



Humphrey FDT

Model 710

User Manual



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(1) Safety Information

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



Note: If a serious incident has occurred in relation to this medical device, to the user, or to another person, then the user (or responsible person) must report the serious incident to the medical device manufacturer or the distributor. In the European Union, the user (or responsible person) must also report the serious incident to the Competent Authority in the state where the user is established.

Summary



CAUTION: Before connecting the power cord to the appliance inlet, verify that the voltage selector switch is correctly set (115 V or 230 V) to match the power requirements in your region.



CAUTION: Always replace fuses with the same type and rating (T 0.400 A 250 V). Refer to Fuse Replacement section for instruction on changing fuses.



CAUTION: Do Not Sterilize the instrument or any of its components.



CAUTION: After unpacking the instrument, pull down the printer door (below the LCD display), using the finger cutouts on the sides of the door (near the top), and remove the foam shipping wedge before using the printer. Close the printer door. Be sure the paper is sticking out through the slot in the door. Failure to remove the shipping wedge will result in improper operation of the printer.



CAUTION: Do not use the instrument near other equipment which produces strong magnetic fields (such as MRI). The video monitor performance may be adversely affected.

Product Safety

This instrument is classified as follows:



- Class I Equipment – Protection against electrical shock.
- Type BF – Degree of protection against electric shock of applied part (forehead rest and Patient Response button).
- Ordinary Equipment (IPX0) – Degree of protection against ingress of liquids (none).
- Continuous Operation – Mode of operation.



WARNING: This device contains visual stimuli, including flickering light and flashing patterns, between 5 and 65 Hz. Medical professionals need to determine whether this device should be used for patients who may be photosensitive, including those with epilepsy.



WARNING: To prevent electric shock, the instrument must be plugged into an earthed ground outlet. Do not remove or disable the ground pin.



CAUTION: Do not use the printer or the instrument with an extension cord or a power strip (multiple portable socket outlet).



WARNING: Do not open the instrument covers. Opening the instrument covers could expose you to electrical and optical hazards and will VOID the warranty.



CAUTION: If a table is available, do not reconfigure system components on the table, nor add non-system devices or components to the table, nor replace original system components with substitutes not approved by Carl Zeiss Meditec. Such actions could result in failure of the table height adjustment mechanism, instability of the table, tipping and damage to the instrument, and injury to operator and patient.



WARNING: This instrument may cause ignition of flammable gases or vapors. Do NOT use in the presence of flammable anesthetics such as nitrous oxide, or in the presence of pure oxygen.



WARNING: The instrument itself is transportable and may be moved from one location to another. However, if the instrument is placed on a power table provided by CZM, do not move the table to another location while the instrument and any other peripherals are placed on it. Doing so may cause the system components to tip over and cause harm to the patient, the operator, or others in the vicinity.



CAUTION: Avoid tipping. Do not use the instrument on an uneven or sloped surface. Also, do not roll the instrument table in deep pile carpet or over objects on the floor such as power cords. Failure to observe these precautions could result in tipping of the instrument and/or table and resulting injury to operator or patient and damage to the instrument.



CAUTION: (United States) Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.



WARNING: SERVICE or REPAIR to be performed by QUALIFIED, AUTHORIZED PERSONNEL ONLY. There are NO USER SERVICEABLE PARTS INSIDE the Humphrey FDT instrument. Disassembly of the instrument presents a possible ELECTRICAL SHOCK hazard and will VOID the warranty. If the unit fails, contact CZM for instructions.



WARNING: REPLACEMENT PARTS and ACCESSORIES – Use only approved replacement parts and accessories.



CAUTION: The appliance coupler is the main disconnect device of the instrument. Position the instrument in such a way to have easy access to disconnect the appliance coupler in case of an emergency.



CAUTION: In case of an emergency, disconnect the appliance coupler.

Symbols and Labels



WARNING



CAUTION



WARNING: Follow instructions for use. Failure to read and follow instructions may result in hazards that can lead to serious injury. Instructions may also describe potential serious adverse reactions and safety hazards.



Type BF applied parts: The Patient Forehead Rest and Patient Response button.



Alternating Current



Power: Off On



Manufacturer



Authorized European Community Representative



Serial number



Catalog number / part number



Model number



European Conformity



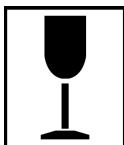
Disposal of the Product within the EU. Do not dispose via domestic waste disposal system or communal waste disposal facility.



Protective Packing Symbols

The protective packing symbols specify the handling requirements and the transport and storage conditions.

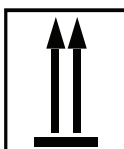
Handling Requirements



Fragile, Handle with Care

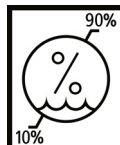


Keep Dry

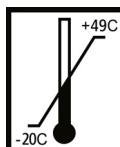


This end up

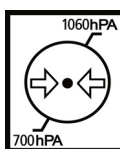
Transport and Storage Conditions



Relative Humidity (10% to 90%, non-condensing)



Temperature (-20 to +49 deg. C)



Atmospheric Pressure Limits (700 hPa to 1060 hPa)

Product Labels and Serial Number Location

The Product label is on the side of the instrument. The Serial Number label is located on the bottom of the instrument.

External Device Equipment



WARNING: To maintain patient safety, if the instrument is externally connected to non-medical peripheral devices (i.e. printer, storage devices, etc.), the complete system must continue to meet the applicable medical requirements of IEC 60601-1 safety standard. This standard requires the usage of an Isolation Transformer to power the non-medical peripheral device if located within 1.5 m from the patient. If the peripheral device is located outside the patient environment (beyond 1.5 m) and is connected to the FDT 710, a separation device must be used or there shall be no metal to metal connection between the non-medical peripheral device and the FDT 710.

The person or the responsible organization connecting additional devices or reconfiguring the system must evaluate the complete system to ensure compliance to the applicable IEC 60601-1 requirements. The instrument operator must not attempt to touch the patient and the peripheral device simultaneously.

Failure to observe this warning could result in electrical shock to the patient and/or operator.

Standards

Product Compliance



Complies with 93/42/EEC Medical Device Directive.



OR



Complies with US and Canadian medical electrical system safety requirements.

Electromagnetic Compatibility (EMC)



CAUTION: MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the following EMC information provided.



CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.



CAUTION: The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity of the equipment.



CAUTION: The FDT should not be used adjacent to or stacked with other equipment.



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

Guidance and Manufacturer's Declarations

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Humphrey FDT is intended for use in the electromagnetic environment specified below. The customer or user of the Humphrey FDT should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Humphrey FDT 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 FDT are suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Humphrey FDT is intended for use in the electromagnetic environment specified below. The customer or user of the Humphrey FDT should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	± 6kV Contact ± 8kV Air	± 6kV Contact ± 8kV Air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic material, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	±2kV Mains ±1kV I/O	±2kV Mains Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	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	>95% Dip in 0.5 Cycle 60% Dip in 5 Cycles 30% Dip for 25 Cycles >95% Dip in 5 Seconds	>95% Dip in 0.5 Cycle 60% Dip in 5 Cycles 30% Dip for 25 Cycles >95% Dip in 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Humphrey FDT requires continued operation during power mains interruptions, it is recommended that the Humphrey FDT be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz 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.

Guidance and Manufacturer's Declaration – Emissions			
The Humphrey FDT is intended for use in the electromagnetic environment specified below. The customer or user of the Humphrey FDT should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz (outside ISM bands)	V1 = 3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Humphrey FDT, including cables, than the recommended separation distances calculated/listed below: $d = \left(\frac{3.5}{3}\right)\sqrt{P}$ $d = \left(\frac{3.5}{3}\right)\sqrt{P} \quad 80 \text{ to } 800 \text{ MHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E1 = 3 V/m	$d = \left(\frac{7}{3}\right)\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where P is the max power in watts and d is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (3 Vrms and 3 V/m). Interference may occur in the vicinity of equipment containing a transmitter.</p>

Guidance and Manufacturer's Declaration – Recommended Separations Distances between portable and mobile RF Communications equipment and the Humphrey FDT

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

Max Output Power (watts)	Separation (m) 150kHz to 80MHz $d = (1.167)\sqrt{P}$	Separation (m) 80 to 800MHz $d = (1.167)\sqrt{P}$	Separation (m) 800MHz to 2.5GHz $d = (2.3333)\sqrt{P}$
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

(2) Introduction

Intended Use

Humphrey FDT is an AC-powered device intended to determine the extent of the peripheral visual field of a patient. The device is intended to determine the amount of visual field loss in a patient, which can then be used to diagnose/track the progression of glaucoma and other eye diseases.

Indications for Use

Humphrey FDT is an AC-powered device intended to determine the extent of the peripheral visual field of a patient. The device is intended to determine the amount of visual field loss in a patient, which can then be used to diagnose/track the progression of glaucoma and other eye diseases.



Note: These perimetry results are an aid to interpretation, not a diagnosis. The doctor's judgment is still the most important element in determining the clinical significance of the results, including considering the limitations of the statistical package.

Essential Performance

The main essential performance of the instrument is to provide accurate visual field mapping.

Patient Population

The Humphrey FDT may be used on all adults in need of diagnostic evaluation of the eye. This includes (but is not limited to) patients with the following disabilities or challenges:

- Wheelchair user
- Very low or not measurable visual acuity
- Fixation problems
- Deafness
- Large body, but not those above 99th percentile based on anthropomorphic data

There is a general requirement that the patient be able to sit upright and be able to place their face in the forehead rest of the instrument (with or without supplemental human or mechanical support).

Part of the Body

The Humphrey FDT physically interacts with the patient's forehead and chin. The patient's hand and fingers (or similar ability) are also required to press the Patient Response button.

Application

The Humphrey FDT is designed for continuous use, although it is expected that most sites operate the instrument for 10 hours or less per day, indoors, within a medical office or hospital setting. This setting shall have clean air free of soot, vapors from adhesives,

grease, or volatile organic chemicals. Other Operating Environment specifications are given in Chapters 1 and 6, Safety and Specifications. Application related warnings are given in this chapter and elsewhere.

User Profile

We assume that users are clinicians with professional training or experience in the use of ophthalmic equipment, and in diagnostic interpretation of the tests. Specific assumptions regarding the profiles of individuals performing instrument operation or data interpretation are given below. This manual contains information that will aid in the proper instrument operation and interpretation of the resultant data.

Instrument Operation**Demographic**

The user should be adult, and at least one of the following:

- Ophthalmologist or other Medical Doctor
- Optometrist or equivalent
- Nurse
- Certified Medical Technician
- Ophthalmic Photographer
- Non-certified Assistant

Occupational Skills

The user should be able to perform all of the following tasks:

- Power on the instrument
- Enter, find, and modify patient identifying data
- Clean surfaces that contact patient
- Instruct the patient
- Align the patient with the instrument
- Select and initiate a test
- Review and save a test or try again
- Generate an analysis report
- Review the analysis report for completeness
- Save, print, or export the analysis report
- Archive data
- Power off the instrument

Data Interpretation**Demographic**

The user should be one of the following:

- Ophthalmologist or other Medical Doctor
- Optometrist or equivalent

Job Requirements

The user should have training and certification in the analysis and treatment of ophthalmic diseases or other eye-related medical issues as required by governing bodies.

About the User Manual

The User Manual is designed to help you understand the capabilities and operation of the Humphrey FDT Visual Field Instrument with Frequency Doubling Technology. To achieve satisfactory results, the operator should read this manual thoroughly before using the instrument. An FDT Quick Reference Guide is provided for the convenience of experienced operators.



Instrument Overview

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

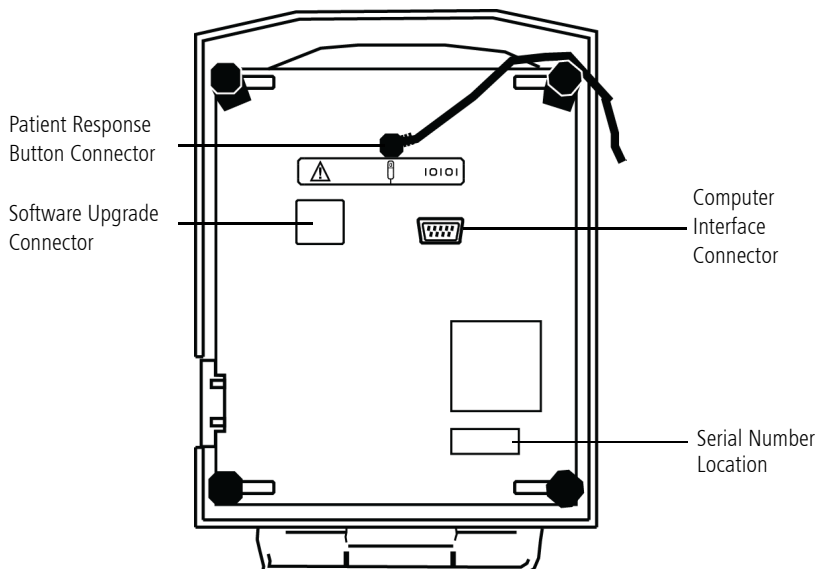
Key features of the FDT Visual Field Instrument include:

- Supra-threshold screening tests in less than 1 minute per eye
- Threshold tests in approximately 4 minutes per eye
- Easy to use; no special training is needed/minimal operator instruction
- No corrective (trial) lens needed; patients can wear their own correction or none at all (must only be within 6D of patient's refraction)
- No eye patch needed for the opposite (untested) eye - it's automatically occluded
- Not affected by ambient lighting - can be used in normal room lighting
- Not affected by pupil size (as small as 2 mm)
- Extensive age-normative reference database incorporated
- World-class clinical validation by leading researchers in the field
- Software upgrade capability for future enhancements

Controls and Connectors



LCD Display Contrast – Use the UP and DOWN arrows adjacent to the contrast symbol below the LCD display to adjust the LCD contrast for optimum viewing, based on lighting conditions.

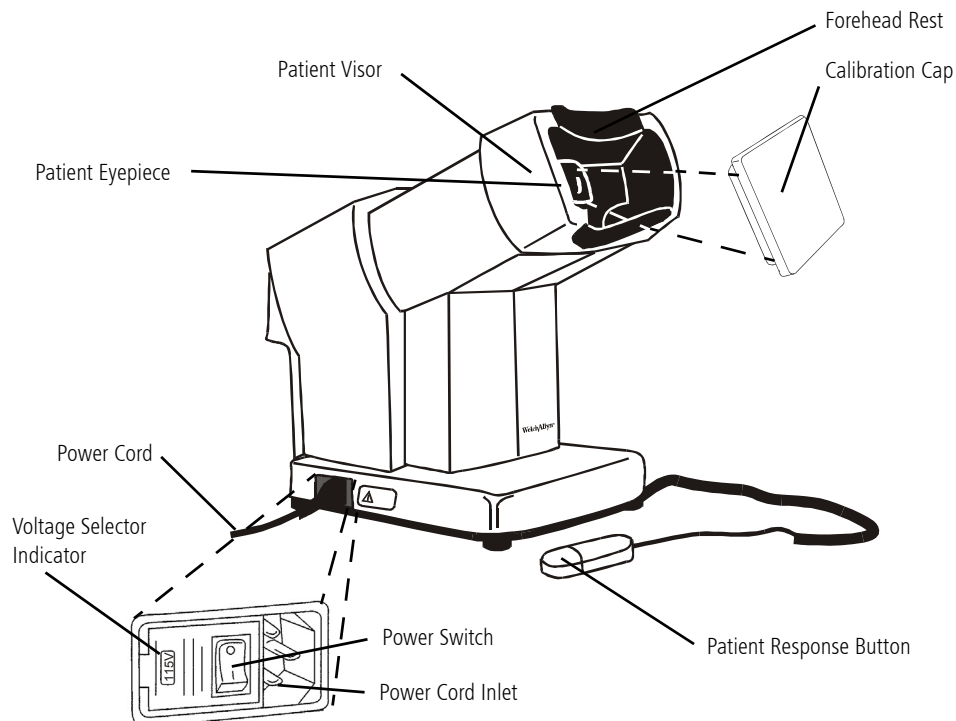
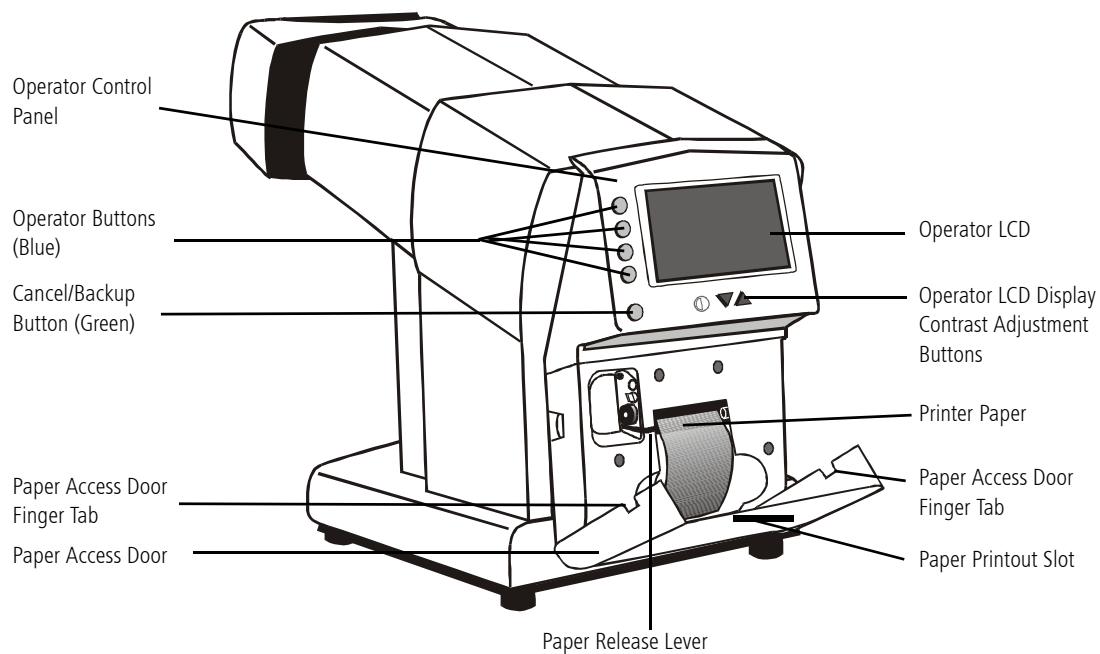


PATIENT RESPONSE BUTTON CONNECTOR – Connect ONLY the patient response button supplied with the instrument or an approved replacement to the patient response button connector on the bottom of the instrument. Connection of any other device to the patient response button connector may damage the instrument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



COMPUTER INTERFACE CONNECTOR – Connect only RS-232 serial compatible computer ports to the computer interface connector on the bottom of the instrument. Use the null-modem configuration computer interface cable supplied with the instrument or an approved replacement cable. Connection of any other computer port or device to the computer interface connector may damage the instrument. Refer to the computer interface instructions for additional information.

SOFTWARE UPGRADE CONNECTOR – The blank label on the bottom of the unit adjacent to this symbol covers the SOFTWARE UPGRADE CONNECTOR. The blank label should only be removed during a software upgrade and should be replaced when the upgrade is complete. Refer to the software upgrade instructions to update the instrument software.

Instrument Components, Patient Side**Instrument Components, Operator Side**

Instrument Components

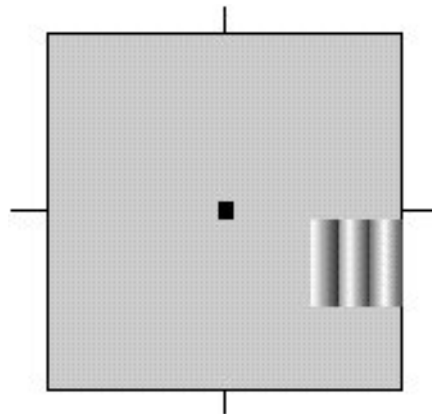
The instrument has seven Buttons to control the operation of the instrument, located adjacent to the Operator's Liquid Crystal Display (LCD).

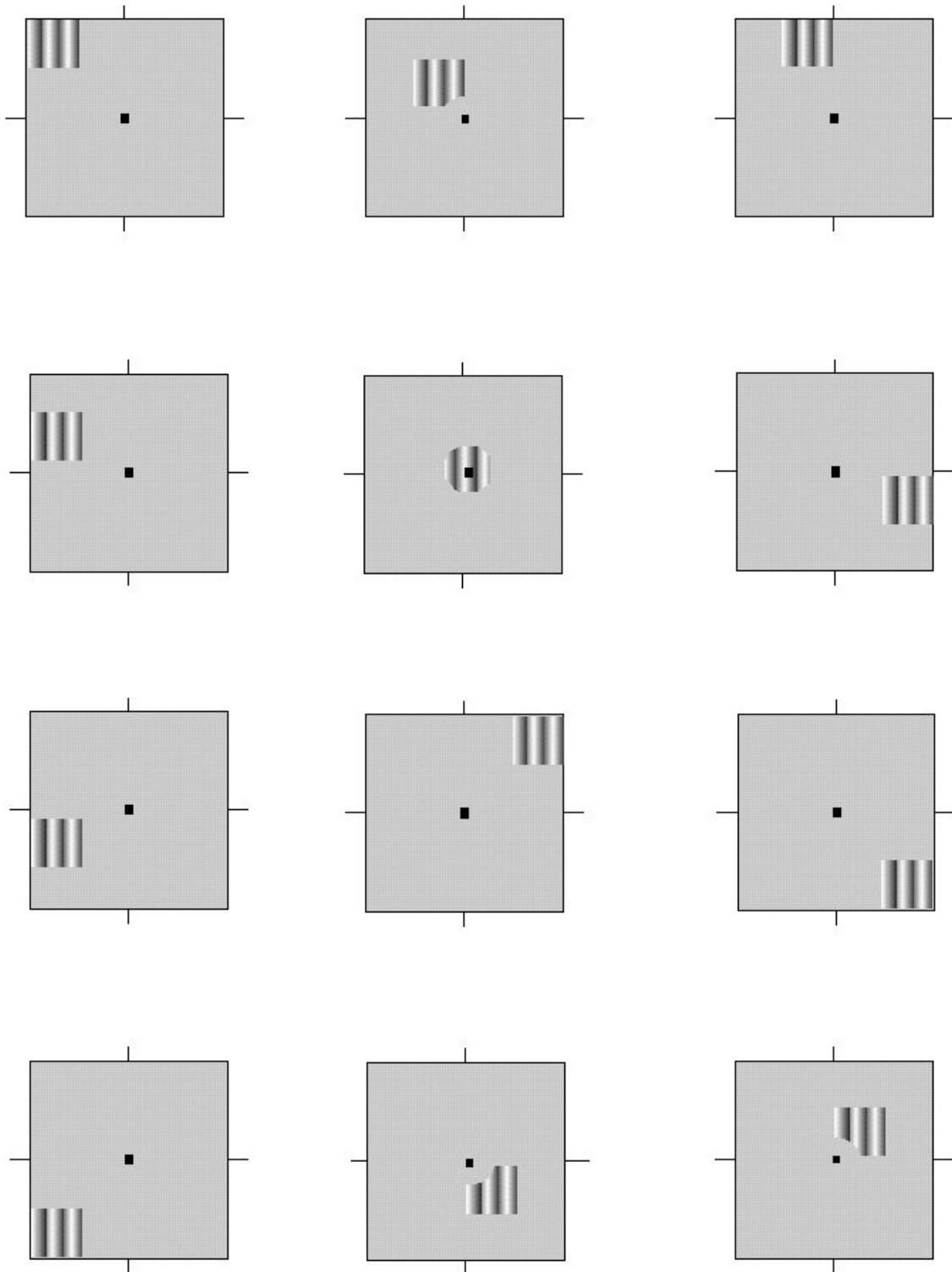
- Four BLUE Operator Buttons along the left side of the Operator LCD Display
- A GREEN Cancel/Backup Button below the four BLUE Buttons
- Two Operator LCD Display Contrast Adjustment Buttons (Down Arrow and Up Arrow) adjacent to the Contrast Symbol and directly below the LCD Operator Display

Further below the Operator LCD Display is a Paper Access Door which opens to provide access to the internal thermal printer for replacement of paper, when needed. The instrument has a sliding Patient Visor which aids in the selection of the eye to be tested and automatically occludes the opposite (untested) eye. Detachable Patient Response Button, Power Cord, and Calibration Cap are also provided.

FDT Overview

FDT isolates a subset of 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 of these cells in the disease process makes FDT efficient and effective for the detection of visual field loss.



Patient Video Screen Patterns

(3) Operation

Unpacking

Personnel using this instrument should read and understand the operating instructions manual before using the instrument. Interpretation of the results should be performed only by appropriately trained eyecare professionals.

Open the shipping box by carefully cutting the packing tape securing the top flaps of the box. Lift out the foam insert containing the Patient Response Button, Power Cord and extra roll of paper. 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 FDT Visual Field Instrument. Use of an adjustable height chair and/or table is recommended when performing testing.

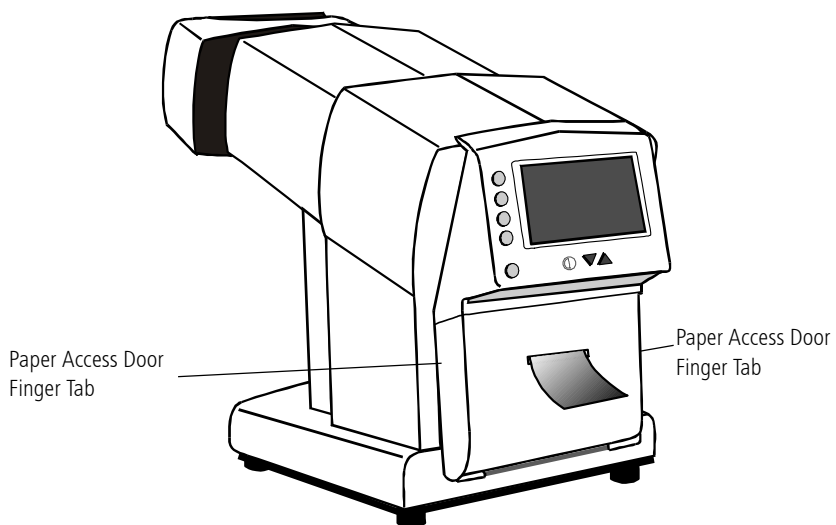
After you have unpacked the instrument and its components, confirm that you have received the following items in good condition:

- Humphrey FDT Visual Field Instrument
- Calibration Cap (covering the Patient's Eyepiece inside the Patient Visor)
- Patient Response Button
- Power Cord (appropriate for local operating voltage)
- Extra roll of paper

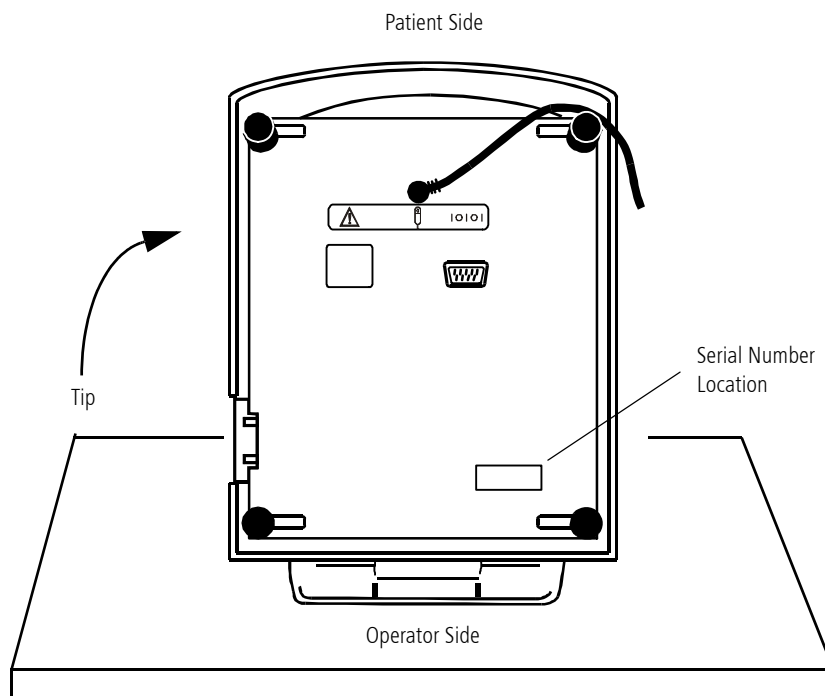


Note: Retain the shipping materials (box and packaging) in the event of shipping damage or for return, if necessary, to an authorized service or distribution location at any time in the future.

After unpacking the instrument, pull down the Paper Access Door (below the LCD display) using the Finger Tabs on the sides of the door. Remove the foam shipping wedge *before* using the printer. Close the Paper Access door while guiding Printer Paper through the Paper Slot in the door. Failure to remove the shipping wedge will result in improper operation of the printer.



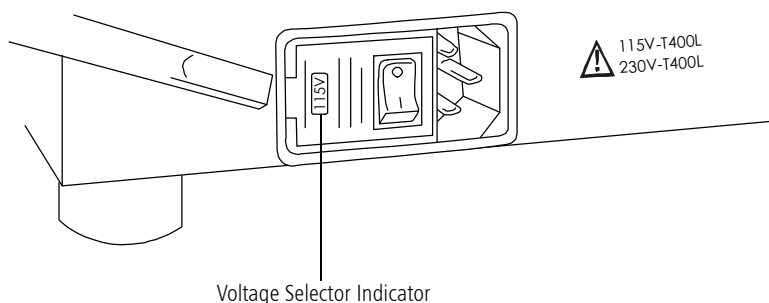
Preparation For Use and Power On



While facing the Patient Side of the FDT instrument, tilt the instrument to plug the **Patient Response Button** connector into the small round connector jack. The jack is located underneath the base of the unit (at the center) and near the patient response button symbol.

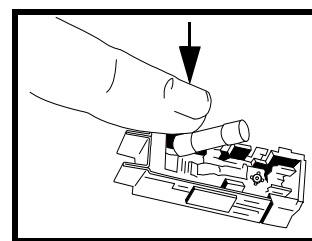
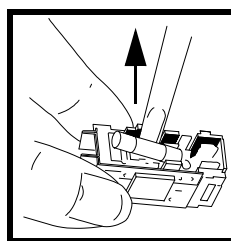
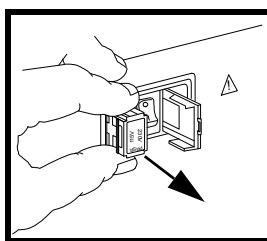
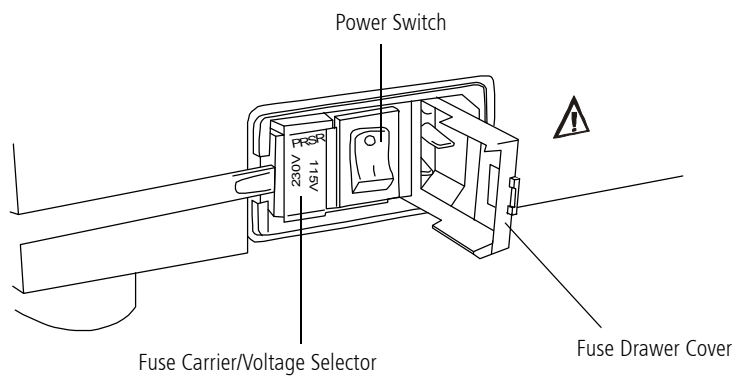


CAUTION: VERIFY OPERATING VOLTAGE SELECTION — The FDT voltage selector switch is normally set to the appropriate operating voltage before shipment (115 V or 230 V). Before applying power to the FDT, verify that the Voltage Selector Indicator adjacent to the O/I Power Switch displays the appropriate operating voltage (115 V or 230 V) in your region.

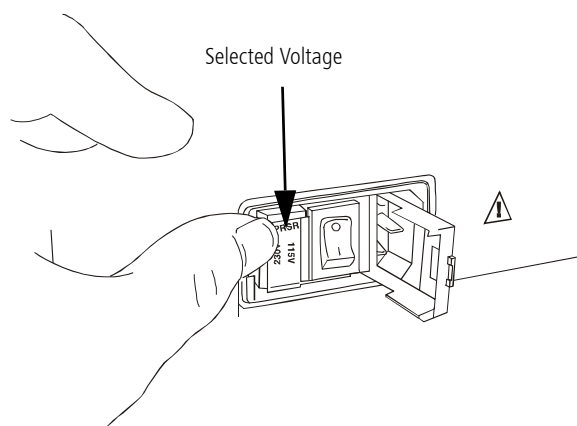


In case you need to change the operating voltage, make sure that the Power Cord is NOT connected and use a flat screwdriver to pry open the Fuse Drawer Cover. Remove the Fuse Carrier/Voltage Selector, by again using a flat screwdriver. Rotate the Fuse Carrier/Voltage Selector so the proper voltage will be visible when the Fuse Drawer Cover is closed. Re-install the Fuse Carrier. Close the Fuse Drawer Cover and check to be sure the proper voltage appears in the Voltage Selection Window.

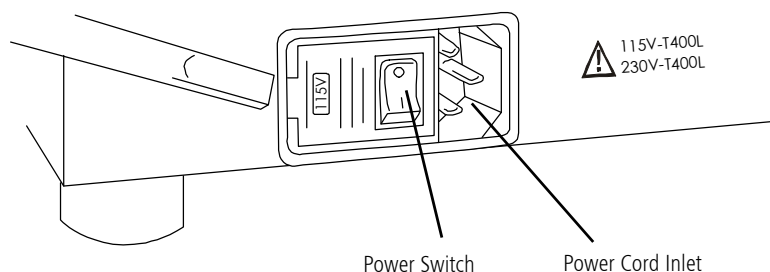
In case you need to replace the fuses, remove the fuse carrier/voltage selector as described above. Replace both fuses on the two sides of the fuse carrier with new fuses (Type T 0.400 A 250 V). Reinstall the fuse carrier making sure the voltage selection is correct.



Make sure that the two fuses are inserted so that they are closest to the protruding metal flanges.



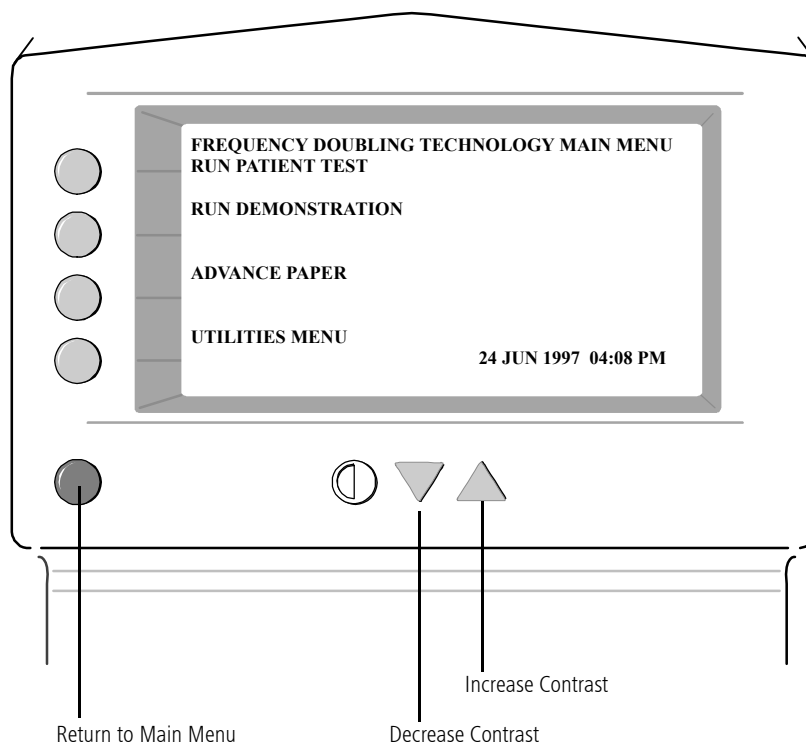
Plug the appropriate approved Power Cord into the Power Cord Inlet on the operator's right-hand side and plug the opposite end into a standard power outlet.



To turn the instrument ON, switch the **Power Switch (O/I)**, adjacent to the power connector, to the ON (**I**) position. The instrument will perform internal self-diagnostic checks and after approximately 15 seconds, two double beeps will sound and the **FDT MAIN MENU** will appear on the Operator LCD Display. Refer to the troubleshooting section of this manual if the **FDT MAIN MENU** does not appear.



Note: You may need to adjust the **LCD contrast** in order to read the Operator LCD Display; use the triangle shaped buttons below the Operator LCD Display to increase (up-arrow) or decrease (down-arrow) the LCD contrast.



Note: the **GREEN Button** may be used at any time to back-up to the previous menu and to return to the **FDT MAIN MENU** (it may need to be pressed several times to reach the **FDT MAIN MENU**).

Preparing for a Patient Test

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 in the Patient Eyepiece.

Select **RUN PATIENT TESTS** from the **FDT MAIN MENU** to prepare for a **SCREENING C-20 TEST**, **SCREENING N-30 TEST**, **THRESHOLD C-20 TEST** or a **THRESHOLD N-30 TEST**.

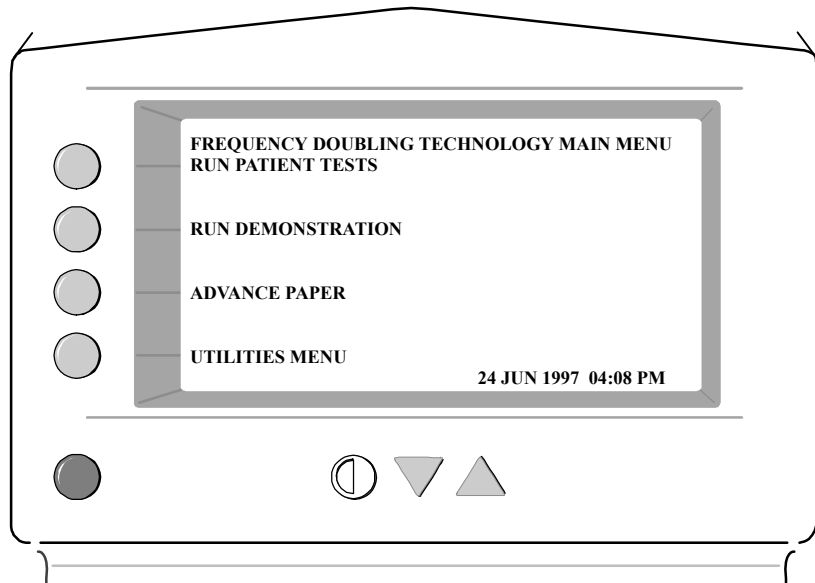
There are two screening test programs. The N-30 Screening program adds two additional test locations presented above and below the horizontal midline between 20 and 30 degrees eccentricity in the nasal visual field, like with the N-30 Threshold test. Also, there are two screening level options for each screening program: the -5 (default) and -1. The Screening C-20-5 and N-30-5 programs utilize the P=5% significance limit as the baseline normal contrast level, whereas the Screening C-20-1 and N-30-1 programs utilize the P=1% significance limit as the baseline normal contrast level. See the clinical example and refer to the Primer for Frequency Doubling Technology for a further explanation of the -5 and -1 screening level options.

To change the default screening level found in the SCREENING TEST MENU from the C-20-5 & N-30-5 (5% level) programs to the C-20-1 & N-30-1 (1% level) programs, follow these keystrokes:

==> UTILITIES MENU ==> SET-UP INSTRUMENT MENU

==> SET-UP OPTIONS MENU ==> SET DEFAULT SCREENING LEVEL

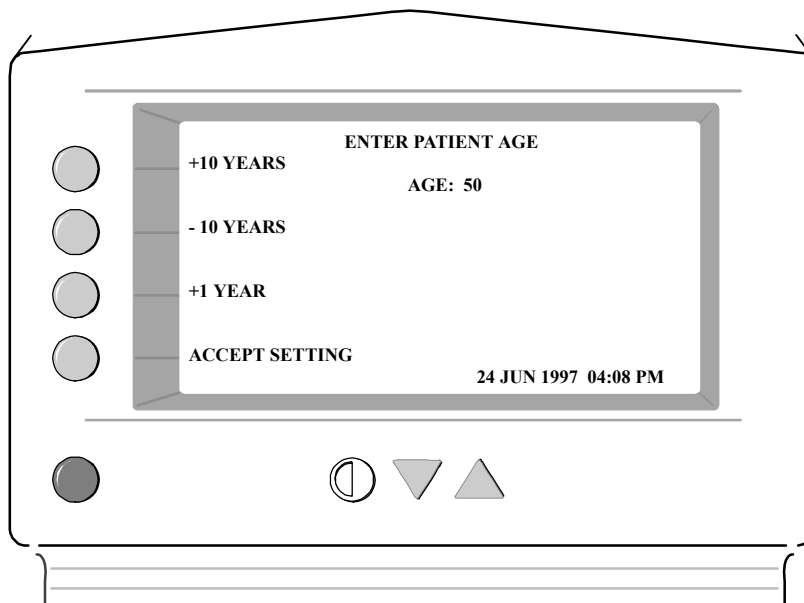
and use NEXT CHOICE and ACCEPT SETTINGS to select SCREENING - 1%



Note: Once **RUN PATIENT TESTS** is selected, typical FDT stimulus presentations are automatically displayed to demonstrate the test to the patient until the test actually starts.

Enter the Patient's Age

The unit will start with an **AGE** of 50 years. Select **+10 YEARS** (TOP BLUE Button) to increase the **AGE** by 10 year increments (e.g. to 60, 70, and so on). Select **-10 YEARS** (2nd BLUE Button from the top) to decrease the **AGE** by 10 year increments. Select **+ 1 YEAR** (3rd BLUE Button from the top) to increase the **AGE** in 1 year increments to adjust to the exact age of the patient (e.g. 51, 52, and so on). Select **ACCEPT SETTING** (BOTTOM BLUE Button) when the correct **AGE** is displayed.



Slide the **Patient Visor** to the **right eye test position** (this is to your right when looking at the patient from the operator's side).



Note: If you want to skip the right eye (i.e., only test the left eye), then slide the **Patient Visor** to the **left eye test position** now (this is to your left when facing the patient from the operator's side) and select **SKIP RIGHT EYE**.

Prepare the Patient

Place the **Patient Response Button** in the patient's hand and show them how to press it. Ask the patient to place their forehead on the **Forehead Rest** and look into the **Patient Eyepiece** at the video screen. Adjust the height of the chair or table (or both) to obtain a comfortable position for the patient. Confirm that the patient can see the entire lit video screen, including all four corners, in the Patient Eyepiece and the black dot in the middle of the screen.



Note: Be sure the patient is positioned comfortably (not hunched over) by adjusting the height of the chair or table (or both).

Patient Refraction

The **FDT** test may be taken with or without the patient's correction (if the patient is within 6D of their refraction). If a patient is wearing glasses, confirm that their glasses frame does not obscure any of the lit portion of the display. Ask the patient to remove their glasses for

the test if their lenses or contact lenses are tinted or change contrast based on lighting conditions (photochromatic). Tests may be taken with bifocal or progressive lenses (unless the progressive lenses have more than 3D equivalent sphere distance correction).

Explain the Test Procedure to the Patient

"A demonstration of the test is running now. Can you see the black dot in the center and the entire lit video screen? You need to stare at the black dot in the center of the screen during the entire test."

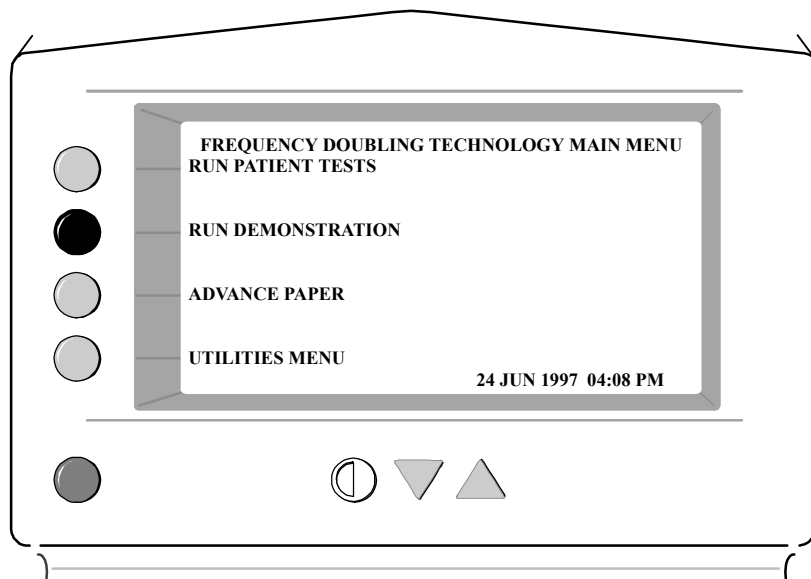
"From time to time, you will see patterns of flickering black and white vertical bars that will briefly appear in different areas of the screen. The patterns will sometimes be very faint and at other times be very distinct. You are not expected to see the bar patterns at all times. Each time you see the flickering black and white vertical bars of one of the patterns, press the response button once. Can you see these patterns in the demonstration running now? You may practice now by pressing the Button to respond to the patterns."

"It is OK to blink and a good time to blink is when you press the response Button. If you need to rest or ask questions during the test, you can pause the test at any time by pressing and holding down the response Button. Do you have any questions? Do you understand how to take the test?"

"I will now start the test. There will be a few brief flashes and then the test will begin. Press the response Button once each time you see the flickering black and white vertical bars of one of the patterns, even if the bars are very faint. Please remember to stare at the black dot in the center of the screen during the entire test."



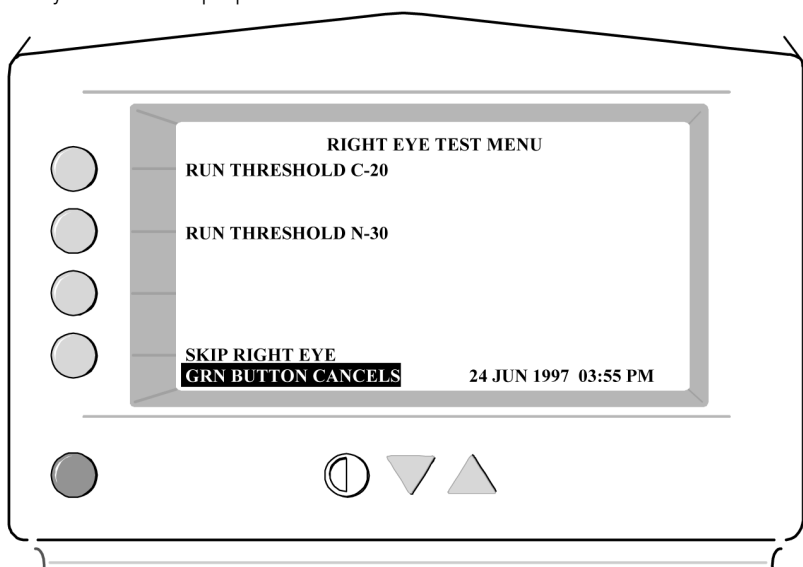
Note: A separate demonstration test is available from the **FDT MAIN MENU** to help facilitate the patient's understanding of the test, if needed. To run a practice test, select **RUN DEMONSTRATION (2nd BLUE Button from the top)** from the **FDT MAIN MENU**. A demonstration of the test stimulus automatically begins. The patient should use this time to become familiar with the test and practice using the **PATIENT RESPONSE BUTTON** (Ask the patient to look into the Patient Eyepiece within the Patient Visor and then test the procedure.) Press the **GREEN Button** to cancel the practice test and return to the **FDT MAIN MENU**.



Be sure to prepare the patient as described above before running a practice test.

Running a Screening or Threshold Patient Test

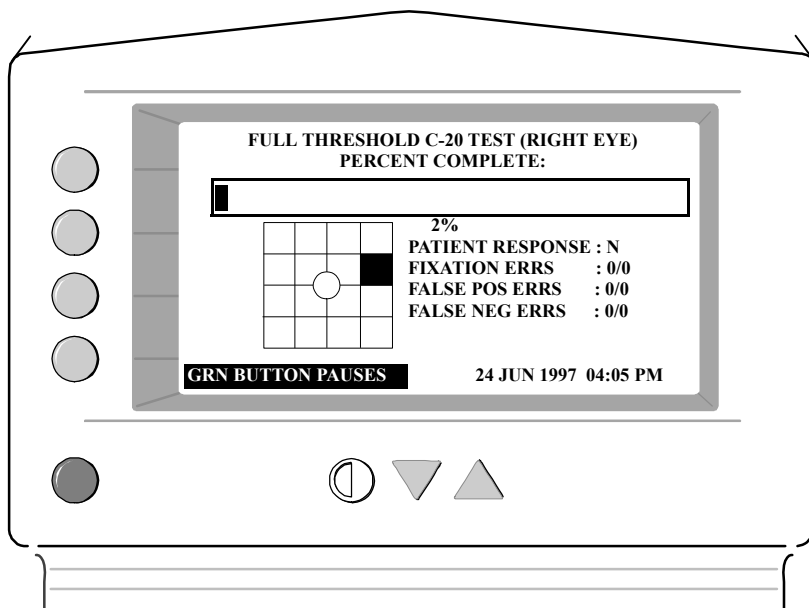
Select either **SCREENING TEST MENU** or **THRESHOLD TEST MENU** from the **RIGHT EYE TEST MENU**. If running a screening test, choose either **RUN SCREENING C-20-1** (or -5) or **RUN SCREENING N-30-1** (or -5). If running a threshold test, choose either **RUN THRESHOLD C-20** or **RUN THRESHOLD N-30**. The right eye test will begin immediately after a momentary check of the proper calibration..



Note: To skip the right eye test and proceed directly to the left eye test, select **SKIP RIGHT EYE (BOTTOM Operator Button from the top)** *before* selecting a **SCREENING** or **THRESHOLD** test.



Note: The Operator LCD Display will indicate if there is too much ambient light to perform a reliable test. Lower the room lighting or change the test location until suitable test conditions are achieved. Also, if the Patient Response Button is not connected or the Patient Visor is in the wrong eye position, this will be indicated on the Operator LCD Display.



The **PERCENT COMPLETE** scale, field location being tested, **PATIENT RESPONSE**, **FIXATION ERRORS**, **FALSE POS ERRORS** and **FALSE NEG ERRORS** are displayed on the Operator LCD Display during the test. Remind the patient to keep looking at the dot in the middle of the screen and inform them of the approximate percent complete 3 or 4 times during the test to encourage good patient compliance. Monitor the catch trials (**FIXATION ERRS**, **FALSE POS ERRS**, and **FALSE NEG ERRS**) during the test. The catch trial display fields will be highlighted on the Operator LCD Display if 2 or more catch trials have been responded to by the patient. A high ratio on any of the catch trials indicates unreliable results and that the test should be restarted or repeated.

For the right eye, near the end of a **SCREENING N-30 TEST** or a **THRESHOLD N-30 TEST**, the FDT will pause for approximately 15 seconds. The internal fixation target will move to the right on the screen. This allows two extra nasal points to be tested. At the same time the following instructions will appear on the screen: "Inform Patient Fixation Moved Right." Advise the patient to re-fixate on the black spot in its new position and continue to press the Button until the test completes. The instruction will note fixation moved to the left when testing the left eye.

Patient reliability (Fixation, False Positive, and False Negative) errors that exceed 1 are highlighted on the operator LCD and marked with an asterisk (*) on the results printout.

False Negative and False Positive catch trial presentations are indicated by the symbols (+) & (-) on the operator LCD so they can be distinguished from regular teststimulus presentations.

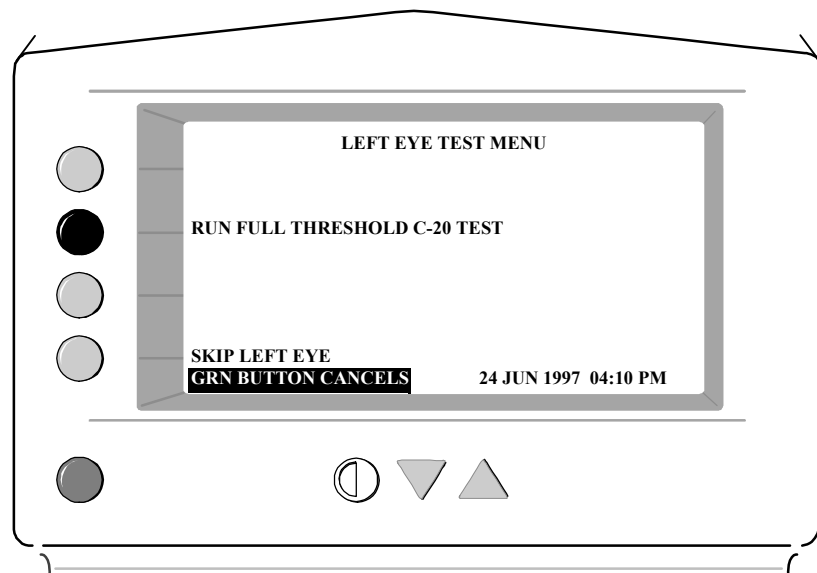


Note: You can **PAUSE** or **RE-START** the test by pressing the **GREEN Button** at any time during the test. Follow the Operator LCD Display instructions to **CONTINUE TEST** or to **RE-START TEST** from a **pause**. The patient can also **PAUSE** the test (for a break, etc.) by simply pressing and holding down the **Patient Response Button**. The test will resume automatically once the patient releases the **Patient Response Button**. During patient pause, you may also select **OPERATOR PAUSE (GREEN Button)** so that the test will remain paused until you restart it.



Note: A **SCREENING C-20 TEST** takes less than **1 minute** (per eye) to complete, a **THRESHOLD C-20 TEST** takes approximately **4 minutes** (per eye) to complete and a **THRESHOLD N-30 TEST** takes about 4-1/2 minutes.

At the end of the right eye test, the Operator LCD Display will prompt for a left eye test. Slide the **Patient Visor** to the **left eye test position** (this is to your left when facing the patient from the operator's side). **Prepare the patient**. Select **RUN SCREENING C-20 TEST** (TOP Operator Button), **RUN THRESHOLD C-20 TEST** (2nd Operator Button from the top), or **RUN THRESHOLD N-30 TEST** (3rd Operator Button from the top) from the **LEFT EYE TEST MENU** to begin the left eye test immediately after a momentary check for proper calibration.

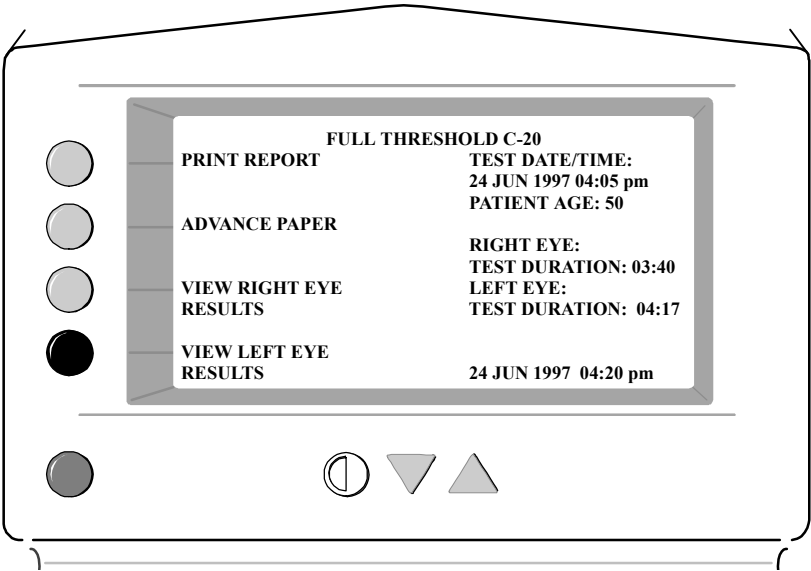


Note: To skip the left eye test, select **SKIP LEFT EYE** (Bottom Operator Button) to proceed to the results menu.

Displaying and Printing the Test Results

You can both view the results on the Operator LCD Display and print them out from the test results menu. At the end of a test, the results will be automatically printed (default set-up is automatic printing) and then the test results menu will automatically appear on the Operator LCD Display.

Select either **VIEW RIGHT EYE RESULTS** (3rd Operator Button from the top) or **VIEW LEFT EYE RESULTS** (Bottom Operator Button) to view the individual eye results for the patient just tested on the Operator LCD Display. Use the **GREEN Button** to back-up to the previous screen to allow you to toggle between the eye results or to return to the **FDT MAIN MENU** (press it twice if necessary). Select **PRINT REPORT** (TOP Operator Button) to obtain additional copies of the results for the patient just tested (you can print as many copies as you'd like).



Note: Once the test is completed, you can also select **LAST PATIENT RESULTS** (3rd Operator Button from the top) from the **FDT MAIN MENU** to display or print out the results of the patient just tested. The results of the most recently tested patient will remain in memory *only until you begin a new test or until the instrument power is turned off.*

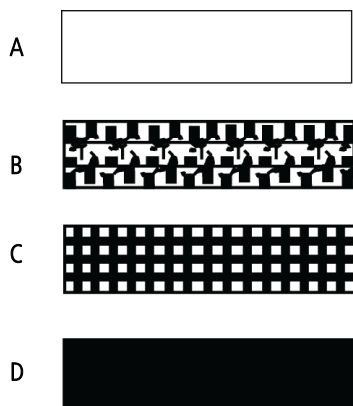
Using the RS-232 Serial Computer Interface



The instrument includes an external serial RS-232 serial computer interface connector located on the bottom of the instrument. This interface provides the user with the ability to upload results from the instrument to a computer when the accessory computer interface cable and software are used. For detailed information on using the computer interface, reference the FDT PC operating instructions, available from authorized representatives.

Understanding the Screening C-20 and N-30 Test Results

A plot of the 17 visual field locations tested will be printed (see samples on the following pages) and displayed on the Operator LCD Display for the supra-threshold **SCREENING C-20 TEST** for each eye tested. There are 19 visual field locations tested with the **SCREENING N-30 TEST**. Each test location will be either *clear white* or will have one of three possible levels of shading.



- A** **"WITHIN NORMAL LIMITS"** — The patient *responded positively* (on either the first or second opportunity) when tested at the contrast level that **99% ($P \geq 1\%$)** of normal subjects of the same age would respond to for the test location with this shading.
- B** **"MILD RELATIVE LOSS"** — The patient *failed to respond positively* when tested at the **1% age normative contrast level ($P = 1\%$)** after being *given 2 opportunities* to do so (the instrument will re-test any point missed at the **1% age normative level** a second time) for the test location with this shading.
- C** **"MODERATE RELATIVE LOSS"** — The patient *failed to respond positively* after being *given 3 opportunities* to do so; twice at the **1% age normative contrast level ($P = 1\%$)** and a third time at the **0.5% age normative contrast level ($P = 0.5\%$)** for the test location with this shading.
- D** **"SEVERE LOSS"** — The patient *failed to respond positively* after being *given 4 opportunities* to do so for the test locations with this shading; the 3 opportunities listed above and a fourth at the **maximum** contrast level of the instrument.

When reviewing the results of the visual field test, careful consideration must be given to the **reliability indicators** (catch trials). The following two test reliability indicators appear on the printed report and Operator LCD Display for the screening test. 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. For example, **1/3** indicates that the patient responded to **1** of the **3** catch trials presented.

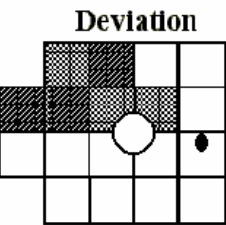
FIXATION ERRORS - The ratio of the number of times the patient responded to a target placed in the blind spot versus the total number of times fixation was tested (i.e., total number of targets placed in the blind spot). Three **FIXATION catch trials** will be randomly presented for each eye. Fixation 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. Three **FALSE POSITIVE catch trials** will be randomly presented for each eye. False positive errors indicate the patient is pressing the Button even if the patient doesn't see any patterns or does not understand the test.

FIXATION ERRS: 0/3
FALSE POS ERRS: 0/3

Because the FDT Screening N-30-1 (or C-20-1) and N-30-5 (or C-20-5) programs utilize different baseline normal contrast levels, they also differ in how they flag (shade) test locations as being outside normal limits. With the N-30-1 (or C-20-1) test, points are initially flagged when they reach the $P < 1\%$ probability significance level (i.e. the sensitivity level which is found less than 1% of the time in the normal population). With the N-30-5 (or C-20-5) test, points are initially flagged when they reach the $P < 5\%$ probability significance level (i.e. the sensitivity level which is found less than 5% of the time in the normal population), and thus there is a greater chance that any point may be deemed outside normal limits. Therefore, the N-30-5 (or C-20-5) test is slightly more sensitive, readily identifying more extensive loss. Below is a clinical example that demonstrates this difference with a comparison between the Screening N-30-1 and N-30-5 programs.

Screening N-30-1
NAME: _____
AGE: **64** ID: _____
04 MAR 2001 2:35 pm
RIGHT EYE
Test Duration: **01 : 12 min**

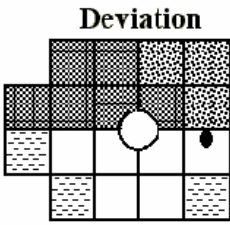


Fixation Errs: 0/3
False Pos Errs: 0/3

Probability Symbols

	$P \geq 1\%$
	$P < 1\%$
	$P < 0.5\%$
	NOT SEEN AT MAXIMUM

Screening N-30-5
NAME: _____
AGE: **64** ID: _____
04 Mar 2001 02:40 pm
RIGHT EYE
Test Duration: **01 : 42 min**








Fixation Errs: 0/3
False Pos Errs: 0/3

Probability Symbols

	$P \geq 5\%$
	$P < 5\%$
	$P < 2\%$
	$P < 1\%$

Understanding the Threshold C-20 and N-30 Test Results

A plot of the 17 or 19 visual field locations tested will be printed (see samples on the following pages) and a combination plot will be displayed on the Operator LCD Display for the **THRESHOLD C-20 and N-30 TEST** for each eye tested. The first printed results plot will contain a numerical contrast threshold level in units of **dB** for each location tested. The second printed results plot is a deviation plot and will be either *clear white* or will have *one of four possible levels of shading* corresponding age normative significance levels for each location tested. The results combination plot displayed on the Operator LCD Display will indicate both the numerical contrast threshold level and the shading for each location tested.

- | | | | |
|---|---|---|--|
| A |  | A | The patient achieved a threshold level in the range that 95% ($P \geq 5\%$) of normal subjects of the same age achieved for the test locations with this shading. |
| B |  | B | 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. |
| C |  | C | 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. |
| D |  | D | 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. |
| E |  | E | 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 will be indicated). |

When reviewing the results of the visual field test, careful consideration must be given to the **reliability indicators** (catch trials). The following three indicators appear on the printed report and on the LCD Display for the threshold test. 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. For example, **1/3** indicates that the patient responded to **1** of the **3** 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). Six **FIXATION catch trials** will be randomly presented for each eye in the C-20 TEST and N-30 TEST. Fixation errors indicate the patient is not maintaining good fixation during the test, is misaligned, or does not understand the test.

FIXATION ERRS: 0/0
FALSE POS ERRS: 0/0
FALSE NEG ERRS: 0/0

FALSE POSITIVE ERRORS - The ratio of the number of times the patient responded to a “pause” in the testing sequence (i.e., with no target presented) versus the total number of “pauses” in the testing sequence. Six **FALSE POSITIVE catch trials** will be randomly presented for each eye in the C-20 TEST, eight in the N-30 TEST. False positive errors indicate the patient is pressing the Button even if patient does not see any patterns or the patient 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. Three **FALSE NEGATIVE catch trials** will be randomly presented for each eye in the C-20 TEST, five in the N-30 TEST. False negative errors indicate the patient is likely to not be paying attention, does not understand the test, or has a severe loss at the location of the FALSE NEGATIVE catch trial(s).

For the threshold tests, the device utilizes a staircase threshold strategy known as a **Modified Binary Search (MOBS)**¹. 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 $\log_{10}(2048/c) \cdot 10 \cdot H$ where c ranges from 1 (minimum contrast) to 2048 (maximum contrast) and H is approximately 2. Note that **XX dB** will be displayed, if the threshold cannot be 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 device also provides **MD & PSD** global statistical indices calculated from points over the entire visual field for the threshold test. 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 **MD & PSD** indices. The actual formulas used for the MD & PSD indices calculations can be found in the references (2, 3).

“The **MD (Mean Deviation)** index signifies overall severity of field loss. It is affected both by the degree of loss and the number of affected locations. A positive number indicates that the average sensitivity is above the average normal for age, whereas a negative number indicates that the average sensitivity is below the average normal value.”²

When the **MD** value is **LESS** than that of **95%** of normal FDT fields, the percentile probability is given ($P < 5\%$, $P < 2\%$, $P < 1\%$, or $P < 0.5\%$) on the Operator LCD Display and on the printed report.

“The **PSD (Pattern Standard Deviation)** index is the standard deviation of the difference of each sensitivity value from an expected value (based on the normal value at that location and the mean deviation index), each difference weighted according to the variance of the normal values at that point. The **PSD** is small in a normal field, or in a field where all points are equally abnormal. The **PSD** becomes large as some points are more affected than others, and thus the **PSD** is an index of localized change in the field.”³

When the **PSD** value is ***GREATER*** than that of **95%** of normal FDT fields, the percentile probability is given ($P < 5\%$, $P < 2\%$, $P < 1\%$, or $P < 0.5\%$) on the Operator LCD Display and on the printed report.

Pattern Deviation plots are displayed and printed with Threshold test results. Refer to the Primer for Frequency Doubling Technology for information on Pattern Deviation plots.

- 1 Tyrrell RA, Owens DA: A New Technique to Rapidly Assess the Resting States of the Eyes and Other Threshold Phenomena: the Modified Binary Search (MOBS) Whitely Psychology Laboratories, Pennsylvania State University.
- 2 Anderson, DR: Automated Static Perimetry Mosby Year Book, St. Louis, 1992; p. 84.
- 3 Anderson, DR: Automated Static Perimetry Mosby Year Book, St. Louis, 1992; p. 86.

Screening C-20 Test Result Sample

SCREENING C-20

NAME _____

AGE 67 ID _____

30 JUN 1997 03:02 pm

RIGHT EYE

Test duration : 00:43 min

Deviation

A 5x5 grid with a central octagon. A horizontal line passes through the center, with '30°' labeled on the left. A vertical line passes through the center. A black dot is located at the intersection of the horizontal line and the second vertical line from the center.

FIXATION ERRS 0/3

FALSE POS ERRS 0/3

LEFT EYE

Test duration : 00:40 min

Deviation

A 5x5 grid with a central octagon. A horizontal line passes through the center, with '30°' labeled on the right. A vertical line passes through the center. A black dot is located at the intersection of the horizontal line and the second vertical line from the center.

FIXATION ERRS 0/3

FALSE POS ERRS 0/3

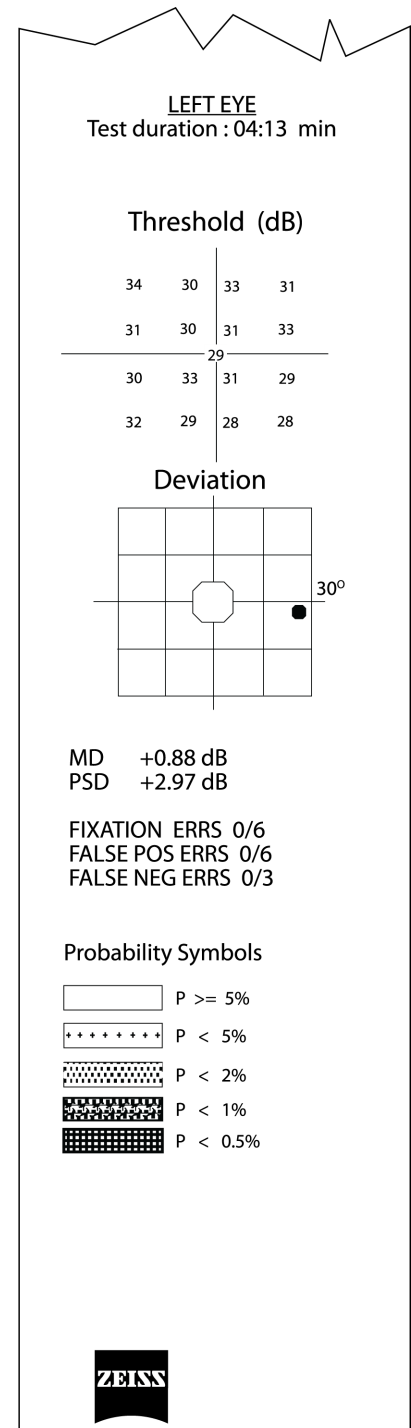
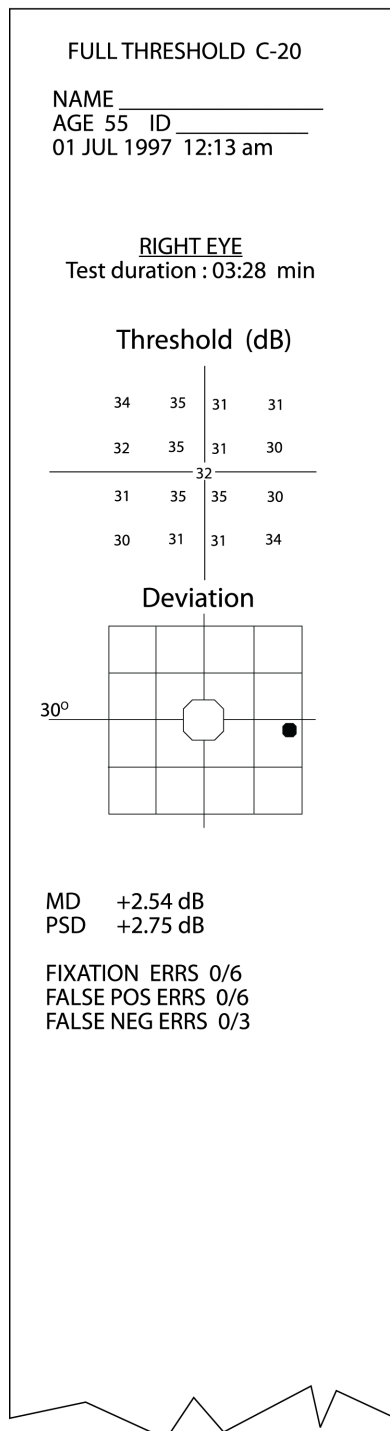
WITHIN NORMAL LIMITS

MILD RELATIVE LOSS

MODERATE RELATIVE LOSS

SEVERE LOSS

Threshold C-20 Test Results Sample



Threshold N-30 Test Results Sample

FULL THRESHOLD N-30

NAME _____

AGE 79 ID _____

30 JUN 1997 06:45 am

RIGHT EYE

Test duration : 04:07 min

Threshold (dB)

36	41	36	35
30	41	37	40
31	45	40	40
36	40	40	36

37

Deviation

MD +6.10 dB

PSD +4.36 dB

FIXATION ERRS 0/6

FALSE POS ERRS 0/8

FALSE NEG ERRS 0/5

LEFT EYE

Test duration : 04:40 min

Threshold (dB)

38	28	40	36
32	36	40	40
36	34	33	34
36	33	32	36

34

Deviation

MD +4.07 dB

PSD +4.01 dB

FIXATION ERRS 0/6

FALSE POS ERRS 0/8

FALSE NEG ERRS 0/5

Probability Symbols

	P >= 5%
	P < 5%
	P < 2%
	P < 1%
	P < 0.5%

ZEISS

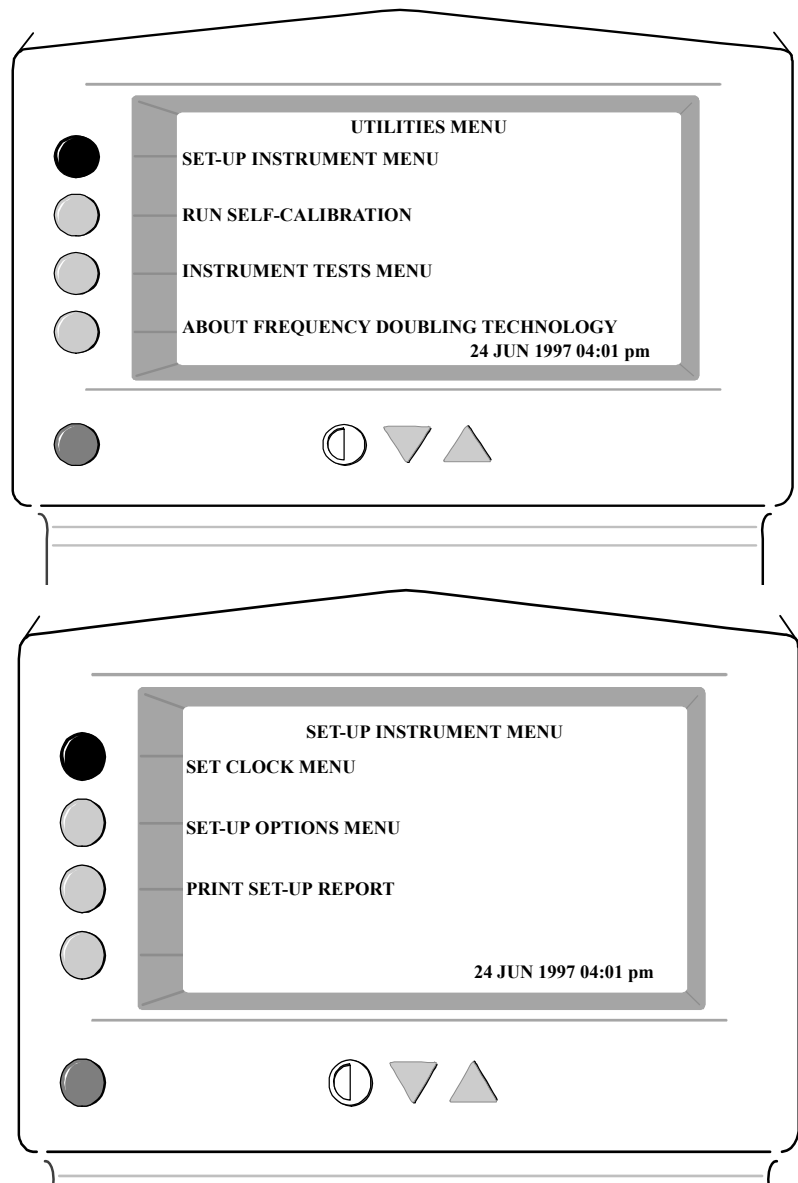
(4) Calibration and Set-up

Calibration and Set-up

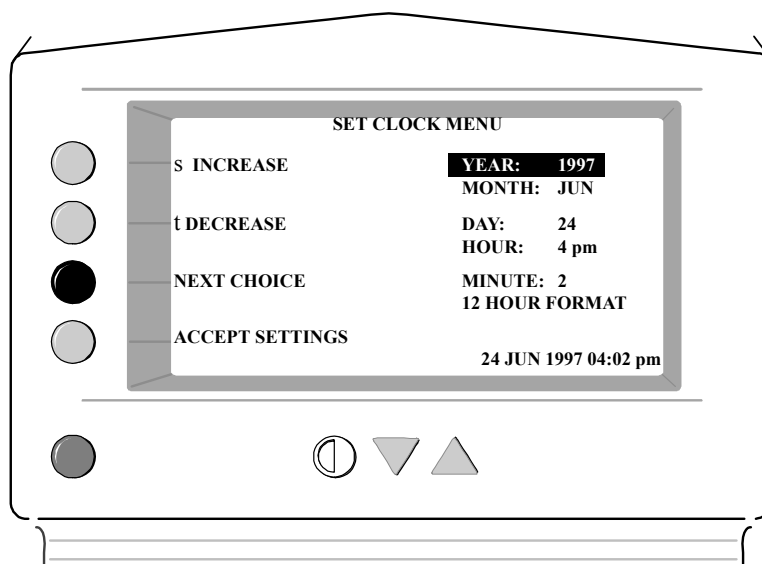
The **UTILITIES MENU** on the **FDT MAIN MENU** should not be needed unless calibration or a change of the instrument set-up defaults is needed (set-ups are set to defaults and date and time (EST) have been pre-set).

Set Date and Time

To set the date and time, select **UTILITIES MENU** (BOTTOM Operator Button) from the **FDT MAIN MENU** then select **SET-UP INSTRUMENT MENU** (TOP Operator Button) in the **UTILITIES MENU** and select **SET CLOCK MENU** (TOP Operator Button) in the **SET-UP INSTRUMENT MENU**.



Select **NEXT CHOICE** (3rd Operator Button from the top) to select the clock setting you want to change. (s) **INCREASE** (TOP Operator Button) and (t) **DECREASE** (2nd Operator Button from the top) to change the setting. Select **ACCEPT SETTINGS** (BOTTOM Operator Button) when the **correct CLOCK** settings are displayed. Press the **GREEN Button** twice to return to the **FDT MAIN MENU**.



Set-up Instrument Options

To **SELECT LANGUAGE** or **OPTIONS**, select **SET-UP OPTIONS MENU** (2nd Operator Button from the top). Select **SELECT LANGUAGE** (top Operator Button) from the **SET-UP OPTIONS MENU** to choose the desired language for the Operator LCD Display and results printout. Use **NEXT CHOICE** (3rd Operator Button from the top) to select the desired language from the list.

Select **ACCEPT SETTINGS** (Bottom Operator Button) when the desired language choice is highlighted. Press the **GREEN Button** three times to return to the **FDT main menu**.

Select **OPTIONS** (2nd Operator Button from the top) from the **SET-UP OPTIONS MENU** to change instrument default settings.

Select **NEXT CHOICE** (3rd Operator Button from the top) to select the setting to change. Select **TOGGLE ON/OFF** (Top Operator Button) to change the highlighted setting. The settings include: **MAKE CLICK SOUND AT EACH BUTTON PRESS** and **AUTO PRINT REPORT AFTER TEST**. Both are selected as defaults.

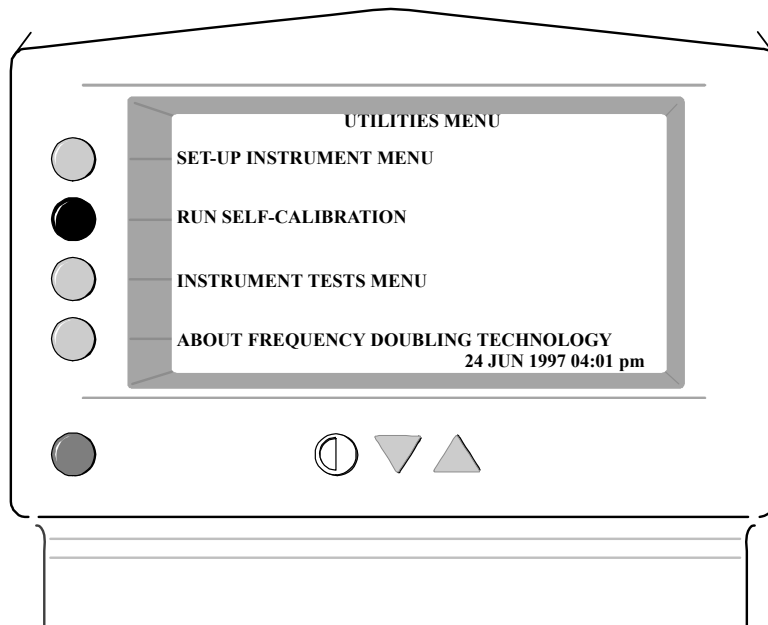
Select **ACCEPT SETTINGS** (BOTTOM Operator Button) when the desired options are set. Press the **GREEN Button** three times to return to the **FDT MAIN MENU**.

Select **RESET TO DEFAULTS** (3rd Operator button from the top) in the **SET-UP OPTIONS MENU** and **ACCEPT SETTINGS** in the **OPTIONS MENU** to restore the options to factory defaults. Press the **GREEN Button** three times to return to the **FDP MAIN MENU**.

Calibration

This instrument does not require scheduled calibration. The instrument calibration is 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. Calibration may be performed at any time, not only when requested by the instrument.

To calibrate the instrument, select **UTILITIES MENU** (BOTTOM Operator Button) from the **FDT MAIN MENU** and then **RUN SELF-CALIBRATION** (2nd Operator Button from the top) in the **UTILITIES MENU**. Follow the Operator LCD Display instructions to start the calibration. The calibration will take several minutes and requires no operator interaction during calibration. If the calibration cannot be completed successfully, repeat the **RUN SELF-CALIBRATION** sequence again (up to 3 times). If SELF-CALIBRATION cannot be completed after 3 attempts, record the information on Operator LCD Display and contact an authorized customer service representative for assistance.



Note: Be sure to cover the **Patient Eyepiece** with the Calibration Cap shipped with each unit. If the Calibration Cap is not available, substitute something that will temporarily block light from entering the Patient Eyepiece or perform the calibration in a completely darkened room (black cloth over Patient Visor, etc.). The Operator LCD Display will indicate if there is too much ambient light to complete the calibration.

Software Upgrade

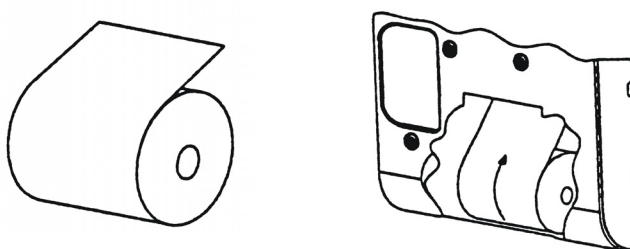
This instrument is designed with the ability to upgrade the operating software. For detailed software upgrade information, reference the software upgrade instructions available from authorized representatives.

The current software version is available in the **ABOUT FDT SCREEN** and on the bottom of the each **RESULTS PRINT-OUT**.

Maintenance

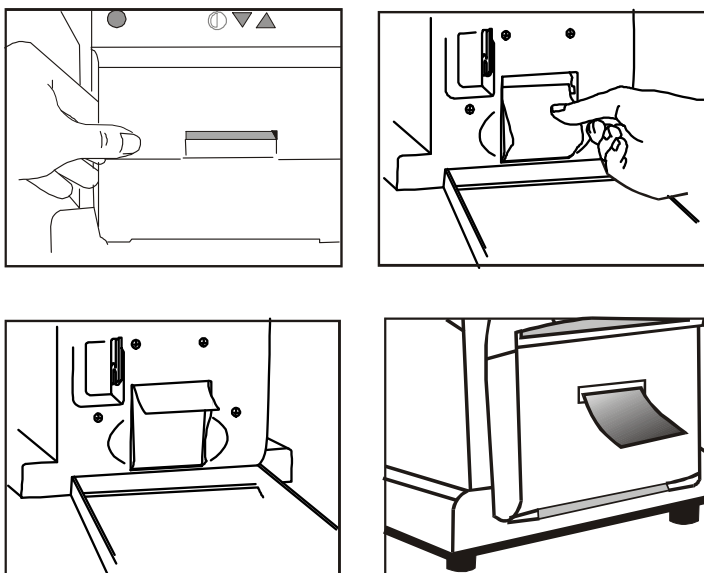
This instrument requires no preventive inspection or maintenance. The only user maintenance required is replacing the printer paper and surface cleaning as necessary.

Printer Paper Replacement



To load a new roll of paper, pull down the **Paper Access Door** (below the Operator LCD Display) using the Finger Tabs on the sides of the door (near the top). Remove the empty paper spool from the paper well.

Unwrap the paper from its bag, loosen the leading edge of the paper from the roll, and place the new roll of paper into the paper well with the leading edge of the paper facing toward the outside of the unit (toward you – see the diagram on the inside of the printer door).

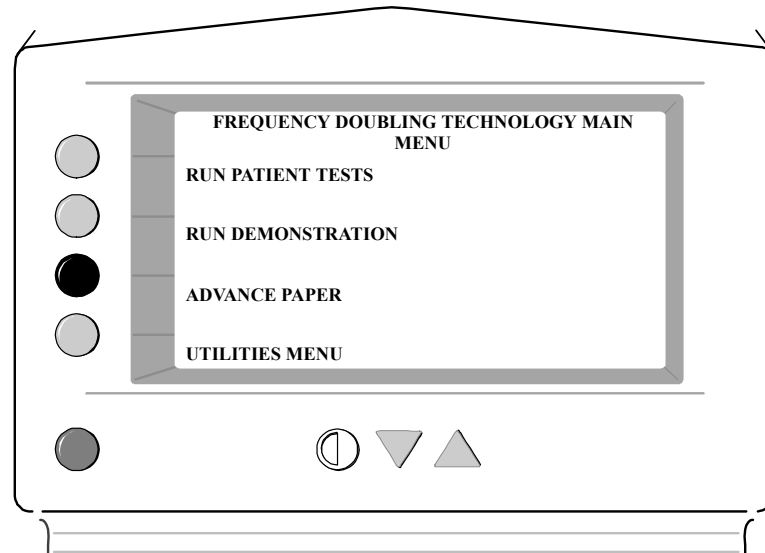


Place the leading edge of the paper onto the metal bar and push it into the unit under the roller bar. The instrument will automatically feed the paper through once you have inserted it far enough.

Close the Paper Access Door, being sure the paper is sticking out through the slot in the door. Tear off any excess paper if desired.



Note: The printer paper can be advanced by selecting **ADVANCE PAPER** (2nd Operator Button from the top) in the results menu or by selecting **ADVANCE PAPER** (3rd Operator Button from the top) in the **FDT MAIN MENU**.



Note: Use only an appropriate heat-sensitive printer paper designed to be used with the Seiko Instruments 5000 series printer inside the instrument (reverse wound rolls only) or the print quality may be degraded, the printer life may be shortened, and the instrument warranty voided. Appropriate paper may be ordered through any authorized representative. Refer to the Replacement Parts and Accessories section of this manual for part number and ordering information.



Note: Because the printer paper is thermally activated, no printing will appear on the paper if it is inserted backwards.



Note: The printer paper is thermally activated, so it must be stored in a cool, dry, dark location to prevent exposure and degraded performance over time.



Note: Do not use transparent adhesive tape on printed portions of the printout, as those portions of the printout will then fade.



Note: Do not store the printed side of the printout in contact with plastic folders or sheets, as those portions of the printout will then fade.



Note: Do not allow any cleaning or disinfection solutions or other liquids to come into contact with the printer paper. Degraded print quality or printer damage may occur for new printouts and degraded printouts of previously printed results may occur (especially with Isopropyl alcohol).

Fuse Replacement

For fuse replacement, see page 3-4.

FDT Replacement Parts and Accessories

DESCRIPTION	PART NUMBER
FDT - Printer Paper (box of 5)	2660021101300
FDT - Dust Cover	0000001096628
FDT - Calibration Cap	0000001034279
FDT - ViewFinder™ Software Kit*	0000001272153
FDT - Computer Interface Cable	0000001272743
FDT - Patient Response Button	0000001045678
FDT - Patient Response Button Holder	0000001054028
Fuse - Type T .400A 250V (2 required)	2660021131921
Power Cord - USA, Japan, Canada	2660100022511
Power Cord - Europe	0000001145999
Power Cord - United Kingdom	2660021133168
Power Cord - Australia	2660021131890
FDT - User Documentation Disk**	2660021134021
<p>**Included on the Document Disk are the following FDT documents:</p> <ul style="list-style-type: none"> • User Manuals: EN, FR, IT, DE, ES • Quick Reference Guides: EN, FR, IT, DE, ES • Primer, English only 	



Note: Item part numbers and descriptions are subject to change.

To order: In the U.S., call 800-341-6968. Outside the U.S., contact your local Carl Zeiss affiliate or distributor.

* ViewFinder Software is a PC-based application that enables the FDT exam to be serially transferred to a local computer running the ViewFinder software. ViewFinder Software is available as a kit and includes the software on CD, a serial cable, and instructions.

Cleaning, Disinfection, Sterilization and Disposal

Cleaning

Clean the instrument as necessary by wiping the housing surfaces with a soft dry cloth or a soft cloth that has been **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

Patient contact surfaces (the Forehead Rest and Patient Response Button) may be disinfected as necessary by wiping the surfaces with a soft cloth that has been lightly dampened with 10% Clorox™/water solution or 70% Isopropyl alcohol. Be sure to 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 or into the user Buttons. Do not spray cleaning or disinfection solutions or other liquids directly onto the instrument. Damage to internal components may occur.



Note: Do not allow any cleaning or disinfection solutions or other liquids to come into contact with the printer paper. Degraded print quality or printer damage may occur for new printouts and degraded printouts of previously printed results may occur (especially with Isopropyl alcohol).

Sterilization



CAUTION: Do not sterilize the instrument or any of its components.

Instrument Disposition

When it comes time to upgrade the FDT, please contact Carl Zeiss Meditec to inquire about trade-in or upgrade values we may offer. Should you not wish to trade in the instrument, please dispose of it in accordance with local and national electrical and electronic equipment recycling requirements.

Disposal

This product contains electronic components. At the end of its lifetime, the product should be disposed of in accordance with the relevant national regulations.



Disposal of the Product within the EU

Packaging materials should be retained for future relocation or repair. If you wish to dispose of the packaging material, contact a recognized collection system for recycling.

The device contains electronic components. At the end of its lifetime, the product and its integrated batteries should be disposed of in accordance with the relevant national regulations.

In accordance with applicable EU guidelines and national regulations at the time at which the product was brought onto the market, the product specified on the consignment note is not to be disposed of via the domestic waste disposal system or communal waste disposal facilities.

For further information on disposal of this product, please contact your local dealer or the manufacturer or its legal successor company. Please read the latest Internet information provided by the manufacturer.

Where the product or its components are resold, the seller must inform the buyer that the product is to be disposed of in accordance with the currently applicable national regulations.

Troubleshooting

The **INSTRUMENT TESTS MENU** (from the **UTILITIES MENU**) provides the ability to test the instrument's inputs, outputs, serial port and A/D circuitry, if needed, for troubleshooting. Follow the menu choices to test the area of concern.

If the unit fails to power on (Operator LCD Display is off, no double beep), confirm:

- Approved power cord is connected to a power outlet and to the instrument Power Cord Inlet
- Power Switch is on (I)
- Operator LCD Display contrast is set to allow the display to be visible (use the triangular Up/Down Contrast Adjustment Buttons)
- Proper operating voltage selection
- Power outlet is live
- Fuses condition



Note: Refer to the Preparation for Use and Power On section of this manual for instructions to select the proper operating voltage or to inspect or change the fuses.

If the instrument does not print out the results, confirm the foam shipping wedge has been removed. Pull down the **Paper Access Door** below the Operator LCD Display) using the Finger Tabs on the sides (near the top) and remove the foam shipping wedge if not already removed. Close the printer door. Be sure the paper is sticking out through the slot in the door. Failure to remove the shipping wedge will result in improper operation of the printer.

If the results printout is blank, confirm the paper is inserted correctly. Blank printouts will occur if the printer paper is inserted backwards. Also, confirm the correct type printer paper is being used. Improper paper type may cause blank or faint printouts. Refer to the Printer Paper Replacement section of this manual for instructions.

If you have an instrument problem that you cannot resolve, refer to the Service Information section of this manual for Technical Assistance information.

(5) Service Information



WARNING: Service or repair to be performed by qualified, authorized CZMI-personnel only. There are no user serviceable parts inside the instrument. Disassembly of the instrument beyond the extent required to change the printer paper, fuses, or patient response button as described in this manual, presents a possible electrical shock hazard and will void the warranty.

All repairs on products under warranty must be performed or approved by an authorized service location. Unauthorized repairs will void the warranty. Products out of warranty should be repaired by an authorized service location or other qualified electronics personnel.

Technical Assistance Information

If you have an instrument problem that you cannot resolve, 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 Meditec authorized service location or distributor for assistance.

Carl Zeiss Meditec, Inc.

5160 Hacienda Drive
Dublin, California 94568
1-800-341-6968
Fax: 925-557-4101

Carl Zeiss Meditec AG

Goeschwitzer Strasse 51-52
07745 Jena, Germany
Phone: +49 36 41 22 03 33
Fax: +49 36 41 22 01 12

(6) Specifications

Instrument

Dimensions:	25 cm [10"] wide x 48 cm [19"] deep x 43 cm [17"] high
Weight:	Less than 9 kg [20 lbs.]
Patient display size:	40° horizontal by 40° vertical square
Power requirements:	115/230 V~, 50/60 Hz, 0.4/0.2 A,
Power Connection:	IEC-320 standard power inlet connector for worldwide use
Power Cord:	Approved power cord
Computer Interface:	RS-232 Serial, 9-pin D male connector, null-modem cable
Printer:	High-speed, high-resolution internal thermal printer

Environmental

Operating Conditions

Temperature:	+15° C to +35° C
Humidity:	10% to 90% non-condensing
Pressure:	700 hPa to 1060 hPa
Altitude:	Up to 3000 m above sea level

Storage and Shipping Conditions

Temperature:	-20° C to +49° C
Humidity:	0% to 95% non-condensing
Pressure:	700 hPa to 1060 hPa

Test

Screening Test Strategies:

- Supra-threshold 20° (SCREENING C-20 - 1)
 - Contrast values: $p = 1\%$ (2 times), $p = 0.5\%$, maximum contrast
- Supra-threshold 20° (SCREENING C-20 - 5)
 - Contrast values: $p = 5\%$ (2 times), $p = 1\%$, maximum contrast
- Supra-threshold 20° (SCREENING N-30 - 1)
 - Contrast values: $p = 1\%$ (2 times), $p = 0.5\%$, maximum contrast
- Supra-threshold 20° (SCREENING N-30 - 5)
 - Contrast values: $p = 5\%$ (2 times), $p = 1\%$, maximum contrast

Threshold Test Strategies:

- Threshold 20° (THRESHOLD C-20)
- Threshold Nasal 30° (THRESHOLD N-30)
- MOBS computer automated staircase thresholding procedure
 - Initial Contrast: $p = 0.5\%$ contrast level
 - Staircase completion consists of at least four staircase reversals as well as upper and lower staircase boundaries within $0.3 \log_{10}$ units of each other.
 - MOBS threshold is calculated to be the mean of the last upper and last lower presentations satisfying the staircase completion criteria.

Reliability Indices:

- Fixation Monitoring: Heijl-Krakau fixation monitor
 - Catch trial contrast: 6 dB (~ 50%)
 - 3 catch trials in **SCREENING C-20 and N-30 TESTS**
 - 6 catch trials in **THRESHOLD C-20 and N-30 TESTS**
 - Presentation Order: Pseudo-Random
 - Pattern: 1° diameter circular FDT stimulus
- False Positive Catch Trials:
 - Catch trials contrast: 56 dB (~ 0%)
 - 3 catch trials in **SCREENING C-20 and N-30 TESTS**
 - 6 catch trials in **THRESHOLD C-20 TEST**
 - 8 catch trials in **THRESHOLD N-30 TEST**
 - Presentation Order: Pseudo-Random
- False Negative Catch Trials:
 - Catch trial contrast 0 dB (~ 100%)
 - 3 Catch trials in **THRESHOLD C-20 TEST**
 - 5 Catch trials in **THRESHOLD N-30 TEST**
 - Presentation Order: Pseudo-Random
 - Pattern: 1 of 17 FDT Patterns, Random

Stimulus:

- 17 or 19 FDT patterns plus OD and OS fixation catch trial patterns (4 patterns per visual field quadrant plus a central 5° radius pattern)
- Presentation Order: Random
- Spatial Frequency: 0.25 cycles/degree, cosinusoidal modulation
- Temporal Frequency: 25 Hz counter-phase flicker
- Duration: 200 to 400 ms
- Color: black and white
- Mean Background Illumination: 100 cd/m² nominal
- Contrast Range: 56 dB (~ 0%) to 0 dB (~ 100%) in log₁₀ steps
- Interstimulus Interval: 0 to 500 ms, Random

Screening Test Results:

- Deviation Plot with 4 qualitative loss classifications (Within Normal Limits, Mild Relative Loss, Moderate Relative Loss, Severe Loss) based on age-related normative references
- Reliability Indices: Fixation and False Positive Catch Trials ratios

Threshold Test Results:

- Threshold (dB) Plot
- Deviation Plot 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



Carl Zeiss Meditec, Inc.

5160 Hacienda Drive

Dublin, CA 94568

USA

Toll Free: 1 800 341 6968

Phone: +1 925 557 4100

Fax: +1 925 557 4101

info@meditec.zeiss.com

www.meditec.zeiss.com



Carl Zeiss Meditec AG

Goeschwitzer Strasse 51-52

07745 Jena

Germany

Phone: +49 36 41 22 03 33

Fax: +49 36 41 22 01 12

info@meditec.zeiss.com

www.meditec.zeiss.com



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Humphrey FDT User Manual

Specifications subject to change without notice