

Operators Manual



Iris Diagnostics

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English

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Français

Italiano

Español

Português



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Introduction

Intended Use

The iChem™100 Urine Chemistry Analyzer is a semi-automated urine chemistry analyzer intended for use only with iChem™ 10 SG Urine Chemistry Strips for the in vitro measurement of the following analytes in urine: glucose, protein, bilirubin, urobilinogen, pH, specific gravity, blood, ketones, nitrite, leukocytes, ascorbic acid, color and user-defined clarity.

This document is the Operators Manual for the iChem100 Urine Analyzer. It is intended to explain system operation in detail and to be used as the basis for training new operators. Retain this manual for future use. It is an information guide and a troubleshooting reference. It explains program settings and gives maintenance instructions.

How to use the Operator's Manual

This manual contains important information on the functions of the iChem100 distributed by Iris Diagnostics. This manual contains instructions for the operation, maintenance and troubleshooting of the iChem100.

Before operating the iChem100, read this manual carefully.



Precautions and Warnings

The Operators Manual includes information and warnings that must be observed by the operator in order to ensure safe operation of the system. Important messages are highlighted with borders and special icons identifying the type of message enclosed.

There are four types of messages: Notes, Cautions, Warnings and Biological Warnings.

Notes



NOTE: Highlights important facts, gives helpful information and tips and clarifies procedures.

Cautions



CAUTION: Electrical caution! Unplug before handling.



CAUTION: Important information on the proper operation of the iChem100 Urine Analyzer. This information is crucial in preventing instrument damage and maintaining the analyzer.



CAUTION: Laser light caution. A laser is used to read the barcodes. Protect eyes from the laser light.

Warnings



WARNING: Identifies potentially hazardous situations that could result in serious injury to laboratory personnel.

Biological Warnings



WARNING: Use care when handling urine samples or used test strips. Always wear gloves to prevent exposure to pathogens. Incorrect or imprecise procedures may result in exposure to pathogens. This unit must only be used by operators trained in proper procedures for clinical testing and handling of biohazardous waste.

Warnings, Precautions, Limitations

- Do not place the iChem100 in water.
- Do not drop or throw the instrument.



- Operate the instrument on a dry, level surface.
- Do not move the instrument while a test is in process.
- Plug the instrument into a grounded power source.
- Avoid sources of bright light/heat.

Iris Diagnostics Contact Information

Customer opinion and input is extremely important to us. Iris Diagnostics wants to design products that meet your needs. Comments on this manual should be directed to:

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Fax +1-818-700-9661

E-mail clinsupport@proiris.com

Warranty

Iris Diagnostics, a Division of IRIS International, Inc. (Iris) warrants that the products manufactured by it or its affiliates and sold hereunder shall be free from defects in material and/or workmanship, under normal use and service, for the period expiring twelve (12) months from the completion of installation, or upon Purchaser's signature on Iris Diagnostics Warranty/ Acceptance form, or fifteen (15) months from shipment, whichever occurs first. No warranty extended by Iris Diagnostics shall apply to any products which have been modified, (including any third party software), altered, or repaired by persons other than those authorized or approved by Iris Diagnostics or to products sold as "used."

Iris Diagnostics' obligation under this warranty is limited SOLELY to the repair or replacement, at Iris Diagnostics' option, of defective parts, F.O.B. warehouse or local Iris Diagnostics office, or as otherwise



specified by Iris Diagnostics. Repairs or replacement deliveries shall not interrupt or prolong the term of this warranty. Iris Diagnostics' warranty does not apply to consumable materials, except as specially stated in writing, nor to products or parts thereof manufactured by the Purchaser.

This limited warranty is made on condition that immediate written notice of any defect be given to Iris Diagnostics and that Iris Diagnostics inspection reveals that the Purchaser's claim is valid under the terms of this warranty.

IRIS DIAGNOSTICS MAKES NO WARRANTY OTHER THAN THE ONE SET FORTH HEREIN OR THAT WHICH MAY BE PROVIDED IN A SEPARATE WARRANTY COVERING THE APPLICABLE PRODUCT CATEGORY. SUCH LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY EXPRESSED OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSES AND SUCH CONSTITUTES THE ONLY WARRANTY MADE WITH RESPECT TO THE PRODUCTS.

Limitation of Liability

Iris Diagnostics shall not be liable for any loss of use, revenue or anticipated profits, or for any consequential or incidental damages resulting from the sale or use of the products.



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Theory of Operation

The iChem100 is a semi-automated urine chemistry analyzer performing measurements of urine chemical constituents utilizing test strips. The iChem100 is a reflectance densitometer.

Features

The iChem100:

- reads and interprets without operator variability
- processes and analyzes urine strips with a throughput of 210 samples per hour
- enables entry of microscopic results
- enables automated urine color determination with up to twelve programmed choices
- · reads ascorbic acid for interference detection
- allows users to correct or compensate for urine discoloration
- allows batch and stat mode for sample processing

Test Strips

The test strips have reagent-impregnated specialty paper pads to perform chemical analysis of:

- bilirubin
- urobilinogen
- ketones
- ascorbic acid
- glucose
- protein
- blood
- pH
- nitrite
- leukocytes
- specific gravity

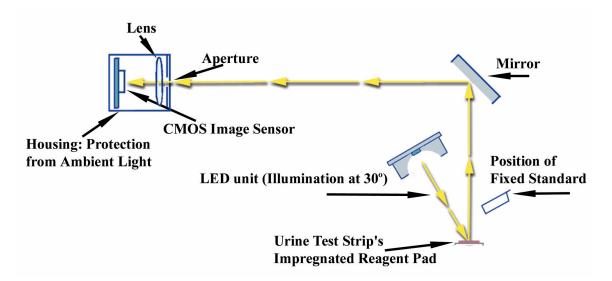
The advantage of this approach is ease of testing. The process requires that an operator dip the urine test strip with its reagent-impregnated pads into and out of a urine sample. This action brings the reagent-impregnated pads into contact with the urine containing the analytes to be



tested. Once the test strip has been dipped into the urine, color develops on each of the reagent-impregnated pads in direct proportion to the amount of analyte present in the sample. The test strips have a compensation pad to determine the color of the urine as well as correct for color interference on the impregnated reagent pads.

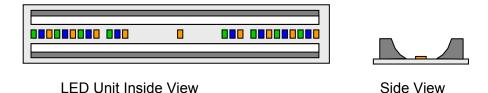
After the test strips are placed on the Test Strip Tray with correct orientation, they are automatically transported to the measurement window and the remainder of the operation is performed automatically by the iChem100.

Optics



LED Unit

For the illumination of the measurement, a LED Unit with three different wavelengths LEDs (450nm, 530nm and 625nm) is used. To increase homogeneity, the LED's are not placed regularly over the measurement window but are placed mainly towards the outer area of the LED Unit. In order to achieve a very high light intensity, one reflector and one anti-reflector are placed beside the LED line. With this optical design, the entire urine test strip is illuminated.





CMOS Image Sensor

Unlike most of the reflectometers in the market for urine test strip analysis, the iChem100 does not use a photodiode detector to measure the reflected light, but instead utilizes a CMOS (Complementary Metal Oxide Semiconductor) image sensor that captures a color image of each of the test pads. The CMOS image sensor is able to photograph almost the whole length (100mm) of the urine test strip and all of its width. As seen in the figure above, the CMOS image sensor has been placed perpendicular to the measurement level, and since the height of the instrument limits the optical length, a mirror has been used for changing the direction of the beam.

Optics Calibration

Prior to each measurement, the optics assembly is calibrated using a "fixed standard" and it permits a one-point calibration. The iChem100 is also capable of performing an internal, automated two-point calibration if the one-point calibration done before each specimen determination falls outside of the acceptable limits. A secondary "movable standard" is automatically moved into place and readings from it in conjunction with the "fixed standard" are used to perform a two-point calibration. No external calibration strips or procedures are required.

Measurement

Once calibrated, the urine test strip is sequentially illuminated by the LEDs (Red, Blue, Green) that are located at a 30° angle to the impregnated reagent pads, and the reflected signals are sent via the mirror through the lens and captured by the CMOS camera. The captured signal is evaluated and a completed result is provided for each of the chemistries.

The iChem100 uses a compensation pad to determine the color of the urine as well as correct for color interference on the impregnated reagent pads. Since the iChem100 is capturing a pixelized image of the blood pad, a special algorithm has been developed using more than a reflectance to differentiate between intact and hemolyzed red blood cells.



Instrument Components

Front



- 1 Keyboard
- 2 Transport mechanism enclosure
- 3 Display screen
- 4 Paper roll
- 5 Transport belt opening (for placement of strip)
- 6 Clarity and specimen type barcode labels
- 7 Hand-held barcode reader

Back



- 1 Power switch
- 2 Keyboard/barcode reader cable connection
- 3 External printer connection
- 4 RS232 connection
- 5 Power supply connection



Most user inputs are designed to be via the keyboard or the barcode reader.

The keyboard is used for navigating within a screen, between screens, making selections and entering data inputs.

The barcode reader enables you to enter information via barcoded data into selected entry fields, (e.g., patient identification, specimen identification, color, clarity, etc.).



Software

Data Entry Fields

Data entry fields are areas in a screen where information is entered. One screen can have several data entry fields, but only one field can be selected and active for entering data at a time. Pressing an alpha or a numeric key will input that character into the data entry field. If you exceed the number of allowable characters in a field, you cannot enter more characters until some characters have been deleted.

To select a data entry field, use the keyboard $[\uparrow]$ or $[\downarrow]$ keys to move the cursor up or down in the screen. To move back and forth between left and right columns, use the [Tab] key. The contents of the field will be reverse highlighted to show that they are selected or active.

To delete contents from a data field, select the field using the keyboard's \uparrow or \downarrow or \downarrow

To erase contents from data field one character at a time, select the field using the keyboard's \uparrow or \downarrow or \uparrow or \uparrow

Toggle Fields

Toggle fields are fields setup in a circular fashion allowing you to choose one field out of a series of pre-setup fields (e.g., blank, trace, few, moderate, many, etc.). A toggle field will be indicated by a double-headed arrow $[\leftrightarrow]$. Only one toggle field can be active at a given time.

To select a toggle field, use the keyboard keys \uparrow or \downarrow to move the cursor into the desired field.

To view the choices in a toggle field, use the keyboard keys $[\leftarrow]$ or $[\rightarrow]$ to advance through the selections. To switch back and forth from a left toggle field to a right toggle field, press the [Tab] key.

To confirm or lock in a selection, you may press the [**Enter**] key or use the keys [\uparrow] or [\downarrow]. Either one will lock in the selection and advance you to the next field.



Function Keys

Pressing a function key, [F1] through [F10], will allow you to access the described function associated with it. For example, to choose to run a patient sample, press [F2] while the *Main Menu* screen is displayed. The function keys will only perform the function that is associated with it in the currently displayed screen.

Menu Diagram

Main Menu

03/10/2006 1:50PM

MAIN MENU

F1 WORKLIST F5 SETUP

F2 RUN PATIENT F6 MICROSCOPIC

F3 RESULTS F7 SERVICE

F4 CONTROLS

Worklist Menu

WORKLIST MENU

F1 CREATE

F2 DOWNLOAD

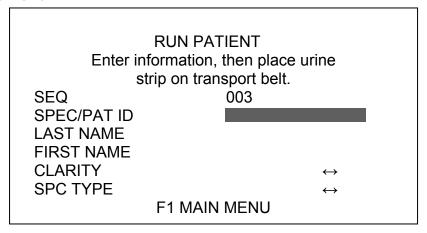
F3 VIEW/EDIT

F4 RUN

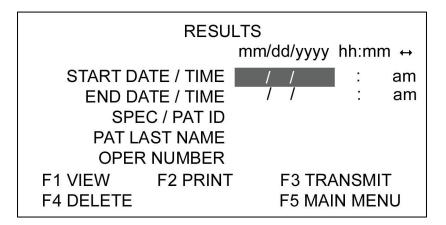
F5 PRINT



Run Patient Menu



Results Menu



Controls Menu

CONTROLS MENU		
	LOT#	EXP
FILE 1	1212UC2006	03/20/2006
FILE 2	1213UC2006	03/20/2006
FILE 3		
FREQ	1	Hours ↔
F1 SETP	F2 VIEW	F3 RUN
F4 PRINT	F5 DELETE	F6 MAIN MENU



Setup Menu

SETUP MENU

F1 UNITS
F2 FLAGGING
F3 TEST SEQ
F4 LOG ON ID
F5 MAIN MENU

Microscopic Menu

MICROSCOPIC ENTRY

mm/dd/yyyy hh:mm

am

am

START DATE / TIME / /
END DATE / TIME / /

SPEC / PAT ID PAT LAST NAME

F1 ENTER F2 MICROSCOPIC F3 MAIN MENU

Service Menu

SERVICE MENU

F1 DATE/TIME F4 DIAGNOSTICS

F2 PRINTER F5 TRANSMIT

F3 LANGUAGE F6 TEST STRIP

F7 MAIN MENU



Specifications

Technology	Reflectance Photometry LEDs (450nm, 520nm, 625nm) with Color Image Sensor
Test Strips	iChem 10 SG
Throughput	210 Urine Test Strips per hour
Data Storage	2,000 Patient results 300 Quality Control results
Reporting Units	Conventional, S.I., Qualitative or Combination
Flagging	Results requiring confirmatory tests / Microscopic examination Abnormal Quality Control results
Display	LCD backlit (8 lines x 40 characters)
Printer	Thermal (built-in)
Interfaces	RS 232, parallel printer port, 5-pin DIN socket
Physical Specifications	19.5 x 10.8 x 9.8 in (49.5 x 27.5 x 25 cm) 16.5 lbs (7.5 kg)
Power	100 to 250 VAC ± 10%, 50/60 Hz
Operating Range	59° F to 90° F (15° C to 32° C) 20% to 80% Relative Humidity
Package	iChem100 instrument PC /AT keyboard Hand-held barcode reader (Optional)



Consumables or Part Replacement

REF Number	Description
800-7504	Transport belts
800-7505	External power supply
800-7506	Power Supply Adapter
800-7507	Transport mechanism enclosure
800-7508	Barcode reader and cable
800-7509	Keyboard (English)
800-7510	Keyboard (German)
800-7511	3 Rolls of Thermal Paper
800-7014	Incubation Belt
800-7004	iChem 10 SG Urine Chemistry Strips (US)
800-7005	iChem 10 SG Urine Chemistry Strips (Int'l)
800-3203	Iris System Cleanser

3. Set Up



3 Set Up

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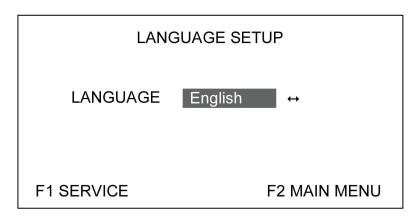


Setting the Language

This screen allows you to select the desired language with which to display screens. The instrument can be set to one of six different languages:

English Deutsch Français Italiano Español Português

- 1. From the *Main Menu*, press the **[F7]** key to access the *Service Menu*.
- 2. From the **Service Menu**, press the **[F3]** key. The **Language Setup** screen will be displayed.



- 3. Use the [←] or [→] arrow keys to toggle through the six language options.
- 4. Press the **[F1]** key to lock in your selection and return to the **Service Menu** screen, or press the **[F2]** key to lock in your selection and return to the **Main Menu** screen.



Setting Date and Time

This screen allows you to enter the correct date and time and select the format for the instrument displays and printouts.

1. From the *Main Menu*, press the **[F7]** key. The *Service Menu* screen will be displayed.

SERVICE MENU

F1 DATE/TIME F4 DIAGNOSTICS
F2 PRINTER F5 TRANSMIT
F3 LANGUAGE F6 TEST STRIP
F7 MAIN MENU

2. Press the **[F1]** key to display the **Set Date/Time** screen.

SET DATE / TIME

DATE FORMAT mm/dd/yyyy

TIME FORMAT am / pm

DATE 03/23/2006

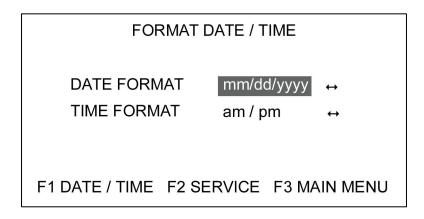
TIME 10:00 pm ←

F1 FORMAT F2 SERVICE F3 MAIN MENU



Setting the Date or Time Format

1. From the **Set Date/Time** screen, press the **[F1]** key to display the **Format Date/Time** screen.



- 2. Use the $[\leftarrow]$ or $[\rightarrow]$ arrow keys to toggle through three date options:
 - dd.mm.yyyy
 - mm/dd/yyyy
 - yyyy/mm/dd
- 3. Press the [↑] or [↓] arrow keys, or the [Enter] key to lock in your selection and move to the next field.
- 4. Use the $[\leftarrow]$ or $[\rightarrow]$ arrow keys to toggle through the two time options:
 - 24 hour
 - am/pm
- 5. Press the **[F1]** key to return to the **Date/Time** screen.

Changing the Date and Time

- 1. From the *Date/Time* screen, use the [↑] or [↓] arrow keys or the [Enter] key to move to the desired field (e.g., DATE, TIME or am/pm).
- 2. To enter or change the date, select the DATE field, and then enter the correct date using the keyboard numeric keys.



NOTE: You must enter two digits for the month and the day (e.g., 01 for January, etc.)

3. Set Up



3. To enter or change the time, select the TIME field, and then enter the correct time using the keyboard numeric keys.



NOTE: You must enter two digits for the hour and the minutes (e.g., 01:01 for 1:01, etc.).

- 4. To change the am/pm selection (if desired), select the am/pm field, use the [←] or [→] arrow keys to select am or pm.
- 5. Press the **[F2]** key to return to the **Service Menu** screen, or press the **[F3]** key to return to the **Main Menu** screen.



Setting the Reporting Units

This screen allows you to select the reporting units for the results of the test strips chemistries. You may select from the following options:

- Conventional (mg/dL)
- S.I. (Standard International—µmol/L and mmol/L)
- Qualitative (+)
- Customized (a combination of all three)
- From the *Main Menu*, press the [F5] key. The *Setup Menu* will be displayed.

SETUP MENU

F1 UNITS

F2 FLAGGING

F3 TEST SEQ

F4 LOG ON ID

F5 MAIN MENU

2. From the **Setup** Menu, press the **[F1]** key. The **Units** screen will be displayed.

UNITS

Conventional (mg/dL)

S. I. (umoL and mmol/L)

Qualitative (+)

Customized (mg/dL or umol/L or +)

F1 VIEW / EDIT F2 PRINT F3 SETUP F4 MAIN MENU

3. To select either conventional, S.I., or qualitative units exclusively, select the desired unit option using the [↑] or [↓] arrow keys, then press the [F1] function key.



Conventional (mg/dL) Units

CONVENTIONAL UNITS

Bili: mg/dL Prot: mg/dL
Uro: mg/dL Bld(Hgb): mg/dL
Ket: mg/dL Bld (RBCs): RBCs/uL
A. Acid: mg/dL Nit: Pos
Gluc: mg/dL Leu: WBCs/uL
F1 UNITS F2 SETUP F3 MAIN MENU

Standard International (µmol/ L) units

S. I. UNITS

Bili: umol/L Prot: g/L
Uro: umol/L Bld(Hgb): mg/L
Ket: mmol/L Bld (RBCs): RBCs/uL
A. Acid: mmol/L Nit: Pos
Gluc: mmol/L Leu: WBCs/uL
F1 UNITS F2 SETUP F3 MAIN MENU

Qualitative (+) units

QUALITATIVE UNITS

Bili: + Prot: +
Uro: + Bld(Hgb): +
Ket: + Bld (RBCs): RBCs/uL
A. Acid: + Nit: +
Gluc: + Leu: WBCs/uL
F1 UNITS F2 SETUP F3 MAIN MENU

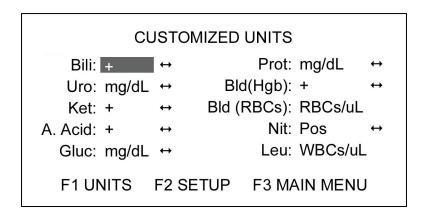
Press the **[F1]** key to return to the *Units* screen from any of these display screens.



Customized Units

This option allows you to report out chemistry results with units specifically selected for each of the chemistries.

From the Units screen, select Customized (mg/dL or μmol/L or +) using the [↑] or [↓] arrow keys, then press the [F1] key. The Customized Units screen will be displayed.



- Toggle through the unit selections for the first chemistry using the [←] or [→] arrow keys. Once the desired units are displayed, press the [↓] arrow key, or [Tab] key, or the [Enter] key to move to the next chemistry unit field.
- 3. Continue until all unit selections have been made, then press the **[F1]** key to lock in the selections and return to the *Units* screen.

Printing Units

- 1. From the *Units* screen, select the desired units and then press the **[F2]** key. The instrument will begin printing the selected units.
- 2. Press the **[F1]** key to stop printing, if desired. Press the **[Pg Up]** key to feed the paper into the printer.



Sample Print Layout

The figure below displays an example of a unit printout.

Midtown County Health 10257 Cresent Blvd., Suite 3 Monroe, Texas 12345 Telephone: 555-555-7755

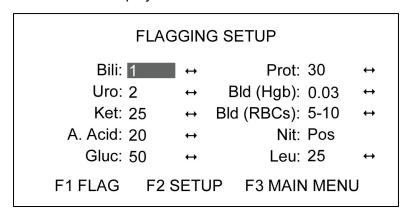
CONVENTIONAL UNITS



Setting the Flagging Criteria

This option allows you to adjust flagging criteria for each chemistry to your own patient population. The flagging defaults in the instrument are set to the first positive level for each chemistry test. Any chemistry result at or higher than the selected positive result will be flagged when printed or displayed.

1. From the **Setup** Menu, press the **[F2]** key. The **Flagging Setup** screen will be displayed.



- Toggle through the result selections for the first chemistry using the [←] or [→] arrow keys. The field will display all positive reportable results for the units selected. Once your selection is displayed, press the [↓] arrow key, the [Tab] key, or the [Enter] key to move to the next chemistry unit field.
- 3. When all flagging selections have been made, press the **[F1]** key to lock in the selections. The *Flag Selection* screen, which allows you to determine how each chemistry will be flagged, will be displayed.

```
FLAG SELECTION

Bili: ★ ↔ Prot: # ↔

Uro: ★ ↔ Bld (Hgb): # ↔

Ket: ★ ↔ Bld (RBCs): # ↔

A. Acid: ★ ↔ Nit: # ↔

Gluc: ★ ↔ Leu: # ↔

F1 FLAGGING F2 SETUP F3 MAIN MENU
```

3. Set Up



For example, an asterisk (*) may be used to signal an abnormal result and that an additional confirmation test is required. The use of a number sign (#) may signal that a microscopic examination is required.

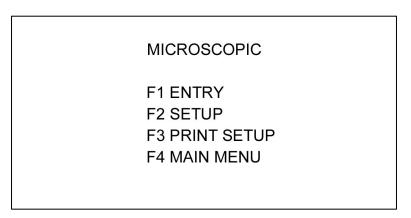
- 4. Toggle through the flagging selections for the first chemistry using the [←] or [→] arrow keys. The flagging choices are:
 - Blank no flag will be displayed
 - * displays an asterisk after the result
 - # displays a number sign after the result
- 5. Once your selection is made, press the [↓] arrow key, the [Tab] key or the [Enter] key to move to the next field.
- 6. When all flagging selections have been made, press the **[F1]** key to lock in the selections and return to the *Flagging Setup* screen.
 - Press the [F2] key to lock in the selection and return to the Setup Menu screen.
 - Press the [F3] key to lock in the selection and return to the Main Menu screen.



Microscopic

This function provides you with the means to set up your preferences for reporting microscopic exams performed on urine specimens, print out your set up quantifiers, as well as the ability to enter microscopic results.

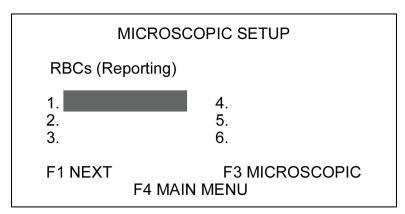
1. From the *Main Menu*, press the **[F6]** key. The *Microscopic* screen is displayed.





NOTE: Since the setup information becomes the basis for the quantifiers used in reporting microscopic exams, anytime this information is altered, all existing patient data is deleted to avoid reporting the wrong microscopic information. A warning screen will alert you to this prior to allowing you to establish the new microscopic quantifiers.

2. From the *Microscopic* screen, press the **[F2]** key to display the following *Microscopic Setup* screen.

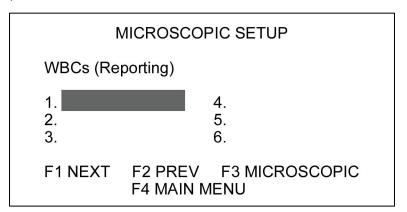


A series of screens similar to this one provide you with the ability to record, display, and print microscopic examinations consistent with reporting results for the specified parameter for your laboratory.



For example, shown above is the screen for entering quantifiers for RBC's. You have six text fields in which to enter the descriptors consistent with your laboratory's results for RBC's, e.g., trace, 1+, 1-3 HPF, etc. Each text field will hold up to 10 alphanumeric characters. Once entered, these fields will be the toggle fields used when you select the quantities present in the microscopic exam for RBC's.

- 3. To enter a microscopic quantifier for a parameter, type the desired information into the text field, then press the [↑] or [↓] arrow keys, the [Tab] key or the [Enter] key to move to the next field. The [Delete] key can be used to delete existing entries in the field allowing the operator to change the information.
- 4. Once you have entered all the quantitative descriptions desired for the current parameter, press the **[F1]** key to bring up the next microscopic parameter screen.



5. To enter the quantifiers for the next microscopic parameter, type the desired information into each of its text fields, then press the [↑] or [↓] arrow keys, the [Tab] key or the [Enter] key to move to the next field. To go back to the previous parameter, press the [F2] key.

There are a total of 11 parameters listed. Each parameter has up to six fields in which to enter quantitative results. The parameters are as follows:

- RBCs (red blood cells)
- WBCs (white blood cells)
- Bacteria
- Epis (Epithelial cells)
- Crystals
- Yeast

3. Set Up



- Casts
- Trich (Trichomonas)
- Oval fat (Oval fat bodies)
- Mucus
- Sperm
- Continue entering parameter quantifier information until you have entered it for all parameters desired. Press the [F3] key to return to the *Microscopic* screen or press the [F4] key to return to the *Main Menu* screen.

Print a Copy of Microscopic Setup

- From the *Microscopic* screen, press the [F3] key to print a copy of the microscopic parameters.
- 2. Press the **[F1]** key to stop *printing*, if desired.

All printouts will include:

- Header information (see Setting Up the Printer.)
- The printout identifier: Microscopic Setup.
- Each parameter with up to six quantifiers.

Midtown County Health 10257 Cresent Blvd., Suite 3 Monroe, Texas 12345 Telephone: 555-555-7755 Microscopic Setup **RBCs** 1. 0-5 HPF 4. 21-50 HPF 2. 6-10 HPF 5. 51-75 HPF 3. 11-20 HPF 6. 75+ HPF **WBCs** 1. 0-5 HPF 4. 21-50 HPF 2. 6-10 HPF 5. 51-75 HPF 3. 11-20 HPF 6. 75+ HPF Bacteria 4.4+ 1.1+ 2.2+ 5. 3.3+ 6. **Epis** 4.4+ 1.1+ 2.2+ 5. 6. 3.3+

Crystals



Setting the Test Sequence

This screen allows you to display and print the individual chemistry tests in a specific order. The default test setup sequence is shown below.

TEST SEQUENCE SETUP		
Bili: 1		Blood: 7
Uro: 2		pH: 8
Ket: 3		Nit: 9
A. Acid: 4		Leu: 10
Gluc: 5	S. C	Gravity: 11
Prot: 6		
F1 MICRO	F2 SETUP	F3 MAIN MENU

- 1. From the **Setup Menu**, press the **[F3]** key to display the Test **Sequence Setup** screen.
- 2. To change the sequence order of any of the chemistries, select the field next to the chemistry and using the keyboard, enter a number from 1 to 11.
- 3. Once your selection is made, press the [↓] arrow key, the [Tab] key or the [Enter] key to move to the next field.
 - If a test result is not to be displayed or printed, do not enter a number next to that test parameter.
 - You may not use the same number in more than one field. To do so will result in an error when you go to lock in the selections.
- 4. When all test selections have been numbered, press the **[F1]** key to lock in the selections and display the default reporting order for the microscopic examination.



TEST SEQUENCE SETUP

 RBCs
 :
 1
 Casts
 :
 8

 WBCs
 :
 2
 Casts
 :
 9

 Bacteria
 :
 3
 Trich
 :
 10

 Epis
 :
 4
 Oval Fat
 :
 11

 Crystals
 :
 5
 Mucus
 :
 12

 Crystals
 :
 6
 Sperm
 :
 13

Yeast: 7

F1 CHEM F2 SETUP F3 MAIN MENU

- 5. To change the sequence order of any of the microscopic parameters, select the field next to the microscopic results and using the keyboard, enter a number between 1 and 13.
- 6. Once your selection is made, press the [↑] or [↓] arrow keys, the **[Tab]** key or the **[Enter]** key to move to the next desired parameter field.
 - If a result is not to be displayed or printed, do not enter a number next to that test parameter.
 - You may not use the same number in more than one field. To do so will result in an error when you go to lock in the selections.
- 7. When all desired test selections have been numbered, press the **[F1]** key to return to the **Test Sequence Setup** screen displaying the chemistry parameters.
 - Press the [F2] key to return to the Setup Menu screen.
 - Press the [F3] key to return to the Main Menu screen.



Setting the Log On Identifiers

This function allows you to record the operator who performed an analysis along with the results of the specimen by requiring users to log onto the instrument.

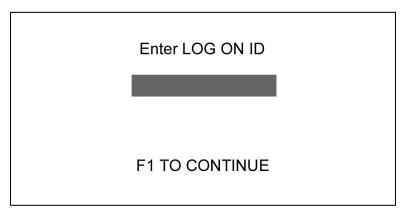
If **Log On Required** is selected, a user must "Log On" to operate the instrument. The instrument will automatically display the "Log On" screen before allowing the operator to access the **Main Menu**.

If **Log On Not Required** is selected, the instrument will go directly to the **Main Menu** screen when turned on.



NOTE: A generic "Log On" will permit operation of the instrument should the operator forget their password.

- 1. From the **Setup Menu**, press **[F4]** to access the **Log On Setup** screen.
- 2. To require "Log On" to the iChem100 instrument, select **Log On Required** on the **Log On Setup** screen.



- 3. Once the "Log On Required" is highlighted, press either **[F1]** or **[F2]** and the instrument will automatically take you to the **Enter Log On ID** screen.
- 4. Type **iris** (all lowercase) in the "Enter Log On ID" field and press **[F1]**. The instrument will take you to the *Main Menu* screen.

If you enter the password incorrectly, an error message will appear advising you to re-enter the password.



Adding a New User

This option allows you to add a "Log On ID" to be used when logging on to the analyzer. A "Log On ID" must be specific for an operator and must be in lowercase only, last and first names can include uppercase. Up to 24 users can be entered. The software will check to insure that an identifier is not currently in use by another operator. If a desired identifier is already in use, you will be notified, the "Log On ID" field will be blanked and you will be asked to enter a new identifier

- 1. From the *Main Menu*, press [F5] to access the *Setup Menu*.
- 2. Press [F4] to access the Log On Setup screen.
- 3. Press [F1] to display the *Log On Setup Change or Delete* screen.
- Use the [↓] arrow key to advance to the first empty position. Press
 [F2] to display the Log On ID Setup—Add/Change screen.

LOG ON ID SETUP - ADD / CHANGE

OPER NO.

01

LAST NAME

Brown

FIRST NAME

Stephanie

LOG ON ID

VERIFY LOG ON ID

USE ONLY LOWER CASE FOR LOG ON ID!! F1 LOG ON F2 SETUP F3 MAIN MENU

- 5. Enter the operator's last name in the "Last Name" text field (up to 15 alpha characters). Press the **[Enter]** key or use the **[↑]** or **[↓]** arrow keys to advance to the next field.
- 6. Enter the operator's first name in the "First Name" text field (up to 10 alpha characters). Press the **[Enter]** key or use the **[↑]** or **[↓]** arrow keys to advance to the next field.
- 7. Enter a personal identifier in the "Log On ID" text field (between 4 and 10 lower case alphanumeric characters). Press the **[Enter]** key or use the **[**↑] or **[**↓] arrow keys to advance to the next field.
- 8. Re-enter the personal identifier in the "Verify Log On ID" text field.



- 9. Press any **[F]** key displayed on the screen. The software will automatically accept the Log On ID identifier unless:
 - the entered "Log On" identifier and the Verify Log On Identifier do not match
 - the entered "Log On" identifier is already in use
 - no information was entered, or insufficient information was entered

In these cases, a screen will appear identifying the error and it will allow you to either:

- **[F1]** return to the previous screen to correct the deficiency,
- [F2] disregard and return to the Setup menu without the "Log On" ID being setup,
- **[F3] disregard** and return to the Main Menu without the "Log On" ID being setup.
- 10. Press the **[F1]** key to return to the **Log On Setup** screen.
- 11. Press the **[F2]** key to return to the **Setup Menu** screen, or press the **[F3]** key to return to the **Main Menu** screen.

Editing a User Information

- 1. If an operator is "Logged On", he/she must "Log Off" and log back on:
 - a. From the *Main Menu*, press [F8] to display the *Enter Log ON ID* screen.
 - b. Type **iris** as a generic Log On ID and then press the **[F1]** key.
- From the *Main Menu*, press [F5] to display the *Setup Menu* screen, then [F4] to display the *Log On Setup* screen, and then press [F1] to display the *Log On Setup Change or Delete* screen.

LOG ON SETUP CHANGE OR DELETE			
01	Brown	Stephaniene	
02	Smith	Mike	
03	Allen	Susan	
04	Wright	Michele	
05	S		
06	Russo	Michael	
07	Richardson	Julianne	
80	Monroe	Marilyn	
F1 NE	XT F2 ADD / CHANGE	F3 DELETE	
	INT F5 SETUP	F6 MAIN MENU	



3. Press the **[F1]** key if the desired operator name is not displayed on this screen. This will advance you to the next screen of operator names.

A total of 24 positions are available.

- 4. Once the desired operator name is displayed on the screen, use the $[\uparrow]$ or $[\downarrow]$ arrow keys or the **[Enter]** key to select it.
- 5. Press the **[F2]** key. A message will appear warning that all results will be deleted.



WARNING: All stored results will be deleted from memory

6. Press the **[F1]** key to continue. This will display the **Log On ID Setup—Add/Change** screen.

LOG ON ID SETUP - ADD / CHANGE

OPER NO. 01

LAST NAME Brown

FIRST NAME Stephanie

LOG ON ID

VERIFY LOG ON ID

USE ONLY LOWER CASE FOR LOG ON ID!! F1 LOG ON F2 SETUP F3 MAIN MENU

- 7. To change any of the information shown, use the \uparrow or \downarrow arrow keys to move to the desired text field to highlight it.
- 8. Enter the change desired using the keyboard keys.



NOTE: If you make an entry in the "Log On ID" field, you must make the same entry in the "Verify Log On ID" field.

- 9. Press the **[F1]** key to lock in the changes made and return to the **Log On Setup** screen.
- 10. Press the **[F2]** key to lock in the changes made and return to the **Setup Menu** screen, or press the **[F3]** key to log in the changes made and return to the **Main Menu** screen.



Deleting a User

- 1. If an operator is Logged On using their own identifier, they must Log Off and log back on using the generic "**iris**" (all lower case) "Log On ID".
- Press [F5] to display the Setup Menu screen, then [F4] to display the Log On Setup screen, and finally press [F1] to display the Log On Setup Change or Delete screen. This screen will allow you to delete one or more "Log On" identifiers.
- 3. Press the **[F1]** key if the desired operator name is not present on this screen. This will advance you to the next screen of operator names.
- 4. Use the $[\uparrow]$ or $[\downarrow]$ arrow keys or the **[Enter]** key to select the user.
- 5. If you wish to delete the selected (highlighted) operator information, press the **[F3]** key. A message will appear warning that all results will be deleted.

LOG ON SETUP CHANGE OR DELETE

WARNING! Changing a used LOG ON results in deleting data from patient storage permanently!!

F1 CONTINUE
F2 LOG ON SETUP F3 MAIN MENU

6. If you press the **[F1]** key, the **Log On Setup Delete** screen will be displayed.



LOG ON SETUP DELETE

Delete current LOG ON ID? YES

Delete current LOG ON ID? NO

F1 CONTINUE

- 7. If you press the **[F2]** key the **Log On Setup** screen will be displayed, or pressing the **[F3]** key the **Main Menu** screen will displayed.
- 8. If you selected the [F1] option above, use the [↑] or [↓] arrow keys or the [Enter] key to select (highlight) your choice.
- 9. If you select **YES** and press the **[F1]** key, the instrument will delete the existing operator information and return you to the **Log On Setup Change or Delete** screen.

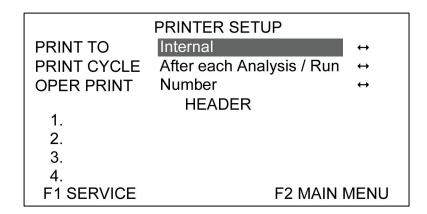
If you select **NO** and press the **[F1]** key, the instrument will return you to the **Log On Setup Change or Delete** screen without deleting the operator information.



Setting Up the Printer

To set up the printer functions, press the [F7] key with the *Main Menu* screen active, then press the [F2] key with the *Service Menu* screen active. The *Printer Setup* screen will be displayed.

This screen allows you to configure certain printer functions as well as configure the printout header.



- 2. The printer can be set to print using one of three options:
 - Internal—printing will be on the instrument printer only
 - External (Letter)—printing will be sent to an external printer that uses letter size paper
 - External (A4) printing will be sent to an external printer that uses
 A4 size paper
- 3. Use the $[\leftarrow]$ or $[\rightarrow]$ arrow keys to toggle through the options, then use the $[\uparrow]$ or $[\downarrow]$ arrow keys, or the [Enter] key to lock in the selection and move to the next field.
- 4. The Print Cycle can be set to print:
 - After each Analysis/Run—printer will print results after each analysis or "worklist" run
 - Print Function only—printer will print results only when the Print Function keys are selected
- 5. Use the [←] or [→] arrow keys to toggle through the options, then use the [↑] or [↓] arrow keys, or the [Enter] key to lock in the selection and move to the next field.

3. Set Up



- 6. The Operator print function allows the laboratory to print, if desired, the name or number of the operator performing the tests with the corresponding results using one of three options:
 - Number—printer will print the operator identifier number on each printout
 - Name—printer will print the operator name on each printout
 - Blank—printer will not print operator ID or name on printout

The remaining fields on this screen allow you to create the print header to be displayed and printed when results are sent to the printer.

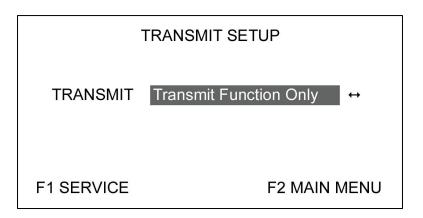
- 7. Four lines with up to 30 alphanumeric characters each may be entered. Once you have entered the desired information, use the [↑] or [↓] arrow keys, or the [Enter] key to lock in the selection and move to the next line.
- 8. Press the **[F1]** key to lock in your selection and return to the **Service Menu** screen, or press the **[F2]** key to lock in your selection and return to the **Main Menu** screen.



Setting Transmitting Results

This function provides you with the ability to configure when to transmit data to your host computer.

1. From the *Main Menu* screen, press the **[F7]** key, then press the **[F5]** key. The *Transmit Setup* screen will be displayed.



- 2. The instrument can be set to transmit using one of two options:
 - After each Analysis/Run data will be transmitted to the host computer after each analysis/run
 - Transmit Function Only data will be transmitted only when the transmit function [F3] is accessed from the *Results* screen.
- 3. To setup the Transmit option, use the $[\leftarrow]$ or $[\rightarrow]$ arrow keys to toggle through the two options, then use the $[\uparrow]$ or $[\downarrow]$ arrow keys, or the [Enter] key to lock in the selection and move to the next field.
- 4. Press the **[F1]** key to return to the **Service Menu** screen, or press the **[F2]** key to return to the **Main Menu** screen.



4

Specimen Processing

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Powering the Instrument On

When powered on, the instrument will perform an internal systems check and then go directly to the screen shown below, unless "Log On Required" has been previously selected.

iChem100 URINE CHEMISTRY ANALYZER

F1 MAIN MENU

Boot Program: Meter Program: 2.01.01 2.01.01

Press [F1] to proceed to the *Main Menu* screen. Prior to displaying the *Main Menu* screen, the display will ask whether you have emptied the waste container or not. Press [F1] if not emptied or [F2] if emptied, and the *Main Menu* screen will be displayed.



NOTE: Anytime the transport mechanism enclosure is removed while the instrument is on, you will be alerted that it is ajar and you must indicate whether the waste container was emptied or not. Once it is back in place, the incubation belt will run for approximately 110 seconds to clear any strips that may be on the belts and then the *Main Menu* screen will appear.

Logging On

The following screen is displayed when you power up of the iChem100 instrument if the *Log On Required* option has been selected in the *Setup Menu*. Refer to *Setting Log On Identifiers*.

1. Press the **[F1]** key to advance to the **Enter Log On ID** screen shown below.



Enter LOG ON ID

F1 TO CONTINUE

- 2. Enter your assigned identifier using the keyboard keys. To delete entered characters, press the **[Backspace]** key.
- 3. Press the **[F1]** key to enter your identifier and advance to the *Main Menu* screen.

03/10/2006 1:50PM

MAIN MENU

F1 WORKLIST F5 SETUP

F2 RUN PATIENT F6 MICROSCOPIC

F3 RESULTS F7 SERVICE

F4 CONTROLS F8 LOG OFF



NOTE: If the *Enter Log On ID* screen reappears with the message "Unacceptable Log On", re-enter your identifier. If the *Main Menu* screen still does not appear, refer to *Setting Log On Identifiers*.

Logging Off

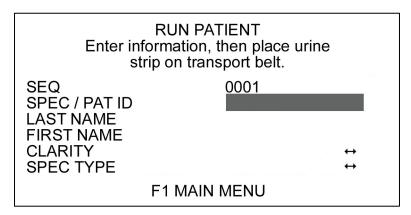
To log off of the instrument, from the *Main Menu*, press the **[F8]** key. This will log off the current operator and the *Enter Log On ID* screen will be displayed. The **[F8] LOG OFF** does not appear on the Main Menu screen unless "Log On Required" is selected.



Running Single Specimen Analysis

Entering Patient Information

From the *Main Menu* screen, press the [F2] key to display the *Run Patient* screen (below) and to activate the urine strip sensor. The illuminated green LED on the instrument indicates that the sensor is active.





NOTE: If the waste container is nearly full (> 125 strips), you must empty it prior to beginning "Run Patient" analysis.

The *Run Patient* screen allows you to identify and run a patient specimen. You can identify the sample using a sequence number, a specimen/patient ID, a name, or all three options. Data for only one patient at the time can be entered in this screen.

Sequence Number

The sequence number field is only active for the first specimen run after entering *Run Patient*. Thereafter, the sequence number is automatically assigned by the software each time a new patient specimen is analyzed.

Specimen/Patient ID

2. If desired, enter specimen or patient ID (up to 15 alphanumeric characters) by using the keyboard or the barcode reader. Press the [Enter] key or use the [↑] or [↓] arrow keys to move to the next field.

Last Name

3. If desired, enter the patient last name (up to 15 characters) using the keyboard or the barcode reader. Press the [Enter] key or use the [↑] or [↓] arrow keys to move to the next field.





First Name

4. If desired, enter the patient first name (up to 10 characters) using the keyboard or the barcode reader. Press the **[Enter]** key or use the **[**↑] or **[**↓] arrow keys to move to the next field.

Clarity

5. You can enter clarity by either toggling through the list of clarity options found in the software or by using the barcode reader. Barcodes are located at the top left of the instrument.

Using keyboard entry		Using barcode entry	
Options	Blank field Clear Hazy Slt. Cloudy Cloudy Turbid Bloody Other	Options	CLEAR SLT. CLOUDY CLOUDY BLOODY OTHER
Press the [←] or [→] arrow keys until the desired clarity result appears. Press the [Enter] key or use the [↑] or [↓] arrow keys to accept and move to the next field.		To select clarity using the barcode reader, determine the clarity result and click the barcode reader over its respective barcode.	





Specimen Type

6. You can enter the specimen type by either toggling through the list in the software or by using the barcode reader. Barcodes are located at the top left of the instrument.

Using keyboard entry		Using barcode entry	
Options	Blank field Random CL catch Cath Peds First am 24 hours Fasting Gluc tol S pubital Other	Options	RANDOM CL CATCH CATH PEDS OTHER
Press the [←] or [→] arrow keys until the desired type appears. Press the [Enter] key or use the [↑] or [↓] arrow keys to accept and move to the next field.		To select specimen type using the barcode reader, click the barcode reader over its respective barcode.	



Analyzing the Urine

Once all the patient identification information has been entered, proceed to analyzing the urine.



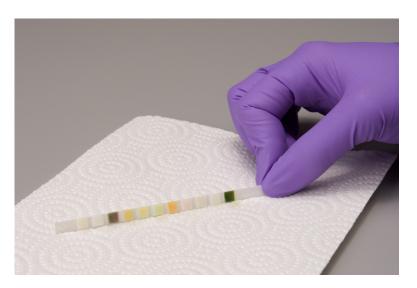
NOTE: The urine specimen should be fresh, well-mixed and uncentrifuged. If refrigerated, allow the specimen to return to room temperature.

1. Dip the urine test strip into the urine, making sure all the test pads are wet.

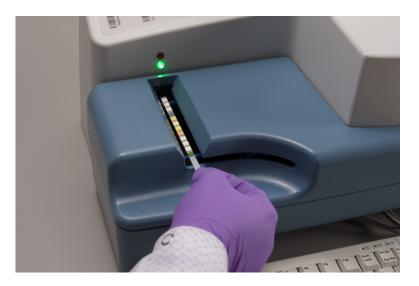


- 2. Immediately remove the urine test strip from the urine, dragging the edge of the strip against the side of the container as you remove the strip.
- 3. Blot the urine test strip by touching the edge of the strip to a paper towel. Do not drag the strip across the paper towel; touch the edge only.





4. Place the urine test strip on the transport belt of the instrument with the test pads facing up. Slide the strip forward until the strip touches the end stop. A sensor will detect the presence of the strip and the red LED light will be turned on along with the green LED light.





NOTE: If you move the strip away from the sensor prior to being transported, you will be prompted to remove the urine strip from the transport belt and press the **[F1]** key to continue.

5. Approximately two minutes after the urine strip is transported for analysis the printer will print the results; unless printing has been set to "Print Function Only" (see *Setting up the printer*.)



To run another specimen, repeat from *Entering Patient Information*, then *Analyzing the Urine*. If no test strip is placed on the transport belt within ten (10) minutes, the screen will return to the *Main Menu* screen.

You may return to the *Main Menu* screen at any time by pressing the **[F1]** key. However, if the analysis of the strip is not complete, a message will appear requesting that you wait for analysis to finish.

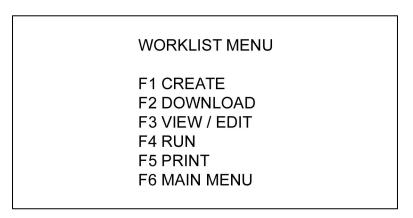


Running Batch Specimen Analysis

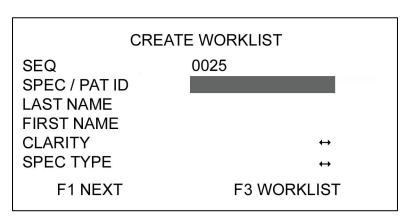
Creating a Worklist

The *Create Worklist* screen allows you to generate a list of specimen samples that will run in a batch mode. To create a worklist, you must enter information in at least one of the identifier fields. An error message will direct you to enter missing information before advancing to the next specimen. The sequence number field is only active for the first specimen in the *Create Worklist* option. After the first specimen, the instrument will automatically advance one sequence number each time a new patient specimen is entered.

1. From the *Main Menu* screen, press the **[F1]** key to display the *Worklist Menu* screen.

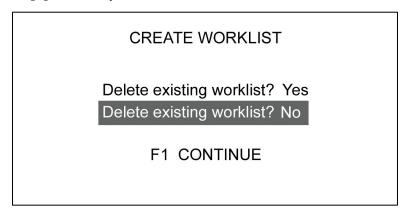


2. From the *Worklist Menu* screen, press the **[F1]** key to display the *Create Worklist* screen.

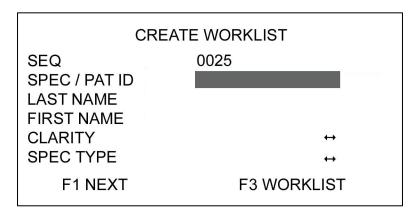




3. The following screen will appear only if a worklist exists. Use the [↑] or [↓] arrow keys to select **YES** or **NO**.



- a. If you select **YES** and press the **[F1]** key, the instrument will delete the existing worklist and advance you to the *Create Worklist* screen.
- b. If you select **NO** and press the **[F1]** key, the instrument will return you to the *Worklist Menu* screen.





Sequence Number

4. To reset the sequence number, change it while the initial specimen screen is active or you will need to return to the initial specimen screen in the worklist where the sequence number field will again be active.

Specimen/Patient ID

5. If desired, enter specimen or patient ID (up to 15 alphanumeric characters) by using the keyboard or the barcode reader. Press the **[Enter]** key or use the **[**↑] or **[**↓] arrow keys to move to the next field.



Last Name

6. If desired, enter the patient last name (up to 15 characters) using the keyboard or the barcode reader. Press the **[Enter]** key or use the **[↑]** or **[↓]** arrow keys to move to the next field.

First Name

7. If desired, enter the patient first name (up to 10 characters) using the keyboard or the barcode reader. Press the **[Enter]** key or use the **[↑]** or **[↓]** arrow keys to move to the next field.

Clarity

8. You can enter clarity by either toggling through the list of clarity options found in the software or by using the barcode reader. Barcodes are located at the top left of the instrument.



Using keyboard entry		Using barcode entry	
Options	Blank field Clear Hazy Slt. Cloudy Cloudy Turbid Bloody Other	Options	CLEAR SLT. CLOUDY CLOUDY BLOODY OTHER
Press the [←] or [→] arrow keys until the desired clarity result appears. Press the [Enter] key or use the [↑] or [↓] arrow keys to accept and move to the next field.		To select clarity using the barcode reader, determine the clarity result and click the barcode reader over its respective barcode.	



Specimen Type

9. You can enter the specimen type by either toggling through the list in the software or by using the barcode reader. Barcodes are located at the top left of the instrument.



Using keyboard entry		Using barcode entry	
Options	Blank field Random CL catch Cath Peds First am 24 hours Fasting Gluc tol S pubital Other	Options	RANDOM CL CATCH CATH PEDS OTHER
Press the [←] or [→] arrow keys until the desired type appears. Press the [Enter] key or use the [↑↑] or [↓] arrow keys to accept and move to the next field.		To select specimen type using the barcode reader, click the barcode reader over its respective barcode.	

- 10. Once the desired patient identification information has been entered for the current specimen, proceed to the next sample by pressing the [F1] key. A blank *Create Worklist* screen will be displayed ready for the next sample. The sequence number will automatically advance by one number. Repeat this process until information has been entered for all specimens.
- 11. You can return to the previous specimen information by pressing the **[F2]** key.
- 12. When all specimens have been entered, press the **[F3]** key to return to the *Worklist Menu* screen.

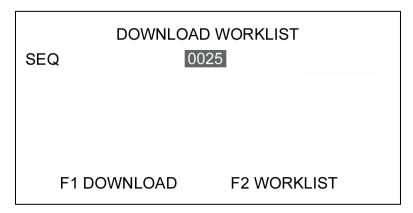


Downloading a Worklist

- 1. From the *Main Menu*, press the **[F1]** key to display the *Worklist Menu* screen.
- 2. From the *Worklist Menu*, press the **[F2]** key. The *Download Worklist* screen will be displayed, except when a worklist already exists; then the following screen will be displayed.



- 3. If the screen above appears, use the \uparrow or \downarrow arrow keys to select **YES** or **NO**.
 - a. If you select YES and press the [F1] key, the instrument will delete the existing worklist and display the *Download Worklist* screen.
 - b. If you select **NO** and press the **[F1]** key, the instrument will return to the *Worklist Menu* screen.
 - c. If there is no existing worklist, the following screen will be displayed.





This screen allows you to generate a list of specimen samples that is downloaded from an interfaced computer or a Laboratory Information System (LIS).

- 4. The sequence number field is active and may be altered. If you do not alter the sequence number before pressing the **[F1]** key, the instrument will begin with the number that is present on the screen. To specify a particular sequence number, enter it before downloading the worklist and the instrument will automatically advance one number each time a new patient specimen is downloaded.
- 5. Press the [F1] key to start the download process. The instrument will notify the interfaced computer that information for the worklist is being requested. After communication between the computer and instrument is established, the worklist transfer begins. The instrument can accept up to 100 patient demographics. The Worklist Menu screen will reappear when the download is complete.



NOTE: For each sample, the instrument must download either a specimen/patient ID or patient name (last and first). If neither is available, the instrument will skip to the next patient specimen.

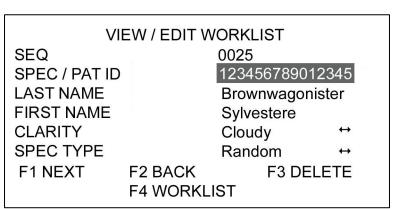
6. If you do not wish to download a worklist, press the **[F2]** key to return to the **Worklist Menu** screen.

Viewing and Editing a Worklist



NOTE: To add clarity and specimen type information to the worklist, you need to access the *View/Edit Worklist* screen.

 From the Worklist Menu screen, press the [F3] key. The View/Edit Worklist screen will be displayed.





This screen allows you to review, edit, and/or delete current specimens from the existing worklist. The first specimen's information in the current worklist will be displayed on the screen.

To select a data text field, advance through the fields using the [↑] or [↓] keyboard keys until you are in the desired field.

RUN WORKLIST

Place the urine strip for this specimen on the transport belt.

SEQ 0025

SPEC / PAT ID 123456789012345 LAST NAME Brownwagonister

FIRST NAME Sylvestere

F1 WORKLIST F2 MAIN MENU F3 RUN STAT

- 3. To edit the field, press the **[Del]** key to delete the entire contents of the data field, and re-enter the appropriate information.
- 4. To delete the specimen and all associated information from the worklist, press the **[F3]** key. A confirmation message asking you to confirm the deletion will be displayed. Using the **[Enter]** key:
 - a. Select **YES** and then press the **[F1]** key to delete the specimen;
 - b. Select **NO** and then press the **[F1]** key if you do not wish to delete the specimen.
- 5. To move to the next specimen on the worklist, press the [F1] key.
- 6. To return to the previous specimen on the worklist, press the **[F2]** key.
- 7. Once you have finished making any changes to the worklist, press the **[F4]** key to return you to the **Worklist Menu** screen.



Running a Worklist

- 1. From the *Main Menu* screen, press the *[F1]* key to display the *Worklist Menu* screen.
- From the Worklist Menu screen, press the [F4] key to display the Run Worklist screen. The first specimen's information from the stored worklist will be displayed, thus identifying the specimen to be run by the operator.

The green LED light on the instrument will be illuminated, indicating that the instrument is activated and waiting for a urine test strip to be placed on the transport mechanism.



NOTE: If the waste container is nearly full (> 125 strips), you must empty it before beginning "Run Patient" analysis.



NOTE: The urine specimen should be fresh, well-mixed and uncentrifuged. If refrigerated, allow the specimen to return to room temperature.

3. Dip the urine test strip into the urine, making sure all the test pads are wet.



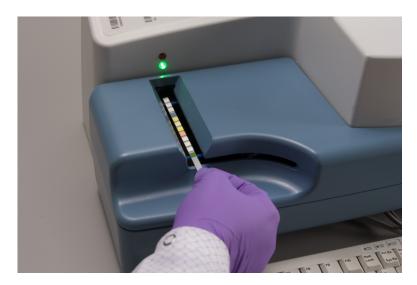
4. Immediately remove the urine test strip from the urine, dragging the edge of the strip against the side of the container as you remove the strip.



5. Blot the urine test strip by touching the edge of the strip to a paper towel. Do not drag the strip across the paper towel; touch the edge only.



6. Place the urine test strip on the transport belt of the instrument with the test pads facing up. Slide the strip forward until the strip touches the end stop. A sensor will detect the presence of the strip and the red LED light will be turned on along with the green LED light.





NOTE: If you move the strip away from the sensor prior to being transported, you will be prompted to remove the urine strip from the transport belt and press the **[F1]** key to continue.



- 7. Approximately two minutes after the urine strip is transported for analysis, the printer will print the results; unless printing has been set to "Print Function Only".
- 8. Once the strip is transferred to the incubation belt, the transport belt will stop, the green LED light will again come on and the screen will be updated to identify the next specimen to be run. Place the next specimen on the transport belt and the system will repeat the process. Continue until all samples have been tested.
- After the last specimen has been analyzed from the worklist, the
 printer will print the results for all of the specimens processed from the
 worklist, unless printing has been set to "Print Function Only". Refer
 to Setting up the printer.

Printing a Worklist

- 1. From the **Worklist Menu** screen, press the **[F5]** key to print a copy of the worklist.
- 2. The screen notifies you that the worklist is being transmitted to and printed by the printer (internal or external).
- 3. To stop the printing process, press the **[F1]** key. This will return you to the **Worklist Menu** screen.
- 4. All printouts begin with a customized header (refer to *Setting up the printer* or the instrument name.) Following the header information is the sequence number and specimen information for each of the specimens on the worklist. If the information for a line is not present, the line is skipped.

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WORKLIST

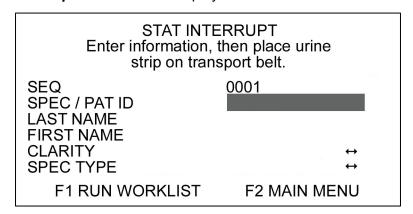
- 1 123456789012345 Last Name, First Name
- 2 123456789023456
- 3 LastName, First Name
- 4 123456789034567 Last Name, First Name



Running a Stat

While you are running a batch of urines in the "Worklist" mode, you can interrupt the batch mode operation to run one or more stat specimens.

1. From the *Run Worklist* screen, press the **[F3]** key. The *Stat Interrupt* screen will be displayed.



When entering the "Run Stat" mode the urine strip sensor will be active and the green LED will be illuminated.



NOTE: If the waste container is nearly full (> 125 strips), you will be required to empty it prior to beginning "Run Patient" analysis.

2. To run a stat specimen, you can enter patient identification information, such as patient ID, first and last name, or you can use the sequence number assigned by the software.



NOTE: The sequence number assigned to the stat specimen will be the next number following the last patient specimen assigned when you created the current "worklist" (e.g., sequence number for last specimen created in current "worklist" was 25, the stat sequence number will be 26).

- 3. If desired, enter the urine clarity and specimen type, see *Clarity* and *Spec Type*.
- 4. Dip the urine test strip into the urine. Make sure all the test pads are wet.





- 5. Immediately remove the urine test strip from the urine, dragging the edge of the strip against the side of the container as you remove the strip.
- 6. Blot the urine test strip by touching the edge of the strip to a paper towel.

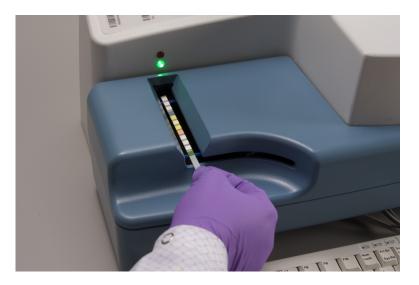




NOTE: Do not drag the strip across the paper towel, touch the edge only.



7. Place the urine test strip with the test pads facing up on the transport belt of the instrument until the strip touches the end stop. A sensor will detect the presence of the strip and the red LED light will be turned on along with the green LED light.





NOTE: If you move the strip away from the sensor before it is transported, a message screen will prompt you to remove the urine strip from the transport belt and press the **[F1]** key to continue.

- 8. The incubation belt transports the strip to be analyzed and then on to the waste container. At the end of analysis, the internal printer will print the results, unless otherwise setup (see Setting up the printer.) The screen then displays the Stat Interrupt screen, ready for another stat specimen.
- 9. To run another stat sample, enter the patient information, dip the urine test strip, then place it onto the transport belt as described previously.
- 10. To return to the worklist interrupted by the Stat, from the **Stat Interrupt** screen, press the **[F1]** key to return to the **Run Worklist** screen.
- 11. If the stat specimen analysis is not completed, the screen will notify you that the "Urine strip is still on the incubation belts for analysis. Please wait for end of measurement(s)." As soon as the results are printed for the stat(s), the screen will return to the Run Worklist screen, and the next specimen to be run is displayed. The instrument will continue displaying the previously created worklist until all samples have been analyzed.

5. Controls



5 Controls

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Setting the Control Run Frequency

- From the *Main Menu*, press the [F4] key to display the *Controls Menu* screen. This screen allows you to set up new control files, view or edit file setup information, print, view or delete control file results, or run a control and store the results in the highlighted file. In addition, it allows you to set a reminder to run controls at a specified frequency.
- 2. From the **Controls Menu** screen, use the [↑] or [↓] arrow keys or the **[Enter]** key to move to the left field of the frequency fields.

CONTROLS MENU			
	LOT#	EXP	
FILE 11212	UC2006	03/20/2006	
FILE 21213	UC2006	03/20/2006	
FILE 3 FREQ	1	Hours	\leftrightarrow
F1 SETP F4 PRINT	F2 VIEW F5 DELETE	F3 RUN F6 MAIN N	ЛENU

- 3. To specify how often a control is to be run, enter a number between 1 and 30 in the text field. Press the [→] arrow key or the [Enter] key to move to the right frequency field.
- 4. The right frequency field allows the operator to toggle through the following options:
 - Blank entry field
 - Hours
 - Days
 - Weeks
 - Months
- 5. Use the [←] or [→] arrow keys to select the desired option. The entries will be locked in when exiting the screen.



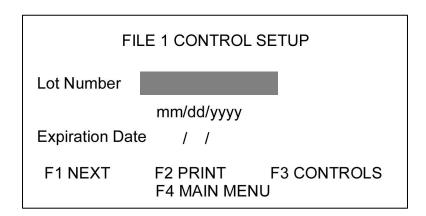
NOTE: The frequency time applies to all controls. When the designated frequency timing for running controls has been exceeded, the instrument will prompt the user to run control(s). The prompt will appear before each specimen is run in the "Run Patient" mode, or before the first specimen in the "Worklist" mode is run. A control must be run before the timer will reset.



Setting a Control File

Creating a Control File

- 1. From the *Main Menu*, press the **[F4]** key to display the *Controls Menu* screen.
- 2. From the *Controls Menu* screen, use the [↑] or [↓] arrow keys, the [Tab] key or the [Enter] key to select the file to setup.
- 3. Press the **[F1]** key to display *File # Control Setup* screen. This screen allows you to enter a lot number and expiration date for a specific quality control material.



- 4. Enter the desired lot number in the *Lot Number* text field (up to 12 alphanumeric characters). Press the [↓] arrow key or the [Enter] key to move to the next field.
- 5. Enter the desired expiration date in the *Expiration Date* text field. Press the [↓] arrow key or the [Enter] key to move to the next field.
- 6. Press the **[F1]** key to lock in the selections made and advance to the assay portion of the *File 1 Control Setup* screen.



l F	ILE 1 CONT	ROL S	SETUP	
	TOWEDIN	AT -	ÜPPER LM	т
Dilimakin	LOWER LI	VI I	OLEEK LIM	I
Bilirubin	35	\longleftrightarrow	70	\leftrightarrow
Urobilinogen	70	_ ↔	200	\leftrightarrow
Urobilinogen Ketones	25	\leftrightarrow	300	\leftrightarrow
Asc. Acid	20	\leftrightarrow	40	\leftrightarrow
Glucose	150	\leftrightarrow	≥1000	\leftrightarrow
Protein	30	\leftrightarrow	≥500	\leftrightarrow
Blood	++	\leftrightarrow	+++	\leftrightarrow
pH	6	\leftrightarrow	8	\leftrightarrow
Nitrite	Pos	\leftrightarrow	Pos	\leftrightarrow
Leukocytes S. Gravity	75	\leftrightarrow	500	\leftrightarrow
S. Gravity	1.010	\leftrightarrow	1.020	\leftrightarrow
F1 PRINT	F2 CONTF	ROLS	F3 MAIN ME	NU

7. This screen allows you to enter the appropriate assay information for each of the chemistries. There are two toggle fields for each of the chemistries, a lower and an upper limit.



NOTE: The toggle fields contain values dependent upon which units have been selected in **Setup**, (i.e., conventional, S.I., or qualitative). Refer to **Setting units** on Chapter 3 - Setup. A control value that falls outside of the selected values will be flagged with an * when the results are displayed or printed.

- 8. Use the [←] or [→] arrow keys to move through the options in each toggle field and select the desired control value for both the upper and lower limit. Use the [↑] or [↓] arrow keys, the [Tab] key or the [Enter] key to move between fields.
- 9. If desired, press the **[F1]** key to print out a copy of the control file information.



Editing Control File Information



WARNING: Making edits in a control file will delete all results stored in memory for this file.

- 1. From the *Main Menu*, press the **[F4]** key to display the *Controls Menu* screen.
- From the *Controls Menu* screen, to select a file to be edited, use the [↑] or [↓] arrow keys to move to the desired file number, and then press the [F1] key to display the *File Control Setup* screen. A message will appear warning that all results for this file will be deleted.

FILE 1 CONTROL SETUP

DELETE LOT # and EXP?

DELETE ASSAY INFO, LOT # and EXP?

EDIT EXISTING INFO?

PRINT EXISTING SETUP INFO?

F1 CONTINUE F2 CONTROLS F3 MAIN MENU

This screen allows you to:

- Delete Lot # and Exp?—delete the existing lot number, expiration date, and run data.
- Delete Assay Info, Lot # and Exp?—delete all existing file information (lot #, exp. date, assay information and run data).
- Edit Existing Info?—leave all existing information intact, allowing the editing of desired parameters only (such as lot numbers), but deleting run data of the selected file.
- Print Existing Setup Info?—print existing control set up information for the selected file.
- 3. Use the [↑] or [↓] arrow keys to move between the choices. Press the [F1] key to lock in the highlighted field selection and perform the action requested.

5. Controls



- 4. Make the appropriate modifications and press the **[F3]** key to lock in the selections and return to the *Controls* Menu screen.
- 5. Press the **[F4]** key to lock in the selections and return to the *Main Menu* screen.

Deleting Control File Information

- 1. From the *Main Menu*, press the **[F4]** key to display the *Controls Menu* screen.
- 2. From the *Controls Menu* screen, use the [↑] or [↓] arrow keys to select the desired file number and press the [F1] key. If "File 1" had been selected, a screen similar to the following will be displayed.

FILE 1 CONTROL SETUP

WARNING*

The results of selected file will be deleted.

Press F1 to delete and continue.

F1 CONTINUE F2 CONTROLS F3 MAIN

- Press the [F1] key if you wish to carry out the desired deletion. The instrument will advance to the *File # Control Setup* screen when finished.
- 4. Press the **[F2]** key to return to the **Controls Menu** screen without deleting anything.
- 5. Press the **[F3]** key to return to the *Main Menu* screen without deleting anything.



Running Controls

- 1. From the *Main Menu* screen, press the **[F4]** key to display the *Controls Menu* screen.
- 2. Using the [↑] or [↓] arrow keys, select the control file corresponding to the control material you want to run.
- 3. From the *Control Menu* screen, press the **[F3]** key to display the *Run Controls* screen. The green LED light on the instrument will be illuminated, indicating the instrument is activated and waiting for a urine test strip to be placed on the transport mechanism.

RUN CONTROLS
Please place the urine strip
on transport belts.

SEQ 001 FILE NUMBER FILE 1

LOT NUMBER 1212UC06 EXP. DATE 03/20/2006

F1 CONTROLS F2 MAIN MENU

This screen allows you to run a specified quality control material and have its results stored in the selected file. The sequence number of the control is displayed at the top of the screen and reflects the number of controls that have been run for this specific control file. The instrument has the capability to store up to 100 runs in each file.



NOTE: You cannot run a control material that has not been previously set up in a control file. Refer to **Setting a Control File**.

4. Dip a urine test strip into the control material corresponding to the control identified on the screen. Place the test strip onto the transport belt with the test pads facing up. Slide the strip forward until the strip touches the end stop.



NOTE: If you move the strip away from the sensor prior to being transported, a message screen will appear requesting that you remove the urine strip from the transport belt and press the **[F1]** key to continue.



5. At the end of the analysis, the results will be displayed on the screen for review and acceptance.

FILE 1		SEQ	021
Bili 35 Uro 140 Ket 100 A. Acid 20 Gluc 50* Prot 100		Leu	8 Pos
F1 ACCEPT	F2 REJECT	F3 M	IAIN MENU



NOTE: Results for a parameter that fall outside the identified limits will be flagged with an * on all displays or printouts of those results. The flagging information will be stored along with the results in the control file.

To accept the results

6. Press the **[F1]** key to accept the displayed results. The results will then be stored in the appropriate control file, and printed on the internal printer, unless printing has been set to "Print Function Only" (refer to **Setting up the printer**). The instrument will then return the display to the **Controls Menu** screen where you can select a different control material and repeat this process.

To reject the results

- 7. Press the **[F2]** key to reject the displayed results. Rejecting the results will remove the results from memory and return the display to the *Run Controls* screen where the control material may be rerun.
- 8. Press the **[F3]** key to exit this screen, reject the results and remove them from memory, and return the display to the *Main Menu* screen.



NOTE: When the control file is full, it will prevent the addition of any more results until the entire file has been cleared. (See *Deleting Control File Information*.)



Control Results

Viewing Control Results

- 1. From the *Main Menu* screen, press the **[F4]** key to display the *Control Menu* screen.
- 2. From the **Control Menu**, use the [↑] or [↓] arrow keys to select the file to be viewed. Press the **[F2]** key to display the **View QC Runs** screen for the selected file.

FILE 1 - VIEW QC RUNS - FILE 1			
Bilirubir	1	Blood	
Urobilin	ogen	рН	
Ketones	3	Nitrite	
Asc. Acid		Leukocytes	
Glucose	Э	S. Gravity	
Protein			
F1 VIEW	F2 CONTROLS	F3 MAIN MENU	

This screen allows you to review the quality control results for each of the chemistry parameters.

3. Use the [↑] or [↓] arrow keys or the [Tab] key to select a parameter and then press the [F1] key. The screen will display a series of screens allowing you to view all the stored results (along with flagging) for the selected chemistry.

	FILE 1 - VIEW	QC RUNS	- Glu	cose
Run#	Date	Time	Opr	Results
91	03/23/2006	08:25	1	>1000*
92	03/23/2006	12:30	2	500
93	03/23/2006	22:15	3	500
94	03/23/2006	08:25	21	150
95	03/23/2006	12:30	22	500
96	03/23/2006	22:15	23	500
97	03/23/2006	08:25	11	150
98	03/23/2006	12:25	12	500
	F1 NEXT F	F2 PREV	F3 VI	IEW QC



- 4. Each screen displays up to 10 results for the designated chemistry. No units are displayed. Each control file holds the results for up to 100 runs. The results are displayed with the run number, date and time run, and the operator's numerical identifier (if available).
 - Press the [F1] key to display the next series of results for that chemistry.
 - Press the [F2] key to display the previous series of results for that chemistry.
 - Press the [F3] key to exit the display screen and return to the View QC Runs screen where you may select to view another chemistry control.

Printing Control Results

- 1. From the *Main Menu* screen, press the **[F4]** key to display the *Control Menu* screen.
- 2. From the *Control Menu*, use the [↑] or [↓] arrow keys to select the control file to be printed, and then press the [F4] key.

All printouts will include:

- Header information
- Name of file, followed by lot number and expiration date
- All results and flagging for each of the chemistry parameters, the date and time of the run and the operator's identifier.
- 3. Press the **[F1]** key to stop printing, if desired. The printing will stop after print queue is emptied.
- 4. At the end of printing the screen will return to the **Controls Menu** screen.

Deleting Control Results

- 1. In the *Controls Menu* screen, use the [↑] or [↓] arrow keys to select the control file to delete, and then press the [F5] key. A message will appear warning you that you are about to permanently delete all the control results for that file and asking for confirmation.
 - Press the [F1] key to delete all control results for that file.
 When complete, the screen will return to the *Controls Menu* screen.

5. Controls



- Press the **[F2]** key to exit the screen without deleting any results from the selected file. The screen will return to the **Controls Menu** screen.
- Press the **[F3]** key to exit the screen without deleting any results from the selected file. The screen will return to the **Main Menu** screen.

6. Results



6 Results

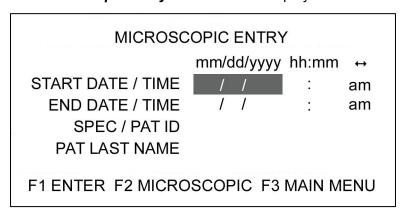
Entering Microscopic Results	83
Viewing Results	
Limiting Result Parameters	
Printing Results	
Transmitting Results	
Deleting Results	



Entering Microscopic Results

This function provides you with the ability to recall urine specimens that have already had chemistry analysis, so that you may enter their microscopic analysis information. Specimens for microscopic exam entry or editing can be accessed by date, time, specimen / patient ID, or patient last name.

1. From the *Main Menu*, press the **[F6]** key, then press the **[F1]** key. The *Microscopic Entry* screen will be displayed.



 Once you have entered the search criteria for the urine specimens you want to access, press the [F1] key to display the *Enter Microscopic* screen for the first urine specimen.

This screen will display the patient's / specimen's ID number and last name, if entered, along with the date and time of the chemistry analysis. Microscopic entry is completed exclusively with toggle fields. Many of the parameters have the ability to change the descriptors as well as enter a quantifier.

```
123456789012345 Johnson
                                      0025
                  03/23/2006
                                    12:07 pm
1. RBCs
2. WBCs
3. Bacteria
4. Epis
5. Crystals
6. Crystals
7. Yeast
8. Casts
F1 MORE
                        F4 CHEM
F5 MICROSCOPIC
                        F6 MAIN MENU
```



1234567890	12345		0025
		03/23/2006	12:07 pm
1. RBCs			\leftrightarrow
2. WBCs			\leftrightarrow
3. Bact Rods	$s \leftrightarrow$		\leftrightarrow
4. Epis	\leftrightarrow		\leftrightarrow
5. Crystals 6. Crystals	\leftrightarrow		\leftrightarrow
6. Crystals	\leftrightarrow		\leftrightarrow
7. Yeast	\leftrightarrow		\leftrightarrow
8. Casts	\longleftrightarrow		\leftrightarrow
F1 MORE		F4 CHEM	
F5 MICROS	COPIC	F6 MAIN	MENU

The parameters allowing for the changing of descriptors are as follows:

Descriptors	Sub- category Abbrev.	Full Name
RBCs		
WBCs		
Bacteria	BacChain BactCoci BactRods	Bacterial chains Bacterial cocci Bacterial rods
Epis	Sq Epi Trans Epi Renal Epi	Squamous epithelials Transitional epithelials Renal epithelials
Crystals	Tri Phos CaOx Ca Carb Ca Phos Uric Acid Leuc Cyst Tyro Amorph Na Urate AmBiurat	Triple phosphate Calcium oxalate Calcium carbonate Calcium phosphate Uric Acid Leucine Cystine Tyrosine Amorphous urates/phosphates Sodium urates Ammonium biurate
Yeast	YeastBud YeastHyp	Budding yeast Hyphaed yeast
Casts	HyalCast Epi Cast WBC Cast	Hyaline cast Epithelial cast White Blood Cells cast



Descriptors	Sub- category Abbrev.	Full Name
	RBC Cast Gr Cast FnGrCast CrGrCast CellCast Brd Cast Fat Cast Waxy Cast	Red Blood Cells cast Granular cast Fine granular cast Coarse granular cast Cellular cast Broad cast Fatty cast Waxy cast
Trich		Trichomonas
Oval Fat	Oval Fat Fat Drop	Oval fat body Fat droplets
Mucus		
Sperm		

- 3. Use the [↑] or [↓] arrow keys, the [Enter] key, or the [Tab] key to move around within the toggle fields to select (highlight) a desired field.
- Use the [←] or [→] arrow keys to toggle through the selections. For example, you wish to change the Bacteria descriptors. With the Bacteria identifier field active, toggle through the bacteria selections, (e.g., BacChain, BactCoci, or BactRods to access the desired descriptor).



NOTE: The quantifier selections for each of the microscopic parameters can be viewed by printing them out (see *Print a Copy of Microscopic Setup*).

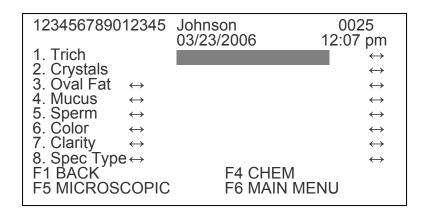
5. Once you have made your selection, use the [↑] or [↓] arrow keys, or the [Enter] key to lock in your selection and move to the next field.



NOTE: Any microscopic field with an associated quantifier field that is left blank will not be reported or stored under Results.

6. Enter desired information for all parameters on this screen. If necessary, press the [F1] key to move to the next *Enter Microscopic* screen for additional parameter entries for this specimen.







NOTE: This is the only place you can also edit the color, clarity and specimen type for the urine results presented in this screen.

7. To enter results for the next specimen press the **[F3]** key. The next specimen's fields for entering or editing microscopic results will be displayed. (If there are no microscopic results to be entered or edited for a specimen, press the **[F3]** key to advance to the next specimen.)

1234567890 03/23/2006	12:07	Johns	son
Bili Uro Ket A. Acid Gluc Prot	Neg Norm 100 Neg 150 Neg	Bld pH Nit Leu S.G.	Neg 7 Pos 75 1.015
F2 PR F5 MICROS	EV F3 NE COPIC	EXT	F4 MICRO F6 MAIN MENU

8. To view a specimen's chemistry results, press the **[F4]** key while displaying the specimen's microscopic entry screen.



NOTE: No editing of chemistry results is allowed. This screen is for viewing the chemistry results for this specimen only.

6. Results

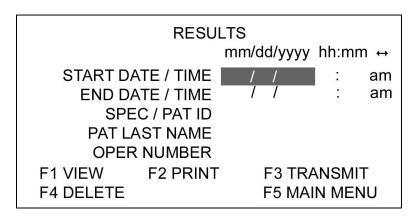


- 9. To display the same specimen's microscopic results again, press the **[F4]** key while displaying the specimen's chemistry results. This will return you to the first *Microscopic Entry* screen.
- 10. Press the **[F5]** key to return to the *Microscopic Entry* screen or press the **[F6]** key to return to the *Main Menu* screen.



Viewing Results

1. Press the **[F3]** key with the *Main Menu* screen active to bring up the *Results* screen.



This screen provides you with the ability to review, print, delete or transmit results on specimens that have already been run and are stored in patient storage. The specimens may be recalled by date, specimen or patient ID, patient last name, and/or operator number.



NOTE: Not all fields for date and time are required. For example, to bring up all specimens for one day, enter the "Start Date" and "End Date". To bring up all specimens for one day during a particular hour, enter the "Start Date / Time" and the "End Date / Time".

Limiting Result Parameters

In addition to viewing complete results from the *Results* screen, it is also possible to limit your results by the following parameters:

To view results	Press the [F1] key after doing this
by start date	enter the desired start date by month, day, year, and time
for more than one day	to enter both a start date and end date (both are required
by specimen or patient ID	enter the specimen or patient ID
by last name	enter the patient's last name
by operator number	enter the number associated with the operator name and Log On ID



RESULTS

mm / dd / yyyy hh:mm ↔ 03 / 23 / 2006 12:00 pm

START DATE / TIME 03 / 23 / 2006 12:00 pm END DATE / TIME 03 / 24 / 2006 02:00 pm SPEC/PAT ID 12345678901234

PATIENT LAST NAME
OPERATOR LAST NAME

F1 VOIR F2 IMPR F3 TRANSMETTRE F4 SUPPRIMER F5 MENU PRINC

You can also search using more than one field, (e.g., start date and patient ID, start and end date, etc. as shown above). With the desired search fields defined, press the **[F1]** key to view results.

The instrument will display the results for each specimen of the search through a combination of two screens (one for chemistry results and one for microscopic results.

03/23/2006 12:07 pn	า
Bili Neg Bld ++# Uro Norm pH 6 Ket Neg Nit Pos# A. Acid Neg Leu 75# Gluc ≥1000* S.G. 1.030 Prot ≥500# Color Yellow	•
Clarity Slt Cloudy S. Type Random F1 MICRO F2 PREV F3 NEXT F4 RESULTS	

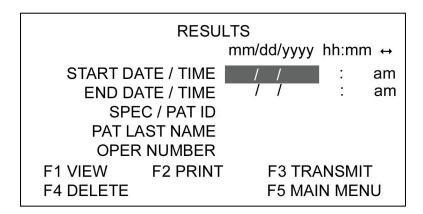
Use the **[F1]** key to toggle between these two screens, the **[F2]** key to view the previous result, the **[F3]** key to view the next result, and the **[F4]** key to return to the **Results** screen.

Rey to retain to the results coreen.						
123456789012345		Johns 03/23/	on /2006	0025 12:07 pm		
RBCs WBCs Bacteria Epis Crystals Crystals Yeast	3-5 25-50 ++ Few	Casts Casts Trich Oval F Mucus Spern	-at s			
F1 CHEM	F2 PREV	F3 NEXT	F4 RI	ESULTS		



Printing Results

1. Press the **[F3]** key with the *Main Menu* screen active to bring up the *Results* screen.



- Select the results you wish to print by specifying the date, specimen or patient ID, patient last name, or operator number in the search fields.
- 3. Press the **[F2]** key to print results. A screen will appear indicating that results are being printed.
- 4. Press the **[F1]** key to stop printing, if desired. The printing will stop after the print queue is emptied.
- 5. At the end of printing, the screen will revert back to the **Results** screen.



An example printout is shown below.

Printed results will include:

- Header Information
- Date and time of analysis
- Sequence Number
- Patient First and Last Name, if available
- Specimen or patient ID
- Operator, if available
- Clarity, if available
- Color
- Specimen Type
- Chemistry results
- Microscopic results if available

Midtown County Health 10257 Crescent Blvd. Suite 3 Monroe, Texas 12345 Telephone: 555-555-7755

DATE 03/25/2006 SEQ 0001 TIME 11:36am

Pt Stephen Brown

Spec/Pat ID 1234567890

OP 21

Clarity Cloudy
Color Amber
Spec Type Random

Bilirubin Neg Urobilinogen Norm Ketones Neg Asc. Acid Neg Glucose 150

Glucose 150 mg/dL *
Protein Neg
Blood 0.03 mg/dL #

pH 8 Nitrite Pos

Leukocytes 75 WBCs/uL #

S. Gravity 1.030 RBCs 5-10 HPF WBCs 25-50 HPF

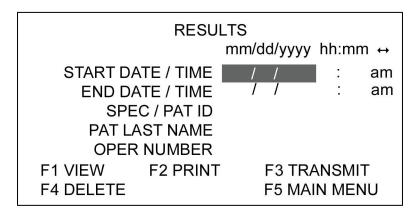
BacChain 2+ Sq Epi 2+ Tri Phos Few YeastBud Moderate

COMMENTS



Transmitting Results

1. Press the **[F3]** key with the *Main Menu* screen active to bring up the *Results* screen.

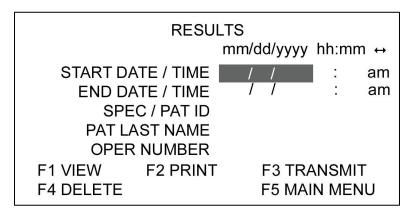


- 2. Select the results you wish to transmit by specifying desired date(s), specimen or patient ID, patient last name, or operator number in the search fields.
- 3. Press the **[F3]** key to send results to the laboratory information system (LIS). A screen will appear indicating that results are being transmitted. Transmitted results will include:
 - Date and time of analysis
 - Sequence number
 - Patient first and last name, if available
 - Specimen or patient ID
 - Operator's name, if available
 - Specimen type, if available
 - Color
 - Clarity, if available
 - Chemistry results with flagging
 - Microscopic results, if available
- 4. Press the **[F1]** key to stop the transmission, if desired.
- 5. At the end of transmission, the screen will revert back to the **Results** screen.



Deleting Results

1. From the *Main Menu*, press the **[F3]** key to bring up the *Results* screen.



- 2. Select the results you wish to delete by specifying desired date(s), specimen or patient ID, patient last name, or operator number in the search fields.
- 3. Press the **[F4]** key to delete results from patient storage.



WARNING: If no entry has been made into any of the search fields, the instrument will delete **ALL** results from patient storage. You will receive a warning message asking for confirmation to delete results.

DELETE RESULTS

DATA FROM PATIENT STORAGE
PERMANENTLY!!

F1 DELETE F2 RESULTS F3 MAIN MENU

- Press [F1] confirm the deletion and return to the Results screen.
- Press [F2] return to the Results screen without deleting results.
- Press [F3] return to the *Main Menu* screen without deleting results.



7 Maintenance & Service

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Maintenance

Recommended Maintenance & Cleaning

Instrument parts that may be cleaned or disinfected:

- Main Housing
- Transport Mechanism Enclosure
- Waste Container
- Chassis
- Strip Catch Plate
- Pulleys

DO NOT wash or rinse:

- Keyboard
- Printer
- Power supply
- LCD display screen
- Electrical or computer connection

Daily Maintenance

Material needed: Iris System Cleanser (REF 800-3203)

- 1. Power OFF instrument.
- 2. Wipe (do not spray) surfaces that come in contact with specimens/ strips with Iris System Cleanser. Rinse with water and dry with a soft cloth or paper towel. Avoid excess moisture.
- 3. Empty waste container of strips and clean with Iris System Cleanser. Rinse with water and dry with a soft cloth or paper towel. Refer to *Emptying Waste Container*.
- 4. Examine belt assembly and pulleys for debris, damage, belts off track, twisting or spills.



Weekly Maintenance

1. Clean belt assembly. Refer to *Cleaning the Belt Assembly*.

Emptying Waste Container

Material needed: Iris System Cleanser (REF 800-3203)

1. To empty the waste container, slide the transport mechanism enclosure towards you and away from the instrument.



2. Set the container on the counter or some other flat surface. (An error message may be displayed on the screen.)

WARNING!

Transport mechanism enclosure is ajar.

Please remove all urine strips on belts!

After replacing enclosure, Press F1 if enclosure was not emptied, or Press F2 if enclosure was emptied.

F1 NOT EMPTIED F2 EMPTIED

3. Remove the lid of the transport mechanism enclosure.





- 4. Remove the waste container from the enclosure and discard the urine test strips in an appropriate waste container.
- 5. Clean with Iris System Cleanser, rinse with water and dry with a soft cloth or paper towel.



- 6. The entire transport mechanism enclosure can be cleaned with Iris System Cleanser and then rinsed with water and dried, or wiped with a damp cloth at this time, if needed.
- 7. Replace the waste container in the transport mechanism enclosure and replace the lid.



8. Slide the transport mechanism enclosure back on the instrument until you hear a click. This assures you that it is properly positioned for running.



9. Press **[F2]** if you emptied the waste container, or press **[F1]** if you did not. The instrument will reset the counter when emptied.



Cleaning the Belt Assembly

Material needed: Iris System Cleanser (REF 800-3203)

- 1. Press the power switch located at the back right of the instrument to power the instrument off.
- 2. Remove the transport mechanism enclosure by sliding it towards you and away from the instrument. The belt assembly is now visible.
- 3. Gently remove belts from transport and incubation pulleys. Wash with soap and water, and then dry them with a soft cloth or paper towel.



NOTE: Do not soak the belts.



4. Wipe the incubation and transport rollers with Iris System Cleanser and dry carefully.





5. Replace the belts in their original grooved positions.



- Replace the cover and slide the transport mechanism enclosure back on the instrument until you hear a click indicating that it is properly positioned for running.
- 7. Press the power switch located at the back right of the instrument to power the instrument on.
- 8. After replacing the belts (and prior to running strips), run the Transport **[F3]** and Incubation **[F4]** drives for 1 minute to reseat belts and remove any twists. Refer to *Load Drive Test* and *Inc Drive Test*.



Replacing the Belts

Material needed: 3 incubation belts (REF 800-7014) 1 transport belts (REF 800-7504)

- 1. Press the power switch located at the back right of the instrument to power the instrument off.
- 2. Remove the transport mechanism enclosure by sliding it towards you and away from the instrument. The belt assembly is now visible.



- 3. Remove the front blue transport belt by sliding it towards you and off of the pulley assembly; discard it.
- 4. Repeat this process with the three incubation belts and the last transport belt.

The belt pulleys are color-coded for easy identification and replacement of the belts. The grooves of the center transition pulley are colorless for the three (3) incubation belts and blue for the two (2) transport belts.

5. Replace the back transport belt first, by sliding the belt around the middle pulley. Then pulling slightly, slide the other end of the belt around the far left pulley, as shown below.





- 6. Position the belt, without twisting it, into the blue grooves.
- 7. Take an incubation belt and slide it around the far right pulley. Pulling slightly, slide the other end of the belt around the middle pulley, as shown below.



- 8. Position the belt, without twisting it, into the clear grooves.
- 9. Repeat steps 7 and 8 for the 2nd and 3rd clear incubation belts.
- 10. Replace the front transport belt last, by sliding the belt around the far left pulley, then pulling slightly, slide the other end of the belt around the middle pulley.



- 11. Position the belt, without twisting it, into the blue grooves.
- 12. Replace the transport mechanism enclosure by sliding it back on the instrument until you hear a click indicating that it is properly positioned for running.
- 13. Press the power switch located at the back right of the instrument to power the instrument on.
- 14. After replacing the belts, and prior to running strips, check the belts using the [F3] and [F4] *Diagnostic* menu options, see *Load Drive Test* and *Inc Drive Test*. Run the belts for at least one minute to reseat the belts and remove any twists.



As needed - Replacing the Paper Roll

Material needed: Thermal paper rolls (REF 800-7511)

- 1. Tear off any excess paper from the paper feed.
- 2. Pull out the remaining paper and remove the empty core.
- 3. Feed the paper manually under the printer roller with the inside face of the paper upward and away from you.



- 4. Make sure the instrument is powered on.
- 5. Press the **[Page Up]** key until the paper comes through the opening at the top of the instrument as shown above.
- 6. Place the paper roll into the paper holder at the top of the instrument.



Diagnostics

This function provides you with a set of diagnostic functions to help troubleshoot an instrument performance issue. Selecting one of the functions will activate the instrument to perform the specific function.

1. From the *Main Menu* screen, press the **[F7]** key, then press the **[F4]** key. The *Diagnostics* screen will be displayed.

DIAGNOSTICS

F1 LCD TEST F6 RGB TEST

F2 PRINTER TEST F7 MECHANICAL TEST F3 LOAD DRIVE TEST F8 INTERNL STD TEST F4 INC DRIVE TEST F9 SERVICE MENU F5 LED TEST F10 MAIN MENU



NOTE: The transport mechanism enclosure can be removed while performing any of the tests.

LCD Test

From the *Diagnostics* screen, press the [F1] key to activate the LCD display to perform a number of diagnostic procedures that tests its operational capabilities, (completely reversed screen, clear screen and a screen with alphanumeric characters). Press the [F1] key until the *Diagnostics* screen is displayed.

Printer Test

- 1. Insure that paper is present before testing.
- 2. From the *Diagnostics* screen, press the **[F2]** key to print several lines of alphanumeric characters.



Load Drive Test

This test is performed after cleaning or replacing the transport belts to reseat belts and remove any twists.

1. From the *Diagnostics* screen, press the **[F3]** key to activate the transport belts on which the urine test strips are loaded. After one minute, press the **[F1]** key to stop the belts.

Inc Drive Test

This test is performed after replacing the incubation belts to reseat belts and remove any twists.

 From the *Diagnostics* screen, press the [F4] key to activate the incubation belts on which the urine test strips are transported for analysis. After one minute, press the [F1] key to stop the belts.

LED Test

- 1. Remove the transport mechanism enclosure before performing the test.
- 2. From the *Diagnostics* screen, press the **[F5]** key to bring up the LED Test screen.

LED TEST Please select with function keys

F1 GREEN LED ON F2 RED LED ON F3 LEDs ON F4 LEDs OFF

F5 CONTINUE

3. Use the designated function keys to activate the different LED light combinations and observe the LED lights located above the transport belts on the left side of the instrument.



Press the [F] key	LED ON	LED OFF
[F1]	Green	Red
[F2]	Red	Green
[F3]	Red and Green	-
[F4]	-	Red and Green

4. When completed, press the **[F5]** key to return to the *Diagnostics* screen.

RGB Test

- 1. Remove the transport mechanism enclosure while performing the test.
- 2. From the Diagnostics screen, press the **[F6]** key to bring up the following RGB (Red, Green, and Blue LEDs) optics test screen.

RGB TEST Please select with function keys

F1 START RGB MEASUREMENT F2 CONTINUE

- 3. Press the **[F1]** key to activate the RGB test. Observe under the second incubation roller (right of the instrument) to see if all three wavelengths (red, green and blue) illuminate. Repeat this step, if necessary.
- 4. Press the **[F2]** key to return to the *Diagnostics* screen.



Mechanical Tests

- 1. Remove the transport mechanism enclosure while performing the test.
- 2. From the *Diagnostics* screen, press the **[F7]** key to bring up the *Mechanical Test* Screen.

MECHANICAL TEST
Please select with function keys

F1 STOP POSITION F2 PASS POSITION F3 HOME POSITION F4 INTERNAL STANDARD DOWN

F5 CONTINUE

3. Use the designated function keys to activate the different mechanical functions. Check for correct positions under the optics.

Press the [F] key	Action	Use for
[F1]	Position the urine test strip alignment device at its lowest position.	Stopping the urine test strips for alignment and measurement at the optics.
[F2]	Position the urine test strip alignment device at its middle position.	Allowing the urine test strips to pass the optics and to go into the waste container.
[F3]	Return the urine test strip alignment device to its home position.	
[F4]	The internal standard should move to its lower position touching the incubation belts.	Test the functionality of the internal moveable standard.
[F5]	Return to the Diagnostics screen.	



Internal Standard Test

This test is designed to verify the optics system via a check of the non-moveable "fixed" standard.

- 1. Make sure the transport mechanism enclosure is in place on the instrument before performing the test.
- 2. From the *Diagnostics* screen, press the **[F8]** key to initiate the test. The screen will display "Internal Standard will be measured. Please wait."
- If the calibration check is acceptable, the screen will return to the Diagnostics screen. If the calibration check fails, the following screen will be displayed.

FAILURE

Call Technical Service.

Measurement cannot be run anymore.

ERROR#:

XXXX

F1 TO CONTINUE

If this test fails, repeat it at least one more time. If it fails again, contact Iris Technical Support group (see **Before Calling for Service**).

Exit Diagnostics

You may exit the *Diagnostics* screen at anytime by pressing the [F9] key to return to the *Service Menu* screen, or pressing the [F10] key to return to the *Main Menu* screen.



Before Calling for Service



NOTE: Before calling for Service, please make a note of any error messages displayed.

In the US Call Technical Services for assistance:

Iris Diagnostics 9172 Eton Avenue Chatsworth, CA 91311 USA

Telephone

+1-800-PROIRIS (776-4747) +1-818-709-1244

Fax +1-818-700-9661

Outside the US, call your Local Distributor for assistance

Stay close to the system and be prepared to explain the nature of the problem.

Provide:

- Your name
- Account name
- Telephone number with area code
- *iChem100* serial number

Describe:

- Error messages
- Operation in process when problem/error occurred
- Problem



Maintenance Log

nce Log	Instrument Serial Number:		9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 26 27 28 29 30 31					As needed	Replace Paper Roll	Initials
QC/Maintenance Log			3 4 5 6 7 8							
Unine Chemistry Analyzer	Month Year:	Daily	Mipe surfaces with Iris Cleanser	Empty waste container	Examine belts and pulleys	Run Controls	Initials	Weekly	Clean the Belt Assembly Replace the Belts	Initials



8

Installation

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Shipping Cartons

The iChem100 is shipped in one carton. Open the carton and check the packaged items. If any of the items are damaged or missing, immediately notify Iris Diagnostics or your distributor.

Unpacking

1. Position the shipping container upright and open the top flaps.



NOTE: If using a utility knife, extend the blade to an appropriate length to avoid cutting any internal components.

- 2. Remove accessories and set aside.
- 3. Remove secondary cardboard organizer.
- 4. Remove the instrument by slowly lifting it vertically out of the shipping container by the foam end caps. Place the instrument on a stable surface.
- 5. Remove foam end caps and place them in the shipping container for storage.
- 6. Check the contents of the box with the shipping list shown below:
 - iChem100 Urine Chemistry Analyzer
 - Keyboard
 - Keyboard Cover
 - External Power Supply
 - Power Supply Adapters (US, EU)
 - 2 sets of Belts (Transport and Incubation)
 - Operators Manual
 - 3 rolls of Thermal Paper
 - Barcode Reader and Cable (Optional)



NOTE: If the instrument is stored at a temperature below 59°F and above 90°F (below 15°C and above 32°C) or at a humidity below 20% and above 80% relative humidity (RH), allow the instrument to acclimate to the final environment temperature for a minimum of two (2) hours.



Installation

1. Place the iChem100 Urine Chemistry Analyzer on a clean, dry, and flat surface.



NOTE: Always make sure the instrument's power switch is in the "OFF" (down) position before connecting or disconnecting the cables or accessories.

2. Attach the cable from the barcode reader to the instrument, as shown below. The barcode reader has a split cable. The longer cable segment attaches to the instrument.



3. Attach the cable from the keyboard to the barcode reader cable.



NOTE: The barcode reader has a **split** cable. The shorter cable segment attaches to the **keyboard**.

- 4. Attach the power adapter attachment that is appropriate for your wall socket to the external power supply.
- 5. Attach the power supply's cable plug into its receptor located on the back of the instrument.
- 6. Plug the external power supply into a wall power outlet. Make sure the instrument is plugged into a grounded power line that meets the voltage requirements: 100 to 250 VAC ± 10%, 50/60 Hz.





NOTE: Use only a power **adaptor** providing an output of 7.5 Vdc @ 3.3 A.

7. Remove the red magnetic shield (if present) from the optics area before powering on the instrument. To access the optics area, remove the transport mechanism enclosure by sliding it towards you and away from the instrument (see figure below). To remove the shield, gently pull downward on the edges of the red magnetic shield.



- 8. Slide the transport mechanism enclosure back on the instrument until it clicks in place. This assures you that it is properly positioned for running.
- 9. Press the power switch located on the back right of the instrument to power the instrument on.



Install the paper roll

- 1. Discard the first 10" 12" of the paper roll to prevent printer jamming due to the glue.
- 2. Feed the paper manually under the printer roller with the inside face of the paper upward and away from you.



- 3. Press the **[Page Up]** key until the paper comes through the opening at the top of the instrument as shown above.
- 4. Perform the initial setup see *Chapter 3*.
- 5. Consult *Chapter 4 Specimen Processing* prior to analyzing specimens for the first time.

Appendix



Appendix

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Table of Results

Parameter	Conventional Units	S. I. Units	Qualitative Units
Bilirubin	Neg	Neg	Neg
	1mg/dL	17µmol/L	+
	2mg/dL	35µmol/L	++
	4mg/dL	70µmol/L	+++
Urobilinogen	Norm	Norm	Norm
	2mg/dL	35µmol/L	+
	4mg/dL	70µmol/L	++
	8mg/dL	140µmol/L	+++
	12mg/dL	200µmol/L	+++
Ketones	Neg	Neg	Neg
	25mg/dL	2.5mmol/L	+
	100mg/dL	10mmol/L	++
	300mg/dL	30mmol/L	+++
Ascorbic Acid	Neg	Neg	Neg
	20mg/dL	1.14mmol/L	+
	40mg/dL	2.28mmol/L	++
Glucose	Neg	Neg	Neg
	50mg/dL	3mmol/L	+
	150mg/dL	8mmol/L	++
	500mg/dL	28mmol/L	+++
	≥1000mg/dL	≥56mmol/L	++++
Protein	Neg	Neg	Neg
	30mg/dL	0.3g/L	+
	100mg/dL	1g/L	++
	≥500mg/dL	≥5g/L	+++
Blood Hemoglobin	Neg	Neg	Neg
	0.03mg/dL	0.3mg/L	+
	0.2mg/dL	2mg/L	++
	1mg/dL	10mg/L	++
Blood RBCs	Neg	Neg	Neg
	5-10RBCs/µL	5-10RBCs/µL	5-10RBCs/µL
	50RBCs/µL	50RBCs/µL	50RBCs/µL
	300RBCs/µL	300RBCs/µL	300RBCs/µL



Parameter	Conventional Units	S. I. Units	Qualitative Units
рН	5	5	5
	6	6	6
	7	7	7
	8	8	8
	9	9	9
Nitrite	Neg	Neg	Neg
	Pos	Pos	+
Leukocytes	Norm	Norm	Norm
	25WBCs/µL	25WBCs/µL	25WBCs/µL
	75WBCs/µL	75WBCs/µL	75WBCs/µL
	500WBCs/µL	500WBCs/µL	500WBCs/µL
Specific Gravity	1.000	1.000	1.000
	1.005	1.005	1.005
	1.010	1.010	1.010
	1.015	1.015	1.015
	1.020	1.020	1.020
	1.025	1.025	1.025
	1.030	1.030	1.030
	1.035	1.035	1.035

Parameter	
Color	Blank, Colorless, Straw, Yellow, Orange, Amber, Red, Red Brown, Green, Brown, Black, Other
Clarity	Via barcode reader: Clear, Slt Cloudy, Cloudy, Bloody, Other Via keyboard: Clear, Hazy, Slt Cloudy, Cloudy, Turbid, Bloody, Other
Specimen Type	Via barcode reader: Random, Cl Catch, Cath, Peds, Other Via keyboard: Random, Cl Catch, Cath, Peds, First am, 24 hrs, Fasting, Gluc Tol, S Pubital, Other



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