CELLAVISION

CellaVision® DC-1

Instructions for Use

7.0

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Caution!
US federal law restricts this device to sale by or on the order of a physician (or properly licensed medical practitioner).

Note: Some products or features described in this manual may not be available in all markets.

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CONTENTS

1 INTRODUCTION

CellaVision® DC-1 is an automatic cell-locating device that is used to analyze blood cell morphology in peripheral blood samples.

These Instructions for Use describe how to process peripheral blood samples on the analyzer. For information on how to review processed orders, see the CellaVision Review Software Instructions for Use.

For all available instructions and settings, see the built-in help. To access the built-in help, on the **Help** menu, click **Help**.

Note: The applicability of some sections in this document depends on which applications are installed on the analyzer. Contact your local vendor for more information.

1.1 Intended use of the CellaVision® DC-1

The CellaVision® DC-1 is an automated cell-locating device intended for in-vitro diagnostic use in clinical laboratories. The CellaVision® DC-1 is intended to be used by operators, trained in the use of the device.

1.1.1 Intended use of the CellaVision Peripheral Blood Application

The CellaVision Peripheral Blood Application is intended for differential count of white blood cells (WBC), characterization of red blood cell (RBC) morphology and platelet estimation.

The CellaVision® DC-1 with the CellaVision Peripheral Blood Application automatically locates blood cells on peripheral blood smears. The application presents images of the blood cells for review. A skilled operator trained in recognition of blood cells, identifies and verifies the suggested classification of each cell according to type.

1.2 Warnings and precautions

Carefully study the meaning of safety alerts and symbols. Read all the safety information and instructions in this manual before you use the system.

Warning!
If you are not suitably trained or fail to follow the instructions provided in this manual, it can damage or deteriorate the system and cause misleading results or even injury.

1.2.1 Safety alerts

Make sure that you always read, understand, and follow all safety alerts that may appear in this manual.

Alerts	Explanation
Warning!	Can cause personal injury.
Warning!	Risk of infection.
Caution!	Can cause damage to the system.
Important!	Can cause misleading results.

1.2.2 Symbols

Depending on the product, you may find the following symbols on the analyzer or the packaging material.

Symbol	Meaning
	Caution. Indicates the need to consult the Instructions for Use for important cautionary information, such as warnings and precautions, that cannot be presented on the medical device itself.
	Risk of infection. Indicates that there are potential biological risks associated with the medical device.
IVD	In vitro diagnostic medical device. Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
18°C 31°C	Temperature limitation. Indicates the temperature limits to which the medical device can be safely exposed.
20 % 80	Humidity limitation. Indicates the range of the humidity to which the medial device can be safely exposed.
LOT	Batch code. Indicates the manufacturer's batch code so that the batch or lot can be identified.

Symbol	Meaning
	Catalog number. Indicates the manufacturer's catalog number so that the medical device can be identified.
	Serial number. Indicates the manufacturer's serial number so that the medical device can be identified.
	Manufacturer. Indicates the medical device manufacturer.
	Date of manufacture. Indicates the date when the medical device was manufactured.
	The in vitro diagnostic system described in this manual is marked with a CE-mark which shows conformity to the applicable European directives and regulations.
	This symbol is only valid in the European Community and indicates separate disposal of waste of electrical and electronic equipment.
	The EAC mark shows that the product conforms to all technical regulations of the Eurasian Customs Union assessment procedures.
	Consult Instructions for Use or consult electronic Instructions for Use. Indicates the need for the user to consult the Instructions for Use.
	Standby button.
	Slide positioning in the loading tray. Make sure that the labeled or frosted end of the slide is facing right. If the slide is placed any other way, the analyzer might use a bad part of the smear. This can cause unreliable results.
	Direct current. Indicates that the analyzer is suitable for direct current only.

1.2.3 General safety

Warning!
Only trained personnel may perform service and maintenance on this analyzer.

Warning!
Only trained service personnel may install this analyzer.

Warning!
To avoid injury from electrical shock, take the following precautions before and during maintenance work:

- Avoid standing on damp floors.
- Disconnect the power plug from the mains supply electrical outlet before working on any high-voltage circuitry.
- Read and follow all warning and caution labels.
- Make sure that your test equipment is in good working condition.

Warning!
If the analyzer is not used in a manner specified by the manufacturer, the protection provided by it may be impaired.

Warning!
Do not tamper with any sensors or safety devices. They help to prevent personal injury and damage to the system.

Warning!
Risk of infection. When you perform any work on the analyzer, such as preparation, testing, postprocessing, and maintenance, always wear protective disposable gloves. When finished, wash your hands thoroughly with soap and water and then apply a disinfectant.

Warning!
Risk of infection. Handle samples with caution. Use protective disposable gloves and tweezers when removing broken slides from the analyzer. Glass shards from broken slides can cause serious cuts and pose a danger of infection. If infectious material enters the eyes or an open wound, wash with copious amounts of water and seek for immediate medical advice.

Warning!

Avoid getting immersion oil on your skin as it may cause skin sensitization. Wear protective gloves before you handle the oil pack, slides, or other parts that can come into contact with immersion oil. If you get immersion oil on your skin, clean it off with soap and water.

Caution!

Place the analyzer in a location where it is not exposed to bumps or vibrations, excessive temperature variations or direct sunlight.

Caution!

Leave at least 20 cm clearance around the analyzer to ensure adequate ventilation.

Caution!

Place the analyzer so that it's easy to operate and disconnect from the mains power supply.

Caution!

Do not place magnets on any parts of the analyzer.

Caution!

Do not install or run any software that is not supplied with the analyzer. You may install an anti-virus program but we recommend that you do not scan the database files.

Caution!

Fluids spilled on the surfaces of the analyzer may cause it to malfunction or deteriorate. Immediately wipe off any spilled fluids using a soft tissue.

Important!

Report any serious incident that occurs about the analyzer to the manufacturer and the competent authority in the European Union (EU) Member State where the user is located.

Important!

To have the analyzer comply with current medical device registrations, always use the original CellaVision AB spare parts and their specified components. These spare parts are safe to use, and comply with regulatory requirements and approvals.

If the analyzer contains components that are not original CellaVision AB spare parts, CellaVision AB is not liable:

- Under any warranty (whether express or implied, by law or otherwise) of such analyzer.
- For any malfunction of such analyzer.
- For any lack of compliance with current registrations of such analyzer.

1.2.4 Electrical safety

Warning!

Connect the system only to a grounded electrical outlet. To maintain electromagnetic compatibility, use only original CellaVision AB spare parts and their specified components.

Warning!

The mains power supply cord and plug used with the system must comply with any national regulations.

Warning!

The power supply must have proper ventilation around it and be free of any covering objects.

Warning!

To disconnect from mains supply, pull off the power plug from the mains supply electrical outlet. Do not use the standby switch.

Warning!

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case you may need to take measures to mitigate the interference.

Warning!

Do not use this device in close proximity to sources of strong electromagnetic radiation, as these may interfere with proper operation. Evaluate the electromagnetic environment before you operate the device.

Warning!
Use only the UL recognized battery CR2032 with maximum 10 mA abnormal charging current.

The battery must be changed by trained service personnel. Using other than specified battery or installing the battery incorrectly can cause fire or explosion.

Caution!
Use only the power supply that came with the analyzer.

Important!
External computing devices connected to the LAN or the communication connector on the analyzer must have Limited Power Source and SELV circuit according to the standards UL 60950 for US, CAN/CSA-C22.2 No. 60950 for Canada and IEC60950-1 for other countries.

1.2.5 Mechanical safety

Warning!
Keep clothing and fingers away from moving components.

1.3 Theory of operation

From a peripheral blood sample, typically flagged by a cell-counter indicating an abnormal morphology, a thin blood film is wedged on a glass slide (a blood smear). The blood smear is then stained with Romanowsky stain.

The operator places the slide in the loading tray of the analyzer.

The operator enters the order ID for the slide, either manually or using an optional barcode reader. If a Laboratory Information System (LIS) is used, the analyzer automatically fetches order data for the sample from the LIS. Otherwise, the operator enters this information manually.

The operator closes the input hatch and starts the processing. The analyzer automatically moves the slide under the microscope.

The analyzer looks for a monolayer in the smear. Once a monolayer is found, the analyzer scans the monolayer in a battlement pattern. While doing this, the analyzer locates WBCs and stores high quality images of each located WBC. The analyzer also locates and stores an image of a part of the RBC monolayer. When enough WBCs and the image of the RBC monolayer have been captured, the analyzer moves the slide back to the loading tray.

The analyzer pre-classifies each located WBC. It also pre-characterizes the RBC morphology. These preliminary results, that is, the pre-classifications, pre-characterization, and the images are stored in a database.

A skilled operator, trained in the use of the software and in recognition of blood cells, then opens the order to review and verify the preliminary results. The review can be done either at the analyzer or using the CellaVision Remote Review Software.

1.4 Applications

The analyzer supports the CellaVision Peripheral Blood Application.

1.4.1 CellaVision Peripheral Blood Application

The CellaVision Peripheral Blood Application is included in the CellaVision DM Software. You can use it for WBC classification, RBC characterization, and platelet estimation.

The CellaVision Peripheral Blood Application:

- Presents an image of every located nucleated cell or object.
- Presents and suggests cell classification (pre-classification) for WBCs.
- Allows you to identify, confirm or modify (re-classify) the suggested classification of WBCs.
- Presents an overview image from the RBC monolayer.
- Presents and suggests RBC morphological characteristics (pre-characterization) in the form of grades.
- Allows you to confirm or modify the pre-characterization of RBC morphology.
- Presents an overview image and facilitates platelet estimation.

WBC classification

The CellaVision Peripheral Blood Application automatically pre-classifies WBCs into these classes:

- Band neutrophils
- Segmented neutrophils
- Eosinophils
- Basophils
- Lymphocytes
- Monocytes
- Promyelocytes
- Myelocytes
- Metamyelocytes
- Blast cells
- Lymphocytes, variant forms
- Plasma cells

The CellaVision Peripheral Blood Application automatically pre-classifies non-WBCs into these classes:

- Nucleated RBC
- Giant thrombocytes
- Thrombocyte aggregations
- Smudge cells
- Artefacts

Cells and objects pre-classified with a low confidence level are pre-classified as Unidentified.

You can manually re-classify cells and other objects to any of the above classes and also to these classes:

- Reactive lymphocytes
- Abnormal lymphocytes
- Immature eosinophils
- Immature basophils
- Promonocytes
- Prolymphocytes
- Large granular lymphocytes
- Hairy cells
- Sézary cells
- Megakaryocytes
- Up to 15 user-defined cell classes
- Other. You can use this class for cells that are identified as WBCs other than those listed above, and that you want to include in the differential count.
- Not classed. You can use this class for cells and objects that you can't identify, and want to exclude from the differential count.

Quantitative results for WBCs are the number of user classified cells in each cell class, and its percentage of the total number of WBCs counted.

Quantitative results for non-WBCs are the number of user classified cells or objects per 100 WBCs.

RBC characterization

The CellaVision Peripheral Blood Application pre-characterizes the RBC morphology by shape, color and size, and suggests preliminary grading for these morphological characteristics:

- Polychromatic cells
- Hypochromatic cells
- Anisocytosis

- Microcytes
- Macrocytes
- Poikilocytosis

You can change the suggested preliminary grading for the above morphological characteristics, and manually specify grading for these morphological characteristics:

- Target cells
- Schistocytes
- Helmet cells
- Sickle cells
- Spherocytes
- Elliptocytes
- Ovalocytes
- Teardrop cells
- Stomatocytes
- Acanthocytes
- Echinocytes
- Howell-Jolly bodies
- Pappenheimer bodies
- Basophilic stippling
- Parasites
- Up to 10 user-defined characteristics

Semi-quantitative results for RBC morphology depend on grading criteria entered by the laboratory.

Platelet estimation

For the platelet estimation, the analyzer captures an overview image of the RBC monolayer.

Depending on the software configuration, you can use one of these methods to calculate platelet concentration:

- Count platelets in one part (grid square) of the overview image at a time and enter the number of platelets for each grid square.
- Estimate an average number of platelets per grid square.
- Manually estimate platelet concentration.

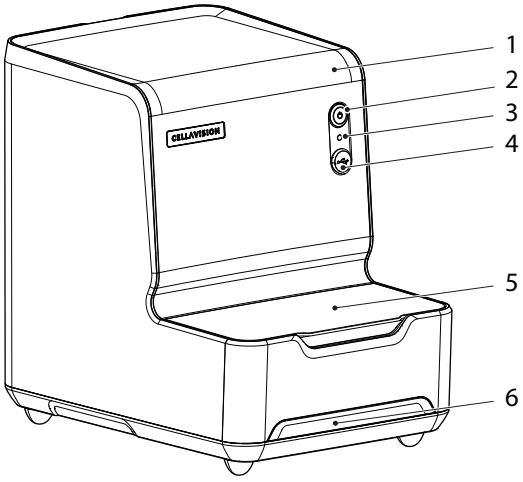
Semi-quantitative estimates of PLT concentration depend on grading criteria entered by the laboratory.

Quantitative estimates of PLT concentration are the average number of PLTs per HPF multiplied by the PLT estimate factor x10e9/L.

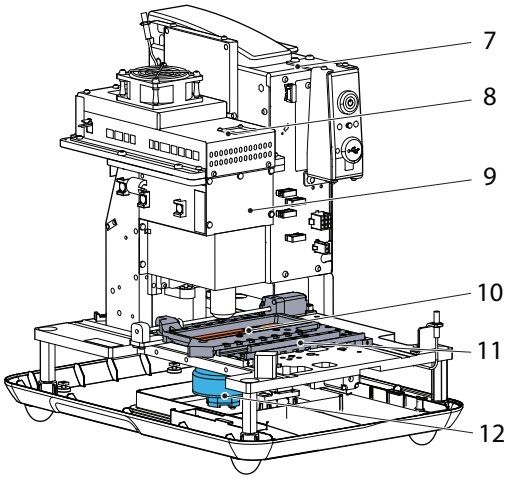
1.5 Components and mechanical operation

Major parts of the analyzer

- System computer
  An embedded PC that runs Windows® and the CellaVision DM Software.
- XY stage module
  Moves the slide to and under the microscope.
- Microscope module
  Consists of an objective, a relay lens, and a focus mechanism.
- Imaging module
  Captures images and controls the motors.
- LED module
  Provides light to the microscope.



1 Hood
2 Stand-by button
3 Status light
4 USB
5 Input hatch
6 Drip tray



7 System computer
8 Imaging module
9 Microscope module
10 Loading tray
11 XY stage module
12 LED module

1.6 References to scientific literature

Bain, B. J., Bates, I., Laffan, M. A., & Lewis, S. M. (2012). *Dacie and Lewis Practical Haematology (11th ed.).* London: Churchill Livingstone.

Galagan, K. A., Blomberg, D., Cornbleet, P. J., & Glassy, E. F., (Eds.). (2006). *Color Atlas of Body Fluids, An Illustrated Field Guide Based on Proficiency Testing.* Northfield, Illinois: College of American Pathologists.

Glassy, E. F. (Ed.). (1998) Color Atlas of Hematology, *An Illustrated Field Guide Based on Proficiency Testing, College of American Pathologists Hematology and Clinical Microscopy Resource Committee.* Northfield, Illinois: College of American Pathologists.

Gulati, G. (2009). *Blood Cell Morphology, Grading Guide.* Chicago, Illinois: American Society for Clinical Pathology Press.

Gulati, G., & Caro, J. (2014). *Blood Cells, Morphology & Clinical Relevance (2nd ed.).* Chicago, Illinois: American Society for Clinical Pathology Press.

O'Connor, B. H. (1984). *A Color Atlas and Instruction Manual of Peripheral Blood Cell Morphology.* Baltimore, Maryland: Williams & Wilkins.

1.7 References to standards

CLSI. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition*. CLSI document EP05-A3. Wayne, PA: Clinic and Laboratory Standards Institue; 2014.

NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second edition.* NCCLS document EP9-A2 [ISBN 1-56238-472-4]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.

NCCLS. *Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrument Method.* NCCLS document H20-A [ISBN 1-56238-131-8]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 1992.

Clinical and Laboratory Standards Institute. *Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard—Second Edition.* CLSI document H20-A2 [ISBN 1-56238-628-X]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007.

1.8 Patents

CellaVision AB has the following hardware and software patents:

Patent no.
AU 2015259903
CN 200980153358.5, CN 201210433235.0, CN 201580024601.9
DE 60045076, DE 602004008471, DE 602007037624, DE 60231032, DE 602008017260, DE 602009011617, DE 602010005069
EP 1377865
FR 1210634, FR 1377865, FR 1646964, FR 1986046, FR 2383600, FR 2204686, FR 2310892

Patent no.
GB 1210634, GB 1377865, GB 1646964, GB 2383600, GB 1986046, GB 2204686, GB 2310892
JP 5198476, JP 5215474, JP 5461630, JP 5539489, JP 6235168
SE 0101319, SE 9902863, SE 1350568-0, SE 1550394-9
US 6268611, US 6341180, US 7034883, US 7327901, US 9672447, US 9676095, US 7450762, US 8914255, US 9180593

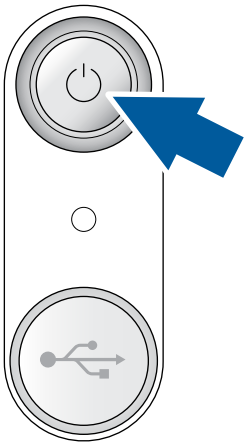
Other patents pending.

2 OPERATING PROCEDURE

This section provides information on how to use the analyzer and the CellaVision DM Software to process samples.

2.1 Turn on the analyzer

1. Make sure that the hood and the input hatch are closed.
2. Press the **Stand-by** button on the analyzer.



   The status light is steady yellow during analyzer start.

3. Press CTRL+ALT+DEL and log on to Windows® using these credentials:
   User name: cvuser
   Password: pass
4. Wait for the analyzer to start and the status light to be steady green. Do not open the input hatch during startup.
   If the startup test fails due to a mechanical error, the status light flashes red.
   Error messages may occur during startup. For more information, see 6.8 Startup error messages on page 88.
5. Double-click the CellaVision DM Software icon on the desktop.
6. When the **Log On** dialog appears, enter your **User name** and **Password**.
   If you want to log on using your Windows® user name, select **Use Windows Authentication**.
   If you want to process samples without logging on, select **Start without logging on**. With this option, you can process samples in the **System Control View** . No patient data is visible.

7. In the **Database** list, click the database you want to log on to, and then click **OK**.

   Note: You must be connected to a database to review slides. If you don't see the database that you want to connect to in the **Database** list, create the connection as instructed in 4.1.1 Manage databases on page 48.

The analyzer performs self tests at software start up and during operation.

At software start up, the analyzer tests both the hardware and the software components for defects, and for various requirements necessary to operate the analyzer. If LIS communication is enabled, it also checks the connection to the LIS.

After each processed slide, the analyzer checks the motor positions. At certain points during operation, the analyzer compares the database size to the rules set for archiving or automatically deleting old entries. This is to make sure that the database is kept at a maintainable size.

During operation, the analyzer also tests communication with and response of the hardware. If an error occurs during slide processing or other operation, an error message is displayed.

2.2 Prepare slides

Warning!

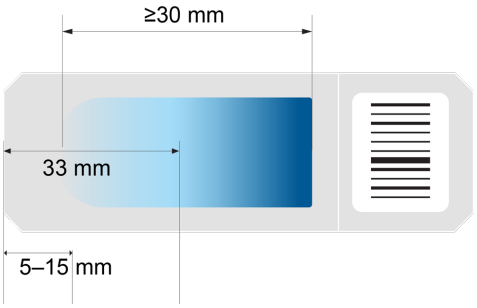
Wear protective gloves when handling blood or any other samples of human origin, or equipment contaminated with such samples. Discard the gloves, wash your hands thoroughly with soap and water, and then apply a disinfectant. Any samples of human origin can transmit infectious diseases.

If blood or any other samples of human origin enters the eyes or an open wound, wash with copious amounts of water and seek immediate medical advice.

You need well-prepared slides to get valid results. When the analyzer processes the slide, it starts scanning the slide 33 mm from its end.

The blood smear must:

- Be at least 30 mm long.



- Terminate 5 to 15 mm from the end of the slide.
- Start near the labeled or frosted end of the slide with a gradual transition in thickness and without any grainy streaks, troughs, ridges, holes, or bubbles.

If an issue occurs during slide processing, you receive a warning with information about the issue.

2.2.1 Prepare peripheral blood smears

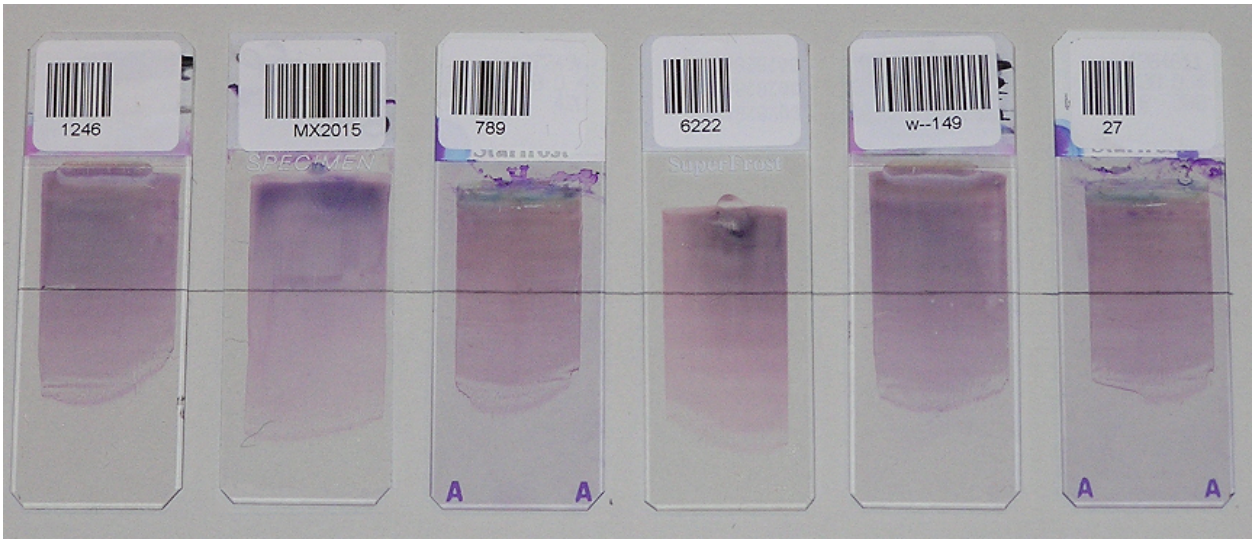
We recommend that you use an automatic slide maker-stainer, but you can also smear and stain slides manually.

To prepare a peripheral blood slide

1. Collect blood from a vein or by skin puncture in an EDTA sample tube (K_2EDTA or K_3EDTA, 1.5 ±0.15 mg/mL in liquid or powder form).
2. Mix the sample carefully with the anticoagulant.
3. Store the tube at room temperature.
4. Prepare the blood smears according to your laboratory's procedure.
   We recommend that you prepare the blood smears within 4 hours of blood collection.

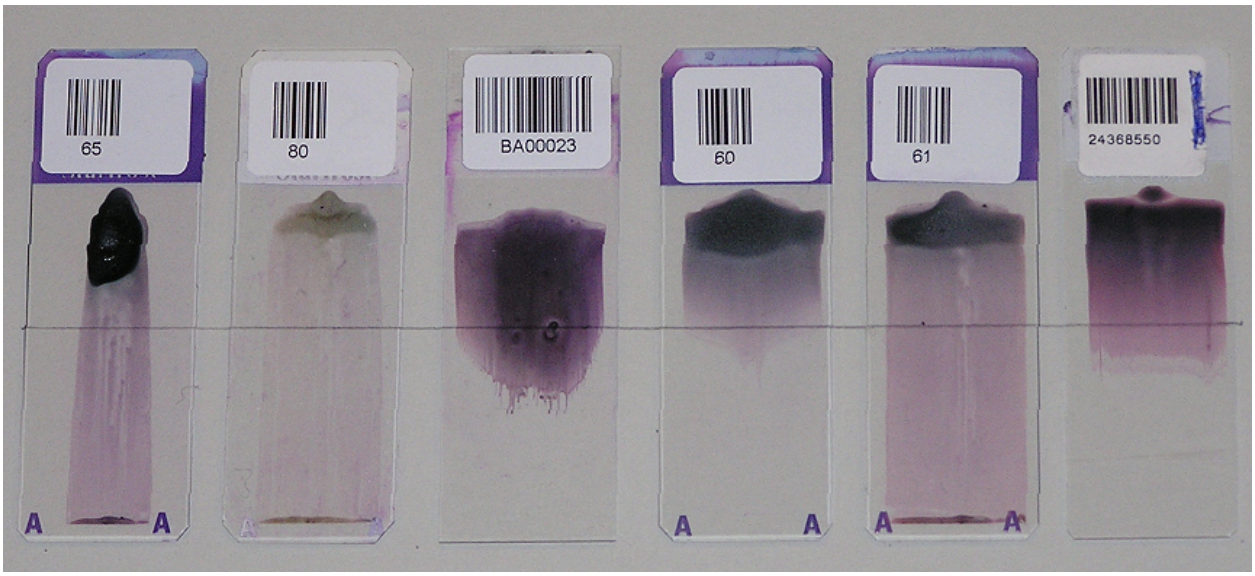
Examples of acceptable blood smears

These slides meet the specifications and can be processed with the analyzer.



Examples of unacceptable blood smears

These slides don’t meet the specifications and can't be processed with the analyzer.



Related topics

- For more information on what types of slides to use, see 7.3.1 Slides on page 104.
- For more information on recommended staining recipes, see 2.2.3 Staining below.

2.2.2 Label slides

You must label all slides that are processed on the analyzer with patient or order information stated in your laboratory policy. If you use the optional handheld barcode reader, you can have a barcode label on your slides. Print the label and place it correctly on the slide according to specifications in 7.3.2 Barcodes on page 105.

2.2.3 Staining

The analyzer is optimized to process slides stained with May Grünwald Giemsa (MGG) stain, Wright stain, and Wright-Giemsa stain.

If you use a slide maker-stainer, use the staining recipes recommended by the manufacturer.

If you stain your slides manually, use the staining recipes recommended by the reagents provider.

Note: Differences in staining results can result, for example, from alterations in pH and reagents. To achieve best results, you may need to do local adjustments. Pay attention to pH variations in water.

2.3 Process slides

You can use the analyzer to process slides with blood smears from peripheral blood. The processing time depends on the type of analysis and the concentration of WBCs.

To process a slide

1. Open the input hatch and place the slide, with the blood smear facing up, in the loading tray.

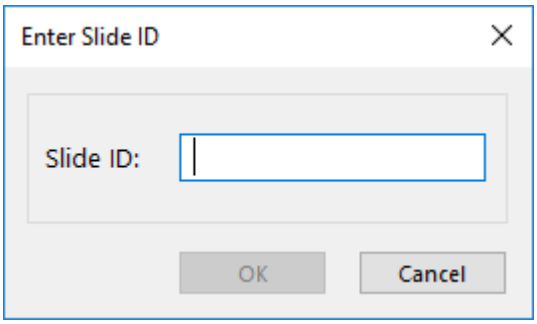
   Important!
   Make sure that the labeled or frosted end of the slide is on the right. If the slide is placed any other way, the analyzer might scan a bad part of the smear. This can cause unreliable results.

2. If a dialog is open, close it.

3. In the **System Control View**, click in the **Slide ID** text box.

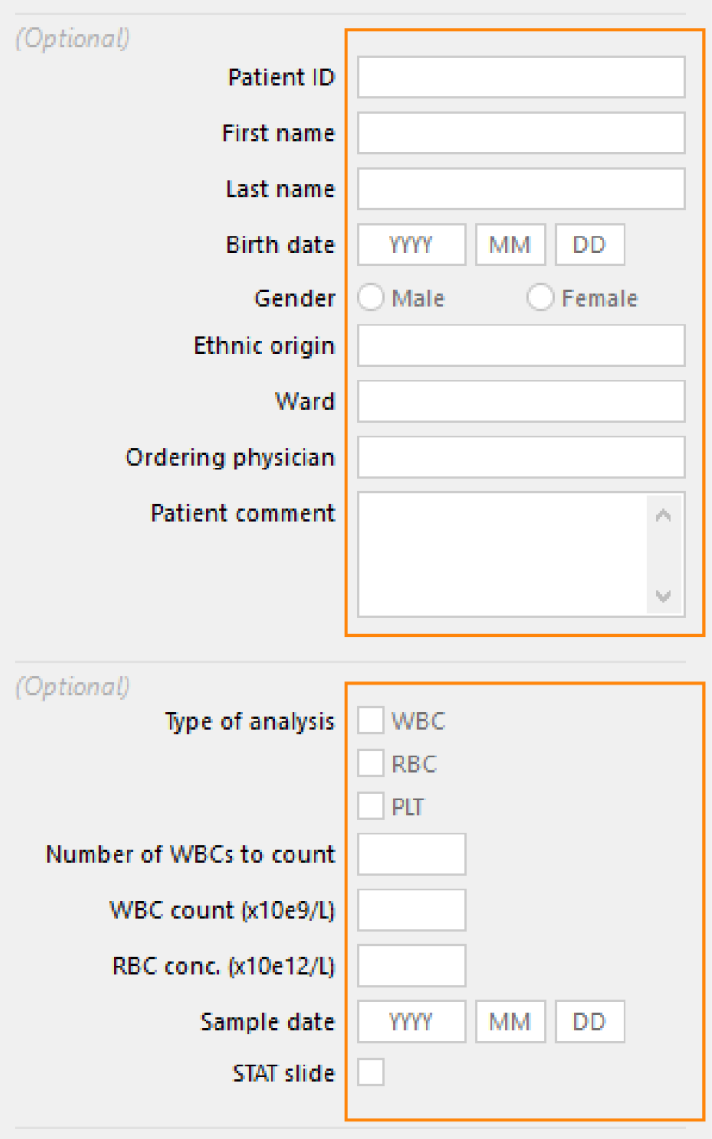
   Note: You can also use an optional barcode reader to read the barcode on the slide.

4. In the **Enter Slide ID** dialog, enter the **Slide ID** exactly as written on the slide.



5. Click **OK**.

6. If the analyzer isn't connected to the LIS, or if the order is not available in the LIS, you can enter additional patient information and choose what type of analysis to perform.



7. Hold the tip of the oil bottle close to the slide without touching it, aim for the red colored marker, and place two drops of the immersion oil on the slide.

Important!

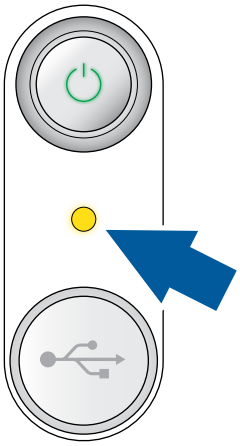
Use only CellaVision® immersion oil with the analyzer. Make sure that there are no air bubbles present in the oil as they can interfere with slide processing.

Warning!

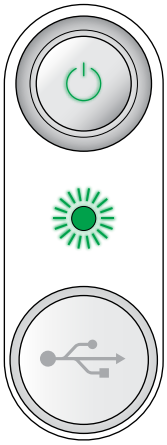
Avoid getting immersion oil on your skin. Wear protective gloves before you handle the oil, slides, or other parts that can come into contact with the oil. Immersion oil can cause skin sensitization. If you get oil on your skin, clean it off with soap and water.

8. Close the input hatch.

9. To start processing the slide, in the **System Control View**, click **Start** .
   The status light is steady yellow while the analyzer processes the slide.



10. Wait for the processing to finish. This takes a couple of minutes.
    The status light flashes green when the processing is complete.



Note: If an issue occurs during slide processing, you receive a warning with information about the issue.

11. Open the input hatch and remove the slide. The status light is steady green indicating that the analyzer is in idle mode.

12. If a dialog is open, close it.

Note: Depending on the slide processing issue, images and preliminary results may still be available. You need to assess if the smear quality is good enough to review the results.

Related topics

- For more information on what types of slides to use, see 7.3.1 Slides on page 104.
- For more information on how to add order information manually to the database before processing a slide, see 2.3.2 Add orders manually on the facing page.
- For more information on how to keep the database from growing too large, see 4.1.2 Manage database size on page 50.

2.3.1 Mark emergency samples (STAT)

You can mark orders as STAT in the **Database View** on the **Processed Orders** tab. You can also mark orders as STAT on the **Pending Orders** tab when you add orders manually or before you process the manually added orders. You can send the STAT status via the LIS with the order information.

To mark orders as STAT on the Processed Orders tab

1. In the **Database View** on the **Processed Orders** tab, select the order or orders you want to mark as STAT.
   - To select a consecutive group of orders, click the first order, hold down Shift, and then click the last order.
   - To select non-consecutive orders, hold down Ctrl, and then click each order that you want to select.
2. If you selected only one order, do one of the following:
   - Click **Mark as STAT** .
   - Right-click the selected order, and then select **Mark/Unmark as STAT**.
3. If you selected several orders, do one of the following:
   - Click **Mark as STAT** , then select **Mark all selected orders** and click **OK**.
   - Right-click the selected orders, select **Mark/Unmark as STAT**, then select **Mark all selected orders** and click **OK**.

To mark orders as STAT on the Pending Orders tab

Note: You can mark an order as STAT directly when you manually add it.

1. In the **Database View** on or the **Pending Orders** tab, select the order or orders you want to mark as STAT.
   - To select a consecutive group of orders, click the first order, hold down Shift, and then click the last order.
   - To select non-consecutive orders, hold down Ctrl, and then click each order that you want to select.
2. Right-click the selected order or orders.
3. If you selected only one order, select **Mark/Unmark as STAT**.
4. If you selected several orders, select **Mark/Unmark as STAT**, then select **Mark all selected orders** and click **OK**.

2.3.2 Add orders manually

If you need to process a slide that belongs to an order not available in the LIS, you can add the order to the database manually. You must do this before you process the slide. Otherwise the analyzer uses the default analysis settings for processing.

You can specify what type of analysis you want the analyzer to perform on the slide, and enter patient and order information. The slide can then be processed on any of the analyzers connected to the database with the analysis settings you specified.

Orders that you add manually are listed in the **Database View** on the **Pending Orders** tab where they wait for processing. When an order is processed, it is moved to the list on **Processed Orders** tab.

To add an order to the Pending Orders list

1. In the **Database View**, on the **Pending Orders** tab, click **Add** + .
2. In the **Order Data** dialog, enter the **Order ID** exactly as it's labeled on the slide.
3. Under **Type of order**, specify the types of analyses you want to perform.
4. If the order is an emergency sample, select **STAT**.
5. Enter other needed details for the order.

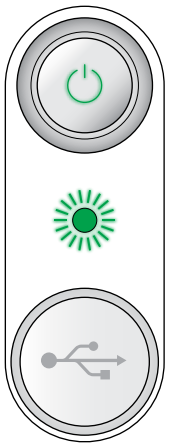
   Note: The **Number of WBCs to count** can be set to a maximum of 1000.
6. To add the order to the **Pending Orders** list, click **Add**.
7. Click **Close**.
8. Process the slides as instructed in 2.3 Process slides on page 26.

2.3.3 Stop slide processing

You can stop slide processing at any time, for example if you need to turn off the analyzer or process an emergency sample. In that case images and results are discarded and an icon  is displayed in the **Processed Orders** list. You can reprocess the slide using the same **Slide ID**.

To stop slide processing

1. In the **System Control View**, click **Stop** .
2. When you receive the **Do you want to stop the slide processing?** message, click **Yes**.
   The analyzer moves the slide to the input hatch and the status light flashes green.

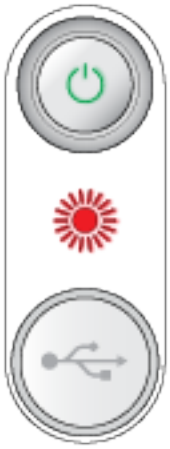


3. Open the input hatch and remove the slide.
   The status light is now steady green indicating that the analyzer is in idle mode.

If you stop the slide processing or restart the analyzer, you must manually resume slide processing under **System control**. To resume, click **Start** .

2.3.4 Slide processing fail due to a mechanical error

If slide processing fails due to a mechanical error, the status light flashes red. Restart the CellaVision DM Software. If the startup test fails, the status light flashes red again. For more information, contact your local vendor's technical support.

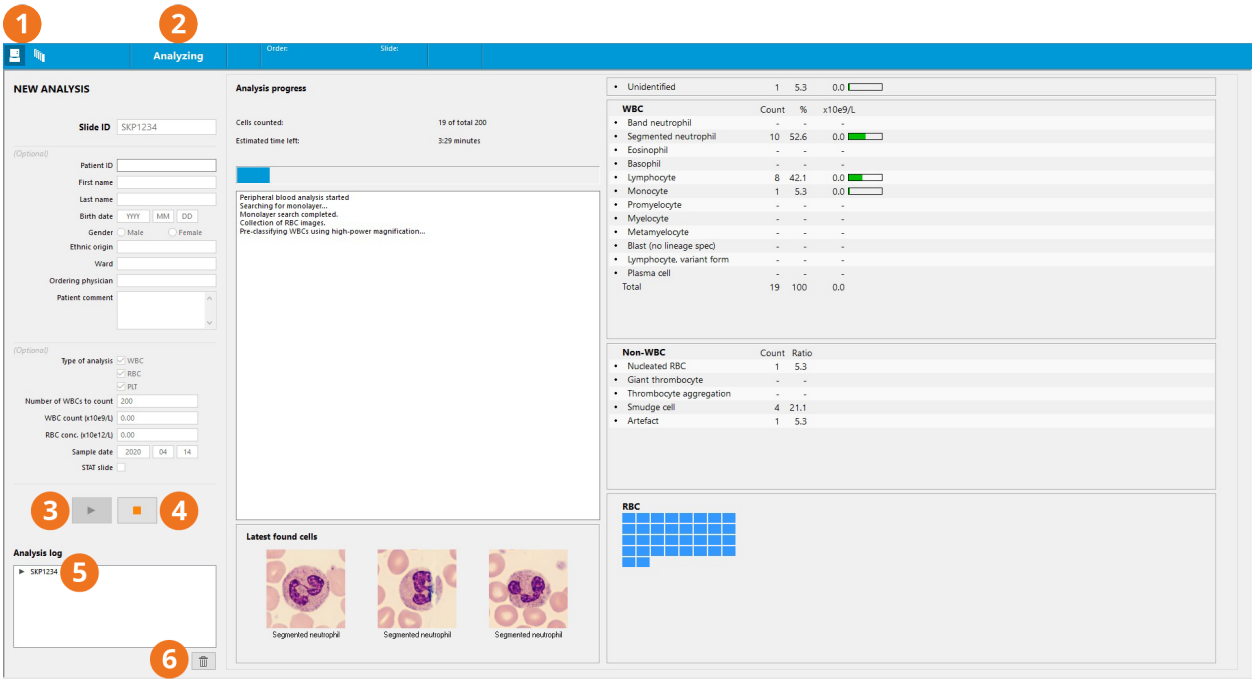


2.3.5 View processing status

The **System Control View** is used to process orders.

In the **System Control View**, under **Analysis log**, you can view status information on the processed slides. You can clear the log from all information.

In the **System Control View** you can also view information on analysis progress, latest found cells, and the number of WBCs, non-WBCs and RBCs from the processed orders.



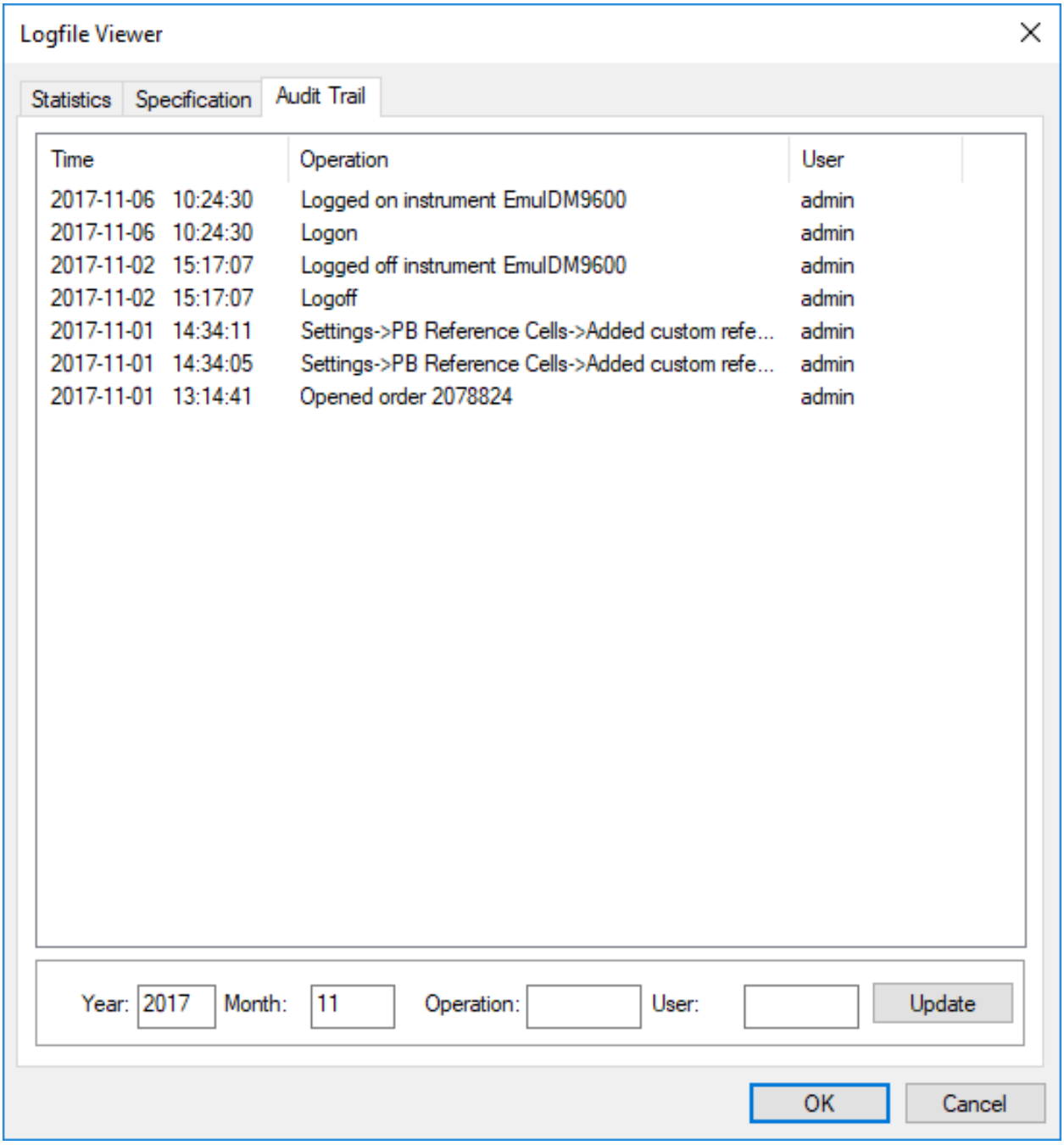
1 System Control View
2 Analysis status
3 Autostart or resume slide processing
4 Stop slide processing
5 Analysis log
6 Clear log

Related topics

- For more information on buttons, icons and indicators in the **System Control View**, see:
  - 8.1 System Control View on page 109
  - 8.2 Slide status on page 109
  - 8.3 PPA status on page 110

2.3.6 View the usage log

The analyzer continuously saves data about its activity. To view the log, select **Tools** and then **View log**.



You can access the **Audit Trail** tab only with access levels **Administrator** or **Service**. The **Audit Trail** tab contains a list of any user activity on a slide or a changed setting. You can search for entries in the **Audit Trail** tab by **Year**, **Month**, **Operation** and **User**. Enter text in the desired text box and click **Update**.

You can access the **Specification** tab only with access levels **Administrator** or **Service**. The **Specification** tab contains a list of analyzer events with dates and times, for example start and completion of slide processing and hardware malfunctions.

The **Statistics** tab contains dates and times for program installations and for creation and modification of the usage log. It also shows the number of successfully processed and failed slides, the number of signed analyses, and the total processing time.

Related topics

- For more information on user access levels, see 4.2.2 User access levels on page 56.

2.4 Use pay-per-analysis

If you use pay-per-analysis (PPA) with your analyzer, you must have a valid PPA smart card in the connected smart card reader to process slides. The PPA smart card status is shown on the toolbar.

When properly connected, the **Smart card connected** icon is displayed together with the balance remaining on the card.

Balance withdrawal is done automatically from the PPA smart card when the analysis is successfully performed and before the results are sent. With digital scans, the balance withdrawal is done when the scan is completed. An analysis is considered successful if:

- No mechanical failure occured
- Analysis wasn't stopped manually
- Ordered cells were found

If the analysis is unsuccessful or if you run QC-labelled slides, no balance is withdrawn from the PPA card. To avoid extra cost, we recommend that the service personnel also run QC-labelled slides during installation and maintenance.

To use pay-per-analysis

1. Insert the PPA smart card into the smart card reader that is connected to your analyzer.

   Note: The PPA smart card must be in the smart card reader during the entire analysis, and you need to have at least one analysis remaining on your PPA card.

2. Process the slide as described in 2.3 Process slides on page 26.

2.5 Scan slides for digital images

If you're logged on to a scan database, you can scan a slide to generate digital images. You can use the digital overview images to find cells and other objects of interest in the sample. You can change the scan area and resolution before you start the scan.

Important!
A digital image provides a general overview of the prepared slide within the intended use of the application. All other use is for research use only and not for use in diagnostic procedures.

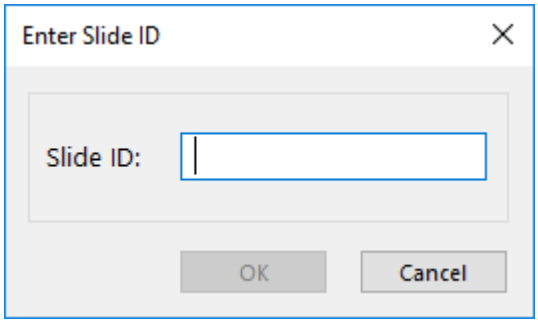
Related topics

- For more information on how to set up a scan database, see 4.1 Database settings on page 47.

2.5.1 Scan slides

1. Start the CellaVision DM Software and log on to a scan database.
2. Use the correct type of slide as specified in 7.3.1 Slides on page 104.
   You can use cover slips if the total thickness of the slide and the cover slip is within specifications. If you use cover slips, make sure that the scan area is within the cover slip area.
3. Open the input hatch and place the slide, with the blood smear facing up, in the loading tray.
4. In the **System Control View** , click in the **Slide ID** text box.

   Note: You can also use an optional barcode reader to read the barcode on the slide.
5. In the **Enter Slide ID** dialog, enter the **Slide ID** exactly as written on the slide.



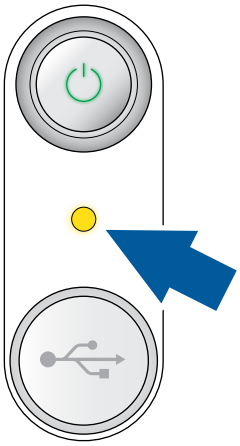
6. Click **OK**.
7. Hold the tip of the oil bottle close to the slide without touching it, aim for the red colored marker, and place three drops of the immersion oil on the slide.
   Note: More oil is required when you scan a slide, so we recommend three drops of oil.

> **Important!**
> Use only CellaVision® immersion oil with the analyzer. Make sure that there are no air bubbles present in the oil as they can interfere with slide processing.

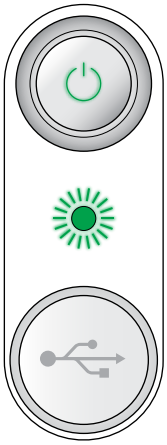
> **Warning!**
> Avoid getting immersion oil on your skin. Wear protective gloves before you handle the oil, slides, or other parts that can come into contact with the oil. Immersion oil can cause skin sensitization. If you get oil on your skin, clean it off with soap and water.

8. Close the input hatch.

9. To start processing the slide, in the **System Control View**, click **Start** .
   The status light is steady yellow while the analyzer processes the slide.



10. Wait for the processing to finish. This takes a couple of minutes.
    The status light flashes green when the processing is complete.



Note: If an issue occurs during slide processing, you receive a warning with information about the issue.

11. Open the input hatch and remove the slide. The status light is steady green indicating that the analyzer is in idle mode.

Related topics

- For more information on what types of slides to use, see 7.3.1 Slides on page 104.
- For more information on how to change the scan area and resolution, see 4.9 Scan settings on page 70.

2.6 Turn off the analyzer

Caution!

Always exit the CellaVision DM Software before you restart or turn off the analyzer. If your turn off the analyzer abruptly, for example, break the power supply or press and hold the stand-by button, the database may become corrupt.

1. Wait for the slide to be processed or stop slide processing manually.
   For more information, see 2.3.3 Stop slide processing on page 31.
2. On the **File** menu, click **Exit**.
3. Click **Start**, select **Power**, and then select **Shut down**.
4. Press the **Stand-by** button the analyzer.

Note: Make sure that the input hatch is closed when the analyzer is not in use.

3 QUALITY CONTROL PROCEDURE (QC)

The quality control procedure is a cell location test to validate the slide preparation process and verify the ability of the analyzer to locate cells. The quality of the slide and sample must be good enough for the analyzer to locate the cells and do the analysis.

3.1 Cell location test for peripheral blood

Important!
Cell location test helps to prevent misleading results caused by the analyzer failing to locate nucleated cells. Run a cell location test at least once a day and after any changes in the staining procedure or staining solutions. We recommend that you run the cell location test even more often with analyzers that have a heavy work load.

When you run a cell location test, the analyzer first tries to locate a monolayer on a peripheral blood slide and then locate 200 WBCs in that monolayer. Once the test is run, you can see an overview image with the located cells marked.

To verify that the analyzer located all nucleated cells, you must examine the overview image and count any cells that were not located. Based on your count, the analyzer then calculates the percentage of located nucleated cells.

3.1.1 Prepare and process cell location slides

1. Use a freshly stained slide from a blood sample with a normal WBC count.
   Note the following:

   - Prepare the slide in the same way as a normal slide, and according to your laboratory's procedure and 2.2 Prepare slides on page 24.
   - We recommend that the WBC count is higher than 7×10^9/L. If the concentration is lower, the test takes more time.
   - The analyzer must locate at least 100 nucleated cells on the slide. Otherwise, the test result is discarded.
   - The percentage of non-nucleated cells must be below 50% of the total number of objects on the slide.
     Non-nucleated cells are objects that the analyzer doesn't pre-classify as WBCs or NRBCs, for example smudge cells.

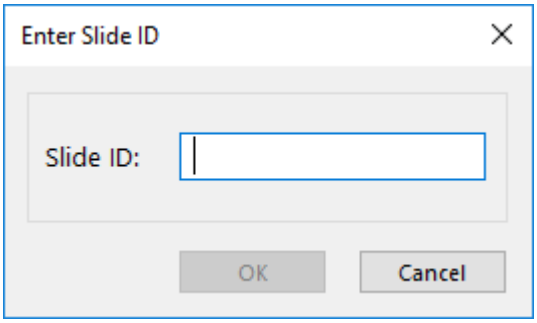
2. Open the input hatch and place the slide, with the blood smear facing up, in the loading tray.

> **Important!**
> Make sure that the labeled or frosted end of the slide is on the right. If the slide is placed any other way, the analyzer might scan a bad part of the smear. This can cause unreliable results.

Note: If you use the optional barcode reader, your slides must be equipped with barcode labels that begin with "QC". These are available from your local vendor.

3. In the **System Control View** , click in the **Slide ID** text box.

4. In the **Enter Slide ID** dialog, enter **QC** and then the **Slide ID** exactly as written on the slide.



5. Click **OK** .

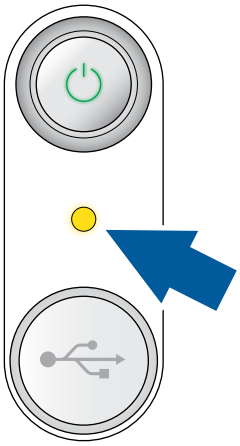
6. Hold the tip of the oil bottle close to the slide without touching it, aim for the red colored marker, and place two drops of the immersion oil on the slide.

> **Important!**
> Use only CellaVision® immersion oil with the analyzer. Make sure that there are no air bubbles present in the oil as they can interfere with slide processing.

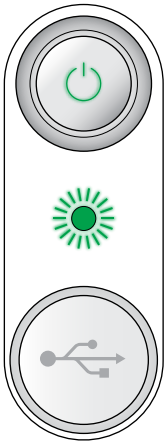
> **Warning!**
> Avoid getting immersion oil on your skin. Wear protective gloves before you handle the oil, slides, or other parts that can come into contact with the oil. Immersion oil can cause skin sensitization. If you get oil on your skin, clean it off with soap and water.

7. Close the input hatch.

8. To start processing the slide, in the **System Control View**, click **Start** .
   The status light is steady yellow while the analyzer processes the slide.



9. Wait for the processing to finish. This takes a couple of minutes.
   The status light flashes green when the processing is complete.



   Note: If an issue occurs during slide processing, you receive a warning with information about the issue.

10. Open the input hatch and remove the slide. The status light is steady green indicating that the analyzer is in idle mode.

11. When the slide is processed, examine it as described in 3.1.2 Examine images from cell location slides below.

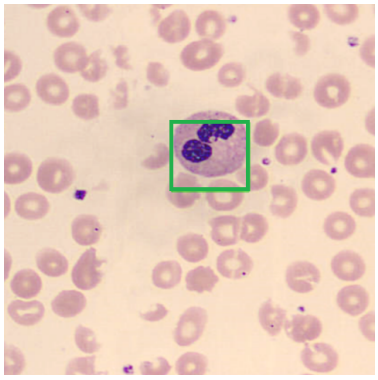
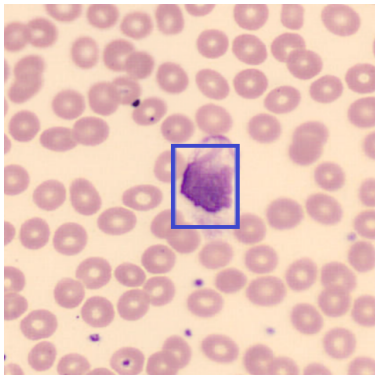
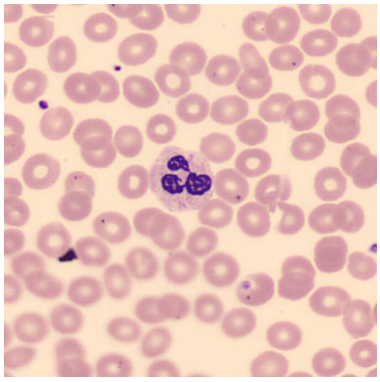
3.1.2 Examine images from cell location slides

1. On the **Tools** menu, click **Cell location**.

2. In the **Cell location slides** list, click the cell location slide that you want to examine.
   CellaVision DM Software opens the first image from that slide.

3. In the overview image, count all nucleated cells that the analyzer didn't locate, and enter the number in the **WBCs + NRBCs missed** text box.

   Note: The analyzer located a cell if it's marked with a green, blue, or black box. For more information on cell location markings, see 3.1.6 Identify cell location markings on page 44.

Example: located	Example: located	Example: not located
		

4. To show the next image on the slide and repeat the count of non-located cells, click **Next** ›.

5. When you have examined all the images on the slide, the analyzer automatically calculates the results of the cell location test.
   The result is shown under **Total result** as **Ratio of WBCs + NRBCs found**.

6. When you have examined the slide, evaluate the result as described in 3.1.3 Evaluate cell location test results below.

Note: An overview image consists of 4x4 sub-images. When the analyzer has found the required number of objects, the image collection stops. This can give the last overview image a cropped appearance.

As a general rule, the analyzer saves the cell location test results with related images for five days, and then deletes them. The analyzer always saves the three most recent cell location test results with related images even if they are older than five days. To review a saved test, click the slide ID in the **Cell location slides** list.

The analyzer keeps track of all run cell location tests. To view a chart of the 30 latest results, click **Show History**.

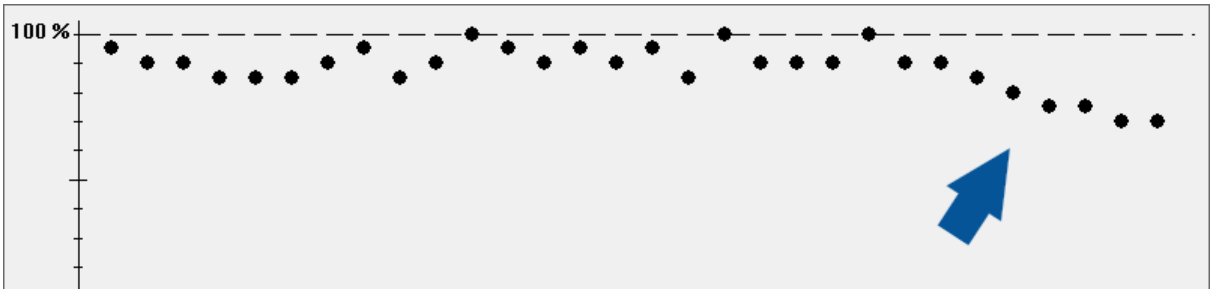
3.1.3 Evaluate cell location test results

Note: If your blood sample has a normal WBC count ($7x10^9$/L to $11x10^9$/L), the analyzer needs 20 to 80 overview images to find the required number of objects. If the analyzer needs fewer or more images, this indicates poor slide preparation, and you may need to adjust the slide preparation process.

1. Under **Total result**, check that the **Ratio of WBCs + NRBCs found** is within your laboratory's established limits.

2. Click **Show History**.

3. Check the **Cell location history** chart that shows the percentage of identified cells for any shifts or trends that may indicate an issue that needs further review.



Important!
Don't process any patient slides if the result of the cell location test isn't within your laboratory's established limits.

When you have resolved all occurring cell location issues, run another cell location test. When the result of the cell location test is within your laboratory's established limits, you can start processing slides.

Related topics

- For more information on performance characteristics when using standardized staining and smear preparation procedures, see 7.2.1 Performance specification for CellaVision Peripheral Blood Application on page 99.
- For more information on how to resolve possible cell location issues, see 6.4 Cell location issues with peripheral blood on page 81.

3.1.4 Print and sign QC results

You can print the QC result of a single cell location test for manual signing, or generate a report (.pdf) with digitally signed cell location tests.

To print the result of a single cell location test for manual signing

Click **Print result**.

To generate a report with digitally signed cell location tests

1. Click **Generate Report**.
2. Select the desired date interval.
3. Click **Generate Report**.
4. Enter a name and select a location for the report file.
5. Click **Save**.

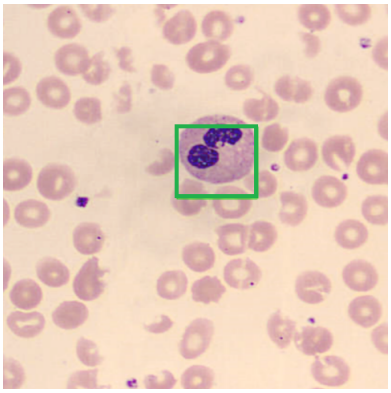
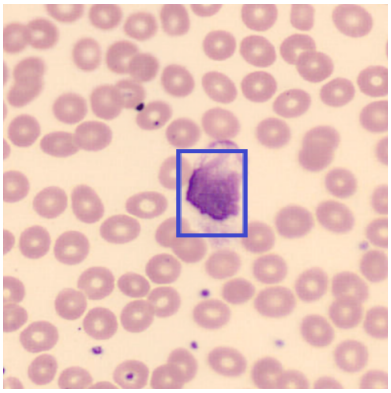
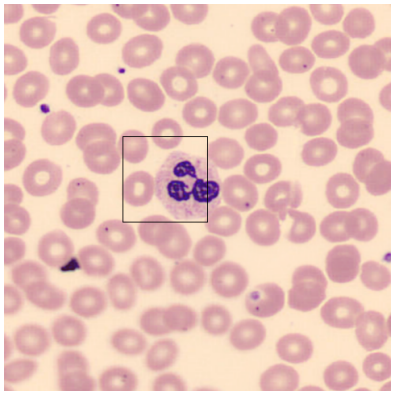
3.1.5 Perform manual correction

If the analyzer incorrectly pre-classifies any objects as nucleated cells (that is, marks them with a green box instead of a blue box, or vice versa), you can manually correct the total result. Don't perform manual correction for objects marked with a black box as those are already excluded from the calculation.

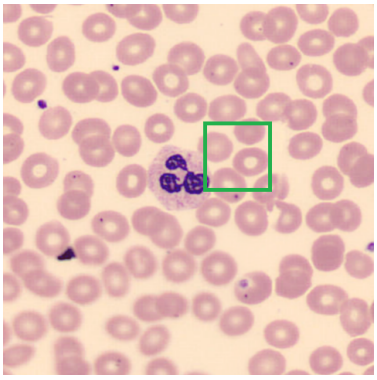
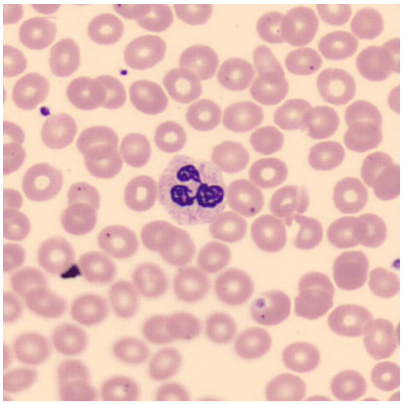
1. To calculate the correct number of WBCs and NRBCs, subtract the number of objects incorrectly pre-classified as nucleated cells from the number of **WBCs + NRBCs found** shown under **Total result**.
   For example, if the analyzer locates 187 nucleated cells, but you identify 3 of them as non-nucleated cells, the correct number of WBCs and NRBCs is 184 *(187 - 3 = 184)*.
2. In the **Manual correction** text box, enter the correct number of WBCs + NRBCs.
   The analyzer uses this number for the calculation.

3.1.6 Identify cell location markings

The purpose of the cell location test is that the analyzer locates each cell, not that it correctly pre-classifies each cell. The color of the box indicates how the analyzer pre-classified the located object. You can perform a manual correction for objects that the analyzer incorrectly pre-classified as nucleated cells as described in 3.1.5 Perform manual correction above.

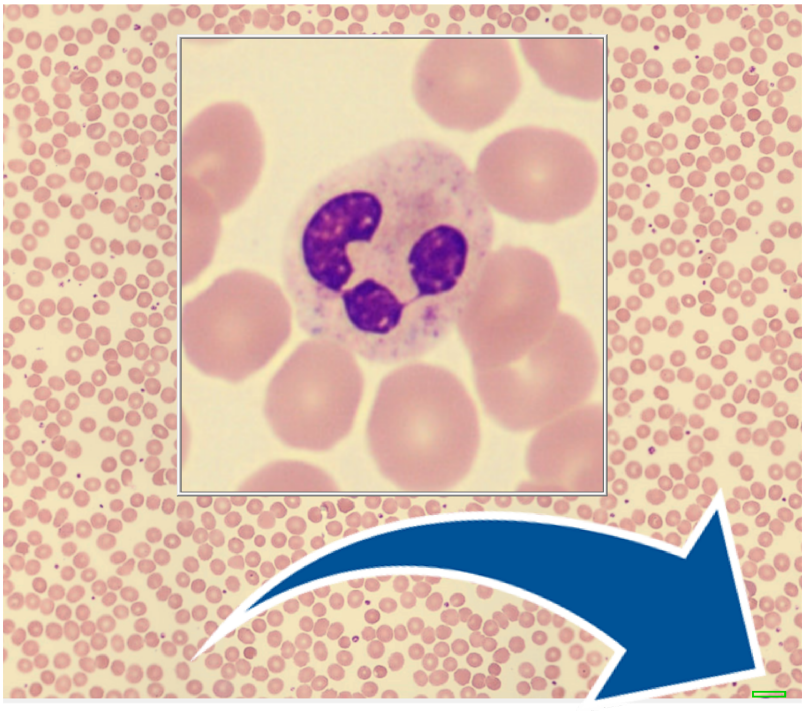
Example: green box	**Example: blue box**	**Example: black box**
		
This object is located and pre-classified as a nucleated cell.	This object is located and pre-classified as a non-nucleated cell. The object may be, for example, a smudge cell.	This object is located but not pre-classified. The object is excluded from the cell location test since enough WBCs are already located.

The box isn't always centered over the cell. It may cover part of the cell or may even be completely separate from the cell. As long as there is a box associated with a cell, you can consider it located.

Example: located	**Example: not located**
	

If a cell is near the edge of the overview image, click it to view it in a magnified image.

Example: located (box near the edge of the overview image)



Icons shown in the **Cell location slides** list:

✓ All images on this slide are examined and the analyzer has located all nucleated cells.

✓ All images on this slide are examined but the analyzer hasn't located all nucleated cells.

✕ Slide error that may be caused by failure in slide processing (for example if the analyzer couldn't locate enough nucleated cells). For more information on the error, click the slide in the list. The cause of the error is shown in the text box under **Total result**.

Icons shown in the **Overview images** list:

✓ This image is examined and the analyzer has located all nucleated cells.

✓ This image is examined but the analyzer hasn't located all nucleated cells.

4 SETTINGS

This section describes settings for processing slides and using the CellaVision DM Software.

Important!
Most settings that you can change in the software affect all analyzers and review stations that use the same database.

These settings affect all analyzers and review stations that use the same database:

- Database settings
- Archiving settings
- User account settings
- Analysis settings, except PLT estimate factor
- Report settings
- Order signing settings
- Standard comment settings
- Reference cells settings
- LIS settings
- Digital slides settings

Depending on your access level, you may not have access to all settings. For more information, see 4.2.2 User access levels on page 56.

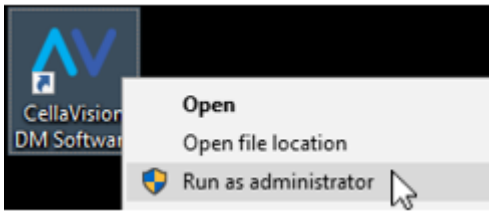
Note: Your service personnel may have disabled some settings.

4.1 Database settings

Important!
These settings apply only to your system so your changes won't affect other systems that use the same database.

Note: To manage databases, you must start the CellaVision DM Software with administrator privileges.

1. On the **File** menu, click **Exit**.
2. If the software doesn't restart automatically, right-click the CellaVision DM Software icon on the desktop, and select *Run as administrator*. For information on user name and password, see the IT Configuration Guidelines or contact your local vendor.



Images and order data are stored in databases.

We recommend that you always keep a backup of your databases. If you use the archiving function and your database is lost, you can't access orders in the archive anymore.

Important!
To prevent any data loss, always use the latest online backup script available at www.cellavision.com.

For information on how to back up and restore databases, see the IT Configuration Guidelines or contact your local vendor.

These database types are available:

- **Processing database (Normal)**: used for slide processing.
- **Scan database**: used for digitized images scanned from slides.
- **Export database**: used for orders exported from other databases (can't be used for slide processing).

A processing or scan database requires 20 GB of disk space and an export database requires 1 GB.

Note: Having many databases reduces system performance.

4.1.1 Manage databases

Important!
These settings apply only to your system so your changes won't affect other systems that use the same database.

To view a list of databases and connections to databases

On the **Tools** menu, click **Settings**, and then click the **Database** tab.

The icons in the list have these meanings:

Database on your system computer

Connection to a database on a server or on another system computer

To create a new database

Note: When you create a new database, it inherits certain settings from the database you're currently logged on to. Before you start processing slides, log on to the new database and make sure that all settings are correct .

1. On the **Tools** menu, click **Settings**, and then click the **Database** tab.
2. Click **Create**.
3. In the **Create a database** dialog box, in the **Database name** text box, enter a name for the new database.
4. In the **Description** text box, you can enter a descriptive text for the new database.
5. In the **Home directory** box, enter the location where you want the new database to be stored. You can also click browse (**...**) and browse for a location.

   Note: You can create a database only on the local hard drive.
6. Under **Type of database**, choose a database type for the new database.
7. Click **Create**.

To delete a database

1. On the **Tools** menu, click **Settings**, and then click the **Database** tab.
2. In the **Database list**, click the database you want to delete.
3. Click **Delete**.

To connect to a database

1. On the **Tools** menu, click **Settings**, and then click the **Database** tab.
2. Click **Connect**.
3. In the **Connect to a database** dialog box, in the **Database name** text box, enter the name of the remote database.
4. In the **Description** text box, you can enter a descriptive text for the remote database.
5. In the **Remote computer** box, enter the name of the computer where the remote database is located.
   If you don't know the name of the remote computer, on the server or the system computer where the remote database is located, start the CellaVision Server Software or the CellaVision DM Software, and then, on the **Help** menu, click **System information**.
6. Click **OK**.

If the server or the system computer where the database is located is behind a firewall, you must configure the firewall to allow other clients to connect to the database. Make sure that these ports are open in the firewall:

- 1360 (Mimer SQL)
- 40201 (CellaVision DM Software Service)

To disconnect from a database

1. On the **Tools** menu, click **Settings**, and then click the **Database** tab.
2. In the **Database list**, click the remote database that you want to disconnect from.
3. Click **Disconnect**.

4.1.2 Manage database size

Important!
These settings apply only to your system so your changes won't affect other systems that use the same database.

Important!
Make sure that there is always free disk space available on the partition where the database is stored. If that partition becomes full, you can't use the system anymore.

To keep the system operational, you need to keep the database from growing too large. That is, you must remove images from the database at the same rate as new slides are processed.

To automatically remove images from the database, you can:

- Let the system auto-delete signed orders (including images) after a specified time.
- Keep all signed orders but let the system move the images to an archive after a specified time.

We also recommend that you manually remove failed and old unsigned orders from the database at regular intervals.

Consider these factors when you set up the system to automatically remove images from the database:

- Number of slides processed (and added to the database) daily.
- Maximum allowed size for the database:
  - 200 GB (approximately 15 000 peripheral blood slides) for a database located on a server that runs the CellaVision Server Software.
  - 20 GB (approximately 1500 peripheral blood slides) for a database located on a system computer.

For example, if you process 20 peripheral blood slides per day, it takes 65 days to reach the maximum capacity of 1500 slides. So you should set up the system to auto-delete signed orders after 65 days.

If you need to save signed orders for a longer time, set up the system to archive orders instead of deleting them.

When an order is archived, the related images are moved from the database to an archive. The archive is typically stored on a server. You can still open and view archived orders.

Note: The archiving function is not a backup function.

We recommend that you always keep a backup of your databases. If you're using the archiving function, and the database is lost, you can't access orders in the archive anymore.

Important!
To prevent any data loss, always use the latest online backup script available at www.cellavision.com.

For information on how to back up and restore databases, see the IT Configuration Guidelines or contact your local vendor.

You can protect individual orders from being auto-deleted or archived.

You can also manually export orders from the database.

If you at any time exceed the maximum capacity for the database, you need to compress the database as described in 5.2.2 Compress databases on page 74.

To view the database size

On the **Help** menu, click **System information**.

To auto-delete signed orders

1. On the **Tools** menu, click **Settings**, and then click the **Archiving/Auto-delete** tab.
2. In the **When signed orders are older than (days)** text box, enter how many days you want to keep the signed orders in the database before they are deleted.
3. Click **Delete the orders**.

To auto-delete unsigned orders

1. On the **Tools** menu, click **Settings**, and then click the **Archiving/Auto-delete** tab.
2. Select **Automatically delete unsigned orders that are older than (days)**.
3. Enter how many days you want to keep the unsigned orders in the database before they are deleted.

To archive signed orders

1. On the **Tools** menu, click **Settings** and then click the **Archiving/Auto-delete** tab.
2. In the **When signed orders are older than (days)** box, enter how many days you want to keep the images of signed orders in the database before they are moved to the archive.
3. Select **Archive those orders to this location** and, in the text box, enter a path to the disk or server where you want to store the archived images.
   The specified path must be accessible from the system computer or server where the database is located.
4. Under **Images to archive**, choose what images and how many from each cell class you want to save in the archive.
   You can reduce the size of the archive by choosing to save fewer images in the archive (for example, only 10 images per cell class). Here you can see which cell classes belong to each category:

   Peripheral blood cell images

Normal WBCs	Abnormal WBCs	Non-WBCs
Segmented neutrophils Eosinophils Basophils Lymphocytes Monocytes	Band neutrophils Promyelocytes Myelocytes Metamyelocytes Immature eosinophils Immature basophils Promonocytes Prolymphocytes Blast cells Lymphocytes, variant forms Reactive lymphocytes Abnormal lymphocytes Plasma cells Large granular lymphocytes Hairy cells Sezary cells User defined WBCs	Nucleated RBC Giant thrombocyte Thrombocyte aggregation Megakaryocyte Smudge cell Artefacts User defined Non-WBCs Other Not classed

To auto-delete digital slides

This setting is available when you're logged on to a scan database.

1. On the **Tools** menu, click **Settings**, and then click the **Auto-delete** tab.
2. Select **Automatically delete orders that are older than** and, in the text box, enter how many days you want to keep digital slides in the database.

3. If you want to keep regions of interest, select **For orders containing regions of interest, keep the order data and the regions of interest**.
   The order data and the regions of interest are kept in the database, but the overview image is deleted.

4.1.3 Dashboard statistics

The system continuously stores statistical data on processed and signed slides. You can access various status and statistical data on analyzers and reviewers via the CellaVision Dashboard.

You can also turn off data collection and erase all stored statistics.

Note: Stored statistics contain no patient data.

To turn off data collection

1. On the **Tools** menu, click **Settings**, and then click the **Database** tab.
2. Clear the selection for **Enable collection of data in order to see statistics in the CellaVision Dashboard**.

To erase all dashboard statistics

1. On the **Tools** menu, click **Settings**, and then click the **Database** tab.
2. Click **Clear**, and then click **Yes**.

4.2 User account settings

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

You can create user accounts with different access levels for everyone who needs access to the system. With existing users, you can change their access level, full name, password, and email address but not their user name.

If a user account is not used, you can deactivate or delete it.

A user account is valid for the database on which it was created. A user can log on to the database from any system or review station that has a connection to that database.

To create a new user account

1. On the **Tools** menu, click **Settings**, and then click the **Users** tab.
2. To open the **User Information** dialog box, click **New**.
3. In the **User name** text box, enter a unique user name for the new user.

4. In the **Full name** text box, enter the name of the new user.
5. In the **Password** and the **Password again** text boxes, enter the same password for the new user.
6. In the **Email** text box, enter the email address of the new user.
7. To fetch user information for the new user from an active directory, in the **Active Directory user name** text box, enter the user name the user has in the active directory, or click **Search...** to search for the user among listed active directory users.

   Note: You must be logged on to the domain to use the search function.
8. In the **Access Level** list, select the level of authorization you want to give to the new user.
9. Make sure that **Account active** is selected.
10. Click **OK**.

A user name and a password can:

- Contain only characters A–Z, a–z, and 0–9
- Start either with letters or numbers

You can't use these words as a user name: *create, get, grant, if, in, is, local, of, on, or, out, select, set, sys, sysadm, system, table, to, update,* and *user*.

Description of different user access levels

User access level	Rights
Observer	Can view images and results without locking the slide.
User	Can review WBC, RBC, and PLT results but can't sign slides.
Authorized	Can review WBC, RBC and PLT results, and sign slides and orders.
Restricted	Has the same rights as the **Authorized** but with restricted database access. For more information on database access for the restricted user, see 4.2.1 Options for restricted users on the facing page.
Administrator	Has full access to the system.
Service	Has full access to the system except for patient data and user settings.

For more detailed information on each user access level, see 4.2.2 User access levels on page 56

To edit a user account

1. On the **Tools** menu, click **Settings**, and then click the **Users** tab.
2. Select the user account you want to edit, and then click **Edit**.
3. In the **User Information** dialog box, make your changes, and then click **OK**.

To deactivate a user account

1. On the **Tools** menu, click **Settings**, and then click the **Users** tab.
2. Clear the check box selection next to the user account you want to deactivate.
   To reactivate the user account, select the check box next to it.

To delete a user account

1. On the **Tools** menu, click **Settings**, and then click the **Users** tab.
2. Select the user account you want to delete, and then click **Delete**.

Note: You can't delete the user account of a user that has signed slides in the database. You can only deactivate their user account.

Related topics

- For more detailed information on access levels, see 4.2.2 User access levels on the next page.

4.2.1 Options for restricted users

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

By default, a user with access level **Restricted** can only view signed slides.

You can allow them to view unsigned slides, which means that they can also review results, and sign slides and orders (as **Authorized** users) without having full access to the database.

You can also allow them to search for slides by patient ID, order ID, or both in the **Database View**. But they can't search by any other criteria, such as patient name or ordering physician.

1. On the **Tools** menu, click **Settings**, and then click the **Users** tab.
2. Under **Restricted**, to allow the restricted user to:
   - find, open, and view unsigned slides, select **View unsigned slides**.
   - search for slides by patient ID, select **Search by Patient ID**.
   - search for slides by order ID, select **Search by Order ID**.

For more detailed information on restricted users, see 4.2.2 User access levels on the next page.

4.2.2 User access levels

Slide processing and verification	Observer	User	Restricted	Authorized	Administrator	Service
Start slide processing		●		●	●	●
Verify WBC pre-classification		●	●	●	●	●
Verify RBC pre-characterization		●	●	●	●	●
Estimate platelets		●	●	●	●	●
Add comments		●	●	●	●	●
Add comments to signed slides		●	●	●	●	●
Confirm cell counter results		●	●	●	●	●
Sign slides and orders			●	●	●	●
Send results to LIS			●	●	●	●
Send images via email	●	●	●	●	●	●
Exclude PLT analysis		●	●	●	●	●
Exclude RBC analysis		●	●	●	●	●
Mark orders for pathology review		●	●	●	●	●
Mark pathology review as finished		●	●	●	●	●
Add comments to pathology review		●	●	●	●	●
Add WBC reference cells				●	●	●

Database	Observer	User	Restricted	Authorized	Administrator	Service
Find orders by order ID	●	●	○ [1]	●	●	●
Find orders by patient ID	●	●	○ [2]	●	●	
Find orders by patient name	●	●		●	●	
Find orders by ordering physician	●	●		●	●	
Find orders by comment text	●	●		●	●	
Find orders by pathology review status	●	●		●	●	●
Find orders by other properties	●	●		●	●	●
Mark orders as STAT		●		●	●	●
Add, edit, and remove pending orders		●	●	●	●	●
Edit order data				●	●	
Protect orders from archiving and auto-delete				●	●	●
Delete unsigned orders and slides				●	●	●

1 Depending on settings.

2 Depending on settings.

Database	Observer	User	Restricted	Authorized	Administrator	Service
Delete signed orders					●	●
Export orders				●	●	●
Change order ID of orders in export database				●	●	
Mark an order for CellaVision Transfer Tool		●		●	●	●
Change order ID of orders beginning with “ER”				●	●	

Maintenance	Observer	User	Restricted	Authorized	Administrator	Service
Export log files	●	●	●	●	●	●
View log: Audit trail					●	●
View log: Specification					●	●
Perform cell location tests				●	●	●
Prime oil		●		●	●	●

Analysis settings	Observer	User	Restricted	Authorized	Administrator	Service
Change default processing settings				●	●	●
Change re-classifications settings					●	●
Change report settings					●	●
Change standard comments				●	●	●
Enable RBC pre-characterization					●	●
Change RBC grading and size limits					●	●
Change intervals for PLT concentration levels					●	●
Set PLT estimate factor					●	●
Set manual PLT concentration estimation		●	●	●	●	●
Change default scan area		●		●	●	●

General settings	Observer	User	Restricted	Authorized	Administrator	Service
Change email settings					●	●
Change order signing settings					●	●
Change user accounts					●	
Change worklist settings				●	●	●
Compress database					●	●
Configure auto-delete and archiving					●	●
Create databases					●	●
Connect to databases					●	●
Enable audible alarm (optional)		●		●	●	●
Enable LIS					●	●

4.3 Analysis settings

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

4.3.1 Default processing settings

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

You can set the default processing values to specify how the system should process a slide if the order ID isn't available in the database (in the **Pending orders** list) or from the LIS.

To set the default values for peripheral blood analysis

Note: These values are used only to process new slides that the system can't find in the LIS or in the **Pending orders** list.

1. On the **Tools** menu, click **Settings**, and then click the **Analysis** tab.
2. Under **PB default values**, in the **Number of WBCs to count** text box, enter the number of WBCs you want the system to locate.

   Note: The **Number of WBCs to count** can be set to a maximum of 1000.
3. Under **Type of order**, select the types of analyses you want to perform on the slide.
4. If you want to, you can select the worklist items as specified in 4.3.3 Worklist settings on the next page.

To set the default values for image scan

Note: These values are used only to process slides that the system can't find in the **Pending orders** list.

1. Make sure you are logged on to a scan database.
2. On the **Tools** menu, click **Settings**, and then click the **Analysis** tab.
3. Under **Scan default values**, select a resolution for the scan images.

4.3.2 LIS settings

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

You can enable the analyzer to interact with the LIS. Once enabled, the analyzer retrieves order data from the LIS and sends results back to the LIS. Before you enable the interaction, you must set up the connection to the LIS as described in the IT Configuration Guidelines. For more information on the LIS interaction, see the LIS Interface Manual.

To enable interaction with the LIS

1. On the **Tools** menu, click **Settings**, and then click the **Analysis** tab.
2. Select **Enable LIS**.
3. Restart the CellaVision DM Software.

4.3.3 Worklist settings

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

You can set the analyzer to automatically add processed peripheral blood slides to the worklist for all logged on users as soon as the slides are processed.

If the network is slow, you can also set the analyzer to preload manually added slides to the worklist in the background. These slides are locked for other users.

To add slides automatically to the worklist

Note: This feature is intended for a single analyzer setup. We recommend that you don't use this feature with the CellaVision Server Software.

1. On the **Tools** menu, click **Settings**, and then click the **Analysis** tab.
2. Select **Add processed slide to worklist**.

To preload and lock slides added manually to the worklist

1. On the **Tools** menu, click **Settings** and then click the **Analysis** tab.
2. Select **Preload and lock slides that I add to worklist**.

4.3.4 PB re-classification settings

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

You can set the analyzer to automatically forward cells of certain classes or types to other specific cell classes or types after pre-classification or pre-characterization.

To set the analyzer to forward WBCs

1. On the **Tools** menu, click **Settings**, and then click the **PB Re-classification** tab.
2. Under **Forward pre-classified cells**, select the cell classes you want the analyzer to automatically forward.

4.3.5 RBC pre-characterization settings

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

The analyzer can automatically pre-characterize and grade the RBC morphology of a sample. You can change the grading limits the analyzer uses for automatic grading, and the size limits that the analyzer uses to determine if a cell is a microcyte, a macrocyte, or a normal sized cell.

Important!
Make sure you use the same grading limits throughout your network for all equivalent morphologies. If slides are processed on analyzers in your network that have different grading limits, the limits will differ between the slides.

CellaVision® DC-1 uses the same method to measure anisocytosis as the optional CellaVision Advanced RBC Application. This methods is called **Anisocytosis (CV)**. Make sure to set the grading limits appropriately for **Anisocytosis (CV)** in the CellaVision DM Software on your analyzer.

Important!
The method used to measure anisocytosis in other types of analyzers in your network that use standard RBC (no CellaVision Advanced RBC Application installed) is called **Anisocytosis**. Make sure to understand the difference between this method and **Anisocytosis (CV)** when grading and reviewing samples.

To enable RBC pre-characterization

1. On the **Tools** menu, click **Settings**.
2. Click the **RBC Pre-characterization** tab.
3. Select **Enable RBC pre-characterization**.

To change RBC grading and size limits

Important!
You need to set your own RBC limits according to your laboratory's policy.

Important!
If your analyzer is connected to an existing database, settings are fetched automatically from that database. This may not apply if the analyzer is connected to a database that is also connected to analyzers that run additional CellaVision® applications. In that case, check the **RBC Pre-characterization** tab to ensure that all values are entered.

1. On the **Tools** menu, click **Settings**, and then click the **RBC Pre-characterization** tab.
2. Click **RBC Limits**.
3. Under **Grading limits (%)**, enter the grading limits (in percentage) for grades 1, 2, and 3 for each RBC type.
   By default, the grading limits are set to 0 (zero).

4. Under **Size limits (micrometers)**, enter the smallest and largest size (in micrometers) for a cell to be regarded as normal.
   Smaller cells are regarded as microcytes and larger cells as macrocytes.

4.3.6 PLT settings

For the platelet estimation, the analyzer captures an overview image of the RBC monolayer.

Depending on the software configuration, you can use one of these methods to calculate platelet concentration:

- Count platelets in one part (grid square) of the overview image at a time and enter the number of platelets for each grid square.
- Estimate an average number of platelets per grid square.
- Manually estimate platelet concentration.

If you want to count platelets, you need to specify the intervals where you consider PLT concentration to be significantly decreased, decreased, normal, or increased. You also need to determine and enter a PLT estimate factor.

You can also change the default properties for the PLT view, such as grid size and how to calculate and report PLT concentration.

Important!
You must determine and enter a PLT estimate factor before it's possible to calculate PLT concentration. By default, the PLT estimate factor is set to 0.

To set manual PLT concentration estimation

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

This setting applies to all slides in an order once one of them is opened for the first time. Once a slide has been opened, this setting can’t be changed for any slides in that order.

1. On the **Tools** menu, click **Settings** and then click the **PLT** tab.
2. Select **Use only manual PLT concentration estimation**.

To change the intervals for PLT concentration levels

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

1. On the **Tools** menu, click **Settings**, and then click the **PLT** tab.
2. Under **Intervals for average PLTs/HPF value**, enter values where you consider PLT concentration to be:
   - **Significantly decreased**
   - **Decreased**
   - **Normal**
   - **Increased**

To change the default properties for the PLT view

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

These settings specify how the PLT view looks and functions. You can change any of these values temporarily in the PLT view when performing the review.

1. On the **Tools** menu, click **Settings**, and then click the **PLT** tab.
2. In the **Grid size** drop-down, select how many grid squares you want to divide the PLT image into.
3. In the **PLT count** drop-down, select if you want to count or approximate the number of PLTs.
   - **Count PLTs per grid square** allows you to enter the number of PLTs for each grid square separately.
   - **Approximate PLTs per grid square** allows you to approximate the number of PLTs per grid square, and then enter the average number of PLTs per grid square.
4. In the **PLT concentration** drop-down, select how you want to report the PLT concentration.
   - **Calculated estimate** reports the calculated number of PLTs per litre based on the counted or estimated number of PLTs per grid square.
   - **Calculated level** reports the calculated level of PLT concentration (increased, normal, and so on) based on the counted or estimated number of PLTs per grid square.
   - **Manual level** allows you choose the level of PLT concentration (increased, normal, and so on) manually.

To calculate and set the PLT estimate factor

Important!
These settings apply only to your system so your changes won't affect other systems that use the same database.

1. Use a cell counter to perform automated PLT counts on 30 consecutive blood samples.
2. Prepare and stain one smear from each sample.
3. Process the slides with the analyzer.
4. With each slide, count and enter the number of PLTs in each grid square.
   This way you perform the PLT analysis on each processed slide and let the software calculate the average PLTs/HPF value for them.
5. Calculate the conversion factor for each sample: divide the PLT value from the cell counter by the average PLTs/HPF value from the analyzer.
6. Calculate the **PLT estimate factor** (the average conversion factor): add the conversion factor for each sample and divide it by 30.
7. On the **Tools** menu, click **Settings**, and then click the **PLT** tab.
8. In the **PLT estimate factor** text box, enter the calculated PLT estimate factor.
   By default, the PLT estimate factor is set to 0 (zero).

4.4 Report settings

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

You can change the default content and appearance of the report that the system generates when you sign a slide. Choose one of the report templates that are delivered with the system or modify or create your own report templates.

To set a default report template

1. On the **Tools** menu, click **Settings** and then click the **Report/Sign** tab.
2. In the **Report template** list, click the template you want to use, and then click **Set active**.
3. The arrow (→) in the **Name** column now points to the report template you have set as the default report template.
4. If you want to preview the report template, click the template in the **Report template** list and then click **Edit**.

To edit a report template

1. On the **Tools** menu, click **Settings** and then click the **Report/Sign** tab.
2. In the **Report template** list, click the template you want to edit, and then click **Edit**.

3. In the **Add/Edit report template** window, modify the report template as needed. Don't change the text variables, that is the text surrounded by % (for example %AnalysisLabId%).
4. When you're done with the report template, click **OK**.

To create or import a new report template

1. On the **Tools** menu, click **Settings** and then click the **Report/Sign** tab.
2. If you want to create a new report template based on an existing report template, click that template in the **Report template** list.
3. Click **Add**, and then click **Yes** or **No** depending on if you want to use an existing template or not.
4. Create your new template or click **Import from file** to import a template from a text file.
5. When you're done with the report template, click **OK**.

To remove a template

1. On the **Tools** menu, click **Settings** and then click the **Report/Sign** tab.
2. In the **Report template** list, click the template you want to remove and then click **Delete**.

4.5 Order signing settings

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

You can change what is filled in by default in the **Sign slide** dialog box when it opens.

To change the default values for the sign slide dialog

1. On the **Tools** menu, click **Settings** and then click the **Report/Sign** tab.
2. Under **Default settings for sign dialogs**, choose how you want the **Sign slide** dialog box to be set up by default.

4.6 Standard comment settings

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

You can create standard comments that you can add to any of the analyses (WBC, RBC, or PLT). You need to assign a unique identifier (code) to each standard comment, and you can choose if you want

the analyzer to include that code in the comment or not.

To add a new standard comment

1. On the **Tools** menu, click **Settings**, and then click the **Standard Comments** tab.
2. Click **New**.
3. In the **Code** text box, enter a unique code to identify the comment.
4. Under **Comment type**, select the type of analysis you want to use the comment for, or click **General** to use the comment for any analysis.
5. In the **Comment** text box, enter your comment text.
6. Click **OK**.
7. If you want the code to be inserted before the comment text, select **Include code in comment**.
8. If you want to see the list of standard comments in the comments dialog box, select **Always show expanded**.

To edit a standard comment

1. On the **Tools** menu, click **Settings**, and then click the **Standard Comments** tab.
2. In the list, click the comment you want to edit, and then click **Modify**.

To delete a standard comment

1. On the **Tools** menu, click **Settings**, and then click the **Standard Comments** tab.
2. In the list, click the comment you want to delete, and then click **Delete**.

4.7 Reference cell settings

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

You can save a WBC or a non-WBC as a reference cell on the **WBC** tab when you review a processed PB slide.

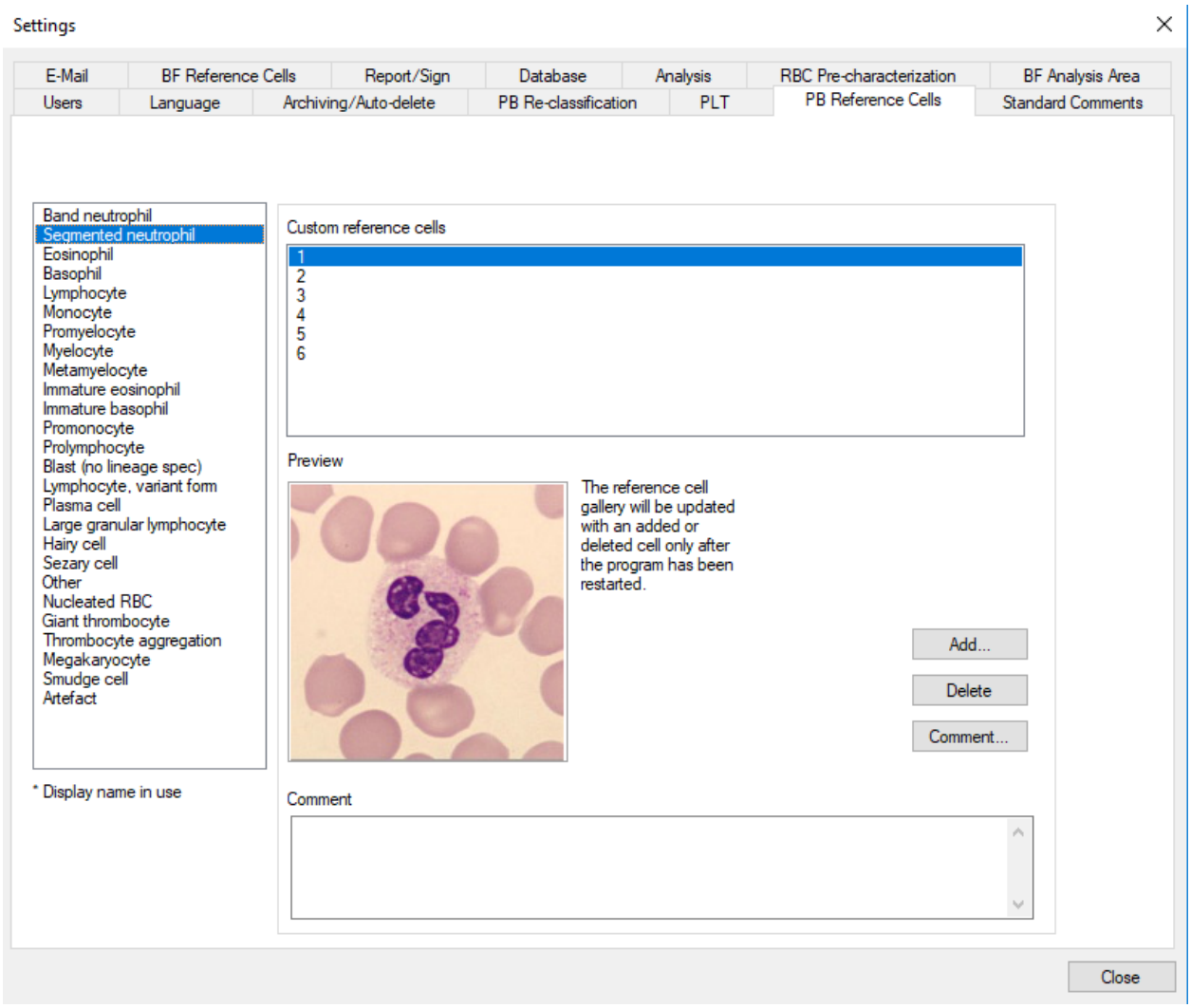
You can also add an image from your computer as a reference cell.

To add a custom reference cell when reviewing a processed slide

1. Right-click the cell image and select **Save as custom ref. cell**.
2. Restart the CellaVision DM Software.

To add a custom reference cell from your computer

1. On the **Tools** menu, click **Settings**.
2. Click the **PB Reference Cells** tab or the **BF Reference Cells** tab.
3. In the list of cell classes, click the cell class that you want to add reference cells to.
4. Click **Add**, locate the image you want to add as a reference cell, and then click **Open**.
   You can add 24-bit .bmp images or .jpg images. The added reference cell appears in the **Preview** frame.
5. If you want to add a comment to the reference cell, click **Comment**.
6. Restart the CellaVision DM Software.



To delete a custom reference cell

1. On the **Tools** menu, click **Settings**.
2. Click the **PB Reference Cells** tab or the **BF Reference Cells** tab.
3. In the list of cell classes, click the cell class of the reference cell you want to delete.
4. In the **Custom reference cells** list, click the reference cell you want to delete, and then click **Delete**.
5. Restart the CellaVision DM Software.

4.8 E-mail settings

Important!
These settings apply only to your system so your changes won't affect other systems that use the same database.

You can set up your system to allow you to send WBCs and non-WBCs via e-mail.

To set up e-mail

1. On the **Tools** menu, click **Settings**, and then click the **E-Mail** tab.
2. In the **Default recipient** text box, enter an e-mail address for pre-selection.
   You can always change this address before sending the e-mail.

   Note: Make sure the default recipient e-mail address belongs to a user on the same domain as your mail server.
3. In the **Mail server** text box, enter the address to the mail server you want to use.
4. In the **E-mail from** text box, enter the e-mail address that you want to appear as the sender of all e-mails from the analyzer.

   Note: These settings apply to everyone who uses this system, even those who use a different user account or a different database.

4.9 Scan settings

Important!
These settings apply to all systems that use the same database so your changes may affect other systems.

These settings are available only when you're logged on to a scan database.

You can change the default scan area and resolution for new orders that you add to the database (in the **Pending Orders** list). The analyzer uses these values also to process a slide with an order ID that is not in the database.

When you add a new order to the **Pending Orders** list, you can choose a different scan area and a different resolution than the default. The greater the resolution, the bigger the file.

The maximum scan area depends on the selected resolution.

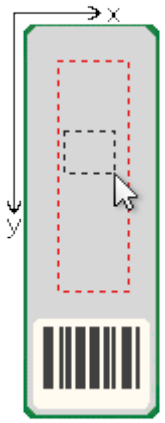
Resolution	Maximum scan area
Low	14 x 45 mm
Medium	14 x 20 mm
High	10 x 10 mm

To set the default resolution

1. On the **Tools** menu, click **Settings**, and then click the **Analysis** tab.
2. Under **Scan default values**, select the resolution you want you use.

To set the default position and scan area size

1. On the **Tools** menu, click **Settings**, and then click the **Default Scan Area** tab.
2. To define the scan area, do one of the following:
   - Enter values in the text boxes to specify the scan area.
   - Use your mouse to draw a rectangle on the slide. The rectangle must be within the red dotted rectangle on the slide.



Use your mouse to draw a rectangle for the area you want to scan.

4.10 Language settings

Important!
These settings apply only to your system so your changes won't affect other systems that use the same database.

You can change the language for the CellaVision DM Software user interface and for the Instructions for Use.

You can choose from languages that were installed during analyzer installation.

To change the language for the user interface

1. On the **Tools** menu, click **Settings**, and then click the **Language** tab.
2. Under **Language for the user interface**, choose a language from the list.
3. Restart the CellaVision DM Software.

To change the language for the Instructions for Use

1. On the **Tools** menu, click **Settings**, and then click the **Language** tab.
2. Under **Language for the instructions for use**, choose a language from the list.
3. Restart the CellaVision DM Software.

5 MAINTENANCE

Warning!
Only trained personnel may perform service on this analyzer.

Caution!
Be careful not to bend or put excessive force on any part of the analyzer interior.

5.1 Weekly maintenance

Performing these maintenance measures once a week, helps to ensure the analyzer's optimal performance.

5.1.1 Restart the analyzer

Caution!
Always exit the CellaVision DM Software before you restart or turn off the analyzer. If your turn off the analyzer abruptly, for example, break the power supply or press and hold the stand-by button, the database may become corrupt.

1. Wait for the slide processing to finish or stop it manually.
   For more information, see 2.3.3 Stop slide processing on page 31.
2. On the **File** menu, click **Exit**.
3. Click **Start**, select **Power**, and then select **Shut down**.
4. To restart the analyzer, see 2.1 Turn on the analyzer on page 23.

5.1.2 Delete unsigned orders

1. Click **Database View**.
2. Under **Search criteria**, in the drop-down list, select **View unsigned**, and then click **Search for orders**.
3. In the **Processed Orders** list, select the orders you want to delete.
   - To select a consecutive group of orders, click the first order, hold down Shift, and then click the last order.
   - To select non-consecutive orders, hold down Ctrl, and then click each order that you want to

select.

4. Click **Delete**, and then click **Yes**.

You can also set to auto-delete unsigned orders. See 4.1.2 Manage database size on page 50.

5.1.3 Clean the analyzer

Caution!
Use only a soft cloth moistened with water. Other solvents and sharp or abrasive cleaning tools may cause damage to the analyzer.

1. Wipe the outer casing with a moist cloth.
2. Wipe any excess oil from the loading tray.
3. Pull out the drip tray and wipe clean of any immersion oil.

5.2 Remedial maintenance

5.2.1 Check and back up databases

To help prevent loss of data, back up your database at regular intervals. For information on how to back up and restore the database, see the IT Configuration Guidelines or contact your local vendor.

To check database size

1. On the **Help** menu, click **System Information**.
2. Check the **Database size**.
   Take steps to reduce database size if it's more than:
   - 20 000 MB for a local database.
   - 200 000 MB for a remote database located on a server.

Related topics

- For more information on how to reduce database size, see 4.1.2 Manage database size on page 50.

5.2.2 Compress databases

Important!
These settings apply only to your system so your changes won't affect other systems that use the same database.

Important!
Make sure no users are logged on to the database you want to compress. This includes users logged on via the CellaVision DM Software on other analyzers, via the CellaVision Remote Review Software, or via the CellaVision Server Software.

When images are removed from the database (manually, by auto-delete, or by archiving), the database still allocates the same amount of hard disk space. You can free this hard disk space, that is actually reducing the size of the physical file where the data is stored, by compressing the database.

Compressing a database requires free disk space equal to the size of the database.

When a database is being compressed, no clients can use or connect to that database. This is why you can't compress the database that you logged on to when you started the CellaVision DM Software. Any users who are still connected to the database when you start the compression receive an error message.

To compress a database

1. Make sure no users are logged on to the database you want to compress.
2. Start the CellaVision DM Software.
3. Log on to a database other than the one you want to compress with access level **Administrator** or **Service**.
4. On the **Tools** menu, click **Settings**, and then click the **Database** tab.
5. In the **Database list**, click the database you want to compress, and then click **Compress**.
6. In the **Compress database** dialog, check that the value for **Available on harddisk** is the same or bigger than **Original size**.
   If the value for **Available on harddisk** is less than **Original size**, you need to free more disk space before you compress the database.
7. Click **Compress database**.

Note: It may take a long time to compress a database. For example, a database larger than 10 GB may take several hours to compress.

6 TROUBLESHOOTING

This section describes issues that may occur during operation, along with possible causes and suggested solutions.

To investigate and resolve issues

1. Observe any unusual circumstances surrounding the issue.
2. Note any error messages displayed.
3. Follow the relevant troubleshooting steps.
4. If the issue persists, export the log files, and then contact your local vendor for assistance.

   Note: Always export the log files before contacting your local vendor.

To export log files to folder

1. On the **Tools** menu, click **Export Log Files**.
2. Select **Export to folder**.
3. Select **Compress files before export**.
4. Enter or browse (...) to a location where you want to export the log file, and then click **OK**.
5. Click **Export/Burn.**

6.1 Connection issues

Issue	Solution
Can't connect to the database.	Restart the analyzer. Check your network connection. Make sure that there is no firewall blocking the network port. If the server or the system computer where the database is located is behind a firewall, the firewall must be configured to allow other clients to connect to the database. Make sure that port 1360 (Mimer SQL) and port 40201 (CellaVision DM Software Service) are open in the firewall.
Can't log on to the CellaVision DM Software.	Check your user name and re-enter your password. Make sure that Caps lock is turned off. Log on to the CellaVision DM Software as instructed in 2.1 Turn on the analyzer on page 23.

6.2 General processing issues

Image is blurry	
Cause	**Solution**
Not enough oil on the slide.	1. Wipe the slide clean from oil. 2. Hold the tip of the oil bottle close to the slide without touching it, aim for the red colored marker, and place two drops of the immersion oil on the slide. Check carefully for air bubbles before processing the slide. Don't agitate or shake the oil bottle. If the issue reoccurs, clean the objective lens as instructed in 6.12 Clean objective lens on page 92.
Air bubbles in the oil.	
Slide not properly positioned during slide processing because the barcode label is placed too close to the edge of the slide.	Check the slide positioning and the size of the barcode as instructed in 7.3.2 Barcodes on page 105.
Dust particles in the loading tray.	Wipe the loading tray with a lint free tissue to remove any dust particles. If the issue occurs on a regular basis, make this activity as part of your daily or weekly maintenance.

WBC images are visible but not centered.	
Cause	**Solution**
Analyzer needs calibration or alignment.	Contact your local vendor’s technical support.

⚠ **Incomplete analysis** **Less than the ordered number of cells are collected.**	
Cause	**Solution**
Low WBC count in the sample.	Prepare and process more slides from the same sample.
Monolayer area found is too small.	Prepare the slides with longer blood smears.
Artefacts (staining precipitates) on the slide.	Make sure that the reagents are changed according to the recommendations in 2.2.3 Staining on page 26.

⚠ **Incomplete analysis** **No RBC/PLT image is saved.**	
Cause	**Solution**
Excessive amount of small artefacts in the smear or too light a stain.	Make sure that the slides are prepared according to the recommendations in 2.2 Prepare slides on page 24.
	Check your smear making procedure using the CellaVision SmearChecker.
	See also 6.6 Smear and staining issues on page 84.

⚠ **Analysis failure**	
Cause	**Solution**
No monolayer found.	Make sure that the slides are prepared according to the recommendations in 2.2 Prepare slides on page 24.
	See also 6.6 Smear and staining issues on page 84.
Slide is placed incorrectly in the loading tray.	Make sure that the slide is placed in the loading tray with the blood smear facing up and that the labeled or frosted end of the slide is on the right.
Not enough oil on the slide.	1. Wipe the oil from the slide. 2. Hold the tip of the oil bottle close to the slide without touching it, aim for the red colored marker, and place two drops of the immersion oil on the slide.Check carefully for air bubbles before processing the slide. Don't agitate or shake the oil bottle. If the issue reoccurs, clean the objective lens as instructed in 6.12 Clean objective lens on page 92.
Air bubbles present in the oil.	

✕ **Light error.**	
Cause	**Solution**
Smear is too dark or too thick.	Make sure that the slides are prepared according to the recommendations in 2.2 Prepare slides on page 24.
	Check your smear making procedure using the CellaVision SmearChecker.
	See also 6.6 Smear and staining issues on page 84.
LED issue.	Contact your local vendor’s technical support.

Database access is slow.	
Cause	**Solution**
Database service needs to restart.	If you use a local database service, restart the analyzer.
	If you use the CellaVision Server Software, restart the server.
Database is too large.	Keep the database size below the maximum allowed size as instructed in 5.2.1 Check and back up databases on page 74.
Database files are fragmented.	Compress the database as instructed in 5.2.2 Compress databases on page 74.
Large network delays.	Make sure that the network connections are stable.
	Make sure that the network communication delays are small.

When scanning a slide, it gets status " Analysis failure" with additional information "No image data in scanned area".	
Cause	**Solution**
Too little specimen on the slide.	Prepare a slide with more specimen.
Wrong area selected on the slide.	Select the correct area and reprocess the slide.

Same cell is counted more than once or duplicate cell images are shown.	
Cause	**Solution**
Sample contains disintegrated cells or smudge cells, and the analyzer identifies different parts of a cell as two or more different cells.	To minimize the amount of disintegrated cells, make sure the smear is prepared within four hours of blood collection. For more information, see 2.2.1 Prepare peripheral blood smears on page 25.
	To minimize the amount of smudge cells, verify your smear preparation process.
	To identify and exclude duplicate cells, activate the **Show cell markers** function during review.

Cells are split into two or more parts.	
Cause	**Solution**
Too little staining.	You may need to increase fixation and staining time.
	Check your smear making procedure using the CellaVision SmearChecker.
	See also 6.6 Smear and staining issues on page 84.
Too much rinsing.	You may need to correct the rinsing technique so that it's adequate but not excessive.
	Check your smear making procedure using the CellaVision SmearChecker.
	See also 6.6 Smear and staining issues on page 84.

6.3 LIS error messages

⚠ **Default values** **The slides are analyzed with default values even though LIS is used for order information.**	
Cause	**Solution**
Order is not in the LIS.	Make sure that the order is available in the LIS.
Connection to the LIS is broken.	Check the connection to the LIS.

LIS status: ✕	
Cause	**Solution**
Connection to the LIS is broken.	Check the connection to the LIS. Results are automatically resent when connection is re-established.

6.4 Cell location issues with peripheral blood

Too many non-nucleated cells in the sample.	
Cause	**Solution**
Too many smudge cells found.	Run another slide from another patient. If the issue persists, check your smear making procedure using the CellaVision SmearChecker.
	Verify sample preparation procedure as instructed in 2.2.1 Prepare peripheral blood smears on page 25.
Too many artefacts found.	Increase rinse time.
	Filter the stain.
	Make sure that the stain has not exceeded the expiration date.

6 Troubleshooting

Too many non-nucleated cells in the sample.	
Cause	**Solution**
Cells are incorrectly classified as non-nucleated cells.	Run another slide. If the issue persists, prepare new staining reagents.

Too few nucleated cells located in the sample.	
Cause	**Solution**
WBC count is low.	Prepare a new slide with a higher WBC count.
Smear is too short.	Prepare longer smears.
Smear is of poor quality.	Verify sample preparation procedure as instructed in 2.2.1 Prepare peripheral blood smears on page 25.

Too many missed cells in the sample.	
Cause	**Solution**
WBC count is too high.	Do not process slides with a WBC count higher than 100 × 10^9/L.
Staining is of poor quality.	Verify your staining procedure. See also 2.2.3 Staining on page 26.
Analyzer needs calibration or alignment.	Contact your local vendor's technical support.

Processing time is long.	
Cause	**Solution**
WBC count is low.	Prepare a new slide with a higher WBC count.
Staining is of poor quality.	Verify your staining procedure. See also 2.2.3 Staining on page 26.

Nearly all boxes are far from the cells.	
Cause	**Solution**
Positioning error.	Contact your local vendor's technical support.

A cell is marked with more than one box.	
Cause	**Solution**
Too little staining.	You may need to increase fixation and staining time.
Too much rinsing.	You may need to correct the rinsing technique so that it's adequate but not excessive.

The analyzer needs fewer than 20 or more than 80 overview images to find the required number of objects.	
Cause	**Solution**
Smear is of poor quality.	Verify sample preparation procedure as instructed in 2.2.1 Prepare peripheral blood smears on page 25.
Staining is of poor quality.	Verify your staining procedure. See also 2.2.3 Staining on page 26.

6.5 Barcode issues

Barcode is not read.	
Cause	**Solution**
Handheld barcode reader (optional) can't read the barcode.	Make sure that the barcode reader cable is connected to the analyzer.
	In the **System Control View**, manually enter the **Slide ID** exactly as written on the slide.
Quiet zone is missing.	Make sure that a quiet zone is present as specified in 7.3.2 Barcodes on page 105.
	Make sure that the barcode is not printed too close to a logotype.
Contrast between the bars and the background is too low.	Adjust the printer.
	Use slides with a white, smooth, frosted area.
Print is of poor quality.	Clean the printer head in the barcode printer.
	Replace the printer ribbon in the barcode printer.

Barcode is not read.	
Cause	**Solution**
Barcode is damaged (barcode cells are missing).	Adjust the printer.
	Use slides with a white, smooth, frosted area.
No barcode is found.	Check the barcode positioning and size as instructed in 7.3.2 Barcodes on page 105.
Barcode is blurry because of immersion oil.	Make sure the barcode is resistant to immersion oil.
	Print the barcode as instructed in 7.3.2 Barcodes on page 105.

6.6 Smear and staining issues

Note: Check your smear making procedure using the CellaVision SmearChecker.

Note: Depending on the slide processing issue, images and preliminary results may still be available. You need to assess if the smear quality is good enough to review the results.

⚠ **Smear Warning** **Monolayer: Bad quality** **Monolayer: Short or uneven**	
Cause	**Solution**
Smear is of poor quality.	Verify sample preparation procedure as instructed in 2.2 Prepare slides on page 24.
Slide is placed incorrectly in the loading tray.	Make sure that the slide is placed in the loading tray with the blood smear facing up and that the labeled or frosted end of the slide is on the right.
Not enough oil on the slide. Air bubbles in the oil.	1. Wipe the oil from the slide. 2. Hold the tip of the oil bottle close to the slide without touching it, aim for the red colored marker, and place two drops of the immersion oil on the slide.Check carefully for air bubbles before processing the slide. Don't agitate or shake the oil bottle. If the issue reoccurs, clean the objective lens as instructed in 6.12 Clean objective lens on page 92.

⚠ Smear Warning **WBC distribution: Uneven**	
Cause	**Solution**
Smear is of poor quality.	Verify sample preparation procedure as instructed in 2.2 Prepare slides on page 24.

⚠ Smear Warning **Smear: Too red/Too blue/Too light/Too dark/Too blue or too dark.**	
Cause	**Solution**
Staining is of poor quality.	Verify your staining procedure. See also 2.2.3 Staining on page 26.

⚠ Smear Warning **All WBCs have collected in a limited area. The cell distribution may be distorted.**	
Cause	**Solution**
WBC concentration is high.	To get a more representative differential count, increase the number of ordered WBCs and reprocess the slide. This warning may persist even with increased number of ordered WBCs.

The RBCs appear bright red or pale. Poor pre-classification of WBCs. Pale nucleus and/or granula.	
Cause	**Solution**
Too little staining.	You may need to increase fixation and staining time.
Too much rinsing.	You may need to correct the rinsing technique so that it's adequate but not excessive.
Stain, buffer or rinse used is too acidic.	Check the pH of the buffer with a pH meter, and adjust if needed.
Acidity of the stain or buffer is increased due to exposure to acid fumes.	Use a new batch of stain or buffer.

The RBCs appear dark, the nuclear chromatin is deep blue or black and the granules of the neutrophilic granulocytes are deeply overstained and appear large and prominent. The granules of the eosinophils appear dark.	
Cause	**Solution**
Too much staining.	Decrease the fixation time. You may need to decrease the amount of stain (shorten the staining time) and increase the amount of buffer (increase the stain/buffer time).
Too little rinsing.	Increase rinse time.
Stain or buffer is too alkaline.	Check the pH of the buffer with a pH meter, and adjust if needed.
Smear is too thick.	Prepare a thinner smear.

The RBCs pre-classified as artifacts, thrombocyte aggregation or WBCs.	
Cause	**Solution**
Too much staining.	Decrease the fixation time. You may need to decrease the amount of stain (shorten the staining time) and increase the amount of buffer (increase the stain/buffer time).
Too little rinsing.	Increase rinse time.
Stain or buffer is too alkaline.	Check the pH of the buffer with a pH meter, and adjust if needed.
Smear is too thick.	Prepare a thinner smear.

Samples have dark areas of stain or other artefacts.	
Cause	**Solution**
Smear was not completely dry when stained.	Make sure the smear is completely dry before staining it.
Slide is dirty.	Use clean slides.
Too little rinsing (not enough rinsing to remove the metallic scum).	Increase rinse steps.
Stain forms a precipitate in the solution.	Filter the stain. Make sure that the stain has not exceeded the expiration date.

Same cell is counted more than once or duplicate cell images are shown.	
Cause	**Solution**
Sample contains disintegrated cells or smudge cells, and the analyzer identifies different parts of a cell as two or more different cells.	To minimize the amount of disintegrated cells, make sure the smear is prepared within four hours of blood collection. For more information, see 2.2.1 Prepare peripheral blood smears on page 25.
	To minimize the amount of smudge cells, verify your smear preparation process.
	To identify and exclude duplicate cells, enable **Show cell markers** during review.

Cells are split into two or more parts.	
Cause	**Solution**
Too little staining.	You may need to increase fixation and staining time.
Too much rinsing.	You may need to correct the rinsing technique so that it's adequate but not excessive.

6.7 General startup issues

Log on to system takes time.	
Cause	**Solution**
System computer not restarted in over a week.	Restart the system computer. Restart the analyzer.
Database is too large.	Keep the database size below the maximum allowed size as instructed in 5.2.1 Check and back up databases on page 74.
Database files are fragmented.	Compress the database as instructed in 5.2.2 Compress databases on page 74.
Large network delays.	Make sure that the network connections are stable.
	Make sure that the network communication delays are small.

6.8 Startup error messages

Could not log on to the system. Make sure you entered your user name and password correctly.	
Cause	**Solution**
Wrong user name or password.	Check your user name and re-enter your password.
Caps lock is on.	Turn off Caps lock.

Unable to contact the database host computer computer name. Check your network connection and verify that the computer is turned on.	
Cause	**Solution**
Can't connect to local database service.	Restart the analyzer.
Can't reach server that runs CellaVision Server Software.	Check your network connection.
	Make sure that the server is turned on and that the CellaVision Server Software is running.
	Restart the server.

Unable to connect to the database service. Make sure that the database service has not been stopped and that the network port is not blocked by a firewall.	
Cause	**Solution**
Can't connect to local database service.	Restart the analyzer.
Can't reach server that runs CellaVision Server Software.	Check your network connection.
	Make sure that the server is turned on and that the CellaVision Server Software is running.
	Restart the server.
	Make sure that there is no firewall blocking the network port. For more information on what network ports are used, see 5.2.2 Compress databases on page 74.

There is not enough disk space on the drive where the database is located.	
Cause	**Solution**
Database is located on the C drive.	Move the database to the D drive.
Partition where the database is located is full.	Reduce the database size as instructed in 4.1.2 Manage database size on page 50.

The configuration of the system is incorrect.	
Cause	**Solution**
Analyzer has lost its configuration.	To reconfigure the analyzer, contact your local vendor's technical support.

Jam error occurred during initialization.	
Cause	**Solution**
Motor specified in the error message reports a positioning failure.	Restart the CellaVision DM Software. If the error message re-occurs, contact your local vendor's technical support.
Slide is in the wrong position.	Open the input hatch and remove the slide.

Temperature is too high.	
Cause	**Solution**
Less than 20 cm clearance around the analyzer.	Make sure there is enough free space around the analyzer for ventilation purposes.
Room temperature is too high.	Make sure the room temperature does not exceed the temperature specified in 7.1.2 Environmental specification on page 97.
Air filter is dirty.	Check the condition of the air filter. To replace the filter, contact your local vendor's technical support.
Fan is defective.	To replace the fan, contact your local vendor's technical support.

File system or registry failure.	
Cause	**Solution**
File system or registry is corrupt.	Reinstall the CellaVision DM Software as specified in its Installation Instructions.

An unknown error occurred when archiving slides. One or more slides have not been archived.	
Cause	**Solution**
One or more slides opened by another user.	Make sure that the slides are closed.
	Restart the server or the system computer where the database is located.

An unknown error occurred when the system tried to autodelete old slides. One or more slides could not be deleted.	
Cause	**Solution**
One or more slides opened by another user.	Make sure that the slides are closed.
	Restart the server or the system computer where the database is located.

Can't open this order because the archive wasn't found.	
Cause	**Solution**
Server or system computer where the database is located can't connect to the archive.	Check the network connection.
Archive files were moved to another location.	Move the archive files back.
	In the **Archiving location** text box, enter the new path to the archive files.

6.9 Hardware error messages

Temperature is too high.	
Cause	**Solution**
Less than 20 cm clearance around the analyzer.	Make sure there is enough free space around the analyzer for ventilation purposes.
Room temperature is too high.	Make sure the room temperature does not exceed the temperature specified in 7.1.2 Environmental specification on page 97.
Air filter is dirty.	Check the condition of the air filter. To replace the filter, contact your local vendor's technical support.
Fan is defective.	To replace the fan, contact your local vendor's technical support.

File system or registry failure.	
Cause	**Solution**
File system or registry is corrupt.	Reinstall the CellaVision DM Software as specified in its Installation Instructions.

Positioning failure.	
Cause	**Solution**
Motor specified in the error message reports a positioning failure.	Restart the CellaVision DM Software. If the error message re-occurs, contact your local vendor's technical support.

6.10 Slide processing error messages

No connection to the database service. Check your network connection and verify that the service is running.	
Cause	**Solution**
Connection to database is lost.	If you see status **No connection**, wait up to a minute for the connection to re-establish, and then re-start slide processing.
	Check the network connection.
	If you have a database on the analyzer, restart the analyzer.
	If you use the CellaVision Server Software, restart the server.

There was a problem when accessing the database.	
Cause	**Solution**
Order ID contains non-ASCII characters.	Make sure that the order ID follows the specification in 7.3.2 Barcodes on page 105.

Critical internal error during cell collection.	
Cause	**Solution**
Temporary software error.	Restart the CellaVision DM Software.

Critical internal error.	
Cause	**Solution**
Temporary software error.	Restart the CellaVision DM Software.

6.11 Slide processing issues

Status light flashes red.	
Cause	**Solution**
Motor positioning failure.	Restart the CellaVision DM Software. If the error message occurs again, contact your local vendor's technical support.

Analyzer doesn't process slides.	
Cause	**Solution**
Slide processing is stopped.	Click **Restart the slide processing** ▸ .
Input hatch is open.	Close the input hatch.
PPA smart card is empty.	Put a new PPA smart cart in the reader.
No PPA smart card in the reader .	Put a PPA smart cart in the reader.

6.12 Clean objective lens

Note: Always clean the objective lens gently and according to recommendations. It's sensitive and a vital part for good quality analysis.

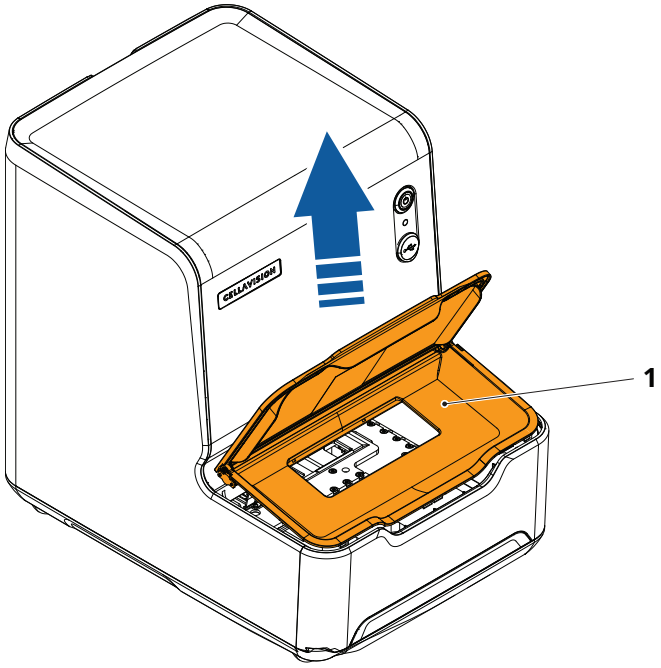
To clean the objective lens, you must remove the input hatch and hood.

Caution!
To help prevent damage to the analyzer, don't use excessive force when removing or assembling the input hatch and the hood.

To remove the hood and the input hatch

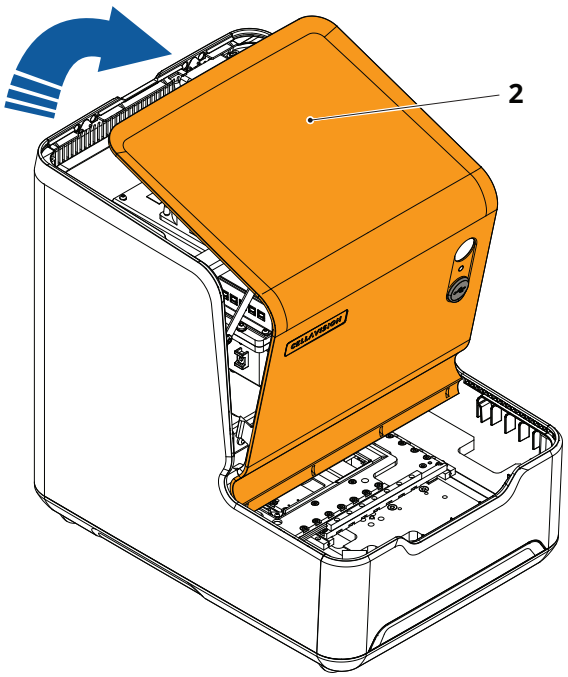
1. On the **Maintenance** menu, click **Open hood position**.
2. Open the lid of the input hatch (1).

3. To remove the input hatch (1), pull it from the rear edge and up.



1 Input hatch

4. To open the hood (2), place a hand on the top of the cover and pull it up and forward.
5. To remove the hood (2), pull it up.



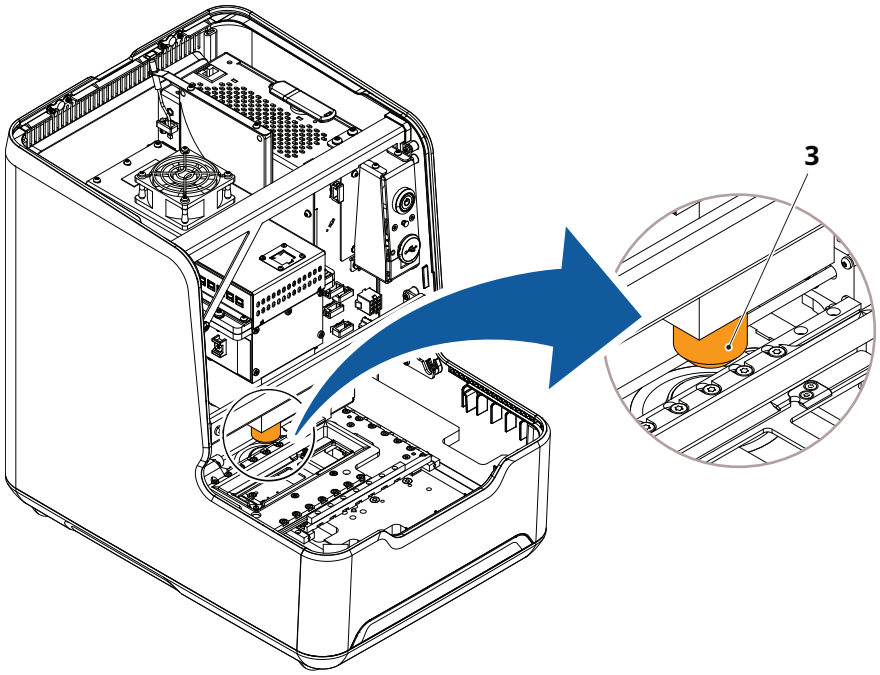
2 Hood

Caution!
Be careful not to damage any cables or connectors when removing the hood.

To clean the objective lens

Caution!
To help prevent damage to the analyzer, don't use any detergents to clean the objective lens.

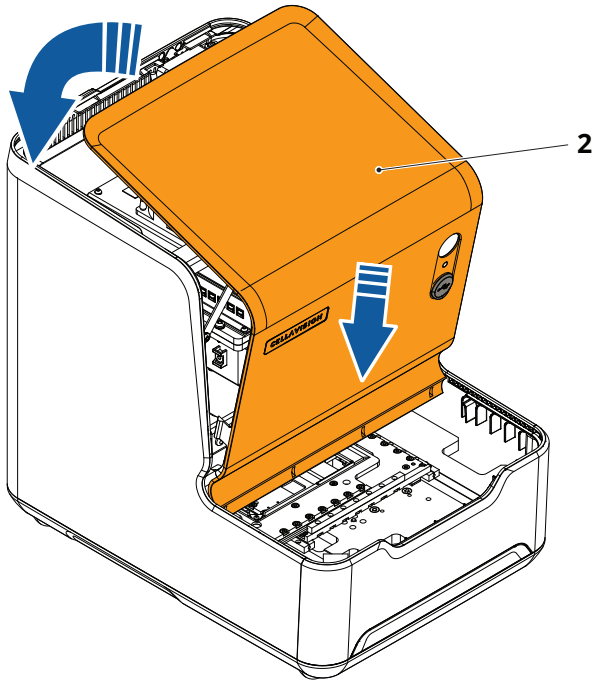
1. With a new lens paper, gently wipe the 100x objective (3) lens.
   Discard the lens paper after use.



3 100x objective

To assemble the hood and the input hatch

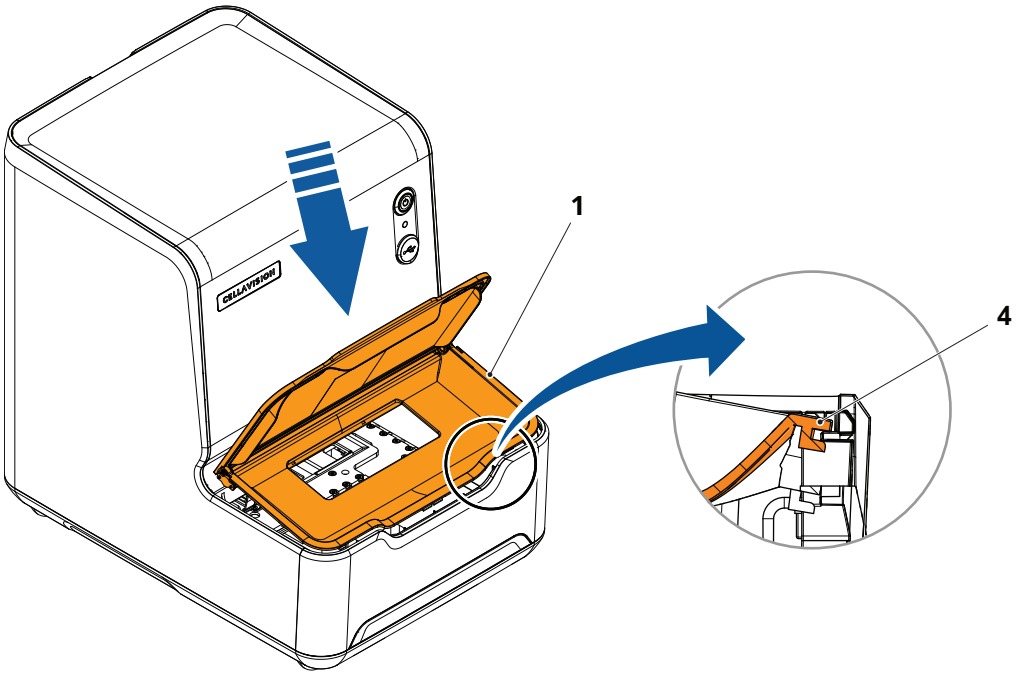
1. To put back the hood (2), gently push it down until it snaps into place.



2 Hood

2. Close the hood (2).
3. Open the lid of the input hatch (1)
4. Angle the input hatch (1) and place the hooks (4), located in its front bottom, on the edge inside of the casing side cover.

5. Push down the input hatch (1) from the rear edge until it snaps into place.



1 Input hatch
4 Hooks

6. Close the input hatch (1).
7. Restart the CellaVision DM Software.

To verify functionality

1. Run a cell location test as instructed in 3 Quality control procedure (QC) on page 39.
2. If the cell location test fails or if the images are blurry, run a second cell location test.
3. If the second cell location test fails or if the images are blurry, restart the cleaning procedure.

7 TECHNICAL INFORMATION

7.1 System specifications

7.1.1 Storage and handling specification

Specification	Description
Storage temperature	–10°C to 60°C
Relative humidity	20% to 80%, non-condensing

The analyzer delivery should be unpacked by trained personnel. We recommend saving the packaging material for possible future transports.

Acclimatize the system to operating conditions for 24 hours before taking it into use. For specifications of operating conditions, see 7.1.2 Environmental specification below.

7.1.2 Environmental specification

Specification	Description
Temperature	18°C to 31°C
Relative humidity	20% to 80%, non-condensing
Altitude	Up to 2 000 m
Other	Indoor use only

7.1.3 Physical specification

Specification	Description
Weight	11 kg
Width	280 mm
Depth	390 mm
Height	370 mm

7.1.4 Electrical specification

Analyzer

Specification	Description
Voltage input	12 VDC
Current input	7 ADC

This system complies with the emission and immunity requirements described in the IEC 61326-2-6:2012 (EN 61326-2-6:2013).

This system complies with the requirements described in the IEC 61010-2-101:2015 (EN 61010-2-101:2017), IEC 61010-1:2010 (EN 61010-1: 2010), UL 61010-1 (3rd Edition, May 11, 2012, Revised July 15, 2015), CAN/CSA-C22.2 No. 61010-1-12 (3rd Edition, Revision dated July 2015)

Power supply cord, USA and Canada

Specification	Description
Manufacturer	Various
Type/Model	UL Listed and CSA certified, min. type SV.
Technical Data	Minimum 18 AWG 3 conductors, rated min. 60 °C Provided with grounding-type (NEMA 6-15P) attachment plug, rated 125 V AC or 250 V AC, min. 2.5 A Opposite end terminates in IEC 320 style connector, rated 125 V AC or 250 V AC, min. 2.5 A.
Standard	UL62, UL498 or UL817
Required Marks or Conformity	C-ULus or UL and CSA

Power supply cord, other countries

Specification	Description
Manufacturer	Various
Type/Model	Cord type min. H05RR-F or min. H05VV-F or min. H05VVH2-F
Technical Data	3 × 0.75 mm^2 Minimum 60 °C Provided with grounding-type attachment plug, rated 250 V AC, min. 2.5 A Opposite end terminates in IEC 320 style connector, rated 250 V AC, min. 2.5 A
Standard	Set: IEC60799. Cord: IEC60245 or IEC 60227 Plug: IEC 60884
Required Marks or Conformity	<HAR>

7.1.5 Noise specification

The analyzer does not produce any hazardous noise levels.

7.1.6 Disposal specification

Specification	Description
Oil bottle	Dispose of contents/container according to local regulations.
Analyzer	Contact your local vendor for information on how to dispose of the analyzer.

7.2 Performance specifications

7.2.1 Performance specification for CellaVision Peripheral Blood Application

Average WBC cell-location and display of at least 97% with a standard deviation less than 2%.

Throughput[1] : Approximately 10 slides per hour for complete orders containing RBC, PLT, and 100 WBCs.

WBC comparison study

[1] Depending on WBC concentration, number of non-WBCs, and smear quality.

7 Technical information

Comparison studies were conducted at 3 sites. The results from the CellaVision® DC-1 were compared with the CellaVision Peripheral Blood Application running on CellaVision® DM1200 as a reference. The positive, negative, and overall agreements (95% confidence interval within brackets) for the individual morphologies were calculated according to CLSI document H20-A2 *Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods, Approved Standard-Second Edition*. The results are presented in the table below.

Cell class	Overall Agreement	Positive Agreement	Negative Agreement	Number of samples
Segmented neutrophils	94.8% (92.7% - 96.3%)	92.5% (87.0% - 95.7%)	95.6% (93.3% - 97.1%)	598
Band neutrophils	99.3% (97.8% - 99.7%)	-	99.8% (98.6% - 100.0%)	402
Lymphocytes	93.8% (91.6% - 95.5%)	87.0% (81.1% - 91.2%)	96.5% (94.3% - 97.9%)	598
Monocytes	92.0% (89.5% - 93.9%)	80.9% (73.5% - 86.6%)	95.2% (92.9% - 96.8%)	598
Eosinophils	97.3% (95.7% - 98.3%)	91.3% (79.7% - 96.6%)	97.8% (96.2% - 98.8%)	598
Basophils	96.0% (94.1% - 97.3%)	67.4% (53.4% - 78.8%)	98.5% (97.2% - 99.3%)	598

Accuracy results for WBC differential count

Comparison studies were conducted at 3 sites. The results from the CellaVision® DC-1 were compared with the CellaVision Peripheral Blood Application running on CellaVision® DM1200 as a reference. 200-cell differential counts were performed by qualified blood examiners. The study was performed according to CLSI document H20-A2*Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods, Approved Standard-Second Edition*. The results are presented in the table below.

Cell class	Slope	Intercept (%)	R^2	Number of samples
Segmented neutrophils	0.999	0.0012%	0.98	598
Band neutrophils	0.7047	0.0011%	0.6831	402
Lymphocytes	0.991	0.0001%	0.98	598
Monocytes	0.9874	0.0014%	0.94	598
Eosinophils	1.0079	0.0011%	0.96	598
Basophils	0.9431	0.003%	0.928	598

Repeatability for WBC differential count

Repeatability studies were run at 3 sites based on the CLSI document EP05-A3 *Evaluation of Quantitative Measurement Procedures; Approved Guideline-Third Edition*. From each sample, 2 slides were prepared (slide A and B). The slides were then run 2 times a day (both A and B at each run) for

20 days. The results are presented in the table below for a representative low and a high concentration sample respectively.

Cell class	Concentration	Mean Concentration (%)	SD (%)	CV (%)
Segmented neutrophils	Low	17.25%	0.33%	1.93%
	High	90.07%	1.78%	1.97%
Band neutrophils	Low	0.08%	0.26%	314.2%
	High	13.32%	1.65%	12.41%
Lymphocytes	Low	3.10%	0.87%	28.1%
	High	50.93%	2.53%	4.96%
Monocytes	Low	0.92%	0.57%	61.96%
	High	27.86%	1.41%	5.08%
Eosinophils	Low	0.06%	0.17%	298.14%
	High	4.24%	1.06%	25.04%
Basophils	Low	0.01%	0.06%	894.43%
	High	10.6%	1.81%	17.03%

Reproducibility for WBC differential count

The reproducibility study was run based on the CLSI document EP05-A3 *Evaluation of Quantitative Measurement Procedures; Approved Guideline-Third Edition*. From each sample, 5 slides were prepared. The slides were then run at 3 sites for 5 days at each site. The results are presented in the table below for a representative low and a high concentration sample respectively.

Cell class	Concentration	Mean Concentration (%)	SD (%)	CV (%)
Segmented neutrophils	Low	26.33%	1.52%	5.79%
	High	82.92%	3.40%	4.10%
Band neutrophils	Low	0.09%	0.24%	271.15%
	High	1.96%	1.55%	79.02%
Lymphocytes	Low	10.75%	2.89%	26.90%
	High	44.53%	15.51%	34.84%
Monocytes	Low	1.41%	1.16%	82.50%
	High	24.35%	4.62%	18.98%
Eosinophils	Low	0.01%	0.06%	866.03%
	High	11.55%	1.86%	16.14%
Basophils	Low	0.01%	0.08%	627.5%
	High	0.83%	0.51%	61.40%

RBC comparison study

Comparison studies were run at 3 sites. The results from the CellaVision® DC-1 were compared with the CellaVision Peripheral Blood Application running on CellaVision® DM1200 as a reference. The positive, negative, and overall agreements (95% confidence interval within brackets) for the groups color, size, and shape were calculated according to CLSI document EP12-A2 User *Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second Edition*. The results are presented in the table below.

Comparison	Overall Agreement	Positive Agreement	Negative Agreement	Number of samples
Color	79.9% (76.4% - 82.9%)	87.8% (82.3% - 91.8%)	76.3% (71.9% - 80.2%)	586
Size	88.2% (85.3% - 90.6%)	89.8% (86.3% - 92.2%)	84.8% (79.0% - 89.2%)	585
Shape	85.2% (82.0% - 87.8%)	87.3% (82.3% - 91.0%)	83.8% (79.6% - 87.3%)	586

Repeatability of RBC morphological characteristics

Repeatability studies were run at 3 sites based on the CLSI document EP05-A3 *Evaluation of Quantitative Measurement Procedures; Approved Guideline-Third Edition*. From each sample, 2 slides were prepared (slide A and B). The slides were then run 2 times a day (both A and B at each run) for 20 days. The grading agreement for each sample was then calculated by determining the relation between the occurrence of true grade for each morphological characteristic and the total number of runs. The achieved agreement for each morphological characteristic is presented in the table below.

Morphology	Agreement
Polychromatic cells	62.5% - 100%
Hypochromatic cells	50.0% - 100%
Anisocytosis (CV)	60.0% - 100%
Microcytes	85.0% - 100%
Macrocytes	56.25% - 100%
Poikilocytosis	96.25% - 100%

Reproducibility of RBC morphological characteristics

The reproducibility study was run on 4 samples based on the CLSI document EP05-A3 *Evaluation of Quantitative Measurement Procedures; Approved Guideline-Third Edition*. From each sample, 5 slides were prepared. The slides were then run at 3 sites for 5 days at each site. The grading agreement for each sample was then calculated by determining the relation between the occurrence of true grade for each morphological characteristic and the total number of runs. The achieved agreement for each morphological characteristic is presented in the table below.

Morphology	Agreement
Polychromatic cells	36% - 100%
Hypochromatic cells	63% - 100%
Anisocytosis (CV)	51% - 100%
Microcytes	96% - 100%
Macrocytes	51% - 100%
Poikilocytosis	65% - 80%

PLT comparison study

Comparison studies were run at 3 sites. The results from the CellaVision® DC-1 were compared with the CellaVision Peripheral Blood Application running on CellaVision® DM1200 as a reference. The agreement between the two methods was evaluated by summarizing the results in the table below.

DC-1 (number of samples)	DM1200 (number of samples)				Total
	Significantly decreased	Decreased	Normal	Increased	
Significantly decreased	140	16	0	0	156
Decreased	6	135	13	0	154
Normal	0	10	173	10	193
Increased	0	0	17	78	95
Total	146	161	203	88	598

The achieved Cohen's Kappa coefficient was 0.89.

Repeatability of PLT analysis

Repeatability studies were run at 3 sites based on the CLSI document EP05-A3 *Evaluation of Quantitative Measurement Procedures; Approved Guideline-Third Edition*. From each sample, 2 slides were prepared (slide A and B). The slides were then run 2 times a day (both A and B at each run) for 20 days. The agreement for each PLT level was then calculated as a relation between the number of runs reporting the sample PLT level and the total number of runs. . The achieved agreement for the different PLT levels are presented in the table below.

PLT Level	Agreement (%)
Significantly decreased	100%
Decreased	100%
Normal	100%
Increased	100%

Reproducibility of PLT analysis

The reproducibility study was run on 4 samples based on the CLSI document *Evaluation of Quantitative Measurement Procedures; Approved Guideline-Third Edition*. From each sample, 5 slides were prepared. The slides were then run at 3 sites for 5 days at each site. The agreement for each PLT level was then calculated as a relation between the number of runs reporting the sample PLT level and the total number of runs. The achieved agreement for the different PLT levels are presented in the table below.

PLT Level	Agreement (%)
Significantly decreased	100%
Decreased	100%
Normal	97.3%
Increased	98.6%

7.2.2 Performance specification for scan

Throughput data and disk space requirements for the scanned slides

Scan area size	Resolution	Processing time	Disk space (MB)
5 x 5 mm	Low	10 min.	30
5 x 5 mm	Medium	10 min.	125
5 x 5 mm	High	15 min.	500
10 x 10 mm	Low	35 min.	125
10 x 10 mm	Medium	35 min.	500
10 x 10 mm	High	60 min.	2000

The given values are only approximates. Processing time and required disk space vary depending on sample.

7.3 Accessories

7.3.1 Slides

You can use slides with ground edges and clipped, round, or right angle corners with the analyzer.

Specification	Description
Standard	ISO 8037/1-1986
Material	Glass
Length	75.0 to 76.0 mm
Width	25.0 to 26.0 mm
Thickness	0.9 to 1.2 mm
Corners	Clipped, round, or right angle.
Edges	Ground edges.
Labeling	We recommend that you label the slide with a barcode as specified in 7.3.2 Barcodes below.

7.3.2 Barcodes

This section applies only if you use the optional barcode reader.

You must label all slides with an order ID. If you use the optional barcode reader, you can label your slides with a barcode containing the order ID. The barcode mustn't contain any other order data.

The order ID can be up to 24 characters (ASCII) long, including spaces. It can't begin with:

- PB
- BFS
- ERR
- QC (reserved for cell location test slides)
- A space

You can print the barcode on a label or directly onto the slide. The print must be in high contrast to the background, and it must be resistant to immersion oil.

If you print the barcode directly onto a slide, it must be printed on a white, smooth, frosted area of the slide.

Leave at least 1 mm between the edge of the slide and the actual label. Otherwise, there is a risk that the slide is not properly fixed during slide processing.

If, for some reason, you can't print barcodes containing the order ID, you can use pre-printed barcode labels with the prefix "ER". You can enter an order ID manually for all slides that begin with letters "ER". You can order the pre-printed labels from your local vendor.

Important!
Avoid getting immersion oil on the barcode as it may prevent the analyzer from reading the barcode correctly.

Supported linear barcodes

The analyzer supports these standards for linear barcodes:

- Code 39
- Code 128
- Codabar/NW-7
- Interleave 2 of 5

Supported 2D barcodes

The analyzer supports these standards for 2D barcodes:

- Data Matrix
- QR

Barcode resolution

Barcode standard	Cell size, mil
QR	13
Data Matrix	9
Code 39	7
Code 128	7
Codabar/NW-7	7
Interleave 2 of 5	7

CellaVision AB has verified these barcode resolutions.

Quiet zone

You must leave a blank region, free from all markings, around the barcode. This region is called the "quiet zone". The following table specifies the minimum size of the quiet zone.

Barcode standard	Minimum quiet zone, all sides
Data Matrix	1 light module
QR	4 light modules
Other	According to barcode standard specification.

Examples of barcodes where the quiet zone is marked in orange for illustrative purposes.

7.3.3 Immersion oil

Warning!
Avoid getting immersion oil on your skin. Wear protective gloves before you handle the oil, slides, or other parts that can come into contact with the oil. Immersion oil can cause skin sensitization. If you get oil on your skin, clean it off with soap and water.

Caution!
To help prevent slide processing faults and damage to the analyzer, use only the CellaVision® immersion oil.

Firefighting procedure

Specification	Description
Flash point	> 149°C (> 300°F)
Upper explosive limit	Not applicable
Lower explosive limit	Not applicable
Fire fighting media	Carbon dioxide, foam and dry chemical
Unusual fire and explosion hazards	Containers should be kept cool in the event of fire

8 BUTTONS, ICONS, AND INDICATORS

This section describes the buttons, icons and indicators you can see in the CellaVision DM Software in the System Control View. To view the tooltip for a button, point to it with your mouse.

The buttons, icons and indicators for other views in the CellaVision DM Software are described in the CellaVision Review Software Instructions for Use.

8.1 System Control View

System Control View is the view on the analyzer where you process slides.

System control buttons

Stop slide processing.

Start or resume slide processing.

Clear log.

Analyzer status

Analyzer status is shown as text on the toolbar.

- Idle
- Analyzing
- Stopped
- Paused
- Error

Analyzer indicators

Hood is open.

Input hatch is open.

Input hatch and hood are open.

8.2 Slide status

Slide status is shown in the **System Control View**.

Processing. Slide is being processed.

Finished. Slide was processed without warnings or errors.

Warning. A problem occurred. Images and preliminary results were saved to the database and you may still be able to perform review and verification.

Stopped: User stopped slide processing and no results exist.

Error. All ordered analyses failed and no results exist.

8.3 PPA status

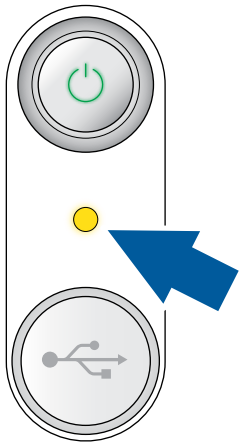
PPA status is shown on the status bar in the **System Control View**.

Valid PPA card. Balance remaining on the card is shown next to the icon.

No connected PPA card.

8.4 Status light

Status light on the analyzer provides you with information on its current state.



Status light	Description
Steady yellow	Analyzer is starting up. Analyzer is processing a slide.
Flashing green	Analyzer has finished the startup procedure. Analyzer has completed slide processing. You can now remove the slide.
Steady green	Analyzer is idle and ready to use.
Flashing red	Mechanical error.

REVISION HISTORY

Revision 2021-10-31

Section	Change
1.2.2 Symbols on page 10	Symbol for date of manufacture added. References to specific directives removed for symbols manufacturer and CE-marks.

Revision 2021-09-13

Section	Change
1.2.3 General safety on page 12	Information added that users must report any serious incidents that occur in relation to the analyzer.
1.4 Applications on page 16	Information added on whether the applications are qualitative, semi-quantitative, or quantitative.
1.4 Applications on page 16	Information added about the mathematical methods used when calculating the results.
2.2.3 Staining on page 26	Staining recipes removed.
7.1.4 Electrical specification on page 98	Power supply specification removed.
7.2.1 Performance specification for CellaVision Peripheral Blood Application on page 99	Performance data updated in accordance with document variant PM-10895-03, submitted to FDA in October 2020.
Revision history above	Appendix with revision history added.

GLOSSARY

A

analysis

The overall process of using the system, including loading slides, processing slides, verification, signing, and reporting results.

anisocytosis

Variation in size among RBCs.

C

characterization

To determine the morphology characteristics of an RBC sample. The result of the characterization is reported as grades.

confirm cell counter results

To confirm the cell counter results for WBC, RBC, or PLT instead of doing a full manual analysis. When the user chooses to confirm cell counter results, only a confirmation flag for that result is sent to the LIS.

D

duplicate slide differential

Two different persons sign one slide each in the order. The average result is presented.

G

grade

A number representing the relative amount of cells of a certain type in an RBC sample.

grid square

A section of the PLT or RBC overview image.

H

HPF

Microscopic high-power field

I

in-vitro

Outside the living body; in an artificial environment.

L

LIS

Laboratory Information System.

M

MGG

May Grünwald Giemsa, a Romanowsky stain for blood smears.

mini map

An overview image of the analysis area.

multi-slide order

An order including more than one slide from one sample.

N

non-WBC

Cells and objects identified as not being WBCs.

not classed

Cells and objects that the user cannot identify and wants to exclude from the differential count.

O

operator

The person who works with the system. Also referred to as user.

order

An order contains patient data and the information about what type of analyses that are to be performed (for example WBC, RBC) on the slides belonging to that order. Each order is identified by its order ID and the concept of the order and the order ID is used throughout the entire analysis to keep track of patient data, images, results, and so on. An order is generally received from the LIS or created in CellaVision DM Software.

order ID

Unique order identifier. There can be several slides with the same Order ID but with different slide numbers.

other

Cells that the user identifies as WBCs, but of a type other than those listed. Will be included in the differential count.

P

pathology review

A function that allows you to mark any slide so that a pathologist can find and review it.

patient ID

A unique identifier for the patient.

pending order

An order manually added to the database, waiting to be processed.

PID

Positive Identifier. Generally refers to the barcode on the slide.

PLT

Platelet, thrombocyte.

PLT estimate

Estimation of the PLT concentration.

PLT estimate factor

A pre-determined factor to calculate the PLT estimate.

poikilocytosis

Presence of abnormally shaped red blood cells.

pre-characterization

The characterization that the system suggests for the RBC morphology of a sample.

pre-classification

The classification that the system suggests for each WBC.

processing slides

The sequence of events from when the system starts working with a slide until it is finished.

R

RBC

Red blood cell, erythrocyte.

re-classification

The user changes the pre-classification.

reference cells

A collection of WBCs with typical characteristics, available in the Peripheral Blood Application.

Romanowsky stain

An eosin-methylenblue solution for staining of blood smears. Wright and MGG are examples of different Romanowsky stains.

S

sign

The final confirmation of the analysis results before locking and reporting them.

slide ID

The barcode number on the slide (PID). Same as Order ID.

slide number

A sequential number to identify each slide in a multi-slide order.

U

unidentified

Cells and objects which the system cannot pre-classify.

V

verification

The user's review of WBC, RBC, and PLT. For example re-classification and confirmation of WBCs.

W

WBC

White blood cell, leukocyte.

Wright

A Romanowsky stain for blood smears.

Wright-Giemsa

A Romanowsky stain for blood smears.

INDEX

U

CE

Document: PM-10895-01
Revised: 2021-10-31