

[Company Logo]

ASTUTE140™ METER

[PHOTO HERE]

User Manual

For performance evaluation only.



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Table of Contents

INTRODUCTION.....	5
INTENDED USE	5
PRINCIPLES OF OPERATION.....	5
METER KIT COMPONENTS.....	6
MATERIALS NEEDED BUT NOT PROVIDED	7
OPTIONAL ACCESSORIES.....	7
CONTACTING ASTUTE MEDICAL, INC. (TECHNICAL SUPPORT)	7
PRODUCT SPECIFICATIONS.....	7
WARNINGS, HAZARDS, PRECAUTIONS, AND LIMITATIONS	8
<i>Safety Symbols</i>	8
<i>Safety Information</i>	9
<i>Limitations</i>	10
METER FEATURES.....	11
USER TYPES	13
<i>Operator</i>	13
<i>Supervisor</i>	14
INSTALLATION.....	14
AC POWER SUPPLY	14
INSTALLATION AND REPLACEMENT OF BATTERIES.....	15
INSTALLING OR CHANGING THE PAPER.....	16
POWERING ON THE METER.....	17
SUPERVISOR INSTRUCTIONS: CONFIGURATION AND SETTINGS	18
<i>Adding the First Supervisor User</i>	18
<i>Set or change Time</i>	20
<i>Set or Change Date</i>	21
<i>Set or Change the Language</i>	22
<i>Updating System Software</i>	23
<i>Update Meter Languages</i>	23
METER OPERATION	23
STARTUP	23
<i>Power on the Meter</i>	23
<i>Log in</i>	24
RFID CARDS FOR DEVICE AND LOT REGISTRATION.....	24
EQC DEVICE REGISTRATION.....	24
ELECTRONIC QUALITY CONTROL (EQC)	26
LIQUID CONTROL LOT REGISTRATION	28
EXTERNAL LIQUID QUALITY CONTROL (LQC)	30
TEST LOT REGISTRATION	32
TESTING A PATIENT SAMPLE	34
REVIEW AND MANAGE TEST RESULTS.....	37
<i>Patient Results</i>	37
<i>LQC Results</i>	38
<i>EQC Results</i>	40
<i>Send Results to LIS</i>	41
SHUTDOWN	42
CARE AND MAINTENANCE	42

CLEANING AND DECONTAMINATION	42
CHANGING THE PAPER.....	43
CHANGING THE BATTERIES	43
DISPOSING OF THE BATTERIES.....	43
DISPOSING OF THE METER	43
LABELS AND SYMBOLS	43
TROUBLE SHOOTING TIPS	45
ERROR MESSAGES.....	47
END USER LICENSE AGREEMENT.....	48
GLOSSARY OF TERMS (LISTED ALPHABETICALLY).....	50
APPENDIX.....	53
MAIN MENU STRUCTURE.....	54
REVIEW DATA MENU STRUCTURE.....	55
OPERATOR MENU STRUCTURE	56
SUPERVISOR MENU STRUCTURE	57

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.

The Astute140 Meter is used in conjunction with a test cartridge to measure the concentration of a target analyte (such as a protein marker) in a sample.

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 test cartridge. After the test cartridge containing the sample is inserted into the 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 “Electronic Quality Control (EQC)”, p. XX and “External Liquid Quality Control (LQC)”, p. XX for details).

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

Meter Kit Components

Inspect the shipping container for obvious shipping damage prior to opening. Unpack the shipping container and inspect the contents for damage. The following components are included in the Astute140 Meter Kit (For re-ordering information, visit www.astutemedical.com or contact your Astute Medical, Inc. sales representative):

Astute140 Meter Kit component	Part number for re-ordering
--------------------------------------	------------------------------------

- | | |
|--|--------|
| • Astute 140 Meter | |
| • AC power adapter pack (includes AC power cord, switching power supply, and country specific adapter) | 100007 |
| • USB cord | 100002 |
| • Astute140™ Electronic Quality Control (EQC) Device | 400001 |
| • Astute140™ Electronic Quality Control (EQC) RFID card | 400001 |
| • Astute140 User Manual | 300005 |
| • Quick Start Guide | 300007 |
| • Instructional DVD | 300006 |
| • Printer paper rolls (2) | 100000 |
| • AA batteries (4) | |

If the shipping container or its contents are damaged, or if any components are missing, contact Astute Medical, Inc. Technical Support (For contact information, see “Contacting Astute Medical, Inc.” o p. X).

NOTES:

DO NOT use any other power adapter with the Astute140 Meter or you may damage the Meter.

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 “Batteries”, p. X for further details.

Materials Needed but Not Provided

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

- Test Kits
- Liquid Control Set

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 Meter include an external barcode reader and an external keyboard. External barcode readers and external keyboards are not available from Astute Medical, Inc. and must be purchased elsewhere.

Contacting Astute Medical, Inc. (Technical Support)

For Technical support, please contact Astute Medical, Inc. at Astute Medical, Inc., 3550 General Atomics Ct., Building 2, San Diego, CA 92121, USA.




Product Specifications

Astute140™ Meter Information	
Product Number:	
Dimensions:	
Weight:	
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	
Altitude:	
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 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 Medical, Inc. Technical Support (for contact information, see "Contacting Astute Medical, Inc." on p. X).

Limitations

The Astute140 Meter does not contain a "batch mode" function. The Meter times the incubation period for the test, and only one test can be run at a time; therefore, each test cartridge must be run immediately after being inoculated with the patient sample or liquid control. The time delay in testing that would result from inoculating more than one cartridge at a time may lead to inaccurate test results.

Meter Features

[Photo of front of Meter here with labels]

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 Button	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 test cartridge and the electronic quality control cartridge into the Meter
13 Battery cover	Covers the battery compartment

[Photo of back of Meter here with labels]

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

[Photo of bottom of Meter here with labels]

1 Battery Cover	Covers the battery compartment
2 Serial Number	Unique number used to identify the Meter
3 In-Vitro Diagnostic device labels and symbols	Regulatory labels and symbols used to provide information about the Meter and its proper use (See “Labels and Symbols”, p. XX, for definitions)

[Photo of Main Menu screen here]

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

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 Meter settings, manage users, obtain Meter information, or view error logs

User Types

There are two types of users defined for the 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 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 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 Meter information (hardware/firmware/bootware/serial number/IP address)

Installation

AC Power Supply

The 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 “Batteries” on p. X.).

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, and connect them as shown:

[Show picture depicting connection of the 3 cords]

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

[Show picture depicting connection 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 Meter.

[Show picture depicting insertion of the switching power adapter into the port on the back of the Meter]

NOTE: To avoid damage to the 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 Meter prior to unplugging it from the electrical power source.

Installation and Replacement of Batteries

The Meter is generally meant to be powered by plugging the AC power adapter into an electrical power source (see “AC Power Adapter, p. X); 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 a electricity failure or if the Meter must be operated in a location where there is no electric output).

When using alkaline or Li batteries under a temperature operating range of 20° to 25° C, the Meter will allow approximately 15 user tests to be performed before requiring battery replacement.

The Meter includes a low battery indicator.

[Insert picture depicting the low battery indicator unlit]

The batteries should be changed when the low battery indicator is lit.

[Insert picture depicting the low battery indicator when lit]

When the low battery indicator is lit, the Meter can run at least 3 additional tests within 1 hour under the same operating conditions before the batteries will need to be replaced.

To install or replace four AA batteries into the Meter or change the batteries:

1. Press the Eject Button to the left of the LCD display to open the Meter drawer and ensure there is not a cartridge in the Meter.
2. Power off the Meter.
3. Gently turn the Meter over so the bottom is facing up and place it on a flat surface.

[Insert image depicting Meter turned upside down, and placed on a flat surface]

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

[Insert image showing bottom of Meter with thumb pressing on and sliding battery cover to the left]

5. If replacing the batteries, remove the old batteries and properly discard them (see “Disposing of the batteries”, p. XX).
6. Insert 4 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,

[Insert diagram of the battery compartment with symbols visible]

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

Installing or Changing the Paper

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

1. Remove the printer cover by pulling up on the blue 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 Meter display.

[INSERT PHOTO DEPICTING STEP 3]

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

[insert photo depicting step 4]

5. To feed the paper further out the top of the printer press [paper button].

Powering On the Meter

To power on the 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.

[Insert screen shot of self-test screen]

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

[Insert screen shot of 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 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 Meter the self-test fails again, contact Asute Medical, Inc. Technical Support (See “Contacting Astute Medical, Inc.” on p. X).

Supervisor Instructions: Configuration and Settings

Adding the First Supervisor User

The first Supervisor user must be added to the Meter before any default settings may be set or changed. The Meter comes from the factory with a default Supervisor login 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.

Perform the following steps to add the first supervisor user:

1. After powering on the Meter, the Log In screen will be displayed after a brief self test (see “Powering on the Meter” on p. X for details.)

[Insert screen shot of 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 [down arrow navigation key] 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.

[Insert screen shot of Main Menu with Supervisor icon highlighted]

6. When the Supervisor Menu is displayed, **General Meter Settings** is highlighted. Use the [down arrow navigation key] 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.

[Insert screen shot of #7]

8. When the Options pop-up menu is displayed, use the [down arrow navigation key] 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 [right and left arrow navigation keys] keys to toggle between operator and Supervisor. Select Supervisor.
10. After selecting Supervisor, use the down arrow navigation key to highlight **Name**. Use the numeric keypad or an external keyboard, if connected, to enter a user name.
11. Use the down arrow navigation key to highlight **ID**. Use the numeric keypad or an external keyboard, to enter a numeric ID.
12. Once a numeric ID is entered, use the down arrow navigation key to highlight **Password**. Use the numeric keypad or an external keyboard, if connected, to enter a password.
13. After entering a password, use the [down arrow navigation key] key to re-enter the password.
14. Confirm that the correct information is displayed. To make changes to the entries, use the [up and down arrow navigation keys] keys to highlight the field to be changed. Use the [backspace key] 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.
15. After accepting the new user information entered, the **Existing User List** screen will again be displayed. The user information just created should now appear in the list, including the user ID, Name, and Mode (Supervisor or Operator).
16. Press the left soft key to return to the main Supervisor menu.

17. Press the left soft key to return to the Main Menu.
18. Press the left soft key to log out of the system.
19. 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.
20. After entering your user ID, use the [down arrow navigation key] key to highlight the **Password** field.
21. Use the numeric keypad or an external keyboard, if connected, to enter your new password.
22. Confirm that the correct log in information is displayed. To make changes to the entries, use the [up and down arrow navigation keys] keys to highlight the field to be changed. Use the [backspace key] 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.

Set or Change Time

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

1. Press the [picture of menu button] key to display the **Main Menu**.
2. Use the navigation keys to highlight the **Supervisor Menu icon**.
[Insert screen shot of Main Menu with Supervisor 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 Meter Settings screen.
5. When the General Meter 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 [left and right arrow navigation 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 [down arrow navigation key] key to highlight the **Hours** field.
9. Use the numeric keypad to enter the correct hour.
10. After the correct hour is entered, use the [down arrow navigation key] to highlight the **Minutes** field.
11. Use the numeric keypad to enter the correct minutes.
12. After entering the correct minutes, use the [down arrow navigation key] to highlight the **AM or PM** field.
13. Use the [left and right arrow navigation 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 [up and down arrow navigation keys] to highlight the field to be changed and use the [left and right arrow navigation 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.

Set or Change Date

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

1. Press the [picture of menu button] key to display the **Main Menu**.
2. Use the navigation keys to highlight the **Supervisor Menu** icon.

[Insert screen shot of Main Menu with Supervisor 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 Meter Settings screen.
5. When the General Meter 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 [down arrow navigation key] key to highlight **Date & Date Format**.
7. Use the [left and right arrow navigation 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 [down arrow navigation key] 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 [down arrow navigation 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 [down arrow navigation key] to highlight the **Year** field.
13. Use the numeric keypad to enter to 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 [up and down arrow navigation keys] to highlight the field to be changed and use the [left and right arrow navigation 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.

Set or Change the Language

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

1. Press the [picture of menu button] key to display the **Main Menu**.
2. Use the navigation keys to highlight the **Supervisor Menu** icon.

[Insert screen shot of Main Menu with Supervisor 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 Meter Settings screen.
5. When the General Meter 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 [down arrow navigation key] key to highlight **Language**.
7. Press the right soft key to display the Language Menu

8. When the Language menu is displayed, use the [up arrow navigation key] or [down arrow navigation key] keys to highlight the desired default language.
9. Press the right soft key to select the highlighted default language.

Updating System Software

Software updates for the 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.

Update Meter Languages

When new languages for the 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 Meter languages by downloading language updates through the USB and/or Ethernet port.

Meter Operation

Startup

Power On the Meter

To power on the 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.

[Insert screen shot of self-test screen]

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

[Insert screen shot of 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 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 Meter the self-test fails again, contact Astute Medical, Inc. Technical Support (See “Contacting Astute Medical, Inc.” on p. X).

Log in

After successfully powering on the 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, if connected.
2. After entering your user ID, use the [down arrow navigation key] 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 [up and down arrow navigation keys] to highlight the field to be changed. Use the [backspace key] 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.

RFID Cards for Device and Lot Registration

Each new EQC device, Liquid Control lot, and test lot must be registered prior to first use. Operators may register 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 EQC device, Liquid Control lot or test lot, see “EQC Device Registration” (p. X), “Liquid Control Set Registration” (p. X), and Test Lot Registration” (p. X).

EQC Device Registration

The EQC procedure verifies the calibration of the 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 EQC Device should be stored in its original packaging away from light. If lost, a replacement EQC device may be ordered from Astute Medical, Inc. at www.astutemedical.com or by contacting your Astute Medical, Inc. sales representative.

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

To register the EQC device, locate the EQC RFID card included in the Meter Kit and perform the following steps:

1. Press the [picture of menu button] 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** icon.

[Insert screen shot of Main Menu with Operator 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 [down arrow navigation key] key to highlight **Manage EQC Devices** and press the right soft key to display the **Registered EQC Devices** screen.

[Insert screen shot of the Registered EQC Devices screen]

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

[Insert screen shot of Options pop-up menu]

7. When the Options pop-up menu is displayed, **Print List** is highlighted. Use the [down arrow navigation key] key to highlight **Register Device** and press the right soft key.
8. When prompted, hold the RFID card for the EQC device next to or against the numeric keypad to register the EQC Device information and select “OK” by pressing the right soft key.
9. If registered correctly, a screen indicating that the EQC device number was successfully read from the RFID card will appear. Press the right soft key to select “Accept”. The EQC device that was just registered should now appear in the list of registered 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 Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. XX).
11. After use, return the RFID card to its sleeve and store it with the EQC device in its original packaging.

Electronic Quality Control (EQC)

The EQC procedure verifies the calibration of the 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 to the best practices of your institution. The required frequency for running EQC may be set by a Supervisor in the general Meter default settings (for instructions on setting the required frequency, see “Quality Control Settings”, p. X).

Prior to running the first EQC procedure, the EQC Device must be registered (For instructions on registering the EQC device, see “EQC Device Registration”, p. X).

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

1. Press the [picture of menu button] key to display the **Main Menu** if needed. .
2. Use the navigation keys to highlight the **Run EQC** icon.
3. Press the right soft key to select **Run EQC**. The Meter drawer will automatically open.
4. When prompted, place the EQC device into the recess inside the Meter drawer in the direction of the arrow marked on the EQC device and gently close the drawer until it clicks.

[Insert photo of gloved hand inserting EQC device into the open drawer of the Meter]

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

[Insert photo of temporary screen showing EQC procedure countdown here]

6. When the EQC procedure completes, press the eject button to open the drawer. 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 [down arrow navigation key] key to highlight **Next Control** and press the right soft key.
 - c. Repeat steps 4-5. When the EQC procedure completes, the 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 procedure failed, contact Astute Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. XX). Press the eject button to open the drawer.
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 menu is displayed, **Print** is highlighted. To print the EQC results, press the right soft key.
 - c. To hide the Options Menu, use the [down arrow navigation key] 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, store the EQC Device in its original packaging away from light.

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 test cartridges and assay-specific reagents.

Each assay-specific liquid control set includes a high and a low liquid control. Each liquid control in the set 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 controls product insert for storage instructions when the liquid control set 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 liquid control set, 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 RFID card for the liquid control lot to be registered (i.e. the high liquid control RFID card if registering the high liquid control, or the low liquid control RFID card if registering the low liquid control).

2. Press the [picture of menu button] 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** icon.

[Insert photo of Main Menu with Operator 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 [down arrow navigation key] 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 [down arrow navigation key] key to highlight **Register Lot** and press the right soft key.
9. When prompted, hold the 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**.
10. If registered correctly, a screen indicating that the liquid control lot number was successfully read from the 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 Medical, Inc. Technical Support (for contact information, see "Contacting Astute Medical, Inc." on p. XX).
12. After use, return the 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 meter, 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 test cartridges
- With each new shipment of 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 Meter default settings (for instructions on setting the required frequency, see "Quality Control Settings", p. X).

Prior to running the first LQC procedure, both the high and low liquid controls in the liquid control set must be registered if they are from a new liquid control lot (for instruction on registering liquid controls, see "Liquid Control Registration", p. X).

The LQC procedure must be run twice: once with the high liquid control and once with the low liquid control. Both high and low liquid controls must have passed for a given lot of test cartridges within the time window set in the default settings before patient samples can be run using 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 [picture of menu button] key to display the **Main Menu** if needed.
2. Use the navigation keys to highlight the **Run LQC** icon.

[Insert screen shot of Main Menu 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.

[Insert photo showing screen shot of “Run LQC – Select Lot” screen]

5. Use the [up and down arrow navigation keys] 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. XX. After the lot is registered, repeat steps 1-6.
6. After selecting the liquid control lot to be tested, the Meter drawer will automatically open.
7. Prepare the test cartridge with the liquid control (high or low) as instructed in the assay-specific Control Product Insert.
8. When prompted, place the prepared test cartridge into the recess inside the Meter drawer in the direction of the arrow marked on the test cartridge, and gently close the drawer until it clicks.

[Insert photo of gloved hand correctly inserting the cartridge into the Meter]

9. After closing the drawer, a temporary screen will appear indicating that the 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 Meter drawer will automatically open and 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 [down arrow navigation key] key to highlight **Next Control** and press the right soft key.
 - c. Repeat steps 4-9. 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 Medical, Inc. Technical Support (For contact information, see “Contacting Astute Medical, Inc.” on p. X). Press the eject button to open the drawer.
11. Remove the cartridge from the Meter drawer 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 menu is displayed, **Print** is highlighted. To print the LQC results, press the right soft key.
 - c. To hide the Options Menu, use the [down arrow navigation 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 [down arrow navigation key] key to highlight **Next Control** and press the right soft key. Repeat steps 4-12.

Test Lot Registration

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 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 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 assay-specific product insert for test cartridge storage instructions.

To register a test lot, perform the following steps:

1. Locate the RFID card included in the test kit from the test lot to be registered.
2. Press the [picture of menu button] key to display the **Main Menu** if needed.
3. Use the navigation keys to highlight the **Operator** icon.

[Insert Main Menu screen shot with Operator 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 [down arrow navigation key] key to highlight **Register Lot** and press the right soft key.

10. When prompted, hold the 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.
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 Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc., Inc.” on p. XX).
13. After use, place the RFID card in its sleeve and return it to the test cartridge kit from which it came. Once all the cartridges in the kit have been used, the RFID card and the test cartridge kit may be discarded.
14. To register another test lot, locate the RFID card for the test lot to be registered and repeat steps 7-13.

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 test cartridges from that lot. For test lot registration instructions, see “Test Lot Registration” on p. X.

To test a patient sample, perform the following steps:

1. Press the [picture of menu button] 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**.

[Insert screen shot of Main Menu 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 scanner (if connected).
4. If available, a Sample ID may be entered; otherwise, this field may be left blank. To enter a Sample ID, use the [down arrow navigation key] 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 scanner (if connected). NOTE: an external keyboard and barcode scanner 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 Meter drawer will automatically open.
7. Prepare the test cartridge with the patient specimen according to the assay-specific Product Insert for the test to be run.

NOTE: Each 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 Meter times the incubation period for the test, and only one test can be run at a time; therefore, inoculating additional samples before testing on the first has completed may result in inaccurate test results due to a time delay in testing after inoculation.

8. When prompted, place the prepared test cartridge into the recess inside the Meter drawer in the direction of the arrow marked on the test cartridge, and gently close the drawer until it clicks.

[Insert photo of gloved hand correctly inserting the cartridge into the Meter]

9. After closing the drawer, a temporary screen will appear indicating that the 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 kit lot.

[Insert screen shot of temporary screen “Reading Test Lot Info Please Wait”]

- 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”, p. X) before running the test again.
- b. If the lot has been registered, but high and low LQC measurements have not passed for the test kit lot, the patient test will not be run and a message indicating that passed LQC measurements are required will be displayed.

[Insert screen shot of error message showing “Cassette Lot Locked”]

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

1. Press the right soft key to select **OK** and close the error message.
2. Discard the test cartridge prepared with the patient sample
3. Run high and low LQC measurements (for instructions, See “External Liquid Quality Control”, p. X).
4. When high and low LQC measurements have passed, repeat steps 1-9.

10. If LQC measurements for the cartridge test 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 Meter drawer will automatically open and 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 menu is displayed, **Print** is highlighted. To print the patient test results, press the right soft key.
 - c. To hide the Options Menu, use the [down arrow navigation key] key to highlight **Hide Options** and press the right soft key.
 - d. To return to the Main Menu, press the left soft key.
13. Remove the cartridge from the Meter drawer 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 [down arrow navigation key] key to highlight Next Patient and press the right soft key. Repeat steps 4-13.

Review and Manage 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 [picture of menu button] key to display the **Main Menu**.
2. Using the navigation keys, highlight the **Review Data** icon and press the right soft key.

[Insert screen shot of Main Menu 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 by entering a specific patient ID, sample ID, or Operator ID. Use the [up and down arrow navigation keys] 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 [down arrow navigation key] 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 [up and down navigation 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 [picture of menu button] key to display the Main Menu.
2. Using the navigation keys, highlight the **Review Data** icon and press the right soft key.

[Insert screen shot of main menu with review data icon highlighted]

3. When the Review Data menu is displayed, **Patient Results** is highlighted. Use the [down arrow navigation key] 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 [down arrow navigation key] 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 [down arrow navigation key] 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 [left and right navigation keys] keys to display the desired control lot.
 - c. **To select LQC results from a specific test lot**
 - i. Use the [down arrow navigation key] 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 [left and right navigation keys] 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 [down arrow navigation key] 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 [up and down navigation 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 [picture of menu button] key to display the **Main Menu**.
2. Using the navigation keys, highlight the **Review Data** icon and press the right soft key.

[[Insert screen shot of Main Menu with Review Data icon highlighted]]

3. When the Review Data menu is displayed, **Patient Results** is highlighted. Use the [down arrow navigation key] 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 EQC control device, use the [right and left arrow navigation keys] 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 down arrow navigation 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 [down arrow navigation key] 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 [down arrow navigation key] 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 [up and down navigation 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 [picture of menu button] key to display the **Main Menu**.
2. Using the navigation keys, highlight the **Review Data** icon and press the right soft key.

[Insert screen shot of Main Menu with Review Data icon highlighted]

3. When the Review Data menu is displayed, **Patient Results** is highlighted. Use the [down arrow navigation key] 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 any of the other types of results to send to the LIS, use the [down arrow navigation key] 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 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.

Remove batteries to reduce risk of electrical shock.



To reduce the risk of electrical shock:

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

Cleaning and Decontamination



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

Gently wipe only the external surface of the 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 Meter drawer, press the eject button on the left side of the LCD display.

[Insert photo of the eject button with label]

Changing the Paper

To change the paper in the internal printer, see instructions for “Installing and Changing the Paper” on page XX.

Changing the Batteries

For information on when and how to change the batteries in the Meter, see “Batteries” on page XX.

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 Meter

In conformance with the WEEE (Waste Electrical and Electronic Equipment) Directive, the Meter should be considered infectious waste. Dispose of the 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 Meter.

Symbol	Definition
	The manufacturer of the device.
	Date of manufacture.
	Authorized representative in the European Community.
	The user should consult the instructions for use for proper operation of the device.
	The catalog number for the device.
	Serial number.
	The upper and lower relative humidity limits for the device.
	The upper and lower temperature limits for operation of the device.
	The device requires safe disposal in conformance with the WEEE Directive.
	Caution, consult accompanying documents.
	Electrical shock warning.
	Biological risks.
	Fragile, handle with care.
	Do not use if package is damaged.
	Keep dry.

Trouble Shooting Tips

Problem	Action to Take
Meter will not power on	<p>When AC power is being used:</p> <ol style="list-style-type: none"> 1. Ensure that the proper AC power adapter is connected correctly and securely to a power source and to the meter. 2. If the problem continues, connect the AC power adapter to a different power source 3. If the problem persists, call Astute Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X). <p>When battery power is being used:</p> <ol style="list-style-type: none"> 1. Disconnect the AC power adapter from the meter. 2. Ensure that the 4 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. X). 3. If the problem continues, replace the 4 AA batteries 4. If the problem persists, call Astute Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X).
Test cartridge drawer is jammed	<p>Press the Eject button. Do not pull or force the drawer open or closed. Reset the 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 meter to manually open the drawer.</p> <p>[Insert photo of paper clip being inserted into small hole]</p> <p>If the drawer still does not open, call Astute Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X.).</p>
Keypad and/or Power On/Off button do not respond	<p>Reset the 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 Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X.).</p>

Unable to register cartridge lot	Operators can only register a cartridge lot if permission has been granted by the Supervisor 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 a cartridge lot still cannot be registered, memory capacity may be full. Delete a registered cartridge lot and try to register a new cartridge lot. If this approach fails, then call Astute Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X.).
Unable to register an EQC Device	Operators can only register an EQC device if permission has been granted by the Supervisor 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, memory capacity may be full. Delete a registered EQC device and try to register a new EQC device. If this approach fails, then call Astute Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X.).
Unable to register a liquid control lot	Operators can only register a liquid control lot if permission has been granted by the Supervisor 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 liquid control lot still cannot be registered, memory capacity may be full. Delete a registered LQC lot and try to register a new LQC lot. If this approach fails, then call Astute Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X.).
Unable to run EQC	Make sure the EQC device has been registered. If the device has not been registered, register it and try running EQC again (See “EQC Device Registration” on p. X for registration instructions). If the device has been properly registered and EQC will not run, call Astute Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X.).
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” for registration instructions). If both high and low liquid control lots have been registered and LQC will not run, call Astute Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X.).

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 Meter off and then on again. If the self-test fails a second time, discontinue use and call Astute Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X.).
Login 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 Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X.).
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 Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X.).
No such test lot error	The test lot is not registered.	Register the test lot (See “Test Lot Registration, p. X). If the problem persists, call Astute Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X.).
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 cartridge lot is required.	Perform LQC for the test lot. If the problem persists, call Astute Medical, Inc. Technical Support (for contact information, see “Contacting Astute Medical, Inc.” on p. X.).
Measurement Errors		
Measurement Locked	A passing EQC measurement is required.	Perform an EQC measurement. If it fails repeatedly call Astute Medical, Inc. Technical Support

		(for contact information, see “Contacting Astute Medical, Inc.” on p. X.).
<u>Print Errors</u>		
Printer out of paper error	The internal printer is out of paper.	Refill printer with paper. See “Installing or Changing the Paper” on p.X for instructions.
	There is a paper jam in the internal printer.	Open internal printer cover and remove the paper roll. Reinsert the roll according to instructions given on p. X.

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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 by the purchaser pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.

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

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Glossary of Terms (listed alphabetically)

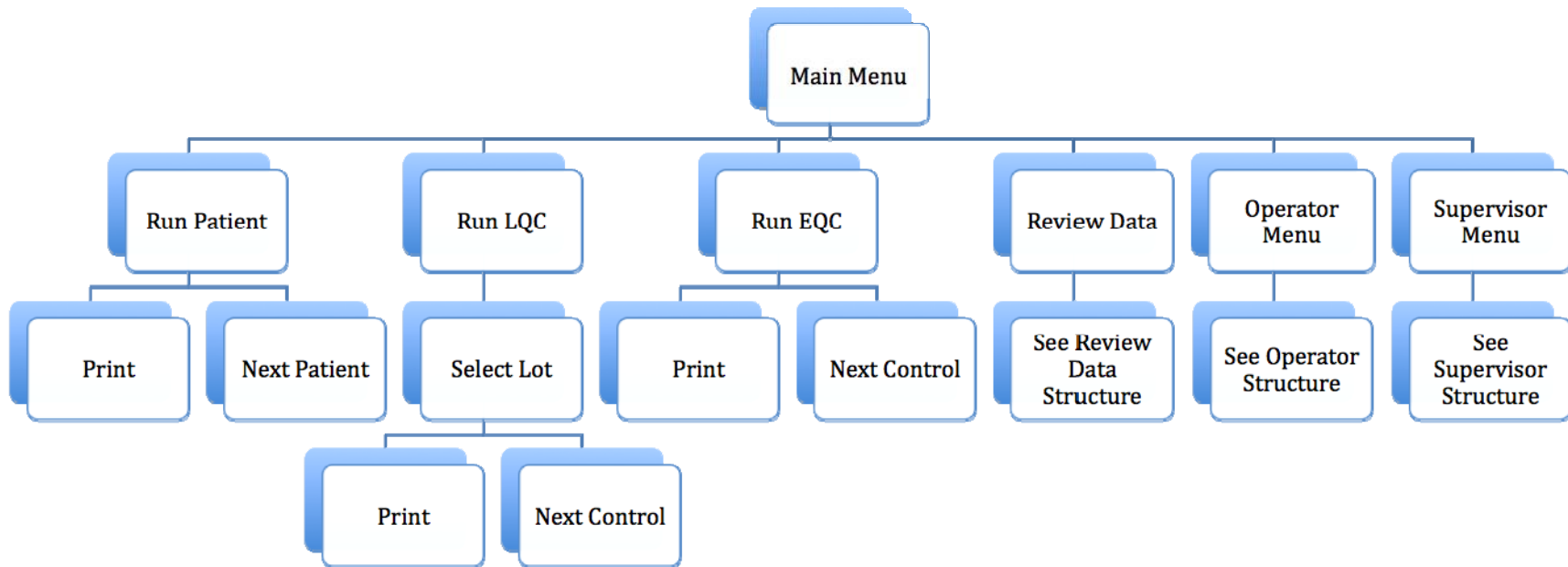
Analyte	A substance or chemical constituent that is undergoing analysis.
Assay	Analysis to determine the presence, absence, or quantity of one or more components of a substance
Barcode	A code consisting of a group of printed and variously patterned bars and spaces and sometimes numerals that is designed 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 checks the calibration, alignment, optical system, and other internal systems of the Meter to confirm that the Meter is functioning properly.
Immunoassay	A technique of identifying a substance

	by its ability to bind to an antibody
In Vitro Diagnostic	<p>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 <i>in vitro</i> for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:</p> <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)	Positive and negative external quality control procedures to verify the precision and accuracy of the assay procedure, including the performance of the meter, test cartridges and assay-specific reagents.
Operator User	Type of user with privileges to perform day to day meter operations.
Quality Control (QC)	An aggregate of activities designed to ensure adequate quality, especially in

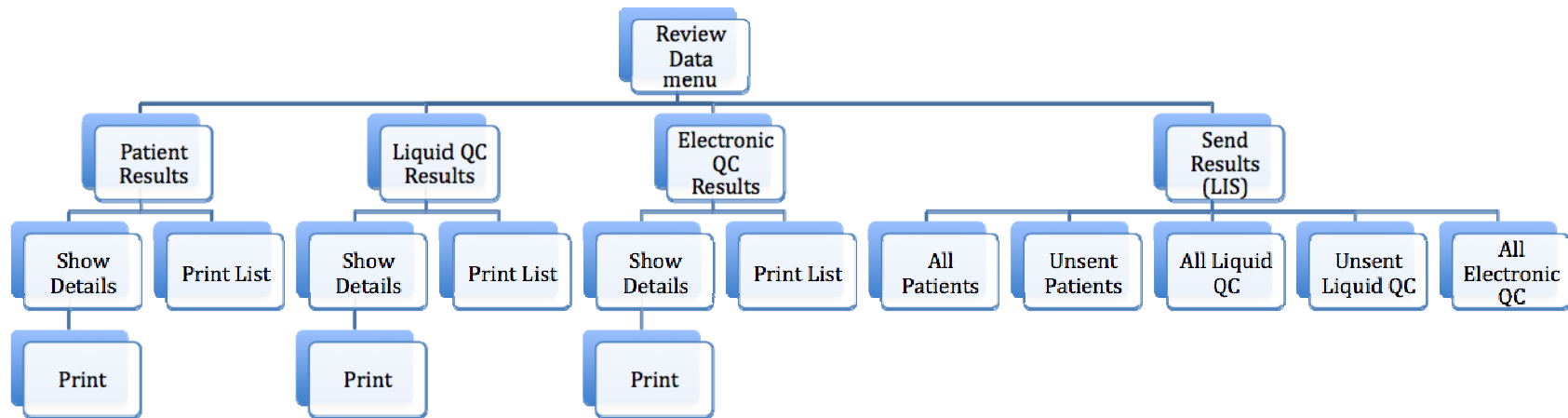
	manufactured products, or accuracy, reliability, and consistency of data, assays, or tests.
RFID card	Radio Frequency Identification: A data collection technology that uses tags for storing data. The RFID card contains information that can be automatically transmitted to the Meter via an internal reader.
Supervisor User	Type of user with privileges to perform advanced meter operations, in addition to operator user functions
Test Cartridge	A module that holds the biological sample and is designed to be inserted into the meter for testing. The cartridge contains reagents that react with the biological sample, allowing the Meter to detect the level of the analyte present in the sample.

Appendix

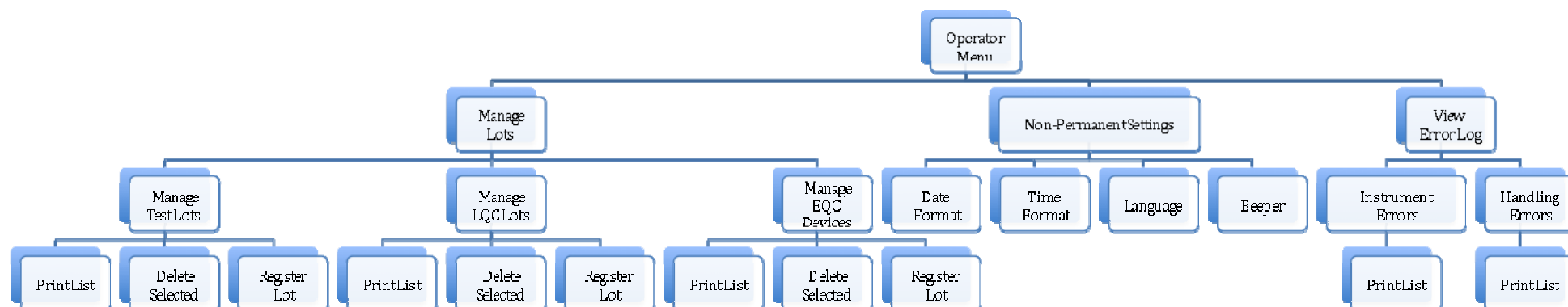
Main Menu Structure



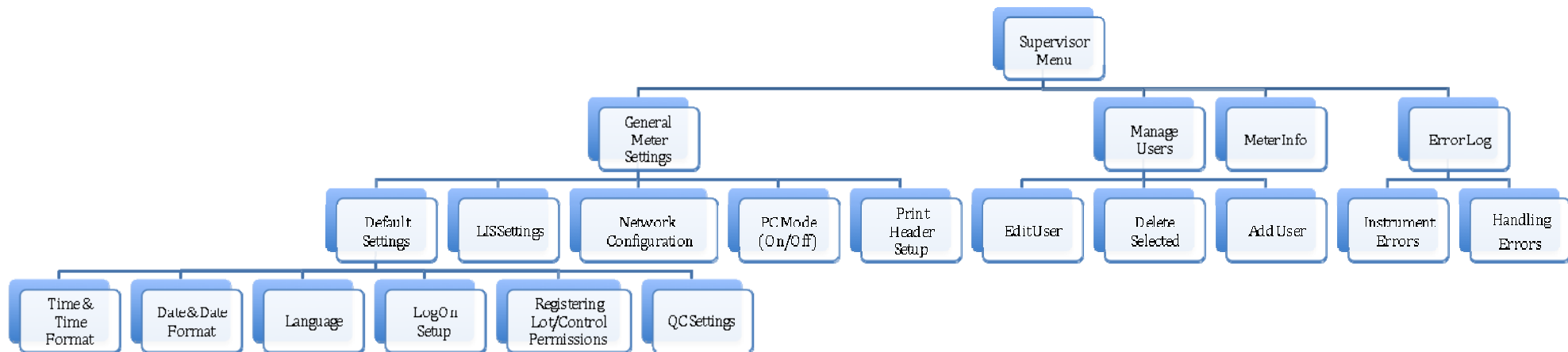
Review Data Menu Structure



Operator Menu Structure



Supervisor Menu Structure





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