	Analizator biochimic, semiautomat, cu siste	em de tip deschis	
Analizator semiautomat, destinat analizalor biochimice, cu sistem de tip deschis de			
Descriere	reactivi		
Parametrul	Specificația solicitata	Specificatii tehnice ofertate Stat Fax 3300 Nr. inregistrare AMDM: DM000437979	
Tip sistem	Sistem deschis de reactivi	Sistem deschis de reactive- manual de utilizare, pag 3	
	Ser: da	Ser, manual de utilizare, pag 1	
Tip proba	Plasma : da	Plasma, manual de utilizare, pag 1	
	Urina: da	Urina, manual de utilizare, pag 1	
Reagenti lichid	da	Da – se anexeaza instructiuni de utilizare a citorva tipurilor de reagenti ce pot fi utilizati la acest dispozitiv, iar litere SL ce apar dupa fiecare denumire de reagent, inseamna Stabil Lichid, fapt ce demostreaza ca tipul reagentului este lichid	
Cu posibilitatea de a substituiti	fi da	Da-(Sistem deschis de reactive) manual de utilizare, pag 9; (capacitate >100 metode de lucru) - manual de utilizare, pag 3	
Incubator	Temperatura de termostatare 37°C	Temperatura de termostatare 37°C- brosura, pag 1	
	Capacitatea min 8 tuburi	Capacitatea 18 tuburi- brosura, pag 1	
	Punct final: da	Punct final: da - manual de utilizare, pag 1	
Regimuri de masura	re Cinetic: da	Cinetic: da - manual de utilizare, pag 1	
	Multipoint cinetic: da	Multipoint cinetic: da- manual de utilizare, pag 1	
Sursa de lumina	Min 6 lungimi de unda	6 lungimi de unda (340, 405, 505, 545, 580, 630nm) – in configuratia standarda, brosura 1	
Data management	Display: da	Display: da - brosura 1	
	Memorie interna: da	Memorie interna: da- brosura 1	
	Imprimanta integrate: da	Imprimanta integrate: da - brosura 1	
	Calibrare automata: da	Calibrare automata: da – maual de utilizare pag 2,28,29, 109	
Alimentare	Retea electrica 220V, 50Hz: da	Retea electrica 220V, 50Hz: da brosura 1	
Accesorii	Bec≥3 buc	Bec - 3 buc	
Consumabile	Sa fie incluse eprubete (cuve) pentru incubarea reactivelor compatibile cu analizatorul ≥1000 eprubete (cuve)	Incluse eprubete pentru incubarea reactivelor compatibile cu analizatorul - 1000 eprubete	

Stat Fax 3300 Technical Specifications

Photometer

Tube or cuvette	-0.2 to 2.5 absorbance units
With flowcell	-0.2 to 3.5 absorbance units
Stability.	drift of no more than 0.005A in 8 hours/bichromatic
Light source	tungsten halogen lamp, with lamp saver feature
Standard wavelengths	340, 405, 505, 545, 580, 630nm plus 2 optional
Filter types	ultra long life multiple cavity IAD hard coat

Sampling

Sample Volume - Flowcell	programmable 250 L-750 L
Flowcell Body	surgical grade stainless steel
Windows	Pyrex
Illuminated volume	21 L
Minimum Volume - Tube (12mm)	1mL
Minimum Volume - Cuvette	400 L

Electronic

Processor	. Z180
Program Memory	1 megabit
Non-volatile Memory	1 megabit
RAM	32k byte
Internal printer	40/80 column thermal
Display	Graphical LCD 240x128
Keyboard	20 key, domed membrane
PC keyboard	compatible with standard PS2 keyboard
Output - RS232	9600 8 data, 1 stop, no parity
Output - Parallel	Any IBM printer with simple ASCII compatibility

Operating Modes

Single and multipoint standardization	1
Rate (factor/standard)	live graphical display of reaction
Curve fit	linear, point to point, or regression
Miscellaneous	blank and curve recall, sample blanking

Special Features

	the second se
Password Protection for test results	and parameters
Levey Jennings, patient reports, job	creation concerned and a
User tests	more than 100
Stored patient results	more than 500
Stored control results	more than 500
Optional external heat block	18 wells, controlled temp @ 37°C
Optional read cell cooling	Peltier cooling system - cell only
Enclosure	fire retardant ABS and steel
Dimensions	16" (40cm) x 14.5" (37 cm) x 5.5" (14 cm)*
	*12" - 30 cm tall with screen up
Weight	(17 lbs) 6.4 kg



AWARENESS TECHNOLOGY INC

Awareness Technology, Inc. Palm City, Florida USA Awareness Technology reserves the right to change spe tice due to design impro Doc. Stat Fax® Model 3300 S2V3 - 05/07

Stat Fax 3300 Chemistry Analyzer



shown with optional incubation accessory and external keyboard

Welcome io a new generation of Siai Fax



STAT FAX® 3300 OPERATOR'S MANUAL



© Copyright 2005 Awareness Technology, Inc. 05/2007 Doc. 3300P Rev. E

1. INTRODUCTION	1
1.1 APPLICATIONS	1
1.1.1 Intended Use	1
1.1.2 Summary of the Instrument	1
1.2 SPECIFICATIONS	3
1.3 WARNING MARKINGS	7
1.3.1 Safety Symbols	7
1.3.2 Safety Terms	7
1.4 SAFETY PRECAUTIONS	8
1.5 Setup	. 11
1.5.1 Unpacking	.11
1.5.2 Installation/Preparation	. 15
1.5.3 Keypad Description	.20
1.6 CHECKOUT PROCEDURE	.22
1.7 FIRST START UP PROCEDURE	.24
2. MAIN MENU / GENERAL SELECTIONS	25
2.1 F1 = RUN TEST	.25
2.1.1 Utility Tests	.26
2.1.2 Run a Stored User Test	.27
2.1.3 Password Control Menu	. 30
2.1.4 Entering a New Password	. 32
2.1.5 Login with Administrator Password	. 33
2.1.6 Change Password	. 34
2.1.7 Lock Menus	. 35
2.1.8 Log Off	. 36
2.2 F2 = PROGRAM	. 37
2.2.1 Create / Run a New User Test in Program Mode	. 37
2.3 F3 = WORKLIST	. 39
2.3.1 Modify the Patient Worklist	. 39
2.4 F4 = TOOLS	.44
2.4.1 Stored Data Utilities	.45
2.4.1.1 User Test Menu	.46
2.4.1.2 Control Data Menu	. 47
2.4.1.3 Patient Result Data Menu	. 48
2.4.2 Flowcell Configuration	.49
2.4.3 Printer Setup	. 51
2.4.3.1 Internal Printer	. 52
2.4.3.2 External Printer	. 53
2.4.3.3 Internal Printer Font Sample	. 54
2.4.3.4 Serial Port Data Output	.55
2.4.3.5 Print on Demand Feature	. 56
2.4.4 Diagnostics Menu	.57
2.4.4.1 Filter Voltages	.58
2.4.4.2 Filter Wheel Speed	.58
2.4.4.3 Usage Count.	.59
2.4.4.4 Cell, Block Heat Calibration	.59
	.60
2.4.4.6 Self Check	.61

2 4 5 1 Set Date and Time	62
2.4.3.1 Set Date and Time	63
2.4.5.2 Laboratory Name Options	64
2.4.5.3 Sample/Reagent Volume Option	
2.4.5.4 Cell & Block Heat Control	
3. OPERATING PROCEDURES	
3.1 GENERAL SELECTIONS	72
3.1.1 External Ports	
3.1.2 Serial Port	12 72
3.1.4 External Keyboard	12 72
3 1 5 Units of Measurement	72
3 1 6 Entering Names	73
3.1.7 Ranges and Controls	
3.1.7.1 Setup Ranges	
3.1.7.2 Setup Controls	78
3.1.8 Blanking	83
3.1.9 Reading Samples	84
3.1.9.1 Using Tubes or Cuvettes	84
3.1.9.2 Using the Flowcell	
3.1.10 Bichromatic Operation (Differential Filter)	
3.1.11 Saving Tests	87
3.1.12 Reports	
	04
4. CALCULATION PROGRAMS	91
4. CALCULATION PROGRAMS	91 91
 4. CALCULATION PROGRAMS 4.1 ABSORBANCE MODE 4.2 SINGLE STANDARD MODE 4.2 SINGLE STANDARD MODE 	91 91 95
 4. CALCULATION PROGRAMS 4.1 ABSORBANCE MODE 4.2 SINGLE STANDARD MODE 4.3 FACTOR MODE 4.4 Multithe Double Mode 	91 91 95 102
 4. CALCULATION PROGRAMS 4.1 ABSORBANCE MODE 4.2 SINGLE STANDARD MODE 4.3 FACTOR MODE 4.4 MULTI-POINT MODE 4.5 PATE MODE 	91 91 95 102 109 117
 4. CALCULATION PROGRAMS 4.1 ABSORBANCE MODE 4.2 SINGLE STANDARD MODE 4.3 FACTOR MODE 4.4 MULTI-POINT MODE 4.5 RATE MODE 4.6 INDEX MODE 	91 91 95 102 109 117 130
 4. CALCULATION PROGRAMS 4.1 ABSORBANCE MODE 4.2 SINGLE STANDARD MODE 4.3 FACTOR MODE 4.3 FACTOR MODE 4.4 MULTI-POINT MODE 4.5 RATE MODE 4.6 INDEX MODE 	
 4. CALCULATION PROGRAMS 4.1 ABSORBANCE MODE 4.2 SINGLE STANDARD MODE 4.3 FACTOR MODE 4.3 FACTOR MODE 4.4 MULTI-POINT MODE 4.5 RATE MODE 4.6 INDEX MODE 5. CLEANING AND MAINTENANCE 	91 91 95 102 109 130 133
 4. CALCULATION PROGRAMS. 4.1 ABSORBANCE MODE. 4.2 SINGLE STANDARD MODE. 4.3 FACTOR MODE. 4.3 FACTOR MODE. 4.4 MULTI-POINT MODE. 4.5 RATE MODE. 4.6 INDEX MODE. 5. CLEANING AND MAINTENANCE. 	
 4. CALCULATION PROGRAMS. 4.1 ABSORBANCE MODE. 4.2 SINGLE STANDARD MODE. 4.3 FACTOR MODE. 4.4 MULTI-POINT MODE. 4.5 RATE MODE. 4.6 INDEX MODE. 5. CLEANING AND MAINTENANCE. 5.1 CLEANING. 5.1.1 Exterior. 	91 91 95 102 109 130 133 133 133
 4. CALCULATION PROGRAMS 4.1 ABSORBANCE MODE 4.2 SINGLE STANDARD MODE 4.3 FACTOR MODE 4.3 FACTOR MODE 4.4 MULTI-POINT MODE 4.5 RATE MODE 4.6 INDEX MODE 5. CLEANING AND MAINTENANCE 5.1 CLEANING 5.1.1 Exterior 5.1.2 Flowcell 	91 91 95 102 109 130 133 133 133 133 133
 4. CALCULATION PROGRAMS. 4.1 ABSORBANCE MODE. 4.2 SINGLE STANDARD MODE. 4.3 FACTOR MODE. 4.3 FACTOR MODE. 4.4 MULTI-POINT MODE. 4.5 RATE MODE. 4.6 INDEX MODE. 5. CLEANING AND MAINTENANCE. 5.1 CLEANING	91 91 95
 4. CALCULATION PROGRAMS. 4.1 ABSORBANCE MODE. 4.2 SINGLE STANDARD MODE. 4.3 FACTOR MODE. 4.3 FACTOR MODE. 4.4 MULTI-POINT MODE. 4.5 RATE MODE. 4.6 INDEX MODE. 5. CLEANING AND MAINTENANCE. 5.1 CLEANING. 5.1.1 Exterior. 5.1.2 Flowcell. 5.1.3 Waste Bottle	91 91 95 102 109 117 130 133 133 133 133 134 135 135
 4. CALCULATION PROGRAMS 4.1 ABSORBANCE MODE 4.2 SINGLE STANDARD MODE 4.3 FACTOR MODE 4.3 FACTOR MODE 4.4 MULTI-POINT MODE 4.5 RATE MODE 4.6 INDEX MODE 5. CLEANING AND MAINTENANCE 5.1 CLEANING 5.1.1 Exterior 5.1.2 Flowcell 5.1.3 Waste Bottle 5.2 MAINTENANCE 5.2 MAINTENANCE 5.2 Opening the Instrument 	91 91 95 102 109 109 130 133 133 133 133 135 135 135 135
 4. CALCULATION PROGRAMS 4.1 ABSORBANCE MODE 4.2 SINGLE STANDARD MODE 4.3 FACTOR MODE 4.3 FACTOR MODE 4.4 MULTI-POINT MODE 4.5 RATE MODE 4.6 INDEX MODE 5. CLEANING AND MAINTENANCE 5.1 CLEANING 5.1.1 Exterior 5.1.2 Flowcell 5.1.3 Waste Bottle 5.2 MAINTENANCE 5.2 1 Calibration and Linearity 5.2.2 Opening the Instrument 5.2.3 Lamp replacement 	91 91 95 102 109 109 130 130 133 133 133 135 135 135 135 135 135
 4. CALCULATION PROGRAMS 4.1 ABSORBANCE MODE 4.2 SINGLE STANDARD MODE 4.3 FACTOR MODE 4.3 FACTOR MODE 4.4 MULTI-POINT MODE 4.5 RATE MODE 4.6 INDEX MODE 5. CLEANING AND MAINTENANCE 5.1 CLEANING 5.1.1 Exterior 5.1.2 Flowcell 5.1.3 Waste Bottle 5.2 MAINTENANCE 5.2 MAINTENANCE 5.2 Opening the Instrument 5.2.3 Lamp replacement 5.2.4 Flowcell Tubing Replacement 	91919195102102109130133133133133135135135135137141
 4. CALCULATION PROGRAMS 4.1 ABSORBANCE MODE 4.2 SINGLE STANDARD MODE 4.3 FACTOR MODE 4.3 FACTOR MODE 4.4 MULTI-POINT MODE 4.5 RATE MODE 4.5 RATE MODE 4.6 INDEX MODE 5. CLEANING AND MAINTENANCE 5.1 CLEANING 5.1.1 Exterior 5.1.2 Flowcell 5.1.3 Waste Bottle 5.2 MAINTENANCE 5.2 MAINTENANCE 5.2 Opening the Instrument 5.2.3 Lamp replacement 5.2.4 Flowcell Tubing Replacement 	91 91 95 102 102 109 130 133 133 133 135 135 135 135 137 141 143

6. TROUBLESHOOTING	145
6.1 FLAGS AND ERROR MESSAGES	
6.1.2 Error Messages	
6.2 INCORRECT CONTROL READINGS	
6.3 Poor Linearity	149
6.4 ERRATIC READINGS	149
6.5 LAMP FAILURE	149
6.6 NO SAMPLING	
6.7 RESTORE CALIBRATION DATA	
6.7.1 Restore Electronic Calibration	
6.8 ELOWCELL ALICNMENT	
0.8 FLOWCELL ALIGNMENT	
7. ACCESSORIES	155
7.1 EXTERNAL KEYBOARD	
7.2 INCUBATION UNIT	
7.3 Peltier Cooling Accessory	
7.4 THERMAL PRINTER PAPER	
7.5 REDI-CHECK [®] Photometer QA Kit	
8. USER TEST MENU LOG	156
9. CONTACT INFORMATION	157

1. INTRODUCTION

1.1 Applications

1.1.1 Intended Use

This instrument is intended to be used to read and calculate the results of in-vitro clinical diagnostic assays, as well as any other application requiring absorbance or concentration readings at or near the available wavelengths. This general purpose instrument is intended to be used by laboratory professionals capable of selecting the appropriate features and options for each specific clinical application.

1.1.2 Summary of the Instrument

Stat Fax[®] **3300** is designed for the processing of biochemistries, tube method immuno assays, and drug assays from human serum, plasma, or urine. A removable Flowcell installs in the read well to provide extremely rapid fluid sampling with low carryover. A built-in vacuum pump and an external waste bottle with level sensing are supplied standard. When the Flowcell is removed, the instrument accepts standard 12 mm round tubes as well as 1 cm square cuvettes. The design of the instrument includes many features to minimize operator error, such as stable factory calibration, automatic zeroing, complete operator prompting, detailed labeling, pre-programmed calculations, visual and audible feedback, flags and error messages, and minimal maintenance requirements; and user-friendly features such as the print on demand feature in Rate Mode. The operating modes are:

Absorbance Mode

Reads monochromatic or bichromatic differential absorbances at userselected wavelengths.

• Standard Mode

Reports concentrations based on a single standard concentration. Differential samples (against sample blanks) are supported

• Rate Mode

Reports concentrations either based on the average Δ absorbance per minute multiplied by a user supplied factor (Rate by Factor), or based on the Δ absorbance per minute of a standard (Rate by Standard). A fixed-time kinetic mode calculates based on Δ absorbance over a specified interval. The Rate Mode includes a "Batch" option that permits kinetic assays to be run simultaneously. There is also a Multi-Point Fixed Time Kinetic Mode available. The print on demand feature allows the user to turn the internal printer on to print patient data or a graph while the internal and external printers are set to off in the printer setup [Tools menu] by pressing the More key.

• Factor Mode

Reports concentrations by multiplying absorbance values by a specified factor. Differential samples (against sample blanks) are supported.



Awareness Technology, Inc.

Multi-Point Mode •

Reports concentrations or percent absorbance values based on the point-topoint connection of up to seven user-entered standards. These are used to calculate the concentrations of unknown samples according to Beer's Law. The resulting calibrator curve is a series of line segments connecting the calibrator points. If you wish to use the point (0,0), you must include it as a calibrator. Differential samples (against sample blanks) are supported.

Index Mode

A calculating feature where you enter the values for each assay upon the prompt for that assay result and print what is entered. The instrument calculates the index result, saves the index result, and includes it in the patient report.

Test parameters, and standard curves are stored in memory for later recall. The Stat Fax® 3300 will store up to 120 tests in memory to be recalled for later use; allows for creation of Levey-Jennings plots for QC. In addition, it will store 512 Patient Results, 512 Control Results, 20 Patients on Worklist, and 15 tests per patient.



1.2 Specifications

Specif Model Spectr Optica o Usable Syster	ication Date
Calcul	ating Modes:
0	Absorbance
0	Single Standard
	 Differential samples
0	Differential samples
0	Multi Standard Mode (up to 7 standards)
Ũ	 Differential samples
0	Multi Standard % Abs (up to 7 standards)
	• Differential samples
0	Kinetic Mode (consecutively, or simultaneously (Batch))
0	Fixed Time Kinetic
0	 By Factor or by Standard
0	Index Mode
Chanr	nels
Source	e of Radiation:
0	Tungsten Halogen, 10 Watt, with automatic lamp saver
Select	ion of WavelengthBy filter
Filter	lype: A covity interference, long life ion beam appieted deposition
0 Wavel	ength Accuracy +/- 3 nm
Filter I	
0	After sample (heat absorbing filter before sample)
Filter S	Selection:
0	Automatic by software or via keyboard



Wavelengths:

- 340, 405, 505, 545, 580, 630 nm supplied standard
- Other/additional filters optional

Half Bandwidth..... < 10 nm 1/100 Bandwidth 14 nm at 340 nm False Radiant Energy Ratio < 0.001 at 340 and 405 nm

Cuvette:

o 1 cm square, 12 cm round, flow through Supplied Type..... Flow-through

Material:

o 316 stainless, borosilicate windows Geometry:

 Cylindrical, 2.3 mm dia x 5 mm +/- 0.05 mm Illuminated Volume 21 µl Minimum Read Volume...... 250 µl Aspiration/Purge:

• Vacuum pump at 18 cm of Hg Valve..... Silicone pinch type

Cuvette Holder:

 Thermostatically controlled compartment at 37° C Detector:

Gallium-Arsenide-Phosphide photodiode

Signal Processing and Display

Display Type:

240x128 Graphic LCD w/ Backlight

Scale of Display

Absorbance:

- -0.5 to 3.5 (flow-through mode)
- -0.5 to 2.5 (tube or 1 cm cuvette)

Concentration Maximum 999,999 **Kinetic Results:**

 Abs/min with resolution of 0.0002 A/min Zero Compensation Automatic Range--0.5 to 2.5 absorbance



Signal Outputs:

Parallel Centronics/IBM-PC compatible Serial:

 RS-232 at 9600 baud, 8 data, 1 stop, no parity Bi-Directional Data Input:

- 1) 20 Key Keypad,
- 2) PS2 101 Keyboard (connector available at back of instrument)

Spectrophotometric Inaccuracy

Flow-through:

- < 0.5 % at 1 absorbance, 340/630 nm NADH solution
- o < 1% at 2 absorbance, 340/630 nm NADH solution
- < 3 % at 3 absorbance, 340/630 nm NADH solution
- < 0.5 % at 1 absorbance, 405/630 nm PNP solution
- < 1 % at 2 absorbance, 405/630 nm PNP solution
- < 3 % at 3 absorbance, 405/630 nm PNP solution

Stability:

- Better than 0.003 A/hr monochromatic after warm-up
- Better than 0.001 A/hr bichromatic after warm-up

Warm-up Time:

- 90 seconds photometric
- 15 minutes for temperature compartment

Electronics:

- Z180 Microprocessor 18 MHz
- o 128k EEPROM
- 32 K bytes Nonvolatile RAM (NVRAM)

Power:

- Auto-Switching Power Supply
- Voltage source: 90 264 VAC Frequency: 50/60 Hz
- Power consumption: 60 watts
- Installation Category: CAT II
- o Fuses:
 - o 2.5A/250V Fast 5-20 mm Glass Fuse,
 - 2.0A/250V Fast 5-20 mm Ceramic Fuse,
 - (2) 6/10 250V Slow Blow 3AG Fuses

Dimensions and Weight:

- 40cm (L) x 37 cm (W) x 14 cm (H) lid closed (30 cm lid opened), 6.4 kg

Environmental Conditions for Safe Operation:

- Indoor Use
- Altitude up to 2000m.
- Temperature 5°C to 40°C. (Although it may be safe to operate in these conditions, it may not be suitable for the performance of the user's tests. Check with supplier.)
- Humidity 85% for temperatures up to 31°C decreasing linearly to 50% humidity at 40°C.
- Mains supply voltage fluctuations not to exceed ±10% of the nominal voltage.

Recommended Operating Temperature 15-35°C Recommended Operating Humidity Between 10 and 85%, non-condensing

Design and instrument specifications are subject to change without notice.

1.3.1 Safety Symbols

Safety symbols which may appear on the product:



Protective Ground (Earth) Terminal

CAUTION



FUSE: For continued protection against the risk of fire, replace only with fuse of the specified type and current ratings. Disconnect equipment from supply before replacing fuse.

1.3.2 Safety Terms

These terms may appear on the product:	
DANGER	indicates an injury immediately accessible as you read this marking
WARNING	indicates an injury hazard not immediately accessible as you read this marking
CAUTION	indicates a hazard to property, including the product

These terms may appear in this manual:	
WARNING	WARNING statements identify conditions or practices that could result in injury or loss of life. WARNING indicates an injury hazard not immediately accessible as you read this marking.
CAUTION	CAUTION statements identify conditions or practices that could result in damage to this product or other property.
BIOHAZARD	BIOHAZARDS are biological agents that can cause disease in humans. Lab workers handling potentially infectious materials must use universal precautions to reduce the risk of exposure to these agents.



1.4 Safety Precaution	1.4 Safety Precautions		
To assure operator safety and prolong the life of your instrument, carefully follow all instructions outlined below.			
Read Instructions	Take time to read this manual carefully before using this instrument. Review the following safety precautions to avoid injury and prevent damage to this instrument or any products connected to it. To avoid potential hazards, use this instrument only as specified. For best results, familiarize yourself with the instrument and its capabilities before attempting any clinical diagnostic tests. Refer any questions to your instrument service provider.		
Servicing	There are no user-serviceable parts inside the instrument. Refer servicing to qualified service personnel. Use only factory-authorized parts. Failure to do so may void the warranty.		
Wear Protective Apparel	Many diagnostic assays utilize materials that are potential biohazards. WARNING: Always wear protective apparel and eye protection while using this instrument.		
Follow Operating Instructions	WARNING: Do not use this instrument in a manner not specified by the manual, or the protection provided by the instrument may be impaired.		
Use Proper Power Cord	WARNING: Use only the power cord specified for this product and certified for the country of use.		
Observe All Terminal Ratings	WARNING: To avoid fire or shock hazard, observe all ratings and markings on the instrument. Consult this manual for further ratings information before making connections to the instrument.		
Install as Directed	Stat Fax [®] 3300 should be installed on a sturdy, level		

surface capable of safely supporting the instrument's weight (10 kg). The mounting surface should be at least 61cm deep and free of vibrations. **Provide Proper** Refer to the installation instructions for details on installing Ventilation the product so it has proper ventilation. The instrument should be surrounded by the following clearances: 10cm around perimeter of unit and 10cm on top. **Do Not Operate WARNING:** Do not operate this instrument with covers and Without Protective panels removed. Covers



Safety Precautions	Safety Precautions (Continued)	
Use Proper Fuse	WARNING: Use only the fuse type and rating specified by the manufacturer for this instrument.	
Avoid Exposed Circuitry	WARNING: Do not touch exposed connections and components when power is present.	
Avoid Excessive Dust	Do not operate in an area with excessive dust.	
Do Not Operate With Suspected Failures	WARNING: If you suspect there is damage to this instrument, have it inspected by a qualified service person.	
Do Not Operate in Wet/Damp Conditions	WARNING: Do not operate instrument in wet/damp conditions.	
Do Not Operate In An Explosive Atmosphere	WARNING: Do not operate instrument in an explosive atmosphere.	
Keep Instrument Surfaces Clean and Dry	 CAUTION: Solvents such as acetone or thinner will damage the instrument. √ Do not use solvents to clean the unit. Avoid abrasive cleaners; the display overlay is liquid-resistant, but easily scratched. √ Clean the exterior of the instrument with a soft cloth using plain water. If needed, a mild all-purpose or nonabrasive cleaner may be used. √ Use as a disinfectant a 10% solution of chlorine bleach (5.25% Sodium Hypochlorite) or 70% isopropyl alcohol. √ Take special care not to spill liquid inside the instrument 	
Operating Precautions	Be sure to run a sufficient number of controls in each assay. If controls are not within their acceptable limits, disregard test results.	

Safety Precautions (Continued)		
Biohazard Precautions	Ŕ	
\sim	BIOHAZARD	
₹ ₹	WARNING - If the Waste bottle is overturned during operation, immediately set the power switch to OFF (0). If this occurs, the instrument may discharge a small amount of waste material from the waste bottle via the fitting on the bottom of the instrument. This material should be treated as potentially bio- hazardous. Appropriate clean up of the material should be observed.	



1.5.1 Unpacking

Carefully unpack the instrument, removing it from its plastic bag. Report any damage to your freight carrier at once. Retain the original packing material for future use in the event that the instrument is shipped to another location or returned for service. The following items should be packed with the instrument. Please locate each item now before continuing.

ITEM	DESCRIPTION
Heat Block (optional accessory)	External Incubation Block
Waste bottle	Plastic bottle
Cleaning solution	Plastic bottle containing Flowcell cleaning solution
Bottle cap assembly	Bottle caps, tubes, sensor wires
Thermal printer paper P/N 15003	(1) roll Thermal Printer Paper
Paper roll cover	Black, Flat, Rectangular
Power cable	Heavy cord
Flowcell	"T"-shaped object with square extension, in plastic box
Tool Kit	Not applicable
Spare Parts Kit P/N 033011	Contents:
	(1) Replacement Thermal Printer Paper Roll P/N 150003
	(1) Replacement Lamp P/N 112004
Operator's Manual	This document



Unpacking (Continued)

ITEM	DESCRIPTION
Flowcell Spare Tubing Kit P/N 033040	Contents: (1) pc 9" Silicone Valve Tubing (2) pcs 8.5" Teflon Sample Tubing, swaged, for Sample volume >200µl
	(1) pc 5" Teflon Exit Tubing(1) male Luer
	(1) pc 9/16" PVC Tubing Support, white opaque
	(1) pc Insulating Tube Gasket, foam rectangle with round hole
	(1) pc Tubing Gripper, rectangle of emery paper
	(1) Hex Wrench – 1.6 mm

Contact your distributor if anything is missing.



NOTICE: REMOVE THE SHIPPING VALVE BLOCK AS DESCRIBED BELOW BEFORE **OPERATING THE INSTRUMENT.**

Take notice of Document 953355A which is shown below and accompanies your instrument. The shipping valve block must be removed. Failure to remove the valve block will affect the operation of the instrument.

Step 1: Turn the instrument over. On the bottom, near the front, find the square plastic cover (Figure 1).



instrument shown.

Bottom of

Find the square plastic cover.

Figure 1

Step 2: Using a flat blade screwdriver, or similar instrument, pry off the plastic cover at the slot shown (Figure 2).



Use a flat blade screwdriver to pry off the plastic cover at the slot as shown.

Figure 2

Awareness Technology, Inc.

Step 3: Locate the small green valve block. Grasp the valve block and pull up to remove. Make sure that the tubing remains in place in the valve.

Replace the cover back into the slot and snap into place.

Figure 3



1.5.2 Installation/Preparation

Installation/Prepara	tion:
Instrument Placement and Use	Place the instrument on a flat working surface capable of safely supporting the weight of the instrument, approximately 10 kg (22 lbs.). A clearance of at least 10 cm (4") around the instrument is required to assure optimal ventilation.
Complete this procedure to prepare the instrument for operation	Place the Waste bottle on the work surface behind the instrument. Position the Waste bottle so that the tubing and sensor lead are not kinked, twisted, or strained. CAUTION: Do not place undue stress on the tubing connections or sensor lead connector. Tighten the bottle cap firmly.
	Connect the Waste bottle tubes to the rear panel fittings. The tubing connections are color-coded; match the male Luer cap to the color-coded ring on the rear panel. The vacuum line fittings are blue and the waste line fittings are black. Turn the fittings clockwise only until finger-tight. Do not over tighten.
	Plug the sensor lead into the sensor jack on the rear panel.
	Place the Waste bottle into the harness provided for it on the rear of the unit. Pull the strap so that the bottle is held tightly then press it together so that the Velcro seals.
Assure Clean Power Availability	The circuit used should be substantially free of large voltage transients (Kilovolt amp loads) such as large pumps, large centrifuges, refrigerators and freezers, air conditioners, large autoclaves, ovens, and dryers. The instrument may fail to operate normally if the power supply is interrupted. If this occurs, turn the instrument off for a moment. When the instrument is turned back on, it will resume normal operation, but data that was not stored in nonvolatile memory will be lost.



Installation/Preparation: (Continued)	
Power Switch Position	Look at the rear panel of the instrument (<i>Figure 1.5.2-1</i>) to check that the power switch is in the OFF (0) position. Install the power cord with the unit power switch in the OFF (0) position.
Power Switch	
Power Cord Connection	
	Figure 1.5.2-1 Rear Panel of Instrument-
Power Cord Requirements	Connect the supplied power cable to the rear of the instrument (see <i>Figure 1.5.2-1</i>). Plug the other end of the power cable into an AC outlet. Use only the power cord specified for this product and certified for the country of use.
	For 110-120 V units used in the US, use a UL listed cord set consisting of a minimum 18 AWG, Type SVT or SJT three conductor cord, maximum 3 meters (10 feet) in length, rated 10 A, 125 V, with a parallel blade, grounding type attachment plug.
	For 220-240 V units used inside the US, use a UL listed cord as above, except rated <u>250 V</u> , with a <u>tandem</u> blade, with grounding type attachment plug. The cord set provided by the manufacturer meets these requirements.
	For other locations, use the power cord certified for the country of use.
	For 220-240 V units used inside the US, use a UL listed cord as above, except rated <u>250 V</u> , with a <u>tandem</u> blade, with grounding type attachment plug. The cord set provided by the manufacturer meets these requirements.
	For other locations, use the power cord certified for the country of use.

Installation/Preparation: (Continued)	
Safety Grounding	WARNING : Do NOT alter or defeat the safety grounding methods provided.
	To avoid the risk of electric shock, the third prong of the AC power plug must be connected to conductive parts internal to the equipment.
$\overline{27}$	Internal fasteners to grounding points are marked by the IEC 417 symbol 5019
	WARNING : Do NOT loosen or remove these fasteners or connections. An alternate method of grounding is provided by connecting the grounding terminal located on the rear panel to a suitable ground.
	WARNING : To avoid electric shock, the power cord protection ground conductor must be connected to ground.
Fuse Requirements	The fuses are located inside the instrument; there is a fuse in both power supplies and one in the Main AC Supply. Fuse failure is a very rare occurrence and should indicate malfunction of the equipment requiring service by qualified personnel.
	The power supply mounted on top requires a 2.5A/250V Fast 5-20 mm Glass Fuse. The power supply mounted to the chassis requires a 2.0A/250V Fast 5-20 mm Ceramic Fuse. The Main AC Supply requires (2) 6/10 250V Slow Blow 3AG Fuses.
A	WARNING: For continued protection against risk of fire, always use the specified fuse for replacement. Disconnect power cord from mains supply before replacing fuses.
	Set the power switch at the left rear of the instrument to ON (I). The display shows:



18

Installation/Preparation (Continued)		
The printer will print several lines. Wait until it has stopped. If there is no printing, the internal printer is disabled. Refer to Section 2.4.3 Printer Set-Up .		
Load paper	 Locate the roll of printer paper. 	
	 Roll out 15 cm (6") of paper from the roll. Be sure that the leading edge of the paper is straight. 	
	 Feed the leading edge of the paper into the slot inside the printer paper compartment. 	
	 While feeding the paper, press the Line Feed key (see <i>Figure 1.5.3-1 Keypad Layout</i>) on the key pad repeatedly until the paper "catches" and begins to feed into the printer. 	
	 Stop pressing the Line Feed key when the paper is seen at the top of the printer. 	
	 Pull the paper to help with alignment. 	
	 Place the paper roll into the printer well. 	

1.5.3 Keypad Description



Figure 1.5.3-1 Keypad Layout

Figure 1.5.3-2 Screen Display

The Function Keys (F1 through F4) shown in *Figure 1.5.3-1 Keypad Layout* correspond to the four keys shown at the bottom of the screen in the same order in *Figure 1.5.3-2 Screen Display*.

Function Key	Function
F1	RUN TEST
F2	PROGRAM
F3	WORKLIST
F4	TOOLS

NOTE: The instrument keypad will be overridden in the event of a keypad key sticking. The instrument will emit a series of beeps and the external keyboard (optional) will be enabled.



Keypad Description (Continued)



Figure 1.5.3-1 Keypad Layout

When applicable, the **Enter Key** on the main keypad performs the same function as the **ENTER Function Key** shown on the display screen.

Lamp	Toggles the lamp ON or OFF.
Line Feed	Internal Printer feeds one line at a time.
	External Printer skips one line.
Form Feed	External Printer initiates the printer to print all data stored in its internal memory.
READY Light	Instrument is ready to read samples or blanks.
STANDBY Light	When using the instrument, but not yet using the read screen, this light is ON. It is also ON when reading a sample.



1.6 Checkout Procedure

Follow this procedure to verify that the instrument is ready for use.

In this procedure, it is assumed that the Flowcell is being used. If using the instrument with tubes or square cuvettes, disregard the Flowcell information.

Checkout Procedure:		
Visually confirm the following	items:	
Waste bottle is connected to	the correct fittings.	
Sensor lead is plugged in.		
Waste bottle is empty.		
Waste bottle cap is tight.		
Power cable is plugged into r	ear of unit and into an AC outlet.	
INSERTING THE FLOWCELL:		
Use extreme caution: Forcing the Flowcell to seat improperly may damage it or the instrument.	 ✓ Flowcell is fully seated in read well and luer fitting is connected (if Flowcell is in use.) Insert the Flowcell in the read well so that the sample tube is toward the front. Press the Flowcell gently down and towards the rear into the read well. Verify that the Flowcell is seated firmly. 	
√ Heat Block is connected. (Optional Accessory)		
External Keyboard is connected. (Optional Accessory)		
Power switch is set to OFF (0)).	

Checkout Procedure: (Continued)							
The instrument is now ready for power-up.	Confirm that the instrument responds as described.						
Set the power switch at the right rear of the instrument to ON (1).The screen will display as shown in Figure 1.6-7 Screen Display (Checkout).							
The screen will display: the instrument model, software revision, and the date and time.							
 ▲ 36.8/36.8°C Image: Program Program ▲ 36.8/36.8°C Image: Program Program ■ Program ■ Stored User Test PROGRAM: Create/Run a New User Test WORKLIST: Modify the Patient WorkList TOOLS: Instrument Utilities ACME Labs 							
RUN TEST) (PROGRAM) (WORKLIST) (TOOLS)							
Figure 1.6-1 Screen Display (Checkout)							
NOTE : If the Flowcell is enabled, "Time" is replaced by "V= #.#" (software version) on the status line; the Tube icon will be replaced by a Flowcell icon.							
If using either an internal or external printer, a header will be printed at power-up, showing the instrument model, software revision, date and time.							
If "Date and Time" are not correct, refer to Section: 2.4.5 General Configurations .							
Allow the instrument to equilibrate for at least 15 minutes.							
Cell and Block temperature can be set, if required. See Section 2.4.5 General Configurations .							
If the instrument produces results other than those described here, set the power switch to OFF (O) .							
Refer to the Section 1.5.2 Installation/Preparation and review all steps carefully. Repeat the Checkout Procedure.							
If the instrument still produces results other than those described here, refer to Section 6 Troubleshooting , or contact your dealer for assistance.							

1.7 First Start Up Procedure

First Start Up Procedure:

- Clean the Flowcell. Refer to Section 5.1.2 Cleaning the Flowcell.
- Run Self Check. Refer to Section 2.4.4.6 Self Check.
- At the beginning of every test run in Flowcell Mode, the valve will be checked for proper operation.
- The instrument will emit a noise as it checks the aspiration valve. Do not be alarmed, this is typical.
- The EEPROM, NV RAM, Vacuum System, and Photometer are all checked.
- Test results will be reported on the display and printer.
- An error will be immediately reported on the display and the printout.



2. MAIN MENU / GENERAL SELECTIONS

2.1 F1 = RUN TEST

F1 (RUN TEST) is used to run utility tests and user tests stored in the instrument's memory.

Tests programmed and saved on the instrument will be displayed in the Test Menu and sorted by their test number.

The Stat Fax[®] 3300 stores up to 120 complete test setups in nonvolatile memory, making it easy for the user to recall complete test configurations.

Each of the test parameters, including the mode, wavelengths, standards, units, and the ranges are all stored for reuse.

Blanks and standards (including entire standard curves) that have been read are also saved.

When the test is recalled, the user has the option of using the previous curve or reading a new one.

2.1.1 Utility Tests

To access the six Utility Tests see steps in Section 2.1.2 Run a Stored User Test. Enter the test number when prompted to select a test number.

Utility Test	Test Description		
213	Prints stored serial number, absorbance factor, cell temperature correction, block temperature correction		
214	Sets the lamp shut off to one hour and enables Flowcell		
222	Keypad test		
223	Password feature (allows user to disable or change password) See Sections 2.1.3 through 2.1.6 for details		
248	Enter Filter Labels for #7 and #8		
249	Resets the filter labels to their default settings		

26

2.1.2 Run a Stored User Test

Run a Stored User Test:		Prompt/Response:				
To run a stored user test, press:		F1 RUN TEST				
RUN TEST: Run a Stored User Test PROGRAM: Create/Run a New User Test WORKLIST: Modify the Patient Worklist TOOLS: Instrument Utilities RUN TEST PROGRAM			st	F1		
and prompt:			Use the numeric keys to select the			
Select a test number			test number of the test to run, and press ENTER			
QUIT	QUIT MORE CLEAR ENTER					
Press:						
Function K		T: To return to Mair	n Menu.			
Function Key 2 F2 MORE: To advance the screen to the next page.						
The display will prompt: Print Test Header Y/N						
Print Test Header?						
QUIT NO YES						
The display will prompt:		Use Stored B	lank Y/N			
Use Stored Blank?						
QUIT		NO	YES			


Run a Stored User Test: (Continued)	Prompt/Response:	
Press:		
Function Key 4 F4 YES: To use the stored blank. The signal just been read.	stored value will be used as if it had	
Function Key 3 F3 NO: To read a new blank.		
Function Key 1 F1 QUIT: To return to Main Menu.		
The curve data will display:		
ABS 0.000 -B -0.000		
Press:		
Function Key F4 ACCEPT: To accept curve.		
Function Key F3 DISCARD: To discard curve.		
Function Key F2 PRINT: To print the curve.	Plotting to Internal Printer	
Function Key F1 QUIT: To return to the Main Menu.		
If recalling a Multi-Point % Abs Mode, and choosing to use the stored calibration, the user will be prompted to read the first calibrator and displays the curve as shown above.	READ THE BLANK Y/N	
If a stored curve is not used, the display prompts the user to read the sample.		

28

Run a Stored User Test: (Continued)	Prompt/Response:	
If the test is assigned to a patient in the Worklist, the display prompts:	Run Current Worklist?	
(See Section 2.3 F3=WORKLIST for details.)		
To use the current stored Worklist, select:	YES	
To continue without using Worklist, select:	NO	
Finally, the screen will display one of three prompts:	READ THE BLANK	
	READ STANDARD #	
	READ SAMPLE #	
If there were no stored blank or standard curve, or the user has chosen not to use them, the values that are read will be automatically saved under the recalled test, unless an "Invalid Curve" is created.		
When recalling the test the next time, the option to use the stored calibration as described above will be displayed.		



2.1.3 Password Control Menu





Password Control Menu: (Continued)	Prompt/Response:
The Password Control Menu will appear on the screen.	The current status of the password feature will be
The display will read:	highlighted (ON or OFF).
PASSWORD CONTROL	
Password Feature is: ON OFF	Password Feature is: OFF
QUIT ON OFF OK	
Password Control Menu Function Keys:	The current status of password control will be
F1 QUIT return to Main Menu with no changes	highlighted (see below).
F2 ON ENABLE password feature	
F3 OFF DISABLE password feature	
F4 OK accept change of status	
To ENABLE password protection, press:	Function Key F2 ON
PASSWORD CONTROL	
Password Feature is: ON OFF	
QUIT ON OFF OK	Password Feature is: ON
To DISABLE password protection, press:	Function Key F3 OFF
PASSWORD CONTROL	
Password Feature is: ON OFF	
	Password Feature is: OFF

2.1.4 Entering a New Password

Entering a New Password:	Prompt/Response:	
Enable password protection (as shown in the steps above for Password Control Menu) by pressing:	F2 ON	
To ENTER A NEW PASSWORD, press:	F2 ON followed by the Enter key	
The display prompts:	Enter New Password: (up to 15 characters)	
Enter New Password: (up to 15 characters) CHARACTER SELECTION:	(See Section 3.1.6 Entering Names for details).	
ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijklmnopgrstuvwxyz	Numeric and Function key attributes:	
!"#\$%&()*+,/0123456789: :<=>?@[]^	F1 QUIT	
, .eti <u>-</u>	F2 BACK SPACE	
TO MOVE CURSOR 4=LEFT 6=RIGHT 2=UP 8=DOWN	F3 SELECT	
QUIT BACK SP. SELECT OK	F4 OK	
	Numeric 4 key MOVE CURSOR LEFT	
Position the cursor under the character desired using the numeric keys, press F3 to select.	Numeric 6 key MOVE CURSOR RIGHT	
When finished press F4 OK.	Numeric 2 key MOVE CURSOR UP	
	Numeric 8 key MOVE CURSOR DOWN	
NOTE: Password is CaSe SeNsItIvE.		



2.1.5 Login with Administrator Password





2.1.6 Change Password

Change Password:	Prompt/Response:	
The screen will display:	ADMINISTRATOR	
ADMINISTRATOR	Administrator Menu Options:	
1 = Change Password 2 = Lock Menus	CHANGE PASSWORD	
3 = Log Off	Press: Numeric Key 1	
	LOCK MENUS	
	Press: Numeric Key 2	
	LOG OFF	
QUIT	Press: Numeric Key 3	
To change the paperword, proces:	Numaria Kay 1	
To change the password, press.	Change Baseword	
	Enter New Deceward (up to 45	
The display will prompt:	characters)	
Enter New Password: (up to 15 characters) CHARACTER SELECTION: ABCDEFGHIJKLMNOPQRSTUVWXYZ	(See Section 3.1.6 Entering Names for details).	
▲ abcdefghijklmnopqrstuvwxyz	Numeric and Function key <u>attributes:</u>	
;<=>?@[]^_	F1 QUIT	
	F2 BACK SPACE	
	F3 SELECT	
QUIT BACK SP. SELECT OK	F4 OK	
Position the cursor under the character desired using the	Numeric 4 key MOVE CURSOR LEFT	
When finished press F4 OK.	Numeric 6 key MOVE CURSOR RIGHT	
NOTE: Password is Caso ScholthyE	Numeric 2 key MOVE CURSOR UP	
NOTE. Password is Cade densitive.	Numeric 8 key MOVE CURSOR DOWN	



2.1.7 Lock Menus

Lock Menus	Prompt/Response:
To Lock Menus, press:	Numeric Key 2
ADMINISTRATOR 1 = Change Password 2 = Lock Menus 3 = Log Off QUIT OK	LOCK MENUS
The Lock Menus will display menu items available to be locked or unlocked:	e Press the numeric key that corresponds with the menu item on the LOCK MENUS.
LOCK MENUS 1=PROGRAM Button 2=User Test Menu 3=Edit Control Data 4=Print Control Data 5=Print Patient Report 6=Delete Patient Report 7=Flowcell Configuration 9=General Configuration 9=General Configuration QUIT OK Press the item number corresponding to the menu to toggle between LOCK and UNLOCK (indicated by the status being highlighted when chosen). NOTE: Users without password access will not be allowed access to any menus marked "LOCK" from this poin forward unless the Administrator a) logs off, or b) changed the selections.	The current status is highlighted.



Lock Menus: (Continued)				Prompt/Response:
For example, by pressing the nur PROGRAM menu was changed to in the display below. To change so press the numeric key again.	neric key 1 from LOCK status back	the to UNLOC to LOCK,	ĸ	LOCK MENUS (Continued)
LOCK MENUS 1=PROGRAM Button 2=User Test Menu 3=Edit Control Data 4=Print Control Data 5=Print Patient Report 6=Delete Patient Report 7=Flowcell Configuration 8=Diagnostic Menu 9=General Configuration	LOCK LOCK LOCK LOCK LOCK LOCK LOCK	INLOCK UNLOCK UNLOCK UNLOCK UNLOCK UNLOCK UNLOCK UNLOCK		

2.1.8 Log Off





2.2.1 Create / Run a New User Test in Program Mode



F2 Progra	am Mode Menu Options:	Section No.
1	Absorbance Mode Reads monochromatic or bichromatic differential absorbance values at user-selected wavelengths.	Section 4.1
2	Single Standard Mode Reports concentrations based on a single standard concentration. Differential samples (against sample blanks) are supported.	Section 4.2
3	Factor Mode Reports concentrations by multiplying absorbance values by a specified factor. Differential samples (against sample blanks) are supported.	Section 4.3
4	Multi-Point Mode Reports concentrations or percent absorbances based on the point-to-point connection of up to seven user-entered Calibrators. Differential samples (against sample blanks) are supported.	Section 4.4
5	Rate Mode Reports concentrations either based on the average Δ absorbance per minute multiplied by a user supplied factor (Rate by Factor), or based on the Δ absorbance per minute of a standard (Rate by Standard). A fixed- time kinetic mode calculates based on Δ absorbance over a specified interval. A multi-point fixed time kinetic mode is also available. The Rate Mode includes a "Batch" option that permits kinetic assays to be run simultaneously.	Section 4.5
6	Index Mode A calculating feature where test results are user entered and index results are calculated and compared with normal ranges and printed on test reports. The instrument saves the index result, and includes it in the patient report.	Section 4.6

2.3 F3 = WORKLIST

2.3.1 Modify the Patient Worklist







Awareness Technology, Inc.

Modify the Patient Worklist: (Continued)	Prompt/Response:
The screen will display:	Patient Worklist Menu
PATIENT WORKLIST MENU 1 = Add a Patient to Work List 2 = Delete a Patient from Work List 3 = Print the Current Work List 4 = Delete all of Current Work List 5 = Print all Patients Enter Menu Number: QUIT	
To add a patient select press:	Numeric key 1
	Add a Patient To Work List
The display will prompt:	Enter Patient Name for ID #
Enter Patient Name for ID # 1	Function key attributes:
ABCDEFGHIJKLMNOPQRSTUVWXYZ	
▲ abcdefghijklmnopqrstuvwxyz	
!"#\$%&()*+,/0123456789: <=>2@[]^	F3 SELECT
, · · · · · · · · · · · · · · · · · · ·	r4 Ur. Numoric kov attributos:
TO MOVE CURSOR 4=LEFT 6=RIGHT 2=UP 8=DOWN	Numeric 4 key MOVE CURSOR I FET
QUIT BACK SP. SELECT OK	Numeric 6 key MOVE CURSOR RIGHT
Lies the numeric keys to may the surger to create the	Numeric 2 key MOVE CURSOR UP
alpha numeric patient name.	Numeric 8 key MOVE CURSOR DOWN
Use F3 to select each alpha/numeric character.	Refer to Section 3.1.6 Entering
Press F4 OK when finished.	Names

Modify the Patient Worklist: (Continued)	Prompt/Response:
The display will prompt:	Create a List of Test Numbers for this Patient.
Create a List of Test Numbers for this Patient To END type 0	
Maximum # of Test/Patient = 15	
	New Patient Job List
The printer will printout:	Select a test number:
The screen will display the Test Menu and prompt:	Select a test number.
Select a test number:	
	NOTE: Fifteen tests per patient is the maximum allowed.
As tests are entered for the patient, the printer will add them to Patient Job List.	
Press:	
Function Key 1 F1 QUIT: To return to Main Menu.	
Function Key 2 F2 MORE: To advance the screen to the	e next page.
Function Key 3 F3 CLEAR: To clear a typed entry.	
To delete a patient from work list, press:	Numeric key 2
PATIENT WORKLIST MENU 1 = Add a Patient to Work List 2 = Delete a Patient from Work List 3 = Print the Current Work List 4 = Delete all of Current Work List 5 = Print all Patients Enter Menu Number: QUIT	Delete a Patient from Work List



Modify the Patient Worklist: (Continued)	Prompt/Response:
The display will prompt:	Select Patient Number
Patient ID List 1 Burr, R 2 Fields, G 3 Brown, F Select Patient Number: QUIT MORE CLEAR ENTER	
Select the numeric key corresponding to the patient ID and press F4 ENTER. The printer will print:	Patient # was deleted
To print the current work list, press:	Numeric key 3
PATIENT WORKLIST MENU 1 = Add a Patient to Work List 2 = Delete a Patient from Work List 3 = Print the Current Work List 4 = Delete all of Current Work List 5 = Print all Patients Enter Menu Number: QUIT	Print the Current Work List
The printer will print out the patient name and the associated stored test number and test name. For example:	
Current Patient Work List:	
Test # Test Name	
31 T3	
32 T4	
Burr, R	

Modify the Patient Worklist: (Continued)	Prompt/Response:
To delete the entire work list, press:	Numeric key 4
PATIENT WORKLIST MENU 1 = Add a Patient to Work List 2 = Delete a Patient from Work List	Delete all of Current Work List
3 = Print the Current Work List 4 = Delete all of Current Work List	Press Yes to confirm
5 = Print all Patients	Press No to continue
Enter Menu Number:	
QUIT	
NOTE : When running a test, if patients in the Work List are scheduled for the test, the instrument will prompt:	Run the Current Work List?
Run the Current Work List?	
QUIT NO YES	
To run the patients in the Work List that need this test, select:	YES
The instrument will prompt for the corresponding samples.	
	Numeric key 5
1 = Add a Patient to Work List 2 = Delete a Patient from Work List 3 = Print the Current Work List 4 = Delete all of Current Work List 5 = Print all Patients Enter Menu Number:	Print all Patients

2.4 F4 = TOOLS

F4 TOOLS is used to access Instrument Utilities.

Instrument Utilities:		Prompt/Response:
To access Instrument Utilities, press:		F4 TOOLS
RUN TEST: Run a Stored User Test PROGRAM: Create/Run a New User Test WORKLIST: Modify the Patient Worklist TOOLS: Instrument Utilities RUN TEST PROGRAM WORKLIST TOOLS		Test list F4
Display will pr	ompt:	Instrument Tools Menu
INSTRUM 1 = Sto 2 = Flo 3 = Pri 4 = Dia 5 = Ge Enter Me QUIT	MENT TOOLS bred Data Utilities bwcell Configuration nter Setup agnostics Menu eneral Configuration nu Number:	Enter Menu Number: Select the numeric key that corresponds with the Instrument Tool desired. See Sections 2.4.1 through 2.4.5 for further details.
 Press: Numeric Key 1 Stored Data Utilities. See 2.4.1 Stored Data Utilities. Numeric Key 2 Flowcell Configuration. See 2.4.2 Flowcell Configuration. Numeric Key 3 Printer Setup. See 2.4.3 Printer Setup. Numeric Key 4 Diagnostics Menu. See 2.4.4 Diagnostic Menu. Numeric Key 5 General Configuration. See 2.4.5 General Configuration. Function Key F1 QUIT returns to Main Menu 		

2.4.1 Stored Data Utilities

Stored Data Utilities:	Prompt/Response:
To access Stored Data Utilities from the Instrument Tools Menu, press:	Numeric key 1
The display will prompt: STORED DATA UTILITIES 1 = User Test Menu 2 = Control Data Menu 3 = Patient Result Data Menu 4 = Return to the TOOLS Menu Enter Menu Number: QUIT	STORED DATA UTILITIES Enter Menu Number: A short description of each utility follows below. Select the numeric key that corresponds with the utility desired.

Press:

- Numeric Key 1 To manipulate stored user tests. See 2.4.1.1 User Test Menu. •
- Numeric Key 2 To manipulate stored controls. See 2.4.1.2 Control Data Menu.
- Numeric Key 3 To manipulate stored patient results. See 2.4.1.3 Patient Result Data Menu.
- Numeric Key 4 Return to Instrument Tools Menu
- Function Key F1 QUIT To return to Main Menu •

2.4.1.1 User Test Menu

User Test Menu:	Prompt/Response:
To access Stored User Test Menu from the Stored Data Utilities menu, press:	Numeric key 1
The display will prompt:	STORED USER TEST MENU
Stored User Test Menu 1 = Print Menu of Stored Tests 2 = Delete all Stored Tests 3 = Delete a Stored Test 4 = Edit A Stored Test 5 = Return to Previous Menu Enter Menu Number: QUIT	Enter Menu Number: A short description of each option follows below. Select the numeric key that corresponds with the option desired.

Press:

- . Numeric Key 1 To print a menu of all stored user tests
- Numeric Key 2 To delete all of the stored user tests
- Numeric Key 3 To delete a single stored user test
- Numeric Key 4 To edit a stored user test (See NOTE)
- **Numeric Key 5** To return to the Stored Data Utilities Menu
- Function Key F1 QUIT To return to Main Menu

NOTE: Editing a test will erase any stored blank or standard values for that test, as well as any patient results and stored results (if available).

All of the test's parameters will be recalled and printed.

The instrument will prompt a series of questions. The questions depend on the *mode* of the test being edited. For example, if editing a Factor Mode Test, the user can change the "Factor". When editing a Rate Mode Test, the user is prompted if the "Lag" and "Read" times will change.

If choosing YES, enter the new value just as when the test was originally stored.

Upon completing the questions, the instrument prints "Edit Complete".

2.4.1.2 Control Data Menu

Control Data Menu:	Prompt/Response:
To access Stored Controls Menu from the Stored Data Utilities menu, press:	Numeric key 2
The display will prompt: STORED CONTROLS MENU 1 = Modify Stored Control Setup 2 = Delete all Stored Controls 3 = Delete Ctrls by Test/Lot # 4 = Print Stored Ctrls by Test # 5 = Levey-Jennings Report 6 = Return to Previous Menu Enter Menu Number: QUIT	Stored Controls Menu Enter Menu Number: A short description of each option follows below. Select the numeric key that corresponds with the option desired.

Press:

- Numeric Key 1 To modify the stored control setup associated with a selected stored user test.
- Numeric Key 2 To delete all of the stored controls in the instrument.
- Numeric Key 3 To delete controls associated with a test and lot # the user selects.
- Numeric Key 4 To print the controls associated with a stored test # the user selects.
- Numeric Key 5 To print a Levy-Jennings report. Select the test to use as well as the type of controls.
- Numeric Key 6 To return to the Stored Data Utilities Menu.
- Function Key F1 QUIT To return to the Main Menu.

2.4.1.3 Patient Result Data Menu

Patient Result Data Menu:	Prompt/Response:	
To access Stored Patient Result Menu from the Stored	Numeric key 3	
Data Utilities menu, press:		
·		
The display will prompt:	Stored Patient Result Menu	
STORED PATIENT RESULT MENU 1 = Print Patient Report by Pat. ID 2 = Delete ALL Results by Pat. ID 3 = Delete ALL Results by Test # 4 = Delete ALL Patient Results 5 = Print ALL Patient Reports 6 = Return to Previous Menu Enter Menu Number: QUIT	Enter Menu Number: A short description of each option follows below. Select the numeric key that corresponds with the option desired.	

Press:

- **Numeric Key 1** To print a patient report by entering the patient's ID number.
- **Numeric Key 2** To delete all results associated with a patient ID number the user entered.
- **Numeric Key 3** To delete all stored patient results associated with a test number the user entered.
- Numeric Key 4 To delete all stored patient results.
- Numeric Key 5 To print all patient reports using the stored results.
- **Numeric Key 6** To return to the Stored Data Utilities Menu.
- Function Key F1 QUIT to return to the Main Menu.

NOTE: Every "result" is stored by this instrument.

If a Patient ID was entered using the Work List or the "Instant Patient ID" feature, the result will be stored referencing the ID the user enter.

If no ID is entered, "No Name" will be used as the default Patient ID.

The "No Name" patient can be removed by deleting "Patient by ID number".

The storage feature is capable of saving the last 512 results. Beyond that, the oldest result is overwritten with each new result.

Awareness Technology, Inc.

2.4.2 Flowcell Configuration

Flowcell Configuration:		Prompt/Response:	
To access Flowcell Configuration from the Instrument Tools Menu, press:			Numeric Key 2
The screen will display:		Current Flowcell STATUS =	
Current Flowcell		The current status of the Flowcell will be highlighted (ON or OFF).	
	et τ	To toggle between Flowcell Mode (ON) and Tube Mode (OFF), press:	
ON/OFF VOI	LUME CAL MENU	ОК	F1 ON/OFF
The screen will displ	ay the current aspiration	n volume.	Current Aspiration VOLUME =
To change the volume, press:			F2 VOLUME
The display will prompt:			Enter Aspiration Volume:
ASPIRATION V	OLUME		Make a selection from the seven volume choices.
0 = 750 3 1 = 600 4	= 450 6 = 300 = 400 7 = 250		Press ENTER (F4) to accept.
2 = 500 5	= 350		Press CLEAR (F3) to entry.
Enter Aspiration Volume:		Press QUIT (F1) to return to the Main Menu.	
QUIT	CLEAR	ENTER	
NOTE : When reading sample in Flowcell Mode, remember to have more sample than the aspiration volume selected. Attempting to aspirate the exact amount of sample may result in poor results due to air mixing with sample. User technique, the shape of the bottom of vessel being			

Awareness Technology, Inc.

used, and the location of the tube during sampling can affect this process.

Flowcell Configuration: (Continued)		Prompt/Response:	
To calibrate the Flowcell from the Flowcell Configuration menu, press:		F3 CAL MENU	
The screen will display:			FLOWCELL CALIBRATION
	1 = Read Water Reference 2 = Flowcell Alignment		Enter Menu Number: A short description of each option follows below.
	Enter Menu Number:		Select the numeric key that corresponds with the option desired.
NOTE : These options may only be used if the Flowcell is active.			

Press:

Numeric Key 1 Read Water Reference:

The instrument references water instead of air when reading with the Flowcell. These reference values are stored in non-volatile memory and used whenever the Flowcell is active and until new values are read.

In order to insure good *blanks* when using the Flowcell, conduct Read Water Reference on a regular basis; time intervals depend upon instrument usage and when encountering unexpected (very high, very low) blank values.

Numeric Key 2 Flowcell Alignment:

NOTE: This option is not necessary under normal operating conditions.

Necessary when a new Flowcell is used, or if a lamp replacement has occurred. Conduct Read Water Reference before and after Flowcell Alignment.

Function Key F1 QUIT to return to Main Menu



2.4.3 Printer Setup

The built-in 40 column thermal graphics printer is used to list information and provide a record of the samples. Connection to an external printer is via the parallel or serial port, located on the rear of the instrument. The internal and external printers can be used at the same time.

NOTE: Before connecting to an external printer or a computer, power OFF the instrument. To advance the paper or send a line feed, press Line Feed. Make sure to set the external printer status to ON.

Printer Setup:	Prompt/Response:
To access Printer Setup from the Instrument Tools Menu, press:	Numeric Key 3
The screen will display:	PRINTER TYPE
PRINTER TYPE 1 = Internal Printer 2 = External Printer 3 = Internal Printer Font Sample 4 = Serial Port Data Output 5 = Return To Previous Menu Enter Menu Number: QUIT	Enter Menu Number: A short description of each option follows below. Select the numeric key that corresponds with the option desired.
Drees	

- Press:
- Numeric Key 1 For Internal Printer see 2.4.3.1 Internal Printer.
- Numeric Key 2 For External Printer see 2.4.3.2 External Printer.
- **Numeric Key 3** For Internal Printer Font Sample see 2.4.3.3 Internal Printer Font Sample.
- Numeric Key 4 Serial Port Data Output see 2.4.3.4 Serial Port Data Output.
- Numeric Key 5 To return to Instrument Tools Menu.
- Function Key 1 F1 QUIT To return to Main Menu.



2.4.3.1 Internal Printer

It is advisable to print at contrast level 3. Higher contrast levels may degrade after several lengthy printouts.

Internal Printer:	Prompt/Response:
To access Printer Setup from the Instrument Tools Menu, press:	Numeric Key 3
The screen will display:	PRINTER TYPE
PRINTER TYPE1 = Internal Printer2 = External Printer3 = Internal Printer Font Sample4 = Serial Port Data Output5 = Return To Previous MenuEnter Menu Number:QUIT	Enter Menu Number: Press Numeric Key 1 for Internal Printer
The screen will display:	Internal Printer STATUS =
Internal Printer STATUS = ON Internal Printer Status CONTRAST = 1 2 3 4 5 Adjustment Range: 1 (Light) to 5 (Dark) Internal Print QUALITY = Letter X Draft X STATUS CONTRAST QUALITY OK	 The current STATUS of the internal printer is highlighted (ON or OFF). The current CONTRAST setting is highlighted. The current QUALITY setting is highlighted. NOTE: It is advisable to print at contrast level 3. Higher contrast levels may degrade after several lengthy printouts.
Press:	

- . Function Key 1 F1 STATUS: Choose printer type (Internal or External).
- Function Key 2 F2 CONTRAST: Press F2 to move to the desired setting (lighter contrast settings print faster). It is advisable to print at contrast level 3. Higher contrast levels may degrade after several lengthy printouts.
- Function Key 3 F3 QUALITY: The Letter setting is a higher quality print compared to the Draft setting and has a much slower print time.

Function Key 4 F4 OK: To return to the Instrument Tools menu.



2.4.3.2 External Printer

External Printer:	Prompt/Response:	
To access Printer Setup from the Instrument Tools Menu, press:	Numeric Key 3	
The screen will display:	PRINTER TYPE	
PRINTER TYPE 1 = Internal Printer 2 = External Printer 3 = Internal Printer Font Sample 4 = Serial Port Data Output 5 = Return To Previous Menu Enter Menu Number: QUIT	Enter Menu Number: Press Numeric Key 2 for External Printer	
The screen will display:	External Printer STATUS =	
External Printer STATUS = ON OFF Current Maximum LINES per PAGE = 18 STATUS LINES/PG OK	The current STATUS of the external printer is highlighted (ON or OFF). The current LINES/PG is displayed.	
Press:		
 Function Key F1 STATUS: To toggle Status ON of OFF. Function Key F2 LINES/PG: To change the lines per page. Use the numeric keys to type at the "Enter Maximum Lines /Page" prompt. Press F4 ENTER when finished. Function Key F4 OK: To return to the Instrument Tools menu. 		



2.4.3.3 Internal Printer Font Sample

Internal Printer Font Sample:	Prompt/Response:	
To access Printer Setup from the Instrument Tools Menu, press:	Numeric Key 3	
The screen will display:	PRINTER TYPE	
PRINTER TYPE1 = Internal Printer2 = External Printer3 = Internal Printer Font Sample4 = Serial Port Data Output5 = Return To Previous MenuEnter Menu Number:QUIT	Enter Menu Number: Press Numeric Key 3 for Internal Printer Font Sample	
The internal printer will print a list of characters in both L available contrast settings:	etter and Draft quality in the five	
Internal Prin	ter ON	
Quality = Letter	Contrast = 5	
ABCDEFGHIJKLMNOPQRSTUVWXYZ		
abcdefghijklmnopqrstuvwxyz		
!"#\$%() *+,/0123456789:		
;< => ?@[]^_		
NOTE: Internal Printer STATUS = ON		

54

2.4.3.4 Serial Port Data Output

Serial Port Data Output:	Prompt/Response:	
To access Printer Setup from the Instrument Tools Menu, press:	Numeric Key 3	
The screen will display:	PRINTER TYPE	
PRINTER TYPE 1 = Internal Printer 2 = External Printer 3 = Internal Printer Font Sample 4 = Serial Port Data Output 5 = Return To Previous Menu Enter Menu Number: QUIT	Enter Menu Number: Press Numeric Key 4 Serial Port Data Output	
The screen will display:	SERIAL OUTPUT	
SERIAL OUTPUT 1 = Printer Data 2 = Laboratory Information System 3 = Return To Previous Menu	Enter Menu Number: A short description of each option follows below.	
Enter Menu Number:	Select the numeric key that corresponds with the option desired.	
QUIT OK		
Press:		
• Numeric Key 1 Printer Data: Sends the same data as the internal printer.		
 Numeric Key 2 Laboratory Information System (LIS): Sends data via a serial cable to an external personal computer. To enable/disable the LIS feature, press F4 TOOLS/Printer Setup/Serial Port Data Output. 		
• Numeric Key 3 Return to Previous Menu: To return to the Printer Type menu.		

Function Key F1 QUIT: to return to Main Menu.

Serial Port Data Output: (Continued)		Prompt/Response:
Serial	Port Data Output format is:	
•	Date	
•	Time	
•	ID of Reading [(such as B(Blank), S(Standard)]	
•	%Abs (only in Multi-Point %Abs Mode)	
-	NOTE : Regarding Column 4, "%Abs", this column column will contain a number from 0 to 100 with ne Absorbance.	will be blank if not a "%Abs" mode. The o decimal places if the test mode is %
•	Absorbance	
•	Result	
•	Flagging	
•	Patient Name	
•	Test Number	
•	Test Name	

2.4.3.5 Print on Demand Feature

Specific to Rate Mode, the print on demand feature allows the user to print an individual sample by pressing the More key while the internal and external printers are set to OFF in printer options [Tools Menu].



2.4.4 Diagnostics Menu

Diagnostics Menu:	Prompt/Response:
To access Diagnostics Menu from the Instrument Tools Menu, press:	Numeric Key 4
The screen will display: DIAGNOSTICS MENU 1 = Filter Voltages 2 = Filter Wheel Speed 3 = Usage Count 4 = Cell, Block Heat Calibration 5 = Current Vac, Temp, Waste Count 6 = Self Check 7 = Return to the TOOLS Menu Enter Menu Number: QUIT	DIAGNOSTICS MENU Enter Menu Number: A short description of each option follows below. Select the numeric key that corresponds with the option desired.

Summary:

- Numeric Key 1 Filter Voltages: Displays all filter voltages for the instrument. See 2.4.4.1.
- **Numeric Key 2 Filter Wheel Speed**: Displays the filter wheel speed in seconds per revolution. See 2.4.4.2.
- **Numeric Key 3 Usage Count**: Shows the number of "Blanks", "Standards", "Samples", "Controls", and the total of those items. See 2.4.4.3.
- Numeric Key 4 Cell, Block Heat Calibration: Enables cell temperature correction and heat block (optional item) temperature correction. See 2.4.4.4.
- Numeric Key 5 Current Vac, Temp, Waste Count: Displays the current "Vacuum", "Heat Cell", "Heat Block", and "Waste" counts. See 2.4.4.5.
- Numeric Key 6 Self Check: The instrument continuously self-checks to insure proper operation. Any error will be immediately reported. The "Self-Check" feature provides additional tests. See 2.4.4.6.
- Numeric Key 7 Return to the TOOLS Menu: To return to the Instrument Tools Menu.
- Function Key 1 F1 QUIT: to return to Main Menu.

Awareness Technology, Inc.

2.4.4.1 Filter Voltages

Filter Voltages	5:				Prompt/F	Response:
To access Filter V press:	/oltages fro	m the Diag	nostics Men	U,	Numeric K	ey 1
The screen will d	isplay:				Lamp War	mup: xx Secs
Where xx Secs is	the time in	seconds.			Calculating	g Filter Voltages
The screen will d	isplay all filt	er voltages	for the instr	ument:		
	nm	Abs	Count	Vol	t Pot]
	SP2	3.670	59384	0.00	2 32	
	340	0.080	1307	9.94	3 95	
	405	0.227	3679	7.06	9 79	
	505	0.194	3152	7.62	5 55	
	545	0.282	4572	6.21	7 79	
	580	0.326	5285	5.61	1 32	
	630	0.307	4975	5.86	67 40	
	SP1	3.625	58658	0.00)2 32	
	QUIT		PRI	NT	ОК	
Press:						
Function Key 4 F4 OK: To return to the Diagnostics Menu						
Function Key 3 F3 PRINT: To print the results						
Function Key 1 F1 QUIT: To return to the Main Menu						

2.4.4.2 Filter Wheel Speed

Filter Wheel Speed:	Prompt/Response:
To access Filter Wheel Speed from the Diagnostics Menu, press:	Numeric Key 2
The screen will display the filter wheel speed in seconds per revolution.	Wheel Speed x.xxx Secs/rev Press ENTER to print result and
Print result and return to Diagnostics Menu.	return
To return to the Main Menu, press:	Function Key 1 F1 QUIT

2.4.4.3 Usage Count

Usage Count:	Prompt/Response:			
To access Usage Count from the Diagnostics Menu, press:	Numeric Key 3			
The screen will display the number of blanks, standards, samples, controls, and the total of those items.				
Press:				
Function Key 4 F4 ENTER: To return to the Diagnostics Menu				
Function Key 3 F3 CLEAR: To reset all categories to zero				
Function Key 1 F1 QUIT: To return to the Main Menu				

2.4.4.4 Cell, Block Heat Calibration

Cell, Block Heat Calibration:		Prompt/Response:
To access Cell, Block Heat Calibration from the Diagnostics Menu, press:		Numeric Key 4
The screen will display:		 HEATER MENU
	HEATER MENU	
	1 = Cell Heat Calibration	Enter Menu Number:
	2 = Block Heat Calibration 3 = Return to the Previous Menu	Select the numeric key that corresponds with the option desired.
	Enter Menu Number:	
	QUIT	



Cell, Block Heat Calibration: (Continued)	Prompt/Response:		
For Cell Heat Calibration, press:	Numeric Key 1		
Display will prompt:	Cell Temp Correction =		
Type in cell temp correction, press:	ENTER		
For Block Heat Calibration, press:	Numeric Key 2		
Display will prompt:	Block Temp Correction =		
Type in block temp correction, press:	ENTER		
Press:			
Numeric Key 3 Return to Previous Menu: To return to the Diagnostics Menu			
Function Key 1 F1 QUIT: To return to Main Menu			

2.4.4.5 Current Vacuum, Temperature, Waste Count

Current Vacuum, Temperature, Waste Count:	Prompt/Response:
To access option Current Vac, Temp, Waste Count from	Numeric Key 5
the Diagnostics Menu, press:	
The screen will display:	Current Vacuum, Heat Cell, Heat Block, and Waste Count
VAC. COUNT: #.#	
CELL COUNT: ###.#	
BLOCK COUNT: ###.#	
WASTE COUNT: ###.# Press Enter to Return to Menu	Press Function Key 4 F4 ENTER to return to Diagnostics Menu
QUIT ENTER	
where ## represents numbers	
To return to the Main Menu, press:	Function Key 1 F1 QUIT



2.4.4.6 Self Check

Self Check:	Prompt/Response:
To access Self Check from the Diagnostics Menu, press:	Numeric Key 6
NOTE : Remove the Flowcell or tubes to use this function.	
The screen will display:	Lamp Warmup: xx Secs
Lamp Warmup: xx Secs	
QUIT ENTER where xx represents Seconds	
The screen will display:	The EEPROM, NV RAM, Vacuum System, Aspiration Valve, and
System Diagnostics:	Photometer are all checked.
EEPROMOKNV RAMOKVacuum SystemOKAspiration ValveOKPhotometerOKREPEATENTER	Test results will be reported on the display and printer. An error will be immediately reported on the display and the printout. For more information on error messages, see Section 6 Troubleshooting .
To return to the Main Menu, press:	Function Key 1 (F1) QUIT



2.4.5 General Configuration

General Configuration:	Prompt/Response:
To access General Configuration Menu from the Instrument Tools Menu, press:	Numeric Key 5
The screen will display: GENERAL CONFIGURATION 1 = Set Date and Time 2 = Laboratory Name Option 3 = Sample/Reagent Vol. Option 4 = Cell & Block Heat Control 5 = Custom Unit Setup 6 = Return to the TOOLS Menu Enter Menu Number: QUIT	GENERAL CONFIGURATION Enter Menu Number: A short description of each option follows below. Select the numeric key that corresponds with the option desired.

Summary:

- Numeric Key 1 Set Date and Time: Display will prompt to choose Date Format. See . 2.4.5.1.
- Numeric Key 2 Laboratory Name Option: Allows user to enter a specific laboratory name. See 2.4.5.2.
- Numeric Key 3 Sample/Reagent Vol. Option: Allows user to enter a reagent and sample volume when programming a test when this feature is enabled. The values are stored with the test and printed during recall. This feature remains active until disabled. See 2.4.5.3.
- Numeric Key 4 Cell & Block Heat Control: Enables cell temperature control and heat block (optional item) temperature control. See 2.4.5.4.
- Numeric Key 5 Custom Unit Setup: Allows user to enter or delete a custom unit. See . 2.4.5.5.
- Numeric Key 6 Return to the TOOLS Menu: To return to the Instrument Tools Menu.
- Function Key 1 F1 QUIT: to return to Main Menu.



2.4.5.1 Set Date and Time

Set Date and Time:	Prompt/Response:
To access Set Date and Time from the General Configuration Menu, press:	Numeric Key 1
The display will prompt:	Select a Date Format:
Select a Date Format:	0 = MM/DD/YY
0 = MM/DD/YY 1 = DD.MM.YY	1 = DD.MM.YY
QUIT CLEAR ENTER	
NOTE: If using a Chinese instrument, the date format is fixed at YY.MM.DD.	
For MM/DD/YY date format, press:	Numeric Key 0 Press Enter
For Eurodate format DD.MM.YY, press:	Numeric Key 1 Press Enter
NOTE : Remember to separate entries with a decimal point before pressing Enter.	
Press:	l
Numeric Key 3 CLEAR: To clear the entry.	
Function Key F1 QUIT: To return to Main Menu.	
The display will prompt:	Enter Date as:
	The date format will display based on
	option chosen above.
Enter Date as:	
QUIT CLEAR ENTER	


Set Date and Time: (Continued)	Prompt/Response:	
The display will prompt:	Enter Time as: HH.MM.SS	
	Where HH equals Hours,	
	MM equals Minutes,	
Enter Time as: HH.MM.SS	SS equals Seconds.	
QUIT CLEAR ENTER	Enter time remembering to insert decimals as separators.	
	Press ENTER.	
Press:		
Function Key 1 F1 QUIT to return to the Main Menu.		
Function Key 4 F4 ENTER to return to the General Configurations Menu.		

2.4.5.2 Laboratory Name Options

Laboratory Name Options:	Prompt/Response:
To access Laboratory Name Options from the General Configuration Menu, press:	Numeric Key 2
The display will prompt:	LABORATORY NAME:
LABORATORY NAME:	Enter Menu Number:
1 = Enter Laboratory Name 2 = Delete Laboratory Name 3 = Return to Previous Menu	Select the numeric key that corresponds with the option desired.
Enter Menu Number:	
To enter laboratory name, press:	Numeric Key 1



Laboratory Name Options: (Continued)	Prompt/Response:
The display will prompt:	Enter Your Laboratory Name:
Enter Your Laboratory Name: CHARACTER SELECTION: ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijklmnopqrstuvwxyz !"#\$%&()*+,/0123456789: ;<=>?@[]^_ TO MOVE CURSOR 4=LEFT 6=RIGHT 2=UP 8=DOWN	Z Function key attributes: F1 QUIT F2 BACK SPACE F3 SELECT F4 OK Numeric key attributes: Numeric 4 key MOVE CURSOR
QUIT BACK SP. SELECT OK	
	RIGHT
	Numeric 2 key MOVE CURSOR UP
	Numeric 8 key MOVE CURSOR DOW
	Refer to Section 3.1.6 Entering Names
To delete laboratory name, press:	Numeric Key 2
To return to the previous menu, press:	Numeric Key 3

2.4.5.3 Sample/Reagent Volume Option

	Sample/Reagent Volume Option:	Prompt/Response:
(To access Laboratory Name Options from the General Configuration Menu, press:	Numeric Key 3
	The display will prompt:	Enable this Feature?
	When programming a test, the User will be prompted for a Reagent and a Sample Volume. These values will be stored with the test and printed during recall.	
	Enable this Feature?	NOTE: This facture remains active
	QUIT NO YES	until turned off.
Press:		
Function Key F4 YES Enable: Enables this feature to prompt user for a reagent and sample volume when programming a test.		
Function Key F3 NO Disable: Disables this feature.		
Function Key F1 QUIT: To return to the Main Menu.		



2.4.5.4 Cell & Block Heat Control

NOTE: Allow at least 15 minutes for the instrument to equilibrate after enabling or disabling cell or block temperature control. When installing a room-temperature cuvette or the flowcell to an instrument that has already reached temperature equilibration, allow at least 5 minutes for the cuvette or the flowcell to equilibrate after insertion.

Cell & Block Heat Control:	Prompt/Response:
To access Cell & Block Heat Control from the General Configuration Menu, press:	Numeric Key 4
The display will prompt:	TEMPERATURE CONTROL:
TEMPERATURE CONTROL: 1 = Cell Temperature Control 2 = External Block Temp. Control 3 = Return to Previous Menu	Enter Menu Number: Select the numeric key that corresponds with the option desired.
Enter Menu Number:	
For Cell Temperature Control, press:	Numeric Key 1 Cell Temperature Control
Screen will display:	Cell Temperature Control:
Cell Temperature Control:	The current STATUS is highlighted (ON or OFF).
Heat / Cool ON OFF Display ON OFF Temperature Setting 25 30 37 C	NOTE: Temperature settings 25 and 30 are only displayed if the Peltier option is available.
Enable Menu Number:	

Cell & Block Heat Control: (Continued)	Promnt/Resnanse:
	r rompartesponse.

Press		
Pless.		
 Function Key F1 ON/OFF: Toggle ON to enable the cell holder or read well temperature to be set at 37° C. Toggle OFF to leave the cell holder at ambient temperature. 		
NOTE : Even with temperature control disabled, the ambient temperature of the cell is somewhat higher than room temperature.		
 Function Key F2 DISPLAY: With cell temperature ON, allows user to display the temperature on the instrument. 		
Function Key F3 TEMP: Allows user to select temper	rature setting.	
 Function Key F4 OK: To return to the Temperature Control menu. 		
To access Cell & Block Heat Control from the General Configuration Menu, press:	Numeric Key 4	
The display will prompt:	TEMPERATURE CONTROL:	
TEMPERATURE CONTROL:	Enter Menu Number:	
1 = Cell Temperature Control 2 = External Block Temp. Control 3 = Return to Previous Menu	Select the numeric key that corresponds with the option desired.	
Enter Menu Number:		
For External Block Temperature Control (available as an optional accessory), press:	Numeric Key 2 External Block Temperature Control	



_				
(Cell & Block Heat Control: (Continued)	Prompt/Response:		
S	Screen will display:	External Block Temperature Control:		
	External Block Temperature Control			
		The current STATUS is highlighted		
	Heat ON DEE	(ON or OFF).		
	Tomporature Setting 27 C			
	Enter Manus Number			
	Enter Menu Number:			
F	Press:	•		

Function Key F1 ON/OFF: Toggle ON to enable the cell holder or read well temperature to be set at 37° C. Toggle OFF to leave the cell holder at ambient temperature.

NOTE: Even with temperature control disabled, the ambient temperature of the cell is somewhat higher than room temperature.

- Function Key F2 DISPLAY: With cell temperature ON, allows user to display the temperature on the instrument.
- Function Key F4 OK: To return to the Temperature Control menu.

2.4.5.5 Custom Unit Setup

NOTE: If a Custom Unit has been entered previously, entering a new one will overwrite it. The Custom Unit appears as the last one in the list when the "Select Unit" screen is displayed during programming of a Calculation Mode.

Custom Unit Setup:	Prompt/Response:
To access Custom Unit Setup from the General Configuration Menu, press:	Numeric Key 5
The display will prompt:	CUSTOM UNIT SETUP:
CUSTOM UNIT SETUP:	Enter Menu Number:
1 = Enter Custom Unit 2 = Delete Custom Unit 3 = Return to Previous Menu Enter Menu Number:	Select the numeric key that corresponds with the option desired.
For option Enter Custom Unit, press:	Numeric Key 1
Screen will display:	Enter Custom Unit (6 Chars Max):
Enter Custom Unit (6 Chars Max):	Function key attributes:
CHARACTER SELECTION: ABCDEFGHIJKLMNOPORSTUVWXYZ	F1 QUIT
	F2 BACK SPACE
!"#\$%&()*+,/0123456789:	F3 SELECT
;<=>?@[]^_ TO MOVE CURSOR 4=LEET 6=RIGHT 2=LIP 8=DOWN	F4 OK
	Numeric key attributes:
DACK OF. BLEOT OK	Numeric 4 key MOVE CURSOR
Use the numeric keys to move the cursor to create the	
alpha/numeric custom unit name.	Numeric 6 key MOVE CURSOR RIGHT
One character at a time, use F3 to select the alpha/numeric characters.	Numeric 2 key MOVE CURSOR UP
Press F4 OK when finished.	Numeric 8 key MOVE CURSOR DOWN

Сι	ustom Unit Setup: (Continued)	Prompt/Response:
Refer to Section 3.1.6 Entering Names		
Press:		
•	 Numeric Key 2 Delete Custom Unit: To delete the custom unit. 	
•	• Numeric Key 3 Return to Previous Menu: To return to the General Configuration Menu.	
•	Function Key F1 QUIT: To return to the Main Menu.	



3. OPERATING PROCEDURES

3.1 General Selections

3.1.1 External Ports

An external printer may be connected to the parallel port on the rear of the unit. Use any IBM[®] compatible printer and standard parallel cable with the parallel port. The serial port on the Stat Fax[®] 3300 is "Multi-Directional" (transmits and receives data).

The receiving device may stop the transmission from the instrument momentarily. It will resume automatically when the receiving device is ready. Refer to Section 6 Troubleshooting if any error messages occur.

3.1.2 Serial Port

To connect a computer with a serial port to the instrument, use a standard RS232 Cable (Null Modem Serial Cable). The data format is 9600 baud, 8 bits, 1 stop bit, and no parity. Contact your distributor to obtain a serial printer cable.

3.1.3 PC Connection

The serial port pinout is configured to allow direct connection to a PC. To view the output on a PC use a program such as HyperTerminal[®] once the communications protocol in the program has been set to the Stat Fax® 3300 data format.

- **3 TD** (TRANSMIT DATA output)
- 5 GND (SIGNAL GROUND)
- 8 CTS (CLEAR TO SEND input)

3.1.4 External Keyboard

The Stat Fax[®] 3300 can also be operated using an external keyboard (optional) attached to the port on the rear panel.

The lamp, line feed, form feed and Enter key functions may be executed via the external keyboard as shown below:

Function Key	Description
F9	LAMP
F10	LINE FEED
F11	FORM FEED
F12	ENTER

NOTE: The instrument keypad will be overridden in the event of a keypad key sticking. The instrument will emit a series of beeps and the external keyboard (optional) will be enabled.



3.1.5 Units of Measurement

In all modes except "Absorbance Mode", the option of selecting units of measurement is given. Units are provided to label the calculated concentrations, but have no bearing on the actual calculation.

The display shows the "Available Units / Enter Unit Code" screen. Press the numeric key that corresponds to the choice and **ENTER**. The units selected must be confirmed.

To leave units blank, use Unit #14.

NOTE: Unit #14 will only be blank if custom units were not created. (Refer to Item 5 Custom Unit Setup in *Section 2.4.5 General Configuration*.)

3.1.6 Entering Names

The following explains Keypad Entry and External Keyboard Entry:



Use the numeric keys to move the cursor to create the alpha/numeric name.



74

External Keyboard Entry:

The keypad menu screen will not appear if the External Keyboard is active.

NOTE: Instant Patient ID - When running a test, a Patient # (or name, if using External Keyboard) can be entered just before the patient's Sample is read. The corresponding results will be saved referencing this Patient ID.

3.1.7 Ranges and Controls

In all modes except "Absorbance Mode", the user has the option of entering ranges and/or controls.

3.1.7.1 Setup Ranges

Setup Ranges:	Prompt/Response:
At the Results Parameters Menu the display will prompt:	Enter Menu Number:
RESULT PARAMETERS 1 = Setup Ranges 2 = Setup Controls 3 = Setup is Complete Enter Menu Number:	Select the numeric key that corresponds with the option desired.
To select Setup Ranges, press:	Numeric Key 1 Set Up Ranges



Setup Ranges: (Continued)	Prompt/Response:	
If applicable, enter the range values as prompted:	Minimum Blank Abs =	
RANGES: MIN: MAX:	Maximum Blank Abs =	
Diank Aba	Low Normal Range =	
Normal Range	High Normal Range =	
Linear Range	Low Linearity Range =	
COMPLETE	High Linearity Range =	
	Press Enter to accept value, otherwise use Enter to skip a value field.	
RANGES:MIN:MAX:Blank Abs.Normal Range25.0Linear Range45.055.0	When Setup Ranges is finished, COMPLETE appears highlighted in the lower corner of the display screen.	
COMPLETE Press Enter to Save QUIT Output CLEAR ENTER		
To save all values, press:	Press Enter to Save	
Press:		
Function Key F4 ENTER to skip over a value field, or accept an entry.		
Function Key F3 CLEAR to erase a value before pressing the enter key.		
Function Key F2 ARROW to move to any of the range fields.		





Setup Ranges: (Continued)	Prompt/Response:
When the instrument takes a reading that is not within the "Normal" or "Linear" Range, one of the following will appear as a " FLAG " at the right of the concentration on both the Display and the Printer. If the concentration is within the "Normal" range, there will be no flag.	LOW The concentration is lower than the "Minimum" value of the Normal range, but within the Linear range.
NOTE: To view the "CD" and " $0/CV$ " data for the Data	HIGH
Mote: To view the SD and %CV data for the Rate Modes, the user must enter a maximum "SD" value in the "Set Ranges" segment of the test setup. After each sample, the user may press the " MORE " key to view the interval results and the "SD" and "%CV" data.	The concentration is higher than the "Maximum" value of the Normal range, but within the Linear range.
	Ουτ
	The concentration is outside the Linear range.

3.1.7.2 Setup Controls

Controls are designated samples with specified concentration ranges that provide a reference for comparison.

Up to three Controls per test can be entered and named.

Setup Controls:	Prompt/Response:
At the Result Parameters Menu, the display will prompt:	Enter Menu Number:
RESULT PARAMETERS	
1 = Setup Ranges 2 = Setup Controls	
3 = Setup is Complete	
Entor Monu Numbor:	
	Numeric Key 2
	Set Up Controls
The display will display the Control Selection Menu and	CONTROL SELECTION
CONTROL SELECTION	Enter Menu Number:
1 = Normal Control	Select the numeric key that
2 = Abnormal Control	corresponds with the option desired.
3 = Other Control 4 = Save All Changes, Return	
QUIT	
NOTE: The information and screen prompts shown in this	section, Setup Controls, apply to each
option shown on the Control Selection menu.	

Setup Controls: (Continued)	Prompt/Response:
To access the Normal Control option on the Control Selection Menu, press:	Numeric Key 1
	Normal Control
The screen will display:	Normal Control
Normal Control QUIT ENABLE DISABLE	
To enable normal control, press:	Function Key 3 ENABLE
The display will prompt:	Enter Normal Control Name:
CHARACTER SELECTION:	Function key attributes:
ABCDEFGHIJKLMNOPQRSTUVWXYZ ▲	F1 QUIT
abcdefghijklmnopqrstuvwxyz !"#\$%&()*+/0123456789:	F2 BACK SPACE
;<=>?@[]^_	F3 SELECT
TO MOVE CURSOR 4=LEFT 6=RIGHT 2=UP 8=DOWN	F4 OK
	Numeric key attributes:
QUIT BACK SP. SELECT OK	Numeric 4 key MOVE CURSOR LEFT
Use the numeric keys to move the cursor to create the alpha/numeric normal control name.	Numeric 6 key MOVE CURSOR RIGHT
One character at a time, use F3 to select the alpha/numeric characters	Numeric 2 key MOVE CURSOR UP
Press F4 OK when finished.	Numeric 8 key MOVE CURSOR DOWN

Setup Controls: (Continued)	Prompt/Response:
The display will prompt:	Enter Normal Control Lot Number:
CHARACTER SELECTION: ABCDEFGHIJKLMNOPQRSTUVWXYZ	Function key attributes:
	F1 QUIT
!"#\$%&()*+,/0123456789:	F2 BACK SPACE
;<=>?@[]^_	F3 SELECT
TO MOVE CURSOR 4=LEFT 6=RIGHT 2=UP 8=DOWN	F4 OK
	Numeric key attributes:
QUIT BACK SP. SELECT OK	Numeric 4 key MOVE CURSOR LEFT
Use the numeric keys to move the cursor to create the alpha/numeric normal control name.	Numeric 6 key MOVE CURSOR RIGHT
One character at a time, use F3 to select the alpha/numeric characters.	Numeric 2 key MOVE CURSOR UP
Press F4 OK when finished.	Numeric 8 key MOVE CURSOR DOWN
The display will prompt:	Enter Control Expiration Date:
Normal Control Enter Control Expiration Date:	Use Format MM.YY
Use Format MM.YY	
QUIT CLEAR ENTER	
Use the keypad or keyboard to enter the expiration date in the MM.YY format.	For example, for expiration date September 2007, enter 09.07
When finished, press:	F4 ENTER



Setup Controls: (Cont	inued)			Prompt/Response:
The display will prompt:				RANGE SETUP
Norm RANG	al Control GE SETUP			Enter Low Range Limit:
Enter Low Range L	imit:			
QUIT	CLEAR	ENTER		
This information is printed on the running of a test. Type in a range, press:	for reference onl	y; it has no effe	ect	Function Key F4 ENTER
The display will prompt:				Enter High Range Limit:
Normal Control RANGE SETUP Enter High Range Limit: QUIT CLEAR ENTER				
Type in a range, press:				Function Key F4 ENTER



Setup Controls: (Continued)	Prompt/Response:	
The display will prompt:	Choose a Reaction for a FAILED	
Normal Control Choose a Reaction for a FAII FD Control		
1 = Warn, Save to Q.C., Continue 2 = Warn, Do Not Save to Q.C. Continue W/No Interp. & Saving 3 = Warn, Do Not Save, End Test 4 = Warn, Never Saves Ctrl Data Enter Menu Number: QUIT	Select the numeric key that corresponds with the option desired. The display will return to the Control Selection Menu.	
Select another control from the Control Selection Menu CONTROL SELECTION 1 = Normal Control 2 = Abnormal Control	NOTE : The information and screen prompts shown in this section, Setup Controls, apply to each option shown on the Control Selection menu.	
3 = Other Control 4 = Save All Changes, Return Enter Menu Number:		
QUIT		
To save all changes and return to the Result Paramete	ers Numeric Key 4	
	Save All Changes, Return	
Control results can be saved (see Section 2.4.1.2 Control Data Menu) and used later to generate a Levey-Jennings report (refer to Section 3.1.12 Report).		



Setup Controls: (Continued)	Prompt/Response:
At the Result Parameters Menu, the display will prompt:	Enter Menu Number:
RESULT PARAMETERS 1 = Setup Ranges 2 = Setup Controls 3 = Setup is Complete Enter Menu Number: QUIT	Select the numeric key that corresponds with the option desired.
When finished, select Setup is Complete, press:	Numeric Key 3
NOTE: During the test, a Controls button will display allowir the user the opportunity to initiate the next sample to be on of the predefined controls.	ng Setup is Complete e
To return to the Main Menu, press:	Function Key 1 QUIT)

3.1.8 Blanking

By pressing the **BLANK** key, blanking can be done anytime and as many times as the user chooses.

The blank absorbance that is printed is relative to air when in Tube Mode. In Flowcell Mode, it is relative to the stored water values. The user should evaluate the suitability of the blank before using it.

Blanking:	Prompt/Response:
Each time a mode is selected or a test is recalled (optional) the instrument prompts:	Read the Blank
Insert a tube containing blank material, or sample the blank material using the Flowcell.	
The absorbance of the blank will print with a 'B' in place of the sample number.	
NOTE: In "Rate Mode" the value of the blank is not printed. To re-blank the instrument without re-selecting the mode, press:	BLANK



3.1.9 Reading Samples

Procedures for reading samples with tubes or cuvettes, and using the Flowcell follow.

3.1.9.1 Using Tubes or Cuvettes

Using Tubes or Cuvettes:	Prompt/Response:
The display will prompt:	Read Blank or Read Sample
Insert the tube or cuvette into the read well.	
The instrument takes the reading, and displays and prints the result.	
After the result is displayed, the tube may be removed.	
The instrument prompts to insert the next tube.	

3.1.9.2 Using the Flowcell

Using the Flowcell:	Prompt/Response:
When the ready indicator light is on, the screen display will prompt::	Read Blank or Read Sample
Hold the container with the fluid to be sampled so that the sample tube is below the fluid surface.	
Do not allow the sample tube to lie against the bottom of the container.	
Activate the sample sensor.	The instrument will sample the preset amount.
The screen will display:	READING
Remove the sample container from the sample tube.	
When the reading is complete the Sample will be automatically purged from the Flowcell and drawn into the Waste Bottle at the rear of the instrument.	
If the Waste bottle becomes full while running a test in Flowcell Mode, the instrument will display the warning:	WASTE IS FULL!!!

Using the Flowcell: (Continued)	Prompt/Response:
After approximately five aspirations, a continuous beeping sound will be emitted, and a new warning will be displayed:	EMPTY WASTE - PRESS ENTER TO GET SAMPLE
The pump will turn off, and the message will continue to display until the Enter key is pressed. Empty Waste bottle and press Enter.	Press ENTER
The instrument is ready for the next sample when the indicator lights on the keypad:	READY
A Standby button is available for use at any time, while in Flowcell Mode. This option pauses the aspiration vacuum allowing the Waste bottle to be emptied without exiting the test. Select Function Key F2 MORE, and then select Function Key F3 Standby.	STANDBY

3.1.10 Bichromatic Operation (Differential Filter)

The instrument allows the user to read bichromatically with no increase in read time.

- Bichromatic readings should be performed whenever possible, especially in Rate • Mode. The absorbance at the differential wavelength is subtracted from the absorbance at the primary wavelength.
- Differential (bichromatic) reading is recommended. Precision is significantly • improved by removing the effect of optical imperfections and non-uniform wall thickness when using disposable plastic cuvettes or glass tubes.
- In order to preserve sensitivity, it is important to choose a differential wavelength ٠ for which the chromophore being assayed exhibits minimal absorbance.

WAVELENGTH	CHROMOPHORE
340	UV
405	Purple
505	Blue Green
545	Emerald Green
580	Yellow
630	Red

To test a chromophore, read a darkly colored solution in the absorbance mode at the operating wavelength with no differential filter, and again at the operating wavelength with the differential filter selection.

If the two absorbance readings are within 10% of each other, then bichromatic differential reading is beneficial. If the difference between the absorbance readings with and without a differential wavelength is greater than 25%, then the chromophore is absorbing at or near the differential wavelength and bichromatic reading at this wavelength is probably not desirable.



If a bichromatic wavelength is not selected, exercise every measure to enhance repeatability. Choose a better quality reading vessel and wipe fingerprints from each tube before reading. Mark each tube for uniform orientation when multiple readings are desired. Determine the acceptability of the precision by reading the same tube several times and observing the variation of the readings. Depending on the precision requirements of the assay, monochromatic reading may or may not be acceptable with certain plastic tubes.

- $\sqrt{}$ Wipe any dust, moisture, or fingerprints from the tubes before using.
- $\sqrt{}$ Do not read tubes that contain bubbles or condensation.
- $\sqrt{}$ Use a blank material with absorbance of less than 0.400A.
- $\sqrt{}$ Use the same type and size of tube for the blank and samples.

3.1.11 Saving Tests

Saving Tests:	Prompt/Response:
During programming of a test, the user will be prompted to save and name the test. When a test is saved, it will always be saved as the next available number - 1, 2, 3, 4, etc.	
The display will prompt:	SAVE THE TEST?
Save the Test?	
QUIT NO YES	

Saving Tests: (Continued)	Prompt/Response:
If YES, the display will prompt: Name the Test?	NAME THE TEST?
The display will prompt:	Enter User Test Name:
Enter User Test Name:	Function key attributes:
	F1 QUIT
ABCDEFGHIJKLMINOPQRSTOVWXYZ	F2 BACK SPACE
abcdefghijklmnopqrstuvwxyz I"#\$%&()*+ - /0123456789	F3 SELECT
;<=>?@[]^_	F4 OK
TO MOVE CURSOR 4=LEFT 6=RIGHT 2=UP 8=DOWN	Numeric key attributes:
QUIT BACK SP. SELECT OK	Numeric 4 key MOVE CURSOR LEFT
Use the numeric keys to move the cursor to create the	Numeric 6 key MOVE CURSOR RIGHT
alpha/numeric user test name.	Numeric 2 key MOVE CURSOR UP
One character at a time, use F3 to select the alpha/numeri characters.	C Numeric 8 key MOVE CURSOR DOWN
Press F4 OK when finished.	
The screen will display the test number and test name:	Saving Test #



3.1.12 Reports

The instrument provides reports to the internal and/or external printer, showing the stored patient data, an interpretation along with logged information, such as: the test name, date and time, and space for laboratory information.

Patient data is stored and retrieved by "Patient Name" with room provided for 512 results. See **Section 2.4.1 Stored Data Utilities** for more information.

Using new or stored control values the **Stat Fax**[®] **3300** creates Levey-Jennings plots for quality control. A separate chart for each test and for each lot, with up to 31 points on a graph can be created. When a shift in the value occurs due to a new lot it is explained on the chart, as new SDs are calculated from that point forward.

See Section 2.4.1.2 Control Data Menu for the following information:

- Modify the stored control setup associated with a selected stored user test.
- Delete all of the stored controls in the instrument.
- Delete controls associated with a test and lot number the user selects.
- Print the controls associated with a stored test number the user selects.
- Print a Levey-Jennings Report. Select the test to use as well as the type of controls such as Normal, Abnormal, or Other. The instrument will prompt the user to enter "Which Month.Year?" Enter the MM.YY of the "stored" date. If the search does not result in finding the date and year entered, the instrument will emit a series of beeps, display and print "No Stored Controls matched the criteria".



Sample Levey-Jennings printout

NOTES:



4. CALCULATION PROGRAMS

4.1 Absorbance Mode

In Absorbance Mode, the instrument reads and prints sample absorbances at selected wavelengths. The instrument prints the date and time and the mode of operation.



Absorbance Mode Menu: (Continued)	Prompt/Response:
The screen will display::	SELECT FILTERS
SELECT FILTERS PRIMARY FILTER $1 = 340$ $2 = 405$ $3 = 505$ $4 = 545$ $5 = 580$ $6 = 630$ $6 = 630$ $4 = 545$ DIFFERENTIAL FILTER $1 = 340$ $2 = 405$ $3 = 505$ $4 = 545$ $5 = 580$ $6 = 630$ $0 = NO$ DIFFERENTIAL $ENTER$	Use the numeric keys to select the desired wavelengths, press Enter. Refer to Section 3.1.10 Bichromatic Operation for details.
The display will prompt:	SAVE THE TEST?
Save the Test? QUIT NO YES	Refer to Section 3.1.11 Saving Tests.
Press:	
Function Key 4 YES to save the test and continue.	
Function Key 1 QUIT and return to the Main Menu.	



Absorbance Mode Menu: (Continued)	Prompt/Response:
If YES, the display will prompt:	NAME THE TEST?
Name the Test?	
QUIT NO YES	
Press:	•
Function Key 4 YES to name the test and continue.	
Function Key 3 NO to continue without naming test.	
Function Key 1 QUIT and return to the Main Menu.	
If YES, the display will prompt:	Enter User Test Name:
Enter User Test Name:	Function key attributes:
ABCDEFGHIJKLMNOPQRSTUVWXYZ	F1 QUIT
▲ abcdefabiikImpoparstuwwyyz	F2 BACK SPACE
!"#\$%&()*+,/0123456789:	F3 SELECT
;<=>?@[]^_	F4 OK
TO MOVE CURSOR 4=LEFT 6=RIGHT 2=UP 8=DOWN	Numeric key attributes:
QUIT BACK SP. SELECT OK	Numeric 4 key MOVE CURSOR LEFT
Use the numeric keys to move the cursor to create the alpha/numeric user test name.	Numeric 6 key MOVE CURSOR RIGHT
One character at a time, use F3 to select the alpha/numeric characters.	Numeric 2 key MOVE CURSOR UP
Press F4 OK when finished.	Numeric 8 key MOVE CURSOR DOWN



Absorbance Mode Menu: (Continued)	Prompt/Response:
If YES, the display will prompt:	Read the Blank
Absorbance Mode	
Read the Blank	
QUIT	
NOTE:	
In Tube Mode, the instrument takes an air reference reading	
If Flowcell is active, the instrument references the stored wat	er blank.
Insert the blank tube or sample the blank material. When finished reading, remove the tube or sample material.	See Section 3.1.8 Blanking for details
To re-blank at any point, press:	Function Key F4 BLANK
The display will prompt:	Read Sample 1
Absorbance Mode	Read the sample and repeat as necessary.
Read Sample 1	Refer to Section 3.1.9 Reading Samples.
QUIT	
Press Function Key 1 QUIT to exit Absorbance Mode and reinstrument prints "Test Ended" and returns to the Main Menu	turn to the main prompt. The screen.

94

4.2 Single Standard Mode

In Single Standard Mode, the instrument reads and prints absorbance values, and calculates concentrations based on a standard material of known concentration. Results are calculated according to Beer's Law. The calibration factor is printed for future use.



Single Standard Mode Menu: (Continued)	Prompt/Response:
The display will prompt:	Differential Samples?
Standard Mode Differential Samples?	
QUIT NO YES	
Press:	
Function Key 4 YES to use differential samples. Each sample	ble will have its own Blank. The
Function Key 3 NO to continue without using differential sam	Innles
Function Key 1 QUIT and return to the Main Menu.	ipico.
The display will prompt:	Use the numeric keys to select
SELECT FILTERS	the desired wavelengths, press Enter.
PRIMARY FILTER 1 = 340 2 = 405 3 = 505 4 = 545 5 = 580 6 = 630	Refer to Section 3.1.10 Bichromatic Operation for details.
DIFFERENTIAL FILTER 1 = 340 2 = 405 3 = 505 4 = 545 5 = 580 6 = 630	
0 = NO DIFFERENTIAL	
QUIT	

Single Standard Mode Menu: (Continued)	Prompt/Response:
The display will prompt:	Enter Standard #1 Value:
Standard Mode Enter Standard #1 Value: QUIT CLEAR ENTER	Enter the value of the standard (or calibrator) and press ENTER. NOTE: The instrument will not accept a factor that is up to seven digits, and there can be up to two decimal places.
Press:	
Function Key 3 CLEAR to clear an error and re-enter the val	lue.
Function Key T QUIT and return to the Main Menu.	
The display will prompt:	Enter Unit Code:
AVAILABLE UNITS 0) Conc 1) g/L 2) g/dL 3) mg/dL 4) ug/L 5) ug/dL 6) U/L 7) meg/dL 8) mmol/L 9) mcmo/L 10) IU/mL 11) ukat/L 12) umol/L 13) mol/L 14)	Enter the Unit Code 0 – 17 and press ENTER. See Section 3.1.5 Units of Measurement for details.

Single Standard Mode Menu: (Continued)	Prompt/Response:
Press:	
Function Key 4 ENTER to accept the value.	
Function Key 3 CLEAR to clear an error and re-enter the va	lue.
Function Key 2 MORE to display Units 15, 16 and 17.	
Function Key 1 QUIT and return to the Main Menu.	
The screen will display:	Unit Selected = xx
AVAILABLE UNITS	ACCEPT? x
0) Conc 1) g/L 2) g/dL 3) mg/dL 4) ug/L 5) ug/dL 6) U/L 7) meg/dL 8) mmol/L 9) mcmo/L 10) IU/mL 11) ukat/L 12) umol/L 13) mol/L 14) Unit Selected = xx QUIT NO YES where X equals the selected entry.	
Press:	
Function Key 4 VES to accort colocted unit	
Function Key 1 QUIT and return to the Main Menu.	



Single Standard Mode Menu: (Continued)	Prompt/Response:
The display will prompt:	Result Parameters
RESULT PARAMETERS	Enter Menu Number:
1 = Setup Ranges 2 = Setup Controls 3 = Setup is Complete	Use the numeric keys to select the desired result parameters, press Enter.
Enter Menu Number:	See Section 3.1.7 Ranges and Controls for more on this option.
The display will prompt:	SAVE THE TEST?
Save the Test? QUIT NO YES	Refer to Section 3.1.11 Saving Tests.
Function Key 4 YES to save the test and continue. Function Key 3 NO to continue without saving test. Function Key 1 QUIT and return to the Main Menu.	


Single Standard Mode Menu: (Continued)	Prompt/Response:
If YES, the display will prompt:	NAME THE TEST?
Name the Test ? QUIT NO YES	
Press:	
Function Key 4 YES to save the test and continue.	
Function Key 3 NO to continue without saving test.	
Function Key 1 QUIT and return to the Main Menu.	
If YES, the display will prompt:	Enter User Test Name:
	Function key attributes:
Enter User Test Name:	F1 QUIT
ABCDEFGHIJKLMNOPQRSTUVWXYZ	F2 BACK SPACE
▲ abcdefahiikImnoparstuvwxvz	F3 SELECT
!"#\$%&()*+,/0123456789:	F4 OK
;<=>?@[]^_	Numeric key attributes:
TO MOVE CURSOR 4=LEFT 6=RIGHT 2=UP 8=DOWN	Numeric 4 key MOVE CURSOR LEFT
QUIT BACK SP. SELECT OK	Numeric 6 key MOVE CURSOR
Use the numeric keys to move the cursor to create the	
alpha/numeric user test name.	Numeric 2 key MOVE CURSOR UP
One character at a time, use F3 to select the alpha/numeric characters.	Numeric 8 key MOVE CURSOR DOWN
Press F4 OK when finished.	

Single Standard Mode Menu: (Continued)	Prompt/Response:		
If YES, the display will prompt:	Read the Blank		
Standard Mode Read the Blank	See Section 3.1.8 Blanking for details.		
NOTE:			
In Tube Mode, the instrument takes an air reference reading.			
If Flowcell is active, the instrument references the stored wat	er blank.		
Insert the standard tube or sample the standard material. The instrument will read the absorbance and determine the factor such that the concentration of the standard is the value specified.	Refer to Section 3.1.9 Reading Samples.		
When finished reading, remove the tube or standard material.			
To re-blank at any point, press:			
	BLANK		
The display will prompt:	Read Standard # 1		
Standard Mode Read Standard # 1	Read the standard and repeat as necessary.		
Press Function Key 1 QUIT to exit Single Standard Mode. The instrument prints "Test Ended" and returns to the Main Menu screen.			

4.3 Factor Mode

In Factor Mode, the instrument reads absorbances at the selected wavelengths, and calculates concentrations by multiplying the absorbance by the user supplied factor.



Factor Mode Menu: (Continued)	Prompt/Response:
The display will prompt:	Differential Samples?
Factor Mode	
Differential Samples?	
·	
Drees	
	te d'une e la constante d e e
instrument will prompt for the blank preceding each sample.	le will have its own blank. The
Function Key 3 NO to continue without using differential sam	ples.
Function Key 1 QUIT and return to the Main Menu.	
· · · · · · · · · · · · · · · · · · ·	
The screen will display:	SELECT FILTERS
SELECT ELLTERS	
PRIMARY FILTER	Use the numeric keys to select
1 = 340 2 = 405 3 = 505 4 = 545 5 = 580 6 = 630	the desired wavelengths, press
1 = 340 2 = 405 3 = 505 4 = 545	Refer to Section 3.1.10 Bichromatic Operation for
5 = 580 $6 = 630$	details.
0 - NO DIFFERENTIAL	



Factor Mode Menu: (Continued)	Prompt/Response:
The display will prompt:	Enter Factor:
FACTOR MODE	NOTE: The instrument will not accept a factor that is up to seven digits, and there can be up to two decimal places.
QUIT CLEAR ENTER	
Press:	
Function Key 4 ENTER to accept the value.	
Function Key 3 CLEAR to clear an error and re-enter the va	lue.
Function Key 1 QUIT and return to the Main Menu.	
The display will prompt:	Enter Unit Code:
AVAILABLE UNITS 0) Conc 1) g/L 2) g/dL 3) mg/dL 4) ug/L 5) ug/dL 6) U/L 7) meg/dL 8) mmol/L 9) mcmo/L 10) IU/mL 11) ukat/L 12) umol/L 13) mol/L 14)	Enter the Unit Code 0 – 17 and press ENTER. See Section 3.1.5 Units of Measurement for details.
Enter Unit Code:	
QUIT MORE CLEAR ENTER	

Factor Mode Menu: (Continued)	Prompt/Response:		
Press:			
Function Key 4 ENTER to accept the value.			
Function Key 3 CLEAR to clear an error and re-enter the value.			
Function Key 2 MORE to display Units 15, 16 and 17.			
Function Key 1 QUIT and return to the Main Menu.			
The screen will display:	Unit Selected = xx		
AVAILABLE UNITS	ACCEPT? x		
0) Conc 1) g/L 2) g/dL 3) mg/dL 4) ug/L 5) ug/dL 6) U/L 7) meg/dL 8) mmol/L 9) mcmo/L 10) IU/mL 11) ukat/L 12) umol/L 13) mol/L 14) Unit Selected = xx QUIT NO YES where X equals the selected entry.			
The display will prompt:	Result Parameters		
RESULT PARAMETERS	Enter Menu Number:		
1 = Setup Ranges 2 = Setup Controls 3 = Setup is Complete	Use the numeric keys to select the desired result parameters, press Enter.		
Enter Menu Number:	Controls for more on this option.		



Factor Mode Menu: (Continued)	Prompt/Response:
The display will prompt:	SAVE THE TEST?
Save the Test ?	Refer to Section 3.1.11 Saving Tests.
QUIT NO YES	
Press:	
Function Key 4 YES to save the test and continue.	
Function Key 3 NO to continue without saving test.	
Function Key 1 QUIT and return to the Main Menu.	
If YES, the display will prompt:	NAME THE TEST?
Name the Test ? QUIT NO YES	
Function Key 4 YES to save the test and continue.	
Function Key 3 NO to continue without saving test.	
Function Key 1 QUIT and return to the Main Menu.	



Factor Mo	de Menu: (Co	ntinued)			Prompt/Response:
If YES, the display will prompt:				Enter User Test Name:	
Enter User Test Name:			Function key attributes:		
ABCD	EFGHIJKLMNC	HON: PQRSTUVW	XYZ		F1 QUIT
▲ abcdef	ahiiklmnonarsti	1\/\//Y\/7			F2 BACK SPACE
!"#\$%	o&()*+,/01234	56789:			F3 SELECT
;<=>?@	@[]^_				F4 OK
TO MOVE	CURSOR 4=LEFT	6=RIGHT 2=UP	8=DOWN		Numeric key attributes:
QUIT	BACK SP.	SELECT	ОК		Numeric 4 key MOVE CURSOR LEFT
Use the num	eric keys to mov	ve the cursor to	o create the		Numeric 6 key MOVE CURSOR RIGHT
alpha/numer	alpha/numeric user test name.		ic	Numeric 2 key MOVE CURSOR UP	
characters.					Numeric 8 key MOVE CURSOR
Press F4 OK when finished.			DOWN		
If YES, the display will prompt:				Read the Blank	
Factor Mo	ode				
Read the Blank					
NOTE:					
In Tube Mode, the instrument takes an air reference reading.					
If Flowcell is active, the instrument references the stored water blank.					



Factor Mode Menu: (Continued)	Prompt/Response:	
Continue with normal sampling following the prompts given by the instrument.		
See Section 3.1.8 Blanking and Section 3.1.9 Reading Samples for details.		
To re-blank at any point, press:	BLANK	
To exit Factor Mode and return to the Main Menu, press:	Function Key 1 QUIT	





4.4 Multi-Point Mode

The instrument reads a number of calibrators (up to 7) and calculates concentrations based on the point-to-point calibration curve. Calibrator materials of known concentrations are used to calibrate the instrument so that concentrations of unknown samples may be calculated.

The resulting calibrator curve is a series of lines connecting the calibrator points, which may be entered in ascending or descending order of absorbance.

The direction of slope between the first and second calibrators determines the direction of the curve. If the direction of the curve changes direction, the curve will be flagged as being "invalid" and no interpretations will be printed.

Differential samples (against sample blanks) are supported. Reference Section 3.1.8 Blanking and Section 3.1.9 Reading Samples.

Unknown samples are calculated as follows:

 The unknown sample's absorbance is read and compared to the absorbance of the calibrator.

The line selected as the calibration curve used to determine the concentration of the unknown Sample is the line that connects the pair of Calibrators with absorbance values closest above and below the value of the unknown absorbance of the Sample.

(An unknown Sample, with absorbance higher than the calibrator with the highest absorbance value, is calculated using a line that passes through the two Calibrator points with the highest absorbance value. An unknown Sample with absorbance lower than the lowest Calibrator absorbance is calculated from the line that passes through the two Calibrators with the lowest absorbance values.)



Multi-Point Mode Menu: (Continued)	Prompt/Response:		
The screen will display:	MODE MENU		
MODE MENU 1 = Absorbance Mode 2 = Single Standard Mode 3 = Factor Mode 4 = Multi-Point Mode 5 = Rate Mode 6 = Index Mode	Enter Menu Number: Press Numeric Key 4 for Multi- Point Mode		
Enter Menu Number:			
QUIT			
The display will prompt:	SELECT MODE TYPE		
SELECT MODE TYPE	Enter Menu Number:		
1 = Standard Multi-Point Mode 2 = Multi-Point % Absorbance Mode	Select the numeric key that corresponds with the option desired.		
Enter Menu Number:			
QUIT			
The Multi-Point % Absorbance Mode is similar in calculation to the Standard Multi-Point Mode, except that the percent absorbance (%Abs) is calculated and printed, and the standards must be in descending order.			
In Standard Multi-Point Mode, the standards should be in or	der from <u>lightest to darkest</u> .		
In Multi-Point % Absorbance Mode, standards must be in order from darkest to lightest.			
Press:			
Numeric Key 1 for Standard Multi-Point Mode			
Numeric Key 2 for Multi-Point % Absorbance Mode			
Function Key 1 QUIT and return to the Main Menu.			

Multi-Point Mode Menu: (Continued)	Prompt/Response:	
The screen will display::	SELECT FILTERS	
SELECT FILTERS PRIMARY FILTER 1 = 340 2 = 405 3 = 505 4 = 545 5 = 580 6 = 630	Use the numeric keys to select the desired wavelengths, press Enter.	
DIFFERENTIAL FILTER 1 = 340 2 = 405 3 = 505 4 = 545 5 = 580 6 = 630 0 = NO DIFFERENTIAL	Refer to Section 3.1.10 Bichromatic Operation for details.	
QUIT		
The display will prompt:	Number of Standards =	
MULTI-POINT MODE	Type in the number of standards and press ENTER.	
Number of Standards =		
QUIT CLEAR ENTER		
Press:		
Function Key 4 ENTER to accept the value.		
Function Key 3 CLEAR to clear an error and re-enter the va	lue.	
Function Key 1 QUIT and return to the Main Menu.		



Prompt/Response:			
ter Standard #1 Value			
e in the standard value in is and press ENTER.			
Press: Function Key 4 ENTER to accept the value. Function Key 3 CLEAR to clear an error and re-enter the value. Function Key 1 QUIT and return to the Main Menu.			
ter Unit Code:			
er the Unit Code 0 – 17 and ss ENTER. Section 3.1.5 Units of asurement for details.			

Multi-Point Mode Menu: (Continued)	Prompt/Response:	
Press:		
Function Key 4 ENTER to accept the value.		
Function Key 3 CLEAR to clear an error and re-enter the va	lue.	
Function Key 2 MORE to display Units 15, 16 and 17.		
Function Key 1 QUIT and return to the Main Menu.		
The screen will display:	Unit Selected = xx	
AVAILABLE UNITS	ACCEPT? x	
0) Conc 1) g/L 2) g/dL 3) mg/dL 4) ug/L 5) ug/dL 6) U/L 7) meg/dL 8) mmol/L 9) mcmo/L 10) IU/mL 11) ukat/L 12) umol/L 13) mol/L 14) Unit Selected = xx QUIT NO YES where X equals the selected entry.		
The display will prompt:	Result Parameters	
RESULT PARAMETERS 1 = Setup Ranges 2 = Setup Controls 3 = Setup is Complete Enter Menu Number:	Enter Menu Number: Use the numeric keys to select the desired result parameters, press Enter. See Section 3.1.7 Ranges and Controls for more on this option.	
QUIT		

Multi-Point Mode Menu: (Continued)	Prompt/Response:
The display will prompt:	SAVE THE TEST?
Save the Test ? QUIT NO YES	Refer to Section 3.1.11 Saving Tests.
Press:	
Function Key 4 YES to save the test and continue.	
Function Key 3 NO to continue without saving test.	
Function Key 1 QUIT and return to the Main Menu.	
If YES, the display will prompt:	NAME THE TEST?
Name the Test ? OUIT NO YES	
If YES, the display will prompt:	Enter User Test Name:
Enter User Test Name: CHARACTER SELECTION: ABCDEFGHIJKLMNOPQRSTUVWXYZ ▲ abcdefghijklmnopqrstuvwxyz !"#\$%&()*+,/0123456789: ;<=>?@[]^_	Function key attributes: F1 QUIT F2 BACK SPACE F3 SELECT F4 OK
TO MOVE CURSOR 4=LEFT 6=RIGHT 2=UP 8=DOWN	Numeric key attributes:
QUIT BACK SP. SELECT OK	Numeric 4 key MOVE CURSOR LEFT
Use the numeric keys to move the cursor to create the	Numeric 6 key MOVE CURSOR RIGHT
One character at a time, use F3 to select the alpha/numeric	Numeric 2 key MOVE CURSOR
characters. Press F4 OK when finished.	Numeric 8 key MOVE CURSOR DOWN

Multi-Point Mode Menu: (Continued)	Prompt/Response:
If YES, the display will prompt:	Read the Blank
Multi-Point Mode	
Read the Blank	
NOTE	
	-
In Tube Mode, the instrument takes an air reference reading.	The lamp will warmup.
If Flowcell is active, the instrument references the stored wat	er blank.
The instrument prompts to read each of the standards in turn.	Read Standard #1
Insert the standard tube or sample the standard material.	
If any of the standards is less than the previous standard (greater than if using Multi-Point % Abs Mode), it will be marked with an "X" and the instrument will print:	-CURVE INVALID!
Since this invalidates the results, repeat the procedure from the beginning.	
Continue with normal sampling following the prompts given by the instrument.	See Section 3.1.8 Blanking and Section 3.1.9 Reading Samples
The instrument will prompt to Read Sample. Insert the tube or sample the material. The concentration is calculated as described above. Repeat this step as desired.	TOF GETAILS.
To re-blank at any point, press:	BLANK
The screen displays the standard curve on the graph.	





4.5 Rate Mode

In Rate Mode, the instrument takes periodic readings of a sample at intervals.

The user supplies the Lag Time and the Read Time, both in seconds:

- Lag Time is the length of time that the instrument pauses before it takes the first reading, and is measured from the point at which the user inserts the tube or aspirates the sample.
- Read Time is the total length of time over which the reaction is monitored.
 - The Lag Time is two seconds minimum.
 - The Read Time can be any number of seconds 30 or more, but no greater than 1798.
 - The combined total of Lag Time plus Read Time cannot exceed 1800 seconds.

Lag Time + Read Time < 1800 seconds

- Read Interval is the interval at which the intermediate readings are taken and recorded, and is fixed at 30 seconds.
- The ΔA/min. or rate of the standard is determined by a linear regression calculation covering the read interval. This ΔA/min. is printed beside S1 and is used to determine the rate factor.

$$\frac{\text{Concentration of Standard}}{\Delta A/\text{min}} = Factor$$

Choose from four calculation methods in Rate Mode:			
Rate by Factor:	Enter a factor that the instrument uses to calculate the concentration of the sample at each reading.		
	······································		
Rate by	Supply a standard material that the instrument reads and uses		
Standard:	to calculate a factor to obtain the concentration of each sample.		
Fixed Time	Enter a factor or supply a standard material as described		
Kinetic:	above. However, results are based on total Δ , not ΔA /min.		
Multi-Point Fixed Time Kinetic:	Similar to Fixed Time Kinetic, except users enter multiple calibrators. The calibrators must be read before running the samples. As in Multi-Point, the standard curve can be edited.		

In addition, Rate by Factor and Rate by Standard tests may be performed individually (consecutively) or in batch mode (simultaneously).

NOTE: Most rate reactions are temperature dependent. Make sure that the cell temperature control is enabled as described in the section "Temperature Control". Allow a minimum of 15 minutes for the cell temperature to equilibrate.

- If the instrument is left idle in Rate Mode, the lamp may be OFF. Be sure to • turn the lamp on and allow the instrument warm-up time before starting a reaction.
- Bichromatic readings should be used in any Rate Mode test. Always select a • differential filter. 630 nm is suggested for readings at 340 or 405 nm. (Reference "Bichromatic Readings")
- When using round test tubes in Rate Mode, the tube gasket supplied MUST be • used. Place the gasket (included with the instrument) on the surface of the read well.

Rate factors for determining units per liter (U/L) must be derived from the following standard formula:		
U/L = <u>ΔA/min. x 1000 x TVmL</u> x TF MA x SVmL x LPcm where:		
U/L	units per Liter	
ΔA/min	mean change in absorbance per minute	
TV	total volume of the reaction mixture (in ml)	
MA	molar absorptivity (ie, the MA of NADH at 340nm = 6.22×10^{3})	
SV	sample volume (in ml)	
LP	cuvette light path (in cm)	
TF	temperature factor used to convert assayed activity to the desired temperature	

Refer to the sections "Rate by Standard" and "Fixed Time Kinetics".

Specific to Rate Mode, the print on demand feature allows the user to print an individual sample by pressing the More key while the internal and external printers are set to OFF in printer options [Tools Menu].



Rate Mode Menu: (Continued)	Prompt/Response:
Summary:	1
• Numeric Keys 1 & 2 Rate By Standard/I except that the factor is determined by div by its ΔA /min. This factor is used to determ samples. The prompts are similar to those standard absorbance is greater than 2.50 returns to the main prompt.	Rate By Factor: Similar to Rate by Factor iding the given concentration of the standard nine the concentration of the unknown e listed above for Rate by Factor. If the the mode is cancelled and the instrument
• Numeric Keys 3 & 4 Batch Mode- Rate Mode is used in conjunction with Rate by simultaneously, rather than consecutively. this way, the prompt is unavailable. Also, prompts to enter the number of samples. I Calibrator (or Standard) must be included of samples = 12.	By Standard/Rate By Factor: Batch Rate Standard or Rate by Factor to read tests Because Fixed Time cannot be performed prior to running the blank, the instrument Note that if running Rate by Standard, the as one of the samples. The maximum number
After the blank is read, the display shows:	
Rate by (Factor or Standard) Add Serum/ Press Enter	
Add the patient samples to the pre-warme timed manner will ensure that the lag time samples have been added, press ENTER time is completed, the display will prompt same uniformly-timed manner in which the when the display is prompting to read that initial reading of the first sample is taken.)	d reagent tubes. Adding them in a uniformly- is consistent across the batch. After all to begin the lag time countdown. After the lag to read the samples. Read the samples in the e samples were added. Assign control labeling sample. (The read time will begin when the
NOTE: The choice to set up controls does in Batch Mode treat it like a sample and co	not function in Batch Mode. To use a control pount it as one of the samples.

Rate Mode Menu: (0	Continued)
--------------------	------------

Prompt/Response:

Summary:

• Numeric Keys 3 & 4 Batch Mode- Rate By Standard/Rate By Factor: (Continued)

After all samples in the batch have had their initial reading, the instrument will count down the remainder of the read time. At the end of the read time, the user will be prompted again to read the samples. Again, read the samples in the same uniformly-timed manner in which the samples were added. After each sample is read, its results will be printed. The instrument will print the actual read time for each sample, and will compensate with a corrected Abs/min result. Note that interval data and plotting are not available, because the sample does not remain in the cuvette well during the rate reaction.

After the last sample has been read, the Rate Mode will discontinue and the printer will print:

*** END OF BATCH ***

- Numeric Keys 5 & 6 Fixed Time Kinetics By Standard/By Factor: Similar to the other Rate Mode variations. However, instead of basing the final calculation on the ΔA/min. of the sample, the calculation is based on the change in absorbance over the read interval. In addition, the Low Activity and Check Linearity conditions will not be displayed, and neither Batch Rate nor interval data reporting is available. This is also true for Batch Rate Modes.
- Numeric Key 7 Multi-Point Fixed Time Kinetic: Similar to Fixed Time Kinetic mode. However, in this mode, the user enters multiple calibrators. These calibrators are read before the Samples are read. The specific points are then plotted. Also uses a user entered lag and read time. As in Multi-Point Mode, the standards curve can be edited (reference 4.4 Multi-Point Mode).

Rate Mode Menu: (Continued)	Prompt/Response:
The screen will display:	Enter Menu Number:
RATE MODE SELECTIONS1 = Rate by Standard2 = Rate by Factor3 = Batch Mode, Rate By Standard4 = Batch Mode, Rate By Factor5 = Fixed Time Kinetic, By Standard6 = Fixed Time Kinetic, By Factor7 = Multipoint Fixed Time KineticEnter Menu Number:QUIT	Press Numeric Key 1 for Rate by Standard
The screen will display:	SELECT FILTERS
SELECT FILTERS PRIMARY FILTER 1 = 340 2 = 405 3 = 505 4 = 545 5 = 580 6 = 630	Use the numeric keys to select the desired wavelengths, press Enter.
DIFFERENTIAL FILTER 1 = 340 2 = 405 3 = 505 4 = 545 5 = 580 6 = 630 0 = NO DIFFERENTIAL	Refer to Section 3.1.10 Bichromatic Operation for details.
QUIT ENTER	
T	
i ne screen will display:	Standard =
Standard Lag Time Read Time Number of Read Intervals Seconds per Interval	Input the value of the Standard, press ENTER
Standard =	
QUIT	

Rate Mode Menu: (Continued)	Prompt/Response:		
NOTE : The combination of the Lag and Read times cannot add up to more than 1800 seconds.			
Standard Lag Time Read Time Number of Read Intervals Seconds per Interval	Enter the value of the Lag Time (2 seconds minimum) and press ENTER. Enter the Read Time (must be greater than or equal to 30 seconds) and press ENTER		
COMPLETE	Enter the Number of Read Intervals (may range from 1 to 80) and press ENTER.		
QUIT CLEAR ENTER	Enter the Seconds per Interval (may range from 5.0 to Read		
NOTE : If the user enters a Seconds/Interval that does not divide evenly into the Read Time, then the Seconds Per Interval will automatically adjust so that it will divide evenly into the Read Time.	An Invalid Entry message will appear if inputs are not within range.		
Press:			
Function Key 4 ENTER to accept the values.			
Function Key 3 CLEAR to clear an error and re-enter the value.			
Function Key 2 ARROW to return to any of the entered var	iables.		
Function Key 1 QUIT to return to the Main Menu.			
The display will prompt:	Enter Unit Code:		
	Enter the Unit Code 0 – 17 and press ENTER.		
3) mg/dL 4) ug/L 5) ug/dL 6) U/L 7) meg/dL 8) mmol/L 9) mcmo/L 10) IU/mL 11) ukat/L 12) umol/L 13) mol/L 14)	See Section 3.1.5 Units of Measurement for details.		
Enter Unit Code:			
QUIT MORE CLEAR ENTER			

Rate Mode Menu: (Continued)	Prompt/Response:		
Press:			
Function Key 4 ENTER to accept the value.			
Function Key 3 CLEAR to clear an error and re-enter the	value.		
Function Key 2 MORE to display Units 15, 16, and 17.			
Function Key 1 QUIT and return to Main Menu.			
The screen will display:	Unit Selected = xx		
	ACCEPT? X		
0) Conc 1) g/L 2) g/dL 3) mg/dl 4) ug/l 5) ug/dl	Press Function Key 4 YES		
6) U/L 7) meg/dL 8) mmol/L	Press Function Key 3 NO		
12) umol/L 13) mol/L 14)	Press Function Key 1 QUIT		
Unit Selected = xx ACCEPT? x			
QUIT NO YES			
	J		
where X equals the selected entry.			
The display will prompt:	Result Parameters		
RESULT PARAMETERS	Enter Menu Number:		
1 = Setup Ranges 2 = Setup Controls 3 = Setup is Complete	Use the numeric keys to select the desired result parameters, press Enter.		
Enter Menu Number:	See Section 3.1.7 Ranges and Controls for more on this option.		
NOTE: To view the SD and %CV data for the Rate modes, the user must enter a maximum SD value in the "Set Ranges" segment of the test setup. After each sample, the user may press the "More" key to view the interval results and the SD and %CV data.			

Rate Mode Menu: (Continued)		Prompt/Response:		
The display will prompt:		SAVE THE TEST?		
Save the Test ? QUIT NO YES			Refer to Section 3.1.11 Saving Tests.	
Press:				
Function Key 4 YES to say	e the test and co	ontinue.		
Function Key 3 NO to cont	inue without savi	ng test.		
Function Key 1 QUIT and	return to the Mair	n Menu.		
If YES, the display will pro	mpt:			NAME THE TEST?
Enter User Test Name	Enter User Test Name:			Enter User Test Name:
CHARACTER SELE ABCDEFGHIJKLM	CTION: NOPORSTUVW	XYZ		Function key attributes:
				F1 QUIT
abcdefghijklmnopqrstuvwxyz !"#\$%&()*+,/0123456789:				F2 BACK SPACE
;<=>?@[]^_				F3 SELECT
TO MOVE CURSOR 4=LE	FT 6=RIGHT 2=UP	8=DOWN		F4 OK
QUIT BACK SP	SELECT	ок		Numeric key attributes:
				Numeric 4 key MOVE CURSOR LEFT
Use the numeric keys to move the cursor to create the alpha/numeric user test name.			Numeric 6 key MOVE CURSOR RIGHT	
One character at a time, use F3 to select the alpha/numeric characters.		Numeric 2 key MOVE CURSOR UP		
Press F4 OK when finished.			Numeric 8 key MOVE CURSOR DOWN	
The display will prompt:				Referencing Air



Rate Mode Menu: (Continued)	Prompt/Response:	
The screen will display:	Rate by Standard	
Reference Sections 3.1.8 Blanking and Section 3.1.9 Reading Samples.	Read the Blank	
The value of the blank will print.		
The display will prompt:	Read the Standard	
Insert the tube or sample the material.		
The Lag Time will begin to count down.		
The screen will display:		
Rate by Standard 405/580 Reading S#: Lag Time: Absorbance: U/L: S1 2 0.0002 Image: Absorbance: U/L: S1 2 0.0002 Image: Absorbance: U/L: The Read Time will count down while charting the activity on the bottom right side of the screen. Dread:		
Press:		
sufficient data to report a valid result.		
After the instrument is finished reading a sample, there will be three buttons displayed at the bottom of the screen: QUIT (F1), MORE (F2), and BLANK (F4).	Press Function Key F2 MORE	



Rate Mode Menu: (Continued)	Prompt/Response:		
Summary:			
Function Key F1 LEFT used to toggle between the two lines. The far right line indicating the end of read interval and the left line at the beginning of the read interval. Pressing this button once will change its label to RIGHT.			
Function Key F2 and F3 ARROWS allow the user to move the two lines in order to select a portion of the graph for purposes of calculating ΔA /Min. by Linear Regression.			
Function Key F4 OK press to end. The instrument then p	rints the new $\Delta A/Min$. and Factor.		
NOTE: After modifying starting and/or ending times, the provinginal readings. If you want to record the changes, you make the changes of the changes of the changes.	rint data function still gives the nust print the modified graph.		
To plot and print the graph, press:	Function Key F2 PLOT		
The plot shows the absorbance along the vertical axis and the time along the horizontal axis. Note that a vertical line indicates the break between the lag phase and the read phase, and the read time label of the horizontal axis begins at the left bar.			
If ranges were entered, the range interpretation is printed to the right of the concentration.			
To print the interval data, press:	Function Key F3 DATA		
The absorbance at 0 and each 30 second interval is printed along with the mean absorbance per minute for each interval. The instrument will automatically add a linefeed after printing interval data for one Sample, and before printing results for the next Sample.			
If any of the absorbance values for the sample are greater than 2.5 in tube mode, or 3.5 in Flowcell, a message is printed stating "Absorbance > 2.5 or 3.5" and the display shows the same.			
If the absorbance per minute for any of the intervals is less than 0.010, the printer outputs "Low Activity" and the display shows "Low Activity" next to "Sample Done".			
The option to print the data may then be taken by pressing the DATA button. The data can be examined to determine if the sample was not active, if the substrate was exhausted early, or if the reaction started later in the Read Time. If the latter is the case, the Lag Time may need to be increased.			

Rate Mode Menu: (Continued)	Prompt/Response:
If the absorbance per minute for any of the intervals was more than 20% from the mean absorbance per minute, the printer shows "Check Linearity" and the display shows the same next to "Sample Done".	Function Key F3 DATA (Continued)
Once again, the DATA button may be pressed to examine the data.	
If both Low Activity and Check Linearity are not flagged, the interval data may still be printed by pressing the DATA key.	
To view more options, press:	Function Key F4 MORE
The screen will display:	
Function Key F2 PURGE: Press this key to purge the Flowcell.	
Function Key F4 RETURN: Press this key to return to sampling.	
Re-Blanking may be done at any point by pressing:	BLANK
To exit Rate Mode and return to the main prompt, press:	QUIT
The instrument returns to the main prompt, and the printer outputs:	Test Ended

4.6 Index Mode

Sometimes a test result is not a measurement, but a calculation made from other measurements. Index Mode is a calculating feature where test results are user entered and index results are calculated and compared with normal ranges based on a formula entered. These are printed on test reports and saved with patient results as any other test would be.



Index Mode:	Prompt/Response:

Summary:

Numeric Key 1 Enter a Constant: Enter a non-variable number, if necessary, for the formula.

Numeric Key 2 Enter a Parameter (Maximum 4): Enter a name for the parameter to be used in the calculation using either an external keyboard or the keypad. Parameters are assigned letters A – D.

Numeric Key 3 Enter an Operator: Enter the operator type using the Function keys.

Numeric Key 4 Enter Parenthesis (): Place parentheses in the formula using the corresponding Function key.

Numeric Key 5 Formula Complete =: Finish the formula.

The instrument prints the formula and the parameters.	Formula and parameters print
The display will prompt:	Enter Ranges:
RANGES: MIN: MAX: Normal Range	Reference Section 3.1.7 Ranges and Controls.
COMPLETE Low Normal Limit = QUIT CLEAR ENTER	
The display will prompt:	Save the Test?
Save the Test ? QUIT NO YES	Reference Section 3.1.11 Saving Tests.

Index Mode:		Prompt/Response:		
If yes, the display will prompt:		Name the Test?		
If yes, the dis	splay will promp	t:		Enter User Test Name:
Enter User Test Name:			Function key attributes:	
CHARACTER SELECTION: ABCDEFGHIJKLMNOPQRSTUVWXYZ		F1 QUIT		
		F2 BACK SPACE		
abcdefghijklmnopqrstuvwxyz !"#\$%&()*+,/0123456789: ;<=>?@[]^_		F3 SELECT		
		F4 OK		
TO MOVE CURSOR 4=LEFT 6=RIGHT 2=UP 8=DOWN		Numeric key attributes:		
QUIT	BACK SP.	SELECT	ок	Numeric 4 key MOVE CURSOR LEFT
Use the numeric keys to move the cursor to create the			Numeric 6 key MOVE CURSOR RIGHT	
alpha/numeric user test name.		Numeric 2 key MOVE CURSOR		
One character at a time, use F3 to select the		UP		
Brees E4 OK when finished		Numeric 8 key MOVE CURSOR DOWN		
I he display will prompt:		Ready to Run Sample #1:		
Press:				
Function Key F4 RUN SMPL: Runs the stored formula. The user will be prompted to enter the parameter values as needed. The formula results are printed along with the				

interpretations.

Function Key F3 PAT ID.: Enter a Patient ID using either the optional external keyboard or the keypad. When finished, the Sample Patient ID = is displayed on the screen. The result will be stored with this Patient ID and is available to be printed later (see Section 3.1.11 Reports for details on printing the Patient Results).

Function Key F1 QUIT: To exit the mode and return to the Main Menu.

5.1 Cleaning

5.1.1 Exterior



CAUTION: Solvents such as acetone or thinner will damage the instrument! Use only water and recommended cleaners! Avoid abrasive cleaners. The keypad and display areas are liquid-resistant, but are easily scratched.

The exterior of the instrument may be cleaned with a soft cloth using plain water. If needed, a mild all-purpose (nonabrasive) cleaner may be used. A 1.5% solution of chlorine bleach or 70% isopropyl alcohol may be used as a disinfectant. Take special care not to spill any liquid into the read well.

5.1.2 Flowcell

The Flowcell should be cleaned when the instrument will not be used for an extended period, e.g. overnight, end of shift, and when storing the Flowcell. Proper cleaning will help to prevent clogging of the Flowcell tubing and valve tubing. Cleaning is extremely important to obtaining accurate, repeatable results. If reagent, serum, or other proteinaceous fluid is allowed to dry in the Flowcell, it is difficult to remove and its presence can affect test results.

To clean the Flowcell:		
1)	From the Main Menu, press Function Key 4 TOOLS.	
2)	The Instrument Tools Menu will display. Enter Menu Number 2, Flowcell Configuration.	
3)	The screen will display: Current Flowcell STATUS =. If Status is not ON, press Function Key 1 ON/OFF. If Status is ON, press Function Key 4 OK.	
4)	Purge with air for at least five seconds.	
5)	Locate the bottle of Flowcell cleaning solution. Open the bottle and position the sample tube immersing it in the solution.	
6)	Aspirate a small amount of Flowcell cleaning solution into the Flowcell by pressing the sample bar. Allow the solution to remain in the Flowcell for three minutes.	
7)	Remove the bottle of Flowcell cleaning solution and replace the cap.	
8)	Position a container of distilled water so that the sample tube remains immersed.	
9)	Press the sample bar to aspirate distilled water into the Flowcell. Allow the water to remain in the Flowcell for three minutes.	

To clean the Flowcell: (Continued)		
OPTIONAL	Aspirate 0.1N hydrochloric acid (HCI). Allow the solution to remain in the Flowcell for three minutes.	
	Purge with at least 15 mL of deionized water.	
10)	Press and hold the sample bar to purge until no more liquid can be seen flowing into the Waste bottle.	
11)	Leave the Flowcell filled with water.	
NOTE : If preparing the Flowcell for storage, follow same instructions but purge completely after cleaning.		

5.1.3 Waste Bottle

The waste bottle may be cleaned with a commercially available all-purpose cleaner or disinfectant. A 1.5% chlorine bleach solution or 70% isopropyl alcohol may also be used. Always turn instrument "OFF" before disconnecting the waste bottle.



5.2 Maintenance

5.2.1 Calibration and Linearity

Each instrument is calibrated during manufacturing using standards that are traceable to the National Institute for Standards and Testing (NIST), and is tested to verify its linearity to 2A. This preset calibration is very stable. Absolute calibration can be verified with the use of NIST filters, or by periodic comparison to a reference instrument that is known to be calibrated to NIST filters.

Calibration may be confirmed using Awareness Technology's Redi-Check[®]; a commercially available calibration check set which can be obtained from your distributor. A periodic verification of instrument linearity is advised.

Since most lab test results are based upon standards rather than upon absolute absorbance, the linearity of the instrument is the more critical indicator of instrument performance. A reduction in linearity with age may be indicative of optical filter deterioration. In this event, filter replacement is required for continued reliable operation.

The best way to assure quality instrument performance is to include a sufficient number of controls in each assay to cover the entire operational range.

5.2.2 Opening the Instrument

Refer to Figure 2 - Instrument Interior.

The cover is hinged at the rear panel, and can be raised to allow access to the inside of the instrument.

Disconnect the power cable, the tubing, and the sensor lead from the rear panel. Move the instrument forward until the front edge overhangs the work surface.

Locate and remove the two cover screws from the underside, one on each side.

Gently lift the front of the cover upward, taking care to clear the photometer. Prop the cover open with a suitable object.

Do not force the cover backwards. Damage to the cover or fittings may result.

To reinstall the cover, reverse the procedure. Carefully lower the cover until it seats on the chassis, taking care to clear the incubation block and the Flowcell Luer fitting.




Figure 2 – Instrument Interior

Component Identification Table			
R	Reference Figure 2 – Instrument Interior		
Α	Main PCB		
В	Power Supply		
С	Photometer		
D	Valve		
E	Pump		
F	Fan		

NOTE: Figure 2 view has the back plastic hatch door removed.



5.2.3 Lamp replacement

The lamp should be replaced only if it fails to light, or several filter voltages are reported as low.

To replace the lamp, follow the procedure below. Turn Power "Off" and unplug instrument.

Open the instrument as described in "Opening the Instrument".

Locate the photometer and the lamp at the right side of the photometer.

Lamp removal

• Refer to Figure 3, for lamp removal and replacement diagram. The figure shows the right side view of the photometer assembly.



CAUTION: LAMP IS HOT. ALLOW THE LAMP TO COOL BEFORE HANDLING.

- Loosen but do not remove the two center lamp connector screws. Remove the lamp by lifting upward.
- Use a pair of tweezers to handle the new lamp.



- CAUTION: Avoid handling with bare skin.
- Insert the lamp leads into the connector until they hit bottom.

Lamp alignment

• Refer to Figure 3, for lamp alignment. The lamp filament must be centered on the lens and the lamp body must be parallel with the lens bracket. While holding the lamp in alignment, tighten the lamp connector screws.

Spot alignment

- Set the power switch to ON.
- Observe the projection of the light from the lamp onto the cell holder (behind the lens).
- Refer to Figure 3, for spot alignment.
- The spot should be small and centered on the oval hole in the cell block (behind the lens).
- If the spot is not centered, use the adjustment screws to position the spot.
- The vertical adjustment screw raises and lowers the lamp bracket.
- The lamp bracket is slotted at the horizontal adjustment screw, so that the lamp bracket can be moved.
- The horizontal adjustment screw serves to lock down the lamp bracket.

Awareness Technology, Inc.



Figure 3 – Lamp Replacement

Test the alignment by inserting a borosilicate 12 mm tube filled with plain water into the read well.



- CAUTION: Do not use a soda-lime glass tube as it does not transmit at 340nm.
- Follow the instruction below to test the alignment. Peak values should be between 4 to 10 volts.



Test the alignment. From the Main Menu:			Prompt/Response:				
Tł	The screen will display:				DIAGNOSTICS MENU		
	DIAGNOSTICS MENU 1 = Filter Voltages 2 = Filter Wheel Speed 3 = Usage Count 4 = Cell, Block Heat Calibration 5 = Current Vac, Temp, Waste Count 6 = Self Check 7 = Return to the TOOLS Menu Enter Menu Number: QUIT			Enter Menu Number: 1 Select Filter Voltages			
Tł	ne screen w	ill display:					
	nm SP2 340 405 505 545 580 630 SP1 QUIT	Abs 3.670 0.080 0.227 0.194 0.282 0.326 0.307 3.625]	Count 59384 1307 3679 3152 4572 5285 4975 58658 PRIM	Volt 0.002 9.943 7.069 7.625 6.217 5.611 5.867 0.002	Pot 32 95 79 55 79 32 40 32 0K		Peak values should be between 4 to 10 volts. If not re-align lamp.
N(pt	OTE: The pe irposes.	eak values	shown here	are for e	xample		

5.2.4 Flowcell Tubing Replacement

The Flowcell utilizes 1.2 mm I.D. Teflon tubing for the sample and exit tubes.

Replacement tubing is included with the tubing kit. Follow this procedure to replace the Flowcell tubing.

• Remove the Flowcell. Gently lift the Flowcell out of the read well.



• Remove the cover screws and lift off the upper Flowcell cover.

Reference Figure 4 as you read the following instructions:

- Disconnect the exit tube from the steel tube.
- Pull the exit tube out through the bulkhead.
- Remove the cell insert screws and pull the cell insert and the sample tube out.
- Remove the sample tube from the steel tube.
- Locate the sample tube in the tubing kit.
- Carefully press fit the end of the sample tube, swaged end, to the steel tube on the cell insert, and feed the other end upward through the cell body.

• Hint: grasp the tubing with a small piece of #400 grit emery paper.

- Do not kink the tubing.
- Refer to Figure 4 for the proper orientation.
- Do not reverse the orientation as improper sampling will result.
- Install the cell body and screws.
- Feed the exit tube in through the rear of the Flowcell.
- Press the exit tube over the steel tube.



• CAUTION: Use extreme caution not to damage the fitting.



Figure 4 - Flowcell Tubing Replacement

	Elowcoll Tubing Donlocoment Darts List				
	Flowcell Tubing Replacement Parts List				
Α	PVC tubing	K	Outlet tube		
В	Tube support	L	Exit tube		
С	Flowcell handle	М	Flow cell handle base		
D	Machine screws (2) 4-40 x 1/4	Ν	Flow cell contact		
Е	Pan head screws (2) 4-40 x 3/8 w/split lock washers	0	Retainer plate		
F	Flat head machine screws (2) 2-56 x 3/16	Ρ	Machine screws (4) 1-72 x ¹ / ₄		
G	Upper cell body	Q	O-ring		
Н	Lower cell body	R	Cell window		
Ι	Adjustment set screw	S	Seals (2)		
J	Inlet tube	Т	Cell insert		

5.2.5 Valve Tubing Replacement

It is not recommended to replace any tubing while the instrument is performing properly. However, the short length of silicone tubing used in the sampling valve may become clogged or worn with age. A replacement is included in the tubing kit.

- Set the power switch to OFF (O).
- Open the instrument as described in "Opening the instrument".
- Refer to Figure 5. Locate the valve beside the photometer. Note: The valve is shown inverted in the callout view in Figure 5.
- Pull back the pinch bracket and remove the valve tubing from the valve body.
- Disconnect the valve tubing from the fittings at both ends noting orientation.
- Install the replacement tubing to the valve body in a similar manner.
- Push the tubing over the tubing barbs until seated. Be especially careful not to kink, stretch, or tension the tubing.
- Lower the cover and replace the screw.



Figure 5 – Valve Tubing Replacement



NOTE: Callout view shows valve inverted.



5.2.6 Storage

The instrument may be stored under the following recommended environmental conditions:

- Temperature: 10 to 50°C •
- Humidity: Less than 80% relative humidity, non-condensing. •

Before storing the instrument, clean the Flowcell as described in Section 5.1 Cleaning. Store the instrument using original packaging if possible.

Pe	rform the following steps before storing:
~	Set the power switch to OFF (O) and remove the power cord.
~	Disconnect tubing and the sensor lead from the rear panel. Unhook the waste bottle strap and remove the waste bottle. Remove the waste bottle cap.
~	Empty the waste bottle and autoclave, or disinfect with a 1.5% chlorine bleach solution.
~	Remove the Flowcell and allow the Flowcell and waste bottle to dry overnight.
~	Place the instrument, Flowcell, waste bottle in the original packaging material.
 ✓ 	When returning the instrument to service from storage, it is recommended that functional tests be performed as if setting up the instrument for the first time.
NC	DTE: It is especially important to verify sample volume accuracy and photometric linearity before performing any clinical assays.





6. TROUBLESHOOTING

6.1 Flags and Error Messages

Flags are displayed to alert the operator when certain limits are approached. After displaying the warning the instrument will continue to function normally.

Error Messages are displayed when the instrument fails to operate correctly. They are intended to help the operator locate the problem.

6.1.1 Flags

Flag Alert Messages:	
****	Printed in the concentration field if the absorbance is greater than 2.5 when using tubes, or greater than 3.5 when using the Flowcell.
	To obtain an accurate absorbance and/or concentration for this sample it is necessary to further dilute the sample(s), or dilute the specimen(s) and rerun the assay.
>10**7	Printed in the concentration column when the result of the concentration is greater than 7 digits and cannot be printed in the concentration column.
—CURVE INVALID!!—	 Printed in the Multi-Point Mode when a curve cannot be drawn between the standards that were read. An "X" will be printed after the standard which causes the curve to be invalid. Check to make sure the standards were in decreasing order of absorbance in the Multi-Point % Abs, or in increasing order if in Multi-Point Mode. Since this invalidates the results, the test must be restarted.

6.1.2 Error Messages

Frror Message /	Solution:
Problem:	
Aspiration Valve Error – Check Valve Tubing	At the beginning of every test run in Flowcell Mode, the valve will be checked for proper operation.
	If the valve fails the check, the message "Aspiration Valve Error – Check Valve Tubing" will display and print. Refer to section "No Sampling".
Check Linearity	In Rate Mode, if the absorbance per minute for any of the intervals is more than 20% from the mean absorbance per minute, the printer shows "Check Linearity", and the screen will display this message next to "Sample Done". Press the DATA button to examine the data. See section "Rate Mode".
Check Vac System	The instrument detected an inability to achieve vacuum. Check the waste bottle cap and fittings.
External Printer Not Ready. Retry? Y/N	If the receiving device does not have a large enough buffer, the instrument times out and the "Ext Printer Not Ready, Retry? Y/N" error message appears on the display. This error message refers to any receiving device (printer, PC, external serial or parallel port).
Lamp Failure	The lamp does not appear to be sufficiently illuminated. This can be caused by either lamp failure or degraded filters. See the section "Lamp Replacement". If replacing the lamp does not correct this, the instrument may require service to replace the filters.
Low Activity	In Rate Mode, if the absorbance per minute for any of the intervals is less than 0.010, the printer outputs "Low Activity" and the screen will display the message next to "Sample Done". To print the data, press the DATA button. The data can be examined to determine if the sample was active, if the substrate was exhausted early, or if the reaction started later in the Read Time. See section "Rate Mode".
Memory is full	The test cannot be stored because there is no available memory. Delete unused tests.
Printer Not Ready	The external printer attached to the parallel port or serial port is out of paper or otherwise unable to print.



Error Message / Problem: (Continued)	Solution:
Printer Paper Jam	The internal printer paper path is obstructed. The internal printer will be disabled, and the user will be allowed to continue. Clear the paper path by gently pulling the obstruction from the printer, and restarting the instrument.
Retry? Y/N	In the event that the external printer or PC buffer becomes full (the instrument has sent as much data as the printer's memory can hold), the instrument will display "Retry? Y/N". Press Yes to continue to output once the printer o PC has emptied its buffer. Press No to turn off communication to external ports.
Serial Receiver Not Ready	If the external printer or PC is enabled, and the printer or PC is connected but is off-line, an error results only while in a mode, the instrument attempts to communicate.
	Until the problem is corrected, the instrument stops and displays "serial receiver not ready".
Stuck key on keypad	If a key on the keypad becomes stuck in position, the firmware will produce an override to enable an external keyboard to be used with the device. The device will emit a series of thirty beeps before disabling the keypad.
Vacuum High!	Visual warning appears while in Flowcell Mode if vacuum > 8.0
Check System	Check the tubing connection at blue luer.
Vacuum Standby (1)	Vacuum Standby when the Waste bottle is full:
	When running a test in the Flowcell Mode, if the Waste bottle becomes full, the pump will shut off while the message "WASTE IS FULL!! Empty Waste – Press Enter to Get Sample" is displayed. Select Enter. The Waste bottle can be emptied without exiting the test.
Vacuum Standby (2)	Vacuum Standby when the Waste bottle is not full:
	In Rate Mode tests, the Waste bottle can be emptied at any time.
	Press Function Key F2 MORE. Select F3 STANDBY. The display will beep. Proceed to remove the waste bottle as needed; press ENTER when ready to resume.

Error Message / Problem: (Continued)	Solution:
Waste is Full!!! (Bottle in top right corner of screen)	Displayed when the waste material has reached the level sensors. The instrument will begin "beeping" and will not stop until the waste bottle is emptied.

The following messages may indicate an electronic problem with the main PCB. If these messages appear frequently, the instrument may require service.

Error Message / Problem:	Solution:
Canceled	This message will display immediately following a filter wheel error to indicate that the test or mode has ended.
Do ABS Calibration Test	The stored absorbance adjustment has been lost or corrupted. Refer to the section "Restore Calibration Data".
Do Temperature Calibration Test	The stored temperature adjustment has been lost or corrupted.
	Refer to the section "Restore Calibration Data".
Filter Labels 7&8 Clrd!	The stored filter labels have been lost or corrupted. Refer to the section "Restore Filter Labels".
Filter Wheel Err	There is a mechanical problem with the instrument. Turn off the power switch, wait 15 seconds, then turn on the power switch.
Memory Error	The checksum is invalid for a test that is being recalled.
	The corrupted test will automatically delete.
Water Values Reset	The Flowcell is active and no water values are found in memory. The stored water values are reset to 0.000.
	New water values must be read to ensure correct results. Refer to "Flowcell Configuration".

148

6.2 Incorrect Control Readings

Check that the procedures and materials used were valid. Turbid or contaminated reagents may affect absorbance readings. Reading reference dyes can be very helpful in separating instrument problems from reagent problems. Be sure that the appropriate wavelengths were selected for the chromophore being read. Tubes should have no bubbles, condensation, scratches or smudges.

6.3 Poor Linearity

If the instrument is several years old, or has been operated in very humid conditions, new optical filters may be needed. The instrument incorporates interference filters of an advanced technology, and will provide extended life in humid environments when compared to standard soft interference filters. However, excessive humidity should be avoided. The instrument will require service to replace the filters.

6.4 Erratic Readings

One possible source of erratic readings (excessive dither) is trapped air in the Flowcell. This can be caused by improper installation of the Flowcell tubing. Refer to the section "Flowcell Tubing Replacement". Check the insertion depth of the Flowcell tubes. Ensure that a leak-free seal is made.

6.5 Lamp failure

The lamp is rated to read over 300,000 tubes, and the lamp saver feature minimizes lamp idle time. Lamp replacement is only indicated when the lamp fails to light, or when the message "Lamp output low!" is displayed. Press LAMP to turn the lamp on or off. If the lamp fails to light, refer to the sub-section "Lamp Replacement" under the Maintenance section.

6.6 No sampling

At the beginning of every test, the valve will be checked for proper operation.

If the valve fails the check then the message "Aspiration valve error - Check valve tubing" will be displayed and printed.

If you can hear the valve cycle, but no sample is drawn up, the valve tubing may be blocked.

- Press and hold PURGE several times.
- Disconnect the Luer fitting at the rear of the Flowcell.
- Press PURGE and listen for aspiration. If air is heard entering the fitting, the valve tubing is clear, but the Flowcell is blocked.
- Refer to the sections "Cleaning" and "Replacing Flowcell tubing".

If the valve clicks but the pump does not run when pressing the **PURGE** key, the valve tubing may be stuck closed.

- If this happens, remove the front cover screw and lift open the cover.
- Pull the pinch bracket against the spring tension (to open the valve manually).
- Gently pull the tubing slightly to break the seal.
- See the section "Valve Tubing Replacement" for a diagram and more information about the valve tubing.



6.7 Restore Calibration Data

Each unit is electronically calibrated at the factory. The calibration values are entered by the keyboard and stored in nonvolatile memory. The instrument will not accept a change greater than +/- 10% (.900-1.100) for the absorbance factor, nor will it accept a temperature offset change greater than +/- 2.5°C. Only minimal calibration adjustments are accepted from the keyboard.

```
Do Temperature Calibration Test
Do ABS Calibration Test
```

If either of these messages are printed or displayed, it indicates that the calibration values have been lost. These messages will be printed each time the instrument is turned on, a mode is selected, or a test is recalled.

The instrument will continue to operate, but the calibration <u>mus</u>t be restored to ensure the accuracy of the instrument.



WARNING:

DO NOT ALTER ANY POTENTIOMETER SETTINGS! CHANGING THESE SETTINGS WILL MAKE THE FACTORY CALIBRATION DATA INVALID.

DO NOT ENTER VALUES OTHER THAN THOSE RECORDED ON THE CALIBRATION LABEL.

6.7.1 Restore Electronic Calibration

Res	store Electronic Calibration:
1)	Set the power switch to OFF (0) . Remove any tubes or cuvettes from the read well. Carefully lift up the instrument and locate the Calibration Data Label on the underside of the unit.
	The Absorbance, Cell Temperature, and Block Temperature values are recorded there. Make note of these numbers as they will be used in the steps that follow.
2)	Set the power switch to ON (1) .
3)	If the date and time have been reset or are incorrect, enter the correct date and time. See the section "Set Date and Time".
4)	Access the Instrument Utilities feature by pressing Function Key 4 TOOLS on the main menu. Select numeric key 4 Diagnostics Menu.



Res	tore Electr	onic Calibration: (Continued)	
	The screer	n will display:	
	E	IAGNOSTICS MENU 1 = Filter Voltages 2 = Filter Wheel Speed 3 = Usage Count 4 = Cell, Block Heat Calibration 5 = Current Vac, Temp, Waste Count 6 = Self Check 7 = Return to the TOOLS Menu Inter Menu Number: QUIT	
	Enter Men	u Number:	
	Numeric H heat block Menu for a	Key 4 Cell, Block Heat Calibration : Enables cell (optional item) temperature correction. (Reference additional information.)	temperature correction and e Section 2.4.4 Diagnostics
5)	Select nun	neric key 4 Cell, Block Heat Calibration.	
6)	The screer	n will display:	
	HEAT 1 = 0 2 = 1 3 = 1 Enter	ER MENU Cell Heat Calibration Block Heat Calibration Return to the Previous Menu Menu Number:	
7)	Select nun	neric key 1 Cell Heat Calibration, press Enter. The	e display will prompt: Cell
	i emp Corr	rection =. Enter the number and press Enter.	
8)	Select numeric key 2 Block Heat Calibration, press Enter. The display will prompt: Block Temp Correction =. Enter the number and press Enter.		
9)	Press Function Key 1 QUIT.		
10)	From the Main Menu, press Function Key 1 RUN TEST. The display will prompt: Select a test number. Type in test number 213 and press Enter. The screen and printer will display the current Abs Factor, Cell Temp Correction, and Block Temp Correction values. Ensure these values are the same as those found on the Calibration Data Label. Contact technical support with any questions.		

6.7.2 Restore Filter Labels

Like the calibration data, the wavelengths for the two optional filters are stored in nonvolatile memory. In the event this data is lost or corrupted, the following message will display and print:

Filter Labels 7&8 Clrd!

Res	store Filter Labels:
1)	Set the power switch to OFF (0) . Open the instrument and locate the filter label on the side of the photometer cover. Make note of these numbers as they will be used in the steps that follow.
2)	Filter labels need to be re-entered for two of the filters. Open the instrument and locate the filter label on the side of the photometer cover. Make note of the filter numbers shown in position 7 and 8. These numbers are necessary for the steps that follow.
3)	Position Filter 7 xxx
	8 xxx
	where "xxx" is a three-digit wavelength value.
	NOTE: If there are no 7th or 8th filters, they are listed as BLOCKED.
4)	Close the instrument. Set the power switch to ON (1) .
5)	From the Main Menu, press Function Key 1 RUN TEST. At the Select a test number prompt, type in 248, and press Enter.
6)	The display will prompt: Key 7 = ??? nm. Type in the wavelength numbers that was shown on the label, and press Enter.
7)	The display will prompt: Key 8 = ??? nm. Type in the wavelength numbers that was shown on the label, and press Enter.
8)	The instrument will return to Main Menu.
NO will	TE : If values for Key 7 and Key 8 are entered when there are no filters present, the filters be flagged as "low" when Self Check is run.



6.8 Flowcell Alignment

Flowcell Alignment	Prompt/Response:
Flowcell Alignment . Not needed under normal operating conditions. Necessary when a new Flowcell is to be used, or if a lamp replacement has occurred. Read Water Reference should be done before AND after Flowcell Alignment.	Choosing 2 and Enter shows the Flowcell Alignment Screen.
First, the Flowcell should be active but NOT inserted into the read well.	
To print the current reading, press:	Press F3 (PRINT)
Insert the Flowcell into the read well.	
Submerge the end of the tubing into a container of water and press:	Press the Sample bar
The Sample Bar should be held until water starts to flow into the Waste Bottle to decrease the likelihood of air bubbles interfering with an accurate reading.	
This reading should be slightly over half of the original reading. If it is not, the Flowcell must be adjusted.	
If the displayed value is less than 50% of the reading with the Flowcell removed, purge and remove the Flowcell.	
Adjust the set screw with the hex wrench supplied.	Turn the set screw 1/4 turns in either direction and replace the Flowcell.
Sample water again. If the value increases, turn the set screw in the same direction.	
If the value decreases, turn the setscrew in the opposite direction.	
Repeat until the value is >50%. When complete, press:	ENTER to return to the previous prompt. New water values must be read as described above in Read Water Reference .
To return to the Tools menu, press:	F4 (COMPLETE)



7. ACCESSORIES

7.1 External Keyboard

The **Stat Fax 3300** instrument is compatible with a standard computer keyboard for ease of data input.

7.2 Incubation Unit

The optional 37°C incubation block contains twelve stations. The incubator will accommodate 12 mm diameter round test tubes.

When the instrument is powered on, heating begins. In 20-30 minutes, depending on ambient temperatures, stable temperatures are reached.

Refer to the accessory manual for details on precautionary warnings and user instructions.

7.3 Peltier Cooling Accessory

The Peltier Cooling Accessory is an electronic cooling device which, when an electric current passes through it, gets very hot on one side, and very cold on the other. At ambient temperature, the Peltier Cooling Accessory is capable of maintaining 25, 30 and 37 degree temperatures within + or -.5.

7.4 Thermal Printer Paper

Reorder replacement Thermal Printer Paper Roll P/N 150003.

7.5 REDI-CHECK[®] Photometer QA Kit

REDI-CHECK[®] is a photometer check set used to verify the absorbance calibration, linearity, and precision of filter photometers on a routine basis. The kit contains four different chromophore solutions to cover a wide range of wavelengths between 340nm and 630nm. Instructions are included for preparing dilutions of the chromophore to check linearity.

Acceptance ranges are provided for both bichromatic and monochromatic readings, with technical information traceable to NIST. The kit, which is designed for monthly use, also includes a record keeping system which visually indicates instrument performance and performance trends.

For more information on REDI-CHECK[®], contact your dealer.



8. USER TEST MENU LOG

Stat Fa	ax® 3300	(SN:)	User Test Menu Log	Page
Test #	Analyte:	Stored By:	Date: No	otes:

9. CONTACT INFORMATION

In the unlikely event that a problem occurs with the instrument, please consult your dealer first.

Dealer:

If the dealer is unable to resolve the problem, support staff at Awareness Technology, Inc. are happy to assist, and can be reached in the United States by:

Telephone: USA 772-283-6540

Fax: USA 772-283-8020

E-mail: <u>support@awaretech.com</u>

Mailing Address:

Awareness Technology, Inc. P.O. Drawer 1679 Palm City FL 34991 USA

Important: When contacting us, please have the Model and Serial Number of the instrument in question. Have a description of the problem with as much detail as possible. Save any relevant printouts and send or e-mail us the information.



ALT/GPT 4+1 SL

ALSL

ALSL-0250	R1 8 x	20 mL	+ R	2 8 x	5 mL
ALSL-0455	R1 4 x	44 mL	+ R	2 4 x	11 mL
ALSL-0410	R1 2 x	50 mL	+ R	2 1 x	26 mL
ALSL-0430	R1 4 x	50 mL	+ R	2 2 x	26 mL
ALSL-0510	R1 5 x	100mL	+ R	2 1 x	127 mL

CE

FTRO-ALSL-v20 (02/2022) (PIT-ALSL-4-v20)

☞SCOPUL UTILIZĂRII

ELITech Clinical Systems ALT/GPT 4+1 SL este un reactiv de diagnostic in vitro destinat pentru determinarea cantitativă a alaninaminotransferaza (ALT) în probele de ser și plasmă umană pe analizoare automate sau semi-automate.

Acest dispozitiv de diagnostic in vitro este doar pentru uz profesional.

☞SEMNIFICAȚIE CLINICĂ⁽¹⁻³⁾

Alaninaminotransferaza (ALT) este o transaminază, cunoscută și ca glutamat piruvat transaminază (GPT). ALT catalizează transferul grupului amino al L-alaninei la α-ketoglutarat pentru a rezulta L-glutamatul. Cele mai mari nivele se găsesc în ficat și rinichi.

Nivelele ALT sunt mărite marcant în hepatita acută (virală sau toxică), și, într-o măsură mai mică, în hepatita cronică, ciroză, icter, carcinoame hepatice sau după administrarea diverselor medicamente. Nivelele ALT pot crește și în bolile cardiace. ALT este mai specifică ficatului decât AST (aspartataminotransferaza). Măsurarea AST și ALT pot ajuta la diferențierea hepatitei de deteriorarea celulară extrahepatică.

Măsurarea ALT este indicată pentru examinarea pacienților cu risc de boli hepatice și pentru a ajuta la diagnosticarea sau monitorizarea bolilor hepatice.

◄LIMITAREA UTILIZĂRII

Analiza cantitativă doar a alaninaminotransferaza (ALT) nu poate fi utilizată pentru diagnosticarea unei boli sau a unei patologii specifice.

Rezultatele trebuie interpretate în conjuncție cu alte rezultate ale testelor de diagnosticare, constatările clinice și istoricul medical al pacientului.

◄ METODĂ ȘI PRINCIPIU⁽⁴⁾

Metoda IFCC fără piridoxal fosfat (P-5'-P). Cinetică.

ALT

L-alanină + a-ketoglutarat ----- Piruvat + L-glutamat

Piruvat + NADH + H⁺ \longrightarrow L-lactat + NAD⁺

LDH = Lactat dehidrogenază

∝COMPOZIȚIE

Reactivul 1: R1

Tampon Tris, pH 7.	50 (30	°C)	
L-alanină		680	mmol/L
LDH	\geq	2000	U/L
Azidă de sodiu	<	0.1	% (m/m)
Reactivul 2: R2			
a-ketoglutarat		97	mmol/L
NADH		1.1	mmol/L
Azidă de sodiu	<	0.1	% (m/m)

☞MATERIALE NECESARE DAR NEFURNIZATE

- CALI-0550 ELICAL 2
- CONT-0060 ELITROL I
- CONT-0160 ELITROL II
- Soluție salină obișnuită (NaCl 9g/L)
- Aalizoare automate sau semi-automate.
- Echipamente generale de laborator (de ex. pipetă).

- Nu utilizați materiale care nu sunt necesare, după cum este indicat mai sus.

☞AVERTISMENTE ŞI PRECAUŢII

- Consultați Fișa cu dațe de Securitate (FDS) pentru o manipulare adecvată.

- Reactivii conțin azidă de sodiu care poate reacționa cu plumbul sau cuprul pentru a forma azide metalice cu potențial exploziv. În momentul eliminării acestor reactivi, spălați întotdeauna cu apă din abundență pentru a preveni acumularea de azide.

- Luați măsurile de precauție obișnuite și urmați buna practică de laborator.

- Utilizați doar echipamente de laborator curate sau de unică folosință pentru a evita contaminarea.

Nu interschimbați fiolele de reactiv din truse diferite.

STABILITATE

A se depozita la 2-8 °C și a se proteja împotriva luminii. A nu se îngheța.

A nu se utiliza după data de expirare indicată pe etichetele fiolelor.

Stabilitatea la bord:

Stabilitatea la bord este specifică pentru fiecare analizor. (Consultați § DATE PRIVIND PERFORMANȚA).



PREGĂTIRE

Reactivii sunt gata pentru utilizare.

DETERIORAREA PRODUSULUI

- Produsul trebuie să fie limpede. Aspectul tulbure indică deteriorarea produsului.

- Nu utilizați produsul dacă există semne vizibile de contaminare sau deteriorare (de ex. materia cu particule).

- Deteriorarea containerului de reactiv poate afecta negativ performanța produsului. Nu utilizați reactivul dacă există dovezi fizice de deteriorare (de ex. scurgeri sau container perforat).

∞EŞANTIOANE

Specimene necesare (1,5)

- Ser.

- Plasmă (heparinizată de litiu).

- Utilizarea oricărui alt tip de specimen trebuie validată de laborator.

Avertismente și precauții

- Eșantioanele trebuie să fie libere de hemoliză. (1,3)

- Eșantioanele trebuie colectate în conformitate cu Buna Practică de Laborator și liniile directoare corespunzătoare care pot fi în vigoare.

Depozitare și stabilitate ^(1,3,5)

- 3 zile la temperatura camerei.

- 7 zile la 2-8°C,

- Pentru o mai mare stabilitate, a se depozita la -70°C.

☞VALORI DE REFERINȚĂ^(1,4)

Ser, plasmă	U/L	µkat/L
Bărbați	\leq 45	≤ 0.74
Femei	\leq 34	≤ 0.56

Notă: Intervalul menționat ar trebui să servească doar ca un ghid. Se recomandă ca fiecare laborator să verifice acest interval sau să stabilească un interval de referință pentru populația țintă.

☞PROCEDURĂ

<u>Procedura manuală</u>

lungime de unda :	340 nm
Drum optic:	1 cm
Raport probă/reactiv :	1:20
Temperatura:	37 °C
Cititi fată de un apă dis	tilată.

, , .	
Reactiv de lucru	1000 µL
(4 volume de R1 + 1 volum de R2)	
Eşantion	50 µL

Amestecați și după 1 minut de incubare, se citiți absorbanța la intervale de 1 minut timp de 3 minute. Calculați modificarea absorbanțelor pe minut ($\Delta A/min$)

Procedura automată

Acești reactivi pot fi utilizați pe mai multe analizoare automate. Pentru analizoarele ELITech tip Selectra, aplicațiile validate sunt disponibile la cerere. Pentru software-ul Selectra TouchPro, utilizați aplicația inclusă în codul de bare disponibil la sfârșitul acestui insert.. Valorile mari ale ALT pot induce rezultate scăzute în mod fals datorită golirii substratului (consumul total de NADH înainte de citirea rezultatului). Pentru Analizoarele Selectra ELITech Clinical Systems, aplicația conține o alarmă specifică pentru a avertiza utilizatorii.

∽CALCUL

Activitate (U/L) = $\Delta A / \min x 3333$

Factor de conversie: U/L x $0.0167 = \mu \text{kat/L}$

CALIBRARE

ELICAL 2 este trasabil pentru metoda de referință IFCC.

<u>Frecvența de calibrare</u>: Calibrarea este specifică pentru fiecare analizor. (Consultați § DATE PRIVIND PERFORMANȚA).

◄CONTROLUL CALITĂŢII

Se recomandă ca serurile pentru controlul calității precum ELITROL I și ELITROL II să fie utilizate pentru a monitoriza performanța analizei.

Controalele trebuie efectuate:

- Înainte de a analiza eșantioanele pacientului,
- Cel puțin o dată pe zi,
- după fiecare calibrare
- și/sau în conformitate cu cerințele laboratorului și de reglementare.

Rezultatele trebuie să fie în intervalele definite. Dacă valorile sunt în afara intervalelor definite, fiecare laborator trebuie să ia măsurile corective necesare.

☞MANAGEMENTUL DEŞEURILOR

Eliminarea tuturor deșeurilor trebuie să fie în conformitate cu cerințele de reglementare locale, statale și federale. (vă rugăm să consultați Fișa cu date de securitate (FDS)).

☞PERFORMANŢE

Au fost obținute performanțe pe Selectra ProM, urmând recomandările tehnice CLSI, în condiții de mediu controlate.

Interval de măsurare

10.0 to 450.0 U/L (0.17 to 7.50 $\mu kat/L).$

Eșantioanele care au concentrații mai mari vor fi automat diluate 1:10 cu soluție de NaCl 9 g/L și re-analizate. Această procedură extinde intervalul de măsurare până la 4500.0 U/L (75.00 μ kat/L).

Nu raportați rezultatele în afara acestui interval extins.

Pentru utilizatorii cu software Selectra TouchPro, funcția "dilute" efectuează automat diluarea probei. Rezultatele iau în considerare diluția.

- Limita de detecție (LoD) și Limita de cuantificare (LoQ) LoD = 2.9 U/L (0.05 μkat/L)

 $LoQ = 5.0 \text{ U/L} (0.08 \ \mu\text{kat/L})$



- Precizie

Datele privind imprecizia au fost obținute pe 2 analizoare Selectra ProM timp de 20 de zile (2 cicluri pe zi, teste efectuate de două ori).

		Medie		În	Total
				interiorul	
				ciclului	
	n	U/L	µkat/L	CV (%	%)
Nivelul 1	80	34.2	0.57	1.1	4.4
Nivelul 2	80	71.2	1.19	0.2	2.9
Nivelul 3	80	367.0	6.12	0.5	1.8

Rezultatele reprezentative sunt prezentate mai jos :

- Corelație

A fost efectuat un studiu comparativ între reactivul ALT/GPT 4+1 SL pe un analizor Selectra ProM și un sistem similar disponibil în comerț pe eșantioane de ser uman 100.

Concentrațiile eșantioanelor au fost între 10.2 și 542.2 U/L (0.2 – 9.0 μ kat/L).

Rezultatele sunt după cum urmează:

Coeficient de corelație: (r)=0.996

Regresie liniară: $y = 1.017x + 0.6 \text{ U/L} (0.01 \text{ }\mu\text{kat/L})$

- Limitări/ Interferențe analitice

- ALT poate fi subestimată în cazul deficienței severe de vitamina B6. $^{(3)}$

- Eșantioanele hemolizate nu trebuie utilizate întrucât hemoliza semnificativă poate crește concentrația ALT din cauza nivelelor înalte ale ALT în eritrocite. $^{(3)}$

- Au fost efectuate studii pentru a determina nivelul interferenței de la diferiți compuși.

Au fost testate următoarele nivele ale ALT: 35.0 U/L și 350.0 U/L.

Nu este definită nicio interferență semnificativă printr-o recuperare ≤±10% din valoarea inițială.

<u>Bilirubină neconjugată</u>: Nicio interferență semnificativă până la 30.0 mg/dL (513 µmol/L).

<u>Bilirubină conjugată</u>: Nicio interferență semnificativă până la 29.5 mg/dL (504 µmol/L).

<u>Trigliceride</u>: Nicio interferență semnificativă până la 2300 mg/dL (25.99 mmol/L).

Piruvat: Nicio interferență semnificativă până la 3.0 mg/dL.

<u>Acid ascorbic</u>: Nicio interferență semnificativă până la 20.0 mg/dL.

Acid acetilsalicilic: Nicio interferență semnificativă până la 200.0 mg/dL.

<u>Acetaminofen</u>: Nicio interferență semnificativă până la 30 mg/dL.

- În cazuri foarte rare, gamopatiile monoclonale (mieloame multiple), în special de tipul IgM (macroglobulinemia Waldenstrom) poate duce la rezultate nefiabile. ⁽⁶⁾

- Multe alte substanțe și medicamente pot interfera. Unele dintre acestea sunt enumerate în reviste publicate de Young. ⁽⁷⁻⁸⁾

- Stabilitatea la bord/Frecvența calibrării

Stabilitatea la bord: 28 zile

Frecvența calibrării:28 zile

Recalibrați când loturile de reactiv se schimbă, când rezultatele controlului calității sunt în afara intervalului stabilit și după o operație de întreținere.

•Aceste performanțe au fost obținute cu ajutorul analizorului ELITech Selectra ProM. Rezultatele pot varia dacă se utilizează un alt instrument sau o procedură manuală.

Performanțele aplicațiilor nevalidate de ELITech nu sunt garantate și trebuie definite de utilizator.

☞DECLARAREA INCIDENTULUI GRAV

Vă rugăm să notificați producătorul (prin intermediul distribuitorului dumneavoastră) și autoritatea competentă a Statului Membru din Uniunea Europeană în care este stabilit utilizatorul și/sau pacientul, cu privire la orice incident grav care a avut loc legat de dispozitiv. Pentru alte jurisdicții, declararea incidentului grav trebuie să fie în conformitate cu cerințele reglementare locale, statale și federale.

Prin raportarea unui incident grav, furnizați informații care pot contribui la siguranța dispozitivelor medicale *in vitro*.

☞ASISTENŢĂ TEHNICĂ:

Contactați distribuitorul dumneavoastră local sau ELITech Clinical Systems SAS (<u>CCsupport@elitechgroup.com</u>).

☞BIBLIOGRAFIE

1. Panteghini, M., Bais, R., *Enzymes*, <u>Tietz Fundamentals of</u> <u>Clinical Chemistry</u>, 6th Ed., Burtis, C.A., Ashwood, E.R., Bruns, D.E., (W.B. Saunders eds.), (2008), 317.

2. Wu, A.H.B., <u>Tietz Clinical guide to laboratory test</u>, 4th Ed., (W.B. Saunders eds.), (2006), 64.

3. Dufour, R., *The liver: Function and Chemical Pathology*, <u>Clinical Chemistry: Theory Analysis, Correlation</u>, 5th Ed., Kaplan, L.A., Pesce, A.J., (Mosby Inc. eds.), (2010), 586 and appendix.

4. Schumann, G., et al., Clin Chem Lab Med., (2002), 40, 718.

5. Guder, W.G., et al., Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples. (2002). WHO/DIL/LAB/99.1 Rev.2.

6. Berth, M. & Delanghe, J., *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, <u>Acta Clin Belg.</u>, (2004), **59**, 263.

7. Young, D.S., <u>Effects of preanalytical variables on clinical</u> <u>laboratory tests</u>, 2nd Ed., AACC Press, (1997).

8. Young, D.S., <u>Effects of drugs on clinical laboratory tests</u>, 4th Ed., AACC Press, (1995).



∞SIMBOLURI

Simbolurile utilizate sunt definite în standardul ISO 15223-1, cu excepția celor prezentate mai jos:

CONT	Conținut
R1	Reactivul 1
R2	Reactivul 2
¢.	Modificare față de versiunea anterioară
CE	Conformitate europeană

Notă:

Doar pentru ref. **ALSL-0250/ALSL-0455**, utilizată cu software-ul Selectra TouchPro.







AMYLASE SL

AMSL

AMSL-0230	R	6 x 20 mL
AMSL-0390	R	1 x 50 mL
AMSL-0400	R	6 x 50 mL

CE

FTRO-AMSL-v21 (11/2021) (PIT-AMSL-4-v21)

☞SCOPUL UTILIZĂRII

ELITech Clinical Systems AMYLASE SL este un reactiv de diagnostic in vitro destinat pentru determinarea cantitativă a amilazei în probele de ser și plasmă umană pe analizoare automate

Acest dispozitiv de diagnostic in vitro este doar pentru uz profesional.

SEMNIFICAŢIE CLINICĂ⁽¹⁻²⁾

 α -Amilaza este o enzimă în principal de origine pancreatică sau salivară care hidrolizează legăturile 1,4- α -glucozidice, ajutând astfel la digestia amidonului. O creștere a amilazei serice poate fi observată în special în pancreatita acută, precum și în multe alte situații precum alte patologii pancreatice sau intra-abdominale și afecțiunile glandelor salivare. În timpul pancreatitei acute, nivelul amilazei serice începe să crească după câteva ore și poate fi mărită până la de 6 ori, ajungând la un nivel de vârf după 12-72 de ore, și revenind la nivelul normal în aproximativ 4 zile.

În practica clinică, măsurarea activității amilazei este utilizată în special pentru a ajuta la diagnosticarea și monitorizarea pancreatitei acute, și poate ajuta și la diagnosticarea și urmărirea altor boli pancreatice.

◄LIMITAREA UTILIZĂRII

Analiza cantitativă doar a amilazei nu poate fi utilizată pentru diagnosticarea unei boli sau a unei patologii specifice.

Rezultatele trebuie interpretate în conjuncție cu alte rezultate ale testelor de diagnosticare, constatările clinice și istoricul medical al pacientului.

☞METODĂ ȘI PRINCIPIU⁽³⁾

CNP-G3 / Standardizare conform metodei IFCC - cinetică

Substratul CNP-G₃ este hidrolizat prin acțiunea catalitică a α -Amilazei pentru a produce CNP (2-cloro-4-nitrofenol) care absoarbe la 405 nm.

α-Amilază 5 CNP-G₃ → 3CNP + 2CNP-G₂+ 3 Maltotrioză + 2 Glucoză CNP-G₃ = 2-cloro-4-nitrofenil-a-maltotriozidă CNP-G₂ = 2-cloro-4-nitrofenil-a-maltozidă

Rata de creștere în absorbanță este măsurată la 405 nm și este direct proporțională cu activitatea a-amilazei în eșantion

≈COMPOZIȚIE

Reactiv: R

Tampon Good, pH 6.15CNP-G32.27mmol/LAzidă de sodiu<</td>0.1% (m/m)Conține și clorură de calciu și de sodiu, precum și tiocianat de
potasiu pentru performanță optimă

- CALI-0550 ELICAL 2
- CONT-0060 ELITROL I
- CONT-0160 ELITROL II
- Soluție salină obișnuită (NaCl 9g/L)
- Aalizoare automate.
- Echipamente generale de laborator (de ex. pipetă).

- Nu utilizați materiale care nu sunt necesare, după cum este indicat mai sus.

☞AVERTISMENTE ȘI PRECAUȚII

- Consultați Fișa cu dațe de Securitate (FDS) pentru o manipulare adecvată.

- Reactivul R conține azidă de sodiu care poate reacționa cu plumbul sau cuprul pentru a forma azide metalice cu potențial exploziv. În momentul eliminării acestor reactivi, spălați întotdeauna cu apă din abundență pentru a preveni acumularea de azide.

- Luați măsurile de precauție obișnuite și urmați buna practică de laborator.

- Utilizați doar echipamente de laborator curate sau de unică folosință pentru a evita contaminarea.

- Saliva și transpirația conțin amilază. Astfel, se recomandă purtarea mănușilor și a unei măști pentru a evita contaminarea reactivului.
- In contact cu acizi, degajă un gaz foarte toxic.

STABILITATE

A se depozita la 2-8 °C și a se proteja împotriva luminii. A nu se îngheța.

A nu se utiliza după data de expirare indicată pe etichetele fiolelor.

Stabilitatea la bord:

Stabilitatea la bord este specifică pentru fiecare analizor. (Consultați § DATE PRIVIND PERFORMANȚA).

PREGĂTIRE

Reactivul este gata de utilizare.



☞DETERIORAREA PRODUSULUI

- Produsul trebuie să fie limpede. Aspectul tulbure indică deteriorarea produsului.

- Nu utilizați produsul dacă există semne vizibile de contaminare sau deteriorare (de ex. materia cu particule).

- Deteriorarea containerului de reactiv poate afecta negativ performanța produsului. Nu utilizați reactivul dacă există dovezi fizice de deteriorare (de ex. scurgeri sau container perforat).

☞EŞANTIOANE

Specimene necesare (4)

- Ser.

- Plasmă (heparină de litiu).

- Utilizarea oricărui alt tip de specimen trebuie validată de laborator.

Avertismente și precauții

Eșantioanele trebuie colectate în conformitate cu Buna Practică de Laborator și liniile directoare corespunzătoare care pot fi în vigoare.

Depozitare și stabilitate (4)

- 1 săptămână la temperatura camerei

1 săptămână la 2-8 °C

- 1 an la -20 °C

◄VALORI DE REFERINȚĂ⁽⁵⁾

Ser, plasmă	U/L	µkat/L	
Adulți	31 - 107	0.52 - 1.78	

Notă: Intervalul menționat ar trebui să servească doar ca un ghid. Se recomandă ca fiecare laborator să verifice acest interval sau să stabilească un interval de referință pentru populația țintă.

PROCEDURĂ

<u>Pentru analizoarele ELITech Clinical Systems tip Selectra.</u> aplicatiile sunt disponibile la cerere.

Lungime de unda 405 nm Temperatura: 37 °C Citiți față de un blank de reactiv

Reactiv R	300 µL
Eşantion/ Calibrator	3 µL

Amestecați și după o incubație de 50 de secunde, măsurați modificarea absorbanței pe minut (ΔA /min.) timp de 159 de secunde.

- Cu software-ul Selectra TouchPro, utilizați aplicația inclusă în codul de bare disponibil la finalul acestui insert.

CALCUL

A∆ Proba

n = concentrație Calibratorul

 $A\Delta$ Calibratorul

<u>Factor de conversie</u>: U/L x $0.0167 = \mu \text{kat/L}$

x n

CALIBRARE

ELICAL 2 este trasabil pentru metoda de referință IFCC.

<u>Frecvența de calibrare</u>: Calibrarea este specifică pentru fiecare analizor. (Consultați § DATE PRIVIND PERFORMANȚA).

☞CONTROLUL CALITĂŢII

Se recomandă ca serurile pentru controlul calității precum ELITROL I și ELITROL II să fie utilizate pentru a monitoriza performanța analizei.

Controalele trebuie efectuate:

- Înainte de a analiza eșantioanele pacientului,
- Cel puțin o dată pe zi,
- după fiecare calibrare,
- și/sau în conformitate cu cerințele laboratorului și de reglementare.

Rezultatele trebuie să fie în intervalele definite. Dacă valorile sunt în afara intervalelor definite, fiecare laborator trebuie să ia măsurile corective necesare.

MANAGEMENTUL DEŞEURILOR

Eliminarea tuturor deșeurilor trebuie să fie în conformitate cu cerințele de reglementare locale, statale și federale. (vă rugăm să consultați Fișa cu date de securitate (FDS)).

☞PERFORMANŢE

Au fost obținute performanțe pe Selectra ProM, urmând recomandările tehnice CLSI, în condiții de mediu controlate.

- Interval de măsurare

20 - 1500 U/L (0.33 - 25.00 µkat/L)

Eșantioanele care au concentrații mai mari vor fi automat diluate 1:10 cu soluție de NaCl 9 g/L și re-analizate. Această procedură extinde intervalul de măsurare până la 15 000 U/L (250.00 μ kat/L).

Nu raportați rezultatele în afara acestui interval extins.

Pentru utilizatorii cu software Selectra TouchPro, funcția "dilute" efectuează automat diluarea probei. Rezultatele iau în considerare diluția.

Limita de detecție (LoD) și Limita de cuantificare (LoQ)
 LoD = 6 U/L (0.10 μkat/L)
 LoQ = 13 U/L (0.22 μkat/L)

Precizie

Datele privind imprecizia au fost obținute pe 2 analizoare Selectra ProM timp de 20 de zile (2 cicluri pe zi, teste efectuate de două ori).

rezultatele reprézentative suit prezentate mai jos :						
		Medie		În	Total	
				interiorul		
				ciclului		
	n	U/L µkat/L		CV (%)		
Nivelul 1	80	82	1.37	1.3	2.7	
Nivelul 2	80	204	3.40	0.9	2.2	
Nivelul 3	80	992	16.53	1.5	2.6	

Rezultatele reprezentative sunt prezentate mai jos :

- Corelație

A fost efectuat un studiu comparativ între reactivul AMYLASE SL pe un analizor Selectra ProM și un sistem similar disponibil în comerț pe eșantioane de ser uman 100.



Concentrațiile eșantioanelor au fost între 21 și 1439 U/L ($0.35 - 23.98 \mu kat/L$).

Rezultatele sunt după cum urmează: Coeficient de corelație: (r)=0.999 Regresie liniară: $y = 0.976x - 1 \text{ U/L } (0.02 \ \mu\text{kat/L})$

- Limitări/ Interferențe analitice

- Au fost efectuate studii pentru a determina nivelul interferenței de la diferiți compuși.

Au fost testate următoarele nivele ale amilazei : 80 și 1 000 U/L.

Nu este definită nicio interferență semnificativă printr-o recuperare $\leq \pm 10\%$ din valoarea inițială.

<u>Trigliceride</u>: Nicio interferență semnificativă până la 3000 mg/dL (33.9 mmol/L).

<u>Bilirubină neconjugată</u>: Nicio interferență semnificativă până la 30.0 mg/dL (513 µmol/L).

<u>Bilirubină conjugată</u>: Nicio interferență semnificativă până la 29.5 mg/dL (504 µmol/L).

<u>Hemoglobină</u>: Nicio interferență semnificativă până la 500 mg/dL.

Acid ascorbic: Nicio interferență semnificativă până la 20.0 mg/dL.

Acid acetilsalicilic: Nicio interferență semnificativă până la 200 mg/dL.

Acetaminofen: Nicio interferență semnificativă până la 30 mg/dL.

- În cazuri foarte rare, gamopatiile monoclonale (mieloame multiple), în special de tipul IgM (macroglobulinemia Waldenstrom) poate duce la rezultate nefiabile. ⁽⁶⁾

- Multe alte substanțe și medicamente pot interfera. Unele dintre acestea sunt enumerate în reviste publicate de Young. ⁽⁷⁻⁸⁾

- Stabilitatea la bord/Frecvența calibrării

Stabilitatea la bord: 28 zile

Frecvența calibrării:28 zile

Recalibrați când loturile de reactiv se schimbă, când rezultatele controlului calității sunt în afara intervalului stabilit și după o operație de întreținere.

☞DECLARAREA INCIDENTULUI GRAV

Vă rugăm să notificați producătorul (prin intermediul distribuitorului dumneavoastră) și autoritatea competentă a Statului Membru din Uniunea Europeană în care este stabilit utilizatorul și/sau pacientul, cu privire la orice incident grav care a avut loc legat de dispozitiv. Pentru alte jurisdicții, declararea incidentului grav trebuie să fie în conformitate cu cerințele reglementare locale, statale și federale.

Prin raportarea unui incident grav, furnizați informații care pot contribui la siguranța dispozitivelor medicale *in vitro*.

☞ASISTENȚĂ TEHNICĂ:

Contactați distribuitorul dumneavoastră local sau ELITech Clinical Systems SAS (<u>CCsupport@elitechgroup.com</u>).

☞BIBLIOGRAFIE

1. Panteghini, M. & Biais, R., *Enzymes,* <u>Tietz Fundamentals of</u> <u>Clinical Chemistry</u>, 6th Ed., Burtis, C.A., Ashwood, E.R., Bruns, D.E., (W.B. Saunders eds.), (2008), 317.

2. Dufour, D.R., *The Pancreas: Function and Chemical Pathology*, <u>Clinical Chemistry: Theory Analysis, Correlation</u>, 5th Ed., Kaplan, L.A., Pesce, A.J., (Mosby Inc. eds.), (2010), 651 and appendix.

3. Winn-Deen, E.S., et al, Clin. Chem., (1988), 34, 2005

4. Guder W.G, et al., Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma, and serum samples, (2002). WHO/DIL/LAB/99.1 Rev.2.

5. Schumann, G., et al. Clin. Chem. Lab Med., (2006), 44, 1146.

6. Berth, M. & Delanghe, J., *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, <u>Acta Clin Belg.</u>, (2004), **59**, 263.

7. Young, D.S., <u>Effects of preanalytical variables on clinical</u> <u>laboratory tests</u>, 2nd Ed., AACC Press, (1997).

8. Young, D.S., <u>Effects of drugs on clinical laboratory tests</u>, 4th Ed., AACC Press, (1995).

∽SIMBOLURI

Simbolurile utilizate sunt definite în standardul ISO 15223-1, cu excepția celor prezentate mai jos:

CONT	Conținut
R	Reactiv
b	Modificare față de versiunea anterioară
CE	Conformitate europeană

<u>Notă</u>

Doar pentru ref. **AMSL-0230**, utilizate cu software-ul Selectra TouchPro.



ELITech Clinical Systems SAS Zone Industrielle-61500 SEES Franța www.elitechgroup.com



CHOLESTEROL SL

CHSL

	CHSL-0497	R 1 x 100 mL	+ Std 1 x 5 mL
	CHSL-0507	R 6 x 100 mL	+ Std 1 x 5 mL
	CHSL-0707	R 4 x 250 mL	+ Std 1 x 5 mL
	CHSL-0250	R 12 x 20 mL	
	CHSL-0500	R 6 x 100 mL	
	CHSL-0700	R 4 x 250 mL	
	CHSL-0250	R 12 x 20 mL	
7	CHSL-5505	R 100 mL	
3	CHSL-5710	R 250 mL	
7	CHSL-5220	R 20 mL	
			<i>(</i>

FTRO-CHSL-v29 (06/2023)_(PIT-CHSL-4-v29)

SCOPUL UTILIZĂRII

ELITech Clinical Systems CHOLESTEROL SL este un reactiv de diagnostic in vitro destinat pentru determinarea cantitativă a Colesterolul total în probele de ser și plasmă umană pe analizoare automate sau semi-automate.

Standardul este destinat pentru calibrarea reactivului.

Aceste dispozitive de diagnostic in vitro sunt doar pentru uz profesional.

SEMNIFICAȚIE CLINICĂ⁽¹⁻³⁾

Colesterolul total din ser este derivat din sursele alimentare sau este sintetizat endogen, în special în celulele hepatice și intestinale. Colesterolul este o componentă structurală importantă a membranelor celulare și ale organitelor. Acesta este un precursor al acizilor biliari, vitaminei D și hormonilor steroizi. Colesterolul, fiind insolubil în apă, circulă în asocierea cu lipoproteinele (HDL, LDL, VLDL și chilomicronii).

În practică, măsurarea colesterolului total este necesară pentru evaluarea predispoziției pacienților la risc cardiovascular ca parte dintr-un profil lipidic și pentru a monitoriza strategiile terapeutice asociate. Măsurarea colesterolului total este, de asemenea, importantă pentru diagnosticarea hiperlipoproteinemiei.

LIMITAREA UTILIZĂRII

Analiza cantitativă doar a colesterolul total nu poate fi utilizată pentru diagnosticarea unei boli sau a unei patologii specifice. Rezultatele trebuie interpretate în conjuncție cu alte rezultate ale

testelor de diagnosticare, constatările clinice și istoricul medical al pacientului.

METODĂ ȘI PRINCIPIU⁽⁴⁾

Enzimatică / PAP - Punct final.

Colesterol esterază

Ester de colesterol+H2O ----- Colesterol+Acizi grași

Colesterol oxidază

Colesterol + O_2 \longrightarrow Colest-4-en-3-unu + H_2O_2

Peroxidaza $2H_2O_2 + Fenol + 4-AAP \longrightarrow Quinoneimină + 4H_2O$

4-AAP = 4-Aminoantipirină

COMPOZIȚIE

Reactiv: R				
Tampon Good, pH 6.7	7			
Fenol		24	mmol/L	
4-Aminoantipirină		0.5	mmol/L	
Colesterol esterază	\geq	180	U/L	
Colesterol oxidază	\geq	200	U/L	
Peroxidază	\geq	1 000	U/L	
Azidă de sodiu	<	0.1	% (m/m)	
Conține și surfactanți optimă.	și sărı	ıri de ma	agneziu pent	tru performanță
Standard : Std (Ref	: CHS	5L-0497/	/0507/0707)	
Colesterolul		200	mg/dL	

5.17 mmol/L

MATERIALE NECESARE DAR NEFURNIZATE

- CALI-0550 ELICAL 2
- CONT-0060 ELITROL I
- CONT-0160 ELITROL II
- Soluție salină obișnuită (NaCl 9g/L)
- Aalizoare automate sau semi-automate.
- Echipamente generale de laborator (de ex. pipetă).

- Nu utilizați materiale care nu sunt necesare, după cum este indicat mai sus.

AVERTISMENTE ȘI PRECAUȚII

- Consultați Fișa cu dațe de Securitate (FDS) pentru o manipulare adecvată.

- Reactivul R conține azidă de sodiu care poate reacționa cu plumbul sau cuprul pentru a forma azide metalice cu potențial exploziv. În momentul eliminării acestor reactivi, spălați întotdeauna cu apă din abundență pentru a preveni acumularea de azide.

- Luați măsurile de precauție obișnuite și urmați buna practică de laborator.

- Utilizați doar echipamente de laborator curate sau de unică folosință pentru a evita contaminarea.



1 / 4

STABILITATE

A se depozita la 2-8 °C și a se proteja împotriva luminii. A nu se îngheța.

A nu se utiliza după data de expirare indicată pe etichetele fiolelor.

Standardul trebuie să fie imediat inchis cu capacul pentru a preveni contaminarea și evaporarea.

Stabilitatea la bord:

Stabilitatea la bord este specifică pentru fiecare analizor. (Consultați § DATE PRIVIND PERFORMANȚA).

PREGĂTIRE

Reactivii și Standardul sunt gata pentru utilizare.

DETERIORAREA PRODUSULUI

- Produsul trebuie să fie limpede. Aspectul tulbure indică deteriorarea produsului.

- Nu utilizați produsul dacă există semne vizibile de contaminare sau deteriorare (de ex. materia cu particule).

- Deteriorarea containerului de reactiv poate afecta negativ performanța produsului. Nu utilizați reactivul dacă există dovezi fizice de deteriorare (de ex. scurgeri sau container perforat).

EŞANTIOANE

Specimene necesare ^(1,2)

- Ser.

- Plasmă (heparină de litiu).

- Utilizarea oricărui alt tip de specimen trebuie validată de laborator.

Avertismente și precauții

- Eșantioanele depozitate trebuie să fie amestecate adecvat într-un mixer cu bol Vortex înainte de a fi testate. $^{(2)}$

- Pentru determinarea unui profil lipic se recomandă utilizarea unei probe prelevate de la pacienti care fie au respectat o dietă (nu au ingerat nimic intr-un interval orar) fie care nu au respectat o dietă. Repetarea profilului lipidic pentru o probă prelevată după utilizarea unei diete ar putea fi efectuată în cazurile în care se cunoaște un rezultat al trigliceridelor pentru o probă fără dieta > 400 mg / dL (4.5 mmol / L) sau hipertrigliceridemie.⁽³⁾

 Eşantioanele trebuie colectate în conformitate cu Buna Practică de Laborator şi liniile directoare corespunzătoare care pot fi în vigoare.

Depozitare și stabilitate⁽⁵⁾

- 7 zile la 2-8°C.

- 3 luni la -20°C.

VALORI DE REFERINȚĂ⁽³⁾

Cele mai recente publicații recomandă adaptarea limitelor colesterolului total ca parte a unei evaluări generale a riscului. La nivel de laborator, Federația Europeană de Chimie Clinică și Medicină de Laborator (EFLM) recomandă ca următoarele concentrații să fie raportate ca fiind anormale:

Ser/ Plasmă	mg/dL	mmol/L	
	≥190	\geq 5.0	

<u>Notă</u>: Laboratoarele ar trebui să respecte recomandările aplicabile la nivel local pentru valorile de prag lipidice dacă acestea diferă de cele raportate mai sus.

☞INSTALARE ȘI UTILIZARE

Pentru utilizare pe analizoare Selectra Pro:

- Consultați manualul operatorului :

- Instrucțiuni speciale de programare: Programarea instrucțiunilor speciale este obligatorie atunci când unele combinații de teste sunt efectuate împreună pe analizor. Consultați Instrucțiunile de utilizare pentru ACID SOLUTION & SYSTEM CLEANING SOLUTION pentru o programare adecvată (a se vedea PIT-SOL).

☞PROCEDURĂ

Procedura manuală

lungime de unda :	505 nm
Drum optic:	1 cm
Raport probă/reactiv :	1:100
Temperatura:	37 °C
Citiți față de un blank d	le reactiv.

	CALIBRARE	TEST
Reactiv R	1 000 µL	1000 µL
Calibrator/	10 ul	-
Standardul	iθμ	
Eşantion	-	10 µL

Amestecați și citiți absorbanțele (A) după o incubație de 5 minute.

Procedura automată

Acești reactivi pot fi utilizați pe mai multe analizoare automate. Pentru analizoarele ELITech tip Selectra, aplicațiile validate sunt disponibile la cerere. Pentru software-ul Selectra TouchPro, utilizați aplicația inclusă în codul de bare disponibil la sfârșitul acestui insert.

CALCUL

(A) Proba	
x n	n = concentrație Calibratorul /standardul
(A) Calibratorul / Standardul	
Factor de conversie:	$mg/dL \ge 0.0259 = mmol/L$ $mg/dL \ge 0.01 = g/L$

☞CALIBRARE

ELICAL 2 și Standardul Cholesterol Standard 200 mg/dL sunt trasabile pentru metoda de referință ID-GC-MS (Diluție izotopică - cromatografie de gaz - spectrometrie de masă).

<u>Frecvența de calibrare</u>: Calibrarea este specifică pentru fiecare analizor. (Consultați § DATE PRIVIND PERFORMANȚA).

CONTROLUL CALITĂŢII

Se recomandă ca serurile pentru controlul calității precum ELITROL I și ELITROL II să fie utilizate pentru a monitoriza performanța analizei.

Controalele trebuie efectuate:

- Înainte de a analiza eșantioanele pacientului,
- Cel puțin o dată pe zi,
- după fiecare calibrare
- şi/sau în conformitate cu cerințele laboratorului şi de reglementare.

Rezultatele trebuie să fie în intervalele definite. Dacă valorile sunt în afara intervalelor definite, fiecare laborator trebuie să ia măsurile corective necesare.

MANAGEMENTUL DESEURILOR

Eliminarea tuturor deseurilor trebuie să fie în conformitate cu cerințele de reglementare locale, statale și federale. (vă rugăm să consultați Fișa cu date de securitate (FDS)).

PERFORMANTE

Au fost obținute performanțe pe Selectra ProM, urmând recomandările tehnice CLSI, în condiții de mediu controlate.

Interval de măsurare

20 - 600 mg/dL (0.52 - 15.52 mmol/L).

Eșantioanele care au concentrații mai mari vor fi automat diluate 1:5 cu soluție de NaCl 9 g/L și re-analizate. Această procedură extinde intervalul de măsurare până la 3000 mg/dL (77.59 mmol/L).

Nu raportați rezultatele în afara acestui interval extins.

Pentru utilizatorii cu software Selectra TouchPro, funcția "dilute" efectuează automat diluarea probei. Rezultatele iau în considerare dilutia.

Limita de detecție (LoD) și Limita de cuantificare (LoQ) LoD: 1 mg/dL (0.03 mmol/L)

LoQ: 10 mg/dL (0.26 mmol/L)

- Precizie

Datele privind imprecizia au fost obținute pe 2 analizoare Selectra ProM timp de 20 de zile (2 cicluri pe zi, teste efectuate de două ori).

Rezultatele reprezentative sunt prezentate mai jos.

		M	edie	În interiorul ciclului	Total
	n	mg/dL	mmol/L	CV (%	%)
Nivelul 1	80	115	2.97	1.1	2.1
Nivelul 2	80	184	4.76	0.7	1.9
Nivelul 3	80	292	7.55	1.9	2.7

- Corelație

A fost efectuat un studiu comparativ între reactivul CHOLESTEROL pe un analizor Selectra ProM și un sistem similar disponibil CRMLN certificat în comerț pe eșantioane de ser uman 100.

Concentrațiile eșantioanelor au fost între 20 și 575 mg/dL (0.52 -14.87 mmol/L)

Rezultatele sunt după cum urmează:

Coeficient de corelație: (r) = 0.999

Regresie liniară: y = 1.016 x + 0 mg/dL

- Limitări/ Interferențe analitice

- Au fost efectuate studii pentru a determina nivelul interferentei de la diferiti compusi.

Au fost testate următoarele nivele ale colesterolul total : 116 și 309 mg/dL

Nu este definită nicio interferență semnificativă printr-o recuperare ≤±10% din valoarea inițială.

Bilirubină neconjugată: Nicio interferență semnificativă până la 6.0 mg/dL (103 μmol/L).

Bilirubină conjugată: Nicio interferență semnificativă până la 5.9 mg/dL (101 µmol/L).

Hemoglobină: Nicio interferență semnificativă până la 300 mg/dL.

Turbiditate: Nicio interferență semnificativă până la 614 mg/dL (6.9 mmol/L) echivalent trigliceride.

Acid ascorbic: Nicio interferență semnificativă până la 4.0 mg/dL.

Metil-dopa: Nicio interferență semnificativă până la 1.6 mg/dL.

Acid uric: Nicio interferență semnificativă până la 23.7 mg/dL (1410 µmol/L).

-Nu utilizați eșantioane icterice sau hemolizate.

- În cazuri foarte rare, gamopatiile monoclonale (mieloame multiple), în special de tipul IgM (macroglobulinemia Waldenstrom) poate duce la rezultate nefiabile.⁽⁶⁾

- Rezultatele pot fi reduse fals prin nivele semnificative în eșantion de NAC (N-Acetil-Cisteină), NAPQI (metabolit de acetaminofen (paracetamol)) sau metamizol.

Multe alte substanțe și medicamente pot interfera. Unele dintre acestea sunt enumerate în reviste publicate de Young. (7-8)

Stabilitatea la bord/Frecvența calibrării

Stabilitatea la bord: 28 zile

Frecvența calibrării:28 zile

Recalibrați când loturile de reactiv se schimbă, când rezultatele controlului calității sunt în afara intervalului stabilit și după o operație de întreținere.

Aceste performante au fost obținute cu ajutorul analizorului ELITech Selectra ProM. Rezultatele pot varia dacă se utilizează un alt instrument sau o procedură manuală.

Performanțele aplicațiilor nevalidate de ELITech nu sunt garantate si trebuie definite de utilizator.

DECLARAREA INCIDENTULUI GRAV

Vă rugăm să notificați producătorul (prin intermediul distribuitorului dumneavoastră) și autoritatea competentă a Statului Membru din Uniunea Europeană în care este stabilit utilizatorul și/sau pacientul, cu privire la orice incident grav care a avut loc legat de dispozitiv. Pentru alte jurisdicții, declararea incidentului grav trebuie să fie în conformitate cu cerintele reglementare locale, statale și federale.

Prin raportarea unui incident grav, furnizați informații care pot contribui la siguranța dispozitivelor medicale in vitro.

ASISTENȚĂ TEHNICĂ:

Contactați distribuitorul dumneavoastră local sau ELITech Clinical Systems SAS (ccsupport@elitechgroup.com).



ELITech Clinical Systems SAS Zone Industrielle-61500 SEES Franța www.elitechgroup.com

BIBLIOGRAFIE

1. Rifai, N., Warnick, G.R., Remaley, A.T., *Lipids, lipoproteins, apolipoproteins and other cardiovascular risk factors.* <u>Tietz</u> <u>Fundamentals of Clinical Chemistry</u>, 6th Ed., Burtis, C.A., Ashwood, E.R., Bruns, D.E. (W.B. Saunders eds.),(2008), 402.

2. Burnett, J.R., *Coronary Artery Disease: Lipid metabolism.* <u>Clinical Chemistry: Theory, Analysis, Correlation</u>, 5th Ed., Kaplan, L.A, Pesce, A.J., (Mosby Inc. eds.), (2010), 691 and appendix.

3. Langlois, M.R., *et al.* for the European Atherosclerosis Society (EAS) and the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Joint Consensus Initiative, <u>Clin.</u> <u>Chem. Lab. Med.</u>, (2020), **58**, 496.

4. Allain, C.C., et al., Clin. Chem., (1974), 20, 470.

5. Guder, W.G., et al., Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples. (2002). WHO/DIL/LAB/99.1 Rev.2.

6. Berth, M. & Delanghe, J., Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature, Acta Clin Belg., (2004), **59**, 263.

7. Young, D.S., <u>Effects of preanalytical variables on clinical</u> <u>laboratory tests</u>, 2nd Ed., AACC Press, (1997).

8. Young D.S., <u>Effects of drugs on clinical laboratory tests</u>, 4th Ed., AACC Press, (1995).

∽SIMBOLURI

Simbolurile utilizate in documentatie sunt definite conform standardului ISO-15223-1 cu exceptia celor prezentate in glosarul de simboluri disponibil pe site-ul ELITech. (Symbols glossary)

