acucy™

SYSTEM MANUAL

1-WARNINGS AND SAFETY PRECAUTIONS

1-1. Important Safety Instructions

Please read the following warnings and safety precautions before using the Acucy System.

DANGER – Misuse of electrical equipment can cause electrocution, burns, fire and other hazards. Basic warning and safety precautions should always be taken, including all those listed below.

1-2. Warnings and Precautions

⚠	**Caution:** Use only the power supply that is provided with the Acucy System. Use the appropriate power supply for the region. Do not connect to a multiple socket outlet or extension cord. The correct power supply is required to maintain the safety and electromagnetic compatibility of the System.
⚠	**Caution:** Do not place the System in a location where it can be exposed to liquids or water. If the System becomes wet, unplug it before touching it.
⚠	**Caution:** The System should not be placed near equipment that generates a magnetic field, electronic noise, or radio waves.
⚠	**Caution:** Portable radio frequency (RF) communications equipment should be used no closer than 30 cm (12 inches) to any part of the System, including cords specified by the manufacturer. Otherwise, degradation of the performance of the System could result.
⚠	**Caution:** The System should not be placed in a location where it is exposed to direct sunlight or exposed to a bright light source.
⚠	**Caution:** Connection to the power supply: Where protective grounding is required, plug the equipment into a supply outlet which has a ground connection.
⚠	**Caution:** The System should be placed on a stable, level surface that does not shake or vibrate.
⚠	**Caution:** Do not operate the System or the power supply if it has been opened, damaged, dropped, or exposed to moisture, condensation or rain. **NOTE:** Examples of defects include, but not limited to: damage to the power cord or its plug; damage caused by dropping the System; damage caused by dropping the System into water or splashing water onto it.
⚠	**Caution:** Do not let the System or power cord come into contact with surfaces which are too hot to touch.
⚠	**Caution:** Do not drop or place anything into the openings of the System.
⚠	**Caution:** Do not use the System where aerosol sprays are being used, exposed to corrosive gases, or where oxygen is being administered.
⚠	**Caution:** Use only the Exclusive USB Memory Drive provided.
⚠	**Caution:** When operating the Reader, take care in opening and closing the drawer. Do not use excessive force when operating the touch panel.
⚠	**Caution:** Do not place any objects on top of the Reader.
⚠	**Caution:** Do not move the Reader while a test is in progress.
⚠	**Caution:** Always operate the System at room temperature 15℃ – 30°C (59°F-86°F); humidity less than 70% (non-condensing); air pressure 700 hPa – 1060 hPa (altitude <3000 m, <9840 ft). The System should be used in an environment where drastic temperature changes do not occur.
⚠	**Caution:** Always store and transport the System -5℃ – 45°C (23°F-113°F); humidity 5% - 85% (non-condensing); air pressure 700 hPa – 1060 hPa (altitude <3000 m, <9840 ft).

⚠	**Caution:** Only operate the System for its intended purpose and in accordance with this System Manual and warnings. Protection provided by the System may be impaired if the System is used in a manner not consistent with the instructions in this manual. No modification of the System is allowed. Do not replace any parts not specified by the manufacturer.
⚠	**Caution:** It is recommended that the users take all necessary precautions to ensure the Exclusive Memory Drive provided with the System remains virus free.
⚠	**Caution:** It is recommended that an 8-digit password be used and changed periodically for added security.
⚠	**Caution:** Access to the System, documentation and data should be restricted to authorized personnel.
☣	**Biohazard:** Use of protective personal equipment is recommended when handling patient samples.
☣	**Biohazard:** Follow proper infection control guidelines for handling all samples, Test Cassettes, Extraction Buffer, and swabs. Properly dispose of all contaminated waste according to federal, state, and local requirements.

1-3. Warning and Safety Symbol Definitions

The following is important information about safety.
This product was shown to be in compliance with the standards: IEC 61010-1, IEC 61010-2-101, IE 61326-1, and IEC 61326-2-6.

SYMBOL	DESCRIPTION OF WARNINGS
⚠	**Caution:** Indicates a situation which could result in damage to the System or incorrect results generated if not avoided. Care should be taken when handling the product
☣	Biohazard
📖	Consult Instructions For Use
⊘	Do not
6V ⎓	Reader rated at 6V DC
~	AC (Alternating Current)
▢	Reader rated at 6V DC
SN	Serial Number
🌡	Temperature
REF	Catalog Number
▲▲▲	Manufacturer/Manufactured By
⧗	Expiration Dating
℞ only	Caution: Federal Law restricts sale of this Test Cassette to or on the order of a licensed practitioner.

2- INTENDED USE

The Acucy System is composed of the Acucy Reader, Acucy Printer, Exclusive USB Memory Drive, Power Converters, Power Cords, System Manual, Password Card, and Acucy Calibration Device. Acucy is intended for professional and laboratory use.

Rx Only

2-1. Summary and Explanation

The Acucy Reader is a reflectometric reader that is part of the Acucy System. The Acucy Reader detects the insertion of an Acucy Test Cassette and reads the cassette barcode to detect the test information. Once it recognizes the test type, the Acucy Reader illuminates the cassette in the drawer and measures the intensity of the control and test lines. Test cassettes should not be visually read outside of the Acucy Reader.

2-2. Principles of Operation

The Acucy Reader is an optoelectronic instrument that uses a reflectance-based measurement method to evaluate the line signal intensities on the test strip, and a specific algorithm to determine the presence or absence of any target analyte(s).

The Acucy Reader determines the line intensity at each of the spatially-defined test and control line positions, interprets the results using a scoring algorithm, and reports a positive, negative, or invalid result based on pre-set thresholds. A liquid crystal display (LCD) on the Acucy Reader communicates status and results to the operator.

The Acucy Reader supports the use of different assays by reading an assay-specific barcode (2D) on the Test Cassette. The Acucy Reader is configured with a touch panel design. The Acucy Reader and Acucy Test Cassettes are suitable for use in laboratory or patient point of care environments.

3- SYSTEM COMPONENTS

Materials Provided
- 1 Acucy Reader
- 1 Acucy Printer
- 1 Acucy Drawer
- 2 AC/DC Power Converters
- 2 AC Power Cords
- 1 Exclusive USB Memory Drive
- 1 Acucy System Manual
- 1 Acucy System Quick Reference Guide (QRG)
- 1 Printer Roll
- 1 Master Password Card

Materials Required But Not Provided
- 1 Acucy Calibration Device (CAL-Device)

NOTE: If any of the items are missing, contact Sekisui Diagnostics Technical Support at 800-332-1042 (U.S. Only) or 781-652-7800 (outside the U.S.).

NOTE: There are no user serviceable components in the system.

NOTE: Internal 3V lithium battery

3-1. Acucy System Components

Acucy Reader	
Front View	**Rear View**
Touch Screen — USB Port — Scanner — Drawer	DC 6V Power Port — Power Switch — Printer Port
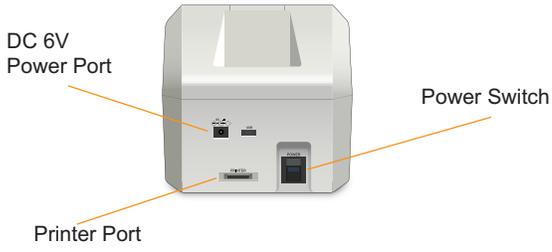
Acucy Printer	
Front View	**Rear View**
Printer Cover — Printer Cord — Printer Knob	DC 6V Power Port — Cable Port

Acucy System Accessories	
AC Power Cord (Quantity – 2)	**AC/DC Power Converter (Quantity – 2)**
Printer Roll	**Exclusive USB Memory Drive**
Calibration Device (CAL-Device)	**Master Password Card**
Acucy System Manual	**Quick Reference Guide**

4- INSTALLATION METHOD

Follow the recommendations below when installing and setting up the Acucy Reader for the first time.
• The Reader should not be placed near equipment that generates a magnetic field, electronic noise, or radio waves.
• The Reader should not be placed in a location where it is exposed to direct sunlight.
• The Reader should be placed on a stable, level surface that does not shake or vibrate.
• The Reader should be placed in a location where it will not be exposed to water.
• The Reader should not be placed in a location where it will be exposed to corrosive gases.
• The Reader should only be used in the following environmental conditions:
  ◆ Temperature 15°C - 30°C (59°F - 86°F);
  ◆ Humidity less than 70% (non-condensing);
  ◆ Air pressure 700 hPa – 1060 hPa (altitude <3000 m, <9840 ft)
  ◆ The Reader should be used in an environment where drastic temperature changes do not occur.
• The Reader should only be transported and stored in the following environmental conditions:
  ◆ Temperature -5°C - 45°C (23°F - 113°F);
  ◆ Humidity 5% - 85% (non-condensing);
  ◆ Air pressure 700 hPa – 1060 hPa; (altitude <3000 m, <9840 ft)

4-1. Installation and Set-Up

1. Remove the System from its protective wrapping. Sekisui Diagnostics recommends retaining the packaging materials in a secure location.
2. The Reader comes from the manufacturer with an 8-digit Master Password that is specific to its serial number (SN) located on the bottom of the Reader. For the initial set-up of the Reader, the Supervisor (or person responsible for managing the security settings in the Reader) should use the password on the Acucy Reader Master Password Card to unlock the Reader.

   NOTE: After unlocking the Reader, place Master Password stickers in a secure location.
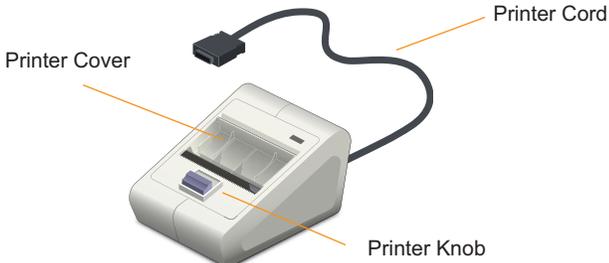
3. Before using the System, visually inspect the contents for damage. If damage is apparent, contact Sekisui Diagnostics Technical Support at 800-332-1042 (U.S. Only) or 781-652-7800 (outside the U.S.).

4-2. Connect to Power and Turn On

Place the System on a flat counter top within reach of an electrical outlet. The System is portable and can be moved to a suitable location for testing.

1. Plug the AC/DC Power Converter into the Power Port in the back of the Reader. ⚠ Do not use excessive force when plugging in or unplugging the Power Convertor.	Power Port
2. Plug the appropriate, country specific AC Power Cord into the AC/DC Power Converter of the Reader.	AC/DC Power Convertor
3. Plug the other AC/DC Power Converter into the Power Port in the back of the Printer.	Power Port
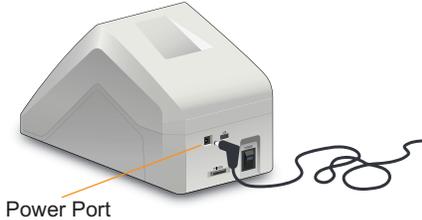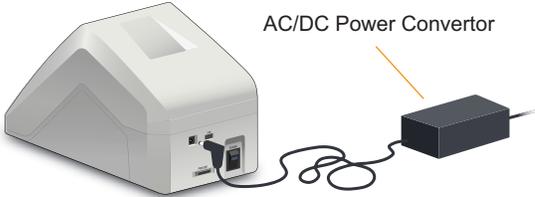
4. Plug the other appropriate, country specific AC Power Cord into the AC/DC Power Converter of the Printer.	AC/DC Power Convertor
5. Plug Printer Cord into the Printer Port on the Reader.	Printer Port Printer Cord
6. Insert Drawer into the Reader.	Drawer
7. Insert the Exclusive USB Memory Drive firmly into the USB Memory Port located at the top of the Reader.	USB Memory Drive USB Port
8. Load printer roll into the printer by sliding Blue Printer Knob up to release and firmly lift the Printer Cover up.	Blue Printer Knob
9. Peel the outside paper away from the printer roll, creating a paper tail. 10. Drop in Printer Roll into Printer so that it spins in the direction shown and pull some paper out to feed through the slot of the cover.	Paper Tail
11. Close Printer Cover until it clicks into place.	
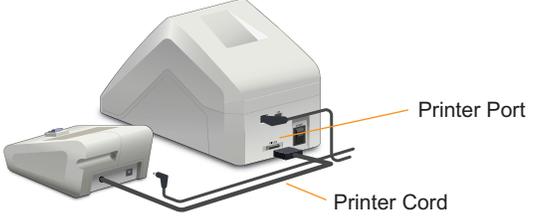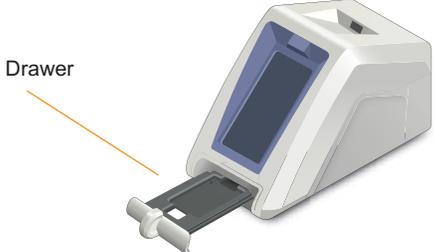
12. Plug Power Cords for both the Reader and the Printer into appropriate electrical outlets.	
13.Turn the Reader on using the power switch located on the rear panel, it will automatically proceed to the OPERATOR PASSWORD input screen after about 5 seconds.	Power Switch
14.Reader screen will display "INPUT OPERATOR PASSWORD." Enter Master Password, then press ENTER. **NOTE:** If needed, the Master Password can be used to unlock all password screens. **NOTE:** For additional password assistance, please contact Sekisui Diagnostic's Technical Support at 800-332-1042 (U.S. Only) or 781-652-7800 (outside the U.S.).	MENU INPUT SUPERVISOR PASSWORD THEN PRESS ENTER < > 1 2 3 4 5 6 7 8 9 DEL 0 ENTER

4-3. Power Off Procedure

The Reader can be safely powered off after use.

1. Return to the MAIN MENU after testing has completed.	LOG OUT MAIN MENU RUN TEST QC TEST CALIBRATION REPORTS SETTINGS 11 days until CALIBRATION is required QC TEST required before RUN TEST can be selected
2. To power off the Reader push the power switch located on the rear panel to the off position.	Power Switch
3. Visually confirm that the Reader has been turned off.	

5- BASIC USER INSTRUCTIONS

This section contains basic instructions for routine Operator use after the System has been installed and set up by the Supervisor. See Installation Method (Section 4) and Setting Parameters (Section 10) for more detailed information on Reader installation, set up and settings options.

ℹ️ Instructions For Use (IFU) require that Operators only use consumables within their expiration date.

ℹ️ Please refer to the IFU of the Test to be run for specific instructions and procedures for running patient samples.

5-1. Overview for Operators

Tips for Navigating the Menu Screens:

• Use the buttons on the touch screen for RUN TEST, QC TEST, CALIBRATION, REPORTS and SETTINGS.

NOTE: Access to the SETTINGS requires the use of a SUPERVISOR PASSWORD.

• Follow the prompts displayed on the Reader screen.

• The BACK button will always return to the previous screen. BACK

• When present, use the up (▲) and down (▼) arrow buttons to scroll through the SETTINGS MENU options.

• The Reader has an auto log off function. After 60 minutes of inactivity, the Reader will return to the OPERATOR PASSWORD input screen.

• The Supervisor will select the desired development mode (READ NOW or WALK AWAY/NORMAL) before any specific tests are performed.

• The Calibration Device and Test Cassettes must be placed in the drawer in the orientation seen in Diagram 1. The notch found on of the back of the Calibration Device and Test Cassettes must be placed over the pin found in the top left corner of the drawer.

NOTE: Do not open the drawer of the Reader when a test is in process.

NOTE: If needed, complete CALIBRATION procedure to activate the RUN TEST and QC TEST menu buttons. RUN TEST and QC TEST will be grayed out until a successful calibration is completed.
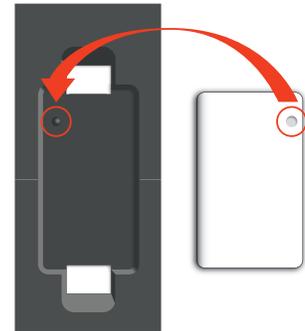
Diagram 1

5-2. Acucy Reader: Operator Types

5-2.1. Operators

Operators that do not have Supervisor authorization, have access to the following functions:
• Power on / Power off the Reader
• Perform Calibration (CALIBRATION)
• Run External Controls (QC TEST)
• Run patient samples (RUN TEST)
• Access CALIBRATION, QC TEST, and PATIENT test results (REPORTS)

5-2.2. Supervisors

Operators with Supervisor authorization, have access to the following functions via the SETTINGS menu, following entry of a Supervisor password:
• BRIGHTNESS: increase or decrease screen brightness.
• AUTO PRINT: ability to set the printer to automatically print every calibration, quality control and patient test result at completion.
• DATA TRANSFER: ability to transfer test results to the Exclusive USB Memory Drive.
• MONITORING: ability for test results to be automatically displayed, at each minute of testing during the development of the cassette in WALK AWAY/NORMAL Mode.
• READ NOW: testing mode that allows for batching of multiple patient samples that have been set up and developed on the benchtop, then read by the Reader.
• TEST SELECTION: ability to change the Reader to automatically detect test type based on Test Cassette barcode.
• DATE & TIME: ability to set current date and time.
• DATE FORMAT: ability to select the date format.
• OPERATOR ID MANAGEMENT: ability to input Operator ID's.
• PASSWORD MANAGEMENT: ability to change the Operator and Supervisor password.

- ALARM TONE: ability to change the volume and tone.
- ID ON/OFF: ability to turn off the requirements for Operator and Patient ID entry.
- ERASE REPORT DATA: ability to delete all Calibration, QC Test and Patient Test results from the internal memory.
- LANGUAGE: ability to change the language (English or Japanese).

NOTE: For information regarding TEST MENU UPDATE and FIRMWARE UPDATE, please contact Sekisui Diagnostics Technical Support at 800-332-1042 (U.S. only) or 781-652-7800 (outside the U.S.).

6- QUALITY CONTROL MANAGEMENT

There are three types of Quality Control (QC) for the System: Reader Calibration, Test Cassette Built -in Internal Control, and External Quality Control.

6-1. Acucy Reader Calibration

A Calibration Device (CAL-Device) is supplied to allow the Operator to perform a functional calibration on the Reader.

For lost, or damaged Calibration Devices (CAL-Device) please contact Sekisui Diagnostics Technical Support at 800-332-1042 (U.S. Only) or 781-652-7800 (outside the U.S.).

For expired Calibration Devices (CAL-Device) please contact your Distribution Retailer for ordering information. (Catalog # 1031).

NOTE: Acucy Reader calibration is on a 30-day cycle. The 30-day cycle is displayed by the Reader each day on the MAIN MENU screen. Calibration is required after the 30-day cycle has elapsed.

Calibration should be performed:

- When installing a new Acucy Reader
- Every 30-days
- As directed during troubleshooting
- After Acucy Reader time/date settings are changed

6-1.1. Perform a Calibration Test

1. Press the power switch located on the rear panel of the Reader. The Reader must complete a 5 second power on self-test before it is ready for use.	Power Switch
2. Input OPERATOR PASSWORD then press ENTER. 3. Select CALIBRATION from the MAIN MENU.	
4. Following the prompts open the drawer slowly until it clicks into place and insert the CAL-Device into the drawer of the Reader. The Reader will read the information from the 2D barcode on the CAL-Device automatically.	

5. Once barcode is read and Close the drawer is displayed, close the drawer completely and the Reader will automatically begin the test. **NOTE:** Insert the drawer all the way in until it stops.	**⑤** CALIBRATION CAL-DEVICE Serial No. 040150 detected Close the drawer

	⑥ CALIBRATION RESULTS	⑦ CALIBRATION RESULTS
6. When the calibration is complete in approximately 10 seconds, the Reader displays CALIBRATION RESULTS. The results will be either PASSED or FAILED. 7. Select NEXT on the screen.	**CALIBRATION PASSED** DATE/TIME 2018-02-12 12:19:02PM CAL-DEVICE Serial No. 040190 Line1: 25.6 mABS PASSED Line2: 226 mABS PASSED OPTICS: PASSED ALIGN: PASSED PRINT DATA TR. NEXT	**CALIBRATION FAILED** DATE/TIME 2018-02-12 12:19:02PM CAL-DEVICE Serial No. 040190 Line1: 1010 mABS FAILED Line2: 854 mABS FAILED OPTICS: PASSED ALIGN: PASSED RETRY CALIBRATION PRINT DATA TR. NEXT
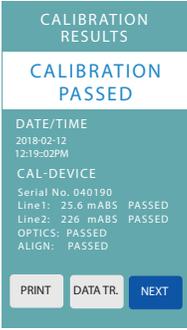
	⑧
8. Open the drawer and remove the CAL-Device. Return the CAL-Device to the storage case. Touch the screen to return to the MAIN MENU.	
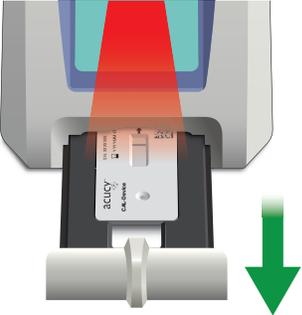
NOTE: Ensure that the CAL-Device is stored in the provided storage case between uses to protect from exposure to light.

NOTE: If Calibration does not pass, notify the on-site Supervisor or contact Sekisui Diagnostics Technical Support for assistance at 800-332-1042 (U.S. Only) or 781-652-7800 (outside the U.S.).

6-2. Test Cassette Built-In Internal Control

The Test Cassette contains a built-in internal control feature. Each time a test is run in the Reader, the internal control zone is scanned by the Reader and the result is displayed on the screen. A "VALID" test result displayed by the Reader indicates that the internal control was present, demonstrates that the test flowed correctly, and that the functional integrity of the Test Cassette and reagents was maintained. An "INVALID" test result displayed by the Reader indicates that the internal control was not present, demonstrates that the test did not flow correctly, and that the functional integrity of the Test Cassette and reagents was not maintained. Should this occur, review the procedure and repeat the test using a new patient sample, Test Cassette and reagent.

6-3. External Quality Control

The External Controls ensure that the assay-specific reagents, Test Cassettes and the Reader are functioning properly. It also ensures that the operator performed the test properly.

NOTE: Please refer to the Instructions For Use for the Assay to be run for specific External Quality Control requirements and instructions.

External Quality Control requirements should be established in accordance with local, state, and federal regulations or accreditations requirements. Minimally, Sekisui Diagnostics recommends that positive and negative controls be run with each new lot, shipment received, and with each new untrained operator.

6-3.1. External QC TEST

To run the External Controls, refer to the assay-specific Instructions for Use for each specific test's step-by-step instructions.

External Quality Control (QC) may be tested to demonstrate that the assay-specific reagents, Test Cassette and assay procedures are performing correctly.

Collect the Test specific supplies provided with each test kit:

• Positive and Negative External Control samples
• Assay Test Kit (Test Cassettes and reagents for the QC tests)
• Instructions For Use (IFU) for the specific Assay

Please **NOTE** the following:

• If an error occurs, please refer to the Error List (Refer to Section 12-2).
• Do not perform patient tests or report patient test results if external control testing fails.

6-3.2. Run QC

1. From the MAIN MENU, select QC TEST. 2. Select appropriate OPERATOR ID (Use the down ▼ arrow buttons to scroll, if needed.)	**1** MAIN MENU: LOG OUT / RUN TEST / QC TEST / CALIBRATION / REPORTS / SETTINGS / 11 days until CALIBRATION is required / QC TEST required before RUN TEST can be selected **2** MENU / SELECT OPERATOR ID / 1. MICHAEL / 2. WILLIAM / 3. ALEX / 4. DANIEL / ▼
3. Select appropriate TEST TO RUN (example - FLU A&B).	**3** MENU / BACK / SELECT TEST TO RUN / 1. FLU A&B **NOTE:** Refer to the assay-specific Package Insert for each specific test for step-by-step instructions

6-3.3. QC Results

QC TEST results will be displayed upon completion.

The results will be displayed as PASSED or FAILED (example – FLU A&B) 1. To continue to the MAIN MENU, select NEXT, and follow the on-screen prompts.	QC TEST RESULTS / QC TEST PASSED / DATE/IME 2018-02-12 12:19:02PM / OPERATOR ID SUSAN / FLU A + PASSED / FLU B + PASSED QC TEST RESULTS / QC TEST FAILED / DATE/IME 2018-02-12 12:19:02PM / OPERATOR ID SUSAN / FLU A + PASSED / FLU B + FAILED / Retry QC TEST / PRINT / DATA TR. / NEXT

If External Quality Control testing fails, repeat the test using new control sample, reagents, and Test Cassettes or contact Sekisui Diagnostics Technical Support for assistance at 800-332-1042 (U.S. only) or 781-652-7800 (outside the U.S.) before running patient samples.

7. RUN TEST (PATIENT SAMPLES)

The Reader may be set to two different modes.   When testing using the WALK AWAY/NORMAL Mode (default), a Test Cassette is placed in the Reader, the sample is immediately added, and the Test Cassette is developed inside the Reader.

When utilizing the READ NOW Mode, the Test Cassette development time is tracked by the operator, outside of the Reader. This allows for batching of multiple patient samples that have been set up and developed on the benchtop, which are then read by the Reader. The READ NOW Mode is selected in the Setting Parameters (see Section 10).

NOTE: Refer to the assay-specific Instructions For Use for sample collection and preparation procedures.

NOTE: The Acucy Test Cassettes are for use with the Acucy Reader only.

NOTE: The Test Cassettes should not be visually interpreted.

7-1. Procedure to RUN TEST: WALK AWAY/NORMAL MODE

In the WALK AWAY/NORMAL mode, Test Cassettes are inserted into the Reader. Then, after the addition of the sample, the development and timing of the test occur within the Reader. This allows the user to "walk away" until the test result has been completed.

7-1.1. Monitoring Mode

When in WALK AWAY/NORMAL Mode, MONITORING Mode can be set to ON from the SETTINGS menu. (see Section 10-5) The Reader will read the Test Cassette every minute of the Test Cassette development time. If a positive result is detected, it will display POS (+) and then will continue to run the test until the assay-specific time limit has been reached. When the test is complete, the results will be displayed on the Reader PATIENT RESULTS screen. The test result will be printed automatically if the AUTO PRINT setting is ON (default). The results can also be printed by pressing the PRINT button on the screen.

7-1.2. Set-Up Reader to WALK AWAY/NORMAL Mode (If needed, set Reader to WALK AWAY/NORMAL Mode.)

1. From the MAIN MENU screen, select SETTINGS. 2. Input **SUPERVISOR PASSWORD**, press **ENTER**.	**1** MAIN MENU — LOG OUT / RUN TEST / QC TEST / CALIBRATION / REPORTS / SETTINGS / 11 days until CALIBRATION is required / QC TEST required before RUN TEST can be selected **2** MENU — INPUT SUPERVISOR PASSWORD THEN PRESS ENTER / 1 2 3 / 4 5 6 / 7 8 9 / DEL 0 ENTER
3. Use the down ▼ arrow button to scroll through the SETTINGS MENU. Scroll to SETTING MENU 2/4, then select 5. READ NOW. 4. Confirm the READ NOW Mode is in the OFF position (highlighted white). If not, press the OFF button, which will highlight white and press ENTER to turn off the READ NOW Mode.	**3** MENU — SETTINGS MENU 2/4 / ▲ / 5. READ NOW / 6. TEST SELECTION / 7. DATE & TIME / 8. DATE FORMAT / ▼ **4** 5. READ NOW — ON OFF / CANCEL ENTER
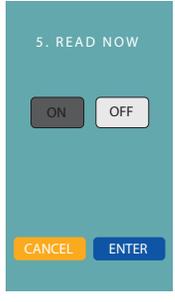
7-1.2. WALK AWAY/NORMAL MODE TEST PROCEDURE

Refer to the assay-specific Instructions for Use for specimen handling and preparation. (Below is an example of Flu A&B.)

1. From the MAIN MENU select RUN TEST

2. Select appropriate OPERATOR ID (Use the down ▼ arrow buttons to scroll, if needed)

3. The PATIENT ID screen will be displayed. Press BARCODE or KEYPAD.

1

LOG OUT
MAIN MENU
RUN TEST
QC TEST
CALIBRATION
REPORTS
SETTINGS
11 days until CALIBRATION is required
QC TEST required before RUN TEST can be selected

2

MENU
SELECT OPERATOR ID
1. MICHAEL
2. WILLIAM
3. ALEX
4. DANIEL
▼

3

MENU   BACK
SELECT PATIENT ID input method
BARCODE
KEYPAD

---

4. If barcode is selected, scan patient's ID barcode using the Reader scanner and press ENTER.

OR

If KEYPAD is selected, use the keypad to enter PATIENT ID and press ENTER.

4

MENU   BACK
INPUT PATIENT ID
<   >
RESCAN   ENTER
Scan PATIENT ID then press ENTER

OR

MENU   BACK
INPUT PATIENT ID
<   >
ENTER
Q W E R T Y U I O P
A S D F G H I K L
Z X C T V D M
123 SPACE BACK SPACE

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5. From the SELECT TEST TO RUN screen, select FLU A&B.

6. Open the Test Cassette foil pouch and label the Test Cassette with the PATIENT ID.

NOTE: Test cassette must be used within 30 minutes of opening or will need to be discarded.

NOTE: Do not cover barcode with PATIENT ID.

NOTE: Do not write on back of Test Cassette.

5

MENU   BACK
SELECT TEST TO RUN
1. FLU A&B

6

acucy™
FLU A&B
5 drops
99114628

&B 99114628

Do not cover barcode

---
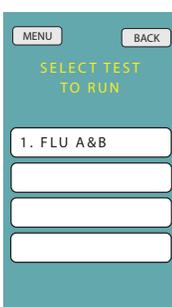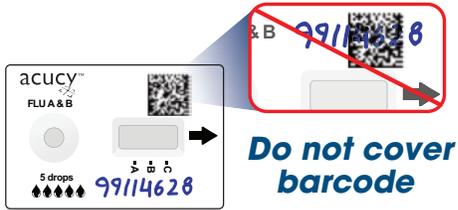
7. Open the drawer slowly until it clicks into place.

Insert Test Cassette with arrow facing the Reader.

NOTE: The Reader will automatically scan the Test Cassette. Once the beep is heard the test is detected and you can proceed with adding the sample.

7

MENU   BACK
TEST CASSETTE DETECTED
TEST NAME
FLU A&B
OPERATOR ID
SUSAN
PATIENT ID
99114628
Add sample drops to sample well Close the drawer within 10 seconds

---
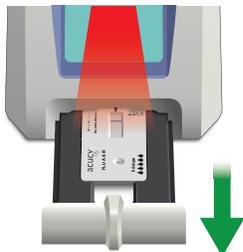
8. Gently mix the Extraction Buffer vial to agitate sample.

9. While Test Cassette is in the drawer, invert the Extraction Buffer vial vertically above the Test Cassette so that the tip is approximately half an inch above the sample well.

Gently and carefully squeeze 5 drops into the sample well of the Test Cassette. DO NOT add sample to the read well of the Test Cassette.

NOTE: Allow for full drops to form and freely fall from dropper tip. Adding more than 5 drops of sample to the sample well of the Test Cassette may generate invalid or false results.

8

9

10. Close the drawer within 10 seconds. The Reader will automatically time the 15-minute development. **NOTE:** After the 15 minutes is complete, the Reader will automatically display and print the test results.	**ANALYZING** **TEST NAME** FLU A&B **PATIENT ID** 99114628 Do not open the drawer **TIME REMAINING** **15:00 sec** CANCEL
11. Press the NEXT button, open the drawer and remove the Test Cassette. Dispose of the Test Cassette in the proper biohazard container and press the NEXT button on the screen to return the MAIN MENU.	**PATIENT RESULTS** FLU A NEG(-) FLU B POS(+) **DATE/TIME** 2010-01-08 12:34:56PM **OPERATOR ID** SUSAN **PATIENT ID** 99114628 PRINT DATA TR. NEXT **NOTE:** Refer to the assay-specific Interpretation of Results Section in the Instructions for Use for details on how to interpret results for specific tests.
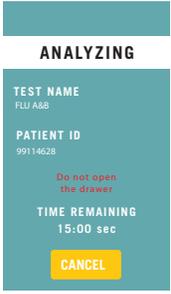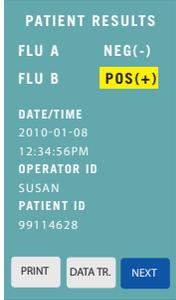
NOTE: If the results are INVALID, repeat the test using new patient sample, reagent and Test Cassette.

NOTE: If an error occurs, please refer to the Error List (Section 12-2).

7-2. Procedure to RUN TEST: READ NOW MODE

NOTE: Be sure to keep track of the required development time, specific to each Test Cassette, when using READ NOW Mode.

NOTE: Allow each Test Cassette in a batch to develop for the specified time before placing it in the Reader to be read. The use of an external timer is recommended.

7-2.1. SET-UP READER TO READ NOW Mode (If needed, set Reader to READ NOW Mode.)

1. From the MAIN MENU screen, select SETTINGS. 2. Input SUPERVISOR PASSWORD, press ENTER.	LOG OUT MAIN MENU RUN TEST QC TEST CALIBRATION REPORTS SETTINGS 11 days until CALIBRATION is required QC TEST required before RUN TEST can be selected MENU INPUT SUPERVISOR PASSWORD THEN PRESS ENTER < > 1 2 3 4 5 6 7 8 9 DEL 0 ENTER
3. Use the down ▼ arrow button to scroll through the SETTINGS MENU. Scroll to SETTING MENU 2/4, then select 5. READ NOW. 4. Confirm the READ NOW Mode is in the ON position (highlighted white). If not, press the ON button, which will highlight white and press ENTER to turn off the READ NOW Mode.	MENU SETTINGS MENU 2/4 ▲ 5. READ NOW 6. TEST SELECTION 7. DATE & TIME 8. DATE FORMAT ▼ 5. READ NOW ON OFF CANCEL ENTER
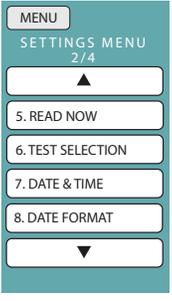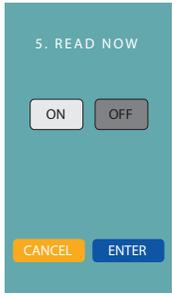
7-2.2. READ NOW MODE TEST PROCEDURE

Refer to the assay-specific Instructions for Use for specimen handling and preparation. (Below is an example of Flu A&B.)

1. Open the Test Cassette foil pouch and label the Test Cassette with the PATIENT ID. **NOTE:** Test cassette must be used within 30 minutes of opening or will need to be discarded. **NOTE:** Do not cover barcode with PATIENT ID. **NOTE:** Do not write on back of Test Cassette. 2. Gently mix the Extraction Buffer vial to agitate sample.	**1** *Do not cover barcode*	**2**
3. While Test Cassette is on a flat surface, invert the Extraction Buffer vial vertically above the Test Cassette so that the tip is approximately half an inch above the sample well. Gently squeeze 5 drops into the sample well of the Test Cassette. DO NOT add sample to the read well of the Test Cassette. **NOTE:** Allow for full drops to form and freely fall from dropper tip. Adding more than 5 drops of sample to the sample well of the Test Cassette may generate invalid or false results. 4. Start an external timer for 15 minutes. **NOTE:** It is important to allow the Test Cassette to develop for the full 15 minutes before placing it into the Reader drawer. Allowing the Test Cassette to develop for more than 45 minutes may generate erroneous results.	**3**	**4** *15 minutes*
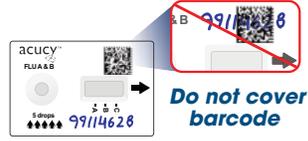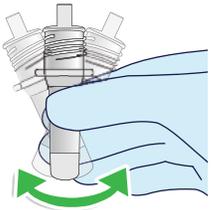
7-2.3. PREPARE READER

1. From the MAIN MENU select RUN TEST 2. Select appropriate OPERATOR ID (Use the down ▼ arrow buttons to scroll, if needed) 3. The PATIENT ID screen will be displayed. Press BARCODE or KEYPAD.	**1** LOG OUT MAIN MENU RUN TEST QC TEST CALIBRATION REPORTS SETTINGS 11 days until CALIBRATION is required QC TEST required before RUN TEST can be selected	**2** MENU SELECT OPERATOR ID 1. MICHAEL 2. WILLIAM 3. ALEX 4. DANIEL ▼	**3** MENU BACK SELECT PATIENT ID input method BARCODE KEYPAD
4. If barcode is selected, scan patient's ID barcode using the Reader scanner and press ENTER. OR If KEYPAD is selected, use the keypad to enter PATIENT ID and press ENTER.	**4** MENU BACK INPUT PATIENT ID < > RESCAN ENTER Scan PATIENT ID then press ENTER	**OR**	MENU BACK INPUT PATIENT ID < > ENTER Q W E R T Y U I O P A S D F G H I K L Z X C T V D M 123 SPACE BACK SPACE

5. **STOP:** Wait the full 15 minutes before continuing to the next step. 6. Once the 15 minutes is complete, select TEST TO RUN (example - FLU A&B) 7. Open the drawer until it clicks into place. Insert Test Cassette with arrow facing the Reader. **NOTE:** The Reader will automatically scan the Test Cassette.	**5** STOP	**6** MENU BACK SELECT TEST TO RUN 1. FLU A&B **7** MENU BACK **READ NOW MODE** Reading Barcode on the test cassette Insert the test cassette in the drawer
8. Once the beep is heard the test is detected, immediately close the drawer tightly. Reader will automatically display and print the test results. 9. Press the NEXT button.	**8** MENU BACK TEST CASSETTE DETECTED **READ NOW MODE** **TEST NAME** FLU A&B **OPERATOR ID** SUSAN **PATIENT ID** 99114628 **Close the drawer** → **READ NOW MODE** **FLU A** ANALYZING **FLU B** ANALYZING **PATIENT ID** 99114628 **Do not open the drawer**	**9** **PATIENT RESULTS** **FLU A** POS(+) **FLU B** NEG(-) **DATE/TIME** 2010-01-08 12:34:56PM **OPERATOR ID** SUSAN **PATIENT ID** 99114628 PRINT DATA TR. NEXT
10. Open the drawer and remove the Test Cassette. Dispose of the Test Cassette in the proper biohazard container. **NOTE:** If additional samples are being tested and need to be analyzed, press NEXT and follow the on-screen prompts or select FINISH to return to the MAIN MENU.	**10** **Remove the test cassette from the drawer** Press NEXT for the next test cassette FINISH NEXT → LOG OUT MAIN MENU RUN TEST QC TEST CALIBRATION REPORTS SETTINGS 11 days until CALIBRATION is required QC TEST required before RUN TEST can be selected	
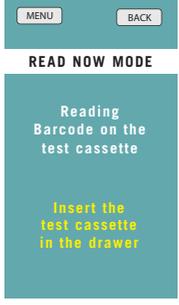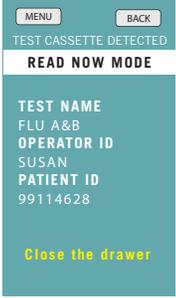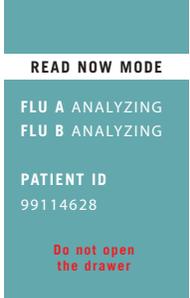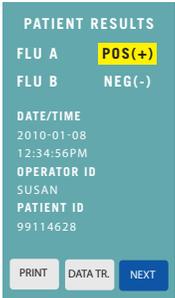
8- INTERPRETATION OF RESULTS

When the test is complete, the results will be displayed on the PATIENT RESULTS screen. The results can be automatically printed on the Acucy Printer (if this option is selected). The Reader screen will individually provide a POS (+) or NEG (-) result for the test being measured. An INVALID result will be displayed in the event an error has occurred while analyzing the Test Cassette.

NOTE: If the test result is INVALID, retest with a new patient sample, using new reagents and new Test Cassette.

NOTE: The Test Cassette results should not be visually interpreted.

8-1. Patient Results

NOTE: Refer to the assay-specific Instructions For Use for interpretation of results.

NOTE: It is recommended all test results are printed in case of loss of electronic data.

8-2. CSV Data File

Each result generated from a Calibration, External QC, or Patient Test can be transmitted to a comma-separated values (CSV) file. This allows for the import of data to a computer or other external device for troubleshooting and development purposes only. This file contains the following information:

	Description
Result Type	"CAL" for Calibration, "QCS" for QC Test or "PAT" for Run Test
Result Number	Test result number for QCS and PAT results
Operator ID	Operator that performed testing
Control Lot/Patient ID	Control Lot Information for QCS or Patient ID for PAT
Date Run	Date of Analysis
Time Run	Time of Analysis
Test Run	CAL-Device, Control Type, or Test Name
Test Cassette Lot	Cal-Device Lot or Test Cassette Lot
Test Cassette Expiration	Cal-Device Expiration Date or Test Cassette Expiration Date
Control Expiration	Expiration Date of Control
Line1 Result	Result for Test Line 1
Line2 Result	Result for Test Line 2
Measure Mode	NORMAL (WALK AWAY), READ NOW or MONITORING
Error Code	Error Code
Measure Cancel	CANCELED will be displayed if test was canceled
Note1	Value of Test Line 1
Note2	Value of Test Line 2 (as applicable)
Note3	Value of Control Line
Serial Number	Reader Serial Number

The naming convention for the CSV file is: **"R"+"file creation date"_"instrument serial number".CSV**

NOTE: Always use the provided Exclusive USB Memory Drive.

NOTE: DATA Transmission is limited to the Exclusive USB Memory Drive. USB communication cable transmission is not available at this time.

9- REPORTS

The Reader allows an operator to review, reprint or retransmit data from a Calibration, External QC Test, or Patient Test.

9-1. Report Review

The Reader allows an operator to review data from a Calibration, External QC Test, or Patient Test.

	①	②
1. Select REPORTS from the MAIN MENU. 2. Select PATIENT DATA, QC TEST DATA, or CALIBRATION DATA to review the reports.	LOG OUT MAIN MENU RUN TEST QC TEST CALIBRATION REPORTS SETTINGS 11 days until CALIBRATION is required QC TEST required before RUN TEST can be selected	MENU REPORTS PATIENT DATA QC TEST DATA CALIBRATION DATA

	3	4
3. Select the TEST. 4. Select the desired report. Use the up ▲ and down ▼ arrow buttons to scroll through the SELECT REPORT screen, then select report to be reviewed.	**MENU** **BACK** **SELECT TEST** 1. FLU A&B	**MENU** **BACK** **SELECT REPORT** 26-02-2018 12:58PM NO. 4 <99114628 > 26-02-2018 12:40PM NO. 3 <99114627 > 26-02-2018 10:32PM NO. 2 <99114625 > 26-02-2018 09:22PM NO. 1 <99114622 > ▼
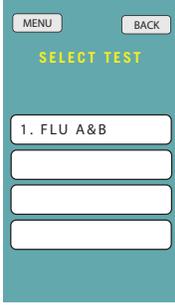
9-2. Report Print

The Reader allows an operator to reprint data from a Calibration, External QC test, or patient test.

After selecting the desired report, select PRINT to print the results.	**PATIENT RESULTS** FLU A **POS(+)** FLU B NEG(-) **DATE/TIME** 2010-01-08 12:34:56PM **OPERATOR ID** SUSAN **PATIENT ID** 99114628 PRINT DATA TR. NEXT
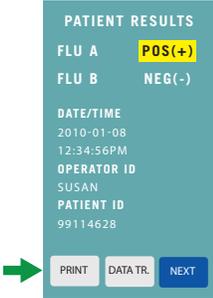
9-3. Report Data Transfer (DATA TR.)

The Reader allows an operator to retransmit data from a Calibration, External QC test, or patient test.

After selecting the desired report, select DATA TR. to transfer results to the Exclusive USB Memory Drive. **NOTE:** Always use the provided Exclusive USB Memory Drive.	**PATIENT RESULTS** FLU A **POS(+)** FLU B NEG(-) **DATE/TIME** 2010-01-08 12:34:56PM **OPERATOR ID** SUSAN **PATIENT ID** 99114628 PRINT DATA TR. NEXT

10- SETTING PARAMETERS

Access to the SETTINGS MENU screen is restricted to Supervisors. The Reader comes from the manufacturer with a default Master Password that is specific to the Reader and Serial Number (see Acucy Reader Master Password Card), that is utilized during initial set up or used to unlock all password screens at any time. The Master Password Card should be kept in a safe and secure place with restricted access.

NOTE: First Time Use
When you unlock the Reader, you will notice the MAIN MENU screen. The SETTINGS MENU screen will be locked.

To unlock the SETTINGS MENU screen:
       1. Press SETTINGS
       2. Enter the Master Password again
       3. Press ENTER

After unlocking the Reader for the first time, set the Supervisor and Operator passwords **(see Password Management in Section 10-11)**.

10-1. Changing the Settings

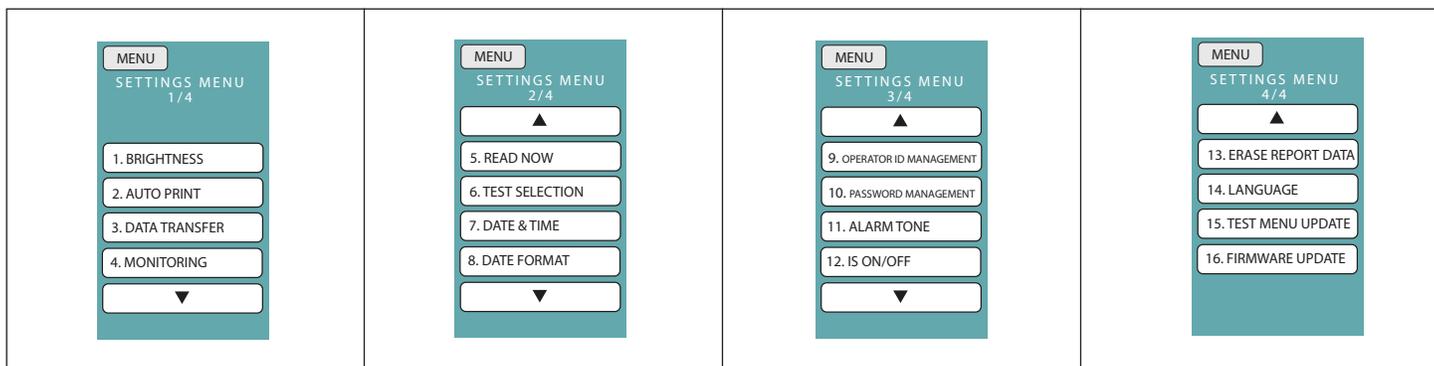The SETTINGS MENU contains the parameters that may be modified by the Supervisor. Use the up (▲) and down (▼) arrow buttons to scroll through the SETTINGS MENU.

MENU	MENU	MENU	MENU
SETTINGS MENU 1/4	SETTINGS MENU 2/4	SETTINGS MENU 3/4	SETTINGS MENU 4/4
	▲	▲	▲
1. BRIGHTNESS	5. READ NOW	9. OPERATOR ID MANAGEMENT	13. ERASE REPORT DATA
2. AUTO PRINT	6. TEST SELECTION	10. PASSWORD MANAGEMENT	14. LANGUAGE
3. DATA TRANSFER	7. DATE & TIME	11. ALARM TONE	15. TEST MENU UPDATE
4. MONITORING	8. DATE FORMAT	12. IS ON/OFF	16. FIRMWARE UPDATE
▼	▼	▼	

10-2. Brightness

1. To increase screen brightness, touch the [+] button, then hit ENTER

2. To decrease screen brightness touch [-] button, then hit ENTER

1. BRIGHTNESS

- +

CANCEL   ENTER

10-3. Auto Print

1. To set Auto Print ON touch the ON button to highlight, then hit ENTER.

NOTE: ON causes the printer to automatically print every test result at the completion of the test.

2. To set Auto Print OFF touch the OFF button to highlight, then hit ENTER.

NOTE: This screen displays the default setting for AUTOPRINT (ON)

2. AUTO PRINT

ON   OFF

CANCEL   ENTER

10-4. Data Transfer

When AUTO TRANSFER is ON, test results will automatically be saved to the Exclusive USB Memory Drive (USB MEMORY) if inserted fully into the USB MEMORY PORT.

NOTE: When the AUTO TRANSFER is OFF, test results are saved to internal memory.

NOTE: The internal memory of the Reader can store up to 200 test results. When the memory is full, the oldest result is automatically overwritten when a new result is added.

3. DATA TRANSFER

AUTO TRANSFER

ON   OFF

DATA TRANSFER PORT

USB MEMORY

USB CONNECTION

CANCEL   ENTER

10-5. Monitoring

When in WALK AWAY/NORMAL Mode, MONITORING Mode may be set to ON.

If MONITORING Mode is set to ON, the Reader will read the Test Cassette every minute during the development of the test. If a positive result is detected, it will display POS (+) and continue to run the test until the assay-specific time limit has been reached.

To set MONITORING ON touch the ON button to highlight, then hit ENTER. **NOTE:** This screen displays the default setting for MONITORING Mode (OFF) 1. ON causes the results to be displayed after each minute of test development, automatically. 2. To set MONITORING OFF touch the OFF button to highlight, then hit ENTER.	**4. MONITORING** ON OFF CANCEL ENTER
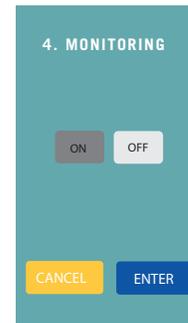
10-6. Read Now

When utilizing the READ NOW Mode, the Test Cassette development time is tracked by the Operator, outside of the Reader. This allows for batching of multiple patient samples that have been set up and developed on the benchtop, which are then read by the Reader.

1. To set READ NOW Mode ON, touch the ON button to highlight and then hit ENTER. **NOTE:** ON causes the Reader to take a reading immediately after a Test Cassette is inserted into the Reader. An external timer is used to time the development of the Test Cassette. 2. To set READ NOW Mode OFF, touch the OFF button to highlight, then hit ENTER. **NOTE:** This screen displays the default setting for READ NOW Mode (OFF)	**5. READ NOW** ON OFF CANCEL ENTER
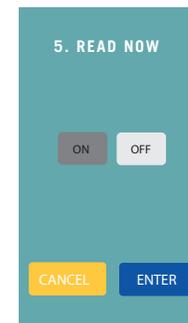
10-7. Test Selection

1. To set TEST SELECTION to MANUAL, touch the MANUAL button to highlight, then hit ENTER. **NOTE:** MANUAL causes the Reader to require the Operator to select the test to run. 2. To set TEST SELECTION to AUTO touch the AUTO button to highlight, then hit ENTER. **NOTE:** The Reader will automatically detect test type based on Test Cassette barcode. **NOTE:** This screen displays the default setting for TEST SELECTION (MANUAL)	**6. TEST SELECTION** MANUAL AUTO CANCEL ENTER

10-8. Date & Time

1. To set DATE & TIME, use the arrow buttons and the keypad to set date and time.

2. Once both DATE & TIME are set, then hit ENTER.

NOTE: On this screen, the date format is always displayed as DD-MM-YYYY.

NOTE: If ENTER is pressed, whether or not date and/or time have been changed, CALIBRATION will be required before RUN TEST and QC TEST can be selected.

7. DATE & TIME
DD-MM-YYYY
26-02-2018
11:31:22AM

← →
AM PM
1 2 3
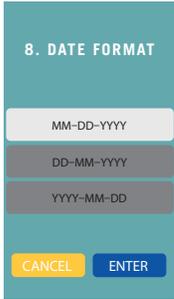4 5 6
7 8 9
CANCEL 0 ENTER

10-9. Date Format

1. To change the DATE FORMAT press the format button with desired format. This will highlight the button, then hit ENTER.

NOTE: This screen displays the default setting for DATE FORMAT (MM-DD-YYYY)

8. DATE FORMAT

MM–DD–YYYY

DD–MM–YYYY

YYYY–MM–DD

CANCEL ENTER

10-10. Operator ID Management

1. To add an Operator, select 9. OPERATOR ID MANAGEMENT from SETTING MENU 3/4.

2. Select the desired Operator Number (1. to 10.). Use the down (▼) arrow buttons to scroll down to see 5. to 10.

3. Using the keypad on the touch screen, input the Operator ID with a maximum of eight (8) characters, then hit ENTER.

NOTE: A maximum of ten (10) operators can be registered.

BACK
9. OPERATOR ID MANAGEMENT
SELECT OPERATOR ID
1. MICHAEL
2. WILLIAM
3. ALEX
4. DANIEL
▼

MENU BACK
INPUT OPERATOR ID
< >
CANCEL ENTER
Q W E R T Y U I O P
A S D F G H I K L –
Z X C T V D M
123 SPACE BACK SPACE

MENU BACK
INPUT OPERATOR ID
< MICHAEL >
CANCEL ENTER
Q W E R T Y U I O P
A S D F G H I K L –
Z X C T V D M
123 SPACE BACK SPACE

To remove or change the OPERATOR ID, select the Operator Number for the Operator. Click on BACK SPACE to remove or change the last entered character. To fully remove the Operator ID, continue to click on BACK SPACE until all characters are removed. Then hit ENTER to save.

10-11. Password Management

Select PASSWORD MANAGEMENT and then select OPERATOR or SUPERVISOR to set or change the password.

NOTE: First Time Use
When you unlock the Reader, both the SUPERVISOR **and** OPERATOR passwords need to be set up.

After unlocking the Reader, you will notice the MAIN MENU screen. If this is the very first time you are setting the Supervisor and Operator passwords the SETTINGS MENU screen will be locked.

To unlock the SETTINGS MENU screen:
1. Press SETTINGS
2. Enter the Master Password again
3. Press ENTER

10-11.1. Operator Password

To set or change the OPERATOR password (as needed).

NOTE: All Operators will use the same OPERATOR password.

1. Use the up (▲) and down (▼) arrow buttons to scroll through the SETTINGS MENU. Scroll to SETTING MENU 3/4, then select 10. PASSWORD MANAGEMENT.	**1** MENU **SETTINGS MENU 3/4** ▲ 9. OPERATOR ID MANAGEMENT 10. PASSWORD MANAGEMENT 11. ALARM TONE 12. ID ON/OFF ▼

2 .Select OPERATOR. 3. Input a new operator password (maximum of 8 numbers) and then press ENTER.	**2** BACK **10. PASSWORD MANAGEMENT** SELECT THE PASSWORD TO CHANGE OPERATOR SUPERVISOR	**3** **10. PASSWORD MANAGEMENT** < > INPUT A NEW OPERATOR PASSWORD THEN PRESS ENTER CANCEL ENTER 1 2 3 4 5 6 7 8 9 DEL 0

|	
4. Select BACK and then MENU to return to the MAIN MENU. **NOTE:** It is recommended that the passwords are changed periodically for added security.	**4** BACK **10. PASSWORD MANAGEMENT** SELECT THE PASSWORD TO CHANGE OPERATOR SUPERVISOR

10-11.2. Supervisor Password

To set or change the SUPERVISOR password (as needed).

NOTE: Only the SUPERVISOR password can access SETTINGS to set or change OPERATOR or SUPERVISOR passwords.

1. Use the up (▲) and down (▼) arrow buttons to scroll through the SETTINGS MENU. Scroll to SETTING MENU 3/4, then select 10. PASSWORD MANAGEMENT.	**1** **MENU** **SETTINGS MENU 3/4** ▲ 9. OPERATOR ID MANAGEMENT 10. PASSWORD MANAGEMENT 11. ALARM TONE 12. ID ON/OFF ▼

2. Select SUPERVISOR. 3. Input a new supervisor password (maximum of 8 numbers) and then press ENTER.	**2** BACK — 10. PASSWORD MANAGEMENT — SELECT THE PASSWORD TO CHANGE — OPERATOR — SUPERVISOR **3** 10. PASSWORD MANAGEMENT < > INPUT A NEW OPERATOR PASSWORD THEN PRESS ENTER CANCEL ENTER 1 2 3 4 5 6 7 8 9 DEL 0

4. Select BACK and then MENU to return to the MAIN MENU. **NOTE:** It is recommended that the passwords are changed periodically for added security.	**4** BACK — 10. PASSWORD MANAGEMENT — SELECT THE PASSWORD TO CHANGE — OPERATOR — SUPERVISOR

10-12. Alarm Tone

Provides the ability to change the volume and tone of the Reader alarm.

1. Using the number buttons, select the desired alarm setting, which will be highlighted. A sample of the alarm will play when the button is pressed. 2. After alarm tone is selected, then hit ENTER.	11. ALARM TONE 1 2 3 CANCEL ENTER
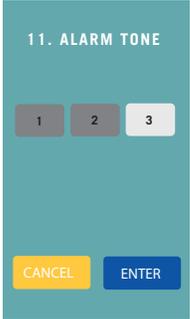
10-13. ID ON/OFF

When OPERATOR ID and/or PATIENT ID is on, the Reader requires that the OPERATOR ID and/or PATIENT ID be entered before testing is allowed.

1. Using the ON/OFF button beneath OPERATOR ID, select whether or not the Operator ID is required. 2. If OPERATOR ID is set to ON, an Operator ID must be selected in order to run a test. 3. Using the ON/OFF button beneath PATIENT ID, select whether or not the Patient ID is required. 4. If PATIENT ID is set to ON, a Patient ID must be entered or scanned in order to run a patient test.	**12. ID ON/OFF** **OPERATOR ID** ON OFF **PATIENT ID** ON OFF CANCEL ENTER

10-14. Erase Report Data

Provides the ability to delete all Calibration, External QC and patient test results from the internal memory.

1. To erase report data select CONFIRM to delete all the saved Calibration, External QC and Patient Test data. **NOTE:** Once CONFIRM is selected, the data will no longer be available to view, print or transmit.	**13. ERASE REPORT DATA** **PATIENT DATA** **QC TEST DATA** **CALIBRATION DATA** CAUTION: This will delete all of the above data from the instrument CANCEL CONFIRM

10-15. Language

1. To change the language on the Reader, select ENGLISH or JAPANESE. 2. After language selection, then hit ENTER.	**14. LANGUAGE** ENGLISH JAPANESE CANCEL ENTER
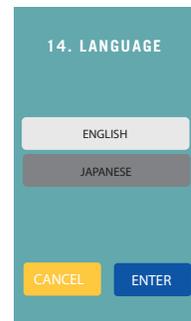
10-16. Test Menu Update

For information regarding TEST MENU UPDATE, please contact Sekisui Diagnostics Technical Support at 800-332-1042 (U.S. only) or 781-652-7800 (outside the U.S.).

10-17. Firmware Update

For information regarding FIRMWARE UPDATE, please contact Sekisui Diagnostics Technical Support at 800-332-1042 (U.S. only) or 781-652-7800 (outside the U.S.).

10-18. Default Settings

The following table lists the default settings for the Reader. Use the blank column marked "New Settings" to record your settings.

Table 1: DEFAULT SETTINGS FOR THE ACUCY READER

Settings	Default	New Settings
2. Auto Print	ON	
3. Data Transfer	-	-
Auto Transfer	ON	
Data Transfer Port	USB MEMORY	
4. Monitoring	OFF	
5. Read Now	OFF	
6. Test Selection	MANUAL	
8. Date Format	MM-DD-YYYY	
10. Password Management	See Master Password Card	
11. Alarm Tone	3	
12. ID ON/OFF	-	-
OPERATOR ID	ON	
PATIENT ID	ON	
14. Language	English	

11- MAINTENANCE, CLEANING AND SAFEKEEPING

NOTE: Ensure that the Reader is unplugged before performing any maintenance or cleaning.

⊘ Do not attempt to clean the interior of the Reader.

NOTE: Only use 70% isopropyl alcohol or 10% bleach solutions to clean the Reader.

⊘ Do not use soap or other solutions.

NOTE: There are no user serviceable components. Service provided only by manufacturer. For technical issues or questions, please contact Sekisui Diagnostics Technical Support at 800-332-1042 (U.S. Only) or 781-652-7800 (Outside U.S.)

11-1. Acucy Reader Care and Cleaning

It is recommended that a visual inspection be performed, and the Reader be cleaned on a daily basis after the unit has been powered off.

11-1.1. Cleaning Procedure

Power off the Reader. (see Section 4.3)

- The outer case and display may be wiped lightly with a clean towel moistened with 70% isopropyl alcohol (IPA) or 10% bleach solution.
- Dispose of waste cleaning materials as chemical/biohazardous waste according to the appropriate local laws and regulations.
- Ensure that the Reader is dry and the surface is free of fluid prior to powering on and returning to use.
- The Printer can be wiped lightly with a moistened clean towel.

⊘ Do not introduce cleaning solutions or any other liquids directly into the Reader.

⊘ Do not use a saturated towel which may introduce liquid into the case or display seams.

11-1.2. Drawer Sterilization Procedure

- If moisture or any other foreign substances/fluids get into the drawer, power off the Reader, remove and clean the drawer with a clean towel moistened with 70% isopropyl alcohol (IPA) or 10% bleach solution.
- Allow to air dry prior to reinstalling the drawer. After reinstalling the drawer, the Reader may be powered on.

11-2. Servicing and Ordering

There are no user serviceable components in the Reader. For technical issues or questions, please contact Sekisui Diagnostics Technical Support at 800-332-1042 (U.S. Only) or 781-652-7800 (outside the U.S.)

11-3. Transportation and Storage

The Reader and Printer should be transported and stored at -5°C – 45°C (23°F-113°F).

11-4. Manufacturer Maintenance

Maintenance and repair to be performed by manufacturer authorized service providers only. Please contact Sekisui Diagnostics Technical Support for more information at 800-332-1042 (U.S. Only) or 781-652-7800 (outside the U.S.).

12 - TROUBLESHOOTING

Below are common Error Messages displayed by the Acucy Reader. If an Error Message is displayed, contact Sekisui Diagnostics Technical Support at 800-332-1042 (U.S. Only) or 781-652-7800 (outside the U.S.)

Phenomenon	Action Needed
The power does not turn on (Reader and Printer)	Check that the power cord and Reader are connected. Check that the power cord and Printer are connected. Check that the power switch is set to ON.
Unable to read the barcode	Reposition the Test Cassette under the barcode scanner. Ensure the barcode is not obstructed or defaced.
Testing is interrupted	Do not insert or remove the drawer during the measurement. Check if the drawer is fully inserted into the Reader.
Data is not transferred to the Exclusive USB Memory Drive	Ensure that you are using the Exclusive USB Memory Drive that comes with the Reader. Ensure that an error message is not displayed during the data transfer. Remove USB drive from port, reinsert, and then manually attempt data transfer by selecting DATA TR.

12-1. Messages

Below are common Messages displayed by the Acucy Reader. If a Message is displayed perform the required action, if the Message still occurs, contact Sekisui Diagnostics Technical Support at 800-332-1042 (U.S. only) or 781-652-7800 (outside the U.S.).

Message	Description	Required Action
DRAWER OPENED	Drawer has been opened during a test.	Repeat the test.
MONITORING CANCELED	Monitoring was canceled.	Repeat the test.
ANALYZING	The Reader is performing a measurement.	Do not move the Reader.
Close Drawer	To begin the measurement, close the drawer.	Gently close the drawer as soon as possible.
INSERT USB DRIVE	Exclusive USB Memory Drive is not inserted	Confirm the Exclusive USB Memory Drive is fully inserted in the USB MEMORY port.
Password is incorrect	Password is incorrect	Enter the correct password

12-2. Error List

Below are common Errors displayed by the Reader. If an Error is displayed perform the required action, if the Error still occurs, contact Sekisui Diagnostics Technical Support at 800-332-1042 (U.S. only) or 781-652-7800 (outside the U.S.).

12-2.1 Calibration

Error Message	Description	Required Action
DEVICE CAN NOT BE DETECTED	The CAL-Device barcode cannot be read correctly.	Confirm the CAL-Device barcode is not obstructed or defaced. Repeat calibration. On subsequent occurrences, contact Sekisui Diagnostics Technical Support
CAL-Device is EXPIRED	The CAL-Device expiration date has passed.	Repeat calibration with a CAL-Device that is within the expiration date. On subsequent occurrences, contact Sekisui Diagnostics Technical Support.
WRONG TEST CASSETTE DETECTED	The operator is attempting to make the Reader read a barcode other than the CAL-Device barcode.	Repeat calibration with correct CAL-Device.
FAILED RETRY CALIBRATION DRAWER OPENED	Operator opened the drawer during calibration.	Repeat calibration.
FAILED RETRY CALIBRATION	Results invalid.	Repeat calibration.
FAILED CALL CUSTOMER SUPPORT	Calibration fails twice; System abnormality.	Contact Sekisui Diagnostics Technical Support

12-2.2. External QC TEST

Error Message	Description	Required Action
CONTROL CAN NOT BE DETECTED	The Control barcode cannot be read correctly.	Confirm the Control barcode is not obstructed or defaced. Repeat the test. On subsequent occurrences, contact Sekisui Diagnostics Technical Support
CONTROL EXPIRED	The control expiration date has passed	Check the control expiration date. Repeat using a control within the expiration date. On subsequent occurrences, contact Sekisui Diagnostics Technical Support
WRONG CONTROL DETECTED	The operator is attempting to make the Reader read a barcode other than the Control barcode.	Check that the correct Control barcode is being used.
CASSETTE CAN NOT BE DETECTED	The Test Cassette barcode cannot be read correctly.	Confirm the Test Cassette barcode is not obstructed or defaced. Repeat the test. On subsequent occurrences, contact Sekisui Diagnostics Technical Support
CASSETTE EXPIRED	The Test Cassette expiration date has passed.	Check the Test Cassette expiration date.
WRONG CASSETTE DETECTED	Operator inserts an incorrect Test Cassette into the drawer rather than the test that was selected to be run	Check test name on Test Cassette.
A) See Section 12-3.3 Run Test: INVALID DRAWER OPENED B) INVALID (1) ~ (6)	Problem occurred during testing	Repeat the test using new Control swabs, replace swab with sample reagents and Test Cassettes
FAILED RETRY QC TEST or CALL CUSTOMER SUPPORT	QC test results are abnormal	Repeat the test using new Control sample, reagents and Test Cassettes. Contact Sekisui Diagnostics Technical Support.

12-2.3. Run Test

Error Message	Description	Required Action
WRONG CASSETTE DETECTED	Operator inserts an incorrect Test Cassette into the drawer rather than the test that was selected to be run	Check test name on Test Cassette
INVALID DRAWER OPENED	Operator opened the drawer during testing	Repeat the test using new patient sample, reagent and Test Cassette
MONITORING CANCELLED	Operator cancelled the test	Repeat the test using new patient sample, reagent and Test Cassette
ID CAN NOT BE READ	Patient ID barcode cannot be read correctly	Confirm the Test Cassette barcode is not obstructed or defaced. Press RESCAN or BACK for keypad input
CASSETTE CAN NOT BE DETECTED	The Test Cassette barcode cannot be read correctly	Confirm the Test Cassette barcode is not obstructed or defaced. Rescan the Test Cassette
CASSETTE EXPIRED	The Test Cassette expiration date has passed.	Check the Test Cassette expiration date
INVALID (1) ~ (7)	Problem occurred during testing	Repeat the test using new patient sample, reagents and Test Cassette.

13 - APPENDIX

13.1 Specifications

Dimensions	120 mm (W) x 235 mm (D) and 145 mm (H)
Weight	READER - 1.7 kg (approximately)
	PRINTER - 0.5 kg
	POWER CORD - 0.25 kg
Power Supply Input	100 – 240V AC 1.67A MAX 50-60 Hz
Reader Input	6V DC 0.6A MAX
USB Port	USB MEMORY port: USB 2.0/3.0
Display	4.3-inch color LCD touch screen
Operating Temperature	15℃ – 30℃ / 59℉ – 86℉
Operating Humidity	Less than 70% non-condensing
Installation Category	II
Pollution Degree	2
Altitude	Less than 3000 m
Use Environment	Indoor use
Communication Port	Exclusive Connector for use with the Acucy Printer (Hirose Electric Co., Ltd. DH-60A-17P equivalent) USB MEMORY port (USB 2.0/3.0)
Test Result Storage	Patient Results 200 External Quality Control Results 100 Calibration Results 200 (Overwrites oldest data once limit is exceeded)

13.2 Contact Information

For Sekisui Diagnostics Technical Support
Telephone: 800-332-1042, Option 3 (U.S. Only)
              781-652-7800 (outside the U.S.)
Email: SDADiagnosticsTSDL@sekisuidiagnostics.com

13.3 Reorder Information

Acucy System (Catalog # 1039)
Acucy Exclusive USB Memory Drive (Catalog # 1021)
Acucy Calibration Device (Catalog # 1031)
Acucy Printer Roll (Catalog # 1019)

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Because every result matters™