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Stat Fax® 2100

Operator's Manual

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1. INTRODUCTION

1.1 Applications

1.1.1 Intended Use

The Stat Fax® 2100 is a laboratory instrument intended for in-vitro diagnostic use. It is a compact, microprocessor-controlled, photometer system designed to read and calculate the results of assays, including in-vitro clinical diagnostic assays, which are read in microtiter plates. This general purpose instrument is intended to be used by trained laboratory professionals.

1.1.2 Summary of the Instrument

This instrument reads monochromatically or bichromatically and has 3 models: a four filter model (405, 450, 492, and 630 nm), a six-filter UV model (405, 450, 492, 630, 545, and 340 nm), and a six-filter VIS model (405, 450, 492, 630, 545, and 600 nm). Substitute wavelengths in the range of 340 nm-700 nm are available on specially ordered models. It accepts all standard microplates, whether the wells have flat or round bottoms. Trays containing microstrips may also be read. The instrument can be configured to read and format printed data in either the 12-well (1-12) direction or the 8-well (A-H) direction to accommodate both types of assays. The instrument automatically positions the plates, blanks, reads, calculates, and sends the results to an external serial printer. Alternately, the data may be output to a computer which has been programmed to accept serial data. A serial cable is provided as a standard accessory. More information about the printer requirements and instructions for serial connection are given in this manual.

Besides providing absorbance readings, this instrument also offers pre-programmed modes for performing the most commonly used calculations, multiple convenience features, and user programmable memory to further facilitate testing.

Pre-programmed Modes

The basic calculations are permanently stored in memory and include several single and multi-point equations. Provisions are made in certain cases for reading specimens in duplicate and/or using the mean reading in calculations. Each calculation mode is described in detail in section *2.2-Calculation Programs*. These modes are keyboard selectable and self-prompting to reduce error and simplify operation. The following general purpose modes are offered: absorbance mode, single calibrator mode, cutoff mode, % absorbance multi-point mode, point-to-point mode, and best fit determinations for linear and quadratic functions (regression and polynomial modes).

Convenience Features

Convenience features include the ability to indicate the locations and outcomes of positive, negative, and low positive controls via the keyboard, the ability to enter positive and negative cutoffs for automatic interpretations, options for automatic blanking, the ability to end reading at a user-designated well, and the ability to plot and edit curves in the multi-point calculation modes. A convenient built-in mixer is also available to provide plate agitation for a timed interval. A “Self Check” key offers automatic function testing to facilitate daily instrument QC requirements and troubleshooting. Instructions for the use of each of these features are provided in this manual.

User-programmable Memory

User-programmable memory allows the operator to store test protocols in a numbered test menu. Thereafter, these tests may be readily recalled for later use with minimal set up. Standard curves are also stored in this memory. Test protocols remain stored until either changed or deleted by the user. Instructions for using this memory are given in section *2.3.5-Test Menu*.

Besides quick, accurate, and reproducible results, this instrument offers versatility, economy, and easy maintenance-free operation. A stable, factory-calibrated, durable design and a timed lamp saving feature further assure the reliability of the Stat Fax® 2100 microplate reader.

1.1.3 Principles of Operation

The plate carrier precisely positions each well into the optical path for reading. Light energy from an overhead lamp is focused by an integral lens, directed through an aperture, and then passed vertically through the sample. Below the sample, a continuously rotating wheel positions the filters so that readings can be taken very quickly at both the operating and differential wavelengths. (Using bichromatic differential absorbance values corrects for optical imperfections in the plastic wells and removes the effects of meniscus and turbidity.) A photodetector converts transmitted light energy into electrical signals, which are amplified and interpreted.

A single optical system reads each well, one-by-one, thus assuring identical optical conditions and providing an economical and low maintenance design. A 96 well plate can be read and printed in the absorbance mode in about 2 minutes.

1.2 Warning Markings

1.2.1 Safety Symbols

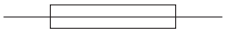
Safety symbols which may appear on the product:

WARNING
Risk of Shock

Protective Ground
(Earth) Terminal

CAUTION
Refer To Manual

BIOHAZARD
Risk of Infection



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.

1.2.2 Safety Terms

These terms may appear on the product:

DANGER indicates an injury immediately accessible as you read the marking.

WARNING indicates an injury hazard not immediately accessible as you read this marking.

CAUTION indicates a hazard to property including the product.

Terms which 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 the 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.

1.3 Safety Precautions

To assure operator safety and prolong the life of your instrument, carefully follow all instructions outlined below.

Read Instructions
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.

Personal Protective Equipment
Many diagnostic assays utilize materials which are potentially biohazardous. Always wear protective apparel and eye protection while using this instrument.

Follow Operating Instructions
Do not use the instrument in a manner not specified by the manual or the protection provided by the instrument may be impaired.

Use Proper Power Cord
Use only the power cord specified for this product and certified for the country of use.

Ground the Product
This product is grounded through the grounding conductor of the power cord. To avoid electric shock, the grounding conductor must be connected to earth ground. An alternate method is to attach a ground strap from the external grounding terminal on the rear panel of the instrument to a suitable ground such as to a grounded pipe or some metal surface to earth ground.

Observe All Terminal Ratings
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
The (name unit) should be installed on a sturdy, level surface capable of supporting the instrument's weight (25 lbs, 11.4 kg) safely for safety and ventilation purposes. The mounting surface should be free of vibrations.

Provide Proper Ventilation
Refer to the installation instructions for details on installing the product so it has proper ventilation. The instrument should be surrounded by the following clearances: 8 cm around perimeter of unit and 8 cm on top.

Do Not Operate Without Covers
Do not operate this instrument with covers and panels removed.

Use Proper Fuse. Use only the fuse type and rating specified by the manufacturer for this instrument. Use of a fuse with an improper rating may pose a fire hazard. Refer to the section on Trouble Shooting for details on fuse replacement.

Avoid Exposed Circuitry
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
If you suspect there is damage to this instrument, have it inspected by a qualified service person.

Do Not Operate in Wet/Damp Conditions

Do Not Operate In An Explosive Atmosphere

Keep Instrument Surfaces Clean and Dry
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 is easily scratched.

The exterior of the instrument may be cleaned with a soft cloth using plain water. If needed, a mild all-purpose or nonabrasive cleaner may be used. A 10% solution of chlorine bleach (5.25% Sodium Hypochlorite) or 70% isopropyl alcohol may be used as a disinfectant. 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.

Biohazard Precautions

BIOHAZARD

WARNING - If any materials are overturned during operation, immediately set the power switch to OFF (0). This material should be treated as potentially biohazardous. Appropriate clean up and disposal of the material should be observed.

1.4 Installation

1.4.1 General Installation

Unpack Instrument

Carefully unpack the instrument, removing it from its plastic bag. Report any damage to your freight carrier at once. The box should also contain the User's Manual and a serial cable.

Remove Shipping Screw from Bottom of Instrument

This screw prevents movement of the plate transportation mechanism and should **ALWAYS** be in place during shipping. During shipments, use the original packaging material or other suitable protective foam, and remember to install the shipping screw.

NOTE: Retain the original packing material (and shipping screw) for future use in the event that the instrument is shipped to another location or returned for service.

Instrument Mounting and Use

Place the instrument on a flat working surface capable of safely supporting the weight of the instrument (approx. 21 lbs, 9.5 kg). Excessive vibration during reading may cause poor repeatability; thus, a sturdy working surface is required. A clearance of at least 3 inches (8cm) around the instrument is required to assure optimal ventilation. It is recommended that the instrument be operated within an ambient temperature range of 18-35°C and humidity of less than 80%.

Power Switch Position

When installing the power cord or if changing the setting on the voltage select switch the unit should be turned off. Look at the rear panel of the instrument to check that the power switch is in the Off position. A diagram of the rear panel can be found in Section 1.6 "Parts and Controls".

Power Cord Requirements

Use only the power cord specified for this product and certified for the country of use. For 110-120 V units used inside 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 250 V, with a tandem blade, grounding type attachment plug. The cord set provided by the manufacturer meets these requirements.

Safety Grounding

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. Internal fasteners to grounding points are marked by the IEC 417 symbol 5019  . 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.

To avoid electric shock, the power cord protection ground conductor must be connected to ground.

Voltage Select Switch
Locate the voltage select switch on the rear panel. This is a 2-position slide switch that will configure the instrument to accept either 230V or 115V input. Do not connect equipment to the power supply before changing the line voltage selection switch.

 **Warning:**To prevent permanent damage to the instrument, this switch must be set for the appropriate input voltage before powering up.

When you can see the 230V label, the instrument is set for 230V input. If you plug the instrument into a 115V power supply while 230V is selected, the instrument will have insufficient operating power.

To select 115V input, insert a straight screwdriver blade (or similar instrument) into the slot on the switch, and slide it into its alternate position. Upon sliding the switch, you will see the 115V label appear.

 **Warning:** If the instrument is configured to accept 115V and you plug it into a 230V power supply, the fuses will blow and permanent damage to the electronics may result.

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 you turn the instrument back on, it will resume normal operation, but a standard curve which was not stored in non-volatile memory will be lost.

Fuse Requirements
The fuses are located internally in the instrument; there are two fuses, fusing both sides of the main power supply. Fuse failure is a very rare occurrence and should indicate malfunction of the equipment requiring service by qualified personnel.

The fuses used within this instrument are 1/2 Amp T rated (slow blow), 250 V. Cartridge size is 3AG or size “0”, dimensions 1/4 x 1-1/4” (6.3 x 32 mm).

 **WARNING:** For continued protection against risk of fire, use the same fuse for either 115 or 230 V line voltage selection. Disconnect power cord from mains supply before replacing fuses.

1.4.2 Printer Requirements

Either an off-line printer or a computer must be used with this reader to record the test data and results. The printout provides a permanent record of the date and time, modes, filters and other test parameters used. If data is output to a via the serial port, you will require software for data management. Contact your dealer for information on serial connection to a PC.

The instrument does not require a PC. It is designed for use with a serial printer that prints 80 characters per line and has a buffer capacity of at least 2000 characters (2K bytes). This specification is met or exceeded by most commercially available printers. Any print type (i.e. ink jet, thermal, impact, etc.) may be used. The instrument uses EPSON emulation; other emulation modes may provide incorrect handling of control codes, resulting in incorrect bolding, underlining, condensed printing, etc. Serial printers are also available from Awareness Technology; consult your dealer.

Alternately, you may choose to use your Stat Fax® 2100 microplate reader with the additional parallel interface. If so, you may use a standard parallel cable (DB-25 connector) to connect your parallel printer. The parallel port is located on the rear of the instrument (above the rear panel) in the center of the back part of the hatch cover. NEVER USE THE PARALLEL PORT OR CABLE FOR A SERIAL DEVICE. With the parallel interface, you will have full handshake. Both serial and parallel ports may be used simultaneously.

1.4.3 Serial Connection

For connecting the instrument to either a serial printer or a computer serial port, a custom double-ended cable is provided. It is a nonstandard cable available through your instrument dealer. If your equipment requires a different plug configuration, you may need to purchase the appropriate adapter. CAUTION: Consult the manual of the PC or printer for the correct pin connections and type of connector before transmitting data. Also, consult the instruction manual of your printer or PC to set up the receiving equipment for serial data input. This is generally done by setting dip switches.

The serial receptacle of the plate reader is located on the left side of the rear panel. Interface: “DB-9P” is configured for data terminal equipment (“D” connector with 9 male pin contacts.) Pin 1 is ground, Pin 2 is the transmit data output.

Data is transmitted at 2400 baud, with 1 start bit, 1 stop bit, 8 data bits in ASCII Code, and no parity bit (RS-232 signal levels).

With both the instrument and the external printer off, plug in both ends of the cable provided. Then plug in and turn on the printer, installing printer paper if needed. Finally, turn on the plate reader. It is important to have the receiving equipment ready before starting up the plate reader; otherwise, data might be lost. The display will indicate **“Stat Fax 2100,”** followed by a software code, the time and date. This information will also be printed, as well as “6 FILTER VISIBLE” or “6 FILTER UV,” if applicable, and the instrument's serial number. Then the reader displays **“SELECT MODE,”** the date and time. Check that the clock and calendar are correctly set for your time zone. If you need to set the time and/or date, follow the instructions in section *2.4.7-Clock and Calendar*.

1.4.4 Parallel Printer Operation

The 2100 series can output text and graphs to an external printer connected to the parallel port. Compatible printers are:

Hewlett Packard Desk Jet series (parallel only)

Canon Bubble Jet (BJ) series (parallel only)

Epson Dot Matrix Printers (and others capable of Epson emulation – serial or parallel)

Configuration

To select a pagination mode, select Test 101, and press ENTER. The display will show "**New test…new page Y/N**".

Select YES to print a new sheet each time you begin a new test.

Select NO to print continuously with page breaks determined by the lines allowed per page.

At power-up, the printed header will indicate "**Test form feed on**" or "**Test form feed off**".

To configure the instrument for parallel output to **Canon BJ** series or **Hewlett Packard Desk Jet** printers, select **test 102.** The display will show:

"Select printer: HP DeskJet"

To select HP DeskJet, press YES. Select NO and the display will show:

"Select printer: Canon Bubble Jet"

To select Canon Bubble Jet, press YES. Select NO and the display will show:

"Select printer: Epson/Dot Matrix"

To select Epson/Dot Matrix, press YES. Select NO and the display will return to the first printer selection prompt.

After the printer type is selected, the display will show:

"Select paper type: Letter"

Press YES for Letter size paper (8 ½" x 11"). Select NO and the display will show:

"Select paper type: A4"

Press YES for A4 size paper (210mm x 297mm). Select NO and the display will return to the first paper selection prompt.

After selecting the printer configuration, the display will return to the main prompt.

Note that the default settings are Dot Matrix with Letter size paper.

Operation

To view data, such as calibrator results or curve plots, or to print a partial page, press the PAPER key. The HP printer will print data stored in its memory; the Canon will expel the partially printed page and load the next sheet. Subsequent entries and results will be printed on the next sheet. Note that the instrument does not reset its page number count each time the PAPER key is pressed.

1.5 Check-out Procedure

After installation, perform the following instrument checkout procedure. If any portion of this procedure indicates improper function, do not use the instrument. Contact your dealer to arrange for assistance.

Ensure that the shipping screw has been removed. Press the self check key labeled "SelfCk." The instrument will automatically check the intensity of the lamp output, the rotation of the filter wheel, the X-Y motion of the plate carrier, the alphanumeric display, and the printer.

When you press the SelfCk key, the instrument will display **"SYSTEM DIAGNOSTICS: Remove Plate è ENTER."** After you press ENTER, it begins a 45 second lamp warm-up. You can observe the countdown on the display: **"LAMP WARMUP: XXX SECS,"** where XXX represents seconds remaining. Listen for a double beep when the countdown is completed. The instrument will check the lamp intensity at this time and display the results of the check using one of these messages: **"LAMP OUTPUT OK"** or **"LAMP OUTPUT LOW!"**

Then the instrument will check the positioning of each filter in the rotating filter wheel, and display the outcome using one of these messages **"PHOTOMETER OPERATION OK"** or **"FILT XXX VOLTAGE IS LOW"** where **"XXX"** identifies the wavelength that did not pass the test.

Next, the plate carrier will exercise its entire range of motion, then return to the starting position. Watch the display to see **"PLATE TRANSPORT OKAY"** or **"MECHANISM FAILURE."**

When the self check is done, the printer will have recorded the results of the tests for lamp output, filter selection, and plate transportation mechanism. The printed message **"SYSTEMS CHECK OKAY"** indicates that you are ready to select a mode and begin testing. The entire alphanumeric and symbol set of characters will be sent to the printer to test printer function. Observe the printout for accurate presentation.

If errors are detected, review the troubleshooting guide and contact your dealer for assistance.

The message **FILTER LABELS RESET** or **RUN TEST #248 TO RESET FILTERS** occurs when the memory of the instrument is affected in such a way as to lose the filter labels stored in RAM. If this occurs, see the *Flags and Error Messages* section of this manual (section 2.4.5) for instructions.

1.6 Parts and Controls

The following labeled sketches serve to clarify the nomenclature which is used in this manual to describe parts and controls of the Stat Fax® 2100. More details on the operation of each feature are provided in section *2-Operating Procedures*.

1.6.1 Parts of the Instrument

A Cover

B Base

C Rear panel

D Deck

E Microplate in Plate Holder (in home position)

F Alphanumeric display

G Keyboard

H Right rear well "A-1"

I Hatch Cover

J Parallel port

K Power switch

L Power cord set

M Ground pin - alternately, the instrument may be supplied with a standard Euro-plug (2 round pins) for European clients.

N Voltage selec switch

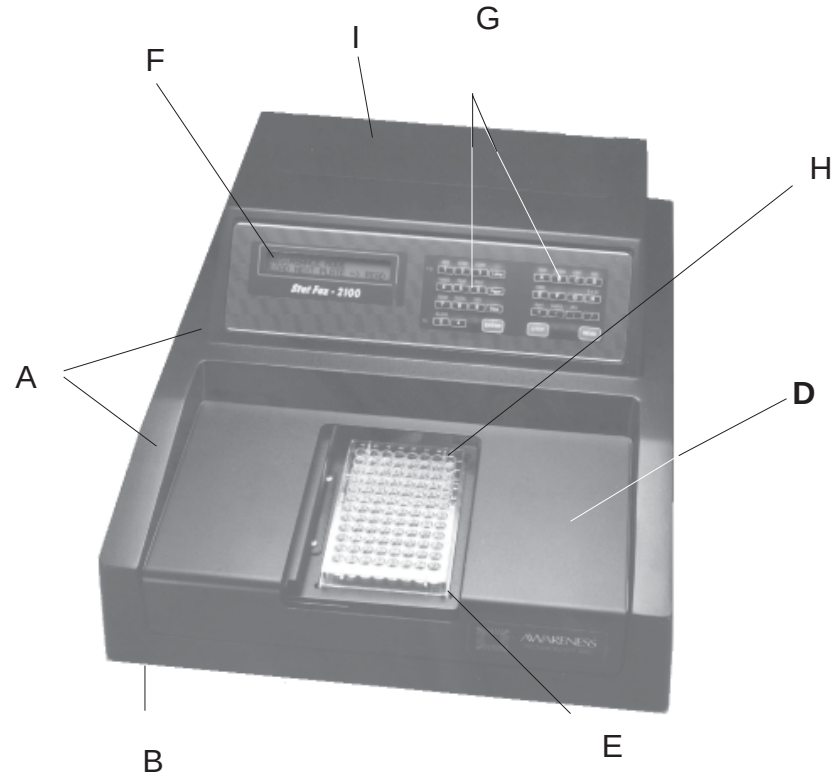
O Serial output connector

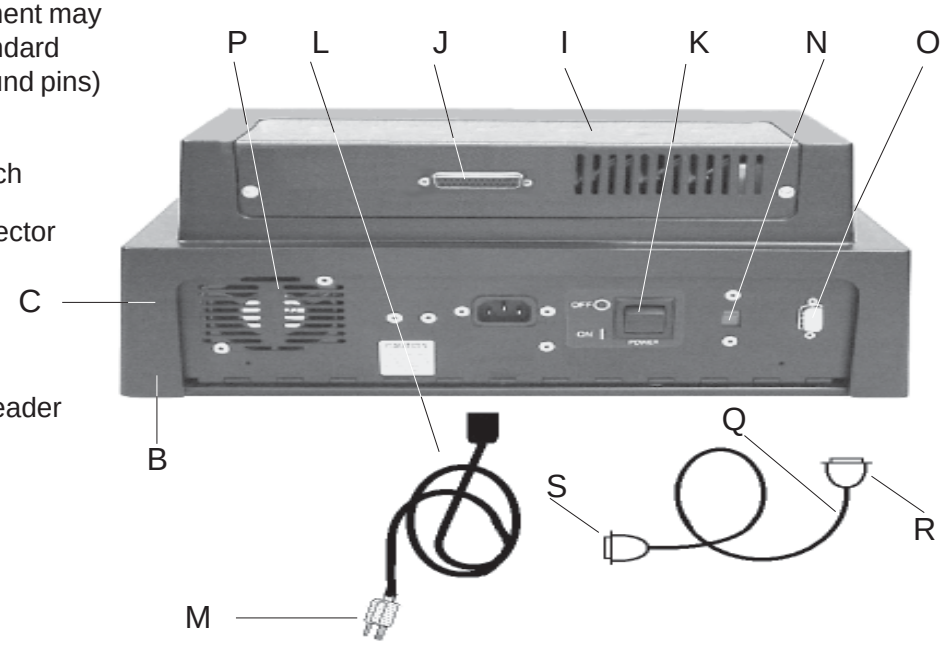
P Vent holes

Q Serial Cable

R Female 9-DB for reader

S Male 25 pin DB for SERIAL printer





1.6.2 Keyboard Functions

The keyboard is divided into two sets of keys. The numeric keys are located in the left-most set and the alpha characters (A-H) are located in the right-most set. These keys are used to indicate well locations. Standard microplates are labeled as 8 rows (A-H) with 12 wells in each row (1-12). Whenever the plate is loaded into the Stat Fax® 2100 with well A-1 at the right rear position, these keyboard designations may be used.

In addition to locating wells, the numeric keys are used to input numeric information such as standard values, number of standards, number of seconds, etc. They are also used to designate filter choices as follows:

Four Filter Model:

Key 1 = 405nm , Key 2 = 450nm , Key 3 = 492nm , Key 4 = 630nm and Key 0 = no differential filter

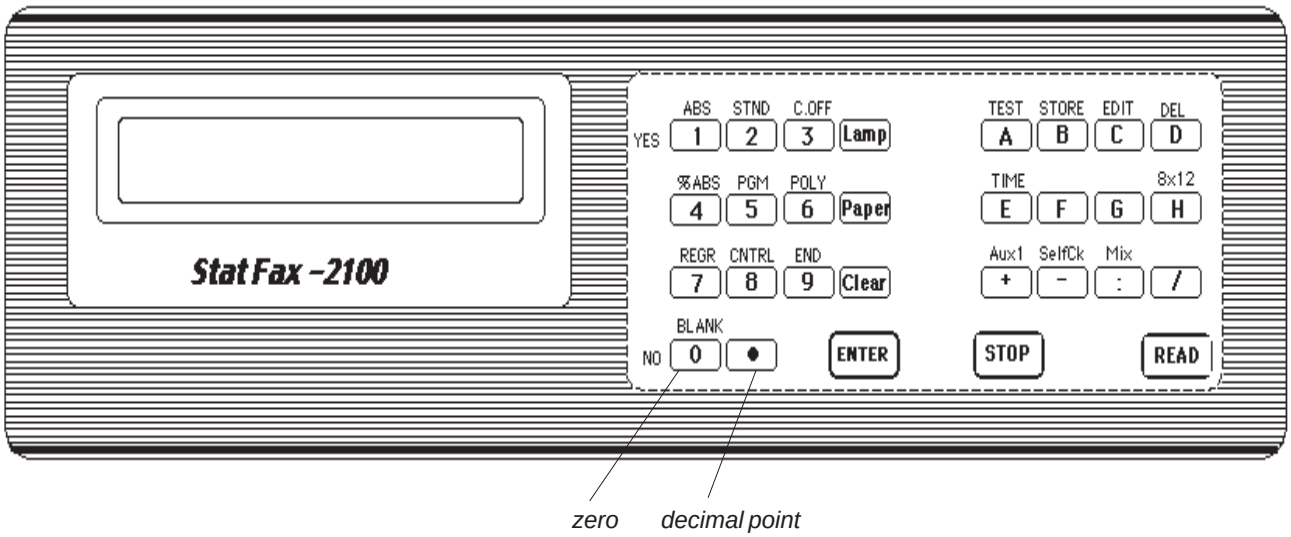
Six Filter UV Model:

Key 1 = 405nm , Key 2 = 450nm , Key 3 = 492nm , Key 4 = 630nm

Key 5 = 545nm, Key 6 = 340nm and Key 0 = no differential filter

Six Filter VIS Model:

Key 1 = 405nm , Key 2 = 450nm , Key 3 = 492nm , Key 4 = 630nm



Key 5 = 600nm, Key 6 = 545nm and Key 0 = no differential filter

Most of the keys serve several functions. Key function is determined by the question asked in the display. Key number 1, for example, will serve as a number 1 whenever the instrument is asking for numeric input. It will select the 405nm filter if a filter choice is being requested. It will answer YES if a Yes or No question is being asked. Otherwise, it will select the Absorbance Mode. The upper functions on the first 7 numeric keys represent the pre-programmed general purpose calculation modes. These modes are initiated by keyboard selection whenever the instrument is not asking for a number, yes or no, or for a filter selection. If the instrument is seeking numeric input and you wish to cancel that request in order to select a new mode, press the CLEAR key twice and then select the desired mode.

SAMPLE KEY

upper function used to select the mode

ABS

1

lower function used to designate number one only when the instrument is requesting a numeric value

The following key designations are used to identify the pre-programmed general purpose calculation modes:

ABS =	Absorbance Mode	STND =	Single Calibrator Mode
C.OFF =	Cutoff Modes	%ABS =	Percent Absorbance Multi-Point
PGM =	Point to Point Mode	POLY =	Best Fit Polynomial Function
REGR =	Best Fit Linear Function		

The other upper functions on the numeric key set are these:

CNTRL = Indicates the well locations of and criteria for controls.

END = Designates the last well to be read if desired.

BLNK = Blanks on the first well of the next plate in Absorbance Mode.

The numeric set also includes these keys:

Lamp: Turns the lamp on and off. This serves to extend lamp life.

Paper: Sends a carriage return to the printer.

Clear: If pressed once, before using the ENTER key, the Clear key removes a keyboard entry, allowing for immediate correction of typing errors. If pressed twice, the Clear key clears the mode of operation.

ENTER: Communicates to the instrument that the operator is finished providing keyboard input. Generally, the ENTER key causes the instrument to move on to the next prompt.

YES and NO keys are used to answer yes and no questions. They are on the 1 and 0 keys and only serve these functions when a yes or no question is asked in the display.

The Alpha Set: The primary function of the alpha keys A-H is to locate wells. The other lower functions on this key set are the positive and negative signs, a colon (used in editing time) and a slash mark (used in editing date). Just as with the numeric keys, lower functions are only available when a question requiring their use is being displayed by the instrument. Use of non-volatile memory involves the upper function keys: STORE , DEL, EDIT, and TEST. STORE is used to add a new test number; DEL (=DELETE) is used to completely erase a test number making that memory location available for a future test; EDIT is used to edit a test in memory and also to change the time and date; and TEST is used to recall a rest from the stored test menu.

TEST: Accesses stored user tests

TIME: Pressing EDIT TIME allows for changing the time and date

8X12: Configures the reader for 8 or 12-well reading format

Aux1: Format Plate; Allows the user to set up a plate containing multiple tests.

SelfCk: Initiates an automatic function check

Mix: Causes the plate to move inside the instrument and mix for a specified time interval

STOP: Stops the instrument from reading or mixing and returns the plate to its home position

READ: Initiates plate positioning and reading. There will be a 45 second delay for lamp warm-up, if this key is pressed when the lamp is off.

TO PRINT THE ENTIRE USER MENU, SELECT TEST # 99, AND PRESS ENTER

TO CLEAR THE ENTIRE USER MENU, SELECT TEST #183, AND PRESS ENTER

1.7 Specifications

Photometric

Linear Measurement Range	0.00 to 3.0 Absorbance Units (A)
Photometric Accuracy	+/- (1% of the reading + 0.01 A from 0 to 1.5 A) +/- (2% of the reading + 0.01 A from 1.5 to 3.0 A)
Stability	Drift of no more than 0.005 A in 8 hours
Warm up time	45 seconds, built-in
Light Source	Tungsten Lamp
Standard Wavelengths	2100: 405, 450, 492, and 630nm 2100: Six Filter UV: 405, 450, 492, 630, 545, and 340 nm 2100: Six Filter VIS: 405, 450, 492, 630, 600, and 545 nm (Substitute filters from 340 nm-700 nm, available on special order)
Type of filter	Multiple cavity sealed interference, 10 nm half bandpass typical
Vessel	Standard 96 well plates (round or flat bottom wells); also accepts strip trays of standard size (8x12 configuration)

Electronic and Software

Microprocessor	Z80A
Speed	Reads, calculates and prints results for 1 plate in about 2 minutes
Display	24 character x 2 line liquid crystal display (LCD)
Keyboard	29 key, enunciating, membrane switch
Calculation Modes	Absorbance only, single point calibration from a standard, cutoff, % absorbance multi-point curve fit, point to point curve fit, best fit linear, ln, log-logit, and quadratic
Other features	Mixer, real-time clock, self check system, controls locator, partial plate reading, complete user prompting, flags and error messages, cutoff comparisons, curve editing and graphing, monochromatic option, read format 8 vs 12 direction
Serial Port	Output only, 2400 Baud, 1 start bit, 8 data, 1 stop, no parity, no handshake serial cable provided
Power	Switch selectable power supply (115V or 230V indicated) Voltage Source: 110-120V/220-240V Frequency: 50 to 60Hz Power Consumption less than 50 Watts Fuse: two 1/2 A, T rating, 250V slo blo, 3AG type fuses All power cords must be approved for the country of use

Certifications and Compliances ..... Listed to UL Standard 1262, Laboratory Equipment
CE Certificate of Conformity. Conforms to the following standards: EN 50082-1 and EN 55022 following the provisions of the 89/336/EEC directive

Physical

Enclosure ..... Fire-retardant ABS Plastic cover with metal base

Dimensions ..... Approx. 43 x 37 x 18 cm, 11.4 kg

Environmental Conditions for Safe Operation

Indoor use
Altitude up to 2000m
Temperature 5ºC to 40ºC (Although it may be safe to operate in these conditions, it may not be suitable for the performance of your tests; check with your supplier).
Humidity 80% for temperatures up to 31ºC, decreasing linearly to 50% humidity at 40ºC
Mains supply voltage fluctuations not to exceed ±10% of nominal voltage

Recommended Environmental Conditions

Recommended Operating Temperature 18-35ºC

Recommended Operating Humidity ..... Less than 80%

Optional Accessories ..... Serial printer, DRI-DYE® Check Strips (for instrument QC)

2. OPERATING PROCEDURES

To begin, the reader must be programmed to calculate and to label wells and results according to the operator's specifications. For test procedures with many entries, it is recommended that inexperienced operators prepare a list of their selections before beginning operation. Alternately, these tests can be stored in non-volatile memory to reduce set up requirements to a single step for subsequent uses. When tests are recalled from the user menu, all of the general selections will have been predetermined. Section *2.1-General Selections* provides information about making general selections such as mode, filter, blank, replicates, cutoffs, and controls. Section *2.2-Calculation Programs* follows with mode-specific instructions for each general purpose calculation program. Section *2.3-Test Menu* explains how to create and use your own test menu (stored in non-volatile memory). Finally, section *2.4-Special Features* provides specific details on the operation of each additional special feature (i.e. mixer, date and time, printer, etc.).

2.1 General Selections

Although many features are available to aid the user, this instrument may be operated in most modes by pressing ENTER to bypass questions relating to extra optional features.

For every test, the instrument will require a mode selection and filter combination. Thereafter, only those questions that pertain to the mode selected will be asked. In the absorbance mode, for example, there are no further selections required.

Here is a list of questions to review before beginning a test:

1. What calculating program will be used?

2. What filters are optimal? (operating and differential wavelengths)

3. If reading monochromatically, how much absorbance offset is necessary?

4. Is a blank required? desired?

5. How many calibrators will be used? Note: for the purpose of this manual, the terms calibrator and standard are used interchangeably to designate reference materials of known concentrations

6. What is the calibrator value or values?

7. Will calibrators and /or specimens be read in duplicate, or singly? Note: for the purpose of this manual, the terms specimen and sample are used interchangeably to mean materials of unknown concentrations.

8. Will locations of 1 or more controls be marked? If so, you will need to indicate plate number, row number, and well number for each.

9. Will acceptance cutoffs or ranges for controls be entered for automatic comparison? If so, what cutoffs or ranges are to be used for each?

10. Will a cutoff value be used to label positive samples? If so, the value which begins the positive range will be required.

11. Will a cutoff value be used to label negative samples or define an equivocal zone? If so, results less than what cutoff should be labeled as negative?

12. Will this test be stored? If so, you must remember to store it before you cancel the mode.

13. For multi-point modes with duplicate standards, the instrument will ask if you wish to delete points from the standard curve before proceeding. What criteria will be used to determine “bad curves?” If you do not accept a curve, you will be asked which points you wish to delete. Again, some preestablished criteria for selecting “bad points” and perhaps a maximum number of acceptable deletions might be needed.

2.1.1 Selecting a Plate Format

To begin, turn the instrument on and see **“SELECT MODE”** in the display. The lamp will warm up for 45 seconds. During this time, you may begin making your selections. If the lamp warm up is not completed by the time you press the READ key, the display will indicate **“LAMP WARM UP XXX SECS”** where XXX represents the number of seconds remaining. When the instrument is ready, a double beep will be heard, and the instrument will read.

Standard microplates can be read in either the left/right direction (8 well strips) or in the front/back direction (12 well strips) beginning at well A-1. It may be necessary to switch formats in order to perform assays from different manufacturers. Your plate reader can be configured for reading and presenting data using either format. Once a format is selected, it stays selected until you change it, or until a stored test of different format is run.

To select a plate format, first press the 8X12 key [H key]. The display will ask **“READ MODE: A to H Y/N.”** If you answer YES [1 key], the plate will read in the left/right direction (8 well strips), and data will be printed as A-1, B-1, C-1, etc. If you answer NO [0 key] to this display, the plate will be read in the front/back format (12 well strips), and data will be printed as A-1, A-2, A-3, etc.

After you make your format selection, your choice will be printed, and the display will return to **“SELECT MODE.”**

You may change formats as needed whenever **“SELECT MODE”** is being displayed. If you store a test in the menu, the read direction is also saved.

2.1.2 Selecting a Mode

Stat Fax® 2100 contains several pre-programmed general purpose calculations which have been selected to facilitate data handling for enzyme immunoassays and other similar tests.

1. Absorbance only (ABS key)

2. Single calibrator (STND key)

3. Cutoff Modes (C.OFF key)

4. % Absorbance Multi-Point Mode (%ABS key)

5. Point to Point Mode - curve constructed from point-to-point connection (PGM key)

6. Best fit by polynomial regression (POLY key)

7. Best fit by linear regression (REGR key)

8. Alternately, a previously-stored test could be recalled from your user test menu at this time. (Instructions for this are found in section *2.3-Test Menu*.)

The pre-programmed general purpose calculation mode designations are located above the numbered keys on the keypad. When any of these is selected, the printer will print the name of the mode that you have selected, either 8 or 12 to indicate the plate format, the page number of the test (Page 1), and the date and the time. The display will then indicate your next instruction.

A brief description of each mode follows. For more details, see the section *2.2-Calculation Programs*.

In the **Absorbance Mode**, the Stat Fax® 2100 reads and prints the monochromatic or bichromatic differential absorbances at the user-selected wavelengths. Blanking is optional, through use of the BLANK key.

Modes with one calibration point:

In the **Single Calibrator Mode**, the instrument first accepts a calibrator singly or in duplicate, then calculates concentrations based on a single-point standard curve passing through the point (0,0). A blank is required in the first well, to determine the (0,0) point. A factor (equal to the concentration of calibrator ÷ the absorbance of calibrator) is generated in this mode, and then multiplied by subsequent absorbances to determine concentrations.

Multi-point calibration modes:
In the **% Absorbance Multi-Point Mode**, the instrument accepts a number of calibrators (from 2 to 7) read singly or in duplicate. It then calculates concentrations based on the point-to-point calibration curve, assigning the highest absorbance calibrator as 100%. Blanking, graphing, and editing options are available.

In the **Point to Point Mode**, the instrument accepts a number of calibrators (from 2 to 7) read singly or in duplicate. It then calculates concentrations based on the point-to-point calibration curve. Blanking, graphing, and editing options are available.

In the **Polynomial Mode**, the instrument accepts a number of calibrators (from 3 to 7), subsequently calculating concentrations based upon the best fit (polynomial regression) calibration curve. The polynomial mode is designed for parabolas that open downward, and the lower concentration result is reported. No blank is allowed. Graphing and editing options are available.

In the **Regression Mode**, the instrument accepts a number of calibrators (from 2 to 7), subsequently calculating concentrations based on the best fit (linear regression). Data may be entered for linear-linear, ln (= natural log)-linear, linear-ln, or ln-ln calculations. A logit-log calculation is also available. Blanking, graphing and editing options are available. Absorbance, or ln of (1000 * absorbance), is always on the “Y” axis, and concentration, or ln of concentration, is always on the “X” axis.

Cutoff modes:
In the **Cutoff Control Test**, a number of negative controls are read, then a number of Cutoff Controls, followed by a number of positive controls. Blanking on the first well is optional. The instrument calculates the mean of each set of controls and uses the mean of the cutoff controls as the cutoff value. It also calculates the ratio of the means for QC purposes.

In the **Cutoff Mode**, a number of negative controls are read, followed by a number of positive controls. Blanking on the first well is optional. You may choose either the regular cutoff mode (positive >= cutoff, negative < cutoff), or the reverse cutoff mode (positive <= cutoff, negative > cutoff). The instrument calculates the mean of the positives and the mean of the negatives. It also calculates the ratio of the means for QC purposes. It adds three terms: one user-entered number "X" multiplied by the mean of the negative controls, another user-entered number "Y" multiplied by the mean of the positive controls, and a third user-entered number "Fac." This determines a cutoff point for interpretation of subsequent specimens.

2.1.3 Quitting a Mode

If a test is to be saved in the user test menu, this must be done before canceling the mode. See the section *2.3-Test Menu* for instructions on adding a test.

To cancel a mode, press the Clear key twice. This may be done at any time.

2.1.4 Selecting Filters

The modes all begin by asking you to choose an operating filter and a differential filter. The filter choices, along with their keyboard assignments, will be displayed. Note: The instrument should be used bichromatically. Use monochromatic readings only when no appropriate bichromatic wavelength is available.

The filter choices are shown below along with their keyboard assignments:

	2100	2100 Six UV	2100 Six VIS
key 1:	405nm	405nm	405nm
key 2:	450nm	450nm	450nm
key 3:	492nm	492nm	492nm
key 4:	630nm	630nm	630nm
key 5:	-	545nm	600nm
key 6:	-	340nm	545nm

When you see **"SELECT FILTERS"** in the display, press the key corresponding to the wavelength of your choice. See your selection in the display. If it is incorrect, press the clear key once and select again. When you see the correct selection in the display, press the ENTER key.

"SELECT DIFFERENTIAL FILT" will then be displayed. Again, use the numbered keys to select the desired wavelength, or the 0 (zero) key for no differential wavelength, and press ENTER. Your filter choices will be printed, and the operating mode will continue.

When reading monochromatically, you may want to exercise a special feature called offset absorbance. See the section *2.4.9-Monochromatic and Offset Absorbance* for more details.

The instrument will read every well at both wavelengths, reporting the difference of the two absorbances (absorbance at operating filter minus absorbance at differential filter). Be sure to select a differential wavelength at which your chromophore has little or no absorbance; otherwise, sensitivity may be lost.

2.1.5 Selecting a Blank

If the instrument is not "blanked," the readings are made relative to reading air (no plate or contents). The difference between a water blank and an air blank read bichromatically is typically less than 0.010 A.

The Single Calibrator Mode requires that a blank be used in well A-1. The material of choice is a reagent blank that best defines the absorbance of "zero-concentration." The polynomial mode operates without a blank. For all other modes, use of a blank is optional.

If a blank material is used, it must always be in well A-1, and it is always read singly. **"BLANK"** will be printed to indicate that the absorbance of the first well has been blanked. The absorbance which is printed for well A-1 is the absorbance of the blank material relative to air. This absorbance value is automatically subtracted from subsequent absorbances before printing and calculating.

In the absorbance mode, blanking is accomplished by pressing the BLANK key prior to reading a plate. In all other modes with a blanking option, the question **"BLANK Y/N"** will be shown in the display during the test set up. Press the YES key to blank, and well A-1 of the first plate will be blanked.

TIPS:

• wipe any dust or fingerprints from the bottoms of the plates before using.

• Do not read plates that contain bubbles or condensation.

• Use the same volume for the blank as you use for the samples.

2.1.6 Selecting Units

In all modes other than Absorbance Mode and the Cutoff Modes, you are given the option of selecting units for your concentration values. When the display prompts **"Select units (0-13),"** you may select the unit code you wish to use. Entering 99 will print out the available unit codes, shown here:

0 = Conc	1 = AU/mL	2 = Ratio	3 = ugEq/mL
4 = IU/mL	5 = uIU/mL	6 = % CAL	7 = GPL/mL
8 = MPL/mL	9 = EV	10 = U/mL	11 = A/mL
12 = Abs	13 =		

Selecting unit code 13 will give no unit code. To select a unit code, enter the number of the code you wish to use. The unit code assigned the number you have entered will display on the screen, and you may either press Enter to confirm and select, or press Clear to choose another unit code. Pressing Enter at the **"Select units (0- 13)"** prompt will display the default of Conc, and you still must press Enter again to confirm.

2.1.7 Selecting Duplicates

In most modes requiring one or more calibrators, the operator is given the option of reading either one well or two consecutive wells of each calibrator. In the latter case, the mean absorbance reading is used as the reference absorbance for that standard.

The operator will also be given a choice of reading specimens singly or in duplicate. If duplicate specimens are selected, the mean absorbance reading will be used to calculate a single concentration, and any subsequent labeling of that sample will be based upon that single result.

Remember that the blank well is always read singly.

To make your selections, use the YES and NO keys to answer the following two questions when they come up in the display: **"DUPLICATE CALIBRTRS? Y/N,"** then **"DUPLICATE SAMPLES? Y/N."** If you choose duplicates in either case, your selections will be printed.

Duplicates must be pipetted into consecutive wells. Plates read in the 12 well direction are calculated beginning with well A-1, A-2, A-3, A-4 ... to A-12 and then B-1, B-2, B-3, etc. Side-by-side duplicates (A-1, B-1) will not pair up. Plates read in the 8-well direction are calculated beginning with well A-1, B-1, C-1 ... to H-1 and then A-2, B-2, C-2, etc.

If samples are being read singly, the instrument will assume that controls are also being read singly; if samples are being read in duplicate, the instrument will assume that controls are also being read in duplicate. When using the controls locator feature, it will only be necessary to label the location of one member of the control duplicate pair. (See section *2.1.8-Selecting Control Options* below for more information about the controls locator feature.)

When using the best fit modes, the absorbances of duplicates will be averaged to designate a single point. For example, consider a 3-point linear regression for which the 3 calibrators are read in duplicate. For calculating the standard curve, n=3, n≠6. If one well of a pair is deleted during an editing cycle, then the other well will represent the mean point and n=3, n≠2.

2.1.8 Selecting Control Options

There are two optional features that facilitate the location and analysis of positive, negative, and/or low positive control outcomes. First, the locations of up to 3 (total) controls will be indicated on the printout, if programmed by the operator. Additionally, the operator may enter positive and low positive control acceptance ranges. If so, the instrument will print the upper and lower limits, then automatically compare the resulting concentrations of "located" controls with this range. Controls which do not fall within the designated range are flagged in bold face type.

Control locations and acceptance ranges are entered using the CNTRL key. Control locations may be designated in any mode (except the absorbance and cutoff modes) when **"LOAD NEXT PLATE è [READ]"** is being displayed. The location of only one well of a duplicate pair is needed to identify a control being read in duplicate. Control locations must be designated in order to make automatic comparisons to user-entered acceptance ranges. The control ranges and the locations of the controls are saved in non-volatile memory when tests are stored in the user-test menu.

After pressing the CNTRL key, you will see **"Select control type Pos C. Y/N."** To identify the location of a positive control, press the YES key. For all controls, the instrument will first ask for the plate number by displaying **"PLATE # (1-9)?"** Use only 1-9 and then press ENTER. The instrument will then ask for the row designation as **"ROW # (A-H)?"** Identify the row using the keys A-H, and then press ENTER. Next the instrument asks for the well number as **"WELL # (1-12)?"** Type in the well number (1-12) and then press ENTER. Leading zeros are not needed.

When you finish locating the first positive control, the instrument asks for the greatest acceptable value for the positive controls by displaying **"Pos C. must be =< ?"** The upper and lower values that you enter for the positive controls will be considered in range, while values lower than the low value or higher than the high value will be considered out of range. You must enter the limits using the same concentration units which are used for your calibrators. Type in the upper limit and press ENTER. Then the instrument will display **"Pos C. must be = > ?"** Type in the lower limit and press ENTER. All criteria must be entered for the controls; do not press ENTER to bypass any QC checks. The instrument will then display **"LOAD NEXT PLATE á [READ]"** again.

If you answer NO to the prompt **"Pos C. Y/N,"** you will see **"Neg C. Y/N."** If you want a negative control, press the YES key. Position this control by Plate #, Row #, and Well #. The instrument will then display, **"ENTER CONTROL LIMITS. Neg C. must be =< ?"** As with the positive control, enter the high limit for the control. Negative controls do not have a lower limit.

If you wish to enter a low positive control, answer NO to the prompts **"Pos C. Y/N"** and **"Neg C. Y/N"** You will then see **"Lo Pos Y/N."** Answer YES. Position this control by Plate #, Row #, and Well #, then enter its limits as you would those of a positive control.

After cycling through **"Pos C. Y/N," "Neg C. Y/N,"** and **"Lo Pos Y/N,"** you will see **"Exit Y/N."** If you wish to enter more controls, select no, then enter any additional positive, negative, or low positive control locations. A total of 3 controls (any combination) may be located, and all of the controls of each type will be compared to the range you entered with the first one of that type.

If control locations are entered for wells that have been reserved for either the blank or calibrators, then the blank and calibrator indicators will override positive and negative control indicators when the sample identifications are printed.

To find controls on the printout, look for **"Pos Control," "Neg Control,"** or **"Lo Pos Ctrl"** printed immediately after the well number in the SAMPLE ID column. In the column labeled "Interpretation," look for the words **"Control is HI"** or **"Control is LO"** to determine whether or not the control values are in range. In-range controls have nothing printed in the "Interpretation" column.

2.1.9 Selecting Cutoffs

Samples may also be labeled as Positive, Equivocal, or Negative according to operator-entered criteria. The criteria used can be either a single upper cutoff or both an upper and lower cutoff. When a single upper cutoff is used, any concentration which is equal to or greater than the cutoff will be labeled as positive. **"Positive"** is printed in bold type in the column entitled "Interpretation." All other samples are labeled as **"Negative"** in this same column. If an upper and a lower cutoff are both used, then the concentrations which are greater than or equal to the upper cutoff are still labeled as positive, but only concentrations less than the lower cutoff are labeled as negative. All other concentrations are labeled **"Equivocal."**

Here is how to make cutoff selections in all modes (other than Absorbance Mode and Cutoff Mode). After choosing the mode, filters, calibrators, and replicates, the instrument will display **"POSITIVE >= ?"** If you do not want any cutoffs, press the ENTER key to move on. Otherwise, type in the upper cutoff and then press the ENTER key. Next the instrument will display **"NEGATIVE < ?"** If you do not need a lower cutoff, press the ENTER key to bypass this step. Otherwise enter the value of the lower cutoff and press ENTER. Your cutoff(s) will be printed. Check to see that they are correct before proceeding.

If you choose a positive cutoff, an additional calculation will automatically be performed. The results are printed in a column labeled "INDEX." The index equals the resulting concentration divided by the positive cutoff.

2.2 Calculation Programs

2.2.1 Absorbance Mode (ABS)

When you select the ABS key, the printer prints **"ABSORBANCE MODE,"** 8 or 12 to indicate the plate format, **"PAGE 1"** (indicating the page number of the test), the date, and the time. Spaces will be provided to write in the lot number, expiration date, and the name of the analyst.

In the absorbance mode, the monochromatic or bichromatic absorbances at the user-selected wavelengths will be read. The differential absorbance will be displayed and printed.

If a blank is required, fill well A-1 with the blank material. In this mode, the instrument will not blank unless you press the BLANK key before the READ key. After the filters are selected, if you chose no differential, the Offset Absorbance questions will follow (see section *2.4.9-Monochromatic and Offset Absorbance* for instructions). Then, the reader displays **"LOAD NEXT PLATE è READ."** You may use the "End" function at this time to read only part of a plate by following the instructions in section *2.4.3-End.* Place the plate into the carrier so that the first well (A-1) is at the right rear. When the plate is in place, press the READ key. If the lamp is off, it will turn on and begin to warm up as a built-in 45 second countdown is displayed. The countdown will end with an audible signal, indicating that the instrument is ready.

The instrument will automatically transport the samples through the optical system and back out again. Readings will be displayed as **plate #, row, well #, absorbance reading.**

Results are printed after each row is read (two rows in the A-H direction) in either an 8 X 12 or a 12 X 8 matrix pattern, depending upon the selected plate format. A plate is completely read and printed in about 2 minutes in this mode. If the operator has selected to blank by pressing the blank key, the instrument will show this by printing **"BLANK MUST BE WELL #1"** before the column headings. The absorbance value of the blanked well (well A-1) will be subtracted from the subsequent readings.

To unload a plate, simply lift the plate straight up. The display will indicate **"LOAD NEXT PLATE è READ."** To continue reading in the absorbance mode, load the next plate and press the READ key.

Press the STOP key any time after the test has begun to read the second strip (third strip in the A-H direction) if you want to stop the reading without quitting the mode. If you want to store this test in your user-test menu, be sure to store it prior to canceling (see section *2.3.1-Storing a Test*). Press the CLEAR key twice to cancel the mode and return the plate to the home position.

2.2.2 Single Calibrator Mode (STND)

When you select the STND key, the printer prints **"CALIBRATOR MODE,"** 8 or 12 to indicate the selected plate format, **"PAGE 1"** (indicating the page number of the test), the date, and the time. Spaces will be provided to write in the lot number, expiration date, and the name of the analyst.

In this mode, a single calibrator material of known concentration is used so that concentrations of unknown samples may be calculated according to Beer's Law. The monochromatic or bichromatic absorbances at the user selected wavelengths will be read, and the instrument will automatically blank on well A-1 and subtract its absorbance from each subsequent well.

After the filters are selected, if you chose no differential, the Offset Absorbance questions will follow (see section *2.4.9-Monochromatic and Offset Absorbance* for instructions). The display then prompts you to enter your desired unit code with **"Select units (0- 13)"** (see section *2.1.6-Selecting Units* for instructions). The instrument will then display "KEY VAL. C1 è ENTER." Type the concentration value assigned to your calibrator material, then press the ENTER key. The printer will print **"CALBRTR #1= XXX,"** where XXX is the calibrator value you have entered. The instrument can accept calibrator values up to 7 digits, and calibrators less than 1000 can accept 2 decimal places. If 2 decimal places are desired for calibrators or concentration values, the first calibrator must have a 2 decimal place value assigned.

The display will ask **"DUPLICATE CALIBRTRS Y/N."** Answer by pressing the YES or NO key. Next, the display will ask **"DUPLICATE SAMPLES Y/N."** Again, answer by pressing either YES or NO. If duplicates are selected, this will be indicated on the printout. The instrument will then prompt for the cutoff options: **"Positive = > ?"** and **"Negative < ?"** Refer to section *2.1.9-Selecting Cutoffs* for instructions. Finally, you will see **"LOAD NEXT PLATE è READ."** You may locate controls and set their ranges at this time, following the instructions in section *2.1.8-Selecting Control Options*. You may use the "End" function at this time to read only part of a plate by following the instructions in the section *2.4.3-End.*

Place the first plate into the holder so that the blank well (A-1) is at the right rear. When the plate is in place, press the READ key. If the lamp is off, it will turn on and begin to warm up as a built-in 45 second countdown is displayed. The countdown will end with an audible signal, indicating that the instrument is ready.

The instrument will automatically transport the samples through the optical system and back to the home position. Readings will be displayed as **plate #, row, well #, absorbance reading.**

Results are printed after each row is read (two rows in the A-H direction). The calculated results will be printed out with one line per well. **"Blank"** will appear beside the first well number in the sample ID column, indicating that its absorbance is subtracted from subsequent readings. Well 2 will be labeled **"CALIBRATOR 1"** in the sample ID column, indicating that this well contained calibrator material. In the event that calibrators are read in duplicate, well 3 will also be labeled as a calibrator. Controls will also be identified in this column. In the interpretation column, look for data relating to cutoffs and control outcomes.

To unload a plate, wait for the transport mechanism to come to a stop and then lift the plate straight up. The display will show **"LOAD NEXT PLATE è READ."** To continue reading in the Calibration mode, load the next plate and press the READ key (only the first plate must have the blank and calibrator materials).

If a calibrator has an absorbance reading greater than 3.0 A, the printer will print **">3.00*"** for the absorbance reading, and the concentration will be calculated and printed. The test mode will continue; however, it is not advisable to use such a highly absorbing material as a reference. If a sample has an absorbance reading greater than 3.0 A, the printer will also print **">3.00*"** for the absorbance reading, and the concentration will be calculated and printed. Again, it is not advisable to use calculations made from absorbance readings above the 3.00 Abs level.

If a concentration is too great to print in the concentration field, the message **">10**7"** will be printed for that result.

Press the STOP key any time after the test has begun to read the second strip (third strip in the A-H direction) if you want to stop the reading without quitting the mode. If you want to store this test in your user-test menu, be sure to store it prior to canceling (see section *2.3.1-Storing a Test*). Press the CLEAR key twice to cancel the mode and return the plate to the home position.

2.2.3 Cutoff Mode (C.OFF)

In the Cutoff Mode, X is multiplied by the mean of the negative controls, Y is multiplied by the mean of the positive controls, and each of these two numbers are added to the FAC to get the cutoff value.

For example, your package insert says that the cutoff value is .1 * the mean of the positive controls + .02. You would enter 0 for X, .1 for Y, and .02 for FAC.

a.) To select this mode, press the C.OFF key. The display will then show **"CUTOFF CONTROL TEST Y/N."** If you wish to use cutoff controls, press YES and go on to section 2.2.3-b; otherwise, when you press NO the display will show:

COV = X*mNC+Y*mPC+FAC Y/N

where mNC is the mean of the negative controls, mPC is the mean of the positive controls, and C/O is the cutoff absorbance. X, Y, and Fac are user entered coefficients that can have any positive or negative numerical value (including 0 and 1). Press YES. After the filters are selected, if you chose no differential, the Offset Absorbance questions will follow (see section *2.4.9-Monochromatic and Offset Absorbance* for instructions).

Then, the instrument will give you the choice for reverse cutoff. The display will show:

REVERSE COV Y/N

If you press NO, you will go into the regular cutoff mode, where samples with values higher than the cutoff are labeled as positive. If you press YES, you will go into the reverse cutoff option, where the samples with values lower than the cutoff are labeled as positive. If you choose this option, be careful to follow the < and > signs in the prompts for entering cutoffs and ranges, since they will be the reverse of those described here. In addition, the "Blank" is not subtracted in the reverse cutoff option. The following description is for the normal cutoff mode.

The instrument will then prompt **"BLANK Y/N."** If you press yes, the instrument will display **"Blank must be =< ?"** The reader will use this value to check that the blank is valid. Type the greatest acceptable absorbance value for the blank material relative to air, and then press ENTER. The blank absorbance will be subtracted from all subsequent wells, and will be flagged if it exceeds the set limit.

The instrument now prompts for the X, Y and FAC (cutoff factor) values. Type each of these values followed by the ENTER key.

After these values are entered into the equation, the instrument prompts **"EQUIVOCAL RANGE Y/N."** If you answer YES, you will be able to enter an equivocal range based on factors of the cutoff value. The instrument will prompt **"NEG < X*COV: X= ?"** Enter a number which, when multiplied by the cutoff value, will be the upper limit of the Negative range (enter 1 if you want Negative values to be all values less than the cutoff value). The display will then prompt **"POS >= X*COV: X= ?"** Now enter a number which, when multiplied by the cutoff value, will be the lower limit of the Positive range (enter 1 if you want Positive values to be all values greater than or equal to the cutoff value). Any samples with absorbances falling between these ranges will be labeled "Equivocal."

The Cutoff Mode also offers you the option of adding a QC parameter for the minimum cutoff value. In the event the mNC absorbance reads less than the specified minimum, the Min COV is used as the cutoff.

After entering the X, Y, and FAC values, and the Equivocal range prompts: If Y=0 and FAC=0, the display will prompt **"Use Min COV Y/N"**. Press NO unless your test specifies a minimum absorbance value for the cutoff. Press YES to use the minimum COV as the cutoff (instead of the mNC) if the mNC absorbance reads less than the specified minimum COV. The display then shows "Min COV=?". Enter the minimum cutoff value. If X*mNC>Min COV the cutoff will be X*mNC. If X*mNC<Min COV the cutoff will be Min COV.

The instrument then asks for the number of each type of control to be read. It will also ask for the absorbance acceptance criteria for the mean of each type of control.

# of Neg. Controls = ?

Neg C. must be =< ?

# of Pos. Controls =?

Pos C. must be => ?

NOTE: All controls plus the blank must fit into 8 wells.

Next, the instrument will prompt for an additional quality control value. This is a check of the ratio between the means of the positive and negative controls to assure adequate distinction. When you see the prompt **"mP/mN must be = > ?"** enter the lowest acceptable ratio for the mean of the positive controls to the mean of the negative controls.

Many options not required can be bypassed by pressing ENTER. Otherwise, type each value and press ENTER. Once all information has been entered, the instrument will display **"LOAD NEXT PLATE è READ."** You may use the "End" function at this time to read only part of a plate by following the instructions in section *2.4.3-End.* Load the first plate and press the READ key. The instrument will then begin to read the plate and print the results, labeling the controls as "Neg Control" or "Pos Control."

Press the STOP key any time after the test has begun to read the second strip (third strip in the A-H direction) if you want to stop the reading without quitting the mode. If you want to store this test in your user-test menu, be sure to store it prior to canceling (see section *2.3.1-Storing a Test*). Press the CLEAR key twice to cancel the mode and return the plate to the home position.

b.) **CUTOFF CONTROL TEST**

After you select the cutoff control test, filter selection is prompted. In this test, instead of using the means of the negative and positive controls to determine the cutoff, controls (labeled COV Controls) are used to do so. The positive and negative controls are used for QC criteria. After filter selection, the instrument will prompt **"BLANK Y/N."** In this mode, the photometer can be blanked on air by pressing NO. Alternately, the instrument can be blanked on the material in well A-1 by pressing YES. If yes, the instrument will display **"Blank must be =< ?"** The reader will use this value to check that the blank is valid. Type the greatest acceptable absorbance value for the blank material relative to air, then press ENTER. The blank absorbance will be subtracted from all subsequent wells, and will be flagged if it exceeds the set limit.

The instrument will then prompt **"Correction Factor = ?"** This Correction Factor is multiplied by the mean of the COV Controls to result in the actual cutoff value. Pressing ENTER will bypass this option, setting a Correction Factor equal to 1.

The instrument then prompts **"EQUIVOCAL RANGE Y/N."** If you answer YES, you will be able to enter an equivocal range based on factors of the cutoff value. The instrument will prompt **"NEG < X*COV: X= ?"** Enter a number which, when multiplied by the cutoff value, will be the upper limit of the Negative range (enter 1 if you want Negative values to be all values less than the cutoff value). The display will then prompt **"POS >= X*COV: X= ?"** Now enter a number which, when multiplied by the cutoff value, will be the lower limit of the Positive range (enter 1 if you want Positive values to be all values greater than or equal to the cutoff value). Any samples with absorbances falling between these ranges will be labeled "Equivocal."

The instrument then asks for the number of each type of control to be read. You may select 0 for # of Neg Controls and/or Pos Controls, but you must choose at least one Cutoff Control. The instrument will also ask for the absorbance acceptance criteria for the mean of each type of control.

# of Neg Controls = ?

Neg C. must be =< ?

# of COV Controls = ?

COV C. must be => ?

# of Pos Controls =?

Pos C. must be => ?

NOTE: All controls plus the blank must fit into 8 wells.

Next, you will be prompted to enter an additional quality control value. This is a check of the ratio between the positive and negative controls to assure adequate distinction. When you see the prompt **"mP/mN must be = > ?"** enter the lowest acceptable ratio for the mean of the positive controls to the mean of the negative controls, or press enter to bypass the option.

Many options not required can be bypassed by pressing ENTER. Once all values have been entered, the instrument will display **"LOAD NEXT PLATE è READ."** You may use the "End" function at this time to read only part of a plate by following the instructions in section *2.4.3-End.* Load the first plate and press the READ key. The instrument will then begin to read the plate and print the results, labeling the controls as "Neg Control," "Cutoff Ctrl," or "Pos Control." The mNC must be less than the mCC, and the mCC must have an absorbance greater than 0.000; otherwise, the test will be invalid and interpretations will not be reported.

Press the STOP key any time after the test has begun to read the second strip (third strip in the A-H direction) if you want to stop the reading without quitting the mode. If you want to store this test in your user-test menu, be sure to store it prior to canceling (see section *2.3.1-Storing a Test*). DO NOT store a test after an invalid test run, as this test will not recall properly. Press the CLEAR key twice to cancel the mode and return the plate to the home position.

2.2.4 % Absorbance Multi-Point Mode (%ABS)

The %-Absorbance Multi-Point Mode is a multi-point calibrator mode that allows the operator to enter as many as seven different calibrator concentrations. When you select the %ABS key, the printer prints **"% ABSORBANCE MULTI-PT ,"** 8 or 12 for the plate format, **"PAGE 1"** (indicating the page number of the test), the date, and the time. Spaces will be provided to write in the lot number, expiration date, and the name of the analyst.

In this mode, calibrator materials of known concentrations are used to calibrate the instrument so that concentrations of unknown samples may be calculated according to Beer's Law. In addition, the highest absorbance calibrator will be assigned a value of 100 in the field "% A Hi Cal," and each sample and calibrator is reported in that field as a percent of the absorbance of the highest calibrator. If you wish to use the point (0,0) as a calibrator, you must put the blank material in a calibrator well and assign it a concentration of 0. Be sure to use at least 2 calibrators, since two points are necessary to describe a line. 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, the curve will be flagged as "invalid" and no interpretations will be printed.

Unknown samples are calculated as follows:

First, the unknown sample's absorbance is read and compared to the calibrator absorbances. Then, the line selected as the calibration curve for determining the concentration of the unknown is the line connecting the pair of standards whose absorbances are closest above and below the unknown absorbance. An unknown sample whose absorbance is greater than the greatest calibrator absorbance is calculated on the line passing through the greatest 2 calibrator points. An unknown sample whose absorbance is lower than the lowest calibrator absorbance is calculated from the line passing through the two lowest standards.

For calibrators read in duplicate, dispense the duplicates in consecutive wells. When reading in the 12 well direction with no blank, for example, put the first calibrator into both wells A-1 and A-2. The second calibrator will be pipetted into well A-3 and A-4, and so on. The mean absorbance reading of each pair will be used in the calculations. After the filters are selected, if you chose no differential, the Offset Absorbance questions will follow (see section *2.4.9-Monochromatic and Offset Absorbance* for instructions). The instrument will then ask **"BLANK Y/N?"** Use the YES or NO key to indicate your choice.

Then the reader will ask how many calibrators will be used, by displaying **"KEY # OF CALS. è [ENTER]."** Up to 7 may be used if read singly in either 8 well or 12 well format, or if read in duplicate in the 8 well format. The entire calibration curve, including any blank, must be contained in 12 wells for the 12 well format (i.e., 6 duplicate calibrators without a blank, or 5 with a blank). Type the number of calibrators, then press the ENTER key.

The display then prompts you to enter your desired unit code with **"Select units (0- 13)"** (see section *2.1.6-Selecting Units* for instructions). Next, the instrument will ask you to enter the first calibrator value by displaying **"KEY VAL. C1 è ENTER."** Type the concentration value assigned to your first calibrator material. Then press the ENTER key.

The instrument will then ask you to enter the second calibrator value by displaying **"KEY VAL. C2 è ENTER."** Type the concentration value assigned to your second calibrator material. Then press the ENTER key. This will continue until all calibrator values have been entered.

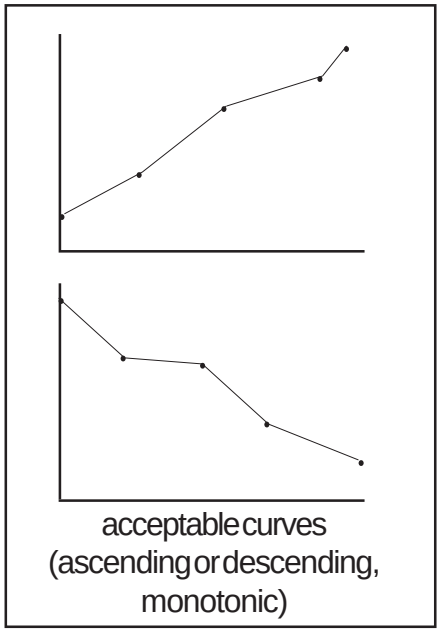
Then, the printer will print

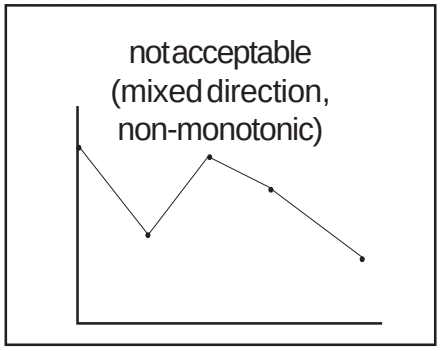
"CALBRTR #1= XXXX"

"CALBRTR #2= XXXX"

"CALBRTR #3= XXXX"....

where XXXX represents the calibrator values you entered. The instrument can accept calibrator values up to 7 digits, and calibrators less than 1000 can accept 2 decimal places. If 2 decimal places are desired for calibrators or concentration values, the first calibrator must have a 2 decimal place value assigned.





The display will ask **"DUPLICATE CALIBRTRS Y/ N."** Use the YES or NO keys to answer. Then the display will ask **"DUPLICATE SAMPLES Y/N."** Again, answer with YES or NO. If duplicates are selected, this will be indicated on the printout and mean readings will be used. Cutoff options will follow: **"Positive => ?"** and **"Negative < ?"** Refer to section *2.1.9-Selecting Cutoffs* for instructions.

Then the instrument will display **"LOAD NEXT PLATE è READ."** You may locate controls and set their ranges at this time, following the instructions in section *2.1.8-Selecting Control Options*. You may use the "End" function at this time to read only part of a plate by following the instructions in section 2.4.3-*End.* Place the first plate into the carrier so that well A-1 is at the right rear, then press READ. The lamp turns on and begins to warm up. A built-in 45 second countdown is displayed. It ends with an audible signal, indicating that the instrument is ready. (NOTE: If the lamp is already on, the warm up step is bypassed.) The reader will automatically transport the samples through the optical system. Absorbance readings will be displayed and printed. Calibrators are identified as **"CALIBRATOR 1," "CALIBRATOR 2"** etc. in the sample ID column. After the first strip is read (2 strips in the 8 well format), the reader will pause to ask if you would like to see the curve printed out. Answer YES or NO

when you see the display **"PLOT CURVE Y/N."** The plotted curve shows the calibration curve, with Concentration on the x-axis and % A Hi Cal on the y-axis.

If calibrators were read in duplicate, the display will ask **"EDIT WELLS Y/N."** Use the YES or NO key to answer. If NO is pressed, the instrument will proceed to read and calculate the samples. If YES is pressed, you will see **"DELETE WELL #"** displayed. Even if well A-1 was the blank, consider it as well #1. The second well read is #2; the third well read is #3, and so on. Type in the well number that you wish to delete and press ENTER. Again, you will see **"DELETE WELL #"** displayed. If you wish to delete another well, type in its well number and press ENTER. You may delete as many as one from each pair, but **you may not delete an entire point**. When no more deletions are desired, press ENTER again. The standard curve will be recalculated showing an "X" beside the deleted well(s). When a duplicate absorbance is deleted, the remaining well will be used as the value for that standard point. Again, the operator will have an opportunity to plot and to edit. This may be repeated as many times as desired until either an acceptable curve is obtained, or the mode is cancelled. To read and calculate specimens, answer NO to the question **"EDIT WELLS Y/N."** The remainder of the plate will be read, calculated, and printed.

To unload a plate, simply lift the plate straight up. The instrument will display **"LOAD NEXT PLATE è READ."** To continue reading in the % Absorbance Multi-Point Mode, load the next plate and press the READ key. (Only the first plate must contain calibrator materials.)

If a calibrator has an absorbance reading greater than 3.0 A, the printer will print **">3.00*"** for the absorbance reading, and the concentration will be calculated and printed. The test mode will continue; however, it is not advisable to use such a highly absorbing material as a reference. If a sample has an absorbance reading greater than 3.0 A, the printer will also print **">3.00*"** for the absorbance reading, and the concentration will be calculated and printed.

Press the STOP key any time after the test has begun to read the second strip (third strip in the A-H direction) if you want to stop the reading without quitting the mode. If you want to store this test in your user-test menu, be sure to store it prior to canceling (see section *2.3.1-Storing a Test*). Storing this test will not store the calibration curve. Press the CLEAR key twice to cancel the mode and return the plate to the home position.

2.2.5 Point to Point Mode (PGM)

The Point to Point Mode is a multi-point calibrator mode that allows the operator to enter as many as seven different calibrator concentrations. When you select the PGM key, the printer prints **"POINT TO POINT MODE,"** 8 or 12 for the plate format, **"PAGE 1"** (indicating the page number of the test), the date, and the time. Spaces will be provided to write in the lot number, expiration date, and the name of the analyst.

In this mode, calibrator materials of known concentrations are used to calibrate the instrument so that concentrations of unknown samples may be calculated according to Beer's Law. If you wish to use the point (0,0) as a calibrator, you must put the blank material in a calibrator well and assign it a concentration of 0. Be sure to use at least 2 calibrators, since two points are necessary to describe a line. 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, the curve will be flagged as "invalid," no interpretations will be printed, and (in the event the test has been stored) the curve will not be stored. Unknown samples are calculated as follows:

First, the unknown sample's absorbance is read and compared to the calibrator absorbances. Then, the line selected as the calibration curve for determining the concentration of the unknown is the line connecting the pair of standards whose absorbances are closest above and below the unknown absorbance. (An unknown sample whose absorbance is greater than the greatest calibrator absorbance is calculated on the line passing through the greatest 2 calibrator points. An unknown sample whose absorbance is lower than the lowest calibrator absorbance is calculated from the line passing through the two lowest standards.)

For calibrators read in duplicate, dispense the duplicates in consecutive wells. When reading in the 12 well direction with no blank, for example, put the first calibrator into both wells A-1 and A-2. The second calibrator will be pipetted into well A-3 and A-4, and so on. The mean absorbance reading of each pair will be used in the calculations. After the filters are selected, if you chose no differential, the Offset Absorbance questions will follow (see section *2.4.9-Monochromatic and Offset Absorbance* for instructions). The instrument will then ask **"BLANK Y/N?"** Use the YES or NO key to indicate your choice.

Then the reader will ask how many calibrators will be used, by displaying **"KEY # OF CALS. è [ENTER]."** Up to 7 may be used if read singly in either 8 well or 12 well format, or if read in duplicate in the 8 well format. The entire calibration curve, including any blank, must be contained in 12 wells for the 12 well format (i.e., 6 duplicate calibrators without a blank, or 5 with a blank). Type the number of calibrators, then press the ENTER key.

The display then prompts you to enter your desired unit code with **"Select units (0- 13)"** (see section *2.1.6-Selecting Units* for instructions). Next, the instrument will ask you to enter the first calibrator value by displaying **"KEY VAL. C1 è ENTER."** Type the concentration value assigned to your first calibrator material. Then press the ENTER key.

The instrument will then ask you to enter the second calibrator value by displaying **"KEY VAL. C2 è ENTER."** Type the concentration value assigned to your second calibrator material. Then press the ENTER key. This will continue until all calibrator values have been entered.

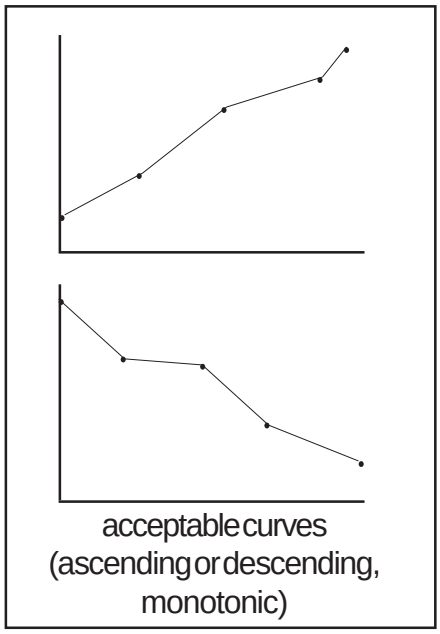
Then, the printer will print

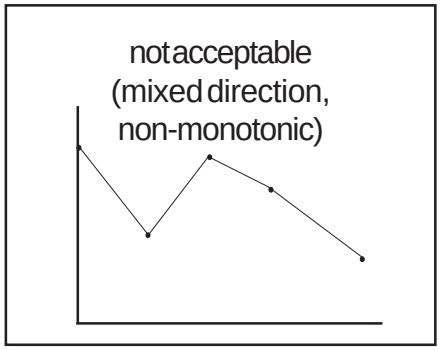
"CALBRTR #1= XXXX"

"CALBRTR #2= XXXX"

"CALBRTR #3= XXXX"....

where XXXX represents the calibrator values you entered. The instrument can accept calibrator values up to 7 digits, and calibrators less than 1000 can accept 2 decimal places. If 2 decimal places are desired for calibrators or concentration values, the first calibrator must have a 2 decimal place value assigned.





The display will ask **"DUPLICATE CALIBRTRS Y/N."** Use the YES or NO keys to answer. Then the display will ask **"DUPLICATE SAMPLES Y/N."** Again, answer with YES or NO. If duplicates are selected, this will be indicated on the printout and mean readings will be used. Cutoff options will follow: **"Positive => ?"** and **"Negative < ?"** Refer to section *2.1.9-Selecting Cutoffs* for instructions.

Then the instrument will display **"LOAD NEXT PLATE** è **READ."** You may locate controls and set their ranges at this time, following the instructions in section *2.1.8-Selecting Control Options*. You may use the "End" function at this time to read only part of a plate by following the instructions in section *2.4.3-End.* Place the first plate into the carrier so that well A-1 is at the right rear, then press READ. The lamp turns on and begins to warm up. A built-in 45 second countdown is displayed. It ends with an audible signal, indicating that the instrument is ready. (NOTE: If the lamp is already on, the warm up step is bypassed.) The reader will automatically transport the samples through the optical system. Absorbance readings will be displayed and printed. Calibrators are identified as **"CALIBRATOR 1," "CALIBRATOR 2"** etc. in the sample ID column. After the first strip is read (2 strips in the 8 well format), the reader will pause to ask if you would like to see the curve printed out. Answer YES or NO when you see the display **"PLOT CURVE Y/N."** (If you do not answer the prompt within 2 minutes, the instrument will continue to read the plate until completion). The plotted curve shows the calibration curve, with Concentration on the x-axis and Absorbance on the y-axis.

If calibrators were read in duplicate, the display will ask **"EDIT WELLS Y/N."** Use the YES or NO key to answer. (If you do not answer the **"EDIT WELLS Y/N"** prompt within 2 minutes, the plate is read to completion). If NO is pressed, the instrument will proceed to read and calculate the samples. If YES is pressed, you will see **"DELETE WELL #"** displayed. Even if well A-1 was the blank, consider it as well #1. The second well read is #2; the third well read is #3, and so on. Type in the well number that you wish to delete and press ENTER. Again, you will see **"DELETE WELL #"** displayed. If you wish to delete another well, type in its well number and press ENTER. You may delete as many as one from each pair, but **you may not delete an entire point**. When no more deletions are desired, press ENTER again. The standard curve will be recalculated showing an "X" beside the deleted well(s). When a duplicate absorbance is deleted, the remaining well will be used as the value for that standard point. Again, the operator will have an opportunity to plot and to edit. This may be repeated as many times as desired until either an acceptable curve is obtained, or the mode is cancelled. To read and calculate specimens, answer NO to the question **"EDIT WELLS Y/N."** The remainder of the plate will be read, calculated, and printed.

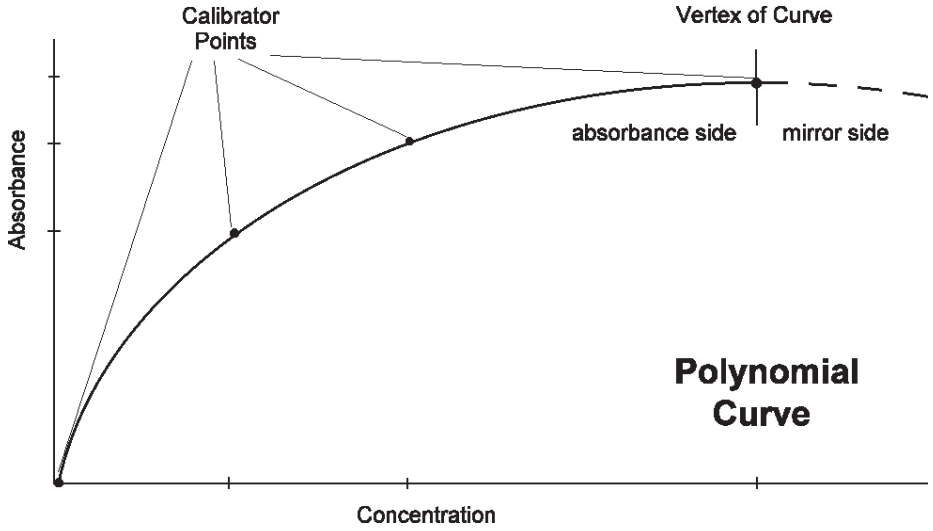
To unload a plate, simply lift the plate straight up. The instrument will display **"LOAD NEXT PLATE** è **READ."** To continue reading in the Point To Point Mode, load the next plate and press the READ key. (Only the first plate must contain calibrator materials.)

If a calibrator has an absorbance reading greater than 3.0 A, the printer will print **">3.00*"** for the absorbance reading, and the concentration will be calculated and printed. The test mode will continue; however, it is not advisable to use such a highly absorbing material as a reference. If a sample has an absorbance reading greater than 3.0 A, the printer will also print **">3.00*"** for the absorbance reading, and the concentration will be calculated and printed.

Press the STOP key any time after the test has begun to read the second strip (third strip in the A-H direction) if you want to stop the reading without quitting the mode. If you want to store this test in your user-test menu, be sure to store it prior to canceling (see section *2.3.1-Storing a Test*). Press the CLEAR key twice to cancel the mode and return the plate to the home position.

2.2.6 Polynomial Mode (POLY)

The Polynomial Mode operates similarly to the Point-to-point mode, except that rather than connecting the points with a series of linear segments, a smooth curve is generated. The curve is the best fit quadratic equation calculated from the calibration points, using a least-squares method of fit. Choose this mode only for parabolas in which the vertex is at the top and represents the highest absorbance that can be interpolated to a concentration value. The parabola opens downward, ideally crossing the x-axis close to the point (0,0). The quadratic equation is then solved for each absorbance and the lower mathematical solution becomes the specimen concentration.



The standard curve will have the equation y = ax**2 + bx + c where a < 0. (Absorbances must have positive values.) The coefficients a, b, and c will be printed, as will the maximum absorbance and concentration (vertex point). Then the operator will be given the opportunity to print the curve for visual examination and to edit the curve by deleting one or more duplicates, before calculating samples.

When you select the POLY key, the printer prints **"POLYNOMIAL MODE,"** 8 or 12 to indicate the selected plate format, **"PAGE 1"** (indicating the page number of the test), the date, and the time. Spaces will be provided to write in the lot number, expiration date, and the name of the analyst. After the filters are selected, if you chose no differential, the Offset Absorbance questions will follow (see section *2.4.9-Monochromatic and Offset Absorbance* for instructions). No blank is used in the Polynomial Mode.

The reader then asks for the number of calibrators to be used. Up to 7 may be used if read singly in either 8 well or 12 well format, or if read in duplicate in the 8 well format. The entire calibration curve must be contained in 12 wells for the 12 well format (i.e., 6 duplicate calibrators). In any case, at least 3 calibrators must be used. After typing the number of calibrators, press the ENTER key.

The display then prompts you to enter your desired unit code with **"Select units (0- 13)"** (see section *2.1.6-Selecting Units* for instructions). The instrument will then ask you to enter the concentration values of each standard, one-by-one. You may read your standards in any order, although the values must be entered in the same order that they will be read, and duplicates must be in consecutive wells. The instrument can accept calibrator values up to 7 digits, and calibrators less than 1000 can accept 2 decimal places. If 2 decimal places are desired for calibrators or concentration values, the first calibrator must have a 2 decimal place value assigned.

The display will ask **"DUPLICATE CALIBRTRS Y/N."** Use the YES or NO keys to answer. Then the display will ask **"DUPLICATE SAMPLES Y/N."** Again, answer with YES or NO. If duplicates are selected, this will be indicated on the printout and mean readings will be used. Cutoff options will follow: **"Positive => ?"** and **"Negative < ?"** Refer to section *2.1.9-Selecting Cutoffs* for instructions.

The instrument will then prompt **"LOAD NEXT PLATE è READ."** You may locate controls and set their ranges at this time, following the instructions in section *2.1.8-Selecting Control Options*. You may use the "End" function at this time to read only part of a plate by following the instructions in section 2.4.3-*End.*

Then load the first plate with well A-1 at the right rear and press the READ key. After the first strip is read (two strips in the 8 well format), the instrument will pause to ask if you would like to see a graphic representation of the curve printed. **"PLOT THE CURVE Y/N"** is displayed. (If you do not answer the prompt within 2 minutes, the instrument will continue to read the plate until completion). Press YES, ENTER, to print the polynomial curve, or NO, ENTER to bypass the option. Then the coefficients and vertex will be printed. Check the coefficient "a" to be sure that it is negative. If "a" is not negative, then the POLY mode is not applicable to the particular calibration data.

If calibrators were read in duplicate, the display will ask **"EDIT WELLS Y/N."** Use the YES or NO key to answer. (If you do not answer the **"EDIT WELLS Y/N"** prompt within 2 minutes, the plate is read to completion). If NO is pressed, the instrument will proceed to read and calculate the samples. If YES is pressed, you will see **"DELETE WELL #"** displayed. The first well read is well #1; the second well read is #2, and so on. Type in the well number that you wish to delete and press ENTER. Again, you will see **"DELETE WELL #"** displayed. If you wish to delete another well, type in its well number and press ENTER. You may delete as many as one from each pair, but **you may not delete an entire point**. When no more deletions are desired, press ENTER again. The standard curve will be recalculated showing an "X" beside the deleted well(s). When a duplicate absorbance is deleted, the remaining well will be used as the value for that standard point. Again, the operator will have an opportunity to plot and to edit. This may be repeated as many times as desired until either an acceptable curve is obtained, or the mode is cancelled. To read and calculate specimens, answer NO to the question **"EDIT WELLS Y/N."** The remainder of the plate will be read, calculated, and printed.

To unload a plate, simply lift the plate straight up. The instrument will display **"LOAD NEXT PLATE è READ."** To continue reading in the Poly Mode, load the next plate and press the READ key (Only the first plate requires the calibrator materials).

In the event that the absorbance reading of a calibrator is greater than 3.0 A, the printer will indicate **"> 3.00*"** in the absorbance field. The test mode will not be cancelled. If a sample has an absorbance reading greater than the absorbance maximum on the best fit curve, the instrument will print **"OFF"** next to the concentration.

Press the STOP key any time after the test has begun to read the second strip (third strip in the A-H direction) if you want to stop the reading without quitting the mode. If you want to store this test in your user-test menu, be sure to store it prior to canceling (see section *2.3.1-Storing a Test*). Press the CLEAR key twice to cancel the mode and return the plate to the home position.

2.2.7 Regression Mode

This is a multi-point calibrator mode that calculates a best fit linear equation based upon the standard points. It is designed for use with either linear or logarithmic data, with absorbance on the y-axis and concentration on the x-axis.

When you select the REGR key, the printer prints **"REGRESSION MODE,"** 8 or 12 to indicate the selected plate format, **"PAGE 1"** (indicating the page number of the test), the date, and the time. Spaces will be provided to write in the lot number, expiration date, and the name of the analyst.

After the filters are selected, if you chose no differential, the Offset Absorbance questions will follow (see section2.4.9-*Monochromatic and Offset Absorbance* for instructions). Then you will see **"AXES SETUP: SELECT."** There are four possible formats. The first choice displayed is **"Y= ABS, X=CONC"** for the case where both the absorbance data (y) and the concentration data (x) are linear. To select this option, press YES. Otherwise, press NO to see the next option, **"Y=Ln (1000*ABS), X=CONC."** This is used when the natural log of the absorbance is plotted against the concentration. Resulting concentrations will be the same no matter what base is used (ln or log), however, slopes and intercepts will vary. The absorbance values are multiplied by 1000 before taking the logs. Press YES for this format, otherwise press NO and see **"Y=ABS, X=Ln CONC"** displayed. This is a log-linear option. Use the YES key to select this. If NO is pressed, then the log-log option will be displayed as **"Y= Ln (1000*ABS), X= Ln CONC."** If NO is pressed, then the logit-log option will be displayed as **"Y= Logit(Abs), X= Log(Conc)."** If the NO key is pressed, the 4 options are cycled again.

After the axes are formatted, the instrument asks whether or not there will be a blank. Then the number of the calibrators, the units, and the value of the calibrators will be requested. It will be necessary to enter the values in the same order that the materials are pipetted for accurate pairing. Unlike the polynomial mode, the Regression mode may be used for both positive and negative slopes. When using a format which calculates the ln of the concentration, do not use 0.0 for the concentration, since ln 0 is not defined. The smallest number for which this instrument can calculate an accurate ln is 0.5. Likewise, when using ln of 1000*Abs, the absorbance values must be nonzero and positive. If the absorbance value of a well is negative, "******", will be printed in the CONC field. The instrument can accept calibrator values up to 7 digits, and calibrators less than 1000 can accept 2 decimal places. If 2 decimal places are desired for calibrators or concentration values, the first calibrator must have a 2 decimal place value assigned.

When all of the calibrator values have been entered, the duplicate selections and cutoff options will be displayed. Remember to use cutoff options with care, especially for equations having negative slopes.

Then the instrument will display **"LOAD NEXT PLATE è READ."** You may locate controls and set their ranges at this time, following the instructions in section 2.1.8-*Selecting Control Options*. You may use the "End" function at this time to read only part of a plate by following the instructions in section *2.4.3-End.*

Press the READ key. As in the Point-to-point and Polynomial modes, there will be a pause after the first 12 wells are read (16 wells for the 8-well format). The instrument will ask if you want to see the regression line plotted. Use the YES and NO keys to answer. (If you do not answer the prompt within 2 minutes, the instrument will continue to read the plate until completion). The slope and intercept of the linear regression will be printed. The correlation coefficient (r) will also be given as an aid in determining the acceptability of the curve.

If calibrators were read in duplicate, the display will ask **"EDIT WELLS Y/N."** Use the YES or NO key to answer. (If you do not answer the "EDIT WELLS Y/N" prompt within 2 minutes, the plate is read to completion). If NO is pressed, the instrument will proceed to read and calculate the samples. If YES is pressed, you will see **"DELETE WELL #"** displayed. Even if well A-1 was the blank, consider it as well #1. The second well read is #2; the third well read is #3, and so on. Type in the well number that you wish to delete and press ENTER. Again, you will see **"DELETE WELL #"** displayed. If you wish to delete another well, type in its well number and press ENTER. You may delete as many as one from each pair, but **you may not delete an entire point**. When no more deletions are desired, press ENTER again. The standard curve will be recalculated showing an "X" beside the deleted well(s), and the new slope, intercept, and correlation coefficient will be printed. When a duplicate absorbance is deleted, the remaining well will be used as the value for that standard point. Again, the operator will have an opportunity to plot and to edit. This may be repeated as many times as desired until either an acceptable curve is obtained, or the mode is cancelled. To read and calculate specimens, answer NO to the question **"EDIT WELLS Y/N."** The remainder of the plate will be read, calculated, and printed.

To unload a plate, simply lift the plate straight up. The instrument will display **"LOAD NEXT PLATE è [READ]."** To continue reading in the Regression Mode, load the next plate and press the READ key (Only the first plate must contain the calibrator materials).

In the event that the absorbance reading of a calibrator is greater than 3.0 A, the printer will indicate **"> 3.00*"** in the absorbance field. The test mode will not be cancelled. If a sample has an absorbance reading greater than 3.0, the printer will also print **">3.00*"** for the absorbance reading, and will calculate and print the result.

In the log-logit mode, any sample with an absorbance greater than that of the reference well will be flagged as **"> Reference".**

Note that in the logarithmic modes, any values which would require the log of a zero or negative number are invalid, and will either invalidate the curve (if in the standards) or invalidate the specimen.

Press the STOP key any time after the test has begun to read the second strip (third strip in the A-H direction) if you want to stop the reading without quitting the mode. If you want to store this test in your user-test menu, be sure to store it prior to canceling (see section *2.3.1-Storing a Test*). Press the CLEAR key twice to cancel the mode and return the plate to the home position.

2.3 Test Menu

The Stat Fax® 2100 offers the operator 8K bytes of non-volatile memory. This is user programmable memory (enough for 36 tests) that will not be lost when the instrument is turned off. Test selections may be stored so that set up time is significantly reduced when the same assay is repeated. Calibration curves are also stored. The time and date are maintained using this same type of memory. Items in non-volatile memory may be entered, changed, or deleted from memory by the operator following the instructions in this section.

2.3.1 Storing a Test

User tests are stored in the test menu by number. The first test that you store will be test number 1, the next test will be test number 2, and so on. When you want to recall a test, you will be asked to enter the test number. A running list or log book should be kept with your instrument, to identify your numeric entries. A sample format for this log can be found in the appendices of this manual. Photocopies of that format can be made as new log sheets are needed. Each time you store a test, the instrument will assign the next available test number. The instrument will record the date and time that each test was stored or last modified. Remember to update your log.

The STORE key is used to save a test in the menu. Any time after you have made your general selections and read the plate containing the standards, but before either turning the instrument off or canceling the mode, you may press the STORE key to store a test. When the STORE key is pressed, the display will ask the question **"NAME THE TEST Y/N."** To store a name with the test, press the YES key. A string of characters (ABCDEFGHIJKLMNOPQRSTUVWXYZ 1234567890-%_) is shown in the display. Use the "4" key to move the cursor to the left, the "6" key to move to the right. When the cursor is positioned over the correct character, press the READ key. When you have finished entering the test name, press the ENTER key. The instrument will print and display **"SAVED AS USER TEST #XX; YY UNUSED,"** where XX represents the next available test number and YY represents the remaining number of available test spaces. Be sure to update your test log.

2.3.2 Deleting a Test

To completely remove a test from the user menu, press the DEL key. The instrument will ask for the test number to be deleted. Type in the number and press the ENTER key. The instrument will display **"DELETE USER TEST XX Y/N."** Use the YES key to confirm the deletion of this test. The test number will then be available for the next user stored test. Be sure to update your log. Pressing the NO key will abort the deletion.

To erase the entire memory (delete all user tests), press TEST and enter 183. **"ERASE ALL TESTS Y/N"** will be displayed. If you select YES, the display will return to **"SELECT MODE"** and the time and date will be displayed. All stored tests will be cleared.

2.3.3 Recalling a Test

To select a stored test, press the TEST key, and you will see **"SELECT STORED TEST; ENTER TEST NUMBER."** Press the key(s) corresponding to the test number of your choice, then press ENTER. The instrument will print its number, the mode name, the plate format, **"PAGE 1"** (indicating the page number of the test), the date and time last modified, lines to write in lot number, expiration, and operator, the wavelengths, calibrators, blank, replicates, control options, and cutoff options which were previously selected.

If you are recalling a test with a stored curve , the display will ask **"USE STORED CURVE Y/N."** If you select YES, then your plate will be read as if all of the wells contained samples. The standard curve stored in memory will be recalled to calculate the concentrations. If you select NO, the instrument will assume that the new plate contains new standards. The plate will be read using all of the selections in memory, but a new standard curve will be generated using the new absorbance readings. The new curve will automatically replace the old curve in memory. If you want to enter additional control options, do this using the CNTRL key just before reading the first plate. The test will be updated after the standard points are read.

2.3.4 Editing a Test

The edit function is a convenience feature that allows you to make changes to stored tests without reentering all of the selections, and without causing the user test numbers to change. This is especially useful when a new lot of reagent is received with no test parameter changes required except for the entry of the new calibrator values. **The stored curve is automatically erased when a user test is edited.**

Press the EDIT key followed by the TEST key to make changes to a test in the user test menu. The instrument will ask for the test number that you wish to change. Then, all of the test parameters will be printed for your review. One by one, the selections will be displayed. If you want to edit the displayed parameter, select YES, ENTER. If you want to maintain the current selection, press NO and ENTER to move on. The display starts with **"EDIT TEST NAME Y/N"** If you press YES, you may edit the name of the test. If you press NO, the display will show **"EDIT WAVELENGTHS Y/N"** If you press YES, you will have the opportunity to make new wavelength selections. If you press NO, the display will show **"EDIT CALIBRATORS Y/N"** If you choose YES, you must key in the number of calibrators, then you will see **"KEY VAL. C1 è ENTER"** This will continue until all of the parameters have been reviewed. Duplicate selections, cutoff options, and control options will follow. Note: if you choose to edit the controls (other than in cutoff mode), you must edit <u>all</u> the controls. Then you will see **"EDIT MODE ENDED"** printed. To run the test with the new parameters, press the TEST key and select that test by its number. When you are ready to read the first plate, a new standard curve will be generated. The new curve will be stored under the same test number as before. Be sure to update your log.

2.3.5 Test Menu

Test #99 will print out a Menu of the user tests. This menu will list the test number, the test name (if any), the mode the test uses, and the date and time last modified.

2.3.6 Multi-Test Format (Aux1)

The multi test mode is not actually a test; it is used for running a multiple number of stored tests in one plate (2, 3, or 6 tests in the A-H direction, or 2 or 4 tests in the 1-12 direction). The tests must be set up individually <u>prior</u> to selecting the Aux1 key (i.e., you must store any necessary calibrators, etc. that you wish to use ahead of time).

Follow these points carefully:

1. Ensure that all tests are set up in the same read direction (8-way or 12-way). If a test has been set up with an opposing read direction to the one chosen, when the Multi-Test Format is run, the mechanism will jam while attempting to run the incorrectly formatted test, the error message **"MECHANISM ERROR"** will be printed, and the test will be ended.

2. Ensure that all tests are of the same mode type. If the tests are of different mode types (e.g., one is a single calibrator mode and another is a cutoff mode), the test will not run properly.

3. Be certain that all the controls are entered in the first two strips. The locations of the controls and calibrators will be automatically transposed to the appropriate section of the plate.

4. When you have entered all your controls and duplicate options, press the STORE key, then follow the directions under *2.3.1-Storing a Test*. You can then press the CLEAR key twice to cancel the test, then set up the next test.

5. When using this option, you may not use any stored curves. However, the curve generated (if valid) will be stored over any curve previously stored with that test.

After setting up all your tests, you are now ready to run the Multi-Test Format. Press the Aux1 key, which is used to format the plate for running the multiple tests.

In the A to H direction, the plate can be divided into halves (with each section consisting of 6 8-well strips), thirds (with each section consisting of 4 strips), or sixths (with each section consisting of 2 strips). In the 1 to 12 direction, the plate can be divided into halves (with each section consisting of 4 12-well strips), or quarters (with each section consisting of 2 strips).

The first question the instrument will ask is for the read direction: **"READ MODE: A to H Y/N."** Answer YES if you are reading 8-well strips, and NO if you are reading 12-well strips.

The instrument will begin formatting the plate by asking **"HOW MANY TESTS IN PLATE?"** This question is used to divide the plate into sections. If you want to divide the plate in half, press 2, ENTER; if you are running more than two tests, or if you have a smaller run and wish to have less empty space between tests (e.g., if you are running two tests and have only enough samples to fill 2 strips each), select 3 or 6 in the A to H mode, or 4 in the 1 to 12 mode. If you enter a number of sections greater than the number of tests to be read, the additional sections will not be read.

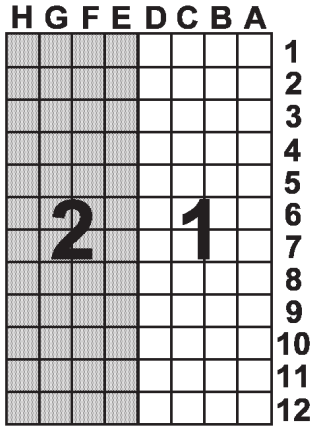
Next, you will see **"SELECT STORED TEST, ENTER TEST NUMBER."** Select the number of the test you want to put in the first section. The display will then ask **"SELECT ANOTHER TEST Y/N."** Press the YES key to enter another test, then select its test number. This step will repeat until you either reach the number of tests you selected to put in the plate, or you answer NO to the **"SELECT ANOTHER TEST Y/N"** prompt.

The printout of this mode will show the appropriate transposed locations of the controls. You may then run the plate. If you have fewer tests than you have plate sections, the instrument will only read until the end of the final test, then end the test.

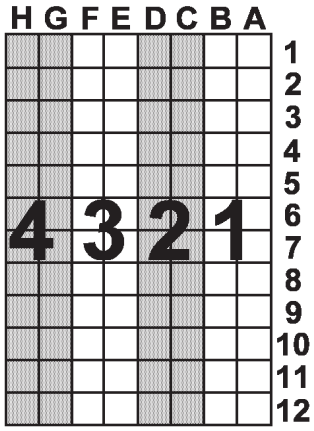
Multi - Test Format Options:

1 - 12 Direction

2 Tests

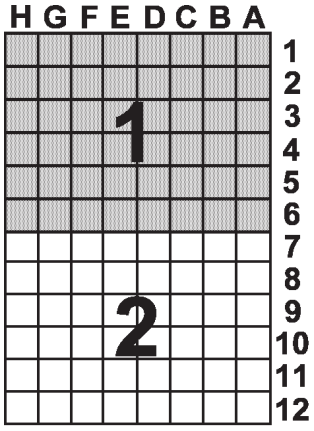


4 Tests

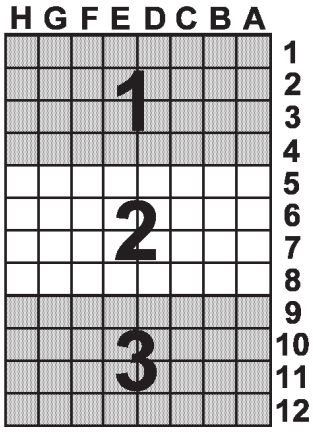


A - H Direction

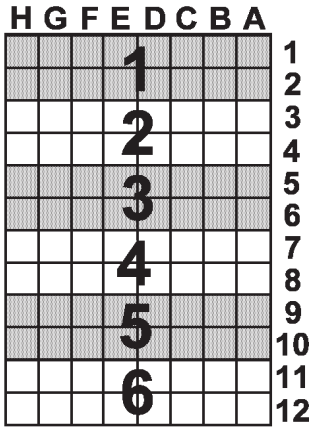
2 Tests



3 Tests



6 Tests



2.4 Special Features

2.4.1 Mixer

To mix the contents of a plate, load the plate and press the MIX key. The display will read **"MIX MODE; KEY MIX TIME IN SECONDS."** Type in the number of seconds (maximum time = 999 seconds) and press ENTER. The display will show "LOAD NEXT PLATE è READ." Press the READ key. The plate will be transported into the instrument, then mixed until the time has elapsed. Then the plate will return to the home position.

2.4.2 Printer

For information on the selection and installation of the printer, refer to section *1.4-Installation.*

An external serial printer will provide a full detailed report of all selections made. The printout also shows plate, row, and well numbers, locations of standards, blanks, and controls, absorbance readings, mean absorbances (when duplicates are selected), concentration results, and all other optional interpretation labels and calculations. Concentration values, user test numbers, end marks, certain flags, the labels for positive specimens and for controls that are out of range, and other significant messages are printed in bold type for convenience. In the absorbance mode, the absorbance values are printed in either an 8-line by 12- column format like a 12-well strip microplate, or in a 12-line by 8-column format for 8-well strip plates. In all other modes, there is one line printed for each well.

The paper may be advanced at any time by pressing the "Paper" key. Each time the key is pressed, a carriage return will be sent to the printer. This key is used to allow extra spacing between data as required by the operator.

Test #101 - Test Form Feed On/Off - Selecting Test #101 will toggle the instrument between printing all tests consecutively on the paper, and sending a form feed at the beginning of each test to begin each test at the top of the page. When the instrument is turned on, the status (Form Feed On, or Form Feed Off) will be printed. When you turn the instrument power on, you must start at the top of the page. Do not advance the paper manually, but take the printer off line and use the line-feed function. This allows the printer to track the spacing correctly. This function may not work properly when curves are plotted.

2.4.3 End

This key allows you to stop reading at a designated well. It may be used in any mode when the display is showing **"LOAD NEXT PLATE."** When you press the END key, the display will show **"Where is Last well?"** The instrument will first ask for the plate number (1-9), then the row letter (A-H), and finally the well number (1-12). Leading zeros are not needed. Ensure that all calibrators and controls will have been read before the selected end location is reached.

Only one End location may be entered for each plate. After that location is read, the plate reader will stop and return to home. END OF RUN will be printed. The mode will not be cancelled.

End locations are not stored in non-volatile memory when tests are saved.

2.4.4 Lamp Saver Feature

To prolong the lamp life, the instrument is programmed to turn off the lamp automatically after about 10 minutes of idle time. To turn the lamp back on, press the “Lamp” key. The lamp will warm up for 45 seconds, after which you may select a new mode, or proceed to operate in the current mode with no need to re-blank or recalibrate. Pressing the READ key while the lamp is off will also cause the lamp to turn on and warm up. If you want to turn off the lamp without turning off the instrument, use the Lamp key.

2.4.5 Flags and Error Messages

Flags and error messages are printed to alert the operator when he approaches certain limitations of the reader. After printing the warnings, the instrument will continue to perform regardless of the implications, except where indicated below. The Stat Fax® 2100 employs these messages:

“> 3.00*” is printed in the absorbance field whenever any absorbance exceeds 3.0 A.

“> Reference” is printed when a sample exceeds the absorbance of the reference well (well 1) in a log-logit test.

“>107”** is printed as the concentration value whenever the calculated result is greater than 7 digits and can not be properly printed in the concentration field.

“Curve is invalid!!!” is printed in the interpretation field in the % Absorbance Multipoint or Point to Point Modes when a non-monotonic curve (a curve in which the slope is neither consistently positive OR consistently negative) is read.

“Invalid Regression!” is printed in a logarithmic regression if the standard curve requires the log of a negative or zero number.

“OFF” is printed in the Polynomial Mode when an absorbance exceeds the maximum.

“****”** is printed in the Ln(1000*ABS) regression mode when an absorbance is negative (<0.0).

“CONTROL BUFFER FULL” is displayed if a fourth control location is attempted.

“MEMORY FULL!” is displayed when no more user tests can be stored. Deletions must be made before adding any new tests.

“MEMORY ERROR” is printed when an error occurs in recalling a test. This feature assures that recalled values are the same as those which were stored.

“MECHANISM ERROR AT PS-W” where **P** is the plate number, **S** is the strip (A-H), and **W** is the well number, is displayed when a mechanical problem in the plate transportation system is detected. The printer will also print **“MECH. ERR PS-W READ ENDED.; TEST ENDED.”** See the section *2.4.8-Mechanical Control* for information about this message.

“FILTER WHEEL ERR” is printed when there is a mechanical problem with the instrument. If this occurs, turn the unit off and then on again. If this fails to clear the problem, return the unit for service.

"FILTER LABELS RESET," or **"RUN TEST #248 to RESET FILTERS"** is displayed when the RAM has been affected such that the filter labels have been erased. To restore filter labels, select test #248. The filters' wavelengths and their respective positions in the filter wheel are listed inside the rear hatch cover on the right-hand side. To access this list, remove the two screws on the back of the hatch cover, then pull the hatch cover free to view the list. The hatch cover will remain attached to the instrument by a cable. **CAUTION:** Note that the positions listed on the filter label list do not correspond directly to the key numbers. When the display prompts **"KEY 5 = ???"** type in the wavelength for the filter in **position 3** on the filter label list, **"ENTER."** When the display prompts **"KEY 6 = ???"** type in the wavelength for the filter in **position 2** on the filter label list, **"ENTER."**

2.4.6 Calibration and Linearity

Every instrument is calibrated during manufacturing, using standards that are traceable to NIST, and each instrument is tested to verify its linearity. No calibration adjustment is accessible to the operator, since the preset calibration is very stable. Absolute calibration cannot be readily verified without using a specifically designed product called DRI-DYE® Check Strips, available from your instrument supplier. This is because in vertical photometry, the fill volume and degree of meniscus determine the pathlength; and absorbance is proportional to pathlength.

Since lab test results are typically based upon standards rather than upon absolute absorbances, the linearity of the instrument is the more critical indicator of instrument performance. A reduction in linearity may be indicative of filter deterioration. In this event, filter replacement is required for continued reliable operation. A monthly verification of instrument linearity is generally required to comply with regulatory agencies. DRI-DYE® Check Strips can also be used to verify linearity. Alternately, the degree of linearity can be checked by reading a 1:2 serial dilution of a material having a peak absorbance at or near one of the wavelengths, and observing a 1:2 ratio in the absorbance readings. If you prepare dilutions to verify linearity, uniform pipetting (pathlength) and minimal transfer error are important, since the tolerance limits which you will establish must take into consideration the sources of error that are not due to the instrument. Pipetting errors can be identified by comparing duplicate readings. The instrument should give the expected value ± (1% of the expected value + .01A). For example, if the 1/4 dilution reads .520 A, then you can expect your 1/2 dilution sample to read twice as much or 1.04 A ± [(1% of 1.04) +0.01 A], which is ± .02. A good working instrument would then give a result between 1.02 A and 1.06 A You will know that your filters are deteriorating when your darkly colored solutions consistently read lower than expected.

Since the procedures for verifying the calibration and linearity of a vertical photometer are quite cumbersome and not conducive to stringent criteria, the best way to assure quality instrument performance is with DRI-DYE® Check Strips. When running assays, you should also include a sufficient number of controls in each assay to cover the entire clinical range.

2.4.7 Clock and Calendar

Before setting the time and date, you may select the preferred date format (either day, period, month, period, year; or month, slash, day, slash, year). To do this, press the TEST key and enter 100 to access the date format switch located at TEST 100. To select MM/DD/YY press the 0 key, and to select the DD.MM.YY format press the 1 key.

To set the time and date, press the EDIT key followed by the TIME key. If the MM/DD/YY format has been selected, the display will ask for the month (1-12), the day, and the year (2 digits for each entry). Separate the entries using the slash key, and press ENTER when the date is correctly displayed. Alternately, if the DD.MM.YY format has been selected, the display will ask for the day, month (1-12), and the year (2 digits for each entry). Separate the entries using the decimal point key, and press ENTER when the date is correctly displayed.

Then the instrument will ask you to enter the hour (1-24), minutes (0-59), and seconds (0-59). When entering hour, use military time ... 13 for 1 PM, 14 for 2 PM, etc. Separate hours from minutes (and minutes from seconds) using the colon key. Press ENTER when the displayed time is correct. Once set, the time and date will not be lost when the instrument is turned off.

The time may be viewed whenever a mode is cleared, since the instrument displays both the date and time. Whenever a mode is selected, the printer prints the date and time on the report. The dates and times of changes made to the test menu are also recorded in the non-volatile memory.

2.4.8 Mechanical Control

Accurate positioning of each well in the optical system is a requirement affecting instrument precision. To assure exact positioning, the instrument is programmed to check its alignment in the home position before reading every plate. If your instrument seems to pause momentarily before reading, it is correcting for any slight movement of the plate carrier which may have occurred during the normal loading and unloading of plates.

If you are reading microstrips in trays, it is very important that the strips are well seated down into the trays. Otherwise they may obstruct plate transportation. If for any reason the plate carrier can not advance, the display will show **"MECHANISM ERROR AT PS-W"** and the printer will print an error message as the mode is cancelled. The plate will return to home position. Remove the plate from the carrier. Push the strips down into it. Turn the instrument off and then back on again.

The full range of mechanical motion required to read a plate is tested as part of the Self Check Function. A periodic check (done by pressing the SelfCk key) is recommended.

2.4.9 Monochromatic and Offset Absorbance

This instrument requires two filter selections: the operating filter and a differential filter (which may be selected as 0 to read with no differential). Use of the bichromatic differential absorbance increases precision, since the element of variation that is caused by imperfections in plastic microtiter strips is removed from the results.

In order to preserve the sensitivity, however, it is important not to choose a differential filter for which the chromophore being assayed exhibits substantial absorbance. A monochromatic option is available for use in scanning the filters independently. To read using only a primary filter (= monochromatically), select 0 for the differential filter.

When reading monochromatically, the absorbance is elevated relative to the curvature of the meniscus. A correction can be entered by the user to compensate for this effect. The correction is termed "Offset Absorbance."

To determine the correct offset absorbance, read a well of your blank material in the absorbance mode, monochromatically, without blank or offset. Determine the difference between the observed and expected value, and use this number as your offset absorbance.

When no differential filter is selected, the message **“OFFSET BLANK ABS Y/N”** will be shown. If you answer YES, you will see **“OFFSET ABS = .”** Enter the value that you determined should be used as the offset absorbance. This value will be subtracted from all absorbance readings to correct for the meniscus effect.

3. ADDITIONAL TIPS AND INFORMATION

3.1 Operating Precautions

Most errors in clinical laboratory testing are not due to bad reagents or malfunctioning instrumentation, but rather to operator error. We have taken several steps in the design of Stat Fax® 2100 to minimize operator error: stable factory calibration, automatic zeroing, complete operator prompting, detailed labeling, pre-programmed calculations, comprehensive visual and audible feedback, flags and error messages, and minimal maintenance requirements. The following precautions are offered to further assure quality laboratory results:

- Read your instrument instruction manual before performing any testing, then keep it handy as a reference. Be sure that you fully understand the purpose and limitations of this instrument. Use of the bichromatic differential absorbance, for instance, generally increases precision, since the element of variation caused by imperfections in disposable plastic plates is removed from the results. In order to preserve sensitivity, however, it is important not to use differential readings at 630nm when the chromophore which you are reading exhibits substantial absorbance at or near 630nm. It is also advisable to make dilutions of solutions that exceed 2A, and understand the relationship of read volume to absorbance.

- Use clean plates, and follow the instructions for blanking and standardizing very closely. (Use of the appropriate blanking material is also very important ... water is not always specified.) Do not read wells with bubbles or condensation.

- Check your display and printed results during operation. Your display and printer provide useful information such as the values you enter, the mode of operation you select, blanking, and all absorbance readings. Monitoring the printer and display during operation may help you detect an error in the making.

- Check the calibration and linearity of your instrument against some standard reference periodically. DRI-DYE® Check Strips or a carefully pipetted serial dilution of a stable, darkly colored substance may be used.

- Appropriate controls should be run with each assay as indicated in the package inserts of the chemistry products used. If controls do not give expected results, the assay is invalid.

3.2 Maintenance

It is important to follow the installation instructions carefully as described in section *1.4-Installation*. Adequate clearance and ventilation should be provided as well as a vibration free surface. Connections to main circuits with large pumps, compressors or refrigerators should be avoided.

The Stat Fax® 2100 is designed to be a maintenance free instrument. To insure optimum trouble free performance, the instrument should be kept dry and operated in an area free from excessive dust. This instrument employs interference filters of advanced technology, and will provide extended life in humid environments when compared to standard soft interference filters. In general however, excessive humidity should be avoided. Optimum operating conditions are from 18 to 35° centigrade, and less than 80% relative humidity. Storage temperatures should not exceed -10 to +50° centigrade.

Cleaning should be done when necessary. Use a slightly damp soft cloth to remove dirt or spills. For decontamination, 70% isopropanol is recommended. Use of other chemicals or abrasive cleaners is not recommended. Care should be exercised not to wet the keypad excessively.

3.3 Troubleshooting

Using the following guidelines, simple problems can often be isolated and corrected by the operator. If your instrument continues to malfunction, you may need to speak with someone from technical services for more information, or send your instrument to be repaired. Service and repair work should be performed only by trained service personnel. Consult your dealer to make arrangements if service is needed.

Problem: The lamp does not light or the LAMP OUTPUT LOW message appears.

Solution: Lamp replacement is an infrequent event since your lamp is rated to read over 1000 hours, and your lampsaver feature minimizes idle time. Lamp replacement is only indicated if the lamp does not light or if the output message indicates low intensity. Call your dealer to arrange for lamp replacement service.

Problem: The instrument is several years old and has lost some linearity with time.

Solution: Filters are expected to last for at least 3 years under normal environmental conditions. Most will last much longer than that, but eventually you may need new filters. Return the instrument for replacements. To retard the deterioration of filters, store the instrument in an air conditioned environment, and do not expose to severe temperature shock. If necessary, call your dealer to arrange for service.

Problem: Incorrect answers are obtained.

Solution:

a.) Check that the procedures and materials used were valid.

b.) Be sure that you are reading in the specified range of the instrument and using an appropriate wavelength combination for your chromophore.

c.) Wells should not have bubbles, condensation, floating material, severe scratches or smudges.

d.) Review the procedure for blanking. Remember to use the same volume for the blank and the samples.

e.) Be certain that you are reading in the correct position. Refer to the operating instructions for correct placement of the blank and calibrator materials.

f.) Check the printer to be sure that no flags were printed that would indicate improper results. (see section *2.4.5-Flags and Error Messages* for a review of flags and error messages.)

Problem: The instrument lacks reproducibility.

Solution:

a.) Be certain that the table or lab bench is free of vibration.

b.) If reproducibility of a plate is poor, check that the reaction has completely stopped.

c.) Remove the plate, press the BLANK key, and press the READ key, to check the repeatability of the instrument on air. If there are no electronic problems, readings should be within 0.000 ± 0.003. If greater values are observed, the instrument will require service.

d.) Check that the wells are positioning properly. This can be done by inserting a DRI-DYE®-Check Strip for multiple readings OR a plate with water and surfactant in all wells. (A plate of 96 wells of uniformly pipetted water/surfactant, read in the absorbance mode and blanked on the first well, should consistently provide results within ± 0.01A.)

e.) Very high absorbance readings are noisier than lower readings. Be sure you are operating within the acceptable range of the instrument. For best results, read dilutions of very dark samples and choose a blank <0.4A.

f.) Check that the plate fits snugly into the plate carrier. The Stat Fax® 2100 is designed to accept any of the commonly available standard-sized plates. If plates are of slightly smaller dimensions, they may not be usable.

Problem: The normal operation of the instrument is suddenly interrupted.

Solution: As with all microprocessor-controlled devices, fluctuations and interruptions of the power supply may cause the instrument to fail (or “crash”). The keys may not respond to touch, and the display may remain fixed. Turn the power switch off and wait for about 5 seconds. Then turn it back on. The instrument will start up normally.

If this interruption to normal operation occurs with frequency, you should try plugging your instrument into a different circuit. Choose a circuit that is free of large transient voltages such as pumps, refrigerators, etc. If this is not possible, install a commercially available surge protector (or noise filter).

Problem: The printer fails to print.

Solution: Consult the manual for the printer to be certain that the dip switches are set to accept output from the reader. Refer to section *1.4.2-Printer Requirements* for information concerning the printer. If only one setting is wrong, the printer will either print nonsense characters or nothing.

3.4 References

1. Engineering data supplied by Awareness Technology, Inc. Palm City, Florida (1987-1990)

2. Data on DRI-DYE® Check Strips, provided by Awareness Technology, Inc. Palm City, Florida (1989-1990)

3.5 Dri-Dye® Check Strips

DRI-DYE® CHECK STRIPS

Dri-Dye® Check Strips offer an easy means of verifying proper calibration and linearity on a routine basis. The charts provided allow simple interpretation of results. If a strip or plate reader can repeatedly obtain acceptable results with this kit, then the instrument demonstrates linearity, calibration, filter integrity, repeatability, and lack of stray light.

Proper use of the Dri-Dye® Check Strips, along with good record keeping, will constitute compliance with most quality control and licensing agency requirements for instrument performance verification.

Dri-Dye® Check Strips allow the instrument owner to perform testing that is very similar to the Q.A./Q.C. testing initially done by the instrument manufacturer. Dye absorbance values are determined by a reference instrument that is routinely calibrated with materials traceable to the National Institute of Standards and Technology (NIST, formerly NBS). Dyes are then precisely dispensed into the wells, dried, and packaged.

Using predispensed dyes reduces the degree of pipetting precision required to reconstitute the check set strips. Since the readers look through the samples from top to bottom, volume is proportional to pathlength, and hence, to absorbance. If a well is reconstituted with too much water, the decrease in concentration will be corrected by the increase in pathlength. Simply stated, the system is self correcting for random pipetting errors up to 10%.

The charts provided in this kit are designed to replace the normal calculations with easy to visualize, built-in, acceptance ranges.

Available for the following wavelengths:

DRI-DYE® Check Strips-405 - for 405nm

DRI-DYE® Check Strips-450 - for 450nm

DRI-DYE® Check Strips-492 - for 492nm

3.6 Sample Printouts

```
STAT FAX 2100          :W  6 FILTER VISIBLE              03/09/98        15:26:29
READ MODE: 1 to 12
ABSORBANCE MODE       12   PAGE   1                      03/14/98        08:53:12
LOT NUMBER:_____EXP. DATE:_____USER:_____
WAVELENGTHS=450NM 630NM
 BLANK MUST BE WELL #1
      1     2     3   4     5     6     7     8     9   10    11    12
1A   0.012 0.455 0.228 0.223 0.457 0.431 0.848 0.920 1.842 1.853 1.853 0.000
      BLANK
1B  -0.001 0.454 0.221 0.224 0.458 0.462 0.917 0.925 1.877 1.805 1.864-0.001

1C  -0.002 0.458 0.221 0.221 0.455 0.449 0.922 0.917 1.868 1.851 1.858 0.001

1D  -0.001 0.461 0.223 0.228 0.455 0.459 0.920 0.923 1.861 1.816 1.797 0.001

1E  -0.002 0.459 0.226 0.222 0.455 0.445 0.923 0.894 1.833 1.801 1.717 0.003

1F  -0.001 0.452 0.218 0.224 0.461 0.412 0.916 0.920 1.832 1.781 1.689-0.000

1G  -0.001 0.456 0.225 0.225 0.464 0.451 0.926 0.915 1.829 1.772 1.699-0.000

1H  -0.000 0.456 0.223 0.219 0.449 0.444 0.908 0.940 1.920 1.912 1.881-0.003
 TEST ENDED

READ MODE: A to H
CALIBRATOR MODE       8   PAGE   1                      03/09/98        15:36:43
LOT NUMBER:_____EXP. DATE:_____USER:_____
WAVELENGTHS=492NM 630NM
 BLANK MUST BE WELL #1
CALIBRTR#1=          50.0 MPL/mL
Positive      =>     40.0
 Negative      <     20.0
Pos C. Well is at: 1F-01
Pos C. must be =<  100.0 MPL/mL
Pos C. must be =>   40.0 MPL/mL
Neg C. Well is at: 1G-01
Neg C. must be =<   20.0 MPL/mL
SAVED AS USER TEST #   1;  37  UNUSED
  Last Well is at: 1H-02
PLTE/WELL  SAMPLE ID     ABS          MPL/mL   INTERPRET.              INDEX
1A- 1 Blank_________    0.033          0.0
1B- 1 CALIBRATOR __1    0.584         50.0                             1.25
1C- 1 1_____________    0.520         44.5   Positive                  1.11
1D- 1 2_____________    0.526         45.0   Positive                  1.12
1E- 1 3_____________    0.514         44.0   Positive                  1.10
1F- 1 Pos Control___    0.765         65.5                             1.63
1G- 1 Neg Control___    0.007          0.6                             0.01
1H- 1 4_____________    0.271         23.2   Equivocal                 0.58

1A- 2 5_____________    0.004          0.3   Negative                  0.00
1B- 2 6_____________    0.404         34.6   Equivocal                 0.86
1C- 2 7_____________    0.148         12.6   Negative                  0.31
1D- 2 8_____________    0.071          6.0   Negative                  0.15
1E- 2 9_____________    0.123         10.5   Negative                  0.26
1F- 2 10____________    0.224         19.1   Negative                  0.47
1G- 2 11____________    0.120         10.3   Negative                  0.25
1H- 2 12____________    0.006          0.5   Negative                  0.01
 END OF RUN
 TEST ENDED
```

COV=X*mNC+Y*mPC+FAC 8 **PAGE 1** 03/09/98 15:43:00

LOT NUMBER:_____ EXP. DATE:_____ USER:_____

WAVELENGTHS=492NM 630NM

BLANK MUST BE WELL #1

Blank must be =< 0.100

COV= 1.00*mNC 0.500*mPC+ 0.100

POS >= 1.25COV;NEG < 0.75COV

# of Neg Controls= 2

Neg C. must be =< 0.500

# of Pos Controls= 2

Pos C. must be => 0.500

mP/mN must be => 1.500

Last Well is at: 1H-02

PLTE/WELL	SAMPLE ID	ABS	Abs/COV	INTERPRET.	
1A- 1	Blank	0.033			1A- 1
1B- 1	Neg Control	0.191			1B- 1
1C- 1	Neg Control	0.180			1C- 1
Mean of 2 NCs= 0.186					
1D- 1	Pos Control	0.531			1D- 1
1E- 1	Pos Control	0.515			1E- 1
Mean of 2 PCs= 0.523					
C/O ABS= 0.547					
1F- 1	1	0.768	1.402	**Positive**	1F- 1
1G- 1	2	0.008	0.014	Negative	1G- 1
1H- 1	3	0.271	0.495	Negative	1H- 1
1A- 2	4	0.002	0.003	Negative	1A- 2
1B- 2	5	0.403	0.736	Negative	1B- 2
1C- 2	6	0.150	0.274	Negative	1C- 2
1D- 2	7	0.070	0.128	Negative	1D- 2
1E- 2	8	0.123	0.224	Negative	1E- 2
1F- 2	9	0.224	0.409	Negative	1F- 2
1G- 2	10	0.406	0.742	Negative	1G- 2
1H- 2	11	0.005	0.010	Negative	1H- 2

END OF RUN

TEST ENDED

COV=X*mNC+Y*mPC+FAC 8 **PAGE 1** 03/09/98 15:48:43

LOT NUMBER:_____ EXP. DATE:_____ USER:_____

WAVELENGTHS=492NM 630NM

POS <=COV ;NEG >COV

BLANK MUST BE WELL #1

Blank must be => 0.500

COV= 0.50*mNC+ 0.050

# of Neg Controls= 2

Neg C. must be => 0.500

# of Pos Controls= 2

Pos C. must be =< 0.500

mP/mN must be =< 1.500

Last Well is at: 1H-02

PLTE/WELL	SAMPLE ID	ABS	INTERPRET.	
1A- 1	Blank	2.335		1A- 1
1B- 1	Neg Control	1.899		1B- 1
1C- 1	Neg Control	1.727		1C- 1
Mean of 2 NCs= 1.813				
1D- 1	Pos Control	0.357		1D- 1
1E- 1	Pos Control	0.493		1E- 1
Mean of 2 PCs= 0.425				
C/O ABS=	0.956			
1F- 1	1	1.102	Negative	1F- 1
1G- 1	2	1.145	Negative	1G- 1
1H- 1	3	0.303	**Positive**	1H- 1
1A- 2	4	0.287	**Positive**	1A- 2
1B- 2	5	0.446	**Positive**	1B- 2
1C- 2	6	1.099	Negative	1C- 2
1D- 2	7	1.135	Negative	1D- 2
1E- 2	8	0.503	**Positive**	1E- 2
1F- 2	9	0.566	**Positive**	1F- 2
1G- 2	10	1.096	Negative	1G- 2
1H- 2	11	1.192	Negative	1H- 2

END OF RUN

TEST ENDED

CUTOFF CONTROL TEST 8 **PAGE 1** 03/09/98 15:40:41
LOT NUMBER:_____EXP. DATE:_____USER:_____
WAVELENGTHS=492NM 630NM
BLANK MUST BE WELL #1
Blank must be =< 0.100
Correction Factor= 0.500
COV= 0.50*mCCs
POS >= 1.10COV;NEG < 0.90COV
# of Neg Controls= 1
Neg C. must be =< 0.300
# of COV Controls= 3
COV C. must be => 0.300
# of Pos Controls= 1
Pos C. must be => 0.500
mP/mN must be => 2.000
Last Well is at: 1H-02

PLTE/WELL	SAMPLE ID	ABS	Abs/COV	INTERPRET.	
1A- 1	Blank	0.033			1A- 1
1B- 1	Neg Control	0.086			1B- 1
Mean of 1 NCs= 0.086					
1C- 1	Cutoff Ctrl	0.522			1C- 1
1D- 1	Cutoff Ctrl	0.529			1D- 1
1E- 1	Cutoff Ctrl	0.515			1E- 1
Mean of 3 CCs= 0.522					
1F- 1	Pos Control	0.768			1F- 1
Mean of 1 PCs= 0.768					
C/O ABS=	0.261				
1G- 1	1	0.008	0.030	Negative	1G- 1
1H- 1	2	0.271	1.039	Equivocal	1H- 1
1A- 2	3	0.005	0.019	Negative	1A- 2
1B- 2	4	0.406	1.554	**Positive**	1B- 2
1C- 2	5	0.151	0.578	Negative	1C- 2
1D- 2	6	0.071	0.273	Negative	1D- 2
1E- 2	7	0.123	0.472	Negative	1E- 2
1F- 2	8	0.226	0.865	Negative	1F- 2
1G- 2	9	0.404	1.546	**Positive**	1G- 2
1H- 2	10	0.007	0.026	Negative	1H- 2

END OF RUN
TEST ENDED

% ABSORBANCE MULTI-PT 8 **PAGE 1** 03/09/98 15:58:09

LOT NUMBER:_____EXP. DATE:_____USER:_____

WAVELENGTHS=492NM 630NM

BLANK MUST BE WELL #1

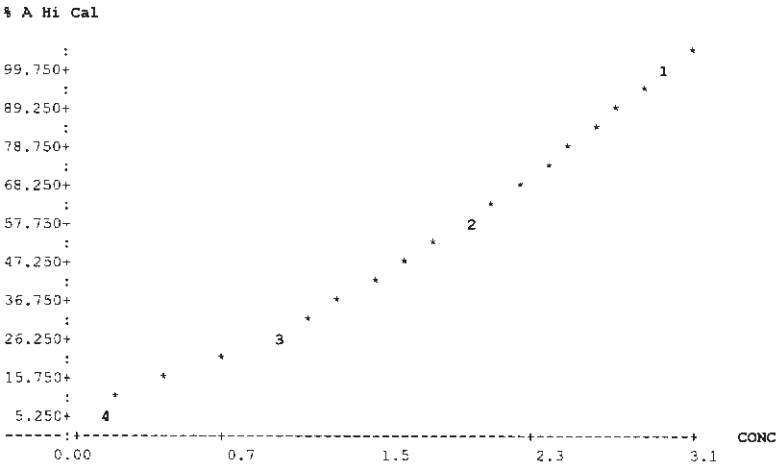
CALIBRTR#1= 3.0 EV
CALIBRTR#2= 2.0 EV
CALIBRTR#3= 1.0 EV
CALIBRTR#4= 0.1 EV

DUPLICATE SAMPLES

Positive => 1.7
Negative < 0.8

Lo Pos Well is at: 1F-01
Lo Pos must be =< 2.4 EV
Lo Pos must be => 1.8 EV
Last Well is at: 1H-02

PLTE/WELL	SAMPLE ID	ABS		EV	INTERPRET.	% A Hi Cal	INDEX
1A- 1	Blank_____	0.079		**0.0**			
1B- 1	CALIBRATOR __1	1.870		**3.0**		100.0	
1C- 1	CALIBRATOR __2	1.091		**2.0**		58.3	
1D- 1	CALIBRATOR __3	0.502		**1.0**		26.8	
1E- 1	CALIBRATOR __4	0.171		**0.1**		9.1	0.05
1F- 1		1.183					
1G- 1	Lo Pos Ctrl___	0.880	1.032	**1.9**		55.1	1.08
1H- 1		0.267					
1A- 2	1_____	0.211	0.239	0.2	Negative	12.7	0.16
1B- 2		0.325					
1C- 2	2_____	0.367	0.346	0.5	Negative	18.5	0.32
1D- 2		1.036					
1E- 2	3_____	1.199	1.117	2.0	**Positive**	59.7	1.16
1F- 2		0.580					
1G- 2	4_____	0.916	0.748	1.4	Equivocal	40.0	0.81
1H- 2		0.821					



END OF RUN
TEST ENDED

POINT TO POINT MODE 8 **PAGE 1** 03/09/98 16:01:20

LOT NUMBER:_____EXP. DATE:_____USER:_____

WAVELENGTHS=450NM 630NM

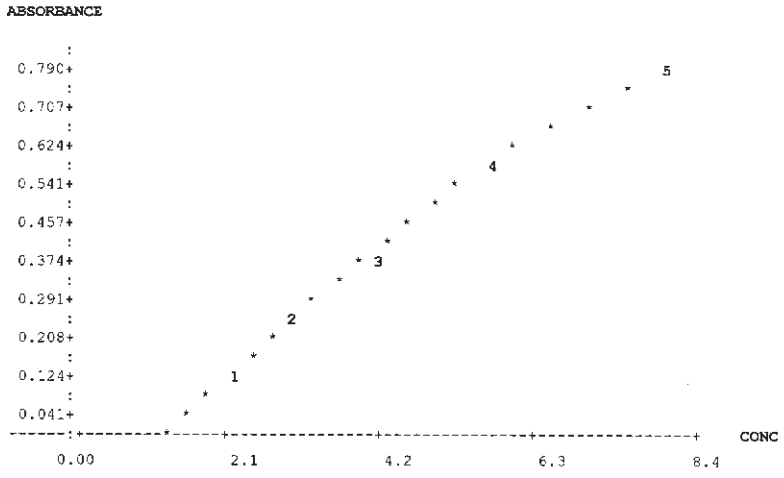
BLANK MUST BE WELL #1

CALIBRTR#1= 2.0 Conc
CALIBRTR#2= 2.8 Conc
CALIBRTR#3= 4.0 Conc
CALIBRTR#4= 5.6 Conc
CALIBRTR#5= 8.0 Conc

Positive => 4.0
Negative < 2.8

Last Well is at: 1H-02

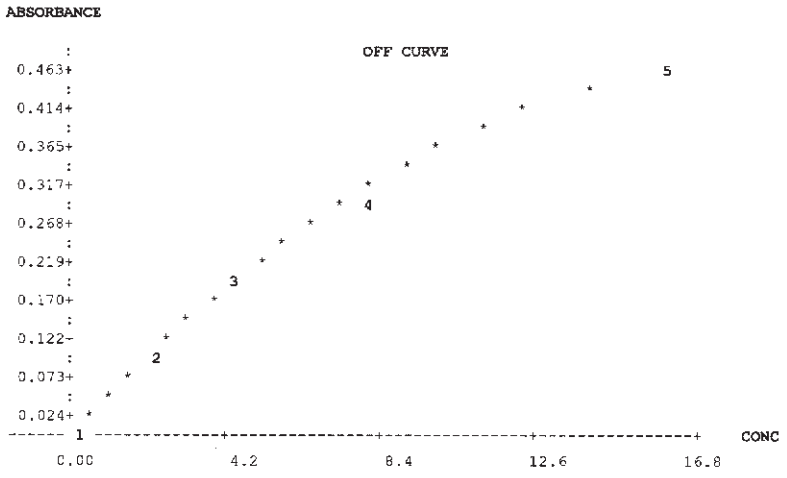
PLTE/WELL	SAMPLE ID	ABS	Conc	INTERPRET.	INDEX
1A- 1	Blank	0.020	**0.0**		
1B- 1	CALIBRATOR 1	0.130	**2.0**		
1C- 1	CALIBRATOR 2	0.254	**2.8**		
1D- 1	CALIBRATOR 3	0.403	**4.0**		
1E- 1	CALIBRATOR 4	0.600	**5.6**		
1F- 1	CALIBRATOR 5	0.792	**8.0**		2.00
1G- 1	1	0.811	**8.2**	**Positive**	2.05
1H- 1	2	0.192	**2.4**	Negative	0.60
1A- 2	3	0.306	**3.2**	Equivocal	0.80
1B- 2	4	0.138	**2.0**	Negative	0.51
1C- 2	5	0.319	**3.3**	Equivocal	0.83
1D- 2	6	0.838	**8.5**	**Positive**	2.14
1E- 2	7	0.344	**3.5**	Equivocal	0.88
1F- 2	8	0.207	**2.5**	Negative	0.62
1G- 2	9	0.695	**6.7**	**Positive**	1.69
1H- 2	10	0.394	**3.9**	Equivocal	0.98



END OF RUN
TEST ENDED

POLYNOMIAL MODE 8 **PAGE 1** 03/09/98 16:09:16
LOT NUMBER:_____EXP. DATE:_____USER:_____
WAVELENGTHS=492NM 630NM
CALIBRTR#1= 0.0 Conc
CALIBRTR#2= 2.0 Conc
CALIBRTR#3= 4.0 Conc
CALIBRTR#4= 8.0 Conc
CALIBRTR#5= 16.0 Conc
Positive => 10.0
Negative < 6.0
Last Well is at: 1H-02

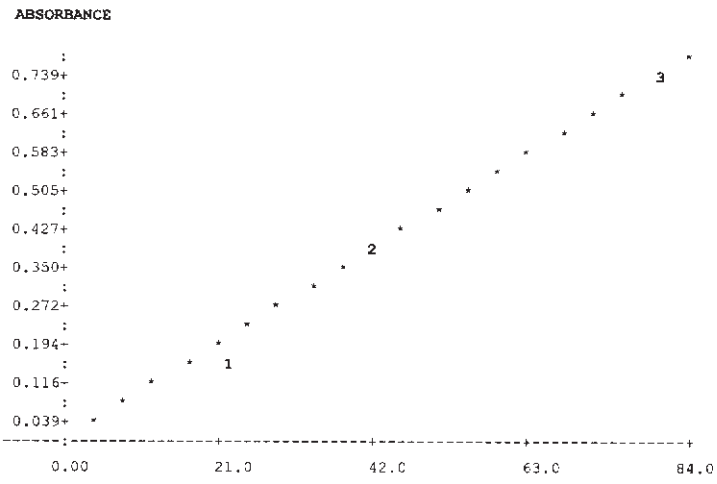
PLTE/WELL	SAMPLE ID	ABS		Conc	INTERPRET.	INDEX
1A- 1	CALIBRATOR 1	0.014		**0.0**		
1B- 1	CALIBRATOR 2	0.112		**2.0**		
1C- 1	CALIBRATOR 3	0.204		**4.0**		
1D- 1	CALIBRATOR 4	0.313		**8.0**		
1E- 1	CALIBRATOR 5	0.464		**16.0**		
1F- 1	1	0.604	**OFF**	**0.0**	Negative	0.00
1G- 1	2	0.626	**OFF**	**0.0**	Negative	0.00
1H- 1	3	0.162		**3.2**	Negative	0.32
1A- 2	4	0.246		**5.5**	Negative	0.55
1B- 2	5	0.119		**2.2**	Negative	0.22
1C- 2	6	0.255		**5.7**	Negative	0.57
1D- 2	7	0.632	**OFF**	**0.0**	Negative	0.00
1E- 2	8	0.274		**6.3**	Equivocal	0.63
1F- 2	9	0.171		**3.4**	Negative	0.34
1G- 2	10	0.526	**OFF**	**0.0**	Negative	0.00
1H- 2	11	0.311		**7.5**	Equivocal	0.75



Y(ABS)=A*X^2 +B*X+C A*1000= -1.282,B= 0.048,C= 0.01
MAX. ABS ON CURVE= 0.473 , MAX. CONC.= 18.80
END OF RUN
TEST ENDED

REGRESSION MODE 8 **PAGE 1** 03/09/98 16:12:40
LOT NUMBER:_____EXP. DATE:_____USER:_____
WAVELENGTHS=492NM 630NM
AXES SETUP: Y=ABS, X=CONC
BLANK MUST BE WELL #1
CALIBRTR#1= 20.0 A/mL
CALIBRTR#2= 40.0 A/mL
CALIBRTR#3= 80.0 A/mL
DUPLICATE CALIBRTRS
Positive => 50.0
Negative < 50.0
Last Well is at: 1H-02

PLTE/WELL	SAMPLE ID	ABS		**A/mL**	INTERPRET.	INDEX
1A- 1	Blank	0.031		**0.0**		
1B- 1	CALIBRATOR 1	0.186		**20.0**		
1C- 1	CALIBRATOR 1	0.178	0.182	**20.0**		
1D- 1	CALIBRATOR 2	0.409		**40.0**		
1E- 1	CALIBRATOR 2	0.432	0.420	**40.0**		
1F- 1	CALIBRATOR 3	0.689		**80.0**		
1G- 1	CALIBRATOR 3	0.792	0.740	**80.0**		
1H- 1	1	0.273		**27.5**	Negative	0.55
1A- 2	2	0.005		**0.0**	Negative	0.00
1B- 2	3	0.398		**41.2**	Negative	0.82
1C- 2	4	0.150		**14.0**	Negative	0.28
1D- 2	5	0.115		**10.2**	Negative	0.20
1E- 2	6	0.124		**11.2**	Negative	0.22
1F- 2	7	0.223		**22.0**	Negative	0.44
1G- 2	8	0.418		**43.3**	Negative	0.86
1H- 2	9	0.008		**0.0**	Negative	0.00



R= 0.994 YC= 0.02 SLOPE= 0.0092 ;REGRESSION LINE
TEST ENDED

3.7 User Test Menu Log

Stat Fax® 2100 (SN_______) User Test Menu Log page______

Test No.	Analyte	Stored By	Date	Notes

3.8 Contact Information

In the unlikelihood that you should ever experience a problem with your instrument, please consult your dealer first.

Dealer:

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

- Phone: (772) 283-6540
- Fax: (772) 283-8020
- E-mail: info@awaretech.com
- Mail: Awareness Technology, Inc.

P.O. Drawer 1679

Palm City, FL 34991

USA

When contacting Awareness Technology, please provide the following:

- the serial number of your instrument
- a description of the problem with as much detail as possible
- printouts, which can be submitted to us by mail, fax or email.