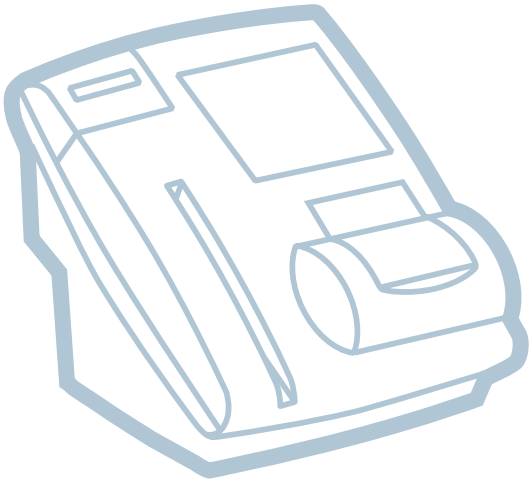
DCA Vantage®
Analyzer

For self-test use



Operator's Guide

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The information in this manual was correct at the time of printing. However, Siemens Healthcare Diagnostics continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

If the DCA Vantage® system 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.

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Appendix D: Symbols

Appendix E: Specifications

1 Installation

This section provides installation instructions for the DCA Vantage® system. Follow the installation steps correctly to ensure proper installation, operation, and service.

Choosing a Location for the System

Ensure the following when placing the system:

- Place the system where it will not be subjected to extreme temperature variations.
- Avoid placing the system near open windows, direct sunlight, ovens, hot plates, open burners, and radiators.
- Do not place the DCA Vantage system on the same table top as something that vibrates.
- Provide at least 8 cm on all sides of the system to allow free air circulation around the system.

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.

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 system
    - Cleaning Kit
    - Optical Test Cartridge (in system cartridge compartment)

- Power Cord for your region
- Air Filter Replacement Kit
- Spare Fuses
- HbA_{1c} Quick Reference Guide
- Documentation CD
- Paper Roll
- Self Adhesive Label Stock for onboard printer

Figure 1-1: DCA Vantage System Parts

5. Retain the shipping carton and packing for several weeks.

   If you need to ship the system, the shipping carton provides the best protection against damage.

6. Place the system on a firm, level work surface.
7. Check that the system is level, and that the back and sides of the system are at least 8 cm (3 inches) from any wall.

Recording the Warranty Information

1. Locate the serial number.
    - To find the serial number physically on the system, remove the air filter from the back of the system. The serial number is on a label between the fan and the power connector.
    - To find the serial number from the user interface, select **Menu > System Settings > View Settings**.

1	Serial number

Figure 1-2: Serial Number Location, Air Filter Removed

2. Write the installation date and serial number in *Appendix B, Warranty and Support Information*.

Connecting the System Power

1. Check 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.

1	Power plug
2	Power switch (off)
3	Power switch (on)

Figure 1-3: External Connections and Power Connections

Loading Paper in the Onboard Printer

Install a roll of printer paper for the onboard printer and reinstall the printer cover.

If no paper is available at the start of printing, the printer does not attempt to print. The printer stops printing when it runs out of 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. If the system is on, 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 printer cover off. See *Figure 1-4* .

WARNING
Be careful when touching the printer. It may be hot causing bodily injury.

4. Lift the paper feeder up.
5. Push the plastic paper cover down.
6. If you are changing the paper, remove the existing 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. If you are changing the paper, 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.

1	Printer cover
2	Paper feeder

Figure 1-4: Removing the Printer Paper

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 1-5: Inserting Paper into the Printer

12. Load the paper into the paper feeder.

1	Printer cover
2	Paper feeder

Figure 1-6: Loading the Paper into the 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.

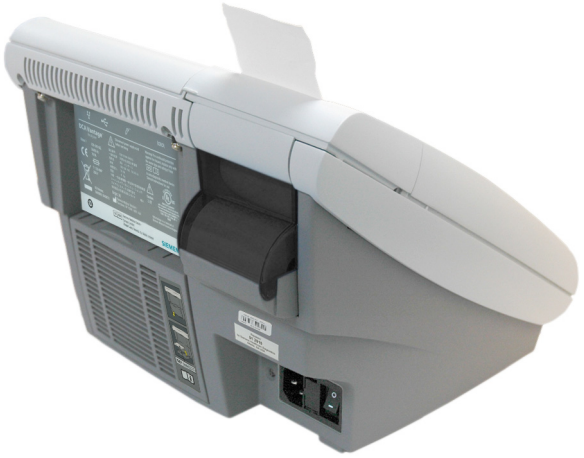


Figure 1-7: Closing the Cover

Starting the System

After the system is properly installed, start the DCA Vantage system by toggling the power button to the On position. The system displays the following information:

- Model Name
- System Software Version
- Copyright Information

A message displays explaining that the system is starting up, and runs a series of tests.

The DCA Vantage system checks that the compartment door is closed and performs hardware functionality tests to check that the internal optics and the mechanical system are working correctly.

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

Customizing the System

Using the System Settings Wizard

The first time you turn on the DCA Vantage system, the System Settings Wizard automatically runs to help you customize the system. The wizard displays the screens that are frequently used to set user preferences such as language, date, and time.

The System Settings Wizard only runs the first time you set up the DCA Vantage system.

Follow the instructions below to enter configuration information for your system.

1. On the Select Language screen, scroll through the list of languages, touch a language to select it, and select **Next**.
2. On the next screen, in response to the question **Will this system be used in Japan?** select **No**.

   Note Selecting Yes displays units for use in the Japanese market. If you accidentally select Yes, see *Disable Japanese Mode* on page 88 to reset the system. You must have a level 1 operator defined on the system to disable Japanse units, see *Designating a Level 1 Operator* on page 17.

   The Introduction to the Settings Wizard screen displays.
3. Select **Next**. to continue entering settings for your system.
4. On the Set System Time screen, select a time format:
   - 12-hour
   - 24-hour
5. Use the up and down arrows to select the hour and the minutes.
6. Select **AM** or **PM**.

   Note You only have this option if you select a 12-hour time format.
7. Select **Next**.

8. On the Set System Date screen, select a date format:
    - MM/DD/YYYY
    - DD.MM.YYYY
    - YYYY.MM.DD
9. Use the up and down arrows to select the month, day, and year.
10. Select **Next**.
11. On the Select Sequence Number screen, select a sequence number reset:
    - 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
12. Select **Next**.
13. On the Select Urine Creatinine Units screen, select **Next** to continue.

    Note Do not set units, as the system is not used for urinalysis.

    The Wizard Completed screen displays.
14. Select **Next** to return to the Home screen, or select **System Settings** and go to step 3 in *Designating a Level 1 Operator* to continue configuring the system.

Setting IFCC Units

The system defaults to reporting %HbA1c. Set IFCC units to report concentration in mmol/mol.

To set IFCC Units, you must first designate a Level 1 operator.

Designating a Level 1 Operator

1. At the Home screen, select **Menu**.
2. Select **System Setting**s from the Menu screen.
3. At the System Settings menu, select **Additional Settings**.
4. Select **General**.
5. Select **System Access**.

6. Confirm that the system access level is **Unrestricted**.
7. Select **Operators**.
8. To add an operator, select **ADD**.

   Use the alphanumeric keypad to enter an Operator ID in the Name field. The Operator ID can include letters and numbers. The Operator ID can be up to 16 characters.
9. Select **Enter** to save the Operator ID.
10. To add an access code, select **Edit** to the right of the ID field.

    Use the alphanumeric keypad to enter an access code. The access code field can include letters and numbers, with the letters entered as uppercase A–Z. The access code can be up to 13 characters.
11. Select **Enter**.
12. At the Add Operator screen, select **Save**.

    The operator information is saved.
13. Select **Save** twice to finish saving the settings.
14. Select **Home** to return to the Home screen, or continue with step 4 in *Setting IFCC Units* to continue configuring the system.

Setting IFCC Units

1. At the Home screen, select **Menu**.
2. Select **System Settings** from the Menu screen.
3. At the System Settings menu, select **Additional Settings**.
4. Select **HbA1c Reporting Units**.

   The access code screen displays.
5. Enter the access code.
6. Select **Enter**.

   The HbA_{1c} Reporting Units screen displays.
7. Select the IFCC for the Primary Reporting units.
8. Select the optional Secondary Reporting units.

9. Select **Save**.
10. Select **Home** to return to the Home screen, or continue with step 4 in *Setting Prompt for Patient Information* to continuing configuring the system.

Setting Prompt for Patient Information

1. At the Home screen, select **Menu**.
2. Select **System Settings** from the Menu screen.
3. At the System Settings menu, select **Additional Settings**.
4. At the Additional Settings menu, select **Patient Tests**.
5. Select **Data Entry**.
6. Select **Enabled** then select **Required** for each of the following options:
    - Last Name
    - First Name
7. To save the settings, select **Save**.
8. Select **Home** to return to the Home screen, or continue with step 3 in *Setting Auto-Print* to continuing configuring the system.

Setting Auto-Print

1. At the Home screen, select **Menu**, and then select **System Settings**.
2. At the System Settings menu, select **Additional Settings**.
3. At the Additional Settings menu, select **Printers**.
4. Select **Onboard Printer**.
5. Select **Enable.**
6. Select **Automatically print**.
7. Use the up and down arrows to select the number of copies of the report you want to print.
8. Select **Save**.
9. Select **Home** to return to the Home screen.

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

Siemens Healthcare Diagnostics recommends running the optical test cartridge before you analyze samples for the first time.

Note The optical test cartridge is reusable; do not discard.

1. Ensure the system is at the Home screen.
2. Locate the barcode on the optical test cartridge.
3. Hold the cartridge so that the barcode faces right.
4. Insert the cartridge into the barcode track.

5. Smoothly slide the cartridge down the barcode track.

   A beep sounds to signal a successful scan.

Figure 1-8: Scanning the Optical Test Cartridge

6. Open the reagent cartridge compartment door.
7. Hold the optical test cartridge so that the barcode faces to the right.
8. Insert the cartridge into the reagent compartment until you hear a click.

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

Figure 1-9: Inserting the Optical Test Cartridge into Compartment

9. Close the door.

   The test runs for 6 minutes.

   The system automatically provides results. If the test fails, contact your local technical support provider or distributor.

10. Print the results.

11. Remove the cartridge:

    a. Open the reagent cartridge compartment door.

    b. Locate the button on the right side of the cartridge compartment.

    c. Push and hold down the button 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 reagent compartment.

    f. Store the cartridge for future use.

2 Overview

Intended Use

The DCA Vantage system is designed to measure Hemoglobin A_{1c} (HbA_{1c}) in blood. The measurement of HbA_{1c} is recommended for monitoring how well you are managing your blood sugar levels.

Tests performed using the DCA Vantage system are intended for *in vitro* diagnostic use and are for self-test use.

How the System Works

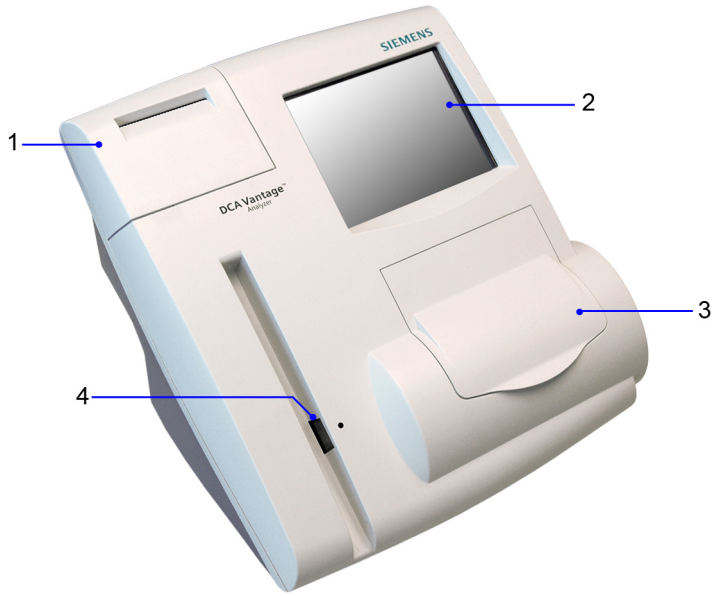
The DCA Vantage system and reagent cartridges measure the HbA_{1c} values in blood. Once the reagent cartridge containing the blood sample is loaded into the test compartment, it is spun to mix the blood with reagents and activate the reaction.

The test time is approximately 6 minutes. At the end of the test, the result is automatically calculated by the DCA Vantage system and displayed in mmol/mol values, the International Federation of Clinical Chemistry (IFCC) standard.

System Hardware

The DCA Vantage system has the following areas:

- reagent cartridge compartment
- onboard barcode reader
- display/touch screen
- printer



1	Printer
2	Display/touch screen
3	Reagent cartridge compartment
4	Onboard barcode reader

Figure 2-1: DCA Vantage System

Use the touch screen to interact with the system. View messages, options, and requests for information , and respond by selecting items on the screen.

CAUTION
Do not use anything hard or pointed on the touch screen. It can damage the touch screen.

Use the onboard barcode reader to scan the calibration cards, 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.

Power

Ensure that the power cord connects into the power cord receptacle. To turn the system on, press the power switch to the On position.

1	Power plug
2	Power switch (off)
3	Power switch (on)

Figure 2-2: Power Connections

Power Save

When the system is not in use for more than 30 minutes, Power Save automatically turns on. The system checks to ensure that no tests are in progress and data is not being imported or exported before entering power save. Touch the screen, open a cartridge compartment door or use the internal barcode scanner to resume operations.

Turning Off the System

You can leave the DCA Vantage system powered on except during maintenance and cleaning procedures. If you need to power off the system, refer to *Turning Off the DCA Vantage System* on page 55.

Note You do not have to reconfigure system settings when turning the power on. The system stores the saved settings.

Menus and Screens

Home Screen

The Home screen displays after the DCA Vantage system starts. The Home screen displays the time and date and the state of the system. It is the starting point for all testing.

From the Home screen, you can select:

- Help
- Turn Off
- Recall (advanced operators)
- Menu

If the system is in the Not Ready state and you cannot start a patient or quality control test, an alert displays explaining why the system is not ready. If the system is in the Ready state, you can start a patient test and scan an HbA_{1c}cartridge.

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

Help Menu, Software Version, and System Serial Number

The Help menu provides information about the DCA Vantage system. The software version number and system serial number also appear on the Home Help screen. To access the Help menu, select **Help** from the Home screen.

Recall Menu

The Recall menu provides access to patient test results, quality control test results, and calibration data. This function is only for use in an advanced environment.

System Menu

Select **Menu** from the Home screen to access Quality Control Tests, System Maintenance, System Settings, and System Tests.

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 optional quality 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 Event Notification window closes after you clear all events.

3 Performing an HbA_{1c} Test

You can test blood for the concentration of HbA_{1c}. Results are available in approximately 6 minutes.

Note Power Save turns on when the system not in use for more than 30 minutes. Touch the screen, open a cartridge compartment door or use the barcode scanner to wake up the system.

CAUTION
Do not use anything hard or pointed on the touch screen. It can damage the touch screen.

Disinfecting the Front of the System

If testing is not performed by a healthcare professional, disinfect the front of the system before use.

Disinfect the front of the system with a damp cloth or wipe with 10% bleach solution (0.525% Sodium Hypochlorite). Do not spray the solution directly onto the system.

Scanning the Calibration Card

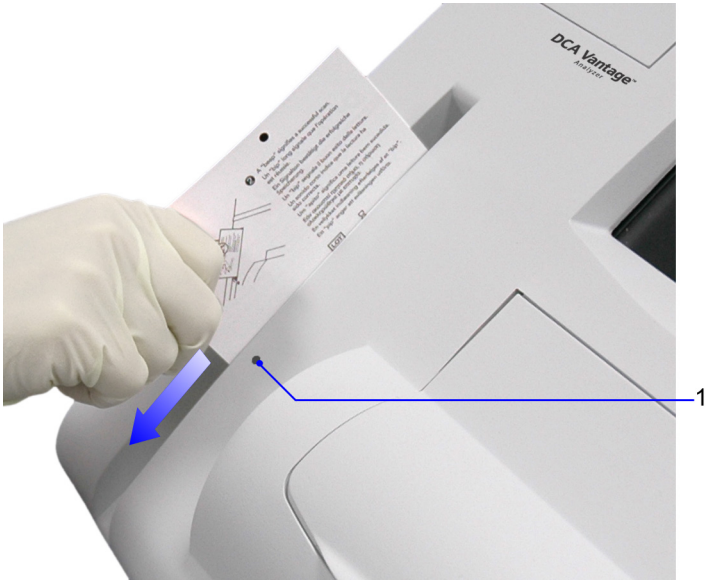
If you use a new lot of reagent cartridges, you need to scan a calibration card before running a test.

If you do not scan the calibration card into the system for a new reagent lot, the system software prompts you to scan the calibration card.

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.
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* on page 71.



1	Barcode track dot

Figure 3-1: Scanning Hemoglobin A_{1c} Calibration Card

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

Opening the Reagent Package

CAUTION

If you have stored the reagent cartridge in a refrigerator, bring the reagent cartridge to room temperature before starting a test.

The reagent cartridge must be used within 60 minutes after opening the foil pouch.

1. Remove one foil package (containing a reagent cartridge) from storage.

2. Bring the package to room temperature, if refrigerated.

   For more information, see *Recommended Procedures for Handling Reagent Cartridges* in the DCA® Systems Reagent Kit package insert.

3. Open the foil package as shown in Figure 3-2.

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.

Figure 3-2: Opening Reagent Cartridge Package

4. Remove the contents of the package.

The foil package includes the contents displayed below:

CAUTION
When handling the reagent cartridge, do not touch or otherwise contaminate the optical window as this may generate error codes during testing.

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

Figure 3-3: DCA Systems Reagent Cartridge Package

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.

Opening the Capillary Holder

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. Peel back the white plastic film from the clear plastic blister.

   Do not push the capillary holder through the plastic.

2. Inspect the capillary holder for the presence of the following parts:
   - absorbent pad
   - glass capillary

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

1	Glass Capillary
2	Absorbent Pad

Figure 3-4: Capillary Holder

Collecting a Sample

BIOHAZARD

To reduce the chance of infection:

- Make sure to wash the puncture site with soap and water, or wipe with alcohol, before sampling.
- Never share a lancet or a lancing device with anyone.
- Always use a new, sterile lancet—lancets are for single-use only.
- Wear gloves when assisting another individual.

1. Clean the finger with an alcohol wipe, or wash the hands in warm, soapy water. Dry the fingertip before taking a blood sample.
2. Using a lancing device, prick the finger according to the manufacturer's instructions.
3. Gently squeeze from the base of the finger to form a round drop of blood. If the blood smears or runs, wipe it off with a tissue and gently squeeze another round drop of blood.

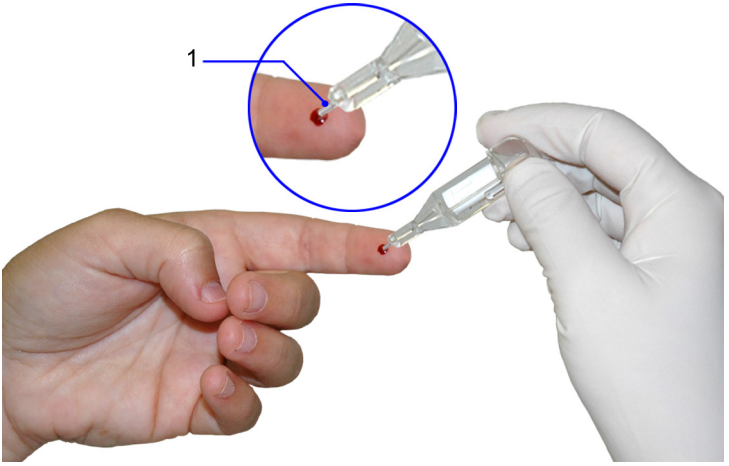
Filling the Glass Capillary with Blood

Fill the capillary using blood from a finger stick.

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

1. Hold the capillary holder at an angle.
2. Touch only the tip of the capillary to the small drop of blood on the finger until the capillary fills.

Note 1 µL of blood is required to fill the capillary.



1	Glass capillary tip

Figure 3-5: Filling Capillary Holder with Blood from Finger Stick

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

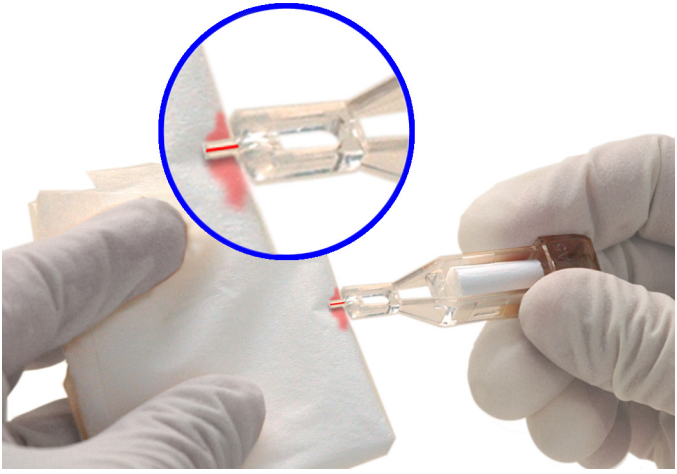


Figure 3-6: Wiping the Outside of the Glass Capillary

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.

4. Check the glass capillary for bubbles.

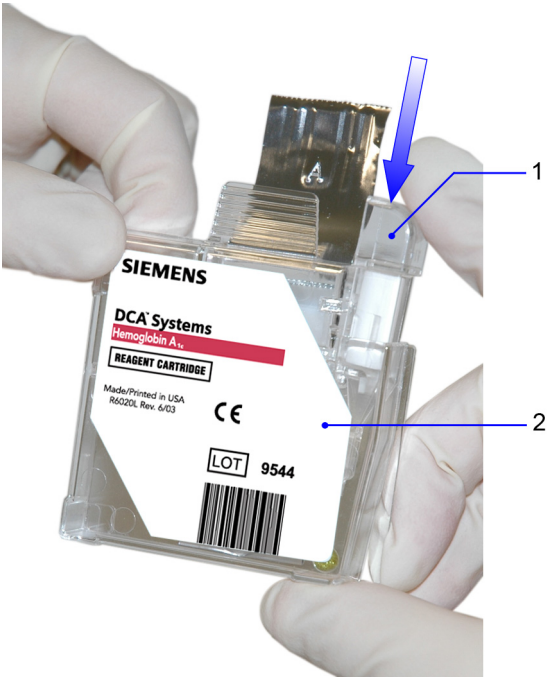
   If bubbles are obvious, discard the capillary holder and repeat the procedure using a new capillary holder.

Inserting the Capillary Holder

CAUTION
Use care when inserting the capillary holder into the cartridge. If the sample is shaken from the glass capillary it may impact the results.

1. Place the capillary holder flat side towards the cartridge, to complete the cartridge corner.

2. Insert the capillary holder into a reagent cartridge with the flat side towards cartridge, until the holder snaps into place.



1	Glass Capillary
2	Reagent Cartridge

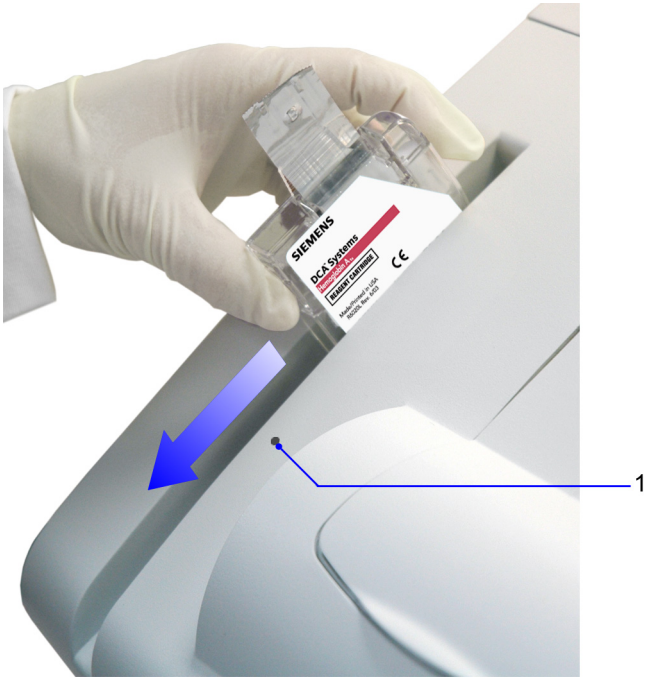
Figure 3-7: Inserting Capillary Holder into a Reagent Cartridge

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 into the barcode track above the black dot.
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* on page 71.



1	Barcode track dot

Figure 3-8: 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 click 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 3-9: Inserting the Reagent Cartridge into the Cartridge Compartment

4. Hold the cartridge in place.
5. Using a smooth, slow, continuous motion, pull the flexible pull-tab completely out of the reagent cartridge.
6. 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 reopen the door and pull the tab. Do not attempt to open the DCA Vantage door or remove the DCA HbA_{1c} cartridge while the test is in progress.

Entering the Patient Name

The Sample Data screen displays once the test is in progress. Use this screen to enter the patient name.

1. Select **Last Name**, and enter the patient's last name.
2. Select **First Name**, and enter the patient's first name.
3. Select **Next**.

   The countdown screen displays.

Reporting the Result

Print or record the results from the screen.

Note Do not make any decision of medical relevance without first consulting your healthcare provider.

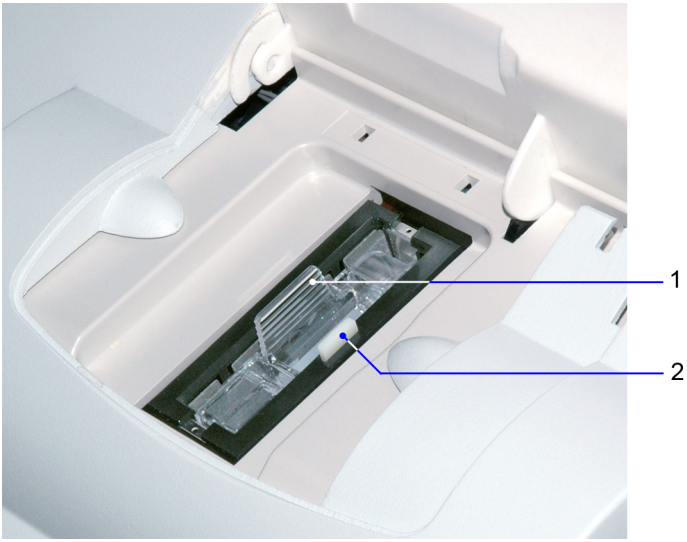
Removing the Reagent Cartridge

When the test is complete, remove the reagent cartridge from the system.

1. Select **Next**.
2. Open the cartridge compartment door.
3. Locate the button on the right side of the cartridge compartment.
4. Push and hold it down with your right hand.

5. With your left hand, gently push the tab on the cartridge to the right.

   This action releases (unlocks) the cartridge.



1	Reagent Cartridge
2	Release Button

Figure 3-10: Removing the Reagent Cartridge

6. Pull the reagent cartridge out of the compartment.

CAUTION
When handling the reagent cartridge, do not force the removal of the cartridge. This can cause physical injury to you and damage to the system.

7. Close the system door.
8. Discard the cartridge in a proper container. Consult your healthcare provider regarding local waste disposal requirements.

Canceling a test

You can cancel a test anytime. While a test is running, a display shows the time remaining and a Cancel button. If a test in progress is canceled, you must discard the sample.

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

4 Quality Control

Quality Control (QC) testing ensures that the reagent cartridges are reacting and being read correctly. Quality control testing also detects errors resulting from user techniques. Follow the manufacturer's storage and handling instructions for control material. Improper storage and handling of control materials can cause wrong results. Refer to the control material package insert for proper handling instructions.

Run quality control tests under the following conditions:

- when using a new shipment of reagents
- when using a new lot number of reagent
- whenever test results are in doubt

All quality control results must be within the acceptable range before any sample is tested and the results are reported. If a quality 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*.

Opening the Reagent Package

CAUTION

If you have stored the reagent cartridge in a refrigerator, bring the reagent cartridge to room temperature before starting a test.

The reagent cartridge must be used within 60 minutes after opening the foil pouch.

1. Remove one foil package (containing a reagent cartridge) from storage.

2. Bring the package to room temperature, if refrigerated.

   For more information, see *Recommended Procedures for Handling Reagent Cartridges* in the DCA® Systems Reagent Kit package insert.

3. Open the foil package as shown in Figure 4-1.

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.

Figure 4-1: Opening Reagent Cartridge Package

4. Remove the contents of the package.

The foil package includes the contents displayed below:

CAUTION
When handling the reagent cartridge, do not touch or otherwise contaminate the optical window as this may generate error codes during testing.

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

Figure 4-2: DCA Systems Reagent Cartridge Package

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.

Opening the Capillary Holder

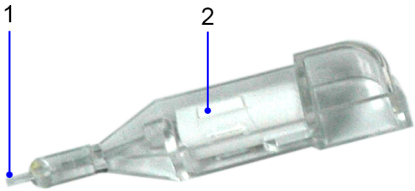
Note You can save unused capillary holders and use them with any lot of DCA Hemoglobin A_{1c} reagent cartridges.

1. Open the plastic wrap of the capillary holder by tearing the wrap at the serrated edge with the arrow. Peel back the white plastic film from the clear plastic blister.

   Do not push the capillary holder through the plastic.

2. Inspect the capillary holder for the presence of the following parts:
   - absorbent pad
   - glass capillary

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



1	Glass Capillary
2	Absorbent Pad

Figure 4-3: Capillary Holder

Preparing Controls

CAUTION

If you have stored the reagent cartridge in a refrigerator, bring the reagent cartridge to room temperature before starting a test.

Use the following procedure to prepare controls:

Note Prepare the controls according to the manufacturer's instructions.

1. Remove and unwrap the capillary holder from the reagent kit.
2. Mix the QC 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.

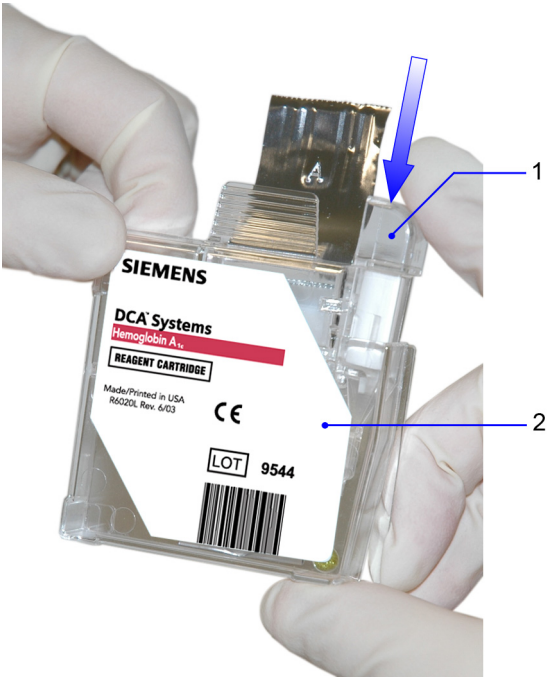
Note If bubbles are obvious, discard the capillary and repeat the collecting procedure.

Inserting the Capillary Holder

CAUTION
Use care when inserting the capillary holder into the cartridge. If the sample is shaken from the glass capillary it may impact the results.

1. Place the capillary holder flat side towards the cartridge, to complete the cartridge corner.

2. Insert the capillary holder into a reagent cartridge with the flat side towards cartridge, until the holder snaps into place.



1	Glass Capillary
2	Reagent Cartridge

Figure 4-4: Inserting Capillary Holder into a Reagent Cartridge

Running a Quality Control Test

1. Ensure you are at the Home screen.

   You must start the control test from the Home screen; otherwise the system does not recognize that a quality control test is being run. The system will not save the quality control data to memory.

2. Locate the Siemens control card.

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

3. Locate the dot on the system next to the barcode track.

4. Locate the barcode on the control card.
5. Hold the card so that the barcode faces to the right.
6. Insert the control card into the top of the barcode track.
7. Hold the control card gently against the right side of the track and smoothly slide the card down.

1	Barcode track dot

Figure 4-5: 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* on page 71.

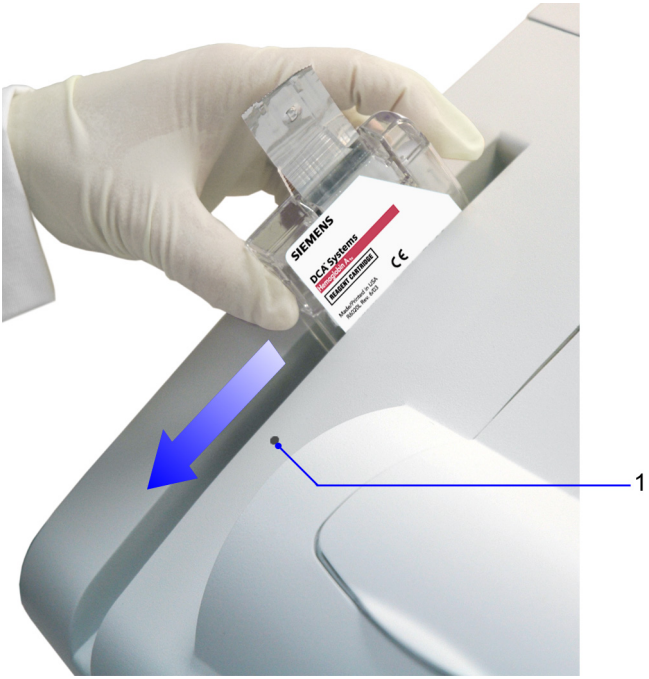
Scanning the Reagent Cartridge

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 into the barcode track above the black dot.
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* on page 71.



1	Barcode track dot

Figure 4-6: 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 click 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 4-7: Inserting the Reagent Cartridge into the Cartridge Compartment

4. Hold the cartridge in place.
5. Using a smooth, slow, continuous motion, pull the flexible pull-tab completely out of the reagent cartridge.
6. Close the door and dispose of the flexible pull-tab.

   Five seconds after the door is closed, a beep sounds and the assay begins.

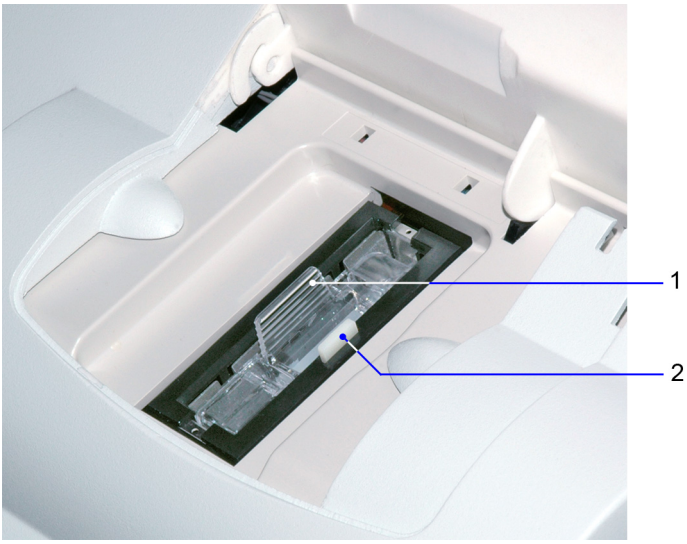
   Note If you accidentally close the door before you pull the flexible plastic tab, you have 5 seconds to reopen the door and pull the tab. Do not attempt to open the DCA Vantage door or remove the DCA HbA_{1c} cartridge while the test is in progress.

Removing the Reagent Cartridge

When the test is complete, remove the reagent cartridge from the system.

1. Select **Next**.
2. Open the cartridge compartment door.
3. Locate the button on the right side of the cartridge compartment.
4. Push and hold it down with your right hand.
5. With your left hand, gently push the tab on the cartridge to the right.

   This action releases (unlocks) the cartridge.



1	Reagent Cartridge
2	Release Button

Figure 4-8: Removing the Reagent Cartridge

6. Pull the reagent cartridge out of the compartment.

CAUTION
When handling the reagent cartridge, do not force the removal of the cartridge. This can cause physical injury to you and damage to the system.

7. Close the system door.
8. Discard the cartridge in a proper container. Consult your healthcare provider regarding local waste disposal requirements.

Quality Control Errors

If the quality 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.

If the problem persists, contact your local technical support provider or distributor.

5 Maintenance

Maintenance Schedule

BIOHAZARD
Wear gloves when performing maintenance.

Perform maintenance on the following schedule:

- Clean the onboard barcode reader window and exterior of the system weekly.
- Change the air filter and perform the optical test quarterly.
- All other maintenance can be done on an as-needed basis.

Turning Off the DCA Vantage System

WARNING
Turn the power off and disconnect the power cord before cleaning the DCA Vantage system.

Perform these steps to turn the system off:

Note You do not have to reconfigure system settings when turning the power on, the system stores the saved settings.

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**.

   The system begins shutting down.

3. After shutdown completes, turn the power switch to the off position.

Note Wait until shutdown completes before turning the power switch to the off position.

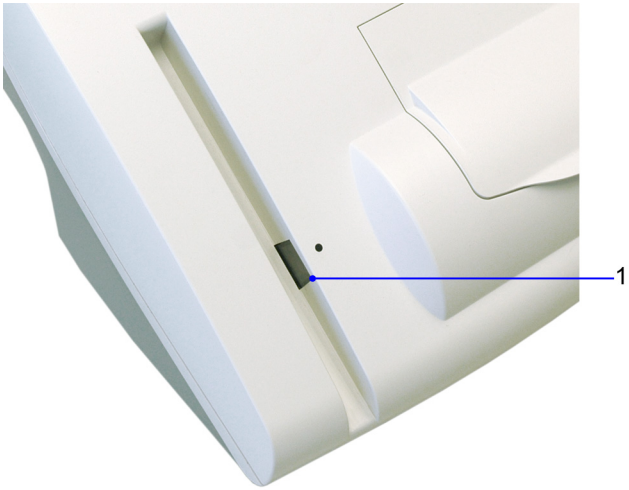
Cleaning the Onboard Barcode Reader Window

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.



1	Onboard barcode reader

Figure 5-1: Cleaning the Onboard Barcode Reader Window

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

Cleaning the Exterior of the System

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.

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

Note See *Disinfecting the Front of the System* on page 29 for information on disinfecting the system.

Removing and Cleaning the Cartridge Spring and Cartridge Area

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 gloves when performing maintenance.

Materials Required:

- lint-free cloth
- water or ethanol
- paper clip or similar device
- mild detergent
- sponge swab

1. Ensure the power is off.
2. Open the cartridge compartment door as far as possible.
3. 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.
4. Dry the surface using a clean, dry, lint-free cloth.
5. Locate the cartridge return spring inside the cartridge holder.

6. Insert the tip of a straightened paper clip (or other like device) into the top hole on the spring.

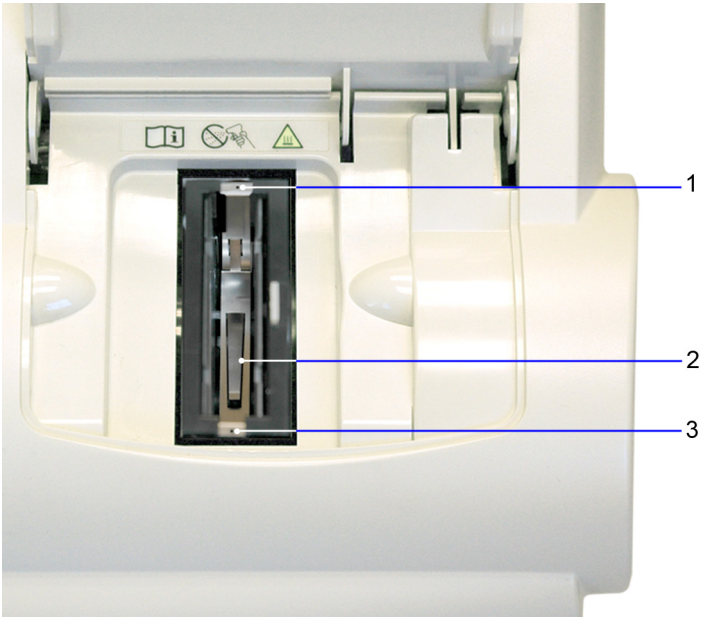


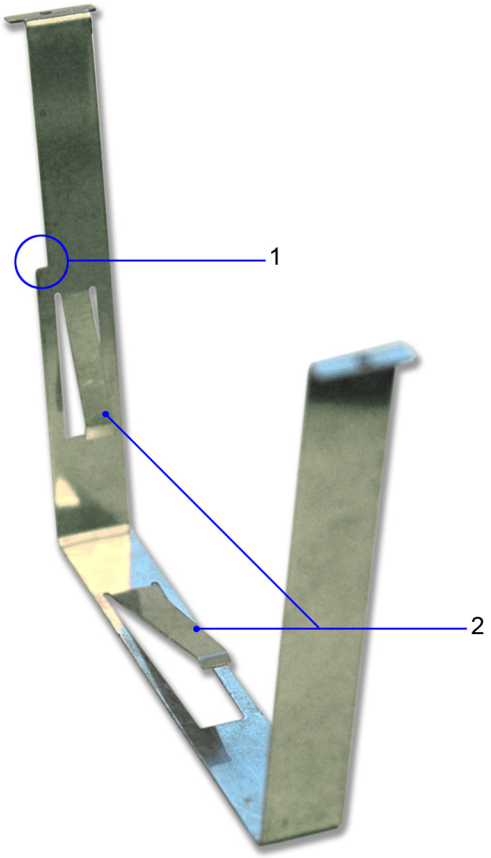
Figure 5-2: Return Spring in Cartridge Compartment

1	Top hole
2	Leaf spring
3	Bottom hole

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

9. Pull the cartridge return spring completely out of the system.
10. 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 Ensure the leaf springs are not bent or damaged while cleaning. Damaged leaf springs do not function properly.



1	Spring cut-out
2	Leaf springs

Figure 5-3: Return Spring

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

CAUTION
Do not use a cotton swab. Cotton fibers left on the surface can interfere with system optics.

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

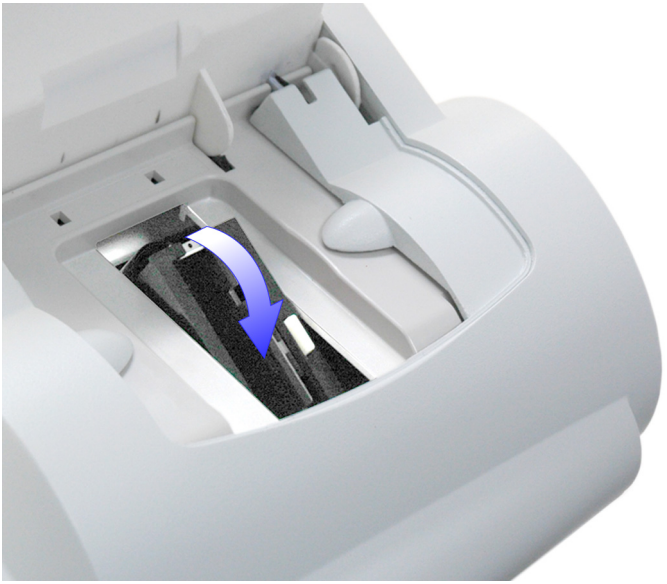


Figure 5-4: Rotating the Cartridge Compartment

14. Dampen a sponge swab with water or ethanol.
15. 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.

16. Locate the vertical grooves inside the cartridge compartment.

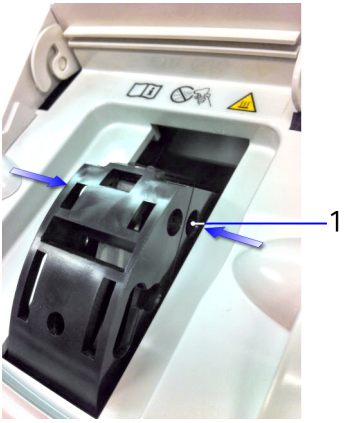
17. Locate the front and back slots near the top of the compartment.
18. Locate the leaf spring on one side of the cartridge return spring.
19. With the leaf spring oriented toward the back of the system, complete the following steps to lower the spring into the system:
    a. Hold on to both sides of 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 d to attach the opposite side of the cartridge return spring to the cartridge compartment.

Cleaning the Cartridge Compartment Optical Window

BIOHAZARD
Wear gloves when performing maintenance.

1. Remove the air filter from the back of the system.
2. Rotate the cartridge holder with the compartment door partially closed to locate the optical window. See *Figure 5-4: Rotating the Cartridge Compartment* on page 61.

3. With the cartridge holder fully rotated, locate the 2 round holes on either side of the cartridge compartment. The optical window is the lower of the 2 openings, nearest the cover.



1 Optical window

Figure 5-5: Location of Optical Window Openings

4. Fully open the cartridge compartment cover.
5. Using a canister of pressurized, compressed air, carefully direct the spray of air through the optical window holes on both sides of the cartridge holder, aiming the nozzle toward the side or back of the system.

CAUTION
When using compressed air, hold the canister as vertically as possible, tilting the system if necessary. If you hold the canister at a sharp angle to the vertical, liquid propellant can escape from the canister and damage the optics. You must hold the canister in a nearly vertical position to get only a spray of air with no liquid.

6. Return the cartridge holder to its original position and close the compartment door.
7. Replace the air filter.

8. If the problem persists, contact the Siemens Technical Support Center or your local technical service provider.

Changing the Air Filter

Materials Required:

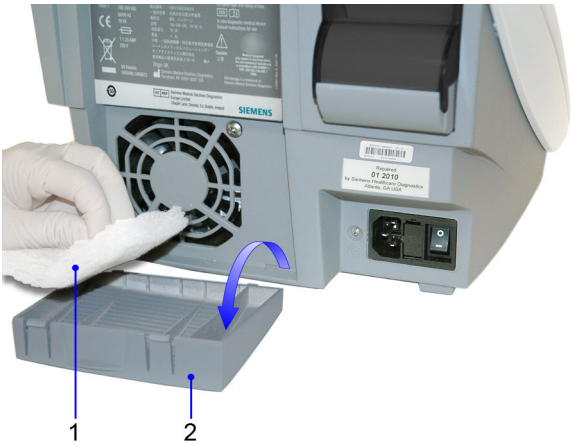
- air filter

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

1	Filter cover

Figure 5-6: Filter Location

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



1	Air filter
2	Air filter holder

Figure 5-7: Removing the Air Filter

4. Place the filter holder back on the system.

Replacing the Fuse

The fuse holder is located in the back panel between the power cord and the power switch. It contains 2 fuses; both fuses are required. There are 2 grooves above the fuse cover and 2 grooves below the fuse cover. Place the screwdriver blade in the smaller groove to remove the cover.

Materials Required:

- Flat-head screwdriver
- Fuse: 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 2 grooves on the top of the fuse holder.

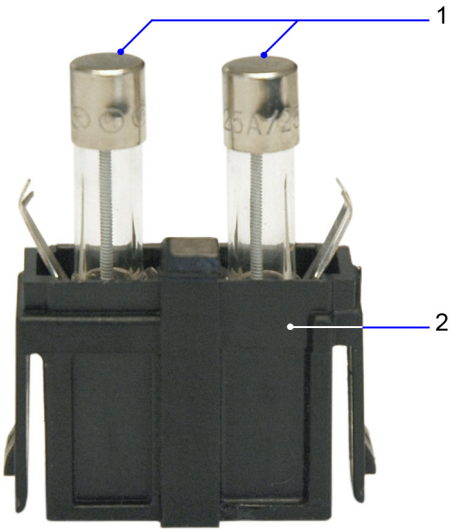
CAUTION
Ensure you place the screwdriver blade in the smaller groove. You can damage the fuse block by placing the blade in the larger groove.

2. Insert the blade of a small flat-head screwdriver into the smallest groove.
3. Exert pressure to unsnap the top of the fuse holder.

1	Small groove

Figure 5-8: Removing Fuse Holder

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



1	Fuse
2	Fuse block

Figure 5-9: Fuse

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

Performing User System Tests

The User System Tests screen enables you to test the DCA Vantage system. If any of the tests fail contact your local technical support provider or distributor.

1. At the System Menu screen, select **System Tests**.
2. From the System Test menu, select **User System Tests**.
3. Select the checkbox of the test you want to perform.

4. To initiate the test, select **Start**.

   The tests that require no additional action automatically run.

Note Some options may not be available because they were not configured in your system.

The following table explains the different tests you can perform, if enabled, 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	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.
Onboard Printer	Verify that the onboard printer prints a report.
Lamp	The system automatically runs the test.
Motor Control	The system automatically runs the test.
Measurement System	The system automatically runs the test.

Calibrating the Touch Screen

Calibrate the touch screen 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.

Running the Optical Test

Run an optical test quarterly or as needed, see *Running the Optical Test* on page 20 for details.

6 Troubleshooting

If an operational or system problem occurs, use the information in this section to correct the problem.

If you are unable to resolve the problem or have questions, contact your local technical support provider.

Troubleshooting the System

If the system is not responding correctly, find the symptom and follow the recommended action to correct the problem.

Symptom	Probable Cause	Action
Barcode cannot be read using the Onboard barcode reader	Not at the Home Screen.	Ensure you are at the Home Screen before scanning the cartridge or card.
	Are you scanning the cartridge or card too quickly?	Rescan the cartridge or card using a slower motion. If you are still having problems, try scanning upward instead of down.
	The barcode is on the wrong side.	Ensure the barcode is facing right. Refer to *Scanning the Reagent Cartridge* on page 37.
	Is the label smudged or contains extra marks?	Verify label is clean and clear of extra markings.
	Does the problem only occur when scanning the calibration card?	The Calibration card must be held flat against the scanner slot or it will not read the barcode.

Symptom	Probable Cause	Action
	Does the problem only occur when scanning the reagent barcode?	Document the issue with the reagent lot and replace the reagent. Contact your local support provider.
Buffer Tab Hard to Pull	If you pull the foil tab too fast, it can tear the foil and impede the full buffer release.	Slowly pull the buffer tab while anchoring the cartridge with 2 fingers.
Calibration Lot Expired	Check the date on the control card. If the date is valid, the DCA Vantage system may be set with an incorrect date.	Refer to *Setting the Date Format and Current Date* on page 90.
Cartridge is stuck in the system		If the cartridge tab has broken off, do not try to remove the cartridge. Contact your local technical support provider. If the cartridge tab is not broken and you are unable to remove the cartridge using the steps in *Removing the Reagent Cartridge* on page 40, contact your local technical support provider.

Symptom	Probable Cause	Action
Cartridge is difficult to remove from the system.		After removing the cartridge, follow the steps in *Removing and Cleaning the Cartridge Spring and Cartridge Area* on page 58. When the system returns to normal operating temperature, perform the steps in *Running the Optical Test* on page 20.
Cartridge is wet when removing from the system.		After removing the cartridge, follow the steps in *Removing and Cleaning the Cartridge Spring and Cartridge Area* on page 58. When the system returns to normal operating temperature, perform the steps in *Running the Optical Test* on page 20.
Door Open error	Reagent compartment door is open.	Verify the compartment door is closed. Rerun the test.
	Reagent compartment door sensor is defective.	If this problem continues after verifying the door the closed, contact your local technical support provider.
Display is blank	Is the power cord connected to the system and the electrical outlet?	Check that the power cord is firmly connected to the system and into a live electrical outlet.
	Is the system turned off?	Turn system power on.
	Is the system in power save?	Touch the screen, open the cartridge compartment door or use the internal barcode scanner to resume operations.

Symptom	Probable Cause	Action
	Touch screen electronics are defective.	Contact your local technical support provider.
	The fuse needs to be replaced.	Replace the fuse. See *Replacing the Fuse* on page 65.
Display is dim	Contrast is set too low.	Adjust contrast. Refer to *Setting the System Display* on page 92.
System is inactive	Is the power cord connected to the system and the electrical outlet?	Check that the power cord is firmly connected to the system and into a live electrical outlet.
	The fuse needs to be replaced.	Replace the fuse. See *Replacing the Fuse* on page 65.
Onboard Printer is not working	Is the printer enabled in software?	Verify that the printer is enabled. Refer to *Setting up the Onboard Printer* on page 92.
	Is there paper in the printer? Is it loaded correctly? Is the printer door closed?	Check the printer area.
Test Canceled	Test not started within 15 minutes of scanning the reagent cartridge.	Rerun test within the time parameters.
Test will not start	A door is open.	Verify all doors are closed.

Symptom	Probable Cause	Action
	Not at Home screen, system is not ready, or error codes require correction before running test.	Return to the Home screen. The Home screen should display Ready. If an error code displays, correct the error to continue.
	Calibration data does not exist for the reagent lot.	No calibration data for the lot of reagent cartridges. You must enter the calibration data to continue.
Touch screen not responding or not responding correctly.	Touch screen needs to be calibrated.	Run the touch screen calibration. Refer to *Calibrating the Touch Screen* on page 69.

Troubleshooting Reagents

The following problems may occur with the reagent cartridge.

Symptom	Possible Cause	Action
Temperature indicator is red.	Product was not shipped or stored properly.	If the temperature indicator on the carton is red, the cartridges should be discarded.
Reagent not absorbed by cartridge filter at the end of the test.	The DCA Vantage system is not on a level work surface.	Verify that the system is properly installed on a level surface.
	The filter in the capillary holder is not absorbent.	Contact your local technical support provider.

Errors Codes and Corrective Actions

This section of the guide lists error codes and messages, along with a description and corrective actions.

If you cannot correct the error or the problem persists, record the error code and contact your local technical service provider for assistance.

Error Code	*Description*	*Action*
E10 Motor position sensor error	The Home/Index sensor has an issue.	1. Discard the sample. 2. Restart the system. 3. Rerun the test.
E12 Motor position error	There was an issue detected during a motor rotation operation.	1. Discard the sample. 2. Restart the system. 3. Rerun the test.
E20 Dark offset measurement is out of range	This may indicate an electronic failure.	Contact your local technical support provider.
E21 Lamp Failure	May be caused by: • incorrect position of cartridge holder • lamp assembly issue	1. Discard the sample. 2. Power off the system. 3. Clean the cartridge area. Refer to *Removing and Cleaning the Cartridge Spring and Cartridge Area* on page 58 and *Cleaning the Cartridge Compartment Optical Window* on page 62. 4. Restart the system.

Error Code	*Description*	*Action*
E22 Optical reading is out of range	May be caused by: • lamp assembly issue • optical system error	1. Discard the sample. 2. Power off the system. 3. Clean the cartridge area. Refer to *Removing and Cleaning the Cartridge Spring and Cartridge Area* on page 58 and *Cleaning the Cartridge Compartment Optical Window* on page 62. 4. Restart the system.
E23 Excessive noise on the Sample channel	May be caused by: • low lamp intensity • lamp alignment/ rotation • variations in lamp intensity	1. Discard the sample. 2. Power off the system. 3. Clean the cartridge area. Refer to *Removing and Cleaning the Cartridge Spring and Cartridge Area* on page 58. 4. Check/replace the air filter. 5. Clean the cartridge holder with compressed air while rotating the holder. See *Cleaning the Cartridge Compartment Optical Window* on page 62. 6. Restart the system. 7. Run an optical test.

Error Code	*Description*	*Action*
E24 Excessive noise on the Reference channel	May be caused by: • low lamp intensity • lamp alignment/ rotation • variations in lamp intensity	1. Discard the sample. 2. Power off the system. 3. Clean the cartridge area. Refer to *Removing and Cleaning the Cartridge Spring and Cartridge Area* on page 58. 4. Check/replace the air filter. 5. Clean the cartridge holder with compressed air while rotating the holder. See *Cleaning the Cartridge Compartment Optical Window* on page 62. 6. Restart the system. 7. Run an optical test.
E26 Excessive noise in sample reading	May be caused by: • low lamp intensity • lamp alignment/ rotation • variations in lamp intensity	1. Discard the sample. 2. Power off the system. 3. Clean the cartridge area. Refer to *Removing and Cleaning the Cartridge Spring and Cartridge Area* on page 58. 4. Restart the system.
E27 Excessive Lamp Drift	May be caused by: • dust in the optical path • lamp orientation	1. Discard the sample. 2. Power off the system. 3. Clean the cartridge area. Refer to *Removing and Cleaning the Cartridge Spring and Cartridge Area* on page 58. 4. Restart the system.

Error Code	*Description*	*Action*
E30 Thermal control system error - low	May be caused by: • defective heater plate • defective thermistor assembly • defective connector • defective electrical circuit	1. Discard the sample. 2. Restart the system.
E31 Cartridge temperature is very low	May be caused by: • defective heater plate • defective thermistor assembly • defective connector • defective electrical circuit • cold cartridge	1. Ensure the reagent cartridge was properly prepared for testing. Reagents should be at room temperature for testing. 2. Power off the system. 3. Rerun the test.
E32 Cartridge temperature too low during measurement	May be caused by: • defective heater plate • defective thermistor assembly • defective connector • defective electrical circuit • cold cartridge	1. Ensure the reagent cartridge was properly prepared for testing. Reagents should be at room temperature for testing. 2. Power off the system. 3. Rerun the test.

Error Code	*Description*	*Action*
E33 Cartridge temperature too high during measurement	May be caused by: • defective heater plate • defective thermistor assembly • defective connector • defective electrical circuit • hot cartridge	1. Ensure the reagent cartridge was properly prepared for testing. Reagents should be at room temperature for testing. 2. Power off the system. 3. Rerun the test.
E34 Cartridge temperature very high	May be caused by: • defective heater plate • defective thermistor assembly • defective connector • defective electrical circuit • hot cartridge	1. Ensure the reagent cartridge was properly prepared for testing. Reagents should be at room temperature for testing. 2. Power off the system. 3. Rerun the test.
E35 Thermal control system error - high	May be caused by: • defective heater plate • defective thermistor assembly • defective connector • defective electrical circuit	1. Restart the system. 2. Rerun the test.

Error Code	*Description*	*Action*
E36 Temperature control failure	May be caused by: • defective heater plate • defective thermistor assembly • defective connector • defective electrical circuit	1. Restart the system. 2. Rerun the test.
E37 Internal instrument temperature error–low	May be caused by: • damaged ambient temperature thermistor • circuit failure	1. Restart the system. 2. Rerun the test.
E38 Internal instrument temperature error–high	May be caused by: • damaged ambient temperature thermistor • circuit failure	1. Restart the system. 2. Rerun the test.
E40 Barcode read error	The number of digits read by the barcode reader does not match what is expected. Possible causes: • incorrect barcode • partial barcode scan • barcode reader is not working properly	1. Swipe the cartridge or card from the bottom of the track to the top. 2. Rescan the barcode more slowly or quickly. 3. Clean the barcode window. 4. Use another barcode label.

Error Code	*Description*	*Action*
E41 Incorrect barcode data	The barcode has the correct number of digits, but the character does not match the expected pattern. Possible causes: • incorrect barcode • partial barcode scan • barcode reader is not working properly	1. Swipe the cartridge or card from the bottom of the track to the top. 2. Rescan the barcode more slowly or quickly. 3. Clean the barcode window. 4. Use another barcode label.
E60 Database Failure	The database is not functioning properly. The database may be corrupted or the system was not properly powered down.	1. Turn off the system from the Home screen and wait until system shutdown is complete. 2. Restart the system.
E61 Database read error	An attempt to read the database fails, and returns no data or corrupt data.	1. Turn off the system from the Home screen and wait until system shutdown is complete. 2. Restart the system.
E62 Database write error	An error is returned when writing data. The database may be corrupted.	Restart the system.
E63 Database is full	The database is filled to the allotted capacity for storing sample test results.	Delete some old data records by: • Deleting specific old data records. • Setting the system to automatic purge mode.

Error Code	*Description*	*Action*
E70 Internal Printer Failure	The internal printer failed because of a hardware error.	Restart the system.
E99 Internal System Error	An internal system failure occurred or the system is not ready.	Contact your local technical support provider.
E101 HbA_{1c} Cartridge Error - buffer absorbance is too low	May be caused by: • no cartridge present • an optical alignment problem	1. Discard the sample. 2. Repeat the test with a new cartridge. 3. If the error still occurs, contact your local technical support.
E102 HbA_{1c} Cartridge Error - buffer absorbance is too high	May be caused by: • condensation on the cartridge • cartridge not located in the proper position • buffer tab not removed • optical window defect	1. Discard the sample. 2. Verify that the cartridge is inserted completely. 3. Pull the flexible tab. 4. Repeat the test with a new cartridge. 5. If the error still occurs, run the optical test cartridge.
E103 HbA_{1c} Cartridge Error - high variation in buffer readings	May be caused by condensation on the cartridge.	1. Discard the sample. 2. Repeat the test with a new cartridge. 3. If the error still occurs, contact your local technical support.

Error Code	*Description*	*Action*
E104 HbA_{1c} Sample Error - low total hemoglobin	May be caused by: • no or low blood reaction • no capillary holder inserted • improper constitution of controls or use of non-DCA controls • hemoglobin < 7 g/dL = anemic patient • buffer tab not removed	1. Discard the sample. 2. Repeat the test with a new sample. **Note** Wait no more than 5 minutes after filling the capillary to start the test. 3. If the error still occurs, contact your local technical support.
E105 HbA_{1c} Sample Error - high total hemoglobin	May be caused by: • excess blood on capillary • irregularity in patient red blood cells (rare) • hemoglobin > 24 g/dL = patient has abnormally high hemoglobin	1. Discard the sample. 2. Repeat the test with a new sample. 3. Verify that the capillary has no excess blood on the capillary holder. 4. If the error still occurs, contact your local technical support.

Error Code	*Description*	*Action*
E106 HbA_{1c} Sample Error - low total hemoglobin	May be caused by: • no or low blood reaction • no capillary holder inserted • improper constitution of controls or use of non-DCA controls • hemoglobin < 7 g/dL = anemic patient • buffer tab not removed	1. Discard the sample. **Note** Wait no more than 5 minutes after filling the capillary to start the test. 2. Repeat the test with a new sample.
E107 HbA_{1c} Sample Error - high total hemoglobin	May be used by: • excess blood on capillary • irregularity in patient red blood cells (rare) • hemoglobin > 24 g/dL = patient has abnormally high hemoglobin	1. Discard the sample. 2. Repeat the test with a new sample. 3. Verify that the capillary has no excess blood on the capillary holder. 4. If the error still occurs, contact your local technical support.
E108 HbA_{1c} Cartridge Error - high variable in hemoglobin measurement	Sample may be contaminated.	1. Discard the sample. 2. Repeat the test with a new sample. 3. If the error still occurs, contact your local technical support.

Error Code	*Description*	*Action*
E109 HbA_{1c} Cartridge error - reading for glycated hemoglobin is too low	The cartridge may have been exposed to excessive humidity or temperature	1. Discard the sample. 2. Repeat the test with a new sample. **Note** Verify that the reagent kit was stored properly. 3. If the error still occurs, contact your local technical support.
E110 HbA_{1c} Cartridge Error - reading for glycated hemoglobin is too high	The cartridge may have been exposed to excessive humidity or temperature.	1. Discard the sample. 2. Repeat the test with a new sample. **Note** Verify that the reagent kit was stored properly. 3. If the error still occurs, contact your local technical support.
E111 HbA_{1c} Cartridge Error - low glycated hemoglobin response	The cartridge may have been exposed to excessive humidity or temperature.	1. Discard the sample. 2. Repeat the test with a new sample. **Note** Verify that the reagent kit was stored properly. 3. If the error still occurs, contact your local technical support.
E112 HbA_{1c} Cartridge Error - very large glycated hemoglobin response	The cartridge may have been exposed to excessive humidity or temperature.	1. Discard the sample. 2. Repeat the test with a new sample. **Note** Verify that the reagent kit was stored properly. 3. If the error still occurs, contact your local technical support.

Error Code	*Description*	*Action*
E113 HbA_{1c} Cartridge Error - irregular reaction kinetics (A_1)	The cartridge may have been exposed to excessive humidity or temperature.	1. Discard the sample. 2. 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. 3. If the error still occurs, contact your local technical support.
E114 HbA_{1c} Cartridge Error - irregular reaction kinetics (A_2)	The cartridge may have been exposed to excessive humidity or temperature.	1. Discard the sample. 2. 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. 3. If the error still occurs, contact your local technical support.

Error Code	*Description*	*Action*
E115 HbA_{1c} Cartridge Error - final hemoglobin reading is greater than the previous check point	Blood may have been left in the capillary too long	1. Discard the sample. 2. Repeat the test with a new sample. **Note** Wait no more than 5 minutes after filling the capillary to start the test. 3. If the error still occurs, contact your local technical support.
E116 HbA_{1c} Cartridge Error - irregular reaction kinetics (high variability)	The cartridge may have been exposed to excessive humidity or temperature.	1. Discard the sample. 2. 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. 3. If the error still occurs, contact your local technical support.

Disable Japanese Mode

Use this procedure to disable Japanese Mode if it is accidentally set during initial setup:

1. Select **Menu > System Settings > Additional Settings > Japanese Mode**.
2. Enter your Level 1 access code.

   See *Designating a Level 1 Operator* on page 17 if you have not set a Level 1 operator on your system.
3. Select **Off**.
4. Select **Save**.
5. Change the reporting units to IFCC. See *Setting IFCC Units* on page 17.

7 Customizing the System

Running the System Settings Wizard

The System Settings Wizard only runs the first time you set up the DCA Vantage system.

If you want the System Settings Wizard to run the next time the system is turned on, follow these procedures:

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

See *Using the System Settings Wizard* on page 16 for details on using the wizard.

General Settings

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, date, and sequence number options. Most of these settings are initially set during installation using the System Settings Wizard.

Setting the Language

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

1. At the Home screen, select **Menu**.
2. Select **System Settings** from the Menu screen.
3. At the System Settings menu, select **Additional Settings**.
4. At the Additional Settings menu, select **General**.

5. Select **Language**.
6. Select the language that you want to display on the system.
7. To save the language selection, select **Save**.

Setting the Time Format and Time

Use the Time screen to select the time format as 12-hour or 24-hour and 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 Home screen, select **Menu**.
2. Select **System Settings** from the Menu screen.
3. At the System Settings menu, select **Additional Settings**.
4. At the Additional Settings menu, select **General**.
5. Select **Time**.
6. Select a time format:
   - 12-hour
   - 24-hour
7. Use the up and down arrows to select the hour and the minutes.
8. Select **AM** or **PM**.

   Note You only have this option if you select a 12-hour time format.
9. 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 Home screen, select **Menu**.
2. Select **System Settings** from the Menu screen.
3. At the System Settings menu, select **Additional Settings**.
4. At the Additional Settings menu, select **General**.
5. Select **Date**.

6. Select a date format:
    - MM/DD/YYYY
    - DD.MM.YYYY
    - YYYY.MM.DD
7. Use the up and down arrows to select the month, day, and year.
8. To save the date format, select **Save**.

Setting the Sequence Number Options

Use the Sequence Number screen to specify whether and when the sequence number resets.

1. At the Home screen, select **Menu**.
2. Select **System Settings** from the Menu screen.
3. At the System Settings menu, select **Additional Settings**.
4. At the Additional Settings menu, select **General**.
5. Select **Sequence Number**.
6. Select a sequence number reset:
    - 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
7. To save the sequence number setting, select **Save**.

Volume and Display

Use the System Settings menu to access screens to configure the sound volume and display contrast and brightness.

Setting the Sound Volume

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

1. At the Home screen, select **Menu**.
2. Select **System Settings** from the Menu screen.
3. At the System menu, select **System Settings**.
4. Select **Sound Volume**.

5. Select one of the following options:
   - High
   - Medium
   - Low
   - Off

   Note If you select Off, no beeps will sound, even when indicated in procedures.
6. 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 Home screen, select **Menu**.
2. Select **System Settings**, from the Menu screen.
3. Select **Display**.
4. Use the up and down arrows to adjust the contrast of the color display.
5. Select **Save**.

   The system display is set.

Setting up the Onboard Printer

1. At the Home screen, select **System Settings**.
2. At the System Settings menu, select **Additional Settings**.
3. At the Additional Settings menu, select **Printers**.
4. Select **Onboard Printer**.

   The Onboard Printer screen displays.
   - To enable the onboard printer, select **Enable**.
   - To disable the onboard printer, select **Disable**.
5. To automatically print the test results, select **Automatically print**.

   Note You must select Enable to automatically print.

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

Viewing the Current System Settings

You can view the system settings including serial number, software version number, patient test settings, patient printed report type, quality control test settings, reminders, time format, and MAC address.

Viewing and Printing a Partial System Settings Report

To print a partial System Settings Report, perform the following steps:

1. At the Home screen, select **Menu**.
2. Select **System Settings** from the Menu screen.
3. To view the partial Systems Settings Report, select **View Settings**.

   The View Settings screen displays the current system settings.
4. To print the current system settings, select **Print**.

Printing a Full System Settings Report

To print a full System Settings Report, perform the following steps:

1. At the Home screen, select **Menu**.
2. Select **System Settings** from the Menu screen.
3. Select **Additional Settings** from the System Settings screen.
4. Select **Print**.

Advanced Features

There are additional features such as advanced operator management; advanced security settings; quality control management; connectivity; offered on the DCA Vantage System that are intended for use by a healthcare professional, and are not described for self-test use. Please contact your local technical support provider or distributor if you have any questions.

Appendix A: Safety Information

Protecting Yourself from Biohazards

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, strictly follow the following procedures:

- If testing is not being performed by a healthcare professional, disinfect the front of the system before each use.
- Wear gloves when interacting with the system.
- Wash your hands after working with the system, or when you remove or change gloves.
- Keep your hands away from your face.
- Cover all superficial cuts and wounds before starting any work.
- Dispose of contaminated materials according to your local biohazard control procedures.

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.

Electromagnetic Emissions Safety

The system complies with the emission and immunity requirements described in IEC 61326-1 and IEC 61326-2-6 series.

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 generates, uses and can radiate ratio 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

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, O_2, or nitrous oxide. The risk of explosion exists if the system is operated in a potentially explosive environment.
- Do not use this system in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.
- Use of this system in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
- 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.

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.

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

Contact your local technical support provider for assistance:

- if the error message continues to display after performing the steps described on the screen and in the Troubleshooting chapter
- if additional assistance is required concerning a 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* on page 100. 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

siemens-healthineers.com/poc

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 touch screen operating properly?	
	If NO:	
	• Have you performed the touch screen test?	
	• Have you calibrated the touch screen?	
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 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: • Repeat the test. • If expected results are not recovered, repeat testing with new QC material. • If QC is out of range, record the QC lot and cartridge lot. • Consult your technical support provider.	
7.	Is the system in the proper operating environment and location as described in *Appendix E, Specifications*?	
8.	What is the revision level of the system software? To find this information, select Help from the Home screen. The system displays the current software revision level.	
9.	Are any error messages or warnings being displayed?	
	If so, list the error description and any numbers that display.	
10.	Have you performed the appropriate steps suggested on the display for the error being displayed?	

Appendix C: Orderable Supplies

Accessory Items

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

Hemoglobin A_{1c}

REF Number	Description
10888739	DCA HbA_{1c} Self Test Reagent Kit
10311161	DCA Normal & Abnormal Control Kit
10888741	HbA_{1c} Capillary Holder (strip of 10)

Note Part numbers are subject to change without notice.

Replacement Parts

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

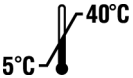
REF Number	Description
10219275	NA Power Cord for System
10323672	Euro Power Cord for System
10323838	UK Power Cord for System
10282130	Filter Holder
10282132	Cartridge Return Spring
10320798	Fuse: T-1.25 A, Slow Blow; 250 volt
10337473	Cleaning Swabs (10)
10282131	Optical Test Cartridge
10282129	Air Filter (3) Replacement Kit
10314709	Printer Paper (pack of 5)
10324219	Printer Paper Self Adhesive Stock (pack of 5)

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.

Symbol	Description
	This symbol is used for both Warnings and Cautions. • 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 identifies a hazardous area on the equipment.
	This symbol alerts you to a biohazard.
	This symbol alerts you to an electrical hazard.
	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.

Symbol	Description
	This symbol identifies the location of a barcode scanner.
	This symbol identifies the location of a keyboard port.
	This symbol identifies the location of a serial port.
	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 instrument or system has a temperature limitation. You need to store the product between 5–40°C.
	This symbol indicates an *in vitro* diagnostic device or an *in vitro* 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.

Symbol	Description
	This symbol indicates that you should keep the product dry.
	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.
	This symbol indicates the number used for ordering a part or product.
	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.

Symbol	Description
EC REP	This symbol indicates the manufacturer's authorized representative within the European community.
UP	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.
RESY	This symbol is intended to facilitate recycling of corrugated materials. The number is licensed in Germany and printed on corrugated shippers.
CE	This symbol indicates that the product complies with the applicable directives of the European Union.
TÜV C NRTL US	This symbol indicates that the instrument is safety tested by TUV SUD, a national certification body, for conformity to global markets, including Canada, US, and EU.
	This symbol indicates information about the fuse.

User Interface

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

Symbol	Name	Description
	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.

Symbol	Name	Description
	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.

Symbol	Name	Description
	HbA_{1c} Blood Test	This symbol indicates a HbA_{1c} Blood test.
	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

Dimension	Value
Depth	27.7 cm (10.5 inches)
Height	25.4 cm (9.0 inches)
Width	28.7 cm (11.5 inches)
Weight	3.88 kg (9 lb)

Environmental Specifications

Specification	Value
Ambient Operating Temperature	15–32°C (61–88°F) - Hemoglobin A_{1c}
Relative Humidity	15–80%, non-condensing, actively controlled
Indoor Use Only	

Electrical Requirements

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

Results Calculation

Percent HbA_{1c} Calculation

The system calculates the values for HbA_{1c} for patient tests. To calculate the HbA_{1c} percentage, the system uses the concentration of HbA_{1c} divided by the total hemoglobin concentration.

% HbA_{1c} = (HbA_{1c}/Total Hemoglobin) x 100

Dual Reporting Calculations – HbA_{1c} and IFCC Units

The dual reporting calculations convert the NGSP percentages to IFCC mmol/mol. The source for the following calculations is http://www.ngsp.org.

Mode	From IFCC to %HbA_{1c}	From %HbA_{1c} to IFCC mmol/mol
NGSP	NGSP = (0.09148 x IFCC) + 2.152	IFCC = (10.93 x NGSP) – 23.50

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