

R-5011-D



lifeSign

D*Express*<sup>TM</sup>



Cat. No. LSR-2000

***User Manual***



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## Foreword

Thank you for purchasing the **DXpress™ Reader**. The reader has been designed to provide qualitative and quantitative results for LifeSign and selected compatible lateral flow immunochemistry membrane tests. The **DXpress™ Reader** features user-friendly menus, enabling operation with minimal training. The patient and QC data can be easily transferred via a standard RS-232C or USB port to a laboratory information system. A barcode scanner quickly loads in patient, user and test information. An on-board printer provides hard copy test and QC results for filing and reporting.

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## Warnings, Precautions and Limitations

- ◆ Operate the **DXpress™ Reader** on a dry, level surface away from direct sunlight.
- ◆ The Calibrator is light-sensitive and should be stored in the pouch provided when not in use.
- ◆ Do not move the **DXpress™ Reader** while a test is in progress.
- ◆ Ensure all sample fluids have absorbed into the test device prior to placing the test in the **DXpress™ Reader** to prevent internal contamination of the reader.
- ◆ Ensure the black tray pocket is fully engaged with the tray frame after cleaning.
- ◆ Although the DXpress Reader is capable of portable, battery-powered operation, printing is not available while operating in battery mode.
- ◆ Do not use the **DXpress™ Reader** where it is subject to shock or vibration.
- ◆ Do not use the **DXpress™ Reader** near water.
- ◆ Only use parts (barcode scanner, power adapter, Data Chip, etc.) recommended by the manufacturer to avoid damage to the **DXpress™ Reader**.
- ◆ Do not use the **DXpress™ Reader** with other devices or equipment.
- ◆ Using the **DXpress™ Reader** in a manner not specified by the manufacturer may void the warranty.
- ◆ Connecting the **DXpress™ Reader** or any parts to other equipment in a manner not specified by the manufacturer may result in damage to some or all components and may void the warranty.
- ◆ Caution: Danger of explosion if battery is incorrectly replaced. Replace only with the same or equivalent type recommended by the manufacturer. Dispose of used batteries according to the manufacturer's instructions.

The following symbols are used on the **DXpress™ Reader** and throughout this manual.



Direct current



Input



CE mark



UL mark



Consult instructions for use

**REF**

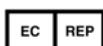
Catalogue number

**SN**

Serial number



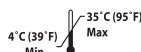
Manufactured by



Authorized representative



*In vitro* diagnostic medical device



Store between 4–35°C



This marking shown on the product or its literature, indicates that it should not be disposed with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take this item for environmentally safe recycling.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial wastes for disposal.



For use with tests that are designed specifically for analysis using this reader (instrument).



Alerts you to conditions that may prevent successful operation of the reader



Provides useful information to help you use the reader more efficiently

**DXpress™** and **DXpress™ Reader** is a trademark of LifeSign, LLC. All rights reserved.

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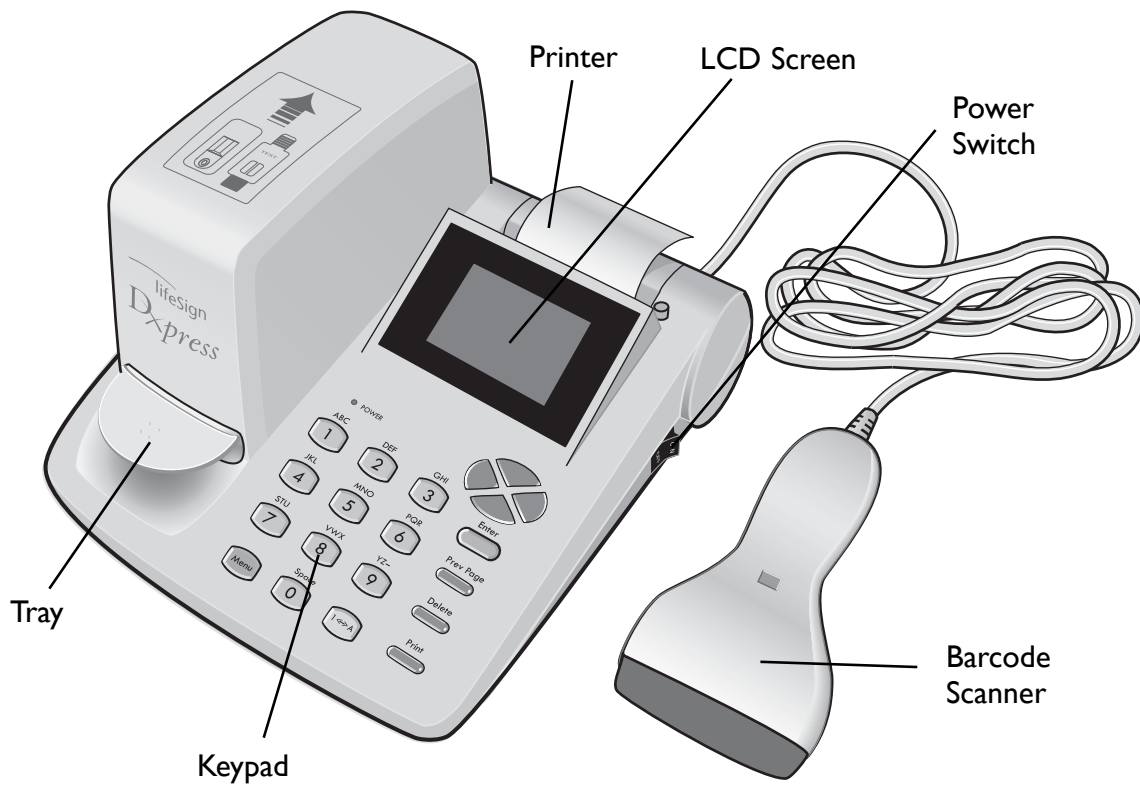
# I. Introduction

This manual contains instructions for the use and maintenance of the **DXpress™ Reader** and general instructions for testing specimens and quality control materials. Refer to specific product inserts for test parameters and operating instructions.

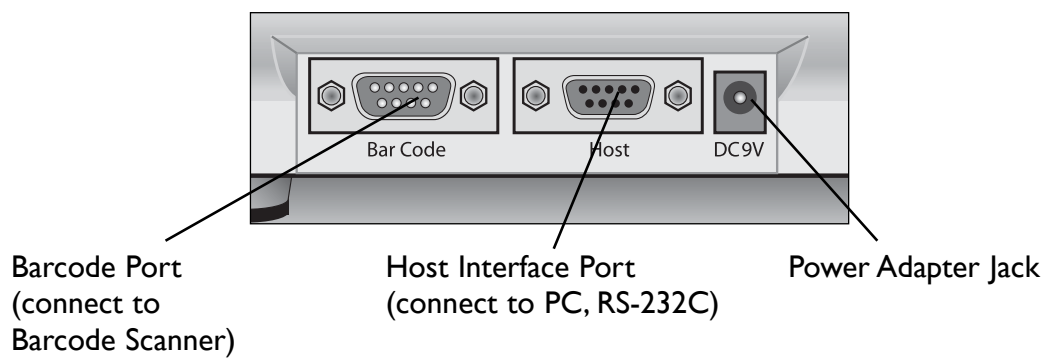
The **DXpress™ Reader** is a multi-functional portable tabletop camera-based instrument used to read results of *in vitro* immunodiagnostic assays manufactured according to standards developed by LifeSign, LLC. The instrument is for use in alternate site point-of-care and/or central laboratory settings.

Test devices are run with patient specimens or quality control materials. The **DXpress™ Reader** uses an LED light source to illuminate an inserted test device. The reader captures and analyzes the reflected image. For quantitative tests, the reader converts the intensity of the test result line into a concentration of analyte using a calibration profile contained in a pre-programmed Data Chip provided with each lot of test devices. For qualitative tests, the reader reports a qualitative positive or negative result.

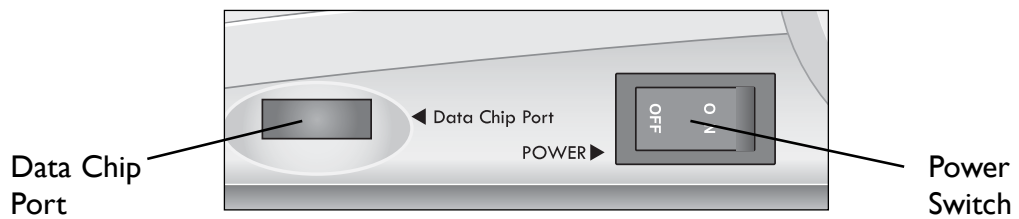
The **DXpress™ Reader** monitors the internal procedural control of each test device as well as functions and parameters of the reader. The **DXpress™ Reader** also contains password-protected safeguards to assure that QC parameters are followed and that only authorized personnel use the reader and can change the parameters.



### Rear panel



### Right panel





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## I.1 Description

### **What is the DXpress™ Reader?**

The **DXpress™ Reader** is a multi-functional, portable tabletop image-scanning instrument used to interpret and record the result of lateral flow immunochemistry tests manufactured according to standards established by LifeSign, LLC. The reader can be used in a laboratory or a point-of-care setting. It features serial port connectivity to laboratory information systems. Lot-specific calibration information for each quantitative test is loaded into the **DXpress™ Reader** through a Data Chip provided with the test kit (qualitative tests do not require a Data Chip).



The microprocessor computes analyte concentration based on a pre-programmed calibration profile in the Data Chip provided with quantitative test kits. The microprocessor reports qualitative positive or negative results for qualitative test kits.

The microprocessor also controls parameter settings, quality control functions, running and retrieving test results, uploading new firmware and transferring test results to the laboratory information system. In addition, the **DXpress™ Reader** stores up to 1000 patients, 60 Self Checks, 60 Calibration QC and 60 External QC results for recall.

The printer provides hard copies of test and quality control results.

The barcode scanner enables rapid entry of information, including lot number, expiration date, and operator and patient identification.

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The liquid crystal display (LCD) displays the menus and results of all **DXpress™ Reader** functions.

A light emitting diode (LED) light source inside the reader illuminates a test device that has been inserted into the **DXpress™ Reader**. The camera captures the image, and the microprocessor then compares it to a standard profile.

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## 1.2 Reader Specification

### Physical

Size (W x L x H)	210 x 230 x 145 mm (8.25 x 9.0 x 5.7 inches)
Weight	1.25 kg (2.74 lbs.) without batteries
Electrical	9V DC, 2.0 A
Keypad	20 alphanumeric and special function keys

### Environment

Indoor use	
Temperature	4–35 °C
Humidity	10–80 % (RH)
Location	Dry, clean, flat horizontal surface away from direct sunlight

### Optical

Light source	LED
Detection	CMOS image sensor

### Memory capacity

Flash Memory	8 MB	
RAM	8 MB	
Information Storage	Patient Results	1000
	Self Check Results	60
	Calibration QC Results	60
	External QC Results	60

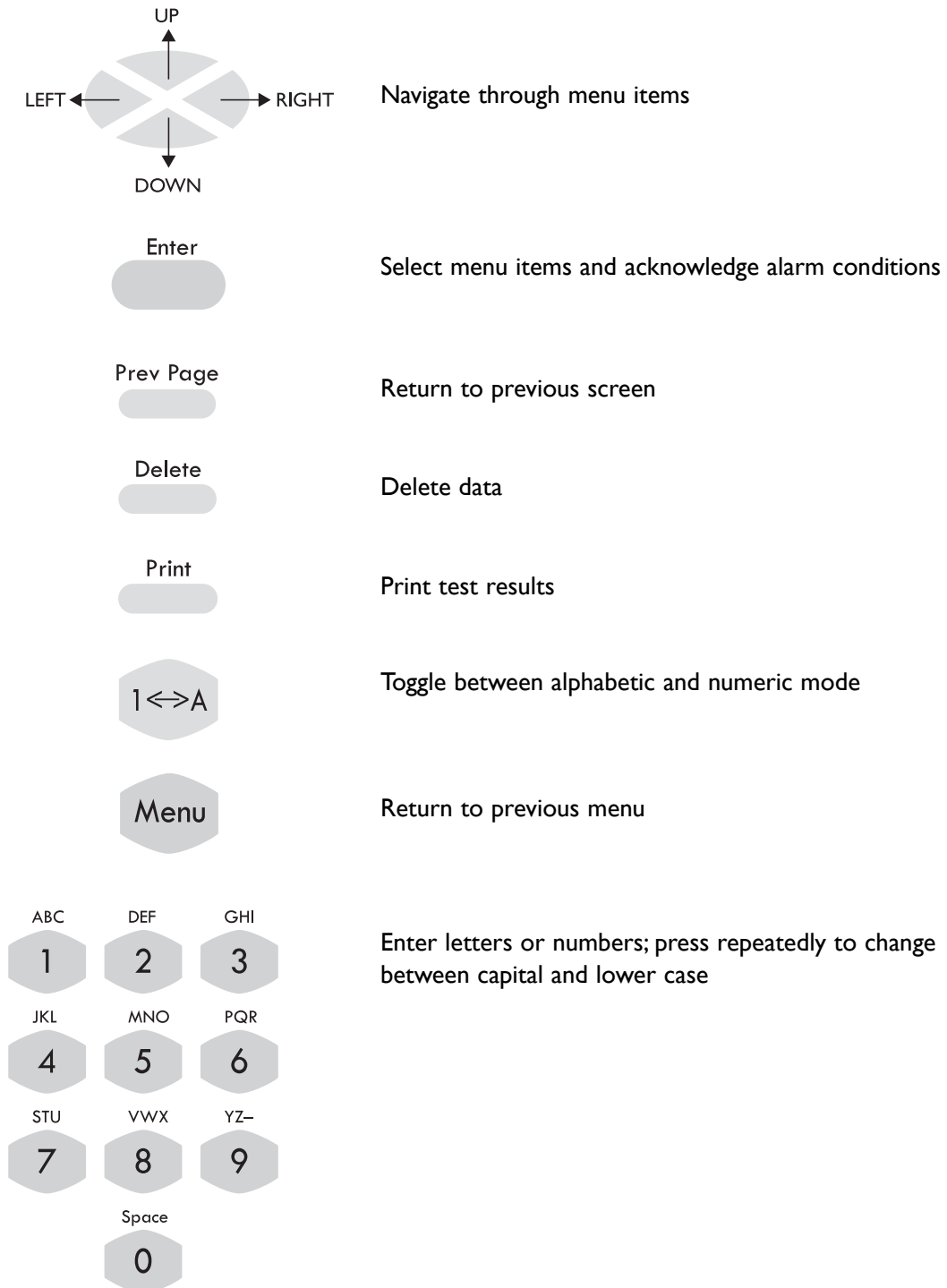
### Miscellaneous

Power switch	Turn the <b>DXpress™ Reader</b> on and off
DC 9V power adapter jack	
Host Computer interface port (RS-232C serial)	
Barcode scanner interface port	
Thermal printer	
LCD display screen	
Data Chip Port	Data Chip contains test and calibrator lot / device specific data for use in providing quantitative test results

### Options

USB adapter cable for connection to computers with USB ports instead of RS-232C serial ports

## Keypad (from top right corner)



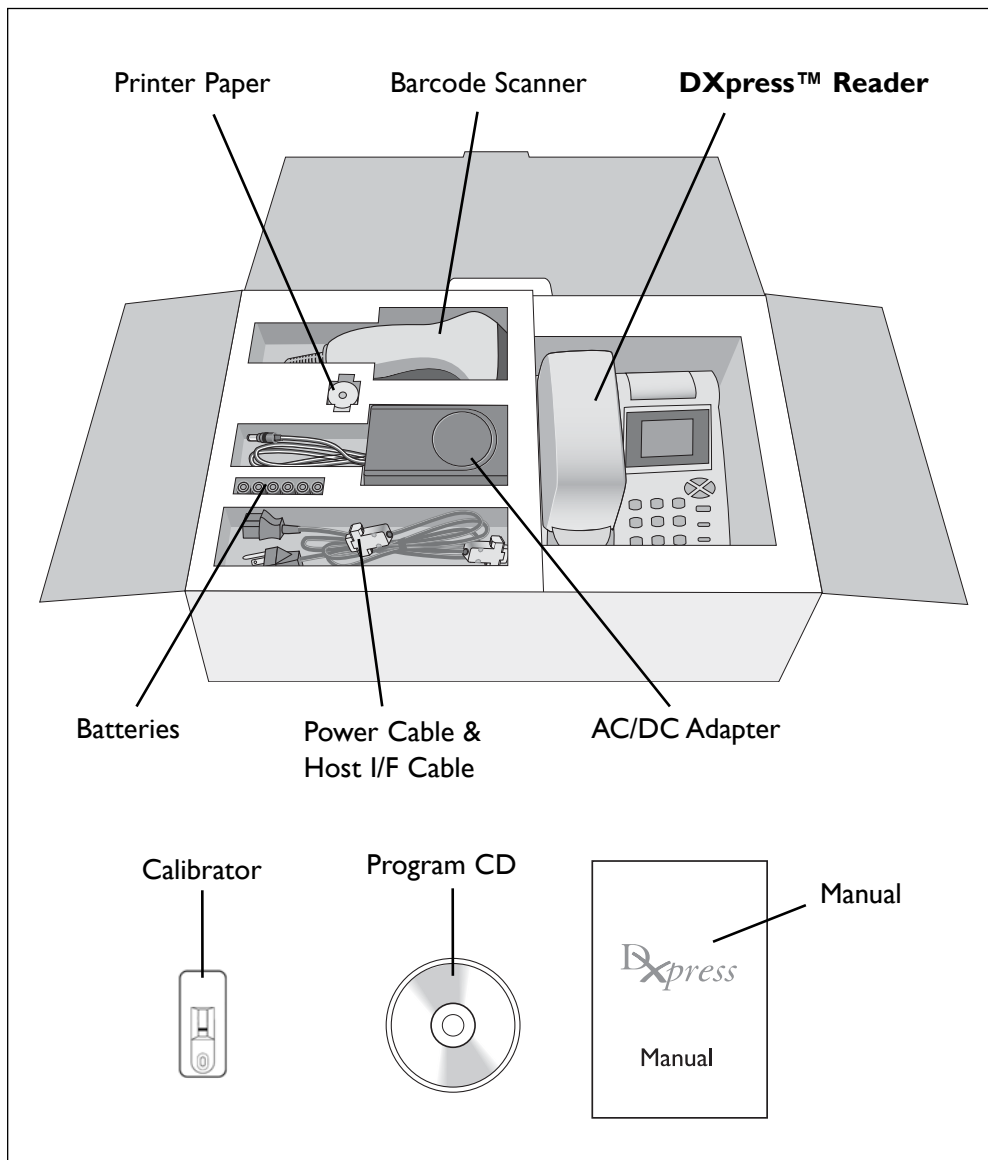
## 2. Installation

### 2.1 Unpacking

The **DXpress™ Reader** and included items are packed in a single box.

Test devices are packaged and sold separately and include instructions for use, specific to each test. If you have any questions or if anything is missing, contact your vendor or LifeSign Customer Support at 1 (800) 526-2125 (in the U.S.A. and Canada) or 1 (732) 246-3366 (outside of the U.S.A. and Canada).

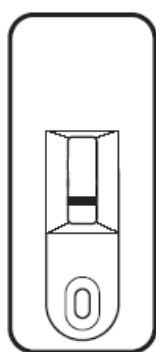
### 2.2 Contents and Part Listing



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The complete **DXpress™ Reader** carton (Cat. No. LSR-2000) contains the following items:

- ◆ **DXpress™ Reader** (Cat. No. R-9001)
- ◆ Barcode Scanner (Cat. No. R-9011)
- ◆ AC/DC Power Adapter (9V, 3.33A output; Cat. No. R-9021)
- ◆ Power Cable (Cat. No. may vary by country)
- ◆ 6 Batteries (AA, 1.5V Alkaline)
- ◆ Host interface cable (RS-232C) for connection to a PC (Cat. No. R-9041)
- ◆ Calibrator (Cat. No. R-2612). 1 ea



Calibrator

- ◆ Printer paper, 1 roll (Cat. No. R-9801)
- ◆ Manual (Cat. No. R-5011)
- ◆ Program CD containing manuals and drivers (Cat. No. R-9901)

**Optional (not included)**

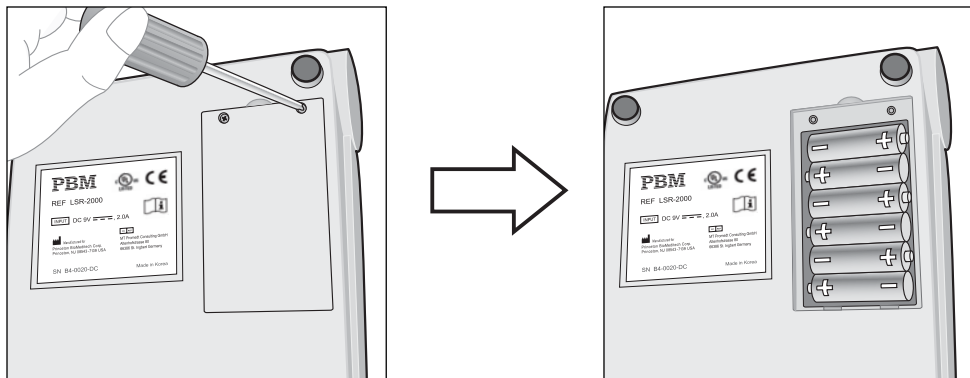
- ◆ USB to RS-232C adapter cable (Cat. No. 9051)
- ◆ Blank Calibrator for double-window cassette (Cat. No. R-2020)
- ◆ Blank Calibrator for single-window stick (Cat. No. R-2810)
- ◆ Blank Calibrator for double-window stick (Cat. No. R-2820)

## 2.3 Setup

### 2.3.1 Loading batteries

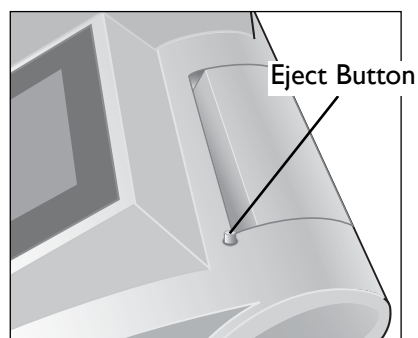
Remove the battery cover located on the bottom of the reader using a Phillips-head screwdriver. Install 6 x 1.5V AA batteries (alkaline recommended). Insert with the correct orientation.

Replace the battery cover and the two screws.



### 2.3.2 Loading paper

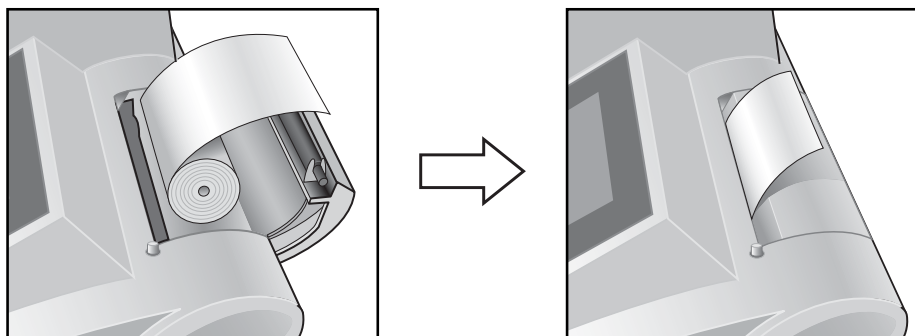
Open the Printer Cover by pressing the Eject button.



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Place a roll of thermal paper into the paper holder with the coated (glossy) surface facing the LCD screen. Pull about 2 inches (5 cm) of paper from the roll and press it toward the LCD screen. Close the printer cover.

Make sure printer paper comes out of the printer roller and then close the cover.



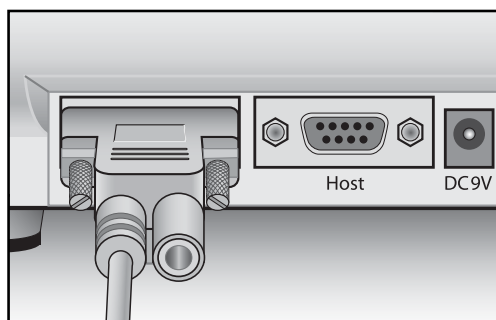
*If the reader produces blank prints, turn the paper over and try again.*



*Only use thermal paper less than 10 meters long. Paper rolls longer than 10 meters may not allow the printer cover to close properly.*

### 2.3.3 Connecting the Barcode Scanner

Connect the Barcode Scanner to the Barcode port at the rear of the reader.

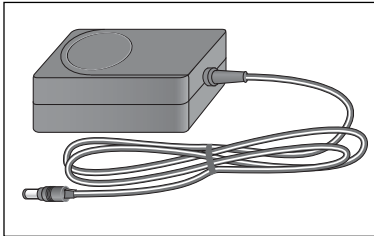


*Before connecting the Barcode Scanner, first make sure the power is OFF.*

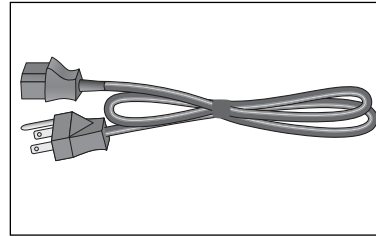


### 2.3.4 Connecting the AC/DC Power Adapter and Power Cable

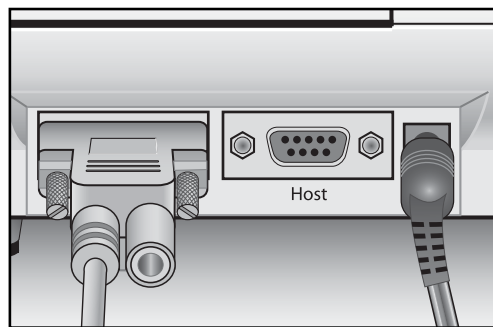
Connect the 9V AC/DC Power Adapter to the DC 9V jack on the **DXpress™ Reader**. Attach the Power Cable to the 9V AC/DC Power Adapter. Plug the Power Cable into a 110-240V AC outlet.



AC/DC Adapter

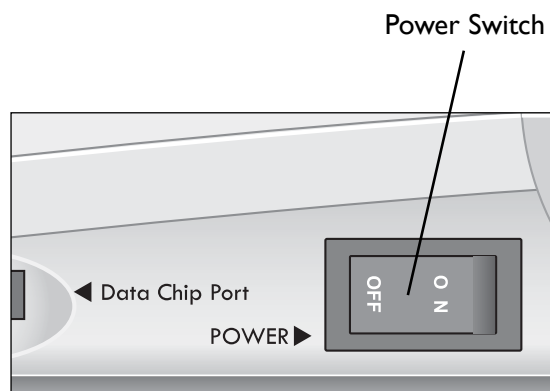


Power Cable



### 2.3.5 Power on

Locate the Power Switch on the lower right-hand side of the reader. Use the Power Switch to turn on the reader.



## 3. Startup

When first turned on, the **DXpress™ Reader** conducts two checks:

- ◆ Self Check
- ◆ Calibration QC




*If less than 24 hours have elapsed since the last Calibration QC, the reader will skip the Calibration QC at power on.*

### 3.1 Self Check

Each time the reader is turned on, it will conduct a Self Check, which will take about 15 seconds. The reader checks the hardware and software. (See section 4.2.1 Self Check for more details.) In addition, the reader can be configured to perform a Self Check at daily intervals even if the reader is not turned off and on. (See section 4.5.3.1 Self Check.)

SELF CHECK	
Date:	Feb.14.07 14:41
Serial Number:	B40123DC
Software:	F2.50 P1.0
Hardware	PASS
ProductDB	PASS
[Enter] to continue	

If the reader is operating properly, the results for each parameter will state PASS. If FAIL is displayed for any item, use  to see the error codes. Refer to the Troubleshooting section of the manual for further assistance with the error codes.

After completion of the Self Check, the reader will print a hard copy of the result and store it in memory.

### 3.2 Calibration QC

Calibration QC checks and calibrates the reader optical system using the reference values in a Calibrator (included) to read test devices accurately. The Calibration QC is required at preset daily intervals determined by the laboratory supervisor. After the power-on and completion of the Self Check, the reader will instruct you to perform a Calibration QC if more than 24 hours have elapsed since the last calibration. (See section 4.2.2 Calibration QC.)

Calibration QC requires a Calibrator which is included with each DXpress. The barcode contains the quality control parameters for the Calibrator.

After completion of the Calibration QC, the reader will print a hard copy of the result and store it in memory.

## 4. Operation

### Symbol legend


A  indicates a screen/menu name.

Example:  MAIN MENU


**BOLDED SMALL CAPITAL LETTERS** indicate a choice displayed on the screen.






Example: **[1] RUN PATIENT**

An image indicates a keypad button.



Example: 

### How to “SELECT” menu choices

Menu navigation is described in the following fashion: “From , **SELECT [1] RUN PATIENT.**” There are two ways to **SELECT** choices displayed on screen:

- Use , ,  and  to highlight the choice, then press .
- Directly select choices that have bracketed numbers (i.e., [1], [2]) by pressing that number on the keypad.

### Entering data

To **SCAN** a barcode, place the head of the Barcode Scanner against the barcode, then press the button located under the handle. The Barcode Scanner will beep when it scans successfully. To **ENTER** data using the keypad, use the alphanumeric keys, then press . Toggle between alpha (ABC) and numeric (123) characters by pressing . In alpha mode, press a key repeatedly until you see the desired character in lower case or CAPITAL.



**Data entered in the reader are case sensitive; lower case and capital letters are different.**




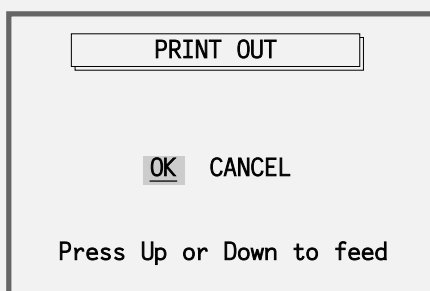
**Operator and Patient IDs may be up to 16 characters long. Sample IDs may be up to 10 characters long. Do not scan IDs exceeding these lengths.**



**The supervisor password is numeric only and may be up to 10 digits long.**

### Printing


Print a result displayed on the screen by pressing . Only result screen displays can be printed. The printout will include the reader serial number.





PRINT OUT

OK CANCEL

Press Up or Down to feed

**SELECT OK** or press  to print. **SELECT CANCEL** to return to the result screen.



To feed printer paper forward or backward, use  or .

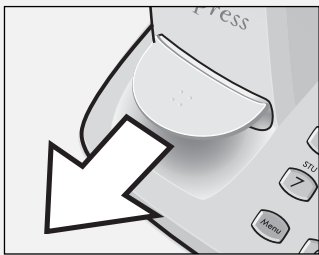


If the printer does not print, check and adjust the printer paper or cover.

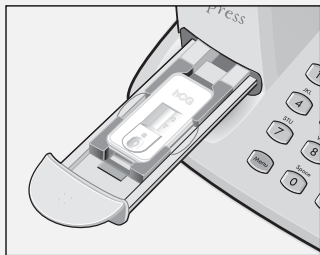


Printed results should be copied to more permanent paper or electronic format for longer-term storage. Light, heat and handling may cause thermal paper printouts to fade.

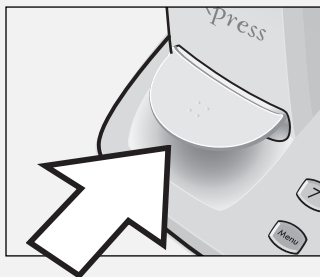
## Inserting test device



1. Pull out the Tray. Stop at the click-stop.



2. Place the test device in the Tray as indicated on the reader housing.



3. Close the Tray fully.



Make sure the window is facing up and the sample well is pointing toward the Tray handle; otherwise, the result will be incorrect.



Keep the Tray closed when not in use, to prevent excessive dust and debris from entering the reader.

The **DXpress™ Reader** is operated through six menus that can be selected from

**MAIN MENU**:

- [1] RUN PATIENT
- [2] RUN QC
- [3] RECALL PATIENT RESULTS
- [4] RECALL QC RESULTS
- [5] SUPERVISOR MENU
- [6] SHUTDOWN



*The example screens in this manual may display NT-proBNP as an example of quantitative test or hCG(SIU) as an example of qualitative test. Data are fictional. Actual screens may look different depending on the test.*

Before you can run patient tests, you must first add an operator (see section 4.5.4) and perform Calibration QC (See section 4.2.2).

## 4.1 Run Patient

MAIN MENU

- [1] RUN PATIENT
- [2] RUN QC
- [3] RECALL PATIENT RESULTS
- [4] RECALL QC RESULTS
- [5] SUPERVISOR MENU
- [6] SHUTDOWN

SELECT [1] RUN PATIENT.

RUN PATIENT

Scan or enter Lot Number to start a test.

LOT NO :

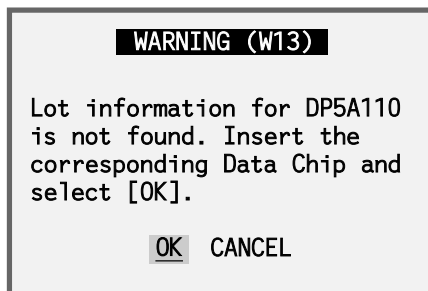
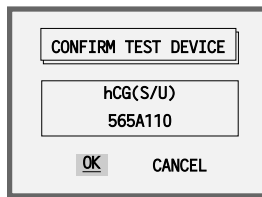
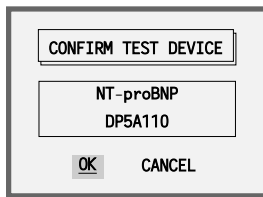
Scan the Lot Number barcode on the box or pouch (if available) or enter the Lot Number using the keypad.



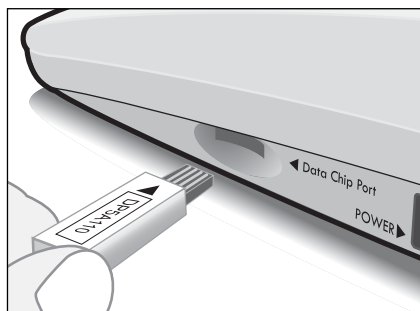
Confirm the Product Name and Lot Number displayed on the screen. **SELECT OK** to go to the next step or **CANCEL** to re-enter the Lot Number.

The reader will automatically check whether this Lot Number and associated calibration profile exist in the reader database.

- Example Screens

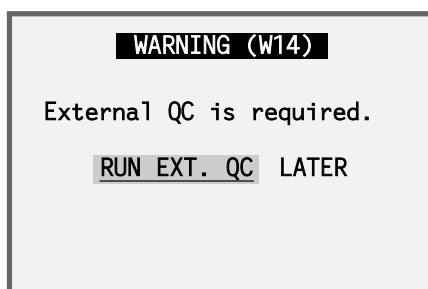


*If this is the first time running the Lot Number, the reader will prompt you to insert the Data Chip that was supplied with the test kit.*



*Insert the Data Chip for the Lot Number and **SELECT OK** to continue or **CANCEL** to return to **INPUT LOT NUMBER**.*

The reader will automatically check whether External QC is required for this Lot Number. For each new lot, External QC will be required.



***SELECT RUN EXT. QC** to proceed with External QC. (See section 4.2.4 External QC.) To skip External QC and continue with the test, **SELECT LATER**.*

*Consult package insert of specific test for more information on External QC.*

INPUT OPERATOR ID

Scan or enter Operator ID

ID : █ \_\_\_\_\_

123

SCAN or ENTER the Operator ID (up to 16 characters).



To add an Operator ID, go to **SUPERVISOR MENU** ▶ **[4] ADD/DELETE OPERATORS** (see section 5.4.1 ADD OPERATORS).



To prevent the reader from requesting the Operator ID, go to **SUPERVISOR MENU** ▶ **[2] SET PARAMETERS** ▶ **[4] OPERATOR CHECK** and **SELECT OFF**.

INPUT PATIENT ID

Scan or enter Patient ID

ID : █ \_\_\_\_\_

123

SCAN or ENTER the Patient ID (up to 16 characters).



SAMPLE TYPE

Select sample type.

Urine  
Blood  
Plasma/Serum

For certain tests, the reader will prompt you to **SELECT** sample types (**URINE, BLOOD, PLASMA** or **SERUM**, as appropriate). Refer to specific product insert for details.

INCUBATION TIME

[Product Name]  
XX min

READ-NOW BATCH SCHEDULER

Confirm the incubation time of the test you are running. **SELECT** from three different operation modes: **READ-NOW, BATCH** or **SCHEDULER**.

## READ-NOW:

Use this mode to read tests that are ready to read, without waiting for onboard incubation.

Lot No. ▶ Confirm Product ▶ Operator ID ▶ Patient ID ▶ “Read-Now” ▶ Insert Test ▶ Read ▶ Result

## BATCH:

Use this mode to repeat the “Read-Now” function using the same test, Lot No. and Operator ID for each repetition. This information does not need to be entered repeatedly for each test.

Lot No. ▶ Confirm Product ▶ Operator ID ▶ Patient ID ▶ [“Batch”] ▶ Insert Test ▶ Read ▶ Result

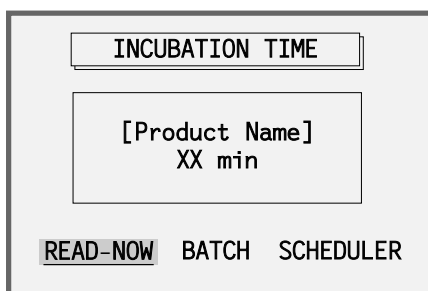
## SCHEDULER:

Use the reader’s internal Scheduler (timer) to track incubation times for multiple tests. The reader will prompt for each test to be read after the appropriate incubation time. Various tests can be mixed into the schedule using this function.

Lot No. ▶ Confirm Product ▶ Operator ID ▶ Patient ID ▶ “Scheduler” ▶ Add Sample & [Enter] ▶ Wait for Incubation ▶ Read ▶ Result

### 4.1.1 Read-Now Mode

Read-Now mode is used to read a device without waiting for incubation; i.e., a test that has already been run to completion with the use of an external timer.

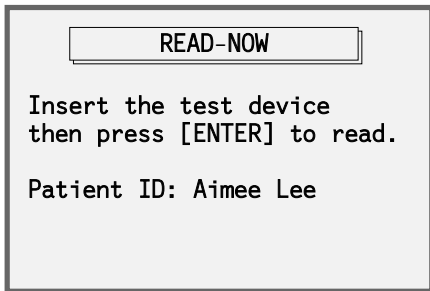



Consult package insert of specific test for incubation period. At the end of the incubation period, **SELECT READ-NOW**.

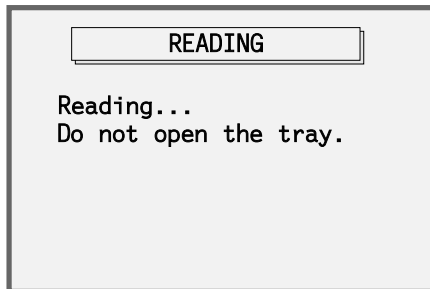


*This function may be used while the Scheduler is in use, except when less than one minute remains before the next scheduled test.*





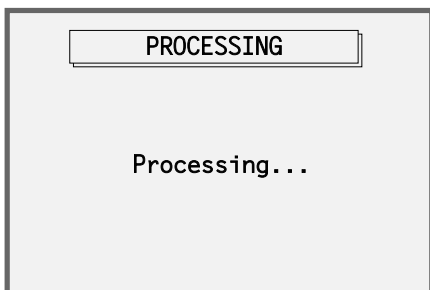
Insert the test device, then press  to read the device.



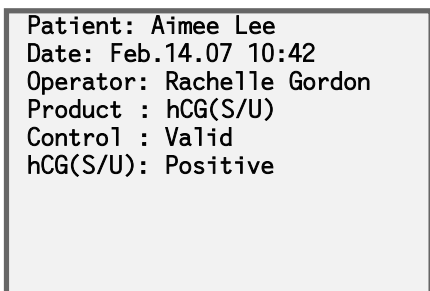
The reader will immediately read the device.



*Do not open the tray while reading.*






The reader processes the image. At this point, you can open the tray and insert the next device if needed.



After processing, results are displayed.



To view results for double-window devices, press  or  to switch between windows. Pressing  will print results for both windows in one step.

## 4.1.2 Batch Mode

Use Batch Mode to read multiple tests with the same lot number. Enter the lot number information just once to read a batch of tests. This mode is suitable for laboratory environment use.

INCUBATION TIME

[Product Name]  
 XX min

READ-NOW
BATCH
SCHEDULER

SELECT **BATCH**.



The same test, Lot No., and Operator ID are used for each repetition.



Batch Mode is not available while the Scheduler is in use.

BATCH MODE

Insert the test device  
then press [ENTER] to read.

Patient ID: Aimee Lee

Insert the test device, then press Enter to read the device.

Patient: Aimee Lee  
 Date: Feb.14.07 10:48  
 Operator: Racheille Gordon  
 Product : hCG(S/U)  
 Control : Valid  
 hCG(S/U): Positive

The result screen is displayed. Print the screen or press Enter to proceed to the next test in the batch.



**INPUT PATIENT ID**

Insert the test device  
then scan or enter  
Patient ID to read.

ID :

**123**

To read the next test, insert the test device, then *SCAN* or *ENTER* the Patient ID to read the device. The reader will immediately read the device.

To exit **BATCH MODE**, press  or .

### 4.1.3 Scheduler Mode

Use Scheduler Mode to track incubation times for multiple tests. The reader will prompt for each test to be inserted and read after the appropriate incubation time.

**INCUBATION TIME**


[Product Name]  
XX min

READ-NOW BATCH **SCHEDULER**

**SELECT SCHEDULER.**

**ADD SAMPLE**

Add Sample to test device  
and press [ENTER]

Add sample to the device as described in the package insert, then press  to add it to the Scheduler and start the internal timer.



**WARNING (W17)**


There is a pending test.  
Please wait for...

1 min 30 sec



*Tests can be added to the Scheduler only when there is no overlap with a pending test. The Scheduler ensures that there is enough time between tests (minimum 1 minute and 30 seconds per test). After this time expires, the reader will return to **ADD SAMPLE**.*

No	Patient(Sample)ID	Wait
1	Bruce Draine	10min
2	Clark Brent	15min

**SCHEDULER** appears when the test is successfully entered. The name of the test corresponding to the highlighted patient (or sample) is displayed below the SCHEDULER BOX.

To add another test to the Scheduler, press  and then **SELECT [1] RUN PATIENT**.



To switch between **SCHEDULER** and **MAIN MENU**, press . Pressing  from **MAIN MENU** any time there is a pending test takes you back to **SCHEDULER**.






While a test is pending in the Scheduler, only **[1] RUN PATIENT** and **[2] RUN QC ▶ [3] EXTERNAL QC** are available from **MAIN MENU**. To access other functions, wait until all scheduled tests are completed.



Up to 10 tests can be scheduled at a time.



To delete a specific schedule from the scheduler, highlight the test to be deleted using  and  and then press .

**DELETE SCHEDULE**

Do you want to delete the selected schedule?

Schedule Number: 1  
Patient: Bruce Draine

**OK** Cancel

**SELECT OK** to delete the schedule from the Scheduler.

00:30	SCHEDULER	
	NT-proBNP	
No	Patient(Sample)ID	Wait
1	Bruce Draine	30sec
2	Clark Brent	4min
3	Emelyne Smith	6min
4	Peter Marker	10min
5	Selina Pyle	13min
NEXT: (NT-proBNP) Bruce Draine		

At 30 seconds before the next read time, the reader will beep three times and automatically display **SCHEDULER** to notify the operator to insert the device. Insert the next device before the timer counts down to zero.

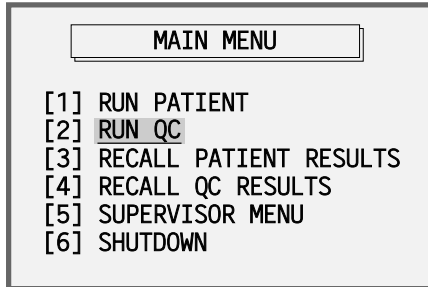
After the reader reads the test device, remove the test device. If there are additional tests scheduled, you may insert the next test device at this time.



*Always monitor the next scheduled read time in the top left corner of the screen while you perform other tasks. To allow enough time for the next scheduled reading, complete any function in progress at least 40 seconds before the next scheduled reading.*

## 4.2 Run QC

Run QC tests from this menu

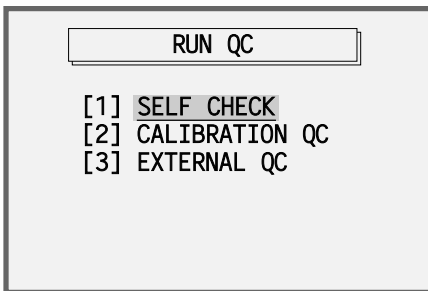


From **MAIN MENU** , SELECT **[2] RUN QC** .

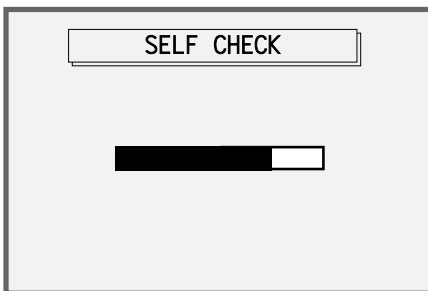
### 4.2.1 Self Check



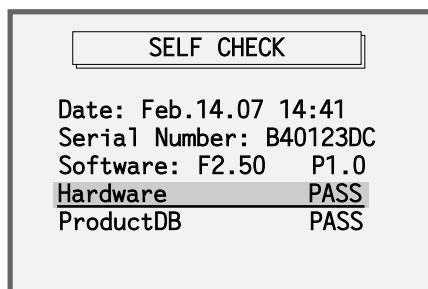
When a blinking “S” appears in the top right corner of the screen, the reader is requesting a Self Check.



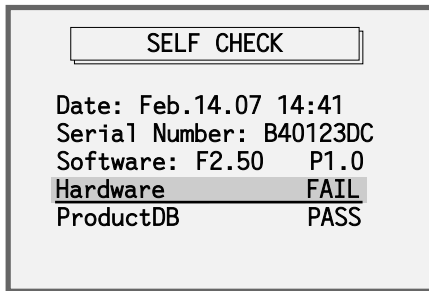
From **RUN QC** , SELECT **[1] SELF CHECK** .



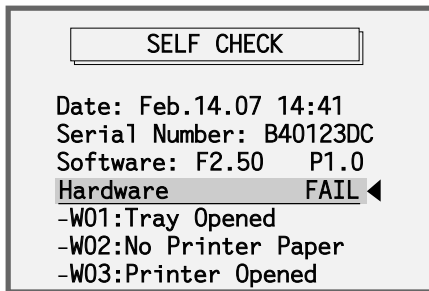
The Self Check will take about 15 seconds.



When Self Check passes, all items will state PASS.



When Self Check fails, one or more items will state FAIL.



Press → to display details for the failure.

Press ← to hide the details.

Refer to the Troubleshooting section for more information on errors.

## 4.2.2 Calibration QC



When a blinking “C” appears in the top right corner of the screen, the reader is requesting a Calibration QC.

Calibration QC checks and calibrates the reader optical system using the reference values in a Calibration Set (one barcoded Calibrator and optional Blank Calibrator(s)).

The reader will request performance of Calibration QC at preset daily intervals determined by the supervisor (unless the supervisor disables the daily reminder).

Calibration QC initially requires a barcoded Calibrator. The barcode contains the quality control parameters for the Calibrator. Calibration QC is successful when the actual value obtained using the Calibrator matches the reference value within a predefined tolerance range.

If the actual value obtained using the Calibrator does not match the reference value within the predefined tolerance range, the reader will perform a full recalibration automatically.

The full recalibration process may require several cycles of reading the Calibrator. Recalibration is successful when the actual value obtained using the Calibrator is essentially equal to the reference value.



Make sure the Calibrator is NOT expired and the surface is clean.



Always store the Calibrator in the clean pouch provided. Make sure the devices are free of scratches and dust. If the Calibrator is damaged, contact your vendor or LifeSign Customer Support to obtain a replacement.



If the reader is unable to calibrate successfully, the screen will display "CALIBRATION FAILED". For further assistance in this case, contact your vendor or LifeSign Customer Support.

MAIN MENU

[1] RUN PATIENT  
 [2] RUN QC  
 [3] RECALL PATIENT RESULTS  
 [4] RECALL QC RESULTS  
 [5] SUPERVISOR MENU  
 [6] SHUTDOWN

From **MAIN MENU** , SELECT **[2] RUN QC**.

RUN QC

[1] SELF CHECK  
 [2] CALIBRATION QC  
 [3] EXTERNAL QC

From **RUN QC** , SELECT **[2] CALIBRATION QC**.

INPUT OPERATOR ID

Scan or enter Operator ID

ID : █ \_\_\_\_\_

123

SCAN or ENTER Operator ID.



To add an Operator ID, go to **SUPERVISOR MENU** ▶ **[4] ADD/DELETE OPERATORS** ▶ **[1] ADD OPERATORS**.



To skip entering Operator IDs, go to **SUPERVISOR MENU** ▶ **[2] SET PARAMETERS** ▶ **[4] OPERATOR CHECK**, then SELECT OFF.

INPUT CALIBRATOR ID

Scan or enter Calibrator ID.

ID : █ \_\_\_\_\_

abc

SCAN or ENTER Calibrator QC ID from the barcode on the Calibrator.



Insert the Calibrator and  
Press [ENTER]

Insert the Calibrator in the reader and press

Enter



CALIBRATION QC - PASS  
QC Strip: QS50000607  
Date: Feb.14.07 11:29  
Operator: Rachelle Gordon  
Integration Time: 6000  
Reference Value: 5000  
Actual Value: 5010  
Press [Enter] to continue

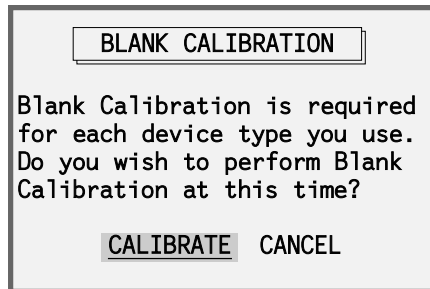
The reader displays the "Calibration QC – Pass"  
result screen, which can be printed. Press <sup>Enter</sup>  
to continue.

Enter



*If the value obtained using the Calibrator does not match the reference value within a predefined tolerance range, the reader will perform a full recalibration automatically.*

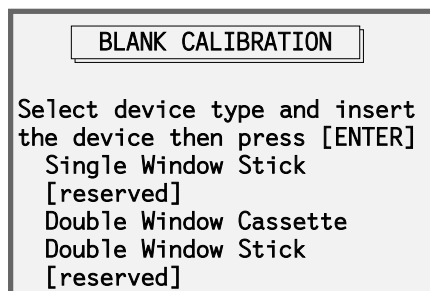
### 4.2.3 Blank Calibration for Different Device Types




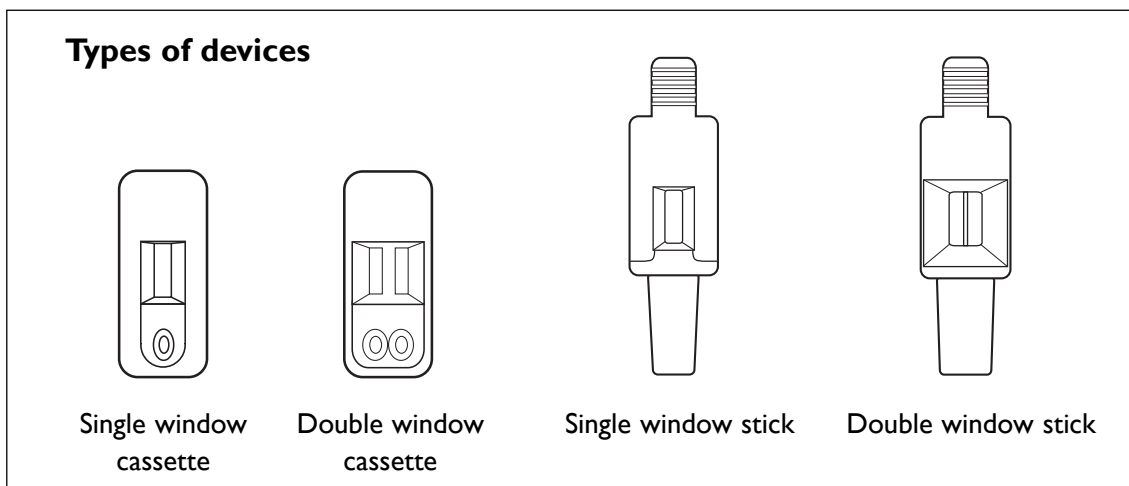
After Calibration QC completes successfully, you must perform a separate Blank Calibration for each additional type of test device you use. Blank Calibration will precisely measure the lighting conditions and reflection pattern of each additional device type for optimum accuracy. **SELECT CALIBRATE** or, if you run only single window cassette devices, **SELECT CANCEL**.



Perform Blank Calibration only on device types that you use. For example, if you do not normally run double window stick devices, there is no need to perform Blank Calibration for the double window stick device type. Consult with your vendor or LifeSign Customer Support for device types.



**SELECT** the device type, insert the corresponding Blank Calibrator, then press .



Perform Blank Calibration with a clean device (Cat. No. R-2010, R-2020, R-2810 or R-2820, as appropriate). Do NOT use devices with scratches, lines, etc.



If the Calibration QC fails, contact LifeSign Customer Support for assistance or to obtain a Calibrator replacement. In the U.S.A. and Canada, call 1 (800) 526-2125; outside of the U.S.A. and Canada, call 1 (732) 246-3366.

## 4.2.4 External QC

Run Quality Control samples to verify that reader and test device performance are satisfactory.

MAIN MENU

[1] RUN PATIENT  
 [2] RUN QC  
 [3] RECALL PATIENT RESULTS  
 [4] RECALL QC RESULTS  
 [5] SUPERVISOR MENU  
 [6] SHUTDOWN

From MAIN MENU , SELECT [2] RUN QC.

RUN QC

[1] SELF CHECK  
 [2] CALIBRATION QC  
 [3] EXTERNAL QC

From RUN QC SELECT [3] EXTERNAL QC.

INPUT SAMPLE ID

Scan or enter Sample ID.

ID : █ \_\_\_\_\_

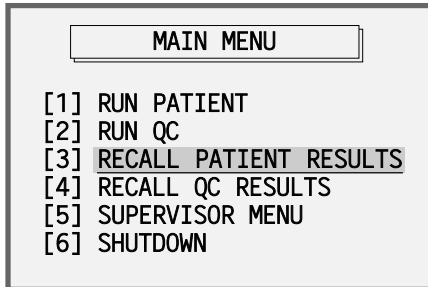
123

External QC follows the same procedure as Run Patient. The only difference is that Run Patient requires a Patient ID, whereas External QC requires a Sample ID. Consult package insert of specific test for more information on External QC.



*Sample ID can be up to 10 characters long.*

## 4.3 Recall Patient Results



From **MAIN MENU**, **SELECT [3] RECALL PATIENT RESULTS**.

No	Patient ID	Date
13	Bruce Draine	Feb.14.07
12	Maya Arugula	Feb.14.07
11	Andy Feigenson	Feb.14.07
10	Adam Thomas	Feb.13.07
9	James Shaw	Feb.13.07

The list is displayed in chronological order, newest results on top. Press to display oldest results on top.

**SELECT** the patient result to display the details.

```

Patient: Bruce Draine
Date: Feb.14.07 11:17
Operator: Rachelle Gordon
Product: NT-proBNP
Control : Valid
proBNP : 100.00 pg/ml
  
```

The patient result will be displayed and may be printed.

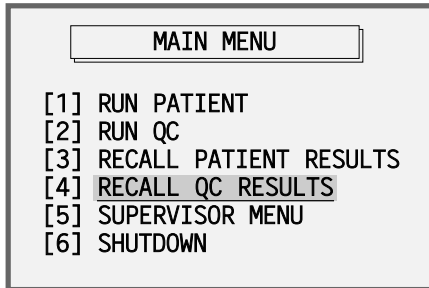


To view results of a double-window device, press and to switch between the left and right windows. Pressing will print results for both windows in one step.

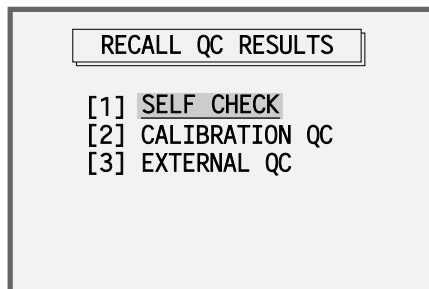


To delete a result, go to **SUPERVISOR MENU** ► **[5] DELETE RESULTS** (section 4.5.5).

## 4.4 Recall QC Results



From **MAIN MENU**, **SELECT [4] RECALL QC RESULTS**.



**RECALL QC RESULTS** will be displayed.

- ◆ **SELF CHECK:** Recall previous Self Check results.
- ◆ **CALIBRATION QC:** Recall previous Calibration QC results.
- ◆ **EXTERNAL QC:** Recall previous External QC results.



*Recall QC results in the same fashion as patient results (section 4.3).*

QC results will be displayed in chronological order, newest results on top.  
Each result can be viewed by pressing  from the list, and then printed if desired.

## 4.5 Supervisor Menu

The Supervisor Menu is used to:

- ◆ Manage authorized operators and supervisor password;
- ◆ Set **DXpress™** parameters;
- ◆ Set QC function parameters;
- ◆ Delete results; and
- ◆ Connect to a PC to download or browse test results and upload new firmware.



*Only the supervisor can access the Supervisor Menu.*

MAIN MENU

[1] RUN PATIENT  
 [2] RUN QC  
 [3] RECALL PATIENT RESULTS  
 [4] RECALL QC RESULTS  
 [5] SUPERVISOR MENU  
 [6] SHUTDOWN

From MAIN MENU , SELECT **[5] SUPERVISOR MENU**.

INPUT PASSWORD

Enter password.

PASSWORD :

123

Enter the supervisor password.

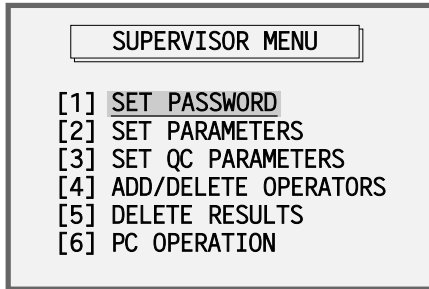
The default supervisor password is 0000.

SUPERVISOR MENU

[1] SET PASSWORD  
 [2] SET PARAMETERS  
 [3] SET QC PARAMETERS  
 [4] ADD/DELETE OPERATORS  
 [5] DELETE RESULTS  
 [6] PC OPERATION


SUPERVISOR MENU will appear.

### 4.5.1 Set Password




From **SUPERVISOR MENU**, *SELECT [1] SET PASSWORD.*



Enter a new supervisor password using the keypad, then press . The password may be a number up to 10 digits long.




Re-enter the new password and press .



To cancel and return to **SUPERVISOR MENU**, press .

## SET PASSWORD

Successfully changed.  
Press [ENTER] to continue.

After successfully changing the supervisor password, press  to return to

SUPERVISOR MENU.

## 4.5.2 Set Parameters

## SUPERVISOR MENU

- [1] SET PASSWORD
- [2] SET PARAMETERS
- [3] SET QC PARAMETERS
- [4] ADD/DELETE OPERATORS
- [5] DELETE RESULTS
- [6] PC OPERATION

From **SUPERVISOR MENU**, SELECT [2] SET PARAMETERS.

### 4.5.2.1 Beep

## SET PARAMETERS

- [1] BEEP
- [2] DATE AND TIME
- [3] AUTO PRINT
- [4] OPERATOR CHECK
- [5] POWER SAVING

From **SET PARAMETERS**, SELECT [1] BEEP.

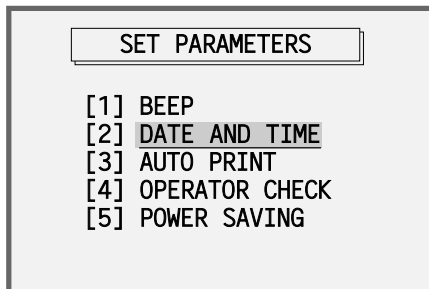
## BEEP

ON OFF

SELECT **ON** or **OFF**. This turns on and off the audible sounds used to notify the operator of events or alarms.








### 4.5.2.2 Date and Time

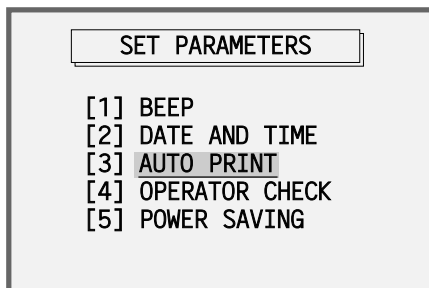


From **SET PARAMETERS**, SELECT **[2] DATE AND TIME**.

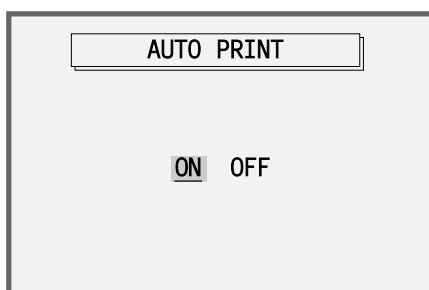


Highlight the month/day/year/time using  and , and change the values using  and . Press  to return to **SET PARAMETERS**.


### 4.5.2.3 Auto Print



From **SET PARAMETERS**, SELECT **[3] Auto PRINT**.



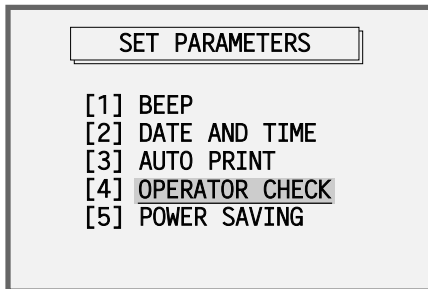
To automatically print any result upon completion, turn this option on.

If this option is turned off, you may use  to manually print a result.

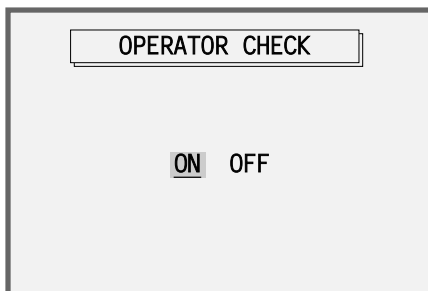


*Printing is not available while operating in battery mode. Turn off the "Auto Print" parameter while operating in battery mode and print results when AC power is available.*

#### 4.5.2.4 Operator Check



From **SET PARAMETERS**, SELECT **[4] OPERATOR CHECK**.

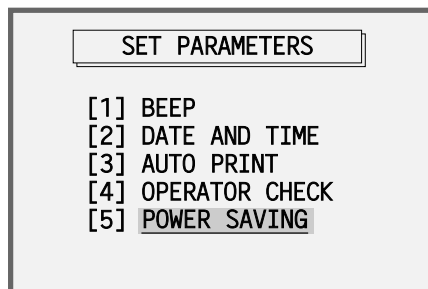


When this option is **on**, the reader prompts for an Operator ID at the Run Patient, Calibration QC, and External QC procedures. If this option is **off**, the reader will not prompt for an Operator ID.

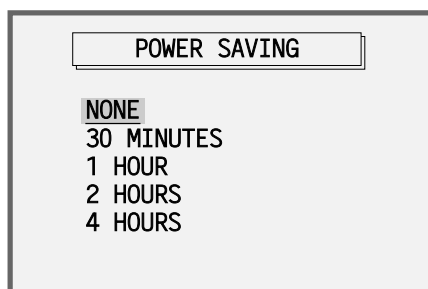


*If this option is off, the Operator ID will be displayed and saved as "NONE".*

#### 4.5.2.5 Power Saving

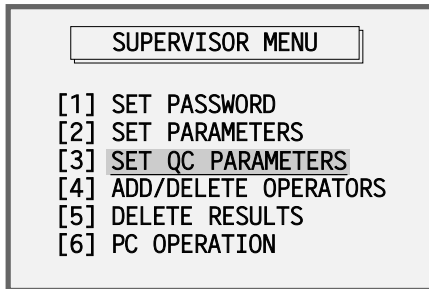


From **SET PARAMETERS**, SELECT **[5] POWER SAVING**.

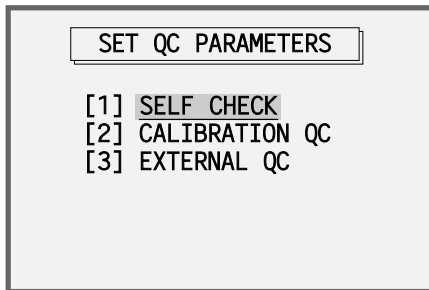


If **NONE** is selected, the **DXpress™ Reader** will remain on. Select one of the times to set the reader to go into Power Saving mode after the selected amount of idle time. The operator can awaken the reader from Power Saving mode by pressing any key.

### 4.5.3 Set QC Parameters



From **SUPERVISOR MENU** , *SELECT* **[3] SET QC PARAMETERS**.



**SET QC PARAMETERS** will be displayed.

### 4.5.3.1 Self Check

From **SET QC PARAMETERS**, **SELECT [1] SELF CHECK**.

*SELECT* the desired frequency.

- ◆ **NONE:** The reader will never prompt the operator to perform Self Check.
- ◆ **EACH DAY:** The reader will prompt the operator to perform Self Check at a specified time each day.



*Self Check will always be performed automatically whenever the power is turned on.*

Set the specified time to perform Self Check.  
Use and to move between Hours and Minutes. Use and to change the time.

### 4.5.3.2 Calibration QC



Configure Calibration QC in the same fashion as Self Check (section 4.5.3.1).

SET QC PARAMETERS

[1] SELF CHECK  
 [2] CALIBRATION QC  
 [3] EXTERNAL QC

From SET QC PARAMETERS, *SELECT* [2]  
**CALIBRATION QC.**

CALIBRATION QC

-FREQUENCY-

NONE  
EACH DAY

*SELECT* the desired frequency.

- ◆ **NONE:** The reader will never prompt the operator to perform Calibration QC.
- ◆ **EACH DAY:** The reader will prompt the operator to perform Calibration QC at a specified time each day.

SET CHECK TIME

00:00

Use and to move between Time and Hour. Use and to change the time.

### 4.5.3.3 External QC

SET QC PARAMETERS

[1] SELF CHECK  
 [2] CALIBRATION QC  
 [3] EXTERNAL QC

From SET QC PARAMETERS , *SELECT* [3]  
**EXTERNAL QC.**

EXTERNAL QC

-FREQUENCY-

NONE  
 EACH NEW LOT  
 NEW LOT AND EVERY 30 DAYS

*SELECT* the desired frequency.

- ◆ **NONE:** The reader will never prompt the operator to perform External QC.
- ◆ **EACH NEW LOT:** The reader will prompt the operator to perform External QC whenever a new lot number is entered.
- ◆ **NEW LOT AND EVERY 30 DAYS:** The reader prompts the operator to perform External QC whenever a new lot number is entered and after 30 days elapse after the last External QC for the lot.

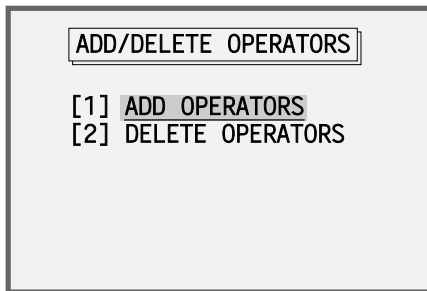
### 4.5.4 Add / Delete Operators

SUPERVISOR MENU

[1] SET PASSWORD  
 [2] SET PARAMETERS  
 [3] SET QC PARAMETERS  
 [4] ADD/DELETE OPERATORS  
 [5] DELETE RESULTS  
 [6] PC OPERATION

From SUPERVISOR MENU , *SELECT* [4]  
**ADD/DELETE OPERATORS.**

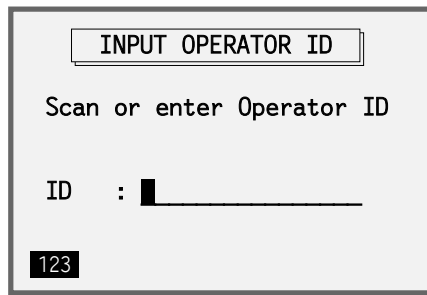
#### 4.5.4.1 Add Operators



ADD/DELETE OPERATORS

[1] ADD OPERATORS  
[2] DELETE OPERATORS

To add an authorized operator, *SELECT [1] ADD OPERATORS*.



INPUT OPERATOR ID

Scan or enter Operator ID

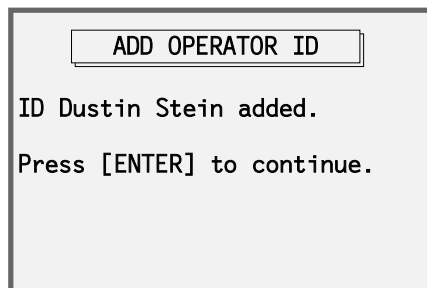
ID : █ \_\_\_\_\_

123

*SCAN* or *ENTER* an operator ID.


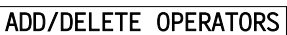



*You cannot add a blank or duplicate ID.*

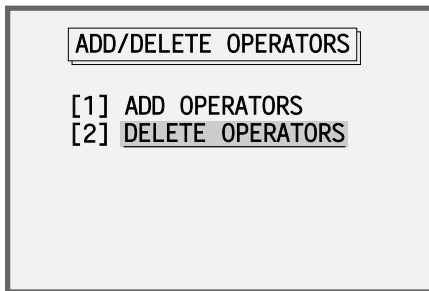


ADD OPERATOR ID

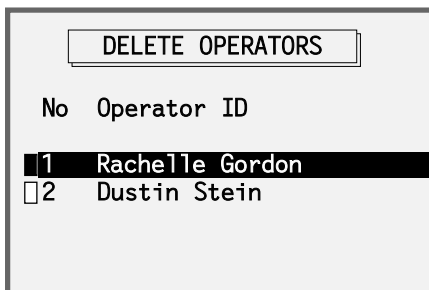
ID Dustin Stein added.  
Press [ENTER] to continue.

To enter another Operator ID, press . To go back to , press .

#### 4.5.4.2 Delete Operators



**SELECT [2] DELETE OPERATORS.**



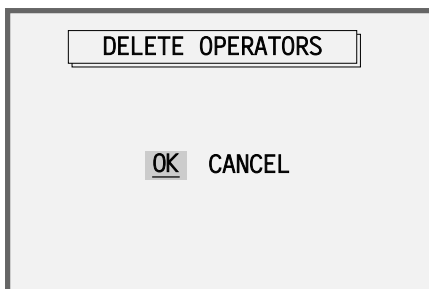
To mark an operator for deletion, highlight, then press . Repeat the procedure to mark additional operators for deletion.



Pressing will select all of the operators.

To unmark an operator, highlight the operator and then press again.

To delete the marked operators, press .



After pressing , the reader will prompt the supervisor to confirm deletion. **SELECT OK** to delete the marked operators. **SELECT CANCEL** to return to **ADD/DELETE OPERATORS**.



## 4.5.5 Delete Results

SUPERVISOR MENU	
[1]	SET PASSWORD
[2]	SET PARAMETERS
[3]	SET QC PARAMETERS
[4]	ADD/DELETE OPERATORS
[5]	DELETE RESULTS
[6]	PC OPERATION



From **SUPERVISOR MENU**, *SELECT* [5] **DELETE RESULTS**.

DELETE RESULTS	
[1]	PATIENT
[2]	SELF CHECK
[3]	CALIBRATION QC
[4]	EXTERNAL QC


*SELECT* a type of result to delete.

### 4.5.5.1 Patient


PATIENT RESULTS		
No	Patient ID	Date
<input checked="" type="checkbox"/>	13 Aimee Lee	Feb.14.07
<input type="checkbox"/>	12 Maya Aruguła	Feb.14.07
<input type="checkbox"/>	11 Andy Feigenson	Feb.13.07
<input type="checkbox"/>	10 Adam Thomas	Feb.13.07
<input type="checkbox"/>	9 James Shaw	Feb.13.07

To mark a patient result for deletion, highlight, then press . Repeat the procedure to mark additional patients. To delete marked patient results, press .




Press  to mark all of the patient results for deletion.

PATIENT RESULTS		
No	Patient ID	Date
<input checked="" type="checkbox"/>	13 Aimee Lee	Feb.14.07
<input type="checkbox"/>	12 Maya Aruguła	Feb.14.07
<input type="checkbox"/>	11 Jay Changstein	Feb.13.07
<input type="checkbox"/>	10 Bob Fromer	Feb.13.07
<input type="checkbox"/>	9 James Shaw	Feb.13.07

To unmark a patient result, highlight the result and then press  again.

To delete the selected results, press  .

DELETE RESULTS	
<input type="checkbox"/>	OK
<input type="checkbox"/>	CANCEL


After pressing , the reader will ask the supervisor to confirm deletion. **SELECT OK** to confirm deletion. **SELECT CANCEL** to return to **DELETE RESULTS** .

#### 4.5.5.2 Self Check / Calibration QC / External QC

DELETE RESULTS	
<input type="checkbox"/>	[1] PATIENT
<input checked="" type="checkbox"/>	[2] SELF CHECK
<input type="checkbox"/>	[3] CALIBRATION QC
<input type="checkbox"/>	[4] EXTERNAL QC


**SELECT** a type of result to delete.

DELETE RESULTS		
No	Date	Time
<input checked="" type="checkbox"/>	10 Feb.14.07	20:14
<input type="checkbox"/>	9 Feb.13.07	22:14
<input type="checkbox"/>	8 Feb.12.07	08:54
<input type="checkbox"/>	7 Feb.11.07	04:16
<input type="checkbox"/>	6 Feb.10.07	14:12

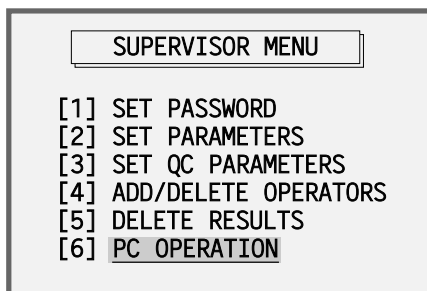
To mark a result for deletion, highlight, then press  . To delete marked results, press

 .



After pressing  , the reader will ask the supervisor to confirm deletion. **SELECT OK** to confirm deletion. **SELECT CANCEL** to return to the previous screen.

#### 4.5.6 PC Operation (optional)

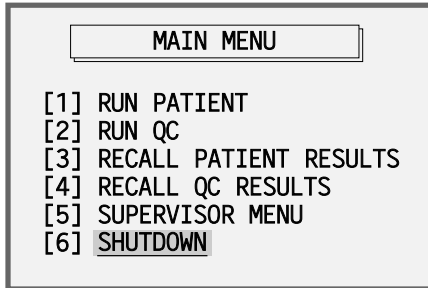


To connect the reader to a PC, **SELECT [6] PC OPERATION**.



Press  to exit PC Operation mode.

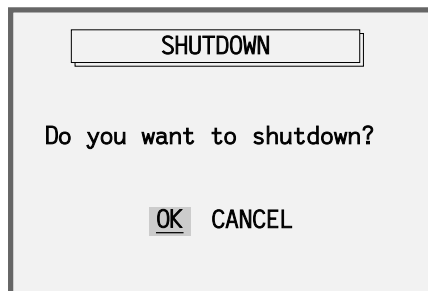
## 4.6 Shutdown



To properly turn off the reader and ensure data integrity, **SELECT [6] SHUTDOWN**. This procedure ensures that all data are safely stored in the **DXpress™ Reader** memory.

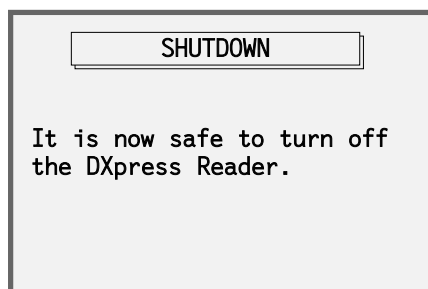


*The **SHUTDOWN** menu choice is not available while a test is pending in the Scheduler. Wait until all scheduled tests are completed before attempting to **SHUTDOWN**.*



To proceed with shutdown, **SELECT OK**.

To resume operation and return to **MAIN MENU**, **SELECT CANCEL**.



Use the Power Switch to turn off the reader.

---

## 5. DXpress™ Quality Assurance

Quality assurance when using the **DXpress™ Reader** to read compatible test devices encompasses three areas: quality control routines built into the reader; procedural and quality control of the test device; and reader software safeguards of quality control routines and data integrity. The **DXpress™ Reader** QC and Patient Testing Log (see end of Manual) provides a recommended format to document your adherence to the **DXpress™ Reader** quality control routines as well as maintain a log of patient test results. The Log may be copied and used as needed.

### Reader

- ◆ Self Check
- ◆ Calibration Quality Control

### Device

- ◆ Internal Procedural Control
- ◆ External Quality Control

### Software

- ◆ Operator ID
- ◆ Supervisor password
- ◆ Instrument QC frequency requirements and alerts
- ◆ External Control frequency requirements and alerts
- ◆ Patient Out of Range flags

## Reader Quality Assurance

### Self Check

- ◆ Reader optical integrity
- ◆ Memory
- ◆ Remaining battery power
- ◆ Printer

The **DXpress™ Reader** will perform a self check each time the reader is turned on. In addition, the supervisor can configure the reader to request performance of a Self Check daily at a specified time. The default setting is daily Self Check.

Run Self Check daily to assure the reader software and hardware are performing properly. If a Self Check parameter fails, use the right arrow key to display further details on the failed parameter.

---

## Calibration Quality Control

- ◆ Reader optical linearity calibration
- ◆ Light source stability
- ◆ Camera alignment

The **DXpress™ Reader** comes with a barcoded Calibrator. The barcode contains the quality control parameters for the Calibrator. The supervisor can configure the reader to alert the operator when Calibration QC should be performed. If the Calibration QC fails to meet the calibration parameter criteria, the reader will perform a full recalibration automatically. If recalibration is not successful, contact LifeSign Customer Support.

## Device Quality Assurance

### Internal Procedural Controls

Test devices compatible with the **DXpress™ Reader** have a built-in Positive Procedural Control indicating that the procedure has been performed properly: the sample volume is adequate; the sample and reagents have migrated; and the internal test control reagents and the conjugated-color indicator are working properly. In addition, the background in the result window will become clear and provide a distinct result, which may be considered an internal Negative Procedural Control.

### External Quality Control

External Quality Control materials can be purchased from your vendor or LifeSign Customer Support. These control materials should be run periodically according to the manufacturer's recommendations for the test being performed or according to your laboratory's quality control procedures. Expected values for these controls are provided; when out of range results are obtained, they should be reviewed by the laboratory's quality control supervisor. The supervisor can configure the **DXpress™ Reader** to request External Quality Controls to be run at three frequency settings:

**None** – use if the laboratory's quality control procedure requires a different schedule for performing External QC.

**Each New Lot of tests**

**Each New Lot of tests and every 30 days that the lot is being used**

The reader will prompt the operator to perform External QC whenever a new lot is used and (optionally) every 30 days, if these parameters are selected.

---

## Software Quality Assurance

### Reader Software Safeguard Purpose

Operator ID	Prevents untrained personnel from using the <b>DXpress™ Reader</b> to read an assay.
Supervisor Password	Prevents inappropriate use and management of the data and changes to the configuration options.
Instrument QC frequency requirements	Configures the frequency with which to perform Self Check and Calibration QC (in Supervisor Menu > Set QC Parameters).
External Control frequency requirements	Configures the frequency with which to perform QC and External Controls (in Supervisor Menu > Set QC Parameters).
Patient Out of Range Flags	Reports patient results outside the linear range of the analyte being tested as <less than the minimum> or <greater than the maximum> value.

## 6. Troubleshooting

The following table lists possible error and warning messages that the reader may present in the course of operation, along with probable causes and recommended corrective actions. Following the recommended steps will correct many simple errors. For more detailed assistance, please contact your vendor or LifeSign Customer Support.

<b>Error Code</b>	<b>Message/Problem</b>	<b>Probable Cause</b>	<b>Corrective Action</b>
E01	Memory Test Failed	Memory Read/Write test failed.	Restart the reader, if the problem persists, contact your vendor or LifeSign Customer Support.
E02	High Printer Temperature	Printer Head is overheated.	Stop printing. Wait for a few minutes and try again.
E03	Image Grab Failed	Image capturing failed, due to a hardware problem.	Contact your vendor or LifeSign Customer Support.
E04	ProductDB Failed Does not exist	The product database may have been erased.	Download the product database or contact your vendor or LifeSign Customer Support.
E11	DATABASE FULL	Patient Result database is full.	Exit the menu by pressing [Menu], then delete results from the Supervisor Menu.
E12	TRAY OPEN	The Tray is open when the reader attempts to read a test device.	Check that the test device is correctly placed in the reader and close the Tray. Press [Enter] to retry.
E13	TRAY EMPTY OR LIGHT ERROR	When the Tray is closed, the reader checks for a test device. Either the tray is empty or there is a lighting problem.	Open the Tray and correctly insert the test device into the Tray. If the problem persists, contact your vendor or LifeSign Customer Support.
E14	Please check the device and tray. Press [Enter] within... 30sec to retry.	The reader has detected a problem with the device and/or Tray while attempting to read the device.	Ensure that the correct device is inserted and close the Tray, then press [Enter] to retry.
E15	INCORRECT PASSWORD	Incorrect password was entered.	Use correct password.
E16	INCORRECT ID	The Operator ID entered is not in the database.	Go to "Add/Delete Operators" in the Supervisor Menu to add a new Operator ID.
E17	WRONG LOT NUMBER	Entered or scanned incorrect lot number.	Double-check and re-enter the lot number. If the problem persists, contact your vendor or LifeSign Customer Support.



<b>Error Code</b>	<b>Message/Problem</b>	<b>Probable Cause</b>	<b>Corrective Action</b>
E18	WRONG ID	Wrong Barcode ID was used.	Check the ID and re-scan or re-enter.
E19	DUPLICATE ID	Entered duplicate ID.	Enter a unique ID
E31	SCHEDULER FULL	No more than 10 tests can be scheduled at a time.	Wait until there is an available slot in the Scheduler. Press [Enter] or [Prev Page] to return to the previous menu.
E32	PRODUCT CODE DOES NOT EXIST	The product code entered does not exist in the database. It may have been entered incorrectly or it may be a new or unsupported product code.	Enter the correct product code or check whether the reader supports the product. Update your Product Database and try again. Contact your vendor or LifeSign Customer Support to obtain a DXpress™ Reader database update. Make sure UPPER case letters are used to enter the lot number.
E33	CALIBRATION FAILED	Calibrator QC failed after 15 retries.	Make sure the Calibrator is clean. Contact your vendor or LifeSign Customer Support if the problem persists.
E34	ROI OFFSET ERROR	Calibration data are corrupt.	Contact your vendor or LifeSign Customer Support.
E35	DEVICE EXPIRED	Product Lot Number entered is expired.	Use an unexpired product.
E36	CAN'T READ-NOW - - A SCHEDULED TEST IS PENDING	User tried to read-now but there is a pending test scheduled to be read in the next 60 seconds.	Wait until the next scheduled test is read and then try again.
E37	CAMERA PARAMETERS DO NOT EXIST	Camera parameters are not loaded correctly or corrupt.	Contact your vendor or LifeSign Customer Support.
E38	CALIBRATION KIT EXPIRED CAN'T PERFORM CAL. QC	The Calibrator is expired.	Purchase a new Calibrator from your vendor.
E39	INVALID BLANK CALIBRATION PERFORM BLANK CALIBRATION AGAIN	Calibration QC was performed but Blank Calibration was not performed.	Perform Blank Calibration with the device type you use.
E41	Device insertion error: Not a Blank Calibrator. Please insert a Blank Calibrator and press [ENTER]	The inserted device was not a Blank Calibrator.	Insert the Blank Calibrator and press [Enter].

<b>Error Code</b>	<b>Message/Problem</b>	<b>Probable Cause</b>	<b>Corrective Action</b>
E42	Device insertion error: Not a Calibrator. Please insert a Calibrator and press [Enter]	The inserted device was not the Calibrator.	Insert the Calibrator and press [Enter].
E43	Press [Enter] to retry	There was an error when trying to read the device.	Press [Enter] to retry.
E44	MACHINE INFORMATION DOES NOT EXIST	Machine Reader parameters are not loaded correctly or corrupt.	Contact your vendor or LifeSign Customer Support.
E45	LIGHT OVERHEATED LIGHT WILL BE OFF AND YOU MUST RESTART SYSTEM	Light was turned on for too long (5 minutes).	Shutdown the reader from the Main Menu, turn the power switch off, then power on again.
E46	FAILED TO GRAB IMAGE	Image capturing failed.	Contact your vendor or LifeSign Customer Support.
E47	No Printer Paper	There is no printer paper or the printer cover is open.	Make sure the printer paper is correctly placed with the printer cover closed.
W01	Tray Open	The Tray is open during a Self Check operation.	Close the Tray. If you still get the message after you close the Tray, contact your vendor or LifeSign Customer Support.
W02	No Printer Paper	There is no printer paper or the printer cover is open.	Make sure the printer paper is correctly placed with the printer cover closed.
W03	Printer Open	The printer cover is open.	Close the printer cover.
W04	Low Battery Power	The reader is in battery operation mode and the remaining battery level is too low.	Replace the batteries.
W11	DATABASE OVER 90 PERCENT FULL PLEASE DELETE UNNECESSARY DATA USING THE SUPERVISOR MENU	Patient Result storage is over 90% full.	To ignore and continue, press [Enter]. To go to the Supervisor Menu and delete results, press [Menu].
W12	DATABASE FULL 10 PERCENT OF OLDEST DATA WILL BE DELETED... PRESS [Prev Page] TO CANCEL	Patient Result database is full.	Pressing [Enter] will delete the oldest 10% of the records. Press [Prev Page] to cancel test deletion and return to the previous screen. Note: some data must be deleted in order to run a new test.
W13	Lot information for XXXXXXXX is not found. Insert the Data Chip and select [OK].	Lot Number entered is not found in the reader database.	Insert the Data Chip that was supplied with the test kit and select YES to load the new lot information.

<b>Error Code</b>	<b>Message/Problem</b>	<b>Probable Cause</b>	<b>Corrective Action</b>
WI4	External QC is required.	The lot number entered is either a new lot number or it has been 30 days since its last External QC.	Select RUN NOW to run the external QC, or select later to skip the External QC for now and continue with the test.
WI5	DEVICE NOT CHANGED	Before reading a test device, the reader checks whether the operator changed the device for the next test. The reader detected that the operator did not change the device.	Open the Tray, and check whether the correct device is inserted, then close the tray. Press [Enter] to retry.
WI6	Calibration QC is required.	More than 24 hours have elapsed since the last calibration.	Insert the Calibrator and select [CALIBRATE].
WI7	There is a pending test. Please wait for...	The scheduler ensures that there is at least 1 minute and 30 seconds between each test. The test you tried to enter to the scheduler overlaps with the 1 minute and 30 second buffer.	Wait for the time indicated and then continue running the test normally.
	There is a blinking S in the upper right corner of the screen.	The daily Self Check is required.	Run Self Check from RUN QC.
	There is a blinking C in the upper right corner of the screen.	The daily Calibration QC is required.	Run Calibration QC from RUN QC.
	Keypad is frozen	One or more keys are stuck, so that no keys respond to the touch of the operator.	Check all keys to make sure none are stuck. One stuck key can "freeze" all of the keys on the keypad.
	No Power	Power Cable is disconnected or bad and batteries are dead or missing.	Plug in or replace Power Cable and/or replace batteries.
	Printer does not print.	Paper is inserted incorrectly or printer cover is open.	Open printer cover and reset paper, then close printer cover and try again. Make sure the Eject button is fully lifted.
	Barcode scanner does not work	Bad connection to the reader	Turn off the power, then check barcode scanner cable connection on back of the reader. If the problem persists, use the keypad to enter the lot number, operator and patient ID (case sensitive). Contact your vendor or LifeSign Customer Support for repair.
	Screen appears faint.	Screen display may vary between readers.	Some variation in the screen display is normal. Use the reader under good lighting conditions.
	"BOOT MENU" popup when turn on the reader.	Firmware file is corrupted.	Do not reset the memory. Contact your vendor or LifeSign Customer Support.

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# 7. Maintenance

## Cleaning:

- ◆ To clean stains on the outer case or LCD screen, lightly rub the stained area with a soft cloth dipped in a neutral detergent or alcohol.
- ◆ Never use highly volatile material such as benzenes, acetone or paint thinner to clean the reader or any of its components.
- ◆ To clean or disinfect the tray, soak it in alcohol. Only the black tray pocket is autoclavable; do not autoclave the tray frame (white) or any other parts.
- ◆ Make sure the Calibrator is free of scratches or dust. If the Calibrator is damaged or the interfering substance cannot be removed, contact your vendor or LifeSign Customer Support for a replacement.
- ◆ Keep the Tray closed when not in use, to prevent excessive dust and debris from entering the reader.

## Servicing:

There are no user-serviceable parts inside the reader. Refer all servicing to your vendor or LifeSign Customer Support. In the U.S.A. and Canada, call 1 (800) 526-2125; outside of the U.S.A. and Canada, call 1 (732) 246-3366.

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## 8. Frequently Asked Questions (FAQs)

### **Is the DXpress™ Reader CLIA Waived or Moderately Complex?**

The CLIA status of the **DXpress™ Reader** is undetermined at this time. The CLIA status of a test performed is dictated by the type of test used with the instrument. Please consult the test device's package insert for additional details.

### **Can I use other tests not manufactured by LifeSign?**

The **DXpress™ Reader** is designed to perform properly only with products manufactured according to standards developed by LifeSign and PBM. There may be tests other than LifeSign- or PBM-labeled products that are certified for use with the **DXpress™ Reader**; contact LifeSign Customer Support for more information.

### **What types of batteries are recommended for the DXpress™ Reader?**

Only alkaline batteries are recommended. The reader uses 6 x 1.5V AA batteries. Insert with the correct polarity.

### **Can I run the test without using the Data Chip?**

The Data Chip corresponding to the lot number is required to produce accurate quantitative results. The Data Chip contains a lot-specific calibration profile and is required just once for each new lot of quantitative tests. You may not need the Data Chip (particularly for qualitative (positive/negative) tests). The reader will prompt you to insert the Data Chip.

### **The reader database is full. How do I free up some memory?**

Delete results from the Supervisor Menu ► Delete Results (see Section 4.5.5). Ensure you have recorded results.

### **My barcode scanner beeps when I press the button, but nothing appears on the reader screen.**

Contact your vendor or LifeSign Customer Support.

### **While the reader is operating in battery mode, I can not print the results.**

Printing is not available while operating in battery mode. Please connect to AC power for printing. All of the results are still stored in the memory.

### **Time and date displayed on the reader screen are not correct. Time and date displayed on the screen do not change when I change time and date through the Supervisor menu.**

Internal system board battery needs to be replaced. Reader operation is not otherwise affected; only the time and date information will be incorrect. Contact your vendor or LifeSign Customer Support to replace the battery.

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