DYNEX

TECHNOLOGIES

The Microtiter® Company

Opsys MR™ Microplate Reader

User's Guide

IMPORTANT
Please read carefully before using the Opsys MR

Revision History

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Questions or comments regarding the content of this manual can be directed to the address below or to your DYNEX representative.

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Table of Contents

About this Manual

This manual has been written for laboratory technicians and provides detailed instructions for using the *Opsys* MR™ Microplate Reader.

This manual gives you the information needed to:

- Install the *Opsys* MR.
- Set up the *Opsys* MR to suit your specific application requirements.
- Understand the *Opsys* MR menus.
- Run assays using the *Opsys* MR.
- Create or modify assays.
- Perform required preventive maintenance.
- Troubleshoot the *Opsys* MR.
- Service the *Opsys* MR.
- Review safety precautions.

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Chapter 1 Introduction

The *Opsys* MR™ is a microprocessor-controlled photometer. It is designed to measure the optical density (OD) of fluid samples in 96-well microplates in order to quantify the absorbance of various colorimetric chemical reactions.

Effect of Pathlength

Light absorption by a material is determined by the Beer-Lambert law. This states that the:

> **Absorbance of Light** is directly proportional to the product of **Pathlength** and **Concentration**.

- **Pathlength** – is the distance in cm which the light beam travels through the absorbing material.
- **Absorbance** – is usually expressed in terms of a standard cell of 1cm pathlength.
- **Concentration** – is expressed as moles per liter of fluid.

The pathlength through a solution in a microplate well is less than 1 cm. But accurate absorbance values can be obtained as long as equal volumes of Blanks, Standards and Test samples are dispensed into wells of equivalent size and shape.

Optical Path

Figure 1 illustrates the optical path through the Reader. A tungsten halogen lamp projects a light beam through a heat absorbing filter and a lens. The beam is focused by the lens and passes through a filter (located on the filter wheel), which allows only light of the desired wavelength range to pass. The beam is then separated into 13 channels, one of which is used as a reference channel to monitor the light output of the lamp. The other 12 beams are directed upwards through a row of 12 wells on the microplate, onto an array of silicon photodiodes. The silicon photodiodes quantify the intensity of light transmitted through the reaction solution. Absorbance of the solution is measured in terms of optical density (OD) and the assay results are interpreted accordingly.

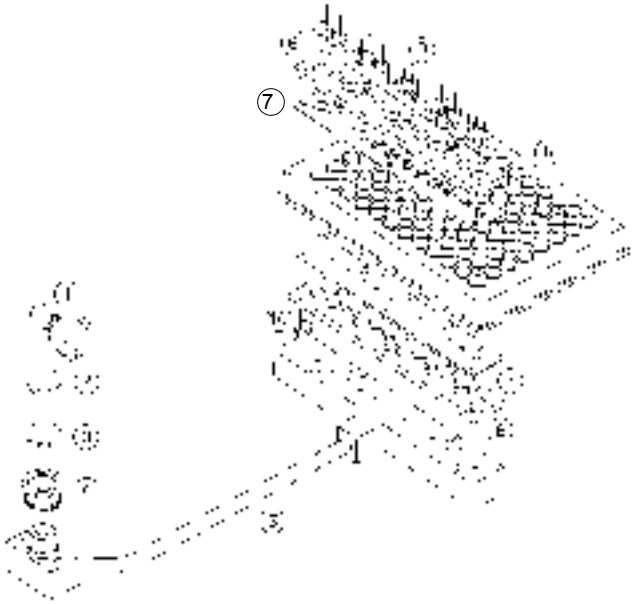


Figure 1. Optical Path of the Reader

1	Lamp	6	Lenses
2	Heat Filter	7	Optic Stops
3	Lens	8	Microplate
4	Filter	9	Photodiodes
5	Optic Fibers	10	Reference Diode

Wavelength Modes

The Reader is able to take readings in three different modes:

- Single--using one test wavelength
- Dual--using one reference wavelength and one test wavelength
- Multiple--using a combination of wavelengths

Single and Dual Wavelength Modes

Using dual wavelength mode can reduce errors caused by dirt and scratches on the bottom of the wells, but single wavelength mode is sufficient for most applications.

The choice of test and reference wavelengths depends on the particular enzyme/substrate system being tested. However, the following rules should usually be followed:

1. The **test wavelength** (λt) should be at or near the maximum absorbance of the reaction product.
2. The **reference wavelength** (λr) should lie outside the absorbance band of the system but not far removed.

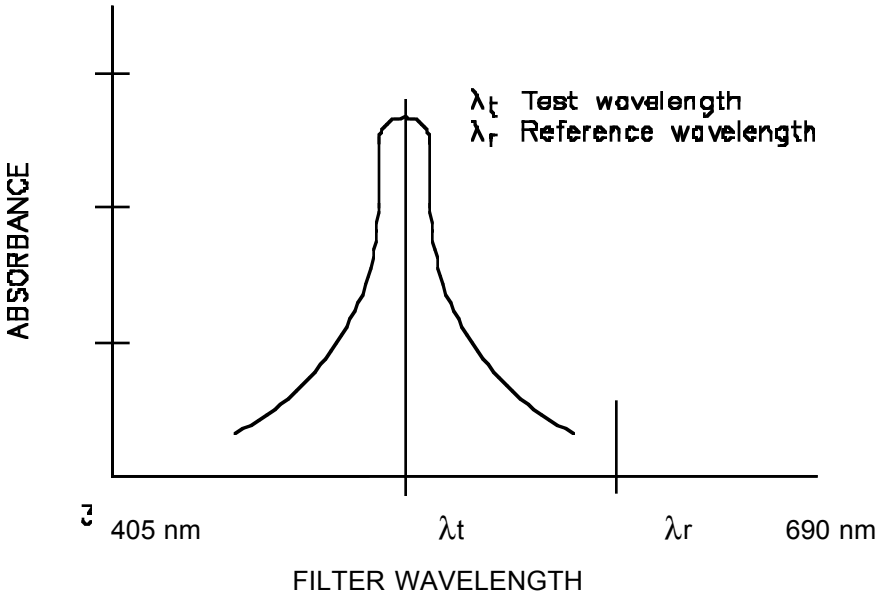


Figure 2. Dual Wavelength Selection

The Reader subtracts the absorbance at the reference wavelength (λr) from the absorbance at the test wavelength (λt) to minimize the effect of systematic errors.

If a test requires particular accuracy, you may specify test and reference filters of the same wavelength. The Reader will average the ODs produced using each filter, giving a more accurate result.

Note: If you have problems choosing filters, use the Spectrum option in the ENDPOINT UTIL Menu to determine the optimum wavelength.

Multiple Wavelength Mode

The multiple wavelength mode reads samples at two different wavelengths and is used to obtain results where the peak absorbance is outside the optical range of the Reader.

The first reading (or the Primary mode) is at or near the peak wavelength. A second reading (or the Secondary mode) of the sample is then obtained at a wavelength that is within the absorbance region but not at the peak.

The Reader automatically uses the Primary mode reading when it calculates results. If, however, the absorbance in the Primary mode exceeds the detection limit of the Reader, the Secondary mode reading is used.

If the Secondary mode reading is used, the peak absorbance is calculated from the secondary mode reading using an algorithm that is selected by the user during configuration of the system.

Blanking

The Reader lets you subtract a reference value from all the ODs. It automatically uses air as a reference, but for certain applications other reference levels may be more appropriate.

For example, you may want to eliminate the absorbance of a reagent solution from the test result. The Reader can hold the OD of this reagent solution in memory and subtract it from all subsequently read ODs.

Blanks may be single wells, or an average of wells.

Applications

Some applications that can be performed on the *Opsys* MR™ are listed below.

These listings are intended to provide a general idea of the kinds of applications that can be used. They are not intended as a comprehensive list of all applications that can be performed.

Research Applications

Test	Discipline	Significance	Filters
Cyclic Nucleotides (e.g. cAMP, angiogenin)	Signal transduction.	Second messenger involved in regulating cellular response.	450 nm
Eicosanoids (e.g., prostraglandins and thromboxanes)	Signal transduction.	Effectors of inflammatory response.	450 nm
Free radicals (e.g. glutathione peroxidase, superoxide dismutase)	Oxidative stress.	Role in artherosclerosis, heart and autoimmune disease.	450 nm
Chemokines (e.g. RANTES, GRO, IL-8)	Signal transduction.	Small, inducible secreted cytokines effecting immune and inflammatory response.	450 nm
Cell Adhesion Molecules (e.g., GM-CSF, VCAM)	Signal transduction/ wound response.	Inflammatory and immune response against wounding and infection.	450 nm
Apoptosis Markers (e.g. Bxl-2, sAPO-1)	Cell cycle.	Markers involved in programmed cell death.	450 nm (test) 595 nm (ref)

Test	Discipline	Significance	Filters
Nucleosome analysis	Apoptosis.	Measure chromatin response to apoptosis.	450 nm (test) 595 nm (ref)
p53	Cell cycle and tumor suppression.	p53 is an essential cell cycle regulator and tumor suppressor.	450 nm
PCR Detection	Molecular biology.	Gene Quantification.	450 nm
RT-PCR Detection	Molecular biology.	Quantification of gene expression.	450 nm

Clinical Applications: Infectious Disease

Test	Clinical Significance	Filters
Chagas disease	Caused by *Trypanosoma cruzi*, an intracelluar parasite. Acute disease may cause fever, tachypnea and tachycardia.	405 nm
Cytomegalovirus	Widespread, with asymptomatic infection.	405 nm
Epstein-Barr virus	Infectious mononucleosis. Also implicated in Burkitt's lymphoma and Nasopharyngeal carcinoma.	405 nm
Herpes Simplex Type 1	Clinical symptoms include gingivostomatitis, keratitis, vesicular skin eruptions and aseptic meningitis. Associated with orolabial infections.	405 nm
Herpes Simplex Type 2	Found primarily in adults. Associated with urogenital infections.	405 nm

Applications

Test	Clinical Significance	Filters
Lyme Disease	Disease cause by tick-transmitted spirochete. Causes Influenza like symptoms. May cause arthrtitic, cardiac or neurological disorders. Severe cases result in giant cell pneumonia and acute encephalitis.	405 nm
Rubella (German Measles) Disease	German measles, a benign and contagious disease in children. Severe risk or fetal death to first trimester pregnant women.	405 nm
Toxoplasma Gondii	Caused by intracellular parasite. High risk group includes immunosuppressed patients and infants.	405 nm
Varicella-Zoster Virus	Herpes-like virus that causes chickenpox and shingles.	405 nm
Legionalla	Detection of Legionella pneumophila.	405 nm
Mycoplasma	Detection of Mycoplasma pneumonia.	405 nm
HIV p24 Antigen	AIDS characterization.	405 nm

Clinical Applications: Automimmune Diseases

Test	Clinical Significance	Filters
ENA (Extractable Nuclear Antigens)	High frequency in systemic rheumatic disease. Extractable nuclear antigens include SS-A/Ro, SS-B/La, Sm, and RNP.	405 nm
Jo-1 (Histidyl-tRNA Synthetase)	Associated with systemic rheumatic diseases (i.e., polymyositis and dermatomyositis).	405 nm
SmRNP	Sm is associated with systemic lupus erythematosus. RNP (RiboNuclear Protein) is associated with connective tissue disease.	405 nm
Scl-70 (Topoisomerase I)	Associated with scleroderma.	405 nm
dsDNA (Double-stranded DNA)	Aid in the diagnosis of systemic lupus erythematosus.	405 nm
Cardiolipin	Thrombosis. Thrombocytopenia. Systemic lupus erythematosus.	405 nm
Myeloperoxidase	Diagnosis of vasculitic disorders caused by anti-neutrophil cytoplasmic antibodies.	405 nm

System Features

The *Opsys* MR™ has a number of performance and convenience features:

- Endpoint data analysis to perform Qualitative and Quantitative data reduction
- Less than 10 second reading time (using single wavelength)
- RS232C port for external control
- On-board self diagnostics
- Optional Verification Plate to perform periodic checks
- Selection of up to six filters
- Single, dual and multiple wavelength reading modes
- Data output to a dot matrix printer (Epson LX-300 or equivalent) or Hewlett Packard LaserJet printers (HP LaserJet Series II or equivalent)
- Easily removable absorbance module for servicing

Software Features

The Endpoint program is designed to perform qualitative and quantitative data reduction absorbance readings obtained by the *Opsys* MR™.

Features and specifications of the Endpoint Program are summarized below:

Menu Language	English
Blanking	Air Individual, paired or average wells Whole plate or last plate Row or column Each well on the plate
Clock Function	Day, date and time
Tests per Plate	12
Short Menu Test Selection	Eight function keys available
Wavelength Modes	Single, dual or multiple
Standard Curves	Linear, quadratic, cubic, quartic, spline, polygon, sigmoid or AKIMA
Additional Data Analysis	Threshold, ratio, QC equations
Flexible Template	Up to eight different well types.

Specifications

Dimensions and Weight

Depth	36 cm (14.2 in)
Width	33 cm (13.0 in)
Height	13 cm (5.1 in)
Weight	7.3 kg (16 lbs)

Performance

Wavelength range	405 - 690nm
Optical range	0.000 - 3.500 OD
Accuracy	± 0.010 OD or 2.5% (0.000 OD to 3.000 OD), whichever is greater
Linearity	± 1% from 0.000 OD to 2.500 OD ± 1.5% above 2.500 OD
Precision	± 0.010 OD below 0.500 OD <1% CV between 0.500 OD and 2.000 OD <1.5% CV between 2.001 OD and 3.000 OD
Resolution	± 0.001 OD

Operation

Read Modes	Single or Dual wavelength
Reading Time	< 10 seconds Single wavelength < 20 seconds Dual wavelength
Data storage	2Mb Flash memory
Printer interface	Parallel Centronics.
Power	60W
Display	2 by 20 character back lit LCD
Keypad	21 key tactile membrane
Output	Display, Printer, RS232C
Filters	6 position wheel
Shaking	Three user selectable modes

Power Requirements

	Voltage	Power	Frequency
Main Unit	100 - 120 V 220 - 240 V	200 VA 200 VA	50/60 Hz 50/60 Hz
Line Voltage Variation	± 10%		
Line Frequency Variation	± 3 Hz		

Environmental

Operating Range	15° C to 30° C 15% to 85% relative humidity (non-condensing)

Computer Interface

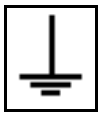
Port	Serial RS-232C port.
Baud Rate	9600
Character Format	8 data bits, 1 stop bit, even parity

Standards

The instrument is designed in accordance with CSA 1010, UL 3101, IEC 1010, EN61010 and EN61386.

Warning Labels

The *Opsys* MR™ or its components may contain certain labels that that either warn the user of a hazard or note an electrical connection. The labels that may be used on the *Opsys* MR are described below.

Label	Description
	Alternating current is present.
	(*English*) Caution symbol. Refer to the *Routine Maintenance* chapter. (*French*) Attention (voir documents d'accompagnement).
	(*English*) Caution, hot surface. (*French*) Attention, surface chaude.
	Protective conductor terminal.
	Earth (ground) terminal.
	(*English*) Caution, risk of electric shock. (*French*) Attention, risque de choc électrique.

Chapter 2 Installation

Unpacking

Materials Provided

The *Opsys* MR™ is packaged in a single carton. The contents of the carton are listed below:

Article	Quantity
Opsys MR	1
Instrument Power Cable	1
Printer Cable	1
Microtiter® Plate Starter Kit	1
Filter Pliers	1
Quick Installation Guide	1
Operator's Manual	1
Quick Reference Guide	1
CD-ROM Video Setup/Installation/ Training	1
Shipping Check List	1
Warranty Card	1
QC Form	1

To unpack the components:

1. Unpack the contents of the carton. Refer to the *Quick Installation Guide* packed with this *Operator's Manual*.

2. Place the *Opsys* MR™ instrument in the position where it will be located.

3. Examine the packaging to be sure that all other materials have been removed. Please save packaging material for possible future use.

4. Verify that all of the materials listed on page 17 have been unpacked.

5. Inspect the components for damage. If damage is observed, contact your shipper and your DYNEX technical service representative immediately.

6. Open the carrier plate door and remove the foam shipping chuck from the carrier plate.

The *Opsys* MR Instrument

The *Opsys* MR™ instrument is shown in Figure 3. All of the components (except the optional printer) are contained with the instrument.

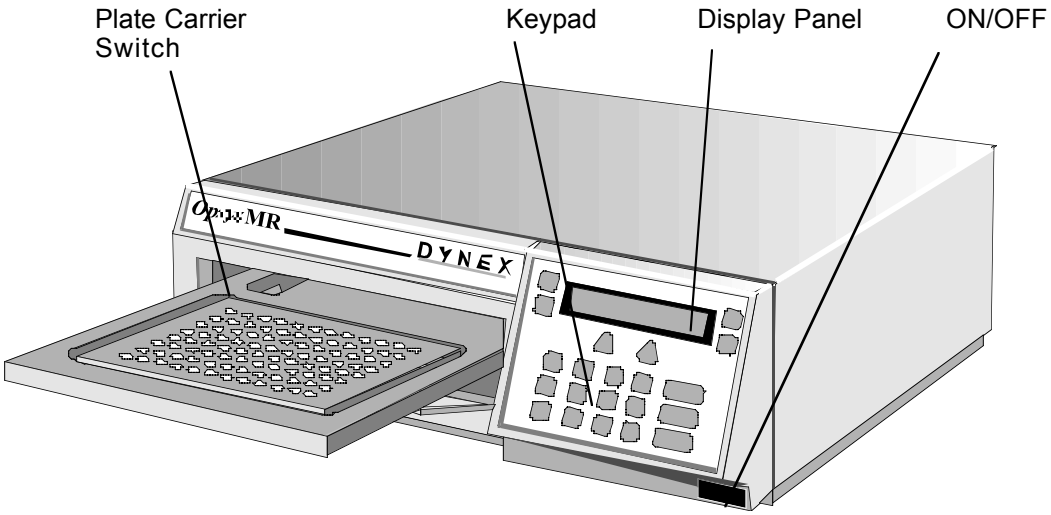


Figure 3. The *Opsys* MR

Hardware Components

The major hardware components of *Opsys* MR are described below.

- **Measurement Chamber**. The measurement chamber contains the plate carrier system and the electro-optical system.
- **Plate Carrier**. The plate carrier aligns each Microtiter® Plate well under the photodiodes so that the absorbance of the reaction mixture in the wells can be read.
- **Electro-optical system**. The electro-optical system measures the absorbance of the contents of each well in the Microtiter® Plate.

- **Display Panel**. The display panel is the means by which the system communicates to the user. All messages, commands, and assay parameters entered by the user are displayed. The display panel can also be used to view results, if a printer is not connected.
- **Keypad**. The keypad is used to select commands and enter assay parameters.
- **Printer** (not supplied). Use of a printer makes it possible to print results.
- **RS232C Interface**. The RS232C interface allows serial communication with a computer.

The rear of the *Opsys* MR™ is shown in Figure 4. Connections for the power cord, the printer, and an external computer are made at the rear of the system.

The access panel for the optical filters is also located at the rear of the instrument.

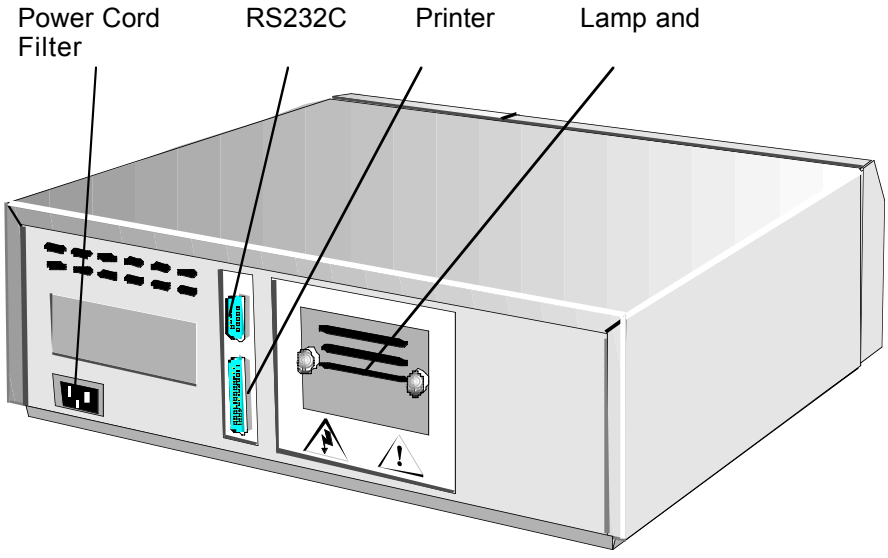


Figure 4. Rear View of the *Opsys* MR System

The Plate Carrier

The plate carrier holds the Microtiter® Plate. During an assay, the plate carrier precisely positions each well under the photometer so the absorbance of that well can be measured.

If needed, the plate carrier can be manually extended from the instrument by pressing the scroll down key (Figure 5). The carrier can also be retracted back into the instrument by pressing the scroll up key.

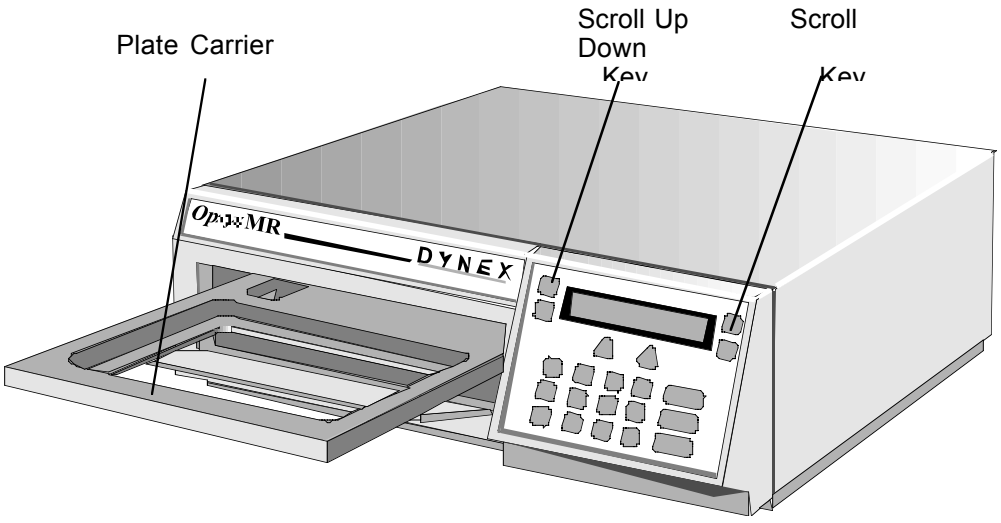


Figure 5. The Plate Carrier

Placement of the Instrument

Determine the area where the system will be located. You will need a level area that is approximately 36 cm (14 inches) wide, 40 cm (16 inches) deep and 15 cm (6 inches) high for the *Opsys* MR™, and additional space for the printer.

The *Opsys* MR must be placed in an area where there is at least six inches of space in front of the instrument to allow the plate carrier to extend from the instrument.

CAUTION: Do not place any other material or equipment in front of the *Opsys* MR.

Connecting a Printer

To connect a printer (if used):

1. Plug the 25-pin end of the printer cable into the printer port receptacle at the rear of the instrument (Figure 4).

2. Plug the other end of the printer cable into the printer cable receptacle marked **PARALLEL** at the rear of the printer.

25-Pin End
Plug Into Printer Port
Printer

Plug Into Port
Located on
of Instrument

Figure 6. Connectors on the Printer Cable

Connecting an External Device

To connect an external device (if used):

1. Plug the communication cable from the external device into the RS232C port at the rear of the instrument. See Figure 4 for the location of the RS232C port.

2. Refer to *Setting Communication Options* in the next chapter for instructions on configuring the system to accommodate the external device.

Turning on the Reader

Note: Depending upon local electrical codes, an uninterruptible power system (UPS) may be required in your laboratory. A UPS is not provided with the *Opsys* MR.

Note: Before turning the system ON for the first time, be sure to check that the foam shipping chuck has been removed from the plate carrier block area.

1. Connect the *Opsys* MR™ and the printer (if used) to the laboratory electrical supply outlet.

CAUTION: The *Opsys* MR instrument and the printer must be connected to properly grounded electrical outlets. Obtain assistance from a qualified electrician to verify that your electrical outlets are properly grounded.

Before connecting the power cables, be sure that the components have been connected to each other as outlined in the previous section.

2. Turn the power to the printer ON (if used).

3. Push the instrument power switch once (Figure 3). After a series of self-tests, the following will be displayed:

```
READY 14JUL98 10:43A
ENDPOINT   SETUP
```

Note: Self-test results indicate whether the system is operating properly. Refer to the following section for a detailed description of the self-tests that are performed.

If a self-test failure is reported, refer to the *Troubleshooting* chapter in this manual. For further assistance, call DYNEX Technical Service at 1.800.336.4543.

Self-Test

Description

The checks that are performed during self-test are described below:

Test	Description
Filter Motor	Operation of the motor and sensing of the index position is checked by rotating the filter wheel through a full revolution.
Plate Motor	The plate carrier is moved IN and OUT to check the operation of the motor and the position sensors along the movement path.
Background Light Level	The level of background light within the chassis is checked to ensure that there is no external light leakage. The dark reading position is checked with the lamp ON to ensure that the dark reading value is within acceptable limits.
Lamp Voltage Test	The lamp voltage is checked to insure that the lamp filament is intact and that the lamp driver circuit is functioning properly.
Lamp Margin Test	The lamp intensity is checked to verify that it is operating at a level below maximum to insure proper regulation of lamp intensity.
Lamp Calibration Test	The lamp intensity is adjusted using the 405 nm filter until the minimum and maximum clear channel readings fall within set limits.
EEPROM	The entire EEPROM is read and the resulting data is analyzed to insure that the EEPROM is functioning properly.

Frequency of Self-Tests

The *Opsys* MR™ performs a self-test whenever the system is turned ON. In addition, the system can be configured to perform a self-test before each test.

Note: Refer to page 42 for instructions to specify a self-test to be run before each test.

Printing Self-Test Results

The *Opsys* MR can be configured to print the self-test results.

Note: Refer to page 42 for instructions to specify printing of self-test results.

Chapter 3 Configuration

The Keypad

The keypad is used to access the various menus and commands for setting up the Reader, entering assay protocols and running your assays. The keypad contains **scroll keys**, **function keys**, and **entry keys** (alphanumeric and equation).

The keys on the keypad are shown in Figure 7.

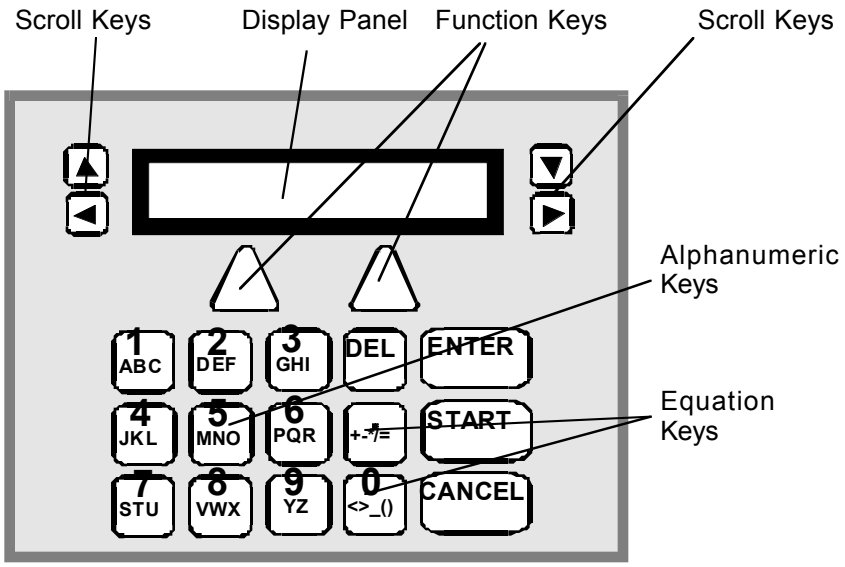


Figure 7. Keys on the Keypad

The use of each key is summarized below:

Key	Purpose
Scroll keys	The functionality of the scroll keys depends on what is being displayed. If a **menu** is active, a vertical scroll down will eject the plate from the Reader and a vertical scroll up will retract the plate into the Reader. Horizontal scrolls will scroll through selections for the selected menu. Repeatedly pressing the horizontal scroll button will show the next two items in a list. A list with only one item will have a blank entry. If you are **entering or editing information**, a scroll will move the cursor through edit fields.
Function keys	Function keys execute the command shown directly above the key on the second line of the display.
"Del" key	Removes the character at the cursor location and moves all characters right of the cursor one space to the left if a field is being edited. When the Reader displays a modifiable entry, selecting Delete will allow field entries to be modified.
"Enter" key	Completes an entry of characters or accepts default prompt data.
"Start" key	Begins an assay. This can be selected from various locations depending on what menu is displayed.
"Cancel" key	Terminates the current function and returns to the previous function.

Alphanumeric Keys	The numeral shown on the key is displayed by pressing the key once. If the key is pressed two to four times rapidly in succession, one of the letters on the key will be displayed. The letter that is displayed depends upon the number of times the key is pressed. For example, for the **1** key, a single press will cause the numeral **1** to be entered, However, if the key is pressed three times rapidly in succession, the letter **B** will be entered.
Equation Keys	This key functions the same as the alpha-numeric keys.

Menus

Once the instrument is turned ON and the self-test routines are successfully completed, the ENDPOINT and SETUP menu headings are displayed:

The ENDPOINT and SETUP menus are accessed by pressing the Δ key immediately below the selection on the display.
A menu selection can be cancelled and the previous (higher level) menu is displayed by pressing the CANCEL key.

The use of the ENDPOINT and SETUP menus are summarized below:

Selection	Purpose
ENDPOINT	The Endpoint menu is used to create, edit, run and analyze assay test procedures. It can be displayed in Long or Short format.
SETUP	The Setup menu is used to configure the Reader.

The SETUP Menu

The SETUP menu menu (Figure 8) contains selections for configuring FILTERS, CLOCK, SYSTEM, MAINT, COMMS, and PARAM. The FILTERS and CLOCK selections are displayed initially, and the other selections are displayed using the right horizontal scroll key.

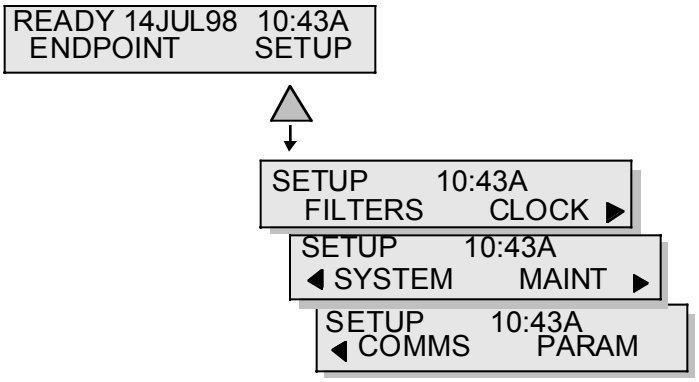


Figure 8. The SETUP Menu

Selection	Purpose
FILTERS	Edit the number of filters and filter wavelength installed on the system.
CLOCK	View and edit the time of day, the date, and the format in which the time and date are presented.
SYSTEM	Specify the language that is used. Specify whether the system beeps whenever a key is pressed. Specify the printer that is used. Enter the laboratory name that appears on reports.
MAINT	Specify whether self-test results are printed, whether the self-test is repeated before a test is read, and whether a maintenance reminder is displayed at a defined interval.
COMMS	Specify instrument communication parameters.
PARAM	Specify absorbance limits, whether data conversion should occur and the plate type.

The ENDPOINT Menu

The contents of the ENDPOINT menu depend upon whether **Long** menus or **Short** menus are specified.

If the *Opsys* MR™ is configured to display the Long menu, this menu contains selections for START, RECALL, UTIL, and PROGRAM (Figure 9). The START and RECALL selections are displayed initially and the other selections are displayed using the right horizontal scroll key.

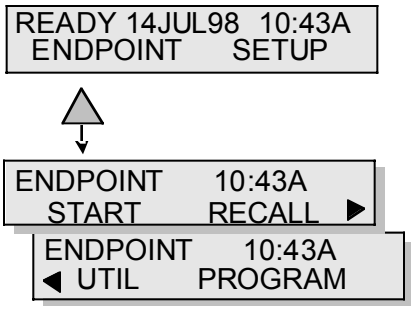


Figure 9. ENDPOINT Long Menu

Selection	Purpose
START	This selection is used to start a test. The system will then prompt for the test number, number of samples and Plate ID (if selected).
RECALL	This selection allows the user to retrieve data for plates that were previously read using the original assay or you may choose to select a new assay.
UTIL	This selection allows the user to perform a manual reading, carry out additional calculations, select whether Long Menus or Short Menus are displayed, and display software version information.
PROGRAM	This selection allows the user to create a new assay, modify an existing assay, print details of an existing assay, or to print a listing of all of the tests and plate data.

If the *Opsys* MR™ is configured to display the Short Menu, the ENDPOINT menu will display eight previously created tests that can be run by pressing a function key (Figure 10). The final selection is named ENDPOINT, which causes the long menu to be restored.

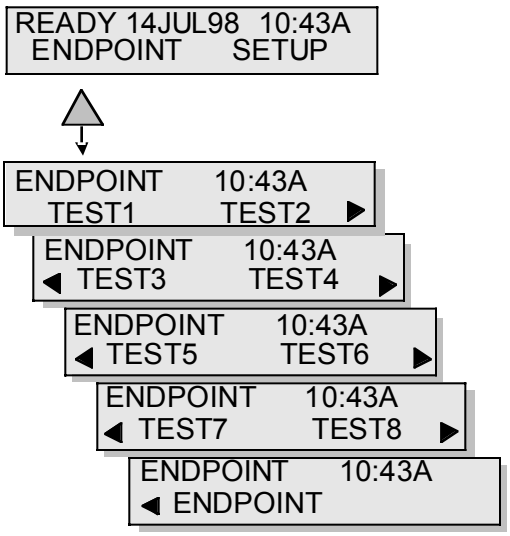


Figure 10. ENDPOINT Short Menu

Note: Select UTIL from the Long Menu display to define and select the Short menu option.

Setting up the System

Before you operate the *Opsys* MR™ for the first time, certain instrument parameters should be configured. The commands for doing this are contained on the SETUP menu:

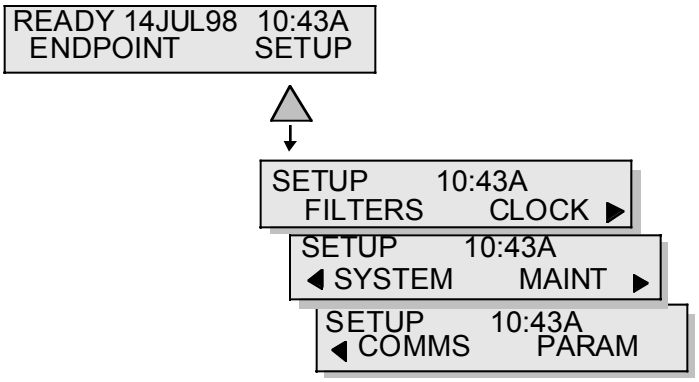


Figure 11. SETUP Menu

The procedures for configuring these parameters are outlined in the following sections.

Specifying the Filters

The FILTERS command allows you to specify the number of filters that are installed and the wavelength of each filter.

To specify the filters:

1. Select SETUP. The display will read:

SETUP	10:43A
FILTERS	CLOCK □

2. Select FILTERS. If four filters are currently installed, the display will read:

NO. OF FILTERS = 4

3. Press ENTER to confirm the number of filters shown, or use the keypad to enter a new number. Once the number of filters has been entered the Reader will prompt for the wavelength of each filter.

FILTER 1=405 nm

4. Use the keypad to modify the wavelength value. Use the ENTER key to accept the displayed wavelength and move to the next filter position.

5. After wavelengths have been entered for all filters, the system will perform an internal calibration. The display will return to the SETUP menu when calibration is completed.

Note: Up to 6 filters can be installed. The filters must be installed in ascending order of wavelength.

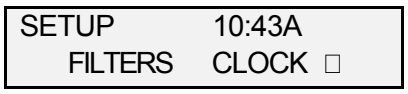
Important: The system is shipped with a 405 nm filter installed in **Filter Position 1**. The 405 nm filter must remain in this position for proper operation.

Setting the Time and Date

The CLOCK command allows you to set the current time and date and to specify the format in which the time and date are reported.

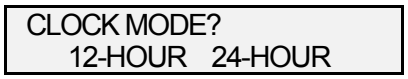
To specify time format and set the time:

1. Select SETUP. The display will read:



2. Select CLOCK. The display will read:

3. Select TIME. The display will read:



4. Select the appropriate format. If you selected the 12-hour format, the display will read:

   If you selected the 24-hour format, the display will read:

5. If the 12-hour format is being used, use the Function keys to select AM or PM.

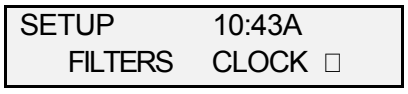
6. Use the numeral keys to enter the correct time. Be sure to enter zeros where they are needed.

7. Press ENTER to save the entered time and time format.

8. Press CANCEL to return to the main menu.

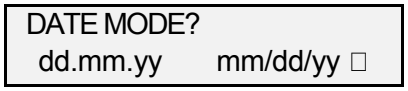
To specify date format and set the date:

1. Select SETUP. The display will read:

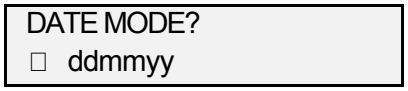


2. Select CLOCK. The display will read:

3. Select DATE. The display will read:



   If necessary scroll right to view the remaining option:



4. Select the appropriate date option.

5. Use the numeral keys to enter the correct date.

6. Press ENTER to save the entered date and date format.

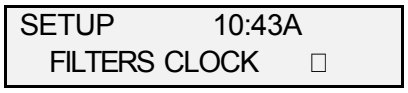
7. Press CANCEL to return to the main menu.

Setting Language, Keypad and Printer Options

The SYSTEM command allows you to specify the language, specify whether the keypad beeps when pressed, specify whether a printer is present, identify the printer that is used, and specify the length and width of the printed page.

To specify the language (if available):

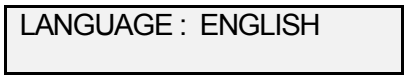
1. Select SETUP. The display will read:



   Scroll right to view the next selections:

2. Select SYSTEM. The display will read:

3. Select LANGUAGE. The display will read:



4. If the language is to be changed, press DELETE. The display will read:

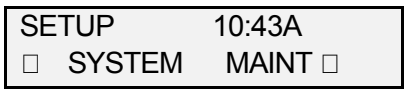
5. Select the desired language by pressing the function key. Then, press ENTER to save the specified language.

> **Note**: Use the scroll keys to display any additional language choices that are available.

To specify keypad beep:

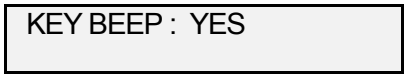
1. Select SETUP. The display will read:

   Scroll right to view the next selections:

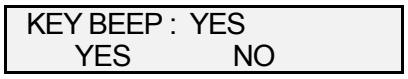


2. Select SYSTEM. The display will read:

3. Select KEYPAD. The display will read:



4. If the keypad beep is to be changed, press DELETE. The display will read:



5. Select the desired option by pressing the function key. Then, press ENTER to save the specified keypad beep.

To specify printer parameters:

1. Select SETUP. The display will read:

```
SETUP          10:43A
   FILTERS   CLOCK    □
```

Scroll right to view the next selections:

```
   SETUP          10:43A
□  SYSTEM    MAINT  □
```

2. Select SYSTEM. The display will read:

```
SETUP?
  LANGUAGE  KEYPAD □
```

Scroll right to view the next selections:

```
SETUP?
□  PRINTER
```

3. Select PRINTER. The display will read:

```
EPSON LX-810                 □
```

Scroll right to view the next selections:

```
□  HPLASERJET                □
```

```
□    NO PRINTER
```

Note: Select Epson LX-810 if the Epson LX-300 printer is being used.

4. Select the desired option. If a printer is selected, the display shows the page length (in inches):

```
PAGE LENGTH= 11.000
```

5. Use the numeral keys to enter the correct page length.

To specify printer parameters (continued):

6. Press ENTER to accept the specified page length. The display shows the page width (in inches):

   PAGE WIDTH= 8.500

7. Use the numeral keys to enter the correct page width.

8. Press ENTER to accept the specified page width. The display shows the laboratory name (up to 16 characters):

   ACE LABORATORIES

9. Use the numeral keys to enter the correct laboratory name.

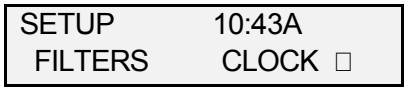
10. Press ENTER to accept the specified laboratory name.

Setting Maintenance Options

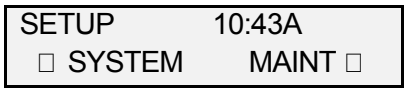
The MAINT command allows you to specify whether the self-test is printed, specify whether a self-test is run before each test, and to specify the frequency at which a maintenance reminder is displayed.

To specify maintenance options:

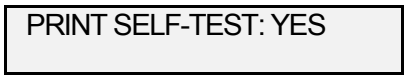
1. Select SETUP. The display will read:



   Scroll right to view the next selections:



2. Select MAINT. The display will read:



3. If the printing of self-test results is to be changed, press DELETE. The display will read:

4. Select the desired option by pressing the function key. Then, press ENTER to save the specified self-test printing option.

5. The display will then read:

6. If performing of a self-test before reading is to be changed, press DELETE. The display will read:

7. Select the desired option by pressing the function key. Then, press ENTER to save the specified self-test option.

8. The display will then read:

```
MAINTENANCE: NO
```

9. If the frequency of the maintenance reminder is to be changed, press DELETE. The display will read:

```
MAINTENANCE: NO
     NO          DAILY
```

Scroll right to view the next selections:

```
MAINTENANCE: MONTHLY
□  WEEKLY  MONTHLY □
```

Note: If you select NO, the reminder will not be displayed.

10. Select the desired option by pressing the function key. Then, press ENTER to save the specified maintenance reminder option.

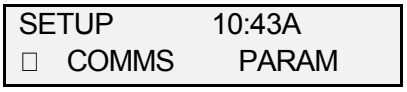
Setting Communication Options

The COMM command allows you to specify communication parameters. These parameters may need to be changed if an external device is connected to the *Opsys* MR™ RS232C port.

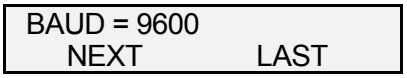
To specify communication options:

1. Select SETUP. The display will read:

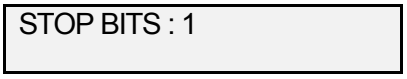
   Scroll right twice to view the final selections:



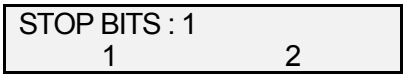
2. Select COMMS. The display will read:



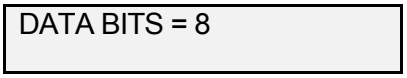
3. Select NEXT or LAST to display the baud rates that can be used. When the correct baud rate is displayed, select ENTER to accept the baud rate and display the stop bits:



4. If the stop bits are to be changed, press DELETE to display the stop bit choices:



5. Press the function key corresponding to the desired stop bits. The selected stop bits are saved and the data bits are displayed:



6. If the data bits are to be changed, press DELETE to display the data bit choices:

```
DATA BITS = 8
      7              8
```

7. Press the function key corresponding to the desired data bits. The selected data bits are saved and the parity setting is displayed:

```
PARITY = EVEN
```

8. If the parity setting is to be changed, press DELETE to display the first parity choices:

```
PARITY = EVEN
  NONE        EVEN □
```

Scroll right twice to view the final selections:

```
PARITY = EVEN
□  ODD
```

9. Press the function key corresponding to the desired parity setting.

10. When the communication options have all been selected, press ENTER to save the settings.

Setting Reader Parameters

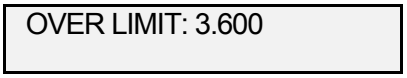
The PARAM command allows you to specify reader parameters.

To specify reader parameters:

1. Select SETUP. The display will read:

   Scroll right twice to view the final selections:

2. Select PARAM. The display will read:



3. If the range of acceptable ODs must be changed, press the DELETE key and use the numeral keys to enter the absorbance limit (from **0.000** to **3.600**).

> **Note**: An absolute value is used for absorbance limit. Absorbance values beyond this limit will not be processed. For example, if the OVER LIMIT is **3.600**, absorbance above **+3.600** will not be processed. This limit is also used as an UNDER LIMIT, and absorbance below -**3.600** will also be rejected.

4. When the correct limit is displayed, select ENTER to accept it. If the limit was modified, the Reader will prompt for the data conversion value.

5. If a data conversion value is to be entered (or changed), press DELETE. The display will read:

DATA CONVERSION: NO
YES NO

6. Select the desired option by pressing the function key and then press ENTER to save the selected option. The Reader will then prompt for both an OVER and UNDER VALUE:

OVER VALUE= 2.000

7. Input the value and press ENTER.

Note: The **OVER** and **UNDER** values are used in quality control equations. If no conversion values are provided QC equations which contain Over or Under Limit ODs will fail. The minimum Over Value is 0.000 and the maximum Over Value is 9.999. The minimum Under Value is –9.999 and the maximum Under Value if 0.000**.**

8. The Reader will prompt for plate type:

PLATE TYPE: 12x8
12x8 10x4

9. Press ENTER to accept the displayed type, or use the Function Key to select the alternative format.

Note: Two plate types are available. The first has 12 columns (named 1 through12) by 8 rows (named A through H), and the second has 10 columns and 4 rows.

10. Press CANCEL to return to the main menu.

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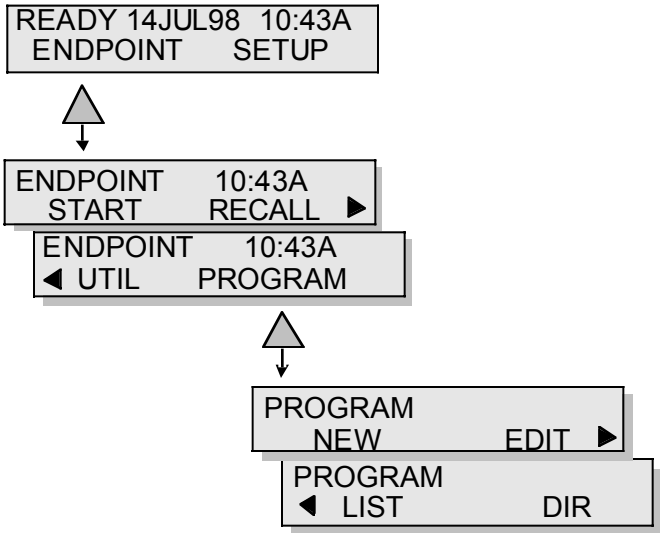
Chapter 4 Assay Programming

Creating and Editing Assays

The commands for creating a new assay procedure or editing an existing procedure are contained under the PROGRAM option on the ENDPOINT menu:



Command	Purpose
NEW	Create a new assay test procedure.
EDIT	Modify or copy an existing assay test procedure.
LIST	Print all the steps in an assay test procedure.
DIR	Print directories of tests or plates.

The procedures for performing these commands are outlined in the following sections.

Creating a New Assay

Once you have configured the *Opsys* MR™, you are ready to define an assay using the NEW command.

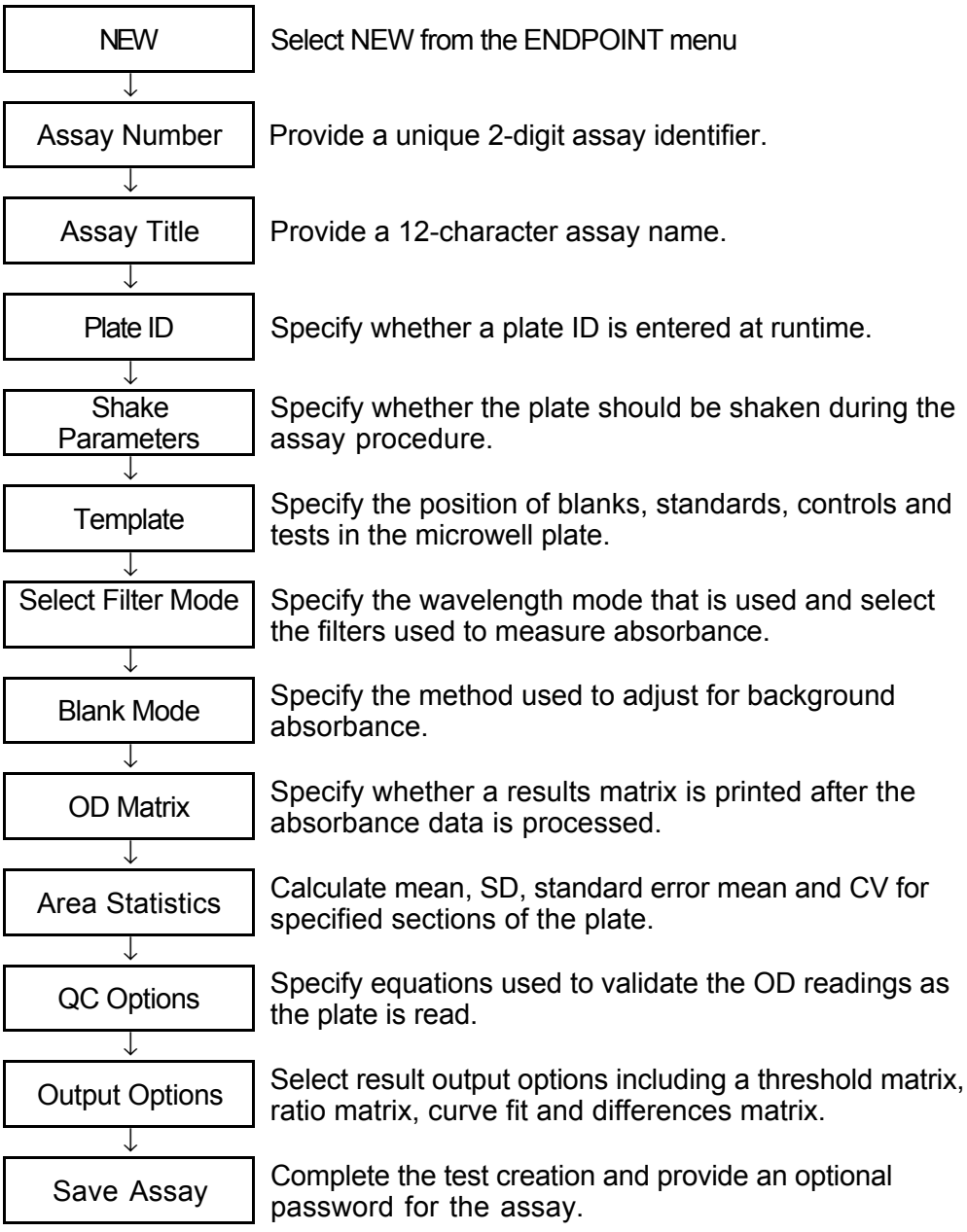
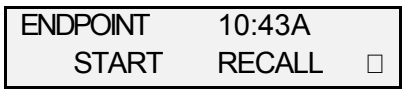


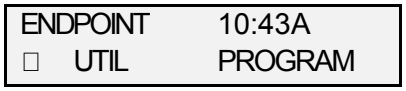
Figure 12. Creating a New Assay (Overview)

To create a new assay:

1. Select ENDPOINT from the Main menu. The display will read:



   Scroll right to view the next selections:



2. Select PROGRAM. The display will read:

3. Select NEW.

Assay Number

1. After NEW has been selected the display will read:

2. Using the keypad or scroll keys input the test number. Press ENTER to save the specified number.

3. If the test number was already used, the name assigned to that number (ABCD in the example) will be shown in the CLEAR TEST display:

4. Select NO to preserve the original test and return to the PROGRAM Menu. Select YES to overwrite the test.

   If you choose to overwrite and the test was protected by a password, the PASSWORD prompt will display:

5. Using the alphanumeric keypad, enter the password. Press ENTER to submit the password, or CANCEL to return to the Endpoint Main menu.

   An incorrect password returns to the Endpoint Main menu.

Assay Title

1. Once a valid test number has been entered, a request for test NAME will be displayed:

2. Using the alphanumeric keypad, enter a test name.

> **Note**: A valid test name is up to 12 characters in length. The name can contain numbers 0-9, a decimal point, and upper-case letters**.**

3. Press ENTER to save the name. Press CANCEL to return to the test number prompt.

Plate ID

1. Saving the assay name displays the Plate ID Prompt:

2. Select YES if you want to specify a plate ID at runtime. If you select NO, the Reader will assign a default ID.

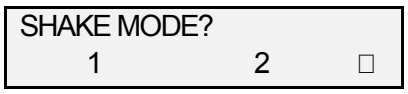
> **Note**: Default IDs are numbered 0000-0099**.** If you use the default option, the Reader will overwrite IDs when no more numbers are available, with no indication of the overwrite. Select YES to facilitate recall of plate data at a later time.

Shake Parameters

1. The next prompt is for SHAKE time:

2. If shake is not required, enter 0. To enable shaking, enter the shake duration in seconds between 1 and 9.

3. If you specified a shake time, the next display will be for shake mode:



4. Select shake mode 1, 2 or scroll right and select mode 3.

Mode	Description	Shake Intensity
1	Low Shake	Frequency 10 Hz and amplitude 4.0 mm
2	Medium Shake	Frequency 15 Hz and amplitude 2.0 mm
3	High Shake	Frequency 20 Hz and amplitude 1.0 mm

Templates

The Template option allows you to assign well types to well positions, rename well types, create and name new well types, and specify the number of replicates, the orientation, and the fill direction.

	1	2	3	4	5	6	7	8	9	10	11	12
A	B1	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	S2
B	B1	T11	T12	T13	T14	T15	T16	T17	T18	T19	T20	S2
C	S1	T21	T22	T23	T24	T25	T26	T27	T28	T29	T30	C5
D	S1	T31	T32	T33	T34	T35	T36	T37	T38	T39	T40	C6
E	C1	T41	T42	T43	T44	T45	T46	T47	T48	T49	T50	B2
F	C2	T51	T52	T53	T54	T55	T56	T57	T58	T59	T60	B2
G	C3	T61	T62	T63	T64	T65	T66	T67	T68	T69	T70	B2
H	C4	T71	T72	T73	T74	T75	T76	T77	T78	T79	T80	B3

Figure 13. A Typical Template

A typical template is shown in Figure 13. For other examples, please refer to Appendix B.

Two replicate Blanks (B) are positioned down the columns in wells A1 and B1. Three replicate Blanks are positioned in wells E12 through G12. A third Blank has been positioned in well H12. Two replicate Standards (S) have been placed in wells C1 and D1. Two replicate Standards are also placed in wells A12 and B12. A total of six individual Controls (C) are positioned in wells E1, F1, G1, H1, C12 and D12. Single Test samples (T) occupy the remaining eighty wells.

The options used to design this template are described in this section. The B/S/T/C option was used to enter the Blanks, Standards, Tests and Controls. The UTILITY/FILL option was used to fill the remaining wells of the template with Test samples after the first Test sample was entered.

Defining a Template

1. After plate ID and shake parameters are input, the Reader will ask if the template should be defined manually or automatically:

2. Selecting the YES option will display a Manual Template Menu consisting of four options:

Command	Purpose
B/S/T/C	Assign **B**lank, **S**tandard, **T**est or **C**ontrol to the selected well locations.
USER	Create and assign your own well types.
UTILITY	Define the template, using various tools.
FINISH	Save the defined template.

Selecting the AUTO option will cause the Reader to prompt for the positioning of Standard and Test wells only.

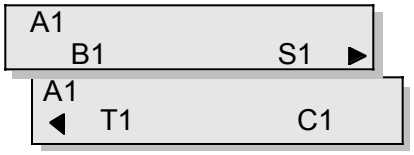
Note: If your template contains Blanks or Controls you must select the manual option.

Procedures for both of these options are described in the following sections.

Manual Definition

To assign B/S/T/C Wells:

1. Select B/S/T/C from the Manual Template menu.



2. Use the up and down cursor keys to select the starting well location, A1 through H12.

3. Use the Function keys to select the well type B(lank), S(tandard), T(est) or C(ontrol). The sequence number (1 in the example) will be automatically assigned.

4. The Reader will prompt for the number of Replicates of this well type:

Note: Replicates are wells filled with the same sample. Replicate wells are averaged into a single value. You can select between 1 and 4 replicates for each sample. You can specify that each sample of a particular well type will contain the same number of replicates or that some samples will contain a different numbers of replicates (mixed replicates).

5. If you want to assign the same number of replicates to all of the samples of this well type, type the number of replicates (1 to 4) and then press ENTER. If you want to assign different numbers of replicates to samples, select MIXED and then press ENTER.

6. If you selected more than one replicate or mixed replicates, the reader will prompt for orientation:

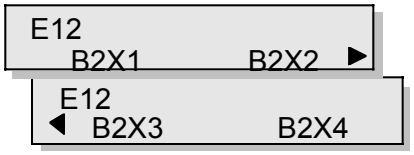
7. Use the Function Keys to arrange the replicates top to bottom (columns) or left to right (rows).

> **Note**: To assign the first two Blanks in the Figure 13, accept **A1** as the starting well, select type **B1**, enter **2** replicates and then specify **column** orientation.

8. The reader will prompt if the next well of this type is to be placed in the next available column or row.

9. Use the Function Keys to select the positioning of the next well of the indicated type.

10. Each time you select a well type that has been assigned in mixed replicates, the Reader will ask you how may replicates you want to assign to this sample.



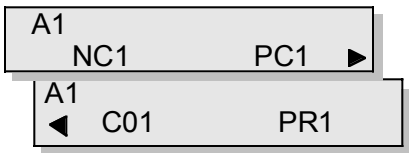
> **Note**: In the above example **E12** is the well position, **B2** indicates this is the second blank sample to be assigned, and **X*n*** is the replicate option. To assign the second Blank sample shown in Figure 13, select **B2X3**.

The Reader will return to the B/S/T/C menu to allow you to specify the next well location.

> **Note**: When you are finished with the B/S/T/C menu, press CANCEL to navigate to other options.

To define User Wells:

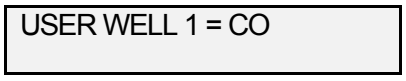
1. Select User from the Manual Template menu.



In addition to the four (B/S/T and C) well types already discussed, four more well type are available.

NC	Negative Control
PC	Positive Control
CO	Cut-off Control
PR	Positive Reference

2. To change the 2-character label for one of these wells use the Function Keys to select the well type (e.g., CO). The display will show:

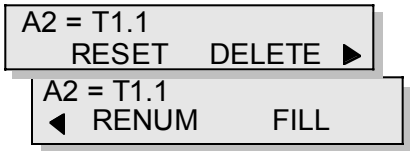


3. Press the DEL key to erase the current label then use the keypad to enter a new label and press ENTER.

4. Once you have updated the labels to reflect your needs, you can assign the User well types in the same manner used to assign B/S/T/C wells.

To use the template utilities:

1. Select UTILITY from the Manual Template menu.



Command	Purpose
RESET	Clears all existing well assignments, allowing you to redefine the template.
DELETE	Deletes the currently displayed well assignment. The cursor keys can be used to scroll through the well locations.
RENUM	Renumbers all well types into unbroken sequences. This is useful if the plate has been edited and some wells have been removed leaving gaps in the numbering sequence.
FILL	Completes the rest of the template once the locations of specified wells have been defined.
CANCEL	Returns to the Manual Template menu.

To save the template:

1. Select FINISH from the Manual Template menu.

2. Select YES to accept the template. Select LIST to print the template.

Automatic Definition

Only Standards and Test wells can be defined in automatic mode. Use the manual method, described in the previous section, if you need to define Blanks and Controls.

To define the template automatically:

1. Select AUTO at the Define Template prompt. The display will prompt for the number of Standards:

   NO. OF STDS=

2. Enter the number of Standards, between 1 and 24, then press ENTER.

3. The reader will prompt whether you want to use the standard 8 row by 12 column format, or the alternative 6x10 format.

   ALTERNATIVE FORMAT?
   YES NO

4. Select YES to denote the 6x10 format and NO for the 8x12 format.

5. The reader will prompt for the number of replicates for Standard wells.

   S WELLS IN

6. Enter the number of replicates (between 1 and 4), and then press ENTER.

7. If you selected more than one replicate, the reader will prompt for orientation.

   REPLICATES IN
   COLUMNS ROWS

8. Use the Function Keys to select the replicate orientation from top to bottom (columns) or left to right (rows).

9. The reader will prompt for the number of replicates for Test wells.

10. Enter the number of replicates (between 1 and 4), and then press ENTER.

11. If you selected more than one replicate, the reader will prompt for orientation.

12. Use the Function Keys to select the replicate orientation from top to bottom (columns) or left to right (rows).

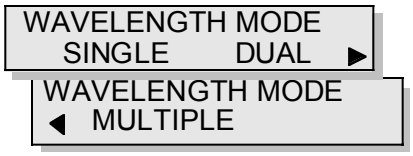
13. After Standards and Tests have been specified, the Reader assigns all the wells automatically and will prompt if the template is correct.

14. Select LIST to print the completed template. Select YES to accept the template.

Wavelength Mode

The plate may be read in SINGLE wavelength mode (with a test filter only), in DUAL wavelength mode (with a test filter and a reference filter) or in MULTIPLE wavelength mode (a combination of filters). Refer to page 5 of this manual for additional information.

1. Once the template is defined, the Reader will prompt for the filter wavelength mode.



2. Use the Function keys to select the wavelength mode.

SINGLE Wavelength Mode

1. If you select SINGLE mode the Reader prompts for the test filter wavelength:

2. Scroll through the list of filters using the NEXT and LAST options. Press ENTER to accept the displayed wavelength or CANCEL to return to the WAVELENGTH MODE option.

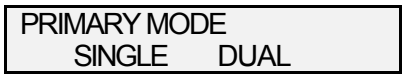
DUAL Wavelength Mode

1. If you select DUAL mode the Reader will prompt for the test filter wavelength as shown under SINGLE mode, and then prompt for the reference filter wavelength:

2. Scroll through the list of filters using the NEXT and LAST options. Press ENTER to accept the displayed wavelength, or CANCEL to return to the WAVELENGTH MODE option.

MULTIPLE Wavelength Mode

1. If you select MULTIPLE mode the Reader will prompt to define filter selections for a primary and secondary reading.



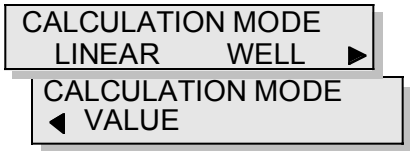
   Select SINGLE or DUAL and then select filter wavelengths as above.

2. After a primary mode is selected, the Reader prompts for a secondary mode:

   Select SINGLE or DUAL and then select filter wavelengths as before.

Note: The primary reading will normally be used, but the secondary reading will be used if any well ODs are above the Reader's Over Limit.

3. The Reader will prompt for procedure to be used in converting the secondary readings to the primary reading:

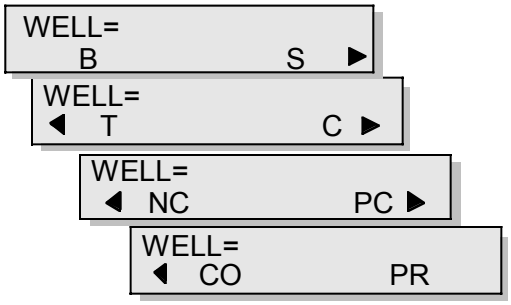


4. Use the Function keys to select the calculation mode.

Selection	Purpose
LINEAR	The Reader will convert the secondary readings using a line of best fit calculated from the two sets of data.
WELL	The Reader will convert the secondary readings using the ratio between the primary and secondary OD for the specified well.
VALUE	The Reader will convert the secondary readings using a multiplier you specify.

WELL

1. If you choose WELL, the Reader will prompt for well type:



2. Use the Function Keys to select the well type. Then press ENTER.

NOTE: The Reader will calculate a ratio between the primary and secondary readings for the selected well. The Reader will use this ratio to adjust other secondary readings.

VALUE

1. If you choose VALUE the Reader will prompt you to input a constant.

2. Enter the constant using the keypad. Use the Function Keys to toggle the sign of the value.

> **Note**: The Reader will multiply the secondary readings by this value.

3. Press ENTER to accept the displayed value.

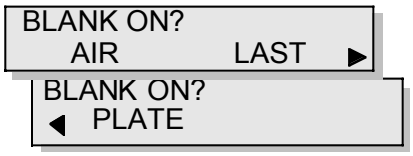
Blank Mode

The *Opsys* MR™ automatically subtracts background from all readings. Air is used as a reference by default, but you may choose another reference. For example, you may choose to subtract the absorbance of a reagent solution from the test results.

A total of eight blanking options are available. However, not all blanking options are available, depending on the template you defined.

Template contains no Blanks

1. If the template contains no Blank wells, the Reader will prompt:



2. Use the Function keys to select the blanking option.

Selection	Purpose
AIR	The absorbance of air is used as a reference level for 100% transmission.
LAST	The blank value from the previously read plate (see *Whole Blank Mode* later in this section) is used as a reference value.
PLATE	The Reader will read a plate and store the readings in memory. When the plate is read a second time the Reader will subtract the previous set of 96 readings.

Number of Blanks equals the sum of other samples

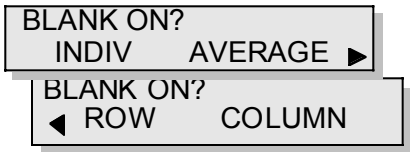
1. If the number of Blank wells in the template equals the sum of all other samples the Reader will prompt:

2. Select YES to pair Blanks with samples. Select NO to display the third Blank menu.

> **Note**: If you select **YES**, the Reader will pair one Blank with each other sample in the following order: Standards, Tests, Controls, Positive Controls, Negative Controls, Cut-off Controls, and Positive Controls.

Number of Blanks between 1 and 95

1. If the number of Blank wells is between 1 and 95 the Reader will prompt:



2. Use the Function keys to select the blanking option.

Selection	Purpose
INDIV	The most recently read Blank OD reading is subtracted from all subsequent samples. Readings are done in columns.
AVERAGE	The average blank OD value is subtracted from each sample.
ROW	The blank value for the row is subtracted from the wells within the row.
COLUMN	The blank value for the column is subtracted from other wells within the column.

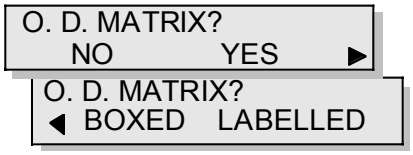
Whole Blank Mode – Number of Blanks equals 96

If the number of blanks equals 96, the Reader will automatically set Whole Blank Mode. This mode should be used in conjunction with LAST mode, described earlier.

The Reader will read the plate and hold in memory an average of all 96 ODs. If LAST mode is selected for the next test, this value will be subtracted from each OD value on the next plate.

OD Matrix

1. A results matrix is a table of values, printed out when the OD data is processed. The Reader will prompt with four options for printing an OD matrix:



Selection	Purpose
NO	Bypass printing a results matrix.
YES	Include an OD matrix in the results.
BOXED	Include a matrix with curve fit, threshold, difference, or ratio sections, if these have been selected as an output option (see *Output Options* later in this chapter).
LABELLED	Include the label of each well, as shown in Figure 14, with curve fit, threshold, difference, or ratio sections, if these have been selected.

2. Use the Function keys to select the desired output option.

	1	2	3	4	5	6	7	8	9	10	11	12
A	B1	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	S2
	BLANK	0.000	1.459	1.098	0.268	0.308	0.076	0.720	1.443	0.001	0.051	0.987
B	B1	T11	T12	T13	T14	T15	T16	T17	T18	T19	T20	S2
	BLANK	1.459	0.076	1.098	1.726	0.268	1.277	1.483	0.306	1.356	0.257	0.980
C	S1	T21	T22	T23	T24	T25	T26	T27	T28	T29	T30	C5
	-0.005	0.001	1.277	1.077	0.970	0.854	0.059	0.066	1.120	0.002	0.050	0.985
D	S1	T31	T32	T33	T34	T35	T36	T37	T38	T39	T40	C6
	-0.004	0.946	0.067	1.459	0.002	0.066	1.080	1.109	0.256	0.312	1.119	1.799
E	C1	T41	T42	T43	T44	T45	T46	T47	T48	T49	T50	B2
	-.0003	1.111	1.195	0.084	0.291	1.004	0.888	0.113	2.137	0.920	0.302	BLANK
F	C2	T51	T52	T53	T54	T55	T56	T57	T58	T59	T60	B2
	0.100	1.660	0.105	1.760	0.979	1.371	0.036	0.849	1.348	0.380	0.922	BLANK
G	C3	T61	T62	T63	T64	T65	T66	T67	T68	T69	T70	B2
	0.300	1.220	0.101	0.035	1.376	1.388	0.097	0.100	1.154	1.443	1.114	BLANK
H	C4	T71	T72	T73	T74	T75	T76	T77	T78	T79	T80	B3
	0.546	0.980	0.101	1.543	0.890	0.003	0.432	0.127	0.333	0.888	0.004	BLANK

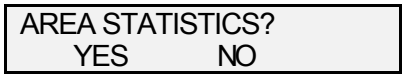
Figure 14. Sample Labelled OD Matrix

Area Statistics

The Area Statistics prompt allows you to designate wells that are to be included in a statistical calculation within a plate.

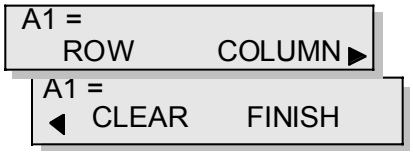
For example, you may be running two lots of controls within a single well type and want to determine the mean value and standard deviation for each lot. The statistics obtained on each designated area are the mean value, the standard deviation (SD), the coefficient of variation (CV), and the standard error of the mean (SEM).

1. After OD Matrix is selected the Reader will prompt:



2. Select YES to include area statistics and divide the template up into sections. Select NO to bypass area statistics.

3. If you select YES the Reader will prompt:



4. Use the vertical scroll key to select the beginning well (for example, **E1**) in a statistical area:

5. Then, use the keypad to specify the identifier for that statistical area (for example, **1**):

Note: Any numeric value between **0** and **49** can be entered.

6. Repeat Steps **4** and **5** to define the remaining wells in the statistical area.

   Or, use the ROW or COLUMN commands to create a statistical area from a series of wells in a row or column. Use the CLEAR command to clear a group of wells from a statistical area. These commands are described below:

Selection	Purpose
ROW	Assign all wells in a row, starting with the displayed well number, to the selected statistical area by selecting ROW.
COLUMN	Assign all wells in a column, starting with the displayed well number, to the selected statistical area by selecting COLUMN.
CLEAR	Clear a row or column by selecting the starting well, selecting CLEAR, and then selecting ROW or COLUMN.

7. Repeat Steps **4** through **6** for each additional statistical area to be created.

> **Note**: At least two wells must be assigned to a statistical area. Be sure to use a different numerical identifier for each statistical area. Clear an individual well from an area by selecting the well and then selecting CLEAR.

8. When all of the statistical areas have been defined, select FINISH from the second panel to save the assignment of the wells to the statistical areas.

9. When FINISH is selected the Reader will prompt:

10. Select YES to accept the template. Select LIST to print the template.

QC Equations

Quality Control (QC) equations are used to validate the OD values that are obtained as the plate is being read. This function allows you to automatically check OD readings and verify whether data for a particular sample or the entire plate are valid. Up to twelve QC equations can be entered. If any QC criteria are not satisfied when the test is run the Reader will prompt to abort the test.

The QC Equation Menu is shown in Figure 15. WELL allows a well type or sample to be included in the equation. OPTIONS provides the statistical values and functions which make up the equation.

> **Note**: When using **Max** or **Min** with a well sample, be sure that parentheses are included before and after the well sample. For definitions and additional information, refer to *QC Equations* and *Statistical Values and Functions* in *Appendix C.*

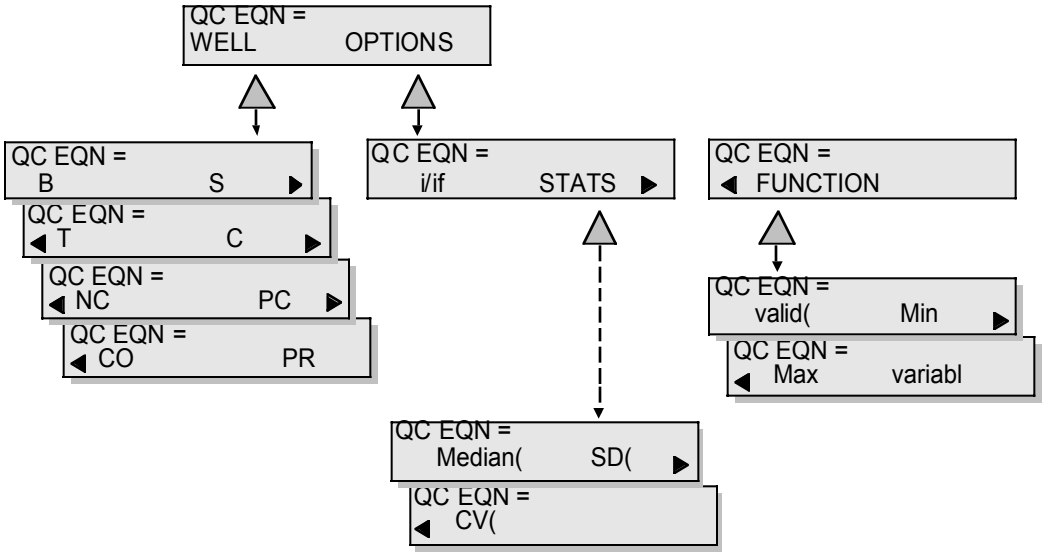


Figure 15. QC Equation Menu

Entering a QC Equation

1. After Area Statistics, the Reader will prompt:

2. Construct an equation by selecting the well(s) and formula to be applied to the well(s) from options available on the QC Equation Menu.

3. Press ENTER to store the displayed equation and input another equation.

Note: Pressing ENTER without any equation displayed continues to the Output Options Menu.

Example

In this example, two equations are set up. The first equation tests the OD value obtained on each Negative Control to determine if it is within 25% of the mean OD of all Negative Controls. The second equation tests that at least two of the Negative Controls must pass the first test.

The first equation uses the replicate option "i". It tests each Negative Control (NCi) against the mean OD of all Negative Controls (NC) +/- 25%. A Negative Control outside this range fails equation one.

QC1 EQN= 0.75*NC<=NCi<=1.25*NC

The second equation uses the validity test. The number of Negative Controls that pass the first equation must be at least 2, or the test will fail.

QC2 EQN= valid(NC)>=2

Step by step procedures for entering these two equations are shown below.

1. Use the keypad to enter 0.75*

2. Select WELL then scroll to and use the Function Key to select the NC well type.

> **Note**: Available well types are B, S, T, C and the 4 user defined well types (refer to *Template*). Default user well types are shown in Figure 15.

3. Use the keypad to enter <=

4. Select WELL then scroll to and use the Function Key to select the NC well type.

5. Select OPTIONS then use the Function Key to insert "i", meaning each replicate.

6. Use the keypad to enter <=1.25*

7. Select WELL then scroll to and use the Function Key to select the NC well type.

8. Press ENTER to store the first equation (QC1). The Reader will prompt for the next equation:

```
QC2 EQN=
  WELL      OPTIONS
```

9. Select OPTIONS then select FUNCTION then select VALID(.

10. Enter the opening parentheses. Then, select WELL and then select the Function Key to specify the NC well type. Finally, enter the closing parentheses.

11. Use the keypad to enter >=2

12. Press ENTER to store the second equation.

13. Press ENTER again to advance to the Output Options Menu.

Output Options

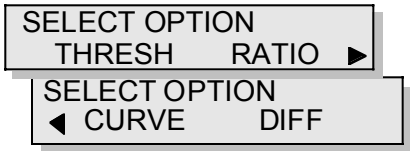
Several data processing options are available for test results:

Command	Purpose
THRESH	Inserts a threshold matrix into the test. Lets you define the ranges for positive and negative results. Also lets you perform quality control checks on the Control well ODs.
RATIO	Inserts a ratio matrix into the test. Lets you use basic addition, subtraction, multiplication and division operators (**+**, **-**, ***** and **/**) to transform the ODs of Control and Test wells into different unit measurements.
CURVE	Inserts a curve fit section into the test. Lets you plot a graph of ODs against concentrations.
DIFF	Inserts a difference matrix into the test. Lets you calculate the difference between ODs from two sets of wells. For example, the top and bottom halves of a microwell plate.

Note: The order in which these options are specified is the order in which they are performed. For example, if you wish to perform threshold processing on normalized data, first specify the ratio and then specify the threshold.

Threshold

After QC Equations, the display will read:



The threshold matrix is printed as a table of symbols denoting positive (+), negative (-) or equivocal (0) results as defined by threshold equations.

	1	2	3	4	5	6	7	8	9	10	11	12
A	0	0	0	0	0	0	0	0	0	+	+	0
B	0	0	0	0	0	0	0	+	-	0	0	0
C	0	0	0	0	0	-	-	0	0	0	0	+
D	0	0	+	0	0	0	0	0	0	0	0	-
E	+	0	0	+	++	0	0	0	-	0	0	0
F	+	0	0	0	0	0	+++	0	0	0	0	0
G	-	0	-	-	0	0	0	0	0	+	0	0
H	-	0	0	-	0	0	0	0	0	0	0	0

Figure 16. Sample Threshold Printout

When you select THRESH you have two options:

- Set OD limits that correspond to positive and negative results by responding NO to the Q.C. Only prompt.
- Enter QC equations to validate the calculated values after the output options data has been processed by responding YES to the Q.C. Only prompt.

The next section describes procedures for setting OD cut-off limits.

The Threshold Menu options available for setting cut-off limits are shown in Figure 17.

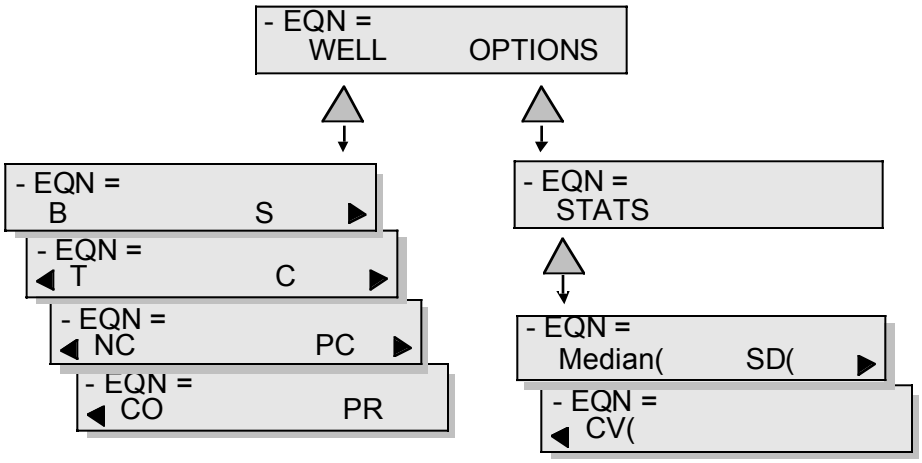


Figure 17. Threshold Cut-off Limit Menu

Note: The **Cut-off Limits** specify the boundary between negative and positive results. The area between adjacent limits, for example between the upper limit of negative and the lower limit of positive, is defined as the **gray zone**.

Entering Cut-off Limits

1. To define threshold limits select THRESH from the SELECT OPTION Menu. The will Reader prompt:

   Q.C. ONLY?
   YES NO

2. Select NO.

3. The Reader will prompt for a negative limit:

   - EQN=
   WELL OPTIONS

4. Enter a number using the keypad, or enter a QC equation as described at the end of this section. Any OD below this value will be recorded as negative.

5. The Reader will prompt for a positive limit:

   + EQN=
   WELL OPTIONS

6. Enter a numeric value using the keypad or enter a QC equation as described at the end of this section. Any OD equal to or above that value will be recorded as positive.

> **Note**: A negative limit is set using the – equation, and a positive limit is set using the + equation. Positive and negative limits are always required. Two additional positive ranges, ++ and +++ can be entered. As you enter a threshold limit the Reader will advance to the next equation. Press ENTER to bypass the ++ or +++ equations.

7. After you have entered limits the Reader will prompt:

```
NO. OF SEGMENTS =
```

8. Enter a number between 1 and 10 to section your matrix between the lower limit of the positive range and the upper limit of the negative range (the gray zone).

9. The Reader will prompt for threshold labels:

```
- LABEL =
```

10. Enter up to 5 characters to create your own threshold limit identifiers or press ENTER to accept the displayed value.

> **Note**: Pressing ENTER on an empty input will use the default label. Default labels are – for negative, + for positive, ++ for double positive, +++ for triple positive and 0 for the neutral (equivocal) area if only 1 segment is defined.

11. If the positive and negative cut-off values are the same the Reader will prompt if the assay is an inverse assay:

```
INVERSE ASSAY?
  YES          NO
```

12. Select YES to designate an inverse assay. Select NO to specify a standard assay.

> **NOTE:** If an assay is marked as inverse, samples with OD values less than or equal to the positive threshold are marked as positive. Samples with OD values greater than the negative threshold are marked as negative.

Validating Control Samples

13. After LABELS are entered, or if you answered YES to the "Q.C. ONLY?" question, the Reader prompts:

```
QC1 EQN=
   WELL      OPTIONS
```

14. QC equations are entered as described in the previous section, *QC Equations*.

Example

Our example flags ODs below 0.1999 as negative and ODs that are equal to and greater than 0.4 above Cut-off Control 1 as positive. It divides the neutral area between these two values into 3 segments. Default labels are accepted. When this test matrix is printed, samples below the negative cut-off value will be marked with –. Samples above the positive cut-off will be marked with +. Samples between the limits will be marked **1, 2** or **3** depending on whether they fall in the lower, middle or top portion of the neutral (gray zone) OD range.

1. Use the keypad to enter 0.1999 for the negative equation then press ENTER.

```
- EQN= 0.1999
  WELL     OPTIONS
```

2. The Reader will prompt for the positive control:

```
+ EQN=
  WELL     OPTIONS
```

3. Select WELL then scroll to and use the Function Key to select the CO well type.

> **Note**: Available well types are B, S, T, C and the four user defined well types (refer to *Template* section). Default user well types are shown in Figure 17.

4. Use the keypad to enter 1+0.4 then press ENTER.

```
QC2 EQN=CO1+0.4
  WELL      OPTIONS
```

5. Press ENTER twice to bypass the ++ and +++ equations.

6. The Reader will prompt:

```
NO. OF SEGMENTS =
```

7. Enter 3.

8. The Reader will prompt for threshold labels:

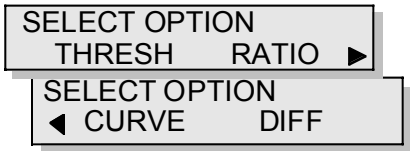
```
- LABEL =
```

9. Press ENTER accepting all the default labels.

> **Note**: For additional information, refer to *QC Equations* and *Statistical Values and Functions* in the *Appendix*.

Ratio

Once QC Equations have been entered the SELECT OPTION menu will be redisplayed:



The RATIO option outputs a printed table of OD values that have been calculated by an equation that is defined by the user.

The RATIO Menu is shown in Figure 18. WELL allows a well type to be included in the equation. OPTIONS provides access to mathematical and logarithmic functions you can use to define the equation.

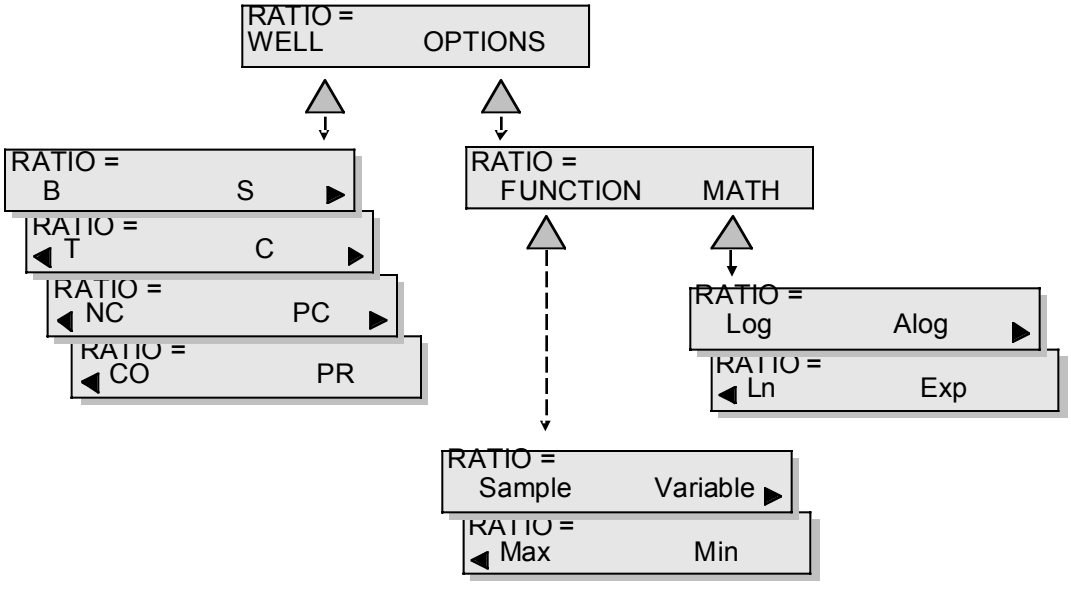


Figure 18. Ratio Menu

Ratio equations are entered just like QC Equations. Refer to QC Equations and the *Appendix* for additional details.

After RATIO equations have been entered the Reader will prompt:

You have the option of entering an International Units (UI) equation to produce a second output matrix.

Curve

Another output option available for interpreting data is the CURVE option. The steps for defining a curve are shown below. Samples curves and their descriptions are provided in the *Appendix*.

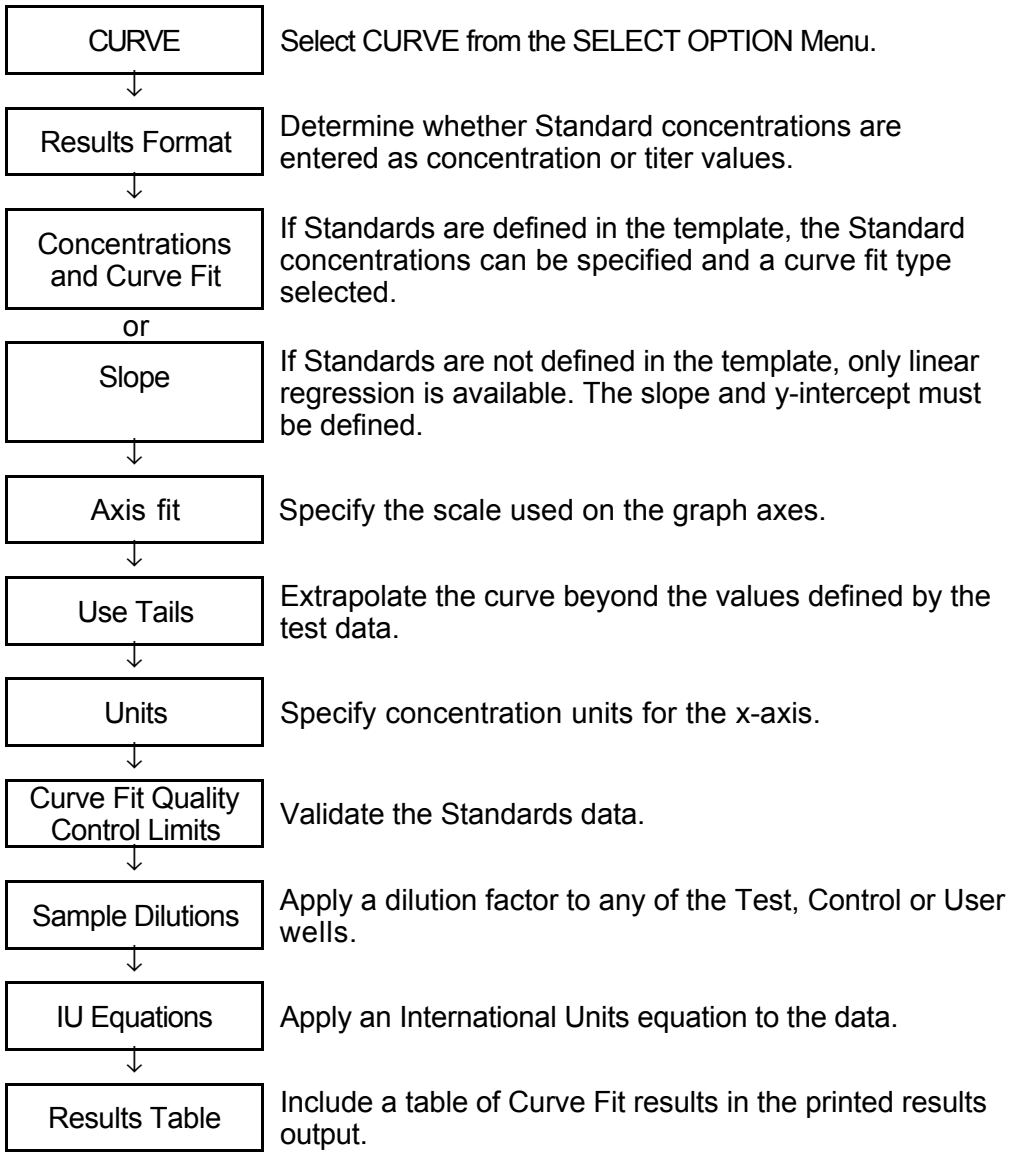


Figure 19. Defining a Curve

1. To quantify OD results by comparing them to a concentration graph, select CURVE from the SELECT OPTION Menu. The Reader will prompt:

```
RESULT FORMAT?
     CONC.      TITER
```

2. Select CONC to input Standard concentrations in concentration values. Select TITER to input Standard concentrations in titer values.

Standards Defined in the Template

If Standards are not defined in the template continue with the section labelled *Standards not defined in Template.*

3. The Reader will ask for the concentrations of each Standard sample defined in your plate.

   If you selected CONC for Results Format, the Reader will prompt:

```
CONC. OF S1 =
  e
```

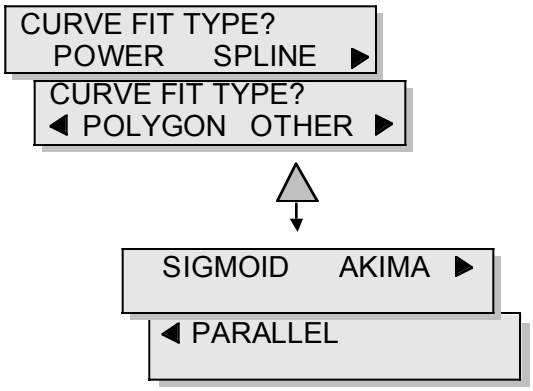
   If you selected TITER for Results Format, the Reader will prompt:

```
TITER OF S1 = 1:
  e
```

4. Enter the value using the keypad. Use the 'e' option to enter an exponential value (e.g. 1e5 = $1x10^5$).

Note: CONC limits are 0.001 to ($1x10^{200}$) for Sigmoid (4PLC), semi-log and log-log fits; 0.000 to ($1x10^{200}$) for all other fits. TITER limits are 1 to 999999.

5. Next the Reader will ask which type of curve fit you require:



Use the Function Keys to select the curve fit, then skip to the section titled *Standards not defined in Template* and continue with Step **8**.

The curve fit formulas that you can choose from are described BELOW. A detailed description of each curve type is contained in *Appendix C*.

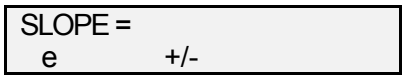
Fit Type	Description and Additional Input
POWER	Polynomial regression. The Reader will prompt you to select one of the following equations: linear regression, quadratic, cubic or quartic equation. Once the curve fit is selected, the reader will prompt for the type of axis transformation: linear, semi-log, log-log or automatic.
SPLINE	Cubic spline fit.
POLYGON	Successive points are joined by straight lines.
SIGMOID	Sigmoidal (4PLC) S-shaped fit. If you select a SIGMOID curve the Reader will allow you to define any of the four parameters of the sigmoid (4PLC) curve. The Reader will prompt FIX PARAMETERS. Select LOGIT to fix the A and D parameters. Select YES to define all four parameters. Select NO to bypass the option to fix parameters. If LOGIT or YES are selected, the Reader will prompt for the numeric value of each parameter. The STOP option allows you to abort the curve definition and return to the Output Options Menu.

Fit Type	Description and Additional Input
AKIMA	Smooth curve which passes through all data points.
PARALLEL	Parallel line bioassay. Used to calculate relative dosages between a set of up to 12 curves. A set of Standards defines the standard curve and sets of Test wells of identical number define the test curves. If the test and standard curves are parallel, the test data is valid. If not, the worst cases are rejected. This selection is only available if one of the following conditions is met: • There must be at least two Standards and they must be in double, triple or quadruple replicates. • Test wells must be arranged in the same number of replicates as Standard wells. • The number of Test wells must be a multiple of the number of Standards.

Note: A residual number may be displayed while data are being processed with a Sigmoid curve fit. If this number remains on the display and the computation halts, the software is unable to compute the curve fit parameters. Use the STOP option to stop the process.

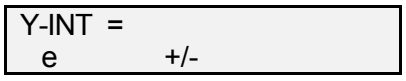
Standards not defined in the Template

3. If you did not define Standards in your template, only linear regression is available. You will be prompted to input the slope of the line:



4. Enter the slope using the keypad. Use the 'e' option to enter an exponential value (e.g. 1e200 = $1x10^{200}$). Use the +/- option to set the slope direction.

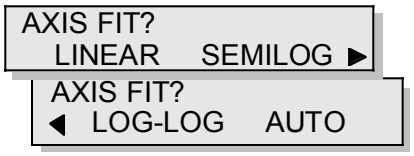
5. The Reader will prompt for the y-intercept:



6. Enter the requested value as described for slope.

Note: The limits for slope are: +/- 0.0001 to 1e200. The limits for y-intercept are 0.0 to 1e200.

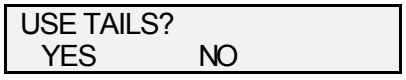
7. Next the Reader will prompt for the type of axis fit. This option controls the scale of the graph.



8. Select the option that will provide the best data distribution.

Selection	Purpose
LINEAR	The Reader will use a linear scale for both axes.
SEMI-LOG	The Reader will use a logarithmic scale for the x-axis (recommended for the Sigmoid curve fit
LOG-LOG	The Reader will use a logarithmic scale for both axes.
AUTO	Allows the Reader to select the best axis fit (only available if a polynomial regression curve was selected).

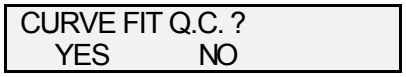
9. Curves can be extrapolated beyond values defined by a test by selecting YES in response to the USE TAILS? prompt:



IMPORTANT: Using the tails option, particularly with the higher order polynomial or spline curve fits, may yield multiple results.

10. The Reader will prompt for the concentration units that were used for the test. These will appear on the x-axis.

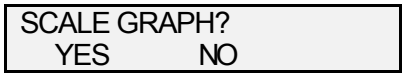
11. QC limits can be applied to the curve fit data. The types of limits you can set depend on the type of curve fit selected.



Respond YES to define values for the limits listed below. If the Standards curve does not meet the specified limits, a failed message will be printed.

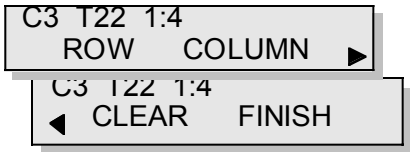
Limit	Description
MIN R-SQR	The minimum R^2 value.
MIN Y-INT	The minimum intercept of the curve fit plot through the y-axis for a polynomial regression.
MAX Y-INT	The maximum intercept of the curve fit plot through the y- axis for a polynomial regression.
MIN SLOPE	The minimum slope value for a linear fit.
MAX SLOPE	The maximum slope value for a linear fit.

12. The SCALE GRAPH option lets you specify the upper and lower limits to be used on the graph.



If you respond YES the Reader will prompt for the maximum and minimum points of the x and y-axes.

13. Use the DILUTION option to apply a dilution factor to any Test, Control or User well.



14. Use the vertical scroll to change the well row and column identifier (C3 in the example). The well type and number (T22 in the example) will automatically update.

15. Select CLEAR to clear the currently displayed dilution factor (4 in the example) then input the new factor using the keypad.

16. Press ENTER to accept the displayed value.

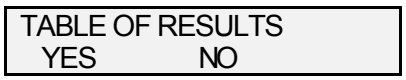
17. Select FINISH to complete the dilution option.

> **Note**: Select ROW to apply the displayed dilution factor to all wells in a row, starting with the displayed well number. Select COLUMN to apply the displayed dilution factor to all wells in a column, starting with the displayed well number.

18. The Reader will prompt for an International Units equation:

If you do not require an IU equation press ENTER. For information on entering IU equations refer to the *QC Equations* section under *Output Options*.

19. The final prompt under CURVE definition determines whether a table of curve fit results is printed in the results output:

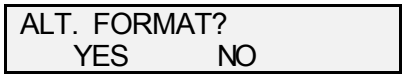


> **Note**: The table of results will increase the size of the output file and may make your test too complicated to process. Use this option cautiously if your test already contains a number of other processing options.

Difference Matrix

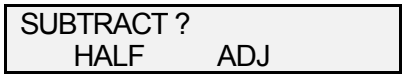
A Difference Matrix is a table of data showing the differences in ODs between subsequent rows or columns of wells, or between one half of the plate and the other.

1. To include a difference matrix select DIFF from the Output Option Menu. The Reader will prompt:



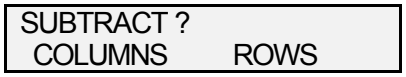
2. Select YES to use a format other than the standard 8x12 format.

3. The Reader will ask if you want to subtract halves of the plate or adjacent readings.



4. Select HALF to subtract one half of the plate OD readings from the other half. Select ADJ to subtract adjacent readings.

5. The Reader will prompt for the row/column orientation.



6. If you specified HALF, select COLUMNS to subtract columns 1-6 from 7-12 or ROWS to subtract rows A-D from E-F. If you specified ADJ determine if you want to subtract adjacent COLUMNS or ROWS.

7. The final prompt is for subtraction order. Select 1st-2nd or 2nd-1st according to the tables below.

> **Note**: Differences are always printed in the lowest well number of the operation. For example E2-E1 will be printed in well position E1 and well E2 will appear as #####

Subtraction Order – HALF Selected

	Order	
Orientation	**1st - 2nd**	**2nd - 1st**
COLUMN	1-7, 2-8, 3-9, 4-10, 5-11, 6-12	7-1, 8-2, 9-3 10-4, 11-5, 12-6
ROW	A-E, B-F, C-G, D-H	E-A, F-B, G-C, H-D

Subtraction Order – ADJ Selected

	Order	
Orientation	**1st - 2nd**	**2nd - 1st**
COLUMN	1-2, 3-4, 5-6, 7-8, 9-10, 11-12	2-1, 4-3, 6-5, 8-7, 10-9, 12-11
ROW	A-B, C-D, E-F, G-H	B-A, D-C, F-E, H-G

Assigning a Password

1. After the test has been entered the Reader will ask if you want to password protect the test:

2. Select YES to enter a password. Select NO to complete the assay creation and exit the Program Menu. If you answer YES the Reader will prompt:

3. Enter the Password at the PASSWORD prompt and again at the RETYPE prompt to confirm your entry.

Note: The password protection option should be used with caution. If you forget the password, you will not be able to edit or overwrite the test. Contact an approved service center for advice.

Editing an Existing Assay

Once you have created an assay test procedure, the EDIT command allows you to modify the assay.

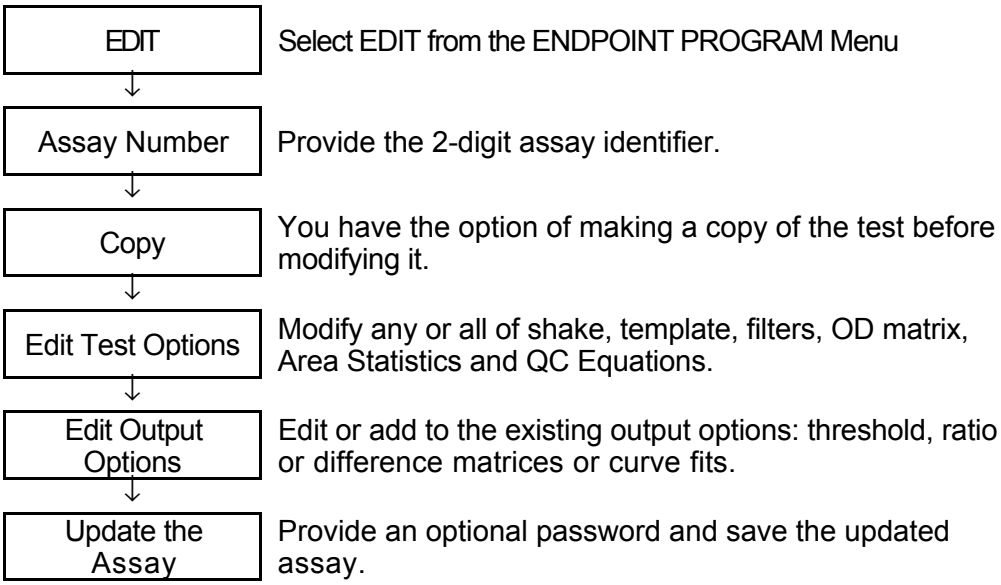
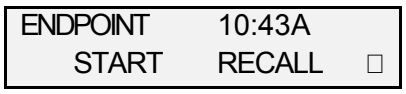


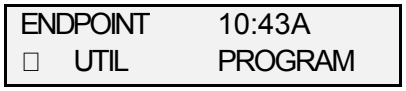
Figure 20. Editing an Existing Assay

To edit an existing assay:

1. Select ENDPOINT from the Main menu. The display will read:



   Scroll right to view the next selections:



2. Select PROGRAM. The display will read:

3. Select EDIT.

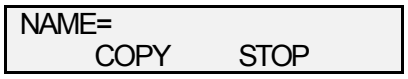
Assay Number

1. After EDIT has been selected the display will read:

2. Using the keypad or scroll keys, input the test number you wish to modify then press ENTER, or select CANCEL to return to the Endpoint Main menu.

> **Note**: If an assay has already been defined for the entered test number, it will be available for editing when ENTER is pressed. If the entered test number is password protected, the Reader will prompt for the password before continuing.

3. When a valid test number is entered, it must be confirmed:



4. Select COPY to copy the test to another test number. Select STOP to stop editing and save the test. Select ENTER to proceed with the edit of the displayed test. Select CANCEL to return to the test number prompt.

Copying the Assay

1. If you select COPY the Reader will prompt for the copied test number:

2. Enter the number for the copied test. You can use the DIR command to print a list of stored tests. If the test number you enter was already used, the name assigned to that number will be shown in the CLEAR TEST display:

3. Select NO to preserve the original test and return to the PROGRAM Menu. Select YES to overwrite the test.

Note: Do not use the original test number for the copied test. If you do the original test will be deleted when you select YES at the CLEAR TEST prompt, and it will no longer be available for copying. If this occurs and INVALID COPY message will be displayed.

Editing Test Options

Each step of the test will be displayed for editing. You can confirm the existing procedure by pressing ENTER or edit it by pressing DEL.

1. The first step displayed will be the plate ID prompt:

```
ID PROMPT: YES
   STOP
```

2. To change the current selection, YES in the example, select DEL to access alternatives, NO in this case.

At anytime during the edit process:

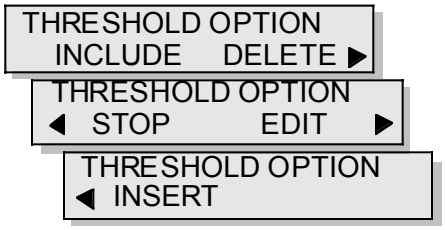
Command	Description
STOP	Saves the test and returns to the Program menu.
ENTER	Accepts the displayed test step and presents the next test step for editing. You can page through the test, step by step using the ENTER key.
DEL	Lets you alter the displayed step.

If Shake was defined in the original test, the Shake option will be displayed next. If the Template was defined manually, it will be presented for editing after the Shake option.

All other test options will be made available in the same order as originally presented. Refer to *Creating a New Assay* for available options.

Editing Output Options

When Output Options are displayed several additional editing tools become available. For example, if the test procedure has a threshold option the Reader will prompt:



Command	Description
INCLUDE	Keep the option as defined
DELETE	Delete the option from the test procedure.
STOP	End the editing process, save the test and return to the Program Menu.
EDIT	Modify the displayed option.
INSERT	Insert an additional Output Option, refer to *Output Options* under *Creating a New Assay*.

If no options were initially defined, or when all options have been updated the Reader will prompt:

Select INSERT to add a THRESH, RATIO, CURVE or DIFF option as described in the *Output Options* section of *Creating a New Assay*.

Modifying the Assay Password

1. After the test has been edited, the Reader will prompt for a password:

2. As before, the Password is optional. Use the DEL key to update this entry. Press STOP or ENTER to update the test procedure and end the edit session.

Printing an Existing Assay

Once you have created an assay test procedure, the LIST command allows you to print the assay procedure.

1. To print an existing assay select PROGRAM from the ENDPOINT Menu: The display will read:

2. Scroll right to view the next selections:

3. Select LIST, and the Display Panel reads:

4. Using the keypad or scroll keys, input the test number you wish to print then press ENTER.

> **Note**: Use the DIR option to print a list of the stored test procedures.

5. If a matching test number is found, the name corresponding to the entered test number will be displayed for confirmation:

6. Press ENTER to confirm the test and begin printing.

Printing Directories

1. To print existing assay data, select PROGRAM from the ENDPOINT Menu. The display will read:

2. Scroll right and select the DIR option:

3. Three output options are available:

4. Use the Function Keys to select the desired output option.

Command	Description
TESTS	Print directory of up to 100 assay test procedures.
PLATES	Print directory of up to 20 plate IDs

Chapter 5 Assay Example

Programming the Assay for Antigen XYZ

This section contains an example of assay programming for Antigen XYZ, a hypothetical substance. The assay is read at 450 nm with no shake.

Template

Triplicates of a reference material are to be placed in the first column. The reference material is used to normalize all samples before calculating threshold data and then standard curve concentration data.

To define the template:

1. Place one replicate of the appropriate blank in well A1.
2. Place triplicates of the reference material in Column 1.
3. Place triplicates of the first standard (S1) in Column 1.
4. Place single replicates of the remaining three standards (S2, S3 and S4) starting at the beginning of Column 2.
5. Place duplicates of the positive control (PC) at the end of Column 1 in a row format.
6. Place duplicates of the negative control (NC) in Column 2 in a row format after S2, S3 and S4.
7. Fill the remainder of the template with duplicate Tests in a row format.
8. The resulting template is shown in Figure 21.

	1	2	3	4	5	6	7	8	9	10	11	12
A	B1	S2	T4	T4	T12	T12	T20	T20	T28	T28	T36	T36
B	REF1	S3	T5	T5	T13	T13	T21	T21	T29	T29	T37	T37
C	REF1	S4	T6	T6	T14	T14	T22	T22	T30	T30	T38	T38
D	REF1	NC1	NC1	T8	T8	T16	T16	T24	T24	T32	T32	
E	S1	T1	T1	T9	T9	T17	T17	T25	T25	T33	T33	
F	S1	T2	T2	T10	T10	T18	T18	T26	T26	T34	T34	
G	S1	T3	T3	T11	T11	T19	T19	T27	T27	T35	T35	
H	PC1	PC1	T7	T7	T15	T15	T23	T23	T31	T31	T39	T39

Figure 21. Template for the Example

QC Equations

Six tests of raw data are carried out in the example. These tests are as follows:

- O.D. of two out of three S1 replicates must be within 10 percent of the median S1 O.D. value
- The average O.D. value for S1 must be greater than or equal to 0.05
- O.D. of the negative control must be less than or equal to 90% of the O.D. of S1
- O.D. of S4 must be less than 3.000
- The quotient of S2 O.D. divided by S1 O.D. must be at least 1.25
- The quotient of S3 O.D. divided by S2 O.D. must be at least 1.05
- The quotient of S4 O.D. divided by S3 O.D. must be at least 1.05

The resulting QC equations are shown in Figure 22.

```
Q.C. EQUATIONS      : Median(S1)*0.9<S1.i<Median(S1)*1.1
                    : Valid(S1)>=2
                    : S1>=0.05
                    : NC<S1*0.9
                    : S4<3.0
                    : S2/S1>=1.25
                    : S3/S2>=1.05
                    : S4/S3>=1.05
```

Figure 22. QC Equations for the Example

Area Statistics

No Area Statistics are included in the example.

Ratio

One ratio calculation is performed in the example. This calculation is performed to normalize the O.D. obtained for each sample against the O.D. value obtained for the reference material. The resulting ratio equation is shown in Figure 23.

Figure 23. Ratio Equation for the Example

Threshold

Qualitative analysis (results are positive, negative or equivocal) is specified for the assay. The qualitative results are determined as outlined below:

- Any result whose O.D. is less than 90% that of S1 O.D. is considered negative
- Any result whose O.D. is greater than or equal to that of S2 O.D. is considered positive
- Negative results are labeled as NEG
- Positive results are labeled as POS
- Equivocal results are labeled as EQU

The resulting Threshold equations are shown in Figure 24.

```
THRESHOLD

  -  EQN              : S1*0.9
  +  EQN              : S1
NO. OF SEGMENTS       : 1
  -  LABEL            : NEG
  0  LABEL            : EQU
  +  LABEL            : POS
Q.C. EQUATIONS        :
```

Figure 24. Threshold Equations for the Example

Curve Fitting

Quantitative analysis is also specified for the assay. The quantitative results are determined as outlined below:

- A polygonal standard curve is used with extrapolation activated
- S1 contains 3 units/mL
- S2 contains 50 units/mL
- S3 contains 100 units/mL
- S4 contains 200 units/mL

The resulting Curve Fitting entries are shown in Figure 24.

```
CURVE FIT

CONC. OF S1          : 3.000 I ML
CONC. OF S2          : 50.000 I ML
CONC. OF S3          : 100.000 I ML
CONC. OF S4          : 200.000 I ML

CURVE FIT TYPE       : POLYGON WITH TAILS
                     : LINEAR AXIS FITTING
CURVE FIT Q.C.       : NO
SCALE GRAPH          : NO
SAMPLE DILUTIONS     : T1 = 1:1      T2 = 1:1      T3 = 1:1
                     : T4 = 1:1      T5 = 1:1      T6 = 1:1
                     : T7 = 1:1      T8 = 1:1      T9 = 1:1
                     : T10 = 1:1     T11 = 1:1     T12 = 1:1
                     : T13 = 1:1     T14 = 1:1     T15 = 1:1
                     : T16 = 1:1     T17 = 1:1     T18 = 1:1
                     : T19 = 1:1     T20 = 1:1     T21 = 1:1
                     : T22 = 1:1     T23 = 1:1     T24 = 1:1
                     : T25 = 1:1     T26 = 1:1     T27 = 1:1
                     : T28 = 1:1     T29 = 1:1     T30 = 1:1
                     : T31 = 1:1     T32 = 1:1     T33 = 1:1
                     : T34 = 1:1     T35 = 1:1     T36 = 1:1
                     : T37 = 1:1     T38 = 1:1     T39 = 1:1
                     : NC1 = 1:1     PC1 = 1:1     REF1 = 1:1
                     :
I.U. EQUATION        :
TABLE OF RESULTS     : YES
```

Figure 25. Standard Curve Entries for the Example

Running the Assay for Antigen XYZ

This section contains an example of the results that might be obtained when the assay described in the previous section is run.

Summary Page

The first portion of the results printout contains summary information for the assay. An example is shown in Figure 26.

DYNEX OPSYS MR

TEST NO. : 08
TEST NAME : AG XYZ
PLATE : 123

W/L MODE : SINGLE
TEST FILTER : 405 nm
REF. FILTER : *

DATE : 12/29/1998
TIME : 11:24A
OPERATOR :

AVERAGE BLANKS:
A1 = 0.042

AVERAGE BLANK = 0.042

QUALITY CONTROL

RATIO EQUATION : Sample/REF

+ EQN = S1
= 0.153
- EQN = S1*0.9
= 0.138

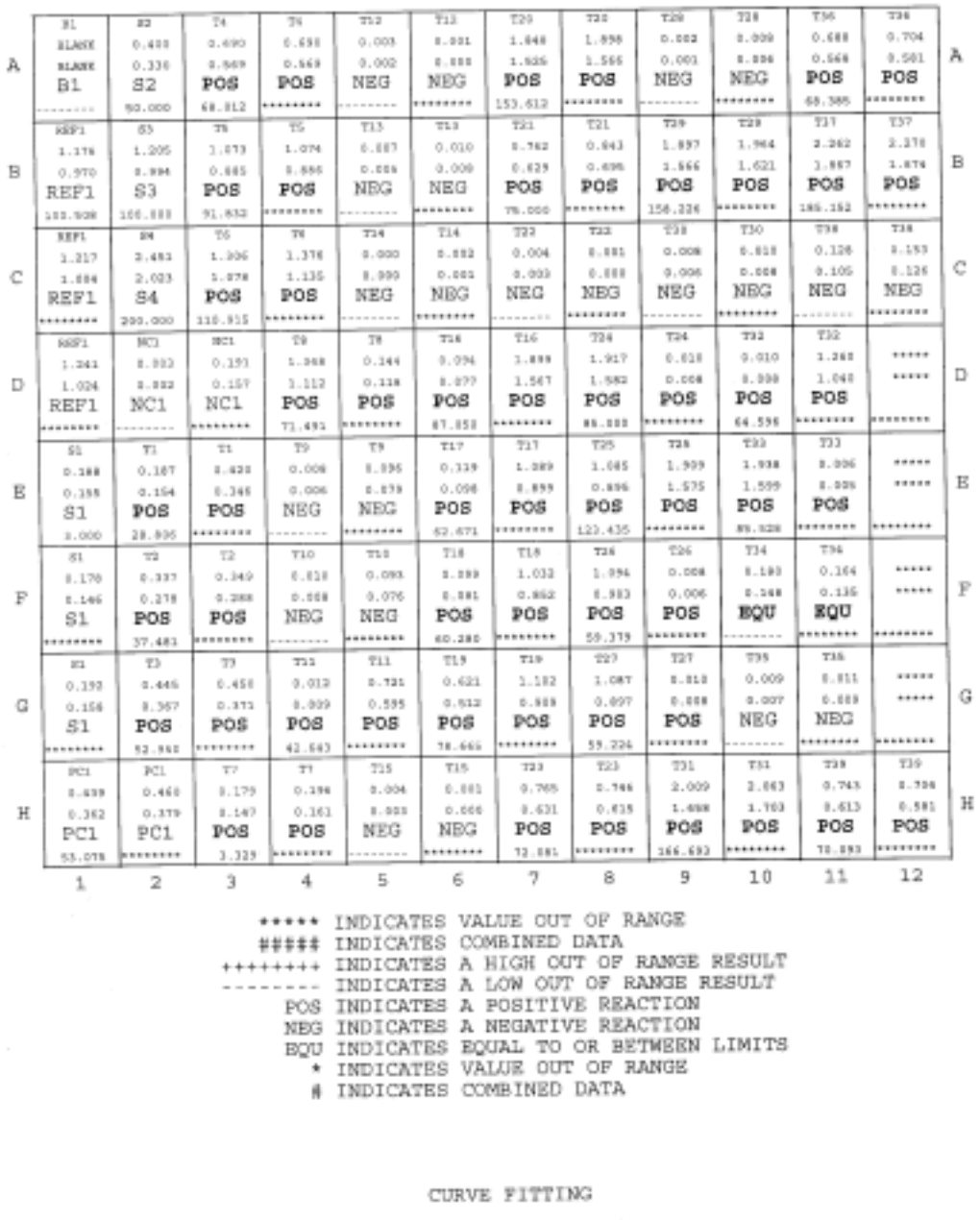
LINEAR POLYGON FIT WITH TAILS

R-SQR = 1.0000

Figure 26. First Page of Results Printout in the Example

Curve Fitting Results

The second portion of the results printout contains curve fitting results for the assay. An example is shown in Figure 27 and Figure 28.



	1	2	3	4	5	6	7	8	9	10	11	12	
A	BLANK	BLANK	B1	S2	POS	POS	NEG	NEG	POS	POS	NEG	NEG	POS	POS	A
B	REF1	S3	REF1	S3	POS	POS	NEG	NEG	POS	POS	POS	POS	POS	POS	B
C	REF1	S4	REF1	S4	POS	POS	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	C
D	REF1	NC1	NC1	NC1	POS	POS	POS	POS	POS	POS	POS	POS	*****	*****	D
E	S1	S1	S1	POS	POS	NEG	NEG	POS	POS	POS	POS	POS	POS	POS	*****	*****	E
F	S1	S1	S1	POS	POS	NEG	NEG	POS	POS	POS	POS	EQU	EQU	*****	*****	F
G	S1	S1	S1	POS	POS	POS	POS	POS	POS	POS	POS	NEG	NEG	*****	*****	G
H	PC1	PC1	PC1	PC1	POS	POS	NEG	NEG	POS	POS	POS	POS	POS	POS	*****	*****	H

***** INDICATES VALUE OUT OF RANGE
INDICATES COMBINED DATA
++++++++ INDICATES A HIGH OUT OF RANGE RESULT
-------- INDICATES A LOW OUT OF RANGE RESULT
POS INDICATES A POSITIVE REACTION
NEG INDICATES A NEGATIVE REACTION
EQU INDICATES EQUAL TO OR BETWEEN LIMITS
* INDICATES VALUE OUT OF RANGE
# INDICATES COMBINED DATA

CURVE FITTING

Figure 27. Curve Fitting Results for Example

LINEAR POLYGON FIT WITH TAILS

R-SQR = 1.0000

Trial #1

STANDARDS

#	LABEL	LOC.	O.D.	MEAN	S.D.	C.V.	S.E.M.	CONC.
S1	_____	E1	0.155					
		F1	0.146					
		S1	0.150	0.153	0.006	3.977	0.003	3.000
S2	_____	A2	0.330	0.350	********	********	********	50.000
S3	_____	B2	0.994	0.994	********	********	********	100.000
S4	_____	C2	2.023	2.023	********	********	********	200.000

***** INDICATES VALUE OUT OF RANGE
? INDICATES INVALID TERM
D INDICATES DELETED TERM

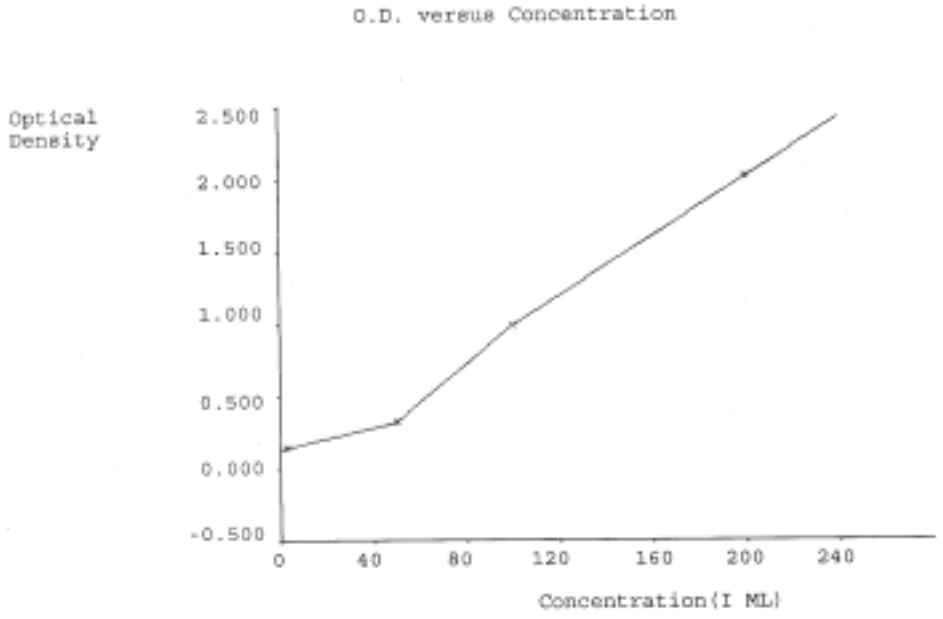
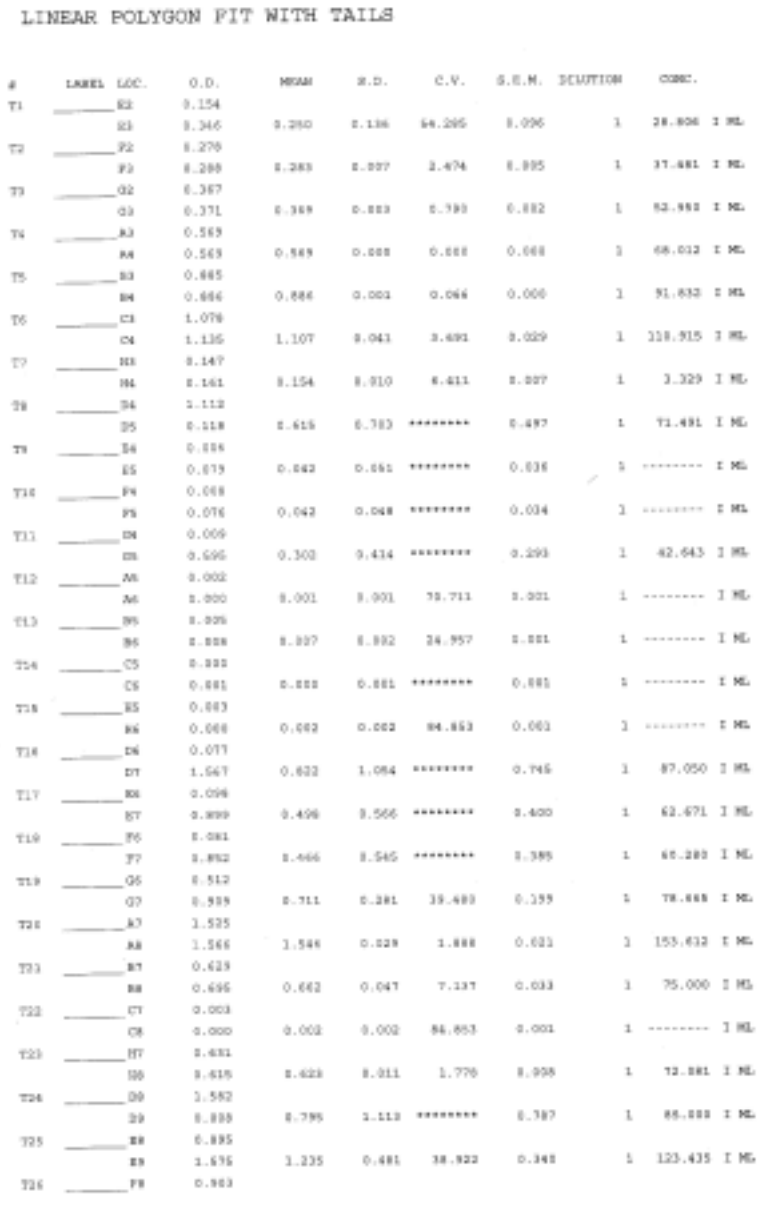


Figure 28. Curve Fitting Results (Continued)

Tabulated Results

The final portion of the results printout contains tabulated results for the assay. An example is shown in Figure 29.



LINEAR POLYGON FIT WITH TAILS

#	LABEL	LOC.	O.D.	MEAN	S.D.	C.V.	S.E.M.	DILUTION	CONC.
T1		E2	0.154						
		E3	0.346	0.250	0.136	54.295	0.096	1	28.906 I ML
T2		F2	0.270						
		F3	0.289	0.283	0.007	2.474	0.005	1	37.681 I ML
T3		G2	0.367						
		G3	0.371	0.369	0.003	0.793	0.002	1	52.953 I ML
T4		A3	0.569						
		A4	0.569	0.569	0.000	0.000	0.000	1	68.012 I ML
T5		B3	0.685						
		B4	0.686	0.686	0.001	0.066	0.000	1	91.633 I ML
T6		C3	1.078						
		C4	1.136	1.107	0.041	3.691	0.029	1	118.915 I ML
T7		H3	0.147						
		H4	0.161	0.154	0.010	6.611	0.007	1	3.329 I ML
T8		D4	1.112						
		D5	0.118	0.615	0.703	********	0.497	1	71.491 I ML
T9		E4	0.004						
		E5	0.079	0.042	0.051	********	0.036	1	-------- I ML
T10		F4	0.008						
		F5	0.076	0.042	0.048	********	0.034	1	-------- I ML
T11		G4	0.009						
		G5	0.595	0.302	0.414	********	0.293	1	42.643 I ML
T12		A5	0.002						
		A6	0.000	0.001	0.001	70.711	0.001	1	-------- I ML
T13		B5	0.005						
		B6	0.008	0.007	0.002	24.957	0.001	1	-------- I ML
T14		C5	0.000						
		C6	0.001	0.000	0.001	********	0.001	1	-------- I ML
T15		E5	0.003						
		E6	0.000	0.002	0.002	84.853	0.001	1	-------- I ML
T16		D6	0.077						
		D7	1.567	0.822	1.084	********	0.765	1	87.050 I ML
T17		E6	0.098						
		E7	0.899	0.498	0.566	********	0.400	1	62.671 I ML
T18		F6	0.081						
		F7	0.852	0.466	0.545	********	0.385	1	60.280 I ML
T19		G6	0.512						
		G7	0.909	0.711	0.281	39.480	0.199	1	78.668 I ML
T20		A7	1.535						
		A8	1.556	1.546	0.029	1.888	0.021	1	155.612 I ML
T21		B7	0.629						
		B8	0.696	0.662	0.047	7.137	0.033	1	75.000 I ML
T22		C7	0.003						
		C8	0.000	0.002	0.002	84.853	0.001	1	-------- I ML
T23		H7	0.631						
		H8	0.615	0.623	0.011	1.776	0.008	1	72.881 I ML
T24		D8	1.582						
		D9	0.008	0.795	1.113	********	0.787	1	88.888 I ML
T25		E8	0.895						
		E9	1.575	1.235	0.481	38.922	0.340	1	123.435 I ML
T26		F8	0.903						

Figure 29. Tabulated Results

Chapter 6 Running a Test

Starting an Assay

The START option lets you operate the Reader using a previously defined assay procedure.

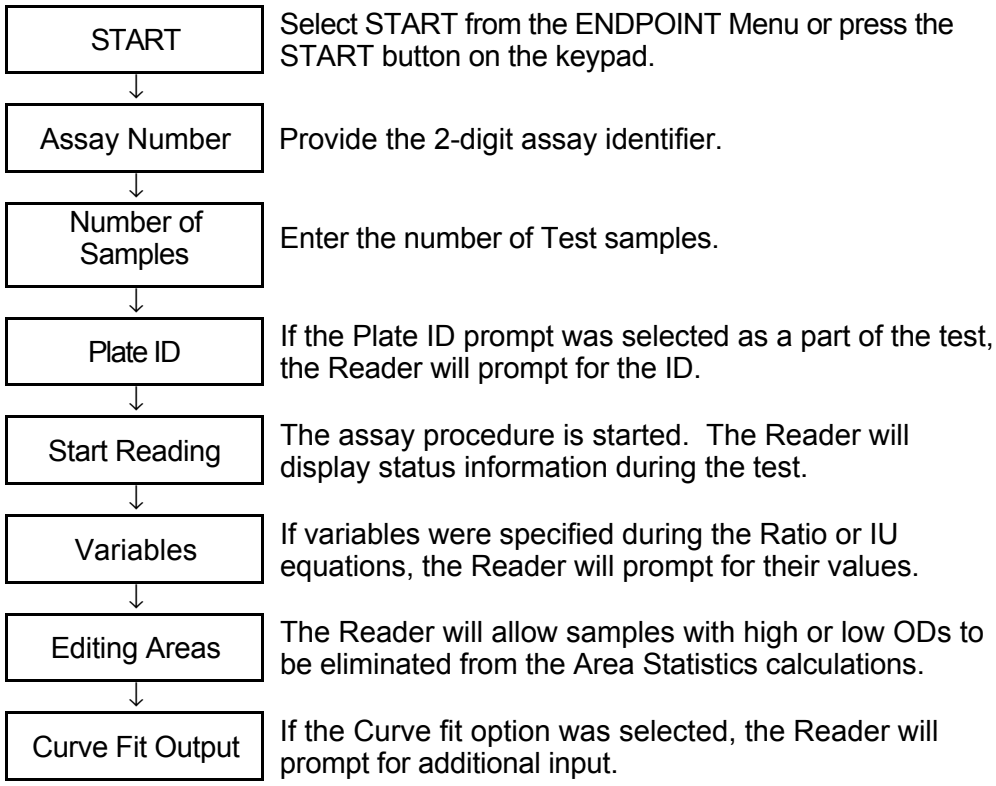


Figure 30. Running a Test

Assay Number

1. Select START to begin an assay the Reader will prompt:

TEST-nn DIR

2. Input a previously created test number. The Display Panel will show the corresponding test name. Press ENTER to start the displayed test.

Number of Samples

1. The Reader will load the stored assay and prompt for the number of samples to be assigned to this test:

NO. OF SAMPLES = 96

2. Press ENTER to accept the displayed. You can change this number to:

   - Run fewer samples
   - Run multiple tests

Running fewer samples

1. Press DELETE. The current number of samples is removed:

   NO. OF SAMPLES =

2. Enter the new number of samples to be processed:

   NO. OF SAMPLES = 36

3. The Reader prompts if you want to assign wells to other tests:

   ANY MORE SAMPLES?
   YES NO

4. Enter NO, which in the above example leaves sixty wells unassigned.

5. The Reader will ask if you want to rearrange the template by shifting columns or rows:

   WELLS IN?
   COLUMNS ROWS

5. If you arranged the template in columns, select columns. If you arranged it in rows, select rows.

Note: The Reader uses the following rules for rearranging the template:

First, unused Test wells are eliminated. Then, if necessary, Blanks are removed. Second, the remaining wells are shifted left if columns were selected or up if rows were selected. Third, Control, Standard and User Wells are left in the same positions you defined, relative to the last full column or row on the plate.

If well reduction is not possible using these rules, the Reader will print an error message. See *Examples of Templates* in *Appendix B*.

You must select the LABELLED OD Matrix option to obtain a printout of the rearranged plate.

Running multiple tests

1. Press DELETE. The current number of samples is removed:

   NO. OF SAMPLES =

2. Enter the number of samples to be processed:

   NO. OF SAMPLES = 36

3. The Reader will ask if you want to assign wells to other tests:

   ANY MORE SAMPLES?
   YES NO

4. Enter YES. The Reader will prompt for a new test. After you select the new test, the Reader will ask if you want to assign all the remaining wells to the new test:

   NO. OF SAMPLES = 60

5. The Reader will prompt for up to 12 tests until all 96 wells have been assigned or you select NO at the ANY MORE SAMPLES prompt. Then, the display will read:

   WELLS IN?
   COLUMNS ROWS

6. Select COLUMNS to assign wells top to bottom. Select Rows to assign wells left to right.

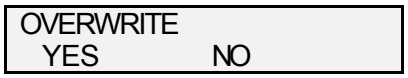
Note: The Reader uses the following rules for assigning wells to multiple tests. If you selected columns, samples are assigned top to bottom, left to right: A1, B1, C1 … A2, B2, C2, up to H12. If you selected rows, samples are assigned left to right, top to bottom, A1, A2, A3 … B1, B2, C2 …up to H12. The Reader counts all wells along the columns or down the rows until it reaches the number of samples you specified. It continues where it left off for the second test, and so on.

Plate ID

1. If you defined your assay procedure to prompt for plate ID, the display will read:

7. Enter the plate ID, up to 12 characters, you want to assign to this test.

3. If a Plate ID exists with the same name as the one entered, you will be asked if you want to overwrite the store plate data:

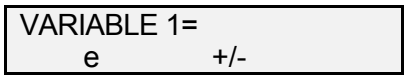


Start Reading

The test will begin and the Reader will show processing steps on the Display Panel.

Variables

1. If the test includes any equations which require runtime variables, the Reader will prompt:

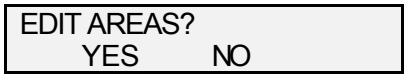


2. Enter a Value for each variable and select ENTER.

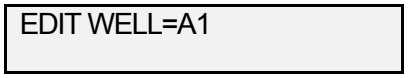
Note: Variables are not stored. If you want to run the test again using the same variable values, you should make a written record of the values and store them for re-entry.

Editing Areas

1. If Area Statistics was included in the test, the Reader will ask:



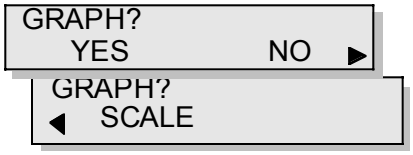
2. To remove wells with unexpectedly high or low ODs select YES. The next display will be for the wells to eliminate:



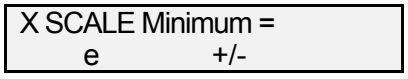
3. Use the keypad to enter a well location, then select ENTER to remove the displayed well from statistical calculations.

Curve Fit with Standards

1. If Curve Fit was included in the test, and the test contains Standards the Reader will ask:



2. Select YES to graph Standards concentrations against their OD values. Select SCALE to adjust the minimum and maximum graph values. If Scale is select the Reader will prompt:



3. Enter minimum and maximum x and y axes values for the Standards graph.

4. Next the Reader will ask if you want to include any previously removed standards or delete any currently included Standards from the curve fit calculations:

```
EDIT STDS?
    YES          NO
```

5. If you select YES the next prompt is for the number of the Standard you want to edit:

```
STD. NO.  (1-4) =  n
```

6. Enter the Standard number, from 1 to 4. The Reader will prompt for a decision on each replicate well for the selected Standard. The prompt will be DELETE if the Standard is currently included in the curve fit calculations:

```
O. D. #1  DELETE
    YES      NO
```

or INCLUDE if the Standard had previously been deleted from the curve fit calculations:

```
O. D. #1  INCLUDE
    YES      NO
```

7. When all replicates for the selected Standard have been displayed, the EDIT STDS prompt will be re-displayed. Edit any remaining standards, selecting NO when edits are complete.

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Chapter 7 Recall Plate and Utilities

Recall Plate

The Recall Plate option recalls data from previously read plate for further processing.

1. If you select RECALL from the ENDPOINT Menu the Reader will prompt for the plate number to recall:

   ```
   PLATE =
     DIR
   ```

2. After a valid plate number has been provided, the Reader will ask which test to use to process the data.

   ```
   TEST-nn
     DIR
   ```

3. The initial display is for the currently selected assay. Use the keypad to enter the desired test number, the display will show the corresponding test name. Select ENTER when the desired test has been selected.

Note: Processing an existing plate using a different test is useful if you want to assess the OD data of the test using a technique not inserted into the original test.

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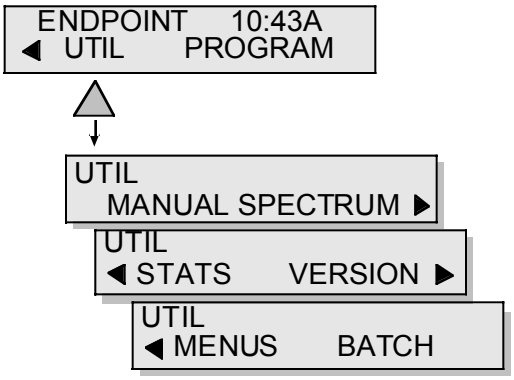
Utilities Overview

The UTIL Menu provides manual Reader operation, wavelength recommendations, statistical analysis of stored data, retrieval of software versions, and Endpoint menu configuration.



Selection	Purpose
MANUAL	Lets you operate the Reader manually.
SPECTRUM	Produces a spectral response curve.
STATS	Runs statistical analysis on stored data.
VERSION	Displays the software version number of the installed Endpoint Program.
MENUS	Lets you select Short or Long Endpoint Menus.
BATCH	Recalls and reprocess stored plate data.

The procedures for performing these commands are outlined in the following sections.

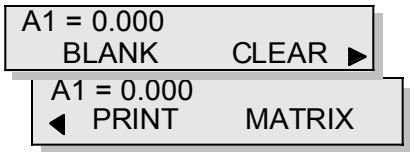
Manual Mode

Select the MANUAL option to perform a manual reading.

1. The Reader will prompt for wavelength mode:

The Reader can be operated in SINGLE or DUAL mode. Refer to page 5 for additional information.

2. When the filters have been chosen the plate is read. The Reader will displays the OD results for each well and prompts for output options:



Selection	Purpose
BLANK	Select BLANK to mark the displayed well as a Blank sample. This well will be reported as zero and the displayed reading will be subtracted from subsequent wells.
CLEAR	Select CLEAR to change a previously blanked reading back to its original value. All subsequently viewed wells will use air blanking.
PRINT	Select PRINT to output the reading displayed for each well location to a connected printer.
MATRIX	Select MATRIX to print an OD matrix.

Spectrum

The Spectrum option lets you produce a spectral response curve for the specified well.

1. The Reader will prompt for the well:

   WELL LOCATION = A1

2. Use the keypad to enter a well location then select ENTER.

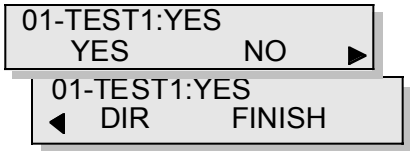
Note: The Reader will perform readings of the specified well using all installed filters. The spectral response curve and suggested test and reference filters will then be printed out. Three or more filters must be installed to use the SPECTRUM option.

Stats

The STATS option calculates statistical data for stored plates. Selections are Coefficient of Variation (C.V.) and STATS:

C.V.

1. The C.V. option checks that the readings from the selected group of plates have an acceptable variation. If you select C.V. the Reader will prompt for the plates to include in this analysis:



2. Use the keypad to enter the test number (01 in the example). Select YES to include the plate (as in the example) or NO to remove the plate.

3. Select FINISH to process the selected plates and print the results.

STATS

1. The Stats option can be used like C.V., above, but it operates on sections of the selected plates identified by the Area Statistics option (refer to *Area Statistics* in *Chapter 3*). If you select STATS, the Reader will prompt for the test number to use.

2. After selection of the test procedure, the Reader will prompt for the plates as described for C.V. above.

Version

Select VERSION to display the version number of the installed software. The Reader will display the information for approximately 3 seconds and then return to the Endpoint UTIL Menu.

```
ENDPOINT VER.  n.nn
```

Menus

The Endpoint Menu described in *Chapter 3* is the standard, Long format Endpoint Menu. The MENUS option allows you to select the Short format Endpoint Menu.

1. If you choose MENUS the Reader will display the currently selected format.

```
MENUS: LONG
```

2. Use the DEL key to modify this value. The Reader will prompt:

```
MENUS ?
  SHORT        LONG
```

3. The SHORT option can be used after you have created assay test procedures. If you select short menus, the Reader will ask you to assign existing test procedures to function keys (F1-F8).

```
F1 = nn
  DIR
```

4. Use the keypad to enter the test number. The Reader will display the corresponding (truncated to 7 characters) test name.

Note: You must assign all eight function keys. If, for example, you only have one test to assign, you must assign this test to all eight function keys.

Batch

The BATCH option recalls stored plate data and reprocesses it using a different test. BATCH operates like RECALL (refer to the previous section), but allows processing multiple plates. When Cancel is selected the batch processing begins.

Chapter 8 Troubleshooting

Operational Problems

Problems that may occur during normal operation of the *Opsys* MR™ are described below. For each problem, the symptom, probable cause and the means for resolving the problem are shown.

Symptom	Probable Cause	Resolution
Neither the plate motor or the filter motor work.	There is a fault on the AM Module Main board.	Replace AM Module Main board.
The display freezes. The system does not respond when a key is pressed.	There is a fault on the AM Module Main board.	Replace AM Module Main board.
The filter motor fails or runs roughly.	The motor is faulty.	Replace the motor.
	There is a fault on the AM Module Main board.	Replace AM Module Main board.
The filter wheel rotates continuously.	There is a fault on the AM Module Main board.	Replace AM Module Main board.

Operational Problems

Symptom	Probable Cause	Resolution
OD readings are incorrect or inconsistent.	There is dust or grease on the lamp or reflector.	Clean dust from lamp using a photographic blower. If lamp is contaminated with greasy deposits, replace the lamp..
	There is a cracked heat filter or dirty or cracked aspheric lens.	Replace the heat filter.
	There is a dirty or cracked filter.	Clean or replace the filter.
	The lens strip, lens stop, or collector ferrule is dirty.	Clean or replace lens strip.
	An optical fibre is damaged.	Replace the fiber optic array.
	Light is entering the reading chamber.	Check that the front door closes correctly. Remove any obstructions.
	There is a fault on the AM Module Main board.	Replace AM Module Main board.
Key presses do not register or are incorrectly registered.	The keypad encoder is faulty.	Replace the keypad.
	There is a fault on the AM Module Main board.	Replace AM Module Main board.
The lamp does not light.	Lamp has blown.	Replace lamp.
	Loose connections.	Check the connections to the lamp assembly.
	There is a fault on the AM Module Main board.	Replace AM Module Main board.

Chapter 9 Routine Maintenance

Routine Maintenance Procedures

The only maintenance procedures that are required for the *Opsys* MR™ are the following:

Daily maintenance:

- Verify that the self-test passes.

> **Note**: Results of the self-test can be printed if desired. Refer to page 42 for specifying printing of self-test results.

- Remove the microplate from the plate carrier. Clean the plate carrier, using a moist towel.
- Clean the external surfaces, using a moist towel.

Yearly maintenance:

- Remove the optical filters and clean them.

Cleaning and Decontamination

The *Opsys* MR™ is constructed from materials that resist chemical attack. However, spills should be cleaned as soon as possible to prevent damage.

If you need to decontaminate the *Opsys* MR instrument (for example, before servicing the instrument), clean the system and then decontaminate it as described below.

CAUTION: Always disconnect the power cable before cleaning the instrument.

To clean external and painted surfaces:

1. Clean external surfaces with a cloth moistened with mild laboratory detergent.

   NOTE: If needed, dilute the laboratory detergent according to the manufacturer's instructions before using.

To decontaminate the system:

1. Wipe the surfaces with a cloth moistened with 10% bleach or 70% alcohol.

Replacing the Lamp

CAUTION: The optics assembly may be hot. Allow at least five minutes for the instrument to cool before opening the optics assembly.

Also, be careful when removing the filter access panel as there is a possibility that the bulb may have broken.

Failure to follow the lamp replacement procedures as described may result in personal injury.

CAUTION: Always disconnect the power cable before removing the filter access panel.

To replace the lamp:

1. Remove the filter access panel (Figure 4) to expose the optical assembly. The bulb is mounted in the upper portion of the optical assembly as shown in Figure 31.

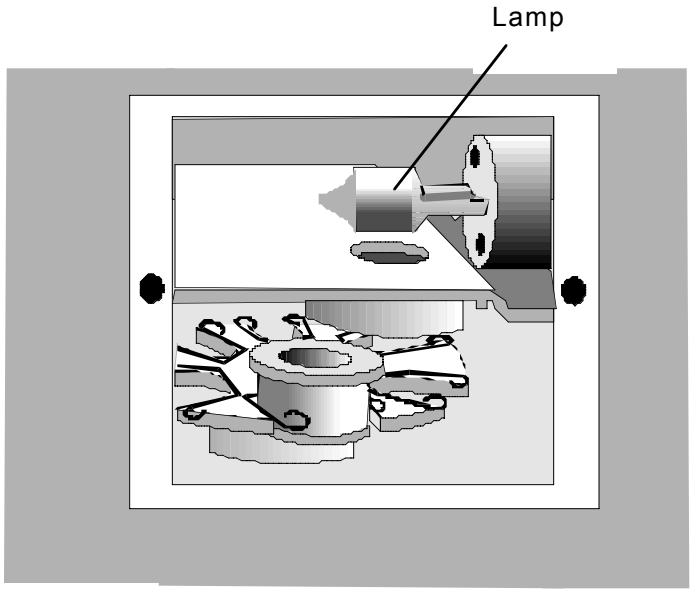


Figure 31. Optical Assembly

2. Put on a pair of rubber or latex gloves.

> **CAUTION**: Gloves are necessary to prevent skin oils from damaging the lamp. Gloves are also worn as a safety precaution should the glass bulb accidentally break.

3. Grasp the lamp with plastic tweezers and pull the lamp out of its receptacle (Figure 32).

> **IMPORTANT**: Use a gloved finger to prevent the bulb from bumping into the metal sidewalls of the enclosure during removal.

4. Obtain a replacement lamp.

5. Grasp the lamp tines with narrow needle nose pliers and align the tines with the corresponding holes in the lamp socket.

6. Firmly insert the lamp into the socket.

7. Replace the filter access panel.

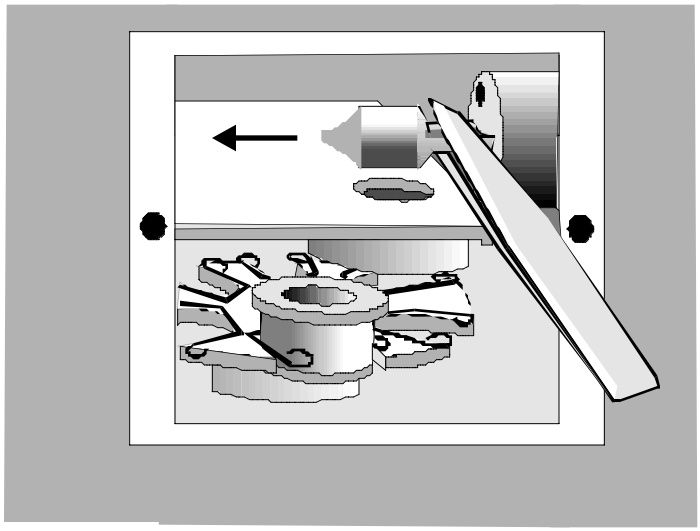


Figure 32. Removing the Lamp

Removing and/or Installing a Filter

CAUTION: The optics assembly may be hot. Allow at least five minutes for the instrument to cool before opening the optics assembly.

Also, be careful when removing the filter access panel as there is a possibility that the bulb may have broken.

CAUTION: Always disconnect the power cable before removing the filter access panel.

To remove a filter:

1. Remove the filter access panel. The filters are mounted on the filter wheel as shown in Figure 31.

2. Locate the filter that is to be removed.

3. Firmly grasp the exterior filter housing with a pair of needle nose pliers (Figure 33).

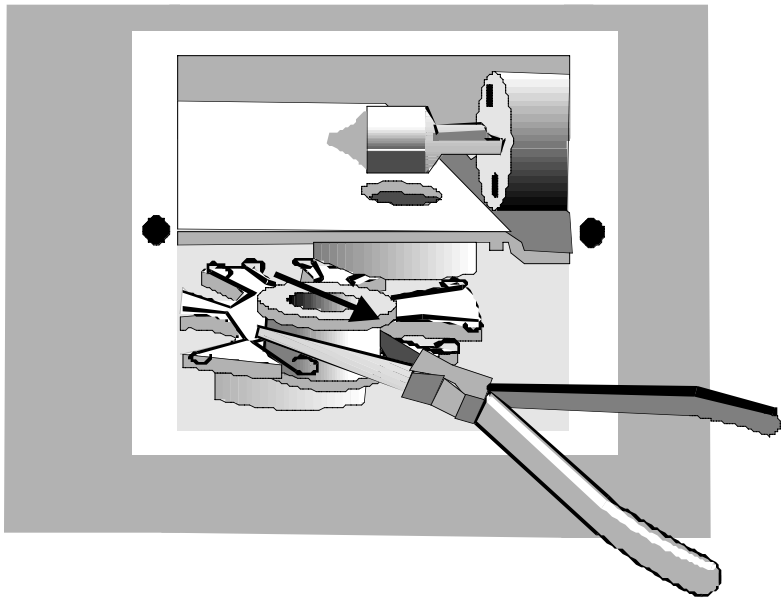


Figure 33. Removing a Filter

4. Pull the filterwheel out of the spring loaded slot.

5. Replace the filter access panel.

To install a filter:

1. Remove the filter access panel. The filters are mounted on the filter wheel as shown in Figure 31.

2. Locate the filter position in which the filter will be installed.

> **IMPORTANT**: Filters must be installed in adjacent filter positions, in the order of their wavelength. There must not be any empty filter positions between the lowest wavelength and highest wavelength filters.

3. Firmly grasp the exterior filter housing with a pair of needle nose pliers.

4. Push the filter wheel into the spring loaded slot.

5. Replace the filter access panel.

> **IMPORTANT**: The bottom groove of the filter must be firmly seated in the filter wheel. If the groove is aligned with the spring on the filter wheel then the filter has been installed incorrectly and will result in invalid instrument performance.

Chapter 10 Service

Service Procedures

The only service procedure that can be carried out for the *Opsys* MR™ is removal and replacement of the optics assembly.

CAUTION: Always disconnect the power cable before removing either the optics assembly.

CAUTION: The optics assembly may be hot. Allow at least five minutes for the instrument to cool before removing it.

.

DYNEX Contacts

Contact your nearest DYNEX facility if you have questions concerning service. The address and telephone numbers of worldwide DYNEX facilities are listed below.

Germany:

DYNEX Technologies (GmbH)
Justinus-Kerner-Strasse 32
D-73766 Denkendorf

Phone: 0711 934 630
FAX: 0711 346 0509
email: info@dynex.de

Czech Republic:

DYNEX Technologies spol s r.o.
Na Cihadle 32
160 00 Praha 6 Prague

Phone: 02-2431 3375
FAX: 02-2432 0133
email: office@dynex.cz

USA:

DYNEX Technologies Inc.
14340 Sullyfield Circle
Chantilly VA 20151

Phone: 703 631 7800
FAX: 703 631 7816
email: info@dynextechnologies.com
web site: dynextechnologies.com

United Kingdom:

DYNEX Technologies (UK) Ltd
Daux Rd, Billingshurst
West Sussex, RH14 9SJ

Phone: 01403 783381
FAX: 01403 784397

France:

DYNEX Technologies (France)
175, rue J-J. Rousseau
92138 Issy-Les-Moulineaux Cedex

Phone: 01 41 09 10 00 Technique: 01 41 09 10 08 / 09
FAX: 01 46 44 30 12 Technique: 01 41 09 10 01
email: dynexfrance@compuserve.com

Absorbance Module Removal and Replacement

To remove the absorbance module:

1. Loosen the four locking rods at the rear of the instrument, using a flat blade screw driver (Figure 34).

2. Firmly grasp the front of the absorbance module and slide it out of the chassis.

To replace the absorbance module:

1. Firmly grasp the absorbance module and slide it into the chassis.
2. Secure the four locking rods at the rear of the instrument.

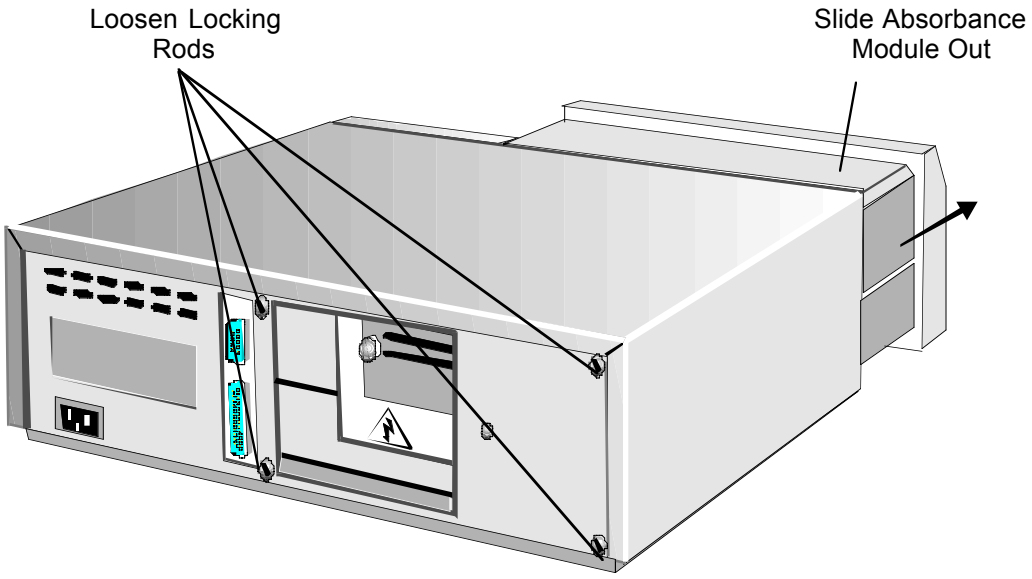


Figure 34. Removal of the Absorbance Module

Returning a Module for Service

If the absorbance module, the chassis, or the entire instrument must be returned for service, it must be cleaned and decontaminated if it has been in contact with potentially infectious body fluids (including human blood), pathological samples, or toxic or radioactive materials.

Note: Refer to page 132 for cleaning and decontamination instructions.

To return a module for service:

1. Contact the nearest DYNEX technical service facility for return authorization.
2. Clean and decontaminate the module.
3. Fill out an Equipment in Transit form (see Appendix D).
4. Insert the foam shipping chuck into the absorbance module, if it is being returned.
5. Pack the module and the Equipment in Transit form for shipment.
6. After you receive a return authorization, ship the module to the nearest DYNEX facility (see page 137).

Appendix A Menus

Menu Hierarchy

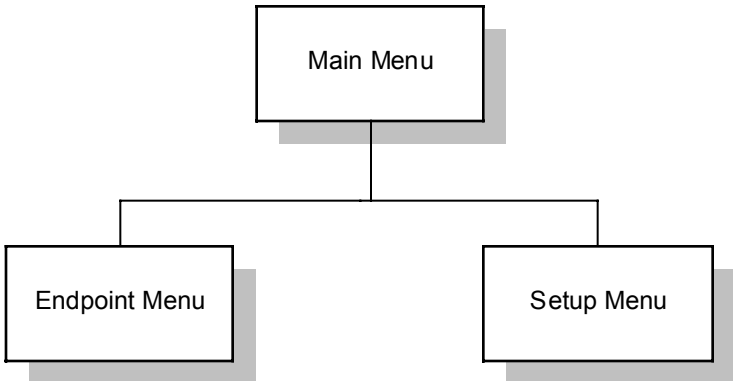


Figure 35. Main Menu

The *Opsys* MR™ Main Menu provides access to two submenus, the Endpoint and Setup Menus. The Endpoint Menu is used to access commands to create, edit, run and analyze assay test procedures. It can be displayed in Long or Short format. The Setup Menu is used to access commands to configure the Reader.

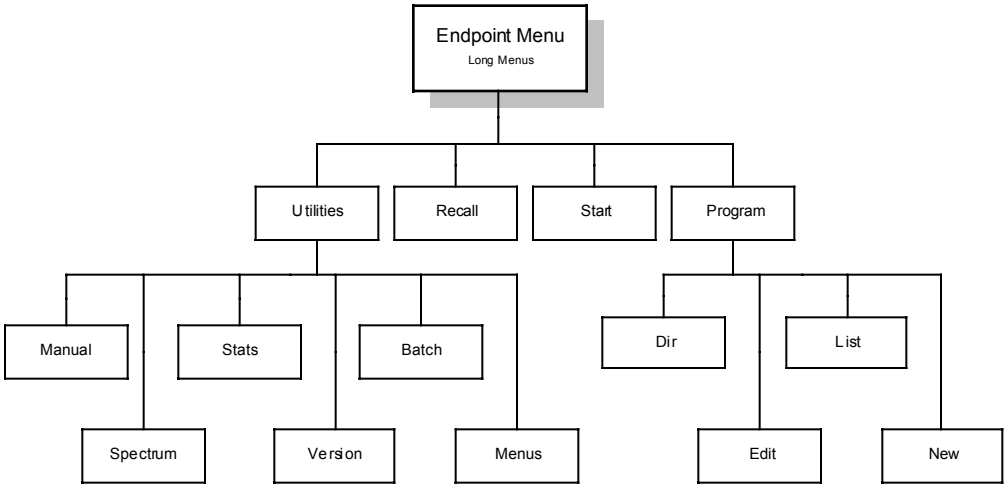


Figure 36. Endpoint Menu - Long Form

The Long Form Endpoint Menu provides access to create, edit print and run customized assay procedures.

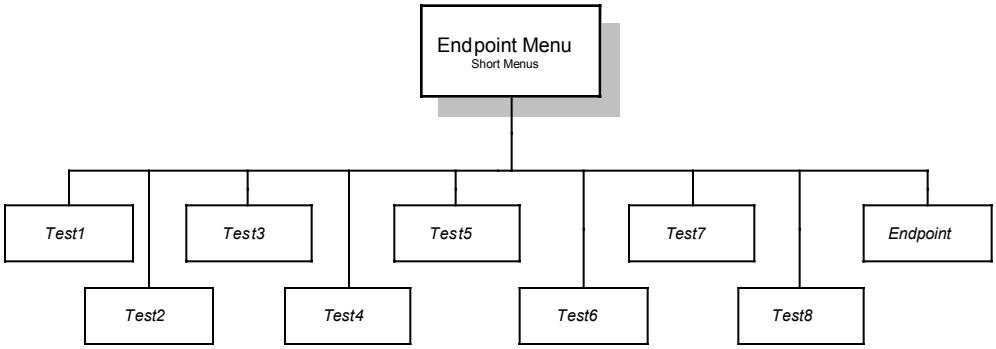


Figure 37. Endpoint Menu - Short Form

The Short Form Endpoint Menu provides function key access to eight previously created tests.

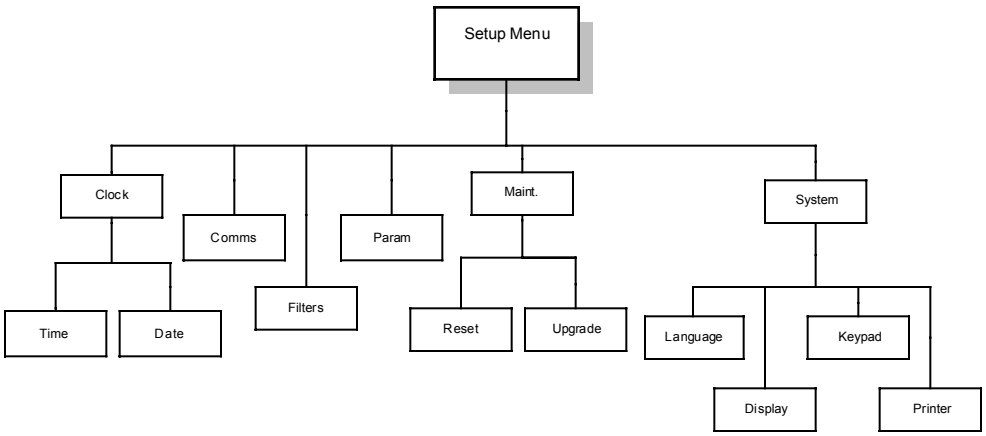


Figure 38. Setup Menu

The Setup Menu provides access to system configuration commands.

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Appendix B Templates

Examples of Templates

Single Well Standards in Rows

	1	2	3	4	5	6	7	8	9	10	11	12
A	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12
B	T1	T2	T3	T4	T5	T6	T7	T8	T9	T1	T1	T1
C	T1	T1	T1	T1	T1	T1	T1	T2	T2	T2	T2	T2
D	T2	T2	T2	T2	T2	T3	T3	T3	T3	T3	T3	T3
E	T3	T3	T3	T4	T4	T4	T4	T4	T4	T4	T4	T4
F	T4	T5	T5	T5	T5	T5	T5	T5	T5	T5	T5	T6
G	T6	T6	T6	T6	T6	T6	T6	T6	T6	T7	T7	T7
H	T7	T7	T7	T7	T7	T7	T7	T8	T8	T8	T8	T8

Single Well Standards in Columns

	1	2	3	4	5	6	7	8	9	10	11	12
A	S1	T1	T9	T1	T2	T3	T4	T4	T5	T6	T7	T8
B	S2	T2	T1	T1	T2	T3	T4	T5	T5	T6	T7	T8
C	S3	T3	T1	T1	T2	T3	T4	T5	T5	T6	T7	T8
D	S4	T4	T1	T2	T2	T3	T4	T5	T6	T6	T7	T8
E	S5	T5	T1	T2	T2	T3	T4	T5	T6	T6	T7	T8
F	S6	T6	T1	T2	T3	T3	T4	T5	T6	T7	T7	T8
G	S7	T7	T1	T2	T3	T3	T4	T5	T6	T7	T7	T8
H	S8	T8	T1	T2	T3	T4	T4	T5	T6	T7	T8	T8

Double Well Standards in Rows; Replicates in Columns

	1	2	3	4	5	6	7	8	9	10	11	12
A	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12
B	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12
C	T1	T2	T3	T4	T5	T6	T7	T8	T9	T1	T1	T1
D	T1	T2	T3	T4	T5	T6	T7	T8	T9	T1	T1	T1
E	T1	T1	T1	T1	T1	T1	T1	T2	T2	T2	T2	T2
F	T1	T1	T1	T1	T1	T1	T1	T2	T2	T2	T2	T2
G	T2	T2	T2	T2	T2	T3	T3	T3	T3	T3	T3	T3
H	T2	T2	T2	T2	T2	T3	T3	T3	T3	T3	T3	T3

Double Well Standards in Columns; Replicates in Rows

	1	2	3	4	5	6	7	8	9	10	11	12
A	S1	S1	T1	T1	T9	T9	T1	T1	T2	T2	T3	T3
B	S2	S2	T2	T2	T1	T1	T1	T1	T2	T2	T3	T3
C	S3	S3	T3	T3	T1	T1	T1	T1	T2	T2	T3	T3
D	S4	S4	T4	T4	T1	T1	T2	T2	T2	T2	T3	T3
E	S5	S5	T5	T5	T1	T1	T2	T2	T2	T2	T3	T3
F	S6	S6	T6	T6	T1	T1	T2	T2	T3	T3	T3	T3
G	S7	S7	T7	T7	T1	T1	T2	T2	T3	T3	T3	T3
H	S8	S8	T8	T8	T1	T1	T2	T2	T3	T3	T4	T4

Triple Well Standards in Rows; Replicates in Columns

	1	2	3	4	5	6	7	8	9	10	11	12
A	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12
B	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12
C	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12
D	T1	T2	T3	T4	T5	T6	T7	T8	T9	T1	T1	T1
E	T1	T2	T3	T4	T5	T6	T7	T8	T9	T1	T1	T1
F	T1	T2	T3	T4	T5	T6	T7	T8	T9	T1	T1	T1
G	-	-	-	-	-	-	-	-	-	-	-	-
H	-	-	-	-	-	-	-	-	-	-	-	-

Triple Well Standards in Columns; Replicates in Rows

	1	2	3	4	5	6	7	8	9	10	11	12
A	S1	S1	S1	T1	T1	T1	T9	T9	T9	T1	T1	T1
B	S2	S2	S2	T2	T2	T2	T1	T1	T1	T1	T1	T1
C	S3	S3	S3	T3	T3	T3	T1	T1	T1	T1	T1	T1
D	S4	S4	S4	T4	T4	T4	T1	T1	T1	T2	T2	T2
E	S5	S5	S5	T5	T5	T5	T1	T1	T1	T2	T2	T2
F	S6	S6	S6	T6	T6	T6	T1	T1	T1	T2	T2	T2
G	S7	S7	S7	T7	T7	T7	T1	T1	T1	T2	T2	T2
H	S8	S8	S8	T8	T8	T8	T1	T1	T1	T2	T2	T2

Alternative Format: Single Well Standards in Rows

	1	2	3	4	5	6	7	8	9	10	11	12
A	*	*	*	*	*	*	*	*	*	*	*	*
B	*	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	*
C	*	T1	T2	T3	T4	T5	T6	T7	T8	T9	T1	*
D	*	T1	T1	T1	T1	T1	T1	T1	T1	T1	T2	*
E	*	T2	T2	T2	T2	T2	T2	T2	T2	T2	T3	*
F	*	T3	T3	T3	T3	T3	T3	T3	T3	T3	T4	*
G	*	T4	T4	T4	T4	T4	T4	T4	T4	T4	T5	*
H	*	*	*	*	*	*	*	*	*	*	*	*

Alternative Format: Quadruple Well Standards in Columns; Replicates in Rows

	1	2	3	4	5	6	7	8	9	10	11	12
A	*	*	*	*	*	*	*	*	*	*	*	*
B	*	S1	S1	S1	S1	T 1	T 1	T 1	T 1	-	-	*
C	*	S2	S2	S2	S2	T 2	T 2	T 2	T 2	-	-	*
D	*	S3	S3	S3	S3	T 3	T 3	T 3	T 3	-	-	*
E	*	S4	S4	S4	S4	T 4	T 4	T 4	T 4	-	-	*
F	*	S5	S5	S5	S5	T 5	T 5	T 5	T 5	-	-	*
G	*	S6	S6	S6	S6	T 6	T 6	T 6	T 6	-	-	*
H	*	*	*	*	*	*	*	*	*	*	*	*

- Denotes Unused Wells

* Denotes Unused Wells in Alternative Format

Template Defined for 96 samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	C1	T8	T1	T2	T3	T4	T4	T5	T6	T7	T8	T8
B	T1	T9	T1	T2	T3	T4	T4	T5	T6	T7	T8	T8
C	T2	T1	T1	T2	T3	T4	T5	T5	T6	T7	T8	T8
D	T3	T1	T1	T2	T3	T4	T5	T5	T6	T7	T8	T9
E	T4	T1	T2	T2	T3	T4	T5	T6	T6	T7	T8	T9
F	T5	T1	T2	T2	T3	T4	T5	T6	T6	T7	T8	T9
G	T6	T1	T2	T3	T3	T4	T5	T6	T7	T7	T8	T9
H	T7	T1	T2	T3	T3	T4	T5	T6	T7	T7	C2	T9

Assay Run with 48 samples – column option

1) The Reader eliminates 48 test samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	C1	T8	T1	T2	T3	T4						
B	T1	T9	T1	T2	T3	T4						
C	T2	T1	T1	T2	T3	T4						
D	T3	T1	T1	T2	T3	T4						
E	T4	T1	T2	T2	T3	T4						
F	T5	T1	T2	T2	T3	T4						
G	T6	T1	T2	T3	T3	T4						
H	T7	T1	T2	T3	T3						C2	

2) The Reader repositions the Control to the original offset relative to end of plate

	1	2	3	4	5	6	7	8	9	10	11	12
A	C1	T8	T1	T2	T3	T3						
B	T1	T9	T1	T2	T3	T4						
C	T2	T1	T1	T2	T3	T4						
D	T3	T1	T1	T2	T3	T4						
E	T4	T1	T2	T2	T3	T4						
F	T5	T1	T2	T2	T3	T4						
G	T6	T1	T2	T3	T3	T4						
H	T7	T1	T2	T3	C2	T4						

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Appendix C - Equations

QC Equations

Component	Example	Entered
Numeric value	0-9 .	Keypad
Operator	+ - * / = < > ( )	Keypad
Well Type [represents the mean OD of all the wells of that type]	B	Select WELL then select well type.
Sample [represents the mean OD of all replicates of that sample]	C1	Select WELL then select well type. Use the keypad to enter the sample number.
One Replicate [represents the OD of the selected replicate of that sample]	C1.2	Select WELL then select well type. Use the keypad to enter the sample and replicate number.
All Samples [tests each sample of that well type]	Ci	Select WELL then select well type. Select “i’ under OPTIONS.
Conditional	If/then/else	Select OPTIONS Use the Function Key to toggle i/if.
Statistical Value	Median(SD(CV(	Select OPTIONS then STAT. Select the desired statistical value.
Statistical Function	valid(Max(Min(variable	Select OPTIONS then FUNCTION. Select the desired statistical function.

The expressions that are used are similar whether the expression is prepared for Raw Data: Q.C., Threshold Q.C., or Curve Fit Q.C. Examples of typical expressions and their use are shown below

Example 1

Template includes 3 Negative Controls and 2 Positive Controls:

If any Negative Control OD is more than 25% higher or 25% lower than the mean of all the Negative Controls it must be rejected:

QC1: 0.75*NC<=NCi<=1.25*NC

If more than one Negative Control OD is rejected the test fails QC:

QC2: valid(NC)>=2

The average of the Negative Control ODs must be more than 0.5:

QC3: NC>0.5

The average of the Positive Control ODs must be less than 20% of the average of the Negative Control ODs:

QC4: PC<0.2*NC

Example 2

Template includes 4 Negative Controls and 2 Positive Controls:

If any Negative Control OD is more than three times higher than the sum of the other three it must be rejected:

QC1: 4*NC-NCi>=NCi

If more than two Negative Control ODs are rejected the test fails QC:

QC2: valid(NC)>=2

The average of the Negative Control ODs should not be greater than 0.2. However, if the average of the Positive Control ODs is greater than 0.7, then average Negative Control ODs of up to 0.3 will be accepted:

QC3: If PC>0.7 then NC<=0.3 else NC<=0.2

The average of the Positive Control ODs must be more than 0.5:

QC4: PC>0.5

Threshold Equations

Component	Example	Entered
Numeric value	0-9 .	Keypad
Operator	+ - * / ( )	Keypad
	** 'power of'	
Well Type [represents the mean OD of all the wells of that type]	B	Select WELL then select well type.
Sample [represents the mean OD of all replicates of that sample]	C1	Select WELL then select well type, then use the keypad to enter the sample number.
One Replicate [represents the OD of the selected replicate of that sample]	C1.2	Select WELL then select well type, then use the keypad to enter the sample and replicate number.
Statistical Value	Median(	Select OPTIONS then select STAT.
	SD(	
	CV(	

Example 1

ODs equal to or above 2.5000 are recorded as positive. ODs below 0.1999 are recorded as negative.

+ **EQN: 2.5000**
- **EQN: 0.1999**

Example 2

ODs equal to or above the Cut-off Control 1 plus 0.4 but less than the Cut-off Control 1 plus 0.6 are recorded as positive. ODs equal to or above the Cut-off Control 1 plus 0.6 are recorded as strong positive. ODs below the Negative Control are recorded as negative.

++ **EQN: CO1+0.6**
+ **EQN: CO1+0.4**
- **EQN: NC**

Ratio Equations

Component	Example	Entered
Numeric value	0-9 .	Keypad
Operator	+ - * / ( )	Keypad
	** 'power of'	
Well Type [represents the mean OD of all the wells of that type]	B	Select WELL then select well type.
Sample [represents the mean OD of all replicates of that sample]	C1	Select WELL then select well type, then use the keypad to enter the sample number.
One Replicate [represents the OD of the selected replicate of that sample]	C1.2	Select WELL then select well type, then use the keypad to enter the sample and replicate number.
Statistical Function	Sample Variable Max Min	Select OPTIONS then select FUNCTION.
Logarithmic Function	Log Alog Ln Exp	Select OPTIONS then select MATH

Statistical Values and Functions

Alog

Inserts an inverse base 10 logarithm.

Example: Analog of Test sample T1

Alog(T1)

CV

Represents the coefficient of variation between ODs in a group of wells.

Example: Coefficient of variation of all Control wells

CV(C)

Exp

Inserts an inverse natural logarithm.

Example: Inverse natural logarithm of all Control wells

Exp(C)

If/then/else

Inserts a conditional expression. The Reader offers **if** the first time this option is selected, **then** the second time and **else** the third time. Else is optional.

Example: The average of the Negative Controls must be greater than 0.7. However, if the average of the Positive Controls is less than 0.2 then average Negative Control ODs greater than 0.5 will be accepted.

If PC<0.2 then NC>0.5 else NC>0.7

Ln

Inserts a natural logarithm.

Example: Natural Log of all Control samples

Ln(C)

Log

Inserts a base 10 logarithm.

Example: Log of all Control samples

Log(C)

Max/Min

Represents the maximum/minimum OD on the plate, or within a group of wells.

Example: The lowest OD of all replicates of Test sample 1.

Min(T1)

Example: The highest OD on the plate.

Max

Note: Be sure to use parentheses when using a well sample.

Median

Represents the middle value in a group of ODs. If the group contains and even number of samples the median is the average of the middle two ODs.

Example: Median of all Blank1 replicates

Median(B1)

Sample

Inserts the individual OD of every well on the plate into the equation

Example: To convert all ODs on the plate to a ratio of the average Positive Control.

sample/PC

SD

Represents the standard deviation between ODs in a group of wells.

Example: Standard Deviation of Test samples.

SD(T)

Valid

Inserts a validity expression. Format is:

valid(well type)expression

Example: The number of Standard wells that pass the quality control equations must be greater than one or the test fails.

valid(S)>1

variable

Represents a variable that must be entered at runtime. Five variables are allowed per test.

Example: You must provide variable1 at runtime.

variable1

Curve Fit Equations

In the case of Power, Spline, Polygon, and Akima modes data is transformed before curve fitting is performed. For Sigmoid and Michael selections, the best fit is calculated using untransformed data.

For all curve fitting routines, data are always plotted in the following way:

X axis represents concentration

Y axis represents measured variables (i.e. optical density, time, or rate of change with time)

Linear Regression

Linear Regression is used to put a "best fit" straight line through a set of data points. The equation for a straight line is:

$$y = mx + c$$

where:

m = the slope
c = the y-intercept defining the line
x = the value for concentration
y = the value for the measured variable.

The linear regression formulae for determining the best straight line through a series of data points are:

$$m = \frac{N \sum x_i y_i - \sum x_i \sum y_i}{N \sum x_i^2 - \left(\sum x_i\right)^2}$$

$$c = \bar{y} - m\bar{x}$$

where $\bar{x}$ and $\bar{y}$ are the mean values of x and y, i.e.:

$$\bar{x} = \frac{\sum x_i}{N}$$

The linear regression coefficient, **R**, is defined by:

$$R^2 = \frac{\left(N \sum x_i y_i - \sum x_i \sum y_i\right)^2}{\left(N \sum x_i^2 - \left(\sum x_i\right)^2\right)\left(N \sum y_i^2 - \left(\sum y_i\right)^2\right)}$$

When $\mathbf{R^2=1}$, all data points lie along the line of best fit.
When $\mathbf{R^2=0}$, the data points are highly scattered.

Once a line of best fit has been established for a set of known Standards, the concentration of an unknown sample can be determined for a measured sample as follows:

$$\text{concentration} = \frac{y - c}{m}$$

Polygon Fitting

The polygon fitting procedure joins successive data points using straight lines.

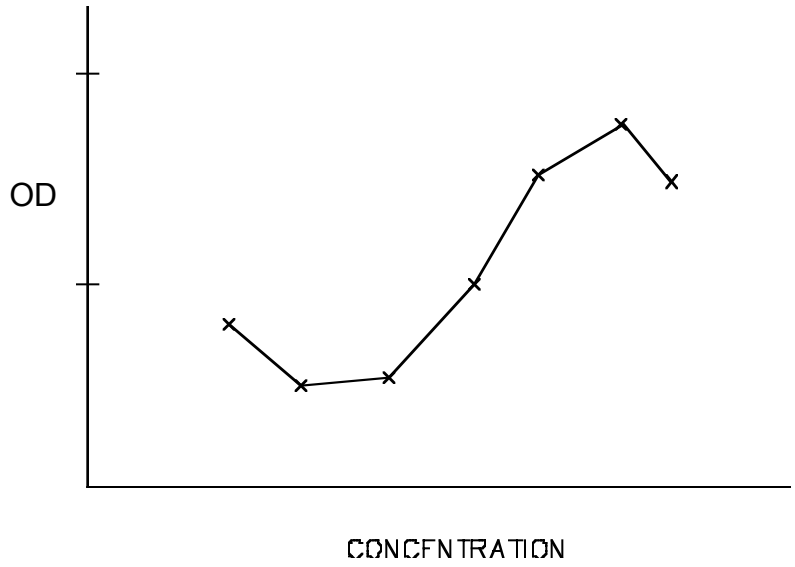

Figure A-1 Polygon Fitting

Non Linear Curve Fitting

The remaining fitting routines all produce curves rather than straight line plots.

The Reader will only calculate one concentration value for each measured variable. The user should examine the printed graph to determine if another curve would provide a better fit for the data points.

Some curves fit functions may not behave as expected if extrapolated beyond the range defined by the data points.

For example, in a particular test, the readings for a set of Standards increase in a non-linear fashion with increasing concentration. The user determines that a quadratic curve fit might give the best fit for such data. However, at concentrations lower than the concentration of the lowest Standard, the curve might turn sharply upwards as shown in Figure A2.

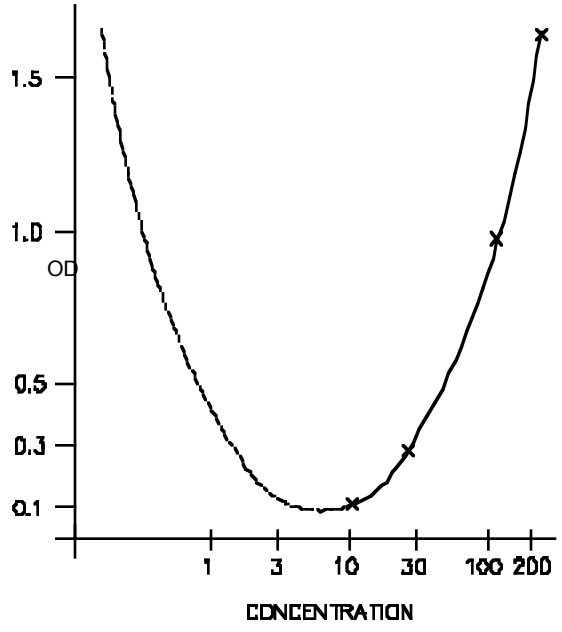

Figure A-2 Using Tails

Quadratic, Cubic and Quartic Regression

Polynomial (quadratic, cubic and quartic) regression is best explained in parallel with linear regression, where the function to fit to experimental data can be written as:

$$y = a + bx^1$$

where:

b = the slope (corresponding to m in straight line equation)

a = the y-intercept of the line (corresponding to c in the equation for a straight line)

A quadratic equation is defined as:

$$y = a + bx + cx^2$$

A cubic equation as:

$$y = a + bx + cx^2 + dx^3$$

And a quartic equation as:

$$y = a + bx + cx^2 + dx^3 + ex^4$$

The procedures to fit such functions to experimental data are closely related to linear regression and have a similar mathematical derivation. Polynomial regression minimizes the deviations of the data points from the polynomial equation (the square of the data point deviations are minimized since positive and negative deviations would otherwise cancel each other out).

There is an analogous regression coefficient **R**, which when $\mathbf{R^2=1}$ indicates that all the data points have been fitted to the curve; when $\mathbf{R^2=0}$, the data points are highly scattered.

Cubic Spline Curve Fitting

Cubic spline curve fitting passes a curve through all the data points. This is not a best fit algorithm since it assumes that the data set is perfect. The relevant equations are given below without explanation.

$$y = a_0 + a_1 x + \sum_{j=1}^{n-2} b_j \Phi_j(x)$$

Where:

$$\Phi_j(x) = \rightarrow_j(x) - \frac{x_n - x_j}{x_n - x_{n-1}} \sqrt{\rightarrow}_{n-1}(x) + \frac{x_{n-1} - x_j}{x_n - x_{n-1}} \sqrt{\rightarrow}_n(x)$$

$$\Phi_j(x) = \begin{cases} 0 & x \leq x_j \\ (x - x_j)^3 & x > x_j \end{cases}$$

Difficulties can arise with spline fitting, if data are highly erratic or the curve bends sharply several times. The curve may break up at high concentrations (see Figure A-3). The Reader will not be able to perform the calculations because of numerical rounding errors generated when attempting to fit the curve. Using a semi-log or log-log axis fit rather than a linear fit, will reduce this problem.

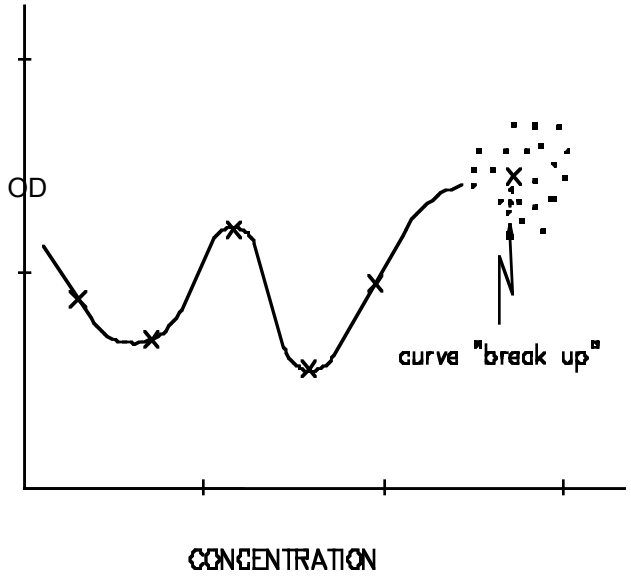

Figure A-3 Spline Curve Break Up

Sigmoid Equation

Many immunological reactions are characterized by an S-shaped or sigmoid curve.

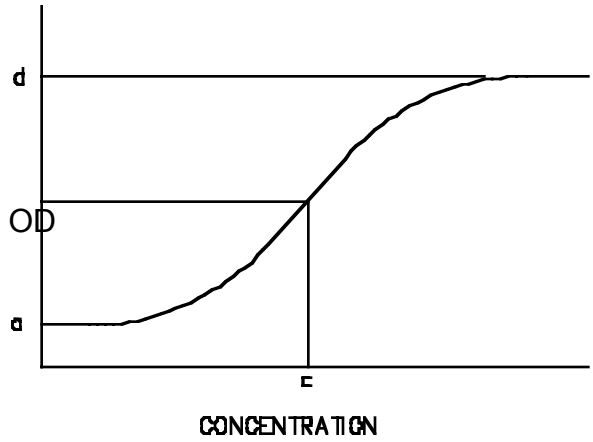

Figure A-5 Sigmoid Curve

The Sigmoid equation can be written as:

$$Y = \frac{[a-d]}{1+\left(\frac{X}{c}\right)^{b}} + d$$

Note: This equation is also known as Rodbard's Four Parameter equation.

The four parameters are:

- **a** the minimum response
- **b** the shape factor (determines the gradient of the curve)
- **c** the response midway between the maximum (d) and the minimum (a) responses
- **d** the maximum response

This definition assumes a positive value for **b**. Where **b** is negative, the definitions for parameters **a** and **d** are reversed.

The Reader contains an efficient algorithm for estimating the four parameters and determining the best fit for the sigmoid curve.

The curve requires at least four Standards (data points): one for each of the four parameters. It is recommended that at least eight Standards are defined to ensure satisfactory statistical significance. The Reader will allow a maximum of 24 Standards.

The sigmoid curve algorithm is iterative, requiring many complex calculations and the Reader may take some time to process the results. If the Reader has difficulty fitting the data to the curve, processing will continue, either until the Reader has processed the data, or until you select **ABORT**. If you have aborted the data processing, examine the data carefully, to see if the number of Standards could be altered to better define the curve.

Akima Curve Fit

The Akima option constructs a smooth curve through the data points. The fitted curve will appear smooth and natural and approximates a manually drawn curve.

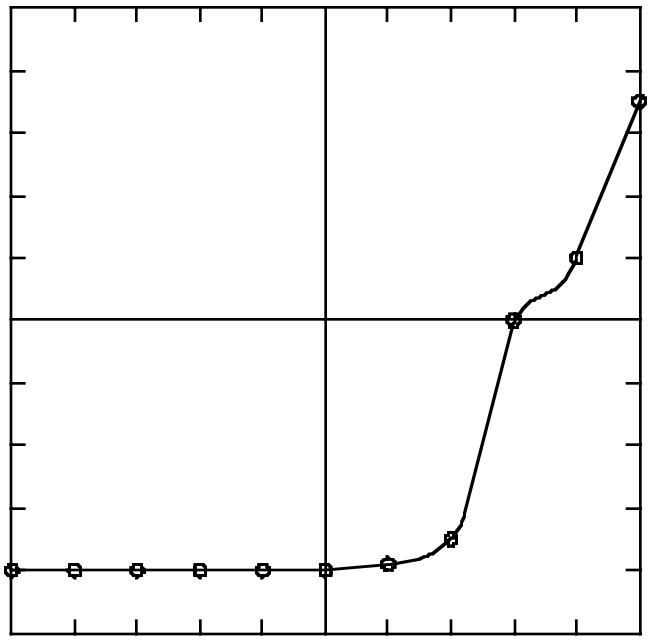

Figure A-6 Points Joined by the Akima Curve Fit Method

The Akima curve fit consists of a set of polynomials which are applied to the set of data points. The slope of the curve at each point is determined by these polynomials. The Akima fit is based on the assumption that each data point is determined locally by five points: The point of interest and two points on either side of it.

Calculation of the Slope of the Curve

Numbering the points 1, 2, 3, 4, 5, the slope of the curve at the point of interest (point 3) is assumed to be determined by:

$$t = \frac{(m_4 - m_3)m_2 + (m_2 - m_1)m_3}{(m_4 - m_3) + (m_2 - m_1)}$$

where **t** is the slope of the curve, and m_1, m_2 m_3, and m_4 are the slopes of the following line segments:

$$\overline{12}, \overline{23}, \overline{34}, \overline{45}$$

Interpolating Between a Pair of Points

With the slopes of the points determined, the portion of the curve between two points is calculated so that the curve:

- passes through both points
- the slopes at the data points are the same as previously determined.

The portion of the curve is expressed as a uniquely determined polynomial in the form:

$$y = p_0 + p_1(x - x_1) + p_2(x - x_1)^2 + p_3(x - x_1)^3$$

where

$p_0 = y_1$ and $p_1 = t_1$

$$p_2 = \frac{3(y_2 - y_1)/(x_2 - x_1) - 2t_1 - t_2}{x_2 - x_1}$$

$$p_3 = \frac{t_1 + t_2 - 2(y_2 - y_1)/(x_2 - x_1)}{x_2 - x_1}$$

Axis Fitting

The normal method of fitting data to the axes of a graph is to use linear scales for the x (concentration) and y (measured variable) axes. Two other methods are available:

- **Semi-Log Fit**
- **Log-Log Fit**

For semi-log fit, all x are transformed in the following way:

$$x = \log(\text{concentration})$$

Thus, to obtain the concentration of a sample using linear regression:

$$\text{concentration} = \text{antilog}\frac{y - c}{m}$$

For log-log fit, all x and y values are transformed as follows:

$$x = \log(\text{concentration})$$

$$y = \log(\text{measured variable})$$

Thus to obtain the concentration of a sample using linear regression:

$$\text{concentration} = \text{antilog}\frac{y - c}{m}$$

Note: These examples use linear regression, but Log-Log and Semi-Log Axes Fits may be used with other curve fitting routines as well.

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Appendix D – Forms

Equipment in Transit Form

DYNEX
TECHNOLOGIES
The Microtiter® Company

EQUIPMENT IN TRANSIT

IMPORTANT: Please include a copy of this form with each instrument.

Return Authorization Number: _____
Contact Technical Coordinator, DYNEX TECHNOLOGIES
phone: (800)336-4543 or (703)631-7800 option#3
fax: (703)631-7816
Equipment: _____
Serial Number: _____

EQUIPMENT DECLARATION

Clearly indicate fault condition or reason for return.

CERTIFICATE OF DECONTAMINATION

I certify that the equipment described above has been disinfected/decontaminated* and is clean, dry and fit for transport.
Signed: _____
Title: _____
Date: _____
(DYNEX Technologies reserves the right to refuse improperly cleaned equipment)

Shipping Address: DYNEX Technologies
Attn.: (Above return number)
14340 Sullyfield Circle
Chantilly, VA 20151-1683

***Suggested decontamination methods:**

Readers- Wash all surfaces with a 10% Hypochlorite solution, Follow that with a mild detergent solution.

Washers- Please follow the "Decontamination Procedure" found in the back of the manual.

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