



ASTUTE
MEDICAL

ASTUTE140 METER



USER MANUAL

For Export Only. Not for Sale in the United States.



Manufactured for Astute Medical, Inc.
3550 General Atomics Ct.
Building 2
San Diego, CA 92121
USA



MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

CONTACT INFORMATION:

Phone: +1 (855) 317-2788

Phone: +1 (858) 500-7000

Fax: +1 (858) 332-0690

technicalsupport@astutemedical.com

Table of Contents

Introduction	5
Intended Use	5
Principles of Operation	5
ASTUTE140 Meter Kit Contents	6
Materials Required But Not Provided	7
Optional Accessories	7
Contacting Astute Medical, Inc. (Technical Support)	7
Product Specifications	8
Warnings, Hazards, Precautions and Limitations	9
Safety Symbols	9
Safety Information	9
FCC Testing	10
Electromagnetic Capability (EMC)	10
Limitations	11
ASTUTE140 Meter Features	12
User Types	15
Operator	15
Supervisor	16
Installation	17
AC Power Supply	17
Installation and Replacement of Batteries	18
Installation and Replacement of Paper	21
Powering On the ASTUTE140 Meter	22
Supervisor Instructions: Configuration and Settings	23
Adding the First Supervisor User	23
Setting or Changing Time	26
Setting or Changing Date	27
Setting or Changing the Language	28
Updating System Software	29
Updating ASTUTE140 Meter Languages	29
Operator Registering Permissions	29
Quality Control Settings	31
LIS Settings	32
Network Settings	34
PC Mode	36
Printer Settings	37
Managing Users	38
ASTUTE140 Meter Information	40
Error Log	42

Table of Contents (Continued)

ASTUTE140 Meter Operation	45
Startup	45
Powering On the ASTUTE140 Meter	45
Logging In	46
Non-Permanent Settings	46
RFID Cards for Device and Lot Registration	48
ASTUTE140 EQC Device Registration	48
ASTUTE140 Electronic Quality Control (EQC)	50
Test Lot Registration	52
Liquid Control Lot Registration	54
External Liquid Quality Control (LQC)	56
Testing a Patient Sample	60
Review and Management of Test Results	63
Patient Results	63
LQC Results	65
EQC Results	66
Send Results to LIS	68
Shutdown	68
Care and Maintenance	69
Cleaning and Decontamination	69
Replacing the Paper	70
Replacing the Batteries	70
Disposing of the Batteries	70
Disposing of the ASTUTE140 Meter	70
Labels and Symbols	71
Troubleshooting Tips	72
Error Messages	74
End User License Agreement	76
Glossary of Terms (Listed Alphabetically)	78
Index	80
Appendix	82
Main Menu Structure	82
Review Data Menu Structure	83
Operator Menu Structure	84
Supervisor Menu Structure	85

Introduction

Intended Use

The ASTUTE140 Meter is a bench top instrument intended to be used by trained medical professionals as an *in vitro* diagnostic device in a laboratory environment for the measurement of fluorescence in various assays manufactured by Astute Medical, Inc.

When the ASTUTE140 Meter is used in conjunction with the NEPHROCHECK Test, the ASTUTE140 Meter converts the fluorescent signals for the individual immunoassays into concentrations and combines these individual concentrations into a single numerical test result.



Please read these instructions carefully before using the ASTUTE140 Meter. Please refer to the assay-specific Product Insert for detailed test information.

Principles of Operation

The ASTUTE140 Meter uses an optical system to measure the fluorescent signal generated from the test sample in the NEPHROCHECK Test cartridge. After the NEPHROCHECK Test cartridge containing the sample is inserted into the ASTUTE140 Meter, the meter converts the fluorescent signal from the immunoassay test into a concentration and provides a test result. Intensity of the fluorescent signal corresponds to the concentration of the target analyte. If a specific test has more than one immunoassay, the fluorescent signals from each immunoassay are converted into concentrations, and these concentrations may be combined into a single test result or reported independently. Multiple quality control procedures are performed to ensure that the test results are accurate (See "ASTUTE140 Electronic Quality Control (EQC)" on p. 50 and "External Liquid Quality Control (LQC)" on p. 56 for details).

Results of the test are displayed on the ASTUTE140 Meter's LCD screen and may be printed using the meter's internal printer, or electronically transmitted to a connected laboratory information system (LIS).

ASTUTE140 Meter Kit Contents

Inspect the shipping container for obvious shipping damage prior to opening. Unpack the shipping container and inspect the contents for damage. Following are components included in the ASTUTE140 Meter Kit along with part numbers for items that can be ordered separately:

ASTUTE140 Meter Kit Component	Part Number for Re-ordering
ASTUTE140 Meter	(1)
Power adapter pack (includes AC power cord, switching power supply and country specific adapter)	(1)
USB cable	(1)
ASTUTE140 Electronic Quality Control (EQC) Device with RFID card*	400013
ASTUTE140 User Manual	(1)
Printer paper rolls (2)	100000
AA batteries (4)	(1)

(1) This component is only available as part of the ASTUTE140 Meter Kit. Additional ASTUTE140 Meter Kits can be ordered using Part Number 500000.

*Packaged and shipped in a separate box.

If the shipping container or its contents are damaged, or if any components are missing, contact Astute Technical Support (See "Contacting Astute Medical, Inc." on p. 7 for contact information).



To avoid damaging the ASTUTE140 Meter, DO NOT use any power adapter other than the one provided.

Batteries are not intended to be used as the main power source for operation of the ASTUTE140 Meter and should only be used as a backup power source if there is no electrical output available (See "Installation and Replacement of Batteries" on p. 18 for further details).

Materials Required But Not Provided

The following materials are required for testing patient samples and may be purchased and shipped separately from Astute Medical, Inc.:

- NEPHROCHECK Test Kits
- NEPHROCHECK Liquid Control Kits

For a list of approved tests and corresponding liquid controls for use with the ASTUTE140 Meter, go to www.astutemedical.com or consult your Astute Medical, Inc. sales representative.

Optional Accessories

Optional accessories that may be used with the ASTUTE140 Meter include an external barcode reader and an external keyboard. A numeric or alphanumeric barcode reader with a PS2 interface will work with the ASTUTE140 Meter, such as the DataLogic DLC6065-MI, Opticon OPR-200I, or the Honeywell 3800G (others have not been tested).

A keyboard with a PS2 interface will work with the ASTUTE140 Meter. Wireless keyboards are not compatible with the ASTUTE140 Meter.

Contacting Astute Technical Support

For technical support, please contact Astute Technical Support at:




Astute Medical, Inc.
3550 General Atomics Ct.
Building 2
San Diego, CA 92121 USA
Phone: +1 (855) 317-2788
Phone: +1 (858) 500-7000
Fax: +1 (858) 332-0690
Email: technicalsupport@astutemedical.com

Product Specifications

ASTUTE140 Meter Information	
Product Number:	500000
Dimensions:	24 cm deep x 16 cm wide x 12.5 cm high
Weight:	3 lbs.
Power Requirements	
AC Power Supply Output Voltage:	6 V DC and 4.16 A
AC Power Supply Input Voltage/ Voltage Range:	100V to 240 V, 47Hz – 63 Hz
Battery Operation:	4 x LR6 – AA batteries
Operating Environment	
Temperature:	+15°C – 30°C
Humidity:	30% – 80% rH, non-condensing at 15°C operating temperature 15% – 80% rH, non-condensing at 30°C
Storage Environment	
Temperature:	-20°C to +60°C
Humidity:	20% – 85% rH, non-condensing

Warnings, Hazards, Precautions, and Limitations

Safety Symbols

Symbol	Definition
	Caution. Consult accompanying documents. Indicates a situation that, if not avoided, could result in damage to the ASTUTE140 Meter or incorrect test results.
	Electrical Shock Warning. Indicates a situation that, if not avoided, could result in electrical shock or bodily harm to the operator or a bystander.
	Biological Risks. Indicates a situation that, if not avoided, could result in a health risk to the operator.

Safety Information



Operate the ASTUTE140 Meter on a level, dry surface.



Do not move the ASTUTE140 Meter while a test is running.



Do not drop the ASTUTE140 Meter.



The ASTUTE140 Meter is designed to provide safe and reliable operation when used according to this User Manual. If the meter is used in a manner not specified in the User Manual, the protection provided by the equipment will be impaired.



Use only the AC power adapter supplied with the ASTUTE140 Meter.



Do not immerse the ASTUTE140 Meter in water or any other liquids.



Unplug the AC power adapter from the power supply before cleaning.



Handle and dispose of test cartridges and patient specimens in accordance with federal, state, and local requirements regarding biohazardous materials.



Handle the ASTUTE140 Meter in accordance with federal, state and local requirements regarding biohazardous materials.



Due to potentially infectious nature of the samples used with the ASTUTE140 Meter, users should wear gloves.

FCC Testing



This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.



Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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

Electromagnetic Capability (EMC)



The electromagnetic environment should be evaluated prior to operation of the Meter. The Meter generates radio frequency (RF) energy. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with proper operation.



Any equipment connected to data ports must be certified to EC61010. If any equipment is connected that is not recommended it must comply with this standard. For questions or additional information, please contact Astute Technical Support (See "Contacting Astute Medical, Inc." on p. 7 for contact information).

Limitations

The ASTUTE140 Meter does not contain a “batch mode” function. The ASTUTE140 Meter times the incubation period for the test, and only one test can be run at a time; therefore, each NEPHROCHECK Test cartridge must be run immediately after being loaded with the patient sample or liquid control. The time delay in testing that would result from loading more than one cartridge at a time may lead to inaccurate test results.

ASTUTE140 Meter Features



Figure 1.
ASTUTE140 Meter

Feature	Function
1 Printer Cover	Covers the printer
2 LCD Display	User interface—displays screens for navigating, entering data, and reviewing data
3 Paper Feed Key	Advances the paper roll
4 Eject Key	Opens the drawer
5 Main Menu Key	Used to return to the Main Menu
6 Navigation Keys	Used to navigate up, down, left, and right within menu screens
7 Left Soft Key	Used to select the menu option displayed above the key
8 Right Soft Key	Used to select the menu option displayed above the key
9 Numeric Keypad	Used to enter numerical values into menus and screens
10 Decimal Point	Used to add decimal points to numerical values
11 Backspace Key	Deletes the character to the left of the cursor
12 Drawer	Used to insert a NEPHROCHECK Test cartridge and the Electronic Quality Control (EQC) device into the ASTUTE140 Meter
13 Battery Cover	Covers the battery compartment

ASTUTE140 Meter Features (Continued)

Figure 2.
ASTUTE140 Meter – back



Feature	Function
1 PS/2 Port	Used to connect the optional external barcode reader or keyboard to the ASTUTE140 Meter
2 Ethernet Port	Used to connect the ASTUTE140 Meter to an LIS or to a computer network to download software
3 AC Power Adapter Port	Used to connect the AC power adapter to the ASTUTE140 Meter
4 USB Port	Used to connect the ASTUTE140 Meter to a computer to download new software
5 On/Off Switch	Used to power the ASTUTE140 Meter on and off

ASTUTE140 Meter Features (Continued)

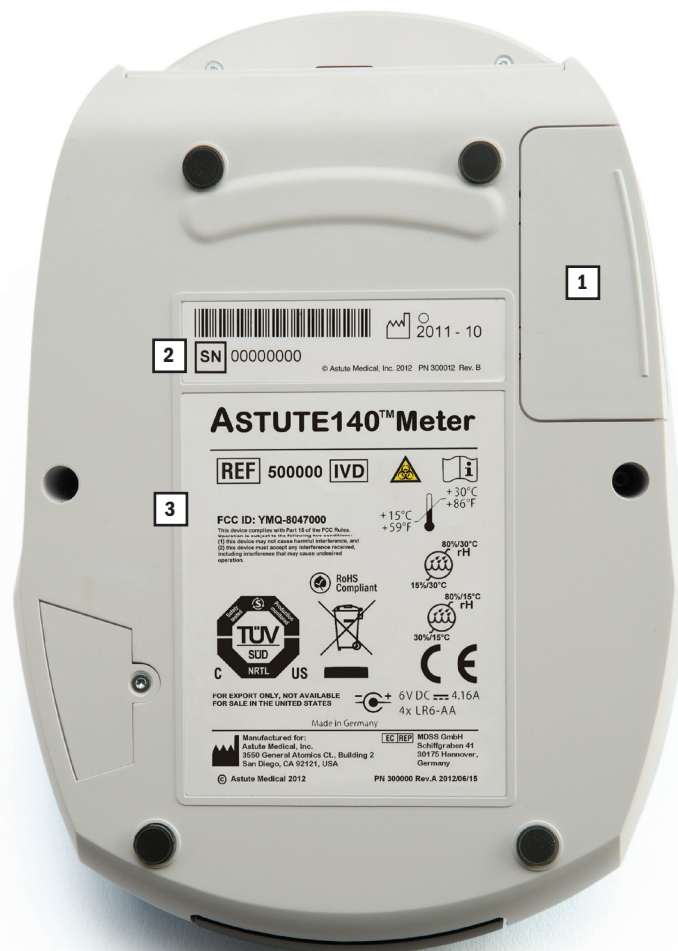


Figure 3.
ASTUTE140 Meter – bottom

Feature

- 1** Battery Cover
- 2** Serial Number
- 3** In-Vitro Diagnostic device labels and symbols

Function

- Covers the battery compartment
- Unique number used to identify the ASTUTE140 Meter
- Regulatory labels and symbols used to provide information about the ASTUTE140 Meter and its proper use (See “Labels and Symbols” on p. 71 for definitions)

ASTUTE140 Meter Features (Continued)

Figure 4.
Main Menu screen



All ASTUTE140 Meter functions are grouped under six icons found on the **Main Menu** (For menu structures, see the Appendix):

Feature	Function
1 Run Patient	Select to run patient tests
2 Run LQC	Select to run high and low liquid controls
3 Review Data	Select to manage patient, LQC and EQC test results
4 Run EQC	Select to run EQC
5 Operator	Select to manage (register or delete) test lots, liquid control lots, and EQC devices; temporarily change non-permanent settings, and view error logs
6 Supervisor	Select to set/change general settings, manage users, obtain ASTUTE140 Meter information, or view error logs

User Types

There are two types of users defined for the ASTUTE140 Meter, **Supervisor** and **Operator**. Supervisors and Operators are permitted to perform different functions, as described below.

Operator

Users logged in as Operators may perform the following functions:

- Power the ASTUTE140 Meter on/off

- Run electronic quality control (EQC)
- Run liquid quality control (LQC)
- Test patient samples
- Review and print data (Patient test results, QC test results)
- View error log

Operators may perform the following functions only if a Supervisor grants permission in the default settings:

- Manage (register/delete/print) test lots
- Manage (register/delete/print) LQC lots
- Manage (register/delete/print) EQC devices

The Operator may change the following settings temporarily while using the ASTUTE140 Meter; the settings will return to the default settings programmed by the Supervisor when the meter is switched off or the Operator is logged out:

- Date format
- Time format
- Language
- Beeper (On/Off)

Supervisor

Users logged in as Supervisors may perform all of the Operator functions and the following additional functions:

- Set or change all default system settings (Time, Date, Language, Log On Setup, registering lot/control permissions, QC settings)
- Set or change LIS settings
- Set PC Mode (On/Off)
- Set or change network settings
- Set or change print headers
- Manage Users (change/add/delete)
- View ASTUTE140 Meter information (hardware/firmware/bootware/serial number/IP address)

Installation

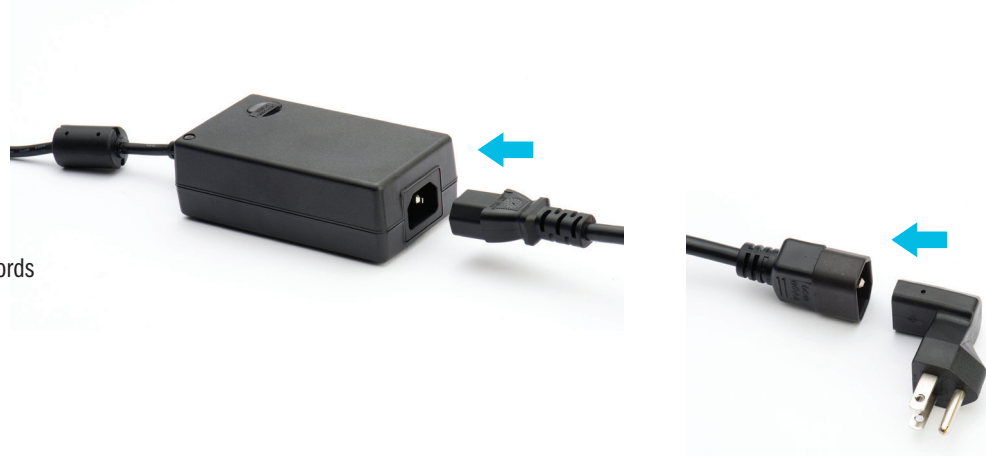
AC Power Supply

The ASTUTE140 Meter is generally meant to be powered by plugging the AC power adapter into a power source; however, power may be supplied temporarily by four AA batteries when an electrical power source is unavailable (See “Installation and Replacement of Batteries” on p. 18). NOTE: If the AC power adapter is in use and the electrical power fails or the power adapter becomes disconnected, the meter will power off even if batteries are installed in the ASTUTE140 Meter.

To connect the AC power adapter:

1. Locate the AC power adapter pack containing the AC power cord, the switching power supply, and the country-specific adapter, then connect them as shown:

Figure 5.
Connecting power cords



2. Insert the end of the country-specific adapter into a power source.

3. Insert the cylindrical end of the switching power adapter into the AC power adapter port on the back of the ASTUTE140 Meter.

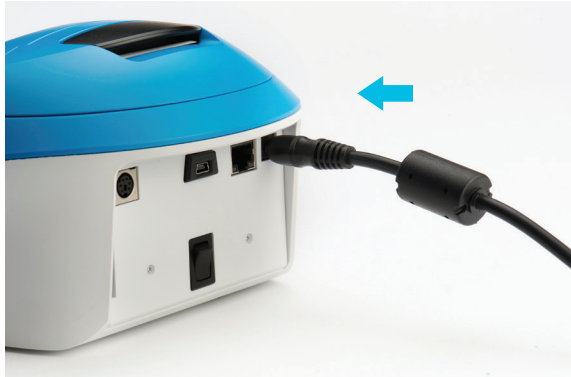


Figure 6.
Connecting AC power
adapter to ASTUTE140
Meter



To avoid damage to the ASTUTE140 Meter from a potential power surge, always plug the AC power adapter into the electrical power source prior to connecting it to the meter. When removing power, disconnect the AC power adapter from the ASTUTE140 Meter prior to unplugging it from the electrical power source.

Installation and Replacement of Batteries

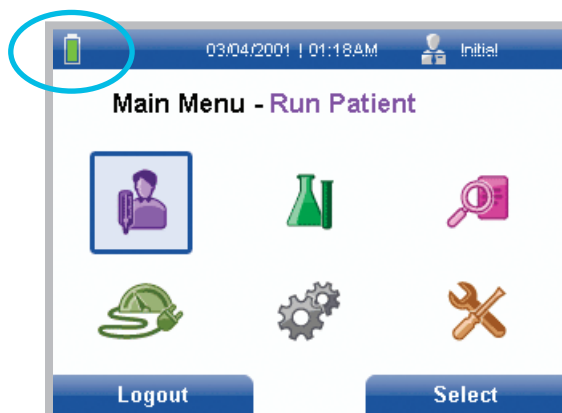
The ASTUTE140 Meter is generally meant to be powered by plugging the AC power adapter into an electrical power source (See “AC Power Supply” on p. 17); however, power may be supplied for a limited period of time by four AA batteries when an electrical power source is unavailable (for example, in the event of electricity failure or if the meter must be operated in a location where there is no electric output).

NOTE: If the AC power adapter is in use and the electrical power fails or the power adapter becomes disconnected, the meter will power off even if batteries are installed in the ASTUTE140 Meter.

When using alkaline or lithium batteries under a temperature operating range of 20° to 25° C, the ASTUTE140 Meter will allow approximately 10 user tests to be performed before requiring battery replacement.

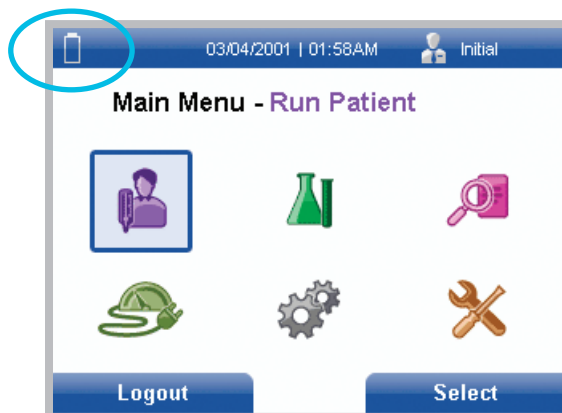
The ASTUTE140 Meter includes a battery strength indicator.

Figure 7.
Battery strength
indicator – full




The batteries should be changed when the battery strength indicator is displayed as empty and blinking.

Figure 8.
Battery strength
indicator – empty and
blinking



When the battery strength indicator is displayed as empty and blinking, the ASTUTE140 Meter can run one additional test within one hour under the same operating conditions before the batteries will need to be replaced.

To install four AA batteries into the ASTUTE140 Meter or to change the batteries:

1. Press the  key to the left of the LCD display to open the ASTUTE140 Meter drawer and ensure there is not a cartridge in the meter.
2. Power off the ASTUTE140 Meter.

3. Gently turn the ASTUTE140 Meter over so the bottom is facing up and place it on a flat surface.



Figure 9.
ASTUTE140 Meter –
bottom facing up

4. Open the battery cover by pressing your thumb firmly on the center of the battery cover and sliding it in the direction shown below:



Figure 10.
Removing battery cover

5. If replacing the batteries, remove the old batteries and properly discard them (See "Disposing of the Batteries" on p. 70).

6. Insert four AA 1.5 volt batteries, making sure that the ends of the batteries facing up correspond to the + and – signs diagrammed in the battery compartment.

Figure 11.
Battery compartment



7. Replace the battery cover by sliding it back into position as shown until it snaps firmly in place.
8. Turn the ASTUTE140 Meter right side up.

Installation or Replacement of Paper

To install or change the internal printer paper, perform the following steps:

1. Remove the printer cover by pulling up on the black handle on top of the cover.
2. If changing the paper, remove the empty spool and any unused paper.
3. Place the paper roll into the holder with the end of the paper coming from under the roll toward the ASTUTE140 Meter display.

Figure 12.
Installing paper



4. Holding the end of the paper, replace the printer cover as shown below until it snaps into place.



Figure 13.
Replacing printer cover

5. To advance the paper feed press .

Powering On the ASTUTE140 Meter

To power on the ASTUTE140 Meter, locate the power switch on the back of the meter and toggle it upwards, holding it in position until the **Self Test** screen appears. The self test feature is intended to check all internal systems of the meter to ensure they are functioning properly, such as the hardware, software, battery voltage, operating temperature, and optical system.

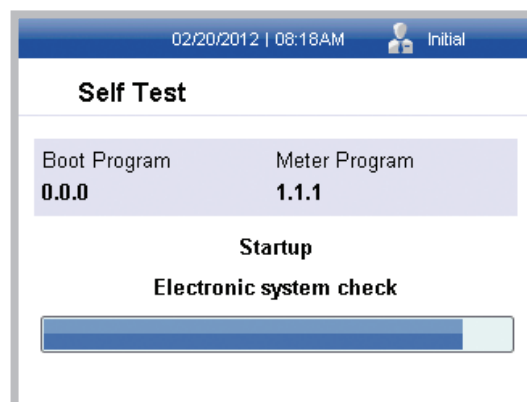


Figure 14.
Self Test screen

If all systems pass, the **Log In** screen will automatically appear, indicating that the ASTUTE140 Meter is ready for use.

Figure 15.
Log In screen



If the self test fails, an error message will be displayed. Press the right soft key to select **OK** and close the error message. Restart the ASTUTE140 Meter by turning it off and back on again (to power off the meter, toggle the power switch upwards and it should immediately shut down). If after restarting the ASTUTE140 Meter the self test fails again, contact Astute Technical Support (See "Contacting Astute Medical, Inc." on p. 7 for contact information).

Supervisor Instructions: Configuration and Settings

Adding the First Supervisor User

The first Supervisor user must be added to the ASTUTE140 Meter before any default settings may be set or changed. The ASTUTE140 Meter comes from the factory with a default Supervisor log in ID (**1234**) that will allow the first Supervisor user to log in and create a user profile. Once the new profile is created, the user must log out of the system and log back in with the new user information before performing any additional functions. After this process is completed, the default log in (**1234**) will need to be manually deleted.

Perform the following steps to add the first Supervisor user:

1. After powering on the ASTUTE140 Meter, the **Log In** screen will be displayed after a brief self test (See “Powering On the ASTUTE140 Meter” on p. 22 for details).



Figure 16.
Log In screen



2. When the **Log In** screen is displayed, **User ID** is highlighted. Enter **1234** using the numeric keypad or an external keyboard (if connected).
3. After entering your user ID, use the  key to highlight the **Password** field.
4. Use the numeric keypad or an external keyboard (if connected) to enter **1234**. Press the right soft key to accept all entries.
5. After logging in, the **Main Menu** will be displayed. Use the navigation keys to highlight the **Supervisor Menu** icon. Press the right soft key to display the **Supervisor Menu**.












Figure 17.
Main Menu screen with
Supervisor Menu icon
highlighted





6. When the **Supervisor Menu** is displayed, **General Settings** is highlighted. Use the  key to highlight **Manage Users** and press the right soft key.

7. The screen should read **Existing User List** across the top; however, no users should be listed. Press the right soft key to display the **Options** pop-up menu.

Figure 18.
Existing User List screen



8. When the **Options** pop-up menu is displayed, use the  key to highlight **Add User** and press the right soft key to display the **Create New User** screen.
9. When the **Create New User** screen is displayed, **Mode** will be highlighted. Use the   keys to toggle between **Operator** and **Supervisor**. Select **Supervisor**.
10. After selecting **Supervisor**, use the  key to highlight **Name**. Use the numeric keypad or an external keyboard (if connected) to enter a user name.
11. Use the  key to highlight **ID**. Use the numeric keypad or an external keyboard or barcode reader (if connected) to enter a numeric ID up to 12 digits in length.
12. Once a numeric ID is entered, use the  key to highlight **Password**. Use the numeric keypad or an external keyboard (if connected) to enter a password up to 12 digits or characters in length.
13. Confirm that the correct information is displayed. To make changes to the entries, use the   keys to highlight the field to be changed. Use the  key to delete the incorrect entry, and then use the numeric keypad or an external keyboard (if connected) to change the entries. To clear all entries on the screen, press the left soft key. Once the correct entries have been made, press the right soft key to accept all entries.
14. After the new user information is accepted, the **Existing User List** screen will again be displayed. The newly created user information should now appear in the list, including the user ID, Name, and Mode (Supervisor or Operator).
15. Press the left soft key to return to the main **Supervisor Menu**.
16. Press the left soft key to return to the **Main Menu**.
17. Press the left soft key to log out of the system.

18. After logging out, the **Log In** screen will appear and **User ID** will be highlighted. Enter your new user ID using the numeric keypad or an external keyboard (if connected).
19. After entering your user ID, use the  key to highlight the **Password** field.
20. Use the numeric keypad or an external keyboard (if connected) to enter your new password.
21. Confirm that the correct log in information is displayed. To make changes to the entries, use the   keys to highlight the field to be changed. Use the  key to delete the incorrect entry, then use the numeric keypad or an external keyboard (if connected) to change the entries. Press the right soft key to accept all entries.

Setting or Changing Time

The Supervisor can set or change the time by performing the following steps:















1. Press the  key to display the **Main Menu**.
2. Use the navigation keys to highlight the **Supervisor Menu** icon.



Figure 19.
Main Menu screen with
Supervisor Menu icon
highlighted

3. Press the right soft key to display the **Supervisor Menu**.
4. When the **Supervisor Menu** is displayed, **General Meter Settings** is highlighted. Press the right soft key to display the **General Settings** screen.
5. When the **General Settings** screen is displayed, **Default Settings** is highlighted. Press the right soft key to display the **Default Settings** screen.
6. When the **Default Settings** screen is displayed, **Time & Time Format** is highlighted. Press the right soft key to display the **Time & Time Format** screen.
7. When the **Time & Time Format** screen is displayed, **Time Format** is highlighted. Use the   keys to choose either a 12- or 24-hour time format for display on the screen and printouts.

8. After the desired time format is selected, use the  key to highlight the **Hours** field.
9. To change an existing entry, use the  key to first delete the entry, then use the numeric keypad or an external keyboard (if connected) to enter the correct hour.
10. After the correct hour is entered, use the  key to highlight the **Minutes** field.
11. To change an existing entry, use the  key to first delete the entry, then use the numeric keypad or an external keyboard (if connected) to enter the correct minutes.
12. After entering the correct minutes, use the  key to highlight the **AM or PM** field.
13. Use the   keys to select **AM or PM**.
14. After confirming that the correct time information is displayed, press the right soft key to accept all entries. To make changes to the entries, use the   keys to highlight the field to be changed and use the   keys to toggle between options, or use the numeric keypad to change numeric entries. To clear all entries on the screen, press the left soft key.

Setting or Changing Date

The Supervisor can set or change the date by performing the following steps:












1. Press the  key to display the **Main Menu**.
2. Use the navigation keys to highlight the **Supervisor Menu** icon.

Figure 20.
Main Menu screen with
Supervisor Menu icon
highlighted



3. Press the right soft key to display the **Supervisor Menu**.
4. When the **Supervisor Menu** is displayed, **General Meter Settings** is highlighted. Press the right soft key to display the **General Settings** screen.

5. When the **General Settings** screen is displayed, **Default Settings** is highlighted. Press the right soft key to display the **Default Settings** screen.
6. On the **Default Settings** screen, use the  key to highlight **Date & Date Format**.
7. Use the   keys to scroll through the available date formats for display on the screen and printouts.
8. After the desired date format is displayed, use the  key to highlight the **Day** field.
9. Use the numeric keypad to enter the day of the month.
10. After the correct day of the month is entered, use the  key to highlight the **Month** field.
11. Use the numeric keypad to enter the month of the year.
12. After the correct month of the year is entered, use the  key to highlight the **Year** field.
13. Use the numeric keypad to enter the correct year.
14. After confirming that the correct date information is displayed, press the right soft key to accept all entries. To make changes to the entries, use the   keys to highlight the field to be changed and use the   keys to toggle between date format options, or use the numeric keypad to change numeric entries. To clear all entries on the screen, press the left soft key.

Setting or Changing the Language

The Supervisor can change the default language by performing the following steps:





1. Press the  key to display the **Main Menu**.
2. Use the navigation keys to highlight the **Supervisor Menu** icon.



Figure 21.
Main Menu screen with
Supervisor Menu icon
highlighted

3. Press the right soft key to display the **Supervisor Menu**.
4. When the **Supervisor Menu** is displayed, **General Settings** is highlighted. Press the right soft key to display the **General Settings** screen.
5. When the **General Settings** screen is displayed, **Default Settings** is highlighted. Press the right soft key to display the **Default Settings** screen.
6. On the **Default Settings** screen, use the  key to highlight **Language**.
7. Press the right soft key to display the **Language Menu**.
8. When the **Language Menu** is displayed, use the  or  keys to highlight the desired default language.
9. Press the right soft key to select the highlighted default language.

Updating System Software

The software version currently running on the ASTUTE140 Meter can be found on the **Self Test** screen during start-up (See “Powering On the ASTUTE140 Meter” on p. 22), as well as on the **Meter Information** screen (See “ASTUTE140 Meter Information” on p. 40). Software updates for the ASTUTE140 Meter will be required periodically. When updates are available, Astute Medical, Inc. will send written notifications by email and postal service including a description of the software update and downloading instructions. Supervisors can download software updates through the USB and/or Ethernet port.


Updating ASTUTE140 Meter Languages

When new languages for the ASTUTE140 Meter become available, Astute Medical, Inc. will send written notifications by email and postal service of the newly available languages and downloading instructions. Supervisors can update the ASTUTE140 Meter languages by downloading language updates through the USB and/or Ethernet port.

Operator Registering Permissions

The Supervisor can grant permission for Operators to register NEPHROCHECK Test cartridge lots, liquid control lots and the EQC device in the default settings. If permission is not granted, only Supervisors can perform these functions.

To set the registering permissions for Operators, perform the following steps:

1. Press the  key to display the **Main Menu**.

2. Use the navigation keys to highlight the **Supervisor Menu** icon.



Figure 22.
Main Menu screen with
Supervisor Menu icon
highlighted




3. Press the right soft key to display the **Supervisor Menu**.
4. When the **Supervisor Menu** is displayed, **General Meter Settings** is highlighted. Press the right soft key to display the **General Settings** screen.
5. When the **General Settings** screen is displayed, **Default Settings** is highlighted. Press the right soft key to display the **Default Settings** screen.
6. On the **Default Settings** screen, use the  key to highlight **Registering** CONTROL LOT and press the right soft key to display the **Registering** screen.



Figure 23.
Registering screen

7. On the **Registering** screen, use the   keys to toggle between **Yes** and **No** to either allow or not allow Operators to register lots and controls.
8. Press the right soft key.

Quality Control Settings

Perform the following steps to set the time intervals at which LQC and EQC must be run. It is recommended that LQC be run every 30 days (as well as with every new lot of NEPHROCHECK Test cartridges, with each new shipment of NEPHROCHECK Test Kits, or in accordance with the best practices of the institution). EQC should be run in accordance with the best practices of the institution.


1. Press the  key to display the **Main Menu**.
2. Use the navigation keys to highlight the **Supervisor Menu** icon and press the right soft key.

Figure 24.
Main Menu screen with
Supervisor Menu icon
highlighted







3. When the **Supervisor Menu** is displayed, **General Meter Settings** is highlighted. Press the right soft key to display the **General Settings** screen.
4. When the **General Settings** screen is displayed, **Default Settings** is highlighted. Press the right soft key to display the **Default Settings** screen.
5. On the **Default Settings** screen, use the  key to highlight **QC Settings** and press the right soft key.

Figure 25.
Default Settings screen
with QC Settings
highlighted



6. When the **QC Settings** screen is displayed, **LQC Interval (Days); O = off** will be highlighted. Use the numeric keypad, or an external keyboard (if connected) to enter the interval in **days** at which LQC must be run. NOTE: entering "0" indicates that LQC is not required to be run at all. To change an existing entry, use the  key to first delete the entry, then enter the new number using the numeric keypad or an external keyboard (if connected).
7. Press the  key to highlight **EQC Interval (Hours); O = off**. Use the numeric keypad, or an external keyboard (if connected) to enter the interval in **hours** at which EQC must be run. NOTE: entering "0" indicates that EQC is not required to be run at all. To change an existing entry, use the  key to first delete the entry, then enter the new number using the numeric keypad or an external keyboard (if connected).
8. Press the right soft key to accept the intervals entered.

LIS Settings

If the ASTUTE140 Meter is connected to an LIS, Supervisors can set the timeout interval, the IP Address, Port Number, and whether results will be automatically transmitted from the meter to the LIS. To set the LIS settings, follow these steps:



1. Press the  key to display the **Main Menu**.
2. Use the navigation keys to highlight the **Supervisor Menu** icon.



Figure 26.
Main Menu screen with
Supervisor Menu icon
highlighted

3. Press the right soft key to display the **Supervisor Menu**.
4. When the **Supervisor Menu** is displayed, **General Meter Settings** is highlighted. Press the right soft key to display the **General Settings** screen.
5. When the **General Settings** screen is displayed, **Default Settings** is highlighted. Use the  key to highlight **LIS Settings** and press the right soft key.

6. If the ASTUTE140 Meter is not connected to an LIS, **LIS available** will be highlighted, **No** will be checked, and none of the LIS parameters may be changed.

Figure 27.

LIS Settings screen when
LIS is not available

The screenshot shows the 'LIS Settings' screen with a blue header bar containing the date '02/04/2012 | 14:39' and a user icon labeled 'Initial'. The title 'LIS Settings' is in orange. The settings are as follows: 'Timeout (sec)' is 0, 'IP Address' is 0.0.0.0, 'Port Number' is 0, and 'Auto Transmit (LIS)' has 'No' selected. The 'LIS available' section is highlighted in orange, with 'No' checked and 'Yes' unchecked. At the bottom are 'Discard' and 'Accept' buttons.

Timeout (sec)	0
IP Address	0.0.0.0
Port Number	0
Auto Transmit (LIS)	No Yes
LIS available	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes




If the ASTUTE140 Meter is connected to an LIS, **Yes** will be checked and the timeout interval, IP Address, Port Number, and whether results will be automatically transmitted to the LIS may be selected.

Figure 28.

LIS Settings screen when
LIS is available

The screenshot shows the 'LIS Settings' screen with a blue header bar containing the date '02/10/2012 | 14:30' and a user icon labeled 'Initial'. The title 'LIS Settings' is in orange. The settings are as follows: 'Timeout (sec)' is 5, 'IP Address' is 0.0.0.0, 'Port Number' is 0, and 'Auto Transmit (LIS)' has 'Yes' selected. The 'LIS available' section is highlighted in orange, with 'No' unchecked and 'Yes' checked. At the bottom are 'Discard' and 'Accept' buttons.

Timeout (sec)	5
IP Address	0.0.0.0
Port Number	0
Auto Transmit (LIS)	No Yes
LIS available	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes

7. To change the numeric LIS settings (Timeout interval, IP Address, and Port Number), use the   keys to highlight the field(s) to be changed. Use the  key to first delete any existing numeric entries, and then enter the new numeric entries using the numeric keypad or an external keyboard (if connected). NOTE: the IP address must be entered in the following format: ###.###.###.###.

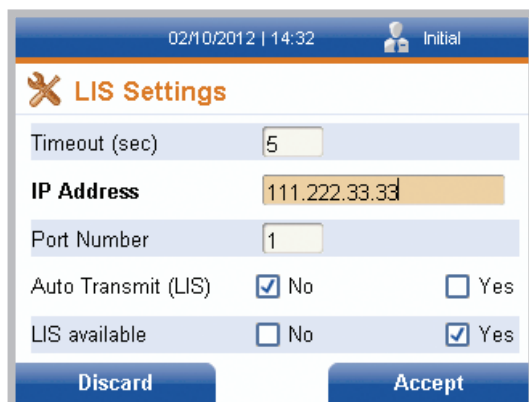






Figure 29.
Correct IP Address format

To specify whether test results will be automatically transmitted to the LIS, use the   keys to highlight **Auto Transmit (LIS)**. Use the   keys to toggle between **No** and **Yes**.

8. Once all of the entries have been confirmed, press the right soft key to accept all entries.

Network Settings

To configure the network settings, perform the following steps:


1. Press the  key to display the **Main Menu**.
2. Use the navigation keys to highlight the **Supervisor Menu** icon.



Figure 30.
Main Menu screen with
Supervisor Menu icon
highlighted




3. Press the right soft key to display the **Supervisor Menu**.
4. When the **Supervisor Menu** is displayed, **General Meter Settings** is highlighted. Press the right soft key to display the **General Settings** screen.
5. When the **General Settings** screen is displayed, **Default Settings** is highlighted. Use the  key to highlight **Network Settings** and press the right soft key.
6. When the **Network Settings** screen is displayed, **IP Setup** will be highlighted. Use the   keys to toggle between **Manual** and **DHCP**. NOTE: If **DHCP** is selected, only the **Port** may be changed.

Figure 31.
Network Settings screen
with DHCP selected



The screenshot shows the 'Network Settings' screen. At the top, it displays the date '02/04/2012 | 14:41' and a user icon labeled 'Initial'. Below the title 'Network Settings', there is a section for 'IP Setup' with two radio buttons: 'Manual' (unchecked) and 'DHCP' (checked). Below this, there are four input fields: 'IP Address' with the value '192.168.1.176', 'Subnet Mask' with '255.255.255.0', 'Std. Gateway' with '192.168.1.254', and 'Port' with '10001'. At the bottom, there are two buttons: 'Discard' and 'Accept'.




If **Manual** is selected, use the   keys to highlight the field to be changed. For **IP Address**, **Subnet Mask** and **Std. Gateway**, enter the correct information using the numeric keypad or an external keyboard (if connected) in the format shown.

Figure 32.
Network Settings screen
with Manual selected



The screenshot shows the 'Network Settings' screen. At the top, it displays the date '02/10/2012 | 14:33' and a user icon labeled 'Initial'. Below the title 'Network Settings', there is a section for 'IP Setup' with two radio buttons: 'Manual' (checked) and 'DHCP' (unchecked). Below this, there are four input fields: 'IP Address' with the value '192.168.1.176', 'Subnet Mask' with '255.255.255.0', 'Std. Gateway' with '192.168.1.254', and 'Port' with '10001'. At the bottom, there are two buttons: 'Discard' and 'Accept'.

To change the Port number, use the  key to first delete the existing entry, if applicable, and then use the numeric keypad or an external keyboard (if connected) to enter the correct port number.

7. Once all of the entries have been confirmed, press the right soft key to accept all entries.

PC Mode

To turn PC Mode off or on, follow these steps:


1. Press the  key to display the **Main Menu**.
2. Use the navigation keys to highlight the **Supervisor Menu** icon.



Figure 33.
Main Menu screen with
Supervisor Menu icon
highlighted




3. Press the right soft key to display the **Supervisor Menu**.
4. When the **Supervisor Menu** is displayed, **General Meter Settings** is highlighted. Press the right soft key to display the **General Settings** screen.
5. When the **General Settings** screen is displayed, **Default Settings** is highlighted. Use the  key to highlight **PC Mode** and press the right soft key.



Figure 34.
PC Mode screen

6. When the **PC Mode** screen is displayed, use the   keys to toggle between turning PC Mode **Off** or **On**.
7. Once the selection has been confirmed, press the right soft key.

Printer Settings

To specify whether test results are automatically sent to the ASTUTE140 Meter's internal printer, or to create a customized header (including institute name, address and telephone number) to be printed on all printouts, follow these steps:


1. Press the  key to display the **Main Menu**.
2. Use the navigation keys to highlight the **Supervisor Menu** icon.

Figure 35.
Main Menu screen with
Supervisor Menu icon
highlighted




3. Press the right soft key to display the **Supervisor Menu**.
4. When the **Supervisor Menu** is displayed, **General Meter Settings** is highlighted. Press the right soft key to display the **General Settings** screen.
5. When the **General Settings** screen is displayed, **Default Settings** is highlighted. Use the  key to highlight **Printer Settings** and press the right soft key.

Figure 36.
General Settings screen
with Printer Settings
highlighted



6. When the **Printer Settings** screen is displayed, **Auto Print** is highlighted. To select whether results will be automatically sent to the ASTUTE140 Meter's internal printer, use the ◀ ▶ keys to toggle between **No** and **Yes**.

The screenshot shows the 'Printer Settings' screen. At the top, it displays the date and time '02/04/2012 | 14:44' and a user icon labeled 'Initial'. The title 'Printer Settings' is in orange. Below it, the 'Auto Print' option is highlighted with a yellow background, showing a 'No' checkbox and a checked 'Yes' checkbox. There are four text input fields: 'Institute' (sample institute), 'Address' (sample address), 'City, State, ZIP' (sample city & zip), and 'Telephone' (000-000-0000). At the bottom are 'Discard' and 'Accept' buttons.

Figure 37.
Printer Settings screen

7. If a print header is desired, use the ▲ ▼ keys to select the fields to be included in the header. For each field selected, use the ⇐ key to delete any existing entries if applicable. Enter numerical information using the numeric keypad or an external keyboard (if connected). An external keyboard must be connected in order to enter alphanumeric information.
8. Once all of the entries have been confirmed, press the right soft key to accept all entries.


Managing Users

Supervisors can register new users, edit existing user information or delete registered users from the ASTUTE140 Meter. To perform these functions, follow these steps:








1. Press the ☰ key to display the **Main Menu**.
2. Use the navigation keys to highlight the **Supervisor Menu** icon.

The screenshot shows the 'Main Menu - Supervisor Menu' screen. At the top, it displays the date and time '02/04/2012 | 13:32' and a user icon labeled 'Initial'. The title 'Main Menu - Supervisor Menu' is in orange. Below it are six icons: a person (user management), a flask (chemistry), a magnifying glass (search), a gear (settings), a wrench and screwdriver (tools), and a document with a checkmark (reporting). The 'Supervisor Menu' icon (wrench and screwdriver) is highlighted with a blue border. At the bottom are 'Logout' and 'Select' buttons.





Figure 38.
Main Menu screen with
Supervisor Menu icon
highlighted









3. Press the right soft key to display the **Supervisor Menu**.
4. When the **Supervisor Menu** is displayed, use the  key to highlight **Manage Users** and press the right soft key.
5. The **Existing User List** screen displays a list of users that have been registered to operate the ASTUTE140 Meter with the user ID number, name and mode of operation (Supervisor vs. Operator user).

To add a new user:




1. From the existing user list, press the right soft key to display the **Options** pop-up menu.
2. When the **Options** pop-up menu is displayed, **Edit User** is highlighted. Use the  key to highlight **Add User** and press the right soft key.
3. When the **Create New User** screen is displayed, **Mode** is highlighted. Use the   keys to toggle between **Supervisor** and **Operator**.
4. To enter a user name, press the  key to highlight **Name**. Use the numeric keypad or an external keyboard (if connected) to enter the user name.
5. To enter the ID, use the  key to highlight **ID** (numeric). Use the numeric keypad or an external keyboard (if connected) to enter the desired ID.
NOTE: The ID must be numeric.
6. To enter the password, use the  key to highlight **Password**. Use the numeric keypad or an external keyboard (if connected) to enter the password.
7. After the password is entered, use the  key to highlight **Confirm Password**. Use the numeric keypad or an external keyboard (if connected) to re-enter the password entered above.
8. Once all of the entries have been confirmed, press the right soft key to accept all entries. To discard all entries and return to the **Existing User** list, press the left soft key.

To edit the information for an existing user:

1. Use the   keys to highlight the user information to be edited and press the right soft key to display the **Options** pop-up menu.
2. When the **Options** pop-up menu is displayed, **Edit User** is highlighted. To edit the user information, press the right soft key.
3. When the **Change User** screen is displayed, **Mode** is highlighted. The current user mode (Supervisor or Operator) is displayed. To change the user mode, use the   keys to toggle between **Supervisor** and **Operator**.


4. To change the user **Name**, use the  key to highlight the name. Use the  key to delete the current name, if applicable, and use the numeric keypad or an external keyboard (if connected) to enter the desired name.
5. To change the user **ID**, use the  key to highlight **ID** (numeric). Use the  key to delete the current ID, and use the numeric keypad or an external keyboard (if connected) to enter the desired ID. NOTE: The ID must be numeric.
6. To change the user **password**, use the  key to highlight **Password**. Use the  key to delete the current password and use the numeric keypad or an external keyboard (if connected) to enter the desired password. Use the  key to highlight **Confirm Password**. Use the  key to delete the current confirmed password and use the numeric keypad or an external keyboard (if connected) to re-enter the password entered above.
7. Once all of the entries are confirmed, press the right soft key to accept all entries. To discard all entries and return to the **Existing User** list, press the left soft key.

To delete an existing user:

1. Use the   keys to highlight the user information to be edited and press the right soft key to display the **Options** pop-up menu.
2. When the **Options** pop-up menu is displayed, **Edit User** is highlighted. Press the  key to highlight **Del. Selected**. And press the right soft key.
3. A confirmation screen will appear asking if you are sure that you want to delete the selected user. To delete the user, press the left soft key to choose **Delete**. To cancel, press the right soft key.

ASTUTE140 Meter Information

To display the ASTUTE140 Meter information, including the installed hardware, firmware and bootware versions, the serial number, and the IP address, follow the steps below:

1. Press the  key to display the **Main Menu**.

2. Use the navigation keys to highlight the **Supervisor Menu** icon.

Figure 39.

Main Menu screen with
Supervisor Menu icon
highlighted




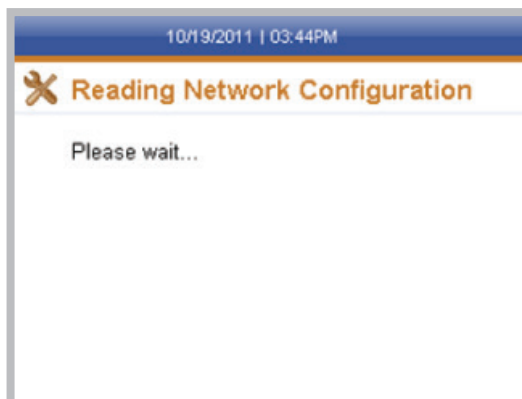
3. Press the right soft key to display the **Supervisor Menu**.
4. When the **Supervisor Menu** is displayed, **General Settings** is highlighted. Use the  key to highlight **Meter Info** and press the right soft key.
5. A temporary screen will appear while the ASTUTE140 Meter is reading the network configuration.

Figure 40.

Temporary screen while
ASTUTE140 Meter is reading
network configuration



- When the ASTUTE140 Meter has read the network configuration, a screen will appear displaying the Hardware, Firmware, and Bootware versions, the serial number, and the IP address.



Figure 41.
Meter Information screen

- Press the left soft key to return to the **Supervisor Menu**.

Error Log

A history of the errors that have occurred while the ASTUTE140 Meter has been in use, including the error code and the date/time of occurrence, may be accessed through the **Supervisor Menu** or the **Operator Menu**. To view the **Error Log** perform the following steps.

From the **Supervisor Menu**:


- Press the  key to display the **Main Menu**.
- Use the navigation keys to highlight the **Supervisor Menu** icon.



Figure 42.
Main Menu screen with
Supervisor Menu icon
highlighted

- Press the right soft key to display the **Supervisor Menu**.


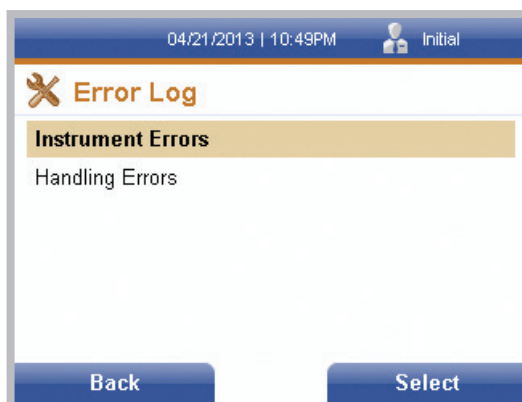
4. When the **Supervisor Menu** is displayed, **General Settings** is highlighted. Use the  key to highlight **Error Log** and press the right soft key.

Figure 43.
Error Log screen



5. On the **Error Log** screen, **Instrument Errors** is highlighted. To display the **Instrument Errors Log**, press the right soft key.

Figure 44.
Instrument Errors Log screen




To display the **Handling Errors Log**, use the  key to highlight **Handling Errors** and press the right soft key.

Figure 45.
Handling Errors Log screen



6. To print the errors log once it is displayed, press the right soft key.
7. To return to the **Error Log** screen, press the left soft key.

From the **Operator Menu**:


1. Press the  key to display the **Main Menu**.
2. Use the navigation keys to highlight the **Operator Menu** icon.



Figure 46.
Main Menu screen with
Operator Menu icon
highlighted


3. Press the right soft key to display the **Operator Menu**.
4. When the **Operator Menu** is displayed, **Manage Lots** is highlighted. Use the  key to highlight **View Error Log** and press the right soft key.



Figure 47.
Operator Menu screen
with View Error Log
highlighted

5. Follow steps 5–7 in the previous section.

ASTUTE140 Meter Operation

Startup

Powering On the ASTUTE140 Meter

To power on the ASTUTE140 Meter, locate the power switch on the back of the meter and toggle it upwards, holding it in position until the **Self Test** screen appears.

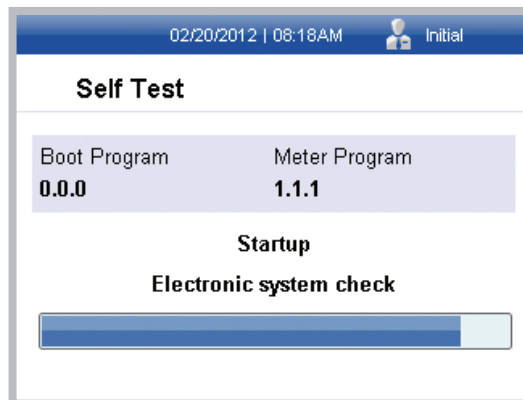


Figure 48.
Self Test screen

If all systems pass, the **Log In** screen will then automatically appear, indicating that the ASTUTE140 Meter is ready for use.







Figure 49.
Log In screen

If the self test fails, an error message will be displayed. Press the right soft key to select **OK** and close the error message, and then restart the ASTUTE140 Meter by turning it off and back on again (to power off the meter, toggle the power switch upwards and it should immediately shut down). If after restarting the ASTUTE140 Meter the self test fails again, contact Astute Technical Support (See "Contacting Astute Medical, Inc." on p. 7 for contact information).

Logging In


In order to operate the ASTUTE140 Meter, the user must log in with a unique user ID and password. This requirement protects access to patient information stored in the ASTUTE140 Meter's memory.

After successfully powering on the ASTUTE140 Meter, the **Log In** screen will automatically appear. Perform the following steps to log in to the system:

1. When the **Log In** screen is displayed, **User ID** is highlighted. Enter your user ID using the numeric keypad or an external keyboard or barcode reader (if connected).
2. After entering your user ID, use the  key to highlight the **Password** field.
3. Use the numeric keypad or an external keyboard (if connected) to enter your password.
4. Confirm that the correct log in information is displayed. To make changes to the entries, use the   keys to highlight the field to be changed. Use the  key to delete the incorrect entry, and then use the numeric keypad or an external keyboard (if connected) to change the entries. Press the right soft key to accept all entries.

Non-Permanent Settings

Although the default settings for the ASTUTE140 Meter are set by the Supervisor through the **Supervisor Menu**, Operator users can select some settings from predefined values that are valid until the meter is switched off or until the Operator is logged out. At such time the settings will revert to the default settings selected by the Supervisor. To temporarily set the date and time formats, the language, and to turn the beeper on or off, follow these steps:

1. Press the  key to display the **Main Menu** (if registering the EQC device immediately after successful log in, the **Main Menu** will automatically be displayed).

2. Use the navigation keys to highlight the **Operator Menu** icon.

Figure 50.

Main Menu screen with
Operator Menu icon
highlighted















3. Press the right soft key to display the **Operator Menu**.
4. When the **Operator Menu** is displayed, **Manage Lots** is highlighted. Use the  key to highlight **Settings** and press the right soft key to display the **Local Settings** screen.

Figure 51.

Local Settings screen



5. When the **Local Settings** screen is displayed, **Date Format** is highlighted. Use the   keys to select the desired date format (mm/dd/yyyy or dd.mm.yyyy) for display on the screen and printouts.
6. Press the  key to highlight **Time Format**. Use the   keys to choose either a 12 or 24-hour time format for display on the screen and printouts.
7. Press the  key to highlight **Language**. Use the   keys to select the desired language.
8. Press the  key to highlight **Beeper**. Use the   keys to turn the beeper on or off.
9. Once all selections have been confirmed, press the right soft key to accept all selections.

RFID Cards for Device and Lot Registration

Each new ASTUTE140 Electronic Quality Control (EQC) Device, liquid control lot and test lot must be registered prior to first use. Operators may register ASTUTE140 Electronic Quality Control (EQC) Devices, liquid control lots and test lots only if Supervisors grant registration permission to Operators in the default settings; otherwise, Supervisors must carry out registrations. To register an ASTUTE140 Electronic Quality Control (EQC) Device, liquid control lot or test lot, see “ASTUTE140 EQC Device Registration” on p. 48, “Liquid Control Lot Registration” on p. 54, and “Test Lot Registration” on p. 52.

ASTUTE140 EQC Device Registration

The EQC procedure verifies the calibration of the ASTUTE140 Meter, including the positioning system, optical system and other internal systems of the meter to confirm that the meter is functioning properly.

When not in use, the ASTUTE140 EQC Device should be stored in its original packaging away from direct light. If lost, a replacement ASTUTE140 EQC Device may be ordered from Astute Medical, Inc. at www.astutemedical.com or by contacting your Astute Medical, Inc. sales representative.

The ASTUTE140 EQC Device must be registered prior to first use. Operators may register the ASTUTE140 EQC Device only if the Supervisor granted registration permission in the default settings; otherwise, Supervisors must register the ASTUTE140 EQC Device.

To register the ASTUTE140 EQC Device, locate the ASTUTE140 EQC RFID Card included in the ASTUTE140 Meter Kit and perform the following steps:


1. Press the  key to display the **Main Menu** (if registering the ASTUTE140 EQC Device immediately after successful log in, the **Main Menu** will automatically be displayed).
2. Use the navigation keys to highlight the **Operator Menu** icon.



Figure 52.
Main Menu screen with
Operator Menu icon
highlighted


3. Press the right soft key to display the **Operator Menu**.
4. When the **Operator Menu** is displayed, **Manage Lots** is highlighted. Press the right soft key to display the **Manage Lots** screen.
5. When the **Manage Lots** screen is displayed, **Manage Test Lots** is highlighted. Use the  key to highlight **Manage EQC Devices** and press the right soft key to display the **Registered EQC Devices** screen.

Figure 53.

Manage Lots screen with
Manage EQC Devices
highlighted




6. On the **Registered EQC Devices** screen, press the right soft key to display the **Options** pop-up menu.

Figure 54.

Registered EQC Devices
screen with options
pop-up menu



7. When the **Options** pop-up menu is displayed, **Print List** is highlighted. Use the  key to highlight **Register Device** and press the right soft key.

8. When prompted, hold the ASTUTE140 Electronic Quality Control (EQC) RFID Card for the ASTUTE140 EQC Device next to or against the numeric keypad to register the ASTUTE140 EQC Device information and select **OK** by pressing the right soft key.

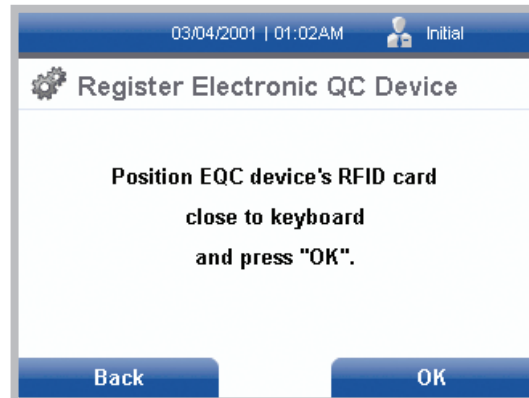


Figure 55.
Register Electronic QC
Device screen

9. If registered correctly, a screen indicating that the ASTUTE140 EQC Device number was successfully read from the ASTUTE140 EQC RFID Card will appear. Press the right soft key to select **Accept**. The ASTUTE140 EQC Device that was just registered should now appear in the list of registered ASTUTE140 EQC Devices.
10. If registered incorrectly, an error message will appear. Press the right soft key to select **OK** and close the error message. Repeat steps 8–9. If registered incorrectly a second time, contact Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).
11. After use, return the ASTUTE140 EQC RFID Card to its sleeve and store it with the ASTUTE140 EQC Device in its original packaging.

ASTUTE140 Electronic Quality Control (EQC)

The EQC procedure verifies the calibration of the ASTUTE140 Meter, including the positioning system, optical system and other internal systems of the meter to confirm that the meter is functioning properly. It is recommended that the EQC procedure be run at a frequency in accordance with the best practices of your institution. The required frequency for running EQC may be set by a Supervisor in the general ASTUTE140 Meter default settings (See “Quality Control Settings” on p. 31 for instructions).

Prior to running the first EQC procedure, the ASTUTE140 EQC Device must be registered (See “ASTUTE140 EQC Device Registration” on p. 48 for details).

To run the EQC procedure, perform the following steps using the ASTUTE140 EQC Device provided with the ASTUTE140 Meter:


1. Press the  key to display the **Main Menu** (if running EQC immediately after successful log in, the **Main Menu** will automatically be displayed).
2. Use the navigation keys to highlight the **Run EQC** icon.
3. Press the right soft key to select **Run EQC**. The ASTUTE140 Meter drawer will automatically open.
4. When prompted, place the ASTUTE140 EQC Device into the recess inside the ASTUTE140 Meter drawer with the Astute Medical logo marked on the ASTUTE140 EQC Device pointed toward the meter. Gently close the drawer until it clicks.




Figure 56.
Inserting ASTUTE140
EQC Device



5. After closing the drawer, a temporary screen will appear indicating that the ASTUTE140 Meter is running the EQC procedure and displaying the amount of time remaining until test completion will be displayed.

Figure 57.
Temporary screen showing
EQC procedure countdown



6. When the EQC procedure completes, the results will be displayed along with the word **Passed** if the meter passed the EQC procedure or **Failed** if it did not. If the EQC procedure failed, run the EQC procedure again following the steps below:
 - a. Press the right soft key to display the **Options** pop-up menu.
 - b. Use the  key to highlight **Next Control** and press the right soft key.
 - c. When the drawer automatically opens, remove the ASTUTE140 EQC Device and repeat steps 4 and 5. NOTE: If a second ASTUTE140 EQC Device is available, the second device should be used.
 - d. When the EQC procedure completes, the results will be displayed along with the word **Passed** if the ASTUTE140 Meter passed the EQC procedure or **Failed** if it did not. If the procedure failed, contact Astute Technical Support (See "Contacting Astute Medical, Inc." on p. 7 for contact information).
7. To manually print the EQC results if Autoprint is disabled:
 - a. Press the right soft key to display the **Options** pop-up menu.
 - b. When the **Options** pop-up menu is displayed, **Print** is highlighted. To print the EQC results, press the right soft key.
 - c. To hide the **Options** pop-up menu, use the  key to highlight **Hide Options** and press the right soft key.
 - d. To return to the **Main Menu**, press the left soft key.
8. After completing the EQC procedure, press the  key to the left of the LCD screen to open the ASTUTE140 Meter drawer. Remove the ASTUTE140 EQC Device and store it in the case provided away from direct light.

Test Lot Registration

Assay-specific test cartridges that are uniquely compatible with the ASTUTE140 Meter are used to test patient samples. The NEPHROCHECK Test cartridges approved for use with the ASTUTE140 Meter should not be used with any other testing device. Similarly, only NEPHROCHECK Test cartridges approved for use with the ASTUTE140 Meter can be used with the meter. For a list of approved tests for use with the ASTUTE140 Meter and to purchase assay-specific test cartridges, go to www.astutemedical.com or consult your Astute Medical, Inc. sales representative.

Each new test lot must be registered prior to use of any NEPHROCHECK Test cartridges from that lot. Operators may register the test lot only if the Supervisor granted registration permission in the default settings; otherwise, Supervisors must register the test lot.

See the NEPHROCHECK Test Kit Package Insert for storage instructions.

To register a test lot, perform the following steps:



1. Locate the NEPHROCHECK Test RFID Card included in the NEPHROCHECK Test Kit from the test lot to be registered.
2. Press the  key to display the **Main Menu** (if registering the test lot immediately after successful log in, the **Main Menu** will automatically be displayed).
3. Use the navigation keys to highlight the **Operator Menu** icon.

Figure 58.
Main Menu screen with
Operator Menu icon
highlighted



4. Press the right soft key to display the **Operator Menu**.
5. When the **Operator Menu** is displayed, **Manage Lots** is highlighted. Press the right soft key to display the **Manage Lots** screen.
6. When the **Manage Lots** screen is displayed, **Manage Test Lots** is highlighted. Press the right soft key to display the **Registered Test Lots** screen.
7. On the **Registered Test Lots** screen, a list of all the previously registered test lots will be displayed. If the lot being registered appears on the list, it has already been registered and need not be registered again. Press the left soft key to return to the **Main Menu**. If the test lot does not appear on the list, proceed to step 8.
8. On the **Registered Test Lots** screen, press the right soft key to display the **Options** pop-up menu.
9. When the **Options** pop-up menu is displayed, **Print List** is highlighted. Use the  key to highlight **Register Lot** and press the right soft key.

10. When prompted, hold the NEPHROCHECK Test RFID Card for the test lot next to or against the numeric keypad to register the test lot information and select **OK** by pressing the right soft key.

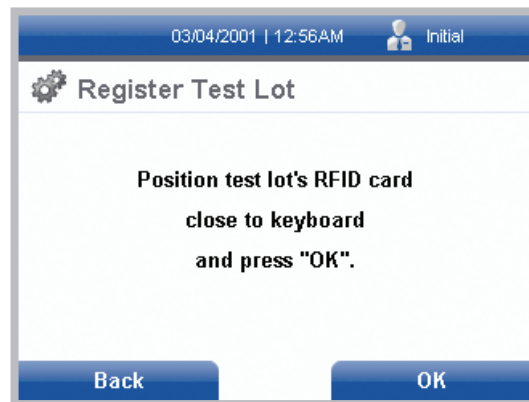


Figure 59.
Register Test Lot screen

11. If registered correctly, a screen displaying the test lot number, the test type and the analytes detected by the test will appear. Press the right soft key to select **Accept**. The test lot that was just registered should now appear in the list of registered test lots.
12. If registered incorrectly, an error message will appear. Press the right soft key to select **OK** and close the error message. Repeat steps 10–11. If registered incorrectly a second time, contact Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).
13. After use, place the NEPHROCHECK Test RFID Card in its sleeve and return it to the kit from which it was removed. Once all the cartridges in the kit have been used, the NEPHROCHECK Test RFID Card and the NEPHROCHECK Test cartridge kit may be discarded in accordance with local regulations.
14. To register another test lot, locate the NEPHROCHECK Test RFID Card for the test lot to be registered and repeat steps 7–13.

Liquid Control Lot Registration

High and low liquid controls must be run to verify the precision and accuracy of the assay procedure, including the performance of the NEPHROCHECK Test cartridges and assay-specific reagents.

Each assay-specific liquid control kit includes a high and a low liquid control. Each liquid control in the kit must be registered prior to first use. Operators may register the liquid controls only if the Supervisor granted registration permission in the default settings; otherwise, Supervisors must register the liquid controls.

See the assay-specific Package Insert for storage instructions when the liquid control kit is not in use. Additional liquid controls may be ordered from Astute Medical, Inc. at www.astutemedical.com or by contacting your Astute Medical, Inc. sales representative.

For each NEPHROCHECK Liquid Control Kit, the liquid control registration process must be carried out twice: once for the high liquid control and once for the low liquid control. To register each control, perform the following steps:




1. Locate the NEPHROCHECK Liquid Control RFID Card for the liquid control lot to be registered (i.e. the NEPHROCHECK High Liquid Control RFID Card if registering the high liquid control, or the NEPHROCHECK Low Liquid Control RFID Card if registering the low liquid control).
2. Press the  key to display the **Main Menu** (if registering the liquid control lot immediately after successful log in, the **Main Menu** will automatically be displayed).
3. Use the navigation keys to highlight the **Operator Menu** icon.

Figure 60.
Main Menu screen with
Operator Menu icon
highlighted



4. Press the right soft key to display the **Operator Menu**.
5. When the **Operator Menu** is displayed, **Manage Lots** is highlighted. Press the right soft key to display the **Manage Lots** screen.
6. When the **Manage Lots** screen is displayed, **Manage Test Lots** is highlighted. Use the  to highlight **Manage LQC Lots** and press the right soft key to display the **Registered LQC Lots** screen.
7. On the **Registered LQC Lots** screen, press the right soft key to display the **Options** pop-up menu.
8. When the **Options** pop-up menu is displayed, **Print List** is highlighted. Use the  key to highlight **Register Lot** and press the right soft key.

9. When prompted, hold the NEPHROCHECK Liquid Control RFID Card for the liquid control to be registered next to or against the numeric keypad to register the liquid control lot information and press the right soft key to select **OK**.

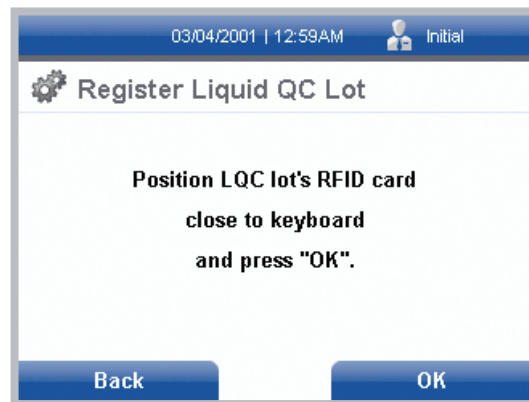


Figure 61.
Register Liquid QC Lot
screen

10. If registered correctly, a screen indicating that the liquid control lot number was successfully read from the NEPHROCHECK Liquid Control RFID Card will appear, and the lot number will be displayed. Press the right soft key to select **Accept**. The lot that was just registered should now appear in the list of Registered LQC Lots.
11. If registered incorrectly, an error message will appear. Press the right soft key to select **OK** and close the error message. Repeat steps 9–10. If registered incorrectly a second time, contact Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).
12. After use, return the NEPHROCHECK Liquid Control RFID Card to its sleeve and store with the corresponding liquid control.
13. To register the second liquid control in the set, or to register another liquid control set from a different lot, repeat steps 7–12.

External Liquid Quality Control (LQC)

High and low liquid controls must be run to verify the precision and accuracy of the assay procedure, including the performance of the NEPHROCHECK Test cartridges and assay-specific reagents.

It is recommended that LQC be performed at the following times:

- Every 30 days
- With each new lot number of NEPHROCHECK Test cartridges
- With each new shipment of NEPHROCHECK Test Kits
- In accordance with the laboratory’s standard quality control procedures

The required frequency for running LQC may be set by a Supervisor in the general ASTUTE140 Meter default settings (See “Quality Control Settings” on p. 31 for instructions).

Prior to running the first LQC procedure, both the high and low liquid controls in the liquid control kit must be registered if they are from a new liquid control lot (See “Liquid Control Lot Registration” on p. 54 for instructions).

The LQC procedure must be run twice: once with the high liquid control and once with the low liquid control. For each lot of NEPHROCHECK Test cartridges, both high and low liquid controls must have passed within the time window set in the default settings before patient samples can be run using NEPHROCHECK Test cartridges from that lot.

To run the LQC procedure, perform the following steps and repeat for the second control in the liquid control set:


1. Press the  key to display the **Main Menu** (if running LQC immediately after successful log in, the **Main Menu** will automatically be displayed).
2. Use the navigation keys to highlight the **Run LQC** icon.

Figure 62.
Main Menu screen with
Run LQC icon highlighted





3. Press the right soft key to select **Run LQC**.

4. A screen showing all liquid control lots previously registered and their expiration dates will be displayed. Controls displayed as "Control +" correspond to high liquid controls and those displayed as "Control –" correspond to low liquid controls.





Figure 63.
Run LQC – Select Lot
screen



5. Use the   keys to highlight the correct liquid control lot being tested and press the right soft key. If the liquid control lot is not listed, register the liquid control lot to be tested by following the steps outlined in "Liquid Control Lot Registration" on p. 54. After the lot is registered, repeat steps 1–6.
6. After selecting the liquid control lot to be tested, the ASTUTE140 Meter drawer will automatically open.
7. Prepare the NEPHROCHECK Test cartridge with the liquid control (high or low) as instructed in the assay-specific NEPHROCHECK Liquid Control Kit Package Insert.
NOTE: The test lot must be registered prior to running LQC (See "Test Lot Registration" on p. 52 for instructions).

8. When prompted, place the prepared NEPHROCHECK Test cartridge into the recess inside the ASTUTE140 Meter drawer with the Astute Medical logo marked on the NEPHROCHECK Test cartridge pointed toward the meter. Gently close the drawer until it clicks.

Figure 64.
Running LQC



9. After closing the drawer, a temporary screen will appear indicating that the ASTUTE140 Meter is running the LQC procedure and the amount of time remaining until test completion will be displayed.
10. When the LQC procedure completes, the results will be displayed along with the word **Passed** if the procedure passed or **Failed** if it did not. If the LQC procedure failed, run the LQC procedure again following the steps below:
 - a. Press the right soft key to display the **Options** pop-up menu.
 - b. Use the  key to highlight **Next Control** and press the right soft key.
 - c. Repeat steps 4–9 using a freshly prepared NEPHROCHECK Test cartridge. When the LQC procedure completes, the results will be displayed along with the word **Passed** if the meter passed the LQC procedure or **Failed** if it did not. If the procedure failed a second time, contact Astute Technical Support (See "Contacting Astute Medical, Inc." on p. 7 for contact information).
11. Press the  key to the left of the LCD screen to open the ASTUTE140 Meter drawer. Remove the cartridge and discard according to the laboratory's standard practices for the type of biological sample used.
12. To manually print the LQC results if Autoprint is disabled:
 - a. Press the right soft key to display the **Options** pop-up menu.

- b. When the **Options** pop-up menu is displayed, **Print** is highlighted. To print the LQC results, press the right soft key.
 - c. To hide the **Options** pop-up menu, use the  key to highlight **Hide Options** and press the right soft key.
 - d. To return to the **Main Menu**, press the left soft key.
13. To run the next liquid control (high or low) after viewing or printing the LQC results, press the right soft key to display the **Options** pop-up menu. Use the  key to highlight **Next Control** and press the right soft key. Repeat steps 4–12.

Testing a Patient Sample

Assay-specific test cartridges that are uniquely compatible with the ASTUTE140 Meter are used to test patient samples. The test cartridges approved for use with the ASTUTE140 Meter should not be used with any other testing device. Similarly, only test cartridges approved for use with the ASTUTE140 Meter can be used. For a list of approved tests for use with the ASTUTE140 Meter and to purchase assay-specific test cartridges, go to www.astutemedical.com or consult your Astute Medical, Inc. sales representative.

Each new test lot must be registered prior to use of any NEPHROCHECK Test cartridges from that lot (See "Test Lot Registration" on p. 52 for instructions).

To test a patient sample, perform the following steps:


1. Press the  key to display the **Main Menu** (if running patient sample immediately after successful log in, the **Main Menu** will automatically be displayed).
2. When the **Main Menu** is displayed, use the navigation keys to highlight the **Run Patient** icon. Press the right soft key to select **Run Patient**.



Figure 65.
Main Menu screen
with Run Patient icon
highlighted


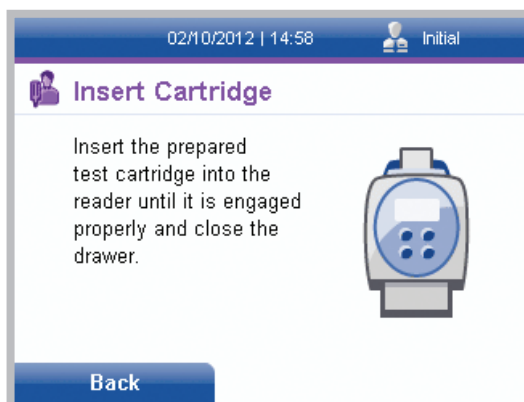
3. When the **Run Patient** screen is displayed, **Patient ID** will be highlighted. Enter the Patient ID manually using the numeric keypad or an external keyboard (if connected) or, if applicable, by scanning the barcode on the patient sample with the optional barcode reader (if connected). (NOTE: Patient identification schemes (i.e. IDs) that contain the following special characters "+", "&" or "@" should be entered into the ASTUTE140 Meter only with a barcode scanner—these characters should not be entered into the ASTUTE140 Meter using an external keyboard.)
4. If available, a Sample ID may be entered; otherwise, this field may be left blank. To enter a Sample ID, use the  key to highlight **Sample ID** and enter the Sample ID manually using the numeric keypad or an external keyboard (if connected) or, if applicable, by scanning the barcode on the patient sample with an optional barcode reader (if connected). NOTE: an external keyboard and barcode reader are optional devices that are not included with the ASTUTE140 Meter kit.
5. After confirming that the correct Patient ID and/or Sample ID have been entered, press the right soft key to select **Run Patient**.
6. After selecting **Run Patient**, the ASTUTE140 Meter drawer will automatically open.
7. Prepare the NEPHROCHECK Test cartridge with the patient specimen according to the NEPHROCHECK Test Kit Package Insert. NOTE: Each NEPHROCHECK Test cartridge must be run immediately after inoculation with the patient sample, and the next cartridge should not be prepared until testing on the first has completed. The ASTUTE140 Meter times the incubation period for the test, and only one test can be run at a time. Inoculating additional samples before testing has completed may lead to inaccurate results.
8. When prompted, place the prepared NEPHROCHECK Test cartridge into the recess inside the ASTUTE140 Meter drawer with the Astute Medical logo marked on the NEPHROCHECK Test cartridge pointed toward the meter. Gently close the drawer until it clicks.

Figure 66.
Insert Cartridge screen



9. After closing the drawer, a temporary screen will appear indicating that the ASTUTE140 Meter is reading the test lot information to determine if the test lot is registered and whether high and low LQC measurements have passed for the test lot.



Figure 67.
Temporary “Reading Test
Lot Info. Please Wait!”
screen

- a. If the lot has not been registered, an error message will appear. Press the right soft key to select **OK** and close the error message. Register the lot (See “Test Lot Registration” on p. 52) before running the test again.
- b. If the lot has been registered, but high and low LQC measurements have not passed for the NEPHROCHECK Test Kit lot, the patient test will not be run and a message indicating that passed LQC measurements are required will be displayed.

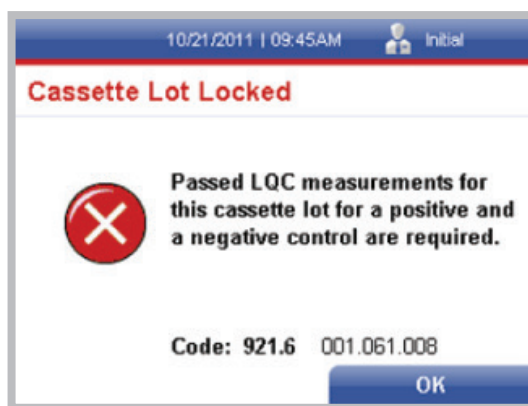




Figure 68.
“Cassette Lot Locked”
error message

If high and low LQC measurements are required, follow these steps:

- i. Press the right soft key to select **OK** and close the error message.
- ii. Discard the NEPHROCHECK Test cartridge prepared with the patient sample.

- iii. Run high and low LQC measurements (See “External Liquid Quality Control” on p. 56 for instructions).
 - iv. When high and low LQC measurements have passed, repeat steps 1–9.
10. If LQC measurements for the NEPHROCHECK Test cartridge lot have passed, a screen indicating the amount of time remaining until test completion will be displayed. To abort the test for any reason, select **Cancel** by pressing the left soft key.
11. Once the test is complete, the test results will be displayed.
12. To manually print the patient test results if Autoprint is disabled:
 - a. Press the right soft key to display the **Options** pop-up menu.
 - b. When the **Options** pop-up menu is displayed, **Print** is highlighted. To print the patient test results, press the right soft key.
 - c. To hide the **Options** pop-up menu, use the  key to highlight **Hide Options** and press the right soft key.
 - d. To return to the **Main Menu**, press the left soft key.
13. Press the eject button to the left of the LCD screen to open the ASTUTE140 Meter drawer. Remove the NEPHROCHECK Test cartridge and discard according to the laboratory’s standard practices for the type of biological sample used.
14. To run the next patient sample after viewing or printing the patient test results, press the right soft key to display the **Options** pop-up menu. Use the  key to highlight **Next Patient** and press the right soft key. Repeat steps 4–13.

Review and Management of Test Results

Patient, LQC and EQC test results can be recalled, printed or sent to the LIS at any time. To perform these functions, follow the instructions below.






Patient Results

1. Press the  key to display the **Main Menu**.

2. Using the navigation keys, highlight the **Review Data** icon and press the right soft key.



Figure 69.
Main Menu screen
with Review Data icon
highlighted

3. When the **Review Data Menu** is displayed, **Patient Results** is highlighted. Press the right soft key to display the **Patient Results** screen.
4. On the **Patient Results** screen, patient results can be selected by entering a range of dates, a range of test sequence numbers or a specific Patient ID, Sample ID, or Operator ID. Use the   keys to select the desired data elements, and enter the data using the numeric keypad or an external keyboard (if connected). NOTE: date fields must be entered in the format specified in the default settings.
5. Once the selection criteria are entered, press the right soft key to display a list of the patient results meeting the selection criteria.
 - a. To print the list of patient test results:
 - i. Display the **Options** pop-up menu by pressing the right soft key.
 - ii. Use the  key to highlight **Print List**.
 - iii. After printing is complete, the list of patient results will again be displayed.
 - b. To display and/or print detailed test results for a particular patient sample:
 - i. Use the   keys to highlight the test of interest.
 - ii. Press the right soft key to display the **Options** pop-up menu.
 - iii. When the **Options** pop-up menu is displayed, **Show Details** will be highlighted. Press the right soft key to select **Show Details**.
 - iv. Details of the patient test results will be displayed. To print the test results, press the right soft key to select **Print**.
 - v. After printing is complete, press the left soft key to return to the list of patient results.

LQC Results













1. Press the  key to display the **Main Menu**.
2. Using the navigation keys, highlight the **Review Data** icon and press the right soft key.

Figure 70.
Main Menu screen
with Review Data icon
highlighted



3. When the **Review Data Menu** is displayed, **Patient Results** is highlighted. Use the  key to highlight **Liquid QC Results** and press the right soft key to display the **Review LQC Results** screen.
4. On the **Review LQC Results** screen, LQC results can be selected by entering a range of dates, or by selecting a specific control lot or test lot number.
 - a. To select LQC results using a range of dates:
 - i. **Start date** will be automatically highlighted. Use the numeric keypad or an external keyboard (if connected) to enter a date. NOTE: date fields must be entered in the format specified in the default settings.
 - ii. Use the  key to highlight **End Date** and enter the end date in the same manner and format.
 - b. To select LQC results from a specific control lot:
 - i. Use the  key to highlight **Control Lot**.
 - ii. The default selection is to display LQC results from all control lots. To select a specific control lot, use the   keys to display the desired control lot.
 - c. To select LQC results from a specific test lot:
 - i. Use the  key to highlight **Test Lot**.
 - ii. The default selection is to display LQC results from all test lots. To select a specific test lot, use the   keys to display the desired test lot.

5. Once all selection criteria are entered, press the right soft key to display a list of the LQC results meeting the selection criteria.
 - a. To print the list of LQC test results:
 - i. Display the **Options** pop-up menu by pressing the right soft key.
 - ii. Use the  key to highlight **Print List**.
 - iii. After printing is complete, the list of LQC results will again be displayed.
 - b. To examine and/or print test results for a particular patient sample:
 - i. Use the   keys to highlight the LQC result of interest.
 - ii. Press the right soft key to display the **Options** pop-up menu.
 - iii. When the **Options** pop-up menu is displayed, **Show Details** will be highlighted. Press the right soft key to select **Show Details**.
 - iv. Detailed LQC results for the selected test will be displayed. To print the detailed results, press the right soft key to select **Print**.
 - v. After printing is complete, press the left soft key to return to the list of patient results.

EQC Results










1. Press the  key to display the **Main Menu**.
2. Using the navigation keys, highlight the **Review Data** icon and press the right soft key.



Figure 71.
Main Menu screen
with Review Data icon
highlighted

3. When the **Review Data Menu** is displayed, **Patient Results** is highlighted. Use the  key to highlight **Electronic QC Results** and press the right soft key to display the **Review EQC Results** screen.

4. On the **Review EQC Results** screen, all EQC controls can be selected, a specific EQC control can be selected, or multiple results can be displayed by entering a range of dates, as follows.
 - a. The default selection is for all EQC control results to be displayed. To display all EQC control results, press the right soft key.
 - b. To select a specific ASTUTE140 EQC device, use the   keys to display the desired control device and press the right soft key.
 - c. To select EQC results falling within a range of dates:
 - i. Use the  key to highlight **Start Date**. Use the numeric keypad or an external keyboard (if connected) to enter a start date. NOTE: date fields must be entered in the format specified in the default settings.
 - ii. Use the  key to highlight **End Date** and use the numeric keypad or an external keyboard (if connected) to enter an end date. NOTE: date fields must be entered in the format specified in the default settings.
5. Once all selection criteria are entered, press the right soft key to display a list of the EQC results meeting the selection criteria.
 - a. To print the list of EQC test results:
 - i. Display the **Options** pop-up menu by pressing the right soft key.
 - ii. Use the  key to highlight **Print List**.
 - iii. After printing is complete, the list of EQC results will again be displayed.
 - b. To examine and/or print test results for a particular EQC result:
 - i. Use the   keys to highlight the EQC result of interest.
 - ii. Press the right soft key to display the **Options** pop-up menu.
 - iii. When the **Options** pop-up menu is displayed, **Show Details** will be highlighted. Press the right soft key to select **Show Details**.
 - iv. Detailed EQC results for the selected test will be displayed. To print the detailed results, press the right soft key to select **Print**.
 - v. After printing is complete, press the left soft key to return to the list of patient results.

Send Results to LIS




1. Press the  key to display the **Main Menu**.
2. Using the navigation keys, highlight the **Review Data** icon and press the right soft key.



Figure 72.
Main Menu screen
with Review Data icon
highlighted

3. When the **Review Data Menu** is displayed, **Patient Results** is highlighted. Use the  key to highlight **Send Results (LIS)** and press the right soft key.
4. On the **Send Results to LIS** screen, results for all patients, unsent patients, all LQC, unsent LQC, all EQC and unsent EQC may be sent to the LIS. Results for all patients will be automatically highlighted. To choose another type of result to send to the LIS, use the  key to highlight the desired results and press the right soft key.
5. Once sending to the LIS is complete, the **Send Results to LIS** screen will again be displayed. Repeat step 4 to send additional results to the LIS.
6. Once all desired results have been sent to the LIS, press the left soft key to return to the **Review Data Menu**.

Shutdown

To power off the ASTUTE140 Meter, toggle the power switch on the back of the meter upwards, and the meter should immediately shut down.

Care and Maintenance

No maintenance is required other than routine external cleaning, changing the paper and changing the batteries.



To reduce the risk of electrical shock:

- Do not disassemble the ASTUTE140 Meter. The warranty will be voided if disassembled.
- Turn off and unplug the ASTUTE140 Meter prior to cleaning.
- Do not immerse the ASTUTE140 Meter in liquid.

Cleaning and Decontamination



To avoid possible electrical shock, turn off and unplug the ASTUTE140 Meter prior to cleaning.


Gently wipe only the external surface of the ASTUTE140 Meter and the inside of the meter drawer with a soft cloth slightly dampened with disinfectant (70% alcohol or 0.5% bleach solution). **Do not clean with soap or other solutions.** To open the ASTUTE140 Meter drawer, press the  key on the left side of the LCD display.



Figure 73.
Eject key

Replacing the Paper

To replace the paper in the internal printer, see instructions for “Installation and Replacement of Paper” on p. 21.

Replacing the Batteries

For information on when and how to replace the batteries in the ASTUTE140 Meter, see “Installation and Replacement of Batteries” on p. 18.

Disposing of the Batteries
























In conformance with Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators (also known as the EU Battery Directive), batteries are to be removed from the ASTUTE140 Meter and disposed of or recovered separately. Do not dispose of the batteries in municipal waste; please check with your local waste disposal authorities for specific requirements for battery disposal.

Disposing of the ASTUTE140 Meter

In conformance with the WEEE (Waste Electrical and Electronic Equipment) Directive, the ASTUTE140 Meter should be considered infectious waste. Dispose of the ASTUTE140 Meter according to the laboratory’s best practices for disposal of biohazardous waste.

Labels and Symbols

The following table defines the symbols located on the bottom of the ASTUTE140 Meter.

Symbol	Definition	Symbol	Definition
	Manufacturer		Caution, consult accompanying documents
	Date of manufacture		Electrical shock warning
	Authorized representative in the European Community		Biological risks
	European Conformity		Fragile, handle with care
	Consult instructions for use		Do not use if package is damaged
	In vitro diagnostic medical device		Keep dry
	Catalog number		Federal Communications Commission
	Serial number		RoHS compliant
	Humidity limitation		Reconstitution required
	Temperature limitation		RFID Lot
	The device requires safe disposal in conformance with the WEEE Directive		Liquid Control Kit
			Sufficient for

Troubleshooting Tips

Problem	Action to Take
ASTUTE140 Meter will not power on	<p>When AC power is being used:</p> <ol style="list-style-type: none"> 1. Ensure that the AC power adapter is connected correctly and securely to a power source and to the ASTUTE140 Meter. 2. If the problem continues, connect the AC power adapter to a different power source. 3. If the problem persists, call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information). <p>When battery power is being used:</p> <ol style="list-style-type: none"> 1. Disconnect the AC power adapter from the electrical power source. 2. Ensure that the four AA batteries are correctly installed, with the ends of the batteries facing up according to the + and – signs diagrammed in the battery compartment (See p. 14). 3. If the problem continues, replace the four AA batteries 4. If the problem persists, call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).
Test cartridge drawer is jammed	<p>Do not pull or force the drawer open or closed. Reset the ASTUTE140 Meter by disconnecting the AC power adapter (or removing the AA batteries if the power adapter is not being used). Wait 30 seconds and reconnect the AC power adapter (or reinsert the batteries if the AC power adapter is not being used). If the drawer is still jammed, insert a paper clip into the small hole on the back of the ASTUTE140 Meter to manually open the drawer.</p> <p>If the drawer still does not open, call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).</p>
Keypad does not respond	<p>Reset the ASTUTE140 Meter by disconnecting the AC power adapter (or removing the AA batteries if the power adapter is not being used). Wait 30 seconds and reconnect the AC power adapter (or reinsert the batteries if the AC power adapter is not being used). If the keypad still does not respond, call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).</p>

Troubleshooting Tips (Continued)

Problem	Action to Take
Unable to register an EQC Device	Operators can only register an ASTUTE140 EQC Device if the Supervisor has granted permission in the default settings. If logged in as an Operator, contact the Supervisor to verify registration permissions. If Operator permission has been granted, or if logged in as a Supervisor and an EQC device still cannot be registered, call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).
Unable to register a liquid control lot	Operators can only register a liquid control lot if the Supervisor has granted permission in the default settings. If logged in as an Operator, contact the Supervisor to verify registration permissions. If Operator permission has been granted, or if logged in as a Supervisor and the liquid control lot still cannot be registered, call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).
Unable to run EQC	Make sure the ASTUTE140 EQC Device has been registered. If the device has not been registered, register it and try running EQC again (See “ASTUTE140 EQC Device Registration” on p. 48 for registration instructions). If the device has been properly registered and EQC will not run, call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).
Unable to run LQC	Make sure both high and low liquid control lots have been registered. If the liquid control lots have not been registered, register them one at a time and try to run LQC again. See “Liquid Control Lot Registration” on p. 54 for registration instructions. If both high and low liquid control lots have been registered and LQC will not run, call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).

Error Messages

Error Type	What it Means	Action to Take
Start-up/ Self Test Error	Hardware, initialization or check firmware errors during start-up.	Power the ASTUTE140 Meter off and then on again. If the self test fails a second time, discontinue use and call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).
Log In Error	The user ID or password is incorrect or the user is expired or disabled.	Carefully re-enter a valid user ID and password. If the error persists, call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).
Cartridge Errors		
Barcode Reader Error	The barcode was not read properly.	Check that the barcode is not damaged or incomplete, and rescan. If the barcode repeatedly cannot be read, retest with a cartridge with a valid barcode. If the problem persists, call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).
No such test lot error	The test lot is not registered.	Register the test lot. See “Test Lot Registration” on p. 52. If the problem persists, call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).
Test lot expired error	The test lot is expired.	Properly discard the expired test lot and use a valid test lot.
Test Lot Locked	Passing positive and negative LQC measurements for the test lot is required.	Perform LQC for the test lot. If the problem persists, call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).

Error Messages (Continued)

Error Type	What it Means	Action to Take
Measurement Errors		
Measurement Locked	A passing EQC measurement is required.	Perform an EQC measurement. If it fails repeatedly call Astute Technical Support (See “Contacting Astute Medical, Inc.” on p. 7 for contact information).
Print Errors		
Printer Out of Paper Error	The internal printer is out of paper.	Refill printer with paper (See “Installation and Replacement of Paper” on p. 21 for instructions).
	There is a paper jam in the internal printer.	Open internal printer cover and remove the paper roll. Reinsert the roll (See “Installation and Replacement of Paper” on p. 21 for instructions).
Database Errors		
LIS Errors		
RFID Errors	Wrong length, parity error.	

End User License Agreement

PURCHASE AND/OR USE OF THIS PRODUCT SHALL CONSTITUTE ACKNOWLEDGMENT AND ACCEPTANCE OF THE TERMS AND CONDITIONS OF THIS END USER LICENSE AGREEMENT

Astute Medical, Inc. (together with its affiliates “Astute”) hereby grants to the purchaser/user (“you”, “your”) of this product the limited license to use this product solely for the purpose as specified on the approved label therefor. You hereby agree that you shall use this product solely for such purpose and for no other purpose.

If you do not agree with each of the terms and conditions set forth in this End User License Agreement, please contact Astute within ten (10) days after receipt of this product to return the unused and unopened product for a full refund.

LIMITED WARRANTY. FOR THE APPLICABLE WARRANTY PERIOD, ASTUTE WARRANTS THAT THIS PRODUCT SHALL BE (A) OF GOOD QUALITY AND FREE OF MATERIAL DEFECTS, (B) FUNCTION IN ACCORDANCE WITH THE MATERIAL SPECIFICATIONS REFERENCED IN THE PRODUCT MANUAL, AND (C) APPROVED BY THE PROPER GOVERNMENTAL AGENCIES REQUIRED FOR THE SALE OF PRODUCTS FOR THEIR INTENDED USE AS DESCRIBED IN THE APPLICABLE PRODUCT MANUAL OR INSERT THROUGHOUT THE PRINTED EXPIRATION DATE, OR IN THE CASE OF THE ASTUTE140 METER FOR A PERIOD OF TWELVE (12) MONTHS FROM THE DATE OF SHIPMENT (THE “LIMITED WARRANTY”). IF THIS PRODUCT FAILS TO MEET THE REQUIREMENTS OF THIS LIMITED WARRANTY, THEN AS YOUR SOLE REMEDY, ASTUTE SHALL EITHER REPAIR OR REPLACE, AT ASTUTE DISCRETION, THIS PRODUCT.

EXCEPT FOR THE LIMITED WARRANTY STATED IN THIS SECTION, TO THE EXTENT PERMITTED UNDER APPLICABLE LAW, ASTUTE DISCLAIMS ANY AND ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT REGARDING THIS PRODUCT.

ASTUTE’S MAXIMUM LIABILITY FOR ANY CUSTOMER CLAIM SHALL NOT EXCEED THE NET PRODUCT PRICE PAID THEREFOR.

NO PARTY SHALL BE LIABLE TO ANY OTHER PARTY FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOSS OF BUSINESS, PROFITS, DATA OR REVENUE, EVEN IF A PARTY RECEIVES NOTICE IN ADVANCE THAT THESE KINDS OF DAMAGES MIGHT RESULT.

The Limited Warranty above shall not apply if this product has been subjected to physical abuse, misuse, abnormal use, use inconsistent with the product manual or insert, fraud, tampering, unusual physical stress, negligence or accidents.

Any warranty claim pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.

You agree to use this product in strict accordance with all applicable local, state and federal laws, regulations and guidelines, and industry practices.

You further agree that you shall not resell or otherwise transfer this product to any other person or entity, without the prior express written approval of Astute Medical, Inc. Information about commercial resale or distribution of the products of Astute Medical, Inc. may be obtained by e-mailing us at info@astutemedical.com or by writing to us at Astute Medical Inc., General Atomics Court, MS 02/641, San Diego, CA, 92121, USA.

No amendment or addition to this End User License Agreement shall be binding upon the parties unless reduced to writing and signed by the respective authorized officers of the parties.

©2016 Astute Medical, Inc. For information regarding trademarks and other intellectual property applicable to this product, please see AstuteMedical.com/about/intellectual-property. PN 0310 Rev B 2016/12/14

Glossary of Terms (Listed Alphabetically)

Analyte	A substance or chemical constituent that is undergoing analysis.
Assay	Analysis to determine the presence, absence or quantity of one or more components of a substance.
Barcode	A code consisting of a group of printed and variously patterned bars, spaces and sometimes numerals that is designed to be scanned and read into computer memory and that contains information (as identification) about the object it labels.
Barcode Reader	An electronic device for reading printed barcodes.
Calibration	The act of checking, adjusting or determining the graduations of a quantitative measuring instrument by comparison with a standard.
Electronic Quality Control (EQC)	A procedure to check the calibration, alignment, optical system and other internal systems of the ASTUTE140 Meter to confirm that the meter is functioning properly.
Immunoassay	A technique that detects and/or measures a substance based on its ability to bind to an antibody.
In Vitro Diagnostic	Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: <ul style="list-style-type: none"> ■ Concerning a physiological or pathological state, or ■ Concerning a congenital abnormality, or ■ To determine the safety and compatibility with potential recipients, or ■ To monitor therapeutic measures.
Liquid Quality Control (LQC)	External quality control materials and procedures that are used to verify the performance of the test system, including the performance of the NEPHROCHECK Test, and the ASTUTE140 Meter.

Glossary of Terms (Continued)

NEPHROCHECK Test Cartridge	A module that holds the biological sample and is designed to be inserted into the ASTUTE140 Meter for testing. The NEPHROCHECK Test cartridge contains reagents that react with the biological sample, allowing the ASTUTE140 Meter to detect the level of the analyte present in the sample.
Operator User	Type of user with privileges to perform day-to-day ASTUTE140 Meter operations.
Quality Control (QC)	An aggregate of activities designed to ensure adequate quality, especially in manufactured products, or accuracy, reliability and consistency of data, assays, or tests.
RFID card	Radio Frequency Identification: A data collection technology that uses tags for storing data. The ASTUTE140 RFID Card, ASTUTE140 Electronic Quality Control (EQC) RFID Card, NEPHROCHECK High Liquid Control RFID Card, NEPHROCHECK Low Liquid Control RFID Card and the NEPHROCHECK Test RFID Card contain information that can be automatically transmitted to the ASTUTE140 Meter via an internal reader.
Supervisor User	Type of user with privileges to perform advanced ASTUTE140 Meter operations, in addition to Operator user functions.

Index

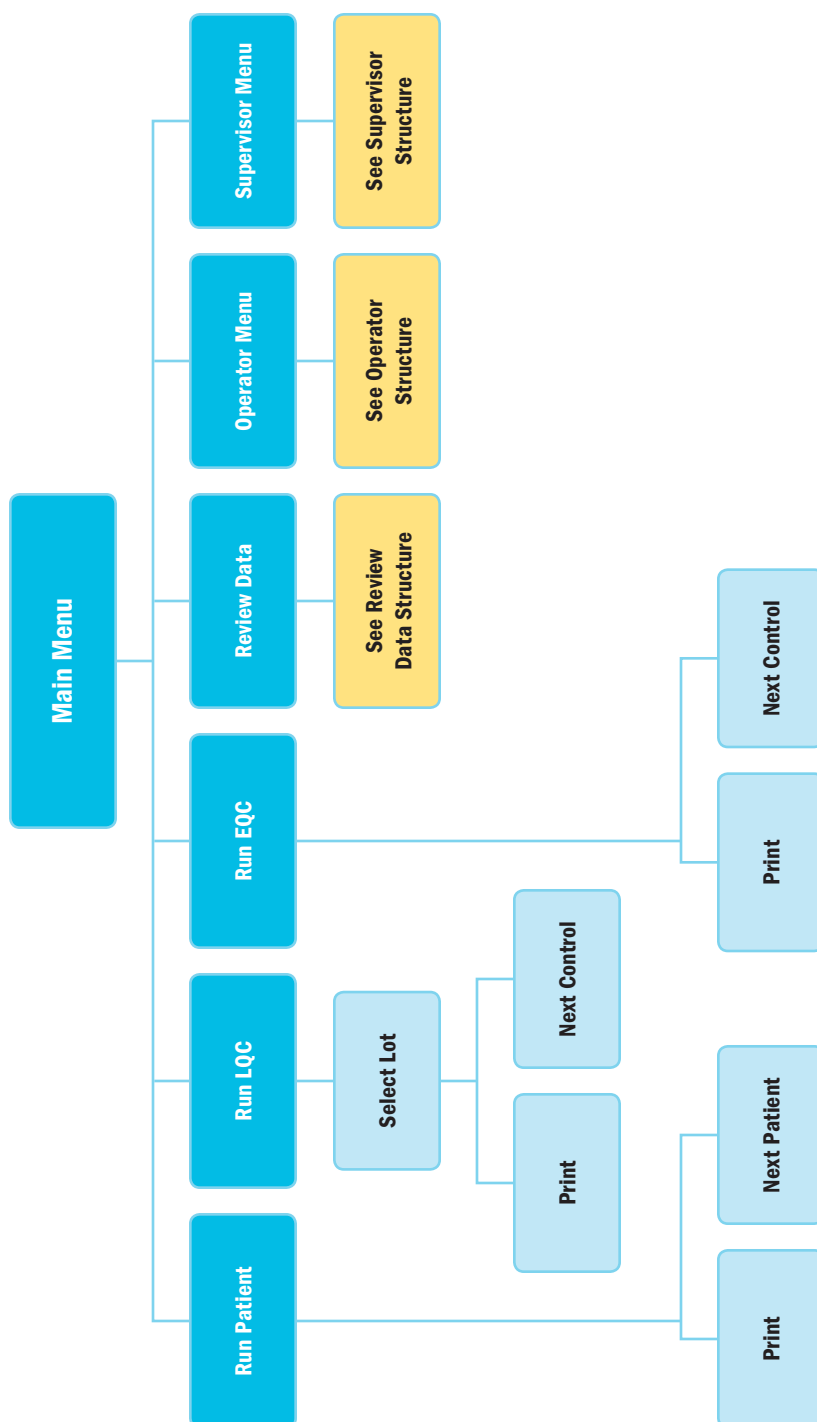
- AC power cord, 9, 17, 72
- Add user, 23–25, 39
- Astute contact information, 7
- Backspace, 12
- Barcode, 78
- Barcode reader, 7, 74, 78
- Batteries
 - Replacing, 18, 70
 - Type, 18
- Cleaning, 69
- Date, 27
- Default language, 29
- Delete user, 40
- Dimensions, 8
- Edit user, 26, 39, 46
- Eject cartridge, 63
- Enter the Patient ID, 61
- Enter the user ID, 39
- Error messages, 74–75
- External Liquid Quality Control, 56, 78
- Hazards, 9
- Installing batteries, 18–21
- Installation, 17–45
- Intended use, 5
- Introduction, 5–16
- IP address, 32
- Keypad, 12
- Labels, 71
- Laboratory Information Systems (LIS), 32, 68
- Limitations, 9, 11
- Logging in as supervisor, 23
- Lot Status (see test lot registration), 52
- Main Menu, 12, 15
- Maintenance, 69–74
- Memory, 46
- Meter: back view, 13
- Meter: bottom view, 14
- Meter: top view, 12
- Operating environment, 8
- Operating humidity, 8
- Operating temperature, 8
- Operator, 15
- Optional accessories, 7
- Paper feed, 12, 22
- Paper out, 75
- Patient test result storage, 63
- Patient information, security of, 46
- Performing a test, 60
- Positive and negative quality controls, 79
- Power supply, 6, 8–9, 17
- Powering on the ASTUTE140 Meter, 22, 45
- Precautions, 9
- Principles of operations, 5
- Printer settings, 37
- Printer paper, 6, 21–22, 70, 75
- Product specifications, 8
- Quality control, 31, 79
- QC results storage, 65–67
- Review patient results, 63
- Run patient specimens, 60
- Safety precautions, 9–10
- Send to LIS, 68
- Set date, 27
- Set language & sound, 28

Index (Continued)

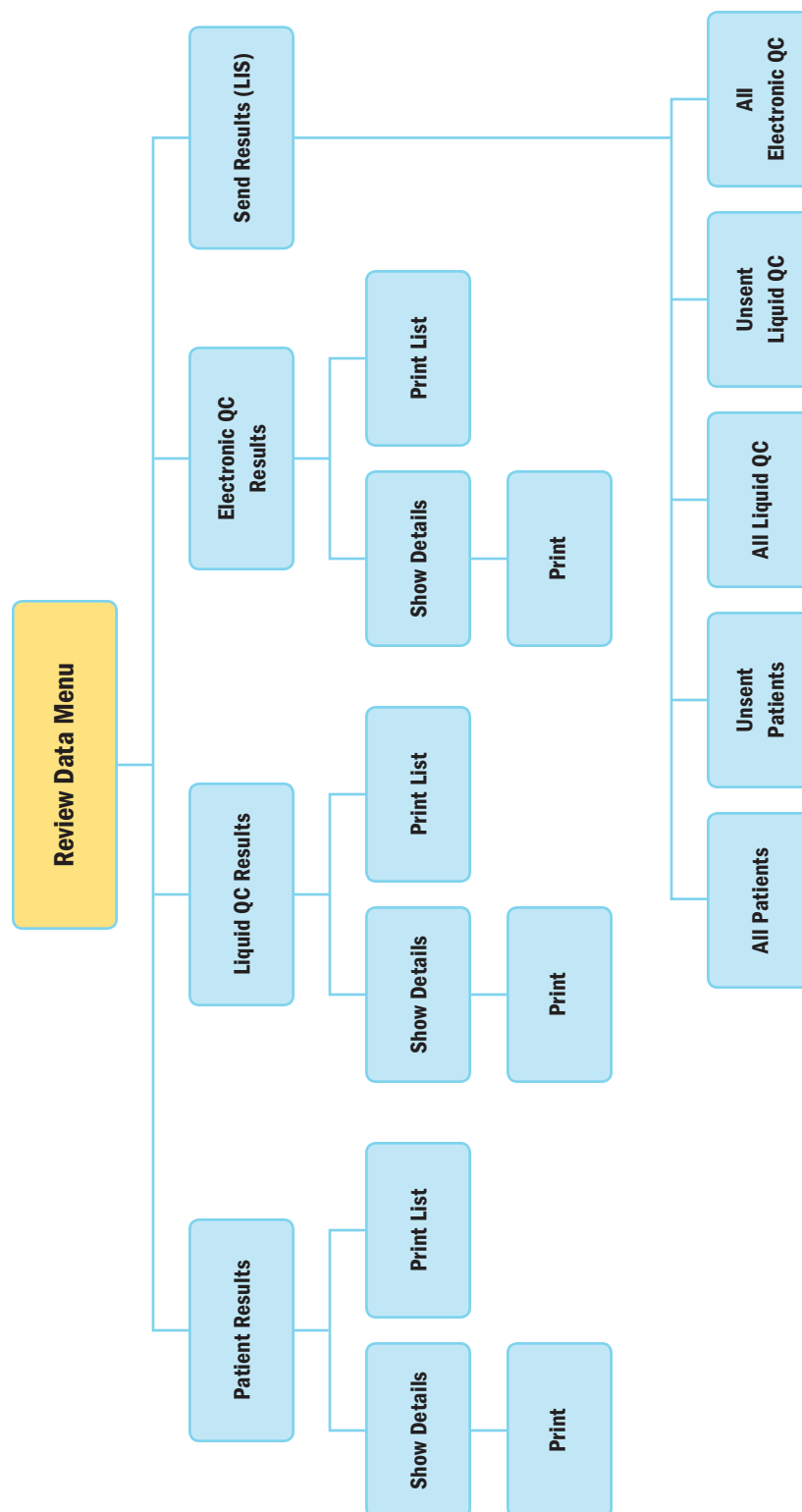
- Set LIS, 32-34
- Set time, 26
- Set user access rights, 29
- Shutdown, 68
- Soft keys, 12
- Storage humidity, 8
- Storage temperature, 8
- Supervisor, 15-16
- Supervisor menu, 24
- Supplies, 6-7
- Symbols, 9, 71
- System components, 6
- Technical Support, 7
- Transporting the monitor, 9
- Troubleshooting, 72
- Unpack, 6
- Up/Down, Left/Right arrows, 12
- Updating system software, 29
- User types, 15
- Warnings, 9
- Warranty, 69, 76
- Weight, 8

Appendix

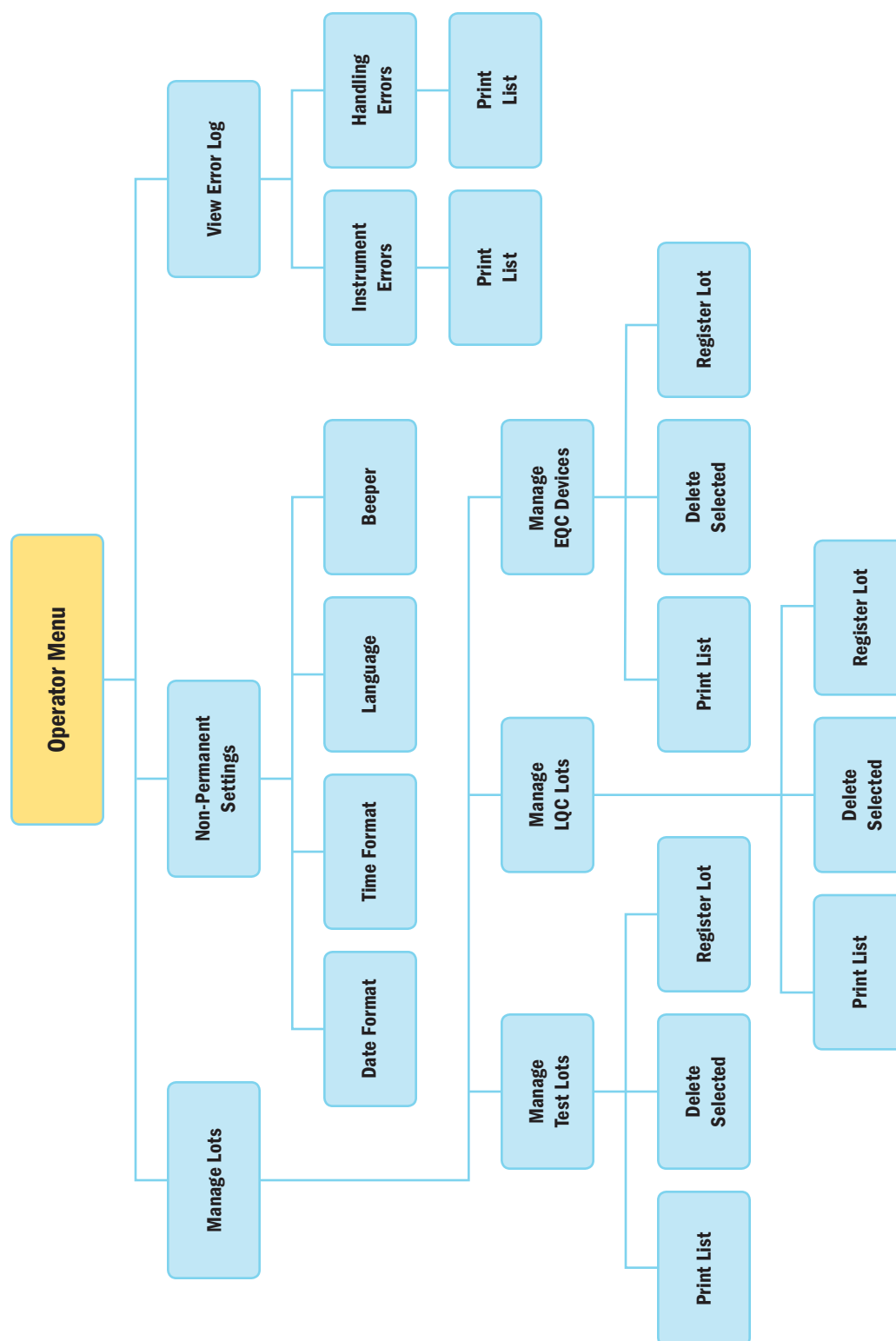
Main Menu Structure



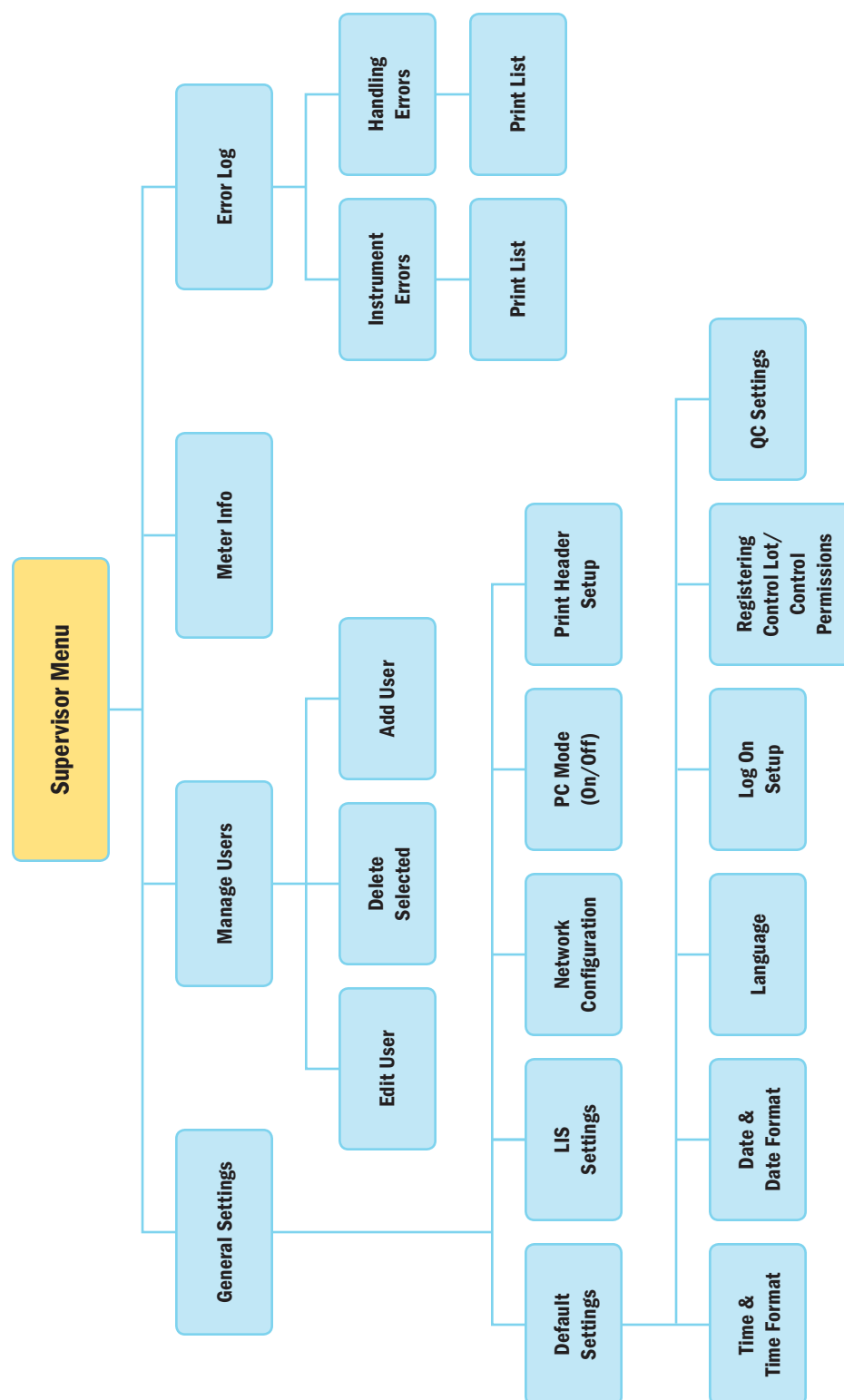
Review Data Menu Structure



Operator Menu Structure



Supervisor Menu Structure





Manufactured for Astute Medical, Inc.
3550 General Atomics Ct.
Building 2
San Diego, CA 92121
USA



MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany