

# **MegaQuant™ Wave**

CHEMISTRY ANALYZER

## **OPERATOR'S MANUAL**





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# 1. Introduction

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## 1.1 Applications

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### 1.1.1 Intended Use

The **MegaQuant Wave** is a laboratory instrument intended for in-vitro diagnostic use. It is a compact, microprocessor-controlled, bichromatic photometer system with six filters (eight optional) and 37°C incubation. The standard diameter for the round tubes used with the instrument is 12mm. The instrument can be used to measure absorbance or concentrations based on standard points or rates of change, as described in this manual. This general purpose instrument is intended to be used by trained laboratory professionals capable of selecting the appropriate features and options for each specific clinical application.

### 1.1.2 Summary of the Instrument

The **MegaQuant Wave** is a compact, standalone instrument. Its streamlined design offers touch screen interface, superb optics, on-board curve-fitting software, and a built-in printer to meet the requirements of modern laboratories.

This instrument is designed for the processing of biochemistries, tube method immuno assays, and drug assays from human serum, plasma, or urine. The instrument can be run using the supplied flowcell, and also accepts standard 12 mm round tubes. The primary function of the instrument is to read and calculate the results of both endpoint and kinetic colorimetric assays. Any test procedure that calls for absorbance reading at or near one of the available wavelengths can be performed with this instrument. Additionally, the most commonly applied data reduction formulae are pre-programmed to further facilitate laboratory testing. These programs include rate calculation and single and multipoint standardization. Through the touch screen display, the instrument prompts the operator to read the tubes in the appropriate sequence. It then performs the necessary calculations and prints out test results.

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

Each mode of operation is self-prompting, to reduce error and simplify operation. In all modes the instrument will reference air, request and read the blank tube, and then read and print automatically whenever a tube is inserted. All modes may be read kinetically.

This instrument includes non-volatile memory, a feature that allows test parameters and standard curves to be stored for rapid future recall.

The instrument also contains a 37°C incubation block with 12 stations. The incubator will accommodate 12 mm diameter round test tubes (size may be specified at time of purchase). A similar self-monitoring incubation system is built into the read well for temperature controlled absorbance reading at 37°C this is often essential to the precision of rate determinations.

The instrument offers quick, accurate, reproducible results; maintenance-free, easy operation; versatility, and economy. The durable design of the instrument includes many features to minimize operator error, such as stable factory calibration, automatic zeroing, complete operator prompting, detailed labeling, pre-programmed calculations, visual and audible feedback, and error messages.

User-friendly features such as an internal printer and a touch screen display. The timed lamp saver feature further assures the continuous reliability of the instrument (see Settings section for more information on Lamp Control).

### 1.1.3 Principles of Operation

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

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## 1.2 Warning Markings Inscriptions d'avertissement

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### 1.2.1 Safety Symbols Le Symboles de Sûreté

Safety symbols which may appear on the product:  
*Les symboles de sûreté peuvent apparaître sur le produit.*

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

### 1.2.2 Safety Terms Terminologie de Sûreté

<p><i>These terms may appear on the product :</i>  <i>Les marques sur le produit</i></p> <p><i>These terms may appear in this manual</i>  <i>Les marques dans l'opérateur manuel</i></p>	
<p>DANGER</p> <p><i>DANGER Le "de marque: DANGER"</i></p>	<p>Indicates an injury immediately accessible as you read this marking</p> <p><i>Indique le risque immédiat de dommages (accessible tandis que vous lisez la marque)</i></p>
<p>WARNING</p> <p><i>AVERTISSEMENT! Le "de marque: WARNING"</i></p>	<p>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.</p> <p><i>Ces rapports identifient les conditions ou les pratiques qui pourraient avoir comme conséquence les dommages ou les pertes humaines.</i></p>
<p>CAUTION</p> <p><i>L'ATTENTION "Le de marque: CAUTION"</i></p>	<p>CAUTION statements identify conditions or practices that could result in damage to this product or other property.</p> <p><i>Ces rapports identifient les conditions ou les pratiques qui pourraient avoir comme conséquence les dommages a ce produit ou a toute autre propriété.</i></p>
<p>BIOHAZARD</p>	<p>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.</p>
<div style="display: flex; justify-content: space-between; align-items: center;">  <h2 style="margin: 0;">CAUTION! L'ATTENTION!</h2>  </div>	
	<p><b>WARNING:</b> 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.</p> <p><i>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 approprié nettoient et des méthodes de disposition.</i></p>

### 1.3 Safety Precautions

<b><i>To assure operator safety and prolong the life of your instrument, carefully follow all instructions outlined below.</i></b>	
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. <b>WARNING:</b> Always wear protective apparel and eye protection while using this instrument.
Follow Operating Instructions	<b>WARNING:</b> Do not use this instrument in a manner not specified by the manual, or the protection provided by the instrument may be impaired.
Use Proper Power Cord	<b>WARNING:</b> Use only the power cord specified for this product and certified for the country of use.
Observe All Terminal Ratings	<b>WARNING:</b> To avoid fire or shock hazard, observe all ratings and markings on the instrument. Consult this manual for further ratings information before making connections to the instrument.
Install as Directed	The instrument should be installed on a sturdy, level surface capable of safely supporting the instrument's weight 10 lbs (4.5 kg). 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 and 10cm on top.
Do Not Operate Without Protective Covers	<b>WARNING:</b> Do not operate this instrument with covers and panels removed.
Avoid Exposed Circuitry	<b>WARNING:</b> Do not touch exposed connections and components when power is present.
Do Not Operate In An Explosive Atmosphere	<b>WARNING:</b> Do not operate instrument in an explosive atmosphere.
Do Not Operate With Suspected Failures	<b>WARNING:</b> If you suspect there is damage to this instrument, have it inspected by a qualified service person.
Do Not Operate in Wet/Damp Conditions	<b>WARNING:</b> Do not operate instrument in wet/damp conditions.
Keep Instrument Surfaces Clean and Dry	<p><b>CAUTION:</b> Solvents such as acetone or paint thinner will damage the instrument.</p> <ul style="list-style-type: none"> <li>• Do not use solvents to clean the unit. Avoid abrasive cleaners; the display overlay is liquid-resistant, but easily scratched.</li> <li>• 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.</li> <li>• Use as a disinfectant a 10% solution of chlorine bleach (5.25% Sodium Hypochlorite) or 70% isopropyl alcohol.</li> <li>• Take special care not to spill liquid inside the instrument.</li> </ul>
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.

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## 1.4 Technical Specifications

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Linear Measurement Range: ..... 0.00 to 3.0 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/bichromatic

Light Source: ..... Tungsten-Halogen lamp with lamp saver feature

Standard Wavelengths: ..... 340, 405, 505, 545, 580, and 630nm alternate filters available from 340 to 700nm; an eight position filter wheel is optional

Filter Type: ..... IAD hardcoat interference, 10nm half bandpass

Tube Size: ..... 12mm round is standard

Minimum Sample Volume: ..... 1mL for 12mm round tube  
250uL for flowcell

### Electronic

Display: ..... Interactive capacitive touch screen 3.5" LCD, color graphic display

Printer: ..... Thermal with graphic capability

Power Requirements: ..... 100V - 240V AC, 1.2A MAX, (universal input, auto sensing)

Microprocessor: ..... 50MHz eZ80, 64K EEPROM

Memory: ..... 2 MB Flash Memory, 1 MB static RAM Memory

Interface: ..... USB mouse; USB port used for thumb drive interface for firmware updates (mouse not included; thumb drive not included). ); USB port B for connection to PC (cable not included)

**Software**

- Speed: ..... Reads, calculates and prints results, 3 seconds per tube
- Calculation Modes:..... Factor, Single Standard, Point-to-Point, Regression, Cubic Spline
- Test Storage:..... Stores 120 tests. Stores all parameters including wavelengths, calculations, unit codes, linear and normal ranges, rate timing, standard values, test names, previously stored curve, controls and Levey-Jennings

**Other**

- Temperature Control:..... Read cell and incubation block, user selectable (OFF/ON)
- Enclosure: ..... Flame-retardant ABS plastic cover and base
- Dimensions: ..... Approximately 9x13.5x5" (24x34x13cm) weight: 10 lbs (4.5kg)
- Certifications: ..... CE, ETL listed, NRTL listed (USA/CAN)

**Recommended Environmental Condition:**

Indoor Use

- Mains supply voltage:                      Fluctuations not to exceed  $\pm 10\%$  of the nominal voltage
- Operating Temperature:                      18-35°C recommended
- Operating Humidity:                          Less than 80% recommended
- 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. NOTE: Retain the original packing material for future use in the event that the instrument is shipped to another location or returned for service. Please locate each item now before continuing.

#### Packing List

<b>45XX CHEMISTRY ANALYZER</b>			<b>*TUBING KIT</b>		
<b>QTY</b>	<b>PART NO.</b>	<b>DESCRIPTION</b>	<b>QTY</b>	<b>PART NO.</b>	<b>DESCRIPTION</b>
1	45XX	Chemistry Analyzer	*1	153022	1/16" Hex Key
1	994070	Waste Bottle Assembly	*1	186585	Tubing Gripper
*1	994082	Flow Cell (In Box)	*3	135206	Teflon Tubing
*1	024050	Flow Cell Cleaning Solution	*1	135235	White PVC Tubing
*1	OM4500	Operator's Manual	*1	135191	Silastic Tubing
			*1	137041	3/32 Male Luer
1	101245 or 101246	US or Euro Power Supply (US Shown)	*1	135102	Modified Luer
*1	045040	*Tubing Kit			
1		**Spare Parts Kit			
1	002195	Gift Pen	<b>**SPARE PARTS KIT</b>		
1	001994	Lab Timer	2	150006	Printer Paper
1		Certificate of Quality	6	157302	Borosilicate Tubes
			1	112004	Halogen Lamp
			1	131100	Clinching Strap
			1	189134	Bottle Strap Anchor
	*Indicates items included only with Flow Cell equipped instruments.				

### 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 10 lbs. (4.5 kg). 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.
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	<p>With the power switch in the OFF 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.</p> <p>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.</p> <p>For 220-240 V used inside the United States, use a UL listed cord as above, except rated <u>250V</u>.</p> <p>For other locations, use the power cord certified for the country of use.</p>

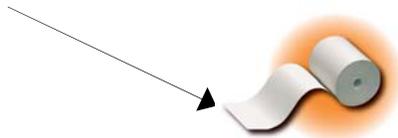
### 1.5.3 Load Paper

Connect the power module to the instrument. The ON/OFF switch is located on the back of the instrument. Locate the roll of thermal printer paper P/N 150006.



**Figure 1.5.3-1 Paper compartment lid location**

Insert finger and lift tab to open lid. Place the paper roll in the well (A) such that the leading edge of the paper feeds upward from the front of the printer from the bottom of the paper roll.



**NOTE:** The printer manufacturer strongly recommends the use of thermal paper part number 150006 to reduce lint and extend printer life. Contact your dealer for replacement rolls.



**Figure 1.5.3-2 Printer paper compartment lid open**

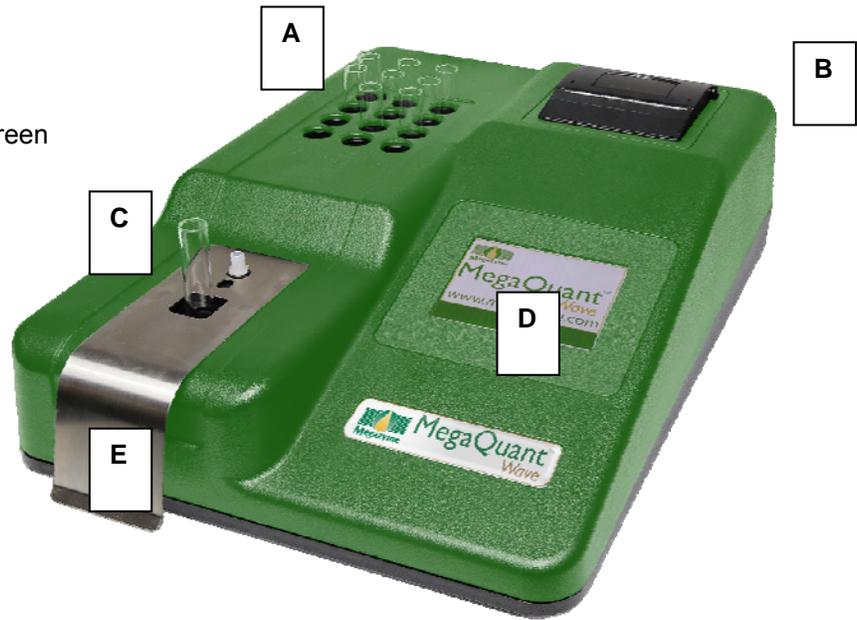
Pull up at least 1 inch of paper and then press the compartment cover down until it snaps closed.

Set the power switch ON and the wake up routine will follow. Music will play briefly during the initialization process. 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).

### 1.5.4 Parts and Controls

- A Heat Block
- B Printer
- C Flowcell
- D Display/Touch Screen
- E Aspiration Bar



**Figure 1.5.4-1** Top view of instrument



**Figure 1.5.4-2**  
Read Well



**Figure 1.5.4-3**  
Waste Bottle



**Figure 1.5.4-4**  
Power Module

## Parts and Controls (Continued)

I	Power Switch		
J	Power Supply Connection	N	Hydrophobic Filter Luer (blue)
K	USB Port Type B	O	Waste Bottle Luer (black)
L	USB Port Type A for use with mouse and USB mass storage device	P	Fan
M	Sensor Lead Jack		



Figure 1.5.4-5 Ports and Connections

### 1.5.5 Flowcell

#### 1.5.5.1 Installing the Flowcell

- Hold the Flowcell handle (reference Figure 1.5.5.1-1) and align the orientation pin (E), the Flowcell (D) and the exit luer (F) into the slots provided on the instrument. Press the button on the Flowcell handle (B) to secure the seal between the luer fittings located on the instrument and on the bottom of the Flowcell handle (F).
- To remove the Flowcell it is necessary to release the seal of the luer fittings. This is accomplished by grasping the Flowcell handle and pulling up with a firm motion. NOTE: Do NOT press the button as you lift the Flowcell. Pressing the button ensures a secure seal of the luer fittings – it does NOT release the seal.

Flowcell assembly



**Figure 1.5.5.1-1 Overview of the Flowcell Assembly**

Flowcell handle  
Button for creating vacuum seal



**Figure 1.5.5.1-2 Top of flowcell assembly**

Orientation pin  
Exit Luer

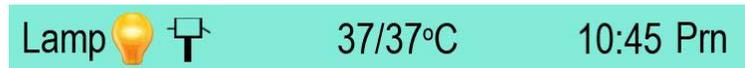


**Figure 1.5.5.1-3 Bottom of flowcell assembly**

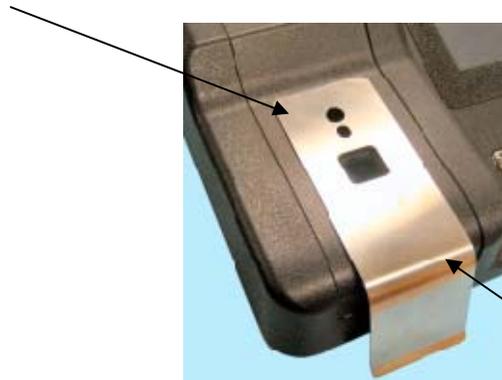
When the Flowcell is installed, the user may access the Flowcell Settings under the Settings Menu to enable and disable the Flowcell, and adjust the Sample Volume. The Default Sample Volume is 500 µl. Press the Save button to store selections.

Enable the Flowcell mode by pressing ON or OFF.

When the Flowcell is enabled the Flowcell icon  displays on the status line on the Main menu.



**Exit Luer**



**Sample Bar**

**Figure 1.5.5.1-4 Flowcell Assembly**

The Exit Luer will seal once the Flowcell is securely installed.

Insert the Flowcell and the Orientation Pin into their locations above the Sample Bar.

### 1.5.5.2 Connecting the Waste Bottle

Before connecting the Waste bottle to the instrument, be sure the two silver colored connectors that are attached to the bottle rubber stopper are not touching. Firmly secure the rubber stopper and then tighten the bottle cap.

Place the Waste bottle on the work surface behind the instrument. Some models have a strap to secure the waste bottle. Position the Waste bottle so that the tubing and sensor lead are not kinked, twisted, or strained.

Assemble the waste bottle before connecting it to the instrument.

1. The wire leads attached to the rubber bottle stopper must not be touching each other.
2. Place the white bottle cap over the assembly of tubing attached to the rubber stopper.
3. Be sure the hydrophobic filter is installed on the vacuum line.
4. Secure the rubber stopper in the neck of the bottle.

**CAUTION:** Do not place undue stress on the tubing connections or sensor lead connector. Close the bottle cap.

Connect the Waste bottle connections to the rear panel fittings. The vacuum line fittings are blue and the waste line fittings are black. Turn the fittings clockwise only until finger-tight. Do not over tighten. Plug the sensor jack into the rear panel. Enable flowcell mode by selecting ON from the Settings menu if the instrument is not already set to flowcell mode.

If the Waste Bottle icon changes to a solid color and the instrument is beeping, unplug the sensor jack. If the instrument continues to show that the waste bottles is full, exit flowcell mode and remove the connections to the waste bottle. Open the cap and rubber stopper assembly. Check to see if the wire leads attached to the rubber stopper are touching. If they are, untangle them.



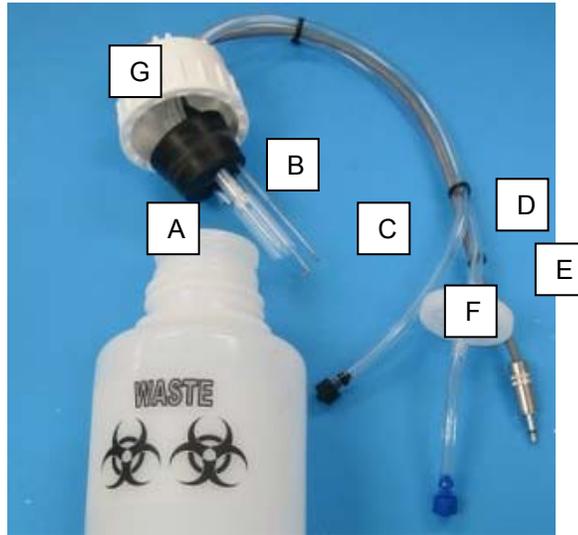
**Fig. 1.5.5.2-1 Waste Bottle empty**



**Fig. 1.5.5.2-2 Waste Bottle full**

If the hydrophobic filter gets wet due to a waste bottle spill, it must be replaced. "Stdby" represents Standby and is available if the waste becomes full during testing mode. Selecting this button releases vacuum pressure from the waste bottle so that it can be safely emptied when necessary. The message "Vacuum Standby Mode" will be displayed to warn the operator that there is no vacuum pressure present for aspiration. Otherwise turn off flowcell through Flowcell Settings under the Settings on the home screen.

- A Waste Bottle
- B Waste Full Sensor Wires
- C Waste Tube (Black Fitting)
- D Hydrophobic Exhaust Filter
- E Sensor Lead
- F Vacuum Fitting (Blue Fitting)
- G Bottle Cap Assembly (white cap and rubber stopper)



**Figure 1.5.5.2-3 Waste Bottle Assembly**

### 1.5.6 Capacitive Touch Screen

Capacitive touch screens must be touched with a finger or a special capacitive pen or glove.

Excessive pressure can damage a touchscreen.

- High touch resolution
- Not affected by dirt, dust, water or light
- Durable technology

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## 1.6 Checkout Procedure

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

<b>Visually confirm the following items:</b>	
<ul style="list-style-type: none"><li>• Power cable is plugged into rear of unit and into an AC outlet.</li><li>• Power switch is set to OFF.</li></ul>	
The instrument is now ready for power-up.	
Confirm that the instrument responds as described.	
Set the power switch on the instrument to the ON position.	
<p>The screen will display as shown in <b>Figure 1.6-1 Screen Display (Checkout)</b>.</p> <p>A musical interlude will play during initialization of the instrument. The screen will display the instrument's logo as the program loads:</p> <p>The printer will print the instrument model, serial number, laboratory name (if defined under the <i>Settings menu Laboratory Name option; the default is no laboratory name</i>), firmware version, revision level, date and time (<b>Figure 1.6-2</b>).</p> <p>If the instrument produces results other than those described here, set the power switch to <b>OFF</b>. Refer to <b>Section 1.5 Installation</b> and review all steps carefully. If the instrument still produces results other than those described here, refer to <b>Section 4 Troubleshooting</b>, or contact your dealer for assistance.</p>	 <p style="text-align: center;"><b>Figure 1.6-1 Screen Display</b></p> <p>MegaQuant Ver:Eng-03.00.00 Serial Number: 1234 11-11-2019                      11:44:32</p> <p style="text-align: center;"><b>Figure 1.6-2 Power up printout</b></p>

## 2. Operating Procedures

### 2.1 Precautions

Avoid lifting, leaning or turning the instrument over when a tube is in place.

	<b>CAUTION! L'ATTENTION!</b>	
	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.	

### 2.2 General Selections

Every test requires a mode selection and filter combination. Thereafter, only those options pertaining to the mode selected will be asked. In the Absorbance Mode, for example, there are no further selections required, although additional options are provided. Review the following questions before beginning a test (refer to the reagent kit insert or kit manufacturer for required information):

1. How will absorbance reading be converted into a final result?
2. Which filters are optimal? (operating and differential wavelengths)
3. How many calibrators will be used?
4. What is the calibrator value or values?
5. Will acceptance ranges for controls be entered for automatic comparison? If so, what ranges are to be used for each?

**NOTE:** For the purpose of this manual, the terms *calibrator* and *standard* are used interchangeably to designate reference materials of known concentrations.

**NOTE:** For the purpose of this manual, the terms *specimen* and *sample* are used interchangeably to mean materials of unknown concentrations.

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## 2.3 Main Display Menu Options

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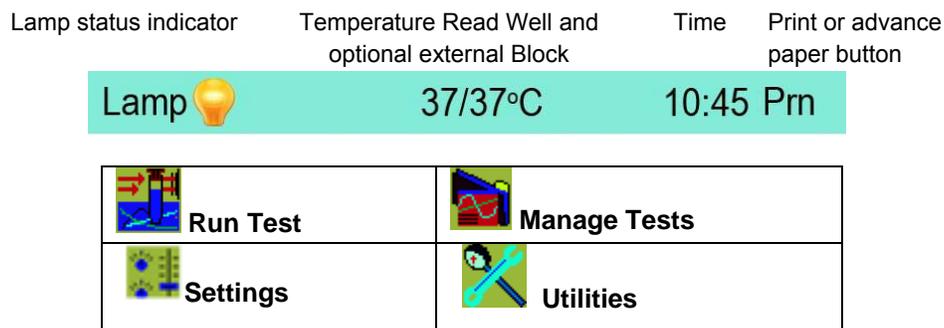
The Main display menu options are:

**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



**Figure 2.3-1 Representation of the Main 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 (Figure 2.3.1-1). The instrument 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 menu. If no tests have been programmed yet, the instrument will open to the TEST DEFINITION screen automatically (Section 2.3.3 Manage Tests). Otherwise, tests programmed and saved on the instrument will display sorted by their test number which is automatically assigned at the time each new test is programmed and stored by the user.

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 previously saved curve or reading a new one.

**NOTE:** Tests created and stored in Tube mode can only be run in tubes, and ones created and stored in Flowcell mode can only be run using the flowcell. Example: the test menu that follows is with tests stored in tube mode and instrument is in tube mode.

## Run Test (Continued)

Select Test to RUN

1 – ALBUMIN	
2 – AMYLASE	
3 – CALCIUM	Cancel
7 – CHLORIDE	>>
5 – CHOLESTEROL	<<
6 – GLUCOSE	By #
11 – HEMOGLOBIN	
15 – MAGNESIUM	
85 – SODIUM	

**Figure 2.3.1-1 Example of test menu for Tube mode tests only**

**Cancel:** Returns to the Main display screen.

**>> and <<:** Utilize the double arrow keys to advance through the stored test menu.

**By #:** Allows selection of any test in the menu by number.

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
Cancel	Returns user to the main screen

### 2.3.2 Settings

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

**Arrow Keys:** Utilize the arrow keys to scroll up and down the list of options or press the option directly from the list; the option will highlight.

**Select:** The high-lighted option is executed once the Select key is pressed.

**Done:** Returns to the Main display screen.

Flowcell Settings	
Printer Setup	
Temperature Control	^
Adjust Date and Time	v
Lamp Control	Select
Laboratory Name	Done
Kinetic Graph Size	
Sound Settings	
External Output	
Results Storage Settings	

## Settings (Continued)

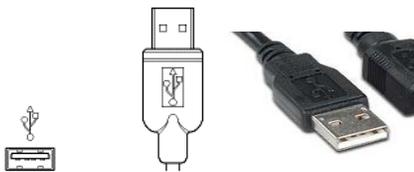
The functions of the Unit Settings features are:

Flowcell Settings	<p>Turns Flowcell ON or OFF, allows selection of aspiration volume, and enables user to purge the flowcell and tubing when not running a test.</p> <p>Look at the top of the screen to see  for using tubes or  for using flowcell. See 3.3 Settings to switch between tube mode and flowcell mode.</p>
Printer Setup	<p>Enables or disables the internal printer. Contrast can be adjusted light to dark. NOTE: It is advisable to print at contrast level 3. Higher contrast levels may degrade after several lengthy printouts. Three font sizes are available – small, medium and large</p>
Temperature Control	<p>Enables or disables cell heat and block heat.</p>
Adjust Date and Time	<p>Provides access to the Set Time option Hours, Minutes, Seconds as well as Month, Day, Year</p>
Lamp Control	<p>Provides access to lamp settings: lamp idle timeout of 30 to 3600 seconds (<b>600 seconds is the default</b>) and lamp warm up 45 to 120 seconds (45 is the default). <b>NOTE:</b> If using the flowcell, with no differential filter (monochromatically), the lamp warmup time is automatically doubled.</p>
Laboratory Name	<p>Allows a laboratory named to be entered using up to 29 characters, including spaces; laboratory name will print at power up.</p>
Kinetic Graph Size	<p>The user may choose the Full Screen option which utilizes the whole screen, or Small. The default is the Small setting. Once saved, the setting remains in effect until changed.</p>
Sound Settings	<p>User can select to use all, some or none of the sounds available.</p>
External Output	<p>When connecting to a PC, turn this option ON.</p>
Results Storage Settings	<p>When this option is ON, the user is prompted to enter an ID after sample is read. User ID is not case specific.</p> <p>If an ID is not entered, a default number is assigned, identified with a leading pound (#) sign.</p> <p>Results are found on the Patient Results screen, which is located on the Utility menu.</p>

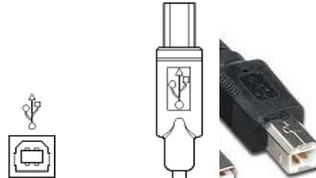
### 2.3.2.1 External Output

To enable output to be sent to a personal computer, a user must have a USB cable with Type A and Type B end connections and use a software application such as SF\_Capture to transmit and store data from the instrument. Refer to Section 7, Appendix A for SF\_Capture software setup

- 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.



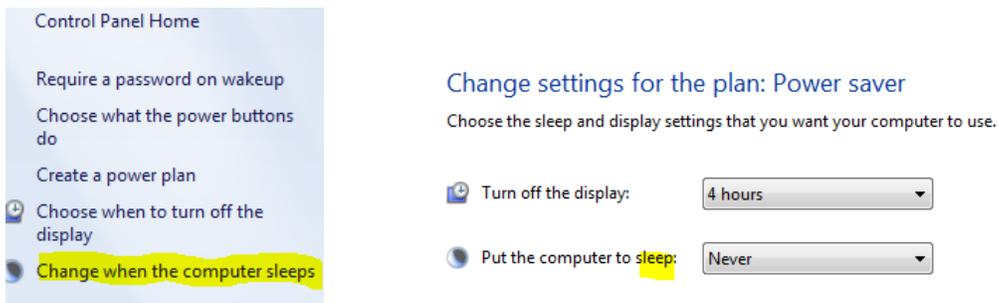
**Fig. 1 USB Type A port and connector**



**Fig. 2 USB Type B port and connector**

NOTE: Some Windows 10 computers, when in sleep mode, could conflict with the instrument when connected via USB. To avoid a potential conflict, change the computer's Sleep setting.

1. Open the computer software's Control Panel.
2. Select Power Options. Change when the computer sleeps. The recommended setting is Never.



### 2.3.2.2 Mouse Connection

To use a USB mouse with the instrument, 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:

- Create Test
- Edit Test
- Delete Test
- Print Test
- Clone Test
- Exit

The functions of the Manage Tests options are:

Feature	Function
Create Test	Depending upon the mode, allows user to: <ul style="list-style-type: none"> <li>• Name the test</li> <li>• Select a mode (Absorbance, Factor, Single Standard, Point to Point, Regression, Cubic Spline)</li> <li>• Read Kinetic (Rate Made)</li> <li>• Select the Primary Filter</li> <li>• Select the Differential Filter</li> <li>• Assign QC values for Blanks</li> <li>• Interpretation Criteria (Positive/Negative results and Normal/Linear ranges)</li> <li>• Select Units</li> <li>• Input # of Decimal places used to report results. (The numbers reported to the right of the decimal point.)</li> <li>• Enable % Absorbance (Yes or No)</li> <li>• Input number of Standards</li> <li>• Manage Controls: Enable; name, low/high ranges, action to take (i.e. warn, continue or end test); record Lot Number; input expiration date).</li> </ul>
Edit Test	Used to change test programming. Editing a test will erase any stored blank or standard values for that test
Clone Test	Allows user to duplicate an existing test; assigns the next available test slot number allowing for the test to be stored.
Delete Test	Allows user to delete tests.
Restore Tests	User can restore just one test or the entire preprogrammed test menu.
Print Test List	Printer will print the list of available tests (maximum 120 tests)
Exit	Returns to the main display screen

## Manage Tests (Continued)

### 2.3.4 Create and Run a Test

On the main screen select Manage Tests. Using the information in the package insert for an assay, follow the prompts available in Create Test. Scroll through the options using the >> button.

Example: Factor Mode Test

TEST DEFINITION			
Name			Exit
Mode			
Tube/Flowcell			^
Kinetic (Rate)			
Primary Filter	405		v
Differential Filter	630		
Blank Options	NO		Edit
Print	Save		>>

SELECT MODE	
Absorbance	Exit
Factor	
Single Standard	^
Point to Point	v
Regression	
Cubic Spline	Select

TEST DEFINITION 2nd page			
Factor	200		Exit
			^
Control 1	Disabled		
Control 2	Disabled		v
Control 3	Disabled		Edit
<<	Save	Run	>>

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.

### 2.3.5 Utilities

Utility menu options are as follows. Use the up and down arrow keys to view the options or scroll along the edge to view the list. To selection an option from the list, press the Select button. Press the Done button when finished.

#### Utility Menu

Change Access Level	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px; text-align: center;">^</div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px; text-align: center;">v</div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px; text-align: center;">Select</div> <div style="border: 1px solid black; padding: 5px; text-align: center;">Done</div>
Show Version Details	
Erase All Tests	
Recall Calibration	
Print Unit Settings	
Filter Voltages	
Flowcell Adj	
Levey-Jennings	
Patient Results	

**Figure 2.3.5-1 Utility Menu options**

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	"Please Confirm: Erase All Tests?" <b>WARNING:</b> Selecting OK will delete <b>ALL</b> stored tests.
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
Flowcell Adj	Reference Appendix 8 for information.
Levey-Jennings	Graphing ability for stored Controls. Section 2.3.5.1
Patient Results	Provides access to stored results. Details are in section 2.3.5.2.

### **2.3.5.1 Levey-Jennings**

Located on the default access level (1) of the Utility menu, this feature provides for the printing and graphing of data for stored Controls.

After selecting this option, the list of stored tests will be displayed. 'Select Control' menu will open with 'Normal Control', 'Abnormal Control' and 'Other Control'.

Enter the month and the year when a Control was read. (The year is a two (2) digit entry.)

"No Lot Numbers Found" will be displayed if no Controls were stored for the test selected, the date selected, or for the Control selected.

The display will have, for example....#1, NC, Lot and date across the top of the screen. The graph can be printed along with the Control data, or just the data can be printed.

### **2.3.5.2 Patient Results**

The instrument will store 500 patient results..

Results will not be stored that are out of min/max range, out of cubic spline range, or if there was an error calculating concentration.

There is an option on the Settings menu to allow ON/OFF for entering patient IDs

When Results Storage is ON, the user is prompted to enter an ID after each sample is read. The User ID is not case specific.

If an ID is not entered, a default number will be assigned, identified with a leading pound (#) sign. Example #08102016.

User can view, print ALL, or print individual results by selecting the Patient ID.

As the number of results becomes greater than 500, the first result will be removed in order to store the next.

There is also an option to delete ALL stored results.

---

## 2.4 General Operation

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### 2.4.1 Reading Samples

#### 2.4.1.1 Using Tubes

When prompted by the visual and audible prompts of the software insert the tube into the read well.

The instrument takes the reading, and displays and prints the result. After the result is displayed, the tube may be removed. The instrument prompts to insert the next tube.

- Whenever possible, readings taken bichromatically are recommended. The use of a primary and a differential filter eliminates the influence of dust, moisture or fingerprints from tubes upon the absorbance readings.
- If it is not possible and readings are to be done monochromatically, be sure to wipe any dust, moisture, or fingerprints from the tubes before using. Do not read tubes that contain bubbles or condensation.
- Use a blank material with absorbance of less than 0.400A.
- Use the same type and size of tube for the blank as you use for the samples - 12 mm round
- Depending on the precision requirements of your assay, monochromatic reading may or may not be acceptable with certain plastic tubes.
- Mark each tube for uniform orientation when multiple readings are desired.
- Determine the acceptability of the precision by reading the same tube several times and observing the variation of the readings.

#### 2.4.1.2 Using the Flowcell

When prompted by the visual and audible prompts of the software, bring the sample up to the flowcell aspiration tube and press the stainless steel aspiration bar with the back of the hand. This enables quick sampling with a one-handed operation.

During sampling, clicks will be heard: two times (quickly) when the sample bar is pressed, to draw the sample (you may hear a “double click” at the end of larger samples making it sound like 3-4 clicks), a pause, a click to start the flowcell purge and then a click at the end of the purge. Be sure that the pickup tube is installed deeply enough in the solution as to not draw air and that you wait until the second click before removing the tube.

- When reading sample in Flowcell Mode, ensure that the volume of sample exceeds the aspiration volume selected (default 500µl).
- If the pickup tube is against the bottom of the tube, less sample will be aspirated. Attempting to aspirate the exact amount of sample may result in poor results due to air mixing with the sample.

## Using the Flowcell (Continued)

- Aspiration volumes are approximate and can vary due to the viscosity of the solution as well as technique.

Attempting to aspirate the exact amount of sample may result in poor results due to air mixing with sample. User technique, the shape of the bottom of vessel being used, and the location of the tube during sampling can affect this process.

When the reading is complete the Sample will be automatically purged from the Flowcell and drawn into the Waste Bottle at the rear of the instrument.

If the Waste bottle becomes full while running a test in Flowcell Mode, the instrument will beep and display the icon: 



A test programmed and stored in flowcell mode will not be shown when the instrument is in tube mode and those stored in tube mode will not be shown when the instrument is running in flow cell mode.

The "Purge" button allows for additional aspirations, but it does not take samples for reading absorbance values. It is simply used to flush liquid, such as DIH<sub>2</sub>O, through the system, particularly useful when using creatinine and other reagents with picric acid.

The flowcell icon  will appear on the display to replace the tube icon. When the temperature controls are set to ON (Settings – Temperature Control feature) Cell and Heat block temperatures are displayed.



### 2.4.2 Bichromatic Differential Operation

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

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.

### 2.4.3 Blanking

The blank absorbance is relative to air when in tube mode. The user should evaluate the suitability of the blank before using it.

When the flowcell is installed it is blanked on water. This value is used to set the baseline (zero) of the instrument instead of the periodic air reading used in the tube reading mode.

Whenever additional blanking is desired, select the BLANK option.

**Note:** It is very important to use the same type and size tube for the blank as will be used for the samples.

#### 2.4.3.1 Differential/sample Blanking

The use of a Sample (also known as Differential) Blank may be selected during entry of parameters in the Standard, Factor, and Multipoint modes. In sample blanking the sample is read and then the same sample is read a second time after a reagent is added.

Differential/sample blanking cannot be used in kinetic tests.

When Sample Blank is selected, there is also the option to use Batch Mode.

#### 2.4.4 Kinetic Tests (Rate Mode)

- Before running a kinetic test, access the Lamp Control feature in Settings from the main menu. Set the Lamp Idle Timeout setting to at least 1200 seconds (20 minutes.)
- This will allow a minimum of 15 minutes for the cell temperature to equilibrate
- If the instrument is left idle, the lamp may be OFF. Be sure that it is ON.

The user selected lamp warmup time will begin to countdown if the lamp is off when a test is set to run. Bichromatic readings should be used in any Rate Mode test.

Always select a differential filter.

When reading kinetically (using rate mode) the instrument takes periodic readings of a sample at timed intervals. To enable a kinetic test, select the field on Test Definition 1<sup>st</sup> page.

TEST DEFINITION			
Name			Exit
Mode	Single Standard		
Tube/Flowcell		Tube	^
Kinetic (Rate)		Yes	
Primary Filter		405	v
Differential Filter		630	
Blank Options		Blank	Edit
Print	Save		>>

**Figure 2.4.4.-1 1st page showing the Kinetic [Rate] field**

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

- Lag Time is the length of time that the instrument pauses before it takes the first reading, and is measured from the point at which the user inserts the tube or aspirates the sample.
- Read Time is the total length of time over which the reaction is monitored.

TEST DEFINITION Kinetic Parameters		
Kinetic Read	YES	
Fixed Time	NO	
Batch Mode	NO	^
Lag Time	30	v
Read Time	120	
Interval	10	Edit
Number of Reads	13	
Kinetic Ranges		Done

**Figure 2.4.4-2 Enter parameters for a Kinetic test**

## Kinetic Tests (Continued)

The Lag Time has a two second minimum. Read time has a 30 second minimum.

The combined total of Lag Time plus Read Time cannot exceed 1800 seconds (a total of 30 minutes). Results can be accepted after the ACCEPT button appears on the display.

If the user has not enabled the cell temperature control and tries to run or recall a rate mode test, a message will post – “Do you want the cell heat on?” If yes is selected, then the Temperature Control screen will open in order to enable the cell heat. The test to be run will reopen.

**\*\*Dilute and REASSAY!\*\*** - To obtain an accurate absorbance and/or concentration for a sample, it may be necessary to further dilute the sample(s), or dilute the specimen(s) and rerun the assay.

### 2.4.4.1 Fixed Time Kinetics

The fixed time option reports the total dAbs over the entire read time.

Select Fixed Time if you want the dAbs (total reaction over a given time) or NO if you want dAbs/min (average reaction per minute)

It does not report the dAbs per minute (except when the read time is exactly 60 seconds). The Low Activity and Check Linearity conditions will not be displayed. Since it is a fixed time mode, interval reporting is not an option.

TEST DEFINITION Kinetic Parameters

		^
Kinetic Read	Yes	v
Fixed Time	Yes	
Lag Time	60	Edit
Read Time	120	

**Figure 2.4.4.1-1 Selecting Fixed Time**

### 2.4.4.2 Batch Mode

In Batch mode, tests can be run simultaneously. Following the prompts, the user reads a blank, then adds reagent.

After all samples in the batch have had their initial reading, the instrument will count down the remainder of the read time. At the end of the read time, the user will be prompted again to read the samples. It is important to read the samples in the same uniformly-timed manner in which the samples were first read..

## Rate Mode (Continued)

After each sample is read, its results will be printed. The instrument will print the actual read time for each sample, and will compensate with a corrected Abs/min result. Note that interval data and plotting are not available, because the sample does not remain in the well during the rate reaction.

Batch mode option can only be used in tube mode. Batch mode is not available when using the Flowcell.

TEST DEFINITION Kinetic Parameters

		^
Kinetic Read	Yes	v
Batch Mode	Yes	
Lag Time	60	Edit
Read Time	120	

**Figure 2.4.4.2-1 Selecting Batch Mode**

### 2.4.4.3 Kinetic Ranges

Kinetic Ranges allows setting of minimum and maximum initial absorbance, delta abs per minute and the maximum SD, as per package insert information.

TEST DEFINITION Kinetic Parameters

Minimum Init Abs	0.300	^
Maximum Init Abs	0.400	v
Min (Delta Abs/Min)	0.500	
Max (Delta Abs/Min)		Edit
Maximum SD	2	
		Done

**Figure 2.4.4.3-1 Kinetic Ranges**

The Standard Deviation will only print out if there is an entry made for the "Maximum SD" under "Kinetic Ranges".

## Kinetic Mode (Continued)

### 2.4.4.4 MORE Options

By Selecting the MORE button following a kinetic read, three options become available.

S#	Abs/min	Conc	Intrp
S1	0.0669	10.0	

Check Linearity

S1	0.066	10.0	
S1	0.066	10.0	
B	0.029		

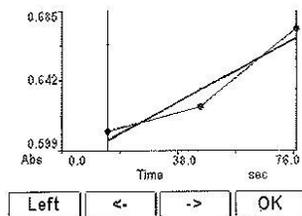
Modify Plot Data Return

**Figure 2.4.4.4-1 – Options after accessing the MORE button**

**Modify** – using the first button, toggle between Left and Right. This moves the beginning (Left) or endpoint (Right) location of the existing curve.

**LEFT** used to toggle between the two lines. The far right line indicating the end of read interval and the left line at the beginning of the read interval. Pressing this button once will change its label to **RIGHT**.

**ARROWS** allow the user to move the two lines in order to select a portion of the graph for purposes of calculating  $\Delta A/\text{Min}$ . by Linear Regression.



**Figure 2.4.4.4-2 Modifying a curve**

**Plot** – this will print the graph, which can be done even when the printer is set to OFF. The plot shows the absorbance along the vertical axis and the time along the horizontal axis.

**Data** – prints out the interval data for review. The information includes the interval read #, the absorbance read at that interval, the time increment and the dAbs/min. The data can be examined to determine if the sample was not active, if the substrate was exhausted early, or if the reaction started later in the Read Time.

The use of Data printout is recommended when either “Check Linearity” or “Low Activity” is reported.

## Kinetic Modes (Continued)

Those two messages are only to notify the user to verify procedure, reagents and temperature settings. A reaction that starts too early, too late or too quickly can cause the "Check Linearity Message", while a reaction that is less than expected due to expired reagent or improper procedure may display the "Low Activity" message.

The "Check Linearity" message will be displayed to alert the user that the rate per minute of an individual interval is more than 20% from the mean rate per minute of all of the intervals.

"Low Activity" – This message is reported if the absorbance per minute for any of the intervals is less than 0.005.

The data for each interval can be printed and analyzed to determine the cause by pressing the "DATA" key. The information includes the interval read #, the absorbance read at that interval, the time increment and the dAbs/min.

### 2.4.5 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. Check the container for the calibrator(s) to determine the units for results. Select the Units field and the list will display. Thirteen units of measurement designations are stored for labeling the concentration column heading on the printed results, plus a blank customizable selection.

TEST DEFINITION Final page

		Exit
Interpretation Mode	Normal	
Units	Conc	^
Decimals	1	v
		Edit
<<	Save	Run
		Print

SELECT UNITS

- Conc
- g/L
- g/dL
- mg/dL
- ug/L
- ug/dL
- U/L
- meq/dL
- mmol/L
- IU/mL
- Umol/L
- Mol/L
- IU/L
- Customize

**Figure 2.4.5-1 Example – Interpretation Mode Test Definition - Final page**

**Figure 2.4.5-2 Example – Option to add a unit 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.

CAUTION: Be sure to use the same units for the calibrators, control criteria and interpretation criteria within a test.

## 2.5 Modes of Operation

Calculation mode options are located under Manage Tests. Select Create Test and the Test Definition screen will open. Press the Mode button and the options will be displayed.

Multi-point Modes	Absorbance	Cancel
	Factor	^
	Single Standard	v
	Point to Point	v
	Regression	v
	Cubic Spline	Select

Mode	Operation
Absorbance	See Section 2.5.1 - The instrument 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 – The instrument 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.

## Modes of Operation (Continued)

Mode	Operation
Point to Point	<p><b>Section 2.5.4</b> – The instrument accepts a number of calibrators and calculates concentrations based on the point-to-point calibration curve. Calibrator materials of known concentrations are used to calibrate the instrument so that concentrations of unknown samples may be calculated. The resulting calibrator curve is a series of lines connecting the calibrator points, which may be entered in ascending or descending order of absorbance. If the direction of the curve changes, the curve will be flagged as being “invalid” and no interpretations will be printed.</p> <p>Unknown samples are calculated as follows:</p> <p>The unknown sample’s absorbance is read and then compared to the absorbance of the calibrators. Its concentration is calculated on the segment connecting the closest points above and below it.</p> <p>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.</p>
Regression	<p><b>Section 2.5.4</b> - A number of calibrators are accepted and calculation of concentration values are based on a best-fit curve (linear regression).</p>
Cubic Spline	<p><b>Section 2.5.4</b> – Cubic Spline Mode accepts a minimum of 3 to a maximum of 8 calibrators and calculates concentrations based on the Cubic Spline (constrained) calibration curve.</p> <p>Calibrator materials of known concentrations are used to calibrate the analyzer 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.</p>

### 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. Press Manage Tests, press Create Test, and the Test Definition window will display.

TEST DEFINITION		
Name		Exit
Mode	Absorbance	
Tube/Flowcell		^
Kinetic (Rate)		
Primary Filter	405	v
Differential Filter	630	

Print	Save	>>
-------	------	----

**Figure 2.5.1-1 Test Definition page**

To display the list of available modes, press the mode field and the Select Mode screen will display.

SELECT MODE	
Absorbance	Exit
Factor	
Single Standard	^
Point to Point	v
Regression	
Cubic Spline	Select

**Figure 2.5.1-2 Select Mode screen**

Use the arrow keys to scroll through the list to the desired mode, and then press the Select button, to highlight a mode on the list and the Test Definition page will display.

Select filter wavelengths by using the arrow key to scroll to the Primary Filter or Differential Filter selection and press the Edit key. The Select Filters window will open and display the available options.

SELECT FILTERS	
340	Cancel
630	
580	^
545	v
505	
405	Select

SELECT FILTERS	
None	Cancel
340	
630	^
580	v
545	
505	Select
405	

**Primary Filter Differential Filter**

## Absorbance Mode (Continued)

Scroll up or down to highlight a selection and then press the Select key.

One by one, insert each sample tube and the absorbance results will print and display.

NOTE: After reading the last sample, the Lamp Idle Timeout feature will automatically turn off the lamp after the time set has expired. 600 seconds (ten minutes) is the default setting. To continue reading, place a tube in the well. The Minimum Lamp Warmup will occur (45 seconds is the default setting), and then operation will resume where it left off.

### 2.5.2 Factor Mode

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.

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

To display the Kinetic Parameters, press the Kinetic [Rate] field and the Kinetic Parameters Test Definition page will display. For more detail, see the Kinetic [Rate] section.

Blank Options allows Blank to be enabled Yes/No, Sample Blank Yes/No, Range Low, and Range High. Scroll up or down to highlight a selection and then press the Select key.

TEST DEFINITION Blank

		^
Enabled	Yes	v
Sample Blank	No	
Range Low		Edit
Range High		Done

**Figure 2.5.2-1 Test Definition - Blank options**

The 2<sup>nd</sup> page of the Test Definition window will display and allow editing of Factor and Controls. Use the arrow keys to advance through the options and press the Edit key to change the values of the selections on the screen.

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

TEST DEFINITION 2nd page

		Exit
Factor	10	
		^
Normal Control	Disabled	
Abnormal Control	Disabled	v
Other Control	Disabled	Edit

<<	Save	Run	>>
----	------	-----	----

**Figure 2.5.2-2 Factor Mode Test Definition 2<sup>nd</sup> page**

Selecting any of the Control fields will open a Test Definition Control screen with options to ENABLE the Control (Yes or No), 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 an Expiration Date. Press the Done button when finished with editing fields.

The final page of the Test Definition window will display and allow editing of Interpretation Mode, Units, and Decimal places. Concentrations can be reported to 4 decimal places.

TEST DEFINITION Final page

		Exit
Interpretation Mode	Normal	
Units	Conc	^
Decimals	1	v
		Edit

<<	Save	Run	Print
----	------	-----	-------

**Figure 2.5.2-3 Factor Mode Test Definition - Final page**

Selecting the Interpretation Mode will open the Test Definition Interpretation window for editing Normal Range Low, Normal Range High, Valid Range Low, and Valid Range High. Use the arrow keys to scroll through the options, press the Edit key to change the value of the selection. Press DONE to save the selections.

Note: it is very important to use the same type and size tube for the blank as will be used for the samples.

TEST DEFINITION Interpretation

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

**Figure 2.5.2-4 Factor Mode Test Definition – Interpretation**

### 2.5.3 Single Standard Mode

To operate in Single Standard Mode, select Manage Tests and then select Create Test. Use the arrow keys to scroll through the mode selections to highlight Single Standard. Select options, including whether running a kinetic test, filters and blanks options. In the example below, the instrument is equipped for both tube and flowcell.

NOTE: Tests stored in tube mode can only be run in tube mode, and tests stored in flowcell mode can only be run in flowcell mode. The “Run Test” menu will reflect only the tests stored in the mode (tube or flowcell) in which the instrument is running.

The Test Definition 1st page will display:

TEST DEFINITION			
Name			Exit
Mode	Single Standard		
Tube/Flowcell		Tube	^
Kinetic (Rate)		Yes	
Primary Filter		405	v
Differential Filter		630	
Blank Options		Blank	Edit
Print	Save		>>

**Figure 2.5.3-1 Test Definition - 1<sup>st</sup> Page**

Sample Blanks can be used, as well as Batch mode. In addition, quality control values can be set for the minimum and maximum acceptable initial absorbance. Both values do NOT need to be entered, as per the information provided in the package insert for the test being run.

Blank Options allows Blank to be enabled Yes/No, Sample Blank Yes/No, Range Low, and Range High. Scroll up or down to highlight the desired selection and then press the Select key.

TEST DEFINITION Blank		
		^
Enabled	Yes	v
Sample Blank	No	
Range Low		Edit
Range High		Done

**Figure 2.5.3-2 Test Definition - Blank options**

The 2<sup>nd</sup> page of the Test Definition window will display and allow editing of Standard Concentration and Controls. 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
Factor	10	
		^
Normal Control	Disabled	
Abnormal Control	Disabled	v
Other Control	Disabled	Edit
<<	Save	Run >>

**Figure 2.5.3-3 Standard Mode Test Definition 2<sup>nd</sup> page**

The final page of the Test Definition window will display and allow editing of Interpretation Mode, Units, and Decimal places.

TEST DEFINITION Final page

		Exit
Interpretation Mode	Normal	
Units	Conc	^
Decimals	1	v
		Edit
<<	Save	Run Print

**Figure 2.5.3-4 Single Standard Mode Test Definition - Final page**

Selecting the Interpretation Mode will open the Test Definition Interpretation window for editing Normal Range Low, Normal Range High, Valid Range Low, and Valid Range High. Use the arrow keys to scroll through the options, press the Edit key to change the value of the selection. Press Done to save the selections.

TEST DEFINITION Interpretation

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

**Figure 2.5.3-5 Single Standard Mode Test Definition – Interpretation**

**Note:** It is very important to use the same type and size tube for the blank as will be used for the samples.

### 2.5.4 Multi-Point Modes

The instrument's firmware 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.

The standard curve, y-intercept (y), slope (m), and correlation coefficient (r) will be printed in Regression mode.

Graphs of point to point curves can be printed even when the internal printer is set to OFF.

The Test Definition 1<sup>st</sup> Page will display the options such as a Test Name field, Mode, Kinetic [Rate], Primary Filter, Differential Filter, and Blank Options.

TEST DEFINITION 1st page

Name		Exit
Mode	Point to Point	
Tube/Flowcell		^
Kinetic (Rate)	No	
Primary Filter	405	v
Differential Filter	630	
Blank Options	Blank	
Print	Save	>>

**Figure 2.5.4-1 Point to Point Test Definition - 1<sup>st</sup> Page**

Blank Options allows Blank to be enabled Yes/No, Sample Blank Yes/No, Range Low, and Range High. Scroll up or down to highlight a selection and then press the Select key.

TEST DEFINITION Blank

		^
Enabled	Yes	v
Sample Blank	No	
Range Low		Edit
Range High		Done

**Figure 2.5.4-2 Test Definition - Blank options**

The Test Definition second page will display and allow editing of % Absorbance, Standards, number of Standards and to enable the use of Controls. Note: The number of Standards must be at least two for Point-to-Point and Regression. Cubic Spline mode requires at least three Standards.

TEST DEFINITION 2nd page

% Absorbance	Yes	Exit
Standards	2	^
Normal Control	Disabled	
Abnormal Control	Disabled	v
Other Control	Disabled	Edit

<<	Save	Run	>>
----	------	-----	----

**Figure 2.5.4-3 Test Definition –2nd Page**

**% Absorbance** assigns a value of 100% to the first Standard, which must be the Standard with the greatest absorbance. Then the % absorbance relative to the first Standard is calculated for each Standard and Sample, in addition to a concentration value. The %Abs value is displayed in the Interpretation field of the report.

**NOTE:** % Absorbance option is used with multipoint uptake assays. The standards must be entered from darkest to lightest.

If replicate Standards are used, the user then 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).

The final page of the Test Definition window will display and allow editing of Interpretation Mode, Units and Decimal places.

TEST DEFINITION Final page

Interpretation Mode	Normal	Exit
Units	Conc	^
Decimals	1	v
		Edit

<<	Save	Run	Print
----	------	-----	-------

**Figure 2.5.4-4 Test Definition - Final page**

Selecting the Interpretation Mode will open the Test Definition Interpretation screen for editing the Normal Range Low, Normal Range High, Valid Range Low, and Valid Range High. Press Save to save the selections. Note, it is very important to use the same type and size tube for the blank as will be used for the samples.

TEST DEFINITION Interpretation

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

**Figure 2.5.4-5 Test Definition – Interpretation**

## 3. Cleaning and Maintenance

### 3.1 Cleaning

#### 3.1.1 Exterior

	CAUTION! Solvents such as acetone or paint thinner will damage the instrument! Use only water and recommended cleansers! Avoid abrasive cleaners. The display area is liquid-resistant, but is easily scratched.
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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 or 70% isopropyl alcohol may also be used as a disinfectant. Take special care not to spill any liquid into the read well.

#### 3.1.2 Flowcell

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

##### To clean the Flowcell:

Enable the Flowcell (use Flowcell Settings under the Settings Menu), and place the Flowcell in the cell opening.

Purge with air for at least five seconds.

Press the Save Button to save settings

Press Done to exit to the Home Screen

Locate the bottle of Flowcell cleaning solution. Open the bottle and position the sample tube immersing it in the solution.

Aspirate a small amount of Flowcell cleaning solution into the Flowcell by pressing the sample bar. Allow the solution to remain in the Flowcell for three minutes.

Remove the bottle of Flowcell cleaning solution and replace the cap.

Position a container of distilled water so that the sample tube remains immersed.

Press the sample bar to aspirate distilled water into the Flowcell. Allow the water to remain in the Flowcell for three minutes.

##### OPTIONAL STEP:

Aspirate 0.1N hydrochloric acid (HCl). Allow the solution to remain in the Flowcell for three minutes.

Purge with at least 15 mL of deionized water.

Press and hold the sample bar to purge until no more liquid can be seen flowing into the Waste bottle.

Leave the Flowcell filled with water.

**NOTE:** If preparing the Flowcell for storage, follow the same instructions as above but purge completely after cleaning.

### **3.1.3 Read Well**

Prevention is an important factor in keeping the read well free from debris. The following is strongly recommended:

Power the instrument 'OFF' when not in use as the cooling fan draws air through the system which may draw in dust. Install the dust cover as a barrier to dust.

**CAUTION:** When using a dust cover, be sure the instrument is powered "OFF" so that it will not overheat.

A puff of air may be used to eliminate dust from the read well.

Wipe wet tubes with a clean lint-free tissue before inserting them into the instrument.

**WARNING!** If there is a spill into the read well, act immediately to power 'OFF' the instrument and clean by wiping with a lint-free tissue or absorbent swab. Dry with an air blower or wait a few hours for complete drying inside before resuming use.

### **3.1.4 Waste Bottle**

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

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## 3.2 Maintenance

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### 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.

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

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

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

### 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.

**NOTE:** If preparing the Flowcell for storage, follow the same instructions found in Cleaning and Maintenance but purge completely after cleaning.

### 3.2.3 Disposal

Dispose of all components according to local regulations.

Before the instrument is removed from the laboratory for storage, disposal, transporting, 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.

	 <b>CAUTION! L'ATTENTION!</b> 
	<b>POTENTIALLY BIOHAZARDOUS</b> Treat all components during use and disposal as you would any biohazardous material. <b>AVERTISSEMENT:</b> Utiliser et disposer des matériaux de la même manière que vous utilisé et disposer des matières infectieuses.

## 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 when there is a user interface error, as 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.

">10**6"	Appears in Concentration Column when Concentration is greater than 10**6 (column only holds six characters maximum)
">3"	Prints in ABS column if an absorbance is greater than the maximum readable absorbance for the device.
"%Absorbance Mode should not be used with negative absorbance!"	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.
"Check Activity" OR "Check Linearity"	<p>The message "Check Activity" is displayed when absorbance per minute of an individual interval is less than 0.005 Abs.</p> <p>The "Check Linearity" message will be displayed when rate per minute of an individual interval is more than 20% from the mean rate per minute of all of the intervals.</p> <p>Pressing the "data" key will print out the results of the individual intervals. The data can be examined to determine if the sample was active, if the substrate was exhausted early, or if the reaction started later in the read time. These messages are displayed to alert the user to a possible problem with the assay reaction and are rarely a result of an issue with the instrument. Please note that if the expected reaction of your assay falls within the parameters of the messages they will still be displayed as an alert although the results may be correct. Since proper temperature, good reagents and procedure are critical to proper reactions, these items should be reviewed.</p>

CONC result of "*****"	Concentration results are not given when the absorbance is >3.00
"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.
"Normal, Abnormal or Other Control FAILED"	Reported if a Control outside the user defined Low and or High range values set during test definition.
"LOW", "HIGH"	Indicates a Control is outside the defined low/high normal concentration range values.
"Must be between XX and XX"	Pop up message that is a number pad range error; occurs when user makes an entry on the number pad that is outside of the range for that value.
"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
"POS"	Sample is >= POS value (or if reversed, sample is <=POS value.
"Pos must be greater than or equal to Neg!"	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, but the positive value is less than the negative value entered.
"Remove Tube" when there is no tube or flowcell installed in the read cell.	Contact Customer Support
SD out of Range - RECHECK	For Quality Control purposes – verify maximum range settings.
Test Data Corrupted!	Checksum for Assay Data (including calibration data) does not match what was stored for that Assay. Delete the test entry and reenter the setup.

## Messages and Flags (Continued)

Test Definition Corrupted!	Checksum for Test Definition does not match what was stored for that Assay. Delete the test entry and reenter the setup.
The word "BAD" next to the filters when running a stored test	A test was previously created and stored with a filter that is no longer installed in the instrument.  Edit or reprogram the test with the filters available in the instrument.
Vacuum Error	The message will flash at the top of the screen if the vacuum has been running continuously for 10 seconds. It will flash for another 20 seconds and then the machine will be placed in Standby Mode with a message box displaying.  <b>“Vacuum Standby Mode”</b>  <b>“Press OK”</b>  <b>“OK”</b>
Flowcell icon on the display is shown as full (solid color) and beeping occurring	If the waste bottle full sensor is triggered, the Waste bottle icon will be shown as full (darkened) If the waste bottle is not full, unplug the waste bottle wiring (gray cable) at the jack on the back of the instrument. If the message goes away, check to be sure the contacts and cap are free of moisture and salts and that the probe wires inside the bottle are not touching.
“When reversed, pos must be less than neg!”	If using both positive and negative interpretations during test definition, AND if the positive value is greater than the negative value, AND Reverse has been selected, this message will be posted.
“Wrong date format (mm.yyyy)!”	Pop up message that appears when the expiration date for a control is not entered in the correct format during test definition.

## 4.2 Error Messages

Error Messages are displayed when the instrument fails to operate correctly or when an invalid range is entered. They are intended to help the user locate 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.

Error Message	Explanation
"i2c Bus error, 0xNN. 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"	In the event calibration has become corrupted. Recall Calibration from the Utility Menu can be used to restore the Factory Calibration.
"Error: Offset value out of range"	Offset value is not in the range of 20 – 250 – contact technical support
Error Saving Assay Data!	Unable to store Assay information into EEPROM. If fewer than 120 assays stored, contact technical support.
"Factory Data Not Saved"	Contact Technical Support.
" Factory Settings Invalid"  or  "User Settings Invalid "	Contact Technical Support
"Lamp/Filter Volts Low"	Lamp could be out of alignment or blocked. Contact technical support
No filters displayed in the filter voltages screen or the word "BAD" next to a filter when a stored test is recalled.	This could be the result of a binding jack shaft causing the filter wheel to slow up or stop. This will cause the filter assignments to disappear and will sometimes cause the instrument to hang depending on when it binds.  Contact technical support.
"Factory Settings Restored"	This will be printed if Recall Calibration option in the Utilities menu has been selected.
"Default Settings Loaded "	Retrieval of unit parameters changed since the instrument was first shipped from the factory could not be completed – the original factory unit parameters were restored.

## Error Messages (Continued)

<p>“Updating internal firmware”</p>	<p>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.</p>
<p>“Abnormal filter index cnt=x”</p> <p>“Please turn instrument off, pause, then back on. Call service if problem persists.”</p> <p>OR</p> <p>Filter Wheel Error, cnt = “x”</p>	<p><u>During startup</u>, if the filter wheel index count does not get 3 consecutive readings that are either 4, 6, or 8, this error message will show on the display. “x”= the count</p> <p><u>When starting an test</u>, if the filter count does not match the count determined at startup, this error message will show on the display. “x” = the count.</p>
<p>FTDI initialization error</p> <p>Hardware Init Error (#10)</p>	<p>This message will be seen if the FTDI startup initialization fails, tries again, but then fails a second time.</p> <p>It may also be seen if the instrument is connected to a Windows 10 computer via USB cable, and the computer is in Sleep mode. To restore the instrument, ‘wake up’ the computer and set the power option detailed in Section 2.3.2.1 External Output.</p> <p>If the problem is not related to Windows 10, turn the instrument off and then back on. If that does not resolve the error, contact technical support.</p>
<p>“Wheel Speed Out of Range”</p>	<p>This message indicates a change in filter wheel speed. This is usually temporary. If it becomes persistent it indicates a need for service.</p>
<p>“Wheel not spinning properly”</p>	<p>This message will be posted if the ‘Wheel Speed out of range’ message is displayed more than 3 times.</p> <p>“Wheel not spinning properly” will be displayed and all screen functions will be disabled.</p> <p>Turn off the instrument. Check that filter wheel and filter wheel motor belts are properly installed. Check rotation of filter wheel motor and filter wheel for possible binding. Check that the filter wheel motor is plugged into its connector. Fix the issue and restart the unit.</p>

## 5. Optional Accessories

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### 5.1 Thermal Printer Paper

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Reorder replacement Thermal Printer Paper Roll P/N 150006. NOTE: The printer manufacturer strongly recommends the use of thermal paper part number 150006. Contact your dealer for replacement rolls.

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### 5.2 REDI-CHECK® Photometer QA Kit

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

Acceptance ranges are provided for both bichromatic and monochromatic readings, with technical information traceable to NIST. The kit, which is designed for monthly use, also includes a record keeping system which visually indicates instrument performance and performance trends. For more information on REDI-CHECK®, contact your dealer.

## 6. Information

## 7. Appendix A – SF\_Capture

SF\_Capture is a **Windows**<sup>®</sup> application software program for use with this instrument. Contact your dealer for a copy of the program.

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 instrument 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 instrument and the PC, Windows<sup>®</sup> will pop up a message box stating that the VNC1-A As Slave is not installed and that drivers will need to be found.

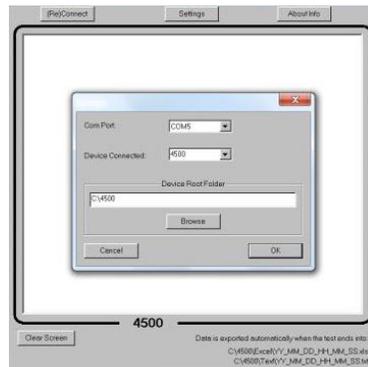
Correct response is to let Windows<sup>®</sup> look for the appropriate driver this one time.

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

The same window will open again. Windows<sup>®</sup> will search for and install USB Serial Port 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:\4500. This can be changed from the default by using the Browse option for the Device Root Folder.

**NOTE:** Some Windows 10 configurations may cause a conflict with the USB port of this instrument. If the computer is in Sleep mode when the instrument is power ON the instrument may post a Hardware Initialization Error. If the computer goes into Sleep mode while the instrument is running, the instrument may stop responding. For best results, ensure that Windows 10 computers do not use Sleep mode while connected to this instrument.

## 8. Appendix B – Flowcell Adjustment

When the flowcell is installed it is blanked on water. This value is used to set the baseline (zero) of the instrument instead of the periodic air reading used in the tube reading mode.

This is originally set at the factory and usually does not need to be reset unless readings or lab procedures require it.

Be sure the instrument is in flowcell mode (Settings menu).

Select the "Utilities" Menu, and then "Flowcell Adj"

**Note:** If you do not see these options, please contact customer support.

Select the "Air Rd" button. When the message appears, be sure the flowcell is removed and select "Yes". When the new Air Reading is displayed, you may print it for reference.

Install the Flowcell, being sure it is properly seated, making sure that the button on the Flowcell handle has been pressed to ensure a seal of the luer fittings.

Put the aspiration tube into a container of DI or distilled water and select the "Purge" button. The instrument will emit a beep, followed by a click sound. Sample material will be aspirated and the pump may emit a sound. Once aspiration ends, the container of DiH<sub>2</sub>O may be removed from the sample tube. **Note:** be sure there is enough liquid in the tube as to not draw air.

The new "Test Reading" will be displayed. This reading should be at least 50% of the "Air Reading". If it is not, the flowcell will need to be cleaned and or adjusted. Be sure to make only minor adjustments, if needed, to the set screw on the bottom of the cell.

You can continue to select "Purge" to aspirate and read additional water after each adjustment until the "Test Reading" value increases to at least 50% of the "Air Reading".

Once the "Test Reading" value is at least 50% of the "Air Reading", print the values for your records and then select the "Sv Blnk" button to save the water blank value.

Before exiting the screen, press the Purge button again in order to remove any remaining fluid into the Waste bottle at the rear of the instrument.

Reference Cleaning and Maintenance Section for information on cleaning the Flowcell and Waste Bottle.

## 9. Appendix C – Firmware Update

1. Erase/delete anything that is on the USB pen drive (or any USB drive).
2. Copy and paste the folder “**romimage.45x**” on to the USB drive
3. Select the Utilities menu.
4. Select Change Access level.
5. Enter 321
6. Scroll to the last item on the list, Firmware Update.
7. Follow instructions on the display. DO NOT TURN OFF the instrument.
8. After the instrument begins a series of beeps, remove your finger from the screen.
9. 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. Bootloader version is on the second line.

## 10. Appendix D – Waste Bottle Strap Installation

- The Velcro strap must be installed in the location shown in Figure 1 to avoid interference with the fan.
- Use Isopropyl alcohol and a clean cloth or cotton ball to clean the upper right hand corner of the instrument cover.
- Remove the backing from the adhesive strip attached to the Bottle Strap Anchor.
- Apply the anchor to the upper right hand corner of the cover, with the latching mechanism closed and facing up. (Figure 1)



**Figure 10-1 Location for Bottle Strap Anchor**      **Figure 10-2 Waste bottle attached**

- Press the anchor firmly in place and let sit for 24 hours so full adhesion can take place.  
**NOTE:** The latching mechanism on the Bottle Strap Anchor should be closed and facing up. (Figure 1)
- Place the Velcro strap through the anchor.
- Place the waste bottle inside the strap, as shown in Figure 2.
- Tighten the strap around the waste bottle.