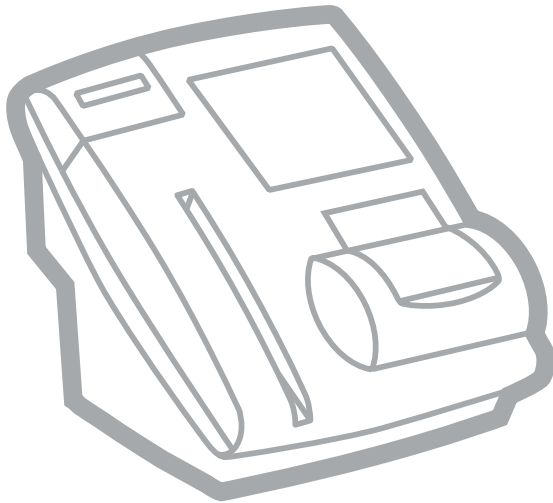


DCA Vantage™

Analyzer

DCA Vantage™ Analyzer

Operator's Guide



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SIEMENS

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If the DCA Vantage™ analyzer is used in a manner differently than specified by Siemens, the protection provided by the equipment may be impaired. Observe all warning and hazard statements.

DCA Vantage Operator's Guide

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Using this Guide




The *DCA Vantage Operator's Guide* provides information for physician's office and laboratory professionals who use the DCA Vantage system.

The following table describes how this manual is organized.

If you want to . . .	then refer to . . .
learn about the system principles, the hardware, and the operating sequence,	Section 1, <i>Overview</i> .
process samples and manage sample results,	Section 2, <i>Operating the System</i> .
learn about calibration and how to print the calibration status,	Section 3, <i>Calibration</i> .
process Quality Control samples,	Section 4, <i>Quality Control</i> .
perform maintenance activities,	Section 5, <i>Maintenance</i> .
investigate and correct system problems,	Section 6, <i>Troubleshooting</i> .
learn about file management,	Section 7, <i>File Management</i> .
install the system or modify system parameters,	Section 8, <i>System Configuration</i> .
review additional information, such as the glossary or the supplies list,	appendices.

Conventions

The *DCA Vantage Operator's Guide* uses the following text and symbol conventions:

Convention	Description
 BIOHAZARD	Biohazard statements alert you to potentially biohazardous conditions.
 WARNING	Warning statements alert you to conditions that may cause personal injury.
 CAUTION	Caution statements alert you to conditions that may cause product damage or loss of data.

Convention	Description
NOTE:	Note statements alert you to important information that requires your attention.
Bold	<p>Bold type indicates text or icons on the user interface. For example, if the word save appears as Save, it refers to the Save key on the user interface.</p> <p>System icons are also indicated by words in bold type. For example, the words Next Screen refer to a system icon.</p> <p>A complete list of system icons and their equivalents is in Appendix D, <i>Symbols</i>.</p>
<i>Italic</i>	Italic type refers to the title of a document or a section title in this manual.

1 Overview

Intended Use

The DCA Vantage is a semi-automated, benchtop system. It is designed to quantitatively measure the percent of Hemoglobin A_{1c} in blood and low concentrations of albumin in urine (microalbuminuria), creatinine in urine, and the albumin/creatinine ratio in urine.

The DCA Vantage system is intended for professional use in a physician's office or hospital laboratory. Tests performed using the DCA Vantage system are intended for *in vitro* diagnostic use. As with all diagnostic tests, do not base a definitive diagnosis on the results of a single test. A physician should make a diagnosis after all clinical and laboratory findings are evaluated.



Figure 1 DCA Vantage System

The system is a spectrophotometer that analyzes the intensity of the light transmitted through the cartridge optical window and reports the results in clinically meaningful units. No calculations are required by the user. When an operator swipes a calibration card, the barcode reader reads the card and the system automatically performs the calibration.

Hardware Overview

User Interface

By default, interaction with the DCA Vantage system is via an integrated touchscreen. Messages, options, and requests for information display, and responses are made by selecting the appropriate key symbol on the screen.



CAUTION

Do not use anything hard or pointed on the touchscreen. It may damage the screen.

You can also use a handheld barcode reader to enter certain information into the system.

The DCA Vantage system user interface is divided into the following 3 modules:

- Test Sequences
- Recall
- System

Testing and Printing Areas

All testing takes place at the DCA Vantage system.

The DCA Vantage system consists of 4 functional areas: the reagent cartridge compartment, the onboard barcode reader, the display screen, and the printer.

The barcode reader is used to calibrate the system and scan the reagent cartridges and control cards. The reagent cartridges are placed in the reagent cartridge compartment where the tests are run, and when testing is complete, an internal thermal printer prints the test results.



Figure 2 User Interface, Testing, and Printing Areas

- 1 Onboard Barcode Reader
- 2 Printer
- 3 Display Screen
- 4 Reagent Cartridge Compartment

Connections and Power

The power cord is connected into the power cord receptacle. Turn the system on by pressing the power switch to the on position. You can connect a Universal Serial Bus (USB) flash memory drive, a printer, an ethernet device, and a handheld barcode reader to the system using the interface connectors.

Memory

The operating system, the system software, the test data, and the system settings for the DCA Vantage system are stored in an onboard (non-removable) flash memory. You can insert a USB Flash memory drive into the system's USB port during the Back up sequence. You can then insert the USB memory drive into another DCA Vantage system and restore the data to the new system.

You can transfer patient data from one DCA Vantage system to another using the software backup and restore sequences in system settings, refer to *System Configuration*, page 125.

NOTE: You cannot import data from a spreadsheet into a DCA Vantage system.



Figure 3 Power Connection, Power Switch, and Connections

- 1 Connections
- 2 Power Switch
- 3 Power Cord

Software Overview

The DCA Vantage system provides an easy-to-navigate and intuitive user interface. When the system is not in use for more than 30 minutes, the Power Save Mode automatically turns on. Touch any location on the screen to resume operation.

Screen Components

The DCA Vantage system software screens use a consistent layout.

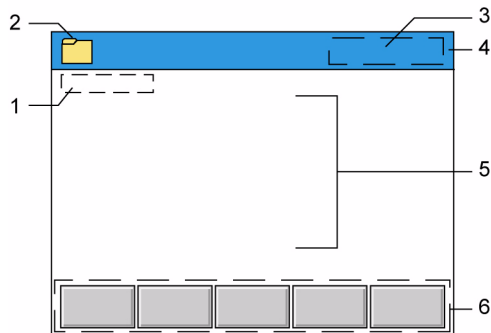


Figure 4 Screen Components

- 1 Screen Title
- 2 Module Icon and Title
- 3 Time and Date
- 4 Title Bar
- 5 Content Area
- 6 Navigation and Contextual Help Button Area

Some options require that you enter information. If selected, a numeric keypad or an alphanumeric keypad displays. An onboard barcode reader is included and reads only barcodes of DCA cartridges and calibration cards.

NOTE: The DCA Vantage system does not support the connection of an external computer keyboard or a mouse to enter data.

Refer to Appendix D, *Symbols*, for a complete list of key symbols used on the DCA Vantage system.

2 **Operating the System**

You can leave the DCA Vantage system on always, except during maintenance and cleaning procedures.

Turning the system off

To save power, you can turn the system off when it is not in use.

1. At the Home screen, select **Turn Off**.
A message displays asking if you want to shut down the system.
2. To shut down the system, select **Yes**.
3. Turn the power switch to the off position when the system shut down is complete.

Overview

You can test blood for the percent concentration of HbA_{1c}, and urine for concentrations of microalbumin and creatinine. Results are available in 6 or 7 minutes.

NOTE: You can use DCA 2000 and DCA 2000+ cartridges on the DCA Vantage analyzer.

Using the Home Screen

The Home screen displays after the DCA Vantage system completes its initialization, refer to *System Configuration*, page 125. The Home screen displays the state of the system and is the starting point for Patient and Control Test Sequences.

If the system is in the Not Ready state and you cannot initiate a Patient or Control Test Sequence, an alert message displays explaining why the system is not ready. If the system is in the Ready state, you can start a patient test and scan either an HbA_{1c} or a Microalbumin/Creatinine test cartridge.

You can access the Recall menu and the System menu from the Home screen.

Notifications or error messages display at the Home screen and provide you with information about the state of the DCA Vantage system.

Viewing Events Notification

An Event Notification window displays at the Home screen when a maintenance task is due, an error event occurs, or a required or optical control test notification is posted.

1. At the Home screen, select **Events**.
The Events List screen displays the information about the notification.
2. Use the up and down arrows to scroll through the notifications.
3. To return to the Home screen, select **Back**.

NOTE: The Events Notification window closes after you clear all events.

System Settings Wizard

The System Settings Wizard is displayed the first time you turn the DCA Vantage system on. The wizard automatically displays the screens that are frequently used to set user preferences. Follow the instructions at the System Settings Wizard screen to set your system preferences.

NOTE: You can access the System Settings Wizard after the initial setup.

Accessing the System Settings Wizard

1. Select **System Settings** from the System menu.
The Settings menu displays.
2. Select **Additional Settings** from the Settings menu.
The General Settings menu displays.
3. Select **Settings Wizard**.
The System Settings Wizard runs the next time the system is turned on.

Test Sequences

The following sections explain the test sequences you can perform using the DCA Vantage system.

Hemoglobin A_{1c}

The following section explains the test sequence for an HbA_{1c} test.

Preparing Patient Samples and Controls for Hemoglobin A_{1c} Test

Materials Required:

- DCA 2000® or DCA Systems Hemoglobin A_{1c} Reagent Kit (for use with the DCA Vantage system)
- Patient sample
- Control Kit or other control
- Lint-free tissue
- Clock or timer

For information on preparing controls, refer to *Quality Control*, page 83.

For information on calibrating, refer to *Calibrating for Hemoglobin A_{1c}*, page 79.

Opening the Foil Package



CAUTION

Do not use scissors to cut open the foil package. Scissors can damage the reagent cartridge, the flexible plastic pull-tab on the cartridge, or the desiccant bag.

1. Remove one foil package (containing a reagent cartridge) from storage. For more information, see *Recommended Procedures for Handling Reagent Cartridges* in the DCA Systems Hemoglobin A_{1c} Reagent Kit package insert for instructions on how and when to open the foil package.
2. Open the foil package.



Figure 5 Opening Reagent Cartridge Package

3. Remove the contents of the package.

Inspecting the Contents of the Foil Package

The foil package includes the contents displayed below:



CAUTION

When handling the reagent cartridge, do not touch or otherwise contaminate the optical window or erroneous test results may occur.



Figure 6 DCA Systems Hemoglobin A_{1c} Reagent Cartridge Package

- 1 Flexible Pull Tab
- 2 Reagent Cartridge
- 3 Desiccant bag
- 4 Optical Window

Discard the reagent cartridge if any of the following conditions exist:

- The cartridge is damaged.
- The flexible pull-tab is loose or missing.
- The desiccant bag is missing or open.
- Loose desiccant particles are found inside the foil package.
- If the foil package is open for more than 60 minutes.

Performing a DCA Hemoglobin A_{1c} Test



BIOHAZARD

Wear personal protective equipment, including safety glasses and gloves. Use universal precautions. Refer to *Safety Information*, page 131, for recommended precautions when working with biohazardous materials.

NOTE: You can save unused capillary holders and use them with any lot of DCA Hemoglobin A_{1c} reagent cartridges.

1. Open the plastic wrap of the capillary holder by tearing the wrap at the serrated edge with the arrow.
2. Inspect the capillary holder for the presence of the following parts:
 - absorbent pad
 - glass capillary
 - latching mechanism

If the capillary holder is missing any of the above parts, discard the capillary holder.

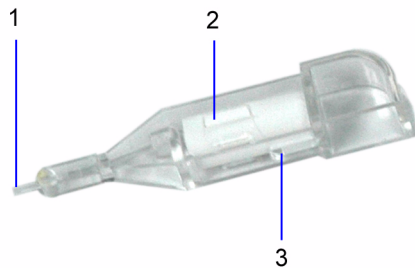


Figure 7 Capillary Holder

- 1 Glass Capillary
- 2 Absorbent Pad
- 3 Latching Mechanism

Filling the Capillary with Whole Blood

When the capillary is filled with the sample, analysis must begin within 5 minutes.

Filling the Glass Capillary with Blood from Finger Stick

1. Hold the capillary holder at an angle.

2. Touch only the tip of the capillary to a small drop of blood on the finger until the capillary fills.

NOTE: 1 μL of blood is required to fill the capillary.

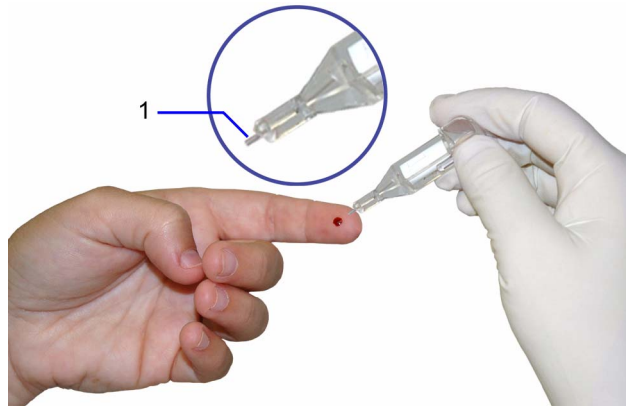


Figure 8 Filling capillary holder with blood from finger stick

1 Glass Capillary Tip

Filling Glass Capillary with Blood obtained by Venipuncture:

1. Mix the sample well (by inversion or use of a tube mixer) to prevent separation of red blood cells and plasma.
2. Remove stopper from blood collection tube in such a way that a small sample of blood remains on the stopper.
3. Hold the capillary holder at an angle.
4. Touch only the tip of the capillary to the blood sample on the stopper.

NOTE: Do not attempt to fill the capillary by touching the glass capillary to blood in a blood collection tube. Attempting to fill the capillary in this manner most often results in blood touching the capillary holder. If blood touches the capillary holder, discard the capillary holder.

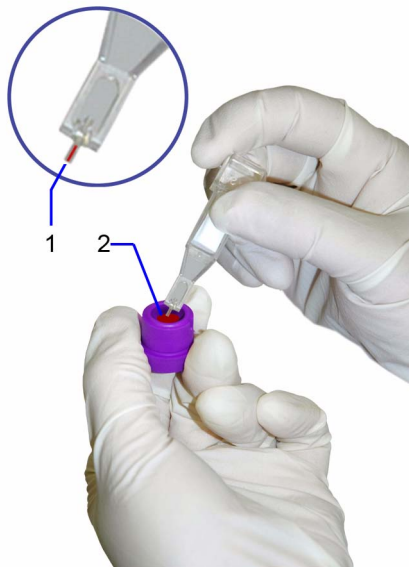


Figure 9 Filling capillary with blood from venipuncture

- 1 Glass Capillary Tip
 - 2 Blood Sample
-

5. Using a lint-free tissue, carefully wipe the outside of the glass capillary.

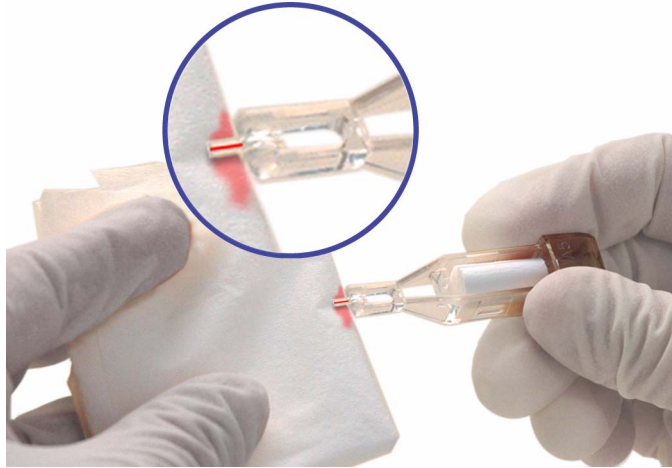


Figure 10 Wiping outside of the glass capillary

NOTE: Do not allow the tissue to touch the open end of the glass capillary. Contact with the open end of the capillary could result in loss of sample (by wicking into the tissue). If sample loss is obvious, discard the capillary holder: Repeat the procedure using a new capillary holder.

6. Inspect the glass capillary for the presence of bubbles.
If bubbles are obvious, discard the capillary holder and repeat the procedure using a new capillary holder.

Inserting Capillary Holder into Reagent Cartridge



CAUTION

Avoid harsh insertion of the capillary holder. Do not dislodge the sample from the glass capillary or erroneous results may occur.

1. Carefully insert the capillary holder into the reagent cartridge until the holder gently snaps into place.



Figure 11 Inserting capillary holder into a reagent cartridge

Scanning the Reagent Cartridge

1. Locate the dot (on the system) next to the barcode track.
2. Locate the barcode on the reagent cartridge.
3. Hold the reagent cartridge so that the barcode faces to the right.
4. Insert the reagent cartridge (above dot) into the barcode track.

5. Quickly and smoothly, slide the reagent cartridge down.

A beep sounds to signal a successful scan.

NOTE: If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to *Troubleshooting*, page 107.



Figure 12 Scanning the reagent cartridge

Inserting the Reagent Cartridge into the System

1. Open the cartridge compartment door.
2. Hold the reagent cartridge so that the barcode faces to the right.
3. Insert the reagent cartridge into the cartridge compartment until a gentle snap is heard or felt.

NOTE: The cartridge is designed to fit only one way into the system. Do not force the cartridge into system.



Figure 13 Inserting the reagent cartridge into the cartridge compartment

4. Using a smooth, slow, continuous motion, pull the flexible pull-tab completely out of the reagent cartridge.
 5. Close the door and dispose of the flexible pull-tab.
Five seconds after the door is closed, a beep sounds and the assay begins.
- NOTE:** If you accidentally close the door before you pull the flexible plastic tab, you have 5 seconds to re-open the door and pull the tab.

Entering Sample Data

The Sample Data menu screen displays when the system detects the system door closes, and indicates a test is in progress after the 5-second delay.

NOTE: You can only enter data during the test if you have configured to enable data entry. For more information, see *Setting Patient Data Entry*, page 56.

You can enter the following sample demographic information:

- Sample ID
 - Patient ID
 - Last Name
 - First Name
1. Select **Sample ID**.
The Sample ID screen displays.
 2. Enter the **Sample ID**.
 3. Select **Enter**.
The Sample ID displays next to the Sample ID button.
 4. Select **Patient ID**.
The Patient ID screen displays.
 5. Enter the **Patient ID**.
 6. Select **Enter**.
The Patient ID displays next to the Patient ID button.
 7. Select **Last Name**.
The Last Name screen displays.
 8. Select **First Name**.
The First Name screen displays.
 9. Select **Comments 1-8**.
The Comment(s) screen display.
 10. Select **User ID**.
The User ID screen displays.

NOTE: If GFR is configured you can calculate the GFR. For more information, see *Setting the GFR calculation*, page 59.

Reporting Ranges and References

The Result screen displays when the system finishes analyzing the sample. This screen displays result values and demographics for each test. You can edit the sample demographics and comments at the Sample Data screen, and you can print the result.

Results of an HbA_{1c} Test

The system displays the following information for each patient HbA_{1c} test.

NOTE: You have to enable some of the data entries in System Settings. For more information, see *Setting Patient Data Entry*, page 56.

Result	Description
System Serial Number	The serial number of the DCA Vantage system.
Test Name	The type of test, either Microalbumin/Creatinine test or HbA _{1c} test.
Sample Sequence Number	The sample sequence number.
Sample ID	The sample ID, if you entered one into the system.
Cartridge Lot Number	The lot number of the cartridge.
Test Cartridge Scan Date and Time	The date and time the test cartridge was scanned.
Patient ID	The patient ID, if you entered one into the system.
Patient Last Name	The last name of the patient, if you entered one into the system.
Patient First Name	The first name of the patient, if you entered one into the system.
UserID	The UserID, if you entered one into the system.
Comments 1 – 8	Any comments you entered regarding the patient.
Glomerular Filtration Rate (GFR) and input data items	The GFR is displayed if calculated.
HbA _{1c} %	The percentage of HbA _{1c} .
Algorithm	The %HbA _{1c} algorithm method name (only if mono-S)
User correction slope and offset	The user correction slope and offset if one is applied to %HbA _{1c} .

Result details

The HbA_{1c} Test displays the Hemoglobin A_{1c} percent. The reporting range for patient samples is 2.5% to 14.0% HbA_{1c} and for control samples is 2.5% to 16.0% HbA_{1c}. The test is linear throughout the range.

A result preceded by a less than (<) sign in the display indicates that the concentration is below the lower limit of the test, that is <2.5%.

A result preceded by a greater than (>) sign in the display indicates that the concentration is above the upper limit of the test, that is >14.0% for patient samples and >16.0% for control samples.

If you set the Reference Range for the HbA_{1c} Patient Test at 3.5% to 12%, a value of 3.2% is displayed as "3.2% -" showing that it is within the Reporting Range but below the Reference Range. Similarly a value of 12.5% is displayed as "12.5% +" showing that it is within the Reporting Range but above the Reference Range. A value of 5.2% is displayed as "5.2%" because it is within both the Reference and Reporting Ranges.

NOTE: You can print, enter, or edit the sample data while the results are displayed.

To print the results, select **Next**.

NOTE: The results only print automatically when the system is set to autoprnt. For more information, see *Printers Menu*, page 68.

To print manually, select **Print**.

NOTE: If the print button is not enabled, then the printer is disabled in setup, or there is no paper.

Removing the Reagent Cartridge

1. Open the cartridge compartment door.
2. Locate the button on the right side of the cartridge compartment.
3. Push and hold it down with your right hand.
4. With your left hand, gently push the tab on the cartridge to the right.
This action releases (unlocks) the cartridge.



Figure 14 Removing the reagent cartridge

5. Pull the reagent cartridge out of the compartment.
6. Close the system door.
7. Discard the cartridge in a proper container, according to your standard laboratory procedures.

Canceling a test

You can cancel a test anytime.

To cancel a test, select **Cancel**.

NOTE: If a test in progress is cancelled, you must discard the sample.

Managing the Printer Paper

The printer stops printing when it runs out of paper. If no paper is available at the start of printing, the printer does not attempt to print.

Microalbumin/Creatinine Test

The following sections explain the test sequence for a Microalbumin/Creatinine test.

Preparing Patient Samples and Controls for the Microalbumin/Creatinine Test

Materials Required:

- DCA 2000 or DCA Systems Microalbumin/Creatinine Reagent Kit (For use with the DCA Vantage system)
- Patient Sample
- Creatinine Control Kit or other control
- Lint-free tissue

For information on preparing controls, refer to *Quality Control*, page 83.

For information on calibrating, refer to *Calibrating for Microalbumin/Creatinine*, page 81.

Opening the foil package



CAUTION

Do not use scissors to cut open foil package. Scissors can damage the reagent cartridge, the flexible pull-tab on the cartridge or the desiccant bag.

1. Remove one foil package (containing a reagent cartridge) from storage.
For more information see *Recommended Procedures for Handling Reagent Cartridges* in the DCA Systems Microalbumin/Creatinine Reagent Kit package insert.

2. Open the foil package.
3. Remove the contents from the package.

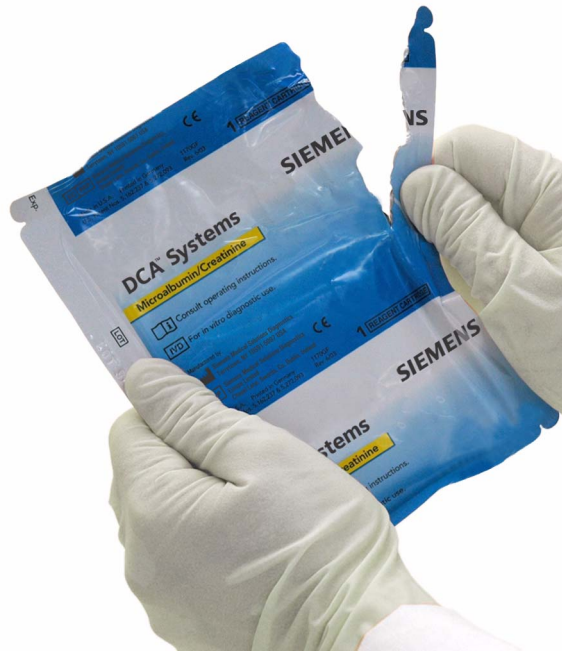


Figure 15 Opening a reagent cartridge package

Inspecting the contents of the foil package

The foil package includes the following contents:



CAUTION

When handling the reagent cartridge, do not touch or otherwise contaminate the optical window or erroneous test results may occur.



Figure 16 DCA Systems Microalbumin/Creatinine Reagent Cartridge

- 1 Flexible Pull Tab
- 2 Reagent Cartridge
- 3 Desiccant Bag
- 4 Optical Window

Discard the reagent cartridge if any of the following conditions exist:

- the cartridge is damaged
- the flexible pull-tab is loose or missing
- the desiccant bag is missing or open
- loose desiccant particles are found inside the foil package

Performing a DCA Microalbumin/Creatinine Test



BIOHAZARD

Wear personal protective equipment, including safety glasses and gloves. Use universal precautions. Refer to *Safety Information*, page 131 for recommended precautions when working with biohazardous materials.

You can save unused capillary holders and use them with any lot of DCA Systems Microalbumin/Creatinine reagent cartridges.

1. Remove a capillary holder and a plunger from the plastic bag.
2. Inspect the capillary holder for the presence of the parts (figure 17).

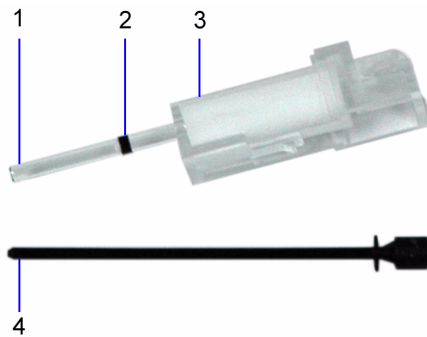


Figure 17 Capillary holder

- 1 Glass Capillary
- 2 Starch Plug
- 3 Absorbent Material
- 4 Plunger

If the capillary holder is missing any of the above parts, discard the capillary holder; also discard it if the starch plug is at the bottom of the capillary tube.

Filling the Capillary Tube with Urine from a Container with a Large Sample Volume

1. Immerse the tip of the capillary tube in the urine sample.
2. Allow enough time for the urine sample to flow into the capillary tube and come in contact with the starch plug, approximately 5 seconds.
Wetting the starch plug seals the capillary tube and keeps the urine within the tube.
3. Remove the capillary tube from the urine sample.
If the urine flows back down the tube, re-immerses the capillary tube in the urine sample again, and allow enough time to ensure that the starch plug becomes saturated.



Figure 18 Filling the capillary with urine

1 Starch Plug

Filling the Capillary Tube with Urine from a Container with a Small Sample Volume

1. Immerse the tip of the capillary tube in the urine sample.

NOTE: 40 μL is required to fill the capillary.

2. Tilt the sample container and the capillary holder to a more horizontal position to increase the rate of flow into the capillary.

Take care not to spill the urine sample.

3. Allow enough time for the urine specimen to flow into the capillary tube and come in contact with the starch plug.

Wetting the starch plug seals the capillary tube and keeps the urine within the tube.

4. Remove the capillary tube from the urine specimen.

If the urine flows back down the tube, re-immerses the capillary tube in the urine specimen again, and allow enough time to ensure that the starch plug becomes saturated.

5. Using a lint-free tissue, carefully wipe the outside of the glass capillary tube.



Figure 19 Wiping the outside of the glass capillary tube

NOTE: Do not allow the tissue to touch the open end of the glass capillary. Contact with the open end of the capillary tube could result in loss of sample (by wicking into the tissue). If sample loss is obvious, discard the capillary holder; then repeat the procedure using a new capillary holder.

6. Inspect the glass capillary tube for the presence of bubbles.
If bubbles are obvious, discard the capillary holder; then repeat the procedure using a new capillary holder.

Inserting the Capillary Holder into Reagent Cartridge

1. Carefully insert the capillary holder into the reagent cartridge until the holder gently snaps into place.



CAUTION

Avoid harsh insertion of the capillary holder. Do not dislodge the sample from the glass capillary or erroneous results may occur.



Figure 20 Inserting the capillary holder into reagent cartridge

Scanning the Reagent Cartridge

1. Locate the dot (on the system) next to the barcode track.
2. Locate the barcode on the reagent cartridge.
3. Hold the reagent cartridge so that the barcode faces to the right.
4. Insert the reagent cartridge (above dot) into the barcode track.
5. Quickly and smoothly, slide the reagent cartridge down.
NOTE: After a 1 second pause a beep sounds to signal a successful scan. If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to *Troubleshooting*, page 107.



Figure 21 Scanning the reagent cartridge

Inserting the Reagent Cartridge into System

1. Open the reagent cartridge compartment door.
2. Hold the reagent cartridge so that the barcode faces to the right.
3. Insert the reagent cartridge into the cartridge compartment until you hear a gentle snap.

NOTE: The cartridge is designed to fit only one way into the system. Do not force the cartridge into the system.



Figure 22 Inserting reagent cartridge into system

4. Insert the plunger into the hole at the top of capillary holder.
5. Depress the plunger into the capillary holder.
The plunger locks into the capillary holder.

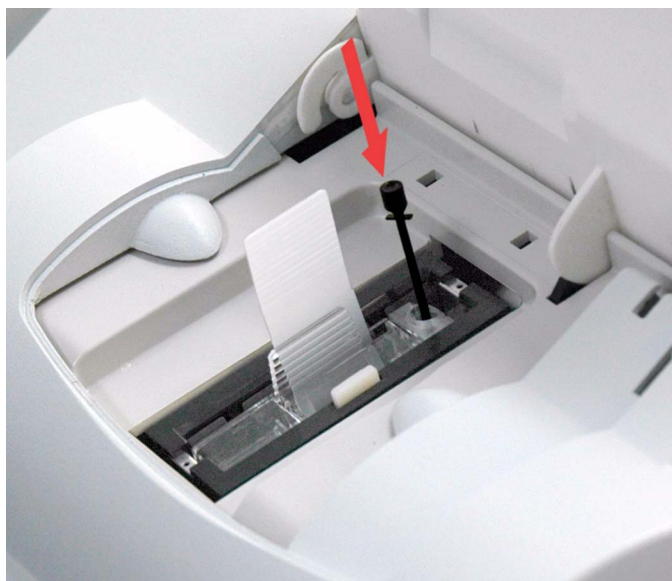


Figure 23 Inserting plunger into capillary

6. Using a smooth, slow, continuous motion, pull the flexible pull-tab completely out of the reagent cartridge.
 7. Close door and dispose of the flexible pull-tab.
Five seconds after the door is closed, a beep sounds and the assay begins.
- NOTE:** If you accidentally close the door before you pull the flexible tab, you have 5 seconds to re-open the door and pull the tab.

Results of a Microalbumin/Creatinine Test

The system displays the following information for each patient Microalbumin/Creatinine test.

NOTE: You have to enable some of the data entries in System Settings.

Result	Description
System Serial Number	The serial number of the DCA Vantage system.
Test Name	The type of test, either Microalbumin/Creatinine test or HbA _{1c} test.
Sample Sequence Number	The sample sequence number.
Sample ID	The sample ID, if you entered one into the system.
Cartridge Lot Number	The lot number of the cartridge.
Test Cartridge Scan Date and Time	The the date and time the test cartridge was scanned.
Patient ID	The patient ID, if you entered one into the system.
Patient Last Name	The last name of the patient, if you entered one into the system.
Patient First Name	The first name of the patient, if you entered one into the system.
UserID	The UserID, if you entered one into the system.
Comments 1 – 8	Any comments you entered regarding the patient.
Glomerular Filtration Rate (GFR) and input data items	The GFR is displayed if calculated.
Albumin concentration results	The albumin concentration results are displayed in units of mg/L.
Creatinine concentration results	The Creatinine concentration results are displayed in mg/dL or mmol/L.
Albumin/Creatinine ratio	The Albumin/Creatinine ratio results are displayed in mg/g units if Creatinine units are mg/dL, or in mg/mmol if creatinine units are mmol/L.
Albumin user correction slope and offset	The Albumin user correction slope and offset are displayed.

Result	Description
Creatinine user correction slope and offset	The Creatinine user correction slope and offset are displayed.

Result Details

The Microalbumin/Creatinine test displays 3 values, the Albumin concentration, the Creatinine concentration, and the Albumin/Creatinine ratio. Both the albumin and creatinine tests are linear throughout their ranges.

NOTE: If there is an asterisk next to the result percent, this indicates that the results were user corrected.

The following table displays the reporting range for each test.

Test	Reporting Range
Albumin	5 to 300 mg/L
Creatinine	15 to 500 mg/dL (1.3 to 44.2 mmol/L)
Albumin/Creatinine ratio	1 to 2000 mg/g (0.1 to 22.6 mg/mmol)

NOTE: If creatinine units are mg/dL, then the Albumin/Creatinine (A/C) ratio is reported as mg/g. If the creatinine units are mmol/L, then the Albumin/Creatinine (A/C) ratio is reported as mg/mmol.

An albumin or creatinine value preceded by a less than sign (<) in the display, indicates that the concentration is below the lower limit of the test, that is less than <5 mg/L for albumin or <15 mg/dL for creatinine.

An albumin or creatinine value preceded by a greater than sign (>) in the display, indicates that the concentration is above the upper reporting limit of the test, that is >300 mg/L for albumin and >500 mg/dL for creatinine.

An Albumin/Creatinine ratio preceded by a less than (<) sign or greater than (>) sign or (---) in the display, indicates that either the albumin and/or creatinine value is above or below the Reporting Range. In certain cases, no ratio is reported (---).

Example 1: If the albumin result is >300 mg/L and the creatinine result is 100 mg/dL (8.84 mmol/L), the ratio is reported as >300 mg/g (>33.9 mg/mmol).

Example 2: If the albumin result is 75 mg/L and the creatinine result is <15 mg/dL (<1.33 mmol/L), the ratio is reported as >500 mg/g (>56.4 mg/mmol).

Example 3: if the albumin result is >300 mg/L and the creatinine result is >500 mg/dL (>44.2 mmol/L), no ratio is reported (---).

Example 4: if the albumin result is <5 mg/L and the creatinine result is <15 mg/dL (<1.33 mmol/L), no ratio is reported (---).

As with HbA_{1c} Patient Tests, you can configure Reference Ranges for Albumin and Creatinine concentrations and the Albumin/Creatinine ratio for Patient Tests. Values above or below the Reference Range limits, but within the Reporting, are followed by the applicable plus (+) or minus (-) sign.

NOTE: You can print, enter, or edit the sample data while the results are displayed.

To print the results, select **Next**.

NOTE: The results only print when the system is set to autoprnt.

To print manually, select **Print**.

NOTE: If the print button is not enabled, then the printer is disabled in setup, or there is no paper.

Removing the Reagent Cartridge

1. Open the cartridge compartment door.
2. Locate the button on the right side of the cartridge compartment.
3. Push and hold it down with your right hand.
4. With your left hand, gently push the tab on the cartridge to the right.
This action releases (unlocks) cartridge.

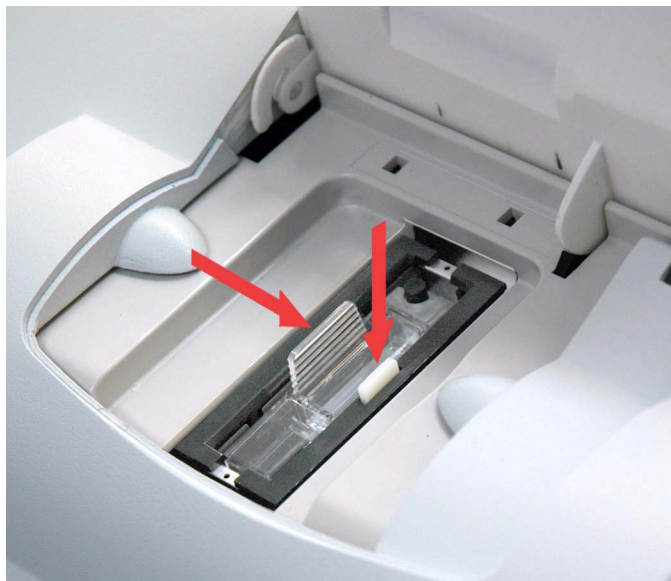


Figure 24 Removing the reagent cartridge

5. Pull cartridge out of compartment.

6. Close the system door.
7. Discard cartridge in proper container, according to your standard laboratory procedures.

Cancelling a test

You can cancel a test anytime.

NOTE: If a test in progress is cancelled, you must discard the sample.

Managing the Printer Paper

The printer stops printing when it runs out of paper. If no paper is available at the start of printing, the printer does not attempt to print.

Recall Menu

The Recall Menu is used to access patient tests, control tests, and calibration data. You can restrict edit and delete functionality to the Recall menu in System Settings, refer to *System Settings*, page 54.

NOTE: The default security setting is set to **Off**.

Accessing Patient Tests

Use the Patient Tests menu to access data for HbA_{1c} or Microalbumin/Creatinine test, or to export data to an external storage device via the USB port.

1. From the Home screen, select **Recall**.
The Recall screen displays.
2. From the Recall menu, select **Patient Tests**.
The Patient Tests menu displays.

NOTE: Use the percent (%) as the wildcard term for searching.

Patient Tests

Use the HbA_{1c} Patient Tests screen and the Microalbumin/Creatinine Patient Tests screens to view the last 10 test results, search for specific results, or graph a patient's HbA_{1c} results.

NOTE: If there is an asterisk next to the result percent, this indicates that the results were user corrected.

Viewing the Last 10 Patient Tests

Use the Last 10 Patient Test screens for HbA_{1c} and Microalbumin/Creatinine to view the last 10 test results performed at the system. The sort order starts with the most recent test performed.

1. From the Home screen, select **Recall**.
The Recall screen displays.
2. From the Recall menu, select **Patient Tests**.
The Patient Tests menu displays.
3. Select one of the following types of patient tests:
 - To view HbA_{1c} patient test results, select **HbA1c**.
 - To view microalbumin/creatinine patient test results, select **Microalbumin/Creatinine**.
4. Select **View Last 10**.
The last 10 patient tests display.
5. Delete a patient test, if needed:
 - a. Select the test.
 - b. Select **Delete**.
A message displays verifying that you want to delete the patient test result.
 - c. Select **OK**.
6. Delete all of the last 10 patient tests, if needed:
 - a. Select **Delete All**.
A message displays verifying that you want to delete all of the last 10 patient tests.
 - b. Select **OK**.

Searching for a Patient ID or Name

Use the Patient ID/Name screen to search by either patient ID number or name.

1. From the Home screen, select **Recall**.
The Recall screen displays.
2. From the Recall menu, select **Patient Tests**.
The Patient Tests menu displays.
3. Search for one of the following:
 - To search for patient ID or name for an HbA_{1c} patient test result, select **HbA1c**.
 - To search for patient ID or name for a microalbumin/creatinine patient test result, select **Microalbumin/Creatinine**.
4. Select **Patient ID/Name**.
The Patient ID/Name screen displays.
5. Enter the patient ID or the patient name that you want to find.

6. Select **Next**.
The search results display.
7. Delete a patient test, if needed:
 - a. Select the test.
 - b. Select **Delete**.
A message displays verifying that you want to delete the patient test result.
 - c. Select **OK**.
8. Delete all of the patient tests, if needed:
 - a. Select **Delete All**.
A message displays verifying that you want to delete all the patient tests.
NOTE: Only the tests that are recalled in the search are deleted.
 - b. Select **OK**.

Searching for a Specific Comment

Use the Comment 1 screen to search for a specific comment.

1. At the Home screen, select **Recall**.
The Recall screen displays.
2. From the Recall menu, select **Patient Tests**.
The Patient Tests menu displays.
3. Search for one of the following:
 - To search for a specific comment for an HbA_{1c} patient test result, select **HbA1c**.
 - To search for a specific comment for a microalbumin/creatinine patient test result, select **Microalbumin/Creatinine**.
4. Select **Comment 1**.
The Comment 1 screen displays.
5. Enter the comment using the keypad.
6. Select **Next**.
The search results display.

Searching within a Specific Date Range

Use the Start Date and End Date screens to set the start and end dates when you want to search by a specific date range.

1. At the Home screen, select **Recall**.
The Recall screen displays.

2. From the Recall menu, select **Patient Tests**.
The Patient Tests menu displays.
3. Search for one of the following:
 - To search within a specific date range for an HbA_{1c} patient test result, select **HbA1c**.
 - To search within a specific date range for a microalbumin/creatinine patient test result, select **Microalbumin/Creatinine**.
4. Select **Date Range**.
The Start Date screen displays.
5. Use the up and down arrows to select the Month, Day, and Year.
6. Select **Next**.
The End Date screen displays.
7. Use the up and down arrows to select the Month, Day, and Year.
8. Select **Next**.
The search results display.
9. To delete a patient test highlight the test.
10. Select **Delete**.
A message displays verifying that you want to delete the patient tests.
11. Select **OK**.
12. To delete all the patient tests select **Delete All**.
A message displays verifying that you want to delete all the patient tests.
NOTE: Only the tests that are recalled in the search are deleted.
13. Select **OK**.

Setting a Lower HbA_{1c} Value for a Search

Use the Set Lower Limit screen to set the lower HbA_{1c} value when you search by result range.

1. At the Home screen, select **Recall**.
The Recall screen displays.
2. From the Recall menu, select **Patient Tests**.
The Patient Tests menu displays.
3. Select **HbA1c**.
The HbA1c Patient Test screen displays.
4. Select **Result Range**.
The Lower Limit screen displays.

5. Use the up and down arrows to set a HbA_{1c} value.

NOTE:The lower limit cannot be lower than 2.0%.

6. Select **Next**.
The search results display.

Viewing the HbA_{1c} Results in Graph Format

You can view the HbA_{1c} test results in a graph format. You can search by patient ID or last name, and then narrow the search by using a date range.

1. At the Home screen, select **Recall**.
The Recall screen displays.
2. From the Recall menu, select **Patient Tests**.
The Patient Tests menu displays.
3. Select **HbA1c**.
The HbA1c Patient test List screen displays.
4. Select **Graph**.
5. Use the keypad to enter a Patient ID.
6. Select **Next**.
All HbA_{1c} results that match the patient ID are graphed.
7. To change the graph date range, select **Change**.
8. To print the graph, select **Print**.

Viewing Patient Test Results

Use the Patient Test Result screen to view information about a specific patient.

1. At the Home screen, select **Recall**.
The Recall screen displays.
2. From the Recall menu, select **Patient Tests**.
The Patient Tests menu displays.
3. Select one of the following:
 - To view patient results for an HbA_{1c} patient test result, select **HbA1c**.
 - To view patient results for an microalbumin/creatinine patient test result, select **Microalbumin/Creatinine**.
4. Select **View Last 10 Patient Tests**.
NOTE:You can view patient result from any search finding.

5. At the Last 10 Patient Tests screen, select the patient and select **View** or one of the Search findings screen.
The Patient Test Result screen displays.
6. To print a copy of the patient results, select **Print**.
7. To send the data to a target computer, select **Send**.
8. To edit the patient test results, select **Edit**.

Selecting a Printer

If an external printer is connected to the DCA Vantage system, use the Printer Selection screen to select an onboard or external printer.

NOTE: This screen only displays when both printers are configured and ready to print.

1. At the Patient Test Result screen, select **Print**.
The Printer Selection screen displays.
2. Select one of the following printer options:
 - Onboard Printer
 - External Printer
3. To print the patient test results, select **Print**.
The patient test results print.

Exporting Data



CAUTION

When you export data that contains patient information, it is your responsibility to comply with your local procedure on HIPAA regulations.



CAUTION

Use a separate external storage device for each individual DCA Vantage analyzer, or archive the data onto another media before you export data from another DCA Vantage analyzer onto the external storage device.

Use the Export Data screen to export files to an external storage device.

1. At the Home screen, select **Recall**.
The Recall screen displays.

2. From the Recall menu, select **Patient Tests**.
The Patient Tests menu displays.
3. From the Patient Tests screen, select **Export**.
4. Insert the storage device into the USB port.
5. To export the files, select **Next**.
The files are exported.
6. When the system directs you, remove the storage device from the USB port.

Using the GFR Wizard

Use the GFR wizard to enter patient information to calculate the GFR for the patient.

1. Select **GFR**.
The GFR wizard displays.
2. Enter the following data, which calculates the GFR for the patient:
 - a. Select the 2-digit age value for the patient.
The patient age range is between 18 and 70.
 - b. Select **Next**.
 - c. Select the Gender of the patient.
 - d. Select **Next**.
 - e. Select the Race of the patient.
 - f. Select **Next**.
 - g. Select the Plasma Creatinine value.
 - h. Select **Next**.
The GFR Calculation results screen displays the GFR value calculated from the information entered at the GFR calculation wizard.

System Menu

Use the System Menu to access Control Tests, System Maintenance, System Settings, and System Tests. You can also schedule and change the configuration of control tests.

For information on system maintenance, refer to *Maintenance*, page 89.

Control Tests

Use the Control Test screen to perform the following tasks:

- specifying the data entered when a control test is run
- viewing the control test log and schedule

- modifying the control test reminder schedule
- enabling or disabling the use of other manufacturer controls

Control Test Data Entry

Use the Control Test Data entry screen to specify if the User ID and Comments 1 through 3 are displayed as required or optional during data entry for control tests.

Control Test Reminders

Use the Control Test Reminders screen to access the Control Test Log where you can view and change the schedule for Control Tests.

Control Test Status

Use the Control Test Status screen to view a list of the current status of required and optional control tests.

Required Control Test

You must perform required control tests when they are scheduled. Patient test is disabled until the required control is performed and passed.

Optional Control Test

You can perform optional control tests when they are scheduled. Patient tests are not disabled when an optional control test is due.

Setting Control Test Data Entry

Use the Control Test Data Entry screen to specify the data and comments you enter when you run a control test, and what data is required or optional. Only the data you select as optional displays. If you select *Required*, you have to enter a value for that specific data before you can exit the screen.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings screen displays.
2. Select **Control Tests**.
The Control Tests screen displays.
3. Select **Data Entry**.
The Control Sample Data Entry screen displays.
4. Select either **Display** or **Required** for each of the following options:
 - User ID
 - Comments 1 - 3
5. To save the settings, select **Save**.

Setting Control Test Reminders

Use the Control Test Reminders screen to access the Control Test Log, and to view or change the schedule for the control tests. The default setting is that none of the Control Test Reminders are selected. After you select the check box for a specific reminder, *Schedule* becomes active.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings screen displays.
2. Select **Control Tests**.
The Control Tests screen displays.
3. Select **Reminders**.
The Control Test Reminders screen displays.
4. To set a control test reminder, select the check box.
The control test reminder is set and the schedule becomes active.
5. To view the schedule, select **Schedule**.
The reminder schedule displays.
6. To change the schedule to optional or required, select **Change**.
The Mode screen displays.
7. Select **Optional** or **Required**.
8. Select **Next**.
The Frequency screen displays.
9. Select one of the following options:
 - Daily
 - Weekly
 - Monthly
10. Select **Next**.
The Control Test Reminder Day screen displays.
11. Use the up and down arrows to select the day or date of the reminder.
12. Select **Next**.
The Control Test Reminder Time screen displays.
13. Use the up and down arrows to select the time of the reminder.
14. Select **Next**.
The Control Test Reminder Information screen displays.
15. Review the data, then select **Save**.
16. To return to the Control Test menu, select **Back**

Setting Other Manufacturer Controls

Use the Other Manufacturer screen to enable the use of other manufacturers' control materials.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. Select **Control Tests**.
The Control Tests screen displays.
3. Select **Other Manufacturer**.
The Other Manufacturer Control screen displays.
4. To allow the use of other manufacturers' controls, select the check box.
5. To save the setting, select **Save**.

System Tests

You or your technical support provider can use the System Test menu screen to perform tests on the DCA Vantage system. The System Test menu screen includes the following 3 types of System Tests:

- User System Tests
- Service System Tests
NOTE: Service System Tests are performed by your technical support provider.
- Optical Tests

NOTE: If the system is set to restricted, to access System Tests you must enter a valid Supervisor ID, refer to *Supervisor ID*, page 55.

Performing User System Tests

The User System Tests screen allows you to test different parts of the system.

1. At the System Menu screen, select **System Tests**.
The System Tests screen displays.
2. From the System Test menu, select **User System Tests**.
3. Select the check box of the test you want to perform.
4. To initiate the test, select **Start**.
The tests that require no additional action automatically run.

NOTE: The tests that require additional action run first.

The following table explains the different tests you can perform, and if they require additional action:

If you select..	then...
Touchscreen	Select each numbered key. The key changes from a number to a check mark. If a section fails, the number remains. NOTE: The test times out if all the buttons are not selected within 60 seconds.
Sound	<ol style="list-style-type: none"> 1. Listen for an alert sound. 2. If you hear an alert sound, select Yes. 3. If you do not hear an alert sound, select No.
Door	Open and close the door to verify that the screen reflects the status of either the open or closed state.
Onboard Barcode Reader	Scan a DCA barcode with the onboard barcode reader to verify that the onboard barcode reader works properly.
External Barcode Reader	Scan a DCA barcode with the external barcode reader to verify that the external barcode reader works properly.
Onboard Printer	Verify that the onboard printer prints a report.
External Printer	Verify that the external printer prints a report.
Serial Port	The system automatically runs the test.
Ethernet Port	The system automatically runs the test.
USB Port	The system automatically runs the test.
Lamp	The system automatically runs the test.
Motor Sequence	The system automatically runs the test.
Measurement System	The system automatically runs the test.

User System Test Results

The User System Test Results screen displays the status of each system test you selected at the User System Test menu screen. The results display after the tests that require user action are complete and while the automatic tests are running on the system.

NOTE: You can cancel the tests while they are running.

System Settings

Use the System Settings menu to set and review the following system settings:

- change the sound volume
- adjust the contrast of the display
- access additional settings for the system
- view the current setting for the system

NOTE: You have to restart the system if you restore system settings.

Setting the Sound Volume

Use the Sound Volume setting to set the volume of the audible alerts.

1. At the System menu, select **System Settings**.
The System Settings screen displays.
2. Select **Sound Volume**.
The Sound Volume screen displays.
3. Select one of the following options:
 - High
 - Medium
 - Low
 - Off
4. Select **Save**.
The sound volume is set.

Setting the System Display

Use the System Display screen to set the contrast of the color display.

1. At the System menu, select **System Settings**.
The System Settings screen displays.
2. Select **Display**.
The Display screen displays.
3. Use the up and down arrows to adjust the contrast of the color display.
4. Select **Save**.
The system display is set.

Viewing the Current System Settings

1. At the System menu, select **System Settings**.
The System Settings screen displays.
2. Select **View Settings**.
The View Settings screen displays the current settings.
3. To print the current setting, select **Print**.

Supervisor ID

The Supervisor ID screen is set up by the supervisor as a security measure to access the Additional Settings menu. The Supervisor ID screen displays when the system access is set to restricted. If you try to edit or delete the data when the system is set to restricted, the Supervisor ID screen displays.

You can add a maximum of 15 supervisor IDs. The supervisor ID can include letters or numbers. The maximum number of characters for supervisor IDs is 7.

After you enter the supervisor ID, the Additional Settings menu displays. For more information about access restrictions, contact your local technical support provider. To add, edit, or delete a Supervisor ID, refer to *Supervisor List*, page 60.

Additional Settings

The Additional Settings menu enables users to change settings and functionality of the system.

Patient Tests

Use the Patient Tests menu to access the screens that specify the data you enter with patient tests, and to view what factors control how some patient test results are calculated.

Setting Patient Data Entry

Use the Patient Data Entry screen to specify the data and comments you enter when you run a patient test, and what data is required or enabled. Only the data you select as enabled displays. If you select required, you have to enter a value for that specific data before you can exit the screen.

1. At the Additional Settings menu, select **Patient Tests**.
The Patient Tests screen displays.
2. Select **Data Entry**.
The Patient Data Entry screen displays.
3. Select either **Enabled** or **Required** for each of the following options:
 - Sample ID
 - Patient ID
 - Last Name
 - First Name
 - User ID
 - Comments 1 – 8
4. To save the settings, select **Save**.

Setting Urine Creatinine Units

Use the Creatinine Units screen to set the units for creatinine results to either mg/dL or mmol/L.

1. At the Additional Settings menu, select **Patient Tests**.
The Patient Tests screen displays.
2. Select **Creatinine Units**.
The Select Creatinine Units screen displays.
3. Select one following unit options:
 - mg/dL
 - mmol/L
4. To save the creatinine unit setting, select **Save**.

Setting the HbA_{1c} Reference Range

Use the Reference Range screen to specify the upper and lower reference range values for HbA_{1c} results.

NOTE: You cannot set the lower limit higher than the upper limit, or allow a difference of less than 0.5% between the upper and lower limits.

1. At the Additional Settings menu, select **Patient Tests**.
The Patient Tests screen displays.
2. Select **Reference Range**.
The HbA1c Reference Range screen displays.
3. Use the up and down arrows to set the upper and lower limits.
4. To set the reference range to the default values, select **Reset Default Values**.
This resets the Lower % to 4.0 and the Upper % to 6.0.
5. To save the HbA_{1c} reference range, select **Save**.
The range is saved.

Setting the HbA_{1c} User Correction

Use the HbA_{1c} User Correction screen to adjust the slope and the offset for HbA_{1c} values.

If results are within the instrument operating range and a user correction is applied, the corrected results are reported with an asterisk (*). Corrected results are not saved in the DCA system memory. Only the original, uncorrected results are saved. Saved data when recalled is displayed as uncorrected if no correction is set in the system, or if a correction is set in the DCA system that correction is applied.

1. Select **Patient Tests** from the Additional Settings menu.
The Patient Tests screen displays.
2. Select **HbA1c User Correction**.
The HbA1c User Correction screen displays.
3. Change the slope, if needed:
 - a. Select **Edit**.
The HbA1c Slope screen displays.
 - b. Enter the slope.
 - c. Select **Enter**.
The HbA1c User Correction screen displays.
4. Change the offset, if needed:
 - a. Select **Edit**.
The HbA1c Offset screen displays.
 - b. Enter the offset.
 - c. Select **Enter**.
The HbA1c User Correction Screen displays.

5. To reset the settings to the default values, select **Reset Default Values**.
This resets the slope to 1.000 and the offset to 0.0.
6. Select **Back**.
The Patient Tests screen displays.

Setting the Albumin User Correction

Use the Albumin User Correction screen to adjust the slope and the offset for Albumin values.

Corrected results are marked with an asterisk (*). Corrected results outside the operating range are reported the same way uncorrected results outside the operating range are reported. Corrected results are not saved in the system memory, only the original, uncorrected results are saved. If a correction is applied, saved data is displayed as uncorrected if no correction is set in the system when it is recalled, or the correction that is currently set in the system is applied.

1. At the Additional Settings menu, select **Patient Tests**.
The Patient Tests screen displays.
2. Select **Albumin User Correction**.
The Albumin User Correction screen displays.
3. Change the slope, if needed:
 - a. Select **Edit**.
The Albumin Slope screen displays.
 - b. Enter the slope.
 - c. Select **Enter**.
The Albumin User Correction screen displays.
4. Change the offset, if needed:
 - a. Select **Edit**.
The Albumin Offset screen displays.
 - b. Enter the offset.
 - c. Select **Enter**.
The Albumin User Correction Screen displays.
5. To reset the settings to the default values, select **Reset Default Values**.
This resets the slope to 1.000 and the offset to 0.0.
6. Select **Back**.
The Patient Tests screen displays.

Setting the Creatinine User Correction

Use the Creatinine User Correction screen to adjust the slope and the offset for creatinine values.

1. At the Additional Settings menu, select **Patient Tests**.
The Patient Tests screen displays.
2. Select **Creatinine User Correction**.
The Creatinine User Correction screen displays.
3. Change the slope, if needed:
 - a. Select **Edit**.
The Creatinine Slope screen displays.
 - b. Enter the slope.
 - c. Select **Enter**.
The Creatinine User Correction screen displays.
4. Change the offset, if needed:
 - a. Select **Edit**.
The Creatinine Offset screen displays.
 - b. Enter the offset.
 - c. Select **Enter**.
The Creatinine User Correction Screen displays.
5. To reset the settings to the default values, select **Reset Default Values**.
This resets the slope to 1.000 and the offset to 0.0.
6. Select **Back**.
The Patient Tests screen displays.

Setting the GFR calculation

Use the GFR Calculation screen to turn the GFR Calculation on or off, and to select the unit of measurement for plasma creatinine.

1. At the Additional Settings menu, select **Patient Tests**.
The Patient Tests screen displays.
2. Select **GFR Calculation**.
The GFR Calculation screen displays.
3. Select one of the following options under GFR Calculation:
 - Enabled
 - Disabled
4. Select one of the following units under Creatinine Units:
 - mg/dL

- mmol/L
5. To save the GFR Calculation settings, select **Save**.

Setting the Patient Recall List Options

Use the Patient Recall List Options screen to set the search criteria for patient results, and how the results are displayed. You can search by either patient ID or last name.

1. At the Additional Settings menu, select **Patient Tests**.
The Patient Tests screen displays.
2. At the Patient Tests menu, select **Patient Recall List Options**.
The Patient Recall List Options screen displays.
3. Select one of the following options:
 - Patient ID
 - Patient Last Name
4. To save the settings, select **Save**.

Control Tests

For information on control tests, refer to *Quality Control*, page 83.

Supervisor List

Use the Supervisor List screen to add, edit, and delete supervisors. Use a different ID and name for each supervisor.

NOTE: The ID is required, and the name is optional.

Adding a Supervisor

1. At the System Settings menu, select **Additional Settings**.
The Additional Setting menu displays.
2. Select **General**.
The General menu displays.
3. Select **System Access**.
The System Access menu opens.
4. Select **Unrestricted**.
The Supervisor button is enabled.
5. Select **Supervisor**.
6. Select **Add**.
The Edit Supervisor screen displays.

7. To add a name select **Edit** to the right of the Name field.
8. Use the alphanumeric keypad to enter a Supervisor Name in the Name field.
9. Select **Enter**.
The supervisor name is saved.
10. To add a supervisor ID, select **Edit** to the right of the ID field.
11. Use the alphanumeric keypad to enter a Supervisor ID in the ID field.
12. Select **Enter**.
13. At the Add Supervisor screen, select **Save**.
The supervisor ID is saved.
NOTE: The supervisor ID can include letters and numbers. The maximum number of characters for a supervisor ID is 7.

Editing a Supervisor

1. At the Additional Settings menu, select **Supervisors**.
The Supervisor List screen displays.
2. Highlight the supervisor you want to edit.
3. Select **Edit**.
The Edit Supervisor screen displays.
4. Edit the supervisor ID or the supervisor name.
5. Select **Save**.

Deleting a Supervisor

1. At the Additional Settings menu, select **Supervisors**.
The Supervisors screen displays.
2. Highlight the supervisor ID you want to delete.
3. Select **Delete**.
A message displays verifying that you want to delete the supervisor ID.
4. Select **Yes**.
The supervisor ID is deleted.

General Setting Menu

Use the General Setting menu to access screens that configure the general settings. This determines what displays on the screen while a test is running. General settings include language, time, and data.

Setting the Language

Use the Language screen to change the language that displays on the system.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **General**.
The General menu displays.
3. Select **Language**.
The Select System Language screen displays.
4. Select the language that you want to display on the system.
5. To save the language selection, select **Save**.

Setting the Time Format and Time

Use the Time screen to select if the system displays the time in a 12-hour or 24-hour format, and to set the current time.

NOTE: We recommend that you manually adjust your system clock for daylight savings time in the spring and the fall.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **General**.
The General menu displays.
3. Select **Time**.
The Set System Time screen displays.
4. Select one of the following time formats:
 - 12 hour
 - 24 hour
5. Use the up and down arrows to select the hour and the minutes.
6. Select one of the following options:
 - AM
 - PM

NOTE: You only have this option if you select a 12-hour time format.

7. To save the time setting, select **Save**.

Setting the Date Format and Current Date

Use the Date screen to set the date format and the current date.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **General**.
The General menu displays.
3. Select **Date**.
The System Set Date screen displays.
4. Select one of the following date formats:
 - MM/DD/YYYY
 - DD.MM.YYYY
 - YYYY.MM.DD
5. Use the up and down arrows to select the Month, Day, and Year.
6. To save the date format, select **Save**.

Setting the Sequence Number

Use the Sequence Number screen to specify if the sequence number resets, and if the sequence number displays.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **General**.
The General menu displays.
3. Select **Sequence Number**.
The Select Sequence Number screen displays.
4. Select one of the following sequence number resets:
 - Resets Daily - the sequence number is reset daily
 - Resets after 999 - the sequence number resets after it reaches 999
 - None - no sequence number is set
5. To save the sequence number setting, select **Save**.

System Access

Use the System Access screen to select restricted or unrestricted access to the Recall and System Setting modules. The default setting is unrestricted.

NOTE: If you set the system access to restricted, you have to add a supervisor.

Setting the System Access to Unrestricted

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **General**.
The General menu displays.
3. Select **System Access**.
The Security screen displays.
4. Select **Unrestricted**.
5. To save the system access setting, select **Save**.

Setting the System Access to Restricted

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **General**.
The General menu displays.
3. Select **System Access**.
The Security screen displays.
4. Select **Restricted**.
5. Select **Save**.

Setting a Test Lockout

Use the Test Lockout screen to prevent a user from performing patient tests when the current test type has a control test due. A supervisor can turn off the Patient Test Lockout to unlock the system if a control test did not pass. Use the remote patient lockout function to perform a lockout from a remote computer via the network connection.

NOTE: You can disable the Remote Patient test Lockout setting from the system if you enter the Support ID.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **General**.
The General menu displays.
3. Select **Test Lockout**.
The Test Lockout screen displays.
4. To lockout patient test because of a control failure, select **Patient Test Lockout on Control Test Failure**.

5. To lockout patient tests from a remote computer, select **Remote Patient Test Lockout**.
6. To save the test lockout setting, select **Save**.

System Settings Wizard

Use the System Settings Wizard screen to configure the System Settings Wizard to run the next time you turn the system on.

Setting the System Settings Wizard to run

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **General**.
The General menu displays.
3. Select **Settings Wizard**.
The System Settings Wizard screen displays.
4. To run the wizard the next time you turn the system on, select **Run System Settings Wizard at Next Power on**.
5. To save this setting, select **Save**.

Deleting Patient and Control Test Data

Use the Storage Mode screen to specify how to delete patient and control test data from the system. You can select to automatically delete tests based on a first in, first out basis, or you can manually delete a test.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **General**.
The General menu displays.
3. Select **Storage Mode**.
The Data Storage Mode screen displays.
4. To automatically delete patient and control test data on a first in, first out basis, select **Automatic Deletion (First In, First Out)**.
5. To manually delete patient and control test data, select **Manual Deletion**.
6. To save the storage mode, select **Save**.

Saving Data and Settings

The Save Data and Settings screen instructs you to insert the storage device into the Universal Serial Bus (USB) port. The entire database is copied to the device.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **General**.
The General menu displays.
3. Select **Save Data and Settings**.
The Save Data and Settings screen displays.
4. Insert a storage device into the USB port, then select **Next**.
The data and settings are saved.
5. Remove the storage device from the USB port.

Deleting Data

Use the Delete Data screen to delete all the patient information that associates the patient with the test result, or both the patient information and test results.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **General**.
The General menu displays.
3. Select **Delete Data**.
The Delete Data screen displays.
4. To delete all of the patient information that associates the patient with the test result, select **Delete Patient Information**.
5. Select **Yes**.
All the patient information is deleted.
6. To delete patient information and test results, select **Delete All Patient Data**.
7. Select **Yes**.
All patient information and test data is deleted.

Restoring Data

The Restore Data screen instructs you to insert the storage device with the saved data into the USB port. Restoring data replaces your current patient and control test data with the data from your storage device.

NOTE: Any existing data in the database is replaced by the data on the backup database. If the current database and the backup database versions are different, the backup fails.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.

2. At the Additional Settings menu, select **General**.
The General menu displays.
3. Select **Restore Data**.
The Restore Data screen displays.
4. To start the restoration, select **Next**.
5. Insert a storage device into the USB port, then select **Next**.
The data is restored.
6. Remove the storage device from the USB port.

Restoring Settings

The Restore Settings screen instructs you to insert the storage device with the saved settings into the USB port. The restoring the system settings replaces your current system settings with the settings from your storage device.

NOTE: Any existing setting in the database is replaced by the settings on the backup database. If the current database and the backup database versions are different the backup fails.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **General**.
The General menu displays.
3. Select **Restore Settings**.
4. Insert the storage device into the USB port.
5. To start the restoration, select **Next**.
The data is restored.
6. Remove the storage device from the USB port.

Installing Software

The Install Software screen instructs you to insert the storage device with the software into the USB port. After the installation is complete, you have to restart the system.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **General**.
The General menu displays.

3. Select **Install Software**.

The Install Software screen displays.



CAUTION

Do not remove the storage device from the USB port or turn off the system while the software is installing.

4. Insert the storage device into the USB port.
5. To start installing the software, select **Next**.
The software is saved.
6. To restart the system, select **Restart**.

Printers Menu

Use the Printers menu to perform the following tasks:

- enable/disable the onboard and external printer
- configure the onboard and external printer
- enter a customized report header that displays on printed reports
- reset printer defaults

Setting the Onboard Printer

Use the Onboard Printer screen to perform the following tasks:

- enable the onboard printer
 - disable the onboard printer
 - specify if a report is automatically printed to the onboard printer when the result displays
 - specify the number of copies of the report that you want to print
1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
 2. At the Additional Settings menu, select **Printers**.
The Printers menu displays.
 3. Select **Onboard Printer**.
The Onboard Printer screen displays.
 4. To enable the onboard printer, select **Enable**.
 5. To disable the onboard printer, select **Disable**.
 6. To automatically print the test results, select **Automatically print**.

NOTE: You have to select Enabled to automatically print.

7. Use the up and down arrows to select the number of copies of the report you want to print.
8. To save the onboard printer setting, select **Save**.

Setting the External Printer

Use the External Printer screen to perform the following tasks:

- enable the external printer
- disable the external printer
- specify if a report is automatically printed to the external printer when the result displays
- specify the number of copies of the report that you want to print

NOTE: The DCA Vantage analyzer only supports Printer Command Language (PCL) type printers for external printers. Network printers are not supported.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Printers**.
The Printers menu displays.
3. Select **External Printer**.
The External Printer screen displays.
4. To enable the external printer, select **Enable**.
5. To disable the external printer, select **Disable**.
6. To automatically print the test results, select **Automatically print**.

NOTE: You have to select Enabled to automatically print.

7. Use the up and down arrows to select the number of copies of the report you want to print.
8. To save the external printer setting, select **Save**.

Customizing Printed Report Headers

Use the Report Headers screen to customize printed report headers. You can customize up to 2 lines of text.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Printers**.
The Printers menu displays.

3. Select **Report Headers**.
The Report Headers screen displays.
4. Select **Line1**.
The Line1 screen displays.
5. Use the alphanumeric data entry screen to enter the first line of the customized header.
6. Select **Enter**.
The printer header Line1 displays.
7. Select **Report Header**.
The Report Header screen displays.
8. Select **Line2**.
The Line2 screen displays.
9. Use the alphanumeric data entry screen to enter the second line of the customized header.
10. Select **Enter**.
The printer header Line2 displays.
11. To return to the Printers menu, select **Back**.

Setting the External Barcode Reader

Use the External Barcode screen to enable or disable the external barcode reader. For information on installing the External Barcode reader, refer to *External Barcode Reader*, page 149.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **External Barcode Reader**.
The External Barcode Reader screen displays.
3. To disable the external barcode reader, select **Disabled**.
4. To enable the external barcode reader, select **Enabled**.
5. To save the external barcode reader settings, select **Save**.

Enabling the Serial Port Menu

Use the Serial Port menu to enable and disable the serial port. You can access the screen to select different options for the serial port.

NOTE: The default setting for the serial port is disabled.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.

2. At the Additional Settings menu, select **Serial Ports**.
The Serial Ports menu displays.
3. Select **Enable Serial Port**.
The serial port is enabled.

Setting the Baud Rate

Use the Baud Rate screen to select the baud rate for the serial signal.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Serial Port**.
The Serial Port menu displays.
3. At the Serial Port menu, select **Baud Rate**.
The Baud rate screens displays.
NOTE: You have to enable the serial port to select a baud rate.
4. Select one of the following baud rates:
 - 19200 bps
 - 9600 bps
 - 4800 bps
 - 2400 bps
 - 1200 bps
 - 300 bpsThe default value is 9600 bps.
5. To save the baud rate setting, select **Save**.

Setting the Parity

Use the Parity screen to select the parity for the serial connections.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Serial Port**.
The Serial Port menu displays.
3. Select **Parity** from the Serial Port menu.
The Parity screen displays.
NOTE: You have to enable the serial port to select parity.
4. Select one of the following parity setting:
 - None
 - Even

- Odd

The default value is None.

5. To save the parity setting, select **Save**.

Setting the Data Bits

Use the Data Bits screen to specify the string length of the data bit for the serial connection.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Serial Port**.
The Serial Port menu displays.
3. At the Serial Port menu, select **Data Bits**.
The Data Bits screen displays.
4. Select a string length for the data bits:
 - 8
 - 7The default value is 8.
5. To save the data bits setting, select **Save**.

Setting the Flow Control

Use the Flow Control screen to enable or disable the Xon / Xoff protocol.

NOTE: The default setting for flow control is disabled.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Serial Ports**.
The Serial Ports menu displays.
3. At the Serial Ports menu, select **Flow Control**.
The Flow Control screen displays.
4. To enable Xon / Xoff, select **Xon / Xoff**.
5. To disable Xon / Xoff, deselect **Xon / Xoff**.
6. To save the flow control setting, select **Save**.

Ethernet Port menu

Use the Ethernet Port menu to access the system setting that you have to configure for ethernet communication.

Enabling the Ethernet Port (RJ 45)

Use the Ethernet Port menu to enable and disable the ethernet port. You can access the screen to select different options for the Ethernet port.

NOTE: The default setting for the ethernet port is disabled.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Ethernet Port**.
The Ethernet Port menu displays.
3. Select **Enable Ethernet Port**.
The ethernet port is enabled.

Setting the Host Name

Use the Host Name screen to enter the alphanumeric name used to identify the DCA Vantage system on the network.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Ethernet Port**.
The Ethernet Port menu displays.
3. At the Ethernet Port menu, select **Host Name**.
The Host Name screen displays.
4. Use the alphanumeric keypad to enter the host name.
5. To save the host name, select **Enter**.

Setting the IP Address to Automatic or Static Mode

Use the IP Setting screen to set the IP address to automatic or static.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Ethernet Port**.
The Ethernet Port menu displays.
3. At the Ethernet Port menu, select **Automatic IP Setting**.
The IP Setting screen displays.
4. Select one of the following IP address settings:
 - Automatic (DHCP)
 - Static
5. To save the IP setting, select **Save**.

Setting the IP Address

Use the IP Address screen to enter the static IP address for the ethernet port. If you select a static IP address, you have to select the following settings:

- IP Address
 - Subnet Mask
 - DNS
 - Default Gateway
 - Remote Computer
1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
 2. At the Additional Settings menu, select **Ethernet Port**.
The Ethernet Port menu displays.
 3. At the Ethernet Port menu, select **IP Address**.
The IP Address screen displays.
NOTE: You have to set the static IP setting to Static IP.
 4. Use the alphanumeric keypad to enter the IP address.
 5. To save the IP address, select **Enter**.

Setting the Port Number

Use the Port Number screen to enter the port number for the system.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Ethernet Port**.
The Ethernet Port menu displays.
3. At the Ethernet Port menu, select **Port Number**.
4. Use the numeric keypad to enter the Port Number.
5. To save the Port Number, select **Enter**.

Setting the Subnet Mask

Use the Subnet Mask screen to enter the subnet mask for the system.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Ethernet Port**.
The Ethernet Port menu displays.

3. At the Ethernet Port menu, select **Subnet Mask**.
The Subnet Mask screen displays.
4. Use the numeric keypad to enter the subnet mask.
5. To save the subnet mask, select **Enter**.

Entering a Domain Name Server

Use the Domain Name Server (DNS) screen to enter the DNS for the system.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Ethernet Port**.
The Ethernet Port menu displays.
3. Select **Domain Name Server**.
The Domain Name Screen displays.
4. Use the alphanumeric keypad to enter the DNS.
5. To save the DNS, select **Enter**.

Entering the Default Gateway

Use the Default Gateway screen to enter the default gateway for the system.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Ethernet Port**.
The Ethernet Port menu displays.
3. Select **Default Gateway**.
The Default Gateway screen displays.
4. Use the numeric keypad to enter the default gateway.
5. To save the default gateway, select **Enter**.

Setting up the Remote Computer

Use the Remote Computer screen to enter the IP address or host name for the remote computer. After you enter the IP address or host name, you can communicate with the remote computer over the network.

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **Ethernet Port**.
The Ethernet Port menu displays.

3. Select **Remote Computer**.
The Remote Computer screen displays.
4. Use the alphanumeric keypad to enter one of the following for the remote computer:
 - IP address
 - host name
5. To save the remote computer, select **Enter**.

Support ID Entry

Use the Support ID Entry screen to enter the password required to access the algorithm selection screen used in calculating the HbA_{1c} value.

NOTE: To receive a support ID, contact your local technical support provider. The password changes daily.

Setting the HbA_{1c} Algorithm

1. At the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
2. At the Additional Settings menu, select **HbA_{1c} Algorithm Selection**.
The HbA_{1c} Algorithm screen displays.
3. Select one of the following options:
 - Default
 - mono-S
4. To save the algorithm selection, select **Save**.

Patient Test Reports

Patient Test Reports contain the results of HbA_{1c} and Microalbumin/Creatinine tests that you generate during analysis and display at the results screen. You can generate printed reports at analysis time and when print requests are issued at Data Recall. You can also generate a printed report when you perform a Demonstrated Patient Test.

Patient Test Graph Report

The Patient Tests Graph Printed Report only prints on an external printer. If you do not have an external printer attached or configured, you cannot print this report. You can only print this report from Data Recall.

Control Test Report

The Control Test Report prints the results for Control Tests generated during analysis, and displays at the Results screen.

Calibration Data Report

The Calibration Data Report prints the results generated when the HbA_{1c} and Microalbumin/Creatinine cards are scanned into the system. The printed reports for a single cartridge scan is generated when you select print when you scan. Calibration Data Reports for all the calibration data stored on the system print when a request is issued at Data Recall.

NOTE: You have to select **Print** after the calibration card is scanned to print the calibration data report.

System Setting Report - Full

The System Settings Report prints the complete settings configuration for the system.

System Setting Report - Partial

The System Setting Report prints selected settings for the system.

Report Components

The following table explains the components of patient test printed report.

Component	Description
Product Name	The Name of the Product
Heading One	Customized heading 1
Heading Two	Customized heading 2
Report Title	Type of printed report
Print Date and Time	The date and time the report prints
Test Date and Time	The date and time the test is performed
Sequence Number	The sequence number
Sample ID	The sample ID
Patient ID	The patient ID
Patient Last Name	The patient last name
Patient First Name	The patient first name
Test Result Data	The results of the test

Component	Description
GFR	The GFR data
Age	The age of the patient
Gender	The gender of the patient
Race	The race of the patient
Plasma Creatinine	The plasma creatinine value
Comments	The user comments
User ID	The user ID
System Serial Number	The serial number of the system
Cartridge Lot Number	The cartridge lot number
Calibration Scan Date	The calibration date
HbA _{1c} Algorithm	The HbA _{1c} algorithm
User Slope	The user slope
User Offset	The user offset

3 Calibration

Overview

Calibration is performed every time the calibration card is scanned.

Values for reagent calibration parameters are encoded on the calibration card provided with each of the reagent cartridges. Scan the calibration barcode before using the reagent cartridges. The DCA Vantage system stores 16 distinct calibrations for the DCA Vantage Hemoglobin A_{1c} and Microalbumin/Creatinine Assay. Each calibration is for a different lot. Scan the lot number and test name before you analyze the sample reagent cartridge barcode. This allows access to the appropriate calibration parameter values and calibration curve for the particular lot of reagent in use.

NOTE: If you do not scan the calibration curve into the system for the particular lot number of cartridges that are in use, the system software prompts you to scan the calibration card.

Calibrating for Hemoglobin A_{1c}

You must scan the calibration card for a lot of reagent cartridges before you can use the lot on the DCA Vantage system. Scanning the calibration card enters the information on the DCA Vantage system.

1. Locate the dot on the system next to the barcode track.
2. Locate the barcode on the calibration card.
3. Hold the card so that the barcode faces to the right.

Calibration

4. Insert the Calibration card into the top of the barcode track.
5. Hold the Calibration card gently against the right side of the track and smoothly slide the card down.

A beep sounds to signal a successful scan.

NOTE: If no beep sounds, repeat the scanning procedure. If you repeatedly fail to hear a beep, refer to *Troubleshooting*, page 107.



Figure 25 Scanning Hemoglobin A_{1c} calibration card

6. To return to the Home screen, select **OK**.

Calibrating for Microalbumin/Creatinine

The calibration card for the Microalbumin/Creatinine reagent cartridges has data on two sides. You must scan both sides of the calibration card for the lot of reagent cartridges before you can use them on the DCA Vantage system.

1. Locate the dot on next to the barcode track.
2. Locate the barcode on one side of the Calibration card.
3. Hold the card so that the barcode faces to the right.
4. Insert the calibration card into the top of the barcode track.

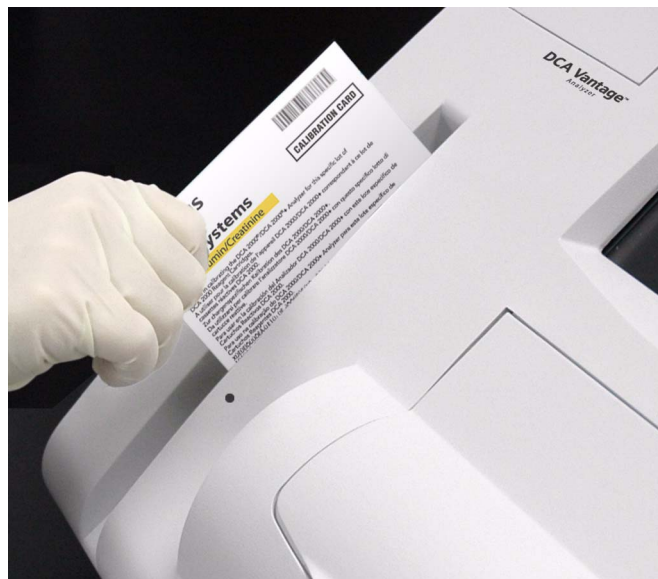


Figure 26 Scanning Microalbumin/Creatinine calibration card

5. Hold the calibration card gently against the right side of the track and smoothly slide the card down.
A beep sounds to signal a successful scan.
If no beep sounds, repeat the scanning procedure. If you repeatedly fail to hear a beep, refer to *Troubleshooting*, page 107.
6. Locate the barcode on the second side of the calibration card.
7. Repeat steps 3 – 5.
8. To return to the Home screen, select **OK**.

Calibration Data

Use the Calibration Data screen to access calibration data including scan date and time, and lot number for DCA HbA_{1c} or Microalbumin/Creatinine.

Viewing calibration data display

1. At the Recall menu, select **Calibration Data**.
The Calibration Data screen displays.
2. Select one of the following options:
 - a. **HbA_{1c}**
The HbA_{1c} calibration data displays.
 - b. **Microalbumin/Creatinine**
The Microalbumin/Creatinine calibration data displays.
3. Highlight the calibration data that you want to display, and select **View**.
The Calibration Data screen displays.
4. To print the calibration data, select **Print**.
5. To return to the Recall menu, select **Recall**.

4 Quality Control

Run controls according to your laboratory's accrediting agency. Quality Control testing provides confidence that the reagent cartridges are reacting and being read correctly. It can also detect errors resulting from user techniques. Refer to your laboratory quality assurance program to ensure quality throughout the entire testing process. Run controls under the following conditions:

- at regular intervals determined by the laboratory procedures
- when using a new shipment of reagents
- when using a new lot number of reagent
- each time a calibration card is scanned
- whenever test results are in doubt
- when training new operators

All control results must be within the acceptable range before any patient sample is tested and the results are reported. If a control result is out of range, troubleshoot the system, correct any problems identified, and run the controls again. When control results are within range, you can test and report on patient samples.

For information about ordering control kits, refer to Appendix C, *Orderable Supplies*.

Collecting Control Specimens

Use the following procedure to collect control specimens:

NOTE: Prepare the controls according to the manufacturer's instructions.

1. Remove and unwrap the capillary holder from the Reagent Kit.
2. Mix the sample well by inversion or using a tube mixer.
3. Open the control bottle.

NOTE: Avoid introducing air bubbles into the sample.

4. While applying pressure to the bulb of the dropper (found in the control kit), insert the tip of the dropper into the control solution.
5. Release the pressure on the bulb to aspirate a small amount of control solution.
6. Fill the glass capillary tube by touching it to the tip of the dropper and fill the tube.

NOTE: Touch only the tip of the capillary tube to the control material. If an air bubble is present in the filled tube, discard the capillary holder and fill a new one.



CAUTION

Prevent the control material from coming in contact with the plastic part of the capillary holder. If control material comes in contact with the capillary holder, discard the capillary holder.

7. Squeeze any excess control material out of the dropper into the control bottle.
8. Close the control bottle.
9. Wipe any control solution off the sides of the glass capillary tube using a lint-free tissue.



CAUTION

Do not touch the tissue to the open end of the tube. Contact with the open end could result in a loss of sample.

10. Inspect the capillary holder for the presence of any bubbles.

NOTE: If bubbles are obvious, discard the capillary and repeat the collecting procedure.

Inserting Capillary Holder into the Reagent Cartridge

1. Place the capillary holder in the correct position to insert it into the reagent cartridge.
2. Insert the capillary holder into the reagent cartridge until the holder gently snaps into place.



CAUTION

Avoid harsh insertion of capillary holder. Do not dislodge the sample in the glass capillary because erroneous results may occur.



Figure 27 Inserting capillary into reagent cartridge

Running a Control

1. Locate the control card.

NOTE: One side of the control card is for a normal control and the other side is for an abnormal control.

2. Locate the dot on the system next to the barcode track.
3. Locate the barcode on the Control card.
4. Hold the card so that the barcode faces to the right.
5. Insert the Control card into the top of the barcode track.
6. Hold the Control card gently against the right side of the track and quickly slide the card down.



Figure 28 Scanning the HbA_{1c} control card

A beep sounds to signal a successful scan.

NOTE: If no beep sounds, repeat the scanning procedure. If you repeatedly fail to hear a beep, refer to *Troubleshooting*, page 107.

To scan the reagent cartridge, refer to *Scanning the Reagent Cartridge*, page 23.

To insert the reagent cartridge, refer to *Inserting the Reagent Cartridge into the System*, page 25.



Figure 29 Scanning the Microalbumin/Creatinine control card

Control Level Selection

Use the control Level Selection screen to run another manufacturer's control sample.

Selecting a control level

1. Select the radio button of the control level you want to run.
2. Select **Next**.

Quality Control Errors

If the control results fall outside the values stated in the package insert, the following sources of error may have occurred:

Possible Cause	Corrective Action
Deterioration of the reagent cartridge test areas due to exposure to light, ambient moisture, or heat.	Use a new reagent cartridge to repeat the quality control procedure. Use a fresh box of reagent cartridges, or a new lot. If the new reagent cartridge fails to give results within the expected values, proceed to the next possible cause.
Deterioration of the control solution.	Use a fresh control solution to repeat the quality control procedure.

For more information, see *Setting Other Manufacturer Controls*, page 52.

5 Maintenance

Maintenance Schedule

Weekly

Cleaning the Barcode Window

Cleaning the Exterior

As Needed

Cleaning the Exterior

Changing the Air Filter

Removing and cleaning the cartridge spring

Quarterly

Removing and cleaning the cartridge spring

Cleaning the Barcode Window

Changing the Air Filter

Running the Optical Test

Running the Optical Test

Calibrating the Touchscreen

Replacing the Fuse

Cleaning the Barcode Window



WARNING

Turn the power off and disconnect the power cord before cleaning the barcode window.

Materials required:

- lint-free cloth
- water or ethanol

1. Clean the barcode window with a lint-free cloth dampened with water or ethanol.



Figure 30 Cleaning the Barcode Window

2. Connect the power cord after the barcode window is clean and dry.

Cleaning the Exterior



WARNING

Turn the power off and disconnect the power cord before cleaning the exterior of the system.



CAUTION

Do not allow liquid to drip into system. If liquid drips into the system, you can damage the optics.

Materials required:

- lint-free cloth
 - water or ethanol
1. Clean the exterior with a lint-free cloth dampened with water or ethanol.
 2. Connect the power cord after the exterior is clean and dry.

NOTE: If you want to disinfect the exterior of the system, expose the surface to 0.5% sodium hypochlorite for 10 minutes. Remove any liquid blood on the system before disinfection.



CAUTION

Do not use any other type of solvent, oil, grease, or silicone spray on any part of the system.

Removing and cleaning the cartridge spring



WARNING

Turn the power off and disconnect the power cord before cleaning the cartridge compartment.



CAUTION

Do not allow liquid to drip into system. If liquid drips into the system, you can damage the optics.



BIOHAZARD

Wear personal protective equipment. Use universal precautions. Refer to *Safety Information*, page 131, for recommended precautions when working with biohazardous materials.

Materials required:

- lint-free cloth
 - water or ethanol
 - paper clip or similar device
 - mild detergent
 - sponge swab
1. Open the cartridge compartment door as far as possible.
 2. Wipe the inside surface of the compartment door and surfaces on both sides of the compartment using a lint-free cloth dampened with water or ethanol.
 3. Dry the surface using a clean, dry, lint-free cloth.

4. Locate the cartridge return spring inside the cartridge holder.
5. Insert the tip of a straightened paper clip (or other like device) into the top hole on the spring.

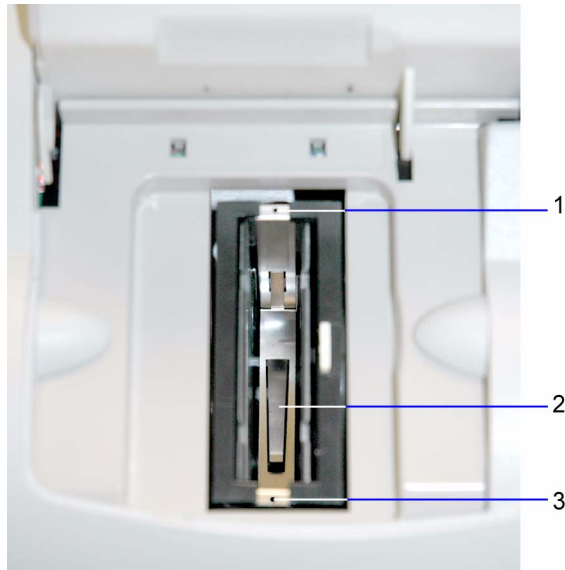


Figure 31 Return Spring in Cartridge Compartment

- 1 Top Hole
- 2 Leaf Spring
- 3 Bottom Hole

-
6. Gently pull the metal end towards the center of the cartridge compartment to release one side of the spring from the cartridge holder.
 7. Repeat step 6 to release the other side of the spring from the cartridge holder.

8. Pull the cartridge return spring completely out of the system.
9. Clean the cartridge return spring using any of the following items:
 - warm solution of mild detergent and water
 - lint-free cloth dampened in water or ethanol

NOTE: Make sure the leaf springs are not bent or damaged while cleaning. Damaged leaf springs do not function properly.

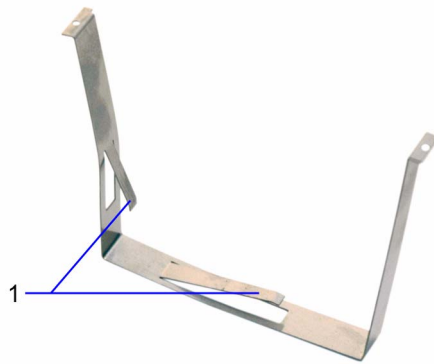


Figure 32 Return Spring

1 Leaf Springs

10. Dry the cartridge return spring with a clean, lint-free cloth.
11. Using a clean, dry, sponge swab (provided in the Cleaning Kit), remove spilled liquid from the cartridge holder.



CAUTION

Do not use a cotton swab. Cotton fibers that are left on the surface can interfere with the system's optical systems.

12. Rotate the cartridge holder with the compartment door partially closed to locate and remove any additional liquid.

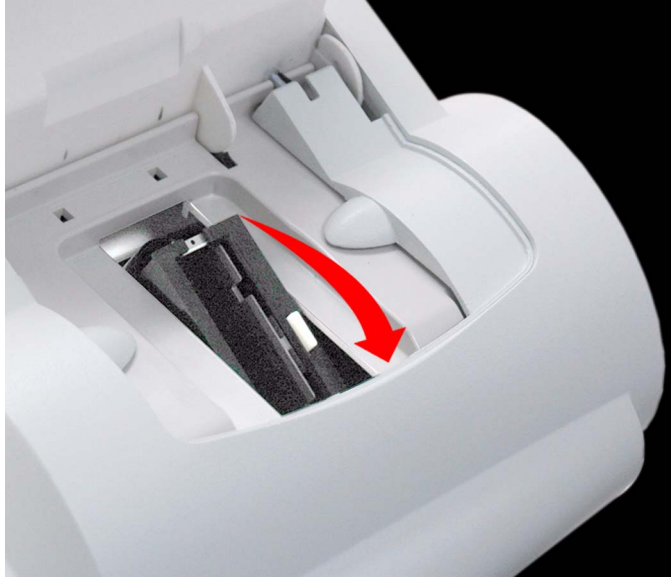


Figure 33 Rotating cartridge compartment

13. Dampen a sponge swab with water or ethanol.
14. Clean the cartridge holder, rotating the cartridge holder as necessary.



CAUTION

Do not allow liquid to drip off of the sponge swab into the system. If liquid drips into the system, you can damage the optics.

15. Locate the vertical grooves inside the cartridge compartment.
16. Locate the front and back slots near the top of the compartment.
17. Locate the leaf spring on one side of the cartridge return spring.
18. With the leaf spring orientated toward the back of the system, complete the following steps to lower the leaf spring into the system:
 - a. Hold on to both sides of the cartridge return spring.
 - b. Pinch the sides together and lower the spring into the system by sliding the sides of the spring between the vertical grooves in the compartment.
 - c. Release the spring.

- d. Gently and carefully push down on the edge of the cartridge return spring and insert the edge into the slot.
- e. Repeat Step c to attach the opposite side of the cartridge return spring to the cartridge compartment.

Changing the Air Filter

Materials required:

- air filter
1. Remove the filter holder from the back of the system:
 - a. Pull the holder off from the top.



Figure 34 Filter location

1 Filter Cover

2. Dispose of the old air filter.
3. Place the new air filter into the filter holder.



Figure 35 Removing the air filter

4. Place the filter holder back on the system.

Running the Optical Test

The optical test cartridge allows you to monitor the performance of the optical system over time. It is recommended that you keep a permanent record of the results obtained, for example, Mean Transmittance, Standard Deviation, and Drift.

NOTE: The optical test cartridge is reusable, do not discard.

Comparing New Values with Initial Values

Compare the new values obtained with the results recorded initially for your system. The Mean Transmittance should be within the range of 0.9500 to 1.0500, and should not vary more than plus or minus 0.0100. The Standard Deviation should be less than 0.0015 and the Drift should be less than 0.0140.

1. Locate the barcode on the optical test cartridge.
2. Hold the cartridge so that the barcode faces right.
3. Insert the cartridge into the barcode track.
4. Quickly and smoothly slide the cartridge down the barcode track.
A beep sounds to signal a successful scan.



Figure 36 Scanning the optical test cartridge

5. Open the cartridge compartment door.
6. Hold the optical test cartridge so that the barcode faces to the right.
7. Insert the cartridge into the compartment until you hear snap.

NOTE: The cartridge is designed to fit one way into the system.



Figure 37 Inserting optical test cartridge into compartment

8. Close the door.
The test runs for 6 minutes.
9. Print the results.
10. Remove the cartridge:
 - a. Open the cartridge compartment door.
 - b. Locate the button on the right side of the cartridge compartment.
 - c. Push and hold it down with your right hand.
 - d. Gently push the plastic tab on the cartridge to the right with your left hand.
This releases the cartridge.
 - e. Pull the cartridge out of the compartment.
11. Compare the results obtained with results obtained initially.

Calibrating the Touchscreen

Calibrate the touchscreen if it does not respond correctly when you touch the screen.

1. At the System Test menu, select **Calibrate Touchscreen**.
2. When the Touchscreen Calibration screen displays, select the **X** target at the center of the screen.
3. Repeat when prompted at each corner.
The Touchscreen Calibration Complete screen displays.

Changing the Paper



CAUTION

Do not touch the printer without observing precautions for handling electrostatic sensitive devices. A risk of electrostatic discharge to the system exists when touching the printer.

1. Ensure the system is at the Home screen.
2. Turn the system so that you are looking at the back.
3. Use the tab to lift the cover off.



WARNING

Be careful when touching the printer. It may be hot.

4. Lift the paper feeder up.
5. Push the plastic paper cover down.
6. Remove the paper roll:
 - a. Lift up the roll.
 - b. Tear the paper between the roll and the printer.
 - c. Remove the core and remaining paper on the roll.

7. Remove any paper remaining in the printer:
 - a. Locate the printer paper release lever.
This lever is colored dark gray and is located on the right of the printer when looking at the front of the system.
 - b. Pinch and lift the front of the lever to raise the paper guide.
 - c. Carefully pull paper through the printer in its normal direction of travel.



Figure 38 Removing the printer paper

- 1 Printer Cover
 - 2 Paper Feeder
-

8. Obtain a new paper roll.
9. Unroll sufficient paper to feed the printer.

10. Hold the roll just above the printer, with the paper unrolling from underneath.
11. Push the paper gently under the roller at the back of the printer.



Figure 39 Inserting paper into the printer

12. Load the paper into the paper feeder.



Figure 40 Loading the paper into the feeder

- 1 Printer Cover
 - 2 Paper Feeder
-

13. Push the plastic tab to cover the paper.

14. Pull the paper feeder down.

15. Pinch and push down on the gray paper release lever to hold the paper in place.

16. Load the paper into the paper slot on the cover.
17. Close the cover.



Figure 41 Closing the cover

Replacing the Fuse

Materials required:

- Flathead Screwdriver
- 250 V, T-1.25 A



CAUTION

Set the power switch to OFF. Disconnect the power cord from the wall outlet. Disconnect the power cord from the system.

1. Locate the groove on the top of the fuse holder.

2. Insert the tip of the screwdriver into the groove.
3. Exert pressure to unsnap the top of the fuse holder.

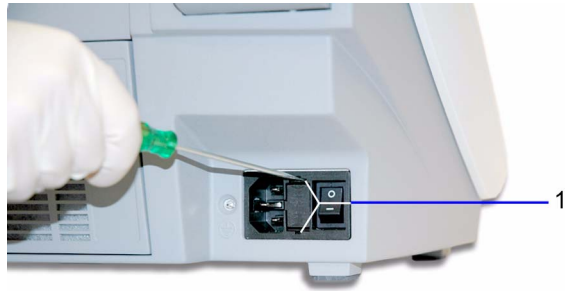


Figure 42 Removing fuse holder

- 1 Top and bottom grooves

4. Repeat step 2 – 3 for the bottom groove.
5. Remove the fuse holder from the system.
6. Remove and dispose of the blown fuse.

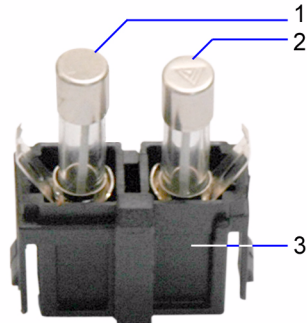


Figure 43 Fuse

- 1 Fuse
- 2 Fuse
- 3 Fuse Block

7. Insert the spare fuse onto the fuse block.
8. Insert the fuse holder into the system.

Viewing System Maintenance Status

Use the System Maintenance Status screen to view the list of maintenance tasks and the status of each task. You can mark a task as completed at this screen, then the task displays at the System Maintenance log screen.

1. At the System Menu screen, select **System Maintenance**.
The System Maintenance Status screen displays with the status of each task.
2. To mark a task as complete select the task.
3. Select **Complete**.

Setting Maintenance Reminders

Use the Maintenance Reminders screen to access the Maintenance Task Log, and to view or change the schedule for the maintenance tasks. The default setting is that none of the Maintenance Reminders are selected. After you select the check box for a specific reminder, Schedule becomes active.

1. At the Additional Settings menu, select **Maintenance**.
The Maintenance Reminders screen displays.
2. To set a maintenance reminder, select the check box.
The maintenance reminder is set and Schedule becomes active.
3. To view the schedule, select **Schedule**.
The Maintenance Schedule displays.
4. To change the schedule, select **Change**.
The Maintenance Reminder Frequency screen displays.
5. Select one of the following frequency options:
 - Daily
 - Weekly
 - Monthly
 - Quarterly
6. Select **Next**.
The Set Maintenance Reminder Day screen displays.
7. Use the up and down arrows to select the day or date of the reminder.
8. Select **Next**.
The Maintenance Reminder Day screen displays.
9. Use the up and down arrows to set the time of the reminder.
NOTE: If a 12-hour clock is configured, you have to select AM or PM.

10. Select **Next**.

The Maintenance Reminder Information screen displays.

11. Select **Save**.

System Maintenance Log

Use the System Maintenance Log screen to view all complete maintenance tasks and to delete all entries from the log.

Viewing the Maintenance Log

1. At the Additional Settings menu, select **Maintenance**.
The Maintenance Reminder screen displays.
2. Select **Log**.
The Maintenance Log screen displays.
3. Use the up and down arrows to view all of the maintenance entries.
4. To delete all maintenance log entries, select **Delete All**.
5. Select **Yes**.
All log entries are deleted.

6 Troubleshooting

General Information

If an operational or system problem occurs, an error code may display on the system screen with an explanation of the problem. This section of the guide lists the various errors and messages, along with a description and corrective actions. If the problem persists, record the error code and contact your local technical service provider for assistance.

If you think DCA cartridges are causing the problem, consult the product insert that comes with the cartridges for troubleshooting information.

If you turn the system off, you must retest the sample that was in process when the error occurred.

With some errors, the system continues to run while the error displays.



CAUTION

Wait at least 15 minutes after the reagent cartridge is removed from the refrigerator to start a test.



CAUTION

Verify that the capillary is completely filled with no air bubbles.

Errors and Corrective Actions

Error Code	Description	Remedy
E10 - Motor position sensor error	The Home/Index sensor failed to detect light to dark or dark to light transitions during a motor homing operation. OR The offset between the home position determined from the Home/Index sensor and the position for the optimum optical signal is greater than +/- 4 half steps.	<ol style="list-style-type: none"> 1. From the User Test menu, perform a Motor test. 2. Run an optical test. 3. If that does not work, then restart the system. 4. Run a motor homing operation. 5. If you are unable to rerun the operation, contact your local technical support provider. <p>NOTE: If test was started discard the sample.</p>
E12 - Motor position error	The wrong number of Home/Index sensor transitions were detected during a motor rotation operation.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Rerun the home operation. 3. Run an optical test. 4. If that does not work, then restart the system. 5. Run a motor homing operation. 6. If you are unable to rerun the operation, contact your local technical support provider.
E20 - Dark offset measurement is out of range	A Dark reading (mean of 16) for a sample or reference channel is outside the acceptance range.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Run an optical test. 3. If you are unable to run an optical test, contact your local technical support provider.
E21 - Lamp Failure	An Air reading for the Sample or Reference channel is too low.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Run an optical test. 3. If you are unable to run an optical test, contact your local technical support provider.

Error Code	Description	Remedy
E22 - Optical reading is out of range	A Sample or Reference channel reading taken during an Air measurement is too high.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Run an optical test. 3. If you are unable to run an optical test, contact your local technical support provider.
E23 - Excessive noise on the Sample channel	The standard deviation of the 16 readings at the Sample channel for Dark or Air reading is too large.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Run an optical test. 3. If you are unable to run an optical test, contact your local technical support provider.
E24 - Excessive noise on the Reference channel	The standard deviation of the 16 readings at the Reference channel for Dark, Air or Sample reading is too large.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Run an optical test. 3. If you are unable to run an optical test, contact your local technical support provider.
E26 - Excessive noise in sample reading	The standard deviation of the 16 readings at the Sample channel during a reading taken is too large in Sample read position.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Run an optical test. 3. If you are unable to run an optical test, contact your local technical support provider.
E27 - Excessive Lamp Drift	The change in mean signal between successive Air readings is too large at either the Sample channel or the Reference channel.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Run an optical test. 3. If you are unable to run an optical test, contact your local technical support provider.
E30 - Thermal control system error - low	The temperature measured by one of the cartridge holder thermistors is $\leq 2^{\circ}\text{C}$.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Restart the system. 3. If you are unable to perform a successful restart, contact your local technical support provider.

Error Code	Description	Remedy
E31 - Cartridge temperature is very low	The temperature measured by one of the cartridge holder thermistors is $<(T_{\text{setpoint}} - 12.9)^{\circ}\text{C}$ while the system is idle, during an Optical Test, during the first 5 minutes of an HbA _{1c} test, or the first 5 minutes of a Microalbumin/Creatinine test.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Contact your technical support provider.
E32 - Cartridge temperature too low during measurement	The temperature measured by one of the cartridge holder thermistors is $\leq(T_{\text{setpoint}} - 0.9)^{\circ}\text{C}$ during critical measurements of a sample test sequence.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Contact your technical support provider.
E33 - Cartridge temperature too high during measurement	The temperature measured by one of the cartridge holder thermistors is $\geq(T_{\text{setpoint}} + 1.1)^{\circ}\text{C}$ during critical measurements of a sample test sequence.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Contact your technical support provider.
E34 - Cartridge temperature very high	The temperature measure by one of the cartridge holder thermistors is $\geq(T_{\text{setpoint}} + 2.1)^{\circ}\text{C}$.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Contact your technical support provider.
E35 - Thermal control system error - high	The temperature measure by one of the cartridge holder thermistors is $\geq 50^{\circ}\text{C}$.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Restart the system. 3. If you are unable to perform a successful restart, contact your local technical support provider.

Error Code	Description	Remedy
E36 - Temperature control failure	Ten minutes after you start the system the cartridge temperature has not reached the operating range of $(T_{\text{setpoint}} - 13.2)^{\circ}\text{C} < T < (T_{\text{setpoint}} + 1.8)^{\circ}\text{C}$, or the cartridge temperature remains outside the same operating range for more than 10 minutes.	Contact your technical support provider.
E37 - Internal instrument temperature error - low	The temperature measured by the ambient temperature thermistor is $\leq 2^{\circ}\text{C}$.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Restart the system. 3. If you are unable to perform a successful restart, contact your local technical support provider.
E38 - Internal instrument temperature error - high	The temperature measured by the ambient temperature thermistor is $\geq 50^{\circ}\text{C}$.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Restart the system. 3. If you are unable to perform a successful restart, contact your local technical support provider.
E40 - Barcode read error	The number of digits read by the barcode reader does not match what is expected.	<ol style="list-style-type: none"> 1. Select OK. 2. Enter the correct barcode data. 3. Clean the barcode window.
E41 - Incorrect barcode data	The barcode has the correct number of digits, but the character does not match the expected pattern.	<ol style="list-style-type: none"> 1. Select OK. 2. Enter the correct barcode data. 3. Clean the barcode window.
E50 - Serial Port communication failure	An attempt to communicate via the RS232 serial port failed.	<ol style="list-style-type: none"> 1. Try to reconnect to the serial port. 2. Restart the system. 3. If you are unable to connect to the serial port, contact your technical support provider.

Error Code	Description	Remedy
E51 - Serial Port communication error	Communication with the serial port is not successful, even after numerous attempts.	<ol style="list-style-type: none"> 1. Disable the serial port. 2. Restart the system. 3. Contact your local technical support provider.
E55 - Ethernet port communication failure	An attempt to communicate via the Ethernet serial port failed.	<ol style="list-style-type: none"> 1. Try to reconnect to the ethernet port. 2. Restart the system. 3. If you are unable to connect to the ethernet port, contact your technical support provider.
E56 - Ethernet port communication error	Communication with the ethernet port is not successful, even after numerous attempts.	<ol style="list-style-type: none"> 1. Restart the system. 2. Disable the ethernet port. 3. Contact your local technical support provider.
E60 - Database Failure	The database is not functioning properly, for example, you do not have read or write access.	<ol style="list-style-type: none"> 1. Restart the system. 2. If the database is still not functioning properly, contact your local technical support provider.
E61 - Database read error	A database read operation fails, resulting in the return of no data or corrupt data.	<ol style="list-style-type: none"> 1. Back up the database. 2. Restart the system. 3. If the database is still not functioning properly, contact your local technical support provider.
E62 - Database write error	An error is returned from a database write operation.	<ol style="list-style-type: none"> 1. Back up the database. 2. Restart the system. 3. If the database is still not functioning properly, contact your local technical support provider.
E63 - Database is full	The database is filled to the allotted capacity for storing sample test results.	<ol style="list-style-type: none"> 1. Delete some old data records by performing one of the following tasks: <ol style="list-style-type: none"> a. Delete specific old data records. b. Set the system to automatic purge mode.

Error Code	Description	Remedy
E70 - Internal Printer Failure	The internal printer failed because of a hardware error.	<ol style="list-style-type: none"> 1. Acknowledge the error. 2. Restart the system. 3. If the internal printer is still not functioning properly, contact your local technical support provider.
E71 - External Printer Failure	The external printer failed because of a hardware error.	<ol style="list-style-type: none"> 1. Acknowledge the error. 2. If the external printer is still not functioning properly, contact your local technical support provider.
E101 - HbA _{1c} Cartridge Error - buffer absorbance is too low	<p>The mean transmittance of the buffer readings (buf1 - buf10) is too high.</p> <p>Possible causes: No cartridge is present. There is an optical alignment problem.</p>	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test with a new cartridge. 4. If the error still occurs, contact your local technical support.
E102 - HbA _{1c} Cartridge Error - buffer absorbance is too high	<p>The mean transmittance of the buffer readings (buf1 - buf10) is too low.</p> <p>Possible causes: There is condensation on the cartridge Cartridge is not located in the proper position. Buffer tab is not removed. Optical window has a defect.</p>	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Verify that the cartridge is inserted completely. 4. Pull the flexible tab. 5. Repeat the test with a new cartridge. 6. If the error still occurs, contact your local technical support.
E103 - HbA _{1c} Cartridge Error - high variation in buffer readings	<p>The coefficient of variation (%CV) of the 10 transmittance readings of the buffer solution in the reagent cartridge is too high.</p> <p>Possible cause: There is condensation on the cartridge.</p>	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test with a new cartridge. 4. If the error still occurs, contact your local technical support.

Error Code	Description	Remedy
E104 - HbA _{1c} Sample Error - low total hemoglobin	The transmittance of the blood pickup reading is too high. Possible causes: No or low blood reaction. No capillary holder was inserted. Improper constitution of controls or use of non-DCA controls. Hemoglobin < 7g/dL = anemic patient. Buffer tab is not removed.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test with a new sample. NOTE: Wait no more than 5 minutes after filling the capillary to start the test. 4. If the error still occurs, contact your local technical support.
E105 - HbA _{1c} Sample Error - high total hemoglobin	The transmittance of the blood pickup reading is too low. Possible causes: Excess blood on capillary. Irregularity in patient red blood cells (rare). Hemoglobin > 24 g/dL = patient has abnormally high hemoglobin.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Verify that the capillary has no excess blood on the capillary holder. 4. Repeat the test with a new sample. 5. If the error still occurs, contact your local technical support.
E106 - HbA _{1c} Sample Error - low total hemoglobin	The mean transmittance of the hemoglobin readings is too high. Possible causes: No or low blood reaction. No capillary holder was inserted. Improper constitution of controls or use of non-DCA controls. Hemoglobin < 7g/dL = anemic patient. Buffer tab is not removed.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. NOTE: Wait no more than 5 minutes after filling the capillary to start the test. 3. Repeat the test with a new sample.

Error Code	Description	Remedy
E107 - HbA _{1c} Sample Error - high total hemoglobin	The mean transmittance of the hemoglobin readings is too low. Possible causes: Excess blood on capillary. Irregularity in patient red blood cells (rare). Hemoglobin > 24 g/dL = patient has abnormally high hemoglobin.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Verify that the capillary has no excess blood on the capillary holder. 4. Repeat the test with a new sample. 5. If the error still occurs, contact your local technical support.
E108 - HbA _{1c} Cartridge Error - high variable in hemoglobin measurement	The %CV of the transmittance of the hemoglobin readings too large. (Particulate contamination)	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test with a new sample. 4. If the error still occurs, contact your local technical support.
E109 - HbA _{1c} Cartridge error - reading for glycated hemoglobin is too low	The absorbance of one of the agglutinations is too low. Possible cause: The cartridge was exposed to excessive humidity or temperature.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test with a new sample. NOTE: Verify that the reagent kit was stored properly. 4. If the error still occurs, contact your local technical support.
E110 - HbA _{1c} Cartridge Error - reading for glycated hemoglobin is too high	The absorbance of one of the agglutinations is too high. Possible cause: The cartridge was exposed to excessive humidity or temperature.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test with a new sample. NOTE: Verify that the reagent kit was stored properly. 4. If the error still occurs, contact your local technical support.

Error Code	Description	Remedy
E111 - HbA _{1c} Cartridge Error - low glycated hemoglobin response	The delta in absorbance between the first and the last agglutination readings is too low. Possible cause: The cartridge was exposed to excessive humidity or temperature.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test with a new sample. NOTE: Verify that the reagent kit was stored properly. 4. If the error still occurs, contact your local technical support.
E112 - HbA _{1c} Cartridge Error - very large glycated hemoglobin response	The delta in absorbance between the first and last agglutination reading is too high. Possible cause: The cartridge was exposed to excessive humidity or temperature.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test with a new sample. NOTE: Verify that the reagent kit was stored properly. 4. If the error still occurs, contact your local technical support.
E113 - HbA _{1c} Cartridge Error - irregular reaction kinetics (A ₁)	The A ₁ parameter from the third order polynomial fit is an unexpectedly large negative number. Possible cause: The cartridge was exposed to excessive humidity or temperature.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test with a new sample. NOTE: Verify that the reagent kit was stored properly, and that the foil package was opened just prior to use. 4. If the error still occurs, contact your local technical support.

Error Code	Description	Remedy
E114 - HbA _{1c} Cartridge Error - irregular reaction kinetics (A ₂)	The A ₂ parameter from the third order polynomial fit is too large. Possible cause: The cartridge was exposed to excessive humidity or temperature.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test with a new sample. NOTE: Verify that the reagent kit was stored properly, and that the foil package was opened just prior to use. 4. If the error still occurs, contact your local technical support.
E115 - HbA _{1c} Cartridge Error - final hemoglobin reading is greater than the previous check point	The difference between the blood pickup absorbance and the mean hemoglobin absorbance is too large. Possible cause: The blood was left in the capillary too long.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test with a new sample. NOTE: Wait no more than 5 minutes after filling the capillary to start the test. 4. If the error still occurs, contact your local technical support.
E116 - HbA _{1c} Cartridge Error - irregular reaction kinetics (high variability)	The Mean Squared Error calculated after the third order polynomial fit of the agglutination readings is too large. Possible cause: The cartridge was exposed to excessive humidity or temperature.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test with a new sample. NOTE: Verify that the reagent kit was stored properly, and that the foil package was opened just prior to use. 4. If the error still occurs, contact your local technical support.

Error Code	Description	Remedy
E301 - Microalbumin/ Creatinine Cartridge Error - buffer absorbance is too low	The mean transmittance of the buffer readings (buf1 - buf10) is too high. Possible causes: No cartridge is present, and there is an optical alignment problem.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test. 4. If the error still occurs, contact your local technical support.
E302 - Microalbumin/ Creatinine Cartridge Error - buffer absorbance is too high	The mean transmittance of the buffer readings (buf1 - buf10) is too low. Possible causes: There is condensation on the cartridge Cartridge is not located in the proper position. Buffer tab is not removed. Optical window has a defect.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test. 4. Verify that cartridge is inserted completely into the system. 5. Remove the flexible tab. 6. If the error still occurs, contact your local technical support.
E303 - Microalbumin/ Creatinine Cartridge Error - variable buffer readings	The percent coefficient of variation (%CV) of the 10 transmittance readings of the buffer solution in the reagent cartridge is too high. (Particulate contamination)	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test. 4. If the error still occurs, contact your local technical support.
E304 - Microalbumin/ Creatinine Cartridge Error - sample blanks absorbance is too low	The percent coefficient of variation (%CV) of the 10 transmittance readings of the buffer solution in the reagent cartridge is too high. (Particulate contamination)	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test. If the error still occurs, contact your local technical support.

Error Code	Description	Remedy
E305 - Microalbumin/ Creatinine Cartridge Error - sample blank absorbance is too high	The mean transmittance of the low sample blank is too low. Possible cause: The urine sample is turbid or highly pigmented.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Centrifuge the sample before assaying if the sample is cloudy. 4. Repeat the test. 5. If the error still occurs, contact your local technical support.
E306 - Microalbumin/ Creatinine Cartridge Error - high variability in transmittance of sample blank	The %CV of the low sample blank is too high.(Particulate contamination)	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test. 4. If the error still occurs, contact your local technical support.
E307 - Microalbumin/ Creatinine Cartridge Error - Microalbumin absorbance is too low	The mean of the Microalbumin transmittance readings is too high. Possible cause: Cartridge was exposed to excessive temperature or humidity.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test. 4. If the error still occurs, contact your local technical support. <p>NOTE: Verify that the reagent was stored properly.</p>
E308 - Microalbumin/ Creatinine Cartridge Error - Microalbumin absorbance is too high	The mean of the Microalbumin transmittance readings is too low.	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test. 4. If the error still occurs, contact your local technical support. <p>NOTE: Verify that the reagent was stored properly.</p>

Error Code	Description	Remedy
E309 - Microalbumin/ Creatinine Cartridge Error - high variation in Microalbumin readings	The %CV of the Microalbumin transmittance reading is too high. (Particulate contamination)	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test. 4. If the error still occurs, contact your local technical support.
E310 - Microalbumin/ Creatinine Cartridge Error - Creatinine absorbance is too low	<p>One of the 26 creatinine absorbance readings is too low.</p> <p>Possible cause: The cartridge was exposed to excessive temperature or humidity.</p>	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test. <p>NOTE: Verify that the reagent was stored properly, and that the foil package was opened just prior to use.</p> <ol style="list-style-type: none"> 4. If the error still occurs, contact your local technical support.
E311 - Microalbumin/ Creatinine Cartridge Error - Creatinine absorbance is too high	<p>One of the 26 creatinine absorbance readings is too high.</p> <p>Possible cause: The cartridge was exposed to excessive temperature or humidity.</p>	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test. <p>NOTE: Verify that the reagent was stored properly, and that the foil package was opened just prior to use.</p> <ol style="list-style-type: none"> 4. If the error still occurs, contact your local technical support.
E313 - Microalbumin/ Creatinine Cartridge Error - high variability in absorbance readings	<p>The Mean Squared Error calculated after the third order polynomial fit of the creatinine readings is too large.</p> <p>Possible cause: The cartridge was exposed to excessive temperature or humidity.</p>	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. The system is ready. 3. Repeat the test. <p>NOTE: Verify that the reagent was stored properly, and that the foil package was opened just prior to use.</p> <ol style="list-style-type: none"> 4. If the error still occurs, contact your local technical support.

Error Code	Description	Remedy
E315 - Microalbumin normalization required	The Microalbumin Normalization was not performed or the Microalbumin Normalization Factor (MNF) was corrupted. Possible cause: System not adjusted to run Microalbumin/Creatinine test.	1. Acknowledge the error. The system is ready. 2. If the error still occurs, contact your local technical support.
E316 - Microalbumin normalization out of range	The Microalbumin Normalization Factor entered is outside of expected range. Possible causes: Normalization cartridge is not located in the proper position. Normalization cartridge is dirty or defective.	1. Acknowledge the error. The system is ready. 2. Verify that the cartridge was inserted completely into the system. 3. Repeat the test. 4. If the error still occurs, contact your local technical support.

Troubleshooting

7 **File Management**

The system stores up to 4000 patient and control tests. In System Settings, you can set up whether you want the system to automatically delete test results when the maximum number is reached, or have the system warn you when the data storage is full. If you choose to have the system warn you, then you have to manually delete some test results to free up space. When the system is full, you cannot run any new tests.

NOTE: You can use the USB port to save patient records to an external storage device, before you delete them.



CAUTION

When you export data that contains patient information, it is your responsibility to comply with your local procedure on HIPAA regulations.

File Management

8 System Configuration

Installation

Overview

This section provides detailed installation instructions for the DCA Vantage system. You must follow the installation steps correctly to ensure proper installation, operation, and service.



CAUTION

Do not drop or handle the system roughly. This can disturb internal calibrated optics and electronics or cause other damage. Always handle the system with care. The DCA Vantage system is a precision system and must be handled accordingly.

Place the system where it will not be subjected to extreme temperature variations. Avoid proximity to open windows, direct sunlight, ovens, hot plates, open burners, radiators, and dry ice baths.

Do not place the DCA Vantage system on the same bench as a source of vibration.

Provide bench space large enough to allow free air circulation around the system (8 cm/3 in on all sides).

Unpacking the System

Your DCA Vantage system is delivered in 1 shipping carton.

1. Carefully remove the contents of the shipping carton.
2. Inspect the carton and system for visible signs of damage.
3. If damage to the system exists, immediately file a complaint with the carrier.
4. Make sure all items are included with your system, and keep them for future use.
 - DCA Vantage analyzer
 - Cleaning Kit
 - Operating Guide
 - Optical Test Cartridge (in system cartridge compartment)
 - NA Power Cord for System
 - Euro Power Cord for System

- UK Power Cord for System
- Replacement Fuse (stored in the fuse holder located inside the system)
- Air Filter Replacement Kit
- HbA_{1c} Quick Reference Guide
- Microalbumin/Creatinine Quick Reference Guide
- Documentation CD
- Paper Roll
- Self Adhesive Label Stock



Figure 44 System Parts

5. Retain the shipping carton and packing for several weeks.
If you need to ship the system, the shipping carton affords the best protection against damage.
6. Place the system on a firm, level work surface in the designated work area.
7. Ensure that the system is level, and that the back and sides of the system are at least 8 cm (3 in) from any adjacent wall.

Installing the System

This section explains how to install the DCA Vantage system.

Record the Warranty Information

1. Locate the serial number.

The serial number is found on the back of the system near the power connector.

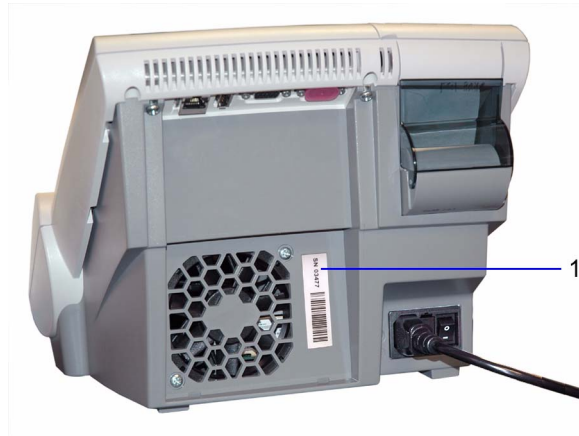


Figure 45 Locate the Serial Number

- 1 Serial number

2. Print the Pre-service Checklist, and the *Warranty Information*, page 133.
3. Write the installation date and serial number in the spaces provided in the Pre-service Checklist, and on the *Warranty Information*, page 133.
4. Contact your Siemens representative for your warranty information if the pre-service checklist is not included in your manual.

Installing Connections

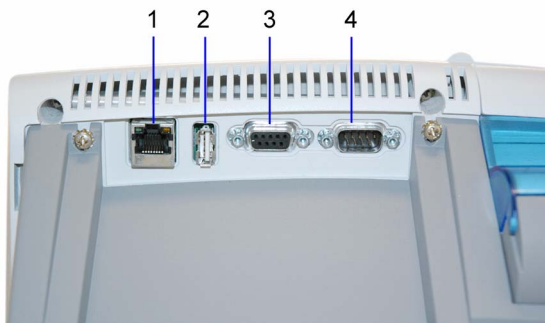


Figure 46 System Connections

- 1 Ethernet Port (RJ 45)
 - 2 USB Port
 - 3 Barcode Reader
 - 4 Serial Port (RS 232) - used for printer or LIS connection
-

Connect the System Power

1. Ensure that the system power switch is in the off position.
2. Connect the power cord to the system and to an appropriate, grounded AC electrical outlet.

Installing the External Barcode Reader

If you order an external barcode reader, it is supplied in addition to the internal barcode reader.

Installing a Roll of Printer Paper

Install a roll of printer paper and re-install the printer cover. Refer to *Changing the Paper*, page 99.

Starting the DCA Vantage System

After the system is properly installed, you can start the DCA Vantage system. To start the DCA Vantage system, turn the power button to the On position. The system displays the following information:

- Model Name
- System Software Version
- Copyright Information

Start Up Tests

After you turn the power on a message displays explaining that the system is starting up. The DCA Vantage system verifies that the compartment door is closed and performs hardware functionality tests to verify that the internal optics and the mechanical system are operating correctly.



CAUTION

Do not turn the system off while it is starting up, this can cause corruption to stored data.

Loading Configuration Settings

The DCA Vantage system loads the current configuration settings. You can use the setup wizard to load configuration settings. Refer to *System Settings Wizard*, page 16.

Verifying that the DCA Vantage System is Ready

The DCA Vantage system displays the current date and time and verifies that no errors occurred. If no errors occurred, the system is ready to run.

Running the Optical Test Cartridge

NOTE: We recommend running the optical test cartridge before you analyze samples for the first time.

The provided optical test cartridge allows you to monitor the performance of the optical system over time. Refer to *Running the Optical Test*, page 96.

Appendix A: Safety Information

Protecting Yourself from Biohazards

This information summarizes the established guidelines for handling laboratory biohazards. This summary is based on the guidelines developed by the Centers for Disease Control, the Clinical and Laboratory Standards Institute, and the Occupational Safety and Health Administration.

Use this summary for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

By definition, a biohazardous condition is a situation involving infectious agents biological in nature, such as the hepatitis B virus, the human immunodeficiency virus, and the tuberculosis bacterium. These infectious agents may be present in human blood and blood products and in other body fluids.

The following are the major sources of contamination when handling potentially infectious agents:

- needlesticks
- hand-to-mouth contact
- hand-to-eye contact
- direct contact with superficial cuts, open wounds, and other skin conditions that may permit absorption into subcutaneous skin layers
- splashes or aerosol contact with skin and eyes

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves while servicing parts of the system that have contact with body fluids such as serum, plasma, urine, or whole blood.
- Wash your hands before going from a contaminated area to a noncontaminated area, or when you remove or change gloves.
- Perform procedures carefully to minimize aerosol formation.
- Wear facial protection when splatter or aerosol formation are possible.
- Wear personal protective equipment such as safety glasses, gloves, lab coats or aprons when working with possible biohazard contaminants.
- Keep your hands away from your face.
- Cover all superficial cuts and wounds before starting any work.
- Dispose of contaminated materials according to your laboratory's biohazard control procedures.

- Keep your work area disinfected.
- Disinfect tools and other items that have been near any part of the system sample path or waste area with 10% v/v bleach.
- Do not eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory.
- Do not mouth pipet any liquid, including water.
- Do not place tools or any other items in your mouth.
- Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands.
- Do not recap, purposely bend, cut, break, remove from disposable syringes, or otherwise manipulate needles by hand. Needlestick injuries may result.

References

1. Centers for Disease Control. *Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings*. 1988. MMWR, 37:377–382, 387, 388.
2. Clinical and Laboratory Standards Institute (formerly NCCLS). *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document M29-A3. [ISBN 1-56238-567-4].
3. Federal Occupational Safety and Health Administration. Bloodborne Pathogens Standard. 29 CFR 1910. 1030.

Appendix B: Warranty and Support Information

Legal Information

To contact the legal representative for Siemens within the European community, contact the Siemens Authorized Representative. For service, contact your local technical support provider.

Siemens Authorized Representative

EC	REP	Siemens Healthcare Diagnostics Ltd. Sir William Siemens Sq. Frimley, Camberley, UK GU16 8QD
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Warranty Information

Installation Details

Please record the following information and keep this sheet in your laboratory for future reference.

Date of Installation: _____
 Serial Number: _____

Manufacturer's Warranty

For warranty information, contact the local Siemens service provider.

Support Information

Call for assistance:

- if the error message continues to be displayed after performing the steps described on the screen and in the Troubleshooting Chart
- if additional assistance is required concerning an system problem
- if the problem is beyond the scope of this manual
- if the problem cannot be solved and an system failure is apparent

Our local technical support providers are available to help you. Before calling, please complete the *Pre-service Checklist*, page 135. Make a photocopy of the checklist first. This information helps your local technical support provider to identify the probable cause of the problem.

Contact Information

www.siemens.com/diagnostics

Siemens Healthcare
Diagnostics Pty Ltd
885 Mountain Highway
Bayswater Victoria 3153
Australia

シーメンスヘルスケア・ダイアグノスティクス株式会社
東京都品川区東五反田 3-20-14
Siemens Healthcare Diagnostics

輸入

Pre-service Checklist

Please record the following information and keep this sheet in the your laboratory for future reference.

Date of Installation: _____

Serial Number: _____

NOTE: After recording the information, make photocopies of this page to use before calling your local technical support provider.

1.	Does the fan come on when the system is turned On?	
	If NO, is the system firmly connected to a live AC electrical outlet?	
2.	Is the touchscreen operating properly?	
	If NO: Have you performed the touchscreen test?	
	Have you calibrated the touchscreen?	
3.	Does the system proceed properly while analyzing reagent cartridges?	
4.	What is the lot number of the reagent cartridges you are using?	
5.	Is the printer functioning properly? Are the appropriate messages and patient results being printed?	
	If NO: Is the internal or an external printer turned ON?	
	Is there paper in the printer?	
	Have you performed the printer test?	
6.	Are reasonable results being displayed and printed for the Quality Control and patient samples?	
	If NO:	
7.	Is the system in the proper operating environment and location as described in Appendix E, <i>Specifications</i> ?	

8.	<p>What is the revision level of the system software? To find this information:</p> <ol style="list-style-type: none"> 1. Turn system power off. 2. Wait approximately 15 seconds. 3. Turn system power on. <p>The software version displays after the initialization screen.</p>	
9.	<p>Are any error messages or warnings being displayed?</p> <p>If so, what are they? List the error description and any numbers that display.</p>	
10.	<p>Have you performed the appropriate steps suggested on the display for the error being displayed?</p>	
<p>If an external device is being used:</p>		
11.	<p>Is the printer and/or host computer/LIS connected and turned On?</p>	
12.	<p>Have the correct parameters for transmission been selected through the Setup menus?</p>	
13.	<p>Is the external printer properly printing the test results?</p>	
14.	<p>Is the external barcode reader working properly?</p>	

Appendix C: Orderable Supplies

Accessory Items

The accessory items available for the DCA Vantage system are listed below.

Hemoglobin A_{1c}

<i>Part Number</i>	<i>Description</i>
5035C	DCA Reagent Kit
5068A	DCA Normal & Abnormal Control Kit

Microalbumin/Creatinine

<i>Part Number</i>	<i>Description</i>
6011A	DCA Reagent Kit
6012A	DCA Low & High Control Kit

NOTE: Part numbers are subject to change without notice.

Replacement Parts

The replacement parts available for the DCA Vantage system are listed below.

<i>Part Number</i>	<i>Description</i>
036 282 46	NA Power Cord for System
060 487 20	Euro Power Cord for System
061 394 40	UK Power Cord for System
064 892 13	Filter Holder
064 892 48	Cartridge Return Spring
044 690 01	Fuse: T-1.25 A, Slow Blow; 250 volt
064 882 09	Cleaning Sticks (10)
064 892 21	Optical Test Cartridge
064 892 05	Air Filter (3) Replacement Kit
011 501 95	Printer Paper (pack of 5)

Part Number	Description
063 527 80	Printer Paper Self Adhesive Stock (pack of 5)

System Documentation









The following table contains the system documentation available for the DCA Vantage system.












Part Number	Description
064 892 56	Multi-language Documentation CD
064 892 64	Operator's Guide (English)
064 892 72	Operator's Guide (French)
064 892 80	Operator's Guide (German)
064 892 99	Operator's Guide (Italian)
064 893 02	Operator's Guide (Spanish)
064 893 10	Operator's Guide (Portuguese)
064 893 29	Operator's Guide (Danish)
064 893 37	Operator's Guide (Swedish)
064 893 45	Operator's Guide (Greek)
064 898 33	Operator's Guide (Norwegian)
064 893 53	Operator's Guide (Japanese)
064 893 61	Operator's Guide (Simplified Chinese)
065 018 84	Operator's Guide (Finnish)











Appendix D: Symbols






System and Packaging

This section describes the symbols that can display in the system documentation, the exterior of the DCA Vantage system, or on the system packaging. The symbols on the system provide you with the location of certain components and with warnings for proper operation. The symbols on the system packaging provide you with other important information. For information on the symbols that can display on the DCA Vantage system reagent packaging and labeling, see the related assay instruction for use. User Interface

Symbol	Description
	<p>This symbol is used for both Warnings and Cautions.</p> <ul style="list-style-type: none"> • A Warning indicates the risk of personal injury or loss of life if operating procedures and practices are not correctly followed. • A Caution indicates the possibility of loss of data or damage to or destruction of equipment if operating procedures and practices are not strictly observed.
	This symbol alerts you to a biohazard.
	This symbol indicates that the input electricity is alternating current.
	This symbol identifies the location of a power connector (power cord).
	This symbol identifies the location of a printer port.
	This symbol identifies the location of a barcode scanner or keyboard port.
	
	This symbol identifies the location of a serial port.







Symbol	Description
	This symbol identifies the location of an ethernet port.
	This symbol identifies the location of the USB port.
	This symbol identifies the Laboratory Information System.
	This symbol identifies that this electronic information product does not contain any toxic or hazardous substances or elements, and is green and environmental. This system can be recycled after being discarded, and should not be casually discarded.
	This symbol indicates that the main power supply is on.
	This symbol indicates that the main power supply is off.
	This symbol indicates that the product has a temperature limitation. You need to store the product between 5° – 40° C.
	This symbol indicates an <i>in vitro</i> diagnostic device or an <i>in vitro</i> diagnostic medical device.
	This symbol indicates that you should consult instructions for use.
	This symbol indicates that the product is fragile and you need to handle it with care.
	This symbol indicates that you should keep the product dry.














Symbol	Description
	This symbol indicates that you should not spray any liquids in this area.
	This symbol indicates that you should keep the product away from sunlight and heat.
	This symbol indicates that the product is heavy, and should only be lifted by two or more persons.
	This symbol indicates a temperature hazard.
	This symbol cautions you to observe precautions for handling electrostatic sensitive devices, to avoid causing a hazard to the product.
	This symbol indicates that the system is type B equipment, which provides a particular degree of protection against electric shock.
	This symbol indicates to follow the appropriate procedures for disposal of electrical and electronic equipment.
REF	This symbol indicates the number used for ordering a part or product.
SN	This symbol indicates the serial number of a part or product.
Rev.	This symbol indicates the revision letter of a part or product.
	This symbol indicates the name and location of the product manufacturer.
	This symbol indicates the date of manufacture of the product.
	This symbol indicates the manufacturer's authorized representative within the European community.

Symbol	Description
	This symbol indicates that the product or container should be oriented in the direction of the arrows.
	This symbol is indicates that the product or container contains recycled material.
	This symbol is intended to facilitate recycling of corrugated materials. The number is licensed in Germany and printed on corrugated shippers.
	This symbol indicates that the product complies with the applicable directives of the European Union.
	This symbol indicates information about the fuse.

User Interface

This section describes the symbols that display on the system user interface.

	Home screen	Select this key to access the Home screen.
	System menu	Select this key to access the System menu.
	Calibrations and System Tests menu	Select this key to access the Calibrations or System Tests menu.
	Data Recall menu	Select this key to access the Data Recall menu.
	Help	Select this key to display a Help screen with information about the screen. Help is not available on all screens.
	Back	Select this key to change the display back to the previous screen in the series.

	Next	Select this key to display the next screen in the series.
	Up	Select this key to display the previous result or entry in descending order.
	Down	Select this key to display the next result or entry in descending order.
	OK, Save	Select this key to save any settings.
	Page Up	Select this key to display the previous page in descending order.
	Page Down	Select this key to display the next page in descending order.
	No, Cancel	Select this key to cancel an action.
	System Busy	This symbol indicates that the system is busy.
	Required Data Entry	This symbol indicates that the data is required.
	Add Comments	Select this key to add comments.
	Shut down System	Select this key to shut down the system.
	HbA _{1c} Blood Test	This symbol indicates a HbA _{1c} Blood test.
	Microalbumin/Creatinine Urine Test	This symbol indicates a Microalbumin/Creatinine Urine test.

Symbols



Quality
Control
Solution Test

This symbol indicates a Quality Control Solution test.

Appendix E: Specifications

System Specifications

This section summarizes the design specifications for the DCA Vantage system.

System Dimensions

<i>Dimension</i>	<i>Value</i>
Depth	27.7 cm (10.5 in)
Height	25.4 cm (9.0 in)
Width	28.7 cm (11.5 in)
Weight	3.88 kg (9 lbs)

Environmental Specifications

<i>Specification</i>	<i>Value</i>
Ambient Operating Temperature	15°C to 32°C (61°F to 88°F) - Hemoglobin A _{1c} 18°C to 30°C (64°F to 86°F) - Microalbumin/ Creatinine
Analyzer Operating temperature	5° C to 40° C (41°F to 104° F)
Relative Humidity	10% to 90%, non-condensing, actively controlled
Indoor Use Only	
Altitude	up to 2000 meters (6000 feet)

Electrical Requirements

Requirement	Value
Electrical Rating	100-240 VAC 50/60 Hertz
Maximum Power Input	70 VA
Fuse Rating	1.25 Amperes

Regulatory Specifications

Requirement	Value
EMC Emissions	FCC 47 CFR Part 15 Class B (USA) EN60601-1-2:2001, electromagnetic emissions for Medical Electric Equipment – Group 1 equipment, Class B for non-life supporting equipment
EMC Immunity	EN60601-1-2:2001, electromagnetic immunity for Medical Electric Equipment – Group 1 equipment, Class B for non-life supporting equipment

Requirement	Value
	UL/CUL with CB scheme CSA – C22.2 No. 601.1-M90 EN60601, 2 nd edition, Medical Electrical Equipment IEC60601, 2 nd edition, Medical Electrical Equipment UL60601, 2 nd edition, Medical Electrical Equipment CLASSIFICATIONS: Type of protection = Class 1 equipment Degree of protection fro electrical shock = TYPE “B” Degree of protection for water degree = Ordinary Method of Sterilization or Disinfection = <i>Maintenance</i> , page 89.
Safety	Degree of Safety with Anesthetic Gases or O ₂ = not suitable Mode of Operation = Continuous
	<hr/> The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice includes the following: <ul style="list-style-type: none"> • use of the accessory in the PATIENT VICINITY • evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard. <hr/>

Electrical Precautions

Observe the following precautions when handling the system:

- Do not operate the system in the presence of a flammable anesthetic mixture with air, O₂, or nitrous oxide. The risk of explosion exists if the system is operated in a potentially explosive environment.
- The system uses a grounded external power cord for connection to a grounded electrical outlet. If you use an adapter, ensure the grounding wire is properly connected to a permanent ground.

NOTE: This system was tested and complied with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This system generalities, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions in the DCA Vantage Operator's guide, may cause harmful interference to radio communications.

There is no guarantee that interference will not occur in a particular installation. If this system does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, try to correct the interference by one or more of the following measures:

- reorient or relocate the receiving antenna
- increase the separation between the system and the receiver
- connect the system into an outlet on a different circuit from the receiver
- consult a dealer or experienced radio/TV technician for help.

Safety Certifications

Refer to the DECLARATION OF CONFORMITY shipped with the DCA Vantage system.

Electromagnetic Compatibility (EMC)

Refer to the DECLARATION OF CONFORMITY shipped with the DCA Vantage system.

Appendix F: External Barcode Reader

General Information

You can use the optional DCA Vantage system handheld barcode reader to input user information, for example, patient information, sample information and comments.

The software in the barcode reader automatically distinguishes between barcode formats.

NOTE: You must configure the barcode before use.

Installing the External Barcode Reader

1. Turn the system power off.
2. Connect the interface cable to the opening at the bottom of the handheld reader.
3. Connect the other end of the cable to the external barcode reader port at the back of the system.

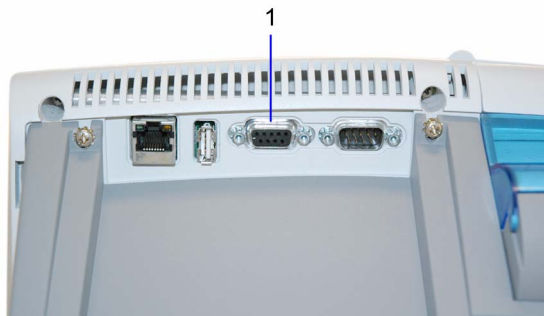


Figure 47 External barcode reader connection

- 1 External Barcode Reader
4. Press in firmly until the connection is secure and you hear a gentle click.
5. Turn the system power on.
6. From the System menu, select System Settings.
The System Settings menu displays.

7. From the System Settings menu, select **Additional Settings**.
The Additional Settings menu displays.
8. Select **External Barcode Reader**.
9. To enable the external barcode reader, select **Enabled**.

Testing the External Barcode Reader

Ensure that your external barcode reader has been correctly installed using the procedure in *Installing the External Barcode Reader*. Ensure that the barcoded labels used in your laboratory comply with the specifications given later in this section.

Troubleshooting

It is important that the labels be printed to the required specifications. Reading errors may occur if any of the following conditions exist:

- the narrow bar width is too small
- the barcode length too great
- the height too small
- the reader is held too far from the label
- the background reflection too high or low

If the reader is not able to consistently read your labels, apply a test label of the format being used to a new specimen tube and perform the Barcode Test. If the reader is able to read the test label, the quality of your labels may be suspect. If the test label cannot be read, the reader itself is suspect.

If you have problems that cannot be resolved, contact your local technical support provider for assistance.

Specifications

Barcode Formats

The DCA Vantage system's external barcode reader meets the requirements of ASTM E1466-92, *Standard Specification for Use of Barcodes on Specimen Tubes in the Clinical Laboratory* (available from ASTM, 100 Barr Harbor Dr., West Conshohocken, PA 19428).

Barcode Symbols and Labels

DCA Vantage accepts the data input of user entered information (Sample ID, Patient ID, Patient last name, Patient first name, User ID (Patient and Control), Comments (Patient and Control)), for the following barcode symbologies:

- Code 93 standard includes check digit

- Code 39 with optional check digit required
- Code 128 standard includes check digit
- Coda Bar without check digit

The following rules apply to data entered by the external barcode reader:

- DCA Vantage can read and display full ASCII character set.
- You can enter and display characters in lower case.
- Search to recall samples associated with the data entered by the external barcodes are not case sensitive.
- The DCA Vantage system serial number entry is supported in Code 128 intended for manufacturing entry.

The barcode symbols, and the labels themselves, must meet certain specifications, detailed below:

Number of Characters: 1 to 30 data characters. A maximum of 13 characters can be displayed, stored, and transmitted by the DCA Vantage system. Remove excess characters as leading or trailing characters.

Narrow Bar Width: 0.15 to 0.51 mm (0.006 to 0.02 in). It is better to be closer to the upper limit (0.51 mm/0.02 in), as long as the entire barcode can be contained within the maximum length.

This measurement effects both the symbol length and how far away from the label you can hold the handheld reader. If the narrow bar width is at the minimum, the symbol length can be no greater than 90 mm (3.5 in), including quiet zones, and the reader can be held no more than 75 mm (3 in) away.

Narrow to Wide Ratio: Must be within the specifications for the format being used. This is generally 2.0 to 3.0.

Symbol Length: Variable. See *Narrow Bar Width* for more information.

Quiet Zone: Minimum of 10 times the narrow bar width at each end of the symbol.

Symbol Height: Minimum of 10 mm (0.40 in).

Total Size of Label: May be greater than the size of the symbol to allow for printing of human readable information. Printing of the specimen ID number in alphanumeric digits is strongly recommended.

Symbol grade: Minimum grade of “C” as defined by ANSI X3.182-1990 (available from American National Standards Institute, 1430 Broadway, New York, NY 10018).

Wavelength of Light: 630 nm (visible red LED).

Maintenance



CAUTION

Do not submerge the reader in water. The reader's housing is not water-tight.

Do not use laboratory wipes, such as Kimwipes, because they may scratch the window.

Do not use any type of solvent, other than recommended solvents, to clean the reader. Harsh chemicals can damage the finish or the window.

Clean the barcode reader window whenever it appears dirty or smeared:

1. Wipe the reader window with a soft cloth or facial tissue dampened with water, or a ethanol solution.
2. If a detergent solution is used, rinse with a soft cloth or facial tissue dampened with water only.
3. Clean the plastic case in the same manner.

Appendix G: Computer Interface (LIS)

General Information

You can connect the DCA Vantage system to a host computer of laboratory Information System (LIS). This appendix contains the specifications needed for the interface cable required. Contact your local technical support provider for additional information on programs to interface the analyzer to a computer or LIS.

Cable and Pin Specifications – Computer

You can use a serial cable, or ethernet cable to interface with the DCA Vantage system.

Serial Connection

The serial transmission between the system and the host is established through the system's serial port using a serial cable. The mechanical and electrical connection for serial binary data bit transmission between system and computer system is described in the serial physical layer. The DCA Vantage system implements and complies with the serial physical layer defined in the ASTM 1381 standard. For more information about this standard, refer to the standard.

Serial cable pin assignments and hardware handshaking are described below.

Architecture

The basic architecture is point-to-point communications between LIS and the DCA Vantage system.

Hardware Link

The hardware link consists of serial asynchronous (RS-232) interface. Communication is normally full duplex at one of the following user-selected baud rates:

- 19200
- 9600
- 4800
- 2400

The system interface port is equipped with a 9-pin, D-type, male connector.

The systems are considered to be Data terminal Equipment (DTE). The signal lines that are supported are listed below.

Signal Line		Pin Number	Type
Data Carrier Detect (not used)	DCD	Pin 1	Control
Received Data	RD	Pin 2	Data
Transmitted Data	TD	Pin 3	Data
Data Terminal Ready (not used)	DTR	Pin 4	Control
Signal Ground	G	Pin 5	Ground
Data Set Ready (not used)	DSR	Pin 6	Control
Request to Send (not used)	RTS	Pin 7	Control
Clear to Send (not used)	CTS	Pin 8	Control
Ring Indicator (not used)	RI	Pin 9	Control

Character Format

You can select the following character format options when you select the LIS communication parameters in setup at the DCA Vantage system.

Option	Selection
data bits	7 bits, 8 bits
parity	odd, even, none

The stop bits are set to 1.

Ethernet Connection

TCP/IP transmission between the system and the host is established through the system's Ethernet network adapter using a RJ45 connector. The DCA Vantage system only supports the system connecting to the host. The host has to listen for connections on the TCP/IP port and needs to accept the connection when the system tries to connect.

To connect from the ethernet port to a network, use a standard straight-through CAT 5 cable. To connect directly to a PC, use a crossover CAT 5 cable.

Appendix H: Glossary

Hardware Terms

The following table defines hardware terms that are commonly used on the DCA Vantage system:

Term	Definition
Air Filter	The filter in front of the cooling fan that keeps the system cool.
Air Vent(s)	The openings that allow air to enter and exit the system for cooling.
Battery	Provides power to the system during shutdown to avoid database corruption when the power switch is turned off.
Cartridge	The reagent cartridges that are inserted into the system to perform HbA1c and Microalbumin/Creatinine tests.
Display	The LCD that displays the graphical software user interface.
Ethernet Connector Port	The connector port where a network Ethernet cable is inserted.
External Barcode Reader	An optional barcode scanner that is connected to the USB connector port on the DCA product. Used to enter data into the DCA Vantage Analyzer.
External Printer	An optional printer that is connected to the USB connector port on the DCA product. Used to print reports.
Onboard Barcode Reader	The barcode scanner used to scan barcodes on DCA Reagent Cartridges and Cards.
Onboard Printer	The integral roll printer.
Onboard Printer Cover	The portion of the DCA Analyzer case that opens and closes to cover the on-board printer.
Power Switch	The switch that turns the system on and off.
Power Cord	The cord that connects the system to an electrical outlet.
Printer Paper Roll	The roll of printer paper the user inserts into the onboard printer.
Serial Connector	A connector used to transferred data between
Speaker	The device that enables the system to emit audio alerts.

Term	Definition
System	The DCA Vantage product.
System Door	The door which covers the opening where reagent cartridges are inserted into the optical system.
Touchscreen	The LCD display overlay which enables users to “touch” or “press” controls on the display.
USB Connector Port	The connector ports where USB cables are inserted.

Software Terms

The following table defines hardware terms that are commonly used on the DCA Vantage system:

Term	Definition
Supervisor	An operator who has been assigned supervisor access privileges on the DCA system.
Alert Message	A message that conveys information about the DCA system to the user.
Alphanumeric	Data comprised of alphabetic and numeric characters.
Audio Alert	Sounds emitted by the DCA system to draw the operators attention to the system.
Cancel	To end a sequence or operation.
Cartridge	The HbA1c, Microalbumin/Creatinine, or Optical Test cartridges that are inserted into the system to perform a test.
Comment	A user entered notation associated with a test result.
Control	Objects displayed on the software UI that the user can manipulate. Buttons, checkboxes, and radio buttons are examples of controls.
Countdown	A numeric display that indicates the amount of time left in an operation.
Data Entry	The act of entering data such as a patient or operator ID into the DCA system.
Data Entry Box	A software UI object which displays data that is entered by the operator.

Term	Definition
Diagnostic Screen	A software UI screen which enables the operator to perform a system diagnostic test when troubleshooting the DCA system.
Disabled	The state when a software UI control, such as a button, is not available to be “touched” or “pressed” by an operator.
Enabled	The state when a software UI control, such as a button, is available to be “touched” or “pressed” by an operator.
Error	An system event that prevents the system from operating as desired.
Error Code	A number display by the system to communicate the occurrence of an error to the operator.
Export	To copy data off of a DCA system to a removable data storage device.
Help	Information presented to the operator to assist them with the completion of a task or operation.
Help Screen	The screen used to display help information to the operator.
Home Screen	The software UI screen operators encounter when the DCA system start up has completed. All software UI navigation begins from the Home screen.
Icon	An image used to label a control.
Import	To copy data on to a DCA system from a removable data storage device.
Maintenance	The area of the software user interface where users can perform and/or record DCA system maintenance tasks.
Menu Screen	A software UI screen that displays buttons to the operator for them to choose from.
Notifications Message	A message that conveys information about the DCA system to the user while on the Home UI screen.
Navigation	The act of moving between the screen which comprise the DCA Vantage software user interface.
Navigation Button	A software UI button control that when “touched” or “pressed” brings the operator to a different software UI screen.
Parity	A serial communication setting.

Term	Definition
Ready	The DCA system state when the system is available to perform tests.
Recall	To access data such as test results stored on the DCA Vantage system.
Restore	The act of copying data back onto a DCA system to restore it.
Required Entry	A sample data entry box that must have data entered into it during a test sequence.
Screen	The software “windows” that fill the entire display area which contain the controls the operators manipulate when operating the DCA system. The DCA system software user interface is comprised of individual screens.
Screen Title	A text label that typically appears in the upper, left corner of a screen which serves as a label for that screen.
Settings	The area of the software user interface where users can configure the DCA system.
Settings Screen	A software UI screen which enables the operator to adjust or configure some aspect of the DCA system.
Sound Volume	The software UI screen where the operator can adjust the volume level for the DCA onboard sound which emits audio alerts.
Test Result	Measured reportable values displayed to the operator at the end of a test sequence.
Test Sequence	A series of software UI screens that guides the operator through the tasks required to perform a test on a sample.
Title Bar	The area along the top of UI screens where the location icon and title appear along with the time and date display.

Acronyms

The following table defines Acronyms that are commonly used on the DCA Vantage system:

Acronym	Full Title
A/C	Albumin/Creatinine
ASTM	American Society for Testing and Measurement.

Acronym	Full Title
ASTM E 1381	ASTM Specification for a low level protocol for transferring messages between clinical laboratory instruments and computer systems.
ASTM E 1394	ASTM Specification for a protocol for transferring messages between clinical laboratory instruments and computer systems.
DHCP	Dynamic Host Configuration Protocol
DNS	Domain Name Server
GFR	Glomerular Filtration Rate
GHb	Glycated Hemoglobin
IP	Internet Protocol
LIS	Laboratory Information System
MNF	Microalbumin Normalization Factor
Mean A	Mean Average
Mean T	Mean Transmittance
NGSP	National Glycohemoglobin Standardization Program
P	Precision
PD	Precision Drift
QC	Quality Control
SN	Serial Number
SD	Standard Deviation
S/R	Signal to Reference Ratio

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