# Clinitek STATUS® Analyzer



# Operator's Manual

# Clinitek STATUS®

## Analyzer

# Operator's Manual

Bayer HealthCare

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The information in this manual was correct at the time of printing. However, Bayer HealthCare continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

If this instrument is used in a manner differently than specified in this manual, the protection provided by the equipment may be impaired.

# Table of Contents

# A Brief Description

**What does the analyzer do?**

Your Clinitek Status® analyzer is a portable instrument for reading Bayer urinalysis strips and Clinitest® immunoassay cassettes. No special training is needed to use this instrument. Several different Bayer urinalysis strips (e.g., Multistix® 10 SG) can be used with the analyzer as well as the Clinitest hCG Pregnancy Test.

The analyzer can be set up to be as simple or sophisticated as you prefer. You may simply insert a dipped urinalysis strip or a Clinitest cassette into the analyzer and the result will be reported (this is called a *Quick Test*).

Or, you have the option to enter an Operator ID, Patient Name and Patient ID. This added information will be reported along with the test results (this is called a *Full Test*).

The touch screen displays instructions and prompts you through operation of the analyzer. In addition, you enter information through the touch screen.

**Do I have to calibrate?**

You do not have to do anything to calibrate. The instrument performs a system test each time it is turned on. Then, each time a test is run, the instrument automatically calibrates. The white calibration bar (on the test table) provides NIST traceable calibration.

**How does it work?**

Testing starts (in the *Quick Test* mode) when either the *Strip Test* or *Cassette Test* is selected on the main menu screen.

Touching the *Strip Test* key prompts you to adjust the test table to accept a urinalysis strip. Then you touch the **START** key. You have 8 seconds to dip the test strip, blot the edge of the strip and place it on the test strip table. The table is partially pulled into the instrument for calibration and then pulled completely into the instrument to read the test strip.

Touching the *Cassette Test* key prompts you to adjust the test table to accept a cassette. Then you touch the **START** key. You have 8 seconds to draw the sample into a pipette and dispense it into the sample well of the cassette. The analyzer automatically calibrates and then pulls the table completely into the instrument where the cassette is read.

In the *Full Test* mode for either a *Strip Test* or *Cassette Test*, you are prompted to enter an Operator ID, Patient Name and/or Patient ID prior to running a test.

# A Brief Description

**How do I get results?**

Results will be displayed on the touch screen and printed (if desired). The results can also be transferred to a computer using a 9-pin null modem serial cable and the RS-232 serial port on the back of the instrument.

The analyzer stores results from 200 patient tests. You are able to recall past patient test results on the analyzer using the ***Recall Results*** function.

**How is the analyzer powered?**

The analyzer can be plugged into an electrical outlet for use on the bench top, or it can be powered by batteries and freely moved from one testing site to another. The batteries fit into an opening on the bottom of the instrument.

**What about this Operator's Manual?**

The Operator's Manual contains the directions you need to unpack

the analyzer, use it for your daily Bayer urinalysis and Clinitest immunoassay testing and keep it in good working condition.

As you read through the Operator's Manual, you will find these symbols:

NOTES: contain useful tips on using the analyzer. *Notes appear in italicized type.*

⚠CAUTION: should be followed carefully to ensure your analyzer operates correctly and is not damaged. **Cautions appear in bold type.**

In the Operator's Manual, you will notice some text is in ***bold/italic*** or **bold.**

***Bold/italic*** text identifies screen names.



**Bold** text identifies a button (touch – sensitive area) on the screen.
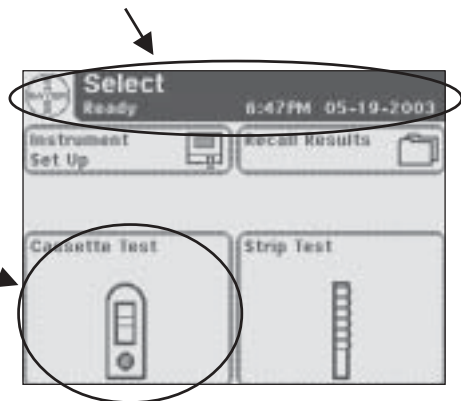
# Understanding the Symbols and Display Icons

**Instrument and Labeling Symbols**

This section describes the symbols that appear on the exterior of the Clinitek Status instrument, the power supply provided with the instrument, the carton in which the instrument was delivered and the supplies of reagent strips and cassettes which you will use with the instrument.

| | |
|---|---|
| ⎓ | Indicates that the input supply is direct current |
| ⩫ | Identifies that the instrument is type B equipment, which provides a particular degree of protection against electric shock |
| Class 1 | Identifies that the instrument is class 1 type equipment, which has basic insulation and additional safety grounding precautions |
| ▣ | Double insulated product or transformer may also identify class 2 equipment (power supply only) |
| c(UL)us LISTED | Identifies that the instrument is listed by Underwriters Laboratories as meeting U.S. and Canadian requirements for safety |
| CE | The CE mark identifies that the product complies with the applicable directives of the European Union |
| ▲ | Manufacturer |
| EC REP | European authorized representative |
| ⏻ | Indicates a power on/off button |
| ⚠ | Caution, consult accompanying documents |
| IVD | *In vitro* diagnostic device |
| 📖 | Consult instructions for use |

# Understanding the Symbols and Display Icons

|O|O|  Indicates a serial port

Temperature limitation (18° - 30° C)

Contents sufficient for (n) tests (100)

Use by YYYY-MM

REF  Catalog number

SN  Serial number

LOT  Batch code

Biohazard

Indicates that this equipment is classified as Waste Electrical and Electronic Equipment under the European WEEE Directive. It must be recycled or disposed of in accordance with applicable local requirements.

Printed on recycled materials

Indicates compliance with RESY packaging standards

Keep this way up

Fragile, handle with care

# Understanding the Symbols and Display Icons

Keep dry

Keep away from sunlight and heat

VDE Testing and Certification Institute - Germany

Manufacturer's mark (FRIWO) and manufacturing location (Hong Kong)

Manufacturer's mark (FRIWO) and manufacturing location (Geratebau, Germany)

Encapsulated safety isolating transformer (short-circuit proof)

Positive Temperature Coefficient (PTC) - A thermistor device used to protect the transformer from short-circuits or overload. This is an auto reset device.

Thermal cut-out (TCO) – This safety device disconnects the supply voltage to the transformer at a specific temperature. The operation temperature is stated below.

Ingress protection rating – protected against the entry of solid objects >1 mm but no protection from liquids.

# Understanding the Symbols and Display Icons

**Display Icons**

The Bayer logo is shown in the top left of the display while some of the system diagnostic tests are being carried out after power-up. There are seven other icons which display in the same position to show the mode of the instrument. They also appear on the selection area for each function. The icons are:

**Instrument Set Up**
This is displayed when the instrument is being set up to suit the users' requirements.

**Strip Test (e.g., Multistix 10SG)**
Shown when a test is being carried out using a reagent strip for urinalysis, and when results are displayed following a strip test.

**Cassette Test (e.g., Clinitest hCG)**
Displayed when a cassette test is being carried out and when results are shown after a cassette test.

**Results recall**
Used to show that results are being recalled from the instrument's memory.

**Printer**
This icon is displayed when results are being printed.

**Data transfer to Personal Computer**
Shows that data, including results, is being transferred to a PC.

**Alert**
Used when an error is being displayed.

There are two icons which may appear in the title bar.

**Battery power**
This has a maximum of four segments which show the level of battery power. It will be shown in the top right corner of the title bar when the instrument is battery powered.

**Paper-out**
Appears in the top of the title bar when the printer paper/ label roll needs replacing.

# 1 Unpacking & Set Up
*Unpacking*

## Unpacking

**1** Carefully remove the contents of the shipping carton. Check the carton and instrument for visible signs of damage; if seen, immediately contact the carrier.

**2** Remove each of the wrappings and check for the following items:



❶ Clinitek Status® analyzer

❷ Test table

⚠ **Do not touch the white calibration bar.**

❸ Test table insert

✎ *If you are using a reagent strip that has 4 or fewer test pads, e.g., Uristix® 4, you must use a short test table insert. This has to be ordered separately (for a list of suppliers see Appendix A, Local Technical Support Providers and Distributors).*

❹ Power Supply

✎ *If the power cord is not the style you need, contact your local Bayer office (for a list of contacts see*

*Appendix A, Local Technical Support Providers and Distributors).*

❺ Paper Roll

❻ Clinitek Status® Check Cassette (not shown)

⚠ **Do not remove the Check Cassette from its foil packaging. The Check Cassette should be available if you need to call Bayer for assistance with an analyzer error. Store the cassette in the pocket located inside the back cover of your Operator's Manual.**

Depending on the model you have received, there may also be a Warranty Registration Card, Unpacking/Setup Guide, and/or Quick Reference Guide included.

## Set Up

### 3 Analyzer Set Up

Place the instrument on a level work surface where the temperature and humidity are fairly constant.

⚠ **The best temperature for using the instrument is between 22°C and 26°C (72°F and 79°F). Do not place the analyzer outside or near windows, ovens, hot plates, or radiators.**

### 4 Plugging Analyzer In

Plug the appropriate end of the power cord into the power inlet socket located on the rear of the Clinitek Status analyzer. Plug the other end of the power cord into an AC electrical wall outlet.



### 5 Installing Batteries
(Optional)

Place the analyzer on its side and remove the battery cover by pressing down on the tab and pulling out. Place the 6 new AA-size batteries into the analyzer. Replace the battery cover and turn the instrument back onto its base.

### 6 Inserting Test Strip Table

Insert the test strip table into the analyzer by holding it by the end opposite the white calibration bar and with the white bar facing up. Push the test table into the analyzer, pushing it in just over halfway.

> ⚠ **Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer.**

> ⚠ **Do not touch the white calibration bar.**



### 7 Loading Test Table Insert

The test table insert adapts for use with a Bayer urinalysis strip or Clinitest immunoassay cassette. One side is used for a strip test and the other side is used for a cassette test.



### 8 Interfacing to a Computer

The instrument can send results to a computer via the serial port located on the back of the analyzer. This requires a 9-pin null modem serial cable that can be purchased separately at an electronics store or from your Bayer Representative (for a list of suppliers see Appendix A, Local Technical Support Providers and Distributors).

## 9 Analyzer Software Upgrades

From time to time Bayer HealthCare will add new features and make improvements to the Clinitek Status instrument software.

These software updates will be available on an electronic memory card which is inserted into the software update socket. This socket is located under the printer cover and is on the left-hand side of the printer when you face the back of the instrument.

Updating the software is a simple procedure. Instructions for updating the software on your instrument will be supplied with the memory card.
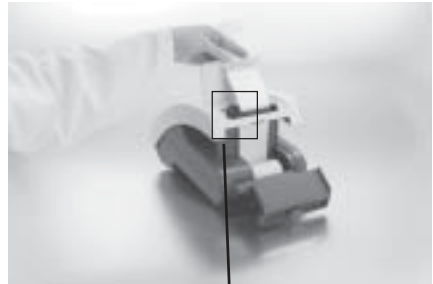
## 10 Loading the Printer Paper or Label Roll

1. Open the printer cover by pulling up on the tab.

2. Open the paper roll compartment cover by pressing down on its tab and pulling out.

3. Lift the paper holding arm into the open, upright position.

4. Place the new paper roll into the printer paper compartment with the paper unrolling from underneath and toward the compartment wall.

5. Feed the paper up along wall and through the printer. Once you have approximately 4 inches (or 10 cm) of paper through the printer then feed the edge of the paper through the printer cover.

6. Push the paper holding arm down in to the closed position.

7. Close the printer and paper roll covers by clicking them into position.



paper holding arm

*The analyzer is set up to automatically print the results (to turn off the automatic print function see Section 5, Instrument Set Up).*

*The analyzer uses ordinary thermal paper as provided, or label stock (for ordering information see Appendix A, Local Technical Support Providers and Distributors).*

**11** **Warranty Registration**

1. Lift the printer cover on the instrument and the serial plate with the instrument's serial number will be visible.

2. Write the serial number and installation date on the Warranty Registration Card. After the instrument has been successfully installed, complete the information on the Warranty Registration Card and return the card to your local Bayer office (for a contact list see Appendix A, Local Technical Support Providers and Distributors).
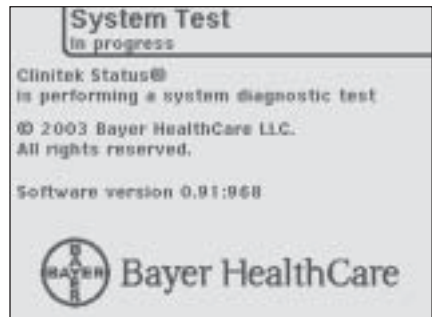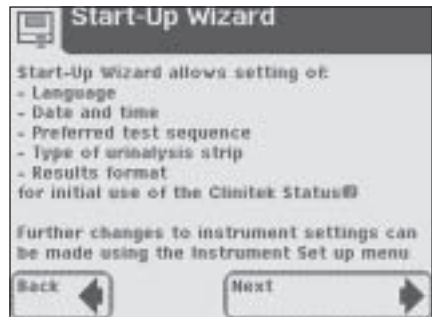
## Powering Up

Press the on/off button ① located on the front of the instrument.



This is the first screen displayed. The analyzer will run an automatic system diagnostic test each time it is turned on.



If this is the first time you have turned on the analyzer, you will be led through a Start-Up Wizard, a quick set-up procedure. If you require further instruction regarding the Start-Up Wizard see Section 3, page 3-1.

## Powering Down

1.  Before turning the analyzer off, always ensure that there is no strip or cassette on the test table and that the table and insert are clean.

2.  Press the on/off button $\textcircled{I}$ for at least 2 seconds. The test table will retract into the analyzer. If there is no strip or cassette on the test table, the door will close and the analyzer will switch off.

If a strip or cassette is still on the test table, the test table will be pushed out and the analyzer will turn off. The test table will remain out. In order to retract the test table into the analyzer, turn the analyzer on, and then off (without a strip or cassette on the test table).

> ⚠ **Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer.**

## Screens

The touch screen will guide you through the operation of the Clinitek Status® analyzer. The screen will display messages, instructions and options to which you respond by touching the appropriate area on the screen.



The first main screen you see is the *Select* screen. It displays the Bayer logo, time and date, and indicates the instrument is ready to perform any of the four actions or tasks shown.

- Instrument Set Up
- Recall Results
- Cassette Test
- Strip Test

Each screen that follows the *Select* screen has an icon, title bar and touch-sensitive active areas.

In some cases, the screen will also display instructions, messages or error messages.

The icon indicates the main section in which you are working (1 of the 4 sections listed on the main *Select* screen).

Icon        Title Bar



Touch-Sensitive Area
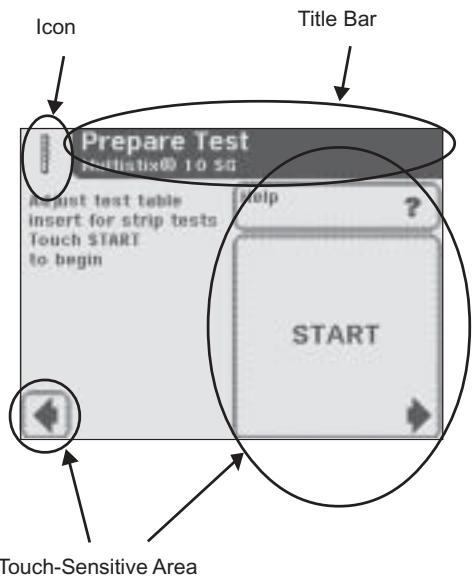
# 2 Interacting with the Touch Screen
*Screens*

## How to Touch the Screens
The screen needs to be touched lightly in the touch-sensitive area to activate a response.

## Where to Touch the Screens
There are three types of areas that respond to touching the screen.
- Round Buttons
- Boxed Areas
- Scroll Arrows

*If a touched area does not respond as expected, slide your finger across the appropriate selection area.*

⚠ **Use of anything hard or pointed on the touch screen may cause damage.**

## Round Buttons
These buttons typically appear on screens that require a selection among several items. The button with a filled circle is the current selection.

To change your selection, touch an unfilled circle. The newly selected circle (button) will now be highlighted. You then touch the **Next** button to move to the next screen.
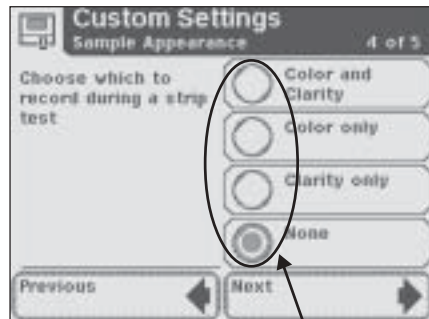


Round Buttons

*In order to proceed, you will always touch the box with a right-pointed arrow labeled **Next**.*

*In order to go back, you will always touch the box with a left-pointed arrow. These "back" option boxes vary in title.*
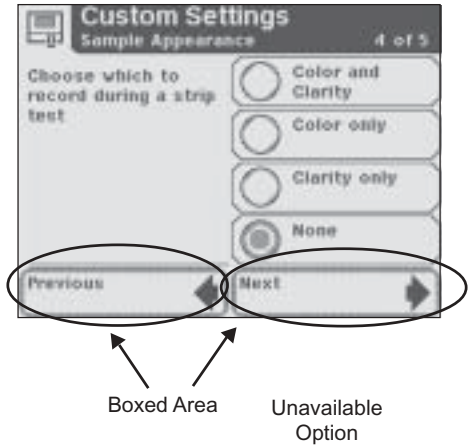
## Boxed Areas

These are areas on the screen enclosed in boxes. Simply touch any area within the box to activate that function.

The boxed areas vary in size. The boxes located on the main *Select* screen are examples of larger areas. Smaller box selections include boxes such as the "Previous" and "Next" boxes found at the bottom of the screen.



Boxed Area     Unavailable Option

## Scroll Arrows

Press the up and down arrows on the right side of the screen to scroll through the list of information on the left side of the screen. Once the information on the left side of the screen is highlighted, touch the **Select** button to confirm your selection and move to the next screen.
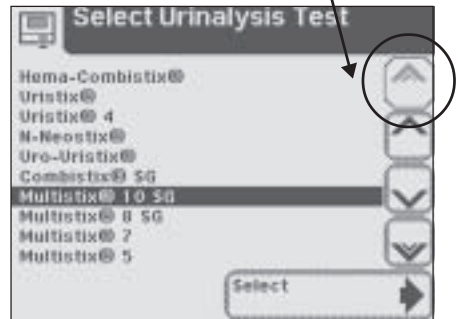
If there are double arrows on the screen, these arrows (when touched) will take you to the top or bottom of the page.



> *When an option can be selected it will be shown with a thick black frame and will respond when touched. If an option is not available, it will be framed with a thin black line and not respond when touched.*

# 2 Interacting with the Touch Screen
*Keyboards*

## Keyboards

### Using the Alpha-Numeric Keyboard

When the screen prompts you to enter information for Operator ID, Patient's Name and/or Patient Identification, a keyboard will appear on the screen.

Depending on how your analyzer is set up, either an alphabetic or numeric keyboard will be displayed first. The first keyboard displayed is referred to as "keyboard priority."
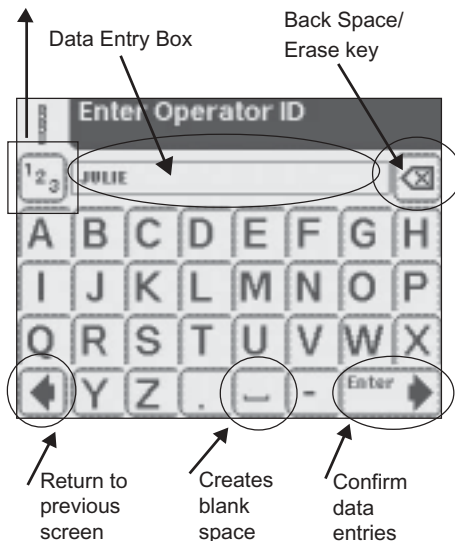
> *If you require further instruction regarding how to change keyboard priority see Section 5, Instrument Set Up.*

To switch between the keyboards, touch the **123** button to get to the numeric keyboard. Touch the **ABC** button to get to the alphabetic keyboard.

To type in a name, number, birth date, etc., touch the appropriate button. Your selections will appear in the data entry box.

If you switch between keyboards, all values will be retained in the data entry box on both keyboard screens.

Press to switch to numeric keyboard

Data Entry Box

Back Space/ Erase key

Return to previous screen

Creates blank space

Confirm data entries

Press to switch to alphabetic keyboard

The maximum number of
characters allowed is 20. An
audible tone will sound when you
have exceeded the maximum
number of characters.

Once you have finished entering
the information, touch **Enter** (from
either keyboard screen).

# 3 Start-Up Wizard

The first time your Clinitek Status® analyzer is turned on (following an automatic system diagnostic test), it will take you through a quick set up procedure. This procedure will allow you to select the basic functions of the analyzer so you can use the analyzer with your choice of settings.

The **Start-Up Wizard** will allow you to select the following settings:

- Language
- Date and time
- Preferred test sequence (e.g., Quick Test or Full Test)
- Type of urinalysis strip
- Results format



*If you require further instruction regarding how to change the settings see Section 5, Instrument Set Up.*

Once you have selected your choices, the analyzer will display a **Confirmation** screen which allows you to check that your preferences are correct.
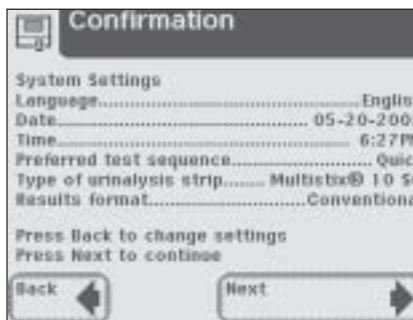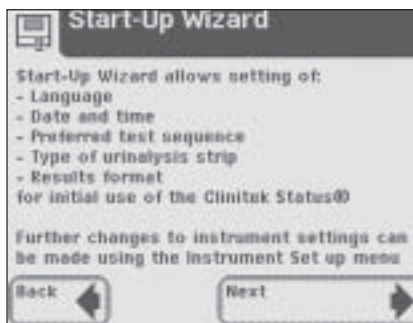
# 4 Testing
*Quick Tests*

## Quick Tests

### Urinalysis Strip Test

 **BIOHAZARD** Wear personal protective equipment. Use universal precautions. Refer to *Appendix H* for recommended precautions when working with biohazardous materials.

Testing is started from the main *Select* screen.

>  *If you require more information regarding use and storage of test strips, please refer to the strip package insert.*

Touch **Strip Test** to conduct a urinalysis strip test.

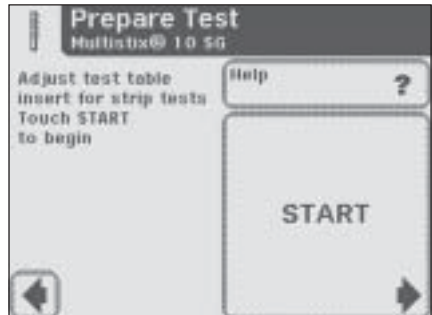The next screen that appears is *Prepare Test*.

>  *If you would like the steps for urinalysis testing to be shown on the screen then touch **Help**.*

Make sure the test table insert has the reagent strip holder facing upward.

Also, have the test strip, urine sample and paper towel ready.

Touch the **START** button.
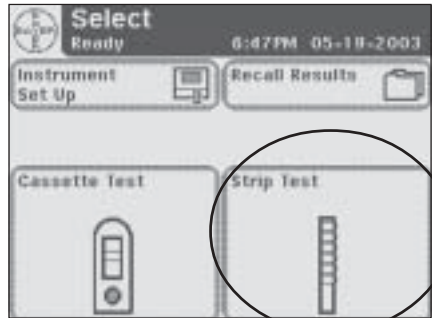
# 4 Testing
*Quick Tests*

The next screen that appears is another ***Prepare Test***. This screen prompts you through the steps to prepare the test strip.



```
Prepare Test
1. Dip test strip in sample
2. Remove excess
3. Blot strip
4. Place on test table

      00:06
```

A timer displays how much time you have remaining to complete the steps.

You have 8 seconds to complete the following four steps:

**1** Dip the reagent strip into the urine sample, wetting all pads. Immediately remove the strip from the urine.

**2** Drag the edge of the strip against the side of the sample container as you remove it.

**3** Blot by touching the edge of the strip to the paper towel to remove excess urine.

⚠ **Do not lay the pads on the paper towel or cover the pads by the paper towel.**



**4** Place the reagent strip in the channel of the table with the test pads facing up. Slide strip to end of the channel.

At the end of the 8 second countdown, the test table and strip will automatically be pulled into the analyzer.



⚠ **Do not push or pull the test table.**

✏ *The Clinitek Status® analyzer will perform an automatic calibration each time a test is run.*

⚠ **Be sure not to move or bump the table while the instrument is calibrating.**
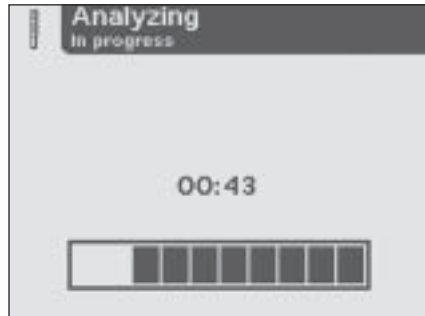
# 4 Testing
*Quick Tests*

The **Analyzing** screen will be displayed when the calibration has been completed and the analysis of the strip has begun.

A timer will count down the time remaining in analyzing the strip results.

> **Analyzing**
> In progress
>
> 00:43

If the analyzer has been set up to automatically print the results, then the **Printing** screen will be displayed until the print out has been completed (otherwise the **Results** screen will appear).

The date, time and test sequence number will be printed along with the test results. "Not Entered" will be printed next to Color and Clarity.

If the results are positive, an asterisk* will appear next to the results (if "mark positive results" was selected in Instrument Set Up).

```
Bayer Diagnostics 2003
Clinitek Status®

Patient:
          _____


Multistix® 10 SG
Test date      05-23-2003
Time              11:36AM
Operator      _____
Test number          0010
Color         Not Entered
Clarity       Not Entered

 GLU Negative
 BIL Negative
 KET Negative
 SG  1.025
 BLO Trace-intact
 pH  5.0
 PRO Negative
 URO 0.2 mg/dL
 NIT Negative
 LEU Negative

--------------------------
```
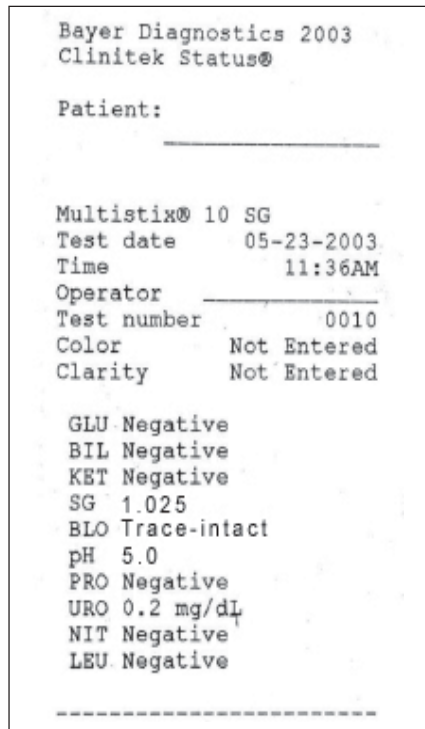
# 4 Testing
*Quick Tests*

The next screen displayed is the **Results** screen. The first page of the test results are displayed on the screen and the test table and strip are automatically pushed out of the analyzer.

To view the remaining test results, touch **More** on the screen.

If the analyzer has not been set up to automatically print the test results, touch **Print** to have the results printed.

The results will automatically be sent to the connected PC if this option is set up in the analyzer.
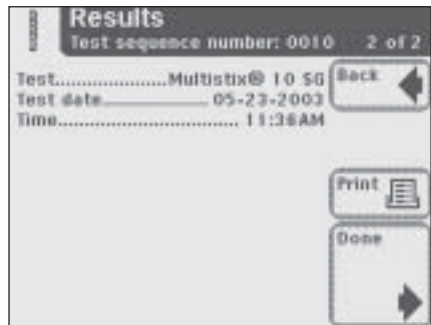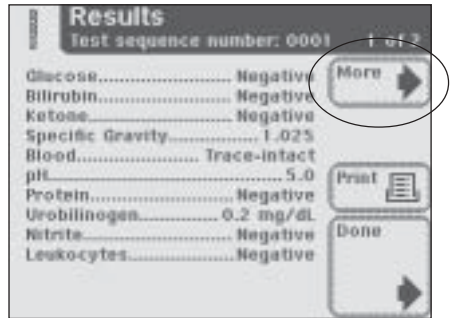
> ✎ *If you require further instruction regarding how to set up the analyzer so the results are printed or sent to a computer automatically see Section 5, Instrument Set Up.*

From the test table, remove the used urinalysis strip and dispose of it according to your standard laboratory procedures. Wipe the table insert, if necessary.

Report the results to a laboratory supervisor or physician.

Touch **Done** to complete the test and return to main **Select** screen.

> ✎ *The results will be displayed on the screen for 2 minutes. After this time elapses, the display will return to main **Select** menu.*

**Results**
Test sequence number: 0001    1 of 2

| | |
|---|---|
| Glucose...................... Negative | More ➤ |
| Bilirubin....................... Negative | |
| Ketone........................ Negative | |
| Specific Gravity.............. 1.025 | |
| Blood...................... Trace-intact | |
| pH.................................... 5.0 | Print 🖶 |
| Protein......................... Negative | |
| Urobilinogen............... 0.2 mg/dL | |
| Nitrite.......................... Negative | Done |
| Leukocytes................. Negative | ➤ |

**Results**
Test sequence number: 0010    2 of 2

| | |
|---|---|
| Test...................Multistix® 10 SG | Back ◄ |
| Test date.............. 05-23-2003 | |
| Time............................... 11:36AM | |
| | Print 🖶 |
| | Done ➤ |

# 4 Testing
*Quick Tests*

## Cassette Test

⚠️ **BIOHAZARD** Wear personal protective equipment. Use universal precautions. Refer to *Appendix H* for recommended precautions when working with biohazardous materials.

Testing is started from the main *Select* screen.

✏️ *Please refer to the Clinitest® hCG cassette test package insert for more information regarding use and storage of test cassettes.*

⚠️ **Bring the test cassette and patient sample to room temperature 20°C to 30°C (68°F to 86°F) prior to testing.**

Touch **Cassette Test** to conduct the test.

The next screen that appears is *Test Type*. Touch the **Clinitest hCG cassette** button.

The next screen that appears is *Prepare Test* screen.

✏️ *If you would like the steps for cassette testing to be shown on the screen then touch* **Help**.
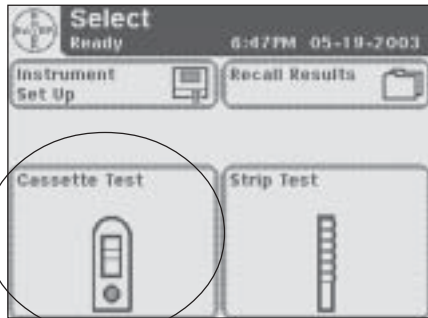
# 4 Testing
*Quick Tests*

Make sure the test table insert is in position for a cassette test.



Remove the test cassette from the foil package and place the cassette on the test table.
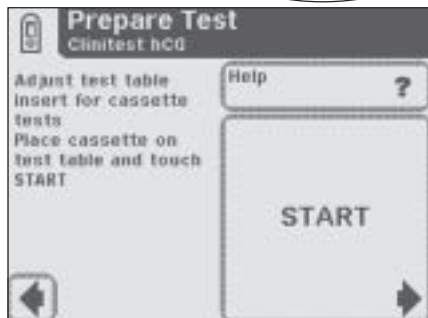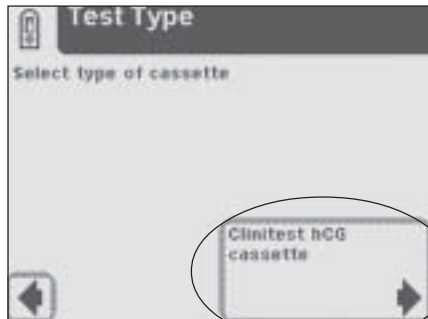
⚠ **Once you touch the START button you have 8 seconds to draw the urine sample into the pipette and add the urine sample into the well on the cassette.**



Touch **START** button.

The next screen that appears is another *Prepare Test*. This screen prompts you through the steps to prepare the cassette test.

A timer displays how much time you have remaining to complete the steps.



Prepare Test
Clinitest hCG

1. Draw sample into pipette
2. Add sample to sample well

00:02
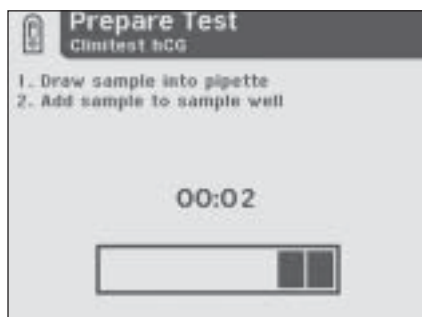
# 4 Testing
*Quick Tests*

You have 8 seconds to complete
the following two steps:

**1** Draw the urine sample to the
line marked on the pipette
(approximately 0.2 mL).



**2** Add entire contents of the
pipette into the sample well of the
test cassette.



At the end of the 8 second
countdown, the test table and
cassette will automatically be pulled
into the instrument.

⚠ **Do not push or pull the test
table**.

✏️ *The Clinitek Status analyzer will perform an automatic calibration each time a test is run.*

⚠️ **Be sure not to move or bump the table while the instrument is calibrating.**

✏️ *The **Analyzing** screen will be displayed when the calibration has been completed and the analysis of the cassette has begun.*



A timer will count down the time remaining in analyzing the cassette results.
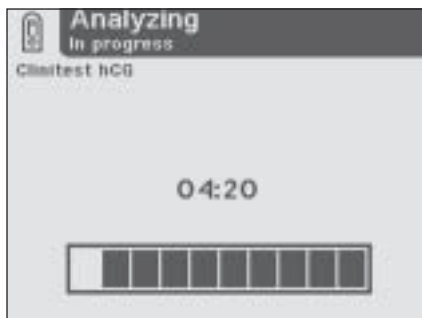


✏️ *The Clinitest hCG test results are either negative, positive or borderline. The analyzer takes approximately 5 minutes to confirm a negative result. If the result is a clear positive, the analyzer will report it sooner. If the result is borderline, then you should retest, with a new sample, in 48 to 72 hours. Please refer to the Clinitest hCG cassette test package insert for complete instructions for use.*

# 4 Testing
*Quick Tests*

If the analyzer has been set up to automatically print the results, the *Printing* screen will be displayed until the print out has been completed (otherwise the *Results* screen will appear).

The date, time and test sequence number will be printed along with the test results.

The next screen displayed is the *Results* screen. The test results are displayed on the screen and the test table and cassette are pushed out of the analyzer.

The results will be printed automatically if this option is set up in the analyzer. If not, touch **Print** to print the results on the analyzer's printer.

The results will automatically be sent to the connected PC if this option is set up in the analyzer.

> ✎ *If you require further instruction regarding how to set up the analyzer so results are automatically printed or sent to a computer see Section 5, Instrument Set Up.*

Remove the used cassette and dispose of it according to your standard laboratory procedures.

Report the results to a laboratory supervisor or physician.

Touch **Done** to complete the test and return to main *Select* screen.

```
Bayer Diagnostics 2003
Clinitek Status®

Patient:
              _____


Clinitest hCG
Test date      05-23-2003
Time               5:40PM
Operator      _____
Test number          0683

 hCG Negative
```

✎ *If the result is positive, an asterisk\* will appear next to the result (if "mark positive results" was selected in Instrument Set Up).*



Results
Test sequence number: 0683

Clinitest® hCG............Negative

Test date................05-23-2003
Time.....................5:40PM

Print

Done
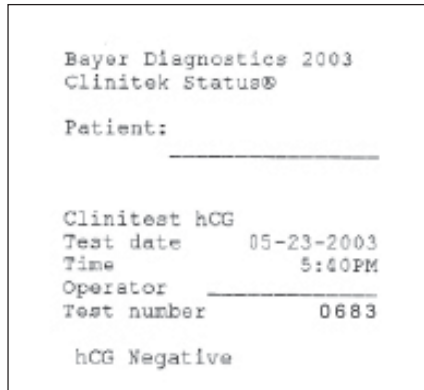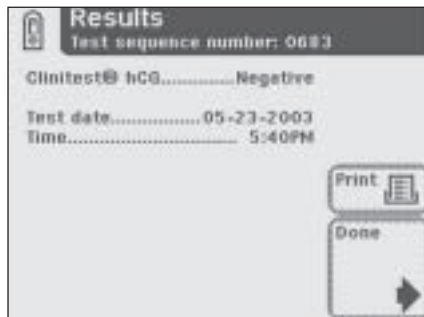
✎ *The result will be displayed on the screen for 2 minutes. After this time elapses, the display will return to main Select menu.*

# 4 Testing
*Full Tests*

## Full Tests

### Urinalysis Strip Test

**BIOHAZARD** Wear personal protective equipment. Use universal precautions. Refer to *Appendix H* for recommended precautions when working with biohazardous materials.

A Full Strip Test allows you the option to enter an Operator ID, Patient Name and/or Patient ID prior to inserting a strip.

The procedures to enter the Operator and Patient data are presented in this section.

The strip testing process is identical to a Quick Strip Test.

*If you require further instruction regarding the procedures required for running a Bayer urinalysis strip test see Section 4, Quick Tests.*

Testing is started from the main *Select* screen.

Touch **Strip Test** to conduct a Bayer urinalysis strip test.
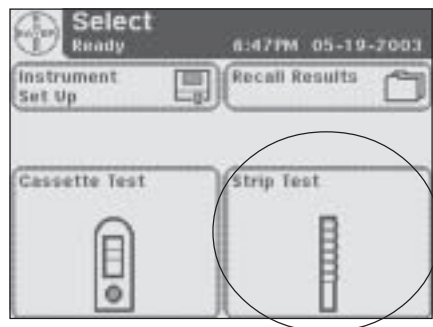
# 4 Testing
*Full Tests*

The next screen that appears is *Operator ID*.



There are two options under Operator ID: **Last Operator** or **Enter New Operator ID.**

## Option 1: Last Operator
If this option is enabled, the last operator that entered his/her ID will be displayed on the screen in the lower right side of the box. If you are this operator, then touch the **Last Operator** button to proceed.

## Option 2: Enter New Operator ID
In order to enter the information for a new operator, touch **Enter New Operator ID** button. The next screen that is displayed is *Enter Operator ID*.



Use the keyboards to enter Operator ID using a maximum of 13 characters. Touch **Enter** when you have finished entering the ID and to move to the next screen.

*If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.*

# 4 Testing
*Full Tests*

The next screen displayed is *Patient Information.*



There are two options under Patient Information: **Recall Patient** or **Enter New Patient**.

## Option 1: Recall Patient

In order to look up previous patients, touch **Recall Patient**.

If previous patient identification has been entered, a list of up to 200 patient results will appear on the screen. Use the up and down arrow buttons to scroll through the list of patients. The most recently performed test will be shown at the top. Once the patient is highlighted, touch **Select** button.
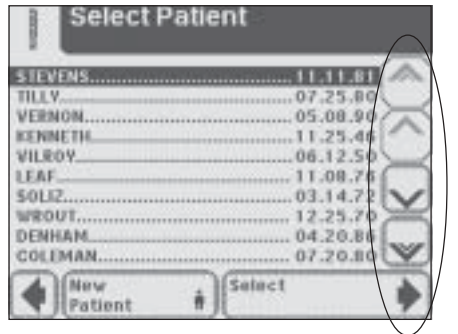


The next screen will be *Prepare Test*.

> *A total of 200 patient tests can be stored in the analyzer. The tests are listed in chronological order. When the limit of 200 has been reached, the oldest test will be deleted from the analyzer. Deleted information cannot be retrieved from the analyzer.*

## Option 2: Enter New Patient

In order to enter the information for a new patient, touch **Enter New Patient** button. The next screen displayed is *Enter Patient Name*.

Use the keyboards to enter Patient Name using a maximum of 20 characters. Touch **Enter** when you have finished entering the patient's name and to proceed to the next screen.
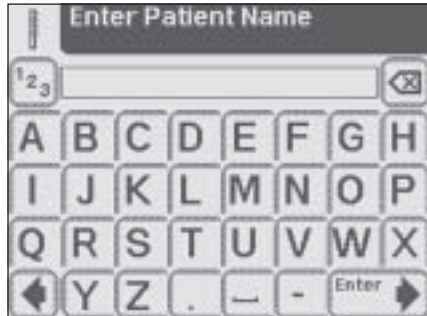
*If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.*

# 4 Testing
*Full Tests*

The next screen displayed is *Patient Identification*. Use the keyboards to enter Patient Identification using a maximum of 13 characters. Touch **Enter** when you have finished entering the patient's ID and to proceed to the next screen.
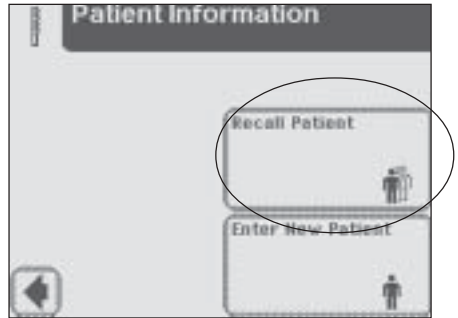
> *If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.*
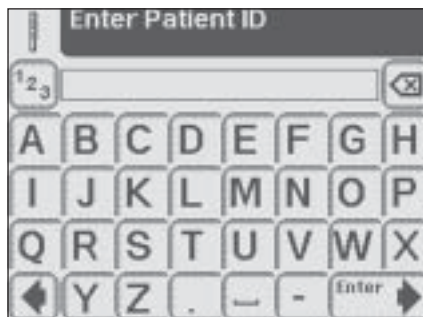
# 4 Testing
*Full Tests*

The next screen that appears is
***Prepare Test***.

> *If you require further instruction
> regarding the procedures for running
> a Bayer urinalysis strip test see
> Section 4, Quick Tests.*

While the strip is being analyzed, a
***Select Appearance*** screen will be
displayed. The urine sample must
be visually observed and then the
appropriate color and clarity must
be selected.

If the urine sample is yellow and
clear, touch the **Yellow and Clear**
button.

If the urine sample is not yellow
and clear, touch the **Other** button
for more choices.

If you touched the **Other** button,
then select the appropriate color by
touching the circle button that
corresponds to the correct
description.
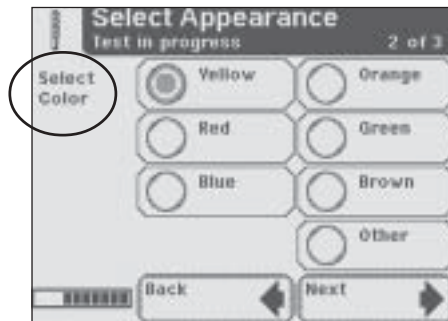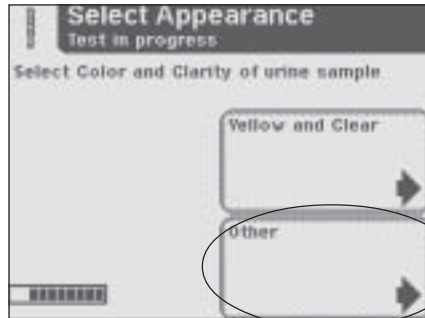
# 4 Testing
*Full Tests*

Select the clarity by touching the circle that corresponds to the correct description. Then touch **Next**.

There is a time indicator on the *Select Appearance* screen that is counting down the time remaining in the analysis of the strip.

After color and clarity have been entered the next screen displayed will either be:

> *Analyzing* – if the strip is still being analyzed
>
> *Results* – if analyzing the strip has been completed
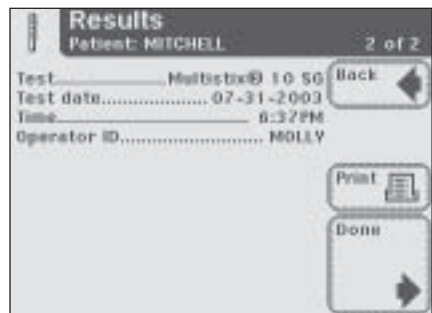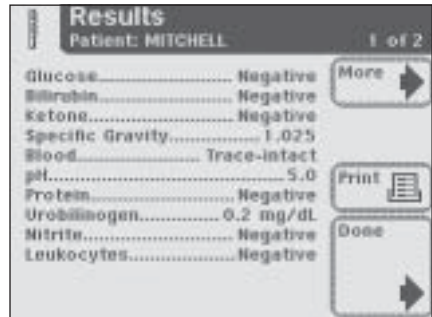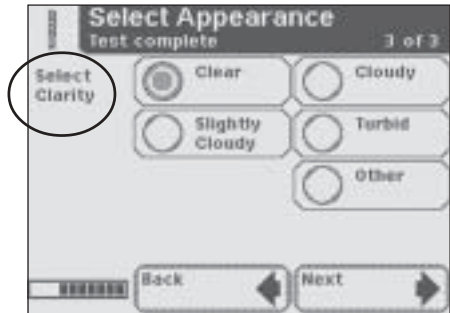
# 4 Testing
*Full Tests*

The test results displayed on the screen and the printout will include the following information:

- Patient Name, ID or both
- Type of strip used
- Test date
- Time
- Operator
- Test Number
- Color
- Clarity
- Results

```
Bayer Diagnostics 2003
Clinitek Status®

Patient:
                 MITCHELL


Multistix® 10 SG
Test date        07-31-2003
Time                 6:37 PM
Operator               MOLLY
Test number             0015
Color                 Yellow
Clarity                Clear

 GLU Negative
 BIL Negative
 KET Negative
 SG  1.025
 BLO Trace-intact
 pH  5.0
 PRO Negative
 URO 0.2 mg/dL
 NIT Negative
 LEU Negative

--------------------------
```

*If the results are positive, an asterisk\* will appear next to the results (if "mark positive results" was selected in Instrument Set Up).*

# 4 Testing
*Full Tests*

## Cassette Test

⚠ **BIOHAZARD** Wear personal protective equipment. Use universal precautions. Refer to *Appendix H* for recommended precautions when working with biohazardous materials.

A Full Cassette Test allows you the option to enter an Operator ID, Patient Name and/or Patient ID prior to inserting a cassette.

The procedures to enter the Operator and Patient data are presented in this section.

The cassette testing process is identical to a Quick Cassette Test.

✎ *If you require further instruction regarding the procedures for running a Bayer Clinitest immunoassay test see Section 4, Quick Tests.*

Testing is started from the main *Select* screen.

Touch **Cassette Test** to conduct an hCG pregnancy test.

The next screen that appears is *Operator ID*.

There are two options under Operator ID: **Last Operator** or **Enter New Operator ID.**
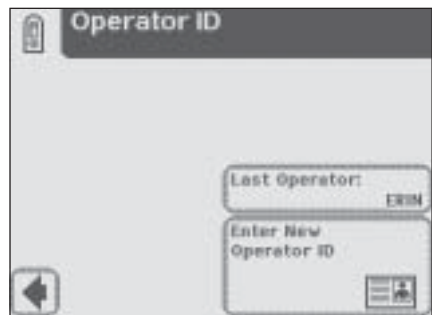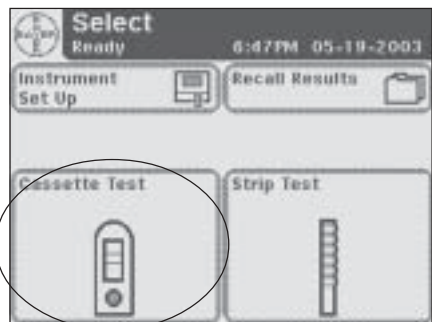
# 4 Testing
*Full Tests*

**Option 1: Last Operator**
If this option is enabled, the last operator that entered his/her ID will be displayed on the screen in the lower right side of the box. If you are this operator, then touch the **Last Operator** button to proceed.

**Option 2: Enter New Operator ID**
In order to enter the information for a new operator, touch **Enter New Operator ID** button. The next screen that is displayed is *Enter Operator ID*.

Use the keyboards to enter Operator ID using a maximum of 13 characters. Touch **Enter** when you have finished entering the ID and to move to the next screen.

> *If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.*

The next screen displayed is *Patient Information.*

There are two options under Patient Information: **Recall Patient** or **Enter New Patient**.
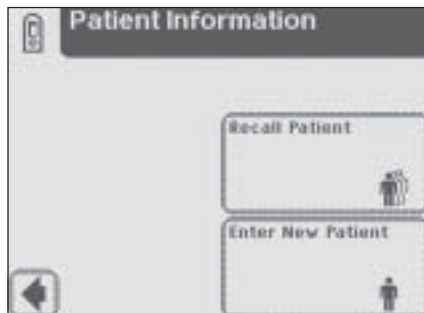
# 4 Testing
*Full Tests*

## Option 1: Recall Patient

In order to look up previous patients, touch **Recall Patient**.



If the previous patient identification has been entered, a list of up to 200 patients will appear on the screen. Use the up and down arrow buttons to scroll through the list of patients. The most recently performed test will be shown at the top. Once the patient is highlighted, touch the **Select** button. The next screen will be *Test Type*.
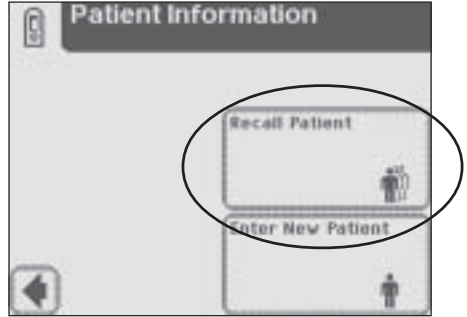
*A total of 200 patient tests can be stored in the analyzer. The tests are listed in chronological order. When the limit of 200 has been reached, the oldest test will be deleted from the analyzer. Deleted information cannot be retrieved from the analyzer.*
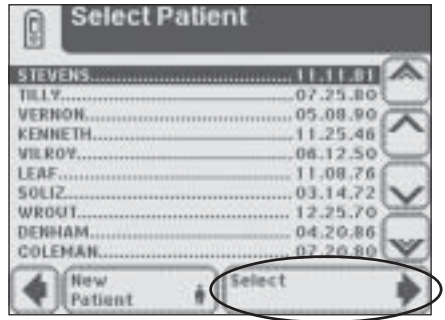
# 4 Testing
*Full Tests*

## Option 2: Enter New Patient

In order to enter the information for a new patient, touch the **Enter New Patient** button. The next screen displayed is *Enter Patient Name*.
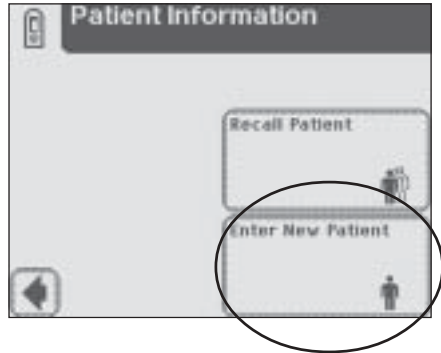


Use the keyboards to enter Patient Name using a maximum of 20 characters. Touch **Enter** when you have finished entering the patient's name and to move to the next screen.

> *If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.*
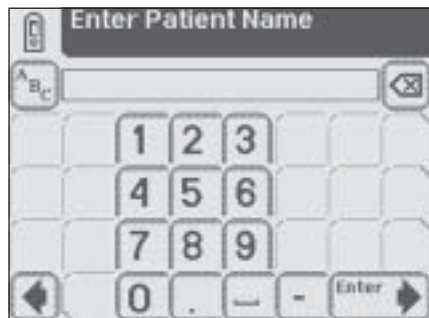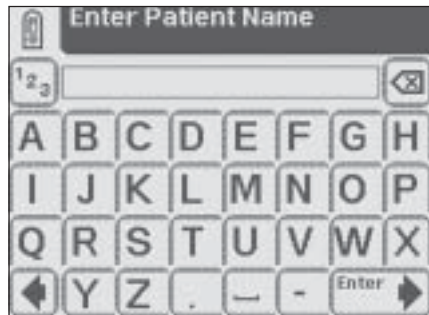
# 4 Testing
*Full Tests*

The next screen displayed is **Enter Patient ID**. Use the keyboards to enter Patient Identification using a maximum of 13 characters. Touch **Enter** when you have finished entering the patient's ID and are ready to proceed to the next screen.



> If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.
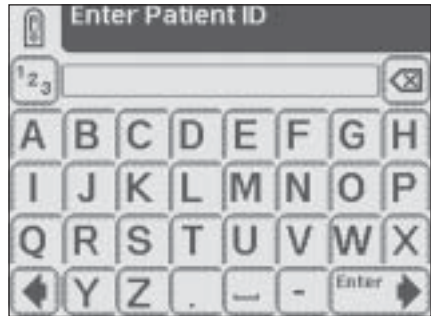
# 4 Testing
*Full Tests*

The next screen that appears is
***Test Type***.

✐ *If you require further instruction
regarding the procedures for running a
Clinitest hCG cassette test see
Section 4, Quick Tests.*
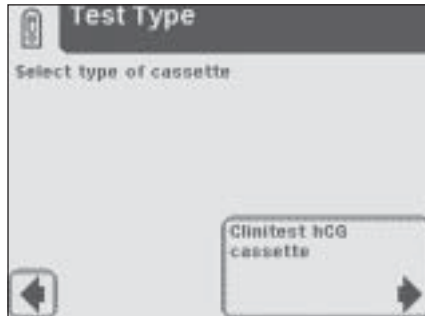


The test results displayed on the
screen and the printout will include
the following information:
- Patient Name, ID or both
- Type of Clinitest cassette test
  Test date
- Time
- Operator
- Test Number
- Result
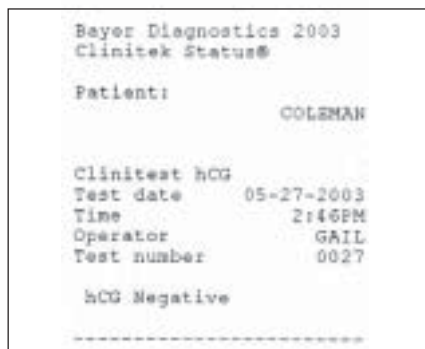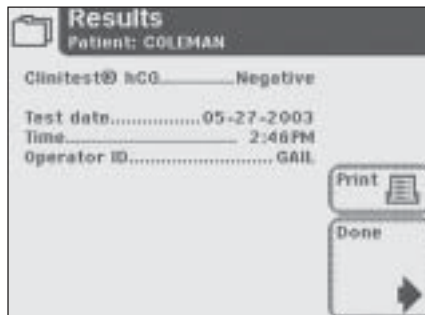




✐ *If the result is positive, an
asterisk\* will appear next to the result
(if "mark positive results" was selected
in Instrument Set Up).*

# 5 Instrument Set Up
*Instrument Set Up*

## Instrument Set Up

Your Clinitek Status® analyzer allows you to change settings to suit your workplace requirements.

> ✏️ *If no customizing is desired, the analyzer will automatically be programmed with default settings (to view default settings please see Appendix D: Instrument Default Settings).*

Touch **Instrument Set Up** in order to initiate changing the settings.

If a password has been set, the *Enter Password* screen will be displayed. Enter the password into the data entry box. The characters you enter will be displayed as asterisks.

Touch **Enter** to proceed to a list of settings.

**Settings**
Use the up and down arrows to scroll through the *Choose Settings* screen.

Touch **Select** when you have highlighted the setting you want to change.

Touch **Done** to return to the main *Select* screen.
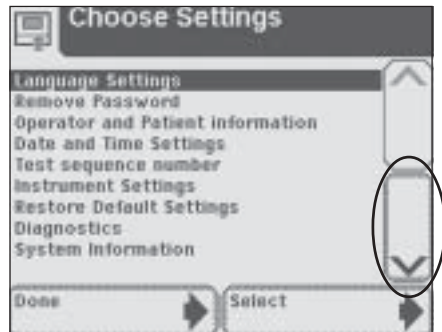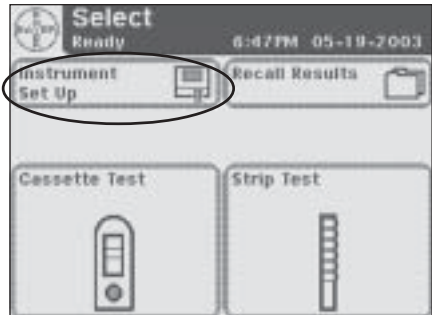
## Language Settings

Use the up and down arrows to scroll through the list of languages. Touch **Select** when you have highlighted the desired language.
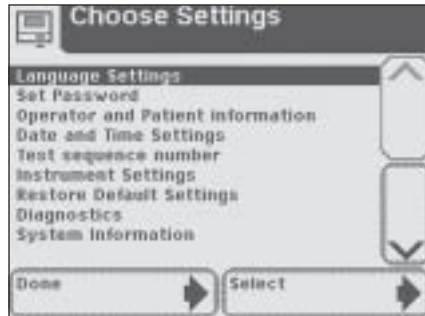
Before changing the language an alert screen will be displayed requesting you to confirm your decision.
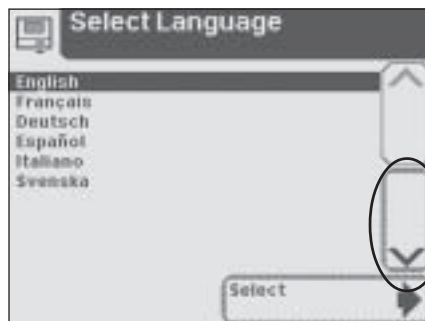
Touch **No** to continue with same language and retain current settings. The display will return to *Choose Settings*.
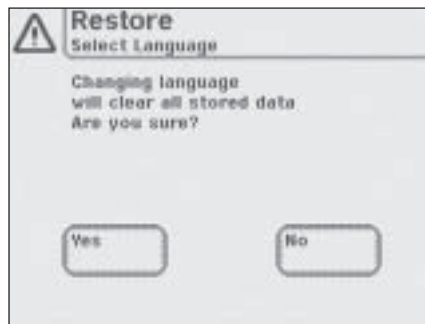
Touch **Yes** to change the language.

⚠ **Changing the language will…**
  ▪ **delete all results from the memory.**
  ▪ **change the instrument settings to the defaults for the new language (default settings are listed in Appendix D: Instrument Default Settings).**

## Password



> When a password has been set, no changes can be made to the **Instrument Set Up** until the password has been entered.

### Set Password
Enter a password into the data entry box using the alphabetic and/or numeric keyboards (maximum 12 characters).

> Keep a record of the password to be sure to have access to **Instrument Set Up** when required.



Touch **Enter** to confirm the password and return to *Choose Settings*.

Touch **Done** to return to main *Select* screen.

### Remove Password
Once a password has been entered the option will change from **Set Password** to **Remove Password**.



Highlight the **Remove Password** option and touch **Select**. The option displayed will change to **Set Password** and a password will no longer be needed to access **Instrument Set Up.**

Touch **Done** to return to the *Select* Menu.
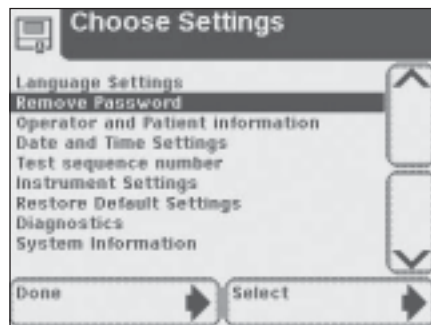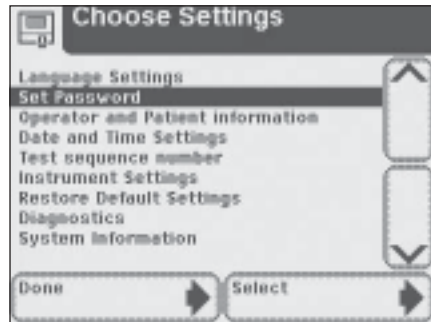
# 5 Instrument Set Up
*Operator and Patient Information*

## Operator and Patient Information

Selecting this option will allow you to choose display options for data entry.

The *Input Settings* screen allows you to select 1 of 3 test sequences.

**Quick Test**
A test without any operator or patient information required. The test will be identified by a sequential test number when the results are displayed or printed.

**Full Test**
The operator will be prompted to enter the following data during testing:

- Operator Identification
- Patient's Name
- Patient Identification
- Sample Appearance (Color and Clarity) of urine sample, when testing with a urinalysis strip.

**Custom Set Up**
This allows you to customize the data to be entered when conducting a test.
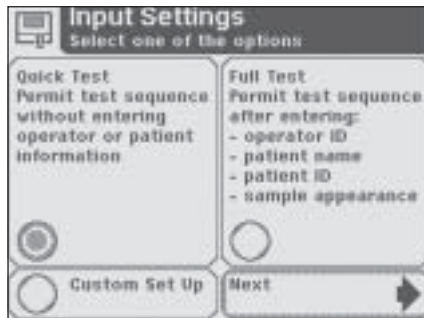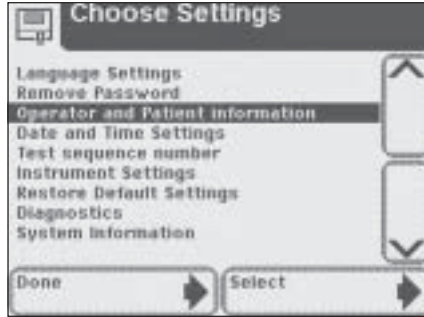
On the *Input Settings* screen, touch a round button in the box of the preferred test sequence. Then touch **Next** for test sequence confirmation.



Touch **Done** on the *Input Settings* screen to return to the *Choose Settings* screen.
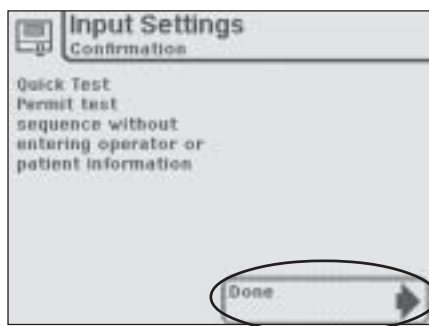
# 5 Instrument Set Up
*Operator and Patient Information*

### *Custom Settings*
Touch the round button in the **Custom Set Up** box to customize selections for data entry. Touch **Next**.

The next 5 screens present choices for customizing your testing.

Choose settings by touching and highlighting a round button for each category.

Proceed through all 5 screens by touching **Next** at the bottom of each screen.

Screen 1 of 5
**Operator ID** – allows you to choose whether Operator ID will be required for running a test – **Enabled** (on) or **Disabled** (off).

**Keypad priority** – allows you to select either the **Numeric** or **Alphabetic** keyboard to be presented as the first keyboard during data entry.
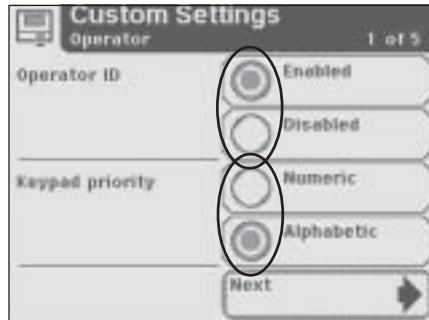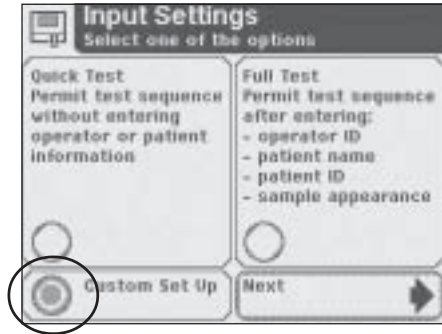
# 5 Instrument Set Up
*Operator and Patient Information*

<u>Screen 2 of 5</u>
**Patient Name** – allows you to choose whether patient name will be required for running a test – **Enabled** (on) or **Disabled** (off).

**Patient ID** – allows you to choose whether Patient ID will be required for running a test – **Enabled** (on) or **Disabled** (off).
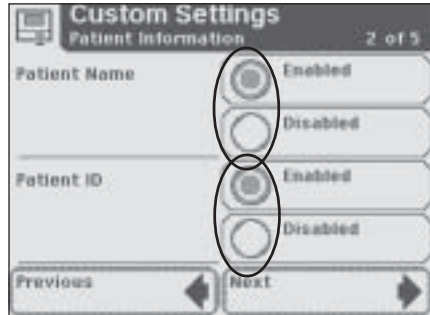
> *A total of 200 patient records can be stored in the analyzer. When the limit of 200 has been reached, the oldest test will be deleted from the analyzer. Deleted information cannot be retrieved from the analyzer. If Patient's Name and Patient ID are both disabled, a sequential test number will be shown with the test results.*

<u>Screen 3 of 5</u>
**Choose which to show in Results list** – allows you to choose whether **Patient Name** or **Patient ID** will be included in the list of results.

**Last Operator's ID displayed** – allows you to choose whether a "Select Last Operator" option is available to the user when you are prompted to enter an Operator ID during Strip or Cassette Testing – **Enabled** (on) or **Disabled** (off).
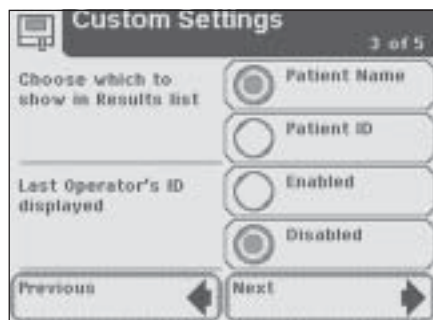
Screen 4 of 5

**Choose which to record during a strip test** – allows you to select which sample details you would like to be recorded during a strip test – **Color and Clarity, Color only, Clarity only** or **None** (no sample information).
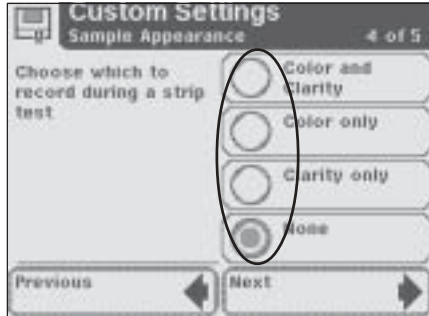
Screen 5 of 5

**Custom Field** – allows you to name the custom field in order to customize data entry.

To name the custom field, touch the **Enter Custom Field** box.
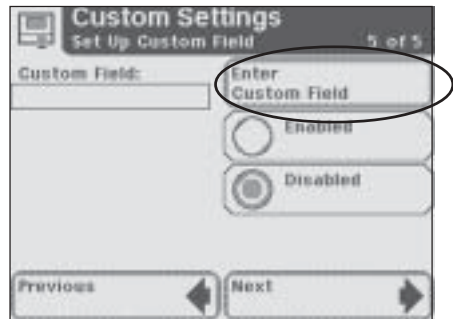
The next screen displayed is *Enter Custom Field*. Use the keyboards to enter a custom field (e.g., Physician Name). Touch **Enter** to return to the *Custom Settings* screen.

> *If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.*

# 5 Instrument Set Up
*Operator and Patient Information*

Touch the round button next to **Enabled** (on) to highlight and activate this custom setting.

Touch the round button next to **Disabled** (off) to deactivate the custom setting.

Touch **Previous** to scroll back through custom setting screens to review.

Touch **Next** to proceed to the *Input Settings* screen which will provide a list of the selections made in **Custom Set Up**.

Touch **Done** to confirm and return to the *Choose Settings* screen.
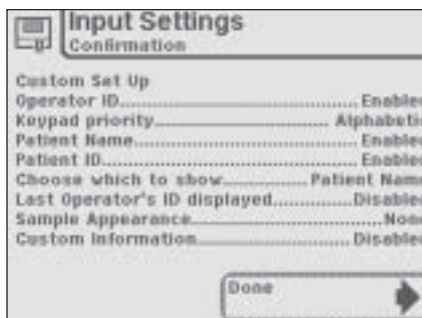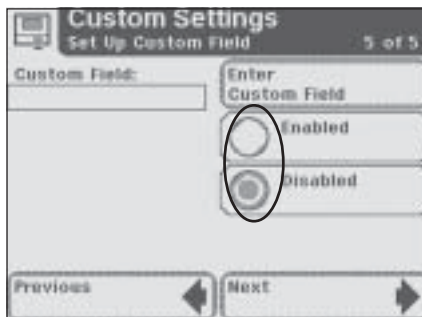
# 5 Instrument Set Up
*Date and Time Settings*

## Date and Time Settings

The date and time are displayed on the *Select* screen and are recorded with test results.

The format of the date and time are displayed along with specific date and time values.



If the date and time values are incorrect, use the up and down arrow buttons to adjust the date and time to the correct values. Touch **AM** or **PM** if you are in the 12-hour time format. Touch **Set** to confirm your choices and move to the next screen.

If the format is not correct for your workplace, for example, you prefer DD-MM-YY to MM-DD-YY or 24-hour clock to 12-hour clock, touch **Choose Format.**
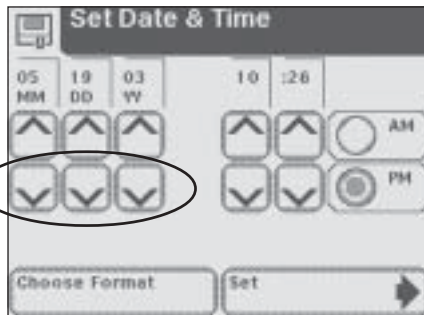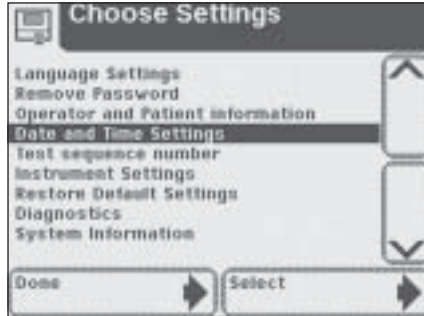


The next screen displayed is *Choose Format*. Touch the round button that corresponds to your choice of a date format and a time format. Touch **Done** to return to *Set Date & Time.*

If the date and time are in the format which you need, select **Done**.
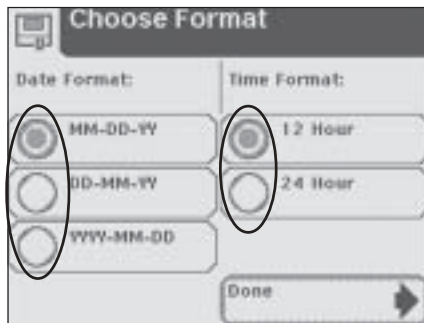
# 5 Instrument Set Up
*Date and Time Settings*

*The **AM** and **PM** selections will not be available if the time is in the 24-hour format.*

The **Set Date & Time** display will show the date and time in the formats selected. Select **Set** to confirm your choices and return to the **Choose Settings** screen.
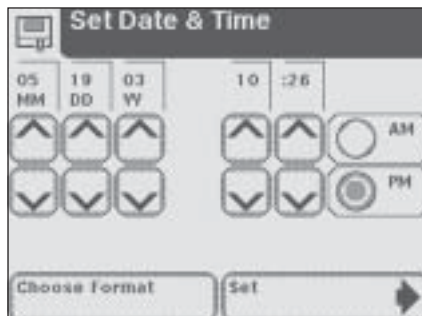
# 5 Instrument Set Up
*Test Sequence Number*

## Test Sequence Number

The test sequence numbers run from 0001 to 9999 and can be reset. The screen shows the next test number.



Touch the **Reset to 0001** round button if you would like to reset the numbers to start at 0001 for the next test.

Touch **Done** to confirm the reset or to leave the screen if you have not selected the option to reset the number. You will return to the *Choose Settings* screen.
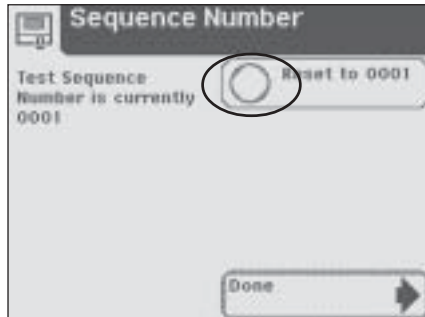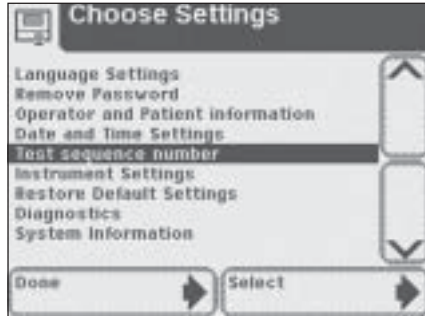
## Instrument Settings

This section has a series of screens which control the way in which the Clinitek Status analyzer displays information and operates.



There are 5 Instrument Setting items.
- Results Format
- System Settings
- Display Contrast
- Connectivity
- Select Urinalysis Test

Use the up and down arrows to highlight a setting item and touch **Select.**



### Results Format
This allows you to select the format in which you would like the results to be displayed and printed.

### *Choose Format*
Screen 1 of 2
**Units Selection** – allows you to select the format in which you would like results by touching the round button next to the appropriate type of format.
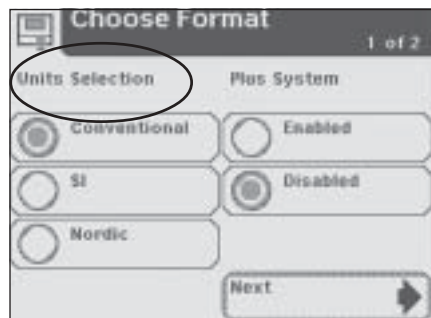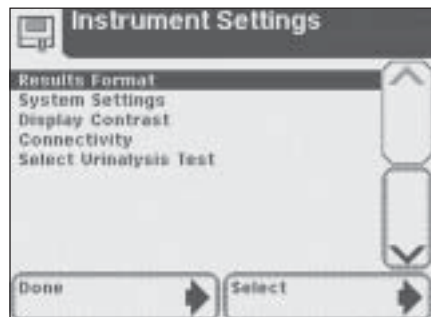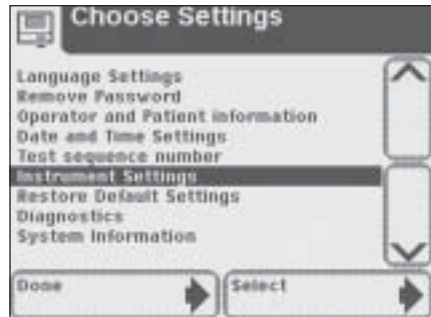
**Plus System** – select **Enabled** (on) if you wish to have results shown in the Plus System. You will also see in Appendix B that results can be recorded in the Plus System (which uses "+" symbols) instead of clinical units such as mg/dL (mmol/L). In some languages there is no difference between the normal system and the Plus System.
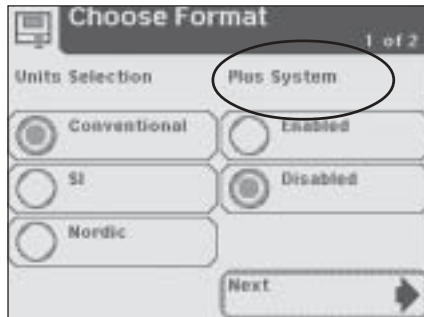


Screen 2 of 2
**Mark Positive Results** – allows you to choose whether positive results should be marked with an asterisk (see Appendix B for results to be shown as positive).

Touch the round button next to **Yes** to mark and record positive results. These will be marked on the display, on a printout and when the data is transferred to a host computer.
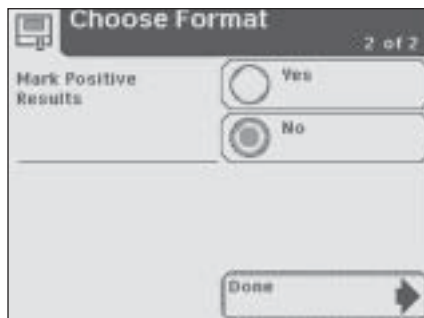
Touch **No** and positive results will not be marked.

Touch **Done** to enter your choice and return to *Instrument Settings*.

# 5 Instrument Set Up
*Instrument Settings*

### System Settings
This allows selections regarding the printer, power and sound.

### *System Settings*
Screen 1 of 2
**Printer** – allows you to select the preferred printing option by touching the round button.

> **Automatic** – Results for each test will be printed automatically when the test is complete.

> **Manual** – Test results will not be printed automatically. They can be perinted by touching the **Print** selection area on the *Results* screen.

> **Off** – Test results will not be printed.

**Power Save** – allows you to enable and disable this feature. If the instrument is powered from an electrical outlet and is not used for 5 minutes, you may choose to have the test table retract and the instrument power down. When it is powered by batteries, Power Save is always enabled and it will power down after 3 minutes of non-use. Touch the **Enabled** (on) to activate or **Disabled** (off) if the Power Save mode is not desired.
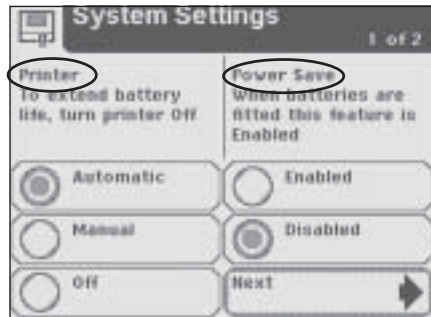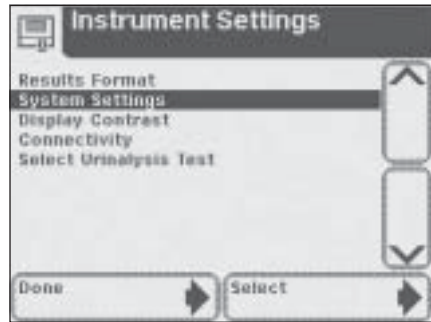
Screen 2 of 2

**Sound** – allows you to adjust the sound by highlighting and selecting a level.

> **Sound on** – The instrument will use a range of audible tones.

> **Sound off** – No audible tones will be made by the instrument.

> **Key clicks only** – Audible clicks will be heard when the user touches an active button or key.
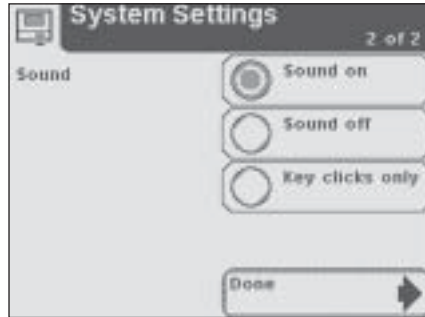
**Display Contrast**

This allows the contrast of the display to be increased or decreased to suit the work area in which it is being operated. Use the up and down arrows to sample the contrast settings and touch **Select** to set and return to the *Instrument Settings* screen.
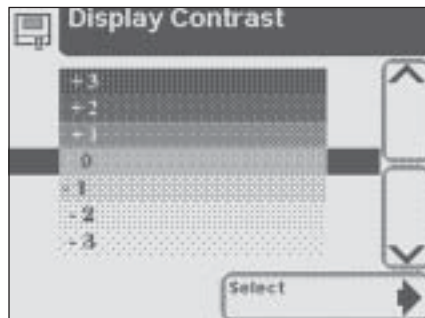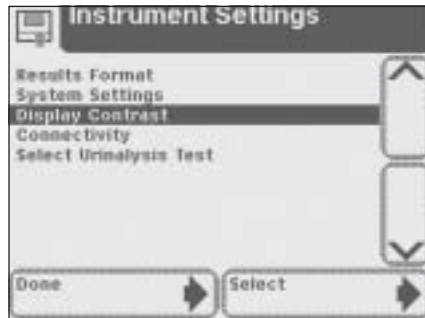
## Connectivity

This allows you to choose connectivity settings.
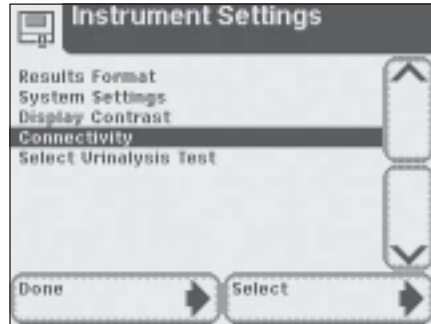


## Allow results to be sent to PC

This allows the instrument to transfer patient results to a host computer. If this function is not required, touch **Done** to return to *Instrument Settings* screen.

Touch the **Enabled** (on) round button to allow transfer of results to a computer. As each test is completed, the results will automatically be sent to the connected PC.
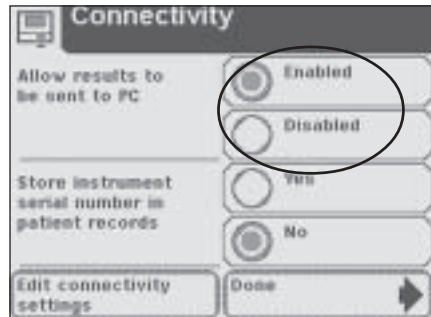
Touch the **Disabled** (off) round button if you do not wish to transfer results to a computer.

# 5 Instrument Set Up
*Instrument Settings*

**Store instrument serial number in patient records**
Touch round button of either **Yes** or **No** depending on whether you choose to include the serial number of your Clinitek Status analyzer as part of the patient results sent to the computer**.**

> *If you have enabled the upload capability, you will need to ensure that the connectivity settings are correct for the data transfer.*
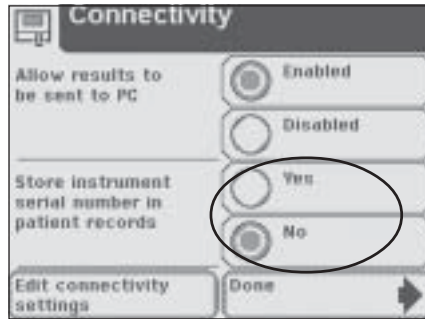
Touch **Edit Connectivity Settings** and a series of 3 screens for *Connectivity Settings* will allow you to edit the settings.
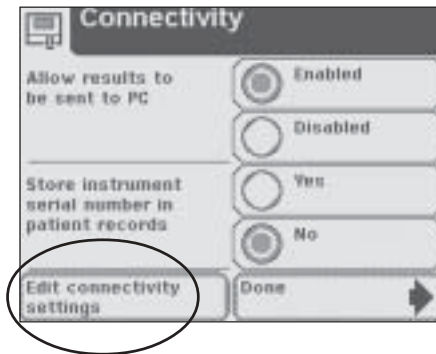
*Connectivity Settings*
<u>Screen 1 of 3</u>
**Baud rate** – Touch a round button to select the correct Baud rate and **Next** to move to the next screen.
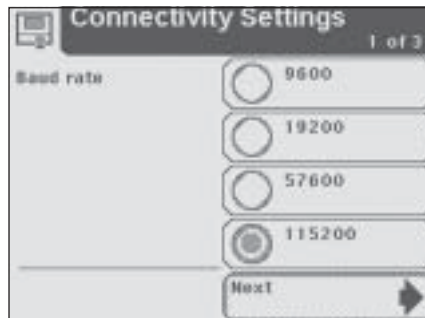
Screen 2 of 3

**Parity rate** – Touch a round button to select the correct Parity rate and **Next** to move to the next screen.
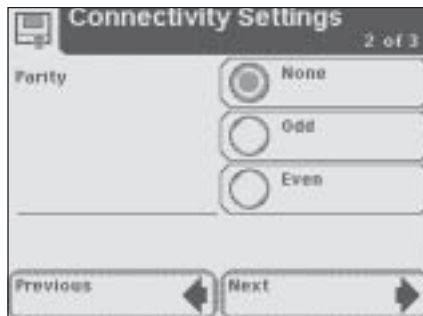


Screen 3 of 3

**Stop Bits** – Touch a round button to select the number of Stop Bits.
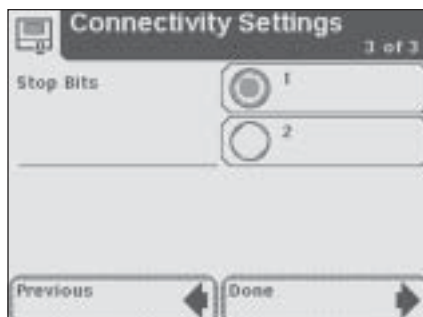


### Select Urinalysis Test

This displays a list of some of the Bayer urinalysis strips which can be used with the Clinitek Status analyzer.
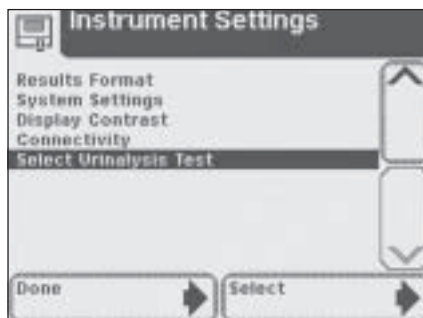
# 5 Instrument Set Up
*Instrument Settings*

Use the up and down arrows to scroll through the list until the type of strip you want to use is highlighted. Touch **Select** to confirm and return to the *Instrument Settings* screen.

> ⚠ **Do not use any reagent strip product other than what is shown on the display. Using the wrong Reagent Strip will give you incorrect results.**

> ✏ *Some strips do not appear on the list (e.g., Clinitek® Microalbumin). The analyzer will automatically identify them through the color ID band on the strip.*

> ✏ *You do not need to select a type of Clinitest® immunoassay cassette within **Instrument Set Up**.*
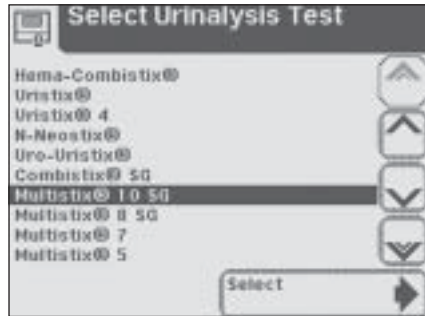
Touch **Done** repeatedly to return to the main *Select* screen.
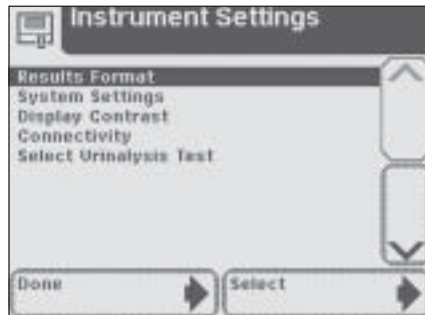
## Restore Default Settings

This option lists the analyzer's original settings.

Use the up and down arrows to view the default settings.
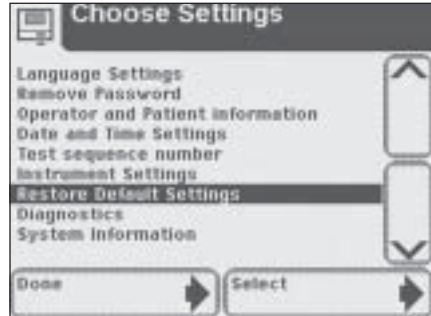
Touch **Restore** in order to return the analyzer to the settings listed.
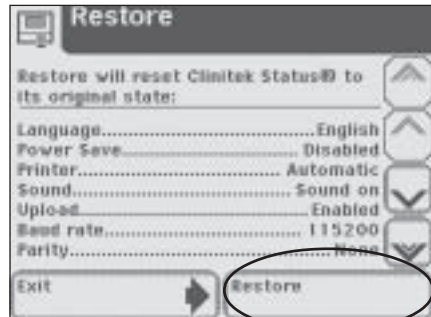
Touch **Yes** to confirm your decision or **No** to maintain the current settings of your analyzer. You will then return to the *Restore* screen. Select **Exit** to return to *Choose Settings*.

⚠ **When the original settings are restored, all results and patient data will be deleted from the memory.**

## Diagnostics

This option lists 7 diagnostic tests which can be conducted.

- Display
- Touch Screen
- Printer
- Test Table
- Light Source
- Electronics
- Check Cassette

⚠ **These diagnostics tests should only be conducted when instructed by a Bayer Customer Service representative. The representative will lead you through the test procedures (see Appendix A for Local Technical Support Providers and Distributors).**
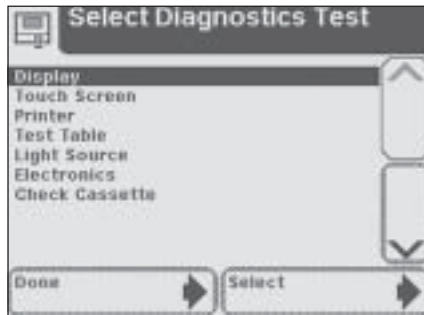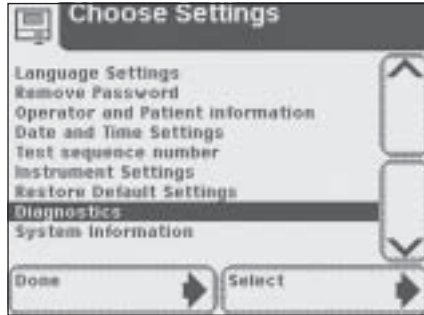
# 5 Instrument Set Up
*System Information*

## System Information

This screen has information about your analyzer.
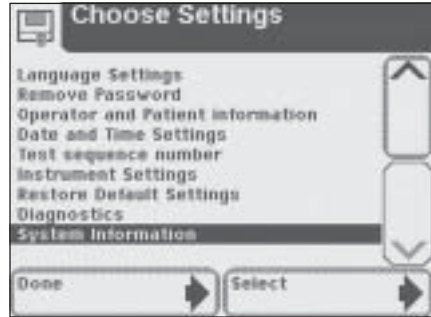
Touch **System Configuration** to view details of the current system configuration. This screen will show the current settings for all the items which can be changed within the **Input Settings** and **Instrument Settings** screens. Scroll through the list using the up and down arrows to view the details and print the information if required.
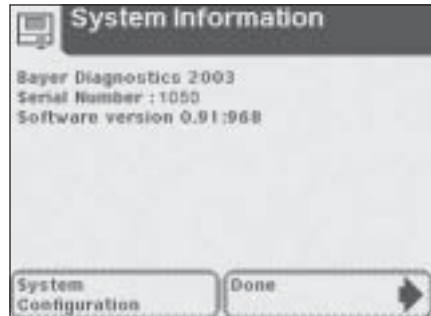
> *If the printer paper roll needs replacing, **Print** will be disabled and you will be able to select **Help** to view instructions on replacing the printer paper (if you require further instruction see page 1-5, Loading the Printer Paper or Label Roll).*

Select **Done** once to return to **System Information** screen and a second time to return to **Choose Settings** screen.
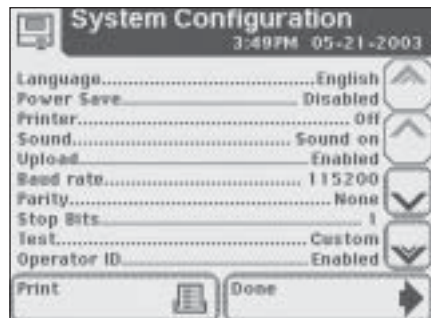
# 5 Instrument Set Up
*System Information*

This completes the settings and choices within **Instrument Set Up**. Touch **Done** to return to the main *Select* screen.
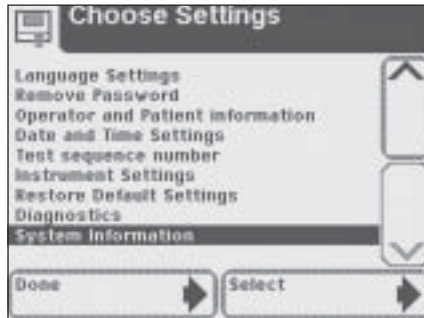
# 6 Recall Results
*Patient Results*

## Patient Results

In order to look up a patient's results, return to the main *Select* screen.



Touch **Recall Results** button.
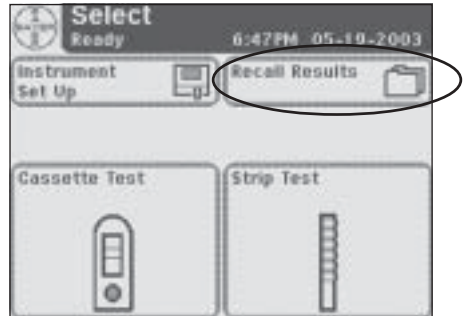
The next screen displayed is *Select Test Results*.



The test results are in chronological order. The most recent test result is displayed at the top of the screen and is highlighted.

Use the up and down arrow keys to scroll through the list of patient tests and highlight the patient you would like to recall.
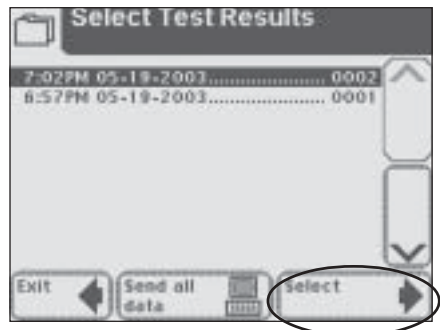
To view details of a patient result, touch the **Select** button.

The results will automatically be sent to the connected computer if this option is set up in the analyzer.

> *If you require further instruction regarding how to set up the analyzer so the results are automatically sent to a computer see Section 5, Instrument Set Up.*

# 6 Recall Results
*Patient Results*

The first page of the patient's results is displayed on the screen.

If more than one page of results exists for the patient, then the **More** button will be present on the screen.
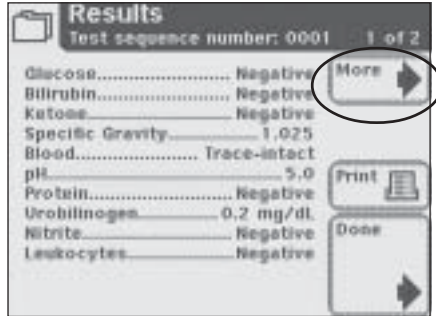
If you would like to print the results, touch the **Print** button. Any information that was entered in regard to the patient will be included on the printout.

When you are finished viewing the patient's results, touch **Done**.
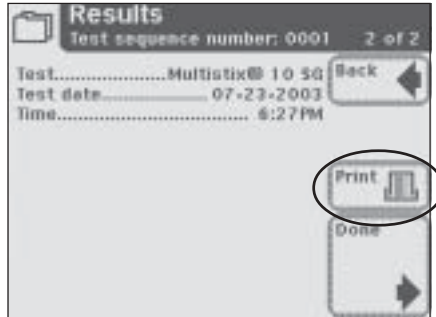
You will return to the *Select Test Results* screen. Press **Exit** to return to the main *Select* screen.
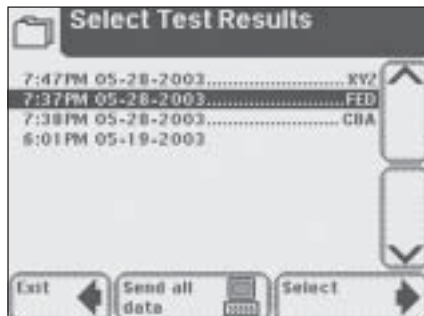
# 6 Recall Results
*Sending Data to a PC*

## Sending Data to a PC

✎ *To send data to a computer; if a computer has been connected to the analyzer, all results can be sent to the computer by touching the **Send all data** button.*
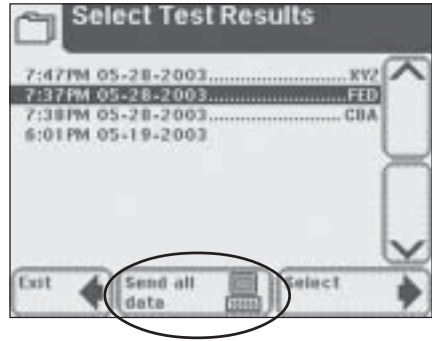
# 7 Troubleshooting

**General Information**
Your Clinitek Status® analyzer will operate properly if you follow the directions for using and cleaning the instrument.

**Error Messages**
Error messages will be displayed to help you when the Clinitek Status analyzer detects something which needs your attention. The format of this advisory information depends upon the importance of the problem and the mode in which the instrument is being used.

> *To correct an error, see the List of Errors and Advisory Messages located at the end of this section.*

**Errors which Disable the Instrument**
If the error is one which prevents the instrument from being used, all selection areas on the screen will be disabled. Taking the corrective action shown will remove the error alert screen and allow you to use the instrument.

**Other Errors**
There are certain errors which need to be corrected to enable testing of samples but do not prevent other instrument functions from being used. You will need to carry out the corrective action to enable testing.

**Advisory Messages**
Errors of less importance will be presented via a message on the main *Select* screen when this screen is next displayed. When you have taken corrective action, the message will be removed from the display. If more than one of this class of error occurs, clearing one message will enable the next to be displayed in order of importance to a user.

**Results Alert**
If an error occurs during testing and the test cannot continue because of the error, this will be presented via the *Results Alert* screen. This will provide details of the error and show that the test has been cancelled. The test table will be extended so that the urinalysis strip or Clinitest® cassette can be removed.

# 7 Troubleshooting

**Battery Power Icon**



The battery icon indicates the power level of the battery. Power can be reduced while testing continues, with an advisory message displayed on the main *Select* screen. If battery level falls too low to power the analyzer, all selection areas on the display will be disabled until the batteries are replaced (if you require detailed instructions regarding how to change the batteries see Section 9, Cleaning and Maintenance).

**Paper-out Icon**



A paper-out icon appears in the top of the title bar when the printer paper/label roll needs replacing. An advisory message will be displayed on the main *Select* screen. Replace with new paper or label roll as instructed in Section 1, Loading the Printer Paper or Label Roll.

**Dashes in Displays**
Dashes are displayed in the *Results* screens and on printouts when no text has been entered for a field enabled in **Instrument Set Up**.

Dashes may appear next to Color and Clarity on test result printouts. This occurs when the instrument is powered by batteries. Color and Clarity are selected in the **Instrument Set Up**, but no selections have been recorded on the *Select Appearance* screens before time-out.

The time-out on these screens is designed to ensure that battery life is preserved. The Color and Clarity description may be added to the printout in writing if needed.

**Irregular or Slow Movement of Test Table**
If movement of the test table is irregular or slow, this may be caused by:

a) heavy buildup of dried urine on the test table. Clean the test table and insert as described in Section 9, Periodic Cleaning of Test Table.

b) low battery power. Replace the batteries as described in Section 9, Cleaning and Maintenance.

# 7 Troubleshooting

**Calling for Assistance**

If your Clinitek Status analyzer is displaying corrective actions for a detected problem, please carry out the displayed instructions before calling for assistance. If this does not correct the problem or no instructions are displayed, contact your local technical support provider (for contact information please see Appendix A, Local Technical Support Providers and Distributors).

If you are calling for assistance with a displayed error, please have the following items ready (this will assist your Bayer Customer Service and Support Center to deal with your inquiry as quickly as possible).

   a)  Error number
   b)  Clinitek Status Check Cassette which was supplied with your instrument.

> ⚠ **Do not remove the check cassette from its packaging unless instructed to do so. If the check cassette is required, instructions for its use will be given by your local technical support provider.**

   c)  Completed Problem Checklist (found at the end of this section).

For customer support, please contact your local technical support provider or distributor (for contact information please see Appendix A, Local Technical Support Providers and Distributors).

**Warranty**

Your Clinitek Status analyzer has a one-year warranty period. This warranty is designed to protect you from the cost associated with repairing systems that exhibit malfunctions due to defects in materials and/or workmanship during the warranty period.

The warranty period commences from the date that the instrument is received at your location. Use the Warranty Registration Card provided with the instrument to register your warranty.

To obtain assistance during the warranty period, please contact your local technical support provider or distributor.

| Clinitek Status Analyzer: | **List of Errors and Advisory Messages** | |
|---|---|---|
| **Error Code** | **Description** | **Action** |
| **E01** | Low battery power | Replace the batteries: a) To view instructions on the display, touch the Error Report selection area, or b) To use the instructions in this manual, see page 9-7, *Changing Batteries*. |
| **E10 or E48** | Loss of test results | 1. Switch the instrument off by pressing the on/off button for 2 seconds. 2. Switch the instrument on again by pressing the on/off button. 3. Repeat the test. |
| **E11** | Failure of test table | 1. Make sure that the test table is in place. Move the test table in or out of the instrument slightly to reposition the test table. 2. If the error remains, with the instrument powered on, unplug the power cord from rear of instrument and plug back in. Turn instrument on by pressing the gray power button. 3. If the error remains with the test table in place, contact your local Bayer Customer Service and Support Centre (contact information is given in Appendix A). |
| **E23** | Low battery power | Replace the batteries: a) To view instructions on the display, touch the Error Report selection area, or b) To use the instructions in this manual, see page 1-2, *Installing Batteries* and/or page 9-7, *Changing Batteries*. If the battery level becomes too low to power the instrument, Error Code E01 will be displayed. |
| **E24** | No printer paper | Replace the printer paper a) See instructions on the inside of the printer paper compartment cover, or b) To view instructions on the display, touch the Error Report selection area, or c) To use the instructions in this manual, see page 1-4, *Loading the Printer Paper or Label Roll*. |
| **E25, E64 or E65** | Failure of automatic calibration | Clean the calibration strip. If the error remains after cleaning, contact your local Bayer Customer Service and Support Center (contact information is given in Appendix A). |
| **E27** | Set Up failure | 1. Switch the instrument off by pressing the on/off button for 2 seconds. 2. Switch the instrument on again by pressing the on/off button. |

# 7 Troubleshooting
*Lists of Errors and Advisory Messages*

| Error Code | Description | Action |
|---|---|---|
| **E28** | Printer error | Lift the printer cover and push the paper holding arm back into position (see page 1-5, *Loading the Printer Paper or Label Roll* for location of paper holding arm). |
| **E50** | Incorrect strip type | Ensure that the strip type selected in Instrument Set Up is being used (see 5-19 and 5-20, *Select Urinalysis Test)*. If the correct type of strip is being used, check the instrument operation by running another test using: a) a yellow and clear sample, or b) Chek-Stix® (see page 8-1, *Quality Control Testing*). |
| **E52** | Invalid barcode | Repeat the test using a Bayer cassette. |
| **E53** | Strip Test selected but cassette detected | Repeat the test using the Cassette Test routine (see page 4-6 or 4-19). |
| **E54** | Cassette Test selected but strip detected | Repeat the test using the Strip Test routine (see page 4-1 or 4-11). |
| **E56** | Incorrect size test table | Repeat the test using the correct test table (see page 4-1). |
| **E57** | Missing strip or cassette | Repeat the test ensuring that the strip or cassette is positioned on the test table (see page 4-1 or 4-6 for strip or cassette testing). |
| **E58** | Misplaced strip | Repeat the test ensuring that the strip is correctly positioned on the test table (see page 4-3). If error remains and you are testing a urine dip strip, examine the test table insert to insure that the small, white line located near the tip of the strip (on strip side of insert) is present and not damaged. If this line is damaged or missing contact your local Bayer Customer Service and Support Center (contact information is given in Appendix A). |
| **E59** | Inverted strip positioned on the test table | Repeat the test ensuring that the strip is correctly positioned on the test table (see page 4-3). |

# 7 Troubleshooting
*Lists of Errors and Advisory Messages*

| Error Code | Description | Action |
|---|---|---|
| **E60** | Tilted strip | Repeat the test ensuring that the strip is correctly positioned on the test table (see page 4-3). |
| **E61** | Dry strip | Repeat the test ensuring that the strip has been in contact with the sample (see page 4-2). |
| **E63** | Failure to find end of strip | Repeat the test ensuring that the strip is correctly positioned on the test table (see page 4-3). |
| **E67 or E68** | Insufficient sample | A sample flow issue with the cassette test may have been detected. One or more of the test indicator lines may be missing or indiscernible from the background, or not enough sample was applied to the cassette. Repeat the test ensuring the pipette is correctly filled and the correct volume of sample is dispensed into the well of the cassette (see page 4-8). |
| **E02** | Failure of calibration data | Contact your local Bayer Customer Service and Support Center (contact information is given in Appendix A). |
| **E12** | Failure of LED | Contact your local Bayer Customer Service and Support Center (contact information is given in Appendix A). |
| **E20** | Failure of clock | Contact your local Bayer Customer Service and Support Center (contact information is given in Appendix A). |
| **E62** | Light Ingress | Contact your local Bayer Customer Service and Support Center (contact information is given in Appendix A). |

# 7 Troubleshooting
*Lists of Errors and Advisory Messages*

| Error Code | Description | Action |
|---|---|---|
| **E03, E04, E05, E06, E07, E08, E21, E22, E90, E91, E92** or **E93** | Failure of computer software | Contact your local Bayer Customer Service and Support Center (contact information is given in Appendix A). |

# 7 Troubleshooting
*Problem Checklist*

| Clinitek Status Analyzer: | **Problem Checklist** |
|---|---|

Serial Number _____

Installation Date_____

|  | YES | NO |
|---|---|---|
| 1. Have you reviewed the error messages on pages 7-4 to 7-7? | ☐ | ☐ |

2. Please record any error messages that have been displayed:

    _____
    _____
    _____

| | YES | NO |
|---|---|---|
| 3. Does the test table move out to the "load" position when the analyzer is first turned on? | ☐ | ☐ |

4. If Question #3 is NO –
  - Is the power cord plugged into a live electrical outlet, into the transformer, and then into the analyzer? ☐ ☐
  - If using batteries, are they fully charged and correctly placed in the analyzer? ☐ ☐

5. Does the display show the *Select* screen or the *Results* screen as expected? ☐ ☐

6. Does the test table move into and out of the analyzer? ☐ ☐

7. Does a quality control solution give the expected result? ☐ ☐

# 7 Troubleshooting
*Problem Checklist*

|  | YES | NO |
|---|---|---|
| 8. Is the name of the Bayer urinalysis strip or Clinitest immunoassay cassette shown on the display the same as the product being used? | ☐ | ☐ |
| 9. Does the display or printout show the correct test names and expected results? | ☐ | ☐ |
| 10. Is the white calibration bar on the test table dirty, scratched, or damaged? | ☐ | ☐ |

11. Additional problem observations, please describe:

_____

_____

_____

_____

_____

# 8 Quality Control Testing

The Clinitek Status system is CLIA waived only when used with Bayer branded urinalysis reagent strips.

For CLIA waived settings, we recommend that a quality control test be performed with each new reagent bottle opened.

## Quality Control for Urinalysis Strip Testing

Test negative and positive controls whenever a new bottle of reagent strips is first opened.

Water should **NOT** be used as a negative control. Contact your Bayer Healthcare representative for additional information on performing QC testing.

> *Refer to the quality control product insert for expected values for each analyte.*

## Quality Control for Cassette Testing

It is recommended that quality control specimens be used with each new reagent box opened.

> ***hCG*** *– Please refer to the Clinitek® hCG cassette test package insert for the appropriate quality control material.*

# 8 Quality Control Testing

**Information regarding CLIA Waiver**

The Clinitek Status system is CLIA waived for all Bayer branded urinalysis reagent strips. Cassette testing is currently categorized as moderate complexity.

Failure to adhere to the instructions for use, including instructions for limitations or intended use, and for performing QC testing, is considered off-label use, resulting in the test being categorized as high complexity and subject to all CLIA regulations.

**Expected Waiver Performance**

Summary tables of the results from the waiver studies and physician office studies are included in Section 10, Appendix F of this operator's manual.

## Cleaning

The test table insert and the test table should be kept clean if the analyzer is to operate properly.



⚠ **Do not autoclave the test table or test table insert.**

⚠ **BIOHAZARD** Wear personal protective equipment. Use universal precautions. Refer to *Appendix H* for recommended precautions when working with biohazardous materials.
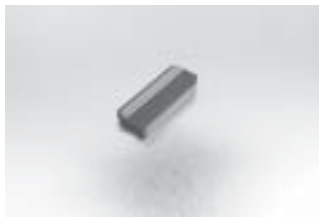
### Routine Cleaning of Test Table Insert

**1** Remove insert and thoroughly clean.

**2** Rinse both sides of the table insert under running water.

**3** Dry and replace insert.



### Periodic Cleaning of Test Table when Required

**1** Remove the test table by pulling it slowly out of the analyzer. Lift the test table insert from the test table, drain the drip tray if necessary.

**2** Wet a cotton-tipped stick with water and carefully clean test table (except for white calibration bar).

**3** Dry the test table thoroughly (except for the white calibration bar) with a soft cloth or lint-free tissue.

⚠ **Care should be taken not to scratch the white calibration bar. Instructions for cleaning the white calibration bar are given later in this section.**



**4** Reinsert the test table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards. Push the test table firmly but slowly, just over halfway into the analyzer.

⚠ **Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer.**

**5** Replace the test table insert.

**Disinfecting the Test Table and Insert**

**1** Prepare one of the following solutions in a tall, narrow container (e.g., empty Multistix® bottle) to a depth of about 4 inches (10 cm):

> • **Precept**, **Cidex**, **Theracide** and **Amphyl** solutions - prepare according to product directions.

> • **Household Bleach** (5% sodium hypochlorite) – this can be used either full strength or dilute with water to as much as 1:20 (i.e., mix 5 mL bleach with 95 mL water for a total of 100 mL).

> ⚠ **Rinse away all bleach residue, as remaining bleach will affect several of the reagent pad chemistries.**

> • **Isopropyl Alcohol** (70% to 85%) - this can be used full strength.

⚠ **Any solutions other than those listed above may damage the test table and insert.**

**2** Place the insert and/or test table into the solution, making sure the white calibration bar on the test table remains above the liquid level.

⚠ **Be sure the solution does not come in contact with the white calibration bar. Do not cover the container while the test table is soaking.**

**3** Soak the table and insert for a minimum of 2 minutes and maximum of 10 minutes. Do <u>not</u> soak longer than 10 minutes.

**4** Rinse the test table and insert thoroughly with water.

**5** Dry with a soft cloth and replace test table and table insert in the analyzer (as described on the previous page).

# 9 Cleaning and Maintenance
*Cleaning*

To enable your Clinitek Status® analyzer to perform as intended and provide reliable test results, it is recommended that you periodically check the white calibration bar on the test table.

In normal use, the white calibration bar should not become dirty or discolored.

⚠ **BIOHAZARD** Wear personal protective equipment. Use universal precautions. Refer to *Appendix H* for recommended precautions when working with biohazardous materials.

**Cleaning the White Calibration Bar**

**1** Remove the insert from the test table.

**2** Remove the test table by pulling it slowly out of the analyzer.

**3** Check the white calibration bar on the test table for dirt or discoloration.



White Calibration Bar

**4** If the white calibration bar is clean and unmarked, replace the table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards. Push the test table firmly but slowly, just over half way into the analyzer.

⚠ **Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer.**

**5** Replace the test table insert.

**6** If the white calibration bar is dirty or discolored, gently wipe and clean it with a new cotton-tipped stick or lint-free cloth wetted with distilled water.

⚠ **Care should be taken not to scratch the white calibration bar. Solvents of any kind must not be used to clean the bar.**



**7** Allow the calibration bar to air dry and then inspect the surface for dust, foreign material, scratches or scuffs. If the calibration bar cannot be cleaned or is still marked, obtain a new test table.

**8** Reinsert the test table as described earlier in point 4.

# 9 Cleaning and Maintenance
*Cleaning*

Always keep the outside of the
Clinitek Status analyzer clean and
free of dust.

⚠ **BIOHAZARD** Wear personal protective
equipment. Use universal precautions.
Refer to *Appendix H* for recommended
precautions when working with
biohazardous materials.

**1** Turn the analyzer off by
pressing the on/off button for
2 seconds.

**2** Wipe the outside (including the
display) with a damp (not wet)
cloth and a mild detergent.

⚠ **Do not use any type of
solvent, oil, grease, silicone spray,
or lubrication on the analyzer.**

⚠ **Do not spray the glass cleaner
directly onto the screen. Do not use
laboratory wipes, such as Kimwipes,
since they may scratch the screen.**

⚠ **Care should be taken to avoid
liquid from entering the printer
compartment.**

*The display may be disinfected
using the same solutions as for the test
table (see earlier in this section). Wipe
the solution on and allow to remain for
10 minutes. Wipe clean using a clean
cloth dampened with water, then dry.*

## Changing Batteries

**Battery-Powered Operation**
The Clinitek Status analyzer is designed to let you carry out the maximum number of tests (approximately 100) from a set of batteries. To achieve this, the Power Save feature is always activated when the instrument is powered by batteries.

If the instrument is not used in 3 minutes when battery-powered, it will automatically power down.

A battery power icon will be shown in the top right corner of the title bar when the analyzer is being powered by batteries. The number of segments displayed represents the amount of power remaining in the batteries.

When power is reduced but testing can continue, an advisory message will be displayed on the main *Select* screen.

> ⚠ **If you do not change the batteries and the level becomes too low to power the analyzer, the error will become critical and all selection areas on the screen will be disabled until the batteries are replaced.**

# 9 Cleaning and Maintenance
*Changing Batteries*

Remove the test table from the
analyzer. Next, place the analyzer
on its side and remove the battery
cover by pressing down on the tab
and pulling out. Remove current
batteries. Place 6 new AA-size
batteries into the analyzer. Replace
the battery cover and turn the
instrument back onto its base.

# 10 Appendices

## Appendix A: Local Technical Support Providers and Distributors

### Legal Information

To contact the legal representative for Bayer within the European community, contact the Bayer Authorized Representative. To order supplies or replacement parts, or to obtain service, contact your local technical support provider.

**Bayer Authorized Representative**
Bayer Diagnostics Mfg (Sudbury) Ltd
Sudbury, CO10 2XQ, UK

Bayer HealthCare LLC
Subsidiary of Bayer Corporation
Tarrytown, NY 10591-5097 USA

EC REP  Bayer Diagnostics Mfg (Sudbury) Ltd
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# 10 Appendices

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## Appendix B: Tables of Results

**Table 1**    **English – Conv.**
Units – Conventional

## Reagent Strip Tests

| Test | Abbreviation | Units | Reported Results | | | |
|------|-------------|-------|-----------------|---|---|---|
| | | | **Normal System** | | **Plus System** | |
| Glucose | GLU | mg/dL | Negative<br>100<br>250 | 500<br>>=1000 | Negative<br>Trace<br>1+ | 2+<br>3+ |
| Bilirubin | BIL | | Negative<br>Small | Moderate<br>Large | Negative<br>1+ | 2+<br>3+ |
| Ketone | KET | mg/dL | Negative<br>Trace<br>15 | 40<br>80<br>>=160 | Negative<br>Trace<br>1+ | 2+<br>3+<br>4+ |
| Specific Gravity | SG | | <=1.005<br>1.010<br>1.015 | 1.020<br>1.025<br>>=1.030 | No Difference | |
| Occult Blood | BLO | | Negative<br>Trace-lysed<br>Trace-intact | Small<br>Moderate<br>Large | Negative<br>Trace-lysed<br>Trace-intact | 1+<br>2+<br>3+ |
| pH | pH | | 5.0    6.5<br>5.5    7.0<br>6.0    7.5 | 8.0<br>8.5<br>>=9.0 | No Difference | |
| Protein<br>Multistix PRO™ | PRO | mg/dL | Negative<br>15<br>30 | 100<br>300 | Negative<br>Low<br>1+ | 2+<br>3+ |
| Protein<br>All other<br>urinalysis<br>strips | PRO | mg/dL | Negative<br>Trace<br>30 | 100<br>>=300 | Negative<br>Trace<br>1+ | 2+<br>3+ |
| Urobilinogen | URO | E.U./dL | 0.2<br>1.0<br>2.0 | 4.0<br>>=8.0 | No Difference | |
| Nitrite | NIT | | Negative | Positive | No Difference | |
| Leukocytes | LEU | | Negative<br>Trace<br>Small | Moderate<br>Large | Negative<br>Trace<br>1+ | 2+<br>3+ |
| Albumin | ALB | mg/L | 10<br>30 | 80<br>150 | No Difference | |
| Creatinine | CRE | mg/dL | 10<br>50<br>100 | 200<br>300 | No Difference | |
| Albumin:<br>Creatinine * | A:C | mg/g | <30 Normal<br><br>30 – 300<br>Abnormal | >300 High<br>Abnormal | No Difference | |

# 10 Appendices
*Appendix B: Tables of Results*

| Test | Abbreviation | Units | Reported Results | | |
|------|--------------|-------|------------------|---|---|
| | | | **Normal System** | | **Plus System** |
| Protein: Creatinine Multistix PRO | P:C | mg/g | Normal Dilute Normal | 300 Abnormal >500 Abnormal | No Difference |
| | | | 150 Abnormal | | |

## Cassette Test

| Test | Abbreviation | Reported Results | | |
|------|--------------|------------------|---|---|
| | | **Normal System** | | **Plus System** |
| Human Chorionic Gonadotropin | hCG | hCG Negative<br><br>hCG Borderline Repeat in 48-72 hours | hCG Positive | No Difference |

The results shown in shaded areas will be marked as positives, if "mark positive results" is selected in **Instrument Set Up**. They will be marked by asterisks when displayed, when printed and when the data is transferred to a host computer.

\* Positive Albumin:Creatinine ratios are not marked when using Clinitek® Microalbumin reagent strip.

# 10 Appendices

*Appendix B: Tables of Results*

## Table 2     English – S.I.
        Units – International (S.I.)

### Reagent Strip Tests

| Test | Abbreviation | Units | Reported Results | | | |
|------|--------------|-------|------------------|---|----------------|---|
| | | | **Normal System** | | **Plus System** | |
| Glucose | GLU | mmol/L | Negative<br>5.5<br>14 | 28<br>>=55 | Negative<br>Trace<br>1+ | 2+<br>3+ |
| Bilirubin | BIL | | Negative<br>Small | Moderate<br>Large | Negative<br>1+ | 2+<br>3+ |
| Ketone | KET | mmol/L | Negative<br>Trace<br>1.5 | 3.9<br>7.8<br>>=15.6 | Negative<br>Trace<br>1+ | 2+<br>3+<br>4+ |
| Specific Gravity | SG | | <=1.005<br>1.010<br>1.015 | 1.020<br>1.025<br>>=1.030 | No Difference | |
| Occult Blood | BLD | Ery/µL | Negative<br>Trace-lysed<br>Trace-intact | Ca 25<br>Ca 80<br>Ca 200 | Negative<br>Trace-lysed<br>Trace-intact | 1+<br>2+<br>3+ |
| pH | pH | | 5.0   6.5<br>5.5   7.0<br>6.0   7.5 | 8.0<br>8.5<br>>=9.0 | No Difference | |
| Protein Multistix PRO | PRO | g/L | Negative<br>0.15<br>0.3 | 1.0<br>3.0 | Negative<br>Low<br>1+ | 2+<br>3+ |
| Protein All other reagent strips | PRO | g/L | Negative<br>Trace<br>0.3 | 1.0<br>>=3.0 | Negative<br>Trace<br>1+ | 2+<br>3+ |
| Urobilinogen | UBG | mmol/L | 3.2<br>16<br>33 | 66<br>>+131 | No Difference | |
| Nitrite | NIT | | Negative | Positive | No Difference | |
| Leukocytes | LEU | Leu/µL | Negative<br>Ca 15<br>Ca 70 | Ca 125<br>Ca 500 | Negative<br>Trace<br>1+ | 2+<br>3+ |
| Albumin | ALB | mg/L | 10<br>30 | 80<br>150 | No Difference | |
| Creatinine | CRE | mmol/L | 0.9<br>4.4<br>8.8 | 17.7<br>26.5 | No Difference | |
| Albumin: Creatinine * | A:C | mg/mmol | <3.4 Normal<br>3.4 – 33.9 Abnormal | >33.9 High Abnormal | No Difference | |

| Test | Abbreviation | Units | Reported Results | | Plus System |
|------|-------------|-------|-----------------|---|-------------|
| | | | **Normal System** | | **Plus System** |
| Protein: Creatinine Multistix PRO | P:C | mg/mmol | Normal Dilute<br><br>Normal<br><br>17.0 Abnormal<br>33.9 Abnormal | 33.9 Abnormal<br><br>>56.6 Abnormal | No Difference |

## Cassette Test

| Test | Abbreviation | Reported Results | | Plus System |
|------|-------------|-----------------|---|-------------|
| | | **Normal System** | | **Plus System** |
| Human Chorionic Gonadotropin | hCG | hCG Negative<br><br>hCG Borderline Repeat in 48-72 hours | hCG Positive | No Difference |

The results shown in shaded areas will be marked as positives, if "mark positive results" is selected in **Instrument Set Up**. They will be marked by asterisks when displayed, when printed and when the data is transferred to a host computer.

* Positive Albumin:Creatinine ratios are not marked when using Clinitek Microalbumin reagent strip.

# 10 Appendices
*Appendix B: Tables of Results*

**Table 3      English – Nordic**
Units – Nordic Plus System

## Reagent Strip Tests

| Test | Abbreviation | Units | Reported Results | | | |
|------|-------------|-------|------------------|---|---|---|
| | | | **Normal System** | | **Plus System** | |
| Glucose | GLU | | Negative ... 3+<br>1+ ... 4+<br>2+ | | Negative ... 2+<br>Trace ... 3+<br>1+ | |
| Bilirubin | BIL | | Negative ... 2+<br>1+ ... 3+ | | No Difference | |
| Ketone | KET | | Negative ... 3+<br>1+ ... 4+<br>2+ ... 5+ | | Negative ... 2+<br>Trace ... 3+<br>1+ ... 4+ | |
| Specific Gravity | SG | | <=1.005 ... 1.020<br>1.010 ... 1.025<br>1.015 ... >=1.030 | | No Difference | |
| Occult Blood | BLD | | Negative ... 1+<br>+/- ... 2+<br>+/- Intact ... 3+ | | No Difference | |
| pH | pH | | 5.0   6.5   8.0<br>5.5   7.0   8.5<br>6.0   7.5   >=9.0 | | No Difference | |
| Protein Multistix PRO | PRO | | Negative ... 2+<br>Low ... 3+<br>1+ | | No Difference | |
| Protein All other reagent strips | PRO | | Negative ... 2+<br>+/- ... 3+<br>1+ | | Negative ... 2+<br>Trace ... 3+<br>1+ | |
| Urobilinogen | URO | µmol/L | 3.2 ... 66<br>16 ... >=131<br>33 | | No Difference | |
| Nitrite | NIT | | Negative ... Positive | | No Difference | |
| Leukocytes | LEU | | Negative ... 3+<br>1+ ... 4+<br>2+ | | Negative ... 2+<br>Trace ... 3+<br>1+ | |
| Albumin | ALB | mg/L | 10 ... 80<br>30 ... 150 | | No Difference | |
| Creatinine | CRE | mmol/L | 0.9 ... 17.7<br>4.4 ... 26.5<br>8.8 | | No Difference | |
| Albumin: Creatinine * | A:C | mg/mmol | <3.4 Normal<br>3.4 – 33.9 Abnormal | >33.9 High Abnormal | No Difference | |
| Protein: Creatinine Multistix PRO | P:C | mg/mmol | Normal Dilute<br>Normal<br>17.0 Abnormal | 33.9 Abnormal<br>>56.6 Abnormal | No Difference | |

# 10 Appendices
*Appendix B: Tables of Results*

## Cassette Test

| Test | Abbreviation | Reported Results | | Plus System |
|------|--------------|------------------|---|-------------|
| | | **Normal System** | | |
| Human Chorionic Gonadotropin | hCG | hCG Negative<br><br>hCG Borderline Repeat in 48-72 hours | hCG Positive | No Difference |

The results shown in shaded areas will be marked as positives, if "mark positive results" is selected in **Instrument Set Up**. They will be marked by asterisks when displayed, when printed and when the data is transferred to a host computer.

* Positive Albumin:Creatinine ratios are not marked when using Clinitek Microalbumin reagent strip.

# 10 Appendices
*Appendix C: Specifications*

## Appendix C: Specifications

**Power Required**
110V AC ± 20%, 45 - 65 Hz
(US only)
220V AC ± 20%, 45 - 65 Hz
(Europe only)
240V AC ± 20%, 45 - 65 Hz (UK
only)
100V - 240V AC ± 20%, 45 - 65 Hz
(with in-line lead)

**Battery Powered Operation**
Size 6 AA non-rechargeable
alkaline batteries

**Dimensions**
Depth - 272 mm (10.7 inches)
Width - 171 mm (6.7 inches)
Height - 158 mm (6.2 inches)

**Weight**
Clinitek Status® instrument only
(unpacked, without batteries or
power supply) – 1.66 kg (3.65 lb)

**Ambient Operating Temperature
Range**
18°C to 30°C (64°F to 86°F)

**Ambient Operating Humidity
Range**
18% to 80% Relative Humidity
(non-condensing)

**Optimum Operating Temperature
Range**
22°C to 26°C (72°F to 79°F)

**Optimum Operating Humidity
Range**
35% to 55% Relative Humidity
(non-condensing)
Optimum ranges insure that the
reagent results are optimized for
performance. At temperatures
under 22°C (72°F), urobilinogen
and leukocyte results may be
decreased, and at temperatures
above 26°C (79°F), increased.

**Altitude:** 2000 m (6562 ft)

**Installation Category**: II

**Pollution Degree**: 2

**Instrument Memory**
200 Patient test results
200 Patient details (Patient's Name
and/or Patient Identification)

**Safety Standards**
The Clinitek Status analyzer is
classed as a Class A computing
device in accordance with Part 15
of FCC Rules.

# 10 Appendices
*Appendix C: Specifications*

**NOTE:** This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

The instrument is listed by the Underwriters' Laboratories (UL) and the Canadian Standards Association (CSA) as certified and complies with the safety standards specified in UL 3101 and CSA-C22, No. 1010.1.

The instrument complies with the protection requirements of
EN 60601-1-2,
EN 50082-1 January 1992,
EN 50081-1 January 1992,
and the safety specifications of
EN 61010-1.

The instrument is certified as meeting the EMC requirements and safety specifications of the In Vitro Diagnostic Directive (98/79/EC).

# 10 Appendices

## Appendix D: Instrument Default Settings – English

**Password**
Password protection not set

**Input Settings**
Quick Test

**Operator ID**
Disabled

**Keyboard Priority**
Alphabetic

**Entry of Patient's Name**
Disabled

**Entry of Patient ID**
Disabled

**Include Patient's Name or ID in Results**
Patient's Name

**Last Operator ID**
Disabled

**Sample Appearance**
Disabled

**Custom Data Entry**
Disabled

**Date Format**
MM-DD-YYYY

**Time Format**
12 hour

**Results Format**
**Units Selection**
Conventional

**Plus System**
Disabled

**Mark Positive Results**
Disabled

**System Settings**
Printer
Automatic

**Power Save**
Disabled

**Sound**
On

**Contrast Setting**
0 (zero)

**Connectivity**
**Allow Results to be Sent to computer**
Enabled

**Instrument Serial Number in Patient Records**
Disabled

# 10 Appendices
*Appendix D: Instrument Default Settings – English*

**Baud Rate**
115200

**Parity**
None

**Stop Bits**
1 (one)

**Urinalysis Test Selected**
Multistix® 10 SG

## Appendix E: System Overview & Principles

**Intended Use of Analyzer**

The Clinitek Status® analyzer is for in vitro diagnostic use in:

- the semi-quantitative detection of albumin, bilirubin, blood (occult), creatinine, glucose, ketone (acetoacetic acid), leukocytes, nitrite, pH, protein, specific gravity and urobilinogen in urine samples. The tests reported depend on the type of Bayer urinalysis strip used.

- the semi-quantitative calculation of albumin-to-creatinine and protein-to-creatinine ratios in urine samples, when certain strips are used.

- the detection of human Chorionic Gonadotropin (hCG) in urine samples, when Clinitest® hCG Cassette Tests are used.

**Description of Optical System**

The optical system consists of six light emitting diodes, a light guide, a mirror, a lens and a detector.

Light from the LEDs travels along the light guide and is reflected off the calibration bar, strip or cassette onto the mirror. It is then directed through an aperture on the lens, from where it is focused onto the detector. The light intensity detected is converted into electrical impulses, which are processed by the instrument's microprocessor and converted into clinically meaningful results.

When carrying out analysis on a urinalysis strip, the test table positions strip pads in the "read area". The light reflected at specific wavelengths (470 nm, 525 nm, 565 nm, 625 nm, 660 nm and 845 nm) from the test pad is dependent upon the degree of color change in the pad and is directly related to the concentration of the particular constituent in the urine. The analyzer's optical system images the entire strip (i.e., all reagent pads at once).

When using a Clinitest immunoassay cassette, the detector will scan the "read area" for the test, reference and control lines that form after urine has been applied. The reference and control lines will

always form whereas the test line will only form if hCG is present in the sample.

## Description of Internal Checks

When the analyzer is first turned *on*, the instrument performs a series of electronic, signal and memory checks, as well as ensuring there is sufficient battery voltage to operate the instrument (if powered by batteries).

Each time a urinalysis strip is read, the instrument positions the table correctly and checks the electronics and signals. It then takes reference readings off the white calibration bar on the test table. The readings are taken at all six wavelengths and are then used to calculate the sample readings.

The table and test strip are pulled into the instrument after the correct placement of the test strip is confirmed. The table then moves completely into the instrument closing the shutter. All test pads are read simultaneously at all six wavelengths. The test and reference readings are then used to determine presence and/or amount of each constituent in the urine sample.

Each time a cassette is read, the instrument positions the table correctly and checks the electronics and signals. It then takes reference readings of the white calibration bar on the test table. The readings are taken at two wavelengths (525 nm and 845 nm) and are then used to calculate the sample readings.

The table and cassette are pulled into the instrument where the presence of the cassette is confirmed. The table then pulls completely into the instrument closing the shutter and the cassette "read area" is scanned at two wavelengths. The test and references readings are then used to determine presence or absence of hCG the urine sample.

## Differences between the Human Eye and Instrumental Optics

There are inherent differences between the colors that are perceived by the human eye and that are detected by any instrument optical system. The human eye is capable of detecting minute differences in shade and very small areas of color; whereas instrument optical systems are less sensitive to such small changes. Conversely,

instrument optics are capable of detecting certain colors that are masked by or blended with other colors to the human eye.

For this reason, exact agreement between visual results and instrument results might not be found. However, agreement is generally within one visual color block or reported level and is equal to or better than the agreement between two visual readers.

| Guidance and manufacturer's declaration - electromagnetic emissions | | |
|---|---|---|
| The Bayer Clinitek Status® is intended for use in the electromagnetic environment specified below. The customer or the user of the Bayer Clinitek Status® should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment — guidance** |
| RF emissions<br><br>CISPR 11 | Group 1 | The Bayer Clinitek Status® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br><br>CISPR 11 | Class A | The Bayer Clinitek Status® is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br><br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions<br><br>IEC 61000-3-3 | Complies | |

| Guidance and manufacturer's declaration — electromagnetic immunity | | | |
|---|---|---|---|
| The Bayer Clinitek Status® is intended for use in the electromagnetic environment specified below. The customer or the user of the Bayer Clinitek Status® should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact ±8 kV air | ±6 kV contact ±15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines ±1 kV for input/output lines | ±2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV differential mode ±2 kV common mode | ±1 kV differential mode ±2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % $U_T$ (>95 % dip in $U_T$) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$) for 5 cycles 70% $U_T$ (30% dip in $U_T$) for 25 cycles <5% $U_T$ (>95 % dip in $U_T$) for 5 sec | <5 % $U_T$ (>95 % dip in $U_T$) for 0.5 cycle *40% $U_T$ (60% dip in $U_T$) for 5 cycles 70% $U_T$ (30% dip in $U_T$) for 25 cycles <5% $U_T$ (>95 % dip in $U_T$) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Bayer Clinitek Status® requires continued operation during power mains interruptions, it is recommended that the Bayer Clinitek Status® be powered from an uninterruptible power supply or a battery.  *Note: Bayer should not provide the 100-240V supply for operation at 100V. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | Not Applicable | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE  $U_T$ is the a.c. mains voltage prior to application of the test level. | | | |

## Guidance and manufacturer's declaration - electromagnetic immunity

The Bayer Clinitek Status® is intended for use in the electromagnetic environment specified below. The customer or the user of the Bayer Clinitek Status® should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment — guidance |
|---|---|---|---|
| Conducted RF IEC61000-4-6 Radiated RF IEC 61000-4-3 | 3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz | 3 V 3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the Bayer Clinitek Status®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$  80 MHz to 800 MHz $d = 2.3\sqrt{P}$  80 MHz to 2,5 GHz where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: $((\cdot))$ |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]  Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Bayer Clinitek Status® is used exceeds the applicable RF compliance level above, the Bayer Clinitek Status® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Bayer Clinitek Status®.

[b]  Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between portable and mobile RF communications equipment and the Bayer Clinitek Status®**

The Bayer Clinitek Status® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Bayer Clinitek Status® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Bayer Clinitek Status® as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$ |
| 0,01 | 0.12 | 0.12 | 0.23 |
| 0,1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The Clinitek Status received CLIA waiver status (42 CFR 493) for the entire urinalysis menu in 2005. Clinitek Microalbumin required a separate CLIA Waiver submission for use on the Clinitek Status. All additional tests using new urinalysis chemistries or new immunoassay analytes will require Clinitek Status system CLIA Waiver approval.

**Clinitek Multistix Expected Waiver Performance**

At 3 sites, 75 untrained users with no laboratory experience, tested randomized samples using Bayer Multistix reagent strips and 35 Clinitek Status urinalysis analyzers. The CLIA waiver study demonstrated that the performance of the Clinitek Status analyzer is acceptable in the hands of non-technical users when only a Quick Reference Guide is used to learn and to perform tests.

The performance of the Bayer Multistix reagent strips with the Clinitek Status analyzer, in the hands of LAY-users, met the primary performance criteria that 90% of the results should be within +/- one level of the expected result.

**TABLE 1**     Percent Agreement of Clinitek Status Results to Target Levels (Bayer Masked Samples) tor LAY-users

| Analyte | Exact Agreement (%) | ± One (1) Level (%) |
|---|---|---|
| | LAY-user | LAY-user |
| Blood (occult) | 96.6 | 98.8 |
| Creatinine | 66.8 | 97.8 |
| Glucose | 87.6 | 99.5 |
| Ketone | 92.7 | 99.9 |
| Leukocyte | 92.8 | 99.9 |
| Nitrite | 100 | 100 |
| pH | 87.8 | 99.5 |
| Protein | 90.9 | 100 |
| Specific Gravity | 58.4 | 96.7 |

The following analyte test results were derived from a Physician Office Laboratory (POL) study conducted at 3 POL sites and 1 clinical laboratory site. The performance of the Clinitek Status analyzer and Multistix reagent for these analytes met the primary performance criteria that 90% of the results should be within +/- one level of the expected result.

**TABLE 2**    Percent Agreement of Clinitek Status Results to Target Levels (Bayer Masked Samples) in POL/clinical laboratory settings

| Analyte | Exact Agreement (%) | ± One (1) Level (%) |
|---|---|---|
|  | POL-user | POL-user |
| Bilirubin | 96.7 | 100 |
| Urobilinogen | 92.6 | 99.5 |

**Clinitek Microalbumin Expected Waiver Performance**

To evaluate the expected performance of the Bayer Clinitek Microalbumin urinalysis product used on the Clinitek Status Analyzer in a CLIA-waived setting, a lay user field study was performed at three non-laboratory study sites. The 72 participants represented diverse demographics, had no previous laboratory experience, and received no training for the study. Participants were provided with six (6) masked samples consisting of two replicate samples at each of three albumin concentrations: negative (0 mg/L), weak positive (35.6 mg/L), and strong positive (179 mg/L). The lay user results were compared to results using a comparator quantitative method. A summary of the performance is shown below.

Lay User Results:  431

Lay Users:  72

The overall accuracy rates for microalbumin were:

| Negative | **100%** (144/144) with 95% CI: (**97.5%** - 100.0%) |
|---|---|
| Weak Positive | **99.3%** (142/143)* with 95% CI: (**96.2%** - 100.0%) |
| Strong Positive | **100%** (144/144) with 95% CI: (**97.5%** - 100.0%) |

*One result was omitted due to an error by the study monitor.

Statistical analysis (Fisher's Exact Test) demonstrated that the observed differences between the three study sites were not significant.

# 10 Appendices
*Appendix G: Training & Educational Materials*

Chek-Stix® Positive and Negative control strips are available for use in your training program for routine urine strip testing (for supply information see Appendix A, Local Technical Support Providers and Distributors). Follow the package insert for instruction on preparation and testing.

# 10 Appendices
*Appendix H: Safety Information*

**Protecting Yourself from Biohazards**

This information summarizes the established guidelines for handling laboratory biohazards. This summary is based on the guidelines developed by the Centers for Disease Control, the Clinical and Laboratory Standards Institute, and the Occupational Safety and Health Administration.

Use this summary for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

By definition, a biohazardous condition is a situation involving infectious agents biological in nature, such as the hepatitis B virus, the human immunodeficiency virus, and the tuberculosis bacterium. These infectious agents may be present in human blood and blood products and in other body fluids.

The following are the major sources of contamination when handling potentially infectious agents:

- needlesticks
- hand-to-mouth contact
- hand-to-eye contact

- direct contact with superficial cuts, open wounds, and other skin conditions that may permit absorption into subcutaneous skin layers
- splashes or aerosol contact with skin and eyes

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves while servicing parts of the system that have contact with body fluids such as serum, plasma, urine, or whole blood.
- Wash your hands before going from a contaminated area to a noncontaminated area, or when you remove or change gloves.
- Perform procedures carefully to minimize aerosol formation.
- Wear facial protection when splatter or aerosol formation are possible.
- Wear personal protective equipment such as safety glasses, gloves, lab coats or aprons when working with possible biohazard contaminants.

- Keep your hands away from your face.
- Cover all superficial cuts and wounds before starting any work.
- Dispose of contaminated materials according to your laboratory's biohazard control procedures.
- Keep your work area disinfected.
- Disinfect tools and other items that have been near any part of the system sample path or waste area with 10% v/v bleach.
- Do not eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory.
- Do not mouth pipet any liquid, including water.
- Do not place tools or any other items in your mouth.
- Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands.

Do not recap, purposely bend, cut, break, remove from disposable syringes, or otherwise manipulate needles by hand. Needlestick injuries may result.

**References**

1. Centers for Disease Control. *Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings*. 1988. MMWR, 37:377-382, 387, 388.

2. Clinical and Laboratory Standards Institute (formerly NCCLS). *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document M29-A3. [ISBN 1-56238-567-4].

3. Federal Occupational Safety and Health Administration. Bloodborne Pathogens Standard. 29 CFR 1910. 1030.

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