Stat Fax® 4200

MICROPLATE READER

OPERATOR'S MANUAL

AWARENESS TECHNOLOGY
Cost Effective by Design™

RayBiotech
Empowering your proteomics

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1. Introduction

1.1 Applications

1.1.1 Intended Use

The ***Stat Fax® 4200*** is a compact, microprocessor-controlled, multi-purpose photometer system designed to read and calculate the results of assays, which are read in 96 well microplates or strip trays.

The ***Stat Fax® 4200*** may be used for in-vitro diagnostics. It is a user-programmable open system with selectable plate formatting, alphanumeric test naming, automatic interpretation options, duplicate well options, curve plotting and editing, flags and error messages from which the user can create a menu of pre-programmed assays for instant recall.

Stat Fax® 4200 is intended to be used as a stand-alone instrument without a PC but it has a connection in the event a user wishes to download results. For a PC-controlled microplate reader ask about the ChroMate ™Model 4300.

It is a general purpose instrument intended to be used by trained laboratory professionals who are capable of selecting the appropriate features and options for each specific clinical application. Contact your company's instrument service provider to arrange for training if the information provided in this manual is not sufficient for your applications.

FOR IN-VITRO DIAGNOSTIC USE

POUR L'USAGE DIAGNOSTIQUE IN VITRO

1.1.2 Summary of the Instrument

This instrument reads monochromatically (optional) or bichromatically (optional) and has two models:

- Four-filter model (405, 450, 492, and 630 nm)
- Six-filter VIS model (405, 450, 492, 545, 600, and 630 nm)

Substitute filters in the range of 405 nm - 750 nm are available on special order models.

Summary of the Instrument (continued)

The ***Stat Fax® 4200*** accepts all standard microplates. Trays containing microstrips may also be read whether they are 12 wells in length, 8 wells or even partial strips.

- **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 *2.5-Modes of Operation***. The following calculation modes are offered: Factor, Single Standard, Point to Point, Regression, Cubic Spline, and Cut Off.

- **User-programmable Memory**

The ***Stat Fax® 4200*** Microplate Reader's software allows the operator to create, edit and store assays. Standard curves are also stored in this memory. Test protocols remain stored until either changed or deleted by the user.

1.1.3 Principles of Operation

The ***Stat Fax® 4200*** Microplate Reader's optical system provides an economical and low maintenance design which reads 8 wells simultaneously. A 96 well plate can be read and printed in the absorbance mode in approximately twenty seconds.

Light from a lamp installed in a sealed light-tight compartment is filtered using a rotating filter wheel. The filtered light is then divided into 8 channels using a fiber optic bundle.

The plate carrier precisely positions each row of 8 wells into the optical path for reading. Light passing through the 8 wells is directed to 8 photo-detectors.

The filter wheel moves to a second position to read the 8 wells at a second wavelength. Using bichromatic differential absorbance values corrects for optical imperfections in the plastic wells and removes the effects of meniscus and turbidity.

The photo-detectors generate electronic signals which are amplified and interpreted by the instrument circuitry.

1.2 Warning Markings Inscriptions d'avertissement

1.2.1 Safety Symbols Le Symboles de Sûreté

Symbols that may appear on the product:

Les symboles de sûreté peuvent apparaitre sur le produit:

			
WARNING *AVERTISSEMENT*	Protective Ground *La Terre Electrique*	CAUTION *L'ATTENTION*	BIOHAZARD *BIOHAZARD*
Risk of Shock *Risque de Choc*	(Earth) Terminal *Prise de Terre*	Refer to Manual *Se Rapportent a Manuel*	Risk of Infection *Risque d'infection*

1.2.2 Safety Terms Terminologie de Sûreté

These terms may appear on the product: Les marques sur le produit: *These terms may appear in this manual: Les marques dans l'opérateur manuel:*	
DANGER *DANGER Le "de marque: DANGER"*	Indicates an injury immediately accessible as you read this marking *Indique le risque immédiat de dommages (assessible tandis que vous lisez la marque)*
WARNING *AVERTISSEMENT! Le "de marque: WARNING"*	WARNING statements identify conditions or practices that could result in injury or loss of life. WARNING indicates an injury hazard not immediately accessible as you read this marking. *Ces rapports identifient les conditions ou les pratiques qui pourraient avoir comme conséquence les dommages ou les pertes humaines.*
CAUTION *L'ATTENTION "Le de marque: CAUTION"*	CAUTION statements identify conditions or practices that could result in damage to this product or other property. *Ces rapports identifient les conditions ou les pratiques qui pourraient avoir comme conséquence les dommages a ce produit ou a toute autre propriété.*
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	Take time to read this manual carefully before using this instrument. Review the following safety precautions to avoid injury and prevent damage to this instrument or any products connected to it. To avoid potential hazards, use this instrument only as specified. For best results, familiarize yourself with the instrument and its capabilities before attempting any clinical diagnostic tests. Refer any questions to your instrument service provider.
Servicing	There are no user-serviceable parts inside the instrument. Refer servicing to qualified service personnel. Use only factory-authorized parts. Failure to do so may void the warranty.
Wear Protective Apparel	Many diagnostic assays utilize materials that are potential biohazards. **WARNING:** Always wear protective apparel and eye protection while using this instrument.
Follow Operating Instructions	**WARNING:** Do not use this instrument in a manner not specified by the manual, or the protection provided by the instrument may be impaired.
Use Proper Power Supply	**WARNING:** Use only the power supply specified for this product and certified for the country of use.
Observe All Terminal Ratings	**WARNING:** To avoid fire or shock hazard, observe all ratings and markings on the instrument. Consult this manual for further ratings information before making connections to the instrument.
Install as Directed	This instrument should be installed on a sturdy, level surface capable of safely supporting the instrument's weight 12 lbs (5.4kg). 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: 10cm around perimeter of unit, 10cm on top, 1.27cm bottom (1/2").
Do Not Operate Without Protective Covers	**WARNING:** Do not operate this instrument with covers and panels removed.
Avoid Exposed Circuitry	**WARNING:** Do not touch exposed connections and components when power is present.
Avoid Excessive Dust	Do not operate in an area with excessive dust.
Do Not Operate With Suspected Failures	WARNING: If you suspect there is damage to this instrument, have it inspected by a qualified service person.
Do Not Operate in Wet/Damp Conditions	WARNING: Do not operate instrument in wet/damp conditions.
Do Not Operate In An Explosive Atmosphere	WARNING: Do not operate instrument in an explosive atmosphere.
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.
Keep Instrument Surfaces Clean and Dry	CAUTION: Solvents such as acetone or paint thinner will damage the instrument. √ Do not use solvents to clean the unit. Avoid abrasive cleaners; the display overlay is liquid-resistant, but easily scratched. √ Clean the exterior of the instrument with a soft cloth using plain water. If needed, a mild all-purpose or nonabrasive cleaner may be used. √ Use as a disinfectant a 10% solution of chlorine bleach (5.25% Sodium Hypochlorite) or 70% isopropyl alcohol. √ Take special care not to spill liquid inside the instrument

CAUTION! *L'ATTENTION!*	
	WARNING: If any materials are overturned during operation, immediately set the power switch to OFF. This material should be treated as potentially biohazardous. Appropriate cleanup and disposal of biohazardous waste should be used. *Avertissement! Lors du fonctionnement, si on renverse des matériaux, coupez immédiatement le courant. Placez le commutateur électrique a AU LOIN(0). Traitez le matériel comme biohazardous, utilisant approprie nettoient et des méthodes de disposition.*

1.3.1 Disposal

Dispose of according to local regulations.

Before the instrument is removed from the laboratory for disposal or servicing, it must be decontaminated.

Decontamination should be performed by a well-trained authorized person, observing all necessary safety precautions. Instruments to be returned must be accompanied by a decontamination certificate completed by the responsible laboratory manager. If a decontamination certificate is not supplied, the returning laboratory will be responsible for charges resulting from non-acceptance of the instrument by the servicing center or from any authority's intervention.

CAUTION! *L'ATTENTION!*	
	**Caution**: Treat all components during use and disposal as you would any biohazardous material. ***L'Attention**: Utiliser et disposer des matériaux de la même manière que vous utilisé et disposer des matières infectieuses.*

1.4 Specifications

Photometric

Linear Measurement Range:	0.0 to 4.0 Absorbance Units (A)
Photometric Accuracy:	+/- (1% +/- 0.010) 0.0 through 1.5 ABS
	+/- (2% +/- 0.010) 1.5 through 3.0 ABS
Stability:	Drift of no more than 0.005A in 8 hours
Light Source:	Halogen lamp with lamp saver feature
Standard Wavelengths:	405, 450, 492, and 630nm. 6-filter: 405, 450, 492, 545, 600, and 630nm. Filter options from 405nm to 700nm.
Filter Type:	IAD hardcoat interference, 10nm half bandpass
Vessel:	Standard 96-well microplates or strip trays

Electronic

Display:	Interactive touch screen 4.5”x3.5” (14.5cm) LCD color graphic display
Printer:	Thermal 64 characters per line, plus graphics
Power Requirements:	100-240V AC, 1.2A, 50-60Hz (universal input, auto sensing)
Microprocessor:	eZ80, 64K EEPROM
Memory:	2MB Flash Memory, 1MB RAM Memory
Interface:	USB mouse; USB port used for thumb drive interface for firmware updates (mouse not included; thumb drive not included)

Software

Speed:	Reads absorbance of 96 wells in about 10 seconds
Calculation Modes:	Factor, Single Standard, Point-to-Point, Regression, Cubic Spline, Cut Off Mode
Test Storage:	Stores 120 tests; stores all parameters including wavelengths, calculations, unit codes, linear and normal ranges, standard values, test names, and previous standard curve.

Other

Enclosure:	Flame-retardant ABS/PVC alloy material cover with aluminum base
Dimensions:	Approximately 13.5”Wx17”Dx8-1/4”H (34.3cmx43.2cmx21cm)
Weight	12 lbs (5.5kg)
Certifications:	CE, ETL listed, NRTL listed (USA/CAN)

Recommended Environmental Conditions
Indoor use

Mains supply voltage:	Fluctuations not to exceed ± 10% of nominal voltage
Recommended Operating Temperature	18-35°C
Recommended Operating Humidity:	less than 80%
Storage Temperature:	10 to 50°C

NOTE: Although it may be safe to operate in these conditions, it may not be suitable for the performance of your tests. Check with your reagent supplier.

Accessories sold separately: Thermal paper (contact your dealer)

1.5 Installation

1.5.1 General

Carefully unpack the instrument, removing it from its plastic bag. Report any damage to your freight carrier at once. Retain the original packing material for future use in the event that the instrument is shipped to another location or returned for service. Items packed with the instrument include:

42XX MICROPLATE READER

QTY	PART NO.	DESCRIPTION
1	42XX	Microplate Reader
1	OM4200	Operators Manual
1		Quick Start Guide
1	101245 or 101246	US or Euro Power Supply (US Shown)
1	042010	*Spare Parts Kit
1		Declaration of Conformity
1		Certificate of Quality

***SPARE PARTS KIT**

	QTY	PART NO.	DESCRIPTION
☐	1	954215	Lamp Replacement Instructions
☐	2	150003	Printer Paper
☐	1	112008	Halogen Lamp
☐	1	004246	Stylus Pen Clip
☐	1	004245	Stylus Pen

1.5.2 Installation/Preparation

Instrument Placement and Use	Place the instrument on a flat working surface capable of safely supporting the weight of the instrument, approximately 5.4 kg (12lbs). A clearance of at least 8cm (3”) around the instrument is required to assure optimal ventilation.
Assure Clean Power Availability	The circuit used should be substantially free of large voltage transients (Kilovolt amp loads) such as large pumps, large centrifuges, refrigerators and freezers, air conditioners, large autoclaves, ovens, and dryers. The instrument may fail to operate normally if the power supply is interrupted. If this occurs, turn the instrument off for a moment. When the instrument is turned back on, it will resume normal operation, but data that was not stored in nonvolatile memory will be lost. If power fluctuations or loss are frequent, an Uninterruptible Power Supply (UPS) is recommended.
Power Switch Position	The ON/OFF switch is on the back of the instrument. The power switch should be in the OFF position (down) before connecting the power cord to the power supply.

Power Cord Requirements	With the power switch in the OFF [down] position, insert the DC connector attached to the end of the power supply module cable to the instrument. Insert the mating end of the AC power cord to the inlet of the power supply module, and plug the other end of the AC power cord into an AC outlet. Use only the power cord and supply module specified for this product and certified for the country of use. For 110-120 V used in the United States, use a UL listed cord set consisting of an 18 AWG, Type SPT-1 two conductor cord maximum 3 meters (10 feet) in length, rated 7 A, 125 V, with a polarized parallel blade type attachment plug. For 220-240 V used inside the United States, use a UL listed cord as above, except rated 250V. For other locations, use the power cord certified for the country of use.

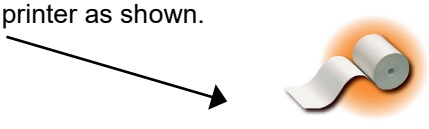
1.5.3 Load Paper

Figure 1.5.3-1 Paper compartment lid

Locate the roll of thermal printer paper P/N 150003.

Press down on the printer paper compartment release button (A) and the paper compartment lid will open.

Place the paper roll in the well such that the leading edge of the paper feeds upward from the front of the printer as shown.



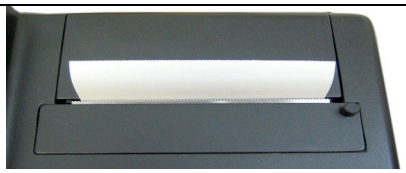


Figure 1.5.3-2 Printer paper installed

Pull up at least 1 inch of paper and then press the compartment cover down until it snaps closed. Turn the power switch OFF and back ON. The wake up routine will follow. The printer will print several lines.

Wait until it has stopped. If there is no printing, the internal printer is disabled (reference Section 2.3.2 Settings).

NOTE: The printer manufacturer strongly recommends the use of thermal paper part number 150003 to reduce lint and extend printer life. Contact your dealer for replacement rolls.

1.5.4 Touch Screen Description

The touch screen responds to touch pressure which causes electrical contact between the conductive and resistive layers. The touch screen provides the following advantages:

- High touch resolution
- Pressure sensitive, works with any stylus
- Not affected by dirt, dust, water or light
- Durable technology

1.6 Parts and Controls

The following terms are used in this manual to describe parts and controls of the ***Stat Fax® 4200*** microplate reader. More details on the operation of each feature are provided in **Section 2- *Operating Procedures***.

A) Door open
B) Printer and printer paper compartment
C) Display

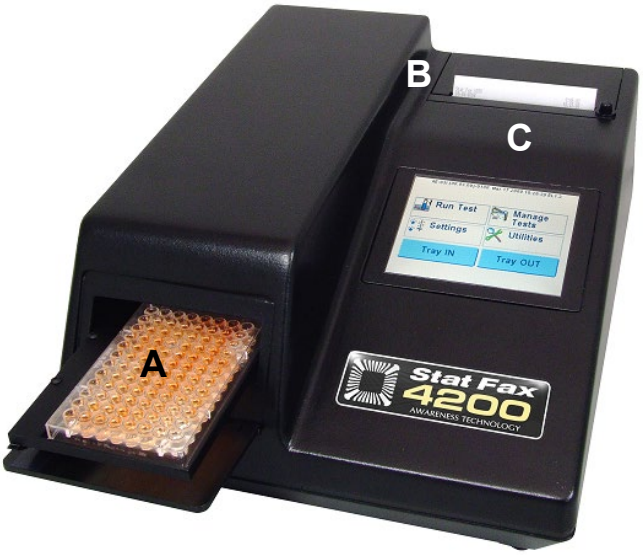


Figure 1.6-1 Front of instrument

A) Power supply module
B) Power switch
C) Power supply connection
D) USB Port
E) USB ports: mouse and thumb drive
F) Stylus

Figure 1.6-2 Connections

1.7 Checkout Procedure

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

Checkout Procedure	
Visually confirm the following items:	
√ Power supply is connected to the unit and the power plug is inserted into an AC outlet.	
√ Power switch is set to OFF.	
The instrument is now ready for power-up. Confirm that the instrument responds as described.	
√ Set the power switch to the ON position.	
The printer will print out the instrument model, serial number, laboratory name (if defined under the *Settings menu Laboratory Name option; the default is no laboratory name)*, firmware version, revision level, date and time (*Figure 1.7-2*). Click Tray Out and make sure door opens and microplate tray extends out. Click Tray In and make sure door closes. Before running any assays, read at least one plate in absorbance mode to verify plate carrier operation If the instrument still produces results other than those described here, refer to *Section 4. Troubleshooting*, or contact your dealer for assistance.	 ***Figure 1.7-1 Power up Screen Display*** Stat Fax 4200 Ver: Eng-01.26.00 Laboratory Name (if defined) Serial Number: 9999 12-20-2018 16:34:40 ***Figure 1.7-2 Representation of the power up print out***

2. Operating Procedures

2.1 Operating Precautions

- Avoid lifting, leaning or turning the instrument over when a plate is in place.
- Be sure to run a sufficient number of controls in each assay. If controls are not within their acceptable limits or if incomplete, disregard test results.

2.2 General Selections

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.

Review the following questions before beginning a test (refer to the reagent kit insert for required information):

1. How will absorbance readings be converted into a final result?
2. Is a Blank required? Which filters are optimal? (primary and differential wavelengths)
3. 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.
4. What is the calibrator value or values?
5. 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.
6. Will locations of one or more controls be marked? If so, indicate plate number, row number, and well number for each.
7. Will acceptance cutoffs or ranges for controls be entered for automatic comparison? If so, what cutoffs or ranges are to be used for each?
8. Will a cutoff value be used to label positive samples? If so, the value that begins the positive range will be required.
9. Will a cutoff value be used to label negative samples or define an equivocal zone? If so, results less than which cutoff should be labeled as negative?
10. Will only a partial plate be read?

2.3 Main Display Menu Options

The Main display menu options are:

- Run Test *explained in Section 2.3.1*
- Settings *explained in Section 2.3.2*
- Manage Tests *explained in Section 2.3.3*
- Utilities *explained in Section 2.3.4*
- Tray In – the plate carrier transports the plate into the and the door closes
- Tray Out – the door opens and the plate carrier extends out for the ease of inserting a test plate on the carrier

Figure 2.3-1 Main display menu screen

The status line displays the Lamp status (OFF or ON) and the time. The printer button (PRN) has two options: 1. to advance the paper, 2. to reprint the last 64 lines of data. NOTE: PRN does not print graphs, only data.

2.3.1 Run Test

The Run Test feature allows the operator to recall user tests that have been stored in the instrument's memory (see example in Figure 2.3.1-1). The ***Stat Fax® 4200*** stores up to 120 complete test setups in nonvolatile memory, making it easy for the user to recall complete test configurations.

Select Run Test from the Main display. Tests programmed and saved on the instrument will display sorted by their test number. Each of the test parameters, including the mode, wavelengths, standards, units, and the ranges are all stored for reuse.

Blanks and standards (including entire standard curves) that have been read are also saved. When the test is recalled, the user has the option of using the previous saved curve or reading a new one.

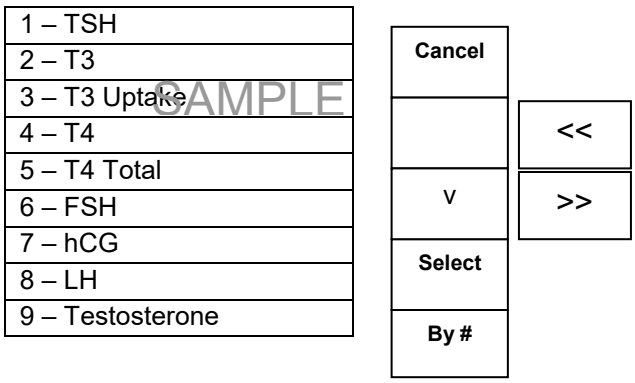


Figure 2.3.1-1 Run Test - Example of stored test menu

Feature	Function
Arrows	Use the ^ UP and V DOWN arrow keys to highlight selection; use the >> side arrows to advance to the next screen; use << arrows for previous screen
Select	The highlighted test is executed once the Select key is pressed
By #	Allows the user to enter a specific test number to recall.
Cancel	Returns to the main power on display screen

2.3.2 Settings

Select the Settings option on the main display screen and the Unit Settings will display:

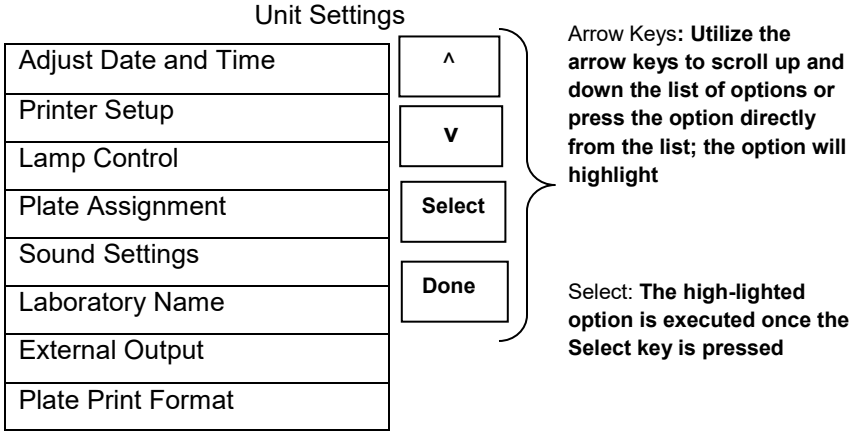


Figure 2.3.2-1 Unit Settings

The functions of the Unit Settings features are:

Feature	Function
Adjust Date and Time	Provides access to the Set Time option Hours, Minutes, Seconds as well as Month, Day, Year
Printer Setup	Enables/disables the internal printer. Graphs can be printed when the internal printer is set to OFF. Allows the contrast to be adjusted light to dark. It is advisable to print at contrast level set at 3. Higher t levels may degrade after several lengthy printouts. Text height options are small, medium and large.
Lamp Control	Lamp idle feature will automatically turn off the lamp; the default setting is 600 seconds (10 minutes). Lamp Warm up range is between 45 and 240 seconds (45 seconds is the default setting).
Plate Assignment	Offers plate format options such as 8 way or 12 way; duplicates side by side.
Sound Settings	Provides access to and status of touch screen sound settings (ON or OFF), and sound volume (1=low to 8=high). Sound options are: start up sound, key press & release and other sounds (i.e. sound when the Quit button is selected).
Laboratory Name	Allows a laboratory named to be entered; laboratory name will print out (reference Checkout Procedure in Section 1.8).
External Output	Allows external output to be turned ON or OFF. Reference the External Output Section 2.3.2.1 for setup instructions.
Plate Print Format	User can select either a 1 to 12 or H to A printout of plate data.

2.3.2.1 External Output

To enable output to be sent to a personal computer, a user must use a software application such as SF_Capture to transmit and store data from the ***Stat Fax® 4200*** and have the following in place:

- Power on the instrument and set the External Output to "ON" by: (a) selecting Settings from the main display, (b) highlight External Output on the Unit Settings display, (c) press the Select button, (d) on the External Output Setup display select the ON button and ensure that the Status field displays ON, (e) select the Save button, and then, (f) select the Done button.
- Connect the type B end of the USB cable to the type B port of the instrument.
- With the personal computer (PC) powered on, connect the type A end of the USB cable to a USB port on the PC.

Type A

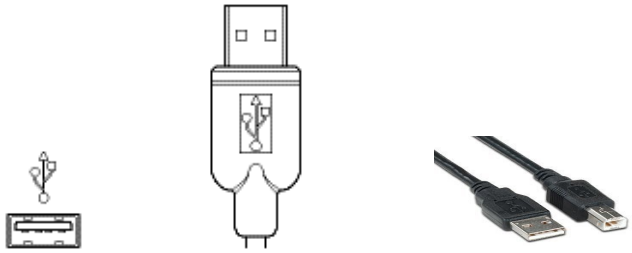


Figure 1 USB Type A port and connector

Type B

Figure 2 ***USB Type B port and connector***

2.3.2.2 USB Mouse Connection

To use a USB mouse with the ***Stat Fax® 4200***, be sure that the mouse is connected to the USB port A on the instrument before the instrument is powered on. If the mouse is plugged in after the instrument is on, it will not be operational.

2.3.3 Manage Tests

Detailed descriptions of the Modes of Operation may be found in Section 2.5.

Select Manage Tests on the Main display screen and the following options will display:

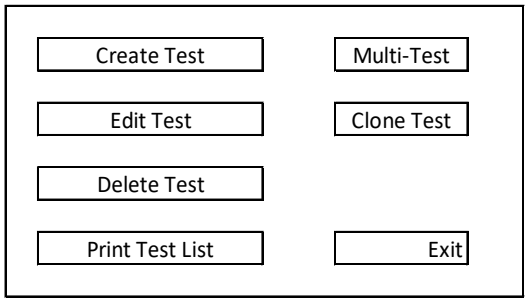


Figure 2.3.3-1 Manage Tests options

The functions of the Manage Tests options are:

Feature	Function
Create Test	Allows user to: • Name the test • Select the Mode (Absorbance, Factor, Single Standard, Point to Point, Regression, Cubic Spline, Cut Off) • Select the Primary Filter • Select the Differential Filter • Enable/Disable Blank (Yes or No) Note: Default is 'yes' for Single Standard Mode. • Set number of blank replicates • Interpretation Criteria (Positive and Negative interpretation, or Normal and Valid Ranges) • Select Units • Input Decimals • Enable % Absorbance (Yes or No) • Input number of Standards • Input number of Sample Replicates • Select Axes • Controls management (Enable; name; number of replicates; input low/high ranges; input action to take (i.e. warn, continue or end test); record Lot Number; input expiration date; location).

Feature	Function
Create Test (Continued)	• Set Blank Minimum and or Maximum • Set Normal Range Low and or High • Define Valid Range Low and or High
Edit Test	Used to change test programming. Editing a test will erase any stored blank or standard values for that test
Delete Test	Allows selection and deletion of user programmed and stored tests
Multi Test	User can select a number of different tests to be read in the same plate. (2, 3, or 6 in an 8-way formatted plate or 2 or 4 in a 12-way formatted plate)
Clone Test	Duplicates an existing test.
Print Test List	Prints the list of stored tests (maximum 120 tests)
Exit	Returns to the Main power on display screen

2.3.3.1 Multi-Test

With the Multi-Test option, any stored assay regardless of mode or wavelength may be used. The read direction (8 or 12-way) will be the instrument was set to read in the Settings menu. With the 8-way format, two, three or six different test modes may be run in the same plate; with the12-way format up to four tests may be run.

If any test is selected to run in the multi-test plate that has a stored curve, the user will be prompted to accept, print or discard the curve.

The instrument will prompt the user to select the next test. To read less than a full plate, select “Cancel” after choosing the last test to be run.

Print Plate will enable the location and absorbance reading of each well to be printed, as shown on the plate map.

In order to print the test information and results, after each test is run, select “Results”.

If all tests in the multi-test plate have the same filter configuration, then the plate is read only one time. The user can select “Print Plate” and “Results” for each test.

If different filters are used for any other test(s), the plate will automatically be read again.

There is no option to select number of wells in Multi-Test.

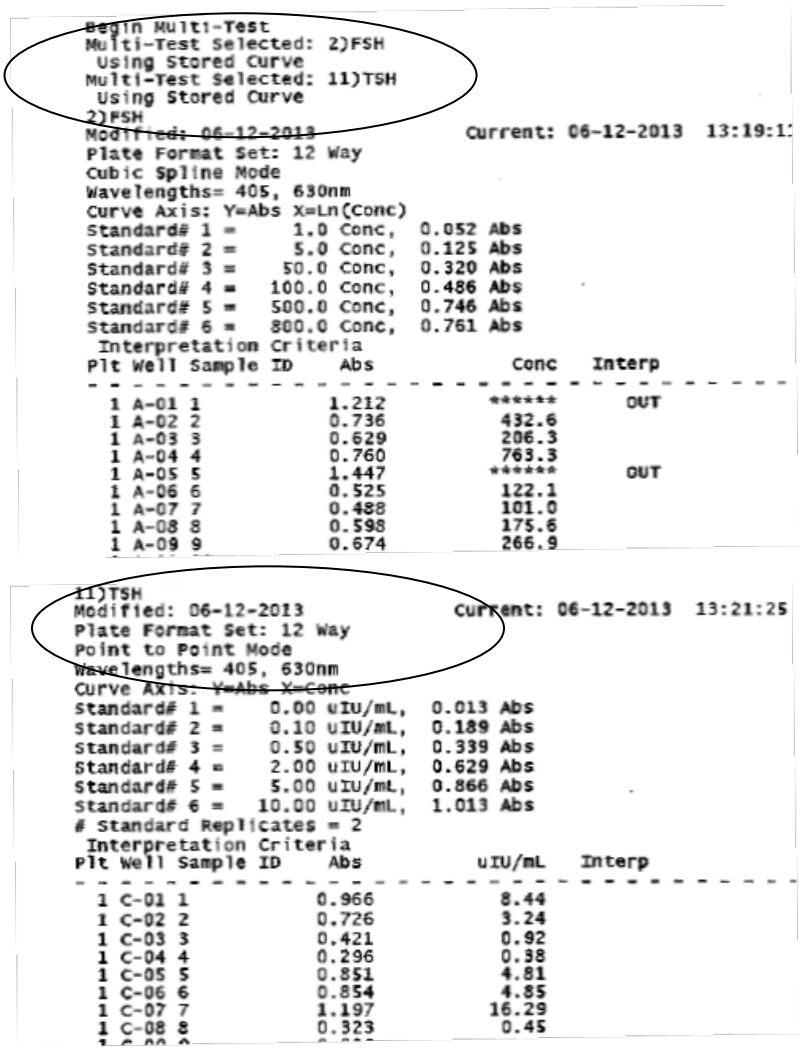
Multi-Test (Continued)

Example 1

1) Two tests with different wavelengths have been selected to run.

2) Select “Read Plate” and the first test will run. When that test is done, use the “Results” button to printout out data. (Print Plate can be used to verify well and well absorbance reading location.)

3) The next test will be recalled and run automatically.



```
Begin Multi-Test
Multi-Test Selected: 2)FSH
 Using Stored Curve
Multi-Test Selected: 11)TSH
 Using Stored Curve
2)FSH
Modified: 06-12-2013                Current: 06-12-2013  13:19:11
Plate Format Set: 12 Way
Cubic Spline Mode
Wavelengths= 405, 630nm
Curve Axis: Y=Abs X=Ln(Conc)
Standard# 1 =     1.0 Conc,  0.052 Abs
Standard# 2 =     5.0 Conc,  0.125 Abs
Standard# 3 =    50.0 Conc,  0.320 Abs
Standard# 4 =   100.0 Conc,  0.486 Abs
Standard# 5 =   500.0 Conc,  0.746 Abs
Standard# 6 =   800.0 Conc,  0.761 Abs
 Interpretation Criteria
Plt Well Sample ID    Abs          Conc   Interp
- - - - - - - - - - - - - - - - - - - - - - - - -
  1 A-01 1          1.212        ******     OUT
  1 A-02 2          0.736         432.6
  1 A-03 3          0.629         206.3
  1 A-04 4          0.760         763.3
  1 A-05 5          1.447        ******     OUT
  1 A-06 6          0.525         122.1
  1 A-07 7          0.488         101.0
  1 A-08 8          0.598         175.6
  1 A-09 9          0.674         266.9
```

```
11)TSH
Modified: 06-12-2013                Current: 06-12-2013  13:21:25
Plate Format Set: 12 Way
Point to Point Mode
Wavelengths= 405, 630nm
Curve Axis: Y=Abs X=Conc
Standard# 1 =    0.00 uIU/mL,  0.013 Abs
Standard# 2 =    0.10 uIU/mL,  0.189 Abs
Standard# 3 =    0.50 uIU/mL,  0.339 Abs
Standard# 4 =    2.00 uIU/mL,  0.629 Abs
Standard# 5 =    5.00 uIU/mL,  0.866 Abs
Standard# 6 =   10.00 uIU/mL,  1.013 Abs
# Standard Replicates = 2
 Interpretation Criteria
Plt Well Sample ID    Abs          uIU/mL   Interp
- - - - - - - - - - - - - - - - - - - - - - - - -
  1 C-01 1          0.966          8.44
  1 C-02 2          0.726          3.24
  1 C-03 3          0.421          0.92
  1 C-04 4          0.296          0.38
  1 C-05 5          0.851          4.81
  1 C-06 6          0.854          4.85
  1 C-07 7          1.197         16.29
  1 C-08 8          0.323          0.45
```

Multi-Test (Continued)

Example 2,

1) Three tests – 2, 1 and 3 - were selected to run;
2) Reading of the Standards in the second test, TSH, results in an invalid curve.
3) The next test in the plate will not run. Multi-test mode is ended.

```
Begin Multi-Test
Multi-Test Selected: 2)Estradiol
 Stored Curve Discarded
Multi-Test Selected: 1)TSH
 Stored Curve Discarded
Multi-Test Selected: 3)
1)Estradiol
Modified: 10-07-2013                Current: 10-07-2013  09:55:48
Plate Format Set: 8 Way
Point to Point Mode
** Using Simulated Absorbances **
Wavelengths= 450, 630nm
Curve Axis: Y=Abs X=Conc
Standard# 1 =      0.0 Conc,  0.213 Abs
Standard# 2 =      1.0 Conc,  0.478 Abs
Standard# 3 =      5.0 Conc,  0.632 Abs
Standard# 4 =     10.0 Conc,  0.899 Abs
Standard# 5 =     50.0 Conc,  1.936 Abs
 Interpretation Criteria
Plt Well Sample ID     Abs            Conc   Interp
- - - - - - - - - - - - - - - - - - - - - - - - - -
Running New Curve
  1 A-01 Standard 1  0.213            0.0
  1 B-01 Standard 2  0.478            1.0
  1 C-01 Standard 3  0.632            5.0
  1 D-01 Standard 4  0.889           10.0
  1 E-01 Standard 5  1.936           50.0
  1 F-01 1           0.383            0.6
  1 G-01 2           0.447            0.8
  1 H-01 3           0.910           10.8
  1 A-02 4           1.874           47.6
  1 B-02 5           0.360            0.5
  1 C-02 6           0.547            2.8
  1 D-02 7           1.487           32.8
  1 E-02 8           2.045           54.2
  1 F-02 9           0.320            0.4
  1 G-02 10          0.658            5.5
  1 H-02 11          0.332            0.4
2)TSH
Modified: 10-07-2013                Current: 10-07-2013  09:58:14
Plate Format Set: 8 Way
Point to Point Mode
** Using Simulated Absorbances **
Wavelengths= 405, 630nm
Curve Axis: Y=Abs X=Conc
Standard# 1 =      0.0 Conc,  0.010 Abs
Standard# 2 =      0.8 Conc,  0.245 Abs
Standard# 3 =      2.0 Conc,  0.459 Abs
Standard# 4 =      4.0 Conc,  0.861 Abs
Standard# 5 =     10.0 Conc,  1.697 Abs
Standard# 6 =     20.0 Conc,  2.585 Abs
 Interpretation Criteria
Plt Well Sample ID     Abs            Conc   Interp
- - - - - - - - - - - - - - - - - - - - - - - - - -
Running New Curve
  1 A-03 Standard 1  0.010            0.0
  1 B-03 Standard 2  0.245            0.8
  1 C-03 Standard 3  0.861            2.0
  1 D-03 Standard 4  0.459            4.0
  1 E-03 Standard 5  1.697           10.0
  1 F-03 Standard 6  2.585           20.0
-- CURVE INVALID! --
End of Test



End Of Multi-Test
```

2.3.4 Utilities

Select Utilities from the Main display screen and Utility Menu options used for diagnostic purposes will display. The arrow keys control movement up and down the list of options as well as using the edge of the list to scroll up and down. To select an option from the list, press the Select button. Press the Done button when finished.

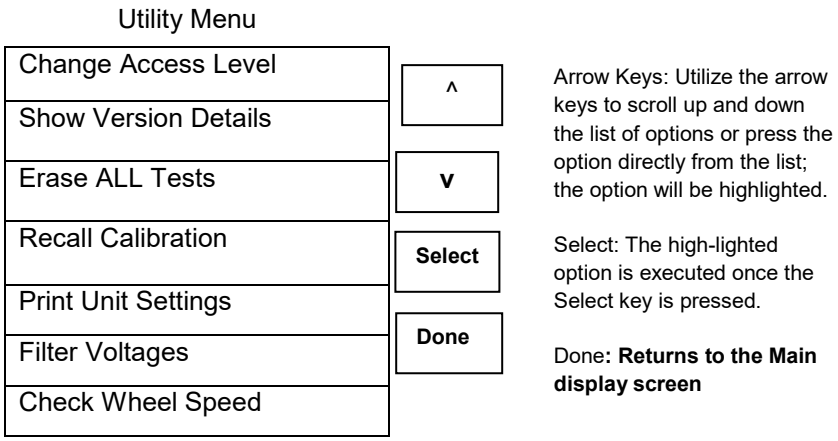


Figure 2.3.4-1 Utility Menu options

The functions of the Utility Menu options are**:**

Feature	Function
Change Access Level	Display prompts to 'Enter Pass Code'. Contact Technical Support for pass code.
Show Version Details	Displays current firmware version, model, serial number, build date, current time.
Erase All Tests	Display will prompt "Please Confirm. Erase All Tests?" press OK to clear all tests or Cancel.
Recall Calibration	Allows user to restore the original factory settings, including calibration.
Print Unit Settings	Prints all information about an individual instrument's calibration settings and other information.
Filter Voltages	Displays real time filter wheel voltages; provides option to print them out. Acceptable range is from 2 to 10 v.
Check Wheel Speed	Displays results as the wheel speed is tested.

2.4 General Operation

2.4.1 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 values corrects for optical imperfections in the plastic wells and removes the effects of meniscus and turbidity.

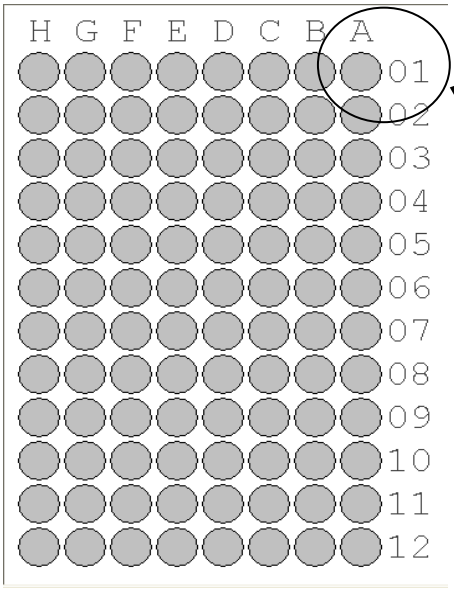
Whenever possible, differential reading is recommended because precision is significantly improved.

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.

2.4.2 Loading and Formatting a Plate

The footprint for most 96 well plates and strip trays are similar and will fit the ***Stat Fax®*** ***4200.*** Test the fit of an empty plate before beginning an assay. Place the plate into the instrument with well A-1 at the rear right corner so that row 1 is going into the reader first. As you press the first row back and down you will feel slight tension on the plate stretching the carrier so that the front fits in. The plate requires a snug fit.



Place the plate into the instrument with well A-1 at the right rear so that row 1 is going into the reader first. When using a single Blank(s) always is located in A1.

Loading & Formatting a Plate (Continued)

When using a strip tray, make sure wells are pushed down into tray so that they will not cause the plate to jam on entry. Use care that well tabs do not extend over other wells.

Do not place the tabbed ends of strips in row 1; they should be in row 12. Be sure to place the strips in the order in which Blanks, Calibrators and Samples are to be read.

When using a Blank, it should always be located in Well A1. If replicate blanks are used, they will be placed on the plate map as the next well from A1, to B1 if reading 8 way strips, or below if reading 12 way strips.

For best results, do not fill wells completely; 200-250µl depending on well total volume is the maximum fill recommended.

Use caution when attaching labels to plates so they do not jam in reader or interfere with read path.

The microplate may be formatted for 8 way or 12 way placement of Blanks, Controls and Samples. Selecting 8 way or 12 way is done on the Settings screen, Plate Alignment option.

2.4.2.1 Locating Controls

Unlike Blank(s), Controls can be located in any location of the strip carrier.

The default location is the well or wells adjacent to the Blank(s). To use a different location, while enabling the use of Controls, select the **Location** field (Figure 2.4.2.1-1).

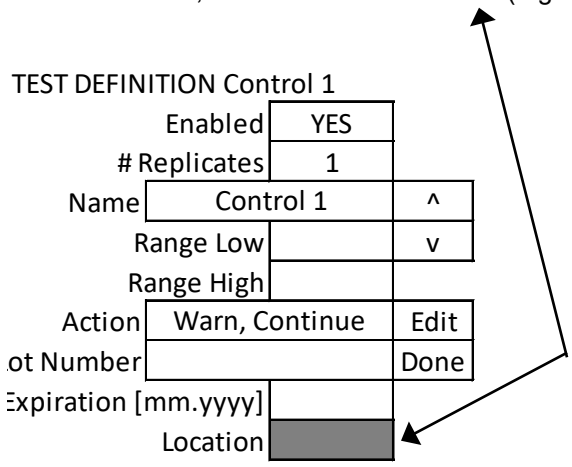


Figure 2.4.2.1-1

A new screen will open up showing the current plate map (Figure 2.4.2.1-2). Controls can be placed anywhere on the map by manually selecting a well location. The well location selected will then be displayed in the box “Location”.

In the example below, a cutoff mode assay is being run and strips are to be read in the 8 way read direction. Duplicate Positive Controls (PC) and a single Negative Controls (NC) are being used in the assay (Figure 2.4.2.1-2).

The Negative control is to be read in well A5. This is done by selecting that box on the screen. The new location is presented in the Location box. .

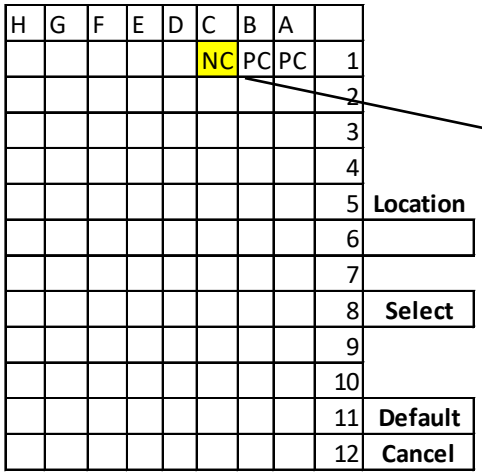


Figure 2.4.2.1-2

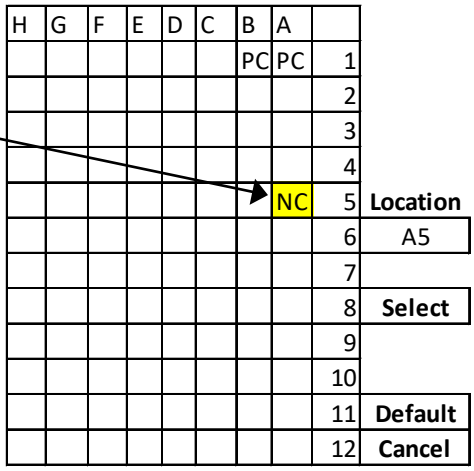


Figure 2.4.2.1-3

When using replicates, only the location of one Control is to be selected. The replicates will follow according to the Plate Alignment chosen in Settings.

NOTE: If the Controls or their Replicates overlap due to the plate setup, an error flag will display to warn the operator:

“Enabled control location already identified!”

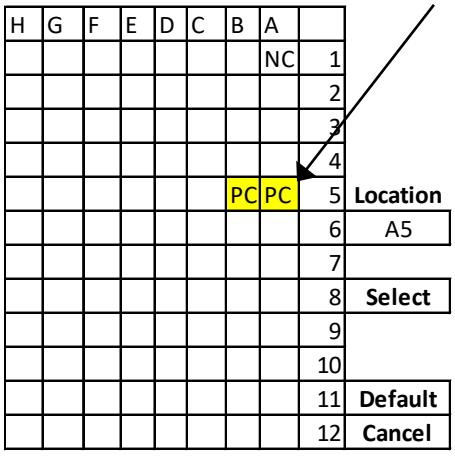


Figure 2.4.2.1-4

2.4.3 Reading a Plate

Select and confirm a stored test, or create a new test. The display will show the plate, indicating where Blanks, Standards and Controls are located.

The example below (Figure 2.4.3.-1) shows the layout of a Point to Point mode assay that has duplicate Blanks, 5 Standards, using all three Controls read in duplicate.

H	G	F	E	D	C	B	A	P1
S6	S5	S4	S3	S2	S1	B2	B1	**1**
2	1	C3	C3	C2	C2	C1	C1	**2**
10	9	8	7	6	5	4	3	**3**
								4
								5
								6
								7
								8
								9
								10
								11
								12
QUIT			**# Samples**				**Read Plate**	

Figure 2.4.3-1

If fewer than a full plate of wells is to be read, select the '#Samples' button. Once the plate has been read (via Read Plate), absorbance readings will be on the display for each well.

There is an option of 'Print Plate' to print out the plate as seen on the display. This is especially useful when running Absorbance mode.

Select the Results button and the test results will be printed. The message "Run another plate of samples" will appear. The user can choose to read more or to Quit.

2.4.4 Unit of Measurement Codes (Unit Code)

To access the list of Unit Codes, select Manage Tests, select Create Test select any mode except Absorbance, and advance to the Test Definition Final Page. Select the Units field and the list will display. Seven units of measurement designations are stored for labeling the concentration column plus a blank customizable selection.

TEST DEFINITION Final page

			Exit
Interpretation Mode		Pos/Neg	
Units		Conc	^
Decimals		1	v
# Sample Replicates		1	
			Edit
<<	Save	Run	Print

Figure 2.4.4-1 Test Definition Final page

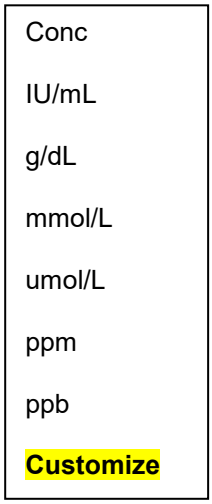
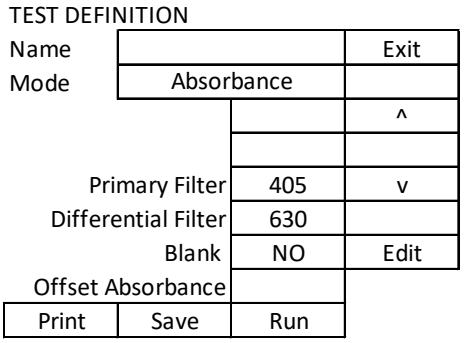


Figure 2.4.4-2 Units of Measure

Create a customized label for the concentration column by selecting the option '**Customize**' from the list of units available. A keyboard will display, enter the desired label name and press Enter. The custom Unit label will display in the Unit field.

2.4.5 Offset Absorbance

If Differential Filter is set to "None", then the Offset Absorbance field is displayed.



Test Definition – Offset Absorbance field displayed

The user should determine the value of the Offset Absorbance. This value will be subtracted from the absorbance readings to correct for the meniscus effect for the test that is being run. Select the Offset Absorbance field and enter the user-determined offset absorbance value. Press the Save button to save the settings.

Offset Absorbance feature is only needed when ***both*** of these conditions occur:

- Monochromatic reading
- No blank well

It is a mathematical blank to correct for the differential between air and liquid with a meniscus.

To determine the user-entered value, pipette a volume of wash buffer into a well that is equal to the total volume in test wells at the read time.

For example, if the well has 100µl of Substrate Part A per 100µl of Substrate Part B, plus 50µl of stop solution, the total volume in the test wells at the read time is 250µl. Therefore read the absorbance of 250µl of colorless wash buffer to determine the correct value for the Offset Absorbance. Typical values are from .250 to .400A.

2.4.6 Lamp Saver and Lamp Warmup

After a period of inactivity, there is a lamp time-out feature that will automatically turn off the lamp. The default setting is 600 seconds (10 minutes). This can be adjusted using the Lamp Control feature located in Settings. The range is 30 to 3600 seconds.

Lamp Warmup has a default setting of 45 seconds. This can also be adjusted from the Lamp Control feature. The range is 45 to 240 seconds.

2.5 Modes of Operation

Mode	Function
Absorbance	*See Section 2.5.1* - Absorbance mode reads and prints the monochromatic or bichromatic differential absorbance at the user-selected wavelengths. Blanking is optional. Most Assays require a mode other than Absorbance Mode. In this mode, no calculations are made - only absorbance values are reported.
Factor	*See Section 2.5.2* – In Factor Mode, the endpoint absorbance readings will be multiplied by a user-entered factor to calculate a result.
Single Standard	*See Section 2.5.3* – Single Standard mode reads a calibrator, and then calculates concentrations based on a single-point standard curve passing through the point (0,0). A blank is required 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 absorbance readings to determine concentrations.
Point to Point	*See Section 2.5.4* – The plate reader accepts a number of calibrators and calculates concentrations based on the point-to-point calibration curve. The resulting calibrator curve is a series of lines connecting the calibrator points, which may be entered in ascending or descending order of absorbance. The direction of slope between the first and second calibrators determines the direction of the curve. If the direction of the curve changes direction, the curve will be flagged as being "invalid" and no interpretations will be printed. Unknown samples are calculated as follows: The unknown sample's absorbance is read and compared to the absorbance of the calibrator. An unknown Sample, with absorbance higher than the calibrator with the highest absorbance value, is calculated using a line that passes through the two Calibrator points with the highest absorbance value. An unknown Sample with absorbance lower than the lowest Calibrator absorbance is calculated from the line that passes through the two Calibrators with the lowest absorbance values.

Regression	*See Section 2.5.4*- In Regression mode, the instrument accepts a number of Calibrators and calculates concentration values based on a best-fit curve (linear regression).
Cubic Spline	See Section 2.5.4– Cubic Spline Mode accepts a minimum of 3 and a maximum of 8 calibrators and calculates concentrations based on the Cubic Spline (constrained) calibration curve. Calibrator materials of known concentrations are used to calibrate the instrument so that concentrations of unknown Samples are calculated from the generated curve. The resulting calibrator curve is a smooth curve connecting the Calibrator points, which may be entered in ascending or descending order of absorbance. A constraining algorithm is applied to prevent curve overshoot.
Cut Off	*See Section 2.5.5* – Cut Off Mode provides Cut Off Value (COV) formula options and Quality Control options.

Mode options are located under Manage Tests on the Main display screen. Select Create Test and the Test Definition screen will display; select the Mode field and the list of Mode options will display.

Each of the seven (7) modes follow the same basic pattern of options, with other variables available for selection dependent upon the mode being used**.**

SELECT MODE

Absorbance	Cancel
Factor	
Single Standard	^
Point to Point	
Regression	v
Cubic Spline	
Cut Off	Select

Available Modes

CAUTION!	
⚠	CAUTION! Verify mode selection matches with the test kit package insert or manufacturer's instructions before reporting test results! Always include normal and abnormal controls.

2.5.1 Absorbance Mode

NOTE: Every user should begin by learning to use the Absorbance Mode.

Absorbance mode will read and print sample absorbance values at user selected wavelengths. All of the other modes that follow function the same way but use the measured absorbance to calculate final results. Press Manage Tests, press Create Test, and the Test Definition window will display.

TEST DEFINITION

Name			Exit
Mode	Absorbance		
			^
	Primary Filter	405	v
	Differential Filter	630	
	Blank	NO	Edit
Print	Save	Run	

Initial Test Definition display

2.5.1.1 Filter Selection

To edit the Primary or Differential Filter wavelength fields, use the arrow keys to advance to the desired field, and then press the Edit key. The Select Filters screen will display the available filter options; make a selection and press the Select button.

SELECT FILTERS

405	Cancel
450	^
492	v
630	Select

Primary Filter display

SELECT FILTERS

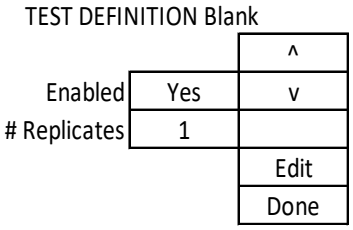
None	Cancel
405	^
450	
492	v
630	Select

Differential Filter display

If Differential Filter is set to "None", then the Offset Absorbance field is displayed.

2.5.1.2 Blank

The Test Definition Blank screen will display when the Blank field is selected. This screen allows for the Blank setting to be enabled (Yes or No); and for inputting the number of Replicates. Press the Done button when editing is completed.



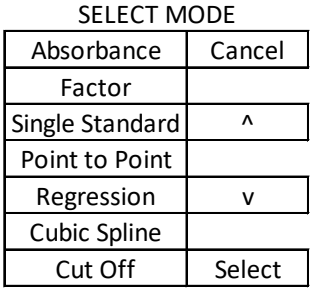
Test Definition Blank display

NOTE: All of the other modes function the same way but use the measured absorbance to calculate final results.

2.5.2 Factor Mode

Factor 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 Manage Tests and then press Create Test. A Test Definition window will display. Press the Mode field and the Select Mode screen will display. Use the arrow keys to advance through the list to the desired mode and press Select or use the stylus to highlight Factor.



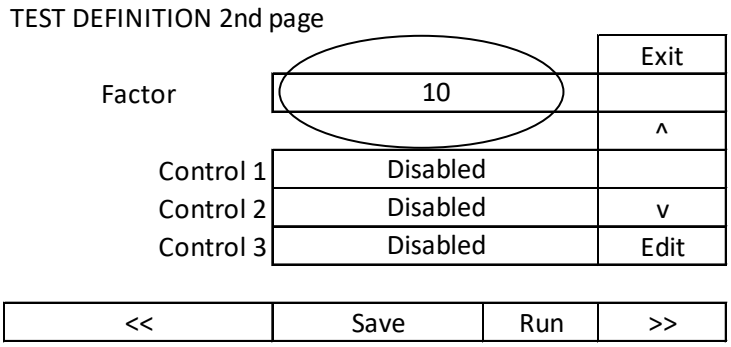
Select Mode screen

The Factor Mode Test Definition first page will display the available options: Name, Mode (Factor), Primary Filter, Differential Filter, and Blank. Enter each as done in Absorbance Mode Section 2.5.1.

Factor Mode (Continued)

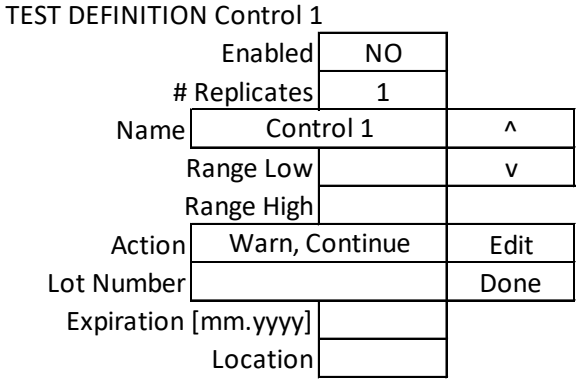
The Test Definition 2nd page will display and allow editing of Factor and Controls. Use the arrow keys to advance through the options, press the Edit key to change the values displayed on the screen.

NOTE: The Factor comes from the assay package insert or from a previous assay in the Single Standard Mode.



Factor Mode Test Definition – 2nd Page

Selecting any of the Control fields will open a Test Definition Control screen with options to enable the Control (Yes or No), input the number of Replicates, Name the Control, input a Low and a High Range, set the Action to Take (Warn, Continue or End Test), input a Lot Number, input an Expiration Date, and input a Location. Press the Done button when finished with editing fields.



Test Definition Control screen

Factor Mode (Continued)

The Factor Mode Test Definition Final Page will display and allow editing of Interpretation Mode, Units, Decimals, and number of Sample Replicates. Selecting the Units field on the Factor Mode Test Definition – Final Page will display a list of seven measurement designations including a customizable selection, which are stored for labeling the concentration column (see Section 2.4.3 Unit of Measurement Codes). Use the arrow keys to advance through the options and press the Edit key to change the values of the selections on the screen. Press Save to save the selections.

TEST DEFINITION Final page

			Exit
Interpretation Mode		Pos/Neg	
Units		Conc	^
Decimals		1	v
# Sample Replicates		1	
			Edit
<<	Save	Run	Print

Factor Mode Test Definition - Final Page

Selecting the Interpretation Mode field will open the Test Definition Interpretation screen for editing the Interpretation controls. Use the arrow keys to advance through the options, press the Edit key to change the value of the selection.

TEST DEFINITION Interpretation

Interpretation		Pos/Neg	^
	Pos >=		v
	Neg <		
	Reversed	NO	Edit
			Done

NOTE: Double check that the interpretation information you entered is correct.

Factor Mode Test Definition –Pos/Neg Interpretation

Editing the Interpretation *Pos/Neg* field will display the Interpretation *Normal* option for inputting Normal Range Low, Normal Range High, Valid Range Low, or Valid Range High.

Press the Done button when editing is completed.

TEST DEFINITION Interpretation

Interpretation	Normal	^
Normal Range Low		v
Normal Range High		
Valid Range Low		Edit
Valid Range High		Done

Factor Mode Test Definition –Normal Interpretation

2.5.3 Single Standard Mode

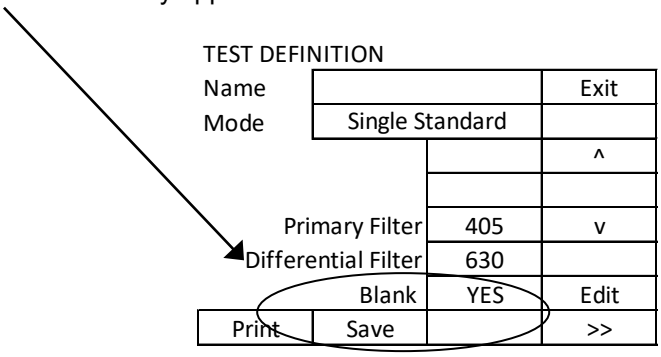
To operate in Single Standard Mode, select Manage Tests and then select Create Test. The Test Definition screen will display. Select the mode field and the Select Mode screen will display the list of modes. Use the arrow keys to scroll through the mode selections to the desired selection and press Select, or use the stylus to highlight Single Standard.

SELECT MODE

Absorbance	Cancel
Factor	
Single Standard	^
Point to Point	
Regression	v
Cubic Spline	
Cut Off	Select

Select Mode screen

The Single Standard Mode Test Definition first page will display the available options: Name, Mode (Single Standard), Primary Filter, Differential Filter, and Blank. These operate the same as in the Absorbance Mode except that the Blank is required, therefore 'YES' will automatically appear in the Blank enabled field.



Single Standard Mode Test Definition – 1st Page

The Single Standard Mode Test Definition 2nd page will display and allow editing of Standard Concentration, Controls, and number of Standard Replicates. Use the arrow keys to advance through the options and press the Edit key to change the values of the selections on the screen.

TEST DEFINITION 2nd page

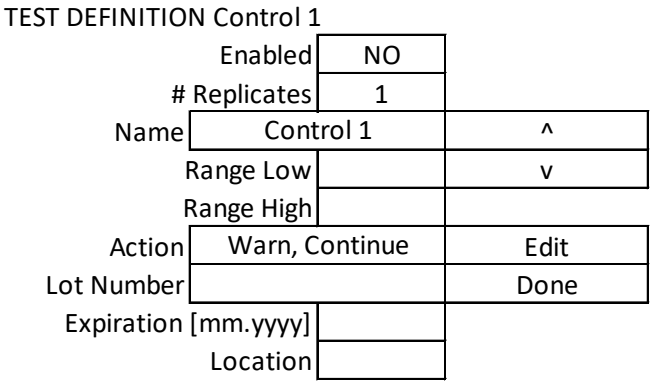
			Exit
Standard Conc	10		
# Std Replicates	1		^
Control 1	Disabled		
Control 2	Disabled		v
Control 3	Disabled		Edit
<<	Save	Run	>>

Single Standard Mode Test Definition –2nd Page

Single Standard Mode (Continued)

Selecting any of the Control fields will open a Test Definition Control screen with options to enable the Control (Yes or No), input the number of Replicates, Name the Control, input a Low and a High Range, set the Action to Take (Warn, Continue or End Test), input a Lot Number, input an Expiration Date, and input a Location. Press the Done button when finished with editing fields.

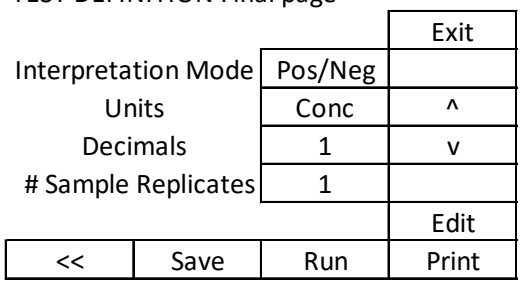
When Controls are read in duplicate, the mean of the duplicates can be calculated and that one value used, or, each Control can be required to fall within the ranges individually. The instrument will prompt 'Check Mean?' once duplicate Controls are selected.



Test Definition Control screen

When setting the Controls, if there are Replicates, the Location will be the starting location. If the Controls or their Replicates overlap due to the plate setup, an error flag will display while running the test to warn the operator.

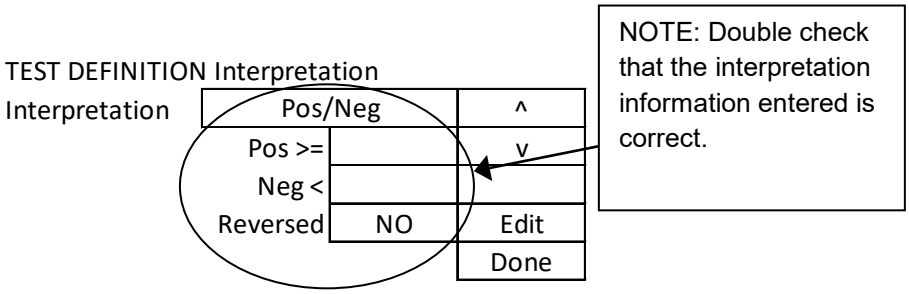
The Single Standard Mode Test Definition Final page will display and allow editing of Interpretation Mode, Units, Decimals, and number of Sample Replicates. Use the arrow keys to advance through the options; press the Edit button to change the values of the selections on the screen. Press Save to save the selections.



Single Standard Mode Test Definition - Final Page

Single Standard Mode (Continued)

Selecting the Interpretation Mode field will open the Test Definition Interpretation screen for editing Interpretation controls. Use the arrow keys to advance through the options, press the Edit key to change the value of the selection. Press the Done button when editing is complete.



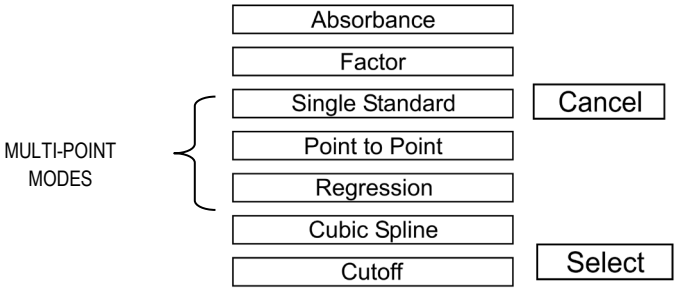
Single Standard Mode Test Definition - Interpretation

2.5.4 Multi-Point Modes (Point to Point, Regression and Cubic Spline)

The *Stat Fax® 4200* offers three varieties of multi-point modes: Point-to-Point, Regression and Cubic Spline.

In Point to Point and Cubic Spline modes, the standard concentrations must be read in either increasing or decreasing order.

All of the Test Definition screens, use of Controls, and items related to Interpretations work the same for each type of multi-point. Use the arrow keys to scroll through the mode selections to the desired selection and press Select or use the stylus to highlight selections.



Select Mode screen

Multi-Point Modes (Point to Point, Regression and Cubic Spline) (Continued)

The Test Definition first page displays the available options.

TEST DEFINITION

Name			Exit
Mode	Point to Point		
			^
	Primary Filter	405	v
	Differential Filter	630	
	Blank	NO	Edit
	Offset Absorbance	0.000	
Print	Save	Run	

Test Definition – 1st page with Offset Absorbance field displayed

If Differential Filter is set to "None", then the Offset Absorbance field is displayed

The Test Definition 2nd page includes use of % Absorbance, number of Standards, number of Standard replicates, selection of Axes, and the use of Controls.

Note: Point-to-Point and Regression require at least two Standards, Cubic Spline mode requires at least three.

TEST DEFINITION 2nd page

	% Absorbance	NO	Exit
	Standards	5	
	# Std Replicates	1	^
Axes	Y=Abs X=Conc		
	Control 1	Disabled	v
	Control 2	Disabled	
	Control 3	Disabled	Edit

<<	Save	Run	>>

Test Definition –2nd Page

2.5.4.1 - % Absorbance

The % Absorbance option is used with multipoint uptake assays.

% Absorbance assigns a value of 100% to the first Standard, which must be entered from darkest to lightest.

An additional calculation (%A/A0) 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.

The %Abs value is displayed in the Interpretation field of the report. This mode does not support ln, logit or log scales for the absorbance axis. Upon recall of a % Absorbance mode test, the user will be asked whether to reread the highest value Standard.

Select the Standards field and the Standards Test Definition screen will open.

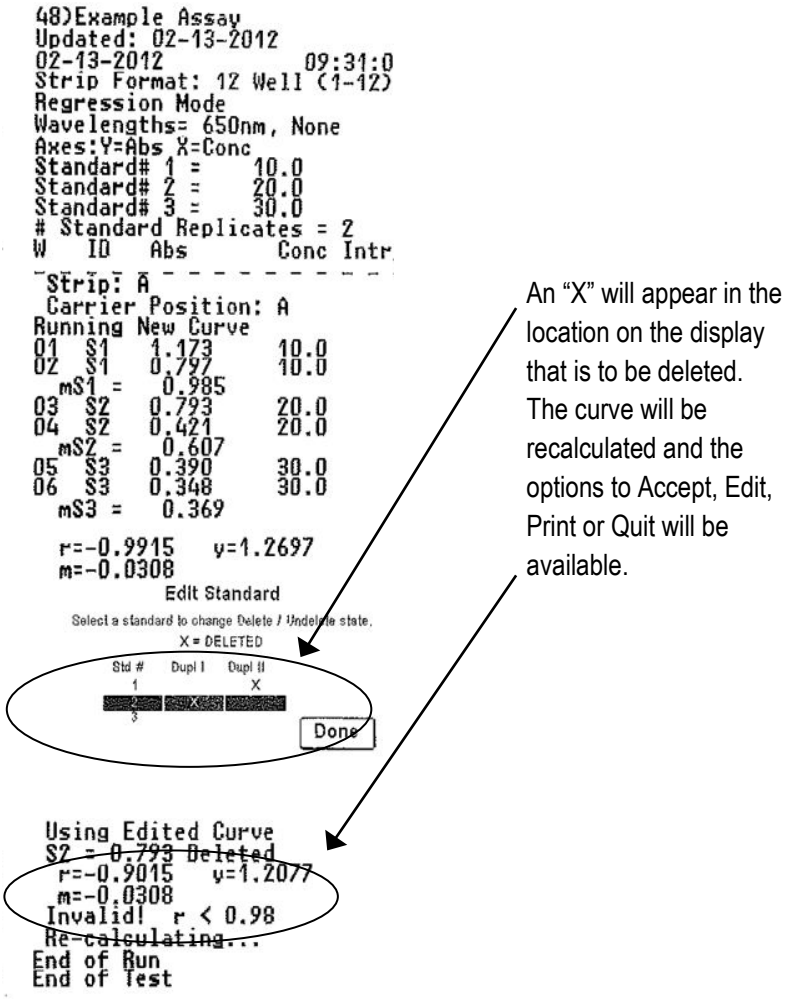
Standards		Exit
Number of Standards	3	^
Std1 Concentration	10.0	v
Std2 Concentration	20.0	
Std3 Concentration	30.0	Edit
		Done

Standards Test Definition screen

2.5.4.2 – Editing a Curve

When Duplicate Standards are used, the curve may be edited by deleting one of any pair of standards. For Point to Point and Regression Modes, the minimum is two; for Cubic Spline Mode, the minimum is three.

Once the curve has been read, select the 'Edit' option before the 'Accept' or 'Print' options. Using the stylus, select the duplicate standard to be deleted**.**



Example of editing a curve with Duplicate Standards

As shown in the example below, Duplicate Standards are labeled as 'Dupl I' and 'Dupl II'.

2.5.4.3 – Select Axes

Axes selections include linear-linear, ln (= natural log)-linear, linear-ln, or ln-ln calculations. A logit-log calculation is also available. Absorbance, or *ln* of (1000 * absorbance), is always on the "Y" axis. Concentration, or *ln* of concentration, is always on the "X" axis.

SELECT AXES

Y=Abs X=Conc	Cancel
Y=Ln(1000*Abs) X=Conc	^
Y=Abs X=Ln(Conc)	v
Y=Ln(1000*Abs) X=Ln(Conc)	Select
Y=Logit(Abs) X=Log(Conc)	

Calculation	Explanation
"Y= ABS, X=CONC"	Both the absorbance data (y) and the concentration data (x) are linear.
"Y=Ln (1000*ABS), X=Conc"	The natural log of the absorbance is plotted against the concentration. The absorbance values are multiplied by 1000 before taking the logs.
"Y=ABS, X=Ln(Conc)"	Absorbance is plotted against the natural log of the concentration.
"Y= Ln (1000*ABS), X=Ln(Conc)"	The natural log of the absorbance is plotted against the natural log of the concentration.
"Y= Logit(Abs), X= Log(Conc)"	Select to calculate unknowns using the equation: Abs Logit = Ln [(sample/0 cal) / 1-(sample/0 cal)]

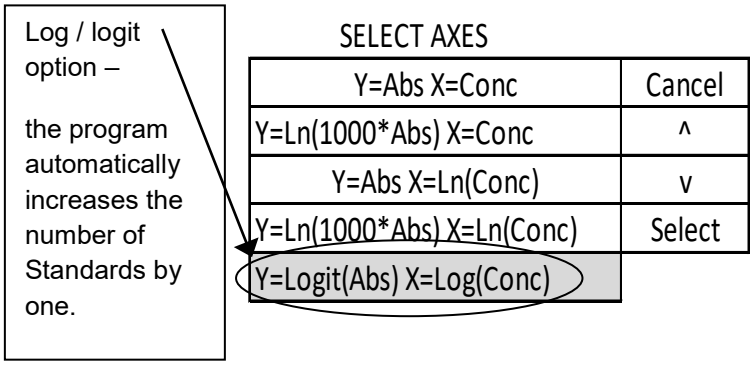
Refer carefully to the Reagent Kit product insert for correct selection.

NOTE: Remember log of 0 is undefined so do not set concentration to 0 (zero) on a logarithmic scale.

Point-to-Point and Regression modes require at least two standards, Cubic Spline requires at least three standards.

Select Axes (Continued)

The Log / Logit option is available under the Point to Point Mode, Regression Mode, and the Cubic Spline Mode. Concentrations must be greater than zero in this axes mode. The program automatically increases the number of Standards by one.



When using a non-linear axis:

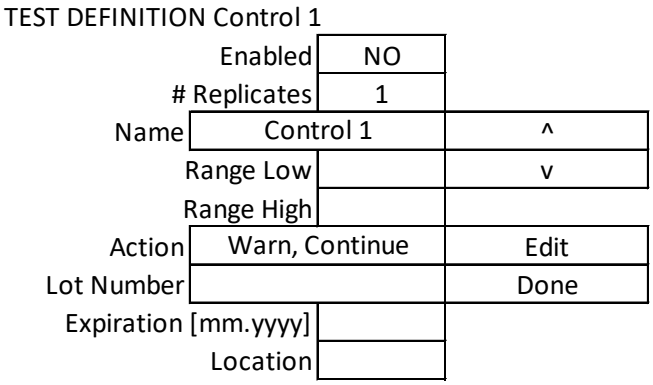
If absorbance of a Sample is > than the highest calibrator's absorbance, " ****** " is reported for the Concentration

- Standards must be read in descending absorbance order
- If no Standard programmed has a 0.0 concentration assigned to it, an additional Standard is forced, and the concentration for that Standard is replaced with a series of stars [****]

2.5.4.4 – Controls

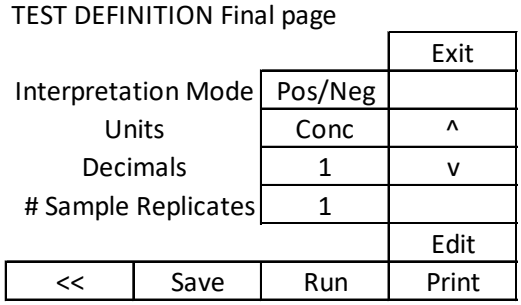
Selecting any of the Control fields will open a Test Definition Control screen with options to enable the Control (Yes or No), input the number of Replicates, Name the Control, input a Low and a High Range, set the Action to Take (Warn, Continue or End Test), input a Lot Number, and input an Expiration Date. Press the Done button when finished with editing fields.

When Controls are read in duplicate, the mean of the duplicates can be calculated and that one value used, or, each Control can be required to fall within the ranges individually. The instrument will prompt 'Check Mean?' once duplicate Controls are selected.



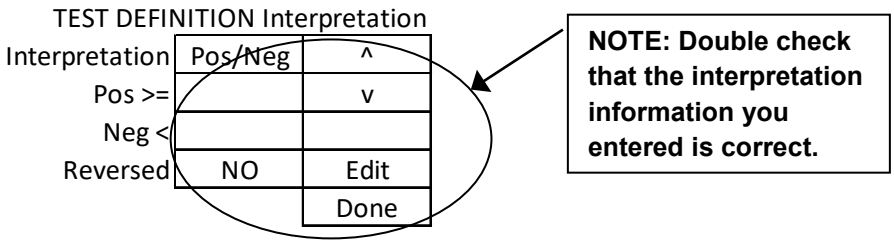
Test Definition Control screen

The Test Definition Final page will display Interpretation Mode, Units, Decimals, and number of Sample Replicates.



Test Definition – Final Page

Selecting the Interpretation Mode field will open the Test Definition Interpretation screen for editing the Interpretation controls**.**



Test Definition –Pos/Neg Interpretation

Editing the Interpretation *Pos/Neg* field will display the Interpretation *Normal* option for inputting Normal Range Low, Normal Range High, Valid Range Low, or Valid Range High.

Press the Done button when editing is completed.

TEST DEFINITION Interpretation

Interpretation	Normal	^
Normal Range Low		v
Normal Range High		
Valid Range Low		Edit
Valid Range High		Done

Test Definition –Normal Interpretation

2.5.5 Cut Off Mode

Many qualitative assays interpret results based on a pre-determined, or cut off, absorbance such that a sample absorbance greater than the cut off absorbance is interpreted as positive (or negative) and samples with absorbance less than the cut off be interpreted as negative (or positive). Companies that manufacture these assays use a variety of means of obtaining (reading or calculating) the essential cut off point. Stat Fax® 4200 employs a universal equation that can be adapted to fit most commercially available kits by inserting user-entered factors 'X' and/or 'Y' as well as a coefficient 'F'. The equation is (X)(mNC) + (Y)(mPC)+F = COV (Cut Off Value).

In the Cut Off 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 is added to 'F' to arrive at the Cut Off Value (COV). The 'X', 'Y' and 'F' factors can be positive or negative numbers, one or zero, or decimals such as 0.5 to fit the test requirements provided in the Kit package insert or as instructed by the Kit manufacturer. In this mode be careful to enter all QC parameters completely and correctly. They are usually provided as Absorbance limits.

To operate in Cut Off Mode, select Manage Tests and then select Create Test. The Test Definition screen will display. Select the Mode field and the Select Mode screen will display the list of modes. Use the arrow keys to scroll through the mode selections to the desired selection and press Select or use the stylus to highlight Cut Off.

SELECT MODE

Absorbance	Cancel
Factor	
Single Standard	^
Point to Point	
Regression	v
Cubic Spline	
Cut Off	Select

Cut Off Mode (Continued)

The Cut Off Mode Test Definition first page displays the available options: Name, Mode (Cut Off), Primary Filter, Differential Filter, and Blank. Enter wavelength and blank as shown in Section 2.5.1 Absorbance Mode.

TEST DEFINITION

Name			Exit
Mode	Cut Off		
			^
	Primary Filter	405	v
	Differential Filter	630	
	Blank	NO	Edit
Print	Save		>>

Sample of Cut Off Mode Test Definition 1st page

The Test Definition Cutoff 2nd page allows editing of Cut Off Value (COV), values of X, Y, and F; Negative Control; Positive Control; and QC Criteria.

TEST DEFINITION Cutoff

COV=	X*mNC+Y*mPC+F		Exit
	X=	1	
	Y=	1	^
	F=	0	v
	Neg Ctrl	Enabled	
	Pos Ctrl	Enabled	Edit

QC Criteria	COV, mNC, mPC		
<<	Save	Run	>>

Sample of Cut Off Mode Test Definition 2nd page

Cut Off Mode (Continued)

Selecting any of the Control fields will open a Test Definition Control screen with options to enable the Control (Yes or No), input the number of Replicates (1 to 5), Name the Control, input a Low and a High Range, set the Action to Take (Warn, Continue or End Test), input a Lot Number, input an Expiration Date, and input a Location. Press the Done button when finished editing fields.

TEST DEFINITION Neg Ctrl

Enabled	YES	
# Replicates	1	
Name	Neg Ctrl	^
Range Low	0.200	v
Range High	0.400	
Action	End Test	Edit
Lot Number	1222	Done
Expiration [mm.yyyy]	12.2013	

Test Definition Control Screen

When Cutoff Controls are read in multiples, the mean of the replicates can be calculated and that value used, or each Control can be required to fall within the ranges set. "Check Mean" will display once replicate Controls are selected.

```
12)anti HSV
Modified: 06-12-2013                Current: 06-12-2013  13:25:24
Plate Format Set: 12 Way
Cut Off Mode
Wavelengths= 405, 630nm
COV =  1.000 * mNC +  1.000 * mPC +  0.500
 Interpretation Criteria
Positive >=   1.000*COV, Negative <   1.000*COV
Use Control: Neg Ctrl (NC)      # Replicates = 3
 Range Check: Mean
 Lot Number: 06122013
 Expiration: 06.2014
Use Control: Pos Ctrl (PC)      # Replicates = 2
 Range Check: Mean
Plt Well Sample ID    Abs          Abs/COV   Interp          Index
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -
COV =  1.967
  1 A-01 Neg Ctrl    0.411                  NEG
  1 A-02 Neg Ctrl    0.159                  NEG
  1 A-03 Neg Ctrl    0.826 0.4657
  1 A-04 Pos Ctrl    1.145
  1 A-05 Pos Ctrl    0.857 1.0011
  1 A-06 1           0.854          0.434   NEG             0.434
  1 A-07 2           0.603          0.307   NEG             0.307
  1 A-08 3           0.320          0.162   NEG             0.162
  1 A-09 4           0.672          0.341   NEG             0.341
  1 A-10 5           0.281          0.143   NEG             0.143
  1 A-11 6           0.622          0.316   NEG             0.316
  1 A-12 7           0.713          0.362   NEG             0.362
End of Run
```

mean

Example - Cut Off Mode output showing mean

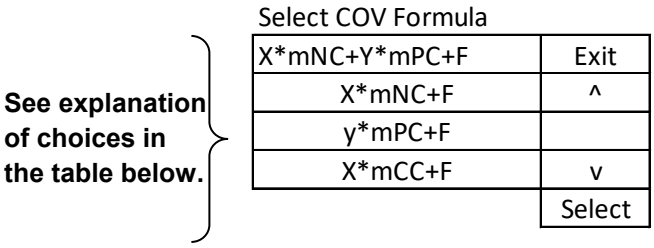
Cut Off Mode (Continued)

Set the Controls by selecting the appropriate control field.

Note: When setting the Controls, if there are Replicates, the Location will be the starting location. If the Controls or their Replicates overlap due to the plate setup, an error flag will display while running the test to warn the operator. (Reference Section 2.4.2.1)

Selecting the 'COV =' field will open the Select COV Formula screen. In addition to the universal equation, Stat Fax® 4200 offers three more optional formulas.

Where COV is the Cutoff Absorbance Value, mNC is the mean of the Negative Controls; mPC is the mean of the Positive Controls. X, Y, and F are user-entered coefficients that can have any positive or negative numerical value including zero and 1.



Highlight the desired formula from the list and press the Select button.

COV Formula options

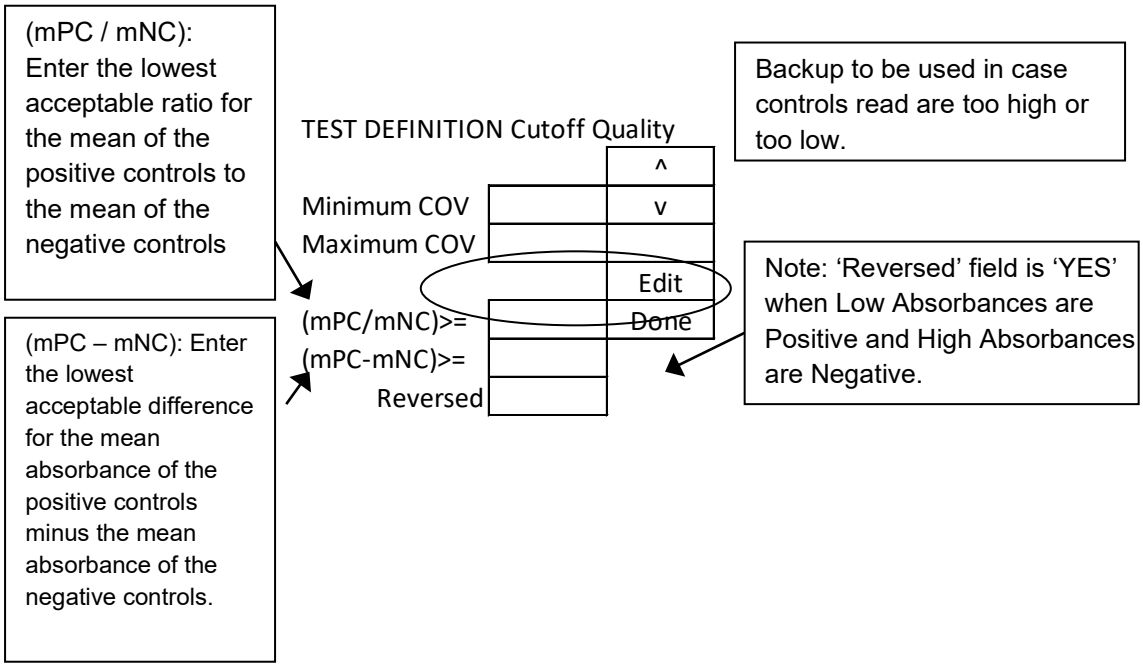
COV Formula	Explanation
X*mean(NC) + Y*mean(PC) + F	Universal equation, used to calculate the cutoff value based upon readings or positive and/or negative controls. • In this equation, NC and PC are used to determine the COV (cutoff value). • Enter the variables provided in the package insert. The software calculates the mean of the positives and the mean of the negatives.
X * mean(NC) + F	• Use this equation if only a negative control is used to determine the COV.

Cut Off Mode (Continued)

COV Formula	Explanation
Y * mean(PC) +F	• Use this equation if only a positive control is used to determine the COV. • For interpretation, you may choose either the Regular Cut Off Mode (positive >= cutoff, negative < cutoff), or the Reverse Cut Off Mode. With the Reverse Cut Off option, the Samples with values lower than the cut off are labeled as “positive”. If you choose this option, be careful to follow the < and > signs in the prompts for entering cut offs and ranges.
X*mean(CC) + F	• COV = cut off value for positive or negative interpretation • X = a variable provided in the Assay Kit package insert. NOTE: X will equal 1 if no value of variable provided. • mCC = the calculated mean of the absorbance values of the cutoff controls when test is run • Blanking is optional, dependent upon the Assay Kit • F = factor added to the mCC. If needed, this value is provided in the Assay Kit package insert. If none provided, use zero for the value of F. • Positive and/or negative controls may be used for QC criteria.

Cut Off Mode (Continued)

Selecting the QC Criteria field opens the Test Definition Cutoff Quality screen:



Quality Criteria screen

The Blank is *not* subtracted in the Reverse Cutoff option. Pay close attention to "<" less than and ">" greater than symbols when entering control limits in this case.

The Cut Off Mode Test Definition final page displays Interpretation Mode, Units, Decimals, and number of Sample Replicates.

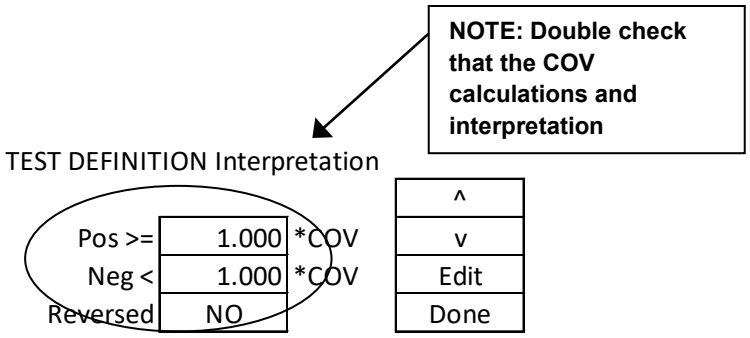
TEST DEFINITION Final page

			Exit
Interpretation Mode		Pos/Neg	
Units		Abs/COV	^
Decimals		3	v
# Sample Replicates		1	
			Edit
<<	Save	Run	Print

Cut Off Mode Test Definition - Final page

Cut Off Mode (Continued)

By selecting Pos/Neg, Positive and Negative Interpretations can be entered. It is not necessary to enter both Positive and Negative. These can also be set to be evaluated in the reverse, where Positive is LESS than or equal to (<=) the value entered.



Cut Off Mode Test Definition – Interpretation

Press the Done button when finished editing.

3. Cleaning and Maintenance

3.1 Cleaning

3.1.1 Exterior

CAUTION: Solvents such as acetone or thinner will damage the instrument! Use only water and recommended cleaners! Avoid abrasive cleaners. The display area 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 (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 any liquid into the read well.

3.2 Maintenance

3.2.1 Calibration and Linearity

Each instrument is calibrated during manufacturing using standards that are traceable to the National Institute for Standards and Testing (NIST), and is tested to verify its linearity to 3A. This preset calibration is very stable. Absolute calibration can be verified with the use of NIST filters, or by periodic comparison to a reference instrument that is known to be calibrated to NIST filters.

Absolute calibration can be verified using a specifically designed product called DRI-DYE® Check Strips, available from your instrument supplier.

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.

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.

Calibration and Linearity (Continued)

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 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.

3.2.2 Storage

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

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

Store the instrument using original packaging if possible.

Perform the following steps before storing:	
✓	Set the power switch to OFF and remove the power cord.
✓	Place the instrument in the original packaging material.
✓	When returning the instrument to service from storage, it is recommended that functional tests be performed as if setting up the instrument for the first time.

4. Troubleshooting

4.1 Messages and Flags

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

Flags are displayed, for example, when an invalid range is entered. They are intended to help the user correct the problem. Some error messages appear as dialog boxes that require action in order to clear; others appear on the display screen and appear on the printout.

Message/Flag	Explanation
>10**6”	Appears in Concentration Column when Concentration is greater than 10**6
“******”	1. A sample has exceeded the absorbance of the reference well in a log-logit test. Curve Axes is Y=Logit(Abs), X=Log(Conc) and Absorbance >reference(zero) absorbance value. 2. Will print if a curve with a log axis tries to log a zero, a negative number, or an invalid curve has been read. 3. Prints in Concentration column whenever an error occurs while calculating the concentration.
“>3”	Prints in ABS column if a read absorbance is greater than the maximum readable absorbance for the device.
“%Absorbance Mode should not be used with negative absorbances!”	This message will display if the user is in %Absorbance Mode and a standard is read which has a negative absorbance.
“Assay Cannot Be Edited!”	User has tried to edit an OEM preprogrammed test that has flag set to prevent it from being edited.
“Cannot match test wavelength with filters currently installed on device!”	Pop up message that appears when running a test; occurs if the device cannot find filters for the wavelengths set in the test definition.
“Do not select the same filter for primary and differential”	Appears on Page 1 of Test Definition when the same wavelengths are entered for the Primary and the Differential filters.

Messages and Flags (continued)

Message/Flag	Explanation
“EQUIV”	This is reported when a Sample is less than the POS cutoff and greater than the NEG cutoff concentration. (If it is reversed, then the sample is > value POS cutoff and < value NEG cutoff.)
“Factory Settings Restored” OR “User Settings Restored “	One of these messages can be triggered when the operator chooses to restore parameters or could be seen at startup if the unit is forced to recover from bad settings.
“Invalid Curve!”	This message indicates that readings for standards cannot be used to obtain a valid curve for the calculation mode being used. If duplicate standards are used, the user has the option to edit the curve if there are enough points (minimum 3 for Point-to-Point and Regression; minimum 4 for Cubic Spline).
“Invalid Curve – Log Error”	An error in the creation of a curve or readings of a negative absorbance will result in this message, followed by Test Ended.
”log(<=0)”	Prints in Interpretation column whenever a curve axis mode with a log tries to log a zero or negative number.
“LOW”, “HIGH”	Prints in Interpretation column whenever a value is lower or higher than the range of values entered to create the test.
“NEG”	Negative – prints if a Sample is <NEG value (or if reversed, sample is >NEG value).
“OUT”	Blank is outside min/max range or sample is outside low/high valid range values. Also appears in Cubic Spline mode when the sample is outside of the range of valid standards.
“POS”	Sample is >= POS value (or if reversed, sample is <=POS value.

Messages and Flags (continued)

Message/Flag	Explanation
“Pos must be greater than or equal to Neg!”	This message appears during test definition when the user is defining positive/negative interpretations. A value was entered for both the positive and negative, but the positive value is less than the negative value entered.
“Range Error”	This indicates there is a limit to the range of numbers that can be entered
“>Ref”	Prints when a sample exceeds the absorbance of the reference well in a log-logit test.. This is usually due to the calibrator concentrations being entered incorrectly or the calibrators being pipetted into the strip incorrectly. The first, or "Zero" calibrator must have the highest absorbance (darker) and the remaining calibrators must be of descending absorbance and increasing concentration.
Test Data Corrupted! OR Test Definition Corrupted!	Test (assay) Data (including calibration data) does not match what was stored. OR Test Definition does not match the data stored. Once a test shows that it is corrupted, there is no way to edit the test. It must be reprogrammed.
“Unable to assign control!”	This message refers to control location in the test definition. If there are Replicates, then the location will be the starting location. If the Controls or their Replicates overlap due to user error (plate setup - direction or side by side duplicates can affect this) the user is warned and the test is ended.
“When reversed, Pos must be less than Neg!”“POS”	Pop up message that appears during test definition when the user is defining Positive/Negative interpretations; a value was entered for both the positive and negative and the reverse was selected, but the positive value is greater than the negative value entered. Sample is >= POS value (or if reversed, sample is <=POS value.
“Wrong date format (mm.yyyy)!”	This message indicates the expiration date for a control is not entered in the correct format

4.2 Error Messages

Error Messages are displayed when the instrument fails to operate correctly. They are intended to help the user locate the problem. Some error messages require action in order to clear. Most require help from technical support.

Error Message	Explanation
Error 102	Open the Utility menu and select Print Unit Settings. Provide this information to Technical Support.
Error 109 “Air Values Too Dark”	Although anything that blocks the path of the light to the photometer can cause this, a burned out lamp is usually the cause.
“201, Read/Plate: Aborted, Plate Movement Error”	If an error occurs during plate movement or during running a test, message will display and terminate the test. Contact Technical Support for assistance.
"i2c Bus error, 0x%02x. Unit may need service. Try power-off, wait, power-on"	If restarting the instrument does not clear this message, contact technical support.
“Calibration Checksum Faulty”	Contact Technical Support
“Check unit Calibration” Or “Check Calibration”	Go to the "Utilities" menu Run "Recall Calibration" Message will be posted “Reload Factory Settings?”. Select YES. “Factory Settings Restored” will be printed. Select “done to return to the main menu” Turn the instrument off, then back on and read a plate to see the message has been eliminated If the message still appears, contact Technical Support.
“Default Settings Loaded”	Indicates a problem was encountered and the instrument’s settings have been returned to the same status as when instrument was shipped from the factory.
“Error Saving Assay Data!”	This indicates the instrument is not able to store assay information into memory. If less than 120 assays have already been stored, contact technical support.
“Factory Data Not Saved”	Contact Technical Support
Factory Settings Invalid OR User Settings Invalid	Contact Technical Support

Error Messages (continued)

Error Message	Description
FTDI initialization error ========== Hardware Init Error (#10)	This message will be seen if the FTDI startup initialization fails, tries again, but then fails a second time. ========== If the FTDI initialization fails again, the user will see this message. If turning the instrument off and then back on does not resolve the error, there is a Troubleshooting button which requires contacting Technical Support for a passcode.
Updating internal firmware	If the system finds an older version of FTDI firmware, this message will be displayed and the update will happen automatically. Do not turn off the unit until the update is complete

5. References

1. Engineering data supplied by Awareness Technology, Inc. Palm City, Florida (1987 to current date)
2. Data on DRI-DYE® Check Strips, provided by Awareness Technology, Inc. Palm City, Florida (1989 to current date)

6. Optional Accessories

6.1 Thermal Printer Paper

Reorder replacement Thermal Printer Paper Roll P/N 15003. NOTE: The printer manufacturer strongly recommends the use of thermal paper part number 150003 to ensure the best print quality and the effective operation of the print head. Contact your dealer for replacement rolls**.**

6.2 Dri-Dye® Check Strips

- ***Dri-Dye® Check Strips*** offer an easy method 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 pre-dispensed 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 path-length, and therefore, to absorbance. If a well is reconstituted with too much water, the decrease in concentration will be corrected by the increase in path-length. Simply stated, the system is self-correcting for random pipetting errors up to 10%.

- ***DRI- DYE® Check Strips*** can be ordered from your dealer.

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

7. Information

In the unlikely event that a problem occurs with the instrument, please contact your instrument supplier.

Factory Information:

Telephone: USA 772-283-6540

Fax: USA 772-283-8020

E-mail: support@awaretech.com

Mailing Address:

Awareness Technology, Inc.

1935 SW Martin Highway

Palm City FL 34990 USA

EC REP EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands

IVD CE

Important: When contacting us, please have the Model and Serial Number of the *Stat Fax® 4200* in question. Have a description of the problem with as much detail as possible. Save any relevant jobs or logs and send or e-mail us the information.

Model:_____

Serial Number:_____

	WARNING: Instruments to be returned must be accompanied by a decontamination certificate completed by the responsible laboratory manager. If a decontamination certificate is not supplied, the returning laboratory will be responsible for charges resulting from non-acceptance of the instrument by the servicing center or from any authority's intervention.

8. Appendix A SF_Capture

SF_Capture is a software program for use with this reader. Contact your dealer for a copy of the program. To install drivers, refer to Section 2.3.2.1 External Output.

Install the program by double clicking on the setup.exe file found in the SF_Capture folder. The installation process is the same as other software – follow the prompts until it is done.

Power on the instrument, connect the serial port to USB cable from the reader to the PC. Verify that External Export has been switched to ON from the instrument's Settings menu

> NOTE: An installation of drivers will need to be done the first time SF_Capture is installed on a PC.

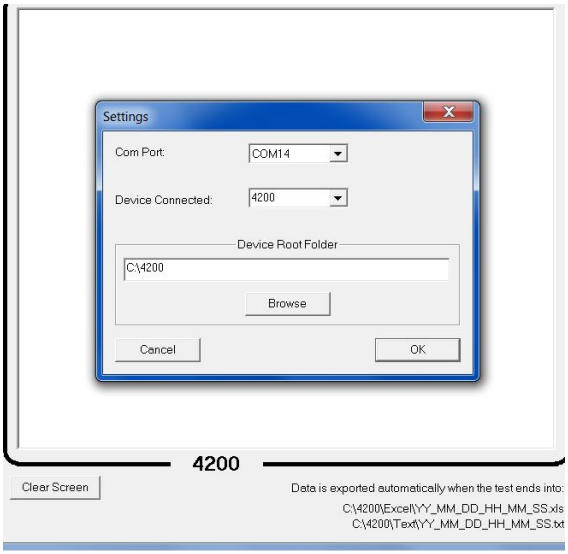
Once the cable connection is made between the reader and the PC, Windows® will pop up a message box stating that the VNC1-A As Slave is not installed and that drivers will need to be found.

Correct response is to let Windows® look for the appropriate driver this one time.

First, it will search for and install USB Serial Converter driver(s).

The cables can be connected and the instrument's power up can be done in any sequence. If the instrument is OFF, but SF_Capture is open and the cable is connected to the instrument, select ReConnect.

Select Settings. This will open a dialog box where you select the instrument type and the COM port connected to on the PC side



Data is exported to Excel, to Notepad and to a Log file each time QUIT/Test Ended occurs.

The default location for these files is C:\4200. This can be changed from the default by using the Browse option for the Device Root Folder.

9. Appendix B Updating Firmware

To update firmware, follow the instructions below. Contact your dealer or technical support if you have any questions.

1. Erase/delete anything that is on the USB pen drive (or any USB drive used).
2. Unzip the attached file and install the folder romimage.42x on the USB drive.
3. Turn off the reader and insert the USB drive with only the one romimage.42x folder on it into the port.
4. Place a finger on the display and then power up the reader.
5. After the instrument begins to beep you can remove your finger from the screen.
6. The update process will take about 3-5 minutes, depending upon the instrument's bootloader version. To determine the version installed, go to Utilities – Show Version Details.

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10. Appendix C Touchpad Alignment

The 'TouchPad Align' feature is enabled via pass code from your Administrator. This feature provides the ability to adjust the touchpad ranges by using the stylus or the mouse.

Selection of each of the eight squares should produce numbers on the display. If an area outside of the acceptable range is pressed with the stylus or mouse, a sound will be produced. Each of the pairs (top, left, bottom and right) must have a difference between them of not more than 3 points, such as on the left, 17 and 20 are good, whereas 17 and 24 are not. The SAVE button will not appear until acceptable points have been selected. It is necessary to select SAVE in order to store the new values.