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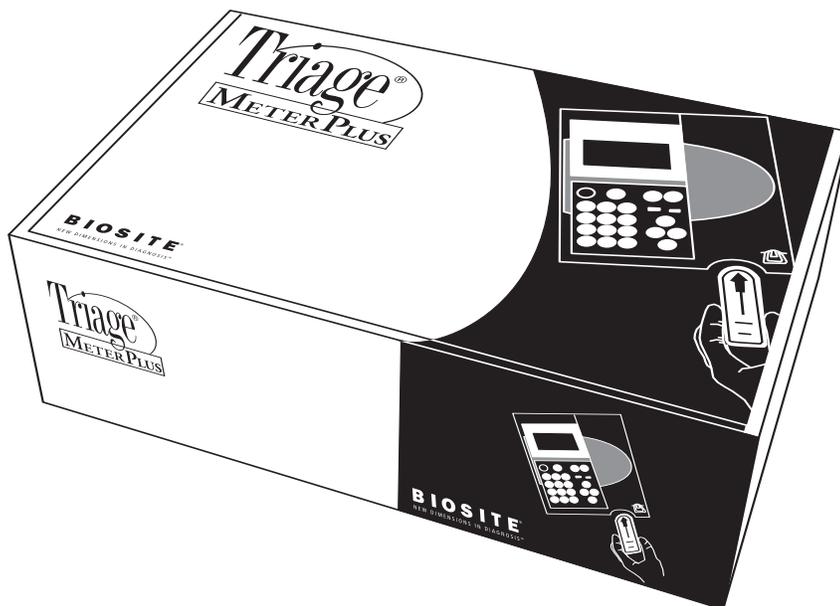
How to Use This Guide

This manual contains:

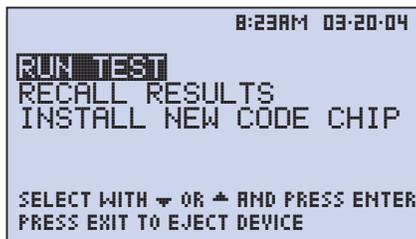
- Instructions for the operation and maintenance of the Triage® MeterPlus, and;
- Basic instructions for testing samples



Note: To run specific tests, such as the Triage® Cardiac Panel, you also will need the detailed information that comes in the package insert with the test device.



The Triage® MeterPlus software has been designed to provide the user step by step instructions. The meter displays test results and menu options in the upper half of the meter screen. In smaller letters at the bottom of each screen, the meter displays instructions pertaining to the task being performed.



The display above is the Main Menu and appears after the meter has been turned on and completed an automatic self-test.

The Triage® MeterPlus User Manual is divided into five sections.

Section 1 – **Introduction:** Provides an overview of Triage® MeterPlus.

Section 2 – **Installation:** Guides the user through first time setup.

Section 3 – **Operation:** Guides the user through running tests, recalling results and deleting results.

Section 4 – **Care & Maintenance:** Total Quality Assurance, Warnings, Precautions and Limitations, Service and Maintenance, Warranty.

Section 5 – **Appendix:** Troubleshooting, Sample Log Sheets, Index of Page Revisions, Software Flowchart, Glossary

Symbols

 = Caution

 = Important

 = Note

 = New Feature

Meter Keys are indicated by

 = Up key

 = Down key

 = Left key

 = Right key

 = On/Off key

 = Delete key

 = Enter key

 = Exit key

 = Paper Feed key

 = Print key

 = Dash key

Screen commands and options are indicated by **A BOLDED FONT WITH SMALL CAPITAL LETTERS**

At the bottom of each page appears the page number and revision. A page revision chart is located in the appendix and will be revised and included whenever a manual update occurs. Use the Page Revision Chart to periodically verify presence of all pages. You may receive an updated copy of this chart at any time by calling our Customer Service Department at **1-888-BIOSITE (1-888-246-7483)**.

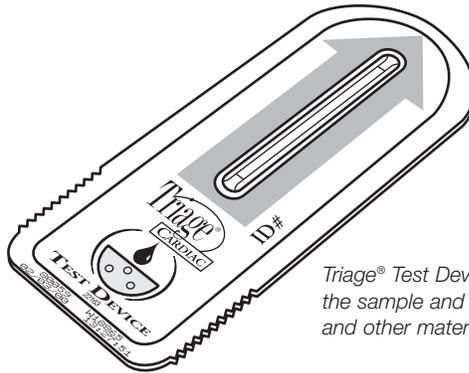
Introduction

Description

What is the Triage® MeterPlus?

The Triage® MeterPlus is a portable fluorescence instrument used to measure the results of tests manufactured by Biosite Incorporated®. The Triage® MeterPlus can be used in a laboratory or in a point-of-care setting.

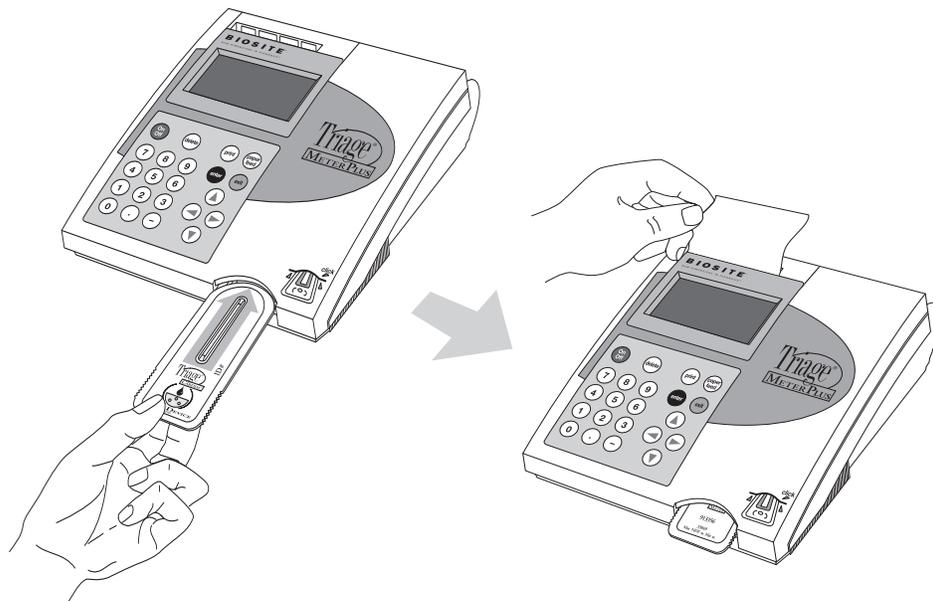
The Triage® MeterPlus uses a laser as a light source. Light from the laser hits a test device that has been inserted in the meter. This causes the fluorescent dye in the test device to give off energy. The more energy the fluorescent dye gives off, the stronger the signal.



Triage® Test Devices. A test device holds the sample and also contains the reagents and other materials needed for the test.

Overview: Running a Test

After a test sample (for example, blood) from a patient is added to the test device, the test device is inserted in the Triage® MeterPlus. The meter measures how much of the substance (a particular protein marker) is present, based on standards that have been pre-programmed into the meter. The patient identification, the User I.D. number and the test results can be printed out on a paper tape.



In addition to testing samples from patients, the Triage® MeterPlus contains pre-programmed Quality Control (QC) functions that allow the person operating the meter to monitor quality control.

Unpacking

The Triage® MeterPlus and the items that come with it are provided in a single box.

Triage® test devices are packaged separately and include instructions for running specific tests. If you have any questions, contact Biosite Incorporated Technical Services at 1-888-BIOSITE (1-888-246-7483).

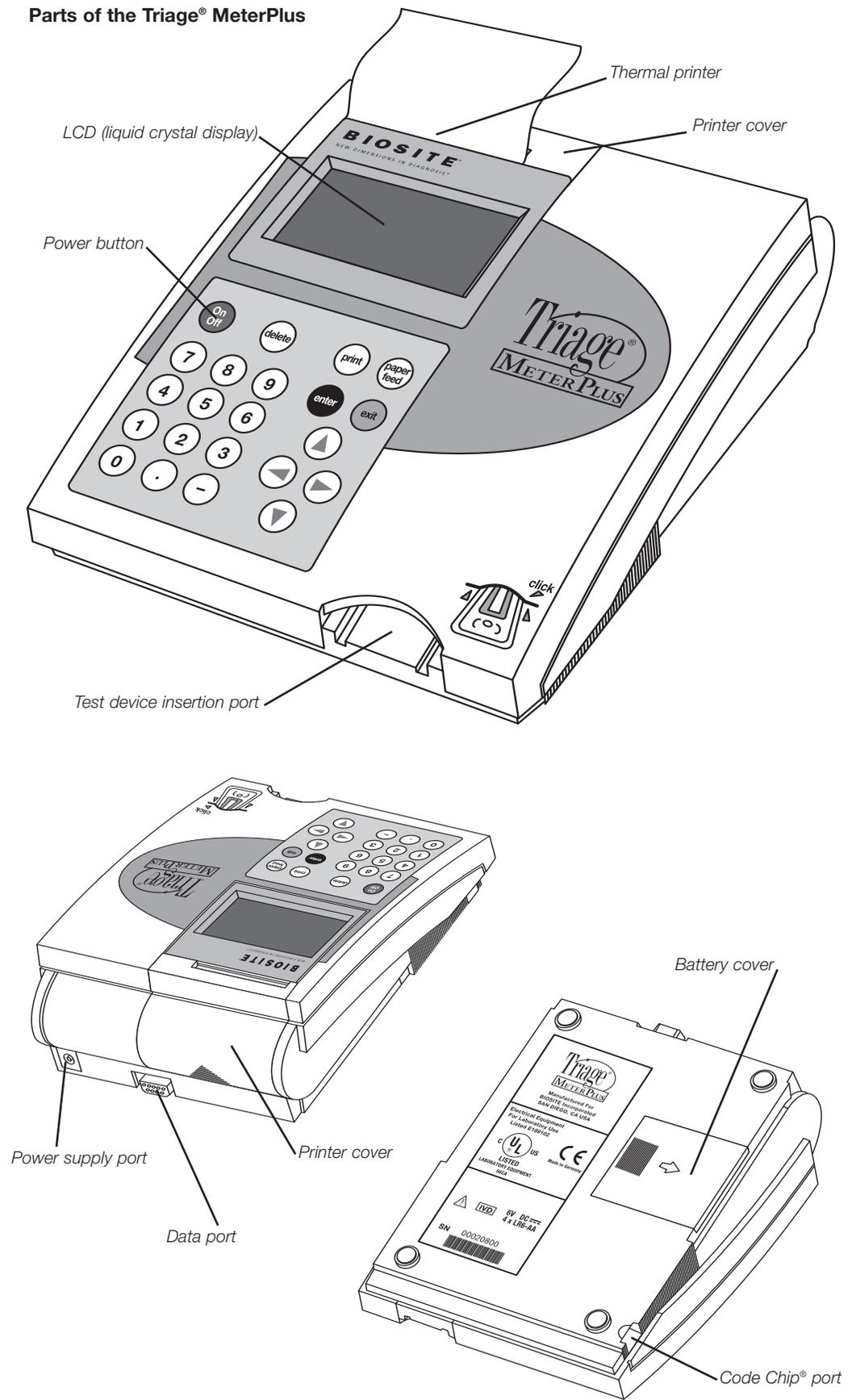
Contents:

- Triage® MeterPlus
- QC Device & Code Chip® (in the QC Device box)
- AC / DC Power Converter
- AA Batteries
- Rolls of Printer Paper (additional rolls are supplied in each box of test devices)
- Supervisor Code Chip & Code Chip Box
- Sticker with Technical Services Hotline Number



Note: The Triage® Meter accepts tests devices that are designed specifically for use with the Triage® Meter. Please refer to the instructions that come with each test for more information. The instructions come in the package with the test devices.

Parts of the Triage® MeterPlus



Power button	Used to turn the Triage® Meter on and off.
Print Button	Used to print the test results or display screen.
Delete Button	Used to delete data.
Enter Button	Allows the operator to select menu items and acknowledge alarm conditions.
Exit button	Used to exit the displayed menu or eject the test device.
Keypad	Used to enter identification numbers.
Arrow Buttons	Used to toggle through menu items.
Thermal Printer	Prints the test result on paper.
Data Port	Connection point for the (optional) Bar Code Scanner, allowing the operator to scan patient or user identification numbers instead of manually entering numbers on the keypad. May also be used to connect to a data management system/LIS.
Code Chip® Port	Insertion point for Code Chips which contain lot / device specific data for use in providing test results.
Power Supply Port	Connection point for the supplied AC / DC Power Converter.
Printer Cover	Cover, which when pulled straight up, reveals the paper roll.
LCD Screen	The LCD (Liquid Crystal Display) Screen shows the menu of possible tests and tasks and prompts the operator to take the next step.

Specifications

Physical

Size	8.5" x 6.25 "x 2.75" (22.5 cm x 19 cm x 7 cm) D x W x H
Weight	1.5 pounds (0.7 kg) without batteries
Electrical	6v DC at 1 amp – supplied via 4 AA batteries or AC/DC Converter
Keypad	Numeric with special function keys (22 total)

Environmental

Temperature	15C – 30C
Humidity	10% – 85%
Location	Dry, clean, flat horizontal surface away from direct sunlight

Optical

Light Source	Laser Diode – <1 milliwatt
Detector	Silicon Photodiode

Memory Capacity

750 Patient Records	20 Reagent Lot Code Chips®
200 QC Sample Results	30 QC Sample Code Chips
70 QC Device Results	4 QC Device Code Chips
600 User ID numbers	

Miscellaneous

RS-232 computer interface port
Thermal Printer
LCD screen display

Options

- External Bar Code Reader (rapid entry of User, Patient or Auxiliary ID numbers).
- Triage Census® Data Management Software.
- Triage Census® Data Management Software with LIS Connectivity.

Test Device Specifications

Test device specific information is provided in the applicable product insert. The instrument analyzes immunoassay test devices manufactured by Biosite Incorporated.

Warnings, Precautions and Limitations

- Operate the Triage® MeterPlus on a level, dry surface away from direct sunlight.
- The QC Device is light-sensitive and should be stored in its black opaque case when not in use.
- Do not move the Triage® MeterPlus while a test is in progress.
- Ensure all sample fluids have absorbed into the test device prior to running the test to prevent internal contamination of the meter.
- Use only the AC / DC power adapter provided with the Triage® MeterPlus. An identifying tag has been placed on the cord for quick identification.
- Do not drop the Triage® MeterPlus.
- Do not place objects on the Triage® MeterPlus.
- Do not immerse the Triage® MeterPlus in water or any liquids.

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Installation

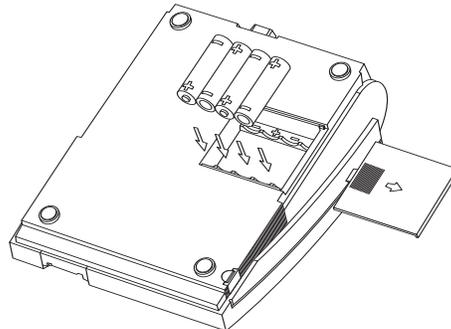
1. Unpack Meter:

- a. Remove the meter from the box and protective plastic bag.

2. Power Meter On:

Batteries

- a. Turn the meter over.
- b. Remove battery cover.
- c. Install 4 AA batteries, paying attention to battery orientation in the battery compartment.



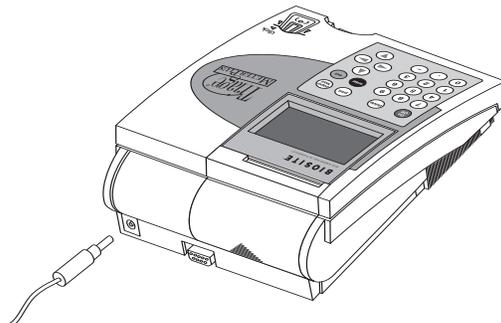
- d. Replace battery cover and turn meter right side up.
- e. Power the meter on by pressing the **on/off** key. Press the **enter** key to run self-test. When the test is completed, the meter display screen will come to rest at the main menu.



The Main Menu

AC Power Supply

- a. Remove the power supply from the box.
- b. Plug one end into an AC outlet.
- c. Plug the opposite end into the round hole in the back of the meter.



 **Note:** The Low Power Indicator monitors the active power source. To verify adequate battery power:

- Navigate to the Main Menu
- Remove the AC power supply
- Press the EXIT key (the meter attempts to eject a device)
- Observe the Main Menu on the meter's display.

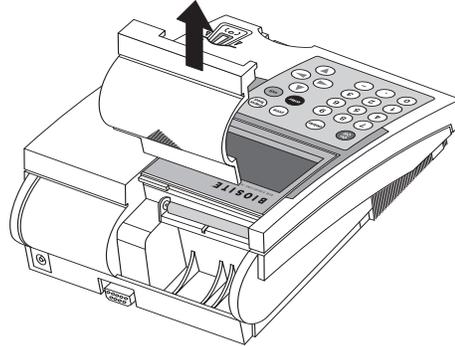
Replace the batteries if the power icon is visible. 

For more details about Installing Paper see the CARE & MAINTENANCE section.

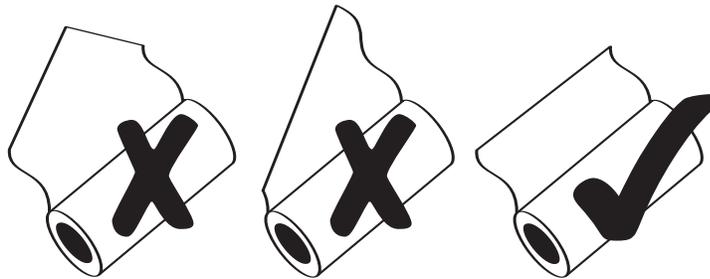
 **Note:** The printer contains a paper sensor and will feed the new paper roll only when paper with a clean straight line is pressed into the paper roller.

3. Install paper:

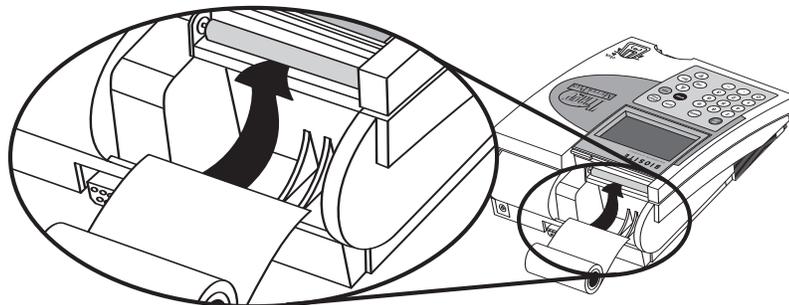
- a. Remove the printer cover by pulling up on the cover as indicated by the arrow on the back of the cover.



- b. Tear or cut a clean, straight edge to feed into the printer. Do not cut paper at an angle, as the printer must sense the edge of the paper along the feed path.



- c. Position the paper such that the paper will feed from under the roll (as opposed to over the top of the roll, see picture).



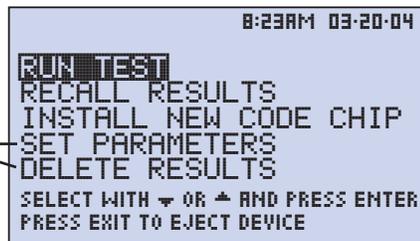
- d. Insert the paper edge under the paper roller (platen) until it firmly seats or resistance is felt.
- e. Press the  key twice, paper will feed through the printer and extend out the meter.
- f. Place the roll of paper into the paper compartment.
- g. Replace the printer cover and continue operation.

4. Insert Supervisor Code Chip®:

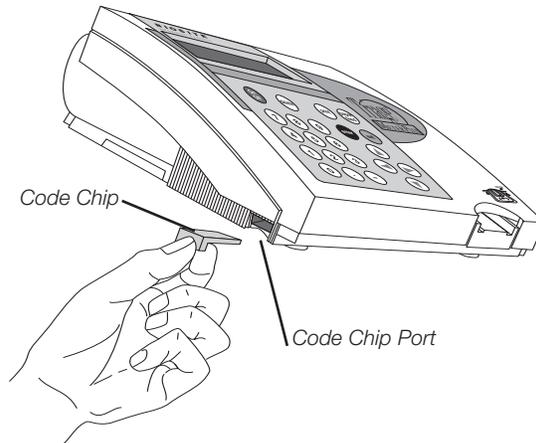
- a. Remove the Supervisor Code Chip Box from the meter box.
- b. Remove the Supervisor Code Chip from its box.
- c. Insert the Supervisor Code Chip into the Code Chip Port. The port is located on the left side of the meter, towards the bottom front corner. Note the orientation of the Code Chip in the drawing below.
- d. Once the Supervisor Code Chip is installed, verify that two additional menu items appear on the display screen.

For more details
about Code Chips
see page N-29.

Menu options
accessible only
when Supervisor
Code Chip inserted.



The Supervisor's Main Menu



For more details about Meter Settings see page N-11.

5. To Change Meter Settings:

- a. Select **SET PARAMETERS** using the   keys and Press .
- b. Select **METER SETTINGS** using the   keys and Press .
- c. Select **ID SETTINGS, DISPLAY SETTINGS** or **COMM SETTINGS** using the   keys and Press .
- d. Select the desired setting using the   keys and change the value of the setting by using the   keys.

ID SETTINGS	Default	Options	New Setting
CHARACTERS USER ID	Min 1	1 - 10	<input type="text"/>
	Max 10	1 - 10	<input type="text"/>
CHARACTERS PAT. ID	Min 1	1 - 12	<input type="text"/>
	Max 12	1 - 12	<input type="text"/>
CHARACTERS AUX ID	Min 1	1 - 12	<input type="text"/>
	Max 12	1 - 12	<input type="text"/>
AUX. ID ENABLE/DISABLE	Disabled	Disabled, Enabled	<input type="text"/>

For reference, record your settings in the space provided.

- e. Press  to save changes to ID Settings.

DISPLAY SETTINGS	Default	Options	New Setting
LANGUAGE	English	English, Français, Italiano, Deutsch, Español, Ελληνικά, Dansk, Svenska, Português	<input type="text"/>
PRINT MODE	Automatic	Automatic, Manual	<input type="text"/>
AUTO POWER-OFF	2 hour	½ hour, 1 hour, 2 hour, 4 hour, None	<input type="text"/>
DISPLAY CONTRAST	4	0 – 8 (8 = heaviest contrast)	<input type="text"/>
PRINTER CONTRAST <i>for Meters with Serial Numbers starting with 29901.</i>	4	0 – 8 (8 = heaviest contrast)	<input type="text"/>

For reference, record your settings in the space provided.



f. Press to save changes to Display Settings.

COMM SETTINGS	Default	Options	New Setting
BAUD RATE	9600	9600, 38400	<input type="text"/>
PAT. RESULT APPROVAL	Enabled	Enabled, Disabled	<input type="text"/>
LIS ENABLE/DISABLE	Disabled	Disabled, Enabled	<input type="text"/>
UPLOAD	Manual	Manual, Automatic	<input type="text"/>
LIS PASSWORD			<input type="text"/>



g. Press to save changes to Communication Settings.

h. Press to save changes to Meter Settings.

For more details about Communications, including entry of a Biosite provided, meter specific password, see page N-17.

For more details about Clock Settings see page N-20.

6. Change Clock:

- a. Select **SET PARAMETERS** using the   keys and Press .
- b. Select **CLOCK** using the   keys and Press .
- c. Select the **HOUR : MINUTE** area using the   keys. Type in the correct time using the number keys.
- d. Press  to move to **AM** or **PM**.
- e. Select **AM** or **PM** using the   keys.
- f. Press  to move to **TIME FORMAT**.
- g. Select **AM/PM** or **24 HR.** using the   keys. If selecting **24 HR.**, the previously entered **HOUR : MINUTE** will change to a 24-hour format and the **AM** or **PM** will disappear.
- h. Press  to move to the **DATE**.
- i. Type in the 6-digit date according to the **DATE FORMAT** below it.
- j. Press  to move to the **DATE FORMAT**.
- k. Select **MM-DD-YY**, **DD-MM-YY** or **YY-MM-DD** using the   keys.
The previously entered **DATE** changes as the **DATE FORMAT** changes.
- l. Press  to save changes.

Setting	Default	Options	New Setting
TIME FORMAT	AM / PM	AM / PM; 24HR.	<input type="text"/>
DATE FORMAT	MM-DD-YY	MM-DD-YY, DD.MM.YY, YY-MM-DD	<input type="text"/>

7. Set User ID:

The Triage® MeterPlus normally requires a User ID to be entered prior to a patient test or a QC test. Refer to page N-21 for instructions. Alternately, this feature may be bypassed. See page N-8.

8. Change Reference Ranges / Thresholds for Tests:

- Select **SET PARAMETERS** using the   keys and Press .
- Select **RANGES** using the   keys and Press .
- Select the test panel type using the   keys.
- Select the analyte and level using   keys. Type in the new value for the **HIGH** or **LOW** cutoff as appropriate.
- Press  to save changes.

9. Change QC Parameters:

- Select **SET PARAMETERS** using the   keys and Press .
- Select **QC PARAMETERS** using the   keys and Press .
- Select the desired setting using the   keys and change the value to the right of the setting by using the   keys.

Setting	Default	Options	New Setting
QC DEVICE FREQ.	Daily	None, 8HR, Daily, Weekly, Monthly	<input type="text"/>
QC SAMPLE FREQ.	Monthly	None, 8HR, Daily, Weekly, Monthly	<input type="text"/>
NUMBER OF CONTROLS	2	1 or 2	<input type="text"/>

- Press  to save changes to QC Parameters.

For more details about Ranges Settings see page N-24.

 **Note:** The lowest value of the Range or Threshold may be disabled for some test panels. Refer to the appropriate Product Insert for specific information.

For more details about QC Parameters Settings see page N-27.

For more details about Bypass Settings see page N-28

 **Note:** If the bypass is **ON**, the user ID feature is disabled and anyone may run a test.

If the bypass is **OFF**, the user ID feature is active and only authorized users may run a test.

To Install User ID numbers, see page N-21.

10. Change Bypass settings:

- Select **SET PARAMETERS** using the   keys and Press .
- Select **BYPASS** using the   keys and Press .
- For **USER ID** select **ON** or **OFF** using the   keys.
- Press  to save changes to the Bypass setting.

11. Prior to commencing patient testing, remove the Supervisor Code Chip® from the meter, return it to the storage box and place in a safe place for future use.

The meter is now ready to run QC Tests in preparation for Patient Testing.

QC Testing should be performed in the following manner:

- Run **QC Device** (see page O-3).
- Run **QC Sample** for each lot of devices (see page O-5).
- If appropriate, Run **Calibration Verification Set** as a patient sample for each test panel type to be used. (Refer to the applicable Procedure Manual and Calibration Verification Set Package Insert for detailed instructions).

Location

The Triage® Meter should be placed on a dry, clean, flat, horizontal surface away from direct sunlight.

Power

The Triage® Meter requires 6-volts DC supplied by either AC or DC. The meter will run approximately 100 tests on batteries. It is recommended to use batteries as a backup in the event of a power outage.



CAUTION: Use only the power supply provided with the meter, failure to do so may cause permanent damage to the meter.

 **Note:** The Triage® Meter will automatically turn off if left unused for 2 hours, unless programmed otherwise by the supervisor. Optional settings allow automated turnoff after 1/2 hour, 1 hour, 2 hours, 4 hours or NONE.

Self-Test

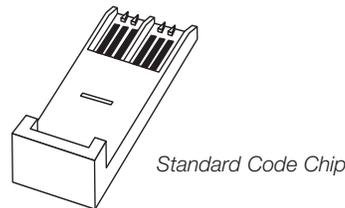
The Triage® MeterPlus checks the system to be sure it is operating properly by running self-tests when powered on and prior to each test.

- **Power On** – includes laser operation, internal standard range, battery power, and software verification.
- **Each Test** – verifies the laser operation, internal standard range and battery power.

Code Chips®

Meter data is updated via a disposable Code Chip. The Code Chip contains microchip circuitry embedded into a plastic housing. When inserted into the meter Code Chip port and activated, the information is transferred into the Triage® Meter's memory. A Code Chip typically needs to be installed only once and remains in the meter memory. A Code Chip does not need to remain in the meter while performing tests.

There are five types of Code Chips which can be distinguished by shape or color.



- **Reagent Test Code Chip** – included in each box of test devices; contains calibration, expiration date and other data about the device lot. (Color varies by test type.)
- **QC Sample Code Chip** – included in each box of QC Sample; contains expiration date and other data about the QC Sample lot including acceptable range. (Color varies by test type.)
- **QC Device Code Chip** – included in the black QC Device box (comes with the Triage® Meter); contains data about how the meter should read its matching QC Device. (Dark gray.)
- **Supervisor Access Code Chip** – included with each Triage® Meter; contains code to activate Supervisor functions. (Light gray.)



- **Software Upgrade Code Chip** – provided when Triage® Meter software upgrades are available; contains new software for the meter.

Set Parameters

Purpose

The **SET PARAMETERS** function allows the supervisor to select a number of settings. Access to these settings is controlled using the Supervisor Code Chip®.

List of Programmable Parameters

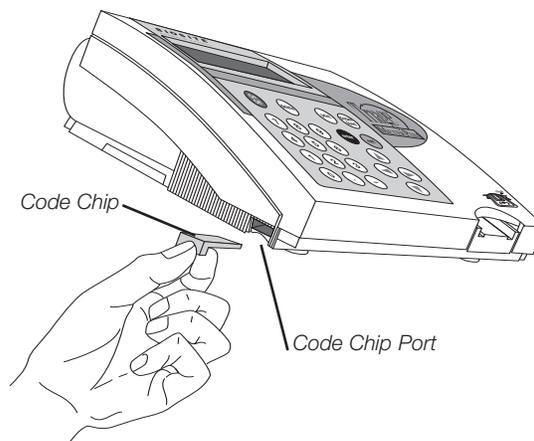
A supervisor can set the following parameters:

Heading	Parameters
METER SETTINGS	
ID SETTINGS	Number of Characters in User ID, Number of Characters in Patient ID, Number of Characters in Auxiliary ID, Enable or Disable Auxiliary ID
DISPLAY SETTINGS	Language, Printer Mode, Auto Power-Off, Display Contrast, Printer Contrast
COMMUNICATIONS	Enable or Disable LIS, Baud Rate, Auto or Manual Upload, Result Approval
CLOCK	Time, Date, and Display Format
USER ID	Add New User ID, Update User ID, Delete User ID or User ID List
RANGES	Test Cutoffs
TEST SETTINGS	Block Analytes, Display Mode
QC PARAMETERS	Minimum frequency for QC Tests, number of controls
BYPASS	Disable User ID requirement

Supervisor Access

A Supervisor Code Chip is shipped with each meter. Installing the Code Chip gives the supervisor access to the **SET PARAMETERS** and **DELETE RESULTS** function.

To insert the Supervisor Code Chip into the Triage® Meter, slide the chip labeled "**SPR**" into the meter's Code Chip port as shown in the picture.

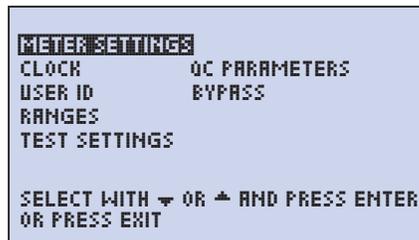


How to Set Parameters: Basic Instructions

All instructions assume:

- The meter is on.
- The meter screen is displaying the main menu.
- The Supervisor Code Chip® is installed.

1. Select **SET PARAMETERS** using   keys.
2. Press the  key.
3. You will see a list of programmable parameters.



The Set Parameters Menu

4. Use the   keys to select the parameter you want to program: **METER SETTINGS, CLOCK, USER ID, RANGES, TEST SETTINGS, QC PARAMETERS, or BYPASSES.**
5. Press the  key.
6. Follow the directions for setting the selected parameter (see the next section).

METER SETTINGS

This menu will allow you to set basic operational criteria for the meter: language, display contrast, maximum length of the patient and auxiliary ID numbers, printer mode and automatic power off.

ID SETTINGS

CHARACTERS USER ID

This setting will set the minimum and maximum number of characters in the User ID.

1. From a list of programmable parameters, choose **INSTRUMENT SETTINGS** using   keys.
2. Press the  key.
3. Use the   keys to select **ID SETTINGS.**
4. Press the  key.

 **Note:** To save changes, press the **ENTER** key.

To cancel changes, press the **EXIT** key.

When either the **ENTER** or **EXIT** keys are pressed, the meter performs the appropriate function and returns to the previous menu.

MAIN MENU

SET PARAMETERS

METER SETTINGS

ID SETTINGS

5. Use the   keys to select the number to the right of **CHARACTERS USER ID** under the **MIN** column.
6. Use the   keys to choose the smallest number of characters that will appear in the User ID number. The minimum number of characters possible is **1**.
7. Use the  key to select the number to the right of **CHARACTERS USER ID** under the **MAX** column.
8. Use the   keys to choose the largest number of characters that will appear in the User ID number. The maximum number of characters possible is **10**.
9. Press the  key to save changes.

CHARACTERS PAT. ID

This setting will set the minimum and maximum number of characters in the Patient ID.

1. From a list of programmable parameters, choose **INSTRUMENT SETTINGS** using   keys.
2. Press the  key.
3. Use the   keys to select **ID SETTINGS**.
4. Press the  key.
5. Use the   keys to select the number to the right of **CHARACTERS PAT. ID** under the **MIN** column.
6. Use the   keys to choose the smallest number of characters that will appear in the Patient ID number. The minimum number of characters possible is **1**.
7. Use the  key to select the number to the right of **CHARACTERS PAT. ID** under the **MAX** column.
8. Use the   keys to choose the largest number of characters that will appear in the Patient ID number. The maximum number of characters possible is **12**.
9. Press the  key to save changes.

CHARACTERS AUX. ID

This setting will set the minimum and maximum number of characters in the Patient ID. If the setting of **AUX. ID ENABLE/DISABLE** is **ENABLED**, a number is mandatory for each patient test.

1. From a list of programmable parameters, choose **METER SETTINGS** using   keys.
2. Press the  key.
3. Use the   keys to select **ID SETTINGS**.
4. Press the  key.
5. Use the   keys to select the number to the right of **CHARACTERS AUX. ID** under the **MIN** column.
6. Use the   keys to choose the smallest number of characters that will appear in the Auxiliary ID number. The minimum number of characters possible is **1**.
7. Use the  key to select the number to the right of **CHARACTERS AUX. ID** under the **MAX** column.
8. Use the   keys to choose the largest number of characters that will appear in the Auxiliary ID number. The maximum number of characters possible is **12**.
9. Press the  key to save changes.

AUX. ID ENABLE/DISABLE

This setting will turn on or turn off the Auxiliary ID function. The Auxiliary ID number may be used for recording test order number, physician ID number or other specialized identifying information.

1. From a list of programmable parameters, choose **METER SETTINGS** using   keys.
2. Press the  key.
3. Use the   keys to select **ID SETTINGS**.
4. Press the  key.
5. Use the   keys to select the word to the right of **AUX. ID ENABLE/DISABLE**.
6. Use the   keys to choose **DISABLED** or **ENABLED**. If **DISABLED** is selected, the Auxiliary ID prompt screens will never appear. If **ENABLED** is selected, a number is mandatory for each patient test.
7. Press the  key to save changes.



Note: The Auxiliary ID is shown only on the New Result display or printout. It is not visible in recalled results. Tracking may be managed through the optional software package, Triage Census® Data Management.

DISPLAY SETTINGS**LANGUAGE**

This setting will determine which language the meter displays.

1. From a list of programmable parameters, choose **METER SETTINGS** using   keys.
2. Press the  key.
3. Use the   keys to select **DISPLAY SETTINGS**.
4. Press the  key.
5. Use the   keys to highlight the name to the right of **LANGUAGE**.
6. Use the   keys to change the language of the Triage® Meter's screen. The choices are **ENGLISH, FRANÇAIS (FRENCH), ITALIANO (ITALIAN), DEUTSCH (GERMAN), ESPANOL (SPANISH), Ελληνικά (GREEK), DANSK (DANISH), SVENSKA (SWEDISH) and PORTUGUÊS (PORTUGUESE)**.
7. Press the  key to save changes.

NEW

PRINT MODE

This setting will determine if the meter prints automatically or only when requested.

1. From a list of programmable parameters, choose **METER SETTINGS** using   keys.
2. Press the  key.
3. Use the   keys to select **DISPLAY SETTINGS**.
4. Press the  key.
5. Use the   keys to select highlight the word to the right of **PRINT MODE**.
6. Use the   keys to choose **AUTOMATIC** or **MANUAL**. If **AUTOMATIC** is selected, the meter will immediately print out the results after each test (patient or QC). If **MANUAL** is selected, the user must use the  button on the keypad to print out results.
7. Press the  key to save changes.

AUTO POWER – OFF

This setting will determine the length of time before an inactive meter will power off.

1. From a list of programmable parameters, choose **METER SETTINGS** using   keys.
2. Press the  key.
3. Use the   keys to select **DISPLAY SETTINGS**.
4. Press the  key.
5. Use the   keys to select the value to the right of **AUTO POWER-OFF**.
6. Use the   keys to choose the desired timer setting for the meter to power itself off when not in use. The choices are: **1/2 HOUR, 1 HOUR, 2 HOURS, 4 HOURS** or **NONE**. If **NONE** is selected, the meter must be manually shut off using the on/off key.
7. Press the  key to save changes.

DISPLAY CONTRAST

This setting will adjust the display contrast.

1. From a list of programmable parameters, choose **METER SETTINGS** using   keys.
2. Press the  key.
3. Use the   keys to select **DISPLAY SETTINGS**.
4. Press the  key.
5. Use the   keys to select the number to the right of **CONTRAST**.
6. Use the   keys to change the contrast of the meter's screen.
The range is from 0 – 8 (8 being the greatest contrast).
7. Press the  key to save changes.



Note: When powered only by batteries, select 1/2 hour to conserve battery life.

Certain screens, when displayed, will not automatically power off. The New Results screen is an example.

PRINTER CONTRAST

This setting will adjust the printer contrast for meters with a serial number starting with 29901.

1. From a list of programmable parameters, choose **METER SETTINGS** using   keys.
2. Press the  key.
3. Use the   keys to select **PRINTER CONTRAST**.
4. Press the  key.
5. Use the   keys to select the number to the right of **CONTRAST**.
6. Use the   keys to change the contrast of the meter's screen. The range is from 0 – 8 (8 being the greatest contrast).
7. Press the  key to save changes.

COMMUNICATION SETTINGS

Prior to activating the LIS feature, obtain the meter's serial number located underneath the meter and call Biosite Technical Services at 1-888-BIOSITE (1-888-246-7483).

The Biosite Technical Services Representative will provide you with a password that, when entered, will allow data to be transmitted.

MAIN MENU

SET PARAMETERS

METER SETTINGS

COMM SETTINGS

NEW

BAUD RATE

1. From a list of programmable parameters, choose **METER SETTINGS** using   keys.
2. Press the  key.
3. Use the   keys to select **COMM SETTINGS**.
4. Press the  key.
5. Use the   keys to select **BAUD RATE**.
6. Use the   keys to choose **9600** or **38400**.
7. Press the  key.

PATIENT RESULT APPROVAL

NEW

Some institutions may wish for patient test results to be verified by the user before printing or sending to the LIS. Activation of this feature displays the result, then requires the user to accept or reject the result before the record is printed and saved. If the test is rejected, the meter will permanently flag it as rejected by the user.

1. From a list of programmable parameters, choose **METER SETTINGS** using   keys.
2. Press the  key.
3. Use the   keys to select **COMM SETTINGS**.
4. Press the  key.
5. Use the   keys to select **PAT. RESULT APPROVAL**.
6. Use the   keys to choose **DISABLED** or **ENABLED**.
7. Press the  key.

When enabled, after a patient result is available and displayed on the meter screen, the user must accept or reject the result before printing, uploading or performing any other meter functions.

The meter prompts the user to **PRESS 1 TO ACCEPT OR 0 TO REJECT**. Once the test has been accepted or rejected, the meter operates normally.

If the test has been rejected, the display and printout will be flagged with **PAT. RESULT REJECTED** or **RESULTS REJECTED BY USER**. Recalled results will display an **R** before the patient ID.

LIS ENABLE

1. From a list of programmable parameters, choose **METER SETTINGS** using   keys.
2. Press the  key.
3. Use the   keys to select **COMM SETTINGS**.
4. Press the  key.
5. Use the   keys to select **LIS**.
6. Use the   keys to choose **DISABLED** or **ENABLED**.
7. Press the  key.
8. If **DISABLED** was selected, a screen showing a **LIS DISABLED** will appear. Press the  key.
9. If **ENABLED** was selected, a screen showing a **ENTER LIS PASSWORD** will appear. Enter the password provided by Biosite Technical Services. Press the  key.
10. Acknowledge the **LIS ENABLED** message by pressing the  key.

NEW

AUTO UPLOAD (This feature is visible after the LIS has been enabled.)

1. From a list of programmable parameters, choose **METER SETTINGS** using   keys.
2. Press the  key.
3. Use the   keys to select **COMM SETTINGS**.
4. Press the  key.
5. Use the   keys to select **AUTO UPLOAD**.
6. Use the   keys to choose **ENABLED** or **DISABLED**.
7. Press the  key.



Note: If you have selected **AM/PM**, **AM** or **PM** appears after the time, as appropriate.

CLOCK

The clock menu sets the time and date of the meter and the format for displaying both. If the meter has lost power, the time and date will blink on the Main Menu.

1. From the list of programmable parameters, choose **CLOCK** using   keys.
2. Press the  key.
3. Use the   keys to select the **HOUR : MINUTE** area. Using the keypad, type in the correct time. The numbers you type will appear from the right and move left as you continue to type. To change a single number use   keys to move to the number. Then type in the new number.
4. Press  to move to **AM** or **PM**. If the **24 HR.**, format has been previously selected, the **AM** or **PM** will not be visible and the **TIME FORMAT** will be highlighted. Proceed to step 7 below.
5. Select **AM** or **PM** using the   keys.
6. Press  to move to **TIME FORMAT**.
7. Use the   keys to select **AM/PM** or **24 HR.** If selecting **24 HR.**, the previously entered **HOUR : MINUTE** will change to a 24-hour format and the **AM** or **PM** will disappear.
8. Press  to move to the **DATE**.
9. Using the keypad, type in the 6-digit date according to the **DATE FORMAT** below it.
10. Press  to move to the **DATE FORMAT**.
11. Use the   keys to select **MM-DD-YY**, **DD-MM-YY** or **YY-MM-DD**.
The previously entered **DATE** changes as the **DATE FORMAT** changes.
12. Press  to save changes.

USER ID

Up to 600 User ID numbers with 1 – 10 digits may be programmed into the meter.

The User ID may alternately be entered using the external Bar Code Scanner (optional).

An additional security feature of the User ID is the partial masking of the ID Number on displays and printouts. This prevents unauthorized individuals from detecting and using an existing User ID number. When the Supervisor Code Chip® is installed in the meter, this feature is overridden and all User ID digits are displayed.

NEW USER ID

1. From the list of programmable parameters, choose **USER ID** using   keys.
2. Press the  key.
3. Select **NEW USER ID** using   keys.
4. Press the  key.
5. Type in a number from 1 – 9999999998 (10 digits). To correct, press  to clear the entire number, or select the incorrect digit by using the   keys. Then type in the correct number.
6. Press the  key.
7. On the next screen, use the   keys to select an expiration date to the right of **USER ID STATUS: 6 MONTHS, 12 MONTHS, VALID** or **EXPIRED**.
8. Press the  key to save changes.

NEW

The Triage® MeterPlus recognizes leading 0's as a unique character. Therefore, '4341' will be recognized separately from '04341.'

Using the barcode scanner will allow the Triage® MeterPlus to accept alpha characters and the following symbols: # () * - . / \

MAIN MENU

SET PARAMETERS

USER ID



Note: **USER ID 9999999999**

(10-9's) is a default setting displayed when the **USER ID BYPASS** is on or when a test is run with the Supervisor Code Chip® installed.



Note: If you type in a User ID number that has already been assigned, the message on the screen states:
USER ### ALREADY EXISTS.

Press **ENTER** to go back and type in a different number.

UPDATE USER ID

1. From the list of programmable parameters, choose **USER ID** using   keys.
2. Press the  key.
3. Select **UPDATE USER ID** using   keys.
4. Press the  key.
5. Type in the user number you want to update. To correct, press  to clear the entire number, or select the incorrect digit by using the   keys. Then type in the correct number.
6. Press the  key.
7. The user ID is displayed with the expiration date. You can change the expiration date to **6 MONTHS**, **12 MONTHS**, **EXPIRED** or **VALID** by using the   keys. **VALID** reconfirms the previously selected interval.
8. Press the  key to save changes.

DELETE USER ID

1. From the list of programmable parameters, choose **USER ID** using   keys.
2. Press the  key.
3. Select **DELETE USER ID** using   keys.
4. Press the  key.
5. Type in the user number to be deleted. To correct, press  to clear the entire number, or select the incorrect digit by using the   keys. Then type in the correct number.
6. Press the  key. The message on the screen states: **USER ID ### WILL BE DELETED.**
7. Press the  key to delete. A message on the screen tells you that the number has been deleted: **USER ID ### DELETED.**



Note: If you type in a User ID number that does not exist, the message on the screen states:

USER ID ### DOES NOT EXIST.

If this happens, press **ENTER** to return to the previous screen and correct the ID number, or press **EXIT**.



Note: If you type in a User ID number that does not exist, the message on the screen states:

USER ID ### DOES NOT EXIST.

If this happens, press **ENTER** to return to the previous screen and correct the ID number, or press **EXIT**.

USER ID LIST

1. From the list of programmable parameters, choose **USER ID** using   keys.
2. Press the  key.
3. Select **USER ID LIST** using   keys.
2. Press the  key.
5. A list is displayed.
6. Use the   keys to select the type of ID list you want: **USER ID**, **FROM EXPIRATION DATE**, **TILL EXPIRATION DATE**.
 - For a list of all ID numbers, select **USER ID**.
 - For a single ID, select **USER ID** and type in the number.
 - For a range of ID numbers, enter the **FROM** and/or the **TO** dates. The dates are entered by typing the month number, the day number and the year number in the format you have chosen. The numbers you type will appear from the right and move left as you continue to type. To change a single number use   keys to move to the number. Then type in the new number.
7. Press the  key.
8. To print the list you have chosen, press .
9. Press the  key.

MAIN MENU

SET PARAMETERS

USER ID

RANGES

Depending on the panel type, the range on the display and printout will be titled

REFERENCE RANGES or **THRESHOLDS**. The low end, when the test displays thresholds, is set to '0' and is unchangeable.

Some analytes are designed for three distinct ranges. The meter distinguishes between two range and three range analytes in the setup screen by differentiating the symbol between the lower and upper values.

NEW

- **Analytes with a dash – Two ranges.** The normal range is any value between the two numbers displayed. Depending on the product, the normal range may be inclusive or exclusive of the upper number. Consult the product package insert or call Biosite Technical Services for clarification. These values will be in reverse video on the patient results.
- **Analytes with a comma – Three ranges possible.** If the lower number is 0.0, the meter treats the analyte as having only two ranges. If the lower number is not 0.0, the normal range is any value less than the lower number. The first abnormal range is any value between the two numbers and is inclusive of these numbers. These values will be boxed on patient results. The second abnormal range is any value greater than the upper number. These values will be in reverse video on patient results. Consult the product package insert or call Biosite Technical Services for clarification.



Note: The field will be disabled if the panel setting is fixed. Consult the specific panel package insert to determine if the setting may be changed.

1. From the list of programmable parameters, choose **RANGES** using   keys.
2. Press the  key.
3. Select the test panel type using the   keys.
4. Select the analyte and level using   keys. The **HIGH** and **LOW** value for each of the analytes can be changed using the keypad to type in the values. To correct, press  to clear the entire number, or select the incorrect digit by using the   keys.
5. To print a list, press the  key.
6. Press the  key to save changes.

TEST SETTINGS**TEST BLOCK**

In certain cases, the lab supervisor may wish to always block one or more analytes from being tested. If blocking an analyte is consistent with the FDA cleared indications for use, Biosite will enable this feature. If a particular analyte may not be blocked, the meter will skip over the setting as the supervisor scrolls through the options. See pages N-26 and O-8 for more details.

TEST SELECT

The lab supervisor may permit users to deselect certain analytes at the time of testing a patient. Deselected analyte results will be displayed as NCAL for Not Calculated. If this option is not available for a panel or individual analyte, the meter will skip over the setting as the supervisor scrolls through the options. See pages N-26 and O-8 for more details.

TEST MODE

It also may be appropriate for some test panels to display certain analytes Qualitatively and others Quantitatively. Presently, Biosite does not have any test that fits this category. This feature is reserved for future use.

TEST SETTINGS

1. From the list of programmable parameters, choose **TEST SETTINGS** using   keys.
2. Press the  key.
3. Select the test panel type using the   keys.
4. Some test panel types allow analyte results to be blocked from view or to be viewed in **QUALITATIVE**, **QUANTITATIVE** or **SEMI-QUANTITATIVE** modes. If allowed for the panel type and you wish to change the mode:
 - Select the analyte using the   keys.
 - Select the desired mode
 - **ACTIVE (ACTIV)**, **INACTIVE (INACT)** or **USER (USER)** using the   keys.
 - ACTIVE** – The analyte will be run on every patient and QC test.
 - INACTIVE (TEST BLOCK)** – The analyte will never be run on patient or QC tests and will be dropped from all displays.
 - USER (TEST SELECT)** – At the time of patient testing, the user has the ability to deselect the analyte.
 - **QUALITATIVE (QUAL)**, **QUANTITATIVE (QUANT)** or **SEMI-QUANTITATIVE (SEMI)** using the   keys.
5. Press the  key to save changes.
6. To print a list, press the  key.



Note: When the analyte is deselected, the value is not calculated nor stored.

QC PARAMETERS

The QC Parameters menu provides the user the options for determining what the maximum frequency is for running the QC Device and QC Sample and whether 1 or 2 levels of control are required for the QC Sample.

QC DEVICE FREQUENCY

The **QC DEVICE FREQUENCY** setting determines the maximum interval between QC Device tests that a user is allowed to run patient tests. When the interval has lapsed, all users are locked out of the **RUN TEST** menu until a QC Device has been successfully run.

It is recommended that the QC Device be run daily when performing patient testing.

1. From the list of programmable parameters, choose **QC PARAMETERS** using the   keys.
2. Press the  key.
3. Use   keys to select the information to the right of **QC DEVICE FREQ.**
4. Using   keys, select on of these options: **NONE, 8 HOURS, DAILY, WEEKLY, MONTHLY.**
5. Press the  key to save changes.

QC SAMPLE FREQUENCY

The **QC SAMPLE FREQUENCY** setting determines the maximum interval between QC Sample tests that a user is allowed to run patient tests on a particular device lot number. When the interval has lapsed, all users are locked out of the **RUN PATIENT TEST** menu until a QC Sample has been successfully run. To view when a particular device lot's QC Sample will expire, use the **RECALL REAGENT LOTS – QC** feature.

It is recommended that the QC Sample be run with every new shipment, new lot or monthly, whichever is less when performing patient testing.

1. From the list of programmable parameters, choose **QC PARAMETERS** using the   keys.
2. Press the  key.
3. Use   keys to select the information to the right of **QC SAMPLE FREQ.**
4. Using   keys, select on of these options: **NONE, 8 HOURS, DAILY, WEEKLY, MONTHLY.**
5. Press the  key to save changes.



Note: If the bypass is **ON**, the User ID requirement is disabled and therefore not required.

When the bypass is **OFF**, the User ID requirement operates as normal and is required.

NUMBER OF CONTROLS

1. From the list of programmable parameters, choose **QC PARAMETERS** using the   keys.
2. Press the  key.
3. Use   keys to select the information to the right of **NUMBER OF CONTROLS**.
4. Using   keys, select one of these options: **1** or **2**.
5. Press the  key to save changes.

BYPASS USER ID

This function allows the supervisor to selectively bypass the requirement to enter a user ID before performing any test.

1. From the list of programmable parameters, choose **BYPASS** using the   keys.
2. Press the  key.
3. Select **USER ID** using the   keys.
4. Use   keys to select from two options: **ON** or **OFF**.
5. Press the  key.

Install Code Chip

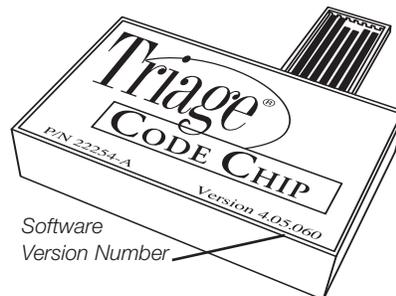
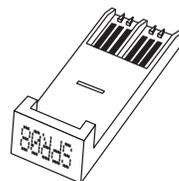
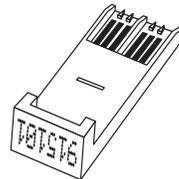
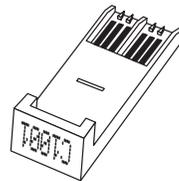
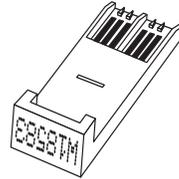
Purpose

The Triage® MeterPlus will prompt the user to install a Code Chip® when required. However, the **INSTALL CODE CHIP** function may be used as an alternate method to transfer information from a Code Chip into the meter's memory. The meter will direct the user to install a Code Chip if it is attempting to run a test and does not have the data in its memory.

Types of Code Chips

There are five types of Code Chips

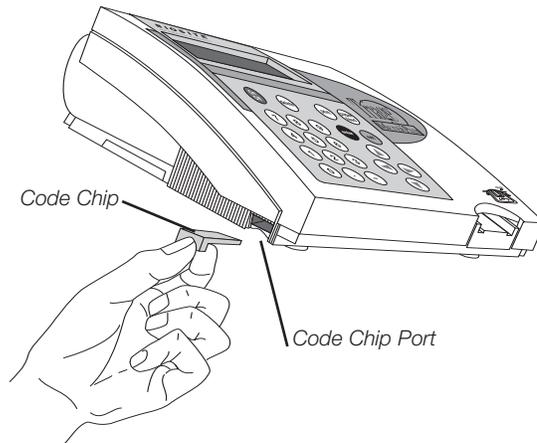
- **Reagent Code Chip** – included in each box of test devices. Lot number begins with a **W**.
- **QC Sample Code Chip** – included in each box of controls. Lot number begins with a **C**.
- **QC Device Code Chip** – included in the black QC Device box (comes with the Triage® Meter) and is labeled with the serial number of the QC Device.
- **Supervisor Access Code Chip** – included with each Triage® Meter. Lot Number begins with **SPR**.
- **Software Upgrade Code Chip** – sent separately when Triage® Meter software upgrades are available.



CAUTION: Running tests with the **Supervisor Code Chip** installed disables all **QC Lockouts**. Remove the Supervisor Code Chip prior to running tests.

Installation of Reagent, QC Sample or QC Device Code Chip®.**INSTALL CODE CHIP**

1. From the **MAIN MENU** select **INSTALL CODE CHIP** using ▲ ▼ keys.
2. Press the enter key.
3. Slide the Code Chip into the Code Chip Port in the Triage® Meter, as shown in the picture.



4. Press the enter key.
5. The meter will display a confirmation message that the information was installed into the Triage® Meter's memory.
6. Press enter to return to acknowledge the message.
7. Remove the Code Chip from the Code Chip Port.

Installation of Supervisor Code Chip

The Supervisor Code Chip needs only to be inserted into the Code Chip Port to activate the supervisor functions. This is an automatic function and standard Code Chip installation is not necessary.

Operation

Access to The Triage® Meter

Function	Use	Restricted to
RUN TEST	Patient Testing	operators with valid User ID numbers*
	Quality Control Testing	operators with valid User ID numbers*
RECALL RESULTS	Patient Testing	
	Quality Control Testing	
INSTALL CODE CHIPS®	Types of Code Chips	
	Installation Procedure	
SET PARAMETERS	Access Control	Supervisor
	Programmable Settings	Supervisor
DELETE RESULTS	Patient Test Results	Supervisor

* Unless User ID is bypassed or the Supervisor Code Chip is installed.



IMPORTANT: The last two functions, **SET PARAMETERS**, and **DELETE RESULTS**, appear on the main menu only when the Supervisor Code Chip is inserted into the Code Chip Port. **The Supervisor Code Chip should be removed from the meter during routine patient and quality control testing.**



Note: Access to various parts of the software should be determined by the policies of the institution using the meter.

Run Test

Purpose

Run Test is used for the analysis of a test.

Options

The Run test function allows you to test:

- QC Device
- QC Sample
- Patient Sample

In order to run a patient sample, the meter requires:

1. A valid User ID has been entered (unless this feature is bypassed or a Supervisor Code Chip® is installed). See page N-21.
2. A QC Device has passed within the specified time period. See page O-3.
3. A QC Sample for the test device lot has passed within the specified time period. See page O-5.

If any of these conditions exist, the meter will not continue and will prompt the user to perform the required steps.



Note: The Supervisor Code Chip provides access to functions that may override these Lockouts.



Note: If the Triage® Meter's internal quality control (QC) results are unacceptable, exclamation points (!) will be displayed on the screen in the place of the patient results.

To obtain results repeat the test using a new device.



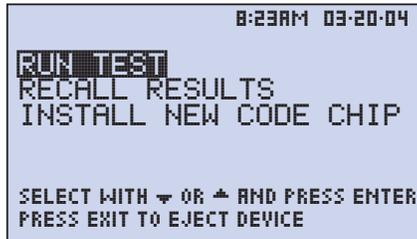
IMPORTANT: The Triage® Meter will alert the user if QC has not been performed for the device lot being tested.

QC DEVICE

The QC Device should be run on each day of patient testing. It is desirable to run the QC Device after the meter has been inactive for at least 30 minutes.

To run the QC Device test:

1. Press the  key to power The Triage® Meter on.
2. Select **RUN TEST** using   keys.



The Main Menu

3. Press the  key.
4. Type in your identification number (User ID). To correct, press  to clear the entire number, or select the incorrect digit by using the   keys then type in the correct number.
5. Press the  key
6. Select **QC DEVICE** using   keys.



"EXP" indicates that the QC Device re-test frequency has expired.

Menu screen as it looks when operator selects QC Device.

7. Press the  key.
8. **Gently** insert the QC Device into the Triage® Meter until you feel the QC Device catch on the pin and hear an audible 'click.'
9. Press the  key.

MAIN MENU

RUN TEST

 **Note:** If the User ID bypass is **ON**, the meter will not ask you to enter a User ID.

 **Note:** The meter will prompt the user to install the QC Device Code Chip® if the QC Device has not been run before.

10. The Triage® Meter pulls in the QC Device and scans it. The test device may partially move in and out of the meter several times.
11. When the test is complete, the meter will beep, eject the device and display the results on the meter's screen.
12. Press the  key to make a printed copy of the results.



*After the test device has been inserted, do not push the device in further or attempt to pull it out. The device may be ejected by returning to the Main Menu and pressing **EXIT**.*



IMPORTANT INSTRUCTIONS FOR ALL TESTS:

- a. **Gently** insert the test device into the Triage® Meter until you feel the device catch on the pin. You will hear an audible 'click' that tells you the test device has been inserted properly.
- b. Press the  key to start the test.
- c. The Triage® Meter pulls in the test device and scans it.
- d. When the test is complete, the meter will beep and display the results on the meter's screen.
- e. Press the  key to make a printed copy of the results.



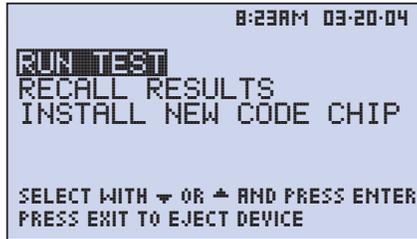
IMPORTANT INSTRUCTIONS FOR QC DEVICE TESTS:

- Dust, lint, fibers and other small particles may interfere with the QC Device. Keep the QC Device free of contaminants.
- The QC Device is light-sensitive and should be stored in its black opaque case when not in use.
- If the QC Device tests fail, wipe the QC Device clean with a lint free cloth to remove any oils, dust, fibers, or fingerprints. Do not apply any liquid to the QC Device. After cleaning the device, repeat the QC Device test.
- If the QC Device test fails after you have cleaned the device, call Biosite Incorporated Technical Services at 1-888-BIOSITE.
- Note: the QC Device does not expire.

QC SAMPLE

To run the Quality Control sample:

1. Press the  key to power The Triage® Meter on.
2. Select **RUN TEST** using   keys.



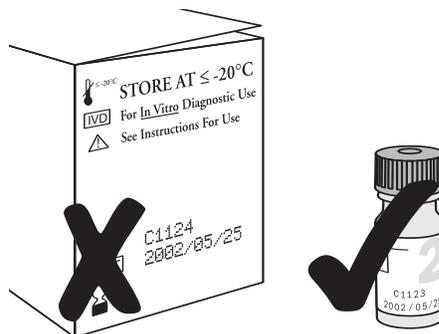
The Main Menu

3. Press the  key.
4. Type in your identification number (User ID). To correct, press  to clear the entire number, or select the incorrect digit by using the   keys then type in the correct number.
5. Press the  key.
6. Select **QC SAMPLE** using   keys.



Menu screen as it looks when operator selects QC Sample.

7. Press the  key.
8. Enter the QC lot number from the label on the side of the bottle (vial) containing the QC Sample.



Enter the lot number from the vial.

MAIN MENU

RUN TEST

 **Note:** If the User ID bypass is **ON**, the meter will not ask you to enter a User ID.

 **Note:** If you enter a QC lot number for which there is no data in the Triage® Meter's memory, you will see a message on the meter's screen:

NO QC SAMPLE DATA IN MEMORY.

To correct this:

Install the QC Sample Code Chip® (see picture on page N-29).

Press **ENTER** to continue.



After the test device has been inserted, do not push the device in further or attempt to pull it out. The device may be ejected by returning to the Main Menu and pressing **EXIT**.

9. To correct, press Delete to clear the entire number, or select the incorrect digit by using   keys. Then type in the correct number.
10. Press the  key.
11. Perform the test according to the instructions provided in the package of test devices you are using.



IMPORTANT INSTRUCTIONS FOR ALL TESTS:

- a. **Gently** insert the test device into the Triage® Meter until you feel the device catch on the pin. You will hear an audible 'click' that tells you the test device has been inserted properly.
- b. Press the  key to start the test.
- c. The Triage® Meter pulls in the test device and scans it.
- d. When the test is complete, the meter will beep and display the results on the meter's screen.
- e. Press the  key to make a printed copy of the results.

12. Repeat steps for each quality control sample.



IMPORTANT INSTRUCTIONS FOR QC SAMPLE TESTS

- a. If the test device's internal quality control (QC) results are unacceptable, the results for the affected analyte(s) will not appear on the screen.
- b. If any of the QC Sample results are out of range, the results for that particular analyte will be in reverse video (light text on a dark background) and flagged with a # symbol.
- c. A panel with multiple analytes will still be able to report patient results on those analytes which passed QC. An analyte that failed QC will not be reported on patient tests.
- d. If an individual analyte is outside the specified range, the Triage® MeterPlus allows the user to rerun only the failed analyte on the next QC Sample Test. When all analytes have passed, the QC Sample timer is set to the date of the first passing analyte.

NEW

PATIENT SAMPLE

1. Press the  key to power The Triage® Meter on.
2. Select **RUN TEST** using   keys.



The Main Menu

3. Press the  key.
4. Type or scan in your identification number (User ID). To correct, press  to clear the entire number, or select the incorrect digit by using the   keys then type in the correct number.
5. Press the  key.
6. Select **PATIENT SAMPLE** using   keys.



Menu screen as it looks when operator selects Patient Sample.

7. Press the  key.
8. Type or scan the patient's identification number (Patient ID). To correct, press  to clear entire number or select the incorrect digit using   then type in the correct number.
9. Press the  key.

MAIN MENU

RUN TEST

 **Note:** If the **User ID bypass** is **ON**, the meter will not ask you to enter a **User ID**.

 **Note:** If the **Bar Code Scanner** is being used, simply point the scanner at the bar code, press the button on the scanner handle and wait for the beep. The number will appear on the display.

10. If the information is correct, press the **enter** key to confirm the Patient ID.

If the information is incorrect:

- Select **CORRECT PATIENT ID** using **▲** **▼** keys.
- Press the **enter** key.
- Press **delete** to clear the entire number or select the incorrect digit using **◀** **▶** keys. Then type in the correct number.
- Press the **enter** key.

11. If the Auxiliary ID feature is activated, type or scan in the number. To correct, press **delete** to clear entire number or select the incorrect digit using **◀** **▶** then type in the correct number.

12. Press the **enter** key.

13. Prepare the test sample and perform the test in accordance to the instructions provided in the package of test devices you are using.

14. If the testing facility has authorized an analyte to be deselected at the time of running a patient test, the user will be prompted to deselect undesired analytes. After the test device has been pulled into the meter, the meter will display a message similar to the following:

```

SELECT TESTS      CARDIAC
* 0 CKMB
* 1 MYO
  2 TNI

SELECT USING KEYPAD
PRESS ENTER TO CONTINUE OR EXIT
  
```

Analytes in reverse video are activated for use. Analytes not in reverse video will not be reported. Analytes with an asterisk may be deselected by the user by pressing the corresponding number on the keypad. Pressing the number a second time will restore the analyte to the test panel. Failure to make a selection will result in the meter running all analytes.

- Deselect the undesired analyte by pressing the corresponding number on the keypad. Analytes without an asterisk can not be deselected.
- Press the **enter** key.
- If the information is correct, press the **enter** key to continue.
- If the information is incorrect, select **CORRECT TEST** using **▲** **▼** keys and press the **enter** key to return to the lists of tests.

NEW

 **Note:** This feature is not available on all Triage Test Panels.

 **Note:** At least one analyte must be selected in order to continue testing.

 **Note:** If the meter is left at either the list of tests or the confirmation screen for more than 30 seconds, the meter will continue. Pressing any key will disable the 30 second timer.



IMPORTANT INSTRUCTIONS FOR ALL TESTS:

- a. **Gently** insert the test device into the Triage® Meter until you feel the device catch on the pin. You will hear an audible ‘click’ that tells you the test device has been inserted properly.
- b. Press the **(enter)** key to start the test.
- c. The Triage® Meter pulls in the test device and scans it.
- d. When the test is complete, the meter will beep, eject the device and display the results on the meter’s screen.
- e. Press the **(print)** key to make a printed copy of the results.

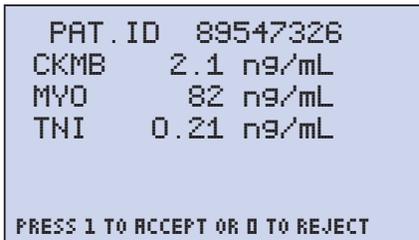


After the test device has been inserted, do not push the device in further or attempt to pull it out. The device may be ejected by returning to the Main Menu and pressing **EXIT**.



IMPORTANT INSTRUCTIONS FOR PATIENT TESTS:

- a. If the test device’s Internal Quality Control (QC) results are unacceptable, the results for the affected analyte(s) will not appear on the screen.
- b. If any of the QC Sample results for the lot being tested were out of range, the results for that particular analyte will not appear on the screen.



Screen displaying patients results below the cut off levels and accept or reject instructions.



Screen displaying patients results above the cut off levels and TNi results in the indeterminate range.

Recall Results

Purpose

Recall Results is used to retrieve results stored in the Triage® Meter's memory.

Function

The Recall Results function can retrieve these results:

- **Last Record**
- **Patient Results**
 - Patient ID
 - Panel Type
 - Test Device Lot Number (L/N)
 - User ID
 - From Date
 - Till Date
- **QC Results**
 - Internal QC Results
 - QC Sample Results
 - QC Device Results
 - Reagent Lots – QC
 - Archive Last Test
- **Print all Results**
 - Patient Results
 - QC Sample Results
 - QC Device Results
- **Upload Results to LIS**

 **Note:** If a result was rejected by the user, and “R” will appear next to the recalled result.

NEW



IMPORTANT NOTE: To safeguard the User ID Lockout, displayed and printed User ID numbers are partially masked. The Supervisor Code Chip® is required to be installed to view the full User ID.

MAIN MENU

RECALL RESULTS

LAST RECORD

Purpose: Last Record is used to retrieve the test results for the last test run.

To retrieve the last record:

1. Press the  key to power The Triage® Meter on.
2. From the **MAIN MENU** select **RECALL RESULTS** using   keys.
3. Press the  key.
4. Select **LAST RECORD** using the   keys.
5. Press the  key.
6. The results from the last test run appear on the screen.
7. Use   to view the entire patient record.
8. Press the  key to make a printed copy.

PATIENT RESULTS

Options: Patient results can be retrieved based on a variety of criteria:

- Patient ID
- Test Device Lot Number (L/N)
- User ID
- From Date
- Till Date

PATIENT ID

To retrieve results based on the patient ID:

1. Press the  key to power The Triage® Meter on.
2. From the **MAIN MENU** select **RECALL RESULTS** using the   keys.
3. Press the  key.
4. Select **PATIENT RESULTS** using   keys.
5. Press the  key.
6. Choose the results you want to see:
 - If you want to see all patient results, press the  key. All the patient results in the Triage® Meter's memory will be displayed.
 - For individual patient results:
 - a. Select Patient ID using   keys.
 - b. Type or scan in the patient ID number. To correct, press  to clear the entire number, or select the incorrect digit by using the   keys. Then type in the correct number.
 - c. To select a patient ID number with alpha characters, use the  key in place of the alpha character.
 - d. Press the  key. All results of the requested patient ID number will be displayed.
7. Press the  key to make a printed copy.

MAIN MENU

RECALL RESULTS

MAIN MENU

RECALL RESULTS

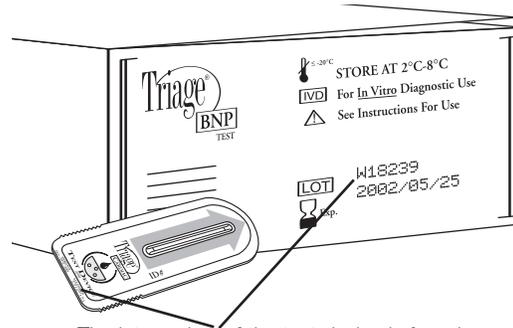
PATIENT RESULTS



Note: You may choose more than one of the options for recalling results in order to define more precisely the information you want to recall from the Triage® Meter's memory. When you choose multiple options, first input numbers in all the categories you have chosen. Then press the **ENTER** key.

TEST DEVICE LOT NUMBER (L/N)

To retrieve results based on the lot number of the test devices used:



The lot number of the test device is found on the device and on the outer box

1. Press the  key to power The Triage® Meter on.
2. From the **MAIN MENU** select **RECALL RESULTS** using the   keys.
3. Press the  key.
4. Select **PATIENT RESULTS** using   keys.
5. Press the  key.
6. Select **DEVICE L/N** using   keys.
7. To display all results, press the  key.
8. To display results specific to one lot, type in the lot number of the test device. To correct, press  to clear the entire number, or select the incorrect digit by using the   keys. Then type in the correct number.
9. Press the  key.
10. All results from test run on the requested lot number are displayed.
11. Press  key to make a printed copy.

USER ID

To retrieve results from tests run on the Triage® Meter starting with the user you select:

1. Press the  key to power The Triage® Meter on.
2. From the **MAIN MENU** select **RECALL RESULTS** using the   keys.
3. Press the  key.
4. Select **PATIENT RESULTS** using   keys.
5. Press the  key.
6. Select **USER ID** using   keys.
7. To display all results, press the  key.
8. To display results specific to one User ID, type in the User ID number. To correct, press  to clear the entire number, or select the incorrect digit by using the   keys. Then type in the correct number.
9. Press the  key.
10. All results from tests run by requested user are displayed.
11. Press the  key to make a printed copy.

MAIN MENU

RECALL RESULTS

PATIENT RESULTS

FROM DATE

To retrieve results from tests run on the Triage® Meter starting with a date you select:

1. Press the  key to power The Triage® Meter on.
2. From the **MAIN MENU** select **RECALL RESULTS** using the   keys.
3. Press the  key.
4. Select **PATIENT RESULTS** using   keys.
5. Press the  key.
6. Select **FROM DATE** using   keys.
7. To display all results, press the  key.
8. To display results specific to one date, type in the date. To correct, press  to clear the entire number, or select the incorrect digit by using the   keys. Then type in the correct number.
9. Press the  key.
10. All results from tests run from the date selected are displayed.
11. Press the  key to make a printed copy.

TILL DATE

To retrieve results from tests run on the Triage® Meter before and including a date you select:

1. Press the  key to power The Triage® Meter on.
2. From the **MAIN MENU** select **RECALL RESULTS** using the   keys.
3. Press the  key.
4. Select **PATIENT RESULTS** using   keys.
5. Press the  key.
6. Select **TILL DATE** using   keys.
7. To display all results, press the  key.
8. To display results specific to one date, type in the date. To correct, press  to clear the entire number, or select the incorrect digit by using the   keys. Then type in the correct number.
9. Press the  key.
10. All results from tests run before and including the date you selected are displayed.
11. Press the  key to make a printed copy.

MAIN MENU

RECALL RESULTS

PATIENT RESULTS



*Note: You may choose more than one of the options for recalling results in order to more precisely define the information you want to recall from the Triage® Meter's memory. When you choose multiple options, first make selections and input numbers in all the categories you have chosen. Then press the **ENTER** key.*

QC RESULTS

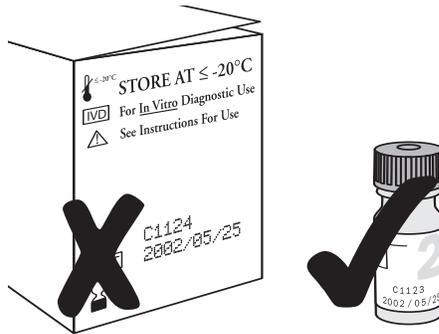
Options: The results of these quality control (QC) tests can be retrieved from the Triage® Meter's memory:

Quality Control (QC test)	Results can be retrieved by:
Internal QC Results (on Patient Tests)	Panel Type Device Lot Number (L/N) User ID Number From Date Till Date View All (Default)
QC Sample Results	Panel Type QC Sample Lot Number (L/N) Device Lot Number (L/N) User ID Number From Date Till Date View All (Default)
QC Device Results	User ID Number From Date Till Date View All (Default)
Reagent Lots – QC	(Defaults to View All)

To retrieve QC Results for the Internal QC, the QC Sample and the QC Device, select the option you want and follow the directions.

QC SAMPLE LOT NUMBER (L/N)

To retrieve results based on the lot number of the QC Sample used:



1. Press the  key to power The Triage® Meter on.
2. From the **MAIN MENU** select **RECALL RESULTS** using the   keys.
3. Press the  key.
4. Select **QC RESULTS** using   keys.
5. Press the  key.
6. Select **QC SAMPLE RESULTS** using   keys.
7. Press the  key.
8. Select **QC SAMPLE L/N** using   keys.
9. Type in the lot number of the test device. To correct, press  to clear the entire number, or select the incorrect digit by using the   keys. Then type in the correct number.
10. Press the  key.
11. All results from test run on the requested QC Sample lot number are displayed.
12. Press  key to make a printed copy.

MAIN MENU

RECALL RESULTS

QC RESULTS

QC SAMPLE RESULTS

 *Note: To display all results, leave the QC Sample L/N blank.*

MAIN MENU

RECALL RESULTS

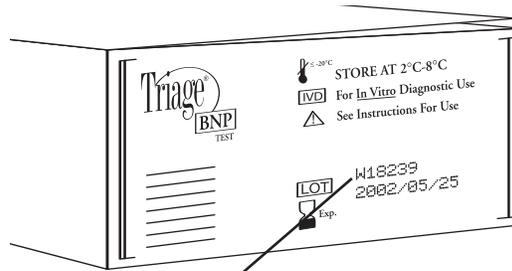
QC RESULTS

INTERNAL QC RESULTS

QC SAMPLE RESULTS

DEVICE LOT NUMBER (L/N)

To retrieve QC Sample results based on the lot number of the test devices used:



The lot number of the test devices is on the box that contains the test devices.

1. Press the  key to power The Triage® Meter on.
2. From the **MAIN MENU** select **RECALL RESULTS** using the   keys.
3. Press the  key.
4. Select **QC RESULTS** using   keys.
5. Press the  key.
6. Select the appropriate menu, **INTERNAL QC RESULTS** or **QC SAMPLE RESULTS** using   keys.
7. Press the  key.
8. Select **DEVICE L/N** using   keys.
9. Type in the device lot number from the side of the box of test devices. To correct, press  to clear the entire number, or select the incorrect digit by using the   keys. Then type in the correct number.
10. Press the  key.
11. All QC results from test run on the requested lot number are displayed.
12. Press  key to make a printed copy.

USER ID

To retrieve QC results from tests run on the Triage® Meter starting with the user you select:

1. Press the  key to power The Triage® Meter on.
2. From the **MAIN MENU** select **RECALL RESULTS** using the   keys.
3. Press the  key.
4. Select **QC RESULTS** using   keys.
5. Press the  key.
6. Select the appropriate menu, **QC SAMPLE RESULTS** or **QC DEVICE RESULTS** using   keys.
7. Press the  key.
8. Select **USER ID** using   keys.
9. Press the  key.
10. Type in the user ID number. To correct, press  to clear the entire number, or select the incorrect digit by using the   keys. Then type in the correct number.
11. Press the  key.
12. All QC results from tests run by requested user are displayed.
13. Press the  key to make a printed copy.

MAIN MENU

RECALL RESULTS

QC RESULTS

QC SAMPLE RESULTS

QC DEVICE RESULTS

MAIN MENU

RECALL RESULTS

QC RESULTS

INTERNAL QC RESULTS

QC SAMPLE RESULTS

QC DEVICE RESULTS

FROM DATE

To retrieve QC results from tests run on the Triage® Meter starting with a date you select:

1. Press the  key to power The Triage® Meter on.
2. From the **MAIN MENU** select **RECALL RESULTS** using the   keys.
3. Press the  key.
4. Select **QC RESULTS** using   keys.
5. Press the  key.
6. Select the appropriate menu, **INTERNAL QC RESULTS**, **QC SAMPLE RESULTS** or **QC DEVICE RESULTS** using   keys.
7. Press the  key.
8. Select **FROM DATE** using   keys.
9. Press the  key
10. Type in the date. To correct, press  to clear the entire number, or select the incorrect digit by using the   keys. Then type in the correct number.
11. Press the  key.
12. All results from tests run from the date selected are displayed.
13. Press the  key to make a printed copy.

TILL DATE

To retrieve QC results from tests run on the Triage® Meter before and including a date you select:

1. Press the  key to power The Triage® Meter on.
2. From the **MAIN MENU** select **RECALL RESULTS** using the   keys.
3. Press the  key.
4. Select **QC RESULTS** using   keys.
5. Press the  key.
6. Select the appropriate menu, **INTERNAL QC RESULTS**, **QC SAMPLE RESULTS** or **QC DEVICE RESULTS** using   keys.
7. Press the  key.
8. Select **TILL DATE** using   keys.
9. Press the  key
10. Type in the date. To correct, press  to clear the entire number, or select the incorrect digit by using the   keys. Then type in the correct number.
11. Press the  key.
12. All results from tests run before and including the date selected are displayed.
13. Press the  key to make a printed copy.

MAIN MENU

RECALL RESULTS

QC RESULTS

INTERNAL QC RESULTS

QC SAMPLE RESULTS

QC DEVICE RESULTS

REAGENT LOTS – QC

A list of Reagent Code Chips® in memory, along with corresponding expiration dates for a QC Sample can be recalled from memory.

The list will contain: **Lot Number, Panel Type, Expiration Date**

- If the QC expiration date has passed (expired), the date will be in reverse video (light text on a dark background).
- If the QC for the lot has failed, the word **FAILED** will appear in place of an expiration date.
- If a Code Chip has been installed for a new lot, but QC has yet to be established, the words **NOT RUN** will appear in place of the expiration date.
- If QC frequency is set to none, the reagent lot expiration date will be displayed.

REAGENT LOTS – QC		
DLN	PANEL	EXP
17544	CARDIAC	DE-22-07
18935	CARDIAC	05-22-05
19985	BNP	NOT RUN
20521	DRUG SCREEN	FAILED

PRESS PRINT OR PRESS ENTER

The Reagent Lots – QC Screen

ARCHIVE LAST TEST

This function will save detailed information regarding the last performed test for analysis by Biosite. Use this function when requested by Biosite Technical Services.

This function should be used when a very unusual test result is received and when the laboratory wishes to have the meter evaluated further. **ARCHIVE LAST TEST** will only be able to save data from the most recent test run.

PRINT ALL RESULTS

Options: All stored results can be printed from the Triage® Meter's memory.

- Patient Results
- QC Sample Results
- QC Device Results

PATIENT RESULTS

To print all Patient Results:

1. Press the  key to power The Triage® Meter on.
2. From the **MAIN MENU** select **RECALL RESULTS** using the   keys.
3. Press the  key.
4. Select **PRINT ALL RESULTS** using   keys.
5. Press the  key.
6. Select **PATIENT RESULTS** using   keys.
7. Press the  key to make a printed copy.

QC SAMPLE RESULTS

To print all QC Sample Results:

1. Press the  key to power The Triage® Meter on.
2. From the **MAIN MENU** select **RECALL RESULTS** using the   keys.
3. Press the  key.
4. Select **PRINT ALL RESULTS** using   keys.
5. Press the  key.
6. Select **QC SAMPLE RESULTS** using   keys.
7. Press the  key to make a printed copy.

MAIN MENU

RECALL RESULTS

MAIN MENU

RECALL RESULTS

PRINT ALL RESULTS



Note: When printing large quantities of patient results, it is recommended to first insert a full roll of paper.

MAIN MENU

RECALL RESULTS

PRINT ALL RESULTS

QC DEVICE RESULTS

To print all QC Device Results:

1. Press the  key to power The Triage® Meter on.
 2. From the **MAIN MENU** select **RECALL RESULTS** using the   keys.
 3. Press the  key.
 4. Select **PRINT ALL RESULTS** using   keys.
 5. Press the  key.
 6. Select **QC DEVICE RESULTS** using   keys.
 7. Press the  key to make a printed copy.
-

MAIN MENU

RECALL RESULTS

QC RESULTS

UPLOAD RESULTS TO LIS

When interfaced directly to an LIS, selecting this feature will send all test results to the LIS. Prior to the first upload, the LIS feature must be activated from the Set Parameter menu item using the Supervisor Code Chip®.

Delete Results

Purpose

The Delete function is used to remove patient test information from the Triage® MeterPlus memory. This becomes necessary when the meter memory becomes full.

The Triage® MeterPlus' Memory

Within the Triage® MeterPlus, Patient Result memory can hold 750 data sets, QC Sample can hold 200 data sets and QC Device memory can hold 70 data sets. When the memory is full, the oldest result is automatically overwritten when a new result is added. The meter display alerts the user as the memory becomes full.



The Memory Alert Screen



IMPORTANT: The Delete function permanently removes all patient data from the meter memory. Before continuing, you may wish to first print results (or upload to your data management system/LIS).

QC Results will not be deleted.

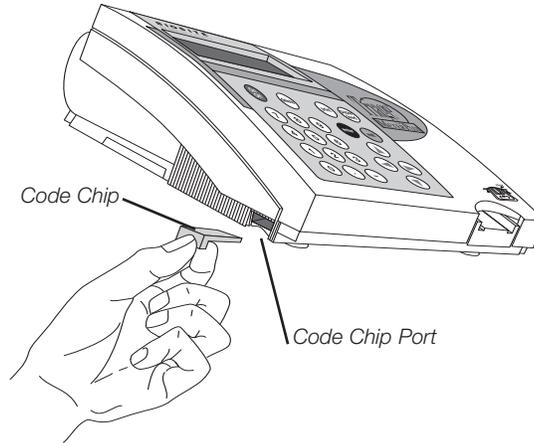


Note: The delete function is available only when the Supervisor Code Chip® is inserted in the Triage® Meter Code Chip Port.

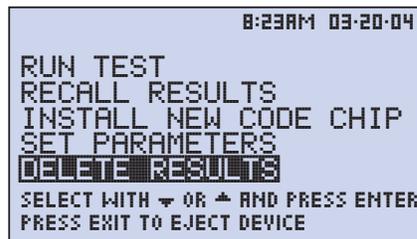
DELETE PATIENT RESULT

This function will delete all patient results in meter memory. Since this action is not reversible, the meter will require two confirmations of intent to delete results.

1. Insert the Supervisor Code Chip® in the Code Chip Port.



2. From the **MAIN MENU**, select **DELETE RESULTS** using   keys.



The Supervisor's Main Menu

3. Press the  key.
4. A warning message on the screen states: **DELETE PATIENT RESULT**.
5. If this is acceptable, press the  key. (If this is not acceptable, press the  key).
6. A message on the screen states: **ALL PATIENT RESULTS WILL BE DELETED**.
7. Press the  key to delete all results. (If you do not want to delete all results, press the  key).

 **Note:** Press the **EXIT** key to cancel at any time before step 7.

Total Quality Assurance

Introduction

Quality assurance programs control and monitor analytical methods. The quality control of analytical methods achieves two basic goals:

1. Ensures that the reagents and instrument are working properly
2. Ensures that the procedure was performed correctly

The mechanism by which analytical methods are traditionally controlled is through the use of liquid control specimens containing known amounts of analytes.

Over the last 15 years advances in technology have changed the manner in which the diagnostic reagents are configured. Assay systems for the Point-of-Care are generally unitized testing devices that are distinct from traditional laboratory based analyzers.

The Triage® tests are unitized tests that do not require additional reagents. Each device contains a full complement of reagents that are required to perform the immunoassay.

The Triage® tests have been designed to include assay controls in each test device that monitor the assay procedure and the reagent integrity. The assay controls present a unique and valuable extension to the traditional approach to quality control using liquid reagents. If the product is stored under specified conditions, proper functioning of the assay controls indicates that the test device is valid and proper adherence to assay protocol has been followed. The assay controls in the Triage® tests require the need to re-think the frequency with which external quality control specimens should be tested.

The Triage® tests have been designed to yield long-term reagent stability. In addition, the system provides quality control parameters in three separate and distinct categories:

- Internal device controls
- Meter electronic controls
- Software controls.

The combination of these quality control features provides more information about the validity of each assay than can be provided by the more traditional methods of reagent and assay procedure validation.

NEW



*Note: For more detailed information, call Biosite Technical Services at **1-888-BIOSITE** (1-888-246-7483) 24 hours a day/7 days a week.*

Quality Assurance Functions

1. Internal Device Quality Assurance
 - Internal Positive Control Zone
 - Baseline Control Zone
 - Timing Control Zone
 - Zone Quality Requirements (Trace QC)
2. Meter Quality Assurance
 - Self Test Mode
 - Internal Calibration Chip
 - Electronic QC Device
 - Bar Code
3. Software Quality Assurance
 - Supervisor Code Chip®
 - User ID#
 - Patient ID#
 - Result memory storage
 - QC Frequency
 - QC Lockouts
4. Quality Control Samples

Internal Device Quality Assurance

The *Internal Positive Control Zone* is a functional immunoassay. This control verifies that the device functioned properly and that the assay was correctly performed. The Internal Positive Control Zone ensures that the antibodies, the reagent reconstitution, the timegate and the device flow are functioning properly. The manufacturer sets acceptable ranges for the control zone for each lot of reagents.

The *Baseline Control Zone* monitors the presence of interfering substances in the patient sample that may alter the immunoassay process. If a specimen contains a substance that has a major effect on the high and low controls and the baseline control and thereby on the immunoassay, the results are not displayed and erroneous results are not reported.

The *Timing Control Zone* monitors assay completion. If an inadequate amount of specimen is added to the test device or if a specimen clots in the device, this control will prevent the display of the results.

A Trace QC algorithm has been programmed which evaluates the size, location and signal to noise ratio of each zone on the device. Aberrations in zone quality exceeding preset limits will cause rejection of one or more of the assay results.

Meter Quality Assurance

The Self-Test Mode is initiated each time the meter is turned ON. In the self-test mode the meter scans an Internal Calibration Chip. Each calibration chip scan is used to validate and adjust, if necessary, the meter calibration. In the self-test mode, the available memory for patient results is checked. When the capacity is below a pre-set limit, the remaining capacity is related via a screen message. The software program is evaluated and is terminated if corrupted. Software test results and Code Chip data are verified for integrity before each use.

A QC Device is provided with each meter to allow the user to further check the integrity of the meter. The simulator contains six fluorescent zones of varying intensity that are measured by the meter. There are pre-programmed acceptable ranges for the six zones. In addition, the zones allow the meter to check for horizontal and vertical alignment of the zone measurement to verify laser alignment and device transport. The QC Device also confirms laser stability.

A Bar Code is printed on the bottom of every test device to identify the reagent lot number and to prevent the use of expired reagents.

Software Quality Assurance

The software QA is controlled through a variety of software features, some of which can be optional depending on the environment in which the assay is performed. In a Point-of-Care location, a designated supervisor can select program parameters to ensure adherence to quality standards. In a central laboratory location selected parameters can be bypassed, if desired.

A *Supervisor Code Chip*[®] is provided with each meter. This Code Chip allows access to meter functions not available to the routine user. The additional functions are selection of parameter settings and downloading and deletion of results from the meter memory.

A *User ID#* can be assigned in the software to limit access to the patient testing mode to only those individuals who have been properly trained and have demonstrated testing proficiency. A User ID# and expiration date are programmed into the meter memory and are subsequently associated with all patient results generated by the user. This allows the supervisor to review users' testing frequency, and in the event of frequent test failures, to identify potential problems in training.

An additional security feature of the User ID is the partial masking of the ID Number on displays and printouts. This prevents unauthorized individuals from detecting and using an existing User ID number. This feature is overridden when the Supervisor Code Chip[®] is installed

A Patient ID# is required for all patient tests performed. All QC sample and patient results are stored in the meter's memory and can be downloaded to a laboratory information system (LIS) or an external data management software program for further viewing and printing of quality control reports.

The Supervisor can select the *QC Frequency* for performing external liquid control samples. When it is time to perform external QC samples, the user must test the external liquid controls and obtain acceptable results before patient samples can be tested. When QC samples have been successfully performed, the user is allowed to perform tests on patient samples. If QC samples are not within an acceptable range, a *QC Lockout* function prevents testing of patient samples. If desired, the supervisor in a central lab setting can bypass this function. If test device controls are out of range, a QC Lockout function is activated and patient test results are blocked from viewing and printing. This prevents unacceptable results to be communicated to and used by the physician.

Additionally, if test devices are expired, a QC Lockout function is activated and prevents testing using expired test devices.

Quality Control Samples

It is still valuable to apply the traditional approach to quality control by testing quality control samples. These controls will check the total integrity of the system. The interval for analyzing these controls, however, can be extended due to the many other Total Quality Assurance features inherent in the Triage® tests.

The Triage® tests have been designed to maximize Total Quality Assurance in any testing environment. The combination of the QC features of the Triage® tests reduce the impact of procedural errors, ensure reagent integrity, and assure that patient results are accurate each and every time a test is performed. Based on the current CLIA guidelines and other regulating bodies, Biosite Incorporated makes the following QC recommendations:

- Run two levels or POS and NEG external liquid control samples as appropriate with each new lot of reagents and once every thirty days with continued use of the same reagent lot number
- Run the QC Device daily

A blue diamond-shaped badge with the word "NEW" in white capital letters, positioned to the right of the list items.

Notes Regarding Software Controls

1. User ID Access
 - To prevent untrained persons from performing a test, a User ID (1-9 digits in length) must be entered before access is given to the **RUN TEST** function if the User ID bypass is **OFF**. If a User ID Bypass is **ON**, then anyone can analyze a test.
 - The User ID Bypass is controlled by the **SET PARAMETERS** function, which requires a Supervisor Code Chip® for access.
 - Access is available to anyone wanting to **RECALL RESULTS** from memory or **INSTALL CODE CHIP**.

2. Out-of-Range Flags

- If a patient is outside the normal range for any of the analytes, then the result will be flagged by reverse video, that is, the background of the result will be black and the value in white numbers. A warning will be displayed below the results:

PATIENT RESULT ABNORMAL

- If the Internal QC zones for the device or a specific analyte are unacceptable, the analyte(s) in question display an exclamation point (!) in place of a value and a warning is displayed: **! INTERNAL QC OUT OF RANGE.**
- If the QC Sample for a specific analyte on that device lot is unacceptable, the analyte in question will display a pound sign (#) in place of a value and a warning is displayed: **# QC SAMPLE OUT OF RANGE.**
- If both QC Sample and Internal QC errors are present for a specific analyte, both a pound sign and an exclamation point (# !) will be displayed in place of a value and a warning is displayed: **# QC SAMPLE ! INT. QC OUT OF RANGE.**

3. Blocked Results

When QC error conditions exist on a test device, whether for a specific analyte or the entire test panel, the analytes in question are blocked from view and replaced with an Out of Range Flag. The error condition must be remedied and the test repeated to obtain a result.

4. QC Sample Frequency

- How often an external liquid control, QC Sample, should be run can be selected under **SET PARAMETERS**. If the time interval has expired, QC Samples must be run and acceptable results obtained before a patient sample can be tested.
- A list of test device lots and the date that the QC Sample expires can be viewed and printed by selecting **REAGENT LOTS – QC** under the **RECALL RESULTS** menu.

5. Supervisor Access

To prevent misuse, the Supervisor Code Chip® is required for access to the **SET PARAMETERS** and **DELETE RESULTS** functions of the software. The Supervisor Code Chip is universal and may be used on any Triage® MeterPlus.

Service and Maintenance Procedures

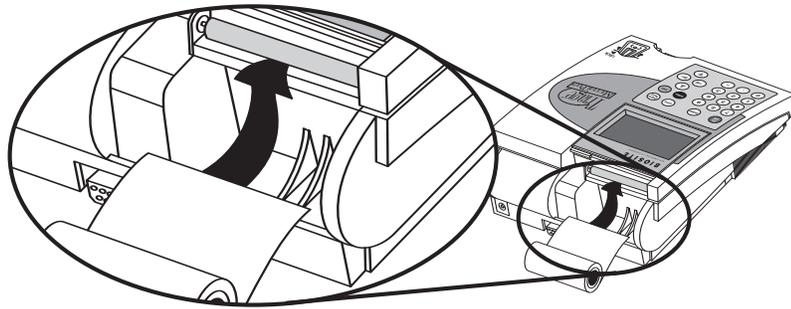
Service and Maintenance Procedures

If any service or maintenance is required, the Triage® MeterPlus should be sent to the manufacturer. No maintenance other than paper / battery replacement and periodic external cleaning is required of the operator.

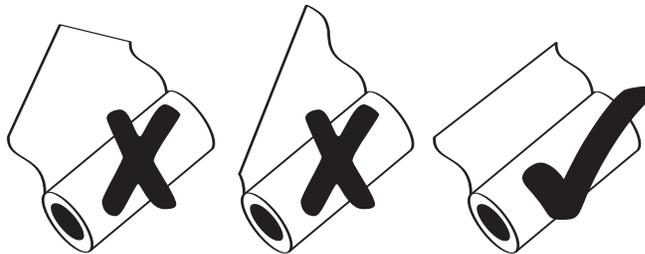
Paper Replacement

Changing Paper Between Functions

1. Tear off any excess paper sticking out of the Triage® MeterPlus.
2. Remove the paper compartment cover by pulling up on the cover as indicate by the arrow on the back of the cover.



3. Remove unused paper or the empty paper spindle from paper compartment.
4. Tear or cut a clean, straight edge to feed into the printer. Do not cut paper at an angle, as the printer must sense the edge of the paper along the feed path.



5. Insert the new roll of paper into the paper compartment.
6. Position the paper such that the paper will feed from under the roll (as opposed to over the top of the roll, see picture, above).
7. Insert the paper edge under the paper roller (platen) until it firmly seats or resistance is felt.
8. Press the  key.
9. Replace the cover of the printer and continue operation.

 **Note:** The printer contains a paper sensor and will feed the new paper roll only when paper with a clean straight line is pressed into the paper roller.

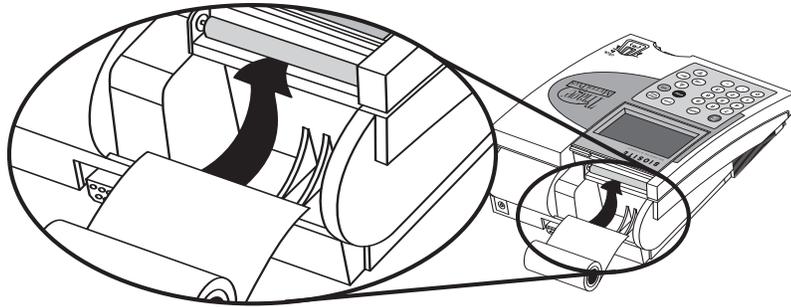
 **Note:** If **PAPER FEED** button is pressed before the printer senses the paper, the printer will not respond to the command.

 **Note:** The printer utilizes thermal paper, if the printed paper is blank after replacing a roll, verify that the paper roll is not upside down.

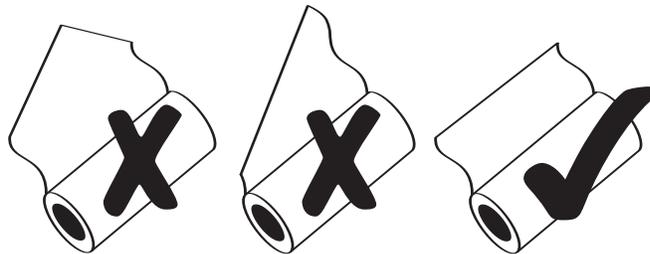
Changing Paper While Printing

If the meter runs out of paper while in the middle of a printing task and is displaying the message **PRINTER FAILURE, CHECK PRINTER OR REPLACE PAPER**, the paper may be changed and the print job continued without loss of data or reprinting from the beginning. Perform the following steps prior to pressing any new keys:

1. Remove the paper compartment cover by pulling up on the cover as indicate by the arrow on the back of the cover.



2. Gently pull remaining paper slowly up through the printer.
3. Remove paper spindle from the paper compartment.
4. Tear or cut a clean, straight edge to feed into the printer. Do not cut paper at an angle, as the printer must sense the edge of the paper along the feed path.



5. Insert the new roll of paper into the paper compartment.
6. Position the paper such that the paper will feed from under the roll (as opposed to over the top of the roll, see picture, above).
7. Insert the paper edge under the paper roller (platen) until it firmly seats or a resistance is felt.
8. Press the  key.
9. When the printer begins to pull the paper in, release the paper. The printer will feed a few lines and re-commence the print job. To ensure no data is lost, the printer will reprint up to the previous 5 lines.
10. After the paper has appeared above the printer, replace the printer cover, taking care to ensure the paper does not get caught inside the meter.

 **Note:** The printer contains a paper sensor and will feed the new paper roll only when paper with a clean straight line is pressed into the paper roller.

 **Note:** If **PAPER FEED** button is pressed before the printer senses the paper, the printer will not respond to the command.

 **Note:** The printer utilizes thermal paper, if the printed paper is blank after replacing a roll, verify that the paper roll is not upside down.

 **Note:** Never insert any tools, swabs, or cleaning materials into the device track.

 **Note:** The meter is designed to perform and print at least 100 tests before new batteries are required to be replaced. When the meter is not in use, it should be turned off. To preserve battery life, ensure the **AUTO POWER-OFF** function is set to **1/2 HOUR**.

 **Note:** Rechargeable batteries are authorized for use, however due to the nature of these types of batteries, it is expected they will require recharging more frequently. The *Triage® MeterPlus* does not contain a built-in battery charger, rechargeable batteries must be recharged outside of the meter.

 **Note:** If the meter does not power on after replacing batteries, verify the batteries are lined up according to the symbols in the battery compartment.

Cleaning

The *Triage® MeterPlus* requires minimal maintenance. Occasional cleaning of the exterior with mild soap and water solution is sufficient. After using a damp, not wet, sponge or cloth to apply a mild soap and water solution on the outside of the meter, wipe the meter dry using a soft cloth or absorbent tissue. Do not allow water to seep into the printer. Do not immerse the meter in water or other liquids.

If blood or other fluids are not allowed enough time to fully absorb into test devices, the device track door may occasionally require cleaning. Using a cotton swab dampened with isopropyl alcohol and a pair of tweezers, carefully lift the door and clean both front and back of the door.

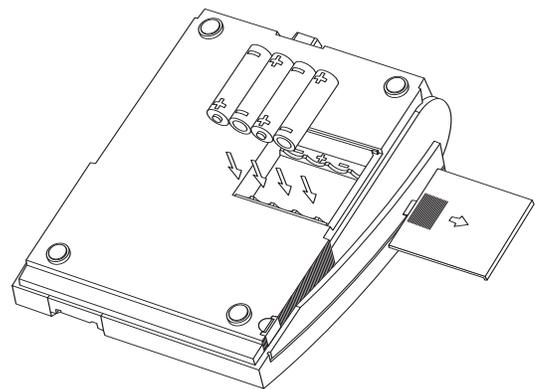


Check Battery Level

The *Triage® MeterPlus* checks the active power source after ejecting a device or printing. To check the battery power, navigate to the Main Menu, disconnect the AC power supply, press the **exit** key (the meter attempts to eject the device), and look for the Low Power Indicator on the Main Menu of the meter display. If the flashing indicator appears, replace the batteries.

Battery Replacement

- Turn off the meter.
- Remove the battery cover from the bottom of the meter by sliding the cover in the direction of the arrow.
- Remove the batteries and discard them in an appropriate waste container.
- Insert four size AA 1.5 volt batteries into the battery compartment. Be sure that the plus (+) and minus (-) signs of the batteries match the same signs embossed in the battery compartment.
- Replace the cover to the battery compartment.



Troubleshooting — Meter Symptoms

Symptom	Probable Cause	Corrective Action
Invalid Results	<ul style="list-style-type: none"> a. Inappropriate body fluid or improperly anticoagulated sample. b. Sample size incorrect—too little sample. Test device’s internal QC controls will be out of range. c. Meter was picked up or carried vertically while test was running. The test device’s internal QC controls will be out of range. 	<ul style="list-style-type: none"> a. Retest sample using a new test device with a proper specimen. b. Retest sample on a new test device. Make sure the entire tube is full. Be certain the lower bulb on the pipette tube contains a small amount fluid before you press the top bulb. c. If less than 30 minutes has passed since preparing the test device, place meter on flat surface and reinsert the test device. If more than 30 minutes has passed, retest sample on new test device. If meter must be moved during test, carry the meter parallel to the floor.
Meter will not pull test device in.	Hook that pulls test device into the meter may be broken.	If meter repeatedly fails to pull the device in, the meter may need to be replaced. Call Technical Services.
Code Chip® will not fit in meter.	<ul style="list-style-type: none"> a. Code Chip may have been inserted upside down. b. Code Chip or Meter contacts could be bent. 	<ul style="list-style-type: none"> a. Re-insert Code Chip right side up. b. Try new Code Chip, if available. If still not a good fit, call Technical Services.
Printer works but no print appears on paper.	Paper may be installed backwards.	Install paper reverse to current position.
Printer jam.	Paper may have been fed into the meter improperly.	Carefully remove old paper out of the printer. Do not insert any tools into the printer.
Printer stops printing or skips a line.	Battery power low.	Replace batteries or verify power cord is installed in the meter and wall outlet.
Meter will not power on or meter powers off when running a test.	<ul style="list-style-type: none"> a. Batteries not installed, drained or incorrectly aligned. b. Power source not plugged in. 	<ul style="list-style-type: none"> a. Verify batteries are installed and correctly aligned (+) and (-); replace batteries if necessary. b. Verify power cord is installed in the meter and wall outlet.
Blinking battery icon. 	Low battery power.	Replace batteries.
Meter contains no batteries or batteries are low when facility has loss of power.		All data is saved in the Meter except date and time. Reset date and time.

Biosite Technical Services 1-888-BIOSITE (1-888-246-7483 24 hours a day/7 days a week)

Troubleshooting — Meter Message or Symptom

Message	Probable Cause	Corrective Action
>XXX.X	Patient sample concentration is above the dynamic range.	See instructions that came in the box of test devices or call Technical Services.
<XX.X	Patient result is below the dynamic range or is a concentration below the statistically determined lowest test concentration.	For some parameters, a 0.0 ng/ml patient result may be appropriate.
BATTERY LOW.	Batteries need replacement.	Replace with 4-AA batteries or use the AC power adapter as a power source.
CANNOT READ BAR CODE	Damaged bar code or meter hook may be broken. (The meter hook pulls the test device into the meter.)	Look for particles on the bar code of the test device. wipe off with a dry cloth. Repeat the test.
CANNOT READ CODE CHIP®.	<p>a. Code Chip error.</p> <p>b. Meter error.</p>	<p>a. • Ensure Code Chip is completely inserted. • Try a reagent Code Chip from a different box of devices of the same lot number. • If a new Code Chip eliminates the message, the original Code Chip is at fault, discard Code Chip.</p> <p>b. If the new Code Chip does not work, install a known working Code Chip to verify proper operation. If the Code Chip fails to work, contact Technical Services.</p>
DETECTOR FAILURE	Optics Detector did not properly power on.	Power meter off and wait 15 seconds. Power meter on. If message fails to clear, contact Technical Services.
MEASUREMENT FAILURE.	<p>a. Inappropriate body fluid or improperly anticoagulated sample.</p> <p>b. Sample size incorrect – too little sample.</p> <p>c. Meter picked up or carried vertically while test is running.</p> <p>d. Sample running slowly</p>	<p>a. Retest sample using new device with a proper specimen.</p> <p>b. Retest sample on new device. Be certain the lower bulb on pipet contains a small amount of fluid and the entire tube is full before dispensing contents.</p> <p>c. Retest sample and leave meter on bench top while performing assay. If meter must be transported during assay, carry meter parallel to the floor. If more than 30 minutes since inoculation, use a new device.</p> <p>d. Possibly due to cold devices or sample, high hematocrit with a whole blood sample, or mechanical issue with device. Have customer immediately reinsert device into meter (if within 30 minutes of sample addition).</p>

Biosite Technical Services 1-888-BIOSITE (1-888-246-7483 24 hours a day/7 days a week)

Troubleshooting — Meter Message or Symptom

Message	Probable Cause	Corrective Action
MOTOR FAILURE.	<p>Motor ceases to function.</p> <ul style="list-style-type: none"> Meter may slow or stop due to object lodged on the Meter track. Test device may stick on the meter track. 	Eject and inspect the device for any sticky substances, labels on top of the device or other items that may interfere with the meter. If problem persists, contact Technical Services.
NO DEVICE DATA IN MEMORY.	Reagent Code Chip® has not been installed.	Install the Code Chip included in the box of test devices (the Reagent Code Chip).
OPTIC FAILURE.	<p>a. Internal standard is out of specification.</p> <p>b. Meter exposed to extreme temperatures.</p>	<p>a. Power meter off then on again. If OPTIC FAILURE message clears, run the QC Device to verify proper operation. If message fails to clear, contact Technical Services.</p> <p>b. Power meter off. Allow meter to sit at room temperature for 1–2 hours. Power meter back on.</p>
PROGRAM CHECK OK. Press ENTER to start existing program or press EXIT to load a new program.	Message appears when the ON/OFF button is pressed when the meter has been without power.	Press the ENTER key.
QC Device—calibration, alignment or laser failed. Messages: CALIB PASS (or FAIL) LASER PASS (or FAIL) ALIGN PASS (or FAIL)	<p>a. May be due to lint or dust affecting reading.</p> <p>b. QC Device was not run regularly.</p>	<p>a. Clean QC Device with a lint-free cloth or spray with canned air and repeat the test.</p> <p>b. QC Device should be run regularly even if patient samples are not run.</p> <p>c. If problem persists, call Technical Services.</p>
TIME/DATE IS BLINKING	Meter temporarily lost all power.	Reset time and date if required. Check the AC/DC power converter plug and batteries.
WARNING: INTERNAL QC OUT OF RANGE	Warning indicates that the internal quality control on the test device was out of range. This may be sample specific. This may be device related.	Repeat sample using a new test device. If problem persists, call Technical Services.
WARNING: PATIENT MEMORY HAS SPACE FOR ### MORE RECORDS.	Message is displayed when meter is turned on if there is space left for less than 100 patient records or space left for less than 20 patient records when running patient sample.	<p>Options:</p> <p>a. Print all results.</p> <p>b. Delete patient results.</p> <p>c. No action is required as the meter will delete the oldest result once the memory is full.</p>

Biosite Technical Services 1-888-BIOSITE (1-888-246-7483 24 hours a day/7 days a week)

Return Procedure

Return Procedure

Should a malfunction occur, call your designated Technical Services Department. If the Technical Services Department determines that the meter should be returned, you will be assigned a return authorization number and be provided shipping instructions.

In the USA: Biosite Technical Services – 888-BIOSITE (888-246-7483)

Immediately after the return has been authorized, Biosite will send out a replacement Triage® MeterPlus. Return the malfunctioning meter to Biosite. Note the return authorization number on both the shipping box and the airbill and send the meter back to Biosite as soon as possible following receipt of the replacement meter.

For International assistance, call your distributor.

Glossary

Analyte: Chemical substance being measured.

Assay: Test.

Calibration: Comparison of result to a reference standard.

Code Chip®: Any of several kinds of chips bearing information that can be downloaded in the Triage® MeterPlus, including Reagent, QC Sample, QC Device, Supervisor and Program.

Code Chip Port: The small slot on the underneath side of the Triage® MeterPlus where a Code Chip can be inserted.

Date formats: DD-MM-YY: Day-Month-Year
MM-DD-YY: Month-Day-Year
YY-MM-DD: Year-Month-Day



Note: All parts of dates should be given as two digit numbers.

For example, the month of May is 05.

Device L/N: Lot number of a test device can be found on the side of the box that contains the test devices and on each test device. The device L/N is a five digit number that may be preceded by one or more letters. The meter disregards all letters.

Digit: One part of a longer number; for example, in the number 231, the 2, 3, and 1 are each a digit.

Fluorescence: The characteristic of a chemical substance that enables it to give off light when stimulated.

ID: Identification.

Immunoassay: A test that uses antibodies to measure substances.

Internal QC: Quality controls in place as part of the Triage® MeterPlus' software or zones built into the test device.

In vitro: Made to occur in a laboratory vessel or other controlled experimental environment rather than in a living organism (literally, in glass).

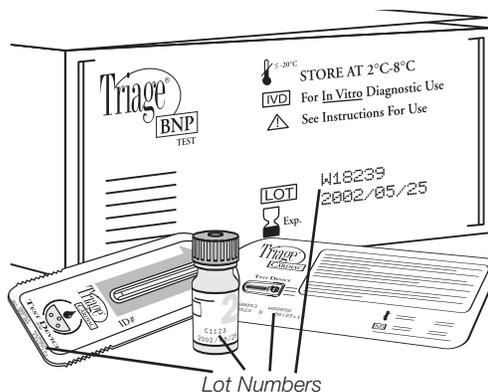
In vitro diagnostic use: For use in a controlled setting.

Laser diode: Light source used in the Triage® MeterPlus.

LCD: Liquid crystal display; the screen on the Triage® MeterPlus. Shows the menu of possible tests and procedures and prompts the operator to take the next step.

Lot number: L/N; identification number given to a group of test devices.

L/N: Lot number; the number that identifies a batch of test devices.



Menu: List of choices displayed on the Triage® MeterPlus' screen.

Parameters: Options; functions.

Photodiode: Detects the light emitted from the fluorescent dye in the test devices used in the Triage® MeterPlus.

Point of Care (POC): Not in a laboratory; at the place where care is being given to a patient.

Glossary

QC: Quality Control.

QC Sample:

External controls; a liquid solution containing chemicals that, when dispensed into a test device, react with the test reagents. Used to verify proper performance of test devices after shipment or long periods of storage.



QC Sample Code Chip: Code Chip that can be downloaded into the Triage® MeterPlus memory to give the meter information needed about the specific lot of QC Sample.

QC Device (previously called QC Simulator):

Test device containing 6 independent zones that verifies proper operation of the Triage® MeterPlus' ability to properly read patient tests across varying analyte concentrations.



QC Device Code Chip: Code Chip that can be downloaded into the Triage® MeterPlus' memory to give the meter information needed about the specific QC Device's performance in the assigned meter.

Quantify, quantifying: To give the results of a test as number.

Reagent: Substance that causes chemical reactions; used in analysis.

Reagent Code Chip: Code Chip loaded with information about a specific test and lot number.

Retrieve: Find, bring back.

Reverse Video: Light text displayed on a dark background.

Screen: The part of the Triage® MeterPlus that displays words and numbers.

Scroll to:

Use arrow keys     to go to the information you want on the screen.

Set Parameters: A function of the Triage® MeterPlus; requires the use of the Supervisor Code Chip.

Software Upgrade Code Chip®:

Code Chip used to download new software onto the Triage® MeterPlus.

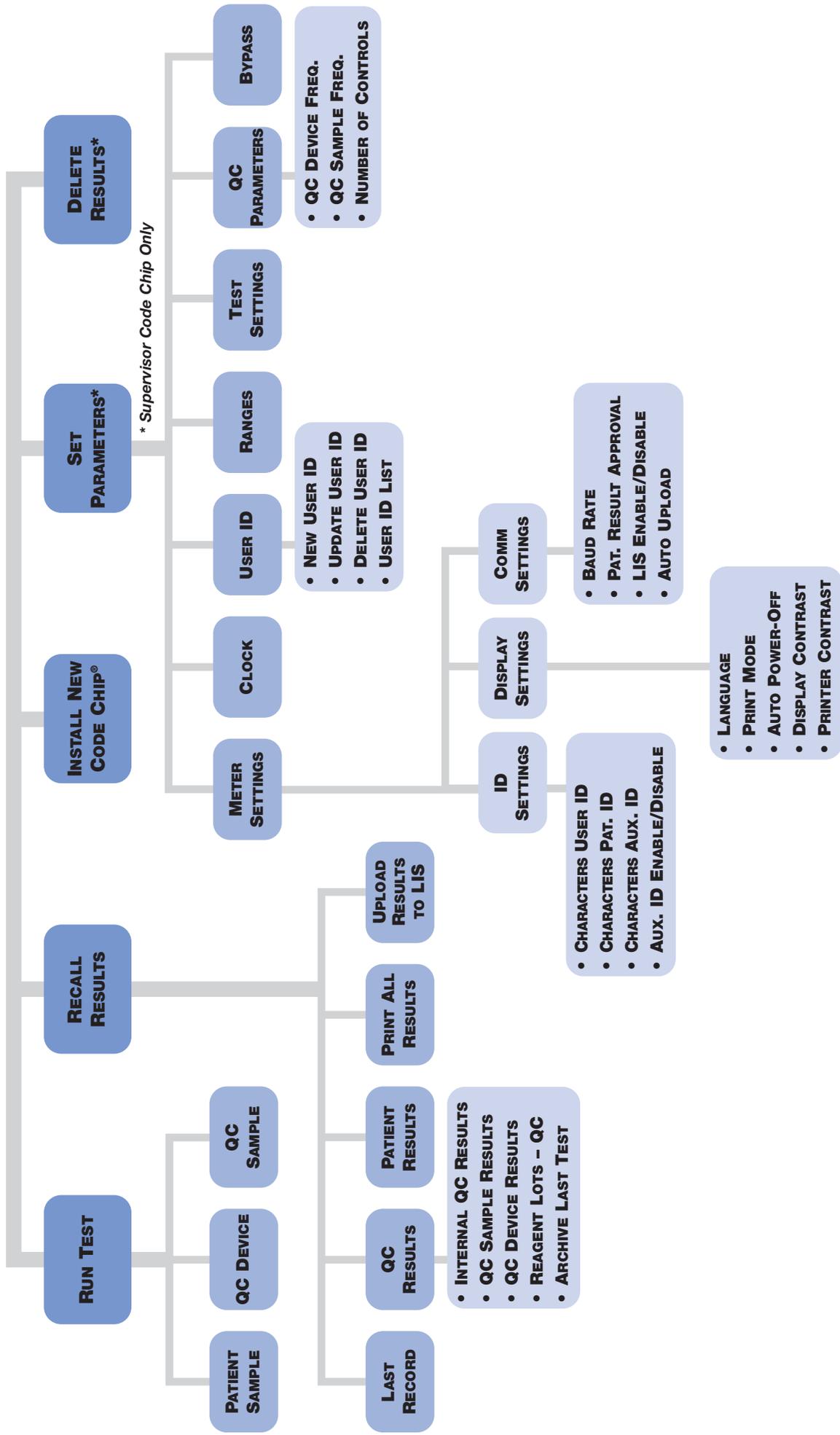


Supervisor Code Chip: The Code Chip that allows a supervisor to set parameters and delete results.

Test device: Holds the sample (for example, blood) from the patient so that it can be inserted into the Triage® MeterPlus for testing. Contains reagent zones that cause reactions to occur that allow the meter to determine analyte levels in the patient.

Test panel: Alternate name for Test device, usually indicative of a Test device with multiple analytes.





Sample Log Sheets

The following log sheets are provided as alternate methods of tracking test results. The Triage® MeterPlus is capable of tracking and printing out test history and providing QC Lockouts to prevent patient testing when outside QC requirements.



Patient Test Log Sheet

Used as an alternate method of tracking patient test history.

Month _____ Laboratory Name _____ Testing Site _____

Date/ Time	Patient ID Number	User Name/ ID Number	Lot Number	Analyte 1	Analyte 2	Analyte 3	Analyte 4	Analyte 5	Analyte 6	Analyte 7	Analyte 8	Analyte 9	Comments	Tech Initials
1														
2														
3														
4														
5														
6														
7														
8														
9														
10														
11														
12														
13														
14														
15														
16														
17														
18														
19														
20														



QC Device Test Log Sheet

Used as an alternate method of tracking QC Device test history

METER Plus

Month _____

Laboratory Name _____

Testing Site _____

Date/ Time	User Name/ ID Number	Calibration (pass/fail)	Laser (pass/fail)	Alignment (pass/fail)	Comments	Tech Initials
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						



QC Sample Test Log Sheet

Used as an alternate method of tracking QC Sample test history.

Month _____ Laboratory Name _____ Testing Site _____

Date/ Time	QC Sample Lot Number	Expiration Date	Level	Analyte 1	Analyte 2	Analyte 3	Analyte 4	Analyte 5	Analyte 6	Analyte 7	Analyte 8	Analyte 9	Comments	Tech Initials
1			Level I Low											
			Level II High											
2			Level I Low											
			Level II High											
3			Level I Low											
			Level II High											
4			Level I Low											
			Level II High											
5			Level I Low											
			Level II High											
6			Level I Low											
			Level II High											
7			Level I Low											
			Level II High											
8			Level I Low											
			Level II High											
9			Level I Low											
			Level II High											
10			Level I Low											
			Level II High											
11			Level I Low											
			Level II High											
12			Level I Low											
			Level II High											
13			Level I Low											
			Level II High											
14			Level I Low											
			Level II High											
15			Level I Low											
			Level II High											

Index of Page Revisions

This chart may be used to page check your User Manual. Additional pages may be requested from your Biosite Customer Services. This page will be updated and included with any manual updates.

Page #	Rev	✓	✓	✓	Page #	Rev	✓	✓	✓
I-1	E				O-5	E			
I-2	B				O-6	D			
I-3	E				O-7	D			
I-4	B				O-8	D			
I-5	D				O-9	D			
I-6	B				O-10	D			
I-7	B				O-11	D			
I-8	D				O-12	D			
I-9	D				O-13	D			
I-10	B				O-14	D			
N-1	D				O-15	D			
N-2	D				O-16	D			
N-3	C				O-17	E			
N-4	D				O-18	D			
N-5	D				O-19	D			
N-6	D				O-20	D			
N-7	D				O-21	D			
N-8	D				O-22	D			
N-9	D				O-23	D			
N-10	D				O-24	D			
N-11	D				O-25	D			
N-12	D				O-26	D			
N-13	D				M-1	D			
N-14	D				M-2	D			
N-15	D				M-3	D			
N-16	D				M-4	D			
N-17	D				M-5	B			
N-18	D				M-6	C			
N-19	D				M-7	C			
N-20	D				M-8	D			
N-21	D				M-9	C			
N-22	D				M-10	C			
N-23	D				M-11	D			
N-24	D				M-12	B			
N-25	D				A-1	D			
N-26	D				A-2	D			
N-27	D				A-3	D			
N-28	D				A-4	B			
N-29	D				A-5	C			
N-30	D				A-6	D			
O-1	D				A-7	C			
O-2	D				A-8	E			
O-3	D				A-9	E			
O-4	D				A-10	E			

First Page Checked Performed: Signature _____ Date _____

Second Page Checked Performed: Signature _____ Date _____

Third Page Checked Performed: Signature _____ Date _____

Assistance

If you have any questions regarding the use of this product, please call Biosite's Technical Services number at 1-888-BIOSITE/1-888-246-7483 (toll-free in the U.S.) or 858-455-4808, 7 days per week, 24 hours per day. In France, Contact Biosite France SAS at 0800 246 800 (toll-free). In Germany, contact Biosite GmbH at 0800 244 4000. For other areas outside the U.S., contact your local Biosite distributor.

EC REP Authorized Representative
BIOSITE EUROPE
Biosite Incorporated Liaison Office
1232, Rue Louis Blériot
78530 Buc FRANCE





NEW DIMENSIONS IN DIAGNOSIS®

Biosite Incorporated, 11030 Roselle Street, San Diego, California 92121 USA

(858) 455-4808 www.biosite.com

Purchase of this product licenses its use under U.S. Patent Number 6,074,616.

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