1. Introduction

1.1 Applications

1.1.1 Intended Uses

Stat Fax® 1904 Plus is a compact, microprocessor-controlled, general-purpose bichromatic photometer system with six filters and 37½C incubation. The standard diameter for the round tubes used with the instrument is 12mm. The instrument can be used to measure absorbances or concentrations based on standard points or rates of change, as described in this manual. FOR PROFESSIONAL USE.

1.1.2 Summary of the Instrument

The primary function of Stat Fax® 1904 Plus is to read and calculate the results of both endpoint and kinetic colorimetric assays. Any test procedure that calls for absorbance reading at or near one of the available wavelengths can be performed with this instrument. Additionally, the most commonly applied data reduction formulae are pre-programmed to further facilitate laboratory testing. These programs include rate calculation and single- and multipoint standardization. Through the alphanumeric display, the instrument prompts the operator to read the tubes in the appropriate sequence. It then performs the necessary calculations and prints out test results.

In addition to the six primary filter choices, the operator may select a differential wavelength for bichromatic reading in any operating mode. This corrects for imperfections in the test tubes and often removes the effects of unwanted turbidity.

Each mode of operation is self-prompting, to reduce error and simplify operation. In all modes the instrument will reference air, request and read the blank tube, and then read and print automatically whenever a tube is inserted. In the **Absorbance Mode**, the instrument reads and prints differential absorbances using operator selected filters. In the **Factor Mode**, the absorbances are multiplied by the operator-entered factor and then reported as concentrations. The **Standard Mode** calculates concentrations according to Beer's Law based on a single standard reading. The **Multipoint % Abs Mode** reports the sample absorbances as percent of the first standard in a multipoint curve. The **Programmable Mode**, or **Multipoint Mode**, calculates concentrations according to Beer's Law, based on the point-to-point connection of multiple (up to 7) standard points. Sample blanking is available in all modes except Absorbance Mode and Rate Mode. The **Rate Mode** determines the average change in absorbance per minute and then either multiplies it by the operator-entered rate factor or bases the concentration on a previously read standard. Intermediate absorbance readings of the kinetic assay may be plotted on the internal graphics printer to verify linearity of the reaction. The Rate Mode includes a "Batch" option that permits kinetic assays to be run simultaneously as well as consecutively.

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Stat Fax® 1904 Plus includes non-volatile memory, a feature that allows test parameters and standard curves to be stored for rapid future recall. The names of 30 of the most common assays are stored in the first 30 test positions, which enables the user to program his or her assays' test parameters under the appropriate names. In addition, other tests can be stored by number in a "User Menu" (and named via the keypad) with a capacity of 69 total tests.

Stat Fax® 1904 Plus also contains a 37½C incubation block with 12 stations. The incubator will accommodate 12 mm diameter round test tubes (size may be specified at time of purchase). A similar self-monitoring incubation system is built into the read well for temperature controlled absorbance reading at 37½C This is often essential to the precision of rate determinations.

Stat Fax® 1904 Plus offers quick, accurate, reproducible results; maintenance-free, easy operation; versatility, and economy. Stable factory calibration, a durable design, and a timed lamp saver feature further assure the continuous reliability of Stat Fax® 1904 Plus.

1.2 General Safety Summary

Review the following safety precautions to avoid injury and prevent damage to this product or any products connected to it. To avoid potential hazards, use this product only as specified.



Warning: Only qualified personnel should perform service procedures.

1.2.1 To Avoid Fire or Personal Injury

- 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.
- Observe All Terminal Ratings. To avoid fire or shock hazard, observe all ratings and markings
 on the product. Consult this manual for further ratings information before making connections to
 the product.
- **Do Not Operate Without Covers.** Do not operate this product with covers or panels removed.
- Use Proper Fuse. Use only the fuse type and rating specified for this product.
- Avoid Exposed Circuitry. Do not touch exposed connections and components when power is
 present.
- **Do Not Operate With Suspected Failures.** If you suspect there is damage to this product, have it inspected by qualified service personnel.

• **Provide Proper Ventilation.** Refer to the installation instructions for details on installing the product so it has proper ventilation.

- Do Not Operate in Wet/Damp Conditions.
- Do Not Operate in an Explosive Atmosphere.
- Keep Product Surfaces Clean and Dry.

1.2.2 Safety Terms and Symbols

Terms in This Manual. These terms may appear in this manual:



Warning: Warning statements identify conditions or practices that could result in injury or loss of life.



Caution: Caution statements identify conditions or practices that could result in damage to this product or other property.

Terms on the Product. These terms may appear on the product:

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

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

CAUTION indicates a hazard to property including the product.

Symbols on the Product. These symbols may appear on the product:



WARNING



Protective Ground



CAUTION

Risk of Shock

(Earth) Terminal

Refer to Manual

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1.3 Installation

1.3.1 General Installation

Carefully unpack the instrument, removing it from its plastic bag. Report any damage to your freight carrier at once.



Note: Retain the original packing material for future use in the event that the instrument is shipped to another location or returned for service.

Place the instrument on a flat working surface capable of safely supporting the weight of the instrument (approximately 10 lbs). A clearance of at least 3 inches around the instrument is required to assure optimal ventilation. The instrument is recommended for operation within an ambient temperature range of 18-35½C and humidity of less than 85%.

Look at the rear panel of the instrument to check that the power switch is in the Off (0) position.

1.3.2 Power Requirements

Locate the voltage select switch on the bottom of the instrument. This is a 2-position slide switch that configures the instrument to accept either 230V or 115V input.



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 (or similar instrument) into the slot on the switch and slide the switch 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 in to a 230V power supply, the fuse will blow and permanent damage to the electronics may result.

The third prong of the AC power plug must be connected to a suitable ground. The circuit used should be substantially free of large voltage transients (Kilovolt amp loads), such as large pumps, large centrifuges, refrigerators, 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 it back on, it will resume normal operation. However, since memory will have been lost, you will need to re-enter the calibrators and stored factors. (see section 3.1)

1.3.3 Electrical Setup and Safety Information

Note: See section 1.4 for additional Safety Information.

1. **Assure Proper Grounding:** The safety classification of this instrument is Class 1.



WARNING: To avoid the risk of electric shock, the third prong of the AC power plug must be grounded at the main socket-outlet and connected to conductive parts internal to the equipment.

The internal connection is provided for when manufactured by means of internal toothed solder lugs and stainless steel screws and nuts, or metal contacts, tooth lock washers and rivets. The location of the protective grounding conductor terminal is marked internally by the IEC 417 symbol 5019 (protective ground; see page 3). DO NOT loosen or remove these screws, rivets or contacts. Do not defeat the safety purpose of the grounding plug. It is the operator's responsibility to ensure the mains supply is properly grounded at the power outlet. If there is doubt that it is not properly grounded, contact a qualified electrician.

2. **Assure Proper Power Availability and Voltage Select Switch Setting:** the power requirements can be found on the specifications page.



CAUTION: The voltage select switch setting must match the local AC line voltage or permanent damage to the instrument may occur. The voltage select switch must be set for the appropriate input voltage prior to powering up.

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 the instrument to the power supply before assuring the proper position of the line voltage selection switch.

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 screw driver 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.



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

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3. **Assure Proper Power Cord Selection:** use only the power cord specified for this product and certified for the country of use.

For units for use at 110-120 V inside the US: Use a listed cord set consisting of a minimum 18 AWG, Type SVT or SJT three conductor cord, maximum 3 meter (9.8 feet) in length, rated 10 A, 125 V, with a parallel blade, grounding type attachment plug. The cord set provided by the manufacturer meets these requirements.

For units for use at 220-240 V inside the US: Use a listed cord as above, except rated <u>250 V</u>, with a <u>tandem</u> blade, grounding type attachment plug.

Connect the supplied power cable to the rear of the instrument as shown. Plug the other end of the power cable into an AC outlet.

- 4. **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 several seconds. When you turn the instrument back on, it will resume normal operation, but information not stored in non-volatile memory will be lost.
- 5. **Fuses:** 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 with this instrument are 0.6 Amp, T rating (slow blow) 250 V. Cartridge size is 3AG or size '0', dimensions $1/4 \times 1$ -1/4'' (6.3 x 32 mm). 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.

Do not attempt to make repairs or adjustments to the circuitry. Do not install any non-specified replacement parts. Awareness Technology will supply all service and accessories. Consult your dealer to make arrangements. Use of a fuse of the improper rating may constitute a fire hazard.

1.3.3 Paper Installation

Remove the optional paper cover by pinching the sides together and pulling up. Unroll about 10 inches of paper and place the roll on the table behind the instrument. Feed a cleanly cut edge of the paper from the back into the printer, along the top of the metal guide inside the printer paper well. A ragged edge or wrinkled paper will be difficult to load and could cause a paper jam. Feed just over 1 inch of paper in and then press the paper advance key (labeled Paper) several times to automatically feed the paper through the printer. You will see the paper appear through the paper slot in front. Drop the roll of paper into the printer paper well in back, spooling up any loose paper. If you have difficulty, cut a new straight edge before trying again. Replace the paper cover by pinching the sides together and pushing it down over the roll of paper. Insert the slotted tabs into the printer panel. Use of the cover is optional for holding the roll of paper down in the printer paper well.

1.3.4 Checkout Procedure

Perform the following checkout procedure after installation. If any portion of this procedure does not check out properly, contact your dealer to arrange for assistance.

Turn the power switch on. The printer should print "Stat Fax 1904Plus:mX," where m indicates MosquitoTM aspiration flowcell capability and X is the software revision level, then "01/01/99 13:37," representing the date and the time. The display shows "STAT FAX 1904P" momentarily, then "B ##.# H C ##.# H." B and C indicate the block and cell (read well) temperatures, and H indicates that the heater is on. Listen for the fan. Look into the tube well for light coming from the optical system.

1.4 Principle of Operation

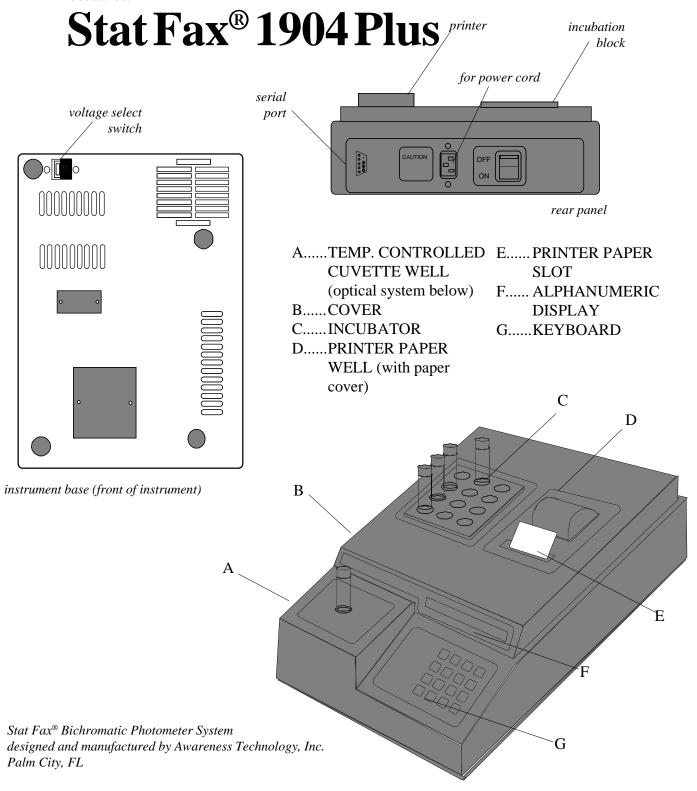
Light energy from the halogen lamp is focused by a lens, directed through an aperture, and then passed horizontally through the sample. A continuously rotating wheel positions the filters so that readings can be taken very quickly at 2 wavelengths. (Using bichromatic differential absorbance values corrects for optical imperfections in the tubes.) A photodetector converts transmitted light energy into electrical signals, which are amplified and interpreted.

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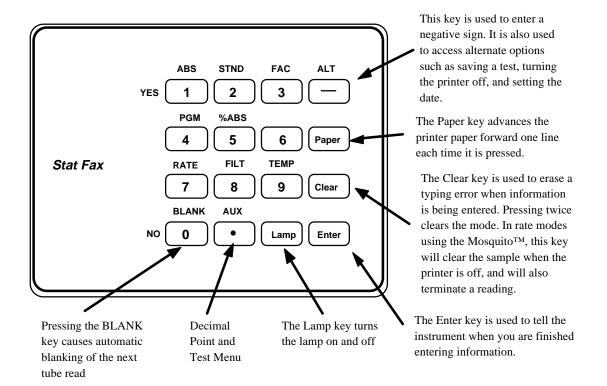
1.5 Parts and Controls

1.5.1 Parts of the Instrument

The following labeled sketches will help you locate and identify the major parts of Stat Fax® 1904 Plus. More details on the operation of each feature are provided in section 2 - *Operating Procedures*.



1.5.2 Keyboard Functions



The numeral keys serve several functions. As numbers, they are used to enter calibration information and to make selections for filters, units, and stored test protocols. Any key serving multiple functions will respond to the displayed request for information.

ABS, STND, FAC, PGM, %ABS, and RATE are the keys used to select a mode of operation. The previous mode is erased when a new mode is selected.

ABS stands for Absorbance Mode.

STND stands for Single Standard Mode

FAC stands for Factor Mode

PGM stands for Programmable Mode - Multipoint Mode

 $\%\,ABS$ stands for Percent Absorbance Multipoint Mode

RATE stands for Rate Mode

Use the key labeled AUX to access the test menu.

Pressing the FILT key causes the printer to list out the key assignments of the filters. Key 1 is 340nm, key 2 is 405nm, key 3 is 450nm, key 4 is 505nm, key 5 is 545nm, and key 6 is 600nm.

Pressing the TEMP key displays the temperatures in the incubation block and in the cell. It also offers an option to turn the cell temperature on and off using the $1\ \text{and}\ 0\ \text{keys}.$

1.6 Instrument Specifications

0.00 to 2.50 Absorbance Units (A) Linear measurement range:

 \pm (1% of the reading + 0.005 A) at 1.5A Photometric accuracy: \pm (2% of the reading + 0.005 A) at 1.5-2A

Stability: drift of no more than 0.005A in 8 hours/bichromatic

Light source: tungsten Halogen Lamp

Wavelengths: 340, 405, 450, 505, 545, 600nm

Typical half bandpass: 10nm

Type of filter: Multiple-cavity sealed interference

Tube size: 12mm round standard

Minimum fill volume: 1 mL

Maximum fill volume: 2 mL (for temperature control to 37½C only)

Temperature: $37\frac{1}{2}C$ ($\pm 0.3\frac{1}{2}$), Block stays on , Cell has on/off switch

Warm up times:

lamp in rate mode 120 seconds, built-in lamp in MosquitoTM Mode 240 seconds, built-in lamp in other modes 45 seconds, built-in

cell

20-30 minutes, dependent on ambient temperature incubation block 20-30 minutes, dependent on ambient temperature

Lamp saver time: after 15 minutes idle, 30 minutes in MosquitoTM Mode

reads, calculates and prints results in 3 seconds Speed:

Display: alphanumeric, 16 character, red, LED

Printer: thermal, dot matrix, 20 characters per line

Keyboard: 16 key, membrane switch, 4X4, audible response

Calculation modes: single point calibration by standard or factor, multipoint calibration

with point to point curve fit, multipoint percent absorbance, rate by

standard or factor (batch or singly), fixed time kinetic

Fuse requirements: 120VAC - 0.6 A, 3AG slo blo

120 V or 240V AC, 50-60 Hz (switch selectable) Power requirements:

Enclosure: painted flame retardant ABS Plastic cover with metal base

Dimensions: 9.5 X 13.25 X 3.75 inches (24 X 34 X 10 cm)

Weight: approx. 10 lbs (4.5 Kg)

Recommended operating temperature: 18-35½C

less than 85% Recommended operating humidity:

Optional Accessories: Redi-Check® Photometer QA (for instrument QC), MosquitoTM As-

piration Flow Cell Accessory, Stat TracksTM

2. Operating Procedures

2.1 General Functions

2.1.1 Start Up

To begin, turn the instrument on using the power switch on the rear panel. The printer will show the following:

"Stat Fax 1904Plus :mX" X = Software Revision, m = mosquito capability "03/01/99 13:37" Date and Time

2.1.2 ALT Menu

Many alternate functions are available via the ALT key. If you wish to select a function, press YES when its prompt comes up; if not, press NO and the next available function will be displayed. Each feature is discussed in more detail in the referenced section of the manual.

"SAVE TEST Y/N"

Select YES if you want to save the test you are running (See section 2.4 - Test Menu). If you press NO, you see:

"EDIT A TEST Y/N"

Select YES if you want to edit a stored test (See section 2.4 - Test Menu). If you press NO, you see:

"DELETE TEST Y/N"

Select YES if you want to delete a stored test (See section 2.4 - Test Menu). If you press NO, you see:

"SET DATE Y/N"

Select YES if you want to set the date and/or time (See section 2.1.3- Set Time). If you press NO, you see:

"SET MOSQUITO Y/N"

Select YES if you want to turn the Mosquito Mode on or off (See section 3.4.1 - Accessories: Mosquito). If you press NO, you see:

"ADD LINFEEDS Y/N"

Select YES if you want to change the linefeed profile of your test printouts (See section 2.2.5 - *Printer*). If you press NO, you see:

"SET PC MODE Y/N"

Select YES if you want to turn the PC Mode on or off. If you press YES, the display will show "**PC MODE ON Y/N**". If your Stat Fax® 1904 Plus is connected to a PC running Stat Tracks™ software, you may select YES and "PC MODE ENABLED" will print out. Otherwise, press NO, and you see:

"PRINTER OFF Y/N"

Select YES if you want to turn your printer off and record information manually (See section 2.2.5 - *Printer*). If you press NO, you will return from the ALT mode.

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2.1.3 Set Time

To configure the date format to MM/DD or DD.MM press the AUX key. The display will prompt "SELECT TEST #." Type 100, then press the ENTER key. The display will prompt "0=MM/DD 1=DD.MM." Press either the 0 or the 1 key and then the ENTER key to make your selection. To change the clock and calendar, press the ALT key. This key presents some options which can be selected by pressing the YES key, or bypassed by pressing the NO key.

If you press YES when "SET DATE Y/N" is in the display, you will see either "DATE: MM.DD.YY," if you are using the MM/DD format, or "DATE: DD.MM.YY," if you are using the DD.MM format. Key in the correct month, day and year (day, month and year, if using the DD.MM format), using two digits for each and separating the entries with a decimal point. When the displayed entry is correct, press the ENTER key.

Then "TIME: HH.MM.SS" will be displayed. To change the time, key in the new hours, minutes, and seconds using two digits for each and separating the entries with a decimal point. Use 13 for 1 PM, 14 for 2 PM, etc. When the displayed entry is correct, press the ENTER key.

2.1.4 Lamp Warm Up

The lamp begins to warm up as soon as it comes on. While you are entering parameters, the 45 second warmup is occurring simultaneously, so you may not see it displayed. If you set up very quickly, however, you might see the last few seconds count down in the display. In the Rate Mode, the warmup is 120 seconds; In MosquitoTM Mode, the warmup is 240 seconds.

2.1.5 Temperature Control

The incubation block and cuvette well are preset to maintain $37\frac{1}{2}C \pm 0.3\frac{1}{2}$. After power up, the display will indicate "**B**: ##.#**H** C: ##.#**H**," where **B** indicates the incubation block, **C** indicates the cell (read well), ##.# indicates the current measured temperatures of each, and the letter **H** indicates heating.

When the instrument is first turned on, heating begins and the temperatures may overshoot a little during initial warming. In 20-30 minutes, depending on ambient temperatures, stable temperatures will be reached. When 37½C is reached, the "H" will pulse on and off as additional heating is required. If you want to operate with temperature control, wait until both temperatures reach 37½C; otherwise, you may proceed at once.

The temperature controlled incubation block is ON whenever the instrument is on; however, the operator may turn the temperature controlled cuvette well (cell) ON/OFF as desired for each assay.

To turn the temperature controlled cell ON or OFF while operating in any mode, first press the TEMP key. The display will read "CELL ON =1 OFF=0" very briefly. Pressing the 1 key immediately will turn the cell temperature control on, while pressing the 0 key immediately will turn it off. The printer will print "CELL TEMP. CNTRL ON," or "CELL TEMP. CNTRL OFF" accordingly. If the cell's temperature control is off when the rate mode is selected, it will automatically be turned on, assuming that all rate reactions will be carried out at controlled temperature. When the Rate Mode is canceled, the cell temperature control will remain on.

To check the temperatures while operating in any mode, press the TEMP key. The display will show "CELL ON =1 OFF=0" very briefly and then display the block and cell temperatures for about 15 seconds before returning to the previous mode of operation.

Note: 37½C is attainable in the incubation block for volumes of 2mL or less; temperature controlled assays should therefore use volumes equal to or below 2mL to achieve 37½C.

2.1.6 Selecting a Mode

Press a mode key to select the desired automatic calculations:

Absorbance Mode	ABS key	(1)
Standard Mode	STND key	(2)
Factor Mode	FAC key	(3)
Programmable Mode	PGM key	(4)
Multipoint % Mode	%ABS key	(5)
Rate Mode	RATE key	(7)

The mode designations are located above the number keys. The printer will print the name of the mode you have selected, and the display will indicate your next instruction. Before reading begins in each mode, the instrument will momentarily reference air. After that, it will recognize the insertion of a tube and read automatically.

To cancel a mode of operation at any time, press the CLEAR key twice.

2.1.7 Filter Selection

When you select a mode, the printer prints the date, time, and mode selected. The display will show "SELECT FILTER." Each available filter has been assigned to a number key as follows:

key 1 is 340nm	key 2 is 405nm	key 3 is 450nm
key 4 is 505nm	key 5 is 545nm	key 6 is 600nm

To print the filter list press the FILT (Filter) key. Select the key for the wavelength at which you would like to read, and then press the ENTER key.

Next the display will show "SELECT DIFF FILT." This instrument operates with a bichromatic differential wavelength as selected by the operator. The absorbance reading at the differential wavelength will be subtracted from the absorbance reading at the operating (first selected) wavelength. If you do not want a differential reading, choose the 0 (zero) key for NO DIFFERENTIAL. After pressing the key for the desired differential wavelength, press the ENTER key. The selected wavelengths will be printed. See the section 2.2.1 - Bichromatic Operation for a detailed discussion of bichromatic differential operation.

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Some glass test tubes have high absorbances at 340nm, which could cause a reduction in the precision and accuracy of your assay. When using this wavelength, you should determine if your test tubes absorb at 340nm. In order to test your tubes, press the ABS key, then select 340-600nm (primary filter = 340, differential filter = 600). Fill a tube with at least 1 ml of deionized water. Insert the tube at the prompt "READ BLANK TUBE." The printed absorbance must be less than 0.400 to maintain precision and accuracy.

2.2 General Operation

2.2.1 Bichromatic Differential Operation

The option to operate this instrument using differential absorbance readings is available for every mode. The absorbance readings at the differential wavelength are subtracted from the absorbance readings at the operating (primary) wavelength. Use of the bichromatic differential absorbance generally increases precision, since the element of variation caused by imperfections in disposable glass and plastic test tubes is removed from the results.

Whenever possible, differential reading is recommended because precision is significantly improved. This is particularly noticeable when using plastic tubes or glass tubes with optical imperfections and non-uniform wall thicknesses.

In order to preserve sensitivity, it is important not to choose a differential wavelength where the chromophore being assayed exhibits substantial absorbance. To test your chromophore, read a darkly colored solution in the absorbance mode at the operating wavelength with no differential filter, and again at the operating wavelength with the differential filter selection. If the two absorbance readings are within 10% of each other, then bichromatic differential reading is beneficial. If the difference between the absorbance readings with and without a differential wavelength is greater than 25%, then the chromophore is absorbing at or near the differential wavelength and bichromatic reading at this wavelength is probably not desirable.

If no bichromatic wavelength is selected, exercise every measure to enhance repeatability. Choose a better quality reading vessel and wipe fingerprints from each tube before reading. Mark each tube for uniform orientation when multiple readings are desired. Determine the acceptability of the precision by reading the same tube several times and observing the variation of the readings. Depending on the precision requirements of your assay, monochromatic reading may or may not be acceptable with certain plastic tubes.

TIPS FOR TUBE READING:

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

2.2.2 Blanking

During normal operation of this instrument in every mode, operator prompting via the display will indicate when to read the blank tube. The blank tube's absorbance is read and printed relative to air and then subtracted from each specimen (also read relative to air). Since the blank's absorbance relative to air is printed, the user will be able to evaluate the suitability of a blank before using it. For example, users can determine whether or not their test tubes absorb at 340nm.

Whenever additional blanking is desired, use the BLANK key. To select blanking, in any mode, first press the BLANK key, then insert the blank tube. Automatic blanking will occur. The letter "B" will be printed adjacent to the sample number to indicate that blanking has occurred.

Automatic blanking for each sample may be selected during entry of parameters in the Standard, Factor, Multipoint, or Multipoint % Abs modes. After filter selection, the display prompts "SAMPLE BLANK Y/N". Answer YES if blanking for every sample is desired. When running the test, "READ BLANK TUBE" will be prompted before each standard and sample.

2.2.3 Unit of Measurement Codes (Unit Code)

25 unit of measurement designations plus a blank selection are stored for labeling the concentration column. These are listed below.

00	Conc	13	umo/L
01	g/L	14	nmo/L
02	g/dL	15	ukat/L
03	mg/L	16	U/L
04	mg/dL	17	IU/L
05	ug/dL	18	IU/mL
06	ug/mL	19	mIU/mL
07	ng/dL	20	uIU/mL
08	ng/mL	21	%
09	mEq/L	22	%UPT
10	mEq/dL	23	ug%
11	umL/L	24	uU/L
12	mmo/L	25	

When the display prompts "**KEY UNIT CODE**," you can press 99 to see the list printed. Otherwise, select the unit by its numerical designation and press ENTER. You will see the selected unit displayed. If you made a mistake, press CLEAR and choose again. If the displayed units are correct, press the ENTER key to confirm. If no units labeling is desired, use the 25 key for none and then press ENTER.

2.2.4 Ranges

Immediately after setting the unit code, the instrument will prompt "SET RANGES Y/N." If you do not want ranges, press NO to go on. To set the normal range and the linear range of an assay, press YES.

The reader will first ask for the low end of the normal range by displaying "KEY LOW NORMAL." Type in the cutoff and press ENTER. The display will then prompt "KEY HIGH NORMAL." Type in the upper cutoff and press ENTER. The display will then prompt "KEY LO LINEARITY." If the assay is linear for only a certain group of values, this feature can label

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any concentrations outside of the linear range. Type in the low limit and press ENTER. See **"KEY HI LINEARITY."** Type in the upper limit of linearity and press ENTER. Any of the range options may be bypassed by pressing ENTER when the instrument is prompting for the range value.

After this, each specimen concentration will be compared to these ranges. If the specimen concentration is greater than the normal range it will be labeled "H" for high. Likewise, if it is lower than the normal range it will be labeled "L" for Low. The "H" and "L" labels will appear under the heading "i," which stands for Interpretation. This column immediately follows the concentration column on the printout. If linear ranges are entered, the calculated concentration is compared to these limits. The letter "R" will be printed in the interpretation column should any value fall outside of the linear range. When tests are stored, the normal and linear ranges are also stored for future use.

2.2.5 Printer

The printer automatically provides a permanent record of the modes, filters, and calibrators used, as well as test results.

The paper may be advanced at any time by pressing the Paper key. Each time the key is pressed, the paper will advance one line. This key is used to feed paper during installation and to allow extra spacing between data as required by the operator.

The printer can be configured to add extra spacing automatically. Press the ALT key and answer NO until "ADD LINFEEDS Y/N" is displayed. Press YES. The display will show "ALL LINES Y/N". If extra spacing between every line is desired, press YES. Press NO and the display will show "RESULTS ONLY Y/N". If spacing between sample results only is desired, press YES. Press NO to return the printer configuration to add no extra spaces. Note that "Results Only" is not offered in Rate modes, and will print without linefeeds.

Your printer requires a good quality thermal paper with a 2.281 (2-9/32) inch width. The paper recommended for use with your instrument is available from your dealer. To install a new roll of paper, follow the instructions given under the section 1.2.3 - Paper Installation.

To conserve printer paper, you can turn off the printer when you do not need a printed report. Use the ALT key to access this feature. Press NO until you see the question "PRINTER OFF Y/N." Pressing YES will turn the printer off, and "***PRINTER OFF***" will be printed. Pressing NO will turn the printer on and "**** PRINTER ON ***" will be printed.

2.2.6 Lamp Saver Feature

To prolong the lamp life, the instrument is pre-programmed to turn off the lamp automatically after about 15 minutes of idle time (30 minutes in Mosquito mode). To turn the lamp back on, either insert the next tube or press the LAMP key. You will see "LAMP WARM UP XX" in the display, where XX represents the warm up countdown. When in tube mode (non-Mosquito mode), there is a 45 second warm up, except in rate mode, which is 120 seconds. The Mosquito requires a 240 second lamp warmup. You will hear a double beep when the lamp is ready. To turn off the lamp without turning off the instrument, use the lamp key. Selecting a new mode of operation will also cause the lamp to turn on and warm up at the appropriate time.

Whenever the lamp is on, you will be able to see light coming from the read well. Lamp replacement is indicated when the lamp fails to light.

2.2.7 Flags and Error Messages

Flags are printed messages used to alert the operator when certain limitations are approached. After printing the warnings, the instrument will continue to perform normally. This instrument employs the following flags:

- "****" is printed in the concentration field in the event that an absorbance is greater than 2.5A. To obtain an accurate absorbance and concentration value for such a sample, further dilution may be required. EXCEPTION: in the Rate by Standard mode, a standard with an absorbance greater than 2.5A will cancel the test.
- ">10**6" is printed whenever a calculated factor or result is greater than 6 digits and thus can not be properly printed in the 6 digit field.
- "—CURVE INVALID!! -" is printed in the Programmable Mode when a curve cannot be drawn between standard points. An "X" will be printed after the standard point which makes the curve invalid. If this occurs, ensure that your standards were read in decreasing or increasing order of absorbance, decreasing for multipoint % Abs mode and increasing for multipoint mode. No interpretation will occur with an invalid curve.
- "Plot Unavailable" is printed if Rate mode Lag and Read times are not evenly divisible by 5, or if total time is greater than 1200 seconds (20 minutes).
- "Int Data Unavailable" is printed if Rate mode Read time is not evenly divisible by 30.
- **Error messages** are printed or appear on the display when the instrument fails to operate. These messages help the operator locate the cause of the failure. Appropriate responses to these messages are discussed in the Troubleshooting section of this manual. This instrument employs the following error messages:
- "MEMORY ERROR" is printed when an error occurs in recalling a test. This feature assures that the recalled values are the same as those that were stored.
- "Stack Underflow" is printed when the instrument attempts to store data at a location which may overwrite previously stored data. The mode will cancel, and subsequent data will be stored at a safe location in memory.
- **"LAMP FAILURE"** is printed when the lamp fails to illuminate sufficiently during an air reference period (between tubes and prior to reading the blank). This message will only print once until the mode is canceled.
- "PRNTER PAPER JAM" is displayed when the printer paper path is obstructed.
- "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.
- "CANCELED" is printed immediately following every filter wheel error to indicate that the test has been terminated.
- **"DO TEMP SET TEST 210"** is printed when the factory set temperature adjustments have been lost from non-volatile memory. See the section 3.1 Restoring Electronic Calibration.
- **"DO ABS SET TEST 212"** is printed when the factory set absorbance gain calibration has been lost from non-volatile memory. See the section 3.1 Restoring Electronic Calibration.

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2.2.8 Calibration and Linearity

Every instrument is calibrated during manufacturing, using standards that are traceable to the NIST, and is tested to verify its linearity to 2A. No calibration adjustment is accessible to the operator, since the preset calibration is very stable. Absolute calibration can be verified with the use of NIST filters, or by periodic comparison to a reference instrument that is known to be calibrated to NIST filters. Calibration may also be confirmed using a calibration check set such as REDI-CHECK®, obtainable from your dealer.

Since most lab test results are 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 with age may be indicative of filter deterioration. In this event, filter replacement is required for continued reliable operation.

A periodic verification of instrument linearity is advisable. This can also be done using REDI-CHECK®. Further information about REDI-CHECK® is available from Awareness Technology. Telephone: (561) 283-6540, Fax: (561) 283-8020.

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

2.3 Modes of Operation

The modes of operation are used to select different methods of data reduction for calculating sample answers. Some of the features which are common to multiple operating modes are discussed in section 2.2, General Operation. These include Bichromatic Operation, Blanking and Sample Blanking, Unit Codes, and Ranges. Some functions may also be different in the Mosquito mode; see section 3.4.1, or the Mosquito Owner's Manual, for additional information. In addition, sample printouts are found in section 3.5.

2.3.1 Absorbance Mode

This mode will read and print sample absorbances at user selected wavelengths. To operate the unit in absorbance mode, press the ABS key. The printer prints the date, time, and mode of operation: "ABSORBANCE." The display will show "SELECT FILTER." Select the wavelengths by pressing the appropriate key for each wavelength followed by the ENTER key.

The selected wavelengths will be printed, as well as the headings "S#" for sample number and "Abs" for absorbance. The lamp will also come on and warm up.

The display will then momentarily indicate "**REFERENCING AIR.**" During the referencing period, do not insert a tube or press a key. After referencing air, the instrument will be able to detect when tubes are inserted for the automatic triggering of future reading, calculating, and printing.

The display will then show "**READ BLANK TUBE.**" Insert the blank tube and the absorbance of the tube referenced to air will be displayed and printed. This value will be subtracted from subsequent readings. The printed "**B**#" indicates that this is the blank. It is very important to use the same type and size tube for the blank as will be used for the samples.

When you remove the blank tube, the display will prompt "**READ SAMPLE.**" One by one, insert each sample tube and see the differential absorbance results printed and displayed.

Fifteen minutes after reading the last sample, the lamp saver feature will automatically turn off the lamp. To continue reading, either press the lamp key or place a tube in the well. The 45 second lamp warm up will occur, and then operation will resume where it left off. In MosquitoTM Mode, lamp timeout is 30 minutes and lamp warmup is 240 seconds.

If re-blanking is desired at any time during operation, press the BLANK key and then insert the blank tube.

2.3.2 Single Standard Mode

This mode will read and print sample concentrations. A single standard material of known concentration is used to calibrate the instrument so that concentrations of unknown samples can be calculated according to Beer's Law. The bichromatic absorbances at the selected wavelengths will be read, printed, and used in the concentration calculations. The calibration factor (standard concentration/standard absorbance) will be printed for future use.

To operate the unit in single standard mode, press the STND key. The printer prints the date, time, and mode of operation: "STANDARD." The display will show "SELECT FILTER." Select the wavelengths by pressing the appropriate key for each wavelength followed by the ENTER key. The selected wavelengths will be printed. The display will prompt "SAMPLE BLANK Y/N". Press YES if each sample requires a separate blank reading. "Sample Blank Mode" will print. Press NO if only an initial blank is desired.

The display will show "**KEY VALUE OF S#1.**" Type the concentration value assigned to your standard material. Then press the ENTER key. The printer will print "**STANDARD #1**= **XXXX**," where XXXX is the standard value you have entered.

Note: The instrument accepts standard values of six or fewer digits, and accepts up to 2 digits after the decimal point if the value is less than 1000.

The display prompts "**KEY UNIT CODE**"; see section 2.2.3-Unit of Measurement Codes. The display then prompts "**SET RANGES Y/N**"; see section 2.2.4-Ranges. The instrument then prints the column headings.

The display will momentarily indicate "**REFERENCING AIR.**" During the referencing period, do not insert a tube or press a key. After referencing air, the instrument will be able to detect when tubes are inserted for the automatic triggering of future reading, calculating, and printing.

The display will then prompt "**READ BLANK TUBE.**" Insert the blank tube and the printer will print the tube's absorbance referenced to air.

Remove the blank tube, and the display will prompt "**READ STANDARD.**" Insert the standard tube. It will be read, and the absorbance and concentration values will be printed. The calculated factor will print on the next line. "S1" indicates that this is the standard tube. See the sample printer output for this mode. When you remove the standard tube, the instrument will prompt "**READ SAMPLE.**" One by one, insert each sample tube and see the results printed and displayed. The concentration units for sample results will always be the same as the concentration units of the standard.

In the event that the absorbance reading of the standard is greater than 2.5 A, the printer and display will indicate "******" in the concentration (units) column. See section 2.2.7 - Flags and Error Messages.

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If a sample has an absorbance reading greater than 2.5A, the printer will print the absorbance reading, and the concentration (units) column will show "*******". See section 2.2.7 - *Flags and Error Messages*.

2.3.3 Factor Mode

This mode will read and print sample concentrations at user selected wavelengths. A previously determined factor is entered by the operator, and the measured absorbance is then multiplied by the factor to obtain concentration.

To operate in factor mode, press the FAC key. The printer prints the date, time, and mode of operation: "FACTOR." The display will show "SELECT FILTER." Select the wavelengths by pressing the appropriate key for each wavelength followed by the ENTER key. The display will prompt "SAMPLE BLANK Y/N". Press YES if each sample requires a separate blank reading. "Sample Blank Mode" will print. Press NO if only an initial blank is desired.

The display will prompt "ENTER FACTOR." Type the factor and press the ENTER key. The printer will print the selected wavelengths and "FACTOR=XXXX," where XXXX is the factor value you have entered.

Note: The instrument accepts factor values of six or fewer digits, and accepts up to 2 digits after the decimal point if the value is less than 1000.

The display prompts "**KEY UNIT CODE**"; see section 2.2.3-Unit of Measurement Codes. The display then prompts "**SET RANGES Y/N**"; see section 2.2.4-Ranges. The instrument then prints the column headings.

The display will momentarily indicate "**REFERENCING AIR.**" The display will then prompt "**READ BLANK TUBE.**" Insert the blank tube and the printer will print the tube's absorbance referenced to air. Remove the blank tube and the display will prompt "**READ SAMPLE.**" One by one, insert each sample tube and see the results printed and displayed.

2.3.4 Programmable Mode (Multipoint)

The Programmable Mode is a multipoint standard mode that allows the operator to enter the concentrations of up to seven different standard materials of known concentrations. These standards are used to calibrate the instrument so that concentrations of unknown samples may be calculated according to Beer's Law. The resulting standard curve is a series of lines connecting the standard points in the order they are entered. In the Programmable Mode (point to point), they must be entered lightest to darkest (lightest is Standard #1). If you wish to run the standards from darkest to lightest (such as for uptake assays), use Multipoint % Absorbance Mode.

To operate the unit in the Programmable Mode, press the PGM key. The printer will print the date, time, and "MULTIPOINT." The display will show "SELECT FILTER."

Select the filters by pressing the appropriate key for each wavelength followed by the ENTER key. The printer will print the selected wavelengths. The display will prompt "SAMPLE BLANK Y/N". Press YES if each sample requires a separate blank reading. "Sample Blank Mode" will print. Press NO if only an initial blank is desired.

The display will prompt "**KEY** # **OF STNDRDS.**" Type the number of standards to be used (from 1 to 7), and then press the ENTER key.

The display will prompt "**KEY VALUE OF S#1.**" Type the concentration value assigned to the first standard and press the ENTER key. The instrument will continue to prompt for standard values until the selected number has been entered. Each standard value will print when the ENTER key is pressed. See the sample printer outputs for this mode.

Note: The instrument accepts standard values of six or fewer digits, and accepts up to 2 digits after the decimal point if the value is less than 1000.

The display prompts "**KEY UNIT CODE**"; see section 2.2.3-Unit of Measurement Codes. The display then prompts "**SET RANGES Y/N**"; see section 2.2.4-Ranges. The instrument then prints the column headings.

The display will momentarily indicate "**REFERENCING AIR.**" The display will then prompt "**READ BLANK TUBE.**" Insert the blank tube and the printer will print the tube's absorbance referenced to air. Remove the blank tube, and the display will prompt "**READ STANDARD.**" One by one, insert each standard tube and the results will be printed and displayed.

After the last standard tube is read and removed, the display will prompt "PLOT CURVE Y/N." Press YES to plot the curve. The display will then show "READ SAMPLE." One by one, insert each sample tube and the results will be printed and displayed.

Unknown samples are calculated as follows:

First, the unknown sample's bichromatic differential absorbance (operator selected wavelengths) is calculated and compared to the standard absorbances. Then, the line selected as the standard 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 with absorbance greater than the highest standard absorbance is calculated on the line passing through the highest 2 standard points, and an unknown sample with absorbance less than the lowest standard absorbance is calculated on the line passing through the lowest 2 standard points.

2.3.5 Multipoint % Abs Mode

The Multipoint % Absorbance mode (%ABS key) is used with multipoint uptake assays, and functions in the same way as the Programmable (point to point) Mode, with the following exceptions:

The standards must be entered from darkest to lightest.

An additional calculation (% A/A $_0$) is calculated, which is the absorbance of the sample divided by the absorbance of the first calibrator, or "percent of first calibrator". The first calibrator is considered 100%, and all subsequent samples are calculated as percent of calibrator.

In using a Multipoint % Abs. user test with a stored curve, there are two options. After you select the test, all the information is printed, and then you are prompted by the display alternately "USE STORED CURVE" and "YES(1) NO(2)." If you choose to use the stored curve (by pressing YES), you must blank (as prompted), and then read your <u>first standard tube only</u>. Then you may continue with the samples. If you choose not to use the stored curve (by pressing NO), you must blank, read all standards, then continue with the samples. For more information on user tests, see section 2.4-Test Menu.

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Except for these differences, follow the procedure as described in section 2.3.4.

2.3.6 Rate Mode

In rate mode, the instrument determines concentration by observing initial and ending absorbances and then dividing by the read time to establish the mean change in absorbance per minute (or rate). This rate is then multiplied by the operator entered factor to yield the concentration result. Rate factors for determining Units per Liter must be derived from the following standard formula:

 $U/L = [{DA/min. X 1000 X TVmL} \div {MA X SVmL X LPcm}] X TF$

where:

U/L is Units per Liter

ĐA/min is the mean change in absorbance per minute

TV is the total volume of the reaction mixture (in mL)

MA is the molar absorptivity (for example, the **MA** of NADH at 340nm is 6.22X10³)

SV is the sample volume (in mL)

LP is the cuvette light path (in cm)

TF is the temperature factor used to convert the assayed activity to the desired temperature.

Note that although "U/L" (unit code 16) is the common unit code for kinetic assays, the user may select any of the 25 unit codes for printout purposes.

Alternatively, the instrument will determine the rate factor by reading a standard of known concentration. In this case, the operator will enter the concentration value assigned to the standard rather than a rate factor.

Most rate reactions are temperature dependent. Before beginning, press the TEMP key to verify that the incubation block and cuvette well are both at 37½C. If the cell temperature control was turned off, selecting the Rate Mode will turn the temperature control back on automatically (however, it will not print that this has occurred). Place the tubes containing the reaction mixture into the incubation block for pre-warming. If the reagents are cold it may take several additional minutes for them to reach 37½C.

During operation in the rate mode, you may verify the temperature when the instrument is not waiting for information or performing a reading. Pressing the TEMP key will display the block and cell temperatures for about 15 seconds, then the display will return to the rate mode and prompt "READ SAMPLE."

In the rate mode, the operator enters the lag time (the time between specimen addition and taking the initial reading), the read time (the time between the initial and final readings) and the rate factor or rate standard (as determined by the chemistry product manufacturer for 37½C). Assays may be performed singly (consecutively) or in batch mode (simultaneously).

In some cases, a "Fixed Time Kinetic" mode is needed, where a specific read time is required, and the ĐA alone is determined (not ĐA/min). This is available if Batch Mode is not selected.

To operate the instrument in rate mode, press the RATE key. The display will prompt "STNDRD OR FACTOR," asking whether a standard will be used to calculate the factor or whether the factor will be entered by the operator. Press the STND key to select rate by standard, or the FAC key for rate by factor.

The printer prints the date, time, and mode of operation: either "RATE BY STANDARD" or "RATE BY FACTOR." In either case the display will then show "SELECT FILTER." Select the filters by pressing the appropriate key for each wavelength followed by the ENTER key. The printer will print the selected wavelengths. The display then shows "BATCH MODE Y/N." Press YES to use batch mode, NO to read kinetic assays individually. If NO, the display shows "FIXED TIME Y/N." If **DA** instead of **DA/min** is desired, select YES, otherwise select NO. The display then shows "KEY IN LAG TIME." Type the lag time in seconds and press the ENTER key. The lag time you entered will be printed. The display then shows "KEY IN READ TIME." Type the read time duration in seconds, and press the ENTER key. The read time you entered will be printed. The display will prompt "KEY VALUE OF S#1" or "ENTER FACTOR" depending on your mode selection.

Enter either the rate factor, corrected for 37°C reading (if using the FACTOR method), or the value assigned to the standard (if using the STANDARD method), and then press the ENTER key. The value that you entered will be printed. For negative factors, press the ALT key before typing the factor value.

Note: The instrument accepts standard and factor values of six or fewer digits, and accepts up to 2 digits after the decimal point if the value is less than 1000.

The display prompts "**KEY UNIT CODE**"; see section 2.2.3-Unit of Measurement Codes. The display then prompts "**SET RANGES Y/N**"; see section 2.2.4-Ranges. The instrument then prints the column headings.

Instructions for proceeding in Batch Mode follow at the end of this section.

The display will momentarily indicate "REFERENCING AIR." The display will then prompt "READ BLANK TUBE" and the printer will print the column headings. Insert the blank tube and the tube's absorbance referenced to air will be displayed. Remove the blank tube, and the display will prompt "READ STANDARD," if STND was selected or "READ SAMPLE XX" if FAC was selected.

Be certain that the lamp is on. If it is not, press the LAMP key, then wait for the lamp warmup to complete. Begin the first reaction by adding the specimen to a pre-warmed reagent tube. Invert the tube two or three times to quickly mix and then immediately insert the first sample tube into the cuvette well. The display will show the lag time counting down on the left side and the continuously updating absorbance reading on the right side. It will look like this: "LT XXXX A 0.000," where XXXX is the time and 0.000 is the absorbance. When the lag time period has elapsed, the instrument will take an initial absorbance reading and the display will change to show the read time counting down on the left side. It will look like this: "RT XXXX A 0.000," where XXXX is the time and 0.000 is the absorbance. At the end of the read time, the instrument will take a final absorbance reading and the printer will print the sample number, the average change in absorbance per minute and the concentration. If you are in "Fixed Time Mode", the change in absorbance will be printed, not the change in absorbance per minute.

Additional information is available if the read time and lag time meet certain criteria. If the read time is a multiple of 30 seconds, you may print the interval absorbance data (at 30 second intervals) and the **ĐA** for each interval. If both the lag time and the read time are a multiple of five seconds, you may plot the curve. By pressing the AUX (.) key after the sample's results have printed, you will see "**PRN INT DATA Y/N**" (if available). Press NO and you will see "**PLOT**

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KINETIC Y/N" (if available). Choose YES for either option to print/plot the information.

When you remove the sample tube, the display will prompt "**READ SAMPLE XX**" to indicate that it is ready for the next sample tube. Begin the second reaction and insert the second tube. If the factor is calculated based upon a standard tube reading, the factor will be printed after the first tube is removed. Perform and read each reaction one by one, removing the tubes only after the results are printed. If you remove a tube prematurely, the rate calculation will cease.

Batch Mode Information:

If "BATCH MODE" was selected, you may read a batch consisting of up to twelve tubes (samples + standard (if applicable)).

Note: Do not use Batch Rate Mode if read time is 30 seconds or less.

After setting the ranges, the display will prompt "# OF SAMPLES=?" Type the number of samples (including the standard, if you are using one), and then press ENTER. The printer will then add "# OF SAMPLES=XX" to the heading. After the display momentarily indicates "REFERENCING AIR," it will prompt "READ BLANK TUBE." You may wish to save the test at this time, since the mode cancels automatically upon batch completion.

After you insert the blank tube, the instrument will display and print "X.XXX," where X.XXX is the absorbance value of the blank tube relative to the air reference. After the blank tube is read and removed, "ADD SERUMS" and "THEN PRESS ENTER" will be alternately displayed. Add patient serums to the pre-warmed reagent tubes in a quick and uniformly timed manner.

When all of the serums have been added to the sample tubes, press ENTER to begin the Lag Time countdown. After the displayed Lag Time has expired, there will be a double beep and the display will prompt "READ STANDARD" if you are using a standard or "READ SAMPLE 1" if you are using a factor. Read the tubes in the same uniformly timed manner that you added the serums. When each sample is placed in the cuvette well the display will show the absorbance. The display will quickly return to "READ SAMPLE ##" when the tube is removed, prompting the reading of the next sample. The absorbance values for the samples can be seen on the printout.

After all the samples in the batch have had an initial reading, the display will indicate the beginning of the Read Time countdown. At the end of the countdown there will be a double beep and the appropriate prompt "READ SAMPLE 1" or "READ STANDARD" will be displayed, after a brief "REFERENCING AIR" message. The printout will indicate the sample number, final absorbance, time in minutes, absorbance per minute, and units based on the factor used. Note that although the actual read time may not be exactly as specified, the final answer is calculated in absorbance per minute and compensates for the varied time. Remove the sample after all the information has been printed. When the instrument is ready to read the next sample, it will give a double beep and display "READ SAMPLE ##," where ## is the next sample number.

After the last sample has been read, the printer will print "**** END OF BATCH ****" and the Rate Mode will discontinue.

2.4 Test Menus

2.4.1 Pre-programmed Test Names

The Stat Fax® 1904 Plus has a built-in menu of 30 assays. After the first use of a menu selection, the instrument will store and recall previously used test parameters (such as: mode, filters, standard values, units, ranges, etc.) You may print the menu by first pressing the AUX (auxiliary) key, and when the display prompts "SELECT TEST #," type 99 and then press ENTER.

a. First Use

Press the AUX (.) key. The display will prompt: "SELECT TEST #." Type in a number followed by the ENTER key to select a test. The test name and "SELECT MODE" will print, and the display will briefly flash "SELECT MODE." Enter the test parameters: mode, filters, standard or factor values, units, ranges, etc. The instrument will reference air and read the blank and standard tube. After reading the standard(s), specimens can be read. Save the test before canceling the mode.

b. Saving a Test

To save the test parameters and the standard curve for future use, press the ALT key. The display will prompt "SAVE TEST Y/N." Answer by pressing the YES key and "SAVED AS TEST ##" will be printed. You may continue to read specimens or press the CLEAR key twice to cancel the mode.

c. Recalling a Test

The next time you call up the same test number the display will prompt alternately: "USE STORED CURVE" and "YES (1) NO (0)." If you press YES, ENTER, the instrument will reference air, blank, and then read specimens, calculating from the stored curve from the previous run. The display will show "READ SAMPLE." The printer will print "USING STORED CURVE." If you press NO, ENTER, the instrument will reference air, blank, and prompt "READ STANDARD." A new curve will be stored based on the new standard value.

d. Editing a Test

You may edit saved parameters. Press the ALT key and the display will prompt: "SAVE TEST Y/N." Press the NO key and the display will prompt: "EDIT A TEST Y/N." Press the YES key and the display will prompt: "SELECT A TEST #." Type the test number you wish to edit, then press the ENTER key, the display will prompt: "EDIT FILTERS Y/N" and the printer will print the test name, date last updated, today's date and time, test mode, wavelengths, and other parameters. Press YES if you wish to edit and NO if you do not. Edited data is entered in exactly the same manner as was initially done. When you press NO to a prompt, the display will prompt you for the next parameter. When editing is complete the printer will print "EDIT COMPLETE." You may not use the edit feature to select a new mode of calculation. For this, you must delete the test, and re-enter the test parameters.

Test Menu

- 1) ALBUMIN
- 2) TOTAL PROTEIN
- 3) BILIRUBIN
- 4) BUN
- 5) GLUCOSE OXI
- 6) GLUCOSE HEXO
- 7) URIC ACID
- 8) CREATININE
- 9) IRON
- 10) CHLORIDE
- 11) CALCIUM
- 12) PHOSPHORUS
- 13) MAGNESIUM
- 14) CHOLESTEROL
- 15) HDL CHOL.
- 16) LDH
- 17) CPK
- 18) TRIGLYCERIDE
- 19) ALK. PHOS.
- 20) SGOT
- 21) SGPT
- 22) ACID PHOS.
- 23) SODIUM
- 24) POTASSIUM
- 25) HEMOGLOBIN
- 26) LIPASE
- 27) CK-MB
- 28) T3
- 29) T4 30) TSH

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e. Deleting a Test

You may delete a test from the menu. This will remove all the stored parameters. The test name will be retained. Press the ALT key and the display will prompt: "SAVE TEST Y/N," press the NO key and the display will prompt: "EDIT A TEST Y/N," press the NO key an the display will prompt "DELETE A TEST Y/N." Press the YES key and the display will prompt "SELECT TEST #." Type the test number and press the ENTER key. The display will alternately prompt "DELETE TEST # XX" and "YES<1> NO<0>" to confirm the deletion. Press the YES key then the ENTER key to delete the test.

To delete all tests from memory press the AUX key. The display will prompt "SELECT TEST #," select test number 183 and press enter. This will also delete all user stored tests.

2.4.2 User Test Menu

a. Creating a User Test

If you want to set up a test that is not named in the menu, you can add it by name and number. Press any Mode key. Enter all the test parameters in the usual fashion. Read the blank and standards. You may save the test any time between reading the last standard and turning the instrument OFF or quitting the Mode. To save the test parameters and the standard curve for future use, press the ALT key. The display will prompt "SAVE TEST Y/N." Press YES, and the display asks "NAME TEST Y/N." If you press NO the test is saved by the lowest available number and named "USER TEST." If you press YES, the first part of the alphabet is displayed. Use the 4 key to move left and the 6 key to move right. A blinking line will indicate the selected letter. Press the ENTER key to select a letter. When selecting the last letter press ENTER twice in rapid succession. Press the YES key and the printer will print "SAVED AS TEST #XX" where XX is the next available test number. You may continue to read specimens or press CLEAR twice to cancel the mode. The user test parameters and curve will be stored by test numbers beginning with number 31. There is memory for 39 user tests. If you try to save more, the error message "MEMORY IS FULL" will be displayed and printed.

A log page is provided in the back of this manual for maintain a list of user tests. Since user tests are stored by number, not by name, this will be an easy method of recalling your user tests.

b. Using a Stored Test

User tests are recalled, edited, and deleted in exactly the same manner as the menu tests described in section 2.4.1.

3. Additional Tips and Information

3.1 Restoring Electronic Calibration

In this instrument, electronic calibration information is entered at the factory as the original calibration data and is maintained in the non-volatile RAM of the instrument. This information is printed on the CALIBRATION DATA label affixed to the bottom of the unit.

DO NOT ALTER ANY POTENTIOMETER SETTING. SUCH ALTERATION RENDERS THE FACTORY CALIBRATION DATA INVALID !!!

If the calibration data is lost (primarily due to power surges or fluctuations), the printout will show the messages, "DO ABS SET TEST #212!", "DO TEMP SET TEST 210", or both, depending on the nature of the loss. If the data is not restored, these messages will continue to be printed each time the unit is turned on and every time a new mode is selected. The mode will operate, but calibration of the absorbance and temperatures must be restored to assure accuracy.

If the date is lost, restore the date (see section 2.1.3-Set Time) **before** restoring the calibration data. Then, to enter the data from the CALIBRATION DATA label:

- 1. Select the indicated test by using the **AUX** key and entering the test number (210 or 212).
- 2. **Test 210**:
- 2a. **Test 210** prompts "**BLOCK =**"; enter the number from the BLOCK TEMP line of the CALIBRATION DATA label.
- 2b. **Test 210** prompts "**CELL** ="; enter the number from the CELL TEMP line of the CALIBRATION DATA label.
- 3. **Test 212: Test 212** prompts "ABS FACTOR=", enter the number from the ABSOR-BANCE line of the CALIBRATION DATA label.
- 4. If the message "ADJUST OUT OF RANGE" appears, select the test again and re-enter the correct data.
- 5. To print a report of the entered data, run **test 213**. The data in test 213 should match the data from the CALIBRATION DATA label.

Note: When the stored calibration data is lost, the absorbance factor is set to 1.000 and the temperature offset adjustments for the block and cell are set to 0.0. The instrument will not accept a change greater than $\pm 10\%$ (.900 - 1.100) in the absorbance factor, nor will it accept a temperature change greater than $\pm 2.5\frac{1}{2}$ C. If the calibration data is lost, these limits assure that the instrument requires only minimal adjustment from the keyboard to remain calibrated.

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Note 2: The absorbance factor is an actual factor, which when entered is multiplied by the current factor in memory. The block temp and cell temp values are offsets, and are added to the current values in memory. Re-entering data when data is already present will result in incorrect calibration data, unless the values already stored in memory are considered.

3.2 Precautions

3.2.1 Assure operator safety and prolong the life of your instrument:

- Use only the prescribed input voltage. The voltage select switch on the base of the instrument will indicate the acceptable input voltage.
- NEVER remove the ground plug.
- NEVER operate the instrument with the cover off.
- Do not attempt to make repairs or adjustments to the circuitry. Do not install any non-specified parts. Awareness Technology will supply all service and accessories. Consult your dealer to make arrangements. Use of the improper fuse rating may be a fire hazard.
- Do not continue to operate a malfunctioning instrument.

3.2.2 Minimize operator error:

Most errors in laboratory testing are due not to bad reagents or malfunctioning instrumentation, but rather to operator error. Many measures have been taken in the design of this instrument 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, for example. The following precautions are offered to further assure quality laboratory results:

- 1. Read your instrument instruction manual before performing testing, then keep it handy as a reference. Be sure that you fully understand how to choose the proper modes of operation and the proper filters. Always work within the specified limitations of this instrument.
- 2. Use clean tubes 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 tubes with bubbles or condensation. Some glass tubes absorb significantly at 405 and 340nm. Be careful not to mix soda lime glass with borosilicate glass within an assay.
- 3. 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 and filters you select, and all absorbance readings. Monitoring the printer and display during operation may help you to detect an error in the making. To correct a typed entry before pressing the ENTER key, press the CLEAR key and type again. To correct a typed entry after pressing the ENTER key, press the CLEAR key twice to clear the mode, and begin again with mode selection.
- 4. Prior to running temperature controlled assays, and periodically while running temperature controlled assays, monitor the block and cell temperature on the display to assure that $37\frac{1}{2}C(\pm .3)$ is being properly maintained.

5. Periodically check the calibration and linearity of your instrument against a standard reference. A carefully prepared serial dilution of a stable, darkly-colored substance such as REDI-CHECK $^{\otimes}$ may be used.

6. 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.

3.3 Maintenance and Service

3.3.1 Preventing Trouble

It is important to follow the installation instructions carefully as described in section 1.2. 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.

Your instrument is designed to be an essentially maintenance free instrument. To insure optimum trouble free performance, the instrument should be kept dry and operated in an area free of excessive dust. The 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 15 to 33° centigrade, and less than 80% relative humidity. Storage temperatures should not exceed -10 to +50° centigrade.

Cleaning should be done when necessary. A puff of air may be used to eliminate dust from the read well. 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.

3.3.2 Troubleshooting Guide

Using the following guidelines, simple problems can often be isolated and corrected by the operator.

IN ANY EVENT, IF THE INSTRUMENT CONTINUES TO MALFUNCTION, CALL YOUR DEALER TO ARRANGE FOR SERVICE.

Service and repair work should be performed only by trained service personnel.

PROBLEM: The paper jam error message is displayed.

REMEDY: This is usually caused by a small piece of paper lodged between the flying print head and the side of the printer mechanism. Turn the instrument off. Reach into the printer mechanism with a pair of tweezers, and carefully remove the paper. If you are unable to clear the jam, call your dealer to arrange for service. Do not attempt to dismantle the printer.

PROBLEM: The lamp does not light.

REMEDY: Lamp replacement is an infrequent event since your lamp is rated to read over 300,000 tubes, and your lampsaver feature minimizes idle time. Lamp replacement is only indicated if the lamp does not light. Instructions for lamp replacement are provided with each replacement lamp.

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

REMEDY: 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 it to severe temperature shock. Call your dealer to arrange for service.

PROBLEM: Incorrect answers are obtained for chemistry controls.

REMEDY:

- a. Check that the procedures and materials used were valid. Turbid or contaminated reagents may affect absorbance readings. Data collected using REDI-CHECK® can be very helpful in separating instrument problems from reagent problems. Be sure that you are reading an appropriate chromophore for the operational and differential wavelengths. Check that the appropriate mode of operation was selected and review the operating procedures for that mode. Tubes should not have bubbles, condensation, severe scratches or smudges.
- b. Check the standard(s) or calibrator values printed on the printer paper for accurate entry.
- c. Review the procedure for blanking. Remember to use the same type of tube for the blank and the samples.
- d. Read the same tube several times to confirm repeatability.

PROBLEM: The instrument lacks reproducibility.

REMEDY:

- a. If repeat readings of a tube show upward or downward drifting, check that the reaction is completed and that the affected tube(s) were not contaminated prior to use (a chromophore releasing or consuming reaction may still be occurring). Next, check that the substance is not affected by the warming of the lamp or temperature controlled cell. This can be done by inserting a tube with water, reading it several times, and observing whether or not the "drifting" disappears. (10 repeat readings of a glass tube containing water, read in the bichromatic absorbance mode and blanked on the first reading should consistently provide results within \pm 0.005A with a warmed up lamp, improving with better quality vessels.) If repeatability on water is good, and the temperature effect seems to be causing the drifting, use the incubation block to pre-warm all of the tubes to $37\frac{1}{2}$ C before reading and then read them in the $37\frac{1}{2}$ C cell.
- b. If repeatability is poor but does not appear to be drifting in any direction, swirl the tube and look for particulate matter. Bubbles, severe scratches or smudges, and condensation on tubes can also cause poor repeatability. Lamp warmup is also important.
- c. Secure tube fit is necessary for good repeatability. Be sure to select a vessel with a snug fit. If the appropriate round glass tube (either 12 mm, or special model) does not fit snugly, return your instrument with several typical tubes for cell holder adjustment. Be sure you are reading at least 1 mL of solution.

PROBLEM: The printing is dim or incomplete.

REMEDY: Use only the specified paper available from your instrument dealer.

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

REMEDY: As with all microprocessor-controlled devices, fluctuations and interruptions of the

power supply may cause instrument failure. 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 switch the instrument 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 instrument does not recognize tube insertion.

REMEDY: Check to see if the instrument is in MosquitoTM mode. If the line "SAMPLE VOL = XXXuL" is printed in the test header, you are in MosquitoTM mode. See section 3.4.1-MosquitoTM for additional information.

3.4 Accessories

3.4.1 MosquitoTM

MosquitoTM is an aspiration cell accessory designed for use with the Stat Fax[®] Chemistry Analyzer and other models in the 1900 series that have temperature controlled 12mm cuvette wells. Minimum aspiration volume is only 250 μ L. MosquitoTM includes: a plug in micro-flow cell with all connections, a control unit including electronically regulated vacuum pump, valve, and interface circuits, a 500mL waste bottle with full sensor, and all cabling.

To set the MosquitoTM on or off, press the ALT key, then press NO until you see "SET MOSQUITO Y/N". Press YES. The display will show "MOSQUITO IN Y/N". If you want to read using the MosquitoTM, press YES; if you want to read tubes, press NO.

WARNING: <u>NEVER</u> READ TUBES IN THE MOSQUITO MODE! The Mosquito mode uses a different pathlength calculation, and answers will be <u>wrong</u>.

Setting up the MosquitoTM and reading with it are discussed separately in the MosquitoTM Owner's Manual. However, it is useful to be aware of the following software specific operations while using the MosquitoTM:

If you wish to cancel a Rate reaction, press the CLEAR key.

If you are working with the printer off, the answers will stay in the display until you press the CLEAR key.

For more information regarding MosquitoTM, contact your dealer.

3.4.2 REDI-CHECK®

REDI-CHECK® is a photometer check set used to verify the absorbance calibration, linearity, and precision of filter photometers on a routine basis. The kit contains 4 different chromophore solutions to cover a wide range of wavelengths between 340nm and 630nm. Instructions are included for preparing dilutions of the chromophores to check linearity. Acceptance ranges are provided for both bichromatic and monochromatic readings, with technical information traceable to NIST. The kit, which is designed for monthly use, also includes a record keeping system which visually indicates instrument performance and performance trends. For more information regarding REDI-CHECK®, contact your dealer.

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3.4.3 Stat TracksTM

Stat TracksTM is a PC program that connects your analyzer to your PC. It provides simple yet powerful tracking and reporting capabilities. With Stat TracksTM, you can store patient lists, setup and run worklists, see curves, print reports, and collect QC data. Stat TracksTM employs a graphical user interface, making the program very simple to use. All functions are menu driven.

Stat TracksTM includes a floppy disk containing the software program, an instruction manual, a serial cable for connecting your analyzer to a computer, and an updated EPROM containing the analyzer software for running Stat TracksTM (if necessary). For more information regarding Stat TracksTM, contact your dealer. Supply your instrument's serial number when requesting information.

4. References

- 1. Engineering data supplied by Awareness Technology, Inc. Palm City, Florida (1988)
- 2. Information on REDI-CHECK® Photometer QA Kit provided by Awareness Technology, Inc., Palm City FL (1990-1991)

5. Sample Printouts

04/08/99 ABSORBANCE WaveIngths=405	14:24 600nm
S# Abs	
B 0.029 1 0.875 2 0.276 3 1.420 4 1.998 5 0.500 TEST ENDED	

04/08/99 12:18 FACTOR Wavelnaths=505 600nm FACTOR= 1250 S# Abs na/dL	
B -0.001 1 0.323 404.2 2 0.080 101.1 3 0.980 1225 4 0.344 430.6 TEST ENDED	

04/08/99 STANDARD Waveln9ths=45 Standard#1= Norms: 20.00t Linear 10.00t S# Abs	14:20 0 600 nm 50.00 0 120.00
1 0.286 2 0.123 3 0.048 4 1.149 5 1.394 TEST ENDED	24.83 10.69L 4.21R 99.66H 120.88R

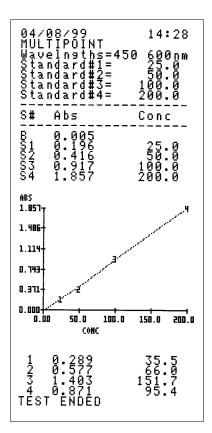
The Absorbance Mode (ABS key, pictured top left) reports absorbance values only.

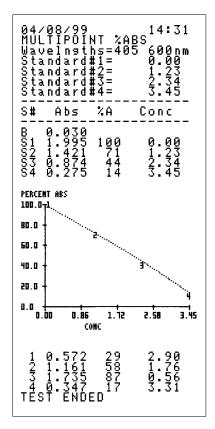
Factor Mode (FAC key, pictured lower left) multiplies the user-entered factor (1250) by the sample absorbance to calculate concentration values, reported in user-entered units (ng/dL, selection option 7).

Standard Mode (STND key, pictured center) calculates concentration values based on Beer's law, using a single user-entered standard value. The assigned standard value is divided by the standard's absorbance, and a factor is generated which is multiplied by sample absorbances to calculate the concentration.

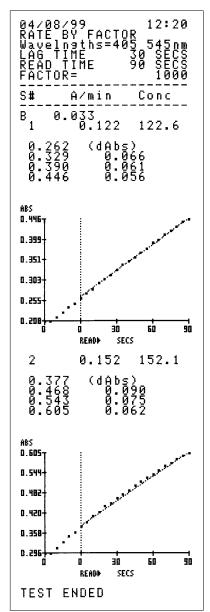
Multipoint Mode (PGM key, pictured top right) calculates concentration values based on Beer's law, using user-entered standard values. You may use up to 7 standards. After the standard curve is run, you may plot the curve, which is generated by point-to-point lines between each subsequent pair of points. The standards must be ascending in absorbance. Sample concentration values are calculated based on the line drawn between the pair of standards it falls between.

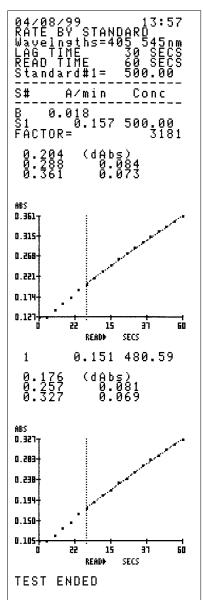
Multipoint %Abs Mode (%ABS key, pictured lower right) is calculated similarly to the Multipoint Mode, and also determines a "%A" value, which is the percent of the first (and highest) calibrator. Calibrator values must be in descending absorbance value.





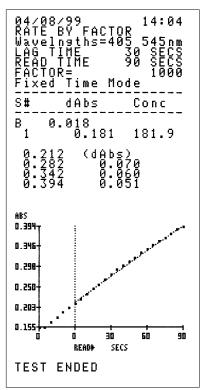
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The Rate Mode (RATE key) performs kinetic assays, by calculating using either a factor (pictured above left) or a standard (pictured above right). By using the AUX key, you may print extended interval data and the kinetic data plot. Variations available on the Rate Mode include Batch Mode and Fixed Time Mode (both pictured on the next page).

LAG TIME 30 SEC READ TIME 60 SEC READ TIME 60 SEC FACTOR MODE # OF SAMPLES = 6 	0 mss0
SAMPLE # 1 A= 0.894 MINS= 1.1 ABS/MIN= 0.74 Conc = 372.7	1 5
SAMPLE # 2 A= 0.591 MINS= 1.1 ABS/MIN= 0.47 Conc = 236.3	1 2
SAMPLE # 3 A= 0.894 MINS= 1.1 ABS/MIN= 0.74 Conc = 370.5	1
SAMPLE # 4 A= 0.173 MINS= 1.1 ABS/MIN= 0.15 Conc = 76.8	<u>1</u> 3
SAMPLE # 5 A= 0.368 MINS= 1.1 ABS/MIN= 0.32 Conc = 160.9	3 2
SAMPLE # 6 A= 0.174 MINS= 1.1 ABS/MIN= 0.14 Conc = 74.4	2
****END OF BATCH***	*



In Batch Mode (pictured above left), the user takes an initial reading on all his samples after the lag time, then takes a final reading after the read time. The change in absorbance per minute is determined. Since no interval data is read, interval data and graphing are not available.

In Fixed Time Mode (pictured above right), the change in absorbance is used, not the change in absorbance per minute. Therefore, the resulting answers (prior to concentration calculations) are reported in dAbs, not A/min. The concentrations may be calculated either by factor or by standard.

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04/08/99	14:20
STANDARD	50 600 nm
Wavelnsths=4!	50.00
Standard#1=	to 60.00
Norms: 20.00	to 120.00
Linear 10.00	g/dL i
S# Abs	g/dL i
	50.00
1 0.286 2 0.123 3 0.048 4 1.1394 5 1.394 TEST ENDED	24.83 10.691R 4.21RH 99.88R

The Standard Mode printout pictured above left is an example test printed without modified line feeds and without sample blanking. It also indicates Norms and Linear ranges. "L" or "H" are printed in the "i" (interpretation) column if the answer exceeds the normal range Low or High, and "R" is printed if the sample exceeds the ranges on either side.

The printout above right shows sample blanking, in which a blank is requested prior to each standard and sample. B is printed to indicate each blank.

The printout mid-right shows the linefeeds set (via the ALT key) to "ALL LINES". For this, an extra space occurs after every line, if increased space in the printout is desired.

The printout lower right shows the line feeds set (via the ALT key) to "**RESULTS ONLY**". An extra space is printed after each result, if increased space between results is desired. If Results Only is selected in the Rate Mode, it will print normally (without linefeeds).

04/08/99 STANDARD Wavelneths=405 Sample Blank M Standard#1= Norms: 1.25to Linear: 0.00to	16:39 600nm lode 6.25 4.50
S# Abs B 0.014 S1 1.184 FACTOR=	0.00 6.25 5.27
B 1 0.02959 B 2 0.05959 B 2 0.08965 B 3 0.08061 B 4 5 0.0806 B 5 0.0806 B 6 0.0806 B 7 0.	1.54 3.12 4.71H 0.10L

04/08/99 16	:42
STANDARD	
Wavelneths=450 60	0 nm
Standard#1= 100	.0
S# Abs %	
B 0.012 0	.0
Si 1.404 100	.0
FACTOR= 7	1.2
1 0.869 61	. 9
2 0.284 20	.3
3 1.151 82	.0
4 0.573 40	. 9
TEST ENDED	

04/08/99 STANOARD Waveln9ths=450 Standard#1= S# Abs B 0.012 S1 1.150 FACTOR= 1 0.283 2 0.868 3 0.573 4 0 017	20.0 100.0 86.8 24.7 75.5 49.8
4 0.017 TEST ENDED	1.5

6. User Test Menu Log

Stat Fax 1904+ (SN) User Test Menu Log page				
Test No.	Analyte Sto	red By Date	Notes	
•				

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Stat Fax® 1904 Plus

Owner's Manual

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