before, during or after the test by selecting the appropriate tab. You may want to note how well the patient maintained fixation during the test, or record pupil diameter information, for example.

At the completion of each eye test, the results are displayed on the Operator LCD. When the testing for both eyes is completed, the results are automatically saved to the instrument's hard drive, to the floppy drive (if enabled), and sent to the printer (if enabled- see System Settings (F5)). The floppy drive is used for automatic short-term backup on a test-by-test basis.

We recommend that you also back up your testing database to a CD-R media every week from the MAIN MENU (F1) or the FILE FUNCTIONS (F4) Screen. As most CD-R disks are limited to about 48 separate writes, you can back up almost a year's worth of tests on a single CD-R media.

It is also a good idea to alternate between two CD-R media with each backup in case a problem develops with one of the media.

EXPLAINING THE TEST PROCEDURE TO THE PATIENT

Explain the test procedure to the patient as follows:

> *"The instrument is going to show you some patterns that flicker, or shimmer, or are striped. Each time you see one of these patterns, press (and release) the button you have in your hand. Please place and keep your forehead on the instrument forehead rest."*
>
> "*Can you see the black spot in the center of the screen? You must keep looking at the black spot in the center at all times during the test."*
>
> *While looking at the black spot in the center, can you see all four triangles at the edge of the screen?"*
>
> *"Are you comfortable?"*
>
> *"A sample of the test is now running. Please press the button whenever you see a pattern that flickers, or shimmers, or is striped. You may pause the test by holding down the button, releasing the button resumes the test. You may blink your eyes whenever you want. A good time to blink is whenever you press the button."*
>
> "*There is a brief flash just before the actual test begins."* [select Start Test Button.] "*The test is beginning now. Please remember to keep looking at the black spot in the center of the screen at all times during the test."*

It is a good idea to encourage the patient throughout the testing to help ensure proper patient alignment, fixation, and attention.

6 VIEWING AND PRINTING TEST RESULTS

VIEWING TEST RESULTS

You may view and print previous visual field test results for a particular patient by selecting a patient from the **VIEW PATIENTS (F2)** Screen and then ***selecting*** the **Recall Tests** Button. You may also select desired individual tests from multiple patients from the **RECALL TESTS (F3)** Screen by using the track pad. Use the track pad and select one test at a time, a section at a time by holding down SHIFT, or select multiple separate entries by holding down CONTROL and selecting each desired test with the track pad (see Figure F).

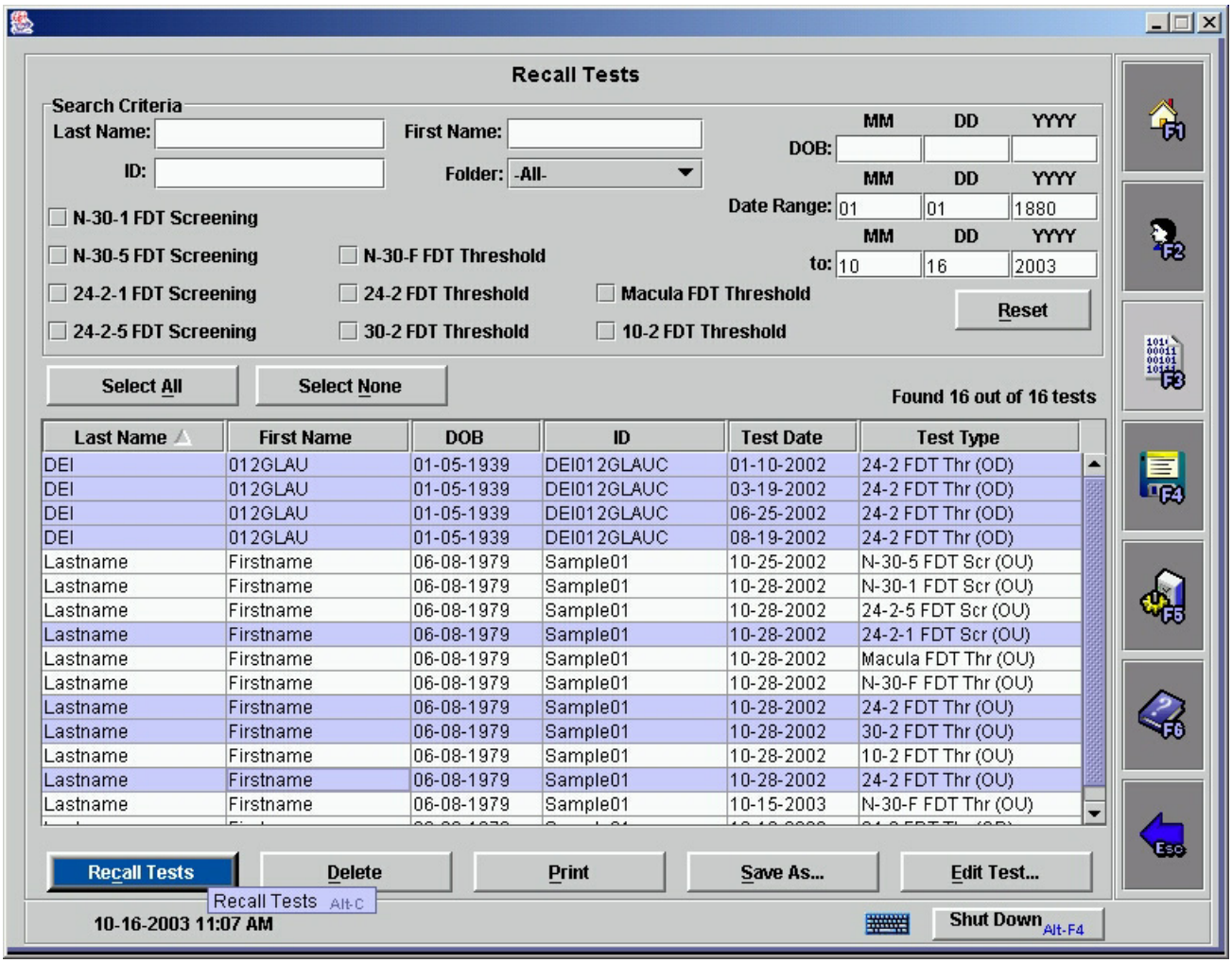


Figure (F)

If you selected multiple entries, choose the pull-down menu at the top of the **TEST DETAILS** Screen (see Figure G) to select a specific test from all selected, or use the **Previous** or **Next** buttons at the bottom of the Test Details Screen to cycle through the selected tests. You may view the raw Threshold (dB) levels of the threshold test results, or you may use the pull-down menu above each chart to select various graphical representations of the test including:

Gray Scale
Total Deviation (dB)
Pattern Deviation (dB)
Total Deviation Probability Plot
Pattern Deviation Probability Plot

Note: Only the Total deviation probability plot is available for screening tests.

You may also select the **OD** (RIGHT) or **OS** (LEFT) eye button above both eye charts for the threshold tests to show two different graphical representations of the same eye (see Figure G)

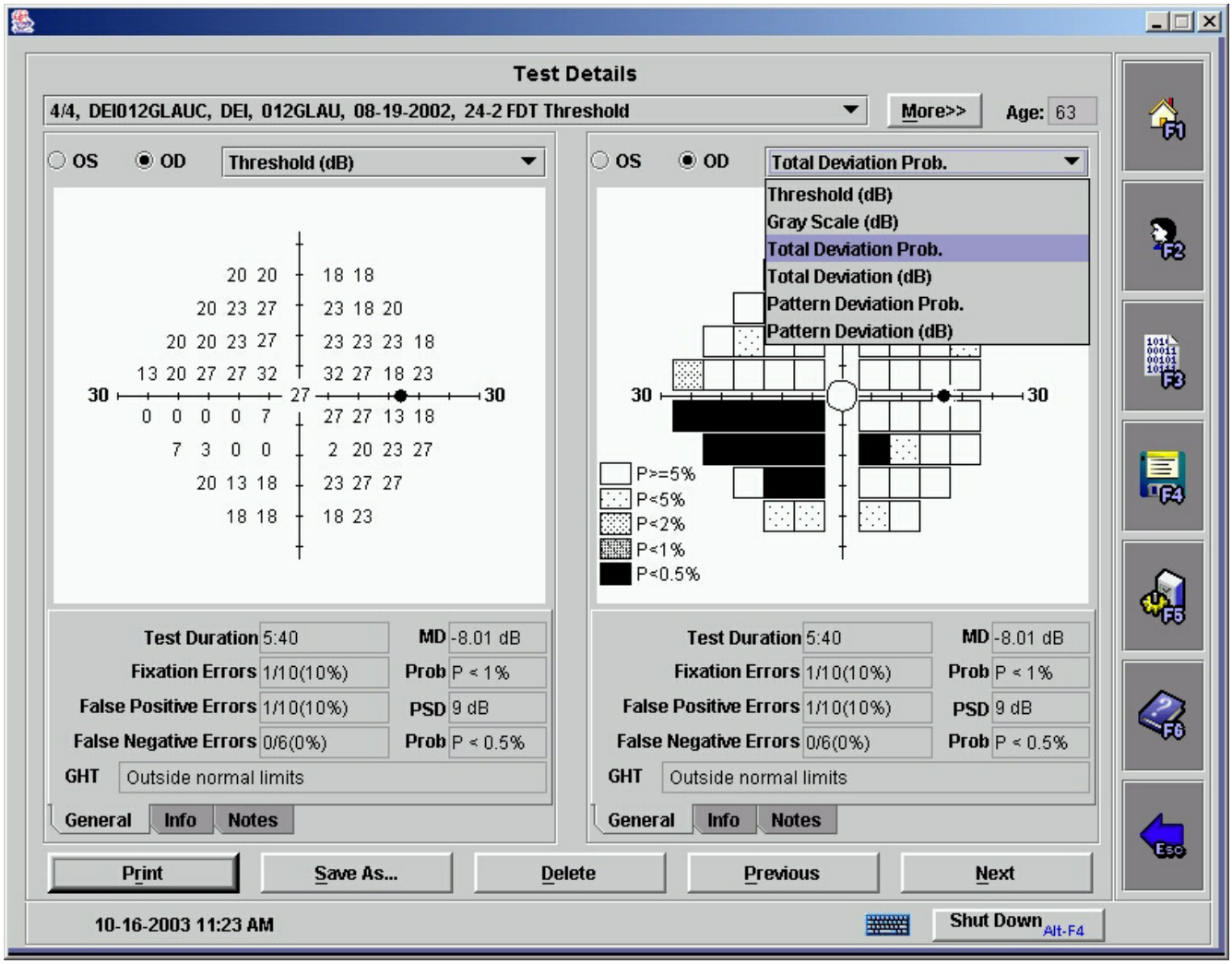


Figure (G)

Test data displayed includes Test Duration, Catch Trials, Mean & Pattern Deviation global indices with statistical significance, and GHT (for the 24-2 & 30-2 tests only). You may also recall and modify any **Notes** or test **Info**rmation you previously entered for the selected test by selecting the appropriate tab below each chart. ***Select*** the **More>>** button at the upper right of the screen to view additional test information generated by the instrument.

PRINTING TEST RESULTS

When viewing a test, you may ***select* Print** to obtain printed test results, ***select* Delete** to permanently delete the selected test from the instrument's database or ***select* Save As...** to save the test to a floppy or CD-R in any of three formats:

- **Database Backup format**, which will save the test in Humphrey Matrix database format, which is only read by a Humphrey Matrix instrument;
- **JPEG**, which will save the test results as a photo image of the printout to view or e-mail using a PC;
- **CSV**, or Comma Separated Value, which will ask you to select a delimiter for formatting the text files created. (CSV is used to access the test results in a text format for clinical research.)

You may also print all selected tests from the View Tests (F3) Screen without viewing them by ***selecting*** the **Print** Button. If you select multiple tests for printing, please consider the implications of printing time or file size for JPEG files (~100KB each eye, ~7 patient tests per floppy).

PRINTER CONTROL PANEL

A printer control panel is available by selecting the printer icon to the right of the shut Down button at the bottom of the Operator LCD Screen. Use the **Status** tab view to observe print jobs, pause/resume printing, and delete selected or all print jobs (see Figure H). Use the **Settings** tab view to change paper size, to view estimated ink levels, and to view the list of approved printers.

It is normal for a delay of up to 30 seconds from when the printing is requested until the printing actually begins.

For other questions regarding the operation of the printer, please refer to the Printer information supplied with the printer.

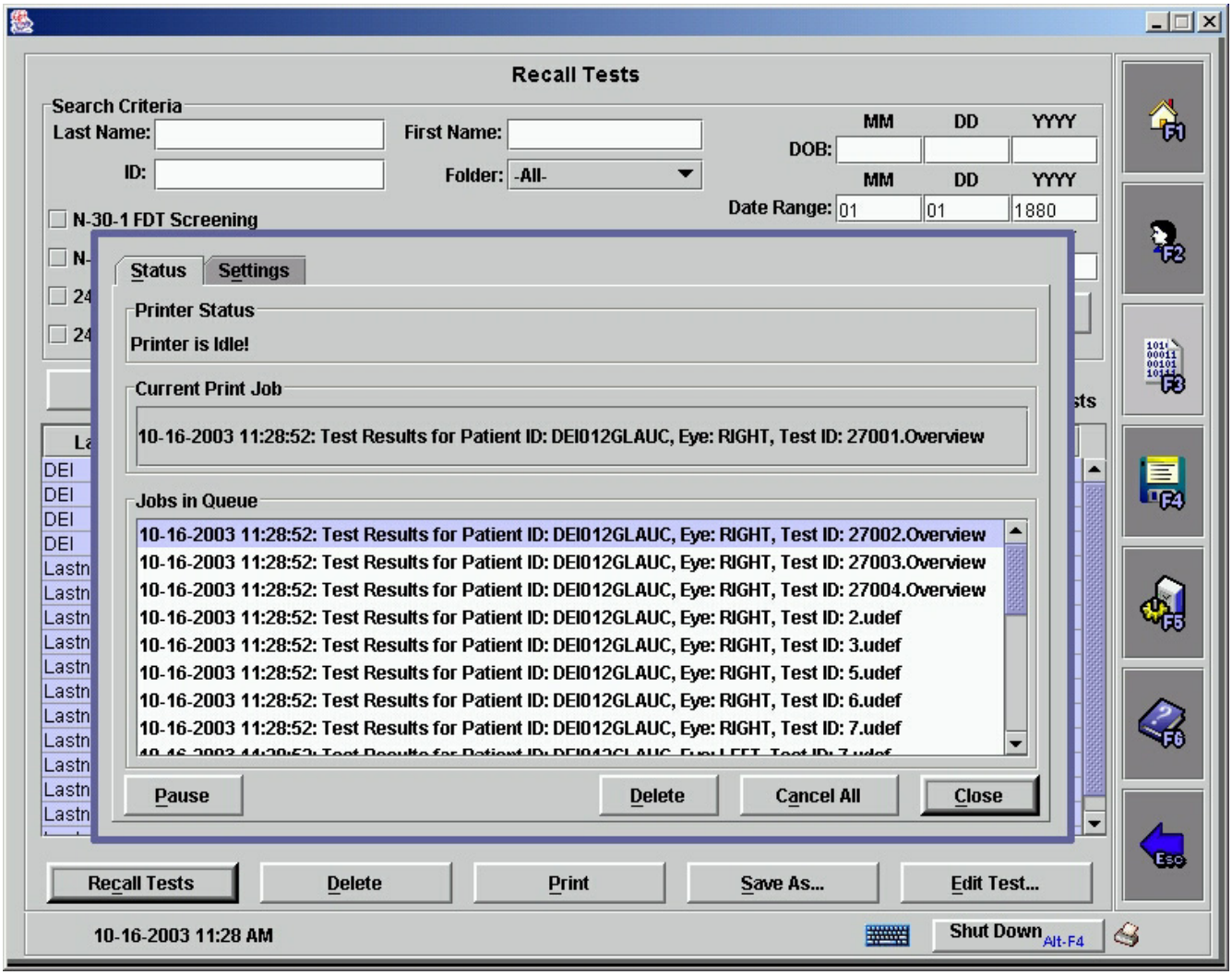


Figure (H)

ANALYSIS

The **Analysis** Button in the **View Patients (F2)** Screen provides the analysis options available. Presently, only the Overview Plot is available (see Figure I).

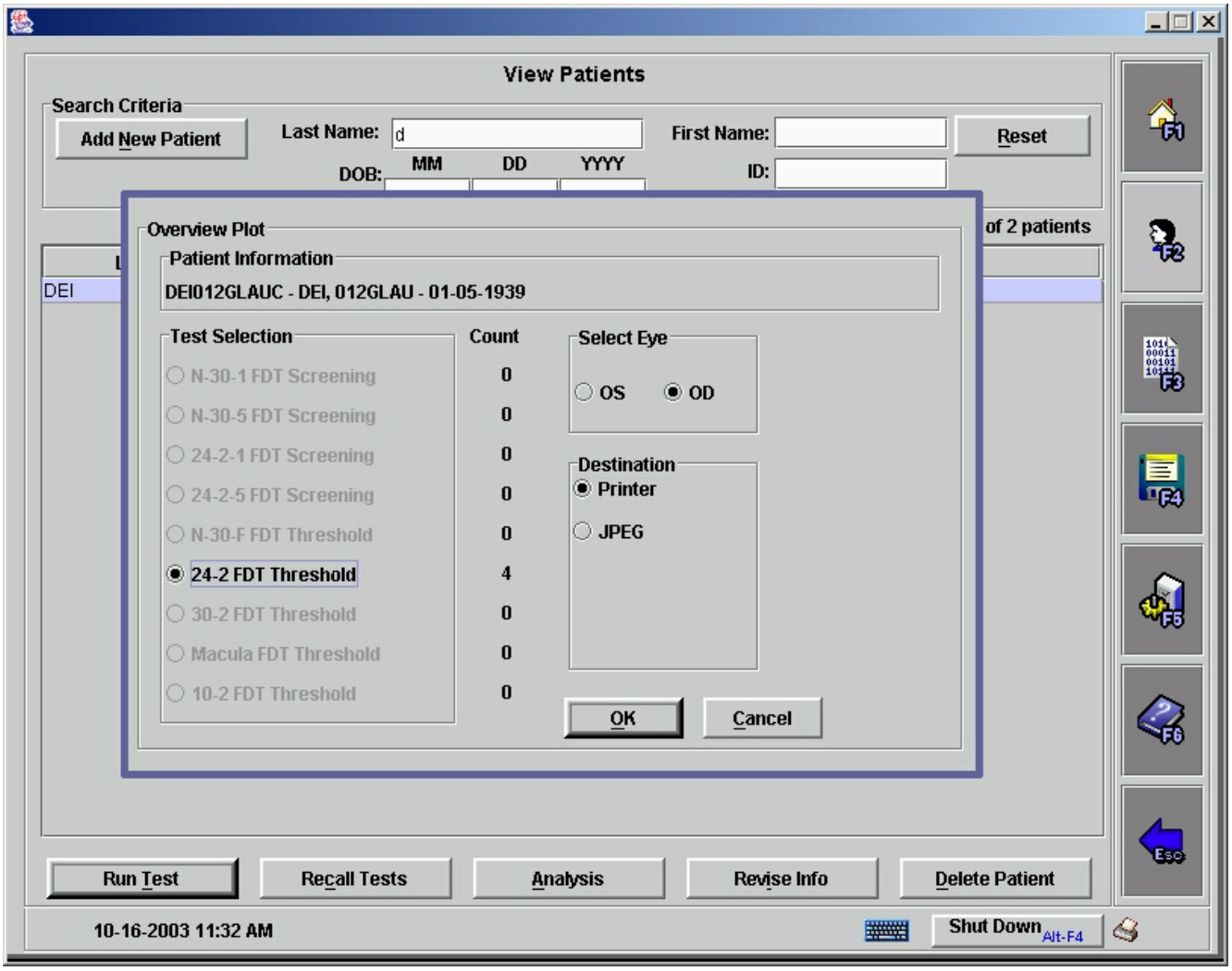


Figure (I)

To generate an **Overview Plot** for the selected patient, ***select*** a **Test Selection**, **Select Eye,** and **Destination. Count** is the number of available tests for each of the Test Selections. A sample Overview Plot is included at the end of this User's Guide for your reference.

7 DATABASE MANAGEMENT

The **File Functions (F4)** Screen provides database management capabilities. A single testing database is used on the Matrix so all your visual field test results are available in the working database.

DATABASE BACKUP

You can back up to the instrument's testing database to removable media (floppy or CD-R). See Figure (J). Back up your database regularly. Pick a backup schedule that fits your practice. Many practices perform weekly backups to protect their patient visual field data.

To make a backup copy of the testing database to either floppy disk or CD-R:

1. Place either a floppy in the floppy drive or a CD-R in the CD-R/W drive.
2. Select the appropriate drive from the **Destination** pull down menu (click on the arrow).
3. ***Select*** the **Begin** Button.

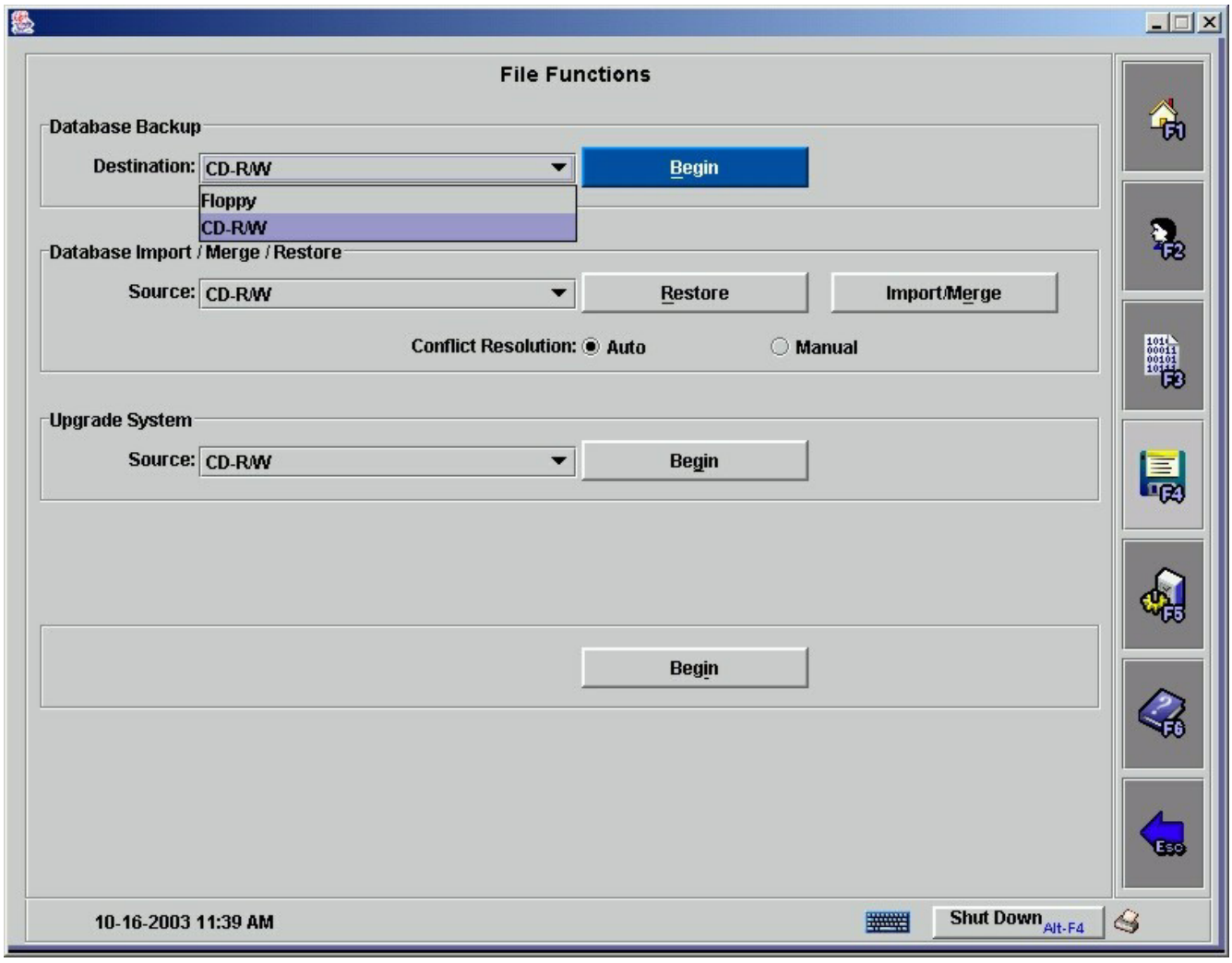


Figure (J)

Note: Most CD-R disks are limited to about 48 separate writes; as a result, you can back up almost a year's worth of tests on a single CD-R media. It is also a good idea to alternate between two CD-R media with each backup in case a problem develops with one of the media.

DATABASE RESTORE

To restore a database backup of the testing database from either a floppy disk or a CD-R media:

1. Place either a floppy in the floppy drive or a CD-R in the CD-R/W drive.
2. Select the appropriate drive from the **Source** pull down menu (click on the arrow).
3. ***Select*** the **Begin** Button.

Note: If **Conflict Resolution** is set to **Manual** and there are two of the same test from the same time for a patient where the user entered information is not the same, one in the database and one on the restore medium, then the operator will receive a prompt to decide which results are placed in the database.

DATABASE MERGE

The user can merge matrix databases (full or partial) from multiple Matrix instruments into one instrument if desired. If more then one instrument is in use at the same location or practice, it is a good idea to merge / synchronize the databases.

1. Using the backup procedure described above, backup the database from each Matrix instrument on separate floppy disk(s) or CD-R media.
2. Place either the floppy or CD-R used to backup the database of one unit into the drive of the other unit.
3. Use steps 2 and 3 from the database restore instructions to load the database of the first unit onto the second.
4. Repeat steps 1 through 3 until all units are synchronized.

UPGRADE SYSTEM (SOFTWARE)

This instrument is designed with the ability to upgrade the operating software using the CD-R/W or floppy drives. ***Select*** the appropriate **Source** media and ***select*** the **Begin** Button in the **Upgrade System** section of the File Functions Screen to upgrade the instrument software. Reference the software upgrade instructions provided with the upgrade for details. The **Help (F6)** Screen will identify which versions of the Humphrey Matrix software are installed.

SET INSTRUMENT DATE AND TIME

To set the date and time, double click on the date and time in the lower left corner of the screen. This will open a window with a calendar and a clock. The arrows next to the year box and time boxes are used to adjust these values, or type the values directly into the boxes. Adjust the month by using the arrows to the right of the month or it can be changed using the month pull down menu. Select the date from the calendar. Once the appropriate changes are made ***select* OK** to save the changes. If no changes were made, or to disregard any changes made, ***select* Cancel**.

SYSTEM SETTINGS (F5)

System Settings are provided to allow you to customize the operation of the Humphrey Matrix instrument to meet your preferences and practice needs (see Figure K). * indicates factory default system settings that probably meet most of your needs already. ***Select* Reset Settings** to return the instrument to the factory default system settings.

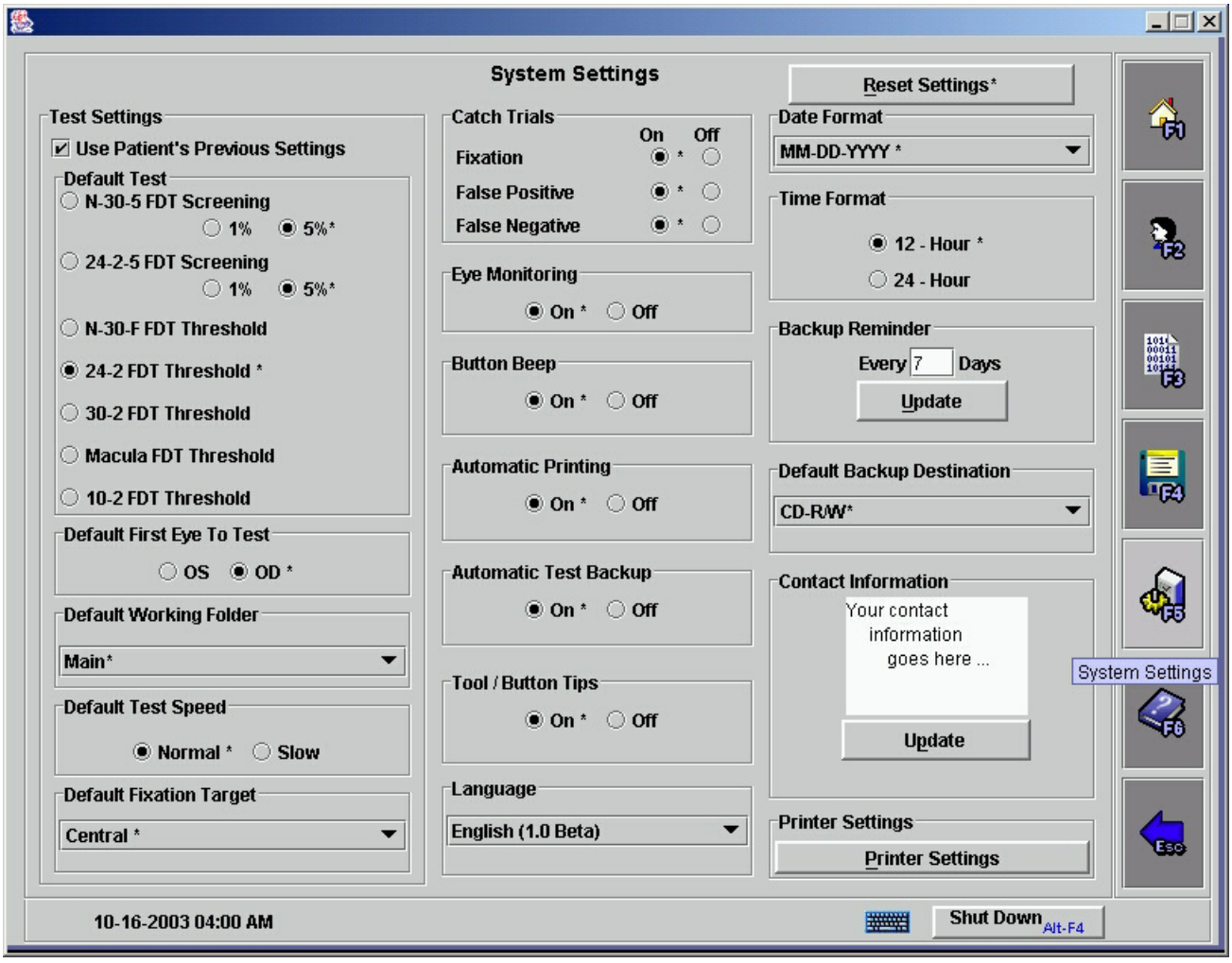


Figure (K)

Default Test: ***Select*** the test that is run when **Enter** is pressed in the **Main Menu (F1)** Screen, or when **Run Test** is selected from the **View Patients (F2)** Screen. You can also choose the test to perform from the Testing Screen. ***Select* 1%** or **5%** to pick the default screening level for each of the screening tests.

First Eye to Test: ***Select*** the first eye for testing when a test is run. You can also choose the eye for testing from the Testing Screen.

Catch Trials: ***Select*** individual catch trials to turn either **On** or **Off**. Refer to the Reliability Measures section of this User's Guide for more information on catch trials.

Eye Monitoring: ***Select*** to turn the Eye Display **On** or **Off** in the Testing Screen.

Beep When Button Pressed: ***Select*** to enable/disable an audible beep when the user button is pressed during testing.

Default Working Folder: ***Select*** the default folder in which each test is saved in. Folders are provided to allow some user defined sorting of the tests in the database. Use of Folders is optional. You can select, edit, or create alternative folders in the testing screen. ***Select*** **Edit Folders...** in the drop down list to add, rename, merge or delete folders if desired.

Automatic Printing: ***Select*** to choose whether Test Results are automatically printed when the test is completed. This setting is probably best left to **Off** if you are not routinely printing test results.

Automatic Test Backup: ***Select*** to choose whether automatic backup of the test results to the floppy drive occurs when the test is completed.

Tool / Button Tips: Turns popup text descriptions of buttons **On** or **Off**.

Language: ***Select*** the language used on the instrument.

Fixation Target: ***Select*** the normal **Central** fixation target or the **Alternative** target for patients with severe central vision loss. The alternative fixation target is a cross approximately one degree wide passing through the center of the screen, extending vertically and horizontally across the entire screen for all but the 10-2 and Macula tests. The Alternative fixation for the 10-2 and Macula tests consist of the central fixation targets and four additional approximately 2 degree diameter targets located approximately 10 degrees diagonally from the central target. You can also change the Fixation Target from the Testing Screen.

Test Speed: Provides ability to slow down the test speed (increase the time between stimulus presentations) in case a patient finds the normal pace of the testing too fast. ***Select*** **Normal** or **Slow** to set the test speed.

Date Format: ***Select*** the date format preferred from the drop down list. The date format selected is used everywhere the date is displayed or printed.

Time Format: ***Select*** either **12-Hour** or **24-Hour** (military) time formats. The time format selected is used everywhere the time is displayed or printed.

Backup Reminder: ***Select*** the number of days after the last database backup until prompted to backup again. ***Select*** **Update** to accept a change.

Default Backup Destination: ***Select*** either the **Floppy** or **CD-R/W** drive as the default destination for testing database backups when **Perform Backup** is ***selected*** from the **Main Menu (F1)** Screen.

Contact Information: ***Enter*** text information for printing on the visual field printouts in the lower right corner. Typical use is to enter information for the practice or doctor. ***Select*** **Update** to accept a change to the Contact Information.

CALIBRATION

The Humphrey Matrix Visual Field Instrument does not require scheduled calibration. The instrument calibration is automatically checked each time the instrument is powered ON and at the start of each test to be sure the unit is properly calibrated. If the instrument detects the need for calibration, the Operator LCD Display will display a needs calibration warning. If not calibrated when the needs calibration warning is displayed, the unit will continue to operate normally until the unit reaches the calibration limits. Once the calibration limits are reached, the unit will not operate normally until a calibration is completed successfully. Perform calibration at any time, not only when requested by the instrument. Calibration will take approximately 15 minutes to complete.

To calibrate the instrument, ***select*** the **Help (F6)** Screen, and then ***select*** the **Calibration** Button. Before selecting the **Calibrate** Button in the **Calibration** Screen (see Figure L), make sure the Patient Eyepiece is covered with the Calibration Cap. Once the Patient Eyepiece is covered, ***select*** **Calibrate.** There is a prompt to ensure the Patient Eyepiece is covered. If the Calibration Cap is not available, substitute something that will temporarily block light from entering the Patient Eyepiece (black cloth over Patient Visor, etc.) or perform the calibration in a completely darkened room. The Operator LCD Display will indicate if there is too much ambient light to complete the calibration. A **Calibration Progress** indicator is provided.

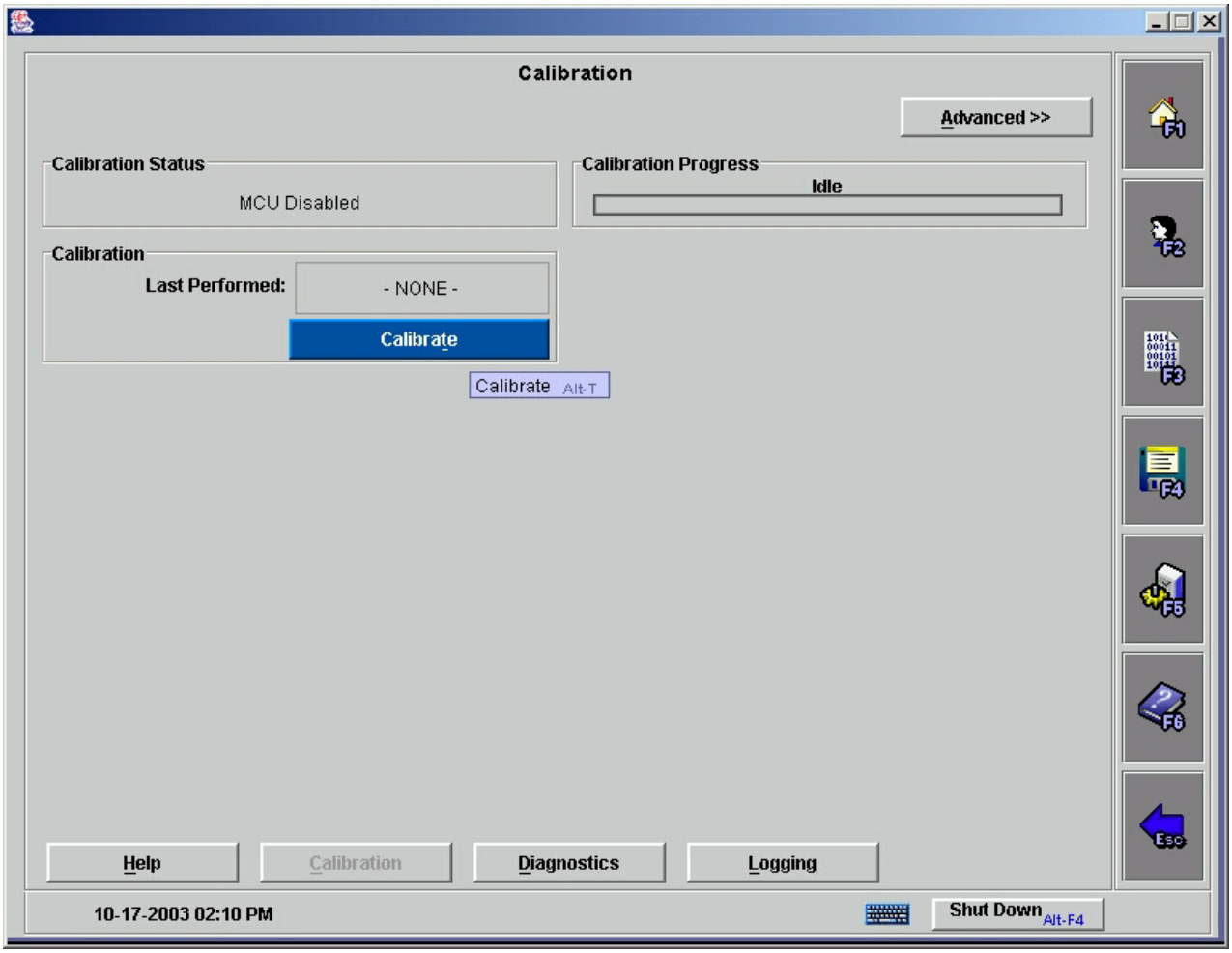


Figure (L)

CLEANING, DISINFECTION, AND STERILIZATION

Cleaning

Clean the instrument as necessary by wiping the housing surfaces with a soft dry cloth or a soft cloth that is lightly dampened with soapy water, 10% Clorox™/water solution, or 70% Isopropyl alcohol. Clean the Patient Eyepiece window and Operator LCD Display window with a soft, lint free cloth lightly dampened with commercially available window cleaners (do not use soap) or 70% Isopropyl alcohol.

Disinfection

Disinfect the patient contact surfaces (the Forehead Rest and Patient Response Button) as necessary by wiping the surfaces with a soft cloth that has been lightly dampened with 10% Clorox™/water solution or 70% Isopropyl alcohol. Allow the surface to dry thoroughly before patient contact.

Note: Do not allow cleaning or disinfection solutions or other liquids to seep into the seams in the housings or along the LCD display. Do not spray cleaning or disinfection solutions or other liquids directly onto the instrument. Damage to internal components may occur and are not covered by the instrument warranty.

Sterilization

Do not sterilize the instrument or any of its components.

9 WARRANTY AND SERVICE INFORMATION

WARRANTY INFORMATION

Carl Zeiss Meditec warrants the Humphrey Matrix Visual Field Instrument, when new, to be free from defects in materials and workmanship and to perform in accordance with the manufacturer's specifications **for a period of one year from the date of purchase** from Carl Zeiss Meditec or its authorized distributors or agents.

Carl Zeiss Meditec will either repair or replace any components found defective or at variance from manufacturer's specifications within this time at no cost to the customer. It shall be the purchaser's responsibility to return the instrument directly to the appropriate regional authorized Service Center. This warranty does not include damage or failure due to tampering, misuse, neglect, accidents, modifications, or shipping. This warranty is also void if the instrument is not used in accordance with the manufacturer's recommendations or if it is repaired by anyone other than Carl Zeiss Meditec or an authorized agent. Purchase date determines warranty.

The warranty for the printer supplied with the Humphrey Matrix Visual Field Instrument is listed in the information supplied with the printer.

NO OTHER EXPRESS WARRANTY IS GIVEN, AND ALL IMPLIED WARRANTIES ARE DISCLAIMED AND NOT APPLICABLE, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

SERVICE INFORMATION

SERVICE or REPAIR to be performed by QUALIFIED, AUTHORIZED PERSONNEL ONLY. There are **NO USER SERVICEABLE PARTS INSIDE** the Humphrey Matrix instrument. Disassembly of the instrument presents a possible **ELECTRICAL SHOCK** hazard and will **VOID** the warranty.

An authorized service location must perform or approve all repairs on products under warranty. ***Unauthorized repairs will void the warranty.*** An authorized service location or other qualified electronics personnel should repair products out of warranty.

TECHNICAL ASSISTANCE INFORMATION

If you have an instrument problem that you cannot resolve using the following troubleshooting guide, call the authorized service center listed below for assistance. Technical service support is available during normal business hours on normal business days at the authorized service location listed below. For customers outside of the USA, contact your nearest Carl Zeiss authorized service location or distributor for assistance.

Carl Zeiss Meditec, Inc.
5160 Hacienda Drive
Dublin, California 94568
• 877-486-7473 • Fax: 925-557-4101
e-mail: info@meditec.zeiss.com
www.meditec.zeiss.com

Carl Zeiss Meditec AG
Goeschwitzer Strasse 51-52
07745 Jena
Germany
•+49-3641-220-333 • Fax: +49-3641-220-282

REPLACEMENT PARTS AND ACCESSORIES

Description	Reference Number
Printer (HP 6122 with cables)	11279
Printer Data Cable	112733
Printer Power Cord	112734
Printer User's Guide Supplement (multi-lingual)	112816-1
Patient Response Button	11229
Patient Response Button Holder	112158-501
Keyboard	112618
Calibration Lens Cap	112641-1
Table Top Tray	112788-501
Dust Cover	112159
Power Cord - USA, Canada, Japan	76401
Power Cord - Europe	76402
Power Cord - UK	76404
Power Cord - Australia	76406
Humphrey Matrix User's Guide - English	701692*
Humphrey Matrix Quick Reference Guide - English*	112753-1
Humphrey Matrix Training Video - CD (English)	112755
Humphrey Matrix Training Video - VHS (English)	SM2519
Humphrey Matrix Primer (English)	112739-1
Humphrey Matrix Service Manual (English)	112761
* Add suffix to order language specific information: FR = French, IT = Italian, GR = German, SP = Spanish, JA = Japanese, CS = Simplified Chinese, KO = Korean	

MODEL NUMBERS

Description	Reference Number
Humphrey Matrix - USA, Japan	00715-11
Humphrey Matrix - Canada	00715-21
Humphrey Matrix - Europe	00715-31
Humphrey Matrix - Spanish	00715-71
Humphrey Matrix - Australia	00715-91

TROUBLESHOOTING GUIDE

Here is a summary of some common problems you may experience. If you are unable to resolve the problem using this guide, contact technical service.

Problem	Area to Check	Possible Solution
Humphrey Matrix will not power up	Check the Humphrey Matrix power cable connections. Ensure that the power cord is inserted firmly in the Humphrey Matrix power input receptacle. The receptacle is located underneath the base of the instrument. Make sure that the outlet being used is on. Plug in a known good device into the outlet and turn that unit on. If the unit comes on then you know the outlet is good.	Replace power cord if defective. Connect instrument power cord to a working outlet.
The Humphrey Matrix will turn on but will not boot up to the Main Menu Screen.	Turn the Humphrey Matrix OFF and let sit for 10 seconds. Turn unit back on and try again.	
The Humphrey Matrix will boot up to the Main Menu Screen but will not perform a test.	Turn the Humphrey Matrix OFF and let sit for 10 seconds. Turn unit back on and try again. Perform a Calibration from the Help (F6) Screen.	
Receive message "Not enough space left on the disk" message	Check to make sure the disk is not write protected.	Try a different disk.
Printer will not power on.	Refer to the Printer Information for troubleshooting help. Check the power cord connection at the back of the printer and at the Humphrey Matrix. Unplug and reseat the power cord at both ends. Press the printer power button again. The printer will not power on automatically.	Refer to the Printer Information for troubleshooting help. Replace the printer power cord if defective. Replace the printer if defective.

Printer will not print	Refer to the Printer information for troubleshooting help. Printer not turned on. Press printer power button. Check the printer USB cable connection at the back of the printer and at the Humphrey Matrix. Unplug and reseat the USB cable at both ends. Cycle the printer power off / on and try again. Check the USB cable on a known working USB peripheral if available. No paper in the printer. Missing or empty ink cartridges.	Refer to the Printer information for troubleshooting help. Shut Down the Humphrey Matrix and cycle power off / on to reboot, then try printing. Check **USB Printer Connectivity** status in the **Help (F6) Diagnostics** Screen that should indicate **Connected and Idle** or **Connected and Printing**. Replace the printer USB cable if defective. Replace the printer if defective.

HELP (INCLUDING DIAGNOSTICS)

The **Help (F6)** Screen (see Figure M) provides basic system information regarding the Humphrey Matrix instrument and buttons to access reference user information and instrument diagnostics. System information provided includes instrument model and serial numbers, software version numbers, calibration information, last database backup date and error log status.

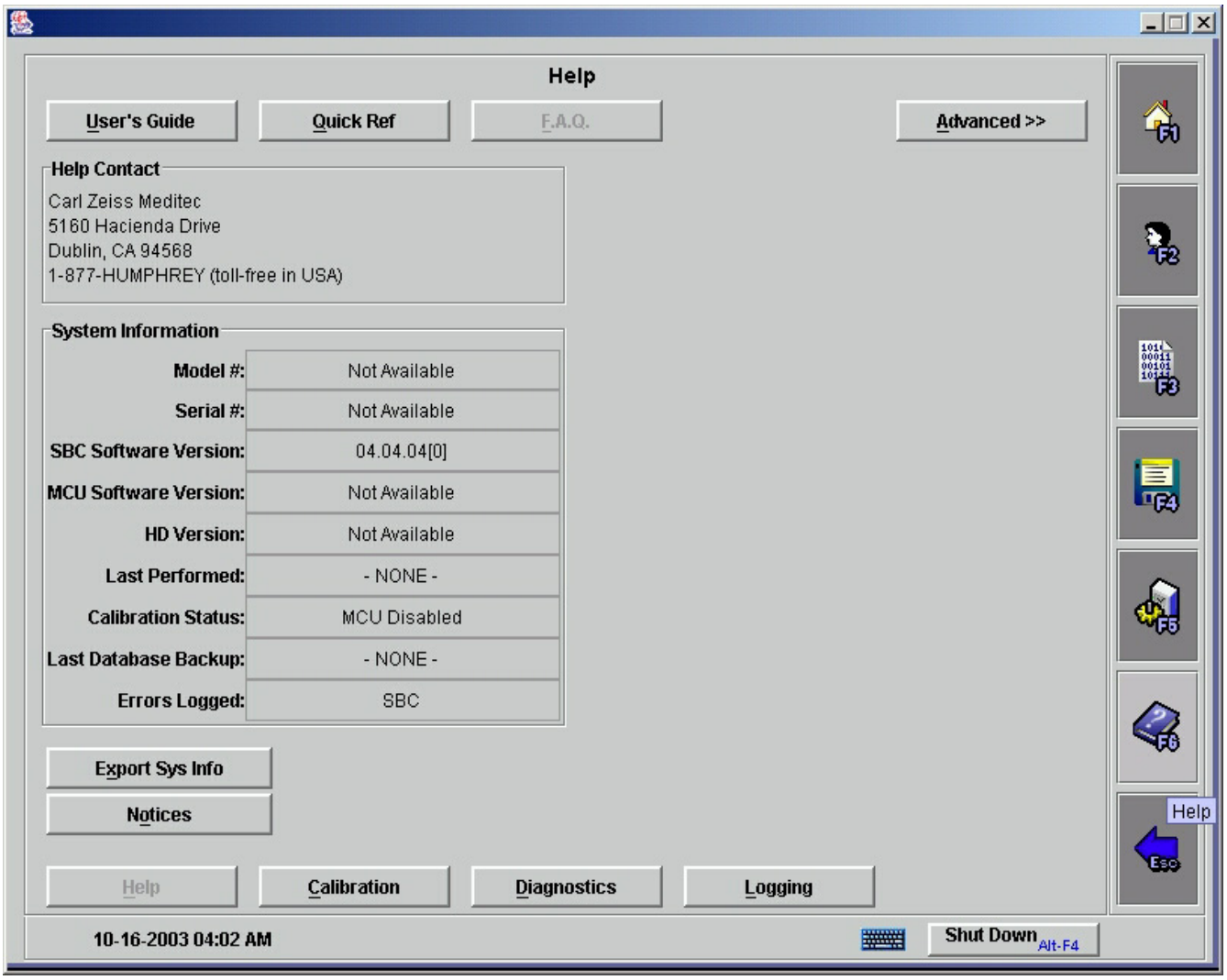


Figure (M)

The **User's Guide** Button displays a PDF version of the Humphrey Matrix User's Guide.

The **Quick Ref.** Button displays a PDF version of the Humphrey Matrix Quick Reference Guide (also included at the end of this User's Guide).

The **F.A.Q.** Button will display a list of frequently asked questions and their answers. If the button is grayed out, no F.A.Q.s are available.

The **Advanced >>** Button displays more system information that may be useful for Technical Service. The button toggles between **Advanced >>** and **Basic <<.**

You may ***select*** the **Export Sys Info** button to send the system information to the printer or to a JPEG file. The buttons along the bottom of the screen allow you to perform **Calibration**,

instrument **Diagnostics**, to review system **Logging** information. These functions are not commonly needed and are typically only used by Technical Service.

Calibration

Refer to the Calibration section of this User's Guide for information regarding instrument Calibration.

The **Advanced >>** button displays Factory Calibration information reserved for Technical Service use. The button toggles between **Advanced >>** and **Basic <<.**

Diagnostics

The **Diagnostics** Screen (see Figure N) provides basic information regarding the operational status of the Humphrey Matrix instrument. This screen is useful if you are experiencing problems with your Humphrey Matrix Instrument. Problem areas are indicated by different color text.

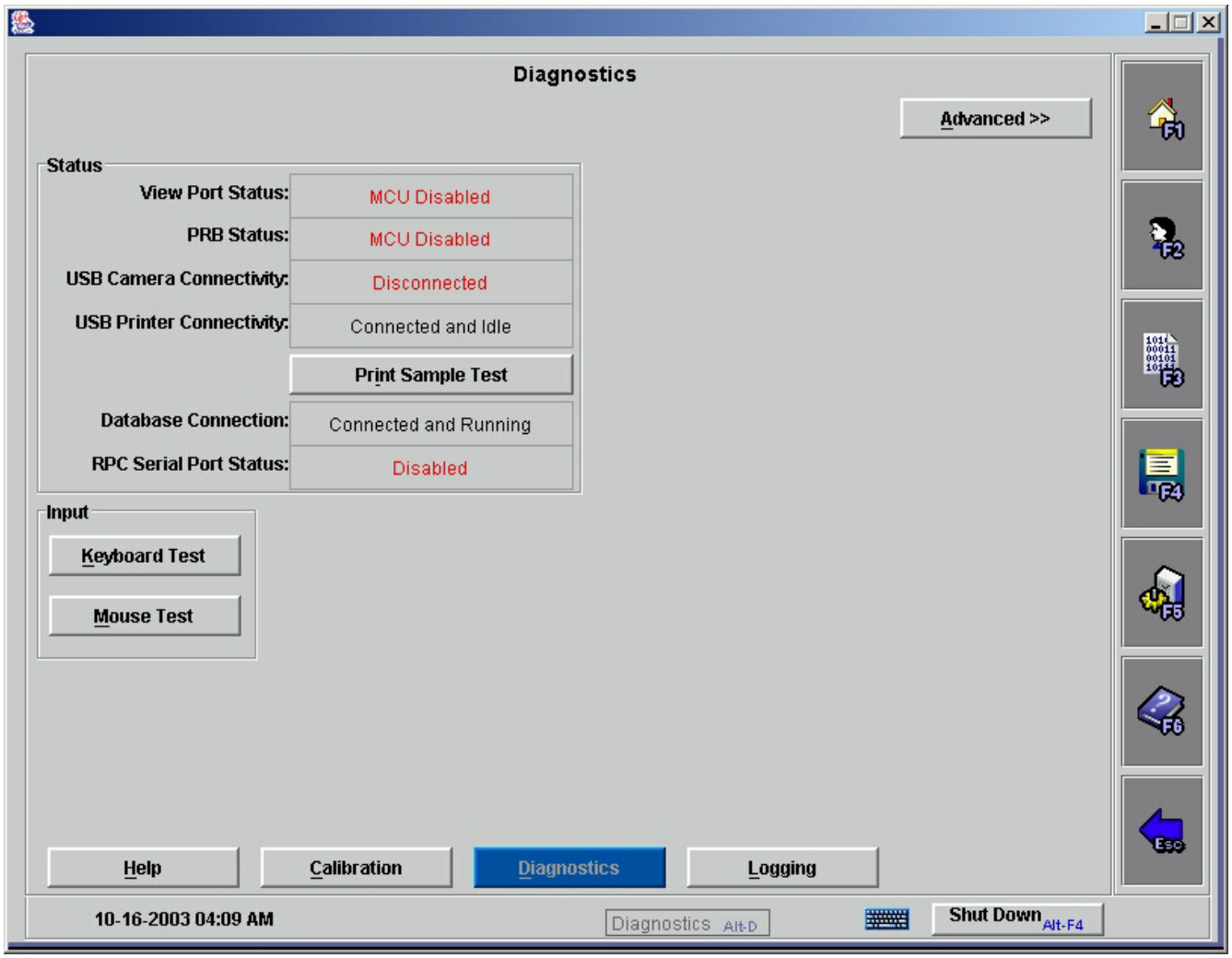


Figure (N)

The Patient **View Port Status** is provided to confirm the internal view port position sensors are operating correctly. The **Patient Response Button (PRB) Status** is provided to confirm the PRB is properly connected and operating correctly. **Print Sample Test**, **Keyboard Test**, and **Mouse Test** buttons are provided to test the operation of these devices.

The **Advanced >>** button displays **Advanced Diagnostics** capabilities that are typically used for technical service. The button toggles between **Advanced >>** and **Basic <<.** The **Advanced Diagnostics** capabilities (see Figure O) include:

Database: Check Database, Repair Database

File I/O: HDD test (Hard Drive), CD/RW Test, Floppy Test

Show LCD Pattern test, **Play Scale** and **MCU Beep** sound tests

CRT tests: View Pattern, Ambient Light test**, Calibration Status** check**, Monitor Brightness** check.

Camera: Camera Display check

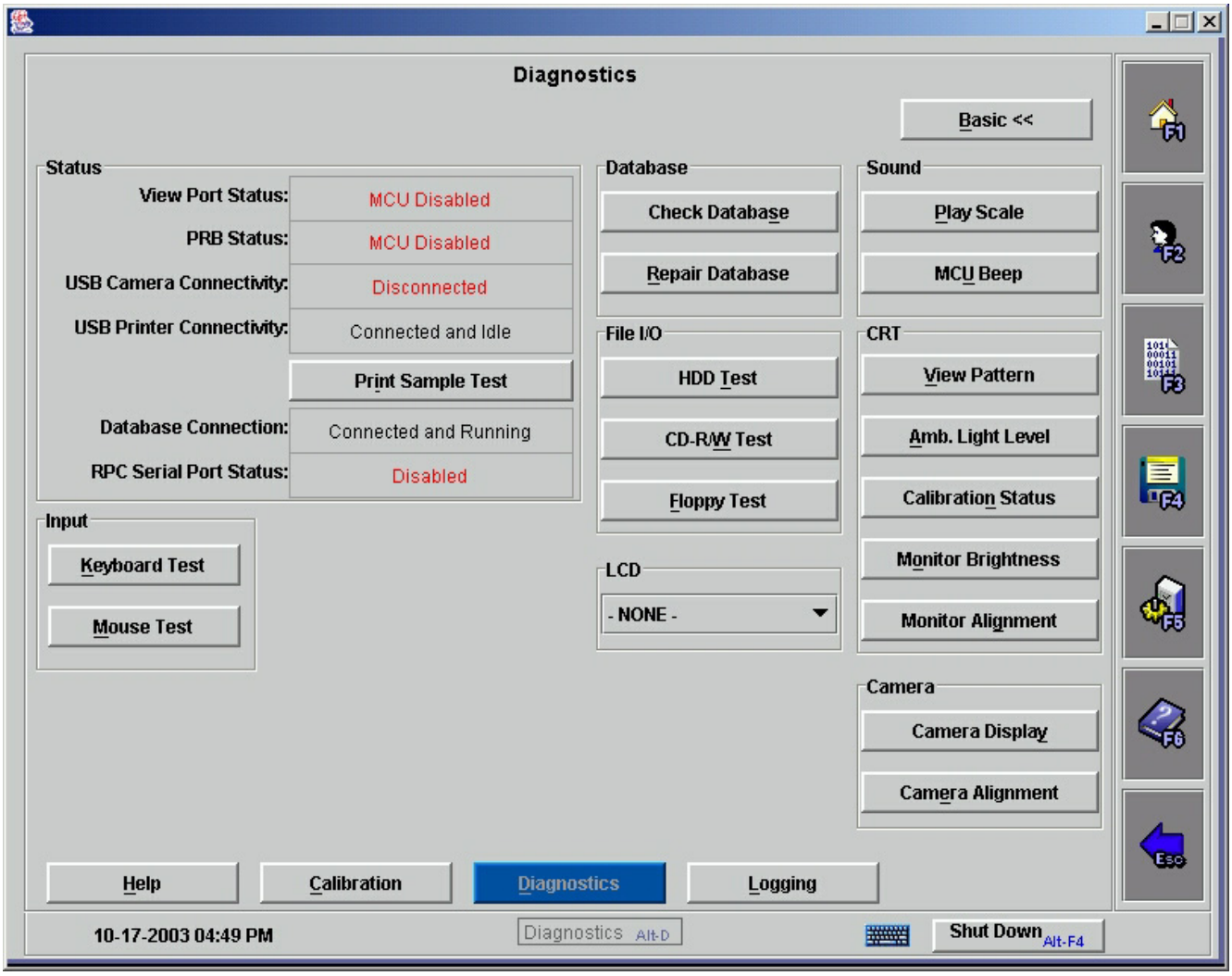


Figure (O)

Logging

The internal computer provides a variety of logging functions during the operation of the Humphrey Matrix instrument that are reserved for Technical Service use in troubleshooting any problems. Export the logs individually or all at once to a floppy, CD-R, or printer. Printing these logs is generally not recommended due to formatting issues and extended printing time for large logs.

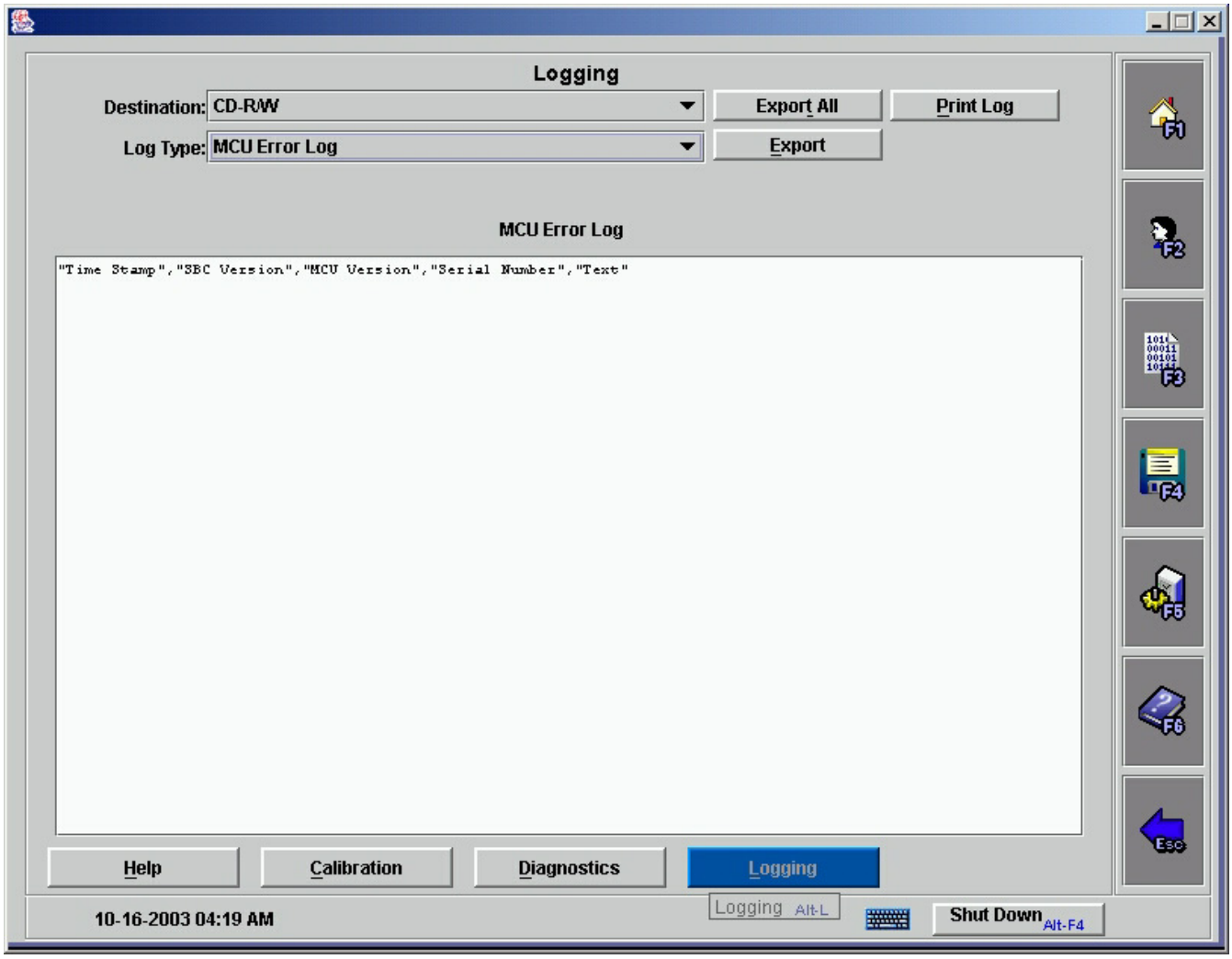


Figure (P)

10 TECHNICAL SPECIFICATIONS

This instrument is manufactured exclusively for CARL ZEISS MEDITEC by:
Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, New York 13153-0220 USA

INSTRUMENT SPECIFICATIONS

Dimensions:
30 cm [12''] wide x 56 cm [22''] deep x 43 cm [17''] high
(nominal dimensions of the instrument without keyboard)

Weight:
14 kg [30 lbs.] nominal

Patient display size:
60° diameter nominal field-of-view

Power requirements:
100-240 VAC, 50/60 Hz, 200 Watts maximum

Auxiliary Power Output:
115 VAC 50/60 Hz, 50 Watts maximum for printer

Power Connection:
IEC-320 standard power inlet connector for worldwide use

Power Cord:
Approved hospital grade detachable power cord

Printer:
External USB color inkjet printer, powered from instrument

PRINTER- Use only the printer and printer cables provided (or approved alternate) with this device to meet medical safety requirements. The Matrix instrument must provide the printer power or patient isolation may be compromised.

Computer Interface:
RS-232 Serial, 9-pin D male connector, null-modem cable

ENVIRONMENTAL SPECIFICATIONS

Operating Conditions
Operating Temperature: +15° C to +35° C [+59° F to +95° F]
Operating Humidity: 30% to 75% non-condensing
Operating Altitude: 700 hPa to 1060 hPa

Storage and Shipping Conditions

Storage Temperature: -20° C to +60° C [-4° F to +140° F]
Storage Humidity: 0% to 90% non-condensing (limited to 90% @ 40° C, 50% @ 50° C)
Storage Altitude: 700 hPa to 1060 hPa

VISUAL FIELD TEST SPECIFICATIONS

FDT Test	Visual Field Locations	Probability Level Classifications	Fixation Catch Trials	False Positive Trials	False Negative Trials	Test Strategy
N-30-5 (-1) Screening	19	4	3	3	0	Supra-Threshold
24-2-5 (-1) Screening	55	2	10	10	0	Supra-Threshold
N-30-F Threshold	19	4	6	6	3	MOBS
24-2 Threshold	55	4	10	10	6	ZEST
30-2 Threshold	69	4	10	10	6	ZEST
10-2 Threshold	44	4	10	10	6	ZEST
Macula Threshold	16	4	6	3	0	ZEST

FDT Test	Field of view tested (degrees)	Approximate Target size (degrees)	Spatial frequency (cycles / degree)	Temporal frequency (Hz)
N-30-5 (-1) Screening	Central 30	10 x 10	0.25	25
24-2-5 (-1) Screening	Central 30	5 x 5	0.50	18
N-30-F Threshold	Central 30	10 x 10	0.25	25
24-2 Threshold	Central 30	5 x 5	0.50	18
30-2 Threshold	Central 30	5 x 5	0.50	18
10-2 Threshold	Central 10	2 x 2	0.50	12
Macula Threshold	Central 5	2 x 2	0.50	12

Threshold Test Results

- Threshold (dB) Plot
- Gray Scale Plot
- Total and Pattern Deviation (dB) Plots
- Total and Pattern Deviation Probability Plots with 5 probability level classifications (P> = 5%, P < 5%, P<2%, P<1%, P<0.5%) based on age-related normative references
- MD (Mean Deviation) and PSD (Pattern Standard Deviation) statistical Global Indices values with 5 probability level classifications (P> = 5%, P<5%, P<2%, P<1%, P<0.5%) based on age-related normative references
- Reliability Indices: Fixation, False Positive, and False Negative Catch Trials ratios
- Glaucoma Hemifield Test (GHT) for 24-2 & 30-2 threshold tests

Screening Test Results

- Total Deviation Plot with 4 loss classifications for N-30-5 (-1) screening test, 2 loss classifications for 24-2-5 (-1) screening test
- Reliability Indices: Fixation and False Positive

Reliability Measures

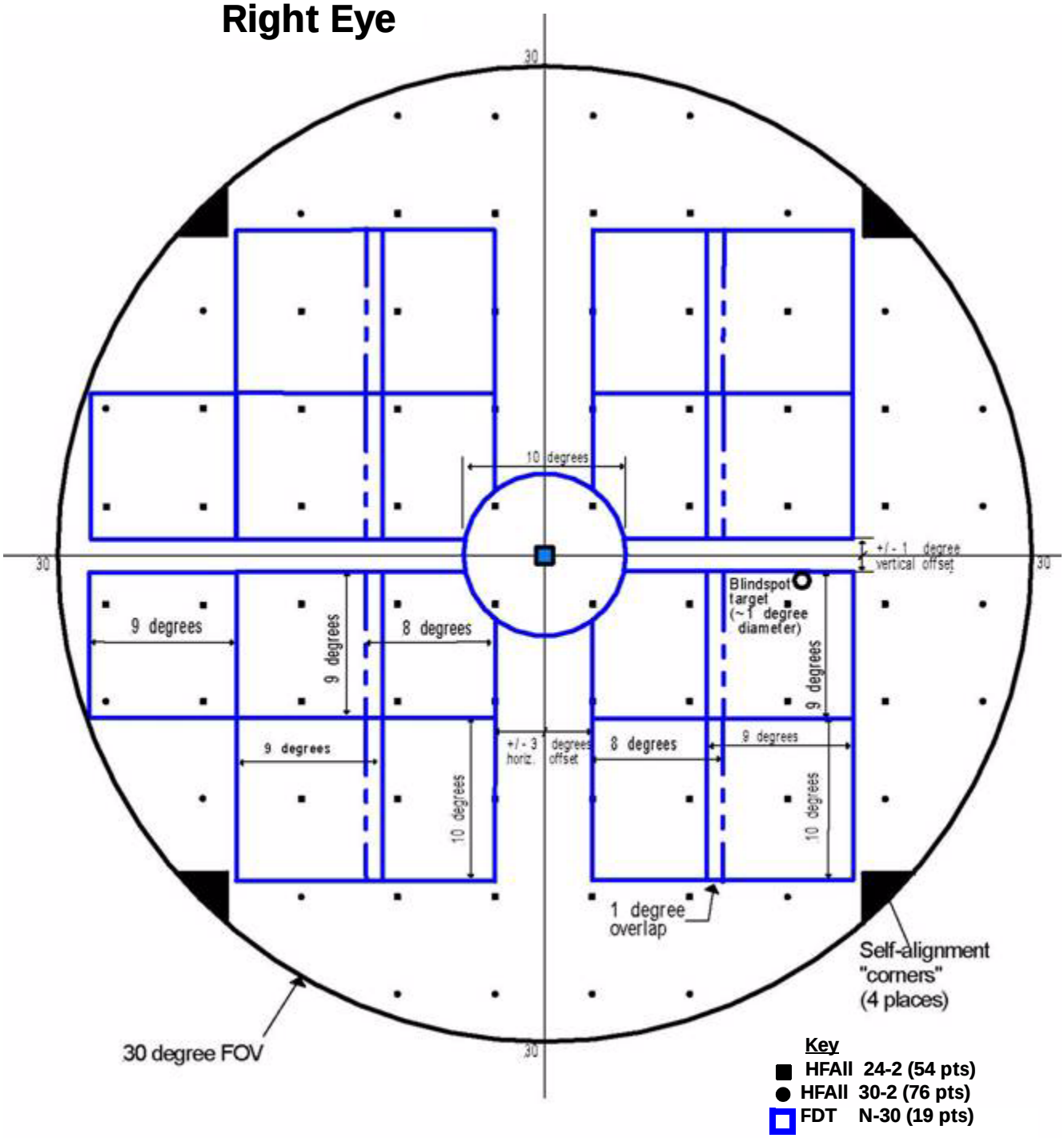
- Fixation Monitoring: Heijl-Krakau method
  - Catch trial contrast: 25%
  - Presentation Order: Pseudo-Random
  - Pattern: approximately one degree diameter circular FDT stimulus
- False Positive Catch Trials:
  - Catch trials contrast: 0%
  - Presentation Order: Pseudo-Random
  - Pattern: one of the FDT stimuli in test pattern presented in a random location
- False Negative Catch Trials:
  - Catch trial contrast: 100%
  - Presentation Order: Pseudo-Random
  - Pattern: one of the FDT stimuli in test pattern presented in a random location where the patient has previously responded (when possible)

Stimulus

- Presentation Order: Random
- Duration: 300 ms nominal
- Cosinusoidal counter-phase flicker modulation
- Color: black and white
- Mean Background Illumination: 100 cd/m2 nominal
- Contrast range N-30 tests: 56 dB (~ 0%) to 0 dB (~ 100%), (~40 dB is the maximum human visual field sensitivity)
- Contrast range 24-2, 30-2, 10-2 & Macula tests: 38 dB (~ 0%) to 0 dB (~ 100%)
- Optical system: Badal type

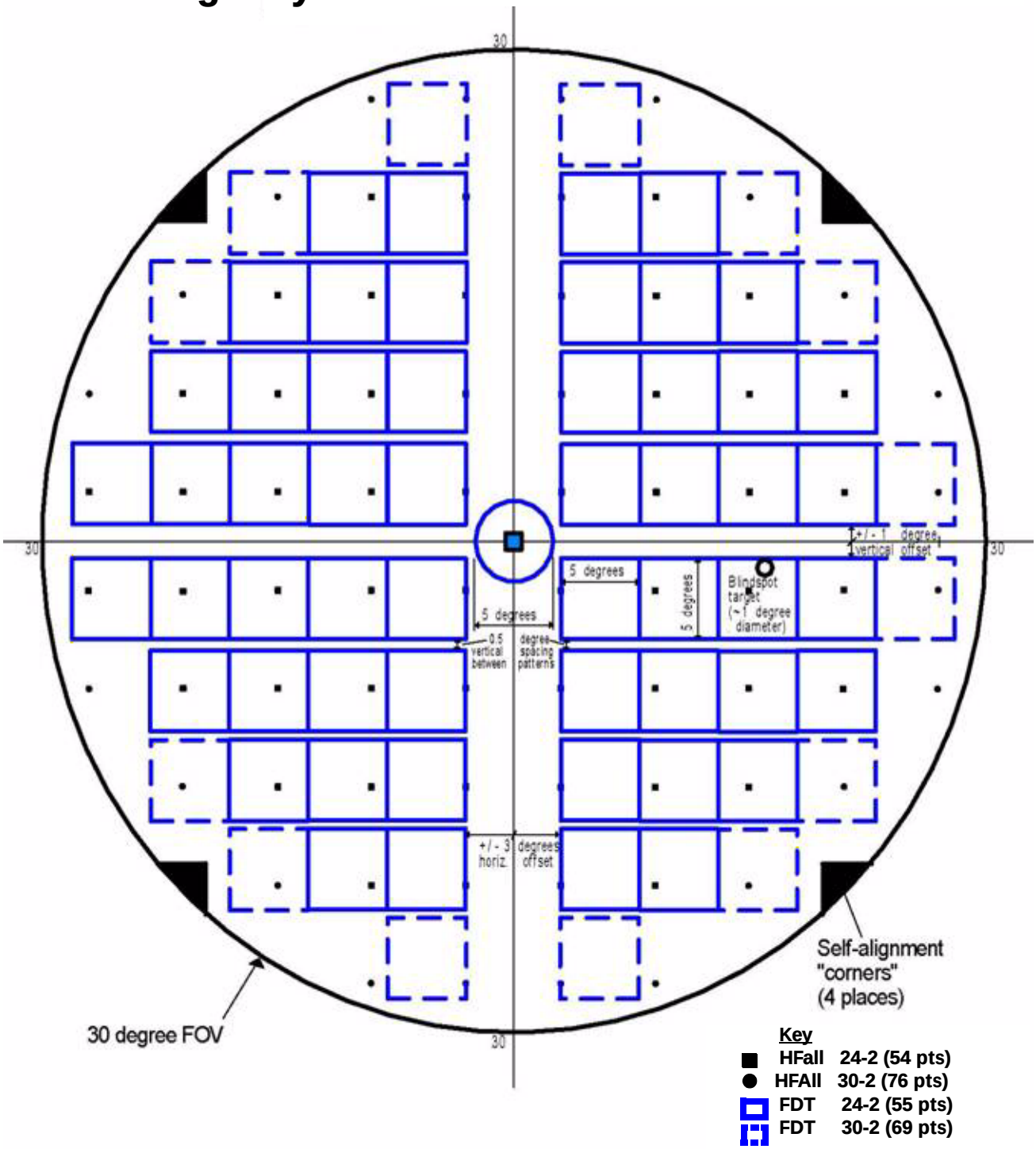
Humphry Matrix N - 30 FDT Tests
8-9x9-10 degree FDT patterns (25 Hz, 0.25 cycles/degree)
Horizontal axis offest +/- 1 degree
Vertical axis offest +/- 3 degrees
(~1 degree square stationary central fixation target)

Right Eye



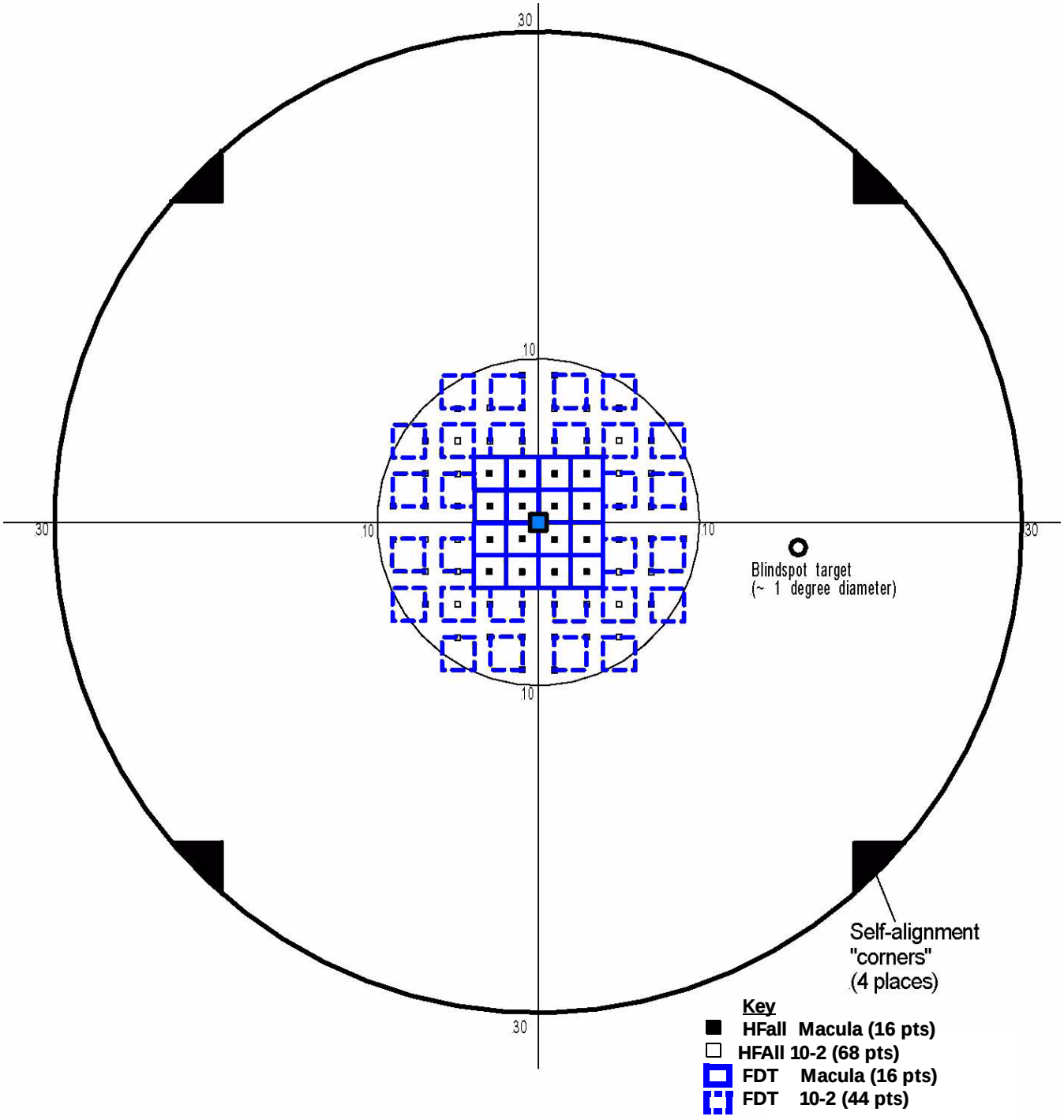
Humphry Matrix N 24- 2 (55 pts.) and 30-2 (69 pts) FDT Tests
5x5 degree FDT patterns (18 Hz, 0.5 cycles/degree)
Horizontal axis offest +/- 1 degree
Vertical axis offest +/- 3 degrees
(~1 degree square stationary central fixation target)

Right Eye



Humphry Matrix Macula (16 pts.) FDT Test and
Humphry Matrix 10-2 (44 pts.) FDT Test
2x2 degree FDT patterns (12 Hz, 0.5 cycles/degree)
No horizontal or vertical axis offest in central 4 degrees,
+/- 1 degree axis offests outside central 4 degrees
(~1 degree square stationary central fixation target)

Right Eye



STANDARDS COMPLIANCE

Regulatory Approvals

Health Insurance Portability and Accountability Act

It is essential that the user understands the features of the Matrix and defines their workflow to achieve compliance with the HIPAA security rule. The Welch Allyn Matrix has the capability to both store and transmit electronic protected health information (PHI) that identifies patients. The Matrix does not contain features that by themselves enable or prevent compliance with the technical safeguards enumerated in the HIPAA security rule for access Control, Authentication, Data Integrity, Audit Control, and Transmission Security. We therefore recommend that the user take appropriate precautions to control access and use of the Matrix and its data to ensure compliance to the HIPAA requirements.

The CE mark on this device indicates it has been tested to and conforms to the provisions noted within the 93/42/EEC Medical Device Directive

Authorized European Representative Address:
European Regulatory Manager
Welch Allyn Ireland
Navan Business Park
Dublin Road
Navan, County Meath
Republic of Ireland
Tel: +353 46 90 67700 • Fax: +353 46 90 67756

N344

WELCH ALLYN PTY LTD
5/38-46 SOUTH
STREET
RYDAL MERE
NSW 2116
AUSTRALIA

EMC Framework of Australia

Product Safety

Class I

IXPO- ordinary equipment

Continuous operation equipment

TYPE BF Indicates this equipment contains Type BF applied parts; the patient forehead rest and patient response button.

TUV listed to comply with

UL 2601-1:1997

CSA C22.2 No. 601.1-M90

IEC 60601-1:1990+A1+A2+A13

IEC 60601-1-2:2001

CB certified to Medical Electrical Equipment IEC60601-1

Complies with:

IEC 60065
IEC 60601-1-4
ANSI/ESNA RP27.1:1996, RP27.2:2000, RP27.3:1996
IEC 60825-1:1994+A1+A2
IEC 60825-9
IEC 60950-1

Electromagnetic Compatibility (EMC)

EN 60601-1-2:2001

- IEC 1000-4-2:1995 Electrostatic Discharge Immunity
- IEC 1000-4-3:1995 Radiated Electromagnetic Field Immunity
- IEC 1000-4-4:1995 Electrical Fast Transient Immunity
- IEC 1000-4-5:1995 Surge Immunity
- IEC 1000-4-6:1996 Conducted RF Immunity
- IEC 1000-4-8:1993 Power Frequency Magnetic Field Immunity
- IEC 1000-4-11:1994 Voltage Dips & Variations
- EN 55011:1998 Radiated & Conducted Emissions; Group 1, Class B
- IEC 61000-3-2:1995+A14 Power Harmonics; Class A
- IEC 61000-3-3:1995 Voltage Fluctuation (Flicker); Section 5

Guidance and manufacturer's declaration - electromagnetic emissions		
The Humphrey Matrix is intended for use in the electromagnetic environment specified below. The customer or the user of the Humphrey Matrix should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The Humphrey Matrix uses RF energy only for its internal function. therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Humphrey Matrix is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Humphrey Matrix is intended for use in the electromagnetic environment specified below. The customer or the user of the Humphrey Matrix should assure that is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ± 8 kV air	±6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/out-put lines	±2 kV for power supply lines ±1 kV for input/out-put lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0,5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5 % U_T (95 % dip in U_T) for 5 sec	<5 % U_T (>95% dip in U_T) for 0,5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5 % U_T (95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Humphrey Matrix requires continued operation during power mains interruptions, it is recommended that the Humphrey Matrix be powered from an interruptible source.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Humphrey Matrix is intended for use in the electromagnetic environment specified below. The customer or the user of the Humphrey Matrix should assure that is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Humphrey Matrix, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d=1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d=1.17\sqrt{P}$ 80 MHz to 800 MHz $d=2.33\sqrt{P}$ 800 MHz to 2,5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Humphrey Matrix is used and exceeds the applicable RF compliance level above, the Humphrey Matrix should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Humphrey Matrix. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Humphrey Matrix

The Humphrey Matrix is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Humphrey Matrix can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Humphrey Matrix as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d=\frac{1.17}{V1}\sqrt{P}$	$d=\frac{1.17}{E1}\sqrt{P}$	$d=\frac{2.33}{E1}\sqrt{P}$
0,01	0.117	0.117	0.233
0,1	0.370	0.370	0.737
1	1.170	1.170	2.330
10	3.700	3.700	7.368
100	11.700	11.700	23.300

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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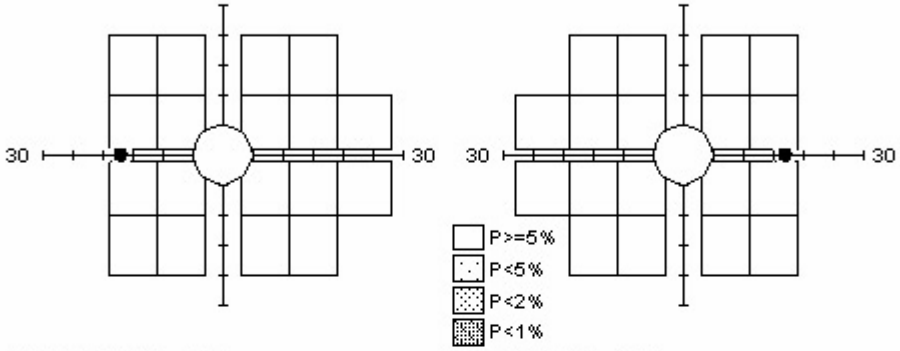
NAME: **Lastname, Firstname** **BOTH**
ID: **Sample01** DOB: **06-08-1979 [23]**

N-30-5 FDT Screening DATE: 10-25-2002 15:07

TEST SPEED:NORMAL

LEFT EYE	RIGHT EYE
PUPIL DIAMETER:	PUPIL DIAMETER:
VISUAL ACUITY:	VISUAL ACUITY:
RX:	RX:

TOTAL DEVIATION



TEST DURATION: 0:35	TEST DURATION: 0:33
FIXATION TARGET: Central	FIXATION TARGET: Central
FIXATION ERRS: 3/3 (100 %)*	FIXATION ERRS: 3/3 (100 %)*
FALSE POS ERRS: 0/3 (0 %)	FALSE POS ERRS: 0/3 (0 %)
NOTES:	NOTES:

SW: M1.0.0[C]
S01.00.11 Beta
P04.04.04[0]
TID: 2.udef (R1)

Humphrey Matrix *with*
Welch Allyn Frequency Doubling Technology

NAME: **Lastname, Firstname**
ID: **Sample01**

BOTH
DOB: **06-08-1979 [23]**

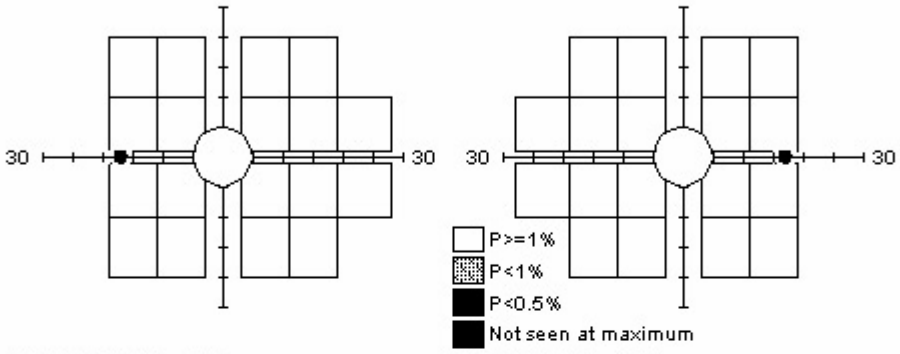
N-30-1 FDT Screening

DATE: 10-28-2002 09:05

TEST SPEED:NORMAL

LEFT EYE	RIGHT EYE
PUPIL DIAMETER:	PUPIL DIAMETER:
VISUAL ACUITY:	VISUAL ACUITY:
RX:	RX:

TOTAL DEVIATION



TEST DURATION: 0:33	TEST DURATION: 0:33
FIXATION TARGET: Central	FIXATION TARGET: Central
FIXATION ERRS: 0/3 (0 %)	FIXATION ERRS: 3/3 (100 %)*
FALSE POS ERRS: 0/3 (0 %)	FALSE POS ERRS: 0/3 (0 %)
NOTES:	NOTES:

SW: M1.0.0[C]
S01.00.11 Beta
P04.04.04[0]
TID: 3.udef (R1)

Humphrey Matrix *with*
Welch Allyn Frequency Doubling Technology

NAME: **Lastname, Firstname**
ID: **Sample01**

BOTH
DOB: **06-08-1979 [23]**

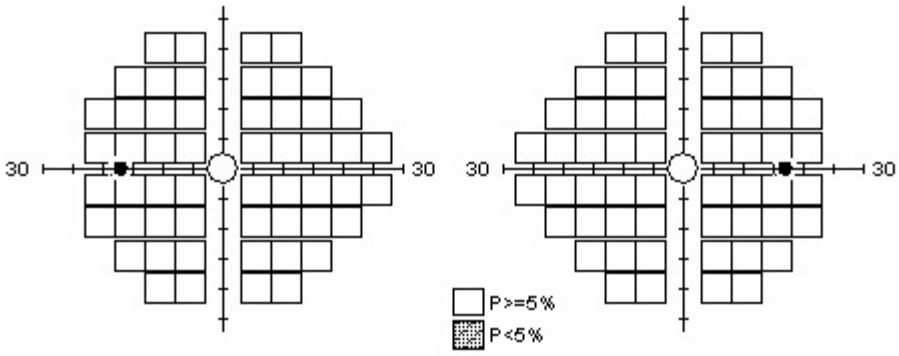
24-2-5 FDT Screening

DATE: 10-28-2002 09:24

TEST SPEED:NORMAL

LEFT EYE	**RIGHT EYE**
PUPIL DIAMETER:	PUPIL DIAMETER:
VISUAL ACUITY:	VISUAL ACUITY:
RX:	RX:

TOTAL DEVIATION



TEST DURATION: 1:35	TEST DURATION: 1:32
FIXATION TARGET: Central	FIXATION TARGET: Central
FIXATION ERRS: 0/10 (0 %)	FIXATION ERRS: 0/10 (0 %)
FALSE POS ERRS: 0/10 (0 %)	FALSE POS ERRS: 1/10 (10 %)
NOTES:	NOTES:

SW: M1.0.0[C]
S01.00.11 Beta
P04.04.04[0]
TID: 5.udef (R1)

Humphrey Matrix *with*
Welch Allyn Frequency Doubling Technology

NAME: **Lastname, Firstname**
ID: **Sample01**

BOTH
DOB: **06-08-1979 [23]**

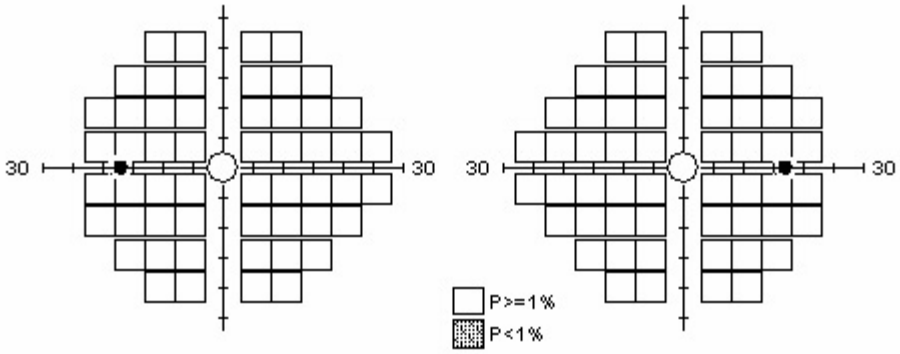
24-2-1 FDT Screening

DATE: 10-28-2002 09:30

TEST SPEED:NORMAL

LEFT EYE	**RIGHT EYE**
PUPIL DIAMETER:	PUPIL DIAMETER:
VISUAL ACUITY:	VISUAL ACUITY:
RX:	RX:

TOTAL DEVIATION



TEST DURATION: 1:31	TEST DURATION: 1:33
FIXATION TARGET: Central	FIXATION TARGET: Central
FIXATION ERRS: 1/10 (10 %)	FIXATION ERRS: 0/10 (0 %)
FALSE POS ERRS: 0/10 (0 %)	FALSE POS ERRS: 0/10 (0 %)
NOTES:	NOTES:

SW: M1.0.0[C]
S01.00.11 Beta
P04.04.04[0]
TID: 6.udef (R1)

Humphrey Matrix *with*
Welch Allyn Frequency Doubling Technology

NAME: **Lastname, Firstname**
ID: **Sample01**

RIGHT
DOB: **06-08-1979 [23]**

TEST DURATION: 2:46
FIXATION TARGET: Central

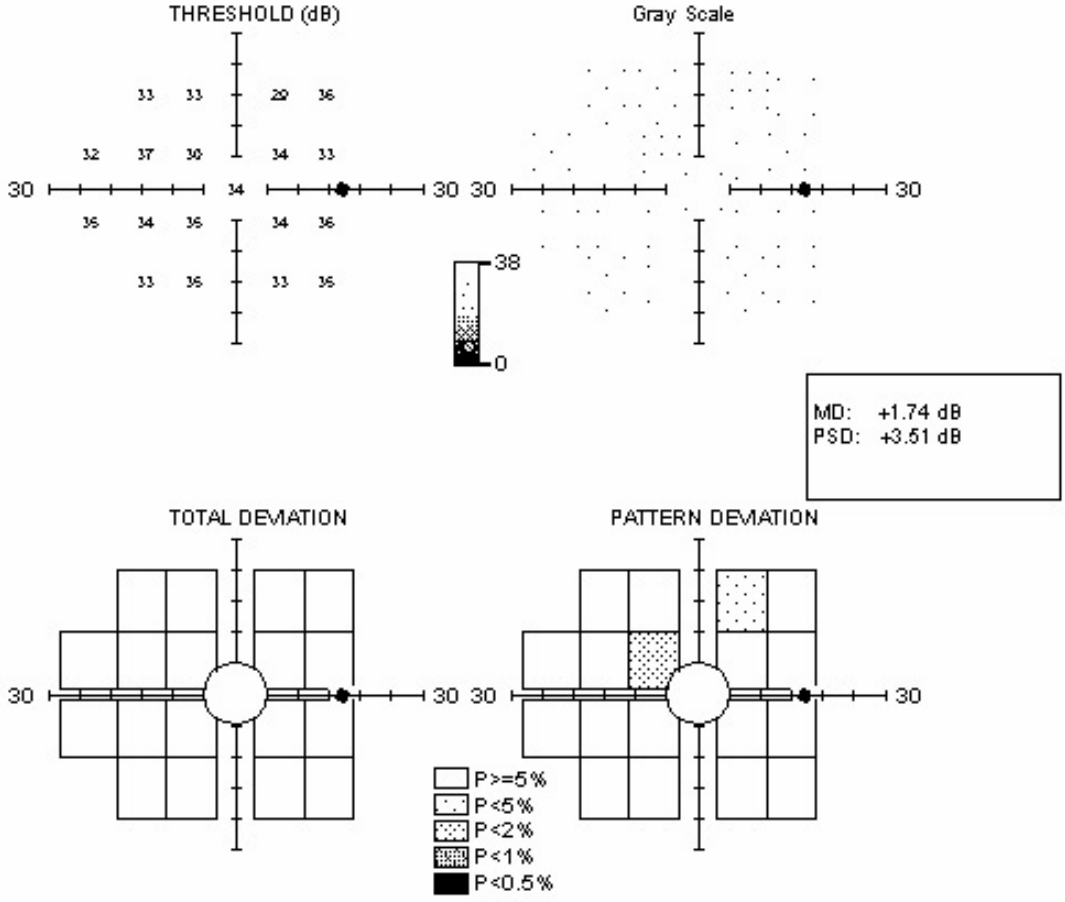
FIXATION ERRS: 0/6 (0 %)
FALSE POS ERRS: 0/6 (0 %)
FALSE NEG ERRS: 0/3 (0 %)

N-30-F FDT Threshold

TEST SPEED:NORMAL

DATE: 10-28-2002 09:41

PUPIL DIAMETER:
VISUAL ACUITY:
RX:



NOTES:

S\W: M1.0.0[C]
S01.00.11 Beta
P04.04.04[0]
TID: 8.udef (1)

Humphrey Matrix *with*
Welch Allyn Frequency Doubling Technology

NAME: **Lastname, Firstname** **RIGHT**
ID: **Sample01** DOB: **06-08-1979 [23]**

TEST DURATION: 4:58
FIXATION TARGET: Central

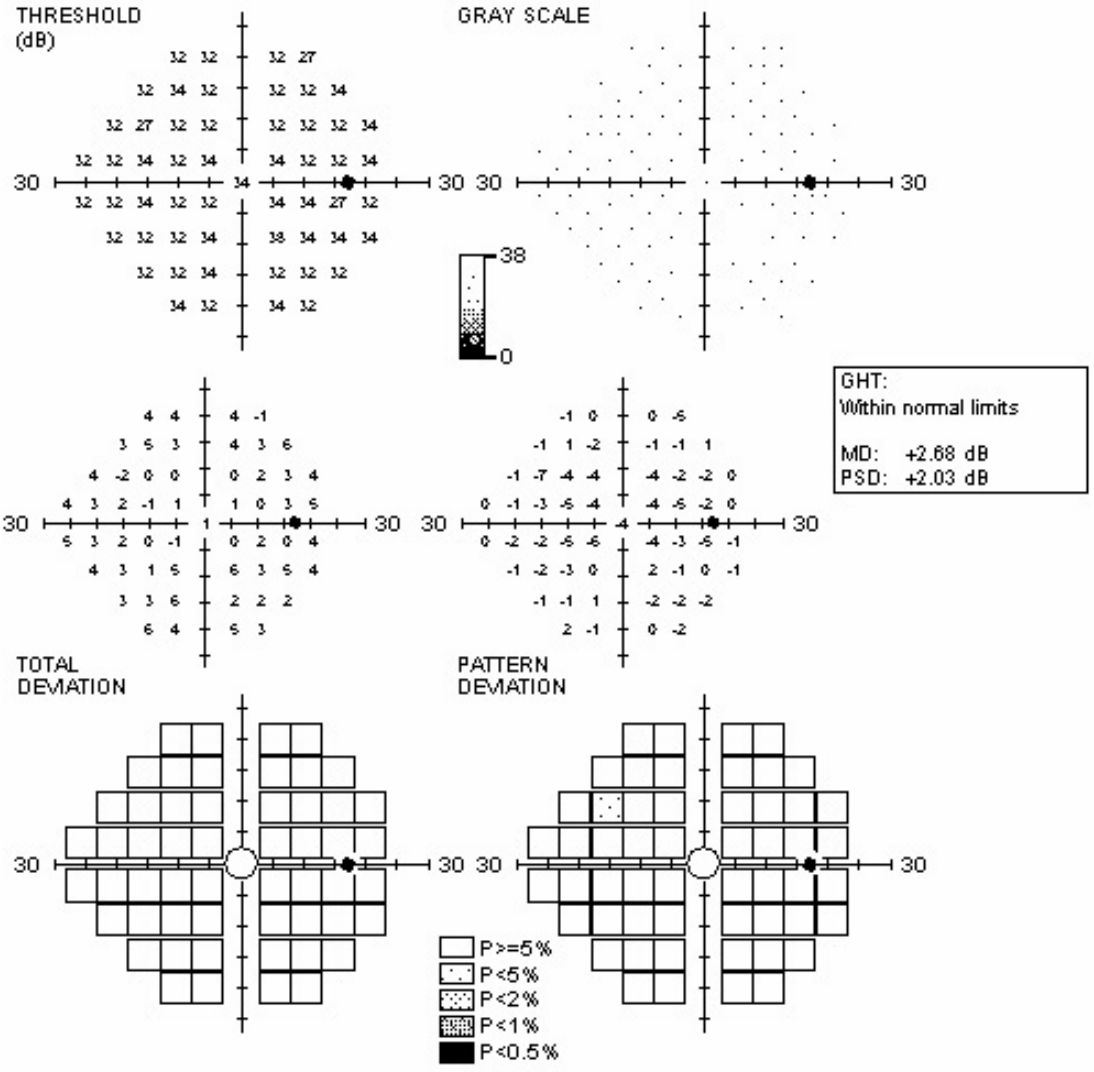
24-2 FDT Threshold

DATE: 10-28-2002 09:50

TEST SPEED:NORMAL

FIXATION ERRS: 0/10 (0 %)
FALSE POS ERRS: 0/10 (0 %)
FALSE NEG ERRS: 0/6 (0 %)

PUPIL DIAMETER:
VISUAL ACUITY:
RX:



NOTES:

SW: M1.0.0[C]
S01.00.11 Beta
P04.04.04[0]
TID: 9.udef (1)

Humphrey Matrix *with*
Welch Allyn Frequency Doubling Technology

NAME: **Lastname, Firstname** **RIGHT**
ID: **Sample01** DOB: **06-08-1979 [23]**

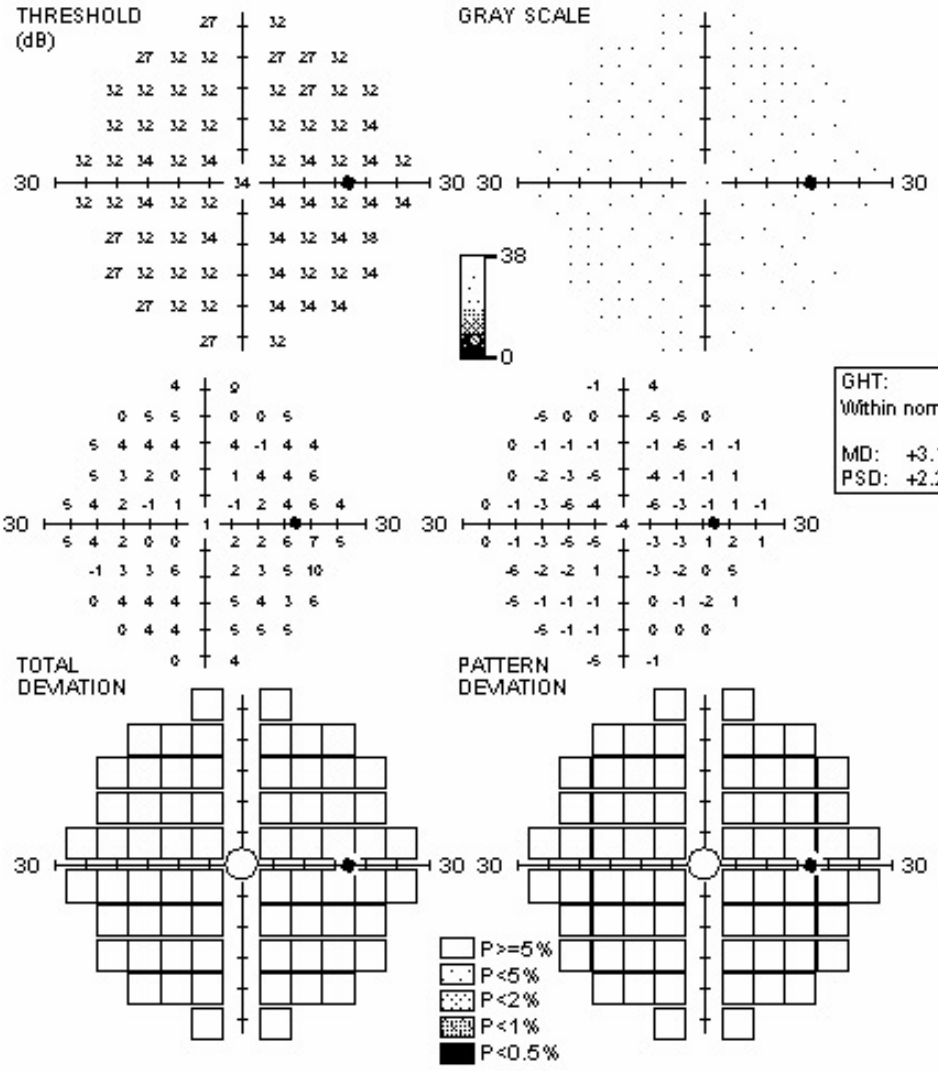
TEST DURATION: 6:10
FIXATION TARGET: Central
FIXATION ERRS: 1/10 (10 %)
FALSE POS ERRS: 0/10 (0 %)
FALSE NEG ERRS: 0/6 (0 %)

30-2 FDT Threshold

TEST SPEED:NORMAL

DATE: 10-28-2002 10:48

PUPIL DIAMETER:
VISUAL ACUITY:
RX:



NOTES:

SW: M1.0.1[0]
S01.00.11 Beta
P04.04.04[0]
TID: 11.udef (1)

Humphrey Matrix *with*
Welch Allyn Frequency Doubling Technology

NAME: **Lastname, Firstname** **RIGHT**
ID: **Sample01** DOB: **06-08-1979 [23]**

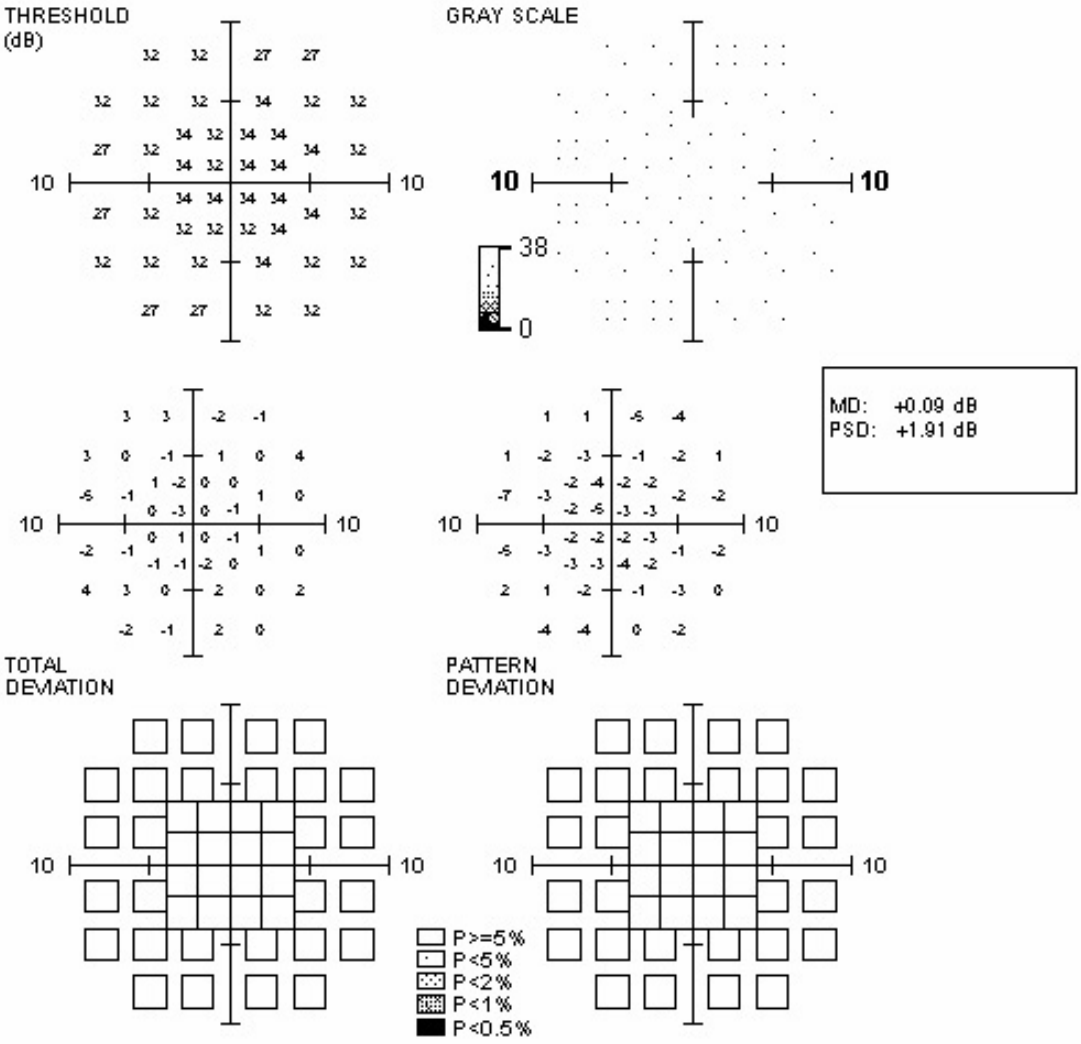
TEST DURATION: 4:11
FIXATION TARGET: Central
FIXATION ERRS: 1/10 (10 %)
FALSE POS ERRS: 0/10 (0 %)
FALSE NEG ERRS: 0/6 (0 %)

10-2 FDT Threshold

TEST SPEED:NORMAL

DATE: 10-28-2002 11:03

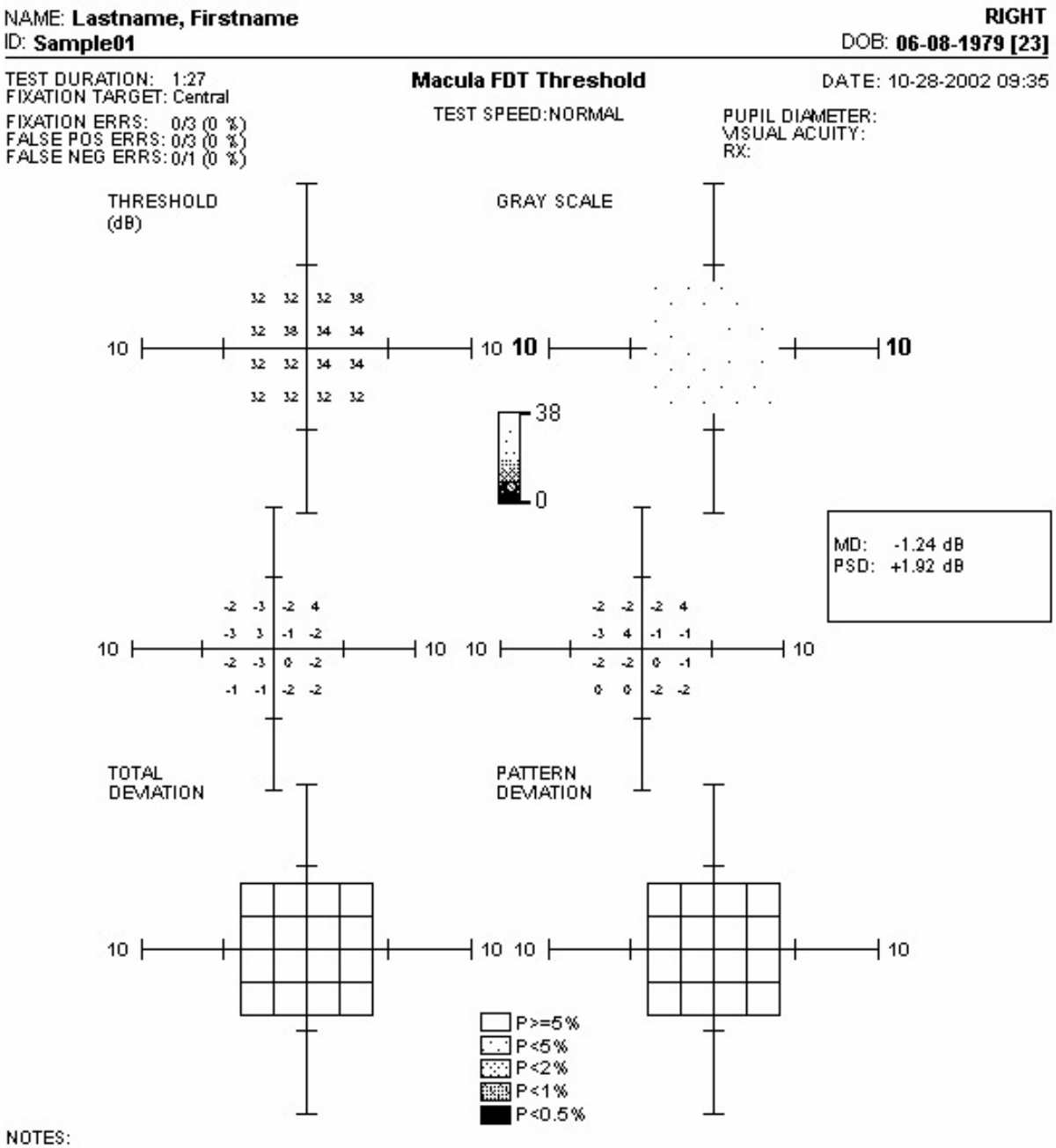
PUPIL DIAMETER:
VISUAL ACUITY:
RX:



NOTES:

SW: M1.0.1[0]
S01.00.11 Beta
P04.04.04[0]
TID: 12.udef (1)

Humphrey Matrix *with*
Welch Allyn Frequency Doubling Technology

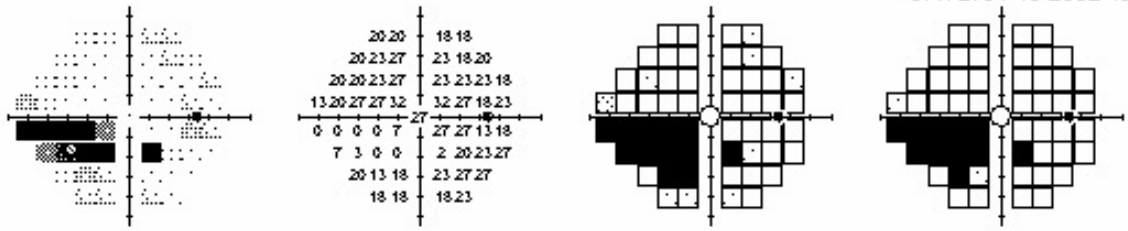

NAME: Lastname, Firstname
ID: Sample01
RIGHT
DOB: 06-08-1979 [23]
TEST DURATION: 1:27
FIXATION TARGET: Central
FIXATION ERRS: 0/3 (0 %)
FALSE POS ERRS: 0/3 (0 %)
FALSE NEG ERRS: 0/1 (0 %)
Macula FDT Threshold
TEST SPEED:NORMAL
DATE: 10-28-2002 09:35
PUPIL DIAMETER:
VISUAL ACUITY:
RX:
THRESHOLD (dB)
GRAY SCALE
38
0
MD: -1.24 dB
PSD: +1.92 dB
TOTAL DEVIATION
PATTERN DEVIATION
P>=5%
P<5%
P<2%
P<1%
P<0.5%
NOTES:
SW: M1.0.0[C]
S01.00.11 Beta
P04.04.04[0]
TID: 7.udef (1)
Humphrey Matrix with
Welch Allyn Frequency Doubling Technology
ZEISS

NAME: **DEI, 012GLAU** **RIGHT**
ID: **DEI012GLAUC** DOB: **01-05-1939**

24-2 FDT Threshold Overview

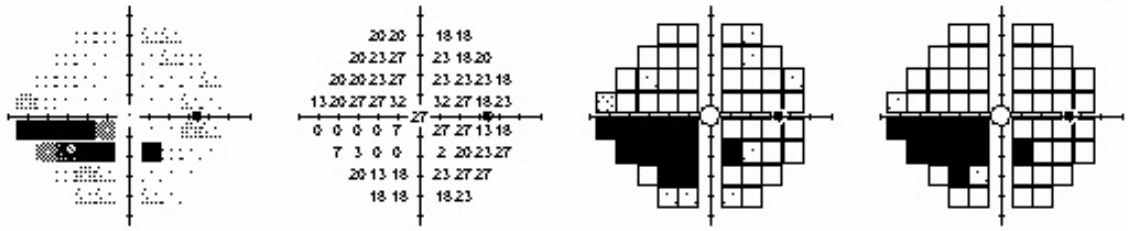
GRAY SCALE | Threshold(dB) | TOTAL DEVIATION | PATTERN DEVIATION

DATE: 01-10-2002 12:08



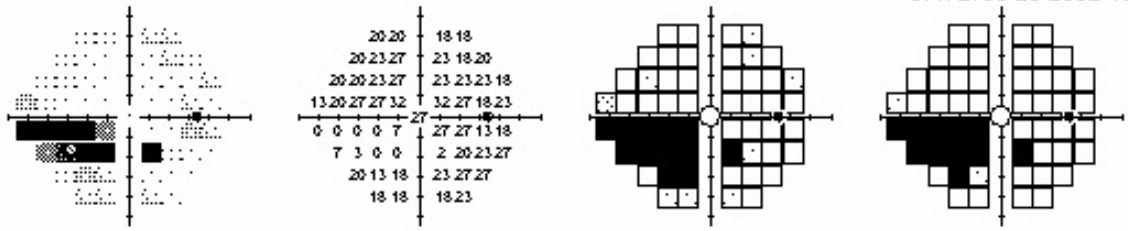
GHT: Outside normal limits
FIXATION ERRS: 1/10 (10 %)
MD: -8.06 dB P<1%
FALSE POS ERRS: 1/10 (10 %)
PSD: +9 dB P<0.5%
FALSE NEG ERRS: 0/6 (0 %)

DATE: 03-19-2002 14:17



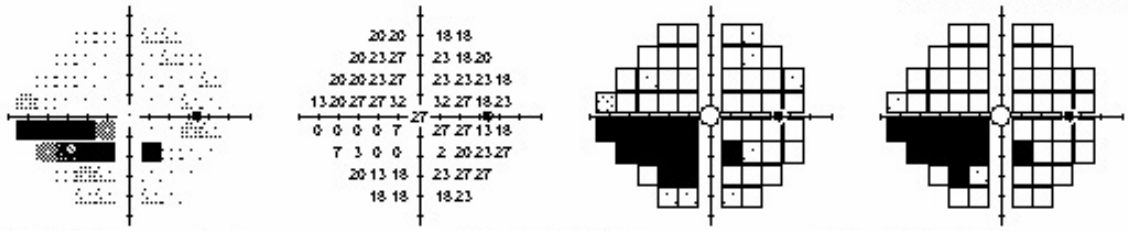
GHT: Outside normal limits
FIXATION ERRS: 1/10 (10 %)
MD: -8.05 dB P<1%
FALSE POS ERRS: 1/10 (10 %)
PSD: +9 dB P<0.5%
FALSE NEG ERRS: 0/6 (0 %)

DATE: 06-25-2002 10:22



GHT: Outside normal limits
FIXATION ERRS: 1/10 (10 %)
MD: -8.02 dB P<1%
FALSE POS ERRS: 1/10 (10 %)
PSD: +9 dB P<0.5%
FALSE NEG ERRS: 0/6 (0 %)

DATE: 08-19-2002 17:58



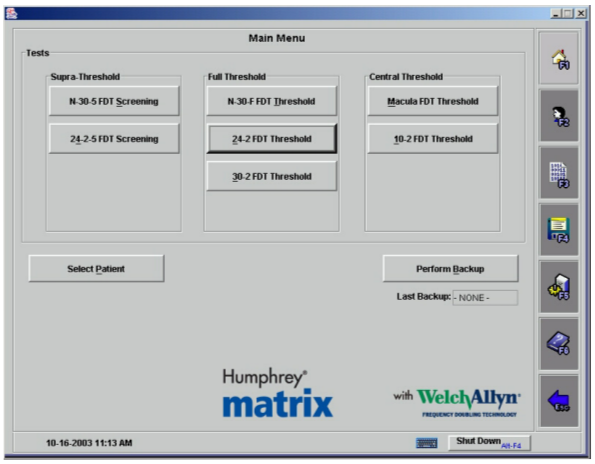
GHT: Outside normal limits
FIXATION ERRS: 1/10 (10 %)
MD: -8.01 dB P<1%
FALSE POS ERRS: 1/10 (10 %)
PSD: +9 dB P<0.5%
FALSE NEG ERRS: 0/6 (0 %)

SW: P04.04.04[0]

Humphrey Matrix *with*
Welch Allyn Frequency Doubling Technology

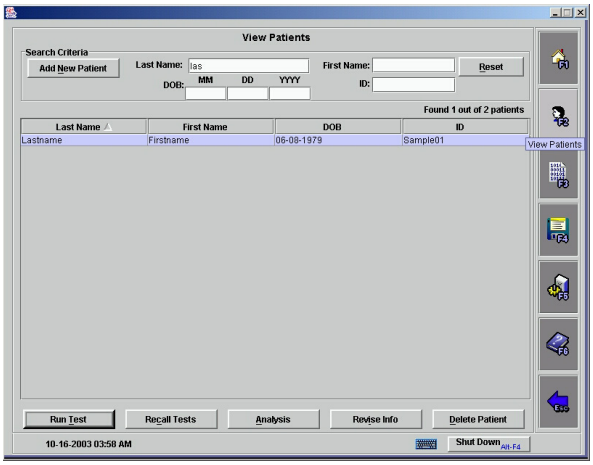
Humphrey® Matrix Quick Reference Guide

Select Test Type



From the **Main Menu Screen (F1),** select one of the **Test Type** Buttons or the **Select Patient** Button with the mouse pad or Hot Key (Alt+ underlined letter). Both selections proceed to the **View Patients (F2) Screen**.

Select Existing Patient or Add New Patient

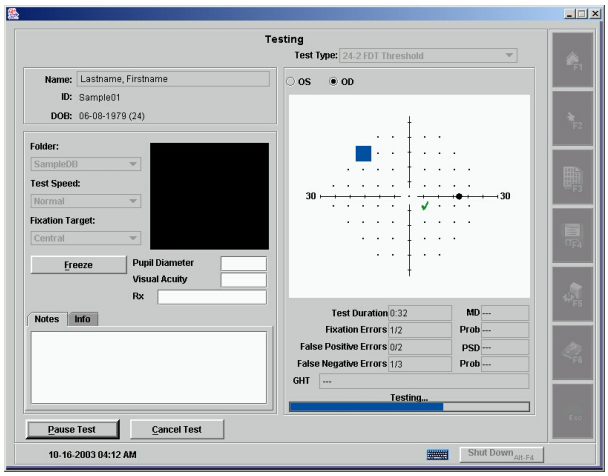


From the **View Patient Screen (F2)**, select an existing patient from the patient listing displayed on the screen by clicking once on the patient name. Clicking the **Run Test** Button brings you to the **Testing Screen**.

or

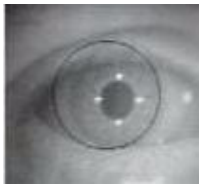
You may add a new patient to the testing database by selecting the **Add New Patient** Button in the **View Patient (F2) Screen**. Required fields (**DOB** in addition to **First** and **Last Name** or **ID**) are marked with an asterisk (*). Once the new patient data has been added to the testing database, the Testing Screen will be displayed.

Start Test



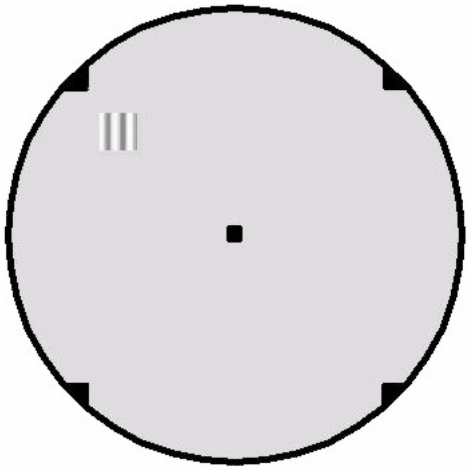
In the **Testing Screen**, check to be sure the proper patient name and test type are displayed. The test type can be changed in the testing screen if necessary. The status box in the lower corner of the screen will state that the **Pre-test Demo** is being performed so the patient is able to view a demonstration of selected test.

- Place the **Patient Visor** so that the Patient Eyepiece is aligned with the eye to be tested.
- **Adjust the position of the patient or the instrument to obtain proper, comfortable patient alignment**. Proper alignment requires the patient to see all four self-alignment points at the same time while fixating on the black square target in the center. It is OK if the fixation target appears fuzzy to the patient.
- When **Eye Monitoring** is turned on, an image of the patient's eye will be displayed on the Testing Screen. The **patient's pupil should be kept inside the circle** on the video image throughout the test. **The pupil does not have to be perfectly centered** for proper alignment, but it should stay within the circle.
- After explaining the test to the patient, click the **Start Test** Button to begin the test. During testing the Pause Test Button can be used to pause the test. The Cancel Test Button provides the option to cancel the test.



Keep patient's pupil INSIDE the circle.

Patient Video Screen Patterns



Explain the Test Procedure to the Patient

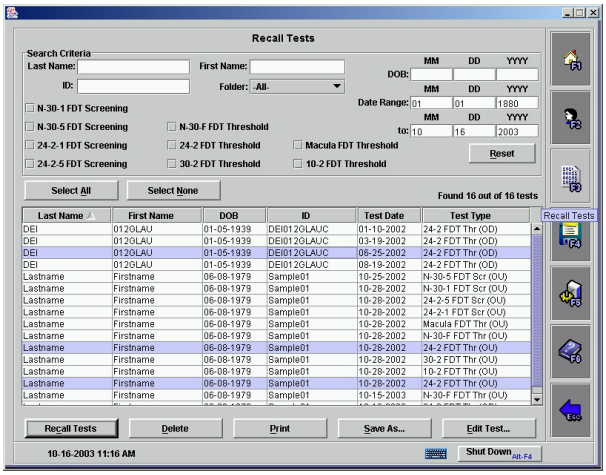
"The instrument is going to show you some patterns that flicker, or shimmer, or are striped. Each time you see one of these patterns, press (and release) the button you have in your hand. Please place and keep your forehead on the instrument forehead rest.

- Can you see the black spot in the center of the screen? You must keep looking at the black spot in the center at all times during the test.
- While looking at the black spot in the center, can you see all four triangles at the edge of the screen?
- Are you comfortable?

A sample of the test is now running. Please press the button whenever you see a pattern that flickers, or shimmers, or is striped. You may pause the test by holding down the button. You may blink your eyes whenever you want. A good time to blink is whenever you press the button.

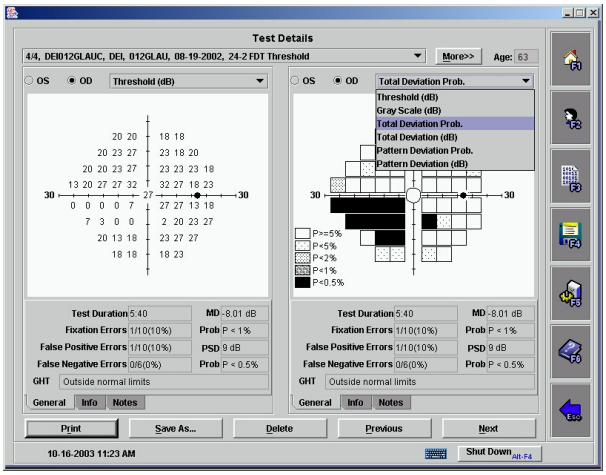
There will be a brief flash just before the actual test begins." [select **Start Test** Button, then when status indicates Testing…] "The test is beginning now. Please remember to keep looking at the black spot in the center of the screen at all times during the test."

Recall Previous Test Results



The **Recall Tests Screen (F3)** provides the ability to view previously stored test results by clicking to highlight the desired tests. Once the desired tests have been highlighted, click the **Recall Tests Button** to view the test details. Alternatively, the **View Patients Screen (F2)** allows all the tests for a particular patient to be recalled and viewed.

View Test Details



In the **Test Details Screen**, the test details for each test selected are displayed. The different types of plots that can be displayed are the same plots from the printouts. They can be selected from the pull down menu with the plot names. The plot pull down menu is located above the plot; it is the bar with the downward pointing arrow. Different plots for the same eye can be selected by choosing the "OD" for both eyes as displayed on the left.

Printing

When testing both eyes: If the system settings are set for Automatic Printing then the test results will automatically print once the tests for both eyes are complete or when either **Done Testing** or **New Test** is selected.

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