

Urine Analyzer HTI CL-50 Plus



Operator's Manual

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| Document Number | : | OM-E-CL-50-20 |
| Revision Level | : | Rev.4 |
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1 Operation introduction

1.1 Introduction

The HIGH TECHNOLOGY INC., CL-50 Plus Urine Analyzer (referred to as the "CL-50 Plus" or the instrument) is a semi-automated urinalysis instrument based on the principle of dual-wavelength reflectance, integrated with electronic, optics and mechanics.

The CL-50 Plus can simultaneously perform the following tests in Urine depending on which reagent test strips is used: Leukocytes, Ketone, Nitrite, Urobilinogen, Bilirubin, Protein, Glucose, Specific Gravity, pH, Blood, Urine Creatinine, Urine Calcium, Microalbumin, and Ascorbic Acid.



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1.2 Specifications

- 1) **Reagent Strips:**
H10, H11, or H13
- 2) **Measuring Principle:**
By dual-wavelength light reflectance testing
- 3) **Throughput:**
120 tests/hour (max) or 60 tests/hour
- 4) **Measuring Mode:**
Continuous automatic testing or single testing
- 5) **Test Items:**
H10 strips: Leukocytes, Ketone, Nitrite, Urobilinogen, Bilirubin, Protein, Glucose, Specific Gravity, pH, and Blood
H11 strips: Leukocytes, Ketone, Nitrite, Urobilinogen, Bilirubin, Protein, Glucose, Specific Gravity, pH, Blood, and Ascorbic Acid
H13 strips: Leukocytes, Ketone, Nitrite, Urobilinogen, Bilirubin, Protein, Glucose, Specific Gravity, pH, Blood, Urine Creatinine, Urine Calcium and Microalbumin
- 6) **Display:**
LCD display screen, English menu, operational information and test results expressed with semi-quantitative symbols and SI international unit
- 7) **Printing:**
Thermal printer paper prints test results, (life span: 600 thousand lines). The system also has a connection for an external printer (serial or parallel interface) which is optional
- 8) **Operating Environment:**
15°C to 30°C RH: ≤80% (recommended)
Extreme Environment:
5°C to 40°C RH: ≤85%
Storage Environment:
-20°C to 55°C RH: ≤80%
- 9) **Control function:**
Self-checking, Testing and malfunction-verification by a microcomputer built-in to the instrument
- 10) **Output Signal Interface:**
Serial interface (output via the RS232), parallel interface and PS/2 interface
- 11) **Storage:**
Up to a 1000 samples can be stored
- 12) **Weight:**
1.3 kg
- 13) **Dimensions:**
240 mm X 190 mm X 115 mm
- 14) **Power Requirement:**
AC 110-240 V, 50/60 Hz
- 15) **Power Dissipation:**
30VA
- 16) **Service Life:**
8 years



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1.3 Unpacking

Inspect the box for any damage. Open the box and check the following:

- (1) Carefully unpack the shipping carton and take out the CL-50 Plus instrument and accessories.
- (2) Check the contents with the packing list as shown in for quantity and check for any breakage
- (3) Please notify the carrier or the local distributor at once if any damage has occurred.

1.4 Structure and principle

1.4.1 Structure

The structure is as Figure 1. This instrument is composed of optional-electronic detector system, transfer-part, I/V converter, CPU, printer, LCD display, keyboard and power supply.

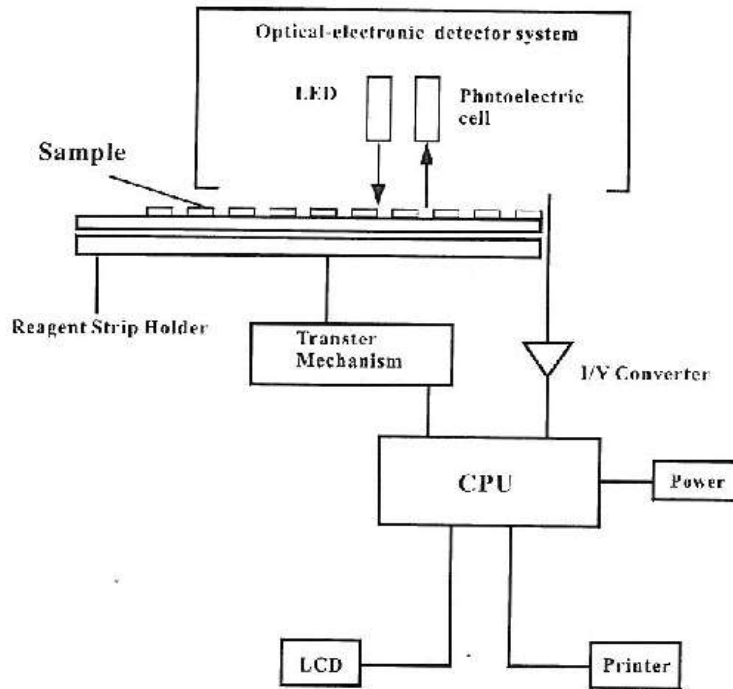


Figure 1



| | |
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1.4.2 Principle

$$R (\%) = \frac{(T_m \times C_s)}{(T_s \times C_m)} \times 100\%$$

- R:** Reflectance ratio
- T_m:** Reflectance intensity of measurement wavelength for test area
- T_s:** Reflectance intensity of reference wavelength for test area
- C_m:** Reflectance intensity of measurement wavelength for calibration pad
- C_s:** Reflectance intensity of reference wavelength for calibration pad

In the Optical Unit, two different ranges of wavelength from the multi-LED fall on the reacted parts of the test strip and the color-tone-compensated section. The strength of the electricity correlates with reflectance. Then the electric signals will be processed by the CPU after being transformed by the 1/V converter, and the test results can be printed out.

1.4.3 Human Eye vs. Instrumental Optics

The human eye is inherently different in the colors that it perceives compared to those detected by an optical system. The human eye is capable of determine differences in shade and color by the minute, whereas the optical system cannot. However, optical systems can detect specific colors that are hidden or masked by other colors apparent to the human eye.

Since there are slight difference between the human eye vs an optical system, an exact agreement between the two options may be hard to find. Yet, agreement between the two can be found visually, if the user reports a value within one visual color block compared to the optical system reading.

Each color block or instrumental result represents a range of values. Because of specimen and reading variability, specimens with analyte concentrations that fall between nominal levels may give results at either level. Results will usually be within one level of the true concentration. Exact agreement between visual results and instrumental results might not be found because of the inherent differences between the perception of the human eye and the optical systems of the instruments.



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1.4.4 The semi-quantitative denotation and concentration of Urine reagent strip

Table-1 shows the test method and data.

There are many factors that may affect the test results, such as when the sample is collected, the freshness of the urine sample, drinking and eating habit of the patient, as well as pre- sports and post-sports activities. Therefore, the semi-quantitative value is good enough for medical diagnoses. The test results are rounded off to a whole number. It is possible that a sample tested at different times may give rise to slight variations in reported values.

| 10 | 11 | 13 | Test | SemiQuantitative Symbol and Concentration | | | | | | | | | |
|----|----|----|------------------|-------------------------------------------|------------|------------|-------|-------|-------------|-----------|-----|-----|-----|
| ● | ● | ● | Leukocytes | SemiQuantitative | — | ± | +1 | +2 | +3 | | | | |
| | | | | Cell/ μ L | 0 | 15 | 70 | 125 | 500 | | | | |
| ● | ● | ● | Ketone | SemiQuantitative | — | ± | +1 | +2 | +3 | | | | |
| | | | | mmol/L | 0 | 0.5 | 1.5 | 4.0 | ≥ 8.0 | | | | |
| ● | ● | ● | Nitrite | SemiQuantitative | — | + | | | | | | | |
| ● | ● | ● | Urobilinogen | SemiQuantitative | Normal | | +1 | +2 | +3 | | | | |
| | | | | μ mol/L | | | 33 | 66 | ≥ 131 | | | | |
| ● | ● | ● | Bilirubin | SemiQuantitative | — | | +1 | +2 | +3 | | | | |
| | | | | μ mol/L | 0 | | 8.6 | 33 | 100 | | | | |
| ● | ● | ● | Protein | SemiQuantitative | — | ± | +1 | +2 | +3 | | | | |
| | | | | g/L | 0 | 0.15 | 0.3 | 1.0 | 3.0 | | | | |
| ● | ● | ● | Glucose | SemiQuantitative | — | ± | +1 | +2 | +3 | +4 | | | |
| | | | | mmol/L | 0 | 2.8 | 5.5 | 14 | 28 | ≥ 55 | | | |
| ● | ● | ● | Specific Gravity | | 1.005 | 1.010 | 1.015 | 1.020 | 1.025 | 1.030 | | | |
| | | | | | | | | | | | | | |
| ● | ● | ● | Occult Blood | SemiQuantitative | — | ± | +1 | +2 | +3 | | | | |
| | | | | Cell/ μ L | 0 | 10 | 25 | 80 | 200 | | | | |
| ● | ● | ● | pH | 4.5 | 5.0 | 5.5 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 |
| | ● | | Ascorbic Acid | SemiQuantitative | — | ± | +1 | +2 | +3 | | | | |
| | | | | mmol/L | 0 | 0.6 | 1.4 | 2.8 | 5.6 | | | | |
| | | ● | Creatinine | SemiQuantitative | * | | | | | * | | | |
| | | | | mmol/L | ≤ 0.9 | 4.4 | 8.8 | 17.6 | ≥ 26.4 | | | | |
| | | ● | Urine calcium | SemiQuantitative | * | | | | | * | | | |
| | | | | mmol/L | ≤ 1.0 | 2.5 | 5.0 | 7.5 | ≥ 10 | | | | |
| | | ● | Micro albumin | SemiQuantitative | | * | | | | | | | |
| | | | | mg/L | 0 | ≥ 100 | | | | | | | |

Table-1

| | | |
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1.5 Outer Appearance and Components

1.5.1 Appearance

1.5.1.1 Front of CL-50 Plus Urine Analyzer (Figure 2)



Figure 2

A: Printer and printer cover

A Thermal printer is used for printing test results; In order to put the thermal printer paper in lift up the printer cover.

B: Display screen

Displays the operating hints and test results.

C: Keys

There are 4 keys on the instrument panel. Press the key according to the operating hints to perform the operation required.

D: Push bar (Also called Urine reagent strip holder)

A platform that holds the reagent test strip which is going to be tested.

1.5.1.2 Rear of CL-50 Plus Urine Analyzer (Figure 3)

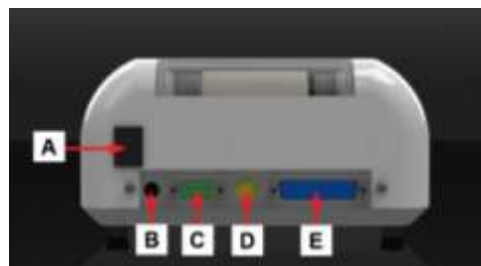


Figure 3

A: Power switch

Turn the power on or off. " I " means power on, " 0 " means power off.



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B: DC 12V input

DC 12V input. Use the adapter which comes with the instrument to insure the instrument operates at the correct voltage.

C: Serial interface

Standard 9-pin socket, RS232 port

D: PS/2 input port

Standard 6-pin mini-DIN socket.

E: Parallel interface

Standard 25-pin socket.



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1.6 Function

1.6.1 Self-checking

Turn on the power, the instrument enters the system checking screen, and "System checking Please Wait ..." message is displayed. When the system checking has completed, the instrument is ready for testing.

1.6.2 Print and display

The test results will be displayed on the screen when the analysis has finished, and the printer will print the results automatically.

1.6.2.1 Print

An example of a printed test result using an H10 test strip is shown in figure 4 and an H13 test strip in figure 5.

```

NO.000001      2005-01-10
ID:XXXXXXXX    10:15:56
LEU   -        0 Cell/ µ L
KET   -        0 mmol/L
NIT   -
URO   Normal
BIL   -        0 µ mol/L
PRO   -        0 g/L
GLU   -        0 mmol/L
SG    1.030
BLD   -        0Cell/ µ L
pH    5.0

```

```

NO: 000001      2005-01-10
ID: XXXXXXXX   10:15:56
WBC   -        0          Cell/uL
KET   -        0          mmol/L
NIT   -
URO   Normal
BIL   -        0          µmol/L
PRO   -        0          g/L
GLU   -        0          mmol/L
SG    1.030
BLD   -        0          Cell/uL
pH    5.0
CR    4.4          mmol/L
Ca    ≤ 1.0        mmol/L
MA    ≥ 100        mg/L

```

Figure 4 H10 Printed results

Figure 5 H13 Printed results

Refer to figure 4

Line 1: No. 000001 means the sequence number and 2005-01-10 is the date: year-month-day

Line 2 for test strip H10: ID: XXXXXXXX is the patient ID scanned in by a barcode reader only when the bar code is turned on. And the time, 10:15:56; hour: minute: second.

Line 3 to line 10 for test strip H10: Test results.

- The first column is an abbreviation of the test name;
- The second column is the medical symbol. The “-” symbol stands for negative and the “+” stands for positive. The difference from the routine expression is that we use “+2” to replace “+ +”, and “+3” to replace “+ + +”.
- The third column is the objective value (the result) of the sample, which is displayed by the semi-quantitative method. The figures of this column correspond to the medical symbol in the second column one by one. It's a reference for the doctor. Symbol “+3+” means a high concentration. For example PRO +3 ≥ 3g/L.
- The fourth column is the international unit of the data.

Refer to figure 5

Line 1: No. 000001 means the sequence number and 2005-01-10 is the date: year-month-day



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Line 2 for test strip H13: time, 10:15:56; hour: minute: second

Line 3 for test strip H13: ID: XXXXXXXX is the patient ID scanned in by a barcode reader only when the bar code is turned on

Line 4 to 13 for test strip 13

- The first column is an abbreviation of the test name;
- The second column is the medical symbol. The “-“ symbol stands for negative and the “+“ stands for positive. The difference from the routine expression is that we use “+2” to replace “+ +”, and “+3” to replace “+ + + “.
- The third column is the objective value (the result) of the sample, which is displayed by the semi-quantitative method. The figures of this column correspond to the medical symbol in the second column one by one. It’s a reference for the doctor. Symbol “+3+” means a high concentration. For example PRO +3 ≥ 3g/L.
- The fourth column is the international unit of the data.

Note: *When the measured result is positive, there will be an “*” in front of the test name as a prompt to the operator. (Please refer to the operating manual for details.)*

1.6.2.2 Display

The LCD display screen shows the test results after each testing. The first display shows the first 6 items, and the next display shows the remaining. They can be reviewed by pressing the “[↑]” or “[↓]” button. If you choose the “Number” as the result unit then the format will be displayed as: Items name plus semi-quantitative denotation. The concentration of an item without a semi-quantitative denotation will directly be displayed without the unit.

If "English" is chosen as the result unit, the result format is displayed as: item name plus the first three English words of the semi-quantitative result. The item without a semi-quantitative will be directly indicated with the corresponding without the unit. The result unit can be revised in the System Setting screen.

Note: The full names of the test items are as shown in Table 2



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Table- 2 Abbreviation of Test Items

| No. | Abbreviation | Full name |
|-----|--------------|--------------------------------|
| 1 | pH | pH VALUE |
| 2 | NIT | NITRITE |
| 3 | GLU | GLUCOSE |
| 4 | PRO | PROTEIN |
| 5 | BLD | BLOOD |
| 6 | KET | KETONE BODY |
| 7 | BIL | BILIRUBIN |
| 8 | URO | UROBILINOGEN |
| 9 | SG | SPECIFIC GRAVITY |
| 10 | LEU | LEUKOCYTES (White blood cells) |
| 11 | Vc | ASORBIC ACID (VITAMIN C) |
| 12 | CR | CREATININE |
| 13 | Ca | CALCIUM |
| 14 | Ma | MICROALBUMIN |

1.6.3 Data storage and review

This instrument can store up to 1000 records for reviewing and printing. The stored data will not be lost when the power supply is turned off. When the data exceed 1000, the oldest will be removed from the memory.

1.6.4 External printer

The CL-50 Plus can be connected to an external printer for printing test results via a serial or parallel interface.

1.6.5 Communication with a computer

The CL-50 Plus can be interfaced to the COM1 or COM2 of a computer via the RS232 port so that the instrument can communicate with the computer.

1.6.6 Communicate with the PS/2 bar code scanner

The CL-50 Plus can be connected to a bar code scanner through the PS/2 port.



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1.7 Installation

1.7.1 Environment requirement

- (1) Install the instrument on a clean, flat and firm surface, which is free from vibrations.
- (2) Avoid exposure to direct sunlight, a strong magnet field and water. Install the instrument in a room with air-conditioner so that there will be a stable temperature and humidity for the instrument. The most appropriate temperature is 15°C - 30°C, and humidity of RH 80%.
- (3) Keep away from the sunlight, oven radiation or explosive air. Avoid excessive dust and vibration platforms.
- (4) Make sure the adapter is connected to an AC outlet of a low-voltage power supply and the AC outlet is well grounded.

1.7.2 Installation of the printer paper (see figure 6)

- (1) Press the tab lock of the printer cover found on the back side and lift the cover up and off the instrument.
- (2) Remove the rubber paper shaft with your index fingers by pressing and rolling the paper roller shaft towards the front of the CL-50 Plus until it comes out of the notch.
- (3) Place the new roll of printer paper into the CL-50 Plus laying the loose end over the printer.
- (4) Place the paper shaft onto the paper and into the notch. Press the paper roller shaft downwards until it clips into place.
- (5) Pull the paper through the slot in the printer cover and replace the cover

Note:

- a) The built in printer can only print on the thermal side of the paper. If the paper is installed incorrectly the printer will not print anything.
- b) The paper should be replaced before running out.
- c) Insure that the paper is dry before installation. If the paper is wet, exchange it with a dry one to avoid problems.
- d) If paper jamming occurs then replace the paper with a new roll.



Figure 6



| | |
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1.7.3 Installing the Push bar (Urine reagent strip holder) (see figure 7)

Carefully push the test strip tray holder into the front center of the instrument. The instrument will automatically adjust the holder's position when turned on.



Figure 7

1.7.4 The connection of the power cord

Connect the DC12V output of the adapter to the CL-50 Plus and the power cord to a well-grounded 110V to 240V AC power socket.

Note: The instrument should use the AC power ADAPTER that comes with the CL-50 Plus.

1.7.5 Connection with an external printer

If the power is on turn it off and connect the instrument to the printer with the 25-pin parallel port or the 9-pin serial port. The printer may come with a suitable connection cable, but if not, please purchase one.

1.7.6 Connection with a computer

If the power is on turn it off and connect the CL-50 Plus to the computer using the computers serial COM1 or COM 2 port.

Note: The Equipment connection with the CL-50 Plus should be consistent with safety criteria.



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1.8 Operation

1.8.1 General Information

The operator can operate and communicate with the CL-50 Plus by pressing the key pads on the instrument. The last line of information shown on the display screen is function hints for the key pads. For convenience, every function hint corresponds with the closest key.

The instrument makes a short beep sound when any of the active keys are pressed and when the corresponding function is performed the screen function hints change at the same time.

| | |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>WARNING: It could be harmful if the instrument is operated by unskilled or untrained people. The incorrect operation may cause inaccurate test results which may cause the wrong diagnosis, harm to the operator or even breakage of the instrument. Therefore, the operator should be trained before using the CL-50 Plus.</p> |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

1.8.2 Operation

1.8.2.1 Powering on the CL-50 Plus

Turn on the power switch found on the back of the instrument. The instrument will then enter the system checking screen and the following message is displayed “**System checking, Please Wait ...**”. When the CL-50 Plus completes the System checking the display screen will change to the Ready screen as shown in figure 8.

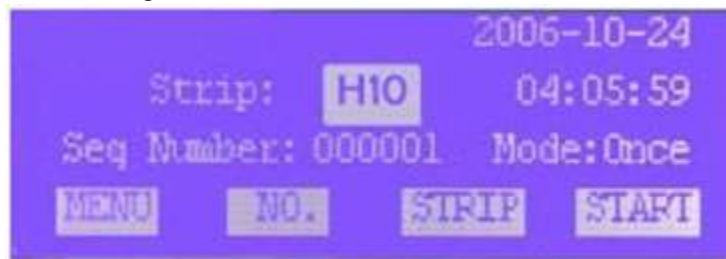


Figure 8

If the strip holder is not clean, the instrument will display: "dirty, please clean it" on the screen. In this case, turn off the power switch, remove the strip holder from the CL-50 Plus, clean the strip holder and reinstall it. After replacing the holder turn the power switch back on.

Note: Please make sure that when the power is on that there is no urine strip or any dust on the strip holder, otherwise the instrument will give a warning that the strip holder is not clean.



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The test paper detector is closed



Sensitivity adjusted

1.8.2.2 Setting

Press the "MENU" key pad on the Ready screen to change the display to the MAIN MENU screen as shown in figure 9.

The MAIN MENU includes the following content: System, Contrast (LCM), Initialize, DataBank, RS232, Info, Printer, Date & Time, GreyMeas. Press the corresponding key pad according to the displayed hint to enter the submenu.



Figure 9

1.8.2.2.1 System:

System Settings menu is displayed in figure 10 and will be explained below.



Figure 10

A) Mode (Test Mode):

Continuous or single test mode is available to select. The continuous test mode means that the instrument will continuously perform testing prompting the user to prepare the next testing sample 30 seconds or 60 seconds in advance. The single test mode means that the instrument will stop testing once a sample test has completed.



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B) Speed (Test Speed):

30s or 60s test time speeds are available for selection.

C) Sensitivity:

The following sensitivities can be selected and adjusted: Default setting, High sensitivity & Low sensitivity. The operator is allowed to adjust every single test item in the Adjust option. For cutoff value, "+" denotes raising the reflectance ratio and decreasing the cutoff value, "-" denotes decreasing the reflectance ratio and raising the cutoff value. For slope, the "+" denotes raising reflectance ratio of high concentration and "-" denotes decreasing reflectance ratio of high concentration.

Note: The adjustable range in the Adjust option is from +10 to -10. This figure is just a relative value of adjustable range not a percentage. It is recommended that the operator collect enough QC test data before using the function of sensitivity adjustment, and check the performance with clinical samples after adjustment.

Adjust option:

- [+]: Used for increasing the reflecting rate
- [-]: Used for reducing the reflecting rate
- [← →]: Switching the positive rate and cutoff
- [↑ ↓]: Moves the cursor to set items. By pressing it for 3 seconds it will save the current setting and exit.

Note: The Sensitivity function is not recommended for general use. Each item can only adjust one kind to compensate, 0: means not to adjust. To save the current settings the user must press the up arrow "[↑]" for 3 seconds, any other way is invalid.



When the middle of the first line displays the following icon, " ", it means the sensitivity is not the default setting. Every time after the instrument performs the System checking, if the sensitivity is not the default setting, the instrument will prompt the user to resume the default setting. Press the [YES] key to resume the default setting. Press the [NO] key to preserve the current setting.

D) Units (Result dimension):

Select Number or English as the testing units. English units and Semi-quantitative units are in accordance with each other as follows:

| | | | |
|----------|---|--------|----|
| Negative | - | Small | +1 |
| Positive | + | Middle | +2 |
| Trace | ± | Large | +3 |

E) Language:

English



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F) Detector (Strip reaction):

The Detector device can be selected to on or off. If the Detector device is on, the instrument will automatically start the testing procedure when the strip has been put in the strip holder. In this case it is not necessary to press START key for initiating the test.



Note: When the middle of the first line displays the following icon, it means the strip detector is Off and the START key will need to be pressed to start the testing procedure.

1.8.2.2.2 Contrast (LCM):

The contrast of the Liquid Crystal Monitor (LCM) can be adjusted by pressing the “[+]” and “[−]” keys.

1.8.2.2.3 Initialize:

Pressing the [Enter] key will cause the instrument to revert back to the initial settings, pressing the [Data] key will clear the testing results which has been automatically stored by the instrument.

Note: The Instrument will clear all the user information when it is initialized returning the CL-50 Plus back to its initial settings. Please select it carefully.

1.8.2.2.4 Databank:

The history records stored in the databank of the instrument can be recalled. When pressing the up arrow key, “[↑]”, the screen will show the previously stored result, pressing the down arrow key, “[↓]”, the screen will show the next stored result, and when continuously pressing the up or down arrow keys, “[↑]” or “[↓]”, the instrument will recall the tenth lower or higher record.

[OUTPUT]: When the Output menu is selected the screen displays the options, (RS232, Print, LPT, ALL), available for data output.

[RS232]: When the RS232 option is selected the test results will be exported through the serial interface.

[PRINT]: When the Print option is selected the test results will be printed out through the internal thermal printer.

[LPT]: When the LPT option is selected the test results will be exported through a parallel port.

[ALL]: When the ALL option is selected the test results will be exported through all the output options: serial interface (RS232), Thermal printer, and parallel port (LPT). After the output selection has been made, the screen will automatically return to the Data Review screen. The hint function on the screen for the [Output] key will then change the hint function to the output option selected. When this key is pressed the present data record will be exported to the selected option. When the key is pressed for 2 seconds, during the “beep” sound, the instrument will export all the records from the current record one to the oldest record. To stop the continuous exporting process, press the key again during the exporting.



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1.8.2.2.5 RS232 (Serial interface):

The **[RS232]**, serial interface, selections are [RS232 OUT: ON] or [RS232 OUT: OFF]. When off is selected the instrument will not export the data when the testing is over.

[FORMAT]: This option enables the type of form to be selected for data export that is suitable to the different computer’s software.

[BAR CODE]: The bar code scanner option is only available in the single test mode. The bar code scanner option has to be enabled for the option to work. When the barcode is enabled an ID column is added to the output format of the thermal printer and the serial and parallel port exporting. The ID column is not stored in the instrument so there will not be any ID column in the data review exporting.

1.8.2.2.6 Info (System information):

This option displays the manufacturer information and software version.

1.8.2.2.7 Printer:

- 1) Inner Printer:
This Option is used to turn on or off the internal thermal printer
- 2) Item Name
The printed result is in English
- 3) LPT [Outer parallel port]:
This Option is used to turn on or off the outer parallel port.

1.8.2.2.8 Date & Time:

This Option is used to change the date and or time.

1.8.2.2.9 GreyMeas:

This Option is for Factory use only.

1.8.2.3 SN (Sequence Number):

This option is to enter the Sequence Number or Patient Number into the CL-50 Plus; In order to change the SN of a sample press the “[+]” key to increase the number or press the “[-]” to decrease the number. After entering the SN press the “[Enter]” key to save it. The Sequence number will always begin with 000001 when the instrument is turned on.

1.8.2.4 Strip setting:

Press **[Strip]** to enter the strip setting screen, there are different choices of reagent strips: H10, H11, H13. Press [← or →] to choose the type you need, press **[Enter]** to store it until the next time it needs to be changed.

1.8.2.5 Start Strip testing:

Press the [Start] key on the ready screen to begin the testing procedure manually.



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1.8.3 Calibration

1.8.3.1 General Introduction:

The check sample (calibration) strips need to be used frequently to perform the calibration on the instrument. There are two check samples (calibration strips) for the instrument. One is for daily use and the other is for standby use. After testing the check sample, compare the results with the reference value. If the results are correct, it means the instrument is working correctly and can be used for testing. Otherwise, use the other check sample strip to calibration again. If the results are still not correct, check if a malfunction has occurred and solve it. It is recommended to perform a QC solution (Please contact the manufacturer to get the QC solution) testing under following situations:

- a) Replacing new reagent strip
- b) Replacing the operator
- c) Questions with testing results

1.8.3.2 Checkout Operation

Make sure the urine reagent test strip being used is the correct type; H10 H11 or H13. If the [Detector] of the instrument is on, put the check sample (calibration strip) on the strip holder and push the strip along with the strip holder to the entrance of the instrument. When the buzzer rings, the instrument will count the time automatically with the completed result displayed and printed in 60 seconds. If the [Detector] is turned off, press the “[Start]” key on the ready screen. When the prompt ring is over, place the check sample on the strip holder according to the requirement. The instrument will display the completed result in 60 seconds.

Note: The check sample should not be soaked in urine or water. Also, if there is debris on the strip holder, please clean the holder before placing the check sample strip on the holder to avoid contaminating it.

1.8.4 Preparations before measurement

Verify the urine reagent test strip type is the correct type H10, H11 or H13. If the incorrect reagent strip type is used then TROUBLE -8 will be displayed on the screen.

Note: The selected reagent strip type will not modify after the turning off the instrument.

Check that the date, time and setting of the printer satisfies the operator’s requirements. Use the **Date & Time** and **Printer option** to make corrections.



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1.8.5 Routine testing

1.8.5.1 Powering on

Securely connect the adapter to the instrument and to the power outlet, then push the power switch to the on, "[|]", position. The instrument will be ready for testing after performing the self-checking.

1.8.5.2 Sample preparation

Prepare the filter paper, urine sample and the urine reagent strip.

1.8.5.3 Measurement

1.8.5.3.1 Single testing mode

If the urine strip Detector is on, totally dip the reagent test strip pads into the urine sample for 2 seconds. Then remove any excess urine on the test strip and place the strip onto the strip holder. Slide the reagent strip along the strip holder into the entrance of the CL-50 Plus. You will hear the buzzer ring. The instrument will automatically start the testing showing the following prompt on the display: "**Testing is going on Please wait...**". The countdown timer on the bottom right-hand side of the screen will start counting down, decreasing by 1 every second. If the bar code import is active, the ID No. can be inputted through the bar code scanner. When the timer shows zero,"0", the results will be displayed. When the strip holder completely comes out, the instrument will return to the Ready screen, however, the screen will still display the results. The tested strip can now be removed from the strip holder and the next sample can be performed.

If the urine strip Detector is off, press the "[Start]" key. The countdown timer will display 65 seconds. The operator has 5 seconds to prepare. When the timer reaches 60 seconds, the buzzer will ring. Then totally dip the test strip reagent pads into the urine sample for 2 seconds, remove any excess urine on the test strip and put the test strip onto the strip holder. When this test is over, the next test can be performed by pressing the "[Start]" key.

1.8.5.3.2 Continuous testing mode

(1) The test speed is set as NORM (normal)

If the urine strip Detector is on, totally dip the reagent test strip pads into the urine sample for 2 seconds. Then remove any excess urine on the test strip and place the test strip onto the strip holder. Push the test strip along the strip holder into the entrance of the CL-50 Plus. You will hear the buzzer ring. The instrument will automatically start the testing showing the following prompt on the display: "**Testing is going on Please wait...**". The countdown timer on the bottom right-hand side of the screen will start counting down, decreasing by 1 every second. When the timer shows "0" or "60" the buzzer rings to remind the user to dip the second sample into the urine, remove the excess urine and be ready for next testing. When the strip holder completely comes out of the CL-50 Plus replace the test strip on the holder and the next sample test will begin.

If the urine strip Detector is off then replace the test strip and press the "[START]" key to begin the next sample. The testing operation is the same as the above except without the detector.



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(2) The test speed is set as FAST (not recommended)

If the urine strip Detector is on, totally dip the reagent test strip pads into the urine sample for 2 seconds. Then remove any excess urine on the test strip and place the test strip onto the strip holder. Slide the test strip along the strip holder into the entrance of the CL-50 Plus. You will hear the buzzer ring. The instrument will automatically start the testing showing the following prompt on the display: **"Testing is going on Please wait... "**. The countdown timer on the bottom right-hand side of the screen will start counting down, decreasing by 1 every second. When the timer shows "38" the buzzer rings to remind the user to dip the next (second) sample into the urine, remove the excess urine and be ready for the next testing, then when the timer has decreased to "12" the buzzer rings again reminding the user to dip into the next (third) sample, remove the excess urine and be ready for the next testing. When the time reaches "0" the results will be displayed and printed, then when the strip holder completely comes out of the instrument replace the test strip on the holder according to the order the test strip was dipped in order to begin the new test.

Note: In the continuous testing mode, the urine reagent test strip should be changed as soon as possible after the reagent strip holder has completely come out. When the reagent strip Detector is on, if the user doesn't change the reagent test strip in time the instrument will show "The strip has not been changed" and the testing will stop. When the reagent strip Detector is off, even if the user doesn't change the reagent test strip, the instrument will continue the testing; it will not stop the testing until there is no reagent test strip on the strip holder.

1.8.5.4 Stop testing

During the testing process when the "[Stop]" key is pressed the instrument will stop the testing process and the strip holder will come out. Also, the testing will automatically stop during the testing if there is no reagent test strip on the strip holder.

1.8.5.5 Turning Off CL-50 Plus

When all the samples have been tested, turn off the CL-50 Plus by pushing the power switch to the off, "[0]", position. If the strip holder is dirty please clean it according to the requirements.

Note: If the CL-50 Plus is not going to be used for a long period of time then turn off the instrument and please remove the power cord from the AC power socket.



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1.8.6 Serial interface

The serial interface in the instrument is a standard RS232 port used to connect a computer or printer to the CL-50 Plus for exporting the results or the history data in the instrument. Turning the serial interface exporting on or off is controlled through the "RS232 OUT" in the "RS232" menu.

- (1) RS232 connector pin assignments**
 - a) The second pin **RXD**: Receive Data
 - b) The third pin **TXD**: Transmit Data
 - c) The fifth pin **GND**: Ground
 - d) Other pins are blank

- (2) Parameter setting**
 - a) Baud rate: 9600BPS
 - b) Data bit:8
 - c) Parity bit: None
 - d) Stop bit: 1 bit

- (3) Exporting data form (Appendix)**
 - a) Regular result exporting form
 - b) Trouble exporting form

1.8.7 PS/2 port

The PS/2 port in the instrument is mainly used for connecting a bar code scanner to the CL-50 Plus. It is used to import the ID No. of the urine sample being tested. Turning the bar code importing port on or off is controlled through the "BAR CODE" option in the "RS232" menu.

- (1) PS/2 port connector pin assignments**
 - a) The first pin: DATA
 - b) The third pin: GND
 - c) The fourth pin: Power supply +5
 - d) The fifth pin: CLK
 - e) The second and the sixth pins are blank.

- (2) Parameter setting**
 - a) Exporting character: LC
 - b) Exporting Finis character: Enter (CR)



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1.9 Maintenance

The CL-50 Plus is a precise instrument that must be handled with care. To make sure that the instrument works well, it is very important to maintain the instrument. If any malfunctions occur, the instrument should be maintained by HTI or by an authorized engineer or be sent to an appointed department for professional maintenance.

(1) General Instrument

- a) Carefully read the operator's manual before operating the instrument.
- b) Always keep the instrument clean for good operating conditions.
- c) If the instrument is not used for a lengthy period of time, cover the instrument with the vinyl dust cover. On resuming instrument operation, conduct a test with the Check Sample before making any determinations.
- d) Do not reconstruct or modify the instrument.

(2) General cleaning

Keep the instrument clean and free of dust. If cleaning is needed, use a wet fabric with a non harsh detergent. Any oil, ester, silica gel and lubricant is forbidden for use.

Use only a soft fabric dipped in alcohol to clean the screen. Water, ketone and aromatic solvent are forbidden for use.

(3) Daily cleaning

Clean the instrument at least once everyday. If uncleanness affects the testing results, please clean the instrument any time.

If there is too much urine debris on the strip holder's groove or flank, the test result might be inaccurate, please remove the strip holder and clean it with a bush.

(4) Removing & Installing the strip holder

When removing the strip holder, turn off the power switch, than gently pull the strip holder outward.

After cleaning, be carefully to push the strip holder into the instrument, then turn on the power switch. The instrument will automatically adjust the holder's position.

Note: Organic solvents are forbidden for cleaning because they may cause damage to the instrument. You can use a moist lint-free cloth for cleaning the CL-50 Plus.



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1.10 Meanings of icons



Warning



Dangerous voltage



Grounding



Power on



Power off

2 TROUBLESHOOTING

2.1 Introduction

The CL-50 Plus Urine Analyzer is a precise instrument. It is very important to operate the instrument carefully. Any damaged accessories or improper operation will affect the instrument's function. If a malfunction occurs, the operator should refer to this section for a solution and deal with it. (Read the operation requirements before maintenance). If the CL-50 Plus still doesn't work, please contact the local distributor. If any problem is caused by the H10, H11 or H13 reagent strip, read the introductions about the reagent data, it may help.

2.2 Maintenance

Only authorized or a trained engineer by HTI can service the instrument. Refer to the instructions of malfunction in this manual to perform corrections and maintenance. It is recommended to replace the parts and accessories if the malfunction cannot be solved.

Note: Beware of the high voltage in the instrument during the maintenance.



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2.3 Troubleshooting Table

Table 3 shows the malfunction codes and trouble-shooting table

Table – 3 Trouble-shooting table

| TROUBLE CODE | CAUSE | CORRECTION |
|---------------------------------------------------------|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| TROUBLE-01 | Electric current of reference light LED is too high | Please contact the local distributor |
| TROUBLE-02 | Electric current of red light LED is too high | |
| TROUBLE-03 | Electric current of green light LED is too high | |
| TROUBLE-04 | Electric current of reference light LED is too low | |
| TROUBLE-05 | Electric current of red light LED is too low | |
| TROUBLE-06 | Electric current of green light LED is too low | |
| TROUBLE-07 (Urine reagent strip is placed wrong) | Improper position of reagent strips | Check the “routine test” chapter to place the strip correctly |
| TROUBLE-08 (reagent strip type are wrong) | Reagent strip type is wrong | Setting the reagent strip type correctly |
| TROUBLE-09 (No urine strip) | No reagent strip | Place reagent strip. |
| TROUBLE-10 (ROM/RAM Trouble) | The instrument isn’t in good condition | Check the battery or repair it |
| TROUBLE-11 (Strip holder is not clean, please clean) | Strip holder isn’t clean | Clean the strip holder or take the dust off |
| TROUBLE-12 | Transfer part has trouble | Check whether the white bar positive symbol on the reagent strip holder is clean or not, whether the strip hold has been pushed in or not |



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H13

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|---|
| 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| STX | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | |
| CR | LF | | N | O | . | ■ | ■ | ■ | | | ■ | ■ | □ | ■ | ■ | □ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 44 | 45 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CR | LF | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 46 | 47 | 48 | 49 | 50 | 51 | 52 | 53 | 54 | 55 | 56 | 57 | 58 | 59 | 60 | 61 | 62 | 63 | 64 | 65 | 66 | 67 | 68 | 69 | 70 | 71 | 72 | 73 | 74 | 75 | 76 | 77 | 78 | 79 | 80 | 81 | 82 | 83 | 84 | 85 | 86 | 87 | |
| CR | LF | ■ | W | B | C | | ■ | ■ | | ■ | ■ | ■ | ■ | C | e | i | i | / | u | L | | | | | | | | | | | | | | | | | | | | | | |
| 88 | 89 | 90 | 91 | 92 | 93 | 94 | 95 | 96 | 97 | 98 | 99 | 100 | 101 | 102 | 103 | 104 | 105 | 106 | 107 | 108 | 109 | 110 | 111 | 112 | 113 | 114 | 115 | 116 | 117 | 118 | 119 | 120 | 121 | 122 | 123 | 124 | 125 | 126 | 127 | 128 | 129 | |
| CR | LF | ■ | N | I | T | | ■ | ■ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 130 | 131 | 132 | 133 | 134 | 135 | 136 | 137 | 138 | 139 | 140 | 141 | 142 | 143 | 144 | 145 | 146 | 147 | 148 | 149 | 150 | 151 | 152 | 153 | 154 | 155 | 156 | 157 | 158 | 159 | 160 | 161 | 162 | 163 | 164 | 165 | 166 | 167 | 168 | 169 | 170 | 171 | |
| CR | LF | ■ | B | I | L | | ■ | ■ | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | |
| 172 | 173 | 174 | 175 | 176 | 177 | 178 | 179 | 180 | 181 | 182 | 183 | 184 | 185 | 186 | 187 | 188 | 189 | 190 | 191 | 192 | 193 | 194 | 195 | 196 | 197 | 198 | 199 | 200 | 201 | 202 | 203 | 204 | 205 | 206 | 207 | 208 | 209 | 210 | 211 | 212 | 213 | |
| CR | LF | ■ | G | L | U | | ■ | ■ | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | |
| 214 | 215 | 216 | 217 | 218 | 219 | 220 | 221 | 222 | 223 | 224 | 225 | 226 | 227 | 228 | 229 | 230 | 231 | 232 | 233 | 234 | 235 | 236 | 237 | 238 | 239 | 240 | 241 | 242 | 243 | 244 | 245 | 246 | 247 | 248 | 249 | 250 | 251 | 252 | 253 | 254 | 255 | |
| CR | LF | | p | H | | | | | | ■ | ■ | ■ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 256 | 257 | 258 | 259 | 260 | 261 | 262 | 263 | 264 | 265 | 266 | 267 | 268 | 269 | 270 | 271 | 272 | 273 | 274 | 275 | 276 | 277 | 278 | 279 | 280 | 281 | 282 | 283 | 284 | 285 | 286 | 287 | 288 | 289 | 290 | 291 | 292 | 293 | 294 | 295 | 296 | 297 | |
| CR | LF | ■ | B | L | D | | ■ | ■ | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | |
| 298 | 299 | 300 | 301 | 302 | 303 | 304 | 305 | 306 | 307 | 308 | 309 | 310 | 311 | 312 | 313 | 314 | 315 | 316 | 317 | 318 | 319 | 320 | 321 | | | | | | | | | | | | | | | | | | | |
| CR | LF | ■ | C | R | | | | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | |
| CR | LF | ■ | C | a | | | | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | |
| CR | LF | ■ | M | A | | | | | | ■ | ■ | ■ | ■ | | | | | | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | |
| CR | LF | ETX | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |



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|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|--|
| 1 | | | | | | | | | | | | | | | | | | | | | |
| STX | | | | | | | | | | | | | | | | | | | | | |
| 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | |
| CR | LF | | N | O | . | ■ | ■ | ■ | | | ■ | ■ | □ | ■ | ■ | □ | ■ | ■ | ■ | ■ | |
| 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | |
| CR | LF | | | | | | | | | | | | ■ | ■ | : | ■ | ■ | : | ■ | ■ | |
| 44 | 45 | 46 | 47 | 48 | 49 | 50 | 51 | 52 | 53 | 54 | 55 | | | | | | | | | | |
| CR | LF | T | R | O | U | B | L | E | □ | ■ | ■ | | | | | | | | | | |
| 56 | 57 | 58 | | | | | | | | | | | | | | | | | | | |
| CR | LF | EXT | | | | | | | | | | | | | | | | | | | |



| | |
|-----------------|---------------|
| Document Number | OM-E-CL-50-20 |
| Revision Level | Rev.4 |
| Prepared by | J.S. Bolio |
| Approved by | S. Titov |
| Effective Date | 12Oct17 |

Operator's manual: HTI CL-50 Plus

CL-50 Plus Analyzer Maintenance records

____ Year ____ Month

| Daily Maintenance | Maintenance Records | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------------------------------|---------------------|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
| 1 Clean cover with a damp cloth and non harsh detergent | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 Clean screen with a soft cloth dipped in alcohol | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 Clean Strip holder | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4 Verify enough thermal paper and replace if needed | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5 Run the Check Sample (Calibration) Test Strip | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6 Run the QC samples | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Comments: _____

Version: 6/2012

