CLINITEK® 50

USER'S GUIDE

Bayer Corporation
Elkhart, IN 46515 USA

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99915549

Contents

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A Brief Description

What does this instrument do?

Your CLINITEK® 50 Urine Chemistry Analyzer is a portable instrument for reading traditional Bayer Reagent Strips for Urinalysis (e.g., MULTISTIX® 10 SG), Bayer MULTISTIX PRO® Reagent Strips, and CLINITEK® Microalbumin Reagent Strips. Refer to the bottle label or carton for the tests that are included with each product. The Analyzer can also report the color of the urine sample. No special training is needed to use the instrument.

The Analyzer can be plugged into an electrical outlet for use on the benchtop, or it can be powered by batteries and freely moved from one testing site to another. The battery pack, which is purchased separately, fits into an opening on the bottom side of the instrument.

Do I have to calibrate?

You do not have to do anything extra to calibrate. The instrument performs a "self-test" and calibration each time it is turned *on*. Then, each time a test is run, the instrument calibrates again, using the white plastic bar located on the end of the test strip table.

How does it work?

Testing starts when either of the two Start keys (labeled "◇") is pressed. You have 10 seconds after the ◇ key is pressed to blot the edge of the wet reagent test strip (if required for the test) and place it on the test strip table. The table is then pulled into the instrument, where the test strip is read. The instrument measures the color and amount of light that is reflected from the test pads on the strip. It then converts these measurements into meaningful results.

How do I get results?

Results can be either printed or displayed. The results can also be transferred to a computer using a special cable that is plugged into the computer port on the back of the instrument.

What about this User's Guide?

The User's Guide contains the directions you need to unpack the instrument, use it for your daily urine testing, and keep it in good working condition. The User's Guide is provided in several languages; please recycle the Guides you will not be using.

As you read through the User's Guide, you will find these symbols:

NOTES contain useful tips on using your instrument. *They appear in italicized type.*

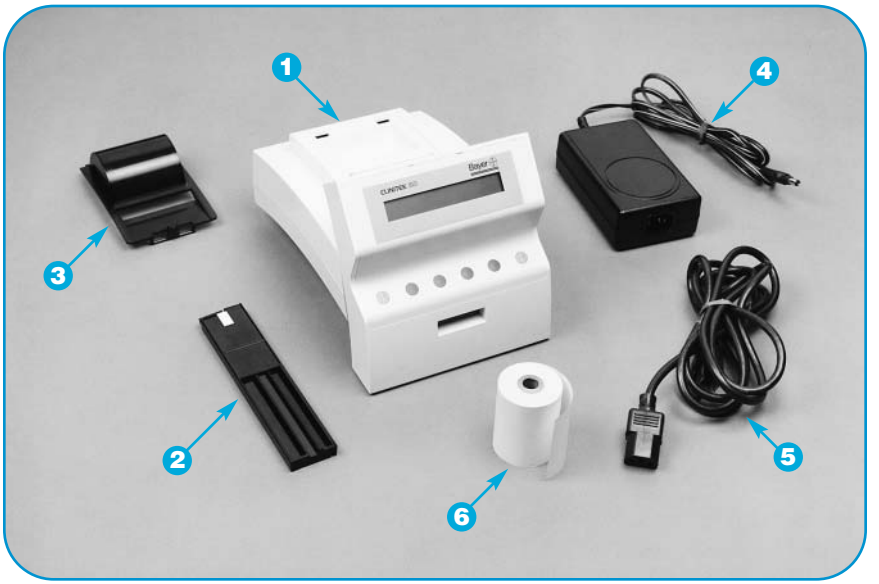
CAUTIONS should be followed carefully to ensure your instrument operates correctly and is not damaged. **Cautions appear in bold type like this.**

Unpacking and Setup

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:



1. CLINITEK® 50 Analyzer
2. Test strip table

   (Do not touch the white bar!)
   If you will be using a Reagent Strip that has four or fewer test pads, you must use a short test strip table, which must be ordered separately (see page 27). (CLINITEK® Microalbumin Strips are run using the long table.)
3. Printer cover
4. Power transformer
5. Power cord
   If the power cord is not the style you need, contact your Bayer office (see page 25).
6. Paper roll

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

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

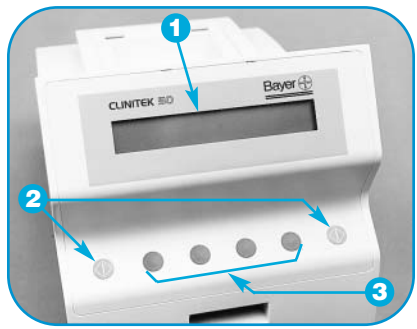
☞ **The best temperature for using the instrument is between 22°C and 26°C (72°F to 79°F). Do not place the instrument near such things as an outside window, oven, hot plate, or radiator.**

4 Locate the following:

1. Display
2. ◇ (START) Keys

   Either green key can be pressed to start a test.
3. Option Keys

   Each dark gray key corresponds to one of four words that may be shown on the bottom line of the display; press the key beneath the word to select that choice.



If you will be using the optional battery pack instead of the power cord and transformer, skip Step 5.

5 Plug the power cord into the transformer, then plug the transformer cord into the instrument. Plug the power cord into an appropriate grounded AC electrical wall outlet.

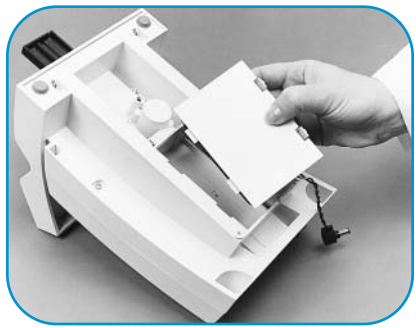
6 Insert the test strip table into the instrument, holding it by the end opposite the white bar and with the flat side facing up. **Do not touch the white bar.** Push the table in about halfway.

7 If you will be sending results to a computer, you must obtain a special Computer Cable/ Connector Kit (see page 26 to order). The kit includes all the information you need to connect and use the cable.

Installing the Battery Pack

1 If you will be using the optional battery pack, place six AA-size batteries into the battery compartment.

2 Turn the instrument over and snap the battery pack into the opening.



3 Plug the cord into the power inlet.

Loading the Paper Roll

1 Insert the two tabs on the printer cover into the two openings on the instrument. Rest the cover on its back edge.

If changing the paper, leave the cover down and pull out the remaining paper. Then raise the cover and remove the empty core to continue.

2 Trim the end of the paper so it has a large "V" shape at least 2 inches (5 cm) long. With the paper unrolling from underneath, insert the paper under the printer roller until the tip comes through the other side of the roller.

3 ***Pulling toward the back,*** gently pull the end of the paper until the full width of the paper is completely exposed.

Do not pull the paper straight up or toward the front, as this will damage the printer.

4 Feed the paper through the printer cover opening and snap the cover into position.

*The cover **must** be latched in order for the instrument to function.*

To prevent damage to the printer, do not tear the paper without the cover in place.

Powering Up

1 Press the power switch on the back of the instrument to the "—" (ON) position.

2 If you want to use the language and units shown on the screen, press the key under the word **YES.** If you want another language and/or units, press the key under the word **NO.**

Refer to pages 29 to 34 for the test abbreviations and results that are used with each of the three options for English. For tests not shown in these tables, refer to the insert included with the product.

3 Press the key under the word **NORMAL** if you want the results to appear in clinical units. Press the key under **+/–** if you prefer plus and minus signs.

4 If you want to use the Bayer Reagent Strip shown on the screen, press the key under the word **YES.** If you want to use a different strip, press the key under the word **NO.**

5 Your selections will be printed. If they are correct, press the key under **YES.** If they are not correct, press **NO** and repeat Steps 2 to 4.

The screens shown in Steps 2, 3, and 4 appear only the first time the instrument is turned on.

The MULTISTIX PRO® and CLINITEK Microalbumin Strips are not included in this list.

6 The instrument briefly displays two screens while it does an internal check. When the check is complete, the READY screen appears. Look for the names of the products that can be used — they are shown after the words "READY FOR TEST."

☞ **Do not use any traditional Bayer Reagent Strip product other than what is shown on the display. Using the wrong Reagent Strip will give you incorrect results.**

MULTISTIX PRO and CLINITEK Microalbumin Reagent Strips are automatically identified by the instrument; if your software cannot identify a test, the test is rejected and the display will show "STRIP PROBLEM – RETEST."

Final Paper Work

1 Find the bar-coded serial number label on the bottom of the instrument. Write this number and today's date on the Problem Checklist on page 24.

2 Fill out and mail the Warranty Registration Card and Customer Information Card if these are included with your instrument.

Selecting Your Options

2

Location of Results and Number of Copies

One copy of each set of results will be printed if you do not change this option.

1 If you want more than one printed copy or if you prefer results to be displayed on the screen, press the key under the word **OUTPUT.**

2 Press the key under your choice.

3 If you pressed **PRINTER,** you can choose to have more than one copy of the results. Press the key under your choice.

Setting the Time

1 Press the key under the word **SET.**

2 Press the key under **TIME** and select the 12 hour (AM/PM) format or the 24 hour (military) format.

3 Press the ↑ key to adjust the hour.

If you press and hold the ↑ key, the numbers will advance more quickly.

4 Press the → key, then press ↑ to adjust the minutes.

5 Press **EXIT.**

Setting the Date

1 Press the key under the word **SET.**

2 Press the key under **DATE** and select a date format:

MDY	Month-Day-Year
DMY	Day-Month-Year
YMD	Year-Month-Day

3 Press the ↑ key to adjust the first number.

4 Press the → key, then press ↑ to adjust the second number.

5 Press the → key, then press ↑ to adjust the third number.

6 Press **EXIT.**

Reporting the Urine Color

1 Press the key under the word **SET.**

2 Press **MORE,** then press **COLOR.** Press the **YES** or **NO** key to make your selection.

3 Press **EXIT** as needed.

*Color will be reported automatically when using Bayer Reagent Strips that include the leukocyte test pad if this option is set to **YES.** If there is no leukocyte pad, lines for manual entry of the color and clarity are printed.*

Color results reported by the instrument may be different from the color seen visually. This is because of the inherent differences between the human eye and the optical system of the instrument.

Setting the Sequence Number

1 If you want to have the sequence number appear, press the key under the word **SET.**

2 Press **MORE,** then press **SEQ#.**

3 Press **YES** to use sequence numbers (or press **NO** if you don't want them displayed).

4 Press **EXIT** as needed.

The sequence number will not be displayed or printed unless you change this option.

If you are already using sequence numbers and the number is greater than 001, you will first be given the option of setting it to 001.

Clearing the Memory and Marking Positives

1 If you want to clear the instrument's memory of all test results, or to turn off the asterisk, press the key under the word **SET.**

2 Press **MORE,** then press **CMPTR.**

3 Press **YES** to clear the memory and reset the sequence number to 001.

4 Then select whether positives will be marked with an asterisk (*).

5 Press **EXIT** as needed.

You can connect the instrument to a computer to transfer results. Fifty sets of results are stored (for transfer only) if the memory is not cleared.

*Check whether your software program can accept the asterisk that marks positive results. Press **NO** if it cannot.*

Printing the Instrument Setup

If you want to print a list of your instrument's setup selections, press the key under the word **LIST.**

Testing Controls

3

Positive and negative control solutions should be tested on a regular basis. This provides a check to ensure that the test strips are reacting properly and the instrument is reading the strips properly. Testing controls also helps detect errors caused by incorrect user technique.

CHEK-STIX® Positive and Negative Control Strips are available for use in your quality control program for routine urine testing (see page 26 for product numbers). Prepare the control solutions as instructed in the package insert that comes with the control product. Then test the control solution using the same procedure as you use when testing patient urines.

Record the control results. If any results are not within the expected range, notify the lab supervisor or physician. Refer to the bottle label and/or package insert for storage information and expiration date.

You should test controls:

- at the start of the day;
- when you open a new bottle of test strips;
- whenever test results are in doubt;
- when training instrument operators.

If using a MULTISTIX PRO® or CLINITEK® Microalbumin Reagent Strip, quality control should be performed using commercially-available controls that include values for each test on the strip; CHEK-STIX Control Strips are not suitable for use with these products. For information about control manufacturers, contact your local Bayer office or representative. In the United States, call the Bayer Technical Care Center at 1-877-229-3711.

Expected values are found in the package insert that comes with the control product.

4 Testing Routine Urines

Procedure

Before beginning the day's testing, check the test strip table to make sure it is clean. If it looks dirty, remove the table and clean it, as described on page 18.

The urine specimen should be fresh, well-mixed, and uncentrifuged. If the urine depth is less than about 3 inches (7.6 cm), pour the specimen into a narrow tube, such as a URIN-TEK® Specimen Tube.

1 **Dip** a Bayer Reagent Strip into the urine. Be sure *all* the test pads are wet.

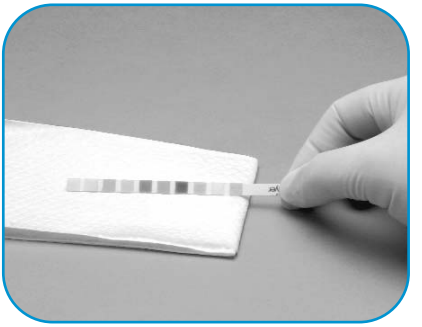
Refer to the direction insert included with your Reagent Strips for complete information on using the strips.

Testing can be started only from the READY FOR TEST screen. Be sure the Reagent Strip name agrees with the strip being used, unless using MULTISTIX PRO® or CLINITEK® Microalbumin Reagent Strips, which are automatically identified after testing begins.

Replace the cap as soon as you remove each strip from the bottle.

2 **Immediately remove** the Reagent Strip from the urine, dragging the edge of the strip against the side of the container as you remove the strip. **At the same time,** press either green ◇ (START) key. You now have 10 seconds to complete Steps 3 and 4.

3 **Blot** the strip to remove excess urine by ***touching the edge*** to a paper towel. Do not drag the strip across the towel; touch the edge only.



4 **Place** the Reagent Strip, **with the test pads facing up,** into the middle trough of the test strip table. Slide the strip along the table until it touches the **end** of the trough.

☞ **You must place the test strip while the message PLACE STRIP ON TABLE is on the screen. It will appear for 10 seconds.**

5 The table is automatically pulled into the instrument for reading. Results are available in one minute. Be sure not to move or bump the table.

6 **Remove** the used Reagent Strip and discard it in the proper container.

Wipe the test strip table with a damp, lint-free tissue. Do this as often as needed to prevent urine from building up. Also, wipe the table after testing a urine that is visibly bloody or that gives a very high result on any test pad.

Summary of Steps:

1 **Dip** a new Reagent Strip into the urine sample.

2 **Press** ◊ as the strip is removed from the urine; at the same time, drag the strip edge against the side of the container.

3 **Blot** by touching the edge of the strip to a paper towel.

4 **Place** it on the test strip table within 10 seconds.

5 **Discard** the strip when the test is finished.

Getting Results

If results are printed:
The test results are automatically printed. Press the **PRINT** key to reprint the last set of test results. Press **PAPER,** if desired, to add blank lines after the results.

If results are displayed:
To view results, press the ↓ key repeatedly. When all results have been displayed and recorded, press **EXIT.** To display the results again, press **DISPL.**

Thermal print will fade with time. Also, do not cover thermally printed results with transparent tape.

When You Are Finished Testing

1 Clean the test strip table and check the white bar at the end of each day or after testing 50 strips, whichever is more often. Follow the directions for "Daily Cleaning," given on page 18.

*You will be prompted to clean the table after every 50 strips. Press **CONT** to return to the READY FOR TEST screen.*

2 Be sure the test table is empty. Then gently push the table about halfway into the instrument.

3 The instrument can be left *on* when it is not being used. However, if you are using the battery pack, turn the instrument *off* to save battery power.

If the battery pack is installed, a unique tone will sound after 15 minutes of nonuse to remind you to turn the instrument off. It will repeat in 5 minutes, then again every minute.

Operating Notes

▲ The instrument does not detect when the internal printer is out of paper. However, a pink edge will appear on the last several feet of paper. Change the roll shortly after you see this.

▲ If you never erase the memory or reset the sequence number, the number will continue to increase until 999 is reached. The next number will then be 001.

5 Cleaning the Instrument

Daily Cleaning

The test strip table must be kept clean if the instrument is to provide accurate test results and operate correctly. Clean the table and check the white bar at the end of every day.

1 Remove the test strip table by pulling it straight out of the instrument.

2 Wet a cotton-tipped stick with distilled water. Thoroughly scrub the trough and surrounding areas. **Do not touch the white bar.** Rinse the entire table (both top and bottom) with distilled water.

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

4 Check the white bar for dust, marks, or scratches. If it is dirty, wet a new cotton-tipped stick and gently wipe the bar. Allow the white bar to air dry and check it again. If it is scratched or scuffed, or if it cannot be cleaned, replace the table (see page 27).

5 If you want to disinfect the table, do that now. Or insert the table into the instrument, pushing it in about halfway.

☞ **Do not use anything that will scratch the white bar. Do not use solvents of any kind to clean the bar.**

Disinfecting the Table

1 Remove, clean, and dry the table.

2 Several solutions are safe to use on the table when they are used for no longer than 10 minutes once a day. Prepare one of the following solutions:

▲ **Cidex®*, Theracide®*,** and **Amphyl®*** — these products (or their equivalent) can be purchased for use in general disinfection. Prepare and use the solution according to the directions that come with the product.

▲ **Household Bleach** (5% sodium hypochlorite) — can be used either full strength or diluted to as much as a 1:20 dilution. To make a 1:20 dilution, add 5 mL of bleach to a container and add 95 mL of water, for a total volume of 100 mL. (To make a 1:10 dilution, combine 10 mL of bleach and 90 mL of water.)

▲ **Isopropyl Alcohol** (70% to 85%) — can be used full strength.

☞ **Use of any other solution may damage the table.**

* **Cidex** (registered trademark of Johnson & Johnson) is a 3.2% glutaraldehyde solution.
Theracide (registered trademark of Lafayette Pharmaceuticals, Inc., Lafayette, IN) is a quaternary ammonium solution.
Amphyl (registered trademark of National Laboratories, L&F Products, Montvale, NJ) is a phenol solution.

3 Fill a tall, narrow container to a depth of about 4 inches (10 cm) with the solution you have prepared.

4 Place the table into the solution, making sure the white bar remains above the liquid level.

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

5 Soak the table for no longer than 10 minutes, then rinse it thoroughly with water.

6 Dry the table with a soft cloth or tissue and insert it into the instrument.

Removing Heavy Buildup

If the table is cleaned each day, heavy buildup should not occur. However, if the urine has dried on the table for many days, you may need to use a stronger solution to clean the table completely.

1 Obtain a small volume of 0.1N sodium hydroxide (NaOH).

2 Remove the table from the instrument and clean it.

3 Wet a cotton-tipped stick with the NaOH. Thoroughly clean the trough and side areas of the table until all urine is removed.

4 Rinse the table **thoroughly** with water to remove the NaOH.

5 Wipe the surface of the table and the grooves on the underside of the table with a damp cloth. Then dry the table with a soft cloth or tissue and insert it into the instrument.

☞ **Do not touch the white bar with the NaOH!**

General Cleaning

Always keep the outside of the CLINITEK® 50 instrument clean and free of dust. You can wipe the outside with a *damp* (not wet) cloth and a mild detergent.

Wipe the display screen with a soft, nonabrasive cloth that has been dampened with a mild glass cleaner. Do not spray the glass cleaner directly onto the screen. Do not use laboratory wipes, such as Kimwipes®, since they may scratch the screen.

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

The keypad and display may be disinfected using the same solutions as for the test strip table (see page 19). Wipe the solution on and allow to remain for 10 minutes. Rinse using a clean cloth dampened with water, then dry.

Appendix

Solving Problems

Your CLINITEK® 50 Analyzer will give you trouble-free operation if you follow the directions for using and cleaning the instrument. If a problem occurs, however, an error message will be displayed. Follow the steps on the next page to help solve the problem.

If the printer is being used, most error messages will also show the word **HELP.** You can press the key under this word to print a description of the error and how to correct it. Press the key under the word **CONT** to continue. With most errors, the display will return to the READY FOR TEST screen; with certain errors, you will be told to turn the power *off,* then *on* again.

If the Bayer Reagent Strips seem to be causing the problem, carefully read the direction insert that comes with the Reagent Strips for information that might help solve the problem.

If the Display is Blank

If there are no words on the display after the instrument has been turned *on,* check for each of these possible causes:

▲ **The printer cover is not latched:** This might occur only if the serial number of your instrument begins with "6510A." If the cover is unlatched, the instrument turns itself *off;* it turns *on* again when the cover is snapped shut. *If a test was being read or results being printed when the cover was raised, the results will be lost and the specimen must be retested.*

▲ **The power cord is not plugged in:** Check the connections at the instrument, transformer, and wall outlet.

▲ **The batteries in the battery pack are dead:** Place fresh batteries into the pack.

▲ **The instrument is broken:** Contact Customer Service (see page 25).

Error Message	Possible Cause and Remedy
REPLACE BATTERIES	The batteries do not have enough power to test any more strips. Turn the power *off* and replace the batteries.
STRIP PROBLEM-RETEST HELP CONT	A test strip is not present, is dry, or is not positioned properly (upside down, not touching the end of the test table, or not laying flat in the middle trough); the wrong table is inserted for the strip being used; or the test being used cannot be identified by the software. Discard the strip, then press **CONT** and retest using a new test strip and the correct table; be sure the name of the strip you are using is shown on the display.
TABLE PROBLEM-RETEST HELP CONT	The test table is not in its correct position. The instrument or table may have been moved or bumped during testing, or the bottom of the table may be dirty. Discard the strip. Remove and clean the table, then reinsert. Press **CONT** and retest with a new test strip.
INSTRUMENT ERROR X HELP CONT	Error 3: The table is not present or is not pushed in far enough to allow movement. Push the table in about halfway. All other Errors: Discard the strip. Turn the instrument *off,* wait several seconds, then turn it back *on.* If the error occurs again, contact Customer Service (see page 25).

If you need additional help, our Technical Care Center is here to assist you. Before you call, please fill out this checklist (you may want to make a photocopy of the page first). Then call the nearest Bayer office using the list on the next page.

CLINITEK® 50 Problem Checklist

Serial Number __ __ __ __ __ __ __ __ __ __ __

Installation Date _____

	YES	NO
1. Have you reviewed the error messages on page 23?	☐	☐
2. Does the test table move out to the "load" position when the Analyzer is first turned *on?*	☐	☐
3. If Step 2 is NO —		
• Is the power cord plugged into a live electrical outlet, into the transformer, and then into the Analyzer?	☐	☐
• If using the battery pack, are the batteries fully charged and correctly placed in the pack and the cord plugged into the Analyzer?	☐	☐
4. Does the display show the expected messages? (If the display is blank, see page 22 for possible causes.)	☐	☐
5. Does the test table move into the Analyzer shortly after the ◇ key is pressed?	☐	☐
6. Does a test strip dipped into a negative control provide correct results?	☐	☐
• Has a second test strip been tried?	☐	☐
7. Is the name of the Bayer Reagent Strip shown on the display the same as the product being used? (If using any of the MULTISTIX PRO® Reagent Strips, is the family name of the product shown on the display?)	☐	☐
8. Does the display or printout show the correct test names and reasonable results?	☐	☐
9. Is the test table or the white bar dirty, scratched, or damaged?	☐	☐
10. Does the test table operate correctly?	☐	☐

If not, describe: _____

_____

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

_____

_____

Where to Call for Service

If you are located in the United States, contact the Technical Care Center of Bayer Corporation by calling toll free:

1-877-229-3711

The office is open from 8:00 AM to 8:00 PM Eastern Time (weekend and holiday schedule may vary).

If you are located in a country other than the United States, call the Bayer office that is nearest you:

Canada

Bayer Inc. Healthcare Division
77 Belfield Road
Toronto, Ontario M9W 1G6
Telephone: 416-248-0771
1-888-406-2222

U.K.

Bayer Plc, Bayer Diagnostics
Bayer House
Strawberry Hill
Newbury RG14 1JA
Telephone: 01635 566211

Australia

Bayer Diagnostics
2 Keith Campbell Court
Scoresby VIC 3179
Telephone (toll free):
1800 034 490

East Asia, Pakistan, Sri Lanka, Bangladesh

Bayer (Singapore) Pte, Ltd.
Regional Headquarters BG-DS
9 Benoi Sector
Singapore 629844
Telephone: 65 261-3389
Fax: 65 266-3376

Ordering Accessories

Product No.	Description
6511	Battery Pack and Batteries
5773	Thermal Printer Paper (5 rolls)
1364	CHEK-STIX® Combo Pak Control Strips (1 bottle each — Positive and Negative Control Strips)
1360	CHEK-STIX® Positive Control Strips for Urinalysis (1 bottle of 25 strips)
6517	Computer Cable/Connector Kit
6521	Software Update Kit (Cable and software disk can also be ordered separately)

Where to Order:

In the United States, you can order these accessory items directly from your authorized CLINITEK distributor.

In countries other than the United States, you can order these accessory items through your nearest Bayer office. You can find the address and phone number on page 25.

Ordering Replacement Parts

Part No.	Description
95001874	Test Strip Table — Long (labeled “L”) (for use with Bayer Reagent Strips with five or more tests and with CLINITEK® Microalbumin Strips)
95001875	Test Strip Table — Short (labeled “S”) (for use with Bayer Reagent Strips with four or fewer tests except for CLINITEK Microalbumin Strips)
50062316	Printer Cover

Where to Order:

In the United States, you can order these replacement parts directly from:

Instrument Service
Bayer Corporation
P.O. Box 2004
Mishawaka, IN 46546

or by calling toll free:
1-800-348-8100

In countries other than the United States, you can order these replacement parts through your nearest Bayer office. You can find the address and phone number on page 25.

Specifications

Power Required:

Power Transformer:
Input: 100-250 V~, 50/60 Hz, 0.5-0.3 A, grounded
Output: +9 V ⎓, 2.78 A

Optional Battery Pack — Holds 6 “AA” standard alkaline or rechargeable NiCad batteries

Up to 200 tests can be run when using new alkaline batteries, fewer with rechargeable batteries.

Instrument Fuse:
4A, 63V, Quick-Acting
(not replaceable by the user)

Line Leakage Current:

<0.5 milliamperes in normal condition
<3.5 milliamperes in single fault condition
(Testing protocol and allowable limits as specified by the safety standards for laboratory equipment outlined in UL 3101-1, CSA 22.2, No. 1010.1, and IEC 1010-1.)

Computer Interface:

Customized RJ11 Cable
(For use in connecting to a computer only)

Dimensions:

Depth — 23.5 cm (9.2 in.)
Width — 15.2 cm (6.0 in.)
Height — 15.5 cm (6.1 in.)

Weight:

Instrument only — 1.25 kg (2.8 lbs.)
Instrument with Battery Pack — 1.42 kg (3.1 lbs.)

Ambient Operating Temperature Range:

18°C to 30°C (64°F to 86°F)

Optimum Operating Temperature Range:

22°C to 26°C (72°F to 79°F)

Ambient Operating Humidity Range:

20% to 85% Relative Humidity

Safety Standards:

The CLINITEK® 50 Urine Chemistry Analyzer (Models 6510 and 6510A) conforms to the Low Voltage Safety Directive 73/23/EEC. The instrument is listed by the Underwriters’ Laboratories, Inc. (UL) and the Canadian Standards Association (CSA) as certified and complies with the safety standards specified in UL 3101 and CSA-C22.2, No. 1010.1.

Model 6510A conforms to EMC Directive 89/336 Amendment 92/31/EEC.

Warning:

This instrument must be used in the manner specified in this User’s Guide in order to provide the safety and performance standards specified.

Symbols:


Refer to User’s Guide for complete information on using this instrument.


DC Voltage Power Input

Computer Interface

CLIA Status:

The CLINITEK 50 Analyzer is “Waived” per CLIA ’88.

Traditional Bayer Reagent Strips

Test	Abbre-viation	Units	Printed/Displayed Results	
			Normal System	+ / – System
Color*			YELLOW ORANGE RED GREEN BLUE BROWN	No Difference
Glucose	GLU	mg/dL	NEGATIVE 100 250 500 > = 1000	NEGATIVE TRACE 1+ 2+ 3+
Bilirubin	BIL		NEGATIVE SMALL MODERATE LARGE	NEGATIVE 1+ 2+ 3+
Ketone	KET	mg/dL	NEGATIVE TRACE 15 40 > = 80	NEGATIVE TRACE 1+ 2+ 3+
Specific Gravity	SG		< = 1.005 1.010 1.015 1.020 1.025 > = 1.030	No Difference
Occult Blood	BLO		NEGATIVE TRACE-LYSED TRACE-INTACT SMALL MODERATE LARGE	NEGATIVE TRACE-LYSED TRACE-INTACT 1+ 2+ 3+
pH	pH		5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 > = 9.0	No Difference
Protein	PRO	mg/dL	NEGATIVE TRACE 30 100 > = 300	NEGATIVE TRACE 1+ 2+ 3+
Urobilinogen	URO	E.U./dL	0.2 1.0 2.0 4.0 > = 8.0	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Leukocytes	LEU		NEGATIVE TRACE SMALL MODERATE LARGE	NEGATIVE TRACE 1+ 2+ 3+

*Color may be preceded with “LT.” or “DK.”

Shaded areas = abnormal results

Table 1

Traditional Bayer Reagent Strips
ENGLISH — CONV.
Units — Conventional

Traditional Bayer Reagent Strips

Test	Abbre-viation	Units	Printed/Displayed Results	
			Normal System	+ / – System
Color*			YELLOW GREEN ORANGE BLUE RED BROWN	No Difference
Glucose	GLU	mmol/L	NEGATIVE 28 5.5 > = 55 14	NEGATIVE 2+ TRACE 3+ 1+
Bilirubin	BIL		NEGATIVE MODERATE SMALL LARGE	NEGATIVE 2+ 1+ 3+
Ketone	KET	mmol/L	NEGATIVE 3.9 TRACE > = 7.8 1.5	NEGATIVE 2+ TRACE 3+ 1+
Specific Gravity	SG		< = 1.005 1.020 1.010 1.025 1.015 > = 1.030	No Difference
Occult Blood	BLD	Ery/µL	NEGATIVE Ca 25 TRACE-LYSED Ca 80 TRACE-INTACT Ca 200	NEGATIVE 1+ TRACE-LYSED 2+ TRACE-INTACT 3+
pH	pH		5.0 6.5 8.0 5.5 7.0 8.5 6.0 7.5 > = 9.0	No Difference
Protein	PRO	g/L	NEGATIVE 1.0 TRACE > = 3.0 0.3	NEGATIVE 2+ TRACE 3+ 1+
Urobilinogen	UBG	µmol/L	3.2 66 16 > = 131 33	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Leukocytes	LEU	Leu/µL	NEGATIVE Ca 125 Ca 15 Ca 500 Ca 70	NEGATIVE 2+ TRACE 3+ 1+

*Color may be preceded with “LT.” or “DK.”

Shaded areas = abnormal results

Table 2

Traditional Bayer Reagent Strips
ENGLISH — S.I.
Units — International (S.I.)

Traditional Bayer Reagent Strips

Test	Abbre-viation	Units	Printed/Displayed Results	
			Normal System	+ / – System
Color*			YELLOW ORANGE RED GREEN BLUE BROWN	No Difference
Glucose	GLU		NEGATIVE 1+ 2+ 3+ 4+	NEGATIVE TRACE 1+ 2+ 3+
Bilirubin	BIL		NEGATIVE 1+ 2+ 3+	No Difference
Ketone	KET		NEGATIVE 1+ 2+ 3+ 4+	NEGATIVE TRACE 1+ 2+ 3+
Specific Gravity	SG		< = 1.005 1.010 1.015 1.020 1.025 > = 1.030	No Difference
Occult Blood	BLD		NEGATIVE + / – + / – INTACT 1+ 2+ 3+	No Difference
pH	pH		5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 > = 9.0	No Difference
Protein	PRO		NEGATIVE + / – 1+ 2+ 3+	NEGATIVE TRACE 1+ 2+ 3+
Urobilinogen	URO	µmol/L	3.2 16 33 66 > = 131	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Leukocytes	LEU		NEGATIVE 1+ 2+ 3+ 4+	NEGATIVE TRACE 1+ 2+ 3+

*Color may be preceded with “LT.” or “DK.”

Shaded areas = abnormal results

Table 3

Traditional Bayer Reagent Strips
ENGLISH — NORDIC
Units — Nordic Plus System

Test	Abbre-viation	Units	Printed/Displayed Results	
			Normal System	+ / – System
Color*			YELLOW ORANGE RED GREEN BLUE BROWN	No Difference
Glucose	GLU	mg/dL	NEGATIVE 100 250 500 > = 1000	NEGATIVE TRACE 1+ 2+ 3+
Bilirubin	BIL		NEGATIVE SMALL MODERATE LARGE	NEGATIVE 1+ 2+ 3+
Ketone	KET	mg/dL	NEGATIVE TRACE 15 40 > = 80	NEGATIVE TRACE 1+ 2+ 3+
Specific Gravity	SG		< = 1.005 1.010 1.015 1.020 1.025 > = 1.030	No Difference
Occult Blood	BLO		NEGATIVE TRACE-LYSED TRACE-INTACT SMALL MODERATE LARGE	NEGATIVE TRACE-LYSED TRACE-INTACT 1+ 2+ 3+
pH	pH		5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 > = 9.0	No Difference
Urobilinogen	URO	E.U./dL	0.2 1.0 2.0 4.0 > = 8.0	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Leukocytes	LEU		NEGATIVE TRACE SMALL MODERATE LARGE	NEGATIVE TRACE 1+ 2+ 3+
Protein	PRO	mg/dL	NEGATIVE 15 30 100 300	NEGATIVE LOW 1+ 2+ 3+
Creatinine	CRE	mg/dL	10 50 100 200 300	No Difference
Protein-to-Creatinine Ratio	P:C	mg/g	NORMAL DILUTE† NORMAL 150 ABNORMAL 300 ABNORMAL > 500 ABNORMAL	No Difference

*Color may be preceded with "LT." or "DK." Shaded areas = abnormal results

†Specimen is too dilute to accurately determine ratio result. Repeat test on new specimen.

Table 4

MULTISTIX PRO Reagent Strips
ENGLISH — CONV.
Units — Conventional

Test	Abbre-viation	Units	Printed/Displayed Results	
			Normal System	+ / – System
Color*			YELLOW GREEN ORANGE BLUE RED BROWN	No Difference
Glucose	GLU	mmol/L	NEGATIVE 28 5.5 > = 55 14	NEGATIVE 2+ TRACE 3+ 1+
Bilirubin	BIL		NEGATIVE MODERATE SMALL LARGE	NEGATIVE 2+ 1+ 3+
Ketone	KET	mmol/L	NEGATIVE 3.9 TRACE > = 7.8 1.5	NEGATIVE 2+ TRACE 3+ 1+
Specific Gravity	SG		< = 1.005 1.020 1.010 1.025 1.015 > = 1.030	No Difference
Occult Blood	BLD	Ery/µL	NEGATIVE Ca 25 TRACE-LYSED Ca 80 TRACE-INTACT Ca 200	NEGATIVE 1+ TRACE-LYSED 2+ TRACE-INTACT 3+
pH	pH		5.0 6.5 8.0 5.5 7.0 8.5 6.0 7.5 > = 9.0	No Difference
Urobilinogen	UBG	µmol/L	3.2 66 16 > = 131 33	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Leukocytes	LEU	Leu/µL	NEGATIVE Ca 125 Ca 15 Ca 500 Ca 70	NEGATIVE 2+ TRACE 3+ 1+
Protein	PRO	g/L	NEGATIVE 1.0 0.15 3.0 0.3	NEGATIVE 2+ LOW 3+ 1+
Creatinine	CRE	mmol/L	0.9 17.7 4.4 26.5 8.8	No Difference
Protein-to-Creatinine Ratio	P:C	mg/mmol	NORMAL DILUTE† NORMAL 17.0 ABNORMAL 33.9 ABNORMAL > 56.6 ABNORMAL	No Difference

*Color may be preceded with "LT." or "DK." Shaded areas = abnormal results

†Specimen is too dilute to accurately determine ratio result. Repeat test on new specimen.

Table 5

MULTISTIX PRO Reagent Strips
ENGLISH — S.I.
Units — International (S.I.)

Test	Abbre-viation	Units	Printed/Displayed Results	
			Normal System	+ / – System
Color*			YELLOW ORANGE RED GREEN BLUE BROWN	No Difference
Glucose	GLU		NEGATIVE 1+ 2+ 3+ 4+	NEGATIVE TRACE 1+ 2+ 3+
Bilirubin	BIL		NEGATIVE 1+ 2+ 3+	No Difference
Ketone	KET		NEGATIVE 1+ 2+ 3+ 4+	NEGATIVE TRACE 1+ 2+ 3+
Specific Gravity	SG		< = 1.005 1.010 1.015 1.020 1.025 > = 1.030	No Difference
Occult Blood	BLD		NEGATIVE +/– +/– INTACT 1+ 2+ 3+	No Difference
pH	pH		5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 > = 9.0	No Difference
Urobilinogen	URO	µmol/L	3.2 16 33 66 > = 131	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Leukocytes	LEU		NEGATIVE 1+ 2+ 3+ 4+	NEGATIVE TRACE 1+ 2+ 3+
Protein	PRO		NEGATIVE LOW 1+ 2+ 3+	No Difference
Creatinine	CRE	mmol/L	0.9 4.4 8.8 17.7 26.5	No Difference
Protein-to-Creatinine Ratio	P:C	mg/mmol	NORMAL DILUTE† NORMAL 17.0 ABNORMAL 33.9 ABNORMAL > 56.6 ABNORMAL	No Difference

*Color may be preceded with "LT." or "DK." Shaded areas = abnormal results

†Specimen is too dilute to accurately determine ratio result. Repeat test on new specimen.

Table 6

MULTISTIX PRO Reagent Strips
ENGLISH — NORDIC
Units — Nordic Plus System

Be kind to the environment.
Please recycle the User's
Guides you do not use.